(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 476 384 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
04.11.2015 Bulletin 2015/45

(51) Int Cl.:
A61B 17/34 *(2006.01)*

(21) Application number: **12164164.1**

(22) Date of filing: **21.11.2007**

(54) **Trocar cannula with atraumatic tip**

Trokarkanüle mit atraumatischer Spitze

Canule de trocart avec embout atraumatique

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC MT NL PL PT RO SE SI SK TR

(30) Priority: **22.11.2006 US 866939 P**

(43) Date of publication of application:
18.07.2012 Bulletin 2012/29

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
07854750.2 / 2 086 430

(73) Proprietor: **APPLIED MEDICAL RESOURCES CORPORATION**
Rancho Santa Margarita, CA 92688 (US)

(72) Inventors:
- **Pravongviengkham, Kennii**
  Rancho Santa Margarita, CA 92688 (US)
- **Kahle, Henry**
  Rancho Santa Margarita, CA 92688 (US)
- **Albrecht, Jeremy J**
  Rancho Santa Margarita, CA 92688 (US)
- **Taylor, Scott V**
  Rancho Santa Margarita, CA 92688 (US)

(74) Representative: **Fitchett, Stuart Paul**
Saunders & Dolleymore LLP
9 Rickmansworth Road
Watford
Hertfordshire WD18 0JU (GB)

(56) References cited:
EP-A1- 0 192 576
EP-A1- 1 557 130
WO-A-03/088854
US-A- 4 795 426
US-A- 5 257 973
US-A1- 2003 004 528
US-A1- 2005 059 934
US-A1- 2005 137 524
US-B1- 7 879 009

EP 2 476 384 B1

Printed by Jouve, 75001 PARIS (FR)

Description

Background

[0001] This invention relates to a medical access device including a trocar cannula with an atraumatic tip.

[0002] During use of a trocar in a surgical procedure, such as a laparoscopic procedure, a trocar is placed across the abdominal wall and the trocar cannula is left disposed across the abdominal wall. The distal tip of the cannula is positioned on the anterior side of the abdominal wall. Laparoscopic procedures can utilize several trocars across the abdominal wall and therefore several cannulas may be disposed across the abdominal wall at the same time. With several cannulas disposed across the abdominal wall, it can be difficult to constantly observe and monitor the positioning of the distal tips of the cannulas while the laparoscopic procedure is being conducted. For example, because of the number of cannulas disposed across an abdominal wall in a laparoscopic procedure, it is possible for a cannula tip to unintentionally engage body tissue out of the surgeon's field of view provided by the laparoscope and camera. The trocar in accordance the present invention minimizes the possibility for a trocar cannula to inadvertently engage and traumatize body tissue in a body cavity, due to accidental misuse.

[0003] The following patent specifications disclose medical devices having features generally in accordance with the preamble of present Claim 1: US 4,795,426 A, US 5,257,973 A, US 2005/059934 A1, which discloses a device according to the preamble of claim 1, US 2005/137524 A1 and WO 03/088854 A.

Summary

[0004] According to the present invention there is provided a medical access device as recited in Claim 1. The invention minimizes the possibility for the trocar cannula to inadvertently engage and traumatize body tissue in a body cavity, due to incidental misuse, by the cannula having an atraumatic distal tip with an elastomeric joint between the tip and an elongate body of the cannula, to permit the tip to be deflected. It also minimizes potential destructive engagement between the tip and the articulating laparoscope.

[0005] Many of the attendant features of the present invention will be more readily appreciated as the same becomes better understood by reference to the foregoing and following description and considered in connection with the accompanying drawings in which like reference symbols designate like parts throughout.

Brief Description of the Drawings

[0006]

FIGs. 1-2 are side views of a trocar system:

FIGs. 3-4 are side views of an operational use of a trocar system;

FIG. 5 is a cross-sectional side view of a trocar cannula;

FIG. 6A is an enlarged cross-sectional side view of a portion of a trocar cannula

FIG. 6B is an enlarged side view of a portion of a trocar cannula without a tip;

FIG. 7 is a side view of a trocar system;

FIG. 8 is a side view of a trocar system;

FIG. 9A is an enlarged cross-sectional side view of a portion of a trocar cannula;

FIG. 9B is an enlarged side view of a portion of a trocar cannula without a tip;

FIG. 10 is a side view of a trocar system;

FIG. 11 is a side view of a trocar cannula in accordance with various aspects of the present invention;

FIG. 12 is a side view of a trocar cannula in accordance with various aspects of the present invention;

FIG. 13 is a side view of a trocar cannula in accordance with various aspects of the present invention; and

FIG. 14 is an enlarged cross-sectional side view of a portion of a trocar cannula.

Detailed Description

[0007] Generally, an access port or trocar is provided with a cannula having an atraumatic distal tip. The trocar is used during minimally invasive surgery to provide an access channel into the body through which a surgeon may insert medical instruments. The cannula in one aspect has a proximal portion, which is formed of a rigid polymer and a distal portion formed of an elastomeric polymer. The elastomeric cannula tip has sufficient column strength to enable passage through a body wall when used in combination with an obturator yet has a lower durometer hardness and is more compliant as compared to the proximal portion of the cannula. The low durometer and compliance of the atraumatic cannula tip prevents the cannula tip from potentially traumatizing, due to accidental misuse, for example, or engaging adjacent body tissue during a surgical procedure such as a laparoscopic procedure. Some trocar cannulas are typically formed of a single material such as stainless steel or polycarbonate. These trocar cannulas can be rigid and

include tapered distal tips, which can engage body tissue and may cause trauma to the engaged body tissue, due to, for example, accidental misuse.

[0008] Referring to FIGS. 1-14, a surgical access port, e.g., a trocar, which comprises a trocar seal housing 11, a trocar cannula 3, and/or an obturator is provided. In this description, "proximal" or "proximally" refers to that portion of the instrument, component, or element that extends toward the user. "Distal" or "distally" refers to that portion of the instrument, component, or element that extends away from the user. The trocar is configured to access a body cavity and to maintain positive pressure at its distal end to prevent loss of surgical insufflation gas such as carbon dioxide used, for example, in laparoscopic procedures to insufflate the body cavity. The trocar seal and trocar cannula is also configured to sealingly engage surgical instruments of various diameters, which would typically be inserted through the trocar, to prevent loss of surgical gas during use of such instruments and/or when no instrument is inserted. In
one aspect, the trocar seal housing is releasably attachable to the trocar cannula to allow the seal to be removed during surgery to enable the extraction of tissue specimens through the trocar. The trocar in one aspect has or is included with an optical obturator having a tip, which includes a smooth outer surface and has a high degree of optical clarity.

[0009] The trocar seal housing 11 in one aspect can be easily detached or removed from a proximal enlarged end of the trocar cannula 3 and easily attached or reattached to the trocar cannula 3 for example during a surgical procedure. During surgery, small tissue specimens may be extracted from a body cavity through a trocar to enable pathological analysis of the tissue specimen. The integrity of the tissue specimen can be maintained or the maintenance facilitated by avoiding or minimizing withdrawal of delicate tissue specimens through a trocar seal. As such, in one aspect, the trocar seal housing 11 is arranged to be removed from the trocar cannula 3 to enable extraction of tissue specimens from a body cavity while maintaining the integrity of the tissue specimen. The trocar seal housing 11 also easily reattaches to the trocar cannula 3 after its initial removal during a surgical procedure.

[0010] Laparoscopic surgery of the abdominal area typically requires the introduction of an insufflation gas into the peritoneal cavity of the patient. The insufflation gas is usually pressurized to about 10 mm Hg above atmospheric pressure. This in turn lifts the abdominal wall away from the organs underlying it. Pressurized insufflation gas in one aspect is introduced through the stopcock of the trocar seal housing 11 into the trocar cannula 3. Trocar seal housing 11, accommodating instrument and/or zero seals, prevents the gas from escaping proximally out from the cannula 3 and allows the insertion and removal of a laparoscope and surgical instruments into and out of the surgical site.

[0011] Also, in one aspect, the trocar seal housing 11 is easily removable from the trocar cannula 3 to enable rapid desufflation of an insufflated body cavity. In one aspect, a trocar lock releasably attaches the trocar cannula to the trocar seal housing. For example, towards the end of a laparoscopic surgical procedure, release of the insufflation gas such as carbon dioxide from the peritoneal cavity of the patient is performed. By opening one or more stopcock valves on the trocar seal, desufflation can be achieved. The flow rate through the stopcock valves, however, can be slow with regard to evacuation of the carbon dioxide from the peritoneal cavity and therefore the time expended to evacuate the insufflation gas can be excessive. By removing the seal housing 11 from the cannula 11, the cannula provides an unobstructed outlet for the insufflation gas to escape thereby decreasing desufflation time.

[0012] During an operational exemplary use, a laparoscope 21 is inserted into and through trocar seal housing 11 and into cannula 3. An endoscopic video camera is attached to the proximal end of the laparoscope. As the surgeon advances the trocar through the body wall, the surgeon can visually observe the tissue through the laparoscope via a video monitor, which is connected to the endoscopic video camera.

[0013] Referring to FIGS. 1-6, the trocar system, i.e., a surgical access port for entry into a body cavity, in one aspect is provided in that an atraumatic distal tip 7 of a trocar cannula 3 prevents or minimizes potentially destructive engagement with laparoscopic instrumentation such as an articulating laparoscope 21. For example, if an articulating laparoscope is placed through a typical cannula, the distal tip of the laparoscope then articulated, and the laparoscope then withdrawn from the cannula, the flexible joint of the laparoscope can contact the distal tip of the cannula resulting in damage to the flexible joint of the laparoscope. The damage to the laparoscope may be such as to require immediate replacement of the laparoscope resulting in an immediate delay in the surgical procedure. Articulating laparoscopes are also typically very expensive in comparison with non-articulating laparoscopes and therefore, it can be very costly for a hospital or a manufacturer to replace or repair a damaged articulating laparoscope. The trocar in accordance with the present invention may address this by providing a cannula 3 with an distal tip 7, which is compliant, and has a low durometer. The atraumatic elastomeric distal tip 7 on the cannula 3 may be sufficiently compliant and soft so as to prevent or minimize potential damage to instrumentation, which engages the cannula tip 7 during withdrawal of the instrumentation.

[0014] The cannula 3 with the atraumatic tip 7 may be a high durometer rigid polymer cannula formed of a material such as polycarbonate. The atraumatic tip comprises a low durometer elastomeric material such as polyurethane. The length of the atraumatic elastomeric tip 7 can range from approximately 0.6 cm (.25") to approximately 2.5 cm (1") long. This length enables the cannula 3 to be disposed across the abdominal wall such that the

rigid portion 5 of the cannula 3 is positioned within the abdominal wall to hold the abdominal wall in a retracted position. The retracted abdominal wall also serves to aid with anchoring the cannula 3 in place and prevents axial movement of the cannula during the surgical procedure. The atraumatic elastomeric tip 7 is positioned within the peritoneal cavity and in one aspect is the only portion of the cannula to be disposed within the peritoneal cavity.

[0015] The cannula tip or distal tip end 4 of the cannula may have a wall thickness smaller than remaining portions of the cannula 3. A proximal portion of the atraumatic tip 7 has may have a wall thickness substantially similar to cannula tip 4 and a distal portion of the atraumatic tip 7 may have a wall thickness substantially similar to a wall thickness of a proximal portion of the cannula 3. The atraumatic elastomeric tip 7 can be formed from a material, e.g., a transparent polyurethane material, or otherwise configured/arranged to ensure that visibility through the tip is maintained. The transparent elastomeric tip assists in positioning the cannula 3 within the abdominal wall. By placing the laparoscope lens just proximal to the tip of the cannula 3, the abdominal wall can be viewed through the cannula tip 6 while positioning the cannula such that only the atraumatic elastomeric tip 7 of the cannula is disposed within the peritoneal cavity. The atraumatic elastomeric tip 7 may be formed with a contrasting tint as compared to the rigid portion 5 of the cannula to further aid with positioning of the cannula within the abdominal wall and the peritoneal cavity.

[0016] The rigid portion 5 of the cannula 3 can be formed from polyethylene, polysulfone, polyethersulfone, polyetherimide, polycarbonate, polyurethane, liquid crystal polymer, nylon, polyester, polypropylene, or ABS (Acrylonitrile Butadiene Styrene). The atraumatic elastomeric tip portion of the cannula can be formed from silicone, polyurethane, polyester, polystyrene, nylon, polyvinyl chloride, mylar, polyethylene, Kraton® thermoplastic elastomers, C-Flex® thermoplastic elastomers, Versaflex® thermoplastic elastomers, Santoprene® thermoplastic elastomers, Carbothane® thermoplastic polyurethanes, copolymer/mineral oil gels, polyisoprene, or natural rubber.

[0017] The cannula 3 may have an ultimate elongation less than the ultimate elongation of the atraumatic tip 7. For example, the ultimate elongation of the cannula 3 is about 120% versus the ultimate elongation of the atraumatic tip 7 being about 410%. In one aspect, the ultimate elongation of the cannula 3 is within the range of about 2% to about 150% versus the ultimate elongation of the atraumatic tip 7 being in the range of about 300% to about 1,000%. In one aspect, the ultimate elongation of the tip is at least three times greater than the ultimate elongation of the cannula. The large or greater ultimate elongation of the tip ensures that the tip does not tear off when a surgical instrument is inserted through the cannula, moved off-axis and/or portions of the instrument articulated off-axis relative to the longitudinal axis of the cannula which may interfere and/or damage the instrument and/or tip portions of which may fall into the surgical site.

[0018] The atraumatic elastomeric tip 7 of the cannula 3 may be formed from an elastomeric material which further softens upon extended exposure to body temperatures. The elastomeric material can therefore be less compliant during the initial insertion of the trocar when lower compliance is used providing a lower insertion force, and upon extended exposure to body temperatures, the atraumatic cannula tip would then soften resulting in a more compliant and therefore a more atraumatic cannula tip. Examples of elastomeric materials with these properties are the Carbothane® thermoplastic polyurethanes available from Noveon.

[0019] The cannula 3 with the atraumatic elastomeric tip 7 may be provided with inside diameters ranging from 1mm to 30mm. A typical wall thickness for the cannula is about .25mm to 1 mm. The cannula with the atraumatic elastomeric tip in one aspect is formed using a dual-shot molding process whereby the rigid portion is first molded and then the elastomeric portion is then over-molded onto the rigid portion using a dual-shot injection mold and a dual-shot injection molding press. The cannula 3 with the atraumatic elastomeric tip 7 can be used in conjunction with non- bladed dilating obturators, non-shielded bladed obturators, shielded bladed obturators, electrosurgical obturators, and blunt tip obturators. In one aspect, the cannula 3 with the atraumatic elastomeric tip 7 can have a semi-rigid or flexible proximal portion to enable placement of the cannula through a body conduit such as a urethra or ureter. The proximal portion of the cannula or catheter would be configured to be less flexible than the distal tip portion of the cannula. In one aspect, the proximal portion 8 of the cannula 3 is enlarged accommodating instrument and/or zero seals, surgical instruments with different diameters and orientation of such instruments, providing finger holds or grips, suture tie slots, and/or a releasable connection to the seal housing 11.

[0020] In one aspect of the present invention, the cannula 3 with the atraumatic elastomeric tip 7 is formed of a single material. The cannula has thinned wall sections or axial slots 25 at its distal tip to provide the distal tip of the cannula with greater flexibility as compared to the proximal portions of the cannula (FIG. 7). In FIG. 8, the cannula in one aspect of the present invention is formed of a single material with a flexible joint 27 between the proximal portion and the distal portion of the cannula. The flexible joint, e.g., bellows, would enable the distal tip or portion of the cannula to pivot in response to contact with body tissue or inserted instrumentation. In one aspect, the flexible joint 27 integrated with and extending from the proximal portion of the cannula 3. The flexible joint 27 is more compliant than the proximal or rigid portion 5 of the cannula 3 and is formed from a material that is different from the material of the other portions of the cannula 3. The tip or distal portion of the cannula is integrated with and extending from an opposing end of the flexible joint away from the distal tip end of the elongate

body. In one aspect, the tip is less compliant than the flexible joint and is formed from a material different from the material of the flexible joint. The tip or distal portion in one aspect is formed from a material corresponding to the material of the proximal portion of cannula 3. In one aspect, the flexible joint is formed of thermoplastic polyurethane and has a flexural modulus substantially smaller than the flexural modulus of the cannula 3.

[0021] In one aspect, the atraumatic elastomeric tip 7 is coated or treated to reduce the friction associated with the movement of instrumentation when the instrumentation contacts the elastomeric tip. The coating or treatment can also reduce the force used to place the trocar through the abdominal wall. Examples of coatings and treatments include parylene coatings, hydrophilic coatings, plasma surface treatments, and chlorination treatments. In one aspect, the atraumatic elastomeric tip is formed from a radiopaque material. A typical radiopaque material includes barium sulfate as an additive.

[0022] Referring now to FIG. 9, in one aspect no in accordance with the invention , the tip of the rigid portion 5 of the cannula 3 is formed with annular barbs 15 to provide a mechanical lock with the over-molded elastomeric tip 7. The tip 4 of the rigid portion 5 of the cannula 3 in one aspect is formed with a series of directionally alternating annular barb configurations, such that the barbs create a mechanical lock increasing axial tension strength of the tip to the rest of the cannula and preventing the elastomeric tip 7 from moving in either a proximal or a distal direction relative to the rigid portion 5 of the cannula 3. The tip 4 of the rigid portion 5 of the cannula 3 in one aspect is formed with annular grooves to provide a mechanical lock with the over-molded elastomeric tip 7. The tip 4 of the rigid portion 5 of the cannula 3 in one aspect is formed with holes and/or axial grooves to provide a mechanical lock with the over-molded elastomeric tip 7. The tip 4 of the rigid portion 5 of the cannula 3, in one aspect, is formed with a thread to provide a mechanical lock with the over-molded elastomeric tip.

[0023] The inside diameter of a distal tapered portion 17 of the atraumatic elastomeric tip 7 in one aspect is configured to slightly interfere with the outside diameter of an obturator 31 such that when the obturator is inserted into the cannula 3, the obturator expands the elastomeric distal tip of the cannula to create a smooth transition between the distal tip of the cannula and the obturator (FIG. 10). The smooth transition between the distal tip of the cannula and the obturator can decrease the possibility for body tissue to wedge between the cannula and the obturator during insertion through the abdominal wall and can therefore reduce the insertion force required to place the trocar through the abdominal wall. The interference fit can also serve to create a seal between the distal tip of the obturator 31 and the cannula 3. The seal can prevent or minimize insufflation gasses from flowing between the interface of the distal tip of the cannula and the obturator. In one aspect, to facilitate the interference fit, the atraumatic tip 7 has an inner diameter that is less than an inner diameter of the elongate body or distal tip end of the cannula 3. The atraumatic tip 7, in one aspect, is chamfered or tapered narrowing and transitioning from a larger inner diameter corresponding to the inner diameter of the rigid portion and/or the distal tip end 4 of the elongate body to the smaller inner diameter of the atraumatic tip 7 (FIG. 15). As such, the taper also provides a smooth transition or lead-in (reducing "catch" points) for the obturator or other surgical instruments being inserted into the cannula and through the tip.

[0024] The greater or larger ultimate elongation of the tip relative to the rigid portion 5 of the cannula 3, as noted above, also assists in the interference fit between the tip and the inserted obturator. The tip 7 is allowed to stretch to accommodate an obturator having an outer diameter larger than the inner diameter of the tip, thereby providing a tight instrument seal and a smooth transition between instrument and tip and tip to cannula. The difference ensures that the tip stretches or expands relative to the cannula allowing the tip to allow passage of the inserted surgical instrument, e.g., a laparoscope, obturator, and others, having an outer diameter larger than the inner diameter of the tip. An interference fit and/or instrument seal is thereby provided with the tip and the inserted surgical instrument.

[0025] The cannula 3 with the atraumatic elastomeric tip 7 in one aspect is formed of reusable materials to enable the product to be autoclave sterilized and re-used. Reusable materials for the cannula and elastomeric tip in one aspect can be polysulfone, polyetherimide, polyethersulfone, silicone, and polyisoprene. The cannula 3 with the atraumatic elastomeric tip 7 in one aspect is formed of stainless steel with abonded elastomeric tip formed of silicone or polyisoprene to enable the product to be autoclave sterilized and re-used.

[0026] In FIG. 11, the cannula 3 in accordance with the present invention has a flexible elastomeric joint 33 between the rigid portion 5 of the cannula and the distal tip 7' of the cannula. The distal tip of the cannula in one aspect is either flexible or rigid. The flexible joint 33 allows the distal tip of the cannula to deflect in response to contact between, for example, body tissue or an instrument thereby preventing potential trauma to the body tissue or potential damage to the instrument. The flexible joint 33 in one aspect has a bellows configuration with a minimal axial length. The minimal axial length of the flexible joint 33 in combination with a rigid or semi-rigid distal tip 7 in one aspect can provide the cannula 3 with greater column strength as compared to a cannula with an over-molded elastomeric tip. The flexible joint in one aspect is formed from silicone, polyurethane, Kraton® thermoplastic elastomers, C-Flex® thermoplastic elastomers, Versaflex® thermoplastic elastomers, polyisoprene, Santoprene® thermoplastic elastomers, Carbothane® thermoplastic polyurethanes, copolymer/mineral oil gels, or natural rubber.

[0027] In FIG. 12, the cannula 3 in accordance with the present invention, has a flexible joint 33 with a seal 35

formed of a gel material located at the distal tip 7' of the cannula. The seal 35 in one aspect is configured to maintain a seal in the absence of inserted instrumentation and the seal, in one aspect, is configured to maintain a seal in the presence of inserted instrumentation. The flexible joint 33 allows the seal 35 and the distal tip 7' to pivot in response to the lateral movement of inserted instrumentation to ensure that a seal 35 is maintained during off-axis movement of the instrumentation. The seal 35 could be formed of a single piece component with the gel for example shaped as a disc with a slit in the center of the disc. In one aspect, as shown in FIG. 13, seal 35' is formed of two opposed gel rollers, such that instrumentation would be inserted between the rollers. The cannula 3 with the seal 35 can also be formed without the flexible joint 33. The elongation and sealing properties of the gel material can enable a seal to be maintained during off-axis movement of inserted instrumentation. The gel material in one aspect is formulated of an SEBS (Styrene Ethylene Butylene Stryrene) copolymer and a mineral oil.

[0028] Referring now to FIG. 14, the atraumatic elastomeric cannula tip 7 in one aspect is formed with an internal wire form 19 to provide greater rigidity and column strength as compared to a cannula tip without an internal wire form. The wire form 19 in one aspect is configured in the shape of a coil spring and a polymer is fused or over-molded over the wire form resulting in a cannula tip 7 with an embedded wire form. The wire form in one aspect also comprises a series of wires radially spaced and embedded within the atraumatic elastomeric cannula tip.

[0029] Although the present invention has been described in certain specific aspects, many additional modifications and variations would be apparent to those skilled in the art. It is therefore to be understood that the present invention may be practiced otherwise than specifically described, including various changes in the size, shape and materials, without departing from the scope of the present invention as claimed. Thus, embodiments of the present invention should be considered in all respects as illustrative and not restrictive.

[0030] bonded elastomeric tip formed of silicone or polyisoprene to enable the product to be autoclave sterilized and re-used.

[0031] The cannula 3 with the atraumatic tip 7 in one aspect has a short length over-molded section at its distal tip. The short length over-molded section can provide for an atraumatic elastomeric cannula tip, yet utilize no or minimal column strength or less axial column strength as compared to a longer length over-molded section. The length of the shortened section in one aspect varies from .025" to .250".

[0032] In FIG. 11, the cannula 3 in one aspect has a flexible elastomeric joint 33 between the rigid portion 5 of the cannula and the distal tip 7' of the cannula. The distal tip of the cannula in one aspect is either flexible or rigid. The flexible joint 33 allows the distal tip of the cannula to deflect in response to contact between, for example, body tissue or an instrument thereby preventing potential trauma to the body tissue or potential damage to the instrument. The flexible joint 33 in one aspect has a bellows configuration with a minimal axial length. The minimal axial length of the flexible joint 33 in combination with a rigid or semi-rigid distal tip 7 in one aspect can provide the cannula 3 with greater column strength as compared to a cannula with an over-molded elastomeric tip. The flexible joint in one aspect is formed from silicone, polyurethane, Kraton® thermoplastic elastomers, C-Flex® thermoplastic elastomers, Versaflex® thermoplastic elastomers, polyisoprene, Santoprene® thermoplastic elastomers, Carbothane® thermoplastic polyurethanes, copolymer/mineral oil gels, or natural rubber.

[0033] In FIG. 12, in one aspect, the cannula 3 with the flexible joint 33 has a seal 35 formed of a gel material located at the distal tip 7' of the cannula. The seal 35 in one aspect is configured to maintain a seal in the absence of inserted instrumentation and the seal, in one aspect, is configured to maintain a seal in the presence of inserted instrumentation. The flexible joint 33 allows the seal 35 and the distal tip 7' to pivot in response to the lateral movement of inserted instrumentation to ensure that a seal 35 is maintained during off-axis movement of the instrumentation. The seal 35 could be formed of a single piece component with the gel for example shaped as a disc with a slit in the center of the disc. In one aspect, as shown in FIG. 13, seal 35' is formed of two opposed gel rollers, such that instrumentation would be inserted between the rollers. The cannula 3 with the seal 35 can also be formed without the flexible joint 33. The elongation and sealing properties of the gel material can enable a seal to be maintained during off-axis movement of inserted instrumentation. The gel material in one aspect is formulated of an SEBS (Styrene Ethylene Butylene Stryrene) copolymer and a mineral oil.

[0034] Referring now to FIG. 14, the atraumatic elastomeric cannula tip 7 in one aspect is formed with an internal wire form 19 to provide greater rigidity and column strength as compared to a cannula tip without an internal wire form. The wire form 19 in one aspect is configured in the shape of a coil spring and a polymer is fused or over-molded over the wire form resulting in a cannula tip 7 with an embedded wire form. The wire form in one aspect also comprises a series of wires radially spaced and embedded within the atraumatic elastomeric cannula tip.

[0035] Accordingly, a trocar cannula with an atraumatic tip is provided. Although the present invention has been described in certain specific aspects, many additional modifications and variations would be apparent to those skilled in the art. It is therefore to be understood that the present invention may be practiced otherwise than specifically described, including various changes in the size, shape and materials, without departing from the scope and spirit of the present invention. Thus, embodiments of the present invention should be considered in all respects as illustrative and not restrictive.

Claims

1. A medical access device comprising an articulating laparoscope and a trocar cannula (3) arranged to receive the articulating laparoscope (21), the trocar cannula comprising:

   an elongate body (5) having a proximal enlarged end comprising a zero seal configured to sealingly engage the articulating laparoscope when the articulating laparoscope is not present and a distal tip end (4) with a lumen extending from the proximal end to the distal end for inserting and removing surgical instruments through the lumen; and
   an atraumatic tip (7) extending from the distal end (4) of the elongate body (5),
   characterized in that the trocar cannula (3) further comprises a flexible elastomeric joint (33) between the elongate body (5) and the atraumatic tip (7); the elongate body (5) is formed of a rigid polymer; and the tip (7) is pivotable in use relative to the elongate body (5) to reduce interference with the articulating laparoscope.

2. The medical access device of claim 1, wherein the atraumatic tip (7) is formed of a material different than that of the elongate body (5) and the atraumatic tip (7) has a flexural modulus of about 10 x 10^6 Pa (1,500 psi) and an ultimate elongation of about 400% and the elongate body (5) has a flexural modulus greater than the flexural modulus of the atraumatic tip (7) and an ultimate elongation less than the ultimate elongation of the atraumatic tip (7).

3. The medical access device of claim 2, wherein the flexural modulus of the elongate body (5) is 2 x 10^{-9} Pa (300,000 psi) and the ultimate elongation of the elongate body is 100%.

4. The medical access device of any of the preceding claims, wherein the atraumatic tip (7) has an inner diameter less than an interior diameter of the elongate body (5).

5. The medical access device of claim 4, wherein the inner diameter of the atraumatic tip (7) is tapered.

6. The medical access device of any of the preceding claims, wherein the inner diameter of the atraumatic tip (7) is chamfered.

7. The medical access device of any of the preceding claims, wherein the atraumatic tip (7) is flexible.

8. The medical access device of any of claims 1 or 4-6, wherein the atraumatic tip (7) is rigid.

9. The medical access device of any of the preceding claims, comprising a second seal (35) formed of a gel material located at the atraumatic tip (7).

10. The medical access device of claim 9, wherein the seal (35) comprises two opposed gel rollers.

11. The medical access device of any of claims 9-10, wherein the gel material comprises a styrene ethylene butylene styrene copolymer and a mineral oil.

12. The medical access device of claim 1, wherein the elongate body (5) and the atraumatic tip (7) are formed of a single material.

13. The medical access device of claim 12, wherein the atraumatic tip (7) further comprises axial slots (25) to provide the atraumatic tip (7) with flexibility.

14. The medical access device of any preceding claim, wherein the atraumatic tip (7) is integrated with and extends from the flexible joint (33) away from the distal tip end (4) of the elongate body (5).

15. The medical access device as claimed in any preceding claim, wherein the trocar cannula further comprises a trocar seal housing (11) removably attached to the enlarged end of the elongate body, the trocar seal housing arranged to sealingly engage with the articulating laparoscope to, in use, prevent loss of gas when the laparoscope is present and provide a zero seal when the articulating laparoscope is not present.

Patentansprüche

1. Eine medizinische Zugangsvorrichtung, die ein gelenkiges Laparoskop und eine Trokarkanüle (3) beinhaltet, die zum Aufnehmen des gelenkigen Laparoskops (21) angeordnet ist, wobei die Trokarkanüle Folgendes beinhaltet:

   einen länglichen Hauptteil (5) mit einem proximalen vergrößerten Ende, das eine Nulldichtung beinhaltet, das dazu ausgelegt ist, dichtend Eingriff mit dem gelenkigen Laparoskop zu nehmen, wenn das Laparoskop nicht vorhanden ist, und einem distalen Spitzenende (4) mit einem Lumen, das sich von dem proximalen Ende bis zu dem distalen Ende erstreckt, zum Einführen und Entfernen von chirurgischen Instrumenten durch das Lumen; und
   eine atraumatische Spitze (7), die sich aus dem distalen Ende (4) des länglichen Hauptteils (5) erstreckt,
   dadurch gekennzeichnet, dass die Trokarkanüle (3) ferner ein biegsames elastomeres Ge-

lenk (33) zwischen dem länglichen Hauptteil (5) und der atraumatischen Spitze (7) beinhaltet, der längliche Hauptteil (5) aus einem starren Polymer gebildet ist, und die Spitze (7) im Gebrauch relativ zu dem länglichen Hauptteil (5) schwenkbar ist, um die Störung des gelenkigen Laparoskops zu verringern.

2. Die medizinische Zugangsvorrichtung gemäß Anspruch 1, wobei die atraumatische Spitze (7) aus einem anderen Material gebildet ist als der längliche Hauptteil (5) und die atraumtische Spitze (7) einen Biegemodul von etwa 10 x 10^6 Pa (1500 psi) und eine äußerste Dehnung von etwa 400% aufweist und der längliche Hauptteil (5) einen Biegemodul aufweist, der größer ist als der Biegemodul der atraumatischen Spitze (7), und eine äußerste Dehnung aufweist, die kleiner ist als die äußerste Dehnung der atraumatischen Spitze (7).

3. Die medizinische Zugangsvorrichtung gemäß Anspruch 2, wobei der Biegemodul des länglichen Hauptteils (5) 2 x 10^{-9} Pa (300 000 psi) beträgt und die äußerste Dehnung des länglichen Hauptteils 100% beträgt.

4. Die medizinische Zugangsvorrichtung gemäß einem der vorhergehenden Ansprüche, wobei die atraumatische Spitze (7) einen Innendurchmesser aufweist, der geringer ist als der Innendurchmesser des länglichen Hauptteils (5).

5. Die medizinische Zugangsvorrichtung gemäß Anspruch 4, wobei der Innendurchmesser der atraumatischen Spitze (7) konisch verengt ist.

6. Die medizinische Zugangsvorrichtung gemäß einem der vorhergehenden Ansprüche, wobei der Innendurchmesser der atraumatischen Spitze (7) abgeschrägt ist.

7. Die medizinische Zugangsvorrichtung gemäß einem der vorhergehenden Ansprüche, wobei die atraumatische Spitze (7) biegsam ist.

8. Die medizinische Zugangsvorrichtung gemäß einem der Ansprüche 1 oder 4-6, wobei die atraumatische Spitze (7) starr ist.

9. Die medizinische Zugangsvorrichtung gemäß einem der vorhergehenden Ansprüche, die eine zweite Dichtung (35) beinhaltet, die aus einem Gelmaterial gebildet ist, das sich an der atraumatischen Spitze (7) befindet.

10. Die medizinische Zugangsvorrichtung gemäß Anspruch 9, wobei die Dichtung (35) zwei gegenüberliegende Gelroller beinhaltet.

11. Die medizinische Zugangsvorrichtung gemäß einem der Ansprüche 9-10, wobei das Gelmaterial ein Styrolethylenbutylen-Styrol-Copolymer und ein Mineralöl beinhaltet.

12. Die medizinische Zugangsvorrichtung gemäß Anspruch 1, wobei der längliche Hauptteil (5) und die atraumatische Spitze (7) aus einem einzelnen Material gebildet sind.

13. Die medizinische Zugangsvorrichtung gemäß Anspruch 12, wobei die atraumatische Spitze (7) ferner axiale Schlitze (25) beinhaltet, um der atraumatischen Spitze (7) Biegsamkeit zu verleihen.

14. Die medizinische Zugangsvorrichtung gemäß einem der vorhergehenden Ansprüche, wobei die atraumatische Spitze (7) mit dem biegsamen Gelenk (33) integriert ist und sich aus diesem von dem distalen Ende (4) des länglichen Hauptteils (5) weg erstreckt.

15. Die medizinische Zugangsvorrichtung gemäß einem der vorhergehenden Ansprüche, wobei die Trokarkanüle ferner ein Trokardichtungsgehäuse (11) beinhaltet, das entfernbar an dem vergrößerten Ende des länglichen Hauptteils angebracht ist, wobei das Trokardichtungsgehäuse so angeordnet ist, dass es dichtend Eingriff mit dem gelenkigen Laparoskop nimmt, um im Gebrauch den Verlust von Gas zu verhindern, wenn das Laparoskop vorhanden ist, und eine Nulldichtung bereitzustellen, wenn das gelenkige Laparoskop nicht vorhanden ist.

Revendications

1. Dispositif d'accès médical comprenant un laparoscope articulé et une canule de trocart (3) disposée de manière à recevoir le laparoscope articulé (21), ladite canule de trocart comprenant :

un corps allongé (5) à extrémité proximale élargie comprenant un joint à étanchéité parfaite configuré de manière à recevoir le laparoscope articulé de manière hermétique quand le laparoscope articulé n'est pas présent et une extrémité à embout distale (4) dont la lumière se prolonge de l'extrémité proximale à l'extrémité distale pour introduire et retirer les instruments chirurgicaux dans et hors de la lumière ; et
un embout atraumatique (7) se prolongeant à partir de l'extrémité distale (4) du corps allongé (5), **caractérisé en ce que** la canule de trocart (3) comprend, en outre, un joint élastomérique flexible (33) situé entre le corps allongé (5) et l'embout atraumatique (7) ; le corps allongé (5) est formé à partir d'un polymère rigide ; et l'embout (7) peut pivoter relativement au corps al-

longé (5) en cours d'utilisation afin de réduire l'interférence avec le laparoscope articulé.

2. Dispositif d'accès médical selon la revendication 1, dans lequel l'embout atraumatique (7) est formé à partir d'un matériau différent de celui utilisé pour le corps allongé (5) et l'embout atraumatique (7) a un module d'élasticité en flexion de l'ordre de 10 x 10^6 Pa (1500 psi) et un ultime allongement d'environ 400 % et le corps allongé (5) a un module d'élasticité en flexion supérieur au module d'élasticité en flexion de l'embout atraumatique (7) et un ultime allongement inférieur à l'ultime allongement de l'embout atraumatique (7).

3. Dispositif d'accès médical selon la revendication 2, dans lequel le module d'élasticité en flexion du corps allongé (5) est de 2 x 10^{-9} Pa (300.000 psi) et l'ultime allongement du corps allongé est de 100 %.

4. Dispositif d'accès médical selon l'une quelconque des revendications précédentes, dans lequel l'embout atraumatique (7) a un diamètre intérieur inférieur au diamètre intérieur du corps allongé (5).

5. Dispositif d'accès médical selon la revendication 4, dans lequel le diamètre intérieur de l'embout atraumatique (7) est effilé.

6. Dispositif d'accès médical selon l'une quelconque des revendications précédentes, dans lequel le diamètre intérieur de l'embout atraumatique (7) est chanfreiné.

7. Dispositif d'accès médical selon l'une quelconque des revendications précédentes, dans lequel l'embout atraumatique (7) est flexible.

8. Dispositif d'accès médical selon l'une quelconque des revendications 1 ou 4 à 6, dans lequel l'embout atraumatique (7) est rigide.

9. Dispositif d'accès médical selon l'une quelconque des revendications précédentes, comprenant un second joint (35) formé à partir d'un matériau géliforme situé à l'embout atraumatique (7).

10. Dispositif d'accès médical selon la revendication 9, dans lequel le joint (35) comprend deux rouleaux à gel opposés.

11. Dispositif d'accès médical selon l'une quelconque des revendications 9 à 10, dans lequel le matériau géliforme contient un copolymère styrène-éthylène-butylène-styrène et une huile minérale.

12. Dispositif d'accès médical selon la revendication 1, dans lequel le corps allongé (5) et l'embout atraumatique (7) sont formés à partir d'un même matériau.

13. Dispositif d'accès médical selon la revendication 12, dans lequel l'embout atraumatique (7) comprend, en outre, des fentes axiales (25) pour conférer une certaine flexibilité à l'embout atraumatique (7).

14. Dispositif d'accès médical selon l'une quelconque des revendications précédentes, dans lequel l'embout atraumatique (7) est intégré avec le joint flexible (33) et se prolonge à partir de celui-ci et est éloigné de l'extrémité distale de l'embout (4) du corps allongé (5).

15. Dispositif d'accès médical selon l'une quelconque des revendications précédentes, dans lequel la canule de trocart comprend, en outre, un logement de joint de trocart (11), fixé de manière amovible à l'extrémité élargie du corps allongé, le logement de joint de trocart étant disposé de manière à recevoir le laparoscope articulé de manière hermétique afin que, durant l'utilisation, il prévienne la perte de gaz quand le laparoscope est présent et fournisse un joint à étanchéité parfaite quand le laparoscope articulé n'est pas présent.

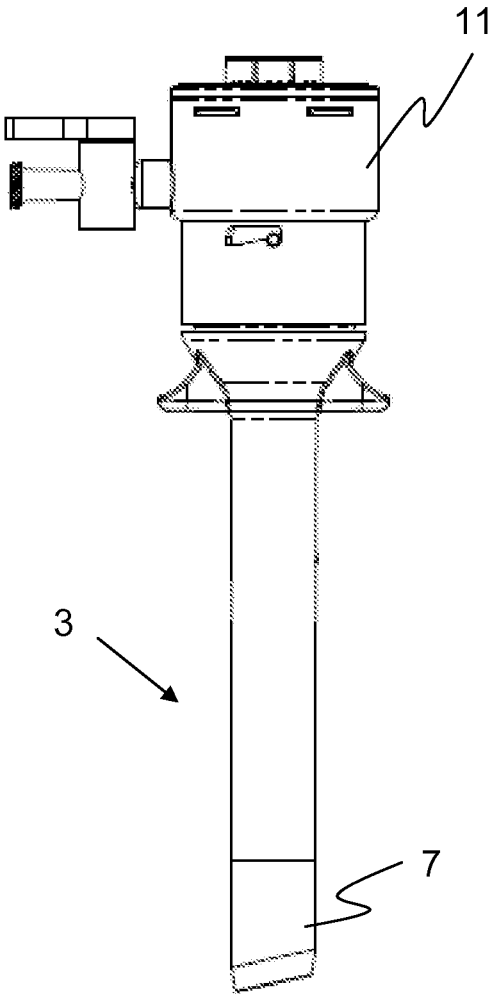

FIG. 1

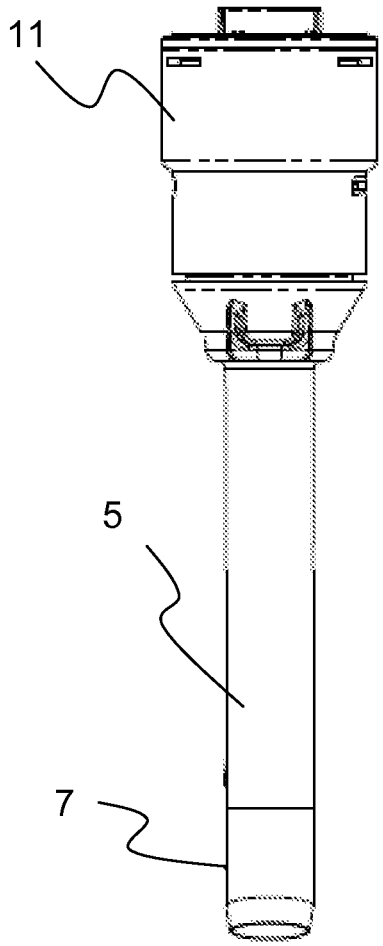

FIG. 2

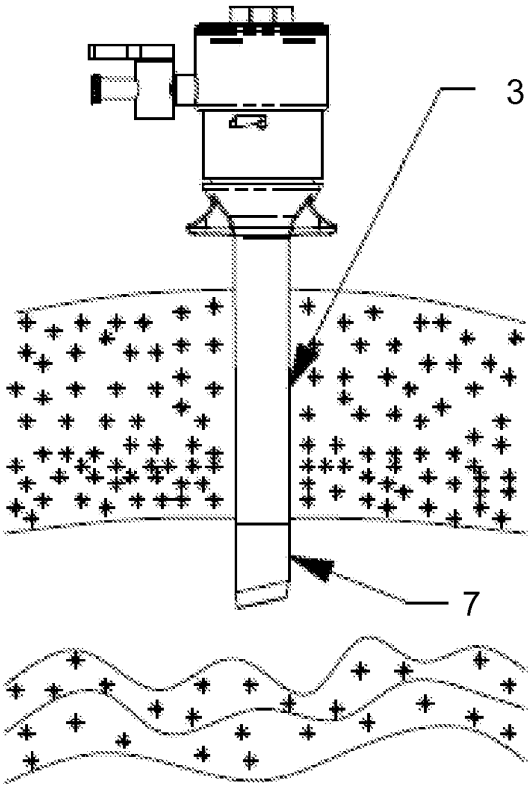

FIG. 3

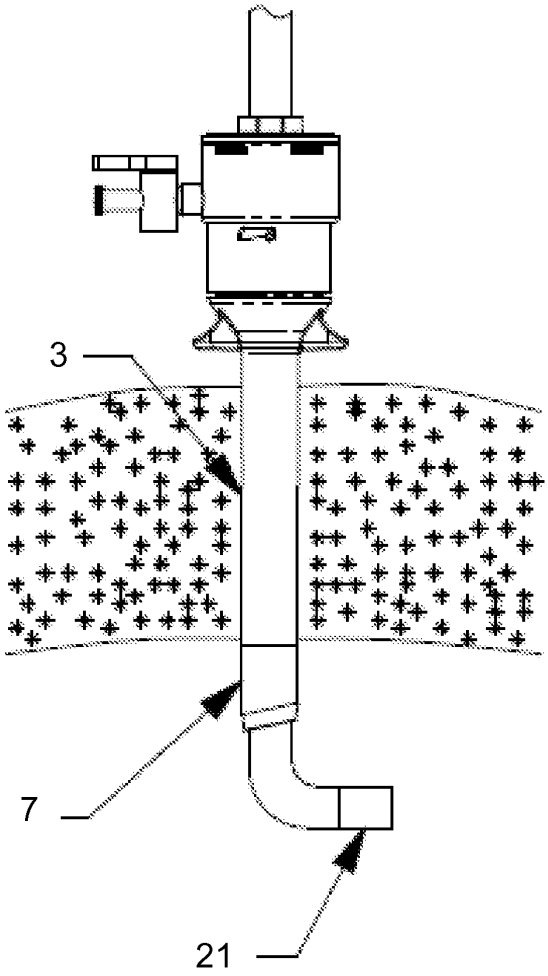

FIG. 4

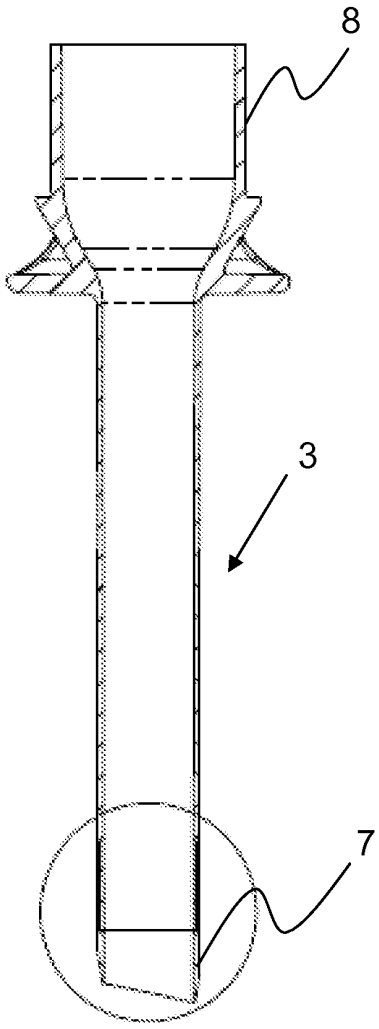

FIG. 5

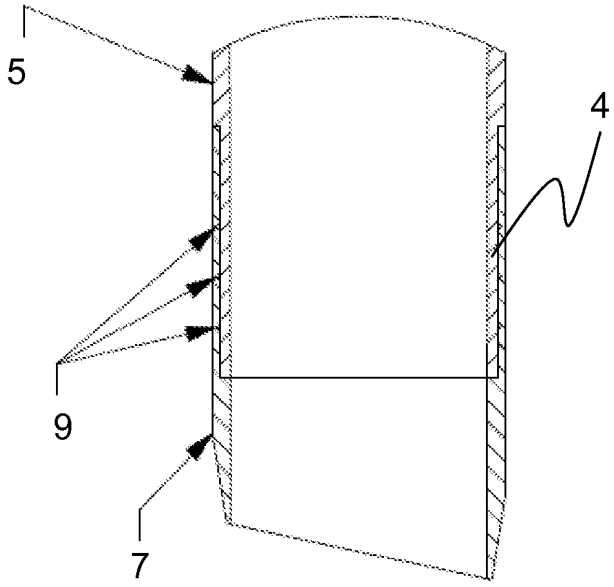

FIG. 6A

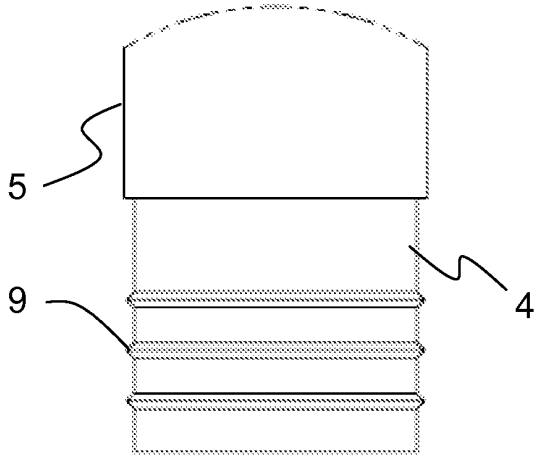

FIG. 6B

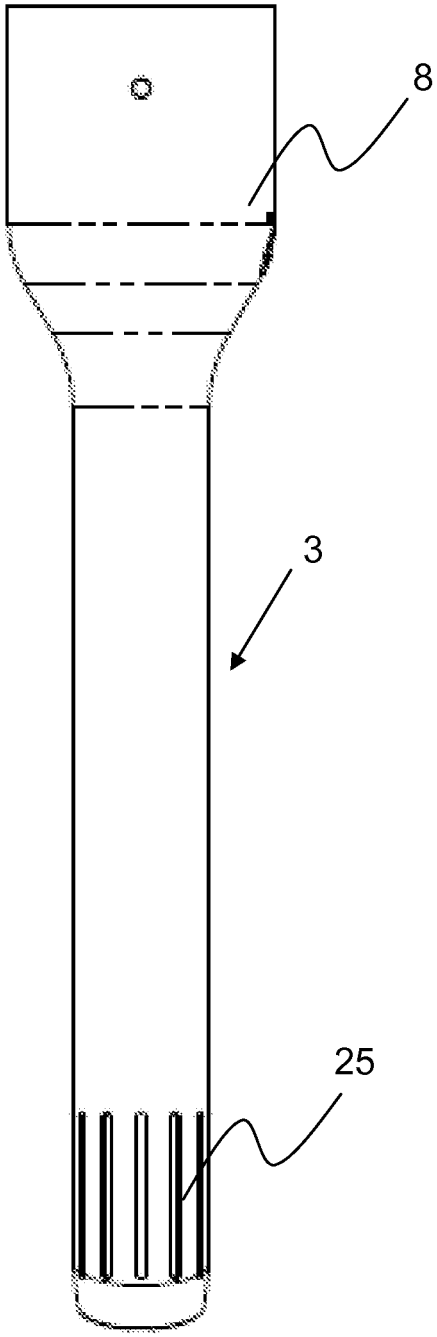

FIG. 7

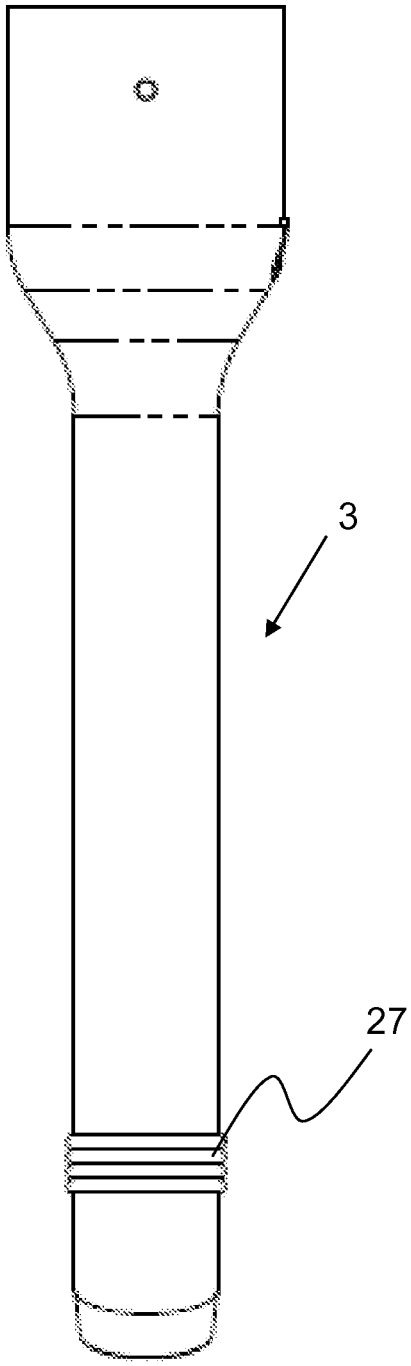

FIG. 8

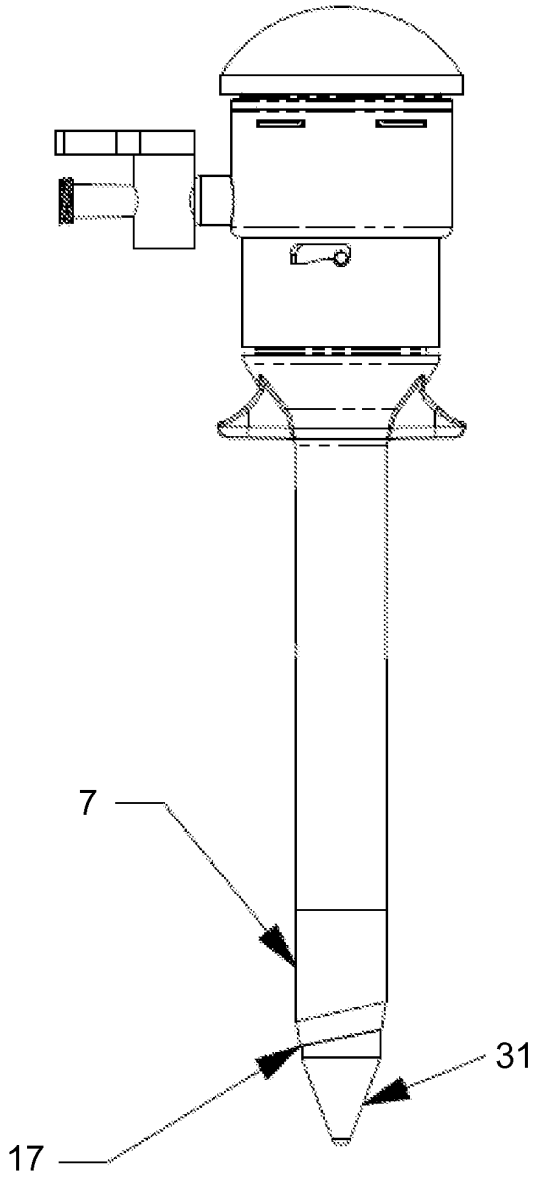

FIG. 10

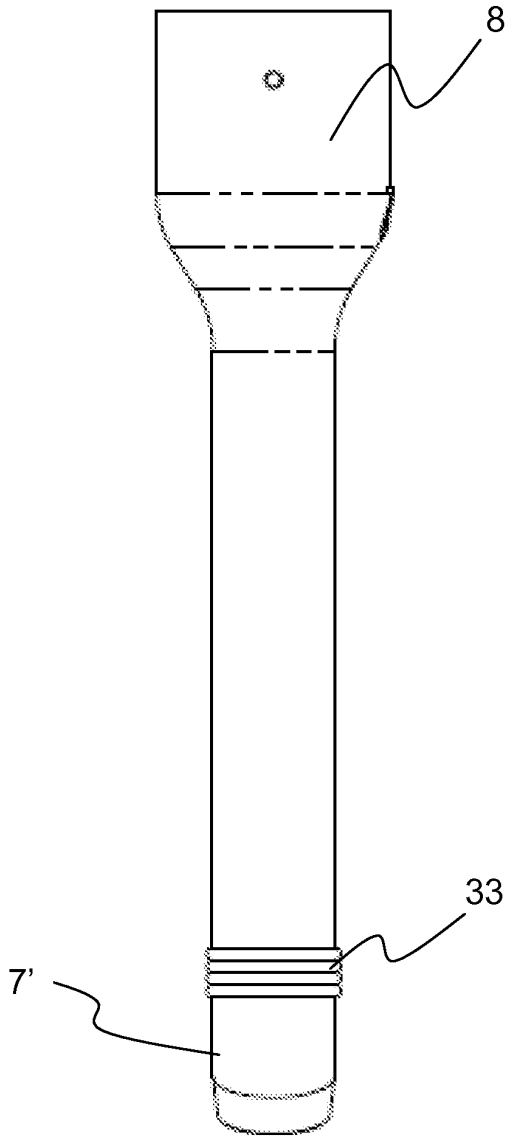

FIG. 11

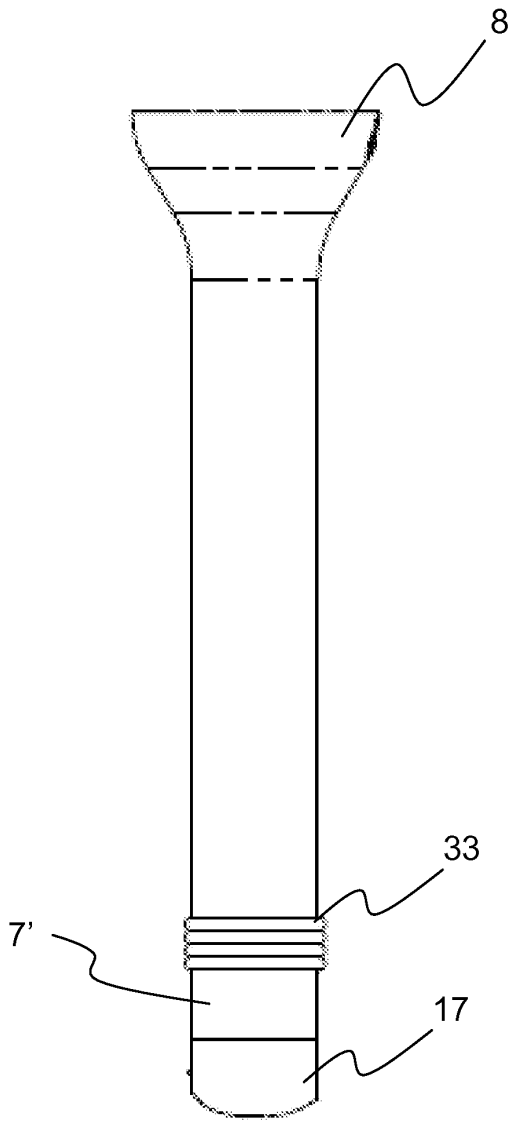

FIG. 12

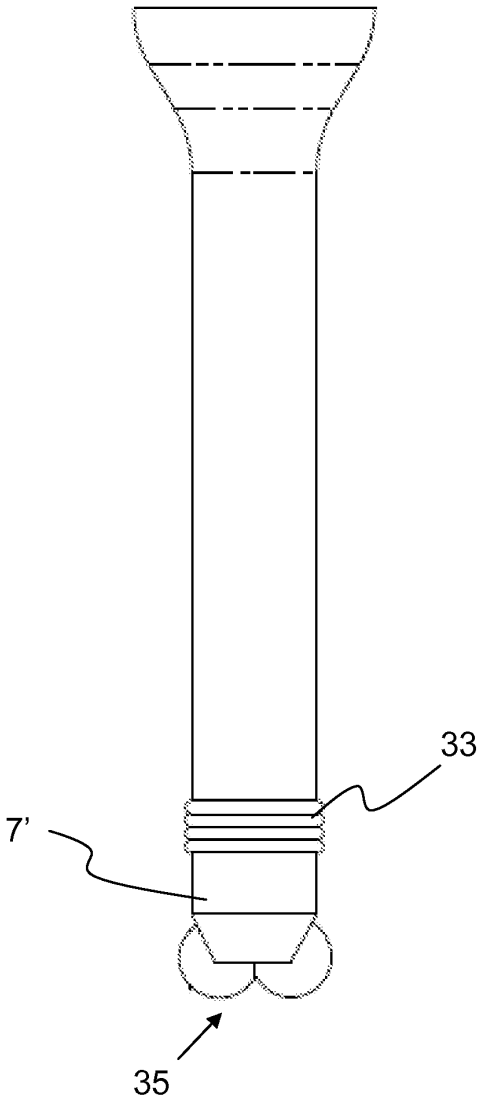

FIG. 13

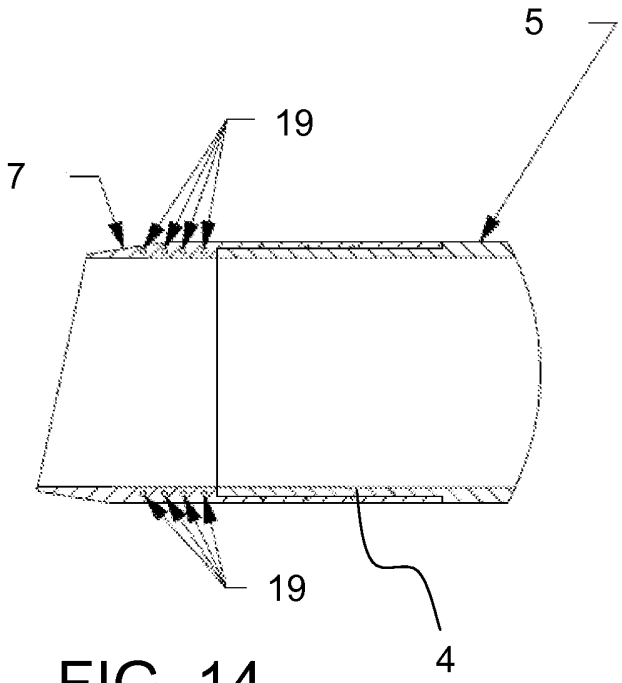

FIG. 14

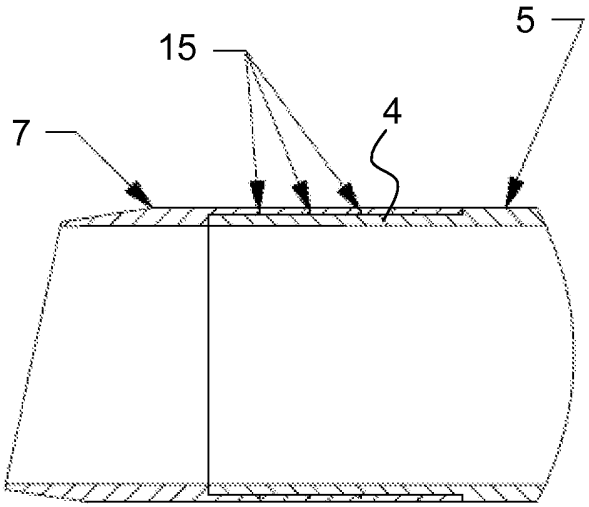

FIG. 9A

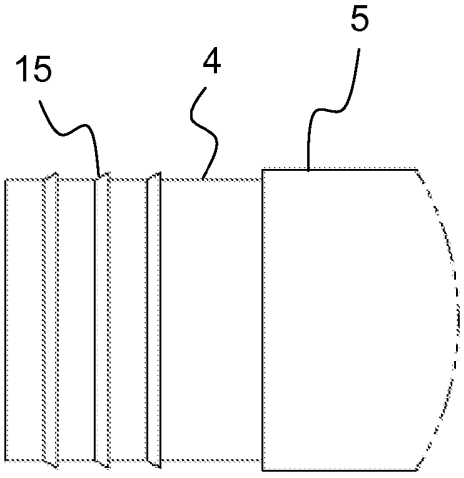

FIG. 9B

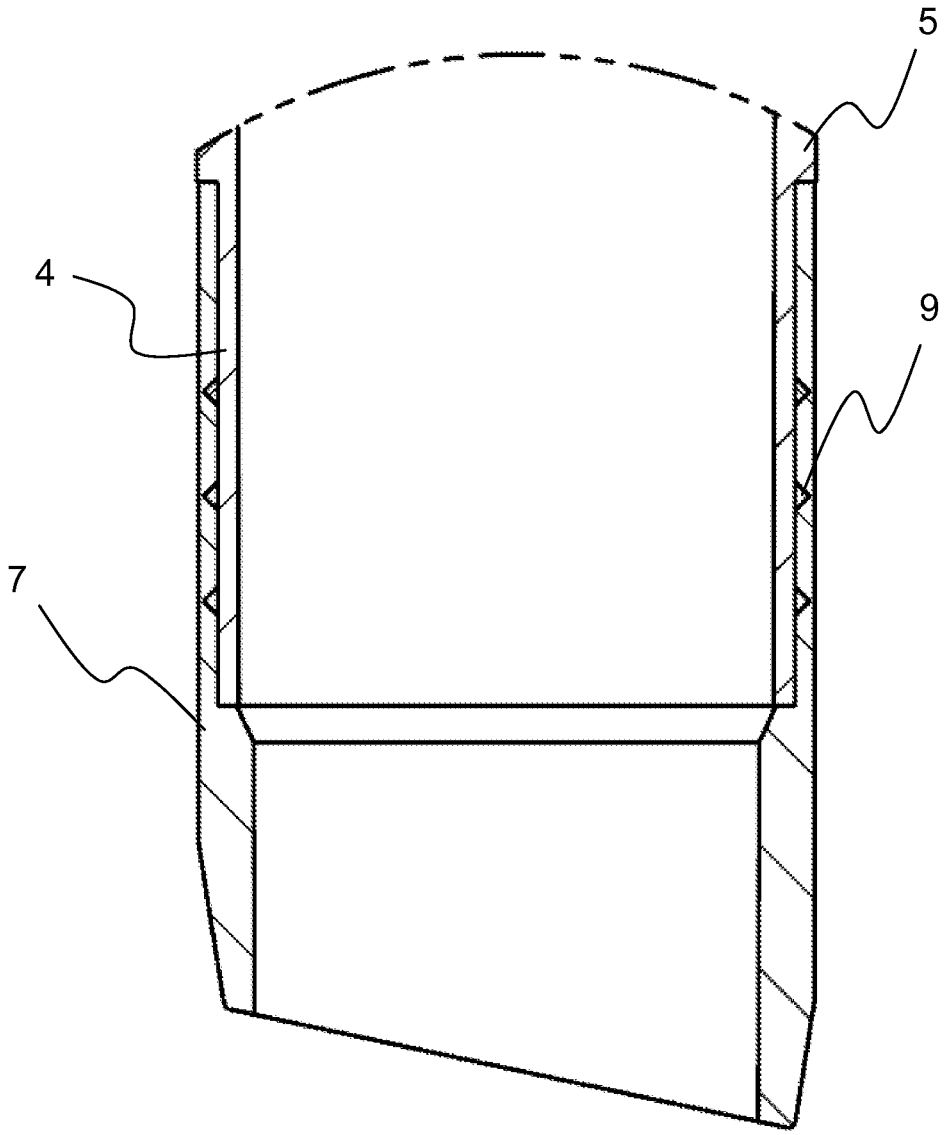

FIG. 15

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 4795426 A **[0003]**
- US 5257973 A **[0003]**
- US 2005059934 A1 **[0003]**
- US 2005137524 A1 **[0003]**
- WO 03088854 A **[0003]**

专利名称(译)	Trocar套管与无创伤尖端		
公开(公告)号	EP2476384B1	公开(公告)日	2015-11-04
申请号	EP2012164164	申请日	2007-11-21
[标]申请(专利权)人(译)	应用医疗资源		
申请(专利权)人(译)	应用医疗资源CORPORATION		
当前申请(专利权)人(译)	应用医疗资源CORPORATION		
[标]发明人	PRAVONGVIENGKHAM KENNII KAHLE HENRY ALBRECHT JEREMY J TAYLOR SCOTT V		
发明人	PRAVONGVIENGKHAM, KENNII KAHLE, HENRY ALBRECHT, JEREMY J TAYLOR, SCOTT V		
IPC分类号	A61B17/34		
CPC分类号	A61B17/3421 A61B17/3494 A61B2017/00473 A61B2017/3441 A61B2090/08021 A61B2017/3456		
优先权	60/866939 2006-11-22 US		
其他公开文献	EP2476384A1		
外部链接	Espacenet		

摘要(译)

外科进入端口设置有套管针套管，该套管针套管具有基本上刚性的部分和无创伤的远侧尖端。无创伤远端尖端相对于套管的刚性部分基本上是柔顺的。套管针套管提供无阻碍的外科手术进入体腔，允许使用最小尺寸的切口或入口通过套管针插管插入和移除手术器械并进入体腔。

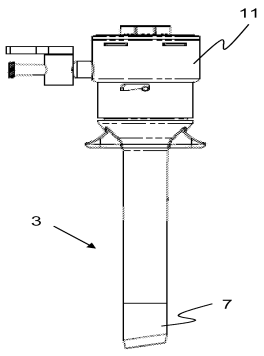

FIG. 1

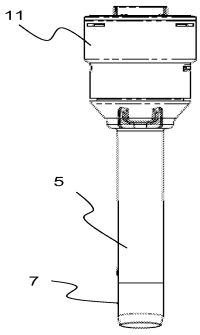

FIG. 2