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(54) **Titre : Laparoscopic Device.**

(57) **Abrégé :**

Disclosed in the present invention is an accessible laparoscopic device for minimally invasive surgeries, comprising a self-correcting camera, plastic top and water-proof elements of the device. The device further comprises a modular housing system, video image autorotation system and strobed illumination system. The modular housing system contains modular components for the camera tube, handle, end caps, seals, cord grip, and cable connectors with different variations that can be made/swapped out depending on user preference, designed to lend itself to be reparable if needed. The modular housing further comprises a cord grip, end cap, proximal large o-ring seal, tube grip, aluminum tube, proximal camera tube o-ring seal, distal large tube o-ring seal, top cap, orientation indicator, distal camera tube o-ring seal, camera tube and camera. The image video autorotation system is embedded in a two-axis tilt sensor in the housing characterized in that the angular information is sent back to the control computer over USB along with the video stream.

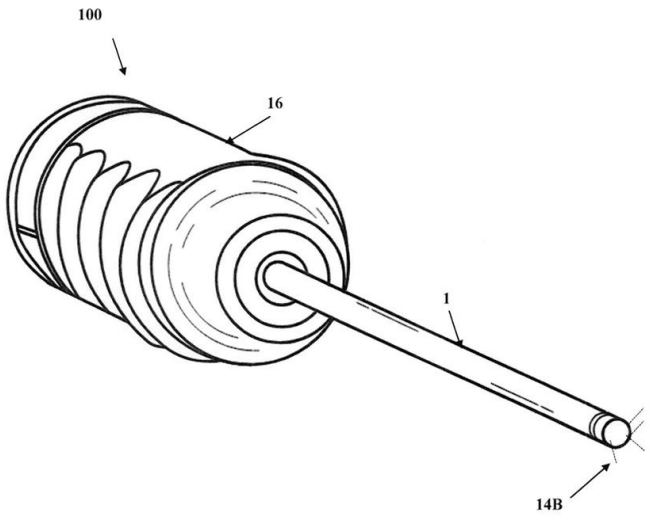


Fig. 1

PATENT SPECIFICATION

Title: Laparoscopic Device

Technical Field of Invention

The present invention relates to the medical field, and in particular, to a laparoscopic device, system and method for minimal keyhole surgery, comprising a self- correcting camera, plastic top and water-proof elements of the device with a modular housing system, a custom miniature camera, a video autorotation system, and a strobed illumination system designed to reduce the cost and complexity of the prior art laparoscopes.

BACKGROUND ART

Laparoscopy is a type of keyhole surgery used to diagnose and treat conditions. It allows a surgeon to use only small cuts and a camera for procedures inside the tummy or pelvis. Laparoscopic surgery is a widely used technique that is performed through keyhole incisions. Compared to traditional surgery, it improves recovery time, leaves smaller scars, and decreases infection. It is the standard of care (SOC) for many operations in high-income countries. However, in low- and middle-income countries (LMICs) the availability can be limited due factors such as lack of resources and supplies and frequent power outages. Conventional laparoscopic devices can further include complex, fragile, and/or expensive components that are difficult to maintain and replace hence the need for improved laparoscopic devices.

Literature Review

Further, laparoscopic surgery is the standard of care in industrially-developed and high income countries for many procedures in the abdomen and chest, such as cancer excision,[11] organ resection, and treatment of other surgical diseases.[4,10] It avoids large incisions associated with open surgery by using a small camera and fine instruments manipulated through keyhole incisions.[33] Advantages of laparoscopic surgery include smaller incisions, decreased pain, improved recovery time, minimized post-surgical infections, and shorter hospital stays.[2]

Patients in low- and middle- income countries (LMICs) would further benefit from laparoscopic surgery since the reduced recovery time would enable patients to return to home and work more quickly, thus mitigating impoverishing health costs.[10,27] Laparoscopic surgeries would reduce postoperative complications in overcrowded wards [3,10] and minimize the stigma associated with certain surgical conditions.[16,30]

Despite these advantages, laparoscopic surgery is rare in LMICs and patients often receive open surgery instead, representing a great health care disparity.[21,35,37] There is an initial equipment purchase cost of approximately USD 133,000 - USD 136,000 for each operating room that includes the components of the laparoscope, viewing monitors and related equipment—a cost that is prohibitive for most health systems in LMICs.[17,29,33,34].

In the US patent number US5246419A of 1992 by Omnivision Inc, the prior art discloses an intra-abdominal insufflation apparatus. The apparatus is for supplying insufflation gas at high flow rates during laparoscopic surgery including some or all of the following features. However, this prior art does not disclose the subject matter being proposed in the present invention.

Current laparoscopic technology uses fragile fiber optic cables, cameras, and lenses that require repair, necessitating annual service contracts.[36] Conventional laparoscopic devices can further include complex, fragile, and/or expensive components that are difficult to maintain and replace. Moreover, the current standard of care laparoscope requires a continuous power source, which is not always attainable in countries with frequent power outages.[12] Laparoscopes are also composed of several components, which must be sterilized and reassembled after each use.[9,31] If one of these parts is lost or broken, it is often difficult to replace in LMICs.[32]

Previous work has explored developing new imaging systems for surgical use. For example, investigators in LMICs have recently described attaching a 10 mm scope to the camera of a smartphone.[15] This system continues to use fiber optic cables for the light source, which are fragile, and thus not ideal for LMICs. It also uses elastic bands to hold the camera in place, while covering the apparatus with plastic sheets to obtain sterility.

The design is cumbersome, and not easily sterilizable. In high-income countries, others have investigated the utility of using a color complementary metal–oxide–semiconductor (CMOS) camera to include fluorescent images in laparoscopic surgery,[1] and those interested in single

incision laparoscopic surgery have devised a laparoscopic port that contains a CMOS camera and light-emitting diodes (LEDs).

The latter two technologies were designed to augment laparoscopic surgery in high-income countries and therefore do not address the needs of LMICs. These designs still rely on expensive components that must be separately sterilized and reassembled after each use. If one component is lost, it is difficult to obtain replacement parts in LMICs, and the device becomes unusable. The port designed for single-incision laparoscopy contains a camera that rotates out of the port after insertion, and it is not difficult to envision that this design will break easily with multiples uses.

Therefore, there is a need to design a laparoscope that is affordable and attends to the technological barriers encountered in LMICs.

To address this unmet clinical need, the present invention provides an accessible and affordable laparoscopic device and system that addresses the technological barriers described above. The design of the laparoscopic device replaces expensive and fragile fiber optics with small LEDs and a CMOS detector that sits at the tip of the laparoscope. This design significantly decreases the associated cost and complexity and does not require disassembly prior to sterilization by immersion. Moreover, images can be displayed on any laptop computer or device screen via a universal serial bus (USB) cord, preventing the need for expensive monitors and preventing loss of function during power outages.

The above therefore justifies the ongoing need for improved laparoscopic devices.

OBJECTS OF THE INVENTION

The main object of the present invention is to provide a laparoscopic device that is designed to reduce the cost and complexity of the prior art laparoscopes.

The other object of the present invention is to further avail a laparoscopic system, comprising a self- correcting camera, plastic top and water-proof elements of the device.

The other object is to provide a modular housing system, a custom miniature camera, a video autorotation system, and a strobed illumination system that is affordable and attends to the technological barriers encountered in LMICs.

The other object of the present invention is to introduce a novel method of assembly and use of a low-cost laparoscopic system for keyhole surgery that replaces expensive and fragile fiber optics with small LEDs and a CMOS detector that sits at the tip of the scope.

The other object of the present invention is to present a laparoscopic system for keyhole surgery designed to enable a significant decrease in cost and complexity of surgery, also for the simple reason that the laparoscope does not require disassembly prior to sterilization by immersion.

The object of the present invention is to bring to the market a laparoscopic system for keyhole surgery with images that can be displayed on any laptop computer or device screen via a universal serial bus (USB) cord, thereby eliminating the need for expensive monitors and preventing loss of function during power outages.

The following summary is an explanation of some of the general inventive steps for the system, method, architecture, and container in the description.

SUMMARY OF THE INVENTION

The Summary is provided to introduce a selection of concepts that are further in the detailed description. This Summary is not intended to identify key or essential features of the claimed subject matter, nor is it intended to be used as an aid in limiting the scope of the claimed subject matter.

One aspect of the present disclosure provides a laparoscopic device comprising a light source and a visual or image detector. In some embodiments, the visual detector comprises a CMOS detector. In some embodiments, the light source comprises a ring of LEDs disposed at a distal end of the device.

Another aspect of the present disclosure provides a laparoscope including: an elongated probe including a proximal end and a distal end; a handle at the proximal end of the probe; a tip at the distal end of the probe, the tip including a shelf having first surface facing the distal end of the probe and a second, opposite surface facing the proximal end of the probe; a plurality of LEDs on the first surface of the shelf; and an image detector comprising a lens adjacent the second surface of the shelf. In some embodiments: an aperture is defined in the shelf; the image detector lens is

adjacent the aperture; and/or the plurality of LEDs are on a ring-shaped substrate that surrounds the aperture.

In some embodiments, the laparoscope includes an anti-reflection coated window between the camera lens and the plurality of LEDs. In some embodiments: the tip includes a sidewall; a groove is defined in the sidewall; and/or the window is held in the groove. In some embodiments: at least one slot is defined in the sidewall; and a power wire and a ground wire extend from the ring-shaped substrate, through the at least one slot, and through the probe. In some embodiments, a distal end of the sidewall is substantially flush with the distal end of the probe. In some embodiments: the tip includes a second shelf at a proximal end of the sidewall; and a head of the image detector is on the second shelf.

In some embodiments, the laparoscope includes a plug at the proximal end of the probe. In some embodiments, the laparoscope includes a waterproof seal at an interface between the handle and the probe and at an interface between the tip and the probe such that the laparoscope can be submerged in liquid for disinfection and/or sterilization. In some embodiments, the tip is fixedly attached to the probe. In some embodiments, the probe has a fixed length. In some embodiments, the probe is rigid. In some embodiments, the probe and the tip are free of optical fibers. In some embodiments, only wires associated with the image detector and the plurality of LEDs extend through the length of the probe and the handle.

In some embodiments: a cable extends from the image detector and/or the plurality of LEDs through the probe and the handle; and the cable is configured to be connected to an electronic device such that images or video from the image detector can be viewed on the electronic device, and/or such that the electronic device can provide power to the image detector and/or the plurality of LEDs.

In some embodiments, the image detector is or includes a CMOS camera. In some embodiments, the plurality of LEDs is coated with a medical grade epoxy. In some embodiments, the laparoscope includes a second window on the plurality of LEDs. The second window may include an aperture axially aligned with the lens of the image detector such that the second window is not in the field of view of the image detector. In some embodiments, the probe and/or the tip includes stainless steel. In some embodiments, the handle includes a polymeric material.

Another aspect of the present disclosure provides laparoscopic system comprising: a laparoscope as described herein, wherein the laparoscope includes a cable including wires from the image detector and/or the plurality of LEDs extending from the handle; and an electronic device configured to receive the cable to connect to the laparoscope to display images and/or video captured by the image detector. In some embodiments, the electronic device is configured to provide power to the laparoscope with the cable connected thereto.

In some embodiments, the electronic device includes software configured to display video captured by the image detector on the electronic device with a frame rate greater than 20 frames per second. In some embodiments, the electronic device includes software configured to white balance images captured by the image detector. In some embodiments, the electronic device includes software configured to transmit images and/or video captured by the image detector to a remote location to interact with the surgery, in real time, enabling surgeons to provide mentorship.

The above summary is not an extensive overview of the invention and does not intend to limit the scope beyond what is described and claimed as a summary.

BRIEF DESCRIPTION OF THE FIGURES

The accompanying figures and examples are provided by way of illustration and not by way of limitation. The foregoing aspects and other features of the disclosure are explained in the following description, taken in connection with the accompanying example figures (also "FIG.") relating to one or more embodiments.

Figure 1 is a front view of the modular housing of a laparoscopic device according to some embodiments of the present invention.

Figure 2 is a side view of the laparoscopic device according to some embodiments of the present invention.

Figure 3 is a back view of the modular housing of a laparoscopic device according to some embodiments of the present invention.

Figure 4 is an exploded view of the modular housing of a laparoscope according to some embodiments of the present invention.

Figure 5 is the second generation of a laparoscope connected to a laptop according to some embodiments of the present invention.

Figure 6 is a section of a laparoscope according to some embodiments of the present invention.

Figure 7 is the bottom of tap of a laparoscope according to some embodiments of the present invention.

Figure 8 is a section of the cap of a laparoscope according to some embodiments of the present invention.

The above figures describe the components in the accessory, their layout, and their location. The drawings identify the various parts and the location of each compartment. The above drawings depict the complete standard accessory location sections. Customization of the mask to an equipment specific model is possible.

DETAILED DESCRIPTION OF THE INVENTION

In the following detailed description of the invention, numerous details, examples, and embodiments of the invention are described. However, it will be clear and apparent to those knowledgeable in the field that the invention is not limited to the embodiments set forth and that the invention can be adapted for a wider range of applications, and that such alteration and further modifications of

the invention as illustrated herein, being contemplated as would normally occur to one skilled in the art to which the invention relates.

In this description, the terms "comprising," "including," "containing," "characterized by," and grammatical equivalents thereof are inclusive or open-ended terms that do not exclude additional, un-recited elements or method acts, but also include the more restrictive terms "consisting of" and "consisting essentially of" and grammatical equivalents thereof. As used herein, the term "may" with respect to a material, structure, feature or method act indicates that such is contemplated for use in implementation of an embodiment of the disclosure and such term is used in preference to the more restrictive term "is" so as to avoid any implication that other, compatible materials, structures, features and methods usable in combination therewith should or must be, excluded.

The singular forms "a," "an," and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise.

The term "and/or" includes any and all combinations of one or more of the associated listed items. As used herein, relational terms, such as "first," "second," "top," "bottom," "upper," "lower," "over," "under," etc., are used for clarity and convenience in understanding the disclosure and do not connote or depend on any specific preference, orientation, or order, except where the context clearly indicates otherwise.

For the purposes of promoting an understanding of the principles of the present disclosure, reference will now be made to preferred embodiments and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the disclosure is thereby intended, such alteration and further modifications of the disclosure as illustrated herein, being contemplated as would normally occur to one skilled in the art to which the disclosure relates.

Articles "a" and "an" are used herein to refer to one or to more than one (i.e. at least one) of the grammatical object of the article. By way of example, "an element" means at least one elements and can include more than one elements.

"About" is used to provide flexibility to a numerical range endpoint by providing that a given value may be "slightly above" or "slightly below" the endpoint without affecting the desired result.

The use herein of the terms "including," "comprising," or "having," and variations thereof, is meant to encompass the elements listed thereafter and equivalents thereof as well as additional elements. As used herein, "and/or" refers to and encompasses any and all possible combinations of one or more of the associated listed items, as well as the lack of combinations were interpreted in the alternative ("or").

As used herein, the transitional phrase "consisting essentially of" (and grammatical variants) is to be interpreted as encompassing the recited materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. Thus, the term "consisting essentially of" as used herein should not be interpreted as equivalent to "comprising."

Moreover, the present disclosure also contemplates that in some embodiments, any feature or combination of features set forth herein can be excluded or omitted. To illustrate, if the specification states that a complex comprises components A, B and C, it is specifically intended that any of A, B or C, or a combination thereof, can be omitted and disclaimed singularly or in any combination.

Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. For example, if a concentration range is stated as 1% to 50%, it is intended that values such as 2% to 40%, 10% to 30%, or 1% to 3%, etc., are expressly enumerated in this specification. These are only examples of what is specifically intended, and all possible combinations of numerical values between and including the lowest value and the highest value enumerated are to be considered to be expressly stated in this disclosure.

As used herein, the term "subject" and "patient" are used interchangeably herein and refer to both human and nonhuman animals. In some embodiments, the subject comprises a human who is undergoing a laparoscopic procedure with a device as prescribed herein. The word "laparoscope" is used interchangeably with the term "laparoscopic device.'

It is noted that any one or more aspects or features described with respect to one embodiment may be incorporated in a different embodiment although not specifically described relative thereto. That is, all embodiments and/or features of any embodiment can be combined in any way and/or combination. Applicant reserves the right to change any originally filed claim or file any new claim, accordingly, including the right to be able to amend any originally filed claim to depend from and/or incorporate any feature of any other claim although not originally claimed in that manner. These and other objects and/or aspects of the present invention are explained in detail in the specification set forth below.

Unless otherwise defined, all technical terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs.

The present disclosure provides a laparoscopic technology that is low-cost, durable, and does not require a constant supply of carbon dioxide or electricity. Rather than having an expensive light

source and camera coupled to fragile fiber optic cables, the presently disclosed device is constructed with low-cost light emitting diodes (LEDs) and a camera disposed at the distal end of the device. The light source and cameras are housed in a metal probe. The device optionally comprises an ergonomic and lightweight handle.

Generally, the present invention describes a medical equipment in form of a laparoscopic device and system. It presents a method of minimal keyhole surgery. The device has a self- correcting camera, blinking light, plastic top and water-proof elements. In addition, the device has a modular housing component, a custom miniature camera, a video autorotation component, and a strobed illumination component designed to reduce the cost and complexity of the prior art laparoscopes.

In some embodiments, the camera can be a consumer-grade color complementary metal-oxide-semiconductor (CMOS) detector. The camera is illuminated by a ring of LEDs specifically designed for the disclosed laparoscope. The device optionally includes a hydrophobic window to prevent fogging of the laparoscope.

The device is electronically connected through to a laptop computer to provide power and to view a live video feed, obviating the need for expensive monitors and cables and preventing loss of function during power outages. The electronic connection can be wired, wireless, or a combination of the two (e.g., USB, Bluetooth, etc.).

In some embodiments, the laparoscope is waterproof. It can be sterilized by submersion, which is particularly advantageous in LMICs, where operating rooms may not have autoclave sterilization units.

In some embodiments, the laparoscope is designed to plug into a laptop computer, an iPad, or other handheld monitor, so that the surgeon can use these devices to display the images during surgery. Additionally, the software to control the device allows a surgeon at a remote location to interact with the surgery, in real time, enabling surgeons to provide mentorship.

Referring to **FIG. 1** – **FIG. 8**, the invention provides various embodiments of a laparoscopic device **100**, system and method for minimal keyhole surgery, comprising a modular housing system, a custom miniature camera, a video autorotation system, and a strobed illumination system designed to reduce the cost and complexity of the prior art laparoscopes.

In **FIG. 1**, the invention presents a front view of the modular housing of a laparoscope according to some embodiments of the present invention. In **FIG. 2**, the invention shows a side view of the laparoscope according to some embodiments of the present invention. In **FIG. 3**, the invention presents a back view of the modular housing of a laparoscope according to some embodiments of the present invention.

In **FIG. 4**, the invention demonstrates an exploded view of the modular housing of a laparoscope according to some embodiments of the present invention. In the drawing, the invention presents the location of a camera module **1** next to a small 'o'-ring **2** that is attached to the top cap **3**. PCB is sled **4** that communicates with tilt server **5** with a small o-ring **2** separating it with the PCB sled **4** that is fixed next to the customer PCB **6**. Further, the exploded laparoscope shows large o-rings **7** that communicates with hand grip **8**, large tube **5** and hand grip **8**. Also shown is a large tube **9**, bottom cap **10**, strain relief **11** and USB cable **12.**

FIG. 5 is the second generation of a laparoscope **100** connected to a laptop with USB cable **12** according to some embodiments of the present invention. **FIG. 6** is a section of a laparoscope according to some embodiments of the present invention. **FIG. 7** is the bottom of tap of a laparoscope according to some embodiments of the present invention. **FIG. 8** is a section of the cap of a laparoscope according to some embodiments of the present invention.

The said laparoscope **100** includes an elongated probe with a camera module **1** having opposite proximal and distal ends. The probe defines a longitudinal axis. A handle having a custom PCB **6** is at the proximal end of the probe. A tip or camera module **1** and LED holder **14A** is at the distal end of the probe designed to emit LED light **14B**. A LED assembly and an image detector or camera **1** are each held by the holder **14A**. In some embodiments, a (first) transparent window such as an anti-reflection coated window or hydrophobic window may be held by the holder **14A**.

The camera probe **1** may have a (constant) diameter of 5 mm or less to allow the camera probe **1** to be received in a standard trocar port. The probe **1** has a fixed length. In some embodiments, the length is between 10 inches and 18 inches. In some embodiments, the probe **1** is a hollow tube. In some embodiments, the probe **1** is rigid (e.g., not bendable without substantial force). The probe **1** may be formed of any suitable material; in embodiments, the probe **1** is metal; in some embodiments, the probe **1** is formed of stainless steel.

In some embodiments, the PCB embedded handle **6** includes first and second handle pieces that are fitted together to form the handle **6**. The small o-ring pieces **2** may be connected by epoxy or by ultrasonic welding to provide a watertight seal. In some other embodiments, the PCB sled handle **6** is a one-piece handle with a top cap **3**. The handle **6** may be formed of any suitable material; in embodiments, the handle **6** is polymeric; in some embodiments, the handle **6** is formed of acrylonitrile butadiene styrene (ABS).

A plug may be provided at the proximal end of the probe **1**. The plug may be at the interface of the probe **6** and the handle **8**. The plug may help to provide a waterproof laparoscope **100** along with other features described herein. The camera **1** and LED holder **14A** (also referred to herein as the tip) is shown in more detail in **FIG. 1**. The holder **6** includes a (first) shelf. The shelf includes opposing

first and second sides or surfaces. The LED assembly may be on the first surface of the shelf. The camera module **1** includes a lens that is adjacent to the second surface of the shelf.

According to **FIG 4**, an o-ring aperture **2** may be defined in the shelf. The camera lens 36 may be adjacent and/or axially aligned with the aperture.

The LED assembly may include a substrate and a plurality of LEDs on the substrate. The substrate may be a printed circuit board (PCB) **6**. In some embodiments, the substrate is o-ring-shaped and surrounds the aperture **2** of the shelf; the substrate may include an aperture that is axially aligned with the aperture **2** of the shelf. In some embodiments, the underside of the substrate (opposite the LEDs), the aperture, and/or side surfaces of the LEDs are coated with black epoxy to black out light leakage from the side of the LEDs into the camera **1**. The LED holder **14A** may include a sidewall. A groove may be defined in the sidewall. In some embodiments, the window is received in the groove.

The sidewall may include a proximal end portion on one side of the shelf and a distal end portion on the other side of the shelf. The proximal end portion of the sidewall may include at least one slot defined therein. The LED holder **14B** assembly may include a power wire and a ground wire. The power wire and the ground wire may extend from the substrate, through the at least one slot 46, and through the probe and handle **6**. In some embodiments, the at least one slot includes first

and second slots, with the power wire extending through the first slot and the ground wire extending through the second slot.

The holder may be received in the probe. In some embodiments, a distal end of the sidewall may be flush or axially coextensive with the distal end of the camera module probe **1**.

A second shelf may be at a proximal end of the sidewall. The camera module **1** may include a head and a body extending from the head toward the proximal end of the probe **1**. The head may be on the second shelf. A slot may be defined in the second shelf and the body may extend through the slot. The proximal end portion of the sidewall may include an o-ring opening **2** for receiving the camera module **1** through the opening. The opening **2** nay also facilitate inserting the window into the groove.

There may be a seal at the interface of the probe **1** and the holder **14A**, at the interface of the probe **1** and the handle **6**, and/or between the pieces of the handle **6** (where multiple pieces are used). The seal may be or include medical grade epoxy. The seal may allow the laparoscope **100** to be waterproof such that the laparoscope **100** can be submerged in liquid for sterilization as taught in **FIG. 1**.

In some embodiments, the holder **14A** is fixedly attached to the probe **1** (e.g., using medial grade epoxy). The holder **6** may be formed of any suitable material; in embodiments, the holder **6** is metal; in some embodiments, the holder **6** is formed of stainless steel. The LEDs 14A may be coated with medical grade epoxy. In some other embodiments, a second transparent window such as a second anti-reflection window or hydrophobic window may be positioned over the LEDs 14A. The second window may be ring-shaped with an aperture axially aligned with the camera lens such that the second window is not in the field of view of the camera. The second window may include apertures or slots to allow the wires, to extend therethrough.

In some embodiments, the laparoscope including the probe **1** and the holder **14A** are free of optical fibers for illumination. Optical fibers can be fragile, and their absence allows for a more robust device. The use of LEDs **14B** instead of optical fibers helps to reduce cost, increase durability, and reduce weight of the device **100**. In some embodiments, only wires from the camera module **1** and/or the LED assembly **14A** (or a cable associated therewith) extend through a

major portion of the length of the probe **1** (including the proximal end **14B**) and the handle **6**. The probe **1** defines an inner cavity (**FIG. 4**).

In some embodiments, the only components in the cavity are the camera **1** and wires and cables associated therewith, the holder, the window, the LED assembly and wires and cables associated therewith, and any attachment or connection features (e.g., epoxy and solder). In some embodiments, the laparoscope **100** consists of or consists essentially of the probe **1**, the handle 18, the camera **1** and wires and cables associated therewith, the holder, the window, the LED assembly **14A** and wires and cables **12** associated therewith, and any attachment or connection features (e.g., epoxy and solder). In some embodiments, the laparoscope **100** weighs less than 1 kg. In some other embodiments, the laparoscope 10 weighs less than 0.5 kg.

Referring to **FIG. 4** and **FIG. 5**, the wires from the camera module **1** and/or the LED assembly **14A** may be included in a cable **12** that may be connected to an electronic device **13** that may be a laptop computer, a desktop computer, a tablet computer, and the like. The connection of the laparoscope to the electronic device **13** allows for images and/or video captured by the camera **1** to be displayed on a display of the electronic device. In addition, the electronic device **13** may provide power to the camera **1** and/or the LEDs **14B** which may be useful in locations with intermittent power. The cable **12** may be a USB cable or cord with a USB connection, but the present invention is not limited thereto and one of ordinary skill in the art will be aware that the cable **12** and electronic device **13** may use some other form of connection (wired or wireless).

In some embodiments, the wires associated with the camera **1** (e.g., data wire(s), power wire, ground wire) may be included in the cable **12** and the wires associated with the LEDs **14B** (e.g., power wire, ground wire) may be included in a second cable **12** that extends from the hand grip handle **8** of the laparoscope **100** as illustrated in **FIG. 4**. The second cable **12** may be connected to an external power source to provide power to the LEDs **14B**. The second cable **12** may be a BNC cable or cord with a BNC connection, but the present invention is not limited thereto and one of ordinary skill in the art will be aware that the cable **12** and power supply may use some other form of connection.

A strain relief **11** may be included on the back of the handle **8** to help prevent damage to connections such as solder joints inside the device **100**.

The following Example is provided by way of illustration and not by way of limitation.

Example

Laparoscopic Device Prototype

Laparoscopic surgery is the standard of care in high-income countries for many procedures in the chest and abdomen. It avoids large incisions by using a tiny camera and fine instruments manipulated through keyhole incisions, but it is generally unavailable in low- and middle-income countries (LMICs) due to the high cost of installment, lack of qualified maintenance personnel, unreliable electricity, and shortage of consumable items. Patients in LMICs would benefit from laparoscopic surgery, as advantages include decreased pain, improved recovery time, fewer wound infections, and shorter hospital stays.

To address this need, the present inventors developed an accessible laparoscopic system, called the laparoscope **100** for use in LMICs. The device includes an integrated camera and LED light source that can be displayed on any monitor. The laparoscope **100** was evaluated with standard optical imaging targets to determine its performance against a state-of-the-art commercial laparoscope. The laparoscope **100** has a comparable resolving power, lens distortion, field of view, depth of field, and color reproduction accuracy to a commercially available endoscope, particularly at shorter, commonly used working distances (3-5 cm).

Additionally, the laparoscope **100** has a cooler temperature profile, decreasing the risk for tissue injury and operating room fires. The device features a waterproof design, enabling sterilization by submersion, as commonly performed in LMICs. A custom desktop software was developed to view the video on a laptop computer **13** with a frame rate greater than 30 frames per second and to white balance the image, which is critical for clinical use. The laparoscope **100** is capable of providing the image quality and overall performance needed for laparoscopic surgery. This portable low-cost system is well suited to increase access to laparoscopic surgery in LMICs.

Laparoscopic surgery is the standard of care in high income countries for many procedures in the abdomen and chest, such as cancer excision, organ resection, and treatment of other surgical diseases. It avoids large incisions associated with open surgery by using a small camera and fine instruments manipulated through keyhole incisions. Advantages of laparoscopic surgery include smaller incisions, decreased pain, improved recovery time, minimized post-surgical infections,

and shorter hospital stays. Patients in low- and middle- income countries (LMICs) would further benefit from laparoscopic surgery since the reduced recovery time would enable patients to return to home and work more quickly, thus mitigating impoverishing health costs. Laparoscopic surgery would reduce postoperative complications in overcrowded wards and minimize the stigma associated with certain surgical conditions.

Despite these advantages, laparoscopic surgery is rare in LMICs, and patients often receive open surgery instead, representing a great health care disparity. There is an initial equipment purchase cost of USD133,000- USD136,000 for each operating room that includes the components of the laparoscope, viewing monitors and related equipment—a cost that is prohibitive for most health systems in LMICs. Current laparoscopic technology uses fragile fiber optic cables, cameras, and lenses that require repair, necessitating annual service contracts. Moreover, the current standard of care laparoscope requires a continuous power source, which is not always attainable in countries with frequent power outages. Laparoscopes **100** are also composed of several components, which must be sterilized and reassembled after each use. If one of these parts is lost or broken, it is often difficult to replace in LMICs.

Previous work has explored developing new imaging systems for surgical use. For example, investigators in LMICs have recently described attaching a 10 mm scope to the camera **1** of a smartphone. This system continues to use fiber optic cables for the light source, which are fragile, and thus not ideal for LMICs. It also uses elastic bands to hold the camera in place, while covering the apparatus with plastic sheets to obtain sterility.

The design is cumbersome, and not easily sterilizable. In high-income countries, others have investigated the utility of using a color complementary metal–oxide–semiconductor (CMOS) camera **1** to include fluorescent images in laparoscopic surgery, and those interested in single incision laparoscopic surgery have devised a laparoscopic port that contains a CMOS camera **1** and light-emitting diodes (LEDs) **14B**. The latter two technologies were designed to augment laparoscopic surgery in high-income countries and therefore do not address the needs of LMICs.

These designs still rely on expensive components that must be separately sterilized and reassembled after each use. If one component is lost, it is difficult to obtain replacement parts in LMICs, and the device becomes unusable. The port designed for single-incision laparoscopy contains a camera that rotates out of the port after insertion, and it is not difficult to envision that

this design will break easily with multiples uses. Therefore, there is a need to design a laparoscope **100** that is affordable and attends to the technological barriers encountered in LMICs.

To address this unmet clinical need, the present inventors designed an accessible device called the laparoscope that addresses the technological barriers described above. The design of our device replaces expensive and fragile fiber optics with small LEDs **14B** and a CMOS detector that sits at the tip of the scope. This design enables a significant decrease in cost and complexity and does not require disassembly prior to sterilization by immersion. Moreover, images can be displayed on any laptop computer or device screen via a universal serial bus (USB) cord **12**, obviating the need for expensive monitors and preventing loss of function during power outages.

Laparoscopic System Design

The laparoscope (**FIG. 1**) contains a custom color 2.0-megapixel CMOS camera for video and image capture surrounded by a custom ring of 8 high intensity white LEDs to illuminate the abdomen with white light. The camera **1** was selected because of its small diameter, which is less than 5.5 mm, allowing it to fit within a standard trocar port. The working distance of the camera is 3–12 cm, which are common distances used by surgeons during laparoscopy. The CMOS camera **1** is joined to a USB cord that can be connected to a laptop computer for imaging. A custom printed circuit board **6** was designed to mount the LEDs **14B**, with an outer diameter less than 5.5 mm and the inner diameter to accommodate the aperture of the CMOS detector.

Rather than using multiple components that must be pieced together after each sterilization, our device has been constructed as an integrated instrument. The camera and light source have been moved to the tip, which is protected by a hydrophobic window to prevent fogging that could obscure the image during surgery. The scope was made from stainless steel while the handle is made from plastic. These materials are easily sterilizable and biocompatible.

The laparoscope and handle contain only the wires from the light source and camera, contributing to a light-weight design of less than 0.25 kg. The resulting cord from the light source and camera can be attached to a laptop computer for image viewing and powering the device. A strain relief is included on the back of the handle to prevent the user from damaging the solder joints inside the device. To prevent any bodily fluids from entering the device and damaging the inner electronics,

waterproof seals were created between the hydrophobic window and probe, between the probe **1** and the handle **8**, and along the handle.

Image Quality Characterization

To assess the image quality and performance of the device, a series of targets were imaged with the device camera and compared to a commercial laparoscope (*Karl Storz, Tuttlingen, Germany*). A custom optical set-up was used to acquire images of various imaging targets as previously described. Each target was imaged at working distances commonly used by surgeons during laparoscopic surgery. Three images were acquired at each working distance, so that an average and standard deviation of various image parameters could be calculated from the images of the targets. To maintain consistent illumination, two lightbulbs angled at 20° to 40° were placed on either side of the target and a white backdrop was placed behind the target. The entire system was then enclosed in a black box to minimize reflections and outside light interference.

First, a USAF 1951 resolution target (*Thorlabs, R3L3S1P*) was used to discern the minimal line width that could be resolved by the camera. The resolving power (in microns) was assessed using open-source software, ImageJ (*University of Wisconsin – Madison*). Specifically, a line was drawn through all of the elements within a group, and the pixel values were plotted using the 'plot profile' function in Image J. The point at which the ratio of peak (white pixels) to trough (black pixels) fell below was considered the limit of resolution. This testing was completed with the laparoscope and compared to the standard of care (SOC) laparoscope **100**.

The radial lens distortion was assessed by imaging a checkerboard geometric distortion target (Applied Image Incl, QI-SFR15-P-CG) at multiple working distances. The images were analyzed using Imatest (Imatest, Boulder CO), which determined if distortion was present. Specifically, the percentage of distortion was calculated by using standard mobile imaging architecture (SMIA) TV Distortion:

$$\%Distortion = \frac{100 \times (A - B)}{B} \qquad (1)$$

$$A = \frac{A_2 - A_1}{2} \qquad (2)$$

where A1 and A2 are the outer side lengths of a square while B is the distance between the midpoints of the sides of the square.

The distortion target was also used to calculate the diagonal of view (DFOV) of the camera in Imatest software. The DFOV was calculated to determine the projected field and compared with the SOC laparoscope 100.

To determine the furthest discernable distance from the camera's tip, the depth of field of the camera probe **1** was assessed by imaging a depth of field gauge (Edmund Optics, 54-440) at various working distances with a similar optical setup as described previously. The images were analyzed using Image and compared to the SOC endoscope. A line was drawn through the column of lines at the right-hand side of the target, which has 5-line pairs per millimeter. The pixel values were plotted using the 'plot profile' function in Image, and the difference between the first full peak (white pixels) to trough (black pixels) was determined. The point at which the difference between the peak and trough fell below half of the initial value was considered the depth of field.

The color accuracy and tone of the camera was assessed by imaging the NIST-calibrated X-Rite Rez Checker Target (Edmund Optics, 87-422). The target was imaged using a similar optical setup. The working distance was adjusted so that the entire color target could be captured in a single image. The images of the color target were assessed using open-source image processing software, Imatest. The software calculated the difference between the known reference and measured color space values using the Euclidean distance equation accounting for luminance differences between the reference and measured data:

$$\Delta E*_{ab} = \left[\sqrt{\left((\Delta L*)^2+(\Delta a*)^2+(\Delta b*)^2\right)}\right] \qquad (3)$$

where ΔL* is the difference in luminance between the reference and measured data, and Δa*and Δb* are the color-opponent dimensions. The perceptible color difference that does not account for luminance difference can be calculated using the following:

$$\Delta C*_{ab} = \left[\sqrt{(\Delta a*)^2+(\Delta b*)^2)}\right] \qquad (4)$$

Characterization of Illumination

Light intensity quantification of the device was completed by mounting the device into the custom optical setup. The illumination was measured with a B&K Precision 615 Light Meter (Digikey, BK615-ND) at common working distances used by surgeons. The device was aimed towards the center of the detector on the lux meter and enclosed in a black box to remove any outside light or interference.

These measurements were then compared to the SOC laparoscope, which could be varied from 0 to 100% illumination. Specifically, for each working distance measurements were taken at 30% intensity (which is the minimum light intensity currently used during surgery) up to where the lux meter was saturated. Three repeated measurements were taken at each working distance from which the average and standard deviation were calculated.

Thermal Testing

To ensure patient safety, thermal testing of the device was conducted. The device was placed in the optical setup described in previous sections, turned on, and measurements were taken at 10-min intervals over a 90-min period using a non-contact IR thermometer (Fluke, 62 Max +). Each measurement was taken at the probe tip, near the inner electronics of the device, at the mid-way point along the probe and at the probe-handle interface.

Waterproofing of Device

Autoclave machines are commonly used in HICs and use pressurized steam at 121 °C for 15–20 min to achieve sterilization of medical instruments. In many LMIC hospitals, autoclave machines are unavailable due to issues with power supply, water pressure, or steam capacity. Thus, it is common practice to sterilize medical instruments by immersion using agents such as bleach, chlorine, or Cidex OPA solutions.

In the device, both the stainless-steel probe and plastic handle are Cidex OPA compatible materials. Waterproof testing was performed to ensure the isolation of the inner electronics of the device. To assess whether the device was adequately waterproofed, the entire laparoscope was submerged in water for 1 hour and then tested for functionality.

RESULTS

Image Quality

A resolution target was imaged with both the laparoscope and the SOC laparoscope. Lower values indicate a superior resolution since smaller objects are more easily discernable. Thus, these results portray that the device has a comparable or better resolution to the SOC laparoscope at working distances ranging from 3 to 12 cm, which covers the range of working distances used during laparoscopic surgery.

During surgery, it is important to have an accurate representation of the size and shape of structures and limit the projected image's distortion percentage. To assess distortion, a distortion target was imaged with both the device and SOC laparoscopes. At 3 cm, the laparoscope has a lower percentage of distortion in comparison to the SOC laparoscope. This analysis shows that the laparoscope does not have significant optical aberrations, indicating that this camera can accurately image targets with minimal distortion.

The diagonal field of view (DFOV) is directly proportional to the area that can be viewed, thus a larger field of view during surgery would allow a surgeon to observe a larger imaging field. It is beneficial during surgery to have an increased field of view to obtain a complete visual of the body. The experimental results show that the device had a larger DFOV in comparison to the SOC. This indicates that the device can capture a larger area at each working distance in comparison to the SOC.

While the DFOV provides information about the area that can be viewed in a single image/frame, the camera's depth of field capabilities determines the distance between the nearest and furthest objects in an image that is in focus with the camera. During surgery, it may be beneficial to achieve a large depth of field in order to obtain all information without needing to refocus or relocate the device. The depth of field assessment in which the device had a superior depth of field at a working distance of 3 cm.

The color accuracy of the projected image is important during surgery because certain procedures require accurate classification of tissue which is dependent on the color. The mean color error can compare the device and the SOC. For both color accuracy tests, the device had a superior color

accuracy in comparison to the SOC laparoscope, which would benefit surgeons during laparoscopy.

Illumination Testing

During laparoscopic surgery, the area under investigation must be illuminated in order to produce a clear image. To assess the illumination quality, a series of experimental tests were conducted at various working distances and compared to the SOC laparoscope at 30% intensity (minimum light intensity currently used during surgery). The device had an inferior light intensity value (lux) in comparison to the SOC because it uses an LED light source. *In vivo* testing will be used to confirm that the light intensity of the device is sufficient for surgery.

Thermal Testing

To determine whether the device operates at a safe temperature for insertion in the human body, thermal testing was completed. First-degree skin burns occur at 48 °C for direct contact with human skin lasting less than 10 minutes in duration, and this is the IEC 60,601 approved temperature limit. The device performed at temperatures of 25–43 °C. This is well below 48 °C, indicating a safe operating temperature for surgical use.

Waterproof Testing

To protect the inner electronics while the laparoscope **100** is in use and during sterilization by immersion, a waterproof design of the entire device is required. As described in the methods section, the laparoscope was also submerged in its entirety for one (1) hour, then tested and demonstrated to be fully functional.

Biological Tissue Imaging

Representative images of human skin acquired with the device and SOC laparoscopes are explained. Both images were taken at a 5 cm working distance. As seen, similar features such as fingerprints and the grains of the blue towel can be detected in each image.

Additionally, the laparoscope was tested in the porcine model and pictures were taken with the laparoscope and SOC laparoscope to enable side by side comparison. Similar anatomical features

and details can be seen, suggesting that the laparoscope can provide comparable image quality *in vivo*.

DISCUSSION

The laparoscope **100** according to **FIG. 1** was uniquely designed to address the specific needs of LMICs. This simple design uses affordable and robust electrical components that are securely enclosed in a lightweight case. The waterproofed enclosure allows for sterilization by immersion, a common technique used in LMICs. Due to elimination of fragile fiber optics and replacement with inexpensive electronics, the need for annual service contracts and expensive replacements are eliminated. Furthermore, the live video image can be displayed via USB to any viewing monitor such as a laptop, smartphone, or television.

It has been shown through various analyses that the device camera has comparable functionality to that of a SOC laparoscope and can be safely used during surgery. The device camera resolved the smallest feature size of 86 μm at a working distance of 3 cm, exceeding the SOC's resolution capability of 109 μm at this working distance. While the device demonstrated a small amount of lens distortion, this value was a fraction of the SOC's image distortion at 3 cm. Further, the device can capture a larger area at all relevant working distances in comparison to the SOC, with a significant increase in diagonal field of view. This allows surgeons to image a larger area and gain more information about the area of interest in the patient.

The laparoscopic device **100** possesses a minor color error of 8%, which is a significant improvement in comparison to the SOC's color error of 20%. Imaging accurate colors allows surgeons to differentiate between diseased and healthy tissue and is a necessity during surgery. The aforementioned camera characterization indicates that the device has comparable imaging capabilities to current commercial laparoscopes and can produce an accurate image during surgery.

The device offers many safety advantages in comparison to current commercial laparoscopic systems. The device scope tip **14B** remained well below 48 °C, a temperature significantly lower than the SOC's operating temperature of 100 °C. The LEDs allow for cooler operating temperatures and can decrease the number of operating room fires. These cooler temperatures will also minimize inadvertent intestinal burns, which can cause delayed bowel perforation and

subsequent abdominal sepsis. Additionally, the current weight of the device (<0.25 kg) is significantly lighter than the SOC laparoscope (6.5 kg). The lightweight handle and elimination of heavy fiber optics contributes to the ergonomic design and will alleviate surgeon fatigue.

Moreover, in the event of a power outage, the device will have continued functionality due to the device's outlet-free design. Because the device can be plugged into any electronic display system via USB, the laparoscope cord length can be adjusted by simply adding a retractable USB extender. This distinct feature would minimize operating room injuries due to tripping over exposed medical equipment cords.

Due to the compact and affordable design, the laparoscope does not have a comparable light intensity to the output of the SOC. Although the lux values are inferior to the SOC, the results indicate that the device achieves approximately a third to half that of the SOC. *In vivo* testing indicates the device light intensity is sufficient to perform surgery. The design of the device will continue to be optimized for manufacturing through work with an industry partner, which will facilitate the construction of more units. Parts that are currently 3D printed will be transitioned to injection molding, and other parts will be available for bulk purchase. These modifications will likely decrease the cost of goods per unit.

Our research team is currently seeking regulatory approval through the Uganda National Drug Authority, after which the laparoscope will be tested in a first-in-human clinical trial at the Ugandan Cancer Institute. Simultaneously, we are establishing a medical device manufacturing company in Uganda with the goal of building and locally distributing laparoscopes in Uganda, followed by other countries in Africa, and in other LMICs.

The laboratory testing of the device prototype indicates comparable performance (resolution, field of view, distortion, depth of field, color accuracy) to the SOC laparoscope while also addressing some of the barriers to implementation in LMICs. Specifically, the device is built with low-cost consumer grade electronics, does not rely on consistent electricity, does not require regular maintenance or qualified maintenance personnel, can be easily sterilized with chemical immersion, and can be used with a standard laptop computer **13**. This portable system is well suited to increase access to laparoscopic surgery in LMICs.

BEST MODE OF CARRYING OUT THE INVENTION

The present invention comprises a novel type of laparoscope**100** as shown in **FIG. 4** for minimally invasive surgeries, but at a low enough cost that it can be readily adopted in developing nations since standard of care laparoscopes currently cost 100s/hundreds of thousands of dollars. It aims to have the same features as these SoC scopes, similar or better video quality, reusability, but also the ability to be constructed in-country without the need for the specialized hardware required in building SoC scopes.

The following are key elements of the laparoscopic device:

- self- correcting camera, and
- plastic top and water- proof elements of the device.

The other related novel features of the invention arise from four main areas:

- a modular housing system,
- a custom miniature self-correcting camera,
- a video autorotation system, and
- a strobed illumination light system.

The first novel part of our invention is the housing of the laparoscope **100**. SoC laparoscopes are typically made out of stainless steel with a complicated arrangement of imaging lenses, and possibly additional attachments for using the camera tube for gas insufflation. This housing alone can cost many thousands of dollars to replace. Part of the reason for this cost is because the camera processing hardware and illumination source must be kept in a large cart next to the operating table since the light source is too hot to be near the body, and the camera body is too large to fit inside the laparoscope **100**.

SoC laparoscope camera bodies normally clip onto the proximal end of the laparoscope. Because we are using a custom camera that sits at the tip of the laparoscope, the housing can be greatly simplified. The housing contains modular components for the camera tube, handle, end caps, seals, cord grip, and cable connectors. Different variations can be made/swapped out depending on user preference. It also lends itself to be repairable if needed.

In **FIG.** 4, the invention shows an exploded view of the modular housing. From bottom-left to top-right: cord grip, end cap, proximal large o-ring seal **2**, tube grip **8**, aluminum tube **9**, proximal

camera tube **1** o-ring seal **2**, distal large tube **9** o-ring seal, top cap **4**, orientation indicator, distal camera tube o-ring seal, camera tube and camera.

The second part of our invention is a custom miniature camera. A specified and technically constructed miniature digital camera which sits at the tip of the laparoscope **100**, and also contains a LED **14B** ring for illumination, and a protective window in front of both. The camera operates at 640x480 30fps and provides crisp video for the surgeon. A major issue in laparoscopy **100** is having sufficient illumination on the target since some parts of the body are less reflective than others.

In the design arrangement, the LEDs **14B** are driven separately so we can pulse them at a high frequency, but low duty cycle. We then sync this strobing with the frame clock of the camera, allowing for bright illumination while the camera is exposing, but keeping the LEDs **14B** off the rest of the time. This greatly reduces heat generation, keeping the tip of the scope cooler. Which is quite important as SoC cameras (using halogen/xenon sources) can get so hot they can burn tissue. Finally, the camera is customized with a wide angle, short working distance lens which allows the user to have a good working FOV, but also keep things in focus, even up close.

The third part of our invention is the image autorotation system. An interesting aspect of SoC laparoscopes is that because the camera **1** is located separately from the part going into the body, the image orientation always appears the same, regardless of the rotation of the inserted part.

In order to eliminate this issue, we have embedded a two-axis tilt sensor in the housing. This angular information is sent back to the control computer over USB along with the video stream, where it is adjusted in real-time to provide the user with a stable image, regardless of how the laparoscope is being rotated. The invention has the custom GUI with a live video feed, also indicating the current rotation angle.

It has live control GUI features. The final part of our invention is the strobed illumination system. LEDs **14B** have a useful property where they can be driven at a higher-than-normal voltage to provide greatly increased brightness. The downside is that the amount of time they can be at this level is less because they need time to cool off. However, because a camera is only actually exposing its sensor to incoming photons for a short period of time (most of the time per frame is used by the electronics to actually read out the pixels), if you can synchronize the LEDs to the

frame timer of the camera, you can pulse the LEDs at a much higher power, but then leave them off most of the time to cool off in between exposures. To that end, we have built a custom LED pulsed power supply which resides in the laparoscope housing, but which is triggered by the frame sync out signal of the camera.

Typically, the LEDs only have to be on about 10% of the time, which helps keep the camera cool but also greatly improves the image quality of the laparoscope.

The control systems described herein can be implemented in hardware, software, firmware, or combinations of hardware, software and/or firmware. In some examples, the control systems described in this specification may be implemented using a non-transitory computer readable medium storing computer executable instruction that when executed by one or more processors of a computer cause the computer to perform operations. Computer readable media suitable for implementing the control systems described in this specification include non-transitory computer-readable media, such as disk memory devices, chip memory devices, programmable logic devices, random access memory (RAM), read only memory (ROM), optical read/write memory, cache memory, magnetic read/write memory, flash memory, and application-specific integrated circuits. In addition, a computer readable medium that implements a control system described in this specification may be located on a single device or computing platform or may be distributed across multiple devices or computing platforms.

The foregoing is illustrative of the present invention and is not to be construed as limiting thereof. Although a few exemplary embodiments of this invention have been described, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the claims. The invention is defined by the following claims, with equivalents of the claims to be included therein.

INDUSTRIAL APPLICATION

The present invention applies to the field of medical equipment. It introduces a laboratory testing of the device prototype indicates comparable performance (resolution, field of view, distortion, depth of field, color accuracy) to the SOC laparoscope while also addressing some of the barriers

to implementation in LMICs. Specifically, the device is built with low-cost consumer grade electronics, does not rely on consistent electricity, does not require regular maintenance or qualified maintenance personnel, can be easily sterilized with chemical immersion, and can be used with a standard laptop computer. This portable system is well suited to increase access to laparoscopic surgery in LMICs.

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CLAIMS

We claim;

1. A laparoscopic device for minimally invasive surgeries, comprising:

   a modular housing component with a plastic top and water-proof elements of the device;

   a self-correcting custom miniature camera

   a video image autorotation component with strobed illumination component.

2. The laparoscopic device of claim 1, wherein the modular housing component contains a plastic top and water-proof elements, modular components for the camera tube, handle, end caps, seals, cord grip, and cable connectors with different variations that can be made/swapped out depending on user preference, designed to lend itself to be repairable if needed.
3. The laparoscopic device of claim 2, wherein the modular housing further comprises a cord grip, end cap, proximal large o-ring seal, tube grip, aluminum tube, proximal camera tube o-ring seal, distal large tube o-ring seal, top cap, orientation indicator, distal camera tube o-ring seal, camera tube and camera.
4. The laparoscopic device of claim 2, wherein the modular housing component is typically made of stainless steel with a complicated arrangement of imaging lenses and possibly additional attachments for using the camera tube for gas insufflation characterized in that the camera processing hardware and illumination source are kept in a large cart next to the operating table since the light source is too hot to be near the body, and the camera body is too large to fit inside the laparoscope.
5. The laparoscopic device of claim 1, wherein the self-correcting custom miniature camera is a specified and technically constructed miniature digital camera which sits at the tip of the laparoscope, and also contains a LED ring for illumination, and a protective window in front of both characterized in that the camera operates at 640x480 30fps and provides crisp video for the surgeon to enable the laparoscopy to have sufficient illumination on the target since some parts of the body are less reflective than others.
6. The laparoscopic device of claim 5, wherein:

the LEDs are driven separately and can therefore be pulsed at a high frequency, but low duty cycle to enable the user to sync the strobing mechanism with the frame clock of the camera;

allowing for bright illumination while the camera is exposed;

keeping the LEDs off the rest of the time so as to reduce heat generation;

keeping the tip of the scope cooler to ensure that the cameras (using halogen/xenon sources) do not get so hot to burn tissue, and

customizing the camera with a wide angle, short working distance lens which allows the user to have a good working FOV, but also keep things in focus, even up close.

7. The laparoscopic device of claim 1, wherein the image video autorotation component is embedded in a two-axis tilt sensor in the housing characterized in that the angular information is sent back to the control computer over USB along with the video stream, where it is adjusted in real-time to provide the user with a stable image, regardless of how the laparoscopic device is being rotated.

8. The laparoscopic device of claim 7, wherein the image autorotation component comprises a camera located separately from the part going into the body so that the image orientation always appears the same, regardless of the rotation of the inserted part.

9. The laparoscopic device of claim 1, wherein the strobed illumination component has an inbuilt custom LED pulsed power supply which resides in the laparoscope housing, but which is triggered by the frame sync out signal of the camera, typically designed in such a way that the LEDs are on for about 10% of the time, which helps keep the camera cool but also greatly improves the image quality of the laparoscope.

10. A laparoscopic device with a modular housing, video image and strobed illumination components designed for minimal keyhole surgery comprising a custom miniature camera, comprising:

a digital camera designed to sit at the tip of the laparoscopic device;

a LED ring for illumination;

a protective window in front of both in that the camera operates at 640x480 30fps, and

a means for crisping video for the surgeon.

11. The laparoscopic device of claim 10, wherein the device has sufficient illumination on the target.

12. The laparoscopic device of claim 10, wherein the LEDs are driven separately to enable pulsation at a high frequency, but low duty cycle so that the sync of the strobing with the frame clock of the camera can allow for bright illumination while the camera is exposing, but keeping the LEDs off the rest of the time characterized in that it greatly reduces heat generation by keeping the tip of the scope cooler.

13. The laparoscopic device of claim 12, wherein the camera is customized with a wide angle, short working distance lens which allows the user to have a good working field of view, keeping things in focus and even up close.

14. A laparoscopic device with a modular housing, video image and strobed illumination components and further comprising:

an elongated probe comprising a proximal end and a distal end;

a handle at the proximal end of the probe;

a tip at the distal end of the probe, the tip comprising a shelf having first surface facing the distal end of the probe and a second, opposite surface facing the proximal end of the probe;

a plurality of LEDs on the first surface of the shelf, and

an image detector further comprising a lens adjacent to the second surface of the shelf.

15. The laparoscopic device of claim 14, wherein:

the shelf further comprises an aperture;

the image detector lens is adjacent to the aperture;

the plurality of LEDs is on a ring-shaped substrate that surrounds the aperture, and

the device further comprises an anti-reflection coated window between the camera lens and the plurality of LEDs.

16. The laparoscopic device of claim 15 wherein the tip of the device further comprises a sidewall, a groove confined in the sidewall and a window is held in the groove, wherein at least one slot is confined in the sidewall, and further comprises a power wire and a ground wire extending from the ring-shaped substrate, through at least one slot through the probe.

17. The laparoscopic device of claim 16 wherein the distal end of the sidewall is substantially flush with the distal end of the probe and the tip comprises a second shelf at a proximal end of the sidewall and a head of the image detector is on the second shelf.

18. A laparoscopic device having a modular housing, video image and strobed illumination components and further, comprising:

a plug at the proximal end of the probe;

a waterproof seal at an interface between the handle and the probe and at an interface between the tip and the probe such that the laparoscope can be submerged in liquid for disinfection and/or sterilization;

a plurality of LEDs;

cable extensions;

a tip is fixedly attached to the probe, and

a probe has a fixed length.

19. The laparoscopic device of claim 18, wherein the probe is rigid.

20. The laparoscopic device of claims 18 and 19, wherein the probe and the tip and are free of optical fibers and comprise stainless steel while the handle comprises a polymeric material.

21. The laparoscopic device of claim 18, wherein the device further comprises wires associated with the image detector and the plurality of LEDs extending through the length of the probe and the handle.

22. The laparoscopic device of claim 21, wherein the image detector comprises a CMOS camera.

23. The laparoscopic device of claim 18, wherein the cables:

are designed to extend from the image detector and/or the plurality of LEDs through the probe and the handle; and

are configured to be connected to an electronic device such that images or video from the image detector can be viewed on the electronic device, and/or such that the electronic device can provide power to the image detector and/or the plurality of LEDs.

24. The laparoscopic device of claim 23, wherein the plurality of LEDs is coated with a medical grade epoxy.

25. The laparoscopic device of claim 24, wherein the device further comprises a second window on the plurality of LEDs.

26. The laparoscopic device of claim 25, wherein the second window further comprises an aperture axially aligned with the lens of the image detector such that the second window is not in the field of view of the image detector.

27. A laparoscopic device comprising:

a laparoscope further comprising a cable comprising wires from the image detector and/or the plurality of LEDs extending from the handle; and

an electronic device configured to receive the cable to connect to the laparoscope to display images and/or video captured by the image detector.

28. The laparoscopic device of claim 27, wherein the electronic device is configured to:

provide power to the laparoscope with the cable connected thereto;

comprises a software configured to display video captured by the image detector on the electronic device with a frame rate greater than 15 frames per second;

comprise a software configured to white balance images captured by the image detector, and

comprise a software configured to transmit images and/or video captured by the image detector to a remote location to interact with the surgery, in real time, enabling surgeons to provide mentorship.

ABSTRACT

Title: Laparoscopic Device

Disclosed in the present invention is an accessible laparoscopic device for minimally invasive surgeries, comprising a self-correcting camera, plastic top and water-proof elements of the device. The device further comprises a modular housing system, video image autorotation system and strobed illumination system. The modular housing system contains modular components for the camera tube, handle, end caps, seals, cord grip, and cable connectors with different variations that can be made/swapped out depending on user preference, designed to lend itself to be reparable if needed. The modular housing further comprises a cord grip, end cap, proximal large o-ring seal, tube grip, aluminum tube, proximal camera tube o-ring seal, distal large tube o-ring seal, top cap, orientation indicator, distal camera tube o-ring seal, camera tube and camera. The image video autorotation system is embedded in a two-axis tilt sensor in the housing characterized in that the angular information is sent back to the control computer over USB along with the video stream.

FIGURES

FIG. 1

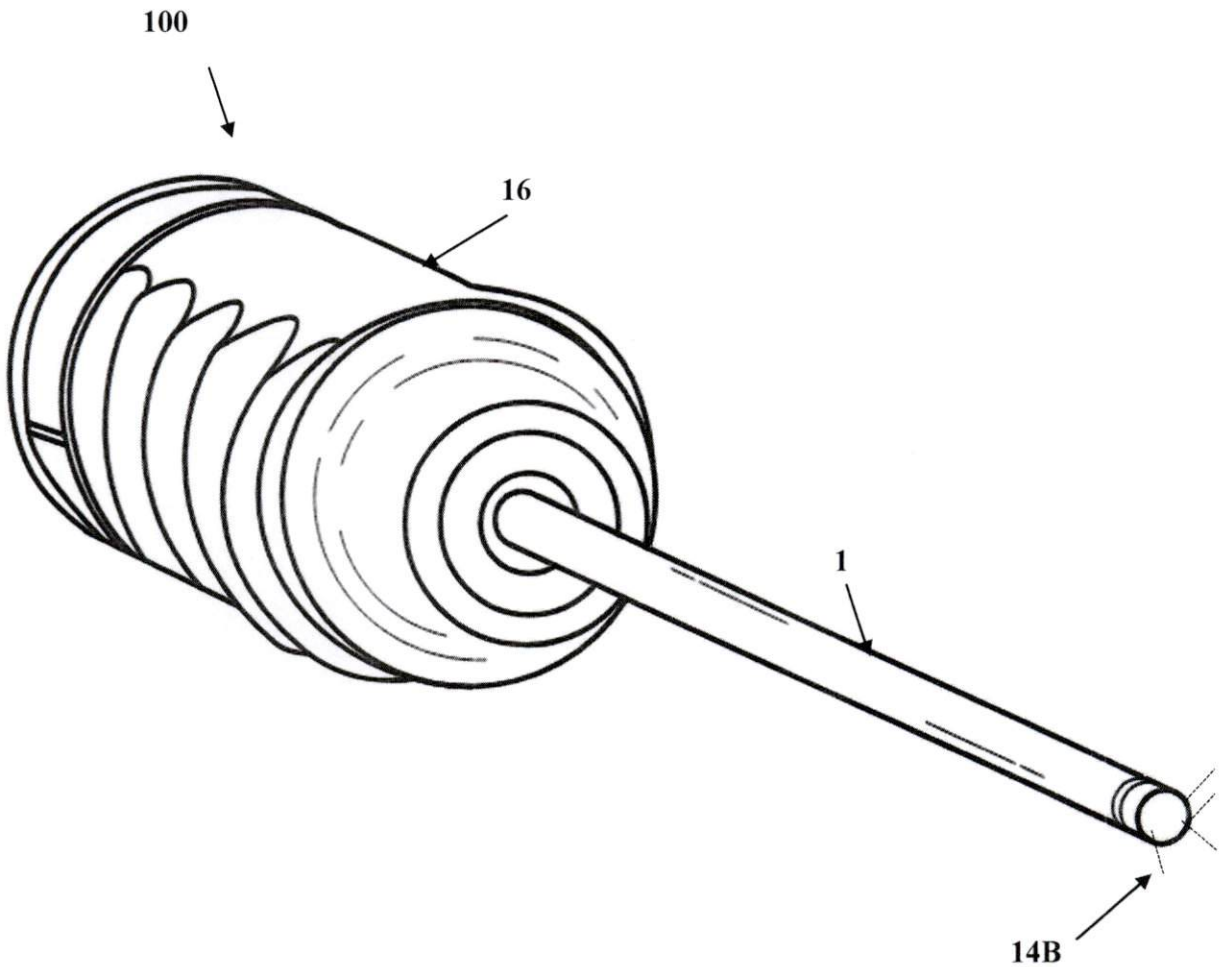
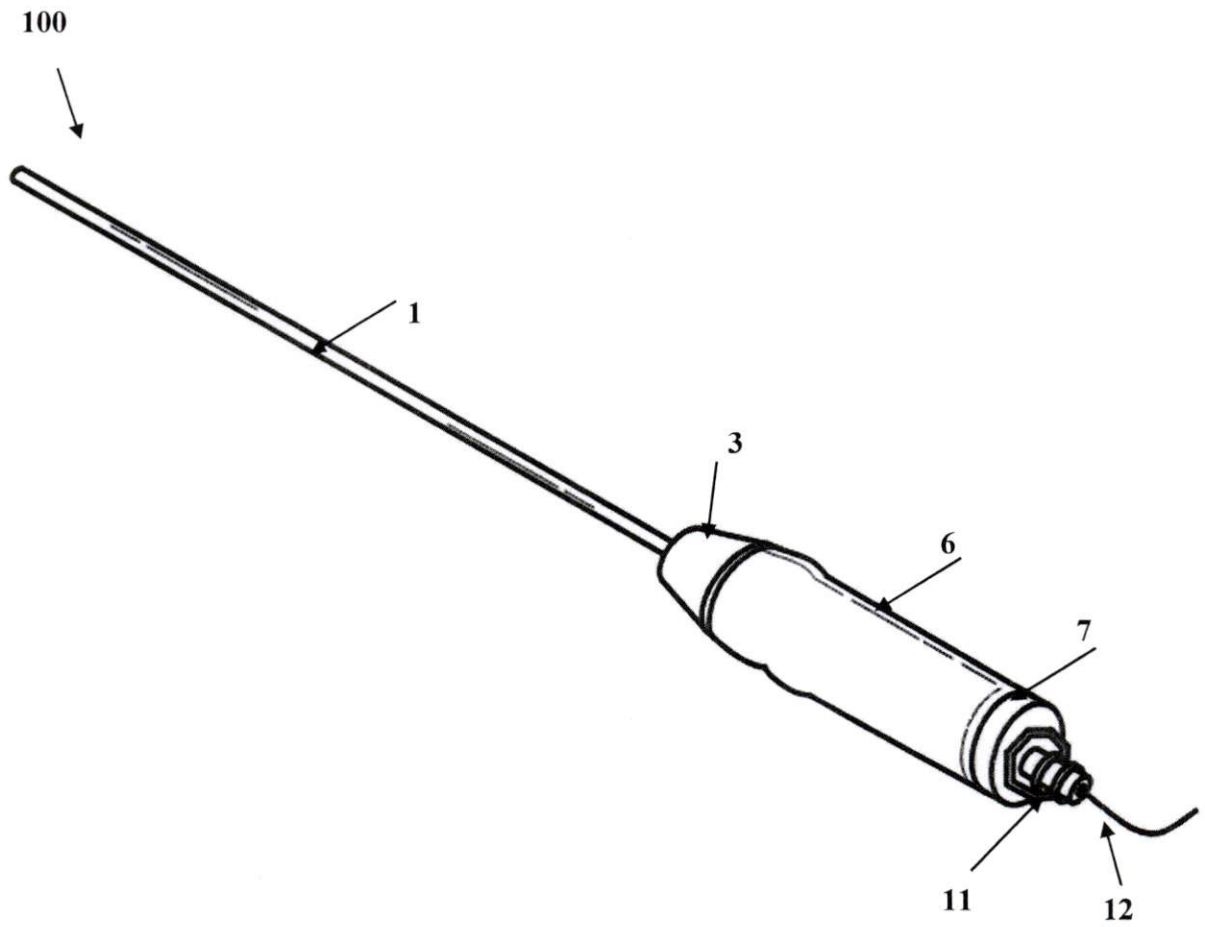


FIG. 1



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FIG. 3

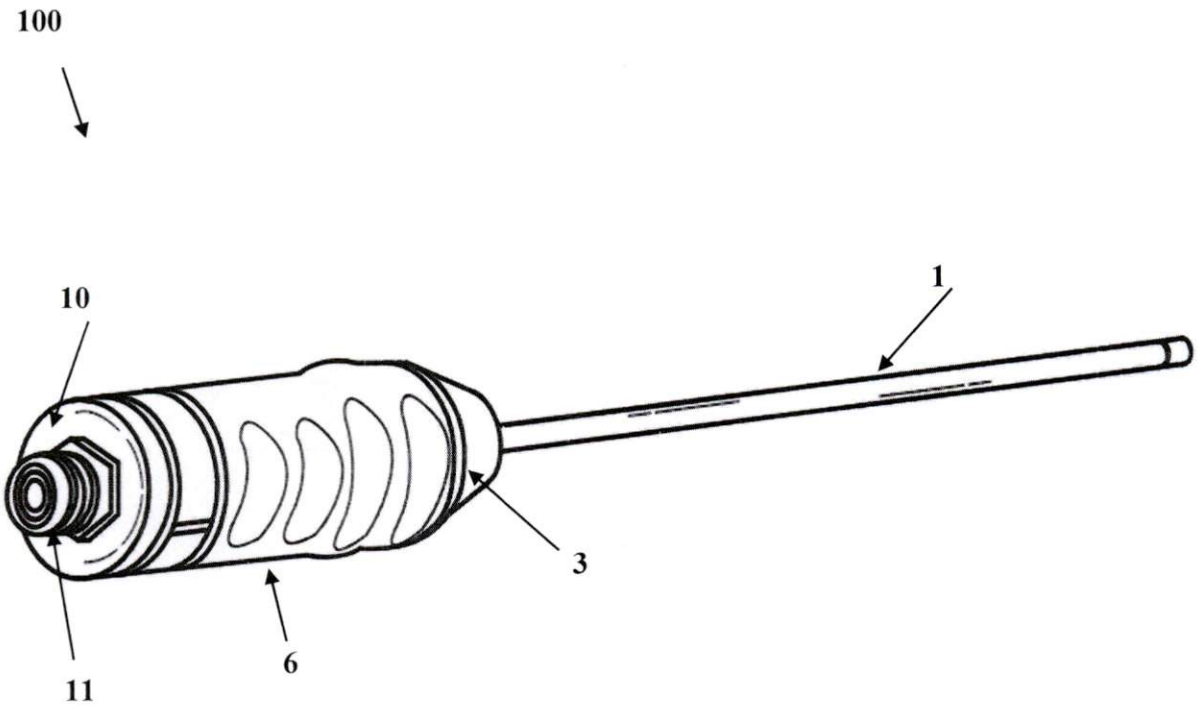


FIG. 4

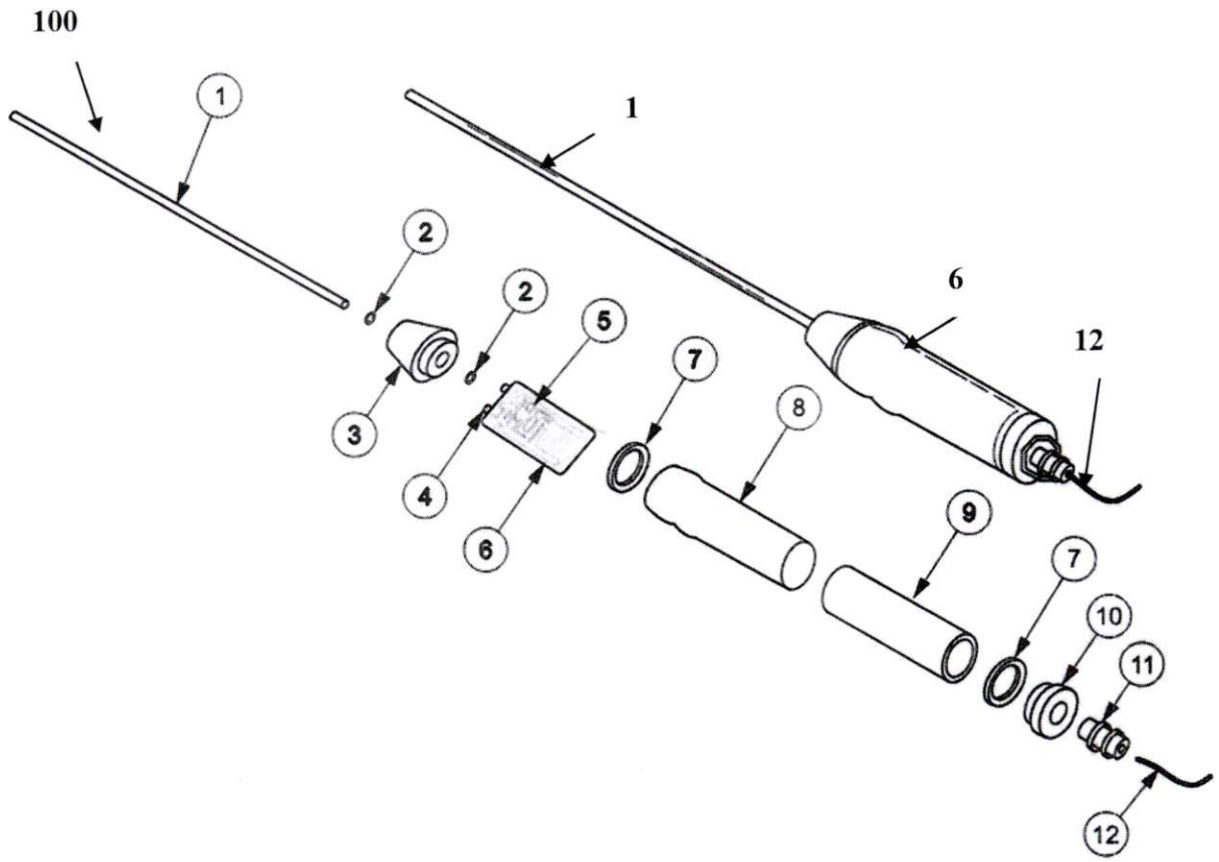


Fig. 5

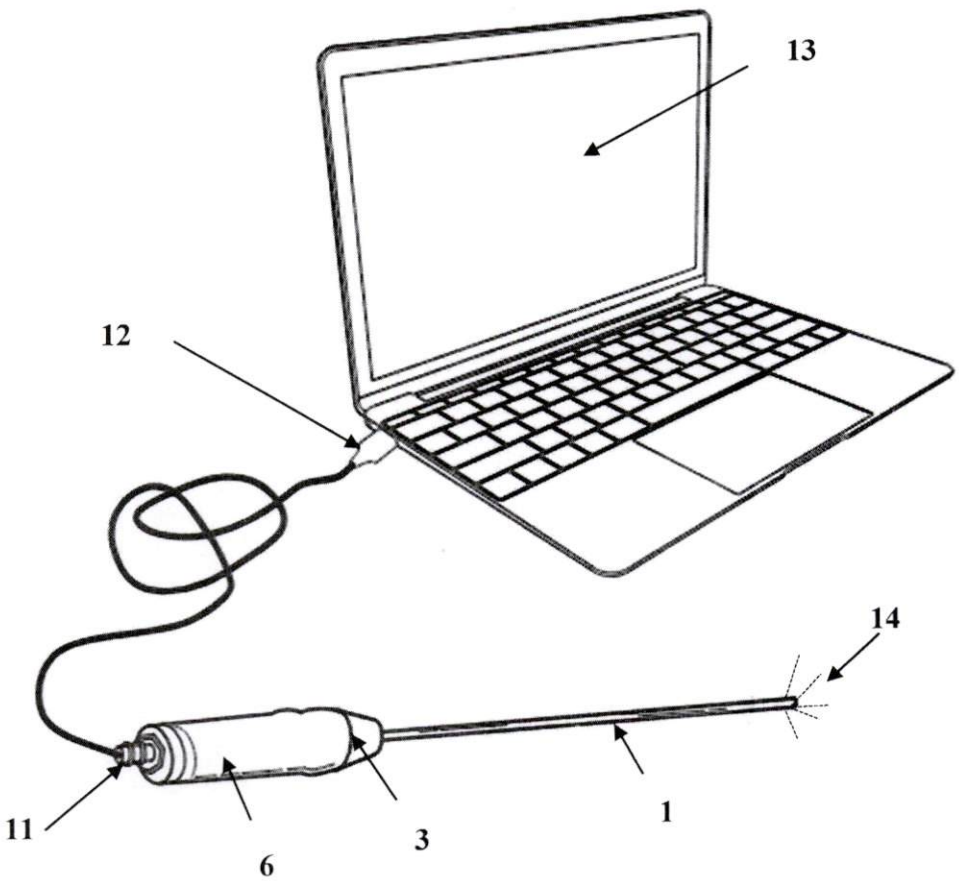


FIG. 6

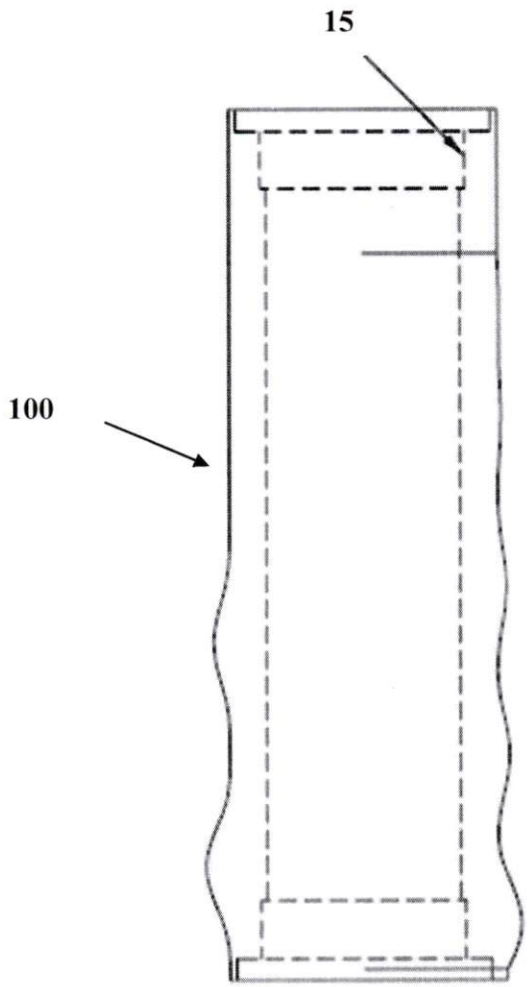
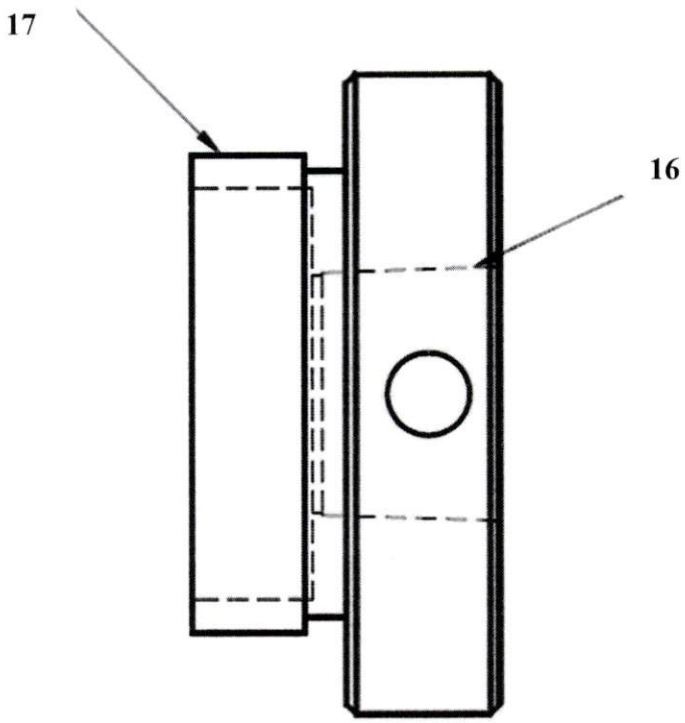
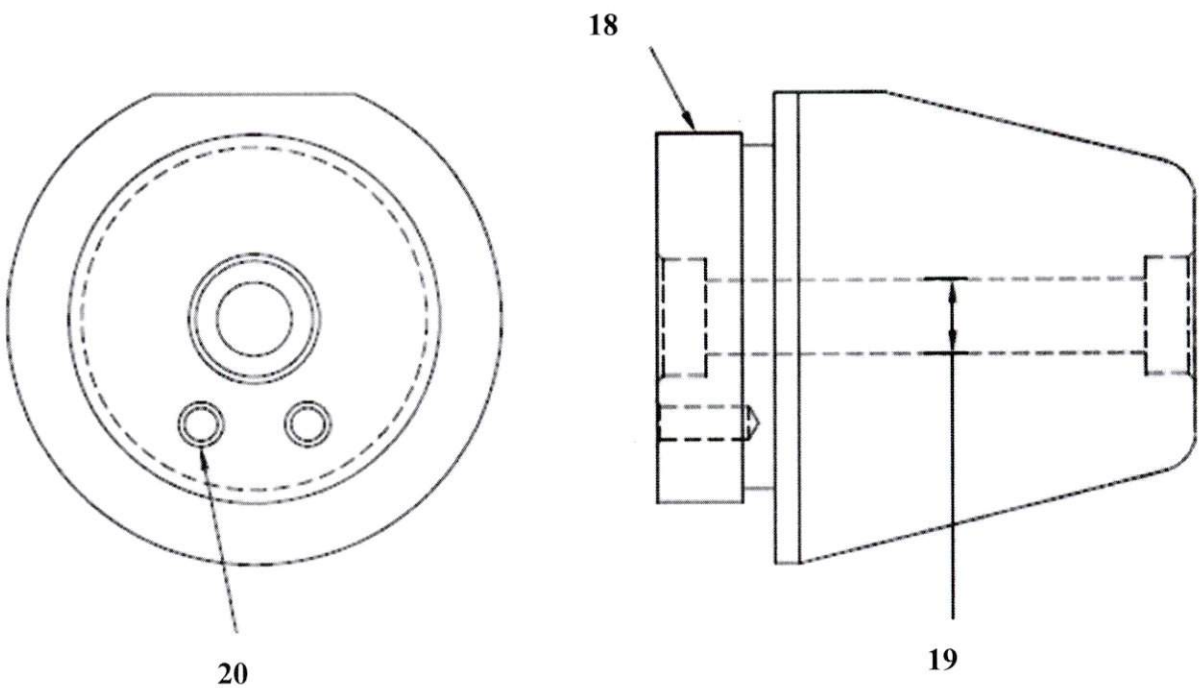


FIG. 7



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FIG. 8



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