US 20150150441A1

(19) **United States**

(12) **Patent Application Publication**

(10) **Pub. No.: US 2015/0150441 A1**

(43) **Pub. Date: Jun. 4, 2015**

Ouyang et al.

(54) **METHOD AND APPARATUSES FOR HYSTEROSCOPY AND COMBINED HYSTEROSCOPY AND ENDOMETRIAL BIOPSY**

(71) Applicant: **Endosee Corporation**, Los Altos, CA (US)

(72) Inventors: **Xiaolong Ouyang**, Palo Alto, CA (US); **Paul D. Indman**, San Jose (US); **Robert K. Deckman**, San Bruno, CA (US); **Shih-Ping Wang**, Los Altos, CA (US)

(21) Appl. No.: **14/614,472**

(22) Filed: **Feb. 5, 2015**

Related U.S. Application Data

(63) Continuation of application No. 14/400,986, filed on Nov. 13, 2014, filed as application No. PCT/US2013/040992 on May 14, 2013, which is a continuation of application No. 13/474,429, filed on May 17, 2012, now Pat. No. 8,460,182.

(60) Provisional application No. 61/646,887, filed on May 14, 2012, provisional application No. 61/667,341, filed on Jul. 2, 2012, provisional application No. 61/664,143, filed on Jun. 25, 2012, provisional application No. 61/672,733, filed on Jul. 17, 2012, provisional application No. 61/676,444, filed on Jul. 27, 2012, provisional application No. 61/681,129, filed on Aug. 8, 2012, provisional application No. 61/692,701, filed on Aug. 23, 2012, provisional application No. 61/709,022, filed on Oct. 2, 2012, provisional application No. 61/709,033, filed on Oct. 2, 2012, provisional application No. 61/803,664, filed on Mar. 20, 2013, provisional application No. 61/803,672, filed on Mar. 20, 2013, provisional application No. 61/813,635, filed on Apr. 18, 2013, provisional application No. 61/818,341, filed on May 1, 2013.

Publication Classification

(51) **Int. Cl.**

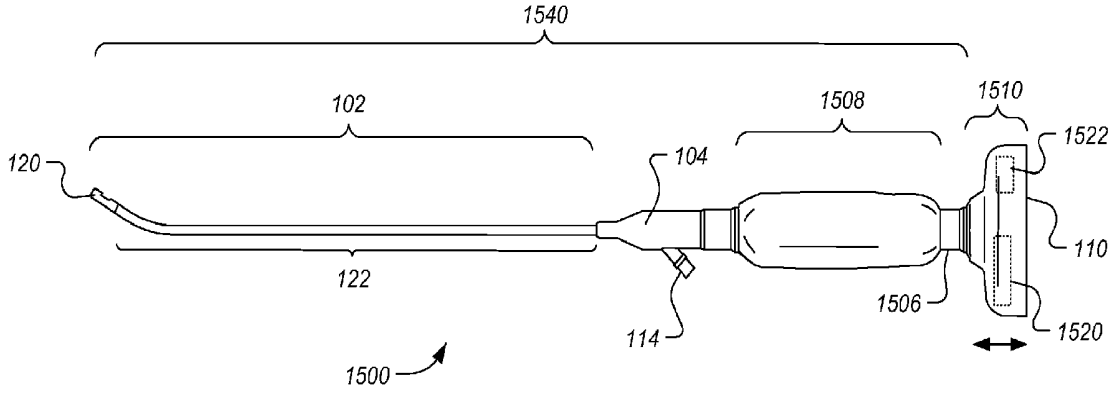
A61B 1/303	(2006.01)
A61B 1/06	(2006.01)
A61B 1/005	(2006.01)
A61B 1/05	(2006.01)
A61B 1/00	(2006.01)
A61B 1/12	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 1/303*** (2013.01); ***A61B 1/00103*** (2013.01); ***A61B 1/00066*** (2013.01); ***A61B 1/00034*** (2013.01); ***A61B 1/126*** (2013.01); ***A61B 1/005*** (2013.01); ***A61B 1/05*** (2013.01); ***A61B 1/06*** (2013.01); ***A61B 1/00052*** (2013.01)

(57) **ABSTRACT**

Instruments and methods are described for performing hysteroscopy and/or combined hysteroscopy and endometrial biopsy. According to some embodiments, the handle, electronics and integrated display screen form a re-usable portion of the instrument while the fluid hub and cannula which includes a CMOS imaging module and LED lighting, form a single use portion of the instrument. The cannula is semi-flexible such that the operator can easily grasp the cannula at some intermediate point along the shaft (e.g. 5 inches from the distal tip) to bend and/or steer the cannula during use. According to some embodiments, the distal tip has a larger diameter than the shaft which has been found to improve fluid management during use in some applications.



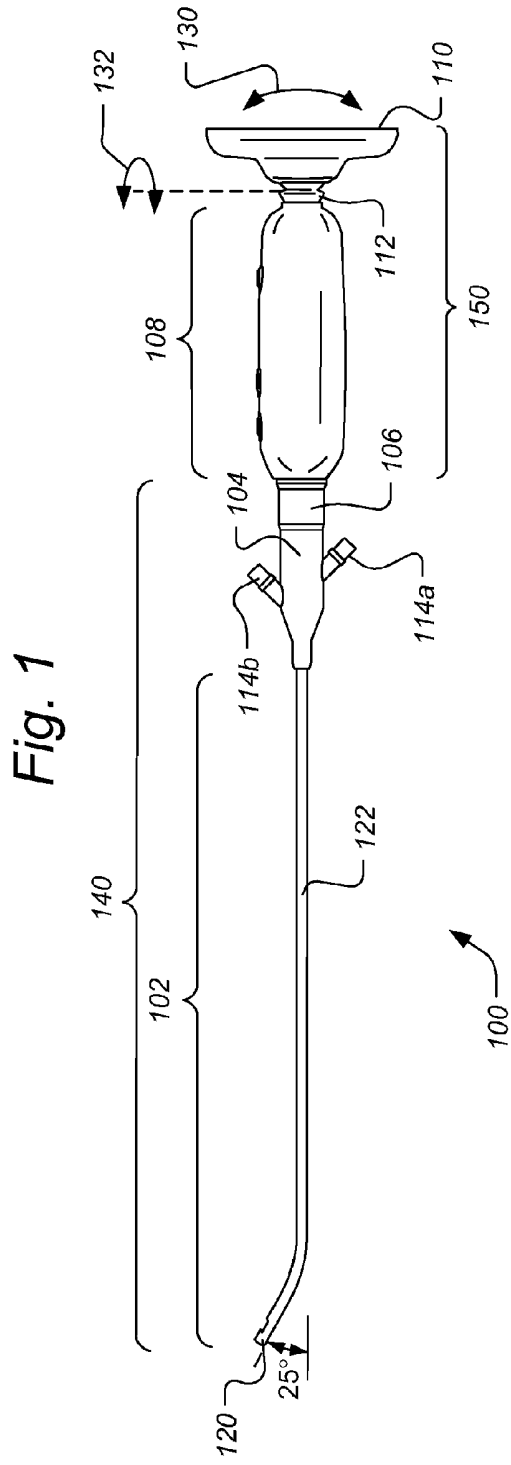


Fig. 1

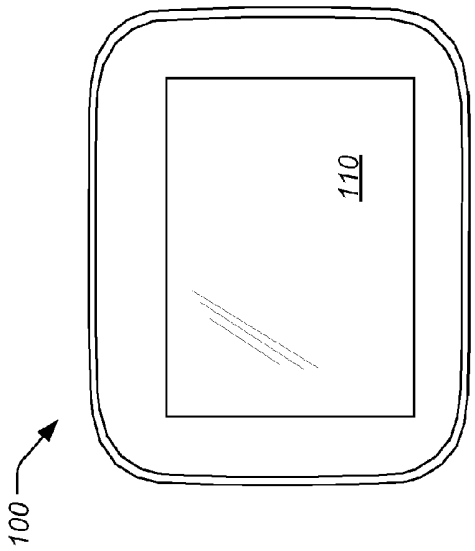


Fig. 3

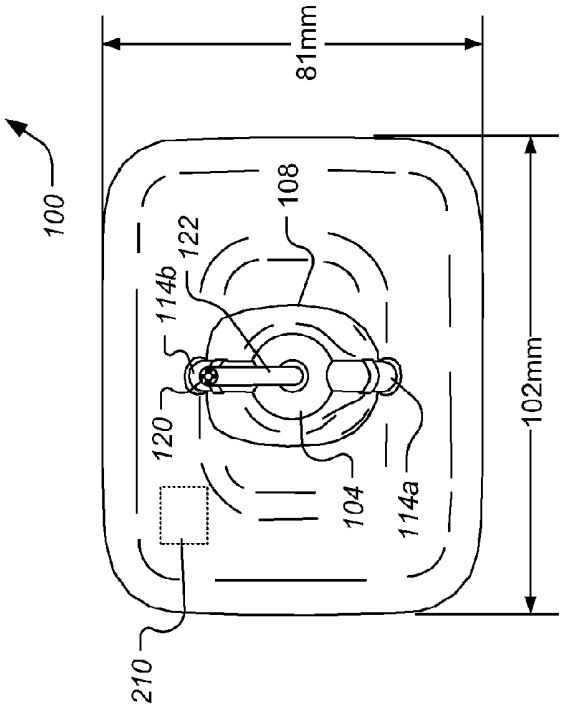
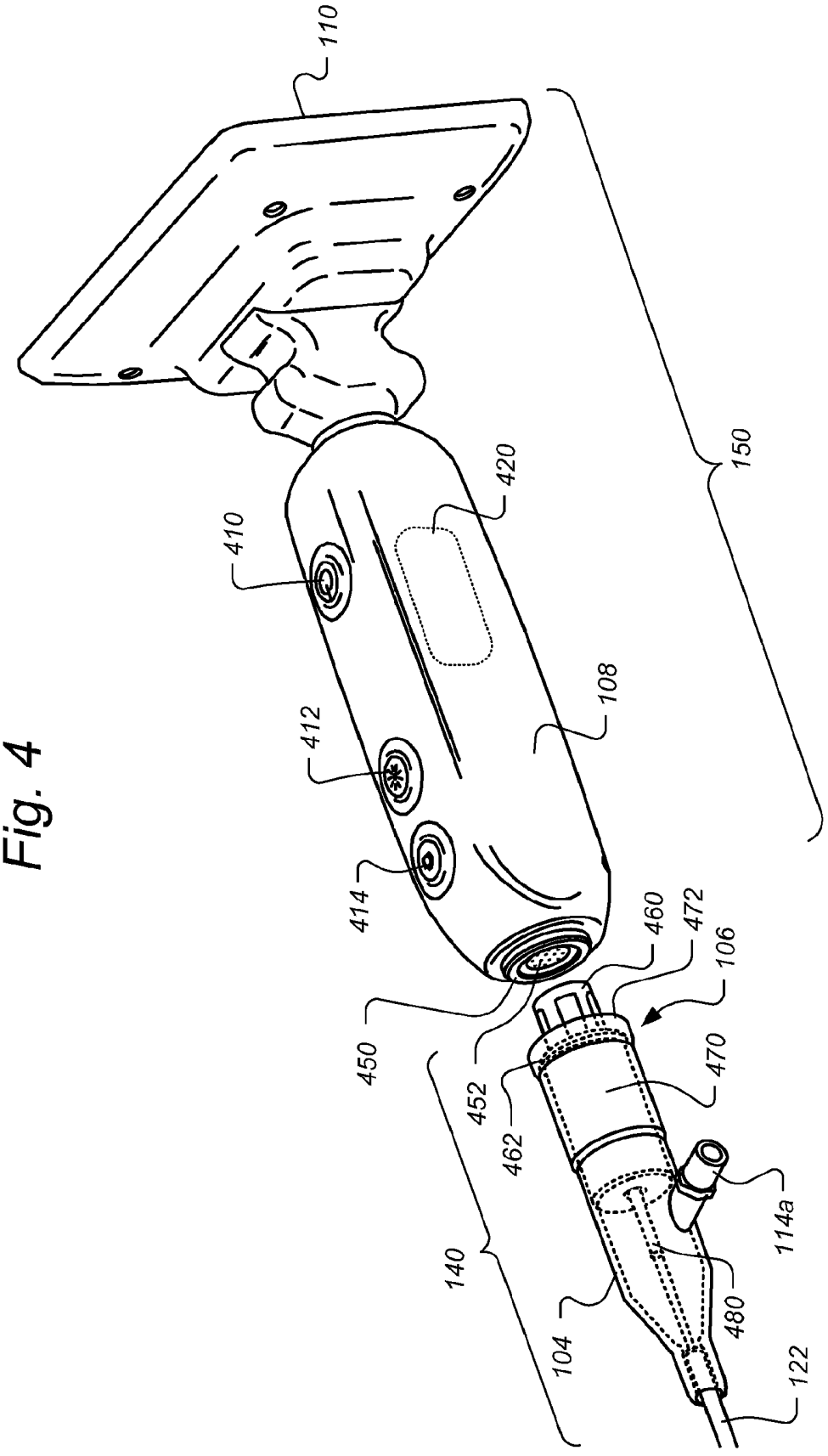


Fig. 2

Fig. 4


110
150
420
410
108
412
414
460
472
106
450
452
470
462
114a
140
104
480
122

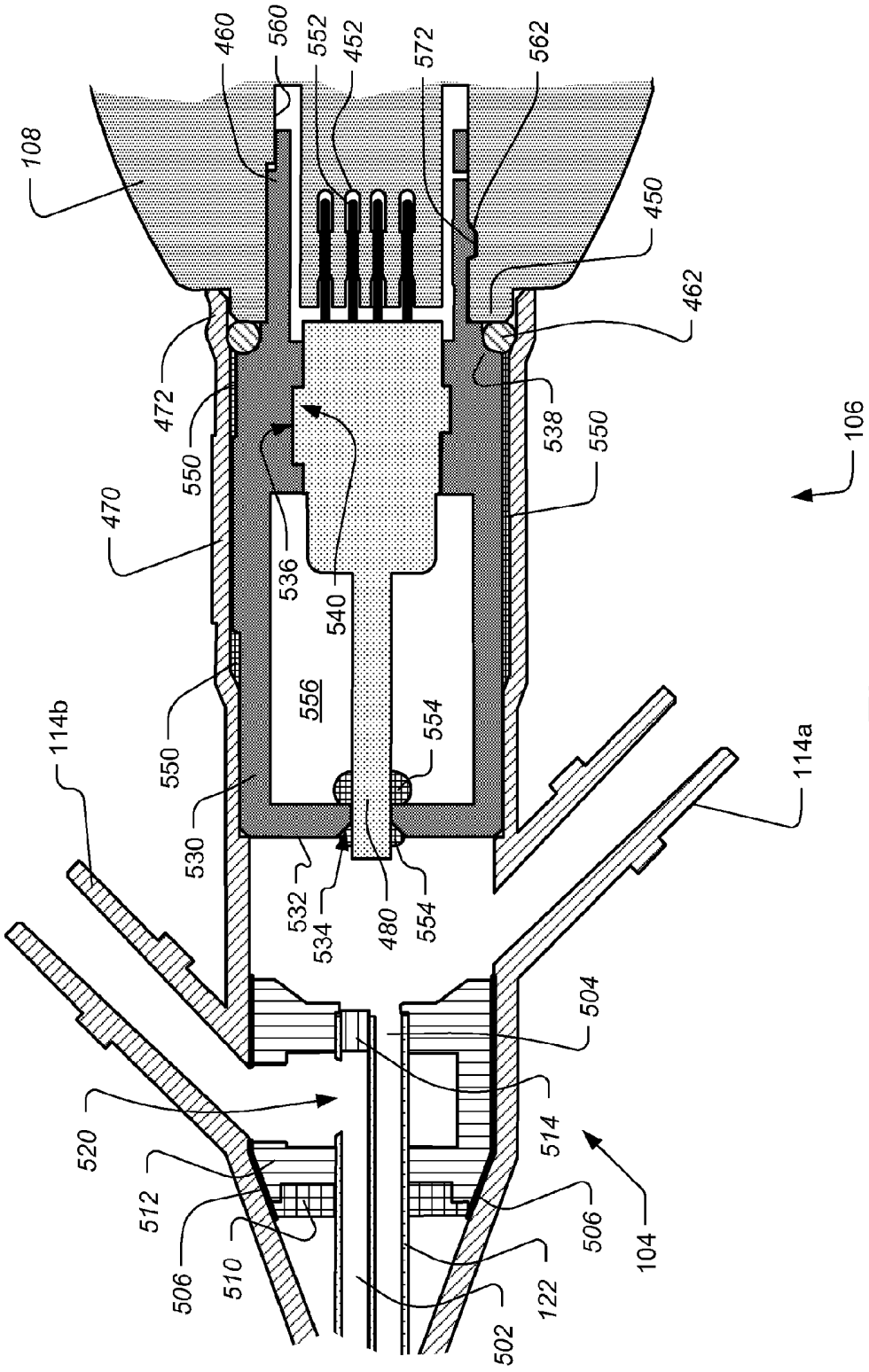

460
560
552
452
572
562
108
450
462
472
550
538
550
106
470
536
540
556
554
550
114b
114a
530
532
534
480
554
504
520
514
512
506
510
506
104
122
502

Fig. 5

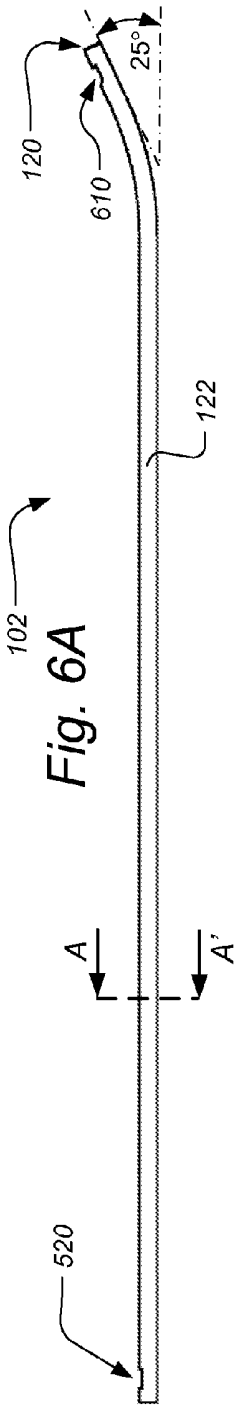


Fig. 6A

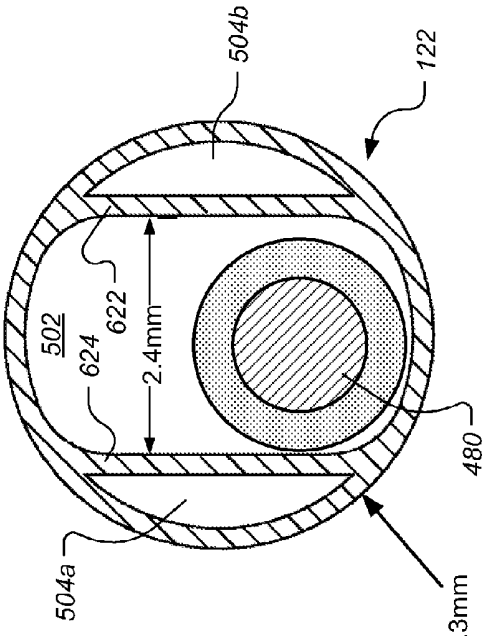


Fig. 6C

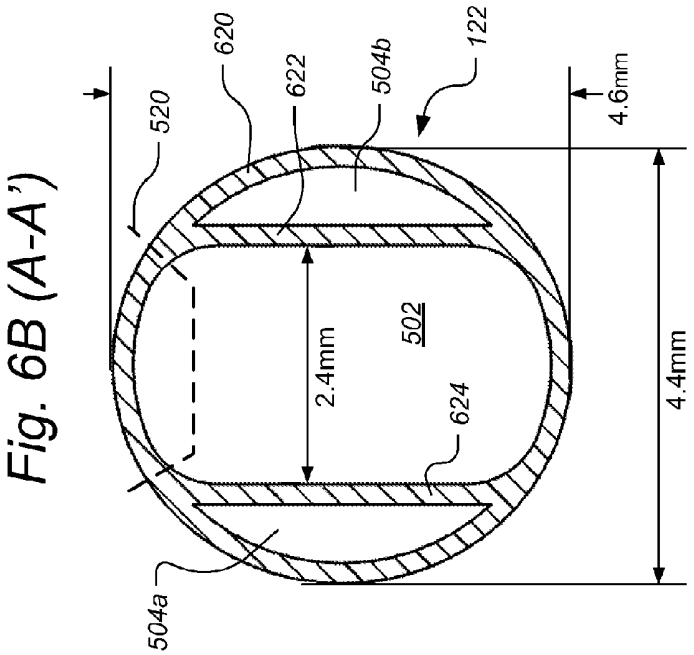


Fig. 6B (A-A')

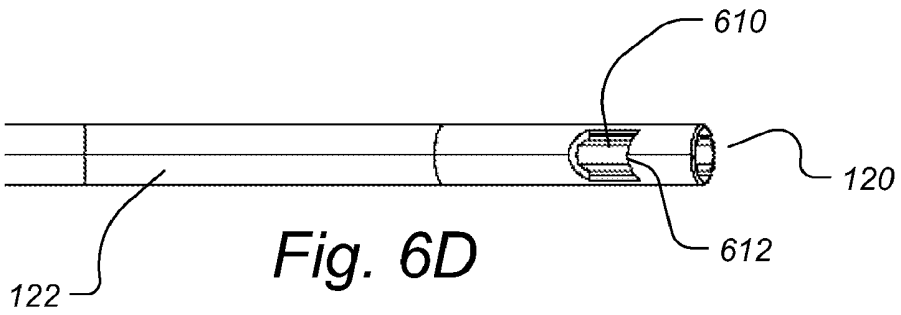


Fig. 6D

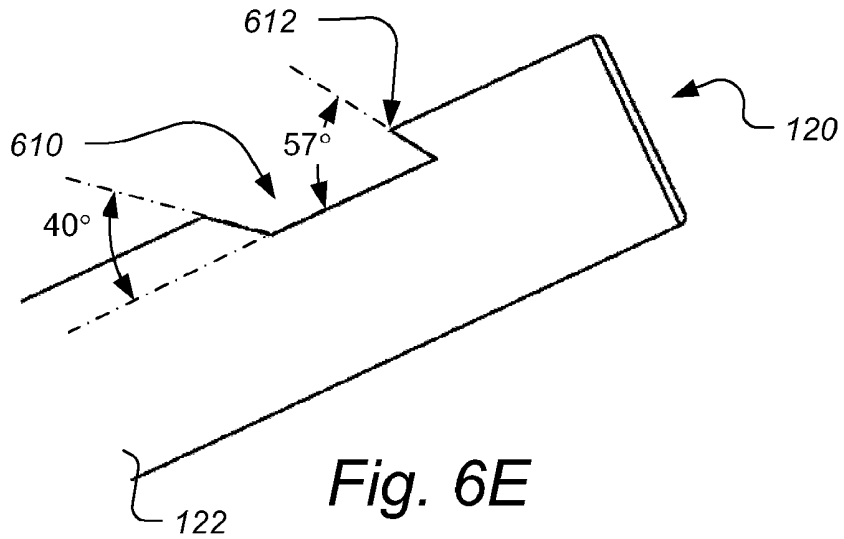


Fig. 6E

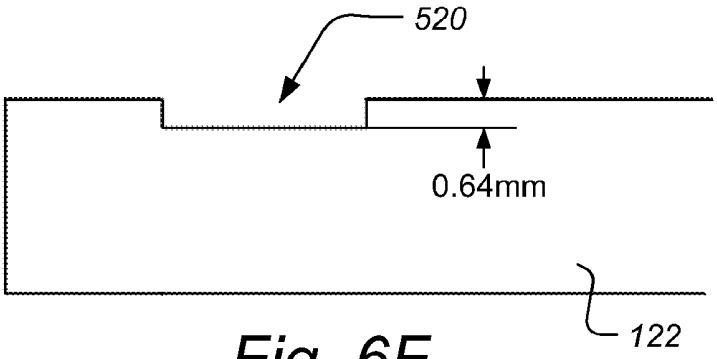


Fig. 6F

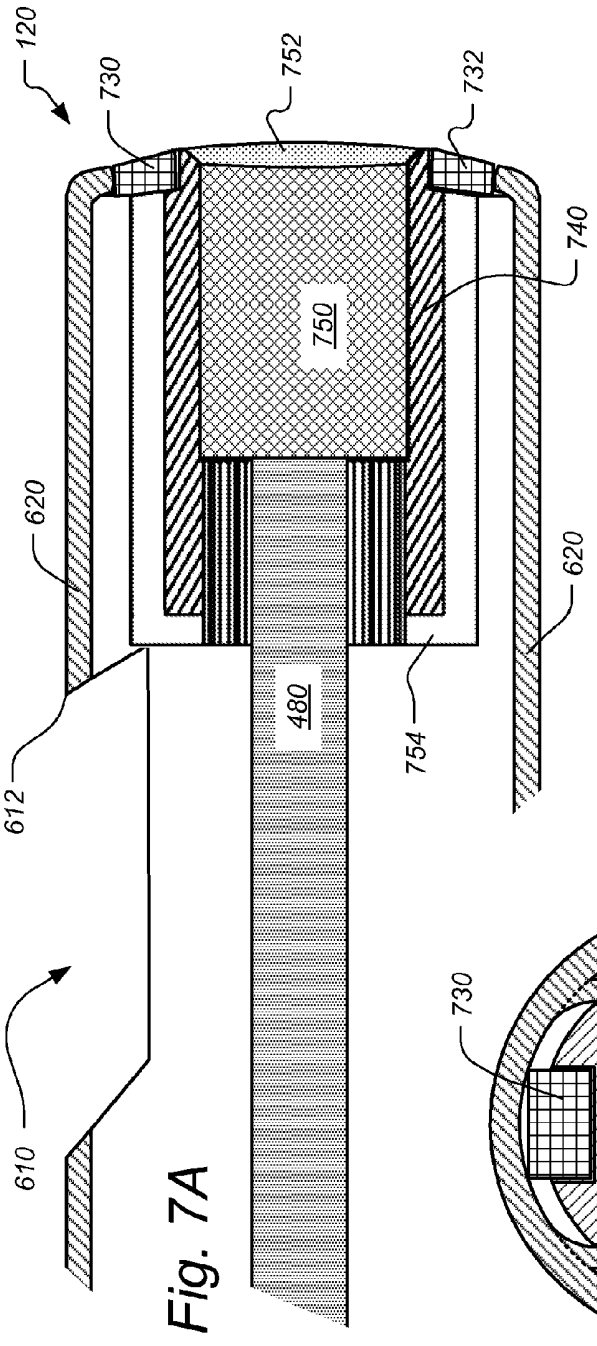


Fig. 7A

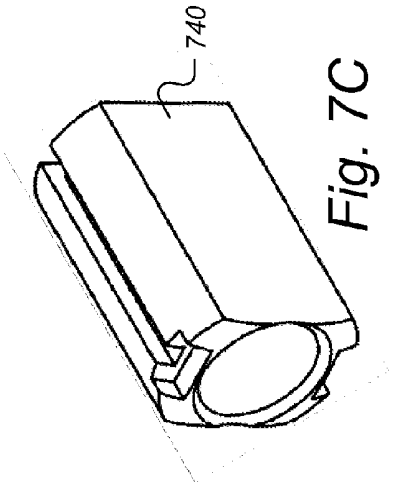


Fig. 7C

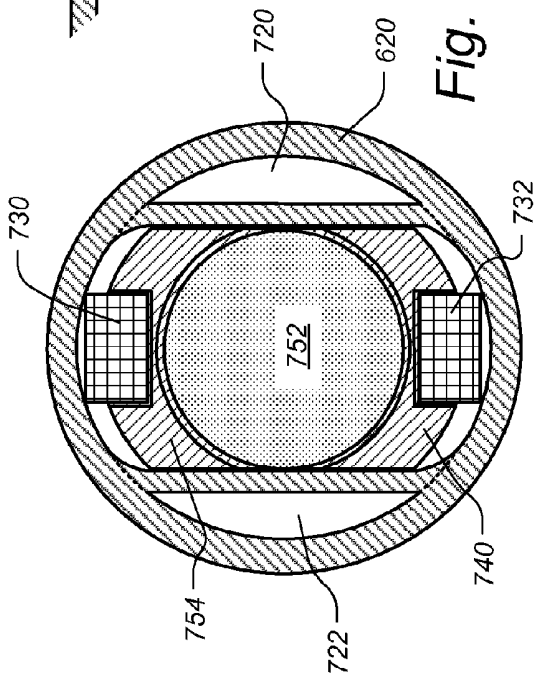


Fig. 7B

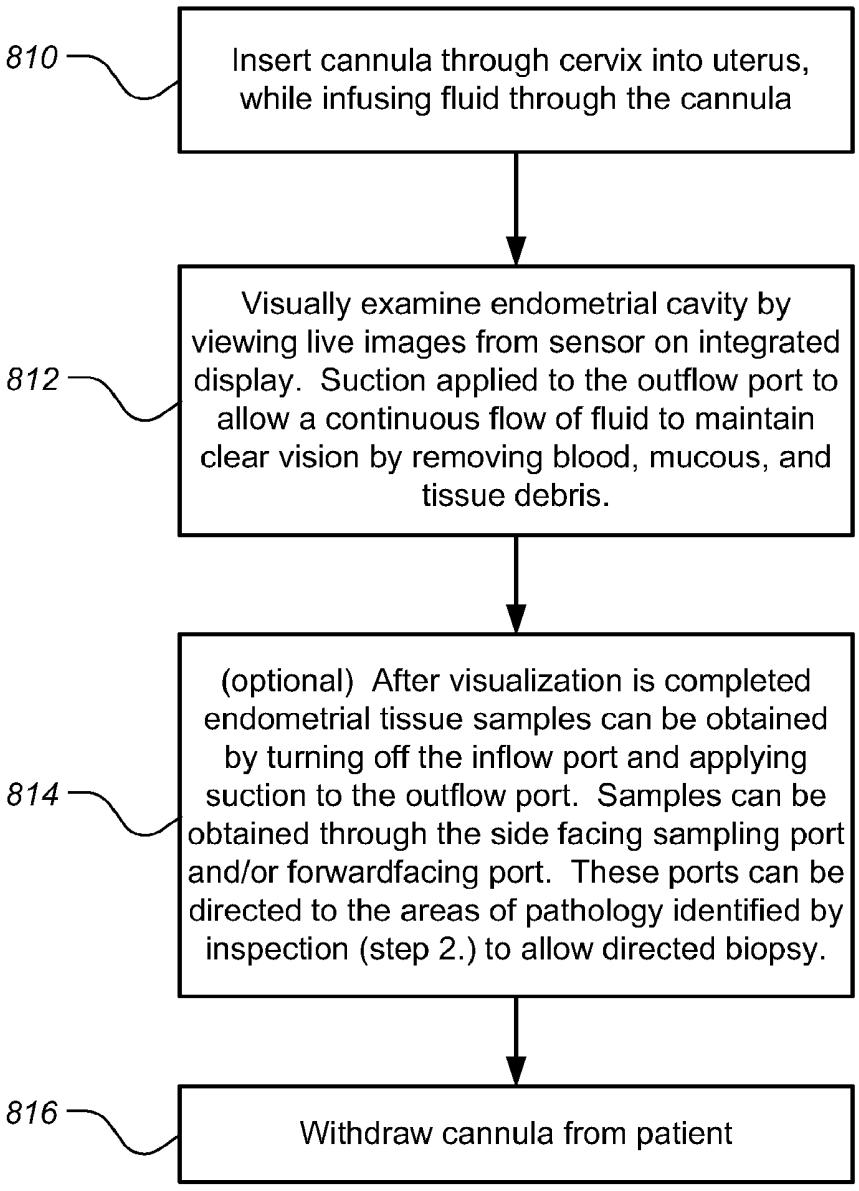

810
Insert cannula through cervix into uterus, while infusing fluid through the cannula
812
Visually examine endometrial cavity by viewing live images from sensor on integrated display. Suction applied to the outflow port to allow a continuous flow of fluid to maintain clear vision by removing blood, mucous, and tissue debris.
814
(optional) After visualization is completed endometrial tissue samples can be obtained by turning off the inflow port and applying suction to the outflow port. Samples can be obtained through the side facing sampling port and/or forwardfacing port. These ports can be directed to the areas of pathology identified by inspection (step 2.) to allow directed biopsy.
816
Withdraw cannula from patient

Fig. 8

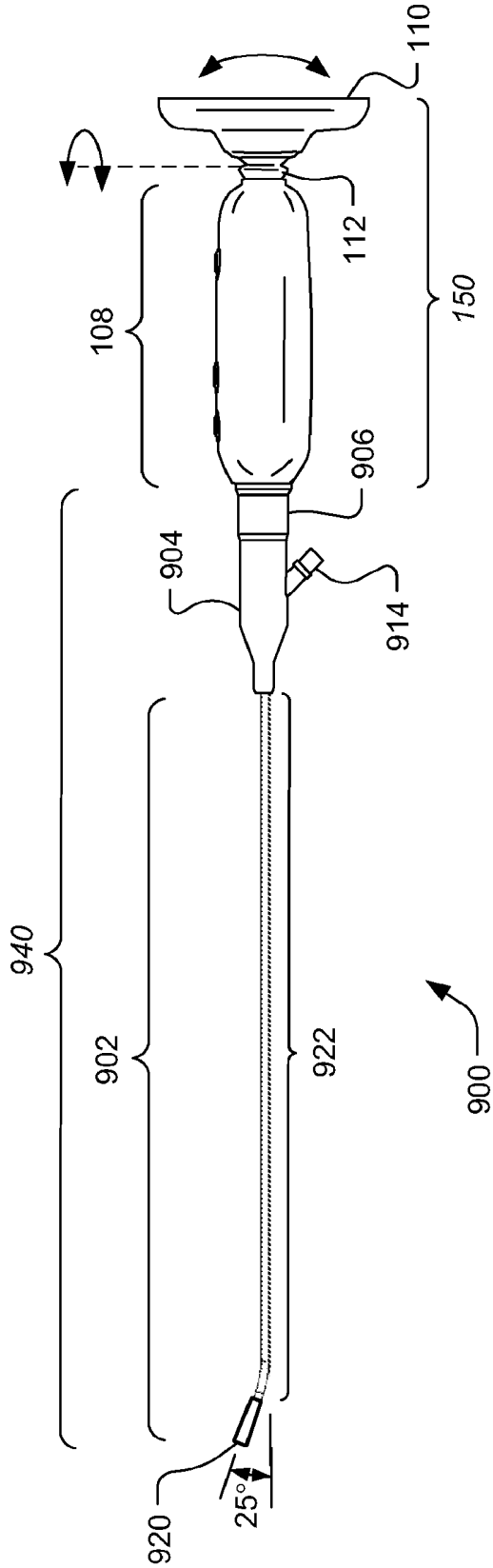


Fig. 9A

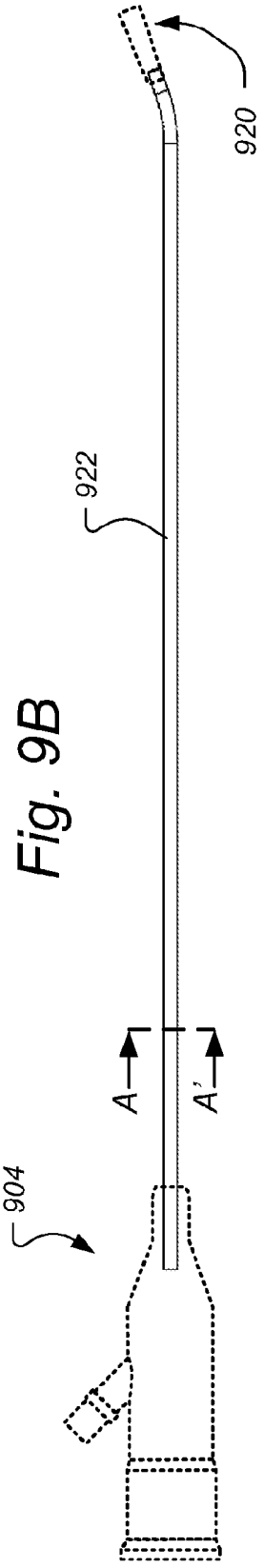


Fig. 9B

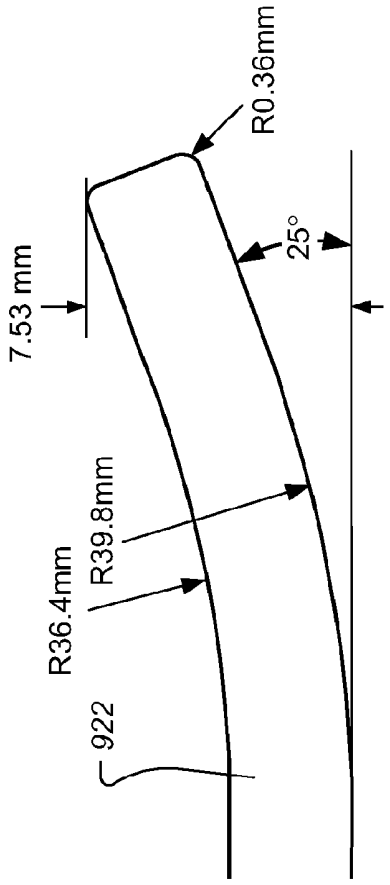


Fig. 9D

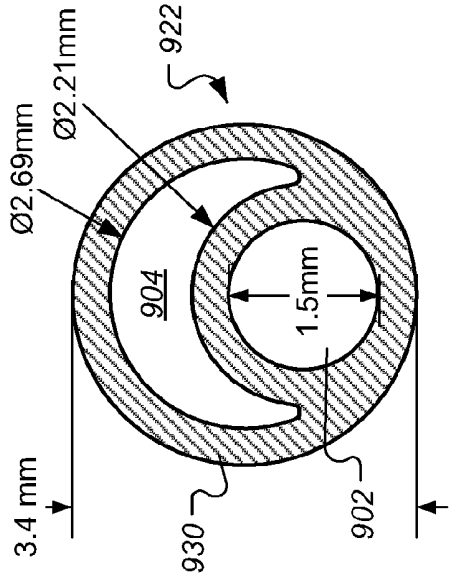


Fig. 9C
(A-A')

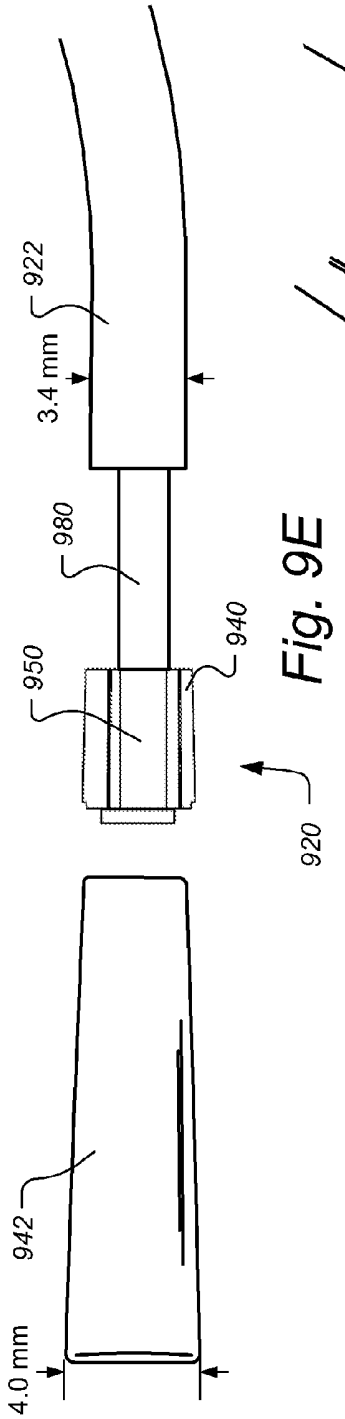


Fig. 9E

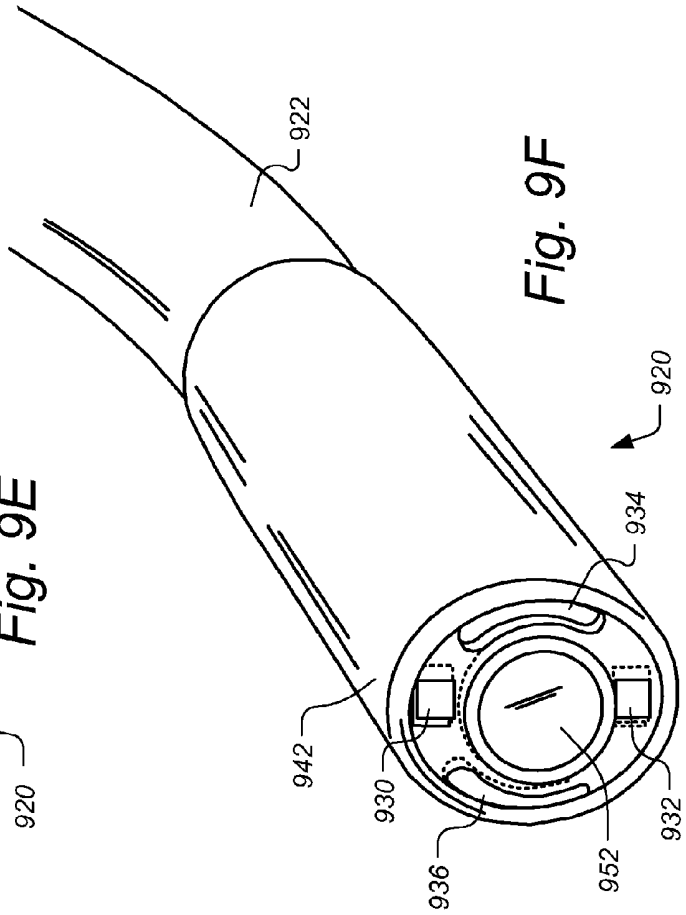


Fig. 9F

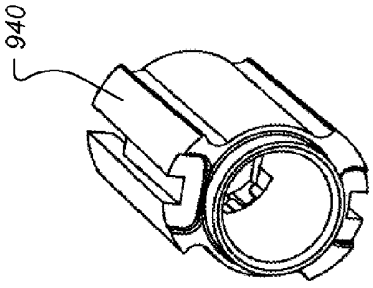


Fig. 9G

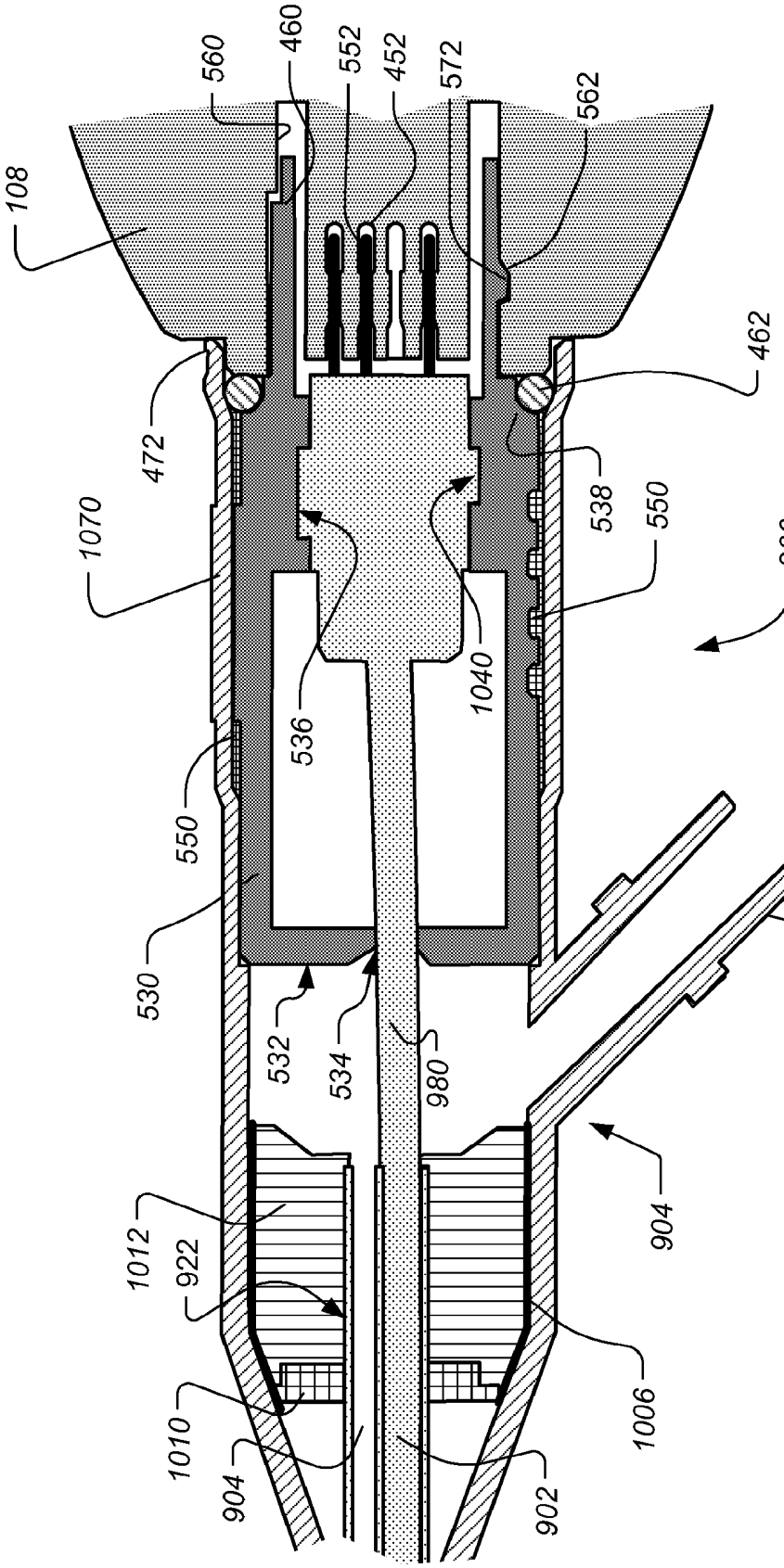

560
460
552
452
572
562
108
462
472
538
550
1070
906
1040
536
550
530
914
532
534
980
904
1012
922
1006
1010
904
902

Fig. 10

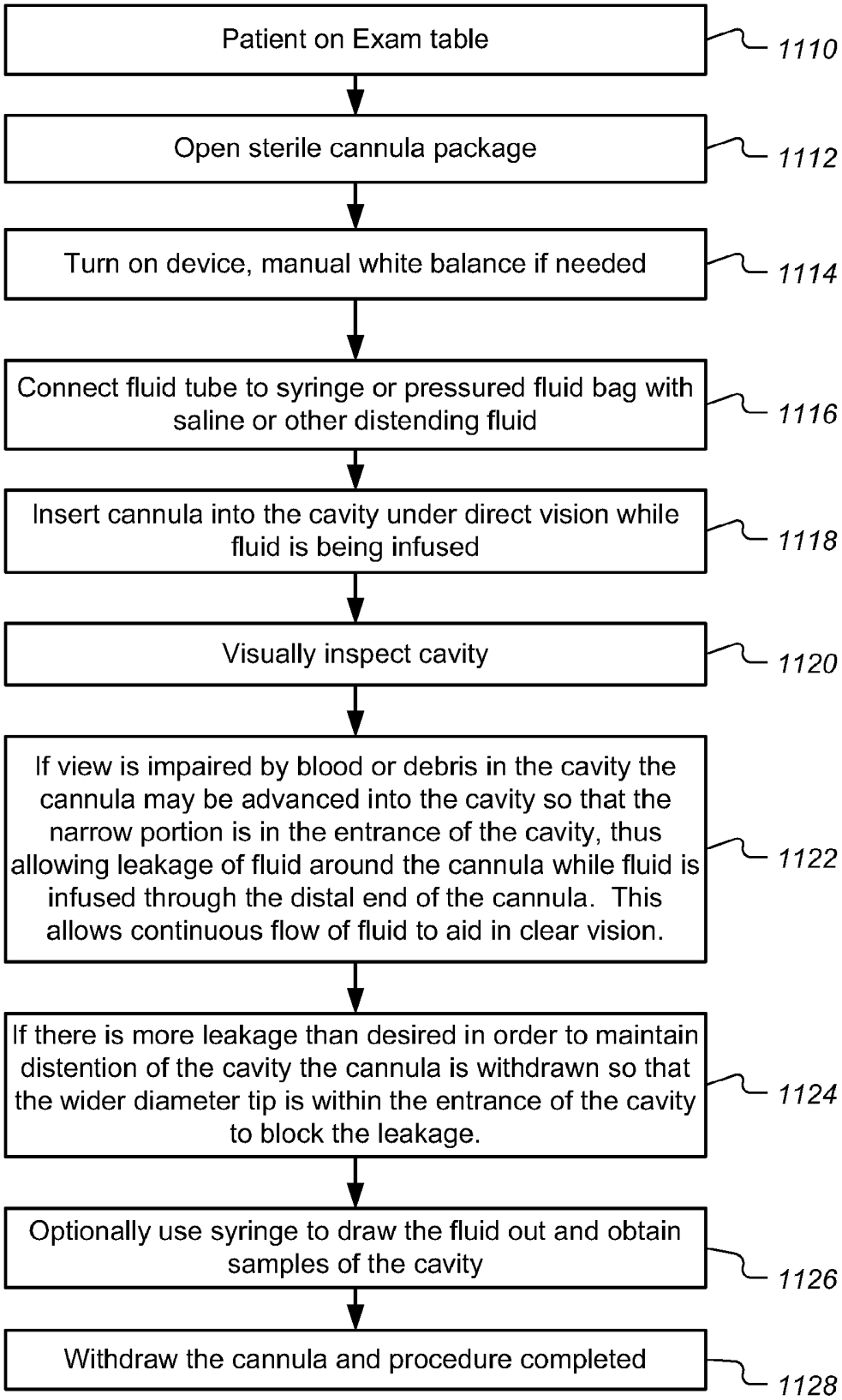

Patient on Exam table
1110
Open sterile cannula package
1112
Turn on device, manual white balance if needed
1114
Connect fluid tube to syringe or pressured fluid bag with saline or other distending fluid
1116
Insert cannula into the cavity under direct vision while fluid is being infused
1118
Visually inspect cavity
1120
If view is impaired by blood or debris in the cavity the cannula may be advanced into the cavity so that the narrow portion is in the entrance of the cavity, thus allowing leakage of fluid around the cannula while fluid is infused through the distal end of the cannula. This allows continuous flow of fluid to aid in clear vision.
1122
If there is more leakage than desired in order to maintain distention of the cavity the cannula is withdrawn so that the wider diameter tip is within the entrance of the cavity to block the leakage.
1124
Optionally use syringe to draw the fluid out and obtain samples of the cavity
1126
Withdraw the cannula and procedure completed
1128

Fig. 11

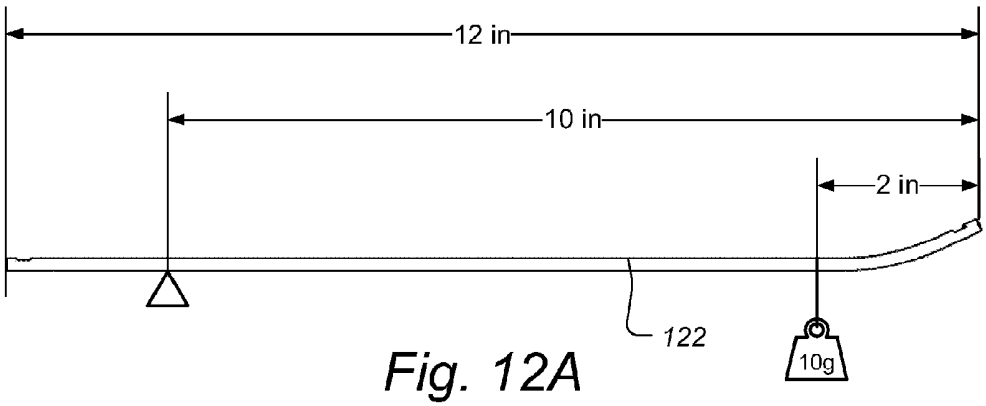


Fig. 12A

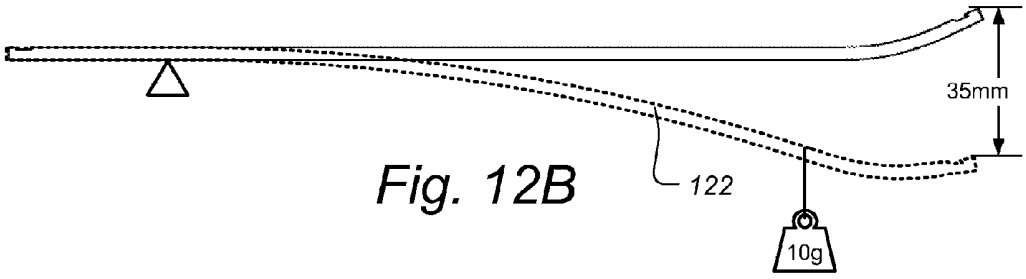


Fig. 12B

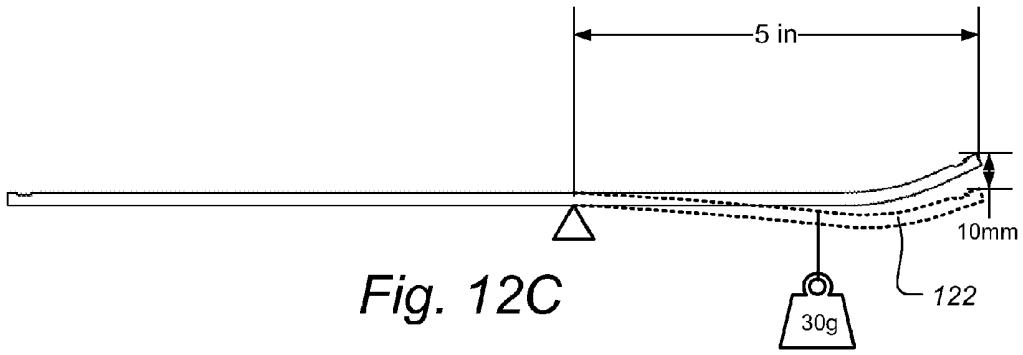


Fig. 12C

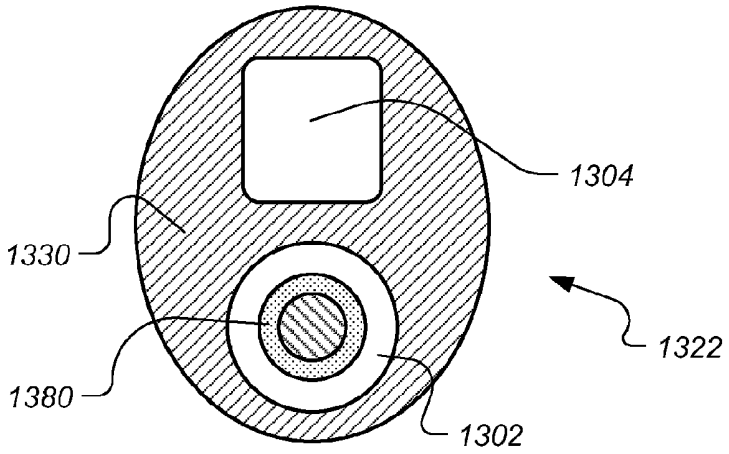
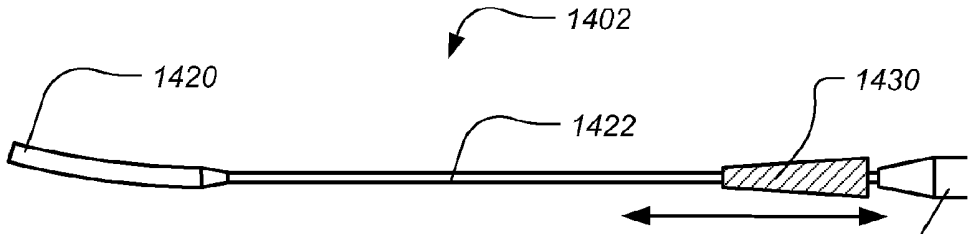


Fig. 13



Plug alternative
(ENDO027)

Fig. 14A

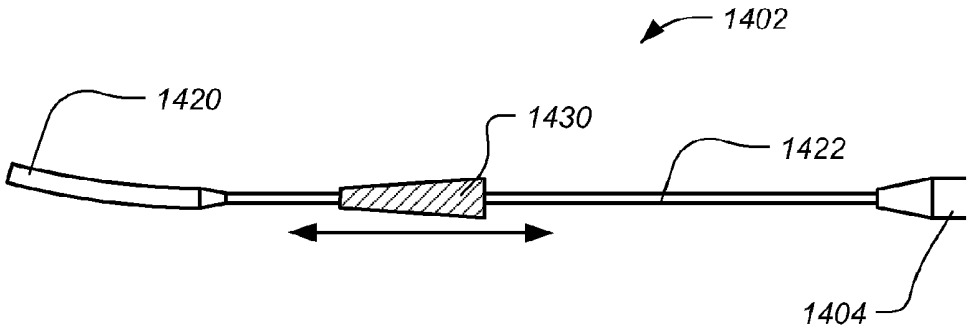


Fig. 14B

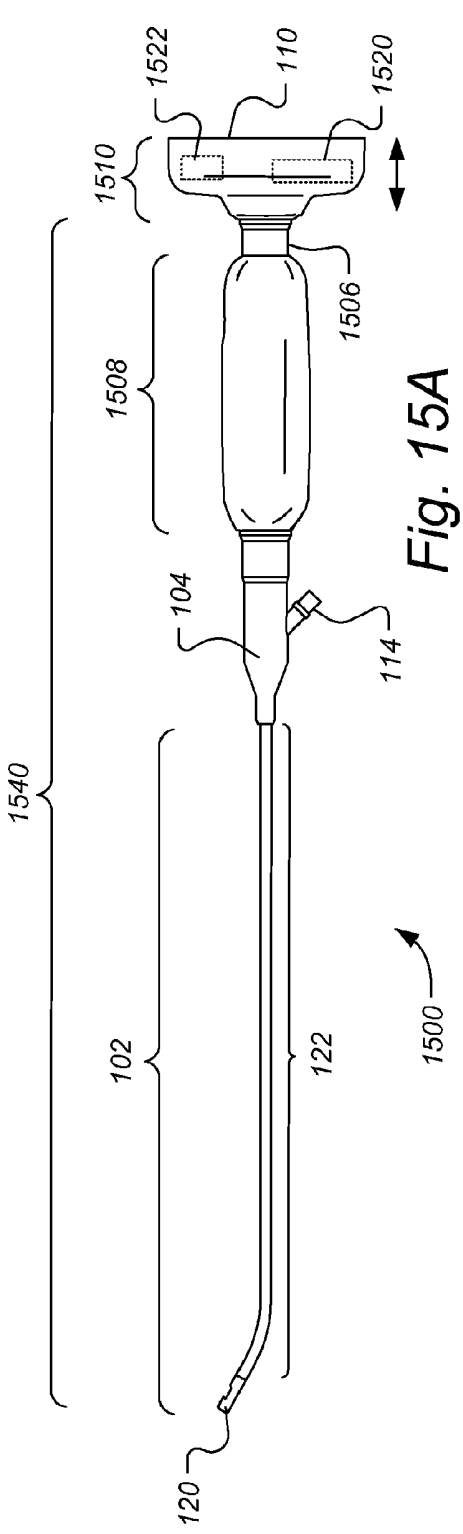


Fig. 15A

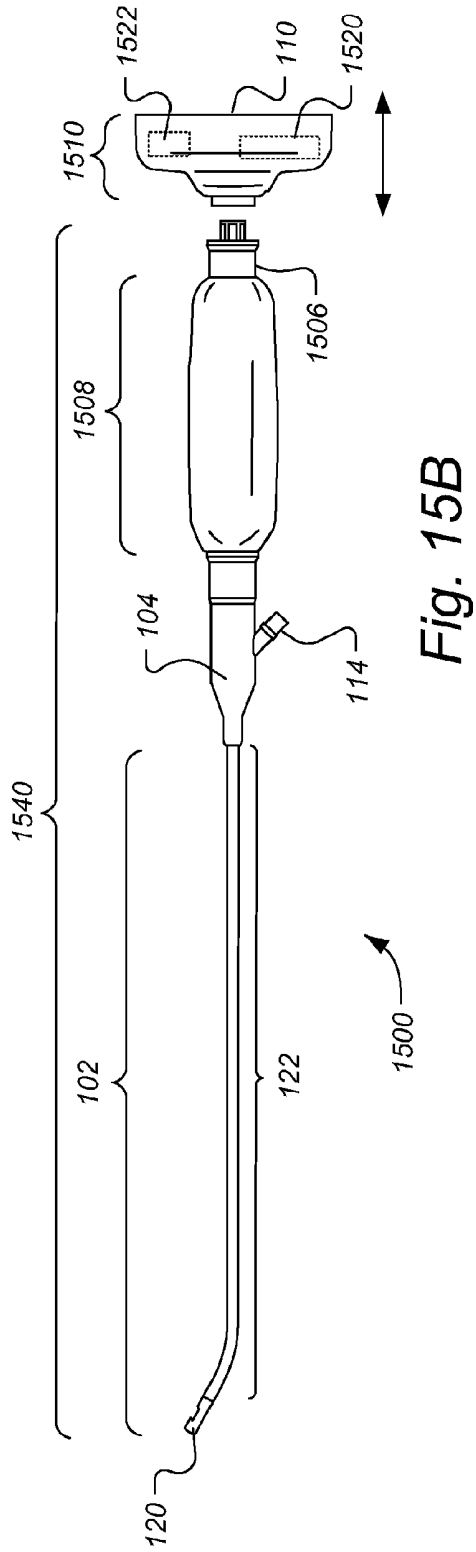


Fig. 15B

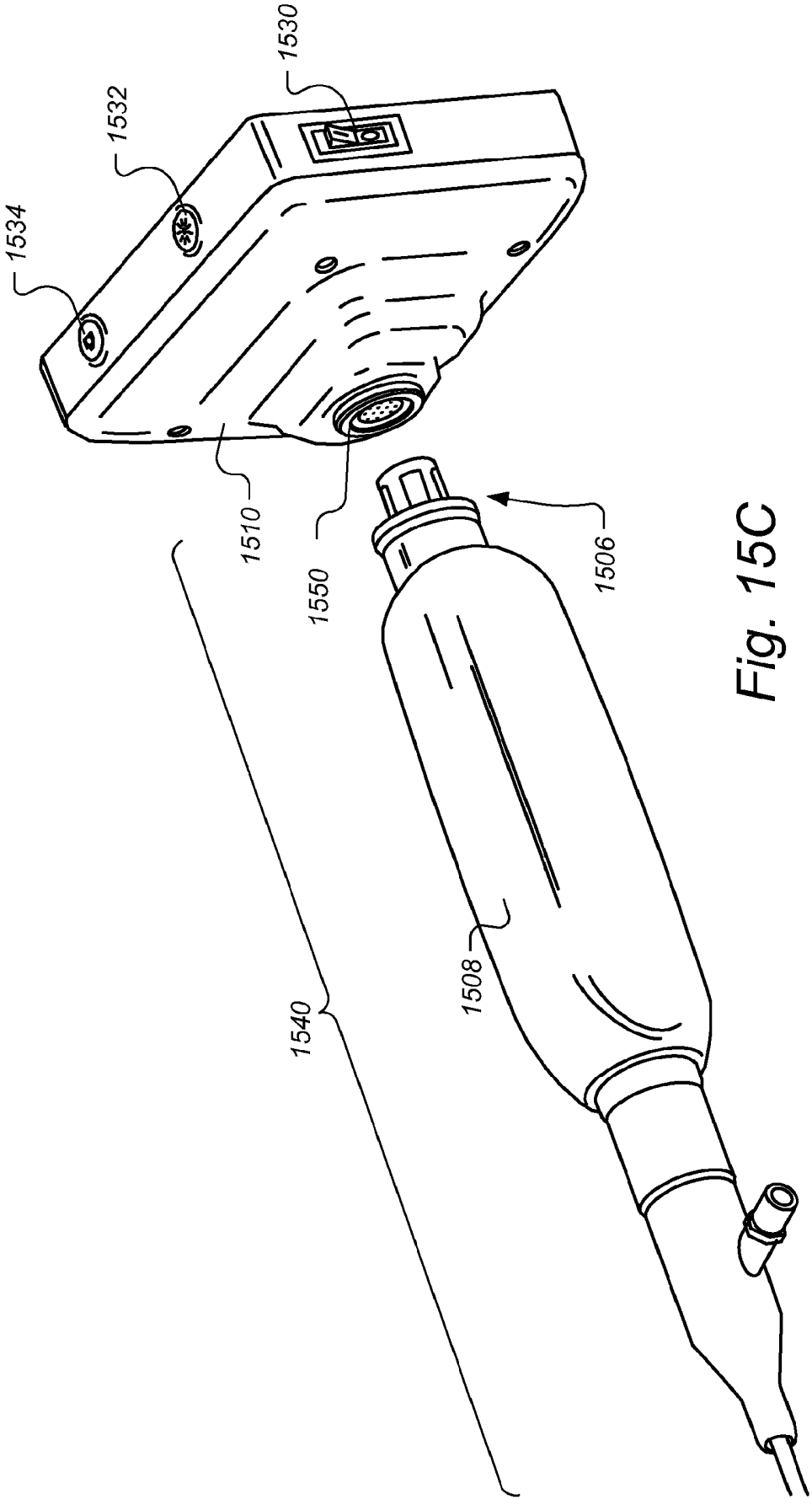


Fig. 15C

METHOD AND APPARATUSES FOR HYSTEROSCOPY AND COMBINED HYSTEROSCOPY AND ENDOMETRIAL BIOPSY

REFERENCE TO RELATED APPLICATIONS

[0001] This patent application is a continuation of U.S. application Ser. No. 14/401,001, filed on Nov. 13, 2014, which is a 371 U.S. National Application of PCT/US2013/040992, dated May 14, 2013, and claims the priority benefit of and incorporates by reference each of the following applications:

[0002] U.S. Prov. Ser. No. 61/646,887 filed May 14, 2012;

[0003] U.S. Prov. Ser. No. 61/667,341 filed Jul. 2, 2012;

[0004] U.S. Prov. Ser. No. 61/664,143 filed Jun. 25, 2012;

[0005] U.S. Prov. Ser. No. 61/672,733 filed Jul. 17, 2012;

[0006] U.S. Prov. Ser. No. 61/676,444 filed Jul. 27, 2012;

[0007] U.S. Prov. Ser. No. 61/681,129 filed Aug. 8, 2012;

[0008] U.S. Prov. Ser. No. 61/692,701 filed Aug. 23, 2012;

[0009] U.S. Prov. Ser. No. 61/709,022 filed Oct. 2, 2012;

[0010] U.S. Prov. Ser. No. 61/709,033 filed Oct. 2, 2012;

[0011] U.S. Ser. No. 13/474,429 filed May 17, 2012;

[0012] U.S. Prov. Ser. No. 61/803,664 filed Mar. 20, 2013;

[0013] U.S. Prov. Ser. No. 61/803,672 filed Mar. 20, 2013;

[0014] U.S. Prov. Ser. No. 61/813,635 filed Apr. 18, 2013; and

[0015] U.S. Prov. Ser. No. 61/818,341 filed May 1, 2013;

The subject matter of this patent specification relates to the subject matter of the following applications, each of which is incorporated by reference herein:

[0016] U.S. Ser. No. 12/911,297 filed Oct. 25, 2010;

[0017] U.S. Prov. Ser. No. 61/415,771 filed Nov. 19, 2010;

[0018] U.S. Prov. Ser. No. 61/418,248, filed Nov. 30, 2010;

[0019] U.S. Prov. Ser. No. 61/429,093 filed Dec. 31, 2010;

[0020] U.S. Prov. Ser. No. 61/431,316 filed Jan. 10, 2011;

[0021] U.S. Prov. Ser. No. 61/437,687, filed Jan. 30, 2011;

[0022] U.S. Prov. Ser. No. 61/444,098, filed Feb. 17, 2011;

[0023] U.S. Prov. Ser. No. 61/450,115, filed Mar. 7, 2011;

[0024] U.S. Prov. Ser. No. 61/453,533, filed Mar. 16, 2011;

[0025] U.S. Prov. Ser. No. 61/476,754, filed Apr. 18, 2011;

[0026] U.S. Prov. Ser. No. 61/482,200 filed May 3, 2011;

[0027] U.S. Prov. Ser. No. 61/482,309 filed May 4, 2011;

[0028] U.S. Prov. Ser. No. 61/485,601 filed May 12, 2011;

[0029] U.S. Prov. Ser. No. 61/490,029 filed May 25, 2011;

[0030] U.S. Prov. Ser. No. 61/494,400 filed Jun. 7, 2011;

[0031] U.S. Prov. Ser. No. 61/506,074 filed Jul. 9, 2011;

[0032] U.S. Prov. Ser. No. 61/515,092 filed Aug. 4, 2011;

[0033] U.S. Prov. Ser. No. 61/539,736 filed Sep. 27, 2011;

[0034] U.S. Prov. Ser. No. 61/544,280 filed Oct. 7, 2011;

[0035] U.S. Prov. Ser. No. 61/550,391 filed Oct. 22, 2011;

[0036] U.S. Prov. Ser. No. 61/555,470 filed Nov. 3, 2011;

[0037] U.S. Prov. Ser. No. 61/556,167 filed Nov. 4, 2011;

[0038] International Patent Appl. No. PCT/US11/51982 filed Sep. 16, 2011;

[0039] U.S. Prov. Ser. No. 61/570,816 filed Dec. 14, 2011;

[0040] U.S. Prov. Ser. No. 61/599,981 filed Feb. 17, 2012;

[0041] U.S. Prov. Ser. No. 61/600,593 filed Feb. 18, 2012;

[0042] U.S. Prov. Ser. No. 61/611,182 filed Mar. 15, 2012;

[0043] U.S. Prov. Ser. No. 61/623,376 filed Apr. 12, 2012; and

[0044] International Patent Appl. No. PCT/US2012/34698 filed Apr. 23, 2012.

The above-referenced provisional and non-provisional patent applications are collectively referenced herein as "the commonly assigned incorporated applications."

FIELD

[0045] The present invention generally relates mainly to a medical device for use in hysteroscopic examinations of the uterus. More particularly, some embodiments relate to a medical device having integrated visualization and endometrial sampling components.

BACKGROUND

[0046] Hysteroscopy, or direct vision of the inside of the uterus (referred to herein as the "uterine cavity" and/or "endometrial cavity"), has been shown to greatly improve diagnostic accuracy. Few gynecologists do office hysteroscopy, however, because of the complexity and expense of the equipment and supplies required. Conventional endoscopes are typically tethered and cumbersome to use. They require skilled staff to operate and maintain. This makes it especially difficult in time critical locations such as an emergency room, operating room, and other areas of a medical facility where multiple devices and instruments are being used simultaneously.

[0047] Office-based endometrial biopsy is a standard diagnostic procedure used by gynecologists. While efficacious in detection of cancer, endometrial biopsy frequently will not detect endometrial polyps, submucous myomas, and other endometrial pathology. While it is possible to take tiny biopsies through some hysteroscopes that have operating channels, the surgeon usually needs to remove the hysteroscope and then do an endometrial biopsy with a different instrument. The repeated insertion and removal of multiple instruments into the patient's uterine cavity can be uncomfortable for the patient and/or may prolong the time required to complete the hysteroscopy and endometrial sampling procedures compared to performing both procedures without the repeated insertion and removal of different instruments. And, such use of multiple instruments for the same inspection/biopsy procedure requires the expense and inconvenience of buying, stocking and sterilizing such instruments.

[0048] The subject matter claimed herein is not limited to embodiments that solve any specific disadvantages or that operate only in environments such as those described above. Rather, this background is only provided to illustrate one exemplary technology area where some embodiments described herein may be practiced.

SUMMARY

[0049] According to some embodiments, a low-cost medical instrument is described for examining a patient's uterus. The instrument includes a single-use portion configured to in a single insertion distend and image a patient's uterus. The single-use portion includes: an elongated conduit having a distal portion configured and dimensioned for insertion into the patient's uterus, and a proximal portion; a fluid connection port formed at the proximal portion of the conduit; one or more distal openings at the distal portion of the conduit configured to provide fluid from the conduit and into the uterus; an imaging system at the distal portion of the conduit configured to image the uterus and provide video signals; an illumination system at the distal portion of the conduit configured to illuminate the uterus at an illumination field viewed by

the imaging system; and an electrical cable extending from a proximal end of the conduit to the imaging system and configured to carry video signals, control signals and electrical power. The instrument also includes a multiple-use portion having interior and exterior surfaces, the multiple-use portion being configured to be attached to the single-use portion for a single use and then detached after a single use, and to be re-used with a second single-use portion without sterilization of the interior surfaces. The multiple-use portion includes an integral image display that is electrically coupled with the imaging system at least in part by the electrical cable, the display being configured to display images provided by the imaging system for viewing by a user. The instrument also includes one or more seals configured to keep fluid in the conduit from contacting any of the interior surfaces of the multiple-use portion.

[0050] According to some embodiments, an integrated endoscopic instrument is described for examining a patient's uterus. The instrument includes an elongate member having a proximal end and a distal end. The elongate member is dimensioned and configured to facilitate insertion of the distal end through a patient's cervix and into the uterus. The elongate member is semi-flexible such that when fixedly held at 5 inches from the distal end and a 50 gram mass is applied two inches from the distal end the distal end bends in a downwards direction between 10 mm and 80 mm. The instrument further includes: an imaging system at the distal portion of the conduit configured to image the uterus and provide video signals; an illumination system at the distal portion of the conduit configured to illuminate the uterus at an illumination field viewed by the imaging system; a fluid opening positioned at the distal end of the elongate member to improve visual inspection using the electronic imaging module by delivering fluid to flow in a distal direction thereby clearing debris close to the imaging module; a handle that is configured and dimensioned to be grasped by a user's hand and manipulated by a user; and an integral image display that is electrically coupled with the imaging system at least in part an electrical cable. The display is configured to display images provided by the imaging system for viewing by the user.

[0051] According to some embodiments, an integrated endoscopic instrument is described for examining a patient's uterus. The instrument includes: an elongate member having a proximal end, a distal end, and a shaft extending from the distal end to the proximal end. The shaft houses a fluid channel and a plurality of electrical conductors. The conductors are configured to carry video and control signals. The shaft has a first outer diameter of less than 5 mm and the distal end has a second outer diameter greater than the first outer diameter. The instrument further includes: an imaging system at the distal portion of the conduit configured to image the uterus and provide video signals; an illumination system at the distal portion of the conduit configured to illuminate the uterus at an illumination field viewed by the imaging system; and a distal facing fluid opening at the distal end of the elongate member and in fluid communication with the fluid channel. The opening is positioned to improve visual inspection using the electronic imaging module by delivering fluid to flow in a distal direction thereby clearing debris close to the imaging module. The instrument further includes: a handle that is configured and dimensioned to be grasped by a user's hand and manipulated by a user; and an integral image display that is electrically coupled with the imaging system at least in part by at least some of the plurality of electrical conductors. The display is configured to display images provided by the imaging system for viewing by the user.

BRIEF DESCRIPTION OF THE DRAWINGS

[0052] To further clarify the above and other advantages and features of the subject matter of this patent specification, specific examples of embodiments thereof are illustrated in the appended drawings. It should be appreciated that these drawings depict only illustrative embodiments and are therefore not to be considered limiting of the scope of this patent specification or the appended claims. The subject matter hereof will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0053] FIG. **1** is a left side view of a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy, according to some embodiments;

[0054] FIG. **2** is a distal end view of a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy, according to some embodiments;

[0055] FIG. **3** is a proximal end view of a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy, according to some embodiments;

[0056] FIG. **4** is a perspective view of a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy, according to some embodiments;

[0057] FIG. **5** is a cross section showing details of a sealed sliding connector for a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy, according to some embodiments;

[0058] FIGS. **6**A-**6**F illustrate various aspects of a cannula for a device configured for combined hysteroscopy and endometrial biopsy, according to some embodiments;

[0059] FIGS. **7**A-C show further detail of a distal tip of a device configured for combined hysteroscopy and endometrial biopsy, according to some embodiments;

[0060] FIG. **8** is a flow chart illustrating aspects of using a multi-lumen cannula with simultaneous in-flow and out-flow for a hysteroscopy procedure, according to some embodiments;

[0061] FIGS. **9**A-**9**G illustrate a single-use portion that includes a cannula configured for fluid-in flow and visualization, according to some embodiments;

[0062] FIG. **10** is a cross section showing details of a sealed sliding connector for a device for hysteroscopy, according to some embodiments;

[0063] FIG. **11** is a flow chart showing aspects of using a variable dimension cannula for visual inspection of a patient's uterus, according to some embodiments;

[0064] FIGS. **12**A-**12**C illustrate a test setup to measure flexibility of a cannula shafts used in a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy, according to some embodiments;

[0065] FIG. **13** is a cross section showing an example of a different internal shaft structures within a cannula for a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy, according to some embodiments;

[0066] FIGS. **14**A-**14**B illustrate aspects of a cannula for a device configured for combined hysteroscopy and endometrial biopsy, according to some alternative embodiments; and

[0067] FIGS. **15**A-**15**C illustrate a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy having a single use cannula, fluid hub and handle, and a re-usable display screen, according to some embodiments.

DETAILED DESCRIPTION

[0068] A detailed description of examples of preferred embodiments is provided below. While several embodiments are described, it should be understood that the new subject matter described in this patent specification is not limited to any one embodiment or combination of embodiments described herein, but instead encompasses numerous alternatives, modifications, and equivalents. In addition, while numerous specific details are set forth in the following description in order to provide a thorough understanding work, some embodiments can be practiced without some or all of these details. Moreover, for the purpose of clarity, certain technical material that is known in the related art has not been described in detail in order to avoid unnecessarily obscuring the new subject matter described herein. It should be clear that individual features of one or several of the specific embodiments described herein can be used in combination with features or other described embodiments. Further, like reference numbers and designations in the various drawings indicate like elements.

[0069] FIG. **1** is a left side view of a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy, according to some embodiments. Many of the elements of the embodiments of hysteroscope **100** shown in FIG. **1** are the same as or similar to those discussed in the embodiments described in the commonly assigned incorporated applications, and such elements may not be described or may only briefly be described. It will also be appreciated that the aspects of the embodiments described in the commonly assigned incorporated applications may also apply to the embodiments described herein.

[0070] The device **100** is particularly advantageous for enabling a physician to perform an efficient combined hysteroscopic examination and an endometrial biopsy, although it is to be appreciated that other uses for hysteroscope **100** are within the scope of the present teachings. For example, as will be described in further detail, infra, the hysteroscope **100** can be fitted with other types of cannulas that are configured for other types of procedures such as hysteroscopy without biopsy. The hysteroscope **100** can bring about substantial efficiencies in terms of keeping equipment costs low and keeping the time required to perform the procedure modest, while at the same time providing the opportunity for better endometrial sample quality over conventional "blind" endometrial sample collection methods. Hysteroscope **100** includes a sampling cannula **102**, fluid hub **104**, sliding connector **106**, handle body **108**, display mount **112** and display **110**. The biopsy sampling cannula **102** is made of a distal tip **120** and a shaft **122**. The fluid hub in this case includes two fluid ports **114***a* and **114***b*. In the example shown in FIG. **1**, fluid port **114***a* is configured to deliver fluid into the device and thus into the uterus, and fluid port **114***b* is configured to apply suction to extract fluid and tissue samples from the uterus. As shown, the shaft **122** is curved near its distal end, for example having a 25 degree bend as shown. According to some embodiments, a bend of between 15 and 35 degrees near the distal end has been found to be suitable for many applications. The distal tip **120** includes a video camera assembly, lighting elements and fluid ports for in-flow (i.e. out of the device **100** and into the patient) and out-flow (i.e. into the device **100** and out of the patient). A sampling port on the upper side of the distal tip **120** also includes a cutting portion, which aids in tissue sample collection, as described in more detail below. According to some embodiments, the outer shell of tip **120** and shaft **122** are constructed of the same material, for example a heat and UV stabilized nylon 12 grade for tube extrusion such as Grilamid® L25. According to some embodiments the display **110** is a touch-screen display, and is able to tilt upwards and downwards by, for example, about 60 degrees each (total range of motion of 120 degrees), and pivot, or "pan" left and right by, for example, 45 degrees each (total range of motion 90 degrees) as shown by arrows **130** and **132** respectively. According to some embodiments, the cannula **102** (including the camera assembly, LED lighting and fluid ports integrated into the distal tip **120**), fluid hub **104** and sliding connector **106** together form a single-use portion **140**, which is designed for a single-use. According to these embodiments the single-use portion **140** is delivered to the medical practitioner in pre-sterilized package and are intended to be disposed of after a single-use, and the handle **108** and display **110** form a re-usable portion **150**, which is designed to be re-used many times.

[0071] According to some embodiments, the device **100** shown for example in FIG. **1** is a hand-held, compact single use endoscope. In these cases, endoscope **100** is provided in a sterile package, so is ready for immediate use without requiring any preparation for diagnostic or therapeutic procedures. According to some embodiments the single use device **100** needs no sophisticated connectors such that the entire endoscope is supplied in a sterile package ready for use.

[0072] FIG. **2** is a distal end view of a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy, according to some embodiments. The tip **120** and shaft **122** can be seen, as well as the fluid hub **104**, fluid ports **114***a* and **114***b*, as well as handle body **108**. Also shown, according to some embodiments is photo/video processing circuitry **210** that can be used to enhance or otherwise manipulate standard video signals and/or images received from the camera module in tip **120**. According to some embodiments, in FIG. **2** as in other figures herein, various dimensions are shown that have been found to be suitable for many applications, but those skilled in the art may vary those dimensions without departing from the teachings of this patent specification.

[0073] FIG. **3** is a proximal end view of a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy, according to some embodiments. Touch-sensitive screen **110** is preferably 3.5 inches (diagonally) in size.

[0074] FIG. **4** is a perspective view of a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy, according to some embodiments. In FIG. **4** the single-use portion **140** is shown disconnected from the re-usable portion **150**. The sliding connector **106** is shown and has an outer shell **470** that includes a lip **472** that fits over an o-ring seal **462** and a protruding mating portion **450** of the handle assembly **108**. Multiple similar seals can be provided along the length of connector **106** to further isolate handle **108** from patient matter and/or fluids that could otherwise contaminate and/or cause connection failure such as electrical failures on handle **108**. Also within connector **106** is a seal which forms a barrier between the proximal end of electrical cable **480** and fluid and/or patient matter. The cable **480** carries video signals and control signals between the camera module and LEDs at distal tip **120** to connection pins housed within sleeve **460**. The sleeve **460** fits into a closed channel on the handle **108** while the connection pins mate with pin receptacles **452** as to form electrical connections with the pins.

[0075] Also visible in FIG. **4** is ON/OFF button **410** is used to toggle the device **100** on or off. According to some embodi-

ments, the power ON/OFF button **410** is backlit using two differently colored LEDs to indicate the status of rechargeable battery **420** to the user. For example, green backlighting can be used to indicate the battery level is OK and red backlighting can be used to indicate the battery **420** is low. According to some embodiments the capacity of battery **420** is about 2500 mAh. According to some embodiments, the LED lighting of button **412** can also be used to indicate battery charging status during re-charging of the battery **420** from an external power source. In this case, the backlighting LED shows red while charging the battery and green when the battery **420** is fully charged. According to some embodiments, the ON/OFF button **410** doubles as a "home" button, such that a shorter press, such as 1 second or less, of button **410** brings up a home screen menu on the display **110**.

[0076] LED brightness control button **412** is used to control the brightness of the LEDs on the distal tip **120**. According to some embodiments a total of four different LED illumination levels has been found to be suitable and the single button **412** controls the level by cycling through the levels, changing the illumination level with each button press. The Snap/Video button **414** is used to capture still images and/or video from the camera in tip **120**. According to some embodiments, pressing Snap/Video button **414** for three seconds or less captures a single still photo, while pressing button **414** for longer than three seconds starts video recording. When video is being recorded, a single press of button **414** stops video capture. According to some embodiments, an audible acknowledgement signal is associated with presses of the buttons **410**, **412** and **414**. For example, a single "beep" is sounded when any of the buttons except for double beeps when either the Snap/Video button **414** or an OK software button is pressed.

[0077] It has been found that providing dedicated hardware buttons on the handle itself have several advantages over touch-screen implemented "soft buttons" and/or hardware buttons located in locations other than the the handle. The handle located hardware buttons, such as shown in FIG. **4**, allow for one-handed operation as well as for operation with gloved and/or wet hands. With one-handed operation, a user can use a single hand to both manipulation of scope and operate buttons such as the "snap" and/or the "LED" buttons. The user's other hand is then free for other procedures or for manipulating the cannula (e.g. bending of cannula and/or steering the cannula). In other examples, for some reason the user's other hand may not be sterile. Furthermore, it has been found that the use of touch-screen implemented soft buttons on touch screen display **110** may not reliably work with gloved and/or wet fingers.

[0078] FIG. **5** is a cross section showing details of a sealed sliding connector for a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy, according to some embodiments. The sliding connector **106** is shown here with an outer shell **470** that includes a lip **472** that fits over an o-ring seal **462** and a protruding mating portion **480** of the handle assembly **108**. Other seals can be provided along the length of connector **106** to further isolate handle **108** from patient matter and/or fluids that could otherwise contaminate and/or cause connection failure such as electrical failures on handle **108**. The cable **480** carries video signals, control signals and electrical power between the camera module and LEDs at distal tip **120** to connection pins housed within sleeve **460**. The sleeve **460** fits into a closed channel on the handle **108** while the connection pins **552** mate with pin receptacles **452** as to form electrical connections the pins. The sliding connector **106** includes a barrier **530** that fits tightly inside outer shell **470**. According to some embodiments, a transparent sealing glue **550** is applied between the barrier **530** and shell **470** as shown in FIG. **5**. Barrier **530** terminates at its proximal end in an extended sleeve **460** that fits into a closed channel **560** in handle **108** such that an outwardly facing bump **572** releasably fits into an inward facing depression **562** in channel **560**. Barrier **530** further includes a distal portion that terminates in a first seal **532** having an opening **534** through which cable **480** passes. An intermediate portion of barrier **530** provides an additional seal by including an inner indentation **536** tightly enveloping a radial projection **540** of the proximal portion of cable **480**. Barrier **530** further includes at its proximal portion a lip **538** that helps form another additional seal by bearing against o-ring **462** to further help ensure that fluid and tissue matter will not reach interior portions of handle **108** when the instrument is in use. According to some embodiments glue **554** is used to enhance the seal between barrier **530** and cable **480** as shown. According to some other embodiments, glue **554** additionally is used to mostly or fully fill the inner void **556** of barrier **530** as well. According to some embodiments, other techniques and/or combinations of techniques are used to implement the fluid barrier between the single use portion **140** and multi-use portion **150** of the device **100**. For example, the seal or seals can be implemented using structures such as gaskets, caps, o-rings alone, with each other and/or in combination with glues and/or ultrasonic welding or bonding techniques.

[0079] Also visible in FIG. **5** is a fluid cap **510** and gasket **512** that are shaped and positioned to provide fluid communication between a cutout **520** in shaft **122** to fluid port **114***b*. For simplicity, the shaft **122** is shown with two fluid lumens. One fluid lumen **502** is in fluid communication with fluid port **114***b* and the other fluid lumen **504** is in fluid communication with fluid port **114***a*. A plug **514** is inserted in the end of lumen **502** to prevent fluid communication between lumen **502** and fluid port **114***a*. As is described infra, the actual cross section of the shaft **122** can be of other layouts and the cut-outs and/or plug shapes and locations depends on the design of the fluid hub and shaft being used. According to some embodiments, transparent sealing glue **506** is used between the outer shell of the fluid hub **104** and the cap **510** and gasket **512**.

[0080] According to some embodiments the fluid barrier and sealing can be implemented by one or more ultrasonic welding processes. In these cases, the outer shell **470** is manufactured as two pre-molded halves (for example split along the central longitudinal axis). Assembling two halves enhances the ability to effectively and evenly apply the glue, such as glue **506** and glue **550**. According to some embodiments, certain interior structural components, such as barrier **530**, gasket **512** and/or cap **510**, are bonded or welded ultrasonically directly to the shell **470**. In such cases, the use of glue **506** and/or **550** can be eliminated or at least supplemented. According to some embodiments, a some or all of barrier **530** is also manufactured as two halves. During assembly the placement of the glue **554** is more easily and robustly applied to form a seal between opening **534** of barrier **530** and cable **480**.

[0081] FIGS. **6**A-**6**F illustrate various aspects of a cannula for a device configured for combined hysteroscopy and endometrial biopsy, according to some embodiments. FIG. **6**A shows a right side view of shaft **122** of cannula **102**, such a shown in device **100** of FIG. **1**. The shaft **122** configured for

hysteroscopy using LED lighting, camera module and forward facing fluid ports on distal tip **120** as well as for taking biopsy tissue samples using a sampling port **610**. The proximal end of shaft **122** includes a cutout section **520** for making fluid communication with one of the fluid lumens to a fluid port located in a fluid hub. By constructing the cannula shaft **122** from a single piece of extruded tubing, the need for additional tubes is eliminated, and it has been found that assembly yield rates are significantly improved. According to some embodiments the shaft **122** is constructed of a heat and UV stabilized nylon 12 grade for tube extrusion such as Grilamid® L25. FIG. **6**B is a cross sectional view along A-A', according to some embodiments. In this case, the shaft **122** is elliptical such that it is slightly taller than it is wide. In the embodiment shown, the outer walls **620** and inner walls **622** and **624** are 0.008" thick and define a central lumen **502** and two side lumens **504***a* and **504***b*. According to some embodiments, each of the side lumens **504***a* and **504***b* have a cross sectional area of 1.22 mm^2. Also shown in FIG. **6**B is the approximate location of the cutout **520**. As can be seen the central lumen **502** can be connected to a fluid port via the cutout **520**. According to some embodiments, the central lumen **502** is used for both the electrical cable **480** (shown in FIG. **4**), as well as for drawing fluid ("out-flow) so as to aid in taking tissue samples by being in fluid communication with fluid port **114***b* (shown in FIG. **5**). The two side lumens **504***a* and **504***b* are both in fluid communication with the in-flow fluid port **114***a*. Note that according to this embodiment, the plug **514** shown in FIG. **5** would be used to plug the proximal end of central lumen **502**, and the plug **514** has a hole for allowing cable **480** to pass through it. On the distal end of the shaft **122**, the two side lumens **504***a* and **504***b* are each in fluid communication with a forward facing fluid port on distal tip **120**, as shown in FIG. **7**B, infra. FIG. **6**C shows another example of a cross section of shaft **122** which in this case is round, having a outer diameter of 4.3 mm. Also visible in FIG. **6**C is the electrical cable **480** which is enclosed in a waterproof jacket.

[0082] FIG. **6**D is a top view of the distal area of shaft **122**, according to some embodiments. Near the distal tip **120**, the sampling port **610** includes a cutting edge **612**, which is sharp and positioned so as to facilitate collection of the endometrial sample by scraping. FIG. **6**E is a side view showing further details of the shape of distal tip **120** of shaft **122**, according to some embodiments. FIG. **6**F shows details of the proximal end of shaft **122** including the cut out **520**, according to some embodiments.

[0083] FIGS. **7**A-C show further detail of a distal tip of a device configured for combined hysteroscopy and endometrial biopsy, according to some embodiments. Visible in FIG. **7**A, on top side of distal tip **120** is the sampling port **610** used to draw fluid out of the patient's uterus as well as collect tissue. On the distal end of the tip **120** is lens sensor stack **750**. According to some embodiments, lens sensor stack **750** consists of a lens set (which includes an iris) precisely positioned on top of a CMOS sensor. Lens sensor stack **750** is held together by a plastic (or in some embodiments stainless steel) housing or holder block **740**. Glass **752** in some embodiments is simply a protective glass cover, and according to some other embodiments is the first element of the lens set. Glass **752** is coated with hydrophobic or hydrophilic film. The lens sensor stack **750**, holder **740** and glass **752** together are referred to herein as camera module **754**. According to some embodiments the camera module **754** also includes a shield (not shown) to block direct entry of light from LEDs **730** and **732** into the sensor lens stack **750**. According to some embodiments, camera module **754** is about 2.2 mm×2.2 mm in cross sectional size.

[0084] According to some embodiments, the CMOS sensor within lens sensor stack **750** includes a low voltage color CMOS image sensor core, image sensor processing and image output interface circuitry on a single chip such as the OmniVision 7675. According to some other embodiments, an additional chip can be used to carry out video processing which is mounted on the same mini-PCB as the CMOS sensor. By providing integrated digital video processing within the sensor module, all video processing can be performed directly on the same PCB as the CMOS sensor, or on the same substrate in which the CMOS is formed such that the imaging plane of the CMOS and the plane along which the video processing circuits extend substantially coincide. In this example, the video signal from the sensor module can be in any suitable video format, such as NTSC, PAL, or another common video format, so that no further video processing would be required to drive widely available displays for common video formats such as TV displays, tablets, computers and hospital workstations.

[0085] Two LEDs **730** and **732** are positioned above and below and mounted to the camera module **754** to evenly illuminate the uterine tissue for visual inspection. According to some embodiments each of the LEDs **730** and **732** are about 1.0 mm×0.5 mm in frontal area. One problem in performing visual inspections of endometrial tissues, and particularly in situations where the endometrial medium, consisting of free tissue, loosely attached tissue and/or fluid, is relatively thick, is that light reflected from tissue particles suspended close to the lens can appear overly-bright and therefore impair imaging of other tissue surfaces. As can be seen in FIG. **7**B, which is a front view of distal tip **120**, two forward facing fluid ports, **720** and **722** are provided to allow fluid to exit the tip and tend to push suspended particulate matter away from the camera so as to enhance image and video capture by camera module **754**. In some cases some tissue debris may collect on the distal surface such that imaging would be impaired in such cases the forward facing ports are useful in clearing away such collected tissue. Also it has been found that the forward facing ports are helpful in aiding insertion of the cannula in many cases as the fluid provides lubrication as well as a partial distending of tissues just ahead of the distal tip during insertion. Since the forward facing ports improve visualization, the risk of accidental damage to the uterus is greatly reduced. FIG. **7**C is a perspective view of the holder block **740** which according to some embodiments is made of a suitable plastic material, such as liquid crystal polymer. The distal tip **120** in this case includes separated fluid channels for fluid in-flow and out-flow. In particular, the central fluid lumen **502** is in fluid communication with the sampling port **610**, and is blocked via the holder block **740** from being in fluid communication with the forward facing ports **720** and **722**. Similarly, the two side fluid lumens **504***a* and **504***b* are in fluid communication with forward facing fluid ports **722** and **720**, respectively.

[0086] In performing a hysteroscopy procedure, it has been found that providing a device that has separated fluid flow channels for in-flow and out-flow has certain benefits including allowing for simultaneous in-flow and out-flow. FIG. **8** is a flow chart illustrating aspects of using a multi-lumen cannula with simultaneous in-flow and out-flow for a hysteros-

copy procedure, according to some embodiments. In step **810**, the cannula **102** is inserted through the cervix into the patient's uterus while in-flowing fluid through the in-flow lumen(s) such as lumens **504***a* and **504***b* shown in FIG. **6**B or **6**C, and through forward facing ports such as ports **720** and **722** shown in FIG. **7**B. In step **812**, the endometrial cavity is visually examined by viewing live images from the sensor in the camera module **754** (shown in FIG. **7**A) and on the integrated display **110** shown in FIGS. **1** and **3**. Suction is applied to the out-flow port (port **114***b*, shown in FIGS. **1**, **2** and **5**) to allow for a continuous flow of fluid which maintains clear visibility by removing blood mucus and other opaque material such as tissue debris. In and optional step **814**, after visualization is completed, one or more endometrial tissue samples can be obtained by turning off the inflow port and applying suction to the outflow port. Samples can be obtained from a side facing port such as port **610** shown in FIGS. **6**A, **6**D and **6**E. The location of the biopsy sampling be based on the areas of pathology identified by the visual inspection step **812** to allow for a directed biopsy. Additionally according to some embodiments where conditions allow it, visualization can continue during step **814** allowing for further visual confirmation of the location of the biopsy. In step **816** the cannula is withdrawn from the patient.

[0087] It has been found that it is very useful to provide the device **100** as divided into two portions: a single use portion, such a portion **140** in FIG. **1**, and a re-usable portion **150** in FIG. **1**. According to some embodiments, the re-usable portion includes the handle and integrated display, where some of the more costly components (such as the display) as well as some of the components that may be difficult or impractical to be re-sterilized (such as some of the electronic components) are located. According to some embodiments the separable design shown allows for different types of single-use portions to be provided that each are configured to operate with a single re-usable portion. Examples of different types of single use portions include cannulas having different port configurations (including the presence or absence of a side-facing port), different fluid hub layout configurations (including the number of fluid ports), as well cannulas having different bend locations and amount, as well as different flexibility characteristics. The selection of which cannula design to use can be a matter of preference by the user but can also be influenced by anatomical variables, as well as what type of procedure is being performed. For example, according to some embodiments at least three main types of single-use cannula are provided that are all compatible with a re-usable handle and display portion: (1) a diagnostic cannula having in-flow capability for distention and visualization, but without a dedicated out-flow port for sampling; (2) a combined visualization and biopsy cannula which is configured for both visualization and taking tissue samples (for example single-use portion **140**); and (3) an operative cannula that includes visualization as well as a working channel for performing one or more different types of surgical procedures.

[0088] FIGS. **9**A-**9**G illustrate a single-use portion that includes a cannula configured for fluid-in flow and visualization, according to some embodiments. As shown in FIG. **9**A, the hysteroscopy device **900** comprises a single-use portion **940** with a sliding connector **906** that is configured to mate with re-useable portion **150** that has been shown and described elsewhere herein. The single use portion **940** also includes a fluid hub **904** having a single fluid port **914** that is in fluid communication with a single fluid lumen within shaft **922**. Cannula **902** includes a shaft **922** and a distal tip **920** which includes one more more forward facing in-flow ports, a camera module and LED lighting as will be described in further detail herein. FIG. **9**B is a right side view of the shaft **922**, and FIG. **9**C is a cross section along A-A'. As can be seen in FIG. **9**C, there is two lumens in shaft **922**. Circular lumen **902** has an inner diameter of 1.5 mm that contains the electrical cable **980** between the distal tip **920** and the connector **906**. Crescent-shaped fluid lumen **904** is in fluid communication with the fluid port **914** at the proximal end of shaft **922** and with forward facing in-flow ports on the distal tip **920**. According to some embodiments, the cross sectional area of fluid lumen **904** is about 2.43 mm^2. Providing a hysteroscopy device having fluid in-flow capabilities with an outer diameter of less than about 4 mm has been found to be desirable, and according to even more preferred embodiments the outer diameter of shaft **922** is less than about 3.6 mm. In the example shown in FIG. **9**C, the outer diameter of shaft **922** is 3.4 mm, and an outer wall thickness of 0.016 inches. FIG. **9**D is a right side view showing further detail of the distal end of shaft **922**, according to some embodiments. According to some embodiments, shaft **922** is constructed of a heat and UV stabilized nylon 12 grade for tube extrusion such as Grilamid® L25.

[0089] FIG. **9**E is a left side view of the distal end of device **900**, showing a separate distal tip shell **942** that surrounds a holder block **940**. Shell **942** can be made, for example, of acrylic or other suitable material. The holder block **940** houses lens sensor stack **950** which can be of the same design as lens sensor stack **750** described herein. According to some embodiments, the distal tip shell **942** is tapered as shown such that the most distal end is of larger dimension than the proximal end (where it mates with the shaft **922**). It has been found that providing a device with variable dimensions, in particular larger distal tip paired with a narrower shaft, allow for certain advantages in facilitating fluid management (which is described in greater detail with respect to FIG. **11**), as well as providing for more frontal area for the front facing fluid ports, LEDs and camera module. According to some embodiments the diameter of the distal end of tip shell **942** is 4.0 mm. It has been found that a differential of 0.4 mm is beneficial for fluid management during many applications. FIG. **9**F is a perspective view of the distal tip **920**, and shows the lens **952**, which may be covered by a glass cover, as well as two LEDs **930** and **932**. Two forward facing in-flow fluid ports **934** and **936** are also provided on the distal end of tip **920** as shown, and are in fluid communication with the fluid lumen **904** in shaft **922** an also to fluid port **914** on fluid hub **904**. FIG. **9**G is a perspective view of holder block **940** which according to some embodiments is made of a suitable plastic material, such as liquid crystal polymer.

[0090] FIG. **10** is a cross section showing details of a sealed sliding connector for a device for hysteroscopy, according to some embodiments. As described, the sliding connector **906** is compatible with the re-useable handle **108**. The fluid hub **904** and connector **906** are similar or identical to hub **104** and connector **106** in many respects other than being configured for only a single fluid-carrying lumen in the cannula shaft as well as a single fluid port on hub **904**. A fluid cap **1010** and gasket **1012** that are shaped and positioned to provide fluid communication between lumen **904** shaft **922** to fluid port **914**. According to some embodiments, transparent sealing glue **1006** is used between the outer shell of the fluid hub **904** and the cap **1010** and gasket **1012**. The sliding connector **906**

is shown here with an outer shell **1070** that includes a lip **472** that fits over an o-ring seal **462** and a protruding mating portion **460** of the handle assembly **108**. Other seals can be provided along the length of connector **906** to further isolate handle **108** from patient matter and/or fluids that could otherwise contaminate and/or cause connection failure such as electrical failures on handle **108**. The cable **980** carries video signals and control signals between the camera module and LEDs at distal tip **920** to connection pins housed within sleeve **460**. The sleeve **460** fits into a closed channel on the handle **108** while the connection pins **552** mate with pin receptacles **452** as to form electrical connections the pins. The sliding connector **906** includes a barrier **530** that fits tightly inside outer shell **1070**. According to some embodiments, a transparent sealing glue **550** is applied between the barrier **530** and shell **470**. Barrier **530** terminates at its proximal end in an extended sleeve **460** that fits into a closed channel **560** in handle **108** such that an outwardly facing bump **572** releasably fits into an inward facing depression **562** in channel **560**. Barrier **530** further includes a distal portion that terminates in a first seal **532** having an opening **534** through which cable **480** passes. An intermediate portion of barrier **530** provides an additional seal by including an inner indentation **536** tightly enveloping a radial projection **1040** of the proximal portion of cable **980**. Barrier **530** further includes at its proximal portion a lip **538** that helps form another additional seal by bearing against o-ring **462** to further help ensure that fluid and tissue matter will not reach interior portions of handle **108** when the instrument is in use.

[0091] FIG. **11** is a flow chart showing aspects of using a variable dimension cannula for visual inspection of a patient's uterus, according to some embodiments. The steps shown in FIG. **11** assume that a variable dimension cannula is being used for the visual inspection, such as cannula **902** in which the shaft of the cannula has a smaller diameter than the distal tip. By using a smaller shaft, fluid can be allowed to drain from the uterus. This is because after larger diameter tip is inserted through the cervix, the portion of the cannula that is in touch with the cervix is kept small which allows the fluid to drain.

[0092] In step **1110**, the patient is on the exam table. In step **1112** the packaging enclosing the sterile single-use portion (e.g. portion **940** in FIG. **9**A) is opened and the single-use portion is attached to the re-usable portion (e.g. portion **150** in FIGS. **1** and **9**A). In step **1114** the device (e.g. device **900** in FIG. **9**A) is turned on and a manual white balance procedure is carried out if desired or needed. In step **1116** a fluid tube and syringe or pressurized fluid bag containing saline or other distending fluid is attached to the fluid port of the device (e.g. port **914** in FIG. **9**A). In step **1118**, the distal end of the cannula is inserted into the cavity, such as a through the cervix to the uterus, under direct vision using the camera module and integrated display screen while fluid is being infused. In step **1120**, the uterus is visually inspected, again under direct vision using the camera module and integrated display screen. In step **1122**, if the view is impaired by blood or debris in the cavity the cannula can be advanced into the cavity so that the narrow portion is in the entrance (e.g. the cervix), thus allowing leakage of fluid around the cannula shaft while fluid is infused through the forward facing ports at the distal end of the cannula. This allows for continuous flow of fluid, which aids in obtaining improved visual images from the camera module. In step **1124**, if the is more leakage than is needed in order to maintain the desired distension of the uterus, then the cannula can be withdrawn so that the wider diameter distal tip is within the entrance so as to effectively block a significant portion of leakage from the uterus. In step **1126**, optionally, the syringe can be used to draw fluid out (out-flow) to obtain samples from the uterus. In step **1128**, the cannula is withdrawn from the uterus and the procedure is completed. According to some embodiments, as mentioned in optional step **1126**, sampling and/or biopsy can be carried out via the two forward facing ports on the distal end.

[0093] Conventional video endoscopes are typically either rigid or flexible. The rigid scopes have a rigid, non-bendable elongated body with a precision rod lens set inside as relay optics. On the other hand, flexible endoscopes are made of flexible elongated body. The tip portion of a flexible endoscope can be bendable or steerable by embedded cable wire that is attached to the levers at the proximal end. The rigid scope is rigidly attached to the scope body and handle so it can be moved in a fashion as a typical rigid body can be moved. On the other hand, the flexible endoscope is weakly coupled to the scope handle or body, and therefore has limited control by the handle and endoscope body. In either case, the handle or scope body has to be moved which is often undesirable.

[0094] According to some embodiments, a semi-flexible (or semi-rigid) endoscope is provided. In one embodiment, the elongated body (the scope cannula) can be easily manipulated spatially to achieve the best visualization of cavity such as a distended uterus or knee joint. Optimal flexibility (or stiffness/rigidity) of the cannula allow the operator clinician to bend or steer the cannula without moving the scope handle or scope body. For example, using a device such as device **100** of FIG. **1** or device **900** of FIG. **9**A, the operator can use one hand to hold the handle **108**, using one finger to control visualization using the LED lighting and/or snap buttons, while the operator uses the other hand to grasp the cannula at some intermediate point along the shaft (e.g. 5 inches from the distal tip) to bend and/or steer the cannula. According to some other embodiments, a selection from multiple cannulas having different lengths is made according to the size of the cavity which is being evaluated.

[0095] FIGS. **12**A-**12**C illustrate a test setup to measure flexibility of a cannula shafts used in a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy, according to some embodiments. FIG. **12**A shows a test set up in which the cannula shaft **122** is held firmly at a point 10 inches from the distal tip, while a force from a mass of 10 grams is applied to a point that is 2 inches from the distal dip. FIG. **12**B shows shaft **122** in a bent state (in dotted lines) under the force applied as shown. In this example the distal tip was moved 35 mm from the applied force. FIG. **12**C show the shaft **122** held at a different point, 5 inches from the distal tip, while a force from a different mass, 30 grams, is applied to a point 2 inches from the distal tip. In this example, the distal tip is deflected 10 mm under the applied force. Tables 1 and 2 show the tip deflections for a cannula shaft **122** which includes separated in-flow and out-flow fluid paths such as for shown in FIG. **6**A. Table 1 shows the measured tip deflections when the shaft is held 10 inches from the distal tip and Table 2 shows the measured tip deflections when the shaft is held 5 inches from the distal tip.

TABLE 1

Cannula Having Separate In-flow and Out-flow Paths. Held at 10 inches from distal tip, and loading weight at 2 inches from distal tip.

Weight (g)	Tip down (mm)
10	35
20	70
30	100
40	130
50	145

TABLE 2

Cannula Having Separate In-flow and Out-flow Paths. Held at 5 inches from distal tip, and loading weight at 2 inches from distal tip.

Weight (g)	Tip down (mm)
10	2
20	6
30	10
40	14
50	17
70	25
90	35
100	39
150	60
170	70
200	80

[0096] Similarly, Tables 3 and 4 show the tip deflections for a cannula shaft **922** which includes a single fluid path such as for shown in FIG. **9**B. Table 3 shows the measured tip deflections when the shaft is held 10 inches from the distal tip and Table 4 shows the measured tip deflections when the shaft is held 5 inches from the distal tip.

TABLE 3

Cannula Having Single Fluid Paths. Held at 10 inches from distal tip, and loading weight at 2 inches from distal tip.

Weight (g)	Tip down (mm)
5	75
10	100
15	135
20	150

TABLE 4

Cannula Having Single Fluid Path. Held at 5 inches from distal tip, and loading weight at 2 inches from distal tip.

Weight (g)	Tip down (mm)
5	4
10	8
15	13
20	18
30	26
40	32
50	41
70	55
90	70

TABLE 4-continued

Cannula Having Single Fluid Path. Held at 5 inches from distal tip, and loading weight at 2 inches from distal tip.

Weight (g)	Tip down (mm)
100	75
120	85
150	95
170	100
200	105

[0097] It has been found that multiple fluid path cannulas having flexibilities of between 60% less deflection (i.e. more stiff), and 40% greater deflection (i.e. less stiff) than the examples shown in Tables 1-2 are suitable for many applications, according to some embodiments. More preferably, cannulas having multiple fluid paths should have flexibilities of between 30% less deflection and 25% greater deflection than the examples shown in Tables 1-2. Even more preferably, cannulas having multiple fluid paths should have flexibilities of between 15% less deflection and 10% greater deflection than the examples shown in Tables 1-2. It has been found that single fluid path cannulas having flexibilities of between 75% less deflection (i.e. more stiff), and 50% greater deflection (i.e. less stiff) than the examples shown in Tables 3-4 are suitable for many applications, according to some embodiments. More preferably, cannulas having a single fluid path should have flexibilities of between 50% less deflection and 25% greater deflection than the examples shown in Tables 3-4. Even more preferably, cannulas having a single fluid path should have flexibilities of between 25% less deflection and 10% greater deflection than the examples shown in Tables 3-4. Another advantage of providing flexibility and stiffness characteristics as described is a potential reduction in risks of injury such as by perforation of the uterine wall.

[0098] Although internal shaft structures shown in FIGS. **6**A, **6**B, and **9**C have been shown and described herein, other internal structures can be provided according to some other embodiments. FIG. **13** is a cross section showing an example of a different internal shaft structures within a cannula for a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy, according to some embodiments. In FIG. **13**, cannula shaft **1322** includes two fluid lumens are provides for separated in-flow and out-flow channels. The wall **1330** defines and upper lumen **1304** that, for example can be used for out-flow, as well as a lower lumen **1302** that can be used for both in-flow as well as housing the electrical cable **1380** which is enclosed in a waterproof jacket.

[0099] FIGS. **14**A-**14**B illustrate aspects of a cannula for a device configured for combined hysteroscopy and endometrial biopsy, according to some alternative embodiments. A cannula **1402** is shown that has a variable diameter (a wider distal tip **1420** and narrower shaft **1422**). The cannula **1402** also includes a fluid hub **1404** and sliding connector (not shown) that mates with a re-usable portion that can include a handle and integrated display screen (such as portion **150** in FIGS. **1** and **9**A). In this case, for purposes of fluid management, a slideable sleeve **1430** is positioned surrounding cannula shaft **1422** can be used to plug the entrance of the body cavity to prevent fluid from draining out of the cavity. The sleeve **1430** can be a soft material and cylindrical in shape disposed such that is surrounds the cannula shaft **1422**, or

according to some embodiments sleeve **1430** can be a piece that can be mounted on the shaft **1422** after insertion of the tip **1420**.

[0100] Although the junction between the single use portion **140** and the re-usable portion **150** is shown between the fluid hub and handle **108** in FIGS. **1** and **9**A, according to some embodiments the junction can be positioned in other locations. It has been found that the most costly components of the endoscopic device are associated with the integrated display. As such, according to some embodiments, the single use portion can include the handle, while the re-usable portion includes the display. FIGS. **15**A-**15**C illustrate a device for hysteroscopy and/or combined hysteroscopy and endometrial biopsy having a single use cannula, fluid hub and handle, and a re-usable display screen, according to some embodiments. FIGS. **15**A and **15**B show a device **1500** having a single use portion **1550** and a re-usable display screen **110** in a display screen assembly **1510**. The single use portion includes: a cannula **102** that has a distal tip **120** and shaft **122**; a fluid hub **140** that has a fluid port **114**; a handle **1508** and a sliding connector **1506**. According to some embodiments, the cannula **102** and fluid hub **104** can be as described herein with reference to FIGS. **1**-**5**, **6**A-F and **7**A-C. According to some other embodiments the cannula and fluid hub can be identical or similar to the cannula **902** and fluid hub **904** shown in FIGS. **9**A-G and **10**. The handle **1508** can include the control buttons, electronics and battery, such as handle **108** described herein. According to some embodiments in-order to reduce the cost of the single-use portion **1550**, some or all of the system electronics **1522** and/or the battery **1520** can be located in the display screen assembly **1510**. A sliding connector **1506** forms a connection between the display assembly **1510** and the handle **1508**. The sliding connector **1506** preferably includes some or all of the fluid barriers and seals described with respect to connector **106**, in order to prevent fluid from entering mating portion of the connector **1506** and/or the system electronics and LCD display in display assembly **1510**.

[0101] FIG. **15**C is a perspective view of device **1500** with the sliding connector **1506** disconnected. The sliding connector mates with a connector **1550** on display assembly **1510**. According to some embodiments, one or more of on/off button **1530**, LED lighting control button **1532** and "snap" button **1534** can be located on the display assembly **1510** so that the user can control the device **1500** using hardware buttons, which may be easier to use with gloved or wet hands, for example, while maintaining a low-cost single-use portion **1550**. According to some other embodiments, soft-buttons can be used on touch screen **110** on display assembly **1510**.

[0102] Although the foregoing has been described in some detail for purposes of clarity, it will be apparent that certain changes and modifications may be made without departing from the principles thereof. It should be noted that there are many alternative ways of implementing both the processes and apparatuses described herein, including for using the described devices or certain aspects thereof for hysteroscopy but not for endometrial biopsy, or for endometrial biopsy but not for hysteroscopy, or for endoscopy and/or biopsy other than of the uterus. For example, in some applications the device shown in FIGS. **50**-**51** could also be used for taking fluid and/or fluid/tissue endometrial samples through the forward facing fluid parts. Accordingly, the present embodiments are to be considered as illustrative and not restrictive, and the body of work described herein is not to be limited to the details given herein, which may be modified within the scope and equivalents of the appended claims.

1-**5**. (canceled)

6. A low-cost medical instrument for examining a patient's uterus, said instrument comprising:

a single-use portion configured to in a single insertion distend and image a patient's uterus, the single-use portion including:

an elongated conduit having a distal portion configured and dimensioned for insertion into the patient's uterus, and a proximal portion;

a fluid connection port formed at the proximal portion of the conduit;

one or more distal openings at the distal portion of the conduit configured to provide fluid from the conduit and into the uterus;

an imaging system at the distal portion of the conduit configured to image the uterus and provide video signals;

an illumination system at the distal portion of the conduit configured to illuminate the uterus at an illumination field viewed by said imaging system; and

an electrical cable extending from a proximal end of the conduit to the imaging system and configured to carry video signals and control signals;

a multiple-use portion having interior and exterior surfaces, the multiple-use portion being configured to be attached to the single-use portion for a single use and then detached after a single use, and to be re-used with a second single-use portion without sterilization of the interior surfaces, said multiple-use portion comprising an integral image display that is electrically coupled with said imaging system at least in part by the electrical cable, the display being configured to display images provided by the imaging system for viewing by a user; and

one or more seals configured to keep fluid in the conduit from contacting any of the interior surfaces of said multiple-use portion.

7. An instrument according to claim **6** wherein said multiple-use portion further comprises a handle having an off-axis profile so as to facilitate grasping by the user's hand and for rotation and tilting of the instrument in use, the handle including a plurality of buttons to control a plurality of features of the instrument, wherein when said single-use and multiple-use portions are attached to one another, the display, handle, elongate member and imaging system are mounted in a fixed relationship so as to rotate about a longitudinal axis of the elongate member in rotational alignment.

8. An instrument according to claim **6** wherein said single-use portion further comprises a handle having an off-axis profile so as to facilitate grasping by the user's hand and for rotation and tilting of the instrument in use.

9. An instrument according to claim **8** wherein said multiple-use portion includes a rechargeable battery and electronics disposed along with said integral image display within a multi-use display housing, and said multi-use display housing is configured to slidably attach to said handle of said single-use portion.

10. An instrument according to claim **6** wherein the conduit comprises:

a first fluid channel in fluid communication with at least a first of the one or more distal openings and with said fluid connection port; and

a second fluid channel in fluid communication with at least a second of the one more distal opening and with a second fluid connection port formed at the proximal portion of the conduit.

11. An instrument according to claim **10** wherein the instrument is configured for a medical procedure in which said distal portion is inserted into the patient's uterus to simultaneously provide (a) improved visual inspection using the electronic imaging system by delivering fluid flow in a distal direction by introducing fluid under positive pressure into said fluid connection port, which fluid passes through said first fluid channel and enters the uterus through at least the first distal opening, (b) drawing fluid under negative pressure from said second fluid connection port, which fluid is drawn from the uterus and into the instrument through at least the second distal opening and passes through said second fluid channel and out of said second fluid connection port, and (c) image of the uterus by illuminating the uterus with said illumination system and imaging the illuminated uterus with said imaging system.

12. An instrument according to claim **6** wherein said elongated conduit is semi-flexible such that when fixedly held at 5 inches from a tip of the distal portion and a 50 gram mass is attached at a location two inches from the tip, the distal portion bends in a downwards direction between 10 mm and 80 mm.

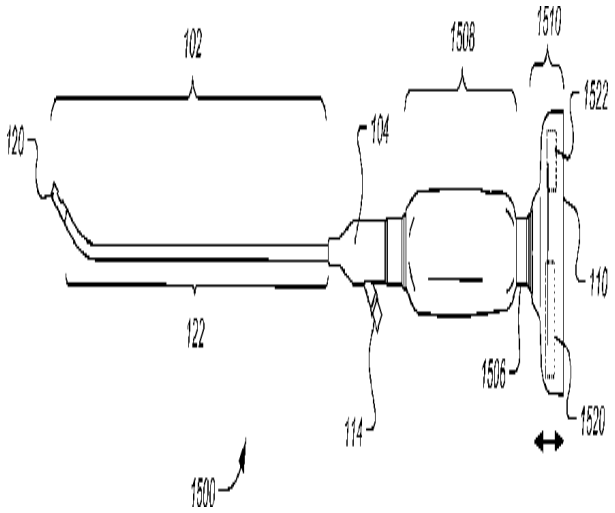
13. An instrument according to claim **6** wherein at least one of the one or more seals is at least partially formed by one or more ultrasonic welding processes during manufacture.

* * * * *

专利名称(译)	用于宫腔镜检查和组合式宫腔镜检查和子宫内膜活组织检查的方法和装置		
公开(公告)号	US20150150441A1	公开(公告)日	2015-06-04
申请号	US14/614472	申请日	2015-02-05
[标]申请(专利权)人(译)	ENDOSEE股份有限公司		
申请(专利权)人(译)	ENDOSEE CORPORATION		
当前申请(专利权)人(译)	COOPERSURGICAL INC.		
[标]发明人	OUYANG XIAOLONG INDMAN PAUL D DECKMAN ROBERT K WANG SHIH PING		
发明人	OUYANG, XIAOLONG INDMAN, PAUL D. DECKMAN, ROBERT K. WANG, SHIH-PING		
IPC分类号	A61B1/303 A61B1/06 A61B1/005 A61B1/05 A61B1/00 A61B1/12		
CPC分类号	A61B1/303 A61B1/00103 A61B1/00066 A61B1/00034 A61B1/00052 A61B1/005 A61B1/05 A61B1/06 A61B1/126 A61B1/00006 A61B1/00032 A61B1/00048 A61B1/00057 A61B1/00071 A61B1/00078 A61B1/00091 A61B1/00094 A61B1/00105 A61B1/00114 A61B1/00124 A61B1/0055 A61B1/015 A61B1/0676 A61B1/0684 A61B1/307 A61B1/317 A61B10/0291 A61B10/04		
优先权	61/692701 2012-08-23 US 61/646887 2012-05-14 US 61/709022 2012-10-02 US 61/709033 2012-10-02 US 61/676444 2012-07-27 US 61/664143 2012-06-25 US 61/818341 2013-05-01 US PCT/US2013/040992 2013-05-14 WO 61/667341 2012-07-02 US 61/803672 2013-03-20 US 61/813635 2013-04-18 US 61/803664 2013-03-20 US 61/681129 2012-08-08 US 61/672733 2012-07-17 US		
外部链接	Espacenet USPTO		

摘要(译)

描述了用于执行宫腔镜检查和/或组合宫腔镜检查和子宫内膜活组织检查的器械和方法。根据一些实施例，手柄，电子设备和集成显示屏形成器械的可重复使用部分，而包括CMOS成像模块和LED照明的流体鞍和套管形成器械的单次使用部分。套管是半柔性的，使得操作者可以在沿轴的某个中间点（例如距离远端尖端5英寸）处容易地抓住套管，以在使用期间弯曲和/或操纵套管。根据一些实施例，远端尖端具有比轴更大的直径，已经发现在一些应用中使用期间改善了流体管理。


102
1506
1510
1522
120
104
110
122
1506
114
1520
1500