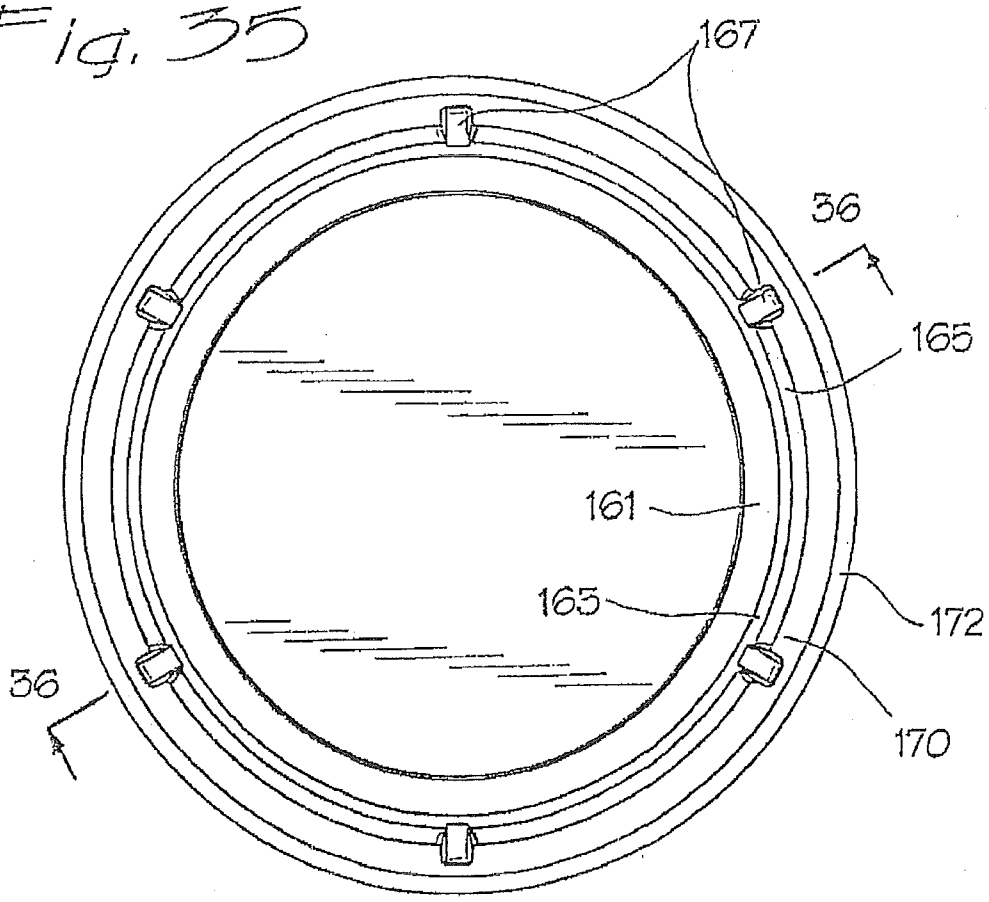
Fig. 35



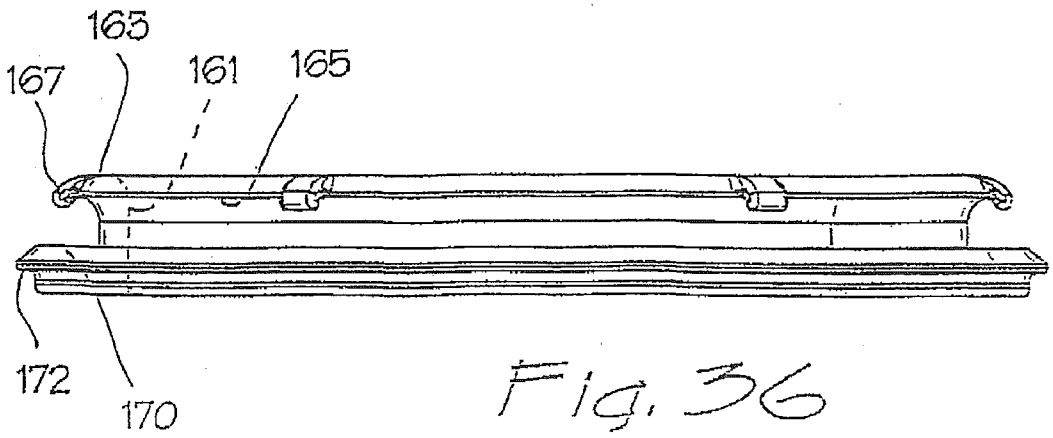


Fig. 36

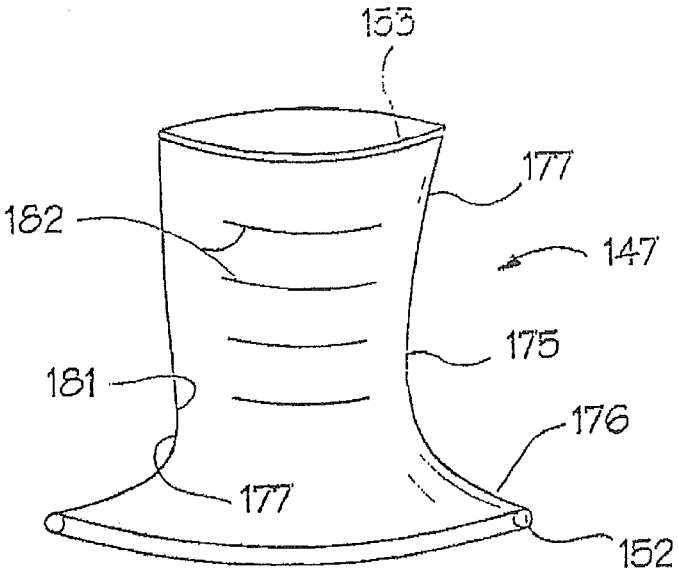

153
177
182
147
175
181
176
177
152

Fig. 37

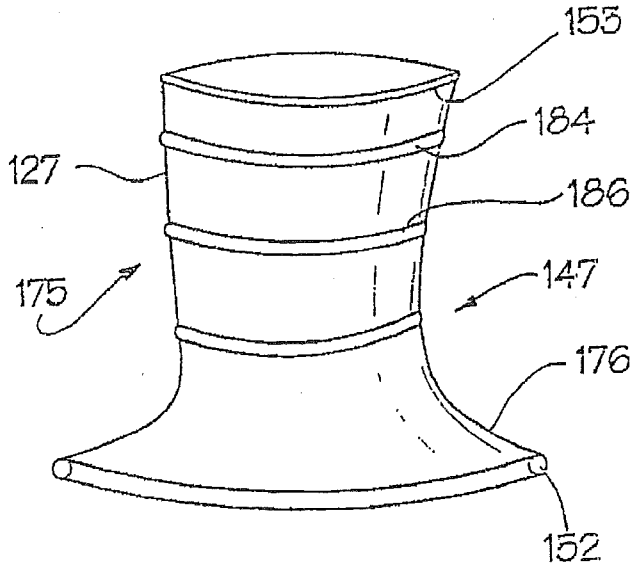

153
184
127
186
147
175
176
152

Fig. 38

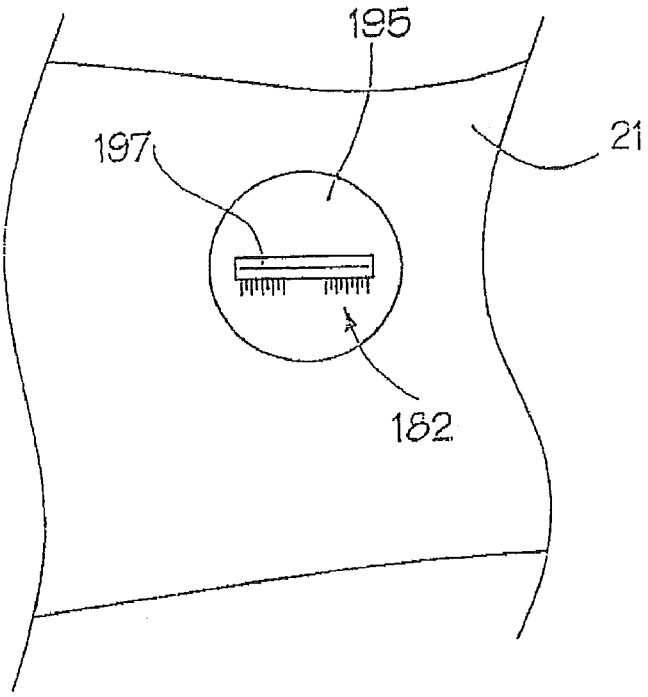


Fig. 39

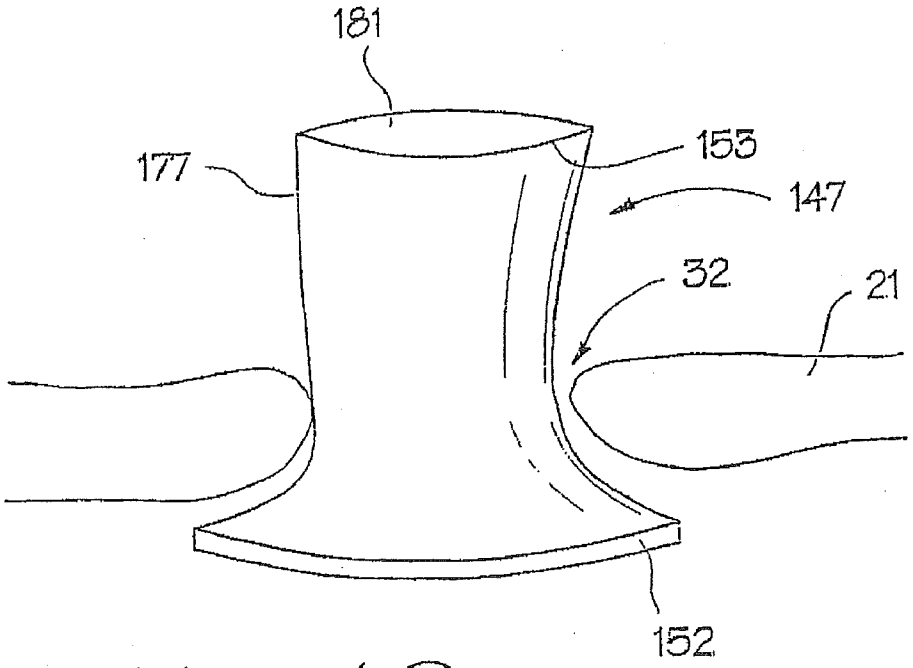


Fig. 40

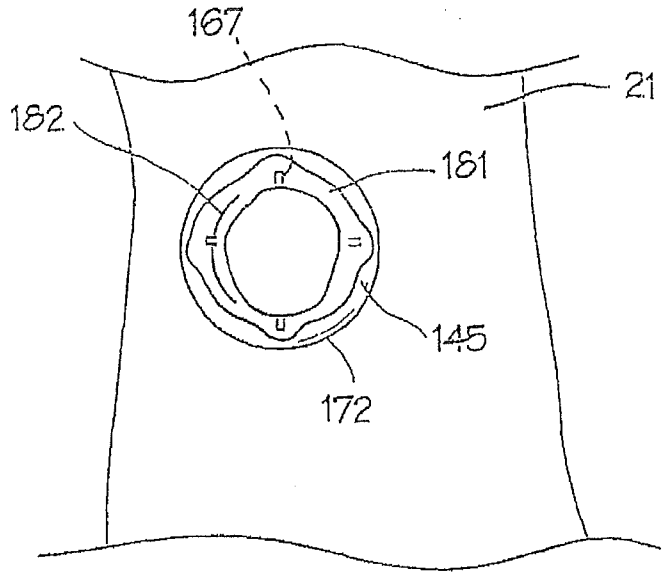


Fig. 41

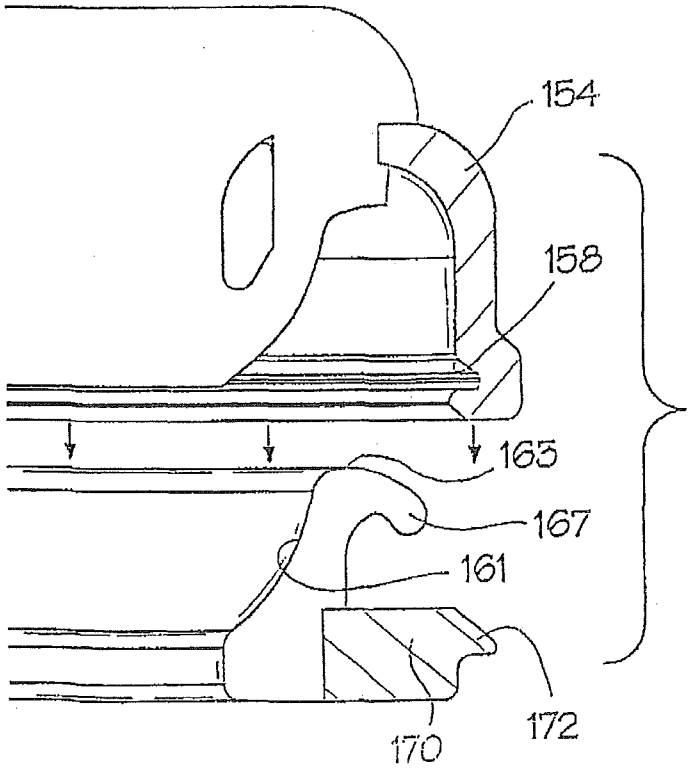


Fig. 42

SURGICAL ACCESS APPARATUS AND METHOD

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation of U.S. application Ser. No. 12/360,710, filed Jan. 27, 2009, which is a continuation of U.S. application Ser. No. 11/244,647, filed Oct. 5, 2005, now U.S. Pat. No. 7,481,765, which is a continuation of U.S. application Ser. No. 10/381,220, filed Mar. 20, 2003, now U.S. Pat. No. 7,473,221, which is the National Phase application under 35 U.S.C. §371 of International Application No. PCT/US2001/029682, filed Sep. 21, 2001, which published in English as International Publication No. WO 2002/034108 A1 on May 2, 2002, which claims the benefit of U.S. Application No. 60/241,958, filed Oct. 19, 2000, all of the disclosures of which are incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to devices and other apparatus facilitating sealed access with surgical instruments, such as a surgeon's hand, across a body wall and into a body cavity.

2. Background of the Invention

In several areas of surgery there exists a need to have mechanisms or devices that can seal a body cavity or space, and yet permit the introduction of surgical instruments such as guidewires, endoscopes, and even the hand of a surgeon. Typical of these areas of surgery is laparoscopic surgery which relies on surgical instruments inserted through the abdominal wall to reach an operative site within the abdominal cavity. In order to increase space around the operative site within the cavity, insufflation gases are typically introduced to inflate the cavity and elevate the abdominal wall. This pressurizing of the abdominal cavity is referred to as pneumoperitoneum. In this context, the need to seal the body cavity or space arises from the need to maintain the pneumoperitoneum even when instruments are present.

Trocars have been commonly used to provide instrument access in laparoscopic surgeries. These trocars have included elaborate seal structures having zero seals which prevent escape of the gases in the absence of instruments, and instrument seals which prevent escape of the gases in the presence of instruments. Unfortunately, the instrument seals have been able to accommodate only a narrow range of instrument diameters. Where wider ranges were desired multiple seal pairs had to be provided.

Some instruments, such as the hand of the surgeon, have been too large for trocar access. Under these circumstances, hand-assisted laparoscopic seals have been provided. Such devices have been large, cumbersome, and largely ineffective in providing the required sealing mechanism. Other access devices, such as Touhy-Borst seals, have been used but only for very small diameter access such as that required by a guidewire.

Each of the prior devices suffers from drawbacks which make the device difficult or cumbersome to use. For example, a Touhy-Borst seal requires two hands to use and does not form a seal when a guidewire or other device is about to be introduced. Present trocar seals and hand-assisted seals require two valves, one forming an instrument seal in the presence of the instrument, and the other forming a zero seal in the absence of the instrument. For example, in hand-assisted devices, elaborate mechanisms have been required to seal around the surgeon's arm. When the arm is removed, a separate zero seal has been required to prevent the escape of blood or insufflation gases.

SUMMARY OF THE INVENTION

These deficiencies of the prior art are overcome with the present invention which includes both a seal apparatus and a method for using this apparatus to perform elaborate surgeries. In one embodiment, the device includes a valve structure formed of a gel including, for example, a thermoplastic base such as KRATON (a trademark of Shell Corporation) and an oil. The resulting elastomer has an excellent tear strength, elongation greater than 1,000 percent, a very low durometer or hardness, and biocompatibility. A process for manufacturing this device is greatly simplified using molding techniques.

Importantly, the access device can function as both a zero seal and an instrument seal. Furthermore, it can accommodate a full range of instrument diameters, such as a range from two French in the case of a guidewire, to three or four inches in the case of a surgeon's hand. In addition, several instruments can be accommodated at the same time with a single access device.

Both tear resistance and sealing capability can be enhanced by encapsulating the gel in a sheath or otherwise providing circumferential reinforcement for the valve structure. Additives can be provided either on or in the gel to enhance properties such as lubricity, appearance, wound treatment and/or protection, anti-cancer protection and anti-microbial protection. Additional chemicals, compounds, pharmaceuticals or even mechanical devices can be mixed with or embedded in the gel material to vary chemical, pharmaceutical or physical properties of the access device.

These and other features and advantageous of the invention will be clarified with a description of preferred embodiments and reference to the associated drawings.

DESCRIPTION OF THE DRAWINGS

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

FIG. **2** is an enlarged side elevation view of the access device of FIG. **1** operatively disposed exteriorly as the abdominal wall;

FIG. **3** is a side elevation view similar to FIG. **2** showing the access device operatively disposed interiorly of the abdominal wall;

FIG. **4** is a side elevation view similar to FIG. **2** showing the access device operatively disposed within an incision in the abdominal wall;

FIG. **5** is a plan view taken along lines **5-5** of FIG. **2**;

FIG. **6** is a side elevation view similar to FIG. **2** and illustrating a further embodiment of the access device having an external flange and an internal flange;

FIG. **7** is a side elevation view similar to FIG. **6** and illustrating the hand of a surgeon being inserted through the access device;

FIG. **8** is an axially cross section view of the access device illustrated in FIG. **6**;

FIG. **9** is a cross section view similar to FIG. **8** and illustrating an embodiment with circumferential reinforcement members;

FIG. **10** is an axial cross section view similar to FIG. **9** and illustrating a double-ring retractor with an access device of the present invention;

FIG. **11** is a radial cross section view similar to FIG. **8** and illustrating an embodiment having a lead-in cavity or pocket;

FIG. **12** is a top plan view of the embodiment illustrated in FIG. **11**;

FIG. **13** is an axial cross section view taken along lines **13-13** of FIG. **12**;

FIG. **14** is an axial cross section view taken along lines **14-14** of FIG. **12**;

FIG. **15** is an axial cross section view similar to FIG. **13** and illustrating an embodiment with a duct-bill valve;

FIG. **16** is an axial cross-section view taken along lines **16-16** of FIG. **15**;

FIG. **17** is a radial cross section view similar to FIG. **13** comprising a softer hand seal and a firmer base seal;

FIG. **18** is an axial cross section view taken along lines **18-18** of FIG. **17**;

FIG. **19** is an axial cross section view of an embodiment having a lead-in cavity or pocket with a conical or funnel configuration;

FIG. **20** is a top plan view of the embodiment illustrated in FIG. **19**;

FIG. **21** is an axial cross section view similar to FIG. **13** and showing another embodiment with a trapezoidal slit;

FIG. **22** is an axial cross section view taken along lines **22-22** of FIG. **21**;

FIG. **23** is an axial cross section view similar to FIG. **22** taken along lines **23-23** of FIG. **21** and illustrating a slit having other than a perpendicular relationship to the plane of the pad;

FIG. **24** is a perspective view of a further embodiment of the access device having an opening formed by multiple slits angularly disposed and axially spaced relative to each other;

FIG. **25** is a side elevation view of an access device with a slit having a spiral configuration;

FIG. **26** is a top plan view of an access device having a spiral slit and axial channel;

FIG. **27** is a side elevation view of an embodiment having a spiral slit and a septum seal;

FIG. **28** is an axial cross section view of a further embodiment including a superelastic conical seal and a flexible base with annular spoke-like cams;

FIG. **29** is an axial cross section view taken along lines **29-29** of FIG. **22**;

FIG. **30** is an axial cross section view taken along lines **30-30** of FIG. **22**;

FIG. **31** is an axial cross section view similar to FIG. **28** and illustrating an embodiment including flappers;

FIG. **32** is a perspective exploded view of a further embodiment including a gel cap, a base, and a retraction sheath;

FIG. **33** is a top plan view of the gel cap of FIG. **32**;

FIG. **34** is an axial cross section view taken along lines **34-34** of FIG. **33**;

FIG. **35** is a top plan view of the base illustrated in FIG. **32**;

FIG. **36** is an axial cross section view taken along lines **36-36** of FIG. **35**;

FIG. **37** is a side elevation view of the retraction sheath illustrated in FIG. **32**;

FIG. **38** is a side elevation view of a further embodiment of the retraction sheath;

FIGS. **39-42** illustrate progressive steps in a preferred method of use associated with the embodiment of FIG. **32**;

FIG. **39** is a top plan view showing use of a template;

FIG. **40** is a top plan view of showing placement of the retraction sheath;

FIG. **41** is a top plan view showing placement of the base ring and securement of the traction sheath; and

FIG. **42** is an axial cross section view partially in section showing placement of the gel cap relative to the base.

DESCRIPTION OF PREFERRED EMBODIMENTS AND BEST MODE OF THE INVENTION

A patient is illustrated in FIG. **1** and designated generally by the reference numeral **10**. The patient **10** is shown in a prone position on an operating table **12**, where abdominal surgery is being performed by a surgeon **14** having an arm **16** and a hand **17**. 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**

Although the specific focus of this disclosure will be on a preferred laparoscopic procedure, it will be noted that laparoscopic surgery is merely representative of a type of operation wherein a procedure can be performed in a body cavity with minimal access through a body wall.

Notwithstanding the foregoing generality, it is important to note that with respect to laparoscopic surgery, it is often desirable that the surgeon **14** be able to insert his/her hand **17** through the abdominal wall **21** and into the abdominal cavity **18**. This insertion of the hand **17** provides the surgeon **14** with direct access to various elements of the anatomy

In order to accommodate the hand **17** and arm **16** of the surgeon **14**, 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 of the surgeon **14**.

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 **29**, scope **30** and hand **27**.

Thus, the trocars **23** and **25** have typically been provided with complex valve structures, including, for each narrow range of instrument sizes, an instrument valve which forms an instrument seal in the presence of an instrument, and a zero valve which forms a zero seal in the absence of an instrument. By providing both an instrument seal and a zero seal the valve structures have been able to inhibit the escape of gases through the trocars both in the presence and the absence of an instrument, respectively.

The instrument seals have been particularly cumbersome, as noted, and have only been effective for a small range of instrument diameters. For example, separate instrument seals have been needed for instruments, such as guidewires, which may have a diameter of only two French to three French. For medium-sized instruments having diameters of three millimeter to five millimeters, a second instrument seal has been required. In some cases, even a third instrument seal has been necessary in order to accommodate instruments having diameters such as nine millimeters to 12 millimeters.

Typically the varying sizes of instruments have also required individual zero seals for each range. Thus, in a complex trocar, such as the trocar **23**, there might be as many as six separate seals associated with the access device.

If not for the desire to maintain the pneumoperitoneum, there would be no need for the trocars **23**, **25** or the access device **34**. 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 incisions. 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 **14**. Thus it is a primary purpose of the access device **34** to form with the incision **32** an access or working channel **34**, and to provide a valve or other sealing structure across the working channel **34** in order to maintain the pneumoperitoneum.

An enlarged view of one embodiment of the access device **34** is illustrated in FIG. **2** which also shows the abdominal wall **21** and the incision **32**. In this simple form, the access device **34** has the general configuration of a pad **35**, meaning that it is generally flat and disposed in a plane such as the plane **38**. Typically parallel to this plane **38** are a pair of major surfaces of **41** and **43** which provide the pad **35** with a substantial surface area. An opening or slit **45** can be formed through the pad **35**, generally along an axis **47** perpendicular to the plane **38**.

When operatively disposed, the opening **45** of the pad **35** is in communication with the incision **32** and, in this case, forms with the incision **32**, the working channel **36**. The alignment of the opening **45** and incision **32** can occur with the pad **35** disposed exteriorly of the abdominal wall as illustrated in FIG. **2**, interiorly of the abdominal wall is **21** as illustrated in FIG. **3**, or within the abdominal wall **21** as illustrated in FIG. **4**. In any of these positions, operative disposition of the pad **35** relative to the abdominal wall **21** requires that the pad **35** be maintained in its operative position and that it form a seal around the incision **32**. Referring to the plan view of FIG. **5**, these two functions are accomplished with an adhesive **50** disposed around the incision **32** between the pad **35** and the abdominal wall **21**.

If this adhesive **50** is formed as a continuous ring **52**, as illustrated in FIG. **5**, the pad **35** can be disposed with the ring **52** positioned circumferentially around the incision **32** to form a seal between the pad **35** and the abdominal wall **21**. In the illustrated example, when the pad **35** is operatively positioned, the escape of insufflation gases is inhibited between the pad **35** and the abdominal wall **21** by the adhesive ring **52**.

The escape of insufflation gases is inhibited through the opening **45** of the pad **35** by the self-sealing characteristics of the material forming the pad **35**. This material and its highly advantageous properties are discussed in significant detail below.

It will be appreciated that the functions of the adhesive ring **52** can be accomplished in many different ways using many different materials and shapes. For example, many materials other than adhesives can be used to maintain the pad **35** in position over the incision **32**. The formation of a seal around the incision **32** can also be accomplished with methods other than adhesion. Furthermore, the shape of the continuous seal formed by the adhesive **50** need not be in the shape of a circle. Rather, any continuous pattern sufficiently large to form a perimeter around the incision **32** could facilitate the desired sealing relationship. Finally, it will be noted that the mere placement of the pad **35**, for example, interiorly of the abdominal wall **21** as illustrated in FIG. **3**, may produce a perimeter seal merely as a result of the insufflation pressure.

A further embodiment of the access device **34** is illustrated in FIG. **6** where elements of structure similar to those previously disclosed or designated with the same reference numeral followed by the lower case "a." In this embodiment, the functions of position-maintenance and sealing are accomplished with an alternative configuration for the access device itself. The pad **35** in this case is disposed within the incision **32** as illustrated in FIG. **4**. However, an external flange **54** and an internal flange **56** are formed integral with the pad **35**. As shown, for example, in the axial cross section view of FIG. **8**, the access pad with flanges is formed monolithically.

When operatively disposed, the external flange **54** is positioned outside of the abdominal wall **21** while the internal flange **56** is disposed interiorly of the abdominal wall **21***a*. In this matter, the pad **35** can be disposed within the incision **32***a* and held in position by the flanges **54**, **56**. When the hand **17** of the surgeon **14** is inserted through the access device **34**, the exterior flange **54** prevents the pad **35***a* from moving distally. Similarly, when the hand **17** of the surgeon **14** is withdrawn, the interior flange **56** prevents the pad **35***a* from moving proximally

In this embodiment, the opening **45***a* extends through the pad **35***a* as well as the flanges **54** and **56**, and completely defines the working channel **34** through the incision **32**.

The primary seal which is required between the access device **34***a* and the abdominal wall **21**, can be formed with the adhesive ring **52***a* as discussed with reference to FIG. **6**. Alternatively, this embodiment including the interior flange **56** may rely merely upon the surface contact between the flange **56***a* and the abdominal wall **21**. In this case, the primary seal can be formed between these structural elements and enhanced by the pneumoperitoneum pressure which forces the interior flange **56** against the abdominal wall as illustrated by a plurality of arrows **58**. This seal is formed primarily in a radial plan generally perpendicular to the axis **47**.

The function of the primary seal may be further enhanced by additional sealing which occurs between the pad **35***a* and the portions of the abdominal wall **21** forming the incision **32**. In this location, the abdominal wall **21** is radially compressed by the mere presence of the pad **35** within the incision **32**. The resulting pressure produces an axial seal between the pad **35***a* and the abdominal wall **21**.

If the adhesive ring **52***a* is desired for this embodiment, it is most advantageously placed around the incision **32**, between the exterior flange **54** and the abdominal wall **21**.

It will be noted that whenever an instrument, such as the arm **16** or hand **17** of the surgeon **14**, is inserted through the pad **35**, the material of the pad conforms to the surface of the instrument and forms the instrument seal with the instrument. Accordingly, during the entire period beginning with insertion of the instrument and ending with withdrawal of the instrument, there is substantially no loss of insufflation gas through the pad **35***a* nor any loss of pneumoperitoneum within the abdominal cavity **18**.

With further reference to FIG. **7**, it will be appreciated that the arm **16** and hand **17** of the surgeon **14** are merely examples of instruments which can be inserted through the access device **34***a*. In the absence of the instrument, or hand **17** in the case of FIG. **7**, the opening or slit **45***a* merely closes against itself to form a zero seal, thus preventing the escape of insufflation gases through the access device **34***a*. When the instrument, such as the hand **17**, is inserted through the opening or slit **45***a*, an instrument seal is formed between the material of the access device **34***a* and the exterior surface of the instrument. This prevents the escape of insufflation gases through the access device **34***a*, even when an instrument is present.

Thus, insufflation pressures can be maintained within the abdominal cavity **18** whether or not the instrument is in place. Note that these seals, the zero seal and the abdominal seal, can be formed as a single valve structure having properties for accommodating a full range of instrument sizes.

Formation of the pad **35***a* will typically be accomplished in a simple molding process described in greater detail below. In such a process, the opening or slit **45***a* may be formed as part of the molding process.

In most cases, the single access opening **45***a* will be sufficient to accommodate the operative procedure. However, a further advantage of the access device **34***a* will be particularly appreciated by the surgeon **14** who requires even more access through the pad **35***a*. Consider for example, the surgeon **14** having his/her arm **16** inserted through the opening **45***a* when he/she decides that a further instrument is required for the operative procedure. Under these circumstances, a further opening through the pad **35***a* can be established by merely inserting the desired operative instrument through the pad **35***a*. In this manner, the instrument can create its own access hole beside the primary opening **45***a*.

Particularly for those operative instruments having pointed distal ends, the instrument can merely be forced through the pad **35***a* forming its own access hole, such as the opening **45***a*, as it is moved distally. This opening, created by the operative instrument itself, would automatically form an instrument seal as the instrument is inserted, as well as a zero seal as the instrument is withdrawn.

For operative instruments not having pointed distal ends, it is possible to form a new access hole using a secondary instrument, such as a trocar obturator. After the access hole is formed, the obturator can be removed, vacating the access hole to receive the operative instrument. Throughout this process of initially forming an access hole and ultimately inserting an operative instrument through the hole, both zero seals and instrument seals are formed to maintain the pneumoperitoneum.

With the advantages associated with 1) the formation of an instrument seal and a zero seal with a single valve accommodating a wide range of diameters, and 2) the formation of an instrument opening using the instrument itself, it will be appreciated that the concept of this invention will typically be embodied with a structure that is particularly dependent upon the material which forms the access device **34**. In a preferred embodiment, the pad **35** is formed of a KRATON/oil mixture including a KRATON Tri-block with a Styrene-Ethylene/Butylene-Styrene (S-E/B-S) structure in combination with a mineral oil. Other tri-block polymers can be used for this application such as Styrene-Isoprene-Styrene, (S-I-S), Styrene-Butadiene-Styrene (S-B-S), Styrene-Ethylene/Propylene-Styrene (S-E/P-S) manufactured under the trademark SEPTON by the Kuraray Co. These general formulas can be further distinguished by the ratio of the styrene to rubber content: for example, Grade 1650 is a S-E/B-S tri-block with a 29/71 styrene to rubber ratio.

In addition to tri-blocks there are also di-block versions of these materials where styrene is present at only one end of the formula, for example, Styrene-Ethylene/Butylene (S-E/B) di-block.

The various base formulas may also be alloyed with one another to achieve a variety of intermediate properties. For example KRATON G1701X is a 70% S-E/B 30% S-E/B-S mixture with an overall Styrene to rubber ratio of 28/72. It can be appreciated that an almost infinite number of combinations, alloys, and Styrene to rubber ratios can be formulated, each capable of providing advantages to a particular embodiment of the invention. These advantages will typically include low durometer, high elongation, and good tear strength.

It is contemplated that the material of the pad **35** may also include silicone, soft urethanes and even harder plastics which might provide the desired sealing qualities with the addition of a foaming agent. The silicone materials can be of the types currently used for electronic encapsulation. The harder plastics may include PVC, Isoprene, KRATON neat, and other KRATON/oil mixtures. In the KRATON/oil mixture, for example, oils such as vegetable oils, petroleum oils and silicone oils might be substituted for the mineral oil. In the broadest sense, all of these mixtures can be described generally as a gel. The gel will typically have properties including an ability to "flow" which approaches that of a fluid. Particularly in the vicinity of any opening or slit **45** extending through the access device **34**, propagation of the opening may be of concern. Stresses resulting from the presence of an instrument will be concentrated at the ends of such an opening or slit. For this reason, a good tear resistance is desired for the gel material. Such a tear resistance is often inherent in the KRATON/oil mixtures and may be enhanced by encapsulating the gel in other materials. For example, a low tear resistant gel could be encapsulated in a urethane sheath to improve the tear resistant qualities of the resulting products. Such a sheath need not be elastic but could be comprised, for example, of overlapping sheets of a non-elastic material.

Any of the gel materials contemplated could be modified to achieve different properties such as enhanced lubricity, appearance, and wound protection, or to provide anti-cancer or anti-microbial activity. Additives can be incorporated directly into the gel, for example in the case of pharmaceuticals, or applied as a surface treatment to the gel, for example, to improve lubricity or appearance. Other compounds could be added to the gel to modify its physical properties or to assist in subsequent modification of the surface by providing bonding sites or a surface charge. Antioxidants and antirads can be added to the mixture to extend the shelf life of the finished product or increase its ability to withstand radiation sterilization.

Sealing materials used in medical access devices of the past have been chosen primarily for their durometer and elongation. It is these properties which measure the ability of the material to move into small spaces and crevices as may be required to form an instrument seal across the working channel of a trocar. For example, in the past, a silicone mixture was used in medical valves. This mixture had the following properties: an ultimate elongation less than about 1000 percent and a durometer not less than about 5 Shore A.

These properties of the prior art materials are far exceeded by the properties associated with the present invention which in some respects provide a full magnitude of advantage. In fact, the difference between the materials of the prior art and the materials of the present invention are sufficiently substantial, that it is perhaps misleading to refer to the present material as merely a gel. According, the material of the present invention, having properties including an ultimate elongation greater than about 1000 percent and a durometer less than about 5 Shore A, will be referred to herein as an "ultragel."

In a preferred embodiment of the present invention, the ultragel includes KRATON and mineral oil and provides a sealing material with the following properties: an ultimate elongation exceeding about 1500 percent, and a durometer of less than about 200 Bloom. The durometer in this case is considerably lower than that of the prior art materials. In fact, the durometer of the present material is so soft it cannot even be measured on the Shore A scale.

The resulting elongation and durometer of the present material facilitates its use with as an access valve which is capable of forming seals with a full range of instrument sizes, but is also capable of functioning as a zero seal. Whereas access devices of the prior art may have required as many as six separate seals in order to accommodate a full range of instrument sizes, access devices can now be made with only a single valve formed of the ultragel material.

In a typical manufacturing process, the KRATON G1651 is mixed with the mineral oil in a ratio by weight of 1 to 9. In order to manufacture this material, the combination is heated to a temperature of about 200° centigrade. In a preferred method of manufacturing, the mold is provided with a circumferential ring insert which is molded into the gel, and slit inserts which can be removed from the gel to form the opening or slit **45**. The resulting gel can be coated with cornstarch to reduce tack and cooled at room temperature.

Many of the properties of the KRATON/oil mixture will vary with adjustments in the weight ratio of the components. In general, the greater the percentage of mineral oil, the more fluid the mixture; the greater the percentage of KRATON, the more rigid the material. Weight ratios of KRATON to oil as low as 1 to 5 have been contemplated for a more rigid structure. As the KRATON/oil weight ratio approaches 1 to 10, the mixture becomes more liquid. Ratios as high as 1 to 15 have been contemplated for this invention.

The processing temperature can also vary considerably as it is primarily dependent on the type of KRATON used. Temperatures in a range of about 150° centigrade to about 250° centigrade have been contemplated.

With an appreciation that these ratios and temperatures can develop considerably different properties, it is now apparent that these materials can be layered to provide generally different properties within each layer. For example, an outer layer might be formed of a KRATON/oil mixture having more rigid properties, thereby providing the pad **35** with an outer layer that is more rigid. After that layer is at least partially cured, another layer of the material can be poured inside of the outer layer. This second layer might be softer providing the pad **35** with the significant sealing properties. It has been found that successive layers will tend to fuse slightly at their interface, but will generally maintain their separate identities. Additional layers could be added to provide a progression of properties in a particular device.

Having discussed the properties desirable for the gel material, and the process of manufacture, one can now address the other embodiments of the concept which may provide additional advantages for particular surgical procedures. An embodiment of the access device **34**, shown in its operative position in FIG. **6**, is illustrated by itself in the axial cross section view of FIG. **8**, wherein the access seal with flanges is formed monolithically.

This same embodiment can be reinforced with o-rings **61** and **63** as illustrated in FIG. **9** where elements of structure are designated by the same reference number followed by the lower case letter "b." Providing these o-rings **61** and **63** may facilitate several functions associated with the access device **34***b*. For example, the rings **61**, **63** will typically aid in maintaining a radial sealing pressure on all sides of the opening **45***b*. The rings **61** and **63** will also tend to maintain the flanges **54***b* and **56***b* respectively, in their generally planar configurations. This further ensures that the flanges **54**, **56** will not collapse into the incision **32** with the insertion or withdrawal of an instrument, such as the surgeon's hand **17**. Of course, the o-rings **61** and **63** must be sufficiently large to accommodate the instrument during insertion and removal.

A further embodiment of the invention is illustrated in FIG. **10**, where elements of structure are similar to those previously disclosed are designated with the same reference numerals followed by the lower case letter "c." This embodiment includes the pad **35***c* with the opening or slit **45***c*. The external perimeter o-ring **61***c* is inserted molded into the circumference of the pad **35***c*. The internal o-ring **63***c* is coupled to the pad **35***c*, for example, by way of attachment to the o-ring **61***c* for example, by a membrane **65**. In this case, the membrane **65** has a generally cylindrical configuration and elastomeric properties. In preferred embodiments, the membrane **65** is formed of urethane, neoprene or isoprene.

When the embodiment of FIG. **10** is being operatively positioned, the internal o-ring **63***b* is initially gathered and inserted through the incision **32** (FIG. **2**). The pad **35***c* and external o-ring **61***c* are left outside the incision **32** so that the only material extending across the incision **32** is the membrane **65**. It will be noted that in this case, the working channel **36***c* is formed by the slit **45***c*, the cylindrical membrane **65**, and the internal o-ring **63***c*.

In this particular embodiment, the pad **35***c* functions generally as described with reference to FIG. **2**. The primary seal between the pad **35***c* and the abdominal wall **21** can be formed either with a circumferential ring, such as the adhesive ring **52***c*, or by relying on the sealing characteristics of the insufflation gas **58***c* against the internal o-ring **63***c* and membrane **65**.

This embodiment of FIG. **10** is of particular advantage as it incorporates the pad **35***c* in perhaps its simplest configuration, while providing a primary seal between the device **34***c* and the abdominal wall **21** which is facilitated by the insufflation pressure. Furthermore, the membrane **65** enhances the sealing characteristics of the device **34***c*, and provides a lining for the incision **32**. With the membrane **65**, the incision **32** need not be stretched to a diameter greater than that required by any instrument inserted through the working channel **36***c*.

A further embodiment of the invention is illustrated in FIG. **11** where elements of structure similar to those previously disclosed are designated with the same reference numeral followed by the lower case letter "d." This embodiment is similar to that of FIG. **8** in that it includes the pad **35***b*, slit **45***d*, exterior flange **54***d*, and internal flange **56***d*. The embodiment of FIG. **11** differs from that of FIG. **8** in that it includes a lead-in cavity **70** which is in communication with the slit **45***d*.

In a preferred embodiment, this cavity **70** is sized and configured to receive the arm **16** of the surgeon **14** in a manner illustrated in FIG. **7**. In this case, the slit **45***d* would function primarily to maintain a zero seal, while the portions of the pad **35***d* or flange **54***d* which form the cavity **70** would function primarily to form the instrument seal.

A further embodiment of the invention is illustrated in the plan view of FIG. **12** and the cross section views of FIGS. **13** and **14**. In this embodiment, elements of structure similar to those previously discussed are designated with the same reference numeral followed by the lower case letter "e." In this case, the lead-in cavity has the general shape of a cylinder **72** with an axis that is collinear with the axis **47***e* of the pad **35***e*.

As perhaps best illustrated in FIG. **13**, the slit **45***e* has a trapezoidal configuration. Thus, it begins proximally with a narrow length which may generally be equivalent to the diameter of the cylinder **32**. From the cavity **70***e*, the length of the slit **45***e* increases with progressive positions distally through the pad **35***e*. In the illustrated embodiment, the trapezoidal slit **45***e* is formed as the frustum of an isosceles triangle.

A further embodiment of the invention is illustrated in FIGS. **15** and **16** wherein elements of structure similar to those previously described are designated with the same ref-

erence numeral followed by the lower case letter "f." As previously discussed with reference to FIG. **12**, this embodiment of the pad **35***f* is formed with a proximal surface **71** and a distal surface **73**. The pad **35***f* also includes the coaxial lead-in cylinder **72***f* and the trapezoidal slit **45***f*. However, in this case, a duck-bill valve **74** is provided to further enhance the characteristics of the zero zeal. As illustrated, the working channel **36***f* is formed by the lead-in cavity **70***f*, the slit **45***f*, and an extension of the slit **45***f* which is defined by the duck-bill valve **74***f*.

The duck-bill valve **72** can be formed with opposing flanges **76** and **78** which extend distally of the distal surface **73**. When operatively disposed, the pad **35***f* can be positioned with its distal surface **73** against the exterior surface of the abdominal wall **21** (FIG. **2**) and with the flanges **76** and **78** extending into the incision **32**. With this configuration and operative disposition, the abdominal wall **21** at the incision **32** will produce opposing forces on the flanges **76** and **78** which tend to close the slit **45***f*, particularly in the absence of an instrument. In this manner, the duck-bill valve **74** can be relied on to enhance the characteristics of the zero seal.

A further embodiment of the invention is illustrated in FIGS. **17** and **18** wherein elements of structure similar to those previously discussed are designated by the same reference numeral followed by the lower case letter "g." In this embodiment of the access device **34***g*, the pad **35***g* can be formed generally as discussed with reference to FIG. **13**. In this embodiment, however, the pad **35***g* can be enclosed along its sides and the distal surface **73***g*, by a base **81**. In this case, the pad **35***g* might be formed by the highly elastic material previously discussed, while the base **81** might be formed of a more rigid but nevertheless flexible material such as a urethane. With this configuration, the duck-bill valve **74***f* would be structured to extend distally of a distal surface **83** associated with the base **81**. This would enable the duck-bill valve **74***f* to be formed of the base material rather than the super-elastic material. This might also improve the zero seal characteristics for particular operative applications.

Another simplified form of the invention is illustrated in FIGS. **19** and **20**, where elements of structure similar to those previously discussed or designated with the same reference numeral followed by the lower case letter "h." The lead-in cavity **78***h*, in this case, is formed as an inverted cone **77** having its base at the proximal surface **71***h* and its apex in proximity to the distal surface **73***h*. Thus, the lead-in cavity **70***h* has an area in radial cross section which decreases with progressive positions distally through the pad **35***h*. In this embodiment, the proximal regions near the base of the cone **87** form the instrument seal, while the distal regions at the apex of the cone form the zero seal. The conical configuration of the lead-in cavity **70***h* also tends to funnel an instrument into the opening **45***h* leading distally to the apex of the cone **87**.

It will be appreciated generally, that the slit **45** and lead-in cavity **70** can be provided with many different individual and cooperative configurations. By way of example, perhaps the simplest form for the pad **35** is illustrated in the embodiment of FIGS. **21** and **22** wherein elements of structure similar to those previously described are designated by the same reference numeral followed by the lower case letter "j." In this embodiment, the pad **35***j* with its proximal surface **71***j* and distal surface **73***j*, is provided with a simple trapezoidal slit **45***j*. In this case, the slit **45***j* extends between the proximal surface **71***j* and the distal surface **73***j*.

The slit **45***j* in this embodiment of FIG. **21** is typical of many structures which will define the slit **45***j* with a planar configuration. In such a case, the portions of the pad **35***j* which form the slit will comprise opposing planar surfaces such as those designated by the reference numerals **90** and **92** in FIG. **22**.

It will be apparent that the slit **45** need not be formed by opposing surfaces having a planar configuration. Nevertheless, these opposing surfaces need to be capable of coming into sealing contact with each other in order to establish the zero seal. Other slit configurations capable of accomplishing this function, may offer further advantages in particular procedures. Other examples of slit configurations are illustrated merely by way of example in FIGS. **23-26**.

The embodiment of FIG. **23** is similar to that of FIG. **22** in that the opening **45***j* comprises a single slit which extends from the proximal surface **71***j* to the distal surface **73***j*. In the case of the FIG. **22** embodiment, the axis **47***j* is disposed within the plane of the slit **45***j*. In the case of the FIG. **23** embodiment, the plane of the slit **45***j* does not include the axis **47***j*. Rather, the slit **45***j* is formed in a plane which has an angular relationship with the axis **47***j*, the proximal surface **71***j*, as well as the distal surface **73***j*. This construction enables the slit **45***j* to have a length greater than the thickness of the pad **35***j*.

In the embodiment of FIG. **24**, elements of structure similar to those previously discussed are designated with the same reference numeral followed by the lower case letter "k." In this case, the opening **45***k* is configured as two slits **94** and **96** formed in individual planes that are angularly spaced with respect to each other. Of course, two or more of the planar slits **94** and **96** may be equally angularly spaced around the axis **47***k*. In one embodiment, the individual planar slits **94** and **96** intersect at the axis **47***k*. Alternatively, the slits **94** and **96** may be axially spaced in order to facilitate formation of the instrument seal.

In the embodiment of FIG. **25**, elements of structure similar to those previously discussed are designated with the same reference numeral followed by the lower case letter "m." In this embodiment, the opening **45***m* is defined as a slit **98** having a curved rather than planar configuration. In the illustrated embodiment, the curved slit **98** is formed as a spiral around the axis **47***m*. Along the axis **47***m*, the opposing surfaces forming the spiral slit **98** can "flow" into sealing proximity in order to produce the zero seal.

FIG. **26** illustrates a similar embodiment including a spiral slit. In this figure, elements of structure similar to those previously discussed are designated by the same reference numeral followed by the lower case letter "n." The spiral slit **98***n* in this embodiment is also formed around the axis **47***n* of the pad **35***n*, but in this case the portions forming the slit **98***n* do not extend completely to the axis **47***n*. As a result, an axial channel **100** is formed at least partially along the axis **47***n*. This channel **100** can function in a manner similar to the lead-in cavity **70** discussed with reference to FIGS. **11-12**. This channel **100** can even be formed with a conical configuration similar to that discussed with reference to FIG. **19**.

In an embodiment where the channel **100** is left open, a zero seal might be provided by positioning a septum valve across the channel **100**. Such an embodiment is illustrated in FIG. **27**, wherein the septum valve is designated with a reference numeral **101** and the other elements of structure similar to those previously discussed are designated with the same reference numerals followed by the lower case letter "p." Thus the embodiment of FIG. **27** includes the spiral slit **98***p*, the pad **35***p*, and the axis **47***p*. This embodiment of FIG. **27** is merely representative of many other embodiments that will combine a slit, such as the slit **98***p*, with other valve structures, such as the septum valve **101**.

Other curved slit configurations would include embodiments wherein the slit is curved, sinusoidal, or S-shaped in a side elevation view. Such configurations provide a slit part having a length greater than the thickness of the pad. Normally, the more circuitous the slit path, the better the sealing characteristics.

A further and more complex configuration for the opening **45** is illustrated in the embodiment of FIG. **28** wherein elements of structure similar to those previously disclosed are designated with the same reference numeral followed by the lower case letter "q." This embodiment is representative of many other complex embodiments which can be formed with intricate shapes and different materials in order to accomplish the desirable function of forming, with a single valve, a zero seal as well as an instrument capable of accommodating a full range of instrument sizes. In the embodiment of FIG. **28**, the pad **35***q* is formed with a base **110** which is disposed circumferentially of a core **112**. In this case, the core **112** is formed of the superelastic material or gel and provided with the shape of the cone **87***q* as discussed with reference to FIGS. **19** and **20**. The base **110** is formed from a material that may not be elastic, but preferably is flexible. In the preferred embodiment, the base **110** is formed of a urethane.

In this construction, the base **110** is provided with a plurality of spokes **114** each of which extends radially inwardly from a base **116** to a tip **118**. The core **112** extends from the axis **47***q* outwardly to the tips **118** of the spokes **114**. In the illustrated embodiment, the core **112** has fingers **121** which extend beyond the tips **118** and toward the bases **116** between each adjacent pair of the spokes **114**. These fingers **121** extend radially outwardly to an end surface **123** which stops short of the base **116** leaving a void **125** therebetween.

The voids **125** are of particular interest to this embodiment and can be incorporated into any of the embodiments previously discussed. Such voids **125** provide a space or absence of material into which the highly elastic material, such as that of the fingers **121**, can expand during insertion of an instrument such as the arm **16** (FIG. **7**). Since the gel material is almost fluid in its properties, the voids **125** permit expansion of the gel with very little resistance. Voids, such as the voids **125** in the embodiment of FIG. **28**, can be defined solely in the gel material or between the gel material and any other base material.

In the case of FIG. **28**, the spokes **114** and fingers **121** are defined generally in planes which are parallel to the axis **47***q*. Similar fingers, illustrated in the embodiment of FIG. **31** are defined generally in a plane which is perpendicular to the axis. In this embodiment, elements of structure similar to those previously disclosed are designated by the same reference numeral followed by the lower case letter "r." As illustrated, the pad **35***r* can be formed with a relatively large opening **45***r* having the configuration of a coaxial cylinder **130**. A plurality of fingers or flaps **132** extend into the opening **45***r* and tend to form a lead-in cavity **70***r* with properties such as those discussed with reference to FIG. **19**. In this case, the annular flaps **132** have a conical configuration extending from a base **134** to an apex **136**. It will be noted that the areas between the flaps **132**, form voids **125***r* into which the flaps **132** can be displaced upon insertion of an instrument, such as the arm **16**.

A further embodiment of the invention is illustrated in FIG. **32** where elements of structure similar to those previously disclosed are designated with the same reference numeral followed by the lower case letter "s." This exploded view of the access device **34***s* includes not only the pad **35***s* but also a complimentary structure for maintaining the position of the pad **35***s*, for forming a seal between the pad **35***s* and the abdominal wall **21**, and for dilating the incision **32** to a variable extent as required by the surgeon **14**. In this case, the access device **34***s* includes three components, a gel cap **143**, base **145**, and a retraction sheath **147**.

The gel cap **143** includes not only the gel pad **35***s*, but also a circumferential cap ring **154** which can be inserted and molded to the pad **35***s*. The resulting gel cap **143** forms a seal with the base **145**, thereby defining the working channel **36***s* through the pad **35***s*, the cap ring **154**, the base **145**, and the retraction sheath **147**. In the manner previously discussed, this working channel **36***s* includes the single valve formed by the gel pad **35***s* which provides both a zero seal and an instrument seal for a wide range of instrument diameters.

The structure associated with the gel cap **143** is described in greater detail with reference to FIGS. **33** and **34**. In the plan view of FIG. **33**, it can be seen that this embodiment includes the gel pad **35***s* centrally disposed within the circumferential cap ring **154**. Holding tabs **156** can be provided to extend radially outwardly of the cap ring **154**. These holding tabs **156** can facilitate the sealing engagement of the gel cap **143** with the base **145** in the manner described in greater detail below.

The gel pad **35***s* can be formed of any of the materials previously discussed although the preferred embodiment includes the KRATON/mineral oil gel. The cap ring **154** for such an embodiment can be advantageously formed of KRATON only. This will make the cap ring **154** more rigid than the gel pad **35***s* while maintaining an excellent material interface between the pad **35***s* and the ring **154**. In a typical manufacturing operation, the cap ring will be pre-disposed in the mold for the gel pad **35***s* with the unitary structure of the gel cap **143** resulting.

The cross section view of FIG. **34** shows the gel cap **143***s* and illustrates an annular void **158** formed on the inner circumference of the cap ring **154**. This void **158** is of particular advantage in forming a sealing relationship with the base **145** in the manner discussed in greater detail below.

The base **145** of this embodiment is shown in greater detail in the plan and cross section of views of FIGS. **34** and **35**, respectively. From these views it will be noted that the base **145** can be provided with a smooth generally cylindrical inner surface **161** which extends proximally to a rounded end surface **163** and outwardly from the end surface **163** along an annular lip **165**. A plurality of tabs **167** can be equally spaced to extend outwardly and distally around the circumference of the lip **165**.

Distally of the inner surface **163**, an annular flange **170** can be provided with an annular projection **172** sized and configured to form the desired sealing relationship between the gel cap **143** and the base **145**. The process of molding the base **145** can be facilitated by forming the base as two separate components divided, for example, by a dotted line **174** in FIG. **35**. In a preferred embodiment, the base **145** is molded from a polycarbonate material.

A preferred embodiment of the retracting sheath **147** is illustrated in FIG. **37**. In this view it can be seen that the retraction sheath **147** includes a tubular wall **175** which has the configuration of the frustum of a cone **176** at its distal end and the configuration of a cylinder **177** at its proximal end. A flexible retaining ring **152** terminates the distal end while a fold **154** is formed at the proximal end. The tubular wall **175** is illustrated to include an outer surface **180** and an inner surface **181**. In a preferred embodiment, the sheath **147** is formed of an elastomer, such as neoprene, so its frustule conical and cylindrical configurations exist primarily in the natural unstretched state.

As the sheath **147** is stretched axially, the diameter of the cylindrical proximal end increases thereby placing radial

forces on the incision **32**. The more the sheath **147** is stretched axially, the greater becomes the diameter of the sheath and consequently the larger becomes the opening through the incision **32**. This feature is of particular advantage as it permits the surgeon to define the size of the incision **32** with an appropriate degree of axial tension on the sheath **147**. By maintaining this tension, the preferred size of the incision **132** is maintained throughout the operation. In a preferred apparatus and method, the axial tension is maintained by stretching the sheath **147** over the tabs **167** (FIG. **34**) of the base **145**. Indicia **182** can be printed on the sheath **147** to provide an indication of the relationship between the axial stretch of the sheath **147** and the size of the incision **32**.

The fold **153** is provided to facilitate a grip on the proximal end of the sheath **147**. This fold **153** can also function to provide reinforcement where the walls of the sheath **147** engage the tabs **167** of the base **145**. In the embodiment illustrated in FIG. **38** additional folds **184**, **186** are provided at spaced axial locations, such as those defined by the indicia **182** in FIG. **37**. With these folds **184** and **186**, additional points of reinforcement are provided to engage the tabs **167** while providing the sheath **147** with predetermined degrees of axial stretch associated with different sizes of the incision **32**.

The method of using the embodiment of FIG. **32** is illustrated the progressive use of FIGS. **39-42**. In FIG. **39**, a top plan view of the abdominal wall **21** of the patient **10** is illustrated with a template **195** positioned to facilitate location of the incision **32**. The size of the incision **32** can be determined with the indicia **182** on the template **195** showing, for example, multiple lengths of a line **197**, each length being equated with a glove size for the surgeon's hand **17** (FIG. **7**). Knowing his/her glove size, the surgeon will merely cut the incision in accordance with an appropriate length of the line **197**. The longer lengths of the line **197** are associated with the larger incisions, the larger glove sizes and accordingly the larger hands **17**. After the incision **32** has been cut along the line **197**, the template **195** can be removed.

As illustrated in FIG. **40**, the retraction sheath **147** can then be mounted through the incision **32**. Initially the ring **152** is compressed and fed through the incision **32**. On the inner surface of the abdominal wall **21**, the ring **152** is free to expand to its larger diameter, as shown by a dotted line **158** in FIG. **40**. The portions of the wall **176** which define the cylinder **177** are left to extend proximally through the opening **32** as shown in FIG. **40**.

Prior to or after inserting the sheath **147**, the base **145** can be disposed around the incision **32**. Then the exposed portions of the sheath **147** will extend through the incision **32** and within the circumferential base **145**. As illustrated in FIG. **41**, the wall **176** of the sheath **147** can then be drawn proximally, outwardly of the page in FIG. **41**, to axially stretch the sheath **147**. As noted, when the sheath **147** is axially stretched, it will create radial forces on the abdominal wall **21** which will tend to enlarge the incision **32**. The greater the axial stretch, the larger the incision **32**.

When the incision **32** has the desired size, the stretched sheath **147** can be drawn over the tabs **167** to maintain the axial stretch and the desired size for the incision **32**. Either the indicia **182**, as shown in FIG. **36**, or the additional folds **184** and **186** as shown in FIG. **37**, can be aligned with the tabs **167** to provide a predetermined size for the incision **32**. At this point, the seal between the abdominal wall **21**, the sheath **147**, and the base **145** is fully established.

A final step remaining in this process is the attachment of the gel cap **143** to the base **145**. This is accomplished as illustrated in FIG. **36** by capturing the lip **172** of the base **145** in the annular void **158** of the gel cap **143**. Bending the holding tabs **156** upwardly and outwardly facilitates this engagement which ultimately forms a seal between the base **145** and the gel cap **143**.

Although this invention has been disclosed with reference to certain structural configurations, it will be appreciated that these products are merely representative of many different embodiments of the invention. Accordingly, one is cautioned not to limit the concept only to the disclosed embodiments, but rather encouraged to determine the scope of the invention only with reference to the following claims.

What is claimed is:

1. A surgical access device adapted for performing laparoscopic surgical procedures with at least one instrument passing through the surgical access device and through a single incision in the abdominal wall of a patient with the abdominal cavity pressurized with an insufflation gas, the surgical access device adapted to provide instrument access to the abdominal cavity for surgical procedures while generally maintaining insufflation pressure in the abdominal cavity, the surgical access device comprising:

an access pad, the access pad comprising a material formed of a mixture comprising a triblock copolymer, an oil, and a foaming agent, the access pad adapted to be disposed within an incision within an abdominal wall, the access pad having an external flange and an internal flange integrally formed with the access pad, the external flange adapted to be disposed external to the abdominal wall in an operative position and the internal flange adapted to be disposed internal to the abdominal wall in the operative position, wherein the access pad is configured to be maintained in the operative position and adapted to form a seal with the abdominal wall; and

at least one opening through the access pad between an external surface and an internal surface of the access pad, wherein the opening when operatively disposed is in communication with the incision and forms a working channel between a location external to the abdominal wall and a location internal to the abdominal wall;

wherein the access pad is adapted to conform to a surface of an instrument inserted through the working channel, at least a portion of the access pad between the external flange and the internal flange and within the incision between an external surface of the abdominal wall and an internal surface of the abdominal wall is adapted to form an instrument seal with the instrument, and wherein locating the access pad within the incision creates a radially compressive force to provide an axial seal between the access pad and the abdominal wall, and wherein the access pad with flanges is formed monolithically.

2. The surgical access device of claim **1**, further comprising a plurality of trocars configured for placement through a plurality of openings.

3. The surgical access device of claim **1**, wherein the at least one opening accommodates a range of instrument diameters.

4. The surgical access device of claim **1**, wherein the access pad is adapted for direct contact with the abdominal wall during use.

5. The surgical access device of claim **1**, wherein the access pad is adapted for direct contact with a plurality of instruments during use.

6. The surgical access device of claim **1**, wherein at least a portion of the external surface is curved.

7. The surgical access device of claim **1**, wherein the material is formed of a mixture consisting essentially of a triblock copolymer, an oil, and a foaming agent.

8. The surgical access device of claim 1, wherein the triblock copolymer comprises a Styrene-Ethylene/Butylene-Styrene structure.

9. A surgical access device adapted for performing laparoscopic surgical procedures with multiple instruments passing through the surgical access device and through a single incision in the abdominal wall of a patient with the abdominal cavity pressurized with an insufflation gas, the surgical access device adapted to provide instrument access to the abdominal cavity for surgical procedures while generally maintaining insufflation pressure in the abdominal cavity, the surgical access device comprising:

an access seal, the access seal adapted to be disposed within an incision within an abdominal wall, the access seal having an external flange and an internal flange, the external flange adapted to be disposed external to the abdominal wall in an operative position and the internal flange adapted to be disposed internal to the abdominal wall in the operative position, wherein the access seal is configured to be maintained in the operative position, and wherein the access seal with flanges is formed monolithically; and

a plurality of access channels through the access seal between an external surface and an internal surface of the access seal, wherein the plurality of access channels when operatively disposed span the thickness of the abdominal wall and form working channels between a location external to the abdominal wall and a location internal to the abdominal wall;

the access seal being formed of an elastomeric material adapted to conform to a surface of an instrument inserted through the working channel to form an instrument seal along a length spanning the thickness of the abdominal wall and the elastomeric material in the operative position is adapted to form an abdominal seal within the abdominal wall.

10. The surgical access device of claim 9, wherein the access seal is adapted to maintain a sealing relationship with a plurality of instruments positioned through the access seal while accommodating relative movement between the plurality of instruments.

11. The surgical access device of claim 9, wherein at least one of the plurality of access channels is configured to self seal in the absence of any instrument extending through the at least one access channel.

12. The surgical access device of claim 9, wherein the elastomeric material is a thermoplastic elastomer.

13. The surgical access device of claim 9, wherein the elastomeric material is formed of a material comprising at least one of a triblock copolymer, a diblock copolymer, an oil, a foam, silicone, a polyurethane, PVC, and isoprene.

14. The surgical access device of claim 9, wherein the elastomeric material is formed of a mixture comprising a triblock copolymer that has a Styrene-Ethylene/Butylene-Styrene structure.

15. The surgical access device of claim 9, wherein the elastomeric material is formed of a mixture comprising a triblock copolymer, an oil, and a foaming agent.

16. The surgical access device of claim 9, wherein the elastomeric material is formed of a mixture consisting essentially of a triblock copolymer, an oil, and a foaming agent.

17. A method of using a surgical access device adapted for performing laparoscopic surgical procedures with at least one instrument passing through the surgical access device and through a single incision in the abdominal wall of a patient with the abdominal cavity pressurized with an insufflation gas, the surgical access device adapted to provide instrument access to the abdominal cavity for surgical procedures while generally maintaining insufflation pressure in the abdominal cavity, the method comprising:

providing an access seal, the access seal having an external flange, an internal flange, and at least one access channel through the access seal between an external surface and an internal surface of the access seal, the access seal being formed of an elastomeric material, and wherein the access seal with flanges is formed monolithically;

disposing the access seal within an incision within an abdominal wall such that the external flange is disposed external to the abdominal wall in an operative position, the internal flange is disposed internal to the abdominal wall in the operative position, and the access channel spans the thickness of the abdominal wall and forms a working channel between a location external to the abdominal wall and a location internal to the abdominal wall in the operative position, wherein locating the access seal within the incision creates a radially compressive force to provide an axial seal between the access seal and the abdominal wall such that the elastomeric material in the operative position forms the axial seal within the abdominal wall; and

inserting at least one instrument through the working channel, wherein at least a portion of the access seal between the external flange and the internal flange and within the incision between an external surface of the abdominal wall and an internal surface of the abdominal wall forms an instrument seal with the instrument, the elastomeric material conforms to a surface of the instrument inserted through the working channel to form the instrument seal along a length spanning the thickness of the abdominal wall.

18. The method of claim 17, wherein the elastomeric material of the access seal is formed of a mixture comprising a triblock copolymer.

* * * * *

EXHIBIT D

US008105234B2

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Ewers et al.

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(54) **SURGICAL ACCESS APPARATUS AND METHOD**

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See application file for complete search history.

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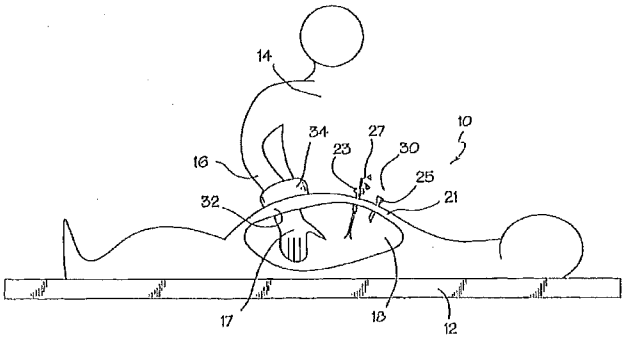
(57) **ABSTRACT**

A surgical access device includes a single valve that forms a seal with the body wall and provides an access channel into a body cavity. The valve has properties for creating a zero seal in the absence of an instrument as well as an instrument seal with instruments having a full range of instrument diameter. The valve can include a gel and preferably an ultragel comprised of an elastomer and an oil providing elongation greater than 1000 percent and durometer less than 5 Shore A. The single valve can be used as a hand port where the instrument comprises the arm of a surgeon, thereby providing hand access into the cavity.

26 Claims, 18 Drawing Sheets



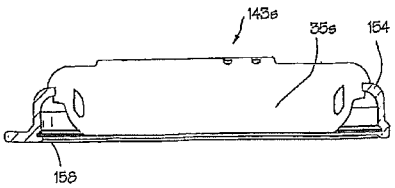


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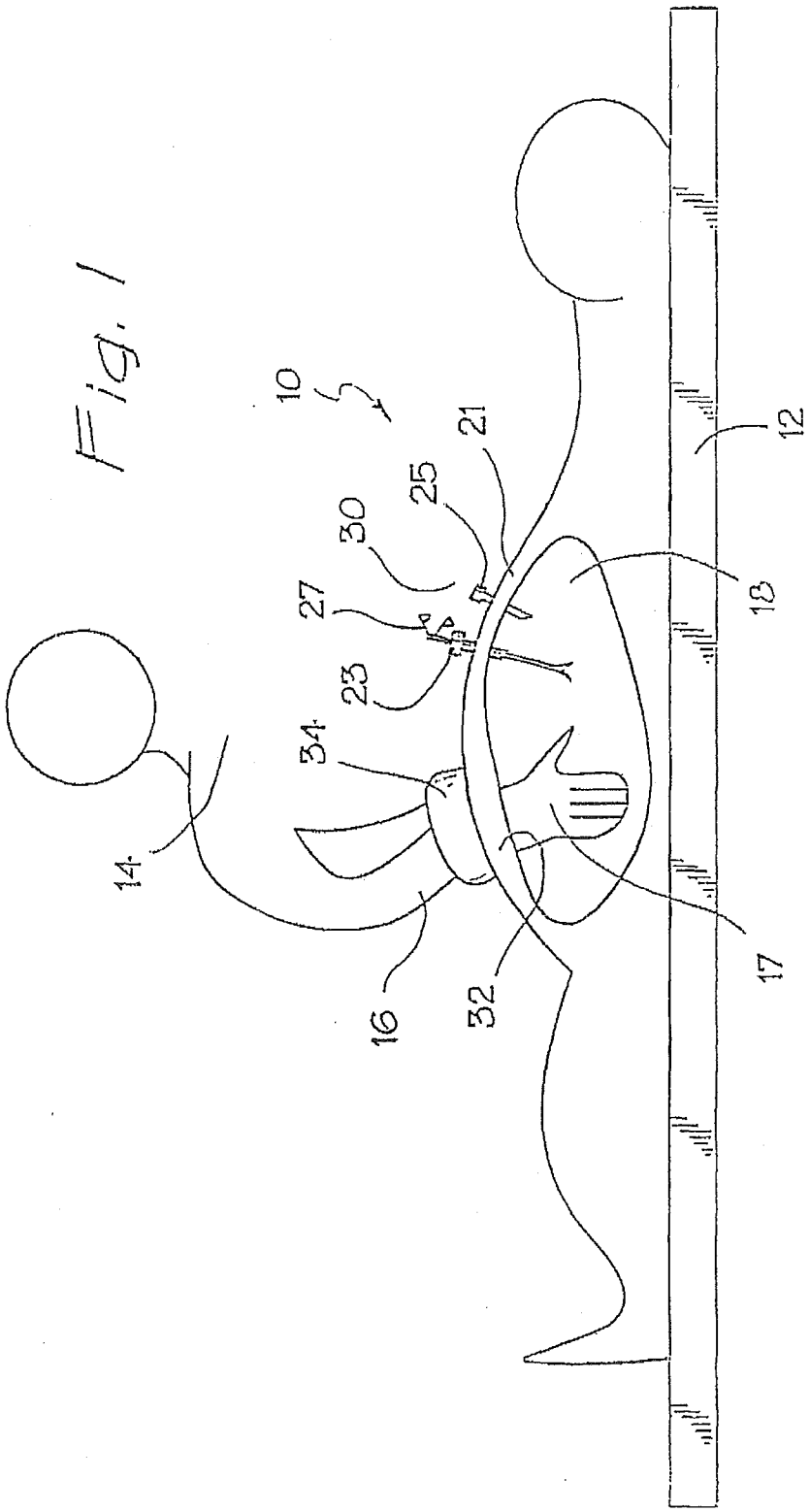
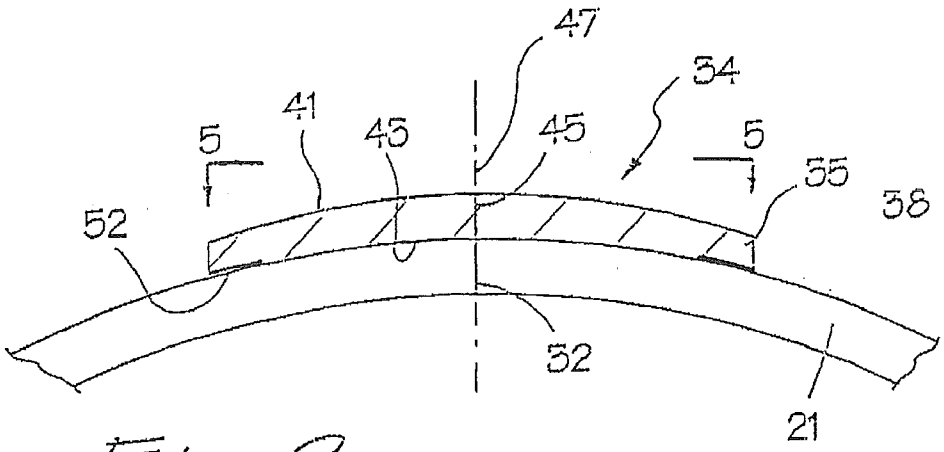
Fig. 1





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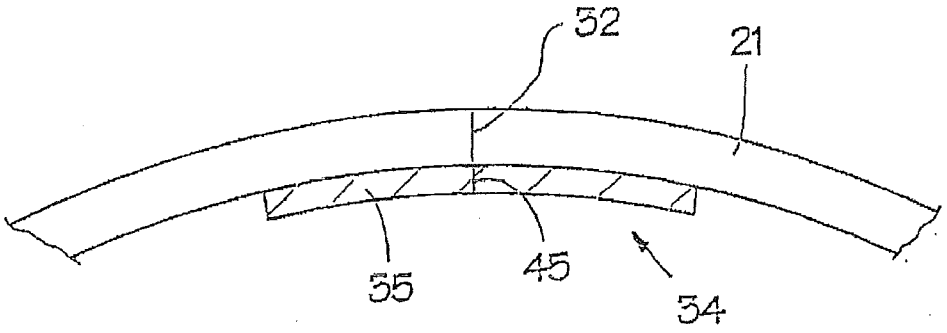


Fig. 3

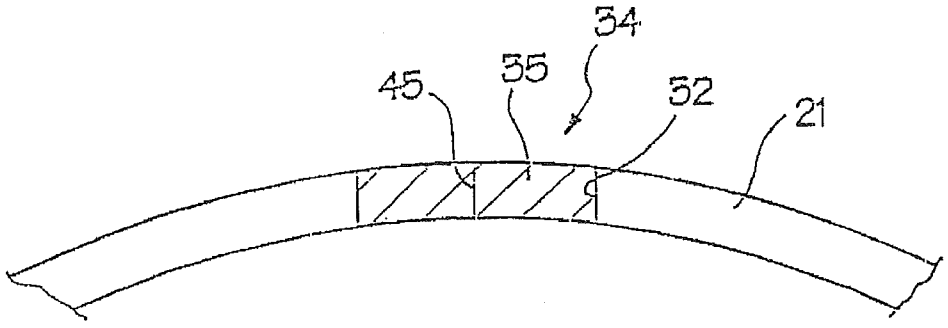
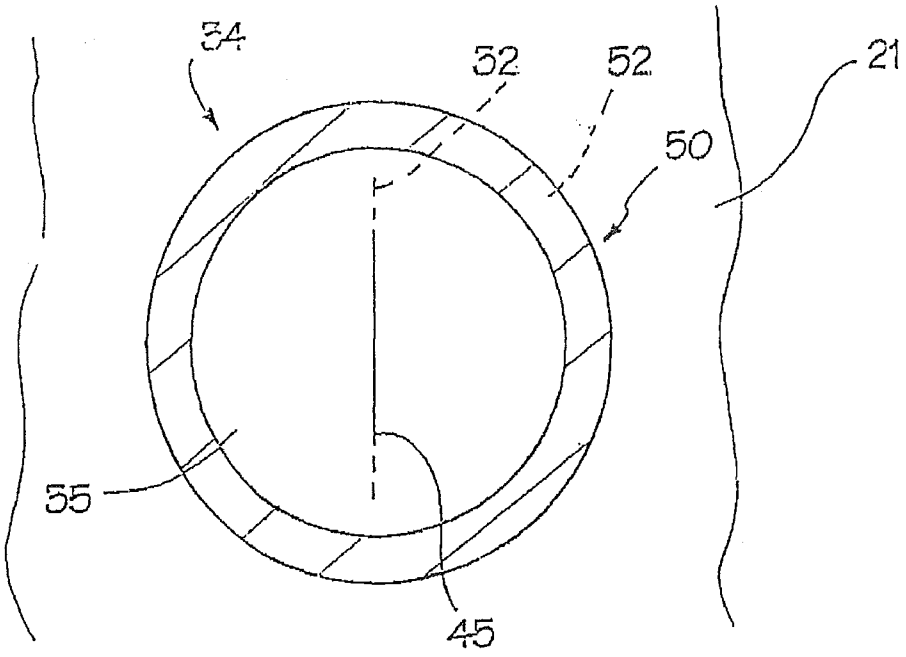


Fig. 4



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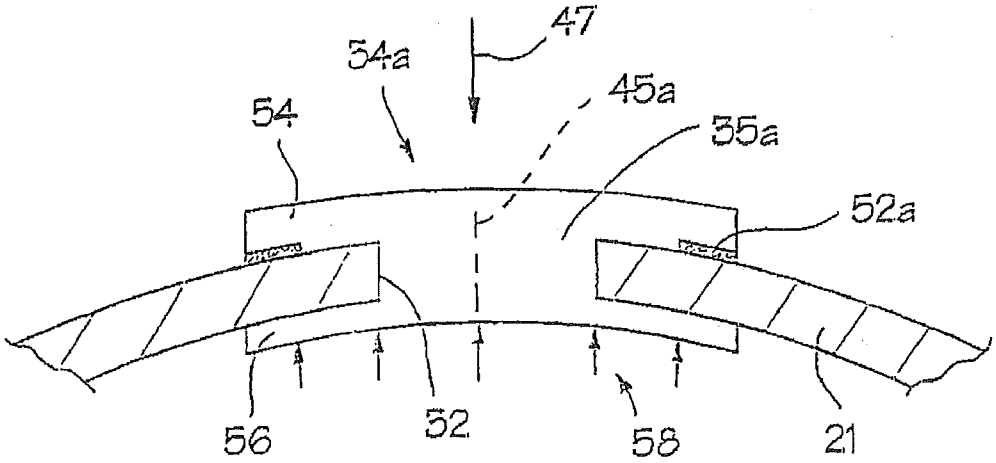

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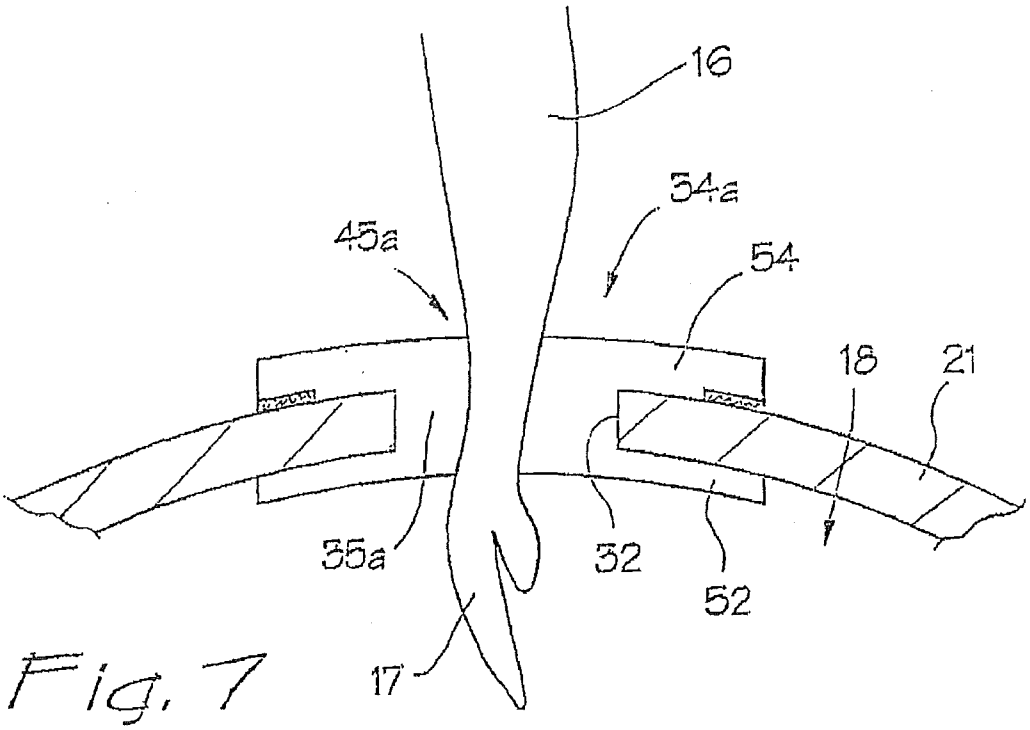


Fig. 7

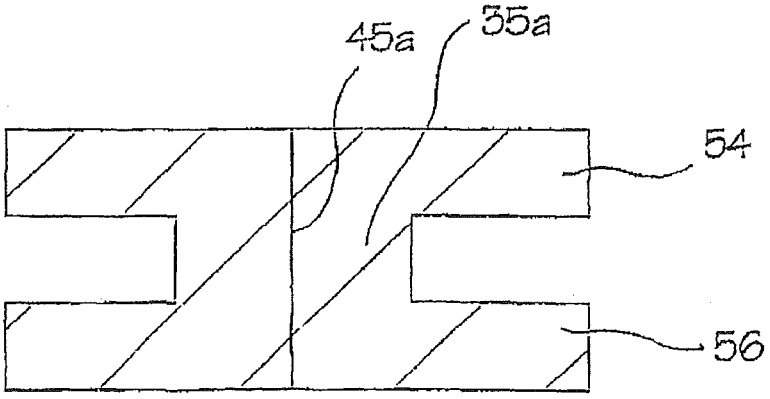


Fig. 8

Fig. 9

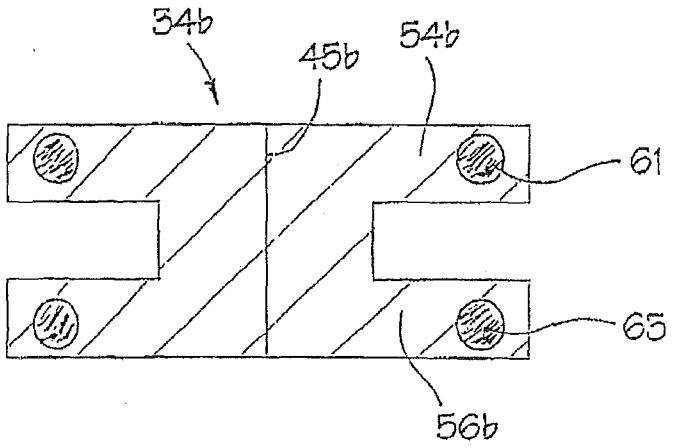


Fig. 10

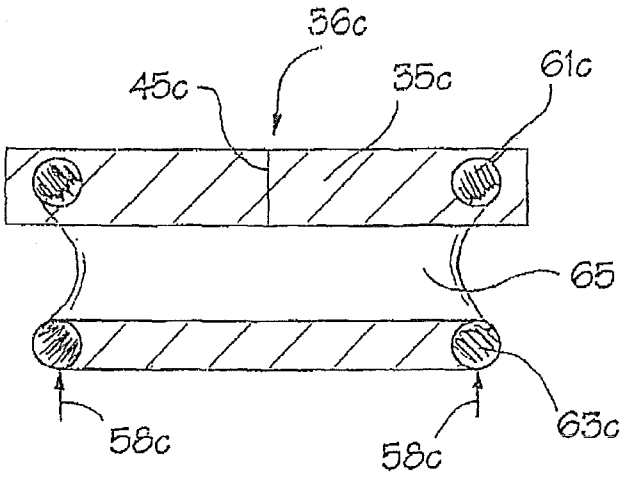
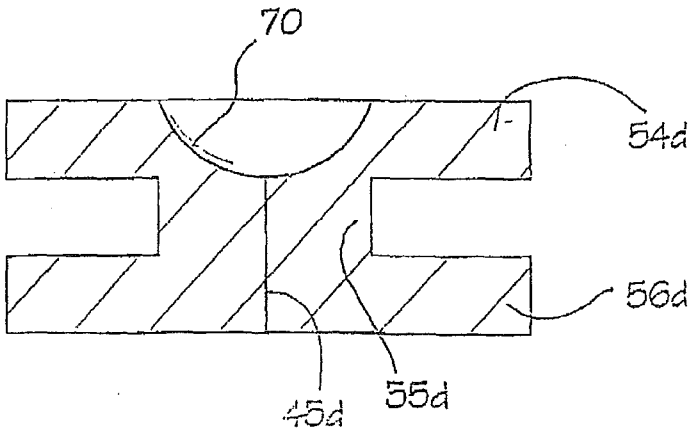


Fig. 11



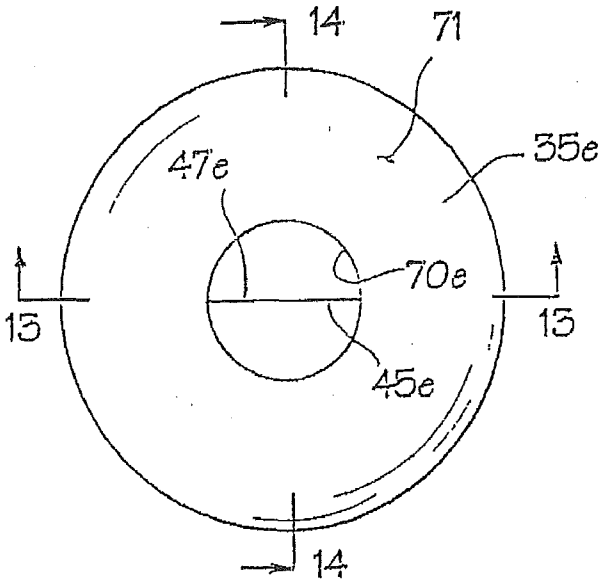


Fig. 12

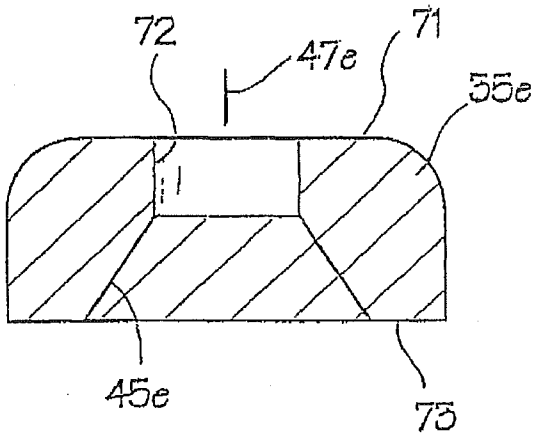


Fig. 13

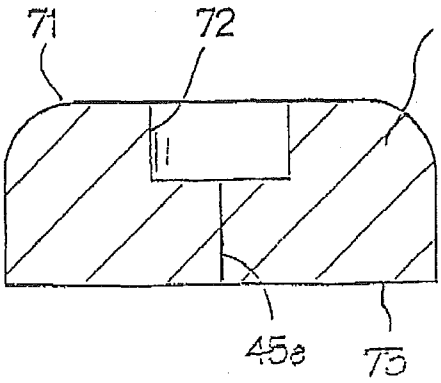


Fig. 14

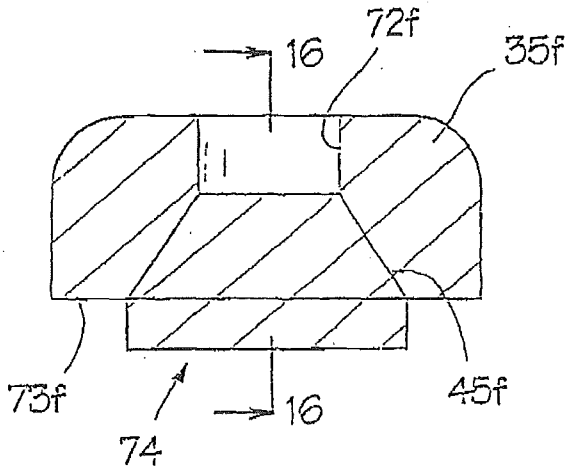


Fig. 15

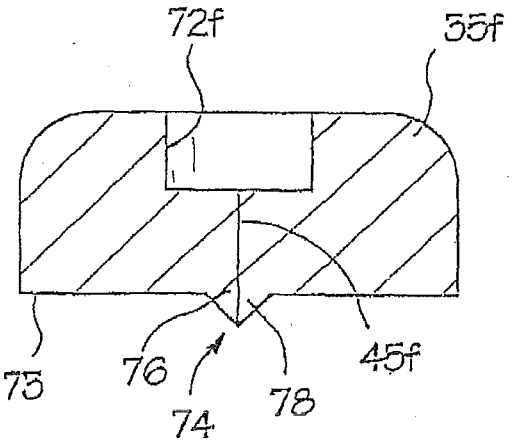


Fig. 16

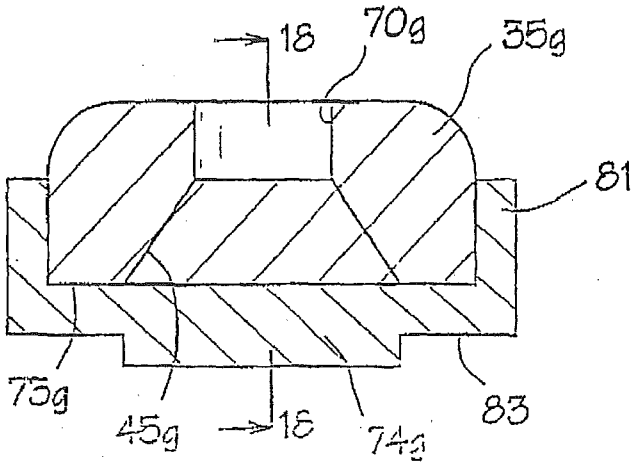
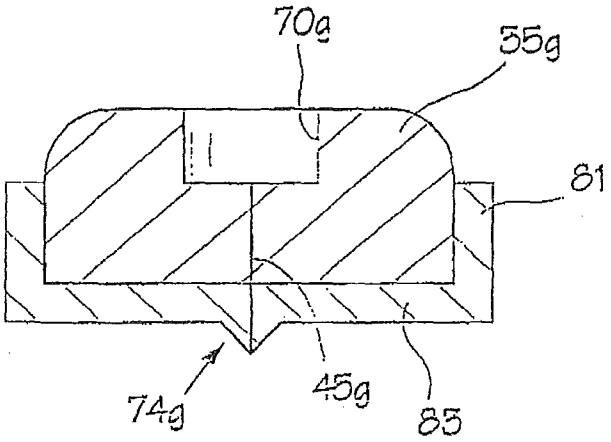


Fig. 17



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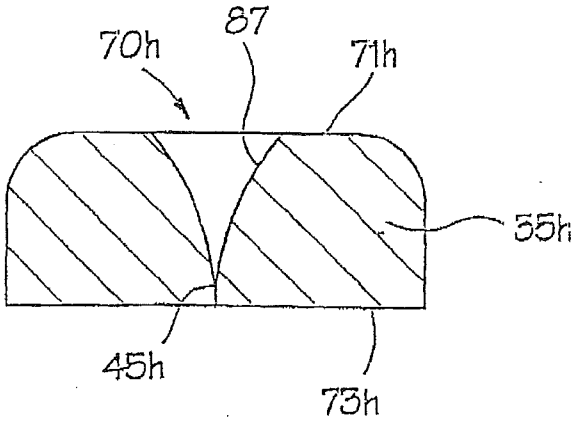


Fig. 19

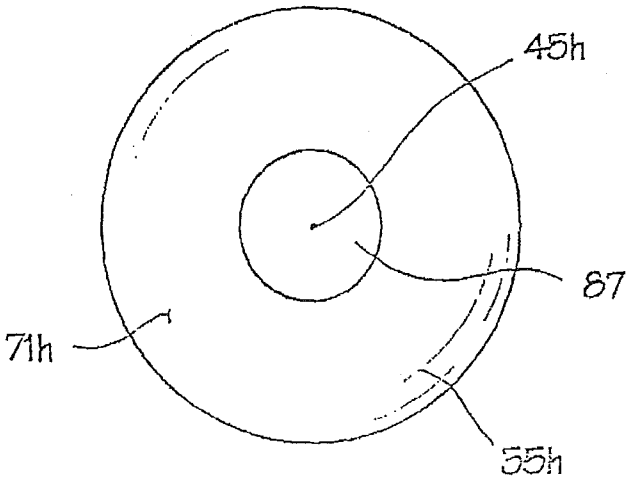
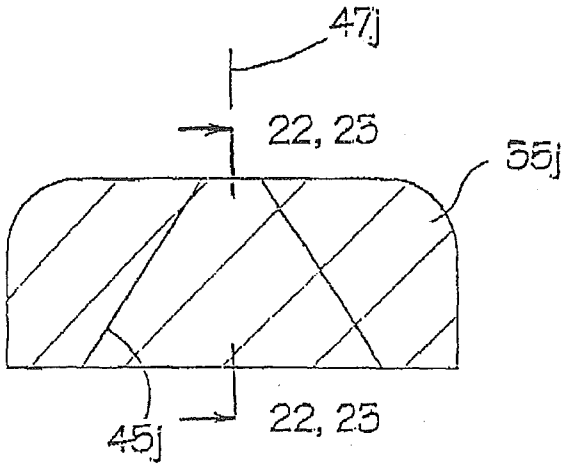


Fig. 20

Fig. 21



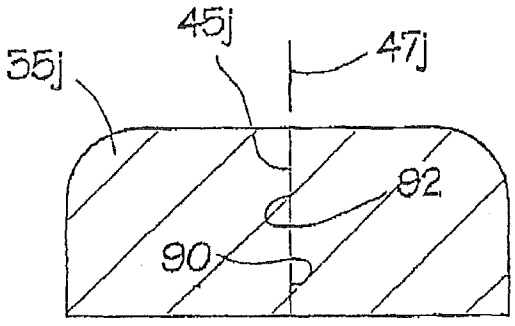
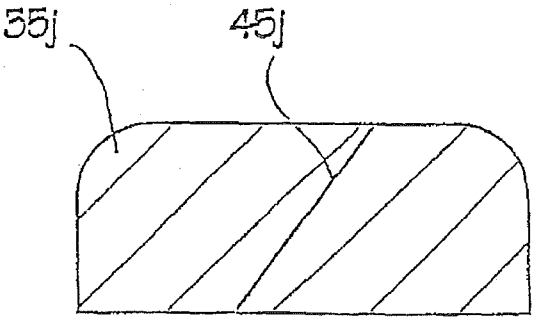


Fig. 22

75j

Fig. 23



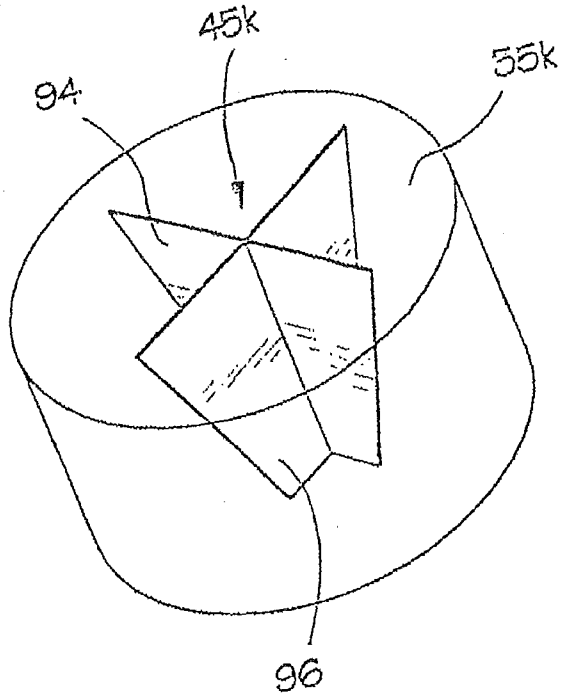


Fig. 24

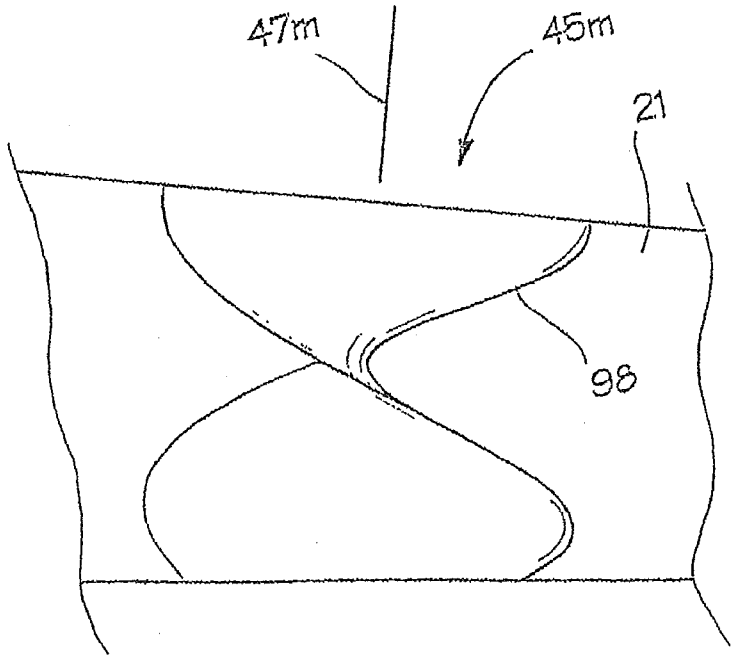
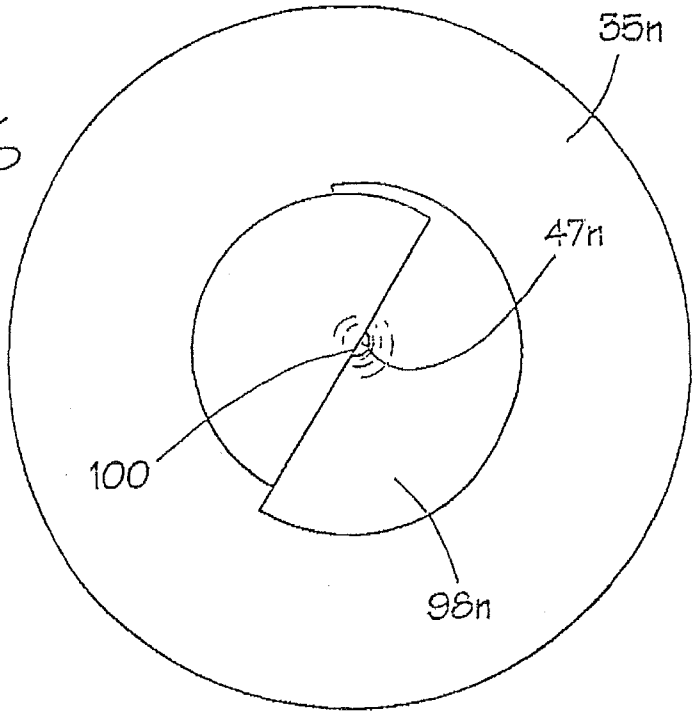


Fig. 25

Fig. 26



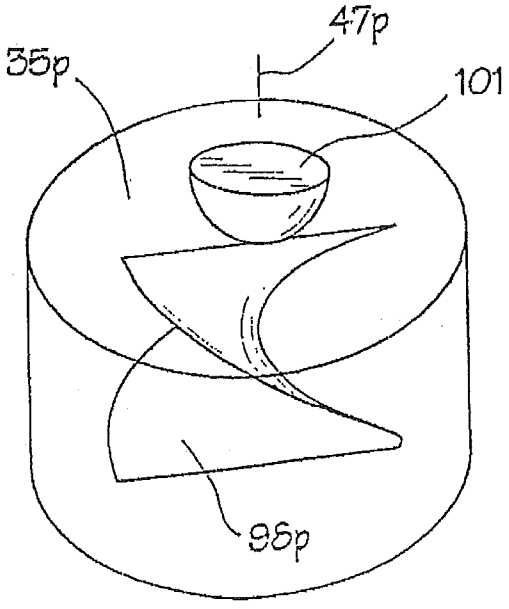


Fig. 27

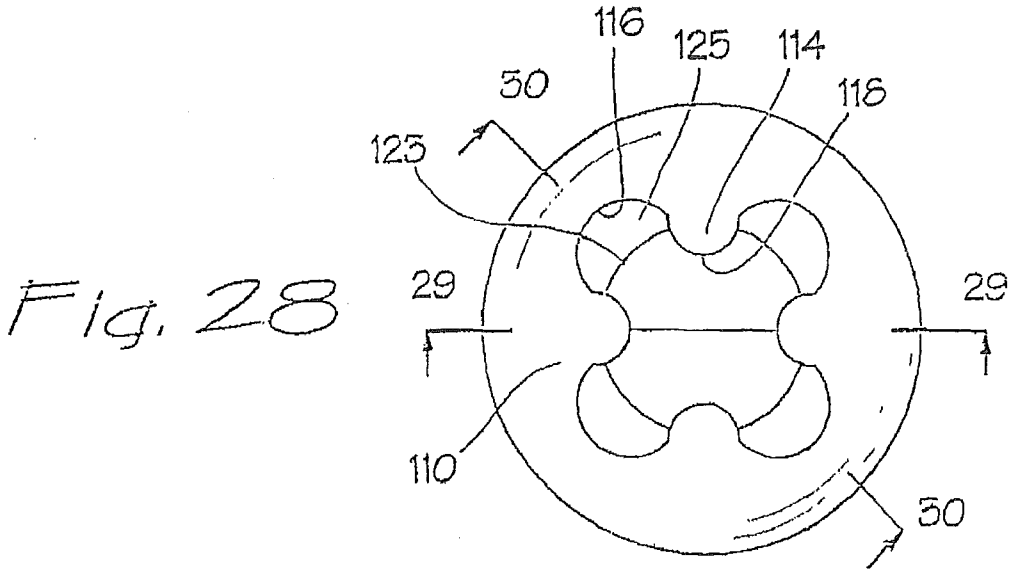
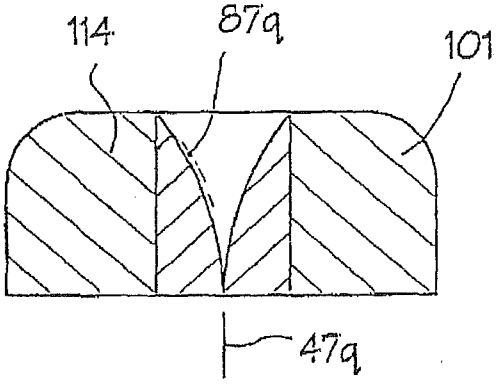


Fig. 28



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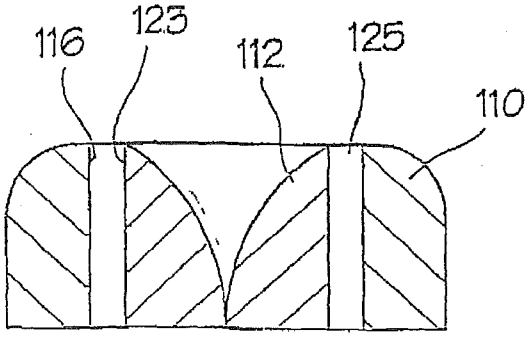


Fig. 30

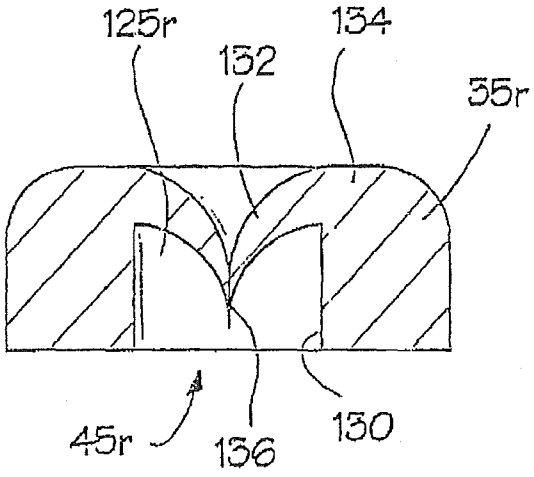


Fig. 31

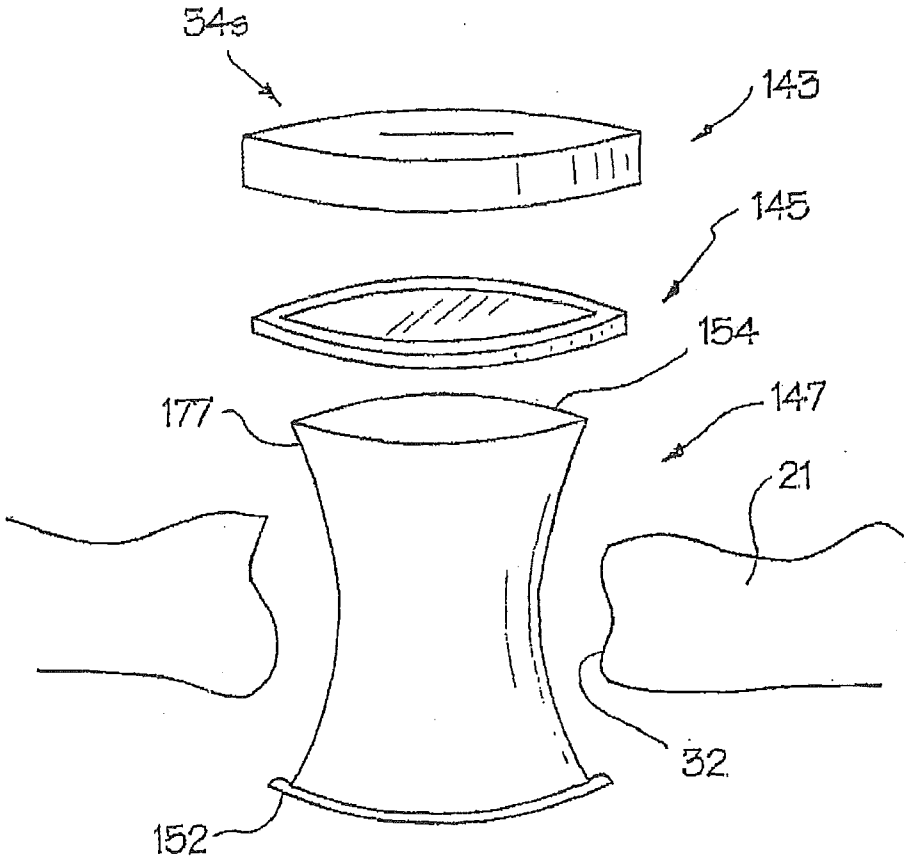
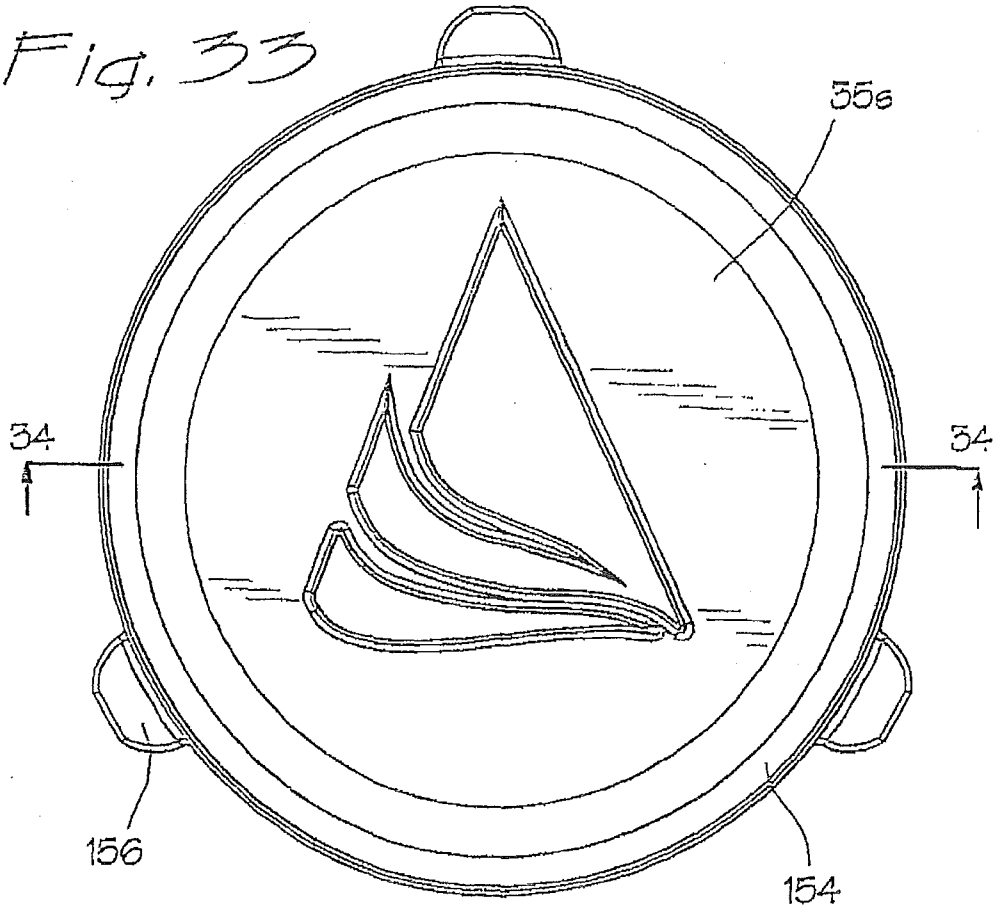


Fig. 32

Fig. 33



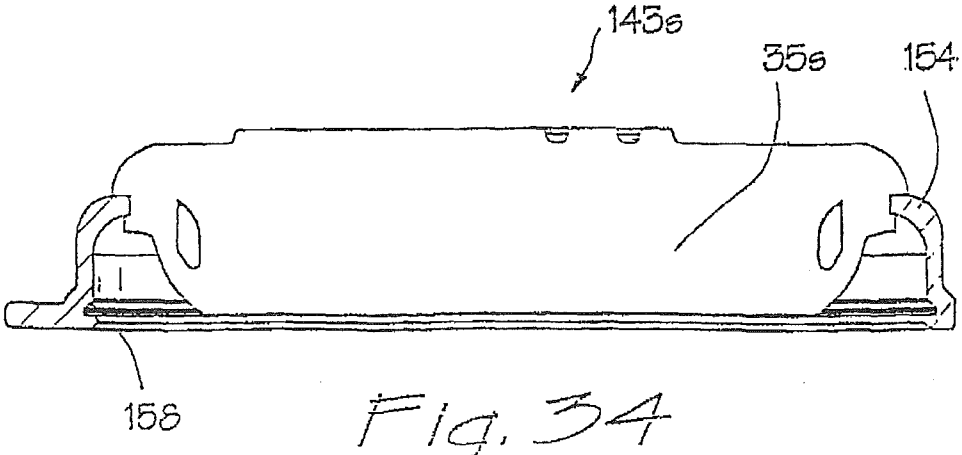
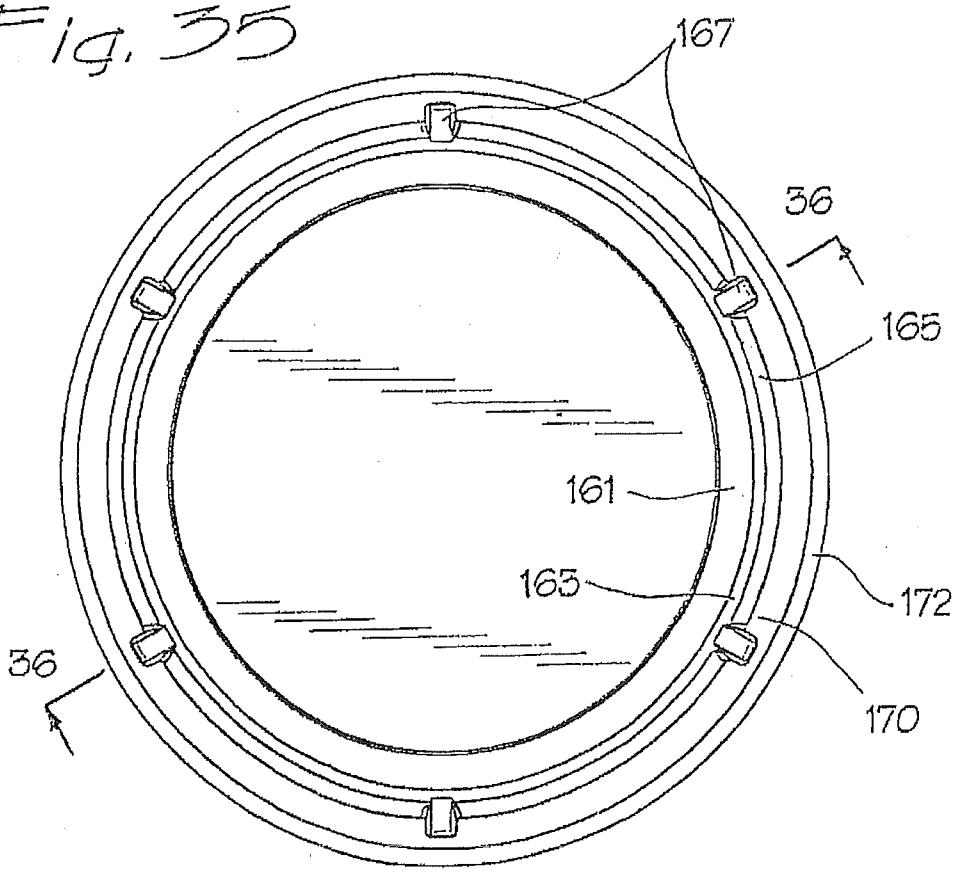


Fig. 34

Fig. 35



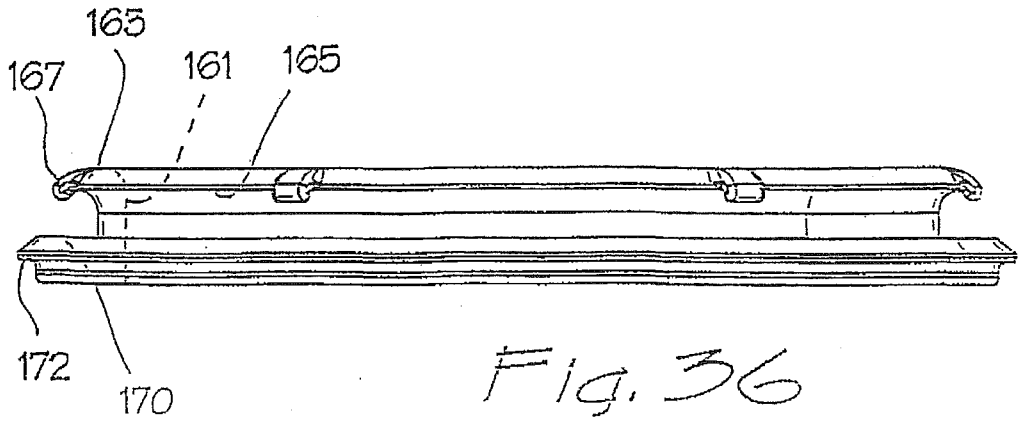


Fig. 36

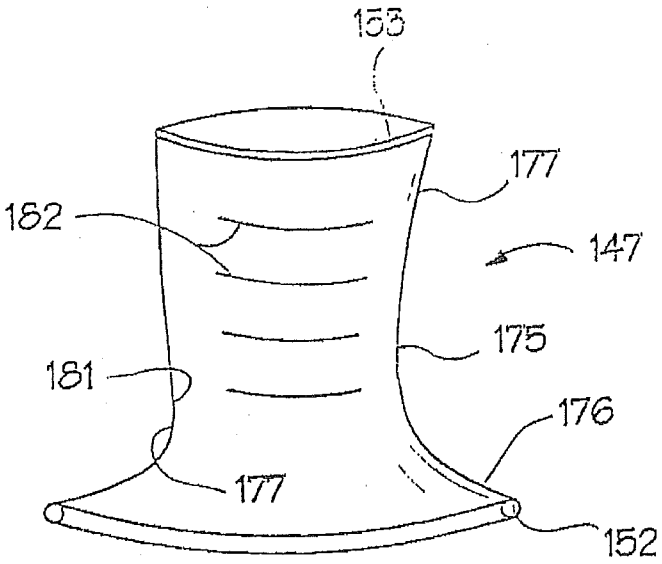

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Fig. 37

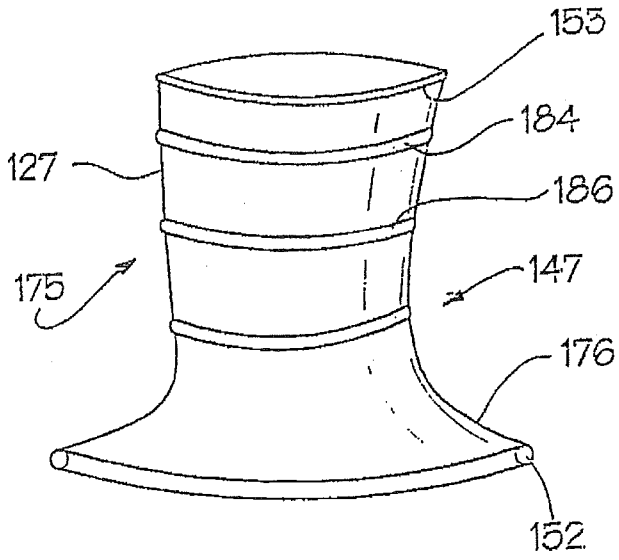
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Fig. 38

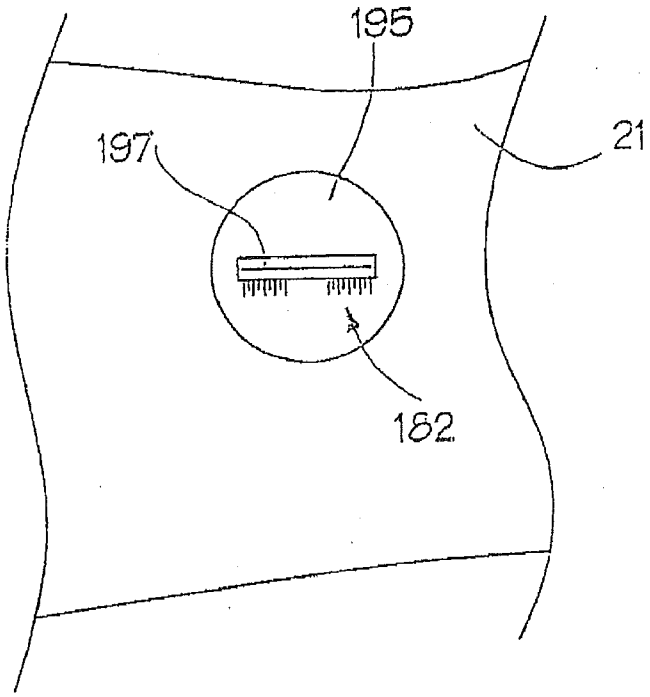

Fig. 39

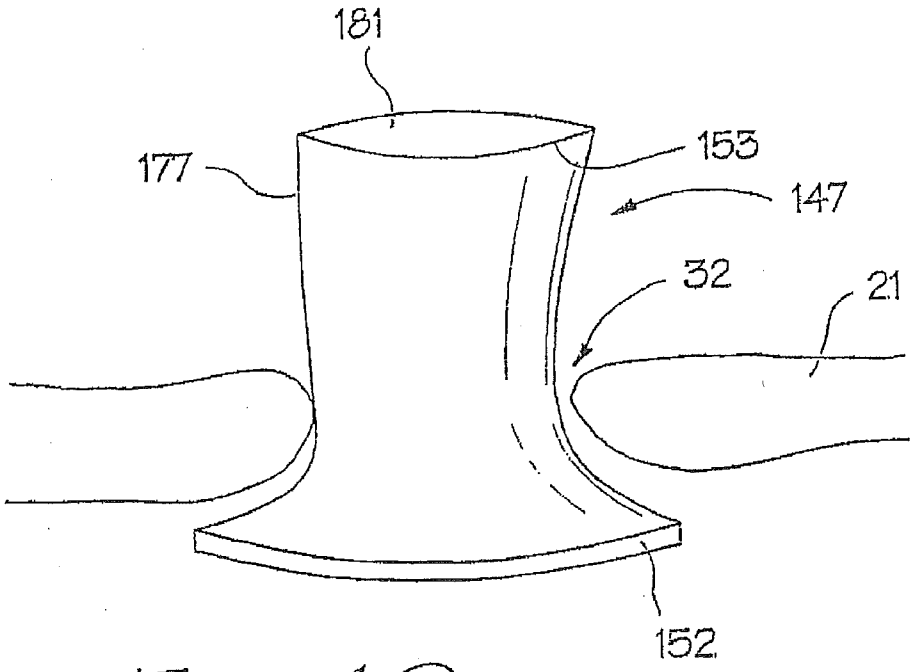

Fig. 40

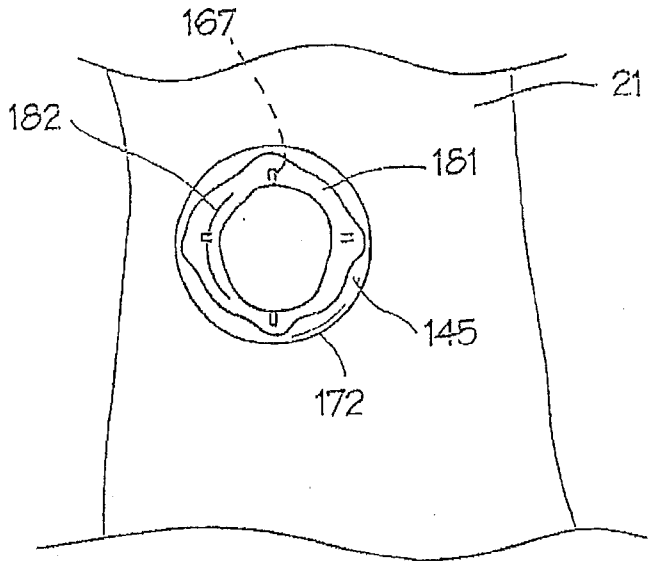

Fig. 41

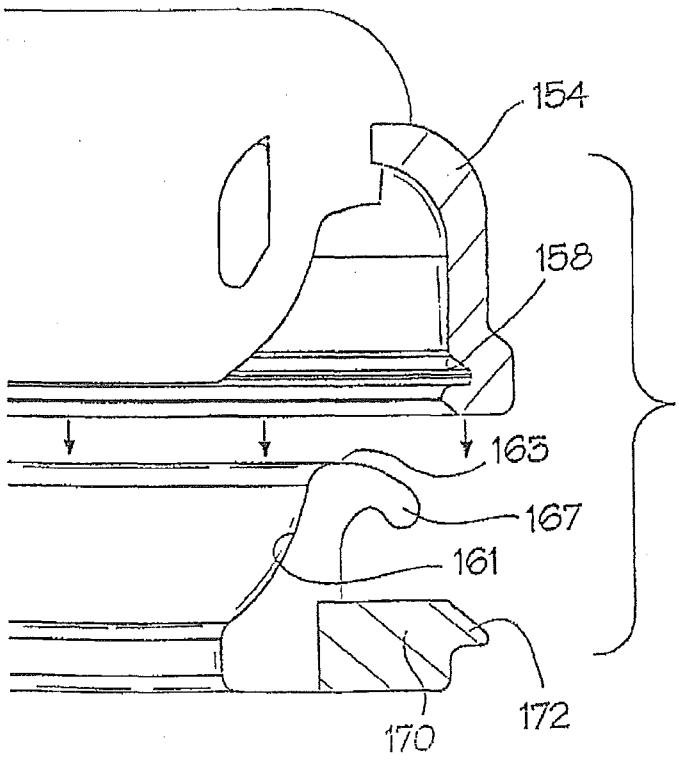

Fig. 42

SURGICAL ACCESS APPARATUS AND METHOD

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation of U.S. application Ser. No. 11/244,647, filed Oct. 5, 2005, now U.S. Pat. No. 7,481,765, which is a continuation of U.S. application Ser. No. 10/381,220, filed Mar. 20, 2003, now U.S. Pat. No. 7,473,221, which is the National Phase application under 35 U.S.C. §371 of International Application No. PCT/US2001/029682, filed Sep. 21, 2001, which published in English as International Publication No. WO 2002/034108 A1 on May 2, 2002, which claims the benefit of U.S. Application No. 60/241,958, filed Oct. 19, 2000, all of the disclosures of which are incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to devices and other apparatus facilitating sealed access with surgical instruments, such as a surgeon's hand, across a body wall and into a body cavity.

2. Background of the Invention

In several areas of surgery there exists a need to have mechanisms or devices that can seal a body cavity or space, and yet permit the introduction of surgical instruments such as guidewires, endoscopes, and even the hand of a surgeon. Typical of these areas of surgery is laparoscopic surgery which relies on surgical instruments inserted through the abdominal wall to reach an operative site within the abdominal cavity. In order to increase space around the operative site within the cavity, insufflation gases are typically introduced to inflate the cavity and elevate the abdominal wall. This pressurizing of the abdominal cavity is referred to as pneumoperitoneum. In this context, the need to seal the body cavity or space arises from the need to maintain the pneumoperitoneum even when instruments are present.

Trocars have been commonly used to provide instrument access in laparoscopic surgeries. These trocars have included elaborate seal structures having zero seals which prevent escape of the gases in the absence of instruments, and instrument seals which prevent escape of the gases in the presence of instruments. Unfortunately, the instrument seals have been able to accommodate only a narrow range of instrument diameters. Where wider ranges were desired multiple seal pairs had to be provided.

Some instruments, such as the hand of the surgeon, have been too large for trocar access. Under these circumstances, hand-assisted laparoscopic seals have been provided. Such devices have been large, cumbersome, and largely ineffective in providing the required sealing mechanism. Other access devices, such as Touhy-Borst seals, have been used but only for very small diameter access such as that required by a guidewire.

Each of the prior devices suffers from drawbacks which make the device difficult or cumbersome to use. For example, a Touhy-Borst seal requires two hands to use and does not form a seal when a guidewire or other device is about to be introduced. Present trocar seals and hand-assisted seals require two valves, one forming an instrument seal in the presence of the instrument, and the other forming a zero seal in the absence of the instrument. For example, in hand-assisted devices, elaborate mechanisms have been required to seal around the surgeon's arm. When the arm is removed, a separate zero seal has been required to prevent the escape of blood or insufflation gases.

SUMMARY OF THE INVENTION

These deficiencies of the prior art are overcome with the present invention which includes both a seal apparatus and a method for using this apparatus to perform elaborate surgeries. In one embodiment, the device includes a valve structure formed of a gel including, for example, a thermoplastic base such as KRATON (a trademark of Shell Corporation) and an oil. The resulting elastomer has an excellent tear strength, elongation greater than 1,000 percent, a very low durometer or hardness, and biocompatibility. A process for manufacturing this device is greatly simplified using molding techniques.

Importantly, the access device can function as both a zero seal and an instrument seal. Furthermore, it can accommodate a full range of instrument diameters, such as a range from two French in the case of a guidewire, to three or four inches in the case of a surgeon's hand. In addition, several instruments can be accommodated at the same time with a single access device.

Both tear resistance and sealing capability can be enhanced by encapsulating the gel in a sheath or otherwise providing circumferential reinforcement for the valve structure. Additives can be provided either on or in the gel to enhance properties such as lubricity, appearance, wound treatment and/or protection, anti-cancer protection and anti-microbial protection. Additional chemicals, compounds, pharmaceuticals or even mechanical devices can be mixed with or embedded in the gel material to vary chemical, pharmaceutical or physical properties of the access device.

These and other features and advantageous of the invention will be clarified with a description of preferred embodiments and reference to the associated drawings.

DESCRIPTION OF THE DRAWINGS

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

FIG. **2** is an enlarged side elevation view of the access device of FIG. **1** operatively disposed exteriorly as the abdominal wall;

FIG. **3** is a side elevation view similar to FIG. **2** showing the access device operatively disposed interiorly of the abdominal wall;

FIG. **4** is a side elevation view similar to FIG. **2** showing the access device operatively disposed within an incision in the abdominal wall;

FIG. **5** is a plan view taken along lines **5-5** of FIG. **2**;

FIG. **6** is a side elevation view similar to FIG. **2** and illustrating a further embodiment of the access device having an external flange and an internal flange;

FIG. **7** is a side elevation view similar to FIG. **6** and illustrating the hand of a surgeon being inserted through the access device;

FIG. **8** is an axially cross section view of the access device illustrated in FIG. **6**;

FIG. **9** is a cross section view similar to FIG. **8** and illustrating an embodiment with circumferential reinforcement members;

FIG. **10** is an axial cross section view similar to FIG. **9** and illustrating a double-ring retractor with an access device of the present invention;

FIG. **11** is a radial cross section view similar to FIG. **8** and illustrating an embodiment having a lead-in cavity or pocket;

FIG. **12** is a top plan view of the embodiment illustrated in FIG. **11**;

FIG. **13** is an axial cross section view taken along lines **13-13** of FIG. **12**;

FIG. **14** is an axial cross section view taken along lines **14-14** of FIG. **12**;

FIG. **15** is an axial cross section view similar to FIG. **13** and illustrating an embodiment with a duct-bill valve;

FIG. **16** is an axial cross-section view taken along lines **16-16** of FIG. **15**;

FIG. **17** is a radial cross section view similar to FIG. **13** comprising a softer hand seal and a firmer base seal;

FIG. **18** is an axial cross section view taken along lines **18-18** of FIG. **17**;

FIG. **19** is an axial cross section view of an embodiment having a lead-in cavity or pocket with a conical or funnel configuration;

FIG. **20** is a top plan view of the embodiment illustrated in FIG. **19**;

FIG. **21** is an axial cross section view similar to FIG. **13** and showing another embodiment with a trapezoidal slit;

FIG. **22** is an axial cross section view taken along lines **22-22** of FIG. **21**;

FIG. **23** is an axial cross section view similar to FIG. **22** taken along lines **23-23** of FIG. **21** and illustrating a slit having other than a perpendicular relationship to the plane of the pad;

FIG. **24** is a perspective view of a further embodiment of the access device having an opening formed by multiple slits angularly disposed and axially spaced relative to each other;

FIG. **25** is a side elevation view of an access device with a slit having a spiral configuration;

FIG. **26** is a top plan view of an access device having a spiral slit and axial channel;

FIG. **27** is a side elevation view of an embodiment having a spiral slit and a septum seal;

FIG. **28** is an axial cross section view of a further embodiment including a superelastic conical seal and a flexible base with annular spoke-like cams;

FIG. **29** is an axial cross section view taken along lines **29-29** of FIG. **22**;

FIG. **30** is an axial cross section view taken along lines **30-30** of FIG. **22**;

FIG. **31** is an axial cross section view similar to FIG. **28** and illustrating an embodiment including flappers;

FIG. **32** is a perspective exploded view of a further embodiment including a gel cap, a base, and a retraction sheath;

FIG. **33** is a top plan view of the gel cap of FIG. **32**;

FIG. **34** is an axial cross section view taken along lines **34-34** of FIG. **33**;

FIG. **35** is a top plan view of the base illustrated in FIG. **32**;

FIG. **36** is an axial cross section view taken along lines **36-36** of FIG. **35**;

FIG. **37** is a side elevation view of the retraction sheath illustrated in FIG. **32**;

FIG. **38** is a side elevation view of a further embodiment of the retraction sheath;

FIGS. **39-42** illustrate progressive steps in a preferred method of use associated with the embodiment of FIG. **32**;

FIG. **39** is a top plan view showing use of a template;

FIG. **40** is a top plan view of showing placement of the retraction sheath;

FIG. **41** is a top plan view showing placement of the base ring and securement of the traction sheath; and

FIG. **42** is an axial cross section view partially in section showing placement of the gel cap relative to the base.

DESCRIPTION OF PREFERRED EMBODIMENTS AND BEST MODE OF THE INVENTION

A patient is illustrated in FIG. **1** and designated generally by the reference numeral **10**. The patient **10** is shown in a prone position on an operating table **12**, where abdominal surgery is being performed by a surgeon **14** having an arm **16** and a hand **17**. 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**

Although the specific focus of this disclosure will be on a preferred laparoscopic procedure, it will be noted that laparoscopic surgery is merely representative of a type of operation wherein a procedure can be performed in a body cavity with minimal access through a body wall.

Notwithstanding the foregoing generality, it is important to note that with respect to laparoscopic surgery, it is often desirable that the surgeon **14** be able to insert his/her hand **17** through the abdominal wall **21** and into the abdominal cavity **18**. This insertion of the hand **17** provides the surgeon **14** with direct access to various elements of the anatomy

In order to accommodate the hand **17** and arm **16** of the surgeon **14**, 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 of the surgeon **14**.

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 **29**, scope **30** and hand **27**.

Thus, the trocars **23** and **25** have typically been provided with complex valve structures, including, for each narrow range of instrument sizes, an instrument valve which forms an instrument seal in the presence of an instrument, and a zero valve which forms a zero seal in the absence of an instrument. By providing both an instrument seal and a zero seal the valve structures have been able to inhibit the escape of gases through the trocars both in the presence and the absence of an instrument, respectively.

The instrument seals have been particularly cumbersome, as noted, and have only been effective for a small range of instrument diameters. For example, separate instrument seals have been needed for instruments, such as guidewires, which may have a diameter of only two French to three French. For medium-sized instruments having diameters of three millimeter to five millimeters, a second instrument seal has been required. In some cases, even a third instrument seal has been necessary in order to accommodate instruments having diameters such as nine millimeters to 12 millimeters.

Typically the varying sizes of instruments have also required individual zero seals for each range. Thus, in a complex trocar, such as the trocar **23**, there might be as many as six separate seals associated with the access device.

Were it not for the desire to maintain pneumoperitoneum, there would be no need for the trocars **23**, **25** or the access device **34**. 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 incisions. 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 **14**. Thus it is a primary purpose of the access device **34** to form with the incision **32** an access or working channel **34**, and to provide a valve or other sealing structure across the working channel **34** in order to maintain the pneumoperitoneum.

An enlarged view of one embodiment of the access device **34** is illustrated in FIG. **2** which also shows the abdominal wall **21** and the incision **32**. In this simple form, the access device **34** has the general configuration of a pad **35**, meaning that it is generally flat and disposed in a plane such as the plane **38**. Typically parallel to this plane **38** are a pair of major surfaces of **41** and **43** which provide the pad **35** with a substantial surface area. An opening or slit **45** can be formed through the pad **35**, generally along an axis **47** perpendicular to the plane **38**.

When operatively disposed, the opening **45** of the pad **35** is in communication with the incision **32** and, in this case, forms with the incision **32**, the working channel **36**. The alignment of the opening **45** and incision **32** can occur with the pad **35** disposed exteriorly of the abdominal wall as illustrated in FIG. **2**, interiorly of the abdominal wall is **21** as illustrated in FIG. **3**, or within the abdominal wall **21** as illustrated in FIG. **4**. In any of these positions, operative disposition of the pad **35** relative to the abdominal wall **21** requires that the pad **35** be maintained in its operative position and that it form a seal around the incision **32**. Referring to the plan view of FIG. **5**, these two functions are accomplished with an adhesive **50** disposed around the incision **32** between the pad **35** and the abdominal wall **21**.

If this adhesive **50** is formed as a continuous ring **52**, as illustrated in FIG. **5**, the pad **35** can be disposed with the ring **52** positioned circumferentially around the incision **32** to form a seal between the pad **35** and the abdominal wall **21**. In the illustrated example, when the pad **35** is operatively positioned, the escape of insufflation gases is inhibited between the pad **35** and the abdominal wall **21** by the adhesive ring **52**.

The escape of insufflation gases is inhibited through the opening **45** of the pad **35** by the self-sealing characteristics of the material forming the pad **35**. This material and its highly advantageous properties are discussed in significant detail below.

It will be appreciated that the functions of the adhesive ring **52** can be accomplished in many different ways using many different materials and shapes. For example, many materials other than adhesives can be used to maintain the pad **35** in position over the incision **32**. The formation of a seal around the incision **32** can also be accomplished with methods other than adhesion. Furthermore, the shape of the continuous seal formed by the adhesive **50** need not be in the shape of a circle. Rather, any continuous pattern sufficiently large to form a perimeter around the incision **32** could facilitate the desired sealing relationship. Finally, it will be noted that the mere placement of the pad **35**, for example, interiorly of the abdominal wall **21** as illustrated in FIG. **3**, may produce a perimeter seal merely as a result of the insufflation pressure.

A further embodiment of the access device **34***a* is illustrated in FIG. **6** where elements of structure similar to those previously disclosed or designated with the same reference numeral followed by the lower case "a." In this embodiment, the functions of position-maintenance and sealing are accomplished with an alternative configuration for the access device itself The pad **35** in this case is disposed within the incision **32** as illustrated in FIG. **4**. However, an external flange **54** and an internal flange **56** are formed integral with the pad **35**.

When operatively disposed, the external flange **54** is positioned outside of the abdominal wall **21** while the internal flange **56** is disposed interiorly of the abdominal wall **21***a*. In this matter, the pad **35** can be disposed within the incision **32***a* and held in position by the flanges **54**, **56**. When the hand **17** of the surgeon **14** is inserted through the access device **34**, the exterior flange **54** prevents the pad **35***a* from moving distally. Similarly, when the hand **17** of the surgeon **14** is withdrawn, the interior flange **56** prevents the pad **35***a* from moving proximally

In this embodiment, the opening **45***a* extends through the pad **35***a* as well as the flanges **54** and **56**, and completely defines the working channel **34** through the incision **32**.

The primary seal which is required between the access device **34***a* and the abdominal wall **21**, can be formed with the adhesive ring **52***a* as discussed with reference to FIG. **6**. Alternatively, this embodiment including the interior flange **56** may rely merely upon the surface contact between the flange **56***a* and the abdominal wall **21**. In this case, the primary seal can be formed between these structural elements and enhanced by the pneumoperitoneum pressure which forces the interior flange **56** against the abdominal wall as illustrated by a plurality of arrows **58**. This seal is formed primarily in a radial plan generally perpendicular to the axis **47**.

The function of the primary seal may be further enhanced by additional sealing which occurs between the pad **35***a* and the portions of the abdominal wall **21** forming the incision **32**. In this location, the abdominal wall **21** is radially compressed by the mere presence of the pad **35** within the incision **32**. The resulting pressure produces an axial seal between the pad **35***a* and the abdominal wall **21**.

If the adhesive ring **52***a* is desired for this embodiment, it is most advantageously placed around the incision **32**, between the exterior flange **54** and the abdominal wall **21**.

It will be noted that whenever an instrument, such as the arm **16** or hand **17** of the surgeon **14**, is inserted through the pad **35**, the material of the pad conforms to the surface of the instrument and forms the instrument seal with the instrument. Accordingly, during the entire period beginning with insertion of the instrument and ending with withdrawal of the instrument, there is substantially no loss of insufflation gas through the pad **35***a* nor any loss of pneumoperitoneum within the abdominal cavity **18**.

With further reference to FIG. **7**, it will be appreciated that the arm **16** and hand **17** of the surgeon **14** are merely examples of instruments which can be inserted through the access device **34***a*. In the absence of the instrument, or hand **17** in the case of FIG. **7**, the opening or slit **45***a* merely closes against itself to form a zero seal, thus preventing the escape of insufflation gases through the access device **34***a*. When the instrument, such as the hand **17**, is inserted through the opening or slit **45***a*, an instrument seal is formed between the material of the access device **34***a* and the exterior surface of the instrument. This prevents the escape of insufflation gases through the access device **34***a*, even when an instrument is present. Thus, insufflation pressures can be maintained within the abdominal cavity **18** whether or not the instrument is in place.

Note that these seals, the zero seal and the abdominal seal, can be formed as a single valve structure having properties for accommodating a full range of instrument sizes.

Formation of the pad **35***a* will typically be accomplished in a simple molding process described in greater detail below. In such a process, the opening or slit **45***a* may be formed as part of the molding process.

In most cases, the single access opening **45***a* will be sufficient to accommodate the operative procedure. However, a further advantage of the access device **34***a* will be particularly appreciated by the surgeon **14** who requires even more access through the pad **35***a*. Consider for example, the surgeon **14** having his/her arm **16** inserted through the opening **45***a* when he/she decides that a further instrument is required for the operative procedure. Under these circumstances, a further opening through the pad **35***a* can be established by merely inserting the desired operative instrument through the pad **35***a*. In this manner, the instrument can create its own access hole beside the primary opening **45***a*.

Particularly for those operative instruments having pointed distal ends, the instrument can merely be forced through the pad **35***a* forming its own access hole, such as the opening **45***a*, as it is moved distally. This opening, created by the operative instrument itself, would automatically form an instrument seal as the instrument is inserted, as well as a zero seal as the instrument is withdrawn.

For operative instruments not having pointed distal ends, it is possible to form a new access hole using a secondary instrument, such as a trocar obturator. After the access hole is formed, the obturator can be removed, vacating the access hole to receive the operative instrument. Throughout this process of initially forming an access hole and ultimately inserting an operative instrument through the hole, both zero seals and instrument seals are formed to maintain the pneumoperitoneum.

With the advantages associated with 1) the formation of an instrument seal and a zero seal with a single valve accommodating a wide range of diameters, and 2) the formation of an instrument opening using the instrument itself, it will be appreciated that the concept of this invention will typically be embodied with a structure that is particularly dependent upon the material which forms the access device **34**. In a preferred embodiment, the pad **35** is formed of a KRATON/oil mixture including a KRATON Tri-block with a Styrene-Ethylene/Butylene-Styrene (S-E/B-S) structure in combination with a mineral oil. Other tri-block polymers can be used for this application such as Styrene-Isoprene-Styrene, (S-I-S), Styrene-Butadiene-Styrene (S-B-S), Styrene-Ethylene/Propylene-Styrene (S-E/P-S) manufactured under the trademark SEPTON by the Kuraray Co. These general formulas can be further distinguished by the ratio of the styrene to rubber content: for example, Grade 1650 is a S-E/B-S tri-block with a 29/71 styrene to rubber ratio.

In addition to tri-blocks there are also di-block versions of these materials where styrene is present at only one end of the formula, for example, Styrene-Ethylene/Butylene (S-E/B) di-block.

The various base formulas may also be alloyed with one another to achieve a variety of intermediate properties. For example KRATON G1701X is a 70% S-E/B 30% S-E/B-S mixture with an overall Styrene to rubber ratio of 28/72. It can be appreciated that an almost infinite number of combinations, alloys, and Styrene to rubber ratios can be formulated, each capable of providing advantages to a particular embodiment of the invention. These advantages will typically include low durometer, high elongation, and good tear strength.

It is contemplated that the material of the pad **35** may also include silicone, soft urethanes and even harder plastics which might provide the desired sealing qualities with the addition of a foaming agent. The silicone materials can be of the types currently used for electronic encapsulation. The harder plastics may include PVC, Isoprene, KRATON neat, and other KRATON/oil mixtures. In the KRATON/oil mixture, for example, oils such as vegetable oils, petroleum oils and silicone oils might be substituted for the mineral oil. In the broadest sense, all of these mixtures can be described generally as a gel. The gel will typically have properties including an ability to "flow" which approaches that of a fluid. Particularly in the vicinity of any opening or slit **45** extending through the access device **34**, propagation of the opening may be of concern. Stresses resulting from the presence of an instrument will be concentrated at the ends of such an opening or slit. For this reason, a good tear resistance is desired for the gel material. Such a tear resistance is often inherent in the KRATON/oil mixtures and may be enhanced by encapsulating the gel in other materials. For example, a low tear resistant gel could be encapsulated in a urethane sheath to improve the tear resistant qualities of the resulting products. Such a sheath need not be elastic but could be comprised, for example, of overlapping sheets of a non-elastic material.

Any of the gel materials contemplated could be modified to achieve different properties such as enhanced lubricity, appearance, and wound protection, or to provide anti-cancer or anti-microbial activity. Additives can be incorporated directly into the gel, for example in the case of pharmaceuticals, or applied as a surface treatment to the gel, for example, to improve lubricity or appearance. Other compounds could be added to the gel to modify its physical properties or to assist in subsequent modification of the surface by providing bonding sites or a surface charge. Antioxidants and antirads can be added to the mixture to extend the shelf life of the finished product or increase its ability to withstand radiation sterilization.

Sealing materials used in medical access devices of the past have been chosen primarily for their durometer and elongation. It is these properties which measure the ability of the material to move into small spaces and crevices as may be required to form an instrument seal across the working channel of a trocar. For example, in the past, a silicone mixture was used in medical valves. This mixture had the following properties: an ultimate elongation less than about 1000 percent and a durometer not less than about 5 Shore A.

These properties of the prior art materials are far exceeded by the properties associated with the present invention which in some respects provide a full magnitude of advantage. In fact, the difference between the materials of the prior art and the materials of the present invention are sufficiently substantial, that it is perhaps misleading to refer to the present material as merely a gel. According, the material of the present invention, having properties including an ultimate elongation greater than about 1000 percent and a durometer less than about 5 Shore A, will be referred to herein as an "ultragel."

In a preferred embodiment of the present invention, the ultragel includes KRATON and mineral oil and provides a sealing material with the following properties: an ultimate elongation exceeding about 1500 percent, and a durometer of less than about 200 Bloom. The durometer in this case is considerably lower than that of the prior art materials. In fact, the durometer of the present material is so soft it cannot even be measured on the Shore A scale.

The resulting elongation and durometer of the present material facilitates its use with as an access valve which is capable of forming seals with a full range of instrument sizes,

but is also capable of functioning as a zero seal. Whereas access devices of the prior art may have required as many as six separate seals in order to accommodate a full range of instrument sizes, access devices can now be made with only a single valve formed of the ultragel material.

In a typical manufacturing process, the KRATON G1651 is mixed with the mineral oil in a ratio by weight of 1 to 9. In order to manufacture this material, the combination is heated to a temperature of about 200° centigrade. In a preferred method of manufacturing, the mold is provided with a circumferential ring insert which is molded into the gel, and slit inserts which can be removed from the gel to form the opening or slit **45**. The resulting gel can be coated with cornstarch to reduce tack and cooled at room temperature.

Many of the properties of the KRATON/oil mixture will vary with adjustments in the weight ratio of the components. In general, the greater the percentage of mineral oil, the more fluid the mixture; the greater the percentage of KRATON, the more rigid the material. Weight ratios of KRATON to oil as low as 1 to 5 have been contemplated for a more rigid structure. As the KRATON/oil weight ratio approaches 1 to 10, the mixture becomes more liquid. Ratios as high as 1 to 15 have been contemplated for this invention.

The processing temperature can also vary considerably as it is primarily dependent on the type of KRATON used. Temperatures in a range of about 150° centigrade to about 250° centigrade have been contemplated.

With an appreciation that these ratios and temperatures can develop considerably different properties, it is now apparent that these materials can be layered to provide generally different properties within each layer. For example, an outer layer might be formed of a KRATON/oil mixture having more rigid properties, thereby providing the pad **35** with an outer layer that is more rigid. After that layer is at least partially cured, another layer of the material can be poured inside of the outer layer. This second layer might be softer providing the pad **35** with the significant sealing properties. It has been found that successive layers will tend to fuse slightly at their interface, but will generally maintain their separate identities. Additional layers could be added to provide a progression of properties in a particular device.

Having discussed the properties desirable for the gel material, and the process of manufacture, one can now address the other embodiments of the concept which may provide additional advantages for particular surgical procedures. An embodiment of the access device **34**, shown in its operative position in FIG. **6**, is illustrated by itself in the axial cross section view of FIG. **8**.

This same embodiment can be reinforced with O-rings **61** and **63** as illustrated in FIG. **9** where elements of structure are designated by the same reference number followed by the lower case letter "b." Providing these O-rings **61** and **63** may facilitate several functions associated with the access device **34***b*. For example, the rings **61**, **63** will typically aid in maintaining a radial sealing pressure on all sides of the opening **45***b*. The rings **61** and **63** will also tend to maintain the flanges **54***b* and **56***b* respectively, in their generally planar configurations. This further ensures that the flanges **54**, **56** will not collapse into the incision **32** with the insertion or withdrawal of an instrument, such as the surgeon's hand **17**. Of course, the o-rings **61** and **63** must be sufficiently large to accommodate the instrument during insertion and removal.

A further embodiment of the invention is illustrated in FIG. **10**, where elements of structure are similar to those previously disclosed are designated with the same reference numerals followed by the lower case letter "c." This embodiment includes the pad **35***c* with the opening or slit **45***c*. The external perimeter o-ring **61***c* is inserted molded into the circumference of the pad **35***c*. The internal o-ring **63***c* is coupled to the pad **35***c*, for example, by way of attachment to the o-ring **61***c* for example, by a membrane **65**. In this case, the membrane **65** has a generally cylindrical configuration and elastomeric properties. In preferred embodiments, the membrane **65** is formed of urethane, neoprene or isoprene.

When the embodiment of FIG. **10** is being operatively positioned, the internal o-ring **63***c* is initially gathered and inserted through the incision **32** (FIG. **2**). The pad **35***c* and external o-ring **61***c* are left outside the incision **32** so that the only material extending across the incision **32** is the membrane **65**. It will be noted that in this case, the working channel **36***c* is formed by the slit **45***c*, the cylindrical membrane **65**, and the internal o-ring **63***c*. Pneumoperitoneum pressure is illustrated by a plurality of arrows **58***c*.

In this particular embodiment, the pad **35**c functions generally as described with reference to FIG. **2**. The primary seal between the pad **35***c* and the abdominal wall **21** can be formed either with a circumferential ring, such as the adhesive ring **52***c*, or by relying on the sealing characteristics of the insufflation gas against the internal o-ring **63***c* and membrane **65**.

This embodiment of FIG. **10** is of particular advantage as it incorporates the pad **35***c* in perhaps its simplest configuration, while providing a primary seal between the device **34***c* and the abdominal wall **21** which is facilitated by the insufflation pressure. Furthermore, the membrane **65** enhances the sealing characteristics of the device **34***c*, and provides a lining for the incision **32**. With the membrane **65**, the incision **32** need not be stretched to a diameter greater than that required by any instrument inserted through the working channel **36***c*.

A further embodiment of the invention is illustrated in FIG. **11** where elements of structure similar to those previously disclosed are designated with the same reference numeral followed by the lower case letter "d." This embodiment is similar to that of FIG. **8** in that it includes the pad **35***b*, slit **45***d*, exterior flange **54***d*, and internal flange **56***d*. The embodiment of FIG. **11** differs from that of FIG. **8** in that it includes a lead-in cavity **70** which is in communication with the slit **45***d*.

In a preferred embodiment, this cavity **70** is sized and configured to receive the arm **16** of the surgeon **14** in a manner illustrated in FIG. **7**. In this case, the slit **45***d* would function primarily to maintain a zero seal, while the portions of the pad **35***d* or flange **54***d* which form the cavity **70** would function primarily to form the instrument seal.

A further embodiment of the invention is illustrated in the plan view of FIG. **12** and the cross section views of FIGS. **13** and **14**. In this embodiment, elements of structure similar to those previously discussed are designated with the same reference numeral followed by the lower case letter "e." In this case, the lead-in cavity has the general shape of a cylinder **72** with an axis that is collinear with the axis **47***e* of the pad **35***e*.

As perhaps best illustrated in FIG. **13**, the slit **45***e* has a trapezoidal configuration. Thus, it begins proximally with a narrow length which may generally be equivalent to the diameter of the cylinder **32**. From the cavity **70***e*, the length of the slit **45***e* increases with progressive positions distally through the pad **35***e*. In the illustrated embodiment, the trapezoidal slit **45***e* is formed as the frustum of an isosceles triangle.

A further embodiment of the invention is illustrated in FIGS. **15** and **16** wherein elements of structure similar to those previously described are designated with the same reference numeral followed by the lower case letter "f." As previously discussed with reference to FIG. **12**, this embodiment of the pad **35***f* is formed with a proximal surface **71** and a distal surface **73**. The pad **35***f* also includes the coaxial lead-in cylinder **72***f* and the trapezoidal slit **45***f*. However, in

this case, a duck-bill valve **74** is provided to further enhance the characteristics of the zero zeal. As illustrated, the working channel **36***f* is formed by the lead-in cavity **70***f*, the slit **45***f*, and an extension of the slit **45***f* which is defined by the duck-bill valve **74***f*.

The duck-bill valve **72** can be formed with opposing flanges **76** and **78** which extend distally of the distal surface **73**. When operatively disposed, the pad **35***f* can be positioned with its distal surface **73** against the exterior surface of the abdominal wall **21** (FIG. **2**) and with the flanges **76** and **78** extending into the incision **32**. With this configuration and operative disposition, the abdominal wall **21** at the incision **32** will produce opposing forces on the flanges **76** and **78** which tend to close the slit **45***f*, particularly in the absence of an instrument. In this manner, the duck-bill valve **74** can be relied on to enhance the characteristics of the zero seal.

A further embodiment of the invention is illustrated in FIGS. **17** and **18** wherein elements of structure similar to those previously discussed are designated by the same reference numeral followed by the lower case letter "g." In this embodiment of the access device **34***g*, the pad **35***g* can be formed generally as discussed with reference to FIG. **13**. In this embodiment, however, the pad **35***g* can be enclosed along its sides and the distal surface **73***g*, by a base **81**. In this case, the pad **35***g* might be formed by the highly elastic material previously discussed, while the base **81** might be formed of a more rigid but nevertheless flexible material such as a urethane. With this configuration, the duck-bill valve **74***f* would be structured to extend distally of a distal surface **83** associated with the base **81**. This would enable the duck-bill valve **74***f* to be formed of the base material rather than the super-elastic material. This might also improve the zero seal characteristics for particular operative applications.

Another simplified form of the invention is illustrated in FIGS. **19** and **20**, where elements of structure similar to those previously discussed or designated with the same reference numeral followed by the lower case letter "h." The lead-in cavity **78***h*, in this case, is formed as an inverted cone **77** having its base at the proximal surface **71***h* and its apex in proximity to the distal surface **73***h*. Thus, the lead-in cavity **70***h* has an area in radial cross section which decreases with progressive positions distally through the pad **35***h*. In this embodiment, the proximal regions near the base of the cone **87** form the instrument seal, while the distal regions at the apex of the cone form the zero seal. The conical configuration of the lead-in cavity **70***h* also tends to funnel an instrument into the opening **45***h* leading distally to the apex of the cone **87**.

It will be appreciated generally, that the slit **45** and lead-in cavity **70** can be provided with many different individual and cooperative configurations. By way of example, perhaps the simplest form for the pad **35** is illustrated in the embodiment of FIGS. **21** and **22** wherein elements of structure similar to those previously described are designated by the same reference numeral followed by the lower case letter "j." In this embodiment, the pad **35***j* with its proximal surface **71***j* and distal surface **73***j*, is provided with a simple trapezoidal slit **45***j*. In this case, the slit **45***j* extends between the proximal surface **71***j* and the distal surface **73***j*.

The slit **45***j* in this embodiment of FIG. **21** is typical of many structures which will define the slit **45***j* with a planar configuration. In such a case, the portions of the pad **35***j* which form the slit will comprise opposing planar surfaces such as those designated by the reference numerals **90** and **92** in FIG. **22**.

It will be apparent that the slit **45** need not be formed by opposing surfaces having a planar configuration. Nevertheless, these opposing surfaces need to be capable of coming into sealing contact with each other in order to establish the zero seal. Other slit configurations capable of accomplishing this function, may offer further advantages in particular procedures. Other examples of slit configurations are illustrated merely by way of example in FIGS. **23-26**.

The embodiment of FIG. **23** is similar to that of FIG. **22** in that the opening **45***j* comprises a single slit which extends from the proximal surface **71***j* to the distal surface **73***j*. In the case of the FIG. **22** embodiment, the axis **47***j* is disposed within the plane of the slit **45***j*. In the case of the FIG. **23** embodiment, the plane of the slit **45***j* does not include the axis **47***j*. Rather, the slit **45***j* is formed in a plane which has an angular relationship with the axis **47***j*, the proximal surface **71***j*, as well as the distal surface **73***j*. This construction enables the slit **45***j* to have a length greater than the thickness of the pad **35***j*.

In the embodiment of FIG. **24**, elements of structure similar to those previously discussed are designated with the same reference numeral followed by the lower case letter "k." In this case, the opening **45***k* is configured as two slits **94** and **96** formed in individual planes that are angularly spaced with respect to each other. Of course, two or more of the planar slits **94** and **96** may be equally angularly spaced around the axis **47***k*. In one embodiment, the individual planar slits **94** and **96** intersect at the axis **47***k*. Alternatively, the slits **94** and **96** may be axially spaced in order to facilitate formation of the instrument seal.

In the embodiment of FIG. **25**, elements of structure similar to those previously discussed are designated with the same reference numeral followed by the lower case letter "m." In this embodiment, the opening **45***m* is defined as a slit **98** having a curved rather than planar configuration. In the illustrated embodiment, the curved slit **98** is formed as a spiral around the axis **47***m*. Along the axis **47***m*, the opposing surfaces forming the spiral slit **98** can "flow" into sealing proximity in order to produce the zero seal.

FIG. **26** illustrates a similar embodiment including a spiral slit. In this figure, elements of structure similar to those previously discussed are designated by the same reference numeral followed by the lower case letter "n." The spiral slit **98***n* in this embodiment is also formed around the axis **47***n* of the pad **35***n*, but in this case the portions forming the slit **98***n* do not extend completely to the axis **47***n*. As a result, an axial channel **100** is formed at least partially along the axis **47***n*. This channel **100** can function in a manner similar to the lead-in cavity **70** discussed with reference to FIGS. **11-12**. This channel **100** can even be formed with a conical configuration similar to that discussed with reference to FIG. **19**.

In an embodiment where the channel **100** is left open, a zero seal might be provided by positioning a septum valve across the channel **100**. Such an embodiment is illustrated in FIG. **27**, wherein the septum valve is designated with a reference numeral **101** and the other elements of structure similar to those previously discussed are designated with the same reference numerals followed by the lower case letter "p." Thus the embodiment of FIG. **27** includes the spiral slit **98***p*, the pad **35***p*, and the axis **47***p*. This embodiment of FIG. **27** is merely representative of many other embodiments that will combine a slit, such as the slit **98***p*, with other valve structures, such as the septum valve **101**.

Other curved slit configurations would include embodiments wherein the slit is curved, sinusoidal, or S-shaped in a side elevation view. Such configurations provide a slit part having a length greater than the thickness of the pad. Normally, the more circuitous the slit path, the better the sealing characteristics.

A further and more complex configuration for the opening **45** is illustrated in the embodiment of FIG. **28** wherein elements of structure similar to those previously disclosed are designated with the same reference numeral followed by the lower case letter "q." This embodiment is representative of many other complex embodiments which can be formed with intricate shapes and different materials in order to accomplish the desirable function of forming, with a single valve, a zero seal as well as an instrument capable of accommodating a full range of instrument sizes. In the embodiment of FIG. **28**, the pad **35***q* is formed with a base **110** which is disposed circumferentially of a core **112**. In this case, the core **112** is formed of the superelastic material or gel and provided with the shape of the cone **87***q* as discussed with reference to FIGS. **19** and **20**. The base **110** is formed from a material that may not be elastic, but preferably is flexible. In the preferred embodiment, the base **110** is formed of a urethane.

In this construction, the base **110** is provided with a plurality of spokes **114** each of which extends radially inwardly from a base **116** to a tip **118**. The core **112** extends from the axis **47***q* outwardly to the tips **118** of the spokes **114**. In the illustrated embodiment, the core **112** has fingers **121** which extend beyond the tips **118** and toward the bases **116** between each adjacent pair of the spokes **114**. These fingers **121** extend radially outwardly to an end surface **123** which stops short of the base **116** leaving a void **125** therebetween.

The voids **125** are of particular interest to this embodiment and can be incorporated into any of the embodiments previously discussed. Such voids **125** provide a space or absence of material into which the highly elastic material, such as that of the fingers **121**, can expand during insertion of an instrument such as the arm **16** (FIG. **7**). Since the gel material is almost fluid in its properties, the voids **125** permit expansion of the gel with very little resistance. Voids, such as the voids **125** in the embodiment of FIG. **28**, can be defined solely in the gel material or between the gel material and any other base material.

In the case of FIG. **28**, the spokes **114** and fingers **121** are defined generally in planes which are parallel to the axis **47***q*. Similar fingers, illustrated in the embodiment of FIG. **31** are defined generally in a plane which is perpendicular to the axis. In this embodiment, elements of structure similar to those previously disclosed are designated by the same reference numeral followed by the lower case letter "r." As illustrated, the pad **35***r* can be formed with a relatively large opening **45***r* having the configuration of a coaxial cylinder **130**. A plurality of fingers or flaps **132** extend into the opening **45***r* and tend to form a lead-in cavity **70***r* with properties such as those discussed with reference to FIG. **19**. In this case, the annular flaps **132** have a conical configuration extending from a base **134** to an apex **136**. It will be noted that the areas between the flaps **132**, form voids **125***r* into which the flaps **132** can be displaced upon insertion of an instrument, such as the arm **16**.

A further embodiment of the invention is illustrated in FIG. **32** where elements of structure similar to those previously disclosed are designated with the same reference numeral followed by the lower case letter "s." This exploded view of the access device **34***s* includes not only the pad **35***s* but also a complimentary structure for maintaining the position of the pad **35***s*, for forming a seal between the pad **35***s* and the abdominal wall **21**, and for dilating the incision **32** to a variable extent as required by the surgeon **14**. In this case, the access device **34***s* includes three components, a gel cap **143**, base **145**, and a retraction sheath **147**.

The gel cap **143** includes not only the gel pad **35***s*, but also a circumferential cap ring **154** which can be inserted and molded to the pad **35***s*. The resulting gel cap **143** forms a seal with the base **145**, thereby defining the working channel **36***s* through the pad **35***s*, the cap ring **154**, the base **145**, and the retraction sheath **147**. In the manner previously discussed, this working channel **36***s* includes the single valve formed by the gel pad **35***s* which provides both a zero seal and an instrument seal for a wide range of instrument diameters.

The structure associated with the gel cap **143** is described in greater detail with reference to FIGS. **33** and **34**. In the plan view of FIG. **33**, it can be seen that this embodiment includes the gel pad **35***s* centrally disposed within the circumferential cap ring **154**. Holding tabs **156** can be provided to extend radially outwardly of the cap ring **154**. These holding tabs **156** can facilitate the sealing engagement of the gel cap **143** with the base **145** in the manner described in greater detail below.

The gel pad **35***s* can be formed of any of the materials previously discussed although the preferred embodiment includes the KRATON/mineral oil gel. The cap ring **154** for such an embodiment can be advantageously formed of KRATON only. This will make the cap ring **154** more rigid than the gel pad **35***s* while maintaining an excellent material interface between the pad **35***s* and the ring **154**. In a typical manufacturing operation, the cap ring will be pre-disposed in the mold for the gel pad **35***s* with the unitary structure of the gel cap **143** resulting.

The cross section view of FIG. **34** shows the gel cap **143***s* and illustrates an annular void **158** formed on the inner circumference of the cap ring **154**. This void **158** is of particular advantage in forming a sealing relationship with the base **145** in the manner discussed in greater detail below.

The base **145** of this embodiment is shown in greater detail in the plan and cross section of views of FIGS. **34** and **35**, respectively. From these views it will be noted that the base **145** can be provided with a smooth generally cylindrical inner surface **161** which extends proximally to a rounded end surface **163** and outwardly from the end surface **163** along an annular lip **165**. A plurality of tabs **167** can be equally spaced to extend outwardly and distally around the circumference of the lip **165**.

Distally of the inner surface **163**, an annular flange **170** can be provided with an annular projection **172** sized and configured to form the desired sealing relationship between the gel cap **143** and the base **145**. The process of molding the base **145** can be facilitated by forming the base as two separate components divided, for example, by a dotted line **174** in FIG. **35**. In a preferred embodiment, the base **145** is molded from a polycarbonate material.

A preferred embodiment of the retracting sheath **147** is illustrated in FIG. **37**. In this view it can be seen that the retraction sheath **147** includes a tubular wall **175** which has the configuration of the frustum of a cone **176** at its distal end and the configuration of a cylinder **177** at its proximal end. A flexible retaining ring **152** terminates the distal end while a fold **154** is formed at the proximal end. The tubular wall **175** is illustrated to include an outer surface **180** and an inner surface **181**. In a preferred embodiment, the sheath **147** is formed of an elastomer, such as neoprene, so its frustule conical and cylindrical configurations exist primarily in the natural unstretched state.

As the sheath **147** is stretched axially, the diameter of the cylindrical proximal end increases thereby placing radial forces on the incision **32**. The more the sheath **147** is stretched axially, the greater becomes the diameter of the sheath and consequently the larger becomes the opening through the incision **32**. This feature is of particular advantage as it permits the surgeon to define the size of the incision **32** with an appropriate degree of axial tension on the sheath **147**. By

maintaining this tension, the preferred size of the incision **132** is maintained throughout the operation. In a preferred apparatus and method, the axial tension is maintained by stretching the sheath **147** over the tabs **167** (FIG. **34**) of the base **145**. Indicia **182** can be printed on the sheath **147** to provide an indication of the relationship between the axial stretch of the sheath **147** and the size of the incision **32**.

The fold **153** is provided to facilitate a grip on the proximal end of the sheath **147**. This fold **153** can also function to provide reinforcement where the walls of the sheath **147** engage the tabs **167** of the base **145**. In the embodiment illustrated in FIG. **38** additional folds **184**, **186** are provided at spaced axial locations, such as those defined by the indicia **182** in FIG. **37**. With these folds **184** and **186**, additional points of reinforcement are provided to engage the tabs **167** while providing the sheath **147** with predetermined degrees of axial stretch associated with different sizes of the incision **32**.

The method of using the embodiment of FIG. **32** is illustrated the progressive use of FIGS. **39-42**. In FIG. **39**, a top plan view of the abdominal wall **21** of the patient **10** is illustrated with a template **195** positioned to facilitate location of the incision **32**. The size of the incision **32** can be determined with the indicia **182** on the template **195** showing, for example, multiple lengths of a line **197**, each length being equated with a glove size for the surgeon's hand **17** (FIG. **7**). Knowing his/her glove size, the surgeon will merely cut the incision in accordance with an appropriate length of the line **197**. The longer lengths of the line **197** are associated with the larger incisions, the larger glove sizes and accordingly the larger hands **17**. After the incision **32** has been cut along the line **197**, the template **195** can be removed.

As illustrated in FIG. **40**, the retraction sheath **147** can then be mounted through the incision **32**. Initially the ring **152** is compressed and fed through the incision **32**. On the inner surface of the abdominal wall **21**, the ring **152** is free to expand to its larger diameter, as shown by a dotted line **158** in FIG. **40**. The portions of the wall **176** which define the cylinder **177** are left to extend proximally through the opening **32** as shown in FIG. **40**.

Prior to or after inserting the sheath **147**, the base **145** can be disposed around the incision **32**. Then the exposed portions of the sheath **147** will extend through the incision **32** and within the circumferential base **145**. As illustrated in FIG. **41**, the wall **176** of the sheath **147** can then be drawn proximally, outwardly of the page in FIG. **41**, to axially stretch the sheath **147**. As noted, when the sheath **147** is axially stretched, it will create radial forces on the abdominal wall **21** which will tend to enlarge the incision **32**. The greater the axial stretch, the larger the incision **32**.

When the incision **32** has the desired size, the stretched sheath **147** can be drawn over the tabs **167** to maintain the axial stretch and the desired size for the incision **32**. Either the indicia **182**, as shown in FIG. **36**, or the additional folds **184** and **186** as shown in FIG. **37**, can be aligned with the tabs **167** to provide a predetermined size for the incision **32**. At this point, the seal between the abdominal wall **21**, the sheath **147**, and the base **145** is fully established.

A final step remaining in this process is the attachment of the gel cap **143** to the base **145**. This is accomplished as illustrated in FIG. **36** by capturing the lip **172** of the base **145** in the annular void **158** of the gel cap **143**. Bending the holding tabs **156** upwardly and outwardly facilitates this engagement which ultimately forms a seal between the base **145** and the gel cap **143**.

Although this invention has been disclosed with reference to certain structural configurations, it will be appreciated that these products are merely representative of many different embodiments of the invention. Accordingly, one is cautioned not to limit the concept only to the disclosed embodiments, but rather encouraged to determine the scope of the invention only with reference to the following claims.

What is claimed is:

1. A surgical hand port for laparoscopic surgical procedures wherein an incision is made in a body wall of a patient and an abdominal cavity is pressurized with an insufflation gas, the hand port is adapted to provide access to the abdominal cavity for surgical procedures while maintaining insufflation pressure in the abdominal cavity, comprising:

a gel seal valve, comprising:

a support ring, wherein the support ring is configured to be aligned with an axis of an access channel defined at least in part by the incision extending through the body wall of a patient; and

a gel pad coupled with the support ring, the gel pad being disposed substantially within the support ring and supported at least partially thereby, the gel pad comprising a molded mixture of an elastomer and an oil, wherein the elastomer comprises at least one of polyurethane, polyvinylchloride, polyisoprene, a thermoset elastomer, a thermoplastic elastomer, a tri-block copolymer, styrene-ethylene/butylene-styrene block copolymer, styrene-isoprene-styrene, styrene-butadiene-styrene, styrene-ethylene/propylene-styrene, and wherein the oil comprises at least one of mineral oil, vegetable oil, petroleum oil, and silicone oil, the gel pad having an ultimate elongation greater than about 1000 percent and a durometer less than about 5 Shore A, the gel pad being sized and shaped for disposition relative to the access channel defined at least in part by the incision extending through the body wall of the patient, the gel pad is configured to form a seal with an instrument extending through the gel pad and form a seal in the absence of any instrument extending through the gel pad, the gel pad is adapted to accommodate a range of instrument sizes from about the size of a guidewire to about the size of a surgeon's arm.

2. The surgical hand port of claim **1**, wherein the gel pad is adapted to accommodate a range of instrument sizes from about two French to about four inches.

3. The surgical hand port of claim **1**, wherein the gel pad is adapted to accommodate a range of instrument sizes from about 3 mm to about three inches.

4. The surgical hand port of claim **1**, wherein the gel pad is molded to the support ring.

5. The surgical hand port of claim **1**, wherein the gel pad comprises an ultra gel.

6. The surgical hand port of claim **1**, wherein the gel pad comprises and mineral oil.

7. The surgical hand port of claim **1**, wherein the elastomer and oil mixture of the gel pad comprises about one part styrene-ethylene/butylene-styrene polymer with about nine parts mineral oil.

8. The surgical hand port of claim **1**, wherein the gel pad comprises a slit.

9. The surgical hand port of claim **1**, wherein the gel pad comprises an unencapsulated gel material.

10. The surgical hand port of claim **1**, wherein the gel seal valve is configured to be coupled to an adjustable wound retractor.

11. The surgical hand port of claim **1**, wherein the gel seal valve is configured to be removably coupled to an adjustable wound retractor.

12. The surgical hand port of claim **1**, further comprising an adjustable wound retractor comprising a distal ring, a proxi-

mal ring, and a retraction sheath extending between the distal ring and the proximal ring during use, wherein the adjustable wound retractor is configured to provide variable retraction of an incision in a patient, provide a seal between the adjustable wound retractor and the incision, and define at least a portion of a working channel.

13. A surgical access device adapted to provide access to a cavity in a patient while maintaining a seal between the cavity and an area outside the patient, comprising:

a gel seal, comprising a ring and a gel pad;

wherein the ring is configured for alignment with an axis of an access channel defined at least in part by an incision extending through a body wall of a patient,

wherein the gel pad is coupled with the ring, disposed substantially within the ring and supported at least partially thereby, the gel pad comprises a mixture of an elastomer and an oil, the gel pad comprises a self-sealing valve and defines at least a portion of an access channel, the self-sealing valve is configured to conform around an object extending through the self-sealing valve and seal the working channel in the absence of an object extending through the self-sealing valve, the gel pad is adapted to accommodate a range of instrument sizes from about the size of a guidewire to about the size of a surgeons' arm, and

wherein the gel pad has an ultimate elongation greater than about 1000 percent and a durometer less than about 5 Shore A.

14. The surgical access device of claim **13**, wherein the gel pad is adapted to accommodate a range of instrument sizes from about two French to about four inches.

15. The surgical access device of claim **13**, wherein the gel pad is adapted to accommodate a range of instrument sizes from about 3 mm to about 12 mm.

16. The surgical access device of claim **13**, wherein the gel pad is adapted to accommodate a range of instrument sizes from about 9 mm to about 12 mm.

17. The surgical access device of claim **13**, wherein the gel pad is adapted to accommodate a range of instrument sizes from about 5 mm to about 9 mm.

18. The surgical access device of claim **13**, wherein the gel pad is adapted to accommodate a range of instrument sizes from about 3 mm to about 5 mm.

19. The surgical access device of claim **13**, wherein the elastomer comprises at least one of polyurethane, polyvinylchloride, polyisoprene, a thermoset elastomer, a thermoplastic elastomer, a tri-block copolymer, styrene-ethylene/butylene-styrene block copolymer, styrene-isoprene-styrene, styrene-butadiene-styrene, styrene-ethylene/propylene-styrene.

20. The surgical access device of claim **13**, wherein the oil comprises at least one of mineral oil, vegetable oil, petroleum oil, and silicone oil.

21. The surgical access device of claim **13**, wherein the gel pad being sized and shaped for disposition relative to the access channel defined at least in part by the incision extending through the body wall of the patient.

22. The surgical access device of claim **13**, wherein the gel pad comprises an ultra gel.

23. The surgical access device of claim **13**, wherein the gel pad comprises a slit.

24. The surgical access device of claim **13**, wherein the gel seal valve is configured to be coupled to an adjustable wound retractor.

25. The surgical access device of claim **13**, wherein the gel seal valve is configured to be removably coupled to an adjustable wound retractor.

26. The surgical access device of claim **13**, further comprising an adjustable wound retractor comprising a distal ring, a proximal ring, and a retraction sheath extending between the distal ring and the proximal ring during use, wherein the adjustable wound retractor is configured to provide variable retraction of an incision in a patient, provide a seal between the adjustable wound retractor and the incision, and define at least a portion of a working channel in communication with the access channel.

* * * * *

EXHIBIT E

APMED.088C3 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Ewers, et al.
App. No	:	13/421,730
Filed	:	March 15, 2012
For	:	SURGICAL ACCESS APPARATUS AND METHOD
Examiner	:	Tuan Van Nguyen
Art Unit	:	3731
Conf No.	:	5977

AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The present Amendment and remarks are in response to the Office Action dated August 20, 2012. Please amend the above-referenced application as follows:

Amendments to the Claims, which are reflected in the listing of claims that begins on page 2 of this paper; and

Remarks, which begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

1. **(Currently Amended)** A surgical access device, comprising:

a non-inflatable access port sized to span a thickness of an abdominal wall of a patient and adapted to permit access of at least one surgical instrument through an incision in ~~an~~ the abdominal wall of ~~a~~ the patient and into an abdominal cavity, wherein the access port comprises a proximal portion, a distal portion, and an intermediate portion between the proximal portion and the distal portion, wherein an opening extends through the access port between the proximal portion and the distal portion,

wherein the proximal portion comprises a proximal flange having a proximal flange diameter, wherein the proximal portion has a proximal surface portion and a distal surface portion, wherein the proximal surface portion at least partially defines a concave area ~~and wherein the proximal portion comprises a proximal surface wherein at least a portion of the proximal surface comprises a concave portion defining a cavity~~,

wherein the distal portion comprises a distal flange having a distal flange diameter,

wherein the proximal flange, the distal flange, and the intermediate portion are monolithically formed of an elastomeric material ~~a flexible material~~, wherein the intermediate portion comprises an outer surface and at least one inner surface, the outer surface has a diameter that is less than the proximal and distal flange diameters, the inner surface at least partially defines the opening, and

wherein the access port is sized and adapted to be disposed within the abdominal wall in an operative position, wherein disposition of the access port within the abdominal wall maintains the access port in the operative position and forms a perimeter seal between the outer surface and the abdominal wall when the intermediate portion is disposed across the incision and positioned within the incision with the proximal flange disposed exteriorly of the abdominal wall and the distal flange disposed interiorly of the abdominal wall, and wherein the access port is adapted to form a seal with the at least one surgical instrument positioned through the access port, wherein the intermediate portion conforms to the surface of the surgical instrument positioned through the opening and forms the seal between the inner surface and the surgical instrument.

2. **(Previously Presented)** The device of Claim 1, wherein the opening accommodates a wide range of instrument sizes.

3. **(Canceled)**

4. **(Original)** The device of Claim 1, wherein the access port is adapted to maintain a sealing relationship with a plurality of instruments positioned through the access port while accommodating relative movement between the plurality of instruments.

5. **(Original)** The device of Claim 1, wherein the proximal flange diameter is equal to the distal flange diameter.

6. **(Currently Amended)** The device of Claim 1, wherein the elastomeric material ~~flexible material~~ comprises a thermoplastic elastomer.

7. **(Currently Amended)** The device of Claim 1, wherein the elastomeric material ~~flexible material~~ comprises a triblock copolymer.

8. **(Currently Amended)** The device of Claim 1, wherein the elastomeric material has a foam structure ~~flexible material comprises a foam material~~.

9. **(Currently Amended)** A surgical access device, comprising:

a non-inflatable access port sized to span a thickness of an abdominal wall of a patient and adapted to permit access of at least one surgical instrument through an incision in ~~an~~ the abdominal wall of ~~a~~ the patient and into an abdominal cavity, wherein the access port comprises a proximal portion, a distal portion, and an intermediate portion between the proximal portion and the distal portion, wherein an opening extends through the access port between the proximal portion and the distal portion,

wherein the proximal portion comprises a proximal flange having a proximal flange diameter, wherein the proximal portion has a proximal surface portion and a distal surface portion, wherein the proximal surface portion at least partially defines a concave area,

wherein the distal portion comprises a distal flange having a distal flange diameter,

wherein the proximal flange, the distal flange, and the intermediate portion are monolithically formed of an elastomeric material ~~a flexible material~~, wherein the intermediate portion comprises an outer surface and at least one inner surface, the outer

surface has a diameter that is less than the proximal and distal flange diameters, the inner surface at least partially defines the opening, wherein the elastomeric material ~~flexible material~~ of the intermediate portion extends between the outer surface and the at least one inner surface, wherein the elastomeric material ~~flexible material~~ comprises a thermoplastic elastomer, and

wherein disposition of the access port within the abdominal wall maintains the access port in an operative position with the intermediate portion exerting a force on the incision forming a seal between the elastomeric material ~~flexible material~~ and the abdominal wall when positioned within the incision with the proximal flange disposed exteriorly of the abdominal wall and the distal flange disposed interiorly of the abdominal wall, and wherein the access port is adapted to form a seal with the surgical instrument positioned through the access port, wherein the elastomeric material ~~flexible material~~ conforms to the surface of the surgical instrument positioned through the opening and forms the seal within the intermediate portion between the proximal flange and the distal flange.

10. **(Currently Amended)** The device of Claim 9, wherein the thermoplastic elastomer ~~flexible material~~ comprises a triblock copolymer.

11. **(Currently Amended)** The device of Claim 10, wherein the triblock copolymer ~~flexible material~~ comprises Styrene-Ethylene/Butylene-Styrene.

12. **(Currently Amended)** The device of Claim 10, wherein the thermoplastic elastomer ~~flexible material~~ comprises an oil.

13. **(Currently Amended)** The device of Claim 12, wherein the thermoplastic elastomer has a foam structure ~~flexible material comprises a foam material~~.

14. **(Canceled)**

15. **(Canceled)**

16. **(Previously Presented)** The device of Claim 9, wherein the opening is configured to self seal in the absence of any instrument extending through the opening.

17. **(Currently Amended)** The device of Claim 9, wherein the ~~proximal portion comprises a~~ proximal surface portion has ~~having~~ a proximal surface area, and the distal portion comprises a distal surface portion having a distal surface area less than the proximal surface area.

18. **(Canceled)**

19. **(Canceled)**

20. **(Canceled)**

21. **(Previously Presented)** The device of Claim 1, wherein the access port has a single opening.

22. **(Previously Presented)** The device of Claim 1, wherein the surgical instrument is a trocar.

23. **(Previously Presented)** The device of Claim 1, comprising a trocar configured for placement through a further opening in the access port.

24. **(Previously Presented)** The device of Claim 13, wherein a second instrument is configured for placement through a second opening in the access port.

25. **(Currently Amended)** A surgical access device, comprising:

a non-inflatable access port and an instrument, wherein the access port is sized to span a thickness of an abdominal wall of a patient and adapted to permit access of the instrument through an opening in ~~a~~ the patient and into a body cavity, wherein the access port comprises a proximal portion, a distal portion, and an intermediate portion between the proximal portion and the distal portion, wherein a channel extends through the access port between the proximal portion and the distal portion,

wherein the proximal portion comprises a proximal flange having a proximal flange diameter, wherein the proximal portion has ~~and~~ a proximal surface portion having a proximal surface area, wherein at least a portion of the proximal surface area defines a concave area ~~is curved~~,

wherein the distal portion comprises a distal flange having a distal flange diameter, wherein the distal portion has a distal surface portion having a distal surface area,

wherein the proximal flange, the distal flange, and the intermediate portion are monolithically formed of an elastomeric material, wherein the intermediate portion comprises an outer surface and an inner surface, the outer surface has a diameter that is less than the proximal and distal flange diameters, the inner surface at least partially defines the channel,

wherein the access port is configured to be positioned within the opening in the patient with the intermediate portion disposed across the opening with the proximal flange disposed exteriorly of the opening and the distal flange disposed interiorly of the opening, wherein disposition of the intermediate portion within the opening provides a compressive force between the access port and the opening, and the instrument is a trocar configured to be positioned through the channel of the access port, wherein the intermediate portion is adapted to provide a seal with the surface of the instrument.

26. **(New)** The device of Claim 25, wherein the distal surface area is less than the proximal surface area.

27. **(New)** The device of Claim 25, further comprising an insufflation device adapted to deliver insufflation gas to the body cavity to pressurize the body cavity with the insufflation gas.

28. **(New)** The device of Claim 1, further comprising an insufflation device adapted to deliver insufflation gas to the abdominal cavity to pressurize the abdominal cavity with the insufflation gas.

29. **(New)** The device of Claim 9, further comprising an insufflation device adapted to deliver insufflation gas to the abdominal cavity to pressurize the abdominal cavity with the insufflation gas.

Application No.: **13/421,730**
Filing Date: **March 15, 2012**

REMARKS

Summary of Interview

Applicants thank the Examiner for the courteous interview and suggestions to clarify the claims and put the present application in condition for allowance. On September 20, 2012, Applicants' representatives, Curtis Huffmire and John Brustad, conducted an in-person interview with Examiner Tuan Nguyen. During the interview, U.S. Patent Nos. 6,099,506, 5,879,290, and 4,016,884 were discussed. Differences between Applicants' claimed inventions and the prior art of record were discussed. There was no dispute or issue during the interview with respect to the disclosure of references and/or prior art included in the IDS documents.

The pending claims were discussed and clarifying amendments were discussed among the Applicants' representatives and the Examiner with respect to Claims 1, 9 and 25. Agreement was reached among the Applicants' representatives and the Examiner on the claims. It was concluded that the agreed-upon amendments would overcome the outstanding rejections. Applicants' representatives agreed to prepare an amendment to put the case in condition for allowance as described herein.

Status of the Claims

Claims 1, 2, 4-13, 16, 17, and 21-29 are currently pending. Claims 3, 14, and 18-20 were canceled previously and Claim 15 is canceled by the present amendment, all without prejudice, disclaimer or disavowal to expedite prosecution of the application, and Applicants reserve the right to otherwise present the subject matter of these claims. Claims 1, 6-8, 9, 10-13, 17 and 25 have been amended by the present amendment. New Claims 26-29 have been added. Support for the amendments and new claims is found in one or more exemplary embodiments shown in Figures 1-31 and described in related portions of the specification and the originally pending claims.

Summary of Office Action

Claims 1, 2, 4, 5, 9, 15-17 and 21-25 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,099,506 to Macoviak et al. in view of U.S. Patent No. 5,879,290 to Bridges et al. Claims 6-9 and 10-13 were rejected under 35 U.S.C. § 103(a) as unpatentable over Macoviak in view of Bridges and further in view of U.S. Patent No. 4,016,884 to Kwan-Gett.

Applicants respectfully traverse the noted rejections, however, to expedite prosecution, Applicants have made clarifying amendments suggested in the interview. Applicants respectfully submit that the cited references, either in combination or individually, do not disclose or suggest the unique combinations of features recited in the currently pending claims. Applicants respectfully submit that the present Application is in condition for allowance.

Amendments Consistent with Examiner's Suggestions

To facilitate expeditious prosecution of this application, Applicants have amended the claims consistent with the clarifying suggestions discussed in the interview. Accordingly, Applicants submit that the claims are now in condition for allowance and respectfully request that the rejections be withdrawn.

For example, with respect to independent Claims 1, 9 and 25, the claims have been amended to clarify that a proximal surface portion at least partially defines a concave area.

Additionally, the term "flexible material" has been replaced with the term "elastomeric material." With respect to dependent Claims 6-8 and 10-13, the claims have been amended consistent with the suggestions discussed in the interview.

Accordingly, Applicants respectfully submit that the amended claims are in condition for immediate allowance.

New Claims are also Allowable

Applicants have added new claims that further distinguish over the art of record. New dependent Claims 26 and 27 recite additional patentable features and depend from independent Claim 25 and are thus in condition for allowance. New dependent Claim 28 recites additional patentable features and depends from independent Claim 1 and thus is in condition for allowance. New dependent Claim 29 recites additional patentable features and depends from independent Claim 9 and thus is in condition for allowance.

Terminal Disclaimer

Applicants have previously submitted a terminal disclaimer in this application.

No Disclaimers or Disavowals

Although the present communication may include alterations to the claims, or characterizations of claim scope or art of record, Applicant is not conceding in this application that previously pending claims are not patentable. Rather, any alterations or characterizations are

being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history should not infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Conclusion

Applicant believes that the claims are in condition for allowance and respectfully request the same. Applicant has submitted herewith the fees required for this Amendment. However, in the event that additional fees are required, the Examiner is authorized to charge such fees, including any fees for additional extension of time, to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: November 20, 2012

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14376609

EXHIBIT F

INTERNATIONAL CENTRE FOR DISPUTE RESOLUTION
International Arbitration Tribunal

In the Matter of the Arbitration between:

Re: 50 133 T 00316 06

Applied Medical Resources Corporation a California corporation	CLAIMANT
vs.	
Gaya Limited an Irish company	RESPONDENT

AWARD OF ARBITRATORS

WE, THE UNDERSIGNED ARBITRATORS, having been designated in accordance with the arbitration agreement entered into between the above-named parties dated February 23, 2000, having been duly sworn, and having duly heard all the proofs and allegations of the Parties which received a full and complete opportunity to present their respective case, do hereby, AWARD, as follows:

FACTS

Gaya was in the business of developing hand assisted laparoscopic surgical devices. ("HALS") On September 16 and 24, 1999, Gaya and Applied entered into a Secrecy Agreement subject to Irish law so they could negotiate a "mutually attractive business arrangement". The Secrecy Agreement had a four year term, and provided that Gaya's information's was confidential.

On February 23, 2000, the parties entered into a Patent License and Option Agreement (PLOA) subject to California law whereby Respondent granted to Claimant an exclusive License to market and sell in the US its "Intromit" product (the "Licensed product"). Under that agreement, Claimant agreed to 1) pay an up-front payment of $400,000, 2) grant 30,000 shares of Claimant's shares valued at $165,000 and 3) a promise to pay a 12.5% royalty on all revenues from the Licensed Products.

On March 23 and 24, 2000, Claimant's VP of Operations and Facilities (Johnson) and the Director of Product Development in the General Surgery Division (Taylor) visited Respondent's facilities in Ireland.

There is considerable dispute and controversy as to what was disclosed during that visit.

On or about July 2000, the Licensed product was introduced to the US market.

On or about May 2000, Claimant started to develop a new and competing product known and marketed as the "Gelport".

On August 31, 2000, Claimant requested and received from Respondent information contained in a "future development file for the Intromit" and design improvement proposals as well as prototypes and conducted an animal lab to test various prototypes including those it received from Respondent.

On October 13, 2000, Claimant's president (Hilal) disclosed and demonstrated to Respondent's president (Caldwell) a "Gelport" prototype and attempted to renegotiate the royalty fee on the Licensed products ("Intromit"). Caldwell remarked during that meeting that the gel seal device was Respondent's idea.

On or about June 2001, the "Gelport" was introduced to the market for $725 each compared to $450 for the Intromit.

On or about October 2002, Claimant launched its "Alexis" wound retractor.

On February 14, 2006, Respondent sued Claimant in Ireland for breach of the Secrecy agreement and consequently of the PLOA. Because of a broad arbitration clause contained in the PLOA, an Irish court ordered that all disputes under the Secrecy and the PLOA agreements be submitted to arbitration.

On July 7, 2006, Claimant filed this arbitration.

Parallel to this arbitration, the parties filed in California various patent infringement claims against each other. That action is unrelated to this arbitration.

In this arbitration, the parties agreed that Respondent would proceed first at the hearing because it had the burden of proof as to breach of the Secrecy Agreement and the PLOA.

CLAIMS

Claimant alleges that it "independently" developed the "Gelport" and "Alexis" products and did not use information provided by Respondent to do so and seeks a declaration from this panel that Claimant did not breach 1) the Secrecy Agreement nor the PLOA agreements and, 2) any duty of confidence and 3) that it be designated the prevailing party under paragraph 11.8 of the PLOA pursuant to which this arbitration was conducted.

Respondent counterclaims that Claimant "blatantly and intentionally breached the Secrecy Agreement and its duty of confidence" in using confidential information disclosed to it by Respondent in developing both the "Gelport" which incorporates concepts for external, detachable, self-sealing valves (such as twist valves and gel-type seals) with separate, adjustable wound retractors as disclosed by Respondent to Claimant, and the "Alexis" products resulting in contractual and other damages including :1) misappropriation damages in the amount of $ 2,716,411.47 (including Irish statutory interest rate of 8% per annum calculated to the date of the hearing); and 2) a 12.5% royalty calculated on the actual sale of the misappropriated product estimated at $1,713,824 as of the date of the hearing; and 3)

uncalculated damages under a disgorgement theory; and 4) unspecified exemplary damages to punish Claimant for its "egregious conduct"; and 5) reasonable attorneys' fees.

ANALYSIS

A threshold question to consider is whether the Secrecy Agreement, September 24, 1999, even applies to this dispute or whether, as Applied claims, it was superseded by the Patent License and Option Agreement.

In support of its argument, Applied points to the integration clause in the Patent License Agreement which provides that:

> It is the mutual desire and intent of the parties to provide certainty ***as to their future rights and remedies against each other*** by defining the extent of their mutual undertakings as provided herein. The parties have in this Agreement incorporated all representations, warranties, covenants, commitments and understandings on which they have relied in entering into this Agreement and, except as provided for herein, neither party has made any covenant or other commitment to the other concerning its future action. ***Accordingly, this Agreement constitutes the entire agreement and understanding between the parties with respect to the matters contained herein, and there are no prior oral or written promises, representations, conditions, provisions or terms related thereto other than those set forth in this Agreement.***

It argues that the PLOA supersedes the Secrecy Agreement to the extent that the California law provision of the PLOA controls this dispute, rather than Irish law as set forth in the Secrecy Agreement. Applied does however agree and accept that the Secrecy Agreement governs the treatment of confidential information exchanged between the parties. (See Applied Post-Hearing Brief, at 7 ("The parties agree that the Secrecy Agreement of September 24, 1999 governed the treatment of confidential information exchanged between the parties.")

The Panel disagrees with Applied on this point.

First, the Panel does not agree that the integration clause supersedes the Secrecy Agreement to the extent Applied asserts. The integration clause in the PLOA provides "*this Agreement constitutes the entire agreement and understanding between the parties with respect to the matters contained herein.*" The Secrecy Agreement, however, does not fully overlap with the PLOA, and to the extent it does not, the PLOA does not supersede it. Further, there is no mention of the Secrecy Agreement in Section 1 of the PLOA.

Second, the Panel does not agree with Applied's argument that California law applies to the Secrecy Agreement in any case. The PLOA states that "The law of the state of California, U.S.A., shall apply to the arbitration proceedings." It strikingly does not state that California law governs the interpretation of the contract, or disputes arising out of it. There is a difference between the substantive law governing the dispute and the procedural law governing an arbitration proceeding, and the PLOA reflects only an intent to have California procedural law apply to the arbitration proceeding..

We find, therefore, that the Secrecy Agreement applies to this dispute and that it should be resolved pursuant to Irish law. We turn to the question of whether, applying Irish law, Applied breached the Secrecy Agreement.

Under the Secrecy Agreement, as governed by Irish law, Claimant was prohibited from disclosing or using any confidential information as defined under such agreement. One of the requirements of the Secrecy Agreement was that any confidential document had to be stamped "confidential" in order to be protected. Irish law further prohibits the recipient of confidential information from using it as a "spring board or head start" to compete with the holder of the confidential information.

Applied has argued that since no document marked as "confidential" was ever disclosed to it during the March visit, and that such information became public through its publication in Gaya's patent applications as early as September 2000, therefore no breach occurred.

In August 31, 2000, Applied requested and received documents from Respondents which were stamped confidential and therefore covered by the Secrecy Agreement and protected under it.

Furthermore, Applied was fully aware of the confidential nature of the relationship existing between the parties as confirmed by Mr. Hillal's testimony to the panel.

Considering the fact that Applied was not in the business of manufacturing HALS devices before it entered into a relationship with Gaya, and considering further that disclosed confidential documents and communications referred to a "self sealing detachable valve", we find that Applied did benefit from a "spring board or head start" from such information and therefore violated Irish law and the Secrecy Agreement because, in the Panel's view, Applied used Gaya's information to develop the Gelport device.

Having found violation of Irish law and breach, we turn to damages.

We believe that damages should be reasonable and not speculative.

While we find that Applied used Gaya's information to develop the Gelport device, we find that that the information that Gaya claims to have been misappropriated played only a minor role in Applied's Gelport products. In this context, we note that the parties agree that the gel in the Gelport device was developed by Applied without the use of any information from Gaya. We are persuaded by Applied's damages evaluation that the appropriate damages here should be premised upon a conservative "head start or spring board" theory of one year and that the sum of two hundred and sixty eight thousand dollars ($268,000) is reasonable under the circumstances, (see Applied's brief at 67).

AWARD

We, the undersigned arbitrators unanimously award as follows:

1. Within thirty (30) days from the date of transmittal of this Award to the Parties, Applied Medical Resources Corporation also hereinafter referred to as Claimant, shall pay to Gaya Limited, hereinafter referred to as Respondent, the sum of TWO HUNDRED AND SIXTY EIGHT THOUSAND DOLLARS ($268,000).

2. This Award is specifically rendered under Irish law as it pertains to the Secrecy Agreement and shall have no bearing on any other action between the parties, specifically in the pending patent litigation in California and any ensuing action.

3. The administrative fees and expenses of the International Centre for Dispute Resolution ("ICDR") totaling $15,750.00 shall be borne as incurred by the parties and the compensation and expenses of the arbitrators totaling $128,527.57 shall be borne equally by the parties.

4. This award is in full settlement of all claims and counterclaims submitted to this Arbitration. Any claim or counterclaim not granted is hereby denied.

We hereby certify that, for the purposes of Article 1 of the New York Convention of 1958, on the Recognition and Enforcement of Foreign Arbitral Awards, this Final Award was made in Washington, DC, USA.

Due to the physical separation of the members of the panel, this Award has been executed in counterparts and the date of the Award shall be the date of execution by the chair, Alain Frecon.

February 21, 2008 — John Fellas, Esq.

February _____, 2008 — Alain Frecon, Esq.

February _____, 2008 — Barbara S. Kinosky, Esq.

State of New York
County of New York } SS:

I, John Fellas, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Award.

February 21, 2008 — John Fellas

State of Minneapolis
County of Hennepin County } SS:

I, Alain Frecon, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Award.

February_____, 2008 — Alain Frecon.

State of Virginia
County of Fairfax County } SS:

I, Barbara S. Kinosky, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Award.

February_____, 2008 — Barbara S. Kinosky

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February_____, 2008 — John Fellas, Esq.

February 23, 2008 — Alain Frecon, Esq.

February_____, 2008 — Barbara S. Kinosky, Esq.

State of New York
County of New York } SS:

I, John Fellas, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Award.

February_____, 2008 John Fellas

State of Minneapolis
County of Hennepin County } SS:

I, Alain Frecon, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Award.

February 13, 2008 Alain Frecon.

State of Virginia
County of Fairfax County } SS:

I, Barbara S. Kinosky, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Award.

February_____, 2008 Barbara S. Kinosky

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Due to the physical separation of the members of the panel, this Award has been executed in counterparts and the date of the Award shall be the date of execution by the chair, Alain Frecon.

February_____, 2008 — John Fellas, Esq.

February_____, 2008 — Alain Frecon, Esq.

February 21, 2008 — Barbara S. Kinosky, Esq.

State of New York
County of New York } SS:

I, John Fellas, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Award.

February_____, 2008 John Fellas

State of Minneapolis
County of Hennepin County } SS:

I, Alain Frecon, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Award.

February_____, 2008 Alain Frecon.

State of Virginia
County of Fairfax County } SS:

I, Barbara S. Kinosky, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Award.

February 27, 2008 Barbara S. Kinosky