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**TROCAR FOR IMPROVED FLUID PRESSURE MANAGEMENT
DURING ENDOSCOPIC SURGERY**

PRIORITY STATEMENT

[0001] This international patent application claims benefit under the Paris Convention to U.S. Provisional Patent Application Serial Number 62/085,771, with a filing date of 1 December 2014.

FIELD OF INVENTION

[0002] Embodiments described herein relate to a trocar for arthroscopic, laparoscopic, and other endoscopic surgeries, marked by an improved seal interface between a surgical instrument and the trocar, thus promoting visual clarity and improved fluid pressure management for maintaining adequate distention of tissues within a body compartment of a surgical patient.

BACKGROUND

[0003] Endoscopic surgery refers to surgical procedures performed through small, puncture-like incisions which serve as an entry point(s) to the surgical site. The incisions are made through skin and subcutaneous tissues using a trocar. One end of a trocar has a tip that is appropriately sized for insertion through a small incision to access the surgical site. A surgeon can then pass other surgical instruments through the trocar to conduct the surgery. Examples of such instruments include scalpels, graspers, scissors, staplers, and scopes, to name a few. Various forms of endoscopic surgery include, without limitation, arthroscopy, laparoscopy, thoracoscopy, cystoscopy, and microsurgery, to name some. In some surgical

disciplines (e.g. orthopedic surgery), the term “cannula” is used synonymously with the term “trocar.”

[0004] Arthroscopic surgery, or arthroscopy, is a type of endoscopic surgery that deals with bones, joints, and connective tissues. It is estimated there are more than 1 million arthroscopies in the U.S. annually involving the knee alone, and studies have indicated a growth rate over the last decade approaching 50%. Visual clarity of the surgical field is an important consideration for endoscopic surgeries. Conventionally, this objective is furthered by a process known as insufflation, which injects a fluid into the body compartment to distend the tissues within or surrounding a body compartment associated with a surgical site. For example, gas is often injected into the body compartment to distend the tissues for laparoscopic surgery, liquid is often used in arthroscopic surgery, and sometimes, depending on the nature of the operation, vapors or powders are used. Often, injection is through a port that can be opened or closed, such as by a stopcock or like structures, located between the trocar's insertion tip and a valve generally positioned proximal to a forward insert region of the trocar.

[0005] However, adequate insufflation requires a steady pressure within the body compartment, or else adequate distention may not be maintained. But considering that the insufflation fluids are injected through a port in the trocar, if the trocar itself is not properly sealed, then leakage of insufflation fluid is likely to occur, and there may not be enough pressure to maintain adequate distention. Conversely, compensating for leakage by over-pressurization might lead to complications and increased risk of adverse events for the patient. While most trocars provide a single diaphragm seal for the purpose of sealing off the external environment, these conventional designs are known to permit fluid to leak out of the end of the trocar – often with the fluid traveling along the tip of the instrument. Such leakage

reduces the pressure in the body compartment and allows fluid to leak into the external surgical field. This can occur during insertion and/or withdrawal of an instrument, or when no instrument is positioned within the trocar. Excessive leakage results in poor pressure management within the body compartment, wastes insufflation fluid, and may create a safety hazard for operating room personnel.

[0006] As previously mentioned, a trocar is used to pass endoscopic surgical instruments into the body compartment of a patient. Conventionally, a surgical instrument is inserted through the trocar, generally through an opening at the rear aspect (i.e., distal to the entry point of the trocar tip as it enters the patient's body compartment). The instrument is then advanced toward the surgical site. Such instruments (i.e., surgical instruments) generally have a tip (i.e., an operational end such as, for example, scissor/cutting members and graspers), a shaft, and a handle. Guided by the surgeon, the tip of the instrument travels from a rear insert of the trocar (proximal to the surgeon) through the body of the trocar until exiting the trocar at a forward insert (distal to the surgeon and positioned within a body compartment of a patient). With conventional designs, as the tip of the instrument enters the trocar, it first passes through a single, flat (i.e., not tapered) diaphragm seal which is positioned proximal to the rear insert and generally within the inner chamber of the trocar body. The instrument tip then passes through a valve within the chamber of the trocar, wherein this valve is proximal to the forward insert. Conventional trocar designs position the diaphragm seal and valve in relatively close proximity.

[0007] A surgical instrument, having a tip, is advanced through the interior of the trocar during operation. Problematically, if the length of the instrument tip exceeds the distance between a conventional outer diaphragm seal and the interior valve, the valve opens before the instrument shaft fully engages the outer seal. The resulting inadequate seal produces

leakage as insufflation fluid, under the pressure needed for injection through the port, passes along the instrument tip. This frequently causes fluid to escape from the trocar housing along the shaft of the instrument, because the partial engagement between the shaft and the diaphragm seal prevents an adequate seal against the external field.

[0008] The present embodiments herein alleviate this problem by enabling full sealing engagement to occur between the instrument shaft and a diaphragm seal, before the tip of the instrument engages the forward-most valve while being advanced after insertion, for example.

SUMMARY OF EMBODIMENTS

[0009] A trocar, according to multiple embodiments and alternatives as provided herein, comprises a diaphragm seal having two opposing tapered portions, at least one of which forms a sealing surface that is tapered, as opposed to flat. Such a dual-taper diaphragm seal arrangement, relative to positioning of valves within the trocar itself, offers the benefits of virtual leak-free performance of the trocar during endoscopic surgery. In some embodiments, a diaphragm seal and one or more valves of the subject trocar are configured such that the diaphragm seal is positioned exterior of the trocar inner chamber, with one or more interior valves positioned inside the trocar inner chamber. The effect is to increase the opening-to-opening distance between the diaphragm seal and the forward-most valve, the latter of which provides access to the surgical site. The added distance prevents insufflation fluid from leaking out prior to the time when the seal is fully formed between the instrument and such diaphragm seal. In some embodiments, the valves are multi-leaflet valves.

[00010] The arrangement provided herein allows for sufficient thickness at the diaphragm seal opening for continuous contact with the instrument to maintain a fluid tight, mechanical seal between the shaft of a surgical instrument and the diaphragm seal.

Moreover, this fluid tight seal withstands pressures at and beyond what is typically exerted by means of insufflation, and the forward-facing tapered portion is configured to redirect insufflation fluid into the interior of the trocar chamber and away from the diaphragm seal opening.

[00011] In some embodiments, the novel diaphragm seal is secured to a seat region of the trocar by means of an end cap, which matably threads to corresponding threads on the housing of the trocar. In some embodiments, multiple diaphragm seals are used, such that a first diaphragm seal is located within the inner chamber of the trocar housing, while a second diaphragm seal can be located either just beyond the rear insert of the trocar housing, or externally through means of the aforementioned end cap. The use of one or more diaphragm seals having a dual taper along with the arrangement of valve(s) and diaphragm seal(s) according to present embodiments provides virtually leak-free handling during the insertion, use, and withdrawal of surgical instruments associated with endoscopic surgeries.

[00012] The shaft of many surgical instruments has a round cross-section axially, generally of a standard diameter depending on several factors, including but not limited to the type of instrument, the nature of the procedure, and the size of the body compartment and patient. According to multiple embodiments and alternatives herein, the design of a trocar, with one or more diaphragm seals, can be scaled and tailored to accommodate use of various instruments based on factors such as those mentioned above. In some embodiments, a diaphragm seal according to these descriptions can be fitted to a conventionally available trocar. Among various options, such a diaphragm seal is included with a new trocar, either being formed integrally with the trocar; or provided as a separate piece that can be fitted over an end cap or seat region of a trocar; or incorporated with a trocar internally. Other features and advantages will be apparent based on the descriptions herein.

BRIEF DESCRIPTION OF THE FIGURES

[00013] The drawings, schematics, figures, and descriptions herein are to be understood as illustrative of structures, features and aspects of the present embodiments and do not limit the scope of the embodiments. The scope of the application is not limited to the precise arrangements, scales, or dimensions as shown in the drawings, nor as discussed in the textual descriptions.

[00014] Fig. 1 is a perspective view of a trocar, according to multiple embodiments and alternatives described herein.

[00015] Figs. 2 and 3 are cross-sectional views of a trocar with an instrument positioned as it would be in use, taken along line II-II of Fig. 1, according to multiple embodiments and alternatives described herein.

[00016] Figs. 4A-4C provide cross-sectional views of the diaphragm seal portion of region “C” denoted in Fig. 3, but without picturing the instrument shaft 5, illustrating several alternatives according to the embodiments herein.

[00017] Figs. 5A and 5B offer a perspective view of a diaphragm seal for a trocar, according to multiple embodiments and alternatives described herein.

[00018] Figs. 6A and 6B offer a perspective view of a diaphragm seal situated on a trocar according to multiple embodiments and alternatives, in which the diaphragm seal is operatively engaged with an instrument shaft.

[00019] Fig. 7 is a cross-sectional view taken lengthwise of an endcap for a trocar such as of the end cap portion along line II-II of FIG. 1, having a seat arranged to accommodate a diaphragm seal, according to multiple embodiments and alternatives described herein.

[00020] Fig. 8 is a cross-sectional view taken lengthwise of a trocar housing with grooves formed in the inner wall surface, taken along line II-II of FIG. 1, according to multiple embodiments and alternatives described herein.

[00021] The surgical instrument shown in some figures, including the tip of the instrument and the shaft, is not part of the claimed embodiments herein.

MULTIPLE EMBODIMENTS AND ALTERNATIVES

[00022] Present embodiments concerning a trocar **10** relate to a number of standard parts related to conventionally designed trocar devices, for use with conventional surgical instruments. For example, Fig. 2 shows the trocar in use with an instrument having a tip **6** (which may be hinged), an instrument shaft **5**, and a handle (not shown). Other elements commonly found in conventional trocar designs, some of which are optional, are shown in various figures, such as Fig. 3 and Fig. 8. These include a cylindrical housing **12**, inner chamber **26**, at least one valve **22**, rear insert **25**, forward insert **27**, skin interface seal **44**, and one or more spiral skin threads **45**. Typically, the skin interface seal **44** and spiral skin threads **45** are involved in gaining access to the body compartment through the patient's skin. Accordingly, the skin interface seal **44** and spiral skin threads **45** generally are positioned proximally relative to the forward insert **27**. By the teachings herein, these structures and the forward insert are oriented "forward" with respect to trocar **10**, while the rear insert **25** is oriented "rear" (or, "rear-ward") with respect to trocar **10**.

[00023] The main function of trocar **10** is to provide access to the body compartment. The shaft **5** of most surgical instruments used for endoscopy has a round cross-section of a standard diameter depending on various factors, e.g., the type of instrument, the nature of the procedure, and the size of the body compartment and patient. The diaphragm seal of trocar **10** must sufficiently engage with an instrument shaft to establish a fluid tight seal along the

abutting surface of the instrument shaft. As used herein, the term “fluid tight seal” indicates that the seal is substantially impermeable to fluids under pressures at and beyond that which is typically exerted by means of insufflation, as described in more specificity below. In addition, the term “fluid,” as used herein, is intended to include gases, such as air, nitrogen, carbon dioxide and the like, liquids, such as water or saline, and/or any matter, substance or combination of compounds substantially not in a solid state, or in an otherwise effectively immobile condensed state.

[00024] The novel diaphragm seal works in conjunction with one or more valves that are positioned within inner chamber **26** of trocar **10**. Conventionally, valves **22**, **23** as depicted in Figs. 2 and 3 are formed from polymer materials as are known in the art, and positioned within inner chamber **26** in order to allow portions of a surgical instrument including the tip **6** to pass through their respective openings (during advancement and withdrawal), while also acting as a seal to prevent fluid passage when an instrument has not been passed through that valve. Figs. 2 and 3 also show diaphragm seal **34** arranged with end cap **24**, as further discussed below in connection with other figures. In some embodiments, the trocar is provided by itself, while optionally a trocar as described herein is combined with particular endoscopic surgical instruments, and intended for single and/or multi-use purposes.

[00025] Suitable materials for trocar **10**, end cap **24**, and diaphragm seal **34** are known in the art. By way of non-limiting example, suitable materials for trocar **10** include polycarbonate acrylic, plastics, and metals such as titanium alloys and steel alloys; suitable materials for end cap **24** include plastics and metals; and suitable materials for diaphragm seal **34** include silicone elastomers and rubbers, to name a few. In an embodiment, the diaphragm seal **34** is formed from a silicone rubber compound that is commercially sold as Dragon Skin[®] High Performance Silicone Rubber, and available from Smooth-On, Inc., of

Macungie, Pennsylvania. As desired, and consistent with various embodiments and alternatives, the aforementioned materials can be machined, molded, injection molded, additively manufactured, or otherwise formed through techniques which are well known in the art.

[00026] As previously referenced, Fig. 2 is a cross-sectional view of a trocar, taken axially along line II-II of Fig. 1. In some embodiments, trocar **10** comprises two valves (**22**, **23**) with a diaphragm seal **34** as described herein arranged with end cap **24**, external to the trocar housing **12**. Alternatively, with reference to Fig. 8, diaphragm seal **34** is positioned internally, for example by forming a press fit within end cap **24**, or by seating outer edge **31'** of the diaphragm seal securely within a grooved portion **77** of the housing, or otherwise positioning it within trocar housing **12**, generally to the rear of the valves **22**, **23**.

[00027] Generally, end cap **24** is at least partially open in its rear-facing orientation to accommodate passage of the tip and shaft of the instrument while advancing through (or being withdrawn axially from) trocar **10**. In some embodiments, valves **22**, **23** are multi-leaflet valves. Accordingly, in the drawings a first valve **22** is referred to synonymously as “forward valve,” and a second valve **23** is referred to as “rear valve.” In both Figs. 2 and 3, an optional spacer sleeve **14** is shown, which can be made from a number of optional materials, including of the same materials which are used in forming the trocar itself. In some embodiments, spacer sleeve **14** is a cylindrical sheath with a hollow central area so as not to impede the passage of instruments through inner chamber **26**, and it fits within inner chamber **26** snugly within trocar housing **12**. In some embodiments, the geometry of spacer sleeve **14** is complementary to that of the interior of trocar housing **12**. By its placement, spacer sleeve **14** urges first valve **22** towards a forward insert **27** along axis **29** in relation to trocar **10**, which generally follows the path of advancement of a surgical instrument during

use, for example as the instrument is advanced and later withdrawn between the rear insert **25** and the forward insert **27**.

[00028] Present embodiments contemplate various alternatives for maintaining suitable distances between valves **22** and **23** and the diaphragm seal **34**, respectively. For example, Fig. 3 shows spacer sleeve **14** for maintaining suitable spacing and distances between the opening **35** of diaphragm seal **34**, and the respective openings of valves **22**, **23**. Preferably, during use the distance between these valves is substantially statically maintained. In addition to a spacer sleeve, other structures can be employed to maintain suitable spacing and distances. In some embodiments, valves **22**, **23** are positioned within the inner chamber **26** by forming grooves **57**, **67** in the inner wall of trocar housing **12**, as shown in Fig. 8. In such embodiments, the circumferential ring of valve **22** seats securely in groove **57** of the housing; likewise, the circumferential ring of valve **23** seats securely in the grooves **67**. Accordingly, the respective grooves each provides a valve seat region to position valves **22**, **23** relative to the other and to diaphragm seal **34**. The distance between these grooves determines the spacing between openings for valve **22**, **23** and by extension the distance between each of those valves and diaphragm seal **34**. The fit between the valves and the grooves is configured to hold each valve in a substantially static position within chamber **26**.

[00029] Fig. 3 is a cross-sectional view of a trocar, showing positioning of a port **41**, which is a conventional port for trocars to provide means for passing insufflation fluids such as carbon dioxide. Fig. 3 also illustrates, in non-limiting fashion, some spacing aspects which are suitable for certain embodiments and for certain uses based on the type of patient, for example as a function of size differences between adult patients and pediatric patients. In some embodiments, the spacing is sufficient to allow, as the instrument shaft advances axially, a fluid tight seal to form at opening **35** before the tip of the surgical instrument passes

through the opening of rear valve **23**. Likewise, upon withdrawal of the instrument axially in a generally rear-ward direction, it is beneficial if a fluid tight seal remains at opening **35** as the tip of the surgical instrument exits the opening of forward valve **22**. Accordingly, in some embodiments, the distance from the diaphragm seal opening **35** to the opening of rear valve **23** is distance “B”, and represented by points “Y” to “Z”. Likewise, the distance from diaphragm seal opening **35** to the opening of forward valve **22** is the sum of distances “A” and “B”, and represented by points “X” to “Z.”

[00030] In view of the above, in some embodiments, a distance from position X to position Y represents the spacing between the opening of valve **22** and the opening of valve **23** (denoted as distance A in Fig. 3). In some embodiments, this distance A measures from about 1 centimeter (cm) to about 2 cm for pediatric applications, and from about 4 cm to about 5 cm for adult applications. Similarly, a distance from point Y to point Z (denoted as distance B in Fig. 3) represents the spacing between the opening of valve **23** and an opening **35** of diaphragm seal **34**, with this distance measuring from about 1 cm to about 2 cm for pediatric applications, and from about 4 cm to about 6 cm for adult applications. Accordingly, in some embodiments, the distance from the diaphragm seal opening **35** to the opening of rear valve **23** is at least 2 cm, and the distance from this diaphragm seal opening to the opening of forward valve **22** is at least 7 cm. Thus, while advancing an instrument, the spacing as described herein allows for the instrument shaft to form a fluid tight seal with diaphragm seal **34** before the instrument tip meets the opening for rear valve **23**. Likewise, during withdrawal of the instrument from the trocar, the spacing allows for the instrument shaft to remain in a fluid tight seal with diaphragm seal **34** as the instrument tip is withdrawn through the opening for forward valve **22**. In this way, the spacing aspects facilitate improved fluid pressure management during endoscopic surgeries.

[00031] The opposing tapered portions of diaphragm seal **34** promote a fluid tight seal around an instrument shaft. Figs. 4A provides an enlarged area of region C of FIG. 3, and Figs. 4B-4C show alternative arrangements. While the views provide additional geometric information, other arrangements are also contemplated. In some embodiments, points U and V (and likewise U' and V') represent the points where diaphragm seal **34** begins to taper inward. Although appearing as distinct lines in the cross-sectional drawing figure, in actuality segment VW together with V'W' represent a surface of diaphragm seal **34** which generally faces a forward insert **27** of the trocar (see Fig. 1). Likewise, segment UW together with U'W' together represent a generally rear-insert facing surface of diaphragm seal **34**, which opposes the forward-insert facing surface. Accordingly, each opposing surface of diaphragm seal **34** tapers inward toward the center of diaphragm seal **34** relative to two distinct axes. That is, as shown in this cross-sectional view, the opposing surfaces represented by segments VW and UW are not parallel, and both segments taper inward toward the center of diaphragm seal **34** relative to one axis which can be considered central axis **29**, and relative to a second axis **30** that is perpendicular to axis **29**. Likewise, segments V'W' and U'W' in this figure are not parallel, and both segments taper inward toward the center of diaphragm seal **34** relative to the same two axes. In some embodiments, on both opposing surfaces, the slope of the taper ranges from about **5** degrees to about **30** degrees from an outer periphery of the diaphragm seal toward the opening **35** (or, more specifically, toward the intersection of central axis **29** and perpendicular axis **30** as depicted in Fig. 4A). In some embodiments, the taper is from about **15** degrees to about **25** degrees (about **15** degrees is preferable), and the opposing surfaces are tapered symmetrically to enhance efficiencies of inserting and withdrawing of an instrument.

[00032] Referring still to Figs. 4A-4C, in some embodiments the distance from where the taper begins (i.e., point V and V') to the center of opening **35** will vary depending on the

type of instrument used, the diameter of the shaft of the instrument, and the needs of the particular surgical patient.

[00033] Referring back to Fig. 1, end cap **24** and diaphragm seal **34** are illustrated in relation to housing **12** and also identifying with a reference numeral the forward insert **27** which enters a patient's body compartment. Now with reference to Figs. 5A and 5B, to facilitate providing a fluid tight seal, each of one or more diaphragm seals **34** of trocar **10** has a dual taper, on opposing sides. In Fig. 5A, a surface of diaphragm seal **34** is shown, which comprises a semi-cylindrical tapered portion **33** descending from an outer edge **31** toward the center of the diaphragm seal to a circular rim **37**. Thus, in some embodiments, rim **37** forms part of a boundary for an opening **35** extending through the full thickness of seal **34**. In some embodiments, opening **35** has a diameter of from about **1** mm to about **10** mm. Though various figures illustrate rim **37** as circular in geometry, other geometries are contemplated within the presently described embodiments.

[00034] A dual taper is provided by opposing tapered portions of diaphragm seal **34**. Fig. 5B shows an opposing surface of diaphragm seal **34** from that shown in Fig. 5A. It is also comprised of a tapered portion **33'** descending from outer edge **31'** toward the center of the diaphragm seal to form a circular rim **37'** which also serves as part of a boundary for the aforementioned opening **35**. Each surface represented by the tapered portions, **33**, **33'** tapers in an opposing direction, thus providing the dual taper of diaphragm seal **34** and effectively bringing the respective tapered portions closer to the other as they approach opening **35**. Accordingly, in some embodiments, the general shape of each tapered portion can be considered as conical, or as a truncated cone, terminating at opening **35**. As shown in Fig. **4B**, the cross-sectional surface areas of the tapered portions surrounding opening **35** are curvilinear surfaces **47**, **47'** respectively, with that area being of sufficient thickness so that

opening **35** maintains adequate contact with the instrument shaft to establish the desired fluid tight seal.

[00035] Alternatively, as shown in Fig. 4C, the cross-sectional surface areas of the tapered portions surrounding opening **35** create a truncated cone – represented by segments VT–TW–WU and V'T'–T'W'– W'U', respectively - again providing area of sufficient thickness so that opening **35** maintains adequate contact with the instrument shaft to establish and maintain a fluid tight seal. Such contact and the resultant sealing force are established and maintained even while surgeons move the instrument through various ranges of motion, resulting in fluctuating and intermittent compressive forces and release of those forces over the surface area that defines opening **35**.

[00036] Having sufficient surface area of material around opening **35** to remain in contact with an instrument shaft helps form and maintain a satisfactory fluid tight seal. For added versatility, opening **35** of diaphragm seal **34** can be made of an appropriate size and shape to accommodate instrument shafts of various diameters to form a fluid tight seal therebetween with an abutting surface of an instrument shaft (such as instrument shaft **5** depicted in Fig. 2) and rim **37**, **37'** of the diaphragm seal **34**. Generally, it is beneficial for the diameter of the opening **35** of diaphragm seal **34** to be slightly smaller than the diameter of the intended instrument shaft. The tapered portion of the diaphragm seal **34** not only serves to form and augment a fluid tight seal, but also provides flexibility with respect to the range of instruments having various shaft diameters that are suitable for use with trocars as described herein. Additionally, the surfaces of forward-facing tapered portion **33'** function not only as part of the seal interface, but also serve to redirect fluid away from opening **35** by causing the flow path of the fluid to revert toward the inner chamber **26** of the housing **12** through deflection.

[00037] In use, as a surgeon passes an instrument through a trocar, the instrument advances axially and is withdrawn axially in a generally linear direction along axis **29**. In so doing, the instrument shaft **5** slideably passes through and interfaces with the opening **35** of diaphragm seal **34**. In practice, a surgeon generally must be able to move the instrument, including shaft **5** (Fig. 2), with significant range of motion and along numerous axes relative to axis **29**. For example, an instrument tip may be formed with a blunt edge spiral thread to help advance the tip through the body compartment wall as the surgeon rotates the body of the trocar, and additional maneuvering is frequently needed once the surgical site is accessed. In conventional designs, such movement along multiple axes often produces or exacerbates leakage. Accordingly, the tapered portions on the rear insert-facing side of the diaphragm seal **34** and the forward insert-facing side thereof, facilitate multi-axis movement of the instrument without disrupting the engagement required for a the fluid tight seal. Additionally, as seen in Fig. 5B and the cross-sectional figures of the diaphragm seal region, in some embodiments the taper associated with the forward insert-facing wall **33'** will – when an instrument is being withdrawn from trocar **10** – tend to urge fluid to rebound off of the surface of the instrument shaft **5** and away from the seal in a direction toward the forward insert **27**, thereby promoting the recycling of fluid into the body compartment, thus increasing the effectiveness of insufflating the body compartment.

[00038] According to present embodiments, the spatial relationships and distances between diaphragm seal **34** and valve **22** are such that the instrument tip does not impinge upon or enter that valve until the diaphragm seal **34** has engaged an abutting surface of the instrument shaft **5** and established a fluid tight seal therebetween. With further reference to Fig. 2 and Fig. 3, in some embodiments, the distance between valves **22**, **23** is such that when withdrawing an instrument, forward valve **22**, e.g., a multi-leaflet valve, sufficiently closes and forms a relatively fluid tight seal between opposing surfaces of the valve leaflets before

the tip of the instrument begins to pass back through rear valve **23** and, in turn, out of trocar **10** through diaphragm seal **34**. In some embodiments, each diaphragm seal(s) **34** is arranged so that the interface formed therebetween with instrument shaft **5** withstands pressures at and beyond what is typically exerted by means of insufflation, e.g., for laparoscopy an insufflation pressure on the order of about **15** mm Hg, and for arthroscopy involving a joint capsule an insufflation pressure on the order of about **70** mm Hg.

[00039] Thus, features of trocars described herein facilitate a desired pressure to be maintained within the trocar and, in turn, within the body compartment where surgery is performed, whereas with conventional designs, this often is not the case. With some conventional trocars, the distance between the diaphragm seal and the multi-leaflet valve is so small that it is prone to leakage either when the first instrument is inserted, or when that one is withdrawn and subsequent instruments are inserted then withdrawn. In contrast, according to present embodiments, the opening-to-opening distance between diaphragm seal **34** and forward valve **22** exceeds the length of most instrument tips. By way of non-limiting example, in some embodiments this distance is no less than about 30 mm (3 cm), but other distances are contemplated.

[00040] Figs. 6A and 6B demonstrate the resilient nature of diaphragm seal **34** according to present embodiments. In Fig. 6A, the forward-pointing arrow signifies insertion of instrument shaft moving toward the forward insert **27** of earlier figures. In response to this forward advancement, tapered portion **33** is seen as somewhat concave due to the force placed upon this surface as a result of the seal created between diaphragm **34** and instrument tip **5** as the instrument advances. Conversely, Fig. 6B's rear-pointing arrow (away from rear insert **25** of earlier figures) is suggestive of withdrawing the instrument, in which the tapered portion **33** bows outward by the created seal.

[00041] In some embodiments, diaphragm seal **34** fits over an end cap joined to the trocar. Fig. 7 provides a cross-sectional view of end cap **24**, which in some embodiments is cylindrical. End cap **24** includes a diaphragm seat region **36** for accommodating a diaphragm seal **34**. With respect to diaphragm seal **34**, rear-facing tapered portion **33** meets rim **31** at the point where the taper begins to angularly slope inwardly and radially toward opening **35**. In turn, rim **31** also meets a diaphragm collar **50**, which in some embodiments extends at approximately **90** degrees relative to the rim in a forward orientation when diaphragm seal **34** is attached to trocar **10**. The collar **50** terminates at a forward periphery **51**, which defines an axially aligned open end to enable diaphragm seal **34** to engage with end cap **24**. Preferably, this open end, the outer portions of which are defined by forward periphery **51**, thus defines an area appropriately sized for diaphragm seal **34** to fit tightly over end cap **24**. The geometry of diaphragm seal **34** is complementary to that of end cap **24**, and/or a diaphragm seat region **36** of the end cap which is discussed below in connection with Fig. 7. Accordingly, if the geometry of end cap **24** (or, diaphragm seat region **36**) is cylindrical, the geometry of the forward periphery **51** is likewise cylindrical.

[00042] In general, the fit between diaphragm seal **34** and end cap **24** is sufficiently secure for the diaphragm seal to remain in place even during forceful manipulations of the instrument associated with surgical techniques, yet able to be manually removed from end cap **24** if desired. One way to accomplish this is to have the diameter of the forward periphery of **51** diaphragm seal **34** equal to or slightly less than the outer diameter of end cap **24** or the diaphragm seat region **36**, such that the flexible material of diaphragm seal **34** allows it to be stretched and force fit over this outer diameter.

[00043] As well, other structures can be employed to hold diaphragm seal **34** to end cap **24**. Fig. 7 illustrates end cap **24** having diaphragm seat region **36**, which includes a lip **39**

that protrudes slightly from the outer diameter of diaphragm seat region **36**. Accordingly, lip **39** provides a capturing ledge to secure the positioning of diaphragm seal **34** so it does not slide off when the trocar is under pressure. End cap **24** is thus arranged to be positioned at an open end of housing **12** proximal to rear insert **25** shown in other figures. In some embodiments, end cap **24** has mating threads (not visible in the figure, but these would be formed along the inner diameter of the end cap). The threads are adapted to mate with corresponding external threads **42** located on housing **12**, as Fig. 8 illustrates. Fig. 8, a cross-sectional view of a trocar housing taken axially, further shows a valve seat region **36** for accommodating valves **22**, **23**, as previously discussed in proximal relation to forward insert **27** of trocar **10**. Accordingly, for reusable versions of trocar **10**, end cap **24** is removable by turning the end cap in a direction opposite that which was used to secure it to the diaphragm seat region **36**. This provides a way for end cap **24** to be cleaned between uses, or for cleaning or replacement of diaphragm seal **34** and valves **22**, **23**.

[00044] It will be understood that the embodiments described herein are not limited in their application to the details of the teachings and descriptions set forth, or as illustrated in the accompanying figures. Rather, it will be understood that the present embodiments and alternatives, as described and claimed herein, are capable of being practiced or carried out in various ways. Also, it is to be understood that words and phrases used herein are for the purpose of description and should not be regarded as limiting. The use herein of such words and phrases as “such as,” “comprising,” “e.g.,” “containing,” or “having” and variations of those words is meant to encompass the items listed thereafter, and equivalents of those, as well as additional items. The use of “including” (or, “include,” etc.) should be interpreted as “including but not limited to.”

[00045] Accordingly, the foregoing descriptions of several embodiments and alternatives are meant to illustrate, rather than to serve as limits on the scope of what has been disclosed herein. The descriptions herein are not intended to be exhaustive, nor are they meant to limit the understanding of the embodiments to the precise forms disclosed. It will be understood by those having ordinary skill in the art that modifications and variations of these embodiments are reasonably possible in light of the above teachings and descriptions.

CLAIMS

What is claimed is:

1. A trocar for use with a surgical instrument, comprising:

a trocar housing with an inner chamber, a rear insert and a forward insert;

at least one tapered diaphragm seal, having two non-parallel, opposing surfaces that taper from an outer edge of the diaphragm seal to form an opening;

a forward valve and a rear valve, each having a valve opening, wherein the rear valve opening is closer to the diaphragm seal opening than is the forward valve opening, and the distance between the rear valve and the forward valve is substantially statically maintained.

2. The trocar of claim 1, wherein the distance from the diaphragm seal opening to the rear valve opening is at least about 2 cm, and the distance from the diaphragm seal opening to the forward valve opening is at least about 7 cm.

3. The trocar of claim 1, further comprising a spacer sleeve positioned between the forward valve and the rear valve for maintaining the distance between them.

4. The trocar of claim 1, further comprising forward and rear grooves formed in the trocar housing providing a secure seating arrangement for said forward and rear valves and for maintaining the distance between them.

5. The trocar of claim 1, wherein at least one diaphragm seal is external to the trocar housing and configured for placement over a diaphragm seat region.

6. The trocar of claim 1, wherein at least one diaphragm seal is positioned within the trocar housing.

7. The trocar of claim 1, wherein the opposing surfaces taper toward the diaphragm seal opening at an angle of about 5 to about 30 degrees.

8. The trocar of claim 7, wherein the opposing surfaces taper toward the opening at an angle of about 15 to about 25 degrees.

9. The trocar of claim 1, wherein the cross-sectional surface areas of the tapered portions at the opening are curvilinear.

10. The trocar of claim 1, wherein the cross-sectional surface areas of the tapered portions at the opening are a truncated cone.

11. A diaphragm seal for a trocar, comprising two non-parallel, opposing surfaces that taper from an outer edge of the diaphragm seal to form an opening, wherein the opposing surfaces taper toward the opening at an angle of about 5 to about 30 degrees, and wherein the diaphragm seal is configured to be secured to an end cap of the trocar.

12. The diaphragm seal of claim 11, wherein the opposing surfaces taper toward the diaphragm seal opening at an angle of about 5 to about 30 degrees.

13. The diaphragm seal of claim 12, wherein the opposing surfaces taper toward the opening at an angle of about 15 to about 25 degrees.

14. The diaphragm seal of claim 11, wherein the cross-sectional surface areas of the tapered portions at the opening are curvilinear.

15. The diaphragm seal of claim 11, wherein the cross-sectional surface areas of the tapered portions at the opening are a truncated cone.

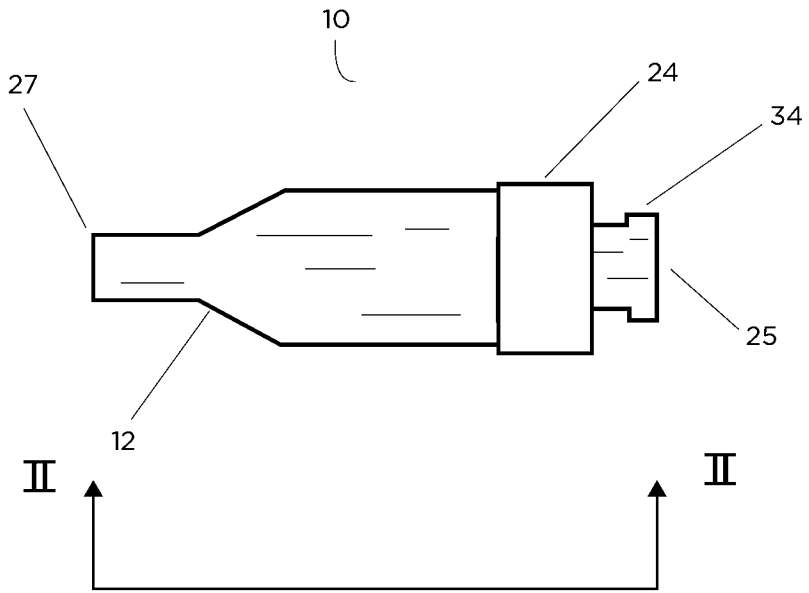


FIG. 1

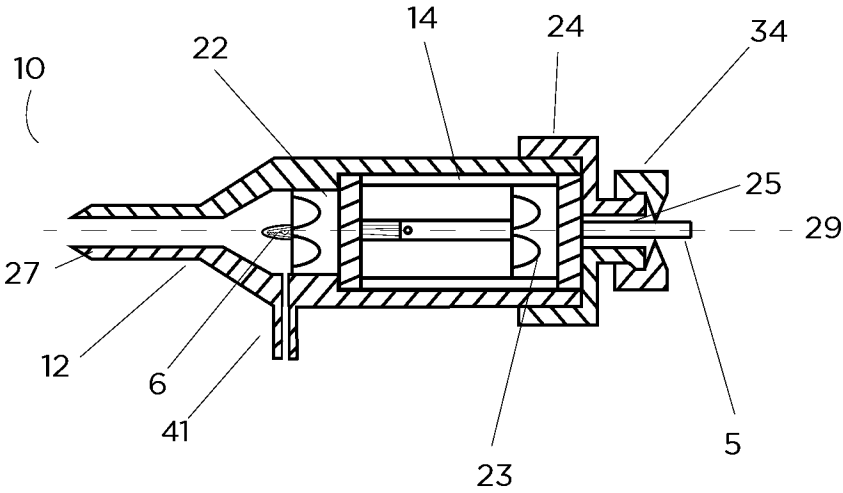


FIG. 2

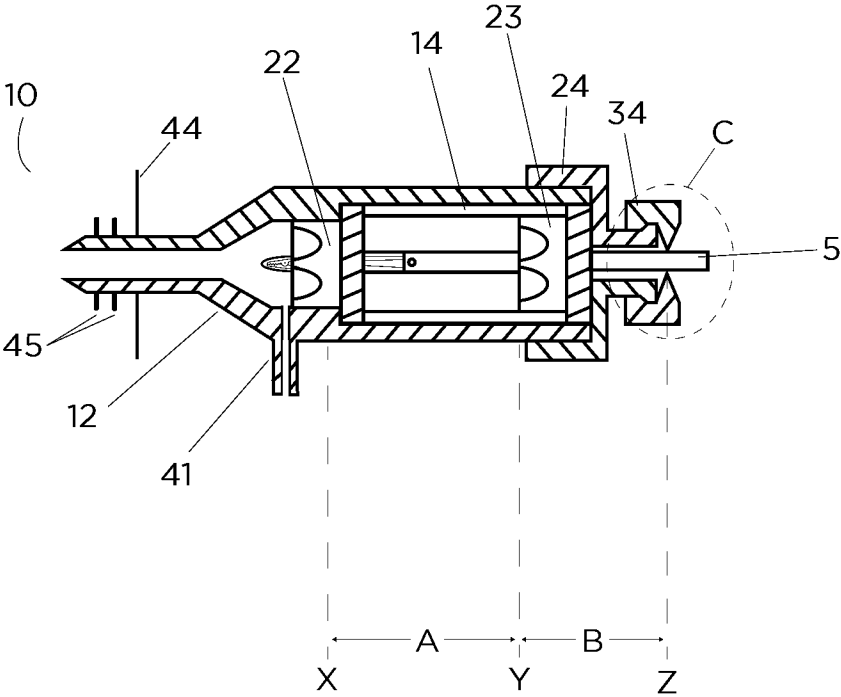


FIG. 3

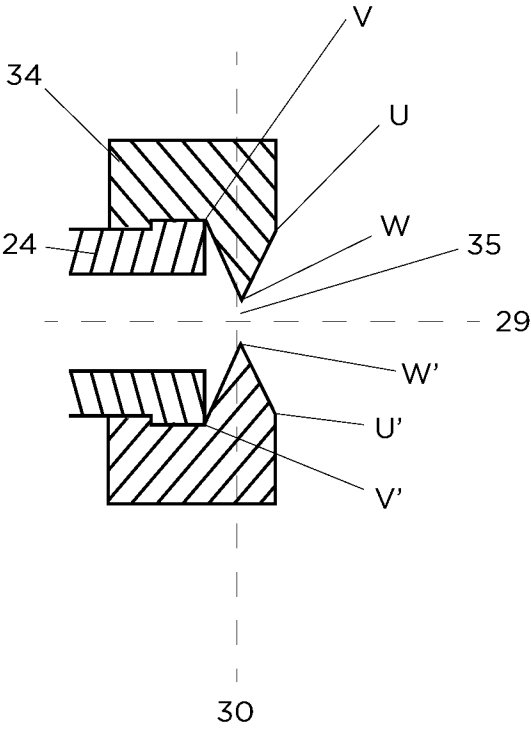


FIG. 4A

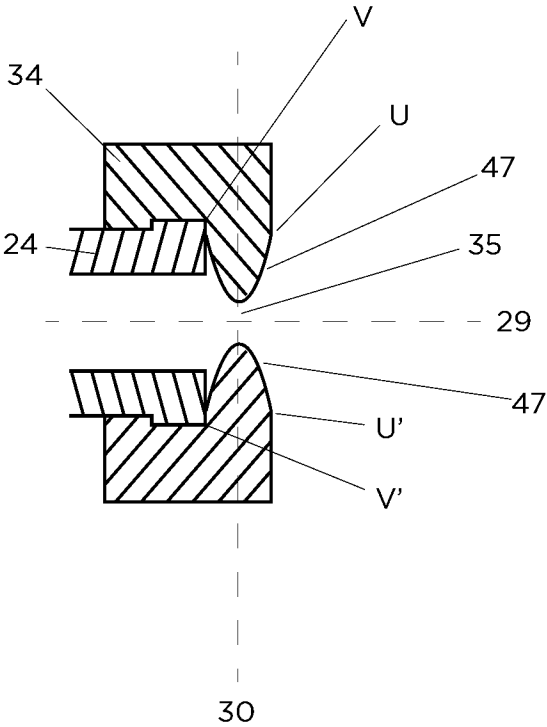


FIG. 4B

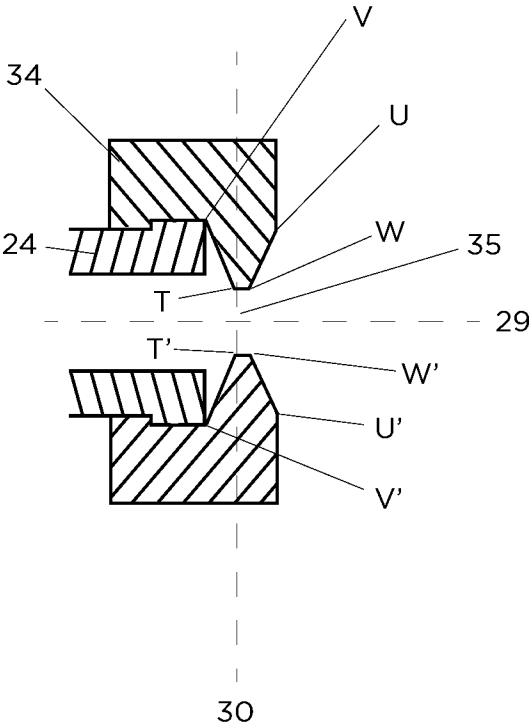


FIG. 4C

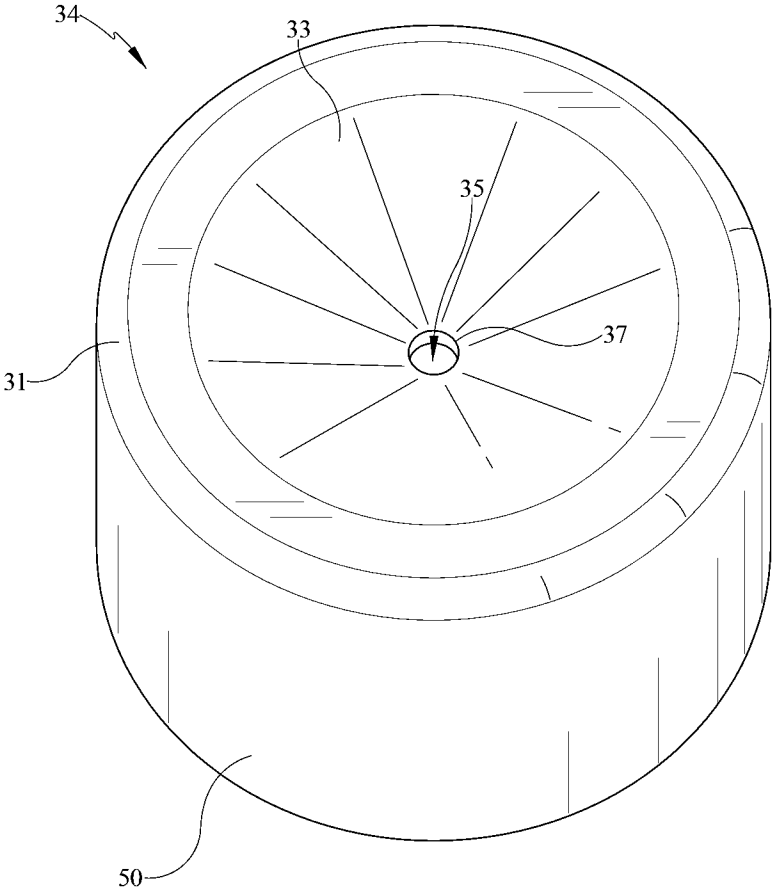


FIG. 5A

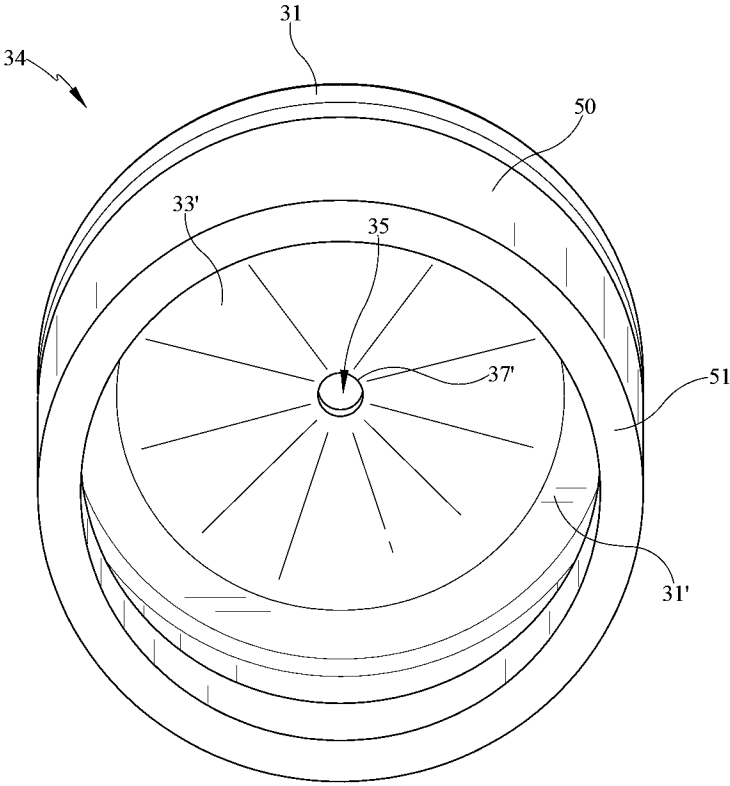


FIG. 5B

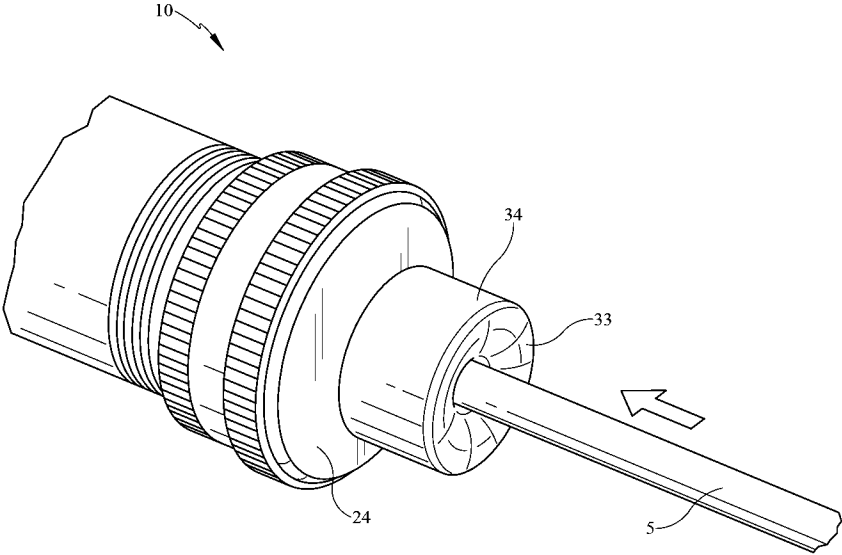


FIG. 6A

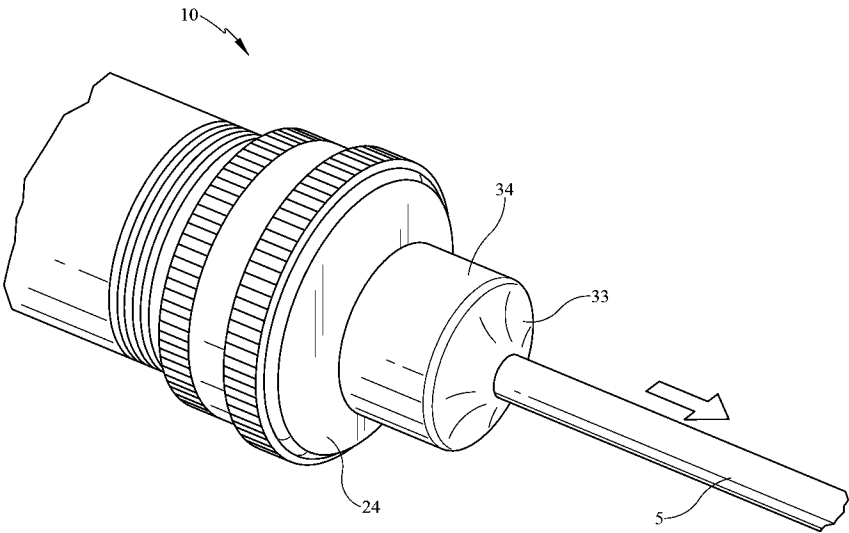


FIG. 6B

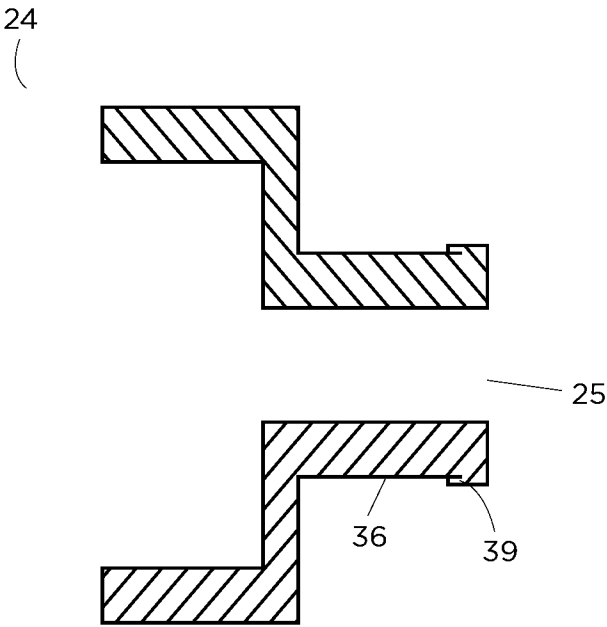


FIG. 7

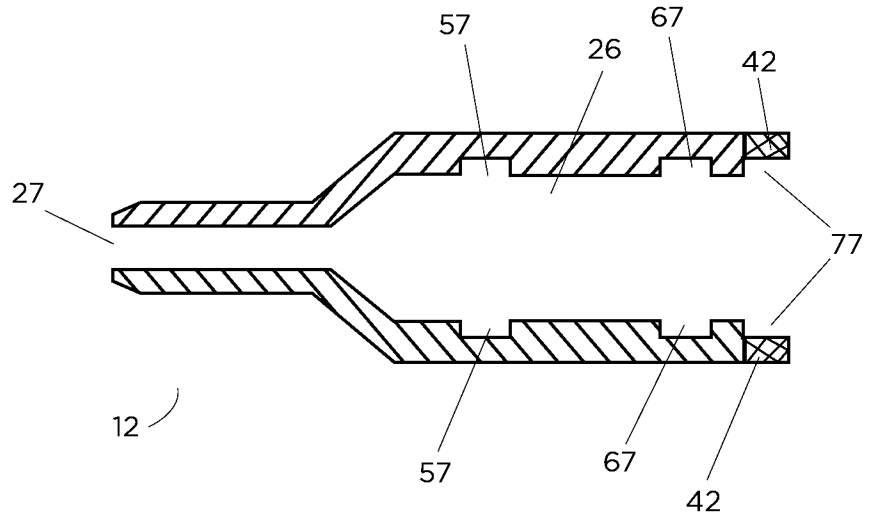


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 15/63125

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/34 (2016.01)

CPC - A61B 2017/3419

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) : A61B 17/34 (2016.01)

CPC : A61B 2017/3419

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

IPC(8) : A61B 17/00 (2016.01)

CPC: A61B 17/00, 17/34, 17/3417

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
 Patbase, Google Patent, Google Scholar: trocar, cannula, taper, cone, conic, nonparallel, diaphragm, septum, membrane, seal, aperture, wiper, edge, surface, leaflet, upper, forward, front, proximal, valve, duckbill, flap, lower, rear, back, distal, dual, double, twin, second, space, gap, sleeve, collet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,411,483 A (LOOMAS et al) 2 May 1995 (02.05.1995) see especially col 9, ln 15-30, col 10, ln 60 to col 11, ln 10, col 17, ln 62 to col 18, ln 8, fig 2, 3D, 6D	11-15
Y	US 2004/0138676 A1 (CRABTREE) 15 July 2004 (15.07.2004) see especially para [0041], [0042], [0060], fig 1-3	1-10
Y	US 2010/0193516 A1 (LaBEAN et al) 5 August 2010 (05.08.2010) see especially para [0034], [0037]-[0039], fig 3	1-10
Y	US 6,439,541 B1 (NOSEL et al) 27 August 2002 (27.08.2002) see especially col 3, ln 23-34, fig 5	5
A	US 2007/0260186 A1 (LANG) 8 November 2007 (08.11.2007) see whole document	1-15
A	US 2002/0058910 A1 (HERMANN et al) 16 May 2002 (16.05.2002) see whole document	1-15
A	US 4,909,798 A (FLEISCHHACKER et al) 20 March 1990 (20.03.1990) see whole document	1-15
A	US 4,895,346 A (STEIGERWALD) 23 January 1990 (23.01.1990) see whole document	1-15

☐ Further documents are listed in the continuation of Box C.


* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 15 January 2016	Date of mailing of the international search report 05 FEB 2016
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774