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(54) Title: METHOD AND APPARATUS FOR ASSISTING IN THE INTRODUCTION OF SURGICAL IMPLEMENTS INTO A BODY

(57) Abstract: A tissue penetration device is provided that includes a bell-like, at least partially transparent housing. A valved port is provided in the housing for introduction of a penetrator therein. The valved port includes both a valve control and a port. A vacuum system, including a vacuum source, is securely and sealably attached through the housing to advance a patient's tissue onto the penetrator.



WO 2008/028126 A2

Method and Apparatus for Assisting in the Introduction of Surgical Implements into a Body

CROSS-REFERENCE TO RELATED APPLICATION

5 The application claims priority to U.S. patent application serial no. 11/848,015
filed 30 August 2007, which is a continuation-in-part of U.S. patent application
serial no. 11/781,159, filed 20 July 2007, which claims priority from U.S.
Provisional patent application serial no. 60/824,393, filed September 1, 2006,
10 each of which is incorporated herein in its entirety by this reference thereto.

BACKGROUND OF THE INVENTION

TECHNICAL FIELD

15 The invention relates to surgical implements. More particularly, the invention
relates to a method and apparatus for assisting in the introduction of surgical
implements into a body.

20 DESCRIPTION OF THE PRIOR ART

Significant morbidity and mortality occurs each year by iatrogenic injuries during
establishment of a pneumoperitoneum prior to the performance of laparoscopic
surgical procedures. The main source of these injuries is inadvertent perforation
25 of blood vessels, intestines, or other viscera within the abdominal (peritoneal)
cavity when the penetration device (needle, trocar, biopsy instrument, etc.) is
advanced too far through the abdominal wall, inadvertently piercing the
underlying organs that are located adjacent thereto. These injuries are more
common with inexperienced surgeons, but can occur even in the most
30 experienced hands. Built-in safety devices exist in the perforation devices

Attorney Docket No. ARAG0015CIP

themselves, but injuries still occur because of the close proximity of the structures that are intended to be perforated and those to be avoided. In addition, significant time, resulting in additional anesthetic time (and consequences) for surgical patients, results from failure to pass the penetration
5 device (needle, trocar, biopsy instrument, etc.) far enough. In such situations, the device tip is incorrectly positioned within the abdominal wall, superficial to the target abdominal (peritoneal) cavity. This failure to position the device correctly requires time to recognize and additional time to correct and verify. During these corrective maneuvers, the patient receives anesthetic.

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Vacuum has been used to fix or distort the body and body cavities. In addition, techniques exist for insufflation or mechanical or vacuum elevation of the abdominal wall during surgical procedures.

15 In U.S. patent no. 6,042,539, a vacuum-actuated tissue-lifting device and method for performing a surgical procedure in an operative space of a patient are disclosed. The preferred device has a shell with a profile configured to surround a tissue surface of the patient, a vacuum port located on the shell for applying a vacuum between the shell and the tissue surface, and an air conduit
20 extending through the shell to permit air to pass into the operative space of the patient when vacuum is applied.

In U.S. patent no. 6,340,358, a trocar is disclosed having a safety shield control mechanism that prevents the inner cannula from rotating and from moving axially
25 when in the locked position. The safety shield control mechanism applies consistent pressure on the safety shield and has an open architecture for ease of sterilization. The trocar provides holding levels for different sizes of hands.

In U.S. patent no. 6,197,041, a pneumatically powered trocar assembly is
30 disclosed that includes a source of compressed gas which releases a metered amount of gas to a chamber. A piston slidably positioned within the chamber is driven forward by the compressed gas introduced therein, and an obturator with

Attorney Docket No. ARAG0015CIP

a tissue piercing tip are advanced thereby. Optionally, a sensor detects the presence of body tissue within the cutting path of the tip and blocks the passage of compressed gas to the chamber, or alternatively, opens an escape vent to release compressed gas therefrom if insufficient body tissue resistance is encountered.

In U.S. patent no. 5,669,883, a Veress needle and cannula assembly is disclosed that includes a stainless steel cannula assembly with a cannula having an outer diameter of approximately 4 mm and a Veress needle assembly having a Veress needle with an outer diameter of approximately 3 mm. The cannula assembly includes a proximal valve assembly and the Veress needle is insertable through the valve assembly.

In U.S. patent no. 5,690,607, an apparatus is disclosed for allowing two retractors to be used to lift the abdominal wall to provide improved visualization and working space in the abdomen of obese patients, and in the lateral regions of the abdomen of normal patients. The apparatus connects a first retractor and a second retractor to a mechanical lifting arm, and comprises a bar, and first, second, and third connecting devices. The apparatus is used by making a first incision and a second incision in the abdominal wall at separated locations. The first retractor is inserted into the first incision, and the second retractor is inserted into the second incision. The first retractor and the second retractor are attached to the crossbar, and a lifting force is applied to the crossbar.

In U.S. patent no. 5,575,759, an apparatus for retracting an organ to gain access to treat a tissue is disclosed. The apparatus has a main envelope, a second envelope, a first inflation device and a second inflation device. The main envelope encloses a main chamber, and includes a window and a removable window. The second envelope covers substantially all the main envelope, except the window and the removable window. The second envelope and the main envelope enclose a second chamber outside the main chamber. The first inflation device passes a fluid into the main chamber to expand the main

Attorney Docket No. ARAG0015CIP

chamber and the second chamber from a compacted state to retract the organ. The second inflation device passes a fluid into the second chamber to further expand the second chamber to maintain the organ in its retracted state after fluid has been released from the main chamber.

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In U.S. patent no. 5,562,603, an apparatus is described for laparoscopically retracting an organ inside the body to provide surgical access to adjacent tissue. The apparatus includes a thin, flexible envelope, which encloses a chamber. The envelope is laparoscopically insertable in a collapsed state into a body cavity, and the chamber is inflatable to an expanded state following introduction of the envelope into the body. Inflation of the chamber causes retraction of adjacent tissue. An elastomeric seal is insertable into the chamber following inflation and is attachable to part of the envelope inside the chamber following inflation of the chamber. The seal provides a gas-tight seal to maintain the chamber in the expanded state, and to maintain the organ in the retracted state, notwithstanding the piercing of an aperture in the part of the envelope covered by the seal.

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In U.S. patent no. 5,531,856, an inflatable apparatus for organ retraction includes a main envelope that forms a main chamber is disclosed. An additional chamber is formed by attaching the periphery of an additional envelope to the outside or the inside of the main envelope. The part of the surface of the main envelope that is not covered by the additional envelope provides a plurality of windows, which, after the additional chamber is inflated, may be at least partially removed to provide apertures through, which treatment or observation can be carried out.

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In U.S. patent no. 5,527,264, a method is disclosed for retracting an organ inside the body to provide access for treating a tissue, a retractor having a main envelope, which defines a main chamber is positioned in a collapsed state adjacent to the organ to be retracted. The main chamber is subsequently inflated to retract the adjacent organ. A surgical instrument is passed through the main envelope into the main chamber to contact the tissue for treatment. In U.S.

Attorney Docket No. ARAG0015CIP

patent no. 5,522,790, a first inflatable retraction device is disclosed having a first inflatable chamber and a non-pressurized chamber inside the main chamber. The non-pressurized chamber is expanded by inflating a second inflatable chamber. The non-pressurized chamber enables the main chamber to remain
5 inflated when an aperture is cut in the envelope of the main chamber, through which treatment is carried out. A second inflatable retraction device has an inflatable retractor and a maintainer. The inflatable retractor retracts the organ and the maintainer maintains the organ in its retracted condition after the inflatable retractor is deflated. The maintainer can be inflatable, and can be
10 inside or outside the inflatable retractor. A self-retracting endoscope has an optical assembly with an expandable retractor fitted to its distal end. The distal end of the endoscope is inserted into the body with the retractor in a collapsed condition. The retractor is then expanded to retract organs that would otherwise obstruct the view from the distal end of the optical assembly. After observations
15 are complete, the retractor is returned to its collapsed condition. An insertion tube enables cylindrical objects, such as packaged inflatable retraction devices, to be pulled, instead of pushed, into the body. The additional chamber of an inflatable retraction device having two inflatable chambers is filled with a slurry of a particulate solid in a liquid. The liquid is removed and the additional chamber
20 evacuated to consolidate the particulate solid. This increases the retracting strength of the additional chamber.

In U.S. patent no. 5,505,689, a fan retractor is disclosed for laparoscopic surgery has a pair of angle-shaped elements with first legs disposed in parallel
25 relationship to one another and second legs extending laterally from the first legs for movement between a juxtaposed collapsed condition and a fanned-out expanded condition responsive to rotation of the first legs about their longitudinal axes. Actuators are provided on the first legs to move the second legs between the collapsed and extended conditions. A first lock engages the actuators to lock
30 the second legs in the extended condition and against movement toward or away from one another. A second lock in the form of a block slidably received on the first legs is selectively engageable between the second legs when in the

Attorney Docket No. ARAG0015CIP

extended condition. When engaged, the second lock serves both to block the second legs from movement toward one another and to restrain the first legs against movement away from one another.

5 In U.S. patent no. 5,465,711, an organ or tissue plane to be retracted is performed to gain access for a surgical instrument to treat an organ or tissue plane to be treated. An inflatable retractor, including a main envelope enclosing a main chamber, is provided with the main envelope in a collapsed state. The main envelope of the retractor is placed adjacent the organ or tissue plane to be
10 retracted. The main chamber is inflated to an expanded state to retract the organ or tissue plane to be retracted. An aperture is pierced in the main envelope to provide access for the surgical instrument passed into the main chamber to contact an organ or tissue plane to be treated while the main chamber is maintained in the expanded state, notwithstanding the aperture pierced in the
15 main envelope.

In U.S. patent no. 5,454,367, an inflatable retractor including a main envelope enclosing a main chamber is provided. The main envelope is provided in a collapsed state. An elastomeric window is also provided. The main envelope of
20 the inflatable retractor is placed adjacent the organ inside the body, and the main chamber is expanded to an expanded state to retract the organ. Following inflation of the main chamber to the expanded state, the elastomeric window is attached to the main envelope inside the main chamber to cover part of the main envelope. The surgical instrument is passed into the main chamber. An aperture
25 is pierced in the pan of the main envelope covered by the elastomeric window to provide access for the surgical instrument to contact the tissue. The elastomeric window provides a gas-tight seal to maintain the main chamber in the expanded state.

30 In U.S. patent application publication no. 20040049127, a system is provided that advances tissue to be perforated onto a stationary perforation device and away from the underlying structures. The simplicity of technique leads to a short

Attorney Docket No. ARAG0015CIP

learning curve and virtually eliminates the possibility of iatrogenic injuries. In one embodiment, tissue to be perforated is advanced onto a perforation device or piercing instrument. A primary intended use of the such embodiment is taught to be for pulling the abdominal wall onto a perforation device, such as a Veress
5 needle, trocar, or punch biopsy cutting tool, and away from abdominal viscera and great vessels for the initial establishment of a pneumoperitoneum. Another intended application for such embodiment is for implanting a device below the skin surface for diagnostic or therapeutic purposes.

- 10 Referring to FIG. 1 and FIG. 2, which are a side and bottom view, respectively, of a perforation device 10 in accordance with United States patent application publication no. 20040049127, positioned over a non-extended abdominal wall 18. The device 10 comprises a housing 12 having a housing pass-through 12C and a housing seal 12A along a perimeter functioning to form a tight seal
15 between the housing 12 and an abdominal wall 18. The housing 12 is manufactured from a strong non-collapsible material to withstand the internal negative pressure in the range of about 50 to 250 mm Hg exerted therein. Suitable materials are specifically designed for medical use and capable of sterilization. The materials include plastic, plastic composite, rubber, rubber
20 composite, fiberglass, epoxy, glass, glass composite, and the like. Plastic, such as polycarbonate and acrylic materials, and plastic composites are particularly well suited due to their superior strength, transparency, rapid manufacturing and low cost. The housing 12 is usually translucent or transparent. Transparency is preferable to allow the physician to monitor the perforation. Housing 12 is sized
25 to accommodate adults and children of different sizes and/or body mass indexes. The diameter of the circumference of housing 12 in contact with the abdomen for adults ranges from about 3 inches to 8 inches and for pediatric patients from 1 ½ to 3 inches.
- 30 A penetrator 14 is securely and sealably positioned through a top center housing 20 of the housing 12. The seal and fixation of the penetrator 14 can be done by means of the O-ring 22. The seal and fixation of the penetrator 14 can also be

Attorney Docket No. ARAG0015CIP

accomplished by other means, e.g. by pressing the operator's fingers on penetrator 14 and braced against the housing pass-through 12C. The penetrator 14 comprises a penetrator device 14C, such as a Veress needle, trocar, or other suitable device, designed to penetrate or cut tissue. The penetrator 14 has a valve 14B for allowing the penetrator tube 14D either to introduce ambient room air, or for connection to a pressurized source of a gas, e.g. carbon dioxide, helium, nitrogen, air, and mixtures thereof, for insufflation. The tissue perforation device 10 further comprises a standard operating room vacuum system 16. A vacuum tube 16A is securely and sealably attached to the housing 12 through a valve or pressure regulator 16B, which functions to regulate the amount of negative pressure exerted within the housing 12.

Referring now to FIG. 3, an extended abdominal wall 18 is shown with an abdominal wall bubble 18A. The abdominal wall bubble 18A is formed by applying negative pressure at vacuum tube 16A, which extends into and is sealed against housing 12. Internal negative pressure within the housing 12 creates an abdominal wall bubble 18A within the housing 10 and elevates the abdominal wall 18 away from the underlying organs and vascular structures. As the abdominal wall bubble 18A enlarges, the abdominal wall 18 is advanced onto the stationary penetrator device 14C. Room air or inert gas introduced through penetrator valve 14B into the peritoneal cavity to further facilitates the separation between the abdominal wall 18 and the underlying organs and vessels. The penetrator device 14C contains an optical device or integral camera 24 at its tip to direct visualization of the passage of penetrator device 14C through tissue. The distance of tissue movement is controlled directly by the operator through regulation of the vacuum. This may be controlled by periodic opening of a vacuum valve, or through a regulator 16B. Optimal vacuum is a function of the tissue characteristics, and is regulated by the operator to achieve the desired tissue displacement. Following penetration and insufflation, the applied vacuum may be released and the housing removed by means of a clamshell housing or by means of an adaptor plate or collar while leaving the perforation device in place through the abdominal wall.

Attorney Docket No. ARAG0015CIP

SUMMARY OF THE INVENTION

5 A tissue penetration device is provided that includes a bell-like, at least partially transparent housing. A valved port is provided in the housing for introduction of a penetrator therein. The valved port includes both a valve control and a port. A vacuum system, including a vacuum source, is securely and sealably attached through the housing to advance a patient's tissue onto the penetrator.

BRIEF DESCRIPTION OF THE DRAWINGS

10 FIG. 1 is a side view of a tissue perforation device positioned over a non-extended abdominal wall;

15 FIG. 2 is a bottom view of the perforation device of FIG. 1;

FIG. 3 is a side view of the perforation device of FIG. 1 exhibiting an extended abdominal wall forming an abdominal wall bubble;

20 FIGS. 4A and 4B provide a perspective view (FIG. 4A) and a side elevation view (FIG. 4B) of a vacuum housing incorporating a valved port for introduction of a penetrator according to an embodiment of the invention;

25 FIGS. 5A and 5B provide a perspective view (FIG. 5A) and a side elevation view (FIG. 5B) of a vacuum housing incorporating a valved port for introduction of a penetrator according to another embodiment of the invention;

30 FIGS. 6A and 6B provide a side elevation view (FIG. 6A) and a top plan view (FIG. 6B) of a vacuum housing incorporating a tear away insert according to a further embodiment of the invention;

Attorney Docket No. ARAG0015CIP

FIGS. 7A and 7B provide a side elevation view (FIG. 7A) and a top plan view (FIG. 7B) of a split shell vacuum housing according to a further embodiment of the invention; and

- 5 FIG. 8 provides a side elevation view of a seal according to a further embodiment of the invention;

FIG. 9 provides a side elevation view of a vacuum release according to a further embodiment of the invention;

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FIG.10 provides a side elevation view of a vacuum housing dome which incorporates two sharp tipped tubes according to a further embodiment of the invention;

- 15 Fig. 11 provides a side elevation view of a vacuum housing dome which incorporates two blunt tipped tubes according to a further embodiment of the invention; and

FIG. 12 provides a side elevation view of a vacuum housing having a collapsible dome wall according to a further embodiment of the invention.

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DETAILED DESCRIPTION OF THE INVENTION

- 25 The invention provides several improvements to the prior art device discussed above in connection with FIGS. 1-3.

FIGURES. 4-A and 4-B provide a perspective view (FIG. 4A) and a side elevation view (FIG. 4B) of a vacuum housing 40 incorporating a valved port 42 for introduction of a penetrator. In FIGS. 4A and 4B, the housing includes a valved port having a valve control 44 and a conduit 49 which allows admission of a needle or trocar or other penetrating device in the housing. The valved port 42

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Attorney Docket No. ARAG0015CIP

is secured to the housing 40 by a plurality of ribbed extensions 43. The housing 40 also includes a sealing surface 48 for sealing the housing to an individual's skin surface. Additionally, a side-mounted vacuum port 41 is coupled to the housing. The vacuum port 41 incorporates a nipple 45 for attachment to an external source of vacuum and a bleed conduit 47 for allowing entry of air into the housing. A valve control 46 is operable to couple the vacuum to the housing via the vacuum port nipple 45, to purge the vacuum from the housing via the purge port 47, or to seal the vacuum port so that neither the vacuum port nipple 45 nor the purge port 47 are coupled to the interior of the housing 40.

FIGURES 5A and 5B provide a perspective view (FIG. 5A) and a side elevation (FIG. 5B) of a vacuum housing 50 incorporating a valved port 52 for introduction of a penetrator according to another embodiment of the invention. In FIGS. 5A and 5B, a housing 50 includes a valved port 52 which includes a conduit 59 which allows admission of a needle or trocar or other penetrating device into the housing and a valve control 54. In this embodiment of the invention, the ribbed members 53 which support the valved port 52 have a reduced profile which allows a user to grasp and operate the valve control 54 with less effort. As with the embodiment of FIGS. 4A and 4B, the housing 50 includes a sealing surface 58 for sealing the housing to an individual's skin surface. Also included is a vacuum port 51 which incorporates a vacuum port nipple 55, a bleed port 57, and a control valve 56, which operate in the same manner as similar elements discussed above in connection with FIGS. 4A/4B.

Significant in the embodiment of FIGS. 4A/4B and 5A/5B is the provision of a valved port. Accordingly, these embodiments to the invention provide the vacuum port nipple on the side of the housing. This permits ready user access to the valve port control (42; FIGS. 4A/4B and 52; FIGS. 5A/5B). The valve assembly of the valved port is preferably a two or three-way valve. In the open position, the valve allows a vacuum to be created within the housing and in the venting position, the housing is vented to the atmosphere. Thus, when the device is used, for example, to lift a patient's abdominal tissue the valve is set to the

Attorney Docket No. ARAG0015CIP

closed or vacuum position, and when the device is to be released from the individual, the valve is turned to the open position to release the vacuum.

Significant to the invention is the use of a compression seal fitting for the valved port. One use of the invention is in, for example, laparoscopic procedures and
5 intervascular procedures. A typical top fitting of a compression seal fitting could be used in this embodiment of the invention. Such assembly is a fitting that allows passage of a catheter or guide wire through a port into an artery without loss of vacuum through the port. The top fitting comprises a valve that allows
10 access of a tool through the port, while maintaining a seal having sufficient integrity to prevent the loss of vacuum through the port to the opening through which the tool is introduced. In the invention herein, any fitting is used that allows the introduction of tools through the port once the housing has drawn a vacuum and lifted the patient's abdominal, for example, tissue upwardly into the housing,
15 where the valve may be tightened sufficiently to hold the tool in place, for example to maintain a stationary location for a penetrator while vacuum is applied, such that the tissue is lifted into the penetrator, in one embodiment, by application of vacuum to the housing. The size of tool accommodated by the port is a function of, *inter alia*, the diameter of the O-ring or other sealing surface
20 within the port of the valve. Thus, in some applications an O-ring may be chosen that is sufficient to seal the port entirely in the absence of a tool therein. In other embodiments, the size of the port is sufficient, when the valve is closed, to prevent most leakage into the housing of the atmosphere as vacuum is applied, and yet provide a sufficient opening to allow introduction of a tool without the risk
25 of damaging the seal and the valve during introduction of the tool therethrough. Thus, the vacuum port may allow for complete sealing of the port, or only partial sealing of the port as desired. In both cases, the valve is adjustable to allow the port to be open sufficiently, in the first case to admit atmosphere into the housing, and in the second case to permit entry therein of a tool.

30 Because the vacuum port has an adjustment valve, the embodiments of FIGS. 4A/4B and 5A/5B include support ribs, as discussed above. The support ribs are

Attorney Docket No. ARAG0015CIP

struts to impart sufficient strength to the housing at the point at which the vacuum port is added such that the housing does not break or crack as the valve adjustment is twisted to open and close the port. In some embodiments of the invention, the cylinder portion of the valve is integrally molded with the support in the housing itself to allow manufacture of the housing, support, and valve cylinder as a single assembly. In other embodiments, the vacuum port may be attached to the housing with a washer and nut, or by gluing thereto. In yet other embodiments of the invention, the entire dome of the housing, including the vacuum port could be detachable from the housing, such that different sized ports with different valve arrangements could be interchanged with a common housing.

The embodiments of the invention discussed above in connection with FIGS. 4A/4B and 5A/5B may be used with various types of devices such as Veress needles and trocars. In the case of using a Veress needle at a first portion of the procedure, the Veress needle may be used in connection with the housing and vacuum to create a pneumoperitoneum. After the pneumoperitoneum is created, the Veress needle may be removed from the individual and the housing may be lifted away. At that point, a trocar may be inserted into the individual and a laparoscopic or endoscopic procedure may then be pursued. In another embodiment, a trocar may be inserted without first creating a pneumoperitoneum. Once the tissue is drawn upwardly in the dome by application of a vacuum and the body cavity wall is pulled upwardly, the trocar may be introduced into the body tissue or the body tissue may be pulled directly over the trocar. At this point, it is not necessary to remove the trocar until the end of the procedure. In such case, it would be advantageous to remove the housing (see Figs. 6A/6B discussed below).

As discussed above in connection with FIGS. 4A/4B and 5A/5B, one embodiment includes support ribs that go further up the shaft of the vacuum port (FIGS. 4A/4B) than that of the other embodiment (FIGS. 5A/5B). In either embodiment, the housing maintains the same volume of tissue. However, as

Attorney Docket No. ARAG0015CIP

discussed above one embodiment provides larger ribs or struts for support, e.g. in a preferred embodiment of about 22 millimeters, as opposed to an embodiment which provides shallower ribs or struts, e.g. in a preferred embodiment of about 15 millimeters. As discussed above, this latter
5 arrangement provides more space for grasping the valve.

FIGURES 6A and 6B provide a side elevation view (FIG. 6A) and a top plan view (FIG. 6B) of a vacuum housing 60 incorporating a tear-away insert 62 according to a further embodiment of the invention. As discussed above, previous
10 inventions have used vacuums to create a space between the skin and the underlying organs to allow safe introduction of a Veress needle for purposes of initiating a laparoscopic procedure. However, these devices are limited to a small diaphragm or portal to maintain vacuum while introducing the Veress needle. Later during the procedure, the Veress needle is exchanged for a larger diameter
15 trocar which is required to deliver devices into the portal for a laparoscopic procedure. The embodiment of the invention shown in FIGS. 6A/6B allows direct introduction of larger devices, such as trocars, which obviates the need for the preliminary step of using a smaller Veress needle to first institute the implementation of a pneumoperitoneum with a device that is smaller than a
20 trocar, and which must ultimately be deployed for the laparoscopic procedure. This embodiment of the invention includes a bell-like, at least partially transparent, housing 60 that is secured to the surface of the individual's skin 64. In a first embodiment, the housing has a removable plug or insert 62 at the top or apex of the bell portion of the housing through which the trocar 61 is placed. The
25 trocar may be either partially or fully pre-loaded through the bell plug or insert to maintain a seal while vacuum is instituted, or it may be placed through the seal after the bell is secured and the vacuum is initiated. Once the vacuum has been implemented, the skin and underlying tissue and fat layers are physically raised above the underlying organs, and the trocar can be safely advanced through this
30 tissue into the body to allow implementation of the laparoscopic procedure. Once the trocar has penetrated the tissue, a pneumoperitoneum can be applied as well by the introduction of insufflating medium into the patient's body cavity. At

Attorney Docket No. ARAG0015CIP

this point, the housing can be removed, for example by breaking a seal between the insert plug and housing, and raising the housing upwards around the removable plug and trocar and out of the sterile field. The removable plug can then be removed. The plug can be a tear-away, split-wing type device 63 that
5 breaks in two or that opens when pulled apart, or it can be a clamshell hinge-type device. In an alternative embodiment (see FIGS. 7A/7B), the entire bell itself may be a tear-away or a clamshell device which facilitates removal thereof so that the trocar may be fully advanced into the fully deployed position for surgical use.

10 In yet other embodiments, a penetrable film or other such material may be disposed at or near the apex of the housing, through which tools or other expedients may be introduced by puncturing the film. The film preferably comprises a material that has sufficient resilience to maintain a seal about a tool
15 after the tool has punctured the film and while the tool is introduced into or withdrawn from the housing. In some embodiments, the film may comprise a self sealing material, or a patch may be provided to maintain the film's vacuum integrity after a tool has punctured the film and then been withdrawn therefrom. The film may be also be provided having a sufficient coverage to allow the
20 housing to be lifted from the work area without having to move or manipulate the tool. In particular, when the housing is lifted from the work area, the penetrable material expands about the tool to allow the dome to be lifted completely free of the tool and out of the work area.

25 FIGURES 7A and 7B provide a side elevation view (FIG. 7A) and a top plan view (FIG. 7B) of a split shell vacuum housing 70 according to a further embodiment of the invention. In this embodiment of the invention, the housing 70 includes a hinge 72 and seal 71, which may be a clasp like seal. The housing has sufficient integrity along the hinge and clasp-like seal to allow maintenance of the vacuum
30 during the initial portion of the procedure when the tissues and skin are lifted away from the internal organs of the patient. As discussed above, a trocar 61 is introduced into the housing through a port 73. Once the trocar has penetrated

Attorney Docket No. ARAG0015CIP

the tissue of the patient and a pneumoperitoneum (if desired) is established, the housing is opened along the sides, and the halves of the housing are spread apart along the hinge. The housing is then readily removed and the procedure may go forward without the housing being in the way of the surgeon performing the procedure. While a hinge and clasp seal are shown in FIGS. 7A/7B, those skilled in the art will appreciate that other arrangements may be used to provide a housing that may separate into two or more sections. For example, the housing may include a bead and mating groove that allows the sections of the housing to seal together, or the housing may be secured by engaging a groove of a resilient silicon member with respective edges of two or more housing hemispheres. This allows the housing to be quickly separated into multiple sections. Further, the housing may be held together by a temporary adhesive seal that is readily dissolved.

The housing used to connect to the invention is typically made of a rigid plastic or metal material that does not always produce adequate skin seals on patients having less elastic or thinner skin, e.g. the elderly or hirsute. FIG. 8 provides a side elevation view of a seal according to a further embodiment of the invention. In this embodiment of the invention, which operates in connection with a housing that is commonly a rigid clear plastic and that is not elastic or conformable, a rubber or elastomeric seal, gasket, or O-ring 81 is placed over a lip at the bottom edge of the housing 80 and makes contact with the patient's skin. The material for the seal may be bonded or press fit over the lip of the housing. Alternatively, a similar result may be obtained by applying a gel-like material on the edge of the housing that contacts the patient's skin or by placing such material directly on the skin of the patient. This embodiment of the invention not only improves the seal quality, but also prevents damage to the skin of the patients, especially those with thinner or less elastic skin.

FIGURE 9 provides a side elevation view of a vacuum release according to a further embodiment of the invention. This embodiment of the invention allows easier release of vacuum from the housing once the needle or trocar has been

Attorney Docket No. ARAG0015CIP

introduced. While pressure within the housing could be released by disconnecting the source of vacuum, for example by using a two or three-way valve in the vacuum tubing feeding the housing as discussed above, the invention according to FIG 9. releases vacuum by allowing user to depress a
5 diaphragm 82 on the housing 80 or by alternatively removing a plug placed in the housing.

As discussed herein, the introduction of needles, trocars, and catheters, especially during emergency procedures, can be fraught with danger due to the
10 delicate organs that lie in close proximity beneath the skin. Significant force is required to deploy these instruments, which can inadvertently be transmitted beyond the desired penetration depth. In addition, many procedures use access to arteries or veins for therapeutic purposes. There may be benefits in speed of treatment if the larger blood vessels in the abdomen could be quickly and safely
15 accessed.

Embodiments of the invention discussed above use a vacuum device to create a space between the skin and underlying organs of a patient to introduce a Veress needle safely for the purpose of initiating a laparoscopic procedure.

20 In a further embodiment of the invention, see for example Figs. 4a, 4b, 5a, and 5b, this same technique is used to introduce other needles, tubes, or other fluid conveying members into a patient's body via, for example, a conduit 49 (Figs. 4a/4b), or a conduit 59 (Figs. 5a/5b), for surgical procedures, such as
25 administration of fluids, such as blood transfusions, hypothermic fluids or alternatively, to drain fluids, for example, to treat dialysis patients directly through the abdomen, as opposed to venous drains in the arms or elsewhere.

A further embodiment of the invention, shown in FIGS. 10-12, includes one or
30 more intrinsic tubes 104 having a sharp tip 108 or hypodermic needles for introduction and recirculation of fluids, such as cooled liquids for inducing hypothermia, e.g. for treatment of stroke or cardiac arrest. Obturators 104 having

Attorney Docket No. ARAG0015CIP

blunt tips 107 are inserted in the tubes, and protrude vertically downward within the dome (FIGS. 10, 11:102) from the top of the dome toward the base of the dome. As a vacuum from a vacuum source 100 is drawn, these tubes puncture the body cavity wall 101 and a recirculating fluid may be introduced and
5 withdrawn through the tubes. This eliminates the need, and time required, to mount and introduce separate trocars and sheaths. If the vacuum is maintained throughout the procedure, there is no need to extend or advance these vertical tubes.

10 In the case where these tubes are too large in diameter to penetrate the body cavity, a separate trocar (FIG. 11: 114) having a blade 117 may be inserted within tubes prior to initiating the vacuum. Once the body cavity has been penetrated, the bladed trocar may be removed. When the bladed trocar is used, the vertical tube 116 is preferably blunt tipped 118 for safety reasons. If the
15 intent is to release the vacuum during the evacuation process, resulting in the need to advance the tubes further, the tubes may be separated from the dome as specified for the laproscopic procedure below.

In the case of laproscopic procedures, the dome may have a single intrinsic
20 vertically protruding tube with a blunt tip to make an opening for the purpose of creating a pneumoperitoneum, and subsequently introducing a camera or working tools. A separate bladed trocar is inserted into the tube prior to implementing the vacuum. Once the body cavity opening has been created, the bladed insert is removed and pneumoperitoneum is instituted. At this point the
25 dome may be removed by releasing a removable cap from the top of the dome or opening the clamshell of the dome, as discussed above. Once the cap is removed, or clamshell opened, the dome may be lifted over the port portion of the device which remains in place, and the dome is removed from the surgical field. The dome cap may be removed with a twist-lock, peel-away, or split-ring
30 mechanism. Alternatively, in place of the removable dome cap, a thin film is provided which can be torn or punctured by the upper section of the port as the dome cap is pulled upward against the port seal.

Attorney Docket No. ARAG0015CIP

The dome itself may be a collapsible device (FIG.12) that obviates the need to remove it from the sterile field during the surgery. The device comprises a dome 120 for receiving and/or retaining one or more vertical tubes 124. The device
5 also has a telescoping section or sections, such as an accordion bellows section 122, that collapse downward, away from the port segment of the device, based on the release of mechanical support pin or pins 122, or other support members.

Finally, an embodiment of the laproscopic device includes a sharp tipped vertical
10 extension tube having a blunt obturator. In this case, the sharp tip is resheathable or retractable for safety reasons, in which case it is used as a separatable port, as specified above; or a blunt tipped port could be inserted within the sharp tipped vertical extension tube. In this case, the dome separates from the port segment as per the various options specified above. In this final
15 case, the blunt tipped port is substantially longer than the sharp vertical tube to prevent subsequent trauma to the patient.

Although the invention is described herein with reference to the preferred embodiment, one skilled in the art will readily appreciate that other applications
20 may be substituted for those set forth herein without departing from the spirit and scope of the present invention. Accordingly, the invention should only be limited by the Claims included below.

Attorney Docket No. ARAG0015CIP

CLAIMS

1. A medical device, comprising:

- 5 a bell-like, at least partially transparent housing;
 a penetrator;
 a valved port for introduction of said penetrator into said housing, said
valved port having a valve control and a port;
 a vacuum system comprising a vacuum source securely and sealably
10 attached through the housing for advancing a patient's tissue onto the
penetrator; and
 means for introducing a needle, tube, or other fluid conveying member
into said patient's body to allow implementation of a surgical procedure.

- 15 2. The device of Claim 1, said housing further comprising:
 a plurality of ribbed members for securing said valved port thereto.

3. The device of Claim 2, said ribbed members comprising a profile that allows a
user to grasp and operate said valved port valve control.

20

4. The device of Claim 1, said vacuum system further comprising:
 a vacuum port mounted to a side portion of said housing, said vacuum
port comprising a vacuum port nipple for coupling said vacuum source to said
housing.

25

5. The device of Claim 1, further comprising:
 a bleed device formed in a side of said housing for selectively allowing
entry of air into said housing.

30 6. The device of Claim 5, said vacuum port further comprising:
 a valve control operable to selectively couple said vacuum source to said
housing via said vacuum port nipple, to purge a vacuum from said housing via

Attorney Docket No. ARAG0015CIP

said bleed conduit, and to seal said vacuum port so that neither said vacuum port nipple nor said bleed conduit are coupled to said housing.

7. The device of Claim 1, said valved port comprising:

5 a compression seal fitting for allowing access of said penetrator through said valved port while maintaining a seal having sufficient integrity to prevent leakage of blood back through said valved port;

 said compression seal fitting comprising adjustable means for securing said penetrator in place in said valved port to maintain a selected, stationary
10 location for said penetrator while vacuum is applied to said housing, such that said patient's tissue is lifted into said penetrator by application of a vacuum to said housing.

8. The device of Claim 7, said valved port further comprising:

15 an opening communicatively coupling an interior of said housing to an ambient, the size of said opening being defined by selective operation of said compression seal fitting, wherein substantially all leakage of said ambient into said housing as vacuum is applied is prevented when said compression seal fitting is closed, and wherein said opening allows introduction of said penetrator
20 into said housing when said valve is opened.

9. The device of Claim 1, said housing further comprising:

 a plurality of integral, ribbed members for securing said valved port thereto; and

25 at least a portion of said valved port integrally formed into said housing.

10. The device of Claim 1, wherein said housing is fabricated of any of a polycarbonate and acrylic material.

30 11. The device of Claim 1, said housing further comprising:

 a dome, said dome comprising said vacuum port;
 wherein said dome is detachable from said housing.

Attorney Docket No. ARAG0015CIP

12. The device of Claim 1, said means for introducing comprising:
a rigid tube extending transversely through said housing.

5 13. The device of Claim 1, said fluid conveying member comprising:
a plurality of tubes for conducting a fluid flow.

14. The device of Claim 1, said fluid conveying member comprising:
a tube having a blunt tip.

10

15. The device of Claim 1, said fluid conveying member comprising:
a tube having a sharp tip which comprises said penetrator.

16. The device of Claim 1, wherein said housing is at least partially collapsible.

15

17. The device of Claim 1, wherein said housing further comprises:
a tear-away insert or penetrable film for allowing direct introduction of a
tool or a needle, tube, or other fluid conveying member into said housing during
a surgical procedure.

20

18. The device of Claim 17, wherein said penetrable film comprises:
a self sealing material, or a patch that maintains vacuum integrity after a
tool has punctured the film and then been withdrawn therefrom.

25 19. The device of Claim 17, wherein said penetrable film has sufficient coverage
to allow the housing to be lifted from a work area without having to move or
manipulate said tool;

wherein when said housing is lifted from the work area, the penetrable film
expands about the tool to allow the housing to be lifted completely free of the
30 tool and out of the work area.

20. A medical device, comprising:

Attorney Docket No. ARAG0015CIP

a bell-like, at least partially transparent housing, said housing further comprising a tear-away insert or penetrable film for allowing direct introduction of a tool or a needle, tube, or other fluid conveying member into said housing during a surgical procedure; and

5 a vacuum system comprising a vacuum source securely and sealably attached through the tear-away insert of said housing for drawing a patient's tissue into said housing.

21. The device of Claim 20, said tear-away insert further comprising:

10 a valved port for introduction of said needle, tube, or other fluid conveying member into said housing, said valved port having a valve control and a port.

22. The device of claim 20, said fluid conveying member comprising:

15 a rigid tube extending transversely through a top portion of said housing at said insert.

23. The device of Claim 20, said fluid conveying member comprising:

a plurality of tubes for conducting a fluid flow.

20 24. The device of Claim 20, said fluid conveying member comprising:

a tube having a blunt tip.

25. The device of Claim 20, said fluid conveying member comprising:

a tube having a sharp tip which comprises a penetrator.

26. The device of Claim 20, wherein said housing is at least partially collapsible.

27. The device of Claim 20, wherein said penetrable film comprises:

30 a self sealing material, or a patch that maintains vacuum integrity after a tool has punctured the film and then been withdrawn therefrom.

28. The device of Claim 20, wherein said penetrable film has sufficient coverage

Attorney Docket No. ARAG0015CIP

to allow the housing to be lifted from a work area without having to move or manipulate said tool;

wherein when said housing is lifted from the work area, the penetrable film expands about the tool to allow the housing to be lifted completely free of the tool and out of the work area.

29. A medical device, comprising:

a bell-like, at least partially transparent housing, said housing further comprising a removable plug or insert at a top or apex of a dome portion of said housing through which a needle, tube, or other fluid conveying member is placed;

a vacuum system comprising a vacuum source securely and sealably attached through the housing for advancing a patient's tissue into said housing;

wherein said needle, tube, or other fluid conveying member is either partially or fully pre-loaded through said plug or insert to maintain a seal while vacuum is instituted, or said needle, tube, or other fluid conveying member is placed through said seal after vacuum is initiated;

wherein once a vacuum has been implemented, skin and underlying tissue and fat layers of a patient are physically raised above underlying organs, and said needle, tube, or other fluid conveying member is advanced into the body to allow implementation of a surgical procedure.

30. The device of Claim 29, further comprising:

means for applying a pneumoperitoneum.

31. The device of Claim 29, said plug or insert further comprising:

a breakable seal between said plug or insert and said housing; wherein, upon breaking said seal, said housing may be lifted away from said removable plug or seal.

32. The device of Claim 29, said removable plug or insert further comprising any of:

Attorney Docket No. ARAG0015CIP

a tear-away, split-wing type device that breaks in two or opens when pulled apart or a clamshell hinge-type device.

33. The device of Claim 29, said fluid conveying member comprising:

5 A rigid tube extending transversely through said housing.

34. The device of Claim 29, said fluid conveying member comprising:

a plurality of tubes as for conducting a fluid flow.

10 35. The device of Claim 29, said fluid conveying member comprising:

a tube having a blunt tip.

36. The device of Claim 29, said fluid conveying member comprising:

a tube having a sharp tip which comprises a penetrator.

15

37. The device of Claim 29, wherein said housing is at least partially collapsible.

38. The device of Claim 29, wherein said housing further comprises:

20 a tear-away insert or penetrable film for allowing direct introduction of a tool or a needle, tube, or other fluid conveying member into said housing during a surgical procedure.

39. The device of Claim 38, wherein said penetrable film comprises:

25 a self sealing material, or a patch that maintains vacuum integrity after a tool has punctured the film and then been withdrawn therefrom.

40. The device of Claim 38, wherein said penetrable film has sufficient coverage to allow the housing to be lifted from a work area without having to move or manipulate said tool;

30 wherein when said housing is lifted from the work area, the penetrable film expands about the tool to allow the housing to be lifted completely free of the tool and out of the work area.

Attorney Docket No. ARAG0015CIP

41. A tissue penetration device, comprising:

a split shell vacuum housing comprising a plurality of housing sections, at least one hinge, at least one seal;

5 a penetrator;

means for introduction of said penetrator into said housing, comprising valved port having a valve control and a port, and

a vacuum system comprising a vacuum source securely and sealably attached through the housing for advancing a patient's tissue onto the
10 penetrator;

wherein said housing sections may be spread apart along said hinge for removal of said housing from at least said penetrator.

42. The device of Claim 41, said means for introducing comprising:

15 a rigid tube extending transversely through said housing.

43. The device of Claim 42, further comprising:

a plurality of tubes for conducting a fluid flow.

20 44. The device of Claim 42, said tube having a blunt tip.

45. The device of Claim 42, said tube having a sharp tip which comprises said penetrator.

25 46. The device of Claim 41, wherein said housing is at least partially collapsible.

47. The device of Claim 41, wherein said housing further comprises:

a tear-away insert or penetrable film for allowing direct introduction of a tool or a needle, tube, or other fluid conveying member into said housing during
30 a surgical procedure.

48. The device of Claim 41, wherein said penetrable film comprises:

Attorney Docket No. ARAG0015CIP

a self sealing material, or a patch that maintains vacuum integrity after a tool has punctured the film and then been withdrawn therefrom.

49. The device of Claim 41, wherein said penetrable film has sufficient coverage
5 to allow the housing to be lifted from a work area without having to move or manipulate said tool;

wherein when said housing is lifted from the work area, the penetrable film expands about the tool to allow the housing to be lifted completely free of the tool and out of the work area.

10

50. A medical device, comprising:

a split shell vacuum housing comprising a plurality of housing sections and a bead and mating groove, interposed member, or adhesive bond that allows the sections of the housing to seal together and to separate apart;

15

a penetrator;

means for introduction of said penetrator into said housing, comprising valved port having a valve control and a port;

20

a vacuum system comprising a vacuum source securely and sealably attached through the housing for advancing a patient's tissue onto the penetrator; and

means for introducing a needle, tube, or other fluid conveying member into said patient's body to allow implementation of a surgical procedure.

51. The tissue penetration device of Claim 50, wherein the penetrator device is
25 selected from a group consisting of a needle and a trocar.

52. The tissue penetration device of Claim 50, wherein the housing comprises a conforming housing seal along a perimeter thereof.

30 53. The tissue penetration device of Claim 51, wherein the housing is manufactured from a strong non-collapsible material.

Attorney Docket No. ARAG0015CIP

54. The tissue penetration device of Claim 50, wherein the material is selected from a group consisting of plastic, plastic composite, rubber, rubber composite, fiberglass, epoxy, glass, and glass composite.

5 55. The tissue penetration device of Claim 51, wherein the housing the material is translucent or transparent.

56. The tissue penetration device of Claim 51, wherein the housing is separable into at least two sections.

10

57. The tissue penetration device of Claim 50, wherein the housing is separable into two half sections, each section having a sealing edge to achieve a vacuum seal and a pass-through to receive the penetrator.

15 58. The tissue penetration device of Claim 51, wherein the housing comprises a bell-shaped body having an opening, and a tear-away adapter plate having a pass-through to receive the penetrator.

20 59. The tissue penetration device of Claim 58, wherein the tear-away adapter plate forms a vacuum seal with the opening.

60. The device of Claim 50, said means for introducing comprising:
a rigid tube extending transversely through said housing.

25 61. The device of Claim 60, further comprising:
a plurality of tubes for conducting a fluid flow.

62. The device of Claim 60, said tube having a blunt tip.

30 63. The device of Claim 60, said tube having a sharp tip which comprises said penetrator.

Attorney Docket No. ARAG0015CIP

64. The device of Claim 50, wherein said housing is at least partially collapsible.

65. The device of Claim 50, wherein said housing further comprises:

5 a tear-away insert or penetrable film for allowing direct introduction of a tool or a needle, tube, or other fluid conveying member into said housing during a surgical procedure.

66. The device of Claim 65, wherein said penetrable film comprises:

10 a self sealing material, or a patch that maintains vacuum integrity after a tool has punctured the film and then been withdrawn therefrom.

67. The device of Claim 65, wherein said penetrable film has sufficient coverage to allow the housing to be lifted from a work area without having to move or manipulate said tool;

15 wherein when said housing is lifted from the work area, the penetrable film expands about the tool to allow the housing to be lifted completely free of the tool and out of the work area.

68. A tissue penetration device, comprising:

20 a vacuum housing;
at least one rigid tube extending into said housing transversely to a top portion thereof;
a penetrator; and
a vacuum system for advancing a patient's tissue onto said penetrator.

25

69. The device of Claim 68, further comprising;

a plurality of rigid tubes for conducting a fluid flow.

70. The device of Claim 68, said penetrator comprising:

30 a sharp tip provided on said rigid tube.

71. The device of Claim 68, wherein said housing is at last partially collapsible.

Attorney Docket No. ARAG0015CIP

72. The device of Claim 68, wherein said housing further comprises:

5 a tear-away insert or penetrable film for allowing direct introduction of a tool or a needle, tube, or other fluid conveying member into said housing during a surgical procedure.

73. The device of Claim 72, wherein said penetrable film comprises:

10 a self sealing material, or a patch that maintains vacuum integrity after a tool has punctured the film and then been withdrawn therefrom.

74. The device of Claim 72, wherein said penetrable film has sufficient coverage to allow the housing to be lifted from a work area without having to move or manipulate said tool;

15 wherein when said housing is lifted from the work area, the penetrable film expands about the tool to allow the housing to be lifted completely free of the tool and out of the work area.

1/8

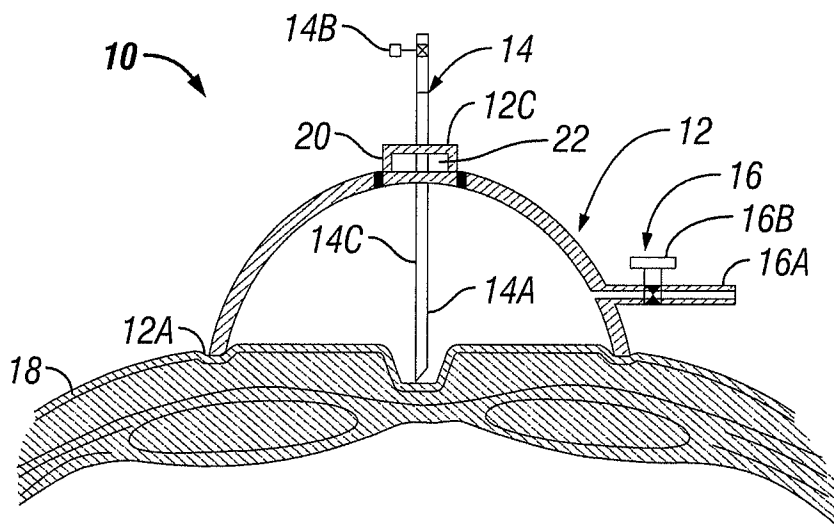


FIG. 1
(Prior Art)

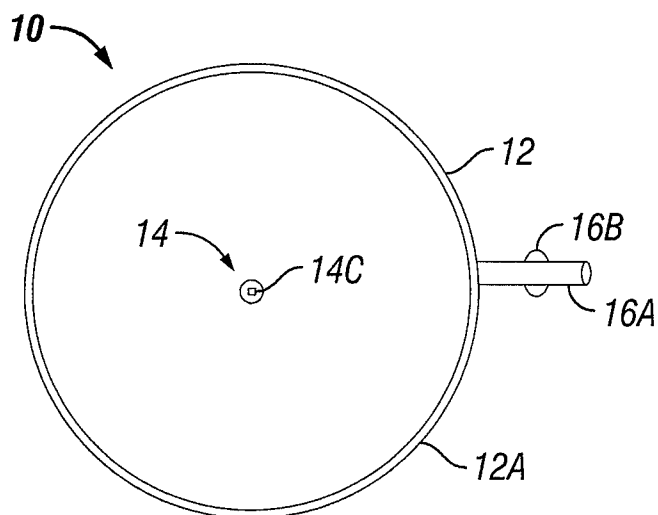


FIG. 2
(Prior Art)

2/8

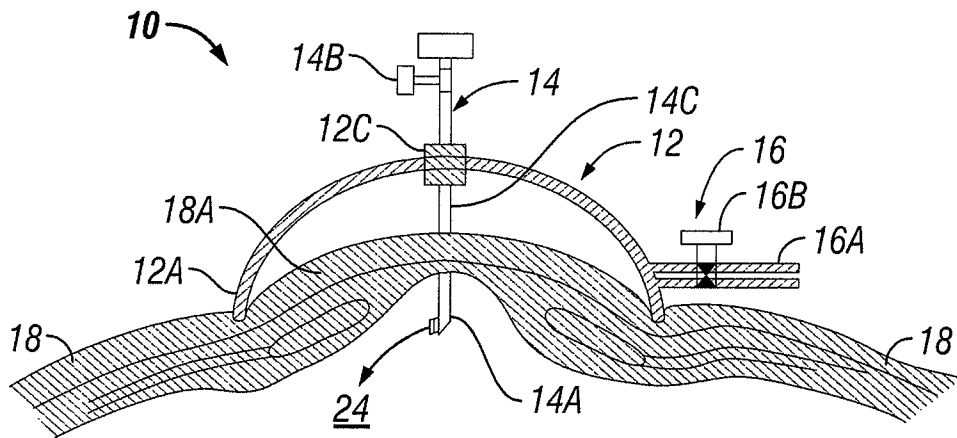


FIG. 3
(Prior Art)

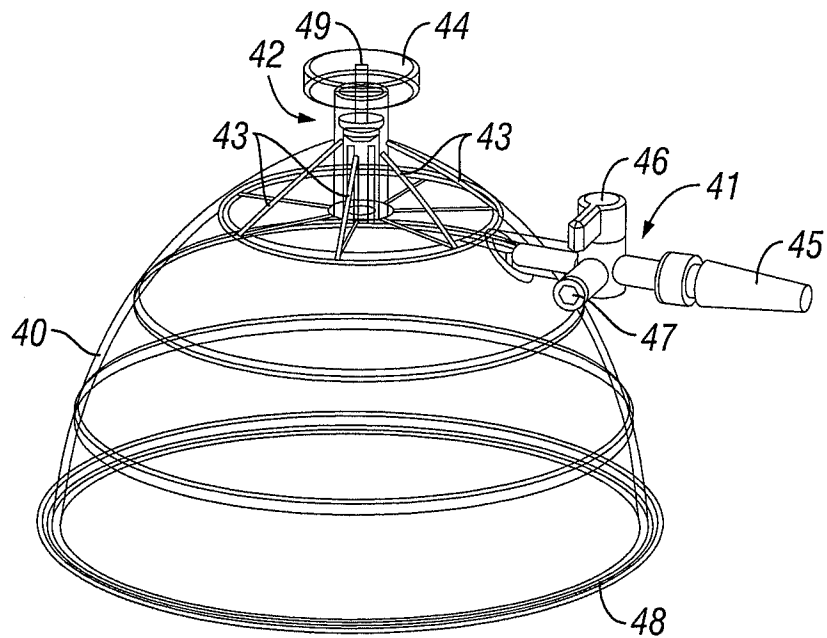


FIG. 4A

3/8

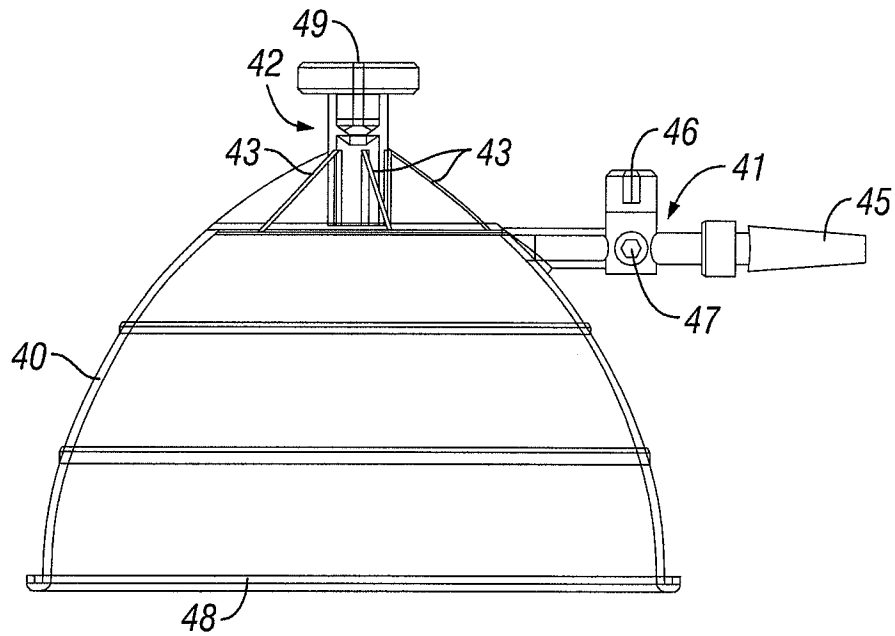


FIG. 4B

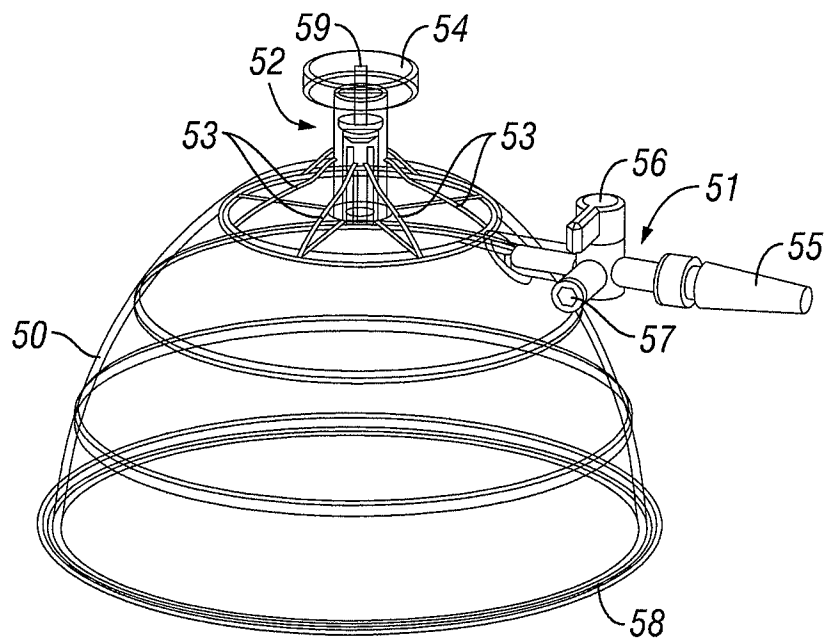


FIG. 5A

4/8

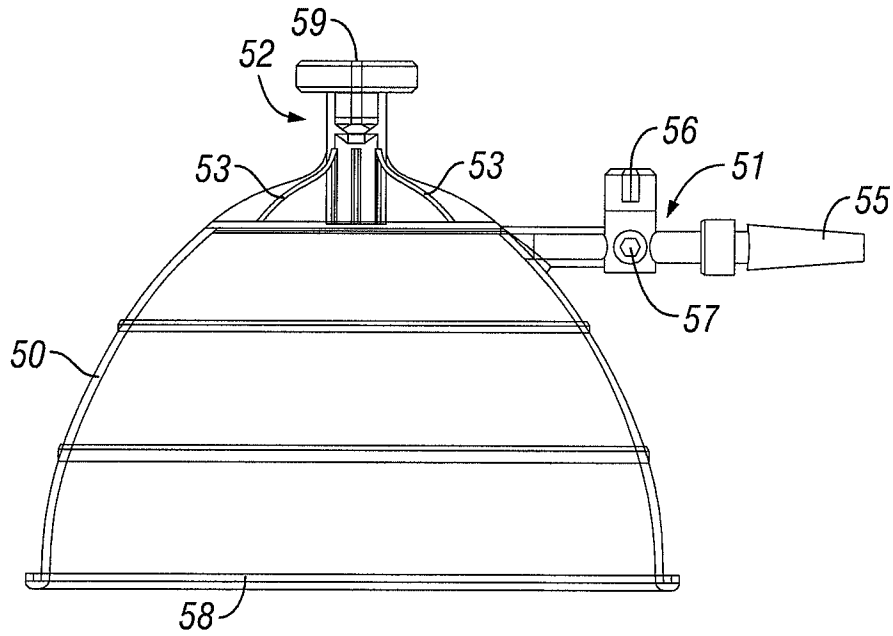


FIG. 5B

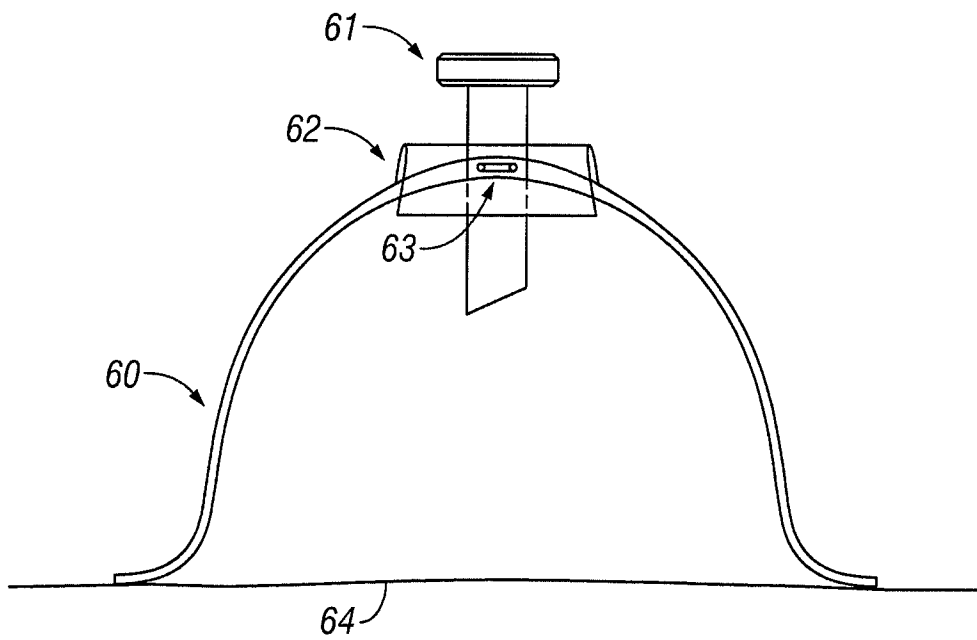


FIG. 6A

5/8

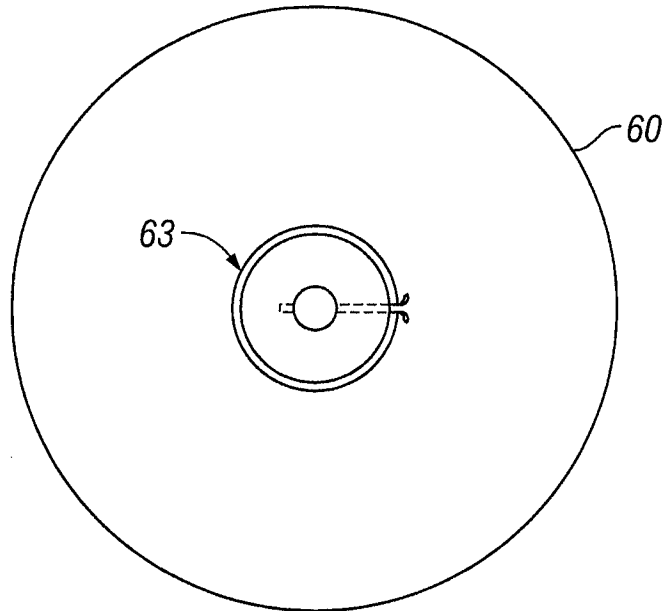


FIG. 6B

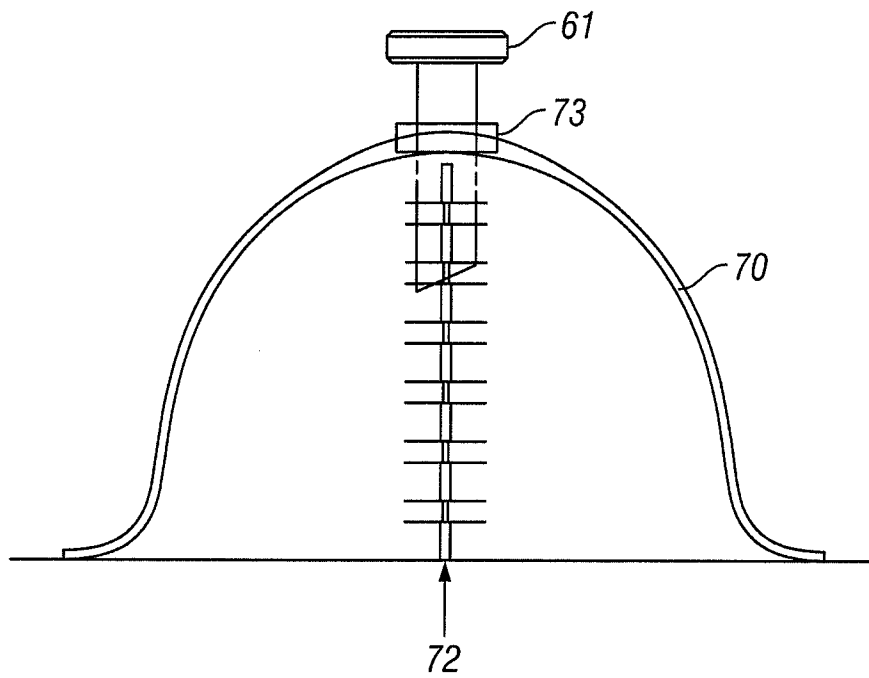


FIG. 7A

6/8

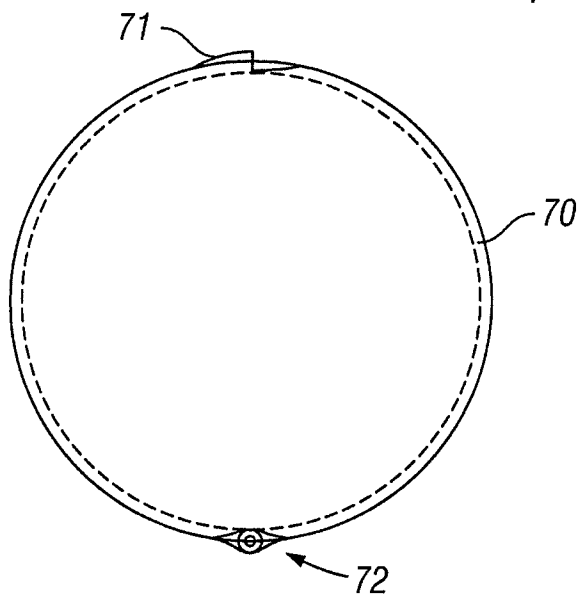


FIG. 7B

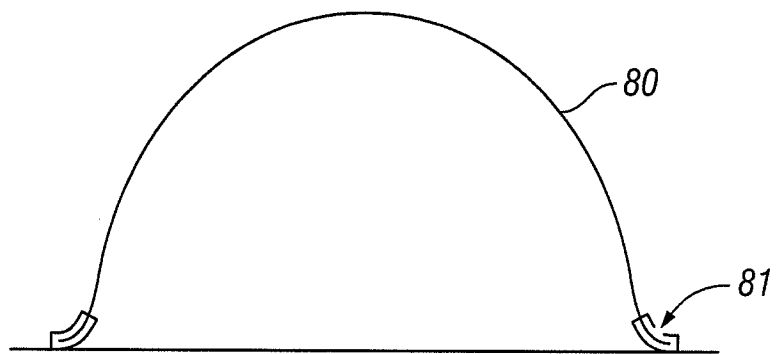


FIG. 8

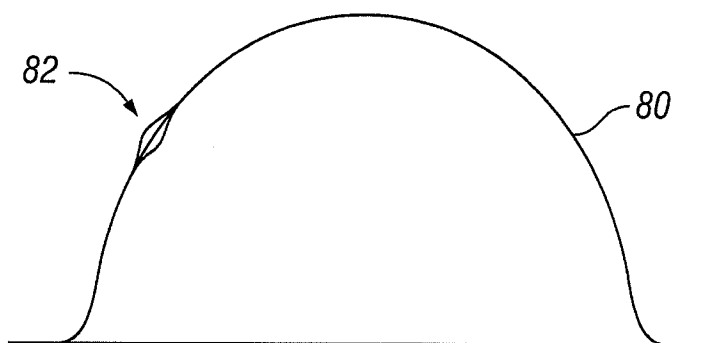


FIG. 9

7/8

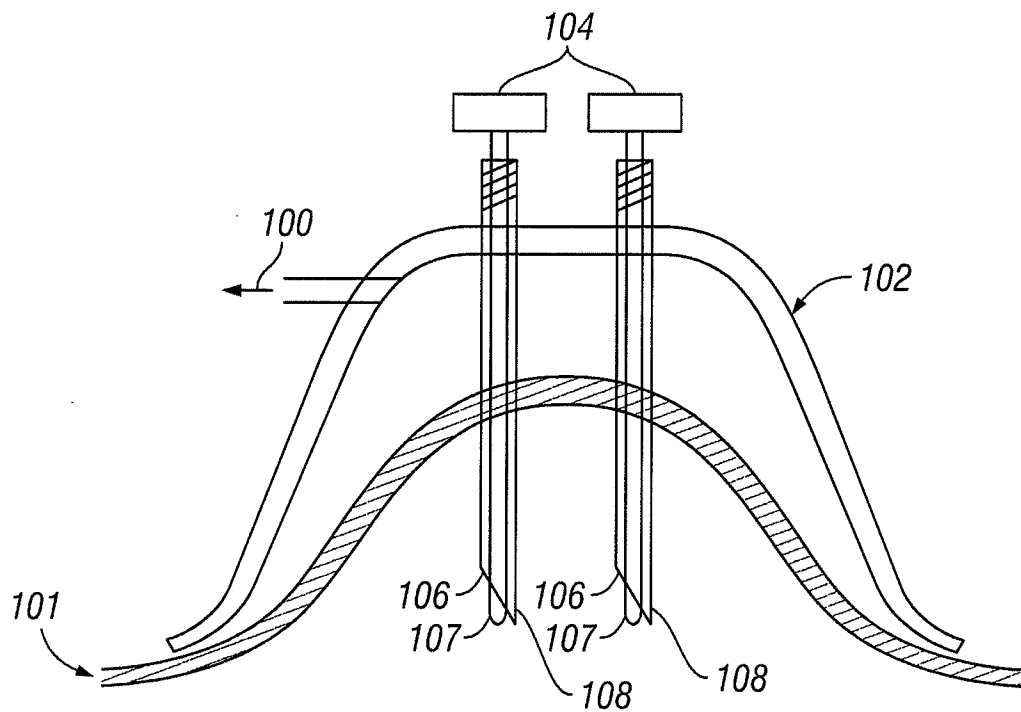


FIG. 10

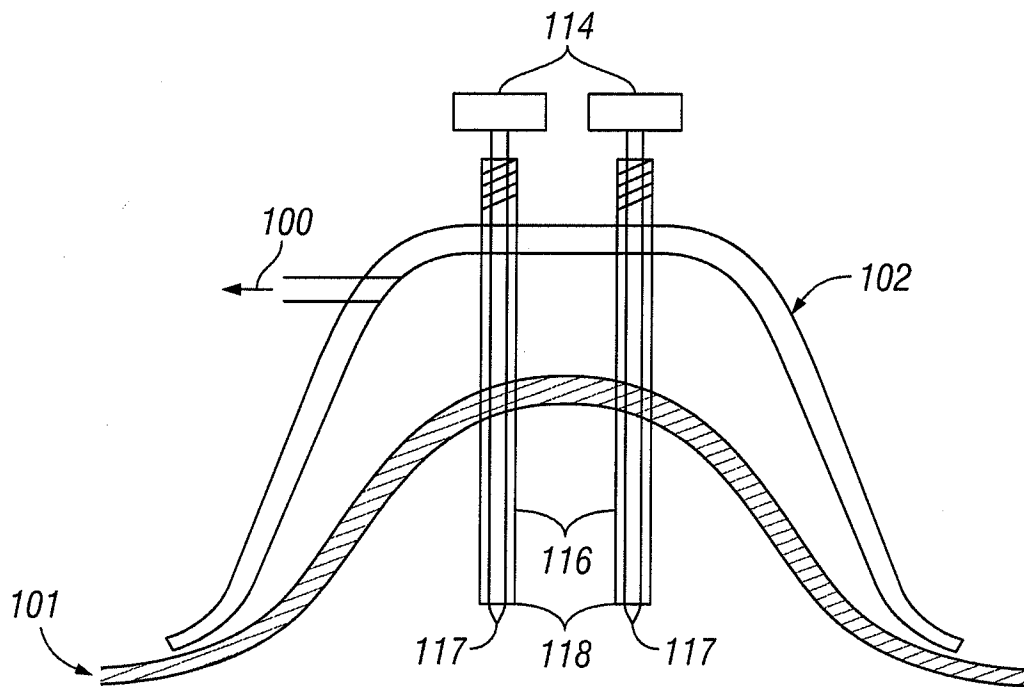


FIG. 11

8/8

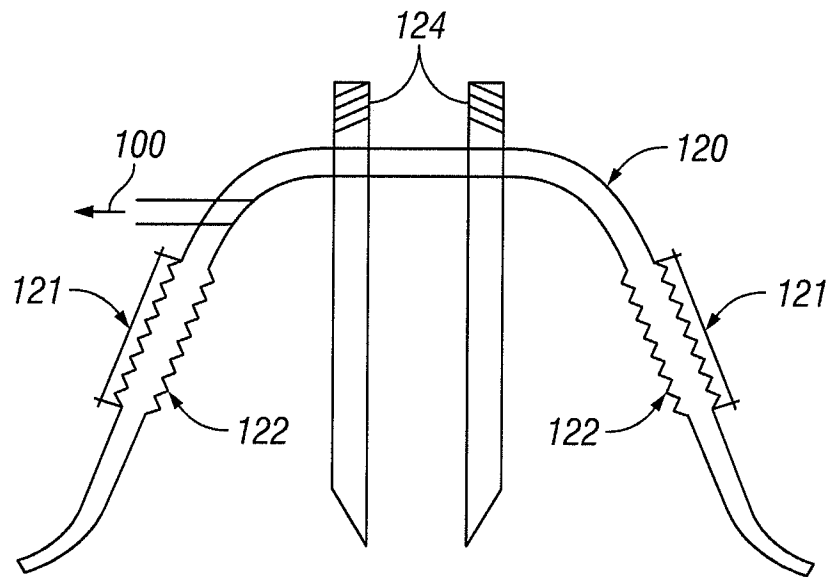


FIG. 12