(54) Title: METHOD AND APPARATUS FOR STABILIZING, STRAIGHTENING, OR EXPANDING THE WALL OF A LUMEN OR CAVITY

(57) Abstract: The present invention comprises the provision and use of a novel endoscopic device which is capable of stabilizing, straightening, expanding and/or flattening the side wall of a body lumen and/or body cavity so as to better present the side wall tissue for examination and/or treatment during an endoscopic procedure. The present invention also comprises the provision and use of a novel endoscopic device capable of steadying and/or stabilizing the distal tips and/or working ends of instruments inserted into a body lumen and/or body cavity, whereby to facilitate the use of those instruments.
METHOD AND APPARATUS FOR STABILIZING, STRAIGHTENING, OR EXPANDING THE WALL OF A LUMEN OR CAVITY

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Reference To Pending Prior Patent Application
This patent application claims benefit of pending prior U.S. Provisional Patent Application Serial No. 61/284,215, filed 12/15/2009 by Jeffrey Milsom et al. for METHOD AND APPARATUS FOR STABILIZING, STRAIGHTENING, EXPANDING AND/OR FLATTENING THE SIDE WALL OF A BODY LUMEN OR BODY CAVITY SO AS TO PROVIDE INCREASED VISUALIZATION OF THE SIDE WALL OF THE BODY
LUMEN OR BODY CAVITY, AND/OR FOR STABILIZING
INSTRUMENTS RELATIVE TO THE SAME (Attorney’s Docket No.
CORN-17 PROV), which patent application is hereby
incorporated herein by reference.

Field Of The Invention

This invention relates to surgical methods and
apparatus in general, and more particularly to surgical
methods and apparatus for stabilizing, straightening,
expanding and/or flattening the side wall of a body
lumen and/or body cavity so as to provide increased
visualization of the same and/or increased access to
the same, and/or for stabilizing instruments relative
to the same.

Background Of The Invention

The human body comprises many different body
lumens and body cavities. By way of example but not
limitation, the human body comprises body lumens such
as the gastrointestinal (GI) tract, blood vessels,
lymphatic vessels, the urinary tract, etc. By way of
further example but not limitation, the human body
comprises body cavities such as the head, chest,
abdomen, nasal sinuses, cavities within organs, etc.
In many cases it may be desirable to endoscopically examine and/or treat a disease process or abnormality located within, or on the side wall of, a body lumen and/or body cavity. By way of example but not limitation, it may be desirable to examine the side wall of the gastrointestinal tract for lesions and, if a lesion is found, to biopsy, remove and/or otherwise treat the lesion.

The endoscopic examination and/or treatment of the side wall of a body lumen and/or body cavity can be complicated by the geometry of the side wall of the body lumen and/or body cavity, and/or by the consistency of the tissue making up the side wall of the body lumen and/or body cavity. By way of example but not limitation, the intestine is an elongated organ having an inner lumen characterized by frequent turns and a side wall characterized by numerous folds, with the side wall tissue having a relatively soft, pliable consistency. It can be difficult to fully visualize the side wall of the intestine, and/or to treat a lesion formed on the side wall of the intestine, due to this varying side wall geometry and its soft, pliable consistency. By way of example but not limitation, in the case of colonoscopies, it has been found that
approximately 5-30% of patients have a tissue geometry and/or a tissue consistency which makes it difficult to fully visualize the anatomy using conventional endoscopes, and/or to fully access the anatomy using instruments introduced through conventional endoscopes.

In addition to the foregoing, it has also been found that some body lumens and/or body cavities can spasm and/or contract when an endoscope is inserted into the body lumen and/or body cavity. This spasming and/or contraction can cause the body lumen and/or body cavity to constrict and/or otherwise move and/or change its configuration, which can further complicate and/or compromise endoscopic visualization of the anatomy, and/or further complicate and/or compromise access to the anatomy using instruments introduced through conventional endoscopes.

Since the ability of medical personnel to directly examine inner surfaces of the body is constantly increasing with the improvement and expansion of new endoscopic devices, it would, therefore, be highly advantageous to provide an endoscopic device capable of stabilizing, straightening, expanding and/or flattening the side wall of a body lumen and/or body cavity so as
to better present the side wall tissue for examination and/or treatment during an endoscopic procedure.

It would also be highly advantageous to provide an endoscopic device capable of steadying and/or stabilizing the distal tips and/or working ends of instruments inserted into a body lumen and/or body cavity, whereby to facilitate the use of those instruments.

Summary Of The Invention

The present invention comprises the provision and use of a novel endoscopic device which is capable of stabilizing, straightening, expanding and/or flattening the side wall of a body lumen and/or body cavity so as to better present the side wall tissue for examination and/or treatment during an endoscopic procedure.

The present invention also comprises the provision and use of a novel endoscopic device capable of steadying and/or stabilizing the distal tips and/or working ends of instruments inserted into a body lumen and/or body cavity, whereby to facilitate the use of those instruments.

In one form of the present invention, there is provided apparatus comprising:
a sleeve adapted to be slid over the exterior of an endoscope;
a proximal balloon secured to the sleeve near the distal end of the sleeve;
a pusher tube slidably mounted to the sleeve, the pusher tube being configured to slidably receive a guidewire therein; and
a distal balloon secured to the distal end of the pusher tube.

In another form of the present invention, there is provided apparatus comprising:
a sleeve adapted to be slid over the exterior of an endoscope;
a proximal balloon secured to the sleeve near the distal end of the sleeve;
a pusher element slidably mounted to the sleeve; a double pull mechanism mounted to the sleeve for moving the pusher element relative to the sleeve; and
a distal balloon secured to the distal end of the pusher element.
In another form of the present invention, there is provided apparatus comprising:

a sleeve adapted to be slid over the exterior of an endoscope;

5 a proximal balloon secured to the sleeve near the distal end of the sleeve;

a pusher element slidably mounted to the sleeve, the pusher element being substantially flexible, having substantial column strength, and having a length substantially shorter than the sleeve; and

10 a distal balloon secured to the distal end of the pusher element.

In another form of the present invention, there is provided a method for performing a procedure in a body lumen and/or body cavity, the method comprising:

providing apparatus comprising:

a sleeve adapted to be slid over the exterior of an endoscope;

15 a proximal balloon secured to the sleeve near the distal end of the sleeve;

20
a pusher tube slidably mounted to the sleeve, the pusher tube being configured to slidably receive a guidewire therein; and

a distal balloon secured to the distal end of the pusher tube;

positioning the apparatus in the body lumen and/or body cavity;

inflating the proximal balloon;

advancing a guidewire through the pusher tube;

advancing the pusher tube along the guidewire;

inflating the distal balloon; and

performing the procedure.

In another form of the present invention, there is provided a method for performing a procedure in a body lumen and/or body cavity, the method comprising:

providing apparatus comprising:

a sleeve adapted to be slid over the exterior of an endoscope;

a proximal balloon secured to the sleeve near the distal end of the sleeve;
a pusher element slidably mounted to the sleeve;
a double pull mechanism mounted to the sleeve for moving the pusher element relative to the sleeve; and
a distal balloon secured to the distal end of the pusher tube;
  positioning the apparatus in the body lumen and/or body cavity;
  inflating the proximal balloon;
  advancing the pusher element distally relative to the sleeve;
  inflating the distal balloon; and
  performing the procedure.

In another form of the present invention, there is provided a method for performing a procedure in a body lumen and/or body cavity, the method comprising:
  providing apparatus comprising:
    a sleeve adapted to be slid over the exterior of an endoscope;
a proximal balloon secured to the sleeve near the distal end of the sleeve;

a pusher element slidably mounted to the sleeve, the pusher element being substantially flexible, having substantial column strength, and having a length substantially shorter than the sleeve; and

a distal balloon secured to the distal end of the pusher element;

positioning the apparatus in the body lumen and/or body cavity;

inflating the proximal balloon;

advancing the pusher element distally relative to the sleeve;

inflating the distal balloon; and

performing the procedure.

Brief Description Of The Drawings

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiments of the invention, which is
to be considered together with the accompanying
drawings wherein like numbers refer to like parts and
further wherein:

Fig. 1 is a schematic side view showing a novel
endoscopic stabilizing platform formed in accordance
with the present invention, wherein the endoscopic
stabilizing platform is shown mounted on an endoscope
and deployed in a body lumen so as to stabilize,
straighten, expand and/or flatten the side wall of the
body lumen in order to provide increased visualization
of the same and/or to provide increased stability for
the distal tips and/or working ends of instruments
inserted into the body lumen;

Figs. 2-6, 6A and 7-12 are schematic views showing
further details of the endoscopic stabilizing platform
shown in Fig. 1;

Figs. 13-15 are schematic views showing a
controller for operating the endoscopic stabilizing
platform of the present invention, and further aspects
of the present invention, including a motorized drive
system for use in conjunction with the endoscopic
stabilizing platform of the present invention;

Fig. 16 is a schematic view showing how radiopaque
markers may be incorporated into and/or onto one or
both of the balloons of the endoscopic stabilizing platform of the present invention;

Figs. 17-33 are schematic views illustrating a preferred method of using the present invention; and

Figs. 34-38 are schematic views showing an additional preferred method of using the present invention.

Detailed Description Of The Preferred Embodiments

The Novel Endoscopic Stabilizing Platform

The present invention comprises the provision and use of a novel endoscopic stabilizing platform for stabilizing, straightening, expanding and/or flattening the side wall of a body lumen and/or body cavity so as to better present the side wall tissue for examination and/or treatment during an endoscopic procedure, and/or for stabilizing instruments relative to the same. By way of example but not limitation, the novel endoscopic stabilizing platform can be used to stabilize, straighten, expand and/or flatten bends and/or curves and/or folds in the side wall of a body lumen and/or body cavity so as to better present the side wall tissue for examination and/or treatment during an
endoscopic procedure, and can provide a stable platform for the performance of numerous procedures within the body lumen and/or body cavity, including the stabilization of an endoscope and/or other surgical instruments within the body lumen and/or body cavity, e.g., during a lesion biopsy and/or lesion removal procedure, an organ resection procedure, etc.

As used herein, the term "endoscopic procedure" is intended to mean substantially any minimally-invasive or limited access procedure, diagnostic and/or surgical, for accessing the interior of a body lumen and/or body cavity for the purposes of viewing, biopsying and/or treating tissue, including removing a lesion and/or resecting tissue, etc.

In accordance with the present invention, and looking now at Fig. 1, there is shown an endoscopic stabilizing platform 5 capable of stabilizing, straightening, expanding and/or flattening the side wall of a body lumen and/or body cavity so as to better present the side wall tissue for examination and/or treatment during an endoscopic procedure using an endoscope 10, and/or for stabilizing the distal tips and/or working ends of instruments (not shown in Fig. 1) relative to the same.
More particularly, endoscopic stabilizing platform 5 generally comprises a sleeve 15 adapted to be slid over the exterior of the shaft of endoscope 10 as will hereinafter be discussed, a proximal (or “aft”) balloon 20 secured to sleeve 15 near the distal end of the sleeve, and a handle 25 secured to sleeve 15 at the proximal end of the sleeve. Endoscopic stabilizing platform 5 also comprises a pusher tube 30 slidably mounted to sleeve 15 as will hereinafter be discussed, and a distal (or “fore”) balloon 35 secured to the distal end of pusher tube 30, whereby the spacing between proximal balloon 20 and distal balloon 35 can be adjusted by the surgeon during use by moving pusher tube 30 relative to sleeve 15. Endoscopic stabilizing platform 5 also comprises a hand piece 40 for enabling operation of endoscopic stabilizing platform 5 by a surgeon.

Looking next at Figs. 1-6 and 6A, sleeve 15 generally comprises an elongated, thin-walled tube configured to be slid over the exterior of the shaft of endoscope 10 so as to make a close fit therewith, such that the sleeve will slide easily over the endoscope during mounting but will have sufficient residual friction with the outer surface of the endoscope that
the sleeve will remain in place during use. Sleeve 15 is sized so that when its distal end is substantially aligned with the distal end of endoscope 10, sleeve 15 (and handle 25) will substantially cover the shaft of the endoscope. Sleeve 15 preferably has a smooth outer surface so as to be non-traumatic to tissue, and is preferably made of a highly flexible material such that the sleeve will not inhibit bending of the endoscope during use. In one preferred form of the invention, sleeve 15 comprises polyethylene. If desired, sleeve 15 can include a lubricious coating on some or all of its interior and/or exterior surfaces, so as to facilitate disposition of the sleeve over the endoscope and/or movement of endoscopic stabilizing platform 5 through a body lumen and/or body cavity, respectively.

Proximal (or “aft”) balloon 20 is secured to sleeve 15 near the distal end of the sleeve. Proximal balloon 20 is disposed concentrically about sleeve 15, and hence concentrically about endoscope 10 disposed within sleeve 15. Proximal balloon 20 may be selectively inflated/deflated by means of a proximal inflation/deflation tube 45 which is secured to the exterior surface of sleeve 15, whereby proximal balloon 20 may be selectively secured to/released from the
adjacent anatomy, respectively, as will hereinafter be discussed. Preferably proximal balloon 20 is disposed a short distance back from the distal end of sleeve 15, i.e., by a distance which is approximately the same as the length of the flexible portion of an endoscope, so that the flexible portion of an endoscope will be disposed distal to the proximal balloon 20 when the endoscope is disposed in sleeve 15. This construction allows the flexible portion of the endoscope to be articulated even when proximal balloon 20 has been inflated in the anatomy so as to stabilize the adjacent non-articulating portion of the endoscope relative to the anatomy, as will hereinafter be discussed in further detail.

Handle 25 is secured to the proximal end of sleeve 15. Handle 25 preferably comprises a substantially rigid or semi-rigid structure which may be gripped by the hand of the surgeon and pulled proximally so as to pull sleeve 15 over the exterior surface of endoscope 10, whereby to mount sleeve 15 to the shaft of the endoscope.

Pusher tube 30 is slidably mounted to sleeve 15, whereby the distal end of the pusher tube can be extended and/or retracted relative to sleeve 15, and
hence extended and/or retracted relative to the distal end of endoscope 10 disposed in sleeve 15.

More particularly, pusher tube 30 is a relatively short element which is slidably disposed in a support tube 50 which is secured to the outer surface of sheath 15. Pusher tube 30 is preferably formed out of a relatively flexible material which provides good column strength, e.g., a superelastic material such as a shape memory alloy. By way of example but not limitation, pusher tube 30 may be formed out of Nitinol. A double pull line 55 is secured to the outer surface of pusher tube 30, e.g., by wrapping the double pull line around the outer surface of the proximal end of pusher tube 30 and gluing it in place (Fig. 6). Double pull line 55 has a retract line 60 which extends proximally through support tube 50 and then crosses over to a retract tube 63. The proximal end of retract line 60 exits retract tube 63 adjacent the proximal end of sleeve 15, e.g., near handle 25. Double pull line 55 also has an extend line 65 which extends distally through support tube 50, around a “pulley” (i.e., bearing structure) 70 (Fig. 5) disposed at the distal end of support tube 50, and then back through an extend tube 75 which is secured to the outer surface of sleeve 15. The proximal end of extend
line 65 exits extend tube 75 adjacent the proximal end of sleeve 15, e.g., near handle 15. As a result of this construction, pulling the proximal end of retract line 60 proximally causes the distal end of pusher tube 30 to retract proximally relative to sleeve 15, and pulling the proximal end of extend line 65 proximally causes the distal end of pusher tube 30 to extend distally relative to sleeve 15.

Thus it will be seen that a pulling motion, selectively applied to retract line 60 or extend line 65, is used for both retracting and extending pusher tube 30 relative to sleeve 15 (and hence relative to an endoscope 10 disposed in sleeve 15). Furthermore, this pulling motion is applied to the relatively short pusher tube 30 fairly close to the distal end of sleeve 15, and the pusher tube is constructed so as to have a relatively high column strength along its length. As a result, this construction permits a substantial extension force to be applied to the distal end of pusher tube 30, which can be important when traversing a tortuous body lumen deep within the anatomy of a patient, as will hereinafter be discussed. At the same time, since retract line 60 and extend line 65 act in tension, they can be highly flexible, and since pusher
tube 30 is relatively short and does not need to extend for the entire length of sleeve 15, pusher tube 30 can be relatively flexible even as it delivers good column strength. As a result, endoscopic stabilizing platform 5 is highly flexible along its length, even as it permits a substantial extension force to be applied to the distal end of pusher tube 30. This is a substantial advance in the art since, in the absence of such a construction, a long pusher tube, having substantial column strength along its entire length, would have to be used to transfer a substantial extension force from the proximal end of the endoscopic stabilizing platform to the distal end of the endoscopic stabilizing platform. But such a long pusher tube, with substantial column strength along its entire length, would undermine the desired flexibility of the endoscopic stabilizing platform.

Thus, as a result of its unique construction, endoscopic stabilizing platform 5 can extend a substantial length into the body, be highly flexible so as to traverse a highly tortuous body lumen (e.g., the GI tract), and still generate a substantial distally-directed force to pusher tube 30.
Pusher tube 30 includes an internal lumen 80 which is sized to accommodate a guidewire 85 therein, which permits pusher tube 30, and hence distal balloon 35 secured to the distal end of pusher tube 30, to be directed by a guidewire 85, as will hereinafter be discussed in further detail. The proximal end of guidewire 85 extends through guidewire tube 87, which is secured to the outer surface of sleeve 15. The proximal end of guidewire 85 exits guidewire tube 87 adjacent the proximal end of sleeve 15, e.g., near handle 25.

Distal (or “fore”) balloon 35 is secured to the distal end of pusher tube 30, whereby the spacing between proximal (or “aft”) balloon 20 and distal (or “fore”) balloon 35 can be adjusted by moving pusher tube 30 relative to sleeve 15. Distal balloon 35 is disposed concentrically about pusher tube 30, and hence concentrically about guidewire 85 disposed within pusher tube 30. Distal balloon 35 may be selectively inflated/deflated by means of a distal inflation/deflation tube 90 which is secured to the exterior surface of sleeve 15, whereby distal balloon 35 may be selectively secured to/released from the adjacent anatomy, respectively. However, the distal
end of inflation/deflation tube 90 is not secured to the exterior surface of sleeve 15, and is preferably relatively flexible, so that inflation/deflation tube 90 can accommodate movement of pusher tube 30 (and hence distal balloon 35) relative to sleeve 15.

Preferably, and looking now at Figs. 6 and 7, a rip sleeve 95 is initially disposed over the deflated proximal balloon 20 and distal balloon 35 so as to facilitate “snag-free” insertion of endoscopic stabilizing platform 5 into and through a body lumen and/or body cavity. When the distal end of endoscopic stabilizing platform 5 has been advanced to the location of use, rip sleeve 95 can be removed by pulling on the proximal end of a rip cord 100, which extends along a rip cord tube 105 which is secured to the outer surface of sleeve 15, whereby to free proximal balloon 20 and distal balloon 35 for subsequent inflation, e.g., in the manner shown in Fig. 8. In this respect it will be appreciated that the proximal end of rip cord 100 exits rip cord tube 105 adjacent the proximal end of sleeve 15, e.g., near handle 25.

Preferably, an overlay sleeve 110 is disposed over exterior surfaces of proximal inflation/deflation tube
45, support tube 50, retract tube 63, extend tube 75, guidewire tube 87, inflation/deflation tube 90 and rip cord tube 105. In one form of the invention, overlay sleeve 110 extends about the entire circumference of sleeve 15 for a portion of the distance between proximal balloon 20 and handle 25. Overlay sleeve 110 helps ensure that the outer surface of endoscopic stabilizing platform 5 is smooth and "snag-free" so that the endoscopic stabilizing platform can move easily within a body lumen and/or body cavity, without causing significant trauma to the tissue. If desired, overlay sleeve 110 can include a lubricious coating on some or all of its exterior surface so as to facilitate movement of endoscopic stabilizing platform 5 through a body lumen and/or body cavity.

Hand piece 40 is shown in Figs. 1, 2 and 9-12. Hand piece 40 enables single-handed operation of endoscopic stabilizing platform 5 by a surgeon who is simultaneously manipulating endoscope 10. More particularly, hand piece 40 comprises a collar 115 which is adapted to mount over endoscope 10. Collar 115 is configured to be slid over the exterior of the shaft of endoscope 10 so as to make a close fit therewith, such that the collar will slide easily over
the endoscope during mounting but will have sufficient residual friction with the outer surface of the endoscope that the hand piece will remain in place during use. Hand piece 40 also comprises an arm 120 which provides controls for advancing/retracting pusher tube 30 relative to sleeve 15, inflating/deflating proximal balloon 20, and/or inflating/deflating distal balloon 35, as will hereinafter be discussed in further detail. Note that arm 120 is configured so as to place the aforementioned controls immediately adjacent to the endoscope controls, whereby to permit easy one-hand operation by the surgeon.

Hand piece 40 is preferably configured to operate in conjunction with a controller 125 (Fig. 13), with hand piece 40 providing the means by which the surgeon controls operation of controller 125. Controller 125 is adapted to supply/withdraw fluid (e.g., air, saline, etc.) to/from proximal balloon 20 and/or distal balloon 35, whereby to selectively inflate/deflate one or the other, or both, of the balloons. Controller 125 is also adapted to control operation of a motorized drive system 130 (Figs. 13 and 14) which is adapted to (i) selectively apply a pulling force to the proximal end of retract line 60, whereby to retract pusher tube 30
relative to sleeve 15, (ii) selectively apply a pulling force to the proximal end of extend line 65, whereby to extend pusher tube 30 relative to sleeve 15, or (iii) not apply a pulling force to either retract line 60 or extend line 65. The ability of motorized drive system 130 to not apply a pulling force to either retract line 60 or extend line 65 is an important aspect of the present invention, since it means that motorized drive system 130 can hold pusher tube 30 (and hence distal balloon 35) in a fixed position relative to sleeve 15 (and hence endoscope 10), which can be extremely important in stabilizing endoscope stabilizing platform 5 relative to the anatomy.

To this end, motorized drive system 130 preferably comprises a retract pull pin 135 and an extend pull pin 140 which are adapted to be selectively moved relative to a base 145. Retract pull pin 135 is adapted to receive an eyelet 150 (Fig. 15) formed at the proximal end of retract line 60, and extend pull pin 140 is adapted to receive an eyelet 155 formed at the proximal end of extend line 65. Preferably, a cassette 160 (Fig. 15) provides support for retract line 60 and extend line 65, with cassette 160 being received on
cassette locating pins 165 disposed on motorized drive system 130.

On account of the foregoing arrangements, a surgeon can use the controls on hand piece 40 to cause controller 125 to selectively inflate/deflate proximal balloon 20, and/or inflate/deflate distal balloon 35. Furthermore, a surgeon can use the controls on hand piece 40 to cause controller 125 to selectively (i) retract pusher tube 30 relative to sleeve 15, (ii) extend pusher tube 30 relative to sleeve 15, or (iii) hold pusher tube 30 stationary relative to sleeve 15.

If desired, one or both of proximal balloon 20 and distal balloon 35 may include radiopaque markers 170 thereon, whereby to facilitate visualization of balloon location under X-ray or fluoroscopic viewing.

Furthermore, if desired, means can be provided (e.g., at controller 125) to monitor the pressure within proximal balloon 20 and distal balloon 35, whereby to prevent balloon rupture and/or the application of excessive balloon pressure against the adjacent anatomy, both of which could cause trauma to the anatomy. Such means will be obvious to a person of ordinary skill in the art in view of the present disclosure.
And, if desired, means could be provided (e.g., at controller 125 and/or motorized drive system 130) to limit the distal extension force applied to pusher tube 30, again to avoid trauma to the anatomy. Such means will be obvious to a person of ordinary skill in the art in view of the present disclosure.

Significantly, all of endoscopic stabilizing platform 5, with the possible exception of hand piece 40 (and, of course related controller 125 and the related motorized drive system 130) may be disposed of at the conclusion of a procedure.

Preferred Method Of Using The Novel Endoscopic Stabilizing Platform

Endoscopic stabilizing platform 5 may be used to stabilize, straighten, expand and/or flatten the side wall of a body lumen and/or body cavity so as to better present the side wall tissue for examination and/or treatment during an endoscopic procedure using endoscope 10, and/or to stabilize the distal tips and/or working ends of instruments relative to the same.
More particularly, in use, hand piece 40 is first mounted to endoscope 10 (Fig. 17), e.g., by pulling collar 115 over the shaft of the endoscope. Next, sleeve 15 is mounted to endoscope 10, i.e., by pulling handle 25 proximally onto the shaft of endoscope 10 (Fig. 18). Then, hand piece 40 has its electrical and fluid connections connected to controller 125 (Fig. 19), and retract line 60 and extend line 65 are connected to motorized drive system 130, e.g., by mounting eyelet 150 of retract line 60 on retract pull pin 135 and mounting eyelet 155 of extend line 65 on extend pull pin 140 (Figs. 13-15). Next guidewire 85 is advanced through guidewire tube 87 and into support tube 30 until the distal tip of the guidewire is adjacent to the distal tip of endoscope 10 (Fig. 20). At this point, endoscope 10 and endoscopic stabilizing platform 5 are ready for insertion as a unit into the patent.

Looking next at Fig. 21, endoscope 10 and endoscopic stabilizing platform 5 are inserted as a unit into a body lumen and/or body cavity of the patient. By way of example but not limitation, endoscope 10 and endoscopic stabilizing platform 5 are inserted as a unit into the gastrointestinal (GI) tract.
of the patient. Endoscope 10 and endoscopic stabilizing platform 5 are advanced along the body lumen and/or body cavity to a desired location within the patient (Figs. 22 and 23).

When endoscopic stabilizing platform 5 is to be used, rip cord 100 is pulled proximally so as to tear away rip sleeve 95 (Fig. 24). Then proximal balloon 20 is inflated so as to stabilize the endoscopic stabilizing platform (and hence endoscope 10) within the body lumen and/or body cavity.

Next, guidewire 85 is advanced a further distance into the body lumen and/or body cavity (Fig. 25). In this respect it will be appreciated that the relatively small and relatively easily-steerable guidewire 85 will be relatively easy to direct to a desired location further down the body lumen and/or body passageway, particularly inasmuch as the guidewire may be advanced some or all of the way under direct visualization from endoscope 10. In this respect it will also be appreciated that inasmuch as the flexible portion of the endoscope resides distal to proximal balloon 20, the endoscope will be able to articulate distal to the balloon so as to facilitate visualization of the anatomy.
Next, pusher tube 30 is advanced distally along the guidewire (Fig. 26). Thus, guidewire 85 acts as guide for moving pusher tube 30, and hence distal balloon 35, distally relative to the endoscope 10.

When pusher tube 30 has advanced distal balloon 35 to the desired position along guidewire 85, distal balloon 35 is inflated (Fig. 27) so as to secure distal balloon 35 to the anatomy. As distal balloon 35 is inflated, the inflated distal balloon 35 and the inflated proximal balloon 20 will cooperate with one another so as to stabilize, straighten, expand and/or flatten the side wall of the body lumen and/or body cavity so as to better present the side wall tissue for examination and/or treatment during an endoscopic procedure using endoscope 10. In this respect it will be appreciated that the inflated distal balloon 35 and the inflated proximal balloon 20 will together expand and tension the side wall of the body lumen and/or body cavity, and pusher tube 30 will tend to straighten the anatomy between the two inflated balloons. In this respect it will also be appreciated that once proximal balloon 20 and distal balloon 30 have both been inflated, they will together define a substantially closed region along the body lumen and/or body cavity
(i.e., an isolated therapeutic zone) which can then be inflated with a fluid (e.g., air, CO₂, etc.). This fluid can significantly enhance visualization of the side wall of the body lumen and/or body cavity.

If desired, distal balloon 35 can be retracted toward proximal balloon 20, while remaining inflated, so as to move the anatomy and further improve visualization (see Fig. 28).

If desired, surgical tools 175 (Fig. 29) may be advanced through endoscope 10 so as to biopsy and/or treat the anatomy. It will be appreciated that such instruments will be advanced out of the distal end of the endoscope, which is highly stabilized relative to the anatomy via proximal balloon 20, so that the working ends of instruments 175 will also be highly stabilized relative to the anatomy. This is a significant advantage over the prior art practice of advancing tools out of the non-stabilized end of an endoscope.

Furthermore, if bleeding were to obscure a tissue site, the isolated therapeutic zone permits rapid flushing of the anatomy and subsequent removal of the flushing liquid (see Figs. 30-32).
Also, if desired, the distal balloon 35 can be directed with high precision to the bleeding site via guidewire 85 and the guidewire-tracking pusher tube 30, whereupon distal balloon 35 may be used to apply topical pressure to the bleeding site in order to enhance bleeding control (see Fig. 33). This can be done under the visualization provided by endoscope 10.

If desired, the distal balloon 35 may be used as a drag brake to control endoscope removal. More particularly, in this form of the invention, the endoscope 10 and the endoscopic stabilizing platform 5 are first advanced as a unit into the body lumen and/or body cavity until the tip of the endoscope is at the proper location, and then guidewire 85 is advanced distally. Next, proximal balloon 20 is inflated, pusher tube 30 is advanced distally along guidewire 85, and distal balloon 35 is inflated (Fig. 35). When the apparatus is to be withdrawn, proximal balloon 20 is deflated, distal balloon 35 is partially deflated, and then the endoscope is withdrawn proximally, dragging the semi-inflated distal balloon 35 along (Fig. 36), with distal balloon 35 acting as something of a brake as the endoscope is pulled proximally, thereby enabling a more controlled withdrawal of the endoscope and hence
better visualization of the anatomy. If at some point it is desired, proximal balloon 20 and distal balloon 35 can be re-inflated, as shown in Fig. 37, with or without introduction of a fluid into the "isolated therapeutic zone" established between the two balloons, so as to stabilize, straighten, expand and/or flatten the anatomy. At the conclusion of the procedures, the system is withdrawn from the anatomy (Fig. 38).

It is also possible to use proximal balloon 20 as a brake when withdrawing the endoscope (and hence endoscopic stabilizing platform 5) from the anatomy, either alone or in combination with braking action from distal balloon 35.

Applications

The novel endoscopic stabilizing platform of the present invention can be used in substantially any endoscopic procedure to facilitate the alignment and presentation of tissue during an endoscopic procedure and/or to stabilize the working end of an endoscope (and/or other instruments advanced through the endoscope) relative to tissue during such a procedure.

The present invention is believed to have widest applications with respect to the gastrointestinal (GI)
tract (e.g., large and small intestines, esophagus, stomach, etc.), which is generally characterized by frequent turns and which has a side wall characterized by numerous folds and disease processes located within these folds. However, the methods and apparatus of the present invention may also be used inside other body cavities (e.g., the cranium, thorax, abdomen, pelvis, nasal sinuses, bladder, etc.) and/or other tubular viscera (e.g., the vagina, ureter, fallopian tubes, urethra, blood vessels, bronchi, bile ducts, etc.).

Thus, for example, the novel endoscopic stabilizing platform of the present invention can be used in the performance of certain specialized endoscopic procedures including Natural Orifice Trans-Endoscopic Surgery (NOTES) procedures, as well as other complex endoscopic procedures which could involve endoscopic surgery.

Modifications

While the present invention has been described in terms of certain exemplary preferred embodiments, it will be readily understood and appreciated by one of ordinary skill in the art that it is not so limited, and that many additions, deletions and modifications
may be made to the preferred embodiments discussed above while remaining within the scope of the present invention.
What Is Claimed Is:

1. Apparatus comprising:
   a sleeve adapted to be slid over the exterior of an endoscope;
   a proximal balloon secured to the sleeve near the distal end of the sleeve;
   a pusher tube slidably mounted to the sleeve, the pusher tube being configured to slidably receive a guidewire therein; and
   a distal balloon secured to the distal end of the pusher tube.

2. Apparatus according to claim 1 further comprising a guidewire disposed in the pusher tube.

3. Apparatus according to claim 1 wherein the sleeve is configured to make a close fit with the exterior of an endoscope such that the sleeve will slide easily over the endoscope during mounting thereon but will remain in place during use.
4. Apparatus according to claim 1 further comprising a handle secured to the sleeve at the proximal end of the sleeve.

5. Apparatus according to claim 1 wherein the sleeve includes a lubricious coating on at least one of its interior surface and its exterior surface.

6. Apparatus according to claim 1 wherein the proximal balloon is spaced from the distal end of the sleeve by a distance which is substantially equal to the length of the flexible portion of an endoscope.

7. Apparatus according to claim 1 wherein at least one of the sleeve and the proximal balloon comprises a radiopaque marker.

8. Apparatus according to claim 1 further comprising a double pull mechanism for moving the pusher tube relative to the sleeve.
9. Apparatus according to claim 8 wherein the double pull mechanism comprises a double pull line attached to the pusher tube at an attachment point, and further wherein the double pull line comprises a retract line which extends proximally from the attachment point and an extend line which extends distally from the attachment point.

10. Apparatus according to claim 9 further comprising a bearing structure attached to the sleeve distal to the attachment point, and further wherein the extend line extends distally from the attachment point, around the bearing structure and then proximally from the bearing structure.

11. Apparatus according to claim 9 further comprising a motorized drive system configured to (i) selectively apply a pulling force to the retract line, (ii) selectively apply a pulling force to the extend
line, or (iii) hold the retract line and extend line against movement.

12. Apparatus according to claim 1 wherein the pusher tube comprises a superelastic material.

13. Apparatus according to claim 1 wherein the pusher tube is shorter than the sleeve.

14. Apparatus according to claim 1 wherein the distal balloon comprises a radiopaque marker.

15. Apparatus according to claim 1 further comprising a rip sleeve for selectively covering at least one of the proximal balloon and the distal balloon prior to inflation.

16. Apparatus according to claim 15 further comprising a rip cord for selectively opening the rip sleeve.
17. Apparatus comprising:

a sleeve adapted to be slid over the exterior of an endoscope;

a proximal balloon secured to the sleeve near the distal end of the sleeve;

a pusher element slidably mounted to the sleeve;

a double pull mechanism mounted to the sleeve for moving the pusher element relative to the sleeve; and

a distal balloon secured to the distal end of the pusher element.

18. Apparatus according to claim 17 wherein the double pull mechanism comprises a double pull line attached to the pusher element at an attachment point, and further wherein the double pull line comprises a retract line which extends proximally from the attachment point and an extend line which extends distally from the attachment point.

19. Apparatus according to claim 18 further comprising a bearing structure attached to the sleeve
distal to the attachment point, and further wherein the extend line extends distally from the attachment point, around the bearing structure and then proximally from the bearing structure.

20. Apparatus according to claim 18 further comprising a motorized drive system configured to (i) selectively apply a pulling force to the retract line, (ii) selectively apply a pulling force to the extend line, or (iii) hold the retract line and extend line against movement.

21. Apparatus according to claim 17 wherein the pusher element is shorter than the sleeve.

22. Apparatus according to claim 17 wherein the pusher element comprises a tube.

23. Apparatus according to claim 22 wherein the tube is formed out of a superelastic material.
24. Apparatus according to claim 22 wherein the pusher element is configured to slidably receive a guidewire therein.

25. Apparatus according to claim 24 further comprising a guidewire disposed in the pusher element.

26. Apparatus according to claim 17 wherein the sleeve is configured to make a close fit with the exterior of an endoscope such that the sleeve will slide easily over the endoscope during mounting thereon but will remain in place during use.

27. Apparatus according to claim 17 further comprising a handle secured to the sleeve at the proximal end of the sleeve.

28. Apparatus according to claim 17 wherein the sleeve includes a lubricious coating on at least one of its interior surface and its exterior surface.
29. Apparatus according to claim 17 wherein the proximal balloon is spaced from the distal end of the sleeve by a distance which is substantially equal to the length of the flexible portion of an endoscope.

30. Apparatus according to claim 17 wherein at least one of the sleeve and the proximal balloon comprises a radiopaque marker.

31. Apparatus according to claim 17 wherein the distal balloon comprises a radiopaque marker.

32. Apparatus according to claim 17 further comprising a rip sleeve for selectively covering at least one of the proximal balloon and the distal balloon prior to inflation.

33. Apparatus according to claim 32 further comprising a rip cord for selectively opening the rip sleeve.
34. Apparatus comprising:
   a sleeve adapted to be slid over the exterior of an endoscope;
   a proximal balloon secured to the sleeve near the distal end of the sleeve;
   a pusher element slidably mounted to the sleeve, the pusher element being substantially flexible, having substantial column strength, and having a length substantially shorter than the sleeve; and
   a distal balloon secured to the distal end of the pusher element.

35. Apparatus according to claim 34 further comprising means mounted to the sleeve for moving the pusher element relative to the sleeve.

36. Apparatus according to claim 35 wherein the double pull mechanism comprises a double pull line attached to the pusher element at an attachment point, and further wherein the double pull line comprises a retract line which extends proximally from the
attachment point and an extend line which extends distally from the attachment point.

37. Apparatus according to claim 36 further comprising a bearing structure attached to the sleeve distal to the attachment point, and further wherein the extend line extends distally from the attachment point, around the bearing structure and then proximally from the bearing structure.

38. Apparatus according to claim 36 further comprising a motorized drive system configured to (i) selectively apply a pulling force to the retract line, (ii) selectively apply a pulling force to the extend line, or (iii) hold the retract line and extend line against movement.

39. Apparatus according to claim 34 wherein the pusher element is shorter than the sleeve.
40. Apparatus according to claim 34 wherein the pusher element comprises a tube.

41. Apparatus according to claim 40 wherein the tube is formed out of a superelastic material.

42. Apparatus according to claim 41 wherein the pusher element is configured to slidably receive a guidewire therein.

43. Apparatus according to claim 42 further comprising a guidewire disposed in the pusher element.

44. Apparatus according to claim 34 wherein the sleeve is configured to make a close fit with the exterior of an endoscope such that the sleeve will slide easily over the endoscope during mounting thereon but will remain in place during use.
45. Apparatus according to claim 34 further comprising a handle secured to the sleeve at the proximal end of the sleeve.

46. Apparatus according to claim 34 wherein the sleeve includes a lubricious coating on at least one of its interior surface and its exterior surface.

47. Apparatus according to claim 34 wherein the proximal balloon is spaced from the distal end of the sleeve by a distance which is substantially equal to the length of the flexible portion of an endoscope.

48. Apparatus according to claim 34 wherein at least one of the sleeve and the proximal balloon comprises a radiopaque marker.

49. Apparatus according to claim 34 wherein the distal balloon comprises a radiopaque marker.
50. Apparatus according to claim 34 further comprising a rip sleeve for selectively covering at least one of the proximal balloon and the distal balloon prior to inflation.

51. Apparatus according to claim 50 further comprising a rip cord for selectively opening the rip sleeve.

52. A method for performing a procedure in a body lumen and/or body cavity, the method comprising:

   providing apparatus comprising:
   a sleeve adapted to be slid over the exterior of an endoscope;
   a proximal balloon secured to the sleeve near the distal end of the sleeve;
   a pusher tube slidably mounted to the sleeve, the pusher tube being configured to slidably receive a guidewire therein; and
   a distal balloon secured to the distal end of the pusher tube;
positioning the apparatus in the body lumen and/or body cavity;
inflating the proximal balloon;
advancing a guidewire through the pusher tube;
advancing the pusher tube along the guidewire;
inflating the distal balloon; and
performing the procedure.

53. A method for performing a procedure in a body lumen and/or body cavity, the method comprising:

providing apparatus comprising:

a sleeve adapted to be slid over the exterior of an endoscope;
a proximal balloon secured to the sleeve near the distal end of the sleeve;
a pusher element slidably mounted to the sleeve;
a double pull mechanism mounted to the sleeve for moving the pusher element relative to the sleeve; and
a distal balloon secured to the distal end of the pusher tube;

positioning the apparatus in the body lumen and/or body cavity;

inflating the proximal balloon;

advancing the pusher element distally relative to the sleeve;

inflating the distal balloon; and

performing the procedure.

54. A method for performing a procedure in a body lumen and/or body cavity, the method comprising:

providing apparatus comprising:

a sleeve adapted to be slid over the exterior of an endoscope;

a proximal balloon secured to the sleeve near the distal end of the sleeve;

a pusher element slidably mounted to the sleeve, the pusher element being substantially flexible, having substantial column strength, and
having a length substantially shorter than the sleeve;
and

a distal balloon secured to the distal end
of the pusher element;

positioning the apparatus in the body lumen
and/or body cavity;

inflating the proximal balloon;

advancing the pusher element distally relative to
the sleeve;

inflating the distal balloon; and

performing the procedure.
FIG. 17

1. Slide handpiece onto scope
2. Pull disposable device over scope then remove condom from tip of scope.
6. Advance to desire location (top view)
7. Stop at desire location in colon

FIG. 23
9. Inflated balloon then extend guide wire
10. Extend fore balloon over guide wire

FIG. 26
12. Retract fore balloon to gain better view of polyp

FIG. 28
13. Use of surgical tools with good control of surgical field
15. Sealed zone is filled with fluid via working channel.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
   IPC(8) - A61B 1/04, A61B 1/00 (2011.01)
   USPC - 600/115
   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)
   IPC(8): A61B 1/04, A61B 1/00 (2011.01)
   USPC: 600/115

   Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
   USPC: 600/101, 114, 121, 124, 125

   Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
   PubWEST (PGPB, USPT, USOCR, EPAB, JPAB); Google Patents; Google Scholar
   Search Terms: balloon, catheter, sleeve, sheath, sliding, push, frictional, lubricious, proximal, distal, guide, wire, endoscope, double, pull, wire, cable, line, filament, retracting, advancing, pulley, motor, rip, cord

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>US 6,575,932 B1 (O'BRIEN et al.) 10 June 2003 (10.06.2003) col 7, In 64-67; col 8, In 1-5, 55-67; col 9, In 2-4; col 10, In 48-52; col 11, In 17-19; col 12, In 16-22; col 13, In 15-17</td>
<td>1-54</td>
</tr>
<tr>
<td>Y</td>
<td>US 6,475,226 B1 (BELEY et al.) 05 November 2002 (05.11.2002) col 12, In 11-13, 24-34</td>
<td>8-11, 17-33, 36-38, 53</td>
</tr>
</tbody>
</table>

☐ Further documents are listed in the continuation of Box C. ☐

* 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 application or patent but published on or after the international filing date
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  "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
  "&" document member of the same patent family

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04 March 2011 (04.03.2011)

Date of mailing of the international search report
18 MAR 2011

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Form PCT/ISA/210 (second sheet) (July 2009)