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Milsom et al.

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(54) **METHOD AND APPARATUS FOR
ENDOSCOPICALLY TREATING RECTAL
PROLAPSE**

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2, 2007.

(51) **Int. Cl.**
A61B 17/10 (2006.01)

(52) **U.S. Cl.**
USPC **606/139**

(58) **Field of Classification Search** 606/139,
606/144-147

See application file for complete search history.

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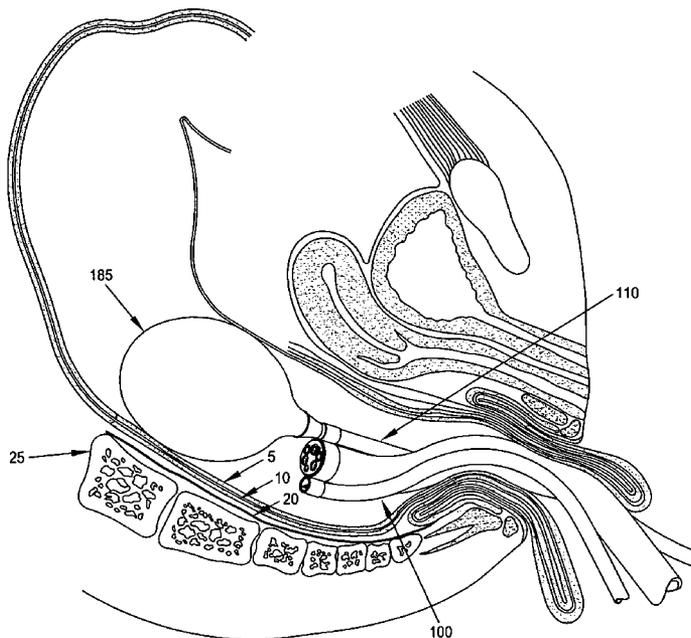
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(57) **ABSTRACT**

In one form of the invention, there is provided a method for
treating rectal prolapse, the method comprising: inserting an
expandable element into a prolapsed rectum via the anus;
expanding the expandable element so that the expandable
element securely engages the rectum; advancing the
expanded element distally so as to return the prolapsed rec-
tum to its normal, non-prolapsed state; and securing the rec-
tum to supporting tissue whereby to retain the rectum in its
normal, non-prolapsed state. In another form of the invention,
there is provided an endoscope assembly for treating rectal
prolapse, the endoscope assembly comprising: an endoscope;
a balloon catheter; and a tacker; wherein the endoscope, bal-
loon catheter and tacker are mounted together for insertion as
a unit.

20 Claims, 14 Drawing Sheets



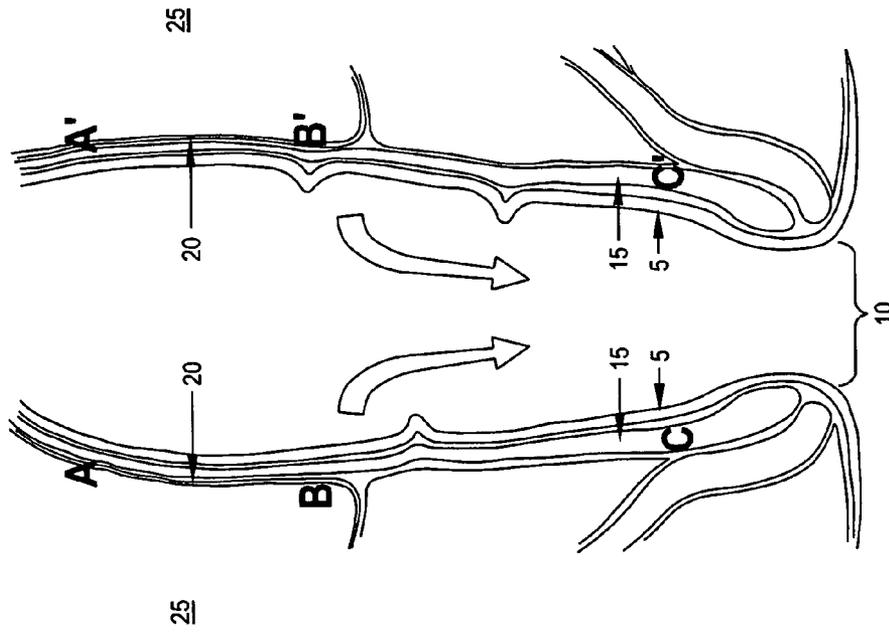


FIG. 1

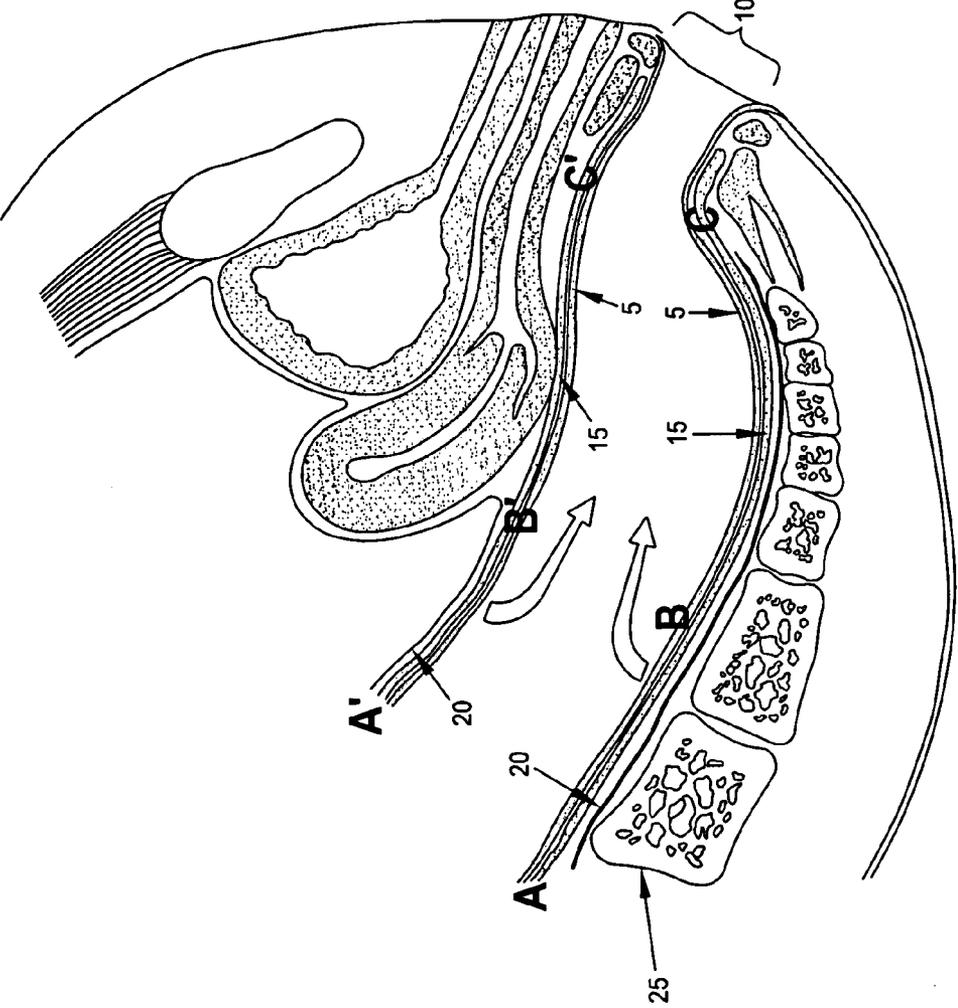


FIG. 2

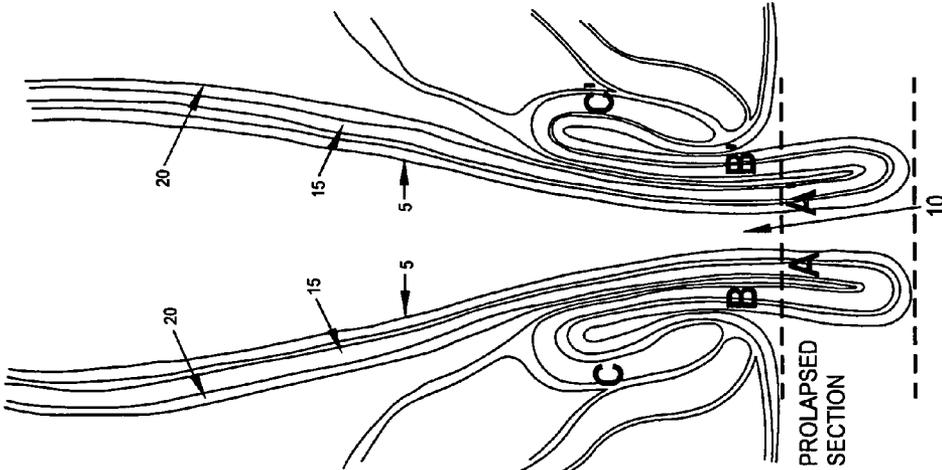


FIG. 3

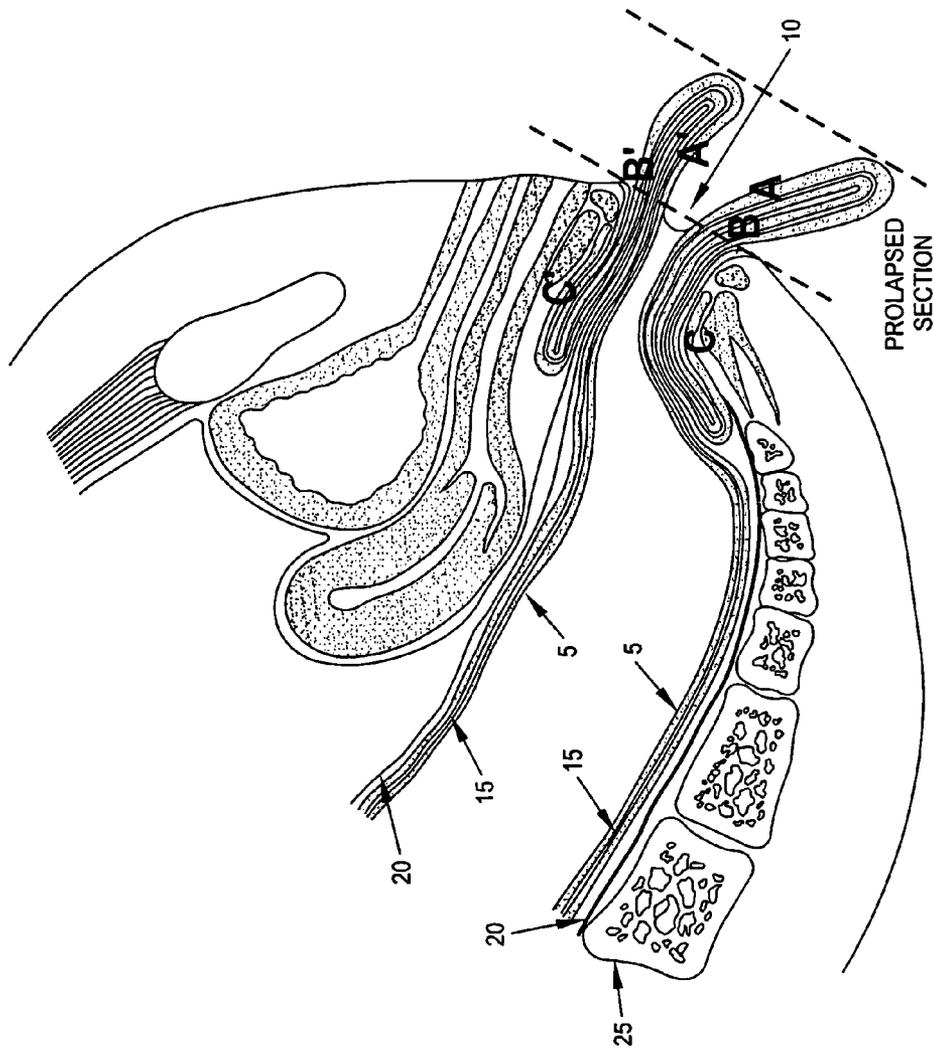
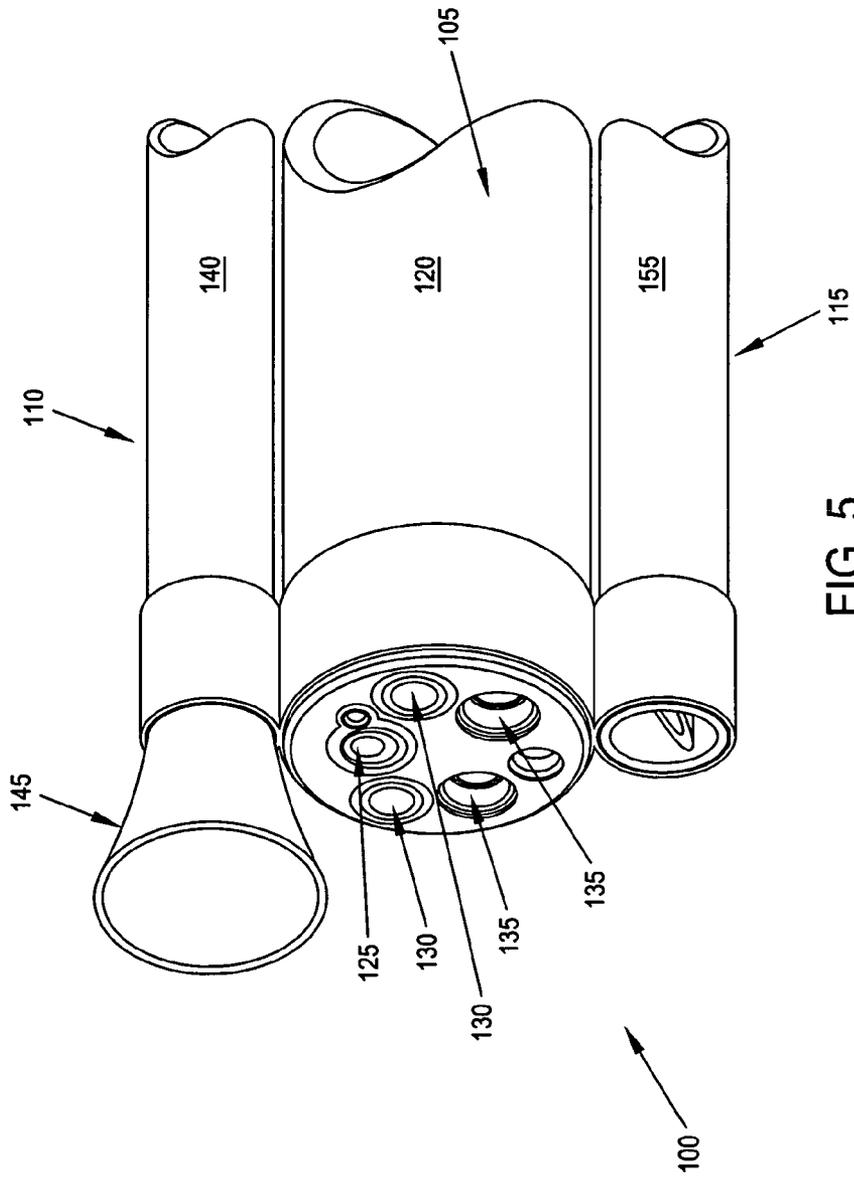


FIG. 4



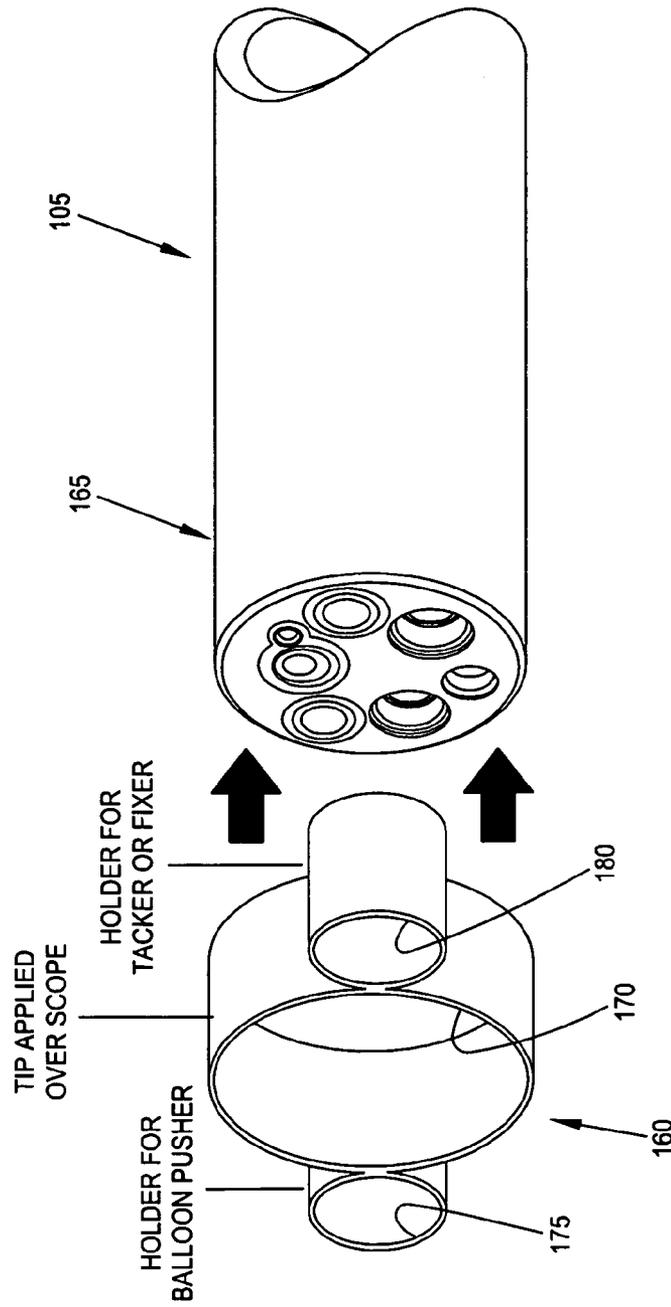


FIG. 6

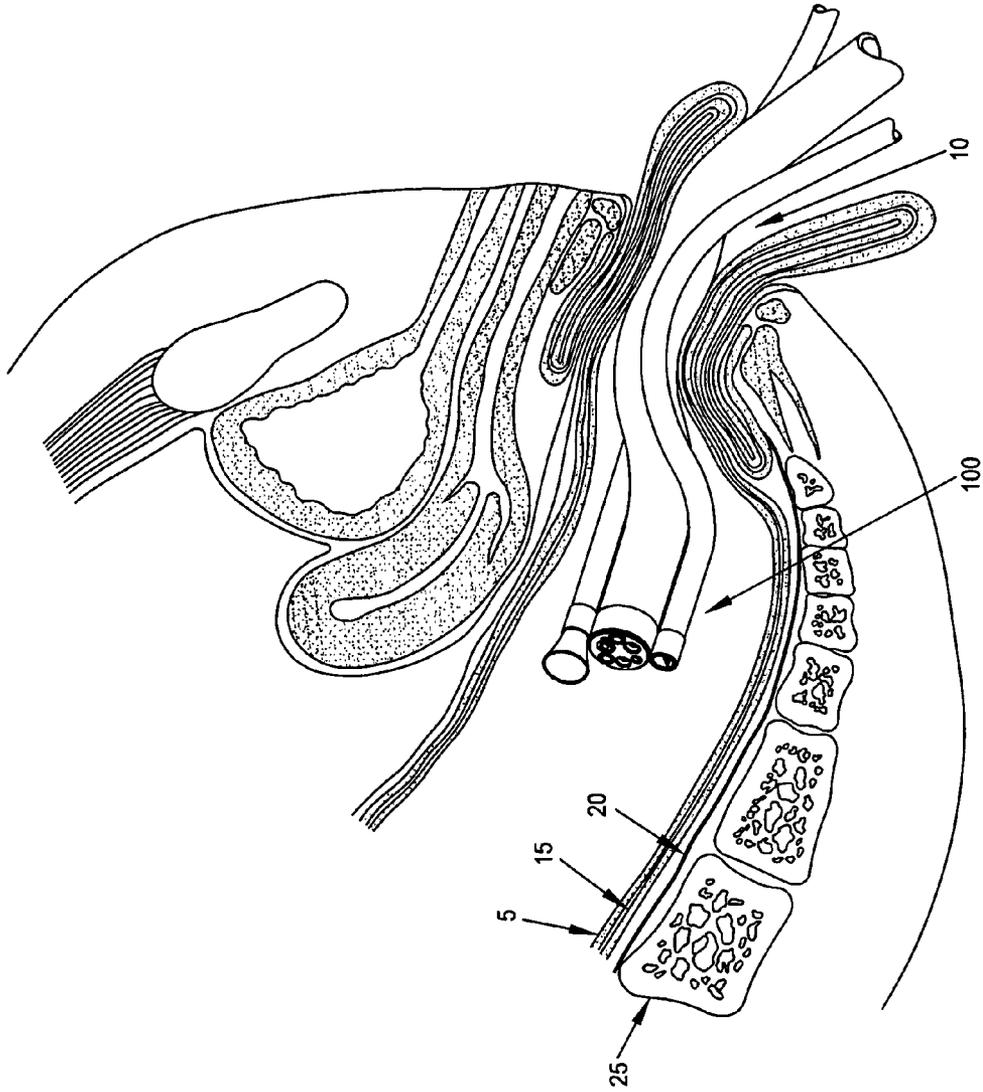


FIG. 7

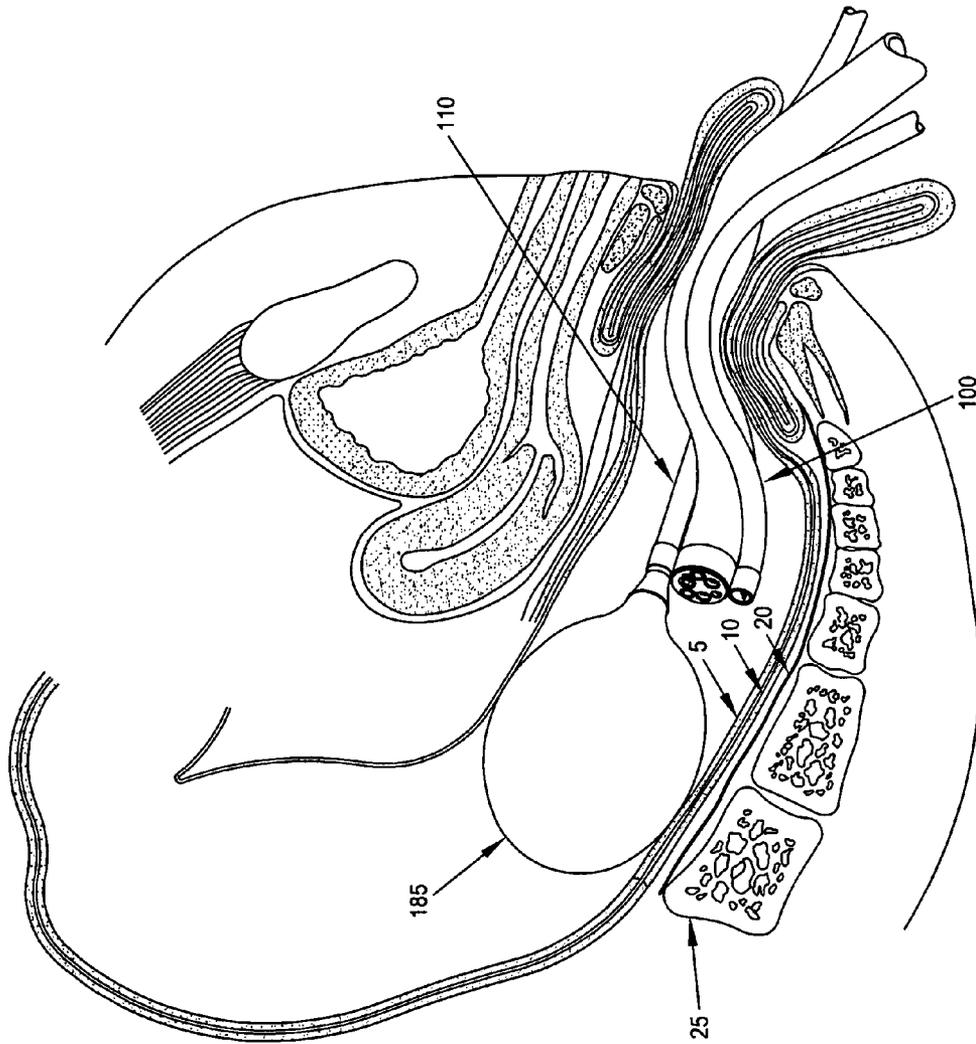


FIG. 8

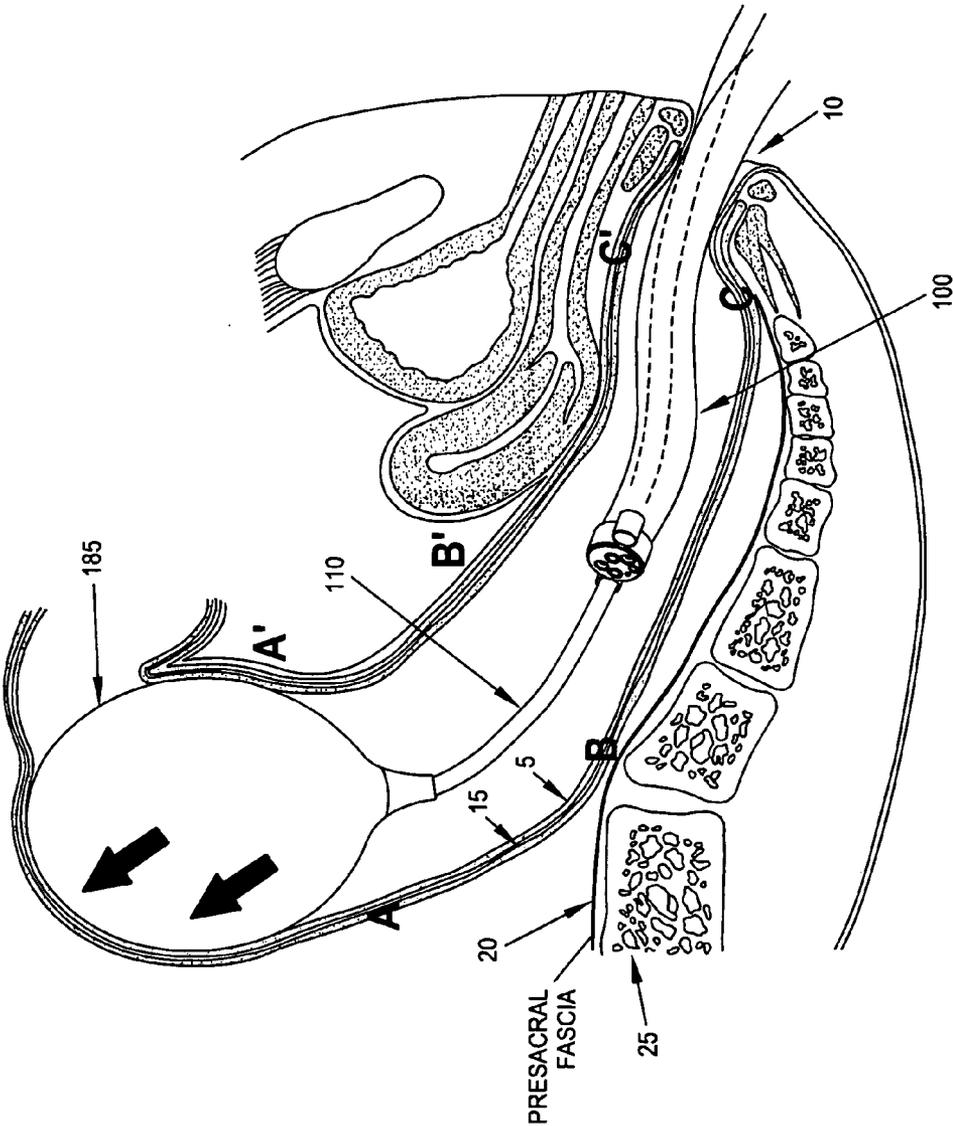
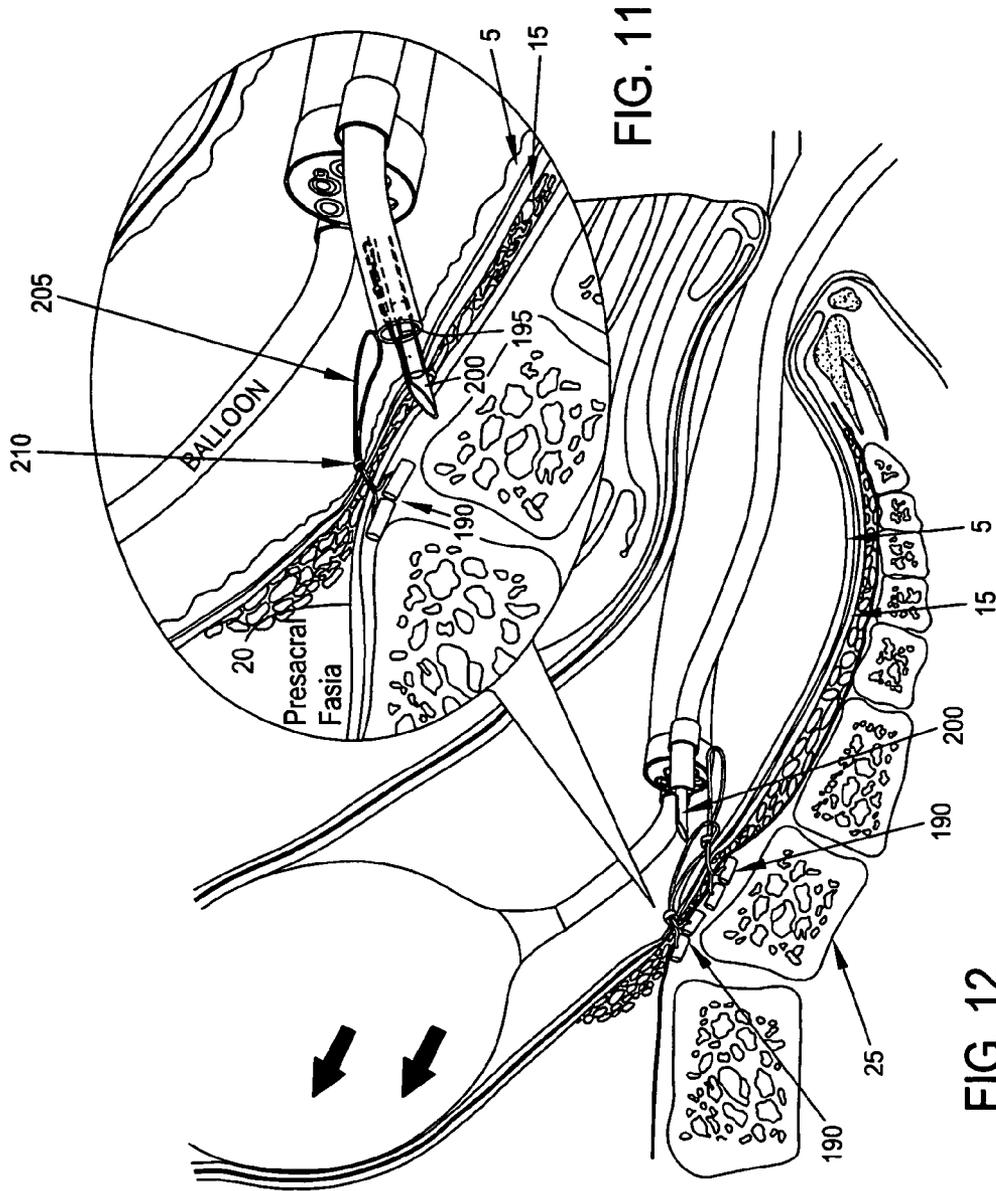


FIG. 9



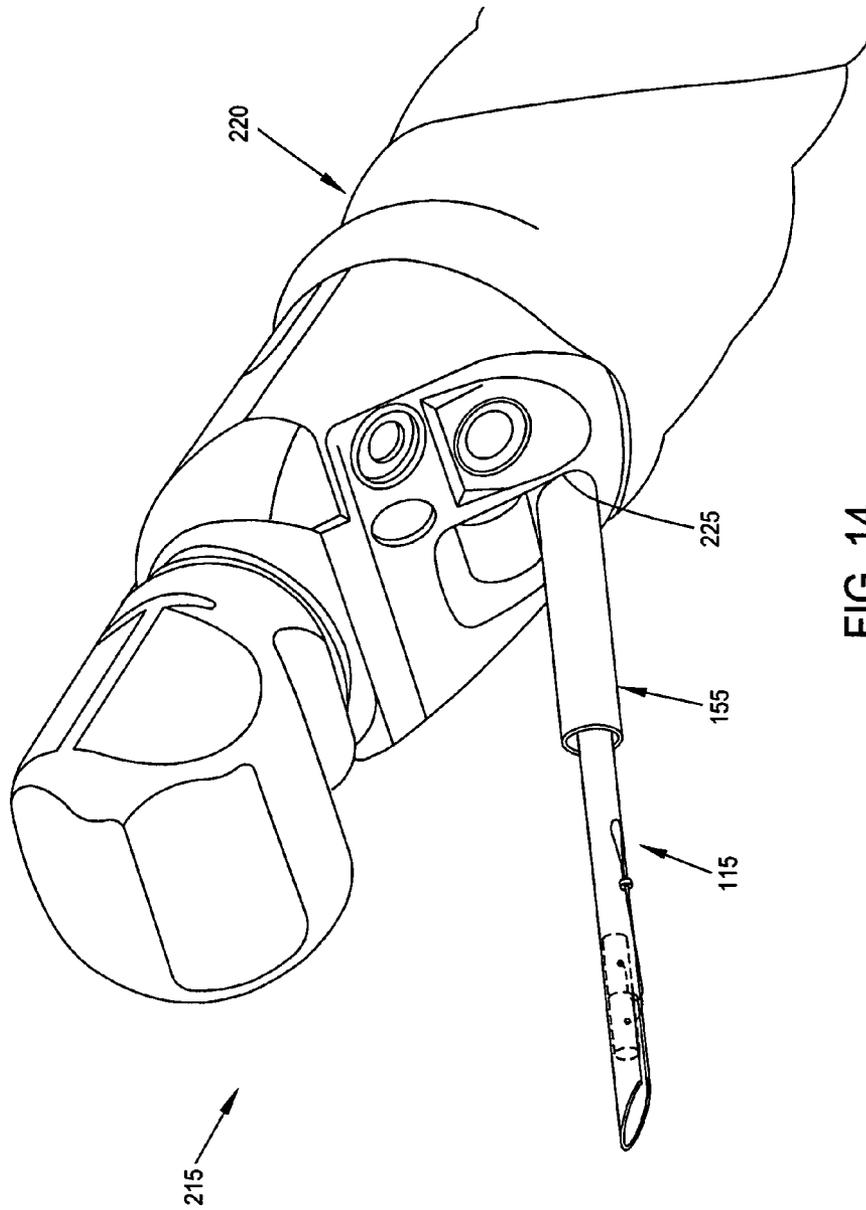


FIG. 14

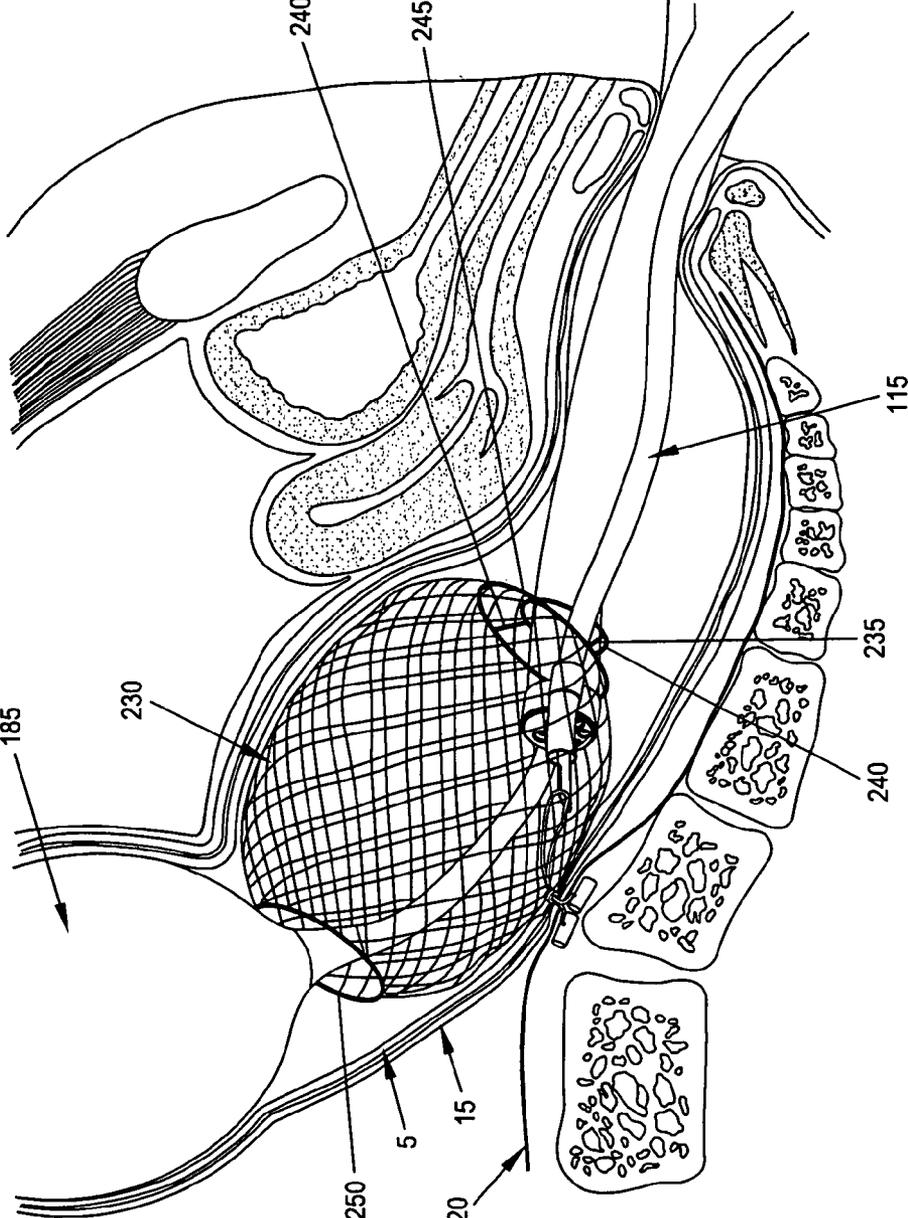


FIG. 15

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METHOD AND APPARATUS FOR ENDOSCOPICALLY TREATING RECTAL PROLAPSE

REFERENCE TO PENDING PRIOR PATENT APPLICATION

This patent application claims benefit of pending prior U.S. Provisional Patent Application Ser. No. 60/985,009, filed Nov. 02, 2007 by Jeffrey Milsom et al. for ENDOSCOPIC RECTOPEXY, 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 treating rectal prolapse.

BACKGROUND OF THE INVENTION

Rectal prolapse is a medical condition in which the walls of the rectum are not properly held in place, so that the rectum prolapses towards the anus and, in many cases, through the anal sphincter and outside the body.

There are three primary conditions which fall under the general category of rectal prolapse: (i) where the entire rectum protrudes through the anus (i.e., so-called "full thickness rectal prolapse"); (ii) where only the rectal mucosa prolapses (i.e., so-called "mucosal prolapse"); and (iii) where the rectum may collapse but not protrude through the anus (i.e., so-called "internal intussusception"). Rectal prolapse may be caused by a variety of conditions, e.g., advanced age, long term straining during defecation, pregnancy and childbirth, etc., and is typically characterized by a progression of symptoms, e.g., prolapse during bowel movements, prolapse during muscular stress (e.g., sneezing), prolapse during routine activities (e.g., walking) and, finally, chronic prolapse in which the rectum ceases to retract.

Mild cases of rectal prolapse can sometimes be treated secondarily, i.e., by reducing rectal straining through dietetic or pharmaceutical approaches. However, more severe cases of rectal prolapse must generally be treated surgically, either through abdominal surgery or perineal surgery. In any case, such surgery is substantial and traumatic in nature.

Thus there is a need for a new and improved approach for treating rectal prolapse, wherein the surgery is performed endoscopically so as to minimize trauma for the patient.

SUMMARY OF THE INVENTION

This and other objects of the present invention are addressed by the provision and use of a new and improved approach for treating rectal prolapse, wherein the surgery is performed endoscopically so as to minimize trauma for the patient.

In one form of the invention, there is provided a method for treating rectal prolapse, the method comprising:

inserting an expandable element into a prolapsed rectum via the anus;

expanding the expandable element so that the expandable element securely engages the rectum;

advancing the expanded element distally so as to return the prolapsed rectum to its normal, non-prolapsed state; and

securing the rectum to supporting tissue whereby to retain the rectum in its normal, non-prolapsed state.

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In another form of the invention, there is provided an endoscope assembly for treating rectal prolapse, the endoscope assembly comprising:

an endoscope;

a balloon catheter; and

a tacker;

wherein the endoscope, balloon catheter and tacker are mounted together for insertion as a unit.

In another form of the invention, there is provided an endoscope assembly for treating rectal prolapse, the endoscope assembly comprising:

an endoscope;

a rectum-gripping and advancing mechanism; and

a tacker;

wherein the endoscope, the rectum-gripping and advancing mechanism, and the tacker are mounted together for insertion as a unit;

and further wherein the rectum gripping and advancing mechanism is selected from the group consisting of a balloon catheter, expandable arms, and an expandable frame.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects and features of the present invention will be more fully disclosed in, 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 view of normal rectal anatomy, as seen in coronal view;

FIG. 2 is a schematic view of normal rectal anatomy, as seen in mid-sagittal view;

FIG. 3 is a schematic view of prolapsed rectal anatomy, as seen in coronal view;

FIG. 4 is a schematic view of prolapsed rectal anatomy, as seen in mid-sagittal view;

FIG. 5 is a schematic view of a novel endoscope assembly, wherein the novel endoscope assembly comprises an endoscope, a balloon catheter and a tacker;

FIG. 6 is a schematic view showing how a distal mount may be secured to the distal end of a conventional endoscope in order to permit the balloon catheter and tacker to be mounted to the endoscope;

FIG. 7 is a schematic view showing the novel endoscope assembly of FIG. 5 deployed in the rectum;

FIG. 8 is a schematic view like that of FIG. 7, except showing the balloon of the balloon catheter having been inflated;

FIG. 9 is a schematic view like that of FIG. 8, except showing the balloon of the balloon catheter having been extended distally from the endoscope so as to reduce rectal prolapse;

FIGS. 10-12 are schematic views showing the tacker of the novel endoscope assembly securing the rectum to supporting tissue;

FIG. 13 is a schematic view showing operation of the tacker shown in FIGS. 10-12;

FIG. 14 is a schematic view showing a combined ultrasound probe/tacker unit; and

FIG. 15 is a schematic view showing an alternative approach for treating a prolapsed rectum.

DETAILED DESCRIPTION OF THE OF THE PREFERRED EMBODIMENTS OF THE INVENTION

Looking first at FIGS. 1 and 2, there is shown a schematic view of normal rectal anatomy. More particularly, it will be

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seen that the rectum **5** generally comprises an elongated tubular structure terminating in the anus **10**. Along its length, rectum **5** is lined by the mesorectum **15**, i.e., the mesentery of the rectum. Along part of its length, mesorectum **15** lies adjacent to the presacral fascia **20** which lines the sacrum **25**.

In the case of a prolapsed rectum, and looking now at FIGS. **3** and **4**, the walls of rectum **5** are not properly held in place, so that the rectum prolapses towards anus **10**. In this respect it should be appreciated that FIGS. **3** and **4** show a so-called “full thickness rectal prolapse” (i.e., where the entire rectum protrudes through the anus), however, these views are intended to be merely exemplary and it should be appreciated that the present invention is applicable to other forms of rectal prolapse as well, i.e., “mucosal prolapse” where only the rectal mucosa prolapses and/or “internal intussusception” where the rectum may collapse but not protrude through the anus.

The present invention provides a new and improved approach for treating rectal prolapse, wherein the surgery is performed endoscopically so as to minimize trauma for the patient.

More particularly, and looking now at FIG. **5**, there is shown a novel endoscope assembly **100** formed in accordance with the present invention. Endoscope assembly **100** generally comprises an endoscope **105** for visualizing the interior of the rectum, a balloon catheter **110** for selectively deploying a balloon within the interior of the rectum, and a tacker **115** for selectively tacking the rectum to supporting structure, all as will hereinafter be discussed in further detail. Endoscope assembly **100** is preferably constructed so that endoscope **105**, balloon catheter **110** and tacker **115** are mounted together for insertion into the rectum as a unit.

Endoscope **105** may comprise a conventional endoscope. By way of example but not limitation, endoscope **105** may comprise a shaft **120** comprising a viewing element **125**, lighting elements **130**, working lumens **135**, etc.

Balloon catheter **110** may comprise a conventional balloon catheter. By way of example but not limitation, balloon catheter **110** may comprise a shaft **140** terminating in a distal end **145** from which a balloon (not shown in FIG. **5**) may be selectively deployed, as will hereinafter be discussed in further detail.

Tacker **115** may comprise a conventional tacker for tacking tissue. By way of example but not limitation, tacker **115** may comprise a shaft **155** containing a tacking mechanism (not shown in detail in FIG. **5**) for tacking tissue, as will hereinafter be discussed in further detail.

In one preferred form of the invention, and looking now at FIGS. **5** and **6**, endoscope assembly **100** may be formed by securing a distal mount **160** to the distal end **165** of endoscope **105**. To this end, distal mount **160** may comprise a central opening **170** sized to fit over distal end **165** of endoscope **105**. Distal mount **160** preferably also comprises a first lateral opening **175** for slidably receiving shaft **140** of balloon catheter **110** therein, and a second lateral opening **180** for slidably receiving shaft **155** of tacker **115** therein.

Endoscope assembly **100** is preferably used in the following manner to endoscopically treat rectal prolapse.

First, and looking now at FIG. **7**, endoscope assembly **100** is advanced into rectum **5** via anus **10**.

Next, and looking now at FIG. **8**, balloon **185** of balloon catheter **110** is inflated so as to securely engage, and thereby “grip”, rectum **5**.

Then, and looking now at FIG. **9**, balloon catheter **110** is advanced distally relative to the remainder of endoscope assembly **100**, e.g., by pushing on the proximal end of shaft **140** of balloon catheter **110**, whereby to cause shaft **140** of

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balloon catheter **110** to slide distally within first lateral opening **175** of distal mount **160** and to cause balloon **185** to move distally within the body. As this occurs, the advancing balloon **185** of balloon catheter **110** carries with it rectum **5**, since balloon **185** securely engages and grips rectum **5**, thereby reducing the prolapse. Preferably, balloon catheter **110** is moved distally by a sufficient distance so as to return the prolapsed rectum to its normal, non-prolapsed state.

Then, and looking now at FIG. **10**, tacker **115** is used to secure rectum **5** to supporting tissue, whereby to retain rectum **5** in its normal, non-prolapsed state.

In one preferred form of the invention, and looking now at FIGS. **10-12**, tacker **115** is used to tack rectum **5** and mesorectum **15** to presacral fascia **20** using one or more tacks **190**. In this respect it will be appreciated that it is generally desirable to secure rectum **5** and mesorectum **15** to presacral fascia **20**, since the presacral fascia generally constitutes excellent supporting tissue. Of course, if desired, rectum **5** and mesorectum **15** may also be secured to other supporting tissue as well. To this end, an ultrasound probe **193** (shown in FIG. **10**, but omitted from FIGS. **11** and **12** for viewing clarity) may be advanced through a working lumen **135** of endoscope **105** so as to locate the sacral promontory (or other satisfactory anatomical landmark), and then shaft **155** of tacker **115** may be advanced relative to the remainder of endoscope assembly **100** (e.g., by sliding shaft **155** of tacker **115** within second lateral opening **180** of distal mount **160**) until the distal end **195** of tacker shaft **155** is proximate the tacking site. Then, a tacker needle **200** is advanced out of tacker shaft **155** and passed through rectum **5**, mesorectum **15** and presacral fascia **20**. Next, a tack **190** is ejected out of tacker needle **200**, and then tacker needle **200** withdrawn back through presacral fascia **20**, mesorectum **15** and rectum **5**, leaving a length of filament **205** extending from tack **190** through the intervening tissue (i.e., through presacral fascia **20**, mesorectum **15** and rectum **5**) and into the interior of rectum **5**. Filament **205** can then be tied off, or otherwise secured with a securement band **210**, so as to secure rectum **5** and mesorectum **15** to presacral fascia **20**. This process can then be repeated as necessary so as to set additional tacks into the tissue, whereby to secure the prolapsed rectum in its normal, non-prolapsed state.

Further details of the operation of tacker **115** are shown in FIG. **13**.

Thereafter, tacker **115** is retracted so that its needle **200** sits within tacker shaft **155**, and then tacker shaft **155** is retracted so that its distal end **195** once again sits substantially adjacent to the distal end of endoscope **105**. Then balloon **185** is deflated, and then balloon catheter **110** is retracted so that its distal end once again sits substantially adjacent to the distal end of endoscope **105**. Then endoscope assembly **100** is withdrawn from the rectum via anus **10**.

Looking next at FIG. **14**, there is shown a combined ultrasound probe/tacker unit **215**. More particularly, combined ultrasound probe/tacker unit **215** generally comprises an ultrasound probe **220** having a working lumen **225** formed therein. Tacker **115** has its shaft **155** slidably disposed within working lumen **225** so that the tacker can be selectively advanced out of ultrasound probe **220**. In this form of the invention, combined ultrasound probe/tacker unit **215** can be movably mounted to endoscope assembly **100** (e.g., by an appropriately configured distal mount **160**), or combined ultrasound probe/tacker unit **215** can be advanced through a working lumen **135** of endoscope **105**, or combined ultrasound probe/tacker unit **215** can be advanced into rectum **5** independently of endoscope **105**.

It should also be appreciated that, if desired, balloon catheter **110** can be advanced through a working lumen **135** of

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endoscope **105**, or balloon catheter **110** can be advanced into rectum **5** independently of endoscope **105**.

Furthermore, it should also be appreciated that, if desired, tacker **115** can be advanced through a working lumen **135** of endoscope **105**, or tacker **115** can be advanced into rectum **5** independently of endoscope **105**.

Looking next at FIG. **15**, in an alternative form of the invention, an expandable net **230** may be deployed within rectum **5** (e.g., after balloon **185** has been used to return the prolapsed rectum to its normal, non-prolapsed state but before tacker **115** has been used to secure rectum **5** to supporting tissue) in order to better hold rectum **5** in position while tacking occurs. In this respect it should also be appreciated that expandable net **230** can also serve to help anchor the endoscope and hold it in place while tacking is effected, thereby facilitating the tacking process. In one preferred form of the invention, expandable net **230** may comprise a collar **235** configured to ride over shaft **120** of endoscope **105**, with struts **240** connecting collar **235** to a proximal support ring **245**. Preferably, a distal support ring **250** is formed on the distal end of expandable net **230**. It should be appreciated that various approaches can be used to hold expandable net **230** in a contracted position prior to expansion. By way of example but not limitation, expandable net **230** may be formed out of Nitinol, and a temperature transition used to transform expandable net **230** from its contracted position to its expanded position.

If desired, balloon catheter **110** can be replaced by an alternative rectum-gripping mechanism, e.g., wherein expandable arms, an expandable frame, etc. are erected within the rectum so as to grip the rectum prior to the distal movement necessary to return the prolapsed rectum to its normal, non-prolapsed state. In this respect it will be appreciated that while it is generally preferred to use a balloon for engaging and pushing the rectum, such alternative rectum-gripping mechanisms (e.g., expandable arms, an expandable frame, etc.) may offer the advantage of better engaging the tissue of the rectum and may provide mechanical advantage for pushing the rectum distally. In this respect it should also be appreciated that while it is generally preferred that the balloon and/or alternative rectum-gripping mechanisms be relatively atraumatic, it may also be desirable to provide tissue-gripping means to facilitate pushing the prolapsed rectum distally. To this end, where a balloon is used, it may be desirable to provide the balloon with a high-friction outer surface; and where expandable arms are used, it may be desirable to provide the arms with tissue-gripping elements (e.g., mechanical jaws, suction mechanisms, etc.); and where an expandable frame is used, it may be desirable to provide openings in the frame to facilitate tissue engagement, etc.

Furthermore, if desired, tacker **115** can be replaced by other tackers. In this respect it should be appreciated that the terms “tack” and “tacker” are intended to encompass substantially any mechanical structure which is capable of securing the rectum to supporting tissue. By way of example but not limitation, the terms “tack” and “tacker” are intended to encompass shaft-type tacks, legged staples, multi-part fasteners, tacks comprising a body having suture extending therefrom, etc.

Furthermore, if desired, tacker **115** can be replaced by appropriate endoscopic suturing apparatus, with the rectum being secured to supporting tissue using conventional suture.

Modifications of the Preferred Embodiments

It should be understood that many additional changes in the details, materials, steps and arrangements of parts, which

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have been herein described and illustrated in order to explain the nature of the present invention, may be made by those skilled in the art while still remaining within the principles and scope of the invention.

What is claimed is:

1. A method for treating rectal prolapse, the method comprising:
 - inserting an expandable element into a prolapsed rectum via the anus;
 - expanding the expandable element so that the expandable element securely engages and thereby grips the rectum;
 - advancing the expanded element distally so as to move the prolapsed rectum distally, thereby returning the prolapsed rectum to its normal, non-prolapsed position; and
 - securing the rectum to supporting tissue whereby to retain the rectum in its normal, non-prolapsed position.
2. A method according to claim 1 wherein the method comprises the additional steps of;
 - returning the expanded element to its contracted state; and
 - withdrawing the expandable element from the rectum via the anus.
3. A method according to claim 1 wherein the expandable element comprises a balloon.
4. A method according to claim 3 wherein the balloon is part of a balloon catheter.
5. A method according to claim 4 wherein the balloon catheter is slidably mounted to an endoscope.
6. A method according to claim 5 wherein the rectum is secured to supporting tissue with a tacker, and further wherein the tacker is slidably mounted to the endoscope.
7. A method according to claim 1 wherein the expandable element comprises at least one selected from the group consisting of a balloon, expandable arms and an expandable frame.
8. A method according to claim 1 wherein the expandable element is expanded with a fluid.
9. A method according to claim 1 wherein the rectum is secured to supporting tissue with a tacker.
10. A method according to claim 1 wherein the rectum is secured to supporting tissue with at least one selected from the group consisting of a tack and suture.
11. A method according to claim 10 wherein the tack is selected from the group consisting of shaft-type tacks, legged staples, multi-part fasteners, and tacks comprising a body having suture extending therefrom.
12. A method according to claim 1 wherein the tack consists of at least one substantially rigid element having a suture attached thereto.
13. A method according to claim 1 wherein the tack further comprises a securement band for securing the suture.
14. A method according to claim 1 wherein the rectum is secured to supporting tissue by suturing.
15. A method according to claim 1 wherein the rectum is secured to the presacral fascia.
16. A method according to claim 1 wherein the securement location is determined by identifying an anatomical landmark.
17. A method according to claim 16 wherein the anatomical landmark is determined from a location within the rectum.
18. A method according to claim 16 wherein the anatomical landmark is identified by an ultrasound probe disposed within the rectum.
19. A method according to claim 16 wherein the anatomical landmark is identified by an endoscope disposed within the rectum.

20. A method according to claim 16 wherein the anatomical landmark is the sacral promontory.

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