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(54) **FALLOPIAN TUBE BIOCOMPATIBLE PLUG**

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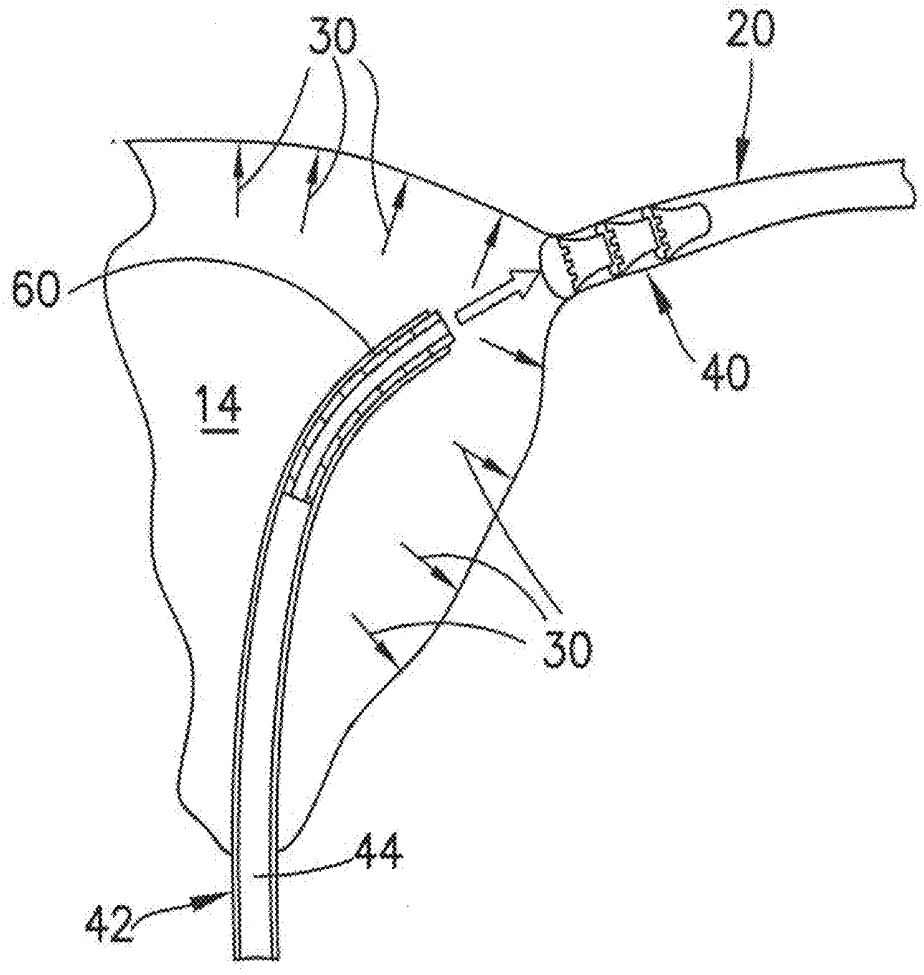
(57) **ABSTRACT**

A method of treating a uterine abnormality of a patient includes: providing an endoscope having a working channel; inflating a uterine cavity with a fluid; delivering a biocompatible plug into an ostium of a fallopian tube of the patient, wherein the biocompatible plug is substantially cylindrical in form and configured to be radially expandable, wherein the biocompatible plug is configured to expand in the ostium of the fallopian tube to seal the fallopian tube from the uterine cavity; delivering a resection device through the working channel; and resecting the uterine abnormality.



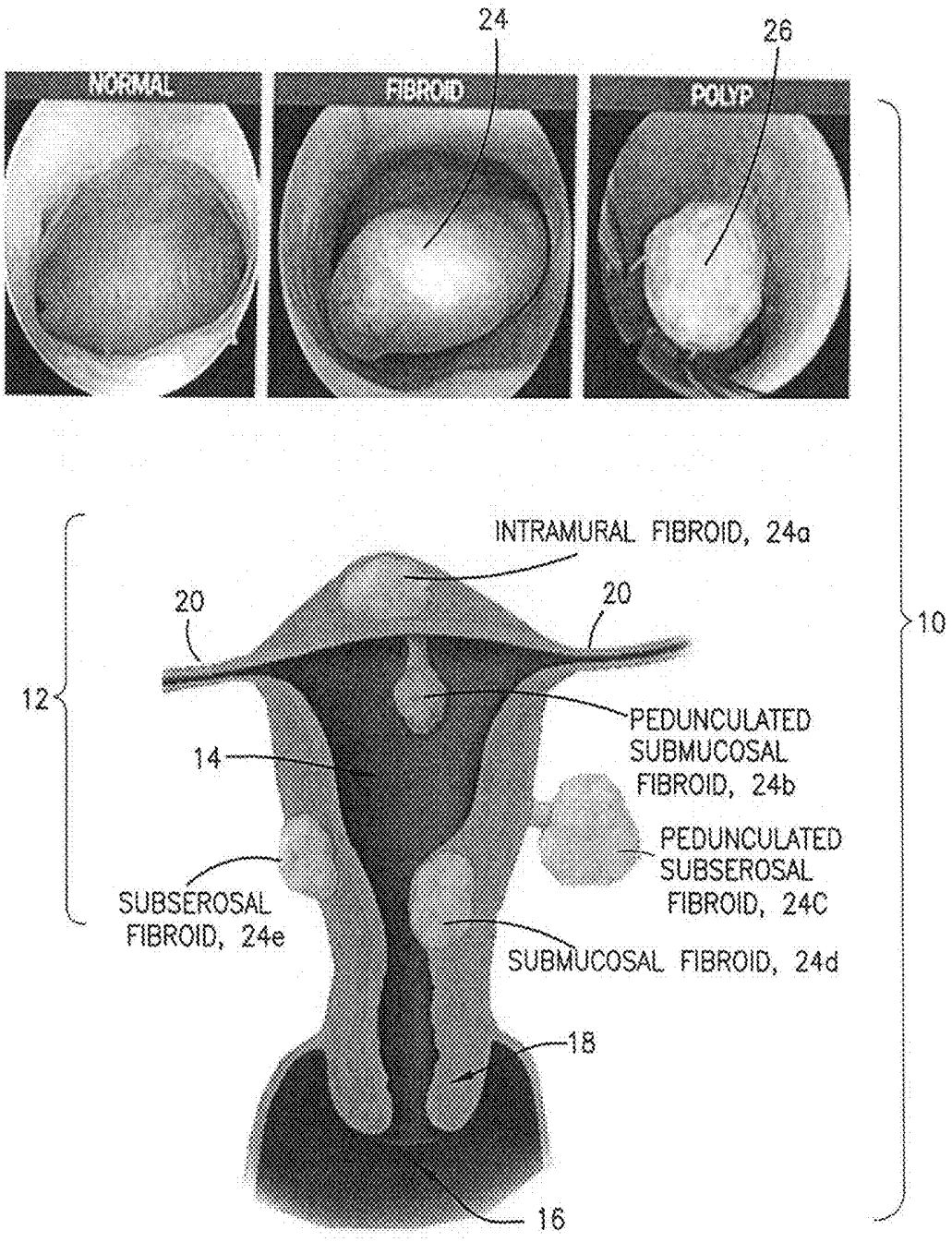

24
26
NORMAL
FIBROID
POLYP
INTRAMURAL FIBROID, 24a
20
20
10
12
PEDUNCULATED SUBMUCOSAL FIBROID, 24b
14
PEDUNCULATED SUBSEROSAL FIBROID, 24C
SUBSEROSAL FIBROID, 24e
SUBMUCOSAL FIBROID, 24d
18
16

FIG. 1

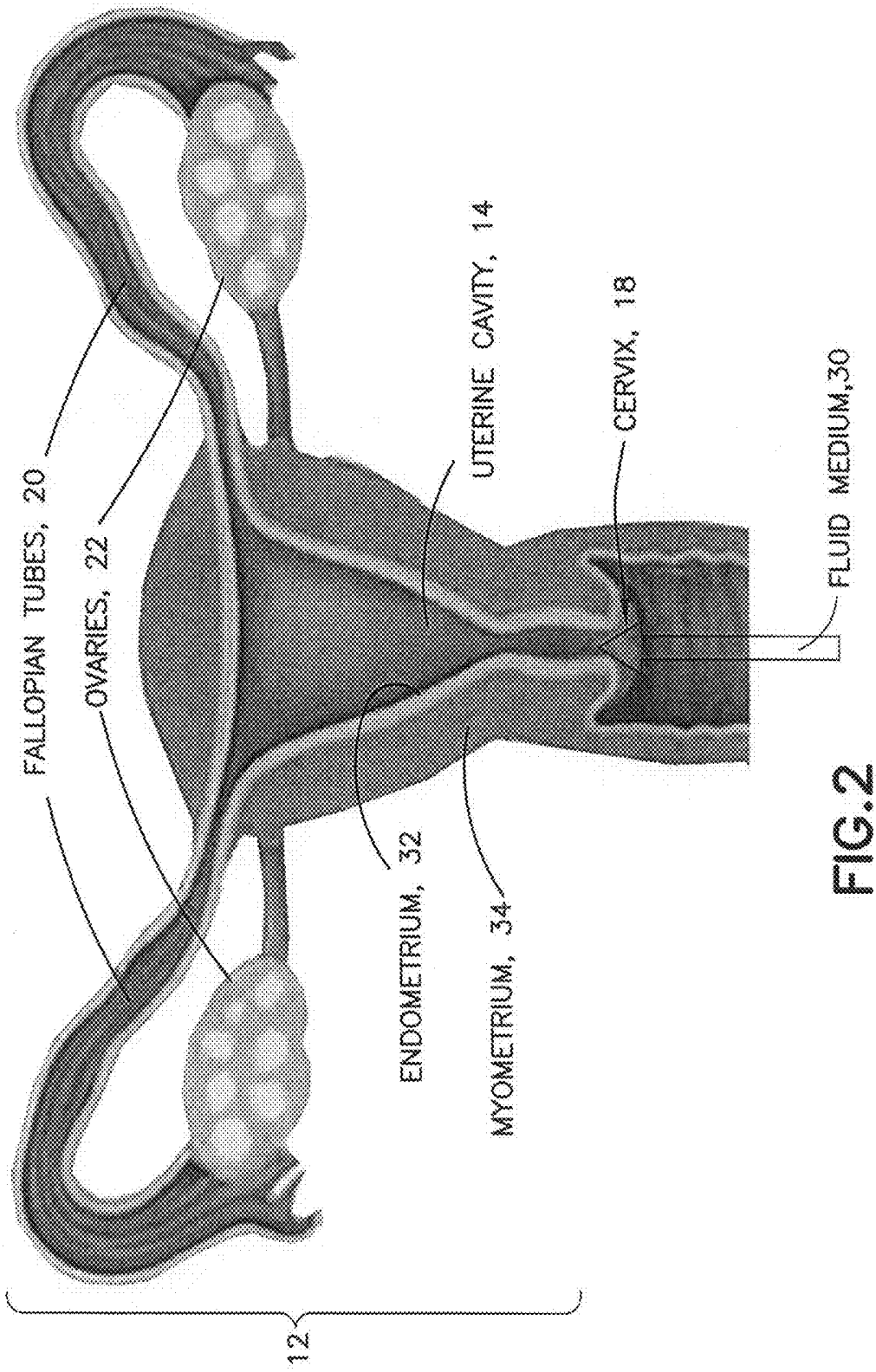

FALLOPIAN TUBES, 20
OVARIES, 22
UTERINE CAVITY, 14
CERVIX, 18
FLUID MEDIUM,30
ENDOMETRIUM, 32
MYOMETRIUM, 34
12

FIG.2

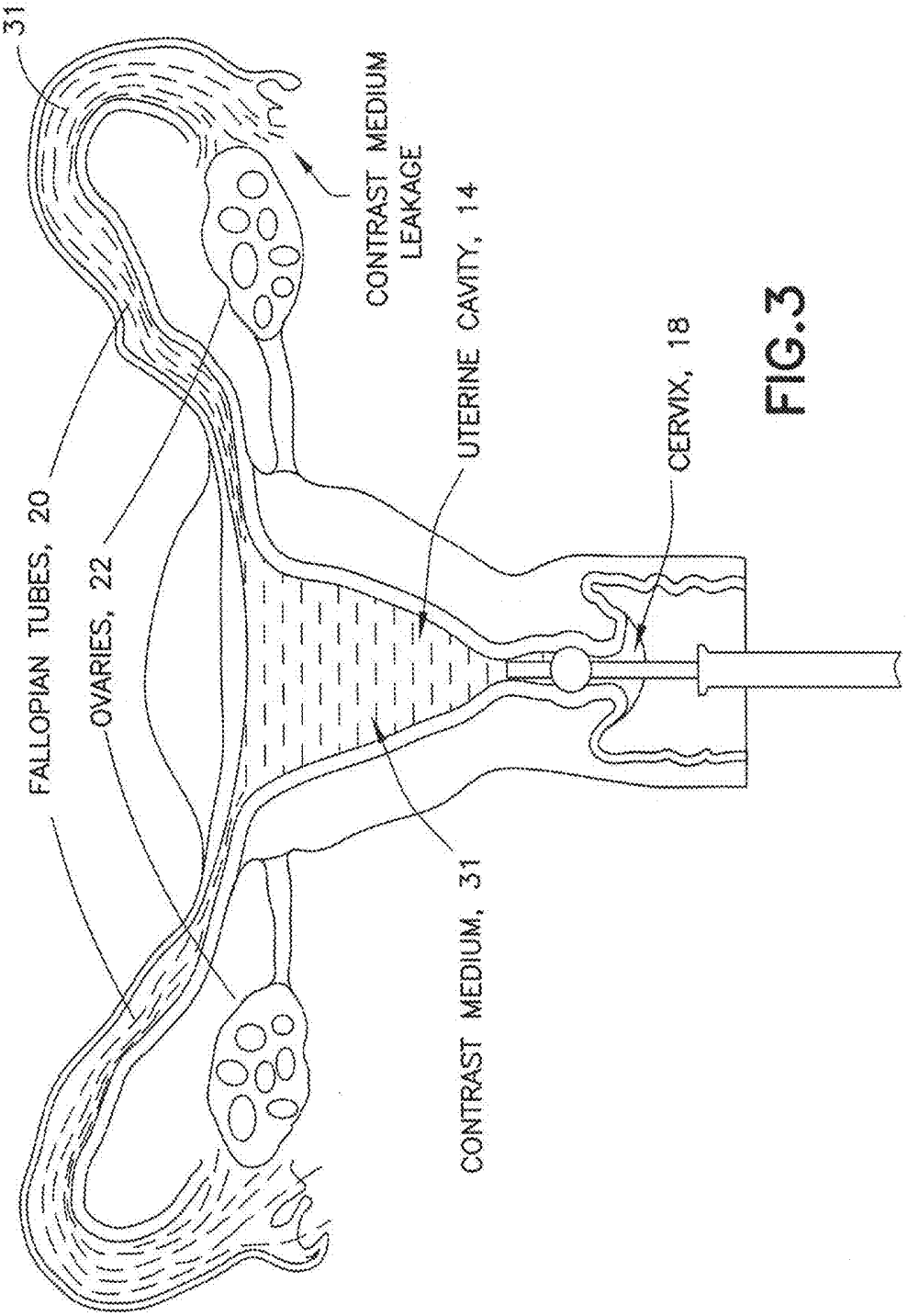

31
CONTRAST MEDIUM LEAKAGE
UTERINE CAVITY, 14
CERVIX, 18
FALLOPIAN TUBES, 20
OVARIES, 22
CONTRAST MEDIUM, 31

FIG.3

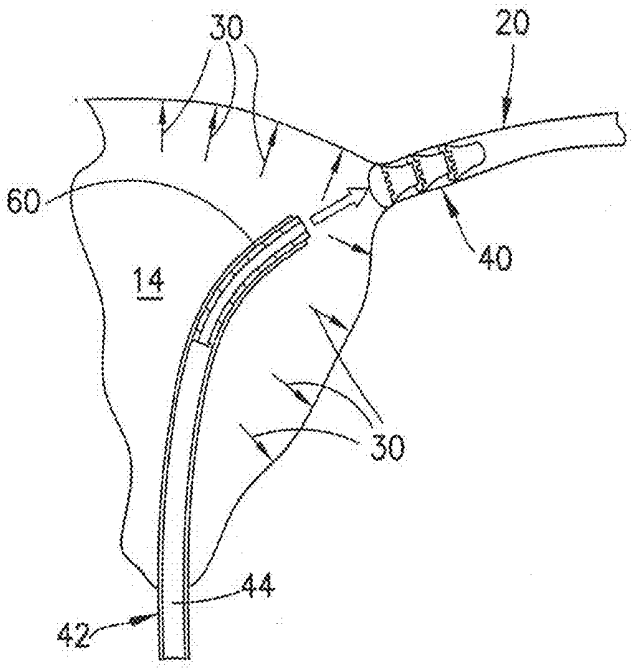


FIG.4

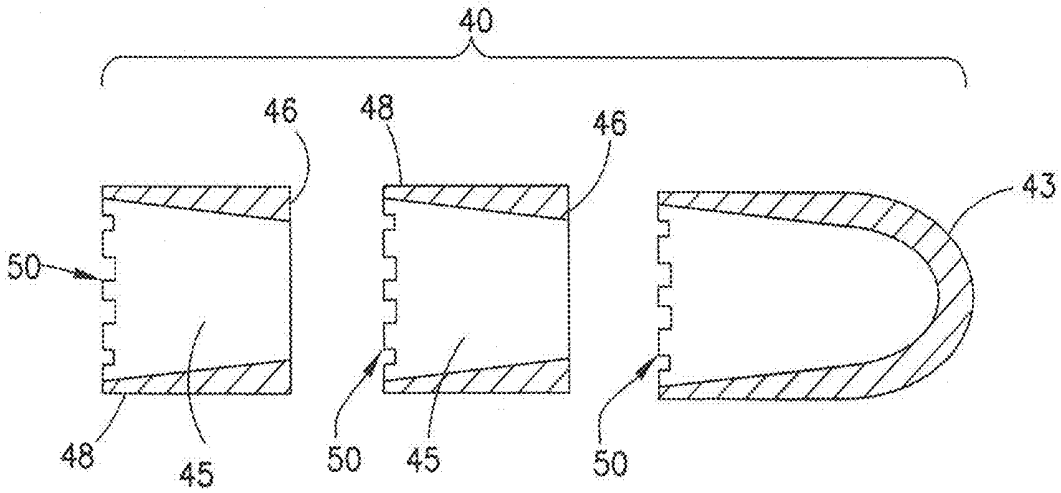


FIG.5

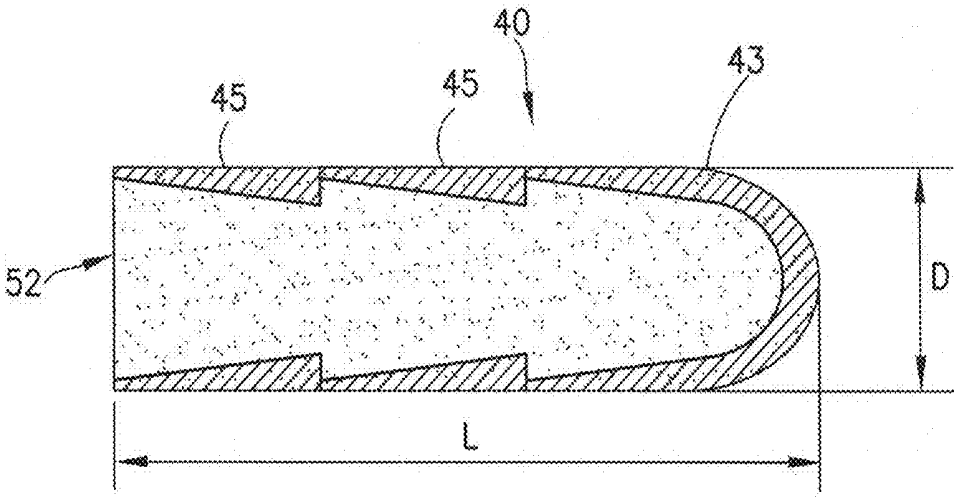


FIG.6

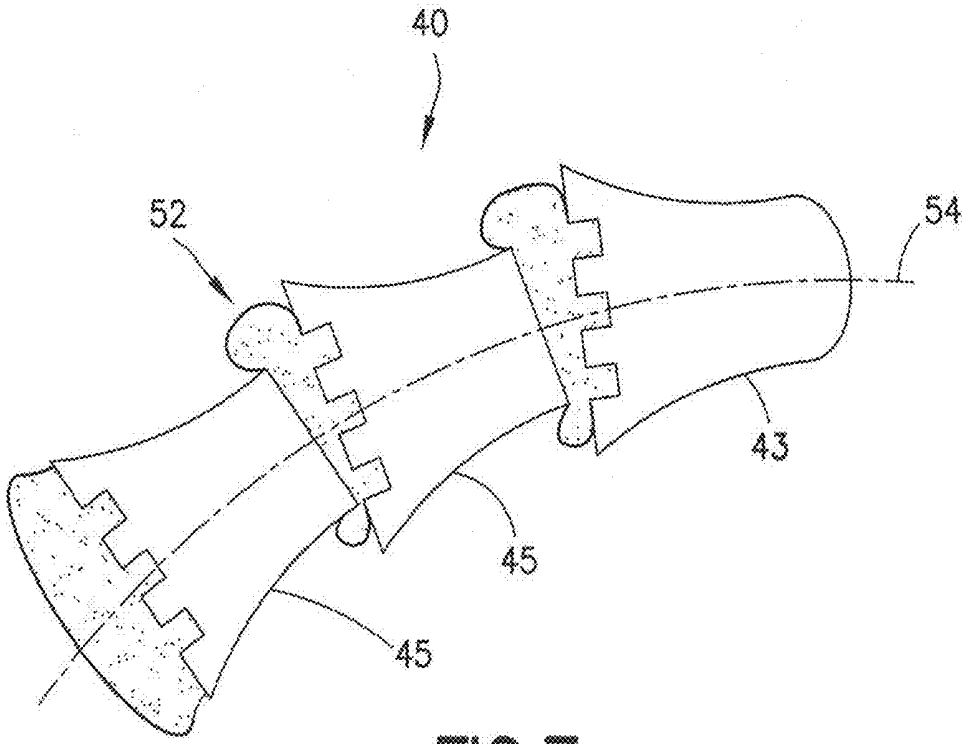


FIG.7

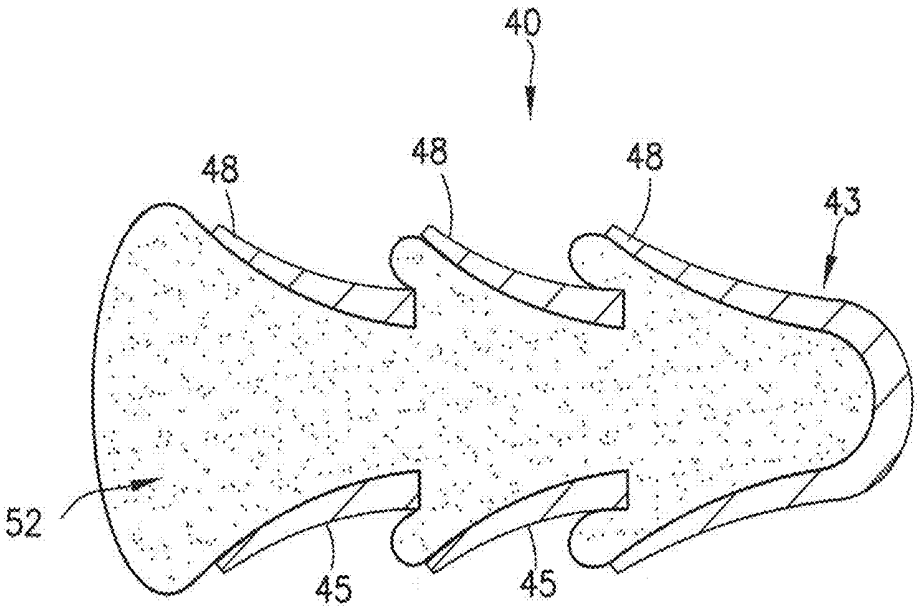


FIG.8

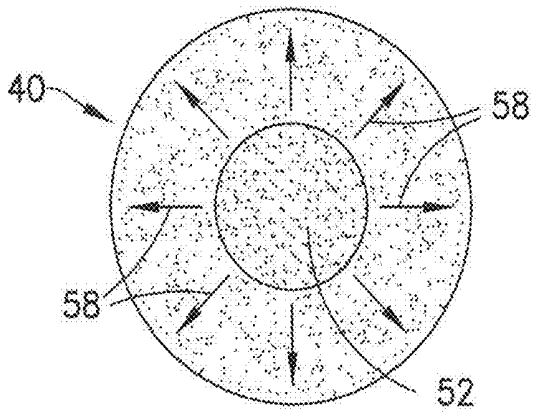


FIG.9

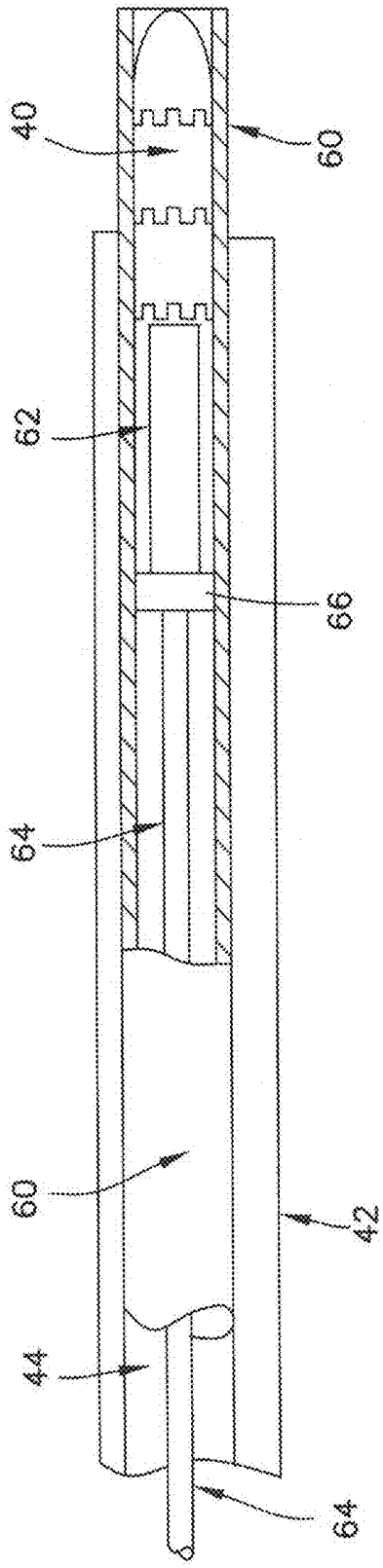


FIG. 10

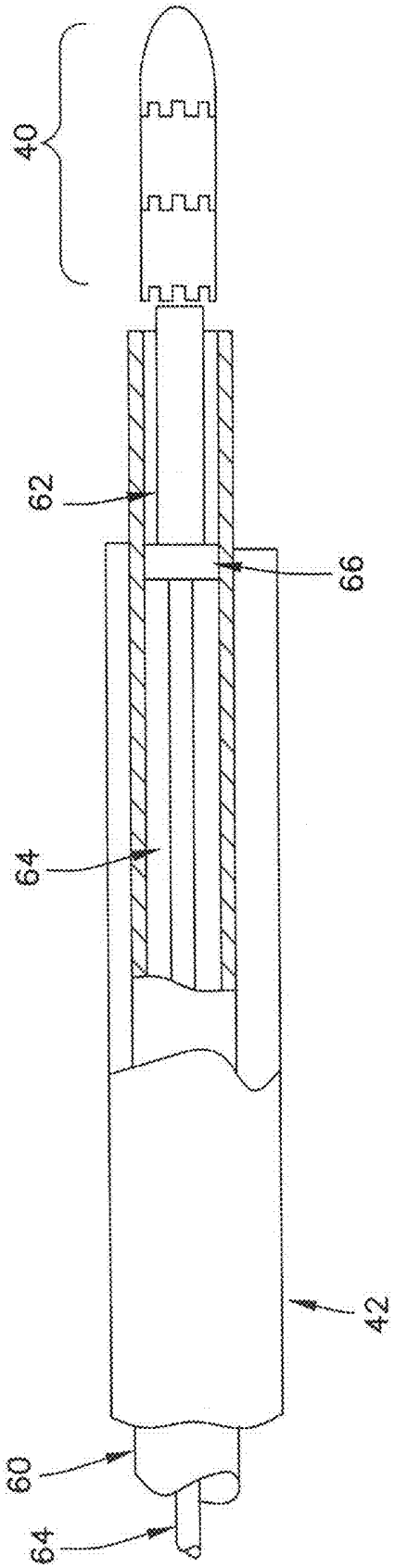


FIG. 11

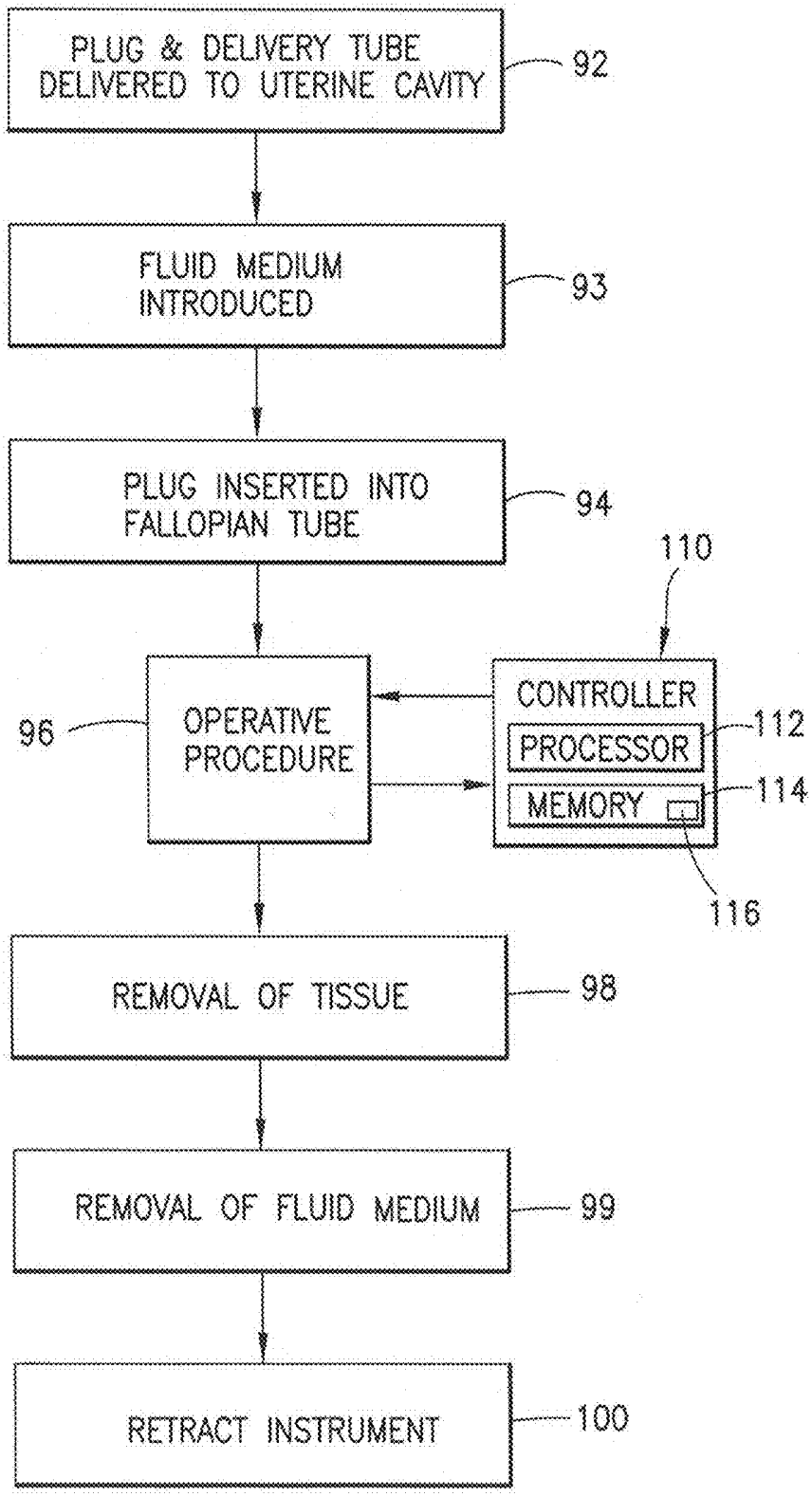

PLUG & DELIVERY TUBE DELIVERED TO UTERINE CAVITY
92
FLUID MEDIUM INTRODUCED
93
PLUG INSERTED INTO FALLOPIAN TUBE
94
110
96
OPERATIVE PROCEDURE
CONTROLLER
PROCESSOR
112
MEMORY
114
116
REMOVAL OF TISSUE
98
REMOVAL OF FLUID MEDIUM
99
RETRACT INSTRUMENT
100

FIG.12

FALLOPIAN TUBE BIOCOMPATIBLE PLUG

BACKGROUND

Field of the Invention

[0001] The exemplary and non-limiting embodiments described herein relate generally to devices and methods that relate to hysteroscopic procedures for the removal of uterine fibroids and other abnormal gynecological tissues. The exemplary and non-limiting embodiments described herein relate more particularly to surgical procedures pertaining to hysteroscopic tissue removal systems having fluid management and/or monitoring capabilities.

BRIEF DESCRIPTION OF PRIOR DEVELOPMENTS

[0002] It is believed that uterine fibroids occur in a substantial percentage of the female population, perhaps in at least 20 to 40 percent of all women. Uterine fibroids are well-defined, non-cancerous tumors that are commonly found in the smooth muscle layer of the uterus. In many instances, uterine fibroids can grow to be several centimeters in diameter and may cause symptoms like menorrhagia (prolonged or heavy menstrual bleeding), pelvic pressure or pain, and reproductive dysfunction. Hysteroscopy may be performed in either a physician's office with or without local anesthesia or in the operating room under monitored anesthesia care (MAC) or regional or general anesthesia. Hysteroscopy has been shown to be a safe and effecti method for the treatment of, for example, uterine polyps, uterine adhesions, intrauterine septa, and abnormal uterine bleeding.

SUMMARY

[0003] In accordance with one aspect of the invention, a medical device assembly comprises: an endoscope having a working channel; a delivery tube configured to be received in the working channel; and a substantially cylindrical plug configured to be deliverable through a uterine cavity and into a fallopian tube of a patient by way of the delivery tube. The plug is configured to expand to internally seal the fallopian tube of the patient following its delivery into the fallopian tube.

[0004] In accordance with another aspect of the invention, a method comprises: delivering an endoscope into a uterine cavity of a patient; expanding or inflating the uterine cavity; and delivering a biocompatible plug from the endoscope into a fallopian tube of the patient. The biocompatible plug is configured to expand against an inner wall of the fallopian tube to seal the fallopian tube from the uterine cavity.

[0005] In accordance with another aspect of the invention, a method of treating a uterine abnormality of a patient comprises: providing an endoscope having a working channel; inflating a uterine cavity with a fluid; delivering a biocompatible plug into an ostium of a fallopian tube of the patient, wherein the biocompatible plug is substantially cylindrical in form and configured to be radially expandable, wherein the biocompatible plug is configured to expand in the ostium of the fallopian tube to seal the fallopian tube from the uterine cavity; delivering a resection device through the working channel; and resecting the uterine abnormality.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] The foregoing aspects and other features of the invention are explained in the following description, taken in connection with the accompanying drawings, wherein:

[0007] FIG. **1** is a schematic representation of a gynecological cavity having various tissue abnormalities;

[0008] FIG. **2** is a schematic representation of a uterus having a fluid medium introduced thereto;

[0009] FIG. **3** is a schematic representation of a uterus having a contrast medium introduced thereto and contrast medium leakage from a fallopian tube;

[0010] FIG. **4** is a schematic representation of one exemplary embodiment of a plug inserted into a fallopian tube;

[0011] FIG. **5** is an exploded view of the plug of FIG. **4**;

[0012] FIG. **6** is a side sectional view of the plug of FIG. **4**;

[0013] FIG. **7** is a side view of the plug of FIG. **4** showing radial expansion and longitudinal curvature;

[0014] FIG. **8** is a side sectional view of the plug of FIG. **4** showing expansion of select portions of the plug;

[0015] FIG. **9** is a cross sectional view of a mandrel of the plug showing radial expansion;

[0016] FIG. **10** is a side sectional view of a hysteroscope showing a delivery tube in a working channel and the plug in the delivery tube;

[0017] FIG. **11** is a side sectional view of the hysteroscope of FIG. **10** showing the plug being deployed from the delivery tube; and

[0018] FIG. **12** is a flow of one exemplary embodiment of a method of performing a hysteroscopic procedure using a biocompatible fallopian tube plug.

DETAILED DESCRIPTION

[0019] Hysteroscopy may be invaluable for diagnosing and treating the intrauterine cavity. Hysteroscopic procedures may be performed using an endoscope, with or without an attached integrated video imaging system, with the use of media suitable for distending the uterus. Examples of fluid media used to distend the uterus include, but are not limited to, liquids such as water or certain aqueous solutions (for example, a saline solution or Ringer's lactate solution) and gases. One exemplary method of distending the uterus using an appropriate gaseous medium involves insufflation or inflation or otherwise expanding with carbon dioxide (CO_2). Upon the distension of the uterus, the surgical procedure carried out may relate to hysteroscopic tissue removal such as the removal of uterine fibroids or other abnormal gynecological tissues.

[0020] Referring to FIG. **1**, a gynecological cavity is shown and designated generally by the reference number **10**. The gynecological cavity **10** includes the uterus **12** defining the uterine cavity **14**, access to which is generally through the vaginal canal **16** and the cervix **18**. The fallopian tubes **20** extend from an upper portion of the uterus **12** and terminate in fimbriated and funnel-shaped openings that wrap partway around the ovaries **22** (shown in FIG. **2**).

[0021] It may be desirable in various situations for medical personnel to perform diagnostic and/or therapeutic procedures within the gynecological cavity **10**. For example, as shown in FIG. **1**, a surgeon may wish to detect, visualize, and/or treat conditions including, but not limited to, various tissue abnormalities such as fibroids **24**, polyps **26**, tumors, adhesions, or other tissue abnormalities within the uterus **12**.

Types of fibroids **24** include, but are not limited to, intramural fibroids **24***a*, pedunculated submucosal fibroids **24***b*, pedunculated subserosal fibroids **24***c*, submucosal fibroids **24***d*, subserosal fibroids **24***e*, and the like. The surgeon may also wish to treat endometriosis or other abnormal bleeding or fertility issues. To facilitate the visualization, detection, and/or, treatment of the above and like conditions, ample space may be needed within the gynecological cavity **10** for the procedure to be performed. Unfortunately, however, in those instances in which the gynecological cavity **10** is the uterine cavity **14**, adequate space does not typically exist naturally. This is because the uterus **12** is a flaccid organ. As such, the walls of the uterus **12** are typically in contact with one another when in a relaxed state (similar to the walls of a deflated balloon). Consequently, active steps are generally taken to create a working space within the uterine cavity **14**. One technique for creating such a working space is to administer a fluid medium to the uterine cavity **14**, transcervically, under sufficient pressure to cause the uterus **12** to become distended.

[0022] Fluid media administered to the uterus **12** can be of low or high viscosity and of low or high molecular weight. The fluid media can also be either electrically conductive or nonconductive based upon the presence or absence of electrolytes in the fluid media. In terms of gaseous fluid media, it is generally accepted that CO_2 can be used as a distending medium for diagnostic hysteroscopy only as it may not be suitable for operative hysteroscopy or diagnostic procedures due to possible bleeding and the collection of blood and tissue debris, which may obscure the optical field of a viewing apparatus.

[0023] Referring now to FIG. **2**, the fluid medium, shown generally at **30**, may be introduced into the uterus **12** to cause the distension. While useful for the performance of hysteroscopy and hysteroscopically directed procedures, the distending fluid medium **30**, if absorbed systemically in sufficient amounts, may have adverse effects on a patient. Consequently, understanding the physical properties and the potential risks associated with the use of the various fluid media used for distending the uterus **12** is beneficial for the safe performance of hysteroscopic procedures. For example, because the fluid medium **30** is administered under pressure (which pressure may be as great as 80-100 millimeters (mm) Hg or greater), there may be a risk of intravasation. Intravasation during hysteroscopy procedures is the absorption of the uterine distension media through the uterine vasculature, thus resulting in such fluids leaking through open uterine channels such as the ostium of the uterine tube or the fallopian tubes **20** where the fluid is then spilled to the peritoneal or abdominal cavity. Factors influencing the amount of intravasation can include, but are not limited to, intrauterine pressure; number and size of the vascular openings in the uterus; duration of the procedure; and the condition of the patient. In other cases, the principal mechanism of systemic absorption of the distending fluid medium **30** may be directly related to surgical disruption of the integrity of the venous sinuses in the deep endometrium **32** and the myometrium **34**. Whether due to intravasation or surgical disruption, when these vessels or sinuses are transected, the fluid medium **30** is provided an opportunity to access the systemic circulation if the uterine pressure is greater than the patient's mean arterial pressure (MAP). Fluid overload in the patient can cause pulmonary edema or other undesirable effects. In terms of large amounts of CO_2 absorption, CO_2 is highly soluble in blood and if sufficiently high amounts reach the systemic circulation of the heart, CO_2 embolism may present, which may result in cardiorespiratory collapse.

[0024] To minimize the opportunities for the fluid medium to access the systemic circulation, intrauterine pressure should be controlled (for example, by close monitoring of the fluids administered) to maintain a balance between too much pressure, which increases the opportunity for fluid to leak into the patient's anatomy, and too little pressure, which decreases the visibility of the uterine cavity. The intrauterine pressure should remain below the patient's MAP. The MAP is the average pressure within an artery over a complete cycle of one heartbeat. Monitoring equipment in a hospital setting usually provides an automatic calculation of the MAP for the anesthesia personnel who can then report the reading to the operative team. In a physician's office, it may be necessary for medical personnel to manually calculate the patient's MAP using data from an automatic blood pressure monitor.

[0025] Referring to FIG. **3**, a determination of one mechanism by which pressurized fluid in the uterine cavity **14** may flow to the abdominal cavity through the fallopian tubes **20** may be carried out via contrast sonography. Contrast sonography may be performed on a patient during an office or outpatient visit and without an anesthetic. To carry out the procedure, a contrast medium **31** such as a sugar solution is injected into the uterine cavity **14** using a catheter. Movement of the contrast medium **31** is monitored using ultrasound, with the contrast medium **31** being monitored as it advances through the fallopian tube **20**. Occasionally, it can only be presumed that the fallopian tubes **20** are open, such being the case when the contrast medium **31** flows out into the abdominal cavity even though the fallopian tubes **20** are not visible. The contrast sonography procedure is generally well-tolerated by most patients, with one side effect being discomfort in the abdominal region.

[0026] The AAGL (American Association of Gynecologic Laparoscopists) Practice Report Practice Guidelines for Management of Hysteroscopic Distending Media states:

[0027] "a. For healthy patients, the maximum fluid deficit of 1000 mL is suggested when using hypotonic solutions. This is based on a decrease in serum sodium of 10 mmol, with absorbed volume of around 1000 mL. The maximum limit for isotonic solution is unclear, but 2500 mL has been advocated in the previous AAGL Guidelines. Individualization and an opinion from an anesthesiologist should be obtained.

[0028] b. When high-viscosity distending media are used, the maximum infused volume should not exceed 500 mL, and in the elderly and those with cardiopulmonary compromise should not exceed 300 mL."

[0029] There are cases where hysteroscopic procedures are aborted due to a large fibroid **24** that needs to be removed but the fluid deficit was reached. The fluid deficit is characterized by the difference between the volume of distension fluid instilled into the uterine cavity **14** and the volume of fluid removed through the out-flow channel of a hysteroscope, plus fluid collected from the drapes or inadvertently lost in drapes and surrounding area of the operative table. The deficit closely represents the amount of fluid that may have been absorbed into the patient's vasculature.

[0030] Referring now to FIG. **4**, one embodiment of a fallopian tube biocompatible plug (which may also be

bioresorbable) is designated generally by the reference number **40** and is hereinafter referred to as "plug **40**." The plug **40** is generally inserted using an endoscope such as a hysteroscope **42** (which may be flexible) in a hysteroscopic procedure, the plug **40** being introduced into the uterine cavity **14** trans-cervically through a delivery device such as a delivery tube **60** inserted through a working channel **44** of the hysteroscope **42**, inserted into the fallopian tube **20**, and expanded via the distension fluid (fluid medium **30**) instilled into the uterine cavity **14**. The plug **40** seals the fallopian tube **20** to prevent spillage of the fluid medium **30**, which may be a saline solution, to the abdominal cavity. The plug may be fabricated of a material capable of being broken down by the body and not requiring mechanical removal from the uterine cavity **14** (similar to sutures and chlorhexhidine chips). In the alternative, the material of the plug **40** may be mechanically removable from the uterine cavity **14**, either by piecewise extraction or by being dissolved (for example, based on pH, enzymes, or temperature).

[0031] Materials from which the plug **40** may be fabricated include, but are not limited to, chitosan, cellulose, collagen, elastin, gelatin, keratin, various polymers such as polyethylene glycol (PEG), acrylates, alginates, and polymers of acrylic acids (such as CARBOPOL, available from Lubrizol Corporation of Wickliffe, Ohio, USA) combinations of the foregoing, and the like. Procedures used for the manufacture of the plug **40** include, but are not limited to, lyophilization, injection molding, UV crosslinking, chemical crosslinking (acid/base), and the like.

[0032] In one embodiment in which the material is expandable and dissolvable, the material may comprise N,O-carboxymethyl chitosan (about 85% to about 70%), methyl cellulose (about 10% to about 5%), hydroxyethyl cellulose (about 15% to about 5%), and xanthan gum (about 10% to about 1%), with an overall chemical dry weight being about 1.6% to about 3.0%. In one alternative, the material may comprise N,O-carboxymethyl chitosan (about 85% to about 65%), carboxymethyl cellulose (about 20% to about 5%), hydroxyethyl cellulose (15% to about 5%), and PEG (about 20% to about 1%), again with an overall chemical dry weight being about 1.6% to about 3.0%. In another alternative, the material may comprise N,O-carboxymethyl chitosan (about 85% to about 65%), sodium polyacrylate (about 20% to about 5%), calcium alginate (about 20% to about 1%), and hydroxyethyl cellulose (about 15% to about 5%), again with an overall chemical dry weight being about 1.6% to about 3.0%.

[0033] In another embodiment in which the material is non-expandable and dissolvable, the material may comprise N,O-carboxymethyl chitosan, polyacrylic acid, and methyl cellulose.

[0034] In another embodiment in which the material is non-expandable and non-dissolvable, the material may comprise silicone and a modified chitosan plug.

[0035] Referring now to FIGS. **5** through **7**, the plug **40** comprises a nose portion **43** and one or more body portions arranged end-to-end to form an elongated member suitable for insertion into the ostium of the fallopian tube **20**. Although two body portions **45** are illustrated, any suitable number of body portions **45** may be employed. The nose portion **43** may be a substantially cylindrical member closed at the forward end and suitably rounded. Each of the body portions **45** may be ring-shaped. Walls of both the nose portion **43** and the body portions **45** may be tapered with leading edges **46** being thicker than trailing edges **48**. The materials of the nose portion **43** and the body portions **45** may be formed as closed cell foams.

[0036] As shown in FIG. **5**, the trailing edges **48** of the body portions **45** as well as the nose portion **43** may include end slots **50**. In embodiments in which the fluid medium **30** is a saline solution, the end slots **50** allow fluid ingress.

[0037] As shown in FIG. **6**, the nose portion **43** and the body portions **45** may be arranged over a flexible mandrel **52** and frictionally retained thereon. The leading edges **46** of the body portions **45** are generally engaged with the trailing edges **48** of the more forward piece, such as another body portion **45** or the nose portion **43**. Once assembled, the diameter D of the plug **40** may be about 0.15 inches (in.) to about 0.2 in., and a length L of the plug **40** may be about 0.75 in. to about 1.0 in.

[0038] As shown in FIG. **7**, the flexibility of the mandrel **52** may allow the nose portion **43** and body portions **45** to bend out of alignment along a longitudinal curvature **54**, thereby conforming to a curvature of the ostium of the fallopian tube **20**. The materials of the mandrel **52** may be formed as expandable open cell foams.

[0039] Referring now to FIGS. **8** and **9**, the material of the mandrel **52** may be expandable in radial directions about 1.5 to about 2 times from the original diameter upon an application of moisture (for example, from the saline solution or other fluid medium **30**) and/or heat. As shown in FIG. **8**, the reduced thicknesses of the walls proximate the trailing edges **48** of the nose portion **43** and the body portions **45** may facilitate increased radial expansion of the plug **40** with material of the mandrel **52** being exuded from openings formed by the radial expansion of the trailing edges **48**, thus resulting in barbed features being formed along the length of the plug **40**. The barbed features allow the plug **40** to be anchored in place in the ostium of the fallopian tube **20** and sealed against the walls of the ostium. As can be seen in FIG. **9**, the material of the mandrel **52** may expand in radial directions **58** to push the trailing edges **48** outward to anchor the plug **40** and seal the fallopian tube **20**.

[0040] Referring now to FIG. **10**, to apply the plug **40** to the fallopian tube **20**, the plug **40** may be inserted from the delivery tube **60** at a distal end of the working channel **44** of the hysteroscope **42**. The plug **40** may be dispensed from the delivery tube **60** using a piston **62** made operable by a push cable **64**. The piston **62** may include a base **66**, with the push cable **64** being coupled to a rearward end of the base **66**. The base **66** has an outer circumference that is frictionally engaged with inner walls of the delivery tube **60**, but which may be configured td maintain a gas-tight seal. The plug **40** may be frictionally retained in the distal end of the delivery tube **60** forward of the piston **62**. At this point, the mandrel **52** is sealed by the outer walls of the nose portion **43** and the body portions **45** of the plug **40** such that the material of the mandrel **52** is not exposed to the fluid medium **30**.

[0041] Referring now to FIG. **11**, application of the plug **40** may involve translating the delivery tube **60**, the piston **62**, and the plug **40** as an assembly through the working channel **44** to a distal end of the hysteroscope **42** when the distal end of the hysteroscope **42** is positioned at the fallopian tube **20**. Once the assembly of the delivery tube **60**, the piston **62**, and the plug **40** is at the distal end of the hysteroscope **42** and the plug **40** is ready to be deployed, the push cable **64**, which may be a stiff wire, is pushed forward to move the piston **62** forward until the piston **62** reaches the

end of the delivery tube **60**, thus pushing the plug **40** out of the delivery tube **60** and into the fallopian tube **20**. As the plug **40** is exposed to the fluid medium **30**, the material of the mandrel **52** absorbs the fluid medium **30** and expands accordingly. It should be understood, however, that the plug **40** is not limited to being introduced into the fallopian tube **20** through the uterine cavity **14**, as the plug **40** may be introduced laparoscopically into the ostium of the fallopian tube **20**.

[0042] Referring to FIG. **12**, a flow of one exemplary method of using the plug **40** in conjunction with a hysteroscope **42** is shown generally at **90** and is hereinafter referred to as "method **90**." In the method **90**, the plug **40** and the delivery tube **60** are installed onto the hysteroscope **42** and delivered into the uterine cavity **14**, in a step **92**. In a step **93**, the fluid medium **30** may be introduced through the working channel **44** of the hysteroscope **42** to inflate or expand the uterus. After inflation or expansion of the uterine cavity **14**, the plug **40** is inserted into the fallopian tube **20** and expanded. Instruments that also may be introduced include, but are not limited to, viewing instruments such as cameras and lighting equipment (if not already present on the hysteroscope **42**) having working channels for the introduction of further instruments such as tissue removal device blades, fluid flow devices, and the like. After inserting the instruments, an operative procedure may be carried out in an operation step **96**. The operation step **96** may comprise the resecting of tissue using the tissue removal device blade. In a removal step **98**, any tissue (such as resected tissue pertaining to an abnormality) may be removed through a suction path of the tissue removal device blade. In a fluid removal step **99**, the fluid medium **30** may be removed. Following removal of tissue (if tissue was resected) and/or the fluid medium **30**, the instruments may be retracted in a retraction step **100**.

[0043] Any of the foregoing step may be carried out using a robot or robotic apparatus and controlled using a controller **110** having a processor **112** and a memory **114**, the memory **114** having software **116**. Although the operation step **96** is shown as being controlled using the controller **110**, it should be understood that any of the described steps could be carried out robotically and using the controller **110**.

[0044] Referring to all the Figures, the proposed invention provides a seal in the uterine cavity by implementing a plug that blocks the pathway into the fallopian tubes to prevent saline (or other fluid) spillage to the abdominal cavity.

[0045] Below are provided further descriptions of various non-limiting, exemplary embodiments. The below-described exemplary embodiments may be practiced in conjunction with one or more other aspects or exemplary embodiments. That is, the exemplary embodiments of the invention, such as those described below, may be implemented, practiced, or utilized in any combination (for example, any combination that is suitable, practicable, and/or feasible) and are not limited only to those combinations described herein and/or included in the appended claims.

[0046] In one exemplary embodiment, a medical device assembly comprises: an endoscope having a working channel; a delivery tube configured to be received in the working channel; and a substantially cylindrical plug configured to be deliverable through a uterine cavity and into a fallopian tube of a patient by way of the delivery tube. The plug is configured to expand to internally seal the fallopian tube of the patient following its delivery into the fallopian tube.

[0047] The plug may be biocompatible and/or bioresorbable. The plug may be fabricated from one or more of chitosan, cellulose, collagen, elastin, gelatin, keratin, and polymer. The plug may comprise a nose portion, at least one body portion, and a substantially cylindrical mandrel, the nose portion comprising a substantially cylindrical member closed at a forward end, and the at least one body portion comprising a ring member having a forward end arranged against a rearward end of the nose portion, wherein the nose portion and the at least one body portion are mounted on an outside of the mandrel. The mandrel may be configured to expand relative to the nose portion and the at least one body portion to expand the rearward end of the nose portion and a rearward end of the at least one body portion. The nose portion and the at least one body portion may be formed as a closed cell foam, and the mandrel may be formed as an open cell foam. Material at the rearward end of the nose portion may be thinner relative to material at the forward end of the nose portion, and material at a rearward end of the at least one body portion may be thinner relative to material at the forward end of the at least one body portion. An expansion of material of the mandrel may be configured to cause a radial expansion of the rearward end of the nose portion and a radial expansion of the rearward end of the at least one body portion.

[0048] In another exemplary embodiment, a method comprises: delivering an endoscope into a uterine cavity of a patient; inflating or expanding the uterine cavity; and delivering a biocompatible plug from the endoscope into a fallopian tube of the patient. The biocompatible plug is configured to expand against an inner wall of the fallopian, tube to seal the fallopian tube from the uterine cavity.

[0049] The method may further comprise using a piston to deliver the biocompatible plug into the fallopian tube. The method may further comprise using a wire to move the piston to deliver the biocompatible plug into the fallopian tube. Expanding the biocompatible plug against an inner wall of the fallopian tube may comprise expanding selected portions of the biocompatible plug. Expanding selected portions of the biocompatible plug may comprise expanding a mandrel around which the biocompatible plug is mounted. The method may further comprise allowing at least a portion of the biocompatible plug to resorb into the uterine cavity of the patient.

[0050] In another exemplary embodiment, a method of treating a uterine abnormality of a patient comprises: providing an endoscope having a working channel; inflating a uterine cavity with a fluid; delivering a biocompatible plug into an ostium of a fallopian tube of the patient, wherein the biocompatible plug is substantially cylindrical in form and configured to be radially expandable, wherein the biocompatible plug is configured to expand in the ostium of the fallopian tube to seal the fallopian tube from the uterine cavity; delivering a resection device through the working channel; and resecting the uterine abnormality.

[0051] Delivering a biocompatible plug may comprise delivering the biocompatible plug from a delivery device in the working channel using a piston to push the biocompatible plug out of the delivery device. Delivering a biocompatible plug may comprise delivering the biocompatible plug laparoscopically to the uterine cavity. Expanding the biocompatible plug in the ostium of the fallopian tube may comprise radially expanding select portions of the biocompatible plug. Radially expanding select portions of the

biocompatible plug may comprise expanding a foam mandrel on which the biocompatible plug is mounted. The method may further comprise allowing the biocompatible plug to resorb into the uterine cavity of the patient. The method may further comprise removing the fluid from the uterine cavity.

[0052] It should be understood that the foregoing description is only illustrative of the invention. Various alternatives and modifications can be devised by those skilled in the art without departing from the invention. Accordingly, the invention is intended to embrace all such alternatives, modifications, and variances which fall within the scope of the appended claims.

What is claimed, is:

1. A medical device assembly, comprising:

an endoscope having a working channel;

a delivery tube configured to be received in the working channel; and

a substantially cylindrical plug configured to be deliverable through a uterine cavity and into a fallopian tube of a patient by way of the delivery tube;

wherein the plug is configured to expand to internally seal the fallopian tube of the patient following its delivery into the fallopian tube.

2. The medical device assembly of claim **1**, wherein the plug is biocompatible.

3. The medical device assembly of claim **2**, wherein the plug is bioresorbable.

4. The device of claim **1**, wherein the plug is fabricated from one or more of chitosan, cellulose, collagen, elastin, gelatin, keratin, and polymer.

5. The device of claim **1**, wherein the plug comprises a nose portion, at least one body portion, and a substantially cylindrical mandrel, the nose portion comprising a substantially cylindrical member closed at a forward end, and the at least one body portion comprising a ring member having a forward end arranged against a rearward end of the nose portion, wherein the nose portion and the at least one body portion are mounted on an outside of the mandrel.

6. The device of claim **5**, wherein the mandrel is configured to expand relative to the nose portion and the at least one body portion to expand the rearward end of the nose portion and a rearward end of the at least one body portion.

7. The device of claim **5**, wherein material at the rearward end of the nose portion is thinner relative to material at the forward end of the nose portion, and wherein material at a rearward end of the at least one body portion is thinner relative to material at the forward end of the at least one body portion.

8. The device of claim **7**, wherein an expansion of material of the mandrel is configured to cause a radial expansion of the rearward end of the nose portion and a radial expansion of the rearward end of the at least one body portion.

9. A method, comprising:

delivering an endoscope into a uterine cavity of a patient;

inflating the uterine cavity; and

delivering a biocompatible plug from the endoscope into a fallopian tube of the patient;

wherein the biocompatible plug is configured to expand against an inner wall of the fallopian tube to seal the fallopian tube from the uterine cavity.

10. The method of claim **9**, wherein the method further comprises using a piston to deliver the biocompatible plug into the fallopian tube.

11. The method of claim **10**, wherein the method comprises using a wire to move the piston to deliver the biocompatible plug into the fallopian tube.

12. The method of claim **9**, wherein expanding the biocompatible plug against an inner wall of the fallopian tube comprises expanding selected portions of the biocompatible plug.

13. The method of claim **12**, wherein expanding selected portions of the biocompatible plug comprises expanding a mandrel around which the biocompatible plug is mounted.

14. The method of claim **9**, further comprising allowing at least a portion of the biocompatible plug to resorb into the uterine cavity of the patient.

15. A method of treating a uterine abnormality of a patient, the method comprising:

providing an endoscope having a working channel;

inflating a uterine cavity with a fluid;

delivering a biocompatible plug into an ostium of a fallopian tube of the patient, wherein the biocompatible plug is substantially cylindrical in, form and configured to be radially expandable, wherein the biocompatible plug is configured to expand in the ostium of the fallopian tube to seal the fallopian tube from the uterine cavity;

delivering a resection device through the working channel; and

resecting the uterine abnormality.

16. The method of claim **15**, wherein delivering a biocompatible plug comprises delivering the biocompatible plug from a delivery device in the working channel using a piston to push the biocompatible plug out of the delivery device.

17. The method of claim **15**, wherein delivering a biocompatible plug comprises delivering the biocompatible plug laparoscopically to the uterine cavity.

18. The method of claim **15**, wherein expanding the biocompatible plug in the ostium of the fallopian tube comprises radially expanding select portions of the biocompatible plug.

19. The method of claim **18**, wherein radially expanding select portions of the biocompatible plug comprises expanding a foam mandrel on which the biocompatible plug is mounted.

20. The method of claim **16**, further comprising allowing the biocompatible plug to resorb into the uterine cavity of the patient.

* * * * *

专利名称(译)	Fallopian Tube BioCompatible Plug		
公开(公告)号	US20190201233A1	公开(公告)日	2019-07-04
申请号	US15/857915	申请日	2017-12-29
[标]申请(专利权)人(译)	捷锐士阿希迈公司(以奥林巴斯美国外科技术名义)		
申请(专利权)人(译)	GYRUS ACMI，INC.D.B.A. OLYMPUS外科技术AMERICA		
当前申请(专利权)人(译)	GYRUS ACMI，INC.D.B.A. OLYMPUS外科技术AMERICA		
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摘要(译)

一种治疗患者子宫异常的方法，包括：提供具有工作通道的内窥镜;用液体给子宫腔充气;将生物相容性塞子输送到患者的输卵管口中，其中生物相容性塞子基本上是圆柱形的并且构造成可径向扩张的，其中生物相容性塞子构造成在输卵管的口中扩张以密封输卵管。子宫腔管;通过工作通道提供切除装置;并切除子宫异常。