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(54) **UTERINE SEALER**

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(58) **Field of Classification Search** 606/45-47,
606/119, 135-137, 113
See application file for complete search history.

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Primary Examiner — Nicholas Lucchesi

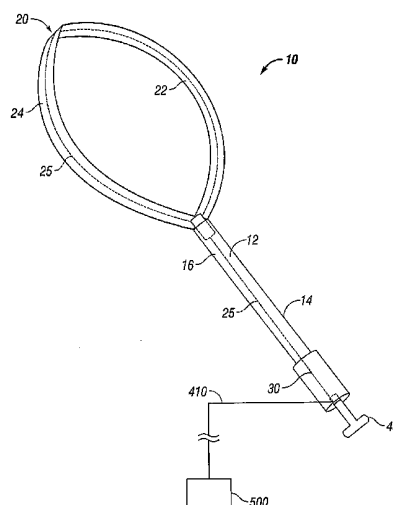
Assistant Examiner — Rebecca E Eisenberg

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ABSTRACT

The present disclosure relates to a device for use with an operating end of a uterine manipulator for sealing tissue that includes a shaft having a handle at an operating end thereof and a ring-like snare at a distal end thereof. The handle has an actuator operable to selectively cinch the snare from a first configuration to a second configuration. An electrode is operably coupled to the snare and is connected to an energy source to energize tissue to create a tissue seal. The shaft is positionable within a surgical cavity such that the snare encircles tissue and operably engages and cinches the operating end of the uterine manipulator under a sealing pressure. Energy is applied to the electrode to seal the tissue disposed between the uterine manipulator and the snare under a working pressure. The tissue may then be resected and removed from the body.

19 Claims, 9 Drawing Sheets



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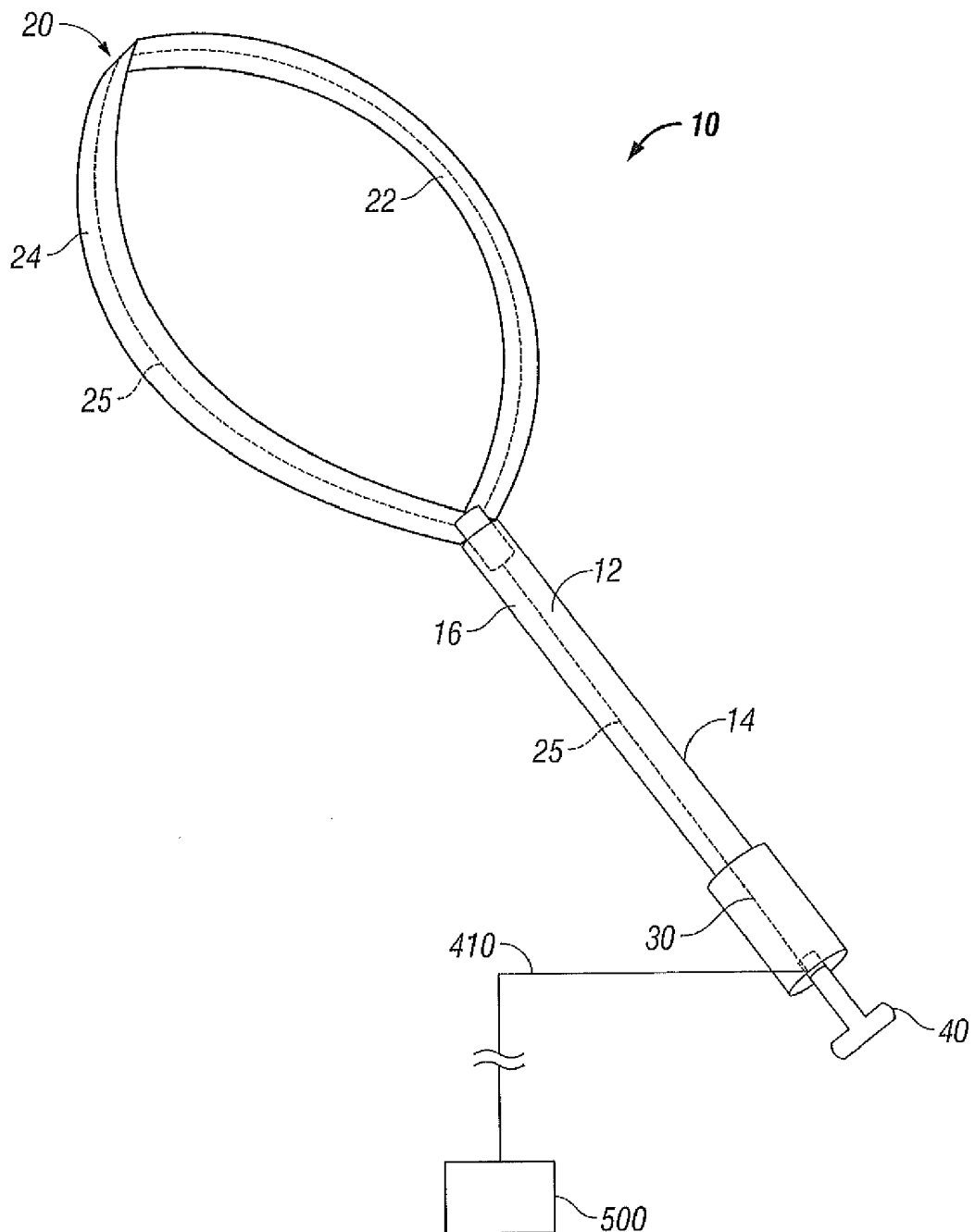


FIG. 1

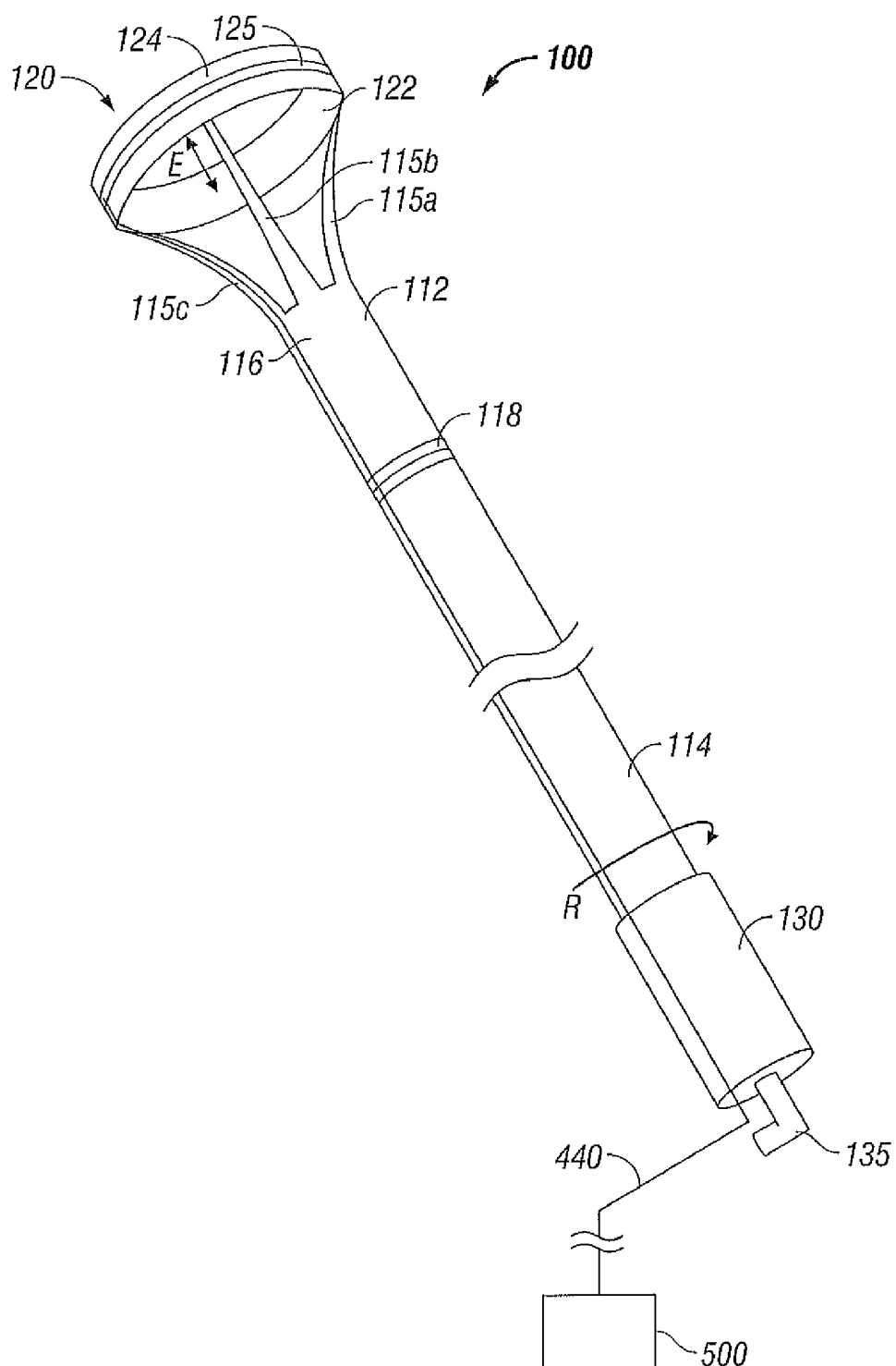


FIG. 2

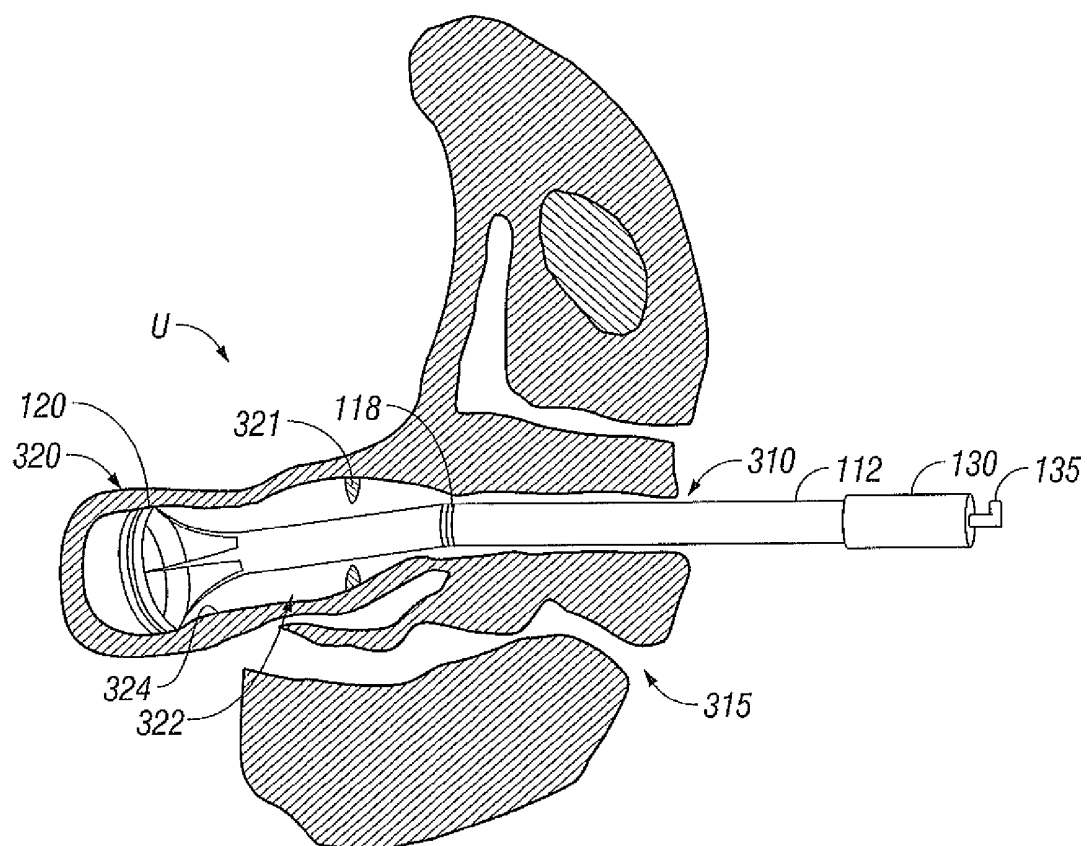


FIG. 3A

FIG. 3B

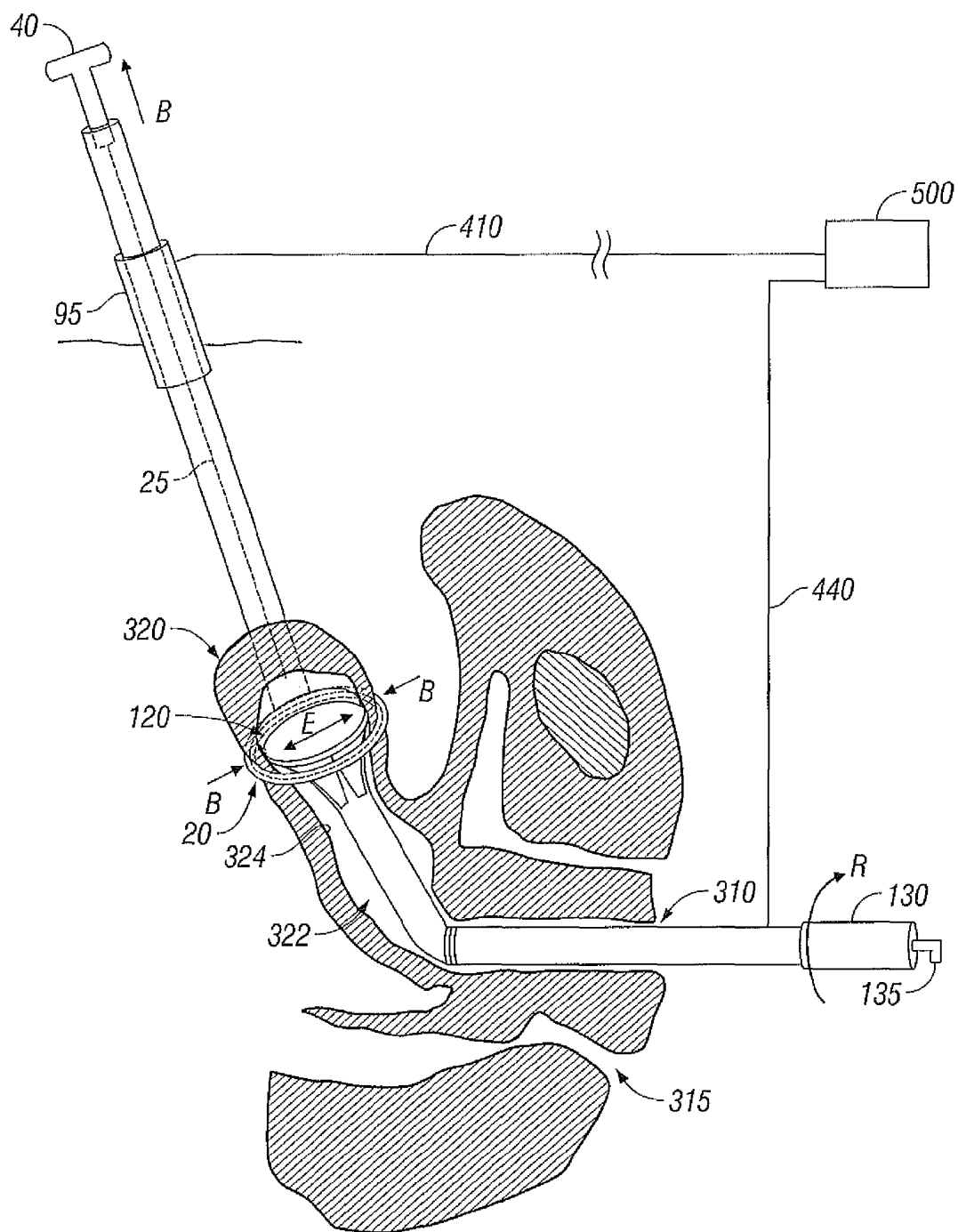


FIG. 3C

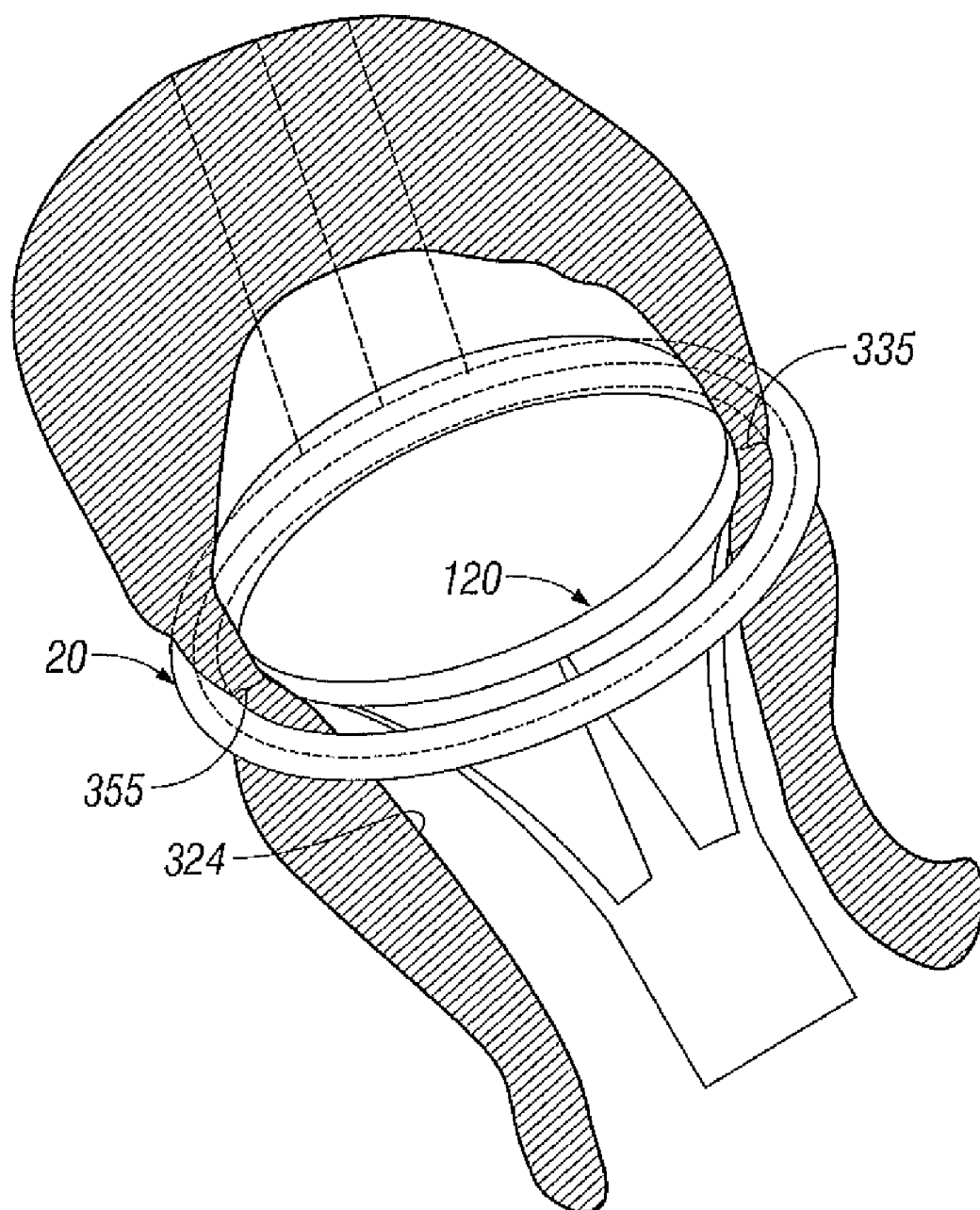


FIG. 3D

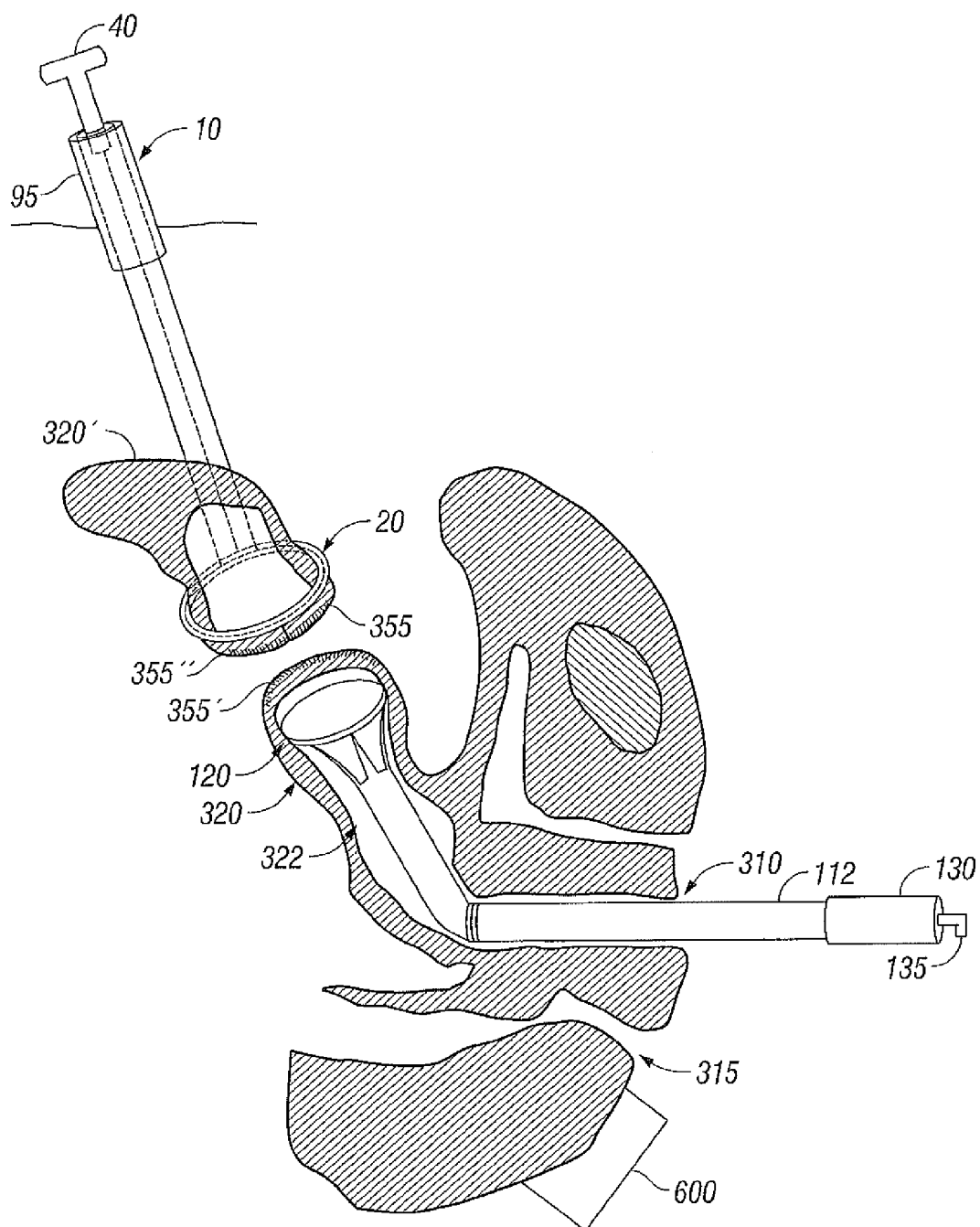


FIG. 3E

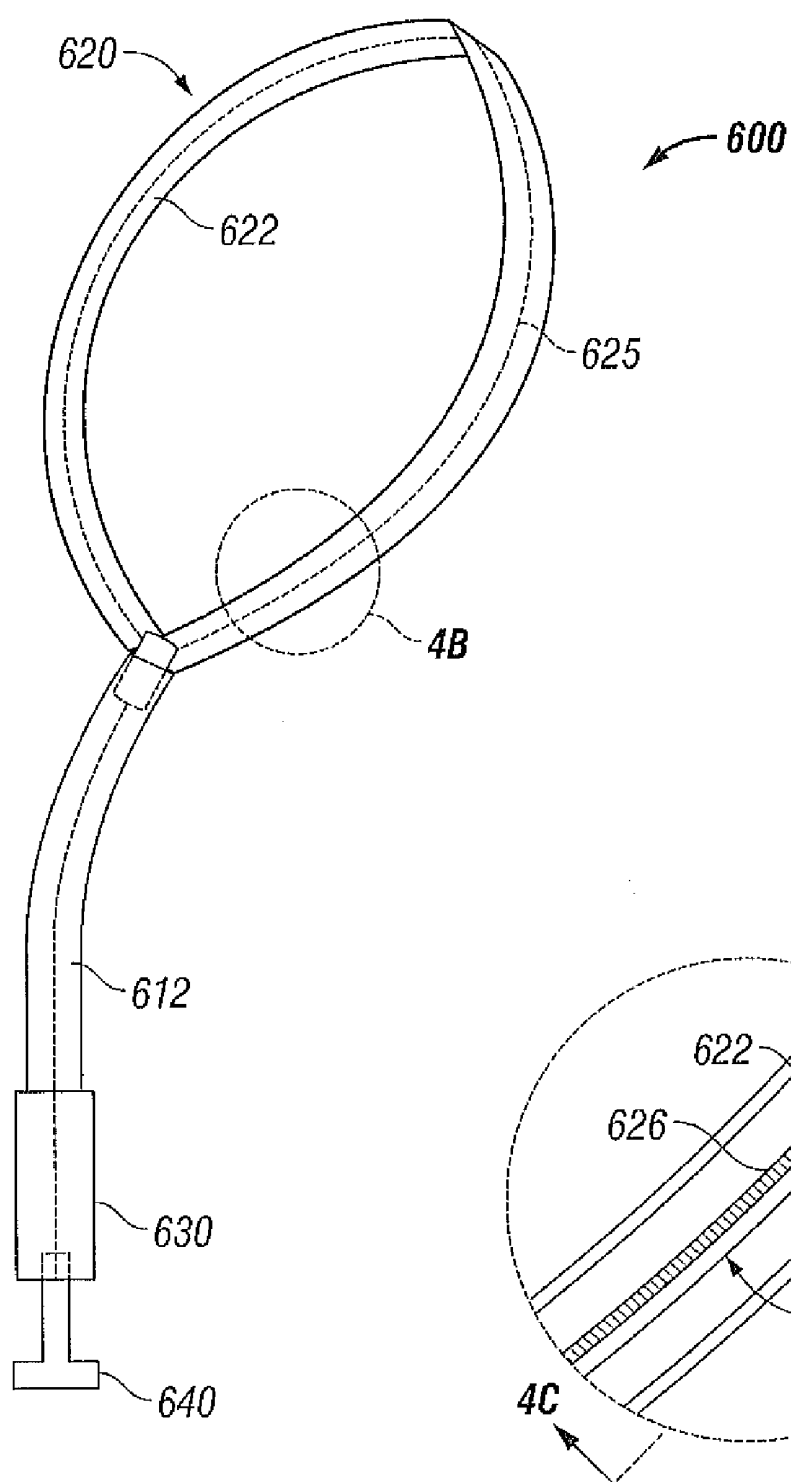


FIG. 4A

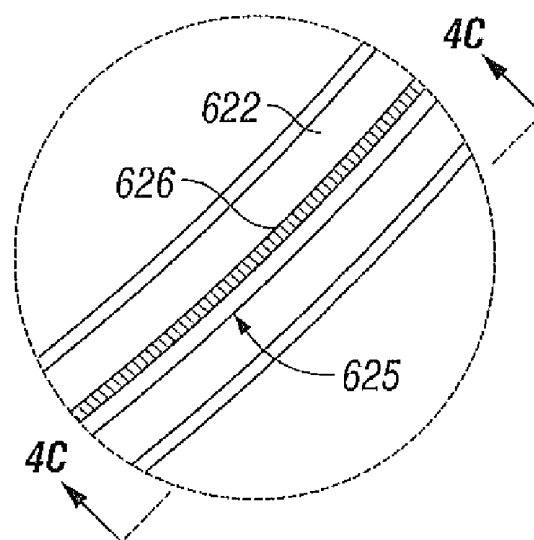


FIG. 4B

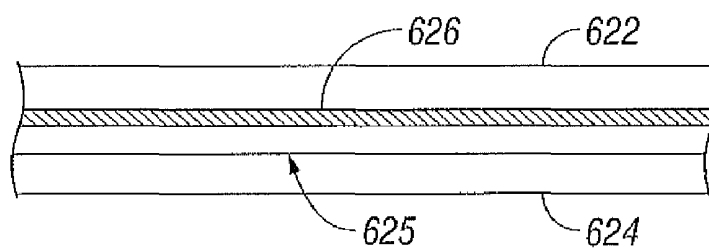


FIG. 4C

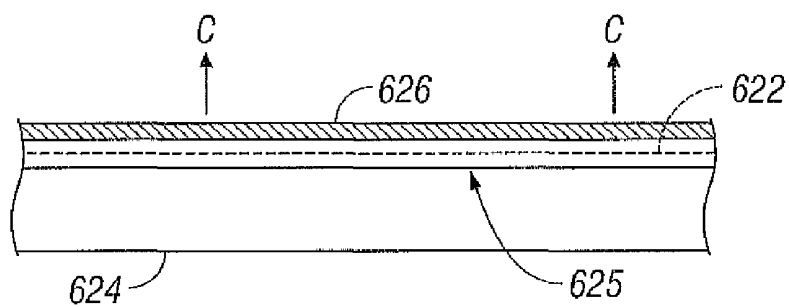


FIG. 4D

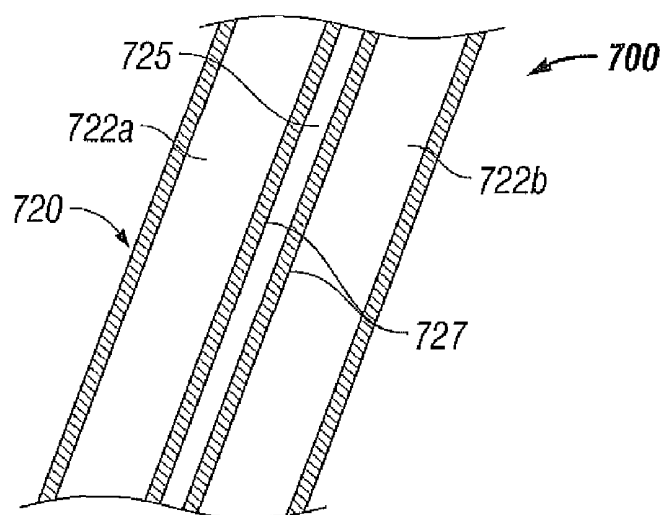


FIG. 5

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UTERINE SEALER

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of priority to U.S. Provisional Application Ser. No. 61/021,582 entitled "UTERINE SEALER" filed Jan. 16, 2008 by Sean T. Dycus, which is incorporated by reference herein.

BACKGROUND

Technical Field

1. Field of the Invention

The present disclosure relates to medical instrumentation, and more particularly to a device for use with a uterine manipulator to facilitate laparoscopically sealing and resecting cervical and uterine tissue.

2. State of the Art

Typically a uterine manipulator is currently deemed necessary by practitioners for many laparoscopic procedures involving the female pelvic organs (e.g., uterus, tubes, ovaries, etc.) as surgery without a uterine manipulator may be more time consuming. For example, laparoscopies in which a uterine manipulator has substantial utility include: tubal ligations; diagnostic laparoscopies for evaluating pelvic pain and infertility; treatment of endometriosis; removal of pelvic scars (adhesions) involving the uterus, fallopian tubes and ovaries; treatment of ectopic pregnancy; removal of uterine fibroids; removal of ovarian cysts; removal of ovaries; tubal repair; laparoscopic hysterectomy; laparoscopic repair of pelvic bowel or bladder; sampling of pelvic lymph nodes; "tying up" the bladder to prevent urine loss; and biopsy of pelvic masses.

Most state of the art manipulators are semi-rigid instruments having a manipulating handle that is grasped outside the vagina and a working end which operatively engages one or more organs in the uterus. Exposure of the vital regions of the pelvis is difficult and surgery with open or laparoscopic instruments is often difficult and, in some cases, suboptimal. For example, the uterus typically can only be safely elevated about 45° from the vaginal axis, or lowered 10°-15° from the same and movement to the right or left is minimal, at most, due to the pelvic bones. Once the uterine organ is in place, the surgeon can perform one of the above mentioned surgical procedures.

One of the most significant complications of any surgical procedure involving the uterus, e.g., partial or complete hysterectomy, is the risk of persistent and excessive bleeding due to the large blood supply in the pelvic region and blood-laden organs. For example, the open technique carries increased risk of hemorrhage due to the need to move the intestinal organs and bladder in order to reach the reproductive organs and to search for collateral damage from endometriosis or cancer. However, an open hysterectomy provides the most effective way to ensure complete removal of the reproductive system as well as providing a wide opening for visual inspection of the abdominal cavity.

Some hysterectomies are done through the manipulation of the cervix and/or uterus utilizing a uterine manipulator and resection of the cervix (total hysterectomy) or uterus (supracervical) utilizing one or more laparoscopic instruments inserted through the navel (or other body access made with a trocar). Even though these techniques tend to reduce the recovery time in most instances, there remains the risk of excessive and persistent bleeding which in this instance is not

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easily controlled due to the blood-laden nature of the cervix and the remote nature of the laparoscopy. As a result, if excessive bleeding does occur, the surgeon may need to convert the procedure to an open procedure to control the bleeding essentially abandoning the benefits of the laparoscopic procedure.

SUMMARY

10 The present disclosure relates to a device for use with an operating end of a uterine manipulator for sealing uterine tissue and includes a shaft having a handle at an operating end thereof and a ring-like snare at a distal end thereof. The handle includes an actuator operable to selectively cinch the ring-like
15 snare from a first configuration having a first diameter to at least one subsequent configuration having a second diameter. An electrode is operably coupled to an inner peripheral surface of the ring-like snare and is adapted to connect to an electrical energy source to energize uterine tissue to create a
20 tissue seal. The shaft is selectively positionable within a surgical cavity such that the ring-like snare encircles uterine tissue and operably engages and cinches the operating end of the uterine manipulator under a sealing pressure. Electrosurgical energy is applied to the electrode to seal the uterine
25 tissue disposed between the uterine manipulator and the ring-like snare.

In one embodiment according to the present disclosure, the electrode is further energized after the successful completion of the tissue seal to resect/or cut the uterine tissue along the
30 tissue seal. In another embodiment, the device includes a second electrode that is adapted to connect to the electrical energy source, the second electrode is energized after the successful completion of the tissue seal to resect the tissue along the tissue seal.

35 In still another embodiment, the electrode is recessed within an inner peripheral surface of the ring-like snare and includes a cutting edge that deploys when the ring-like snare is cinched beyond a predetermined sealing pressure of about 16 kg/cm².

40 The present disclosure also relates to a method for performing a laparoscopic hysterectomy and includes the initial step of providing a uterine manipulator having a shaft having a handle at a proximal end thereof operable by a user and an operating end at a distal end thereof manipulatable by the
45 handle to orient and position tissue. The method also includes the step of providing a uterine sealer having a shaft with a handle disposed at a proximal end thereof and a ring-like snare disposed at a distal end thereof having a diameter. The handle includes an actuator operably associated therewith
50 which selectively cinches and expands the diameter of the snare. The uterine manipulator and/or the uterine sealer includes an electrode disposed at the distal end thereof.

The method also includes the steps of: inserting the uterine manipulator into a body cavity to engage and manipulate
55 tissue; inserting the uterine sealer into a second body cavity to encircle the tissue being manipulated by the uterine manipulator; activating the actuator to cinch the diameter of the snare to engage tissue between the operating end of the uterine manipulator and the snare; energizing the electrode to seal
60 tissue disposed between the operating end of the uterine manipulator and the snare; and resecting the tissue along the tissue seal and removing the resected tissue from the body cavity.

65 In one embodiment according to one particular method, the tissue is engaged between the operating end of the uterine manipulator and the snare under a working pressure of about 3 kg/cm² to about 16 kg/cm². In one method, the uterine sealer

includes the electrode that cooperates with a return electrode located remotely from the operating cavities to seal tissue while in another method both the uterine sealer and the uterine manipulator include electrodes which mutually cooperate in a bipolar fashion to seal tissue.

The method may additionally or alternatively include the step of further manipulating the uterine sealer and/or uterine manipulator to resect tissue along the tissue seal by energizing a cutting electrode disposed on the uterine sealer and/or uterine manipulator. The cutting electrode and the sealing electrode disposed on the uterine sealer (or the uterine manipulator) may be one in the same.

The method may additionally or alternatively include the step of further manipulating the uterine sealer and/or uterine manipulator to resect tissue along the tissue seal by mechanically deploying a tissue cutter to resect tissue along the tissue seal.

The present disclosure also relates to a method for performing a laparoscopic hysterectomy including the steps of:

providing a uterine manipulator having a shaft including a handle at a proximal end thereof operable by a user and an operating end at a distal end thereof manipulatable by the handle to orient and position tissue;

providing a uterine sealer including a shaft having a handle disposed at a proximal end thereof and a ring-like snare disposed at a distal end thereof having a diameter, the handle including an actuator operably associated therewith which selectively cinches and expands the diameter of the snare, the uterine sealer including an electrode disposed at the distal end thereof, the electrode including a sharpened edge;

inserting the uterine manipulator into a body cavity to engage and manipulate tissue;

inserting the uterine sealer into a second body cavity to encircle the tissue being manipulated by the uterine manipulator;

activating the actuator to cinch the diameter of the snare to engage tissue between the operating end of the uterine manipulator and the snare under a sealing pressure;

energizing the electrode to seal tissue disposed between the operating end of the uterine manipulator and the snare; further cinching the diameter of the snare beyond the sealing pressure to deploy the sharpened edge of the electrode to resect tissue; and

removing the resected tissue from the body cavity.

In one particular method, the uterine sealer of the providing step includes an inner peripheral surface that includes the electrode recessed therein. The electrode is selectively deployable beyond the inner peripheral surface to resect tissue when the cinching pressure of the snare on the tissue is beyond the sealing pressure of about 16 kg/cm². The electrode may be energized during the step of further cinching the snare to facilitate resecting the tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

Various particular embodiments of the presently disclosed systems, devices and methods are disclosed herein with reference to the drawings wherein:

FIG. 1 is a schematic representation of a uterine sealer having a ring-like operative end according to an embodiment of the present invention;

FIG. 2 is a schematic illustration of a uterine manipulator for use with the uterine sealer of FIG. 1;

FIGS. 3A-3E are internal schematic illustrations of the uterine sealer and uterine manipulator being used to perform a laparoscopic hysterectomy;

FIG. 4A is a schematic view of another embodiment of a uterine sealer according to the present disclosure having a mechanical cutting blade internally disposed within the inner peripheral surface of the ring-like operative end;

FIG. 4B is an enlarged view of the area of detail of FIG. 4A;

FIG. 4C is a side, cross-sectional view of the ring-like operative end prior to advancement of the cutting blade through the inner peripheral surface thereof;

FIG. 4D is a side cross-sectional view of the ring-like operative end after advancement of the cutting blade through the inner peripheral surface thereof; and

FIG. 5 is a schematic view of another embodiment of a uterine sealer according to the present disclosure configured to include an electrical sealing and cutting electrode disposed on the face of the inner peripheral surface of the ring-like operative end.

DETAILED DESCRIPTION

Referring initially to FIG. 1, one embodiment of a uterine sealer is shown and is generally designated as sealer 10. Sealer 10 includes a generally elongated shaft 12 having proximal and distal ends 14 and 16, respectively. The distal end 16 of the shaft 12 is configured to support a loop-like or ring-like snare or cinch 20 and the proximal end 14 of the shaft 12 is operatively coupled to a handle 30. The shaft 12 may be pliable or semi-rigid to facilitate positioning of the sealer 10 within an operating cavity 80 (See FIG. 3B). More particularly, the shaft 12 may be selectively bendable, rotatable, articulatable or otherwise positionable to orient the ring-like snare 20 about a target organ, e.g., cervix 320 (See FIGS. 3A-3E). Shaft 12 may also be telescopic (not shown), which may prove particularly useful for certain surgical purposes. In view thereof, handle 30 may be configured to include one or more actuators (not shown) that are actuatable to orient the ring-like snare 20 relative to a target organ for ensnarement, as will be explained in more detail below with reference to FIGS. 3A-3E.

Handle 30 also includes an actuator 40 that operatively couples to a control cable 25 internally disposed within shaft 12 and ring-like snare 20. Actuator 40 is configured to reciprocate cable 25 from a first position wherein the cable 25 expands the ring-like snare 20 to a fully open configuration (as shown) to a subsequent or second position that reduces the diameter of the snare 20 such that an inner peripheral surface 22 of the snare 20 grasps and encircles target tissue (See FIG. 3C). Actuator 40 may be configured as a pull knob (as shown) which biases against handle 30 to reciprocate cable 25 or any other suitable type of actuator that is designed to reciprocate a cable 25, e.g., a lever-like actuator, a rotational actuator, an electrical or mechanical winch-like actuator, etc.

As described in detail below with reference to FIGS. 3A-3E, the cable 25 may be configured to act as an electrode and coupled to an electrosurgical energy source, such as an electrical generator 500. In this configuration, the cable 25 may conduct a sealing current therethrough that acts as one pole of a bipolar or monopolar sealing system. Moreover, and again as explained in more detail below, the cable 25 may also operatively communicate with the generator 500 to generate a cutting current to resect the target tissue once sealed. In another embodiment, the cable 25 is configured as a mechanical cutter to resect tissue once the seal is completed, as discussed below with reference to FIGS. 4A-4D.

FIG. 2 shows one embodiment of a uterine manipulator 100 for use in manipulating and positioning the organs of the uterus "U" and tissue for surgical purposes, e.g., tubal ligations; removal or partial removal of the uterus, fallopian tubes

and ovaries; laparoscopic hysterectomy and other surgeries. Uterine manipulator **100** includes a generally elongated shaft **112** having proximal and distal ends **114** and **116**, respectively, and a selectively expandable ring or cuff **120** disposed at the distal end **116** having an outer peripheral surface **124** that is configured to engage tissue for manipulation purposes. Shaft **112** may include one or more hinges **118** configured to allow rotation, pivoting or articulation of the shaft **112** for manipulation purposes.

The proximal end **114** of the shaft **112** includes a handle **130** that allows a user to orient the manipulator **100** within a vaginal cavity **310** (see FIG. 3A) to position and reposition tissue as needed during the surgical procedure. Handle **130** may be equipped with one or more actuators **135** that facilitate rotation, articulation and/or positioning of the manipulator **100** within the vaginal and cervical cavities **310** and **322**, respectively. The manipulator may be inserted within other cavities depending upon particular surgical purposes or to manipulate other organs, e.g., anal cavity **315**. Moreover, the actuator **135** may further facilitate positioning of the manipulator **100** to operatively engage the sealer **10** as described in more detail below.

As mentioned above, the distal end **116** of shaft **112** includes a cuff of ring **120** that is selectively expandable from a first, collapsed configuration for insertion purposes to a second expanded configuration (See FIG. 2) for engaging and manipulating tissue. The distal end **116** includes a series of finger-like projections **115a-115c** that support the cuff **120** for manipulation purposes. Handle **130** may be configured to rotate in the direction of arrow "R" from a first position that maintains the cuff **120** in a collapsed configuration to a second configuration that expands the cuff **120** in the expanded configuration "E" (and vice versa) for manipulation and sealing purposes (See FIG. 3C). The handle **130** may also be configured to lock the cuff **120** in an expanded configuration with enough force to oppose an electrode, e.g., electrode **25** of the uterine sealer **10**, for sealing and cutting tissue, as explained in more detail below. An inner peripheral surface **122** of the cuff **120** may be configured from a semi-rigid material, include struts, scaffolding or support structure (not shown) to accomplish this purpose.

The outer peripheral surface **124** of the cuff **120** supports an electrode **125** therealong that is configured to act both as a support structure for maintaining the integrity of the cuff **120** when expanded and to act as one pole during a bipolar sealing process or a monopolar sealing process, as explained in more detail below. Moreover, the electrode **125** may be configured to produce a cutting current to cut tissue along the tissue seal after the sealing process is complete which is also explained in more detail below. As such, the electrode **125** is connected to the electrosurgical generator **500** by a lead **440** running through manipulator **100** and coupled to the generator **500**.

Electrosurgical generator **500** may be a radiofrequency or high frequency type generator and include control elements that may, for example, increase the radiofrequency power output of electrodes **25** and/or **125** and control other operating parameters to regulate the sealing and/or cutting of cervical or uterine tissue. The generator may be operatively associated with one or more suitable controls or sensors (not shown) mounted to or operatively associated with the uterine manipulator **100** or uterine sealer **10** that monitor or control impedance, temperature, power, current, voltage, or other suitable output parameters. Electrosurgical generator **500** may include a display or screen therein or as a separate system for providing a display of parameters, such as temperature, impedance, power, current, or voltage of the radiofrequency output.

Moreover, generator **500** may include a first sealing algorithm that regulates, monitors or otherwise controls the sealing cycle and a second algorithm that regulates or controls the cutting cycle. More particularly, the generator **500** may include a first algorithm that controls electrode **25** and/or electrode **125** to regulate the electrosurgical energy to effect a tissue seal. Vessel sealing or tissue sealing utilizes a unique combination of radiofrequency energy, pressure and gap control to effectively seal or fuse tissue between two opposing sealing electrodes. Vessel or tissue sealing is more than "cauterization" that involves the use of heat to destroy tissue (also called "diathermy" or "electrodiathermy"). Vessel sealing is also more than "coagulation", which is the process of desiccating tissue wherein the tissue cells are ruptured and dried. "Vessel sealing" is defined as the process of liquefying the collagen, elastin and ground substances in the tissue so that the tissue reforms into a fused mass with significantly-reduced demarcation between the opposing tissue structures.

The generator **500** also includes a second algorithm that controls one or both electrodes **25** and/or **125** to effect a tissue cut. For example, the tissue cut may be produced by one electrode, e.g., electrode **25**, producing a first electrical potential having a cutting effect through the tissue which is returned by a return electrode **600** placed remotely under the patient skin (See FIG. 3E). Alternatively, electrode **125** may act as the return electrode when electrode **25** is the cutting electrode and produces a cutting effect. Alternatively, electrode **125** may also act as a cutting electrode and electrode **25** may also act as a return electrode or the generator may be configured to alternate between electrodes **25** and **125** during the cutting process to produce a particular cutting effect.

A safety switch or circuit (not shown) may be included with the generator **500** such that the electrodes **25** and **125** cannot activate to initiate a seal or a cut unless there is tissue disposed therebetween, e.g., a sensor (not shown) may be employed to determine if tissue is held therebetween. Obviously, this would insure proper placement of the sealer and the manipulator prior to activation.

FIGS. 3A-3E show an intended use of the uterine manipulator **100** and uterine sealer **10** during a laparoscopic hysterectomy or partial hysterectomy. More particularly, and as best shown in FIG. 3A, the cuff **120** of the uterine manipulator **100** is inserted into the vaginal cavity **310** in a collapsed configuration and manipulated into position to engage the opening **321** of the cervix **320**. Once engaged, the cuff **120** of the manipulator **100** is inserted into the opening **321** of the cervix **320** and the handle **130** is rotated in the direction "R" to expand the cuff **120** in the direction "E" within the cervix **320** to exert internal pressure against the internal walls **324** of the cervix **320**. Actuator **135** is then used to orient the cervix **320** into any desired position "M" about hinge **118** for cooperative engagement with sealer **10**, as described below.

As shown in FIG. 3B, sealer **10** is inserted through a trocar **95** into a surgical cavity **80** made above the cervix **320** with the snare **20** in a collapsed configuration and then the snare **20** is expanded to encircle the cervix **320**. The user then manipulates the sealer **10** to encircle the cervix **320**. Actuator **40** is then activated to cinch snare **20** (e.g., reduce the diameter of snare **20**) and engage cuff **120** with cervical tissue disposed between snare **20** and cuff **120**. Prior to exerting the pressure required to produce a proper seal, the cuff **120** and snare **20** may be slid atop the cervix **320** to the proper or desired position or repositioned atop the cervix **320** by reducing the diameter of the cuff **120** or expanding the diameter of the snare **20**. For example, the desired position may be at the vaginal-cervico junction, the utero-cervico junction, or other suitable location. Once the proper position is located for

sealing purposes, the snare **20** is cinched in the direction "B" via actuator **40** against the internal pressure "E" of the cuff **120** and electrosurgical energy is applied to electrodes **25** and/or **125** of the snare **20** and cuff **120**, respectively (See FIG. 3C).

Any suitable working pressure may be utilized; however, in one embodiment, a working pressure of about 3 kg/cm² to about 16 kg/cm² is utilized to effect a proper seal **355** (See FIG. 3D). The duration or activation time to effect a seal is dependent on the thickness of the cervical tissue **320** that may be measured by one or more suitable sensors (not shown) coupled to the sealer **10** or the manipulator **100** or may be determined when a threshold impedance is reached (measured by the generator **500**). It is important to note that the seal **355** (See FIG. 3E) may be created by activating both electrodes **25** and **125** in a bipolar fashion under the appropriate working pressure or alternatively by activating one electrode **25** or **125** and a remote return electrode (e.g., a return pad **600** (See FIG. 3E) in a monopolar fashion).

Once electrosurgical energy is applied to electrode **25** and **125** via generator **500** under the appropriate working pressure to produce seal **355**, the cervical tissue **320** may be resected along the seal plane **355** either mechanically, electrically or electromechanically. For example, and as shown in FIG. 3E, the generator **500** may be configured to produce a cutting algorithm that generates a cutting current to one or both electrodes **25** and/or **125** to cut the tissue along the tissue seal **355** into two distinct sealed sections **355'** and **355''** with little or no bleeding.

The cutting current is typically a higher intensity current than the sealing current. In one particular embodiment, only one electrode, e.g., the smaller width electrode, which may be either **25** or **125** depending on a particular configuration, produces the cutting effect, while the other electrode acts as the return electrode.

In another embodiment, and as best shown in FIGS. 4A and 4B, a uterine sealer **600** includes a snare having a mechanical cutter **625** disposed therein. More particularly, sealer **600** acts in a similar fashion as sealer **10** and includes shaft **612** having handle **630** and actuator **640** that operates snare **620** to cinch tissue for laparoscopic hysterectomies. An electrode **625** is disposed along the inner peripheral surface **622** of snare **620** and is selectively activatable to seal tissue to create a tissue seal **355** in much the same fashion as described above with respect to FIGS. 3A-3E. Electrode **625** includes a sharpened distal edge **626** that during the sealing cycle and under the working sealing pressure remains recessed beneath the inner working surface of the snare **620**, as best shown in FIG. 4C.

During the cutting phase of the laparoscopic hysterectomy, the surgeon exerts a greater cinching pressure beyond the working pressure that causes the sharpened edge **626** of the electrode **625** to pierce the inner working surface **622** of the snare **620** in the direction of arrows "C" and cut the cervical tissue **320** along the seal **355** (See FIG. 4D). In an alternative embodiment, the electrode **625** may be electrified to facilitate cutting the cervical tissue **320** depending upon a particular surgical purpose.

FIG. 5 shows an alternate embodiment of a uterine sealer **700** having an electrical sealing and/or cutting electrode **725** for use with a snare **720**. The snare **720** includes an insulator **727** disposed on either side of the electrode **725** thereby separating the inner peripheral surface into rings **722a** and **722b**. The insulator **727** is configured to isolate electrosurgical current during the sealing and cutting stages to enhance the electrosurgical effect on the cervical tissue **320**.

The present disclosure also relates to a method of performing a laparoscopic hysterectomy (partial or otherwise) and

includes the initial step of providing a uterine manipulator **100** having a shaft **112** including a handle **130** at a proximal end thereof operable by a user and an operating end **120** at a distal end thereof manipulatable by the handle **130** to orient and position tissue.

The method also includes the steps of providing a uterine sealer **10** including a shaft **12** having a handle **30** disposed at a proximal end thereof and a ring-like snare **20** disposed at a distal end thereof, the handle **30** including an actuator **40** operably associated therewith which selectively cinches and expands the diameter of the snare **20**. The uterine manipulator **100** and/or the uterine sealer **10** include one or more electrodes **125**, **25**, respectively, disposed at the distal end thereof that are configured to cooperate to seal tissue, as explained in more detail below.

The method also includes the steps of: inserting the uterine manipulator **100** into a body cavity **310** to engage and manipulate tissue **320** and inserting the uterine sealer **10** into a second body cavity **80** to encircle the tissue **320** being manipulated by the uterine manipulator **100**. Further, the method includes the steps of: activating the actuator **40** to cinch the snare **20** to engage tissue **320** between the distal end of the uterine manipulator **100** and the snare **20** under a working pressure of about 3 kg/cm² to about 16 kg/cm²; energizing the electrode(s) **125** and/or **25** to seal tissue disposed between the distal end of the uterine manipulator **100** and the snare **20**; and resecting the tissue **320** along the tissue seal **355** and removing the resected tissue **320'** from the body cavity **80**.

Both the uterine sealer **10** and the uterine manipulator **100** may include electrodes **25** and **125**, respectively, that mutually cooperate in a bipolar fashion to seal tissue. The method may further include the step of manipulating the uterine sealer **700** and/or the uterine manipulator **100** to resect tissue along the tissue seal by energizing a cutting electrode **725** disposed on the uterine sealer **700** and/or uterine manipulator **100** or mechanically deploying a tissue cutter **625** to resect tissue along the tissue seal.

The present disclosure also relates to a method for performing a laparoscopic hysterectomy including the steps of providing a uterine manipulator **100** having a shaft **112** having a handle **130** at a proximal end thereof operable by a user and an operating end or cuff **120** at a distal end thereof manipulatable by the handle **110** to orient and position tissue. The method also includes the steps of providing a uterine sealer **600** having a shaft **612** with a handle **630** disposed at a proximal end thereof and a ring-like snare **620** disposed at a distal end thereof. The handle **630** includes an actuator **640** operably associated therewith which selectively cinches and expands the diameter of the snare **620**. The uterine sealer **610** includes an electrode **625** disposed at the distal end thereof with a sharpened cutting edge **626**.

The method further includes the steps of inserting the uterine manipulator **100** into a body cavity **310** to engage and manipulate tissue **320** and inserting the uterine sealer **600** into a second body cavity **80** to encircle the tissue **320** that is being manipulated by the uterine manipulator **100**. The method further includes the steps of: activating the actuator **640** to cinch the snare **640** to engage tissue **320** between the distal end of the uterine manipulator **100** and the snare **640** under a sealing pressure and energizing the electrode **625** to seal tissue **320** disposed between the distal end **120** of the uterine manipulator **100** and the snare **620**; further cinching the snare **620** of the uterine sealer **600** beyond the sealing pressure (e.g., about 16 kg/cm²) to deploy the sharpened edge **626** of the electrode **625** to resect uterine tissue **320**; and removing the resected tissue **320'** from the body cavity **80**.

From the foregoing and with reference to the various figure drawings, those skilled in the art will appreciate that certain modifications can also be made to the present disclosure without departing from the scope of the same. For example, variations in the choice of electrical output parameters from the electrosurgical generator **500** to control or monitor the sealing and cutting processes may vary widely depending on the operator's experience, technique, or preference.

Moreover, certain aspects of the sealing process may be automatically controlled and regulated by the generator, e.g., the, current, voltage, duration, and other output parameters to optimize the sealing process and produce a reliable and effective tissue seal. Still further, the generator may control certain aspects of the cutting process and may selectively regulate the cutting electrodes to optimize the cutting effect depending on tissue type, tissue thickness, type of surgical procedure or desired surgical effect.

It is contemplated that the uterine sealer **10**, **600**, **700** may be equipped with both the sealing and cutting electrodes and, as a result, may be utilized with any conventional uterine manipulator **100** and achieve the same desired surgical effect as described herein above. In this instance, it may be necessary to utilize one or more return electrodes (not shown) that operably couple to the generator **500** for the sealing and/or cutting processes. In one embodiment, the shaft **12** and/or **112** of the sealer **10** and/or the manipulator **100**, respectively, may be telescopically adjustable to facilitate positioning relative to one or more internal organs.

While various embodiments of the disclosure have been described, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above descriptions should not be construed as limiting, but merely as exemplifications of particular embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

What is claimed is:

1. A method for performing a laparoscopic hysterectomy comprising the steps of:

- inserting a uterine manipulator into a body cavity to engage tissue;
- inserting a second uterine sealer instrument having a snare into a second body cavity to encircle the tissue;
- cinching a diameter of the snare of the uterine sealer to engage the tissue between an operating end of the uterine manipulator and the snare of the uterine sealer;
- energizing an electrode associated with one of the uterine manipulator and uterine sealer; and
- resecting the tissue along the tissue seal.

2. A method according to claim **1** wherein the tissue is engaged between the operating end of the uterine manipulator and the snare of the uterine sealer under a working pressure of about 3 kg/cm² to about 16 kg/cm².

3. A method according to claim **1** wherein the uterine sealer includes the electrode that cooperates with a return electrode located remotely from the operating cavities to seal tissue.

4. A method according to claim **1** wherein the uterine sealer includes a first electrode and the uterine manipulator includes a second electrode that mutually cooperate in a bipolar fashion to seal tissue.

5. A method according to claim **1**, wherein resecting the tissue along the tissue seal includes the step of:

- further manipulating one of the uterine sealer and uterine manipulator to resect tissue along the tissue seal.

6. A method according to claim **5** wherein the step of further manipulating one of the uterine sealer and uterine

manipulator to resect tissue along the tissue seal includes energizing a cutting electrode disposed on one of the uterine sealer and uterine manipulator.

7. A method according to claim **6** wherein the cutting electrode and the sealing electrode disposed on at least one of the uterine sealer and the uterine manipulator are one in the same.

8. A method according to claim **6** wherein the step of further manipulating one of the uterine sealer and uterine manipulator to resect tissue along the tissue seal includes mechanically deploying a tissue cutter to resect tissue along the tissue seal.

9. A method for performing a laparoscopic hysterectomy comprising the steps of:

- inserting a uterine manipulator into a body cavity to engage tissue;
- inserting a second uterine sealer instrument having a snare into a second body cavity to encircle the tissue;
- cinching a diameter of the snare of the uterine sealer to engage the tissue between an operating end of the uterine manipulator and the snare of the uterine sealer under a sealing pressure;
- energizing an electrode associated with the uterine sealer to seal tissue disposed between the uterine manipulator and the snare of the uterine sealer, the electrode of the uterine sealer including a sharpened edge; and
- further cinching the diameter of the snare of the uterine sealer beyond the sealing pressure to deploy the sharpened edge of the electrode of the uterine sealer to resect the tissue.

10. A method according to claim **9** wherein the sealing pressure is about 3 kg/cm² to about 16 kg/cm².

11. A method according to claim **9** wherein the uterine sealer includes an inner peripheral surface that includes the electrode recessed therein, the electrode of the uterine sealer being selectively deployable beyond the inner peripheral surface to resect tissue when the cinching pressure of the snare of the uterine sealer on the tissue is beyond the sealing pressure.

12. A method according to claim **11** wherein the electrode of the uterine sealer is energized during the step of further cinching the snare of the uterine sealer to facilitate resecting the tissue.

13. A uterine sealer device for use with an operating end of a uterine manipulator for sealing uterine tissue, comprising:

- a shaft having a handle at an operating end thereof and a ring-like snare at a distal end thereof, the handle including an actuator operable to selectively cinch the ring-like snare from a first configuration having a first diameter to at least one subsequent configuration having a second diameter; and
- an electrode operably coupled to an inner peripheral surface of the ring-like snare, the electrode adapted to connect to an electrical energy source to energize uterine tissue to create a tissue seal;

wherein the shaft is selectively positionable within a surgical cavity such that the ring-like snare encircles uterine tissue and operably engages and cinches the operating end of the uterine manipulator under a sealing pressure while electrosurgical energy is applied to the electrode to seal the uterine tissue disposed between the uterine manipulator and the ring-like snare of the uterine sealer.

14. A uterine sealer according to claim **13** wherein the uterine sealer device includes a second electrode that is adapted to connect to the electrical energy source, the second electrode of the uterine sealer being energized after the completion of the uterine tissue seal to resect the uterine tissue along the tissue seal.

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15. A uterine sealer according to claim 14 wherein the electrode of the uterine sealer is further energized after the completion of the uterine tissue seal to resect the uterine tissue along the uterine tissue seal.

16. A uterine sealer according to claim 14 wherein the electrode of the uterine sealer is recessed within an inner peripheral surface of the ring-like snare of the uterine sealer and includes a cutting edge that deploys when the ring-like snare is cinched beyond a predetermined sealing pressure.

17. A uterine sealer according to claim 16 wherein the sealing pressure is about 3 kg/cm² to about 16 kg/cm².

18. A system for performing a laparoscopic hysterectomy, comprising:

a uterine manipulator configured for insertion into a body cavity and configured to operatively engage uterine tissue;

a second uterine sealer instrument configured for insertion into a second body cavity, the uterine sealer including a snare having a diameter selectively;

wherein the diameter of the snare of the uterine sealer is selectively actuatable to encircle uterine tissue and

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selectively cinchable to engage tissue between an operating end of the uterine manipulator and the diameter of the snare of the uterine sealer; and

wherein at least one of the uterine manipulator and uterine sealer includes an electrode adapted to couple to an electrosurgical generator, the generator being selectively energizable to at least one of seal and resect tissue disposed between the operating end of the uterine manipulator and the diameter of the snare of the uterine sealer.

19. A system according to claim 18 wherein the tissue disposed between the operating end of the uterine manipulator and the snare of the uterine sealer is engaged under a working pressure of about 3 kg/cm² to about 16 kg/cm² which effectively seals the tissue upon activation of the electrode of at least one of the uterine manipulator and uterine sealer.

* * * * *

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摘要(译)

本发明涉及一种用于子宫操纵器的操作端的用于密封组织的装置，该装置包括轴，该轴在其操作端具有手柄，并且在其远端具有环状圈套器。手柄具有致动器，该致动器可操作以选择性地将圈套器从第一配置收紧到第二配置。电极可操作地连接到圈套器并连接到能量源以激励组织以产生组织密封。轴可定位在手术腔内，使得圈套围绕组织并在密封压力下可操作地接合和收紧子宫操纵器的操作端。将能量施加到电极以在工作压力下密封设置在子宫操纵器和圈套器之间的组织。然后可以切除组织并从身体移除。

