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(54) Title: METHOD AND APPARATUS FOR ENDOSCOPICALLY TREATING RECTAL PROLAPSE

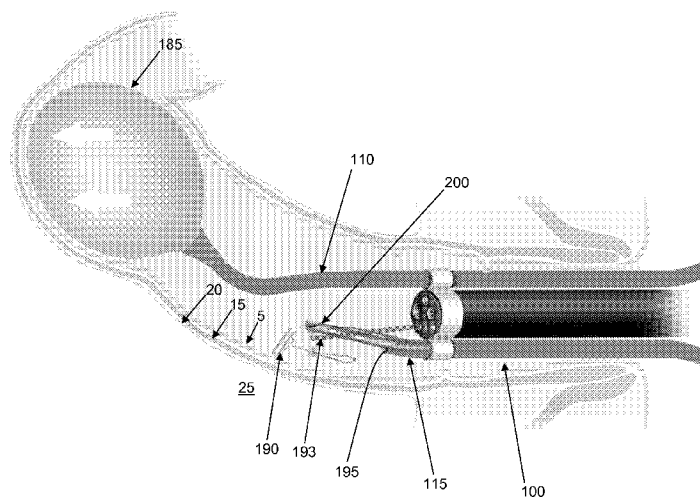


FIG. 10

(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 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. 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.



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METHOD AND APPARATUS FOR ENDOSCOPICALLY
TREATING RECTAL PROLAPSE

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Reference To Pending Prior Patent Application

10 This patent application claims benefit of pending prior U.S. Provisional
Patent Application Serial No. 60/985,009, filed 11/02/2007 by Jeffrey Milsom et
al. for ENDOSCOPIC RECTOPEXY (Attorney's Docket No. CMK-
026.60/CORN-16 PROV/D-4257-01 (US)), which patent application is hereby
incorporated herein by reference.

15

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.

20

Background Of The Invention

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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.

5 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.,
10 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.

15 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.

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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.

5 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.

10 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;

15 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.

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

 an endoscope;

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a balloon catheter; and

a tacker;

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

5 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;

10 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.

15

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
20 with the accompanying drawings wherein like numbers refer to like parts and further wherein:

- 5 -

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;

5 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;

10 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;

15 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;

20 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;

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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;

5 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.

10 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 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. 15 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 20 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

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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.

5 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.

10 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,
15 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.

20 Balloon catheter 110 may comprise a conventional balloon catheter. By way of example but not limitation, balloon catheter 110 may comprise a shaft 140

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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
5 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
10 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
15 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.

20 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

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proximal end of shaft 140 of balloon catheter 110, whereby to cause shaft 140 of 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)

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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

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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
5 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
10 advanced through a working lumen 135 of 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.

15 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
20 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

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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.

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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
5 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,
10 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
15 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 have been herein described and
20 illustrated in order to explain the nature of the present invention, may be made by

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those skilled in the art while still remaining within the principles and scope of the invention.

- 15 -

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;
5 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
10 normal, non-prolapsed state.
2. A method according to claim 1 wherein the method comprises the
additional steps of;
returning the expanded element to its contracted state; and
15 withdrawing the expandable element from the rectum via the anus.
3. A method according to claim 1 wherein the expandable element
comprises a balloon.
- 20 4. A method according to claim 3 wherein the balloon is part of a
balloon catheter.

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5. A method according to claim 4 wherein the balloon catheter is slidably mounted to an endoscope.

5 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
10 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.

15 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
20 supporting tissue with at least one selected from the group consisting of a tack and suture.

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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.

5

12. A method according to claim 1 wherein the tack consists of at least one substantially rigid element having a suture attached thereto.

10

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

15. A method according to claim 1 wherein the rectum is secured to the presacral fascia.

20

16. A method according to claim 1 wherein the securement location is determined by identifying an anatomical landmark.

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17. A method according to claim 16 wherein the anatomical landmark is determined from a location within the rectum.

5 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.

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

21. An endoscope assembly for treating rectal prolapse, the endoscope assembly comprising:

15 an endoscope;

a balloon catheter; and

a tacker;

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

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22. An endoscope assembly according to claim 21 wherein the balloon catheter and tacker are slidably mounted to the endoscope.

5 23. An endoscope assembly according to claim 21 wherein the endoscope has a distal mount thereon, and further wherein the balloon catheter and tacker are slidably mounted to the distal mount.

10 24. An endoscope assembly according to claim 21, wherein the endoscope assembly further comprises an ultrasound probe.

25. An endoscope assembly according to claim 24 wherein the endoscope comprises at least one working channel, and further wherein the ultrasound probe is delivered via the at least one working channel.

15 26. An endoscope assembly according to claim 24 wherein the ultrasound probe and the tacker are combined in a single combined ultrasound probe/tacker unit.

20 27. An endoscope assembly according to claim 22 wherein the tacker is adapted to deploy a tack selected from the group consisting of shaft-type tacks,

- 20 -

legged staples, multi-part fasteners, and tacks comprising a body having suture extending therefrom.

28. An endoscope assembly for treating rectal prolapse, the endoscope
5 assembly comprising:

an endoscope;

a rectum-gripping and advancing mechanism; and

a tacker;

wherein the endoscope, the rectum-gripping and advancing mechanism,
10 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.

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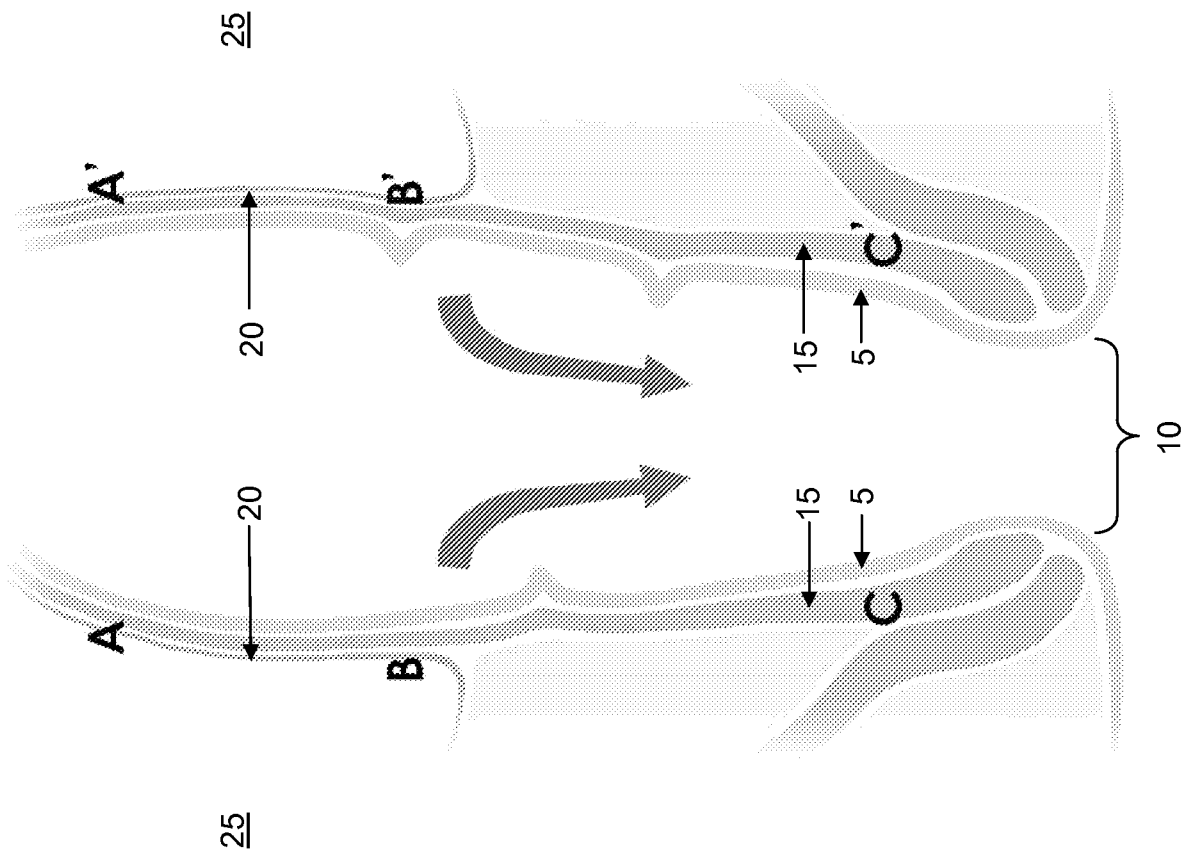


FIG. 1

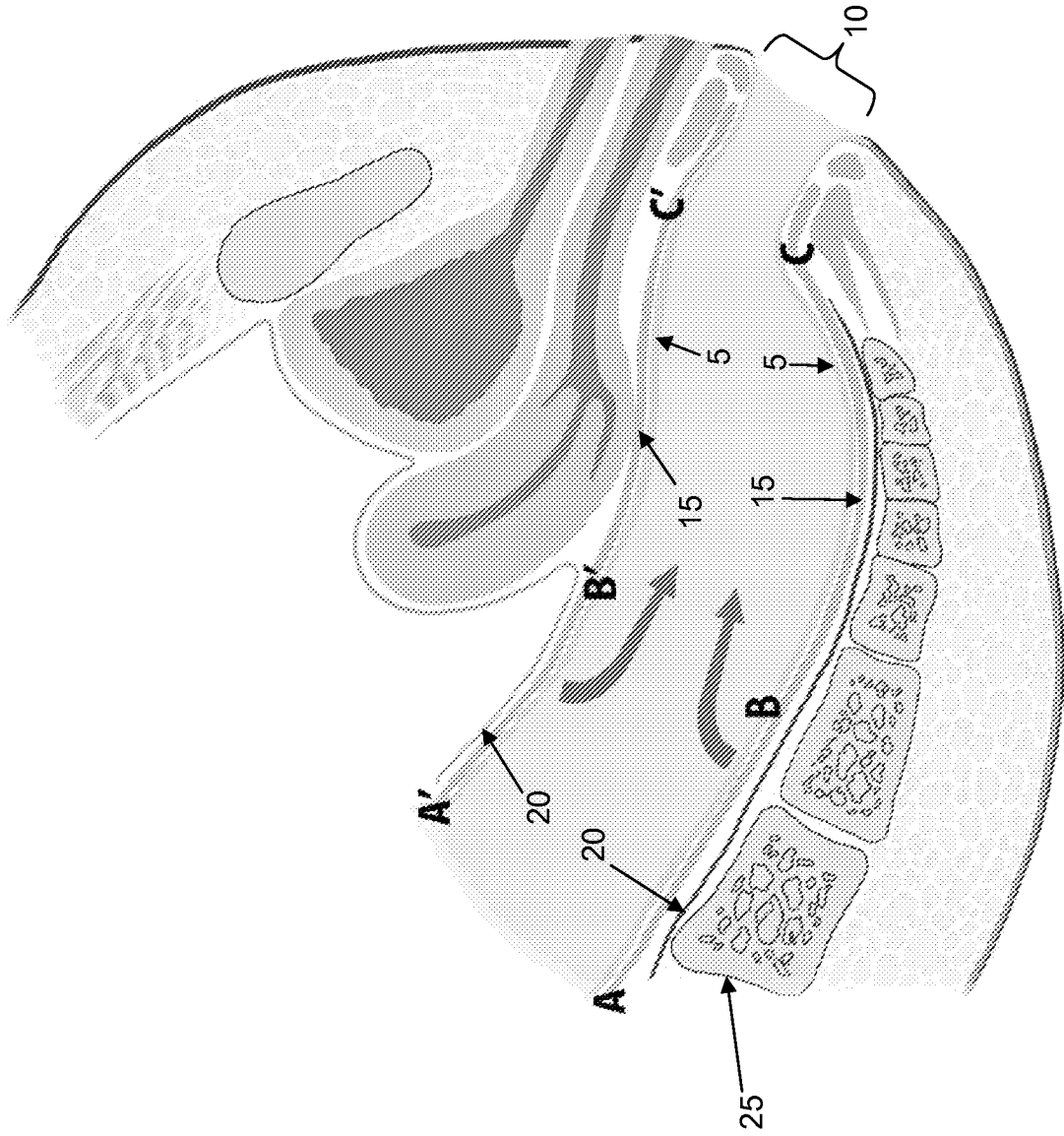


FIG. 2

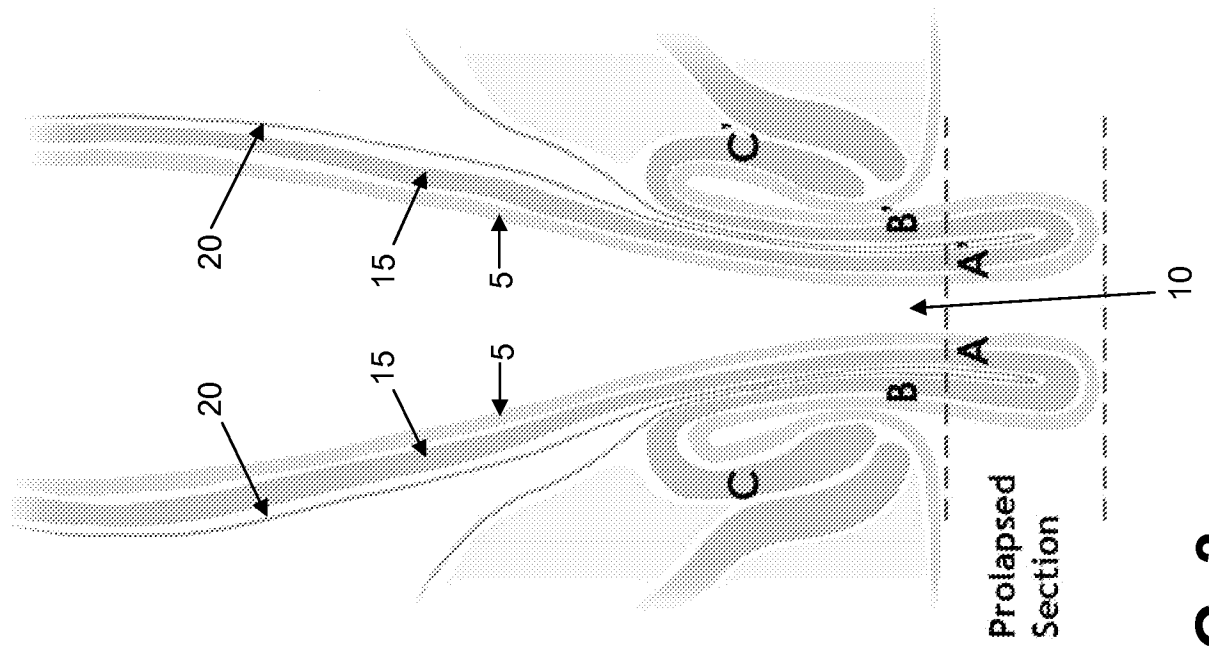


FIG. 3

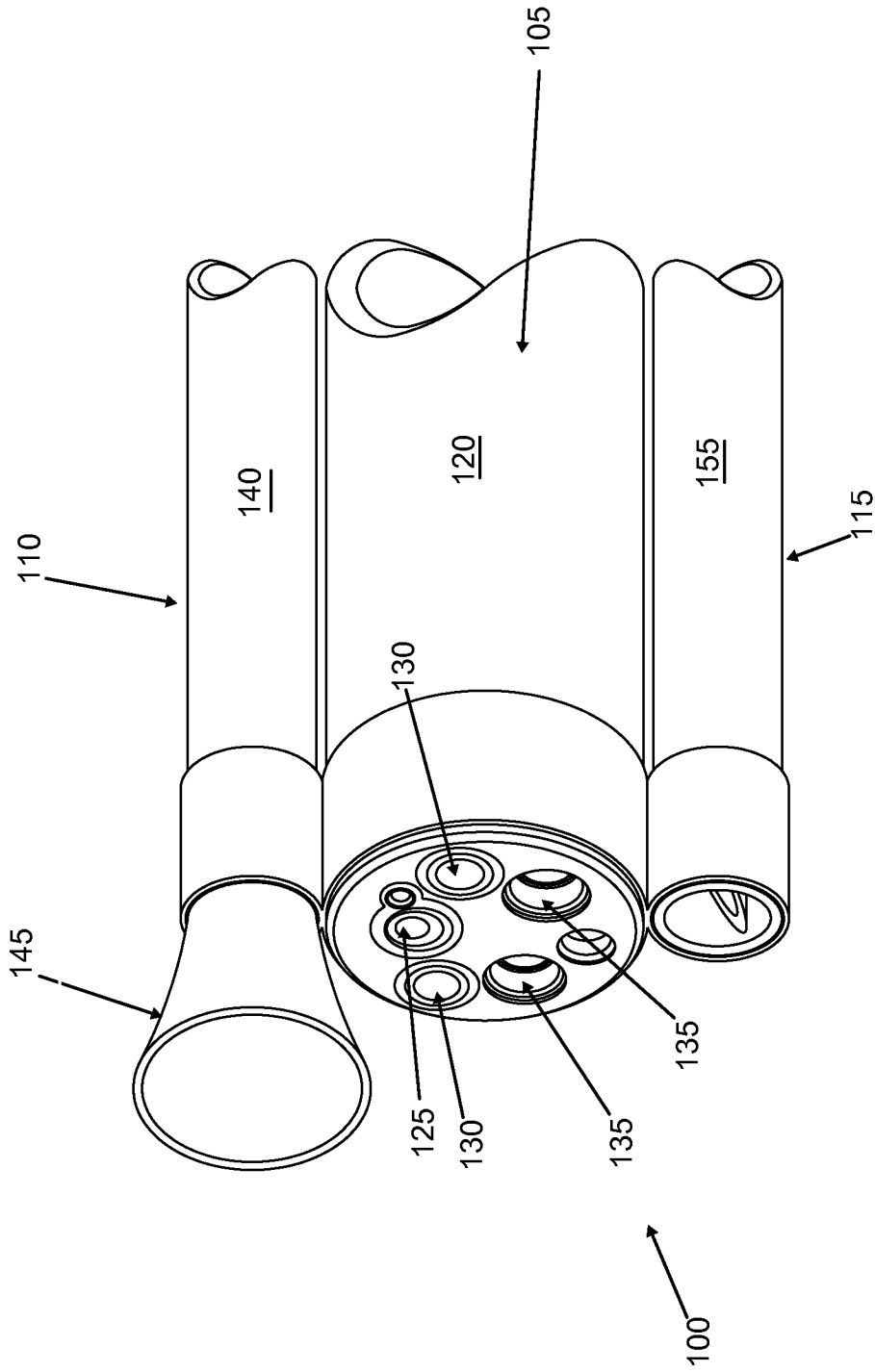


FIG. 5

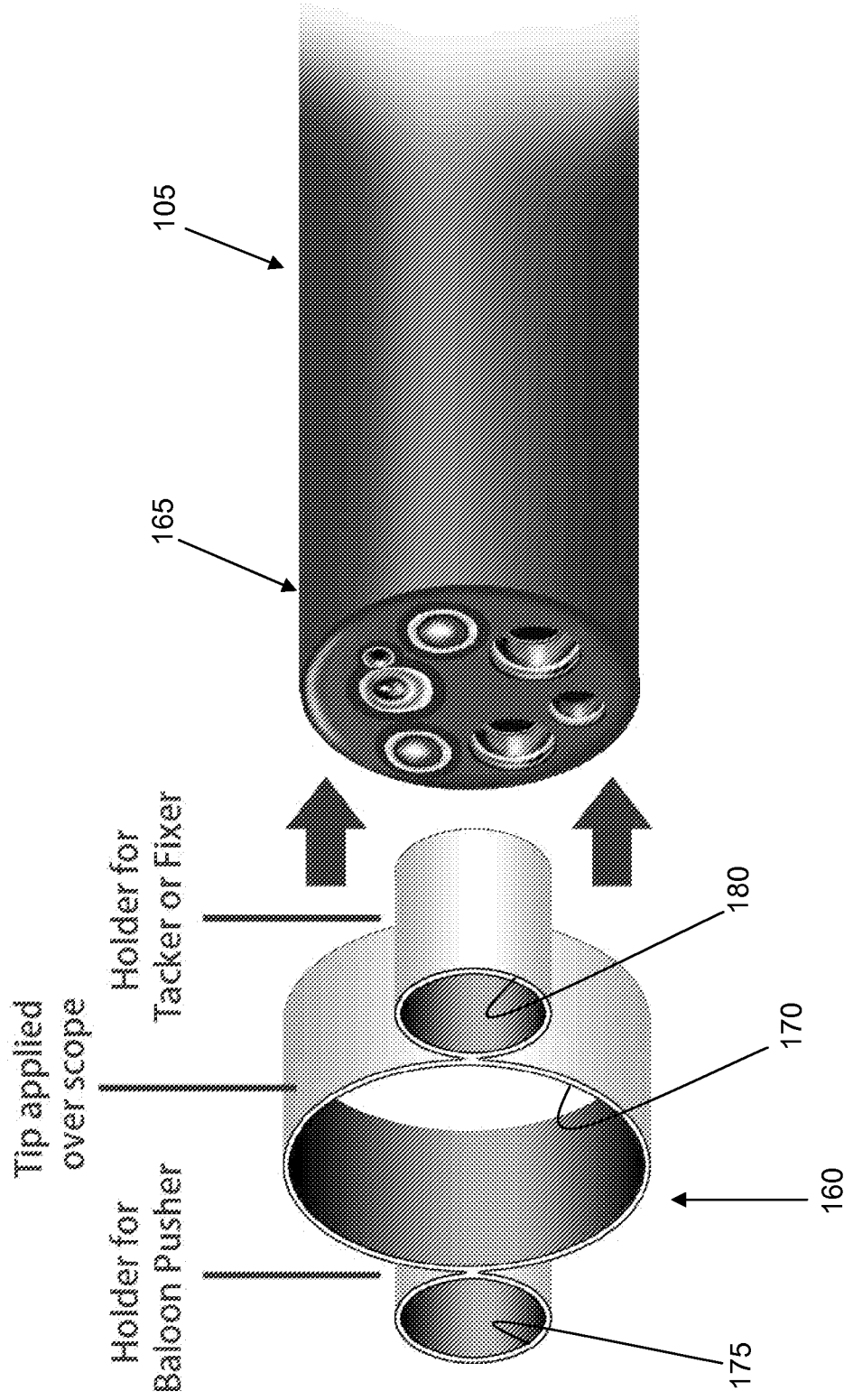


FIG. 6

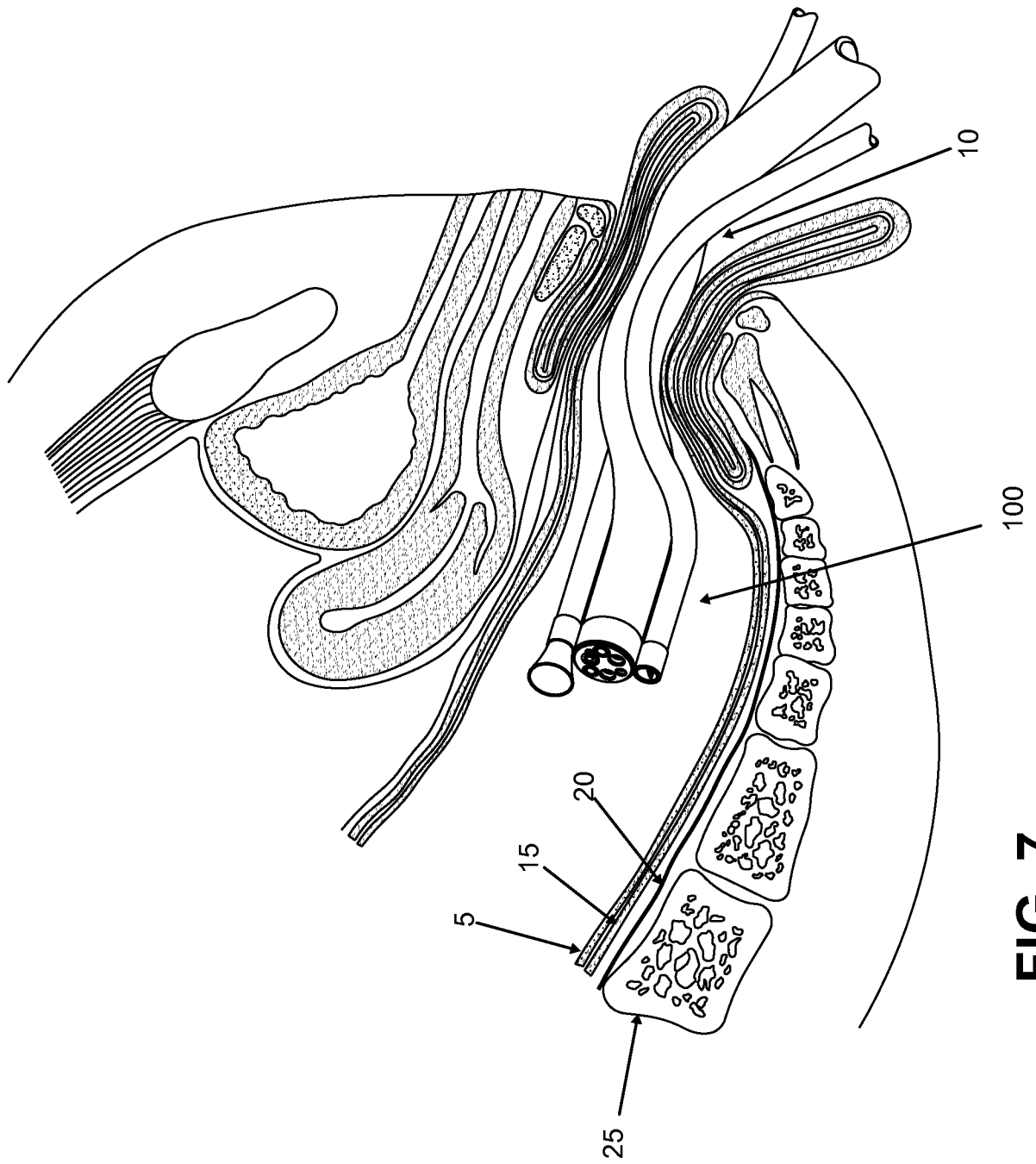


FIG. 7

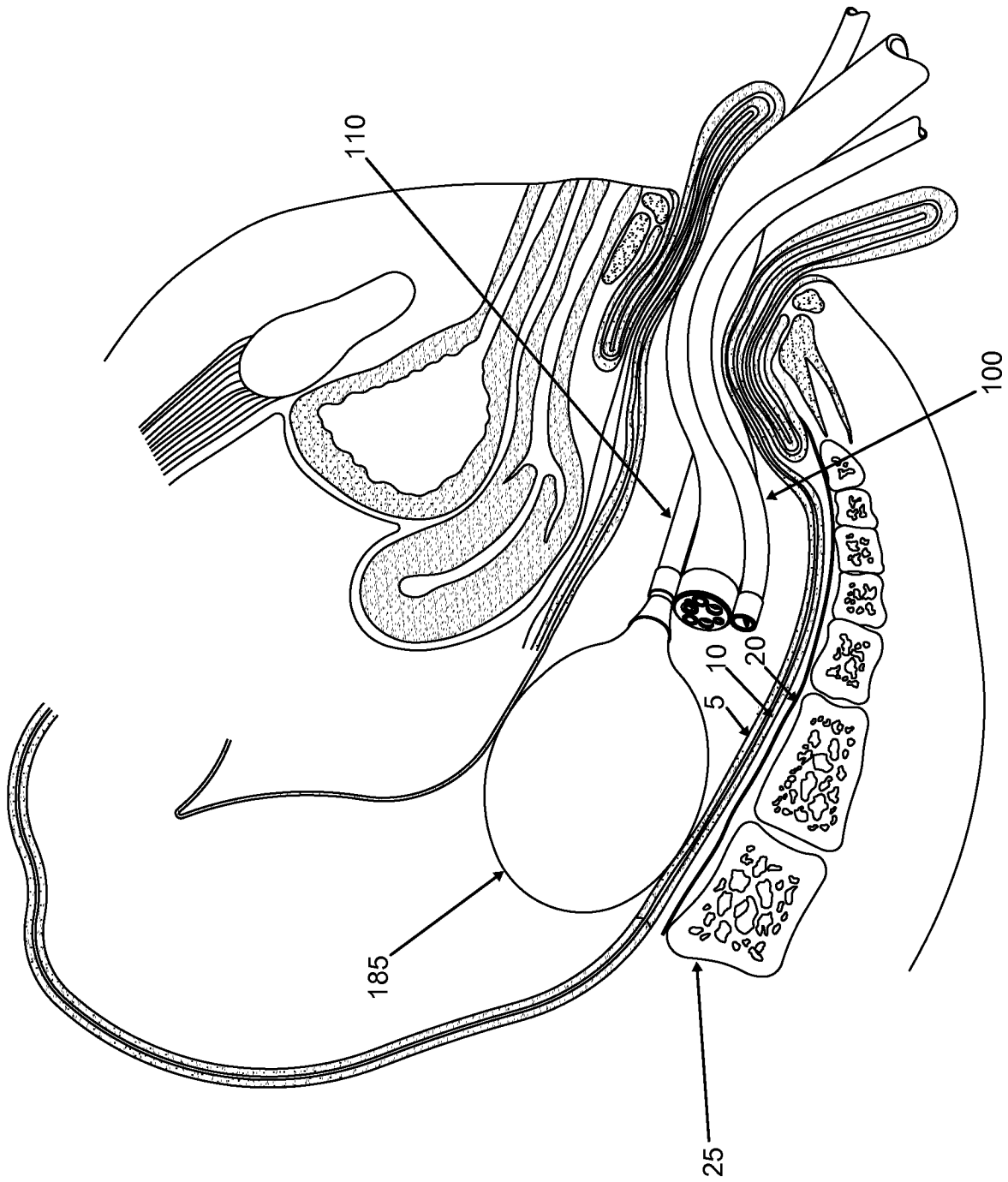


FIG. 8

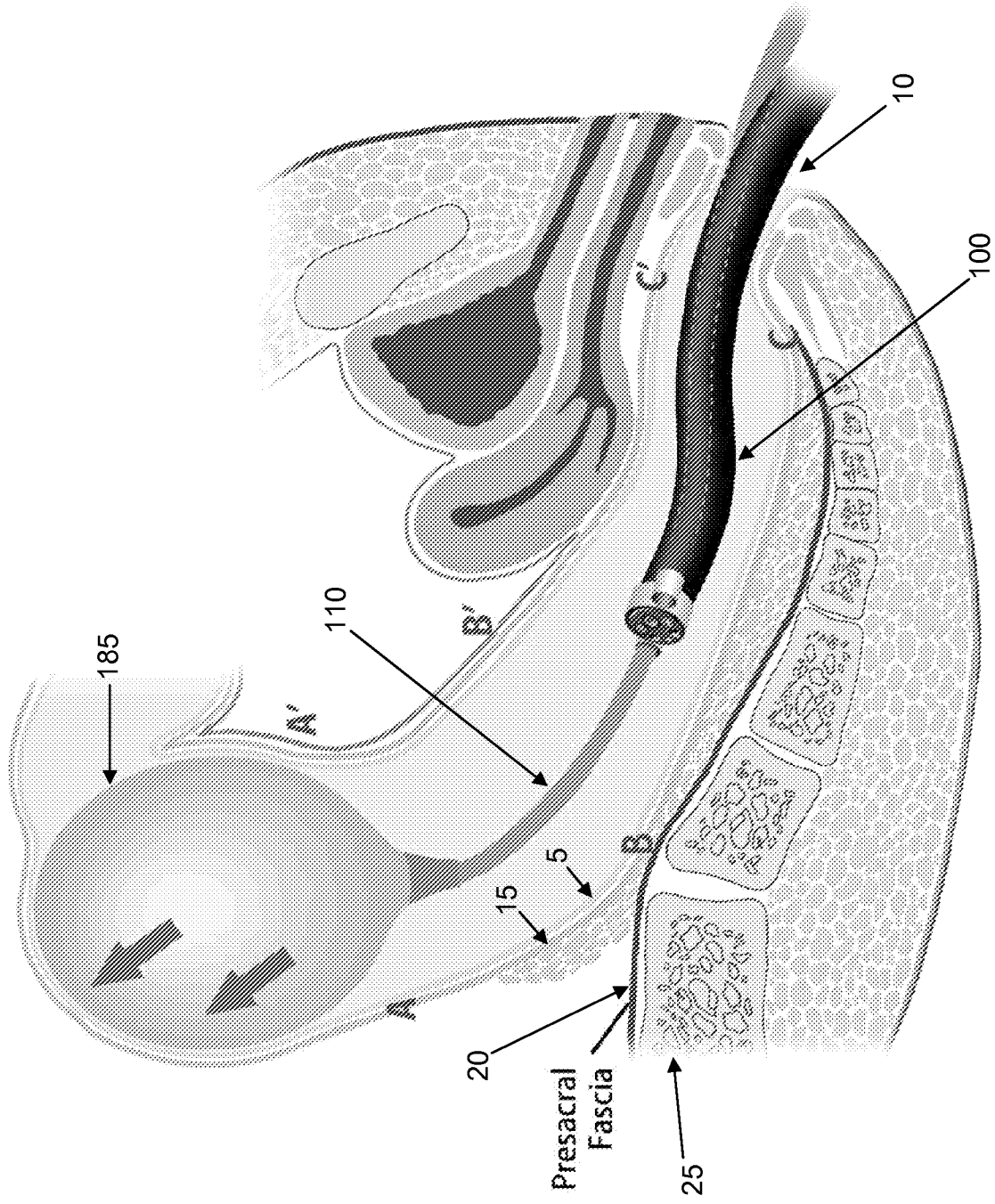


FIG. 9

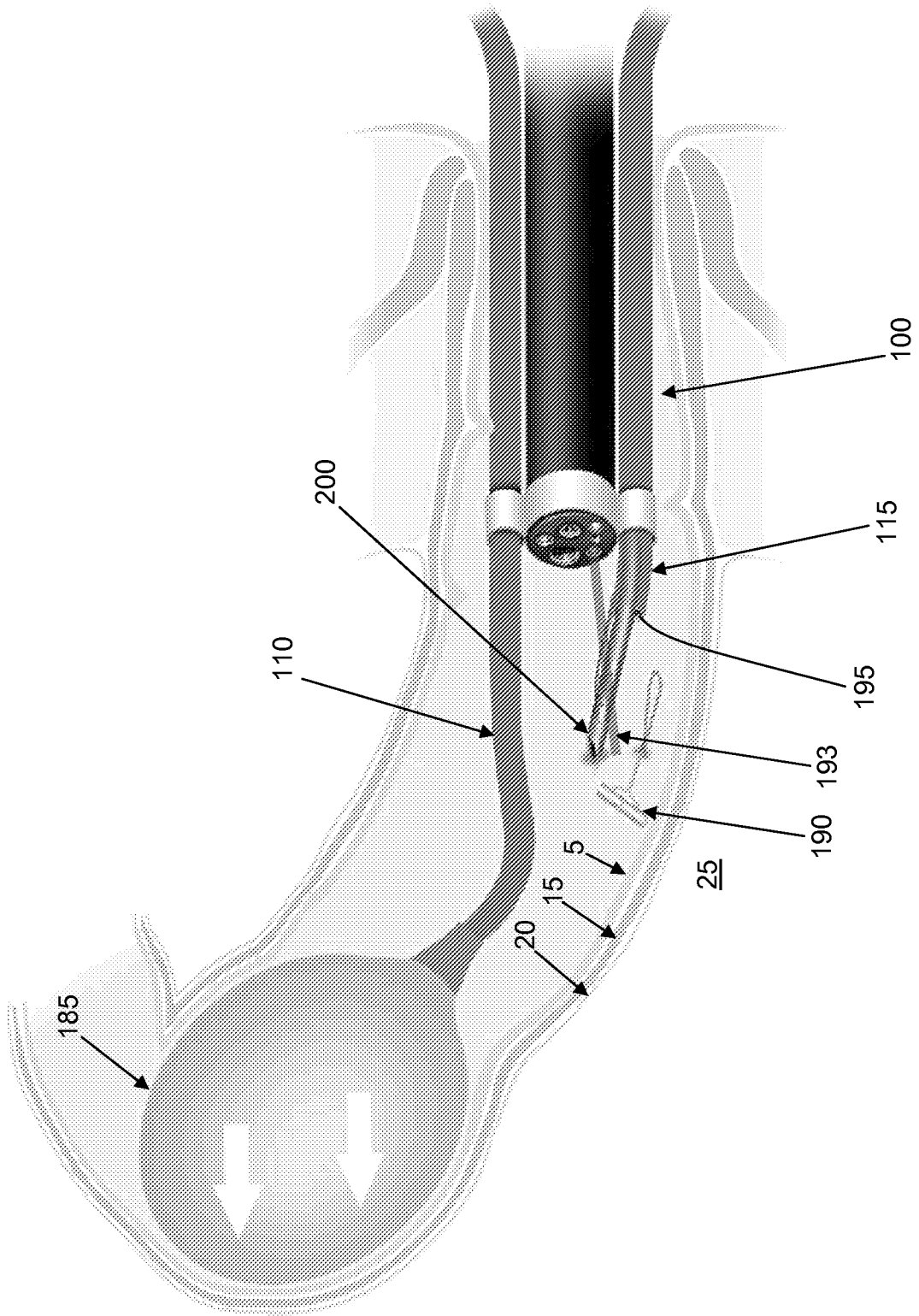


FIG. 10

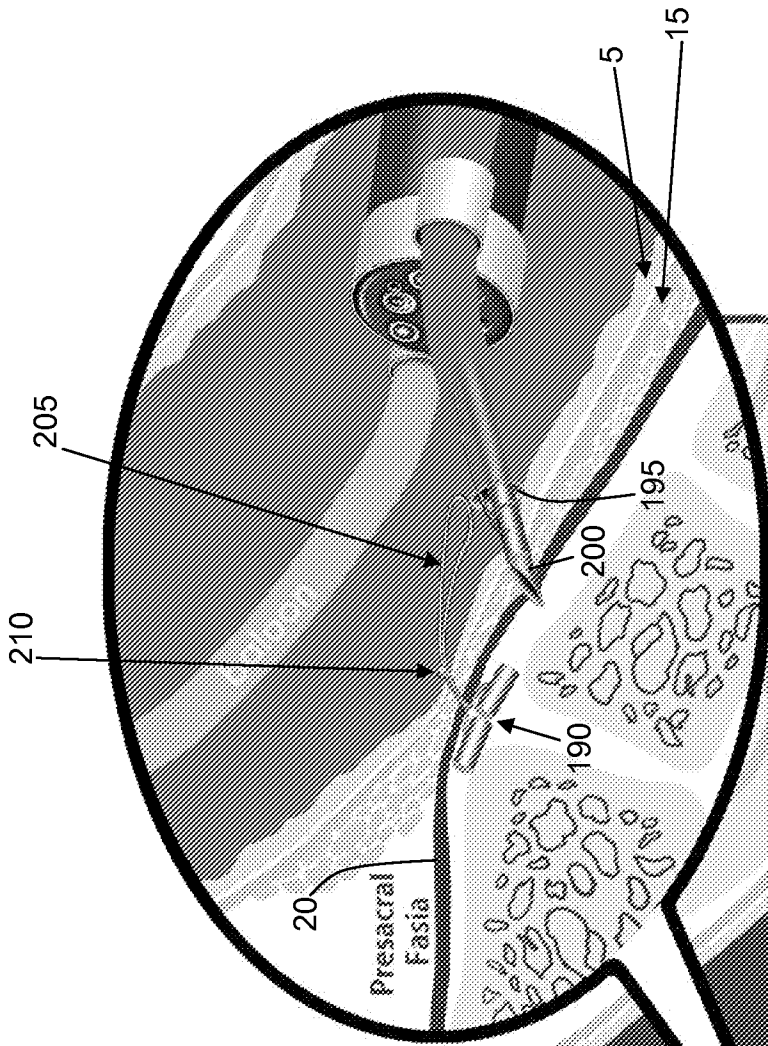


FIG. 11

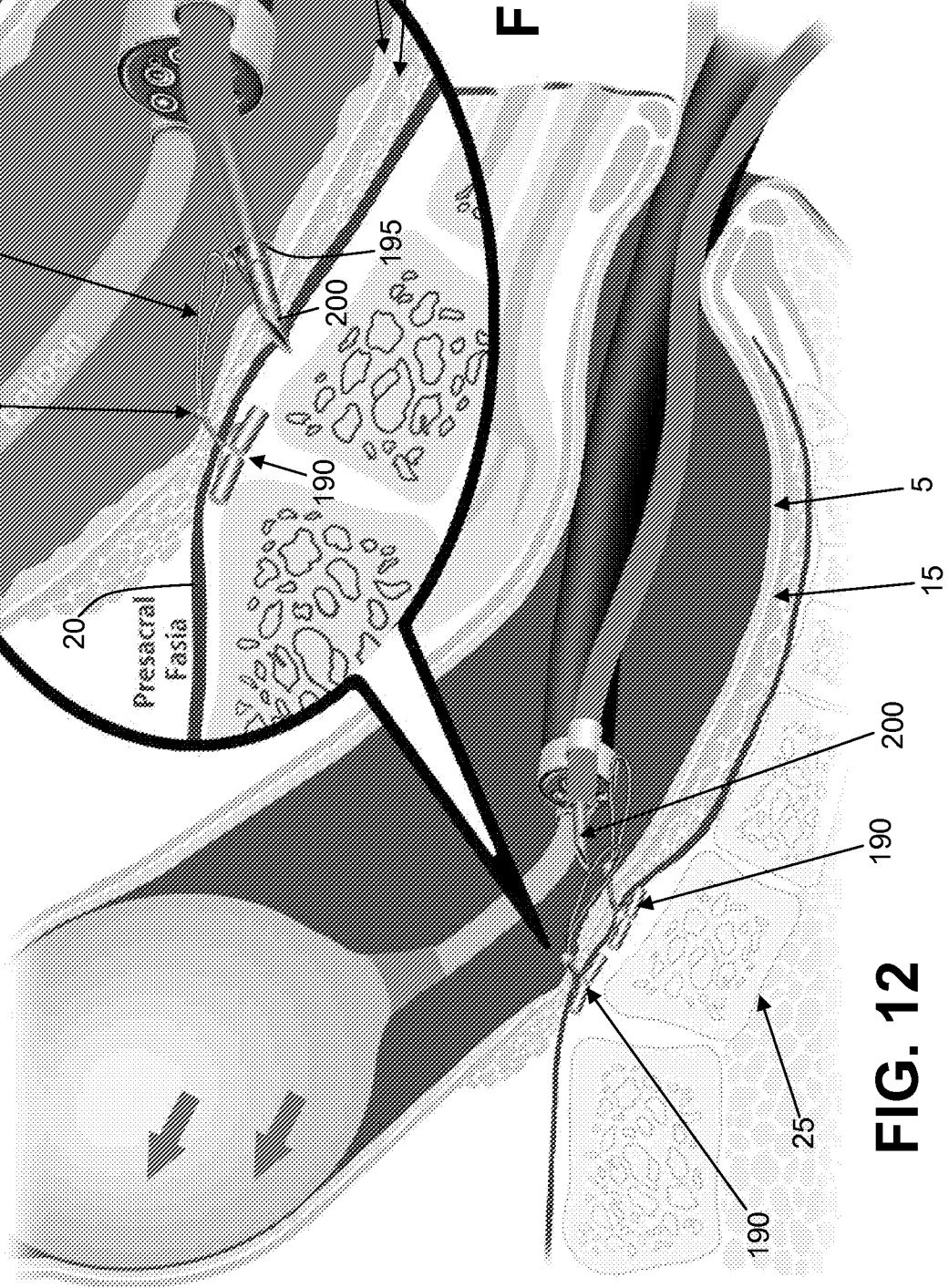


FIG. 12

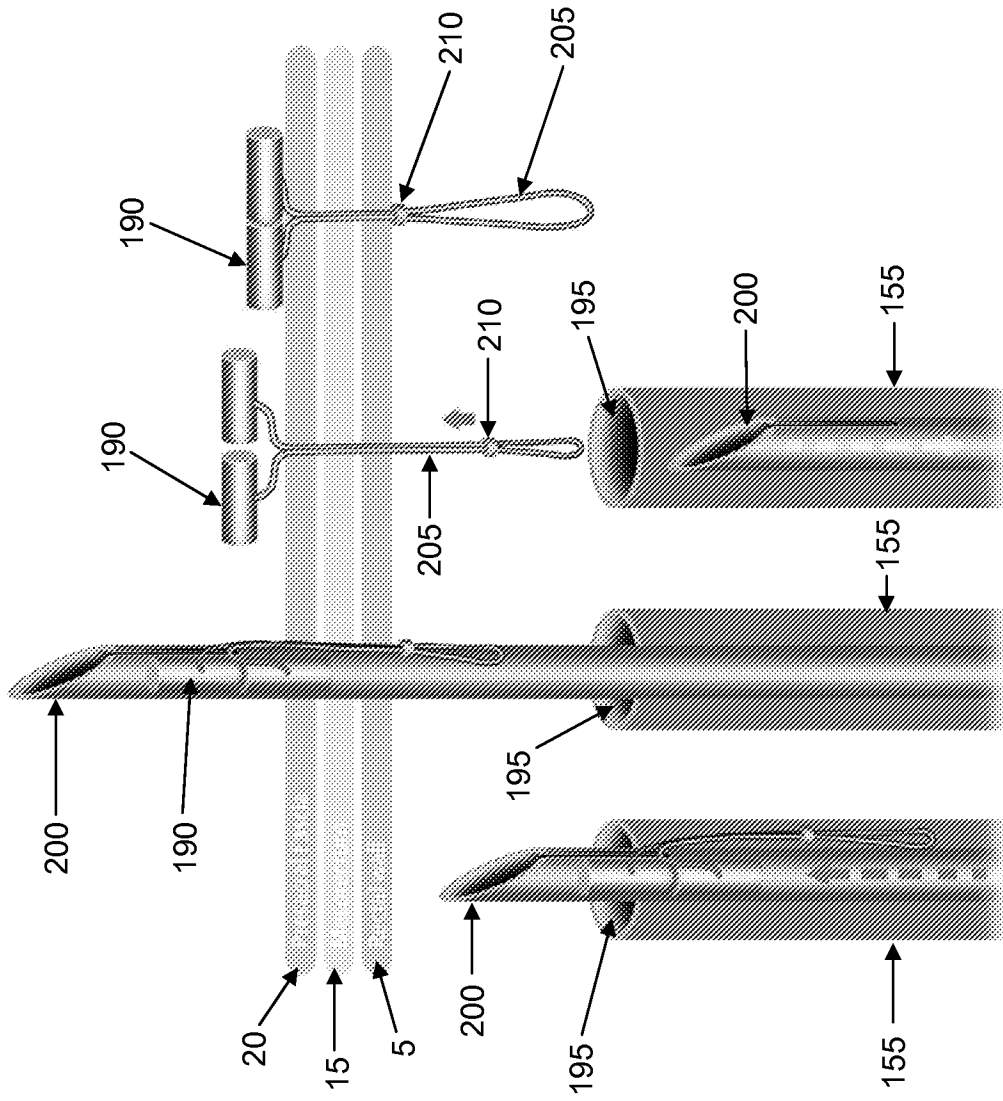


FIG. 13

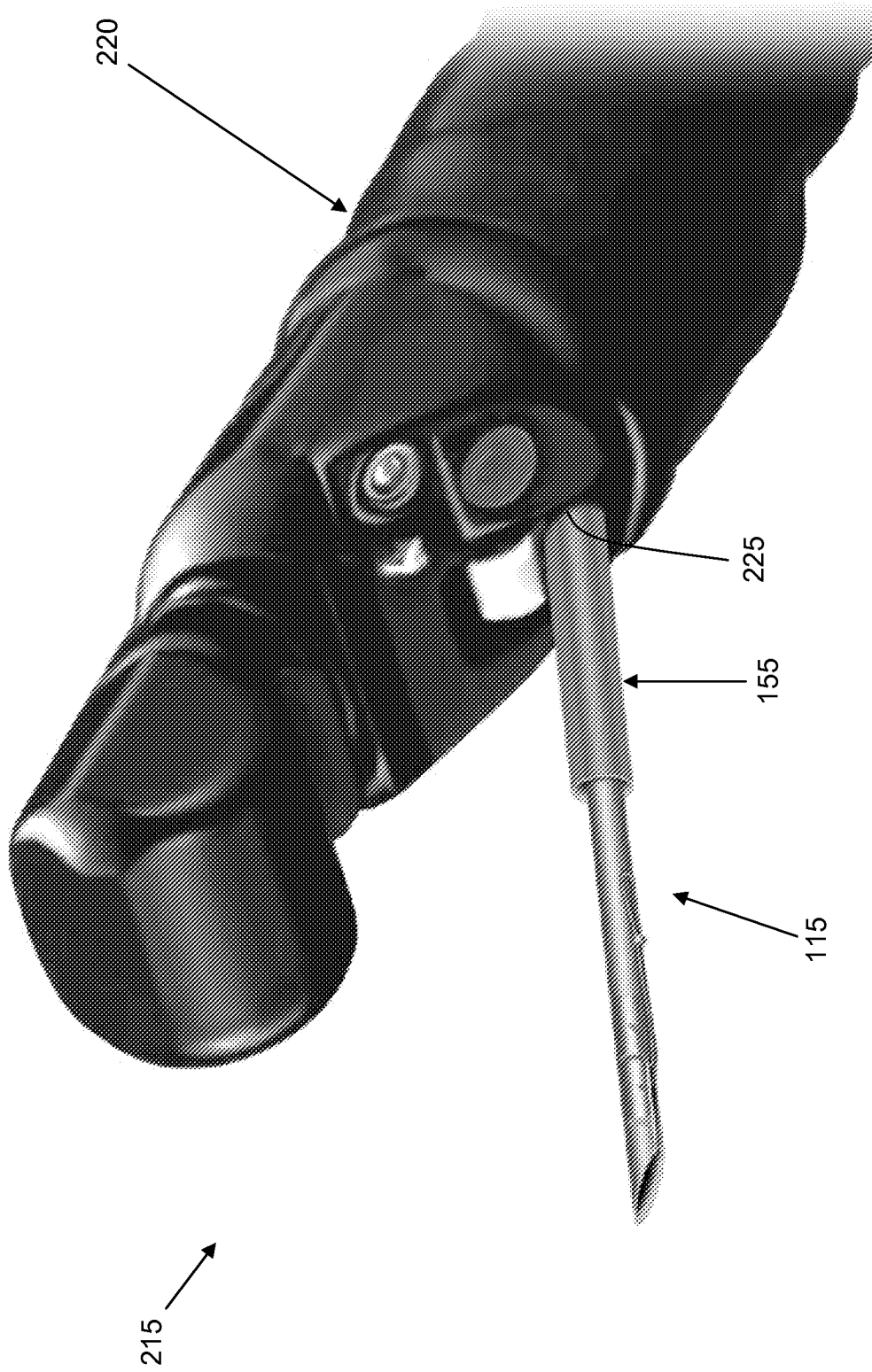


FIG. 14

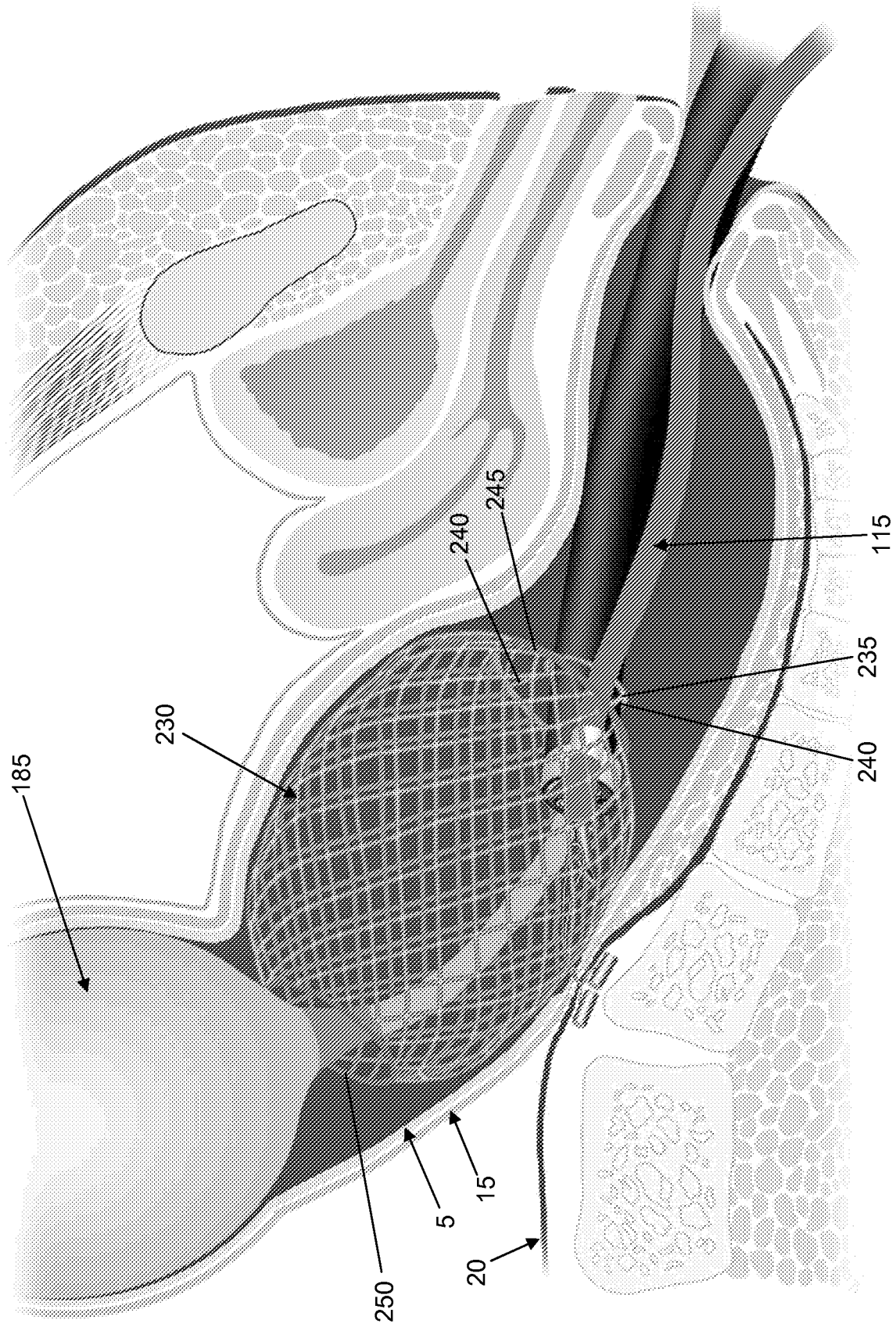


FIG. 15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/82246

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 1/31 (2008.04)
USPC - 600/116
 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)
 USPC - 600/116

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
 PGPB, USPT, USOC, EPAB, JPAB

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
 PubWEST, Dialog, USPT, Google Patents, FreePatentsOnline, WIPO
 search terms: rectal prolapse, endoscope, balloon catheter, surgery, GI, gastrointestinal, tacker, staple, clip, fastener, anatomical landmark, sacral, presacral, intussusception, evaginate, invaginate, inflate, expand, colonoscope, ultrasound, proctoscope, suture

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2005/000111 A1 (Abel et al.) 06 January 2005 (06.01.2005) abstract; pg.4, ln.17-24; pg.4, ln.28-30; pg.5, ln.1-3; pg.21, ln.8-14; pg.4, ln.30-33; pg.9, ln.4-6; pg.20, ln.26-27; pg.7, ln.21-25; pg.21, ln.8-14; pg.7, ln. 21-25	1-28
Y	US 2006/0030884 A1 (Yeung et al.) 09 February 2006 (09.02.2006) para [0201], figs 24-26, uterine tool 163, anchor 144; para [0101]	1-28
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Further documents are listed in the continuation of Box C.

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Date of the actual completion of the international search 17 December 2008 (17.12.2008)	Date of mailing of the international search report 08 JAN 2009
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