US005309896A

# United States Patent [19]

**Moll et al.**

[11] **Patent Number: 5,309,896**

[45] **Date of Patent: May 10, 1994**

[54] **RETRACTION METHODS USING ENDOSCOPIC INFLATABLE RETRACTION DEVICES**

[75] Inventors: **Frederic H. Moll; Charles Gresl, Jr.**, both of San Francisco; **Albert K. Chin**, Palo Alto; **Philip K. Hopper**, Laverne, all of Calif.

[73] Assignee: **Origin Medsystems, Inc.**, Menol Park, Calif.

[21] Appl. No.: **794,590**

[22] Filed: **Nov. 19, 1991**

**Related U.S. Application Data**

[63] Continuation-in-part of Ser. No. 706,781, May 29, 1991, abandoned.

[51] **Int. Cl.**[5] ..... **A61M 29/02**

[52] **U.S. Cl.** ..... **128/20;** 128/898; 606/192

[58] **Field of Search** ..... 606/192; 604/174, 169, 604/164, 101; 128/20, 850, 3, 887, 898

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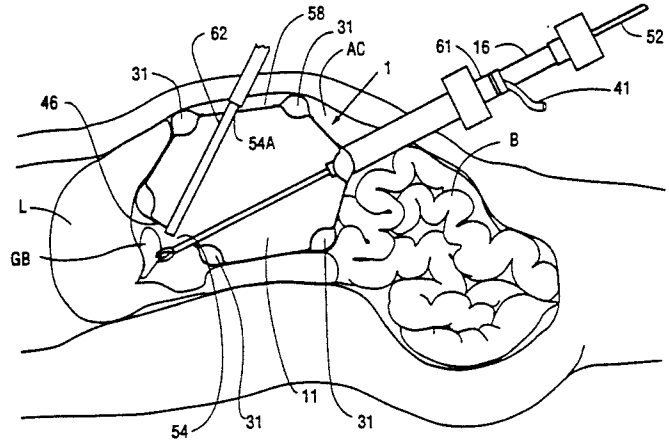
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*Primary Examiner*—Michael H. Thaler
*Attorney, Agent, or Firm*—Limbach & Limbach

[57] **ABSTRACT**

A method for retracting an organ inside the body in the course of treating adjacent tissue. An inflatable retractor is provided. The inflatable retractor includes a flexible wall which may be expanded into place within the body, and which enclosed a main chamber. The inflatable retractor also includes an envelope attached to the flexible wall. The envelope and part of the flexible wall enclose an additional chamber. The inflatable retractor is placed in a collapsed state adjacent tot he organ, and is inflated to expand the flexible wall and to retract the organ. Finally, an aperture is pierced in a part of the flexible wall of the retractor remote from the additional chamber to provide access to the tissue.

**35 Claims, 19 Drawing Sheets**



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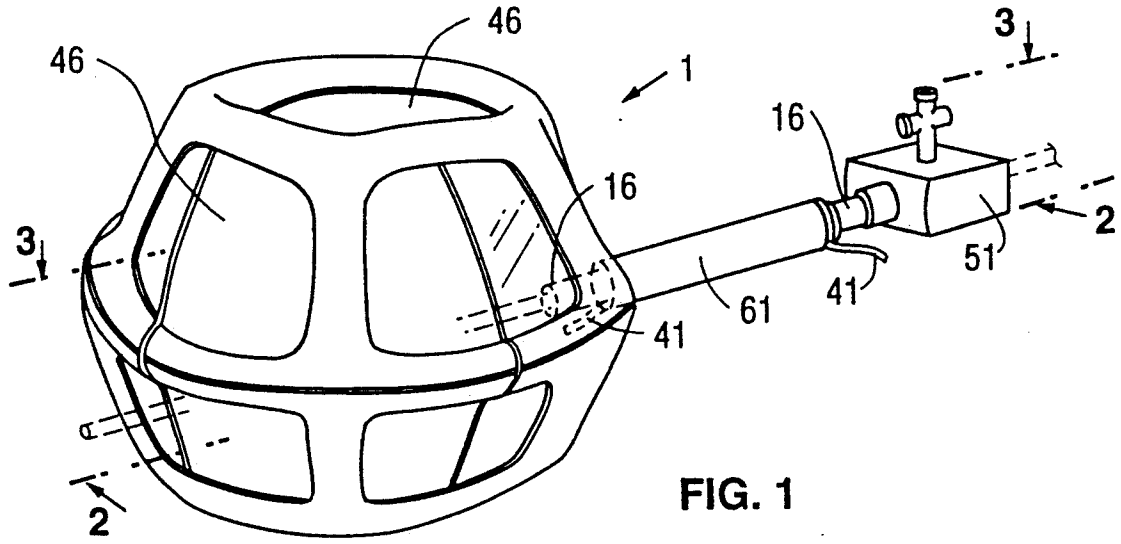



FIG. 1

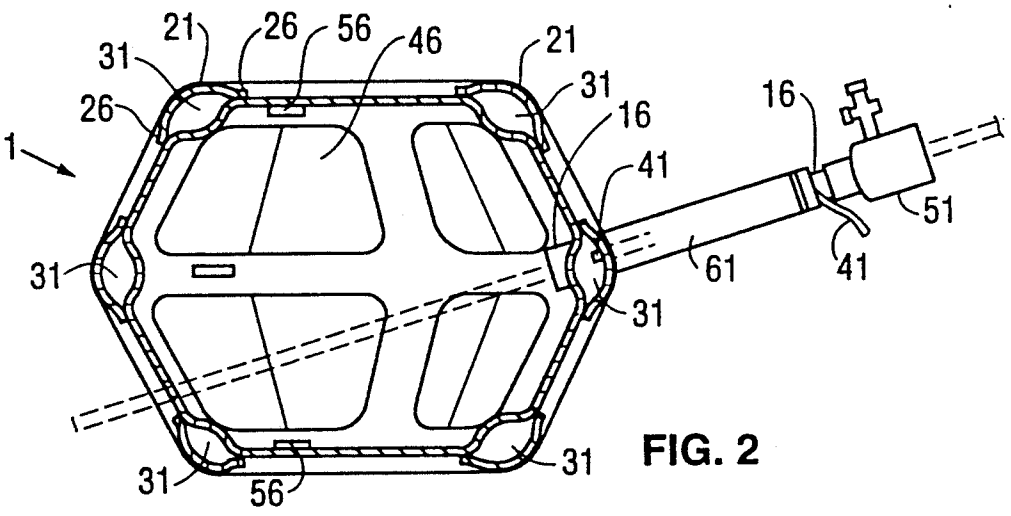



FIG. 2

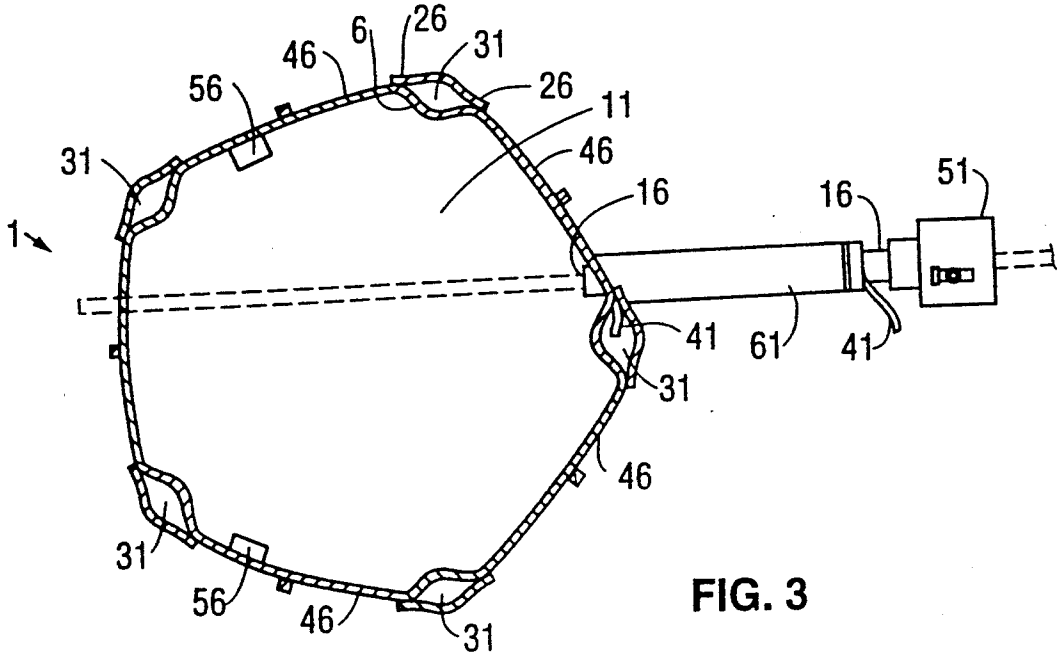



FIG. 3

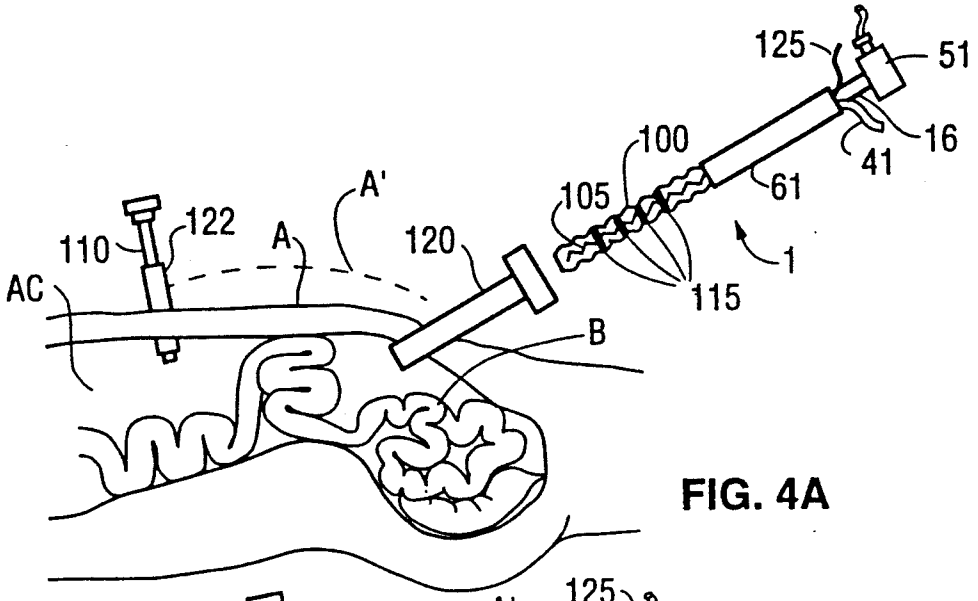



FIG. 4A

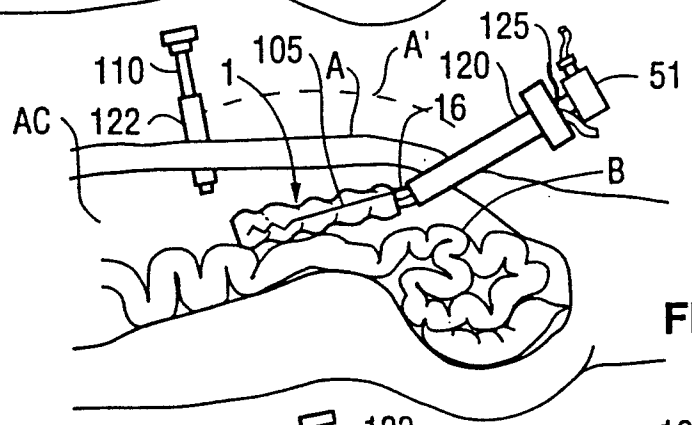



FIG. 4B

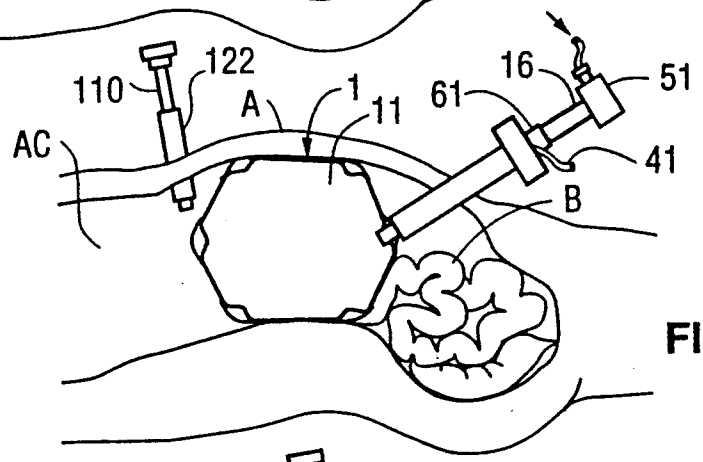



FIG. 4C

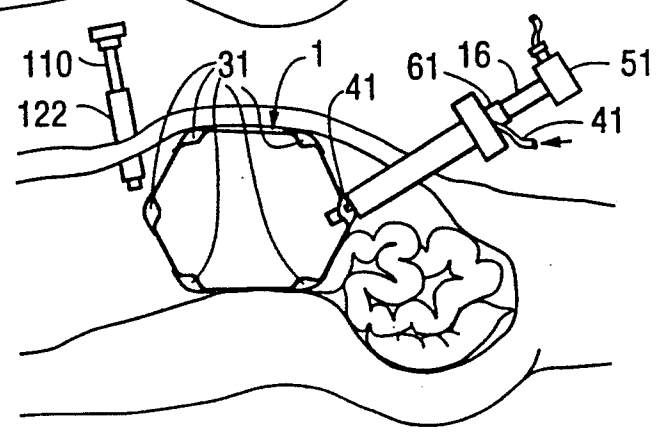



FIG. 4D

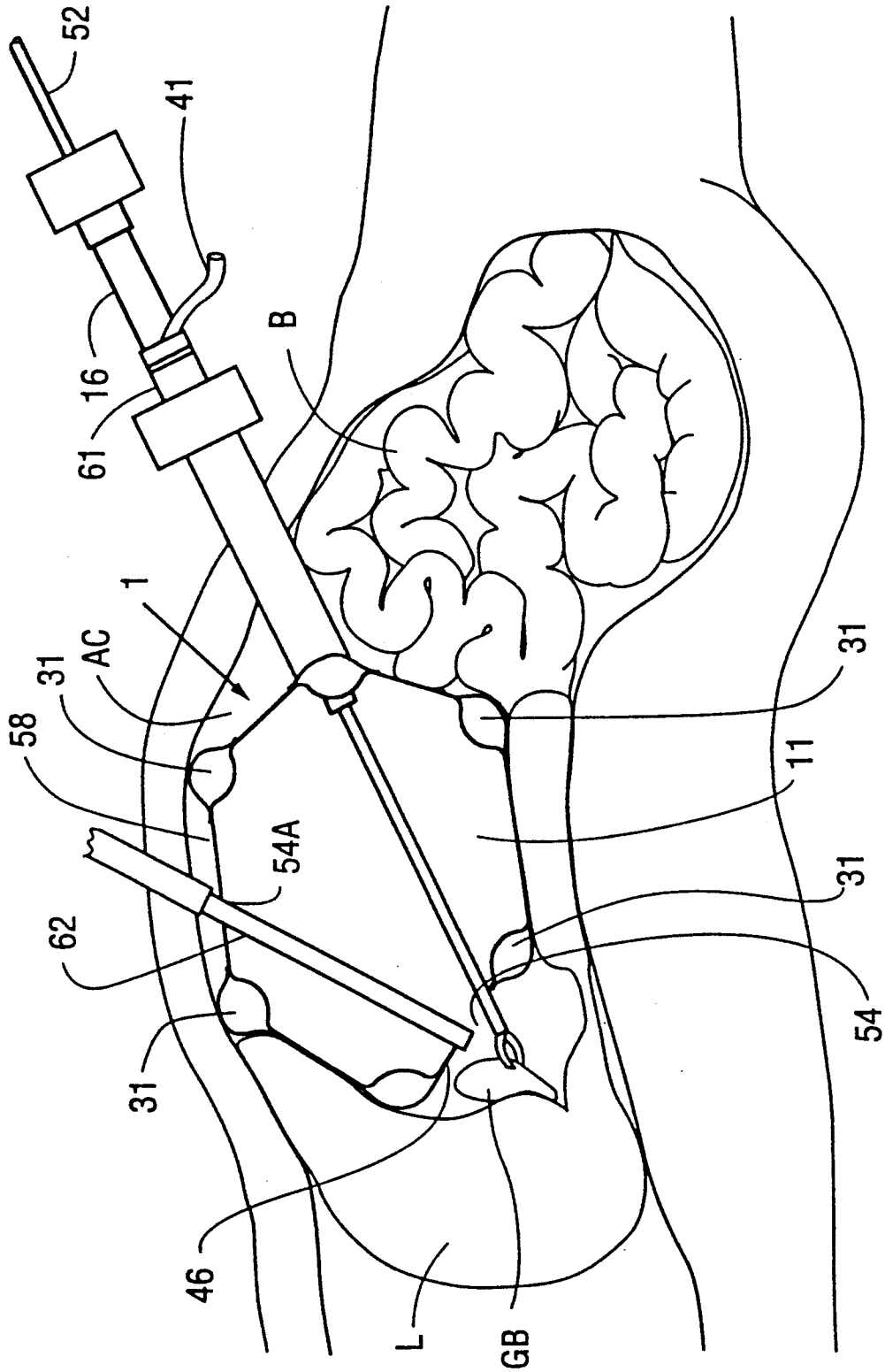



FIG. 5

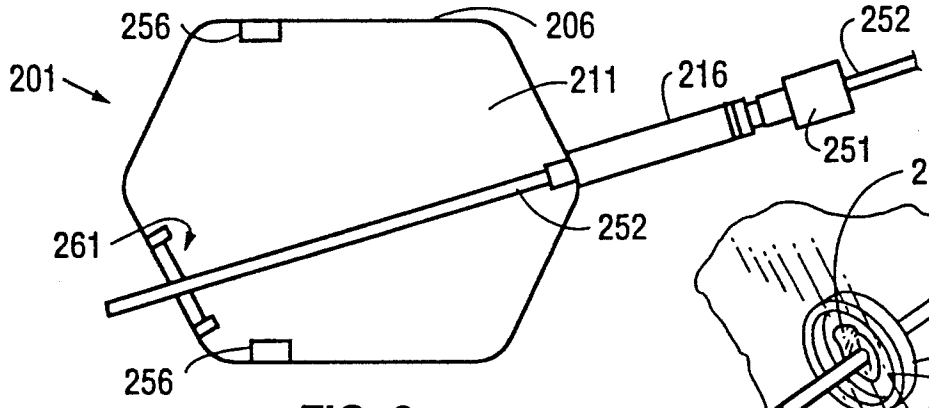



FIG. 6

FIG. 9

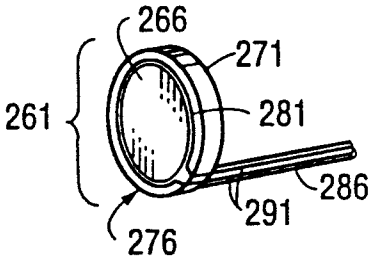



FIG. 7

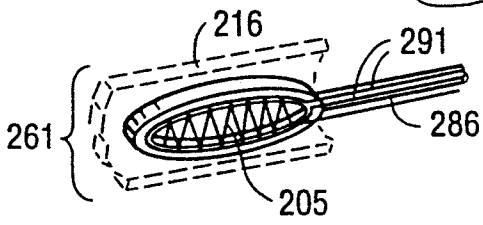



FIG. 8

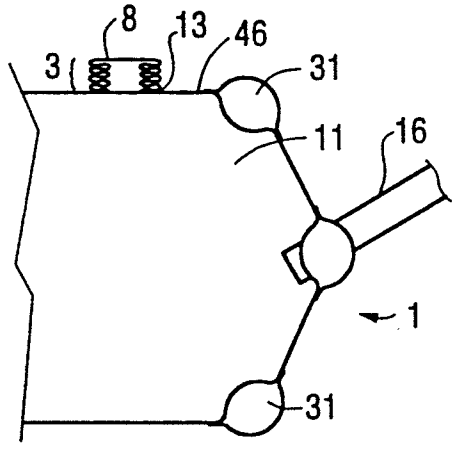



FIG. 12A

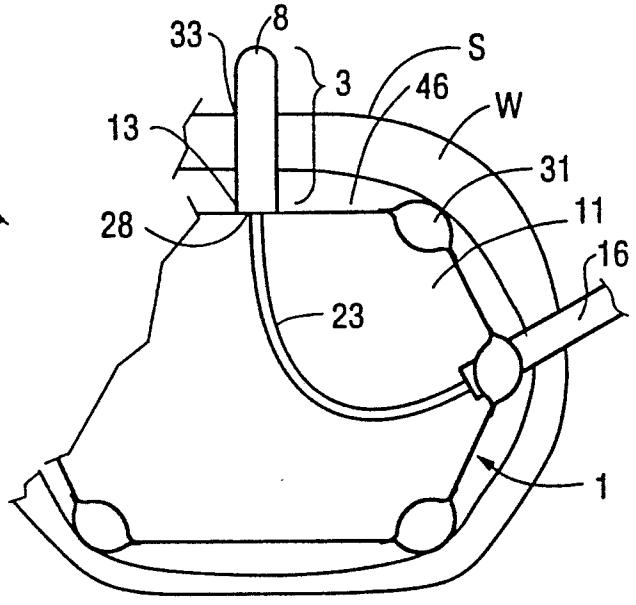



FIG. 12B

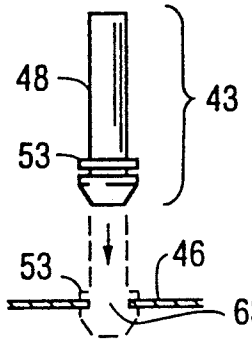



FIG. 12C

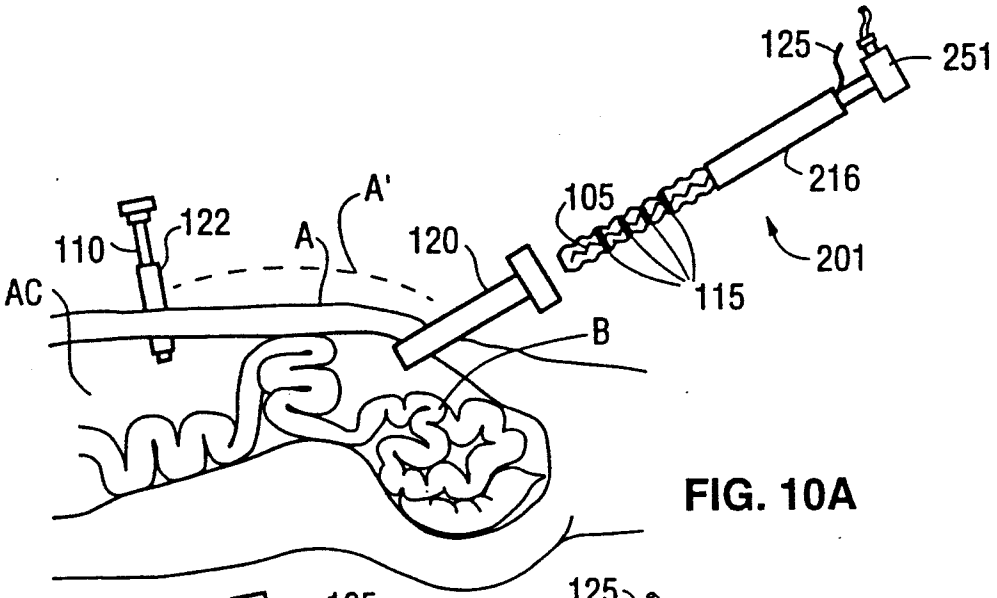



FIG. 10A

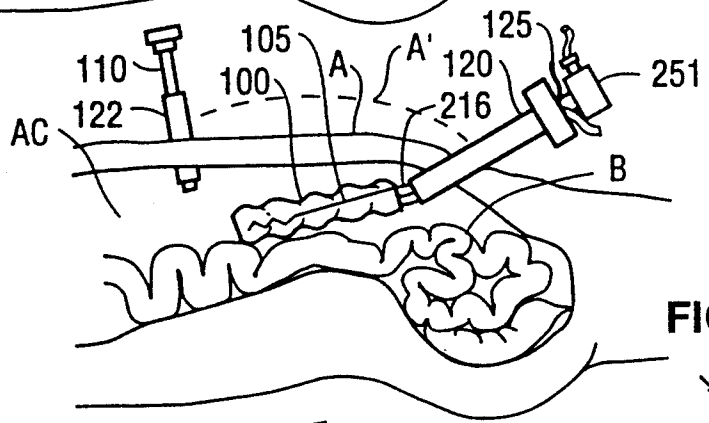



FIG. 10B

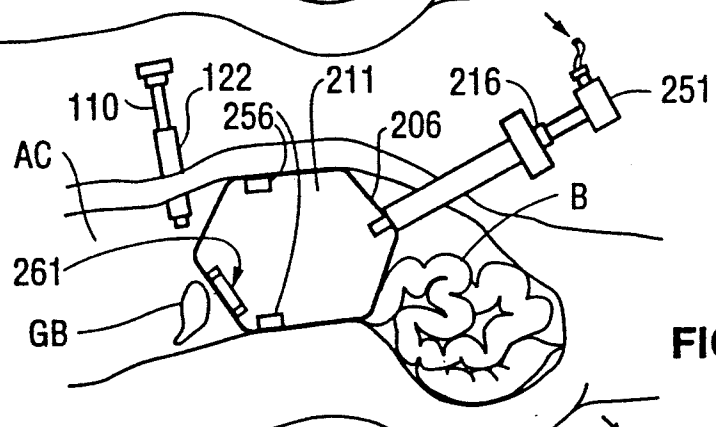



FIG. 10C

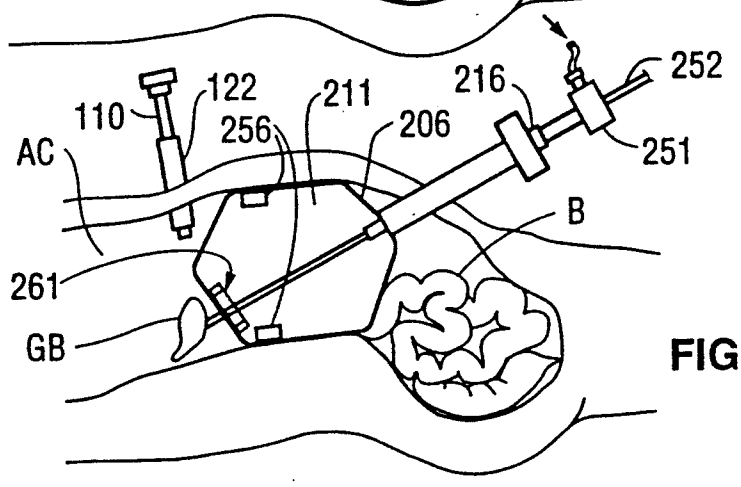



FIG. 10D

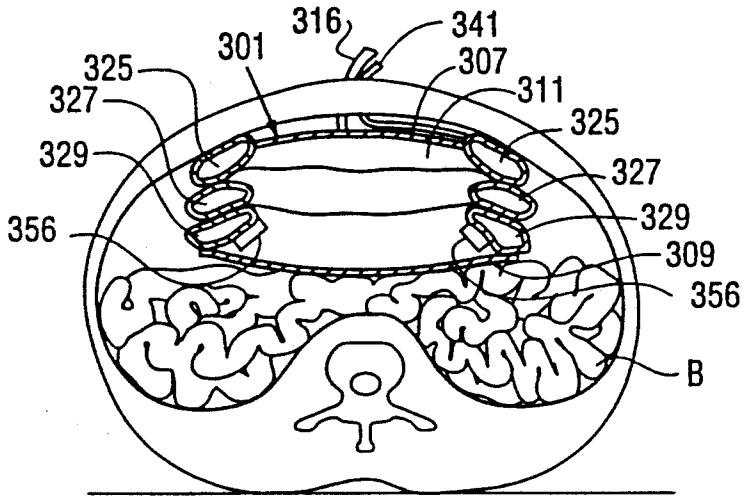



FIG. 11A

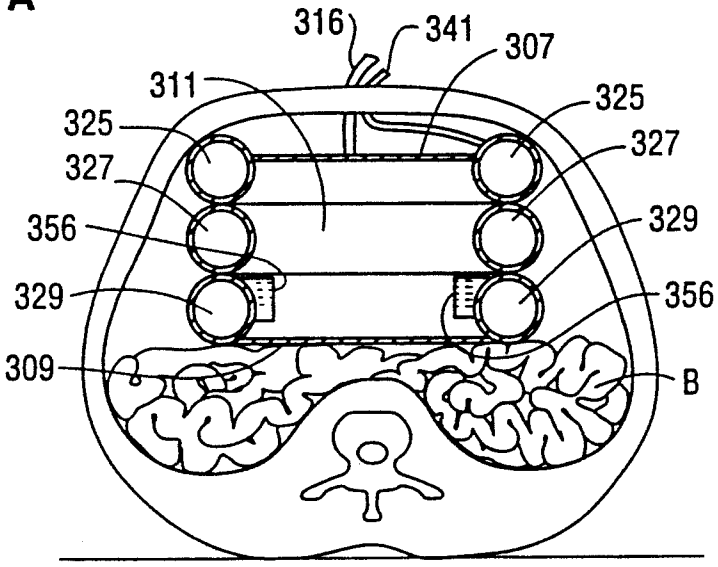



FIG. 11B

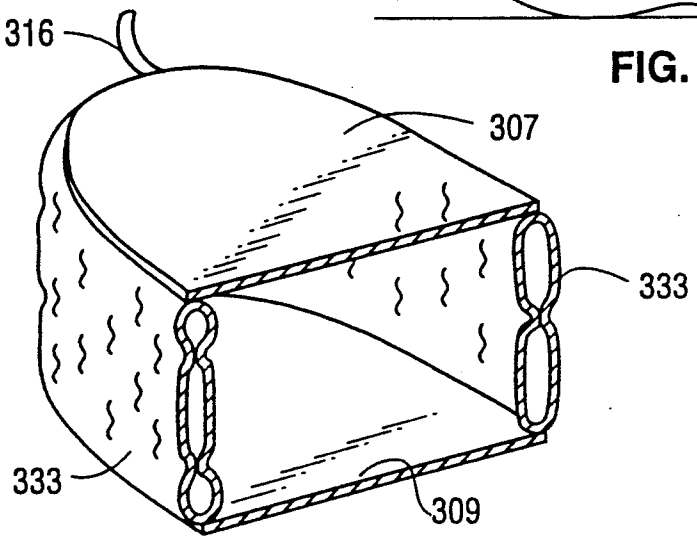



FIG. 11C

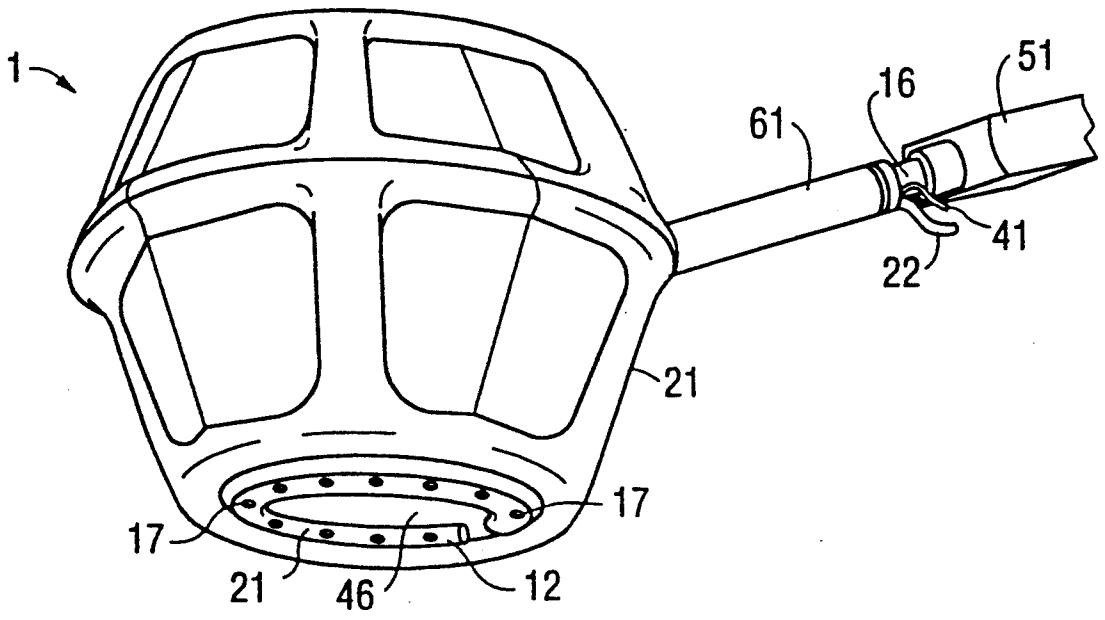



FIG. 13A

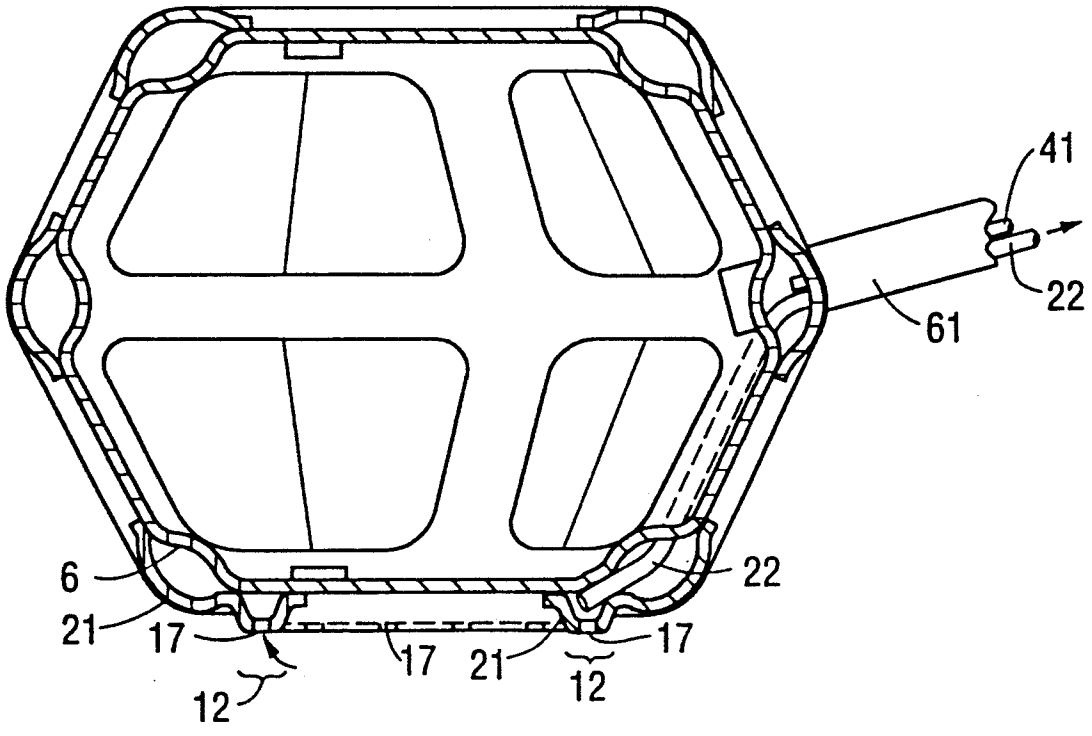



FIG. 13B

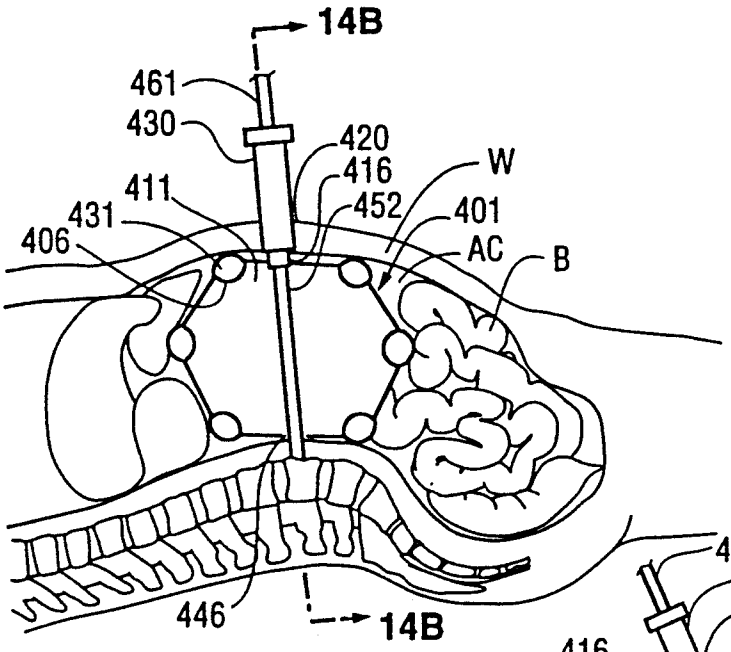



FIG. 14A

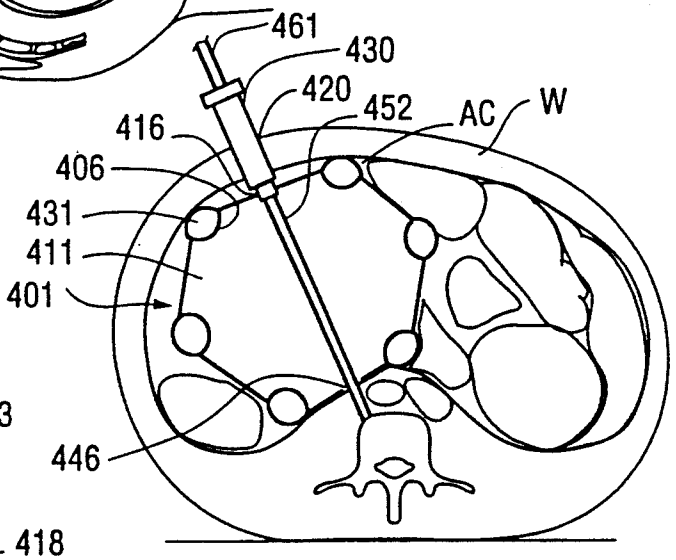



FIG. 14B

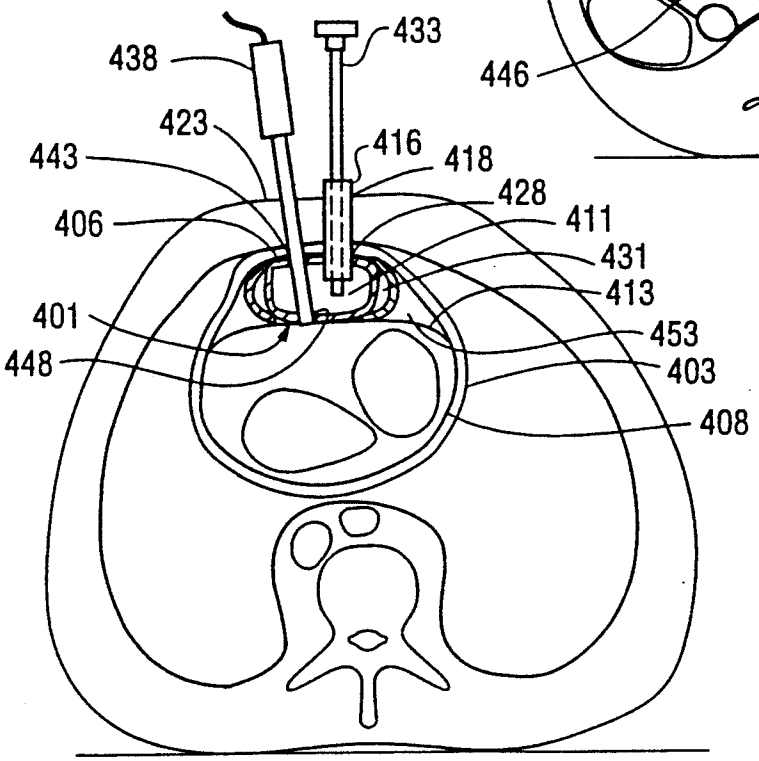



FIG. 15

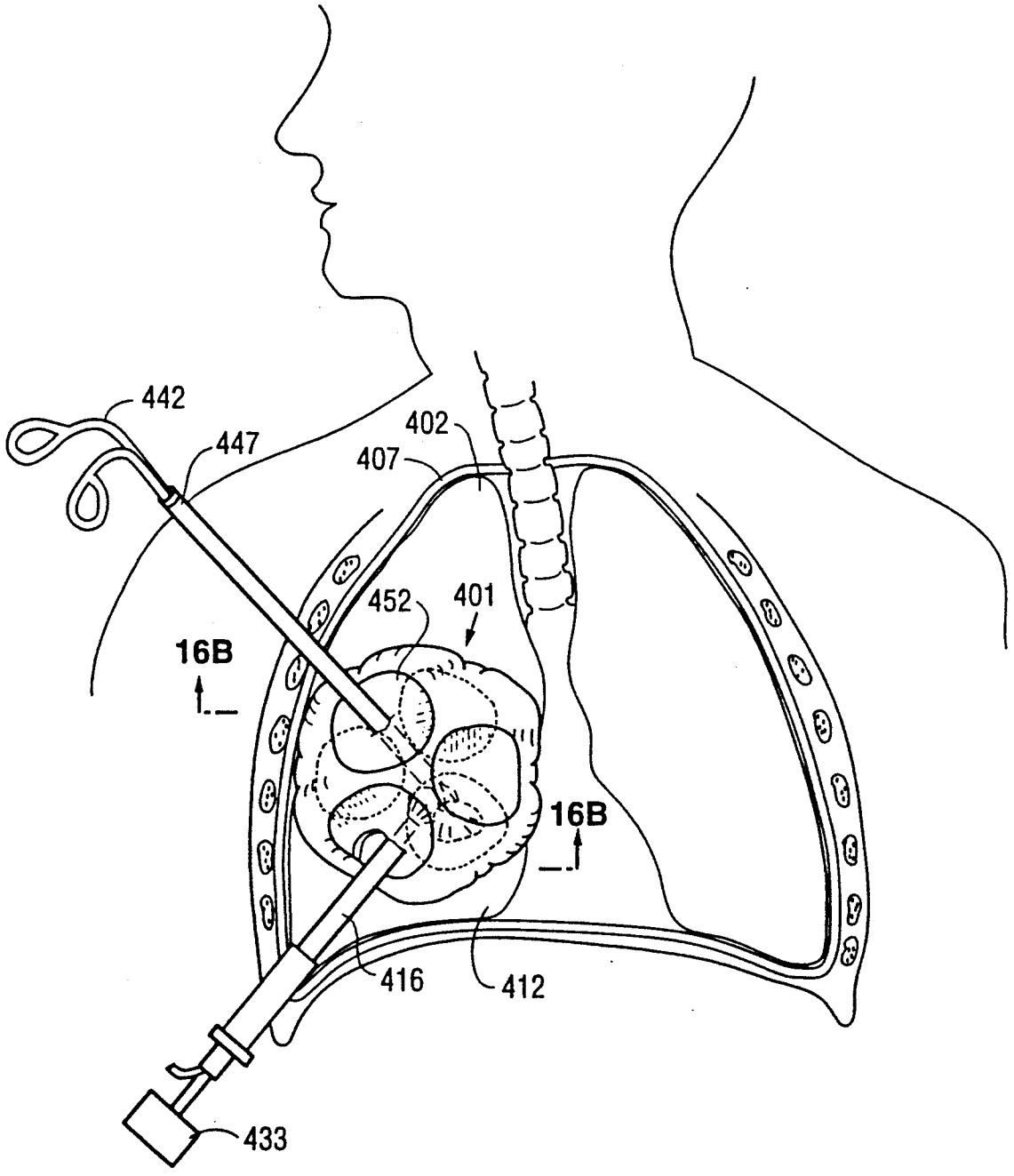



FIG. 16A

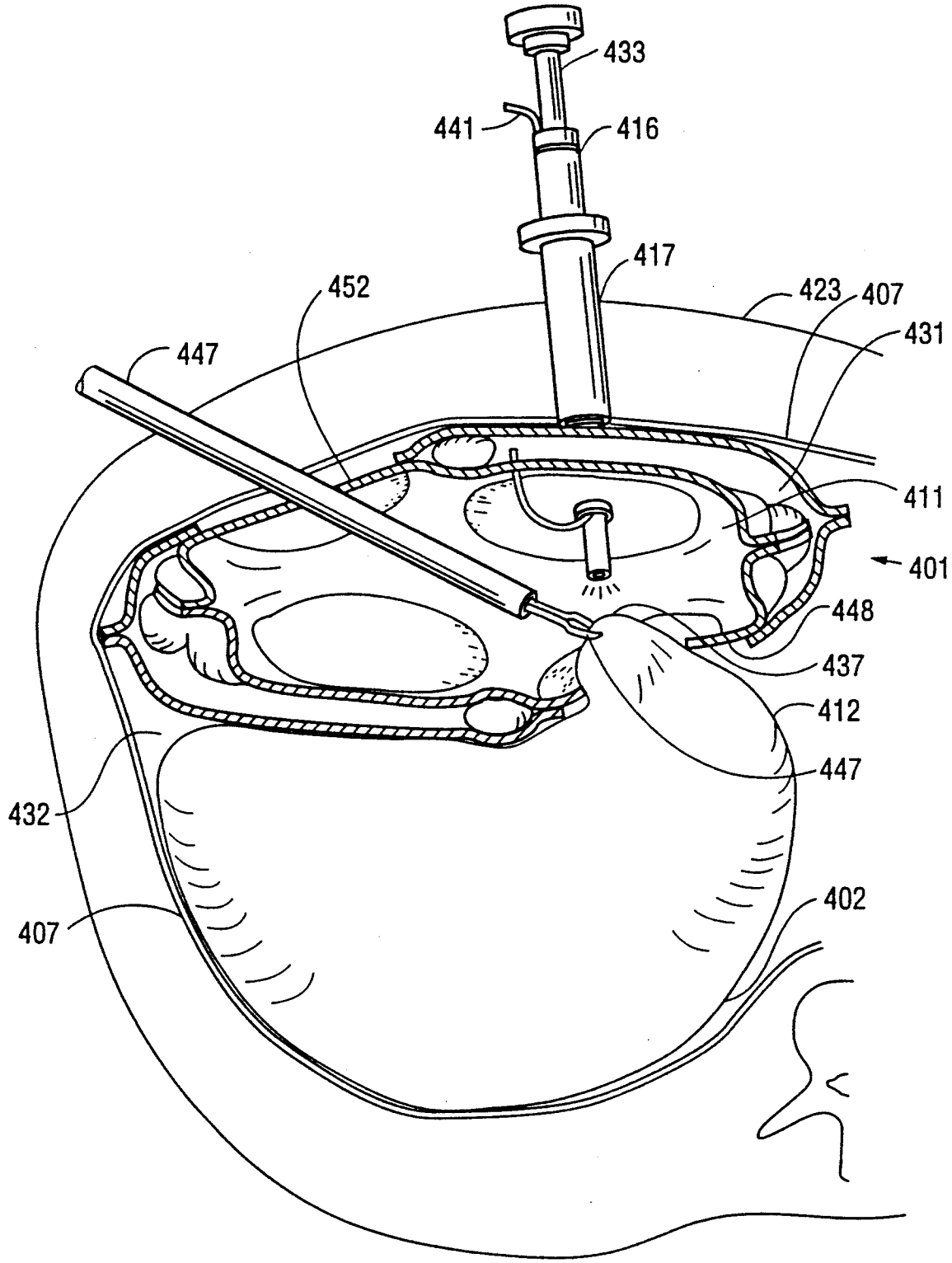

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FIG. 16B

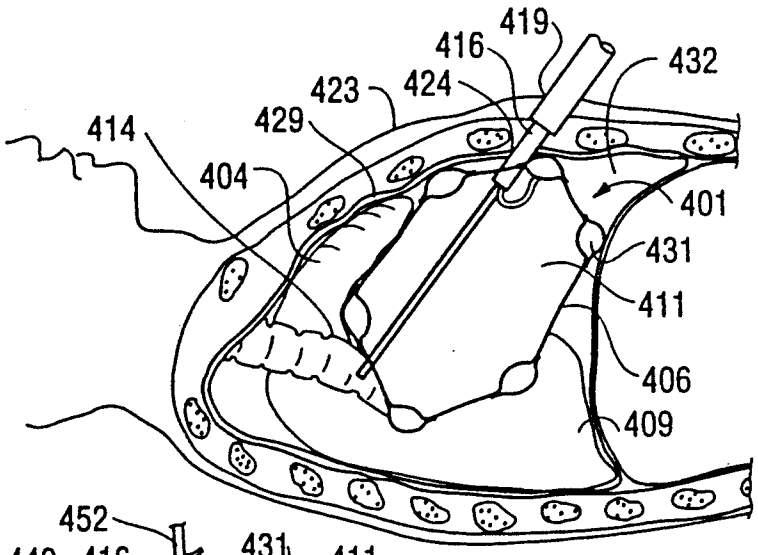



FIG. 17

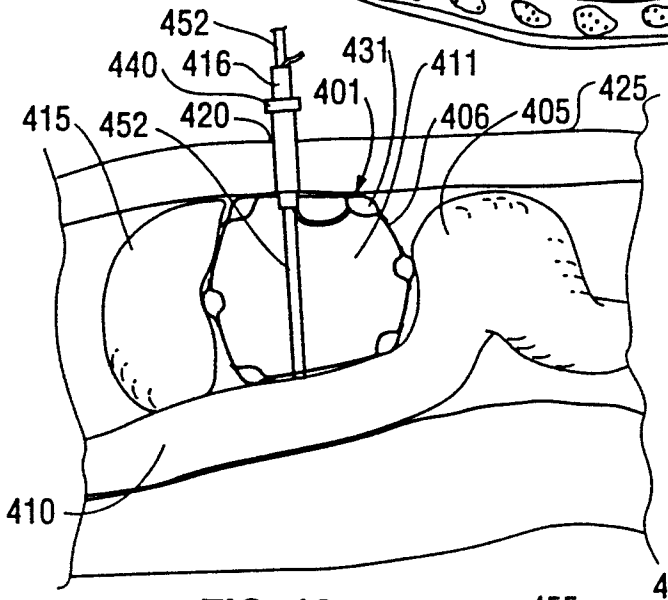



FIG. 18

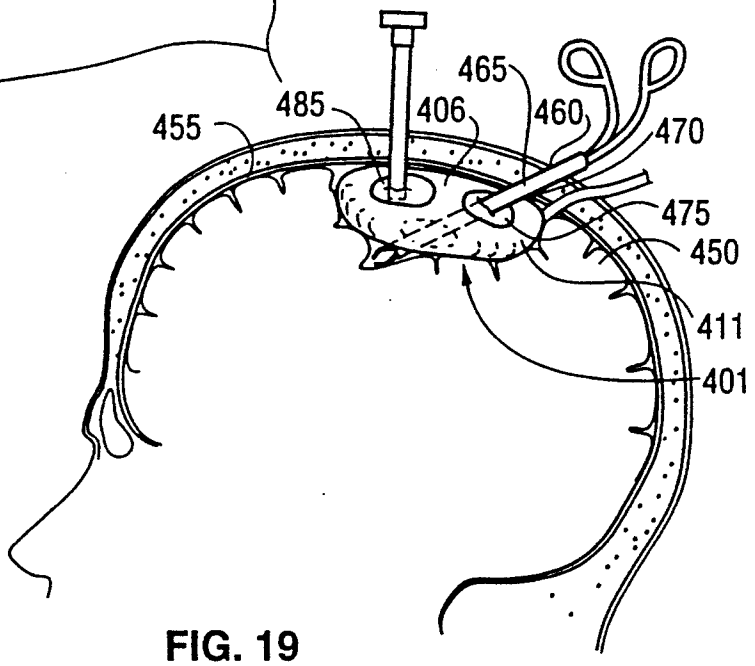



FIG. 19

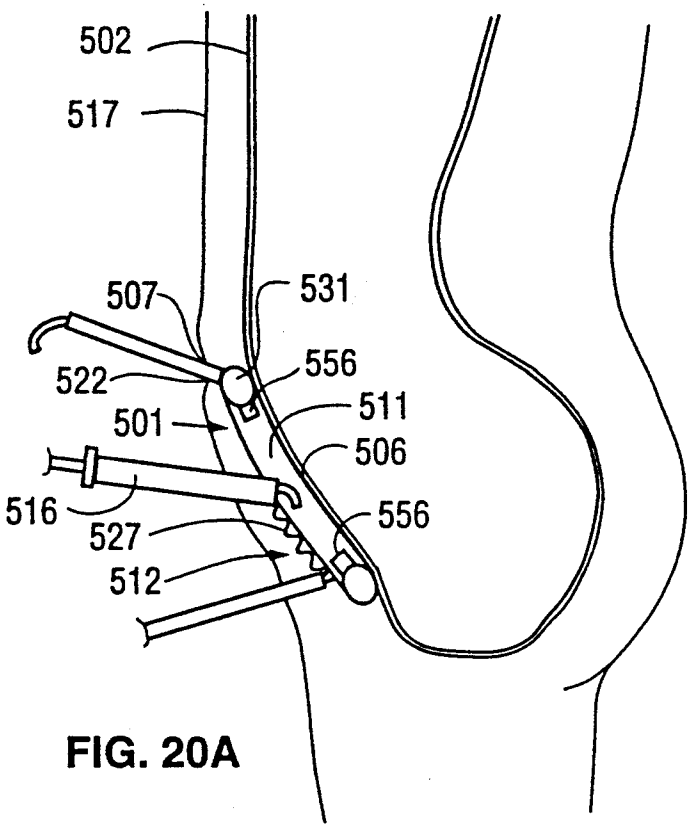



FIG. 20A

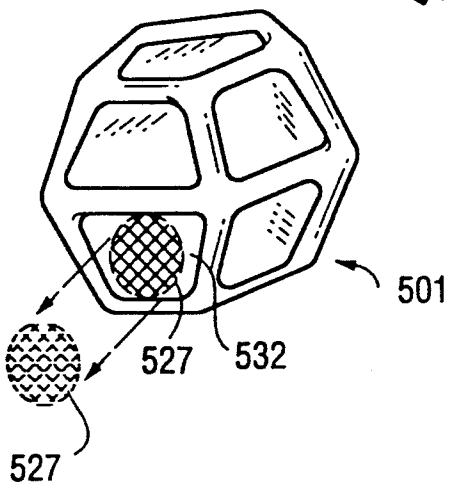



FIG. 21

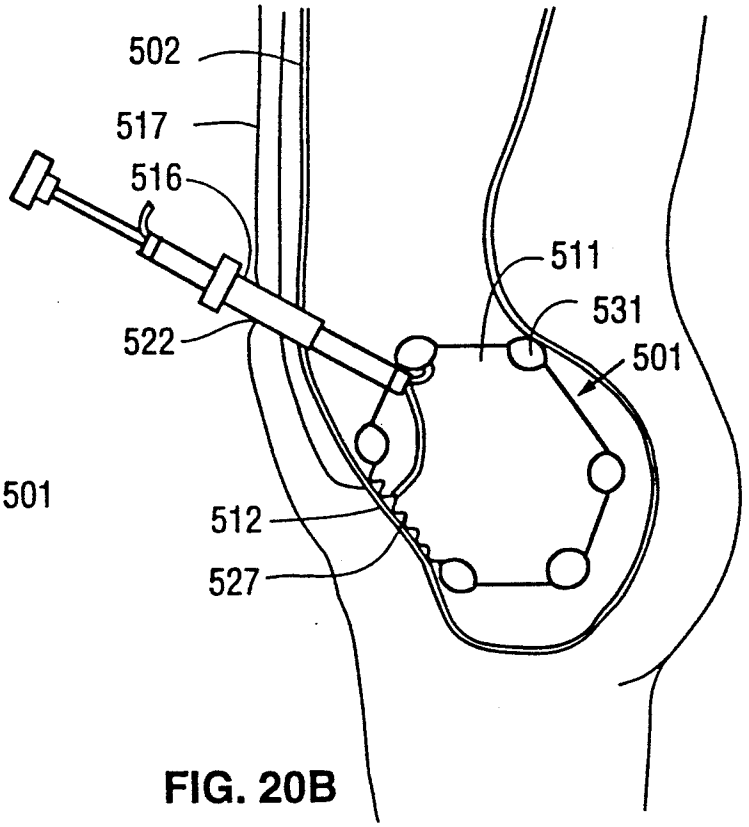



FIG. 20B

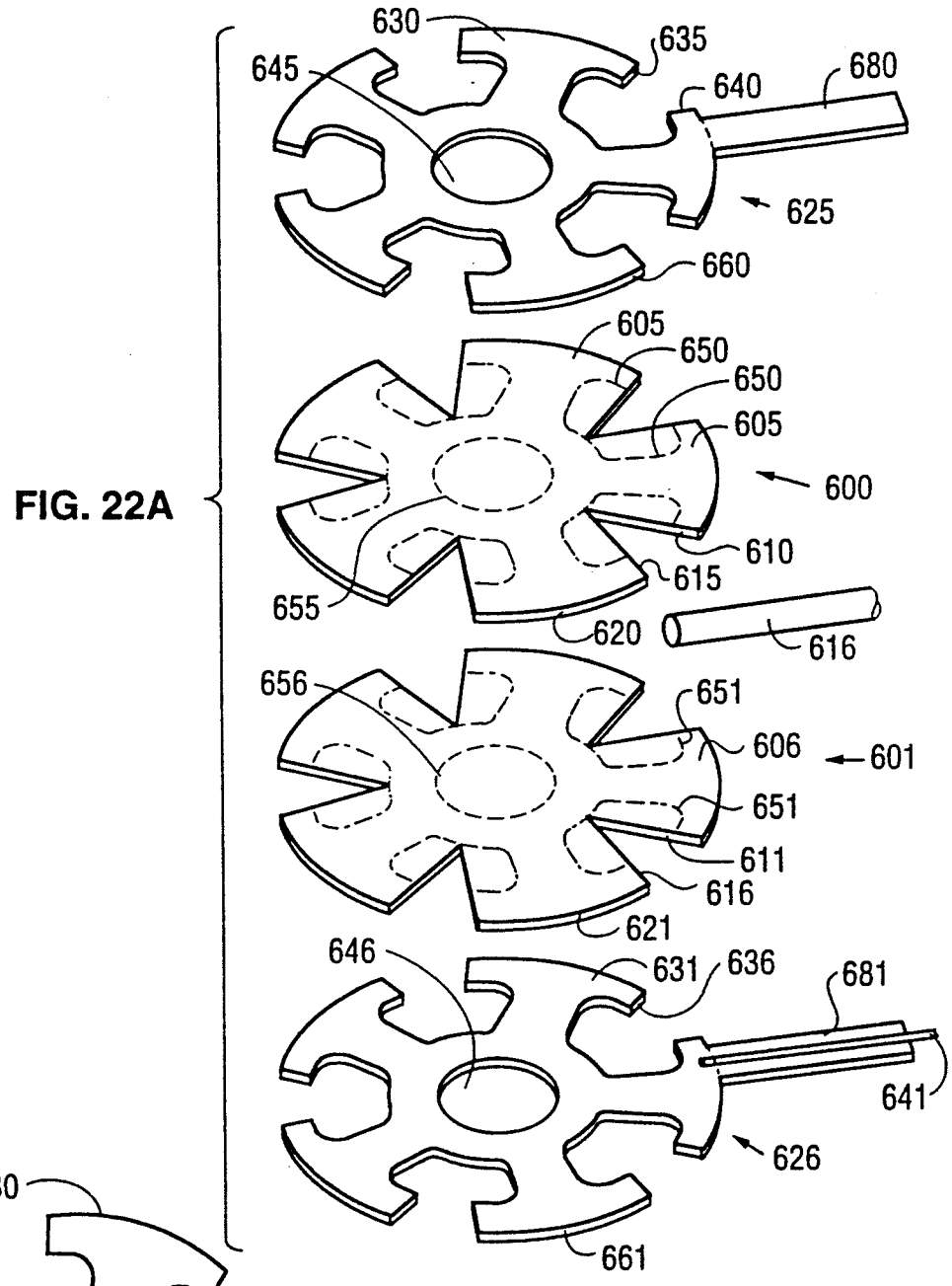



FIG. 22A

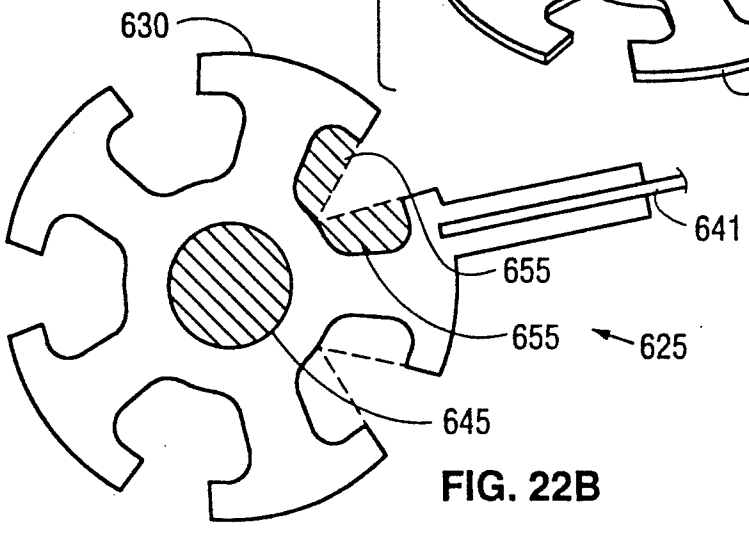



FIG. 22B

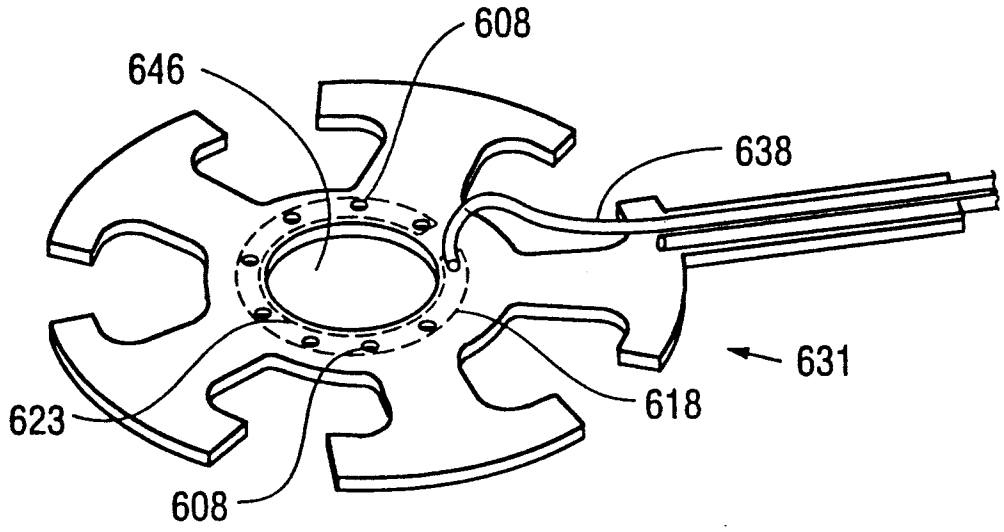



FIG. 23A

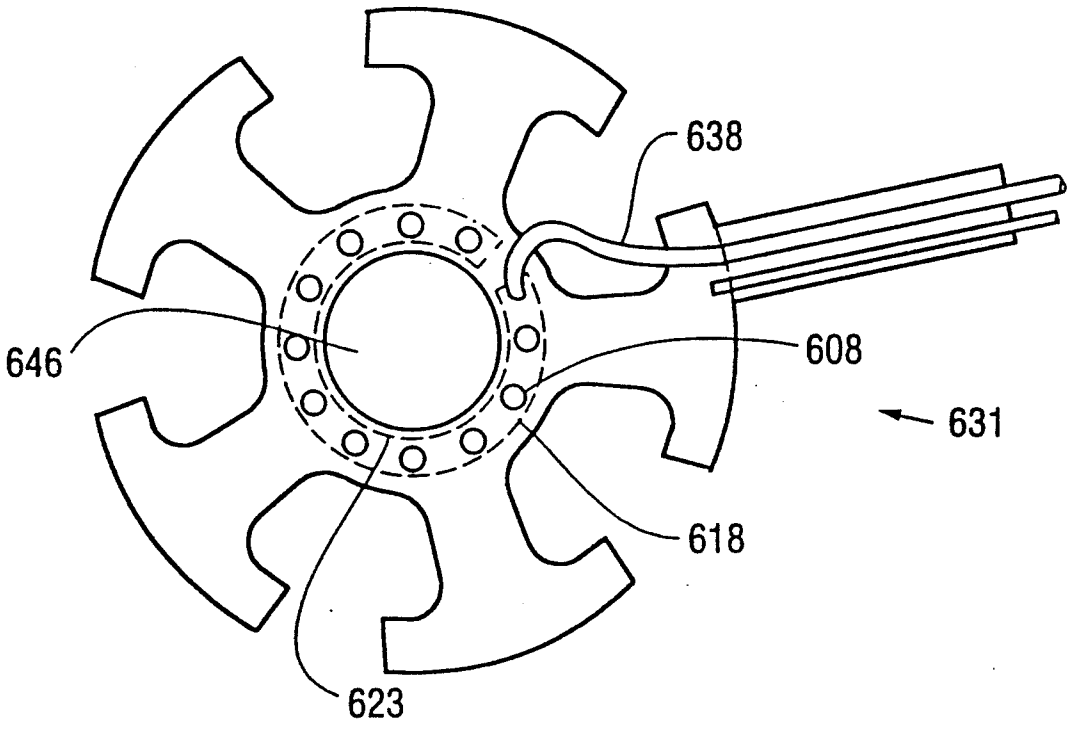



FIG. 23B

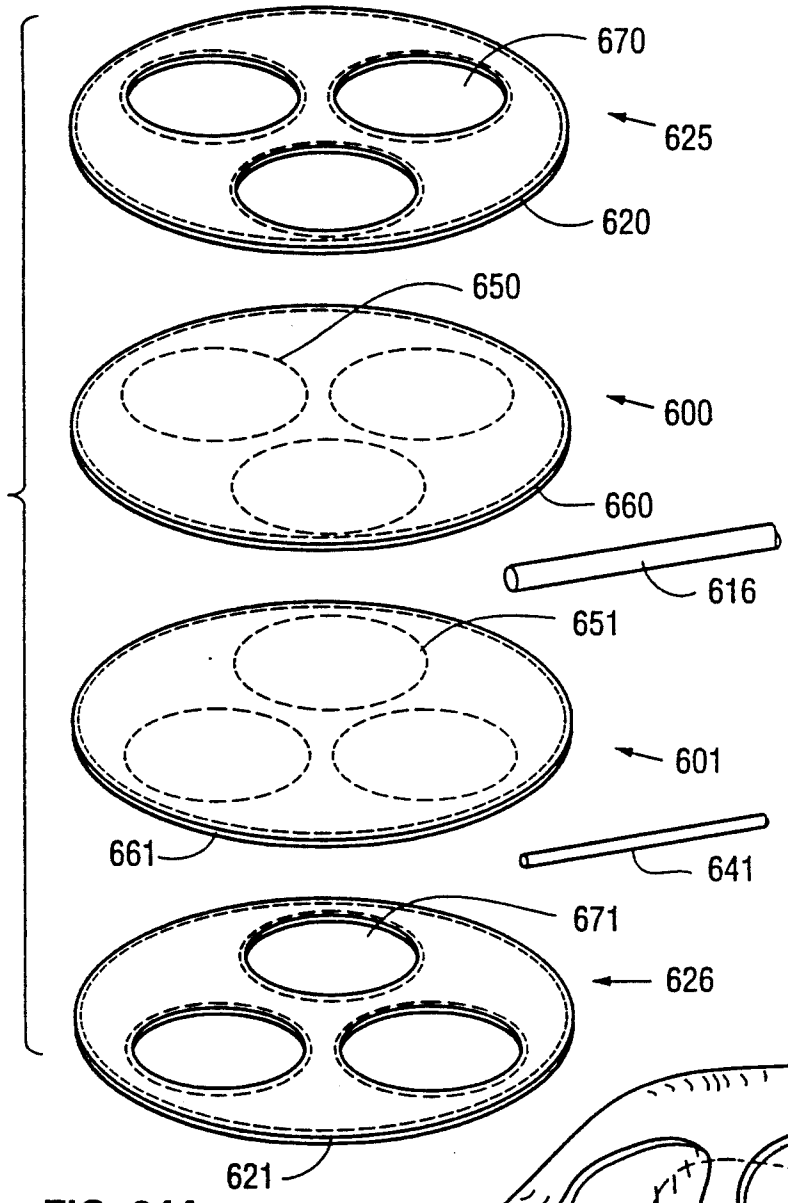



FIG. 24A

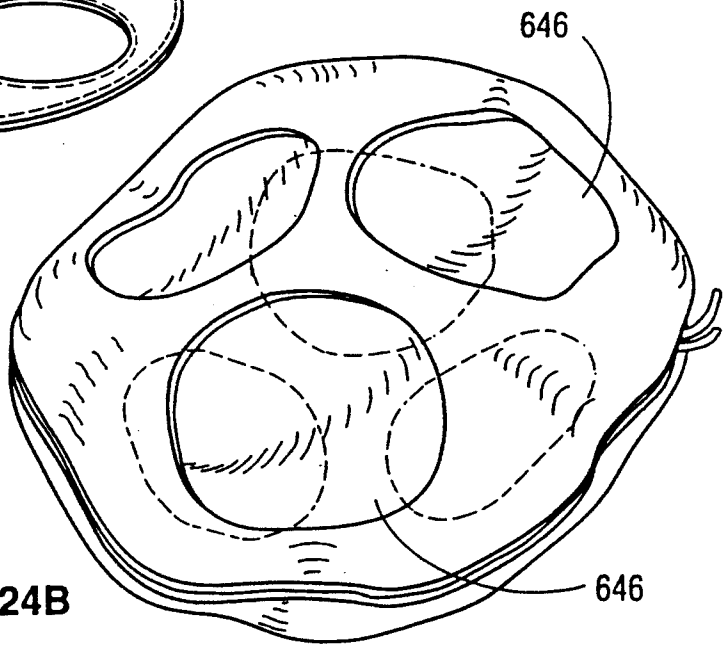



FIG. 24B

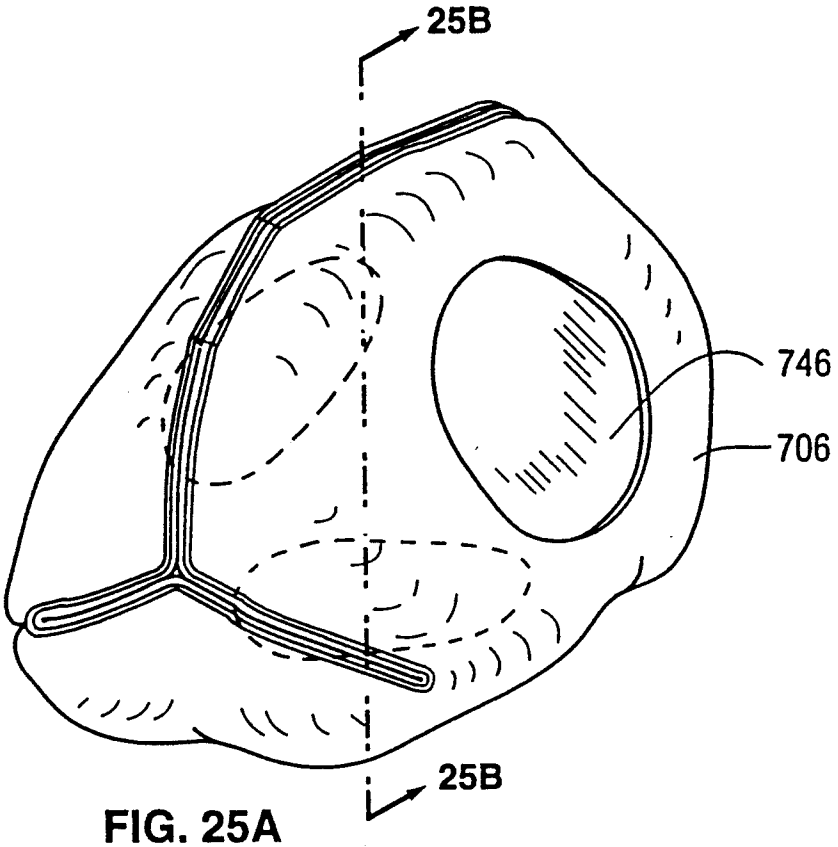



FIG. 25A

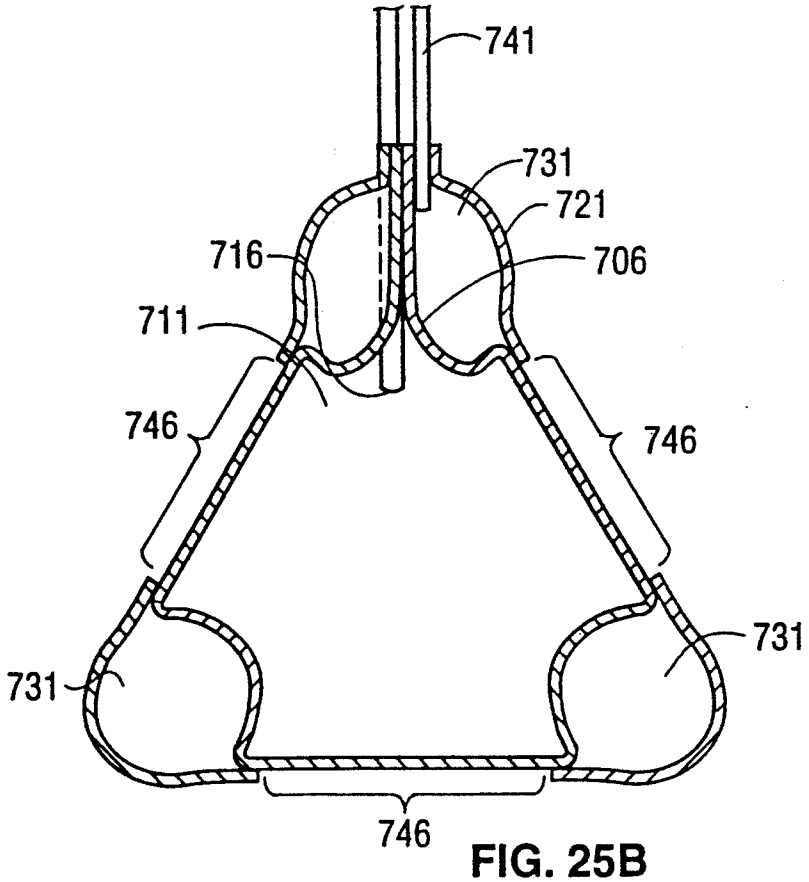



FIG. 25B

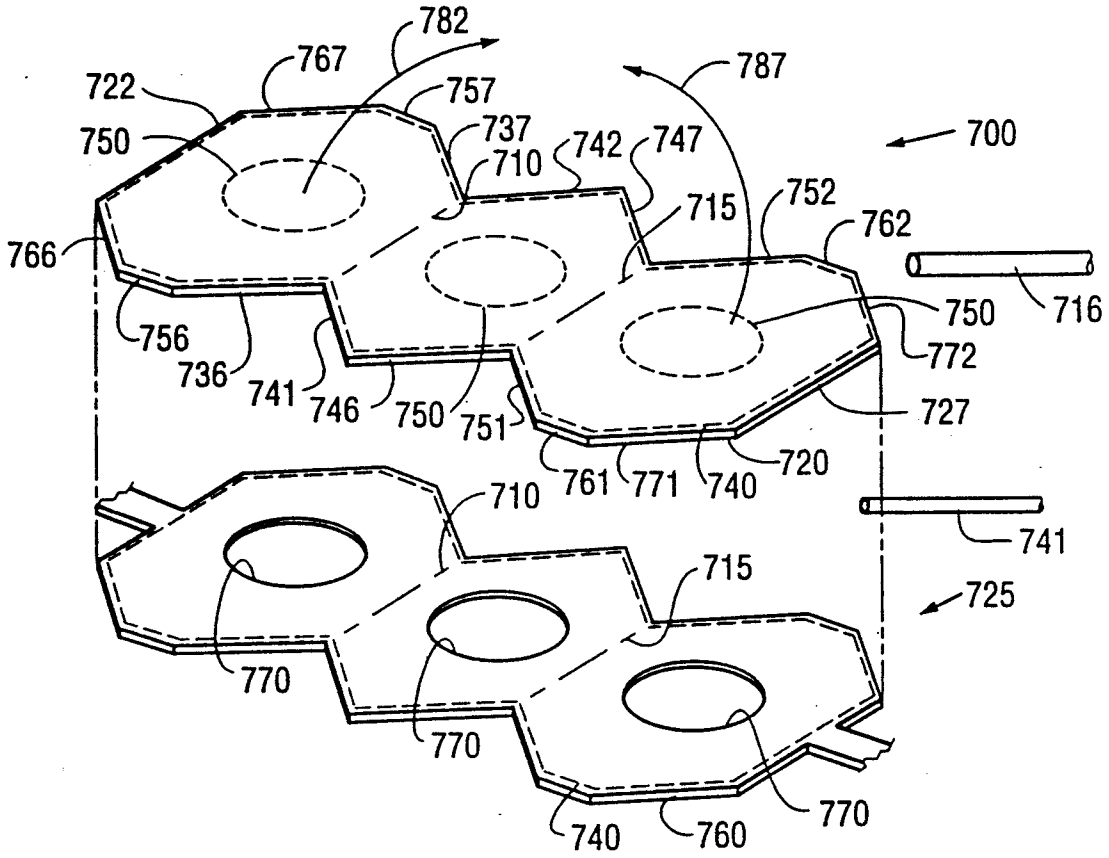



FIG. 25C

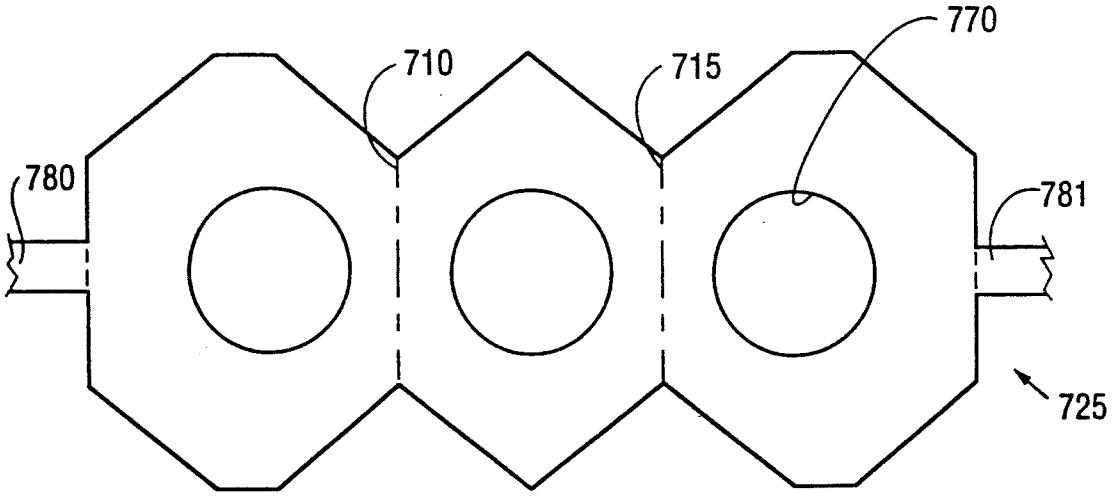



FIG. 25D

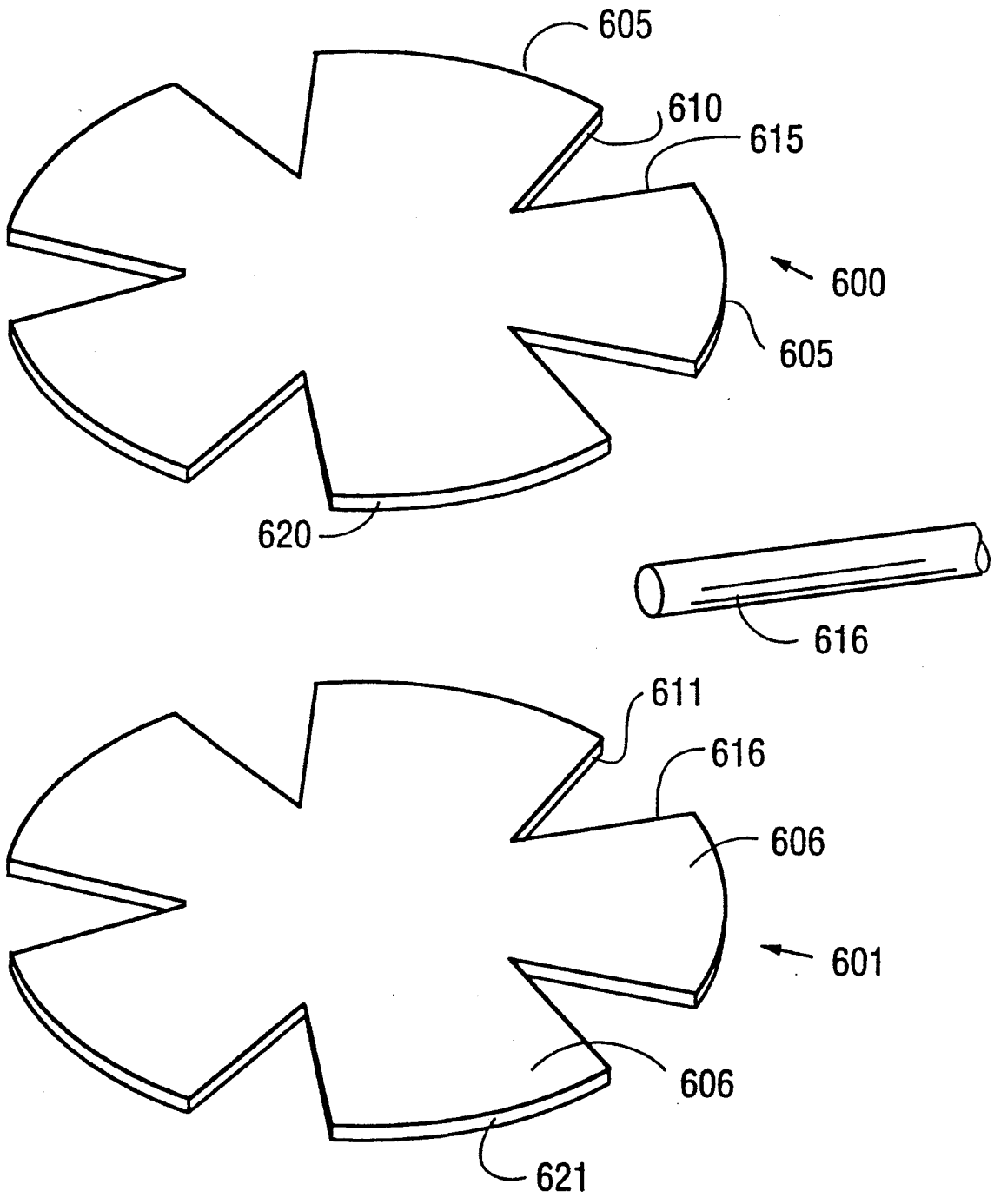



FIG. 26

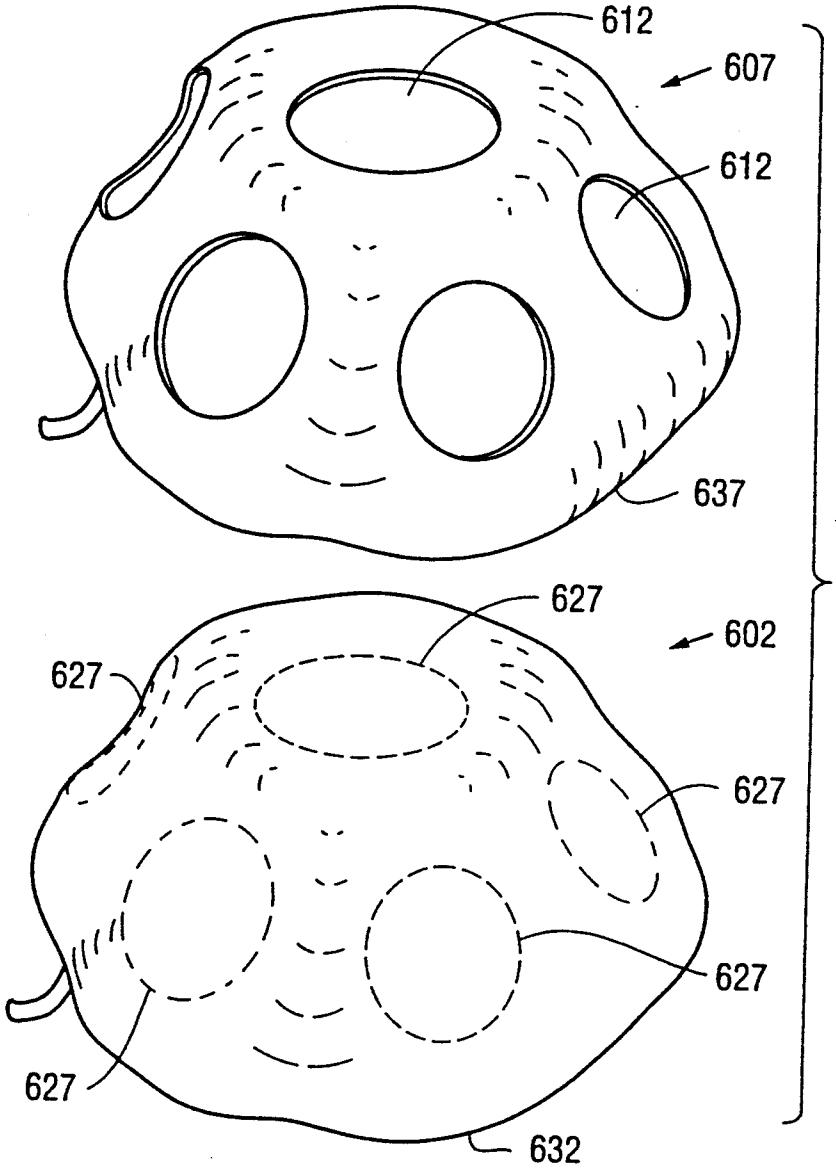

612
607
612
637
627
602
627
627
627
627
632

FIG. 27

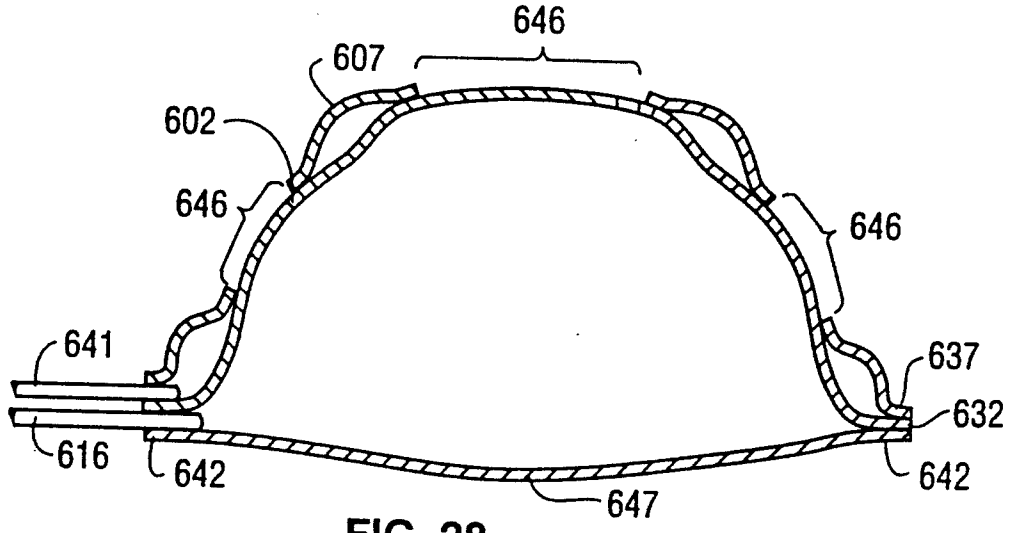

646
607
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616
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647

FIG. 28

# RETRACTION METHODS USING ENDOSCOPIC INFLATABLE RETRACTION DEVICES

This application is a continuation-in-part of application Ser. No. 706,781, filed 29 May 1991, now abandoned, of inventors Frederic H. Moll, Albert K. Chin, Diane E. Caramore, and Frank T. Watkins III.

## BACKGROUND OF THE INVENTION

Laparoscopy dates back to the turn of the 20th Century. Early laparoscopic techniques were used primarily for diagnostic purposes to view the internal organs, without the necessity of conventional surgery. Since the 1930s, laparoscopy has been used for sterilization and, more recently, for the suturing of hernias. U.S. Pat. Nos. 4,919,152 and 4,944,443 are concerned with techniques for suturing hernias. Another very recent innovation is the use of laparoscopic surgery for removing the gallbladaer.

U.S. patent application Ser. No. 706,781, the application of which this application is a continuation-in-part, describes an apparatus and method wherein the abdominal wall is lifted away from the underlying abdominal organs by an inflatable device which is introduced laparoscopically and, once in place, inflated to engage and lift an extensive area of the abdominal wall.

Even when such lifting techniques are used, it is still necessary to retract other organs to gain access to the organ or tissue to be treated or observed. In other procedures, to gain access to the organ or tissue to be treated or observed, it is necessary to separate the organ to be treated from tissue surrounding it. For example, to be able to observe the outer surface the heart, the outer surface of the heart has to be separated from the pericardium. To obtain the necessary retraction, current laparoscopic procedures use several small retractors inserted though a plurality of incisions. Because such retractors have a relatively small surface area, they tend to damage and/or cause trauma to the retracted organs or tissue. Moreover, the requirement for a plurality of incisions to heal may delay the patient's recovery.

It is known to use a modified Foley catheter to retract organs and tissue with less damage. The modified Foley catheter comprises a small, substantially spherical balloon on the end of a catheter which is inserted through a small incision into the body. After insertion, the balloon is inflated. The modified Foley catheter is used in a similar manner to a conventional retractor, but the retracted organ or tissue is contacted by the relatively large surface area of the balloon. Such a retractor reduces damage to retracted organs or tissues, but is inconvenient to use because it has to be kept in place by means of an external clamping arrangement, and its relatively large balloon tends to obstruct access to the site to be treated.

## SUMMARY OF USING THE INVENTION

In the following description, the word "organ" will be used to mean an organ or a tissue that is retracted by the retraction device. The word "treat" will be used to mean both treat and observe, and the word "treatment" will be used to mean both treatment and observation. The word "tissue" or the phrase "tissue to be treated" will both be used to mean the organ or the tissue that is treated through or inside the retraction device.

In a first method according to the invention for retracting an organ inside the body in the course of treating adjacent tissue, an inflatable retractor is provided. The inflatable retractor includes a flexible wall which may be expanded into place within the body, and which encloses a main chamber. The inflatable retractor also includes an envelope attached to the flexible wall. The envelope and part of the flexible wall enclose an additional chamber. The inflatable retractor is placed in a collapsed state adjacent to the organ, and is inflated to expand the flexible wall and to retract the organ. Finally, an aperture is pierced in a part of the flexible wall of the retractor remote from the additional chamber to provide access to the tissue.

In a second method according to the invention for retracting an organ inside the body in the course of treating adjacent tissue, an inflatable retractor and a surgical instrument are provided. The inflatable retractor has a flexible wall which may be expanded into place within the body, and includes a main inflation tube. The inflatable retractor is placed in a collapsed state adjacent to the organ, and is inflated to expand the flexible wall and to retract the organ. An aperture is cut in the flexible wall of the retractor to provide access to the tissue. The surgical instrument is passed from outside the body into the retractor through the main inflation tube, and is passed through the aperture to treat the tissue.

In a third method according to the invention for retracting an organ inside the body in the course of treating adjacent tissue, an inflatable retractor and a surgical instrument are provided. The inflatable retractor includes a flexible wall which may be expanded into place within the body. The flexible wall encloses a main chamber. The inflatable retractor is placed in a collapsed state adjacent to the organ, and is inflated to expand the flexible wall and to retract the organ. An aperture is pierced in the flexible wall of the retractor to provide access to the tissue. The surgical instrument is passed from outside the body into the main chamber. The tissue is pulled into the main chamber though the aperture, and the surgical instrument is used to treat the tissue.

In a fourth method according to the invention for retracting an organ inside the body in the course of treating adjacent tissue, there is provided an inflatable retractor, comprising a main envelope enclosing a main chamber, and an additional envelope attached to the main envelope. The additional envelope and part of the main envelope enclose an additional chamber. The inflatable retractor, in a collapsed state, is placed adjacent to the organ. The retractor is inflated to retract the organ. Finally, an aperture is pierced in a part of the main envelope, remote from the additional chamber, to provide access to the tissue.

In a fifth method according to the invention of retracting an organ inside the body in the course of treating adjacent tissue, an inflatable retractor, in a collapsed state, is placed adjacent to the organ. The retractor is inflated to retract the organ. An aperture is pierced in the retractor to provide access to the tissue. A surgical instrument is passed from outside the body into the retractor. The tissue is pulled into the retractor through the aperture. Finally, the surgical instrument is used to treat the tissue.

The present invention relates to an inflatable retraction device that mechanically retracts organs to provide access to treat tissues. More specifically, the invention is concerned with using a retraction device that retracts organs or tissues by means of an inflatable chamber. The

retraction device is introduced laparoscopically in a collapsed state into the body and, once in place, inflated to engage an extensive area of the organ to be retracted, and to gently retract or displace the organ without damaging it. During laparoscopic treatment procedures, a retraction device according to the invention retains its expanded condition, and hence its ability to provide retraction, while providing access for surgical instruments through itself to the tissue being or allowing a or tissue to be brought inside itself for treatment.

To provide the large surface area required to retract organs gently, the inflatable retraction device is relatively large. As a result, the retraction device is normally juxtaposed between the entry through which surgical instruments pass into the body and the tissue to be treated. The inflatable retraction device avoids obstructing the access of surgical instruments to the tissue to be treated by providing one or more apertures in the envelope of the device. Such apertures allow instruments to pass into and out of the interior of the retraction device, or allow the tissue to be treated to enter the interior of the retraction device for treatment by instruments passed into the interior of the device. Treatment is thus carried out working through or inside the retraction device according to the invention.

In those procedures in which the tissue to be treated enters the interior of retraction device through an aperture, the material of the retraction device surrounding the aperture may form a seal around the tissue, isolating it from the body outside the retraction device. Treatment of the tissue is carried out inside the retraction device.

Inflatable retraction devices employ different ways to retain their ability to provide retraction while providing access for surgical instruments to the tissue to be treated. One type of inflatable retraction device, such a retraction device being designated generally as a Type I retraction device, maintains its ability to provide retraction by means of an additional inflatable chamber, which forms a cage structure inside or outside the main inflatable chamber. The additional inflatable chamber is normally inflated after the main inflatable chamber of the retraction device has been inflated, and the retraction device has produced its desired retraction effect. Such an additional inflatable chamber is smaller and less powerful than the main inflatable chamber. Inflating the additional chamber alone would not always produce sufficient force to provide the desired retraction of the organ. However, the inflated additional chamber provides enough force to maintain an organ that has been retracted by the more powerful main inflatable chamber in its retracted position. The additional inflatable chamber is thus able to maintain the retraction effect of the retraction device after the retraction effect of the main inflatable chamber has been destroyed by piercing an aperture in the envelope of the main chamber to provide access to the tissue to be treated.

The tube used to inflate the main chamber provides primary access for surgical instruments to the interior of the retraction device. If more instruments than can be accommodated by the inflation tube are needed, or if the inflation tube is not conveniently aligned with the tissue to be treated, instruments can additionally or alternatively be inserted through additional incisions. The instruments-enter the retraction device through additional apertures in the envelope of the main chamber. The apertures are cut in the part of the envelope of the main chamber that does not form part of the additional inflatable chamber.

In a second type of inflatable retraction device, the ability of the retraction device to provide a retraction effect during the treatment or observation procedure is maintained by keeping the main chamber of the retraction device in an inflated state during the treatment procedure. Such a retraction device, designated generally as a Type II retraction device, does not require an additional inflation chamber to maintain its retraction effect. An elastomeric window is attached to the inside of the retraction device after the device has been inflated. The elastomeric window provides a gas-tight seal around instruments passed through it, and around a tissue brought into the interior of the retraction device through it.

After the window has been installed, an instrument is passed through the window to pierce an aperture in the part of the envelope of the retraction device covered by the window to provide access to the organ to be treated. Surgical instruments are passed into the interior of the retraction device, primarily through the main inflation tube. The instruments can pass out of the retraction device to the tissue to be treated through the elastomeric window and the aperture in the envelope of the main chamber. Alternatively, the tissue to be treated enters the interior of the retraction device through the aperture and the elastomeric window. The elastomeric window provides a seal around the tissue to be treated enabling the retraction device to be maintained in its inflated state while treatment is carried out.

A retraction device may be provided with tabs attached to the interior surface of the envelope of the device. The tabs are gripped with a suitable gripping tool to adjust the position and orientation of the inflated retraction device relative to the tissue to be treated. The retraction device may be partially deflated to enable adjustments to be more easily made.

A retraction device may be provided, when in its collapsed state prior to inflation, with markings on its surface to aid proper orientation prior to inflation.

A retraction device may further be provided with a flexible sheath for providing a port to allow surgical instruments to pass from outside the body to the main chamber of the retraction device. The interior of the flexible sheath communicates with the main chamber of the retraction device. The flexible sheath is deployed after the retraction device has been inflated. A flexible sheath attached to the envelope of the retraction device may be driven outward through the body wall. Alternatively, the flexible sheath may be driven inward through the body wall to pierce, and to lock into engagement with, the envelope of the retraction device.

The part of the retraction device that is lower-most when the retraction device is deployed in the body is fitted with an integral tubular suction skirt. The suction skirt is connected to the operating room suction line and allows continuous or intermittent drainage of fluid that collects in the bottom of the cavity created by the retraction device during laparoscopic surgery.

An inflatable retraction device is used according to the invention by forming a small opening in the wall of the body and laparoscopically inserting the retraction device into the body in a contracted state. After insertion and orientation, the retraction device is inflated. During the inflation process, the relatively large surface area of the retraction device gently retracts the organ obstructing access to the tissue to be treated.

After the retraction device has been inflated, surgical instruments are passed from outside the body into the retraction device. One or more apertures are created by piercing, and possibly at least partially removing, the envelope of the retraction device adjacent to the tissue to be treated. The one or more apertures in the envelope of the retraction device provide access for the instruments to the tissue to be treated. Treatment is then carried out by working through the one or more apertures in the retraction device. The apertures may also provide access to the interior of the retraction device for surgical instruments passed from outside the body. Alternatively, the tissue to be treated can enter the main chamber of the retraction device through the one or more apertures and be treated inside the retraction device.

After the treatment has been completed, the retraction device is deflated and evacuated prior to its removal from the body in a collapsed state.

When a inflatable retraction device is used in the abdominal cavity, it may be used alone to provide both retraction and lifting of the abdominal wall, or it may be used together with the abdominal lifting devices disclosed in the application Ser. No. 706,781, of which application this application is a continuation-in-part, or together with known insufflation techniques for lifting the abdomen.

The methods according to the invention form the basis of procedures for suturing hernias without breaching the peritoneum, anterior resection of herniated intervertebral discs, resecting the lung, lung lobectomies, and for procedures for observing or treating the heart, the brain, the esophagus, and the prostate.

These procedures involve placing an inflatable retraction device according to the invention inside a part of the body, such as the abdomen, the chest, or the skull via a small, limited incision or puncture site. The inflatable retraction device is placed adjacent to the organ to be displaced. Inflating the retraction device retracts the organ and exposes the tissue to be treated. Treatment of the tissue to be treated is then carried out using instruments passed into the interior of the retraction device. The tissue to be treated may remain outside the retraction device, or can enter the retraction device during treatment.

In a procedure according to the invention to repair a hernia by placing a mesh over the site of the hernia, an inflatable retraction device is used to provide retraction and, additionally, to hold the mesh in place over the site of the hernia while the mesh is stapled in place.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a polyhedral Type IA inflatable retraction device;

FIG. **2** is vertical cross section, along the line **2**—**2** in FIG. **1**, of a polyhedral Type IA inflatable retraction device;

FIG. **3** is horizontal cross section, along the line **3**—**3** in FIG. **1**, of a polyhedral Type IA inflatable retraction device;

FIG. **4A** is a longitudinal cross sectional elevational view of a body showing a packaged collapsed Type IA retraction device ready for insertion into the abdominal cavity in the method of the invention;

FIG. **4B** is a longitudinal cross sectional elevational view of a body showing a packaged collapsed Type IA retraction device after it has been inserted into the abdominal cavity in the method of the invention;

FIG. **4C** is a longitudinal cross sectional elevational view of a body showing a Type IA retraction device during the inflation of its main chamber in the abdominal cavity in the method of the invention;

FIG. **4D** is a longitudinal cross sectional elevational view of a body showing a Type IA retraction device after the additional chamber has been inflated and the inflation pressure has been removed from the main chamber in the abdominal cavity in the method of the invention;

FIG. **5** is a longitudinal cross sectional elevational view of a body showing a Type IA retraction device used to retract the bowel and lift the liver to expose the gall bladder for observation by an endoscope inserted into the main chamber of the retraction device through the main inflation tube;

FIG. **6** is a perspective view of a polyhedral Type II inflatable retraction device showing an elastomeric window attached to the inner surface of its main envelope;

FIG. **7** is a perspective view of an elastomeric window suitable for attaching to the inner surface of the main envelope of a polyhedral Type II inflatable retraction device. The elastomeric window includes an electrical element for heating temperature sensitive adhesive applied to one of the surfaces of the elastomeric window.

FIG. **8** is a perspective view of the elastomeric window of FIG. **7** packaged prior to insertion into the retraction device.

FIG. **9** is a perspective view of the outer surface of the main envelope of a polyhedral Type II inflatable retraction device. An elastomeric window has been attached to the inside of the main envelope and an aperture has been cut in the part of the main envelope covered by the elastomeric window.

FIG. **10A** is a longitudinal cross sectional elevational view of a body showing a packaged collapsed Type II retraction device invention ready for insertion into the abdominal cavity in the method according to the invention;

FIG. **10B** is a longitudinal cross sectional elevational view of a body showing a packaged collapsed Type II retraction device according to a second embodiment of the invention after it has been inserted into the abdominal cavity in the method of the invention;

FIG. **10C** is a longitudinal cross sectional elevational view of a body showing a Type II retraction device during the inflation of its main chamber in the abdominal cavity in the method of the invention;

FIG. **10C** is a longitudinal cross sectional elevational view of a body showing a Type II retraction device in its fully inflated condition in the abdominal cavity in the method of the invention;

FIG. **11A** is a transverse cross sectional elevational view of the abdomen showing a Type IB retraction device during the inflation of its main chamber in the abdominal cavity;

FIG. **11B** is a transverse cross sectional elevational view of the abdomen showing a Type IB retraction device in its fully inflated condition in the abdominal cavity;

FIG. **11C** is a perspective view of a Type IB retraction device showing an alternative form of additional cavity having tacked sidewalls.

FIG. **12A** is a vertical cross sectional view of a polyhedral inflatable retraction device fitted with a first

embodiment of flexible sheath installed in the abdominal cavity with the flexible sheath in its collapsed state..

FIG. **12B** is a vertical cross sectional view of a polyhedral inflatable retraction device fitted with a first embodiment of flexible sheath installed in the abdominal cavity showing the flexible sheath being driven through the abdominal wall.

FIG. **12C** is a vertical cross sectional view of a window of a polyhedral inflatable retraction device showing a second embodiment of a flexible sheath;

FIG. **13A** is a perspective view of a polyhedral Type IA inflatable retraction device fitted with a suction skirt;

FIG. **13B** is vertical cross section, along the line **2—2** in FIG. **1**, of a polyhedral Type IA inflatable retraction device fitted with a suction skirt;

FIG. **14A** is a longitudinal cross sectional elevational view of a body illustrating the use of a retraction device according to the invention in the abdomen to retract the bowel to gain anterior access to the intravertebral discs, the aorta, or the kidneys for treatment or observation.

FIG. **14B** is a transverse cross sectional elevational view of a body illustrating the use of a retraction device according to the invention in the abdomen to retract the bowel to gain anterior access to the intravertebral discs, the aorta, or the kidneys for treatment or observation.

FIG. **15** is a transverse cross sectional plan view of the chest illustrating the use of a retraction device to retract the pericardium from the heart to gain access to the surface of the heart for treatment or observation.

FIG. **16A** is a transverse cross sectional elevational view of the chest illustrating the use of a retraction device to retract the lung away from the pleura to gain access to the surface of the lung for treatment or observation.

FIG. **16B** is a transverse cross sectional plan view of the chest illustrating the use of a retraction device to retract the lung away from the pleura, part of the lung entering the main chamber of the retraction device for treatment or observation.

FIG. **17** is a longitudinal cross sectional elevational view of the chest illustrating the use of a retraction device to retract one lobe of the lung away from the rest of the lung to gain access to occlude part of the bronchial tree during a lobectomy.

FIG. **18** is a longitudinal cross sectional elevational view of the abdomen illustrating the use of a retraction device to retract the liver to gain access to the gastroesophageal junction prior to sectioning the vagus nerve or to treating gastroesophageal reflux.

FIG. **19** is a longitudinal cross sectional elevational view of the head illustrating the use of a retraction device to retract the brain away from the dura mater to gain access to the brain for treatment or observation.

FIG. **20A** is a transverse cross sectional elevational view of the lower abdomen illustrating the use of a retraction device between the abdominal wall and the peritoneum to retract the peritoneum to provide laparoscopic access to the site of a hernia without penetrating the peritoneum. A piece of mesh is shown being held in place over the site of the hernia by the retraction device.

FIG. **20B** is a transverse cross sectional elevational view of the lower abdomen showing a retraction device in its fully inflated condition holding a piece of mesh in position on the inside of the peritoneum over the site of the hernia.

FIG. **21** is a perspective view of a retraction device according to the invention with a piece of mesh attached to the outer surface of the main envelope.

FIG. **22A** is an exploded perspective view of the components of a polygonal Type IA retraction device illustrating the construction of such a device according to the invention.

FIG. **22B** is a plan view of the additional envelope blank of a polygonal Type IA retraction device.

FIG. **23A** is a perspective view of the additional envelope blank of a polygonal Type IA retraction device showing how a suction skirt is formed from the additional envelope blank.

FIG. **23B** is a plan view of the additional envelope blank of a polygonal Type IA retraction device showing how a suction skirt is formed from the additional envelope blank.

FIG. **24A** is an exploded perspective view of the components of a flat Type IA retraction device illustrating the construction of such a device

FIG. **24B** is a perspective view of the assembled and inflated flat Type IA retraction device.

FIG. **25A** is a perspective view of an inflated triangular prism-shaped Type IA retraction device.

FIG. **25B** is a vertical cross sectional view of an inflated triangular prism-shaped Type IA retraction device according to the invention along the line **25B—25B** in FIG. **25A**.

FIG. **25C** is an exploded perspective view of the components of a triangular prism-shaped Type IA retraction device illustrating the construction of such a device.

FIG. **25D** is a plan view of the additional envelope blank of a triangular prism-shaped Type IA retraction device.

FIG. **26** is an exploded perspective view of the components of a polygonal Type II retraction device illustrating the construction of such a device.

FIG. **27** is an exploded perspective view of the components of a substantially hemispherical Type IA retraction device illustrating the construction of such device.

FIG. **28** is a cross sectional view of a substantially hemispherical Type IA retraction device.

## DETAILED DESCRIPTION OF THE INVENTION

### A. Inflatable Retraction Devices

1. Type IA Retraction Device—Basic Embodiment

FIGS. **1**, **2**, and **3** show perspective, and vertical and horizontal cross sectional views, respectively, of a first embodiment **1** of a retraction device. This type of retraction device has an additional inflatable chamber and will be designated as a Type I retraction device. The Type I retraction device shown in FIGS. **1**, **2**, and **3** with a segmented additional chamber will be designated a Type IA retraction device. The retraction device is shown in its inflated condition. The retraction device **1** comprises a main envelope **6** enclosing a main inflatable chamber **11**. The main envelope **6** is made of a relatively inelastic and tough film of a plastic such as Mylar ®, polyethylene, or polyurethane. The preferred material for the main envelope **6** is a polyethylene and nylon composite. The thickness of the main envelope **6** is typically from 0.5 to 5 mils (13 to 130 microns). The proximal end of a main inflation tube **16** is sealed into the main envelope **6**. The main inflation tube **16** allows

an inflation gas to pass into and out of the main chamber **11**. The inflation gas is typically air, nitrogen or carbon dioxide, although other suitable gases may be used. Typical inflation gas pressures are in the range 0.3 to 0.7 pounds per square inch (psi) (0.21 to 0.48 kPa), the preferred pressure being 0.5 psi (0.35 kPa). The main inflation tube **16** is provided with a port **51** on its distal end, through which endoscopes and/or surgical instruments can be passed into the main chamber **11**. The port **51** allows the inflation pressure of the main chamber **11** to be maintained when surgical instruments are passed through the port.

The main envelope **6** of the Type IA retraction device is a polyhedral structure constructed from two segmented, substantially flat pieces of plastic film, which gives the retraction device a substantially polyhedral shape. Alternatively, two non-segmented, substantially flat pieces of plastic film can be used to make a relatively flat Type IA retraction device. In a further alternative, the retraction device can be constructed from curved pieces of plastic film, which gives the retraction device a substantially spherical, spheroidal, or ellipsoidal shape.

The size of retraction device can range from about 2" (50 Mm) wide by about 0.5" (12 mm) high, for use inside the pericardium, to 10"-14" (250-350 Mm) wide by 4"-8" (100-200 mm) high, for use in the abdominal cavity. The size of retraction device required for a given application depends on the application and the size of the patient.

In the preferred embodiment, the additional envelope **21** is made from a film of the same thickness of the same plastic as the main envelope **6**. However, in some applications it may be advantageous make the additional envelope **21** from a film of a different thickness of the same plastic, or the same or a different thickness of a different plastic.

The periphery **26** of the additional envelope **21** is attached to the surface of the main envelope **6**. The additional envelope **21** has a segmented shape such that, when its periphery **26** is attached to the main envelope **6**, and the additional chamber **31** formed between the outside of the main envelope **6** and the inside of the additional envelope **21** is inflated, the additional chamber **31** forms a cage structure inside or outside the main chamber **11**, as shown in the figures. When the main envelope **6** is a polyhedral structure, the cage structure is preferably formed on the faces of the polyhedron. The parts of the main envelope **6** that do not form part of the wall of the additional chamber **31** provide a plurality of windows **46** that can be punctured to provide access for surgical instruments into and out of the main chamber **11**.

The additional envelope **21** is attached, preferably to the outer surface of the main envelope **6**, by welding along the periphery **26** of the additional envelope; alternatively, an adhesive may be applied to the periphery **26** of the additional envelope **21**, and the additional envelope **21** brought into contact with the main envelope **6**. Other methods that produce a flexible, gas-tight seal between the periphery **26** of the additional envelope **21** and the main envelope **6** may also be used.

One end of an additional inflation tube **41** is sealed into the additional envelope **21**. The additional inflation tube **41** allows an inflation gas to pass into and out of the additional chamber **31**. The inflation gas is typically air, nitrogen or carbon dioxide, although other suitable gases may be used. Typical inflation gas pressures are in the range 4 to 6 psi (2.8 to 4.1 kPa), the preferred pressure being 5 psi (3.5 kPa). The inflation gas pressure in the additional chamber is considerably higher than that in the main chamber to enable the additional chamber to exert sufficient force to keep already retracted organs in their retracted state despite the much smaller surface area of the additional chamber. The main inflation tube **16** is sealed through the additional envelope **21**.

In an embodiment of the Type I retraction device designed for use in an insufflated body cavity, the main inflation tube **16** and the additional inflation tube **41** are contained within an inflation tube shield **61**, which forms a gas-tight seal with the retraction device. The outer wall of the inflation tube shield **61** forms a gas-tight seal with the trocar or sheath through which it passes into the body cavity. The inflation tube shield **61** can be a separate component. Preferably, an extrusion can provide the inflation tube shield **61**, the main inflation tube **16** and the additional inflation tube **41** in a unitary structure.

2. Type IA Retraction Device—Alternative Embodiments

The basic embodiment of a Type I retraction device has a single additional chamber **31**. In alternative embodiments, additional chamber **31** is divided into a plurality of sub-chambers (not shown). The sub-chambers are isolated from one another, so that if one or more of them is accidentally punctured while the retraction device is in use, deflation of all of the retraction device can be avoided. Each sub-chamber can be equipped with its own additional inflation tube. Alternatively, each sub-chamber can be connected to an inflation manifold (not shown) through a non-return valve (not shown). This arrangement requires that each sub-chamber be deliberately punctured to deflate the retraction device in preparation for withdrawing the retraction device from the body at the end of the treatment procedure.

In a further alternative embodiment of the Type IA retraction device, the additional envelope **21** may be attached to the inner surface of the main envelope **6**. In this embodiment, the main inflation tube **16** passes through the additional chamber and forms a gas-tight seal with the additional envelope **21** in addition to the main envelope **6**.

In a further alternative embodiment of the Type IA retraction device, the additional envelope **21** need not be segmented. The additional chamber **31** is formed by attaching the additional envelope **21** to the main envelope **6**, the line of attachment forming the periphery of the cage structure of the additional chamber **31**. With this arrangement, each window **46** comprises a double thickness of film. This makes it somewhat more difficult to cut an aperture in a window.

In a further alternative embodiment providing a relatively flat Type IA retraction device shown in FIG. **24B**, neither the main envelope **6** nor the additional envelope **21** are segmented. The additional envelope **21** has a number of holes cut in it. The additional chamber **31** is formed by attaching the periphery of each hole in the additional envelope **21** to the main envelope **6**.

In a further alternative embodiment, figures **25A**, **25B**, **25C**, and **25D** show a Type IA retraction device in the shape of a triangular prism particularly suitable for use in the upper abdomen. In this embodiment, the main envelope **6** and the additional envelope **21** are serrated rectangles, as shown in FIGS. **25C** and **25D**. The additional envelope has three large holes cut in it. The addi-

tional chamber **31** is formed by attaching the periphery of each hole in the additional envelope **21** to the main envelope **6**. Opposite ends of the long axis of the rectangle and the serrations are joined together to form the triangular structure.

All embodiments of the Type IA retraction device may be provided with tabs **56** on the inside the main envelope as shown in FIGS. **2** and **3**. The tabs **56** may be separate components attached to the inside of the main envelope **6** by welding, an adhesive, or some other suitable method. Alternatively, the tabs **56** can be an integral part of the main envelope **6** suitably extended into the main chamber **11**. Tabs **56** provide points inside the main chamber **11** that can be gripped by a suitable gripping tool (not shown) inserted into main chamber **11** through the main inflation tube **16**. The gripping tool allows the inflated retraction device to be manipulated to change its position so that, for instance, one of its windows can be aligned with the organ or tissue to be treated or observed. Partially deflating the inflated retraction device makes repositioning easier.

3. Type IA Retraction Device—Basic Method of Use

In the following description, the word "organ" will be used to mean an organ or a tissue that is retracted by the retraction device. The word "treat" will be used to mean both treat and observe, and the word "treatment" will be used to mean both treatment and observation. The word "tissue" or the phrase "tissue to be treated" will both be used to mean the organ or the tissue that is treated through or inside the retraction device.

FIGS. **4A** through **4D** show a cross sectional elevational view of the abdomen A to illustrate the method according to the invention by which a Type IA retraction device is inserted into the body and used to retract an organ within the body to gain access to treat a tissue. In the method illustrated in FIGS. **4A** through **4D**, the retraction device is inserted into the abdomen A and is used to retract an organ, the bowel B, to gain access to treat a tissue, the gall bladder GB. Similar methods are used to insert a retraction device into other parts of the body.

Inflatable retraction device **1** is supplied in a collapsed state, as shown in FIG. **4A**, in which it is tightly packaged in a configuration that makes it essentially a linear extension of the inflation tube shield **61**. The retraction device **1** is packed so that when pressure is applied to the main inflation tube **16**, the retraction device **1** deploys without tangling. Depending on the size of the retraction device **1**, the packaged retraction device will fit through an insertion tube (usually a trocar tube) of between 3 and 20 mm (0.12"–0.8") in diameter, a typical diameter being 14 mm (0.55"). The retraction device **1** is retained in its collapsed state by the sleeve **100** which, in turn, is held together by one-pull lacing **105**. Alternatively, the sleeve **100** can be fitted with a tear-off strip (not shown). Pulling on the thread **125** detaches the one-pull lacing **105** or the tear-off strip from the sleeve **100**, releasing the collapsed retraction device **1**.

The sleeve **100** can be provided with suitable markings **115** to enable its orientation to be determined and, if necessary, adjusted, after insertion into the body and before inflation.

Prior to starting the procedure, the abdomen A may be lifted to provide additional working space by gas insufflation, or by one of the mechanical devices disclosed in U.S. patent application Ser. No. 706,781, of which application this application is a continuation-in-part. The insufflated condition of the abdomen A is indicated by the broken line A'.

A small incision is made in the skin of the abdomen A and a trocar (not shown) and trocar tube **120** are inserted into the incision and are driven through the wall of the abdomen A. The trocar is withdrawn. A second small incision is made in the skin of the abdomen A and a trocar (not shown) and trocar tube **122** are inserted into the incision and driven through the wall of the abdomen. The trocar is withdrawn and an endoscope **110** is inserted into the trocar tube **122**. The second incision is located so that the endoscope **110** can observe the intended placement site of the retraction device **1**. Alternatively, a small endoscope (not shown), preferably about 2 Mm (0.1") in diameter, may be attached to the collapsed retraction device so that the location of the retraction device inside the abdomen may be determined. With thin approach, the endoscope **110** is not used, and the second incision need not be made.

The collapsed retraction device **1** is threaded, with the aid of its inflation tube shield **61**, through the trocar tube **120** into the abdominal cavity AC, as shown in FIG. **4B**, and manipulated into its correct position. The position of collapsed retraction device **1** in the abdominal cavity AC is observed through the endoscope **110**: the markings **115** enable the orientation of retraction device **1** to be determined and adjusted if necessary. Alternatively, the position of the collapsed retraction device is determined by means of the small endoscope (not shown) attached to the retraction device.

The thread **125** is then pulled to release the sleeve **100** from around collapsed retraction device **1**, and the sleeve **101** is withdrawn from the abdominal cavity AC through the trocar tube **120** by means of the thread **125**.

Once the retraction device **1** is correctly positioned, and released from its sleeve **100**, the main inflation tube **16** is connected to a source of inflation gas (not shown) and the gas supply is slowly turned on to inflate the main chamber **11**. The retraction device **1** slowly expands, as shown in FIG. **4C**, progressively displacing the bowel B as its size increases. Throughout the expansion process, the retraction device **1** presents a relatively large surface area to the bowel B, and thus displaces the bowel B gently, progressively, and without trauma. Although the retraction device **1** retracts the bowel B gently, the main chamber of the retraction device is capable of exerting the force necessary to effect the displacement the bowel B.

Once the retraction device **1** has reached its fully-inflated condition, its position is checked by viewing it through the endoscope **110** and/or an endoscope (not shown) inserted into its main chamber **11** via the main inflation tube **16** and the port **51**. The tissue to be treated must be covered by one of the windows **46** of retraction device **1**.

If the retraction device **1** is not correctly positioned, the inflation gas pressure is reduced slightly to partially deflate retraction device **1**. A suitable gripping tool is passed through the port **51** and the main inflation tube **16** into the interior of the retraction device **1**, to grip one of the tabs **56** (FIGS. **2** and **3**). The gripping tool is manipulated to correct the positioning error while the position of the retraction device **1** is observed through the endoscope **110** or the endoscope (not shown) in the main chamber **11**. Once the error is corrected, the main chamber **11** of the retraction device **1** is reinflated by means of the main inflation tube **16**.

Once the retraction device **1** is correctly positioned, the additional inflation tube **41** is connected to a source of inflation gas (not shown) and the additional chamber **31** is inflated to the required pressure, as shown in FIG. **4D**. After the additional chamber **31** is fully inflated, the source of inflation pressure can be removed from the main chamber **11** and the main inflation tube **16**. The port **51** can be removed from the main inflation tube **16** since a gas-tight seal is no longer required around instruments inserted into the main inflation tube **16**, the main chamber **11** now being at atmospheric pressure.

A cutting instrument **52** is then passed through the main inflation tube **16** into the main chamber **11** to cut a suitable aperture **54** in the window **46** that covers of the tissue to be treated, as shown in FIG. **5**. Alternatively, an additional puncture may be made in the abdominal wall and a cutting instrument **62** passed through this puncture to cut an aperture **54A** in a window **58** to gain access to the main cavity **11**, and thence to cut a suitable aperture **54** in the window **46**. The aperture **54** provides an access to the tissue to be treated; for example, the gall bladder GB. The aperture **54** may simply be a cut in the window **46**, or all or part of the window **46** may be removed to provide the aperture **54**. Those procedures that are carried out using instruments passed through the aperture **54** in the window **46** require that more of the window **46** be removed than those procedures in which the tissue to be treated is pulled inside the retraction device. When the tissue to be treated is treated inside the retraction device, the periphery of the aperture **54** through which the tissue is pulled may form a seal around the tissue and isolate it from the body outside the retraction device.

If the main inflation tube is not conveniently placed relative to the tissue to be treated, or if more surgical instruments than can be accommodated by the main inflation tube **16** are needed to perform the treatment, an alternative way of passing instruments into the main chamber **11** is to make at least one further incision in the body wall, the further incision being made in a location adjacent a further window **58** of the retraction device, as shown in FIG. **5**. A trocar (not shown) with tube **60** is inserted into the further incision and is driven through the body wall to pierce the further window **58**. The trocar is withdrawn leaving the trocar tube **60** in place. Instruments, e.g., instrument **62** are then inserted into the retraction device as required through the trocar tube **60** and the further window **58**.

FIG. **5** additionally shows the retraction device **1** in place in the abdominal cavity AC in its fully inflated form. The main chamber **11** is not pressurized; the shape of the retraction device is maintained by the inflated additional chamber **31**. In FIG. **5**, retraction device **1** was placed before inflation such that when the main chamber **11** was inflated, the expansion of the retraction device **1** displaced the bowel B to the right of the drawing and lifted the liver L upwards to expose the tissue to be treated, i.e., the gall bladder GB.

After the treatment is completed, the additional chamber **31** is disconnected from the source of inflation pressure and the pressure in the additional chamber **31** is released to collapse the retraction device. Collapsing the retraction device is assisted by connecting the additional inflation tube **41** to a vacuum line (not shown) to evacuate the additional chamber **31**. Once the retraction device **1** is fully collapsed, the trocar tube **120** is withdrawn from the abdominal cavity, the retraction device **1** is withdrawn through the small abdominal opening, and the openings in the abdominal wall are closed in the normal way.

4. Type II Retraction Device—Basic Embodiment

FIG. **6** shows an alternative embodiment **201** of a retraction device that maintains its shape while allowing treatment to be carried out working through or inside it. The alternative embodiment lacks the second inflatable chamber of the Type I embodiment shown in FIGS. **1** through **5**, and has only a main envelope **206** enclosing a main chamber **211**. The single chamber embodiment of the retraction device will be designated as a Type II retraction device. The main chamber **211** remains inflated throughout the treatment process, access to the tissue to be treated being provided by an elastomeric window **261** attached to the main envelope **206**. The elastomeric window **261** is self-sealing and maintains inflation pressure in the main chamber **211** by forming a substantially gas-tight seal around instruments passed through it. The elastomeric window **261** also forms a substantially gas-tight seal around the tissue to be treated if the tissue to be treated is pulled through the elastomeric window **261** into the main chamber **211** for treatment.

The main envelope **206** is made of a relatively inelastic and tough film of a plastic such as Mylar ®, polyethylene, or polyurethane. The preferred material for the main envelope is a polyethylene and nylon composite. The thickness of the main envelope **206** is typically from 0.5 to 5 mils (13 to 130 microns). The proximal end of a main inflation tube **216** is sealed into the main envelope **206**. The main inflation tube **216** allows an inflation gas to pass into and out of the main chamber **211**. The inflation gas is typically air, nitrogen or carbon dioxide, although other suitable gases may be used. Typical inflation gas pressures are in the range 0.3 to 0.7 psi (0.21 to 0.48 Pa), the preferred pressure being 0.5 psi (0.35 kPa). Once the main chamber **211** is fully inflated, the inflation gas pressure can be reduced to about 0.3 psi (0.21 kPa). The main inflation tube **216** is provided with a port **251** on its distal end, through which endoscopes and other surgical instruments can be passed into the main chamber **211**. The port **251** provides a gas-tight seal around instruments passed through it and allows inflation pressure to be maintained in the main chamber **211** with instruments present.

The main envelope **206** of the Type II retraction device shown in FIG. **6** is a polyhedral structure constructed from two segmented, substantially flat pieces of plastic film, which gives the retraction device a substantially polyhedral shape. Alternatively, two non-segmented substantially flat pieces of plastic film can be used to make a relatively flat Type II retraction device. In a further alternative, the retraction device can be constructed from curved pieces of plastic film, which gives the retraction device a substantially spherical or spheroidal shape.

The size of Type II retraction devices can range from about 2" (50 Mm) wide by about 0.5" (12 mm) high, for instance for use inside the pericardium, to 10"–14" (250–350 Mm) wide by 4"–8" (100–200 mm) high, for use in the abdominal cavity. The size of retraction device required for a given application depends on the application and the size of the patient.

The lack of a additional chamber in the retraction device **201** shown in FIG. **6** makes orientation less critical. If the main envelope **206** is constructed from one or two curved pieces of film, orientation is particularly uncritical. If the main envelope **206** is a polyhedral

structure having a number of faces, some orientation is required because the tissue to be treated must be substantially centered on one of the faces. The retraction device **201** can be provided with tabs **256** on the inside the main envelope **206**. Tabs **256** may be separate components attached to the inside of the main envelope **206** by welding, an adhesive, or some other suitable method. Alternatively, tabs **256** can be an integral part of the main envelope **206** suitably extended into the main chamber **211**. Tabs **256** provide points on the inside of the main chamber **211** that can be gripped by a suitable gripping tool (not shown) inserted into main chamber **211** through the inflation tube **216** and port **251**. The gripping tool allows the inflated retraction device **201** to be manipulated to change its position so that the desired point on the tissue to be treated can be substantially centered on one of its faces. Partially deflating the inflated retraction device makes repositioning easier.

The elastomeric window **261** is installed on the inside of the main envelope **206** after the retraction device **201** has been placed in the body and inflated. The elastomeric window **261** is shown in FIG. **7** and comprises a flat piece **266** of a film of an elastomeric material such as latex or silicone rubber about 0.5" to 1.5" (12 to 37 Mm) in diameter. The periphery of the elastomeric film **266** is attached by means of a suitable adhesive, such as an acrylic cement or a silicone adhesive to one of the flat faces of a ring **271** having a square cw rectangular cross section. The ring **271** is circular or elliptical in shape and is of a springy material such as polyethylene or stainless steel, so that will regain its circular or elliptical shape after being compressed across one of its diameters to enable it to be passed through the inflation tube **216**. The other flat face **276** of the ring **271** is coated with an adhesive. A pressure-sensitive adhesive such as a contact rubber adhesive may be used. In the preferred embodiment a hot-melt adhesive of the type used in woodworking glue guns is used. If a hot-melt adhesive is used, a heating element **281**, made of a suitable resistance wire, such as Nichrome, is inserted into a narrow groove in the face **276** of the ring **271** to which the adhesive is applied. Suitable electrical leads **291** are connected to the heating element **281**.

Before it can be inserted into the retraction device **201**, the elastomeric window must be wrapped across one of its diameters to reduce its width so that it can pass through the main inflation tube **216**, as shown in FIG. **8**. A one-pull lacing arrangement **205**, or a sleeve with a tear strip (not shown) can be used. Wrapped elastomeric window **261** is attached to a manipulation rod **286** for insertion into the retraction device. Also attached to the manipulation rod is the thread **225** to release the one-pull lacing **205** or the tear strip (not shown) and, if a temperature-sensitive adhesive is used, the electrical leads **291** for the heating element **281** (FIG. **7**).

The wrapped elastomeric window **261** on the end of the manipulating rod **286** is passed through the port **251** and the main inflation tube **216** into the main chamber **211**. The lacing **205** or tear-strip is released, which allows the elastomeric window **261** to resume its circular shape. The elastomeric window **261** is then manipulated to bring it into contact with the main envelope **206** such that the elastomeric window **261** covers the tissue to be treated. If a pressure-sensitive adhesive is used, the face **276** of the elastomeric window is pushed against the main envelope **206** to affix the elastomeric window **261** in place. If a hot-melt adhesive is used, the face **276** of the elastomeric window is placed against the main envelope **206** and a suitable source of electric current (not shown) is applied to the electrical leads **291** for the time required to melt the adhesive and affix the elastomeric window **261** to the main envelope **206**.

Once the elastomeric window **261** is firmly affixed to the main envelope **206**, the manipulating rod **286** is detached from it and withdrawn from the main chamber **211**. A suitable cutting instrument **252** is passed through the port **251** and the main inflation tube **216** into the main chamber **211** and through the elastomeric window **261**, as shown in FIG. **6**. The elastomeric window **261** forms a gas-tight seal around the cutting instrument **252**, and re-seals itself after the cutting instrument **252** is withdrawn. The cutting instrument **252** is used to cut an aperture in the part **296** of the main envelope **206** that is covered by the elastomeric window **261**. The part **296** of the main envelope **206** is shown by shading in FIG. **9**. The aperture **254** may simply be a cut in the part **296** of the envelope **206**, or all or part of the part **296** of the envelope **206** may be removed to provide the aperture **254**. Procedures that are carried out using instruments passed through the elastomeric window **261** require removing more of the part **296** of the envelope **206** than procedures in which the tissue to be treated enters the retraction device through the aperture **254** and the elastomeric window **261**. When the tissue to be treated is treated inside the retraction device **201**, the elastomeric window **261** forms a seal around the tissue and isolates it from the body outside the retraction device. The treatment procedure is then carried out by inserting instruments through the port **251** and the main inflation tube **216** into the main chamber **211** and either working through the elastomeric window **261** or working on the tissue to be treated inside the cavity **211**.

5. Type II Retraction Device—Basic Method of Use

In the method according to the invention of using a Type II retraction device to retract an organ, the retraction device **201** is inserted into the abdomen using a procedure similar to that used to insert a Type IA retraction device. Inflatable retraction device **201** is supplied in a collapsed state, as shown in FIG. **10A**, in which it is tightly packaged in a configuration that makes it essentially a linear extension of the main inflation tube **216**. The retraction device **201** is packed so that when inflation pressure is applied to the main inflation tube **216**, retraction device **201** deploys without tangling. Depending on the size of the retraction device **201**, the packaged retraction device will fit through an insertion tube of between 3 and 20 Mm (0.12"–0.8") in diameter, a typical diameter being 14 mm (0.55"). The retraction device **201** is retained in its collapsed state by a sleeve **10D** which, in turn, is held together by one-pull lacing **105** or a tear strip (not shown).

The sleeve **100** can be provided with suitable markings **115** to enable its orientation to be determined and, if necessary, adjusted, after insertion into the abdomen and before inflation.

Prior to inserting the retraction device, the abdomen A may be lifted to provide additional working space by gas insufflation, or by one of the mechanical devices disclosed in U.S. patent application Ser. No. 706,781, of which application this application is a continuation-in-part. The insufflated state of the abdomen A is indicated by the broken line A'.

A small incision is made in the skin of the abdomen A and a trocar (not shown) and trocar tube **120** are inserted into the incision and are driven through the wall

of the abdomen A. The trocar is withdrawn. A second small incision is made in the skin of the abdomen A and a trocar (not shown) and trocar tube **122** are inserted into the incision and driven through the wall of the abdomen. The trocar is withdrawn and an endoscope **110** is inserted into the trocar tube **122**. The second incision is located so that the endoscope **110** can observe the intended placement site of the retraction device **1**. Alternatively, a small endoscope (not shown), preferably about 2 mm (0.1") in diameter, may be attached to the collapsed retraction device so that the location of the retraction device inside the abdomen may be determined. With this approach, the endoscope **110** is not used, and the second incision need not be made.

The collapsed retraction device **201** is threaded, with the aid of its main inflation tube **216**, through the trocar tube **120** into the abdomen A, and manipulated into its correct position. The position of collapsed retraction device **201** is observed through the endoscope **110**: the markings **115** enable the orientation of the retraction device to be determined and adjusted if necessary. Alternatively, the position of the collapsed retraction device is determined by means of the small endoscope (not shown) attached to the retraction device.

The thread **125** is then pulled to release the sleeve **100** from around the collapsed retraction device **201**, as shown in FIG. **10B**, and the sleeve **100** is withdrawn from the abdominal cavity AC through the trocar tube **120** by means of the thread **125**. The main inflation tube **216** is connected to a source of inflation gas (not shown). The inflation gas pressure is slowly increased to inflate the main chamber **211**. The retraction device **201** slowly expands, progressively displacing the bowel B as its size increases, as shown in FIG. **10C**. Throughout the expansion process, the retraction device **201** presents a relatively large surface area to the bowel B, and thus displaces the bowel gently, progressively, and without trauma. Although the retraction device **201** retracts the bowel B gently, the main chamber of the retraction device **201** is capable of exerting the force necessary to effect the displacement of the bowel.

Once retraction device **201** has reached its fully-inflated condition, its position is checked by viewing it through either the endoscope **110** and/or an endoscope (not shown) inserted into the main chamber **211** of the retraction device **201** via the port **251** and the main inflation tube **216**. The tissue to be treated should be in contact with the main envelope **206** and lie substantially directly in line with the main inflation tube **216**. Further, if the retraction device is a polyhedron, the tissue to be treated should be substantially centered in one of its faces. The position of the retraction device **201** can be adjusted by gripping one or more of the tabs **256** with a suitable gripping tool (not shown), as described above. Once the retraction device **201** is correctly positioned, the elastomeric window **261** may be installed as described above. FIG. **10D** shows the retraction device **201** in its fully inflated state with the elastomeric window **261** installed, and the instrument **252** passed through the elastomeric window **261** and the aperture **254** in the main envelope **206** to treat the tissue to be treated, the gall bladder, GB.

After the treatment is completed, the main chamber **211** is disconnected from the source of inflation pressure and the pressure in the main chamber **211** is released to collapse the retraction device. Collapsing the retraction device is assisted by connecting the main inflation tube **216** to a vacuum line (not shown) to evacuate the main chamber **211**. Once fully collapsed, the retraction device **201** is withdrawn from the abdominal cavity through the opening in the abdominal wall that remains after withdrawing the trocar tube **120**. The elastomeric window **261** is sufficiently flexible to be withdrawn through the opening in the abdominal wall along with the retraction device **201**. The openings in the abdominal wall are then closed in the normal way.

6. Type IB Retraction Device

A variation on the Type I retraction device, designated Type IB, is shown in FIGS. **11A**, **11B**, and **11C**. This variation has the advantage of providing two large, flat windows, but has the disadvantage that it does not allow any access to tissues lying to the side of the retraction device. The retraction device **301** shown in FIGS. **11A** and **11B** is substantially cylindrical in shape. A stack of one or more toroidal chambers forms the additional chamber **331**. The example shown in FIGS. **11A** and **11B** has **3** toroidal chambers **325**, **327** and **329**. Alternatively, as shown in FIG. **11C**, a single chamber having sidewalls **333** that are tacked together can be used for the additional chamber **331**. In this alternative embodiment, the tacked sidewalls form an enclosure having a height that is considerably greater than its width. In FIGS. **11A**, **11B**, and **11C**, the diaphragms **307** and **309** cover the top and bottom, respectively, of the retraction device **301**. The diaphragms **307** and **309**, together the inner walls of the toroidal chambers **325**, **327**, and **329**, form the main chamber **311**.

The main inflation tube **316** is sealed into the main chamber **311** and allows the main chamber to be inflated. The additional inflation tube **341** is sealed into the additional chamber **331**. If more than one toroidal chamber is used to provide the additional chamber, the toroidal chambers may be interconnected and a single additional inflation tube **341** used, or each toroidal chamber may be provided with its own additional inflation tube (not shown). The latter approach prevents the retraction device **301** from collapsing completely if one of the toroidal chambers **325**, **327**, or **329** is accidentally punctured, and also allows the height of the retraction device to be adjusted by selectively inflating the toroidal chambers **325**, **327**, or **329**.

The Type IB retraction device shown in figures **12** and **13** is constructed from similar materials to the Type IA retraction device, and may be fitted with tabs **356**, similar to tabs **56** in the Type IA retraction device, to enable it to be properly positioned after inflation. A similar procedure is used to deploy the Type IB retraction device in the body as is used to deploy the Type IA retraction device, and will not be described in detail. A similar inflation procedure is used, except that the additional chamber may be inflated at least partially at the same time as the first cavity is inflated. The Type IB retraction device depends more for its shape on the additional chamber than the Type IA retraction device. Hence, at least partial inflation of the additional chamber is necessary to enable the retraction device to displace organs to the side of the retraction device. Inflation pressures similar to those used for the Type IA retraction device are used.

Treatment procedures using the Type IB retraction device are similar to those using the Type IA retraction device, except that the Type IB retraction device does not provide access to tissues to the side of the device. The diaphragms **307** and **309** are analogous to the windows **46** (FIG. **1**) of the Type IA retraction device.

Either or both of the windows provided by the diaphragms **307** and **309** may be pierced to provide apertures though which treatment may be carried out, or through which the tissue to be treated may be brought into the retraction device for treatment, or through which instruments may be passed into and out of the main chamber **311**.

7. Flexible Sheaths

Retraction devices may be provided with one or more flexible sheaths to interconnect the main chamber of the retraction device and the outside of the body into which the retraction device is inserted. The flexible sheath provides a tract through the body wall that allows additional surgical instruments or endoscopes to be introduced into the main chamber of the retraction device, and/or allows tissue and the like to be removed. In one embodiment, the flexible sheath is attached to a window of a Type I retraction device or to the main envelope of a Type II retraction device. FIG. **12A** shows a flexible sheath attached to a window **46** of a Type IA retraction device **1**, which is shown as an example. A flexible sheath can also be used with Type IB and Type II retraction devices. The flexible sheath **3** is substantially cylindrical in shape with a closed distal end **8**. The proximal end **13** of the flexible sheath is attached to the outer surface of the window **46**. The sidewall **18** of the flexible sheath **3** is folded concertina-style when the retraction device is packaged, and remains folded after the retraction device has been inflated. After the retraction device **1** has been deployed in the body, as shown in FIG. **12B**, a suitable pointed tool **23** is fed into the main chamber **11** to pierce a hole **28** in the part of the window **46** that is covered by the flexible sheath **3**. The pointed tool **23** is pushed through the hole **28** to engage with the distal end **8** of the flexible sheath **3**. The distal end **8** is first pressed against the inner surface of the body wall W using the pointed tool **23**. The resulting bulge in the skin S on the outside of the body indicates where the flexible sheath **3** will emerge. A small incision **33** is made in the skin S at that point. The flexible sheath **3** is then driven by the pointed tool **23** through the body wall W to emerge through the incision **33**.

With a Type I retraction device, the distal end **8** of the flexible sheath **3** is then opened to provide access to the main chamber **11**. The flexible sheath does not have to be gas-tight in the manner of conventional trocar sheaths, and permits ordinary surgical instruments to be used.

With a Type II retraction device, the flexible sheath is fitted with a gas-tight port similar to the port **251** (FIG. **6**) before the distal end **8** is opened.

The alternative embodiment of a flexible sheath **43**, shown in FIG. **12C**, is not initially attached to the retraction device. A Type IA retraction device **1** is shown in FIG. **12C** as an example. This flexible sheath can also be used with Type IB and Type II retraction devices. The flexible sheath **43** comprises a cylindrical piece of flexible plastic **48** with a coaxial locking device **53** on its proximal end. The distal end of the flexible sheath for a Type II retraction device must be closed by a port (not shown) similar to the port **251** (FIG. **6**) so that pressurization of the main cavity can be maintained after the flexible sheath **43** has been installed.

The flexible sheath **43** is installed after the retraction device **1** has been deployed in the body. A small incision **58** is made in the skin S of the body. The flexible sheath **43** is then driven through the body wall W by a sharp trocar point (not shown). The trocar point pierces a hole **63** in the window **46** of the retraction device **1**, and pushes the locking device **53** of the flexible sheath **43** through the hole **63** to engage the locking device **53** with the window **46**. When used with a Type II retraction device, the locking device **53** forms a gas-tight seal with the window **46**.

8. Suction Skirt

Retractor devices may be fitted with a tubular suction skirt on the part of the retraction device that is lowermost when the retraction device is deployed in the body. FIGS. **13A** and **13B** show, as an example, a polygonal Type IA retraction device of the type used in the abdominal cavity. The suction skirt can be used with other type I and type II retraction devices.

Irrigation is often used during surgery to clear away bleeding or blood clots. This fluid collects in the bottom of the cavity in the body created by the retraction device and needs to be cleared away. The suction skirt **12** on the bottom of the retraction device is connected to a suction line and removes such fluid during the treatment procedure, keeping the cavity clear of accumulated fluids. In the example shown, the suction skirt is a tubular appendage attached to the lower-most extremity of the retraction device. In the retraction device shown in FIGS. **13A** and **13B**, the suction skirt is formed from part of the additional envelope **21** around the bottom window **46**. The bottom or sides of the suction skirt is pierced with between six and twelve holes **17**. In the embodiment shown, the suction skirt is about $\frac{1}{4}$" (6.2 mm) in diameter, and the holes **17** are about $\frac{1}{8}$" (3.1 mm) in diameter.

The suction skirt is made of the polyethylene-nylon composite that is the preferred material for the main envelope **6** of the retraction device. This material is sufficiently resilient that a tubular structure made from it can retain its open cross section under a low vacuum. One end of the suction skirt is closed; the other is connected to a thin-wall polyethylene tube **22** that runs up the side of the retraction device to exit the body through the same incision as is used for the inflation tubes. If, as is shown in FIGS. **13A** and **13B**, the retraction device is used in an insufflated body cavity, the suction skirt tube **22** passes inside the inflation tube sheath **61**. The distal end of the suction skirt tube **22** has attached to it a connector suitable for attaching to an operating room suction line.

B. Surgical Procedures Using Inflatable Retraction Devices

1. Retracting the Bowel to Provide Anterior Access to the Spine, the Aorta, the Kidneys, etc.

The method according to the invention of using a retraction device in a procedure to perform an anterior resection of a herniated intervertebral disc is illustrated in FIG. **14**. A method can be adapted to gain anterior access to the aorta, the kidneys, and other tissues that lie outside the peritoneum. FIG. **14A** shows a longitudinal cross section of the body; and figure **14B** shows a transverse cross section along the line **14B—14B** in FIG. **14A**. Anterior access to the spine is normally difficult due to the difficulty of retracting the overlying bowel using conventional laparoscopic retractors. A Type I or a Type II retraction device is used according to the invention to retract the bowel by forming a small incision **420** in the abdominal wall W and inserting a trocar (not shown) with trocar tube **430** into the incision **420** and driving the trocar into the abdominal cavity AC.

The trocar is removed and the retraction device **401** is passed through the trocar tube **430** into the abdominal cavity AC in its contracted state with the aid of its inflation tube or inflation tube shield (the inflation tube shield **461** of a Type IA retraction device is shown). After insertion and orientation, the main chamber **411** of the retraction device **401** is inflated with a suitable inflation gas passed though inflation tube **416**. During the inflation process, the relatively large surface area of the main chamber **411** of the retraction device gently retracts the bowel B, either upwards or downwards, depending on the position of the disc to be treated. The positioning of the retraction device is checked and adjusted, if necessary, as previously described.

If a Type I retraction device is used, it must be positioned such that the disc that it is desired to treat is centered in one of its windows. The additional chamber **431** is inflated, and the inflation gas pressure in the **411** main chamber is released. The inflated additional chamber maintains the shape of the retraction device.

If a Type II device is used, an elastomeric window (not shown) is installed, as previously described, on the inside of the main envelope in a position that will provide access to the disc to be treated.

The main envelope **406** of both types of retraction device can then be pierced, and partially removed, if necessary. An incision is made in the peritoneum exposed by the retraction device to gain access to and to resect the disc to be treated.

One or more flexible sheaths may be inserted through the abdominal wall to provide access to the interior of the retraction device for surgical instruments. If a Type I retraction device is used, normal surgical instruments may be used, and such tools may be freely manipulated in the space created by the retraction device. Because the main chamber of the retraction device is not under pressure, there is no need to use laparoscopic instruments through rigid trocar tubes. FIGS. **14A** and **14B** show instrument **452** passed from outside the body through the main inflation tube **416** into the main chamber **411**. The instrument **452** passes out of the main chamber **411** through an aperture (not shown) pierced in the window **446**.

Once treatment has been completed, the retraction device is deflated and removed from the body, and the small incisions in the abdominal wall repaired, as already described.

2. Retracting the Pericardium

A procedure according to the invention in which a small, oblate version of a Type I or Type II retraction device is used to displace the pericardium **403** from the heart **408** is shown in FIG. **15**, which shows a transverse cross section of the chest. Displacement of the pericardium allows the outer surface **413** of the heart **408** to be observed, and such procedures as endocardial napping, ablation, transmyocardial revascularization, and defibrillation to be carried out. These procedures have until now been difficult to do laparoscopically because access to the surface of the heart **408** is obstructed by the pericardium **403**.

In the procedure according to the invention, a small puncture **418** is made in the chest wall **423** and through the puncture **418**, a small incision **428** is made in the pericardium **403**. An introducer tube (not shown) is inserted to connect the pericardial cavity **453** to outside the patient. A retraction device **401** is inserted using its inflation tubes (the main inflation tube **416** is shown) through the introducer tube into the pericardial cavity **453** so that it rests between the surface **413** of the heart and the pericardium **403**. The retraction device **401** is then released from its packing (not shown), as described above, and its main chamber **411** is inflated. During the inflation process, the main envelope **406** of the retraction device gently displaces the heart **408** from the pericardium **403**. The position of the retraction device is checked and, if necessary, adjusted.

If a Type I retraction device is used, it must be positioned such that the part of the heart that it is desired to treat is centered in one of its windows. The additional chamber **431** is then inflated and the inflation pressure removed from the main chamber.

If a Type II device is used, an elastomeric window is installed, as previously described, on the inside of the main envelope in a position that will provide access to the part of the heart to be treated.

Once the retraction device is in position, the introducer tube (not shown) can be withdrawn and the main inflation tube **416** used as a path for endoscopes and instruments to pass in to the main chamber of the retraction device.

3. Retracting the Pleura

FIG. **15** shows an endoscope **433** passed through the main inflation tube **416** to observe the outer surface **413** of the heart. FIG. **15** also shows an instrument probe **438** that has been passed through the chest wall **423** to contact the surface **413** of the heart. The instrument probe **438** is passed through the pericardium **403** and the main chamber **411** of the retraction device **401**, piercing a first window **443** and a second window **448** of the retraction device. After the treatment is completed, the retraction device is withdrawn from the pericardial cavity, as already described, and the small incisions in the pericardium and the chest wall are repaired.

FIG. **16** shows a further procedure according to the invention in which a retraction device is used in the pleural cavity to retract the lung from the pleura to allow observation and manipulation. FIG. **16A** shows a vertical cross sectional view of the chest and FIG. **16B** shows a transverse cross section along the line **16B—16B** in FIG. **16A**. A small, oblate version of a Type I or Type II retraction device **401** is used to displace the lung **402** from the pleura **407** to allow resection of a lobe **412** of the lung **402**.

In the procedure, a small incision **417** is made in the chest wall **423** and, through the incision **417**, a trocar (not shown) is inserted to connect the pleural cavity **432** to outside the patient. The trocar point (not shown) is removed leaving the trocar tube (not shown) connecting the pleural cavity **432** to outside the patient. A retraction device **401** is inserted using its inflation tubes (inflation tube **416** is shown) through the trocar tube into the pleural cavity, so that it rests between the surface of the lung **402** and the pleura **407**. The retraction device **401** is then released from its packing (not shown), as described above, and its main chamber **411** is inflated. During the inflation process the main envelope **406** of the retraction device gently displaces the lung **402** from the pleura **407**. The position of the retraction device is checked and, if necessary, adjusted.

If a Type I retraction device is used, it must be positioned such that the part of the lung that it is desired to treat is centered in one of its windows. The additional chamber **431** is then inflated and the inflation pressure removed from the main chamber **411**.

If a Type II device is used, an elastomeric window is installed, as previously described, on the inside of the

main envelope in a position that will provide access to the part of the lung to be treated.

Once the retraction device is in position, the trocar tube (not shown) can be withdrawn and the main inflation tube **416** used as a path for endoscopes and instruments to pass to the inside of the retraction device.

FIG. **16** shows an endoscope **433** passed through the main inflation tube **416** into the main chamber of the retraction device **401**. In the embodiment of the retraction device **401** shown, the main inflation tube **416** enters the main chamber **411** through a first window **443**. Part of a second window **448** has been removed, as already described, to allow a part **437** of the lung **402** to enter the main chamber **411** of retraction device for treatment. A trocar tube **447** passes through the chest wall **423** and enters the retraction device by piercing a third window **452**, and an instrument **442** is passed through the trocar tube **447** to section part of the lung **437**. The part of the window **448** that has not been removed forms a seal around the part **437** of the lung inside the retraction device, and prevents sectioned tissue from entering the pleural cavity. After the treatment of the lung is completed, the retraction device is withdrawn from the pleural cavity, as already described, and the small incisions in the pleura and the chest wall are repaired.

4. Retracting a Lobe of the Lung

In a further procedure, a retraction device is used to retract one lobe of a lung in a lobectomy. This is shown in FIG. **17**, which shows a longitudinal cross section of the chest. The lobes of the lung overlay one another: in performing a lobectomy, access to the hilar portion of the bronchial tree is required so that the branches of the bronchial tree feeding the lobe to be sectioned can be occluded. A Type IA or Type II retraction device **401** is used to displace the lobe **404** away from the rest of the lung **409** to provide access to the bronchial tree **414**.

In the procedure, a small incision **419** is made in the chest wall **423**, and through the incision **419**, a trocar (not shown) is inserted through the chest wall **423** and pleura **429**. The trocar (not shown) is removed and the trocar tube is maneuvered to place its distal end between the lobe **404** and the rest of the lung **409**. A retraction device **401** is inserted using its inflation tubes (inflation tube **416** is shown) through the trocar tube into position between the lobe **404** and the rest of the lung **409**. The retraction device **401** is then released from its packing (not shown), as described above, and its main chamber **411** is inflated. During the inflation process, the main envelope **406** of the retraction device gently displaces the lobe **404** away from the rest of the lung **409**. The position of the retraction device is checked and, if necessary, adjusted.

If a Type I retraction device is used, it must be positioned such that the part of the bronchial tree that it is desired to occlude is centered in one of its windows. The additional chamber **431** is then inflated and the inflation pressure removed from the main chamber.

If a Type II retraction device is used, a elastomeric window (not shown) is applied to the inside of the main chamber **411** in a position such that the part of the bronchial tree that it is desired to occlude can accessed through the elastomeric window.

With both types of retraction device, an aperture is cut in the main envelope **406** through which the procedure for occluding a part of the bronchial tree can be carried out using instruments passed into the main chamber **411** through the inflation tube **416**. Additional instruments can be inserted into the main chamber through flexible sheaths (not shown) and/or, in a Type I retraction device, through apertures pierced in other windows (not shown) of the main envelope **406**. After the bronchial tree has been occluded, the retraction device is deflated and withdrawn, as already described, from between the lobe **404** and the rest of the lung **409**. The procedure for sectioning the lobe is carried out before the small incisions in the pleura and the chest wall are repaired.

5. Retracting the Liver to Gain Access to the Gastroesophageal Junction

Another procedure according to the invention is shown in FIG. **18**. It is necessary to gain access to the gastroesophageal junction between the stomach **405** and the esophagus **410** to be able to section the vagus nerve, or to treat gastroesophageal reflux. The gastroesophageal junction is normally obscured by the liver **415**, which must be retracted provide access for treating this area. A Type I or Type II retraction device **401** is used to displace the liver **415** away from the esophagus **410**. According to the procedure, a small incision **420** is made in the abdominal wall **425**. A trocar (not shown) and trocar tube **440** is inserted through the incision **420** and is driven through the abdominal wall **425** into the abdominal cavity AC and the trocar is removed. The trocar tube is maneuvered to place its distal end between the liver **415** and the esophagus **410**. A retraction device **401** is inserted using its inflation tubes (inflation tube **416** is shown) through the trocar tube into position between the liver **415** and the esophagus **410**. The retraction device **401** is then released from its packing (not shown), as described above, and its main chamber **411** is inflated. During the inflation process the main envelope **406** of the retraction device gently displaces the liver **415** away from the esophagus **410**. The position of the retraction device is checked and, if necessary, adjusted.

If a Type I retraction device is used, it must be positioned such that the gastroesophageal junction is centered in one of its windows. The additional chamber **431** is then inflated and the inflation pressure removed from the main chamber.

If a Type II retraction device is used, a elastomeric window (not shown) is applied to the inside of the main chamber **411** in a position such that the gastroesophageal junction can accessed through the elastomeric window.

With both types of retraction device, an aperture is cut in the main envelope **406** through which the treatment procedure can be carried out using instruments (e.g., instrument **452**) passed into the main chamber **411** through at least the inflation tube **416**. Additionally or alternatively, instruments can be inserted into the main chamber **411** through flexible sheaths (not shown) and/or, in a Type I retraction device, through apertures pierced in other windows (not shown) in the main envelope **406**. After the treatment procedure has been carried out, the retraction device is deflated and withdrawn, as already described, from between the liver **415** and the esophagus **410**, the small incisions in abdominal wall are repaired.

6. Retracting the Dura Mater

Another procedure according to the invention is shown in FIG. **19**, which shows a vertical cross section of the head. To observe and treat the brain **450**, it is necessary to separate the brain from the overlying dura mater **455**. A small, very oblate version of a Type I or

Type II retraction device **401** is used in this procedure. According to the procedure, a small incision **460** is made in the skin of the head, and, working through the incision, a small hole **465** is drilled in the skull to provide access to the dura mater **455**. An incision **470** is made in the dura mater to expose the surface of the brain **450**. A retraction device **401** is inserted using forceps through the incision **460**, the hole **465**, and the incision **470** into the skull between the surface of the brain **450** and the dura mater **455**. The retraction device **401** is then released, as described above, from its packing (not shown), and its main chamber **411** is inflated. During the inflation process the main envelope **406** of the retraction device gently displaces the brain **450** away from the dura mater **455**. The position of the retraction device is checked and, if necessary, adjusted.

If a Type I retraction device is used, it must be positioned such that part of the brain that it is desired to treat is centered in one of its windows. The additional chamber (not shown) is then inflated and the inflation pressure removed from the main chamber.

If a Type II retraction device is used, a elastomeric window (not shown) is applied to the inside of the main chamber **411** in a position such that the part of the brain that it is desired to treat can be accessed through the elastomeric window.

With both types of retraction device, an aperture is cut in the main envelope **406** through which the treatment procedure can be carried out, using instruments passed into the main chamber **411** through the inflation tube **416**. Additionally or alternatively, instruments can be inserted into the main chamber, in a Type I retraction device through apertures pierced in other windows (**475**, **485**) the main envelope **406**. After the treatment procedure has been carried out, the retraction device is deflated and withdrawn, as already described, from between the brain **450** and the dura mater **455**. Finally, the small incisions in the dura mater and the scalp and the hole in the skull are repaired.

7. Hernia Repair

Laparoscopic techniques are already being used to repair hernias, but conventional techniques require that two incisions be made in the peritoneum, the second incision being a relatively large one, and the peritoneum around the second incision be retracted. These unnecessary incisions delay recovery and provide the opportunity for complications. A procedure according to the invention enables hernia repair to be carried out without having to breach the peritoneum. FIG. **20A** shows a vertical cross section of the lower abdomen. A flat, substantially elliptical or rectangular Type IA or Type II retraction device **501** according to the invention is used to retract the peritoneum **502** away from the abdominal wall **517**. In the procedure according to the invention, a small incision **522** is made in the abdominal wall **517** near the umbilicus **507**, and the layers of tissue are cut through as far as the peritoneum. A retraction device **501** is inserted using forceps through the incision **522** into position between the abdominal wall **517** and the peritoneum **502**. The retraction device **501** is then released, as described above, from its packing (not shown), and its main chamber **511** is inflated. During the inflation process the main envelope **506** of the retraction device spreads inferiorly towards the inguinal area, and gently displaces the peritoneum **502** back from the abdominal wall **517**. The position of the retraction device is checked and, if necessary, adjusted.

If a Type I retraction device is used, it must be positioned such that the site of the hernia is centered in one of its windows. The additional chamber **531** is then inflated and the inflation pressure removed from the main chamber.

If a Type II retraction device is used, a elastomeric window (not shown) is applied to the inside of the main chamber **511** in a position such that the site of the hernia can be accessed through the elastomeric window.

With both types of retraction device, an aperture is cut in the main envelope **506** through which the treatment procedure can be carried out using instruments passed into the main chamber **511** through the inflation tube **516**. Additionally or alternatively, instruments can be inserted into the main chamber through flexible sheaths (not shown) and/or, in a Type I retraction device, through apertures (not shown) pierced in other windows of the main envelope **506**. After the hernia has been repaired, the retraction device is deflated and withdrawn, as already described, from between the peritoneum **502** and the abdominal wall **517** and the small incision in the abdominal wall **517** is repaired.

One known technique for repairing a hernia is by suturing or stapling a fine mesh over the site of the hernia. The mesh is preferably installed on the abdominal wall outside the peritoneum to prevent the mesh and its sutures or staples from irritating the bowel. Using conventional laparoscopic techniques to hold the mesh in place while it is cut to size and stapled in position is a very difficult procedure. A piece of mesh **527** is attached, for instance by a suitable adhesive applied to the perimeter of the piece of mesh, to substantially cover the window **532** of the retraction device **501**, as shown in FIG. **21**. The window **532** is the window that will contact the site of the hernia **512** when the retraction device has been deployed. The retraction device with the mesh is then packaged as previously described, and the retraction device is inserted between the peritoneum **502** and the abdominal cavity **517** and inflated, also as previously described.

The position of the retraction device **501** is then adjusted, using tabs **556** and a suitable gripping tool (not shown) to position the mesh-covered window so that the mesh **527** covers the site of the hernia **512**. Once the retraction device is properly positioned, the additional chamber **531** is inflated and the inflation pressure removed from the main chamber. The retraction device **501** holds the mesh **527** in place over the site of the hernia while the mesh is stapled in place and excess mesh is cut off. Part of the window **532** is cut away, using a suitable tool inserted into the main chamber **511** through the inflation tube **516**, to expose the area of the mesh into which staples will be placed. The mesh is stapled to the site of the hernia **512** using staples (not shown) inserted by means of a conventional laparoscopic stapler (not shown). More of the window **532** is then cut away and a suitable laparoscopic cutting tool is inserted into the main chamber **511** to cut the mesh around the stapled area. The excess mesh is removed when the retraction device is removed from the body, as previously described.

In a variation on this procedure, a low irritation Dacron® mesh is installed on the inside of the peritoneum, the retraction device with a piece of mesh covering one of its windows being inserted into the peritoneal cavity before the retraction device is inflated, as shown in FIG. **20B**.

In a variation on both of the above procedures, the mesh is cut to the required size before it is attached to the window of the retraction device. The mesh is attached to the window of the retraction device by one-pull lacing, and the thread for the one-pull lacing is fed through the main inflation tube. After the mesh has been correctly positioned and stapled in place, as previously described, the thread is pulled to release the one-pull lacing, which releases the mesh from the window of the retraction device. The retraction device is then withdrawn as previously described. This variation does not require the mesh to be cut to size after it has been stapled in place.

C. Methods of Constructing Inflatable Retraction Devices

1. Polygonal Type IA Retraction Device

The construction of a polygonal Type IA retraction device is illustrated in FIGS. 22A and 22B. The construction of a dodecahedral retraction device is illustrated. A dodecahedral retraction device gives a good compromise between approximating a spherical or spheroidal shape, and complexity. Increasing the number of faces makes a shape that is more nearly spherical but is more complex to make. The additional chamber of a retraction device that is more nearly spherical provides more retraction force than the additional chamber of a polyhedral retraction device that is more nearly cubic.

The main envelope and the additional envelope of the retraction device are both made of a relatively inelastic and tough film of a plastic such as Mylars ®, polyethylene, or polyurethane. The preferred material is a polyethylene and nylon composite. The thickness of the main envelope is typically from 0.5 to 5 mils (13 to 130 microns). In the preferred embodiment, the additional envelope is made from a film of the same thickness of the same plastic as the main envelope. However, in some applications it may be advantageous make the additional envelope from a film of a different thickness of the same plastic, or from a film of the same or a different thickness of a different plastic.

Two segmented circular main envelope blanks **600** and **601** and two segmented circular additional envelope blanks **625** and **626** are cut from a piece of film, preferably by die cutting.

The main envelope blank **600**, the additional envelope blank **625**, and the formation of an envelope half from them will now be described. A similar explanation applies to the main envelope blank **601**, the additional envelope blank **626**, and the formation of an envelope half from them.

The number of segments in the two main envelope blanks **600** and **601**, plus 2, determines the number of faces that the polyhedral retraction device will have. In the dodecahedral retraction device illustrated, the main envelope blank **600** has five segments **605**. The width and depth of the segments **605** determines the shape of the retraction device: wide, shallow segments result is a relatively flat retraction device, whereas narrow, deep segments result in a relatively tall retraction device.

The number of segments **630** in the additional envelope blank **625** is preferably equal to the number of segments **605** of the main envelope blank **600**; thus, the additional envelope blank **625** has five segments **630** to match the five segments **605** of the main envelope blank **600**. The shape of the segments **630** is substantially the same as that of the segments **605**, except the parts of each segment **630** indicated by shading and the reference numeral **655** in FIG. 22B are cut away compared with the segment **605** in the main envelope blank. When the additional envelope blank **625** is assembled with the main envelope blank **600**, the cut away areas **655** provide the windows **46** (FIG. **1**) in the side of the retraction device. Each area **655** will therefore be called a side window area **655**. Another area **645** in the center of the additional envelope blank **625** is cut away. When the additional envelope **625** is assembled with the main envelope blank **600**, the cut away area **645** forms the window **46** (FIG. **1**) in the top end or the bottom end of the retraction device, and will thus be called the end window area **645**. The end window area is shown with a circular shape in FIG. 22B; alternatively, it could have a polygonal shape. The side and end window areas are preferably cut in the same die-cutting operation in which the additional envelope is die cut from the plastic film.

An envelope half is made by laying the additional envelope blank **625** on the main envelope blank **600** such that the segments **630** coincide with the segments **605**. The broken line **650** in FIG. 22A indicates the position of each side window area **655** when the additional envelope blank **625** is correctly positioned on the main envelope bank **600**. The periphery of each side window area **655** of the additional envelope blank **625** is attached to the main envelope blank **600**, preferably by welding. Alternatively, a line of adhesive applied to the periphery of each side window area **655** can be used. The periphery of the end window area **645** in the additional envelope blank **625** is also attached to the main envelope blank **600**, preferably by welding. Alternatively, a line of adhesive applied to the periphery of the end window area **645** can be used.

The envelope half is then given a 3-dimensional form by joining the edge **610** of each segment **605** in the main envelope blank **600** to the edge **615** of the adjacent segment, and by joining the edge **635** of each segment **630** in the additional envelope blank **625** to the edge **640** of the adjacent segment. The preferred method of joining in this step and the following steps involving joining is overlap welding. Alternatively, butt welding or a line of a suitable adhesive can be used. The envelope half may be formed so that the additional envelope blank **625** is inside or outside the main envelope blank **600**. In the preferred embodiment, the additional envelope blank is inside the main envelope blank.

A second envelope half is made from the main envelope blank **601** and the additional envelope blank **626**, as described above. One of the two envelope halves is then inverted relative to the other, and the two envelope halves are joined together with the periphery **620** in contact with the periphery **621** (main envelope) and the periphery **660** in contact with the periphery **661** (additional envelope). The peripheries of the envelope blanks on the inside are joined first. In the preferred embodiment, which has the additional envelope outside the main envelope, the envelope halves are joined as follows: the peripheries **620** and **621** of the main envelope blanks **600** and **601** are joined first. A small part of the peripheries **620** and **621** of the main envelope blanks is left unjoined. The main inflation tube **616** is a piece of polyethylene tubing with an outside diameter in the range of 2.5 to 19.5 mm (0.1" to 0.77") and of suitable length. The distal end of the main inflation tube **616** is fitted with a port **651** that allows surgical instruments to be passed into the main inflation tube while maintaining

inflation pressure in the main chamber of the retraction device. The port **651** also includes a fitting (not shown) suitable for connecting the port to a source of inflation gas (not shown). The proximal end of the main inflation tube **616** is inserted into the unjoined part of the peripheries **620** and **621** of the additional envelope blanks **600** and **601** and joining the periphery **620** to the periphery **621** is completed. Where the peripheries **620** and **621** contact the main inflation tube **616**, they are joined to the outer wall of the main inflation tube to form a gas-tight seal. The peripheries **660** and **661** of the outer envelope blanks, i.e., the additional envelope blanks **625** and **626**, are then joined to one another and, where they contact the main inflation tube **616**, to the outer wall of the main inflation tube to form a gas-tight seal. A small part of the peripheries **660** and **661** of the additional envelope blanks **625** and **626** is left unjoined. The additional inflation tube **641** is a piece of polyethylene tubing with an outside diameter in the range of 2.5 to 5 mm (0.1" to 0.2") and of suitable length. The distal end of the additional inflation tube **641** is fitted with a fitting (not shown) suitable for connecting it to a source of inflation gas (not shown). The proximal end of the additional inflation tube **641** is inserted into the unjoined part of the peripheries **660** and **661** of the additional envelope blanks **625** and **626**, and joining the periphery **660** to the periphery **661** is completes. Where the peripheries **660** and **661** contact the additional inflation tube **641**, they are joined to the outer wall of the additional inflation tube to form a gas-tight seal.

In the alternative embodiment, with the additional envelope inside the main envelope, the peripheries **660** and **661** of the additional envelope blanks **625** and **626** are joined to one another and to the outer wall of the main inflation tube **616**. The peripheries **620** and **621** of the main envelope blanks **600** and **601** are then joined together, and to the outer wall of the main inflation tube **616** and to the outer wall of the additional inflation tube **641**.

If the retraction device is for use in an insufflated body cavity, the main and additional inflation tubes must be surrounded by an inflation tube shield. The additional envelope blanks for such a retraction device are cut to include an inflation tube seal **680** and **681**. The inflation tube sheath (not shown) is pushed over the main and additional inflation tubes after they have been sealed into the retraction device and the inflation tube seals are joined to one another, preferably by welding. Alternatively, a suitable adhesive can be used. Where the inflation tube seals **680** and **681** contact the inflation tube sheath, they are joined to the outer wall of the inflation tube shield to form a gas-tight seal. The above method can be adapted for use if a single extrusion is used to provide the main and additional inflation tubes and the inflation tube sheath.

An alternative method of making a polygonal type IA retraction device is the same as the method just described, except that the additional envelope blanks **625** and **626** are cut with the same die as the main envelope blanks **600** and **601**. A main envelope blank is attached to an additional envelope blank by welding along the broken lines **650** and **665** (FIG. 22A). Alternatively, a main envelope blank can be attached to an additional envelope blank by a line of a suitable adhesive spread along the broken lines **650** and **665**. The envelope halves are then formed and attached to one another using the method described above.

The additional chamber of a retraction device in which the additional envelope blank and the main envelope blank are cut using the same die is substantially the same shape as the additional chamber of a retraction device in which the additional envelope blank is cut using its own die. The alternative method of construction saves the tooling cost of the die to cut the additional envelope blank. A retraction device made according to this method has a double thickness of film on its windows **46** (FIG. **1**), which makes it somewhat more difficult to cut apertures in the windows prior to carrying out the treatment process.

2. Polygonal Type IA Retraction Device with Suction Skirt

The construction of a polygonal Type IA retraction device including a suction skirt is illustrated in FIGS. **23A** and **23B**. A plurality of holes **608**, preferably between **6** and **12**, are cut around the periphery of the end window area **646** of the additional envelope blank **631**. Each hole **608** is preferably about $\frac{1}{8}$" (3 mm) in diameter. When the retraction device is deployed in the body, it must be oriented such that the additional envelope blank **631** is lower-most. Additionally, a short radial cut **613** is made in the additional envelope blank **631**. Preferably, the holes **608** and the radial cut **613** are die cut, preferably by the same die used to cut the additional envelope blank **631**.

The method of constructing the retraction device is the same as that described above, except that the step of attaching the periphery of the end window **646** of the additional envelope blank **631** to the main envelope blank **601** is changed as follows: additional envelope blank **631** is attached to the main envelope blank **601** by welding along a circular line concentric with the end window area **646** and displaced radially outward by about 0.5" (12.5 mm) to lie outside the line of the holes **608**. The weld line is indicated in FIG. **23** by the broken line **618**. The part of the additional envelope blank **631** forming the periphery of the end window area **646** is then displaced radially outwards by about $\frac{1}{8}$" (3 mm) and is attached to the main envelope blank **601** by a circular weld, indicated by the broken line **623**, inside the line of the holes **608**. Displacing the periphery of the end window area radially outward moves the part of the additional envelope blank **631** between the two welds indicated by the broken lines **618** and **623** away from the part of the main envelope blank that it overlays, and forms a flat tubular structure between the two envelope blanks. One end of the tubular structure is closed by a short radial weld indicated by the broken line **633**, close to the radial cut **613**.

Construction of the retraction device is completed as described above. The proximal end of the suction tube **638**, which is a piece of thin-wall polyethylene tubing about $\frac{1}{4}$" (6 mm) in outside diameter is inserted into the open end of the tubular structure provided by the radial cut **613**. In a retraction device for use in an insufflated body cavity, the suction tube **638** is sealed into the inflation tube sheath.

The method described above can be adapted to provide a suction skirt around one of the side windows of a polygonal Type IA retraction device. Such a suction skirt would be useful if the retraction device is oriented with a side window lower-most when in use. The method can also be adapted to make a flat retraction device with a suction skirt around one or more of its holes or around the junction between its envelope halves. The method can also be adapted to make a tri-

angular prism-shaped Type IA retraction device with a suction skirt around one of its holes or along one or both of the sides of its lower-most face.

3. Relatively Flat Type IA Retraction Device

The construction of a simpler, relatively flat Type IA retraction device is illustrated in FIGS. **24A** and **24B**. The main envelope and the additional envelope of the retraction device are both made of a relatively inelastic and tough film of a plastic such as Mylar ®, polyethylene, or polyurethane. The preferred material is a polyethylene and nylon composite. The thickness of the main envelope is typically from 0.5 to 5 mils (13 to 130 microns). In the preferred embodiment, the additional envelope is made from a film of the same thickness of the same plastic as the main envelope. However, in some applications it may be advantageous make the additional envelope from a film of a different thickness of the same plastic, or from a film of the same or a different thickness of a different plastic.

Two substantially circular or elliptical main envelope blanks **600** and **601**, substantially equal in size, and two substantially circular or elliptical additional envelope blanks **625** and **626**, substantially the same size as the main envelope blanks **600** and **601**, are cut from a piece of film, preferably by die cutting. The die cutting process also cuts holes **670** and **671** in the additional envelope blanks **625** and **626** respectively. The number, shape, and size of holes **670** and **671** depends on the intended application of the retraction device. When the additional envelope blanks **625** and **626** are assembled with the main envelope blanks **600** and **601** respectively, the holes **670** and **671** form the windows **646** (FIG. **24B**) in the retraction device. Increasing the proportion of the additional envelope removed to form holes **670** and **671** increases the window area through which treatment procedures can be carried out, but reduces the ability of the additional cavity of the retraction device to maintain retraction after the main cavity has been punctured.

An envelope half is made by laying the additional envelope blank **625** on the main envelope blank **600**. The positions of the periphery of each hole **670** when the additional envelope blank **625** is properly positioned on the main envelope bank **600** is indicated by the broken line **650** in FIG. **24A**. The periphery of each hole **670** of the additional envelope blank **625** is attached to the main envelope blank **600**, preferably by welding. Alternatively, a line of adhesive applied to the periphery of each hole **670** can be used. A second envelope half is made from the main envelope blank **601** and the additional envelope blank **626**, using the method described above.

One of the two envelope halves is then inverted relative to the other, and the two envelope halves are joined together with the periphery **620** in contact with the periphery **621** (main envelope) and the periphery **660** in contact with the periphery **661** (additional envelope). The envelope halves may be joined such that the additional envelope blanks **625** and **626** are inside or outside the main envelope blanks **600** and **601**. In the preferred embodiment, the additional envelope blanks are inside the main envelope blanks. The method of joining the envelope halves is the same as the method for joining the envelope halves of a polygonal Type IA retraction device, so will not be further described. The completed retraction device is shown in FIG. **24B**.

In an alternative embodiment of the relatively flat Type IA retraction device, the main inflation tube may be connected to the main chamber by piercing a hole in one of the windows **646** and attaching the periphery of the hole to the outer wall of the inflation tube. This embodiment is more useful than the basic embodiment, in which the main inflation tube is connected between the perimeters of the two envelope halves, in procedures in which the convenient entry point in the body for instruments lies more or less directly across the short dimension of the retraction device from the tissue to be treated. Examples of such procedures are shown in FIGS. **15**, **16A**, **16B**, and **19**.

In the alternative embodiment with the additional envelope outside the main envelope, the peripheries **620** and **621** of the main envelope blanks are joined to one another and to the outer wall of the main inflation tube. The peripheries **660** and **661** of the additional envelope blanks are then joined to one another, and to the outer walls of the main and the additional inflation tubes.

The flat Type IA retraction device can also be made with its additional envelope blanks and its main envelope blanks cut using the same die, as described in connection with the polygonal Type IA retraction device. The main and additional envelope blanks are attached by welding or a line of adhesive along the broken lines **650**.

4. Triangular Prism-Shaped Type IA Retraction Device

The triangular prism Type IA retraction device is constructed from two flat envelope blanks, as shown in FIG. **25C**. The main envelope and the additional envelope of the retraction device are both made of a relatively inelastic and tough film of a plastic such as Mylar ®, polyethylene, or polyurethane. The preferred material is a polyethylene and nylon composite. The thickness of the main envelope is typically from 0.5 to 5 mils (13 to 130 microns). In the preferred embodiment, the additional envelope is made from a film of the same thickness of the same plastic as the main envelope. However, in some applications it may be advantageous make the additional envelope from a film of a different thickness of the same plastic, or from a film of the same or a different thickness of a different plastic.

A substantially rectangular main envelope blank **700**, and a substantially rectangular additional envelope blank **725**, substantially the same size as the main envelope blank **700**, are cut from a piece of film, preferably by die cutting. Each envelope blank **700** and **725** can be regarded as being divided lengthwise into three panels. At least the two outer panels have equal length. Each panel is serrated as shown in FIG. **25C**. If the outer panels are larger than the inner panel, their serrations are truncated, as shown. The serrations are preferably die cut at the same time as the envelope panels are die cut. The die cutting process also cuts one hole **770** in each panel of the additional envelope blank **725**, as shown in FIG. **25D**. Substantially circular holes are shown in FIG. **25D**: holes of a different shape, or more than one hole per panel can be cut, depending on the intended application of the retraction device. When the additional envelope blank **725** is assembled with the main envelope blank **700**, the holes **770** form the windows **746** (FIG. **25A**) in the retraction device. Increasing the proportion of the additional envelope removed to form the holes **770** increases the window area through which treatment procedures can be carried out, but reduces the ability of the additional cavity of the retraction device to maintain retraction after the main cavity has been punctured.

Assembly is begun by laying the additional envelope blank **725** on the main envelope blank **700** so that their peripheries overlap. The positions of the periphery of each hole **770** when the additional envelope blank **725** is properly positioned on the main envelope bank **700** is indicated by the broken line **750** in FIG. **25C**. The periphery of each hole **770** of the additional envelope blank **725** is joined to the main envelope blank **700**. The preferred method of joining in this step and the following steps involving joining is overlap welding. Alternatively, a line of adhesive applied to the periphery of the pieces being joined, for example, the periphery of each hole **770**, can be used. The periphery **760** of the additional envelope blank **725** is joined to the periphery **720** of the main envelope blank **700** by welding along the broken line **740**. A small part of the peripheries **720** and **760** is left unjoined.

The additional inflation tube **741** is a piece of polyethylene tubing with an outside diameter in the range of 2.5 to 5 mm (0.1" to 0.2") and of suitable length. The distal end of the additional inflation tube **741** is fitted with a fitting (not shown) suitable for connecting it to a source of inflation gas (not shown). The proximal end of the additional inflation tube **741** is inserted into the unjoined part of the periphery **720** of the main envelope blank **700** and the periphery **760** of the additional envelope blank **725**, and joining the periphery **720** to the periphery **760** is completed. Where the peripheries **720** and **760** contact the additional inflation tube **741**, they are joined to the outer wall of the additional inflation tube to form a gas-tight seal.

The retraction device is then folded, as shown by the arrows **782** and **787**, along the boundaries between the panels, i.e., along the lines **710** and **715**, to bring edge **722** into contact with edge **727** with the main envelope blank **700** on the inside. The following parts of the periphery of the retraction device are then joined: **736** to **741**, **737** to **742**, **746** to **751**, **747** to **752**, **756** to **761**, **757** to **762**, **766** to **771**, **767** to **772**, and **722** to **727**. A small part of the peripheries **722** and **727** is left unjoined.

The main inflation tube **716** is a piece of polyethylene tubing with an outside diameter in the range of 2.5 to 19.5 mm (0.1" to 0.77") and of suitable length. The distal end of the main inflation tube **716** is fitted with a port (not shown) that allows surgical instruments to be passed into the main inflation tube while maintaining inflation pressure in the main chamber of the retraction device. The port also includes a fitting (not shown) suitable for connecting the port to a source of inflation gas (not shown). The proximal end of the main inflation tube **716** is inserted into the unjoined part of the-peripheries **722** and **727** and joining the periphery **722** to the periphery **727** is completed. Where the peripheries **722** and **727** contact the main inflation tube **716**, they are joined to the outer wall of the main inflation tube to form a gas-tight seal.

If the retraction device is for use in an insufflated body cavity, the main and additional inflation tubes must be surrounded by an inflation tube shield. The main and additional envelope blanks for such a retraction device are each cut to include an inflation tube seal **780** and **781**. The inflation tube sheath (not shown) is pushed over the main and additional inflation tubes after they have been sealed into the retraction device and the peripheries of the inflation tube seals are joined to one another. Where the inflation tube seals **780** and **781** contact the inflation tube sheath, they are joined to the outer wall of the inflation tube shield to form a gas-tight seal. The above method can be adapted for use if a single extrusion is used to provide the main and additional inflation tubes and the inflation tube sheath.

The triangular prism-shaped Type IA retraction device can also be made with its additional envelope blank and its main envelope blank cut using the same die, as described in connection with the polygonal Type IA retraction device. The additional envelope blank is attached to the main envelope blank by welding or a line of adhesive along the broken lines **750**.

5. Polygonal Type II Retraction Device

The construction of a polygonal Type II retraction device is illustrated in FIG. **26**. The construction of a dodecahedral retraction device is illustrated. A dodecahedral retraction device gives a good compromise between approximating a spherical or spheroidal shape, and providing windows of a useful size. Increasing the number of faces makes a shape that is more nearly spherical but has smaller faces, which limits the size of elastomeric window that can be used.

The main (and only) envelope of the Type II retraction device is made of a relatively inelastic and tough film of a plastic such as Mylar ®, polyethylene, or polyurethane. The preferred material for the main envelope is a polyethylene and nylon composite. The thickness of the main envelope is typically from 0.5 to 5 mils (13 to 130 microns). To form the main envelope, two segmented circular main envelope blanks **600** and **601** are cut from a piece of film, preferably by die cutting. The number of segments **605** in the two main envelope blanks **600** and **601**, plus 2, determines the number of faces that the polyhedral retraction device will have. In the dodecahedral retraction device illustrated, the main envelope blanks **600** and **601** each have five segments **605**. The width and depth of the segments **605** determines the shape of the retraction device: wide, shallow segments result is a relatively flat retraction device, whereas narrow, deep segments result in a relatively tall retraction device.

An envelope half is formed by joining the edge **610** of each segment **605** in the main envelope blank **600** to the edge **615** of the adjacent segment. The preferred method of joining is overlap welding, but butt welding or a suitable adhesive can also be used. A second envelope half is made using the main envelope blank **601**. One of the two envelope halves is then inverted relative to the other, and the two envelope halves are joined together with the periphery **620** in contact with the periphery **621**. Again, the preferred method of joining is overlap welding, but butt welding or a suitable adhesive can also be used. A small part of the peripheries **620** and **621** of the two main envelope blanks **600** and **601** is left unjoined.

The main inflation tube **616** is a piece of polyethylene tubing with an outside diameter in the range of 2.5 to 19.5 Mm (0.1" to 0.77") and of suitable length. The distal end of the main inflation tube **616** is fitted with a port **651** that allows surgical instruments to be passed into the main inflation tube while maintaining inflation pressure in the main chamber of the retraction device. The proximal end of the main inflation tube **616** is inserted into the unjoined part of the peripheries **620** and **621** and joining the periphery **620** to the periphery **621** is completed. Where the peripheries **620** and **621** contact the inflation tube **616**, they are joined to the outer wall of the inflation tube such that a gas-tight main envelope is formed in contact with the bore of the main inflation tube.

The methods described above for making relatively flat and triangular prism-shaped Type IA retraction devices can easily be adapted to make relatively flat and triangular prism-shaped Type II retraction devices respectively.

6. Curved Type IA and Type II Retraction Devices

Substantially full- or hemi-spherical, spheroidal, or ellipsoidal Type IA and Type II retraction devices can be made from curved pieces of plastic film. The construction of a hemispherical Type IA retraction device from curved plastic film is illustrated in FIGS. **27** and **28**. The method can easily be adapted to make a substantially spherical, spheroidal or ellipsoidal Type IA retraction device by interconnecting two envelope halves made according to the method to be described below using the method for joining envelope halves described above.

The main envelope **602**, the additional envelope **607**, and the bottom diaphragm **647** of the retraction device are all made of a relatively inelastic and tough film of a plastic such as Mylar ®, polyethylene, or polyurethane. The preferred material is a polyethylene and nylon composite. The thickness of the main envelope **602** is typically from 0.5 to 5 mils (13 to 130 microns). In the preferred embodiment, the additional envelope **607** and the bottom diaphragm **647** are made from a film of the same thickness of the same plastic as the main envelope. However, in some applications it may be advantageous make the additional envelope and/or the bottom diaphragm from a film of a different thickness of the same plastic, or a film of the same or a different thickness of a different plastic. A main envelope blank **602**, an additional envelope blank **607** and a bottom diaphragm **647** are cut from a piece of film, preferably by die cutting. The envelope blanks are similar, except that holes **612** are cut in the additional envelope blank **607**. The holes **612** are cut preferably by the same die that is used to cut the additional envelope blank **607**. When the additional envelope is assembled with the main envelope blank, the holes **612** form the windows **646** (FIG. **28**). In FIG. **27**, holes **612** are shown as having a circular shape, but they could have other suitable shapes.

According to one aspect of the method, the main envelope blank **602** and the additional envelope blank **607** are stretched over the surface of a former. The surface of the former is the hemispherical, hemispheroidal, hemiellipsoidal, or other shape that it is desired to impart on the envelope blank. The surface of the former is heated and its temperature sufficiently high, and the envelope blank remains in contact with the surface of the former for sufficiently long a time, for the plastic film of the envelope blank to soften, such that when the envelope blank cools, it adopts the shape of the surface of the former. The surface of the former is cooled, the periphery of the envelope blank is trimmed to the periphery of the surface, and the envelope blank is removed from the former. An envelope blank can also be curved by blowing the envelope blank into a suitably-shaped, heated concavity, or by pressing the envelope blank between suitably-shaped, heated male and female dies.

An envelope half is made by laying the curved additional envelope blank **607** on the curved main envelope blank **602**. The periphery of each hole **612** in the additional envelope blank **607** is attached to the main envelope blank **602**, preferably by welding. Alternatively, a line of adhesive applied to the periphery each hole **612** can be used.

In an alternative method, an envelope half is made by laying the additional envelope blank **607** on the main envelope blank **602**. The periphery of each hole **612** in the additional envelope blank **607** is attached to the main envelope blank **602**, preferably by welding. Alternatively, a line of adhesive applied to the periphery of each hole **612** can be used. The resulting flat envelope half is then curved and trimmed around its periphery using one of the methods described above.

In either of the above methods, the main envelope blank and the additional envelope blank can cut using the same die, and the second chamber can be formed by attaching the additional envelope blank to the main envelope blank by welding or applying adhesive along the broken lines **627**. This method produces a retraction device with a double layer of plastic film on the windows **646** (FIG. **28**), which makes it somewhat less convenient to use.

A substantially hemispherical retraction device can be made by attaching the periphery **632** of the main envelope blank **602** to the periphery **637** of the additional envelope blank **607**, and to the periphery **642** of the bottom diaphragm **647**, preferably by welding, as shown in FIG. **28**. Alternatively, a line of adhesive applied to the periphery of one or both the envelope halves and to the periphery **642** of the bottom diaphragm **647** can be used. A small part of the peripheries **632** and **637** is left unjoined. The additional inflation tube **641** is a piece of polyethylene tubing with an outside diameter in the range of 2.5 to 5 mm (0.1" to 0.2") and of suitable length. The distal end of the additional inflation tube **641** is fitted with a fitting (not shown) suitable for connecting it to a source of inflation gas (not shown). The proximal end of the additional inflation tube **641** is inserted into the unjoined part of the peripheries **632** and **637**, and joining the periphery **632** to the periphery **637** is completed. Where the peripheries **632** and **637** contact the additional inflation tube **641**, they are joined to the outer wall of the additional inflation tube to form a gas-tight seal.

A small part of the joint between the periphery **637** of the additional envelope blank **607** and the periphery **642** of the bottom diaphragm **647** is also left unjoined. The main inflation tube **616** is a piece of polyethylene tubing with an outside diameter in the range of 2.5 to 19.5 mm (0.1" to 0.77") and of suitable length. The distal end of the main inflation tube **616** is fitted with a port **651** that allows surgical instruments to be passed into the main inflation tube while maintaining inflation pressure in the main chamber of the retraction device. The port **651** also includes a fitting (not shown) suitable for connecting the port to a source of inflation gas (not shown). The proximal end of the main inflation tube **616** is inserted into the unjoined part of the peripheries **637** and **642**, and joining the periphery **637** of the additional envelope blank **607** to the periphery **642** of the bottom diaphragm **647** is completed. Where the peripheries **637** and **642** contact the main inflation tube **616**, they are joined to the outer wall of the main inflation tube such that a gas-tight seal is formed.

The methods described above for making curved envelope halves can also be used to make the envelope halves used in constructing a Type II retraction device.

We claim:

**1**. A method for retracting an organ inside the body in the course of adjacent tissue, the method comprising the steps of:

providing an inflatable retractor including:

a flexible wall which may be expanded into place within the body, the flexible wall enclosing a main chamber; and

an envelope attached to the flexible wall, the envelope and part of the flexible wall enclosing an additional chamber,

placing the inflatable retractor adjacent to the organ, the retractor being in a collapsed state,

inflating the inflatable retractor to expand the flexible wall and to retract the organ, and

piercing an aperture in a part of the flexible wall of the retractor remote from the additional chamber to provide access to the tissue.

**2**. The method of claim **1**, wherein the step of inflating the inflatable retractor comprises;

inflating the main chamber,

inflating the additional chamber, and

releasing the inflation of the main chamber.

**3**. The method of claim **1**, wherein;

the retractor includes at least one gripping tab attached to the flexible wall inside the main chamber, and

the step of inflating the retractor comprises:

inflating the main chamber,

optimizing the orientation of the retractor by repeating the sequence of:

observing the orientation of the retractor, and if the orientation is incorrect

partially deflating the main chamber,

reorientating the retractor by gripping the at least one gripping tab with a gripping instrument and manipulating the gripping instrument, and

reinflating the main chamber, until the orientation of the retractor is correct, inflating the additional chamber, and releasing the inflation of the main chamber.

**4**. The method of claim **1**, wherein:

the method additionally comprises the step of providing an insertion tube,

in the step of providing an inflatable retractor, an inflatable retractor maintained in its collapsed state by lacing is provided, and

the step of placing the retractor adjacent the organ includes:

pushing the retractor through the insertion tube from outside the body, and

unlacing the lacing.

**5**. The method of claim **1**, wherein:

the method additionally comprises the step of providing an insertion tube,

in the step of providing an inflatable retractor, an inflatable retractor maintained in its collapsed state by a peelable sheath is provided, and

the step of placing the retractor adjacent the organ includes:

pushing the retractor through the insertion tube from outside the body, and

peeling the peelable sheath away from the retractor.

**6**. The method of claim **5**, wherein;

the peelable sheath includes a tear strip, and

the step of peeling the peelable sheath includes removing the tear strip to release the peelable sheath from the retractor.

**7**. The method of claim **1**, additionally comprising the steps of:

providing a surgical instrument,

piercing an additional aperture in the retractor,

passing the surgical instrument from outside the body through the additional aperture into the retractor, and

passing the surgical instrument through the aperture to treat the tissue.

**8**. The method of claim **7**, wherein:

in the step of piercing an aperture, the aperture is pierced in a window,

in the step of piercing an additional aperture, the additional aperture is pierced in a window, and

the step of passing a surgical instrument from outside the body into the retractor includes passing the surgical instrument through the additional aperture.

**9**. A method for retracting an organ inside the body in the course of treating adjacent tissue, the method comprising the steps of:

providing an inflatable retractor having a flexible wall which may be expanded into place within the body, and including a main inflation tube,

providing a surgical instrument,

placing the inflatable retractor adjacent to the organ, the retractor being in a collapsed state,

inflating the retractor to expand the flexible wall and to retract the organ,

piercing an aperture in the flexible wall of the retractor to provide access to the tissue,

passing the surgical instrument from outside the body into the retractor through the main inflation tube, and

passing the surgical instrument through the aperture to treat the tissue.

**10**. The method of claim **9**, wherein:

in the step of providing an inflatable retractor, there is provided an inflatable retractor additionally including an additional envelope attached to the flexible wall, the additional envelope and part of the flexible wall enclosing an additional chamber, and

the aperture is pierced in a part of the flexible wall remote from the additional chamber.

**11**. The method of claim **10**, wherein:

the main inflation tube is attached to the main chamber, and

the step of passing a surgical instrument form outside the body into the retractor includes passing the surgical instrument through the main inflation tube into the main chamber.

**12**. A method for retracting an organ inside the body in the course of treating adjacent tissue, the method comprising the steps of:

providing an inflatable retractor having a flexible wall which may be expanded into place within the body, the flexible wall enclosing a main chamber,

providing a surgical instrument,

placing the inflatable retractor adjacent to the organ, the retractor being in a collapsed state,

inflating the retractor to expand the flexible wall and to retract the organ,

piercing an aperture in the flexible wall of the retractor to provide access to the tissue,

passing the surgical instrument form outside the body into the main chamber,

pulling the tissue into the main chamber through the aperture, and

using the surgical instrument to treat the tissue.

**13**. The method of claim **12**, wherein:

in the step of providing an inflatable retractor, an inflatable retractor including a main inflation tube is provided, and

the step of passing a surgical instrument from outside the body into the retractor includes passing the surgical instrument through the main inflation tube.

**14**. The method of claim **13**, wherein:

in the step of providing an inflatable retractor, there is provided an inflatable retractor additionally including an additional envelope attached to the flexible wall, the additional envelope and part of the flexible wall enclosing an additional chamber, and

the aperture is pierced in a part of the flexible wall remote from the additional chamber.

**15**. The method of claim **14**, wherein:

the main inflation tube is attached to the main chamber, and

the step of passing a surgical instrument from outside the body into the retractor includes passing the surgical instrument through the main inflation tube into the main chamber.

**16**. The method of claim **12**, wherein:

the step of piercing an aperture in the retractor further includes piercing an additional aperture in the retractor, and

the step of passing a surgical instrument from outside the body into the retractor includes passing the surgical instrument through the additional aperture.

**17**. The method of claim **16**, wherein:

in the step of providing an inflatable retractor, there is provided an inflatable retractor additionally including an additional envelope attached to the flexible wall, the additional envelope and part of the flexible wall enclosing an additional chamber, and

the aperture is pierced in a part of the flexible wall remote from the additional chamber.

**18**. The method of claim **17**, wherein:

the step of piercing an aperture in the retractor pierces the aperture in a window,

the step of piercing an additional aperture in the retractor pierces the additional aperture in a window, and

the step of passing a surgical instrument from outside the body into the retractor includes passing the surgical instrument through the additional aperture.

**19**. A method for retracting an organ inside the body in the course of treating adjacent tissue, the method comprising the steps of:

providing an inflatable retractor, comprising:

a main envelope enclosing a main chamber, and

an additional envelope attached to the main envelope, the additional envelope and part of the main envelope enclosing an additional chamber;

placing the inflatable retractor adjacent to the organ, the retractor being in a collapsed state;

inflating the retractor to retract the organ; and

piercing an aperture in a part of the main envelope remote from the additional chamber to provide access to the tissue.

**20**. The method of claim **19**, wherein the step of inflating the inflatable retractor comprises:

inflating the main chamber,

inflating the additional chamber, and

releasing the inflation of the main chamber.

**21**. The method of claim **19**, wherein:

the inflatable retractor includes at least one gripping tab attached to the main envelope inside the main chamber; and

the step of inflating the retractor comprises the steps of:

inflating the main chamber,

optimizing the orientation of the retractor by repeating the following steps until the orientation of the retractor is correct:

observing the orientation of the retractor; and if the orientation is incorrect:

partially deflating the main chamber,

reorientating the retractor by gripping the at least one gripping tab with a gripping instrument and manipulating the gripping instrument, and

reinflating the main chamber,

inflating the additional chamber, and

releasing the inflation of the main chamber.

**22**. The method of claim **19**, wherein:

the retractor is maintained in its collapsed state by lacing, and

the step of placing the retractor adjacent the organ includes

pushing the retractor through a tube from outside the body, and

unlacing the lacing.

**23**. The method of claim **19**, wherein:

the retractor is maintained in its collapsed state by a peelable sheath, and

the step of placing the retractor adjacent the organ includes

pushing the retractor through a tube from outside the body, and

peeling the peelable sheath away from the retractor.

**24**. The method of claim **23**, wherein:

the peelable sheath includes a tear strip, and

the step of peeling the peelable sheath includes removing the tear strip to release the peelable sheath from the retractor.

**25**. The method of claim **19**, wherein:

in the step of providing the inflatable retractor, an inflatable retractor including a main inflation tube is provided; and

the method additionally comprises the steps of:

passing the surgical instrument from outside the body through the main inflation tube into the retractor, and

passing the surgical instrument through the aperture to treat the tissue.

**26**. The method of claim **25**, wherein:

the main inflation tube is attached to the main chamber, and

the step of passing the surgical instrument from outside the body through the main inflation tube into the retractor includes passing the surgical instrument through the main inflation tube into the main chamber.

**27**. The method of claim **19**, additionally comprising the steps of:

providing a surgical instrument;

piercing an additional aperture in the retractor;

passing the surgical instrument from outside the body into the retractor; and

passing the surgical instrument through the additional aperture to treat the tissue.

28. The method of claim 27, wherein:
the step of piercing an aperture in the retractor pierces the aperture in a window, and
the step of piercing an additional aperture in the retractor pierces the additional aperture in a window.

29. A method for retracting an organ inside the body in the course of treating adjacent tissue, the method comprising the steps of:
providing an inflatable retractor and a surgical instrument,
placing the inflatable retractor adjacent to the organ, the retractor being in a collapsed state,
inflating the retractor to retract the organ,
piercing an aperture in the retractor to provide access to the tissue,
passing the surgical instrument form outside the body into the retractor,
pulling the tissue into the retractor through the aperture, and
using the surgical instrument to treat the tissue.

30. The method of claim 29, wherein:
the retractor includes a main inflation tube, and
the step of passing a surgical instrument from outside the body into the retractor includes passing the surgical instrument through the main inflation tube.

31. The method of claim 30, wherein:
the retractor comprises:
a main envelope enclosing a main chamber, and
an additional envelope attached to the main envelope, the additional envelope and part of the main envelope enclosing an additional chamber, and
the aperture is pierced in a part of the main envelope remote from the additional chamber.

32. The method of claim 31, wherein:
the main inflation tube is attached to the main chamber, and
the step of passing the surgical instrument from outside the body into the retractor includes passing the surgical instrument through the main inflation tube into the main chamber.

33. The method of claim 29, wherein:
the step of piercing an aperture in the retractor additionally includes the step of piercing an additional aperture in the retractor, and
the step of passing a surgical instrument from outside the body into the retractor includes the step of passing the surgical instrument through the additional aperture.

34. The method of claim 33, wherein:
the retractor comprises
a main envelope enclosing a main chamber, and
an additional envelope attached to the main envelope, the additional envelope and part of the main envelope enclosing an additional chamber, and
the aperture is pierced in a part of the main envelope remote from the additional chamber.

35. The method of claim 34, wherein:
the step of piercing an aperture in the retractor pierces the aperture in a window,
the step of piercing an additional aperture in the retractor pierces the additional aperture in a window, and
the step of passing a surgical instrument from outside the body into the retractor includes passing the surgical instrument through the additional aperture.

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