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(54) **ABLATION CATHETERS AND SYSTEMS**

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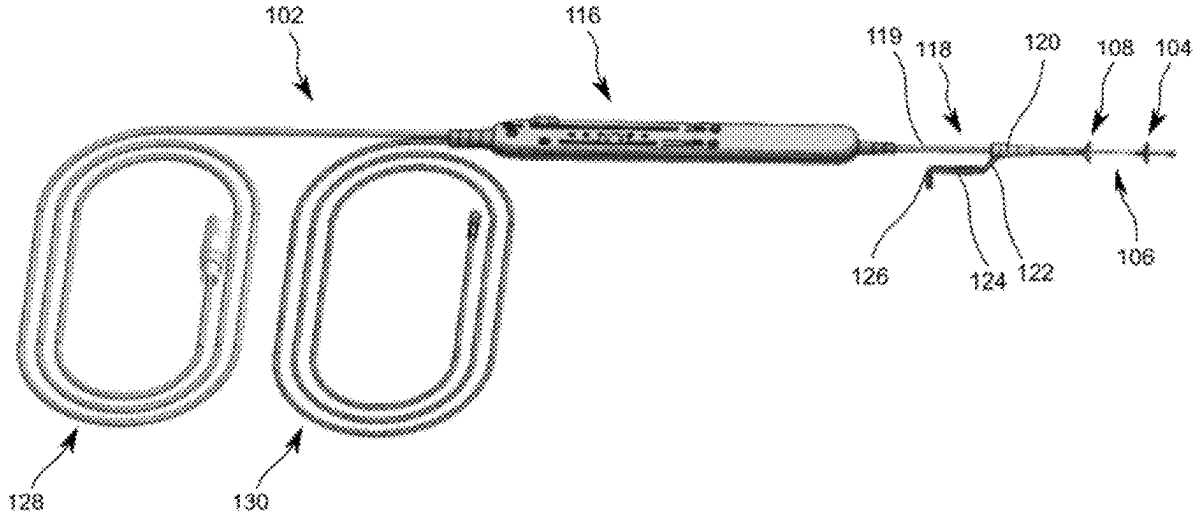
(57) **ABSTRACT**

An ablation catheter and an ablation system for ablating a uterine cavity of a patient. The catheter has ablation ports configured between two positioning elements and at least one port at the center of an atraumatic distal tip. An internal heating chamber is disposed within a lumen of the catheter to heat a fluid and generate vapor. The internal heating chamber comprises an electrode or an array of electrodes that are positioned circumferentially around a central core.



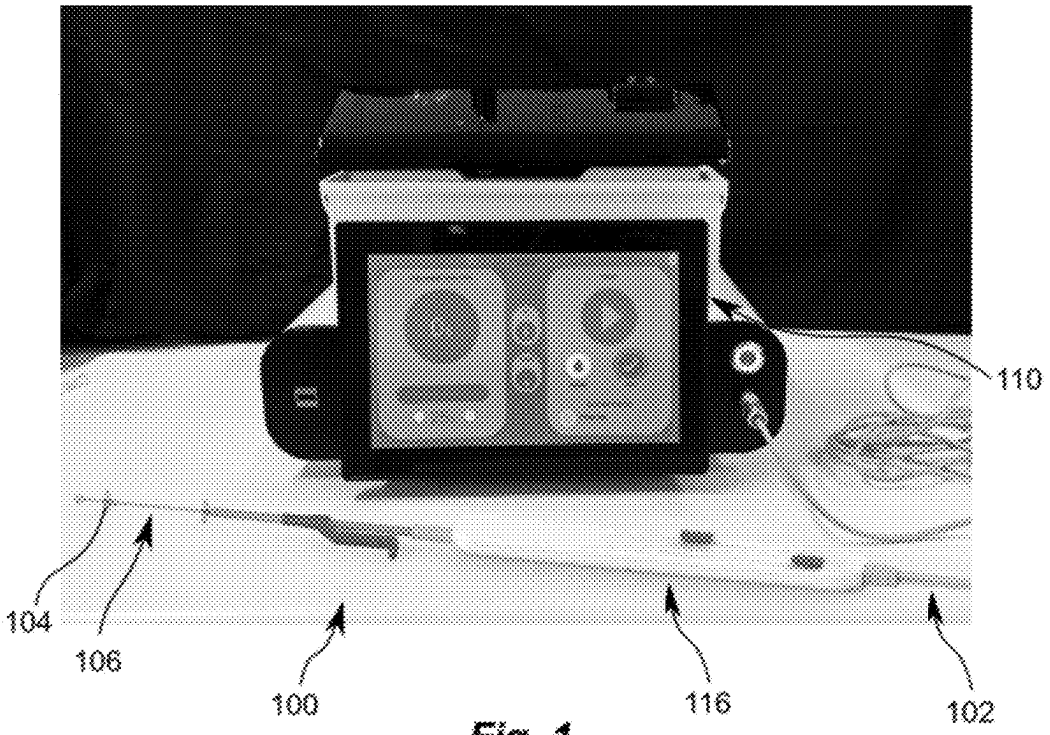

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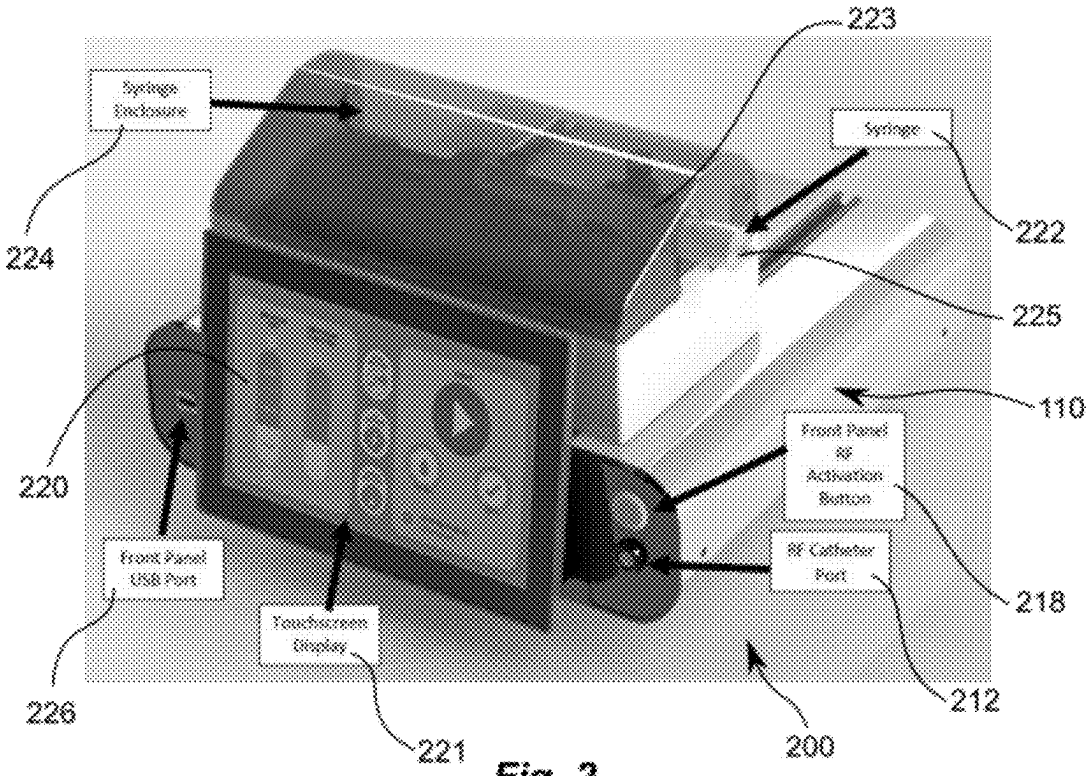
Fig. 1


223
Syringe Enclosure
Syringe
224
222
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110
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Front Panel RF Activation Button
218
Front Panel USB Port
RF Catheter Port
Touchscreen Display
212
226
221
200

Fig. 2

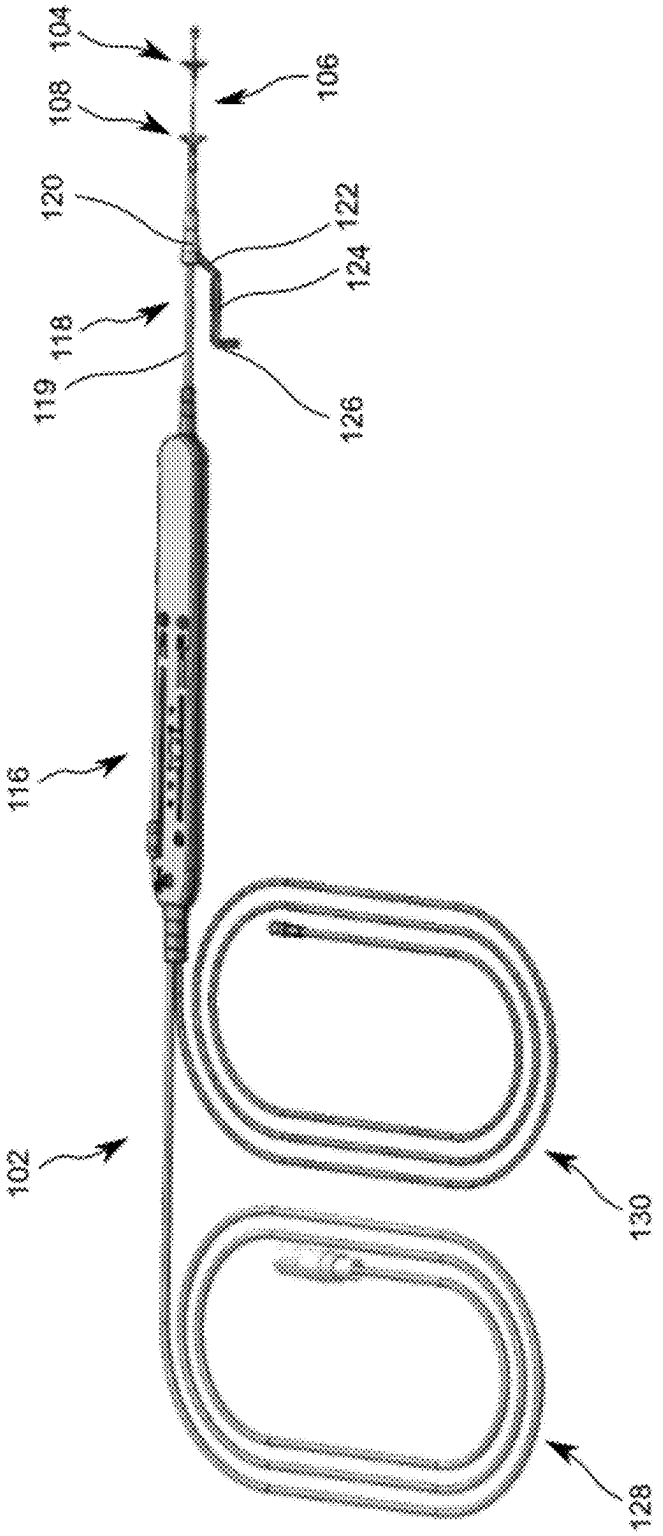
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Fig. 3

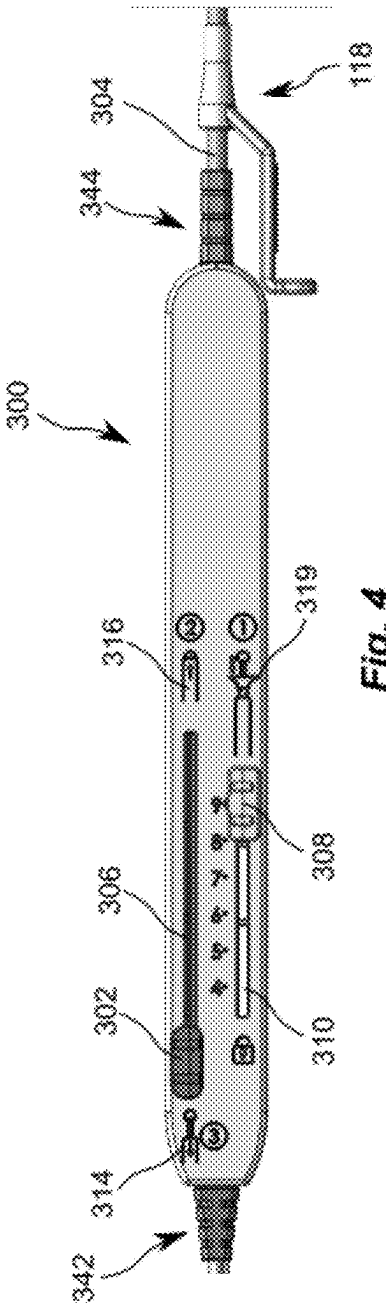
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Fig. 4

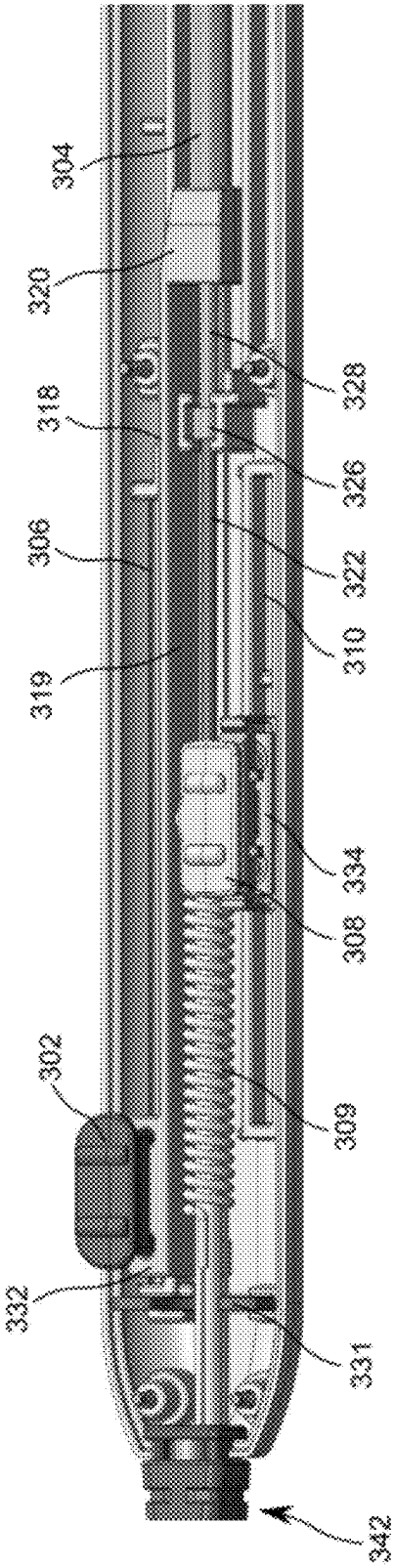


Fig. 5

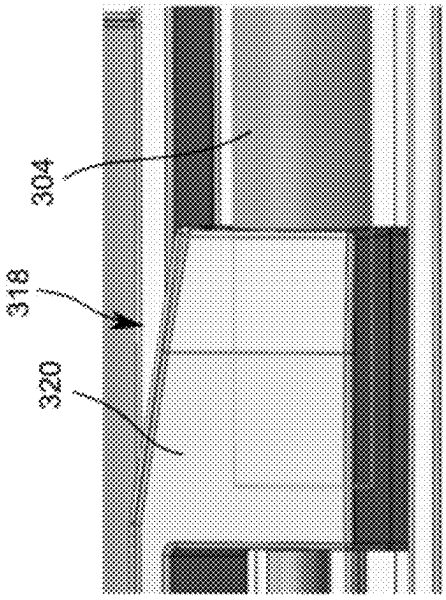


Fig. 7

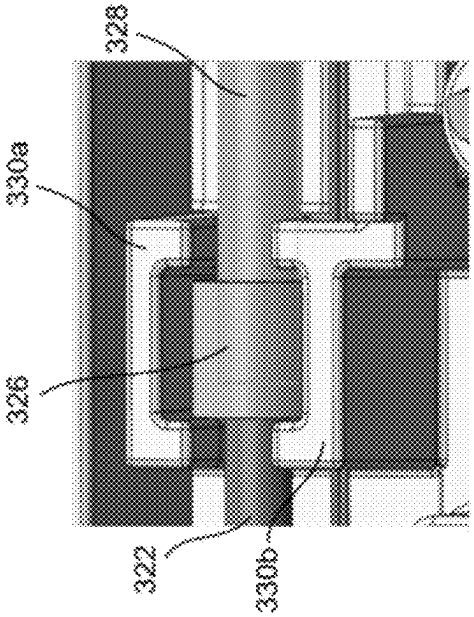


Fig. 6

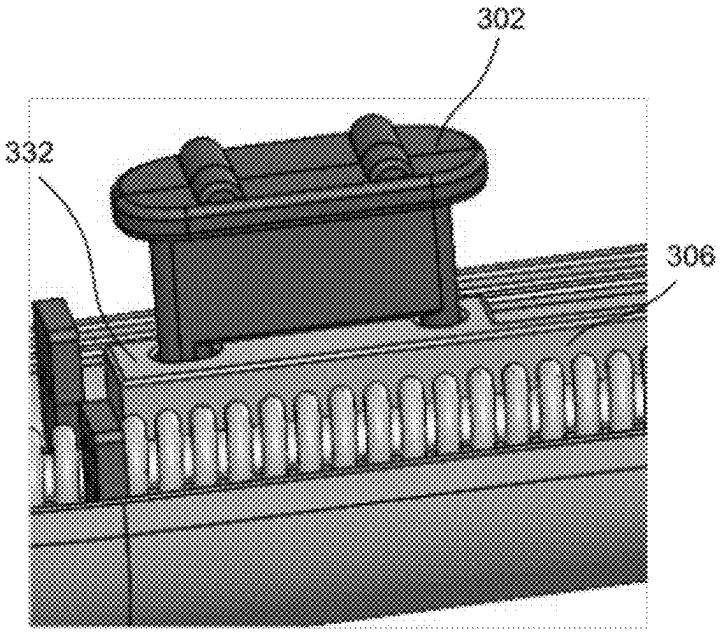


Fig. 8

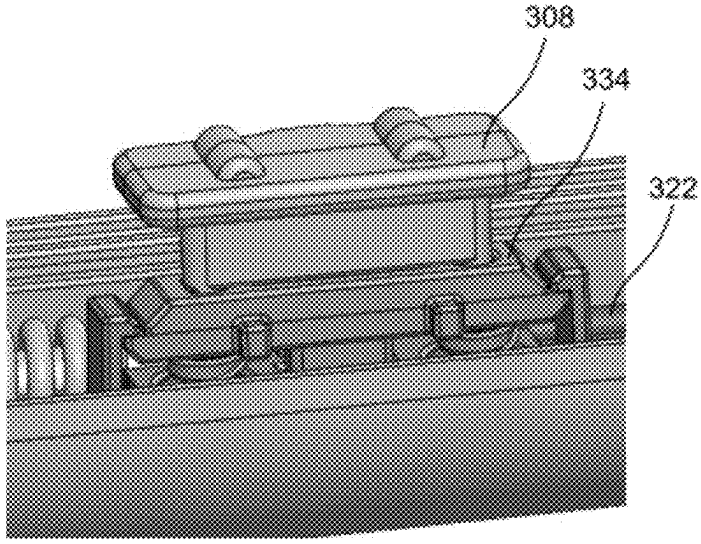
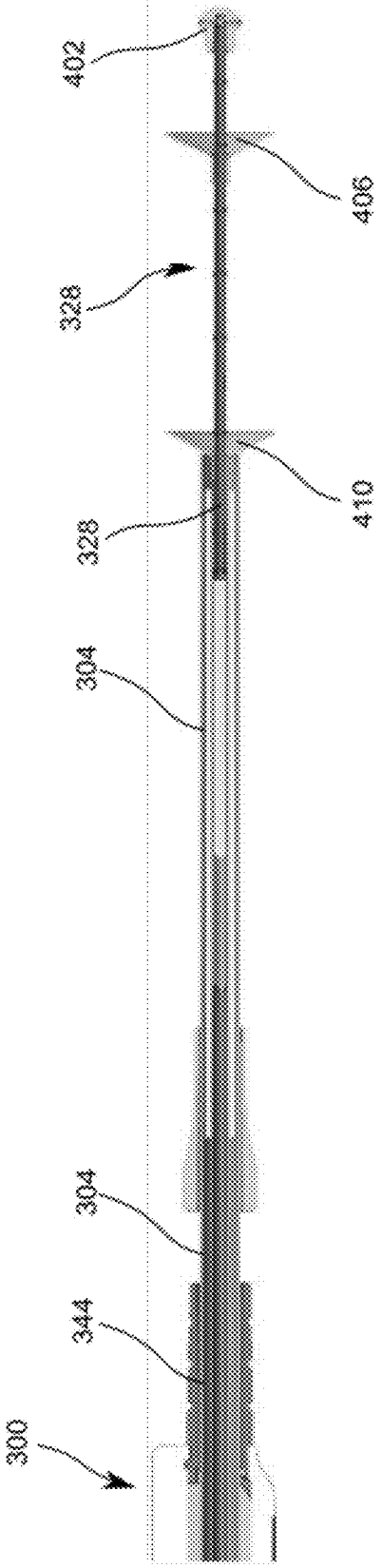


Fig. 9



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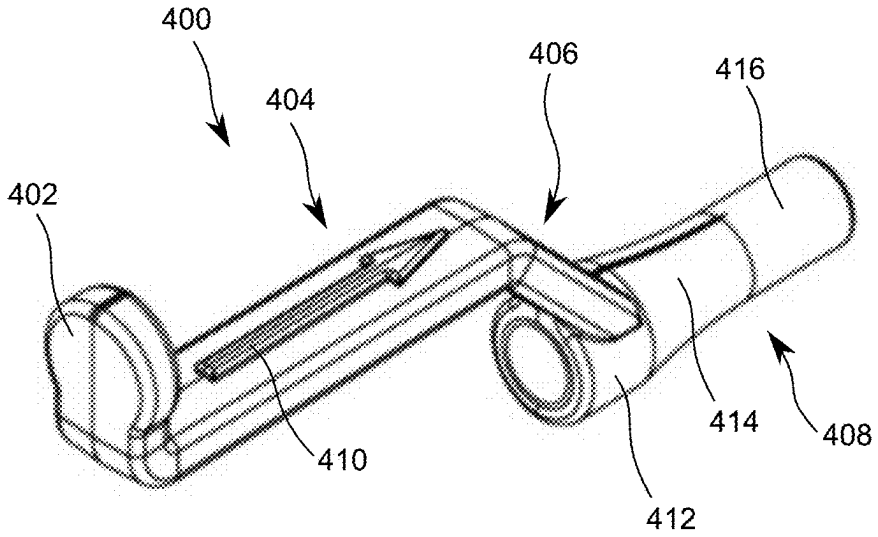

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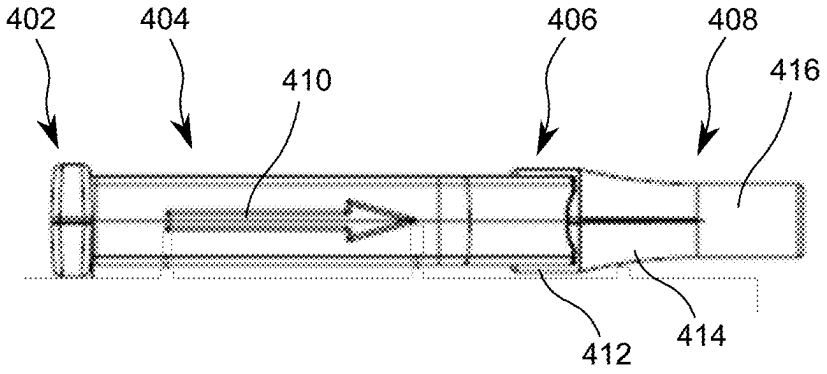

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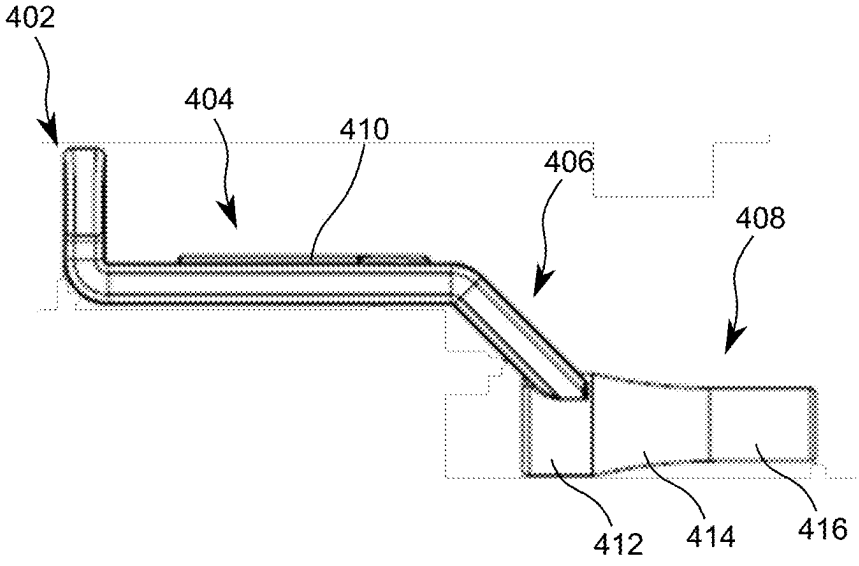

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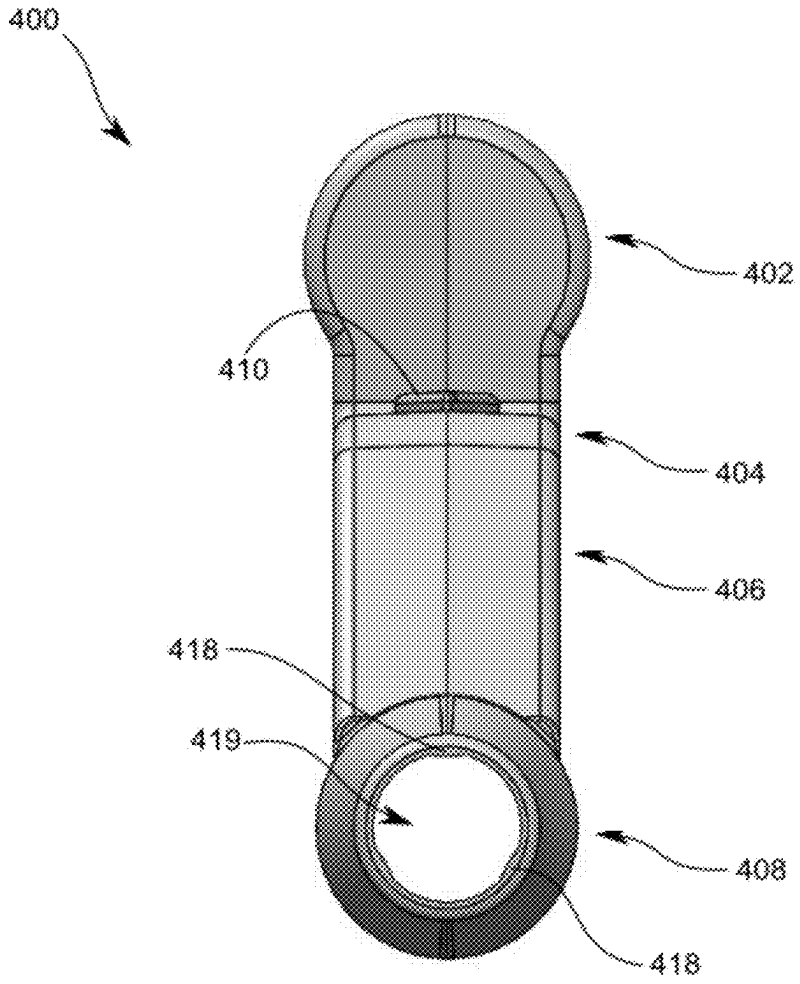
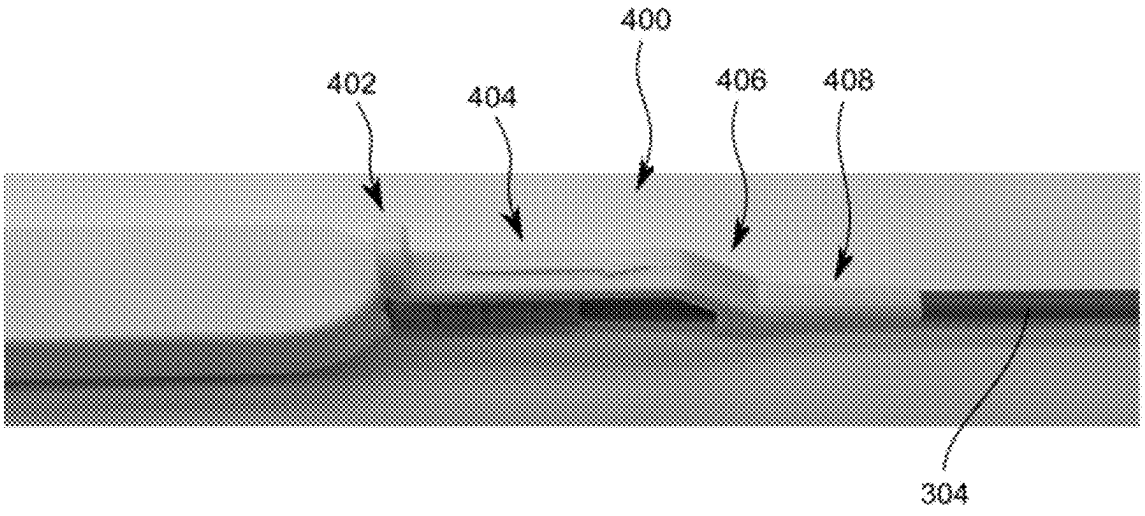


Fig. 14



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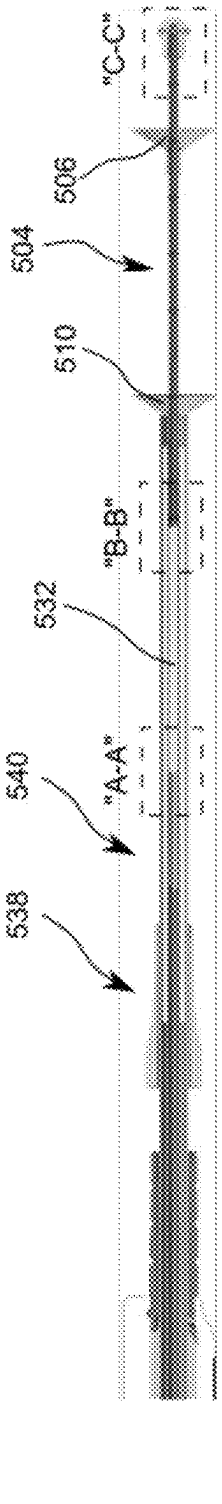
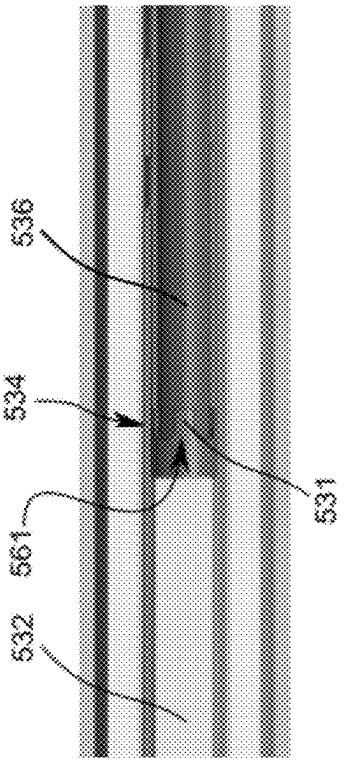
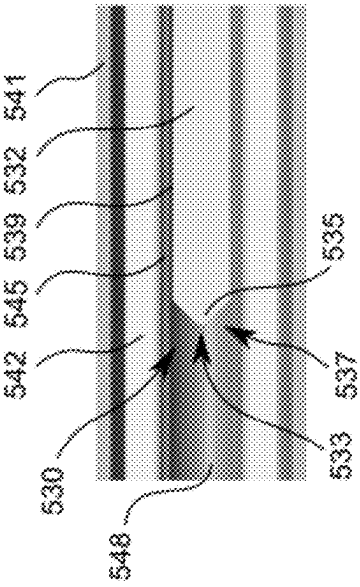


Fig. 16





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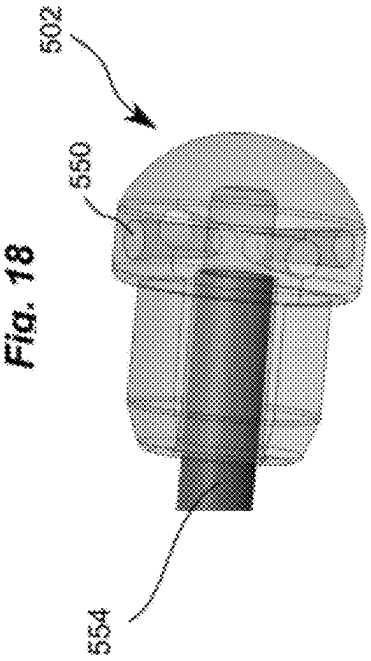

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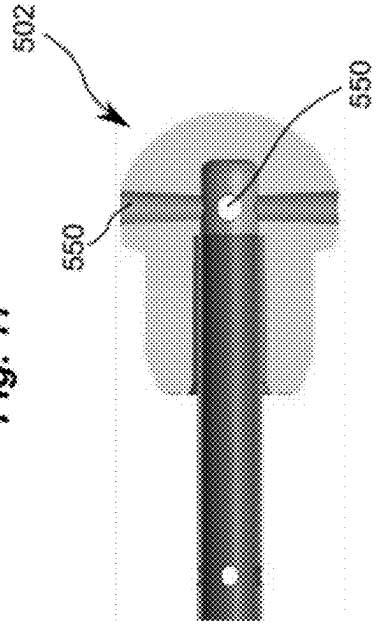

Fig. 19

Fig. 20

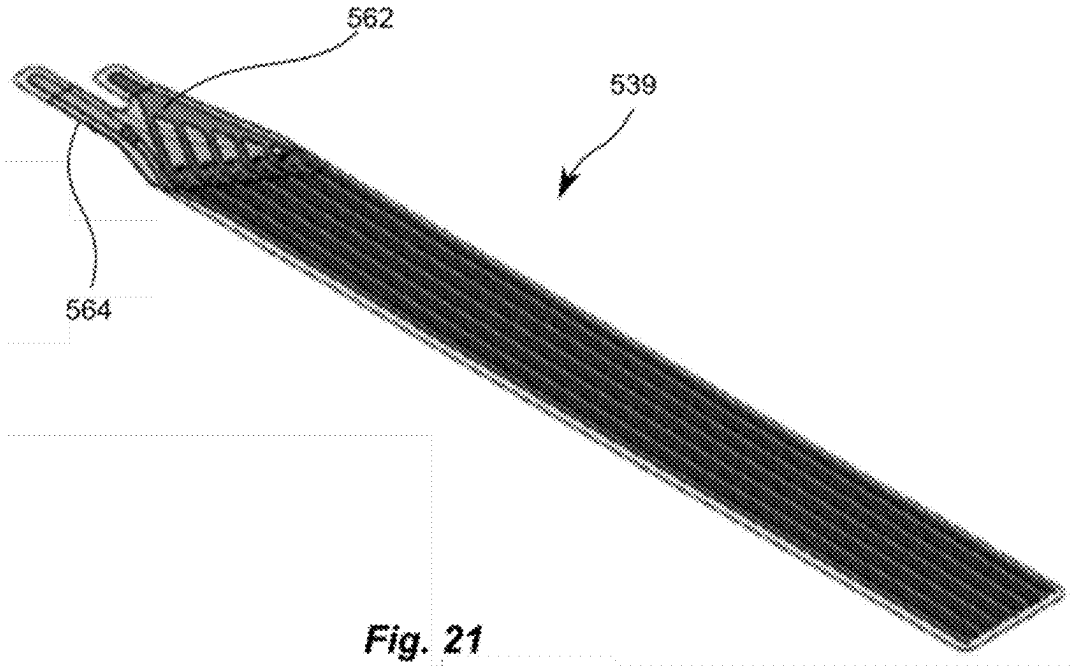
562
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Fig. 21

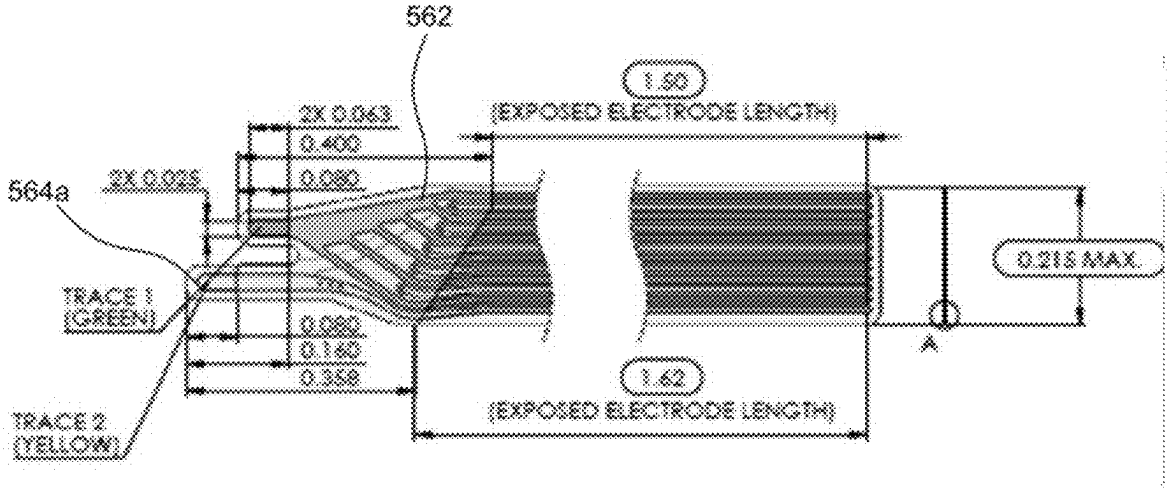
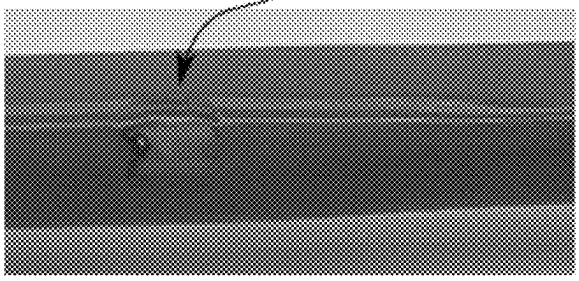

562
1.50
(EXPOSED ELECTRODE LENGTH)
2X 0.043
0.400
0.090
2X 0.025
564a
TRACE 1
(GREEN)
0.090
0.140
0.359
TRACE 2
(YELLOW)
0.215 MAX.
A
1.62
(EXPOSED ELECTRODE LENGTH)

Fig. 22



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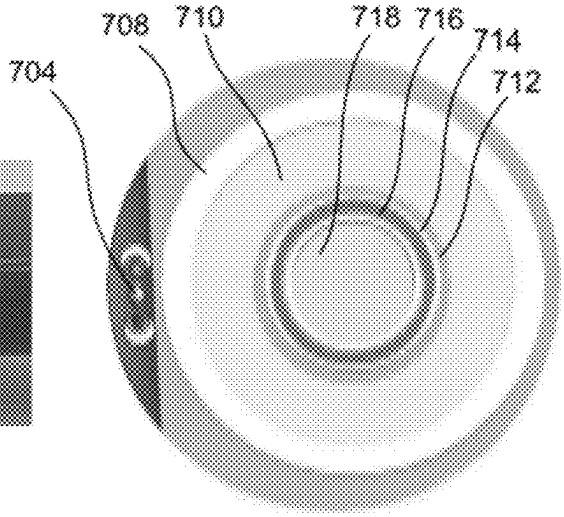


Fig. 24

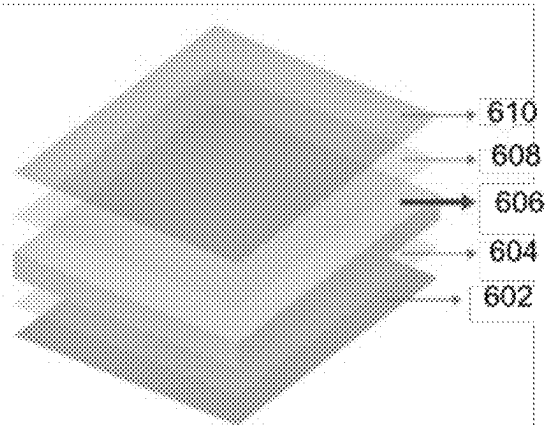


Fig. 25

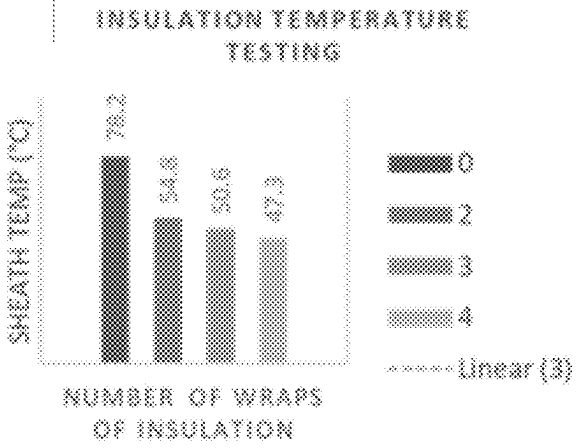


Fig. 25A

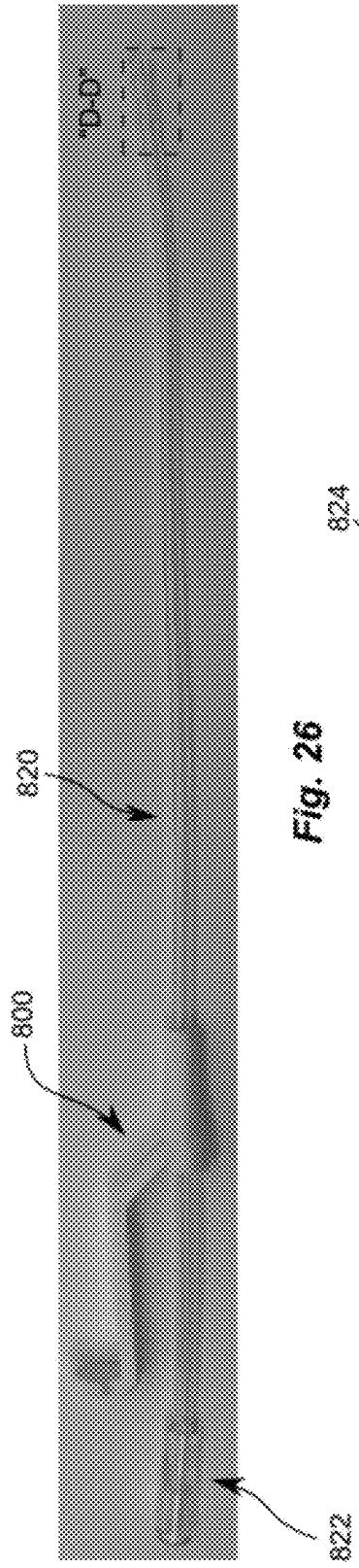


Fig. 26

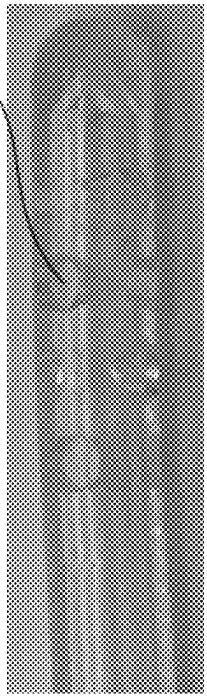


Fig. 27

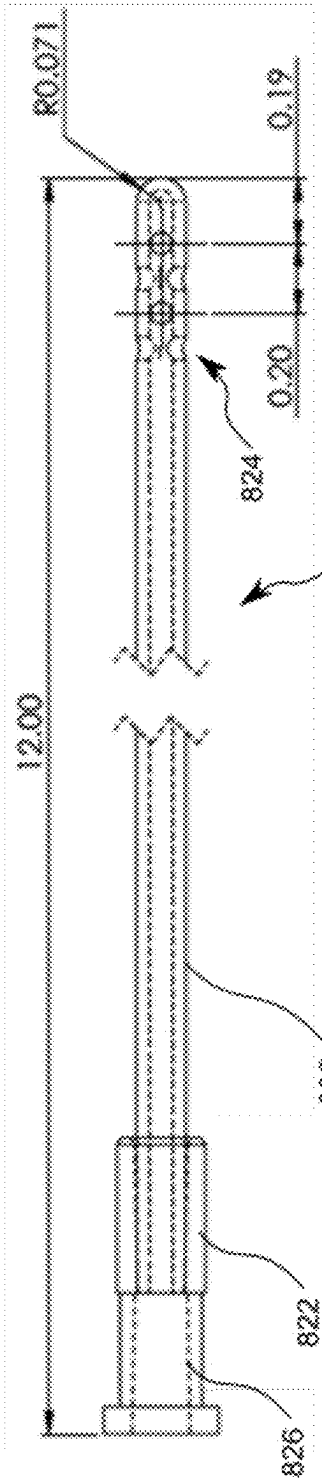
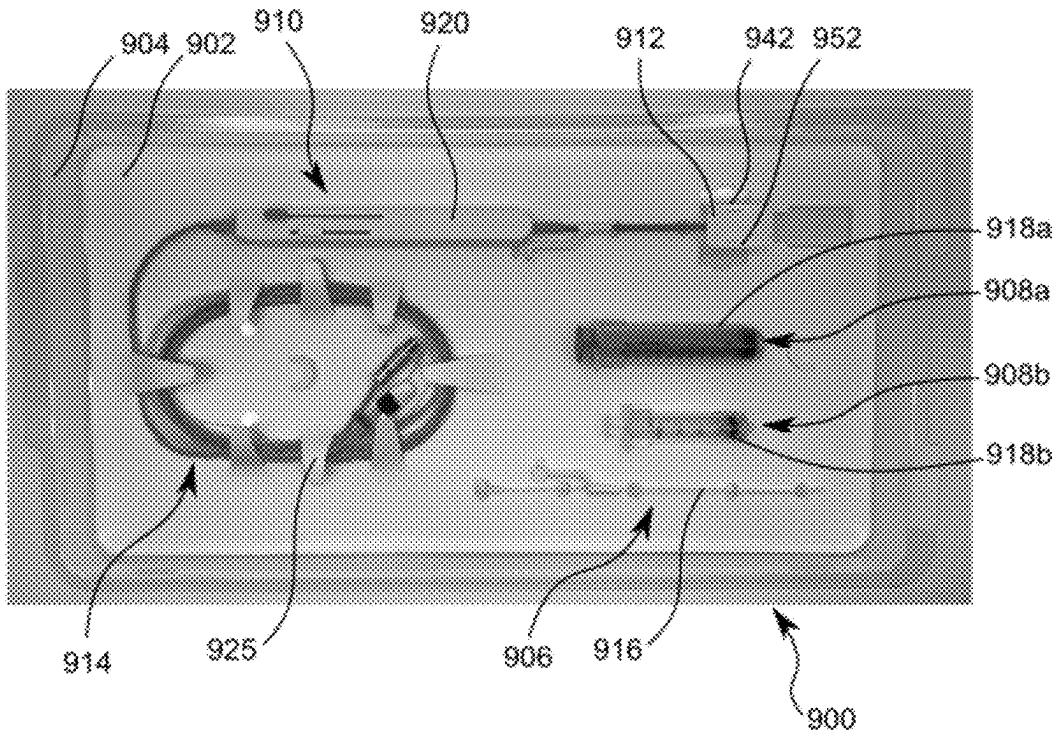


Fig. 28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918a
908a
908b
918b
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906
916
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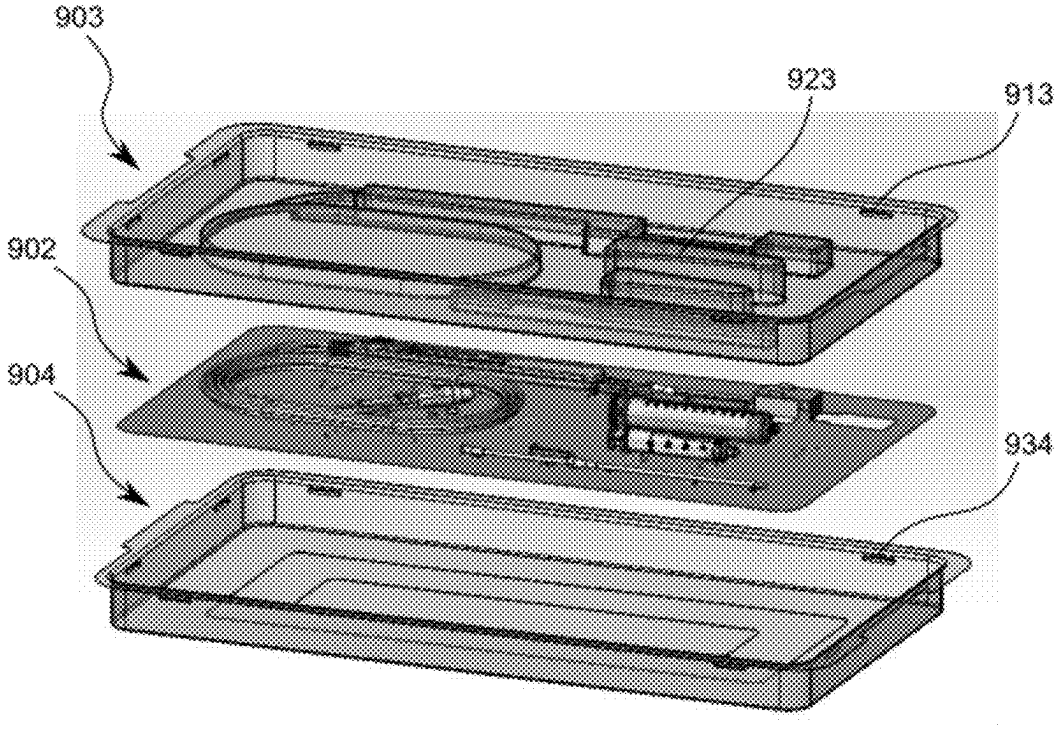
Fig. 29


903
923
913
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904
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Fig. 30

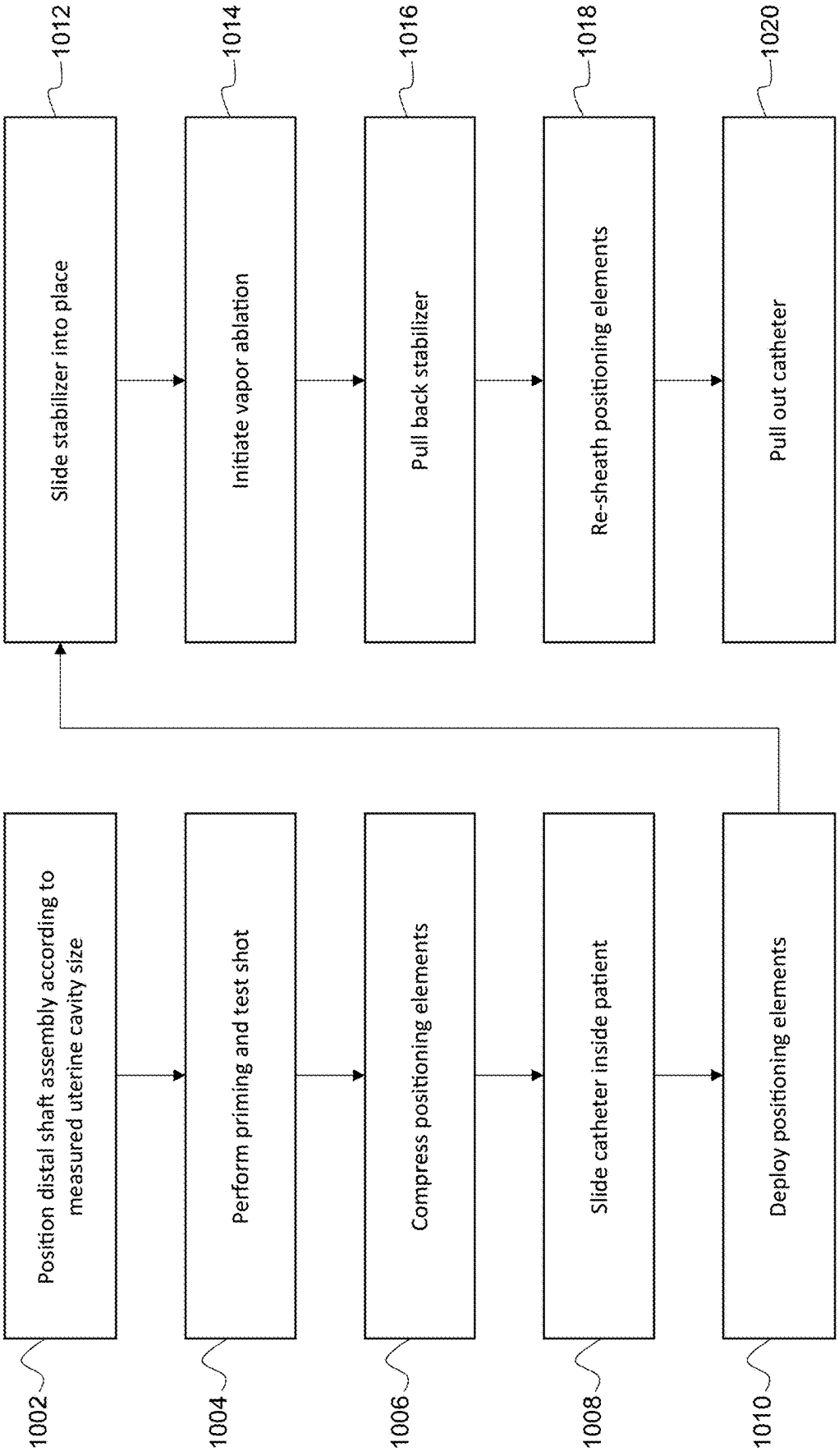
1002
Position distal shaft assembly according to measured uterine cavity size
1004
Perform priming and test shot
1006
Compress positioning elements
1008
Slide catheter inside patient
1010
Deploy positioning elements
1012
Slide stabilizer into place
1014
Initiate vapor ablation
1016
Pull back stabilizer
1018
Re-sheath positioning elements
1020
Pull out catheter

Fig. 31

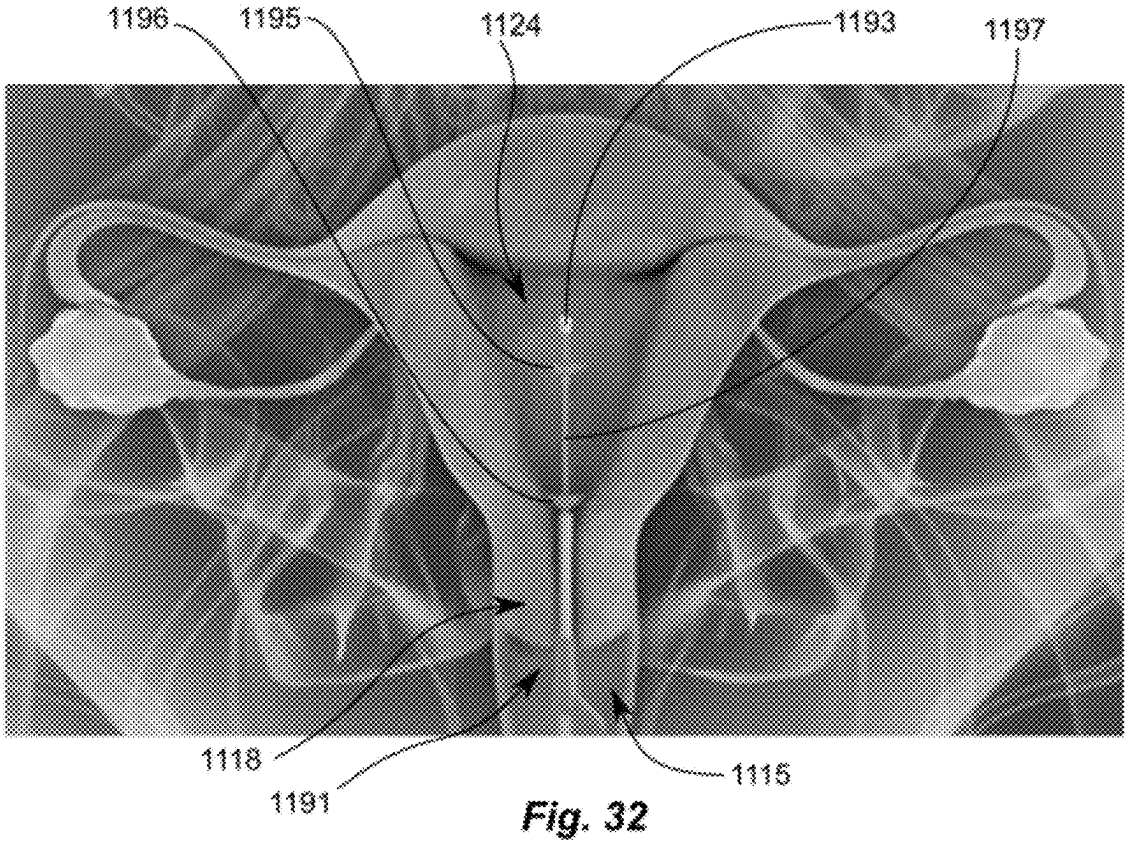

Fig. 32

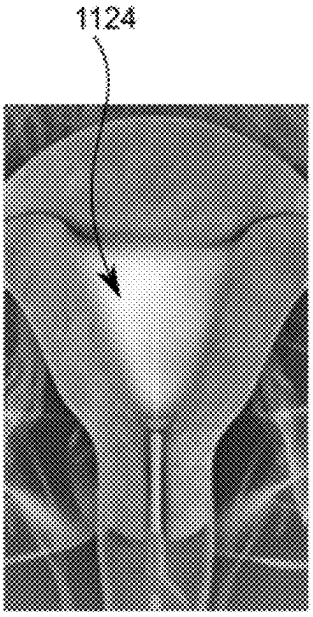

Fig. 33

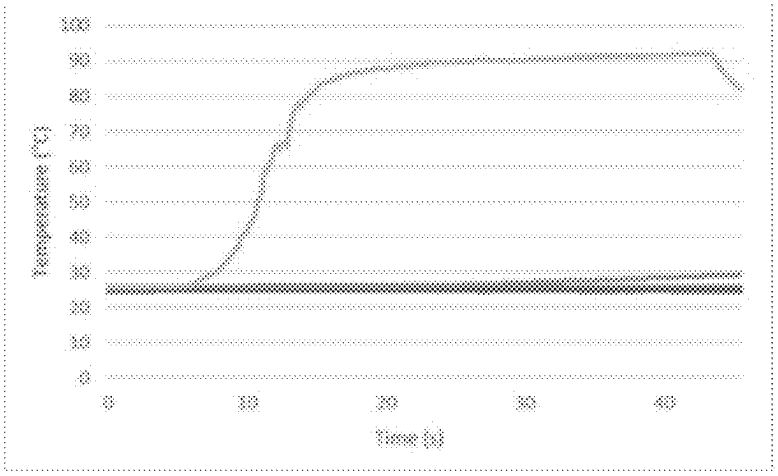

Fig. 34

ABLATION CATHETERS AND SYSTEMS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 63/556,349 filed on Feb. 21, 2024, the entire contents of which are incorporated herein by reference.

FIELD

[0002] The present specification relates to systems and methods configured to generate and deliver vapor for ablation therapy, as well as methods of use of the same.

BACKGROUND

[0003] Ablation, as it pertains to the present specification, relates to the removal or destruction of a body tissue, via the introduction of a destructive agent, such as radiofrequency energy, laser energy, ultrasonic energy, cyroagents, or steam. Ablation is commonly used to eliminate diseased or unwanted tissues, such as, but not limited to cysts, polyps, tumors, hemorrhoids, and other similar lesions. Ablation techniques may be used in combination with chemotherapy, radiation, surgery, and Bacillus Calmette-Guérin (BCG) vaccine therapy, among others.

[0004] Steam-based ablation systems, such as the ones disclosed in U.S. Pat. Nos. 9,615,875, 9,433,457, 9,376,497, 9,561,068, 9,561,067, and 9,561,066, disclose ablation systems that controllably deliver steam through one or more lumens toward a tissue target. One problem that all such steam-based ablation systems have is the potential overheating or burning of healthy tissue. Steam passing through a channel within a body cavity heats up surfaces of the channel and may cause exterior surfaces of the medical tool, other than the operational tool end itself, to become excessively hot. As a result, physicians may unintentionally burn healthy tissue when external portions of the device, other than the distal operational end of the tool, accidentally contacts healthy tissue. U.S. Pat. Nos. 9,561,068, 9,561,067, and 9,561,066 are hereby incorporated herein by reference.

[0005] It is desirable to have steam-based ablation devices that integrate into the device itself safety mechanisms which prevent unwanted ablation during use. It is further desirable to have a catheter handle that allows the user to ergonomically hold the device during a vapor ablation treatment. It also desirable to have steam-based ablation devices, and methods of use and treatment related to the same, which deliver strong, steady, and reliable flows of vapor.

SUMMARY

[0006] The present specification discloses embodiments of an ablation catheter, which may be used for ablating endometrial tissue. The catheter may include an outer sheath with at least one opening, an inner shaft with at least one lumen configured to receive a volume of fluid, at least one positioning element, at least one port, a tip positioned the inner shaft, at least one heating component within the lumen, and a handle coupled to the inner shaft. The specification also discloses embodiments of an ablation system, which may include a disclosed embodiment of a catheter in addition to a fluid reservoir, a pump, and a controller. Also disclosed are embodiments of a kit, which includes multiple components of an embodiment of an ablation system.

[0007] The aforementioned and other embodiments of the present invention shall be described in greater depth in the drawings and detailed description provided below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] These and other features and advantages of the present invention will be further appreciated, as they become better understood by reference to the detailed description when considered in connection with the accompanying drawings.

[0009] FIG. **1** is a photograph of an embodiment of an ablation system for ablating a uterine cavity of a patient.

[0010] FIG. **2** illustrates, with annotations, an embodiment of a generator system used by the ablation system shown in FIG. **1**.

[0011] FIG. **3** illustrates an embodiment of a catheter system used by the ablation system of FIG. **1**.

[0012] FIG. **4** illustrates a top view of an embodiment of a catheter handle as part of an embodiment of a catheter system.

[0013] FIG. **5** illustrates a view of internal components of an embodiment of a catheter handle.

[0014] FIG. **6** illustrates a close-up view of a distal positioning element slider attachment to proximal shaft of the catheter handle of FIG. **5**.

[0015] FIG. **7** illustrates an enlarged view of an outer sheath slider attachment to the outer sheath of the catheter handle of FIG. **5**.

[0016] FIG. **8** illustrates a view of the first slider attached to a proximal end of an attachment of the catheter handle of FIG. **5**.

[0017] FIG. **9** illustrates a view of the second slider attached to proximal end of an attachment of the catheter handle of FIG. **5**.

[0018] FIG. **10** illustrates a cross-section view along a longitudinal axis of an embodiment of a catheter.

[0019] FIG. **11** illustrates a perspective view of an embodiment of a cervical stabilizer.

[0020] FIG. **12** illustrates a top view of the cervical stabilizer of FIG. **11**.

[0021] FIG. **13** illustrates a side view of the cervical stabilizer of FIG. **11**.

[0022] FIG. **14** illustrates a front view of an embodiment of a cervical stabilizer with internal ribbing.

[0023] FIG. **15** illustrates a view of an embodiment of a cervical stabilizer as part of an embodiment of a catheter system.

[0024] FIG. **16** illustrates a cross-section view of an embodiment of a catheter lumen.

[0025] FIG. **17** illustrates an enhanced view of the area identified as "A-A" on FIG. **16**.

[0026] FIG. **18** illustrates an enhanced view of the area identified as "B-B" on FIG. **16**.

[0027] FIG. **19** illustrates an enhanced view of the area identified as "C-C" on FIG. **16**.

[0028] FIG. **20** illustrates side perspective view of an embodiment of a distal tip of a catheter lumen.

[0029] FIG. **21** illustrates a transverse cross-section view of a first array of electrodes and a second array of electrodes as may be employed with disclosed embodiments of a catheter system.

[0030] FIG. **22** illustrates a side view of the arrays of electrodes in FIG. **21** annotated with dimensions in accordance with a disclosed embodiment.

[0031] FIG. **23** illustrates a side view of an embodiment of a catheter shaft.

[0032] FIG. **24** illustrates a cross-section view of the catheter shaft of FIG. **23**.

[0033] FIG. **25** illustrates an embodiment of a set of insulation layers used in an ablation catheter shaft.

[0034] FIG. **25**A is a graph chart showing insulation temperature as compared to the number of wraps of insulation.

[0035] FIG. **26** illustrates an embodiment of a cervical stabilizer over an embodiment of a uterine aspiration catheter assembly.

[0036] FIG. **27** illustrates an enhanced view of the area identified as "D-D" on FIG. **26**.

[0037] FIG. **28** illustrates an exploded side view of an embodiment of a cervical stabilizer over an embodiment of a uterine aspiration catheter assembly annotated with dimensions in accordance with an embodiment a disclosed embodiment.

[0038] FIG. **29** illustrates multiple components forming the ablation system of the present specification, packaged together in a kit.

[0039] FIG. **30** illustrates another view of the packaging elements of the kit, in accordance with some embodiments of the present specification.

[0040] FIG. **31** is a flow chart illustrating a method for preparing and using the ablation catheter device or system described in accordance with the various embodiments of the present specification.

[0041] FIG. **32** shows an embodiment of a catheter positioned within a uterus.

[0042] FIG. **33** shows the catheter of FIG. **33** with vapor being released in accordance with an embodiment of a uterine ablation procedure.

[0043] FIG. **34** is a graph showing temperature in the uterine cavity, the cervical canal and the external fundus, as measured at different points in time during a uterine ablation procedure using disclosed embodiments.

DETAILED DESCRIPTION

[0044] As used in this disclosure, the terms "treat," "treatment," and variations thereof refer to any reduction in the extent, frequency, or severity of one or more symptoms or signs associated with a condition. The term "duration" and variations thereof refer to the time course of a prescribed treatment, from initiation to conclusion, whether the treatment is concluded because the condition is resolved or the treatment is suspended for any reason. Over the duration of treatment, a plurality of treatment periods may be prescribed during which one or more prescribed stimuli are administered to the subject. The term "period" refers to the time over which a "dose" of stimulation is administered to a subject as part of the prescribed treatment plan. The term "controller" refers to an integrated hardware and software system defined by a plurality of processing elements, such as integrated circuits, application specific integrated circuits, and/or field programmable gate arrays, in data communication with memory elements, such as random access memory or read only memory where one or more processing elements are configured to execute programmatic instructions stored in one or more memory elements. The term "vapor generation system" refers to any or all of the heater or induction-based approaches to generating steam from water described in this application.

[0045] As used herein, each of the words "comprise" "include" and "have", and forms thereof, are not necessarily limited to members in a list with which the words may be associated. The terms "comprises" and variations thereof do not have a limiting meaning where these terms appear in the description and claims. The term "and/or" means one or all of the listed elements or a combination of any two or more of the listed elements. Unless otherwise specified, "a," "an," "the," "one or more," and "at least one" are used interchangeably and mean one or more than one.

[0046] Embodiments of the present specification are useful in the treatment of uterine tissue, but it is contemplated within the disclosure that embodiments herein may be used for treatment of genitourinary structures, where the term "genitourinary" includes all genital and urinary structures, including, but not limited to, the prostate, uterus, and urinary bladder, and any conditions associated therewith, including, but not limited to, benign prostatic hyperplasia (BPH), prostate cancer, uterine fibroids, abnormal uterine bleeding (AUB), overactive bladder (OAB), strictures, and tumors.

[0047] Any and all of the needles and needle configurations disclosed in the specification with regards to a particular embodiment, such as including but not limited to, single needles, double needles, multiple needles and insulated needles, are not exclusive to that embodiment and may be used with any other of the embodiments disclosed in the specification in any of the organ systems for any condition related to the organ system such as and not limited to ablation of prostate, uterus, and bladder.

[0048] For purposes of the present specification, 'completely ablating' is defined as ablating more than 55% of a surface area or a volume around an anatomical structure.

[0049] All of the methods and systems for treating the prostate, uterus, and bladder may include optics or visualization as described in the specification to assist with direct visualization during ablation procedures.

[0050] For any method disclosed herein that includes discrete steps, the steps are presumably performed in order each is introduced or described, but it is contemplated within the scope of the disclosure that the steps may be conducted in any feasible order unless specified otherwise. And, as appropriate, any combination of two or more steps may be conducted simultaneously.

[0051] Also herein, the recitations of numerical ranges by endpoints include all numbers subsumed within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, 5, etc.). Unless otherwise indicated, all numbers expressing quantities of components, molecular weights, and so forth used in the specification and claims are to be understood as being modified in all instances by the term "about." Accordingly, unless otherwise indicated to the contrary, the numerical parameters set forth in the specification and claims are approximations that may vary depending upon the desired properties sought to be obtained by the present specification. At the very least, and not as an attempt to limit the doctrine of equivalents to the scope of the claims, each numerical parameter should at least be construed in light of the number of reported significant digits and by applying ordinary rounding techniques.

[0052] Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the specification are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. All numerical values, however, inherently contain a range in

necessarily resulting from the standard deviation found in their respective testing measurements.

[0053] The devices and methods of the present specification can be used to cause controlled focal or circumferential ablation of targeted tissue to varying depth in a manner in which complete healing with re-epithelialization can occur. Additionally, the vapor could be used to treat/ablate benign and malignant tissue growths resulting in destruction, liquefaction and absorption of the ablated tissue. The dose and manner of treatment can be adjusted based on the type of tissue and the depth of ablation needed. The ablation devices can be used for the prostate and endometrial ablation and for the treatment of any mucosal, submucosal or circumferential lesion, such as inflammatory lesions, tumors, polyps and vascular lesions. The ablation devices can also be used for the urinary bladder ablation, and for treating an over-active bladder (OAB). The ablation device can also be used for the treatment of focal or circumferential mucosal or submucosal lesions of the genitourinary tract. The ablation device can be placed endoscopically, radiologically, surgically or under direct visualization. In various embodiments, wireless endoscopes or single fiber endoscopes can be incorporated as a part of the device. In another embodiment, magnetic or stereotactic navigation can be used to navigate the catheter to the desired location. Radio-opaque or sonolucent material can be incorporated into the body of the catheter for radiological localization. Ferromagnetic materials can be incorporated into the catheter to help with magnetic navigation.

[0054] Ablative agents such as steam, heated gas or cryogens, such as, but not limited to, liquid nitrogen are inexpensive and readily available and are directed via the infusion port onto the tissue, held at a fixed and consistent distance, targeted for ablation. This allows for uniform distribution of the ablative agent on the targeted tissue. The flow of the ablative agent is controlled by a microprocessor according to a predetermined method based on the characteristic of the tissue to be ablated, required depth of ablation, and distance of the port from the tissue. The microprocessor may use temperature, pressure or other sensing data to control the flow of the ablative agent. In addition, one or more suction ports are provided to suction the ablation agent from the vicinity of the targeted tissue. The targeted segment can be treated by a continuous infusion of the ablative agent or via cycles of infusion and removal of the ablative agent as determined and controlled by the microprocessor.

[0055] It should be appreciated that the devices and embodiments described herein are implemented in concert with a controller that comprises a microprocessor executing control instructions. The controller can be in the form of any computing device, including desktop, laptop, and mobile device, and can communicate control signals to the ablation devices in wired or wireless form.

[0056] The present invention is directed towards multiple embodiments. The following disclosure is provided in order to enable a person having ordinary skill in the art to practice the invention. Language used in this specification should not be interpreted as a general disavowal of any one specific embodiment or used to limit the claims beyond the meaning of the terms used therein. The general principles defined herein may be applied to other embodiments and applications without departing from the spirit and scope of the invention. Also, the terminology and phraseology used is for the purpose of describing exemplary embodiments and should not be considered limiting. Thus, the present invention is to be accorded the widest scope encompassing numerous alternatives, modifications and equivalents consistent with the principles and features disclosed. For purpose of clarity, details relating to technical material that is known in the technical fields related to the invention have not been described in detail so as not to unnecessarily obscure the present invention.

[0057] It should be noted herein that any feature or component described in association with a specific embodiment may be used and implemented with any other embodiment unless clearly indicated otherwise.

[0058] One embodiment disclosed is an ablation catheter, which may be used for ablating endometrial tissue of a patient. The catheter may include an outer sheath having a first diameter and a length extending between a proximal end and a distal end, the outer sheath configured with at least one opening. The catheter may further include an inner shaft having at least one lumen, wherein the lumen is configured to receive a volume of fluid. At least one positioning element may be positioned proximate a proximal or distal end of the inner shaft, wherein the at least one positioning element is configured to expand from a first compressed delivery configuration to a second expanded deployed configuration. At least one first port positioned may be on the inner shaft. An atraumatic tip may be positioned on a distal end of the inner shaft, wherein the atraumatic tip comprises at least one second port in fluid communication with the inner shaft. At least one heating component may be positioned within the lumen, and the at least one heating component may include at least one electrode positioned circumferentially around a central core, and the at least one heating component may be configured to convert the volume of fluid received by the lumen to a vapor that exits from the at least one first port and the at least one second port. A handle may also be coupled to a proximal end of the inner shaft.

[0059] In further embodiments of an ablation catheter, the at least one electrode may include at least one array of electrodes. The array of electrodes may include at least two electrodes having tapered proximal ends, and the at least two electrodes may be configured to be positioned circumferentially around the central core such that the two tapered proximal ends are offset from one another. A wall of the inner shaft may include at least one insulation layer. The core may tapered at a proximal end of the core. The at least one positioning element may include a wire mesh structure. The handle may include at least one sliding button to control movement of the sheath to control deployment of the at least one positioning element.

[0060] Embodiments of an ablation catheter may further include a stabilizer positioned coaxially around an outer circumference of the sheath on a proximal side of the first positioning element. The stabilizer may configured to stabilize and maneuver the sheath during insertion inside the uterine cavity. The stabilizer may include a first proximal section, a second section attached to and perpendicular the first section, a third section attached to a distal end of, and at an angled orientation relative to, the second section, where the third section extends in a distal direction relative to the second section, and finally a fourth section extending in a distal direction relative to the second section, where the fourth section is attached to a side of a distal end of the third section, and the fourth section is oriented parallel to the second section, and wherein the fourth section is configured to be hollow to accommodate passage of the sheath.

[0061] Embodiments of an ablation system are also disclosed herein. The ablation system may be for ablating endometrial tissue of a patient. The ablation system may include an embodiment of a catheter disclosed herein. The ablation system may further include a fluid reservoir configured to contain the volume of fluid and in fluid communication with the at least one lumen. The ablation system may include a pump configured to pump fluid from the fluid reservoir into the at least one lumen. The ablation system may also include a controller having at least one processor, wherein the controller is configured to deliver an electrical current to the at least one electrode and to cause the volume of fluid to pass into the lumen from the fluid reservoir when activated.

[0062] In further embodiments of an ablation system, the system may include a power source positioned in the controller. The pump may include a syringe pump. The at least one electrode may include at least one array of electrodes. The core may be tapered at a proximal end of the core. The controller may include a foot pedal or switch configured to allow a user to control a flow of fluid to the lumen. The at least one positioning element may include a wire mesh structure. The handle may include at least one sliding button to control movement of the sheath to control deployment of the at least one positioning element. Embodiments of an ablation system may further include a stabilizer positioned coaxially around an outer circumference of the sheath on a proximal side of the first positioning element. The stabilizer may configured to stabilize and maneuver the sheath during insertion inside the uterine cavity. The stabilizer may include a first proximal section, a second section attached to and perpendicular the first section, a third section attached to a distal end of, and at an angled orientation relative to, the second section, where the third section extends in a distal direction relative to the second section, and finally a fourth section extending in a distal direction relative to the second section, where the fourth section is attached to a side of a distal end of the third section, and the fourth section is oriented parallel to the second section, and wherein the fourth section is configured to be hollow to accommodate passage of the sheath.

[0063] Embodiments of a kit are also disclosed herein, where the kit includes multiple components of an ablation system. The kit may include an embodiment of an ablation catheter. The kit may further include at least one pump configured to pump fluid from a fluid reservoir into the at least one lumen. The kit may also include an aspiration catheter. The kit may include a substrate having a plurality of spaces configured to receive the ablation catheter, at least one pump, and aspiration catheter, where at least one first cover portion of the substrate is configured to cover and protect at least one component of the ablation catheter. The kit may include a base configured to receive the substrate. The kit may include a lid configured to be positioned over the substrate and secured to the base.

[0064] In further embodiments of a kit, the at least one first cover portion may be partially cut out from a remainder of the substrate and formed by folding the at least one first cover portion over the at least one component of the ablation catheter. The kid may include at least one second cover portion and at least one third cover portion, where the at least one first, second, and third cover portions are configured to engage with each other to form an enclosure to cover the at least one component of the ablation catheter. The lid may include a plurality of recessed cavities that are recessed according to shapes of the ablation catheter, at least one pump, and aspiration catheter. At least one space of the plurality of spaces of the substrate may be configured to receive the ablation catheter comprising the at least one positioning element configured to expand from a first compressed delivery configuration to a second expanded deployed configuration, wherein the at least one positioning element is in the second expanded deployed configuration when the ablation catheter is positioned within the at least one space, and at least one first cover portion may be configured to cover and protect the at least one positioning element in the second expanded deployed configuration.

[0065] With reference now to the drawings, FIG. **1** illustrates an ablation system **100** for ablating a uterine cavity of a patient, in accordance with some embodiments of the present specification. FIG. **2** illustrates an embodiment of a generator system **200** used in ablation system **100**, in accordance with the present specification. FIG. **3** illustrates an embodiment of a catheter **102** used in ablation system **100**, in accordance with the present specification. Referring simultaneously to FIGS. **1-3**, ablation system **100** comprises a catheter **102** having at least one attachment or positioning element **104** and an internal heating chamber, further described with reference to FIGS. **16-18**, **21**, and **22**, disposed within a lumen of catheter **102** and configured to heat a fluid provided to catheter **102** to change said fluid to a vapor for ablation therapy. The internal heating chamber comprises an electrode or an array of electrodes that, in some embodiments, are positioned circumferentially, or wrapped about, a central core and are separated from thermally conductive elements by a segment of catheter **102** which is electrically non-conductive. In some embodiments, each electrode and the core are configured with tapered proximal ends to help prevent electrode shorting. Additionally, the tapered configuration of the proximal end of the electrode(s) and core ensures that flow of ablation fluid over the electrode(s) is less turbulent, relative to that offered by non-tapered configurations. As an ablation fluid approaches a tapered edge indicating the start of the electrode, the fluid's flow is rendered laminar thus resulting in less turbulence and more consistent contact across electrode surface. In some embodiments, catheter **102** is made of or covered with an insulated material to prevent the escape of ablative energy from the catheter body.

[0066] Catheter **102** comprises one or more delivery ports **106** for the delivery of ablative agent, such as steam. In some embodiments, catheter **102** includes a second positioning element **108** proximal to the first positioning element **104**. In some embodiments, the one or more delivery ports **106** are positioned along the catheter between the first positioning element **104** and the second positioning element **108**. In some embodiments, one or more additional delivery ports **106** are positioned along the catheter distal to the first positioning element **104**. In various embodiments, the first distal attachment or positioning element **104** and second positioning element **108** may be any one of a disc, hood, cap, or inflatable balloon. Embodiments of ablation catheter **102** are packaged and shipped with the two positioning elements **104** and **108** being unsheathed such that they are in an expanded configuration, which is the configuration assumed by the positioning elements **104** and **108** during deployment within the uterine cavity. The positioning elements are packaged and shipped unsheathed since, in compressed

form, there is a possibility that, when the positioning elements are subsequently unsheathed, they might not expand as a result of a sterilization process which, if done on the positioning elements in their compressed configurations, could cause them to remain compressed. When expanded, the second, or proximal, positioning element **108** provides tactile feedback and both the second or proximal positioning element **108** and first, or distal, positioning element **104** position the catheter in a uterus such that the one or more delivery ports provide steam diffusion through uterine cavity. In some embodiments, the first and second positioning elements have a diameter of approximately 1.5 cm in their expanded/deployed states. Both positioning elements **104** and **108** provide scaffolding to ensure there is spacing from delivery port(s) to uterine cavity surface tissue (to avoid blocking of the delivery ports). Additionally, in the deployed (expanded) position, the positioning elements **104** and **108** enable centering of the delivery ports within the volume of the uterine cavity. In embodiments, the delivery ports are provided between the two positioning elements, on a distal side of the distal positioning element, and in the distal tip. In some embodiments, the first positioning element **104** and second positioning element **108** have a wire mesh structure with or without a covering membrane. In some embodiments, the first distal attachment or positioning element **104** and second positioning element **108** include pores for the escape of air or ablative agent. A handle **116** provides slider mechanisms to control the movement of an outer sheath, which when pulled back enables deployment (expansion) of the positioning elements and, optionally, to control the positioning of distal positioning element **104**.

[0067] In some alternate embodiments, a needle catheter is provided (not shown). The needle catheter uses a straight needle for treatment of fibroids within the uterine cavity. The needle catheter enables mechanical pre-dilating of a tunnel or provides a jetting effect of vapor which is delivered at a high pressure to cut tissue.

[0068] FIG. **2** illustrates another view of a generator **200** in accordance with some embodiments of the present specification. FIG. **3** illustrates a view of a catheter **102** with handle **116**. Referring simultaneously to FIGS. **1-3**, a fluid, such as saline, is stored in a reservoir, such as a saline pump attached to generator **200**, connected through syringe **222** to a fluid line **130** of catheter **102**. Additionally, an RF cable **128** connects RF catheter port **212** to controller **110**. Delivery of the ablative agent is controlled by controller **110** of the generator **200** and treatment is controlled by a treating physician via the controller **110**. Prior to a treatment, the entire ablation system is primed, and vapor is generated and passed through the infusion ports momentarily. The test shot is performed after priming, and prior to starting the treatment, to ensure that the ablation system is generating steam. The generator **200** includes a controller **110** comprising at least one processor in data communication with the saline pump. The generator system **200** also includes an RF catheter connection port **212** and the controller **110** is configured to control electrical current delivery to the electrodes of the catheter via the RF catheter connection port **212** and fluid delivery to the catheter via the saline pump and syringe **222**. In some embodiments, at least one optional sensor monitors changes in an ablation area to guided flow of ablative agent. In some embodiments, the optional sensor comprises at least one of a temperature sensor or pressure sensor. In some embodiments, catheter **102** includes a filter with micro-pores which provides back pressure to the delivered steam, thereby pressurizing the steam. The predetermined size of micro-pores in the filter determine the back-pressure and hence the temperature of the steam being generated. In some embodiments, the system further comprises a foot pedal in data communication with controller **5710**, a switch on catheter **102**, or a switch on the controller **102**, for controlling vapor flow. In various embodiments, the switch to control the vapor flow is positioned on the generator or the catheter handle.

[0069] In one embodiment, a user interface **5820** included with the generator system **5800** allows a physician to define device, organ, and condition which in turn creates default settings for temperature, cycling, volume (sounds), and standard RF settings. In one embodiment, these defaults can be further modified by the physician. The user interface also includes standard displays of all key variables, along with warnings if values exceed or go below certain levels. In embodiments, user interface **220** includes a touch-screen display **221**.

[0070] The ablation device also includes safety mechanisms to prevent users from being burned while manipulating the catheter, including insulation, and optionally, cool air flush, cool water flush, and alarms/tones to indicate start and stop of treatment.

[0071] Referring now to FIG. **2**, illustrating generator **200**, fluid such as saline is stored in a reservoir **223**. A pump is positioned in fluid communication with the reservoir. In some embodiments, the pump is a syringe pump **222**. The reservoir and pump arc positioned within an enclosure or housing **224**. The housing **224** can be made from a partially transparent material. Further, pump or syringe **222** is in communication with fluid line **130** of catheter **102** through a fluid port **225**. Delivery of fluid through port **225** into catheter **102** is controlled via controller **110** by a treating physician using interface **220** provided on generator **200** to activate the pump. Interface **210** may be a touch-screen interface **221**. Fluid port **225** can also be positioned toward a side or front surface of generator **200**, allowing the user/physician to view and control through display **220** while attaching the catheter **102**. The generator **200** includes an RF catheter connection port **212** for connecting to an RF cable **128** of the catheter **102**. Generator **200** includes a controller **110** having at least one processor in data communication with interface **220** and configured to control the delivery of RF current, via the RF connection port **212**, and the delivery of fluid, via the fluid port **225**, to the catheter, the pump and catheter fluid port **212** that is in fluid communication with the pump. A button **218** is provided on the front panel of generator **200**, to manually activate ablation of fluid using RF ablation methods. In some embodiments, the front panel of generator **200** also includes at least one USB port **226**. Port **226** can be used to connect a power supply to operate generator **200**, or to charge rechargeable batteries within generator **200**.

[0072] With reference to FIG. **3**, illustrating a side view of catheter **102**, an RF cable **128** is attached to a proximal end of catheter **102**, which is configured to interface with RF catheter port **212** of FIG. **2**. Additionally, a saline fluid line (or cable) **130** is also attached adjacent to cable **128** to the proximal end of catheter **102**, which is configured to interface with the syringe pump through fluid port **225** of FIG. **2**. Handle **116** provides slider mechanisms to control the movement of an outer sheath, which when pulled back enables

deployment (expansion) of the first and second positioning elements **104**, **108**, and optionally to control the positioning of first positioning element **104**.

[0073] FIG. **4** illustrates a view of the top surface of handle **300** of catheter **102**. FIGS. **5-7** illustrate a view of the internal components of handle **300**. FIG. **10** illustrates a cross-section view along a longitudinal axis of catheter device **100** extending from handle **300** toward a distal olive-shaped tip **302**. Referring simultaneously to FIGS. **4-7** and **10**, handle **300** is configured in an elongated flat design with its top surface holding a first slider **302** to control the movement of an outer sheath **304**. Slider **302** is configured to slide smoothly through a pushing action by the user, within a channel **306** of a fixed first length. A second slider **308** is configured parallel to first slider **302** to control the positioning of a distal positioning element **406**. Second slider **308** is configured to slide smoothly through a pushing action by the user, within a channel **310** of a fixed second length. A series of visual markings **312** are embossed or otherwise illustrated alongside the length of channel **310**. Markings **312** enable the user to visualize a length for adjusting the position of second slider **308** corresponding to the size of the uterine cavity. Additional markings are embedded or illustrated on the top surface of handle **300** to indicate the functions of first and second sliders **302**, **308**. For example, a marking **314** at a proximal side of channel **306** indicates that movement of slider **302** in the direction of marking **314** withdraws or pulls back the outer sheath **304** of the catheter to deploy the positioning elements. Similarly, a marking **316** at a distal side of channel **306** indicates movement of slider in the distal direction to cover and compress the positioning elements with the outer sheath **304**. Movement of slider **302** till the most distal position within channel **306** would move outer sheath **304** up to the distal olive-shaped tip **402**, covering and compressing the two positioning elements. Marking **319**, at a distal side of channel **310**, indicates to the user that second slicer **308** controls the positioning of the distal end or first positioning element within the uterine cavity.

[0074] FIGS. **5** and **7** further illustrate an attachment **318** of first slider **302** to outer sheath **304**. In embodiments, attachment **318** is an elongated solid component. A proximal end of attachment **318** provides a platform **332** to fixedly attach first slider **302**. Attachment **318** extends distally parallel to channel **306** and ends in a distal portion **320** that is flared in proportion to the elongated middle portion **319** of attachment **318**. Outer sheath **304** is attached to the distal portion **320** of attachment **318** using an adhesive, in some embodiments.

[0075] FIGS. **5** and **6** further illustrate an attachment **322** of slider **308** to a shaft **328** of the catheter. Attachment **322** is an elongated solid component. A proximal end of attachment **322** provides a platform **334** to fixedly attach second slider **308**. Attachment **322** extends parallel to channel **310** and ends in a distal portion that is configured with a collar **326**. Collar **326** is positioned between a first retaining wall **330***a* and a second retaining wall **330***b*, each positioned on either side of collar **326**, to stabilize the proximal shaft **328** within the handle **300**. FIG. **8** illustrates a view of first slider **302** attached to platform **332** at the proximal end of attachment **306**. FIG. **9** illustrates a view of second slider **308** attached to proximal end **334** of attachment **322**.

[0076] Referring to FIGS. **4** and **5**, a cord grip **342** on a proximal end, and a cord grip **344** on a distal end of handle **300**, strengthen the attachment and flexibility of handle **300**. Cord grip **342** provides protection and stability to the RF cable **128** and fluid cable **130**, referring to FIG. **3**, extending from the proximal end of the handle **300**, and cord grip **344** provides protection and stability to the outer sheath **304** and catheter shaft **328** extending from the distal end of the handle **300**. In some embodiments, a board **331** is positioned within the handle, proximate a proximal end of the handle, and is configured to secure and manage the various components and connections within the handle. In embodiments, the handle includes an RF wire coil **309** for delivering electrical current to the at least one electrode within the heating chamber of the catheter.

[0077] The multiple embodiments of handle mechanism include systems for deployment and retraction of positioning elements, which can be achieved in different ways such as and not limited to buttons, push/pull on distal or proximal end, slide button in a track, rotation with push/pull. The internal components of the embodiments of the handle mechanism are made generally using stainless steel. The external components of the embodiments of the handle mechanism are made generally using a combination of ABS, plastics, rigid polymers, and elastomeric polymers, among other material. The various embodiments also provide for strain relief for the back end for the fluid tube and the electrical cable, and strain relief on the front end to provide support for the catheter segment. In various embodiments, the handles described in the present specification have lengths ranging from 3 inches to 24 inches and diameters or widths ranging from ¼ inch to 5 inches.

[0078] To prepare the catheter, a physician sets a position of second slider **308** within channel **310**, according to the measured size of uterine cavity. Moving slider **308** to the measured uterine cavity size (FIG. **4** shows slider **308** positioned at a size '9') causes distal positioning element **406**, olive tip **402** (referring to FIG. **10**) at the distal end of the catheter, and an internal member within outer sheath **404**, to which both (the distal positioning element and the olive tip) are attached, to move. Slider **308** distance is set at a value that less than a measured uterine cavity size. The uterine cavity size is measured using conventional techniques. In some embodiments, the physician measures the uterine cavity with a conventional uterine sound technique. In embodiments, the uterine cavity is measured using an aspiration catheter with insertable stylet, as discussed with reference to FIG. **26-28**. The units of measurement are expressed herein in centimeters (cm) which typically range from 3 to 6 cm. Using the uterine size obtained, the physician sets the degree of expansion for the positioning elements of catheter, using slider **308**. The distance set using slider **308** is slightly less than the measured uterine cavity size, to ensure that there is enough space distal to the distal end of the catheter (olive tip **402**) for ablative agent to circulate. In an illustrative example, if the slider is set to "5" (indicative of the uterine cavity size), a distal assembly **408** (comprising the distal positioning element **406** and the olive tip **402**) moves such that a distance from a distal surface of a proximal positioning element to the end of the olive tip is slightly less than 5 cm, such as for example 4 cm. In embodiments, slider **308** can be set from "3" to "9". The proximal positioning element **410** is stationary. Once second slider **308** is moved (causing distal assembly **408** to move), slider **308** is locked, thereby locking distal assembly **408** in place.

[0079] In some embodiments, first slider **302** is of a first shape, such as for example an oval shape, and a first color, and second slider **304** is of a second shape, such as a square or a rectangular shape, and a second color, enabling easy distinction between the two sliders that serve different purposes. Button slider support features are added on an inner side proximal to a bottom surface of handle **300**. Buttons of sliders **302** and **308** are press fitted on the platforms/proximal portions **332** and **334** of the sliding mechanisms, using a poka yoke button design.

[0080] Once distal hood slider **308** is locked, a test shot is performed to ensure vapor is being properly generated. Using outer sheath first slider **302**, the outer sheath is advanced distally along the catheter shaft **328** to cover and compress positioning elements **406** and **410**. The outer sheath slides forward to eventually meet olive-shaped tip **402** so that the sheath **304** and olive tip **402** create an atraumatic surface. The atraumatic surface ensures there are no openings in the distal end of the catheter that would catch on tissue as the catheter is inserted into a body cavity. The catheter is then inserted into the patient, outer sheath slider **302** is slid back to uncompress positioning elements **306** and **310**, and a cervical stabilizer **118** is slid into position.

[0081] Referring back to FIG. **3**, a cervical stabilizer **118** is positioned coaxially about the catheter sheath **119**, located on a proximal side to proximal positioning element **108**, and comprises a conical-shaped element **120** having a central lumen through which the catheter shaft extends. The conical-shaped element **120** is attached to a slant portion **122** extending proximally and which is attached to a parallel portion **124** that further extends proximally and, in turn, is attached to a perpendicular portion **126**, where each portion **122**, **124** and **126** of cervical stabilizer **118** is described relative to a central longitudinal axis of the catheter shaft. Cervical stabilizer **118** ensures stability and tactile control of the distal portion of the catheter. A physician holds stabilizer **118** during insertion of the catheter inside cervix, to support its placement. Stabilizer **118** does not actively seal the cervix, where sealing is not required as a result of the small amount of fluid that is dissipated into the tissue during the ablation process. Stabilizer **118** can be positioned depending on anatomy of the patient, to stabilize the catheter.

[0082] FIG. **11** illustrates a perspective view of an embodiment of cervical stabilizer **400**, in accordance with the present specification. FIG. **12** illustrates a top view of cervical stabilizer **400**, in accordance with the present specification. FIG. **13** illustrates a side elevation view of an exemplary embodiment of cervical stabilizer **400**, in accordance with the present specification. FIG. **14** illustrates a three-rib configuration in an embodiment of cervical stabilizer **400**, in accordance with the present specification. FIG. **15** illustrates a photograph of a cervical stabilizer **400**, in accordance with some embodiments of the present specification.

[0083] Referring simultaneously to FIGS. **11-15**, stabilizer **400** is described in four sections—a first most proximal section **402**; a second section **404** attached to and perpendicular to first section **402** and extending in a distal direction relative to the first section **402**; a third section **406** attached to and at an angled orientation relative to second section **404**, and extending in a distal direction relative to the second section **402**; and a fourth section **408** attached to the third section **406** and oriented parallel to second section **404** and extending in a distal direction relative to the third section **406**, wherein a distal end of the third section **406** is attached to a side of the fourth section **408** proximate a proximal end of the fourth section **408**. Together, sections **402**, **404**, **406**, and **408** form cervical stabilizer **400**. Proximal section **402** has a flat circular shape, with a thickness of approximately 0.08 inches to 0.50 inches (preferably 0.160 inches) and a radius of approximately 0.215 inches. First section **402** provides a handle to hold cervical stabilizer **400** during insertion of catheter system (and a uterine aspiration catheter) inside the cervix. A height of first section **402** up to a level of a top surface of section portion **404** is approximately 0.444 inches. Second section **404** is continually attached to first section **402** at a smooth, curved joint with a radius of approximately 0.173 inches. Second section **404** has a flat, elongated rectangular shape, with a thickness of approximately 0.08 inches to 0.50 inches (preferably 0.160 inches), and a length of 0.50 inches to 2 inches, and preferably 1.26 inches. In some embodiments, at a distance of approximately 0.286 inches, an arrow **410** is embossed on a top surface of second section **404**, which extends to point toward a distal direction for a length of approximately 0.973 inches. In some embodiments, thickness of the embossed arrow **410** is approximately 0.029 inches above the surface of second section **404**. Third section **406** is continually attached to second section **404** at an angle of approximately 135° measured from the bottom surface of second section **404**. Third section **406** provides a leverage to maneuver cervical stabilizer **400** by holding from outside the uterine cavity. The lever is a pusher lever used by the physician to push stabilizer **400** forward. Distal end of third section **406** slopes downwards to fixedly attach to a side of a proximal portion **412** of fourth section **408**.

[0084] Fourth section **408** further includes three portions-proximal cylindrical first portion **412** that extends distally into a cone-shaped second portion **414**, which extends further distally into a distal cylindrical third portion **416**. The total length of fourth section **408** is approximately 1.137 inches. First portion **412** has a length of approximately 0.271 inches and an outer diameter of approximately 0.394 inches. Second portion **414** has a proximal diameter to match the outer diameter of first portion **412**. Second portion **414** narrows towards the distal end where it has a diameter in a range of approximately 0.280 inches. The distal end of second portion **414** is continually attached to the third portion **416** which is cylindrical in shape. An outer diameter of third portion **416** is approximately 0.28 inches. First, second, and third portions **412**, **414**, **416**, are configured to be hollow to accommodate passage of outer sheath of ablation catheter or outer sheath of aspiration catheter, where the catheter sheath passes through the length of fourth section **408**. In embodiments, a plurality of ribs **418** are positioned within third portion **416** of fourth section **408**. Three ribs **418** are shown in the illustrated embodiment. Each rib **418** extends inwardly from an inner circumference of third portion **416** proximally for a length of approximately 0.089 inches into a space **419** within the fourth section **408**. Each rib **418** is spaced equally around the circumference of internal circular surface of proximal end of third portion **416**. Gaps between the ribs ensure that no seal is created. Ribs **418** provide a friction fit to the catheter sheath (or aspiration catheter) passing through fourth section **408** of cervical stabilizer **400**. Ribs **418** slide up and down on the catheter sheath when stabilizer **400** is pushed/pulled

by physician, and holds stabilizer **400** to the catheter sheath when released by the physician.

[0085] In embodiments, cervical stabilizer **400** is made from a rigid, non-compliant material, such as for example PP homopolymer profax PF511. In some embodiments, cervical stabilizer **400** is of a bright white color to enable easy spotting and visibility of the device for holding by the physician. In embodiments, stabilizer **400** used with the treatment catheter and with the aspiration catheter are identically designed and provide the same function.

[0086] FIGS. **16-18** illustrate a cross-section view, with selected expanded views thereof, of a catheter lumen **500** including expanded views of a proximal portion **530** of an electrode assembly core **532** and a proximal end **534** of a distal shaft **536**, in accordance with some embodiments of the present specification. A portion of the catheter lumen extending between a cervical stabilizer component **538** and extending up to a proximal end of proximal positioning element **510** comprises an internal heating chamber **540**. The internal heating chamber is encapsulated with an insulation coating **542**. In embodiments, the insulation coating includes materials such as polyimide, aerogel, AcroZero®, and silicone, as further shown and described with respect to FIG. **25**. Insulation coating **542** is configured to prevent tissue damage or burns by limiting the transfer of heat from the internal heating chamber to the uterine cavity. The heating chamber **540** is positioned within a lumen **548** of the catheter. Inside the heating chamber **540** is positioned at least one electrode or an array of electrodes **539** positioned coaxially around, or wrapped about, an electrode core **532**. The electrode core **532** is configured to prevent turbulent flow and maximize fluid contact with the at least one electrode **539**. In embodiments, the electrode core is a solid material and configured in a cylindrical shape. In some embodiments, the electrode core is comprised of polyether ether ketone (PEEK). In some embodiments, the electrode core **532** is also an electrode configured to convert the fluid to vapor. In some embodiments, the heating chamber **540** comprises both at least one electrode **539** positioned circumferentially around an electrode core **532** wherein the electrode core **532** is also an electrode. In some embodiments, the heating chamber **540** comprises only an electrode core **532** wherein the electrode core **532** is an electrode. The electrode core **532** serves to improve vapor generation by reducing the volume for saline to flow through while passing over the electrodes. As the fluid travels in the lumen **548** and approaches the electrode core **532**, the cross-sectional area of the fluid pathway decreases, forcing the fluid to come into contact with the electrodes **539** positioned around the electrode core **532**. In some embodiments, the cross-sectional area of the fluid pathway ranges from 3 mm^2-30 mm^2 before the heating chamber **540** and from 1 mm^2-20 mm^2 within the heating chamber **540**, with a proportional reduction in the cross-sectional area of the fluid pathway ranging from 10% to 90% from pre-heating chamber to within the heating chamber. In embodiments, the proximal end of the electrode core **532** has a tapered configuration with an angle of a ramp ranging from 5 degrees to 85 degrees, starting from the proximal tip **533** of the electrode core **532** to a tapered end **535** of a ramped section **537** of the electrode core **532**. In embodiments, this ramped section **537** improves the uniformity of distribution of the fluid over the electrodes **539** of the heating chamber **540** by at least 10%, wherein uniformity of distribution is quantified as volume of saline over the surface area of each quadrant of the electrode. In embodiments, the improvement of the uniformity of distribution of the fluid over the electrodes by including an electrode core with a tapered proximal end results in improvement of the quality of steam from <25% to >40%, or a 25% improvement, relative to vapor generation absent an electrode core. In embodiments, the electrodes **539** and core **532** are separated from thermally conductive elements of the catheter by segments **544** of catheter which are electrically non-conductive. Each electrode **539** and the electrode core **532** are configured with a tapered edge at their proximal ends **530**. In some embodiments, a length of the tapered proximal end of the electrode core is in a range of 1 mm to 15 mm, and more preferably 2 mm to 10 mm. The tapered configuration of electrode(s) **539** and electrode core **532** prevents electrode shortening and ensures that flow of ablation fluid within lumen **538**, flowing over the tapered ends, is rendered less turbulent, relative to that offered by non-tapered configurations. As an ablation fluid approaches tapered ends indicating the start of the electrodes **539** and electrode core **532**, the fluid's flow is rendered laminar thus resulting in less turbulence and more consistent contact across the surface of the electrodes **539**.

[0087] FIGS. **21** and **22** illustrates a first array of electrodes **562** and a second array of electrodes **564** for positioning around an electrode core within a flexible heating chamber, in accordance with some embodiments of the present specification. Proximal sides of both arrays of electrodes **562** and **564** have a tapered configuration, and further, each tapered edge of electrodes **562** and of electrodes **564** are offset from each other to prevent electrode shorting once positioned inside the heating chamber. FIG. **22** illustrates a close-up view of the tapered proximal edge configurations of arrays of electrodes **562** and **564**, in accordance with embodiments of the present specification. A first tapered proximal edge **562***a* corresponds to electrodes **562** and a second tapered proximal edge **564***a* corresponds to electrodes **564**. Arrays of electrodes **562** are interlaced with arrays of electrodes **564**, such that a width **566** of both arrays **562** and **564** together is approximately 0.215 inches. A length **562***b* of exposed electrodes of arrays of electrodes **562** is approximately 1.5 inches, whereas a length **564***b* of exposed electrodes of arrays of electrodes **564** is approximately 1.62 inches, resulting in an offset at the proximal sides of arrays of electrodes **562** and **564**. Further, length of first tapered proximal edge **562***a* is shorter than length of second tapered proximal edge **564***a*. In some embodiments, length of edge **562***a* is approximately 0.063 inches and that of edge **564***a* is approximately 0.358 inches. The offset solder pads configured at the offset proximal edges **562***a* and **564***a* of the arrays of electrodes **562** and **564** prevents shorting when the two arrays **562** and **564** are wrapped together inside the heating chamber. Therefore, tapered edge **530** configuration of electrodes **532** overcomes a prior design limitation wherein the proximal portion of the electrodes have a straight edge resulting in the possibility that the soldered joints of the proximal edges could touch and short.

[0088] Referring again to FIG. **15-20**, a distal side of electrode core **532** is positioned proximate a proximal side **534** of a distal shaft **536** that extends up to and is attached to an olive-tip **502** at the distal end of the catheter. In embodiments, proximal side **534** of distal shaft **536** is shaped like a "crown" (or like the tip of a rook) to facilitate

the flow of fluid converted to vapor by electrode **532**, into the distal shaft **536**. The crown shape prevents the entirety of proximal end of the distal shaft from contacting the distal end of the electrode core and blocking the flow of vapor. An uneven proximal end **534** shaped in the form of a crown provides gaps **531** for the vapor **561** to flow through in the event that the crown-shaped proximal side **534** touches the distal side of electrode core **532**, thereby improving the flow of vapor.

[0089] In embodiments, olive tip **502** is configured to have at least one vapor delivery port **550** positioned on a side of the olive tip **502** and proximate the distal end dome-shaped tip of the atraumatic olive tip **6302**. In embodiments, the olive tip includes a range of 1 to 20 vapor ports. FIGS. **19** and **20** illustrate a olive-shaped distal tip **502** with a plurality of ports **550**. A distal end **554** of catheter shaft **504** terminates within tip **502** prior to ports **550**. The embodiment includes a total eight ports **550**, some visible with others not shown on the opposite side. All ports are configured through the body of olive tip **502** and may be positioned at equal angles from each other within the circumference of distal tip **502**. Each port extends outwards radially from a center **552** axis of the catheter shaft, toward the outer circumference of olive tip **502**. In embodiments, 1-50 delivery ports, and preferably 12-15 vapor ports **503**, are positioned along the length of the catheter shaft **504** between proximal positioning element **510** and distal positioning element **506**. Once deployed within the uterine cavity, the vapor formed within the heating chamber is released via the ports in the catheter shaft and in the olive tip and extends upwards into the uterus and flows around the surface of the uterus distally to proximally. First-sized ports proximally along the catheter shaft **504** and relatively larger second-sized ports distally on shaft **504** result in more vapor being emitted distally. As the distal assembly (comprising distal shaft **536**, distal positioning element **506** and olive tip **502**) is moved and locked, some vapor ports may become blocked by virtue of remaining positioned within the outer sheath of the catheter at a proximal side of proximal positioning element **510**. In said scenario, configuration of first-sized ports positioned at the proximal side of shaft **504** is an advantage. The blocked ports are of a relatively smaller size, thereby still allowing sufficient vapor to be released in the uterus through the distal ports of relatively larger sizes.

[0090] In embodiments, the catheter is made of or covered with insulated coating **542** to prevent the escape of ablative energy from the catheter body to avoid possibility of burning in the likelihood where the catheter shaft comes in contact with the tissue surface inside the uterus, as the fluid flowing over electrodes **539** is heated. Therefore, insulation coating **532** lowers the surface temperature of the catheter shaft configured to be positioned within the body. In embodiments, the insulation coating **542** is positioned coaxially between an inner wall **545** (or proximal and distal inner shafts) of the catheter shaft and an outer wall **541** of the catheter shaft.

[0091] FIG. **25** illustrates composition that, in embodiments of the disclosure, forms one insulation layer **600** used in some embodiments of the present specification. An innermost material **602** comprises a release lining, a second material **604** covering innermost material **602** includes an adhesive coating, a third material **606** layered over second material **604** comprises a flame and thermal barrier (for example aerogel), a fourth material **608** again provides an adhesive coating over the outer side of third layer **606**, and a fifth outermost material **610** includes a polyimide surface. In some embodiments, at least four layers of insulation, comprising each material of the insulation materials described in FIG. **25**, is wrapped together to comprise the insulation coating **542** of FIG. **16**. Table 1, shown below, demonstrates the time needed to cause a burn when the surface temperature of a catheter shaft is maintained at a certain temperature. Table 1 lists different temperatures, ranging from 45° C. to 60° C. Table 1 also lists the time at each temperature to cause a second degree burn that does not cause irreversible damage. Table 1 further lists the time at each temperature to cause a third degree burn that can result in an injury. Table 1 illustrates, for example, a surface temperature of the catheter shaft will have to be at 51° C. for at least 2 minutes (min) to cause a second degree burn, and for at least 4.2 min to result in a third degree burn.

TABLE 1

Temperature	2^{nd} Degree Burn (No irreversible damage)	3rd Degree Burn (full thickness injury)
45° C.	2 hours	3 hours
47° C.	20 minutes	45 minutes
48° C.	15 minutes	20 minutes
49° C.	8 minutes	10 minutes
51° C.	2 minutes	4.2 minutes
55° C.	17 seconds	30 seconds
60° C.	3 seconds	5 seconds

[0092] FIG. **25**A illustrates another table to demonstrate the results of an insulation test performed with insulation layers **600** in accordance with the embodiments of the present specification. In FIG. **25**A, the X-axis lists the number of insulation layers (wraps) used to coat the outer surface of the catheter shaft, and Y-axis lists the different temperatures (in° C.) achieved on the outer surface of the catheter shaft during an ablation procedure corresponding to the different number of layers. Outer surface temperature of a catheter shaft comprising four layers, in accordance with the present specification, reaches a maximum of 47.3° C., which according to Table 1, would require approximately 45 minutes to cause an irreversible burn injury. The actual time required to complete the ablation process within the uterine cavity is considerably less than 45 minutes.

[0093] Referring now to FIGS. **23** and **24**, in some embodiments, a thermocouple is integrated into the outer layers of the catheter to measure the temperature of the outermost layer of the catheter. In embodiments, the thermocouple is housed within an outer lumen of the catheter shaft configured with multiple lumens. In some embodiments, the thermocouple is housed between the outermost wall and the next to the outermost walls of the catheter, and positioned along the catheter proximate the heating chamber/electrodes. The thermocouple is configured to measure the temperature of the outermost layer of the catheter itself, and not a temperature of the ablative agent or uterine cavity as is typical in the prior art. In some embodiments, the system is configured to measure and confirm the temperature of the outermost layer of the catheter is 51° C. or less for at least 30 seconds. The thermocouple tip is inset into the catheter's outer surface. The ablation system is configured to shut down if catheter shaft temperature rises above a thresh-

old temperature, as measured with the thermocouple. The threshold temperature is a temperature that can damage the patient by causing an injury.

[0094] FIGS. **23** and **24** illustrates a cross-section view **702** of the catheter shaft along an axis perpendicular to the longitudinal axis of the shaft, and a position of a thermocouple **704** is shown in FIG. **23** where thermocouple **704** is positioned within the outer-most lumen of a multi-lumen outer shaft of catheter. FIG. **24** illustrates layers of the catheter shaft comprising: an outer wall **708**, an insulation layer **710** (equivalent to set of layers **600**), a proximal shaft **712** and distal catheter shaft **714** (inner walls), an electrode array **716**, and an electrode core **718**.

[0095] An aspiration catheter is used to clean the field of ablation within the uterine cavity, before and/or after a conventional hysteroscopy. Figure FIGS. **26-28** illustrate a uterine aspiration catheter **820** in accordance with embodiments of the present specification. A cervical stabilizer **800** is positioned coaxially over the uterine aspiration catheter **820** and is configured to stabilize the uterine aspiration catheter **820** during aspiration, similarly to stabilizing the ablation catheter during ablation. A proximal end of uterine aspiration catheter **820** is fitted with a luer connection **822** and a distal portion of catheter assembly **820** includes one or more aspiration ports **824**. In embodiments, uterine aspiration catheter **820** is flexible and includes markings (not shown) along its length. To measure or sound the uterine cavity, in embodiments, a rigid elongated device, such as a stylet (not shown), is inserted into the lumen of the **822** of the uterine aspiration catheter once it has been positioned in the uterus. The markings **821** are then read by the physician and indicate to the physician the size of the uterine cavity. In some embodiments, the stylet includes a handle. Therefore, in embodiments of the present specification, the uterine aspiration catheter **820** is configured to function as both an aspiration catheter and uterine cavity measuring device.

[0096] FIG. **28** illustrates a side elevation view of aspiration catheter **820**. Referring simultaneously to FIGS. **26-28**, Luer connection **822** includes a female luer connector **826** which is configured to secure attachment of aspiration catheter assembly to a syringe. In embodiments, luer connector **826** is configured preferably to interface with a 20 cc syringe for input of fluid such as saline. Tubing **830** is made from a flexible material, such as, for example a flexible polyurethane braiding. In other embodiments, material for tubing **830** is selected from spectrum plastic group P/N: FA2775-100P or equivalent. An internal diameter of tubing **830** ranges from 0.05 inches to 0.071 inches, and external diameter is approximately 0.142 inches. A length of uterine aspiration catheter assembly **820** is, in an embodiment, approximately 12 inches. In some embodiments, at least two ports **824** are aligned along a straight line parallel to a longitudinal axis of tubing **830**, at a distance of approximately 0.20 inches. At least two more ports **824** are aligned along a straight line and offset from the first pair of ports **824** axially by an angle of approximately 90°, as well as linearly by approximately 0.1 inches. The most distal port(s) **824** has a center at a distance of approximately 0.19 inches from the distal tip of tubing **830**. Each port of ports **824** has a radius of approximately 0.071 inches.

[0097] FIG. **29** illustrates multiple components of an ablation system of the present specification, packaged together in a kit **900**. FIG. **30** illustrates another view of the packaging elements of kit **900**, in accordance with some embodiments of the present specification. Referring simultaneously to FIGS. **29** and **30**, a middle layer or substrate of the kit, comprising a card **902**, is configured to house multiple components of the ablation system, including the ablation catheter, syringes, and uterine aspiration catheter. In embodiments, card **902** comprises a plurality of spacings for placement and securing of the components of the ablation system. In some embodiments, card **902** includes first spacing **916**, second spacing **918***a*, third spacing **918***b*, fourth spacing **920**, and fifth spacing **924** for an aspirator catheter **906**, syringes **908***a* and **908***b*, an ablation catheter **910**, and cables **914** of the ablation catheter respectively. As discussed previously, the catheter must be shipped with the positioning elements in their expanded configuration to prevent misshaping of the positioning elements. In embodiments, the card **902** includes at least one first portion or cover **912** configured to cover and protect a component of the ablation system. In embodiments, cover **912** comprises a cut-out flap configured fold away from a flat plane of the card **902** and cover the distal end of the ablation catheter **910** to protect the positioning elements during shipment. In some embodiments, card **902** comprises second and third portions or cover wings **942**, **952** configured to fold away from the flat plane of the card **902** and engage with the at least one first cover **912** to form an enclosure over a component of the ablation catheter **910**. Card **902** (die card) is placed within a bottom layer, base, or rectangular tray **904**. Tray **904** is a thermoformed tray. A top layer, or molded tray lid **903**, is used to cover the top surface of components placed within card **902**. In embodiments, molded tray lid **903** is a thermoformed rectangular tray comprising a plurality of recessed cavities **923** that are recessed according to shapes of stored components within card **902**. In embodiments, lid **903** includes first latching components **913** configured to engage with second latching components **934** of tray **904** to securely lock the lid **903** with the tray **904** with the card **902** in between.

[0098] Cables **914** of ablation catheter **910** are coiled and positioned and clipped within card **972** with adjustable open-ended clips **925** that are cut into card **902**. Embodiments of ablation catheter system are packaged and shipped with two positioning elements being unsheathed such that they are in an expanded configuration, which is the configuration assumed by the positioning elements during deployment within the uterine cavity. The positioning elements are package and shipped unsheathed since, in compressed form, there is a possibility that, when the positioning elements are subsequently unsheathed, they might not expand as a result of a sterilization process which, if done on the positioning elements in their compressed configurations, could cause them to remain compressed. Card **902** and molded tray lid **903** secure the components of the ablation device for transportation and storage. Kit **900** is, in some embodiments, further packaged and scaled inside a Tyvek pouch to ensure a sterile barrier. The pouch can be placed within a box, and can be shipped in a bigger box with other boxes containing a pouch each.

[0099] In embodiments, components of kit **900** are removed and calibrated outside a patient, before a procedure, and while in communication with a generator (**200** of FIG. **2**). In embodiments, slider to control the positioning of the outer sheath of the catheter is pulled all the way back so that the outer sheath is not positioned over any of the positioning elements. Additionally, the slider to control the

distal element comprising the distal positioning element and the olive-shaped tip at the distal end of the catheter, is positioned and locked for the maximum uterine cavity size. In one embodiment, the slider that controls the distal element is positioned at number '5' corresponding to a uterine cavity size of 5 cm, resulting in locking of the device so that the distance from the proximal positioning element to the olive-shaped distal tip is approximately 4 cm. The uterine cavity size is an indication of the measurement from fundus to internal cervical os.

[0100] FIG. **31** is a flow chart illustrating an exemplary method for preparing and using the ablation catheter device or system described in accordance with the various embodiments of the present specification. At step **1000**, a physician positions the distal positioning element slider according to a measured uterine cavity size. Moving the distal positioning element slider to the measured uterine cavity size causes the distal positioning element, olive tip at the distal tip of catheter device, and an internal member within the outer sheath, to which both (the distal positioning element and the olive tip) are attached, to move. The slider distance is set at a value that is less than a measured uterine cavity size. A distance between the proximal positioning element and the distal tip of the catheter is approximately 1 cm less than the measured size of the uterine cavity, thus ensuring that the ablation mechanism placed within the body cavity does not contact the body tissue. The uterine cavity size is measured using conventional techniques. In some embodiments, the physician measures the uterine cavity with a conventional uterine sound technique. The units of measurement are expressed herein in cm which typically range from 3 to 6 cm. Using the uterine size obtained, the physician sets the degree of expansion for the positioning elements of the catheter device, with the slider. A proximal positioning element is stationary. Once the slider is moved (causing the distal assembly to move), the slider is locked, thereby locking the distal assembly in place.

[0101] In some cases, the physician uses the aspiration catheter after the measurement of the uterine cavity to remove water/fluid from the uterine cavity before inserting the catheter to avoid problems of water and steam mixing during ablation.

[0102] At step **1004**, priming and a test shot are performed wherein fluid is passed through the catheter and is heated by electrodes to generate ablation vapor. The generated vapor exits through the infusion ports, including the ones between the positioning elements, the ports distal to the distal positioning element, and the port(s) on the (olive-shaped) distal tip. The vapor exit is visually verified by the physician. Once a puff of vapor is passed, the ablation device is considered to be ready to be used for treatment. The steam is generated by pressing a button on the generator interface or by pressing on a foot pedal. In some embodiments, the vapor is delivered for a period of time that is less than five minutes, and preferably for a period of time within a range of 0 to 120 seconds, and more preferably 90 seconds. The vapor delivered at this stage is for the purpose of priming and preparing the ablation device for treatment before it is inserted and positioned within the patient.

[0103] At step **1006**, the at least one, and preferably two, positioning elements are compressed by pushing forward the outer sheath using the slider for the outer sheath. A distal end of the catheter sheath, during placement, sits snugly up against the olive-shaped distal tip. The distal end of the catheter, with the compressed positioning elements, is then slid inside a cervix of the patient, at step **1008**. At step **1010**, the outer sheath of the catheter is pulled back using the corresponding slider, thereby deploying or expanding the positioning elements. The outer sheath is pulled back until the proximal positioning element abuts the internal os and some resistance is sensed by the physician. At step **1012**, the cervical stabilizer is slid into its position. The cervical stabilizer is pushed by the physician until a resistance is felt. The stabilizer provides stability to the distal section of the catheter as well as tactile control to the physician.

[0104] At step **1014**, at least one vapor ablation cycle is initiated. In some embodiments, the vapor is delivered for a period of time that is less than 60 seconds, and preferably for a period of time less than 30 seconds. A thermocouple positioned on an outer surface of the catheter sheath monitors the cervix temperature. The physician may choose to turn off the vapor if the thermocouple communicates that the temperature within the cervix is high. Further, the ablation device automatically turns off the vapor if the temperature is higher than a pre-defined threshold.

[0105] At step **1016**, the cervical stabilizer is pulled back. At step **1018**, the outer sheath of the catheter is pushed forward using the corresponding slider to compress the positioning elements. At step **1020**, the catheter is finally pulled out of the patient. In some cases, the aspiration catheter is subsequently inserted to clean the ablation area.

[0106] FIGS. **32** and **33** show an embodiment of catheter **100** positioned positioned within uterus **1124**. Distal ends of ablation catheters **1191** having distal olive tips **1193**, positioning elements **1195**, and a plurality of ports **1197** is inserted through a patient's vagina canal **1115** and into and through a portion of the patient's cervix **1111**. During delivery of the catheter's distal end, distal hood **1195**, inner catheter shaft, and a proximal hood **1196** are all disposed within catheter shaft such that olive tip **1193** comprises the distal end of the catheter. Olive tip **1193** is configured to be soft and atraumatic to the vaginal canal **1115**, external cervical os, and cervix **1118** during positioning. During deployment, inner catheter shaft is extended from catheter shaft, through the cervix **1118** and into uterus **1124**, such that inner catheter shaft is positioned within uterus **1124** proximate a fibroid/tumor/lesion that is required to be treated with ablation. Proximal hood **1196** is deployed proximate an internal cervical os to firmly position the inner catheter shaft within the uterus **1124**. The olive tip **1193** is rounded and bulbous and configured to be atraumatic to body tissues. Openings in olive tip **1193** provide an exit for steam out distal to the positioning element **1195** during ablation. Ports **1197** and openings in olive tip **1193** are then used to deliver steam or vapor to ablate the target area. FIG. **33** shows the presence of steam during an ablation procedure, where the steam is output by plurality of ports **1197** as well as openings in olive tip **1193**. In some embodiments, a 40 second cycle of vapor ablation is delivered to the uterus.

[0107] FIG. **34** is a graph showing temperature in the uterine cavity, the cervical canal and the external fundus, as measured at at least three different points in time during an ablation procedure using the embodiments of the present specification. In the illustrated graph, a first line **1202** is the reading from a thermocouple within the uterine cavity, a second line **1204** is from the cervical canal, a third line **1206** is from the left external fundus, and a fourth line **1208** is

from the right external fundus. As depicted in the illustrated graph, no thermal injury occurs in the cervical canal and the external fundus.

[0108] Using embodiments of the present specification for endometrial ablation, 100% ablation of the endometrial tissue can be obtained in all regions of the uterus without causing any thermal injury to the cervix or the fallopian tubes. Tests conducted using embodiments of the present specification with ablation time of 90 seconds achieved the minimal global triphenyl tetrazolium chloride (TTC)-negative endomyometrial ablation depth of 1.64 mm (min: max 0-3 mm) and the maximum global TTC-negative endomyometrial ablation depth of 3.50 mm (min: max 1-5 mm). TTC is a common enzymatic tetrazolium-based viability stain which detects high-temperature ablations via thermal cellular and extracellular protein denaturation. Results of the staining demonstrated complete (100%) full thickness TTC-negative endometrial ablation in all regions of the uterus in all nine samples regardless of the duration of ablation. The median upper cavity (fundus and corpus), lower uterine cavity, and right and left cornua percentages of TTC-negative surface endometrial treatment were 99.4% (range: 95-100%), 100% (range: 100-100%), 100% (range: 100-100%), and 100% (range: 100-100%) (data not shown). For the samples treated for 120 seconds, the mean minimal global TTC-negative endomyometrial ablation depth was 1.78 mm (SD 1.533, min: max 0-9.7 mm). The mean maximum global TTC negative endomyometrial ablation depth was 12.18 mm (SD 3.92; min: max 1-20 mm). For the sample treated for 45s/30s/45s (90s total ablation), the min: max ablation depth was 1.07:4.79 mm, at 60s/30s/45s (105s total ablation) the min: max ablation depth was 1.36:6.71 mm, and at 90 seconds continuous the min: max ablation depth was 1.64:3.50 mm. Therefore, embodiments achieve complete (100%) distribution of vapor within the uterine cavity.

[0109] Imaging capabilities may be added to the ablation systems used for benign prostatic hyperplasia (BPH), abnormal uterine bleeding (AUB), over-active bladder (OAB), and for any other tissue ablation processes described in the embodiments of the present specification. In embodiments, the imaging capabilities are provided in the form of an integrated optical chip with the ablation system or as a coaxial fiber optical wire with the sheath of the catheter of the ablation system.

[0110] The above examples are merely illustrative of the many applications of the system of the present invention. Although only a few embodiments of the present invention have been described herein, it should be understood that the present invention might be embodied in many other specific forms without departing from the spirit or scope of the invention. Therefore, the present examples and embodiments are to be considered as illustrative and not restrictive, and the invention may be modified within the scope of the appended claims.

What is claimed:

1. An ablation catheter for ablating endometrial tissue of a patient, comprising:

an outer sheath having a first diameter and a length extending between a proximal end and a distal end, the outer sheath configured with at least one opening;

an inner shaft having at least one lumen, wherein the lumen is configured to receive a volume of fluid;

at least one positioning element positioned proximate a proximal or distal end of the inner shaft, wherein the at least one positioning element is configured to expand from a first compressed delivery configuration to a second expanded deployed configuration;

at least one first port positioned on the inner shaft;

an atraumatic tip positioned on a distal end of the inner shaft, wherein the atraumatic tip comprises at least one second port in fluid communication with the inner shaft;

at least one heating component positioned within the lumen, wherein the at least one heating component comprises at least one electrode positioned circumferentially around a central core, and wherein the at least one heating component is configured to convert the volume of fluid received by the lumen to a vapor that exits from the at least one first port and the at least one second port;

and

a handle coupled to a proximal end of the inner shaft.

2. The ablation catheter of claim **1**, wherein the at least one electrode comprises at least one array of electrodes.

3. The ablation catheter of claim **2**, wherein the array of electrodes comprises at least two electrodes having tapered proximal ends, wherein the at least two electrodes are configured to be positioned circumferentially around the central core such that the two tapered proximal ends are offset from one another.

4. The ablation catheter of claim **1**, wherein a wall of the inner shaft comprises at least one insulation layer.

5. The ablation catheter of claim **1**, wherein the core is tapered at a proximal end of the core.

6. The ablation catheter of claim **1**, wherein the at least one positioning element comprises a wire mesh structure.

7. The ablation catheter of claim **1**, wherein the handle comprises at least one sliding button to control movement of the sheath to control deployment of the at least one positioning element.

8. The ablation catheter of claim **1**, further comprising a stabilizer positioned coaxially around an outer circumference of the sheath on a proximal side of the first positioning element, wherein the stabilizer is configured to stabilize and maneuver the sheath during insertion inside the uterine cavity, the stabilizer comprising:

a first proximal section;

a second section attached to and perpendicular the first section;

a third section attached to a distal end of, and at an angled orientation relative to, the second section, wherein the third section extends in a distal direction relative to the second section; and

a fourth section extending in a distal direction relative to the second section, wherein the fourth section is attached to a side of a distal end of the third section, and wherein the fourth section is oriented parallel to the second section, and wherein the fourth section is configured to be hollow to accommodate passage of the sheath.

9. An ablation system for ablating endometrial tissue of a patient, comprising:

a catheter comprising:

an outer sheath having a first diameter and a length extending between a proximal end and a distal end, the outer sheath configured with at least one opening;

an inner shaft having at least one lumen, wherein the lumen is configured to receive a volume of fluid;

at least one positioning element positioned proximate a proximal or distal end of the inner shaft, wherein the at least one positioning element is configured to expand from a first compressed delivery configuration to a second expanded deployed configuration;

at least one first port positioned on the inner shaft;

an atraumatic tip positioned on a distal end of the inner shaft, wherein the atraumatic tip comprises at least one second port in fluid communication with the inner shaft;

at least one heating component positioned within the lumen, wherein the at least one heating component comprises at least one electrode positioned circumferentially around a central core, and wherein the at least one heating component is configured to convert the volume of fluid received by the lumen to a vapor that exits from the at least one first port and the at least one second port; and

a handle coupled to a proximal end of the inner catheter shaft;

a fluid reservoir configured to contain the volume of fluid and in fluid communication with the at least one lumen;

a pump configured to pump fluid from the fluid reservoir into the at least one lumen; and

a controller having at least one processor, wherein the controller is configured to deliver an electrical current to the at least one electrode and to cause the volume of fluid to pass into the lumen from the fluid reservoir when activated.

10. The ablation system of claim **9**, further comprising a power source positioned in the controller.

11. The ablation system of claim **9**, wherein the pump comprises a syringe pump.

12. The ablation system of claim **9**, wherein the at least one electrode comprises at least one array of electrodes.

13. The ablation system of claim **9**, wherein the core is tapered at a proximal end of the core.

14. The ablation system of claim **9**, wherein the controller comprises a foot pedal or switch configured to allow a user to control a flow of fluid to the lumen.

15. The ablation system of claim **9**, wherein the at least one positioning element comprises a wire mesh structure.

16. The ablation system of claim **9**, wherein the handle comprises at least one sliding button to control movement of the sheath to control deployment of the at least one positioning element.

17. The ablation system of claim **9**, further comprising a stabilizer positioned coaxially around an outer circumference of the sheath on a proximal side of the first positioning element, wherein the stabilizer is configured to stabilize and maneuver the sheath during insertion inside the uterine cavity, the stabilizer comprising:

a first proximal section;

a second section attached to and perpendicular the first section;

a third section attached to a distal end of, and at an angled orientation relative to, the second section, wherein the third section extends in a distal direction relative to the second section; and

a fourth section extending in a distal direction relative to the second section, wherein the fourth section is attached to a side of a distal end of the third section, and wherein the fourth section is oriented parallel to the second section, and wherein the fourth section is configured to be hollow to accommodate passage of the sheath.

18. A kit comprising multiple components of an ablation system, the kit comprising:

an ablation catheter comprising:

an outer sheath having a first diameter and a length extending between a proximal end and a distal end, the outer sheath configured with at least one opening;

an inner shaft having at least one lumen, wherein the lumen is configured to receive a volume of fluid;

at least one positioning element positioned proximate a proximal or distal end of the inner shaft, wherein the at least one positioning element is configured to expand from a first compressed delivery configuration to a second expanded deployed configuration;

at least one first port positioned on the inner shaft;

an atraumatic tip positioned on a distal end of the inner shaft, wherein the atraumatic tip comprises at least one second port in fluid communication with the inner shaft;

at least one heating component positioned within the lumen, wherein the at least one heating component comprises at least one electrode positioned circumferentially around a central core, and wherein the at least one heating component is configured to convert the volume of fluid received by the lumen to a vapor that exits from the at least one first port and the at least one second port; and

a handle coupled to a proximal end of the inner catheter shaft;

at least one pump configured to pump fluid from a fluid reservoir into the at least one lumen;

an aspiration catheter;

a substrate comprising a plurality of spaces configured to receive the ablation catheter, at least one pump, and aspiration catheter, wherein at least one first cover portion of the substrate is configured to cover and protect at least one component of the ablation catheter;

a base configured to receive the substrate; and

a lid configured to be positioned over the substrate and secured to the base.

19. The kit of claim **18**, wherein the at least one first cover portion is partially cut out from a remainder of the substrate and is formed by folding the at least one first cover portion over the at least one component of the ablation catheter.

20. The kit of claim **18**, further comprising at least one second cover portion and at least one third cover portion, wherein the at least one first, second, and third cover portions are configured to engage with each other to form an enclosure to cover the at least one component of the ablation catheter.

21. The kit of claim **18**, wherein the lid comprises a plurality of recessed cavities that are recessed according to shapes of the ablation catheter, at least one pump, and aspiration catheter.

22. The kit of claim **18**, wherein at least one space of the plurality of spaces of the substrate is configured to receive the ablation catheter comprising the at least one positioning element configured to expand from a first compressed delivery configuration to a second expanded deployed configuration, wherein the at least one positioning element is in the second expanded deployed configuration when the ablation

catheter is positioned within the at least one space, and wherein the at least one first cover portion is configured to cover and protect the at least one positioning element in the second expanded deployed configuration.

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