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(54) APPARATUS AND METHOD FOR DEVELOPING AN ANATOMIC SPACE FOR LAPAROSCOPIC HERNIA REPAIR AND PATCH FOR USE THEREWITH

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Related U.S. Application Data

(60) Continuation of application No. 08/861,913, filed on May 22, 1997, now Pat. No. 6,368,337, which is a continuation of application No. 08/483,293, filed on Jun. 7, 1995, now abandoned, which is a division of application No. 08/124,283, filed on Sep. 20, 1993, now Pat. No. 5,836,961, which is a continuation-in-part of application No. 07/893,988, filed on Jun. 2, 1992, now Pat. No. 6,312,442.

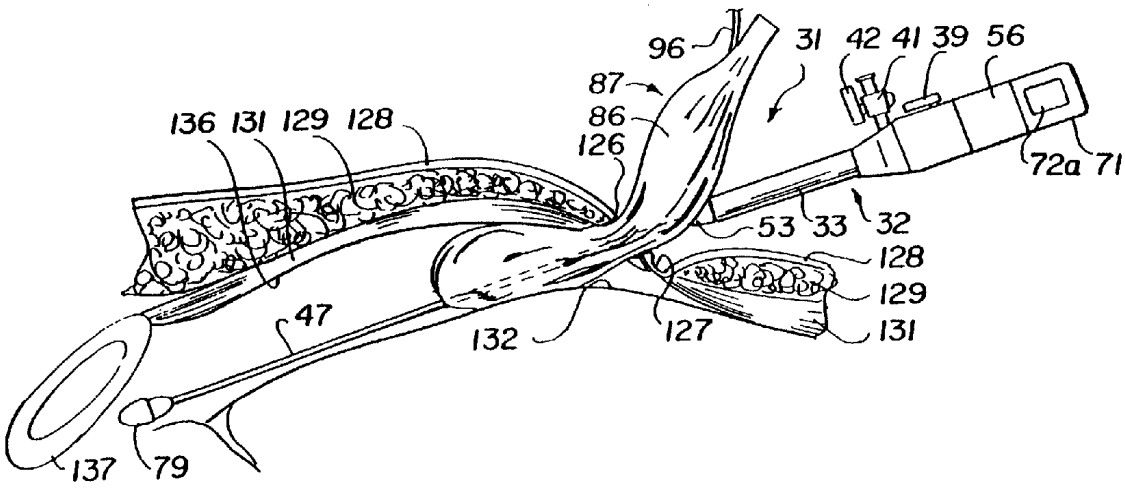
Publication Classification

(51) **Int. Cl.**[7] **A61B 17/08**

(52) **U.S. Cl.** **606/213**

(57) ABSTRACT

An apparatus for creating an anatomic space in tissue in a body comprises an introducer and a sheath. The tubular sheath may surround the introducer, and may have a weakened region along its longitudinal axis. A handle may be provided on the sheath. The handle may be adapted to be pulled proximally to separate the weakened region and allow the sheath to be removed from the introducer. The sheath may be secured to the introducer via detents or latches on the handle.



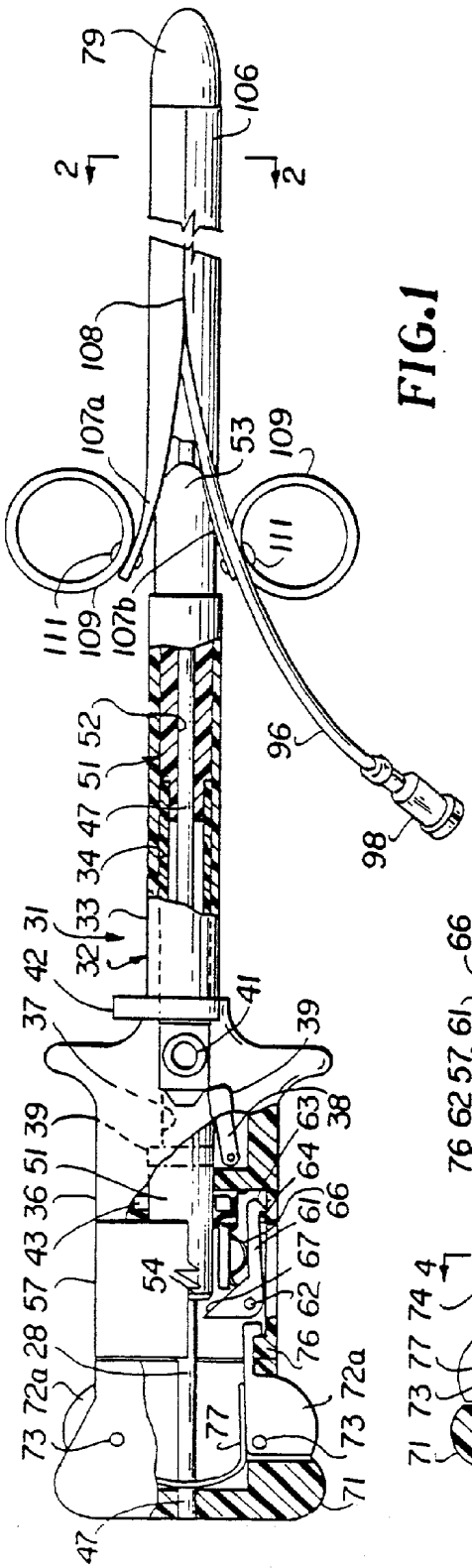


FIG.1

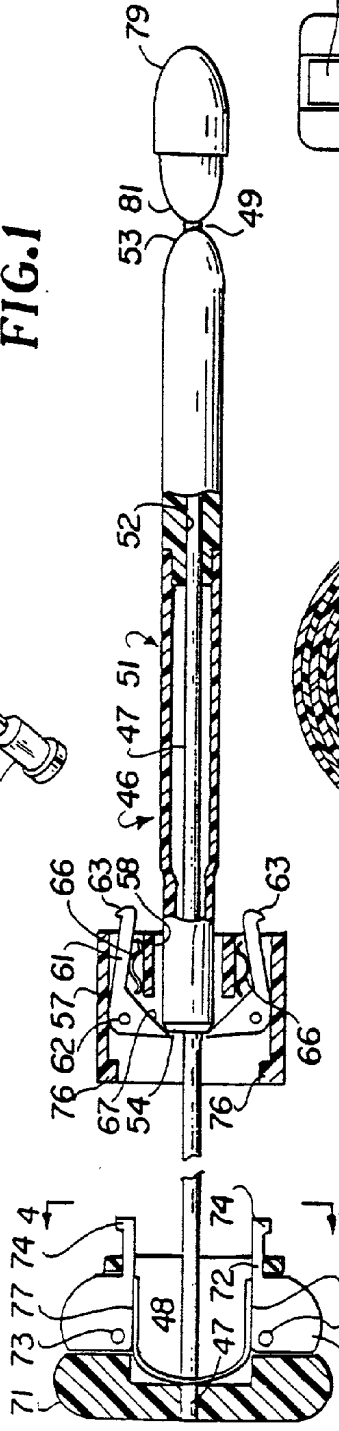


FIG.3

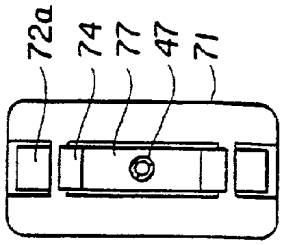


FIG.4

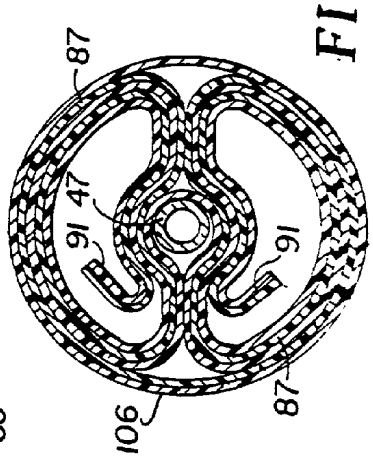
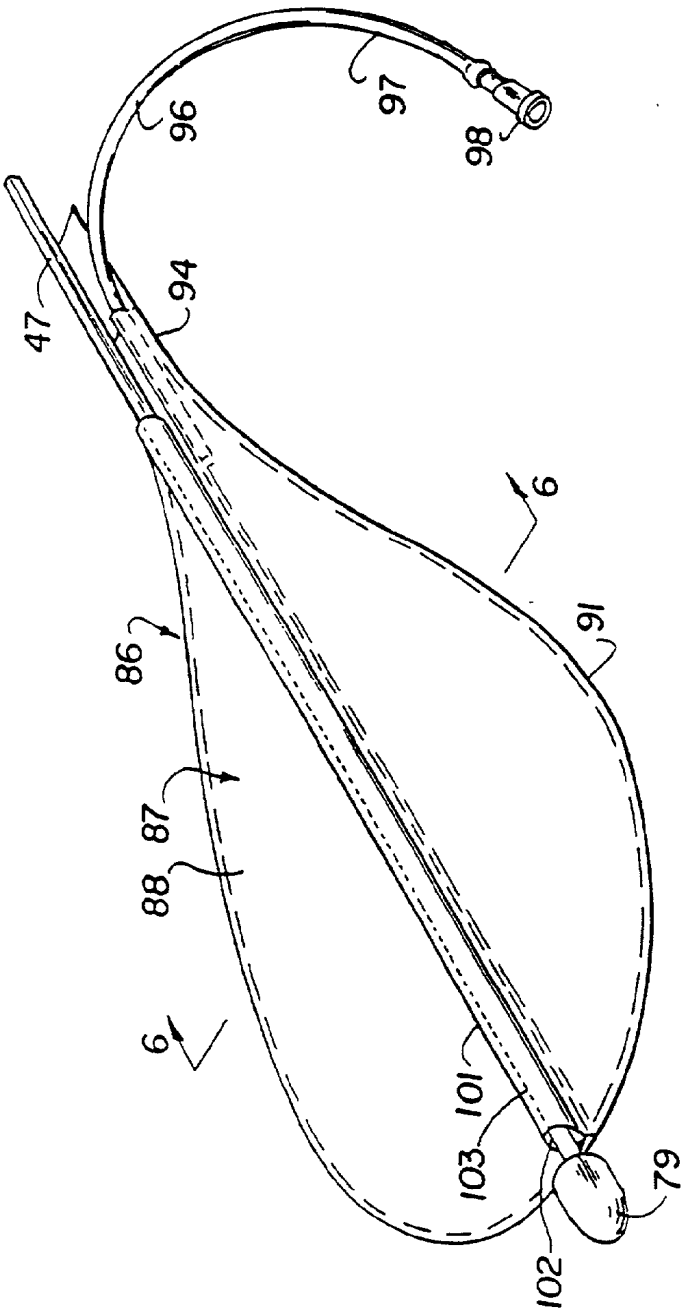


FIG.2



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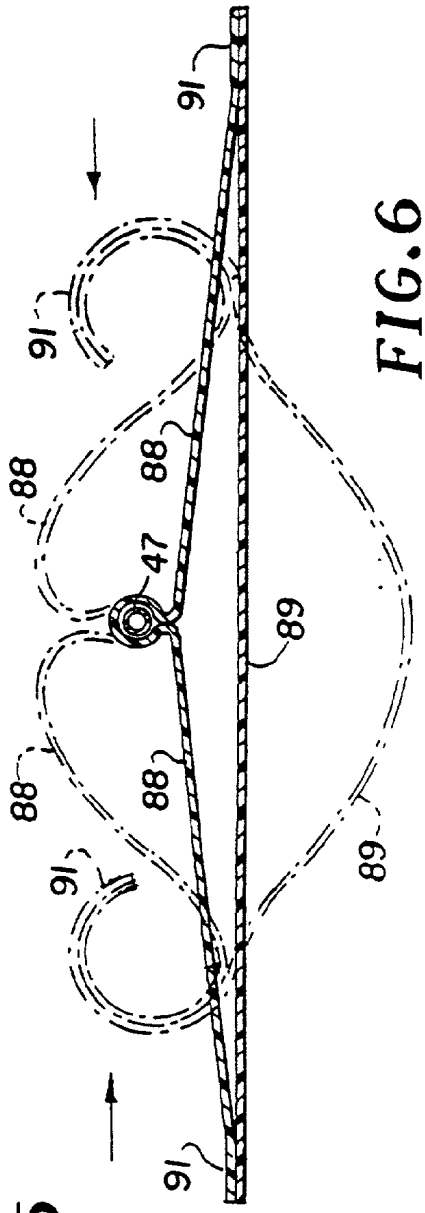

FIG.6

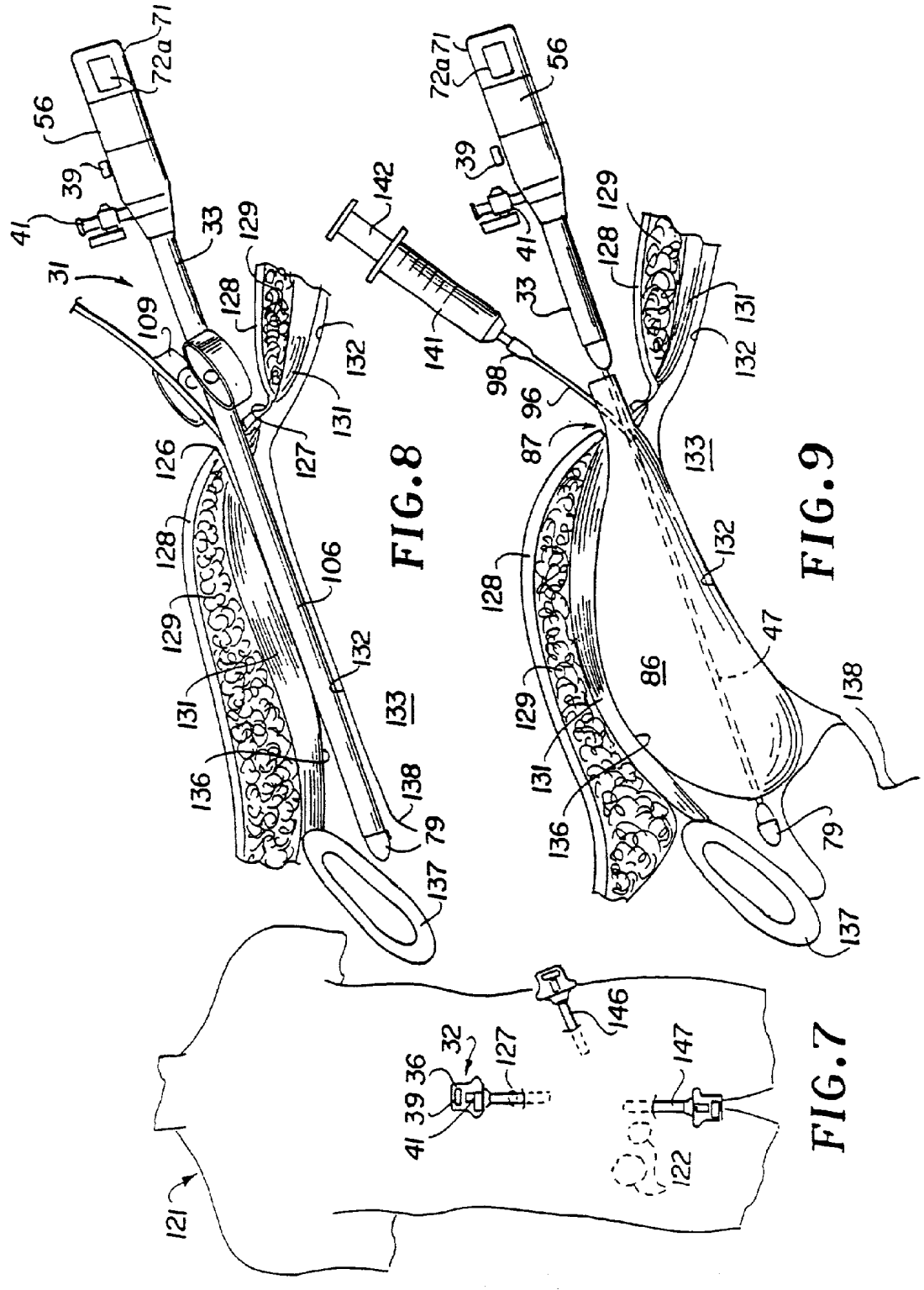

FIG. 8

FIG. 9

FIG. 7

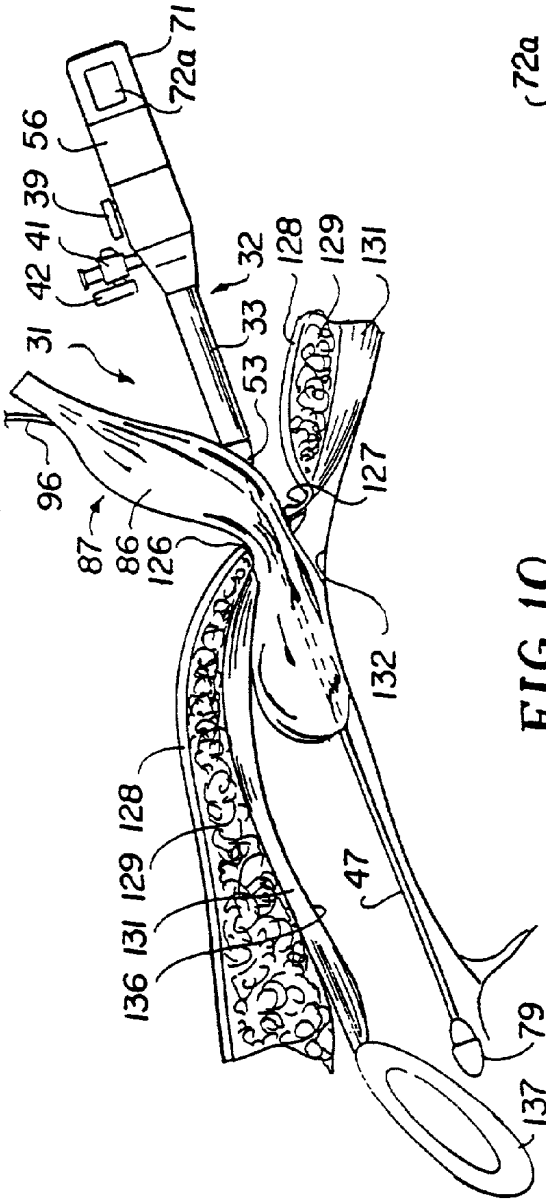
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FIG. 10

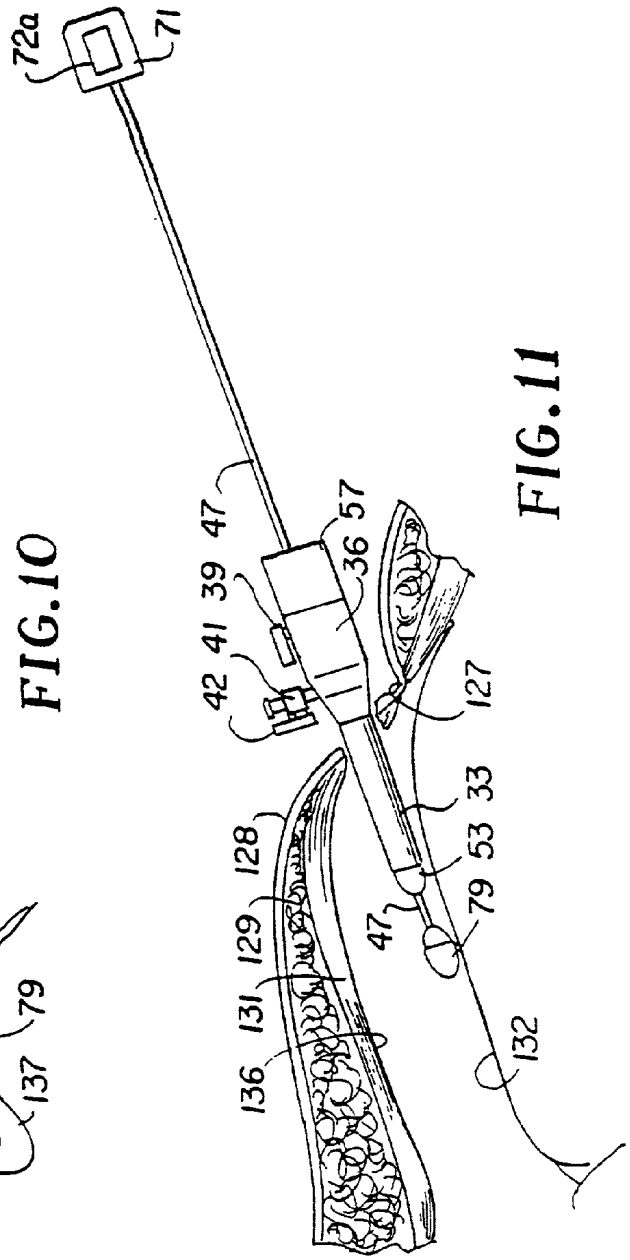
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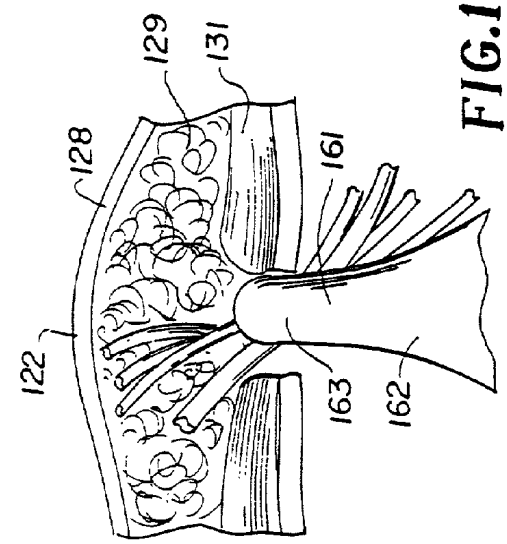
FIG. 11



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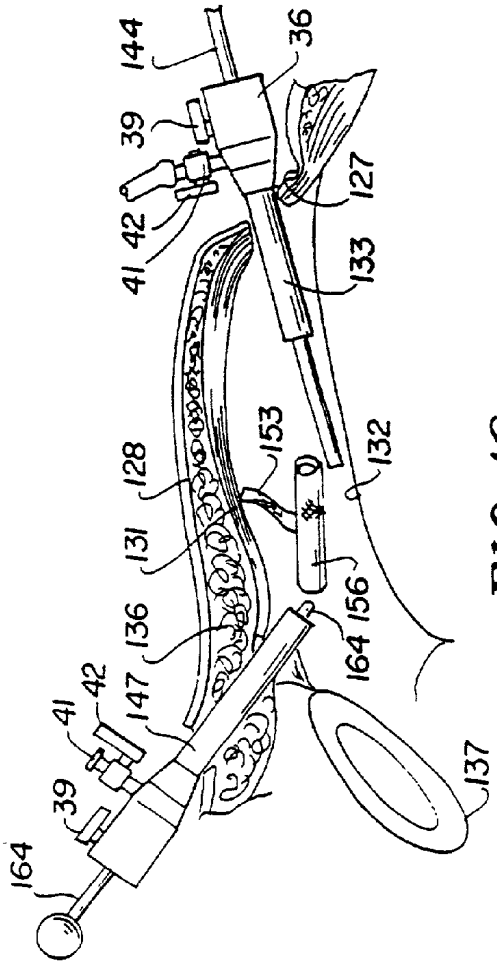

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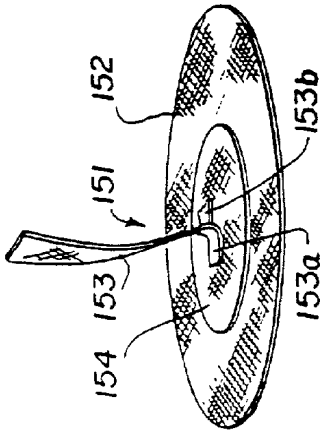

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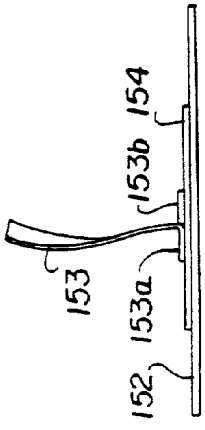


FIG. 13

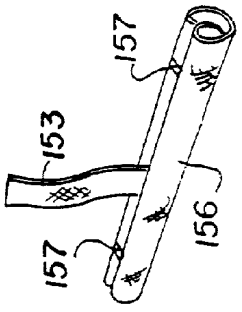
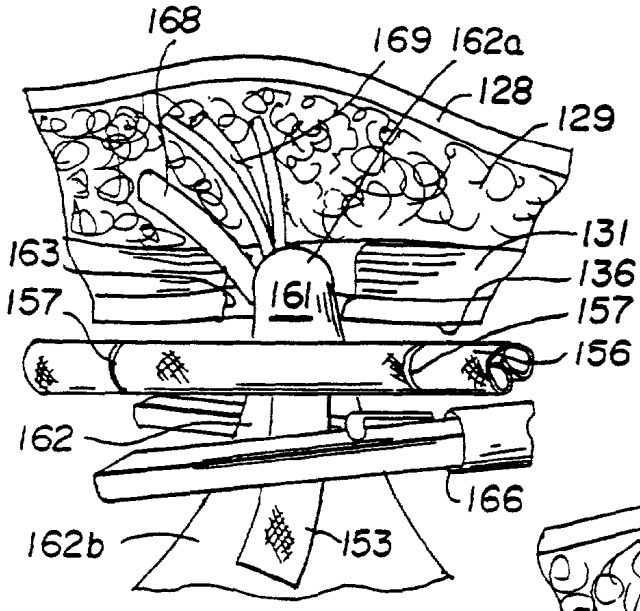


FIG.14



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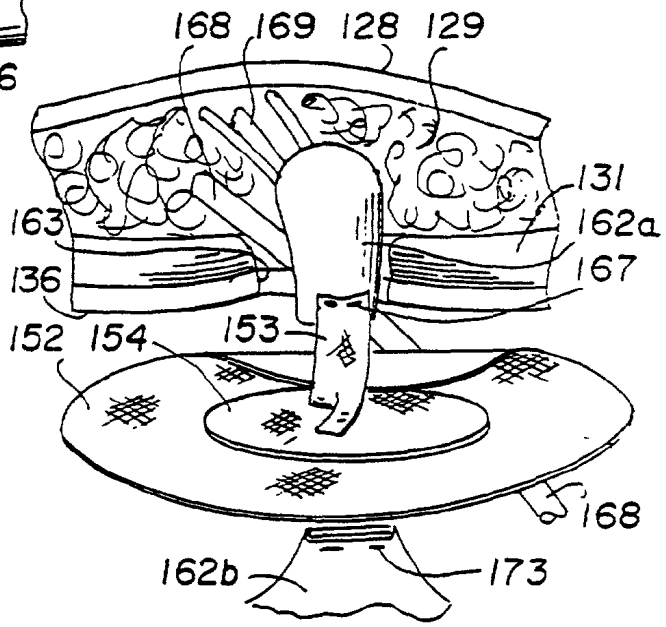

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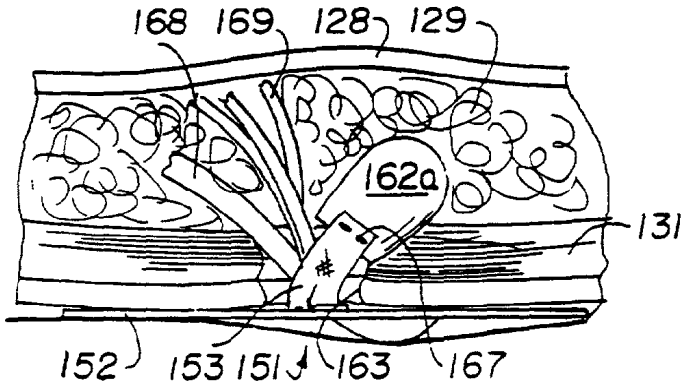

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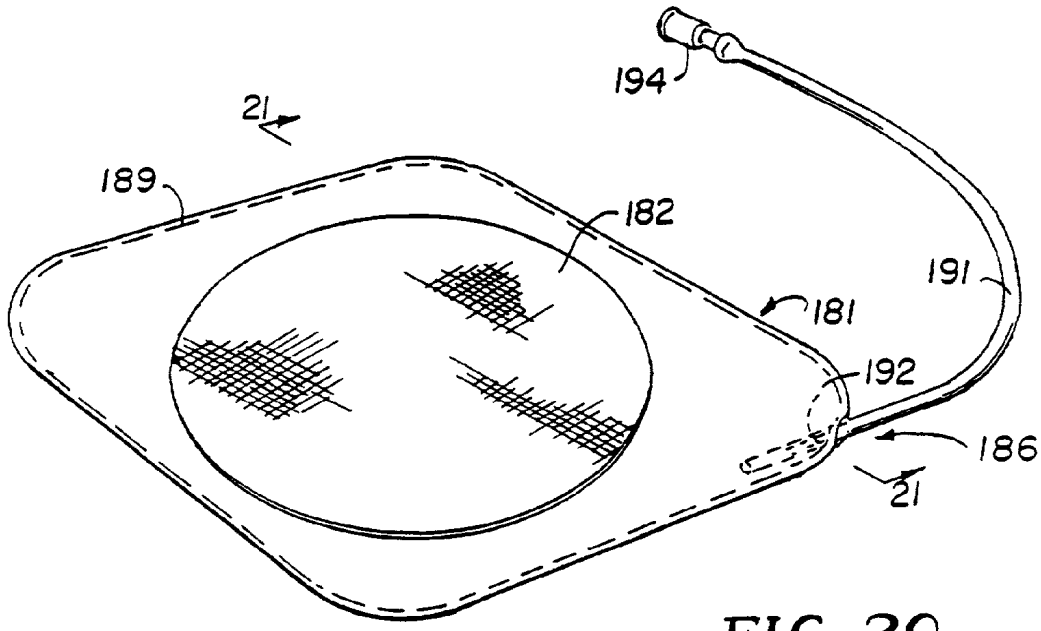

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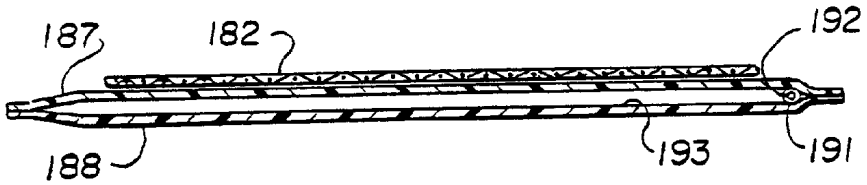

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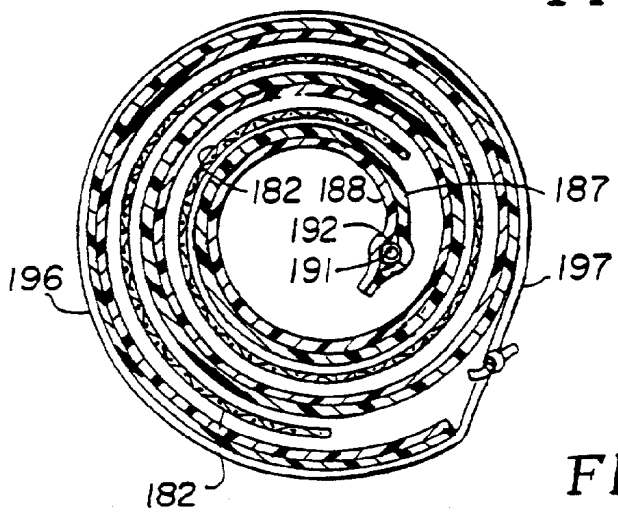

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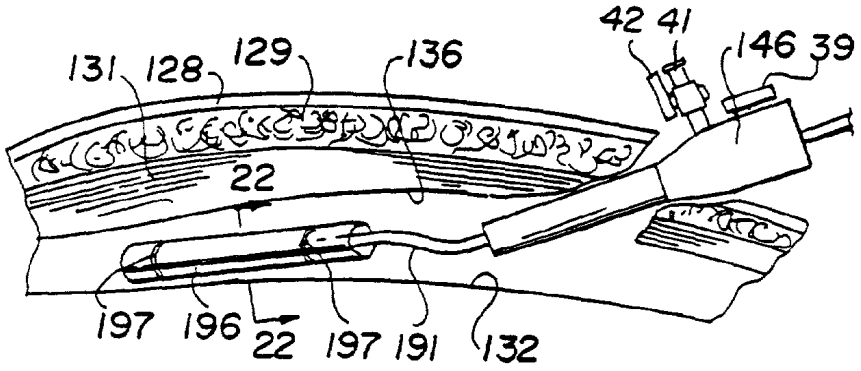
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FIG. 23

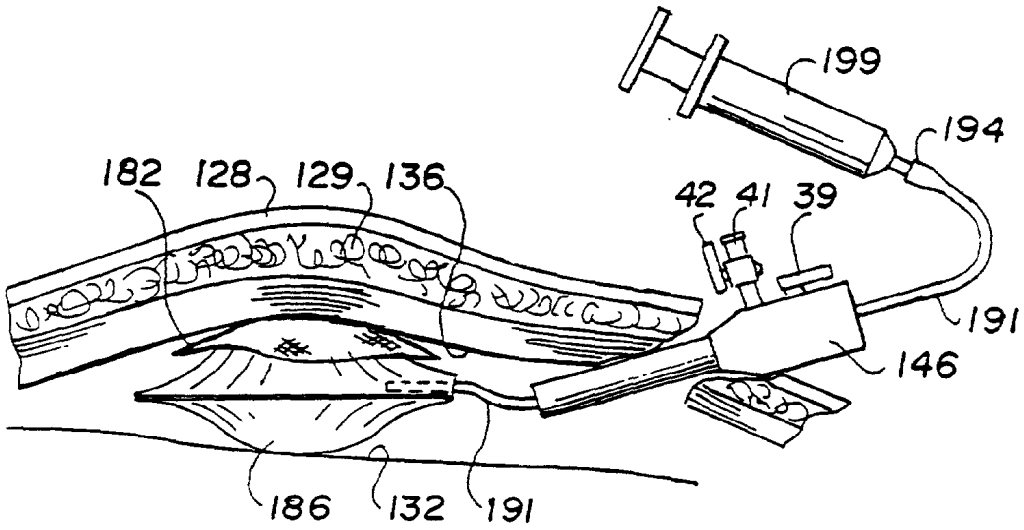
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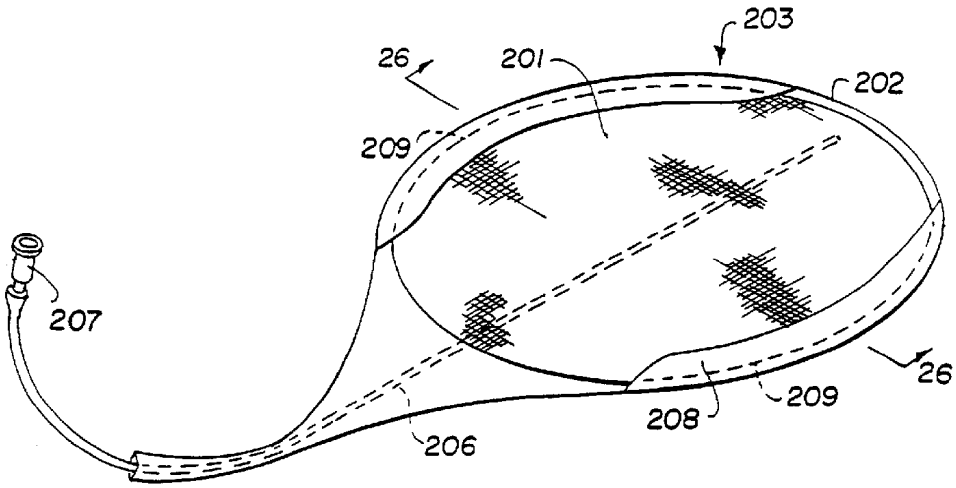
FIG. 24



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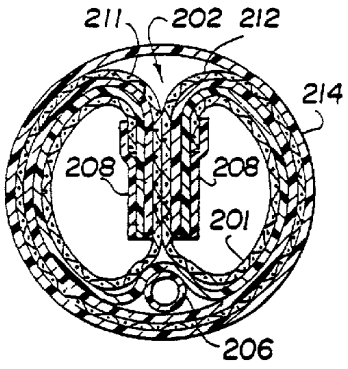

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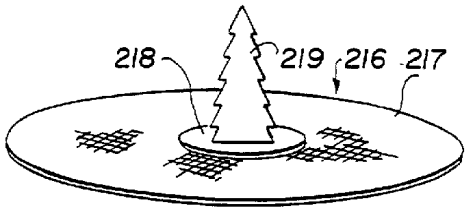


FIG. 27

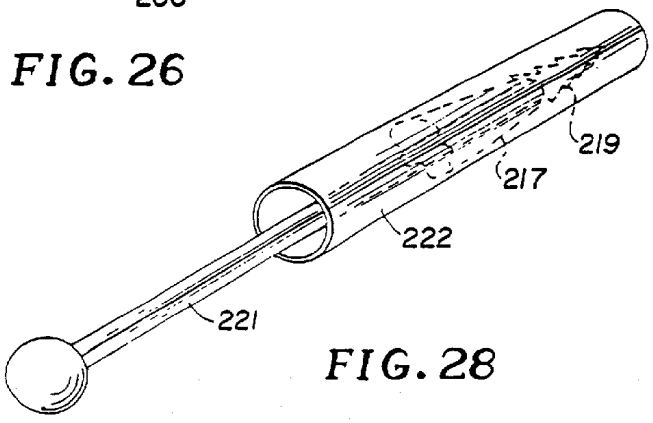


FIG. 28

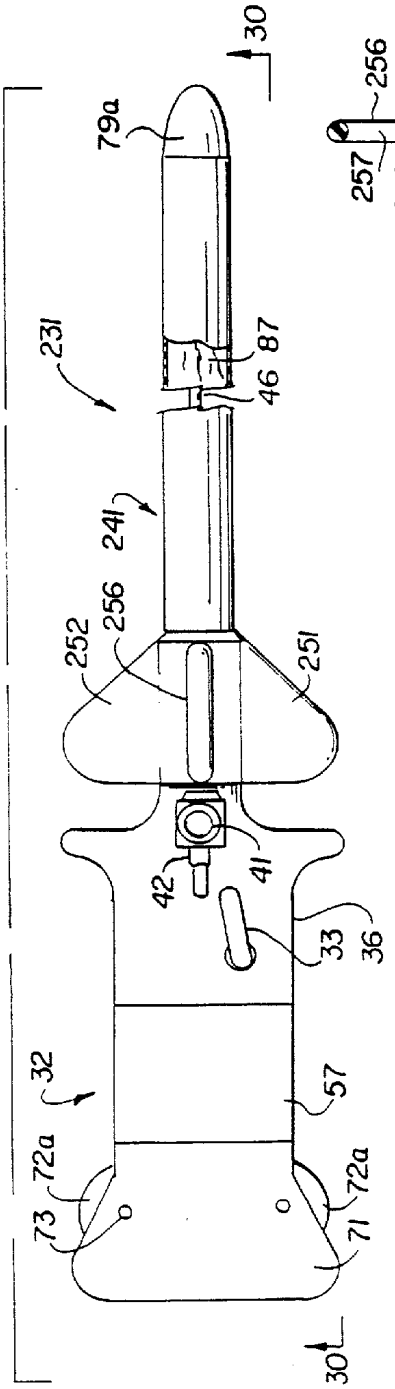


FIG. 29

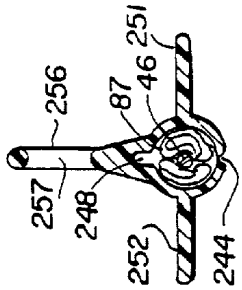


FIG. 31

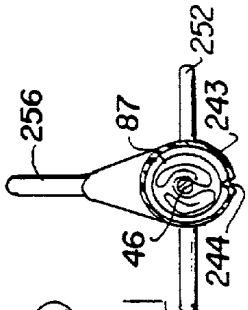


FIG. 32

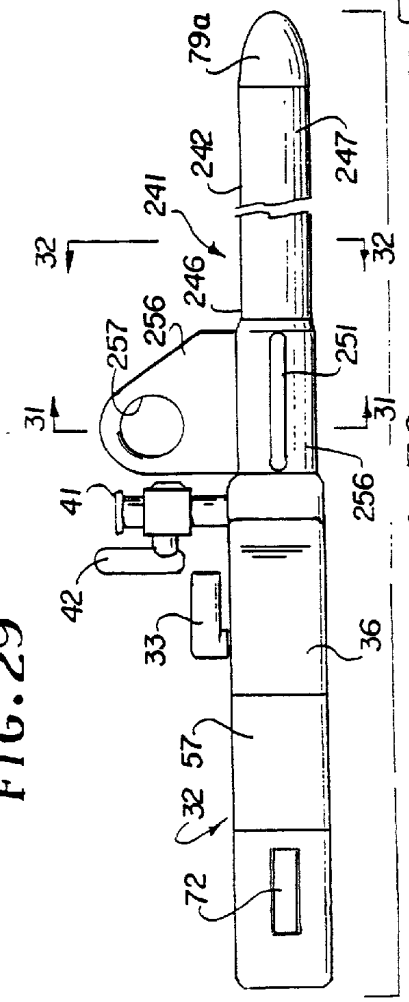


FIG. 30

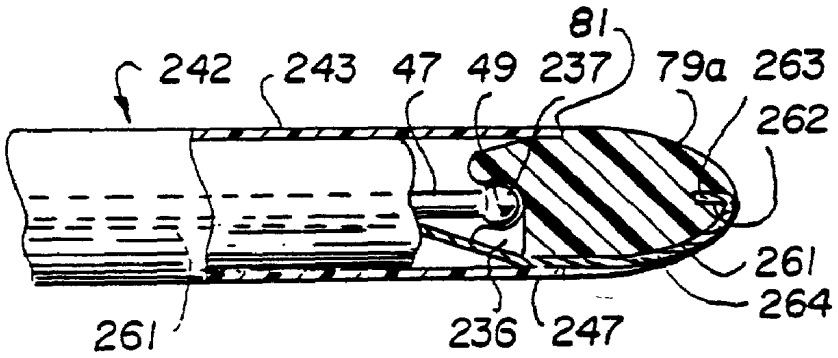


FIG. 33

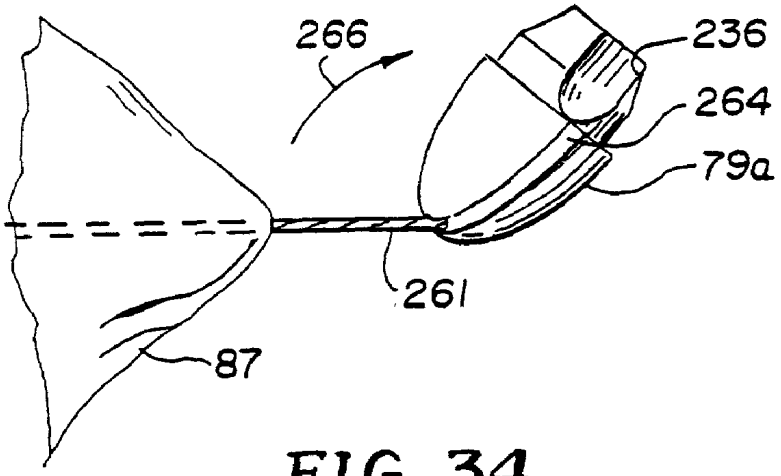
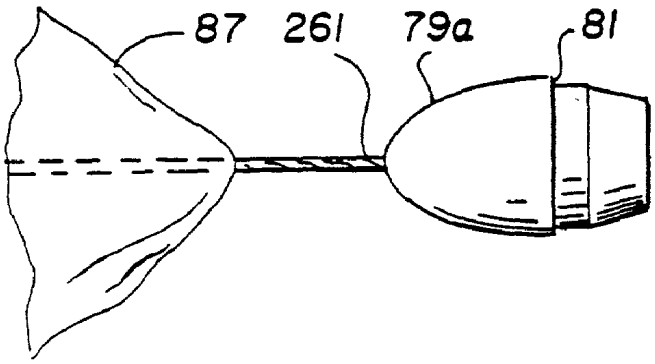


FIG. 34



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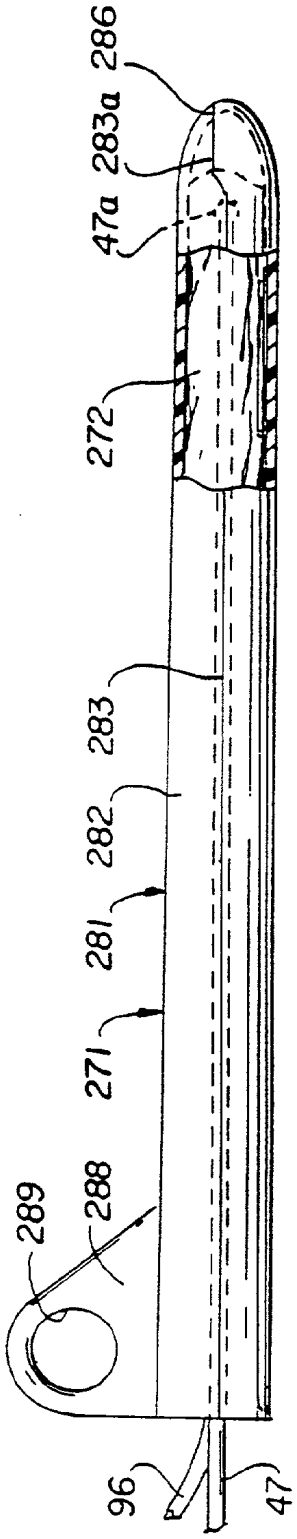

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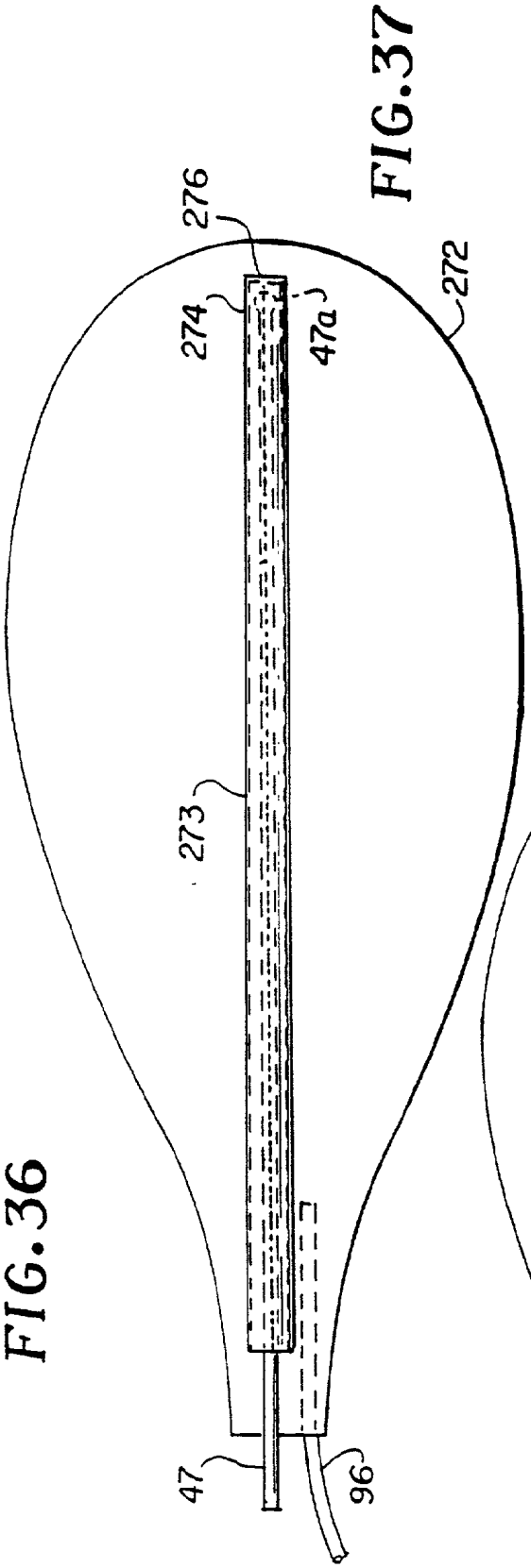

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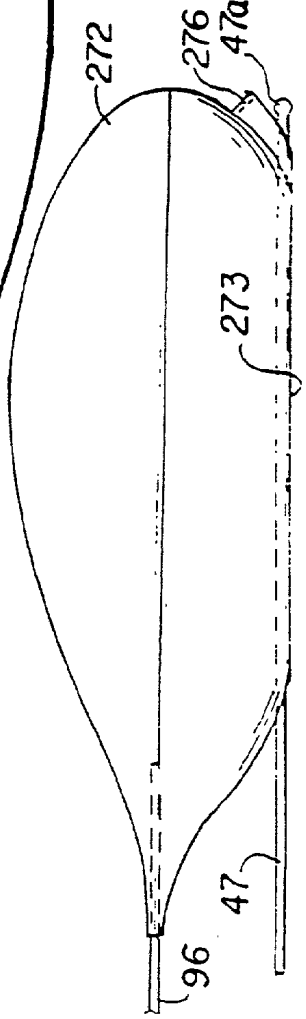

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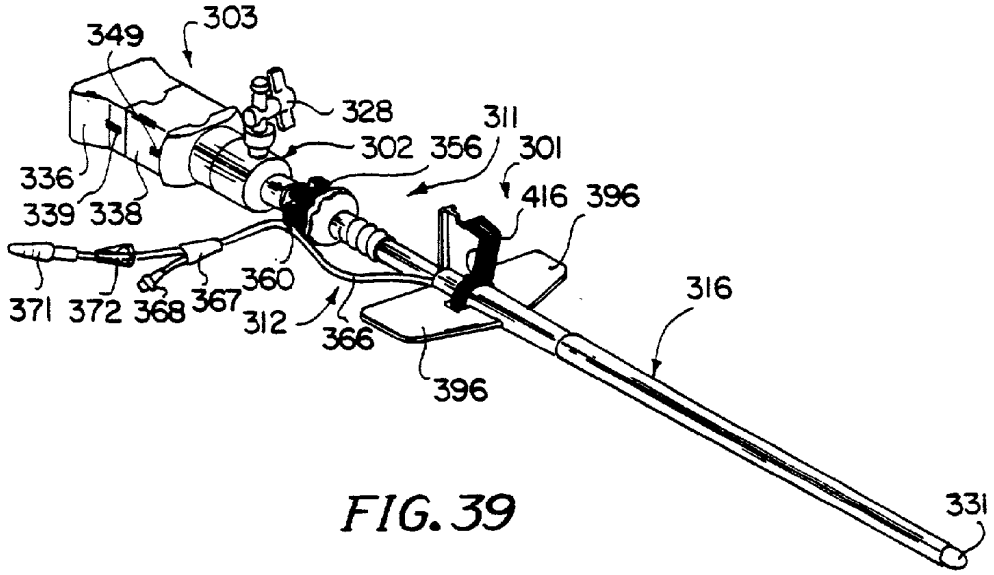
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FIG. 39

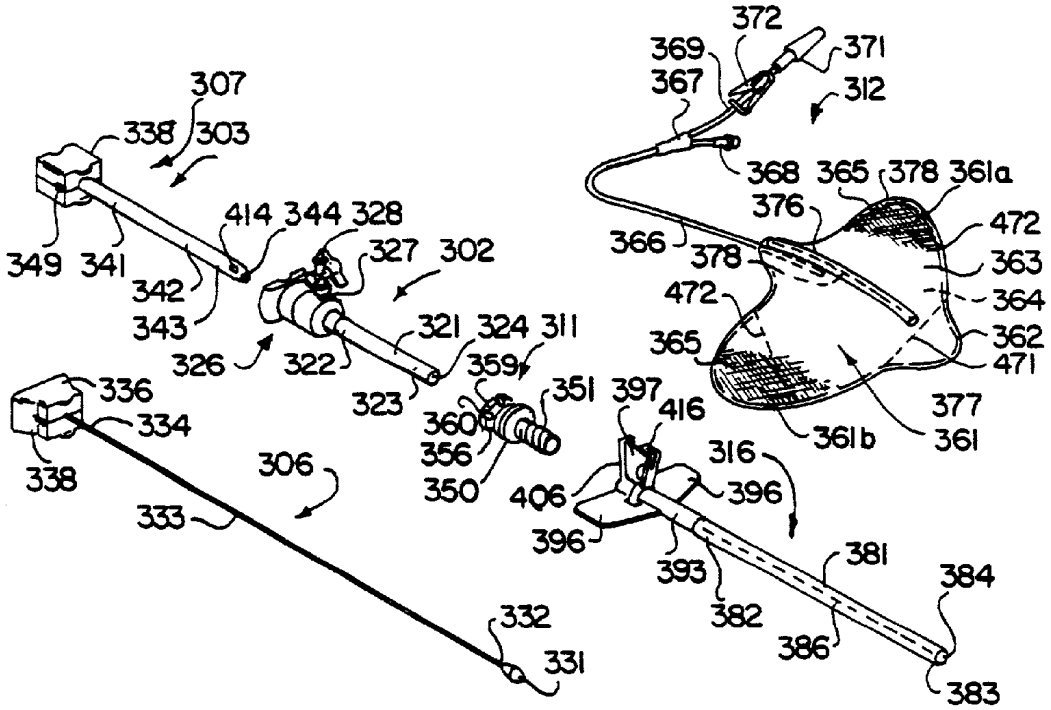
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FIG. 40

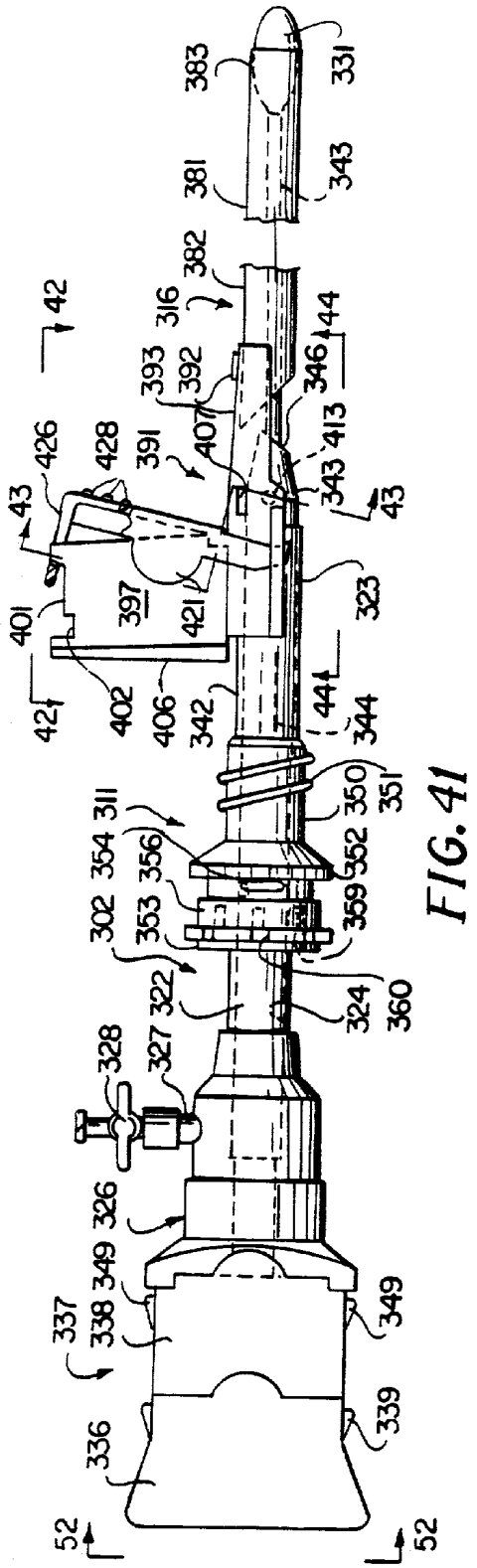
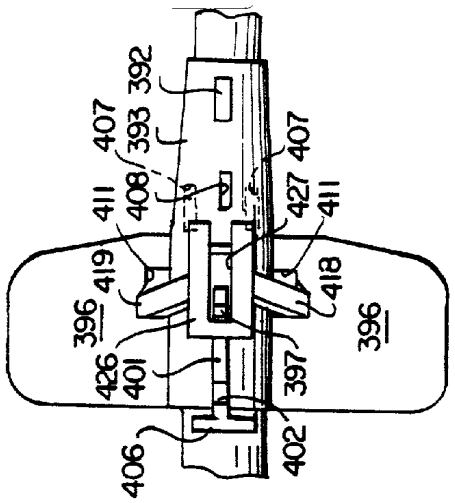


FIG. 41



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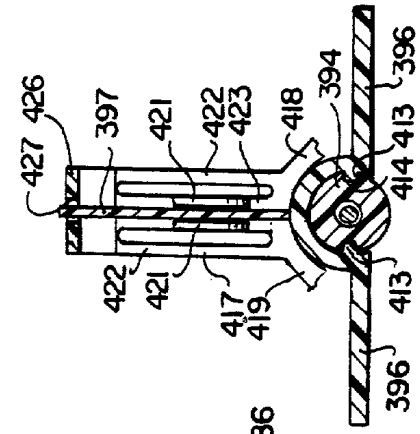

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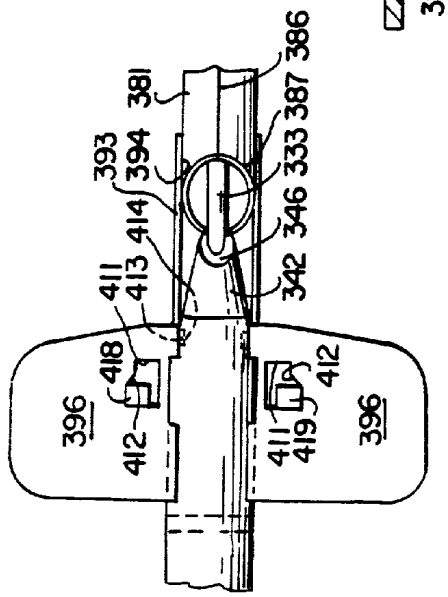
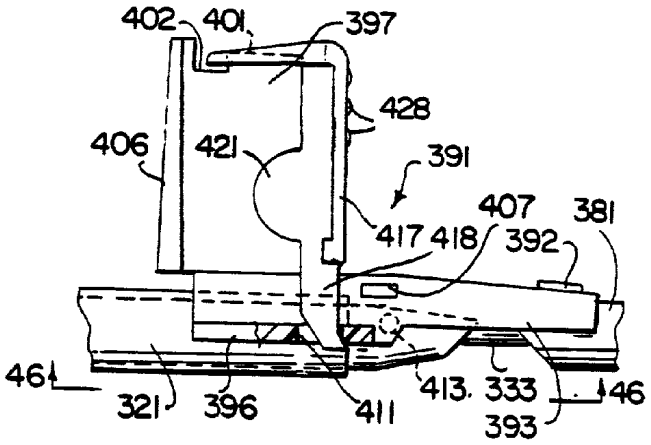


FIG. 44



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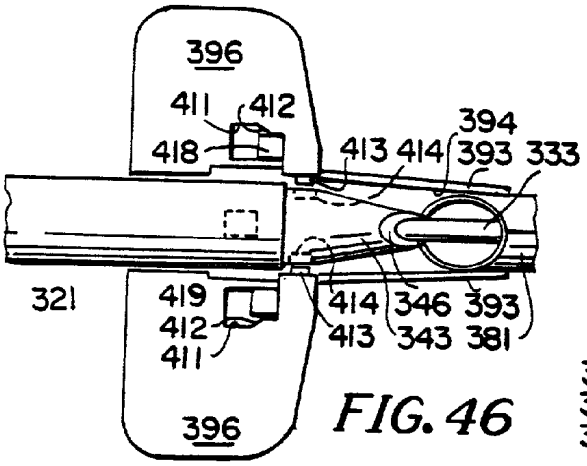
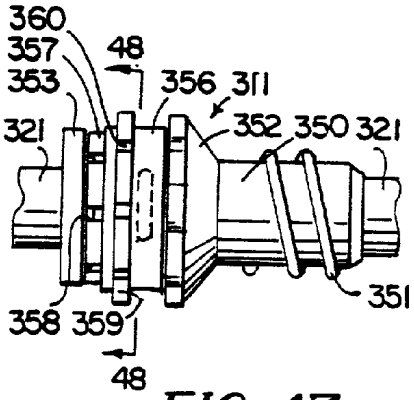


FIG. 46



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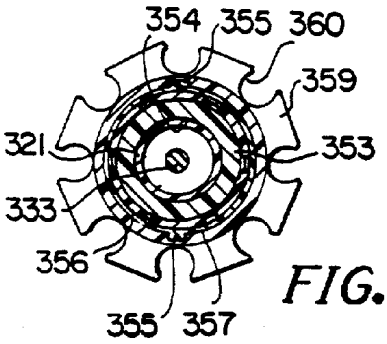

FIG. 48

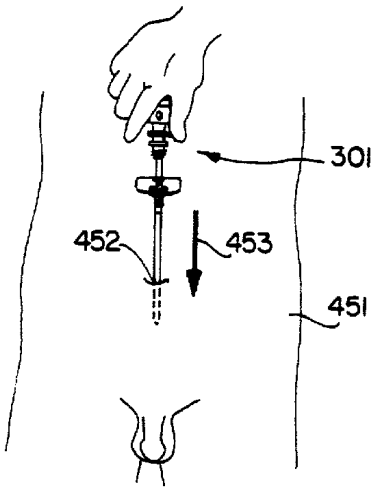

FIG. 49A

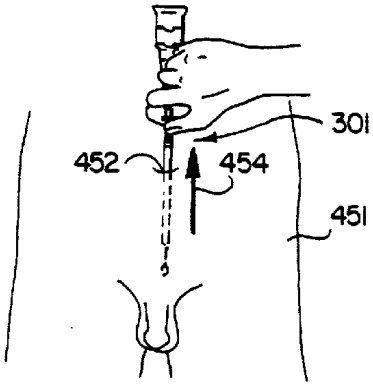

FIG. 49B

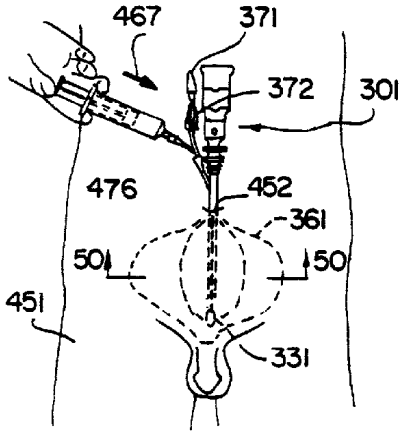

FIG. 49C

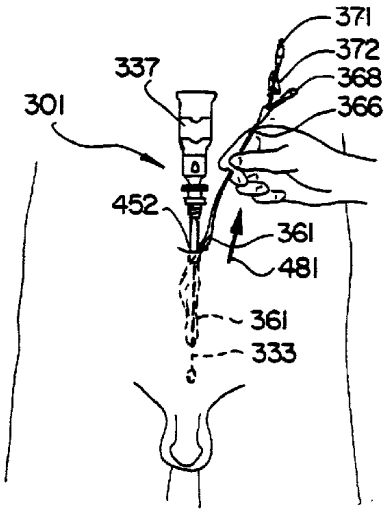

FIG. 49D

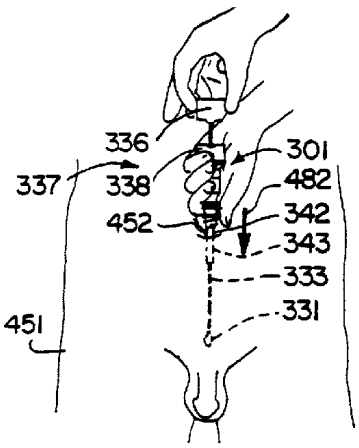

FIG. 49E

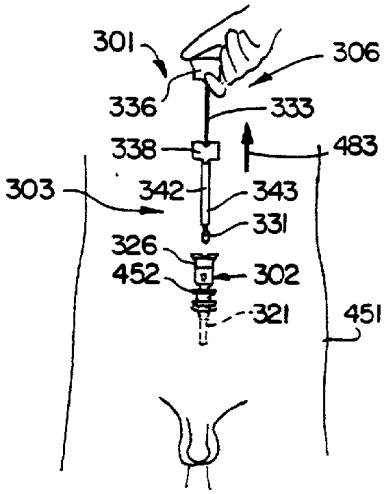

FIG. 49F

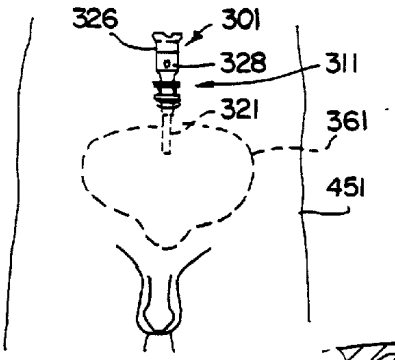

FIG. 49G

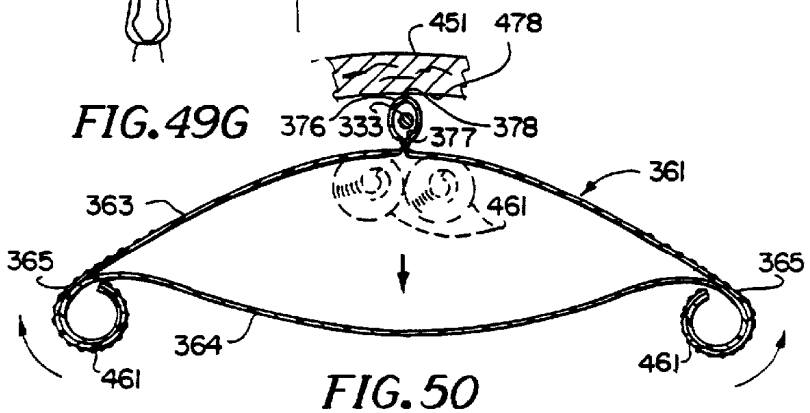

FIG. 50

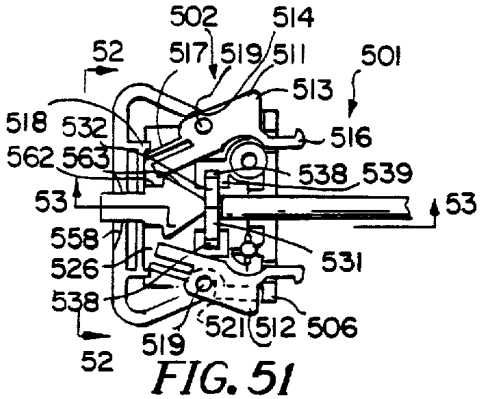

FIG. 51

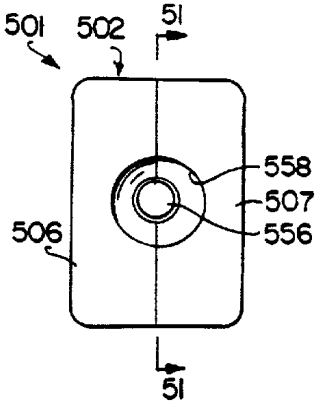

FIG. 52

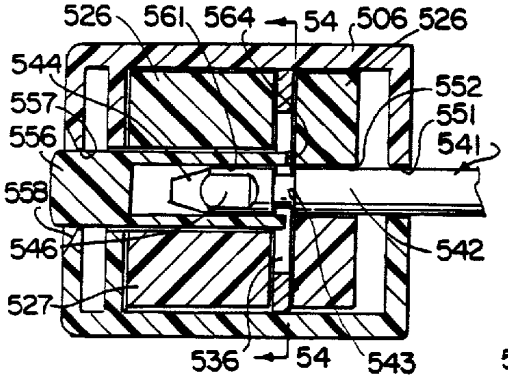

FIG. 53

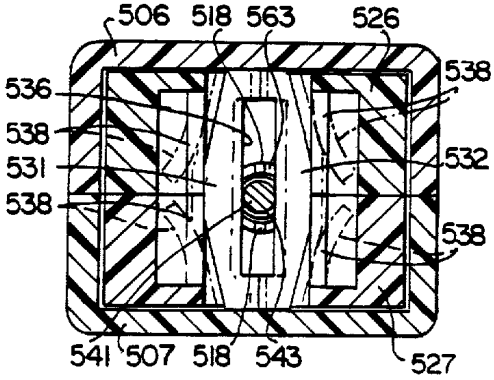

FIG. 54

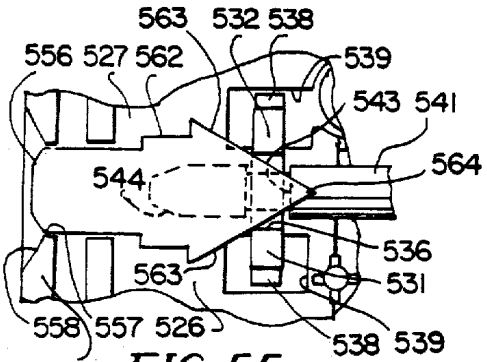

FIG. 55

APPARATUS AND METHOD FOR DEVELOPING AN ANATOMIC SPACE FOR LAPAROSCOPIC HERNIA REPAIR AND PATCH FOR USE THEREWITH

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application Ser. No. 08/861,913, which is a continuation of U.S. application Ser. No. 08/483,293, filed on Jun. 7, 1995, now abandoned, which is a divisional of U.S. application Ser. No. 08/124,283, filed on Sep. 20, 1993, now U.S. Pat. No. 5,836,961, which is a continuation-in-part of U.S. application Ser. No. 07/893,988, filed on Jun. 2, 1992, now U.S. Pat. No. 6,312,442. The disclosure of each of these prior applications is hereby incorporated by reference in their entirety.

[0002] This invention relates to an apparatus and method for developing an anatomic space for laparoscopic hernia repair and a patch for use therewith.

BACKGROUND OF THE INVENTION

[0003] In the past, in developing spaces and potential spaces within a body, blunt dissectors or soft-tipped dissectors have been utilized to create a dissected space which is parallel to the plane in which the dissectors are introduced into the body tissue. This often may be in an undesired plane, which can lead to bleeding which may obscure the field of view and make it difficult to identify the body structures. In utilizing such apparatus and methods, attempts have been made to develop anatomic spaces in the anterior, posterior, or lateral to the peritoneum. The same is true for pleural spaces and other anatomic spaces. Procedures that have been performed in such spaces include varicocele dissection, lymph node dissection, sympathectomy, and hernia repair. In the past, the inguinal hernia repair has principally been accomplished by the use of an open procedure which involves an incision in the groin to expose the defect in the inguinal floor, remove the hernial sac, and subsequently suture the ligaments and fascias together to reinforce the weakness in the abdominal wall. Recently, laparoscopic hernia repairs have been attempted by inserting laparoscopic instruments into the abdominal cavity through the peritoneum and then placing a mesh to cover the hernia defect. Hernia repair using this procedure has a number of disadvantages, principally because the mesh used for hernia repair is in direct contact with the structures in the abdominal cavity, as for example the intestines, so that there is a tendency for adhesions to form in between these structures. Such adhesions are known to be responsible for certain occasionally serious complications. Such a procedure is also undesirable because typically the patch is stapled into the peritoneum, which is a very thin unstable layer covering the inner abdomen. Thus, the stapled patch can tear away from the peritoneum or shift its position. Other laparoscopic approaches involve cutting away the peritoneum and stapling it closed. This is time consuming, however, and involves the risk that important anatomic structures may be inadvertently cut. In addition, such a procedure is undesirable because it requires the use of a general anesthesia. There is therefore a need for a new and improved apparatus and method for developing an anatomic space and particularly for accomplishing hernia repair by laparoscopy.

SUMMARY OF THE INVENTION

[0004] In general, it is an object of the present invention to provide an apparatus and method for developing an anatomic space.

[0005] Another object of the invention is to provide an apparatus and method in which such an anatomic space is developed by applying perpendicular forces to create the anatomic space at the weakest plane to create a more natural, less traumatic and bloodless region in which to work.

[0006] Another object of the invention is to provide an apparatus and method to obtain surgical exposure in the preperitoneal space.

[0007] Another object of the invention is to provide an apparatus and method to create a preperitoneal working space utilizing a balloon dissector.

[0008] Another object of the present invention is to provide an apparatus and method of the above character for developing an anatomic space for laparoscopic hernia repair through the anatomic space.

[0009] Another object of the invention is to provide an apparatus and method for decreasing the time and risk associated with creating a preperitoneal working space.

[0010] Another object of the present invention is to provide an apparatus and method of the above character for a minimally invasive procedure.

[0011] Another object of the invention is to provide an apparatus and method of the above character which can be accomplished without the use of a general anesthesia.

[0012] Another object of the invention is to provide an apparatus and method of the above character which can be accomplished with a spinal or epidural anesthesia.

[0013] Another object of the invention is to provide an apparatus and method of the above character which provides substantially reduced medical costs and a greatly reduced patient recovery time.

[0014] Another object of the invention is to provide an apparatus of the above character which is relatively simple and compact.

[0015] Another object of the invention is to provide an apparatus and method of the above character which can be readily utilized by surgeons.

[0016] Another object of the invention is to provide a patch for use in the apparatus which is firmly secured during the hernia repair.

[0017] Another object of the invention is to provide a balloon which has a modified asymmetric manta ray configuration to aid in providing the desired configuration for the extraperitoneal working space for hernia repair.

[0018] Another object of the invention is to provide a balloon dissection apparatus in which has a balloon cover is detachably secured to the obturator so that the balloon dissection device is relatively rigid to permit the balloon dissection apparatus to be grasped by the handle to operate the same during dissection.

[0019] Another object of the invention is to provide a balloon dissection apparatus of the above character in which

a precise release mechanism is provided for releasing the balloon cover from the obturator so that the surgeon can be assured that the balloon cover has been released before it is removed to release the balloon.

[0020] Another object of the invention is to provide a balloon dissection apparatus of the above character in which the guide rod or obturator remain in place to maintain ready access to the extraperitoneal working space.

[0021] Another object of the invention is to provide a balloon dissection apparatus of the above character in which certain of the parts which are to be moved relative to other parts are color coded to aid the surgeon in use of the apparatus.

[0022] Another object of the apparatus is to provide a tubular member which is provided with a tip having an inclined surface.

[0023] Another object of the invention is to provide a balloon dissection apparatus which is provided with a blunt tip which has a diameter which is less than the diameter of the cannula tube.

[0024] Another object of the invention is to provide a balloon dissection apparatus of the above character in which at least a part of the same can be sterilized and reused.

[0025] Additional objects and features of the invention will appear from the following description in which the preferred embodiments are set forth in detail in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] **FIG. 1** is a side elevational view partially in cross-section of a laparoscopic apparatus incorporating the present invention.

[0027] **FIG. 2** is a cross-sectional view taken along the **2-2** of **FIG. 1**.

[0028] **FIG. 3** is a side elevational view partially in cross-section of the tunneling shaft forming a part of the apparatus shown in **FIG. 1** after it has been removed from the apparatus shown in **FIG. 1**.

[0029] **FIG. 4** is a cross-sectional view taken along the line **4-4** of **FIG. 3**.

[0030] **FIG. 5** is an isometric view of the inflatable balloon utilized in the apparatus in **FIG. 1** secured to the tunneling rod.

[0031] **FIG. 6** is a cross-sectional view taken along the line **6-6** of **FIG. 5**, and showing by dotted lines the manner in which the balloon as it unfolds develops the anatomic space.

[0032] **FIG. 7** is a partial plan view of a prone human body, showing the lower abdomen showing the manner in which the laparoscopic apparatus of the present invention is utilized for performing a hernia repair through the preperitoneal space.

[0033] **FIG. 8** is a sagittal view of the lower abdominal cavity of the human being shown in **FIG. 7** showing the apparatus of the present invention introduced into the preperitoneal space.

[0034] **FIG. 9** is a view similar to **FIG. 8**, but showing the sleeve removed from the apparatus and with the balloon inflated.

[0035] **FIG. 10** is a sagittal view similar to **FIG. 8** showing the balloon deflated and being removed.

[0036] **FIG. 11** is a sagittal view similar to **FIG. 8** showing removal of the tunneling shaft.

[0037] **FIG. 12** is an isometric view of a patch incorporating the present invention.

[0038] **FIG. 13** is a side elevational view of the patch shown in **FIG. 12**.

[0039] **FIG. 14** is an isometric view showing the patch in **FIGS. 12 and 13** in a rolled-up, generally cylindrical configuration.

[0040] **FIG. 15** is a sagittal view showing the hernia sac of hernia that is to be repaired.

[0041] **FIG. 16** is a sagittal view showing the introducer through which the rolled-up patch in **FIG. 17** has been **10** introduced into the preperitoneal space by an introducer rod.

[0042] **FIG. 17** is a sagittal view similar to **FIG. 16** showing the attachment of the patch to the hernia sac.

[0043] **FIG. 18** is a sagittal view similar to **FIG. 17** showing the dissection of the hernia sac and the unrolling of the patch.

[0044] **FIG. 19** is a sagittal view showing the patch in place to provide the hernia repair.

[0045] **FIG. 20** is an isometric view of another embodiment of a balloon with a patch disposed thereon for use with the apparatus of the present invention.

[0046] **FIG. 21** is a cross-sectional view taken along the line **21-21** of **FIG. 20**.

[0047] **FIG. 22** is an enlarged cross-sectional view taken along the line **22-22** of **FIG. 23**.

[0048] **FIG. 23** is a sagittal view showing the manner in which the balloon and patch shown in **FIG. 20** are disposed in the preperitoneal space.

[0049] **FIG. 24** is a sagittal view showing the placement of the balloon and the patch of **FIG. 20**, and the inflation of the balloon in the preperitoneal space.

[0050] **FIG. 25** is an isometric view of another embodiment of a balloon and patch for use with the apparatus of the present invention.

[0051] **FIG. 26** is a rolled-up cross-sectional view of the balloon and patch shown in **FIG. 25**.

[0052] **FIG. 27** is an isometric view of another embodiment of a patch for use with the apparatus of the present invention.

[0053] **FIG. 28** is an isometric view of the patch shown in **FIG. 27** wrapped in an introducer assembly.

[0054] **FIG. 29** is a top plan view of another embodiment of laparoscopic apparatus incorporating the present invention.

[0055] **FIG. 30** is a side elevational view taken along the line **30-30** of **FIG. 29**.

[0056] **FIG. 31** is a cross-sectional view taken along the line **31-31** of **FIG. 30**.

[0057] **FIG. 32** is a cross-sectional view taken along the line **32-32** of **FIG. 30**. **FIG. 33** is an enlarged cross-sectional view of the distal extremity of the laparoscopic apparatus shown in **FIG. 29**.

[0058] **FIG. 34** is a partial plan view showing the balloon after it has been removed from the laparoscopic apparatus with the obturator tip shifting its position.

[0059] **FIG. 35** is a plan view of the balloon shown in **FIG. 34** as it is being removed from the body of the patient and bringing along with it the obturator tip.

[0060] **FIG. 36** is a side elevational view of another embodiment of a laparoscopic apparatus incorporating the present invention.

[0061] **FIG. 37** is a plan view showing the balloon from the apparatus shown in **FIG. 36** in an inflated condition and showing the tunneling rod mounted therein being prevented from being advanced beyond the distal extremity of the balloon.

[0062] **FIG. 38** is a plan view showing the manner in which the balloon is separated from the tunneling rod as it is retracted.

[0063] **FIG. 39** is an isometric view of a surgical dissector with a cannula incorporating the present invention in an assembled condition.

[0064] **FIG. 40** is an isometric exploded view of the components of the surgical dissector with cannula shown in **FIG. 39**.

[0065] **FIG. 41** is a side elevational view of the assembly shown in **FIG. 39**.

[0066] **FIG. 42** is a top plan view looking along the line **42-42** of **FIG. 41**.

[0067] **FIG. 43** is a view partly in crosssection taken along the line **43-43** of **FIG. 42**.

[0068] **FIG. 44** is a view looking along the line **44-44** of **FIG. 41**.

[0069] **FIG. 45** is a partial side elevational view of the assembly shown in **FIG. 1** with the clamping mechanism moved to a release position.

[0070] **FIG. 46** is a view taken along the line **46-46** of **FIG. 45**.

[0071] **FIG. 47** is a partial side elevational view of an assembly shown in **FIG. 41** with the retaining ring moved to a locked position.

[0072] **FIG. 48** is a cross-sectional view taken along the line **4848** of **FIG. 47**.

[0073] FIGS. **49A-49G** are cartoons showing use of the surgical dissector shown in **FIG. 1** in a laparoscopic hernia procedure.

[0074] **FIG. 50** is a cross-sectional view taken along the line **50-50** of **FIG. 49C**.

[0075] **FIG. 51** is a cross-sectional view taken along the line **51-51** of **FIG. 52** showing another embodiment of a balloon dissection apparatus incorporating the present invention.

[0076] **FIG. 52** is an end elevational view taken along the line **52-52** of **FIG. 51**. **FIG. 53** is an enlarged cross-sectional view taken along the line **53-53** of **FIG. 51**.

[0077] **FIG. 54** is an enlarged cross-sectional view taken along the line **54-54** of **FIG. 53**.

[0078] **FIG. 55** is an enlarged cross-sectional view of a portion of the view shown in **FIG. 51** showing the latch members moved to permit removal of the guide rod.

DETAILED DESCRIPTION OF THE DRAWINGS

[0079] In general, the apparatus of the present invention is used for insertion into a body to create an anatomic space. In one embodiment of the invention, the apparatus is comprised of a tubular introducer member having a bore extending therethrough. A tunneling shaft is slidably mounted in the bore and has proximal and distal extremities including a bullet-shaped tip. A rounded tunneling member is mounted on the distal extremity of the tunneling shaft. An inflatable balloon is provided. Means is provided on the balloon for removably securing the balloon to the tunneling shaft. Means is also provided for forming a balloon inflation lumen for inflating the balloon. The balloon is wrapped on the tunneling shaft. A sleeve substantially encloses the balloon and is carried by the tunneling shaft. The sleeve is provided with a weakened region extending longitudinally thereof, permitting the sleeve to be removed whereby the balloon can be unwrapped and inflated so that it lies generally in a plane. The balloon, as it is being inflated, creates forces generally perpendicular to the plane of the balloon to cause pulling apart of the tissue along a natural plane to provide the anatomic space.

[0080] More in particular, as shown in the drawings, the apparatus or device **31** for creating such an anatomic space for use in a laparoscopic procedure (see **FIG. 1**) includes an introducer sleeve or device **32** which consists of a tubular member **33** formed of a suitable material such as plastic which is provided with a bore **34** extending throughout the length thereof. A handle section **36** is mounted on one end of the tubular member **33** and is also formed of a suitable material such as plastic. It is provided with a bore **37** which is in communication with the bore **33**. A flapper valve **38** is mounted within the section **36** and is movable between a position in which it closes off the bore **37** and position out of the way of the bore **37** by a finger operated actuator **39** mounted on the exterior of the section **36**. A stopcock **41** is mounted on the section **36** and is in communication with the passage **37**. A lever **42** is provided for opening and closing the stopcock **41**.

[0081] A tunneling shaft assembly **46** is slidably mounted in the bores **37** and **34** of the introducer sleeve **32**. The tunneling shaft assembly **46** consists of a tunneling shaft **47** formed of a suitable material such as stainless steel, of a suitable length, as for example 18 inches, and a suitable diameter of approximately ⅛ inch. The tunneling shaft **47** is provided with proximal and distal extremities **48** and **49**.

[0082] An introducer member **51** is slidably mounted on the tunneling shaft **47** and is formed of a suitable material

such as plastic. The introducer member **51** is substantially hollow as shown and is provided with a bore **52** through which the tunneling shaft **47** extends. The introducer member **51** is provided with a substantially hemispherical tip **53** to form a rounded protrusion or first obturator through which the shaft **47** extends. The introducer member **51** has a length such that when it is introduced into the bore **34** of the introducer sleeve **32**, it extends out of the distal extremity of the introducer sleeve **32**, as shown particularly in **FIG. 1**. This diameter of the introducer member **51** is sized so that it can be slidably mounted in the bore **34**. The other end of the introducer member **51** is provided with a chamfer **54**.

[**0083**] A disk-type seal **43** having a central opening is provided in the section **36** in alignment with the bore **37**, and is adapted to permit the introduction of the introducer member **51** therethrough.

[**0084**] The section **36** forms one part of a three-piece handle **56** of the laparoscopic apparatus **31** which is sized so that it is adapted to be grasped by the human hand. As can be **35** seen particularly in **FIG. 4**, the handle **56** is generally rectangular in crosssection. The handle **56** is provided with an intermediate section **57** which has a bore **58** extending therethrough in registration with the bore **37** and has the same general diameter as the bore **37** so that the introducer member **51** can travel therethrough. The sections of the handle **56** can be characterized as having first, second, and third sections in which section **36** is the first section and intermediate section **57** is the second section. A latch is provided for interconnecting the intermediate section **57** to the first section **36**, and consists of a pair of oppositely disposed latches **61** pivotally mounted on the pins **62** in the intermediate section **57**. Each of the latches **61** is provided with a latch portion **63** adapted to engage a protrusion **64** provided on the end section **36**, and is yieldably urged into engagement therewith by a spring **66**. Each of the latches is provided with a cam surface **67** which is adapted to be engaged by the chamfer **54** of the introducer member **51** to cam the latch portion **63** out of engagement with the protrusion **64** to release the intermediate section **57** from the first section for a purpose hereinafter described.

[**0085**] The handle **56** also consists of another end section **71**, which can also be characterized as the third section, which is secured to the proximal extremity of the tunneling shaft or rod **47**. A pair of latches **72** are provided in the end section **71** and are pivotally mounted on pins **73**. The latches **72** are provided with latch portions **74** adapted to engage projections **76** provided in the intermediate section **57**. Means is provided for yieldably retaining the latches **72** in engagement with the projections **76** and consists of a U-shaped spring **77** mounted within the end section **71** and engaging the latches **72**. The latches **72** are provided with knurled portions **72**a which extend outwardly and which are adapted to be grasped by the fingers of the hand so that the latch portions **74** can be moved out of engagement with the projections **76** against the force of the spring **77**.

[**0086**] The tunneling shaft assembly **46** also includes a tip **79** which is mounted on the distal extremity of the tunneling shaft **47**. As shown, the tip **79** is substantially olive-shaped and can also be called a second obturator. It is provided with a rounded hemispherical surface on its distal extremity which has a maximum diameter which is slightly less than the diameter of the bores **34** and **37** so that it can pass through the introducer sleeve **32**. The proximal extremity of the tip **79** is of smaller diameter to provide an annular step **81** in the tip. The proximal extremity of the tip **79** is also hemispherical, as shown. The tip **79** can be formed of a suitable material such as plastic and can be secured to the distal extremity of the tunneling shaft **47** by suitable means such as an adhesive. As hereinafter explained, the tunneling shaft or **47** is movable so that the tip **79** can be brought into engagement with the hemispherical end **53** of the introducer member **51** for a purpose hereinafter described.

[**0087**] The laparoscopic apparatus **31** also includes a balloon assembly **86** which is shown in **FIGS. 2, 5**, and **6**. As shown in **FIG. 5**, when the balloon assembly **86** consists of a balloon **87** which in plan, when deflated, has a pear-shaped configuration when viewed in plan. The balloon **87** is preferably formed of a non-elastomeric, medical-grade material of a suitable type such as PVC. Thus, the balloon **87** can be formed of two sheets **88** and **89** of such a material which have their outer margins bonded together by suitable means such as by a heat seal **91** extending around the perimeter of the flat balloon. The balloon **87** is provided with a neck **94** into which a flexible tubular member **96** extends, and is secured therein in a suitable airtight fashion such as by an adhesive. The tubular member **96** is provided with a lumen **97** which is in communication with the interior of the balloon **87** and which can be used for inflating the balloon **87** through a Luer-type fitting **98** mounted on the free end of the tubular member **96**.

[**0088**] Means is provided for removably securing the balloon **87** to the tunneling shaft **47**, and consists of a sleeve **101** formed of the same material as the balloon **87**, and which can be formed integral or separate therefrom and adhered thereto by suitable means such as an adhesive. The sleeve **101** extends longitudinally of the balloon **87** and is disposed generally equidistant from the side margins of the same. The sleeve **101** is provided with a passage **102** extending therethrough which is sized to slidably accommodate the tunneling shaft **47**. Means is provided for permitting separation of the balloon **87** from the tunneling shaft **47** by movement sidewise from the axis of the passage **102** and takes the form of longitudinally spaced apart perforations **103** in the sleeve **101** extending longitudinally the length of the sleeve **101**. The perforations **103** are spaced close enough together to form a weakened region so that the balloon can be readily separated from the tunneling shaft **47** by separating the plastic sleeve **101** by tearing the plastic between the perforations as hereinafter described.

[**0089**] As shown in **FIG. 6**, the sleeve **101** is disposed equidistant from the side margins of the balloon **87**, permitting the balloon **87** to be inflated as hereinafter described and as also shown by the dotted lines in **FIG. 6**, to be inflated around the shaft **47**. When deflated, the side margins of the balloon **87** can be rolled inwardly toward the shaft **47** as shown by the broken lines in **FIG. 6** to permit the same to be folded into a generally cylindrical configuration as shown in **FIG. 2**, and to be enclosed within a removable sheath **106** carried by the tunneling shaft **47**. The removable sheath **106** is formed of a relatively thin-walled tubular member **107** of a suitable material such as Teflon which has a weakened region **108** in its wall extending longitudinally the length thereof. This weakened region **108** can take the form of a slit as shown, or can be a series of perforations or slots formed in the wall, or a combination thereof. The proximal extrem-

ity of the tubular member **107** is provided with split-apart or separable end portions **107***a* and **107***b* to which are secured finger rings **109** of a suitable material such as plastic and secured thereto by fasteners **111**.

[**0090**] Operation and use of the laparoscopic apparatus in performing the method for laparoscopic hernia repair through preperitoneal space may now be briefly described as follows. Let it be assumed that the laparoscopic apparatus **31** has been assembled as shown in **FIG. 1**. As shown in **FIG. 7**, let it be assumed that a human patient **121** is in a prone position and has a hernia **122** in the lower abdominal area which he wishes to have repaired. The patient is prepared in an appropriate manner by administering a suitable anesthesia, as for example a spinal anesthesia, and any other necessary preparation. The surgeon first makes an infraumbilical incision **126** in the skin below the navel or umbilicus **127** and separates the fat **129** and then incises the anterior rectus sheath or fascia **131** in the midline. Care should be taken not to penetrate the peritoneum **132** overlying the abdominal cavity **133** (see **FIG. 8**).

[**0091**] After the incision **126** has been made in the manner hereinbefore described, the laparoscopic apparatus **31** is then taken by one hand of the surgeon, grasping the handle **56** and utilizing the other hand to facilitate the insertion of the rounded blunt tip **79** into the incision **126**. The blunt tip **79** is then caused to enter the slit in the fascia **131** and pass anterior to the peritoneum **132**, in between the rectus muscles (laterally) and enters the potential preperitoneal space. The blunt tip **79** is then utilized as a tunneling device by the surgeon using one hand **56** to advance the blunt tip **79** toward the pubic region of the patient while the surgeon places his other hand on the abdomen to feel the apparatus **31** as it is being advanced. The advance of the apparatus **31** is continued until the blunt tip **79** is below the symphysis pubis **137** as shown in **FIG. 8**, and preferably is disposed between the symphysis pubis **137** and the bladder **138**.

[**0092**] After the apparatus **31** has been properly positioned as shown in **FIG. 8**, the removable sheath **106** is removed by the surgeon using one hand to engage the finger rings **109** which are exterior of the body of the patient and outside of the incision **126**. At the same time, the other hand of the surgeon is utilized to stabilize the portion of the apparatus **31** which is within the preperitoneal space. The sheath **106** can be readily withdrawn since it is formed of Teflon and is split or weakened along its length, by pulling it proximally and away from the longitudinal axis of the tubular member **33**. As the sheath **106** opens and slips off, it exposes the balloon **87** of the balloon assembly **86**. When the sheath **106** is completely removed, a sterile saline solution serving as a balloon inflation medium is introduced into the balloon **87** through the tubular member **96** by connecting a conventional syringe **141** to the Luer fitting **98**. The balloon **87** typically can be inflated to a suitable size by introducing 500 cc or less of normal saline solution into the balloon **87** by pressing on the plunger **142**. As the balloon **87** is inflated, the balloon **87** progressively unwraps with its side margins rolling outwardly from the center while expanding into a plane to cause progressive separation or dissection of tissue (i.e., **131**, **132**) along its weakest points by application of forces generally perpendicular to the plane of the balloon **87** to create the preperitoneal or anatomic space. The balloon **87** expands around the tunneling shaft **47** in the manner shown in broken lines in **FIG. 6** to achieve the progressive separation until complete inflation is achieved. The surgeon can sense the filling of the balloon **87** by feeling the abdomen of the patient **121** as the balloon **87** is inflated. The balloon **87** serves to open up the preperitoneal space **136** to provide a bloodless space for the procedures hereinafter to be performed. Since the balloon **87** is formed of a non-elastomeric material, it is a volume-limited balloon to prevent overexpansion. Different sizes of balloons can be utilized for different patient sizes. With a smaller balloon **87** it is possible to deflate the balloon **87** and then shift the balloon and again reinflate it to obtain the desired bloodless preperitoneal space.

[**0093**] After the desired bloodless anatomic space or pocket is formed, the balloon **87** is deflated by withdrawing the normal saline solution by withdrawal of the plunger **142** of the syringe **141** or via a hospital vacuum aspirator. After the balloon **87** has been deflated, the balloon assembly **86** can be removed by grasping the handle **56** of the laparoscopic apparatus or device **31** with one hand and using the other hand to grasp the tubular member **96** and the proximal extremity of the balloon **87** and to remove the same through the incision **126**, as shown in **FIG. 10**. As the balloon **87** is being removed, it is progressively separated from the tunneling shaft **47** by causing the sleeve **101** to split apart along the longitudinal perforations **103** provided in the sleeve **101**. This makes it possible to separate the balloon **87** from the tunneling shaft **47** without the necessity of removing the tunneling shaft **47** or the introducer sleeve **32**.

[**0094**] After the balloon assembly **86** has been removed, the introducer sleeve **32** can be advanced distally over the tunneling shaft **47** so it extends well into the preperitoneal space **136** as shown in **FIG. 11**. The end section **71** of the handle **56** is then removed by depressing the latches **72** by engaging the portions **72***a* to disengage the latch portions **74** from the intermediate section **57** of the handle **56**. The third section **71** is then withdrawn proximally as shown in **FIG. 11** to bring the olive-shaped tip **79** into engagement with the distal tip of the introducer member **51** to cause both the tip **79** and the introducer member **51** to be withdrawn or retracted. As the introducer member **51** is being withdrawn, its chamfer **54** will strike the cam surfaces **67** of the latches **61** to cause them to disengage from the end piece **36** to carry it along with the introducer member **51** and shown in **FIG. 2**. Thus, it can be seen that the tunneling shaft assembly **46** can be readily removed merely by one motion of the surgeon's hand. Thereafter, a conventional laparoscope **144** (see **FIG. 16**) can be introduced through the introducer sleeve **32** to permit the surgeon to view the preperitoneal space **136**.

[**0095**] The dissected preperitoneal space **136** is then insufflated with carbon dioxide through the stopcock **41** to a pressure ranging from 6 to 8 mm of mercury. Thereafter, two additional trocars **146** and **147** are introduced through the abdominal wall into the dissected preperitoneal space **136** in appropriate locations. Thus, as shown in **FIG. 7**, trocar **146** is introduced into the left side of the abdomen of the patient **121** below the introducer sleeve **32** and the trocar **147** is introduced into the dissected preperitoneal space **136** immediately above the symphysis pubis **137** and directly below the introducer sleeve **32**. As can be appreciated, the locations of the trocars **146** and **147** is generally dictated by the location of the hernia **122** to be repaired.

[0096] A patch **151** of the present invention to be utilized in the hernia repair procedure is shown in detail in **FIGS. 12, 13**, and **14**. The patch **151** can be characterized as a hernia patch or graft and is made of a suitable plastic mesh such as a Prolene mesh manufactured by Ethicon, Inc. The patch **151** can be of any desired configuration. For example, it can be generally circular as shown and consists of a disk **152** of a suitable diameter, as for example 2 inches. A tail **153** is secured to the disk substantially in the center thereof, in a suitable manner. For example, as shown, the tail **153** can be provided with split portions **153***a* and **153***b* which are split apart and offset with respect to each other. The split portions **153***a* and **153***b* are secured to a smaller reinforcing disk **154** formed of the same material as disk **152** and secured to the disk **152** by suitable means such as surgical thread (not shown). The tail **153** is formed of the same material as the disk **152** and **154**, or it can be formed of a different material, such as Goretex. It can have a size such that it has a width of approximately ½ inch and a length of approximately 1½ inches. As shown particularly in **FIG. 14**, the side margins of the disk **152** can be rolled inwardly towards the center adjacent the tail **153** to form a cylindrical roll **156** with the tail **153** extending outwardly therefrom. The roll **156** can be maintained in its rolled-up condition by means of sutures **157** disposed adjacent opposite ends of the roll and on opposite sides of the tail **153**.

[0097] Referring now to **FIGS. 15 and 16**, conventional laparoscopic instruments are used to repair the hernia **161** by placement of the patch **151**. First, the laparoscopic instruments are introduced through the introducer device **32** while being observed through laparoscope **144** to dissect the hernia **161**. The hernia neck **162** may be observed as it is entering the internal inguinal ring **163**. The repair procedure starts by dissecting the hernia space **161** from the surrounding tissue (spermatic duct and vessels) (see **FIG. 15**). The process is facilitated by CO_2 pressure impinging on then neck **162** of the hernia sac **161**. As soon as this dissection is completed, the roll **156** is pushed into the trocar **147** and advanced through the same by suitable means such as a deployment rod **164** (see **FIG. 16**) to enter the dissected preperitoneal space **136** as shown in **FIG. 16**. Alternatively, the roll **156** can be placed in a tubular member (not shown) which can be used to position the roll **156** within the trocar **157**. Thereafter, by the deployment rod **164**, the roll **156** can be pushed out of the tubular member in the he dissected preperitoneal space **136**.

[0098] The roll **156**, after it is in the preperitoneal space **136**, is then manipulated so that its tail **153** is disposed alongside the neck **162** of the hernia sac **161** as shown in **FIG. 17**. With reference to **FIG. 17, a** conventional stapling device **166** is then introduced through the trocar **146** to staple the tail **153** to the neck **162**. These staples **167** serve to divide the neck **162** of the sac **161** into distal and proximal portions **162***a* and **162***b*. As soon as this stapling operation is completed, the two portions **162***a* and **162***b* are separated from each other because of the pressure of the insufflation gas to cause the tail **153** of the patch **151** to be pulled upwardly into the inguinal ring to pull with it the disk **152**. The sutures **157** are cut apart to permit the disk **152** to unroll and to be placed across the inguinal ring **163** which created the main weakness in the abdominal wall permitting the hernia which is being repaired to occur. The proximal portion **162***b* of the neck **162** is stapled together by staples **173** as shown in **FIG. 18**. The proximal portion **162** is then permitted to fold back into the desired anatomical location within the abdomen.

[0099] Thereafter, while observing the procedure under the laparoscope, the dissected preperitoneal space **136** can be deflated by permitting the carbon dioxide gas to escape to the atmosphere through the stopcock **41** in the introducer device **32** by operation of the stopcock lever arm **42**. As deflation is taking place, the movement of the patch **151** is observed through the laparoscope **144** so that it does not become displaced. When the deflation has been completed, the patch **151** is in a position over the inguinal ring **163** and serves to provide reinforcement to prevent the occurrence of another hernia in that area. The tail **153** is disposed with the inguinal ring **163** and retains the mesh disk **152** so that it surrounds the inguinal ring **163**.

[0100] After deflation is complete, the trocars **146** and **147**, as well as the introducer device **32**, can be removed. Small sutures can then be utilized to close the various small openings which have been made in the abdominal wall so that there will be minimal noticeable scars after healing. The scar in the navel or umbilicus typically is nearly invisible.

[0101] It has been found that the use of the laparoscopic apparatus **31** in accomplishing the method as hereinbefore set forth provides a procedure in which the pain after the operation is markedly reduced. This is particularly true since the operation does not involve suturing of any ligaments which typically produces the pain. In addition, the recovery time for the patient is greatly accelerated. In the procedure of the present invention, a patient can return to work within a matter of three to five days, rather than in a number of weeks as in a conventional hernia repair procedure. The procedure also has other advantages. For example, it is not necessary to use a general anesthesia. Another principal advantage of the procedure is that there is no contact of the mesh patch **151** with the intestines of the patient or other intra-abdominal structures, thus greatly reducing the possibility of adhesion formation. In addition, the graft which is formed by the patch **151** is more secure and is positioned in an anatomically correct position. This is because the hernia sac **161** is in exact alignment with the hernia and pulls with it the tail **153** of the graft to ensure that the graft formed by the patch **151** is drawn into the correct position and is maintained in that position to prevent migration. In addition, the graft, by having an additional central disk **154**, ensures that additional reinforcement is provided in the proper location in the center where the weakest region in the abdominal wall has occurred. In addition, by such proper centering, the mesh construction of the patch **151** serves to uniformly reinforce the area surrounding the hernia.

[0102] Another embodiment of the present invention is shown in **FIGS. 20, 21**, and **22** with respect to another embodiment of a balloon assembly **181** and another embodiment of a patch or graft **182**. The balloon assembly **181** consists of a balloon **186** formed of two sheets **187** and **188** which are rectangular in shape, as for example square as shown in **FIG. 20**. The sheets **187** and **188** are heat-sealed together at their outer margins as indicated by the broken line **189**. A tubular member **191** is provided which has one end sealed into one corner of the balloon **186** as shown in **FIG. 20**. The tubular member **191** has a lumen **192** which opens into the interior space **193** of the balloon **186**. The

sheets **187**and **188** are formed of a non-elastomeric material of the type hereinbefore described. A Luer fitting **194** is connected to the free end of the tubular member **191** and is utilized for introducing a saline solution into the balloon **186** for inflating the same.

[**0103**] The graft or patch **182** can have a desired configuration, as for example circular as shown in **FIG. 20**. It is formed of a non-absorbable synthetic surgical mesh, as for example from polypropylene manufactured by Ethicon Inc. As shown, the mesh patch **182** overlies the sheet **187**.

[**0104**] The balloon assembly **181** already made in Ser. No. 324,519 with the patch **182** thereon can be rolled- up into a roll **196** as shown in **FIG. 22** in which the patch or graft **182** is disposed within the roll **196**. The roll **196** can be maintained in the roll configuration by sutures **197** wrapped about the same. As shown in **FIG. 23**, the roll **196** can then be introduced through a side trocar **146** and introduced into the dissected preperitoneal space **136** with the tubular member **191** extending through the trocar **146** and having its Luer fitting **194** disposed outside of the trocar **146**. After the roll **196** has been introduced, the sutures **197** can be removed and the balloon **186** can be inflated by introducing a saline solution through the fitting **194** by use of a syringe **199** (see **FIG. 24**). Before the saline solution is introduced to inflate the balloon **186**, the roll **196** is properly positioned so that when it is inflated and begins to unroll, it will unroll in the proper direction so that the graft or patch **182** carried thereby is properly positioned as shown in **FIG. 24**. After the roll **196** has been completely unrolled, continued inflation of the balloon **186** moves the patch **182** so that it is pressed against the portion of the fascia through which the hernia has occurred as shown in **FIG. 24**. As soon as the graft **182** has been properly positioned, the balloon **186** is deflated. The trocar **146** is then removed, and thereafter the balloon **186** can be withdrawn through the opening in which the trocar was present. Thereafter, the gas utilized for insufflation can be permitted to discharge through another trocar so that the fascia **131** comes into engagement with the peritoneum **132** with the large-area patch **182** held in place therebetween. Thereafter, the trocars can be removed in the manner hereinbefore described to complete the procedure.

[**0105**] Another embodiment of a balloon assembly for deploying a large-area patch or graft **201** through a trocar is shown in **FIG. 25**. The large-area graft **201** shown in **FIG. 25** is formed of a mesh material of the type hereinbefore described and has a generally oval-shaped configuration conforming to the general shape of the balloon **202** of the balloon assembly **203**. The balloon **202** is constructed of a nonelastomeric material in the manner hereinbefore described. A tubular member **206** is provided for inflating the balloon and has a Luer fitting **207** on the free end thereof. Means is provided for retaining the mesh graft **201** on one side of the balloon and consists of plastic flaps **208** provided on opposite sides of the balloon **202**, and secured thereto by a suitable means such as a heat seal along the broken line **209**. The inner margins of the flaps **208** are free and are adapted to receive the outer margins of the graft **201** as shown particularly in **FIG. 25**.

[**0106**] The balloon **202** with the mesh graft **201** thereon can be rolled up into a substantially cylindrical roll **211** by rolling the outer margins of the balloon inwardly on top of the mesh material to provide two rolls **211** and **212** which are brought in adjacent to each other as shown in **FIG. 26** with the mesh graft **201** being wrapped up therewith. The two rolls **211** and **212** can then be inserted into a tubular sheath **214**. The sheath **214** can then be introduced through a trocar in a manner hereinbefore described and then pushed out of the sheath **214** into the abdominal cavity. The balloon **202** can then be inflated with a saline solution to cause the two rolls **211** and **212** to unroll in opposite directions and then for the balloon **202** to inflate to move the patch **201** carried thereby into engagement with the portion of the fascia having the hernia therein. Thereafter, the balloon **202** can be deflated, the trocar removed, the balloon removed, and the dissected preperitoneal space deflated so that the large mesh graft **201** is disposed between the fascia and the peritoneum and is retained in position therebetween.

[**0107**] Another embodiment of a graft which can be utilized in connection with the present invention is shown in **FIG. 27**. The patch or graft **216** is constructed in a manner similar to the graft or patch **151** shown in **FIGS. 12 and 13**, with the exception that it is constructed in a manner so that it can be utilized with a direct hernia rather than an indirect inguinal hernia hereinbefore described. The graft **216** is formed of a sheet of circular mesh in the form of a disk **217** with a reinforcing central disk **218** which has a barbed head **219** secured thereto. The barbed head **219** is formed of a biodegradable material such as polyglycolic acid. The mesh graft **216** can be folded over a deployment rod **221** and introduced into a cylindrical sheath **222** (see **FIG. 28**) which is sized so that it can be introduced through a conventional trocar, then deployed from the sheath **22** by pushing on the deployment rod **221**. After the graft **216** has been deployed into the dissected preperitoneal space **136**, it can be positioned in an appropriate manner so that the barb **219** is positioned so that it is in alignment with the inguinal ring whereby upon deflation of the preperitoneal space **136**, the barb **219** will extend through the inguinal ring to serve to retain the graft **201** firmly in place.

[**0108**] Another embodiment of a laparoscopic apparatus incorporating the present invention is laparoscopic apparatus **231** as shown in FIGS. **29** through **32**. The laparoscopic apparatus **231** includes introducer sleeve or device **32** identical to that hereinbefore described. It also includes a tunneling shaft assembly **46** which is provided with a tunneling shaft or rod **47** and a proximal extremity **49** (see **FIG. 32**). In the previous embodiment of the laparoscopic apparatus, the tunneling shaft assembly is provided with an olive-shaped or bullet-shaped tip **79** which was secured to the distal extremity **49** of the tunneling shaft **47**. In the present embodiment of the apparatus shown in **FIGS. 29 through 32**, the obturator tip **79***a* is detachably mounted on the distal extremity **49** of the tunneling rod **47**. The proximal extremity of the tip **79***a* is provided with a slot **236** which extends through one side of the proximal extremity into the central portion of the proximal extremity of the tip **79***a*. The slot **236** is adapted to receive the rounded extremity **237** provided on the distal extremity **49** of the tunneling rod **47** (see **FIG. 32**). A removable sleeve **241** is provided as a part of a laparoscopic apparatus **231**, and is similar in many respects to the removable sleeve or sheath **106** hereinbefore described. The removable sleeve **241** is formed of a suitable material such as Teflon as hereinbefore described and is provided with a tubular member **242** which is provided with a relatively thin wall **243** that has a weakened portion extending longitudinally thereof in the form of a slit **244** (see **FIG. 31**). The

tubular member **242** is provided with a proximal extremity **246** and a distal extremity **247**. The proximal extremity **246** has a thicker cross-section than the distal extremity **247**, as shown in **FIGS. 31 and 32**. The proximal extremity **246** is provided with a recess **248** formed in the wall which is diametrically opposite the slit **244** that serves as a relief region to permit the movable sleeve **241** to be split apart when it is removed from the balloon.

[**0109**] The proximal extremity **246** is provided with wing-like members **251** and **252** which extend diametrically therefrom, spaced 90° apart from the slit **244**. These outstretched wings **251** and **252** serve to help the physician orient the laparoscopic apparatus **231** as it is being utilized. The proximal extremity **246** is also provided with a handle **256** which is formed integral therewith and which extends radially from the tubular member **242**. The handle **256** is provided with a finger hole **257** extending therethrough through which a finger can be inserted to facilitate pulling the removable sleeve **241** off of the balloon as described in connection with the previous embodiment.

[**0110**] As shown in **FIG. 33**, the tip **79***a* is detachably mounted in the proximal extremity of the removable sleeve **241** so that the tip **79** can serve as a second obturator during introduction of the laparoscopic apparatus **231** as hereinbefore described. Means is provided for securing the detachable tip **79***a* to prevent it from becoming separated from the laparoscopic apparatus **231** and for permitting its withdrawal after the laparoscopic procedure is being completed. As shown in **FIGS. 33 and 34**, such means consists of a flexible elongate element **261** in the form of a braided string formed of a suitable fabric such as Nylon, which has one end **262** secured in a slot **263** provided on the distal extremity of the tip **79***a* by suitable means such as an adhesive (not shown). The flexible elongate element **261** extends from the distal extremity of the tip **79***a* in a recess **264** opening through the external surfaces of the tip **79***a*. The proximal extremity of the flexible elongate element **261** can be secured directly to the balloon **87** or, alternatively, it can extend through the perforated sleeve **101** provided in the balloon along the tunneling shaft so that it extends beyond the proximal extremity of the tunneling shaft.

[**0111**] The use of the laparoscopic apparatus **231** in performing a laparoscopic procedure is substantially identical to that hereinbefore described with the exception that when the removable sleeve **241** is removed from the balloon **87**, the removable sleeve can be pushed forwardly to detach the tip **79***a* from the tunneling shaft **47**. The removable sleeve **241** then can be pulled rearwardly to separate it from the balloon along the slit **244**. As soon as this occurs, the tip **79** becomes free of the sleeve and begins to rotate in the direction of the arrow **266** shown in **FIG. 34**. When the balloon has been inflated and has performed its functions as hereinbefore described and it is now desired to remove the balloon **87**, the balloon **87** can be withdrawn in the manner hereinbefore described, and since the tip **79***a* is tethered to the balloon **87** itself or flexible elongate element **261** attached thereto extends out proximally of the balloon **87**, the tip **79***a* is withdrawn or can be withdrawn with the balloon **87**.

[**0112**] This laparoscopic apparatus **231** with its detachable obturator tip **79***a* will be useful in certain applications of the present invention. With the previous laparoscopic apparatus hereinbefore described, there is a possibility that when the obturator tip **79** is withdrawn, critical structures, as for example small arteries, may be inadvertently incised between the tip **79** and the distal extremity of the tubular member **33** of the introducer device **32**. This possibility is eliminated by having the detachable tip **79***a,* which is withdrawn when the balloon is withdrawn.

[**0113**] Still another embodiment of the laparoscopic apparatus incorporating the present invention is shown in **FIGS. 36, 37**, and **38**, in which the laparoscopic apparatus **271** consists of a balloon **272** of the type hereinbefore described, which is provided with a perforated sleeve **273** through which the tunneling rod **47** extends. The distal extremity **274** of the sleeve is closed by an end piece **276**.

[**0114**] The balloon **272** is wrapped in the manner hereinbefore described around the tunneling shaft **247**. The tunneling shaft or rod **47** is not provided with a tunneling member or second obturator of the type hereinbefore described but its end is rounded as shown by providing a rounded tip **47***a*.

[**0115**] The wrapped balloon **272** is enclosed within a removable sleeve **281** which is similar to those hereinbefore described. It is provided with a tubular member **282** that has a weakened region in the form of a slit **283** extending longitudinally the length thereof. The removable sleeve **281** differs from those hereinbefore described in that rather than being open at the end as in previous embodiments, it is provided with a closed-end, bullet-shaped, or olive-shaped tip **286**. The slit **283** is provided with a curved portion **283***a* which extends through the bullet-shaped tip **286** so that the sleeve can be peeled off of the balloon **272** in the manner hereinbefore described by pulling on the handle **288** having a finger hole **289** therein. During the time that the removable sleeve **281** is being peeled off or separated from the balloon **272**, the balloon is held in place by the tunneling rod **47** which engages the end **276** of the perforated sleeve **273**. The balloon **272**, after it is inflated, can be separated from the tunneling rod **47** by pulling on the balloon and causing its distal extremity to lift up and to break apart at the perforations and peel away from the rounded extremities **47***a* of the tunneling shaft **47** as shown in **FIG. 38**. Continued pulling on the balloon **272** will cause it to separate from the tunneling rod **47** so that the balloon **272** can be removed as hereinbefore described. Thus, it can be seen that there has been provided an embodiment of the laparoscopic apparatus of the present invention in which the need for an obturator carried by the distal extremity of the tunneling rod **47** has been eliminated by providing the second obturator as a part of the removable sleeve **281**. In all other respects, the operation and use of the laparoscopic apparatus **271** is similar to that hereinbefore described.

[**0116**] From the foregoing, it can be seen that there has been provided an apparatus and method for developing an anatomic space by the use of a wrapped balloon which, as it is inflated, gradually unwraps to tend to form a plane to cause forces to be created perpendicular to the plane for pulling apart tissue along a natural plane to provide an anatomic space, thereby providing a dissection in the weakest plane creating a more natural, less traumatic, and bloodless region in which to perform various medical procedures. Such anatomic spaces can be created in various parts of the human body, for example, in the preperitoneal area to

provide a space anterior to the peritoneum for hernia repair and for varicocele dissection. Spaces can also be developed lateral to the peritoneum and spaces posterior to the peritoneum for performing medical procedures such as a sympathectomy and a lymph node dissection.

[0117] As hereinbefore explained, the apparatus and method is particularly appropriate for performing laparoscopic hernia repair, permitting the use of grafts and patches which can be used for direct and indirect hernias with minimal pain to the patient and with the patient being able to return to work within a few days.

[0118] Another embodiment of a laparoscopic apparatus **301** incorporating the present invention is shown in FIGS. **39-48**. The laparoscopic apparatus **301** can also be described as an assembly in the form of a surgical dissector with a cannula which serves as a hand manipulated surgical instrument that can be used during general surgical laparoscopic procedures to dissect the layers of fascia between the skin and the peritoneum as described in conjunction with the previously disclosed embodiments of the invention. The laparoscopic apparatus **301** consists of a cannula **302** with a tunneling device **303** mounted therein. The tunneling device **303** is formed by the combination of an introducer member **307** and the guide rod assembly **306**. The laparoscopic apparatus also includes a skin seal assembly **311**, a balloon assembly **312**, and a balloon cover assembly **316** as shown particularly in **FIGS. 39 and 40**.

[0119] The cannula **302** consists of a cannula tube **321** formed of a rigid plastic having proximal and distal extremities **322** and **323**. A flow passage **324** extends from the proximal extremity **322** to the distal extremity **323**. A cannula housing or handle **326** is mounted on the proximal extremity by suitable means such by molding it directly thereon. As disclosed in copending application, Ser. No. 07/968,201, filed on Oct. 29, 1992, the disclosure of which is hereby incorporated by reference in its entirety, the handle **326** includes first and second valve members (not shown) in which one valve member serves as a duck-bill valve and the other valve member serves as a circular instrument or tool seal. The housing is provided with a Luer-type fitting **327** which is in communication with the interior of the housing outside of the duck-bill valve and is in communication with the passage **324** in the cannula tube **321**.

[0120] As described in said copending application, Ser. No. 07/968,201, filed on Oct. 29, 1992, the cannula **302** is adapted to receive the tunneling device or blunt obturator device **303** which is generally of the type described hereinbefore in the present application. This device **303** consists of the blunt obturator **306** having a blunt tip **331** which is generally olive-shaped as shown (see **FIG. 41**) and is formed of a suitable material such as plastic. The olive-shaped tip **331** is molded on the distal extremity **332** of a rod or a shaft **333** formed of a suitable material such as stainless steel. The blunt tip **331** is sized so that its outside diameter is slightly less than the inside diameter of the cannula tube **321**. The proximal extremity **334** of the rod or shaft **333** has mounted thereon a handle part **336** of a handle assembly **337** which includes a second handle part **338**. The handle parts **336** and **338** are adapted to mate with each other and are detachably connected in a manner described in copending application, Ser. No. 07/968,201, filed on Oct. 21, 1992 by the use of latch means (not shown) adapted to be actuated by spring-operated latch members **339** disposed on opposite sides of the handle part **336** and adapted to be engaged by the fingers of the hand holding the handle assembly **337**. The second handle part **338** forms a part of the introducer device **307** and is mounted on the proximal extremity **341** of a tubular member **342** formed of a suitable material such as plastic. The tubular member **342** is provided with a distal extremity **343** and has a bore **344** extending from the proximal extremity to the distal extremity through an end surface **346** (see **FIG. 41**) which is inclined at a suitable angle, as for example, approximately 45° proximally from the horizontal axis of the bore **344**. The bore **344** is sized so it can slidably receive the shaft **333**.

[0121] The handle part **338** is provided with latch means (not shown) which is adapted to releasably connect the handle part **338** to the cannula housing **326** and includes latch members **349** disposed on opposite sides of the handle part **338** adapted to be engaged by the fingers of the hand holding the handle assembly **337** to permit the handle part **338** to be separated from the cannula housing **326**.

[0122] The skin seal assembly **311** generally can be of the type described in copending application, Ser. No. 08/124,333, filed on Sep. 20, 1993, and as described therein consists of a screw body **350** formed of a suitable material such as plastic having a helical thread **351** and a scalloped flange **352**. A resilient insert **353** is disposed in the screw body **351** and is formed of a suitable resilient material such as silicone. The insert **353** is provided with a bore **354** extending therethrough. A collet **357** having slots **358** therein surrounds the insert **353** and is engaged by a collar **356** movable axially of the screw body **351** and is adapted to move the collet to compress the insert **353** to move the insert between a retaining position for the cannula tube **321** extending through the bore **354** to retain the cannula **302** in a desired longitudinal position with respect to the skin seal assembly **311** and a releasing position in which the cannula **302** can be slidably moved longitudinally inwardly or outwardly with respect to the skin seal **311**. The collar **356** is provided with an annular shoulder **359** having circumferentially spaced-apart slots **360** therein which are used for a purpose hereinafter described. As explained in copending application Ser. No. 08/124,333, filed on Sep. 20, 1993, means is provided to restrain rotation of the collar **356** with respect to the collet **357** and includes longitudinally extending keys **355** spaced 180° apart.

[0123] The balloon assembly **312** consists of a balloon **361** formed of a nonelastomeric, medical grade plastic material, of a suitable type such as polyurethane. The balloon **361** can be characterized as having an asymmetric manta ray configuration when viewed in plan and is provided with a forwardly extending rounded protuberance **362** which has a width substantially less than that of the balloon **361**. The balloon **361** consists of two sheets of material which can be identified as a first or upper sheet **363** and a second or lower sheet **364** which have been die cut to the desired configuration with their edges bonded together in a suitable manner such as by means of a heat seal to form a balloon which has a generally flat configuration when deflated as shown in **FIG. 40**. The upper or outer surface of the first or upper sheet **363** has been roughened in areas **365** as shown in **FIG. 40** on the outwardly extending lobe portions **361***a* and **361***b* for a purpose hereinafter described. The roughening can be

accomplished in any suitable manner such as by embossing the plastic material with a pattern having raised portions therein.

[0124] Means is provided for inflating the balloon with a suitable medium, as for example, a liquid such as a saline solution and consists of a flexible tube **366** that extends into the balloon between the two sheets **363** and **364** and forms a fluid-tight seal therewith. The interior of the balloon can be inflated and deflated by introduction of the fluid through the tube **366**. The tube **366** is connected to a Y-adapter **367** which has one leg of the Y connected to a one-way valve **368** having a Luer fitting and the other leg connected to a tube **369** which is connected to a tapered fitting **371**. A conventional pinch off clamp **372** is mounted on the tube **369**. The tube **366** is adapted to be releasably retained in the slots **360** of the shoulder **359**.

[0125] Means is provided for removably securing the balloon **361** to the tunneling rod or shaft **306** and consists of an elongate tubular member or sleeve **376** which extends along the length of the balloon **361** and is disposed on one side of the balloon **361** which can be called the top side generally centrally of the balloon **361**. The tubular member **376** is provided with a passage **377** therein through which the tunneling or guide rod or shaft **333** extends. As hereinbefore explained, this tubular member or sleeve **376** can be formed as a separate member which is bonded to the top sheet **363** or alternatively can be formed integral with the top sheet **363** with two heat seals being provided above and below to form the sleeve **376** with the passage **377** therein. The tubular member **376** can be provided with spaced-apart elongate slits or perforations (not shown) extending along a line **378** in the tubular member **376** to facilitate separation of the balloon from the tunneling rod **333** as hereinafter described. With such a construction, it can be seen that the tunneling rod or blunt dissector or obturator **306** overlies the balloon **361** for advantageous features hereinafter described.

[0126] The balloon cover assembly **316** consists of a semi-rigid tube **381** formed of a suitable material such as plastic and is provided with proximal and distal extremities **382** and **383**. It is provided with a bore **384** (see **FIG. 42**) which extends from the proximal extremity **382** to the distal extremity **383**. The tube **381** is provided with a weakened region in the form of a partial slit **386** extending from the distal extremity **383** to the proximal extremity **382** of the tube **381** on the bottom side of the tube **381** as viewed in **FIG. 40** (also see **FIG. 42**). The tube **381** is provided with a proximal end wall **387** which extends at a suitable angle, as for example 45° proximally with respect to the axis of the bore **384**.

[0127] The balloon cover assembly **316** also includes a handle **391** which, as shown, can be formed as a separate part and is secured to the proximal extremity **382** of the tube **381** by a metal clip **392**. The handle **391** is provided with a tapered body **393** formed of a suitable material such as plastic which as shown in **FIGS. 42 and 47** is open on the bottom side to make accessible a longitudinally extending recess **394** which is semi-circular in cross-section. A pair of sideways extending wings **396** are formed integral with the body **393** and lie in a plane which is substantially coincident with the axis of the semi-circular recess **394**. As shown, the wings **396** are disposed at the proximal extremity of the body **393**.

[0128] An upwardly extending fin **397** is formed on the body **393** substantially equidistant from the wings **396** in a direction generally perpendicular to the plane in which the wings **396** lie. The fin **397** is relatively narrow and is provided with an upper surface **378** having notches **401** and **402** therein. A vertically extending wall **406** is formed as a part of the fin **397** and extends generally in a direction which is perpendicular to the plane of the wings **396**. The wall **406** extends in a direction at right angles to the fin **397** and has a gradually increasing thickness from the top to the bottom ends of the wall (see **FIG. 46**). The body **393** is provided with a pair of spaced-apart holes **407** spaced approximately 90° apart and 45° from each side of the fin **397**. An elongate slot **408** is formed in the body **393** and is generally in alignment with the fin **397**. A pair of camming slots **411** are provided on opposite sides of the body **393** in the wings **396** adjacent the distal extremities of the wings adjacent the body. The camming slots **411** are provided with inclined camming surfaces **412**.

[0129] The body **393** is provided with a pair of diametrically disposed protrusions **413** which extend into the recess **394** and which are adapted to seat in a pair of diametrically opposed holes **414** provided in the distal extremity of the introducer member **342**.

[0130] The balloon cover assembly **316** also includes a clamping member **416** which is provided with a central body **417** and a pair of downwardly extending legs **418** and **419** (see **FIG. 43**) which extend downwardly into the camming slots **411**. As shown, the central body **417** is disposed just distal of the fin **397** and is provided with semi-circular guides **421** formed integral with the central body **417** and disposed on opposite sides of the fin **397** in a fulcrum region which is just slightly above the point of commencement of the legs **418** and **419**.

[0131] The central body **417** is provided with longitudinally extending reinforcing ribs **422** (see **FIGS. 43 and 45**). It is also provided with a proximally extending latch portion **426** which extends generally at right angles to the central body **417**. The latch portion **426** is provided with a centrally disposed slot **427** extending substantially the entire length thereof which receives the upper extremity of the fin **397** so that when the clamping member **416** is snapped into place over the body **393**, the latch portion **426** is disposed in the notch **401** and cannot clear the uppermost portion of the fin **397**. The clamping member **416** as hereinafter described is adapted to be moved between positions in which it is disposed within the notch **401** or alternatively in the notch **402**. Laterally extending rounded raised portions **428** are provided on the central body **417** are adapted to be engaged by a finger of the hand when moving the clamping member **416** from the notch **401** to the notch **402**.

[0132] Operation and use of the surgical balloon dissection apparatus **301** in performing the method for developing an anatomic space for laparoscopic hernia repair in connection with the apparatus shown in FIGS. **39-48** may now be briefly described as follows in conjunction with the cartoons which are shown in **FIGS. 49*a*** through **FIG. 49*g***. The surgeon in connection with the present method identifies the appropriate fascia layer to be dissected, either by direct visualization of the tissue and/or by manual palpation. Let it be assumed that it is desired to perform a hernia repair on a patient **451** and that it is desired to create an extraperitoneal

working space for performing the surgical repair. The surgeon makes a small incision **452** in the skin of the patient in the umbilicus or slightly lateral of the umbilicus. A retractor (not shown) can then be utilized to open up the incision and to move it laterally to either side to locate the rectus muscles that run longitudinally of the body of the patient on both sides of the umbilicus or navel. As soon as the rectus sheath has been located, the incision is made in the rectus sheath through the incision previously made midway between the two sets of the rectus muscles. The surgeon then grasps the laparoscopic or balloon dissection apparatus **301** by using a hand, as for example, his right hand as shown in **FIG. 49A** to grasp the handle assembly **337** to introduce the blunt end **331** into the incision to engage the anterior wall of the posterior rectus sheath. The balloon dissector **301** is then advanced longitudinally of the patient's body generally parallel to the two sets of rectus muscles as shown by the arrow **453** by using the rectus sheath as a guide to pass the blunt tip **331** to cause separation of tissue and to pass over the arcuate line and transversal is fascia to the level of the symphysis pubis. This can be readily accomplished with the balloon dissector **301** because the balloon cover assembly **316** is latched to and generally rigidly connected to the distal extremity of the introducer member **342** of the introducer device **307** by having the protrusions **413** provided on the tubular cover **381** seated within the holes **414** provided on the distal extremity of the introducer member **342**. This provides a rigid assembly of the balloon dissector **301** so it can be operated by the surgeon grasping the handle assembly **337** without the need to have the physician grasp by the other hand an intermediate part of the balloon dissector to cause a desired manipulation and steering of the blunt tip **331** as the dissection of the tissue is accomplished as it is advanced.

[**0133**] The travel of the blunt tip **331** to the level of the symphysis pubis can be readily ascertained by the surgeon who can use his hand to palpate the abdominal region of the patient and thereby feel the blunt tip **331** as it is advanced until the blunt tip **331** strikes the symphysis pubis. This can be readily ascertained by the right hand holding the handle assembly **337** feeling the impact of the tip **331** striking the symphysis pubis **468** (see **FIG. 50**) which impact is communicated through the rigid structure of the balloon dissector to the handle assembly **337** where it can be felt by the hand of the surgeon. The balloon dissector **301** is then advanced a small additional amount so that the blunt tip **331** drops below the symphysis pubis **468**.

[**0134**] Thereafter, the balloon cover handle **391** is engaged by the same right hand of the physician as shown in **FIG. 49**B and the thumb is used to engage the transverse rounded protrusions **428** by moving the upper extremity of the clamping or latching member **416** proximally to cause the latch portion **426** to move into engagement with the notch **402** carried by the fin **397**. As this is occurring, the legs **418** and **419** carried by the central body **417** are moved from the position shown in **FIG. 42** to the position shown in **FIG. 47** and in doing so engaging the camming surfaces **412** whereby the portions of the wings **396** secured to the body **393** are cammed outwardly so that the protrusions **413** are moved out of engagement with the holes **414**. The direction of movement of the latch or clamping member **416** is indicated by the arrow **454** in **FIG. 49B**. As soon as the handle **391** has been released, the handle **391** is moved proximally with two fingers of the hand grasping the wings **396** to pull them upwardly and proximally to cause the balloon cover assembly **316** to be removed. The balloon **361** is held in place by the tunneling shaft or rod **336** and exits through the slit **386** provided at the bottom of the tubular cover **381** which serves as a tear away sheath. The balloon inflation tube **366** is retained in one of the slots **360** in the shoulders **359** so that it does not become entangled in the wings **396** as the balloon cover assembly **316** is removed. This exposes the balloon **361** which has its side margins rolled inwardly in rolls **461** with one being rolled in a counterclockwise direction and the other being rolled in a clockwise direction so that they underlie the tunneling rod **333** as shown in **FIG. 50**. Also, to provide optimum dissection as hereinafter described before the rolling up occurs the forwardly extending protuberance **362** can be folded inwardly along a fold line **471** and the sidewardly extending lobe portions also can be folded inwardly along fold lines **472**. To inflate the balloon, the pinch off clamp **372** is closed and a conventional 60 cc syringe **476** containing a saline solution is connected to the one-way valve **368**. The syringe **466** is then operated as shown by the arrow **477** to introduce the saline solution from the syringe **476** into the tubular member **366** and into the interior of the balloon **361** to gradually inflate the same. The one-way check valve **368** ensures that saline solution cannot exit therefrom when the syringe **466** is removed. The syringe **476**, after it has been emptied, can be removed and refilled with a saline solution which is introduced into the balloon in the same manner to cause the side margins of the balloon **461** to unwrap in opposite directions as shown in **FIG. 50** on opposite sides of the tunneling rod **333** until they become completely unwrapped. Typically, it may take as many as approximately ten syringes of saline solution to cause the balloon **361** to completely unwrap and the move into an inflated condition as shown in **FIG. 50**. As the balloon is being filled and unwrapping, it continues to separate or dissect tissue overlying the peritoneum to provide an extraperitoneal working space between the transversalis fascia and the rectus muscles.

[**0135**] As hereinbefore described, the balloon **361** in plan has an asymmetric manta ray-like configuration to provide the desired optimum extraperitoneal working space for the hernia repair. The forwardly extending protrusion **362** provided on the balloon **361** as it is inflated dissects distally from the distal extremity of the blunt tip **331** of the guide rod **333** serves to provide good dissection of tissue in the area of Cooper's ligaments and also to dissect laterally around the inguinal rings. By utilizing an asymmetric manta ray-like construction, it is possible to provide a balloon **361** with its wide side margins or lobe portions **361***a* and **361***b* which when inflated to cause forward movement of the balloon **361** to dissect downwardly around the inguinal rings and to wedge the balloon **361** in place. The forwardly extending protrusion **362** as it is inflated dissects like a small balloon down to the Cooper's ligament. In this way, it impossible to obtain an extraperitoneal working space **478** which exposes all the desired anatomy at one time before moving off to the hernia sac and to do the final dissection for the hernia repair. By providing such a large extraperitoneal working space it is unnecessary to manually advance the dissection. The balloon has also been shaped to properly match the anatomy in which the procedure is to be formed so as to reduce to a minimum the amount of manual dissection which may be needed. Since the balloon has a particular shape and is

formed of a nonelastomeric material, the dissection will occur in the desired locations which would not necessarily be the case if the balloon were formed of an elastomeric material which generally would have a tendency to follow the path of least resistance. Additional assurance is provided for ensuring that dissection will occur in the desired locations with the non-elastomeric balloon of the present invention because the balloon is held in place by the tunneling rod **333** underlying the symphysis pubis **468** as shown in **FIG. 50**. Also, by providing roughened areas **365**, these areas frictionally engage overlying tissue so that the lobe portions **361***a* and **361***b* can serve as anchors to prevent displacement of the balloon **361** after the balloon **361** as it is being inflated.

[0136] After the amount of desired tissue dissection has taken place by inflation of the balloon **361** to provide the extraperitoneal working space, the balloon **361** is deflated by connecting the evacuation fitting **371** into an evacuation port (not shown) of an operating room suction system. The pinch clamp **372** is released to open the tube **369** to permit the saline solution which had been introduced into the balloons **361** to be sucked out to completely deflate the balloon from the inflated condition as shown in **FIG. 49C**. After the balloon has been deflated, the tubular member **366** can be grasped by the fingers of the hand as shown, and the deflated balloon **361** pulled out through the incision **452** in the direction as shown by the arrow **481** in **FIG. 49D**. If necessary, the handle assembly **337** can be held by the other hand. The balloon **361**, as it is being pulled off, has its sleeve **376** separates from the tunneling or guide rod **331** by breaking through the linear perforations lying along the line **378**. The guide rod **331** remains in place to preserve an easy entry into the extraperitoneal space which has been created. The balloon **361** can then be discarded.

[0137] After the balloon **361** has been removed, the left hand is used to grasp the lower second handle part **38** with the left hand while the right hand engages the upper or first handle part **336** of the handle assembly **337**. The fingers of the right hand then engage the latch members **339** on opposite sides by the fingers of the hand to release the first part **336** from the second part **338** and to permit the left hand to move the second part **338** in the direction of the arrow **482** shown in **FIG. 49E**. The second part **338** carries with it the cannula **302** attached thereto and the introducer device **307** which extends therethrough with the skin seal assembly **311** mounted on the cannula tube **321**. This advancement over the guide rod **333** is continued until the distal extremity **343** of the introducer member **342** has been advanced into the desired position. As soon as this has been accomplished, the skin seal assembly **311** is slidably advanced on the cannula tube **321** until the skin seal approaches the incision **452**. The screw body **351** is then rotated by the fingers of the hand engaging the flange **352** and/or to the shoulder **359** to screw it into the incision **452** and to form a gas tight skin seal with the skin of the patient. As soon as a good skin seal has been established, the introducer device **307** is clamped in a fixed position with respect to the skin seal assembly **311** by pushing generally downwardly on the collar **356** to engage the collet **357** to form a friction grip between the elastomeric insert **353** and the cannula tube **321**.

[0138] After the cannula **302** is in a fixed in position, the blunt obturator **306** can be removed along with the tunneling device or blunt obturator device **303**. This is accomplished merely by continuing to pull upwardly on the handle part. **336** with the hand in the direction indicated by the arrow **483** as shown in **FIG. 49F**. As this pulling motion continues, the blunt tip **331** will engage the distal extremity **343** of the introducer member **342** causing a withdrawal force to be applied to the second handle part **338** to cause it to automatically release from the housing **326**. This permits the blunt obturator device **303** to be removed through the cannula tube **321**. This is possible because the blunt tip **331** has a diameter which can pass through the interior of the cannula tube **321** and through the valving provided in the housing **326**. In withdrawing the guide rod **333** carrying the obturator tip **331**, it can be seen that it continues to be guided by the introducer member **342** and thus will remain centered with respect to the cannula tube **321** to avoid any pinching action at the distal end **323** of the cannula tube **321**. As soon as the obturator tip **331** strikes the introducer member **342**, the handle part **338** is automatically disengaged from the cannula handle **326**. The latch parts **349** are substantially buried within the second handle part **338** so they are relatively inaccessible to the surgeon ensuring that he will operate the latch parts **339** carried by the first handle **336** which helps to ensure that the surgeon remove the handle parts **336** and **338** in two stages.

[0139] After this has been accomplished, a source of gas such as carbon dioxide is connected to the stop cock valve **328**. The stop cock valve **328** is opened to permit the carbon dioxide to inflate the dissected extraperitoneal working space such as indicated by the dotted lines **476** shown in **FIG. 49G**. The cannula **302** can then be utilized for introducing instruments of various types into the dissected extraperitoneal working space. The inflation gas cannot escape because of the valving provided in the handle **326** of the cannula **302**.

[0140] Additional cannulae can be introduced in various positions in the abdomen of the patient through which additional surgical instruments can be introduced for performing the surgical procedure to be performed in the extraperitoneal working space. The remainder of the hernia repair procedure to be accomplished in the extraperitoneal working space is substantially the same as hereinbefore described and therefore will not be described in detail. By way of example, let it be assumed that a hernia sac has been formed in the patient, as for example, by passing down into the scrotum to form a typical indirect hernia. The hernia sac can be pulled out and ligated in a manner hereinbefore described. Thereafter, a piece of mesh as hereinbefore described can be introduced through another site and rolled out over the region through which the sac had previously passed. The mesh can then be stapled in place, as for example along the Cooper's ligament. After the hernia repair has been completed, the extraperitoneal working space can be deflated by opening the stop cock valve **328** and bleeding the CO_2 contained therein to atmosphere to permit the abdominal wall to return to its normal position to help retain the mesh which has been placed in the desired position.

[0141] In connection with the formation of the extraperitoneal working space with the apparatus of the present invention, it has been found that it is desirable to have the guide rod **333** be in position in which it overlies the balloon **361**, because this helps to ensure that the balloon dissection will occur in appropriate areas because the blunt tip **331** underlying the symphysis pubis is retained in the desired

position even during the time that the balloon is unrolling during inflation. Positioning the guide rod **333** in this manner ensures that the balloon **361** will roll out in the opposite directions from the rod and also to help to push the balloon downwardly during inflation.

[**0142**] In order to make the apparatus more user friendly, the parts which are to be moved for operation with respect to other parts have been color coded, as for example they can be colored black with the remaining parts being of another color, such as grey or white. Thus, the clamping or latch member **416** is of a black color because it must be removed to unlatch the balloon cover assembly **316**. Similarly, the collar **356** of the skin seal assembly **311** is of a black color because it must be moved to clamp the cannula **302** in a desired position.

[**0143**] Similarly, the latch parts **339** and **349** are of black color because they also must be moved to separate the handle parts.

[**0144**] The wings **396** are provided on the balloon cover **316** in addition to serving as means to facilitate grasping of the balloon cover assembly **316** when it is desired to remove the same, as serve to visually indicate the plane in which the balloon **361** of the balloon dissection apparatus **301** causes dissection. Generally this dissection plane is in a plane which is parallel to the plane in which the wings **396** lie.

[**0145**] As hereinbefore explained, the introducer member **342** is provided with an obturator end surface or tip which is inclined. at an angle in a direction away from the normal direction of insertion to inhibit any tendency that the tip **35** might hang up on tissue as it is being advanced through the tissue during dissection.

[**0146**] The sizing of the blunt obturator tip **331** so it is smaller than the inner diameter of the cannula tube **321** helps to ensure that tissue will not become entrapped or pinched between the tip **331** and the cannula tube **321**. In addition, as hereinbefore described, the obturator tip **331** is tapered in both directions into a smaller dimension from the center to also minimize the possibility of any tissue being entrapped between the tip **331** and the cannula tube **321** and thereby ensuring that a shearing action will not occur.

[**0147**] In conjunction with the foregoing disclosure, it has been assumed that the balloon dissection apparatus hereinbefore described typically would be disposed of after each use. In the event it is desired to economize and it is desired to reutilize at least certain portions of the balloon dissection apparatus after a use in a laparoscopic procedure, another embodiment of a balloon dilatation apparatus **501** incorporating the present invention is shown in FIGS. **51-55**. As shown therein, it consists of a handle assembly **502** similar to the handle assembly **337** hereinbefore described which includes a handle part **503** similar to the handle part **336**. Other parts of the balloon dissection apparatus **501** are not shown because they can be identical to those hereinbefore described. The handle part **503** is provided with two sections **506** and **507** which can be fastened together in a suitable manner such as by ultrasonic bonding or an adhesive. Latch members **511** and **512** are provided on opposite sides of the handle part **503** and are provided with finger portions **513** that are adapted to be engaged by fingers of the hand which extend outwardly through recesses **514** in the sections **506** and **507**. The latch members **511** and **512** are each provided with a latch **516** which is yieldably urged in an outward direction by a yieldable spring member **517** engaging a downwardly depending lip **518** provided within the sections **506** and **507**. The latch members **511** and **512** are pivotally mounted between the sections **506** and **507** by pivot pins **519** formed integrally on the latch members **511** and **512** and extending into bosses **521** provided in the sections **506** and **107** which are formed of a suitable material such as plastic.

[**0148**] First and second inserts **526** and **527** formed of a suitable material such as plastic are mounted in the sections **506** and **507**. First and second latch members **531** and **532** formed of a suitable material such as metal are provided which are seated in recesses **533** and **534** provided in the inserts **526** and **527**. The latch members **531** and **532** are generally U-shaped and are yieldably urged into engagement with each other to form an elongate slot **536** extending therethrough. Upstanding legs **538** formed integral with the inserts **526** and **527** are provided in rectangular spaces **539** in the inserts **526** and **527** so that the upper extremities of the legs **538** can be flexed by movement of the latch members **531** and **532** as shown by dotted lines in **FIG. 54**.

[**0149**] A guide rod **541** is provided which is similar to the guide rod **333** with the exception that its distal extremity **542** is also provided with an annular recess **533**. The distal extremity **542** is provided with a chamfer **544** and a pair of opposed flats **546** which extend through the chamfer **544**. The guide rod **541** extends through a hole **551** provided by semicircular recesses formed in the sections **506** and **507** and by a hole **552** formed by semicircular recesses in the inserts **526** and **527**. A larger hole **553** formed by semicircular recesses in the inserts **526** and **527** of a larger diameter than the hole **552** is provided which receives a push-button **556** and extends through a hole **557** also formed by semicircular recesses provided in the sections **506** and **507**. A dish-shaped or concave recess **558** is provided in the sections **506** and **507** and facilitates engaging the push-button **556** by a finger of the hand.

[**0150**] The pushbutton **556** is provided with a bore **561** which is sized so that it can receive the distal extremity **542** of the guide rod **541**. The pushbutton is provided with sideways extending skirts **562** extending 180° with respect to each other and which are provided with distally and inwardly extending camming surfaces **563** which terminate at a tip **564** that is generally V-shaped as shown in **FIG. 51**. The tip **564** is formed so that it is adapted to enter into the slot **536** formed by the U-shaped members **531** and **532**. Thus, when the pushbutton **556** is depressed, the tip **564** will enter the slot **536** in a progressive manner to urge them apart so that the camming surfaces **563** carried thereby engage the U-shaped latch members **531** and **532** in regions just above and below the guide rod **541** so that the guide rod **541** is released by the U-shaped latch members **531** and **532** permitting it to be pulled out of the handle part **503**. Release of the guide rod **541** makes it possible to separate the guide rod **541** from the remainder of the balloon dissection apparatus **501** so that the handle assembly **502** and the other parts carried thereby can be separated from the guide rod.

[**0151**] Thereafter, the guide rod **541**, the balloon **361** and the balloon cover assembly **316** can be disposed of. The other parts of the apparatus can be reutilized after appropriate sterilization. In order to ensure that the other parts survive sterilization, it may be desirable to form the plastic reusable parts of a suitable plastic such as a polysulfone.

[0152] In connection with the foregoing, it can be seen that by making minor changes in the construction it is possible to save a great number of parts of the balloon dissection apparatus for reuse after sterilization. Only the parts which are most difficult to clean are disposed of after a one-time use.

[0153] From the foregoing it can be seen that there has been provided an apparatus and method which is particularly suitable for developing an anatomic space such as an extraperitoneal working space between the abdominal wall and the peritoneum by dissecting tissue with the use of a non-elastomeric balloon. The balloon dissection apparatus has many features facilitating its use in developing such an anatomic space and for particularly developing an extraperitoneal working space for hernia repair.

What is claimed is:

1. An introducer and sheath assembly comprising:

an elongate introducer member,

a tubular sheath adapted to surround said introducer member, said tubular sheath having a weakened region which extends along its longitudinal axis from a proximal region to a distal region of said tubular sheath; and

a handle on the proximal region of said tubular sheath, said handle being adapted to be pulled proximally, thereby causing said weakened region to separate as said weakened region is drawn against said introducer member, thereby allowing said tubular sheath to be removed from said introducer member, said handle having one or more inwardly directed latches adapted to secure said sheath to said introducer member.

2. The introducer and sheath assembly of claim 1 wherein said one or more latches comprise one or more protuberances formed on an inner wall of said handle.

3. An introducer and sheath assembly comprising:

an elongate introducer member,

a tubular sheath adapted to surround said introducer member, said tubular sheath having a weakened region which extends along its longitudinal axis from a proximal region to a distal region of said tubular sheath; and

a handle on the proximal region of said tubular sheath, said handle being adapted to be pulled proximally, thereby causing said weakened region to separate as said weakened region is drawn against said introducer member, thereby allowing said tubular sheath to be removed from said introducer member, said handle having one or more inwardly directed detents for securing the sheath to said member.

4. The introducer and sheath assembly of claim 3 wherein said one or more detents are formed on an inner wall of said handle.

5. An introducer and sheath assembly comprising:

an elongate introducer member,

a tubular sheath adapted to surround said introducer member, said tubular sheath having a weakened region which extends along its longitudinal axis from a proximal region to a distal region of said tubular sheath; and

a handle on the proximal region of said tubular sheath, said handle being adapted to be pulled proximally, thereby causing said weakened region to separate as said weakened region is drawn against said introducer member, thereby allowing said tubular sheath to be removed from said introducer member, said handle having one or more detents formed on an inner wall of said handle to engage said introducer member for securing said sheath to said introducer member.

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专利名称(译)	用于开发用于腹腔镜疝修补的解剖学空间的装置和方法以及与其一起使用的贴片		
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摘要(译)

一种用于在身体组织中产生解剖学空间的装置包括导引器和护套。管状护套可以围绕导引器，并且可以沿其纵向轴线具有弱化区域。手柄可以设置在护套上。手柄可以适于向近侧拉动以分离弱化区域并允许护套从导引器移除。护套可以通过手柄上的棘爪或闩锁固定到导引器上。