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(54) Title: LINER FOR CRYOGENIC TREATMENT SYSTEMS

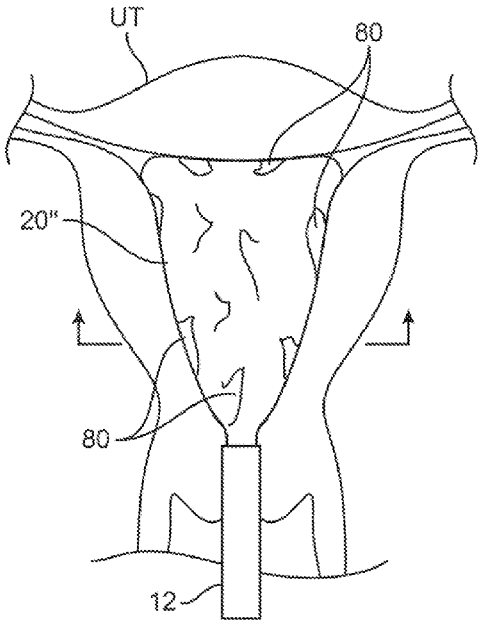


FIG. 5B

(57) Abstract: Liners for cryogenic treatment systems are described where a cryogenic fluid or gas may be introduced into a liner expanded within a body lumen such as the uterine cavity. The liner may be intentionally sized to be substantially larger than the typical size of the uterine cavity, e.g., 1.2 times (or more), greater than the size of the uterine cavity into which the liner is inserted. Because the liner is sized intentionally larger than the body lumen to be treated, the liner may never fully expand when deployed. But even with folds or portions of the liner being folded upon itself, the liner may remain sufficiently supple such that the resulting uncontrolled folds allow for complete conformance of the liner against the anatomy of the contacted tissue.

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LINER FOR CYROGENIC TREATMENT SYSTEMS

FIELD OF THE INVENTION

[0001] The present invention relates to medical devices. In particular, the present invention relates to methods and apparatus for liners which are used in therapeutic devices for cryoablating tissue in bodies with variable anatomy.

BACKGROUND OF THE INVENTION

[0002] In the last few decades, therapeutic intervention within a body cavity or lumen has developed rapidly with respect to delivery of energy via radiofrequency ablation. While successful in several arenas, radiofrequency ablation has several major downsides, including incomplete ablation, frequent lack of visualization during catheter insertion, potential for overlap during treatment (with some areas receiving twice as much energy as other areas), charring of tissues and requirements for frequent debridement, frequent requirements for additional doses of energy after debridement, and potential perforation of the body cavity or lumen due to the rigidity of the RF electrodes.

[0003] The current state of the art would benefit from minimally invasive devices and methods which deliver thermal energy to a desired area or extract energy from a desired area, in a consistent, controlled manner particularly in regions of the body which have variable anatomy.

SUMMARY OF THE INVENTION

[0004] An aspect of the present invention provides a tissue treatment system, comprising:

an elongate probe having a distal tip and a flexible length;

at least one infusion lumen positioned through or along the elongate probe, wherein the infusion lumen defines one or more openings along its length;

at least one delivery lumen slidingly positioned through or along the at least one infusion lumen, wherein translation of the at least one delivery lumen relative to the at least one infusion lumen controls a number of unobstructed openings along the at least one infusion lumen; and

a liner enclosing the elongate probe and being expandable from a delivery configuration to an expanded configuration which is sized to be greater than a body lumen to be treated,

wherein the liner defines a suppleness such that expansion of the liner within the body lumen causes portions of the liner to fold upon itself to form between 1 to 3 layers of the liner while conforming against a tissue surface of the body lumen, and

wherein the liner is formed of two sheets of membrane which are welded to one another to form a flattened shape in which the liner tapers and in its expanded configuration forms a contoured shape.

[0005] A further aspect of the present invention provides a method of treating tissue, comprising:

positioning an elongate probe into a body lumen to be treated;

expanding a liner enclosing the probe from a delivery configuration to an expanded configuration which is sized to be greater than the body lumen, wherein the liner defines a suppleness such that expansion of the liner causes portions of the liner to fold upon itself to form 1 to 3 layers of the liner while conforming against a tissue surface of the body lumen; and where the liner is formed of two sheets of membrane which are welded to one another to form a flattened shape in which the liner tapers and in its expanded configuration forms a contoured shape;

infusing a cryoablative fluid or gas through a delivery lumen such that the fluid or gas passes into an infusion lumen, through the unobstructed openings, and into contact against an interior of the liner; and

further comprising adjusting a position of the delivery lumen relative to the infusion lumen which is positioned through or along the elongate probe such that one or more openings defined along a length of the infusion lumen remain unobstructed by the delivery lumen.

[0006] An elongate shaft may be introduced through the cervix and into the uterus until the distal opening of the shaft is positioned distal to the internal os and a liner may be deployed either from within the shaft or from an external sheath. The liner may be deployed and allowed to unfurl or unwrap within the uterus allowing a cooling probe to be introduced through the shaft and into the balloon interior. The cooling probe positioned within the liner may be variously configured and may include further variations.

[0007] As the cryoablative fluid is introduced into and distributed throughout the catheter lumen, the exhaust catheter may also define one or more openings to allow for the cryoablative fluid to vent or exhaust from the catheter interior and into the interior of the balloon. A coolant reservoir, e.g., nitrous oxide canister, may be fluidly coupled to

the handle and/or elongate shaft via a coolant valve which may be optionally controlled by a microcontroller. The coolant reservoir may be in fluid communication with the cooling probe assembly and with the interior of the liner. Additionally, an exhaust lumen in communication with the elongate probe and having a back pressure valve may also include a pressure sensor where one or both of the back pressure sensor and/or valve may also be in communication with the microcontroller.

[0008] Further details of the various probes and assemblies which may be used with any of the features described herein are described in the following U.S. Pat. Apps. 13/361,779 filed January 30, 2012 and 13/900,916 filed May 23, 2013, each of which is incorporated herein by reference in its entirety. Any of the embodiments described herein are intended to be used in any number of combinations with the features of the devices and methods described in these referenced applications.

[0009] Because the liner is used to contact the tissue and thermally conduct the heat through the liner, the liner material may be comprised of various materials such as polyurethane, fluorinated ethylene propylene (FEP), polyether ether ketone (PEEK), low density polyethylene, polyethylene terephthalate (PET), polyvinylidene fluoride (PVDF), or any number of other conformable polymers. Moreover, the liner material may have a thickness which remains flexible and strong yet sufficiently thermally conductive, e.g., about 0.0005 in (0.0127 mm) to 0.015 in (0.381 mm) or about 0.001 in. (0.0254 mm) on average. Such a thickness may allow for the liner to remain supple enough to conform desirably to the underlying tissue anatomy and may also provide sufficient clarity for visualizing through the material with, e.g., a hysteroscope.

[0010] Once the balloon or liner is initially deployed, it may be expanded by an initial burst of a gas, e.g., air, carbon dioxide, etc., or by the cryogenic fluid. In particular, the tapered portions of the balloon or liner may be expanded to ensure contact with the uterine cornua. The handle assembly may also be used to actuate and control a longitudinal position of the cooling probe relative to the elongate shaft and balloon or liner. The pre-treatment infusion of air as well as the methods for treatment and thawing may be utilized with any of the liner, probe, or apparatus variations described herein. Moreover, the pre-treatment, treatment, or post-treatment procedures may be utilized altogether in a single procedure or different aspects of such procedures may be used in varying combinations depending upon the desired results.

[0011] An infusion line may pass from the handle assembly and along or within the sheath and into the interior of the liner. The infusion line may be aligned along the

probe such that the infusion line is parallel with a longitudinal axis of the probe and extends towards the distal tip of the probe. Moreover, the infusion line may be positioned along the probe such that the line remains exposed to the corners of the liner which extend towards the cornua. With the infusion line positioned accordingly, the length of the line within the liner may have multiple openings formed along its length which act as delivery ports for the infused cryogenic fluid or gas. A separate translating delivery line, e.g., formed of a Nitinol tube defining an infusion lumen therethrough, may be slidably positioned through the length of the infusion line such that the delivery line may be moved relative to the infusion line which remains stationary relative to the probe.

[0012] The openings along the length of the infusion line may be positioned such that the openings are exposed to the sides of the interior of the liner, e.g., cross-drilled. As the cryogenic fluid or gas is introduced through the delivery line, the infused cryogenic fluid or gas may pass through the infusion line and then out through the openings defined along the infusion line. By adjusting the translational position of the delivery line, the delivery line may also cover a selected number of the openings resulting in a number of open delivery ports as well as closed delivery ports which are obstructed by the delivery line position relative to the infusion line.

[0013] By translating the delivery line accordingly, the number of open delivery ports and closed delivery ports may be adjusted depending on the desired treatment length and further ensures that only desired regions of the uterine tissue are exposed to the infused cryogenic fluid or gas. Once the number of open delivery ports has been suitably selected, the infused cryogenic fluid or gas may bypass the closed delivery ports obstructed by the delivery line and the fluid or gas may then be forced out through the open delivery ports in a transverse direction as indicated by the infusion spray direction. The terminal end of the infusion line may be obstructed to prevent the distal release of the infused fluid or gas from its distal end. Although in other variations, the terminal end of the infusion line may be left unobstructed and opened.

[0014] Turning now to the liner itself, the liner may be formed to have, e.g., a nominal 0.001 in. (0.0254 mm) (or more particularly 0.0012 in. +0.0004 in. / -0.0003 in. (0.003048 mm +0.01016 mm / -0.00762 mm)) thick flexible membrane such as polyurethane or PELLETHANE® (Lubrizol Advanced Materials, Inc., Cleveland, OH). The liner **20** may be optionally formed as a composite from one or more sheets of material, e.g., two sheets of membrane which are RF welded. When laid out in a flattened shape, the liner may shaped in a manner which allows the liner to inflate or

expand into a contoured shape which conforms closely to a uterine cavity. The liner itself may be formed to have a uniform thickness over the entire liner. Alternatively, different portions of the liner may also be formed to have differing thicknesses depending upon the desired degree of treatment along differing portions of the liner. For instance, the liner may have varying regions of thickness along proximal portions of the liner relative to distal portions of the liner.

[0015] Moreover, to facilitate smooth retraction of the sheath and consistent deployment, the liner may be pleated to fold and collapse in a consistent manner. Because of the thickness of the liner and its suppleness, the liner may conform against the anatomy of the contacted tissue surface. However, the liner may be intentionally sized to be substantially larger than the typical size of the uterine cavity which can average, e.g., about 10 ml for relatively small cavities, about 20 ml for medium sized cavities, and about 50 ml or greater for relatively large size cavities. For instance, the liner may be sized to be, e.g., 1.2 times (or more), greater than the size of the uterine cavity into which the liner is inserted. Because the liner may be sized to be intentionally larger than the uterine cavity to be treated, the liner may never fully expand when deployed within the uterus.

[0016] Because liner is constrained from fully expanding within the uterus, folds or portions of the liner may overlap upon itself over the surface of the liner in contact against the surrounding tissue. This is particularly so since the material of the liner may be non-distensible so as to prevent the full deployment of the liner within the uterine cavity. Even with folds or portions of the liner being folded upon itself, the liner may remain sufficiently supple such that the resulting uncontrolled folds allow for complete conformance of the liner against the anatomy of the contacted tissue. Moreover, the thickness of the liner may allow for the heat to be sufficiently conducted from the underlying tissue through, e.g., 1 to 3 layers of the liner, which may result in an overall thickness through the folded liner layers of, e.g., 0.001 in. to 0.003 in. (0.0254 mm to 0.0762 mm)

[0017] While the liner may be oversized to enable the liner to deliberately fold upon or over itself when contacting the underlying tissue, the formation of the folds or portions may occur randomly over the expanded liner. Alternatively, portions of the liner may be optionally pleated or folded such that liner expansion may preferentially cause these pleated or folded sections to fold against the surrounding tissue surface. Having the liner intentionally sized to be larger than the uterine cavity (or any other body lumen) into

which the liner is placed may not only ensure that the liner is inhibited from over-expanding, but this also keeps the liner membrane from distending, particularly when frozen, so as to prevent or inhibit the liner from fracturing or ripping during or after treatment.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] Figure 1A shows a side view of an integrated treatment assembly.

[0019] Figure 1B shows an example of the assembly advanced through the cervix and into the uterus where the sheath may be retracted via the handle assembly to deploy the balloon.

[0020] Figure 1C shows a perspective view of a cryoablation assembly having a handle assembly which may integrate the electronics and pump assembly within the handle itself.

[0021] Figure 1D shows the handle assembly in a perspective exploded view illustrating some of the components which may be integrated within the handle.

[0022] Figures 2A and 2B show cross-sectional side views of yet another variation of a cooling probe which utilizes a single infusion line in combination with a translatable delivery line.

[0023] Figures 3A and 3B show top and perspective views of the expanded liner with four pairs of the open delivery ports exposed in apposed direction.

[0024] Figures 4A and 4B show top and perspective views of a liner illustrating its curved features when flattened and expanded and then deployed in a consistent manner.

[0025] Figure 4C shows a perspective view of a liner which may be pleated to fold and collapse in a consistent manner.

[0026] Figure 5A shows the liner in its compacted shape when first deployed or expanded.

[0027] Figure 5B shows an example of the liner having portions folded upon itself when expanded into full conformance within the uterus.

[0028] Figure 5C shows an example of the liner when fully expanded to its maximum configuration outside of the uterus.

[0029] Figure 5D shows a partial cross-sectional end view of the liner folded upon itself when expanded into contact against the tissue surface.

DETAILED DESCRIPTION OF THE INVENTION

[0030] In treating an expandable and/or variably sized body lumen such as the uterus, a device generally having a cooling probe and a reconfigurable liner may be advanced within the body lumen and expanded into contact against the interior tissue surface. The liner may be configured to conform against the interior tissue surface and to resist rupture at low and high temperatures. For example, the liner when expanded may have a shape which approximates the body lumen in which it is inflated and/or come in various sizes to accommodate different patient anatomies. The liner may be formed to taper and have two rounded portions for expanding into intimate contact at the uterine cornu without painful deformation or distention of the uterus at a pressure, e.g., less than 150 mmHg.

[0031] Moreover, the liner may have a wall which is relatively thin (e.g., 0.040 in. or less (1.016 mm or less)) to facilitate thermal conduction through the liner material. The liner may also be sufficiently thin such that folding of the liner on itself does not create a significant thermal barrier allowing for an even ablation in the event that a non-compliant liner is used. Generally, once the elongate shaft has been introduced through the cervix and into the uterus, the distal opening of the shaft may be positioned distal to the internal os and the liner may be deployed either from within the shaft or from an external sheath (described below in further detail). The liner may be deployed and allowed to unfurl or unwrap within the uterus. A cooling probe may be introduced through the shaft and into the liner interior.

[0032] Further details of the various probes and assemblies which may be used with any of the features described herein are described in the following U.S. Pat. Apps. 13/361,779 filed January 30, 2012 and 13/900,916 filed May 23, 2013, each of which is incorporated herein by reference in its entirety. Any of the embodiments described herein are intended to be used in any number of combinations with the features of the devices and methods described in these referenced applications.

[0033] Because the liner is used to contact the tissue and thermally conduct the heat through the liner, the liner material may be comprised of various materials such as polyurethane, fluorinated ethylene propylene (FEP), polyether ether ketone (PEEK), low density polyethylene, polyethylene terephthalate (PET), polyvinylidene fluoride (PVDF),

or any number of other conformable polymers. Moreover, the liner material may have a thickness which remains flexible and strong yet sufficiently thermally conductive, e.g., about 0.0005 in. (0.0127 mm) to 0.015 in. (0.381 mm) or about 0.001 in. (0.0254 mm) on average. Such a thickness may allow for the liner to remain supple enough to conform desirably to the underlying tissue anatomy and may also provide sufficient clarity for visualizing through the material with, e.g., a hysteroscope.

[0034] The cooling probe **22** as well as the balloon assembly may be variously configured, for instance, in an integrated treatment assembly **10** as shown in the side view of Figure 1A. In this variation, the assembly **10** may integrated the elongate shaft **18** having the balloon or liner **20** extending therefrom with the cooling probe **22** positioned translatably within the shaft **18** and balloon or liner **20**. A separate translatable sheath **12** may be positioned over the elongate shaft **18** and both the elongate shaft **18** and sheath **12** may be attached to a handle assembly **14**. The handle assembly **14** may further comprise an actuator **16** for controlling a translation of the sheath **12** for balloon or liner **20** delivery and deployment. The sheath **12** may be configured to have a diameter of, e.g., 5.5 mm or less, to prevent the need for dilating the cervix.

[0035] With the sheath **12** positioned over the elongate shaft **18** and balloon or liner **20**, the assembly **10** may be advanced through the cervix and into the uterus **UT** where the sheath **12** may be retracted via the handle assembly **14** to deploy the balloon or liner **20**, as shown in Figure 1B. As described above, once the balloon or liner **20** is initially deployed from the sheath **12**, it may be expanded by an initial burst of a gas, e.g., air, carbon dioxide, etc., or by the cryogenic fluid. In particular, the tapered portions of the balloon or liner **20** may be expanded to ensure contact with the uterine cornu. The handle assembly **14** may also be used to actuate and control a longitudinal position of the cooling probe **22** relative to the elongate shaft **18** and balloon or liner **20** as indicated by the arrows.

[0036] In another variation of the treatment assembly, Figure 1C shows a perspective view of a cryoablation assembly having a handle assembly **30** which may integrate the electronics and pump assembly **34** within the handle itself. An exhaust tube **32** may also be seen attached to the handle assembly **30** for evacuating exhausted or excess cryoablative fluid or gas from the liner **20**. Any of the cryogenic fluids or gases described herein may be utilized, e.g., compressed liquid-to-gas phase change of a compressed gas such as nitrous oxide (N_2O), carbon dioxide (CO_2), Argon, etc. The cooling probe **22** may be seen extending from sheath **12** while surrounded or enclosed by

the balloon or liner **20**. Hence, the handle assembly **30** with coupled cooling probe **22** and liner **20** may provide for a single device which may provide for pre-treatment puff-up or inflation of the liner **20**, active cryoablation treatment, and/or post-treatment thaw cycles.

[0037] The handle assembly **30** may also optionally incorporate a display for providing any number of indicators and/or alerts to the user. For instance, an LCD display may be provided on the handle assembly **30** (or to a separate control unit connected to the handle assembly **30**) where the display counts down the treatment time in seconds as the ablation is occurring. The display may also be used to provide measured pressure or temperature readings as well as any number of other indicators, symbols, or text, etc., for alerts, instructions, or other indications. Moreover, the display may be configured to have multiple color-coded outputs, e.g., green, yellow, and red. When the assembly is working through the ideal use case, the LED may be displayed as a solid green color. When the device requires user input (e.g. when paused and needing the user to press the button to re-start treatment) the LED may flash or display yellow. Additionally, when the device has faulted and treatment is stopped, the LED may flash or display a solid red color.

[0038] Figure 1D shows the handle assembly **30** in a perspective exploded view to illustrate some of the components which may be integrated within the handle **30**. As shown, the liner **20** and sheath **12** may be coupled to a sheath bearing assembly **38** and slider base block assembly **40** for controlling the amount of exposed treatment length along the cooling probe **22** (and as described in further detail below). An actuatable sheath control **42** may be attached to the slider base block assembly **40** for manually controlling the treatment length of the cooling probe **22** as well. Along with the electronics and pump assembly **34** (which may optionally incorporate a programmable processor or controller in electrical communication with any of the mechanisms within the handle **30**), an exhaust valve **36** (e.g., actuated via a solenoid) may be coupled to the exhaust line **32** for controlling not only the outflow of the exhausted cryoablation fluid or gas but also for creating or increasing a backpressure during treatment, as described in further detail below.

[0039] Alternatively, an active system may be integrated into the handle or coupled to the handle **30** where a heat sink may be connected to a temperature sensor and electrical circuit which is controlled by a processor or microcontroller. The heat sink may promote heat transfer and causes any liquid exhaust to evaporate. When the temperature

of the heat sink reaches the boiling temperature of, e.g., nitrous oxide (around -89 °C), the handle may be configured to slow or stop the delivery of the cryogenic fluid or gas to the uterine cavity.

[0040] The pre-treatment infusion of air as well as the methods for treatment and thawing may be utilized with any of the liner, probe, or apparatus variations described herein. Moreover, the pre-treatment, treatment, or post-treatment procedures may be utilized altogether in a single procedure or different aspects of such procedures may be used in varying combinations depending upon the desired results.

[0041] Additionally and/or optionally, the handle **30** may incorporate an orientation sensor to facilitate maintaining the handle **30** in a desirable orientation for treatment. One variation may incorporate a ball having a specific weight covering the exhaust line **32** such that when the handle **30** is held in the desirable upright orientation, the treatment may proceed uninterrupted. However, if the handle **30** moved out of its desired orientation, the ball may be configured to roll out of position and trigger a visual and/or auditory alarm to alert the user. In another variation, an electronic gyroscopic sensor may be used to maintain the handle **30** in the desired orientation for treatment.

[0042] Figures 2A and 2B show cross-sectional side views of yet another variation of a cooling probe which utilizes a single infusion line in combination with a translatable delivery line. To accommodate various sizes and shapes of uterine cavities, the cooling probe may have a sliding adjustment that may be set, e.g., according to the measured length of the patient's uterine cavity. The adjustment may move along the sheath along the exhaust tube as well as the delivery line within the infusion line. The sheath may constrain the liner **20** and also control its deployment within the cavity.

[0043] In this variation, an infusion line **50** (as described above) may pass from the handle assembly and along or within the sheath and into the interior of liner **20**. The infusion line **50** may be aligned along the probe **22** such that the infusion line **50** is parallel with a longitudinal axis of the probe **22** and extends towards the distal tip **58** of the probe **22**. Moreover, the infusion line **50** may be positioned along the probe **22** such that the line **50** remains exposed to the corners of the liner **20** which extend towards the cornua. With the infusion line **50** positioned accordingly, the length of the line **50** within the liner **20** may have multiple openings formed along its length which act as delivery ports for the infused cryogenic fluid or gas. A separate translating delivery line **56**, e.g., formed of a Nitinol tube defining an infusion lumen therethrough, may be slidably positioned through the length of the infusion line **50** such that the delivery line **56** may be

moved (as indicated by the arrows in Figure 2A) relative to the infusion line **50** which remains stationary relative to the probe **22**.

[0044] The openings along the length of the infusion line **50** may be positioned such that the openings are exposed to the sides of the interior of the liner **20**, e.g., cross-drilled. As the cryogenic fluid or gas is introduced through the delivery line **56**, the infused cryogenic fluid or gas **60** may pass through the infusion line **50** and then out through the openings defined along the infusion line **50**. By adjusting the translational position of the delivery line **56**, the delivery line **56** may also cover a selected number of the openings resulting in a number of open delivery ports **52** as well as closed delivery ports **54** which are obstructed by the delivery line **56** position relative to the infusion line **50**, as shown in the top view of Figure 2B.

[0045] By translating the delivery line **56** accordingly, the number of open delivery ports **52** and closed delivery ports **54** may be adjusted depending on the desired treatment length and further ensures that only desired regions of the uterine tissue are exposed to the infused cryogenic fluid or gas **60**. Once the number of open delivery ports **52** has been suitably selected, the infused cryogenic fluid or gas **60** may bypass the closed delivery ports **54** obstructed by the delivery line **56** and the fluid or gas may then be forced out through the open delivery ports **52** in a transverse direction as indicated by the infusion spray direction **62**. The terminal end of the infusion line **50** may be obstructed to prevent the distal release of the infused fluid or gas **60** from its distal end. Although in other variations, the terminal end of the infusion line **50** may be left unobstructed and opened.

[0046] Figures 3A and 3B show top and perspective views of the expanded liner **20** with four pairs of the open delivery ports **52** exposed in apposed direction. Because the infused fluid or gas **60** may be injected into the liner **20**, e.g., as a liquid, under relatively high pressure, the injected cryogenic liquid may be sprayed through the open delivery ports **52** in a transverse or perpendicular direction relative to the cooling probe **22**. The laterally infused cryogenic fluid **62** may spray against the interior of the liner **20** (which is contacted against the surrounding tissue surface) such that the cryogenic liquid **62** coats the interior walls of the liner **20** due to turbulent flow causing heavy mixing. As the cryogenic liquid **62** coats the liner surface, the sprayed liquid **62** may absorb heat from the tissue walls causing rapid cooling of the tissue while also evaporating the liquid cryogen to a gas form that flows out through the cooling probe **22**. This rapid cooling and evaporation of the cryogenic liquid **62** facilitates the creation of a fast and deep ablation

over the tissue. During treatment, the temperature within the cavity typically drops, e.g., -89° C, within 6-7 seconds after the procedure has started. While the interior walls of the liner **20** are first coated with the cryogenic liquid **62**, the cryogenic liquid **62** may no longer change phase as the procedure progresses.

[0047] Turning now to the liner itself, the liner may be formed to have, e.g., a nominal 0.001 in. (0.0254 mm) (or more particularly 0.0012 in. +0.0004 in. / -0.0003 in. (0.03048 mm +0.01016 mm / -0.00762 mm)) thick flexible membrane such as polyurethane or PELLETHANE® (Lubrizol Advanced Materials, Inc., Cleveland, OH). The liner **20** may be optionally formed as a composite from one or more sheets of material, e.g., two sheets of membrane which are RF welded. When laid out in a flattened shape, the liner **20** may shaped in a manner, as shown in the top view of Figure 4A, which allows the liner **20** to inflate or expand into a contoured shape which conforms closely to a uterine cavity, as shown in the perspective view of Figure 4B. Figure 4A shows one example of a flattened liner **20** which gently tapers from the opening to a curved shape forming a first curved portion **70A** and a second curved portion **70B** opposite to the first curved portion **70A**. The liner **20** may hence taper gently from a first width **W1**, e.g., about 2.4 in. (about 60.96 mm), down to a second width **W2**, e.g., about 0.3 in. (about 7.62 mm), over a length **L1** of, e.g., about 3.5 in. (about 88.9 mm). The neck may form a length **L2**, e.g., about 0.9 in. (about 22.86 mm).

[0048] The region between each of the first and second curved portions **70A**, **70B** may also be curved to have a radius **R1** of, e.g., about 3.5 in. (about 88.9 mm), while curved portions **70A**, **70B** may also be curved to each have a radius **R2** of, e.g., about 0.3 in. (about 7.62 mm). The portion of the liner proximal to the portions **70A**, **70B** may also have a radius **R3**, e.g., about 1.1 in. (about 27.94 mm), and an oppositely radiused portion of radius **R4**, e.g., about 8.0 in. (about 203.2 mm). The region between the liner **20** and neck may further have a radius **R5**, e.g., about 0.2 in. (about 5.08 mm).

[0049] The liner **20** itself may be formed to have a uniform thickness over the entire liner. Alternatively, different portions of the liner **20** may also be formed to have differing thicknesses depending upon the desired degree of treatment along differing portions of the liner **20**. For instance, the liner **20** may have varying regions of thickness **T1**, **T2**, **T3** along proximal portions of the liner relative to distal portions of the liner.

[0050] Moreover, to facilitate smooth retraction of the sheath and consistent deployment, the liner **20** may be pleated to fold and collapse in a consistent manner, as

shown in the perspective view of Figure 4C. The liner **20** may be pleated, e.g., using a fixture during manufacturing.

[0051] Because of the thickness of the liner **20** and its suppleness, the liner **20** may conform against the anatomy of the contacted tissue surface. However, the liner **20** may be intentionally sized to be substantially larger than the typical size of the uterine cavity which can average, e.g., about 10 ml for relatively small cavities, about 20 ml for medium sized cavities, and about 50 ml or greater for relatively large size cavities. For instance, the liner **20** may be sized to be, e.g., 1.2 times (or more), greater than the size of the uterine cavity into which the liner **20** is to be inserted. Because the liner **20** may be sized to be intentionally larger than the uterine cavity to be treated, the liner **20** may never fully expand when deployed within the uterus **UT**. An example is illustrated in the side views of Figures 5A to 5C. Figure 5A shows the liner **20'** in its compacted shape when first deployed or expanded. Figure 5B shows an example of the liner **20''** when expanded into full conformance within the uterus **UT** and Figure 5C shows an example of the liner **20'''** when fully expanded to its maximum configuration outside of the uterus **UT**. The profile of liner **20'''** is provided for comparison against the constrained expansion of the liner **20''** within the uterus **UT**.

[0052] Because liner **20''** is constrained from fully expanding within the uterus **UT**, as shown in Figure 5B, folds or portions **80** of the liner **20''** may overlap upon itself over the surface of the liner in contact against the surrounding tissue. This is particularly so since the material of the liner **20''** may be non-distensible so as to prevent the full deployment of the liner **20''** within the uterine cavity **UT**.

[0053] In other variations, the liner may be optionally distensible so that the liner is able to be stretched to accommodate a body lumen which may be larger than the liner. For instance, the liner may have an internal volume of, e.g., 40 ml, when the liner is expanded but un-distended or un-stretched. For body lumens having a volume greater than 40 ml, the liner may be optionally expanded until stretched to, e.g., about 400 ml when pressurized to less than 20 mmHg, to ensure contact with the tissue surfaces before the liner ruptures. Even with such a distensible liner, the liner may still have folds or portions **80** which may overlap upon itself over the surface of the liner in contact with the surrounding tissue without having any appreciable effect on the thermal heat transfer across the folds.

[0054] Even with folds or portions **80** of the liner being folded upon itself, the liner **20''** may remain sufficiently supple such that the resulting uncontrolled folds allow

for complete conformance of the liner **20''** against the anatomy of the contacted tissue, as shown in the partial cross-sectional end view of Figure 5D. Moreover, the thickness of the liner **20''** may allow for the heat to be sufficiently conducted from the underlying tissue through, e.g., 1 to 3 layers of the liner, which may result in an overall thickness through the folded liner layers of, e.g., 0.001 in. (0.0254 mm) to 0.003 inches (0.0762 mm).

[0055] While the liner **20** may be oversized to enable the liner **20** to deliberately fold upon or over itself when contacting the underlying tissue, the formation of the folds or portions **80** may occur randomly over the expanded liner. Alternatively, portions of the liner **20** may be optionally pleated or folded such that liner expansion may preferentially cause these pleated or folded sections to fold against the surrounding tissue surface. Having the liner intentionally sized to be larger than the uterine cavity **UT** (or any other body lumen) into which the liner is placed may not only ensure that the liner is inhibited from over-expanding, but this also keeps the liner membrane from distending, particularly when frozen, so as to prevent or inhibit the liner **20** from fracturing or ripping during or after treatment.

[0056] While illustrative examples are described above, it will be apparent to one skilled in the art that various changes and modifications may be made therein. Moreover, various apparatus or procedures described above are also intended to be utilized in combination with one another, as practicable. The appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

2014321567 18 May 2018

CLAIMS

What is claimed is:

1. A tissue treatment system, comprising:

an elongate probe having a distal tip and a flexible length;

at least one infusion lumen positioned through or along the elongate probe, wherein the infusion lumen defines one or more openings along its length;

at least one delivery lumen slidingly positioned through or along the at least one infusion lumen, wherein translation of the at least one delivery lumen relative to the at least one infusion lumen controls a number of unobstructed openings along the at least one infusion lumen; and

a liner enclosing the elongate probe and being expandable from a delivery configuration to an expanded configuration which is sized to be greater than a body lumen to be treated,

wherein the liner defines a suppleness such that expansion of the liner within the body lumen causes portions of the liner to fold upon itself to form between 1 to 3 layers of the liner while conforming against a tissue surface of the body lumen, and

wherein the liner is formed of two sheets of membrane which are welded to one another to form a flattened shape in which the liner tapers and in its expanded configuration forms a contoured shape.

2. The system of claim 1 wherein the liner is sized to be substantially larger than a uterine cavity.

3. The system of claim 2 wherein the liner is sized to be at least 1.2 times greater than the uterine cavity into which the liner is inserted.

4. The system of claim 1 wherein the liner is configured to fold upon itself in an uncontrolled manner against the tissue surface.

5. The system of claim 1 wherein the liner is configured to have pre-formed folds or pleats such that the portions of the liner are folded in a controlled manner against the tissue surface.

6. The system of claim 1 wherein the portions are folded to a thickness of between 0.001 in. (0.0254 mm) to 0.003 in. (0.0762 mm) of the liner.

7. The system of claim 1 wherein the delivery lumen comprises a Nitinol delivery tube slidingly positioned through the infusion lumen.

8. The system of claim 1 further comprising a reservoir of a cryoablative fluid in fluid communication with the delivery lumen.

9. The system of claim 8 wherein the cryoablative fluid comprises nitrous oxide or argon.

10. A method of treating tissue, comprising:

positioning an elongate probe into a body lumen to be treated;

expanding a liner enclosing the probe from a delivery configuration to an expanded configuration which is sized to be greater than the body lumen, wherein the liner defines a suppleness such that expansion of the liner causes portions of the liner to fold upon itself to form 1 to 3 layers of the liner while conforming against a tissue surface of the body lumen; and where the liner is formed of two sheets of membrane which are welded to one another to form a flattened shape in which the liner tapers and in its expanded configuration forms a contoured shape;

infusing a cryoablative fluid or gas through a delivery lumen such that the fluid or gas passes into an infusion lumen, through the unobstructed openings, and into contact against an interior of the liner; and

further comprising adjusting a position of the delivery lumen relative to the infusion lumen which is positioned through or along the elongate probe such that one or more openings defined along a length of the infusion lumen remain unobstructed by the delivery lumen.

11. The method of claim 10 wherein the liner is sized to be at least 1.2 times greater than a uterine cavity into which the liner is inserted.

12. The method of claim 10 wherein expanding a liner comprises causing the portions of the liner to fold upon itself in an uncontrolled manner against the tissue surface.

13. The method of claim 10 wherein expanding a liner comprises causing the portions of the liner to fold upon itself in a controlled manner along pre-formed folds or pleats defined along the liner and against the tissue surface.

14. The method of claim 10 wherein expanding a liner comprises folding the portions to a thickness of between 0.001 in. (0.0254 mm) to 0.003 in. (0.0762 mm) of the liner.

15. The method of claim 10 wherein expanding a liner comprises infusing one or more puffs of air into the liner until the liner conforms to the body lumen.

16. The method of claim 10 wherein infusing a cryoablative fluid comprises infusing nitrous oxide or argon into the interior of the liner.

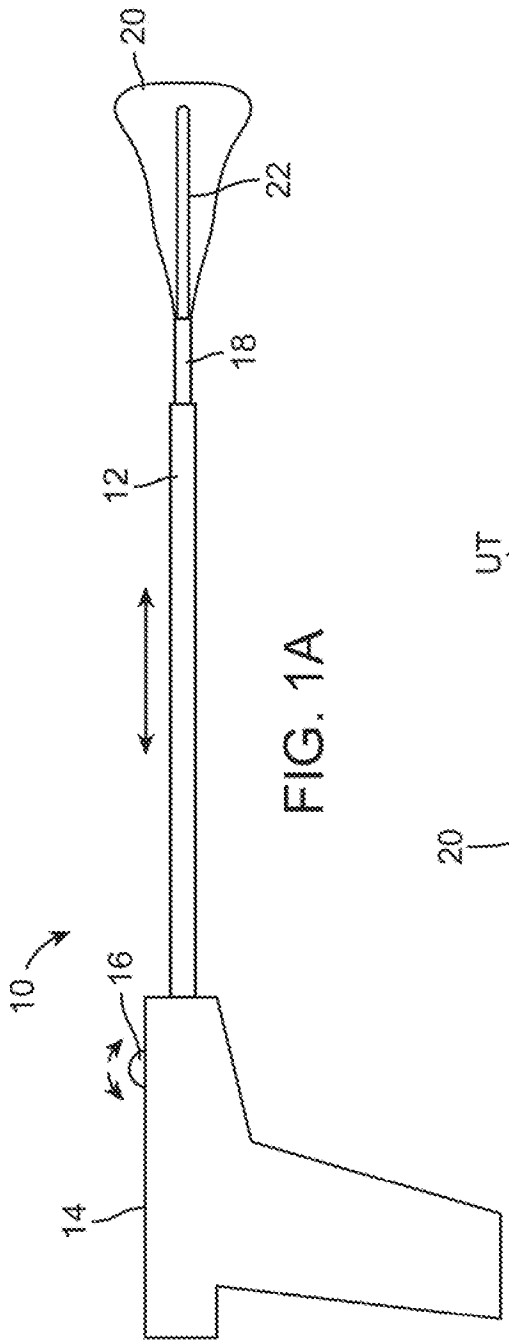


FIG. 1A

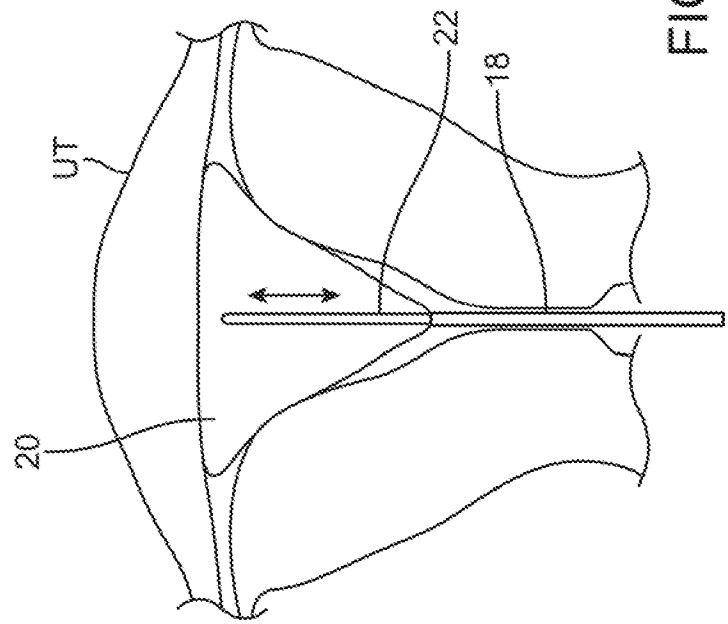


FIG. 1B

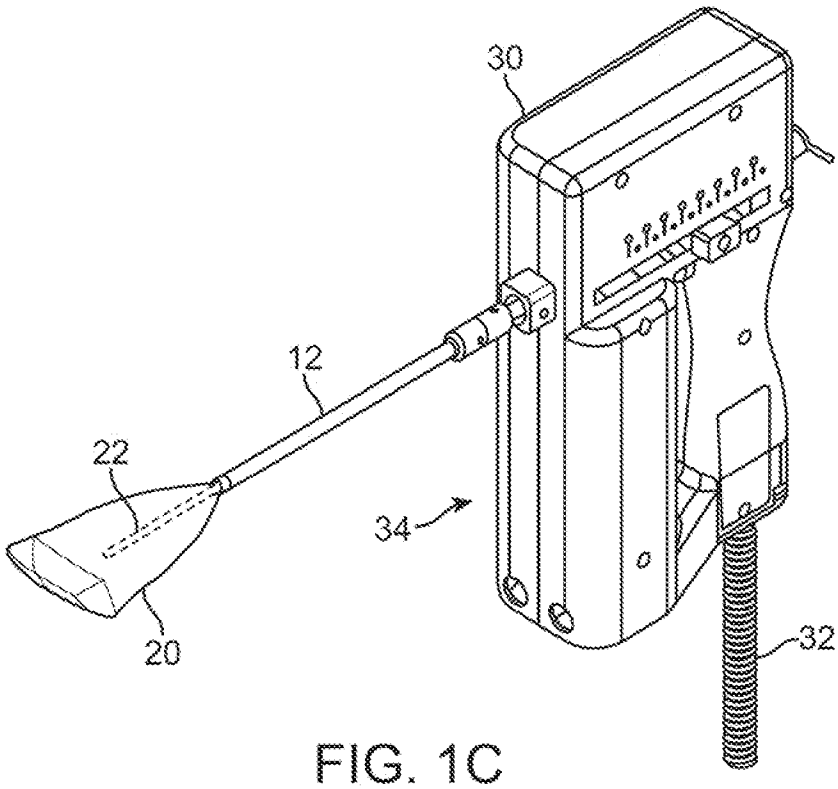


FIG. 1C

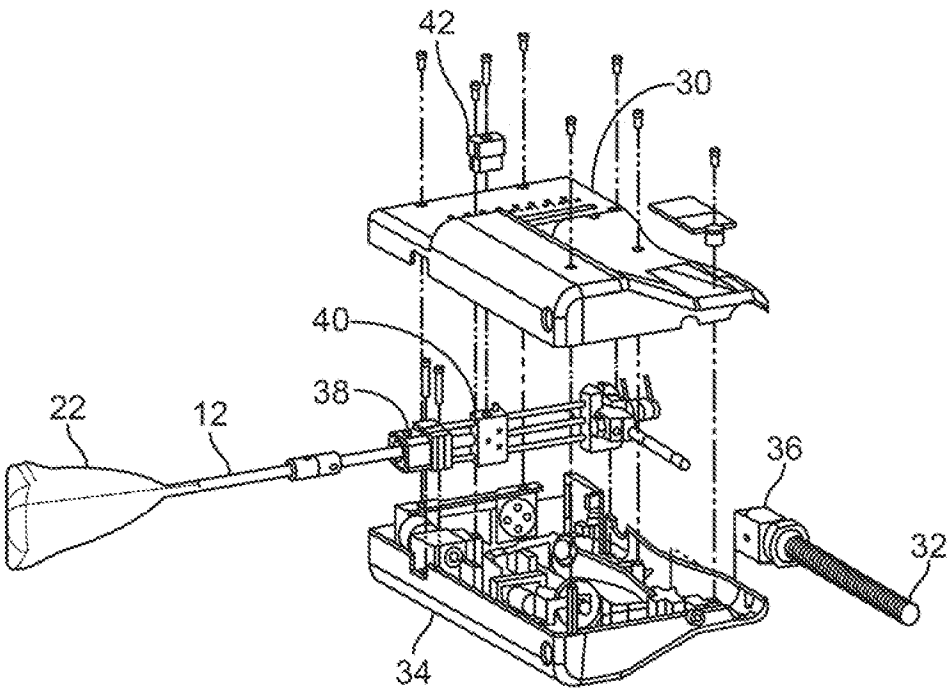


FIG. 1D

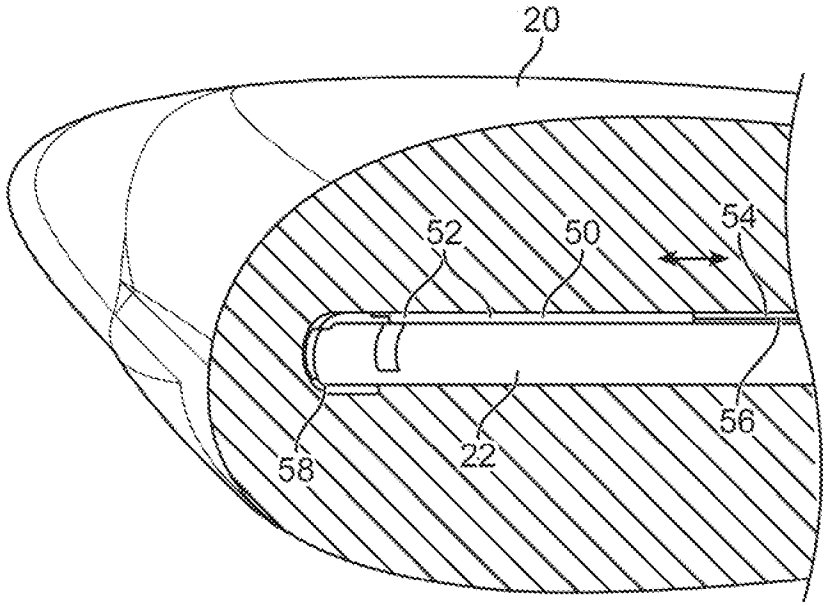


FIG. 2A

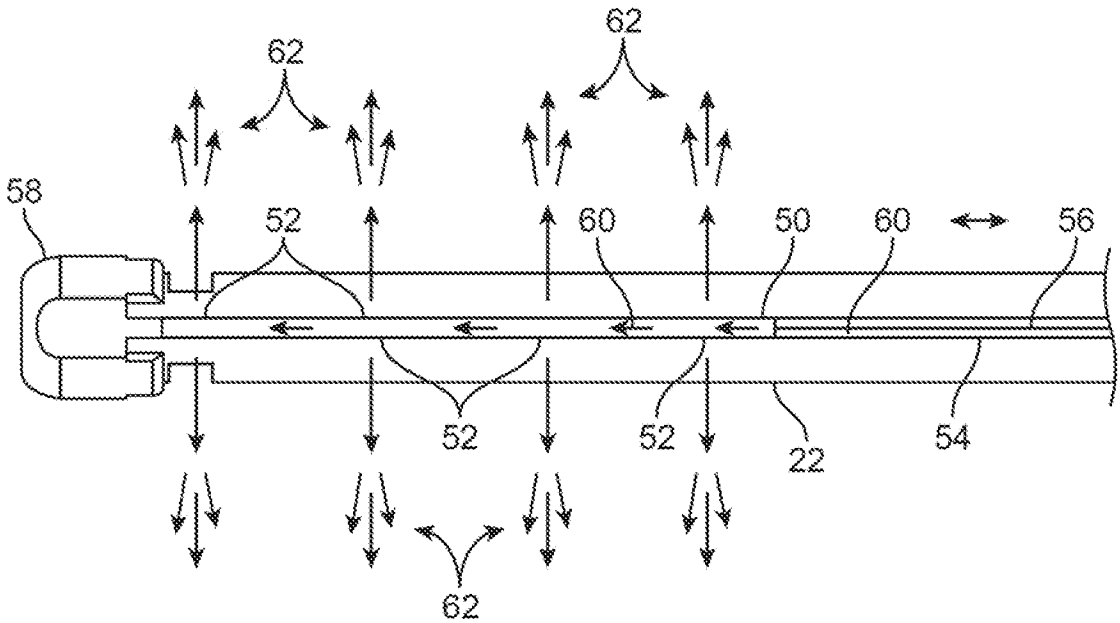


FIG. 2B

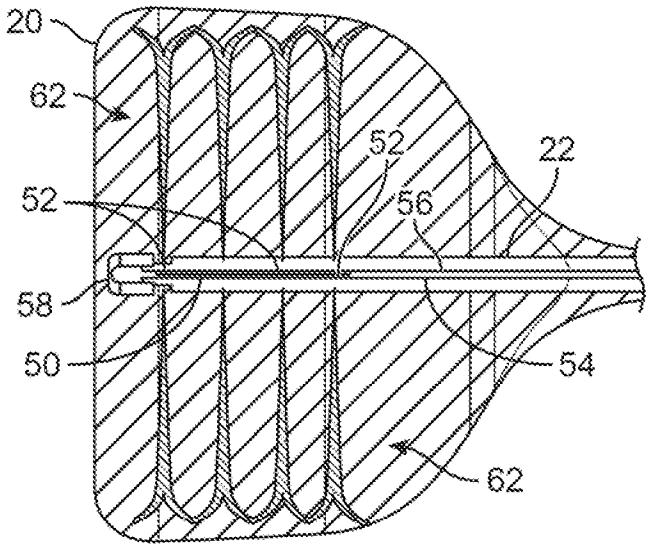


FIG. 3A

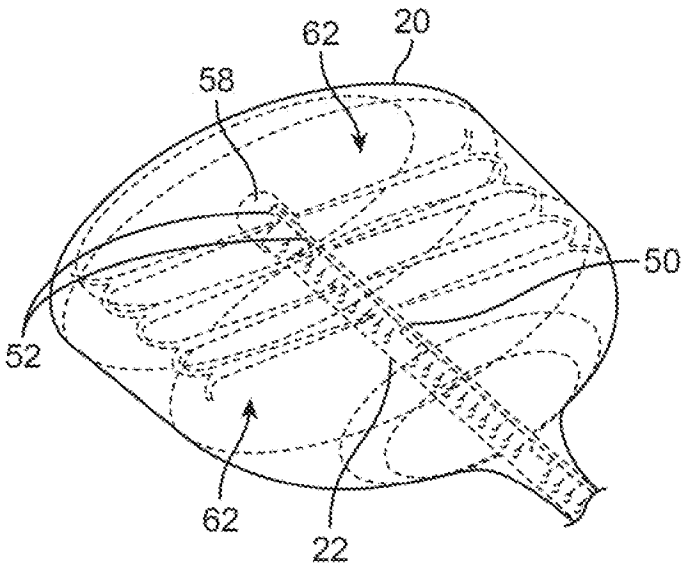


FIG. 3B

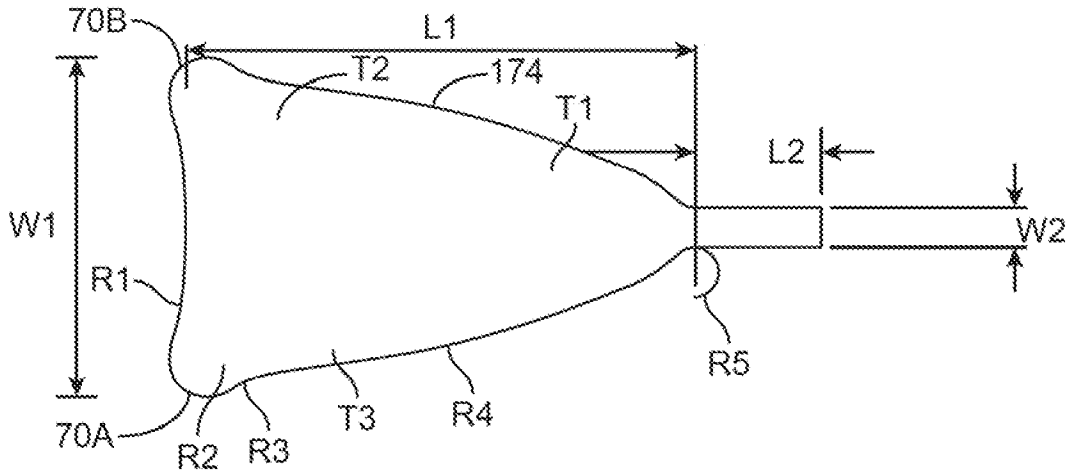


FIG. 4A

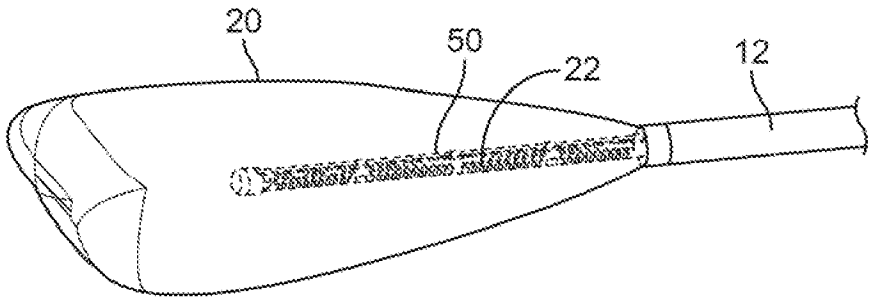


FIG. 4B

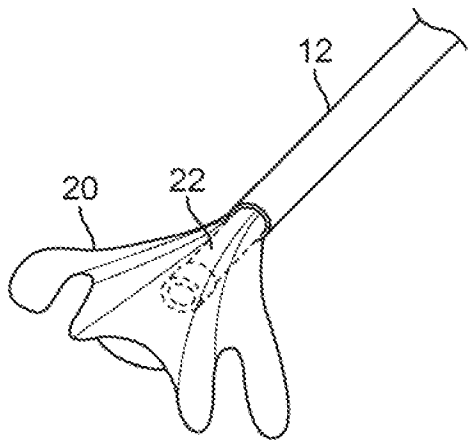


FIG. 4C

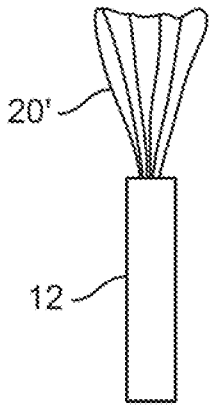


FIG. 5A

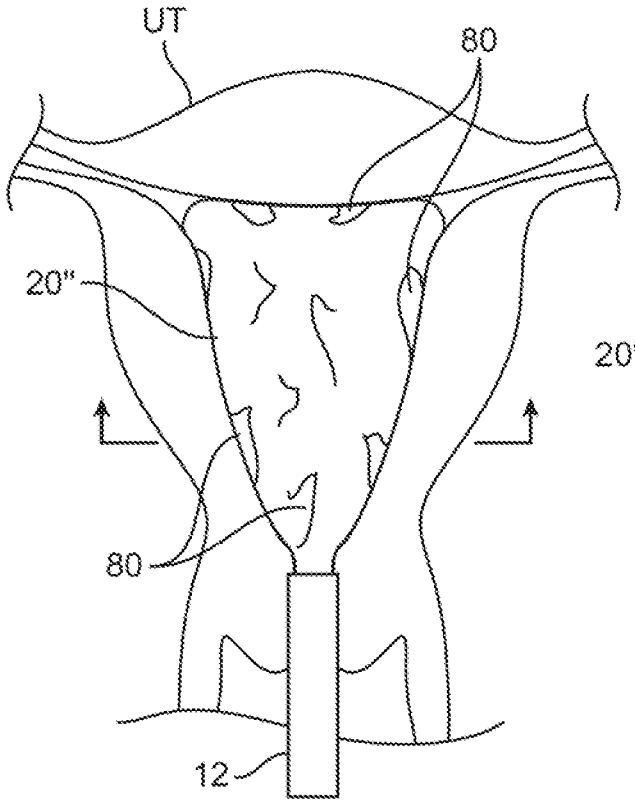


FIG. 5B

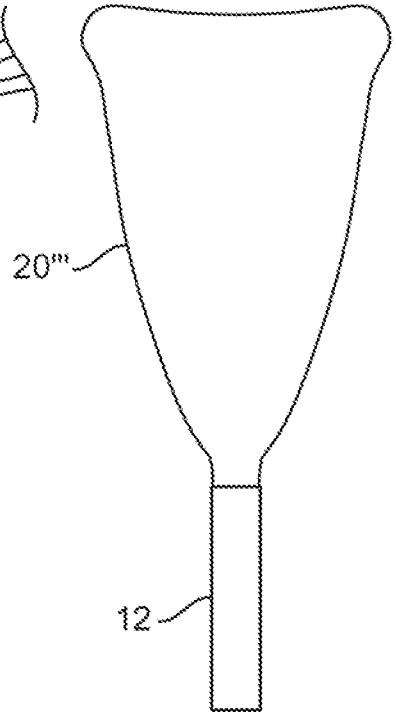


FIG. 5C

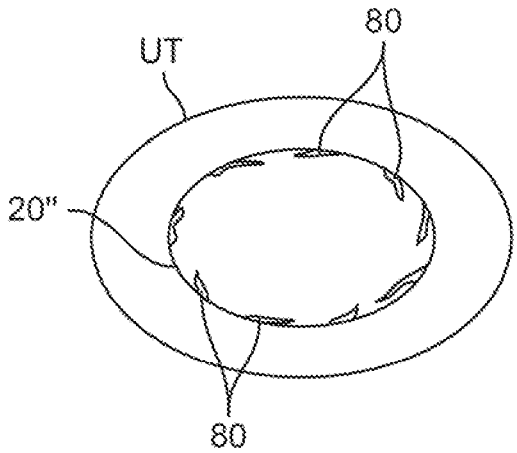


FIG. 5D