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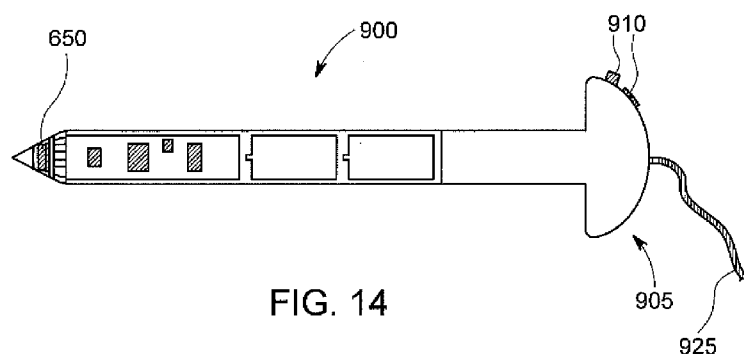
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(54) Title: OPTICAL ENTRY TROCAR CAMERA



(57) Abstract: An optical trocar having a built-in or separately inserted camera module is used to assist with cannula insertion prior to laparoscopic procedures. The camera module has one or more optical sensors that can deliver real-time images out the front of the optical trocar during insertion either wirelessly or via a wired connection. Three dimensional, near field and far field views are possible. Devices for insertion of the camera module into an optical trocar are also disclosed as are optical trocars with self-cleaning capabilities.



Title: Optical Entry Trocar Camera**Inventors: Cornell Wright, III, Kevin H. Lipkin and Eric C. Close****Cross-Reference to Related Applications**

[0001] The present international application claims the benefit of U.S. Provisional Patent Application No. 62/676,887 filed on May 25, 2018 and U.S. Provisional Patent Application No. 62/741,445 filed on October 4, 2018, which are each hereby incorporated by reference in their entireties. In cases where an application incorporated by reference and the present application conflict, the present application controls.

Field of the Invention

[0002] The present invention relates generally to apparatus, methods, and systems to assist with surgical procedures. More specifically, the present invention relates to a single use surgical instrument that will reduce complications associated with the initial entry.

Background of the Invention

[0003] In laparoscopic surgery, surgeons create a small passageway to an operative site within a patient's body. to create a passageway to an operative site. In order to create this passageway, a trocar may be inserted into an opening in a patient's body wall by use of an obturator. When properly positioned, the obturator portion of the trocar is removed while retaining an exterior cannula in place within the body wall to provide access for other surgical instruments to be inserted through the cannula and manipulated inside the body cavity to perform the desired surgical procedures. The initial entry of the trocar into the patient's body, however, is a significant source of unintended injury.

[0004] One currently preferred method of trocar insertion is called optical entry. Using this method, a laparoscope is inserted into the obturator of an optical trocar during insertion. The

surgeon usually makes a small incision and inserts the obturator into the incision and begins to twist the obturator while advancing it into the patient's body. The presence of the laparoscope allows for direct visualization of the layers of the abdominal wall that the surgeon must either cut or push through as the trocar is gradually inserted into the patient. In this way, the surgeon can visually observe exactly when the operative area has been reached. This method of gaining access to the surgical site helps to reduce the frequency with which complications such as perforations of the bowel or other organs occur because the surgeon can see inside the patient's body during entry.

[0005] As illustrated in Figs. 1a and 1b, a rigid 0-degree laparoscope **10** having a cable **20**, with fiber optics and video capabilities, is inserted into an optical trocar **30**, as demonstrated by the arrow in Fig. 1b, having an obturator **40** to assist with visibility when the trocar **30** is inserted into the abdomen of the patient. The tip of the obturator **40** is transparent and typically conical or pyramid-like in shape to allow the laparoscope **10** to provide imagery as the trocar is placed.

[0006] As may be appreciated, having the lengthy laparoscope inserted into the trocar makes for an unwieldy device to be used in a delicate procedure. The long and fragile laparoscope inserted into the smaller trocar is awkward for the surgeon to handle while trying not to push too hard or too far into the patient. This problem is magnified in the case of surgeons of smaller stature or who have smaller hands, as well as with patients who are obese. Additional difficulties include distortion of the video images taken through the conical, transparent tip of the obturator, internal reflections from the obturator tip creating glare in the video feed, and the need to clean and sterilize the laparoscopes, which are often only used for the entry procedure. There are also additional steps involved with the insertion, removal and swap out of the scope, which add time and cost to each surgical procedure. Because operating room time is very valuable, removing unnecessary steps, unreliable equipment, equipment with high capital cost, or equipment that takes up unnecessary real estate in a crowded operating room, saves time and money for the hospital or other treatment facility.

[0007] What is needed, then, is a way to retain the benefits of the use of a laparoscope while reducing the additional risk to the patient and additional expense for the procedure that is created by the use of a laparoscope during trocar insertion.

Brief Description of the Drawings

[0008] The accompanying drawings, which are incorporated in and form a part of the specification, illustrate the embodiments of the invention and together with the written description serve to explain the principles, characteristics, and features of the invention. In the drawings:

[0009] Figure 1a is an illustration of a prior art optical trocar being used with a laparoscope by a surgeon.

[0010] Figure 1b is a prior art trocar.

[0011] Figure 2 is a schematic illustration of a camera module consistent with embodiments of the present invention disclosed herein.

[0012] Figure 3 is an isolated partial perspective view of an obturator tip consistent with an embodiment of the present invention.

[0013] Figure 4 is a mocked-up illustration of a camera module with a sizing sleeve consistent with an embodiment of the present invention.

[0014] Figure 5 is a plan illustration of the interior component of an embodiment of a camera module.

[0015] Figure 6 is a partial plan illustration of a camera module with two cameras.

[0016] Figure 7 is a partial plan illustration of an optical trocar tip.

[0017] Figures 8a-c are a graphical illustration of a process of calibrating a camera module.

[0018] Figure 9 is an illustration of a calibration and glint removal process.

[0019] Figure 10 is an illustration of an insertion device for a camera module.

[0020] Figure 11 is an illustration of a method of rotating the camera module inside the obturator.

[0021] Figure 12 is an illustration of a breakable insertion device for enforcing single use.

[0022] Figure 13a is a perspective view of a camera module with channels to allow gas escape.

[0023] Figure 13b is a cross sectional view of a camera module along plane A-A with channels to allow gas to escape.

[0024] Figure 14 is an illustration of an imaging obturator consistent with an embodiment of the invention.

[0025] Figure 15 is an illustration of an imaging obturator with a side-facing camera.

[0026] Figures 16a-c are illustrations of a distal end of a trocar demonstrating a tip-cleaning wiper.

[0027] Figures 17a-b are illustrations of trocar with an optical tip cleaner installed.

[0028] Figures 18a-b are illustrations of an irrigated cleaning system for an optical tip.

[0029] Figures 19a-b are illustrations of an obturator that splits open to allow a trocar camera to extend through the tip.

Detailed Description of the Invention

[0030] In the following description, for purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of example embodiments. It will be evident to one skilled in the art, however, that embodiments can be practiced without these specific details.

[0031] This document features various embodiments of a camera module that can be employed in a number of ways to assist a surgeon with the installation of a trocar into a patient in advance of a laparoscopic procedure. By way of non-limiting example, the camera module of the present invention can be shaped to be inserted into an optical trocar by surgical staff at or near the time of use, or it can be pre-installed in an optical trocar at the time of manufacture. Either way, there are many features and related aspects disclosed herein, of which one or a plurality, or all features and related aspects may be used in any particular implementation.

[0032] Notwithstanding that there are a variety of implementations, with reference to FIGS. 2 and 3, a first particular embodiment of a camera module **100** for use in an optical trocar **30** is illustrated. In this embodiment, the camera module **100** is cylindrical in shape and is sized to match the inside diameter of an obturator **35** of an optical trocar **30**. Traditionally, this inside cavity was shaped to receive a distal portion of a laparoscope to enable visualization of internal tissues and the present invention takes advantage of this form factor to provide a camera module **100** that takes the laparoscope's place.

[0033] Certain embodiments of the camera module **100** may be between 5 and 10 millimeters in diameter and may have a length of approximately 50 mm; however, the length may vary widely depending on the intended use. Traditional laparoscopic surgery employed trocars having obturators with internal diameters of five and ten millimeters; whereas some newer technologies, such as some robotically assisted procedures, are using obturators with internal diameters as small as three and as large as eight and one half millimeters. All of these diameters are intended to be within the ambit of the present disclosure.

[0034] In certain embodiments, such as in Fig. 4, a small diameter camera module **100** may be used in a larger diameter obturator space by employing a sleeve **105**. Other non-limiting examples include the use of an inflatable balloon to fill any space around a camera module **100** that is smaller in diameter than the internal cavity diameter. Another embodiment employs compliant spring-loaded legs extending from the outside of module **100** and wedging it in place upon insertion. The diameter of the camera module **100** may also be tapered so that it can fit multiple obturators, but at different insertion depths. The trocar insertion module **100** may also be installed with a gap-filling adhesive like an epoxy.

[0035] With reference to Fig. 5, a non-limiting example of the components of a camera module **100** is illustrated and includes a power source **110**, a camera **120** placed at or near the distal end **160**, lighting elements **140**, also generally located near the distal end **160**, and support circuitry **130**. While this example includes a power supply, other embodiments may instead include a port for connecting to an external AC or DC power supply. Further, while this example does not include user controls on the proximal end **150**, it is certainly within the scope of the present invention to include controls for manipulating power status, light status, and

features related to the camera, such as calibration, zoom or focus that will be discussed in further detail.

[0036] As used herein, it is intended that the term “camera,” such as camera **120**, refers to any of a variety of imaging sensors such as charge-coupled device (CCD) sensors, CMOS pixel sensors, or hybrid devices. Lighting elements **140** at the distal end **160** of the camera module **100** include low power usage, low heat generating light sources such as LED lights for example. In certain embodiments, a proximal light source may supply illumination to the distal end of the camera module **100** by way of a fiber optic light guide. Support circuitry **130** is intended to include connective wires or printed electrical pathways that connect the power source **110** to the camera **120** and lighting elements **140**.

[0037] In embodiments, support circuitry **130** may be in the form of a printed circuit board (PCB) and may also include a wireless radio for sending real-time video from the camera to an external monitor. Alternatively, it is also within the scope of the invention to have an adapter that can be included at the proximal end **150** for wired connection electronically connecting the support circuitry **130** to an external monitor or image processing module. In some embodiments, image fiber may enable transmission of an image to a camera in the case of a bundled fiber lens, or from a camera to a processor or external monitor. In yet another embodiment, rod lenses can be employed in a similar manner as is used in many laparoscopes, to transmit an image from the camera or lens to an eyepiece at the proximal end **150** or to an eyepiece adjacent to the obturator in use where it may be viewable by the user via a surgical camera head.

[0038] In addition to a traditional display of images or a video feed, additional embodiments include status information overlaid on the display, a three-dimensional image is presented, multiple displays are used, the image is resampled to provide multiple available resolutions for the display, or the display from the camera module **100** can be sent to a conventional vision cart. In still other embodiments, the display device may be integrated into the obturator or trocar or a consumer display such as a tablet device may be configured to receive the display output. In embodiments, AR or VR goggles may be used to present the display to the surgeon. In another non-limiting example, especially related to robotic surgery, the device may be

integrated with other devices in the OR, for example, displaying the image from the camera module **100** on said other devices, instead of or in addition to other displays discussed herein.

[0039] Fig. 6 illustrates a cut-away view of another alternative embodiment of a distal end **160** of a camera module **100** that is consistent with the teachings of the present invention. In this embodiment, two offset cameras **120** are used, which can create a three-dimensional image that can be used by the surgical team to ensure proper placement of a trocar.

Alternatively, two cameras can be used wherein the first camera is a traditional narrow angle lens, similar to what might be provided by a traditional laparoscope and the second camera could be a wide-angle lens. The user would then have the option of narrow or wide-angle views, depending on the application. In embodiments, of course, the cameras can also employ optical zoom, such as a consumer point and shoot camera does, or a digital zoom that employs software to stretch or crop an image. Software can also be used to crop a portion of the full field, if desired.

[0040] In certain embodiments, software can also be used to correct an image, such as in de-warping an image collected through a curved optical trocar tip, Fig. 7 is a non-limiting example of a camera **120** that must collect images through an obturator tip **170** having a transparent, curved surface.

[0041] Fig. 8 illustrates a calibration process for use with the camera module **100** of the present invention. In certain embodiments, handshake targets **200** contain a machine readable optical code (such as a barcode or QR code) to allow the camera module **100** (in wireless embodiments) to establish communication with a monitor **238** or computer system **240** and for event capture as well as event referencing. In wired embodiments, calibration still occurs, but establishing a communication link occurs in a standard way that is known to those of skill in the art. Once communication is established, the camera module **100** can be focused on a calibration target **210** in order to ensure the camera **140** is properly calibrated. As may be expected, certain embodiments of the computer system will include additional processing components for purposes of communicating either in wired or wireless mode, de-encrypting the wireless video, manipulating signals received from the camera module **100** and displaying the images received for the surgical team to use in ensuring appropriate insertion of a trocar.

[0042] In certain other embodiments, when the camera module **100** is installed in the obturator **40** and pointed at a calibration card **205** containing a calibration pattern **210**, software is employed that calibrates and corrects the images that are captured through the optical tip **40** of the obturator **35**. In certain non-limiting examples, a calibration target **220**, in this case a checkerboard design, is used. The user points the camera **140** in the camera module **100** through the optical tip **40** of the obturator **35** at the calibration target **220** and, upon activation of a calibration software routine housed in memory of the computer system **240**, correction parameters are determined that will remove any distortion from the image or feed. Other methods of calibration of cameras using calibration cards are known to those of skill in the art.

[0043] The acquired digital images or video feed may be enhanced or modified for ease of viewing or interpretation, such as through the use of specialized software as is known in the art. Typical types of modification include automatically de-warping the images or video feed to correct any distortion that is created by the optical tip. While some amount of warping is acceptable for optical entry because the layers of tissue are still readily visible as the obturator passes by them, the warping and glare on the resulting image makes it impossible to visualize any structures once the tip enters the abdominal cavity. The present invention allows for both the near field visualization of the tissue passing the obturator tip as well as the far field visualization of abdominal structure and direct visualization of placement of the working trocars. Glare is reduced by controlling illumination.

[0044] In certain embodiments, the camera is integrated into the obturator, thus allowing for full control of the optical stack. This, in turn, allows for control over image warping and for calibration and software/FPGA-based dewarping of the image, for example by visualizing a checkerboard target and applying a software transformation known to those skilled in the art such that the image rendered on the display is a true checkerboard with minimal warping. From this, the physician is able to visualize abdominal structure and placement of the working trocars without having to remove the obturator from the cannula or insert a traditional laparoscope.

[0045] In still other embodiments, software may enable glint removal. Fig. 9 illustrates a dark or all black calibration target **250**. The user turns on the camera module **100** and provides

illumination through the optical tip **40**. Software may then be used to identify areas of the raw image **42** having internal reflection or “glint” and correcting for those areas to provide an improved image **44**. The brightness of these areas may be lowered and/or these areas may not be taken into account in automatically setting image brightness to prevent the image from “blowing out,” i.e. the brightness getting set unnecessarily low to accommodate the bright areas caused by internal reflection. In certain other embodiments, the image improvement software may include white balance by adjusting the intensity of the rendered colors so that neutral colors will be presented correctly.

[0046] In another embodiment, the images are collected and modified such that the near field focus is closer than the typical working range when performing an optical entry procedure and the far field focus is farther than the maximum typical distance when not performing optical entry. In certain other embodiments, a pinhole lens is employed to bring everything into focus. This provides an infinite depth of field. With focus-free optics, everything within the patient’s abdominal cavity is in focus.

[0047] For de-warping the images collected through the curved optical trocar tip **40**, a checkerboard calibration target **251** can be used. The raw warped image **46** can be improved or corrected through the use of software so that a non-warped image **48** is presented to the user.

[0048] The camera module **100** embodiments discussed thus far are intended to be inserted into a separately provided obturator; however, this presents challenges with respect to, among other things, ensuring proper position and orientation. As illustrated in Figure 10, a non-limiting example of an applicator device **300** for installation of the camera module **100** into an obturator **35** is provided. The applicator device **300** contains a camera module **100** and a plunger **320** sequentially and slidably disposed within a plunger tube **310**, the camera module **100** distal to the plunger **320**. One or more fixed exterior flanges **330** extend from the plunger tube **310**.

[0049] Optical tipped obturators are designed with a cylindrical cavity so that they may receive a laparoscope in surgical procedures performed prior to the present invention. Thus, in operation, the plunger tube **310** is inserted into the cylindrical cavity inside the obturator **35** until the camera module **100** is in its intended place, at which time, the plunger **320** is pressed

against the camera module **100** using the leverage created by the surgeon's fingers against the flanges **330** to keeping the camera module **100** in place while the plunger tube **310** is removed from the obturator **35**.

[0050] In another non-limiting example, the camera module is inserted into the obturator using a simple push rod. In embodiments, the push rod is fixably or removably attached to the proximal end of the camera module and the user simply pushes the camera module **100** into place. Where removable, the push rod can be removed by unscrewing it from the camera module where the distal end has been prepared with a threaded void for such purpose. In yet another non-limiting example, the camera module contains a telescoping rod that, when extended, can be locked to enable it to be used to push the camera module **100** into the obturator **35**.

[0051] In some embodiments, the applicator may contain mechanical features to handle various obturator lengths and diameters. These features include making the applicator longer than all compatible obturator lengths and narrower than all compatible obturator inner diameters so that it fits every possible third party obturator. In other embodiments, certain applicators may only be compatible with a certain group of obturators and the user will have to match the proper applicator with desired obturator. In still other embodiments, the applicator may be more like tweezers or pliers to hold/manipulate the camera module **100** during insertion.

[0052] In certain embodiments, an applicator is delivered with a device to assist the surgical team with identifying the taper in diameter at or near the distal tip **40** of the cylindrical cavity inside the obturator. In embodiments, the camera module **100** may have a distal protrusion, outer cylindrical ring or partial ring, contact sensor, or outer diameter specifically chosen such that it limits the distance the camera module **100** may be inserted into the obturator **35** due to the taper present at the tip **40**. In other embodiments, a rod that can be permanent, removable or folding, extends from the distal end of the camera module **100** to contact the distal tip **40** of the obturator **35** and provide certainty as to the exact distance the camera module **100** is from the distal tip **40**, such as via a scale observable to the user using a mechanical linkage.

[0053] The applicator may still further, in certain embodiments, be provided with a scale having an indicator that shows the distance the camera module **100** is from the distal tip **40**. In embodiments, a device may protrude from the proximal end **102** of the camera module **100** that has markings that can be lined up with the proximal end of the obturator **35** to indicate the exact distance of the camera from the distal tip of the obturator. Some embodiments may have a string disposed on the proximal end of the camera module. Prior to insertion, the user may cut this string to match the desired insertion depth by placing the camera module **100** and string next to the obturator it is to be installed in. The camera module **100** can then be inserted into the obturator until the remaining string lines up with the proximal end of the obturator.

[0054] Still additional non-limiting examples of insertion methods and devices include disposing distance-measuring sensors on the distal end of the camera module or an encoder on the proximal end of the obturator to determine when insertion is complete. Sensors may take measurements by various means, including mechanically or optically. The camera built into the camera module can also be used. A calibration target could be programmed to identify the correct insertion if placed a certain distance away from the tip of the obturator during calibration.

[0055] In addition to installing the camera module the correct distance, it is also important to know or determine the orientation of the camera – which way is “up” in any given image or video feed. In embodiments, then, the applicator contains a mark to indicate the clocking angle of the camera to the user (for example by indicating which direction is “up” in the video). The user would then install the camera module with the obturator at the desired clocking angle. In certain embodiments, an indicator (LED or mechanical) located at the proximal end of the camera module indicates “up” for the video.

[0056] In embodiments, the clocking angle can be modified after the camera module **100** has been installed. Fig. 11 demonstrates the rotation of a camera module **100** through the use of a screwdriver **400**. In this embodiment, the proximal end **150** of the camera module must have either a Philips head or flat head indentation so that the entire module **100** can be rotated.

[0057] In certain other embodiments, the clocking angle can be modified. The user can rotate the video on a monitor in some cases. In other embodiments, video can be autorotated

depending on feedback from gravity sensors or compass readings, both or either of which may be disposed on the camera module **100**. Software may also be used to correct for misalignment of a camera module **100** within an obturator, such as may occur when the module **100** is a smaller diameter than the internal cavity of the obturator.

[0058] Once the camera module **100** is at the correct depth and orientation for the obturator **35** with which it is being used, it is important to make sure it is securely placed. In certain embodiments, the camera module **100** is secured with adhesive that may be optically, by exposure to light, or anaerobically cured, or may be glue, tape or springs. Air pressure may also be used to create a vacuum or, at least, negative pressure at the distal tip of the obturator. Likewise, positive pressure may be used to ensure proper seating of the camera module **100** in the obturator **35**. In embodiments, the module **100** may also be secured by maintaining a high coefficient of friction between the module **100** and the interior walls of the cavity within the obturator **35**, through, among other things, appropriate material selection. In another embodiment, thermal expansion may be used whereby the camera module **100** is kept refrigerated until it is inserted into the obturator, at which point, it expands and pushes against the walls of the internal cavity. A further embodiment provides for screw threads or ribs protruding from the exterior wall of the camera module **100** that secure it in place.

[0059] In certain embodiments, the camera module **100** is intended to be single-use or disposable so that it is not possible to accidentally or improperly re-use a contaminated camera module **100**. In a non-limiting example illustrated by Fig. 12, a method is disclosed whereby removing the camera module **100** from an obturator prevents reuse. Batteries **510** and **520** are held in place and electrically contacted by a plate **505** connected to eyebolt **500**. The plate **505** is held in place by tabs **507** which are strong enough to put pressure on the batteries and make good electrical contact but weak enough such that they bend or potentially break off when forcibly removing the camera module **100** from the obturator **35** using the eyebolt **500**, creating a space between the plate **505** and the batteries **510**, **520** and electrically disconnecting them, causing the camera module **100** to power off and remain off without chance of re-use. The presence of the bendable or breakable tabs **507** prevents the camera module **100** from being re-used.

[0060] In another embodiment, it may be possible to limit multiple uses by only allowing the camera module **100** to turn on and not off. In other words, installing the camera module **100** into an obturator **35** may cause the device to turn on and remain on until the battery dies. Another non-limiting example of a way to ensure the camera module **100** is not improperly reused is to require that the camera module **100** be damaged in order for it to be removed. Further, to the extent that the camera module **100** is secured with threads or ribs, they may be tapered or barbed to only permit one-way motion. In another non-limiting example, the batteries supplied with the camera module **100** can be non-replaceable and contain only enough energy for a single use plus some safety factor. Additional non-limiting examples include a time delay fuse to enforce single use or a software time limit.

[0061] Where it is desirable to re-use an obturator **40** or where the camera module **100** is not designed for re-use, it needs to be safely removed from the obturator **40**. In embodiments, this can require a specialized unlocking tool that allows the user to grasp the camera module **100** and pull it out of the obturator only with use of the tool. A pull string or other graspable appendage can also be used to remove the module. In wired embodiments, the data cable may be reinforced to facilitate its use as a removal option.

[0062] After the camera module **100** has been properly inserted and calibrated, the obturator is ready to be inserted into the body. Some obturators have a hole or gap in the optical tip to facilitate insertion into the abdomen as the abdominal cavity is normally under negative pressure. Insertion then allows air to flow into the abdominal cavity creating space during the insertion and reducing potential for injury. If a camera module in accordance with the present disclosure has been placed in the internal cavity of the obturator, it needs to enable that gas to escape. Fig. 13a illustrates a perspective illustration of a camera module **100** having two channels **600** for allowing gas to either enter or exit the patient's abdomen, depending on the situation. Fig. 13b illustrates a cross-sectional view of a camera module **100** having an embodiment of the channels **600**.

[0063] It is important to control temperature within the optical tip **40** of the obturator **35** given that lights are being used to illuminate the tissue as the obturator is being introduced. Overheating and fogging can create problems with equipment and make it difficult to see the

tissue. Moreover, overheating can also create a tissue damage issue due to potential for burning. Therefore, embodiments of the camera module **100** include a heater to prevent fogging of the optical tip **40**, LED intensity control to control corresponding heat, PWM frequency variation or signal driver waveform shape, and use of a temperature sensor that may optionally be tied to LED intensity for automatic temperature control. In another non-limiting example, an additional element constructed of a material having a high specific heat may be added to act as a heat sink.

[0064] To assist the surgical team, the camera module **100**, in embodiments, is configured to report its status. By way of non-limiting example, the module **100** may report improper installation, error status such as temperature abnormalities or low battery, type of obturator into which the module **100** has been installed, or illumination requirements to avoid overheating. While status may be reported on the display of the video feed, other embodiments of the method of status reporting include one or more of blinking the illumination LED's or separate error reporting LED's, sounds, and vibrations. In embodiments, notifications can be configured to occur in different colors, patterns, intensities, or vibrations, all in accordance with a defined message paradigm. In robotic system embodiments where the camera module **100** integrates with other systems, the reporting mechanisms of the other systems may be co-opted and used by the module **100**.

[0065] In certain embodiments, the camera module **100** can receive user input through input devices located physically on the exterior module or on a separate interface unit. These physical interface mechanisms include one or more of buttons, switches, knobs, joysticks, and trackpads. Other embodiments include receiving user input via hand gestures, voice commands, or movement of the module **100** in a predetermined way.

[0066] Some embodiments of the camera module **100** include a separate interface unit **240** to connect the camera module **100** to one or more displays in the operating room. By way of non-limiting example, the interface unit may include an interface with the module **100** via a wired or wireless connection to receive video, control the module **100**, or provide user input functionality. In certain embodiments, the interface unit **240** connects to a hospital network to send data or video, generate video overlays, record video, images or other data, perform

computation or calibration procedures, display images, video or data, provided status indications or store user preferences or user logs. In a particular embodiment, the interface unit **240** may be configured to show layers of abdominal wall that have been passed with either actual images or cartoon-like illustration. It may also interface with existing vision carts or other devices in the operating room, such as robotic surgery systems, in particular, via wired or wireless connections.

[0067] As those of skill in the art will appreciate, through the use of appropriate material and equipment selection, certain embodiments of the camera module **100** can be manufactured to be disposable, reusable (durable), or a combination of both. By way of non-limiting example, the reusable portion may display video and the disposable portion may be the camera module. In a wired embodiment, the wire could be durable, potentially with a disposable sterile drape. In other wired embodiments, the wire may be disposable.

[0068] The foregoing notwithstanding, in certain embodiments, a camera module **650** is integrated with the obturator **900** during manufacture or assembled as a separate procedure after manufacture and delivered to the surgeon as finished package as seen in Fig. 14. As part of manufacturing of the obturator **900** for a particular embodiment, it could be modified to contain elements to prevent internal reflections and light leakage from the lighting elements into the camera by the addition of opaque elements between the obturator tip through which illumination passes in an outward direction and the area of the obturator tip through which the image is captured. As will be appreciated by those of skill in the art, any item or feature previously discussed in relation to the construction of the camera module **100** can be incorporated into the preinstalled obturator discussed here **900**.

[0069] Referring to Fig. 15, certain embodiments have a side-looking image sensor **800** which may be integrated with the side of the obturator (for example through a flat window in the side of the obturator) to provide an undistorted view in a direction normal to a long axis of the imaging obturator **900** or camera module **100**. Images collected from this additional side-looking image sensor **800** can be stitched together with images taken from the forward-facing camera or cameras **140** to provide the surgeon with an even large field of view in real time.

[0070] During manufacture of the imaging obturator **900**, in embodiments where it is either integrated into the obturator when the obturator is manufactured or assembled after manufacturing of the obturator, calibration for image white balance, image distortion due to the obturator tip or to remove/lessen the effect of internal reflections due to illumination from the lighting elements reflecting from the obturator tip, and other calibrations of the software and or imaging mechanisms described above may be performed at the factory or in a location off-site and prior to delivering the imaging obturator **900** to the user.

[0071] In still other embodiments, such as in the case where the camera module **100** is not fully integrated into an imaging obturator **900** prior to delivery to the surgeon, installation may consist of placing some or all of a camera **120**, illumination devices **140** such as LED's, supporting electronics **130** such as power supplies or converters, image processors, and LED drivers, the wireless transceiver and one or more batteries **110**, in the case of wireless embodiments, inside a provided obturator **900** prior to use. In certain additional embodiments, user controls **910** are located on the proximal portion **905** of the provided obturator **900**, along with a data and/or power wire **925**, in the case of wired embodiments, to connect to a monitor or video interface box (not shown).

[0072] Figs. 16 through 19b illustrate several embodiments of trocars having a mechanism for cleaning the optical tip of the obturator. Fig. 16a illustrates a trocar **1000** having a cannula **1005** and an obturator **1035**. In certain embodiments, a cannula inner surface **1010** contains a wiper **1020** for cleaning the optical tip **1040** of the obturator when it gets smudged with tissue or other debris. As demonstrated by Fig. 16b, to clean the tip **1040** using the wiper **1020**, the user retracts the obturator **1035** into the cannula **1005** past the wiper that is biased to extend away from the cannula inner surface **1010**. Next, as illustrated by Fig. 16c, the user re-extends the obturator **1035**, causing the wiper **1020** to clean the tip **1040**.

[0073] In certain embodiments, the wiper **1020** comprises a wiping arm that is actuated by a user via the use of a lever or actuated through the use of a motor. This wiper **1020** does not interfere with conventional laparoscopic tool use because it is similar in structure to a prior art trocar seal in construction. Figs. 17a-b demonstrate an alternative embodiment of a wiper **1020** wherein the wiper **1020** is located at the distal end of the cannula **1005**.

[0074] As illustrated in Figs 18a-b, another embodiment of an obturator tip cleaner employs one or more irrigation tubes **1100** to carry fluid, which may be saline or some other sterile liquid, to the tip **1040** during use. The liquid can be sprayed on the tip and used in conjunction with or without a wiper **1020**. In certain embodiments, such as Fig. 18b, a plurality of irrigation jets **1105** are situated on or in the obturator **1035** so that they are positioned to spray the tip **1040** with liquid. The tubes **1100** can, in embodiments, be connected to a syringe **1110** containing liquid and a pressure-inducing device, such as a plunger **1115** or a motor or other electromechanical actuator, to advance the liquid onto the tip **1040** for cleaning. In an alternative embodiment, the obturator **1035** contains a reservoir that holds the liquid. In still another embodiment, the liquid reservoir is positively pressurized so that opening a valve is sufficient to cause the liquid to be expelled when needed.

[0075] Figs 19a-b illustrate a fold-open obturator tip **1240** for use when tip **1240** gets dirty on entry. In certain embodiments, the tip is opened as shown in Fig 19b if something smudges or otherwise obscures the optical tip for the camera **1200**. In this way, the smudges are removed from view and the camera **1200** is exposed for direct visualization of the surgical site, such as for assistance with the installation of additional ports, for example. If the camera **1200** subsequently becomes dirty, however, it must be withdrawn from the surgical site and cleaned.

[0076] In certain embodiments, a continuous sheath of clear plastic film wraps over the optical trocar tip **1040** so that it can be advanced when it gets dirty. Eventually, the film that is dirty will circulate back around, but enough film should be on the roll so that clean film can be advanced onto the tip several times without the need for removal of the obturator from the surgical site.

[0077] While various illustrative embodiments incorporating the principles of the present teachings have been disclosed, the present teachings are not limited to the disclosed embodiments. Instead, this application is intended to cover any variations, uses, or adaptations of the present teachings and use its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which these teachings pertain.

We claim:

1. A camera module adapted to be inserted into an internal recess of an obturator portion of an optical trocar to permit safe advancement of the trocar into an abdomen of a patient during a laparoscopic procedure, the module comprising:

a substantially cylindrical body having a distal end, a proximal end, and an exterior surface between the ends, the entire body shaped to fit within the internal recess;

an imaging sensor and one or more lighting elements disposed at the distal end; the imaging sensor and lighting elements oriented to illuminate and collect imagery axially beyond the distal end;

control circuitry inside the body in communication with the imaging sensor for delivering the imagery to a display.
2. The camera module of claim 1 wherein the module is shaped to fittingly conform to the internal recess within the obturator.
3. The camera module of claim 1, wherein the imagery is delivered to the display in real time.
4. The camera module of claim 1, wherein the control circuitry further comprises a wireless radio for delivering the imagery to the display.
5. The camera module of claim 1, further comprising one or more of the following: a power source within the body and a port for receiving a power cord.
6. The camera module of claim 1, further comprising an additional imaging sensor disposed at the distal end for one or more of three-dimensional imaging and wide-angle imaging.

7. The camera module of claim 1, further comprising one or more additional imaging sensors oriented radially and disposed on the body in an area adjacent the distal end for providing a wider view to the display.
8. The camera module of claim 1, further comprising an external sizing mechanism comprising one or more of: an annular spacer, an inflatable bladder, compliant spring-loaded legs extending outward from the body, for providing a secure fit in obturators having recesses with larger diameters.
9. The camera module of claim 1, wherein the exterior surface forms one or more channels for equilibrating gas pressure.
10. The camera module of claim 1, wherein the substantially cylindrical body has a diameter that increases from the distal end to the proximal end, whereby the module is secured by friction upon insertion.
11. The camera module of claim 1, further comprising user controls at the proximal end, the user controls in communication with the control circuitry inside the body.
12. The camera module of claim 11, wherein the user controls control at least one of lighting intensity, imaging sensor calibration, focus and zoom, and power.
13. The camera module of claim 1, further comprising a distance indicator for determining the location of the camera module within the obturator portion.
14. The camera module of claim 13, wherein the distance indicator is one or more of protrusion, external ring or partial ring, electronic sensor, encoder, mechanical linkage, graded scale and a pre-measured string or tape.

15. The camera module of claim 1, further comprising one or more of anti-fogging devices, heaters, illumination intensity and frequency control mechanisms, and heat sinks in order to control temperature within the obturator.
16. A optical trocar comprising
 - an obturator having an internal recess and a cannula, the obturator sleevingly disposed within the cannula; and
 - a camera module securely installed within the obturator.
17. The optical trocar of claim 16, wherein the camera module further comprises:
 - a substantially cylindrical body having a distal end, a proximal end, and an exterior surface between the ends, the entire body shaped to fit within the internal recess;
 - an imaging sensor and one or more lighting elements disposed at the distal end; the imaging sensor and lighting elements oriented to illuminate and collect imagery axially beyond the distal end;
 - control circuitry inside the body in communication with the imaging sensor for delivering the imagery to a display.
18. A disposable optical trocar comprising
 - an obturator and a cannula, the obturator sleevingly disposed within the cannula;
 - a camera module securely installed within the obturator,
 - wherein the attempted removal of the camera module from the obturator disables the module.
19. An applicator device for installing a camera module into an optical trocar having an obturator, the applicator device comprising a tube sized to fit into the obturator, the tube further configured to releasably hold the module until it is in a desired location.

20. An applicator device for installing a camera module into an optical trocar employing an obturator comprising
- a plunger tube having a proximal end, a distal end, and an extended hollow body;
 - an outwardly extending flange disposed on the proximal end and the body extending toward the distal end having an outside diameter sized to fit inside the obturator;
 - a plunger having a handle end and a pusher end slidably disposed within a portion of the plunger tube, the pusher end in series contact with the camera module inside the plunger tube;
- whereby actuation of the plunger into the plunger tube causes the camera module to be installed.
21. The applicator device of claim 20 further comprising a releasable connector mechanism at the pusher end of the plunger whereby the plunger is rotatably affixed to the camera module to enable rotational adjustment of the module within the obturator prior to removal of the applicator device from the trocar.
22. The applicator device of claim 21, further comprising a clocking angle indicator to enable insertion of the camera module and a pre-selected orientation relative to the trocar.
23. An optical trocar with a self-cleaning obturator tip comprising:
- a cannula having an interior surface;
 - an obturator having a clear tip for seeing layers of tissue during installation of the trocar, the obturator slidably movable within the cannula;
 - a wiping assembly attached to and extending inward from the interior surface;
- whereby withdrawal of the obturator tip into the cannula causes the wiping assembly to clean the tip.

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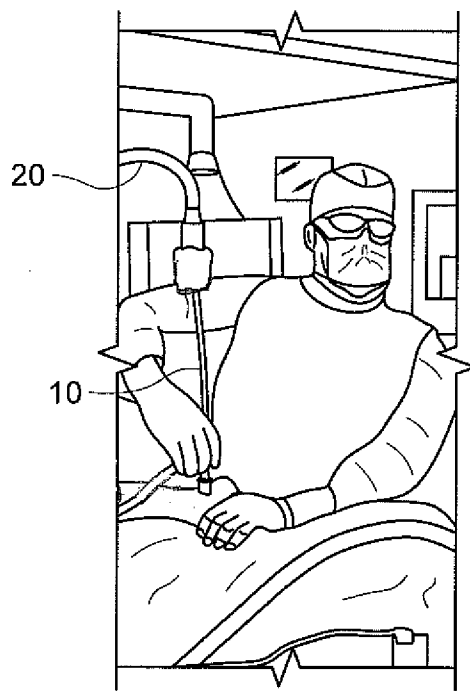


FIG. 1a
(Prior Art)

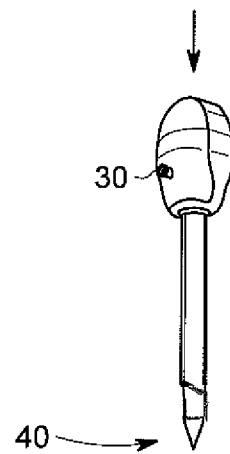


FIG. 1b
(Prior art)

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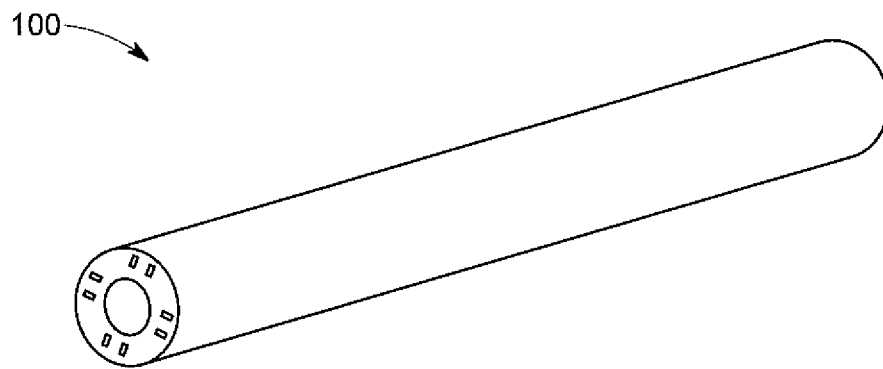


FIG. 2

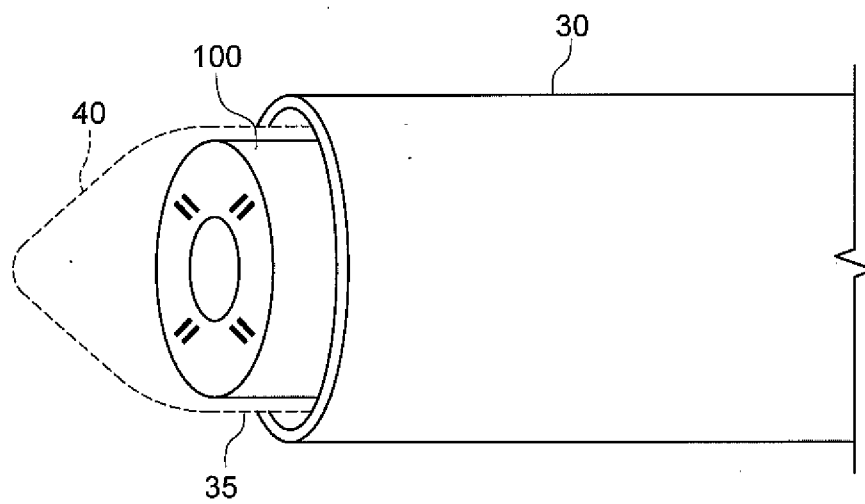


FIG. 3

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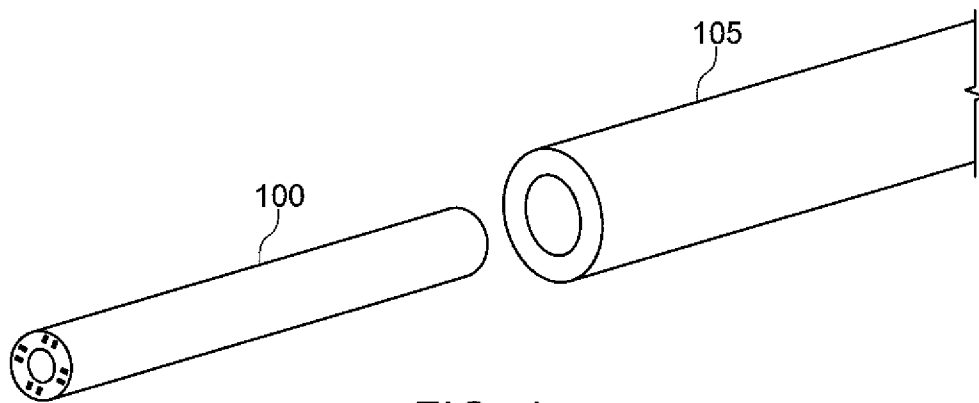


FIG. 4

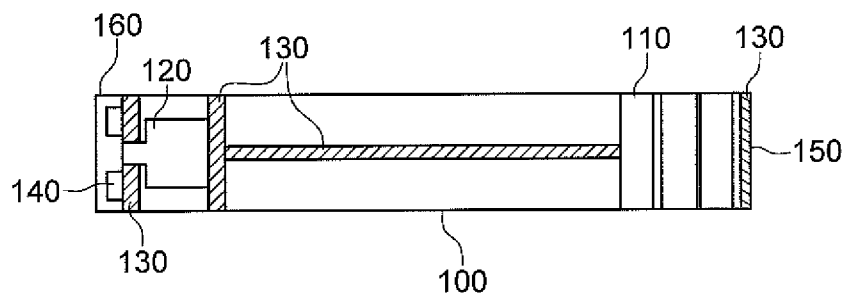


FIG. 5

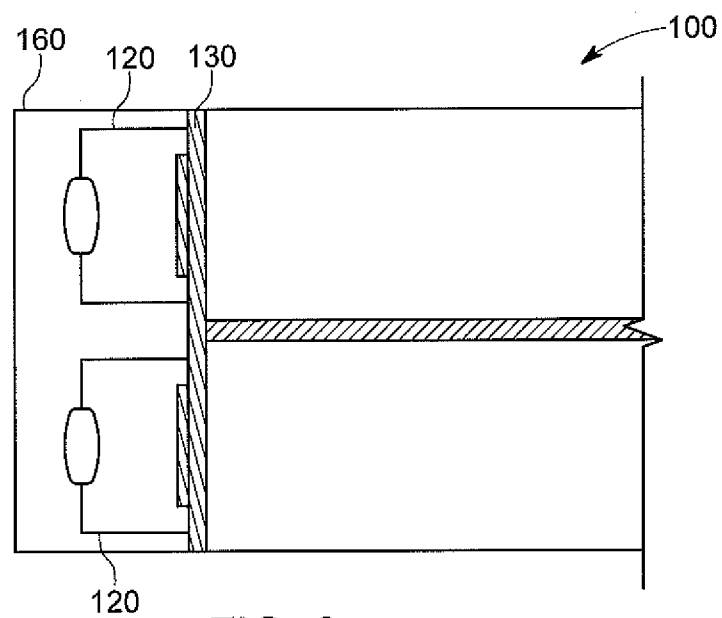


FIG. 6

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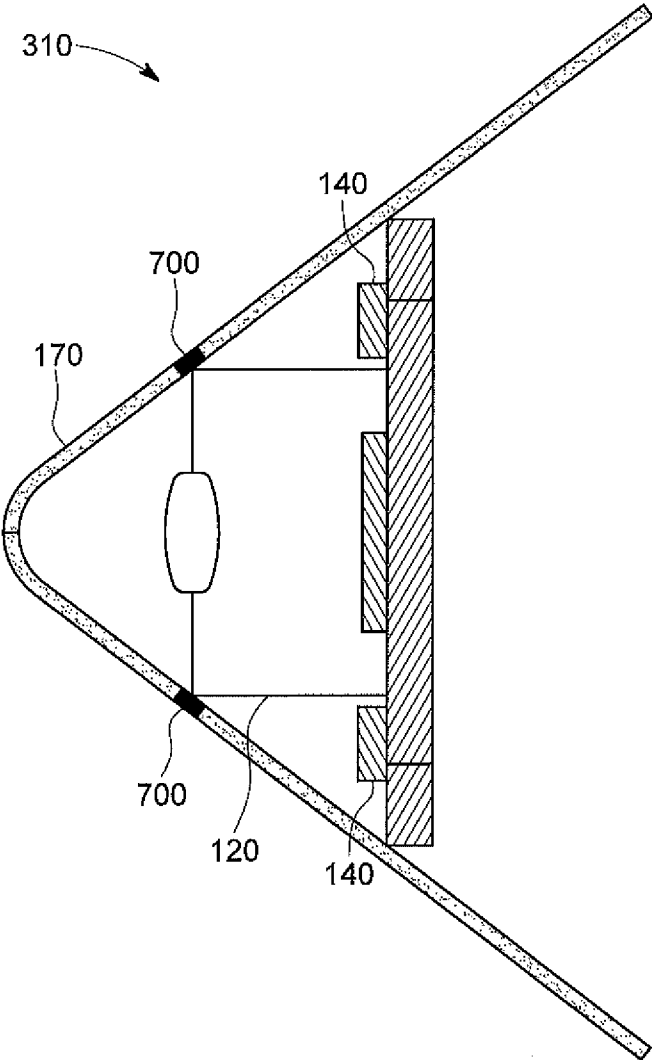


FIG. 7

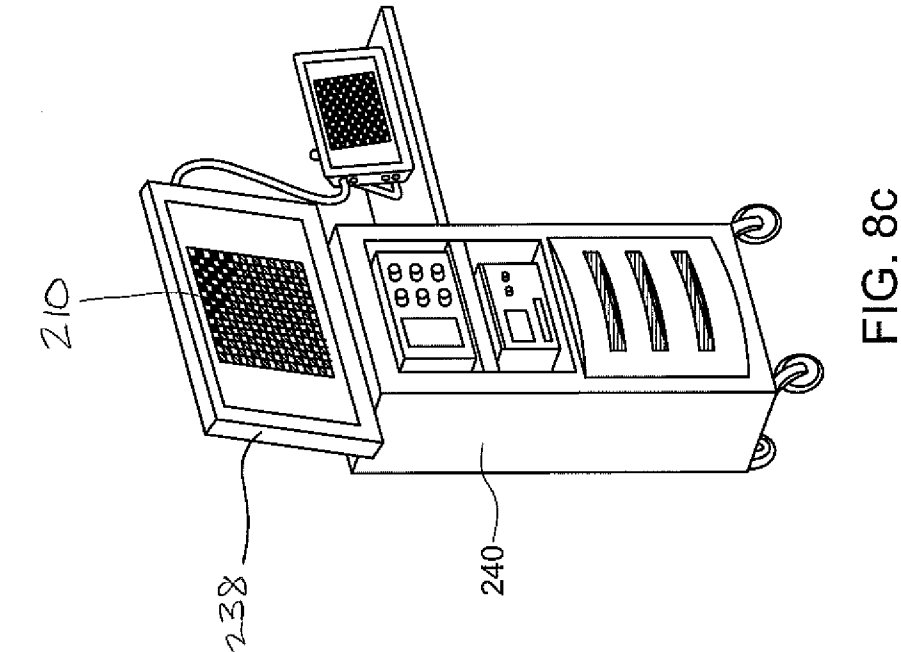


FIG. 8c

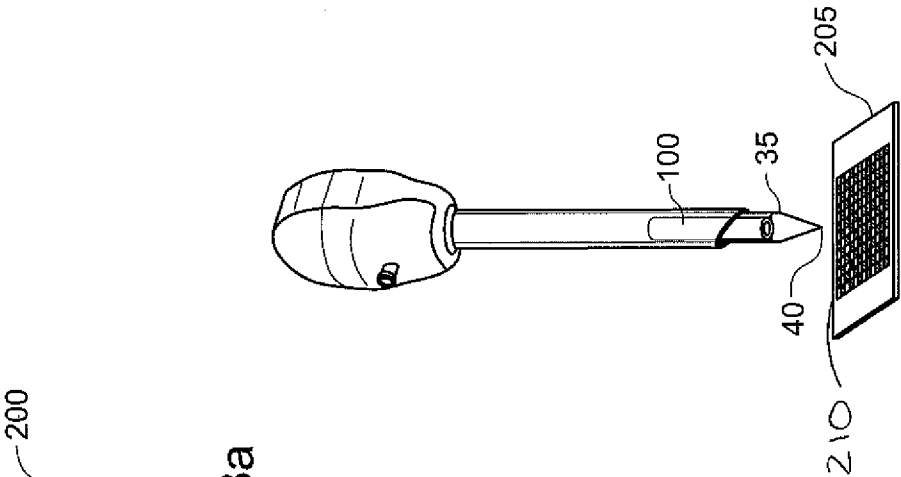


FIG. 8b

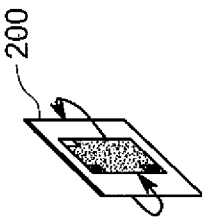


FIG. 8a

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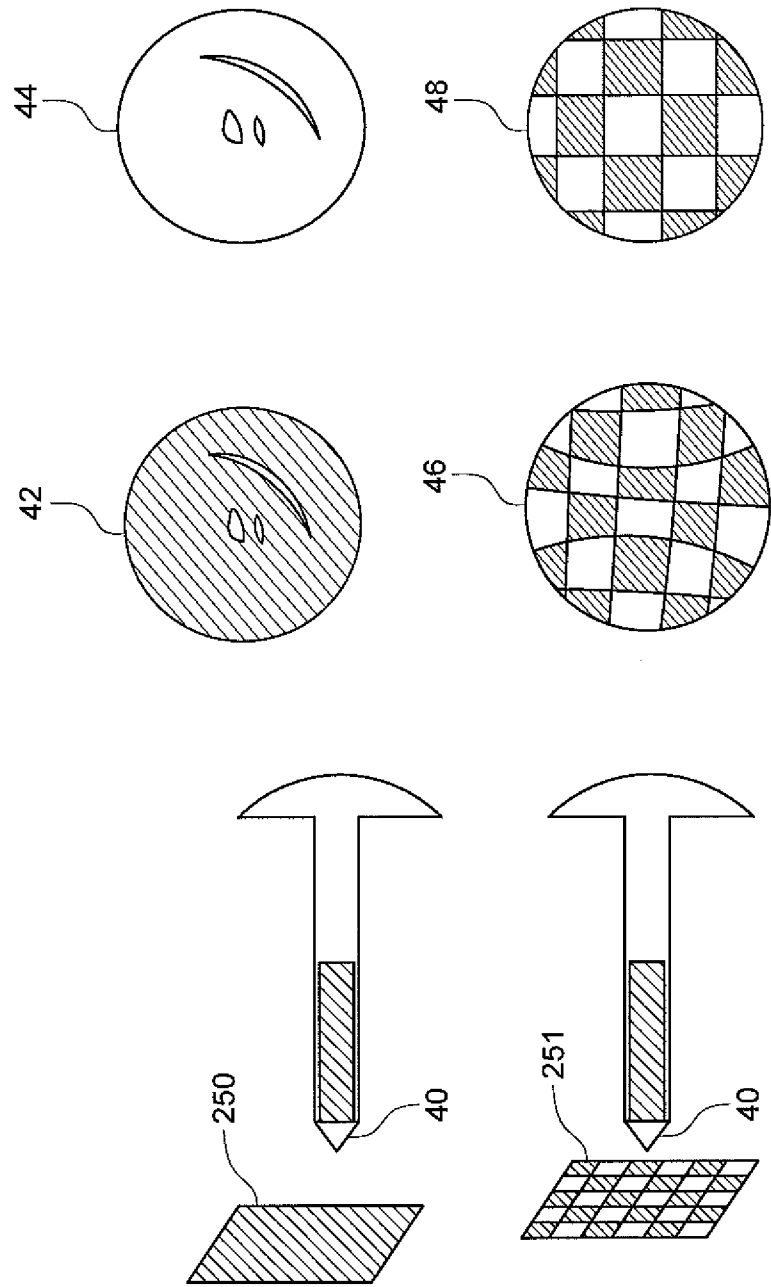


FIG. 9

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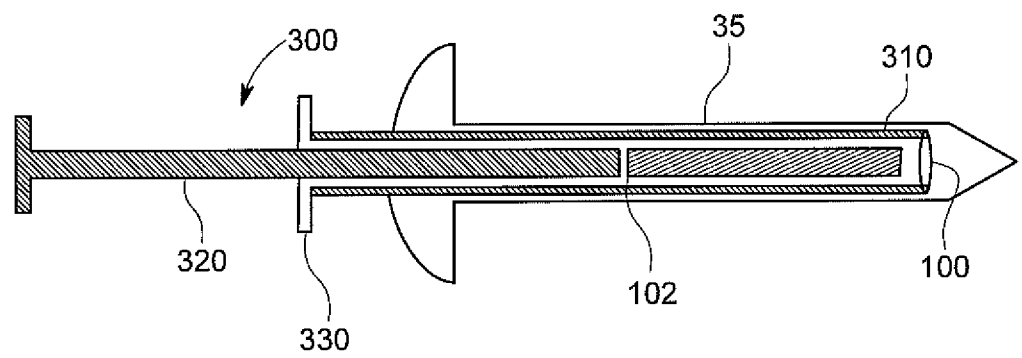


FIG. 10

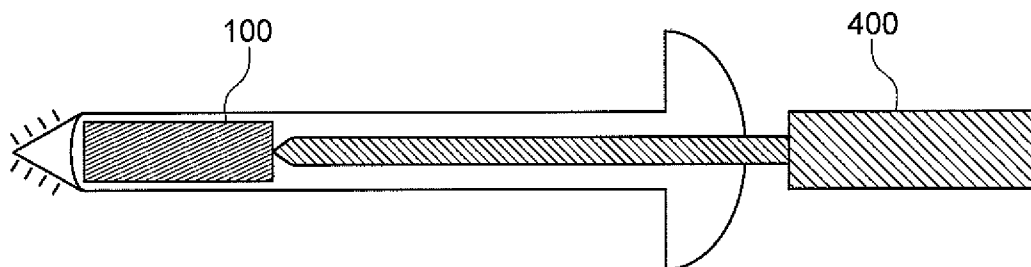


FIG. 11

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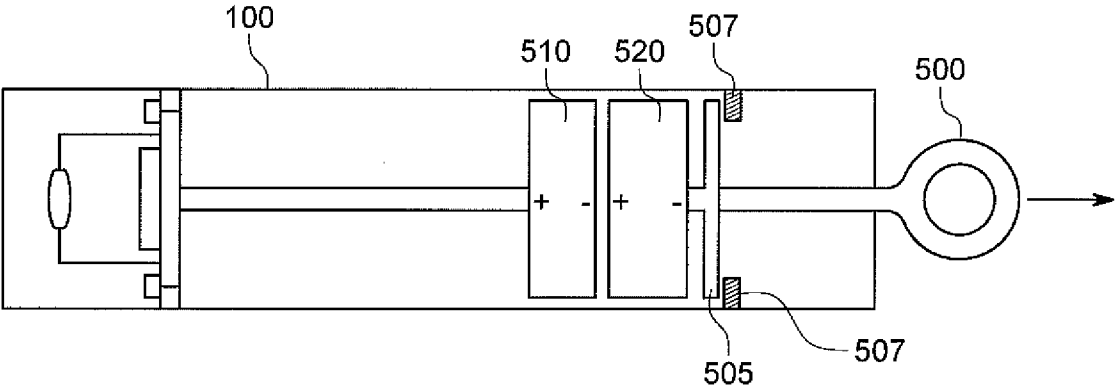


FIG. 12

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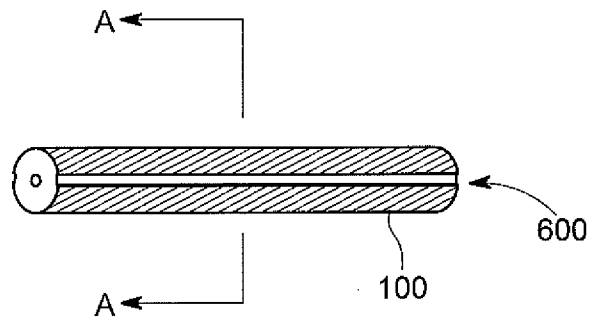


FIG. 13a

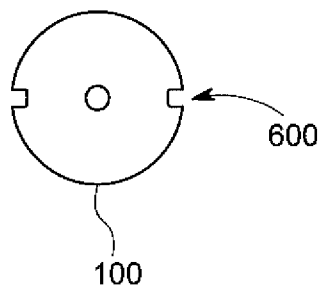


FIG. 13b

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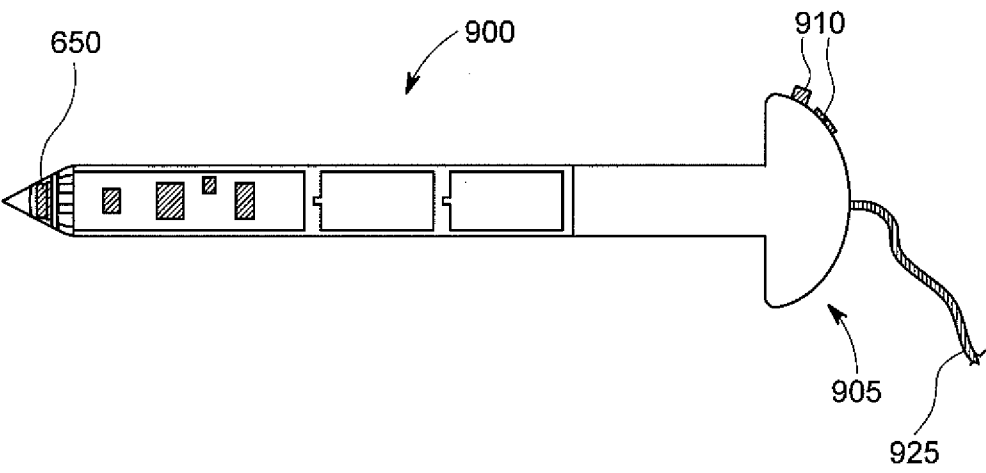


FIG. 14

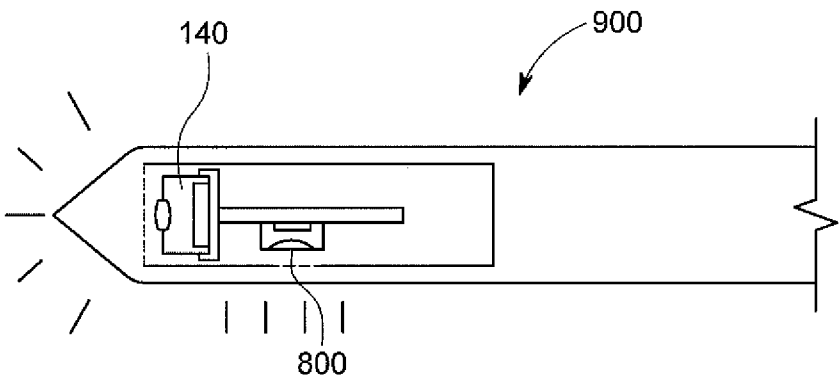
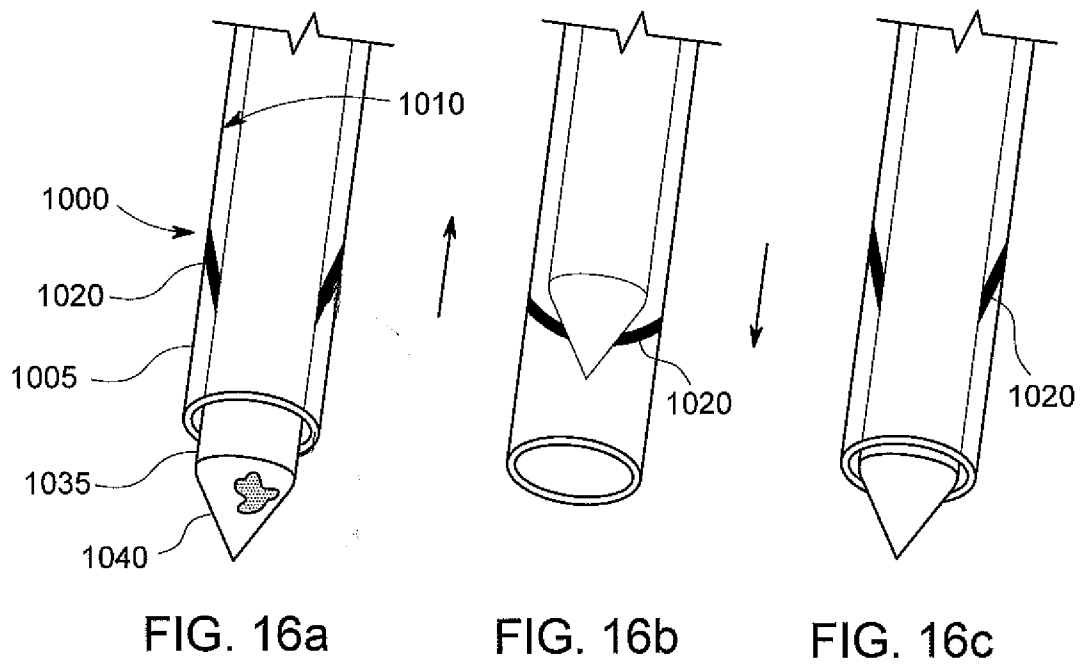


FIG. 15

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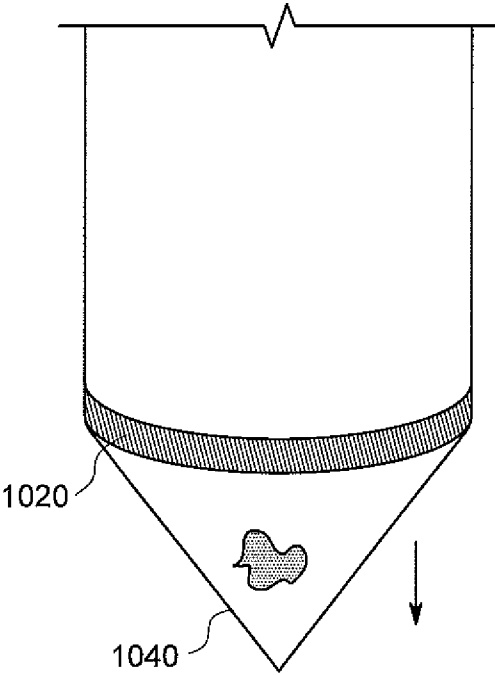


FIG. 17a

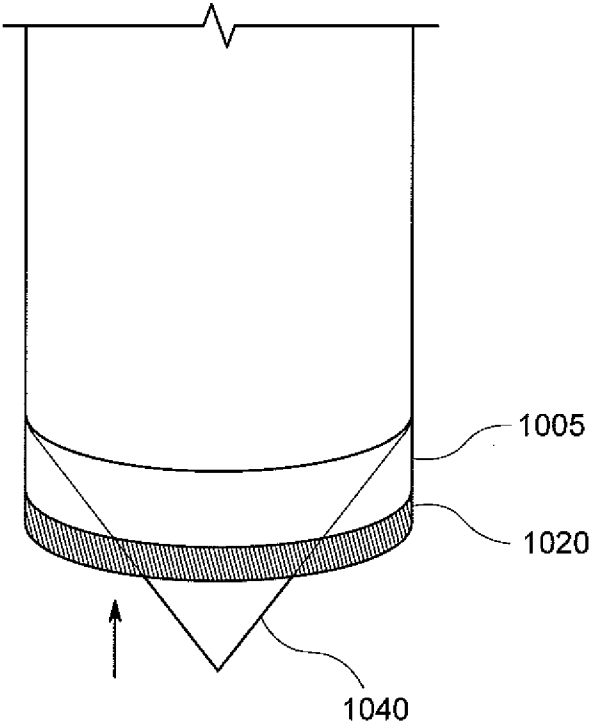


FIG. 17b

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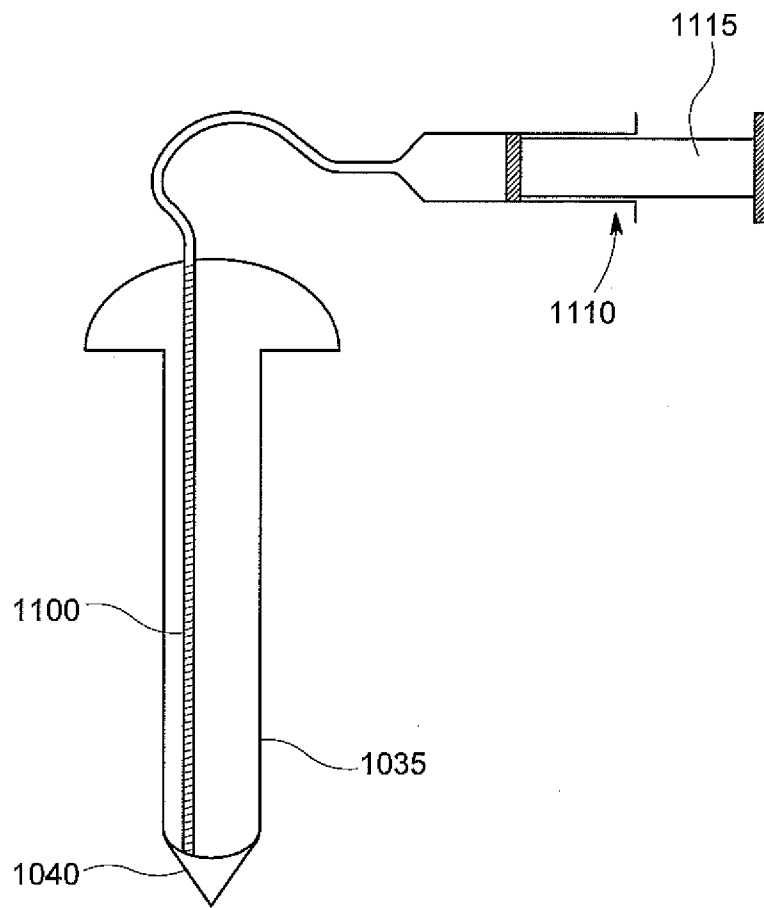


FIG. 18a

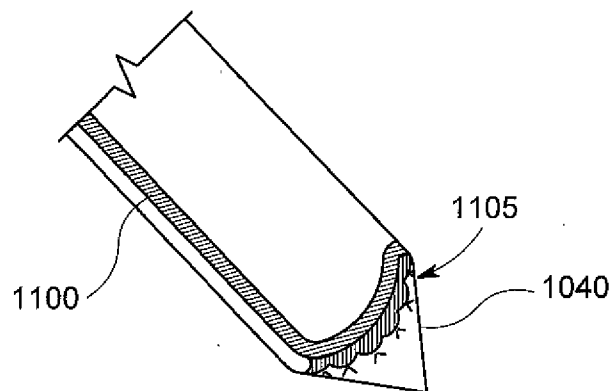


FIG. 18b

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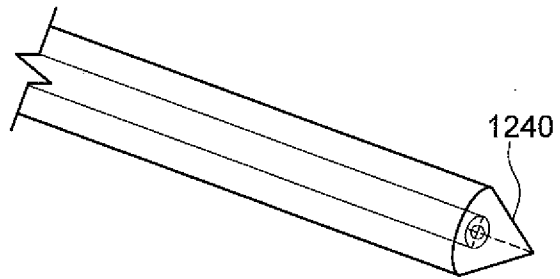


FIG. 19a

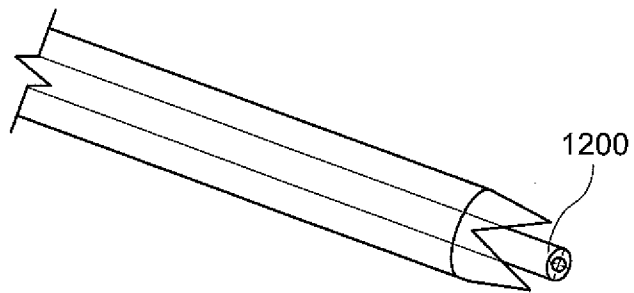


FIG. 19b

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2019/033968

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 1/00; A61B 1/05; A61B 1/06; A61B 17/34 (2019.01)

CPC - A61B 1/00009; A61B 1/00096; A61B 1/00135; A61B 1/00163; A61B 1/05; A61B 90/361; A61B 2017/3454 (2019.08)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

USPC - 600/104; 600/114; 600/160 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/0275771 A1 (OLIVE MEDICAL CORPORATION) 18 September 2014 (18.09.2014)	1-4, 6, 16, 17
---	entire document	---
Y		5, 7, 9, 15
Y	US 2016/0270641 A1 (A M SURGICAL INC) 22 September 2016 (22.09.2016) entire document	5
Y	US 2016/0038018 A1 (VANTAGE SURGICAL SYSTEMS INC) 11 February 2016 (11.02.2016) entire document	7, 15
Y	US 2005/0288622 A1 (ALBRECHT et al) 29 December 2005 (29.12.2005) entire document	9
A	US 2010/0081988 A1 (KAHLE et al) 01 April 2010 (01.04.2010) entire document	1-18

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

26 August 2019

Date of mailing of the international search report

27 SEP 2019

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2019/033968

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet(s).

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-18

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2019/033968

Continued from Box No. III Observations where unity of invention is lacking

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-18, are drawn to a camera module adapted to be inserted into an internal recess of an obturator portion of an optical trocar to permit safe advancement of the trocar into an abdomen of a patient during a laparoscopic procedure.

Group II, claims 19-22, are drawn to an applicator device for installing a camera module into an optical trocar having an obturator.

Group III, claim 23, is drawn to an optical trocar with a self-cleaning obturator tip comprising: a cannula having an interior surface.

The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of the Group I invention: the module comprising: a substantially cylindrical body having a distal end, a proximal end, and an exterior surface between the ends, the entire body shaped to fit within the internal recess; an imaging sensor and one or more lighting elements disposed at the distal end; the imaging sensor and lighting elements oriented to illuminate and collect imagery axially beyond the distal end; control circuitry inside the body in communication with the imaging sensor for delivering the imagery to a display as claimed therein is not present in the invention of Groups II and III. The special technical feature of the Group II invention: a plunger tube having a proximal end, a distal end, and an extended hollow body; an outwardly extending flange disposed on the proximal end and the body extending toward the distal end having an outside diameter sized to fit inside the obturator; a plunger having a handle end and a pusher end slidably disposed within a portion of the plunger tube, the pusher end in series contact with the camera module inside the plunger tube; whereby actuation of the plunger into the plunger tube causes the camera module to be installed as claimed therein is not present in the invention of Groups I or III. The special technical feature of the Group III invention: a cannula having an interior surface; an obturator having a clear tip for seeing layers of tissue during installation of the trocar, the obturator slidably movable within the cannula; a wiping assembly attached to and extending inward from the interior surface; whereby withdrawal of the obturator tip into the cannula causes the wiping assembly to clean the tip as claimed therein is not present in the invention of Groups I or II.

Groups I, II and III lack unity of invention because even though the inventions of these groups require the technical feature of a camera module installed into an optical trocar having an obturator, this technical feature is not a special technical feature as it does not make a contribution over the prior art.

Specifically, US 2010/0081988 A1 to Kahle et al. teaches a camera module installed into an optical trocar having an obturator (Paras. [0058-0059]).

Since none of the special technical features of the Group I, II or III inventions are found in more than one of the inventions, unity of invention is lacking.