US 20040122327A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2004/0122327 A1**

Belson et al. (43) **Pub. Date: Jun. 24, 2004**

(54) **INTRAUTERINE IMAGING SYSTEM**

(76) Inventors: **Amir Belson**, Cupertino, CA (US); **Doron Kreiser**, Herzlia (IL)

Correspondence Address:
LEARY & ASSOCIATES
3900 NEWPARK MALL RD.
THIRD FLOOR, SUITE 317
NEWARK, CA 94560 (US)

(21) Appl. No.: **10/152,164**

(22) Filed: **May 20, 2002**

Related U.S. Application Data

(63) Continuation-in-part of application No. 10/024,656, filed on Dec. 17, 2001.

(60) Provisional application No. 60/256,155, filed on Dec. 15, 2000.

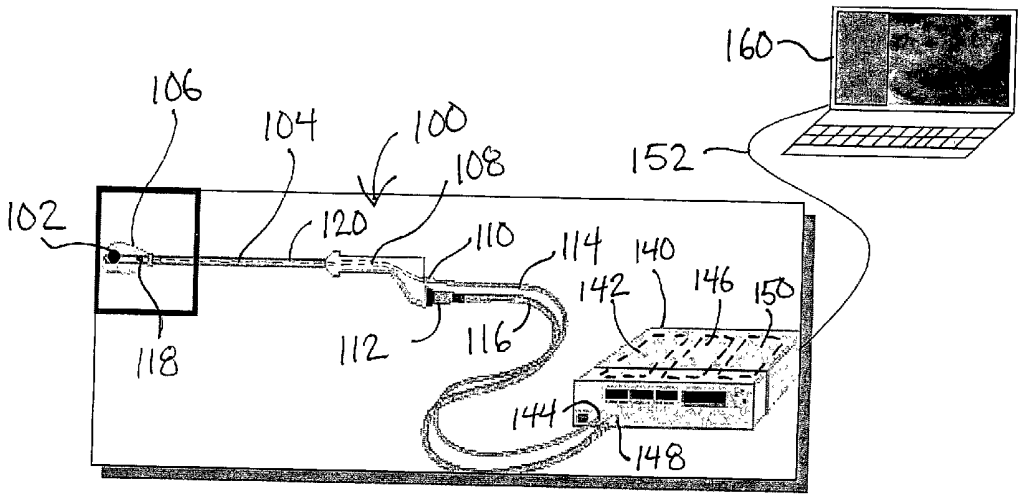
Publication Classification

(51) **Int. Cl.**[7] **A61B 5/05**; A61B 6/00

(52) **U.S. Cl.** **600/476**

(57) **ABSTRACT**

An obstetrical imaging system includes a uteroscope or video-uteroscope for intrauterine imaging, a control unit for operating the uteroscope, a computer imaging station with a video monitor for viewing the images captured by the optical imaging system and a recording system for recording the images. The uteroscope includes an optical imaging system, which preferably includes a panoramic lens for viewing the entire uterine cavity in one image, mounted on an elongated shaft for insertion into the patient's uterus. One or more transparent inflatable balloons are mounted on the elongated shaft surrounding the optical imaging system. An instrument channel is provided in the shaft of the uteroscope for insertion of instruments, such as a suction tube, external to or in between the transparent inflatable balloons.



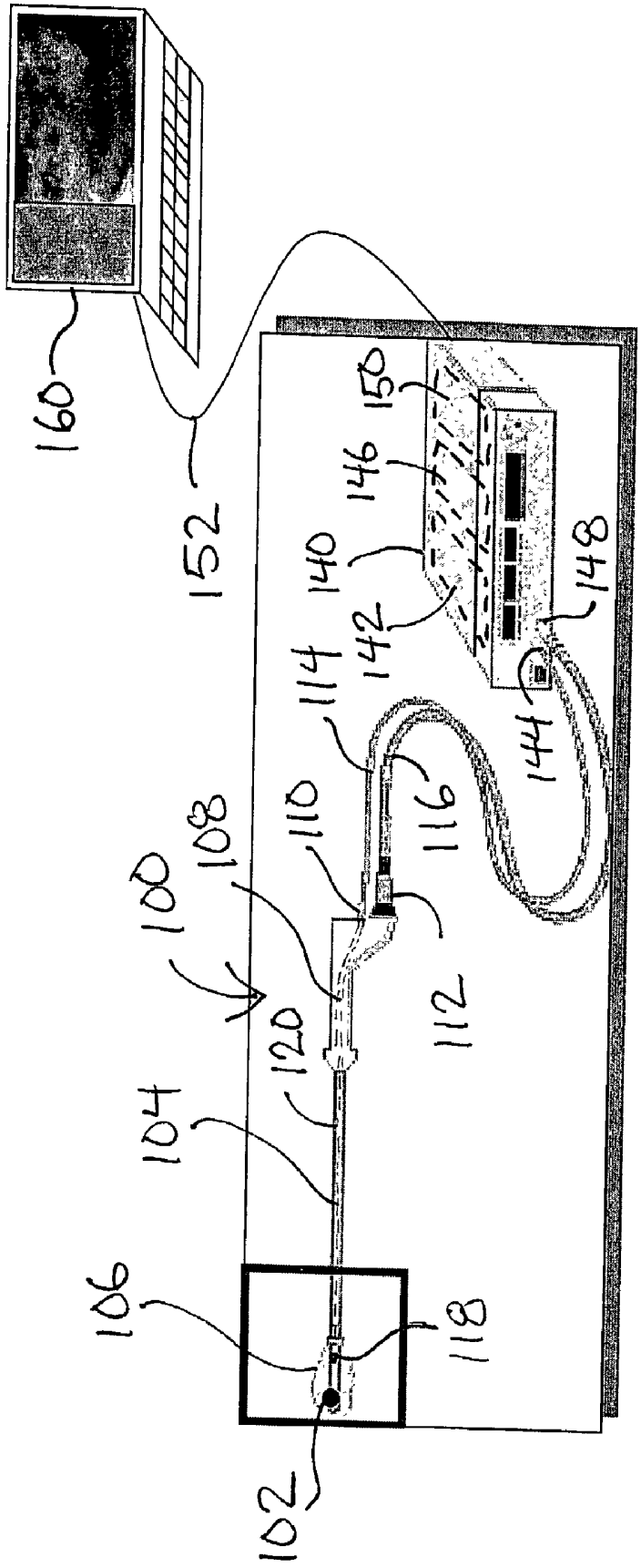

160
152
150
146
140
142
148
144
114
116
110
108
100
112
120
104
106
118
102

FIG 1

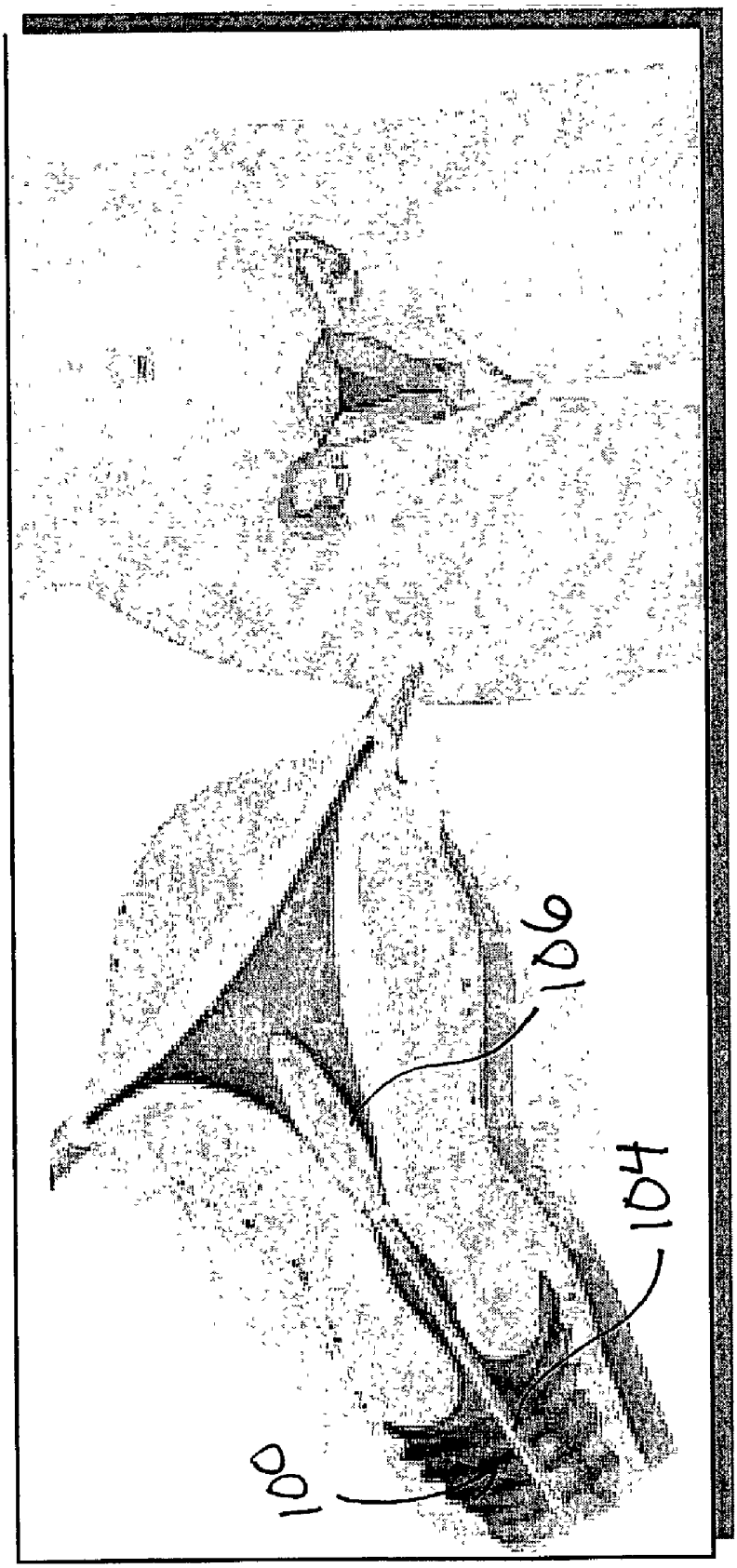


FIG 2

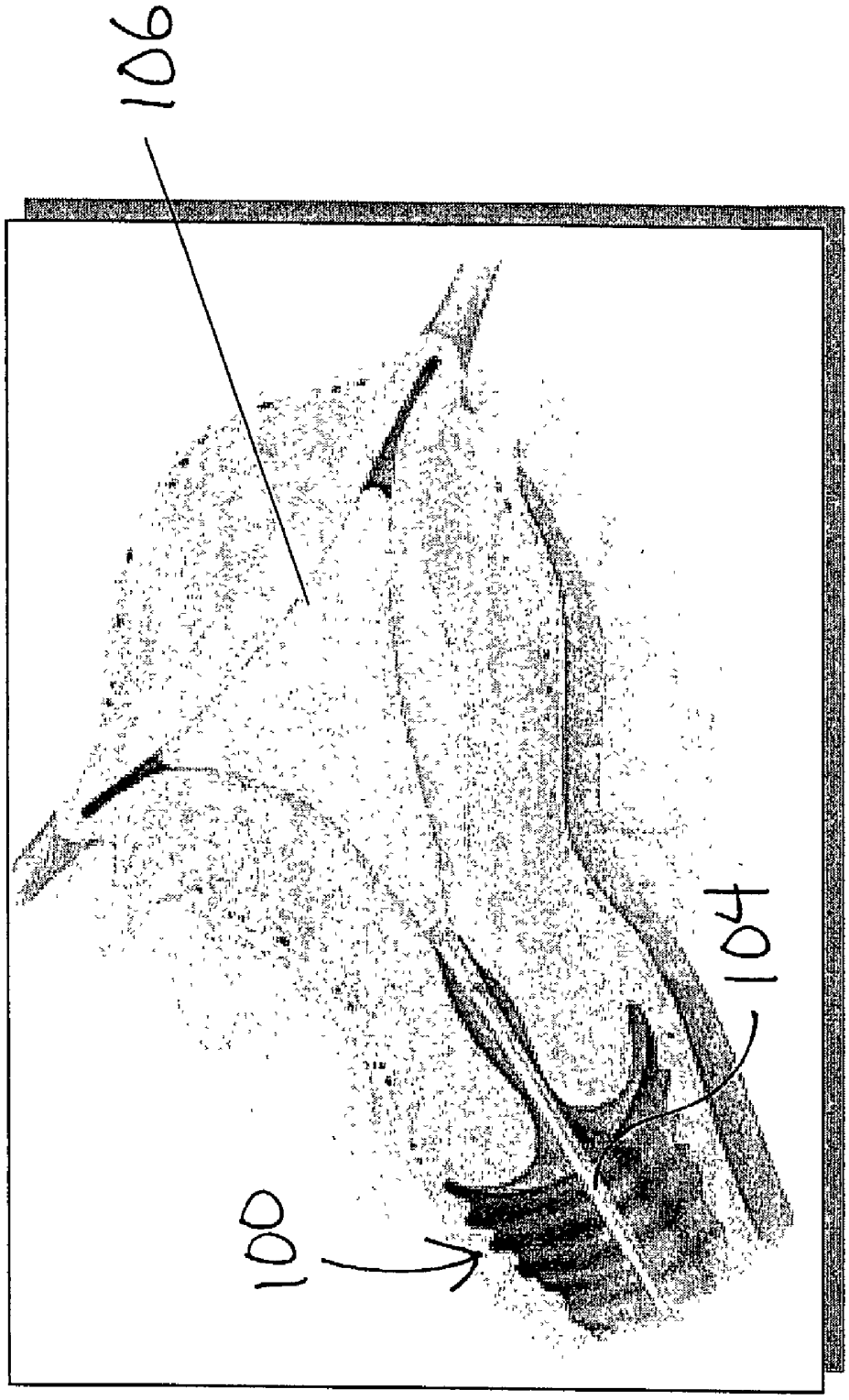


FIG 3

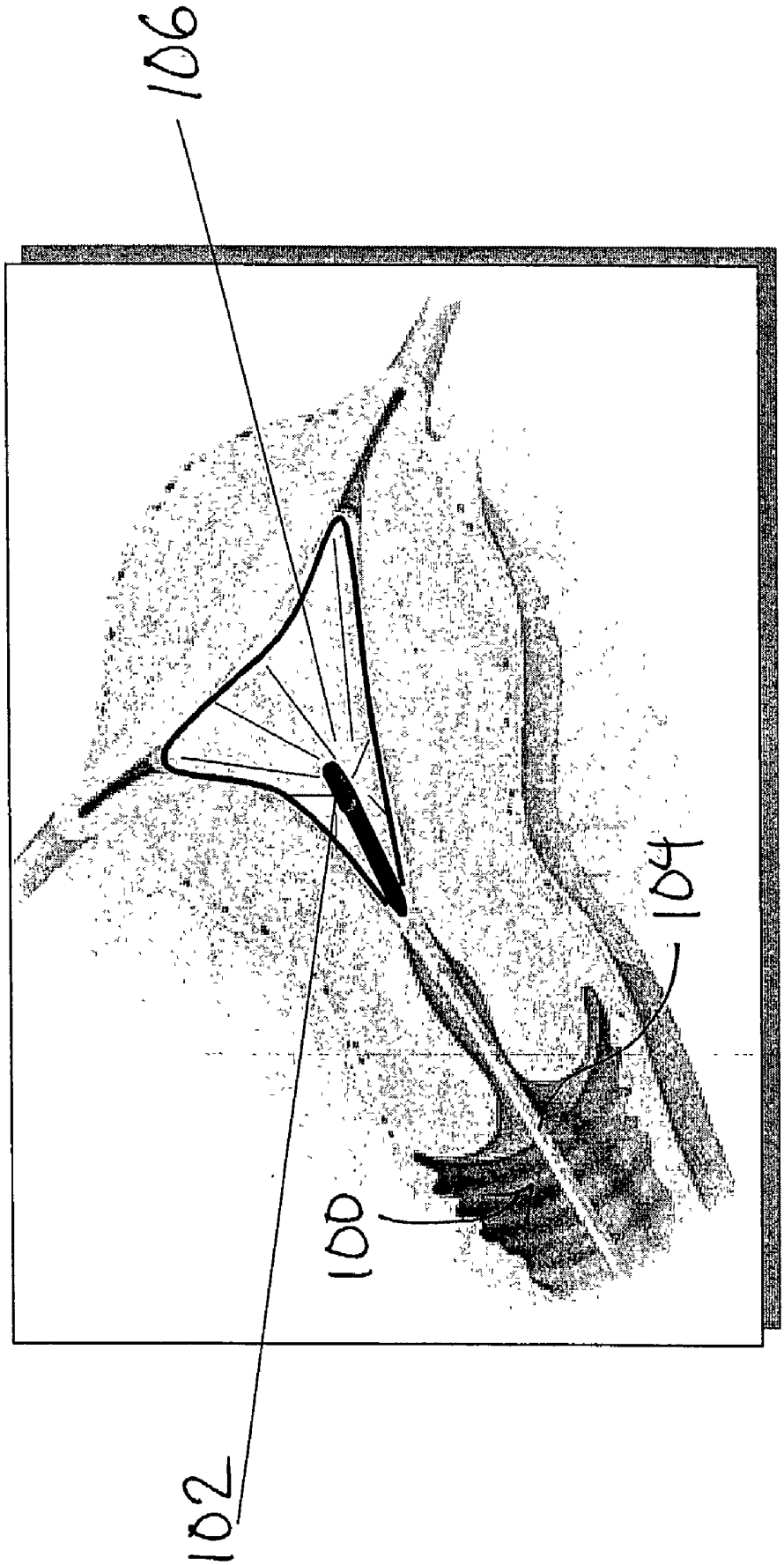


FIG 4

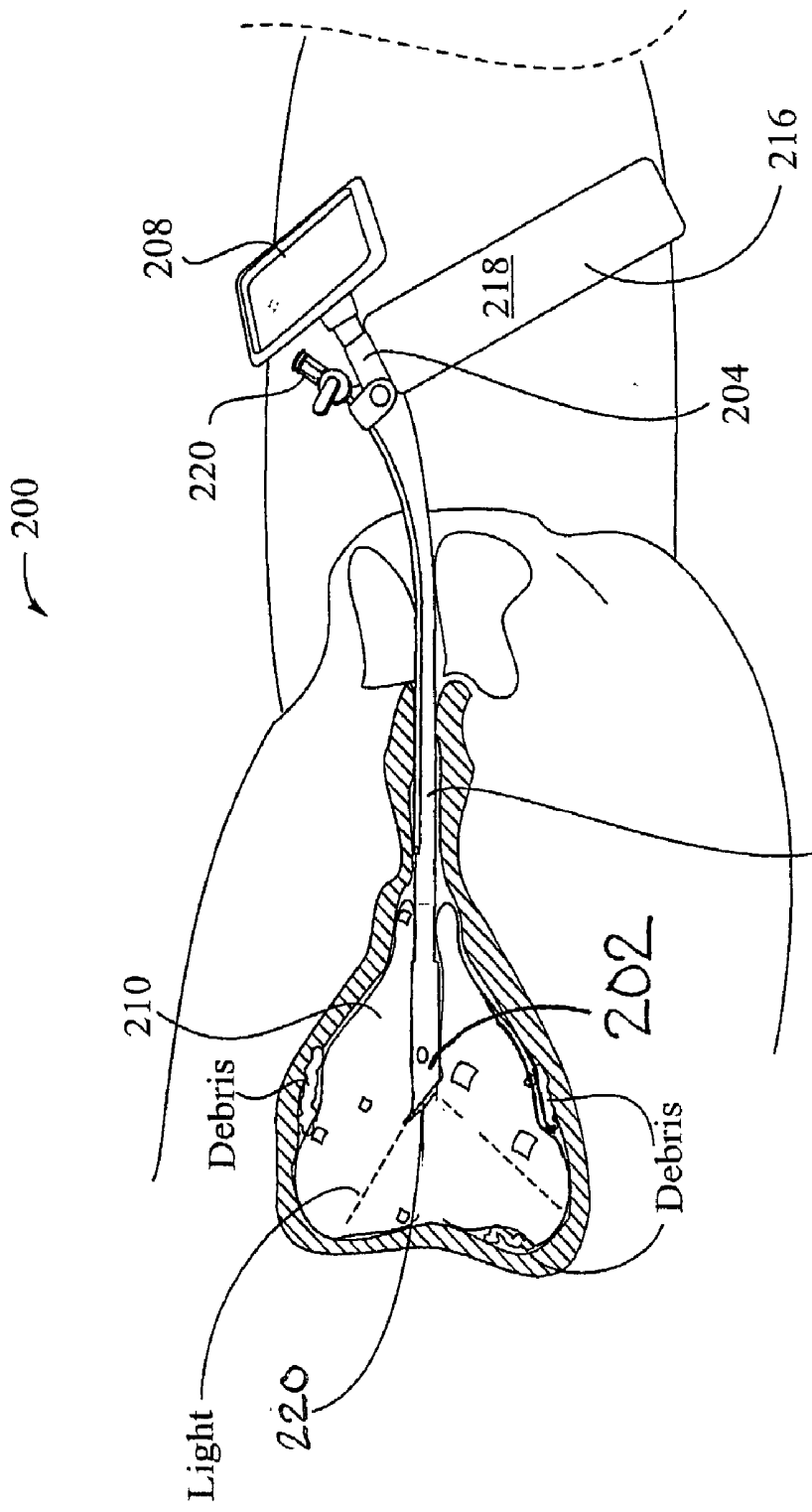


Fig. 5

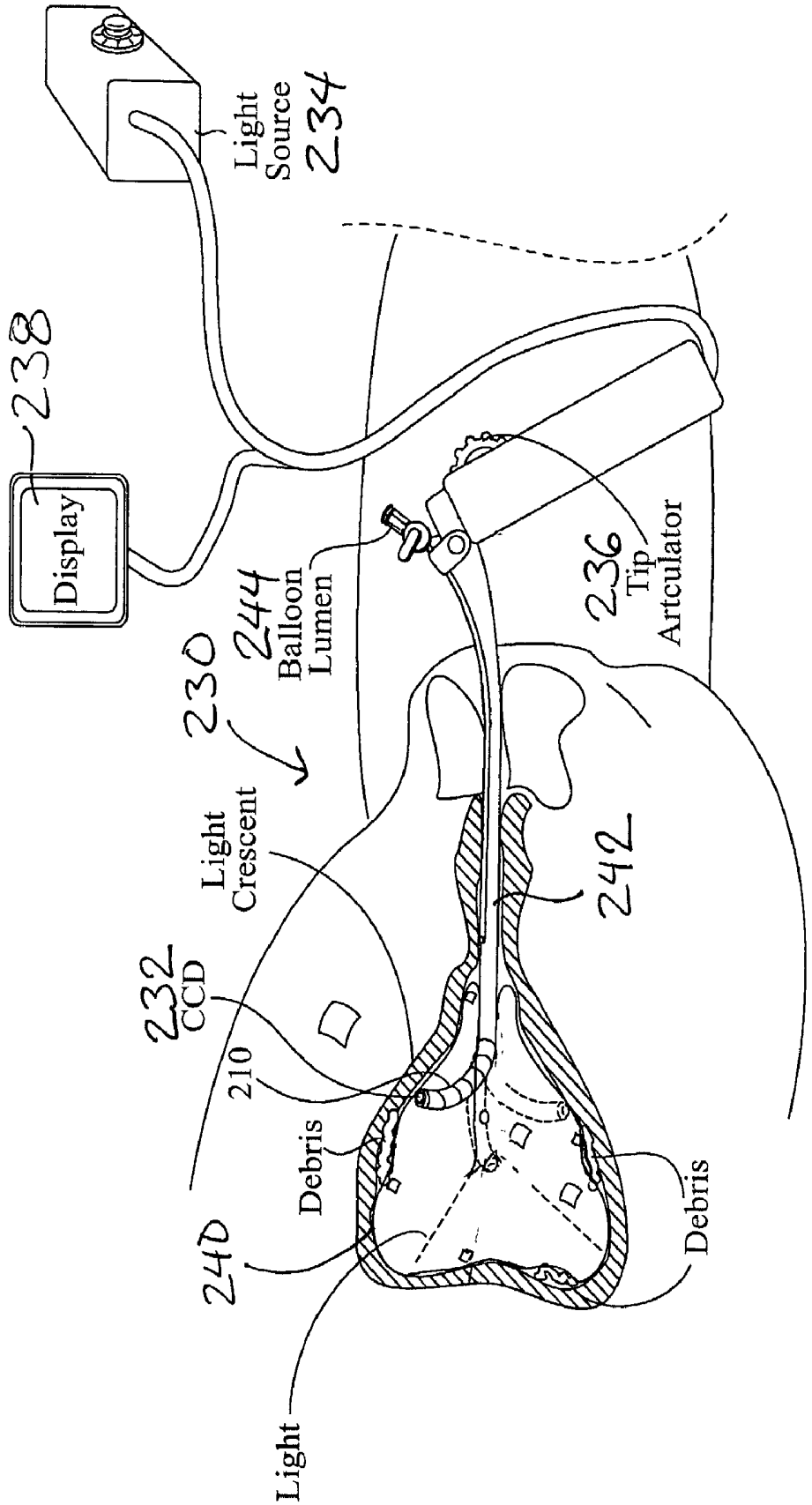

Light Source
234
238
Display
230
244
Balloon Lumen
236
Tip Artculator
Light Crescent
232
CCD
210
242
Debris
240
Debris
Light

Fig. 6

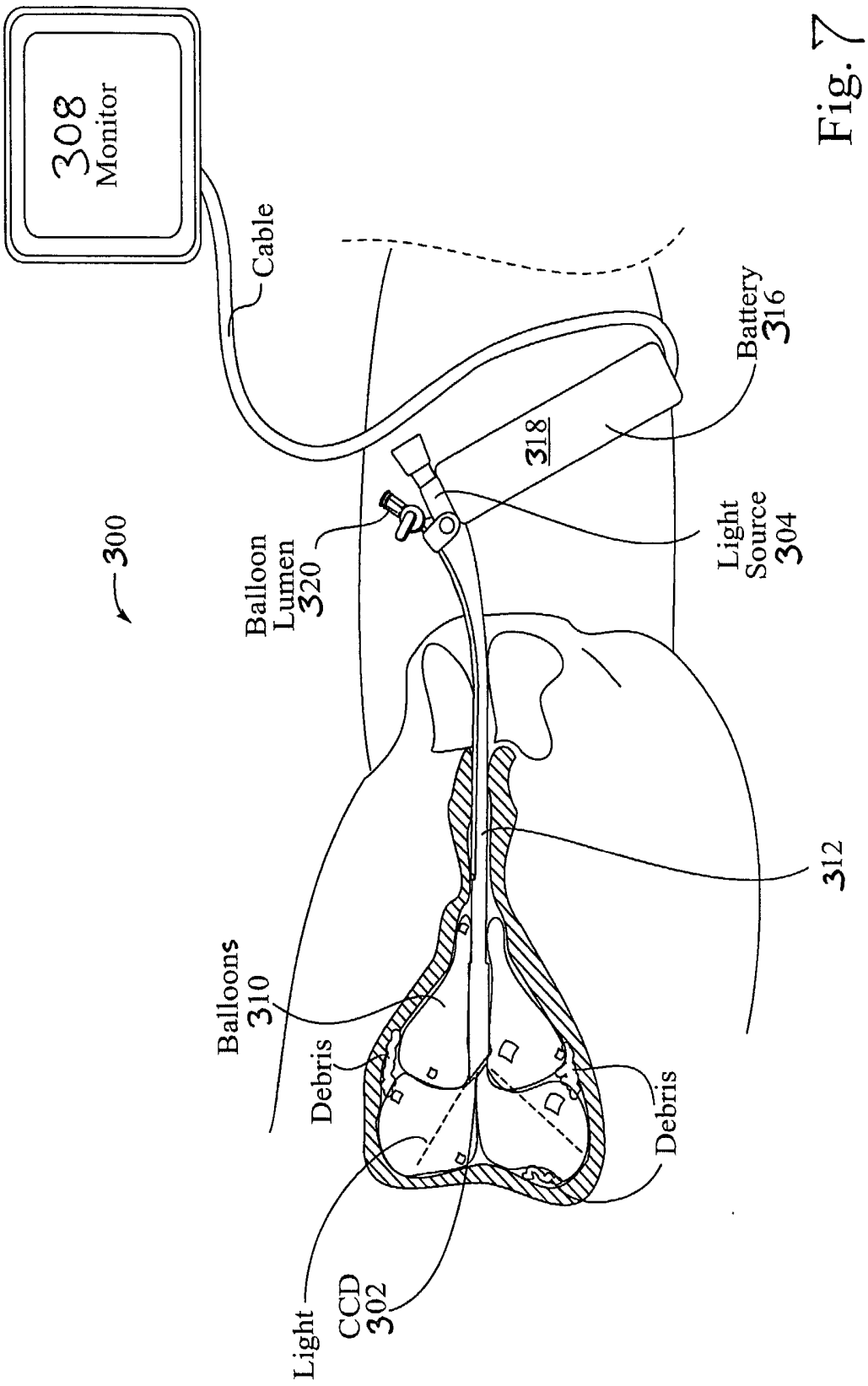

308
Monitor
Cable
300
Balloon
Lumen
320
318
Battery
316
Light
Source
304
312
Balloons
310
Debris
Debris
Light
CCD
302

Fig. 7

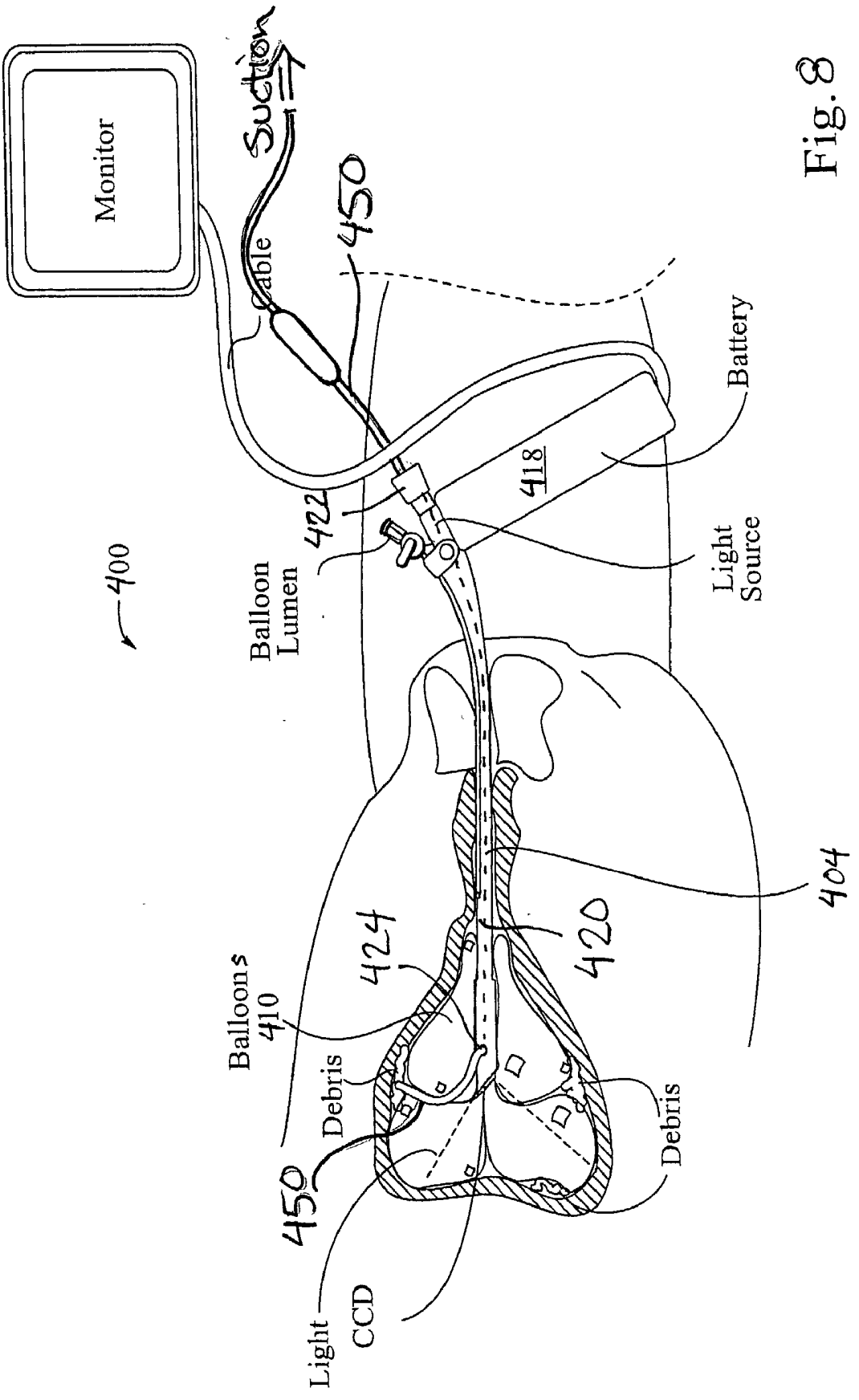

Monitor
Suction
Cable
450
Battery
418
422
Light Source
400
Balloon Lumen
404
424
420
Balloons 410
Debris
450
Debris
Light
CCD

Fig. 8

INTRAUTERINE IMAGING SYSTEM

CROSS REFERENCE TO OTHER APPLICATIONS

[0001] This application is a continuation-in-part of U.S. patent application Ser. No. 10/024,656, filed on Dec. 17, 2001, which claims the benefit of U.S. Provisional Patent Application, serial No. 60/256,155, filed on Dec. 15, 2000.

FIELD OF THE INVENTION

[0002] The present invention relates generally to medical imaging systems and, more particularly, to an obstetrical imaging system that includes a uteroscope or video-uteroscope for intrauterine imaging.

BACKGROUND OF THE INVENTION

[0003] Adequate diagnosis and intervention during labor are crucial to reduce maternal and fetal morbidity and mortality that are inherent risks of vaginal deliveries. Modern obstetrics is still considered to be an "art" instead of a "science", as it is based on the operators' subjective impression and experience rather than analysis of objective clinical findings. The evaluation of the labor process is based on interpretation of digital pelvic examination. Moreover, residents who are still acquiring their skills perform most of the public deliveries in the U.S. Regardless, even the most experienced operators have up to thirty percent error rate.

[0004] The risks to the mother during labor and delivery do not end with the expulsion of the baby. Postpartum complications are caused by rupture of the uterus and more commonly by retained parts of the placenta in the uterine cavity. Similar problems involving retained products of conception in the uterine cavity can be encountered in elective termination of pregnancy or abortion. Retained products of conception (RCP) is a common complication that can be found in histological specimen in 10-15% of normal non-caesarian births and 3-5% of abortions. RPC not extracted may cause intense bleeding from the uterus, intrauterine infections resulting in intrauterine adhesions, long term effects such as infertility and exposure of the medical staff to negligence litigations.

[0005] Current attempts to detect RPC include ultrasonic imaging postpartum partum uterine cavity manual revision and hysteroscopy. Ultrasonic imaging suffers from low sensitivity and specificity due to artifacts caused by air and blood. It requires a high level of operator skill. It lacks the ability to image and document the entire uterine cavity in one picture. Post partum uterine cavity manual revision is performed by insertion of the physician's hand into the uterine cavity and a manual exploration for the uterine wall defect or the retained parts of the placenta. Uterine cavity manual revision is highly painful for the patient and demands profound analgesia or sedation. The procedure requires a high level of operator skill and, even when performed by skilled operators, is not highly reliable. Furthermore, it lacks the ability to image and document the result. Hysteroscopy requires a highly skilled operator for success, in particular due to the narrow field of view that it provides. The procedure depends on expending the uterine cavity with fluid or gas that leaks through the open cervix. It cannot be done acutely post partum and it lacks the ability to document the entire uterine cavity in one picture.

[0006] It would be desirable, therefore, to provide apparatus and methods for diagnostic examination and treatment of retained products of conception and other conditions in a patient's uterine cavity. The apparatus and methods should be safe, simple, reliable and painless and should be adaptable to the normal uterus and also to the post partum uterus. Preferably, the apparatus and methods will provide an ability to image and document the entire uterine cavity in one picture.

SUMMARY OF THE INVENTION

[0007] In keeping with the foregoing discussion, the present invention provides an obstetrical imaging system that includes a uteroscope or video-uteroscope for intrauterine imaging. The uteroscope includes an optical imaging system mounted on an elongated shaft configured for insertion into the patient's uterus. One or more transparent inflatable balloons are mounted on the elongated shaft surrounding the optical imaging system. Preferably, the uteroscope includes a panoramic lens that allows simultaneous one-shot imaging of the entire uterine cavity. The elongated shaft of the uteroscope may be rigid, semi-rigid or flexible and may be articulated or steerable. An instrument channel is provided in the shaft of the uteroscope for insertion of instruments, such as a suction tube, external to or in between the transparent inflatable balloons.

[0008] The obstetrical imaging system may also include a control unit for operating the uteroscope, a computer imaging station with a video monitor for viewing the images captured by the optical imaging system and a recording system for recording the images. Computer hardware and/or software may be provided as part of the system for simultaneous one-shot imaging of the entire uterine cavity and for viewing the images obtained. Alternatively or in addition, the obstetrical imaging system may include a video monitor connected to or integrated with the uteroscope.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] **FIG. 1** shows an obstetrical imaging system according to the present invention, including a video-uteroscope, a control unit and a computer imaging station.

[0010] **FIG. 2** shows the video-uteroscope being inserted in a deflated state into a patient's uterus.

[0011] **FIG. 3** shows the video-uteroscope with the transparent balloon inflated within the patient's uterine cavity.

[0012] **FIG. 4** represents the panoramic imaging capability of the video-uteroscope for imaging and documenting the patient's entire uterine cavity in one picture.

[0013] **FIG. 5** shows a rigid video-uteroscope with a single transparent inflatable balloon inflated within a post partum uterus.

[0014] **FIG. 6** shows an articulable flexible video-uteroscope with a single transparent inflatable balloon inflated within a post partum uterus.

[0015] **FIG. 7** shows a diagnostic video-uteroscope with multiple transparent inflatable balloons inflated within a post partum uterus.

[0016] **FIG. 8** shows a therapeutic video-uteroscope system with multiple transparent inflatable balloons inflated within a post partum uterus.

DETAILED DESCRIPTION OF THE INVENTION

[0017] **FIG. 1** shows an obstetrical imaging system constructed according to the present invention. The obstetrical imaging system includes a uteroscope or video-uteroscope **100**, a control unit **140** and a computer imaging station **104**. The uteroscope **100** includes an optical imaging system **102** mounted on an elongated shaft **104** configured for insertion into the patient's uterus. One or more transparent inflatable balloons **106** are mounted on the elongated shaft **104** surrounding the optical imaging system **102**. The elongated shaft **104** of the uteroscope **100** may be rigid, semi-rigid or flexible and may be articulated or steerable. For therapeutic applications of the uteroscope **100**, an instrument channel is provided in the shaft **104** for insertion of instruments, such as a suction tube, external to or in between the transparent inflatable balloons **106**. The uteroscope **100** will preferably include a proximal handle **108** with an inflation/deflation fitting **110** and a video connector **112** for connecting the uteroscope **100** to the control unit **140** via an inflation/deflation tube **114** and a video cable **116**. An inflation lumen **120** extends through the shaft **104** of the uteroscope **100** from the inflation/deflation fitting **110** to an inflation port **118** in fluid communication with the interior of the balloons **106**.

[0018] The control unit **140** includes an inflation/deflation controller **142** with a fitting **144** for connecting to the uteroscope **100** via the inflation/deflation tube **114**. In one exemplary embodiment, the inflation/deflation controller **142** includes a pressure regulator and an electrically controlled valve circuit connected to a source of inflation fluid, such as compressed carbon dioxide gas or another physiologically acceptable fluid, for inflating the balloons **106** and to a vacuum source for deflating the balloons **106**. In another exemplary embodiment, the inflation/deflation controller **142** would include a motor-driven syringe pump or the like for inflating and deflating the balloons **106**.

[0019] Preferably, the control unit **140** also includes a video controller **146** and an illumination source **150** with a fitting **148** for connecting to the uteroscope **100** via the video cable **116**. The video controller **146** includes circuitry for operating the optical imaging system **102** and for initial processing of the video images captured. The video controller **146** is connected to the computer imaging station **160** via a second video cable **152**. Alternatively or in addition, the obstetrical imaging system may include a video monitor connected to or integrated with the uteroscope. Preferably, the system includes a recording device, which may be located within the control unit **140** or the computer imaging station **104**, for recording the images captured by the uteroscope **100**.

[0020] **FIG. 2** shows the video-uteroscope **100** being inserted through the vagina and cervix into the patient's uterus with the balloons **106** in a deflated state. When in the deflated state, the inflatable balloon or balloons **106** are collapsed against and/or wrapped around the elongated shaft **104** to minimize the insertion profile of the device. Preferably, the inflation/deflation controller **142** draws a vacuum through the inflation lumen **120** to maintain the balloons **106** in the deflated state during insertion.

[0021] **FIG. 3** shows the video-uteroscope **100** with the transparent balloon or balloons **106** inflated within the patient's uterine cavity. Preferably, the transparent balloon or balloons **106** are of thin-walled polymeric construction and inflatable at low pressure to substantially fill the uterine cavity without dilating or distending it. The material of the balloon or balloons **106** may be an elastomer with a low modulus of elasticity that allows it to conform to the interior of the uterine cavity when inflated without dilating or distending it. Alternatively, the balloon or balloons **106** may be configured as a flaccid bag with a volume greater than that of the uterine cavity so that, when inflated, it substantially fills the uterine cavity without dilating or distending it.

[0022] Preferably, the optical imaging system **102** of the video-uteroscope **100** is capable of panoramic imaging to capture the image of the entire uterine cavity in one picture. **FIG. 4** graphically illustrates the panoramic imaging capability of the video-uteroscope **100** for imaging and documenting the patient's entire uterine cavity in one picture. For this purpose, the uteroscope employs a spherical lens or equivalent optical element that provides a panoramic image so that a large portion of the uterine wall can be viewed at once with a minimum of manipulation of the uteroscope. In a particularly preferred embodiment, the spherical lens provides a panoramic image of the entire uterine wall at once. Alternatively or in addition, the uteroscope **100** and/or the optical imaging system **102** may be configured to manually or automatically scan the interior of the uterine cavity using either a spherical lens or ordinary lens to capture images of the entire uterine cavity that can be combined into a panoramic image by the computer imaging station **104**. The panoramic image can be viewed in real time and/or the image data can be captured electronically for later viewing, archiving or image manipulation. The image of the uterine wall can be viewed on the display monitor of the computer imaging station **104** in a panoramic mode or the image can be electronically panned and zoomed to examine various portions of the uterine wall in detail. In addition, the image can be electronically manipulated to eliminate any distortion caused by the spherical lens. The imaging system can also be used to create a map projection of the image so that the entire uterine wall can be viewed with a minimum of image distortion.

[0023] **FIG. 5** shows a video-uteroscope with a single transparent inflatable balloon inflated within a post partum uterus. The uteroscope **200** has a rigid or semi-rigid shaft **212** with a miniaturized video camera **202** mounted at its distal end, a fiber optic light source **204** and a display monitor **208**. The transparent inflatable balloon **210** surrounds a distal portion of the uteroscope **200**. In this exemplary embodiment, the light source **204**, the display monitor **208** and a replaceable or rechargeable battery **216** have been integrated into the handle **218** of the uteroscope **200**. The uteroscope **200** is inserted into the uterus after delivery and the transparent balloon **210** is inflated via an inflation lumen **220** by a pressure controlled pump, preferably using carbon dioxide gas or a physiologic solution, to create a clear field for imaging the uterine walls. Preferably, the miniaturized video camera **202** of the uteroscope **200** includes a spherical lens or other optical element for panoramic imaging to capture the image of the entire uterine cavity in one picture. Alternatively, the miniaturized video camera **202** may have an ordinary lens, which is preferably mounted at an angle with respect to the shaft **212** of the uteroscope **200** so that the entire interior of the uterus can be viewed by rotating the uteroscope **200**. The uteroscope **200**

can be used to identify damage to the uterine wall or retained portions of the placenta and to diagnose other problems. In an alternative embodiment, the rigid uteroscope **200** may include fiber optics or rod optics to transmit images to a video camera connected to the proximal end of the shaft **212**.

[**0024**] The lens **220** of the miniaturized video camera **202** may be located on the interior of the transparent inflatable balloon **210**. Alternatively, to avoid direct contact between the miniaturized video camera **202** and the inflation fluid, the lens **220** of the miniaturized video camera **202** may be position within an invagination in the wall of the inflatable balloon **210** or inside of a balloon-within-a-balloon so that the lens **220** is isolated from the interior of the transparent inflatable balloon **210**.

[**0025**] **FIG. 6** shows an articulable flexible video-uteroscope **230** with a single transparent inflatable balloon **240** inflated within a post partum uterus. The uteroscope **230** has a flexible articulable shaft **242** with a miniaturized video camera **232** mounted at its distal end, a fiber optic light source **234** and a display monitor **238**. The transparent inflatable balloon **240** surrounds a distal portion of the uteroscope **230**. In this exemplary embodiment, the light source **234** and the display monitor **238** are separate from the uteroscope **230**. The uteroscope **230** is inserted into the uterus after delivery and the transparent balloon **240** is inflated via an inflation lumen **244** by a pressure controlled pump, preferably using carbon dioxide gas or a physiologic solution, to create a clear field for imaging the uterine walls. The flexible shaft **242** of the video uteroscope **230** can be rotated and/or articulated with the tip articulator knob **236** to view the entire interior of the uterus. The uteroscope **230** can be used to identify damage to the uterine wall or retained portions of the placenta and to diagnose other problems.

[**0026**] **FIG. 7** shows a diagnostic video-uteroscope **300** with multiple transparent inflatable balloons **310** inflated within a post partum uterus. The uteroscope **300** has a rigid or semi-rigid shaft **312** with a miniaturized video camera **302** mounted at its distal end, a fiber optic light source **304** and a display monitor **308**. The transparent inflatable balloons **310** surround a distal portion of the uteroscope **300**. In this exemplary embodiment, the light source **304** and a replaceable or rechargeable battery **316** have been integrated into the handle **318** of the uteroscope **300** and the display monitor **308** is separate from the uteroscope **300**. The uteroscope **300** is inserted into the uterus after delivery and the transparent balloons **310** are inflated via an inflation lumen **320** by a pressure controlled pump, preferably using carbon dioxide gas or a physiologic solution, to create a clear field for imaging the uterine walls. Alternatively, the uteroscope **300** may be configured with a multiplicity of inflation lumens for separately and independently inflating each of the transparent balloons **310**.

[**0027**] Preferably, the transparent balloons **310** are all of thin-walled polymeric construction and inflatable at low pressure to fill the uterine cavity without dilating or distending it. The material of the balloons **310** may be an elastomer with a low modulus of elasticity that allows them to conform to the interior of the uterine cavity when inflated without dilating or distending it. Alternatively, the balloons **310** may be configured as flaccid bags with a total volume greater than that of the uterine cavity so that, when inflated, they fill the uterine cavity without dilating or distending it. Preferably, the uteroscope **300** includes a spherical lens or other optical element for panoramic imaging to capture the image of the entire uterine cavity in one picture. Alternatively, the miniaturized video camera **302** may have an ordinary lens, which is preferably mounted at an angle with respect to the shaft **312** of the uteroscope **300** so that the entire interior of the uterus can be viewed by rotating the uteroscope **300**. The uteroscope **300** can be used to identify damage to the uterine wall or retained portions of the placenta and to diagnose other problems. In an alternative embodiment, the rigid uteroscope **300** may include fiber optics or rod optics to transmit images to a video camera connected to the proximal end of the shaft.

[**0028**] Preferably, the miniature video camera **302** is located between the transparent inflatable balloons **310** such that, when inflated, the balloons **310** surround the video camera **302**. Alternatively, the miniature video camera **302** may be located on the interior of one of the transparent inflatable balloons **310** or inside of a balloon-within-a-balloon so that the video camera **302** is isolated from the inflation fluid within the interior of the transparent inflatable balloon **310**.

[**0029**] **FIG. 8** shows a therapeutic video-uteroscope **400** with multiple transparent inflatable balloons **410** inflated within a post partum uterus. The therapeutic video-uteroscope **400** is similar in construction to the diagnostic video-uteroscope **300** of **FIG. 7**, with the addition of an instrument channel **420** in the shaft **404** for insertion of instruments, such as a suction tube **450** for aspirating any retained material within the uterus. The instrument channel **420** extends from a proximal instrument port **422** on the handle **418** of the uteroscope **400** to a distal instrument port **424** near the distal end of the shaft **404** in between the transparent inflatable balloons **410**. The suction tube **450** can be manipulated independently of the uteroscope **400** and can move between and/or displace the inflated balloons **410** to access any part of the patient's uterus.

[**0030**] Each of the various embodiments of the obstetrical imaging system may be configured as a piece of durable equipment to be resterilized and reused. Alternatively, some or all of the obstetrical imaging system may be configured as a disposable product for one-time use only.

[**0031**] While the present invention has been described herein with respect to the exemplary embodiments and the best mode for practicing the invention, it will be apparent to one of ordinary skill in the art that many modifications, improvements and subcombinations of the various embodiments, adaptations and variations can be made to the invention without departing from the spirit and scope thereof. For example, many of the features described can be used together in combinations other than those explicitly described.

What is claimed is:

1. An intrauterine imaging system, comprising:

an optical imaging system mounted on an elongated shaft configured for insertion into a uterine cavity of a patient; and

a transparent inflatable balloon mounted on the elongated shaft surrounding the optical imaging system, wherein the transparent inflatable balloon is configured to substantially fill the uterine cavity when inflated.

2. The intrauterine imaging system of claim 1, wherein the optical imaging system comprises a miniaturized video camera.

3. The intrauterine imaging system of claim 1, wherein the elongated shaft is rigid.

4. The intrauterine imaging system of claim 1, wherein the elongated shaft is flexible.

5. The intrauterine imaging system of claim 1, wherein the elongated shaft is articulable.

6. The intrauterine imaging system of claim 1, further comprising a display monitor for displaying images of the interior of the patient's uterine cavity from the optical imaging system.

7. The intrauterine imaging system of claim 1, wherein the optical imaging system is equipped with a panoramic lens for simultaneously imaging a large portion of the interior of the patient's uterine cavity.

8. The intrauterine imaging system of claim 7, further comprising a computer imaging station with a display monitor for displaying a panoramic image of the interior of the patient's uterine cavity.

9. The intrauterine imaging system of claim 7, wherein the computer imaging station is configured with pan and zoom functions for displaying images of selected portions of the interior of the patient's uterine cavity on the display monitor.

10. An intrauterine imaging system, comprising:

an optical imaging system mounted on an elongated shaft configured for insertion into a uterine cavity of a patient; and

a multiplicity of transparent inflatable balloons mounted on the elongated shaft surrounding the optical imaging system.

11. The intrauterine imaging system of claim 10, wherein the multiplicity of inflatable balloons are configured to substantially fill the uterine cavity when inflated.

12. The intrauterine imaging system of claim 10, wherein the optical imaging system comprises a miniaturized video camera.

13. The intrauterine imaging system of claim 10, further comprising a display monitor for displaying images of the interior of the patient's uterine cavity from the optical imaging system.

14. The intrauterine imaging system of claim 10, wherein the optical imaging system is equipped with a panoramic lens for imaging a large portion of the interior of the patient's uterine cavity.

15. The intrauterine imaging system of claim 14, further comprising a computer imaging station with a display monitor for displaying a panoramic image of the interior of the patient's uterine cavity.

16. The intrauterine imaging system of claim 15, wherein the computer imaging station is configured with pan and zoom functions for displaying images of selected portions of the interior of the patient's uterine cavity on the display monitor.

17. The intrauterine imaging system of claim 10, further comprising an instrument channel within the elongated shaft terminating in a distal instrument port positioned between the multiplicity of inflatable balloons.

18. The intrauterine imaging system of claim 17, further comprising a suction tube sized and configured for insertion through the instrument channel.

* * * * *

专利名称(译)	宫内成像系统		
公开(公告)号	US20040122327A1	公开(公告)日	2004-06-24
申请号	US10/152164	申请日	2002-05-20
[标]申请(专利权)人(译)	百盛AMIR KREISER多伦		
申请(专利权)人(译)	百盛AMIR KREISER多伦		
当前申请(专利权)人(译)	百盛AMIR KREISER多伦		
[标]发明人	BELSON AMIR KREISER DORON		
发明人	BELSON, AMIR KREISER, DORON		
IPC分类号	A61B1/12 A61B1/303 A61B5/0448 A61B17/44 A61B19/00 A61B19/04 A61B5/05 A61B6/00		
CPC分类号	A61B1/00052 A61B2019/5217 A61B1/00147 A61B1/303 A61B5/0448 A61B5/6814 A61B5/6834 A61B17/442 A61B19/04 A61B2017/00221 A61B2017/00438 A61B2017/445 A61B2017/447 A61B2019/5206 A61B1/00082 A61B5/0084 A61B5/4325 A61B5/6875 A61B5/6885 A61B42/00 A61B2090/306 A61B2090/3614 A61B2505/05 A61B2562/146		
优先权	60/256155 2000-12-15 US		
外部链接	Espacenet USPTO		

摘要(译)

产科成像系统包括用于子宫内成像的子宫镜或视频 - 子宫镜，用于操作子宫镜的控制单元，具有用于观察由光学成像系统捕获的图像的视频监视器的计算机成像站以及用于记录图像的记录系统。子宫镜包括光学成像系统，其优选地包括用于在一个图像中观察整个子宫腔的全景镜片，其安装在细长轴上以插入患者的子宫中。一个或多个透明可充气气囊安装在围绕光学成像系统的细长轴上。仪器通道设置在子宫镜的轴中，用于在透明可充气气囊的外部或之间插入诸如吸管之类的器械。