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(19) **United States**(12) **Patent Application Publication**
Kahle et al.(10) **Pub. No.: US 2018/0310959 A1**(43) **Pub. Date: Nov. 1, 2018**(54) **FIRST-ENTRY TROCAR SYSTEM***A61B 1/313* (2006.01)*A61B 17/02* (2006.01)(71) Applicant: **Applied Medical Resources Corporation**, Rancho Santa Margarita, CA (US)*A61B 90/00* (2016.01)*A61B 17/00* (2006.01)(72) Inventors: **Henry Kahle**, Corona, CA (US);
Arkadiusz A. Strokosz, Dana Point, CA (US); **Scott V. Taylor**, Rancho Santa Margarita, CA (US)(52) **U.S. Cl.**CPC .. *A61B 17/3474* (2013.01); *A61B 2017/3454* (2013.01); *A61B 1/00154* (2013.01); *A61B 1/3132* (2013.01); *A61B 17/0218* (2013.01); *A61B 17/3423* (2013.01); *A61B 17/3496* (2013.01); *A61B 90/36* (2016.02); *A61B 1/313* (2013.01); *A61B 90/361* (2016.02); *A61B 17/00234* (2013.01); *A61B 2017/00902* (2013.01); *A61B 2017/00907* (2013.01); *A61B 2017/3419* (2013.01); *A61B 17/3417* (2013.01)(21) Appl. No.: **16/028,701**(22) Filed: **Jul. 6, 2018****Related U.S. Application Data**

(63) Continuation of application No. 15/064,049, filed on Mar. 8, 2016, now Pat. No. 10,022,150, which is a continuation of application No. 13/962,557, filed on Aug. 8, 2013, now Pat. No. 9,314,266, which is a continuation of application No. 13/940,707, filed on Jul. 12, 2013, now Pat. No. 9,358,040, which is a continuation of application No. 12/569,652, filed on Sep. 29, 2009, now Pat. No. 8,506,520.

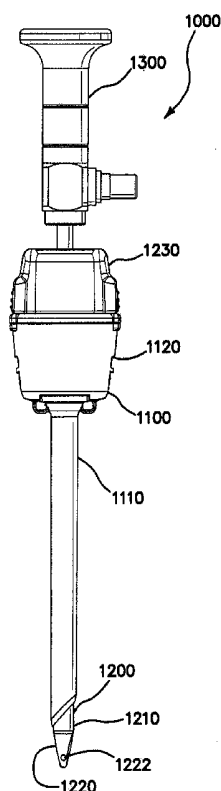
(60) Provisional application No. 61/101,061, filed on Sep. 29, 2008.

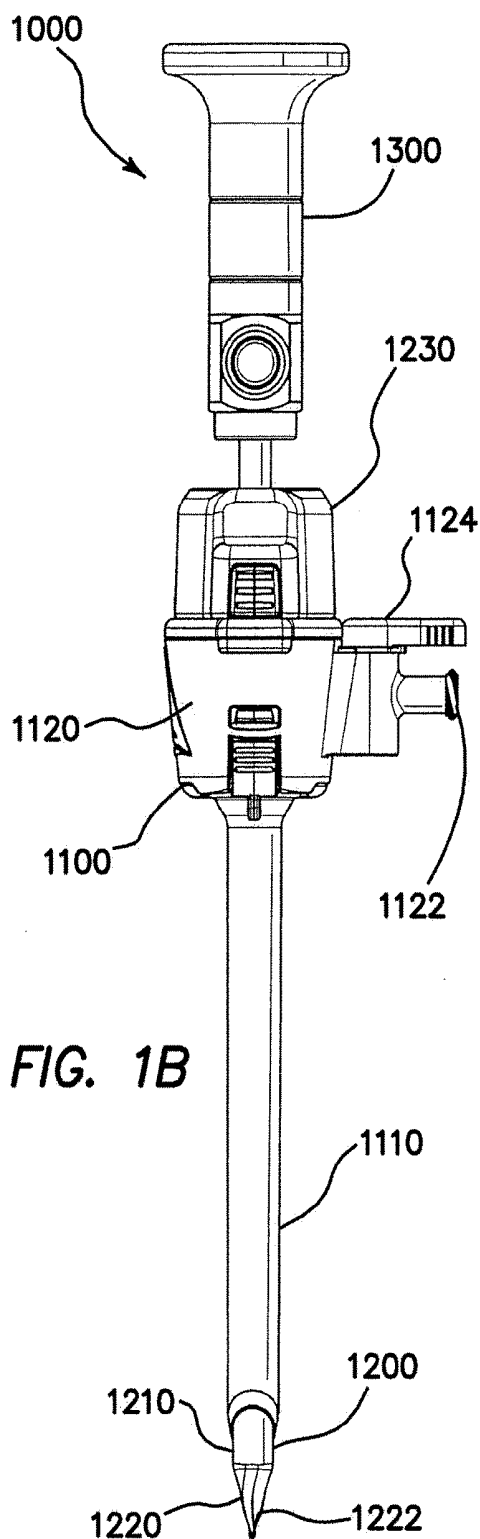
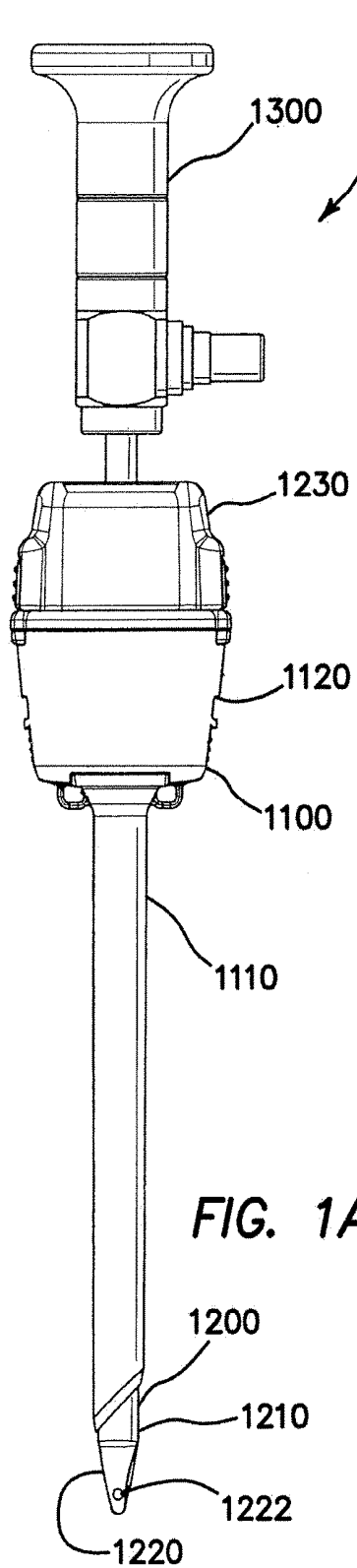
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(57)

ABSTRACT

A surgical access system comprises a trocar, an insufflating optical obturator slidably insertable into the trocar, and a laparoscope slidably insertable into the obturator. A distal end of the obturator comprises a tip, at least a portion of which comprises a wall with a generally uniform thickness comprising a transparent material. At least one vent hole disposed at the obturator tip is fluidly connected to a gas flow channel defined by an interior surface of the obturator and the laparoscope, which is fluidly connected to an insufflation gas inlet disposed at a proximal end of the trocar. Improved optical characteristics of the trocar system permit precise and accurate visual placement thereof into a body cavity. Accordingly the access system is suitable as a first entry surgical access system. Embodiments of the trocar access are also useful for drug delivery, and/or for fluid and/or tissue aspiration.





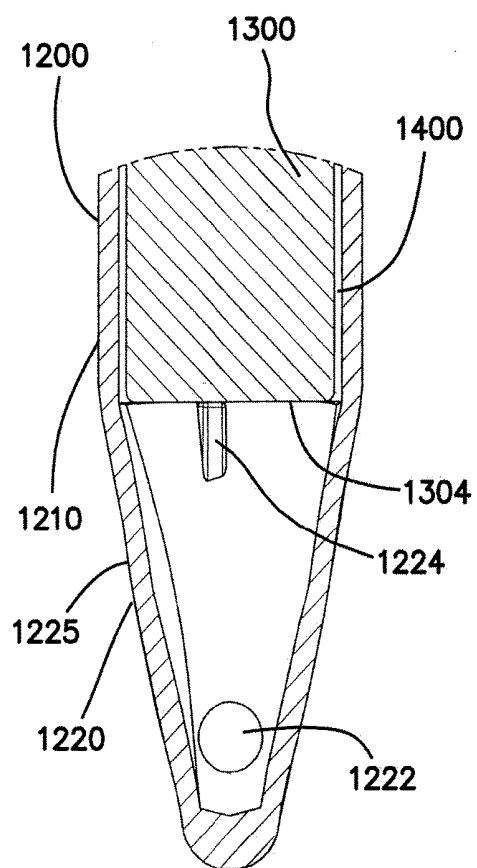


FIG. 1C

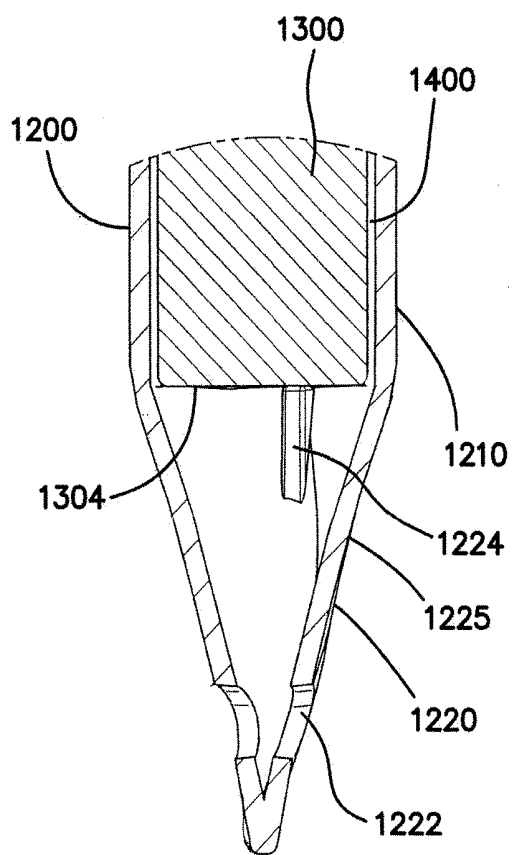


FIG. 1D

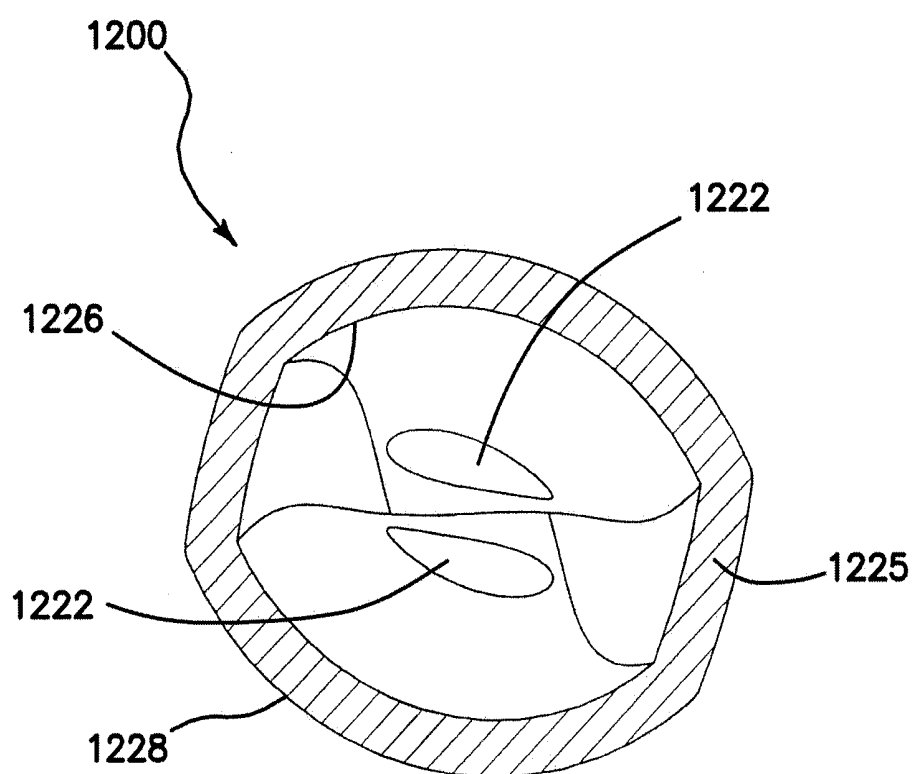


FIG. 1E

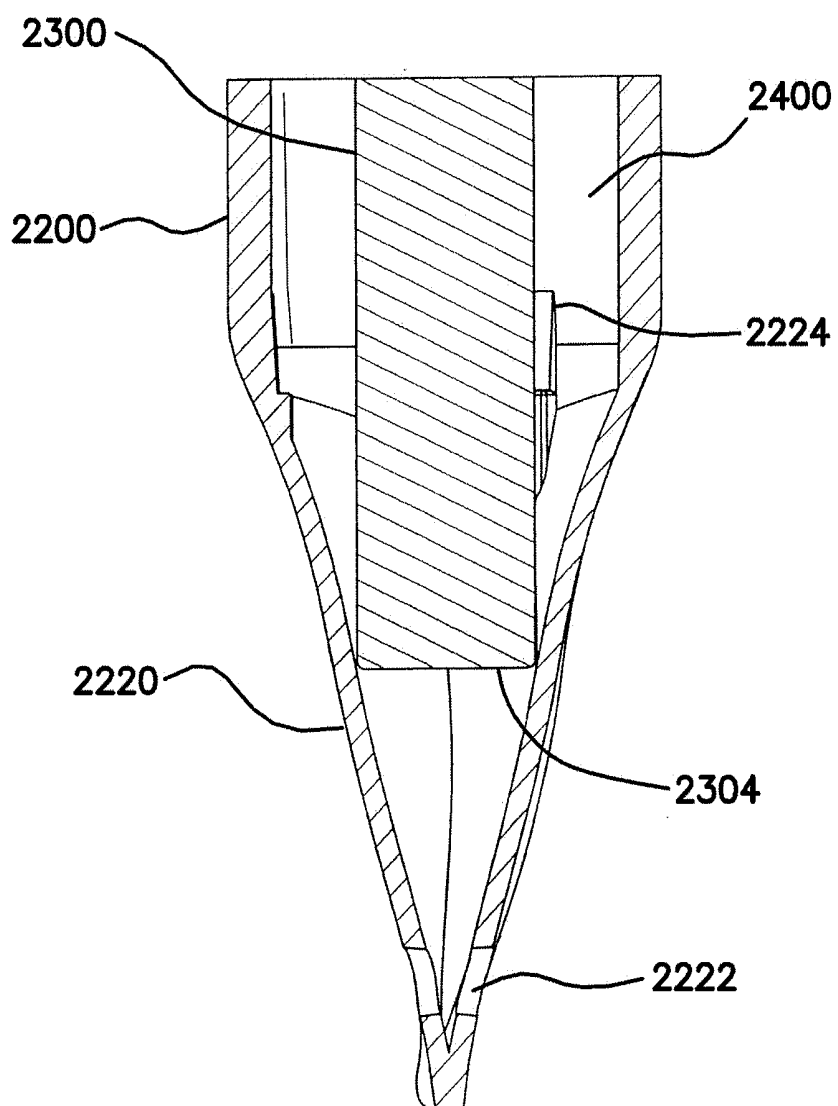


FIG. 2A

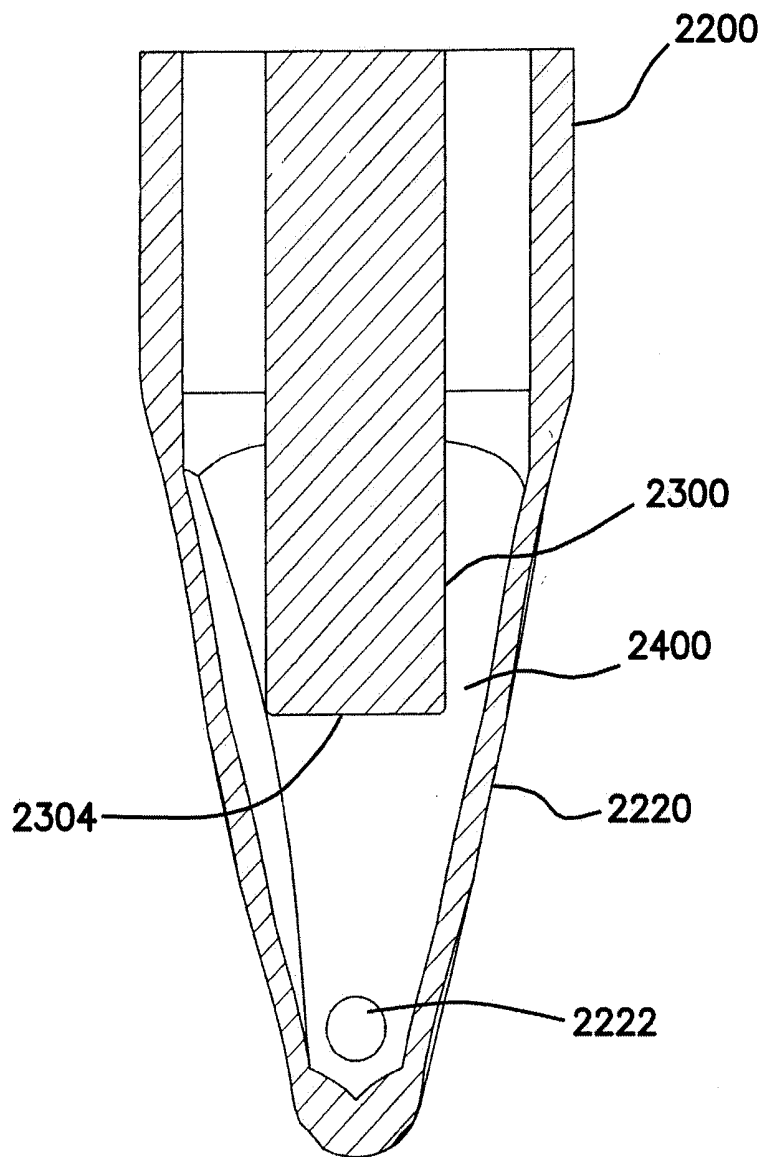


FIG. 2B

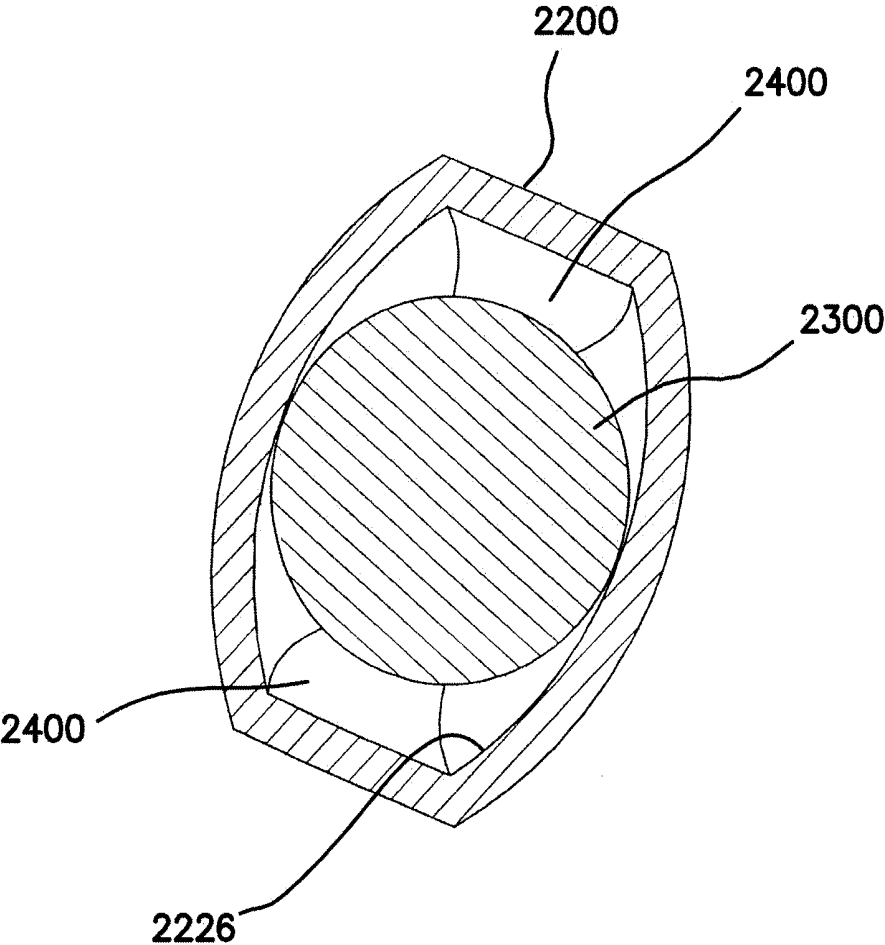
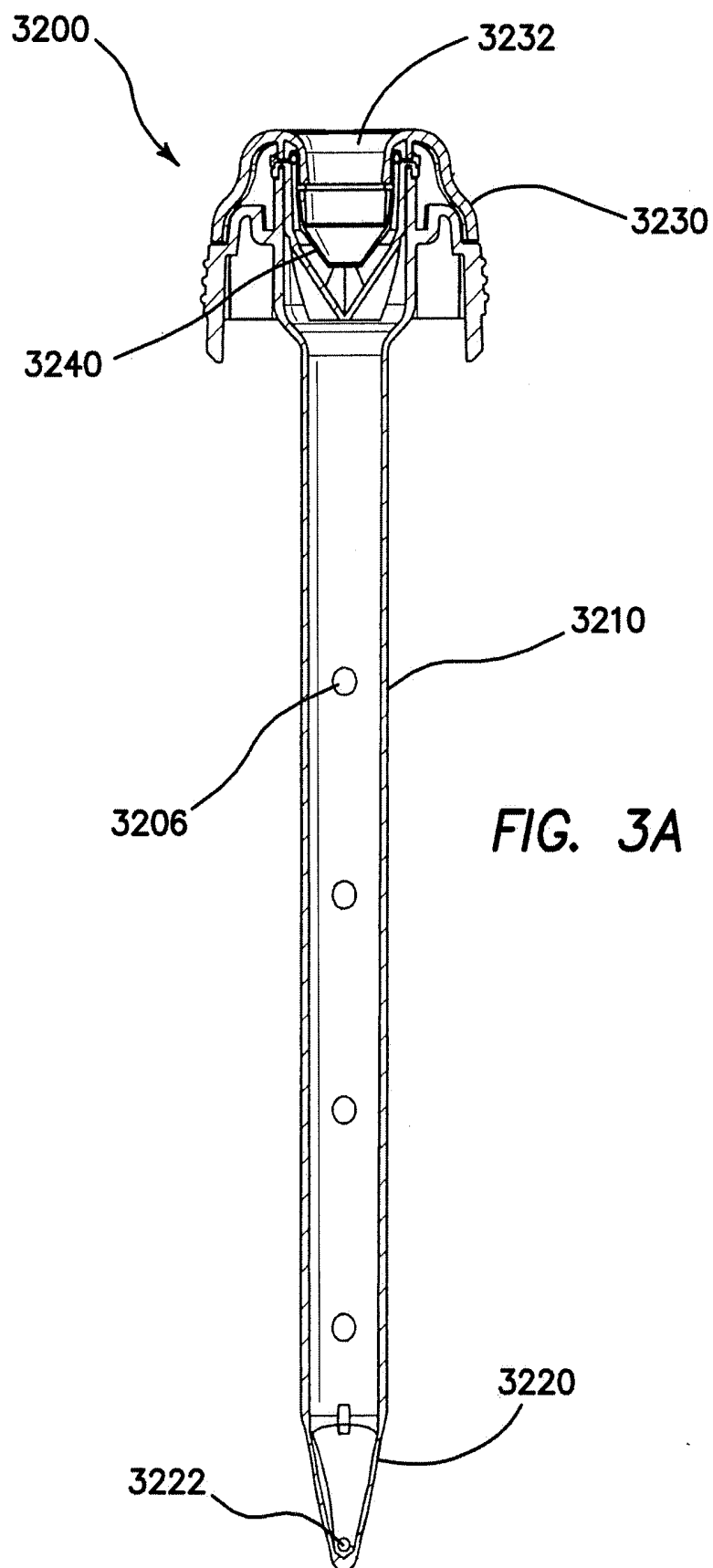


FIG. 2C



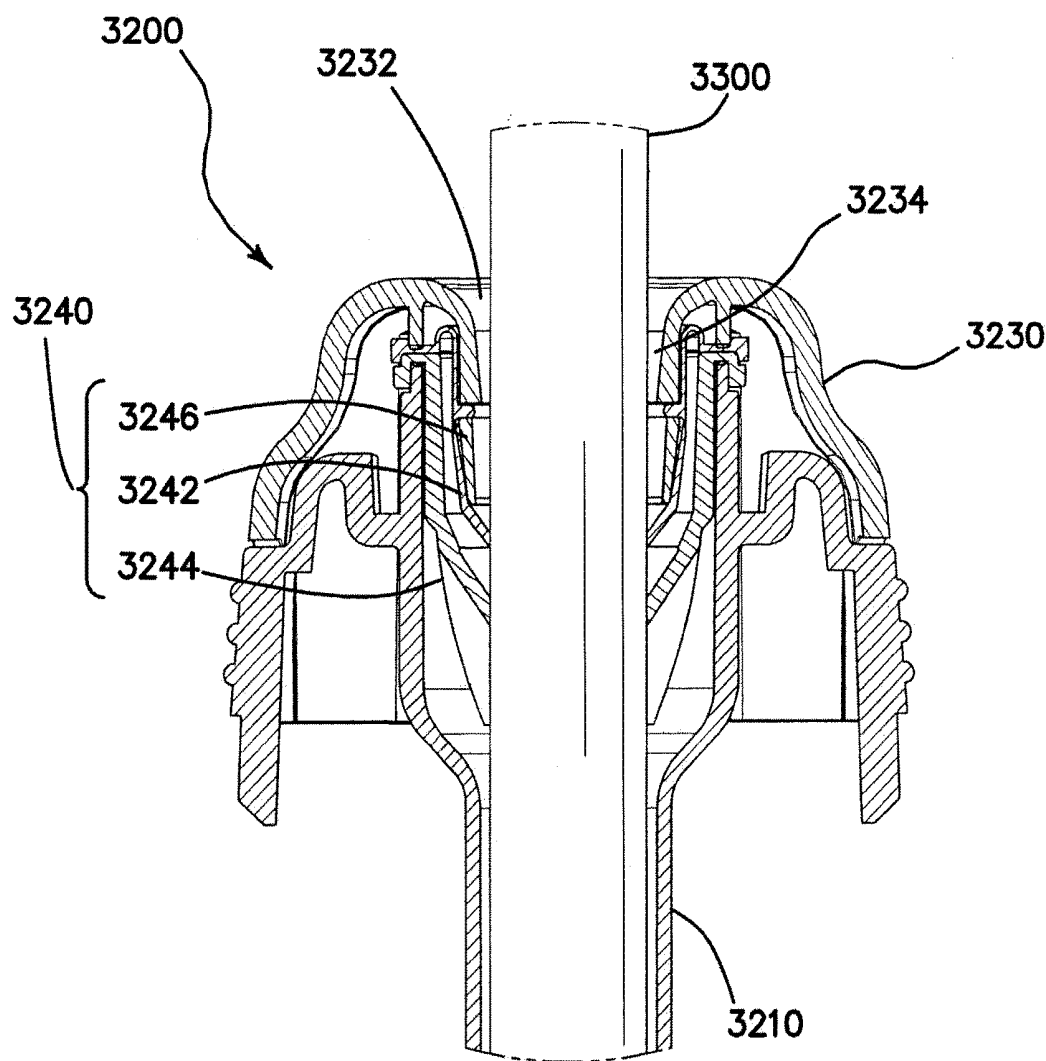


FIG. 3B

FIRST-ENTRY TROCAR SYSTEM

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation co-pending U.S. patent application Ser. No. 15/064,049 filed Mar. 8, 2016 entitled “First-entry trocar system” which is a continuation of U.S. patent application Ser. No. 13/962,557 filed Aug. 8, 2013 now U.S. Pat. No. 9,314,266 issued on Apr. 19, 2016 entitled “First-entry trocar system” which is a continuation of co-pending U.S. patent application Ser. No. 13/940,707 filed Jul. 12, 2013 now U.S. Pat. No. 9,358,040 issued on Jun. 7, 2016 entitled “First-entry trocar system” which is a continuation of application of U.S. patent application Ser. No. 12/569,652 filed on Sep. 29, 2009 now U.S. Pat. No. 8,506,520 issued on Aug. 13, 2013 entitled “Trocar system with laparoscope and gas channel” which claims priority to and benefit of U.S. Provisional Patent Application No. 61/101,061 filed on Sep. 29, 2008 entitled “First entry trocar system” the entire disclosures of all of these applications are incorporated by reference in their entireties herein.

BACKGROUND

1. Technical Field

[0002] This disclosure is generally directed to surgical access devices, and more particularly, to a first-entry surgical access system.

2. Description of the Related Art

[0003] Trocars are used for instrument access to body cavities in minimally invasive surgery, for example, laparoscopic surgery. In laparoscopic surgery of the organs of the abdomen, the abdomen is typically inflated or insufflated with an insufflation gas, for example, carbon dioxide, which lifts the abdominal wall away from the internal organs, thereby facilitating access to the organs, a condition referred to as pneumoperitoneum. Inserting trocars into an abdomen under pneumoperitoneum is relatively easy. Because the abdominal wall is distended away from the internal organs by the pressure of the insufflation gas, inadvertent damage to the organs during insertion is reduced. Before pneumoperitoneum is established, however, the abdominal wall through which the trocar is to be inserted contacts the internal organs directly. Consequently, inserting the first trocar, referred to as first entry, carries an increased risk of damaging the internal organs directly beneath the entry point.

SUMMARY OF THE INVENTION

[0004] A surgical access system comprises a trocar, an insufflating optical obturator slidably insertable into the trocar, and a laparoscope slidably insertable into the obturator. A distal end of the obturator comprises a tip, at least a portion of which comprises a wall with a generally uniform thickness comprising a transparent material. At least one vent hole disposed at the obturator tip is fluidly connected to a gas flow channel defined by an interior surface of the obturator and the laparoscope, which is fluidly connected to an insufflation gas inlet disposed at a proximal end of the trocar. Improved optical characteristics of the trocar system permit precise and accurate visual placement thereof into a body cavity. Accordingly the access system is suitable as a

first entry surgical access system. Embodiments of the trocar access are also useful for drug delivery, and/or for fluid and/or tissue aspiration.

[0005] Some embodiments provide a bladeless trocar that permits visualization of body tissue fibers as they are being separated, thereby permitting a controlled traversal across a body wall. Some embodiments provide a bladeless trocar that accommodates a conventional laparoscope. Some embodiments provide a trocar that enables insufflation of a body cavity and contemporaneous visualization thereof through the distal tip of the obturator.

[0006] Some embodiments provide a surgical access system comprising: a tubular trocar comprising a longitudinal axis, a proximal end, a distal end, an elongate cannula, and a seal assembly disposed at a proximal end of the cannula; an insufflating obturator slidably insertable into the trocar, the obturator comprising a longitudinal axis, a proximal end, a distal end, a tubular shaft, a tip disposed at the distal end of the shaft, at least one vent hole disposed on the tip, and a handle disposed at the proximal end of the shaft; and a fluid inlet disposed at a proximal end of the access system. At least a portion of the obturator tip comprises a wall comprises a transparent material with a substantially uniform thickness, the obturator slidably receives a laparoscope into the obturator shaft, and an interior surface of the obturator shaft and tip, and an outer surface of an inserted laparoscope together define an insufflation gas flow channel fluidly connecting the at least one vent hole to the fluid inlet.

[0007] In some embodiments, the seal assembly comprises a septum seal and a duckbill valve.

[0008] In some embodiments, the fluid inlet is disposed on the proximal end of the trocar.

[0009] In some embodiments, the obturator tip is bladeless. In some embodiments, the wall of the obturator tip is not greater than about 0.65 mm thick. In some embodiments, the obturator tip has a substantially uniform wall thickness. In some embodiments, the obturator shaft and tip are unitary. In some embodiments, the obturator tip comprises at least one of polymer, polycarbonate, polysulfone, PEEK, polyether block amide (PEBAX®), polyester, copolyester, and acrylic.

[0010] In some embodiments, the obturator tip comprises a single vent hole. In some embodiments, the at least one vent hole is at least one of circular, oval, elliptical, tear-drop shaped, slot shaped, slit shaped, chevron shaped, triangular, rectangular, rhomboid, and polygonal.

[0011] Some embodiments further comprise a depth indicator on the obturator tip. In some embodiments, the depth indicator comprises at least one of indicia disposed in a bore of the at least one vent hole, and indicia disposed proximate to the at least one vent hole.

[0012] In some embodiments, the obturator further comprises at least one laparoscope stop disposed on at least one of the interior surface of the obturator tip and the interior surface of the obturator shaft. In some embodiments, the interior surface of the obturator tip comprises a non-circular transverse cross section.

[0013] In some embodiments, the obturator accommodates laparoscopes with varying diameters. In some embodiments, the obturator tip accommodates a distal end of the laparoscope.

[0014] In some embodiments, at least one opening perforates the obturator shaft.

[0015] In some embodiments, a cross-sectional area of the insufflation gas flow channel is at least about 1.6 mm². In some embodiments, a flow rate through the access system is at least about 3.5 L/min at an insufflator setting of about 1.6-2 KPa.

[0016] Some embodiments further comprise a laparoscope.

[0017] Some embodiments further comprise at least one of a gas flow indicator, an audible gas flow indicator, and a visual gas flow indicator.

[0018] Some embodiments provide a method for accessing a targeted body region, the method comprising: inserting a laparoscope into the surgical access system, wherein the obturator is inserted into the trocar; contacting the obturator tip with a body wall; advancing access system through the body wall; observing a position of the obturator tip through the laparoscope; and terminating advancement of the trocar system when the obturator tip is observed to reach a targeted body region.

[0019] In some embodiments, the targeted body region is a body cavity.

[0020] In some embodiments, observing the position of the obturator tip comprises observing the position of the at least one vent hole.

[0021] Some embodiments further comprise coupling the gas inlet of the surgical access system to a source of insufflation gas. Some embodiments further comprise at least one of delivering a medicament through the at least one vent hole to the targeted body region; delivering a fluid; aspirating a fluid; and withdrawing tissue.

[0022] Some embodiments further comprise removing the obturator from the trocar.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] FIG. 1A is a front view and FIG. 1B is a side view of an embodiment of a surgical access system comprising a trocar, an insufflating optical obturator, and a laparoscope. FIG. 1C is a front cross-sectional view and FIG. 1D is a side cross-sectional view a distal end of the insufflating optical obturator illustrated in FIGS. 1A and 1B with a laparoscope inserted therein. FIG. 1E is a top view of a transverse cross section of a tip of the insufflating optical obturator illustrated in FIGS. 1A-1D.

[0024] FIG. 2A is a side cross-sectional view and FIG. 2B is a front cross-sectional view of a distal end of another embodiment of an insufflating optical obturator with a laparoscope inserted therein. FIG. 2C is a top view of a transverse cross-section of a tip of the insufflating optical obturator and laparoscope illustrated in FIGS. 2A and 2B.

[0025] FIG. 3A is a longitudinal cross-section of another embodiment of an insufflating optical obturator. FIG. 3B is a detailed cross section of a handle of the insufflating optical obturator illustrated in FIG. 3A.

DETAILED DESCRIPTION OF CERTAIN EMBODIMENTS

[0026] FIGS. 1A and 1B are front and side views of an embodiment of a surgical access or trocar system 1000, which is suitable, for example, as a first entry trocar system. The illustrated embodiment is suitable, for example, as a 5-mm trocar system, as well as for trocar systems of other sizes. The illustrated access system 1000 comprises a trocar 1100, an obturator 1200, and a laparoscope 1300.

[0027] The trocar 1100 comprises a longitudinal axis, a proximal end, and a distal end. The proximal end is disposed proximal to a user, for example, a surgeon, during use. Conversely, the distal end is disposed away from the user during use. The obturator 1100 comprises a tubular cannula 1110 and a trocar seal assembly 1120 disposed at the proximal end of the cannula 1110. In the illustrated embodiment, the seal assembly 1120 comprises a fluid inlet comprising a Luer fitting 1122 and a stopcock 1124. In other embodiments, the fluid inlet has a different configuration and/or is disposed on another component, for example, on the obturator 1100.

[0028] In the illustrated embodiment, the obturator 1200 is an insufflating optical obturator, as will be described in greater detail below. The obturator 1200 comprises a longitudinal axis, a proximal end, and a distal end. The obturator 1200 comprises an elongate shaft 1210, which is dimensioned for slidable insertion into and removal from the tubular cannula 1110 of the trocar, a tip 1220 disposed at the distal end of the shaft 1210, and a handle 1230 disposed at the proximal end of the shaft 1210. In some embodiments, the obturator tip 1220 is a bladeless tip. In other embodiments, the tip 1220 has another configuration useful for traversing and/or penetrating body tissue, for example, a sharp tip, a pointed tip, a pyramidal tip, a bladed tip, a conical tip, and/or a tip comprising one or more sharp edges or sharpened edges. In other embodiments, the tip 1220 is a radiused blunt tip, which is advantageous for traversing an existing body orifice, and/or relatively soft or fatty tissue.

[0029] The trocar 1100 and obturator 1200 independently comprise any suitable material. Those skilled in the art will understand that different components of the trocar 1100 and/or obturator 1200 comprise different materials in some embodiments. Suitable materials include, for example, at least one of a polymer, metal, ceramic, and the like. Suitable polymers include engineering polymers, polycarbonate, polysulfone, PEEK, polyether block amide (PEBAX®), polyester, copolyester, acrylic, and the like. Some embodiments of the trocar 1100 and/or obturator 1100 further comprise a composite, for example, a fiber-reinforced polymer. In some embodiments, a stronger material permits reducing a wall thickness of a component without reducing the strength thereof. For example, some embodiments of a metal or composite obturator shaft 1210 are thinner than a corresponding polymer version, thereby increasing the diameter of a lumen thereof without increasing the outer diameter. As discussed in detail below, increasing lumen diameter improves gas flow through the device.

[0030] For example, in some embodiments, obturator shaft 1210 comprises a metal tube, for example, a stainless steel tube, with a polycarbonate tip 1220 insert molded onto the tube. In some embodiments, the metal tube has a wall thickness as thin as about 0.003" (about 0.076 mm). An metal obturator shaft 1210 with an inside diameter of about 0.235" (about 6 mm) and an outside diameter of about 0.241" (about 6 mm) provides an acceptable insufflation gas flow rate. The relationship between gas flow rate and component dimensions and configurations is discussed in detail below.

[0031] Embodiments of the cannula 1110 typically comprise a rigid material. Some embodiments of the obturator shaft 1210 comprise a rigid material and/or a flexible

material because the obturator shaft **1210** is largely supported by the cannula **1110** during use in some embodiments.

[0032] The laparoscope **1300** comprises a proximal end and a distal end **1304** (FIGS. 1C and 1D). The laparoscope **1300** is of any suitable type, for example, comprising an eyepiece at a proximal end and an objective at a distal end thereof. The distal end **1304** of the laparoscope **1300** is dimensioned for slidable insertion into and removal from the obturator shaft **1210**.

[0033] FIG. 1C is a front cross-sectional view and FIG. 1D is a side cross-sectional view of the distal end of the insufflating obturator **1200** with a laparoscope **1300** inserted therein. The illustrated embodiment depicts a bladeless obturator **1200** suitable for visualization and insufflation therewith. The device includes a pair of vent holes **1222** at the distal tip **1220** of the bladeless obturator, through which an insufflating gas, such as carbon dioxide, flows into a body cavity, as discussed in greater detail below. Other embodiments comprise more or fewer vent holes **1222**. For example, some embodiments of the tip **1220** of the obturator comprise a single vent hole **1222**. In the illustrated embodiment, the vent holes **1222** are generally circular. In other embodiments, the vent holes **1222** have another shape, for example, oval, elliptical, tear-drop shaped, slot shaped, slit shaped, chevron-shaped, triangular, rectangular, rhomboid, polygonal, and the like. In some embodiments, at least one vent hole **1222** has a different shape from another vent hole **1222**.

[0034] In some embodiments, the obturator **1200** is an optical obturator in which at least a portion of a distal end of the tip **1220** of the bladeless obturator comprises a generally transparent or translucent material, through which tissue is visualized during the insertion of the obturator **1200** through a body wall. Embodiments of the bladeless obturator **1200** are dimensioned and configured to receive therein any suitable laparoscope **1300**, which typically includes an imaging element and fiber optic light fibers (not illustrated). The illustrated embodiment of the tip **1220** comprises at least one laparoscope stop **1224**, which assists in positioning the laparoscope **1300** within the obturator **1200**. In other embodiments one or more laparoscope stops are disposed within the obturator shaft **1210** and/or at the intersection of the shaft **1210** and tip **1220**. Other embodiments do not comprise a laparoscope stop.

[0035] The illustrated embodiment of the bladeless optical insufflating obturator **1200** includes a tip **1220** configuration comprising one or more features that enhance the visualization and clarity through the tip of the obturator. The illustrated transparent tip **1220** of the obturator through which tissue is observed comprises a wall **1225**, at least a portion of which has a substantially uniform thickness. The uniform wall thickness reduces distortion of an image observed through the obturator tip **1220**. In some embodiments, the entire obturator tip **1220** comprises a substantially uniform wall thickness. Embodiments of bladeless optical obturators comprising non-uniform wall thicknesses typically exhibit less clear imaging through the obturator tip because the varying wall thickness distorts the image transmitted there-through, for example, in bladeless optical obturators comprising a generally circular inner contour and a generally rectangular outer contour.

[0036] FIG. 1E is a top view of a transverse cross section of the obturator tip **1220** illustrated in FIGS. 1A-1D. In the

illustrated embodiment, an inner contour **1226** of the obturator tip **1220** has a generally rectangular transverse cross section, which substantially matches an outer contour **1228** of the obturator tip, which also has a generally rectangular transverse cross section. In other embodiments, the inner and outer transverse cross-sectional contours **1226** and **1228** of the obturator tip **1220** have another shape, for example, generally elliptical, hexagonal, S-shaped, or another suitable shape. In some embodiments, a portion of an interior surface the tip **1220** at which the distal end laparoscope **1300** contacts has a contour different from a shape or contour of the distal end of the laparoscope. For example, in embodiments in which the distal end of the laparoscope **1300** is circular, the portion of the tip **1220** at which the distal end of the laparoscope **1300** contacts is not circular, thereby defining a gas flow channel therebetween, as discussed in greater detail below.

[0037] In some embodiments, at least a portion of the wall **1225** of the obturator tip **1220** comprises a thin-wall configuration. The thin-wall configuration enables light to travel through the material with reduced loss in intensity, thereby enhancing the visibility of tissue through the obturator tip **1220** as the obturator is advanced and placed into the targeted body cavity. The thin-wall configuration also reduces distortion of the image viewed through the obturator tip **1220** and maintains the color accuracy of the viewed tissue. Some embodiments of the obturators **1200** have tip wall thicknesses of from about 0.02" (about 0.5 mm) to about 0.025" (about 0.65 mm) for about 5-mm to 12-mm obturators. In some embodiments, the tip wall is thicker, for example, to provide additional strength.

[0038] All transparent materials have a light transmittance value of less than 100%. That is, less than 100% of the light incident on the material is transmitted directly through the material. For a given transparent material, as the wall thickness of the material increases, the amount of light that travels through the material decreases. Moreover, because the illuminating light is directed from within the obturator **1200**, the light must travel through the obturator tip **1220** twice, thereby doubling the loss of light due to the transmittance characteristics or absorption of the obturator tip **1220**. Embodiments of an obturator tip **1220** with a reduced wall thickness reduce the loss of light or absorption thereby, thereby improving the image of the tissue through which the obturator **1200** is advanced, and maintaining the color accuracy and fidelity of the observed tissue.

[0039] In some embodiments, the obturator shaft **1210** and tip **1220** are injection molded as a unitary or single, integral component, which, in combination with the thin-wall tip **1220**, allows positioning or placing a distal end **1304** of the laparoscope (FIGS. 1C and 1D) in close proximity to and/or within the tip **1220** of the obturator. By placing the distal end **1304** of the laparoscope in close proximity to and/or within the tip **1220** of the obturator, an image produced through the laparoscope **1300** is magnified compared with an image produced by a distal end **1304** of the laparoscope **1300** positioned at a greater distance from the obturator tip **1220**. For example, in some embodiments of a 5-mm bladeless optical obturator designed to accommodate laparoscopes with diameters of from about 5 mm to about 5.5 mm, the distal end of the laparoscope is positionable as close as about 0.442" (about 11 mm) from the distal end of the obturator **1200**. Some embodiments of a 12-mm bladeless optical obturator designed to accommodate about 10-mm diameter

laparoscopes, permit positioning the distal end of the laparoscope as close as about 0.79" (about 20 mm) from the distal end of the obturator **1200** or less than about 0.83" (about 21 mm) from the distal end of the obturator **1200**. In these embodiments, the magnification through the 5-mm optical obturator is greater than that for the 12-mm optical obturator.

[0040] The enhanced visibility through the tip **1220** of the obturator also enhances the visibility of the vent holes **1222** in the tip of the obturator. Consequently, in some embodiments, the vent holes **1222** are useful as markers for indicating the penetration depth of the obturator tip **1220**. As the surgeon advances the trocar system **1000** through tissue, the surgeon can view the vent holes **1222** through the laparoscope **1300**, thereby observing when the vent holes **1222** have traversed a body wall, such as the abdominal wall. Once the vent holes **1222** have traversed a body wall and entered a body cavity, the trocar system **1000** need not be advanced further. Accordingly, the enhanced visibility of the obturator tip **1220** permits precise placement of the access system **1000**, and consequently, the trocar **1100** into a body cavity, thereby preventing the trocar **1100** from being advanced too far into the body cavity. Because the surgeon is able to precisely place the trocar system **1000** across a body wall until just the portion of the obturator tip **1200** comprising the vent holes **1222** is positioned within the body cavity, the risk of injury to internal body structures is reduced.

[0041] In some embodiments, one or more indicia are provided on at least one vent hole **1222**, thereby increasing the utility, visibility, and/or prominence of the vent holes **1222** as depth indicators. For example, in some embodiments, one or more contrasting and/or fluorescent colors are printed in the vent hole **1222** bores.

[0042] In some embodiments, one or more marker bands or indicia are disposed proximate to or near at least one vent hole **1222**, for example, by printing one or more contrasting or fluorescent marker bands. The enhanced visibility through the tip **1220** of the obturator permits using the marker bands for monitoring the penetration depth of the obturator **1200**. For example, in some embodiments, the marker band is highly visible through the laparoscope **1300** as a rectangular band positioned just proximal to the vent holes **1222**. In other embodiments, the marker bands have another shape, for example, dots. As a surgeon advances the access system **1000** through the tissue, the surgeon can view the position of the marker band to determine when the vent holes **1222** have traversed a body wall. The enhanced visualization through the obturator tip **1220** enables precise placement of the trocar **1100** into a body cavity, thereby preventing the trocar **1100** from being advanced too far into the body cavity. Precisely placing the access system **1000** across a body wall until just the portion of the obturator tip **1220** with the vent holes **1222** is in the body cavity reduces the risk of injury to internal body structures.

[0043] Referring to FIGS. 1C and 1D, some embodiments provide a device comprising an insufflation flow path or channel **1400** defined by an inner wall of the obturator shaft **1210** and the laparoscope **1300**. For example, embodiments of a 5-mm bladeless optical trocar with a 5-mm obturator are dimensioned and configured to accommodate laparoscopes with diameters of from about 5 mm to about 5.5 mm (from about 0.197" to about 0.217") with an insufflation flow channel **1400** extending longitudinally through the inside of

the obturator between the outside wall of the laparoscope **1300** and the inside wall of the obturator shaft **1210**. The insufflation flow channel **1400** is dimensioned to accommodate a suitable flow of an insufflating gas, for example, carbon dioxide. In some embodiments, a cross-sectional area of the insufflation flow channel is at least about 0.0025 in² (about 1.6 mm²). In the illustrated embodiment, an inside diameter of the obturator shaft **1210** is larger compared with the inside diameter of the obturator shaft of a typical 5-mm optical obturator. Increasing the inside diameter of the obturator shaft **1210** defines a generally cylindrical flow channel **1400** sufficient for insufflation when either a 5-mm or 5.5-mm laparoscope **1300** is inserted into the obturator **1200**. In the illustrated embodiment, an outer diameter of the obturator shaft **1210** is also increased. To accommodate the slightly larger obturator shaft **1210**, in some embodiments, the inner diameter and outer diameter of the trocar cannula **1110** are also increased compared with typical a 5-mm trocar cannula.

Example 1

[0044] A polycarbonate insufflating obturator was manufactured in which the inner diameter of the 5-mm insufflating obturator shaft was 0.235" (6 mm), the outer diameter was 0.272" (6.9 mm), and the wall thickness was 0.018" (0.46 mm). The inner diameter of the mating 5-mm cannula was 0.277" (7 mm), the outer diameter was 0.343" (8.7 mm), and the wall thickness of the cannula was 0.033" (0.84 mm). Based on these dimensions, the cross-sectional area of the obturator flow channel with a 5.5 mm laparoscope inserted therein was 0.0064 in² (4.1 mm²), which provides a carbon dioxide flow rate of about 6 L/min at an insufflator pressure setting of about 1.6-2 KPa (about 12-15 Torr).

Example 2 (Comparative Example)

[0045] For comparison, a polycarbonate 5-mm bladeless optical trocar designed to accommodate 5-mm to 5.5-mm laparoscopes included an obturator with an inner diameter of 0.219" (5.6 mm), an outer diameter of 0.225" (5.7 mm), and a wall thickness of 0.003" (0.076 mm). The mating cannula for this obturator had an inner diameter of 0.227" (5.8 mm), an outer diameter of 0.287" (7.3 mm), and a wall thickness of 0.03" (0.76 mm). For comparison, the cross-sectional area of the obturator flow channel with a 5.5-mm laparoscope inserted in the obturator was 0.00068 in² (0.44 mm²), which provides an insufficient flow of carbon dioxide through the device.

Example 3

[0046] A 5-mm obturator is molded from polycarbonate with an inside diameter of 0.230" (5.8 mm) and a wall thickness of 0.021" (0.53 mm). The carbon dioxide flow rate through this obturator with a 5.5-mm laparoscope inserted therein is about 3.5 L/minute at an insufflator pressure setting of about 1.6-2 KPa (about 12-15 Torr). The increased wall thickness improves the injection molding process for manufacturing the obturator shaft.

[0047] The tip **1220** of a bladeless insufflating obturator is designed to separate and dilate tissue and muscle fibers during traversal of a body wall. Because of the dilating and separating properties of a 5-mm insufflating trocar, increasing the outer diameters of the obturator shaft **1210** and the cannula **1110**, as compared with typically sized 5-mm blade-

less trocars, does not adversely affect the insertion force of the trocar in the illustrated embodiment. The wall thickness of the obturator shaft 1210 is also sufficient to permit injection molding the shaft 1210 and tip 1220 as a single piece, thereby reducing the overall device cost and increasing production capacity.

[0048] FIG. 2A is a side cross-sectional view and FIG. 2B is a front cross-sectional view of a distal end of another embodiment of an insufflating optical obturator 2200 with a laparoscope 2300 inserted therein. FIG. 2C is a top view of a transverse cross section of a tip 2220 of the insufflating optical obturator 2200 and laparoscope 2300 illustrated in FIGS. 2A and 2B. The following description refers to a 12-mm obturator sized to accommodate 10-mm laparoscopes, which defines an insufflation flow channel sufficient for generating pneumoperitoneum. Those skilled in the art will understand that the illustrated embodiment is also scalable to other size trocar systems.

[0049] The illustrated 12-mm obturator also accommodates smaller laparoscopes 2300 such as 5-mm and/or 5.5-mm diameter laparoscopes. The tip 2220 of the obturator is configured such that a distal end 2304 a 5-mm to 5.5-mm laparoscope is insertable deep into a tapered portion of the obturator tip 2220, while still defining an insufflation flow channel 2400 with a sufficient minimum area for a suitable flow of carbon dioxide around the laparoscope 2300. In the illustrated embodiment, a shorter dimension or width of a generally rectangular internal surface 2226 of the tip of the obturator defines a stop for a 5-mm and/or 5.5-mm laparoscope 2300. The insufflation flow channel 2400 is defined by the area between the internal longer dimension or internal length of the internal surface 2226 of the tip and the outside wall of the laparoscope 2300, as best viewed in FIGS. 2A and 2C. The insufflation flow channel 2400 is fluidly connected to one or more vent holes 2222 disposed on the tip. The embodiment illustrated in FIG. 2A also comprises an optional stop 2224 for a 10-mm laparoscope.

[0050] Some embodiments in which distal end of the 5-mm or 5.5 mm laparoscope 2300 and the portion of the inner surface 2226 of the tip that acts as a stop therefor have similar shapes do not provide an insufflation flow channel 2400 with an sufficiently large minimum area to provide a desired insufflation gas flow. For example, inserting a round laparoscope 2300 into an obturator 2200 in which the stop portion of the inner surface 2226 has a circular transverse cross section provides only a small or even no flow channel 2400, thereby effectively isolating the vent holes 2222 from the lumen of the shaft 2210 and preventing gas flow there-through.

[0051] The illustrated trocar system exhibits improved flexibility, versatility, and/or performance, while reducing cost and inventory requirements. Pairing a 5-mm and/or 5.5-mm laparoscope with a 12-mm obturator improves the flow rate of carbon dioxide through the obturator 2200 with the laparoscope inserted therein compared with the flow rate through the obturator 2200 with a 10-mm laparoscope inserted therein. Also, a hospital or clinic may not have any 10-mm zero-degree laparoscopes readily available, whereas many facilities have 5-mm and/or 5.5-mm zero-degree laparoscopes readily available. Another advantage is that the distal end of a 5-mm or 5.5-mm laparoscope is closer to the distal end of the obturator tip 2200 compared with a 10-mm laparoscope, thereby providing a magnified image. For example, in the illustrated embodiment, the distal end of a

5-mm or 5.5-mm laparoscope is positioned at about 0.430" (about 11 mm) from the distal end of the tip 2200 of the obturator, while the distal end of a 10-mm laparoscope is positioned at about 0.790" (about 20 mm) from the distal end of the tip 3220 of the obturator.

[0052] FIG. 3A is a longitudinal cross-section of another embodiment of an insufflating obturator 3200 and FIG. 3B is a detailed longitudinal cross section of a proximal end thereof. The insufflating obturator 3200 comprises a shaft 3210, a tip 3220, and a handle 3230. The handle 3230 comprises a funneled entry 3232 disposed at a proximal end thereof. A seal assembly 3240 is disposed distally thereof. Accordingly, the seal assembly 3240 is spaced from and/or recessed from the proximal end of the obturator 3200, thereby encasing the seal assembly 3240 within the handle 3230. Thus, in the illustrated embodiment, the seal assembly 3240 is protected from direct user contact and/or manipulation. In some embodiments in which a seal assembly 3240 is disposed at the proximal end of the obturator 3200 and externally accessible, one or more components of the seal assembly 3240 are vulnerable to inadvertent deformation, for example, during placement of the trocar system, which can cause loss of pneumoperitoneum. Furthermore, in some embodiments, the seal assembly 3240 is vulnerable to deliberate and/or inadvertent removal and/or loss. The illustrated seal assembly 3240 seals with instruments of varying diameters as well as providing a zero seal in the absence of an instrument. Again, using a 12-mm obturator as an illustrative example, the seal assembly 3240 seals with any of 5-mm laparoscopes, 5.5-mm laparoscopes, and/or 10-mm laparoscopes, thereby preventing leakage of carbon dioxide from the proximal end of the obturator 3200.

[0053] In the illustrated embodiment of the obturator 3200, at least one opening 3206 perforates the shaft 3210, fluidly connecting the interior or lumen with the exterior thereof. When inserted into a suitable trocar, for example, embodiments of the trocar 1110 illustrated in FIGS. 1A and 1B, the at least one opening 3206 fluidly connects the interior or lumen of the obturator 3200 to the fluid inlet 1122, thereby permitting fluid flow from the fluid inlet 1122, through the openings 3210, and out the vent holes 3222. Some embodiments of the obturator 3200 comprise a single opening perforating the shaft. In some embodiments, the opening or openings 3206 independently have another shape, for example, circular, oval, elliptical, tear-drop shaped, slot shaped, slit shaped, chevron-shaped, triangular, rectangular, rhomboid, polygonal, and the like.

[0054] Referring to FIG. 3B, which is a detailed longitudinal cross section of the proximal end of the obturator 3200 illustrated in FIG. 3A, the illustrated seal assembly 3240 comprises an internal septum seal 3242 and an internal duckbill valve 3244 disposed at the proximal end of the obturator shaft 3210. The septum seal 3242 prevents carbon dioxide from leaking from the obturator 3200 when a laparoscope 3300 is inserted therein. The duckbill valve 3244 prevents carbon dioxide from leaking in the absence of a laparoscope 3300, for example, when the laparoscope 3300 is withdrawn from the obturator 3200 or not used at all. The illustrated embodiment also comprises a sleeve 3246 disposed proximally of the septum seal 3242, which prevents and/or reduces inversion of the septum seal 3242 on withdrawal of the laparoscope 3300 therefrom. The septum seal 3242 and the duckbill valve 3444 are disposed between the obturator shaft 3210 and the obturator handle 3230 in the

illustrated embodiment. The obturator handle **3230** comprises a funneled entry **3232** at its proximal end leading into a guide channel **3234**, which guides or directs the laparoscope **3300** into the obturator **3200**. Some embodiments of the obturator handle **3230** comprise a space in the guide channel **3234** sufficient to permit at least some septum seal **3234** inversion during laparoscope **3300** withdrawal without binding the laparoscope **3300**. For example, in some embodiments, the diameter of the cap guide channel **3234** is larger than the diameter of the laparoscope plus the thickness of the inverted septum seal, which is sufficient to prevent binding or lock-up of the laparoscope **3300** during withdrawal from the obturator **3200**.

[0055] In some embodiments, at least one of the septum seal **3242** and duckbill valve **3244** is treated by a chlorination process, which reduces friction when inserting, rotating, and/or withdrawing the laparoscope **3300**, which typically has a polished surface that generates high friction with septum seals **3242** and duckbill valves **3244**. In some embodiments, at least one of the septum seal **3242** and duckbill valve **3244** is coated or treated with one or more other anti-friction materials and/or coatings, such as silicone oil, silicone emulsion, parylene, polytetrafluoroethylene (Teflon®), and/or treated by plasma etching.

[0056] An embodiment of a method for using the surgical access or trocar system refers to the embodiment **1000** illustrated in FIGS. 1A-1E, although the method is applicable to any of the embodiments discussed herein. In the method, the bladeless obturator **1200** is first inserted through the trocar seal **1120** and cannula **1110** of the trocar. A laparoscope **1300** is then inserted into the proximal end of the bladeless obturator **1200** and advanced to the stop **1224** or tip **1220** of the obturator. An endoscopic video camera (not illustrated) is attached to the proximal end of the laparoscope **1300** and the access system **1000** is then axially advanced by a surgeon through a body wall. As the surgeon advances the access system **1000** through the body wall, the surgeon visualizes the tissue as it is being separated, for example, using a video monitor connected to the endoscopic video camera. The surgeon can also readily determine when the body wall has been traversed by observing the distal end of the obturator **1200** entering the body cavity. As discussed above, the distal end of the obturator **1200** includes insufflation vent holes **1222** through which an insufflation gas may flow from the obturator **1200** and into a body cavity.

[0057] In another embodiment, the optical access system **1000** accesses a targeted body area or region under laparoscopic guidance as discussed above, then is used to administer a medicament under vision. In some embodiments, the medicament is delivered through the stopcock **1124** and Luer fitting **1122**, through the obturator **1200**, and out through the vent holes **1222** disposed at the tip **1220** of the obturator. The term “vent hole” is used here for consistency. Those skilled in the art will understand that in some embodiments, gas need not be delivered through the vent holes. Instead, the vent holes are used for another purpose, for example, for delivering a fluid, aspirating a fluid, withdrawing tissue, and/or as a gauge for placing the device, as discussed above. The trocar **1100**, in this embodiment, is rigid, semi-rigid, or flexible. Some embodiments of the obturator **1200** comprise a single vent hole **1222**. In some embodiments, the vent hole **1222** is disposed at the distal end of the tip **1220**, generally along the longitudinal axis of the obturator **1200**, which permits a more precise delivery of

the medicament. The access system **1000** is suitable, for example, for rapidly accessing a trauma site and for rapidly delivering a medicament through the obturator under vision to the trauma site. In some embodiments, the obturator **1200** is usable in this application either with or without a trocar **1100**. In embodiments that do not include a trocar, the obturator **1200** comprises a fluid inlet, for example, a Luer fitting, disposed at or near the proximal end of the obturator **1200**, for example, at the handle **1230**. The fluid inlet is fluidly connected to the vent hole **1222** through the lumen of the obturator shaft **1210**. These embodiments of the trocar system **1100** are also useful for accessing a targeted body area under vision using an inserted laparoscope, then withdrawing a body fluid sample and/or a soft tissue sample through the vent or aspiration hole **1222** of the obturator, for example, for pathology analysis, without a cannula.

[0058] In some embodiments, the access system **1000** further comprises an insufflator comprising a gas flow alarm (not illustrated). In some embodiments, a source of insufflation gas, for example, an insufflator, is connected to the Luer fitting **1122**, the stopcock valve **1124** opened, and the insufflation gas flow activated, for example, a carbon dioxide flow. When the tip **1220** of the obturator is placed in tissue such as the abdominal wall, the gas flow is blocked by the tissue, which in turn activates a gas flow obstruction alarm of the insufflator. The gas flow obstruction alarm will continue as the trocar is advanced through the tissue until the vent holes **1222** in the tip of the obturator are positioned within a hollow body cavity, at which point, carbon dioxide automatically starts flowing into the cavity and the gas flow obstruction alarm on the insufflator deactivates, thereby serving as an audible indicator that the distal tip **1222** of the obturator is properly positioned within the body cavity.

[0059] Some embodiments of the access system **1000** further comprise an integral audible indicator (not illustrated), which indicates gas flow, for example, carbon dioxide, through the device. The audible indicator produces a sound, for example, a high-pitched tone, for example, by mechanically modulating the gas flow through the device. In some embodiments, the audible indicator is disposed in the trocar **1100**. In some embodiments in which the audible indicator is integral to the trocar seal **1120**, the audible indicator is positioned within and/or integrated with the stopcock Luer fitting **1122**. In other embodiments, the audible indicator is disposed in the obturator **1200**. In yet other embodiments, the audible indicator is a detachable component, for example, disposed between and fluidly connecting the stopcock Luer fitting **1122** and the insufflation tubing.

[0060] In some embodiments, the access system **1000** comprising the audible indicator is connected to an insufflator and the carbon dioxide gas flow activated. When the tip **1220** of the obturator is placed in tissue, such as the abdominal wall, the tissue blocks gas flow through the device. As the tip **1220** is advanced through the tissue, the gas flow remains blocked until the vent holes **1222** in the tip of the obturator reach the targeted body cavity. When the vent holes **1222** are positioned within the body cavity, the carbon dioxide automatically starts flowing into the cavity. The gas flow activates the audible indicator, thereby creating a high-pitched tone, which signals that the distal tip **1220** of the obturator is properly positioned within the body cavity.

[0061] Some embodiments of the access system **1000** further comprise a visual indicator (not illustrated), for

example, a flow sight that indicates carbon dioxide flow through the device. Suitable visual indicators include a flapper, a rotor, and/or an oscillating ball. In some embodiments, the visual indicator is integral to the trocar seal **1120**, for example, positioned within and/or integrated with the stopcock Luer fitting **1122**. In other embodiments, the visual indicator is disposed within the proximal portion of the obturator **1200**. In other embodiments, the visual indicator is a detachable component disposed between the Luer fitting **1122** and the insufflation tubing.

[0062] In an embodiment of a method for using the trocar system comprising the integral visual indicator, the trocar system is connected to an insufflator and the carbon dioxide gas flow activated. When the tip **1220** of the obturator is placed in tissue, such as the abdominal wall, the gas flow is blocked. As the tip **1220** is advanced through tissue, the gas flow remains blocked until the vent holes **1222** in the tip of the obturator enter the targeted body cavity. When the vent holes **1222** are positioned within the body cavity, the carbon dioxide automatically flows into the body cavity. The gas flow causes movement of the visual flow indicator, thereby indicating that the distal tip of the obturator is properly positioned within the body cavity.

[0063] Some embodiments of the access system **1000** comprise an electronic gas flow indicator. An output of the gas flow indicator is, for example, audible and/or visible.

[0064] While certain embodiments have been particularly shown and described with reference to exemplary embodiments thereof, it will be understood by those of ordinary skill in the art that various changes in form and details may be made therein without departing from the spirit and scope thereof as defined by the following claims.

We claim:

1. A surgical access system comprising:
 - a tubular trocar comprising a longitudinal axis, a proximal end, a distal end, an elongate cannula, and a seal assembly disposed at a proximal end of the cannula;
 - a fluid inlet disposed at a proximal end of the access system;
 - an obturator slidably insertable into the proximal end of the cannula and through the seal assembly, the obturator comprising a longitudinal axis, a proximal end, a distal end, a tubular obturator shaft, a tapered obturator tip disposed at the distal end of the shaft, at least one vent hole disposed on the tip in fluid communication with the fluid inlet, and a handle disposed at the proximal end of the obturator shaft; the obturator having an inner surface that defines an inner contour and an outer surface that defines an outer contour; the obturator having a wall thickness defined between the inner surface and the outer surface; the obturator being sized and configured to receive a laparoscope having a distal end; and
 - at least one laparoscope stop disposed on at least one of the interior surface of the obturator tip and the interior surface of the obturator shaft.
2. The surgical access system of claim 1 wherein the laparoscope stop is disposed within the obturator shaft and at the intersection of the obturator shaft and obturator tip.
3. The surgical access system of claim 1 wherein the laparoscope stop is disposed within the obturator shaft or at the intersection of the obturator shaft and obturator tip.

4. The surgical access system of claim 1 wherein the inner surface of the obturator tip of the obturator defines a laparoscope stop for a 5.0 mm and/or 5.5 mm laparoscope.

5. The surgical access system of claim 1 wherein the stop is for a 10 mm laparoscope.

6. The surgical access system of claim 1 wherein the inner surface of the obturator tip acts as the laparoscope stop.

7. The surgical access system of claim 1 wherein the obturator shaft includes at least one opening that perforates the obturator shaft and fluidly connects the inner lumen with the exterior thereof.

8. The surgical access system of claim 1 wherein the obturator shaft includes at least one opening that perforates the obturator shaft and fluidly connects the inner lumen of the obturator to the fluid inlet there by permitting fluid flow from the fluid inlet through the at least one opening and out the vent hole.

9. The surgical access system of claim 1 wherein the obturator is configured to receive a laparoscope advanced to the laparoscope stop.

10. The surgical access system of claim 1 further including a laparoscope having a longitudinal axis, a distal end, and a transverse cross section at the distal end that is circular in shape; the distal end of the laparoscope is configured to contact the laparoscope stop defining a gas flow channel between the laparoscope and the inner contour of the tip.

11. The surgical access system of claim 1, in transverse cross-section of the tip, the outer contour has a generally rectangular transverse cross-section which substantially matches the inner contour which also has a generally rectangular transverse cross-section.

12. The surgical access system of claim 1 wherein the wall thickness at the obturator tip is substantially uniform to reduce distortion of an image observed through the obturator tip.

13. The surgical access system of claim 1 wherein the inner surface of the obturator tip and the outer surface of an inserted laparoscope together define an insufflation gas flow channel fluidly connecting the at least one vent hole to the fluid inlet.

14. The surgical access system of claim 1 wherein, in transverse cross-section of the tip, the tip has a generally rectangular cross-section has two oppositely disposed sides having a longer dimension interconnected by two oppositely disposed sides having a relatively shorter dimension; wherein the two oppositely disposed longer sides are outwardly curved.

15. The surgical access system of claim 1 wherein in transverse cross-section of the tip, the tip has a the generally rectangular cross-section that has two oppositely disposed sides having a longer dimension interconnected by two oppositely disposed sides having a relatively shorter dimension; wherein the two oppositely disposed shorter sides are straight.

16. The surgical access system of claim 1 wherein in transverse cross-section of the tip, the tip has a the generally rectangular cross-section that has two oppositely disposed sides having a longer dimension interconnected by two oppositely disposed sides having a relatively shorter dimension; wherein the two oppositely disposed shorter sides are straight and the two oppositely disposed longer sides are outwardly curved.

17. The surgical access system of claim 1 wherein in transverse cross-section of the tip, the tip has a the generally

rectangular cross-section has two oppositely disposed sides having a longer dimension interconnected by two oppositely disposed sides having a relatively shorter dimension; wherein the shorter dimension of the generally rectangular inner surface of the tip of the obturator defines a stop for a laparoscope having a circular cross-section inserted into the obturator.

18. The surgical access system of claim 1 wherein in transverse cross-section of the tip, the tip has a the generally rectangular cross-section has two oppositely disposed sides having a longer dimension interconnected by two oppositely disposed sides having a relatively shorter dimension; wherein the obturator is configured such that a gas flow channel is defined between the longer dimension of the rectangular inner surface of the tip and the outer surface of a laparoscope inserted into the obturator.

19. The surgical access system of claim 1 wherein the obturator accommodates laparoscopes with varying diameters.

20. The surgical access system of claim 1 wherein the obturator tip accommodates the distal end of the laparoscope.

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摘要(译)

一种外科进入系统，包括套管针，可滑动地插入套管针中的吹入式光学填塞器，以及可滑动地插入到闭塞器中的腹腔镜。所述填塞器的远端包括尖端，所述尖端的至少一部分包括具有大致均匀厚度的壁，所述壁包括透明材料。设置在填塞器尖端处的至少一个通气孔流体连接到由填塞器的内表面和腹腔镜限定的气体流动通道，该气体流动通道流体连接到设置在套管针的近端处的吹入气体入口。套管针系统的改进的光学特性允许将其精确且准确地视觉放置到体腔中。因此，进入系统适合作为第一进入外科手术进入系统。套管针通路的实施例也可用于药物输送，和/或用于流体和/或组织抽吸。

