Title: DEPLOYABLE MARKER AND METHOD FOR DEPLOYMENT

Abstract: A marker for marking the location of an internal area in the human body comprising a cap unit, and at least one attachment unit affixed to the cap unit, the at least one attachment unit capable of piercing a surface of a region in response to a vertical force applied to the cap unit.

FIG. 5
before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))
TITLE OF INVENTION

DEPLOYABLE MARKER AND METHOD FOR DEPLOYMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of priority to U.S. Provisional Application Serial No. 61/447,888 filed 01 March 2011, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] This disclosure relates to deployable endoscopic markers and methods for deploying endoscopic markers.

BACKGROUND

[0003] In the course of gastrointestinal (GI) endoscopy, an endoscopist frequently encounters the need to mark a specific location and/or finding either to aid in its subsequent identification or to define its borders. Current methods of marking which includes tattooing, creating cautery marks, and clipping, are limited by risks of procedural complications, lack of effectiveness, costs, and the types of findings which are amenable to marking.

[0004] Therefore, there is a need for a novel marking system for use during GI endoscopy that is effective, safe, cost-effective, and able to broaden the range of findings which can be marked.

SUMMARY OF THE INVENTION

[0005] What is proposed is a tubular element for passage through the therapeutic channel of a GI endoscope. At the proximal end of the tubular element is a control handle which controls actuators which function via the tubular element to effect placement of a deployable marker onto and/or into the wall of the GI tract in order to mark a particular area or finding. In different embodiments of this device, the number of deployable markers per device will vary as will the composition of the marker itself (i.e. stainless steel, ceramic, titanium, nitinol, rubber, polymer, plastic, biodegradables, and/or digestibles). The color of the marker will vary by embodiment; however, in one embodiment, the color will always contrast significantly with the color of the surrounding background mucosa. In another embodiment, the markers will also show up on radiographic studies. This might be accomplished by constructing a hybrid marker
molded with fine titanium particles suspended within a first material (i.e. polymer). In different embodiments of this device, the means of attaching as well as the depth of penetration of the marker into the GI tract wall will vary with a deeper penetration of the marker into the GI tract wall being associated with more permanent endoscopic marking. Deployment of the marker to anchor into the serosal surface would, in addition to allowing for a more permanent marking, be useful for serosal side identifications. An additional solution for a less-permanent endoscopic marker would involve constructing the marker or portions of the marker out of biodegradable and/or digestible materials. This endoscopic marker system, as described, is an elegant solution to the limitations and drawbacks of the current art in endoscopic marking technology.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] FIG. 1 is a top view of a delivery catheter for an endoscopic marker according to one embodiment.

[0007] FIG. 2 is a cross-sectional view of a polyp seen on insertion of a colonoscope, with a cross sectional view of the GI tract, marked with either one or a plurality of markers according to one embodiment so that the polyp can be later relocated.

[0008] FIG. 3 is a top view of a lesion for endoscopic mucosal resection, saline snare resection or endoscopic submucosal dissection, marked with a plurality of endoscopic markers according to one embodiment so that the lesion can then be removed by the endoscopist with confidence that the lesion's margins have been clearly delineated.

[0009] FIG. 4 is a top view of a submucosal nodule or other finding marked with a plurality of endoscopic markers according to one embodiment so that the finding can be rechecked at a later time and possibly examined in more detail with endoscopic ultrasound (EUS). These markers can also help identify this lesion should it need to be removed either surgically or endoscopically.

[0010] FIG. 5 is a side view of a section of the GI tract with a neoplasm marked with endoscopic markers according to one embodiment for later rechecking and/or removal.

[0011] FIG. 6A depicts a side view of one embodiment of a marker.

[0012] FIG. 6B depicts one embodiment of a marker.

[0013] FIG. 6C depicts a side view of one embodiment of a marker.

[0014] FIG. 6D depicts the side view of a marker.

[0015] FIG. 6E depicts a bottom view of a marker.

[0016] FIG. 6F depicts a side view of a marker.
FIG. 6 G depicts a side view of a marker.
FIG. 6 H depicts a side view of a marker.
FIG. 7A depicts a top view of a marker.
FIG. 7B depicts a side view of a marker.
FIGS. 7C-7E depict a delivery unit for a marker.
FIG. 8A depicts a side view of a marker.
FIG. 8B depicts a side view of a marker.
FIG. 8C depicts a side view of a connection between an insertion unit and a plurality of wires.
FIG. 9A depicts a side view of one embodiment of a marker.
FIG. 9B depicts one embodiment of a delivery unit for a marker.
FIG. 9C depicts one embodiment of a delivery unit for a marker.
FIG. 9D depicts a marker embedded in the region.
FIG. 10 depicts one embodiment of a marker.
FIG. 11A depicts a cut away side view of a marker.
FIG. 11B depicts one embodiment of a delivery unit for a marker.
FIG. 12A depicts a top view of a material adhered to a region using a plurality of markers.
FIG. 12B depicts a top view of a plurality of markers surrounding an opening in the wall of the GI tract.
FIG. 13A depicts a top view of one embodiment of a mirror device.
FIG. 13B depicts a top view of one embodiment of a mirror device.

DETAILED DESCRIPTION OF THE INVENTION

The marker may be of any shape including round, square, and triangular, or its shape may simply be that of its legs or other attachment means. Preferably, the marker will be round.

Preferably, the marker will be about 2-4 mm in diameter. The marker may be made of any suitable material including stainless steel, titanium, nitinol, rubber, polymer, ceramic, plastic, biodegradables, digestible, or any combination of these materials.

The marker may be of any suitable color or colors. Preferably, the marker will be of a color which contrasts with the color of the surrounding GI tract wall. In one embodiment, the marker will be black. This may be achieved by either constructing the marker of a black...
material or by coloring the marker black. If coloring is used, the coloring agent will preferably be non-toxic.

[0039] The marker will be attached to the mucosa and/or deeper wall layers of the GI tract via an attachment means which may either be permanent or reversible depending on the specific procedure. In another embodiment, part or all of the marker is made of biodegradable and/or digestible material in order to render the marker non-permanent and/or to dissolve any sharp features of the marker following deployment. In another embodiment the markers can be removed, i.e. detached. As an illustrative example, the marker is removed endoscopically by using a device similar to an endoscopic staple remover. Consistent with this embodiment, the remover is inserted endoscopically and the markers are detached and removed. It is understood that the remover could take other forms, such as modified biopsy forceps. Additionally, the marker itself can be designed to collapse, to disassemble, or to dissolve.

[0040] FIG. 1 shows a catheter-based delivery system for the markers in which a tube or catheter 4 deploys a marker 1 from its distal end in order to mark a finding by the endoscopist. This delivery system will preferentially include a control device which may include a gun-type control, a knob, or a lever at its proximal end to control deployment and placement of the marker 1; although, any control device will work. Also, the delivery system can be loaded with one or a plurality or a packet containing a plurality of markers (not shown). Individual markers will be constrained (i.e. prevented from falling out prematurely) within the catheter-based delivery system until deployed by the endoscopist. This may be accomplished via looping threads or another threadlike material around each marker or by placing a membrane or membrane-like structure of material underneath each marker with the endoscopist breaking the aforementioned thread(s), threadlike material(s), membrane(s), or membrane-like material(s) via the control handle or by some other mechanism during deployment of the marker. However, any type of constraining device which acts to prevent premature marker release from the delivery system will do. The tube or catheter 4 may be reusable, disposable, or reposable.

[0041] FIG. 2 is a side view of a polyp 5 protruding from the wall of the GI tract 3. The polyp 5 is marked with two markers 1, 1; however, any number of markers may be used.

[0042] FIG. 3 shows a top view of lesion 6 in the wall of the GI tract 3. The lesion 6 is surrounded by a plurality of markers 1, 1, etc. The lesion 6 can then be removed by the endoscopist with confidence that its margins have been clearly delineated.

[0043] FIG. 4 shows a top view of a submucosal nodule or other finding 7 in the wall of the GI tract 3. The submucosal nodule or other finding 7 is marked with a plurality of markers 1, so
that the initial endoscopist or another endoscopist can relocate the lesion at a later time for
further evaluation using EUS or other means of evaluation or to possibly sample or remove the
lesion. Additionally, marking such a lesion makes the lesion easier for a surgeon to identify and
remove.

[0044] FIG. 5 is a side view of a portion of the GI tract 64 with a neoplasm 62 on or in its
wall. The neoplasm 62 will be marked with a plurality of markers. As shown in FIG. 5, three
markers 60 will be proximal to the neoplasm 62 and in a roughly triangular configuration around
the circumference of the wall of the GI tract and three markers 66 will be distal to the neoplasm
62 and in a roughly triangular configuration around the circumference of the wall of the GI tract.
This type of marking is particularly useful, for example, to mark a portion of the GI tract to be
resected. It should be noted that the type, number or placement of markers to be used is not
limited.

[0045] FIG. 6A depicts a side view of a marker 1400. The marker 1400 includes a cap unit
1402 and a plurality of micro-bristles 1404 affixed to the lower portion of the cap unit 1402. The
micro-bristles 1404 engage the surface of a region 84 such that the micro-bristles secure
themselves to the region 84. The micro-bristles 1404 may be substantially straight, curved,
barbed or contain any other arrangement to aid in their securing the marker to the wall of the GI
tract.

[0046] FIG. 6B depicts a side view of a marker 1406. The marker 1406 includes a cap unit
1408 and an attachment unit 1410 affixed to the center of a lower portion of the cap unit 1408.
In one embodiment, the marker 1406 may include a plurality of attachment units 1410 affixed to
the lower portion of a cap unit 1408. The attachment units are formed into any shape which is
capable of adhering to the wall of the GI tract. In another embodiment, the attachment unit
1410 is in the shape of a barb. In another embodiment, a plurality of attachment units are
arrayed in any direction and/or orientation in relation to one another. In another embodiment,
the attachment unit is a taper screw which has a base portion affixed to the cap unit 1408 which
tapers to a point on the end opposite the cap unit 1408. In yet another embodiment, the tapered
screw 1408 includes retractable pins which engage the region 84.

[0047] FIG. 6C depicts a side view of a marker 1412. The marker 1412 includes a cap unit
1414 and an adhesive layer 1416 applied to the lower portion of the cap unit 1414. The
adhesive layer 1416 is comprised of a non-toxic adhesive capable of creating a secure bond to
human tissue.
FIG. 6D depicts the side view of a marker 1418. The marker 1418 includes a cap unit 1420, at least three barbs 1422 aligned on the lower surface of the cap 1420 and at least two pins 1424 aligned on the lower surface of the cap 1420. In one embodiment, the barbs 1422 are comprised of a straight shaft having one end secured to the cap unit 1420 and a protrusion extending perpendicular to a side of the shaft at the end opposite the cap unit 1420. The end of the protrusion opposite the surface of the shaft forms into a sharpened point completing the barb 1422. In one embodiment, the hooking portion 1426 of two of the barbs are oppositely facing. However, the barbs 1422 may be aligned in any configuration that allows the marker unit to secure to a region 84 and may include any number or combination of barbs and pins.

FIG. 6E depicts a bottom view of the marker 1418. In one embodiment, the barbs 1422 are aligned along one axis of the lower portion of the surface. In addition, the pins 1424 are aligned along an axis perpendicular to the axis along which the barbs 1422 are aligned.

FIG. 6F depicts a side view of an embodiment of the marker 1418. In this embodiment, the pins 1424 are replaced with two barbs 1428 having hooking portions that are facing away from the center of the cap 1420 and which are angled away from the center of the cap 1420.

FIG. 6G depicts a side view of a marker 1430. The marker 1430 includes a plurality of barbs 1432 affixed to the lower portion of a cap unit 1434. The barbs 1432 include sharpened ends 1436 which face away from the center of the cap unit 1434. In one embodiment, the barbs 1432 are perpendicular to the lower surface of the cap unit 1434. In another embodiment, the barbs 1432 are angled away from the center of the cap unit 1434. In yet another embodiment, each of the barbs 1432 is angled in different directions relative to one another.

FIG. 6H depicts a side view of a marker 1440. The marker 1440 consists of a plurality of barbs 1442 affixed to the lower surface of a cap unit 1444. The barbs 1442 are comprised of a shaft 1446 having one end affixed to the lower portion of the cap unit 1444 and a second end affixed to a top portion of a first pin 1448. The first pin 1448 includes an upper base portion and a lower pointed end. The shaft 1446 is offset from the center of the upper base portion of the first pin 1448 by a predetermined distance. A lower base portion of a second pin 1450 is affixed to the upper base portion of the first pin 1448 such that the sharpened end of the second pin 1450 faces a direction opposite or nearly opposite to the sharpened end of the first pin 1448. Further, the second pin 1450 is sized relative to the first pin 1448 such that a gap
exists between the second pin and the shaft 1446. During deployment, the marker 1440 is
extended downward into a region 84 (not shown) such that the first pin 1448 pierces the region
84 and extends into the region. The marker 1440 continues into the region 84 until the second
pin 1450 is below the surface of the region 84. Because of this arrangement, the second pin
1450 prevents the marker 1440 from exiting the region 84. In another embodiment, the first pin
1448 and/or the second pin 1450 may be blunt instead of sharp. In another embodiment, the
cap unit 1444 may have one or a plurality of holes or gaps that allow for passage of either a
needle or a blunt-tipped stylet or a plurality of either needles and/or blunt-tipped stylets in order
to aid in the deployment of a marker 1440 onto and/or into a region 84.

[0053] In one embodiment, the barbs 1442 are perpendicular to lower surface of the cap
unit 1444. In another embodiment, the barbs 1442 are angled away from the center of the cap
unit 1444. In yet another embodiment, each of the barbs 1442 are angled in different directions
relative to one another. In each embodiment, the barbs may face in the same or different
directions and multiple barbs may be affixed to the lower portion of the cap unit.

[0054] The markers 1400, 1406, 1412, 1418, 1420, 1430 and 1440 are inserted into a
delivery unit such that the upper portion of the cap units are in contact with the lower portions of
another marker. A vertical transmission unit (not shown) applies a force to the center of the cap
units such that the cap unit closest to the region 84 is pushed out of the delivery unit and onto
the surface of the region 84 thereby allowing the entire marker to be secured to the region 84. In
an alternative embodiment, a spacer is employed as part of the delivery unit.

[0055] FIG. 7A depicts a top view of a marker 2200. The marker 2200 includes a cap unit
2202 with at least one opening 2204 and a spring loaded pin 2224. In one embodiment, the cap
unit 2202 includes a plurality of openings 2204 located around the periphery of the top surface
of the cap unit 2202. FIG. 7B depicts a side view of the marker 2200. The marker 2200 includes
the spring loaded pin 2224 in the cap unit. The pin 2224 is angled upward away from the top
surface of the cap unit 2202 and is configured to retract into and out of the cap unit 2204 by a
spring unit (not shown). The marker 2200 also contains a plurality of barbs 2206 affixed to the
lower portion of a cap unit 2202. In one embodiment, the barbs 2206 are arranged around the
periphery of each of the openings 2204. The barbs 2206 include sharpened ends 2208 which
face away from the center of the cap unit 2202. In one embodiment, the barbs 2206 are
perpendicular to the lower surface of the cap unit 2202. In another embodiment, the barbs 2206
are angled away from the center of the cap unit 2202. In yet another embodiment, each of the
barbs 2206 are angled in different directions relative to one another. In one embodiment, a
hollow cylinder 2210 is attached to the lower portion of the cap unit 2202 around the opening 2204. In another embodiment, the barbs 2206 are attached to the hollow cylinder 2210. The distal end of the hollow cylinder 2210 may be blunt or sharp allowing it to be the mechanism which pierces the region 84 along with or instead of the barbs 2206.

[0056] FIG. 7C depicts a delivery unit 2212 for a marker 2200. The delivery unit 2212 includes a tube 2214 with an opening 2216. A plurality of markers 2200 are stacked in the tube 2214 such that the barbs 2206 of one marker 2200 are in contact with the cap unit 2202 of another marker 2200 in the tube 2214. A vertical transmission unit 2218 engages the opening 2204 in the cap unit 2202 and forces the marker 2200 closest to the opening 2216 to move towards a region 84. In another embodiment, a spacer (not shown) is used in between markers 2200.

[0057] In one embodiment, the vertical transmission unit 2218 is a blunt ended stylet that is configured to engage at least one opening in the cap unit 2202 such that the cap unit 2202 is supported by the blunt ended stylet during deployment. In another embodiment, the vertical transmission unit 2218 includes a plurality of blunt ended stylets which are configured to engage the plurality of openings 2204 on the top surface of the cap unit 2202. In yet another embodiment, the vertical transmission unit is a needle or a plurality of needles configured to engage at least one opening in the cap unit 2202.

[0058] In one embodiment, the vertical transmission unit 2218 engages the hollow cylinder 2210. In another embodiment, the vertical transmission unit 2218 is the hollow cylinder 2210. In another embodiment, the barbs 2206 are arranged on the lower surface of the cap unit 2202 such that the barbs 2206 are in contact with the surface of the vertical transmission unit 2218 when the vertical transmission unit engages the opening 2204. In another embodiment, the barbs 2206 are arranged around the plurality of openings 2204 such that the barbs 2206 are in contact with the portions of the vertical transmission unit 2218 passing through each of the plurality of openings 2204.

[0059] As the vertical transmission unit 2218 moves through the opening 2216, the sides of the vertical transmission unit 2218 press against the pin 2224 forcing the pin 2224 into the cap unit 2202. When a notch 2222 located on the side of the vertical transmission unit 2218 is positioned over the pin 2224, a spring unit (not shown) in the cap unit forces the pin 2224 into the notch 2222 preventing the vertical transmission unit 2218 from moving downward through the opening 2204 and positioning the end of the vertical transmission unit 2218 a predetermined distance below the barbs 2206.
As the vertical transmission unit 2218 continues to move downward, the vertical transmission unit 2218 forces the marker 2200 downward. In one embodiment, the vertical transmission unit 2218 is a needle that pierces the region 84 before the barbs 2206. In another embodiment, the vertical transmission unit 2218 is a needle which pierces the region 84 after the barbs 2206 have pierced the region 84. In another embodiment, the vertical transmission unit 2218 is a needle which pierces the region 84 at the same time the barbs pierce the region 84. In yet another embodiment, the vertical transmission unit 2218 is a blunt stylet that does not pierce the region 84. In another embodiment, the vertical transmission unit 2218 includes a first transmission portion which moves the vertical transmission unit 2218 downward and a second transmission portion which separately moves the marker 2200 downward.

Once the barbs 2206 pierce the region 84, the vertical transmission unit 2218 is retracted back through the opening 2204 in the cap unit 2202. As the vertical transmission unit 2218 moves backward, the pin 2224 disengages the notch 2222 and the sides of the vertical transmission unit 2218 force the pin 2224 into the cap unit 2202. In another embodiment, the pin 2224 is located on the vertical transmission unit 2218 and the notch 2222 is located in the cap unit. Consistent with this embodiment, the pin 2224 is coupled to an engagement unit (not shown) that allows a user of the vertical transmission unit 2218 to retract and eject the pin 2224 from the vertical transmission unit 2218. FIG. 7E depicts the marker 2200 engaged with the region 84 after the vertical transmission unit 2218 is removed. In another embodiment, more than one pin 2224 is employed. In another embodiment, a different engagement mechanism is employed (i.e. pincers). In yet another embodiment, no distal engagement mechanism is necessary as the vertical transmission unit 2218 is designed to recoil automatically into the delivery catheter once the marker 2200 has pierced and/or has been deployed into the region 84 or because the vertical transmission unit has been deployed into the region 84 with or alongside the marker 2200.

In one embodiment, the vertical transmission unit 2218 engages the opening 2204 and passes through the hollow cylinder 2210 which moves the hollow cylinder 2210 towards the region 84 until the hollow cylinder 2210 pierces the region 84.

In yet another embodiment, FIGS. 8A-C, the marker 1800 consists of a cap unit 1802 attached to a vertical transmission unit 1804 that is a needle which pierces the region 84. An operator of the marker can pull the insertion unit 1806 which causes the wires 1810 to extend through the openings 1808 into the region 84 securing the marker in place. FIG. 8C depicts a side view of the connection between the insertion unit 1806 and the wires 1810. As the Figure
depicts, each wire 1810 is curved such that an upward motion of the insertion unit 1806 translates into an upward movement of the wire 1810. In addition, a downward motion of the insertion unit 1806 translates into a downward motion of the wire 1810 which results in the wires 1810 retracting back into the vertical transmission unit 1804. In another embodiment, the wires 1810 may point in any direction and different wires may point in different directions. In another embodiment, the wires 1810 may be barbs or any other structure(s), or any combination of wires, barbs, and/or other structures which allow for anchoring of the marker 1800 into the GI wall. In yet another embodiment, all or some of the wires, barbs, and/or other structures will already be exposed prior to deployment of the marker 1800. In the event that all of the wires, barbs, and/or other structures are already exposed prior to deployment, the marker 1800 will not possess an insertion unit 1806.

[0064] FIG. 9A depicts a side view of a marker 1300. The marker 1300 includes a cap unit 1302 and a screw shaped unit 1304 having one end affixed to the center of the lower portion of the cap unit 1302 and another end 1306 sharpened to a point capable of puncturing a region 84 (not shown).

[0065] FIG. 9B depicts a delivery unit 1308 for the marker 1300. The delivery unit 1308 includes an inner tube 1310 that has an opening 1312 and an outer tube 1314 that shares the opening 1312 at one end. The markers 1300 are stacked in the inner tube 1310 such that the sharpened end 1306 of a marker is in contact with the cap unit 1302 of another marker closer to the opening 1312. In one embodiment, the inner tube 1310 is allowed to rotate freely in relation to the outer tube 1314 such that a rotational force is applied to the cap unit 1302 that forces the cap unit 1302 down towards the opening 1312. The rotational force applied by the inner tube 1310 forces the marker downward out of tube. As the marker 1300 moves downward towards the region, the sharpened point 1306 penetrates the region 84. The marker continues downward until the cap unit 1302 is free of the tube. However, any mechanism which allows for the transmission of a rotational force to the marker 1300 effecting its screw-type deployment into a region 84 will do.

[0066] FIG. 9C depicts a delivery unit 1308 for a marker 1300. As FIG. 9C depicts, the cap unit 1302 of the marker 1300 includes a plurality of grooves 1316 that engage at least one gear unit 1318. The inner sidewalls of tube 1320 also include a plurality of grooves 1322 which engage the teeth of the gear unit 1318 such that the top portion of the marker 1300 rotates as the marker 1300 is moved down the tube 1320. Once the marker 1300 is clear of the tube, the gears 1318 fall away. FIG. 9D depicts the marker 1300 embedded in the region 84.
FIG. 10 depicts another embodiment of a marker 800 utilizing a screw-type mechanism to effect deployment. The marker 800 includes a screw 802 wound around a base unit 804. The screw 802 is adhered to a base unit 804 and includes a sharpened pointed end 808 capable of puncturing a region 84 (not shown) that extends beyond an open end of the protective case 806. During deployment, the sharpened end 808 of the screw 802 penetrates into a portion of a region 84. A rotational force is then applied to the screw 802 such that the screw travels into the region 84 to secure the marker 800 into the region 84. It is understood that the base unit 804 may be attached to a cap unit (not shown) or the base unit 804 may extend above and out of the screw 802 and that this base unit 804 may itself mark the site.

FIG. 11A depicts a cut away side view of a marker 1600. The marker 1600 includes a cap unit 1602 which includes a cavity 1604 in the center portion of the cap unit 1602 and an opening 1606 in the lower portion of the cap unit 1602. The sides of the opening 1606 include a plurality of barb units 1608. The marker 1600 also includes a second opening 1610 in the center of the top portion of the cap unit 1602.

FIG. 11B depicts a delivery unit 1612 for the marker 1600. The delivery unit 1612 includes a suction tube 1614 that has an opening 1616. The marker 1600 is held in the opening 1606 such that the lower portion of the marker 1600 extends through the opening 1616. The sides of the marker 1600 are pressed against the inner walls of the suction tube 1614 such that the inner walls create an air tight barrier with the sides of the marker 1600 when suction is applied to the upper portion of the marker 1600. After the marker is placed on the region 84, a suction is created in the tube 1614 causing a portion of the region 84 to extend up into the cavity 1604. When the suction is stopped, the barb units 1608 hold the portion of the region 84 in the cavity 1604. In another embodiment, the suction causes the barb units 1608 to retract against a spring in the cap unit 1602 such that the barbs 1608 pull away from the region 84. After the suction is removed, the barbs 1608 are forced into the region 84 by the spring. The barbs 1608 are oriented horizontally in this figure; however, it is understood that these barbs may be oriented diagonally upward, diagonally downward, or even vertically downward, or any combination of these orientations. Furthermore, it is understood that the second opening 1610 may be of any size in relation to the total diameter of the cap unit 1602. In another embodiment, the second opening 1610 is omitted, and the opening 1616 is relatively larger allowing the suction to be transmitted through this opening 1616. In yet another embodiment, the second opening 1610 is present, and the opening 1616 is also larger, allowing suction to be transmitted
through both openings. It is also understood that cap unit may be of any shape or figure and is not in any way restricted to having a circle shape.

[0070] In all of the embodiments described above thus far, it is understood that the marker unit may be color coded, contain an RFID tag or include a number, letter or symbol on the surface of the wire. Any characters on the marker unit may be indented, notched, etched, printed, written with laser, or by any other means.

[0071] FIG. 12A depicts a top view of a material 1900 adhered to a region 84 using a plurality of markers 1902. Consistent with this embodiment, the markers used to adhere the material 1900 to the region 84 are any of the markers previously described. The material is any material that is non toxic to the human body. As an illustrative example, the material 1900 may be used to cover a tear or an opening in the region 84. The material 1900 is first positioned over the opening and is then adhered to the region 84 using a plurality of markers 1902 that are positioned in portions of the region 84 which can accommodate the markers. Alternatively, the material 1900 may include a bonding agent such as a glue or adhesive to adhere the material to the site within the region 84 or may be composed of a substance, or substances, that naturally bond, adhere and/or attach the material 1900 to the site within the region 84. The markers may be positioned as described above to further ensure that the material will not become displaced. In one embodiment, the material 1900 allows fluid, such as gas or a liquid, to pass through the material 1900 in one direction and restricts fluid from flowing through the material 1900 in the opposite direction. In one embodiment, the material 1900 covers an opening in a colon and the material 1900 allows gas and/or a liquid to flow into a colon and restricts gas and/or a liquid from flowing out of the colon.

[0072] FIG. 12B depicts a top view of a plurality of markers 1904. Each of the markers 1904 include a loop 1906 through which a suture 1908 is positioned. The loop 1906 is affixed to the cap unit of any of the previously described markers. The markers are connected to secure portions of the region 84. The suture 1908 is pulled through each loop 1906 such that both ends of the opening are pulled together to seal the opening. Once both ends are pulled together, the suture is tied together to secure the portions of the region 84 together. In one embodiment, the loop 1906 is recessed into the region 84 where the marker 1904 is inserted.

[0073] FIG. 13A depicts a top view of one embodiment of a mirror device 2000. The mirror device 2000 consists of an extension unit 2002 which retracts into a tube 2004. A vertical transmission unit (not shown) extends the extension unit 2002 out of the tube 2004. The end of the extension unit 2002 is formed into a mirror holding unit 2006. In one embodiment, the mirror
holding unit 2006 has a substantially circular shape. In another embodiment consistent of the present embodiment, the mirror holding unit 2006 has a substantially elliptical shape.

A flexible reflective material 2008 is secured to the edges of the mirror holding unit 2006 which forms a flat reflective surface. The flexible reflective material 2008 has a reflective coating applied to one or both sides of the flexible reflective material 2008 such that light is reflected back from the surface of the flexible reflective material 2008. The edges of the mirror holding unit 2006 are formed of a material having memory capabilities that allow the mirror holding unit and the flexible reflective material 2008 to retract into the tube 2004. These shapes may be flat, concave or convex.

In one embodiment, the mirror device 2000 is used to position the mirror behind a growth on a region such that all sides of the growth are viewable. Additionally, the mirror device 2000 may be used to locate a finding or a previously placed marker device on the backside of a fold, or other structure, within the GI tract. It is understood, that the backside of a fold or structure is meant to mean a portion of the fold or structure out of direct view of an endoscopic device. In another embodiment, the mirror holding unit 2006 is rotatively attached to the extension unit 2004 which allows the mirror holding unit 2006 to rotate and bend in relation to the end of the tube 2004 such that different views of the growth are visible from the mirror. In one embodiment, the mirror holding unit 2006 is made from a material having memory capabilities such that the mirror holding unit 2006 contracts to fit into the tube 2004 when the vertical transmission unit (not shown) pulls the mirror holding unit 2006 into the tube 2004. In another embodiment, the mirror holding unit 2006 is made of a flexible material including, but not limited to, plastic, stainless steel, Teflon®, nitinol, nylon or any other material that is flexible with memory characteristics. In another embodiment, the mirror holding unit 2006 is made from a rigid material that is capable of retracting into the tube 2004 when a force acting to pull the mirror holding unit 2006 into the tube 2004 is applied.

In another embodiment the mirror holding unit 2006 expands into a basket 2010, as shown in FIG. 13B. In one embodiment, the basket 2010 expands to form the flexible reflective material 2008 into a convex lens. In another embodiment, the basket 2010 expands to form the flexible reflective material 2008 into a concave lens. In another embodiment, the flexible reflective material 2008 has a reflective coating on both sides which allows the basket 2010 to be used as a convex or concave mirror depending on the position of the mirror holding unit 2006. In another embodiment, the mirror holding unit 2006 expands into mirror having multiple reflective surfaces. In another embodiment, the mirror device is used to locate a previously
placed marker in a region 84. In another embodiment, the mirror device is used to locate a region 84 in order to deploy a marker.
CLAIMS

Claim 1. A marker for marking the location of an internal area in the human body comprising:
   a cap unit; and
   at least one attachment unit affixed to the cap unit, the at least one attachment unit capable of piercing a surface of a region in response to a vertical force applied to the cap unit.

Claim 2. The marker of claim 1, wherein the cap unit is at least one of: color coded, a radio frequency identification unit, or dissolves over time.

Claim 3. The marker of claim 1, wherein characters are at least one of: indented, notched, etched, printed, written with laser into a top portion of the cap unit.

Claim 4. The marker of claim 1, wherein the at least one attachment unit comprises at least one of micro-bristles, barbs, an adhesive layer, or pins.

Claim 5. The marker of claim 1, wherein the at least one attachment unit is capable of piercing the surface of the region in response to a rotational force applied to the cap unit.

Claim 6. The marker of claim 1, wherein the at least one attachment unit is capable of piercing the surface of the region in response to a horizontal force applied to the cap unit.

Claim 7. The marker of claim 1, wherein the at least one attachment unit is capable of piercing the surface of the region in response to a diagonal force applied to the cap unit.

Claim 8. The marker of claim 1, further comprising:
   a delivery unit comprising:
   a tube holding a plurality of markers; and
   a vertical transmission unit configured to apply a vertical force to a cap unit of a marker to cause the marker to pierce the surface of the region.
Claim 9. A marker for marking the location of an internal area in the human body comprising:
   a cap unit; and
   a screw unit affixed to the cap unit, the screw unit capable of piercing a surface of a region in response to a rotational force applied to the cap unit.

Claim 10. The marker of claim 9, wherein the cap unit is at least one of: color coded, a radio frequency identification unit, or dissolves over time.

Claim 11. The marker of claim 9, wherein characters are at least one of: indented, notched, etched, printed, written with laser into a top portion of the cap unit.

Claim 12. The marker of claim 9, further comprising:
   a delivery unit comprising:
      a tube holding a plurality of markers; and
      a screw mechanism configured to apply a rotational force to a cap unit of a marker to cause the marker to pierce the surface of the region.

Claim 13. The marker of claim 9, wherein the cap unit comprises a plurality of grooves to engage at least one gear unit causing a rotational force to be applied to the cap unit.

Claim 14. A marker for marking the location of an internal area in the human body comprising:
   a cap unit; and
   a plurality of attachment units affixed to sides of an opening in a lower portion of the cap unit, the plurality of attachment units capable of piercing a surface of a region in response to a suction force applied to the cap unit.

Claim 15. The marker of claim 14, wherein the cap unit is at least one of: color coded, a radio frequency identification unit, or dissolves over time.

Claim 16. The marker of claim 14, wherein characters are at least one of: indented, notched, etched, printed, written with laser into a top portion of the cap unit.
Claim 17. The marker of claim 14, wherein the plurality of attachment units comprises at least one of micro-brisles, barbs, or pins.

Claim 18. The marker of claim 14, further comprising:
   a delivery unit comprising:
      a suction tube holding a plurality of markers; wherein the suction tube applies suction causing a portion of the region to extend upwards into a cavity of the marker causing the marker to pierce the surface of the region.

Claim 19. A method for administering a marker to an internal area in a human body, comprising:
   loading a delivery unit with at least one marker;
   placing the delivery unit at a region to be marked; and
   activating a control device of the delivery unit to deploy a marker of the at least one marker, causing the marker to pierce a surface of the region.

Claim 20. The method of claim 19, wherein loading a delivery unit with at least one marker comprises:
   loading the delivery unit with a packet containing a plurality of markers.

Claim 21. The method of claim 19, wherein the control device is at least one of: a gun-type control, a knob, or a lever to control deployment of markers.

Claim 22. The method of claim 19, wherein activating a control device of the delivery unit to deploy a marker of the at least one marker comprises:
   activating a vertical transmission unit that forces a marker closest to an opening of the delivery unit to pierce the surface of the region.

Claim 23. The method of claim 19, wherein the vertical transmission unit is a blunt ended stylet.
A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B19/00
ADD.
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 practicable, search terms used)
EPO-Internal , WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of Box C. See patent family annex.

Date of the actual completion of the international search: 28 June 2012

Date of mailing of the international search report: 10/07/2012

Name and mailing address of the ISA:
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax. (+31-70) 340-3016

Authorized officer: Hel d , Gunter
**INTERNATIONAL SEARCH REPORT**

**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. **X** Claims Nos.: 19-23  
   because they relate to subject matter not required to be searched by this Authority, namely:  
   Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2.  
   Claims Nos.:  
   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:

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.
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