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(54) **SYSTEMS AND METHODS FOR OPTIMIZING AND MAINTAINING VISUALIZATION OF A SURGICAL FIELD DURING THE USE OF SURGICAL SCOPES**

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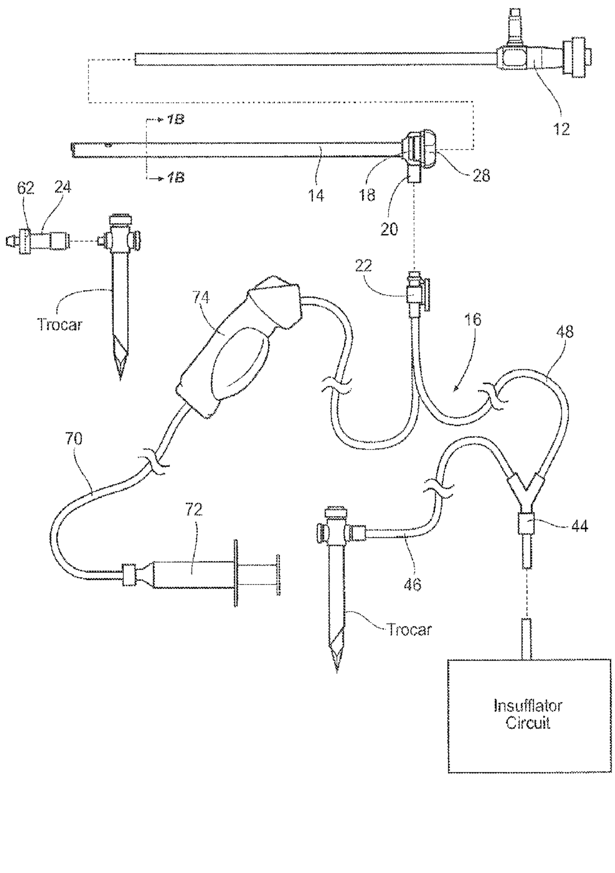
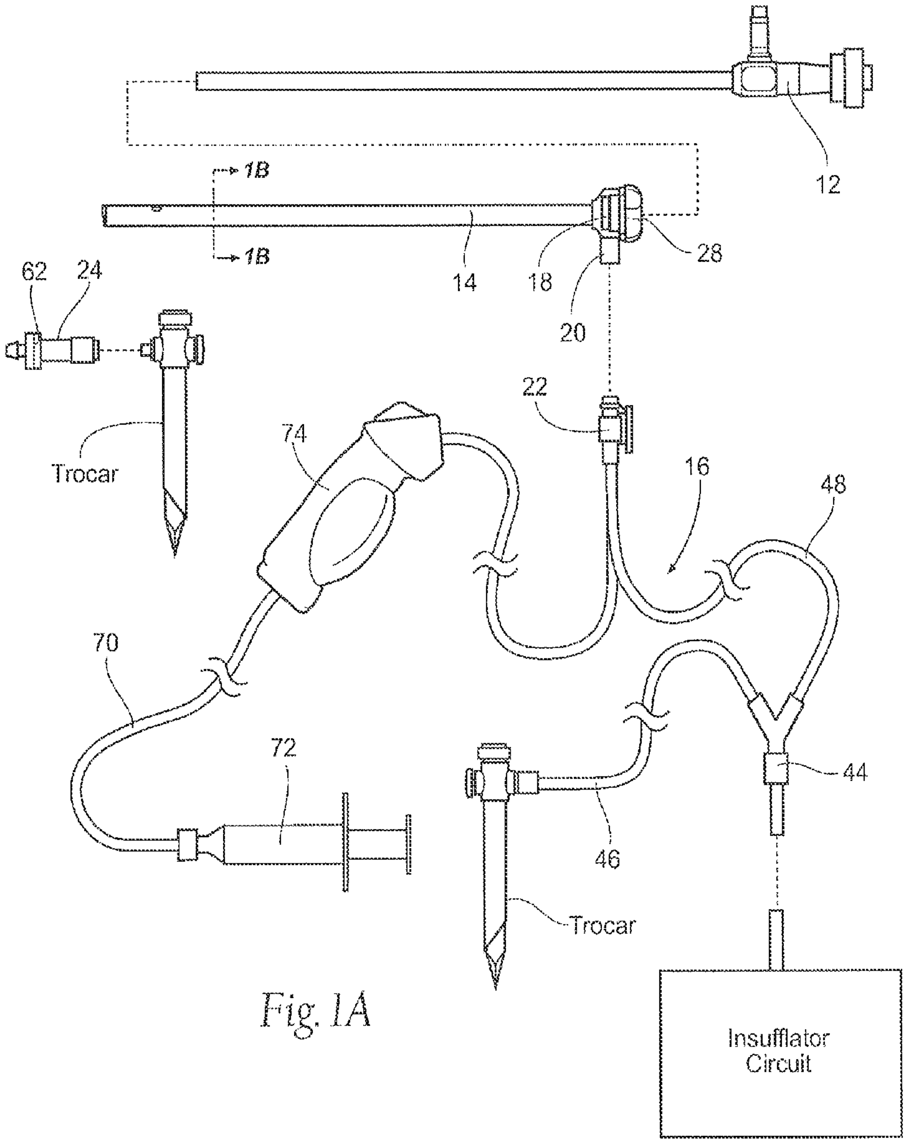
(57) **ABSTRACT**

Systems and methods couple a self-contained air processing or conveying component to a sheath that is sized and configured to receive a laparoscope including a laparoscopic lens providing visualization of an operating cavity. The air processing or conveying component comprises an air flow path having an inlet sized and configured for communication with a source of CO2 and an outlet. The air processing or conveying component includes a driven air moving component in communication with the air flow path sized and configured to continuously convey CO2 from the source through the air flow path to the outlet. The sheath coupled to the air processing or conveying component can include a lumen communicating with the outlet of the air processing or conveying mechanism for passing CO2 continuously conveyed by the driven air moving component across the laparoscopic lens to maintain visualization of the operating cavity. The sheath and self-contained air processing or conveying component can comprise an integrated assembly. The source of CO2 can comprise a laparoscopic access device for accessing the operating cavity insufflated with CO2 by operation of an insufflator circuit. The driven air moving component continuously conveys CO2 from the operating cavity across the laparoscopic lens to maintain visualization of the operating cavity, independent of operation of the insufflations circuit.

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1B
1B
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Trocar
Insufflator Circuit

Fig. 1A

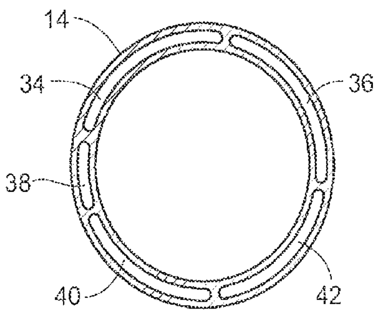
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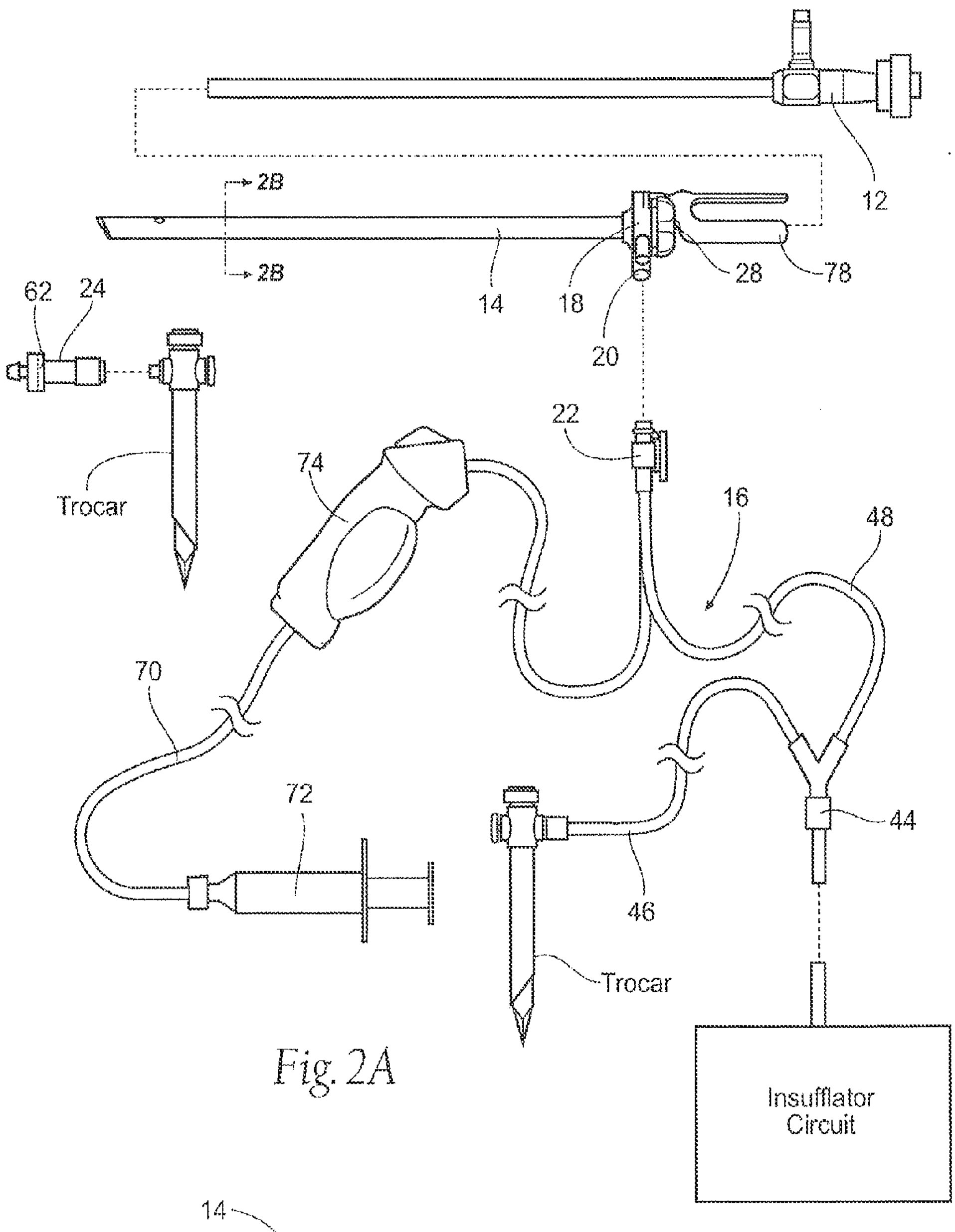
Fig. 1B



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2B
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Trocar
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Trocar
Insufflator Circuit

Fig. 2A

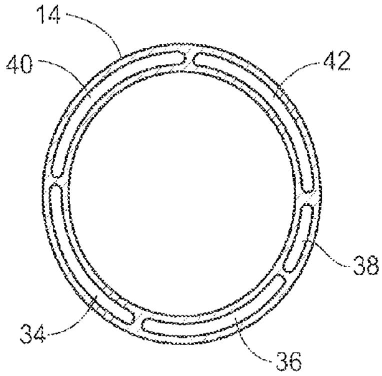

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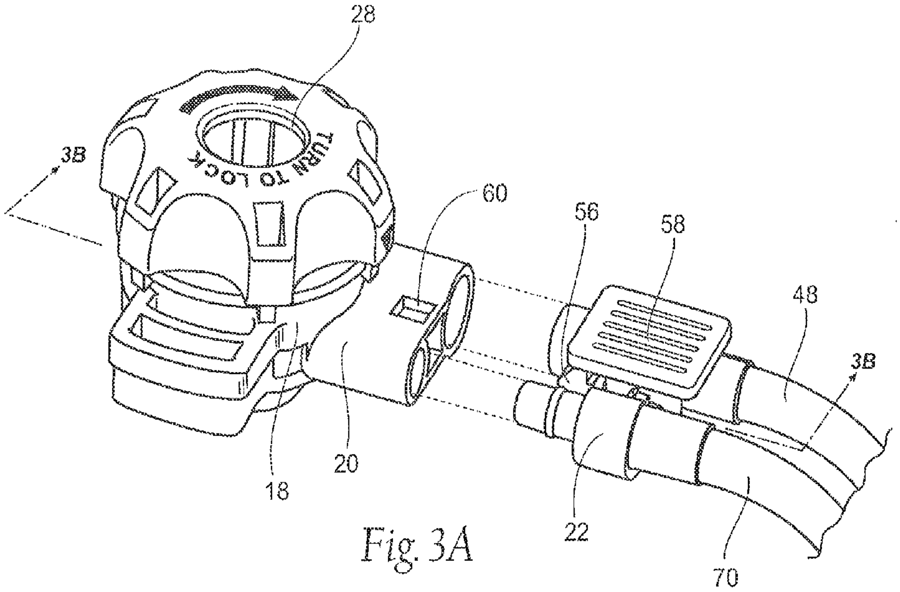
Fig. 2B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3B
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22
70

Fig. 3A

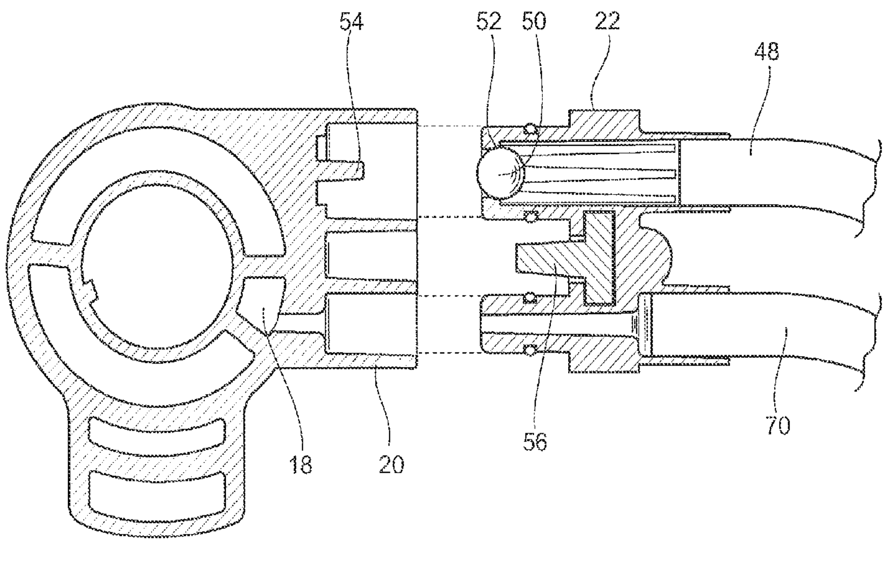
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Fig. 3B

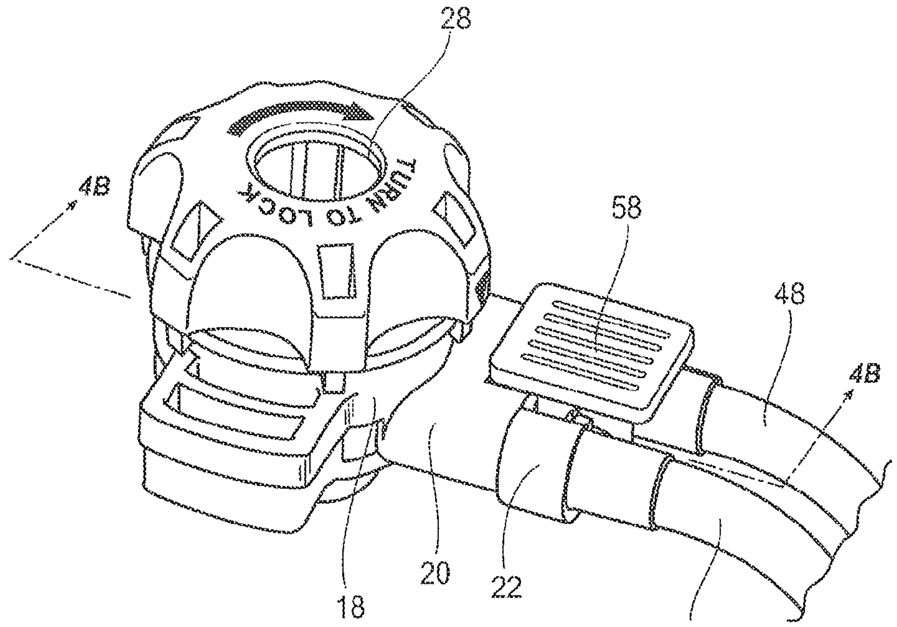


Fig. 4A

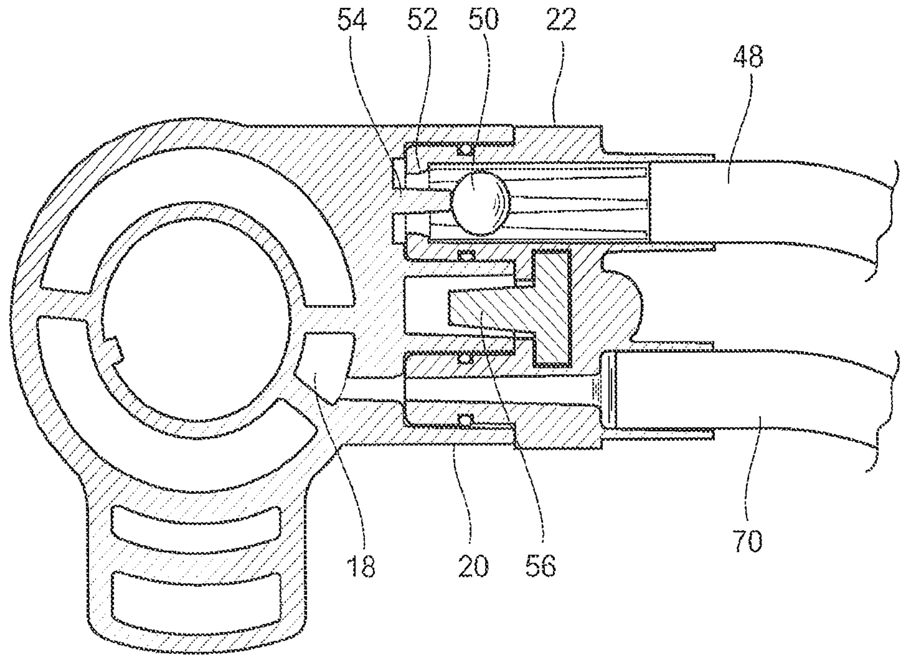


Fig. 4B

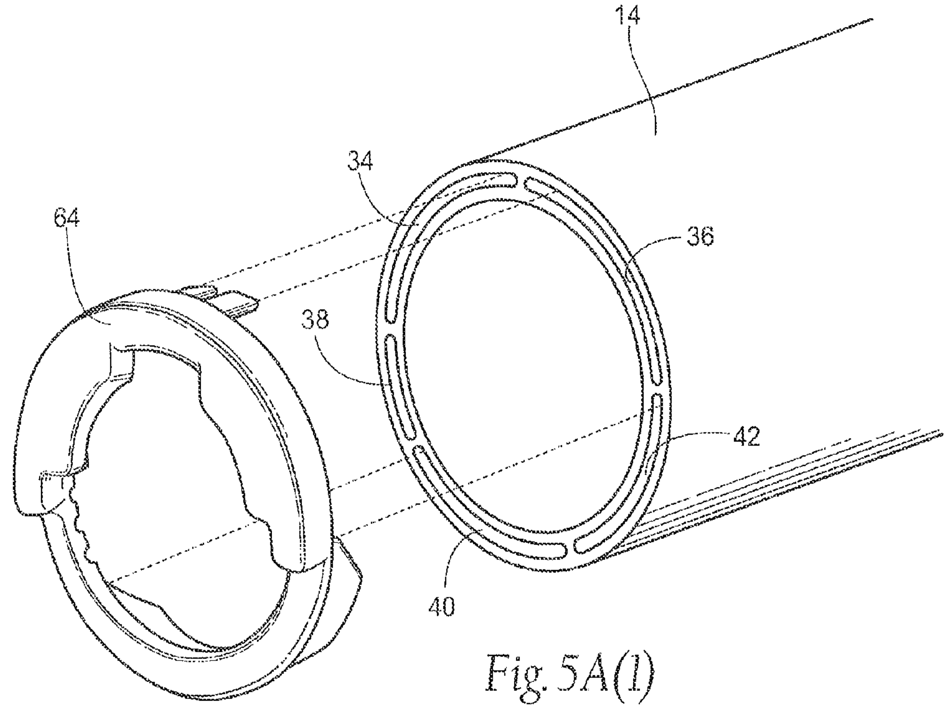


Fig. 5A(1)

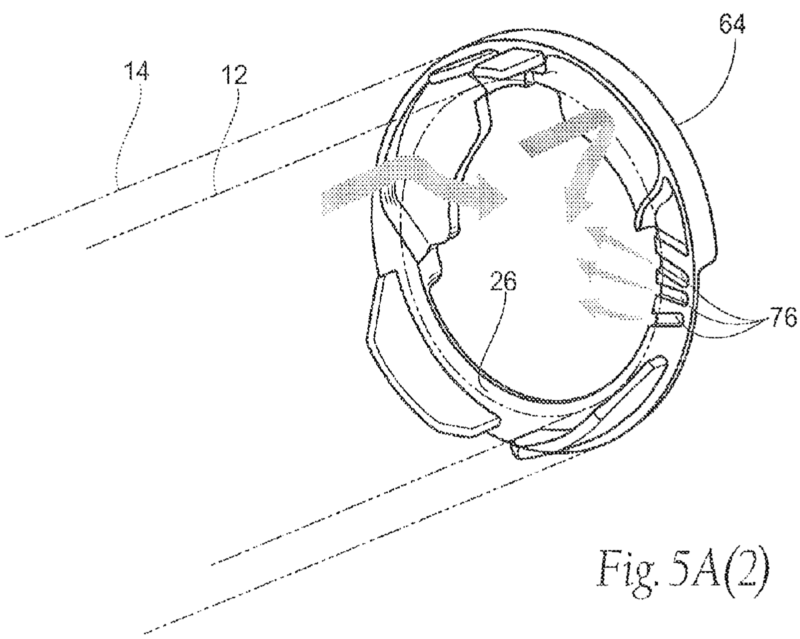


Fig. 5A(2)

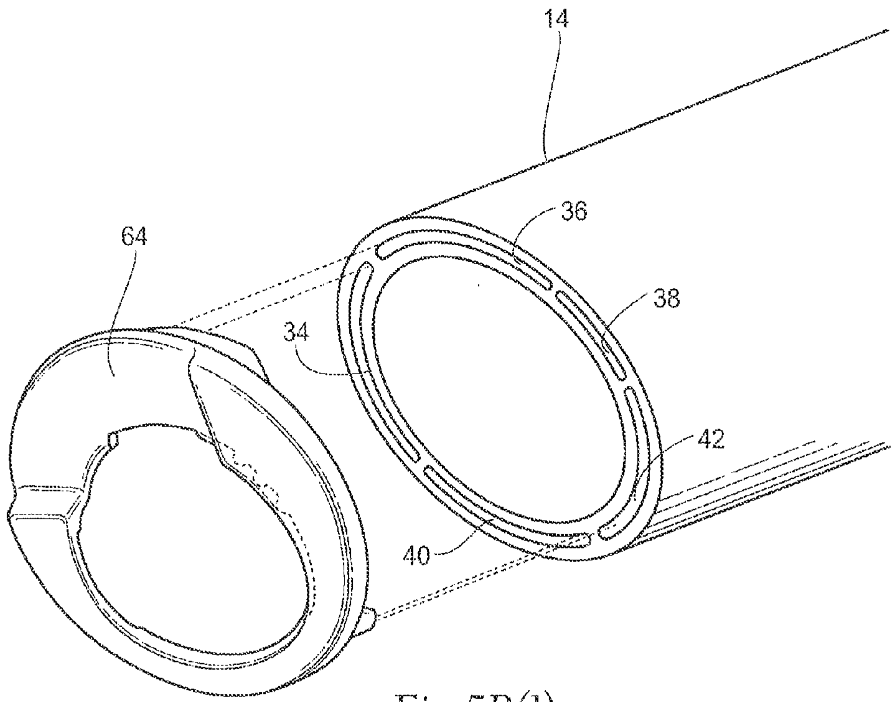


Fig. 5B(1)

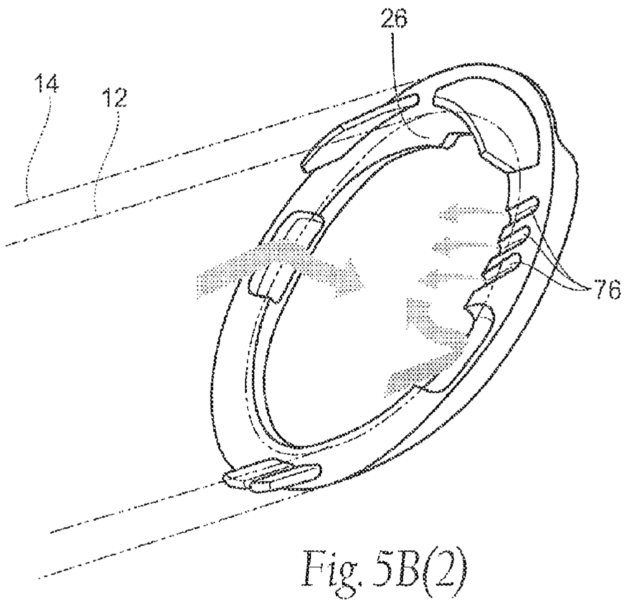
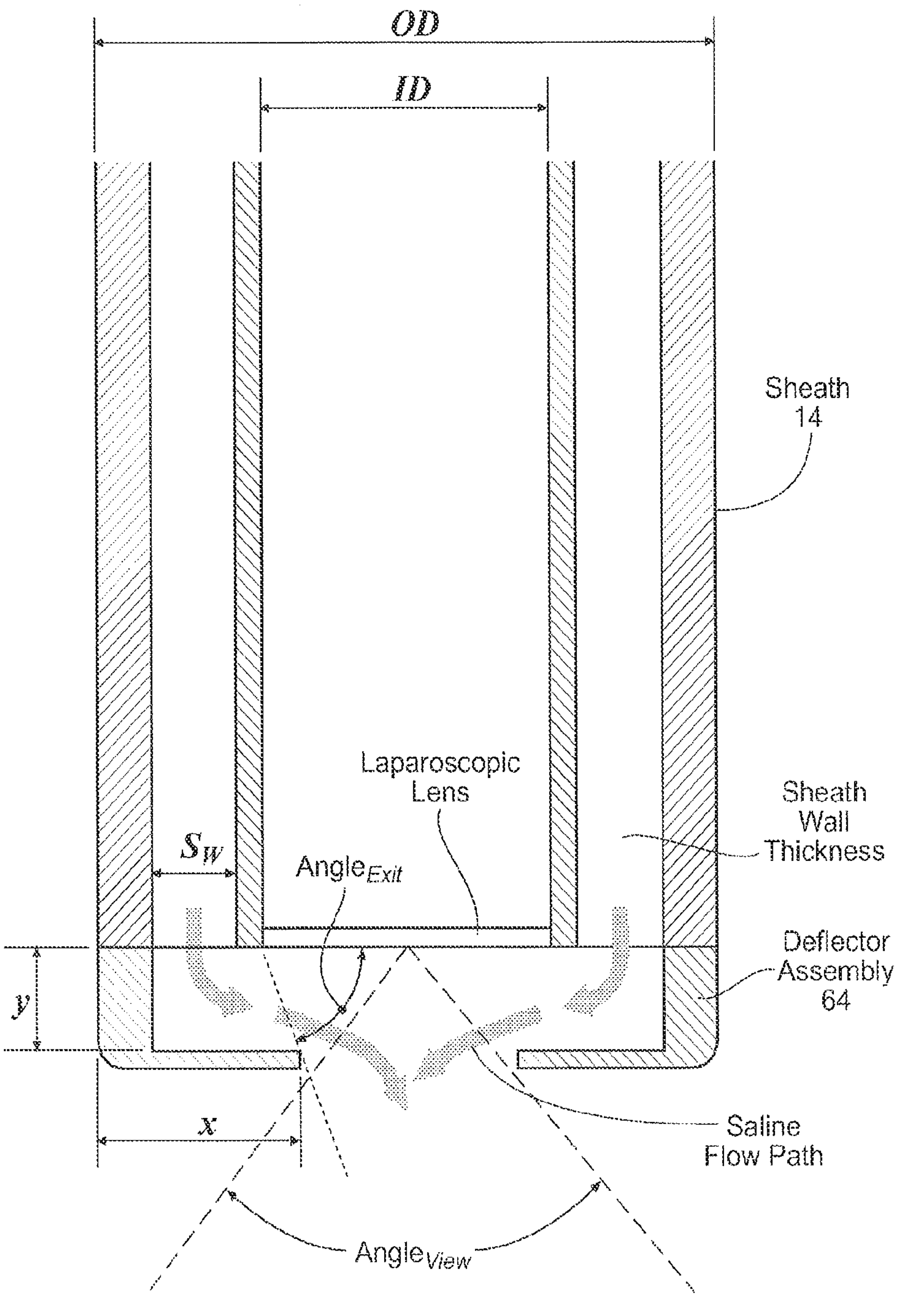


Fig. 5B(2)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Sheath
14
Laparoscopic
Lens
Sheath
Wall
Thickness
S_W
$Angle_{Exit}$
Deflector
Assembly
64
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x
Saline
Flow Path
$Angle_{View}$

Fig. 6

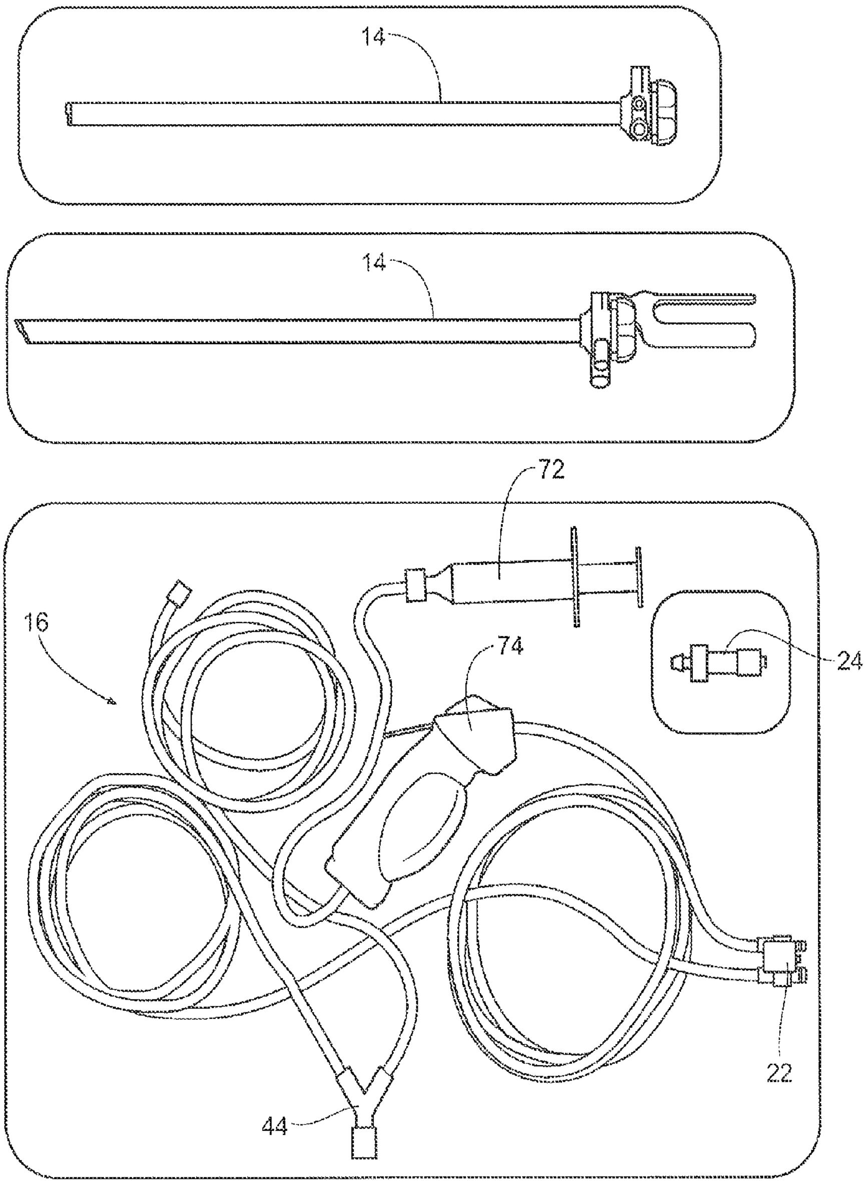


Fig. 7

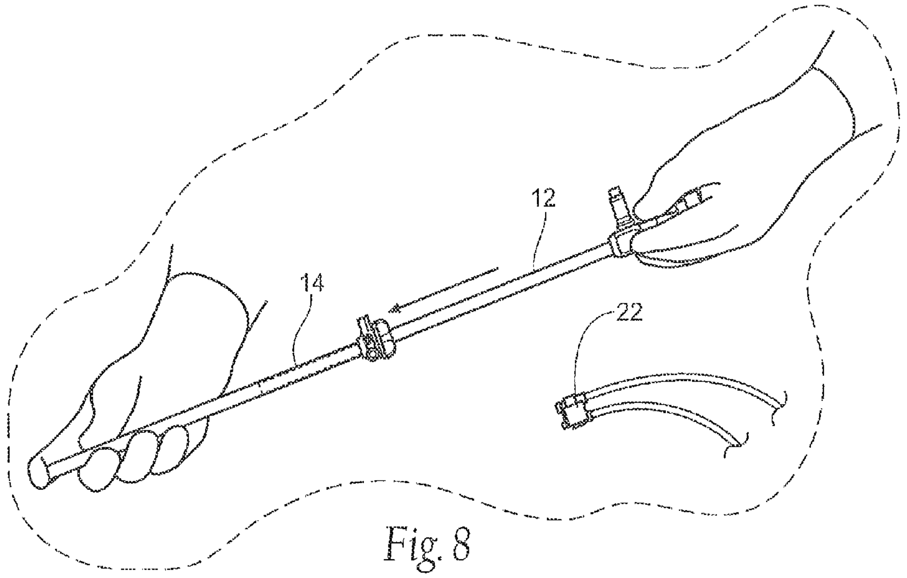


Fig. 8

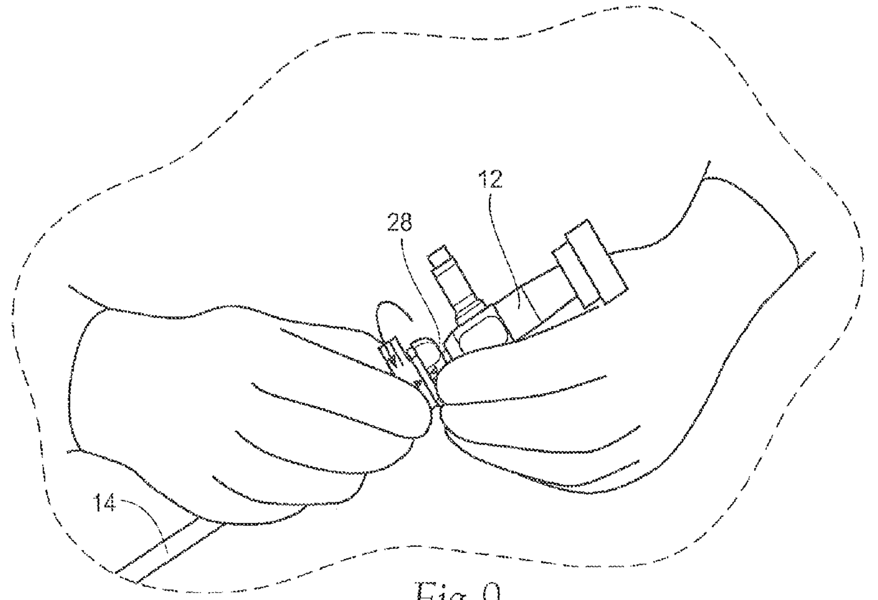


Fig. 9

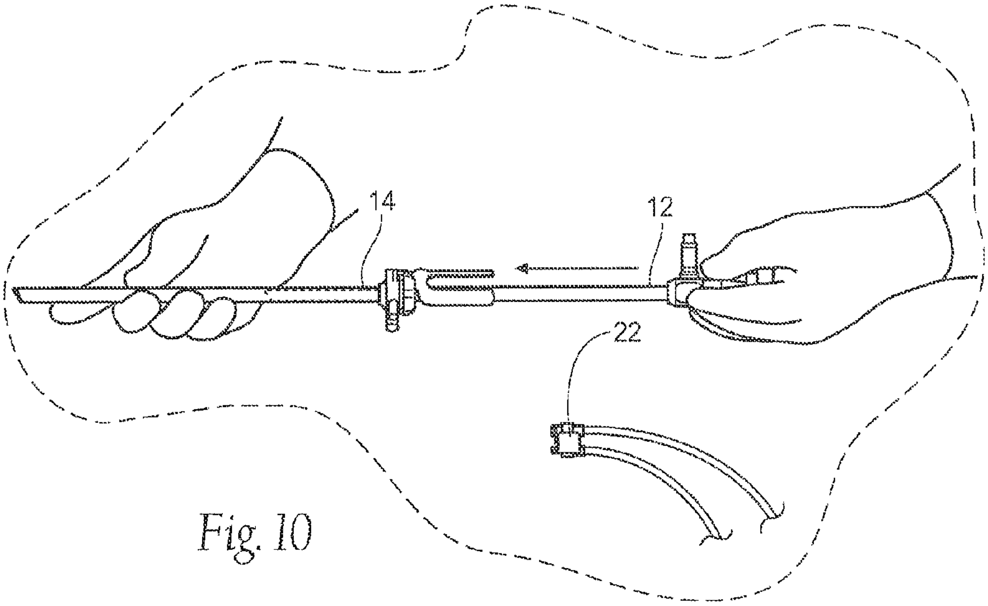
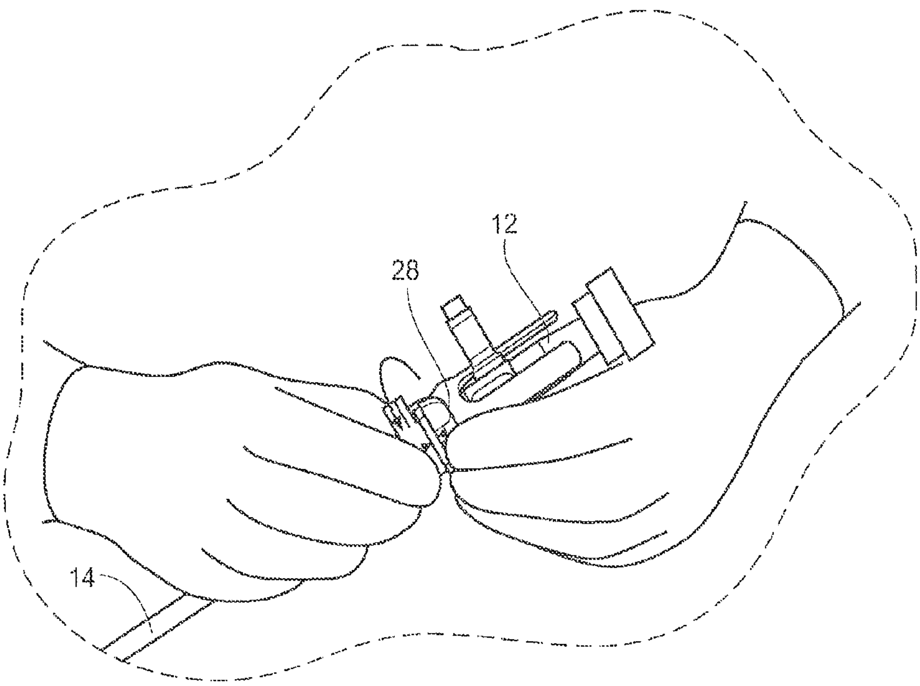


Fig. 10



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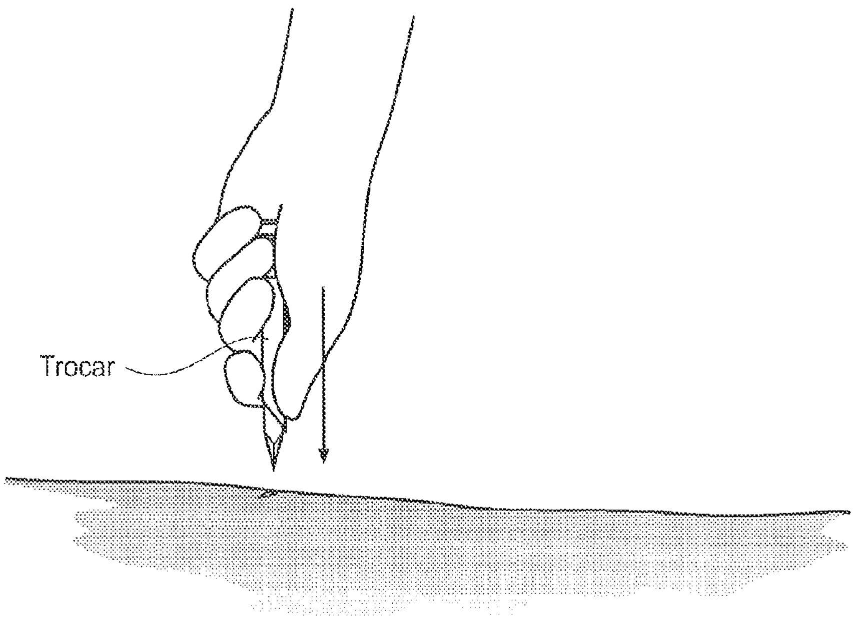
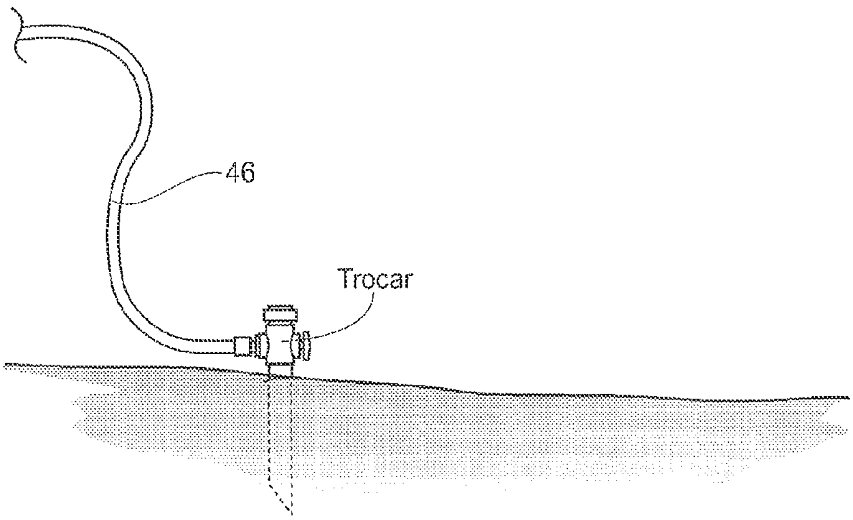


Fig. 12



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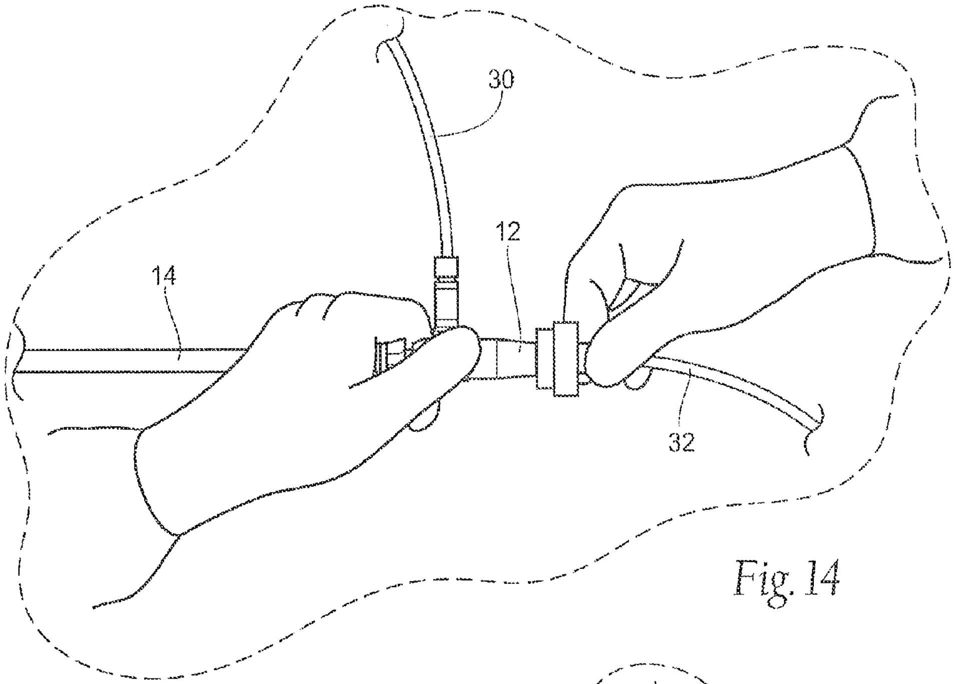

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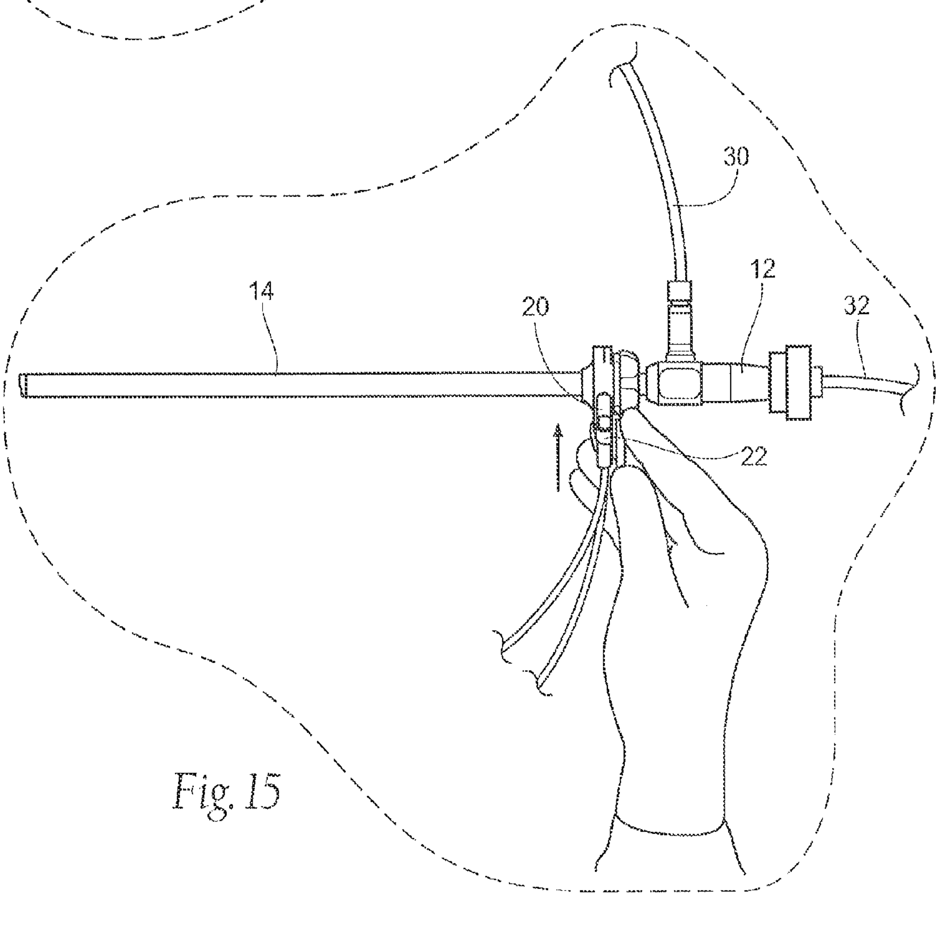

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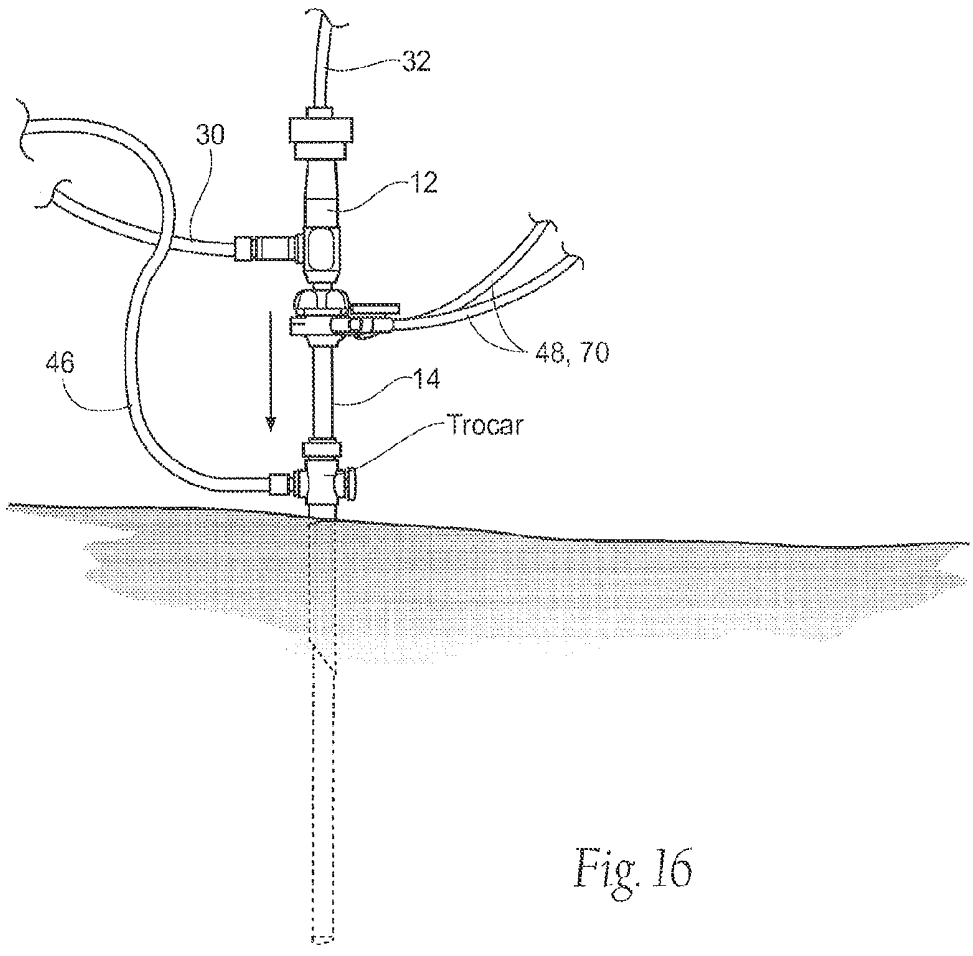

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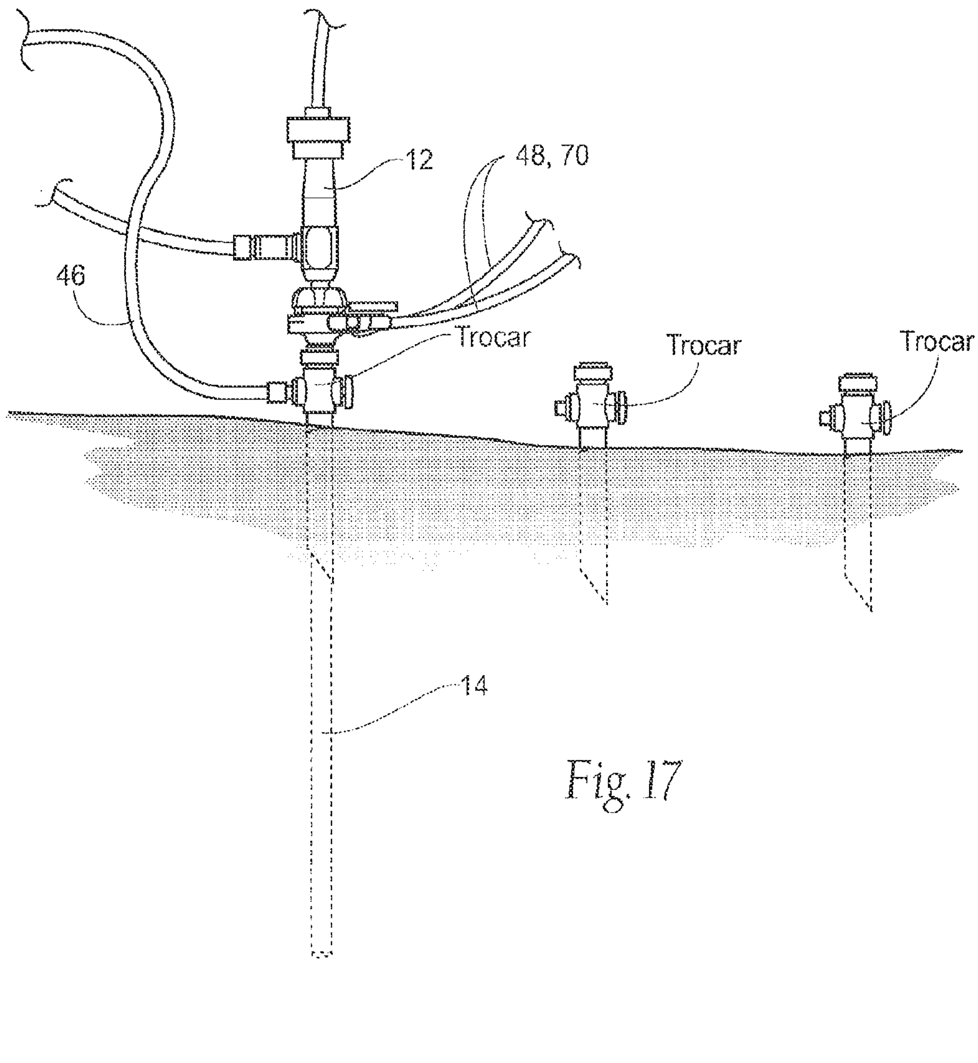

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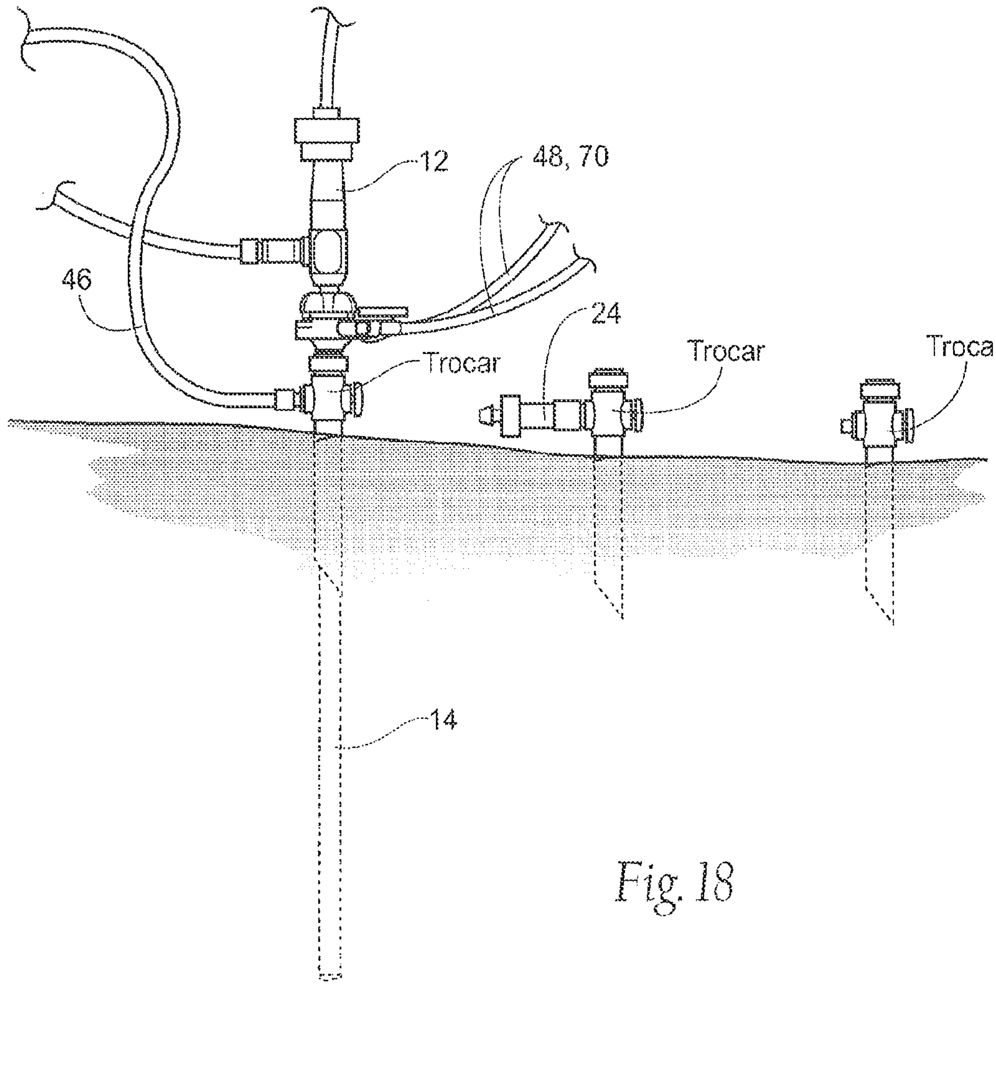

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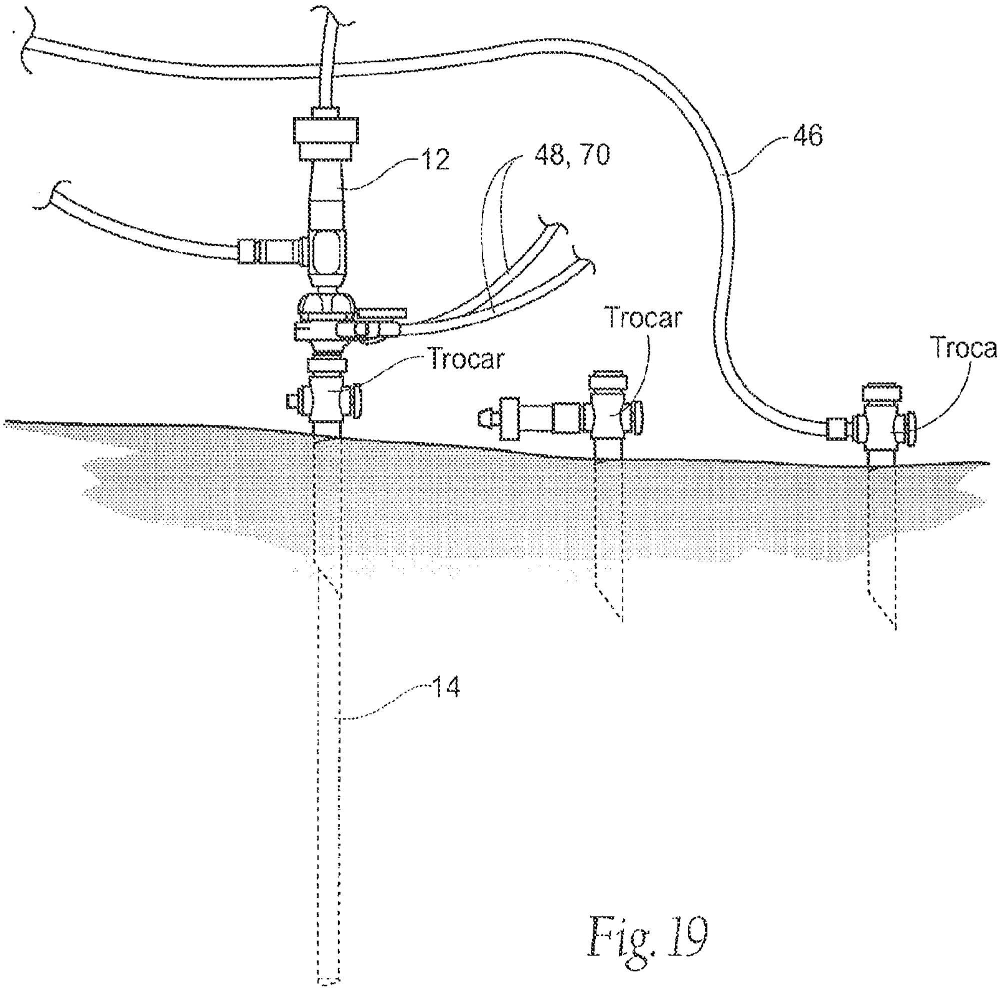

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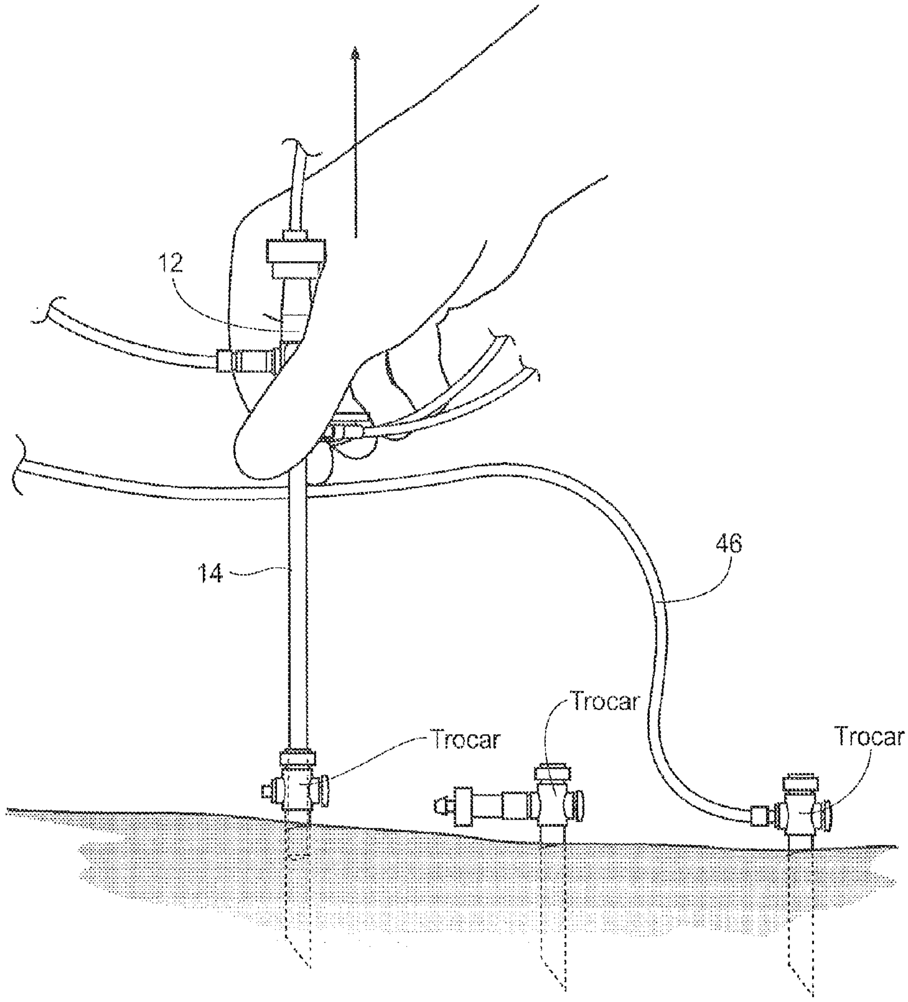

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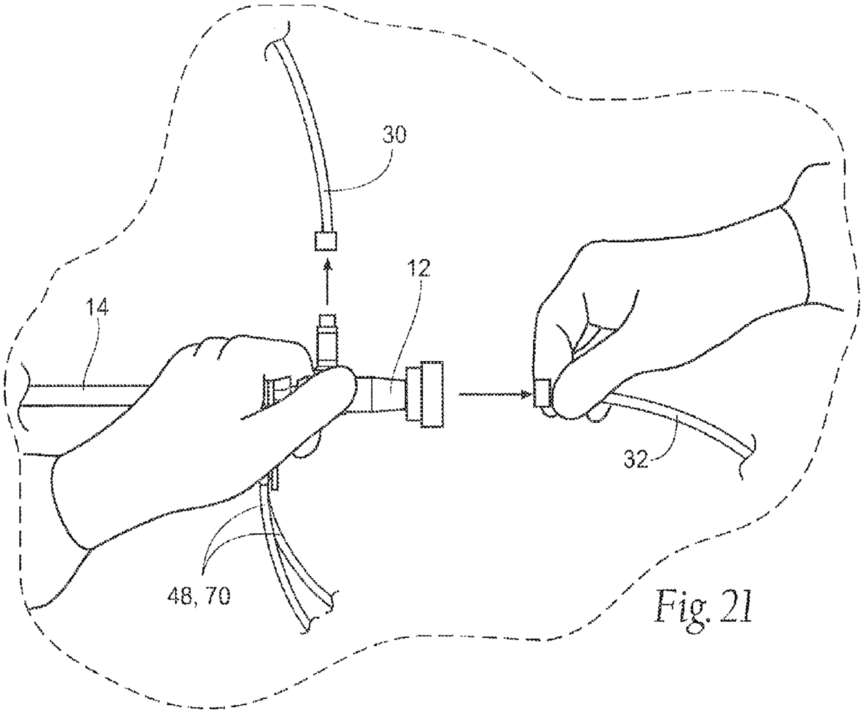

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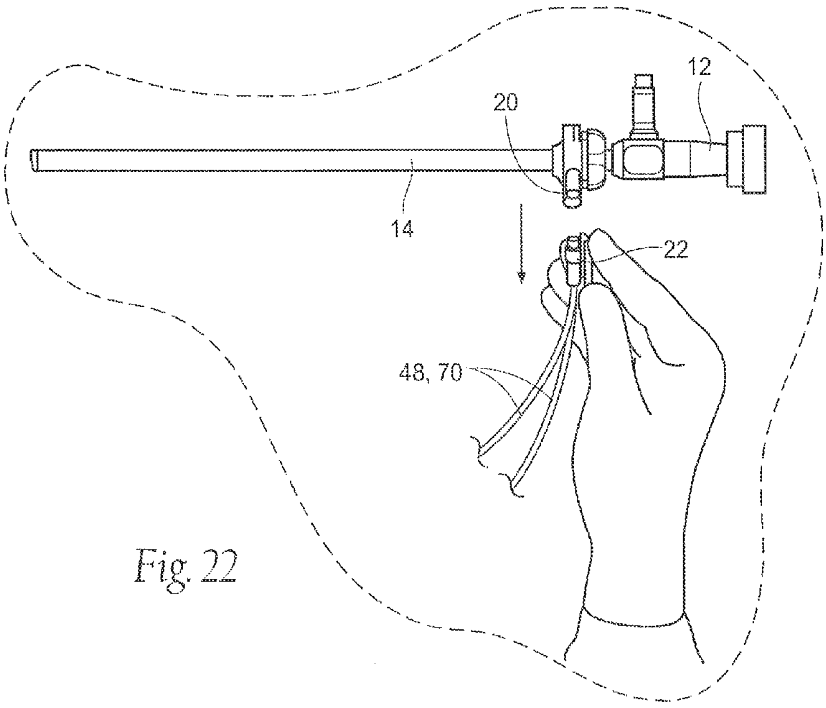

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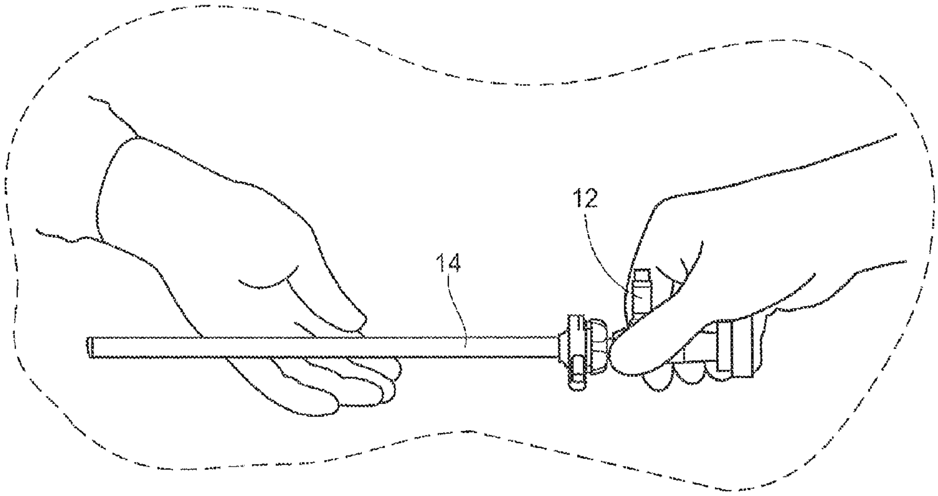

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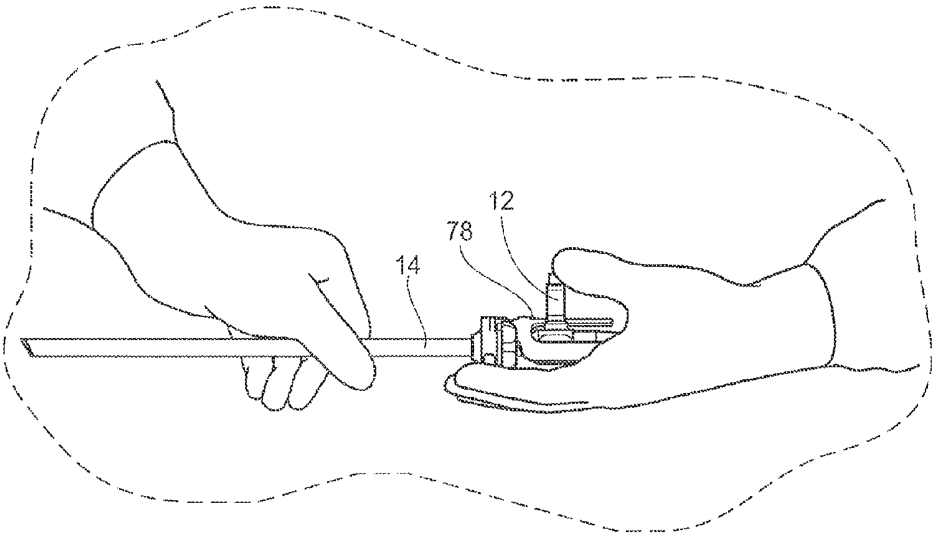

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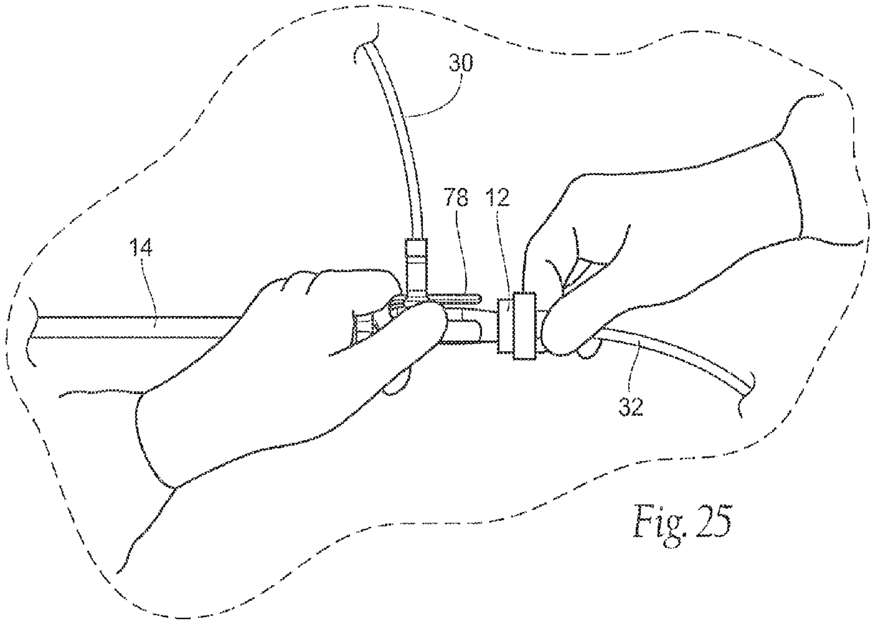

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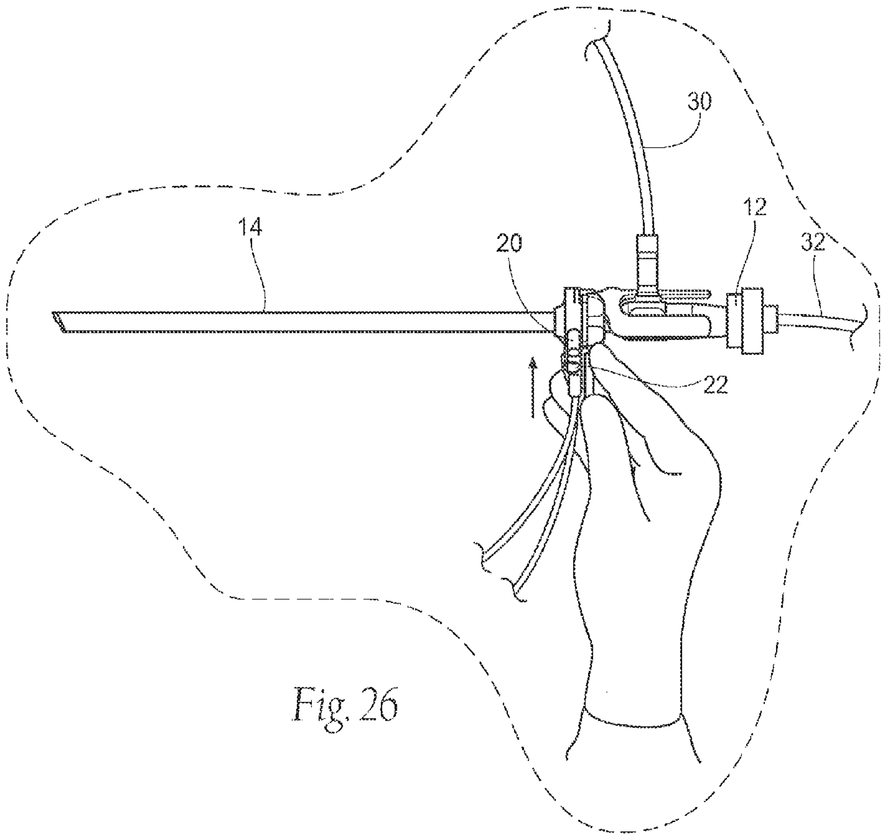

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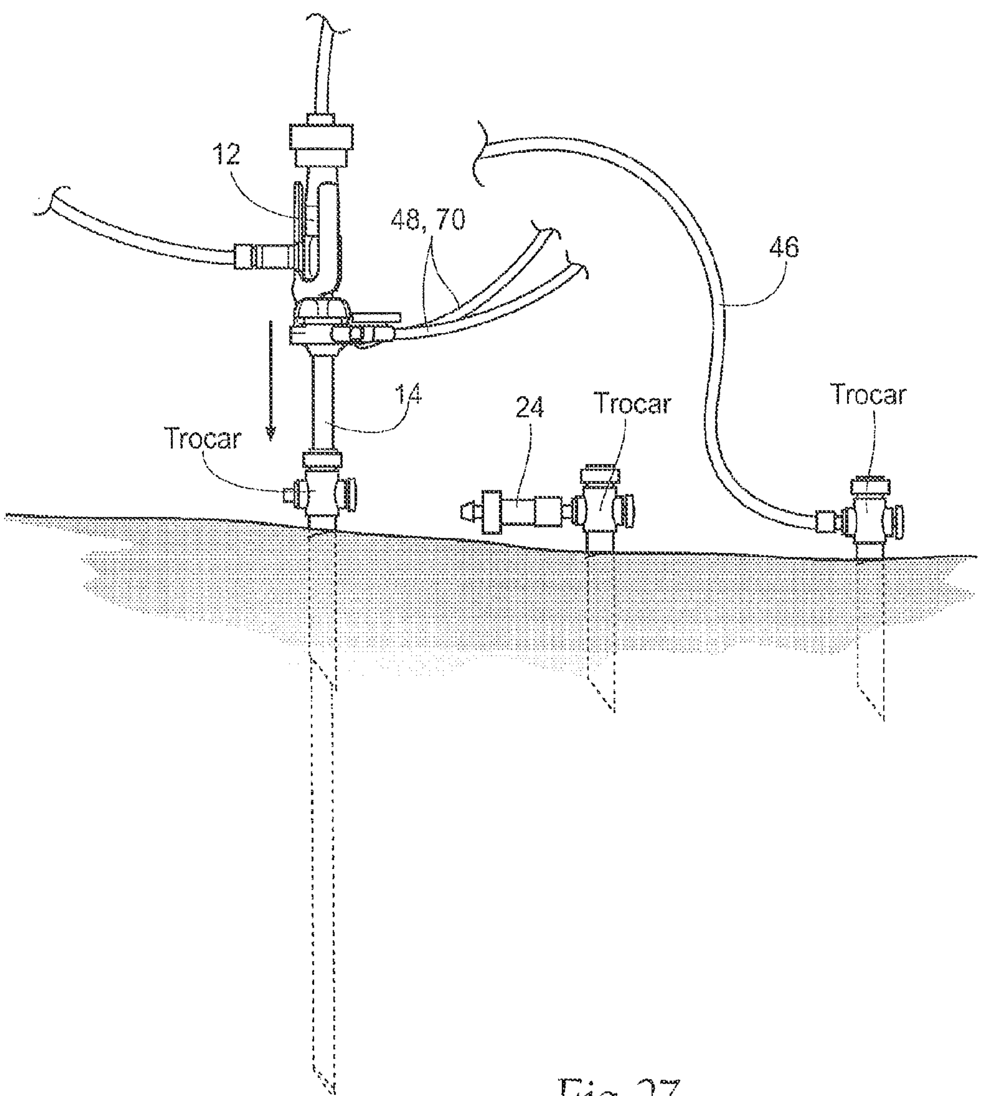
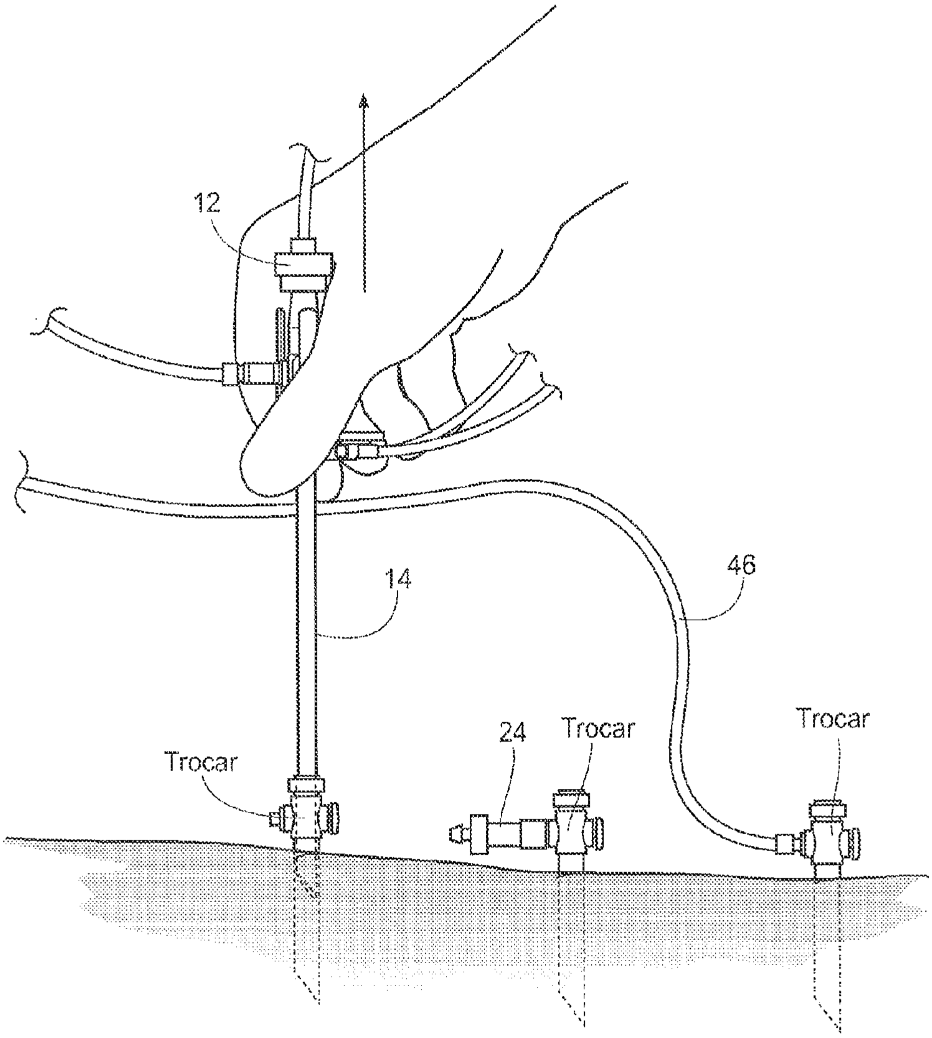


Fig. 27



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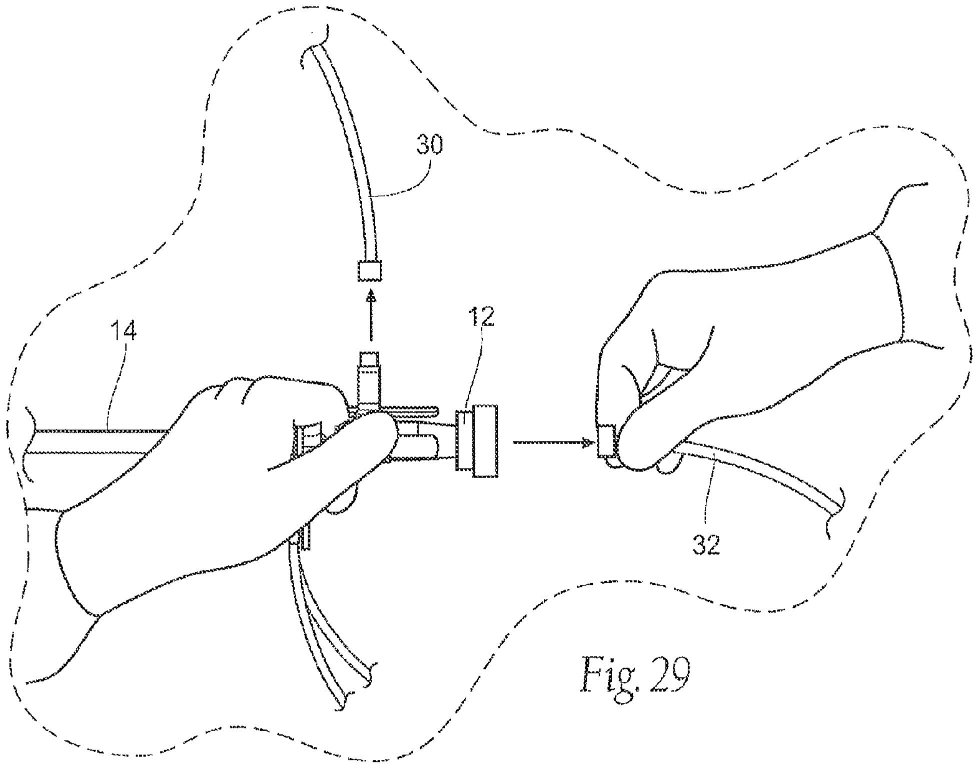

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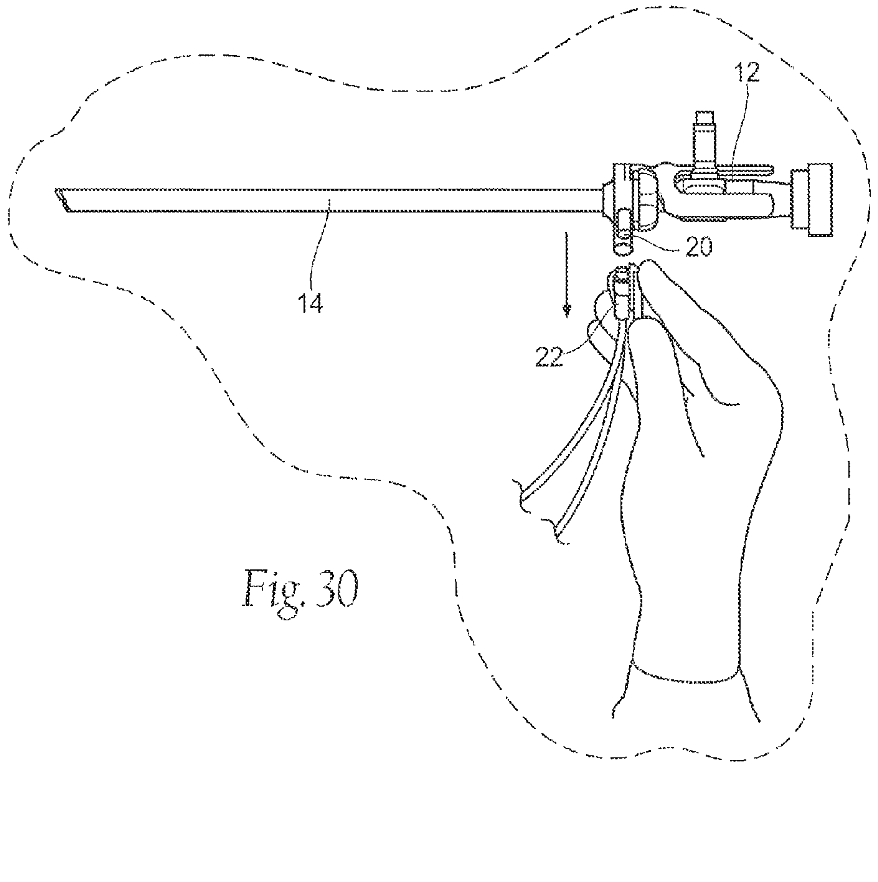
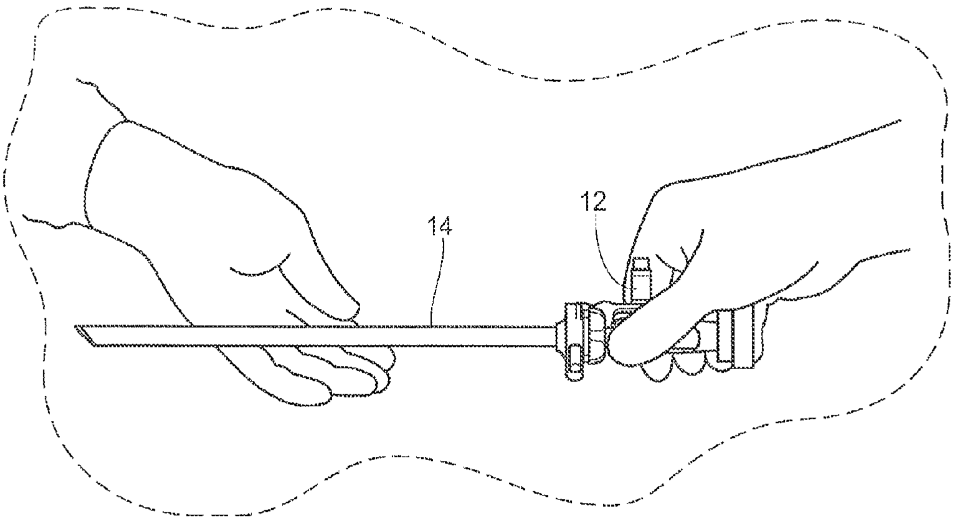


Fig. 30



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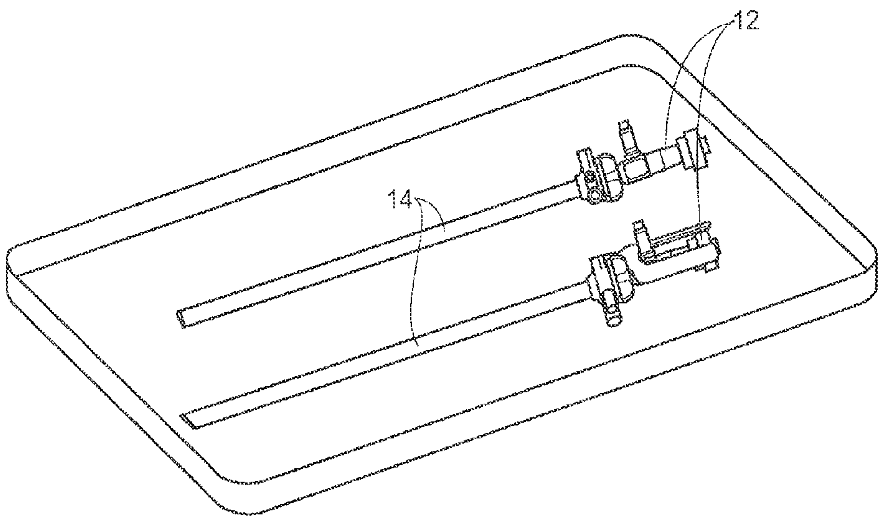

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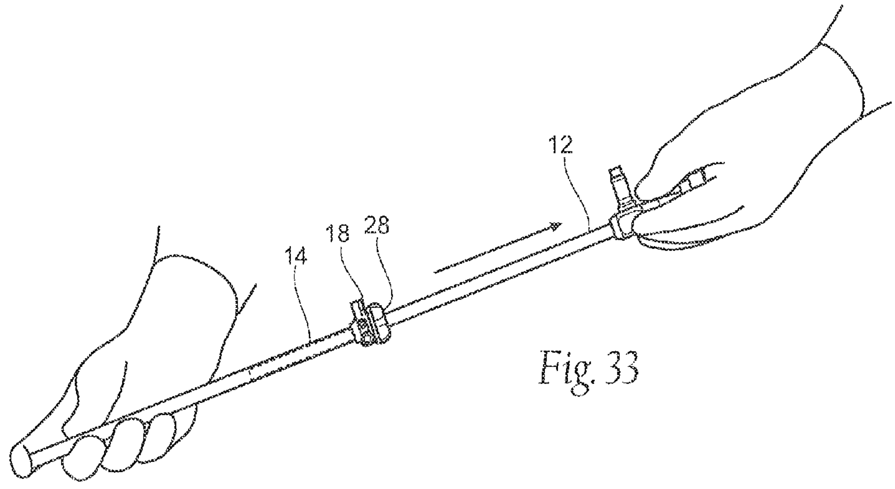

Fig. 33

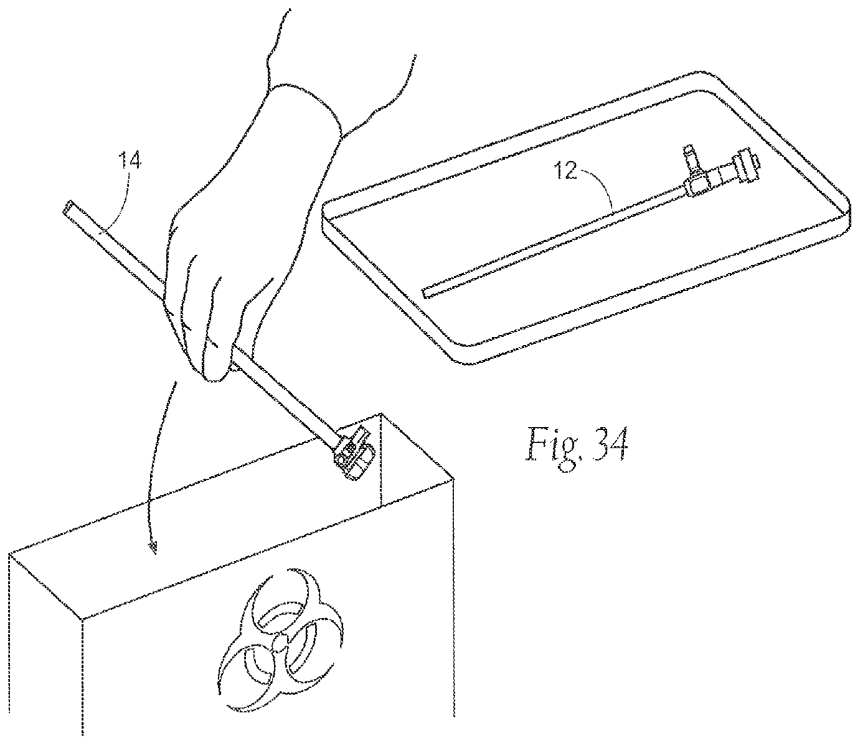

Fig. 34

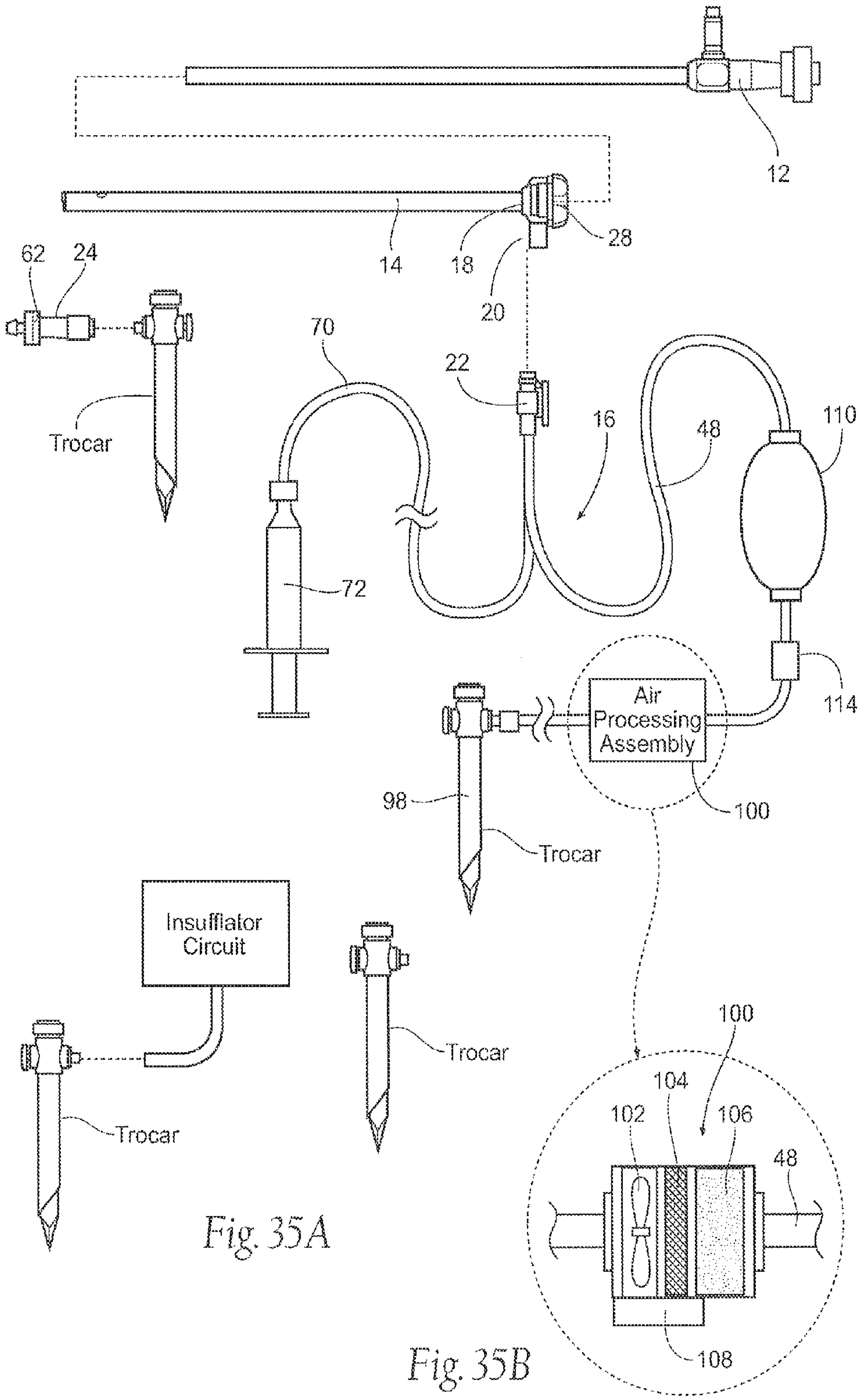

Fig. 35A

Fig. 35B

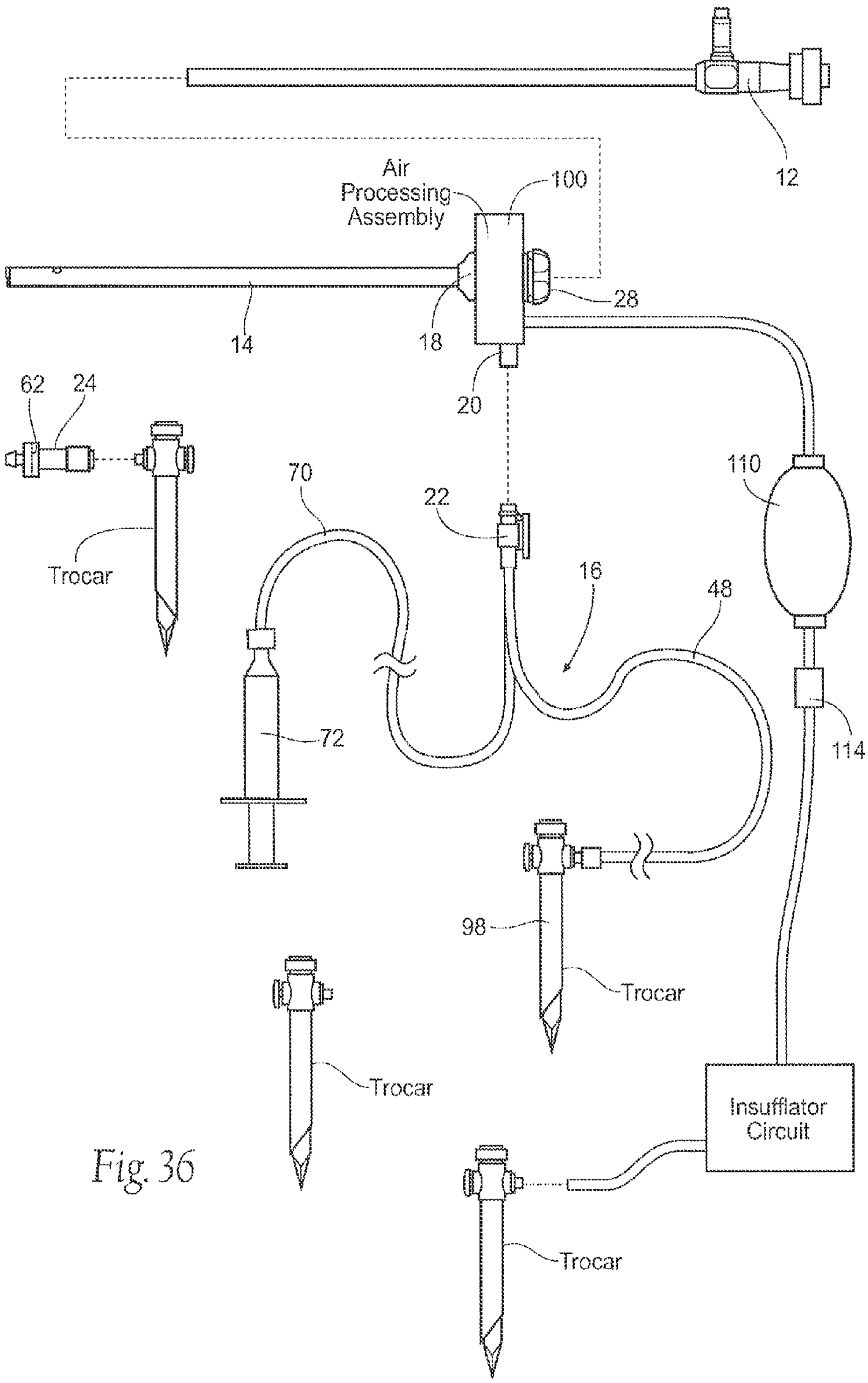
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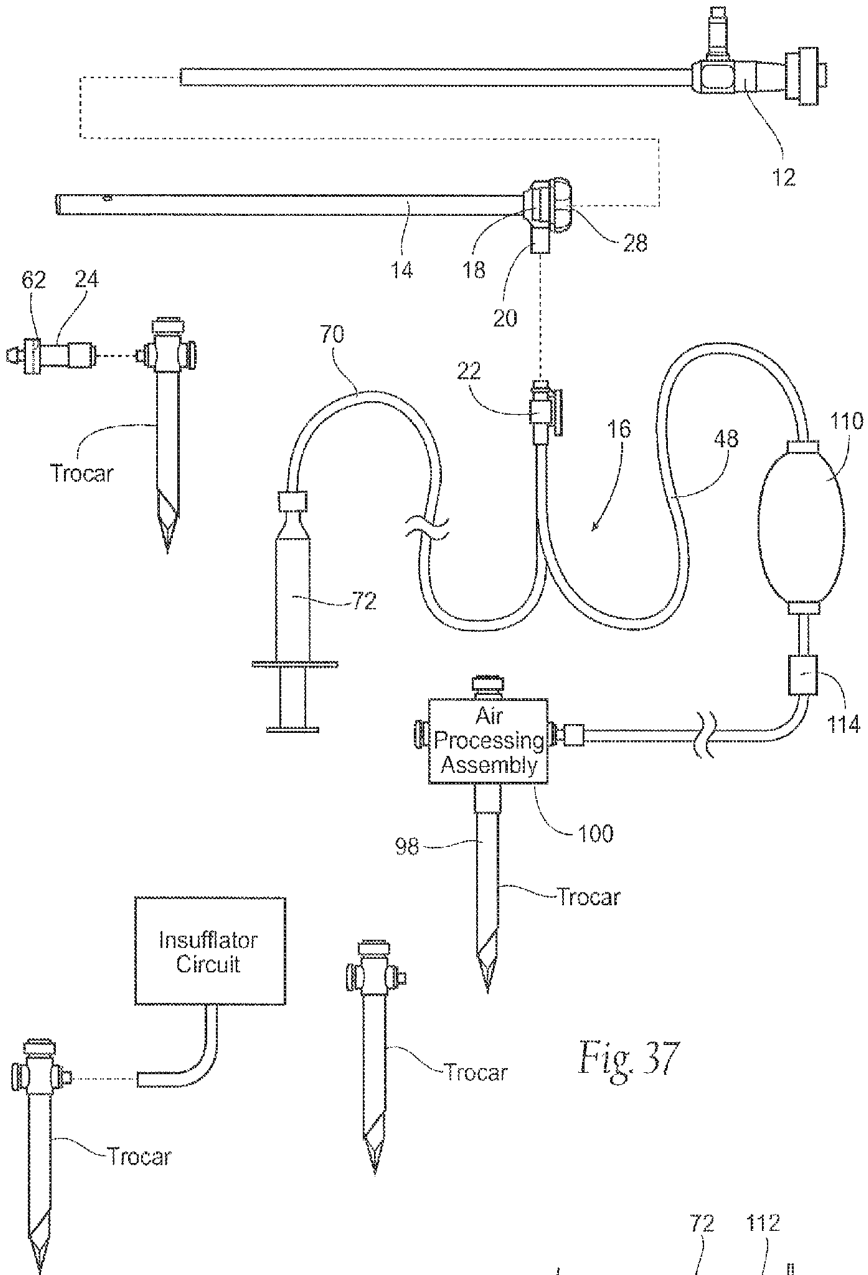
Fig. 36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Trocar

Fig. 37

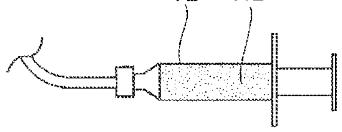
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Fig. 38

SYSTEMS AND METHODS FOR OPTIMIZING AND MAINTAINING VISUALIZATION OF A SURGICAL FIELD DURING THE USE OF SURGICAL SCOPES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 13/004,505, filed Jan. 11, 2011, titled "SYSTEMS AND METHODS FOR OPTIMIZING AND MAINTAINING VISUALIZATION OF A SURGICAL FIELD DURING THE USE OF SURGICAL SCOPES," now U.S. Patent Application Publication No. 2012-0022331, which claims the benefit of U.S. Provisional Patent Application No. 61/335,712, filed Jan. 11, 2010, and titled "SYSTEMS AND METHODS FOR OPTIMIZING AND MAINTAINING VISUALIZATION OF A SURGICAL FIELD DURING THE USE OF SURGICAL SCOPES," each of which is incorporated herein by reference.

FIELD

[0002] The invention generally relates to surgical scopes, and, more particularly, for optimizing and maintaining visualization of a surgical field when using a surgical scope, such as, e.g., a laparoscope.

BACKGROUND

[0003] Minimally invasive surgical procedures utilizing surgical scopes are desirable because they often provide one or more of the following advantages: reduced blood loss; reduced post-operative patient discomfort; shortened recovery and hospitalization time; smaller incisions; and reduced exposure of internal organs to possible contaminants.

[0004] Generally, minimally invasive surgeries utilize scopes, such as laparoscopes, that permit remote visualization of a surgical site within a patient's body while the surgical procedure is being performed. During a laparoscopic procedure, the patient's abdominal or pelvic cavity is accessed through two or more relatively small incisions rather than through a single large incision that is typical in a conventional surgery. Surgical scopes, such as laparoscopes, usually consist in part of a rigid or relatively rigid rod or shaft having an objective lens at one end and an eyepiece and/or integrated visual display at the other. The scope may also be connected to a remote visual display device or a video camera to record surgical procedures.

[0005] In laparoscopic surgeries, the abdomen is typically inflated with a gas through the use of an insufflator, to distend the abdominal space by elevating the abdominal wall above the internal organs and thereby create a sufficient working and viewing space for the surgeon. Carbon dioxide is usually used for insufflation, though other suitable gases may also be used. Conventional insufflators are adapted to cycle on and off to maintain a preset and suitable pressure within the patient's body cavity.

[0006] The local environment within a patient's abdominal space is generally rather warm and humid, and the use of devices such as harmonic scalpels and other cutting and coagulating devices generate mist, smoke, and other debris that is released into the surgical field and often becomes suspended throughout the expanded abdominal space. Additionally, blood, bodily fluids, pieces of tissue, fat or other bodily material may come in contact with or even attach to the lens. As a result of these conditions, visualization through the scope can be significantly diminished. Typically, the only solution to fogging and debris collection on the lens is removal of the scope from the body cavity and defogging or cleaning the lens by wiping it with a cloth, warming the scope tip, or utilizing another defogging method. The need to remove the scope to defog and remove debris from the lens is inconvenient for the scope operator and the surgeon and can interrupt and undesirably prolong surgical procedures.

SUMMARY OF THE DISCLOSURE

[0007] One aspect of the invention provides a system comprising a sheath sized and configured to receive a laparoscope including a laparoscopic lens providing visualization of an operating cavity insufflated with CO2 through operation of an insufflator circuit. The sheath also includes a lumen for passing air from a source across the laparoscopic lens to maintain visualization of the operating cavity. According to this aspect of the invention, the source comprises an air conveying assembly. The air conveying mechanism includes a housing and an air flow path self-contained within the housing. The air flow path comprises an inlet sized and configured for communication with the operating cavity and an outlet sized and configured for communication with the lumen of the sheath. The air conveying mechanism includes an air moving component self-contained within the housing in communication with the air flow path. The air conveying mechanism is powered independent of the insufflator circuit to convey CO2 from the operating cavity through the air flow path for passage across the laparoscopic lens, to thereby maintain visualization of the operating cavity independent of operation of the insufflator circuit.

[0008] In one embodiment, the air conveying assembly can further include an air treatment component self-contained within the housing in communication with the air flow path that removes at least one undesired agent the air flow path and/or a dehumidifying component self-contained within the housing in communication with the air flow path that removes water vapor from the air flow path.

[0009] In one embodiment, the air conveying assembly can further includes a source of power self-contained within the housing for powering the air conveying mechanism and other powered components self-contained within the housing.

[0010] In one embodiment, the inlet of the air flow path can communicate with an air supply trocar.

[0011] Another aspect of the invention provides an assembly comprising a laparoscopic access device for accessing an operating cavity insufflated with CO2 by operation of an insufflator circuit and an air conveying component coupled to the laparoscopic access device. The air conveying component comprises an air flow path having an inlet in fluid communication with operating cavity and an outlet sized and configured for fluid communication with an external instrument. The air conveying component also includes a air moving component in communication with the air flow path sized and configured to be continuously driven independent of the insufflator circuit to convey CO2 from the operating cavity continuously through the air flow path to the external instrument.

[0012] In one embodiment, the laparoscopic access device and the air conveying component comprise an integrated, self-contained assembly.

[0013] Another aspect of the invention provides an air conveying component coupled to a sheath that is sized and configured to receive a laparoscope including a laparoscopic lens providing visualization of an operating cavity. The sheath includes a lumen communicating with the outlet of the air conveying mechanism for passing CO2 continuously conveyed by the driven air coving component across the laparoscopic lens to maintain visualization of the operating cavity. According to this aspect of the invention, the air conveying mechanism includes an air flow path having an inlet sized and configured for communication with a source of CO2 and an outlet. The air conveying mechanism also includes a driven air moving component in communication with the air flow path sized and configured to continuously convey CO2 from the source through the air flow path to the outlet.

[0014] In one embodiment, the sheath and the air conveying mechanism comprise an integrated-self-contained assembly.

[0015] Another aspect of the invention provides a method. The method comprises (i) operating an insufflator circuit to insufflate an operating cavity with CO2, and (ii) visualizing the operating cavity insufflated with CO2 through a laparoscopic lens. The method further includes (iii) independent of (i), operating an air conveying assembly to convey CO2 from the operating cavity through an air flow path outside the operating cavity. The method includes (iv) passing CO2 conveyed during (iii) across the laparoscopic lens to maintain visualization of the operating cavity.

[0016] In one embodiment, the method can include, during (iii), removing at least one undesired agent from the air flow path and/or removing water vapor from the air flow path.

[0017] Another aspect of the invention provides a method that couples a laparoscopic access device for accessing an operating cavity insufflated with CO2 by operation of an insufflator circuit with an air conveying component. The air conveying component comprises an air flow path having an inlet in fluid communication with operating cavity and an outlet sized and configured for fluid communication with an external instrument. The air conveying mechanism includes a air moving component in communication with the air flow path sized and configured to be continuously driven independent of the insufflator circuit to convey CO2 from the operating cavity continuously through the air flow path to the external instrument. The method includes driving the air moving component.

[0018] Another aspect of the invention provides a method that couples an air conveying component with a sheath sized and configured to receive a laparoscope including a laparoscopic lens providing visualization of an operating cavity. The air conveying component comprises an air flow path having an inlet sized and configured for communication with a source of CO2 and an outlet. The air conveying mechanism includes a driven air moving component in communication with the air flow path sized and configured to continuously convey CO2 from the source through the air flow path to the outlet. According to this aspect of the invention, the sheath includes a lumen communicating with the outlet of the air conveying mechanism for passing CO2 continuously conveyed by the driven air coving component across the laparoscopic lens to maintain visualization of the operating cavity. The method includes driving the air conveying mechanism.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] FIG. 1A is a somewhat schematic view of a view optimizing assembly for use with a laparoscope having a 0° shaft tip.

[0020] FIG. 1B is a section view of the sheath, showing internal fluid flow lumens, taken generally along line 1B-1B in FIG. 1A.

[0021] FIG. 2A is a somewhat schematic of a view optimizing assembly for use with a laparoscope having an angled shaft tip.

[0022] FIG. 2B is a section view of the sheath, showing internal fluid flow lumens, taken generally along line 2B-2B in FIG. 2A.

[0023] FIG. 3A is an enlarged perspective view of a manifold that the view optimizing assembly shown in FIG. 1A or FIG. 2A incorporates, including a quick exchange coupling, and a quick exchange coupler that the tubing set shown in FIG. 1A or FIG. 2A incorporates, the coupling and the coupler being disconnected.

[0024] FIG. 3B is a sectional view taken generally along line 3B-3B in FIG. 3A, showing a one way check valve that is normally closed.

[0025] FIG. 4A is an enlarged perspective view of the manifold including a quick exchange coupling and the quick exchange coupler of the tubing set, as shown in FIG. 3A, but now connected.

[0026] FIG. 4B is a sectional view taken generally along line 4B-4B in FIG. 4A, showing the one way check valve that is opened by the connection of the quick exchange coupling and connectors.

[0027] FIGS. 5A(1) and 5A(2) are enlarged, exploded views of the deflector assembly for use with a laparoscope having a 0° shaft tip.

[0028] FIGS. 5B(1) and 5B(2) are enlarged, exploded views of the deflector assembly for use with a laparoscope having an angled shaft tip.

[0029] FIG. 6 is a schematic view of the critical physical, pneumatic, and optical characteristics of the deflector assembly shown in FIGS. 5A and 5B.

[0030] FIGS. 7 to 34 illustrate a representative method including the set up and use of the view optimizing assembly using sterile technique by technicians/operating room personnel.

[0031] FIG. 35A shows a view optimizing assembly for use with a laparoscope having a tubing set with an in-line air processing or conveying assembly.

[0032] FIG. 35B is an enlarged section view of the air processing or conveying assembly shown in FIG. 35A.

[0033] FIG. 36 shows a view optimizing assembly for use with a laparoscope having an air processing or conveying assembly that forms an integrated part of the sheath component of the assembly.

[0034] FIG. 37 shows a view optimizing assembly for use with a laparoscope having an air processing or conveying assembly that forms an integrated part of a trocar that is used in association with the assembly.

[0035] FIG. 38 shows a pump filled with sterile fluid with a "surface-active agent" or surfactant that can be operated in association with a view optimizing assembly like that shown in the preceding drawings.

DETAILED DESCRIPTION

[0036] Although the disclosure hereof is detailed and exact to enable those skilled in the art to practice the invention, the physical embodiments herein disclosed merely exemplify the invention, which may be embodied in other specific structure. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

I. View Optimizing Assembly

[0037] A. Overview

[0038] FIGS. **1**A/**1**B and FIG. **2**A/**2**B show a view optimizing assembly **10** for use in association with a state of the art laparoscope **12**. In FIGS. **1**A/**1**B, the laparoscope **12** possesses at 0° (blunt) shaft tip In FIGS. **2**A/**2**B, the laparoscope possess an angle shaft tip (e.g., a 30° shaft tip or 45° shaft tip). The components of the view optimizing assembly **10** may be made from plastic materials (extruded and/or molded), but other suitable materials, such as metal or a composite material, or combinations thereof could be used.

[0039] As will be described in greater detail, the view optimizing assembly **10** facilitates intra-operative defogging, surgical debris deflection, and cleaning of a laparoscope lens during minimally invasive surgery, while also maintaining visualization of the surgical site. The view optimizing assembly **10** is intended to be a single-use, disposable laparoscopic accessory. The view optimizing assembly **10** is desirably a sterile accessory for immediate set up and use on a sterile operating field.

[0040] As shown in FIGS. **1**A and **2**A, the view optimizing assembly **10** comprises a multi-lumen sheath assembly **14**, which mounts over the shaft of the laparoscope **12**. The end of the shaft is sized and configured to match the size and configuration of the corresponding laparoscope **12**, having a blunt tip in FIG. **1**A and angled tip in FIG. **2**A. The assembly **10** includes a tubing set **16** to connect the sheath **14** to an existing anhydrous carbon dioxide (CO2) insufflation circuit.

[0041] In use, the view optimizing assembly **10** makes possible the practice of a surgical method for maintaining clear visualization of the surgical site without removing the laparoscope **12** from the abdominal cavity for the purpose of cleaning or de-fogging its lens. Furthermore, the view optimizing assembly **10** also makes possible a surgical method for maintaining clear visualization that includes the ability to make a quick exchange of laparoscopes having different operating characteristics (e.g., laparoscopes with different tip angles, lengths, or diameters) entirely on the sterile operating field and without interference with the preexisting surgical set-up on the sterile operating field. The view optimizing assembly **10** integrates with the existing suite of minimally invasive instrumentation. It does not interfere with the surgical set-up, and it requires minimal change in the process or practice of a surgical operating room (OR) team.

[0042] The view optimization assembly **10** desirably comes packaged for use in sterile peel away pouches (see FIG. **7**). As also shown in FIGS. **1**A and **2**A, the pouches contain the components of the view optimization assembly **10**, including the sheath **14** and a manifold **18** that is assembled to the sheath **14** and that includes a quick exchange coupling **20**; the tubing set **16** which includes a quick exchange coupler **22** that mates with the quick exchange coupling **20** on the manifold **18**; and (optionally) a vent device **24**.

[0043] B. The Sheath/Manifold Assembly

[0044] As shown in FIGS. **1**A and **2**A, the sheath **14**/manifold **18** assembly includes a sheath **14** that is sized and configured to receive a laparoscope **12** having a prescribed tip angle, length, and diameter. The sheath **14** includes a stop **26** (see FIGS. **5**A(**2**) and **5**B(**2**) formed adjacent the distal end of the sheath **14**. The stop **26** prevents advancement of the laparoscope **12** beyond the distal end of the sheath **14**, so that lens at the distal end of the laparoscope **12** rests in a desired, generally coterminous alignment with the distal end of the sheath **14**. The sheath **14** also includes a locking collar **28** at its proximal end to frictionally engage the laparoscope **12** and resist axial withdrawal of the laparoscope **12** from the sheath **14**.

[0045] In use, it is expected that the laparoscope **12** will be inserted into the sheath **14** by a scrub nurse during set-up for the operation (see FIGS. **8** to **11**). The assembled laparoscopic and sheath **14** will then be handed as a unit to personnel at the operating room (OR) table at the desired time). The laparoscope **12** is then connected by personnel at the OR table in conventional fashion to a light cable **30** (which directs light to illuminate the operative field) and the camera cable **32** (which takes the image from the scope and displays it on monitors in the OR) (see FIG. **14**). The sheath **14** is sized and configured not to interfere with this normal set-up of the laparoscope **12**.

[0046] In use, the assembled laparoscopic and sheath **14** are placed as a unit through a trocar into the body cavity (e.g., the abdominal cavity), for viewing the surgical procedure as it is performed (see FIG. **16**).

[0047] As shown in FIGS. **1**A and **2**A, and as further shown in FIG. **3**A, the sheath **14**/manifold **18** assembly also includes the manifold **18** at the proximal end of the sheath **14**. The manifold **18** communicates with multiple lumens (five **34** to **42**) are shown in the illustrated embodiment) formed within the wall of the sheath **14** (see FIGS. **1**B and **2**B. In use, the lumens **34** to **42** convey anhydrous CO2 to the distal end of the sheath **14**; vent or exhaust air from the distal end of the sheath **14** through the manifold **18**; and, if desired, convey sterile fluid and bursts of air to the distal end of the sheath **14**. In a representative embodiment (see FIGS. **1**B and **2**B), two lumens **34** and **36** are dedicated to the transport of CO2; two lumens **40** and **42** are dedicated to venting; and one lumen **38** is dedicated to the transports of sterile fluid or air.

[0048] C. The Tubing Set

[0049] As previously described, the tubing set **16** includes a quick exchange coupler **22** that mates with the quick exchange coupling **20** on the manifold **18** (see FIGS. **3**A/**3**B and **4**A/**4**B). The tubing set **16** includes lengths of flexible medical grade tubing with individual end couplers (best shown in FIGS. **1**A and **2**A) that connect to an existing CO2 insufflation circuit and, if desired, a source of sterile fluid (saline or sterile water, preferably with a "surface active agent") on the sterile operating field (e.g., a bag or a syringe). The tubing set **16** includes a Y-connector **44** that divides the anhydrous CO2 output of the insufflation circuit in a first branch **46** for coupling to an insufflation trocar inserted in the body cavity (as will be described later), and a second branch **48** coupled to the quick exchange coupler **22**.

[0050] The second branch **48** diverts a small portion of the CO2 output (e.g., 20% or less) to the quick exchange coupler **22**.

[0051] As shown in FIGS. **3**B and **4**B, the quick exchange coupler **22** includes a one way check valve **50** that communicates with the second branch **48** of the tubing set **16**. In the illustrated embodiment, the check valve **50** comprises a ball valve. Insufflation pressure normally presses the ball valve **50** against a ball valve seat **52** (as shown in FIG. **3**B). A projection **54** in the manifold **18** displaces the ball valve **50** from the valve seat **52** when the quick exchange coupler **22** mates with the quick exchange coupling **20** on the manifold **18** (as shown in FIG. **4**B). Unseating the ball valve **50** opens flow communication through the check valve **50**. In the absence of coupling the quick exchange coupler **22** on the tubing set **16** to the quick exchange coupling **20** on the manifold **18**, the check valve **50** remains closed, normally blocking flow of CO2 through the second branch **48**.

[0052] Thus, the tubing set **16** accommodates the set-up of the supply of the entire CO2 output to a insufflation trocar through the tubing set **16**, separate and independent of the connection of the tubing set **16** to the manifold **18** of the sheath **14**.

[0053] As FIGS. **3**A and **4**A further show, a latch **56** carried on a spring-biased button **58** on the quick exchange coupler **22** "clicks" into a detent **60** on the quick exchange coupling **20** on the manifold **18** to reliably lock the coupler **22** and coupling **20** together for use, opening the check valve to flow CO2 through the second branch **48** (shown in FIGS. **4**A/**4**B). Depressing the button **58** allows the quick exchange coupler **22** and coupling **20** to be separated, and the check valve **50** will close in response to insufflation pressure in the second branch **48** (as shown in FIGS. **3**A/**3**B).

[0054] Connection of the quick exchange coupling **20** on the manifold **18** to the quick exchange coupler **22** on the tubing set **16** is intended to occur at the OR table in the normal course, after the laparoscope **12** is connected to the light cable **30** and the camera cable **32** (see FIG. **15**). Upon coupling, the one way check valve **50** is opened, and the manifold **18** directs the small portion of CO2 from the CO2 insufflation circuit. Disconnection of the of the quick exchange coupling **20** on the manifold **18** to the quick exchange coupler **22** on the tubing set **16** is also intended to occur at the OR table in the normal course, after a removal and/or exchange of a laparoscope **12** (see FIG. **22**).

[0055] D. The Vent Device

[0056] The vent device **24** (see FIGS. **1**A and **2**A) comprises a tube with an inline membrane **62** that restricts air flow through the tube. A proximal end of the tube is sized and configured to couple to a stopcock valve of a conventional trocar, as will be described later. In use, the vent device **24** provides a controlled leak of CO2 from the operating cavity, as will also be described in greater detail later.

[0057] E. The Deflector Assembly

[0058] 1. CO2

[0059] The sheath **14** includes at its distal end a deflector assembly **64** (see FIGS. **5**A(**1**) and **5**A(**2**) for a blunt shaft tip and FIGS. **5**B(**1**) and **5**B(**2**) for an angled shaft tip). The deflector assembly **64** projects a predetermined distance beyond the distal end of the sheath **14**, and thus also a predetermined distance beyond the lens at the distal end of the laparoscope **12**. The deflector assembly **64** communicates with the lumens in the sheath **14**. The deflector assembly **64** is sized and configured to direct the small portion of the CO2 from the insufflation circuit in a prescribed flow path and flow velocity continuously across the laparoscopic lens.

[0060] The desired flow path and flow velocity of CO2 established by the deflector assembly **64** continuously across the laparoscopic lens creates a "wind shear." The wind shear path of anhydrous CO2 prevents fogging. The desired flow path and flow velocity of CO2 established by the deflector assembly **64** continuously across the laparoscopic lens also desirably serves to deflect smoke and surgical debris away from the laparoscopic lens during surgery.

[0061] 2. Physical, Pneumatic, and Optical Characteristics of the Deflector Assembly

[0062] The size and configuration of the deflector assembly are defined and constrained by several, sometime overlapping considerations including (i) prescribed physical characteristics, which are imposed due to the need to access the operating environment in as minimally invasive manner as possible and to be compatible with state of the art laparoscopes and other laparoscopic surgical instruments and techniques; (ii) prescribed pneumatic characteristics, which are imposed due to the need to create a particular "wind shear" effect in terms of the flow path and flow velocity of CO2 across the laparoscopic lens; and (iii) prescribed optical characteristics, which are imposed due to the need to prevent interference with the field of view and the visualization of the operating field by the laparoscope **12**.

[0063] 3. Physical Characteristics

[0064] The size and configuration requirements for minimally invasive access compatible with state of the art laparoscopic instrumentation and techniques are paramount. These requirements impose constrains upon the minimum inside diameter of the sheath **14** as well as the maximum outside diameter of the sheath **14**. Because state of the art laparoscopes are provided with different shaft diameters, lengths, and lens configurations, the sheath dimensions and configuration change for compatibility with them. The view optimizing assembly **10** actually includes a family of sheath **14**/manifold **18** assemblies differently sized and configured to accommodate different classes of laparoscopes, to make possible compatibility with the families of state of the art laparoscopes that are in use.

[0065] For example, state of the art laparoscopes include 10 mm laparoscopes, 5 mm laparoscopes, and, within these sizes, 0° shaft tips, 30° shaft tips, and 45° shaft tips. Further, within these classes of laparoscopes, manufacturing tolerances typically vary from scope to scope, as well as from manufacturer to manufacturer. A given sheath **14**/manifold **18** assembly for a given laparoscope class (e.g., 10 mm or 5 mm) desirably takes these typical manufacturing and manufacturer variances into account, and is desirably sized and configured to fit the largest scope variance encountered within a given laparoscope class.

[0066] To maximize the fluid flow lumen area within the sheath **14**, the minimum inside diameter of a given sheath **14** must closely conform to the maximum outside diameter of the shaft of the particular state of the class of laparoscope **12** selected for use, which the sheath **14** must accommodate in a smooth, sliding fit. Further, a gap between the outside diameter of the laparoscope shaft and the inside diameter of the sheath **14** must be minimized to avoid the transport and leakage of blood and fluids from the operating field. Still further, minimizing the gap also assures that the laparoscope **12** self-centers in the sheath **14**, thereby assuring faithful and accurate visualization through the laparoscope lens.

[0067] For example, for a typical laparoscope **12** in the 10 mm class, which measures 0.392 inch, the inside diameter of the sheath **14** is manufactured to 0.405 inch, providing a gap thickness of 0.0064 inch. For a 5 mm laparoscope **12** in the 5 mm class, which measures 0.196 inch, the inside diameter of the sheath **14** is manufactured to 0.218 inch, providing gap thickness of 0.011 inch.

[0068] The maximum outside diameter of the sheath **14** for minimally invasive access must take into account the minimum inside diameter of the trocar, which the maximum outside diameter cannot exceed.

[0069] For example, for a typical 10 mm trocar that measures 0.509 inch, the outside diameter of the sheath 14 is manufactured to 0.486 inch, providing a gap thickness of 0.0115 inch. For a typical 5 mm trocar that measures 0.324 inch, the outside diameter of the sheath is manufactured to 0.300 inch, providing a gap thickness of 0.012 inch.

[0070] It is desirable, given the particular size and configuration constraints of the laparoscopic instrumentation and techniques used, to maximize the outside diameter to the extent possible. This is because, together the inside and outside diameters of the sheath 14 define the wall thickness for the sheath S_w The wall thickness S_w, together with the length of the sheath 14, in turn, define the maximum area available for the transport of the CO2 and fluids by the sheath 14. The area of the fluid flow lumen or lumens dedicated to the supply of CO2, in turn, defines the maximum flow rate of the CO2 directed by the deflector assembly 64. The flow rate should be sufficient at a minimum, given the output of the insufflator selected for use, to supply anhydrous CO2 across the lens of the laparoscope 12 sufficient to prevent fogging. Also affecting the effectiveness of the CO2 to defog the lens, is the water content of the anhydrous CO2. Given the same flow rate, the less water that is present in the anhydrous CO2, the greater is the defogging capacity of the assembly. Further, the flow rate desirable should also be sufficient to deflect smoke and surgical debris away from the viewing field of the laparoscopic lens during surgery, so that the anhydrous CO2 directed by the deflector assembly 64 both defogs and deflects debris.

[0071] Medical grade CO2 for use with conventional insufflators is typically 99% pure, that is, no more than 1% of the gas is other than CO2, and such medical grade anhydrous CO2 generally has a maximum moisture content of 25 parts per million by volume. Typically, a state of the art insufflator circuit delivers anhydrous CO2 at a max flow rate of about 20 liters per hour. Typically, the insufflator circuit will sense pressure in the circuit and cycle off when the sensed pressure is at or above 15 mmHg and cycle on when the sensed pressure is below 15 mmHg.

[0072] Given the above sheath dimensions, and given the supply of typical medical grade anhydrous CO2, a flow rate of at least about 1.0 liters per minute is critical to achieving this objective. Given the above dimensions, and the supply of typical medical grade anhydrous CO2, a flow rate less than 0.8 liters per minute is not sufficient to prevent significant accumulation of moisture on the laparoscope lens.

[0073] In a representative embodiment, for a sheath 14 having an inside diameter of 0.405 inch and an outside diameter of 0.486 inch, and a length of 11.25 inch (which accommodates passage of a typical 10 mm laparoscope and its own passage through a conventional trocar) (i.e., S_w=0.081 inch), the total area available in the sheath wall is 0.056 square inches. Based upon required structural support within the wall (inside, outside, and radial) the total available area for lumens to transport fluids is 0.027 square inch.

[0074] In a representative embodiment, the total lumen area is occupied by five lumens 34 to 42, two for transporting CO2 (34 and 36), one for sterile fluid (38), and two for passive exhaust air venting (40 and 42).

[0075] The area of each lumen can be maximized by selection of lumen geometry. In a representative embodiment, lumen geometry is generally triangular or pie shaped with rounded corners. The radial walls that separate the lumens within the sheath 14 are sized to minimize the spacing between the lumens.

[0076] In a representative embodiment, CO2 transport is accomplished by two lumens 34 and 36 that extend about 175 degrees about the outer circumference of the sheath 14 and comprising a flow area of 0.013 square inches. Sterile fluid transport is accomplished by one lumen 38 comprising a flow area of 0.003 square inches. Exhaust air venting is accomplished by two lumens 40 and 42 comprising a flow area of 0.011 square inches. The distal openings of the exhaust lumens 40 and 42 desirably are spaced from the distal end of the sheath, to prevent uptake of blood and fluids.

[0077] 4. Pneumatic Characteristics.

[0078] As diagrammatically shown in FIG. 6, the deflector assembly 64 must overhang the laparoscopic lens by a prescribed transverse distance, defining a deflection width X, sufficient to change the direction of CO2 flowing axially through lumens of the sheath 14 (i.e., along the axis of the laparoscope shaft) into a non-axially, transverse path across the laparoscopic lens (i.e., at an angle relative to the axis of the laparoscope shaft). Still, the distance of the deflection width X should not extend to the point that is obstructs the field of the view of the laparoscopic lens. This is an example where a pneumatic characteristic of the deflector assembly 64 overlaps with an optical characteristic. Further optical characteristics will be described in greater detail below.

[0079] The deflector assembly 64 must also project axially beyond the distal terminus of the sheath 14 by a prescribed axial distance, defining an air channel distance Y, sufficient to maintain the CO2 flowing along the path bounded by the deflection width X at a distance sufficiently close (proximal) to the laparoscopic lens to achieve the desired shear flow effect, but without forming an abrupt flow bend that can lead to a reduction in the desired CO2 flow velocity.

[0080] Together, the deflection width X and the channel distance Y define the pneumatic characteristics of the deflection assembly. At the desired minimum flow rate, the pneumatic characteristics create a flow path that conveys CO2 continuously across the laparoscopic lens at the desired flow velocity, in shorthand called the "wind shear." The pneumatic characteristics of the CO2 "wind shear" across the laparoscopic lens prevent fogging, as well as desirably deflect smoke and surgical debris away from the viewing field of the laparoscopic lens during surgery

[0081] Together, the pneumatic characteristics defined by the deflection width X and the channel distance Y create an exit angle A_{EXIT}, measured between the plane of the laparoscopic lens and the terminal edge of the deflector assembly 64. The exit angle A_{EXIT} must be less than a maximum angle of 45 degrees, else the flow path of the CO2 will not pass sufficiently both across and proximal to the laparoscopic lens. To maintain a desired exit angle A_{EXIT}, the channel distance Y should be at least equal to the wall thickness of the sheath S_w and should not exceed 1.5 times the wall thickness of the sheath S_w The deflection width X should be at least equally to two times the channel distance Y, but not extend into the field of view of the laparoscopic lens.

[0082] 5. Optical Characteristics

[0083] The optical characteristics of the deflector assembly 64 are selected (i) to not block or reduce the illuminated image of the operating field provided by the laparoscope 12; (ii) not decrease the intensity of the illumination provided by the laparoscope 12 on the operating field; and (iii) prevent reflection of illumination light at the lens of the laparoscope 12.

[0084] As discussed above, the maximum deflection width X takes into account one of the desirable optical characteristics; namely, the deflection width X should not obstruct the field of the view of the laparoscopic lens.

[0085] To prevent the decrease of the illumination, the deflector assembly **64** is desirably made from a material having high light transmission properties (i.e., transparency), to not interfere with the passage of light through the light cable **30** onto the operating field as well as the passage of the reflected image conveyed to the camera cable **32** of the laparoscope **12**.

[0086] Furthermore, the material and surface finish of the deflector assembly **64** must pose minimal reflectively to light. In a representative embodiment, the deflector assembly **64** is made from Bayer Makrolen Rx1805 with a surface finish defined as SPI/SPE A-3.

[0087] 6. Orientation

[0088] As before described, CO2 transport is accomplished by two lumens **34** and **36** that extend about 175 degrees about the outer circumference of the sheath **14**. For a 0° shaft tip (see FIG. **5**A), the orientation of the deflector assembly **64** relative to the laparoscopic lens is not critical. However, for angled shafts (e.g., 30° shaft tips and 45° shaft tips) (see FIG. **5**B), the orientation of the deflector assembly **64** relative to the laparoscopic lens is critical.

[0089] As FIG. **5**B shows, the angled tip of a typical laparoscope **12** has a high end **66** and a low end **68**. The lens slopes at the prescribed angle between the high end **66** and the low end **68**. In a laparoscope **12** having a angled tip, the illumination cable **30** (transmitting light onto the operating field) is located at the high end **66** of the angled tip, and the camera cable **32** (transmitting reflected light back to the camera) is located at the low end **68** of the angled tip. To provide the desired wind shear effect on an angled tip, it is critical that the deflector assembly **64** be oriented relative to the sloped laparoscopic lens such that the flow CO2 is directed across the sloped plane of the lens from the low end **68** of the tip toward the high end **66** of the tip. In this arrangement, the defogging and debris deflection flow path originates proximal to the camera cable **32**, which effectively comprises the eyes of the OR team. In this arrangement, the desired exit angle A_{EXIT} directs the flow path of the CO2 both sufficiently across and proximal to the sloped plane of the laparoscopic lens to achieve optimal defogging and debris deflection.

[0090] F. Sterile Fluid Flush

[0091] As previously explained, if desired, the tubing set **16** can also include, connected to the quick exchange coupler **22**, a length of tubing **70** sized and configured for connection to a source **72** of sterile fluid, such as saline or sterile water (as shown in FIGS. **1**A and **2**A). Preferably, the sterile fluid includes in solution a "surface-active agent" that stabilizes mixtures of oil and water (e.g., fat) by reducing the surface tension at the interface between the oil and water molecules.

[0092] The quick exchange coupling **20** on the manifold **18** (see FIGS. **3**A/**3**B and **4**A/**4**B) can also include a port to integrally connect the sterile fluid tubing **70** to direct the sterile fluid through the separate lumen **38** in the sheath **14** to the distal end of the sheath **14**. The deflector assembly **64** directs the sterile fluid across the laparoscopic lens.

[0093] As shown in FIGS. **1**A/**2**A, the sterile fluid tubing **70**, if present, desirably includes an in-line pumping device **72**. The in-line pumping device **72** is sized and configured to be operated on demand by a person at the OR table to convey bursts of sterile fluid through the manifold **18** through the lumen to the distal end of the sheath **14**. The in-line pumping device **72** and source can be integrated and comprise, e.g., a 20 cc syringe filled with sterile fluid and connected by a tubing luer-lock on the saline tubing. Alternatively, the in-line pumping device **72** and source can be separate and comprise, e.g., a bag of sterile fluid, a spike connection on the saline tubing of the tubing set **16** to open communication with the bag in conventional fashion, and an inline squeeze bulb or the like to pump burst of sterile fluid from the bag to the quick exchange coupler **22**.

[0094] In this arrangement, the deflector assembly **64** is also sized and configured to direct the burst of sterile fluid in a desired path across the laparoscopic lens. The bursts of sterile fluid serve to flush debris off the end of the lens that may eventually accumulate, thereby cleaning the lens. Thereafter, bursts of air supplied through the deflector assembly **64** by a squeeze pump **74** in the tubing set **16** (see FIGS. **1**A/**2**A) serve to clear residual fluid droplets off the lens and away from the deflector assembly **64** to maintain the desired flow path and flow velocity of CO2 established by the deflector assembly **64** continuously across the laparoscopic lens, to maintain an acceptable view.

[0095] In an illustrative embodiment (see FIGS. **5**A and **5**B), the deflector assembly **64** directs the bursts of sterile fluid or air along a plurality of individual diverging channels **76** (three are shown). The diverging channels **76** distribute the bursts of sterile fluid or air in a fanning pattern across the lens of the laparoscope **12**. In the illustrative embodiment, the diverging channels **76** discharge the bursts of sterile fluid or air in a path that is generally ninety-degrees to the path of CO2. This orientation of the sterile fluid path relative to the CO2 path across the lens, optimal for effective lens cleaning, applies to both 0° shaft tips and angled tips (e.g., 30° shaft tips and 45° shaft tips).

II. Use of the View Optimizing Assembly

[0096] The view optimizing assembly is well suited for use as a single-use disposable laparoscopic accessory device to facilitate intra-operative defogging and debris deflection (due to the flow of anhydrous CO2) and cleaning of the lens of a laparoscope **12** (due to burst of sterile fluid, preferably including a "surface-active agent") during minimally invasive surgery, while also maintaining visualization of the surgical site.

[0097] FIGS. **7** to **34** illustrate a representative method including the set up and use of the view optimizing assembly using sterile technique by qualified technicians/operating room personnel.

[0098] The procedure can be incorporated into written instructions for use that accompany the packaging. The instructions can also be supplied separately, e.g., embodied in separate instruction manuals, or in video or audio tapes, CD's, and DVD's. The instructions for use can also be available through an internet web page.

[0099] The instructions can direct the OR set-up to peel open the outer pouches in which the components of the view optimizing assembly (shown in FIG. **7**), and remove the sterile contents on the sterile field. The sheath **14**/manifold **18** assembly is removed, taking care to prevent damage to the walls of the sheath **14** or to its distal end, and also keeping the tubing set **16** and vent device on the sterile field prior to making necessary connections.

[0100] During set up (see FIGS. **8** and **9**), the sheath **14** (with the manifold **18**, which is integrally connected to the sheath **14** during manufacture, called a sheath assembly) can be assembled to the corresponding laparoscope **12**. In this representative example, it is contemplated that the OR team plan to use a 0-degree laparoscope **12** (see FIGS. **8** and **9**) and at least one angled laparoscope **12** (see FIGS. **10** and **11**), e.g., a 30-degree and/or a 45-degree laparoscope **12**. Therefore, during set-up, a sheath assembly for each laparoscope **12** selected for use will be pre-assembled to the corresponding laparoscope **12**.

[0101] As FIGS. **8** and **10** show, while gently pressing the tip of the sheath assembly against one hand or finger-tip, the laparoscope **12** can be inserted down into the sheath **14**. The sheath **14** is sized and configured so that the laparoscope **12** will slide smoothly through the sheath **14**. Insertion continues until the lens and distal rim of the laparoscope **12** seat against the stop at the distal end of the sheath **14**. The laparoscope **12** will "bottom out" inside the sheath **14** against the stop **26**, assuring correct axial alignment of the lens with the deflector assembly **64**.

[0102] If the laparoscope **12** is angled (as shown in FIG. **10**), the corresponding sheath assembly will also include an alignment fork guide **78**. The light post of the scope seats within the alignment fork guide **78**, therefore assuring correct rotational alignment between the angled lens and the deflector assembly **64**.

[0103] The laparoscope **12** (now fully inserted into the sheath **14**) the manifold **18** are supported by hand, a member of the OR set-up team rotates the locking collar **28** on the sheath assembly in the desired direction, e.g., clockwise (see FIGS. **9** and **11**), indicated by an arrow on the locking collar **28**, until a firm stop is felt tactilely (e.g., after approximately one-third (⅓) of a turn). Registration of an alignment mark on the locking collar **28** and an alignment mark on the manifold **18** serves to visually confirm that the laparoscope **12** is secured against axial movement relative to the sheath **14**.

[0104] The insufflator is set up off the sterile field. Once the patient is draped on the sterile field, and it is expected that the end of the output tubing from the insufflator (originating from the insufflator off the sterile field) will brought onto the sterile field. It is also expected that the light cable **30** and the camera cable **32** for the laparoscope **12** will be brought onto the sterile field.

[0105] As FIGS. **12** and **13** generally show, the OR team makes an incision to gain access to the laparoscopic operating site within the body, e.g., into the abdominal cavity through the abdominal wall. A first trocar with a stopcock valve (which may take the form of an optical trocar) is inserted through the incision. Alternatively, according to physician preference, the first trocar can be pushed through abdominal wall with only a skin incision. The obturator (the sharp inner insert of the trocar) is removed from the first trocar once it is in position.

[0106] The insufflator line of the tubing set **16** on the sterile field is connected to the output tubing of the insufflator circuit on the sterile field. The first branch **46** of the tubing set **16** on the sterile field, originating at the Y-connector **44**, is coupled to the stopcock valve of the first trocar (see FIG. **13**). The stopcock valve is opened, and the insufflator is turned on. CO2 output of the insufflation circuit inflates the abdomen through the first trocar.

[0107] During this time (see FIGS. **8** and **10**), the second branch **48** of the tubing set **16** on the sterile field, also originating at the Y-connector **44**, and the quick exchange coupler **22** integrally attached to it can remain on the sterile field in a free, unconnected condition as the insufflator supplies CO2 through the first branch **46**. The one-way check valve in the quick exchange coupler **22** serves to block flow of CO2 through the second branch **48**, even as the insufflator supplies CO2 through the first branch **46**. The entire CO2 pressure of the insufflator circuit is, at the present, delivered to the first trocar through the first branch **46**.

[0108] The first laparoscope **12** selected for use, which has been pre-inserted into the sheath **14** by the OR set-up team as just described, is handed to personnel at the OR table at the appropriate time. On the sterile field, personnel at the OR table connect the light cable **30** and the camera cable **32** to the laparoscope **12** (see FIG. **14**). On the sterile field, personnel at the OR table now connect the quick exchange coupler **22** of the tubing set **16** to the quick exchange coupling **20** of the manifold **18** (see FIG. **15**). The one way valve opens, and a small portion of the output of the insufflator circuit is routed by the second branch **48** through the manifold **18** into to the sheath **14**.

[0109] The laparoscope/sheath assembly is then placed as an integrated unit through the first trocar to get an initial view of the abdominal cavity (see FIG. **16**). Due to the technical features of the deflector assembly **64**, CO2 flows over the lens, eliminating fogging and also deflecting away debris. If present, the pump (e.g., the 20 cc syringe) filled with sterile fluid (preferably with a "surface-active agent") and connected to the tubing luer-lock, can be operated by personnel at the OR table to flush sterile fluid through the deflector assembly **64** of the sheath **14**. The deflector assembly **64** directs the fluid bursts across the lens in a path generally 90-degrees offset from the CO2 path. Once this is done, the bulb on the tubing set **16** can be pumped several times introduce bursts of air to clear droplets off the lens and away from the tip deflector, to maintain to the continuous directed flow of CO2 across the laparoscopic lens.

[0110] Once a satisfactory view is achieved, additional ancillary trocars with stopcock valves, e.g. three to four, or more, are also placed through incisions to provide access for other instruments (see FIG. **17**). The trocar vent device **24** provided with the view optimizing assembly is desirably placed in the stopcock of one of the ancillary trocars, and the stopcock valve is opened (see FIG. **18**).

[0111] As FIG. **19** shows, a member of the OR team preferable decouples the main insufflation line (the first branch **46** tubing of the Y-connector **44** of the tubing set **16**) from the first trocar to the stopcock valve of another available trocar on the sterile field (except the trocar to which the vent device **24** is coupled). This other trocar then serves as the main insufflation trocar, separate from the first trocar, which now serves as the main visualization trocar. In this way, the main CO2 insufflation provided for the duration of the surgery is provided by an insufflation trocar that is also not the visualization trocar. The controlled leak of insufflation pressure that the vent device **24** provides creates a pressure gradient within the pneumo-peritoneum that helps maintain a generally continuous flow of CO2 from the deflector assembly **64** across the lens, despite periodic cycling of the insufflator. Lumens **40** and **42** in the sheath **14** (previously described) can also serve as additional passive vents, to leak insufflation pressure out through the manifold **18**.

[0112] The surgery proceeds. The deflector assembly **64** provides intra-operative defogging and cleaning of the laparoscope lens during the minimally invasive surgery, while maintaining visualization of the surgical site. The sterile fluid flush mechanism can be used, as desired, if required to augment visualization by flushing the lens. If this is done, the bulb on the tubing set **16** should be pumped several times to clear droplets off the lens and away from the deflector assembly **64** to maintain the CO2 curtain across the lens.

[0113] During the surgery, the OR team can decide, e.g., that one portion of the procedure is better visualized with a different angle scope. The quick exchange features of the coupler of the tubing set **16** and the coupling of the manifold **18**, greatly facilitate the exchange of one laparoscope **12** for another with minimal interruption of the surgical procedure and without compromising the sterile field.

[0114] To exchange one laparoscope **12** for another, a member of the OR team withdraws the laparoscope/sheath assembly an integrated unit from the visualization trocar (see FIG. **20**).). A member of the OR team disconnects the laparoscope **12** from the light cable **30** and camera cable **32** (see FIG. **21**). A member of the OR team uncouples the quick exchange coupler **22** from the quick exchange coupling **20**, freeing the laparoscope/sheath assembly from the tubing set **16** (see FIG. **22**). The disconnected laparoscope/sheath assembly is handed as an integrated unit to a member of the OR team, e.g., a scrub nurse (see FIG. **23**). There is no reason to remove the sheath **14** from the matching laparoscope **12** at this time. This can be accomplished later, after the surgery is all done.

[0115] The laparoscope/sheath assembly that includes the second laparoscope **12** that is to be used, has already been assembled into an integrated unit, as previously described. This pre-assembled unit is handed to a member of the OR team (see FIG. **24**). A member of the OR team connects the second laparoscope **12** to the light cable **30** and camera cable **32** (see FIG. **25**). A member of the OR team couples the quick exchange coupler **22** of the tubing set **16** to the quick exchange coupling **20**, connecting the second laparoscope/sheath assembly in flow communication with the tubing set **16** (see FIG. **26**), completing the quick exchange. The second laparoscope/sheath assembly is inserted into the visualization trocar (see FIG. **27**).

[0116] The quick connect feature functions with a manifold **18** associated with every sheath **14**. The tubing set **16** on the sterile field can be rapidly disconnected, but need not, and desirably is not, exchanged with another tubing set **16**. During a given surgical procedure, the same tubing set **16** serves every laparoscope/sheath assembly used (unneeded tubing sets **16** that came with the additional sheaths can be simply discarded).

[0117] The surgery proceeds using the second laparoscope/sheath assembly.

[0118] Additional quick exchanges of laparoscopes can be accomplished as surgery proceeds in the manner just described.

[0119] Once surgery is completed, all instruments, including the laparoscope/sheath assembly in use are removed from the visualization trocar (see FIG. **28**). A member of the OR team disconnects the laparoscope **12** from the light cable **30** and camera cable **32** (see FIG. **29**). A member of the OR team uncouples the quick exchange coupler **22** from the quick exchange coupling **20**, freeing the laparoscope/sheath assembly from the tubing set **16**. The laparoscope/sheath assembly is handed to a member of the OR team (see FIG. **31**), and placed alongside previously used laparoscope/sheath assemblies (see FIG. **32**).

[0120] Access sites are closed. The insufflator is shut off. The tubing set **16** is disconnected from the insufflator circuit. The lock collars on the manifolds **18** are loosened, and laparoscopes are withdrawn from the sheaths for reuse (FIG. **33**). The sheaths and tubing set **16** are disposed of (FIG. **34**).

[0121] Some trocars are called "optical trocars" that have a lumen within the obturator, that is within the trocar. If the lens of a laparoscope **12** is first placed into the center of an optical trocar to guide the first trocar insertion, then the sheath **14** cannot be present on the laparoscope **12**, as the combination cannot fit through the lumen of the obturator. In this situation, the laparoscope **12** is used without a sheath **14** is used to place the first trocar. The laparoscope **12** is then inserted through the sheath **14**, and connection of the tubing set **16** occurs in the manner just described. With the obturator removed from the trocar, the laparoscope/sheath assembly is placed through the first trocar in the manner described.

III. Self-Contained Supply and Processing of Air for the Deflector Assembly

[0122] FIG. **35**A shows a view optimizing assembly **10** for use in association with a state of the art laparoscope **12**, like that shown in FIGS. **1**A/**1**B (blunt tip) and FIG. **2**A/**2**B (angle shaft tip). In many respects, the assembly **10** shown in FIG. **35**A includes components like that shown in FIGS. **1**A/**1**B and **2**A/**2**B, and common reference numbers are likewise assigned to these common components.

[0123] As shown in FIG. **35**A, the view optimization assembly **10** includes a sheath **14** and a manifold **18** that is assembled to the sheath **14** and that includes a quick exchange coupling **20**; a tubing set **16** which includes a quick exchange coupler **22** that mates with the quick exchange coupling **20** on the manifold **18**; and (optionally) a vent device **24**. The sheath **14** is sized and configured to receive a laparoscope **12** having a prescribed tip angle, length, and diameter.

[0124] In FIGS. **1**A/**1**B and **2**A/**2**B, the tubing set **16** includes lengths of flexible medical grade tubing with a coupler **44** that connected to an existing CO2 insufflation circuit. As previously described, in this arrangement, the deflector assembly **64** is sized and configured to direct the small portion of the CO2 from the insufflation circuit in a prescribed flow path and flow velocity across the laparoscopic lens. In this arrangement, as previously explained, a second branch **48** of the tubing set **16** diverts a small portion of the CO2 output (e.g., 20% or less) of the insufflation circuit to the quick exchange coupler **22**. When coupled to the manifold **18**, the diverted portion of the CO2 output is conveyed through lumens in the sheath **14** to a deflector assembly **64** at the distal end of the sheath **14** (see FIGS. **5**A(**1**) and **5**A(**2**) for a blunt shaft tip and FIGS. **5**B(**1**) and **5**B(**2**) for an angled shaft tip). As previously described, conventional insufflators are adapted to cycle on and off to maintain a preset and suitable pressure within the patient's body cavity. Therefore, when the insufflation circuit is cycled off, the diverted portion of the CO2 output conveyed to the deflector assembly **64** is interrupted.

[0125] The embodiment shown in FIG. **35**A differs from the previously described embodiment in that the second branch of the tubing set **16** is not coupled to the insufflation circuit. Rather, the tubing set **16** is coupled to a separate, dedicated air supply trocar **98** (with stop cock valve). The trocar **98** is placed through an incision, and when the stop cock valve is opened, provides communication with the insufflated CO2 environment present in the operating cavity. With the obturator removed, the trocar **98** may also serve to provide additional access for an instrument into the operating cavity.

[0126] In this arrangement, the second branch **48** includes an in-line air processing or conveying assembly **100** (see also FIG. **35***b*) contained within a housing coupled in air flow communication with the tubing of the second branch **48**. The in-line air processing or conveying assembly **100** serves to draw air from the insufflated CO2 environment present in the operating cavity through the trocar **98**, for delivery by the sheath **14** continuously through the deflector assembly **64**, independent of operation of the insufflation circuit itself. Even when the insufflation circuit is cycled off, the air processing or conveying assembly **100** operates to draw air from the insufflated CO2 environment present in the operating cavity, to the deflector assembly **64** of the sheath **14**. Further, the in-line air processing or conveying assembly **100** can also serve to beneficially process or treat the air drawn from the insufflated CO2 environment present in the operating cavity, after it is removed from the operating cavity and before it is conducted by the deflector assembly **64**, to remove, e.g., smoke, particulates, aerosolized pathogens, and water vapor from the airflow before it is conducted by deflector assembly **64** across the lens of the laparoscope.

[0127] The air processing or conveying assembly **100** can be variously sized, configured, and constructed. In the embodiment exemplified in FIGS. **35**A and **35**B, the air processing or conveying assembly **100** includes, self-contained within the housing, a driven air moving component **102**. In the illustrated embodiment, the driven air moving component **100** comprises a powered turbine or a powered blower or fan **102**. The turbine, blower or fan **102** is powered to rotate and establishing a flow of air from the insufflated CO2 environment present in the operating cavity, through a lumen in the wall of the trocar **98**, and into the second branch **48**. Desirably, the turbine, blower, or fan **102** is sized and configured to deliver airflow through the deflector assembly **64** at a rate of at least 1.0 l/min.

[0128] The air processing or conveying assembly **100** can further include, self-contained within the housing in the path of airflow established by the turbine, blower, or fan **102**, one or more elements **104** that trap smoke, particulates, aerosolized pathogens, odors, chemical toxins, and other undesired agents from a physiologic airflow. For example, the element **104** can include a filter media. The filter media can be sized and configured to beneficially remove, e.g., airborne particles, smoke, pathogens, and toxins from the airflow.

[0129] The filter media **104** can comprise, e.g., at least one layer of an ultra-low particulate air (ULPA) filtration material and/or a high efficiency particular air (HEPA) filtration material to remove a high percentage (e.g., 99+%) of airborne particles from the airflow. Such filtration materials can comprise, e.g., an array of randomly arranged microfibers—e.g., ULPA grade hydrophobic glass, PTFE, or polypropylene microfibers—which are sized and configured to remove small sized pollutants and particles (e.g., as small as 0.1 micron (aerosolized) particles), by interception, impaction, and/or diffusion in association with the media.

[0130] The filter media **104** can comprise, in addition to the ULPA and/or HEPA filtration material, at least one layer of a material that absorbs smoke, odors and chemical toxins from the airflow. The layer can be formed by or incorporate, e.g., carbon or charcoal based material, or a diatomaceous earth material, or other odor removing or reducing agents.

[0131] The air processing or conveying assembly **100** can further include, self-contained within the housing in the flow path established by the turbine, blower, or fan **102**, a dehumidifying unit **106** for removing adsorbing water vapor from the airflow. The dehumidifying unit **106** can be variously sized and configured. The dehumidifying unit **106** can comprise, e.g., one or more desiccant materials having a high affinity for adsorbing water vapor, such as silica gel. The desiccant material can be sized and configured in a "rotor" form, comprising alternate layers of flat and corrugated sheets impregnated with the active component (desiccant) to form a large number of axial air channels running parallel through the rotor structure. As air passes through these channels, moisture is transferred between the air and the desiccant.

[0132] Alternatively, the dehumidifying unit **106** can comprise an electronic dehumidifier, using, e.g., a peltier heat pump to generate a cool surface for condensing the water vapor from the airflow. Electronic dehumidifiers have the benefit of being very quiet when in use, and make possible very small dehumidifying units **106**.

[0133] Desirably, the dehumidifying unit **106** provides a dehumidified airflow having a moisture content of 25 parts per million by volume or less.

[0134] The air processing or conveying assembly **100** desirably includes, self-contained within the housing, a source of power **108** for the driven turbine, blower or fan **102** and other components requiring energy to function, e.g., the electronic dehumidifying unit **106** (if present). The source of energy **108** may comprise, e.g., a battery which is rechargeable, or a disposable battery or batteries which are replaced, or a capacitor.

[0135] In the arrangement shown in FIG. **35**A, the second branch **48** of the tubing set **16** delivers air processed by the air processing or conveying assembly **100** to the quick exchange coupler **22**. When coupled to the manifold **18**, the air processed by the air processing or conveying assembly **100** is continuously conveyed through lumens in the sheath **14** to a deflector assembly **64** at the distal end of the sheath **14**. The deflector assembly **64** is sized and configured to direct the air processed by the air processing or conveying assembly **100** in a prescribed flow path and flow velocity continuously across the laparoscopic lens, in the manner previously described. The desired flow path and flow velocity of air processed by the air processing or conveying assembly **100** established by the deflector assembly **64** across the laparoscopic lens creates a continuous "wind shear," which in this embodiment is independent of operation of the insufflation circuit. The wind shear path of air processed by the air processing or conveying assembly **100** (being dehumidified) prevents laparoscopic lens fogging. The wind shear path or air processed by the air processing or conveying assembly **100** (being also treated to remove smoke and other debris) also desirably serves to deflect smoke and surgical debris away from the laparoscopic lens during surgery, in the manner previously described.

[0136] As further shown in FIG. **35**A, and as previously described, the assembly **10** can include a pump **72** (e.g., the 20 cc syringe) filled with sterile fluid (preferably with a "surface-active agent" or surfactant **112**, as FIG. **38** further shows). As previously described, the pump **72** can be operated by personnel at the OR table to flush sterile fluid through the deflector assembly **64** of the sheath **14**. The deflector assembly **64** directs the fluid bursts across the lens in a path generally 90-degrees offset from the airflow path, as previously described.

[0137] In this arrangement, the tubing set **16** can also include an in-line bulb **110** carried in an upstream flow direction from the air processing or conveying assembly **100**. The tubing set **16** also includes, in an upstream flow direction from the bulb **110**, a one-way valve **114** that prevents fluid flow from the bulb **110** toward the air processing or conveying assembly **100**. The bulb **110** can be pumped several times introduce bursts of air processed by the air processing or conveying assembly **100** through the deflector assembly **64**, to clear liquid droplets off the lens and away from the deflector assembly **64**, to maintain to the continuous directed flow of air processed by the air processing assembly **100** across the laparoscopic lens.

[0138] The air processing or conveying assembly **100** can be incorporated into a view optimizing assembly **10** in various other ways to provide a treated airflow continuously to the deflector assembly **64**, independent of operation of an insufflation circuit.

[0139] For example, as shown in FIG. **36**, the air processing or conveying assembly **100** can be an integrated component of the sheath **14** itself. In this arrangement, the sheath-integrated air processing assembly **100** is supplied by air from the dedicated trocar **98** communicating with the insufflated CO2 environment of the operating cavity, in the manner previously described. In this arrangement, the driven turbine, blower or fan **102**, and optionally the filter media **104** and/or the dehumidifying unit **106** self-contained within the sheath-integrated air processing or conveying assembly **100**, conduct and treat air drawn from the insufflated CO2 environment of the operating cavity for direct conveyance in treated and dehumidified form continuously to the deflector assembly **64**.

[0140] In this arrangement, as shown in FIG. **36**, the in-line bulb **110** and one-way valve **114** assembly used to clear from the lens droplets of sterile fluid delivered by the pump **72**, desirably communicates in parallel with the insufflation circuit, and not in-line with the air processing or conveying assembly **100**. In this arrangement, the bulb **110** is squeezed to pump bursts of CO2 from the insufflation circuit, when desired, to clear the liquid droplets off the lens and away from the deflector assembly **64**.

[0141] In another illustrative embodiment, as shown in FIG. **37**, the air processing or conveying assembly **100** can be an integrated component of the trocar **98** itself. In this arrangement, the driven turbine, blower, or fan **102**, and optionally the filter media **104** and/or the dehumidifying unit **106** self-contained within the trocar-integrated air processing or conveying assembly **100**, conduct and treat air from the trocar **98** for conveyance in treated and dehumidified form continuously to the deflector assembly **64**. In this arrangement, as shown in FIG. **37**, the in-line bulb **110** and one-way valve **114** assembly used to clear from the lens droplets of sterile fluid delivered by the pump **72** desirably communicates in-line with the trocar-integrated air processing or conveying assembly **100**. In use, the bulb **110** is squeezed to pump bursts of air processed by the air processing assembly **100**, when desired, to clear the liquid droplets off the lens and away from the deflector assembly **64**.

[0142] The invention therefore makes possible an assembly comprising a self-contained air conveying component coupled to a sheath that is sized and configured to receive a laparoscope including a laparoscopic lens providing visualization of an operating cavity. The air conveying component comprises an air flow path having an inlet sized and configured for communication with a source of CO2 and an outlet. The air conveying component includes a driven air moving component in communication with the air flow path sized and configured to continuously convey CO2 from the source through the air flow path to the outlet. The sheath coupled to the air conveying component can include a lumen communicating with the outlet of the air conveying mechanism for passing CO2 continuously conveyed by the driven air coving component across the laparoscopic lens to maintain visualization of the operating cavity. The sheath and self-contained air conveying component can comprise an integrated assembly.

[0143] The invention also makes possible an assembly comprising a laparoscopic access device for accessing an operating cavity insufflated with CO2 by operation of an insufflator circuit coupled to a self-contained air conveying component. The air conveying component comprises an air flow path having an inlet in fluid communication with operating cavity and an outlet sized and configured for fluid communication with an external instrument. The air conveying component includes an air moving component in communication with the air flow path. The air conveying component is sized and configured to be continuously driven independent of the insufflator circuit to convey CO2 from the operating cavity continuously through the air flow path to the external instrument. The external instrument can itself comprise a sheath sized and configured to receive a laparoscope including a laparoscopic lens providing visualization of the operating. In this arrangement, the sheath includes a lumen communicating with the outlet of the air conveying component for passing CO2 continuously conveyed by the driven air coving component across the laparoscopic lens to maintain visualization of the operating cavity.

What is claimed is:

1. A system comprising a sheath sized and configured to receive a laparoscope including a laparoscopic lens providing visualization of an operating cavity insufflated with CO2 through operation of an insufflator circuit, the sheath including a lumen for passing air from a source across the laparoscopic lens to maintain visualization of the operating cavity, and the source comprising an air conveying assembly including a housing, an air flow path self-contained within the housing comprising an inlet sized and configured for communication with the operating cavity and an outlet sized and configured for communication with the lumen of the sheath, and an air moving component self-contained within the housing in communication with the air flow path and powered independent of the insufflator circuit to convey CO2 from the operating cavity through the air flow path for passage across the laparoscopic lens, to thereby maintain visualization of the operating cavity independent of operation of the insufflator circuit.

2. A system according to claim **1** wherein the air conveying assembly further includes a source of power self-contained within the housing for powering the air moving component.

3. A system according to claim **2** wherein the source of power comprises a battery.

4. A system according to claim **1** wherein the air moving component comprises a fan.

5. A system according to claim **1** wherein the air conveying assembly includes an air treatment component self-contained within the housing in communication with the air flow path that removes at least one undesired agent the air flow path.

6. A system according to claim **5** wherein the undesired agent comprises one or more of smoke, particulates, pathogens, odors, and toxins.

7. A system according to claim **5** wherein the air treatment component comprises a filter media.

8. A system according to claim **7** wherein the filter media includes an ultra-low particulate air filtration media.

9. A system according to claim **7** wherein the filter media includes a high efficient particulate air filtration media.

10. A system according to claim **7** wherein the filter media includes a material that absorbs at least one of smoke, odors, and toxins.

11. A system according to claim **1** wherein the air conveying assembly further includes a dehumidifying component self-contained within the housing in communication with the air flow path that removes water vapor from the air flow path.

12. A system according to claim **11** wherein the dehumidifying component comprises one or more desiccant materials.

13. A system according to claim **11** wherein the dehumidifying component comprises an electronic dehumidifier.

14. A system according to claim **13** wherein the air conveying assembly further includes a source of power self-contained within the housing for powering the electronic dehumidifier.

15. A system according to claim **1** wherein the inlet of the air flow path communicates with an air supply trocar.

16. A system according to claim **1** wherein the air conveying assembly is an integrated component of an air supply trocar.

17. A system according to claim **1** wherein the inlet of the air flow path communicates with tubing coupled to an air supply trocar.

18. A system according to claim **1** wherein the outlet of the air flow path communicates with tubing coupled to the lumen of the sheath.

19. A system according to claim **1** wherein the air conveying assembly is an integrated component of the sheath.

20. A system according to claim **1** wherein the inlet and outlet of the air flow path communicate with tubing coupled to an air supply trocar and the lumen of the sheath, respectively.

* * * * *

专利名称(译)	用于在手术镜的使用期间优化和维持手术视野的可视化的系统和方法		
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[标]申请(专利权)人(译)	投票WAYNE大号 CRISAFULLI CAROLINE中号 德劳奇GREGORY P		
申请(专利权)人(译)	民意调查显示，WAYNE L. CRISAFULLI，CAROLINE M. 德劳奇，GREGORY P.		
[标]发明人	POLL WAYNE L CRISAFULLI CAROLINE M DRACH GREGORY P		
发明人	POLL, WAYNE, L. CRISAFULLI, CAROLINE, M. DRACH, GREGORY, P.		
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外部链接	Espacenet USPTO		

摘要(译)

系统和方法将独立的空气处理或输送部件连接到护套，护套的尺寸和构造设计成接收包括腹腔镜镜片的腹腔镜，腹腔镜镜片提供操作腔的可视化。空气处理或输送部件包括空气流动路径，该空气流动路径具有入口，该入口的尺寸和构造适于与CO 2源和出口连通。空气处理或输送部件包括与空气流动路径连通的从动空气移动部件，该空气流动路径的尺寸和构造设计成将来自源的CO 2通过空气流动路径连续地输送到出口。连接到空气处理或输送部件的护套可包括与空气处理或输送机构的出口连通的内腔，用于使由驱动空气移动部件连续输送的CO2通过腹腔镜透镜，以保持操作腔的可视化。护套和独立的空气处理或输送部件可包括集成组件。CO 2源可以包括腹腔镜进入装置，用于通过吹入器回路的操作进入充满CO 2的操作腔。驱动的空气移动部件通过腹腔镜镜片连续地从操作腔输送CO 2，以保持操作腔的可视化，而与吹气电路的操作无关。