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(54) **SURGICAL ACCESS SYSTEM**

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(51) **Int. Cl.**
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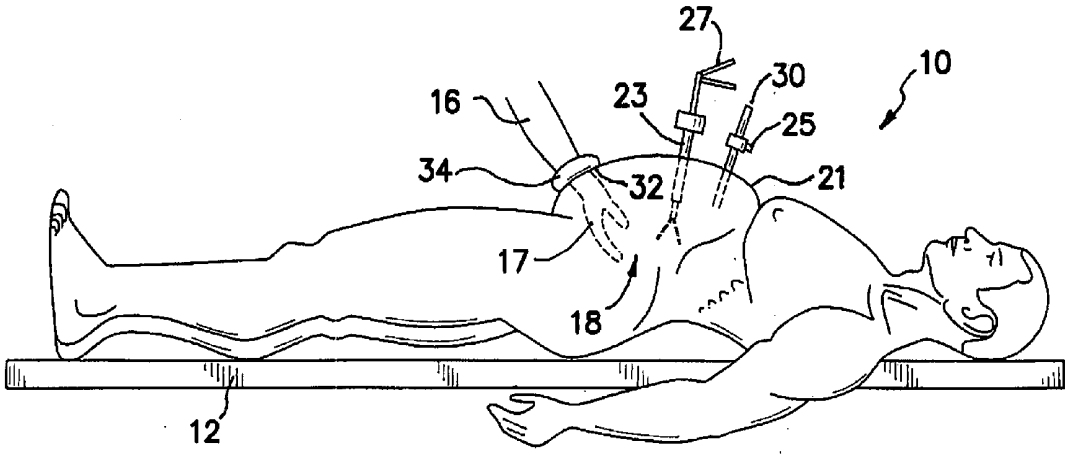
(52) **U.S. Cl.** **600/206**

(57) **ABSTRACT**

The invention is directed to a hand access system that provides hand access to a surgical area while maintaining pneumoperitoneum during laparoscopic surgery. The hand access system comprises a sheath retractor adapted to dilate a wound stretchable to a desired diameter, the sheath retractor includes a first ring being adapted for disposition interiorly of the wound, a second ring being adapted for disposition exteriorly of the wound, and a sheath being disposed in a generally cylindrical form between the first ring and the second ring and operable to exert a radial retraction force on the wound. The hand access system further comprises a detachable hand seal adapted to be removable from the second ring of the sheath retractor. The sheath retractor may be formed of an elastomeric material, and the hand seal may be formed of a gel material and includes a slit providing an instrument seal in the presence of an instrument or hand and a zero seal in the absence of the instrument or hand. In another aspect, there is disclosed a surgical access device adapted for disposition relative to an incision in a patient comprising a valve including a plurality of overlapping sheets defining an access channel, and a ring having an inner diameter for holding the valve by fixing each of the overlapping sheets along a portion of the perimeter, the access channel extends into communication with the incision in the patient. Each of the overlapping sheets includes a portion of the perimeter that is not fixed to the inner diameter of the ring, which provide open edges defining the access channel. The open edges slightly overlap at the center of the ring. The open edges may have different shapes including at least one of a straight edge, concave, convex and a cross-configuration. The hand access device may further comprise a septum seal formed at the proximal and distal ends of the ring.



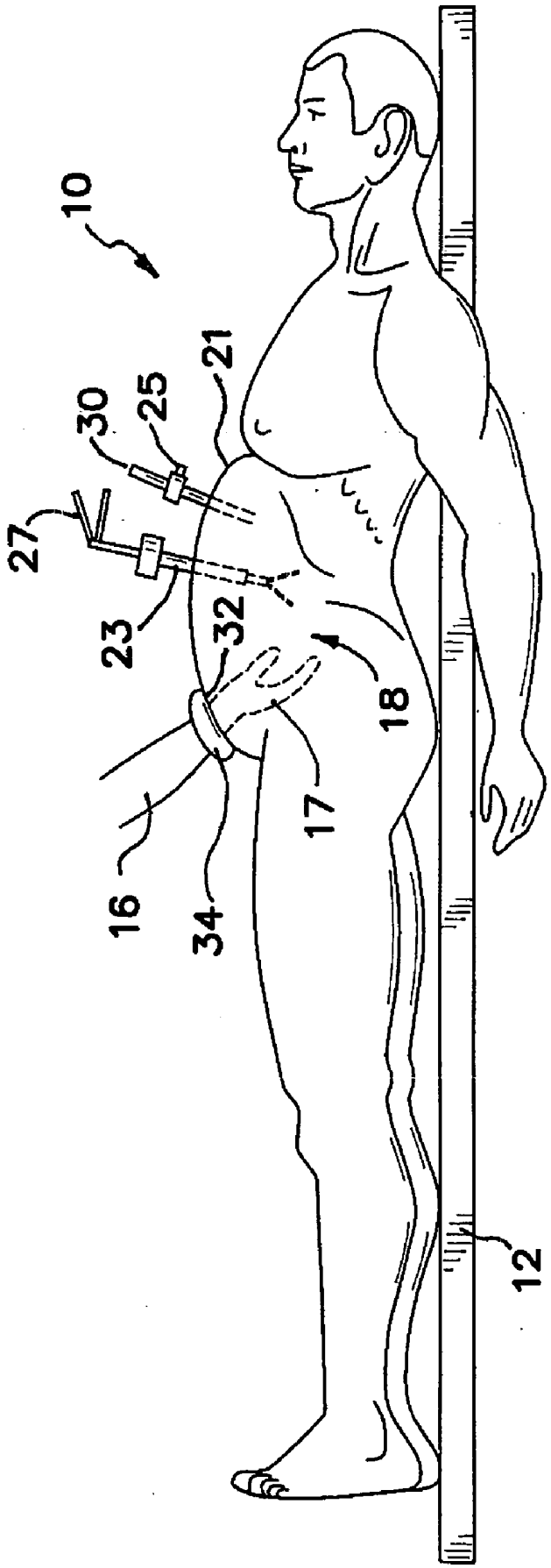


FIG. 1

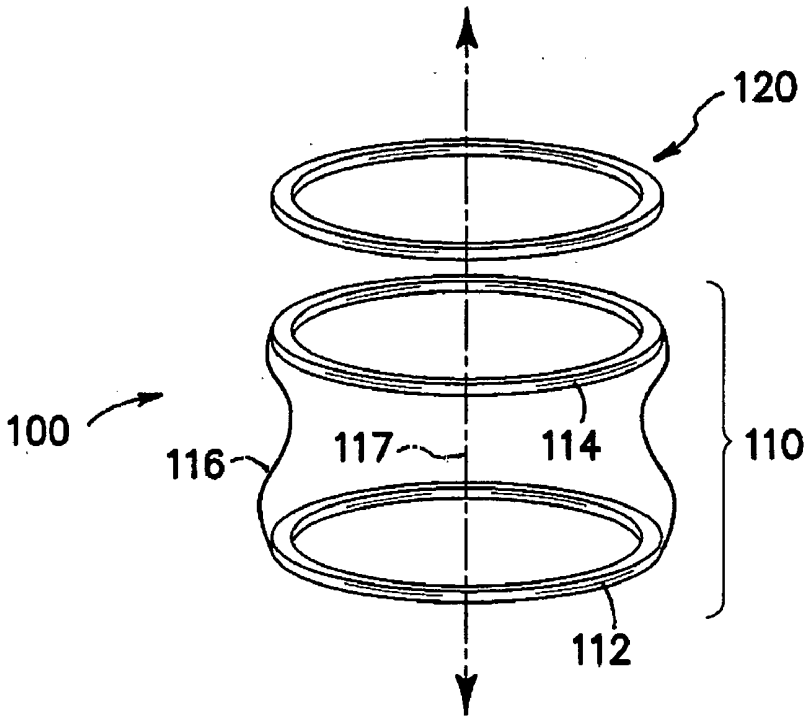


FIG. 2A

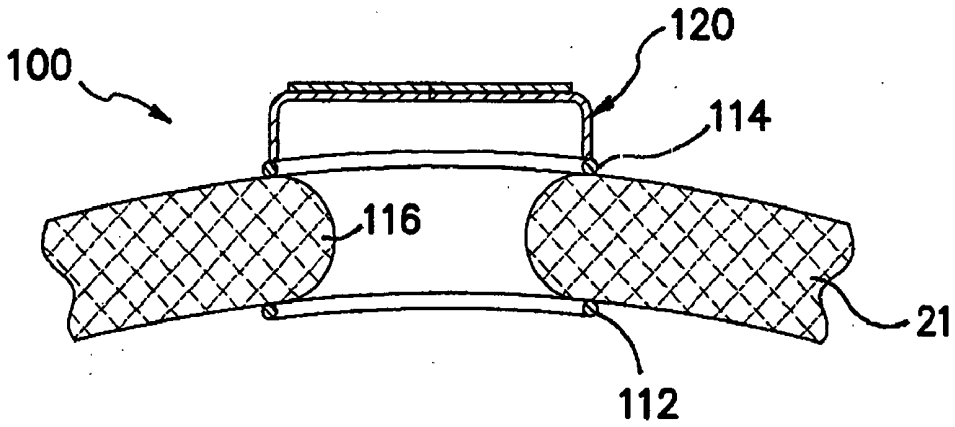
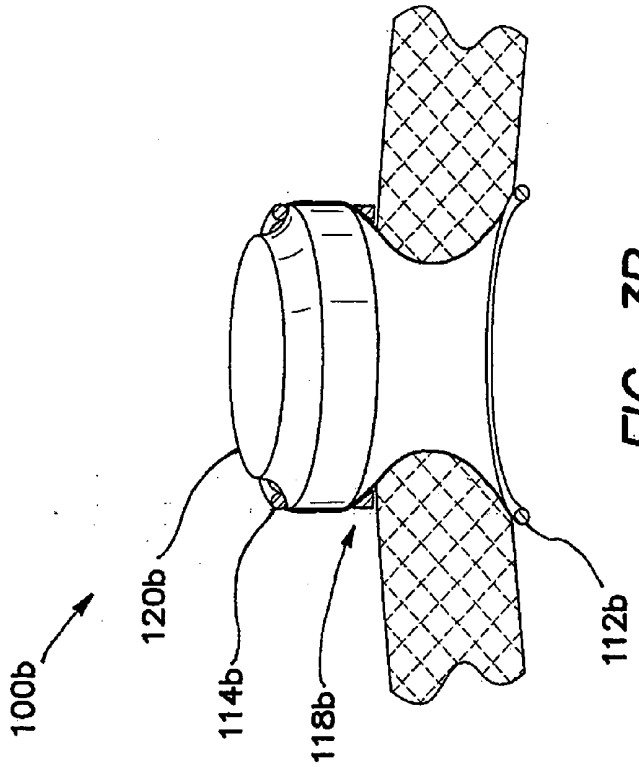


FIG. 2B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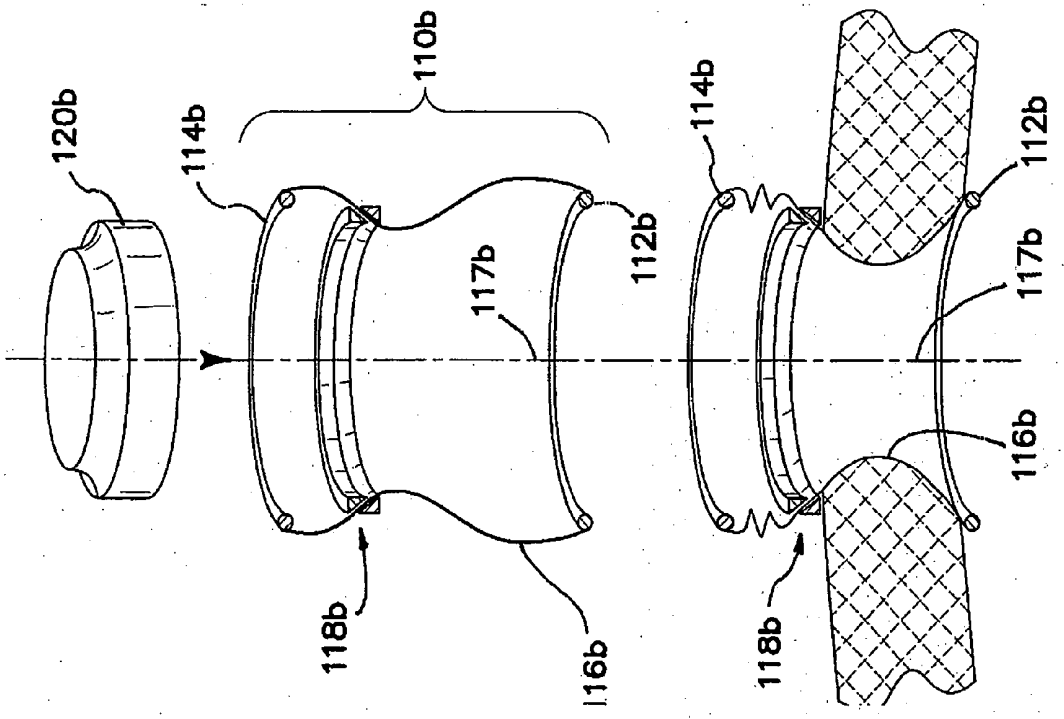
118b
112b

FIG. 3B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118b

FIG. 3A

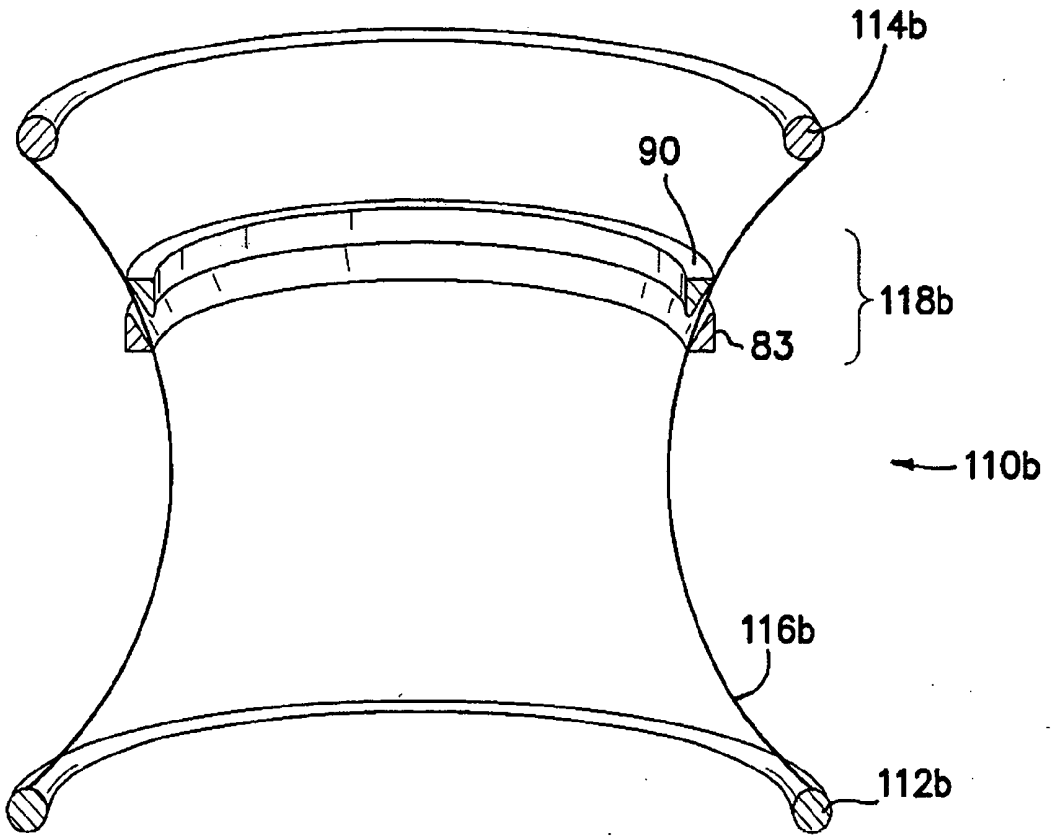


FIG. 3C

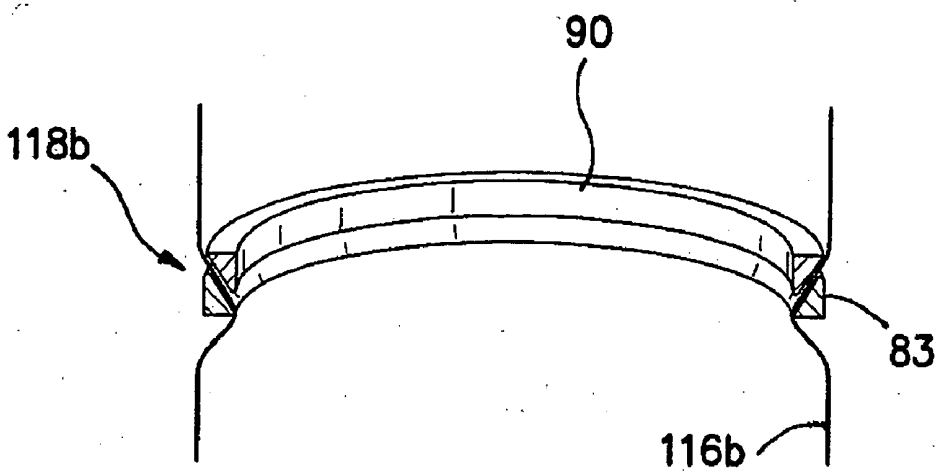


FIG. 3D

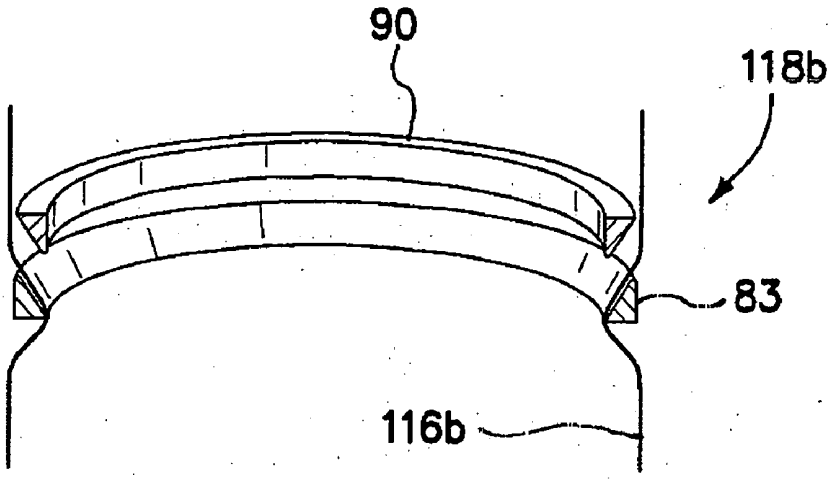
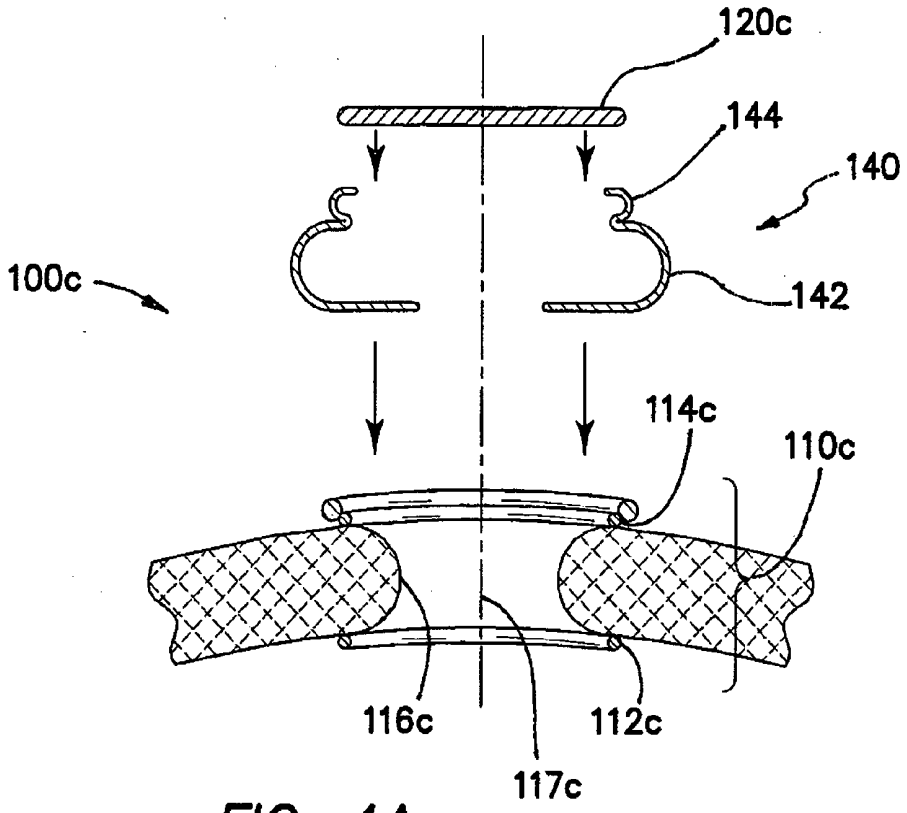


FIG. 3E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114c
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117c

FIG. 4A

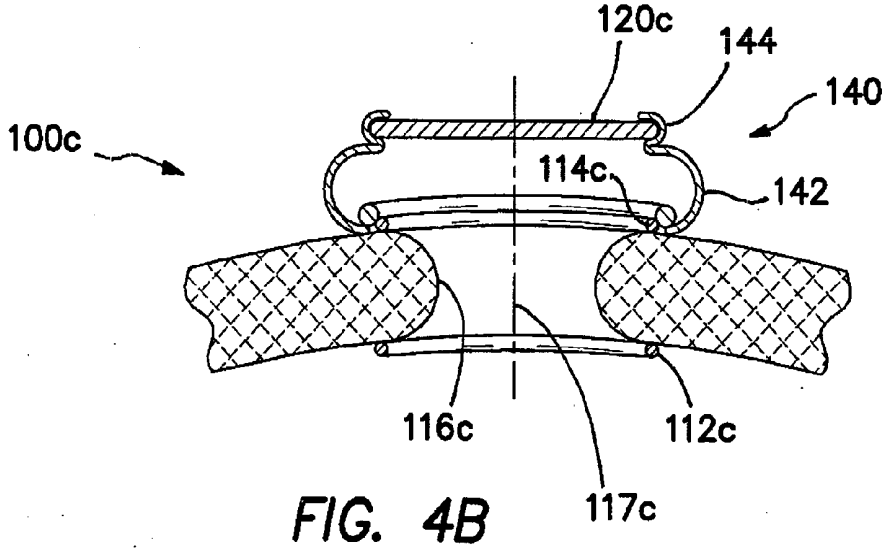
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FIG. 4B

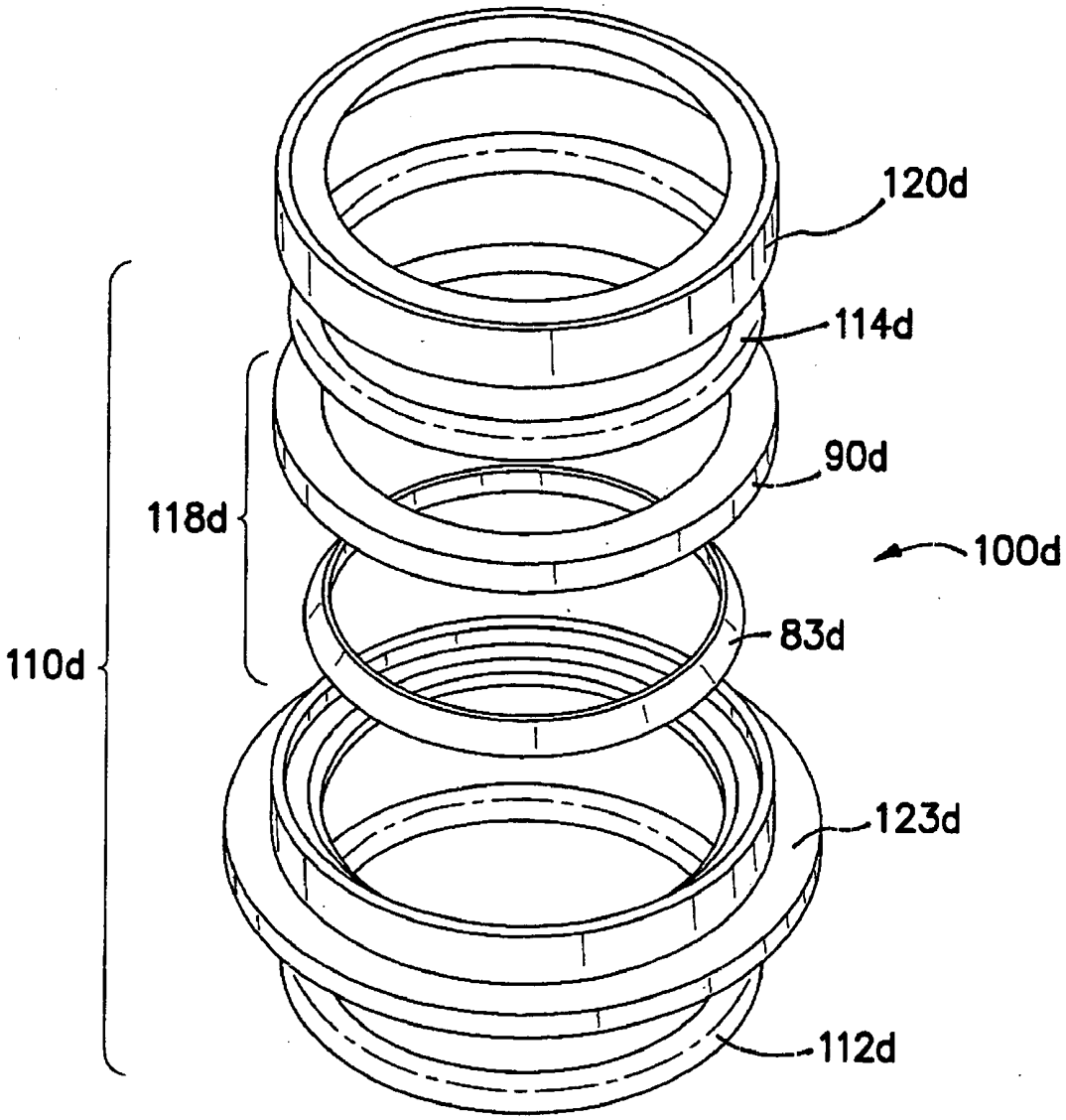


FIG. 5A

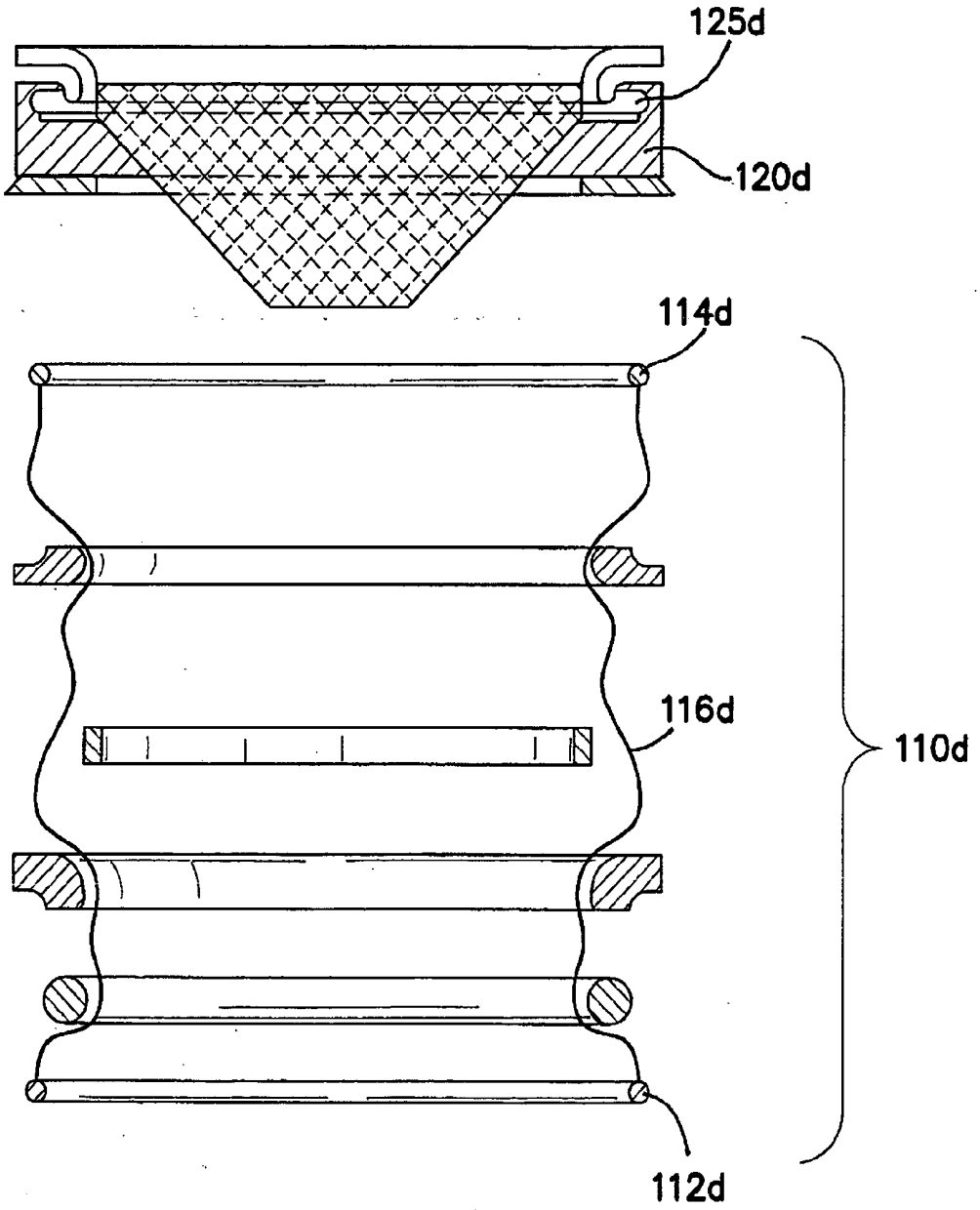


FIG. 5B

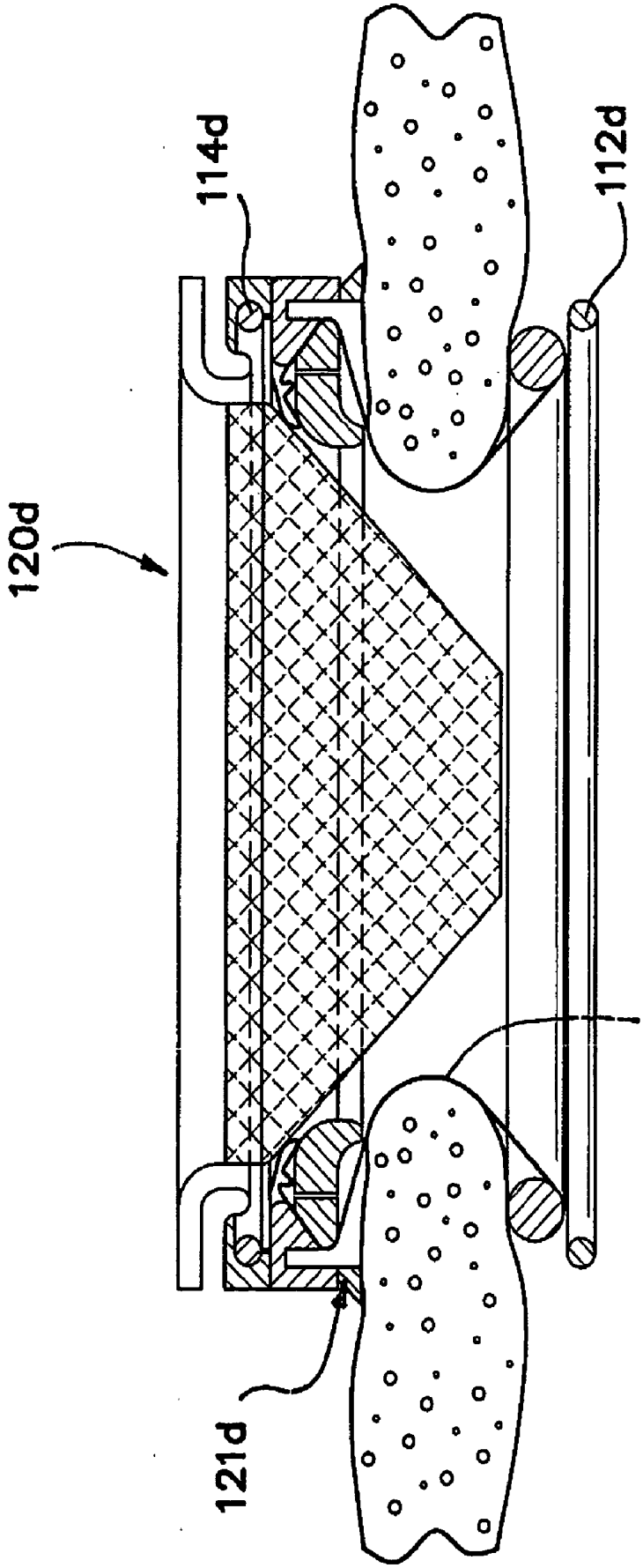


FIG. 5C

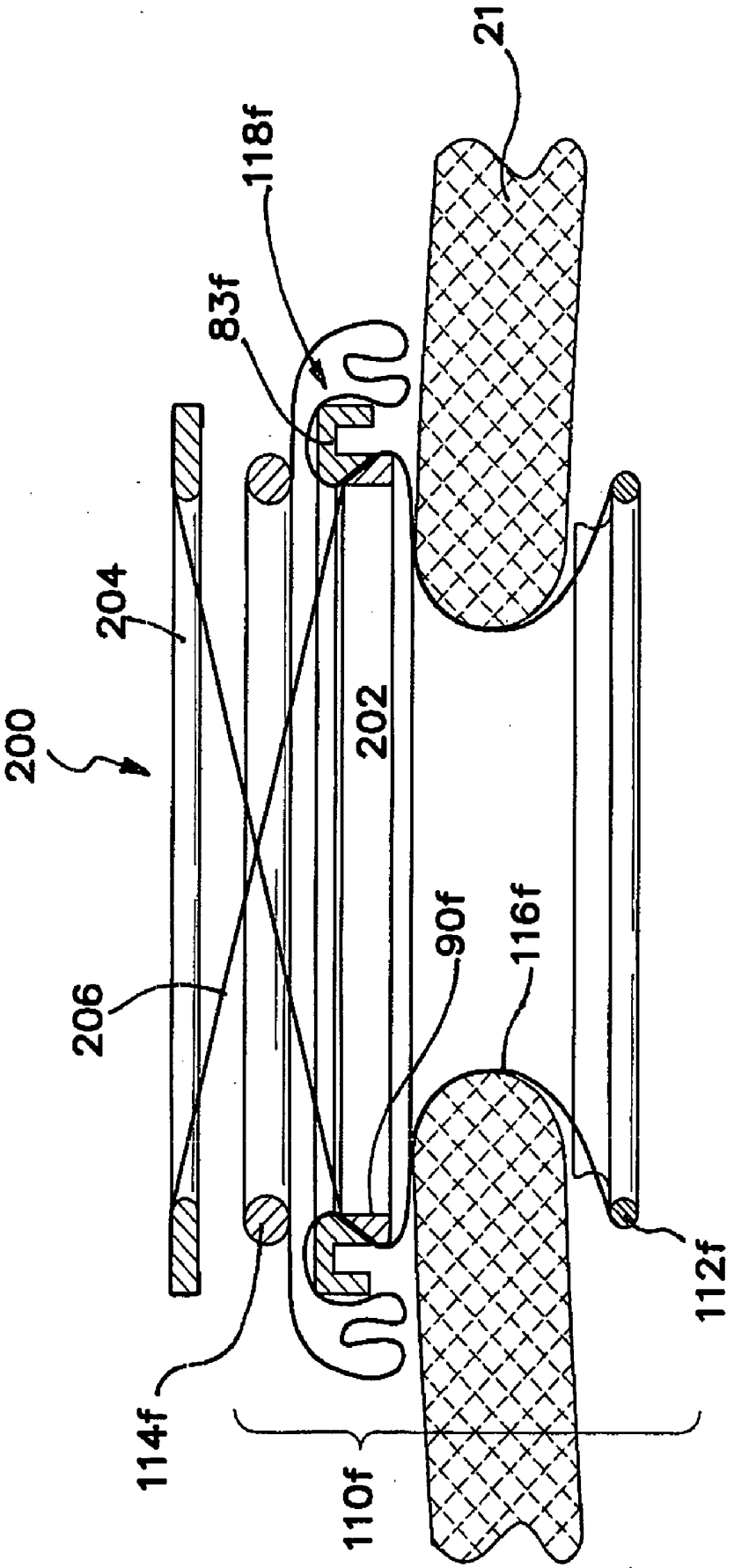


FIG. 6

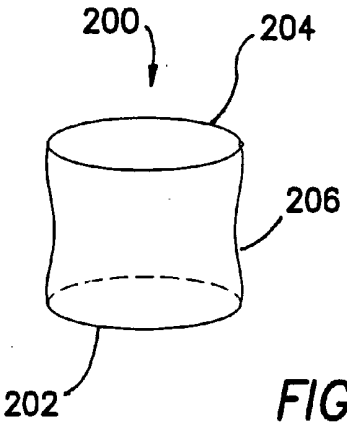
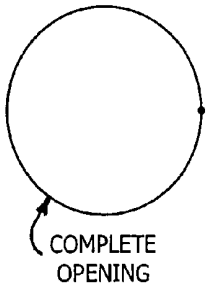


FIG. 7A



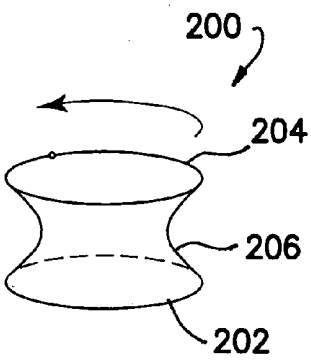
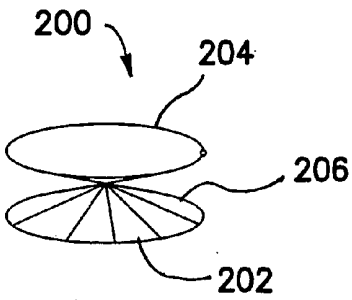


FIG. 7B



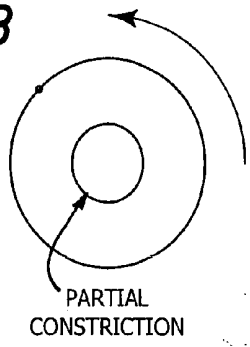
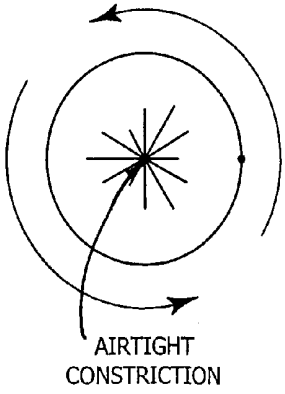


FIG. 7C



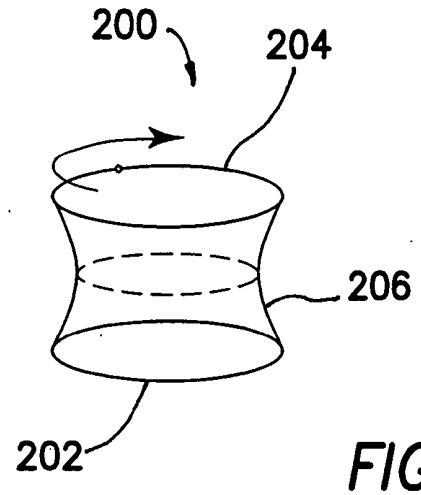
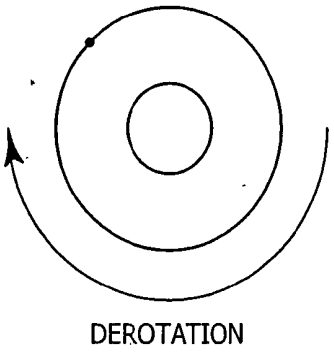


FIG. 7D



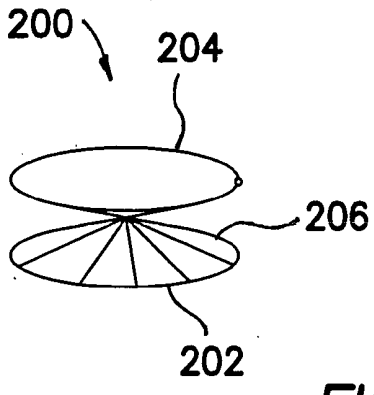
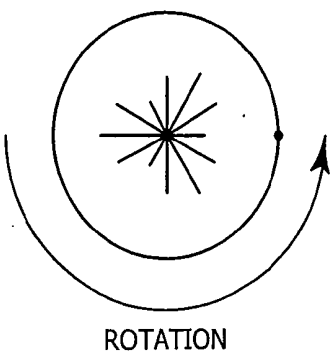


FIG. 7E



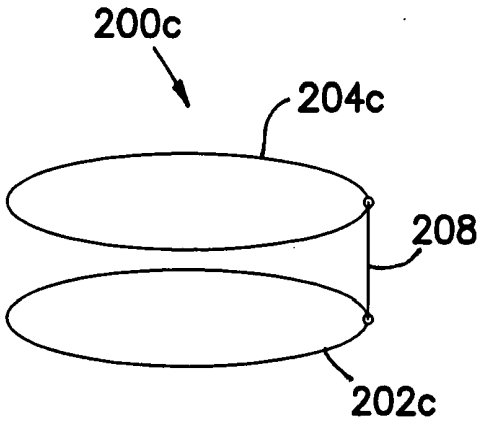


FIG. 8A

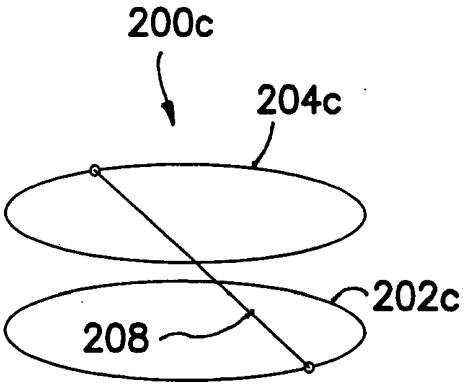


FIG. 8B

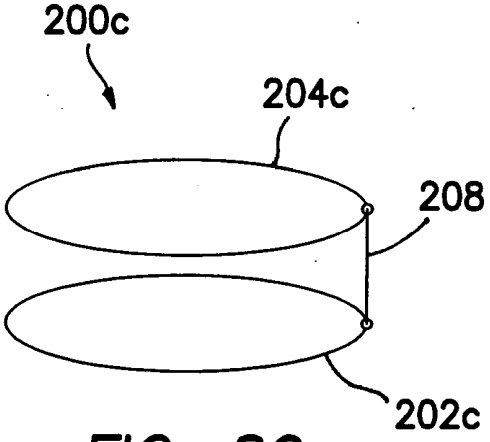


FIG. 8C

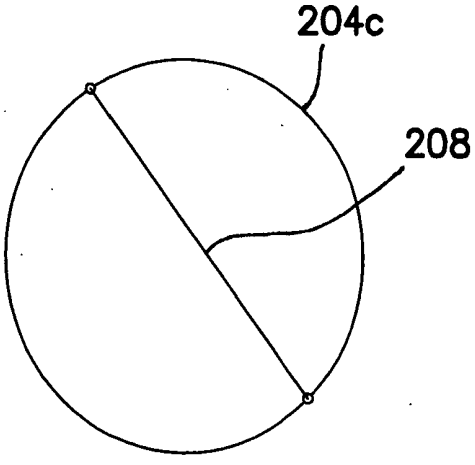


FIG. 9

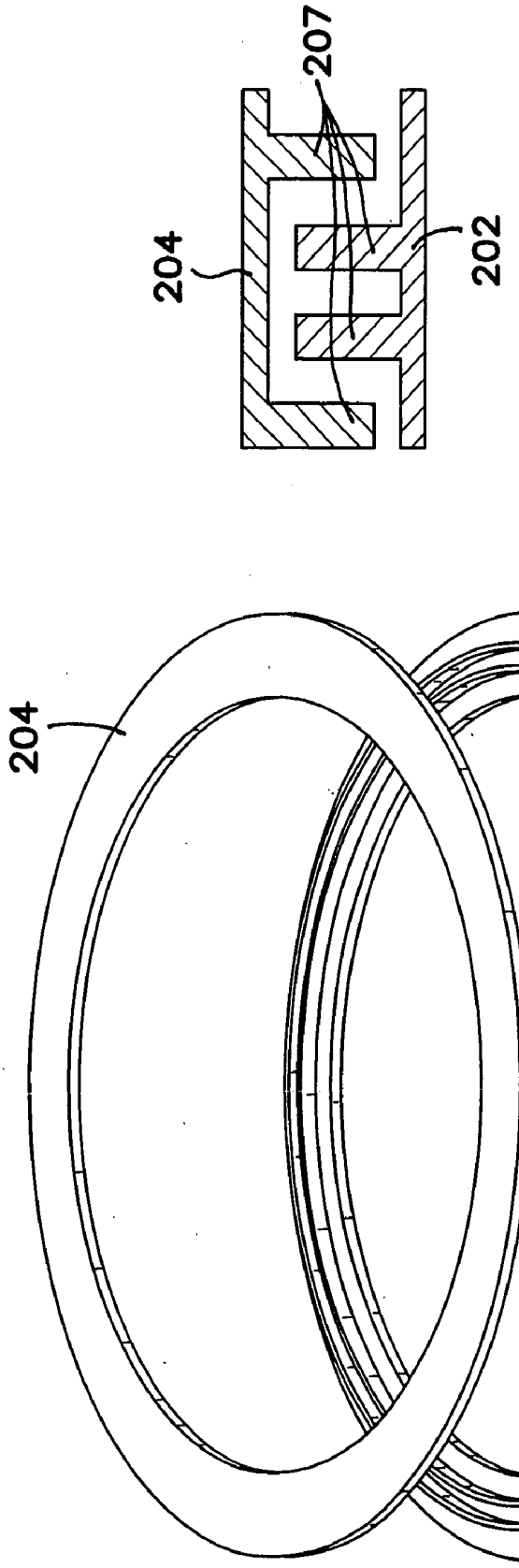


FIG. 10

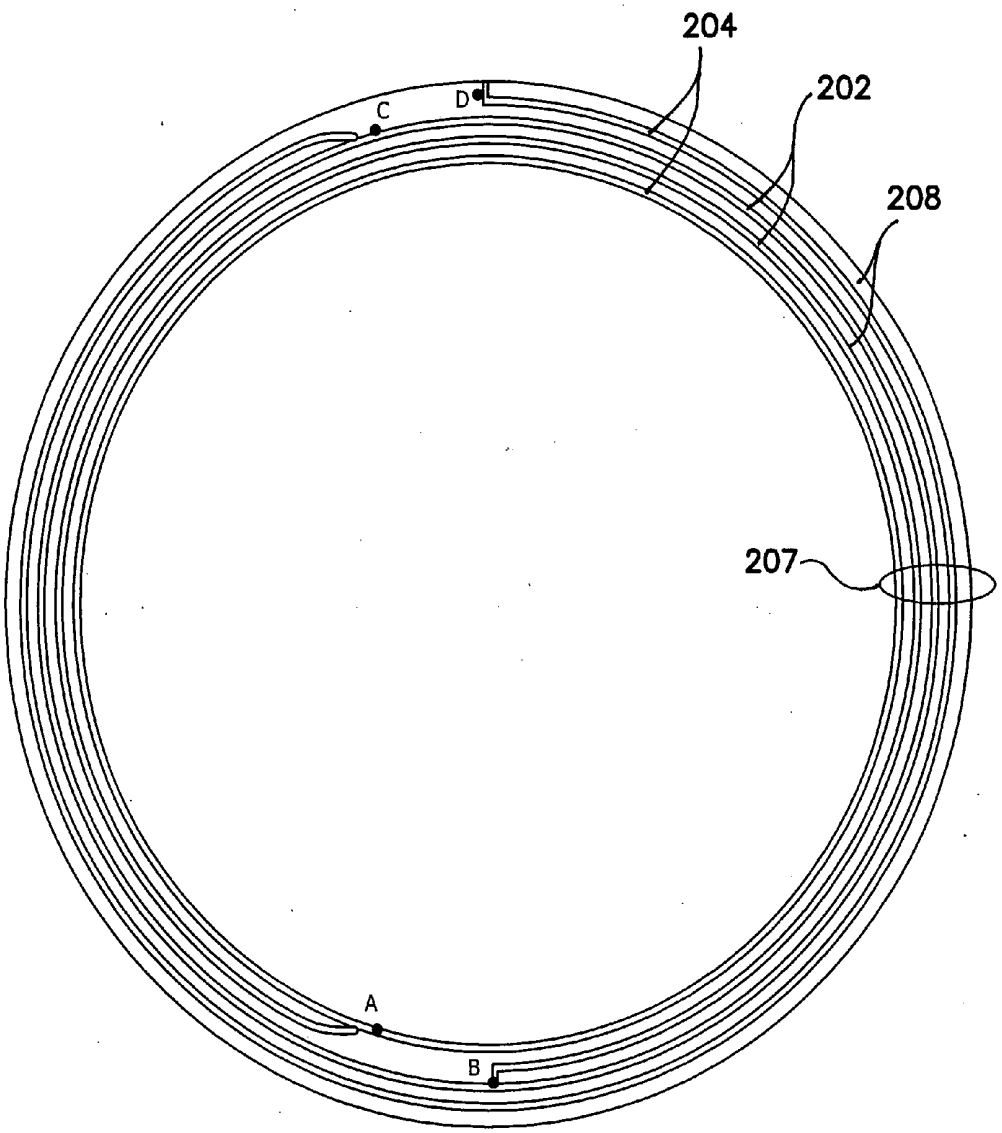


FIG. 11A

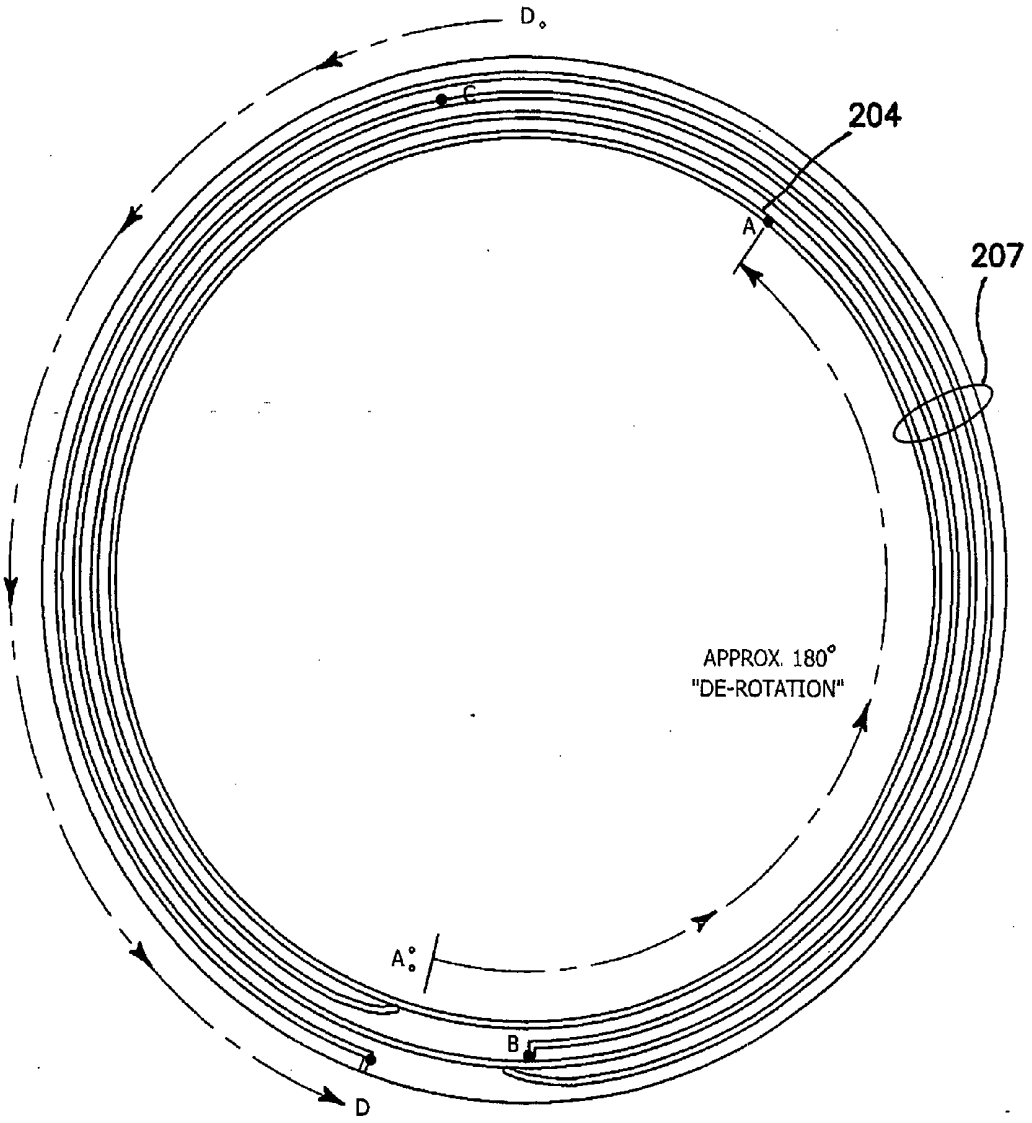


FIG. 11B

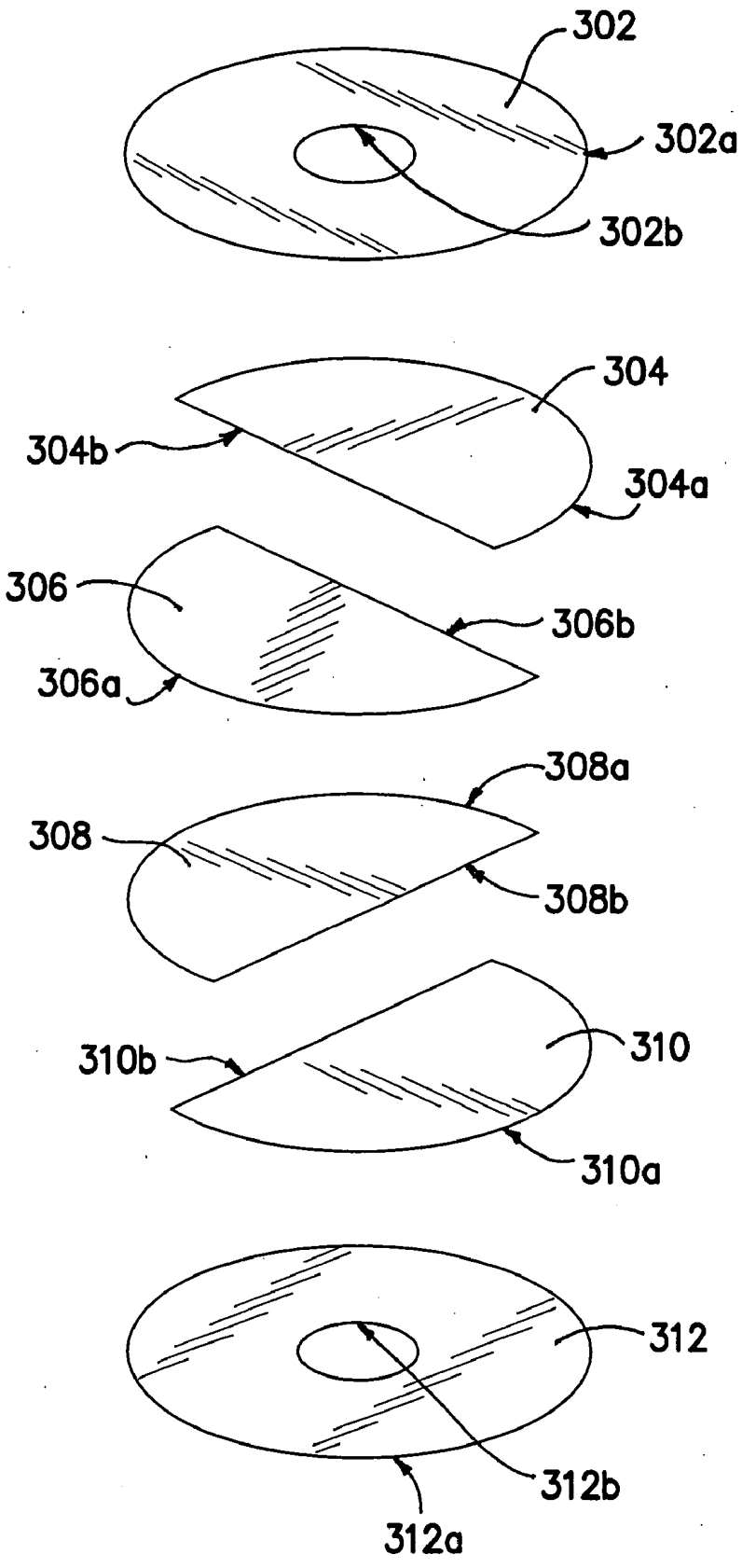

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FIG. 12

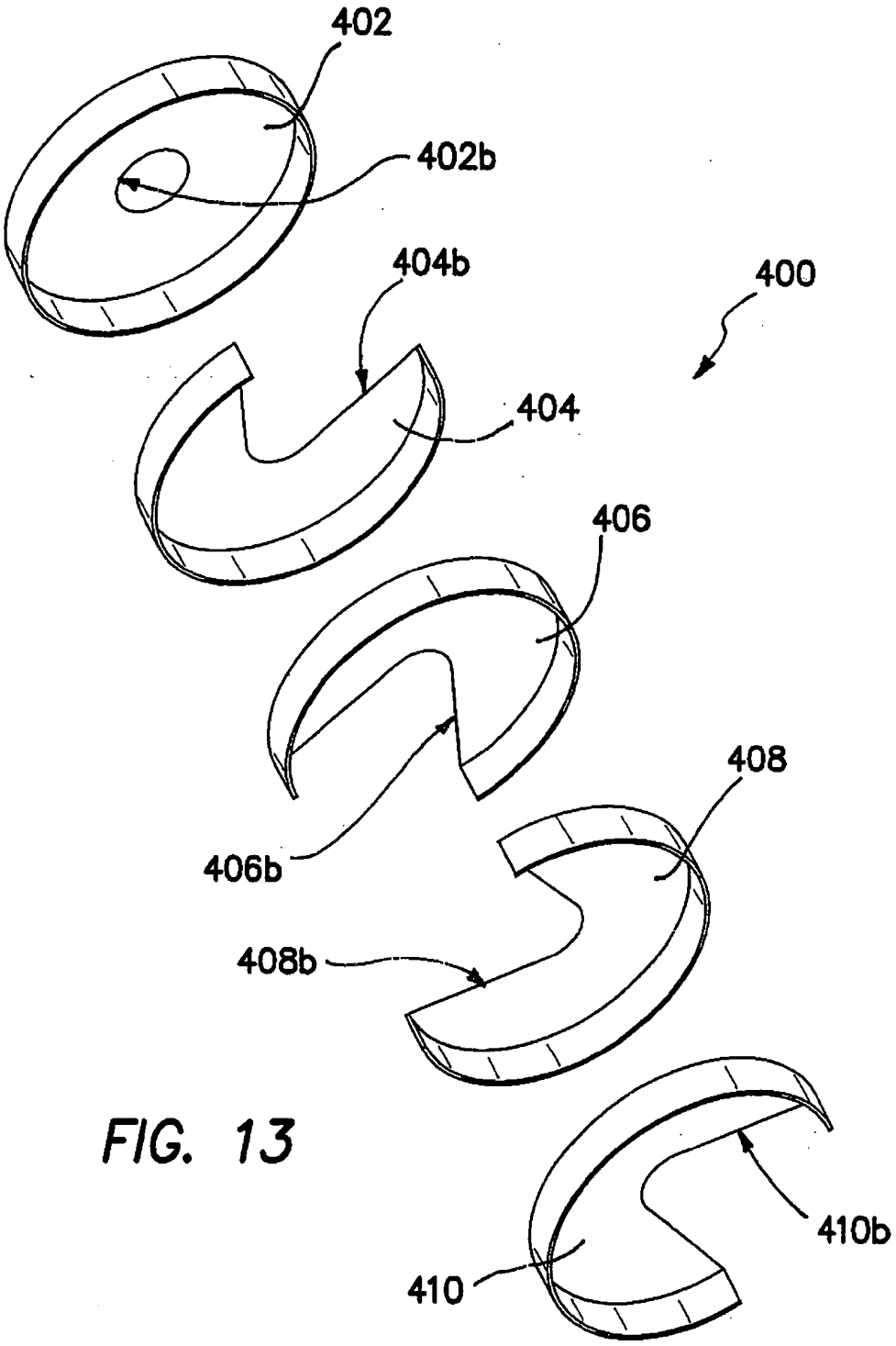

FIG. 13

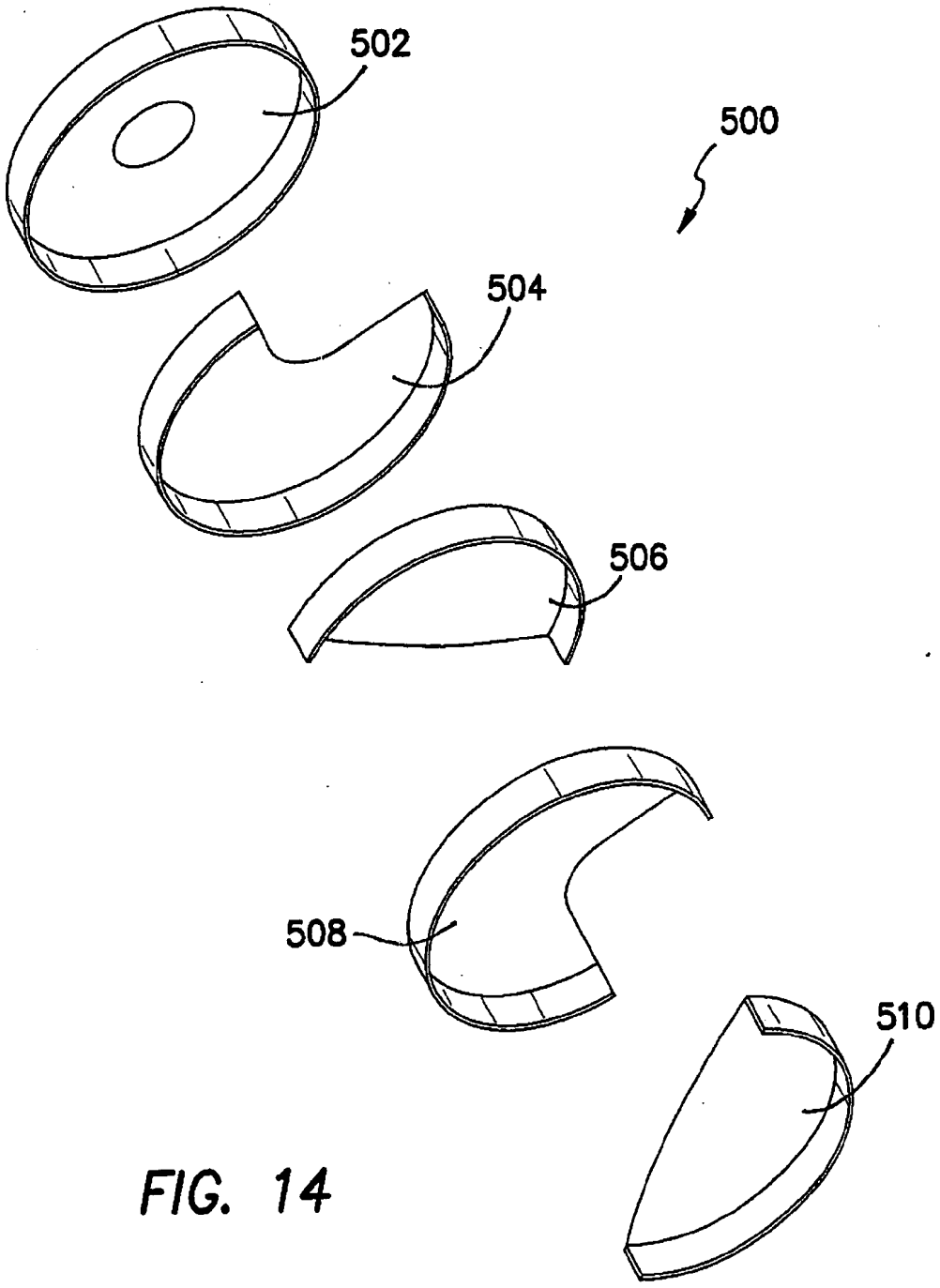

FIG. 14

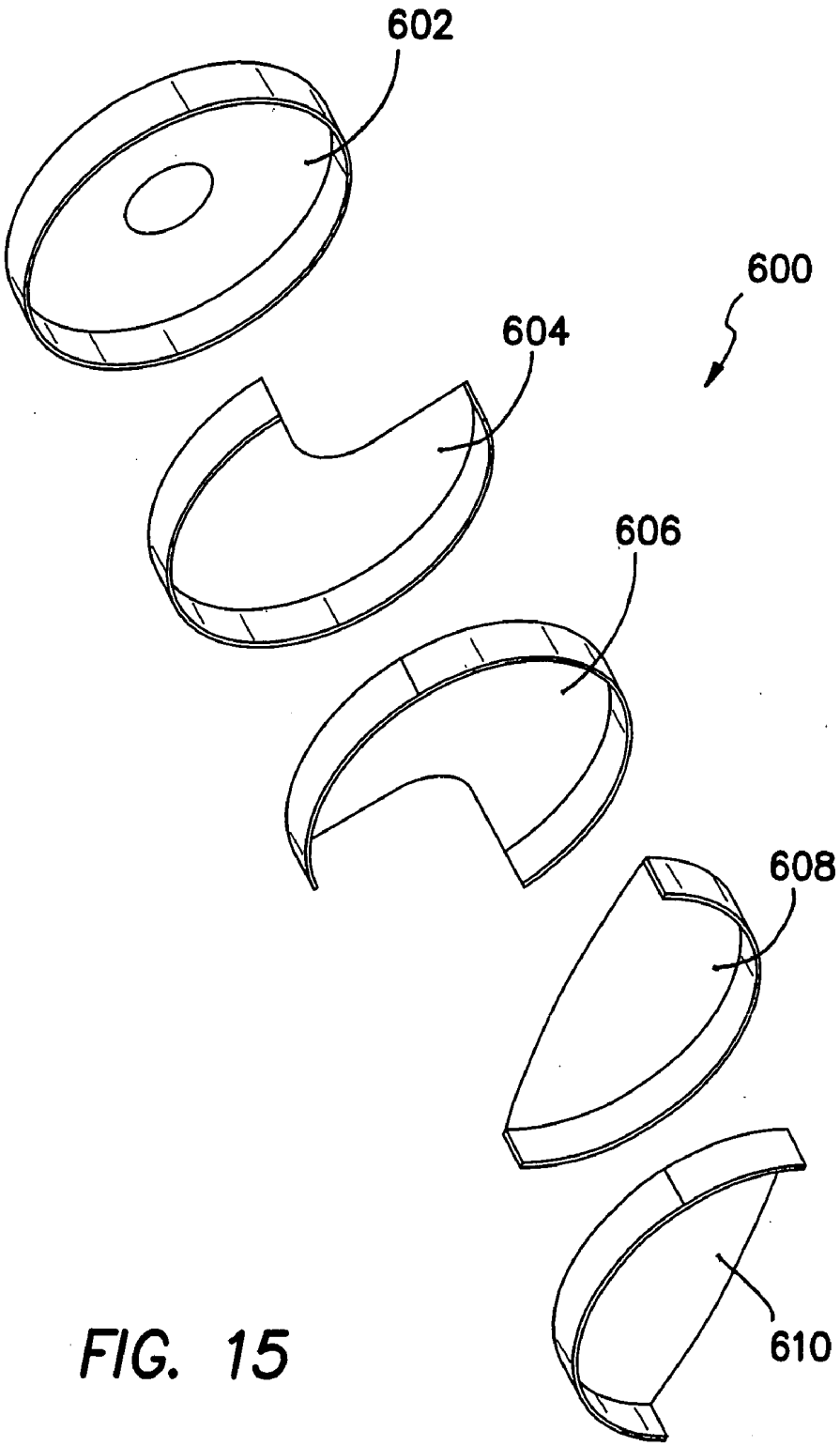

FIG. 15

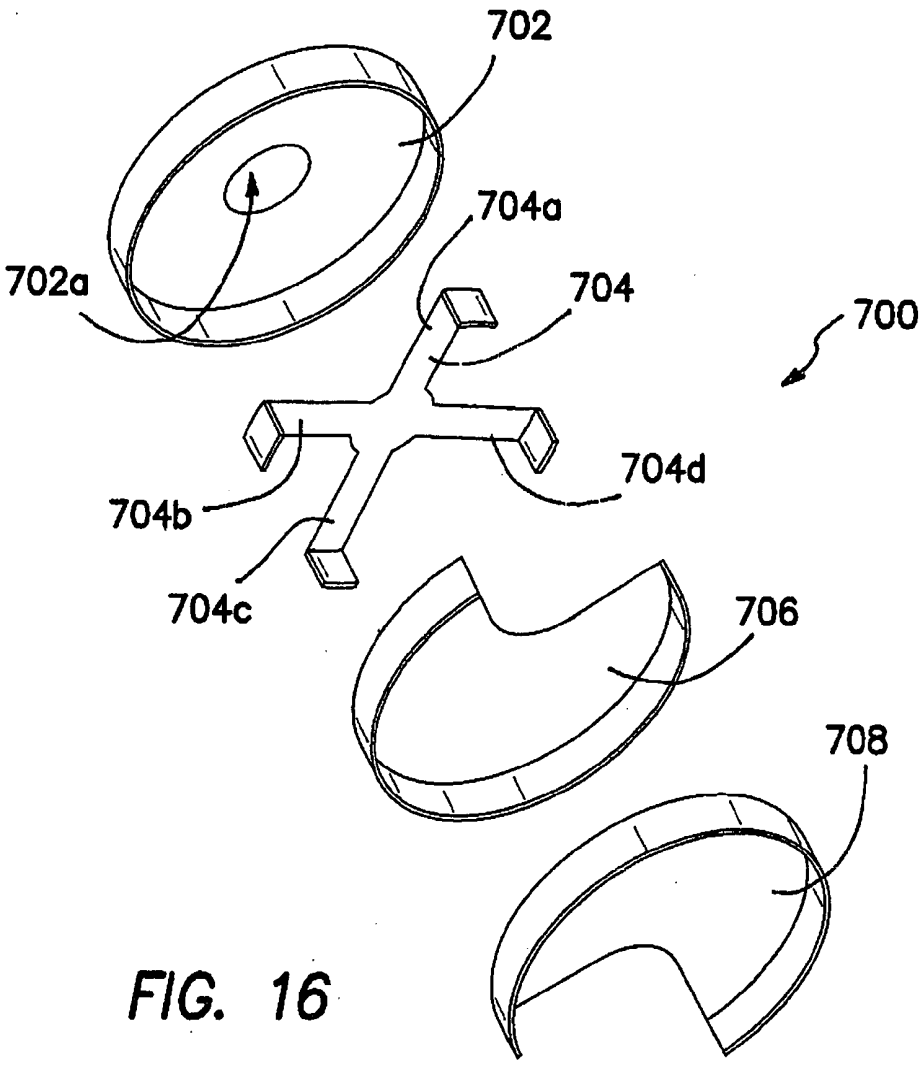

FIG. 16

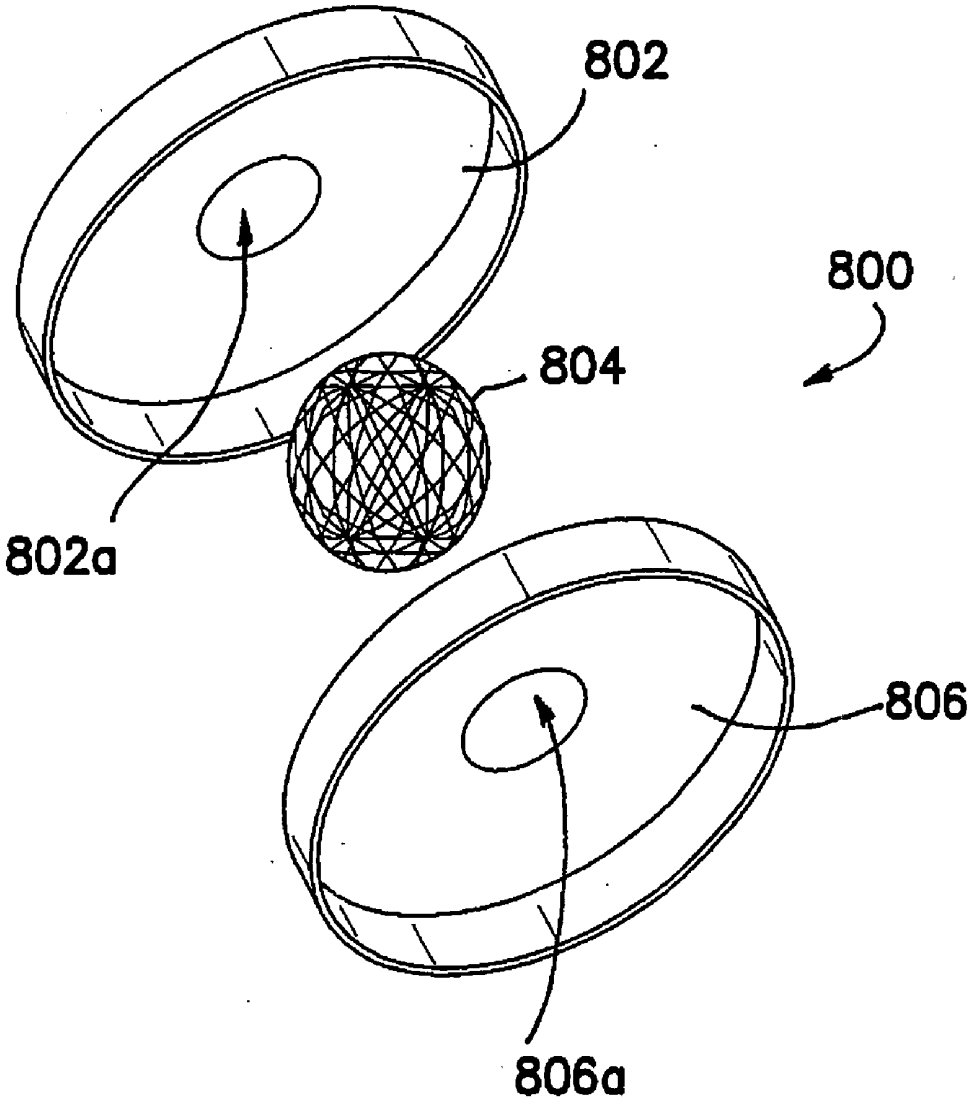

FIG. 17

SURGICAL ACCESS SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This is a continuation application claiming the priority of (1) PCT application Serial No. PCT/US2004/005484, entitled "Sealed Surgical Access Device," filed on Feb. 25, 2004, (2) PCT application Serial No. PCT/US2004/0054-87, entitled "Wound Retractor for Use in Hand-Assisted Laparoscopic Surgery," filed on Feb. 25, 2004, and (3) PCT application Serial No. PCT/US2004/005361, entitled "Apparatus and Method for Illuminating a Peritoneal Cavity During Laparoscopic Surgery," filed on Feb. 24, 2004, all of which claim priority to (4) provisional application Ser. No. 60/449,857, filed on Feb. 25, 2003, entitled "Hand-Assisted Laparoscopy Apparatus and Method," all of which are fully incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] This invention generally relates to surgical access systems that facilitate sealed access across a body wall and into a body cavity during a laparoscopic surgical procedure.

[0004] 2. Discussion of the Relevant Art

[0005] During laparoscopic surgery, it is desirable to inflate the abdominal cavity in order to increase the volume of the working space. This is accomplished with an insufflation gas which must be maintained at a pressure sufficient to inflate the abdomen. Maintaining the pressure of the insufflation gas is difficult when it is also desirable to insert instrumentation through the abdominal wall. If a surgeon is interested in inserting his or her hand in a hand-assisted laparoscopic procedure, the maintenance of insufflation pressure is even more difficult. Currently, several devices exist that accomplish this surgical need although they suffer from drawbacks such as difficult placement and cumbersome use. For example, these hand-assisted devices require elaborate mechanisms such as inflatable cuffs and adhesives to seal around a surgeon's wrist or forearm to maintain the insufflation gases. As such, there is a need for a special seal formed around the wrist or forearm of a surgeon to prevent the escape of insufflation gases. Moreover, it is desirable that the wound be retracted, protected and fixed while maintaining the insufflation seal.

SUMMARY OF THE INVENTION

[0006] The invention is directed to a hand access system that provides hand access to a surgical area while maintaining pneumoperitoneum during laparoscopic surgery. The hand access system comprises a sheath retractor adapted to dilate a wound stretchable to a desired diameter, the sheath retractor includes a first ring being adapted for disposition interiorly of the wound, a second ring being adapted for disposition exteriorly of the wound, and a sheath being disposed in a generally cylindrical form between the first ring and the second ring and operable to exert a radial retraction force on the wound. The hand access system further comprises a detachable hand seal adapted to be attached and detached from the second ring of the sheath retractor. In particular, the hand seal can be detached from the sheath retractor to convert the hand access system from laparoscopic surgery to open surgery. In one aspect, the first ring, second ring and sheath are formed from an elastomeric material, and the hand seal is formed of a gel material and includes a slit providing an instrument seal in the presence of an instrument or hand and a zero seal in the absence of the instrument or hand. The gel material includes, for example, a thermoplastic base such as Kraton® and an oil. The resulting elastomer has excellent tear strength, elongation greater than 1,000 percent, a very low durometer or hardness, and biocompatibility. It is appreciated that the first ring has a first diameter and the second ring has a second diameter, and the first and second diameters are greater than the desired diameter of the wound.

[0007] In another aspect, the sheath retractor further comprises a third ring disposed circumferentially of the sheath and moveable between a plurality of positions between the first ring and the second ring, each of the positions being associated with a different retraction force, the third ring being adapted for disposition exteriorly of the wound. The sheath retractor may further comprise means for retaining the third ring at one of the plurality of positions in order to provide the desired radial retraction force associated with that position. The retaining means may comprise a fourth ring adapted to interlock with the third ring to fix the sheath at the desired position. The retaining means may include a wedge disposed between the third ring and the fourth ring.

[0008] In yet another aspect of the invention, the hand access system may further comprise an adapter having a first adapter cavity for releasably attaching to a ring of the retractor sheath and a second adapter cavity for releasably attaching to the hand seal. The first adapter cavity has a first diameter and the second adapter cavity has a second diameter.

[0009] In other aspects of the invention, the hand seal may include a cavity to receive the second ring of the sheath retractor, the hand seal may further comprise a latch on an inner diameter for latching the third ring, and the third ring may comprise at least a hook to latch the hand seal as the hand seal is attached to the sheath retractor. To facilitate sealing of the peritoneum, a conformable gasket may be provided that may be attached to the first ring or to the sheath of the sheath retractor, or the conformable gasket may float unattached to the sheath and interiorly of the wound.

[0010] In another aspect of the invention, the hand access system may comprise a detachable iris seal in place of the hand seal that is adapted to be attached and detached from the sheath retractor. The iris seal comprises a first iris ring, a second iris ring coaxially attached to the first iris ring, and a cylindrical elastic member connected to the first and second iris rings and having an opening. With this aspect, the first and second iris rings operate to rotate relative to one another in either direction to open or close the opening of the cylindrical elastic member. More specifically, the first and second iris rings may be rotated in opposite directions to create an airtight constriction in the middle of the elastic member. After rotation, at least one of the first and second iris rings may be de-rotated to loosen or enlarge the constriction of the elastic member.

[0011] Each of the iris rings may comprise a plurality of tracks to allow the iris rings to be relatively rotated at predetermined angles. In yet another aspect, the iris seal may further comprise a spring connecting the first and second iris

rings to further facilitate a complete opening, a partial constriction or an airtight constriction of the opening of the elastic member. The spring operates to automatically pull and rotate the iris rings after de-rotation. In particular, as an object is withdrawn from the iris seal, the spring contracts and causes the sheath constriction to tighten automatically. The spring may be formed from an elastomeric material. It is appreciated that the amount the spring stretches and contracts is determined by the length of the spring. Each of the iris springs may comprise a hollow frame and a plurality of interlocking tracks. The interlocking tracks operate to encase the spring to prevent the spring from crossing into an instrument or hand passage area within the iris rings. The interlocking tracks also operate to open and close the seal at predetermined angles.

[0012] In another aspect of the invention, there is disclosed a surgical access device adapted for disposition relative to an incision in a patient comprising a valve including a plurality of overlapping sheets defining an access channel, and a ring having an inner diameter for holding the valve by fixing each of the overlapping sheets along a portion of the perimeter, the access channel extends into communication with the incision in the patient. With this aspect, each of the overlapping sheets includes a portion of the perimeter that is not fixed to the inner diameter of the ring. It is appreciated that the non-fixed portions provide open edges defining the access channel. In one aspect, the open edges slightly overlap for about 0.25" at the center of the ring. The hand access device may further comprise a septum seal formed at the proximal end and at the distal end of the ring, the septum seal having a hole formed at the center of the seal. It is further appreciated that the open edges of the non-fixed portions may have different shapes including at least one of a straight edge, concave, convex and a cross-configuration.

[0013] In yet another aspect of the invention, there is disclosed a surgical access device adapted for disposition relative to an incision in a patient comprising a plurality of septum layers each having a hole at the center of the septum layer and a first diameter, a ball sandwiched between the septum layers and having a second diameter greater than the first diameter, and a ring having an inner diameter for affixing the plurality of septum layers along the perimeter. In another aspect, a surgical access device facilitating a sealing relationship with an instrument or an arm of a surgeon extending through the device and into an incision in a patient is disclosed, the access device comprising a valve structure including a plurality of overlapping sheets defining an access channel, the valve in a first state forming a zero seal in the absence of the instrument or the arm of the surgeon extending through the valve structure, the valve in a second state forming an instrument seal in the presence of the instrument or the arm of the surgeon extending through the valve structure, and the access channel extends into communication with the incision in the patient.

[0014] These and other features of the invention will become more apparent with a discussion of the various embodiments in reference to the associated drawings.

DESCRIPTION OF THE DRAWINGS

[0015] The accompanying drawings, which are included in and constitute a part of this specification, illustrate the embodiments of the invention and, together with the description, explain the features and principles of the invention. In the drawings:

[0016] **FIG. 1** is a perspective view showing a patient prone on an operating table with his abdomen insufflated and with instrument access provided by trocar and the access device of the present invention;

[0017] **FIGS. 2A and 2B** illustrate a perspective view and a cross-sectional view, respectively, of a hand access system in accordance with a first embodiment of the invention;

[0018] **FIGS. 3A-3E** illustrate axial perspective views and cross-sectional views of a hand access system in accordance with another embodiment of the invention including a one-way mechanism;

[0019] **FIGS. 4A and 4B** illustrate cross-sectional views of a hand access system in accordance with another embodiment of the invention including an adapter;

[0020] **FIGS. 5A-5C** illustrate an axial perspective view and cross-sectional views of a hand access system in accordance with another embodiment of the invention including a conformable gasket;

[0021] **FIG. 6** illustrates a cross-sectional view of a hand access system in accordance with another embodiment of the invention including an iris seal;

[0022] **FIGS. 7A-7E** illustrate the rotation of the iris seal rings of the invention to create an airtight constriction in the middle of the sheath;

[0023] **FIGS. 8A-8C** illustrate side views of another embodiment of the iris seal including a spring connecting the two rings;

[0024] **FIG. 9** illustrates a top view of **FIG. 8B**;

[0025] **FIGS. 10 and 11** illustrate perspective and top views of rings of an iris seal having interlocking tracks in accordance with another embodiment of the invention;

[0026] **FIG. 12** illustrates a perspective view of a hand-assisted laparoscopic seal formed by overlapping sheets of elastomeric material in accordance with another embodiment of the invention;

[0027] **FIG. 13** illustrates a perspective view of a hand-assisted laparoscopic seal formed by differently shaped overlapping sheets of elastomeric material in accordance with another embodiment of the invention;

[0028] **FIGS. 14 and 15** illustrate perspective views of a hand-assisted laparoscopic seal formed by overlapping sheets of elastomeric material having concave and convex configurations;

[0029] **FIG. 16** illustrates a perspective view of a hand-assisted laparoscopic seal formed by overlapping sheets of elastomeric material including a central patch supported by spokes in accordance with another embodiment of the invention; and

[0030] **FIG. 17** illustrates a perspective view of a hand-assisted laparoscopic seal formed by two septum layers sandwiching a ball in accordance with another embodiment of the invention.

DESCRIPTION OF THE INVENTION

[0031] Referring to **FIG. 1**, there is shown a typical abdominal surgery on a patient **10** in a prone position on an operating table **12**. **FIG. 1** further illustrates a surgeon having an arm **16** and a hand **17** performing the surgery. In the illustrated example, the operative procedure is performed within an abdominal cavity **18** with instrument access provided through an abdominal wall **21**. In this type of operation, commonly referred to as laparoscopic surgery, trocars **23** and **25** are commonly used to provide minimally invasive access through the abdominal wall **21** for instruments such as a grasper **27** and an endoscope **30**. In addition, it is desirable that the surgeon be able to insert his/her hand **17** through the abdominal wall **21** and into the abdominal cavity **18**. The insertion of the hand **17** provides the surgeon with direct access to various elements of the anatomy.

[0032] In order to accommodate the hand **17** and arm **16** of the surgeon, a small incision **32** is typically created in the abdominal wall **21**. An access device **34** of the present invention can be provided to further facilitate this access by the hand **17** of the surgeon. Particularly in the case of laparoscopic surgery, it is advantageous to insufflate the abdominal cavity **18** with a gas, such as carbon dioxide, in order to elevate the abdominal wall **21** and thereby increase the volume of the working space within the cavity **18**. Maintenance of this insufflation pressure, commonly referred to as pneumoperitoneum, is particularly difficult where access is desired across the abdominal wall **21**, for example, through the trocars **23**, **25**, as well as the access device **34**. For this reason, a substantial effort has been directed to providing such access devices with sealing characteristics both in the presence of instruments and in the absence of instruments, such as the grasper **27**, scope **30** and hand **17**.

[0033] Were it not for the desire to maintain the pneumoperitoneum, there would be no need for the trocars **23**, **25** or the access device **34**. That is, one would merely cut an incision in the abdominal wall **21** and insert the instrument directly through the incision. However, without appropriate valves or seals, the insufflation gases would merely escape through the incision **32**. This would be particularly detrimental in the case of the incision **32** which must be sufficiently large to accept the hand **17** of the surgeon. Thus, the access device **34** operates to form with the incision **32** to provide an access or working channel, and to provide a valve or other sealing structure across the working channel in order to maintain the pneumoperitoneum.

[0034] Referring to **FIGS. 2A and 2B**, there are shown a perspective view and a cross-sectional view, respectively, of a hand access system **100** of the invention. The hand access system **100** provides hand access to a surgical area such as the abdominal cavity **18** while maintaining pneumoperitoneum during laparoscopic surgery. The hand access system **100** comprises a sheath retractor **110** including a peritoneal ring **112**, a proximal ring **114**, and a sheath **116** extending along an axis **117** connecting the peritoneal ring **112** and the proximal ring **114**. The sheath **116** has a generally cylindrical configuration that may be retracted to protect an incision within a body cavity such as the abdominal wall **21**. The peritoneal ring **112** and proximal ring **114** are disposed in respective planes which extend radially of the axis **117**. The hand access system **100** further comprises a detachable hand seal **120** that is operably attachable and detachable to the proximal ring **114** of the sheath retractor **110** as illustrated in **FIG. 2B** to permit insufflation. It is appreciated that the hand seal **120** can be separated from the sheath retractor **110** to allow removal of large organs or to provide open access to the abdominal cavity **18**. Stated another way, the hand seal **120** can be removed at any time to allow conversion from laparoscopic surgery to open surgery.

[0035] It is further appreciated that wound retraction in accordance with the present invention allows a surgeon to easily locate the sheath retractor **110** and to provide a base for the hand seal **120**. The sheath retractor **110** operates to remove the tissue pressure from the wrist during hand-assisted laparoscopic surgery. The sheath retractor **110** further protects tissue at the wound site, for example, from abrasion, bacteria or other contaminated organs, such as donor kidneys to be removed with minimal risk or damage. The sheath retractor **110** also opens the wound providing greater access to the operative site for instruments, such as the hand of the surgeon. In particular, the sheath protector **110** includes the sheath **116** having elastomeric properties that separate the two rings **112**, **114**. During surgery, the peritoneal ring **112** is placed interiorly of the abdominal wall **21** and the proximal ring **114** is placed exteriorly of the abdominal wall **21** and is then stretched beyond its natural state. The diameters of the rings **112**, **114** are greater than that of the wound site so as to provide sufficient footing and tension between the rings **112**, **114**. This tension is created by the elastic material that has been stretched and retained at a distance greater than its natural state. It will be appreciated that in other embodiments, the sheath **116** can be formed of a non-elastic sheathing material. In a similar manner, the rings **112**, **114** may be provided with a rigid configuration or alternatively may be formed of an elastomeric material.

[0036] Referring to **FIGS. 3A and 3B**, there are shown perspective views of a hand access system **100*b*** where elements of structure similar to those previously described are designated by the same reference numeral followed by the lower case letter "b" in accordance with another embodiment of the invention. The sheath retractor **110*b*** comprises a peritoneal ring **112*b***, a proximal ring **114*b***, a sheath **116*b*** extending along an axis **117*b*** connecting the peritoneal ring **112*b*** and the proximal ring **114*b***, and a one-way mechanism **118*b*** (a cylindrical plug) that is placed to extend above the incision. More specifically, the one-way mechanism **118*b*** is placed between the peritoneal ring **112*b*** and the proximal ring **114*b***. The hand access system **100*b*** further comprises a "plug" hand seal **120*b*** that is operably attached to the proximal ring **114*b*** of the sheath retractor **110*b***. The hand seal **120*b*** can be made of a soft gel material including a slit providing an instrument seal in the presence of an instrument or hand and a zero seal in the absence of an instrument or hand. The gel material includes, for example, a thermoplastic base such as Kraton® and an oil. The resulting elastomer has excellent tear strength, elongation greater than 1,000 percent, a very low durometer or hardness, and biocompatibility.

[0037] Referring to **FIGS. 3C-3E**, there are shown axial perspective views of an exemplary embodiment of the one-way mechanism **118*b*** of the invention. Specifically, the one-way mechanism **118*b*** comprises two complimentary interlocking rings **83** and **90**. The proximal ring **114*b*** can be

disposed outwardly of the sheath **116***b* and the locking ring **90** can be disposed inwardly of the sheath **116***b*. These two rings **114***b* and **90** function to clamp the sheath **116***b* so that the ring **83** is maintained in a fixed position by the locking ring **90**. The interlocking rings **83**, **90** of **FIG. 3C** provide for simple operation of the sheath retractor **110***b*. These interlocking rings **83**, **90** can be pushed down so that they rest on the outer surface of the abdominal wall **21**. As the sheath **116***b* is drawn upwardly to achieve the proper degree of tension, it is easily moved between the interlocking rings **83**, **90**. However, any tendency of this sheath **116***b* to move back into the wound site will tighten the interlocking relationship of the rings **83**, **90**. Thus, the desired degree of tension is maintained on the sheath **116***b* until it is again pulled to release the locking ring **90** from the ring **83**.

[**0038**] The one-way characteristics of the interlocking rings **83**, **90** are further illustrated in the progressive views of **FIGS. 3D and 3E**. With reference to these figures, it can be seen that retraction is maintained by preventing the sheath **116***b* from pulling back into the wound by means of the one-way operation of the interlocking rings **83**, **90**. The sheath **116***b* slides easily through the interlocking rings **83**, **90** in the upper direction, but is prevented from sliding through the rings **83**, **90** in the downward direction. In order to disengage or separate the interlocking rings **83**, **90**, one needs only re-tension the sheath **116***b* by pulling it proximally thereby unlocking the rings **83** and **90**. This enables the ring **83** to be removed from the sheath **116***b* in order to remove the retractor **116***b* from the wound site.

[**0039**] In another aspect of the invention, **FIGS. 4A and 4B** illustrate axial perspective views of a hand access system **100***c* comprising a sheath retractor **110***c*, an adapter **140** and a detachable hand seal **120***c*. The sheath retractor **110***c* includes a peritoneal ring **112***c*, a proximal ring **114***c*, and a sheath **116***c* extending along an axis **117***c* connecting the peritoneal ring **112***c* and the proximal ring **114***c*. The adapter **140** comprises a first or lower ring **142** for attaching to the proximal ring **114***c* of the sheath retractor **110***c*, and a second or upper ring **144** for attaching to the detachable hand seal **120***c*. **FIG. 4B** illustrates the hand access system **100***c* with the sheath retractor **110***c*, the adapter **140** and the hand seal **120***c* installed. More specifically, the adapter **140** is first attached to the proximal ring **114***c* of the sheath retractor **110***c*. In turn, the hand seal **120***c* may be attached and detached from the upper ring **144** of the adapter **140** as needed.

[**0040**] It is appreciated that the proximal ring **114***c* may further include a movable ring, which together with the proximal ring **114***c*, may be used to press down on the adapter **140** against the abdomen, for example, to secure it and form an airtight connection. It is further appreciated that the upper ring **144** may have a diameter that is great than, equal to or less than the diameter of the lower ring **142**. In another aspect of the invention, the adapter **140** may further comprise grooves to snap in a self-closing iris seal to gain pneumoperitoneum.

[**0041**] **FIGS. 5A-5C** illustrate perspective and cross-sectional views of a hand access system **100***d* in accordance with yet another embodiment of the invention where elements of structure similar to those previously described are designated by the same reference numeral followed by the lower case letter "d". The hand access system **100***d* comprises a sheath retractor **110***d* and a hand seal **120***d* operably attached to the sheath retractor **110***d*. The sheath retractor **110***d* includes a peritoneal ring **112***d*, a proximal ring **114***d*, a sheath (not shown) connecting the peritoneal ring **112***d* and the proximal ring **114***d*, and a one-way mechanism **118***d* comprising a plurality of interlocking rings **83***d*, **90***d*. The hand seal **120***d* operably attaches to the proximal ring **114***d* of the sheath retractor **110***d*. The hand seal **120***d* may be formed of a soft gel material and includes a small slit to allow passage of a hand or a surgical instrument during surgery. Referring to **FIG. 5B**, there is shown a cross-sectional view of the hand seal **120***d* having a cavity **125***d* inside the gel to receive the proximal ring **114***d* of the sheath retractor **110***d*. Referring to **FIG. 5C**, the hand seal **120***d* may further comprise a latch **121***d* on an inner diameter for latching the one-way mechanism **118***d*. The access sheath material may be placed inside or outside of the hand seal **120***d* after attachment of the hand seal **120***d* and the seal retractor **110***d*.

[**0042**] In another aspect, the one-way mechanism **118***d* may include hooks to latch the hand seal **120***d* as the seal **120***d* is pressed down on the open end of the sheath. As explained above, the hand seal **120***d* includes a small slit in the gel that will not allow air to pass with the absence of an instrument or hand, but the slit will stretch and the gel will compress to allow objects to pass through with little loss of pneumoperitoneum. Compression of the gel onto the proximal ring **114***d* of the sheath retractor **110***d* creates an airtight connection. The sheath retractor **110***d*, as illustrated in **FIG. 5A**, may further include a conformable gasket **123***d* to facilitate sealing of the peritoneum. The comformable gasket **123***d* on the peritoneum ensures an airtight seal inside the incision as opposed to outside the incision. The gasket **123***d* can be attached to the peritoneal ring **112***d* or the sheath **116***d*, or it can float unattached to the sheath. The floating gasket **123***d* is less likely to crease or bunch (a path for air leaks) as the abdominal wall **21**, sheath **116***d* and peritoneal ring **112***d* distort as the sheath **116***d* is pulled up into the incision. Without the need for sealing externally on the skin surface, the conformable gasket **123***d* is not susceptible to air leaks for irregularities on the skin, such as scars or folds. Furthermore, the conformable gasket **123***d* protects the abdominal wall **21** from potential traumatic pressure or abrasion by the peritoneal ring **112***d*.

[**0043**] In all of the above embodiments of the invention, the ability to attach and detach the hand seal from the sheath retractor allows larger objects to pass unfettered through the incision. In addition, the invention is easy to use, it provides increased comfort for the surgeon, and is less traumatic to tissue being passed through the incision. For example, the latching or interlocking feature of the hand seal and the adapter with the sheath retractor makes it fast and simple to use compared to other methods that may involve inflatable cuffs or adhesives. Adhesives often require time to cure and inflation with pumps also creates delay.

[**0044**] In another aspect of the invention, the hand access system may comprise a sheath retractor and an iris seal directly connected to the sheath retractor to form a continuous, seamless sheath. Referring to **FIG. 6**, there is shown a hand access system in accordance with another embodiment of the invention including an iris seal **200**. The iris seal **200** comprises a first ring **202**, a second ring **204** coaxially attachable to the first ring **202**, and a cylindrical elastic

member **206** connected to the first and second rings **202**, **204** and having an opening. The first and second rings **202**, **204** operate to rotate relative to one another in either direction to open or close the opening of the cylindrical elastic member **206**. In particular, the seal **200** operates like the iris aperture of a camera, except that the iris seal **200** is made of a thin film sheath or elastic member **206**. A ring **202**, **204** is attached to each end of the sheath or elastic sheath **206**. Referring to **FIGS. 7A-7C**, the rings **202**, **204** are rotated in opposite directions to create an airtight construction in the middle of the sheath or elastic member **206**. The constriction is maintained as long as the rotation is not undone (termed de-rotation). The sheath or elastic member **206** can be made of an elastic material, which allows objects small in diameter relative to the rings **202**, **204** to pass easily through the constriction without the need for de-rotation. However, objects with large diameters may require de-rotation to loosen or enlarge the constriction in the sheath as illustrated in **FIG. 7D**. Once an object is withdrawn, the rings **202**, **204** must rotate back to create the airtight construction as illustrated in **FIG. 7E**. In another aspect, the rings **202**, **204** may include a plurality of tracks **207** such that they may be relatively rotated to open or close the opening at predetermined angles as further discussed below and illustrated in **FIG. 10**. More specifically, the sectional area of the opening changes in response to the predetermined angle rotation of the rings.

[**0045**] Referring back to **FIG. 6** the iris seal **200** may be attached to a sheath retractor **110***f* having a peritoneal ring **112***f*, a proximal ring **114***f*, a sheath **116***f* connecting the peritoneal ring **112***f* and the proximal ring **114***f*, and a one-way mechanism **118***f* (comprising a plurality of interlocking rings **83***f*, **90***f*). A feature of the iris seal **200** is its constriction can be dilated as wide as the retracted incision and, as such, it may not be necessary for it to be detached from the sheath retractor **110***f*. In this case, the iris seal **200** can be made a permanent part of one of the interlocking rings of the one-way mechanism **118***f*. Thus, the self-closing iris seal **200** and sheath retractor **110***f* combinations allows pneumoperitoneum to be regained more quickly without having to detach and reattach a seal as with previous methods. In another aspect, an iris seal can be easily removed when constructed as part of a two-ring design in the form of a wedge clamp similar to that shown in **FIGS. 3C-3E**. Pulling up on a sheath pushes or un-wedges the seal out of the sheath retractor.

[**0046**] It is appreciated that other hand seals can be used and interchanged as contemplated by the concept of the invention. For example, the iris seal of the invention may further include a spring **208** connecting the first and second rings **202**, **204** to further facilitate the opening and closing of the opening of the cylindrical elastic member **206**. More particularly, one or more springs **208** may be used to connect the first and second rings **202**, **204** to provide a complete opening, a partial constriction or an airtight constriction of the iris seal. Referring to **FIGS. 8A-8C**, there are shown perspective views of the iris seal **200***c* of the invention further comprising the spring **208** connecting the first and second rings **202***c*, **204***c*. **FIG. 9** is a top view of the iris seal **200***c* of **FIG. 8B**.

[**0047**] As illustrated in **FIGS. 8 and 9**, as the rings **202***c*, **204***c* are rotated relative to one another, the spring **208** expands and contracts causing opening and constriction of the seal. More specifically, the spring **208** can be used to pull and rotate the rings **202***c*, **204***c* automatically after de-rotation, for example. The ends of the spring **208** are connected to the rings **202***c*, **204***c* in a manner such that de-rotation causes the spring **208** to stretch as illustrated in **FIGS. 8A and 8B**. Afterwards, the spring **208** contracts and causes the sheath constriction to tighten automatically as large objects are withdrawn (**FIG. 8C**). The amount the spring **208** stretches and contracts is determined by the length of the spring **208**—typically larger objects require longer springs. Longer springs, however, may crossover the area within the rings **202***c*, **204***c* and interfere with the passage of objects as illustrated in **FIG. 9**. To limit interference and to accommodate large objects, longer springs can be housed partially within a series of interlocking tracks **207** of hollow frame rings **202***d*, **204***d* as illustrated in **FIGS. 10 and 11**. In particular, the interlocking tracks **207** on the rings can encase longer springs so they do not cross into the passage area. The interlocking tracks **207** also operate to open and close the seal at predetermined angles. **FIG. 11A** illustrates an axial cross-sectional view of the seal with the springs contracted and the iris closed, and **FIG. 11B** illustrates an axial cross-sectional view of the seal with the springs expanded and the iris opened.

[**0048**] An advantage of rotational adjustment, versus fixed rings, is that a wider range of object sizes can easily pass through the iris seal. A self-closing mechanism of the invention has the advantage of hands-free adjustment. In comparison to other self-closing methods that involve gears and springs that are connected to stationary components external to the iris seal, the spring(s) of the present invention are connected to and contained within the rings, which are integral to the iris seal. With the self-closing mechanism built in, the iris seal is portable and can be more easily adapted to a wide range of access ports, wound retractors and the like.

[**0049**] In another aspect of the invention, a hand-assisted laparoscopy seal **300** is formed by overlapping several sheets **302**, **304**, **306**, **308**, **310**, **312** of elastomeric material as illustrated, for example, in **FIG. 12**. Each of these sheets **302**, **304**, **306**, **308**, **310**, **312** is fixed along a portion of its perimeter to the circumference of a semi-rigid or rigid ring (not shown). As a result, each of the sheets **302-312** has at least a portion **302***a*, **304***a*, **306***a*, **308***a*, **310***a*, **312***a* of its perimeter fixed to the ring and a portion **302***b*, **304***b*, **306***b*, **308***b*, **310***b*, **312***b* not fixed to the ring. These non-fixed portions **302***b*-**312***b* provide open edges within the area of the ring. The sheets **302-312** are laid on top of one another and are rotated so that open edges extend along different planes. These open edges slightly overlap, such as approximately one-quarter inch, at the center of the ring to prevent leakage of the insufflation gas. During operation, an instrument or hand of the surgeon is introduced through the center of the ring forcing the open edges to part, but also causing the open edges to form a sealing structure around the forearm or wrist.

[**0050**] It is appreciated that in the above aspect, the overlapping sheets **302**, **312** may comprise two septum sheets having their full perimeters fixed to the ring and a hole formed at the center of the septum sheets. Referring to **FIG. 13**, there is shown another aspect of the invention where the open edges **404***b*, **406***b*, **408***b*, **410***b* have different shapes, which when laid on top of one another, tend to form

overlapping sections of a circle. It is appreciated that the concept of the invention contemplates any number of overlapping sheets of any material and of any shape. In one simple embodiment, for example, the invention contemplates two semi-circular sheets having slightly straight overlapping edges.

[0051] In another aspect, **FIGS. 14 and 15** show how the open edges can be provided with concave or convex configurations. The sheets or layers having convex open edges **506**, **510**, **608**, **610** tend to flex more while the sheets or layers having concave edges **504**, **508**, **604**, **606** tend to give more support. The septum sheets or layers **502**, **602** provide the most support. Other shapes can be used for the layers as illustrated in the embodiment of **FIG. 16** where one of the layers includes a central patch **704** supported by spokes **704***a*, **704***b*, **704***c*, **704***d* which extend to the ring. The central patch **704** is large enough to cover the hole **702***a* in the septum layer **702**. In the embodiment of **FIG. 17**, two septum layers **802**, **806** sandwich a ball **804** which is movable within the confines of the ring. The ball **804** has a diameter greater than the holes **802***a*, **806***a* in the septum layers **802**, **806**, respectively.

[0052] It will be understood that many other modifications can be made to the various disclosed embodiments without departing from the spirit and scope of the invention. For these reasons, the above description should not be construed as limiting the invention, but should be interpreted as merely exemplary of the disclosed embodiments.

1-57. (canceled)

58. A surgical access device, comprising:

a sealing valve for sealing across an incision in a patient, the sealing valve including at least a first sheet and a second sheet;

wherein the first sheet and the second sheet are movable relative to one another between a first state forming a zero seal in the absence of an instrument and a second state forming an instrument seal in the presence of an instrument; and

wherein in the first state, the first sheet and the second sheet overlap each other.

59. The surgical access device of claim 58, wherein at least one of the first sheet and the second sheet includes a gel material.

60. The surgical access device of claim 59, wherein:

the first sheet includes a gel material; and

the second sheet includes a gel material.

61. The surgical access device of claim 58, wherein the first sheet and the second sheet are biased toward the first state.

62. The surgical access device of claim 58, wherein the overlapping portions between the first sheet and the second sheet are substantially planar.

63. The surgical access device of claim 62, wherein the planes of the overlapping portions are rotatably offset.

64. The surgical access device of claim 58, wherein the first sheet is substantially planar.

65. The surgical access device of claim 58, wherein the second sheet is substantially planar.

66. The surgical access device of claim 58, wherein the overlapping portions of the first sheet and the second sheet part during the introduction of an instrument within the overlapping portions.

67. The surgical access device of claim 58, wherein the sealing valve is configured to be located proximal to the incision in the patient.

68. The surgical access device of claim 58, wherein the surgical access device is configured to be coupled to a sheath retractor.

69. The surgical access device of claim 58, wherein the first sheet is at least partially curved.

70. The surgical access device of claim 58, wherein the second sheet is at least partially curved.

71. The surgical access device of claim 58, wherein:

the first sheet includes a septum layer having a hole therethrough; and

the second sheet includes a septum layer having a hole therethrough.

72. The surgical access device of claim 71, the hole in the first sheet having a diameter substantially equal to a diameter of the hole in the second sheet.

73. The surgical access device of claim 71, further comprising:

a ball positioned between the first sheet and the second sheet, the ball having a diameter greater than a diameter of the hole in the first sheet and greater than a diameter of the hole in the second sheet.

74. A method of accessing an abdominal cavity through an incision in the abdominal wall, comprising:

providing a sealing valve having at least a first sheet and a second sheet, the first sheet and the second sheet overlapping each other and being movable relative to one another between a first state forming a zero seal in the absence of an instrument and a second state forming an instrument seal in the presence of an instrument;

arranging the sealing valve across the incision;

passing an instrument through the sealing valve, thereby causing the first sheet and second sheet to part; and

advancing the instrument distally into the abdominal cavity.

75. The method of claim 74, further comprising positioning the sealing valve proximal to the incision.

76. The method of claim 74, further comprising:

providing a sheath retractor;

retracting the incision within the abdominal wall with the sheath retractor.

77. The method of claim 76, further comprising:

coupling the sealing valve to the sheath retractor.

78. The method of claim 74, wherein the instrument is a surgeon's hand.

79. The method of claim 74, wherein the instrument is a surgical instrument.

* * * * *

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申请(专利权)人(译)	HART CHARLESÇ PINGLETON爱德华Ð		
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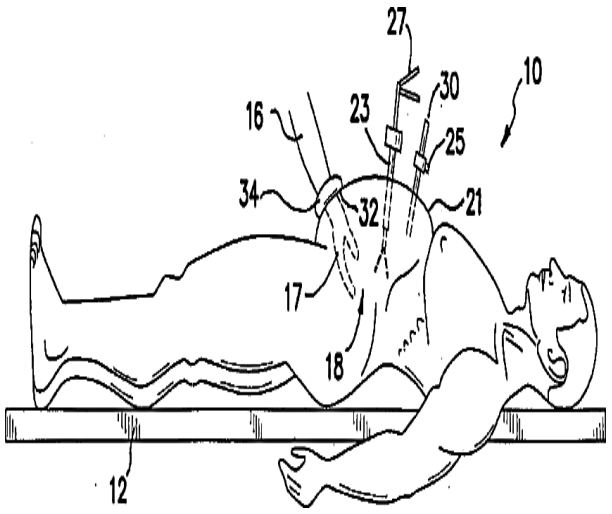
摘要(译)



本发明涉及一种手部进入系统，其在腹腔镜手术期间提供手部进入手术区域同时保持气腹。手部通路系统包括护套牵开器，其适于将可伸展的伤口扩张至所需直径，护套牵开器包括适于布置在伤口内部的第一环，适于布置在伤口外部的第二环和护套。在第一环和第二环之间以大致圆柱形的形式设置，并且可操作以在伤口上施加径向收缩力。手动进入系统还包括可拆卸的手动密封件，其适于可从护套牵开器的第二环移除。护套牵开器可以由弹性材料形成，并且手密封件可以由凝胶材料形成，并且包括在仪器或手的存在下提供器械密封的狭缝以及在没有器械或手的情况下的零密封。 。在另一方面，公开了一种外科进入装置，其适于相对于患者的切口进行布置，所述外科进入装置包括阀，所述阀包括限定进入通道的多个重叠片，以及具有内径的环，所述内径用于通过固定所述阀中的每一个来保持所述阀。沿着周边的一部分重叠片材，进入通道延伸成与患者的切口连通。每个重叠片包括周边的未固定到环的内径的部分，其提供限定进入通道的开口边缘。开口边缘在环的中心处略微重叠。开口边缘可以具有不同的形状，包括直边，凹面，凸面和交叉配置中的至少一种。手动进入装置还可包括形成在环的近端和远端的隔膜密封件。