No. 20-440

IN THE

Supreme Court of the United States

MINERVA SURGICAL, INC.,
Petitioner,

v.

HOLOGIC, INC., CYTYC SURGICAL PRODUCTS, LLC,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

SUPPLEMENTAL APPENDIX

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*Counsels of Record

[Additional counsel listed on inside cover.]

PETITION FOR CERTIORARI FILED SEPT. 30, 2020
CERTIORARI GRANTED JAN. 8, 2021

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Counsel for Petitioner

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NOTICE

The following documents have been omitted from the printing of this Joint Appendix. They may be found in the Appendix to the Petition for a Writ of Certiorari at the following pages:

November 21, 2014

Mr. Csaba Truckai
19566 Arden Court
Saratoga, CA 95070

Re: Request for Signature – Hologic Inventor Declaration for 13.003011 US CON 7

Dear Mr. Truckai,

My name is Mandy Callahan and I work with the patent group in the legal department at Hologic. On August 13, 2013, we filed the 7th U.S. continuation in the above identified family of applications, entitled "Moisture Transport System for Contact Electrocoagulation." Due to new USPTO rules which went into effect in September 2012, the declaration you previously executed along with your co-contributors in the parent case is no longer acceptable for new continuation filings. As such, I wish to kindly request that you sign a new declaration (enclosed) which conforms to the new requirements and send it back to me in the pre-paid and pre-addressed Federal Express envelope provided herein at your earliest convenience. As a reference, I have also attached a copy of the application as published in February 2014.

Many thanks in advance for your assistance and please don't hesitate to contact me (or our in-house counsel, Robert Smith – 508-263-8491) with any questions.

Best regards,

Mandy Callahan

Mandy Callahan
IP Paralegal

Enc.

HOLOGIC

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1:15-cv-01031-JFB-SRF

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Moisture Transport System for Contact Electrocoagulation

As the below named inventor, I hereby declare that:

This declaration is directed to:

- ☐ The attached application, or
- ■ United States application or PCT international application number 13/962,178 filed on August 8, 2013.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Csaba Truckai Date (Optional) :_____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

US 20140046317A1

(19) **United States**

(12) **Patent Application Publication**

Truckai et al.

(10) **Pub. No.: US 2014/0046317 A1**

(43) **Pub. Date: Feb. 13, 2014**

(54) **MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION**

(71) Applicant: **Cytyc Surgical Products**, Marlborough, MA (US)

(72) Inventors: **Csaba Truckai**, Sunnyvale, CA (US); **Russel Mahlon Sampson**, Mountain View, CA (US); **Stephanie Squarcia**, Palo Alto, CA (US); **Alfonso Lawrence Ramirez**, San Jose, CA (US); **Estela Hilario**, Los Altos, CA (US)

(73) Assignee: **Cytyc Surgical Products**, Marlborough, MA (US)

(21) Appl. No.: **13/962,178**

(22) Filed: **Aug. 8, 2013**

Related U.S. Application Data

(60) Continuation of application No. 12/581,506, filed on Oct. 19, 2009, now Pat. No. 8,506,563, which is a continuation of application No. 10/959,771, filed on Oct. 6, 2004, now Pat. No. 7,604,633, which is a division of application No. 09/103,072, filed on Jun. 23, 1998, now Pat. No. 6,813,520, which is a continuation-in-part of application No. 08/632,516, filed on Apr. 12, 1996, now Pat. No. 5,769,880.

(60) Provisional application No. 60/084,791, filed on May 8, 1998.

Publication Classification

(51) **Int. Cl.**

A61B 18/18 (2006.01)

A61B 17/42 (2006.01)

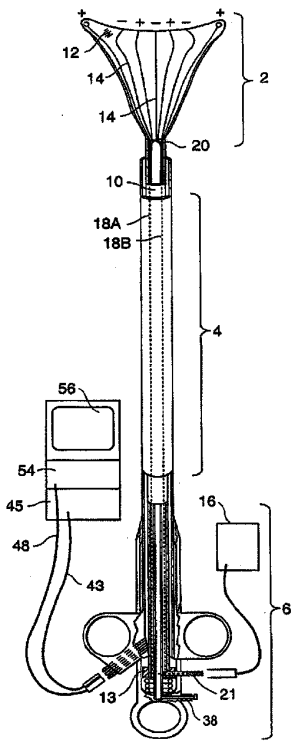
(52) **U.S. Cl.**

CPC ***A61B 18/18*** (2013.01); ***A61B 17/42*** (2013.01)

USPC **606/33**; 606/119

(57) **ABSTRACT**

An apparatus and method for use in performing ablation or coagulation of organs and other tissue includes a metallized fabric electrode array which is substantially absorbent and/or permeable to moisture and gases such as steam and conformable to the body cavity. Following placement of the ablation device into contact with the tissue to be ablated, an RF generator is used to deliver RF energy to the conductive regions and to thereby induce current flow from the electrodes to tissue to be ablated. As the current heats the tissue, moisture (such as steam or liquid) leaves the tissue causing the tissue to dehydrate. Suction may be applied to facilitate moisture removal. The moisture permeability and/or absorbency of the electrode carrying member allows the moisture to leave the ablation site so as to prevent the moisture from providing a path of conductivity for the current.



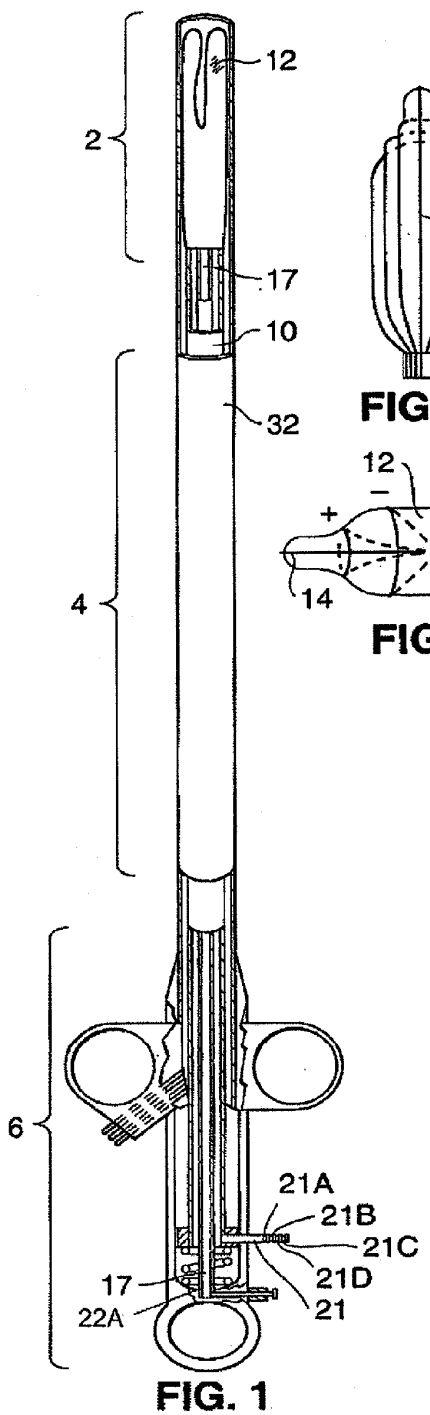


FIG. 1

FIG. 3

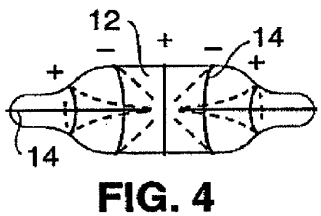


FIG. 4

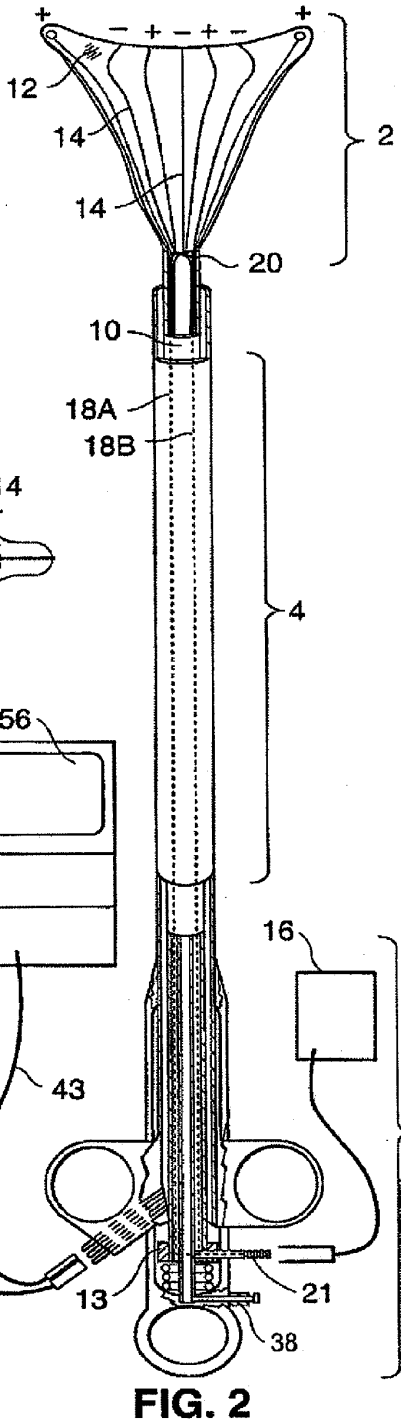


FIG. 2

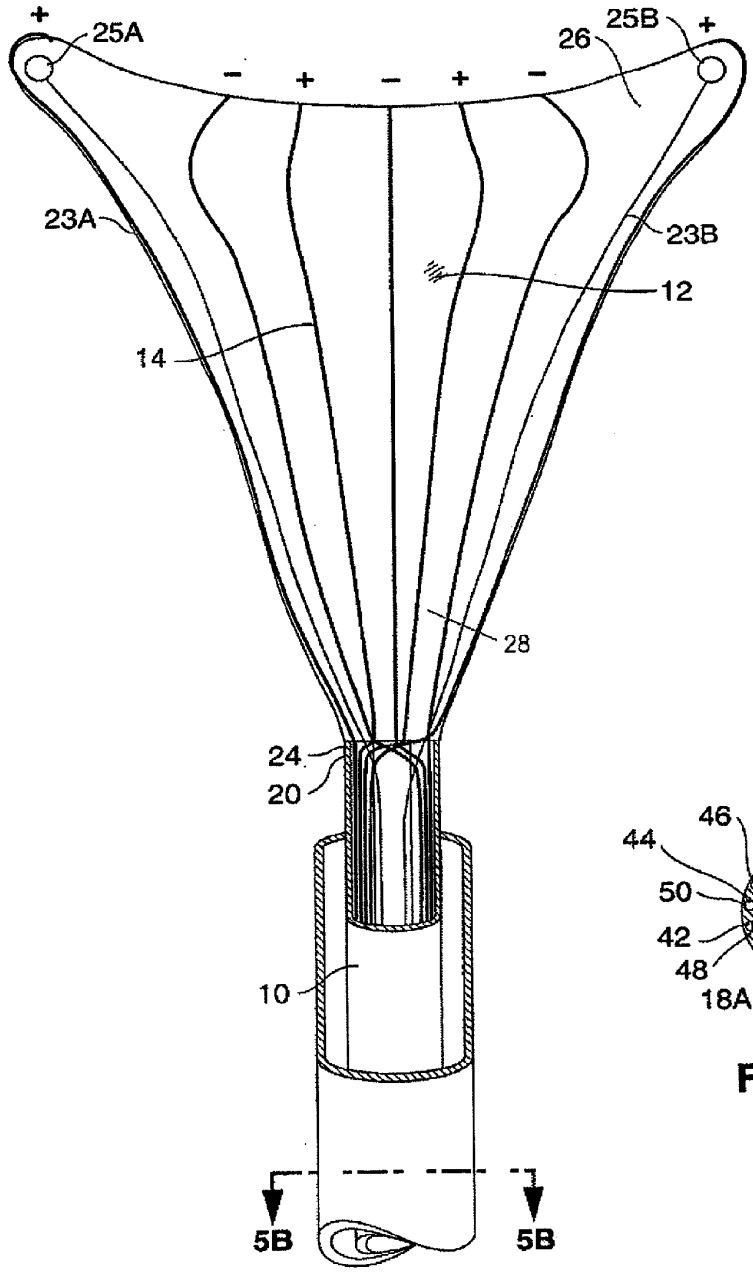

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FIG. 5A

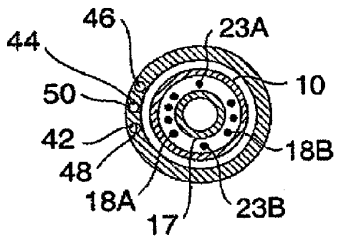
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FIG. 5B

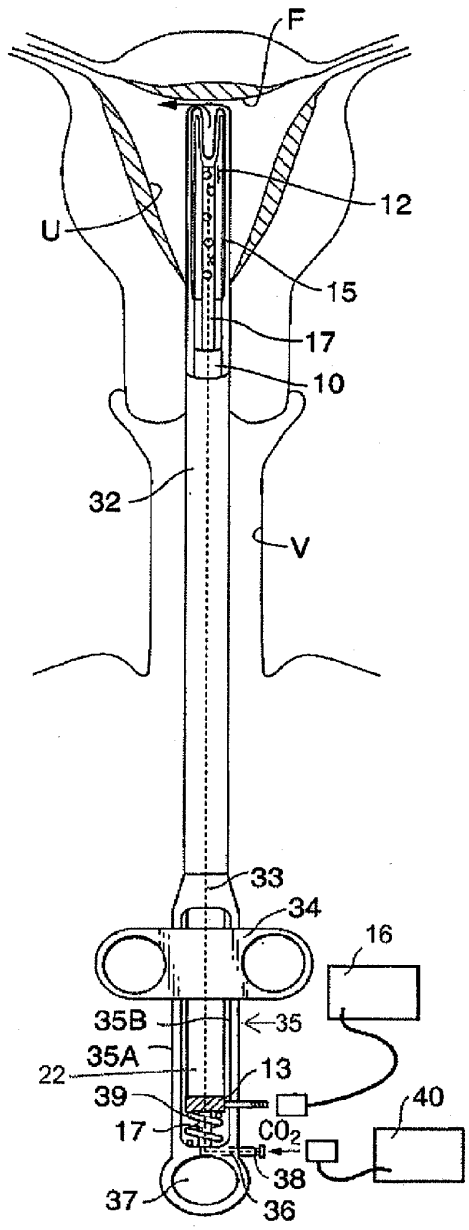
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FIG. 6

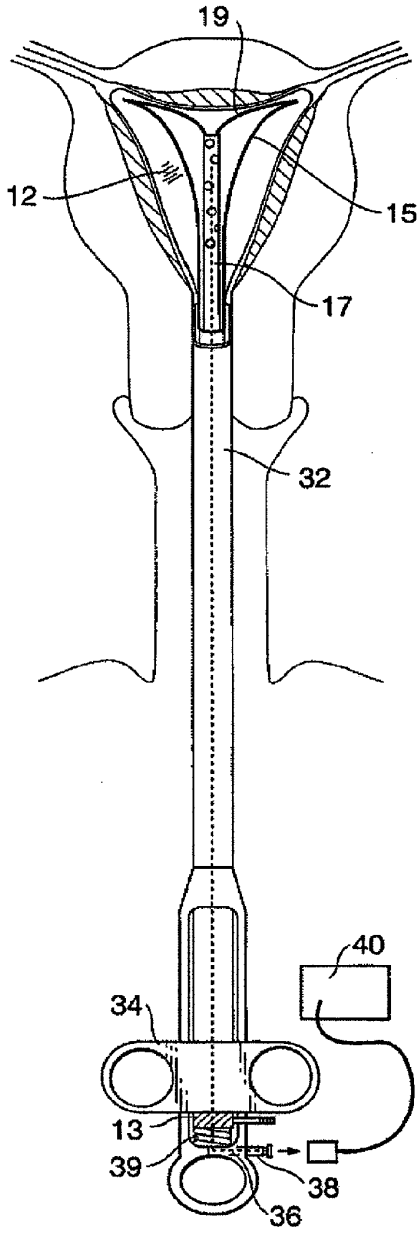
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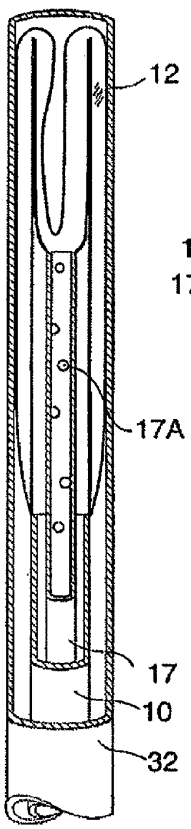
FIG. 7



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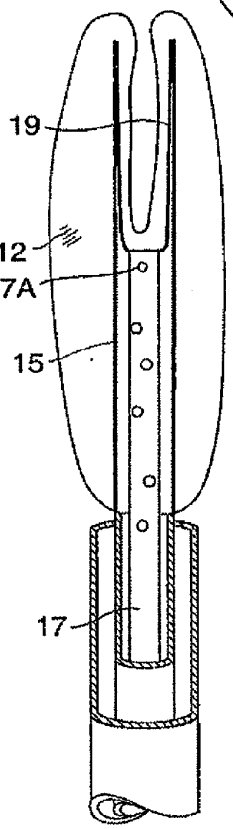

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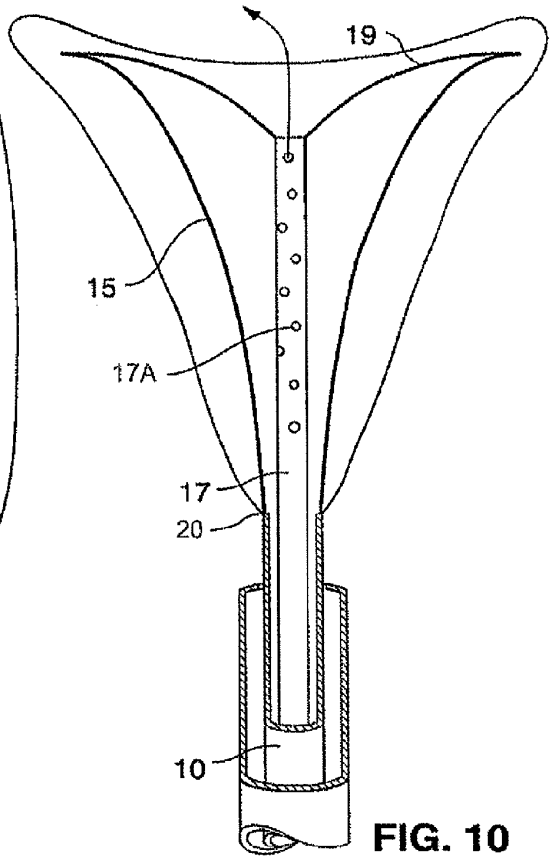

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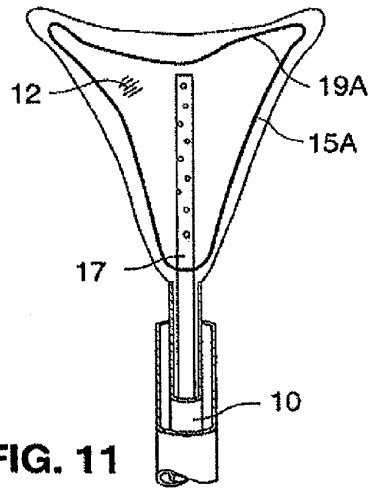

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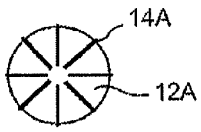

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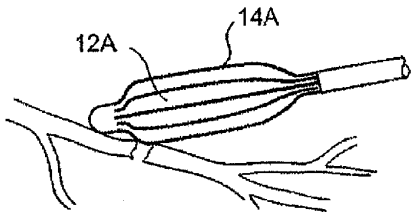

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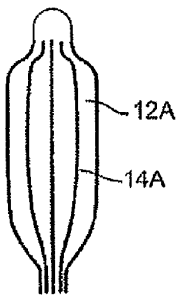

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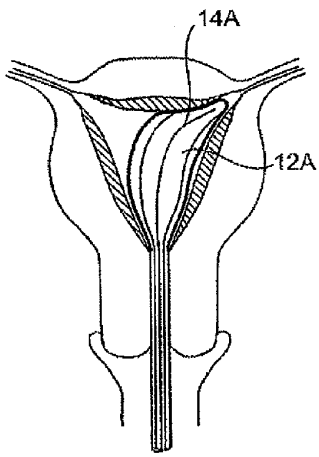

FIG. 15

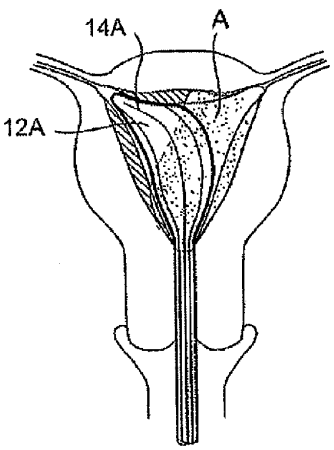

FIG. 16

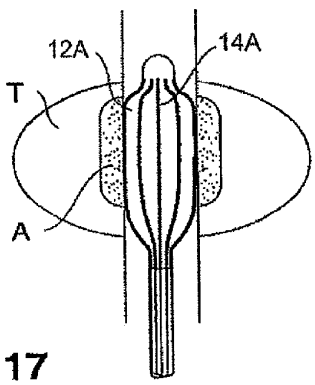

FIG. 17

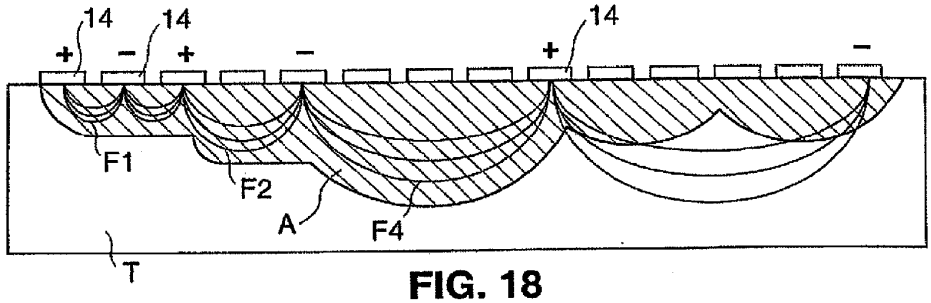

FIG. 18

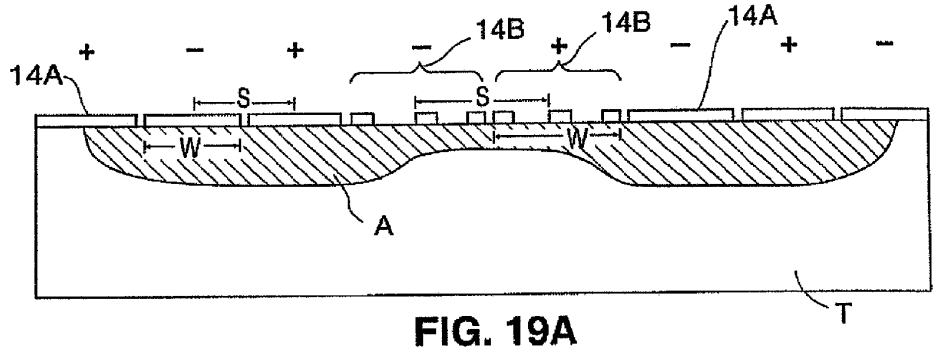

FIG. 19A

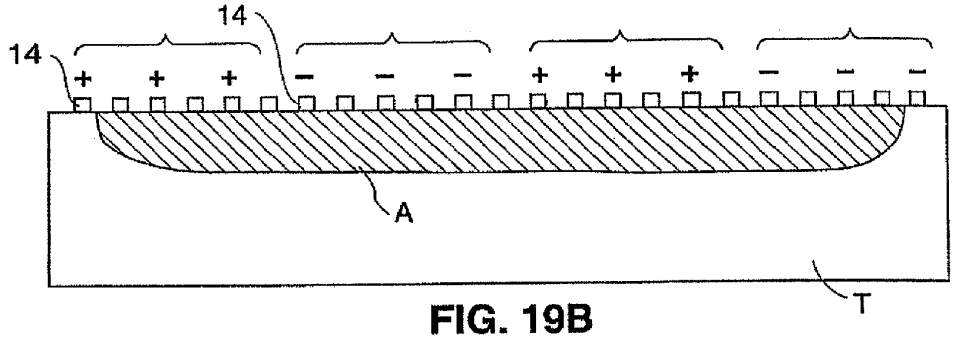

FIG. 19B

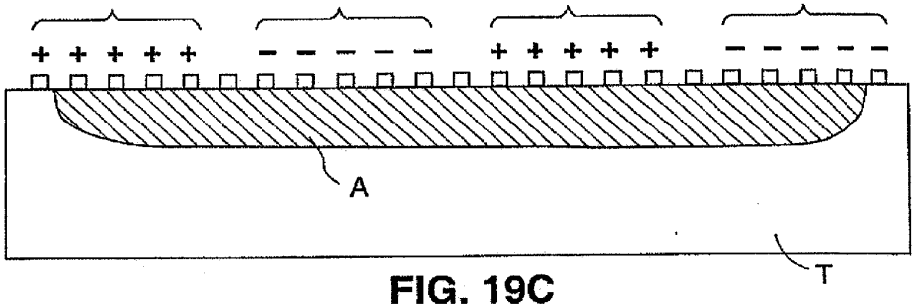

FIG. 19C

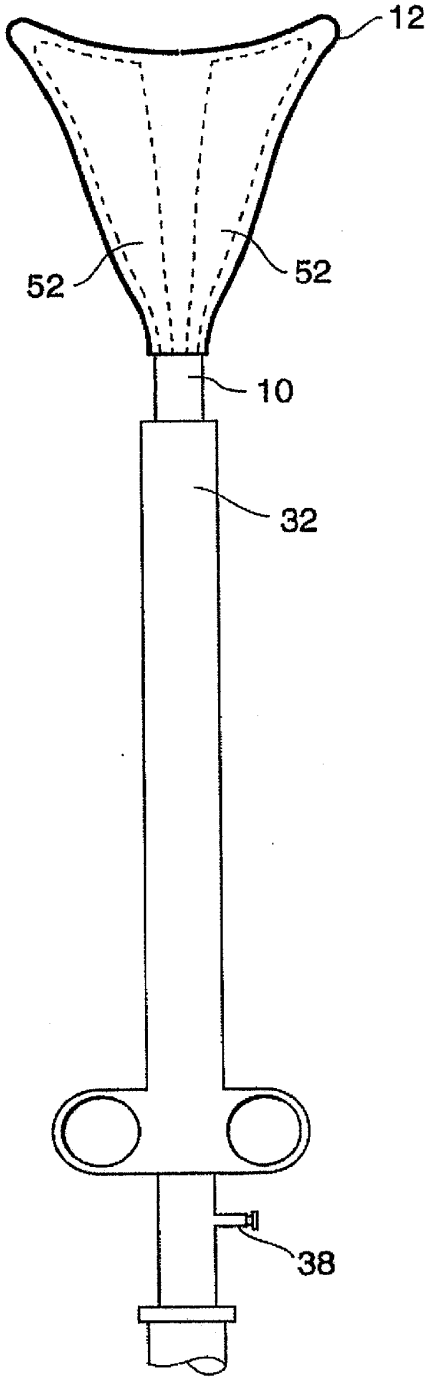

FIG. 20

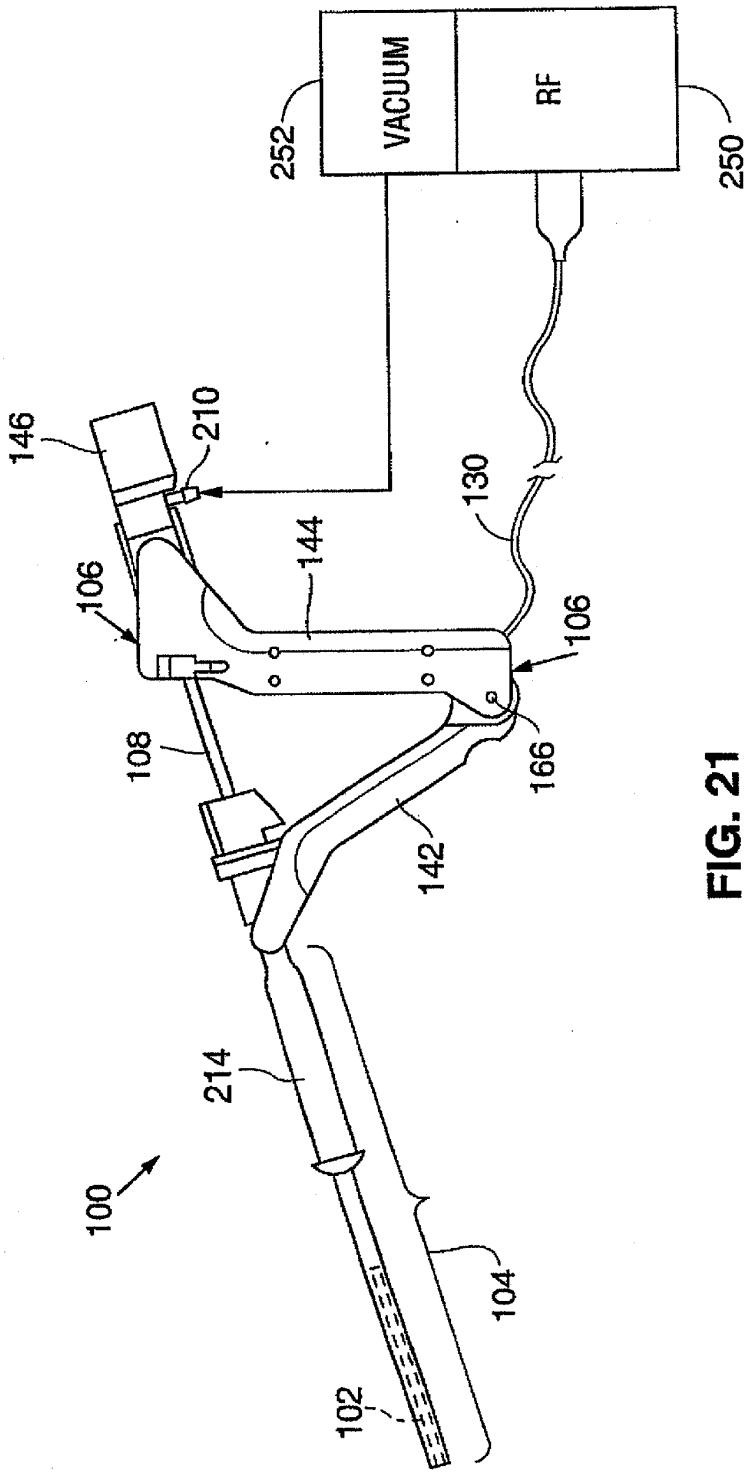
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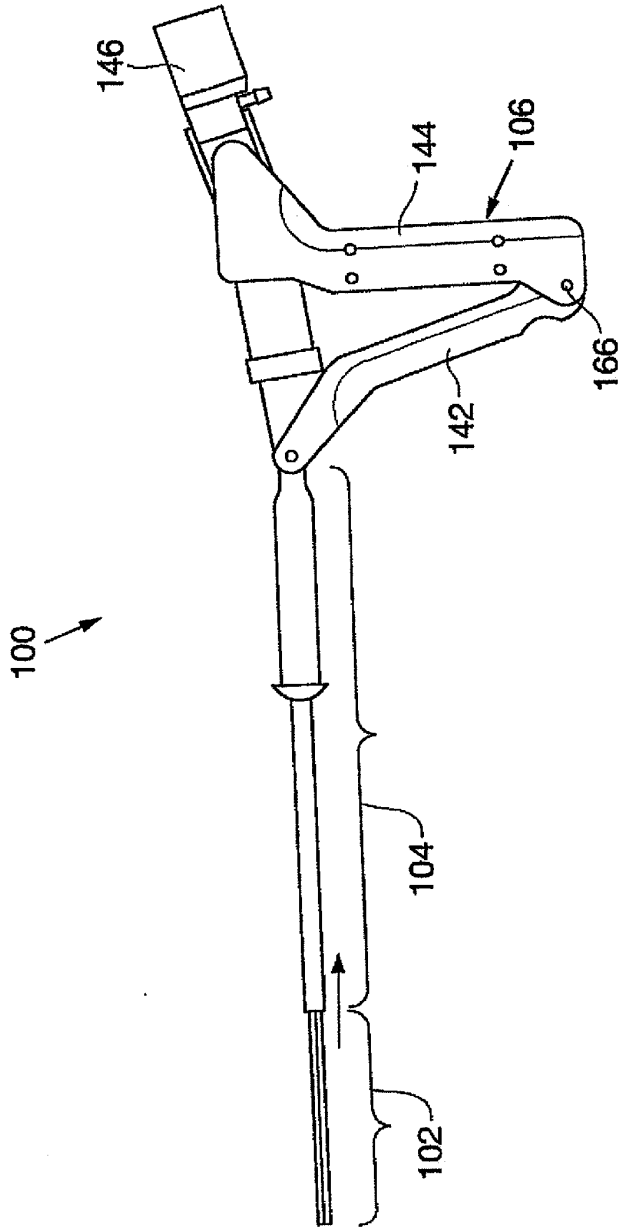
FIG. 21



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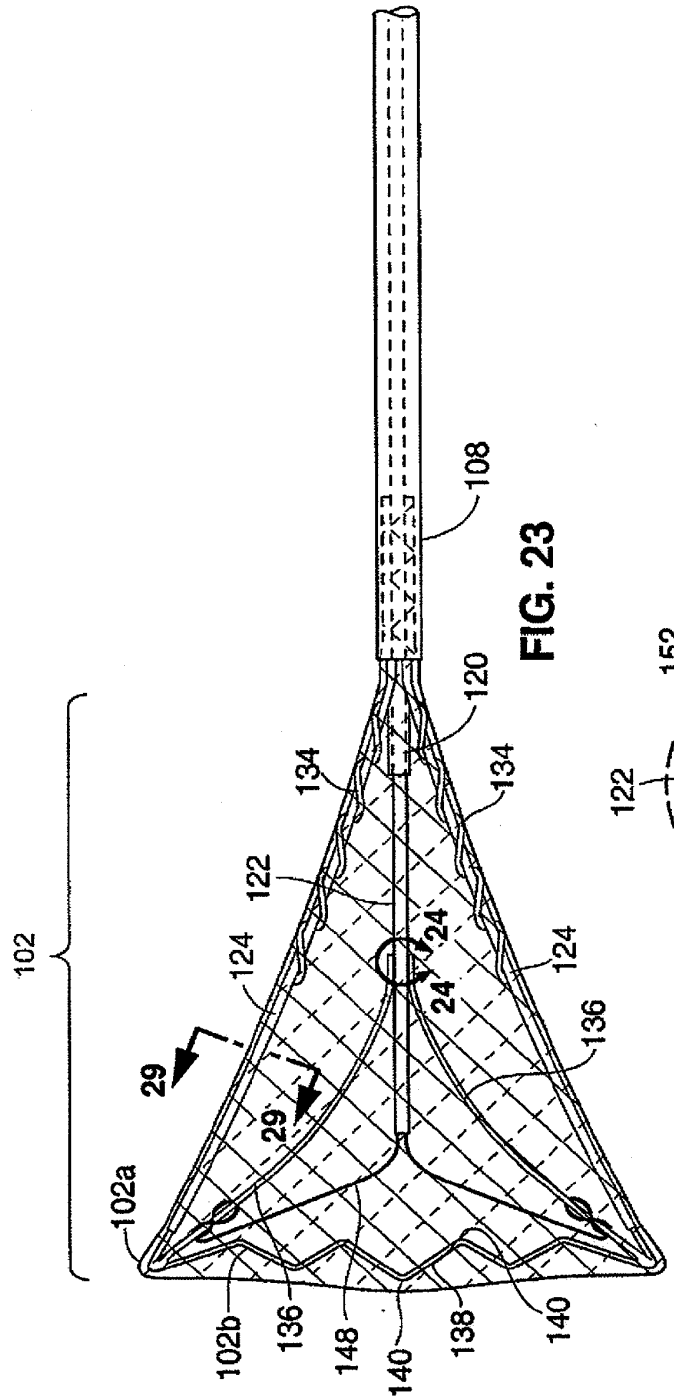
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FIG. 23

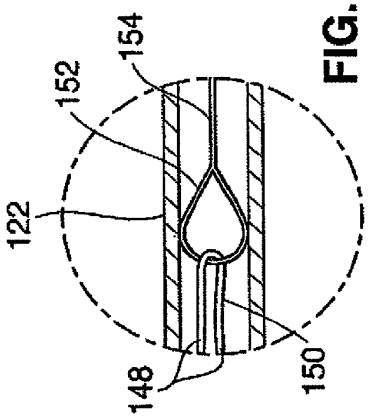
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FIG. 24

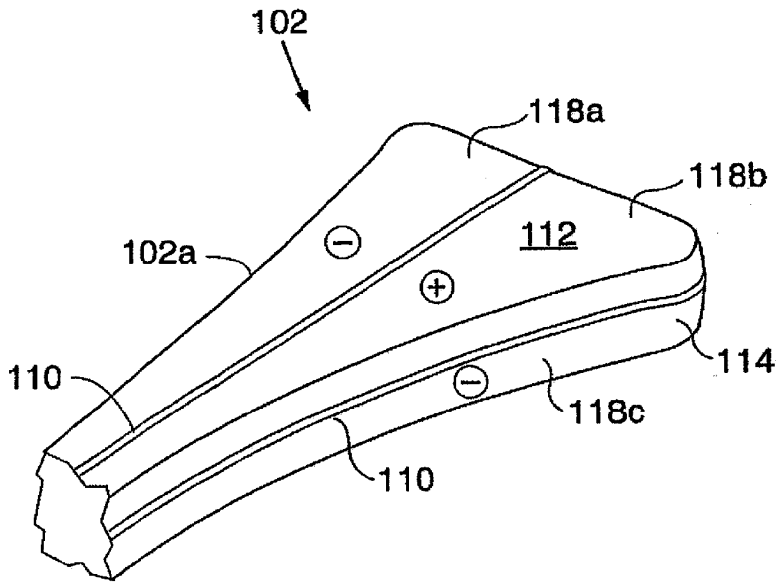


FIG. 25A

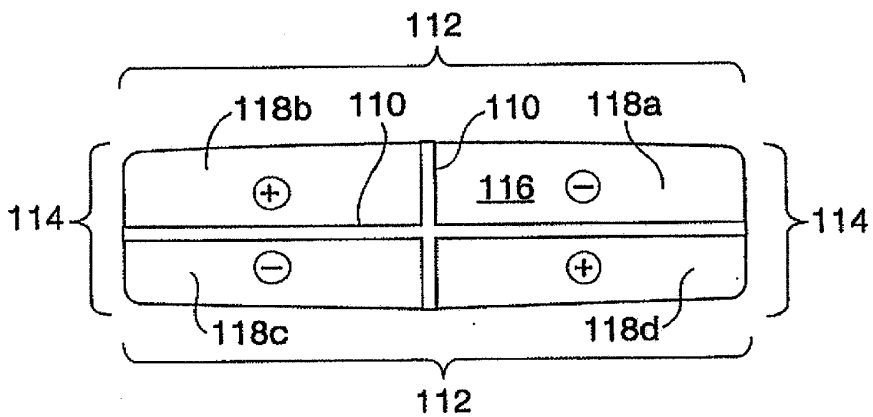


FIG. 25B

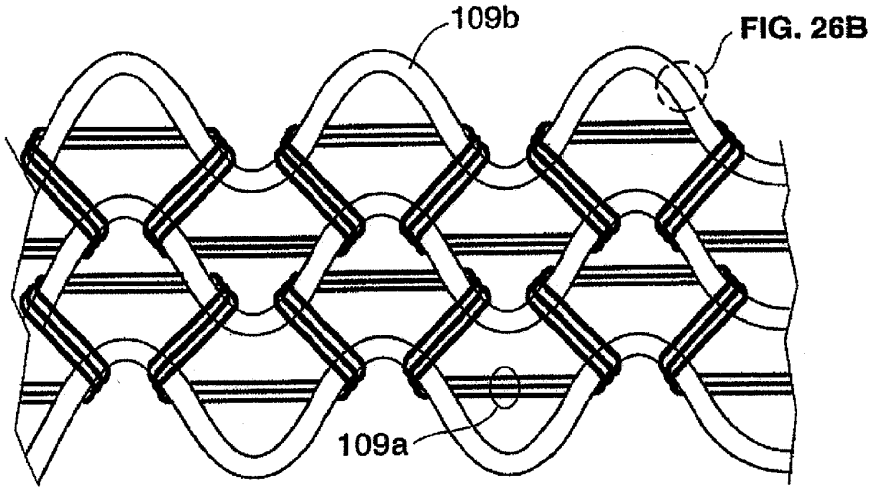


FIG. 26A

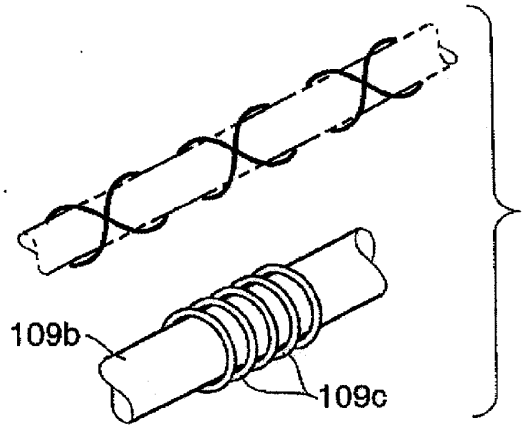
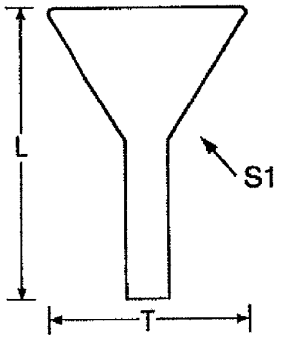


FIG. 26B



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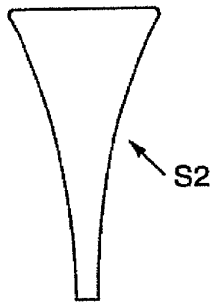


FIG. 27B

FIG. 27C

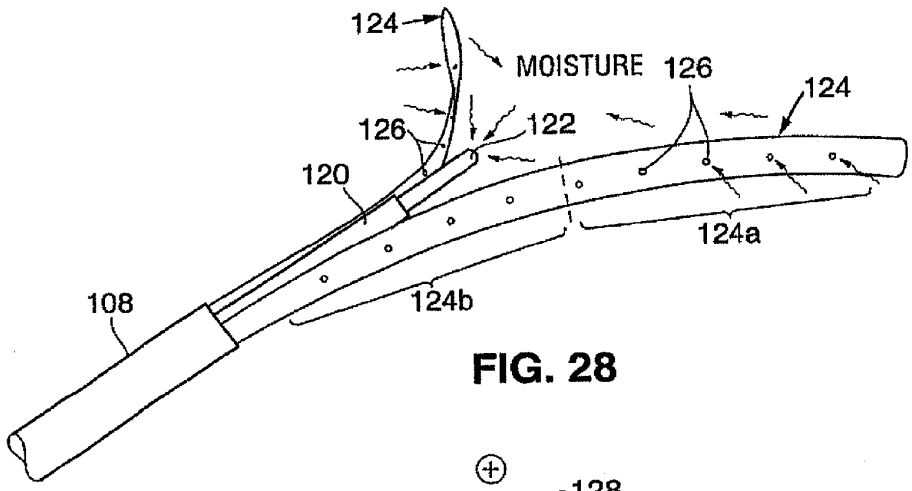


FIG. 28

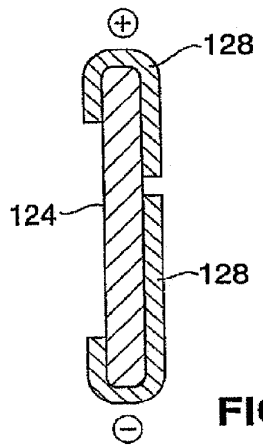


FIG. 29

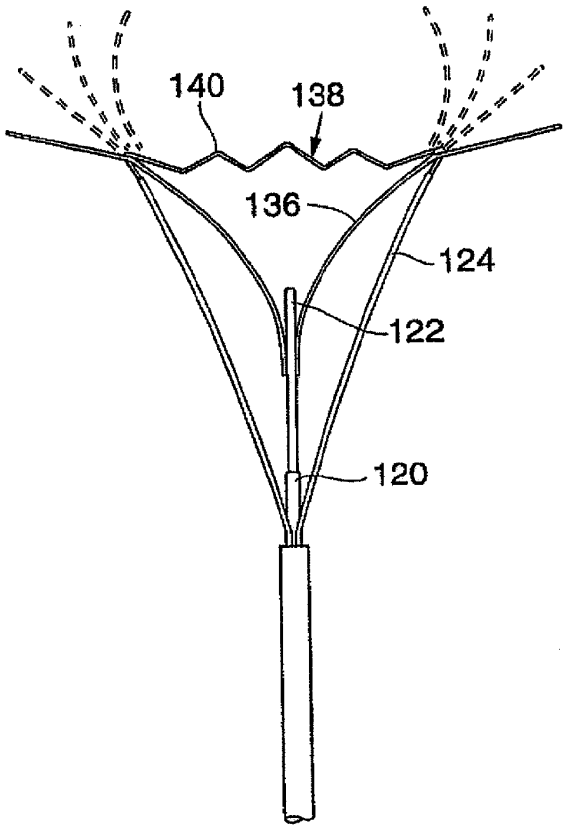


FIG. 30

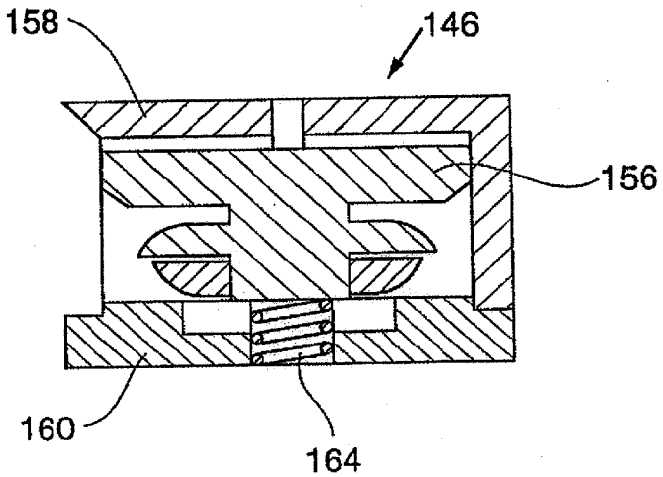


FIG. 31

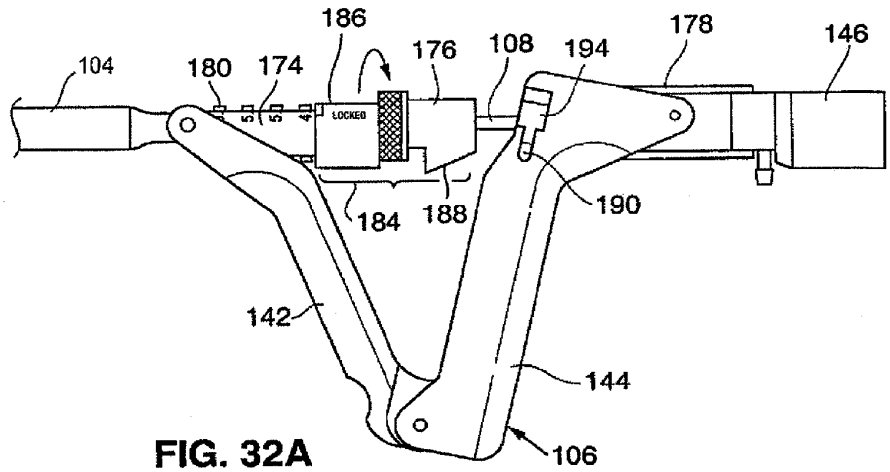


FIG. 32A

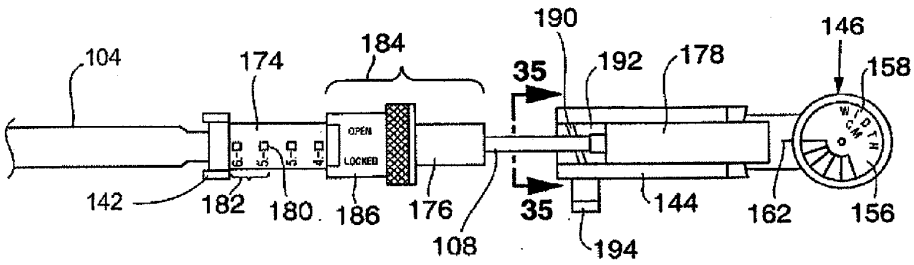


FIG. 32B

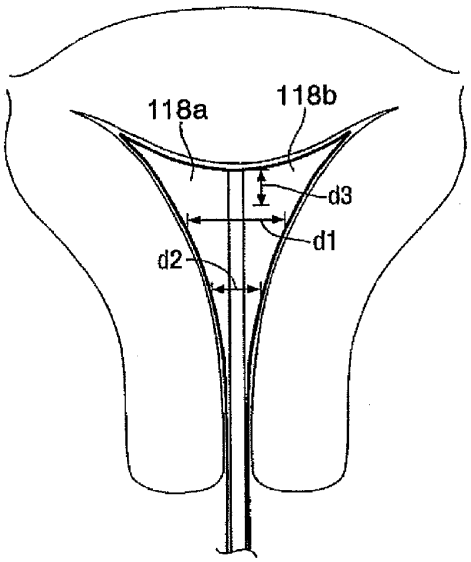


FIG. 33

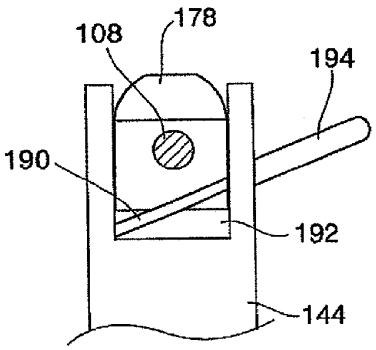


FIG. 35

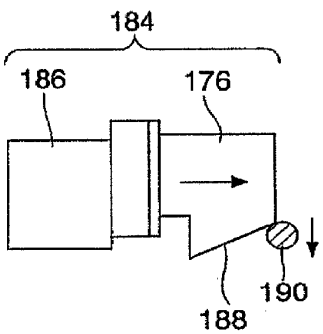


FIG. 36A

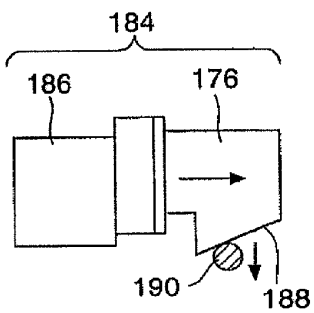


FIG. 36B

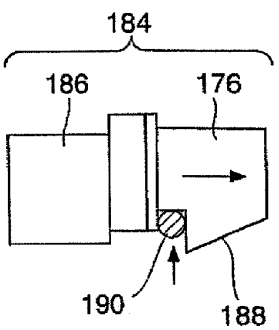
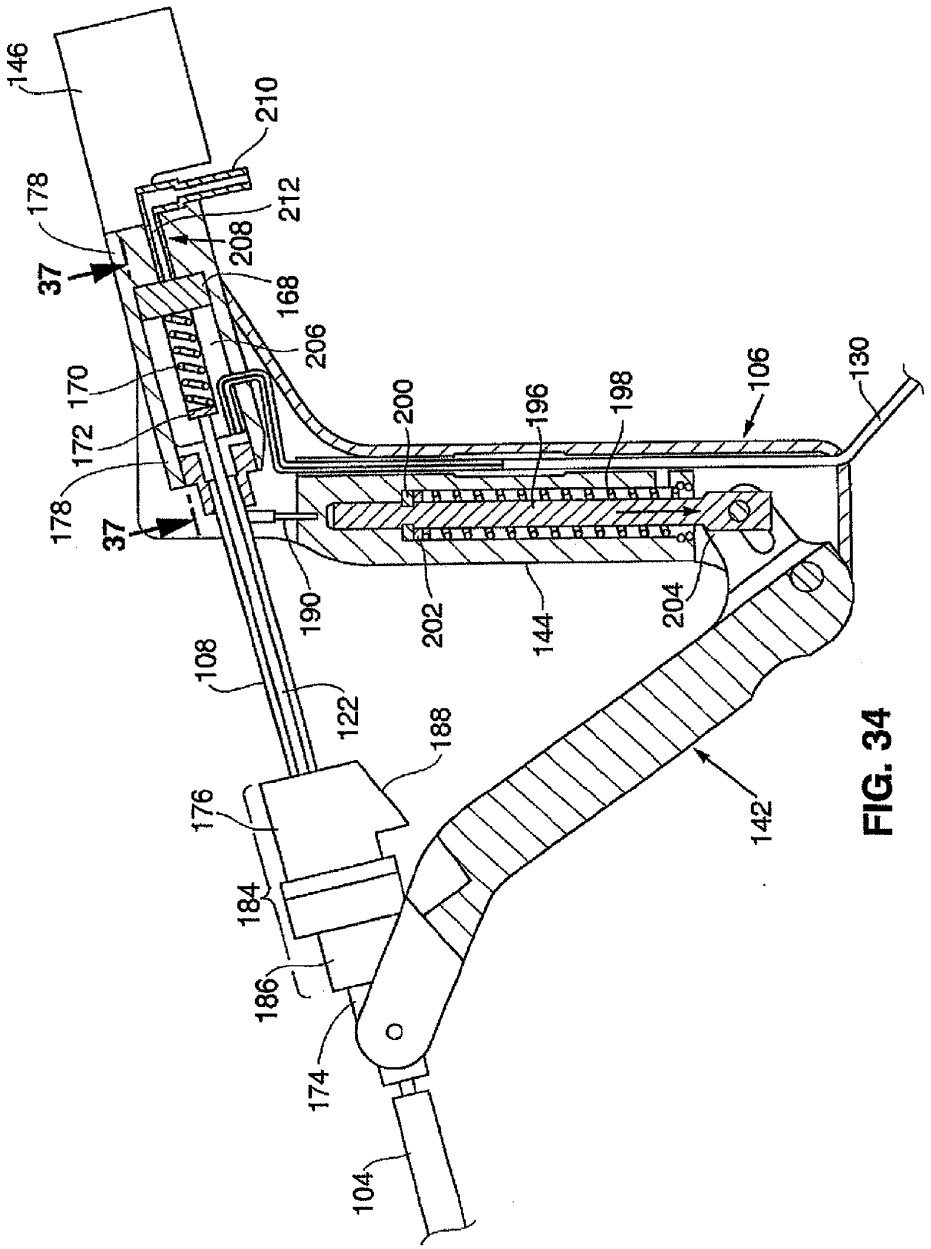


FIG. 36C


146
210
178
212
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37
168
206
170
172
200
196
198
106
130
178
37
190
202
144
204
108
122
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142
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186
174
104

FIG. 34

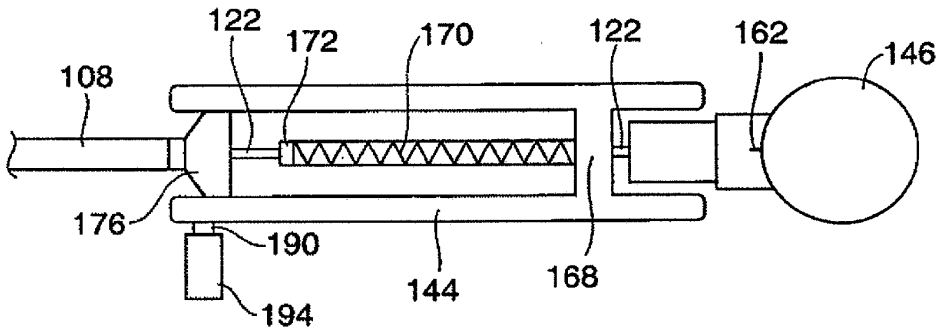

FIG. 37A

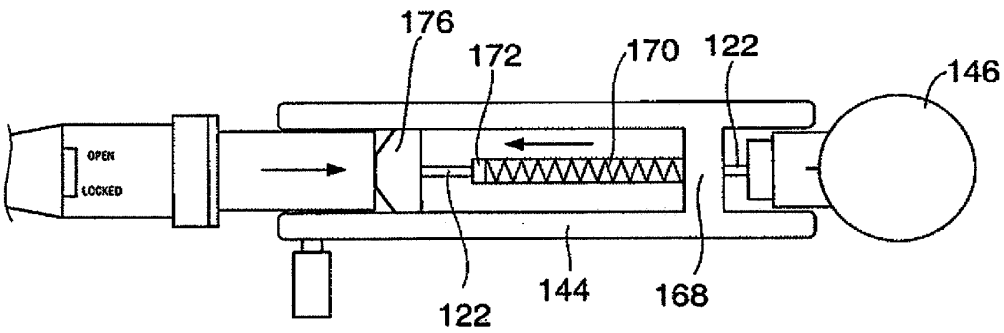

FIG. 37B

MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application Ser. No. 12/581,506 filed Oct. 19, 2009, now U.S. Pat. No. 8,506,563 which is a continuation of U.S. application Ser. No. 10/959,771 filed Oct. 6, 2004, now U.S. Pat. No. 7,604,633, which is a divisional of U.S. application Ser. No. 09/103,072 filed Jun. 23, 1998, now U.S. Pat. No. 6,813,520, which is a continuation-in-part of U.S. application Ser. No. 08/632,516 filed Apr. 12, 1996, now U.S. Pat. No. 5,769,880, and claims the benefit of U.S. provisional application 60/084,791 filed May 8, 1998.

FIELD OF THE INVENTION

[0002] The present invention relates generally to the field of apparatuses and methods for ablating or coagulating the interior surfaces of body organs. Specifically, it relates to an apparatus and method for ablating the interior linings of body organs such as the uterus and gallbladder.

BACKGROUND OF THE INVENTION

[0003] Ablation of the interior lining of a body organ is a procedure which involves heating the organ lining to temperatures which destroy the cells of the lining or coagulate tissue proteins for hemostasis. Such a procedure may be performed as a treatment to one of many conditions, such as chronic bleeding of the endometrial layer of the uterus or abnormalities of the mucosal layer of the gallbladder. Existing methods for effecting ablation include circulation of heated fluid inside the organ (either directly or inside a balloon), laser treatment of the organ lining, and resistive heating using application of RF energy to the tissue to be ablated.

[0004] U.S. Pat. No. 5,084,044 describes an apparatus for endometrial ablation in which a bladder is inserted into the uterus. Heated fluid is then circulated through the balloon to expand the balloon into contact with the endometrium and to ablate the endometrium thermally. U.S. Pat. No. 5,443,470 describes an apparatus for endometrial ablation in which an expandable bladder is provided with electrodes on its outer surface. After the apparatus is positioned inside the uterus, a non-conductive gas or liquid is used to fill the balloon, causing the balloon to push the electrodes into contact with the endometrial surface. RF energy is supplied to the electrodes to ablate the endometrial tissue using resistive heating.

[0005] These ablation devices are satisfactory for carrying out ablation procedures. However, because no data or feedback is available to guide the physician as to how deep the tissue ablation has progressed, controlling the ablation depth and ablation profile with such devices can only be done by assumption.

[0006] For example, the heated fluid method is a very passive and ineffective heating process which relies on the heat conductivity of the tissue. This process does not account for variations in factors such as the amount of contact between the balloon and the underlying tissue, or cooling effects such as those of blood circulating through the organ. RF ablation techniques can achieve more effective ablation since it relies on active heating of the tissue using RF energy, but presently the depth of ablation using RF techniques can only be estimated by the physician since no feedback can be provided as to actual ablation depth.

[0007] Both the heated fluid techniques and the latest RF techniques must be performed using great care to prevent over ablation. Monitoring of tissue surface temperature is normally carried out during these ablation procedures to ensure the temperature does not exceed 100° C. If the temperature exceeds 100° C., the fluid within the tissue begins to boil and to thereby produce steam. Because ablation is carried out within a closed cavity within the body, the steam cannot escape and may instead force itself deeply into the tissue, or it may pass into areas adjacent to the area intended to be ablated, causing embolism or unintended burning.

[0008] Moreover, in prior art RF devices the water drawn from the tissue creates a path of conductivity through which current traveling through the electrodes will flow. This can prevent the current from traveling into the tissue to be ablated. Moreover, the presence of this current path around the electrodes causes current to be continuously drawn from the electrodes. The current heats the liquid drawn from the tissue and thus turns the ablation process into a passive heating method in which the heated liquid around the electrodes causes thermal ablation to continue well beyond the desired ablation depths.

[0009] Another problem with prior art ablation devices is that it is difficult for a physician to find out when ablation has been carried out to a desired depth within the tissue. Thus, it is often the case that too much or too little tissue may be ablated during an ablation procedure.

[0010] It is therefore desirable to provide an ablation device which eliminates the above-described problem of steam and liquid buildup at the ablation site. It is further desirable to provide an ablation method and device which allows the depth of ablation to be controlled and which automatically discontinues ablation once the desired ablation depth has been reached.

SUMMARY OF THE INVENTION

[0011] The present invention is an apparatus and method of ablating and/or coagulating tissue, such as that of the uterus or other organ. An ablation device is provided which has an electrode array carried by an elongate tubular member. The electrode array includes a fluid permeable elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon. During use, the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue to cause the tissue to dehydrate, and moisture generated during dehydration is actively or passively drawn into the array and away from the tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. **1** is a front elevation view of a first embodiment of an ablation device according to the present invention, with the handle shown in cross-section and with the RF applicator head in a closed condition.

[0013] FIG. **2** is a front elevation view of the ablation device of FIG. **1**, with the handle shown in cross-section and with the RF applicator head in an open condition.

[0014] FIG. **3** is a side elevation view of the ablation device of FIG. **2**.

[0015] FIG. **4** is a top plan view of the ablation device of FIG. **2**.

[0016] FIG. **5**A is a front elevation view of the applicator head and a portion of the main body of the ablation device of FIG. **2**, with the main body shown in cross-section.

[0017] FIG. **5**B is a cross-section view of the main body taken along the plane designated **5**B-**5**B in FIG. **5**A.

[0018] FIG. **6** is a schematic representation of a uterus showing the ablation device of FIG. **1** following insertion of the device into the uterus but prior to retraction of the introducer sheath and activation of the spring members.

[0019] FIG. **7** is a schematic representation of a uterus showing the ablation device of FIG. **1** following insertion of the device into the uterus and following the retraction of the introducer sheath and the expansion of the RF applicator head.

[0020] FIG. **8** is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of FIG. **1**, showing the RF applicator head in the closed condition.

[0021] FIG. **9** is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of FIG. **1**, showing the configuration of RF applicator head after the sheath has been retracted but before the spring members have been released by proximal movement of the shaft.

[0022] FIG. **10** is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of FIG. **1**, showing the configuration of RF applicator head after the sheath has been retracted and after the spring members have been released into the fully opened condition.

[0023] FIG. **11** is a cross-section view of a distal portion of an RF ablation device similar to FIG. **1** which utilizes an alternative spring member configuration for the RF applicator head.

[0024] FIG. **12** is a side elevation view of the distal end of an alternate embodiment of an RF ablation device similar to that of FIG. **1**, which utilizes an RF applicator head having a modified shape.

[0025] FIG. **13** is a top plan view of the ablation device of FIG. **12**.

[0026] FIG. **14** is a representation of a bleeding vessel illustrating use of the ablation device of FIG. **12** for general bleeding control.

[0027] FIGS. **15** and **16** are representations of a uterus illustrating use of the ablation device of FIG. **12** for endometrial ablation.

[0028] FIG. **17** is a representation of a prostate gland illustrating use of the ablation device of FIG. **12** for prostate ablation.

[0029] FIG. **18** is a cross-section view of target tissue for ablation, showing ablation electrodes in contact with the tissue surface and illustrating energy fields generated during bi-polar ablation.

[0030] FIGS. **19**A-**19**C are cross-section views of target tissue for ablation, showing electrodes in contact with the tissue surface and illustrating how varying active electrode density may be used to vary the ablation depth.

[0031] FIG. **20** is a side elevation view, similar to the view of FIG. **2**, showing an ablation device according to the present invention in which the electrode carrying means includes inflatable balloons. For purposes of clarity, the electrodes on the electrode carrying means are not shown.

[0032] FIG. **21** is a side elevation view of a second exemplary embodiment of an ablation device according to the present invention, showing the array in the retracted state.

[0033] FIG. **22** is a side elevation view of the ablation device of FIG. **21**, showing the array in the deployed state.

[0034] FIG. **23** is a top plan view of the applicator head of the apparatus of FIG. **21**.

[0035] FIG. **24** is a cross-sectional top view of the encircled region designated **24** in FIG. **23**.

[0036] FIG. **25**A is a perspective view of the electrode array of FIG. **23**.

[0037] FIG. **25**B is a distal end view of the applicator head of FIG. **30**A.

[0038] FIG. **26**A is a plan view of a knit that may be used to form the applicator head.

[0039] FIG. **26**B is a perspective view of a strand of nylon-wrapped spandex of the type that may be used to form the knit of FIG. **26**A.

[0040] FIGS. **27**A, **27**B, **27**C are top plan views illustrating triangular, parabolic, and rectangular mesh shapes for use as electrode arrays according to the present invention.

[0041] FIG. **28** is a perspective view showing the flexures and hypotube of the deflecting mechanism of the applicator head of FIG. **23**.

[0042] FIG. **29** is a cross-section view of a flexure taken along the plane designated **29**-**29** in FIG. **23**.

[0043] FIG. **30** is a top plan view illustrating the flexure and spring arrangement of an alternative configuration of a deflecting mechanism for an applicator head according to the present invention.

[0044] FIG. **31** is a cross-sectional side view of the bobbin portion of the apparatus of FIG. **21**.

[0045] FIG. **32**A is a side elevation view of the handle of the ablation device of FIG. **21**.

[0046] FIG. **32**B is a top plan view of the handle of the ablation device of FIG. **21**. For clarity, portions of the proximal and distal grips are not shown.

[0047] FIG. **33** illustrates placement of the applicator head according to the present invention in a uterine cavity.

[0048] FIG. **34** is a side elevation view of the handle of the ablation apparatus of FIG. **21**, showing portions of the apparatus in cross-section.

[0049] FIG. **35** is a front elevation view of the upper portion of the proximal handle grip taken along the plane designated **35**-**35** in FIG. **32**B.

[0050] FIGS. **36**A, **36**B, and **36**C are a series of side elevation views illustrating the heel member as it becomes engaged with the corresponding spring member.

[0051] FIGS. **37**A and **37**B are cross-sectional top views of the frame member mounted on the proximal grip section, taken along the plane designated **37**-**37** in FIG. **34** and illustrating one of the load limiting features of the second embodiment. FIG. **37**A shows the condition of the compression spring before the heel member moves into abutment with frame member, and FIG. **37**B shows the condition of the spring after the heel member moves into abutment with the frame member.

DETAILED DESCRIPTION

[0052] The invention described in this application is an aspect of a larger set of inventions described in the following co-pending applications which are commonly owned by the assignee of the present invention, and are hereby incorporated by reference: U.S. Provisional Patent Application No. 60/084,724, filed May 8, 1998, entitled "APPARATUS AND METHOD FOR INTRA-ORGAN MEASUREMENT AND ABLATION" (attorney docket no. ENVS-400); and U.S. Pro-

visional Patent Application No. 60/084,712 filed May 8, 1998, entitled "A RADIO-FREQUENCY GENERATOR FOR POWERING AN ABLATION DEVICE" (attorney docket no. ENVS-500).

[0053] The ablation apparatus according to the present invention will be described with respect to two exemplary embodiments.

First Exemplary Embodiment

Structure

[0054] Referring to FIGS. **1** and **2**, an ablation device according to the present invention is comprised generally of three major components: RF applicator head **2**, main body **4**, and handle **6**. Main body **4** includes a shaft **10**. The RF applicator head **2** includes an electrode carrying means **12** mounted to the distal end of the shaft **10** and an array of electrodes **14** formed on the surface of the electrode carrying means **12**. An RF generator **16** is electrically connected to the electrodes **14** to provide mono-polar or bipolar RF energy to them.

[0055] Shaft **10** is an elongate member having a hollow interior. Shaft **10** is preferably 12 inches long and has a preferred cross-sectional diameter of approximately 4 mm. A collar **13** is formed on the exterior of the shaft **10** at the proximal end. As best shown in FIGS. **6** and **7**, passive spring member **15** are attached to the distal end of the shaft **10**.

[0056] Extending through the shaft **10** is a suction/insufflation tube **17** (FIGS. **6-9**) having a plurality of holes **17***a* formed in its distal end. An arched active spring member **19** is connected between the distal ends of the passive spring members **15** and the distal end of the suction/insufflation tube **17**.

[0057] Referring to FIG. **2**, electrode leads **18***a* and **18***b* extend through the shaft **10** from distal end **20** to proximal end **22** of the shaft **10**. At the distal end **20** of the shaft **10**, each of the leads **18***a*, **18***b* is coupled to a respective one of the electrodes **14**. At the proximal end **22** of the shaft **10**, the leads **18***a*, **18***b* are electrically connected to RF generator **16** via an electrical connector **21**. During use, the leads **18***a*, **18***b* carry RF energy from the RF generator **16** to the electrodes. Each of the leads **18***a*, **18***b* is insulated and carries energy of an opposite polarity than the other lead.

[0058] Electrically insulated sensor leads **23***a*, **23***b* (FIGS. **5**A and **5**B) also extend through the shaft **10**. Contact sensors **25***a*, **25***b* are attached to the distal ends of the sensor leads **23***a*, **23***b*, respectively and are mounted to the electrode carrying means **12**. During use, the sensor leads **23***a*, **23***b* are coupled by the connector **21** to a monitoring module in the RF generator **16** which measures impedance between the sensors **25***a*, **25***b*. Alternatively, a reference pad may be positioned in contact with the patient and the impedance between one of the sensors and the reference pad measured.

[0059] Referring to FIG. **5**B, electrode leads **18***a*, **18***b* and sensor leads **23***a*, **23***b* extend through the shaft **10** between the external walls of the tube **17** and the interior walls of the shaft **10** and they are coupled to electrical connector **21** which is preferably mounted to the collar **13** on the shaft **10**. Connector **21**, which is connectable to the RF generator **16**, includes at least four electrical contact rings **21***a*-**21***d* (FIGS. **1** and **2**) which correspond to each of the leads **18***a*, **18***b*, **23***a*, **23***b*. Rings **21***a*, **21***b* receive, from the RF generator, RF energy of positive and negative polarity, respectively. Rings **21***c*, **21***d* deliver signals from the right and left sensors, respectively, to a monitoring module within the RF generator **16**.

[0060] Referring to FIG. **5**A, the electrode carrying means **12** is attached to the distal end **20** of the shaft **10**. A plurality of holes **24** may be formed in the portion of the distal end **20** of the shaft which lies within the electrode carrying means **12**.

[0061] The electrode carrying means **12** preferably has a shape which approximates the shape of the body organ which is to be ablated. For example, the apparatus shown in FIGS. **1** through **11** has a bicornual shape which is desirable for intrauterine ablation. The electrode carrying means **12** shown in these figures includes horn regions **26** which during use are positioned within the cornual regions of the uterus and which therefore extend towards the fallopian tubes.

[0062] Electrode carrying means **12** is preferably a sack formed of a material which is non-conductive, which is permeable to moisture and/or which has a tendency to absorb moisture, and which may be compressed to a smaller volume and subsequently released to its natural size upon elimination of compression. Examples of preferred materials for the electrode carrying means include open cell sponge, foam, cotton, fabric, or cotton-like material, or any other material having the desired characteristics. Alternatively, the electrode carrying means may be formed of a metallized fabric. For convenience, the term "pad" may be used interchangeably with the term electrode carrying means to refer to an electrode carrying means formed of any of the above materials or having the listed properties.

[0063] Electrodes **14** are preferably attached to the outer surface of the electrode carrying means **12**, such as by deposition or other attachment mechanism. The electrodes are preferably made of lengths of silver, gold, platinum, or any other conductive material. The electrodes may be attached to the electrode carrying means **12** by electron beam deposition, or they may be formed into coiled wires and bonded to the electrode carrying member using a flexible adhesive. Naturally, other means of attaching the electrodes, such as sewing them onto the surface of the carrying member, may alternatively be used. If the electrode carrying means **12** is formed of a metallized fabric, an insulating layer may be etched onto the fabric surface, leaving only the electrode regions exposed.

[0064] The spacing between the electrodes (i.e. the distance between the centers of adjacent electrodes) and the widths of the electrodes are selected so that ablation will reach predetermined depths within the tissue, particularly when maximum power is delivered through the electrodes (where maximum power is the level at which low impedance, low voltage ablation can be achieved).

[0065] The depth of ablation is also effected by the electrode density (i.e., the percentage of the target tissue area which is in contact with active electrode surfaces) and may be regulated by pre-selecting the amount of this active electrode coverage. For example, the depth of ablation is much greater when the active electrode surface covers more than 10% of the target tissue than it is when the active electrode surfaces covers 1% of the target tissue.

[0066] For example, by using 3-6 mm spacing and an electrode width of approximately 0.5-2.5 mm, delivery of approximately 20-40 watts over a 9-16 cm2 target tissue area will cause ablation to a depth of approximately 5-7 millimeters when the active electrode surface covers more than 10% of the target tissue area. After reaching this ablation depth, the impedance of the tissue will become so great that ablation will self-terminate as described with respect to the operation of the invention.

[0067] By contrast, using the same power, spacing, electrode width, and RF frequency will produce an ablation depth of only 2-3 mm when the active electrode surfaces covers less than 1% of the target tissue area. This can be better understood with reference to FIG. **19**A, in which high surface density electrodes are designated **14***a* and low surface density electrodes are designated **14***b*. For purposes of this comparison between low and high surface density electrodes, each bracketed group of low density electrodes is considered to be a single electrode. Thus, the electrode widths W and spacings S extend as shown in FIG. **19**A.

[0068] As is apparent from FIG. **19**A, the electrodes **14***a*, which have more active area in contact with the underlying tissue T, produce a region of ablation **A1** that extends more deeply into the tissue T than the ablation region **A2** produced by the low density electrodes **14***b*, even though the electrode spacings and widths are the same for the high and low density electrodes.

[0069] Some examples of electrode widths, having spacings with more than 10% active electrode surface coverage, and their resultant ablation depth, based on an ablation area of 6 cm2 and a power of 20-40 watts, are given on the following table:

ELECTRODE WIDTH	SPACING	APPROX. DEPTH
1 mm	1-2 mm	1-3 mm
1-2.5 mm	3-6 mm	5-7 mm
1-4.5 mm	8-10 mm	8-10 mm

[0070] Examples of electrode widths, having spacings with less than 1% active electrode surface coverage, and their resultant ablation depth, based on an ablation area of 6 cm2 and a power of 20-40 watts, are given on the following table:

ELECTRODE WIDTH	SPACING	APPROX. DEPTH
1 mm	1-2 mm	0.5-1 mm
1-2.S mm	3-6 mm	2-3 mm
1-4.5 mm	8-10 mm	2-3 mm

[0071] Thus it can be seen that the depth of ablation is significantly less when the active electrode surface coverage is decreased.

[0072] In the preferred embodiment, the preferred electrode spacing is approximately 8-10 mm in the horn regions **26** with the active electrode surfaces covering approximately 1% of the target region. Approximately 1-2 mm electrode spacing (with 10% active electrode coverage) is preferred in the cervical region (designated **28**) and approximately 3-6 mm (with greater than 10% active electrode surface coverage) is preferred in the main body region.

[0073] The RF generator **16** may be configured to include a controller which gives the user a choice of which electrodes should be energized during a particular application in order to give the user control of ablation depth. For example, during an application for which deep ablation is desired, the user may elect to have the generator energize every other electrode, to thereby optimize the effective spacing of the electrodes and to decrease the percentage of active electrode surface coverage, as will be described below with respect to FIG. **18**.

[0074] Although the electrodes shown in the drawings are arranged in a particular pattern, it should be appreciated that the electrodes may be arranged in any pattern to provide ablation to desired depths.

[0075] Referring to FIGS. **6** and **7**, an introducer sheath **32** facilitates insertion of the apparatus into, and removal of the apparatus from, the body organ to be ablated. The sheath **32** is a tubular member which is telescopically slidable over the shaft **10**. The sheath **32** is slidable between a distal condition, shown in FIG. **6**, in which the electrode carrying means **12** is compressed inside the sheath, and a proximal condition in which the sheath **32** is moved proximally to release the electrode carrying means from inside it (FIG. **7**). By compressing the electrode carrying means **12** to a small volume, the electrode carrying means and electrodes can be easily inserted into the body cavity (such as into the uterus via the vaginal opening).

[0076] A handle **34** attached to the sheath **32** provides finger holds to allow for manipulation of the sheath **32**. Handle **34** is slidably mounted on a handle rail **35** which includes a sleeve **33**, a finger cutout **37**, and a pair of spaced rails **35***a*, **35***b* extending between the sleeve **33** and the finger cutout **37**. The shaft **10** and sheath **32** slidably extend through the sleeve **33** and between the rails **35***a*, **35***b*. The tube **17** also extends through the sleeve **33** and between the rails **35***a*, **35***b*, and its proximal end is fixed to the handle rail **35** near the finger cutout **37**.

[0077] A compression spring **39** is disposed around the proximal most portion of the suction/insufflation tube **17** which lies between the rails **35***a*, **35***b*. One end of the compression spring **39** rests against the collar **13** on the shaft **10**, while the opposite end of the compression spring rests against the handle rail **35**. During use, the sheath **32** is retracted from the electrode carrying means **12** by squeezing the handle **34** towards the finger cutout **37** to slide the sheath **32** in the distal direction. When the handle **34** advances against the collar **13**, the shaft **10** (which is attached to the collar **13**) is forced to slide in the proximal direction, causing compression of the spring **39** against the handle rail **35**. The movement of the shaft **10** relative to the suction/insufflation tube **17** causes the shaft **10** to pull proximally on the passive spring member **15**. Proximal movement of the passive spring member **15** in turn pulls against the active spring member **19**, causing it to move to the opened condition shown in FIG. **7**. Unless the shaft is held in this retracted condition, the compression spring **39** will push the collar and thus the shaft distally, forcing the RF applicator head to close. A locking mechanism (not shown) may be provided to hold the shaft in the fully withdrawn condition to prevent inadvertent closure of the spring members during the ablation procedure.

[0078] The amount by which the springs **15**, **19** are spread may be controlled by manipulating the handle **34** to slide the shaft **10** (via collar **13**), proximally or distally. Such sliding movement of the shaft **10** causes forceps-like movement of the spring members **15**, **19**.

[0079] A flow pathway **36** is formed in the handle rail **35** and is fluidly coupled to a suction/insufflation port **38**. The proximal end of the suction/insufflation tube **17** is fluidly coupled to the flow pathway so that gas fluid may be introduced into, or withdrawn from the suction/insufflation tube **17** via the suction/insufflation port **38**. For example, suction may be applied to the fluid port **38** using a suction/insufflation unit **40**. This causes water vapor within the uterine cavity to pass through the permeable electrode carrying means **12**, into

the suction/insufflation tube **17** via holes **17***a*, through the tube **17**, and through the suction/insufflation unit **40** via the port **38**. If insufflation of the uterine cavity is desired, insufflation gas, such as carbon dioxide, may be introduced into the suction/insufflation tube **17** via the port **38**. The insufflation gas travels through the tube **17**, through the holes **17***a*, and into the uterine cavity through the permeable electrode carrying member **12**.

[0080] If desirable, additional components may be provided for endoscopic visualization purposes. For example, lumen **42**, **44**, and **46** may be formed in the walls of the introducer sheath **32** as shown in FIG. **5**B. An imaging conduit, such as a fiberoptic cable **48**, extends through lumen **42** and is coupled via a camera cable **43** to a camera **45**. Images taken from the camera may be displayed on a monitor **56**. An illumination fiber **50** extends through lumen **44** and is coupled to an illumination source **54**. The third lumen **46** is an instrument channel through which surgical instruments may be introduced into the uterine cavity, if necessary.

[0081] Because during use it is most desirable for the electrodes **14** on the surface of the electrode carrying means **12** to be held in contact with the interior surface of the organ to be ablated, the electrode carrying means **12** may be provided to have additional components inside it that add structural integrity to the electrode carrying means when it is deployed within the body.

[0082] For example, referring to FIG. **11**, alternative spring members **15***a*, **19***a* may be attached to the shaft **10** and biased such that, when in a resting state, the spring members are positioned in the fully resting condition shown in FIG. **11**. Such spring members would spring to the resting condition upon withdrawal of the sheath **32** from the RF applicator head **2**.

[0083] Alternatively, a pair of inflatable balloons **52** may be arranged inside the electrode carrying means **12** as shown in FIG. **20** and connected to a tube (not shown) extending through the shaft **10** and into the balloons **52**. After insertion of the apparatus into the organ and following retraction of the sheath **32**, the balloons **52** would be inflated by introduction of an inflation medium such as air into the balloons via a port similar to port **38** using an apparatus similar to the suction/insufflation apparatus **40**.

[0084] Structural integrity may also be added to the electrode carrying means through the application of suction to the proximal end **22***a* of the suction/insufflation tube **17**. Application of suction using the suction/insufflation device **40** would draw the organ tissue towards the electrode carrying means **12** and thus into better contact with the electrodes **14**.

[0085] FIGS. **12** and **13** show an alternative embodiment of an ablation device according to the present invention. In the alternative embodiment, an electrode carrying means **12***a* is provided which has a shape which is generally tubular and thus is not specific to any particular organ shape. An ablation device having a general shape such as this may be used anywhere within the body where ablation or coagulation is needed. For example, the alternative embodiment is useful for bleeding control during laparoscopic surgery (FIG. **14**), tissue ablation in the prostate gland (FIG. **17**), and also intrauterine ablation (FIGS. **15** and **16**).

First Exemplary Embodiment

Operation

[0086] Operation of the first exemplary embodiment of an ablation device according to the present invention will next be described.

[0087] Referring to FIG. **1**, the device is initially configured for use by positioning the introducer sheath **32** distally along the shaft **10**, such that it compresses the electrode carrying means **12** within its walls.

[0088] At this time, the electrical connector **21** is connected to the RF generator **16**, and the fiberoptic cable **48** and the illumination cable **50** are connected to the illumination source, monitor, and camera, **54**, **56**, **45**. The suction/insufflation unit **40** is attached to suction/insufflation port **38** on the handle rail **35**. The suction/insufflation unit **40** is preferably set to deliver carbon dioxide at an insufflation pressure of 20-200 mmHg.

[0089] Next, the distal end of the apparatus is inserted through the vaginal opening V and into the uterus U as shown in FIG. **6**, until the distal end of the introducer sheath **32** contacts the fundus F of the uterus. At this point, carbon dioxide gas is introduced into the tube **17** via the port **38**, and it enters the uterine cavity, thereby expanding the uterine cavity from a flat triangular shape to a 1-2 cm high triangular cavity. The physician may observe (using the camera **45** and monitor **56**) the internal cavities using images detected by a fiberoptic cable **48** inserted through lumen **42**. If, upon observation, the physician determines that a tissue biopsy or other procedure is needed, the required instruments may be inserted into the uterine cavity via the instrument channel **46**.

[0090] Following insertion, the handle **34** is withdrawn until it abuts the collar **13**. At this point, the sheath **32** exposes the electrode carrying member **12** but the electrode carrying member **12** is not yet fully expanded (see FIG. **9**), because the spring members **15**, **19** have not yet been moved to their open condition. The handle **34** is withdrawn further, causing the shaft **10** to move proximally relative to the suction/insufflation tube **17**, causing the passive spring members **15** to pull the active spring members **19**, causing them to open into the opened condition shown in FIG. **10**.

[0091] The physician may confirm proper positioning of the electrode carrying member **12** using the monitor **56**, which displays images from the fiberoptic cable **48**.

[0092] Proper positioning of the device and sufficient contact between the electrode carrying member **12** and the endometrium may further be confirmed using the contact sensors **25***a*, **25***b*. The monitoring module of the RF generator measures the impedance between these sensors using conventional means. If there is good contact between the sensors and the endometrium, the measured impedance will be approximately 20-180 ohm, depending on the water content of the endometrial lining.

[0093] The sensors are positioned on the distal portions of the bicornual shaped electrode carrying member **12**, which during use are positioned in the regions within the uterus in which it is most difficult to achieve good contact with the endometrium. Thus, an indication from the sensors **25***a*, **25***b* that there is sound contact between the sensors and the endometrial surface indicates that good electrode contact has been made with the endometrium.

[0094] Next, insufflation is terminated. Approximately 1-5 cc of saline may be introduced via suction/insufflation tube **17** to initially wet the electrodes and to improve electrode elec-

trical contact with the tissue. After introduction of saline, the suction/insufflation device **40** is switched to a suctioning mode. As described above, the application of suction to the RF applicator head **2** via the suction/insufflation tube **17** collapses the uterine cavity onto the RF applicator head **2** and thus assures better contact between the electrodes and the endometrial tissue.

[0095] If the generally tubular apparatus of FIGS. **12** and **13** is used, the device is angled into contact with one side of the uterus during the ablation procedure. Once ablation is completed, the device (or a new device) is repositioned in contact with the opposite side and the procedure is repeated. See. FIGS. **15** and **16**.

[0096] Next, RF energy at preferably about 500 kHz and at a constant power of approximately 30 W is applied to the electrodes. As shown in FIG. **5***a*, it is preferable that each electrode be energized at a polarity opposite from that of its neighboring electrodes. By doing so, energy field patterns, designated F**1**, F**2** and F**4** in FIG. **18**, are generated between the electrode sites and thus help to direct the flow of current through the tissue T to form a region of ablation A. As can be seen in FIG. **18**, if electrode spacing is increased such by energizing, for example every third or fifth electrode rather than all electrodes, the energy patterns will extend more deeply into the tissue. (See, for example, pattern F**2** which results from energization of electrodes having a non-energized electrode between them, or pattern F**4** which results from energization of electrodes having three non-energized electrodes between them).

[0097] Moreover, ablation depth may be controlled as described above by providing low surface density electrodes on areas of the electrode carrying member which will contact tissue areas at which a smaller ablation depth is required (see FIG. **19**A). Referring to FIG. **19**B, if multiple, closely spaced, electrodes **14** are provided on the electrode carrying member, a user may set the RF generator to energize electrodes which will produce a desired electrode spacing and active electrode area. For example, alternate electrodes may be energized as shown in FIG. **19**B, with the first three energized electrodes having positive polarity, the second three having negative polarity, etc.

[0098] As another example, shown in FIG. **19**C, if greater ablation depth is desired the first five electrodes may be positively energized, and the seventh through eleventh electrodes negatively energized, with the sixth electrode remaining inactivated to provide adequate electrode spacing.

[0099] As the endometrial tissue heats, moisture begins to be released from the tissue. The moisture permeates the electrode carrying member **12** and is thereby drawn away from the electrodes. The moisture may pass through the holes **17***a* in the suction/insufflation tube **17** and leave the suction/insufflation tube **17** at its proximal end via port **38** as shown in FIG. **7**. Moisture removal from the ablation site may be further facilitated by the application of suction to the shaft **10** using the suction/insufflation unit **40**.

[0100] Removal of the moisture from the ablation site prevents formation of a liquid layer around the electrodes. As described above, liquid build-up at the ablation site is detrimental in that provides a conductive layer that carries current from the electrodes even when ablation has reached the desired depth. This continued current flow heats the liquid and surrounding tissue, and thus causes ablation to continue by unpredictable thermal conduction means.

[0101] Tissue which has been ablated becomes dehydrated and thus decreases in conductivity. By shunting moisture away from the ablation site and thus preventing liquid build-up, there is no liquid conductor at the ablation area during use of the ablation device of the present invention. Thus, when ablation has reached the desired depth, the impedance at the tissue surface becomes sufficiently high to stop or nearly stop the flow of current into the tissue. RF ablation thereby stops and thermal ablation does not occur in significant amounts. If the RF generator is equipped with an impedance monitor, a physician utilizing the ablation device can monitor the impedance at the electrodes and will know that ablation has self-terminated once the impedance rises to a certain level and then remains fairly constant. By contrast, if a prior art bipolar RF ablation device was used together with an impedance monitor, the presence of liquid around the electrodes would cause the impedance monitor to give a low impedance reading regardless of the depth of ablation which had already been carried out, since current would continue to travel through the low-impedance liquid layer.

[0102] Other means for monitoring and terminating ablation may also be provided. For example, a thermocouple or other temperature sensor may be inserted to a predetermined depth in the tissue to monitor the temperature of the tissue and terminate the delivery of RF energy or otherwise signal the user when the tissue has reached a desired ablation temperature.

[0103] Once the process has self terminated, 1-5 cc of saline can be introduced via suction/insufflation tube **17** and allowed to sit for a short time to aid separation of the electrode from the tissue surface. The suction insufflation device **40** is then switched to provide insufflation of carbon dioxide at a pressure of 20-200 mmHg. The insufflation pressure helps to lift the ablated tissue away from the RF applicator head **2** and to thus ease the closing of the RF applicator head. The RF applicator head **2** is moved to the closed position by sliding the handle **34** in a distal direction to fold the spring members **15**, **19** along the axis of the device and to cause the introducer sheath **32** to slide over the folded RF applicator head. The physician may visually confirm the sufficiency of the ablation using the monitor **56**. Finally, the apparatus is removed from the uterine cavity.

Second Exemplary Embodiment

Structure

[0104] A second embodiment of an ablation device **100** in accordance with the present invention is shown in FIGS. **21**-**37**B. The second embodiment differs from the first embodiment primarily in its electrode pattern and in the mechanism used to deploy the electrode applicator head or array. Naturally, aspects of the first and second exemplary embodiments and their methods of operation may be combined without departing from the scope of the present invention.

[0105] Referring to FIGS. **21** and **22**, the second embodiment includes an RF applicator head **102**, a sheath **104**, and a handle **106**. As with the first embodiment, the applicator head **102** is slidably disposed within the sheath **104** (FIG. **21**) during insertion of the device into the uterine cavity, and the handle **106** is subsequently manipulated to cause the applicator head **102** to extend from the distal end of the sheath **104** (FIG. **22**) and to expand into contact with body tissue (FIG. **33**).

[0106] RF Applicator Head

[0107] Referring to FIG. **23**, in which the sheath **104** is not shown for clarity, applicator head **102** extends from the distal end of a length of tubing **108** which is slidably disposed within the sheath **104**. Applicator head **102** includes an external electrode array **102***a* and an internal deflecting mechanism **102***b* used to expand and tension the array for positioning into contact with the tissue.

[0108] Referring to FIGS. **25**A and **25**B, the array **102***a* of applicator head **102** is formed of a stretchable metallized fabric mesh which is preferably knitted from a nylon and spandex knit plated with gold or other conductive material. In one array design, the knit (shown in FIGS. **26**A and **26**B) is formed of three monofilaments of nylon **109***a* knitted together with single yarns of spandex **19***b*. Each yarn of spandex **109***b* has a double helix **109***c* of five nylon monofilaments coiled around it.

[0109] This knit of elastic (spandex) and inelastic (nylon) yarns is beneficial for a number of reasons. For example, knitting elastic and relatively inelastic yarns allows the overall deformability of the array to be pre-selected.

[0110] The mesh is preferably constructed so as to have greater elasticity in the transverse direction (T) than in the longitudinal direction (L). In a preferred mesh design, the transverse elasticity is on the order of approximately 300% whereas the longitudinal elasticity is on the order of approximately 100%. The large transverse elasticity of the array allows it to be used in a wide range of uterine sizes.

[0111] Another advantage provided by the combination of elastic and relatively inelastic yarns is that the elastic yarns provide the needed elasticity to the array while the relatively inelastic yarns provide relatively non-stretchable members to which the metallization can adhere without cracking during expansion of the array. In the knit configuration described above, the metallization adheres to the nylon coiled around the spandex. During expansion of the array, the spandex elongates and the nylon double helix at least partially elongates from its coiled configuration.

[0112] One process which may be used to apply the gold to the nylon/spandex knit involves plating the knit with silver using known processes which involve application of other materials as base layers prior to application of the silver to ensure that the silver will adhere. Next, the insulating regions **110** (described below) are etched onto the silver, and afterwards the gold is plated onto the silver. Gold is desirable for the array because of it has a relatively smooth surface, is a very inert material, and has sufficient ductility that it will not crack as the nylon coil elongates during use.

[0113] The mesh may be configured in a variety of shapes, including but not limited to the triangular shape **S1**, parabolic **S2**, and rectangular **S3** shapes shown in FIGS. **27**A, **27**B and **27**C, respectively.

[0114] Turning again to FIGS. **25**A and **25**B, when in its expanded state, the array **102***a* includes a pair of broad faces **112** spaced apart from one another. Narrower side faces **114** extend between the broad faces **112** along the sides of the applicator head **102**, and a distal face **116** extends between the broad faces **112** at the distal end of the applicator head **102**.

[0115] Insulating regions **110** are formed on the applicator head to divide the mesh into electrode regions. The insulated regions **110** are preferably formed using etching techniques to remove the conductive metal from the mesh, although alternate methods may also be used, such as by knitting conductive and non-conductive materials together to form the array.

[0116] The array may be divided by the insulated regions **110** into a variety of electrode configurations. In a preferred configuration the insulating regions **110** divide the applicator head into four electrodes **118***a*-**118***d* by creating two electrodes on each of the broad faces **112**. To create this four-electrode pattern, insulating regions **110** are placed longitudinally along each of the broad faces **112** as well as along the length of each of the faces **114**, **116**. The electrodes **118***a*-**118***d* are used for ablation and, if desired, to measure tissue impedance during use.

[0117] Deflecting mechanism **102***b* and its deployment structure is enclosed within electrode array **102***a*. Referring to FIG. **23**, external hypotube **120** extends from tubing **108** and an internal hypotube **122** is slidably and co-axially disposed within hypotube **120**. Flexures **124** extend from the tubing **108** on opposite sides of external hypotube **120**. A plurality of longitudinally spaced apertures **126** (FIG. **28**) are formed in each flexure **124**. During use, apertures **126** allow moisture to pass through the flexures and to be drawn into exposed distal end of hypotube **120** using a vacuum source fluidly coupled to hypotube **120**.

[0118] Each flexure **124** preferably includes conductive regions that are electrically coupled to the array **102***a* for delivery of RF energy to the body tissue. Referring to FIG. **29**, strips **128** of copper tape or other conductive material extend along opposite surfaces of each flexure **124**. Each strip **128** is electrically insulated from the other strip **128** by a non-conductive coating on the flexure. Conductor leads (not shown) are electrically coupled to the strips **128** and extend through tubing **108** (FIG. **23**) to an electrical cord **130** (FIG. **21**) which is attachable to the RF generator.

[0119] During use, one strip **128** on each conductor is electrically coupled via the conductor leads to one terminal on the RF generator while the other strip is electrically coupled to the opposite terminal, thus causing the array on the applicator head to have regions of alternating positive and negative polarity.

[0120] The flexures may alternatively be formed using a conductive material or a conductively coated material having insulating regions formed thereon to divide the flexure surfaces into multiple conductive regions. Moreover, alternative methods such as electrode leads independent of the flexures **124** may instead be used for electrically connecting the electrode array to the source of RF energy.

[0121] It is important to ensure proper alignment between the conductive regions of the flexures **124** (e.g. copper strips **128**) and the electrodes **118***a*-**118***d* in order to maintain electrical contact between the two. Strands of thread **134** (which may be nylon) (FIG. **23**) are preferably sewn through the array **102***a* and around the flexures **124** in order to prevent the conductive regions **128** from slipping out of alignment with the electrodes **118***a*-**118***d*. Alternate methods for maintaining contact between the array **102***a* and the conductive regions **128** include using tiny bendable barbs extending between the flexures **124** and the array **102***a* to hook the array to the conductive regions **128**, or bonding the array to the flexures using an adhesive applied along the insulating regions of the flexures.

[0122] Referring again to FIG. **23**, internal flexures **136** extend laterally and longitudinally from the exterior surface of hypotube **122**. Each internal flexure **136** is connected at its

distal end to one of the flexures **124** and a transverse ribbon **138** extends between the distal portions of the internal flexures **136**. Transverse ribbon **138** is preferably pre-shaped such that when in the relaxed condition the ribbon assumes the corrugated configuration shown in FIG. **23** and such that when in a compressed condition it is folded along the plurality of creases **140** that extend along its length. Flexures **124**, **136** and ribbon **138** are preferably an insulated spring material such as heat treated 17-7 PH stainless steel.

[0123] The deflecting mechanism is preferably configured such that the distal tips of the flexures **124** are sufficiently flexible to prevent tissue puncture during deployment and/or use. Such an atraumatic tip design may be carried out in a number of ways, such as by manufacturing the distal sections **124***a* (FIG. **28**) of the flexures from a material that is more flexible than the proximal sections **124***b*. For example, flexures **124** may be provided to have proximal sections formed of a material having a modulus of approximately 28×106 psi and distal sections having a durometer of approximately 72D.

[0124] Alternatively, referring to FIG. **30**, the flexures **124** may be joined to the internal flexures **136** at a location more proximal than the distal tips of the flexures **124**, allowing them to move more freely and to adapt to the contour of the surface against which they are positioned (see dashed lines in FIG. **30**). Given that uterine sizes and shapes vary widely between women, the atraumatic tip design is further beneficial in that it allows the device to more accurately conform to the shape of the uterus in which it is deployed while minimizing the chance of injury.

[0125] The deflecting mechanism formed by the flexures **124**, **136**, and ribbon **138** forms the array into the substantially triangular shape shown in FIG. **23**, which is particularly adaptable to most uterine shapes. As set forth in detail below, during use distal and proximal grips **142**, **144** forming handle **106** are squeezed towards one another to withdraw the sheath and deploy the applicator head. This action results in relative rearward motion of the hypotube **120** and relative forward motion of the hypotube **122**. The relative motion between the hypotubes causes deflection in flexures **124**, **136** which deploys and tensions the electrode array **102***a*.

[0126] Measurement Device

[0127] The ablation device according to the second embodiment includes a measurement device for easily measuring the uterine width and for displaying the measured width on a gauge **146** (FIG. **21**). The measurement device utilizes non-conductive (e.g. nylon) suturing threads **148** that extend from the hypotube **122** and that have distal ends attached to the distal portion of the deflecting mechanism (FIG. **23**). As shown in FIG. **24**, threads **148** are preferably formed of a single strand **150** threaded through a wire loop **152** and folded over on itself. Wire loop **152** forms the distal end of an elongate wire **154** which may be formed of stainless steel or other wire.

[0128] Referring to FIG. **31**, wire **154** extends through the hypotube **122** and is secured to a rotatable bobbin **156**. The rotatable bobbin **156** includes a dial face **158** preferably covered in a clear plastic. As can be seen in FIG. **32***b*, dial face **158** includes calibration markings corresponding to an appropriate range of uterine widths. The bobbin is disposed within a gauge housing **160** and a corresponding marker line **162** is printed on the gauge housing. A torsion spring **164** provides rotational resistance to the bobbin **156**.

[0129] Expansion of the applicator head **102** during use pulls threads **148** (FIG. **23**) and thus wire **154** (FIG. **24**) in a distal direction. Wire **154** pulls against the bobbin **156** (FIG. **31**), causing it to rotate. Rotation of the bobbin positions one of the calibration markings on dial face **158** into alignment with the marker line **162** (FIG. **32**B) to indicate the distance between the distal tips of flexures **124** and thus the uterine width.

[0130] The uterine width and length (as determined using a conventional sound or other means) are preferably input into an RF generator system and used by the system to calculate an appropriate ablation power as will be described below. Alternately, the width as measured by the apparatus of the invention and length as measured by other means may be used by the user to calculate the power to be supplied to the array to achieve the desired ablation depth.

[0131] The uterine width may alternatively be measured using other means, including by using a strain gauge in combination with an A/D converter to transduce the separation distance of the flexures **124** and to electronically transmit the uterine width to the RF generator.

[0132] Control of Ablation Depth

[0133] The most optimal electrocoagulation occurs when relatively deep ablation is carried out in the regions of the uterus at which the endometrium is thickest, and when relatively shallower ablation is carried out in areas in which the endometrium is shallower. A desirable range of ablation depths includes approximately 2-3 mm for the cervical os and the cornual regions, and approximately 7-8 mm in the main body of the uterus where the endometrium is substantially thicker.

[0134] As discussed with respect to the first embodiment, a number of factors influence the ablation depth that can be achieved using a given power applied to a bipolar electrode array. These include the power supplied by the RF generator, the distance between the centers of adjacent electrodes ("center-to-center distance"), the electrode density (i.e., the porosity of the array fabric or the percent of the array surface that is metallic), the edge gap (i.e. the distance between the edges of adjacent electrode poles), and the electrode surface area. Other factors include blood flow (which in slower-ablating systems can dissipate the RF) and the impedance limit.

[0135] Certain of these factors may be utilized in the present invention to control ablation depth and to provide deeper ablation at areas requiring deeper ablation and to provide shallower regions in areas where deep ablation is not needed. For example, as center-to-center distance increases, the depth of ablation increases until a point where the center to center distance is so great that the strength of the RF field is too diffuse to excite the tissue. It can been seen with reference to FIG. **33** that the center to center distance d**1** between the electrodes **118***a*, **118***b* is larger within the region of the array that lies in the main body of the uterus and thus contributes to deeper ablation. The center to center distance d**2** between electrodes **118***a*, **118***b* is smaller towards the cervical canal where it contributes to shallower ablation. At the distal end of the device, the shorter center to center distances d**3** extend between top and bottom electrodes **118***b*, **118***c* and **118***a*, **118***d* and again contribute to shallower ablation.

[0136] Naturally, because the array **102***a* expands to accommodate the size of the uterus in which it is deployed, the dimensions of the array **102***a* vary. One embodiment of the array **102***a* includes a range of widths of at least approximately 2.5-4.5 cm, a range of lengths of at least approximately 4-6 cm, and a density of approximately 35%-45%.

[0137] The power supplied to the array by the RF generator is calculated by the RF generator system to accommodate the electrode area required for a particular patient. As discussed above, the uterine width is measured by the applicator head **102** and displayed on gauge **146**. The uterine length is measured using a sound, which is an instrument conventionally used for that purpose. It should be noted that calibration markings of the type used on a conventional sound device, or other structure for length measurement, may be included on the present invention to allow it to be used for length measurement as well.

[0138] The user enters the measured dimensions into the RF generator system using an input device, and the RF generator system calculates or obtains the appropriate set power from a stored look-up table using the uterine width and length as entered by the user. An EPROM within the RF generator system converts the length and width to a set power level according to the following relationship:

$$P=L\times W\times 5.5$$

[0139] Where P is the power level in watts, L is the length in centimeters, W is the width in centimeters, and 5.5 is a constant having units of watts per square centimeter.

[0140] Alternatively, the user may manually calculate the power setting from the length and width, or s/he may be provided with a table of suggested power settings for various electrode areas (as determined by the measured length and width) and will manually set the power on the RF generator accordingly.

[0141] Handle

[0142] Referring again to FIGS. **21** and **22**, the handle **106** of the RF ablation device according to the second embodiment includes a distal grip section **142** and a proximal grip section **144** that are pivotally attached to one another at pivot pin **166**.

[0143] The proximal grip section **144** is coupled to the hypotube **122** (FIG. **23**) via yoke **168**, overload spring **170** and spring stop **172**, each of which is shown in the section view of FIG. **34**. The distal grip section **142** is coupled to the external hypotube **120** via male and female couplers **174**, **176** (see FIGS. **32**A and **32**B). Squeezing the grip sections **142**, **144** towards one another thus causes relative movement between the external hypotube **120** and the internal hypotube **122**. This relative sliding movement results in deployment of the deflecting mechanism **102***b* from the distal end of the sheath and expansion of the array **102***a* to its expanded state.

[0144] Referring to FIGS. **32**A and B, rack **180** is formed on male coupler **174** and calibration markings **182** are printed adjacent the rack **180**. The calibration markings **182** correspond to a variety of uterine lengths and may include lengths ranging from, for example, 4.0 to 6.0 cm in 0.5 cm increments.

[0145] A sliding collar **184** is slidably disposed on the tubing **108** and is slidable over male coupler **174**. Sliding collar **184** includes a rotating collar **186** and a female coupler **176** that includes a wedge-shaped heel **188**. A locking spring member **190** (FIGS. **32**B and **35**) extends across an aperture **192** formed in the proximal grip **144** in alignment with the heel **188**. When the distal and proximal handle sections are squeezed together to deploy the array, the heel **188** passes into the aperture **192**. Its inclined lower surface gradually depresses the spring member **190** as the heel moves further into the aperture **192**. See FIGS. **36**A and **36**B. After passing completely over the spring member, the heel moves out of contact with the spring member. The spring member snaps upwardly thereby engaging the heel in the locked position. See FIG. **36**C.

[0146] A release lever **194** (FIG. **35**) is attached to the free end of the spring member **190**. To disengage the spring lock, release lever **194** is depressed to lower spring member **190** so that the inclined heel can pass over the spring member and thus out of the aperture **192**.

[0147] Referring again to FIGS. **32**A and **32**B, sliding collar **184** is configured to allow the user to limit longitudinal extension of the array **102***a* to a distance commensurate with a patient's predetermined uterine length. It does so by allowing the user to adjust the relative longitudinal position of male coupler **174** relative to the female coupler **176** using the rotating collar **186** to lock and unlock the female coupler from the rack **180** and the male coupler **174**. Locking the female coupler to the rack **180** and male coupler **174** will limit extension of the array to approximately the predetermined uterine length, as shown on the calibration markings **182**.

[0148] Once the uterine length has been measured using a conventional sound, the user positions sliding collar **184** adjacent to calibration marks **182** corresponding to the measured uterine length (e.g. 4.5 cm). Afterwards, the user rotates the collar section **186** to engage its internally positioned teeth with the rack **180**. This locks the longitudinal position of the heel **188** such that it will engage with the spring member **190** on the proximal grip when the array has been exposed to the length set by the sliding collar.

[0149] The handle **106** includes a pair of spring assemblies which facilitate controlled deployment and stowage of the array **102***a*. One of the spring assemblies controls movement of the grips **142**, **144** to automatically stow the array **102***a* into the sheath **104** when the user stops squeezing the grips **142**, **144** towards one another. The other of the spring assemblies controls the transverse movement of the spring flexures **124** to the expanded condition by limiting the maximum load that can be applied to the deployment mechanism **102***b*.

[0150] FIG. **34** shows the distal and proximal grips **142** and **144** in partial cross-section. The first spring assembly for controlled stowage includes a handle return mandrel **196** that is slidably disposed within the proximal grip **144**. A compression spring **198** surrounds a portion of the return mandrel **196**, and a retaining ring **200** is attached to the mandrel **196** above the spring **198**. A spring stop **202** is disposed between the spring **198** and the retaining ring.

[0151] The lowermost end of the return mandrel **196** is pivotally engaged by a coupling member **204** on distal grip **142**. Relative movement of the grips **142**, **144** towards one another causes the coupling member **204** to pull the return member downwardly with the proximal grip **144** as indicated by arrows. Downward movement of the mandrel **196** causes its retaining ring **200** and spring stop **202** to bear downwardly against the compression spring **198**, thereby providing a movement which acts to rotate the grips **142**, **144** away from one another. When tension against the grips **142**, **144** is released (assuming that heel **188** is not locked into engagement with spring member **190**) the grips rotate apart into the opened position as the compression spring **198** returns to the initial state, stowing the applicator head inside the sheath.

[0152] The second spring assembly for controlling array deployment is designed to control separation of the flexures. It includes a frame member **178** disposed over yoke **168**, Which is pivotally attached to proximal grip **144**. Tubing **108** extends from the array **102***a* (see FIG. **23**), through the sheath

104 and is fixed at its proximal end to the frame member **178**. Hypotube **122** does not terminate at this point but instead extends beyond the proximal end of tubing **108** and through a window **206** in the frame member. Its proximal end **208** is slidably located within frame member **178** proximally of the window **206** and is fluidly coupled to a vacuum port **210** by fluid channel **212**. Hypotube **120** terminates within the frame. Its proximal end is fixed within the distal end of the frame.

[0153] A spring stop **172** is fixed to a section of the hypotube within the window **206**, and a compression spring **170** is disposed around the hypotube between the spring stop **172** and yoke **168**. See FIGS. **32**B and **34**.

[0154] When the distal and proximal grips are moved towards one another, the relative rearward motion of the distal grip causes the distal grip to withdraw the sheath **104** from the array **102***a*. Referring to FIGS. **37**A and **37**B, this motion continues until female coupler **176** contacts and bears against frame member **178**. Continued motion between the grips causes a relative rearward motion in the frame which causes the same rearward relative motion in external hypotube **120**. An opposing force is developed in yoke **168**, which causes a relative forward motion in hypotube **122**. The relative motion between the hypotubes causes deflection in flexures **124**, **136** which deflect in a manner that deploys and tensions the electrode array. Compression spring **170** acts to limit the force developed by the operator against hypotubes **120**, **122**, thus limiting the force of flexures **124**, **136** acting on the array and the target tissue surrounding the array.

[0155] Referring to FIG. **21**, collar **214** is slidably mounted on sheath **104**. Before the device is inserted into the uterus, collar **214** can be positioned along sheath **104** to the position measured by the uterine sound. Once in position, the collar provides visual and tactile feedback to the user to assure the device has been inserted the proper distance. In addition, after the applicator head **102** has been deployed, if the patient's cervical canal diameter is larger than the sheath dimensions, the collar **214** can be moved distally towards the cervix, making contact with it and creating a pneumatic seal between the sheath and cervix.

Second Exemplary Embodiment

Operation

[0156] In preparation for ablating the uterus utilizing the second exemplary embodiment, the user measures the uterine length using a uterine sound device. The user next positions sliding collar **184** (FIG. **32**B) adjacent to calibration marks **182** corresponding to the measured uterine length (e.g. 4.5 cm) and rotates the collar section **186** to engage its internally positioned teeth with the rack **180**. This locks the longitudinal position of the heel **188** (FIG. **32**A) such that it will engage with the spring member **190** when the array has been exposed to the length set by the sliding collar.

[0157] Next, with the grips **142**, **144** in their resting positions to keep the applicator head **102** covered by sheath **104**, the distal end of the device **100** is inserted into the uterus. Once the distal end of the sheath **104** is within the uterus, grips **142**, **144** are squeezed together to deploy the applicator head **102** from sheath **104**. Grips **142**, **144** are squeezed until heel **188** engages with locking spring member **190** as described with respect to FIGS. **3**BA through **36**C.

[0158] At this point, deflecting mechanism **102***b* has deployed the array **102***a* into contact with the uterine walls. The user reads the uterine width, which as described above is transduced from the separation of the spring flexures, from gauge **146**. The measured length and width are entered into the RF generator system **250** (FIG. **21**) and used to calculate the ablation power.

[0159] Vacuum source **252** (FIG. **21**) is activated, causing application of suction to hypotube **122** via suction port **210**. Suction helps to draw uterine tissue into contact with the array **102**.

[0160] Ablation power is supplied to the electrode array **102***a* by the RF generator system **250**. The tissue is heated as the RF energy passes from electrodes **118***a-d* to the tissue, causing moisture to be released from the tissue. The vacuum source **252** helps to draw moisture from the uterine cavity into the hypotube **122**. Moisture withdrawal is facilitated by the apertures **126** formed in flexures **124** by preventing moisture from being trapped between the flexures **124** and the lateral walls of the uterus.

[0161] If the RF generator **250** includes an impedance monitoring module, impedance may be monitored at the electrodes **118***a-d* and the generator may be programmed to terminate RF delivery automatically once the impedance rises to a certain level. The generator system may also or alternatively display the measured impedance and allow the user to terminate RF delivery when desired.

[0162] When RF delivery is terminated, the user depresses release lever **194** to disengage heel **188** from locking spring member **190** and to thereby allow grips **142**, **144** to move to their expanded (resting) condition. Release of grips **142**, **144** causes applicator head **102** to retract to its unexpanded condition and further causes applicator head **102** to be withdrawn into the sheath **104**. Finally, the distal end of the device **100** is withdrawn from the uterus.

[0163] Two embodiments of ablation devices in accordance with the present invention have been described herein. These embodiments have been shown for illustrative purposes only. It should be understood, however, that the invention is not intended to be limited to the specifics of the illustrated embodiments but is defined only in terms of the following claims.

1-7. (canceled)

8. A device for treating a uterus comprising:

an elongate member having a proximal end and a distal end, the elongate member including a translatable sleeve;

an applicator head coupled to the distal end, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus;

a deflecting mechanism including flexures disposed within the applicator head and a translatable sleeve operably coupled to the flexures, wherein the deflecting mechanism is configured so that translating the translatable sleeve causes the applicator head to transition from the contracted state to the expanded state; and

an indicator mechanism operably coupled to the translatable sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

9. The device of claim **8** wherein the deflector mechanism further comprises a secondary sleeve, and wherein relative motion between the translatable sleeve and the secondary sleeve causes the applicator head to transition from the contracted state to the expanded state.

10. The device of claim **8** wherein the indicator mechanism indicates a distance between the flexures when the applicator head is in an expanded state.

11. The device of claim **8** wherein the applicator head is configured to ablate the uterus.

12. The device of claim **8** wherein the applicator head is configured to deliver radio-frequency energy.

13. The device of claim **8** further comprising a transverse ribbon coupled to a distal end of the flexures, wherein the transverse ribbon is in a relaxed condition when the applicator head is in the expanded state.

14. The device of claim **8** wherein the flexures include a plurality of longitudinally spaced apertures.

15. A device for treating a uterus comprising:

an elongate member having a proximal end and a distal end;

an applicator head coupled to the distal end of the elongate member, the applicator head defined by deformable walls having an expanded state and a contracted state, the expanded state being configured to conform to the shape of the uterus and the contracted state being configured for transcervical insertion;

a deflecting mechanism disposed within the applicator head and configured expand the applicator head from the contracted state to the expanded state; and

an indicator mechanism operably coupled to the deflecting mechanism, the indicator mechanism configured to indicate a dimension of the uterus.

16. The device of claim **15** wherein the deflecting mechanism includes a plurality of flexures having distal tips, and wherein the indicator mechanism is configured to indicate a distance between the distal tips.

17. The device of claim **15** wherein the elongate member includes an internal hypotube and an external hypotube, wherein the internal hypotube is disposed within the external hypotube, and wherein relative movement between the internal hypotube and the external hypotube deploys the deflecting mechanism and causes the applicator head to transition from the contracted state to the expanded state.

18. The device of claim **17** wherein a distance of relative movement between the internal hypotube and the external hypotube is indicative of a dimension of the uterus.

* * * * *

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Truckai et al.

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(45) **Date of Patent: Nov. 2, 2004**

(54) **METHOD FOR ABLATING AND/OR COAGULATING TISSUE USING MOISTURE TRANSPORT**

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(51) **Int. Cl.**[7] **A61F 2/00**
(52) **U.S. Cl.** **607/101**; 604/22; 604/28; 600/372; 600/373
(58) **Field of Search** 607/100, 101, 607/108, 96, 98, 99, 1, 2, 115, 116, 27, 32, 122, 138; 600/372, 373, 377, 591; 604/20, 21, 22, 28, 48, 500, 506, 514, 515, 517, 93.01, 264, 275, 113, 114, 49, 55, 95.01–96.01, 35, 511, 509; 606/47, 119, 191, 193, 198

(56) **References Cited**

U.S. PATENT DOCUMENTS

552,832 A 1/1896 Fort
725,731 A 4/1903 Linn
1,620,929 A 3/1927 Wallerich

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

DE 384246 10/1923
EP 0056178 2/1986
EP 0584930 A1 3/1994

(List continued on next page.)

OTHER PUBLICATIONS

D. E. Haines and A. F. Verow, Observations on Electrode–Tissue Interface Temperature and Effect on Electrical Inpendance During Radiofrequency Ablation of Ventricular Myocardium. Circulation vol. 82, No. 3, Sep. 1990.

(List continued on next page.)

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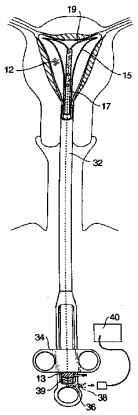
(57) **ABSTRACT**

An apparatus and method for use in performing ablation or coagulation of organs and other tissue includes a metallized fabric electrode array which is substantially absorbent and/or permeable to moisture and gases such as steam and conformable to the body cavity. The array includes conductive regions separated by insulated regions arranged to produce ablation to a predetermined depth. Following placement of the ablation device into contact with the tissue to be ablated, an RF generator is used to deliver RF energy to the conductive regions and to thereby induce current flow from the electrodes to tissue to be ablated. As the current heats the tissue, moisture (such as steam or liquid) leaves the tissue causing the tissue to dehydrate. Suction may be applied to facilitate moisture removal. The moisture permeability and/or absorbency of the electrode carrying member allows the moisture to leave the ablation site so as to prevent the moisture from providing a path of conductivity for the current.

47 Claims, 18 Drawing Sheets



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Next, with the grips **142**, **144** in their resting positions to keep the applicator head **102** covered by sheath **104**, the distal end of the device **100** is inserted into the uterus. Once the distal end of the sheath **104** is within the uterus, grips **142**, **144** are squeezed together to deploy the applicator head **102** from sheath **104**. Grips **142**, **144** are squeezed until heel **188** engages with locking spring member **190** as described with respect to FIGS. **36**A through **36**C.

At this point, deflecting mechanism **102***b* has deployed the array **102***a* into contact with the uterine walls. The user reads the uterine width, which as described above is transduced from the separation of the spring flexures, from gauge **146**. The measured length and width are entered into the RF generator system **250** (FIG. **21**) and used to calculate the ablation power.

Vacuum source **252** (FIG. **21**) is activated, causing application of suction to hypotube **122** via suction port **210**. Suction helps to draw uterine tissue into contact with the array **102**.

Ablation power is supplied to the electrode array **102***a* by the RF generator system **250**. The tissue is heated as the RF energy passes from electrodes **118***a–d* to the tissue, causing moisture to be released from the tissue. The vacuum source helps to draw moisture from the uterine cavity into the hypotube **122**. Moisture withdrawal is facilitated by the apertures **126** formed in flexures **124** by preventing moisture from being trapped between the flexures **124** and the lateral walls of the uterus.

If the RF generator **250** includes an impedance monitoring module, impedance may be monitored at the electrodes **118***a–d* and the generator may be programmed to terminate RF delivery automatically once the impedance rises to a certain level. The generator system may also or alternatively display the measured impedance and allow the user to terminate RF delivery when desired.

When RF delivery is terminated, the user depresses release lever **194** to disengage heel **188** from locking spring member **190** and to thereby allow grips **142**, **144** to move to their expanded (resting condition). Release of grips **142**, **144** causes applicator head **102** to retract to its unexpanded condition and further causes applicator head **102** to be withdrawn into the sheath **104**. Finally, the distal end of the device **100** is withdrawn from the uterus.

Two embodiments of ablation devices in accordance with the present invention have been described herein. These embodiments have been shown for illustrative purposes only. It should be understood, however, that the invention is not intended to be limited to the specifics of the illustrated embodiments but is defined only in terms of the following claims.

We claim:

1. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member and a pair of elongate flexures wherein each flexure includes at least one opening, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon, wherein the fluid permeable elastic member includes metallized fabric;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition by expanding the flexures;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue and allowing at least a portion of the moisture to pass through the openings in the flexures.

2. The method of claim **1** wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

3. The method of claim **2** wherein the metallized fabric includes yarns of spandex and nylon.

4. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member and a pair of elongate flexures wherein each flexure includes at least one opening, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array into an organ and into contact with tissue to be ablated and moving the array to an expanded condition by expanding the flexures;

(c) measuring the approximate length and width of the organ, selecting an ablation power corresponding to the measured length and width, and delivering RF energy through the array to the tissue at approximately the selected power to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue and allowing at least a portion of the moisture to pass through the openings in the flexures.

5. The method of claim **4** wherein the step of measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

6. The method of claim **5** wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

7. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member and a pair of elongate flexures wherein each flexure includes at least one opening, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon, wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition by expanding the flexures;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue and allowing at least a portion of the moisture to pass through the openings in the flexures.

8. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon, wherein the fluid permeable elastic member includes metallized fabric;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member, away from tissue and into the tubular member.

9. The method of claim **8** wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

10. The method of claim **9** wherein the metallized fabric includes yarns of spandex and nylon.

11. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array within an organ and into contact with tissue to be ablated;

(c) measuring the approximate length and width of the organ, selecting an ablation power corresponding to the measured length and width, and delivering RF energy through the array to the tissue at approximately the selected power to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member, away from tissue and into the tubular member.

12. The method of claim **11** wherein the providing step provides the electrode array to be carried by a pair of elongate flexures, and wherein the step of measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

13. The method of claim **12** wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

14. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon, wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member, away from tissue and into the tubular member.

15. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon, wherein the fluid permeable elastic member includes metallized fabric;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue, and applying suction to draw the moisture through the tubular member.

16. The method of claim **15** wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

17. The method of claim **16** wherein the metallized fabric includes yarns of spandex and nylon.

18. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array into and organ and contact with tissue to be ablated and moving the array to an expanded condition;

(c) measuring the approximate length and width of the organ, selecting an ablation power corresponding to the measured length and width, and delivering RF energy to the tissue at approximately the selected power to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue, and applying suction to draw the moisture through the tubular member.

19. The method of claim **18** wherein the providing step provides the electrode array to be carried by a pair of elongate flexures, and wherein the step of measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

20. The method of claim **19** wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

21. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue, and applying suction to draw the moisture through the tubular member.

22. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array within an organ and into contact with tissue to be ablated;

(c) measuring the approximate length and width of the organ, selecting an ablation power corresponding to the measured length and width, and delivering the RF energy to the tissue at approximately the selected power to cause the tissue to dehydrate;

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue; and

(e) applying suction through the tubular member to draw the tissue into contact with the electrode array.

23. The method of claim **22** wherein the step of measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the organ from the relative positions of the flexures in the expanded condition.

24. The method of claim **22** wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

25. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member including metallized fabric having insulating regions and conductive regions thereon, the metallized fabric including yarns of elastic material and yarns of inelastic material;

(b) positioning the electrode array into contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate;

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue and

(e) applying suction through the tubular member to draw the tissue into contact with the electrode array.

26. The method of claim **25** wherein the metallized fabric includes yarns of spandex and nylon.

27. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon, wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction;

(b) positioning the electrode array into contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate;

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue; and

(e) applying suction through the tubular member to draw the tissue into contact with the electrode array.

28. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable bipolar electrode array carried by an elongate tubular member and a pair of elongate flexures wherein each flexure includes at least one opening, the electrode array comprising a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition by expanding the flexures;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue and allowing at least a portion of the moisture to pass through the openings in the flexures.

29. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including a bipolar electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RE energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member, away from tissue and into the tubular member.

30. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable bipolar electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction to the tubular member and through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue, the suction drawing the moisture through the tubular member.

31. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an bipolar electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array into contact with tissue to be ablated;

delivering RF energy through the array to the tissue to cause the tissue to dehydrate;

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue; and

(e) applying suction through the tubular member to draw the tissue into contact with the electrode array.

32. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member and a pair of elongate flexures wherein each flexure includes at least one opening, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition by expanding the flexures;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue and allowing at least a portion of the moisture to pass through the openings in the flexures, the suction substantially eliminating liquid surrounding the electrodes during ablation.

33. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member, away from tissue and into the tubular member the suction substantially eliminating liquid surrounding the electrodes during ablation.

34. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction to the tubular member and through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue, the suction drawing the moisture through the tubular member, the suction substantially eliminating liquid surrounding the electrodes during ablation.

35. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array into contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate;

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue; and

(e) applying suction through the tubular member to draw the tissue into contact with the electrode array, the suction substantially eliminating liquid surrounding the electrodes during ablation.

36. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member and a pair of elongate flexures wherein each flexure includes at least one opening, the electrode array including a fluid permeable elastic member comprising a moisture permeable envelope having a hollow interior and having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition by expanding the flexures;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue and allowing at least a portion of the moisture to pass through the openings in the flexures, wherein the suction causes the moisture to pass into the hollow interior of the fluid permeable elastic member and away from the electrode array.

37. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member comprising a moisture permeable envelope having a hollow interior and having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member, away from tissue and into the tubular member and wherein the suction causes the moisture to pass into the hollow interior of the fluid permeable elastic member and away from the electrode array.

38. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member comprising a moisture permeable envelope having a hollow interior and having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) during step (c), applying suction to the tubular member and through the fluid permeable elastic member to cause moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue, the suction drawing the moisture through the tubular member, and wherein the suction causes the moisture to pass into the hollow interior of the fluid permeable elastic member and away from the electrode array.

39. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member comprising a moisture permeable envelope having a hollow interior and having insulating regions and conductive regions thereon;

(b) positioning the electrode array into contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate;

(d) permitting moisture generated during the dehydration of step (c) to pass into the fluid permeable elastic member and away from the tissue; and

(e) applying suction through the tubular member to draw the tissue into contact with the electrode array and wherein the suction causes the moisture to pass into the hollow interior of the fluid permeable elastic member and away from the electrode array.

40. The method of claim **28**, **29**, **30**, **36**, **37**, **38** or **39**, wherein the suction draws tissue into contact with the electrode carrying member.

41. The method of claim **40** wherein the tissue is inside an organ, and wherein the suction at least partially collapses the organ onto the electrode carrying member.

42. The method of claim **28**, **29**, **30**, **31**, **36**, **37**, **38** or **39**, wherein the tissue is within a uterus, wherein the positioning step passes the electrode array through the cervix and into the uterus, and wherein the method further includes forming a seal around the elongate tubular member at the cervix.

43. The method of claim **28**, **29**, **30**, **31**, **36**, **37**, **38** or **39** wherein the fluid permeable elastic member includes metallized filaments.

44. The method of claim **43** wherein the metallized filaments include elastic and inelastic filaments.

45. The method of claim **44** wherein the metallized filaments include filaments of spandex and nylon.

46. The method of claim **28**, **29**, **30**, **31**, **36**, **37**, **38** or **39** wherein said suction substantially preventing formation of a low-impedance liquid layer around the electrode array during ablation/coagulation using the electrode array.

47. The method of claim **28**, **29**, **30** or **31** wherein substantially the entire bipolar electrode array maintains continuous contact with the tissue to be ablated during said ablation and/or coagulation of the tissue.

* * * * *

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(54) **MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

552,832 A 1/1896 Fort
725,731 A 4/1903 Linn

(Continued)

FOREIGN PATENT DOCUMENTS

DE 384246 10/1923
DE 22 22 820 11/1973

(Continued)

OTHER PUBLICATIONS

"Essure, Permanent Birth Control by Conceptus: What is Essure?" Product Information Sheet [on-line] [retrieved Oct. 19, 2004] Retrieved from the Internet: < URL: http://www.essure.com/consumer/c.sub.--what.sub.--is.sub.--essure.aspx >.

(Continued)

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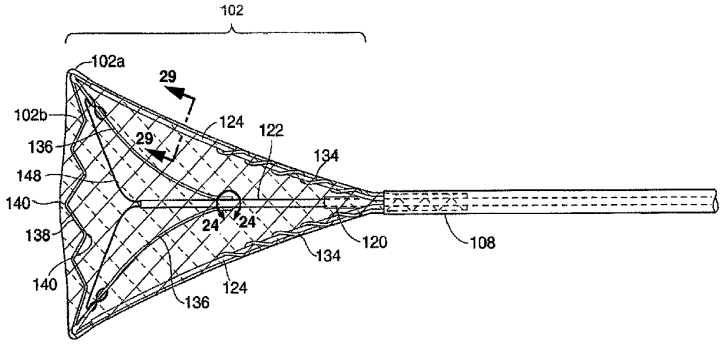
(57) **ABSTRACT**

An apparatus and method for use in performing ablation or coagulation of organs and other tissue includes a metallized fabric electrode array which is substantially absorbent and/or permeable to moisture and gases such as steam and conformable to the body cavity. Following placement of the ablation device into contact with the tissue to be ablated, an RF generator is used to deliver RF energy to the conductive regions and to thereby induce current flow from the electrodes to tissue to be ablated. As the current heats the tissue, moisture (such as steam or liquid) leaves the tissue causing the tissue to dehydrate. Suction may be applied to facilitate moisture removal. The moisture permeability and/or absorbency of the electrode carrying member allows the moisture to leave the ablation site so as to prevent the moisture from providing a path of conductivity for the current.

15 Claims, 18 Drawing Sheets



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(56) **References Cited**

U.S. PATENT DOCUMENTS

1,620,929	A		3/1927	Wallerich	
1,827,306	A		10/1931	Chapman et al.	
2,190,383	A		2/1940	Newman	
2,347,195	A		4/1944	Huff	
2,466,042	A		4/1949	Reich et al.	
3,228,398	A		1/1966	Leonard et al.	
3,324,855	A		6/1967	Heimlich	
3,645,265	A		2/1972	Majzlin	
3,706,307	A	*	12/1972	Hasson	600/591
3,840,016	A		10/1974	Lindemann	
3,845,771	A		11/1974	Vise	
3,858,586	A		1/1975	Lessen	
3,877,464	A		4/1975	Vermes	
3,924,628	A		12/1975	Droegemueller et al.	
3,948,270	A		4/1976	Hasson	
3,967,625	A		7/1976	Yoon	
3,971,378	A		7/1976	Krantz	
4,016,867	A	*	4/1977	King et al.	600/591
4,022,215	A		5/1977	Benson	
4,057,063	A		11/1977	Gieles et al.	
4,082,096	A		4/1978	Benson	
4,094,320	A		6/1978	Newton et al.	
4,158,050	A		6/1979	Zipper	
4,185,618	A		1/1980	Corey	
4,204,548	A		5/1980	Kurz	
4,224,951	A	*	9/1980	Hasson	600/591
4,233,025	A		11/1980	Larson et al.	
4,347,842	A		9/1982	Beale	
4,359,454	A		11/1982	Hoffman	
4,380,238	A		4/1983	Colucci et al.	
4,415,288	A		11/1983	Gordon et al.	
4,449,528	A		5/1984	Auth et al.	
4,465,072	A		8/1984	Taheri	
4,489,732	A	*	12/1984	Hasson	600/591
4,492,231	A		1/1985	Auth	
4,532,483	A		7/1985	Schminke	
4,532,924	A		8/1985	Auth et al.	
4,552,557	A	*	11/1985	Rangaswamy	604/103.1
4,568,326	A		2/1986	Rangaswamy	
4,582,057	A		4/1986	Auth et al.	
4,601,698	A		7/1986	Moulding, Jr.	
4,606,336	A		8/1986	Zeluff	
4,628,924	A		12/1986	Cimber	
4,662,383	A		5/1987	Sogawa et al.	
4,676,258	A		6/1987	Inokuchi et al.	
4,685,474	A	*	8/1987	Kurz et al.	600/591
4,691,703	A		9/1987	Auth et al.	
4,700,701	A		10/1987	Montaldi	
4,739,759	A		4/1988	Rexroth et al.	
4,765,331	A		8/1988	Petruzzi et al.	
4,788,966	A		12/1988	Yoon	
4,807,620	A		2/1989	Strul et al.	
4,832,048	A		5/1989	Cohen	
4,865,047	A		9/1989	Chou et al.	
4,869,268	A		9/1989	Yoon	
4,946,440	A		8/1990	Hall	
4,949,718	A		8/1990	Neuwirth et al.	
4,955,377	A		9/1990	Lennox et al.	
4,960,133	A		10/1990	Hewson	
4,961,435	A		10/1990	Kitagawa et al.	
4,979,948	A		12/1990	Geddes et al.	
4,981,465	A		1/1991	Ballan et al.	
4,983,177	A		1/1991	Wolf	
5,026,379	A		6/1991	Yoon	
5,047,028	A		9/1991	Qian	
5,057,106	A		10/1991	Kasevich et al.	
5,065,751	A		11/1991	Wolf	
5,078,717	A		1/1992	Parins et al.	
5,084,044	A		1/1992	Quint	
5,105,808	A		4/1992	Neuwirth et al.	
5,109,869	A	*	5/1992	Buckley	600/591
5,147,353	A		9/1992	Everett	
5,159,925	A		11/1992	Neuwirth et al.	
5,160,334	A		11/1992	Billings et al.	
5,178,148	A		1/1993	Lacoste et al.	
5,186,181	A		2/1993	Franconi et al.	
5,188,122	A		2/1993	Phipps et al.	
5,188,602	A		2/1993	Nichols	
5,217,473	A		6/1993	Yoon	
5,226,908	A		7/1993	Yoon	
5,242,437	A		9/1993	Everett et al.	
5,248,312	A		9/1993	Langberg	
5,263,585	A		11/1993	Lawhon et al.	
5,275,610	A	*	1/1994	Eberbach	606/198
5,277,201	A		1/1994	Stern	
5,308,327	A		5/1994	Heaven et al.	
5,318,532	A		6/1994	Frassica	
5,322,507	A		6/1994	Costello et al.	
5,334,193	A		8/1994	Nardella	
5,334,209	A		8/1994	Yoon	
5,354,295	A		10/1994	Guglielmi et al.	
5,357,956	A		10/1994	Nardella	
5,358,496	A	*	10/1994	Ortiz et al.	606/198
5,364,393	A		11/1994	Auth et al.	
5,370,649	A		12/1994	Gardetto et al.	
5,374,261	A		12/1994	Yoon	
5,374,283	A		12/1994	Flick	
5,380,317	A		1/1995	Everett et al.	
5,383,917	A		1/1995	Desai et al.	
5,385,544	A		1/1995	Edwards et al.	
5,395,311	A		3/1995	Andrews	
5,405,322	A		4/1995	Lennox et al.	
5,407,071	A		4/1995	Lawhon et al.	
5,423,808	A		6/1995	Edwards et al.	
5,433,708	A		7/1995	Nichols et al.	
5,437,629	A		8/1995	Goldrath	
5,443,470	A	*	8/1995	Stern et al.	607/98
5,451,204	A	*	9/1995	Yoon	604/1
5,474,089	A		12/1995	Waynant	
5,484,400	A		1/1996	Edwards et al.	
5,498,261	A		3/1996	Strul	
5,505,730	A	*	4/1996	Edwards	606/41
5,507,743	A		4/1996	Edwards et al.	
5,514,091	A		5/1996	Yoon	
5,540,655	A		7/1996	Edwards et al.	
5,540,681	A		7/1996	Strul et al.	
5,542,916	A		8/1996	Hirsch et al.	
5,558,672	A		9/1996	Edwards et al.	
5,562,703	A		10/1996	Desai	
5,562,720	A		10/1996	Stern et al.	
5,573,533	A		11/1996	Strul	
5,575,788	A		11/1996	Baker et al.	
5,588,961	A		12/1996	Leone et al.	
5,593,404	A		1/1997	Costello et al.	
5,599,345	A		2/1997	Edwards et al.	

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,599,346	A		2/1997	Edwards et al.
5,609,598	A		3/1997	Laufer et al.
5,613,950	A		3/1997	Yoon
5,620,481	A		4/1997	Desai et al.
5,649,924	A		7/1997	Everett et al.
5,656,013	A		8/1997	Yoon
5,658,316	A		8/1997	Lamond et al.
5,667,520	A		9/1997	Bonutti
5,697,882	A		12/1997	Eggers et al.
5,702,438	A	*	12/1997	Avitall 607/122
5,716,343	A		2/1998	Kriesel et al.
5,722,975	A		3/1998	Edwards et al.
5,730,136	A		3/1998	Laufer et al.
5,730,725	A		3/1998	Yoon
5,733,252	A		3/1998	Yoon
5,769,880	A	*	6/1998	Truckai et al. 607/101
5,779,698	A		7/1998	Clayman et al.
5,797,903	A		8/1998	Swanson et al.
5,800,482	A		9/1998	Pomeranz et al.
5,807,389	A		9/1998	Gardetto et al.
5,810,847	A		9/1998	Laufer et al.
5,827,273	A		10/1998	Edwards
5,843,026	A		12/1998	Edwards et al.
5,843,121	A		12/1998	Yoon
5,846,238	A		12/1998	Jackson et al.
5,865,788	A		2/1999	Edwards et al.
5,871,469	A		2/1999	Eggers et al.
5,879,348	A		3/1999	Owens et al.
5,885,278	A	*	3/1999	Fleischman 606/41
5,885,601	A		3/1999	Sokal
5,888,198	A		3/1999	Eggers et al.
5,891,134	A	*	4/1999	Goble et al. 606/27
5,891,136	A		4/1999	McGee et al.
5,897,551	A		4/1999	Everett et al.
5,897,553	A		4/1999	Mulier et al.
5,935,123	A		8/1999	Edwards et al.
5,935,137	A		8/1999	Saadat et al.
5,938,660	A		8/1999	Swartz et al.
5,944,715	A		8/1999	Goble et al.
5,954,717	A		9/1999	Behl et al.
5,979,446	A		11/1999	Loy
5,997,534	A		12/1999	Tu et al.
6,002,968	A		12/1999	Edwards
6,014,589	A		1/2000	Farley et al.
6,033,397	A		3/2000	Laufer et al.
6,036,687	A		3/2000	Laufer et al.
6,041,260	A		3/2000	Stern et al.
6,042,596	A		3/2000	Bonutti
6,047,700	A		4/2000	Eggers et al.
6,066,139	A		5/2000	Ryan et al.
6,068,613	A		5/2000	Kriesel et al.
6,068,626	A		5/2000	Harrington et al.
6,071,277	A		6/2000	Farley et al.
6,071,281	A	*	6/2000	Burnside et al. 606/41
6,074,386	A		6/2000	Goble et al.
6,077,257	A		6/2000	Edwards et al.
6,096,052	A		8/2000	Callister et al.
6,112,123	A		8/2000	Kelleher et al.
6,117,101	A		9/2000	Diederich et al.
6,123,702	A		9/2000	Swanson et al.
6,135,997	A		10/2000	Laufer et al.
6,139,527	A		10/2000	Laufer et al.
6,139,546	A		10/2000	Koenig et al.
6,152,899	A		11/2000	Farley et al.
6,159,207	A		12/2000	Yoon
6,164,280	A		12/2000	Everett et al.
6,165,172	A		12/2000	Farley et al.
6,179,832	B1		1/2001	Jones et al.
6,183,468	B1		2/2001	Swanson et al.
6,193,713	B1		2/2001	Geistert et al.
6,197,025	B1		3/2001	Grossi et al.
6,200,312	B1		3/2001	Zikorus et al.
6,224,591	B1	*	5/2001	Claren et al. 606/27
6,231,496	B1		5/2001	Wilk et al.
6,231,507	B1		5/2001	Zikorus et al.
6,234,178	B1		5/2001	Goble et al.
6,237,606	B1		5/2001	Zikorus et al.
6,238,393	B1		5/2001	Mulier et al.
6,245,065	B1		6/2001	Panescu et al.
6,245,090	B1		6/2001	Gilson et al.
6,254,601	B1		7/2001	Burbank et al.
6,258,084	B1		7/2001	Goldman et al.
6,258,085	B1		7/2001	Eggleston
6,263,248	B1		7/2001	Farley et al.
6,277,089	B1		8/2001	Yoon
6,293,942	B1		9/2001	Goble et al.
6,296,639	B1		10/2001	Truckai et al.
6,309,384	B1		10/2001	Harrington et al.
6,315,776	B1		11/2001	Edwards et al.
6,322,559	B1		11/2001	Daulton et al.
6,346,102	B1		2/2002	Harrington et al.
6,352,549	B1		3/2002	Everett
6,364,877	B1		4/2002	Goble et al.
6,369,465	B1		4/2002	Swanson
6,395,012	B1		5/2002	Yoon et al.
6,398,780	B1		6/2002	Farley et al.
6,402,742	B1		6/2002	Blewett et al.
6,428,537	B1		8/2002	Swanson et al.
6,432,116	B1		8/2002	Callister et al.
6,451,015	B1		9/2002	Rittman, III et al.
6,475,213	B1		11/2002	Whayne et al.
6,485,487	B1		11/2002	Sherman
6,485,500	B1		11/2002	Kokish et al.
6,490,474	B1		12/2002	Willis et al.
6,508,815	B1		1/2003	Strul et al.
6,554,780	B1		4/2003	Sampson et al.
6,663,626	B2		12/2003	Truckai et al.
6,679,269	B2		1/2004	Swanson
6,712,810	B2		3/2004	Harrington et al.
6,712,815	B2		3/2004	Sampson et al.
6,726,682	B2		4/2004	Harrington et al.
6,743,184	B2		6/2004	Sampson et al.
6,764,488	B1		7/2004	Burbank et al.
6,813,520	B2		11/2004	Truckai et al.
6,964,274	B1		11/2005	Ryan et al.
7,074,217	B2		7/2006	Strul et al.
7,407,502	B2		8/2008	Strul et al.
7,512,445	B2		3/2009	Truckai et al.
7,604,633	B2		10/2009	Truckai et al.
7,717,909	B2		5/2010	Strul et al.
7,731,712	B2		6/2010	Sampson et al.
7,846,160	B2		12/2010	Payne et al.
2001/0041900	A1		11/2001	Callister et al.
2002/0022870	A1		2/2002	Truckai et al.
2002/0029051	A1		3/2002	Callister et al.
2002/0072499	A1		6/2002	Clagett
2002/0072745	A1		6/2002	Truckai et al.
2002/0177846	A1		11/2002	Mulier et al.
2003/0093101	A1		5/2003	O'Heeron et al.
2003/0130711	A1		7/2003	Pearson et al.
2003/0199863	A1		10/2003	Swanson et al.
2004/0054368	A1		3/2004	Truckai et al.
2004/0118166	A1		6/2004	Huang et al.
2004/0172051	A1		9/2004	Ravikumar
2004/0204720	A1		10/2004	Harrington et al.
2004/0255958	A1		12/2004	Harrington et al.
2005/0085880	A1		4/2005	Truckai et al.
2005/0155608	A1		7/2005	Pavcnik et al.
2005/0217680	A1		10/2005	Callister et al.
2006/0135956	A1		6/2006	Sampson et al.
2008/0071269	A1		3/2008	Hilario et al.
2010/0036372	A1		2/2010	Truckai et al.
2010/0217256	A1		8/2010	Strul et al.
2012/0179155	A1		7/2012	Strul et al.

FOREIGN PATENT DOCUMENTS

DE	40 01 086	7/1991
EP	0 056 178	4/1981
EP	0 584 930	7/1993
EP	1 400 182	3/2004
EP	1 568 325	8/2005
FR	774 550	12/1934
FR	2 115 706	7/1972

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

GB	189400141	7/1894
GB	2 317 566	4/1998
JP	48-67586	12/1971
JP	58-32756	2/1983
JP	63-318934	12/1988
WO	92/19145	11/1992
WO	94/00178	1/1994
WO	94/07445	4/1994
WO	94/10948	5/1994
WO	94/23794	10/1994
WO	95/04385	2/1995
WO	95/05869	3/1995
WO	95/07664	3/1995
WO	95/10326	4/1995
WO	96/00042	1/1996
WO	97/12569	4/1997
WO	97/41785	11/1997
WO	98/38932	9/1998
WO	99/58070	11/1999
WO	01/97897	12/2001

OTHER PUBLICATIONS

"Essure: the non-incisional approach to permanent birth control", Patient Information Booklet, .COPYRGT. 2004 by Conceptus Incorporated.

"Tubal Ligation and Resection: Tubal Ligation by Parkland and Irving Methods" Datasheet [on-line] Chapel Hill Tubal Reversal Center, 2004 [retrieved on Oct. 19, 2004] Retrieved from the Internet: <URL: http://www.tubal-reversal.net/print/printer-friendly-tubal.sub.--ligation- .sub.--resection.htm >.

"Tubal Ligation Methods: Coagulation Methods of Tubal Ligation" Datasheet [on-line] Chapel Hill Tubal Reversal Center, 2004, [retrieved Oct. 19, 2004] Retrieved from the Internet: < http://www.tubal-reversal.net/tubal.sub.--ligation. sub.--coagulation.htm >.

"Tubal Ligation—Fimbriectomy: Tubal Reversal is Possible after Fimbriectomy" Datasheet [on-line] Chapel Hill Tubal Reversal Center, 2004 [retrieved on Oct. 19, 2004] Retrieved from the Internet: <URL: http://www.tubal-reversal.net/print/printer-friendly-tubal.sub.--ligation- .sub.--fimbriectomy.htm >.

"Tubal Ligation—Pomeroy Technique: Pomeroy Tubal Ligation and Resection" Datasheet [on-line] Chapel Hill Tubal Reversal Center, 2004 [retrieved Oct. 19, 2004] Retrieved from the Internet: < http://www.tubal-reversal.net/print/printer-friendly-tubal.sub.--ligation-.sub.--Pomeroy.htm >.

"Tubal Ligation—Tubal Ring or Clip: Tubal Ligation with Tubal Rings or Tubal Clips" Datasheet [on-line] Chapel Hill Tubal Reversal Center, 2004 [retrieved Oct. 19, 2004] Retrieved from the Internet: <URL: http://www.tubal-reversal.net/tubal.sub.--ligation-tubal.sub.--ring-tubal- .sub.--clip.htm >.

Adiana options for women—how it works. (Dec. 31, 2005). Retrieved from http://web.archive.org/web/20051124001429/ www.adiana.com/products.sub.--h- ow.php.

C. Nibley et al., "Prevention of Impedance Rise During Radiofrequency Current Catheter Ablation by Intra-Electrode Tip Chilling,"Circulation [Abstracts From the 67th Scientific Sessions, Dallas Convention Center, Dallas, Texas, Nov. 14-17, 1994], vol. 90, No. 4, Part 2, Oct. 1994, p. 460.

D.E. Haines et al., "Observations on Electrode-Tissue Interface Temperature and Effect on Electrical Impedance During Radiofrequency Ablation of Ventricular Myocardium," Circulation, vol. 82, No. 3, Sep. 1990, pp. 1034-1038.

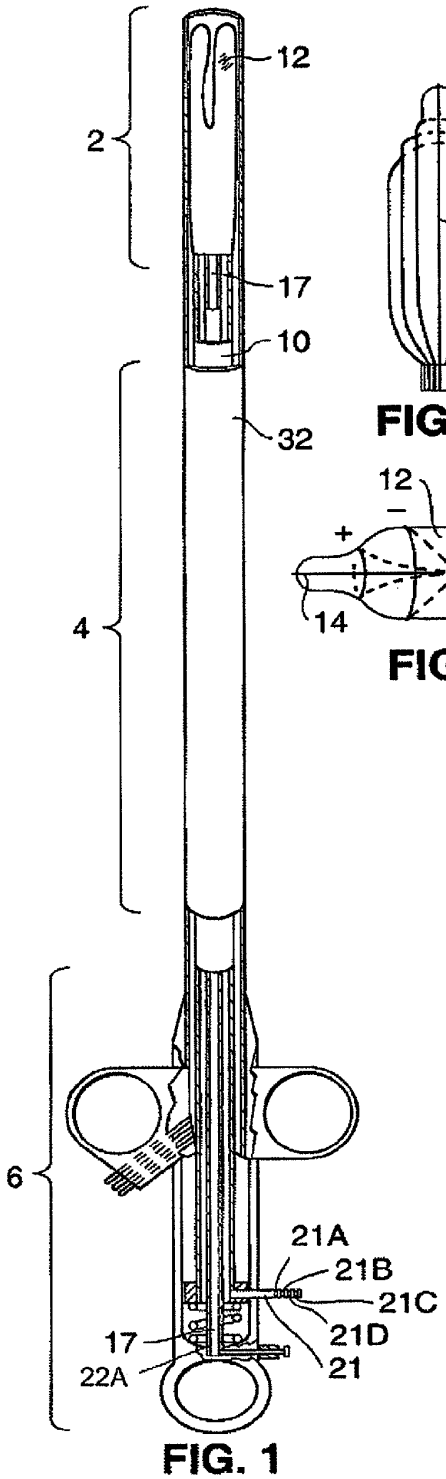
METI-MyriadLase, SteriLase, Powerpoint Presentation, published at least as of Jun. 13, 2006, 6 pp.

W.M. Jackman et al., "Radiofrequency Current Directed Across the Mitral Anulus With a Bipolar Epicardial-Endocardial Catheter Electrode Configuration in Dogs," Circulation, vol. 78, No. 5, Nov. 1988, pp. 1288-1298.

First Request for Ex Partes Reexamination of U.S. Patent No. 5,769,880, filed Jul. 27, 1999, U.S. App. No. 90/005,435.

Second Request for Ex Partes Reexamination of U.S. Patent No. 5,769,880, filed Nov. 22, 2000, U.S Appl. No. 90/005,866.

* cited by examiner



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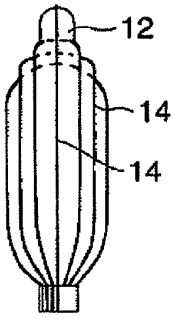

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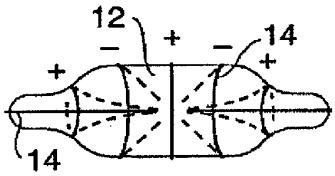

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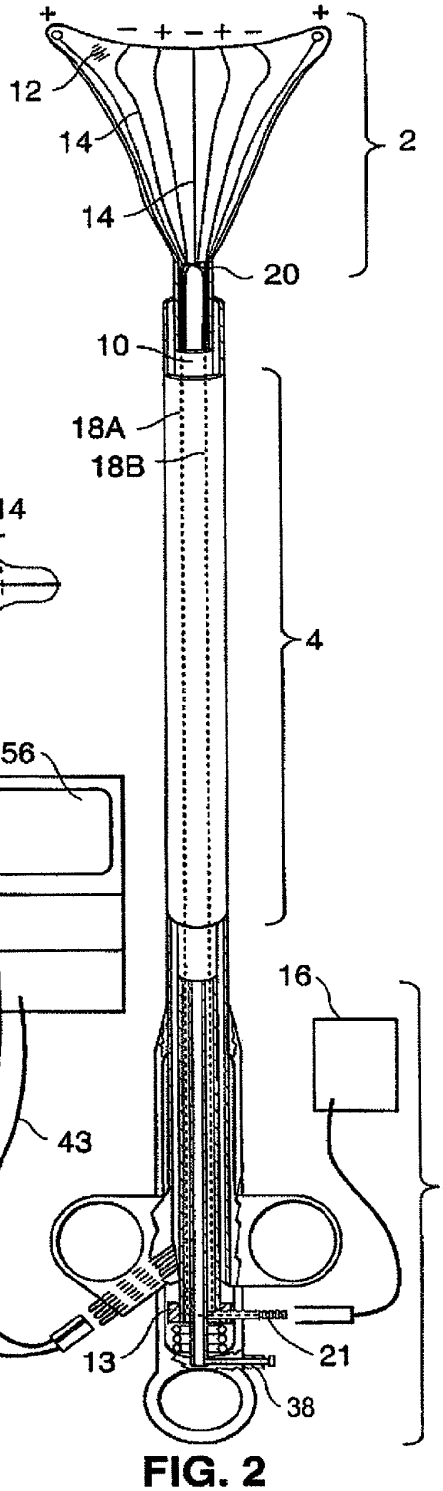

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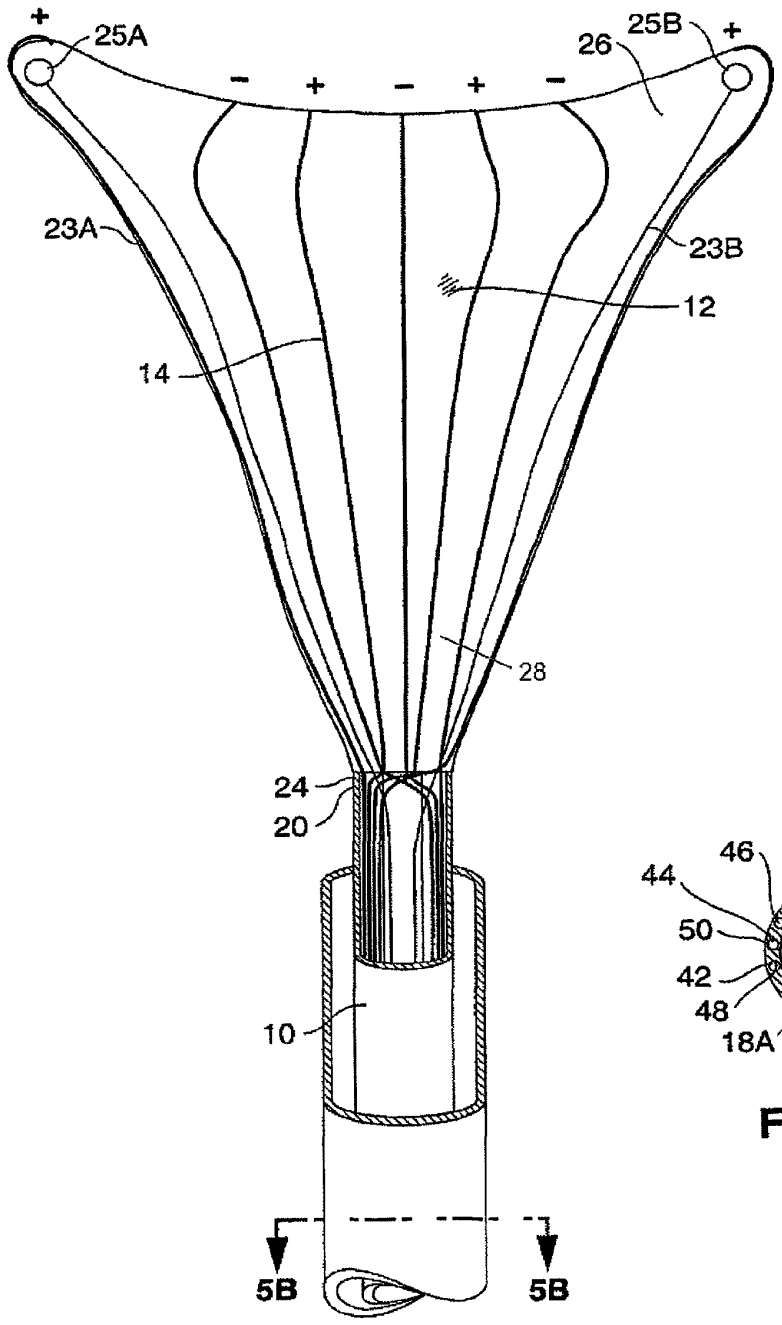
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FIG. 5A

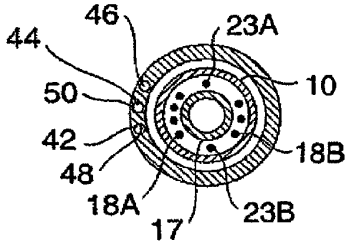
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FIG. 5B

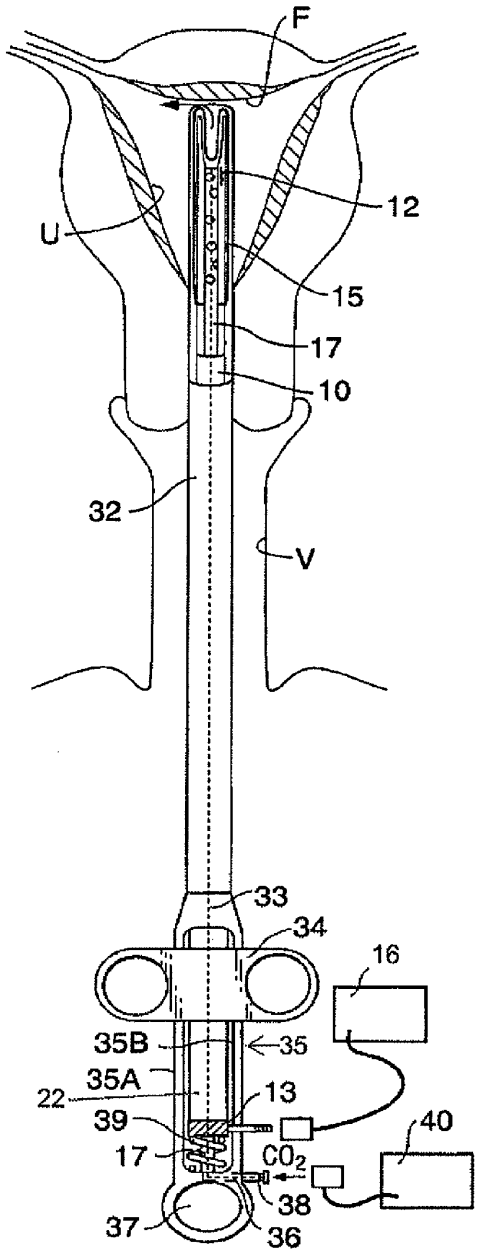
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FIG. 6

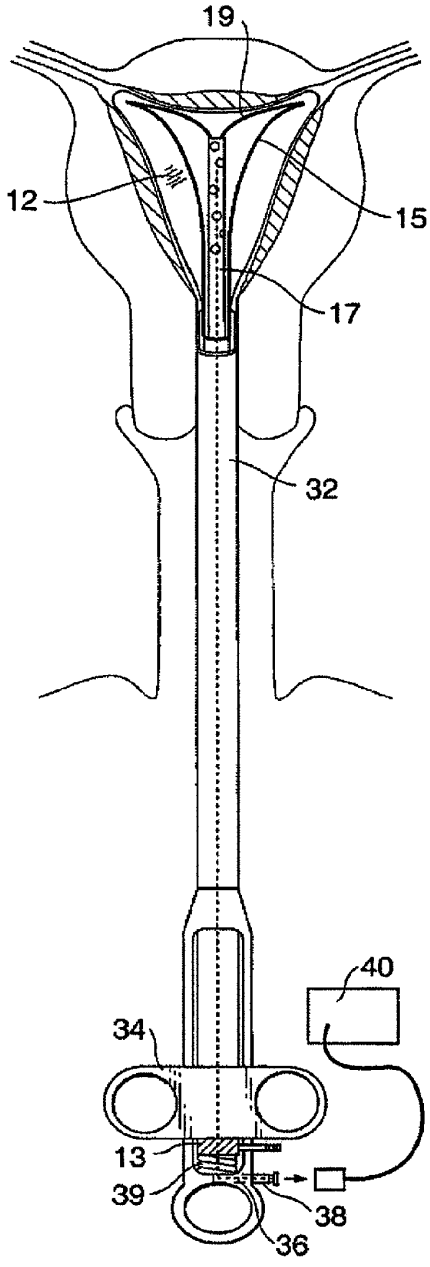
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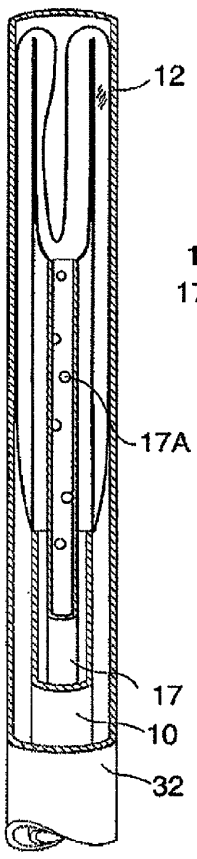
FIG. 7



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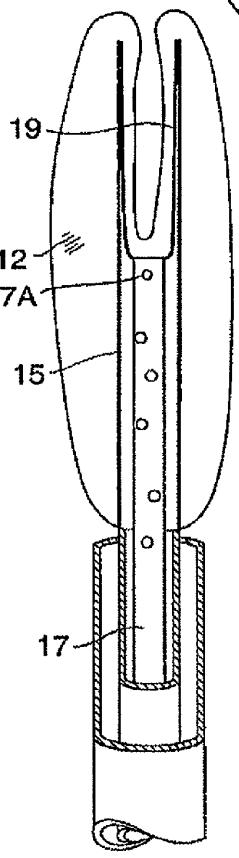

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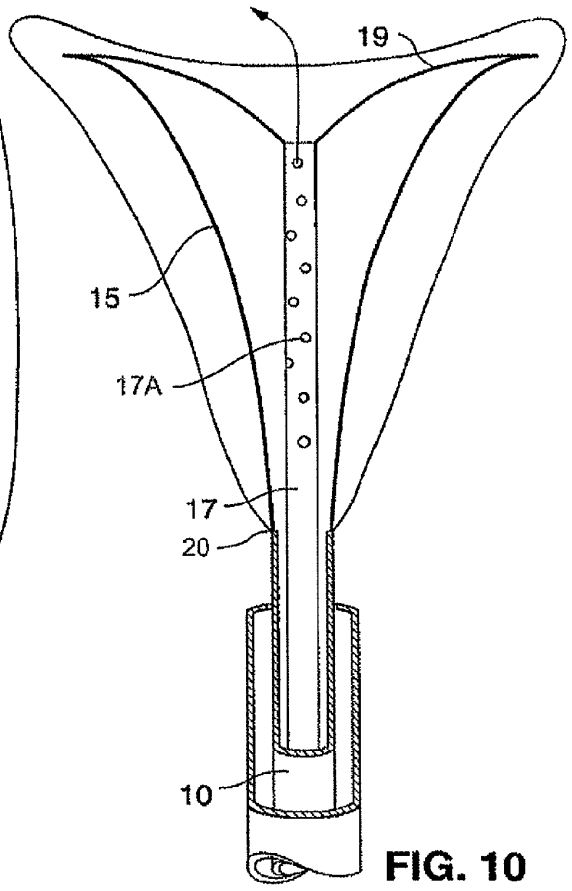

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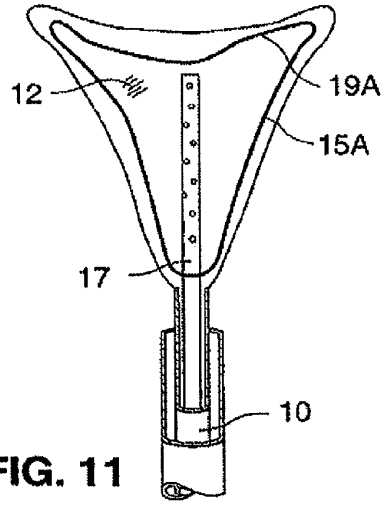

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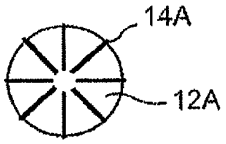
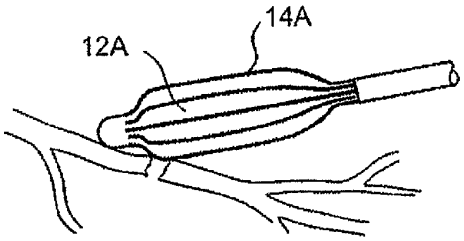


FIG. 13



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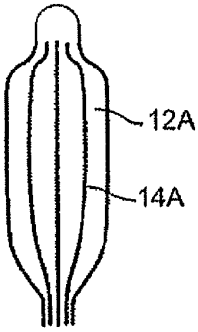

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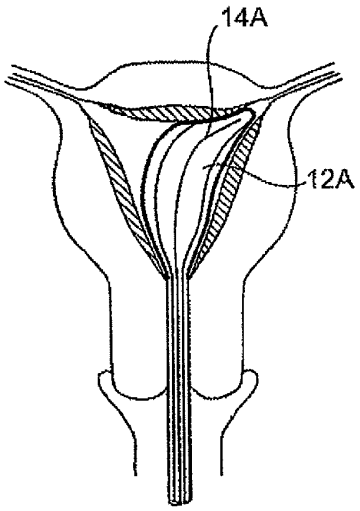

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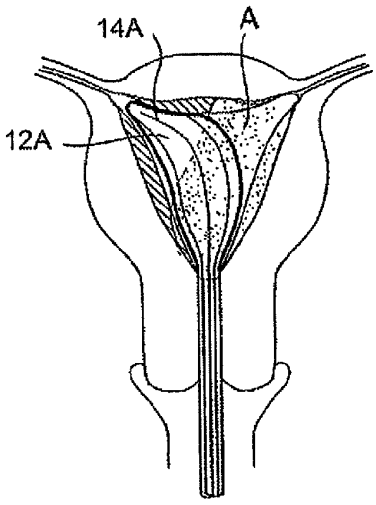

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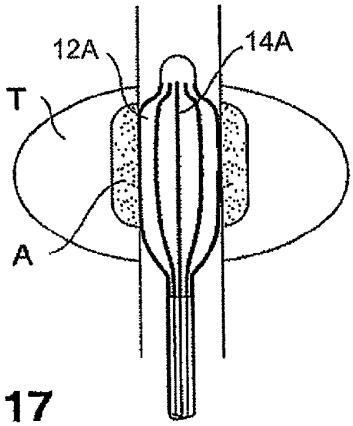

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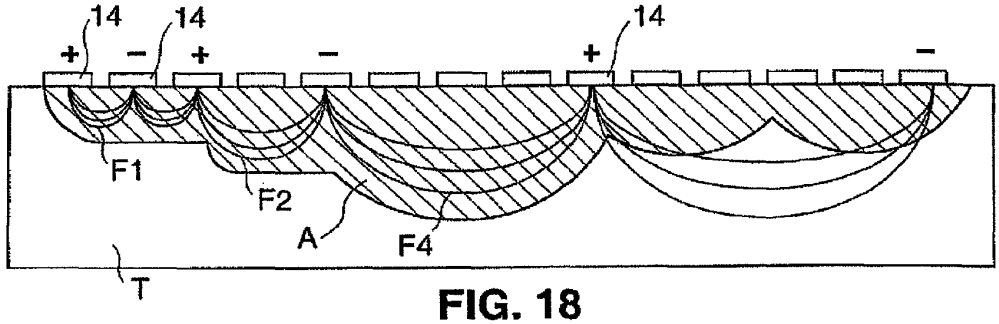

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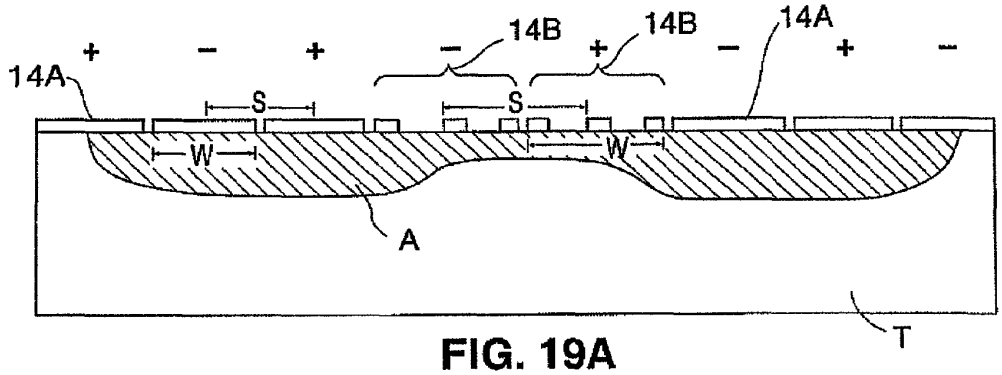

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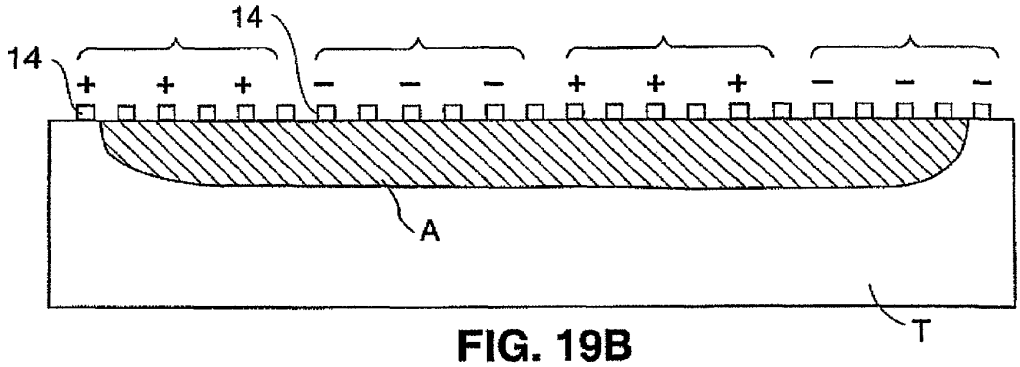

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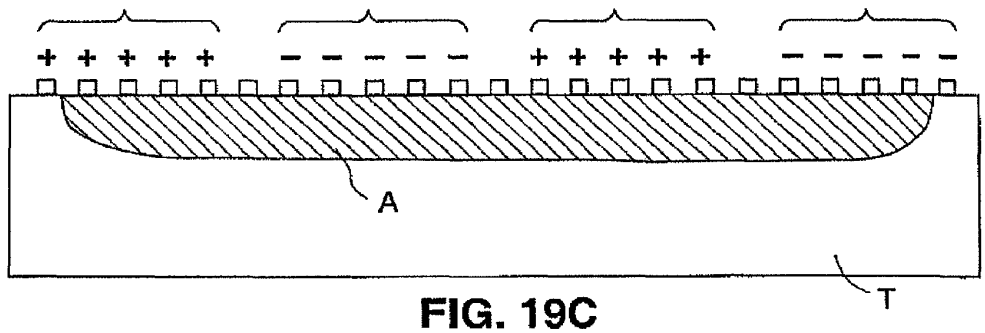


FIG. 19C

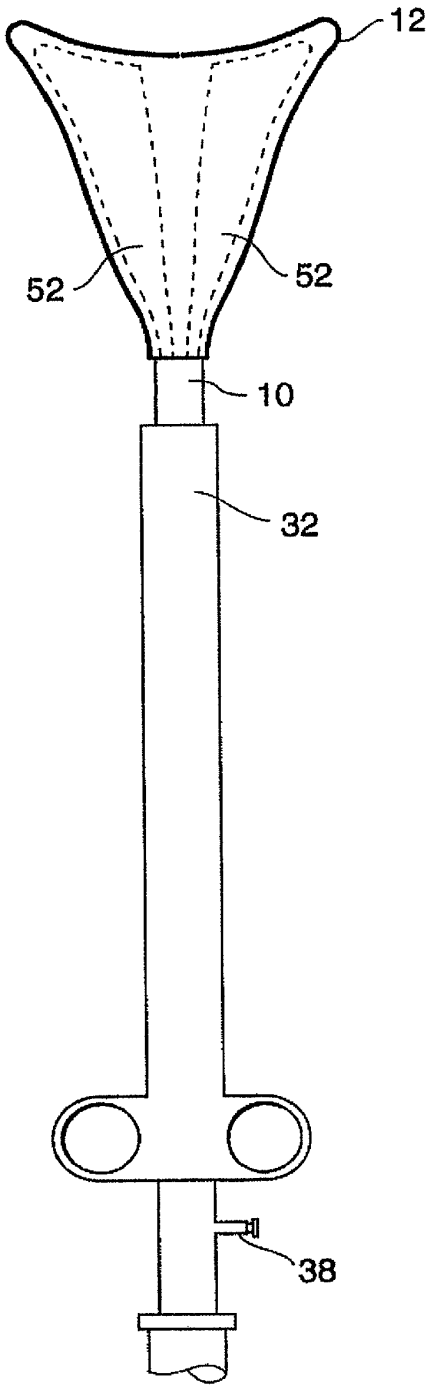
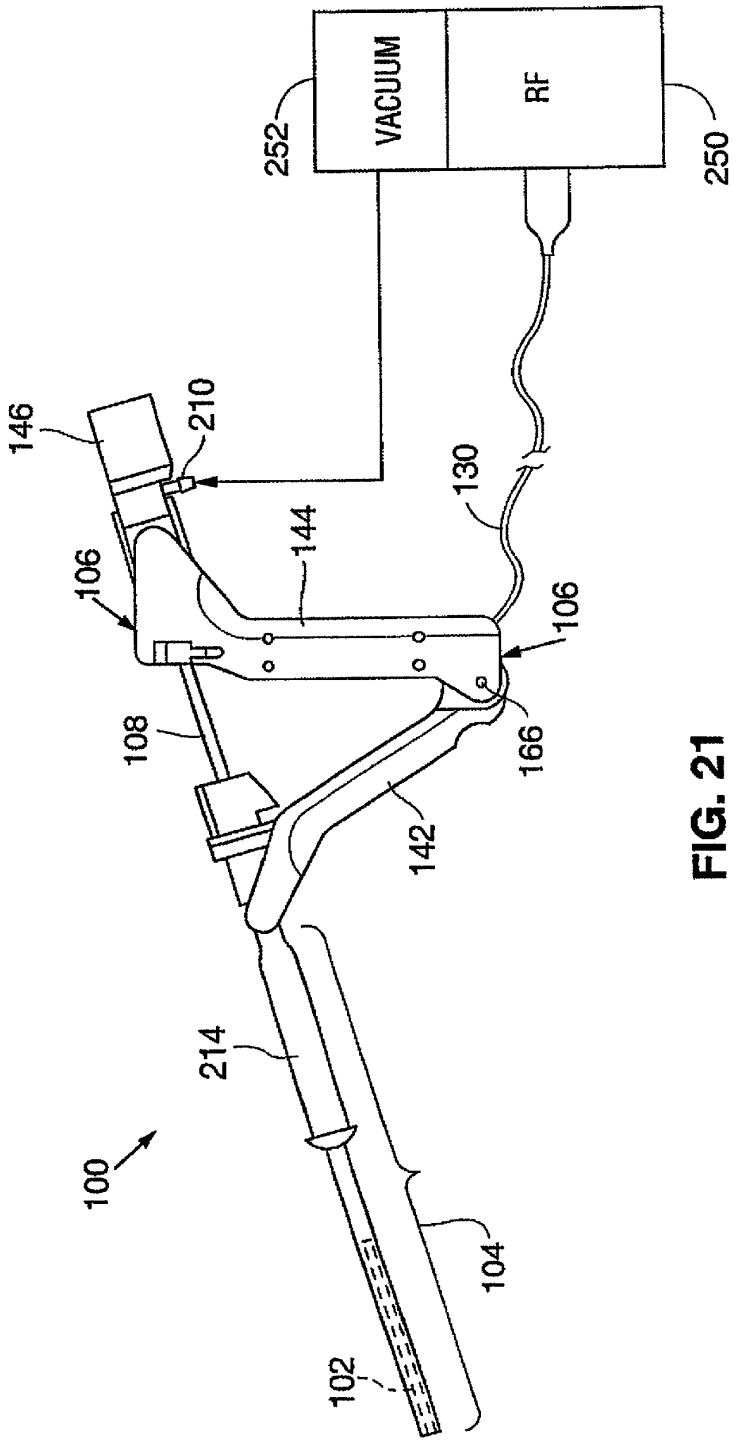


FIG. 20



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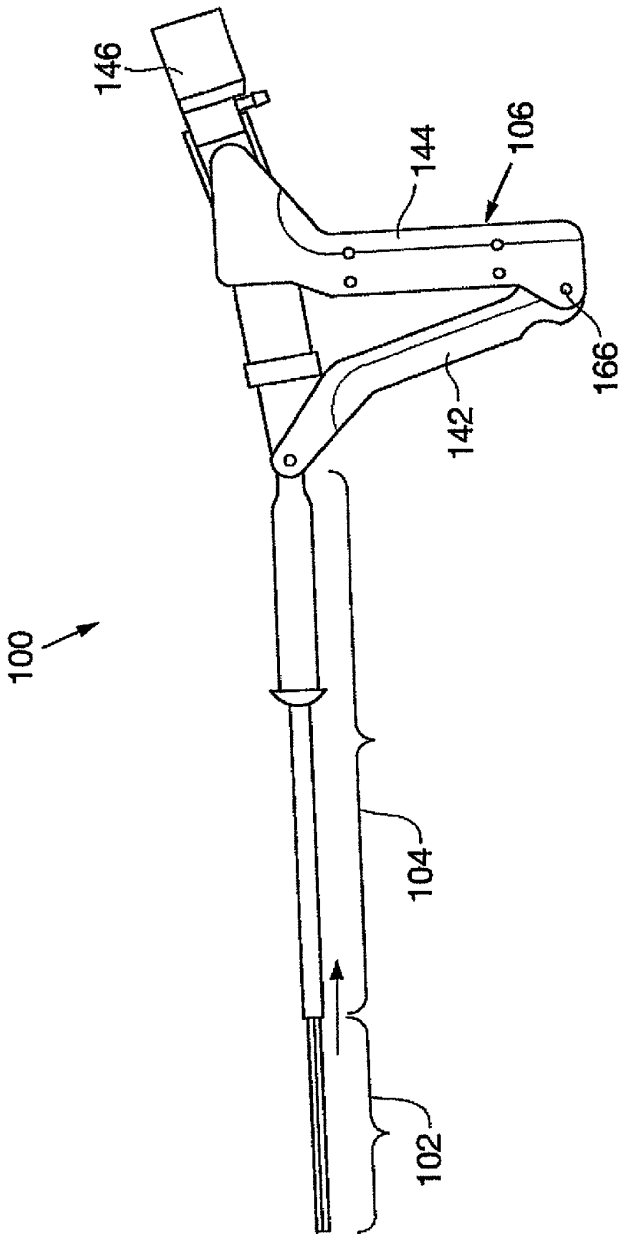
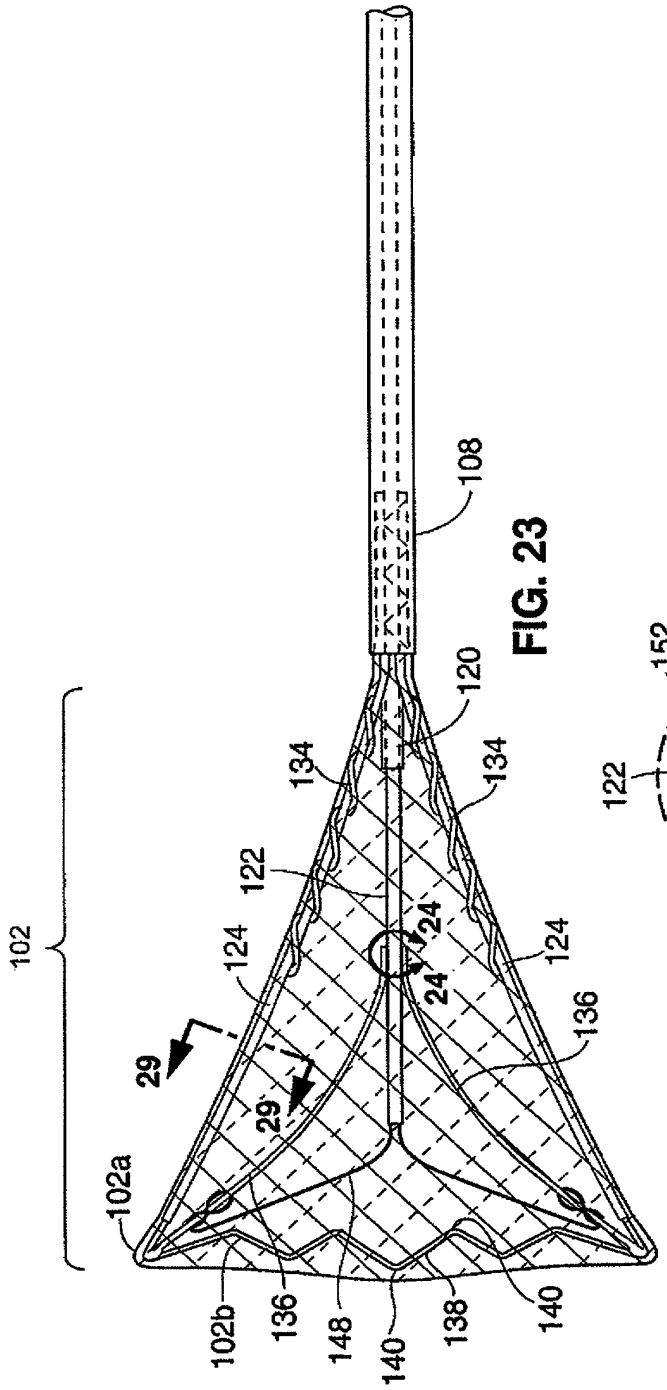


FIG. 22



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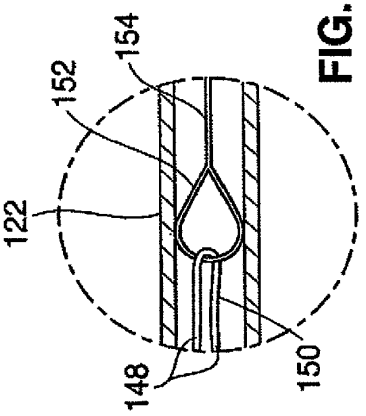
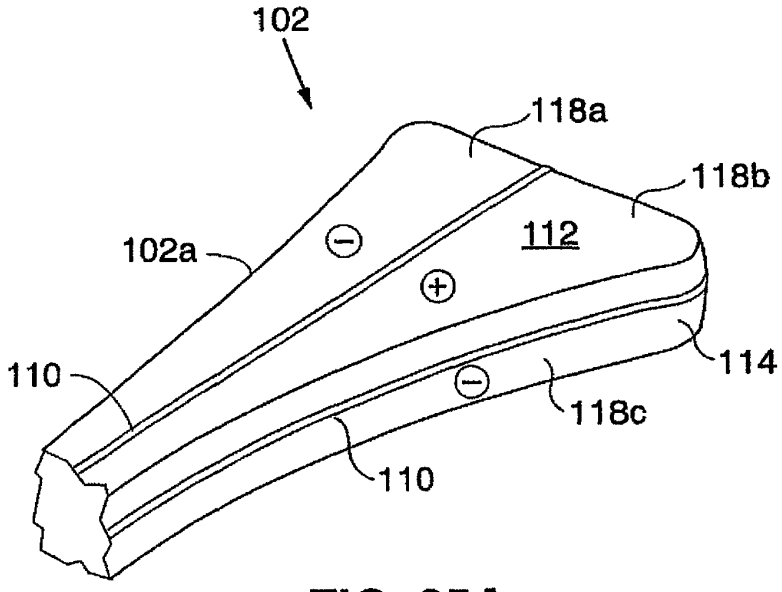


FIG. 24



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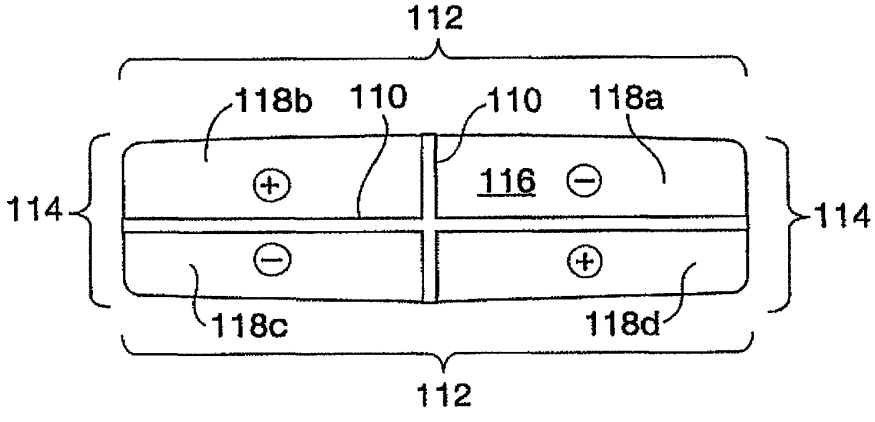
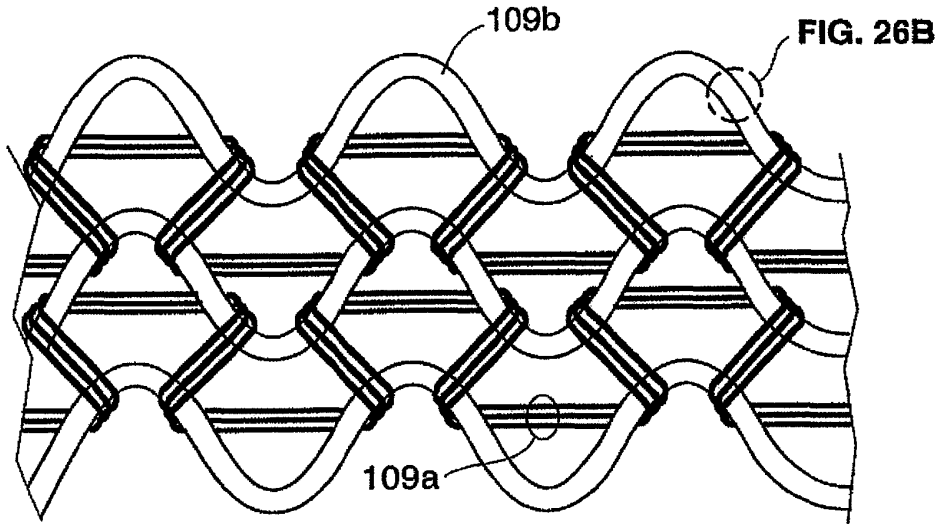


FIG. 25B



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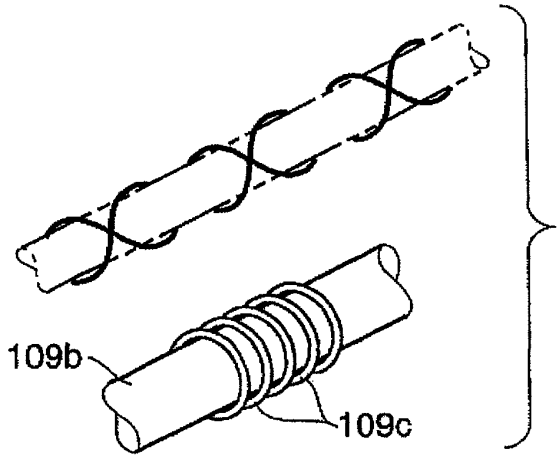
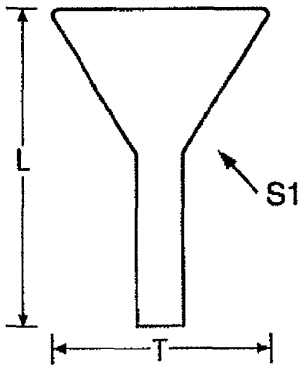


FIG. 26B



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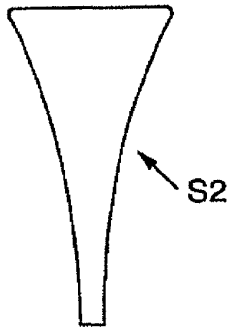


FIG. 27B

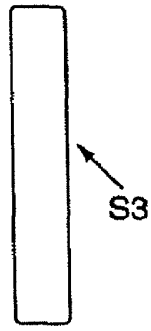


FIG. 27C

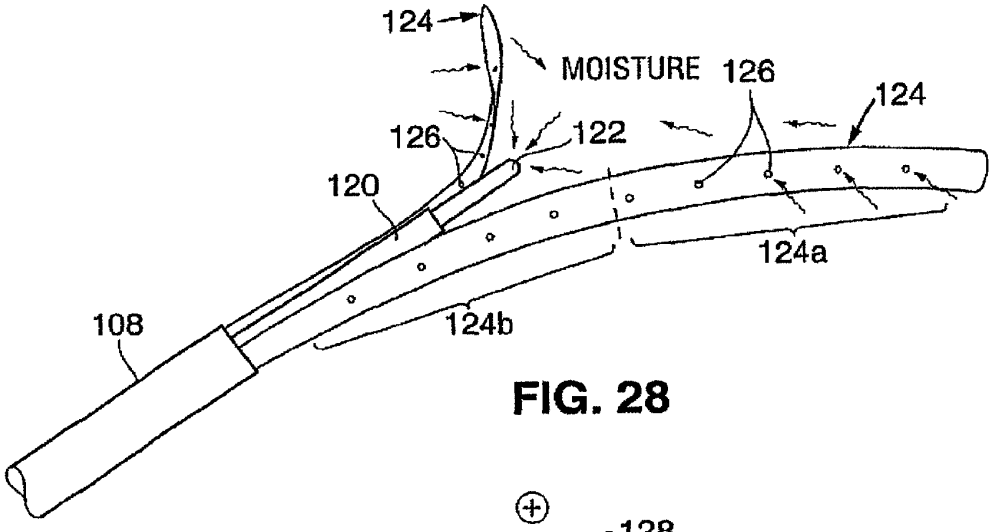


FIG. 28

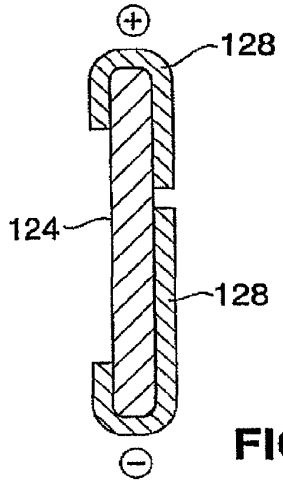
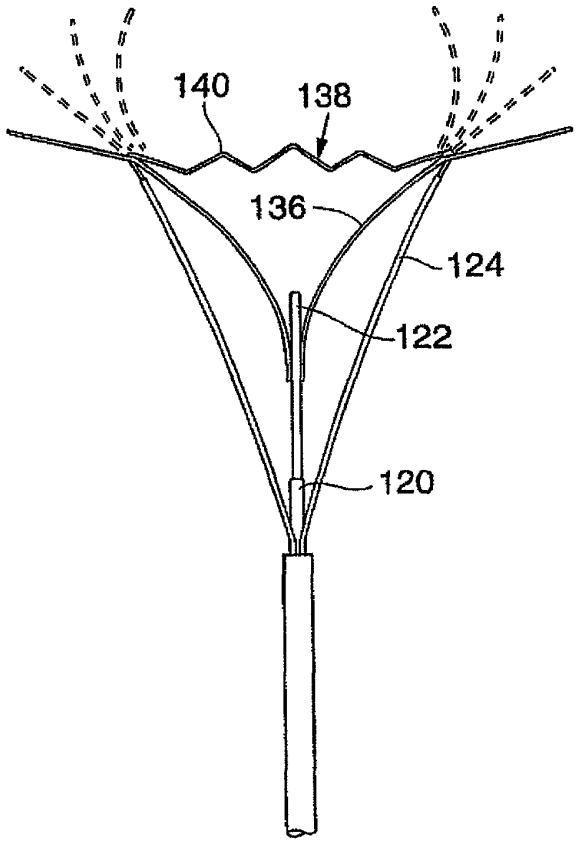


FIG. 29



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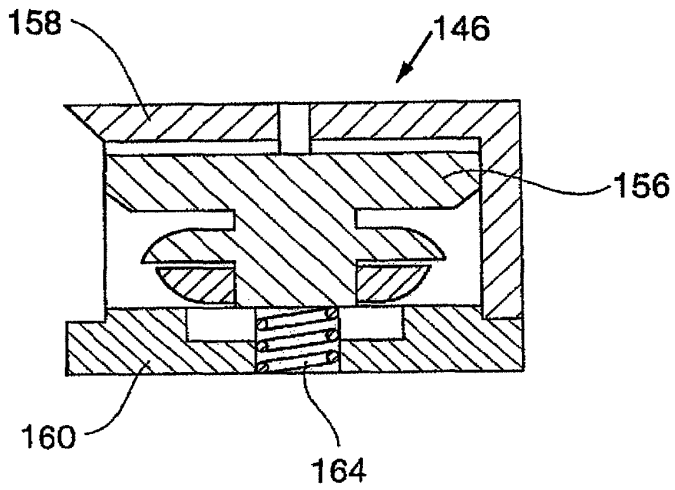

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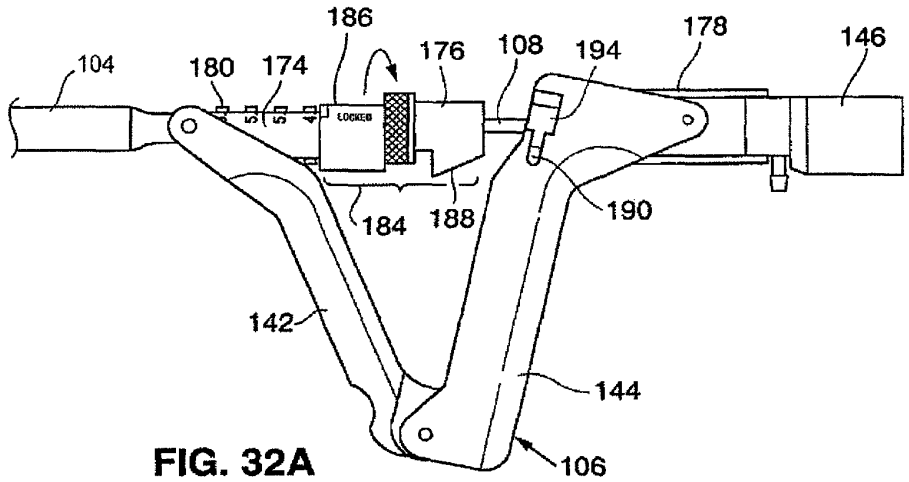
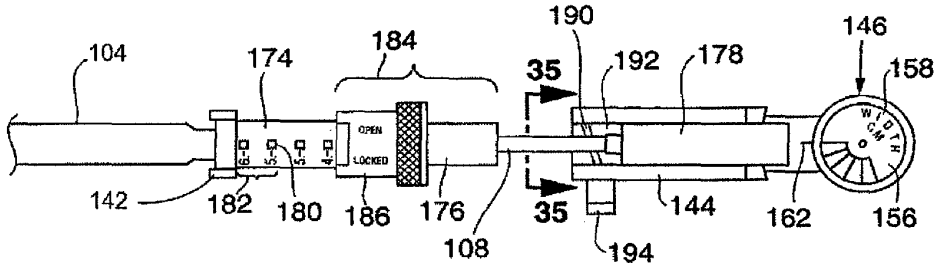


FIG. 32A



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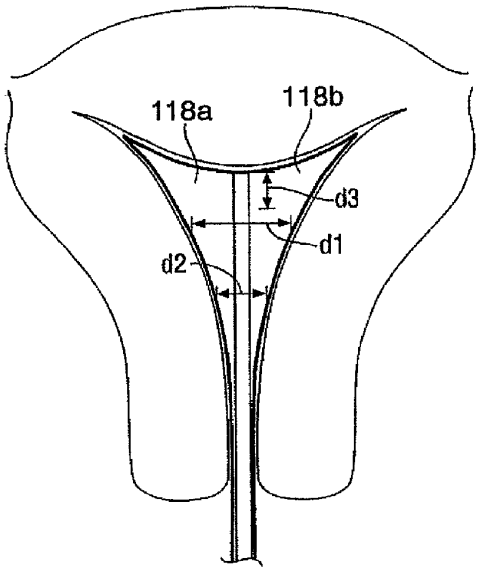

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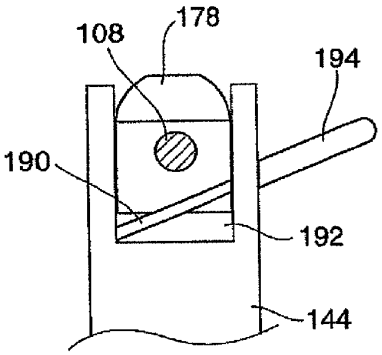

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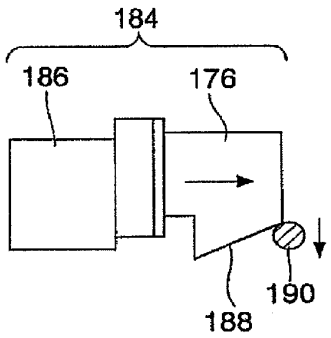


FIG. 36A

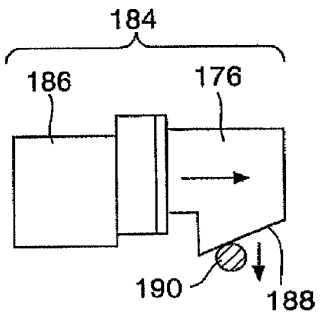


FIG. 36B

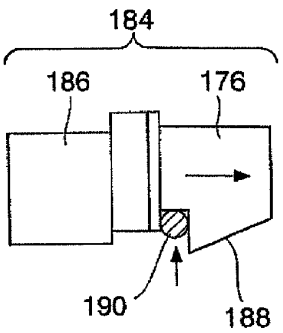


FIG. 36C

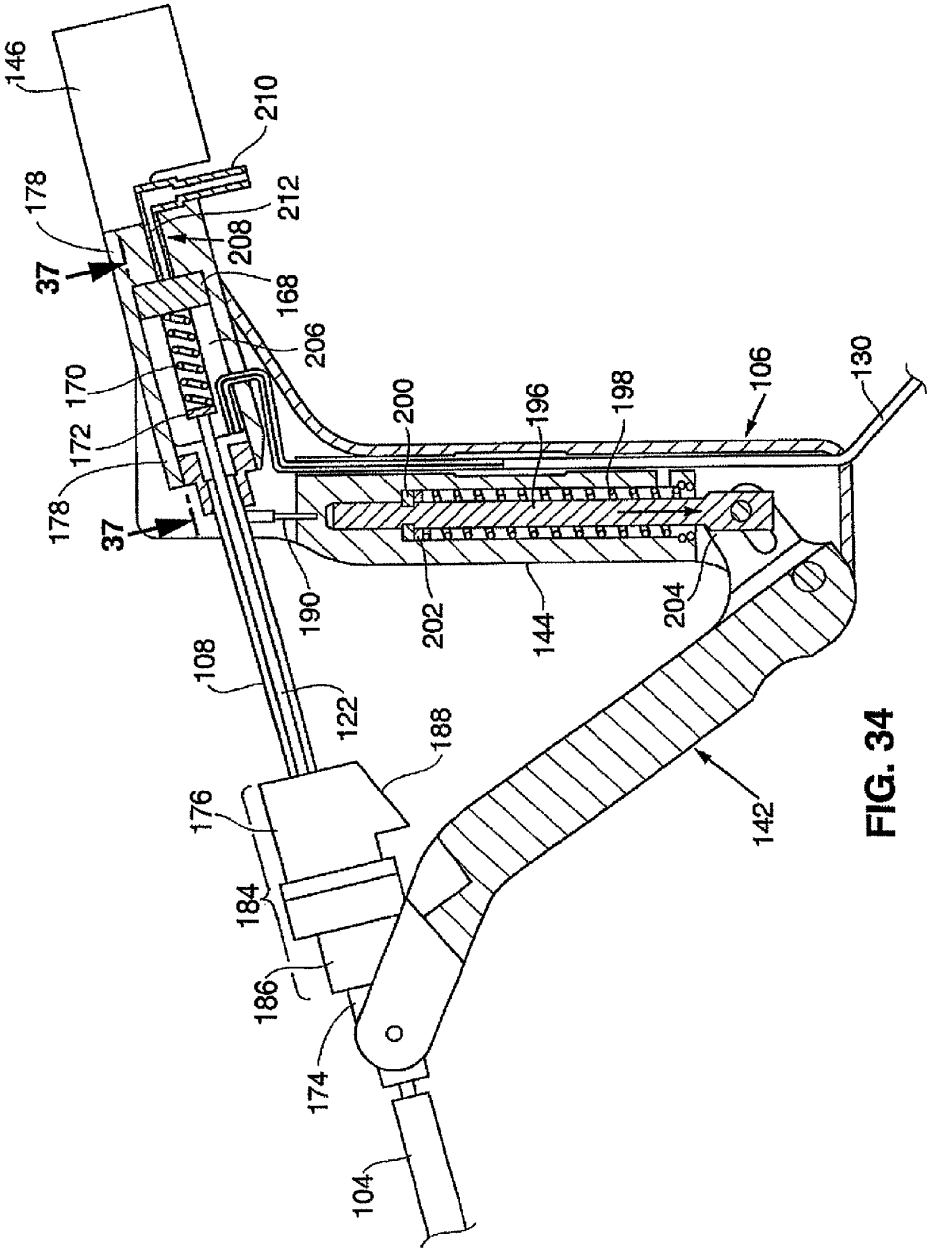
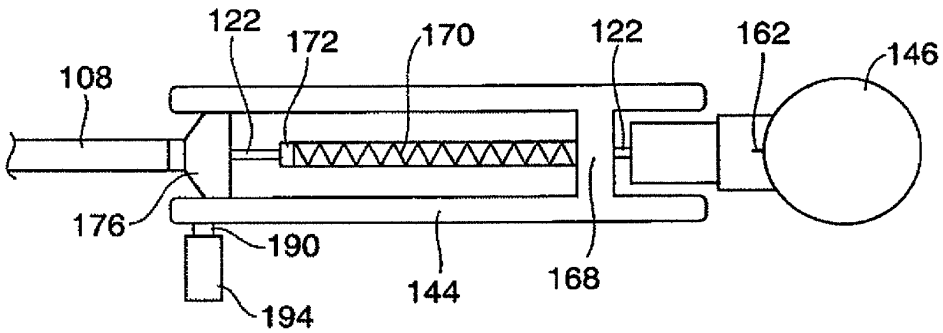


FIG. 34



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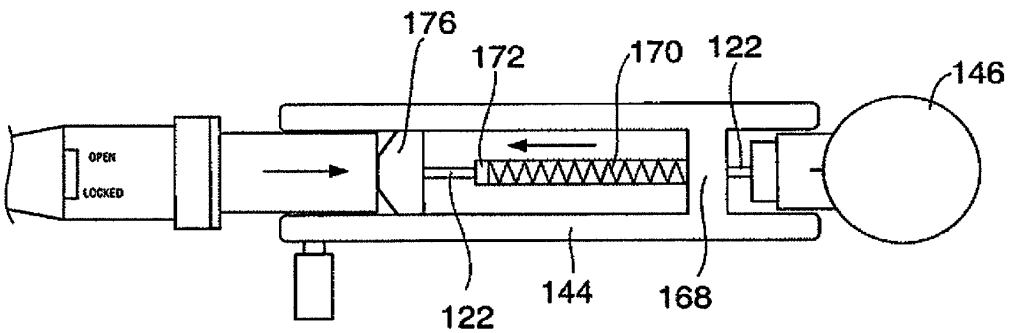


FIG. 37B

MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/581,506 filed Oct. 19, 2009, now U.S. Pat. No. 8,506,563 which is a continuation of U.S. application Ser. No. 10/959,771 filed Oct. 6, 2004, now U.S. Pat. No. 7,604,633, which is a divisional of U.S. application Ser. No. 09/103,072 filed Jun. 23, 1998, now U.S. Pat. No. 6,813,520, which claims the benefit of U.S. provisional application 60/084,791 filed May 8, 1998.

FIELD OF THE INVENTION

The present invention relates generally to the field of apparatuses and methods for ablating or coagulating the interior surfaces of body organs. Specifically, it relates to an apparatus and method for ablating the interior linings of body organs such as the uterus and gallbladder.

BACKGROUND OF THE INVENTION

Ablation of the interior lining of a body organ is a procedure which involves heating the organ lining to temperatures which destroy the cells of the lining or coagulate tissue proteins for hemostasis. Such a procedure may be performed as a treatment to one of many conditions, such as chronic bleeding of the endometrial layer of the uterus or abnormalities of the mucosal layer of the gallbladder. Existing methods for effecting ablation include circulation of heated fluid inside the organ (either directly or inside a balloon), laser treatment of the organ lining, and resistive heating using application of RF energy to the tissue to be ablated.

U.S. Pat. No. 5,084,044 describes an apparatus for endometrial ablation in which a bladder is inserted into the uterus. Heated fluid is then circulated through the balloon to expand the balloon into contact with the endometrium and to ablate the endometrium thermally. U.S. Pat. No. 5,443,470 describes an apparatus for endometrial ablation in which an expandable bladder is provided with electrodes on its outer surface. After the apparatus is positioned inside the uterus, a non-conductive gas or liquid is used to fill the balloon, causing the balloon to push the electrodes into contact with the endometrial surface. RF energy is supplied to the electrodes to ablate the endometrial tissue using resistive heating.

These ablation devices are satisfactory for carrying out ablation procedures. However, because no data or feedback is available to guide the physician as to how deep the tissue ablation has progressed, controlling the ablation depth and ablation profile with such devices can only be done by assumption.

For example, the heated fluid method is a very passive and ineffective heating process which relies on the heat conductivity of the tissue. This process does not account for variations in factors such as the amount of contact between the balloon and the underlying tissue, or cooling effects such as those of blood circulating through the organ. RF ablation techniques can achieve more effective ablation since it relies on active heating of the tissue using RF energy, but presently the depth of ablation using RF techniques can only be estimated by the physician since no feedback can be provided as to actual ablation depth.

Both the heated fluid techniques and the latest RF techniques must be performed using great care to prevent over ablation. Monitoring of tissue surface temperature is normally carried out during these ablation procedures to ensure the temperature does not exceed 100° C. If the temperature exceeds 100° C., the fluid within the tissue begins to boil and to thereby produce steam. Because ablation is carried out within a closed cavity within the body, the steam cannot escape and may instead force itself deeply into the tissue, or it may pass into areas adjacent to the area intended to be ablated, causing embolism or unintended burning.

Moreover, in prior art RF devices the water drawn from the tissue creates a path of conductivity through which current traveling through the electrodes will flow. This can prevent the current from traveling into the tissue to be ablated. Moreover, the presence of this current path around the electrodes causes current to be continuously drawn from the electrodes. The current heats the liquid drawn from the tissue and thus turns the ablation process into a passive heating method in which the heated liquid around the electrodes causes thermal ablation to continue well beyond the desired ablation depths.

Another problem with prior art ablation devices is that it is difficult for a physician to find out when ablation has been carried out to a desired depth within the tissue. Thus, it is often the case that too much or too little tissue may be ablated during an ablation procedure.

It is therefore desirable to provide an ablation device which eliminates the above-described problem of steam and liquid buildup at the ablation site. It is further desirable to provide an ablation method and device which allows the depth of ablation to be controlled and which automatically discontinues ablation once the desired ablation depth has been reached.

SUMMARY OF THE INVENTION

The present invention is an apparatus and method of ablating and/or coagulating tissue, such as that of the uterus or other organ. An ablation device is provided which has an electrode array carried by an elongate tubular member. The electrode array includes a fluid permeable elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon. During use, the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue to cause the tissue to dehydrate, and moisture generated during dehydration is actively or passively drawn into the array and away from the tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a front elevation view of a first embodiment of an ablation device according to the present invention, with the handle shown in cross-section and with the RF applicator head in a closed condition.

FIG. **2** is a front elevation view of the ablation device of FIG. **1**, with the handle shown in cross-section and with the RF applicator head in an open condition.

FIG. **3** is a side elevation view of the ablation device of FIG. **2**.

FIG. **4** is a top plan view of the ablation device of FIG. **2**.

FIG. **5**A is a front elevation view of the applicator head and a portion of the main body of the ablation device of FIG. **2**, with the main body shown in cross-section.

FIG. **5**B is a cross-section view of the main body taken along the plane designated **5**B-**5**B in FIG. **5**A.

FIG. **6** is a schematic representation of a uterus showing the ablation device of FIG. **1** following insertion of the device into the uterus but prior to retraction of the introducer sheath and activation of the spring members.

FIG. **7** is a schematic representation of a uterus showing the ablation device of FIG. **1** following insertion of the device into the uterus and following the retraction of the introducer sheath and the expansion of the RF applicator head.

FIG. **8** is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of FIG. **1**, showing the RF applicator head in the closed condition.

FIG. **9** is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of FIG. **1**, showing the configuration of RF applicator head after the sheath has been retracted but before the spring members have been released by proximal movement of the shaft.

FIG. **10** is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of FIG. **1**, showing the configuration of RF applicator head after the sheath has been retracted and after the spring members have been released into the fully opened condition.

FIG. **11** is a cross-section view of a distal portion of an RF ablation device similar to FIG. **1** which utilizes an alternative spring member configuration for the RF applicator head.

FIG. **12** is a side elevation view of the distal end of an alternate embodiment of an RF ablation device similar to that of FIG. **1**, which utilizes an RF applicator head having a modified shape.

FIG. **13** is a top plan view of the ablation device of FIG. **12**.

FIG. **14** is a representation of a bleeding vessel illustrating use of the ablation device of FIG. **12** for general bleeding control.

FIGS. **15** and **16** are representations of a uterus illustrating use of the ablation device of FIG. **12** for endometrial ablation.

FIG. **17** is a representation of a prostate gland illustrating use of the ablation device of FIG. **12** for prostate ablation.

FIG. **18** is a cross-section view of target tissue for ablation, showing ablation electrodes in contact with the tissue surface and illustrating energy fields generated during bi-polar ablation.

FIGS. **19**A-**19**C are cross-section views of target tissue for ablation, showing electrodes in contact with the tissue surface and illustrating how varying active electrode density may be used to vary the ablation depth.

FIG. **20** is a side elevation view, similar to the view of FIG. **2**, showing an ablation device according to the present invention in which the electrode carrying means includes inflatable balloons. For purposes of clarity, the electrodes on the electrode carrying means are not shown.

FIG. **21** is a side elevation view of a second exemplary embodiment of an ablation device according to the present invention, showing the array in the retracted state.

FIG. **22** is a side elevation view of the ablation device of FIG. **21**, showing the array in the deployed state.

FIG. **23** is a top plan view of the applicator head of the apparatus of FIG. **21**.

FIG. **24** is a cross-sectional top view of the encircled region designated **24** in FIG. **23**.

FIG. **25**A is a perspective view of the electrode array of FIG. **23**.

FIG. **25**B is a distal end view of the applicator head of FIG. **30**A.

FIG. **26**A is a plan view of a knit that may be used to form the applicator head.

FIG. **26**B is a perspective view of a strand of nylon-wrapped spandex of the type that may be used to form the knit of FIG. **26**A.

FIGS. **27**A, **27**B, **27**C are top plan views illustrating triangular, parabolic, and rectangular mesh shapes for use as electrode arrays according to the present invention.

FIG. **28** is a perspective view showing the flexures and hypotube of the deflecting mechanism of the applicator head of FIG. **23**.

FIG. **29** is a cross-section view of a flexure taken along the plane designated **29**-**29** in FIG. **23**.

FIG. **30** is a top plan view illustrating the flexure and spring arrangement of an alternative configuration of a deflecting mechanism for an applicator head according to the present invention.

FIG. **31** is a cross-sectional side view of the bobbin portion of the apparatus of FIG. **21**.

FIG. **32**A is a side elevation view of the handle of the ablation device of FIG. **21**.

FIG. **32**B is a top plan view of the handle of the ablation device of FIG. **21**. For clarity, portions of the proximal and distal grips are not shown.

FIG. **33** illustrates placement of the applicator head according to the present invention in a uterine cavity.

FIG. **34** is a side elevation view of the handle of the ablation apparatus of FIG. **21**, showing portions of the apparatus in cross-section.

FIG. **35** is a front elevation view of the upper portion of the proximal handle grip taken along the plane designated **35**-**35** in FIG. **32**B.

FIGS. **36**A, **36**B, and **36**C are a series of side elevation views illustrating the heel member as it becomes engaged with the corresponding spring member.

FIGS. **37**A and **37**B are cross-sectional top views of the frame member mounted on the proximal grip section, taken along the plane designated **37**-**37** in FIG. **34** and illustrating one of the load limiting features of the second embodiment. FIG. **37**A shows the condition of the compression spring before the heel member moves into abutment with frame member, and FIG. **37**B shows the condition of the spring after the heel member moves into abutment with the frame member.

DETAILED DESCRIPTION

The invention described in this application is an aspect of a larger set of inventions described in the following co-pending applications which are commonly owned by the assignee of the present invention, and are hereby incorporated by reference: U.S. Provisional Patent Application No. 60/084,724, filed May 8, 1998, entitled "APPARATUS AND METHOD FOR INTRA-ORGAN MEASUREMENT AND ABLATION"; and U.S. Provisional Patent Application No. 60/084,712 filed May 8, 1998, entitled "A RADIO-FREQUENCY GENERATOR FOR POWERING AN ABLATION DEVICE".

The ablation apparatus according to the present invention will be described with respect to two exemplary embodiments.

First Exemplary Embodiment—Structure

Referring to FIGS. **1** and **2**, an ablation device according to the present invention is comprised generally of three major components: RF applicator head **2**, main body **4**, and handle **6**. Main body **4** includes a shaft **10**. The RF applicator head **2** includes an electrode carrying means **12** mounted to the distal end of the shaft **10** and an array of electrodes **14** formed on the surface of the electrode carrying means **12**. An RF generator **16** is electrically connected to the electrodes **14** to provide mono-polar or bipolar RF energy to them.

Shaft **10** is an elongate member having a hollow interior. Shaft **10** is preferably 12 inches long and has a preferred cross-sectional diameter of approximately 4 mm. A collar **13** is formed on the exterior of the shaft **10** at the proximal end.

As best shown in FIGS. **6** and **7**, passive spring member **15** are attached to the distal end of the shaft **10**.

Extending through the shaft **10** is a suction/insufflation tube **17** (FIGS. **6-9**) having a plurality of holes **17***a* formed in its distal end. An arched active spring member **19** is connected between the distal ends of the passive spring members **15** and the distal end of the suction/insufflation tube **17**.

Referring to FIG. **2**, electrode leads **18***a* and **18***b* extend through the shaft **10** from distal end **20** to proximal end **22** of the shaft **10**. At the distal end **20** of the shaft **10**, each of the leads **18***a*, **18***b* is coupled to a respective one of the electrodes **14**. At the proximal end **22** of the shaft **10**, the leads **18***a*, **18***b* are electrically connected to RF generator **16** via an electrical connector **21**. During use, the leads **18***a*, **18***b* carry RF energy from the RF generator **16** to the electrodes. Each of the leads **18***a*, **18***b* is insulated and carries energy of an opposite polarity than the other lead.

Electrically insulated sensor leads **23***a*, **23***b* (FIGS. **5**A and **5**B) also extend through the shaft **10**. Contact sensors **25***a*, **25***b* are attached to the distal ends of the sensor leads **23***a*, **23***b*, respectively and are mounted to the electrode carrying means **12**. During use, the sensor leads **23***a*, **23***b* are coupled by the connector **21** to a monitoring module in the RF generator **16** which measures impedance between the sensors **25***a*, **25***b*. Alternatively, a reference pad may be positioned in contact with the patient and the impedance between one of the sensors and the reference pad measured.

Referring to FIG. **5**B, electrode leads **18***a*, **18***b* and sensor leads **23***a*, **23***b* extend through the shaft **10** between the external walls of the tube **17** and the interior walls of the shaft **10** and they are coupled to electrical connector **21** which is preferably mounted to the collar **13** on the shaft **10**. Connector **21**, which is connectable to the RF generator **16**, includes at least four electrical contact rings **21***a*-**21***d* (FIGS. **1** and **2**) which correspond to each of the leads **18***a*, **18***b*, **23***a*, **23***b*. Rings **21***a*, **21***b* receive, from the RF generator, RF energy of positive and negative polarity, respectively. Rings **21***c*, **21***d* deliver signals from the right and left sensors, respectively, to a monitoring module within the RF generator **16**.

Referring to FIG. **5**A, the electrode carrying means **12** is attached to the distal end **20** of the shaft **10**. A plurality of holes **24** may be formed in the portion of the distal end **20** of the shaft which lies within the electrode carrying means **12**.

The electrode carrying means **12** preferably has a shape which approximates the shape of the body organ which is to be ablated. For example, the apparatus shown in FIGS. **1** through **11** has a bicornual shape which is desirable for intrauterine ablation. The electrode carrying means **12** shown in these figures includes horn regions **26** which during use are positioned within the cornual regions of the uterus and which therefore extend towards the fallopian tubes.

Electrode carrying means **12** is preferably a sack formed of a material which is non-conductive, which is permeable to moisture and/or which has a tendency to absorb moisture, and which may be compressed to a smaller volume and subsequently released to its natural size upon elimination of compression. Examples of preferred materials for the electrode carrying means include open cell sponge, foam, cotton, fabric, or cotton-like material, or any other material having the desired characteristics. Alternatively, the electrode carrying means may be formed of a metallized fabric. For convenience, the term "pad" may be used interchangeably with the term electrode carrying means to refer to an electrode carrying means formed of any of the above materials or having the listed properties.

Electrodes **14** are preferably attached to the outer surface of the electrode carrying means **12**, such as by deposition or other attachment mechanism. The electrodes are preferably made of lengths of silver, gold, platinum, or any other conductive material. The electrodes may be attached to the electrode carrying means **12** by electron beam deposition, or they may be formed into coiled wires and bonded to the electrode carrying member using a flexible adhesive. Naturally, other means of attaching the electrodes, such as sewing them onto the surface of the carrying member, may alternatively be used. If the electrode carrying means **12** is formed of a metallized fabric, an insulating layer may be etched onto the fabric surface, leaving only the electrode regions exposed.

The spacing between the electrodes (i.e. the distance between the centers of adjacent electrodes) and the widths of the electrodes are selected so that ablation will reach predetermined depths within the tissue, particularly when maximum power is delivered through the electrodes (where maximum power is the level at which low impedance, low voltage ablation can be achieved).

The depth of ablation is also effected by the electrode density (i.e., the percentage of the target tissue area which is in contact with active electrode surfaces) and may be regulated by pre-selecting the amount of this active electrode coverage. For example, the depth of ablation is much greater when the active electrode surface covers more than 10% of the target tissue than it is when the active electrode surfaces covers 1% of the target tissue.

For example, by using 3-6 mm spacing and an electrode width of approximately 0.5-2.5 mm, delivery of approximately 20-40 watts over a 9-16 cm2 target tissue area will cause ablation to a depth of approximately 5-7 millimeters when the active electrode surface covers more than 10% of the target tissue area. After reaching this ablation depth, the impedance of the tissue will become so great that ablation will self-terminate as described with respect to the operation of the invention.

By contrast, using the same power, spacing, electrode width, and RF frequency will produce an ablation depth of only 2-3 mm when the active electrode surfaces covers less than 1% of the target tissue area. This can be better understood with reference to FIG. **19**A, in which high surface density electrodes are designated **14***a* and low surface density electrodes are designated **14***b*. For purposes of this comparison between low and high surface density electrodes, each bracketed group of low density electrodes is considered to be a single electrode. Thus, the electrode widths W and spacings S extend as shown in FIG. **19**A.

As is apparent from FIG. **19**A, the electrodes **14***a*, which have more active area in contact with the underlying tissue T, produce a region of ablation A**1** that extends more deeply into the tissue T than the ablation region A**2** produced by the low density electrodes **14***b*, even though the electrode spacings and widths are the same for the high and low density electrodes.

Some examples of electrode widths, having spacings with more than 10% active electrode surface coverage, and their resultant ablation depth, based on an ablation area of 6 cm2 and a power of 20-40 watts, are given on the following table:

ELECTRODE WIDTH	SPACING	APPROX. DEPTH
1 mm	1-2 mm	1-3 mm
1-2.5 mm	3-6 mm	5-7 mm
1-4.5 mm	8-10 mm	8-10 mm

Examples of electrode widths, having spacings with less than 1% active electrode surface coverage, and their resultant

ablation depth, based on an ablation area of 6 cm2 and a power of 20-40 watts, are given on the following table:

ELECTRODE WIDTH	SPACING	APPROX. DEPTH
1 mm	1-2 mm	0.5-1 mm
1-2.S mm	3-6 mm	2-3 mm
1-4.5 mm	8-10 mm	2-3 mm

Thus it can be seen that the depth of ablation is significantly less when the active electrode surface coverage is decreased.

In the preferred embodiment, the preferred electrode spacing is approximately 8-10 mm in the horn regions **26** with the active electrode surfaces covering approximately 1% of the target region. Approximately 1-2 mm electrode spacing (with 10% active electrode coverage) is preferred in the cervical region (designated **28**) and approximately 3-6 mm (with greater than 10% active electrode surface coverage) is preferred in the main body region.

The RF generator **16** may be configured to include a controller which gives the user a choice of which electrodes should be energized during a particular application in order to give the user control of ablation depth. For example, during an application for which deep ablation is desired, the user may elect to have the generator energize every other electrode, to thereby optimize the effective spacing of the electrodes and to decrease the percentage of active electrode surface coverage, as will be described below with respect to FIG. **18**.

Although the electrodes shown in the drawings are arranged in a particular pattern, it should be appreciated that the electrodes may be arranged in any pattern to provide ablation to desired depths.

Referring to FIGS. **6** and **7**, an introducer sheath **32** facilitates insertion of the apparatus into, and removal of the apparatus from, the body organ to be ablated. The sheath **32** is a tubular member which is telescopically slidable over the shaft **10**. The sheath **32** is slidable between a distal condition, shown in FIG. **6**, in which the electrode carrying means **12** is compressed inside the sheath, and a proximal condition in which the sheath **32** is moved proximally to release the electrode carrying means from inside it (FIG. **7**). By compressing the electrode carrying means **12** to a small volume, the electrode carrying means and electrodes can be easily inserted into the body cavity (such as into the uterus via the vaginal opening).

A handle **34** attached to the sheath **32** provides finger holds to allow for manipulation of the sheath **32**. Handle **34** is slidably mounted on a handle rail **35** which includes a sleeve **33**, a finger cutout **37**, and a pair of spaced rails **35***a*, **35***b* extending between the sleeve **33** and the finger cutout **37**. The shaft **10** and sheath **32** slidably extend through the sleeve **33** and between the rails **35***a*, **35***b*. The tube **17** also extends through the sleeve **33** and between the rails **35***a*, **35***b*, and its proximal end is fixed to the handle rail **35** near the finger cutout **37**.

A compression spring **39** is disposed around the proximal most portion of the suction/insufflation tube **17** which lies between the rails **35***a*, **35***b*. One end of the compression spring **39** rests against the collar **13** on the shaft **10**, while the opposite end of the compression spring rests against the handle rail **35**. During use, the sheath **32** is retracted from the electrode carrying means **12** by squeezing the handle **34** towards the finger cutout **37** to slide the sheath **32** in the distal direction. When the handle **34** advances against the collar **13**, the shaft **10** (which is attached to the collar **13**) is forced to slide in the proximal direction, causing compression of the spring **39** against the handle rail **35**. The movement of the shaft **10** relative to the suction/insufflation tube **17** causes the shaft **10** to pull proximally on the passive spring member **15**. Proximal movement of the passive spring member **15** in turn pulls against the active spring member **19**, causing it to move to the opened condition shown in FIG. **7**. Unless the shaft is held in this retracted condition, the compression spring **39** will push the collar and thus the shaft distally, forcing the RF applicator head to close. A locking mechanism (not shown) may be provided to hold the shaft in the fully withdrawn condition to prevent inadvertent closure of the spring members during the ablation procedure.

The amount by which the springs **15**, **19** are spread may be controlled by manipulating the handle **34** to slide the shaft **10** (via collar **13**), proximally or distally. Such sliding movement of the shaft **10** causes forceps-like movement of the spring members **15**, **19**.

A flow pathway **36** is formed in the handle rail **35** and is fluidly coupled to a suction/insufflation port **38**. The proximal end of the suction/insufflation tube **17** is fluidly coupled to the flow pathway so that gas fluid may be introduced into, or withdrawn from the suction/insufflation tube **17** via the suction/insufflation port **38**. For example, suction may be applied to the fluid port **38** using a suction/insufflation unit **40**. This causes water vapor within the uterine cavity to pass through the permeable electrode carrying means **12**, into the suction/insufflation tube **17** via holes **17***a*, through the tube **17**, and through the suction/insufflation unit **40** via the port **38**. If insufflation of the uterine cavity is desired, insufflation gas, such as carbon dioxide, may be introduced into the suction/insufflation tube **17** via the port **38**. The insufflation gas travels through the tube **17**, through the holes **17***a*, and into the uterine cavity through the permeable electrode carrying member **12**.

If desirable, additional components may be provided for endoscopic visualization purposes. For example, lumen **42**, **44**, and **46** may be formed in the walls of the introducer sheath **32** as shown in FIG. **5**B. An imaging conduit, such as a fiberoptic cable **48**, extends through lumen **42** and is coupled via a camera cable **43** to a camera **45**. Images taken from the camera may be displayed on a monitor **56**. An illumination fiber **50** extends through lumen **44** and is coupled to an illumination source **54**. The third lumen **46** is an instrument channel through which surgical instruments may be introduced into the uterine cavity, if necessary.

Because during use it is most desirable for the electrodes **14** on the surface of the electrode carrying means **12** to be held in contact with the interior surface of the organ to be ablated, the electrode carrying means **12** may be provided to have additional components inside it that add structural integrity to the electrode carrying means when it is deployed within the body.

For example, referring to FIG. **11**, alternative spring members **15***a*, **19***a* may be attached to the shaft **10** and biased such that, when in a resting state, the spring members are positioned in the fully resting condition shown in FIG. **11**. Such spring members would spring to the resting condition upon withdrawal of the sheath **32** from the RF applicator head **2**.

Alternatively, a pair of inflatable balloons **52** may be arranged inside the electrode carrying means **12** as shown in FIG. **20** and connected to a tube (not shown) extending through the shaft **10** and into the balloons **52**. After insertion of the apparatus into the organ and following retraction of the sheath **32**, the balloons **52** would be inflated by introduction of an inflation medium such as air into the balloons via a port similar to port **38** using an apparatus similar to the suction/insufflation apparatus **40**.

Structural integrity may also be added to the electrode carrying means through the application of suction to the proximal end **22***a* of the suction/insufflation tube **17**. Application of suction using the suction/insufflation device **40** would draw the organ tissue towards the electrode carrying means **12** and thus into better contact with the electrodes **14**.

FIGS. **12** and **13** show an alternative embodiment of an ablation device according to the present invention. In the alternative embodiment, an electrode carrying means **12***a* is provided which has a shape which is generally tubular and thus is not specific to any particular organ shape. An ablation device having a general shape such as this may be used anywhere within the body where ablation or coagulation is needed. For example, the alternative embodiment is useful for bleeding control during laparoscopic surgery (FIG. **14**), tissue ablation in the prostate gland (FIG. **17**), and also intrauterine ablation (FIGS. **15** and **16**).

First Exemplary Embodiment—Operation

Operation of the first exemplary embodiment of an ablation device according to the present invention will next be described.

Referring to FIG. **1**, the device is initially configured for use by positioning the introducer sheath **32** distally along the shaft **10**, such that it compresses the electrode carrying means **12** within its walls.

At this time, the electrical connector **21** is connected to the RF generator **16**, and the fiberoptic cable **48** and the illumination cable **50** are connected to the illumination source, monitor, and camera, **54**, **56**, **45**. The suction/insufflation unit **40** is attached to suction/insufflation port **38** on the handle rail **35**. The suction/insufflation unit **40** is preferably set to deliver carbon dioxide at an insufflation pressure of 20-200 mmHg.

Next, the distal end of the apparatus is inserted through the vaginal opening V and into the uterus U as shown in FIG. **6**, until the distal end of the introducer sheath **32** contacts the fundus F of the uterus. At this point, carbon dioxide gas is introduced into the tube **17** via the port **38**, and it enters the uterine cavity, thereby expanding the uterine cavity from a flat triangular shape to a 1-2 cm high triangular cavity. The physician may observe (using the camera **45** and monitor **56**) the internal cavities using images detected by a fiberoptic cable **48** inserted through lumen **42**. If, upon observation, the physician determines that a tissue biopsy or other procedure is needed, the required instruments may be inserted into the uterine cavity via the instrument channel **46**.

Following insertion, the handle **34** is withdrawn until it abuts the collar **13**. At this point, the sheath **32** exposes the electrode carrying member **12** but the electrode carrying member **12** is not yet fully expanded (see FIG. **9**), because the spring members **15**, **19** have not yet been moved to their open condition. The handle **34** is withdrawn further, causing the shaft **10** to move proximally relative to the suction/insufflation tube **17**, causing the passive spring members **15** to pull the active spring members **19**, causing them to open into the opened condition shown in FIG. **10**.

The physician may confirm proper positioning of the electrode carrying member **12** using the monitor **56**, which displays images from the fiberoptic cable **48**.

Proper positioning of the device and sufficient contact between the electrode carrying member **12** and the endometrium may further be confirmed using the contact sensors **25***a*, **25***b*. The monitoring module of the RF generator measures the impedance between these sensors using conventional means. If there is good contact between the sensors and the endometrium, the measured impedance will be approximately 20-180 ohm, depending on the water content of the endometrial lining.

The sensors are positioned on the distal portions of the bicornual shaped electrode carrying member **12**, which during use are positioned in the regions within the uterus in which it is most difficult to achieve good contact with the endometrium. Thus, an indication from the sensors **25***a*, **25***b* that there is sound contact between the sensors and the endometrial surface indicates that good electrode contact has been made with the endometrium.

Next, insufflation is terminated. Approximately 1-5 cc of saline may be introduced via suction/insufflation tube **17** to initially wet the electrodes and to improve electrode electrical contact with the tissue. After introduction of saline, the suction/insufflation device **40** is switched to a suctioning mode. As described above, the application of suction to the RF applicator head **2** via the suction/insufflation tube **17** collapses the uterine cavity onto the RF applicator head **2** and thus assures better contact between the electrodes and the endometrial tissue.

If the generally tubular apparatus of FIGS. **12** and **13** is used, the device is angled into contact with one side of the uterus during the ablation procedure. Once ablation is completed, the device (or a new device) is repositioned in contact with the opposite side and the procedure is repeated. See. FIGS. **15** and **16**.

Next, RF energy at preferably about 500 kHz and at a constant power of approximately 30 W is applied to the electrodes. As shown in FIG. **5***a*, it is preferable that each electrode be energized at a polarity opposite from that of its neighboring electrodes. By doing so, energy field patterns, designated F**1**, F**2** and F**4** in FIG. **18**, are generated between the electrode sites and thus help to direct the flow of current through the tissue T to form a region of ablation A. As can be seen in FIG. **18**, if electrode spacing is increased such by energizing, for example every third or fifth electrode rather than all electrodes, the energy patterns will extend more deeply into the tissue. (See, for example, pattern F**2** which results from energization of electrodes having a non-energized electrode between them, or pattern F**4** which results from energization of electrodes having three non-energized electrodes between them).

Moreover, ablation depth may be controlled as described above by providing low surface density electrodes on areas of the electrode carrying member which will contact tissue areas at which a smaller ablation depth is required (see FIG. **19**A). Referring to FIG. **19**B, if multiple, closely spaced, electrodes **14** are provided on the electrode carrying member, a user may set the RF generator to energize electrodes which will produce a desired electrode spacing and active electrode area. For example, alternate electrodes may be energized as shown in FIG. **19**B, with the first three energized electrodes having positive polarity, the second three having negative polarity, etc.

As another example, shown in FIG. **19**C, if greater ablation depth is desired the first five electrodes may be positively energized, and the seventh through eleventh electrodes negatively energized, with the sixth electrode remaining inactivated to provide adequate electrode spacing.

As the endometrial tissue heats, moisture begins to be released from the tissue. The moisture permeates the electrode carrying member **12** and is thereby drawn away from the electrodes. The moisture may pass through the holes **17***a* in the suction/insufflation tube **17** and leave the suction/insufflation tube **17** at its proximal end via port **38** as shown in FIG. **7**. Moisture removal from the ablation site may be further facilitated by the application of suction to the shaft **10** using the suction/insufflation unit **40**.

Removal of the moisture from the ablation site prevents formation of a liquid layer around the electrodes. As described above, liquid build-up at the ablation site is detrimental in that provides a conductive layer that carries current from the electrodes even when ablation has reached the desired depth. This continued current flow heats the liquid and surrounding tissue, and thus causes ablation to continue by unpredictable thermal conduction means.

Tissue which has been ablated becomes dehydrated and thus decreases in conductivity. By shunting moisture away from the ablation site and thus preventing liquid build-up, there is no liquid conductor at the ablation area during use of the ablation device of the present invention. Thus, when ablation has reached the desired depth, the impedance at the tissue surface becomes sufficiently high to stop or nearly stop the flow of current into the tissue. RF ablation thereby stops and thermal ablation does not occur in significant amounts. If the RF generator is equipped with an impedance monitor, a physician utilizing the ablation device can monitor the impedance at the electrodes and will know that ablation has self-terminated once the impedance rises to a certain level and then remains fairly constant. By contrast, if a prior art bipolar RF ablation device was used together with an impedance monitor, the presence of liquid around the electrodes would cause the impedance monitor to give a low impedance reading regardless of the depth of ablation which had already been carried out, since current would continue to travel through the low-impedance liquid layer.

Other means for monitoring and terminating ablation may also be provided. For example, a thermocouple or other temperature sensor may be inserted to a predetermined depth in the tissue to monitor the temperature of the tissue and terminate the delivery of RF energy or otherwise signal the user when the tissue has reached a desired ablation temperature.

Once the process has self terminated, 1-5 cc of saline can be introduced via suction/insufflation tube **17** and allowed to sit for a short time to aid separation of the electrode from the tissue surface. The suction insufflation device **40** is then switched to provide insufflation of carbon dioxide at a pressure of 20-200 mmHg. The insufflation pressure helps to lift the ablated tissue away from the RF applicator head **2** and to thus ease the closing of the RF applicator head. The RF applicator head **2** is moved to the closed position by sliding the handle **34** in a distal direction to fold the spring members **15**, **19** along the axis of the device and to cause the introducer sheath **32** to slide over the folded RF applicator head. The physician may visually confirm the sufficiency of the ablation using the monitor **56**. Finally, the apparatus is removed from the uterine cavity.

Second Exemplary Embodiment—Structure

A second embodiment of an ablation device **100** in accordance with the present invention is shown in FIGS. **21**-**37**B. The second embodiment differs from the first embodiment primarily in its electrode pattern and in the mechanism used to deploy the electrode applicator head or array. Naturally, aspects of the first and second exemplary embodiments and their methods of operation may be combined without departing from the scope of the present invention.

Referring to FIGS. **21** and **22**, the second embodiment includes an RF applicator head **102**, a sheath **104**, and a handle **106**. As with the first embodiment, the applicator head **102** is slidably disposed within the sheath **104** (FIG. **21**) during insertion of the device into the uterine cavity, and the handle **106** is subsequently manipulated to cause the applicator head **102** to extend from the distal end of the sheath **104** (FIG. **22**) and to expand into contact with body tissue (FIG. **33**).

RF Applicator Head

Referring to FIG. **23**, in which the sheath **104** is not shown for clarity, applicator head **102** extends from the distal end of a length of tubing **108** which is slidably disposed within the sheath **104**. Applicator head **102** includes an external electrode array **102***a* and an internal deflecting mechanism **102***b* used to expand and tension the array for positioning into contact with the tissue.

Referring to FIGS. **25**A and **25**B, the array **102***a* of applicator head **102** is formed of a stretchable metallized fabric mesh which is preferably knitted from a nylon and spandex knit plated with gold or other conductive material. In one array design, the knit (shown in FIGS. **26**A and **26**B) is formed of three monofilaments of nylon **109***a* knitted together with single yarns of spandex **109***b*. Each yarn of spandex **109***b* has a double helix **109***c* of five nylon monofilaments coiled around it.

This knit of elastic (spandex) and inelastic (nylon) yarns is beneficial for a number of reasons. For example, knitting elastic and relatively inelastic yarns allows the overall deformability of the array to be pre-selected.

The mesh is preferably constructed so as to have greater elasticity in the transverse direction (T) than in the longitudinal direction (L). In a preferred mesh design, the transverse elasticity is on the order of approximately 300% whereas the longitudinal elasticity is on the order of approximately 100%. The large transverse elasticity of the array allows it to be used in a wide range of uterine sizes.

Another advantage provided by the combination of elastic and relatively inelastic yarns is that the elastic yarns provide the needed elasticity to the array while the relatively inelastic yarns provide relatively non-stretchable members to which the metallization can adhere without cracking during expansion of the array. In the knit configuration described above, the metallization adheres to the nylon coiled around the spandex. During expansion of the array, the spandex elongates and the nylon double helix at least partially elongates from its coiled configuration.

One process which may be used to apply the gold to the nylon/spandex knit involves plating the knit with silver using known processes which involve application of other materials as base layers prior to application of the silver to ensure that the silver will adhere. Next, the insulating regions **110** (described below) are etched onto the silver, and afterwards the gold is plated onto the silver. Gold is desirable for the array because of it has a relatively smooth surface, is a very inert material, and has sufficient ductility that it will not crack as the nylon coil elongates during use.

The mesh may be configured in a variety of shapes, including but not limited to the triangular shape S**1**, parabolic S**2**, and rectangular S**3** shapes shown in FIGS. **27**A, **27**B and **27**C, respectively.

Turning again to FIGS. **25**A and **25**B, when in its expanded state, the array **102***a* includes a pair of broad faces **112** spaced apart from one another. Narrower side faces **114** extend between the broad faces **112** along the sides of the applicator head **102**, and a distal face **116** extends between the broad faces **112** at the distal end of the applicator head **102**.

Insulating regions **110** are formed on the applicator head to divide the mesh into electrode regions. The insulated regions **110** are preferably formed using etching techniques to remove the conductive metal from the mesh, although alternate methods may also be used, such as by knitting conductive and non-conductive materials together to form the array.

The array may be divided by the insulated regions **110** into a variety of electrode configurations. In a preferred configuration the insulating regions **110** divide the applicator head

into four electrodes **118***a*-**118***d* by creating two electrodes on each of the broad faces **112**. To create this four-electrode pattern, insulating regions **110** are placed longitudinally along each of the broad faces **112** as well as along the length of each of the faces **114**, **116**. The electrodes **118***a*-**118***d* are used for ablation and, if desired, to measure tissue impedance during use.

Deflecting mechanism **102***b* and its deployment structure is enclosed within electrode array **102***a*. Referring to FIG. **23**, external hypotube **120** extends from tubing **108** and an internal hypotube **122** is slidably and co-axially disposed within hypotube **120**. Flexures **124** extend from the tubing **108** on opposite sides of external hypotube **120**. A plurality of longitudinally spaced apertures **126** (FIG. **28**) are formed in each flexure **124**. During use, apertures **126** allow moisture to pass through the flexures and to be drawn into exposed distal end of hypotube **120** using a vacuum source fluidly coupled to hypotube **120**.

Each flexure **124** preferably includes conductive regions that are electrically coupled to the array **102***a* for delivery of RF energy to the body tissue. Referring to FIG. **29**, strips **128** of copper tape or other conductive material extend along opposite surfaces of each flexure **124**. Each strip **128** is electrically insulated from the other strip **128** by a non-conductive coating on the flexure. Conductor leads (not shown) are electrically coupled to the strips **128** and extend through tubing **108** (FIG. **23**) to an electrical cord **130** (FIG. **21**) which is attachable to the RF generator.

During use, one strip **128** on each conductor is electrically coupled via the conductor leads to one terminal on the RF generator while the other strip is electrically coupled to the opposite terminal, thus causing the array on the applicator head to have regions of alternating positive and negative polarity.

The flexures may alternatively be formed using a conductive material or a conductively coated material having insulating regions formed thereon to divide the flexure surfaces into multiple conductive regions. Moreover, alternative methods such as electrode leads independent of the flexures **124** may instead be used for electrically connecting the electrode array to the source of RF energy.

It is important to ensure proper alignment between the conductive regions of the flexures **124** (e.g. copper strips **128**) and the electrodes **118***a*-**118***d* in order to maintain electrical contact between the two. Strands of thread **134** (which may be nylon) (FIG. **23**) are preferably sewn through the array **102***a* and around the flexures **124** in order to prevent the conductive regions **128** from slipping out of alignment with the electrodes **118***a*-**118***d*. Alternate methods for maintaining contact between the array **102***a* and the conductive regions **128** include using tiny bendable barbs extending between the flexures **124** and the array **102***a* to hook the array to the conductive regions **128**, or bonding the array to the flexures using an adhesive applied along the insulating regions of the flexures.

Referring again to FIG. **23**, internal flexures **136** extend laterally and longitudinally from the exterior surface of hypotube **122**. Each internal flexure **136** is connected at its distal end to one of the flexures **124** and a transverse ribbon **138** extends between the distal portions of the internal flexures **136**. Transverse ribbon **138** is preferably pre-shaped such that when in the relaxed condition the ribbon assumes the corrugated configuration shown in FIG. **23** and such that when in a compressed condition it is folded along the plurality of creases **140** that extend along its length. Flexures **124**, **136** and ribbon **138** are preferably an insulated spring material such as heat treated 17-7 PH stainless steel.

The deflecting mechanism is preferably configured such that the distal tips of the flexures **124** are sufficiently flexible to prevent tissue puncture during deployment and/or use. Such an atraumatic tip design may be carried out in a number of ways, such as by manufacturing the distal sections **124***a* (FIG. **28**) of the flexures from a material that is more flexible than the proximal sections **124***b*. For example, flexures **124** may be provided to have proximal sections formed of a material having a modulus of approximately 28×106 psi and distal sections having a durometer of approximately 72D.

Alternatively, referring to FIG. **30**, the flexures **124** may be joined to the internal flexures **136** at a location more proximal than the distal tips of the flexures **124**, allowing them to move more freely and to adapt to the contour of the surface against which they are positioned (see dashed lines in FIG. **30**). Given that uterine sizes and shapes vary widely between women, the atraumatic tip design is further beneficial in that it allows the device to more accurately conform to the shape of the uterus in which it is deployed while minimizing the chance of injury.

The deflecting mechanism formed by the flexures **124**, **136**, and ribbon **138** forms the array into the substantially triangular shape shown in FIG. **23**, which is particularly adaptable to most uterine shapes. As set forth in detail below, during use distal and proximal grips **142**, **144** forming handle **106** are squeezed towards one another to withdraw the sheath and deploy the applicator head. This action results in relative rearward motion of the hypotube **120** and relative forward motion of the hypotube **122**. The relative motion between the hypotubes causes deflection in flexures **124**, **136** which deploys and tensions the electrode array **102***a*.

Measurement Device

The ablation device according to the second embodiment includes a measurement device for easily measuring the uterine width and for displaying the measured width on a gauge **146** (FIG. **21**). The measurement device utilizes non-conductive (e.g. nylon) suturing threads **148** that extend from the hypotube **122** and that have distal ends attached to the distal portion of the deflecting mechanism (FIG. **23**). As shown in FIG. **24**, threads **148** are preferably formed of a single strand **150** threaded through a wire loop **152** and folded over on itself. Wire loop **152** forms the distal end of an elongate wire **154** which may be formed of stainless steel or other wire.

Referring to FIG. **31**, wire **154** extends through the hypotube **122** and is secured to a rotatable bobbin **156**. The rotatable bobbin **156** includes a dial face **158** preferably covered in a clear plastic. As can be seen in FIG. **32***b*, dial face **158** includes calibration markings corresponding to an appropriate range of uterine widths. The bobbin is disposed within a gauge housing **160** and a corresponding marker line **162** is printed on the gauge housing. A torsion spring **164** provides rotational resistance to the bobbin **156**.

Expansion of the applicator head **102** during use pulls threads **148** (FIG. **23**) and thus wire **154** (FIG. **24**) in a distal direction. Wire **154** pulls against the bobbin **156** (FIG. **31**), causing it to rotate. Rotation of the bobbin positions one of the calibration markings on dial face **158** into alignment with the marker line **162** (FIG. **32**B) to indicate the distance between the distal tips of flexures **124** and thus the uterine width.

The uterine width and length (as determined using a conventional sound or other means) are preferably input into an RF generator system and used by the system to calculate an appropriate ablation power as will be described below. Alternately, the width as measured by the apparatus of the invention and length as measured by other means may be used by the user to calculate the power to be supplied to the array to achieve the desired ablation depth.

The uterine width may alternatively be measured using other means, including by using a strain gauge in combination with an A/D converter to transduce the separation distance of the flexures **124** and to electronically transmit the uterine width to the RF generator.

Control of Ablation Depth

The most optimal electrocoagulation occurs when relatively deep ablation is carried out in the regions of the uterus at which the endometrium is thickest, and when relatively shallower ablation is carried out in areas in which the endometrium is shallower. A desirable range of ablation depths includes approximately 2-3 mm for the cervical os and the cornual regions, and approximately 7-8 mm in the main body of the uterus where the endometrium is substantially thicker.

As discussed with respect to the first embodiment, a number of factors influence the ablation depth that can be achieved using a given power applied to a bipolar electrode array. These include the power supplied by the RF generator, the distance between the centers of adjacent electrodes ("center-to-center distance"), the electrode density (i.e., the porosity of the array fabric or the percent of the array surface that is metallic), the edge gap (i.e. the distance between the edges of adjacent electrode poles), and the electrode surface area. Other factors include blood flow (which in slower-ablating systems can dissipate the RF) and the impedance limit.

Certain of these factors may be utilized in the present invention to control ablation depth and to provide deeper ablation at areas requiring deeper ablation and to provide shallower regions in areas where deep ablation is not needed. For example, as center-to-center distance increases, the depth of ablation increases until a point where the center to center distance is so great that the strength of the RF field is too diffuse to excite the tissue. It can been seen with reference to FIG. **33** that the center to center distance d**1** between the electrodes **118***a*, **118***b* is larger within the region of the array that lies in the main body of the uterus and thus contributes to deeper ablation. The center to center distance d**2** between electrodes **118***a*, **118***b* is smaller towards the cervical canal where it contributes to shallower ablation. At the distal end of the device, the shorter center to center distances d**3** extend between top and bottom electrodes **118***b*, **118***c* and **118***a*, **118***d* and again contribute to shallower ablation.

Naturally, because the array **102***a* expands to accommodate the size of the uterus in which it is deployed, the dimensions of the array **102***a* vary. One embodiment of the array **102***a* includes a range of widths of at least approximately 2.5-4.5 cm, a range of lengths of at least approximately 4-6 cm, and a density of approximately 35%-45%.

The power supplied to the array by the RF generator is calculated by the RF generator system to accommodate the electrode area required for a particular patient. As discussed above, the uterine width is measured by the applicator head **102** and displayed on gauge **146**. The uterine length is measured using a sound, which is an instrument conventionally used for that purpose. It should be noted that calibration markings of the type used on a conventional sound device, or other structure for length measurement, may be included on the present invention to allow it to be used for length measurement as well.

The user enters the measured dimensions into the RF generator system using an input device, and the RF generator system calculates or obtains the appropriate set power from a stored look-up table using the uterine width and length as entered by the user. An EPROM within the RF generator system converts the length and width to a set power level according to the following relationship:

$$P=L\times W\times 5.5$$

Where P is the power level in watts, L is the length in centimeters, W is the width in centimeters, and 5.5 is a constant having units of watts per square centimeter.

Alternatively, the user may manually calculate the power setting from the length and width, or s/he may be provided with a table of suggested power settings for various electrode areas (as determined by the measured length and width) and will manually set the power on the RF generator accordingly.

Handle

Referring again to FIGS. **21** and **22**, the handle **106** of the RF ablation device according to the second embodiment includes a distal grip section **142** and a proximal grip section **144** that are pivotally attached to one another at pivot pin **166**.

The proximal grip section **144** is coupled to the hypotube **122** (FIG. **23**) via yoke **168**, overload spring **170** and spring stop **172**, each of which is shown in the section view of FIG. **34**. The distal grip section **142** is coupled to the external hypotube **120** via male and female couplers **174**, **176** (see FIGS. **32**A and **32**B). Squeezing the grip sections **142**, **144** towards one another thus causes relative movement between the external hypotube **120** and the internal hypotube **122**. This relative sliding movement results in deployment of the deflecting mechanism **102***b* from the distal end of the sheath and expansion of the array **102***a* to its expanded state.

Referring to FIGS. **32**A and B, rack **180** is formed on male coupler **174** and calibration markings **182** are printed adjacent the rack **180**. The calibration markings **182** correspond to a variety of uterine lengths and may include lengths ranging from, for example, 4.0 to 6.0 cm in 0.5 cm increments.

A sliding collar **184** is slidably disposed on the tubing **108** and is slidable over male coupler **174**. Sliding collar **184** includes a rotating collar **186** and a female coupler **176** that includes a wedge-shaped heel **188**. A locking spring member **190** (FIGS. **32**B and **35**) extends across an aperture **192** formed in the proximal grip **144** in alignment with the heel **188**. When the distal and proximal handle sections are squeezed together to deploy the array, the heel **188** passes into the aperture **192**. Its inclined lower surface gradually depresses the spring member **190** as the heel moves further into the aperture **192**. See FIGS. **36**A and **36**B. After passing completely over the spring member, the heel moves out of contact with the spring member. The spring member snaps upwardly thereby engaging the heel in the locked position. See FIG. **36**C.

A release lever **194** (FIG. **35**) is attached to the free end of the spring member **190**. To disengage the spring lock, release lever **194** is depressed to lower spring member **190** so that the inclined heel can pass over the spring member and thus out of the aperture **192**.

Referring again to FIGS. **32**A and **32**B, sliding collar **184** is configured to allow the user to limit longitudinal extension of the array **102***a* to a distance commensurate with a patient's predetermined uterine length. It does so by allowing the user to adjust the relative longitudinal position of male coupler **174** relative to the female coupler **176** using the rotating collar **186** to lock and unlock the female coupler from the rack **180** and the male coupler **174**. Locking the female coupler to the rack **180** and male coupler **174** will limit extension of the array to approximately the predetermined uterine length, as shown on the calibration markings **182**.

Once the uterine length has been measured using a conventional sound, the user positions sliding collar **184** adjacent to calibration marks **182** corresponding to the measured uterine length (e.g. 4.5 cm). Afterwards, the user rotates the collar section **186** to engage its internally positioned teeth with the

rack **180**. This locks the longitudinal position of the heel **188** such that it will engage with the spring member **190** on the proximal grip when the array has been exposed to the length set by the sliding collar.

The handle **106** includes a pair of spring assemblies which facilitate controlled deployment and stowage of the array **102***a*. One of the spring assemblies controls movement of the grips **142**, **144** to automatically stow the array **102***a* into the sheath **104** when the user stops squeezing the grips **142**, **144** towards one another. The other of the spring assemblies controls the transverse movement of the spring flexures **124** to the expanded condition by limiting the maximum load that can be applied to the deployment mechanism **102***b*.

FIG. **34** shows the distal and proximal grips **142** and **144** in partial cross-section. The first spring assembly for controlled stowage includes a handle return mandrel **196** that is slidably disposed within the proximal grip **144**. A compression spring **198** surrounds a portion of the return mandrel **196**, and a retaining ring **200** is attached to the mandrel **196** above the spring **198**. A spring stop **202** is disposed between the spring **198** and the retaining ring.

The lowermost end of the return mandrel **196** is pivotally engaged by a coupling member **204** on distal grip **142**. Relative movement of the grips **142**, **144** towards one another causes the coupling member **204** to pull the return member downwardly with the proximal grip **144** as indicated by arrows. Downward movement of the mandrel **196** causes its retaining ring **200** and spring stop **202** to bear downwardly against the compression spring **198**, thereby providing a movement which acts to rotate the grips **142**, **144** away from one another. When tension against the grips **142**, **144** is released (assuming that heel **188** is not locked into engagement with spring member **190**) the grips rotate apart into the opened position as the compression spring **198** returns to the initial state, stowing the applicator head inside the sheath.

The second spring assembly for controlling array deployment is designed to control separation of the flexures. It includes a frame member **178** disposed over yoke **168**, which is pivotally attached to proximal grip **144**. Tubing **108** extends from the array **102***a* (see FIG. **23**), through the sheath **104** and is fixed at its proximal end to the frame member **178**. Hypotube **122** does not terminate at this point but instead extends beyond the proximal end of tubing **108** and through a window **206** in the frame member. Its proximal end **208** is slidably located within frame member **178** proximally of the window **206** and is fluidly coupled to a vacuum port **210** by fluid channel **212**. Hypotube **120** terminates within the frame. Its proximal end is fixed within the distal end of the frame.

A spring stop **172** is fixed to a section of the hypotube within the window **206**, and a compression spring **170** is disposed around the hypotube between the spring stop **172** and yoke **168**. See FIGS. **32**B and **34**.

When the distal and proximal grips are moved towards one another, the relative rearward motion of the distal grip causes the distal grip to withdraw the sheath **104** from the array **102***a*. Referring to FIGS. **37**A and **37**B, this motion continues until female coupler **176** contacts and bears against frame member **178**. Continued motion between the grips causes a relative rearward motion in the frame which causes the same rearward relative motion in external hypotube **120**. An opposing force is developed in yoke **168**, which causes a relative forward motion in hypotube **122**. The relative motion between the hypotubes causes deflection in flexures **124**, **136** which deflect in a manner that deploys and tensions the electrode array. Compression spring **170** acts to limit the force developed by the operator against hypotubes **120**, **122**, thus limiting the force of flexures **124**, **136** acting on the array and the target tissue surrounding the array.

Referring to FIG. **21**, collar **214** is slidably mounted on sheath **104**. Before the device is inserted into the uterus, collar **214** can be positioned along sheath **104** to the position measured by the uterine sound. Once in position, the collar provides visual and tactile feedback to the user to assure the device has been inserted the proper distance. In addition, after the applicator head **102** has been deployed, if the patient's cervical canal diameter is larger than the sheath dimensions, the collar **214** can be moved distally towards the cervix, making contact with it and creating a pneumatic seal between the sheath and cervix.

Second Exemplary Embodiment—Operation

In preparation for ablating the uterus utilizing the second exemplary embodiment, the user measures the uterine length using a uterine sound device. The user next positions sliding collar **184** (FIG. **32**B) adjacent to calibration marks **182** corresponding to the measured uterine length (e.g. 4.5 cm) and rotates the collar section **186** to engage its internally positioned teeth with the rack **180**. This locks the longitudinal position of the heel **188** (FIG. **32**A) such that it will engage with the spring member **190** when the array has been exposed to the length set by the sliding collar.

Next, with the grips **142**, **144** in their resting positions to keep the applicator head **102** covered by sheath **104**, the distal end of the device **100** is inserted into the uterus. Once the distal end of the sheath **104** is within the uterus, grips **142**, **144** are squeezed together to deploy the applicator head **102** from sheath **104**. Grips **142**, **144** are squeezed until heel **188** engages with locking spring member **190** as described with respect to FIGS. **36**A through **36**C.

At this point, deflecting mechanism **102***b* has deployed the array **102***a* into contact with the uterine walls. The user reads the uterine width, which as described above is transduced from the separation of the spring flexures, from gauge **146**. The measured length and width are entered into the RF generator system **250** (FIG. **21**) and used to calculate the ablation power.

Vacuum source **252** (FIG. **21**) is activated, causing application of suction to hypotube **122** via suction port **210**. Suction helps to draw uterine tissue into contact with the array **102**.

Ablation power is supplied to the electrode array **102***a* by the RF generator system **250**. The tissue is heated as the RF energy passes from electrodes **118***a-d* to the tissue, causing moisture to be released from the tissue. The vacuum source **252** helps to draw moisture from the uterine cavity into the hypotube **122**. Moisture withdrawal is facilitated by the apertures **126** formed in flexures **124** by preventing moisture from being trapped between the flexures **124** and the lateral walls of the uterus.

If the RF generator **250** includes an impedance monitoring module, impedance may be monitored at the electrodes **118***a-d* and the generator may be programmed to terminate RF delivery automatically once the impedance rises to a certain level. The generator system may also or alternatively display the measured impedance and allow the user to terminate RF delivery when desired.

When RF delivery is terminated, the user depresses release lever **194** to disengage heel **188** from locking spring member **190** and to thereby allow grips **142**, **144** to move to their expanded (resting) condition. Release of grips **142**, **144** causes applicator head **102** to retract to its unexpanded condition and further causes applicator head **102** to be withdrawn into the sheath **104**. Finally, the distal end of the device **100** is withdrawn from the uterus.

Two embodiments of ablation devices in accordance with the present invention have been described herein. These embodiments have been shown for illustrative purposes only. It should be understood, however, that the invention is not intended to be limited to the specifics of the illustrated embodiments but is defined only in terms of the following claims.

We claim:

1. A device for treating a uterus comprising:

an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;

an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;

a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a distal grip pivotally attached to one another at a pivot point and operably coupled to the applicator head so that when the proximal grip and the distal grip are moved closer together, the applicator head transitions from the contracted state to the expanded state;

a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state; and

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

2. The device of claim **1** further comprising a transverse ribbon coupled to a distal end of the first and second external flexures, wherein the transverse ribbon is in a relaxed condition when the applicator head is in the expanded state.

3. The device of claim **1** wherein the first internal flexure includes a plurality of longitudinally spaced apertures.

4. The device of claim **1** wherein the proximal grip is coupled to the inner sleeve and the distal grip is coupled to the outer sleeve.

5. The device of claim **1** further comprising an introducer sheath, wherein the inner sleeve and the outer sleeve are disposed within the introducer sheath when the applicator head is in the contracted state, and wherein the distal grip is coupled to the introducer sheath so that proximal movement of the distal grip causes the introducer sheath to move proximally relative to the applicator head.

6. The device of claim **5**, wherein continued movement of the proximal grip and distal grip closer together causes relative movement between the inner sleeve and the outer sleeve.

7. The device of claim **1** wherein when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator.

8. The device of claim **1** further comprising an adjustable locking mechanism configured to limit a degree of expansion of the applicator head.

9. The device of claim **1** further comprising an adjustable locking mechanism configured to limit a distance by which a user can move the proximal grip and the distal grip closer together.

10. The device of claim **1** wherein the first and second external flexures each have a distal end, and wherein the first and second internal flexures are coupled to the first and second external flexures at a location proximal to the distal ends of the first and second external flexures.

11. A device for treating a uterus comprising:

an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve:

a handle coupled to the proximal portion;

an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;

a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating one of the inner and outer sleeves relative to the other causes the applicator head to transition from the contracted state to the expanded state;

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus; and

wherein when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator.

12. The device of claim **1** wherein the applicator head is configured to expand until limited by the dimension of the uterus.

13. The device of claim **11** wherein the first internal flexure includes a plurality of longitudinally spaced apertures.

14. The device of claim **11** further comprising an adjustable locking mechanism configured to limit a degree of expansion of the applicator head.

15. The device of claim **11** wherein the first and second external flexures each have a distal end, and wherein the first and second internal flexures are coupled to the first and second external flexures at a location proximal to the distal ends of the first and second external flexures.

* * * * *

LIMBACH & LIMBACH L.L.P.
2001 F rry Building, San Francisco, CA 94111
415/433-4150

Address to:
Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Attorney's Docket No. ENVS-220
First Named Inventor Csaba Truckai

UTILITY PATENT APPLICATION TRANSMITTAL
(under 37 CFR 1.53(b))

THIS APPLICATION CLAIMS THE BENEFIT OF U.S. PROVISIONAL APPLICATION NO. 60/084,791, FILED MAY 8, 1998, AND IS A CONTINUATION-IN-PART OF COPENDING U.S. APPLICATION NO. 08/632,516, FILED APRIL 12, 1996, NOW U.S. PATENT NO. 5,769,880, ISSUED JUNE 23, 1998.

Transmitted herewith for filing is a **CONTINUATION-IN-PART** patent application entitled:

A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

CERTIFICATION UNDER 37 CFR § 1.10

I hereby certify that this New Application and the documents referred to as enclosed herein are being deposited with the United States Postal Service on this date June 23, 1998, in an envelope bearing "Express Mail Post Office To Addressee" Mailing Label Number EM503277278US addressed to: Box Patent Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

ELIZABETH A. REICKER Elizabeth A. Reicker
(Name of person mailing paper) (Signature)

Enclosed are:

1. X Transmittal Form (two copies required)

2. The papers required for filing date under CFR § 1.53(b):
   i. 49 Pages of specification (including claims and abstract);
   ii. 19 Sheets of drawings.
   __ formal X informal

3. Declaration or oath

   a. X Unsigned Declaration (original or copy)

   b. _ Copy from a prior application (37 CFR 1.63(d))
   (for continuation/divisional with Item 12 completed)

   _____ Incorporation By Reference (to be used if Item 3b is checked)

   The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Item 3b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

   i. __ DELETION OF INVENTOR(S)
   Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b)

4. __ Microfiche Computer Program (Appendix, see 37 CFR 1.96)

5. __ Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
   i. __ Computer Readable Copy
   ii. __ Paper Copy (identical to computer copy)
   iii. __ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

6. __ An assignment of the invention to is attached (including Form PTO-1595).

__ The prior application is assign d of record to ;
Assignment recorded in PTO on _, Reel _, Frame(s) _.
__ The prior application is assigned, and the assignment (copy attached) was submitted to PTO for recording on _.
i. __ 37 CFR 3.73(b) Statement (when there is an assignee)

7. __ Power of Attorney

8. __ An Information Disclosure Statement (IDS) is enclosed, including a PTO-1449 and copies of __ references.

9. __ Preliminary Amendment.

10. X Return Receipt Postcard (MPEP 503 -- should be specifically itemized)

11. __ Other

12. If a **CONTINUING APPLICATION**, ***check appropriate box and supply the requisite information***

__ Continuation
__ Divisional
X Continuation-In-Part (CIP)

of immediately prior application no. 08/632,516, filed April 12, 1996, now Patent No. 5,769,880, issued June 23, 1998 and claims benefit of U.S. Provisional Application No. 60/084,791, filed May 8, 1998.

i. RELATE BACK - 35 USC 120: If one of the above boxes are checked, please amend the specification by inserting before the first line the sentence: --This is a continuation-in-part of Application no. 08/632,516, filed April 12, 1996, now Patent No. 5,769,880, issued June 23, 1998 and claims benefit of U.S. Provisional Application No. 60/084,791, filed May 8, 1998.--

ii. MAINTENANCE OF COPENDENCY OF PRIOR APPLICATION
(This item must be completed and the necessary papers filed in the prior application if the period set in the prior application has run).
[] A petition, fee and response has been filed to extend the term in the pending prior application until _.
[] A copy of the petition for extension of time in the prior application is attached.

iii. CONDITIONAL PETITIONS FOR EXTENSION OF TIME IN PRIOR APPLICATION
(Complete this item and file conditional petition in prior application if previous item (ii) not applicable).
[] A conditional petition for extension of time is being filed in the pending prior application.
[] A copy of the conditional petition for extension of time in the prior application is attached.

13. FOREIGN PRIORITY
[] Priority of application no. _ filed on _ in _ is claimed under 35 USC 119.

The certified copy of the priority application:
_ is filed herewith; or
_ has been filed in prior application no. _ filed on _, or
_ will be provided.

__ English Translation Document (if applicable)

14. **FEE CALCULATION**

a. __ Amendment changing number of claims or deleting multiple dependencies is enclosed.

b. __ Cancel in this application original Claims _ of the prior application before calculating the filing fee.

CLAIMS AS FILED

	Number Filed	Number Extra	Rate	Basic Fee ($790)
Total Claims	31 - 20	* 11	x $22.00	$242.00
Independent Claims	3 - 3	* -0-	x $82.00	-0-
__ Multiple dependent claim(s), if any			$270.00	-0-

*If less than zero, enter "0".

Filing Fee Calculation $1032.00

50% Filing Fee Reduction (if applicable) $516.00

15. Small Entity Status
a. X A small entity statement is enclosed. (unsigned)
b. __ A small entity statement was filed in the prior nonprovisional application and such status is still proper and desired.
c. __ is no longer claimed.

16. Other Fees
__ Recording Assignment [$40.00] . . . . . $
__ Other fees
Specify _____ . . . . . $

Total Fees Enclosed . . . . . $

17. Payment of Fees
__ Check(s) in the amount of $__ enclosed.
__ Charge Account No. 12-1420 in the amount of $__.
A duplicate of this transmittal is attached.

18. All correspondence regarding this application should be forwarded to the undersigned attorney:

Kathleen A. Frost
Limbach & Limbach L.L.P.
2001 Ferry Building
San Francisco, CA 94111
Telephone: 415/433-4150
Facsimile: 415/433-8716

19. Authorization to Charge Additional Fees

X The Commissioner is hereby authorized to charge any additional fees (or credit any overpayment) associated with this communication and which may be required under 37 CFR § 1.16 or § 1.17 to Account No. 12-1420. A duplicate of this transmittal is attached.

LIMBACH & LIMBACH L.L.P.

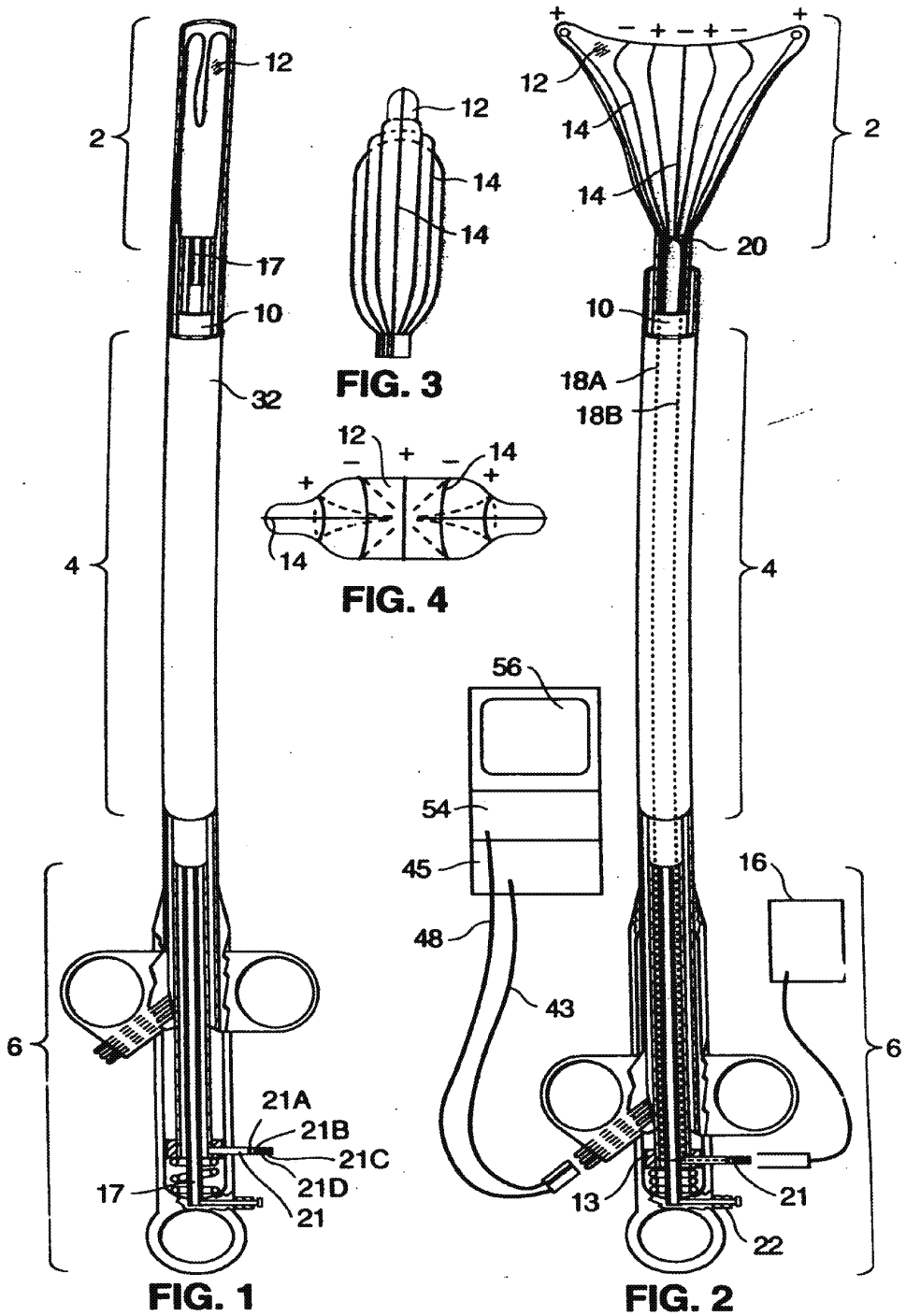
June 23, 1998
(Date)

By: Kathleen A Frost
Kathleen A. Frost
Registration No. 37,326
Attorney(s) or Agent(s) of Record

Attorney Docket No. ENVS-220
[]

PATENTS\APP-TRAN.MRG
Rev. 01/05/98

HOL-MIN_146826



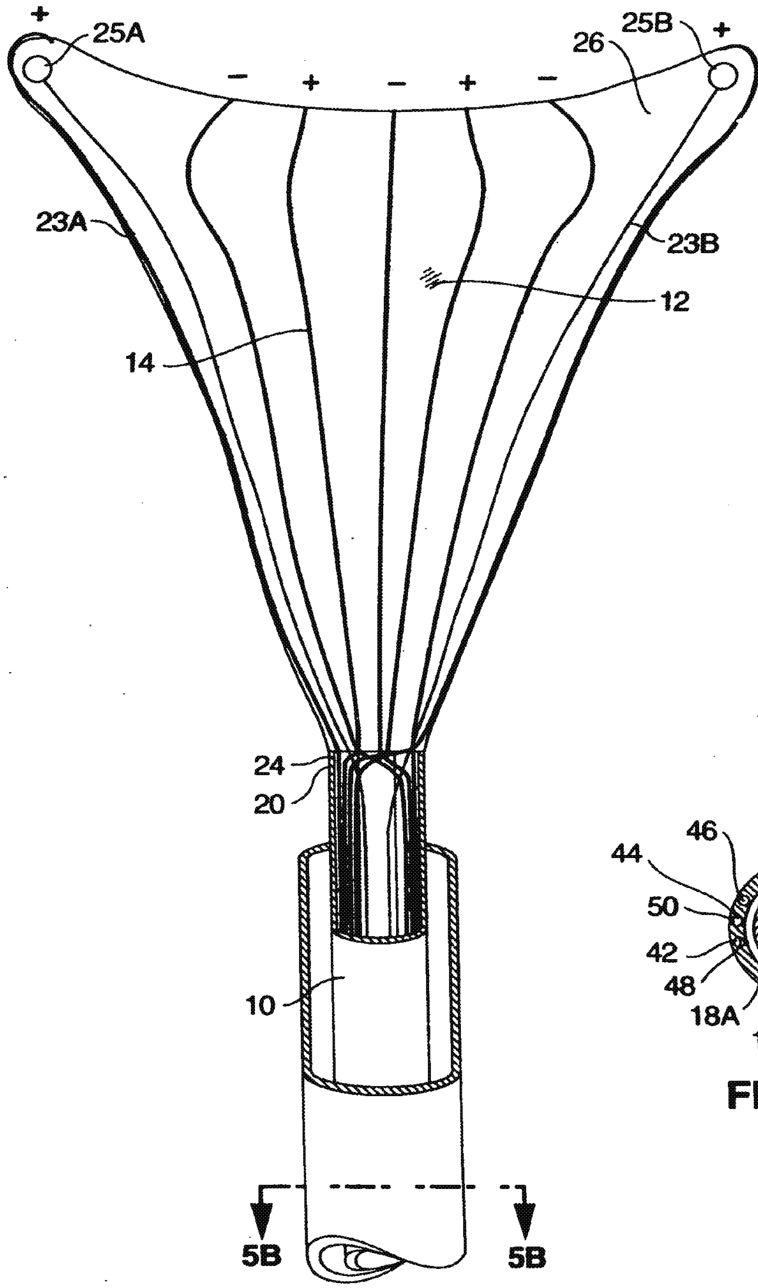


FIG. 5A

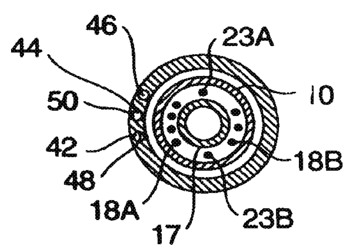


FIG. 5B

HOL-MIN_146828

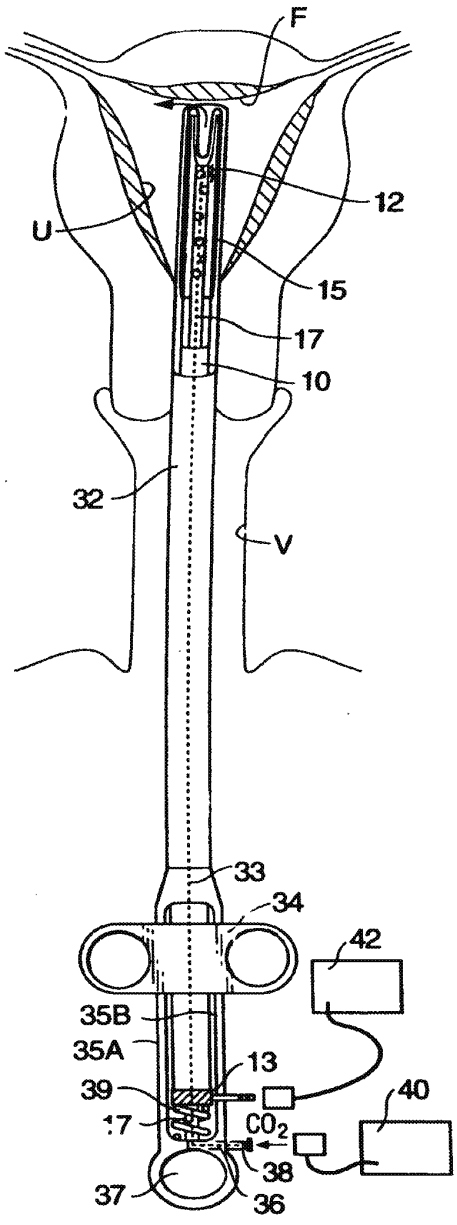

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FIG. 6

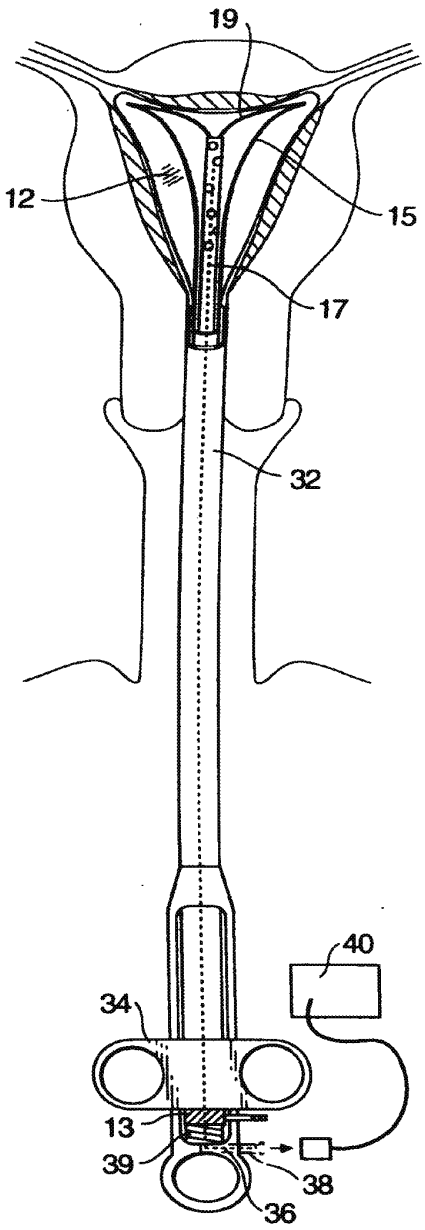
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FIG. 7

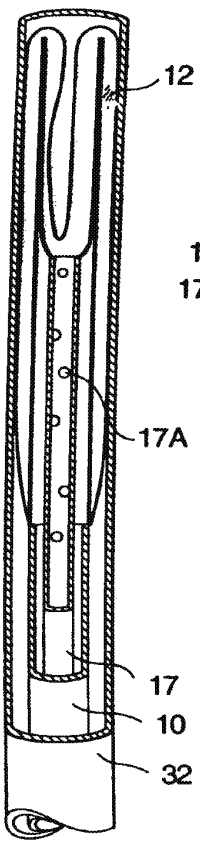

FIG. 8

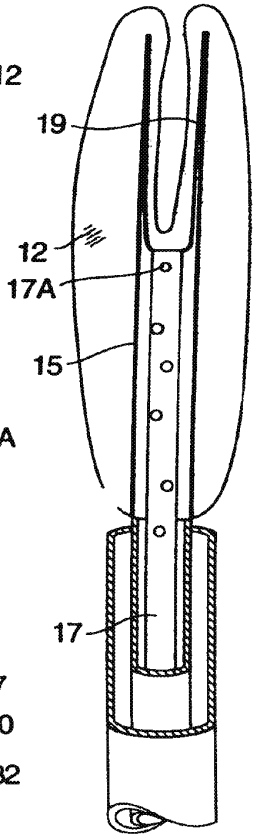

FIG. 9

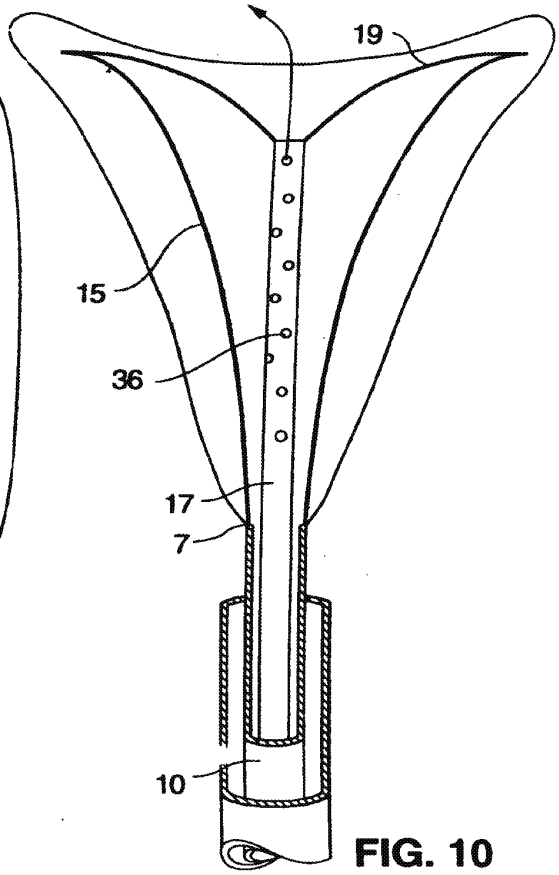

FIG. 10

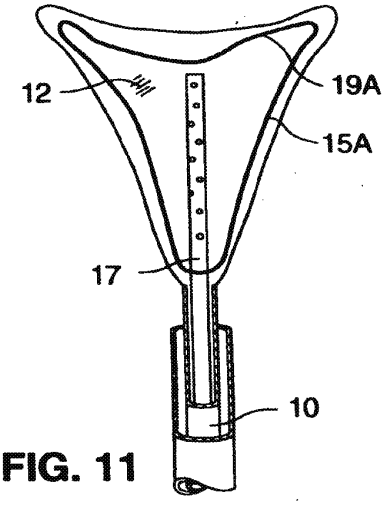

FIG. 11

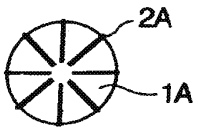

FIG. 13

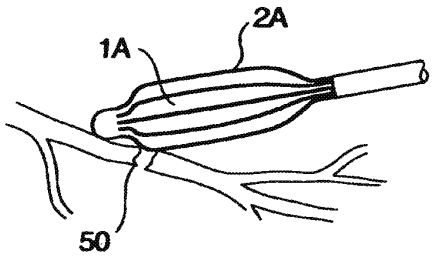

FIG. 14

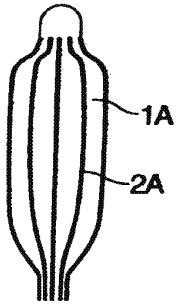

FIG. 12

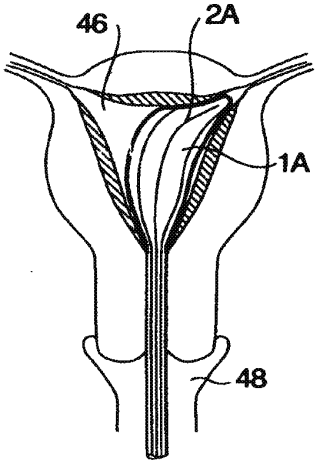

FIG. 15

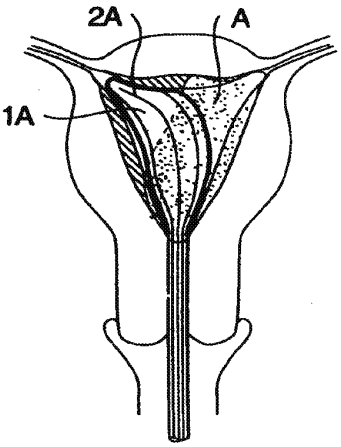

FIG. 16

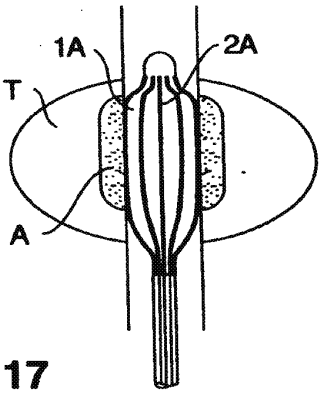

FIG. 17

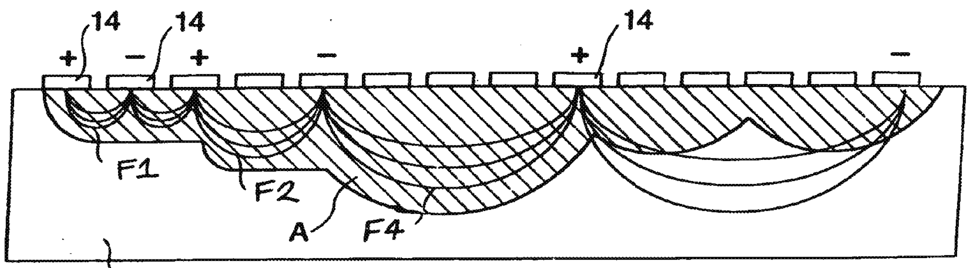

FIG. 18

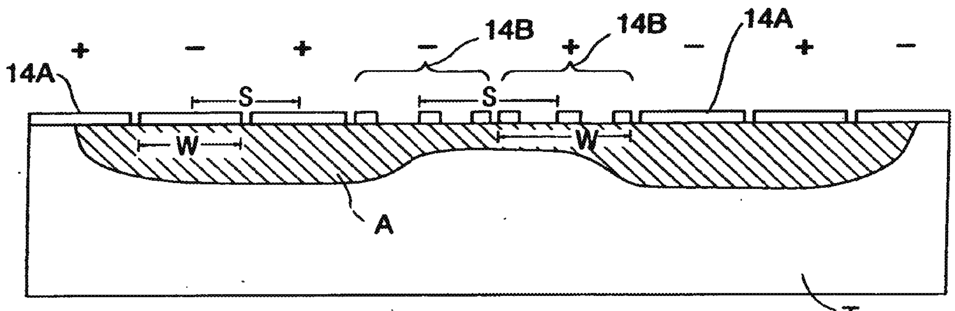

FIG. 19A

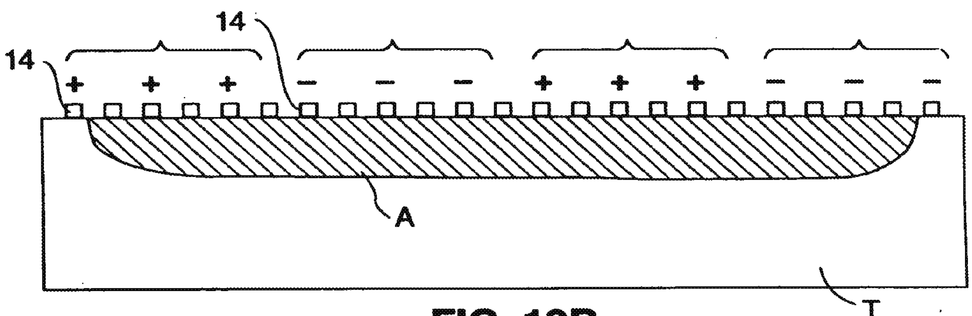

FIG. 19B

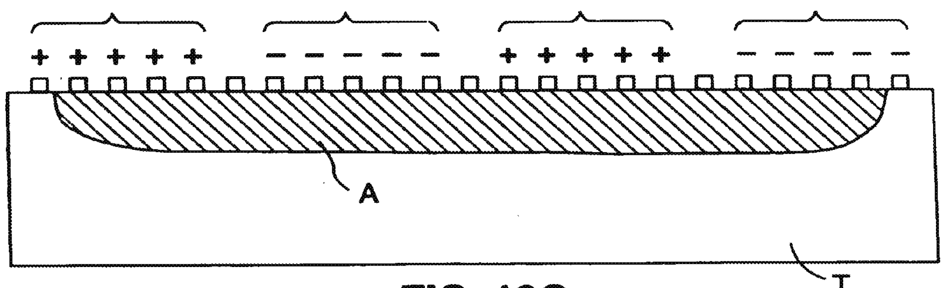

FIG. 19C

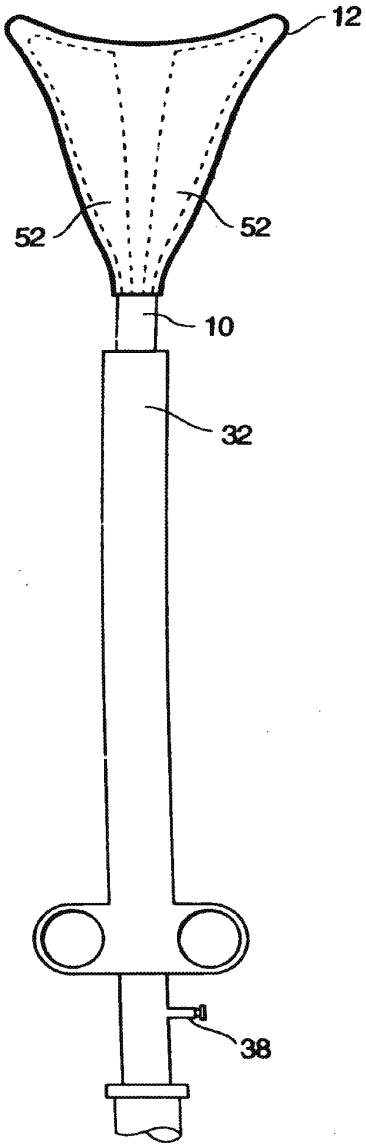

FIG. 20

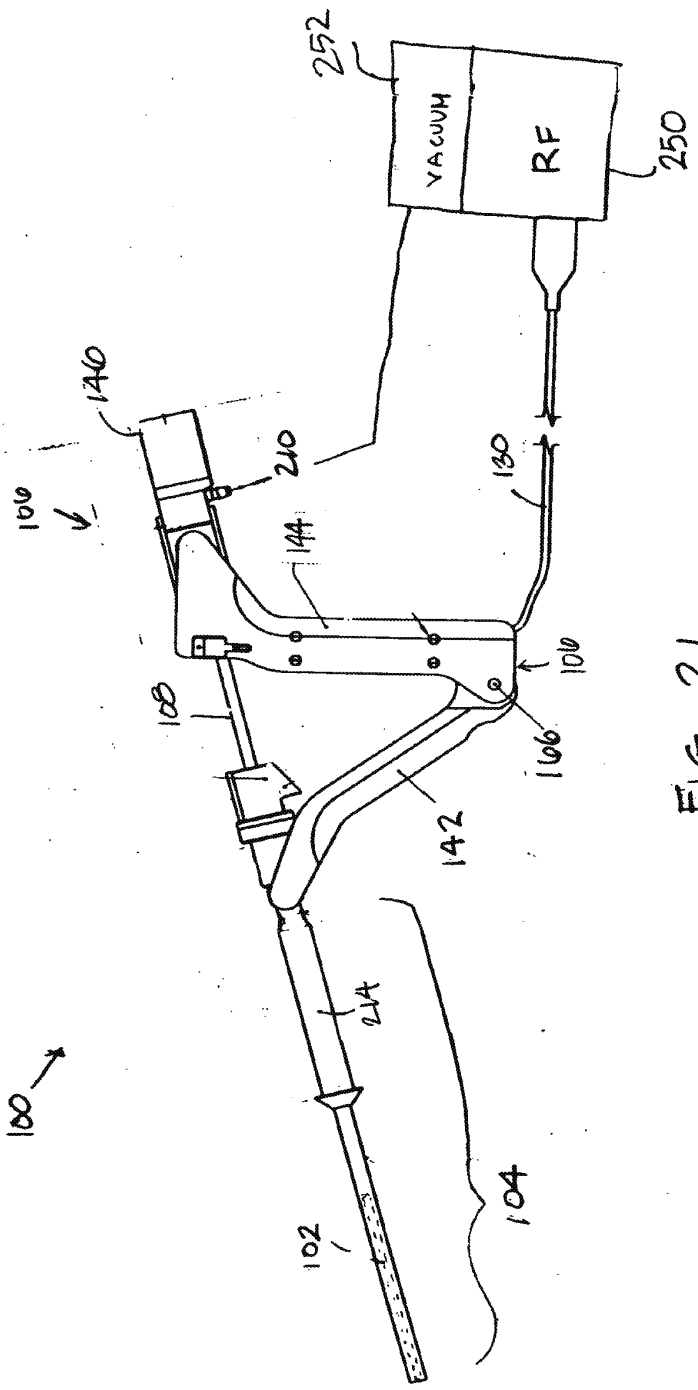

FIG. 21

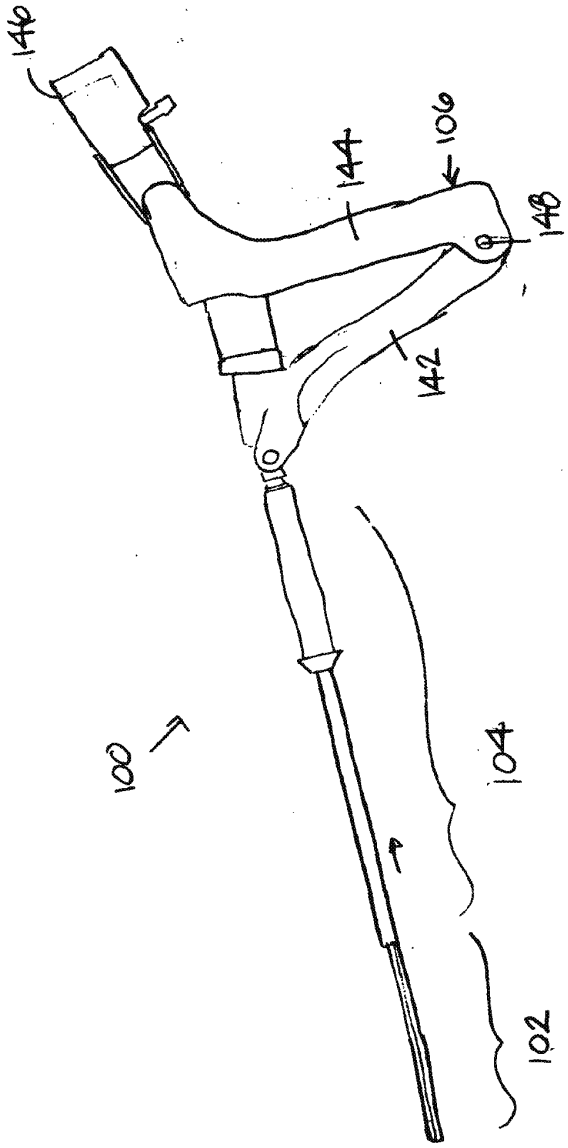

FIG. 22

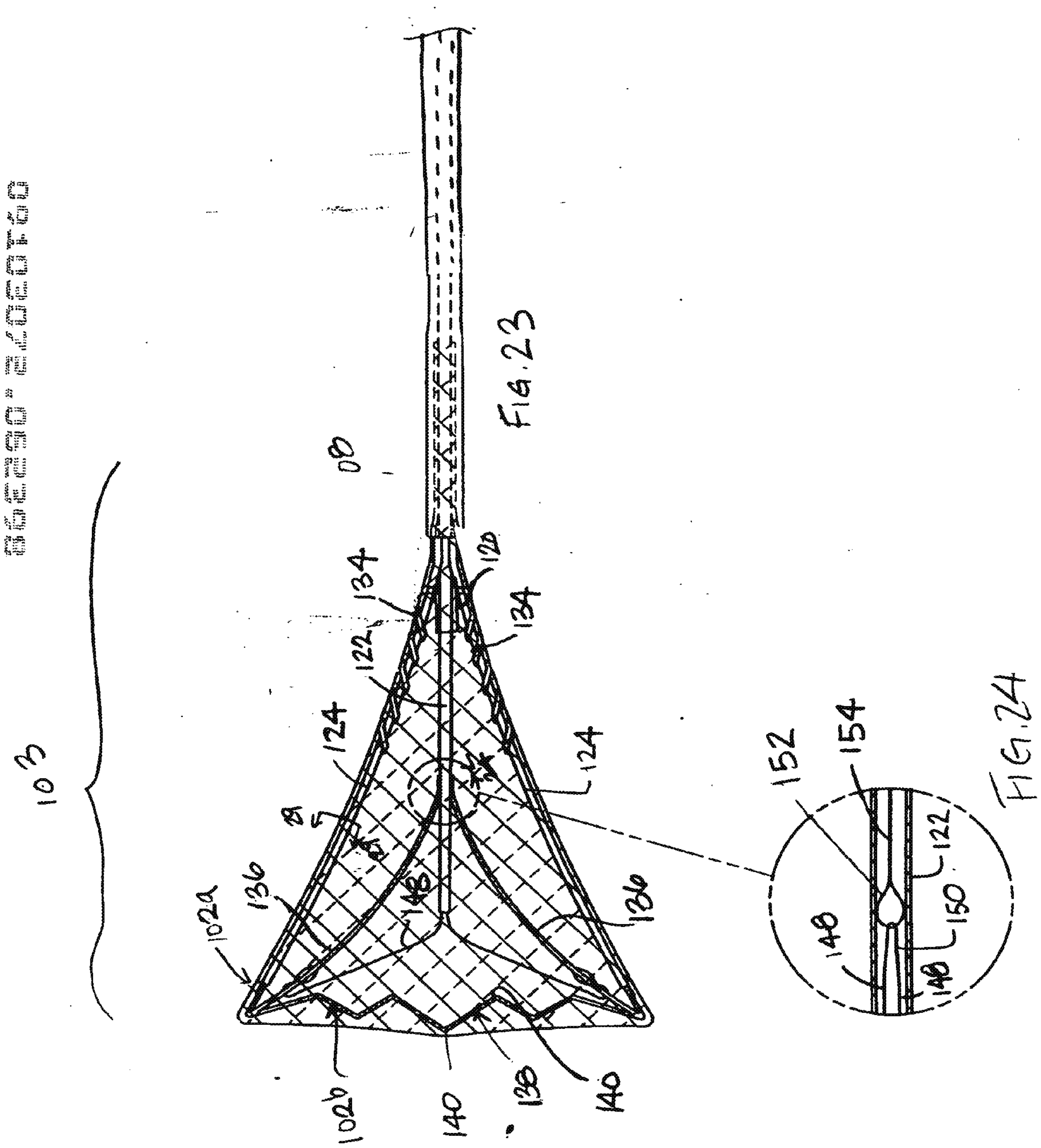

FIG. 23

FIG. 24

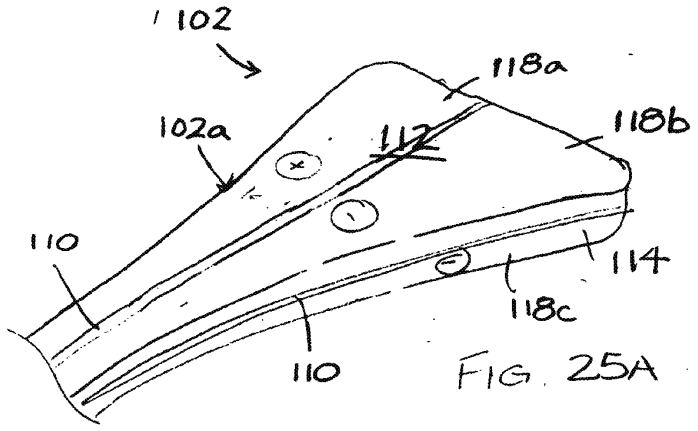

FIG. 25A

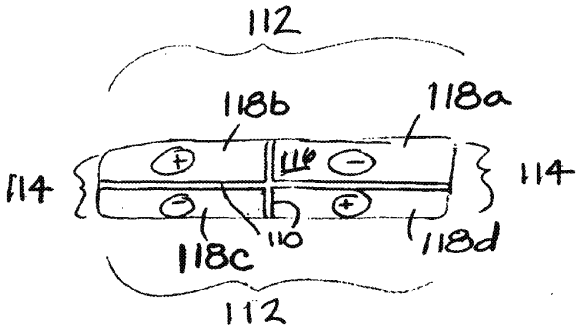

FIG 25B

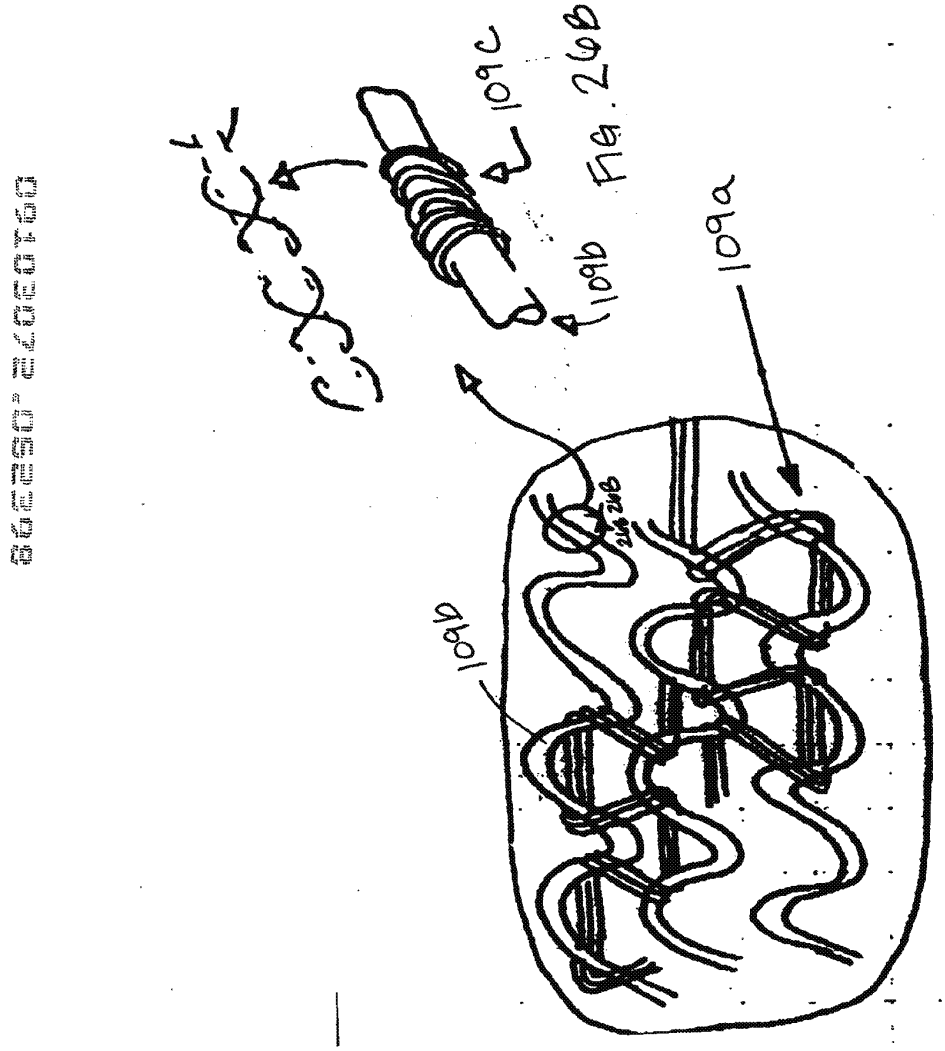

Fig. 26B

Fig. 26A

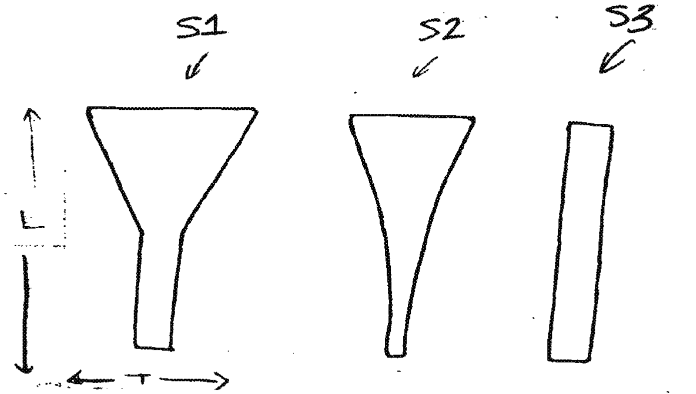

FIG. 27A FIG. 27B FIG. 27C

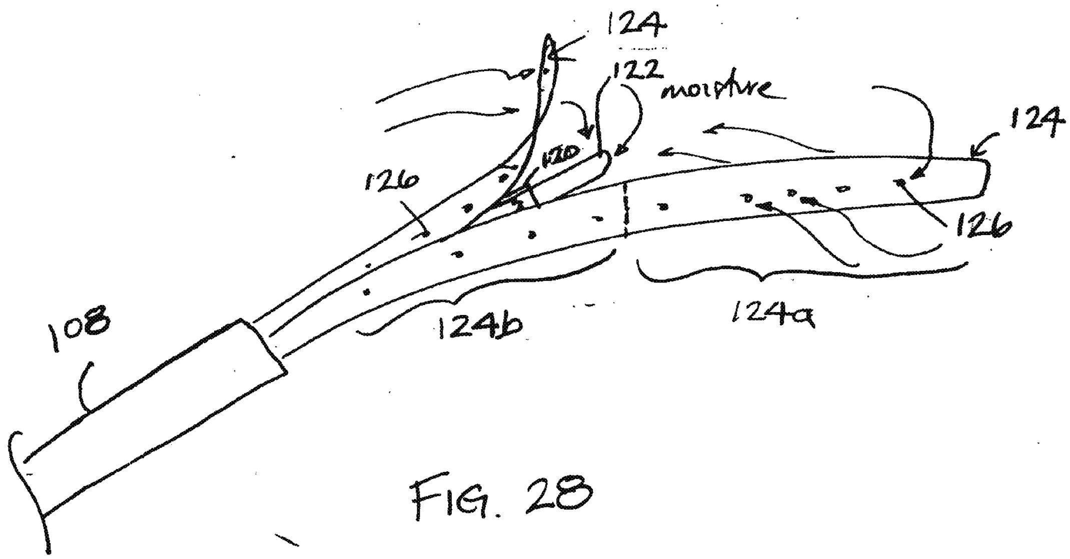

FIG. 28

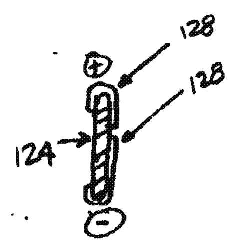

FIG 29

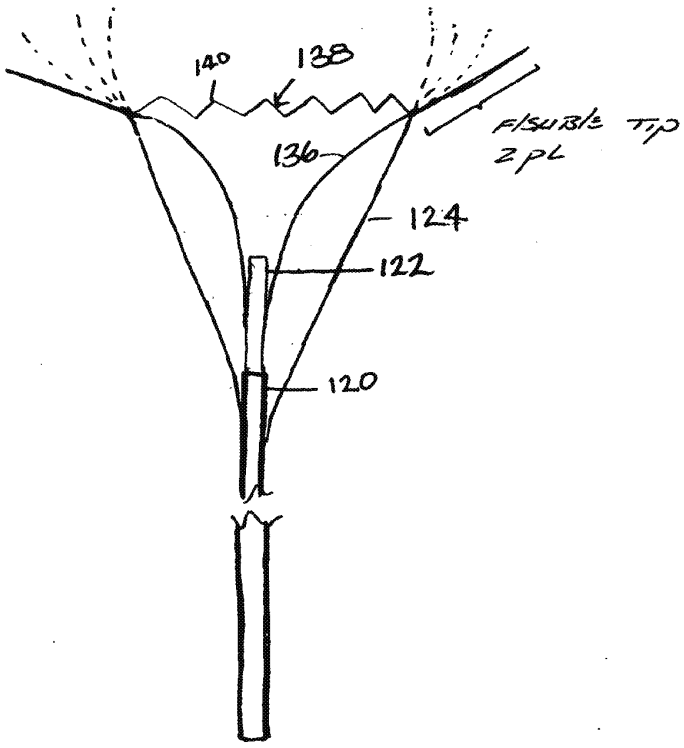

FIG. 30

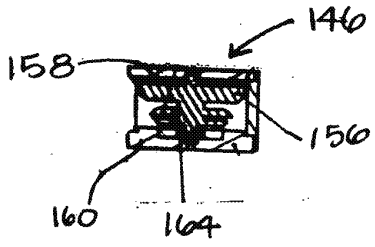

FIG. 31

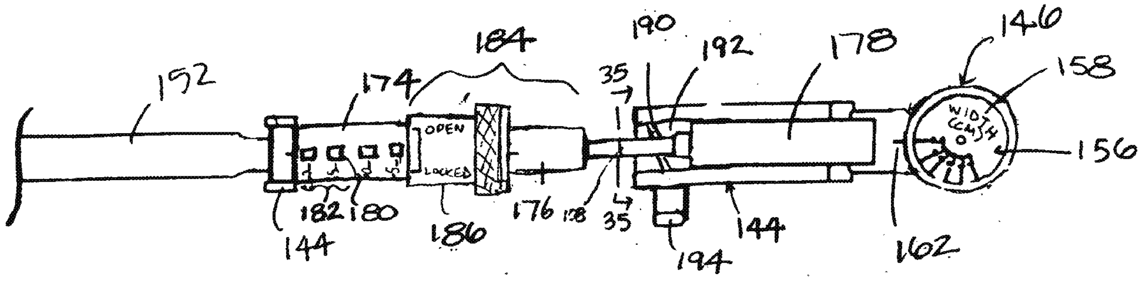

FIG. 32B

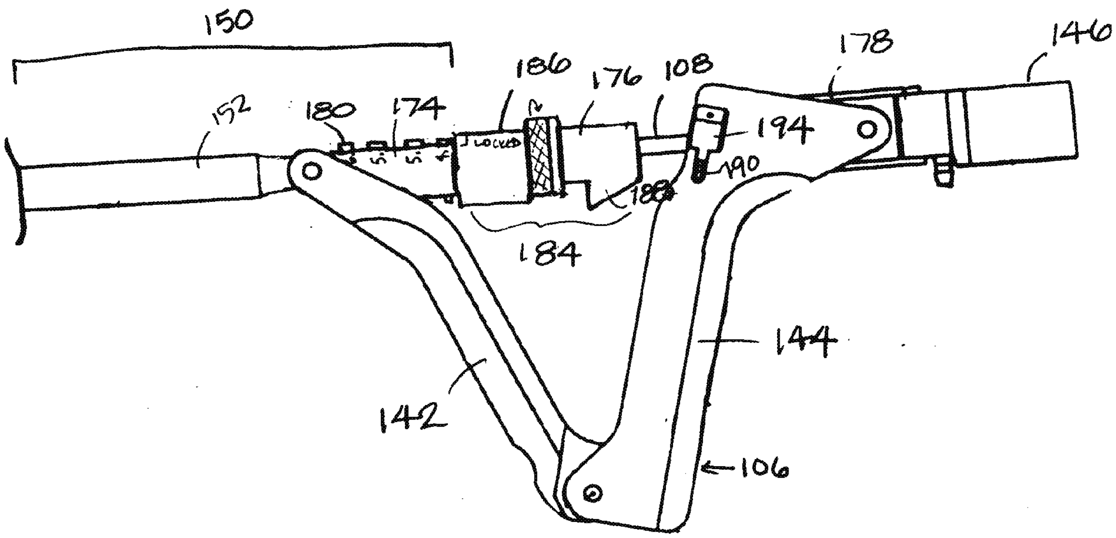

FIG. 32A

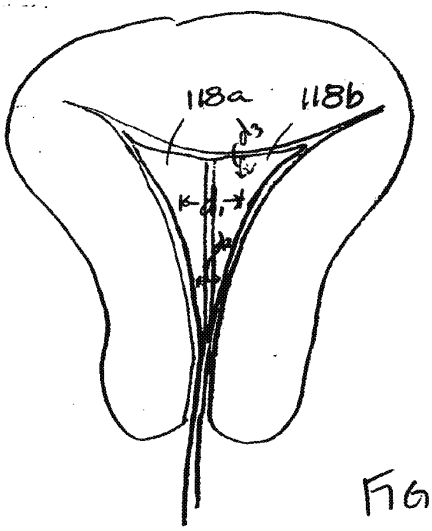

FIG 33

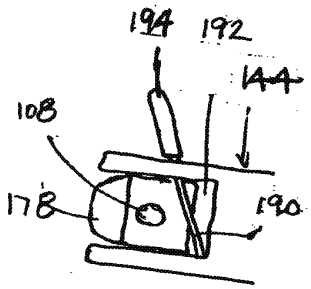

FIG. 35

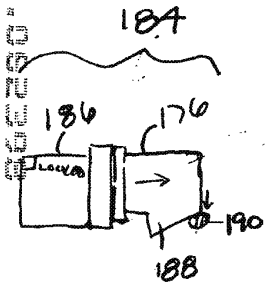

FIG 36A

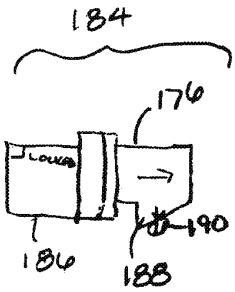

FIG 36B

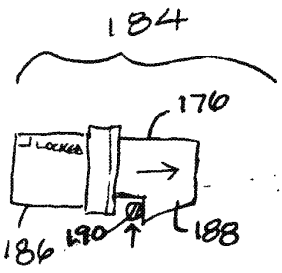

FIG 36C

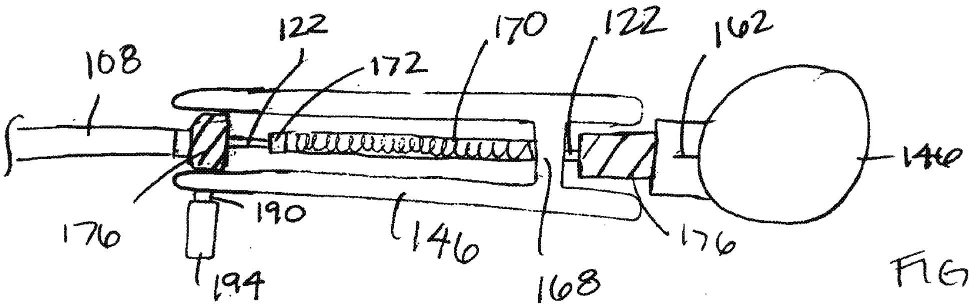

FIG. 37A

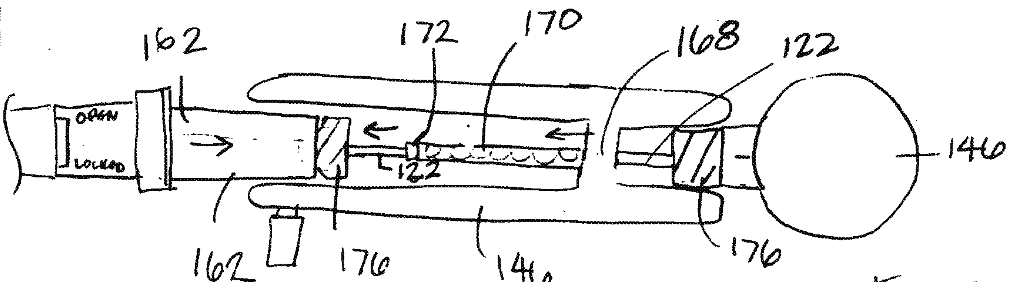

FIG. 37B

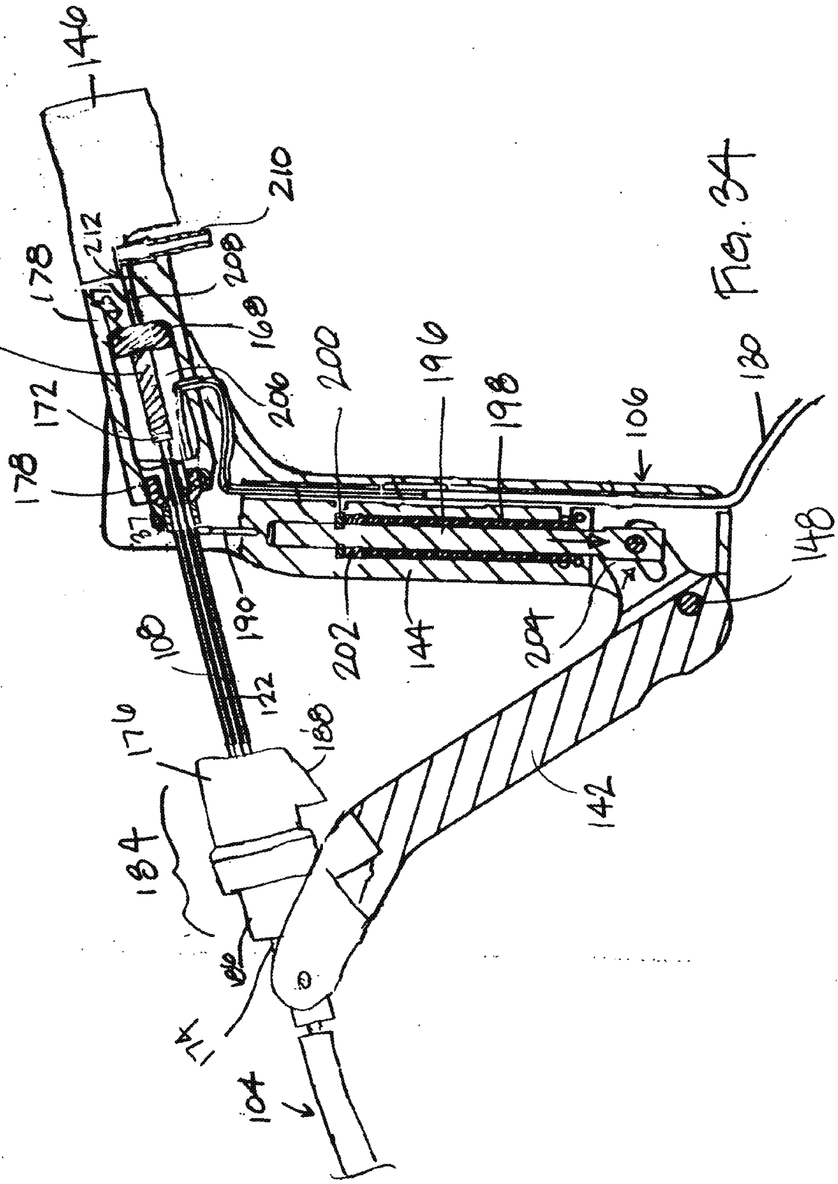
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FIG. 34

PATENT APPLICATION
Express Mailing Label: EM503277278US

A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

Related Applications

This application claims the benefit of U.S. Provisional Application No. 60/084,791, filed May 8, 1998, and is a Continuation in Part of copending U.S. Application No. 08/632,516, filed April 12, 1996, now U.S. Patent No. 5,769,880, issued June 23, 1998.

Field of the Invention

The present invention relates generally to the field of apparatuses and methods for ablating or coagulating the interior surfaces of body organs. Specifically, it relates to an apparatus and method for ablating the interior linings of body organs such as the uterus and gallbladder.

Background of the Invention

Ablation of the interior lining of a body organ is a procedure which involves heating the organ lining to temperatures which destroy the cells of the lining or coagulate tissue proteins for hemostasis. Such a procedure may be performed as a treatment to one of many conditions, such as chronic bleeding of the endometrial layer of the uterus or abnormalities of the mucosal layer of the gallbladder. Existing methods for effecting ablation include circulation of heated fluid inside the organ (either directly or inside a

balloon), laser treatment of the organ lining, and resistive heating using application of RF energy to the tissue to be ablated.

U.S. Patent 5,084,044 describes an apparatus for endometrial ablation in which a bladder is inserted into the uterus. Heated fluid is then circulated through the balloon to expand the balloon into contact with the endometrium and to ablate the endometrium thermally. U.S. Patent 5,443,470 describes an apparatus for endometrial ablation in which an expandable bladder is provided with electrodes on its outer surface. After the apparatus is positioned inside the uterus, a non-conductive gas or liquid is used to fill the balloon, causing the balloon to push the electrodes into contact with the endometrial surface. RF energy is supplied to the electrodes to ablate the endometrial tissue using resistive heating.

These ablation devices are satisfactory for carrying out ablation procedures. However, because no data or feedback is available to guide the physician as to how deep the tissue ablation has progressed, controlling the ablation depth and ablation profile with such devices can only
be done by assumption.

For example, the heated fluid method is a very passive and ineffective heating process which relies on the heat conductivity of the tissue. This process does not account for variations in factors such as the amount of contact between the balloon and the underlying tissue, or cooling effects such as those of blood circulating through the organ. RF ablation techniques can achieve more effective ablation since it relies on active heating of the tissue using RF energy, but presently the depth of ablation using RF

techniques can only be estimated by the physician since no feedback can be provided as to actual ablation depth.

Both the heated fluid techniques and the latest RF techniques must be performed using great care to prevent over ablation. Monitoring of tissue surface temperature is normally carried out during these ablation procedures to ensure the temperature does not exceed 100° C. If the temperature exceeds 100° C, the fluid within the tissue begins to boil and to thereby produce steam. Because ablation is carried out within a closed cavity within the body, the steam cannot escape and may instead force itself deeply into the tissue, or it may pass into areas adjacent to the area intended to be ablated, causing embolism or unintended burning.

Moreover, in prior art RF devices the water drawn from the tissue creates a path of conductivity through which current traveling through the electrodes will flow. This can prevent the current from traveling into the tissue to be ablated. Moreover, the presence of this current path around the electrodes causes current to be continuously drawn from the electrodes. The current heats the liquid drawn from the tissue and thus turns the ablation process into a passive heating method in which the heated liquid around the electrodes causes thermal ablation to continue well beyond the desired ablation depths.

Another problem with prior art ablation devices is that it is difficult for a physician to find out when ablation has been carried out to a desired depth within the tissue. Thus, it is often the case that too much or too little tissue may be ablated during an ablation procedure.

It is therefore desirable to provide an ablation device which eliminates the above-described problem of steam and liquid buildup at the ablation site. It is further desirable to provide an ablation method and device which allows the depth of ablation to be controlled and which automatically discontinues ablation once the desired ablation depth has been reached.

Summary Of The Invention

The present invention is an apparatus and method of ablating and/or coagulating tissue, such as that of the uterus or other organ. An ablation device is provided which has an electrode array carried by an elongate tubular member. The electrode array includes a fluid permeable elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon. During use, the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue to cause the tissue to dehydrate, and moisture generated during dehydration is actively or passively drawn into the array and away from the tissue.

Brief Description Of The Drawings

Fig. 1 is a front elevation view of a first embodiment of an ablation device according to the present invention, with the handle shown in cross-section and with the RF applicator head in a closed condition.

Fig. 2 is a front elevation view of the ablation device of Fig. 1, with the handle shown in cross-section and with the RF applicator head in an open condition.

Fig. 3 is a side elevation view of the ablation device of Fig. 2.

Fig. 4 is a top plan view of the ablation device of Fig. 2.

Fig. 5A is a front elevation view of the applicator head and a portion of the main body of the ablation device of Fig. 2, with the main body shown in cross-section.

Fig. 5B is a cross-section view of the main body taken along the plane designated 5B-5B in Fig. 5A.

Fig. 6 is a schematic representation of a uterus showing the ablation device of Fig. 1 following insertion of the device into the uterus but prior to retraction of the introducer sheath and activation of the spring members.

Fig. 7 is a schematic representation of a uterus showing the ablation device of Fig. 1 following insertion of the device into the uterus and following the retraction of the introducer sheath and the expansion of the RF applicator head.

Fig. 8 is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of Fig. 1, showing the RF applicator head in the closed condition.

Fig. 9 is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of Fig. 1, showing the configuration of RF applicator head after the sheath has been retracted but before the spring members have been released by proximal movement of the shaft.

Fig. 10 is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of Fig. 1, showing the configuration of RF applicator head after the sheath has been retracted and after the spring members have been released into the fully opened condition.

Fig. 11 is a cross-section view of a distal portion of an RF ablation device similar to Fig. 1 which utilizes an alternative spring member configuration for the RF applicator head.

Fig. 12 is a side elevation view of the distal end of an alternate embodiment of an RF ablation device similar to that of Fig. 1, which utilizes an RF applicator head having a modified shape.

Fig. 13 is a top plan view of the ablation device of Fig. 12.

Fig. 14 is a representation of a bleeding vessel illustrating use of the ablation device of Fig. 12 for general bleeding control.

Figs. 15 and 16 are representations of a uterus illustrating use of the ablation device of Fig. 12 for endometrial ablation.

Fig. 17 is a representation of a prostate gland illustrating use of the ablation device of Fig. 12 for prostate ablation.

Fig. 18 is a cross-section view of target tissue for ablation, showing ablation electrodes in contact with the tissue surface and illustrating energy fields generated during bi-polar ablation.

Figs. 19A - 19C are cross-section views of target tissue for ablation, showing electrodes in contact with the tissue surface and illustrating how varying active electrode density may be used to vary the ablation depth.

Fig. 20 is a side elevation view, similar to the view of Fig. 2, showing an ablation device according to the present invention in

which the electrode carrying means includes inflatable balloons. For purposes of clarity, the electrodes on the electrode carrying means are not shown.

Fig. 21 is a side elevation view of a second exemplary embodiment of an ablation device according to the present invention, showing the array in the retracted state.

Fig. 22 is a side elevation view of the ablation device of Fig. 21, showing the array in the deployed state.

Fig. 23 is a top plan view of the applicator head of the apparatus of Fig. 21.

Fig. 24 is a cross-sectional top view of the encircled region designated 24 in Fig. 23.

Fig. 25A is a perspective view of the electrode array of Fig. 23.

Fig. 25B is a distal end view of the applicator head of Fig. 30A.

Fig. 26A is a plan view of a knit that may be used to form the applicator head.

Fig. 26B is a perspective view of a strand of nylon-wrapped spandex of the type that may be used to form the knit of Fig. 26A.

Figs. 27A, 27B, 27C are top plan views illustrating triangular, parabolic, and rectangular mesh shapes for use as electrode arrays according to the present invention.

Fig. 28 is a perspective view showing the flexures and hypotube of the deflecting mechanism of the applicator head of Fig. 23.

Fig. 29 is a cross-section view of a flexure taken along the plane designated 29-29 in Fig. 23.

Fig. 30 is a top plan view illustrating the flexure and spring arrangement of an alternative configuration of a deflecting mechanism for an applicator head according to the present invention.

Fig. 31 is a cross-sectional side view of the bobbin portion of the apparatus of Fig. 21.

Fig. 32A is a side elevation view of the handle of the ablation device of Fig. 21.

Fig. 32B is a top plan view of the handle of the ablation device of Fig. 21. For clarity, portions of the proximal and distal grips are not shown.

Fig. 33 illustrates placement of the applicator head according to the present invention in a uterine cavity.

Fig. 34 is a side elevation view of the handle of the ablation apparatus of Fig. 21, showing portions of the apparatus in cross-section.

Fig. 35 is a front elevation view of the upper portion of the proximal handle grip taken along the plane designated 35-35 in Fig. 32B.

Figs. 36A, 36B, and 36C are a series of side elevation views illustrating the heel member as it becomes engaged with the corresponding spring member.

Figs. 37A and 37B are cross-sectional top views of the frame member mounted on the proximal grip section, taken along the plane designated 37-37 in Fig. 34 and illustrating one of the load limiting

features of the second embodiment. Fig. 37A shows the condition of the compression spring before the heel member moves into abutment with frame member, and Fig 37B shows the condition of the spring after the heel member moves into abutment with the frame member.

Detailed Description

The invention described in this application is an aspect of a larger set of inventions described in the following co-pending applications which are commonly owned by the assignee of the present invention, and are hereby incorporated by reference: U.S. Provisional Patent Application No. 60/084,724, filed May 8, 1998, entitled "APPARATUS AND METHOD FOR INTRA-ORGAN MEASUREMENT AND ABLATION" (attorney docket no. ENVS-400); and U.S. Provisional Patent Application No. _____ filed May 8, 1998, entitled "A RADIO-FREQUENCY GENERATOR FOR POWERING AN ABLATION DEVICE" (attorney docket no. ENVS-500).

The ablation apparatus according to the present invention will be described with respect to two exemplary embodiments.

First Exemplary Embodiment - Structure

Referring to Figs. 1 and 2, an ablation device according to the present invention is comprised generally of three major components: RF applicator head 2, main body 4, and handle 6. Main body 4 includes a shaft 10. The RF applicator head 2 includes an electrode carrying means 12 mounted to the distal end of the shaft 10 and an array of electrodes 14 formed on the surface of the electrode

carrying means 12. An RF generator 16 is electrically connected to the electrodes 14 to provide mono-polar or bipolar RF energy to them.

Shaft 10 is an elongate member having a hollow interior. Shaft 10 is preferably 12 inches long and has a preferred cross-sectional diameter of approximately 4 mm. A collar 13 is formed on the exterior of the shaft 10 at the proximal end. As best shown in Figs. 6 and 7, passive spring member 15 are attached to the distal end of the shaft 10.

Extending through the shaft 10 is a suction/insufflation tube 17 (Figs. 6-9) having a plurality of holes 17a formed in its distal end. An arched active spring member 19 is connected between the distal ends of the passive spring members 15 and the distal end of the suction/insufflation tube 17.

Referring to Fig. 2, electrode leads 18a and 18b extend through the shaft 10 from distal end 20 to proximal end 22 of the shaft 10. At the distal end 20 of the shaft 10, each of the leads 18a, 18b is coupled to a respective one of the electrodes 14. At the proximal end 22 of the shaft 10, the leads 18a, 18b are electrically connected to RF generator 16 via an electrical connector 21. During use, the leads 18a, 18b carry RF energy from the RF generator 16 to the electrodes. Each of the leads 18a, 18b is insulated and carries energy of an opposite polarity than the other lead.

Electrically insulated sensor leads 23a, 23b (Figs. 5A and 5B) also extend through the shaft 10. Contact sensors 25a, 25b are attached to the distal ends of the sensor leads 23a, 23b, respectively and are mounted to the electrode carrying means 12.

During use, the sensor leads 23a, 23b are coupled by the connector 21 to a monitoring module in the RF generator 16 which measures impedance between the sensors 25a, 25b. Alternatively, a reference pad may be positioned in contact with the patient and the impedance between one of the sensors and the reference pad measured.

Referring to Fig. 5B, electrode leads 18a, 18b and sensor leads 23a, 23b extend through the shaft 10 between the external walls of the tube 17 and the interior walls of the shaft 10 and they are coupled to electrical connector 21 which is preferably mounted to the collar 13 on the shaft 10. Connector 21, which is connectable to the RF generator 16, includes at least four electrical contact rings 21a - 21d (Figs. 1 and 2) which correspond to each of the leads 18a, 18b, 23a, 23b. Rings 21a, 21b receive, from the RF generator, RF energy of positive and negative polarity, respectively. Rings 21c, 21d deliver signals from the right and left sensors, respectively, to a monitoring module within the RF generator 16.

Referring to Fig. 5A, the electrode carrying means 12 is attached to the distal end 20 of the shaft 10. A plurality of holes 24 may be formed in the portion of the distal end 20 of the shaft which lies within the electrode carrying means 12.

The electrode carrying means 12 preferably has a shape which approximates the shape of the body organ which is to be ablated. For example, the apparatus shown in Figs. 1 through 11 has a bicornual shape which is desirable for intrauterine ablation. The electrode carrying means 12 shown in these figures includes horn regions 26 which during use are positioned within the cornual

regions of the uterus and which therefore extend towards the fallopian tubes.

Electrode carrying means 12 is preferably a sack formed of a material which is non-conductive, which is permeable to moisture and/or which has a tendency to absorb moisture, and which may be compressed to a smaller volume and subsequently released to its natural size upon elimination of compression. Examples of preferred materials for the electrode carrying means include open cell sponge, foam, cotton, fabric, or cotton-like material, or any other material having the desired characteristics. Alternatively, the electrode carrying means may be formed of a metallized fabric. For convenience, the term "pad" may be used interchangeably with the term electrode carrying means to refer to an electrode carrying means formed of any of the above materials or having the listed properties.

Electrodes 14 are preferably attached to the outer surface of the electrode carrying means 12, such as by deposition or other attachment mechanism. The electrodes are preferably made of lengths of silver, gold, platinum, or any other conductive material. The electrodes may be attached to the electrode carrying means 12 by electron beam deposition, or they may be formed into coiled wires and bonded to the electrode carrying member using a flexible adhesive. Naturally, other means of attaching the electrodes, such as sewing them onto the surface of the carrying member, may alternatively be used. If the electrode carrying means 12 is formed of a metallized fabric, an insulating layer may be etched onto the fabric surface, leaving only the electrode regions exposed.

The spacing between the electrodes (i.e. the distance between the centers of adjacent electrodes) and the widths of the electrodes are selected so that ablation will reach predetermined depths within the tissue, particularly when maximum power is delivered through the electrodes (where maximum power is the level at which low impedance, low voltage ablation can be achieved).

The depth of ablation is also effected by the electrode density (i.e., the percentage of the target tissue area which is in contact with active electrode surfaces) and may be regulated by pre-selecting the amount of this active electrode coverage. For example, the depth of ablation is much greater when the active electrode surface covers more than 10% of the target tissue than it is when the active electrode surfaces covers 1% of the target tissue.

For example, by using 3-6 mm spacing and an electrode width of approximately 0.5 - 2.5 mm, delivery of approximately 20 - 40 watts over a 9-16 cm^2 target tissue area will cause ablation to a depth of approximately 5-7 millimeters when the active electrode surface covers more than 10% of the target tissue area. After reaching this ablation depth, the impedance of the tissue will become so great that ablation will self-terminate as described with respect to the operation of the invention.

By contrast, using the same power, spacing, electrode width, and RF frequency will produce an ablation depth of only 2 - 3 mm when the active electrode surfaces covers less than 1 % of the target tissue area. This can be better understood with reference to Fig. 19A, in which high surface density electrodes are designated 14a and low surface density electrodes are designated 14b. For

purposes of this comparison between low and high surface density electrodes, each bracketed group of low density electrodes is considered to be a single electrode. Thus, the electrode widths W and spacings S extend as shown in Fig. 19A.

As is apparent from Fig. 19A, the electrodes 14a, which have more active area in contact with the underlying tissue T, produce a region of ablation A1 that extends more deeply into the tissue T than the ablation region A2 produced by the low density electrodes 14b, even though the electrode spacings and widths are the same for the high and low density electrodes.

Some examples of electrode widths, having spacings with more than 10% active electrode surface coverage, and their resultant ablation depth, based on an ablation area of 6 cm^2 and a power of 20 - 40 watts, are given on the following table:

ELECTRODE WIDTH	SPACING	APPROX. DEPTH
1 mm	1 - 2 mm	1 - 3 mm
1 - 2.5 mm	3 - 6 mm	5 - 7 mm
1 - 4.5 mm	8 - 10 mm	8 - 10 mm

Examples of electrode widths, having spacings with less than 1 % active electrode surface coverage, and their resultant ablation depth, based on an ablation area of 6 cm^2 and a power of 20 - 40 watts, are given on the following table:

ELECTRODE WIDTH	SPACING	APPROX. DEPTH
1 mm	1 - 2 mm	0.5 - 1 mm
1 - 2.5 mm	3 - 6 mm	2 - 3 mm
1 - 4.5 mm	8 - 10 mm	2 - 3 mm

Thus it can be seen that the depth of ablation is significantly less when the active electrode surface coverage is decreased.

In the preferred embodiment, the preferred electrode spacing is approximately 8 - 10 mm in the horn regions 26 with the active electrode surfaces covering approximately 1% of the target region. Approximately 1 - 2 mm electrode spacing (with 10% active electrode coverage) is preferred in the cervical region (designated 28) and approximately 3 - 6 mm (with greater than 10% active electrode surface coverage) is preferred in the main body region.

The RF generator 16 may be configured to include a controller which gives the user a choice of which electrodes should be energized during a particular application in order to give the user control of ablation depth. For example, during an application for which deep ablation is desired, the user may elect to have the generator energize every other electrode, to thereby optimize the effective spacing of the electrodes and to decrease the percentage of active electrode surface coverage, as will be described below with respect to Fig. 18.

Although the electrodes shown in the drawings are arranged in a particular pattern, it should be appreciated that the electrodes

may be arranged in any pattern to provide ablation to desired depths.

Referring to Figs. 6 and 7, an introducer sheath 32 facilitates insertion of the apparatus into, and removal of the apparatus from, the body organ to be ablated. The sheath 32 is a tubular member which is telescopically slidable over the shaft 10. The sheath 32 is slidable between a distal condition, shown in Fig. 6, in which the electrode carrying means 12 is compressed inside the sheath, and a proximal condition in which the sheath 32 is moved proximally to release the electrode carrying means from inside it (Fig. 7). By compressing the electrode carrying means 12 to a small volume, the electrode carrying means and electrodes can be easily inserted into the body cavity (such as into the uterus via the vaginal opening).

A handle 34 attached to the sheath 32 provides finger holds to allow for manipulation of the sheath 32. Handle 34 is slidably mounted on a handle rail 35 which includes a sleeve 33, a finger cutout 37, and a pair of spaced rails 35a, 35b extending between the sleeve 33 and the finger cutout 37. The shaft 10 and sheath 32 slidably extend through the sleeve 33 and between the rails 35a, 35b. The tube 17 also extends through the sleeve 33 and between the rails 35a, 35b, and its proximal end is fixed to the handle rail 35 near the finger cutout 37.

A compression spring 39 is disposed around the proximal most portion of the suction/insufflation tube 17 which lies between the rails 35a, 35b. One end of the compression spring 39 rests against the collar 13 on the shaft 10, while the opposite end of the compression spring rests against the handle rail 35. During

use, the sheath 32 is retracted from the electrode carrying means 12 by squeezing the handle 34 towards the finger cutout 37 to slide the sheath 32 in the distal direction. When the handle 34 advances against the collar 13, the shaft 10 (which is attached to the collar 13) is forced to slide in the proximal direction, causing compression of the spring 39 against the handle rail 35. The movement of the shaft 10 relative to the suction/insufflation tube 17 causes the shaft 10 to pull proximally on the passive spring member 15. Proximal movement of the passive spring member 15 in turn pulls against the active spring member 19, causing it to move to the opened condition shown in Fig. 7. Unless the shaft is held in this retracted condition, the compression spring 39 will push the collar and thus the shaft distally, forcing the RF applicator head to close. A locking mechanism (not shown) may be provided to hold the shaft in the fully withdrawn condition to prevent inadvertent closure of the spring members during the ablation procedure.

The amount by which the springs 15, 19 are spread may be controlled by manipulating the handle 34 to slide the shaft 10 (via collar 13), proximally or distally. Such sliding movement of the shaft 10 causes forceps-like movement of the spring members 15, 19.

A flow pathway 36 is formed in the handle rail 35 and is fluidly coupled to a suction/insufflation port 38. The proximal end of the suction/insufflation tube 17 is fluidly coupled to the flow pathway so that gas fluid may be introduced into, or withdrawn from the suction/insufflation tube 17 via the suction/insufflation port 38. For example, suction may be applied to the fluid port 38 using a

suction/insufflation unit 40. This causes water vapor within the uterine cavity to pass through the permeable electrode carrying means 12, into the suction/insufflation tube 17 via holes 17a, through the tube 17, and through the suction/insufflation unit 40 via the port 38. If insufflation of the uterine cavity is desired, insufflation gas, such as carbon dioxide, may be introduced into the suction/insufflation tube 17 via the port 38. The insufflation gas travels through the tube 17, through the holes 17a, and into the uterine cavity through the permeable electrode carrying member 12.

If desirable, additional components may be provided for endoscopic visualization purposes. For example, lumen 42, 44, and 46 may be formed in the walls of the introducer sheath 32 as shown in Fig. 5B. An imaging conduit, such as a fiberoptic cable 48, extends through lumen 42 and is coupled via a camera cable 43 to a camera 45. Images taken from the camera may be displayed on a monitor 56. An illumination fiber 50 extends through lumen 44 and is coupled to an illumination source 54. The third lumen 46 is an instrument channel through which surgical instruments may be introduced into the uterine cavity, if necessary.

Because during use it is most desirable for the electrodes 14 on the surface of the electrode carrying means 12 to be held in contact with the interior surface of the organ to be ablated, the electrode carrying means 12 may be provide to have additional components inside it that add structural integrity to the electrode carrying means when it is deployed within the body.

For example, referring to Fig. 11, alternative spring members 15a, 19a may be attached to the shaft 10 and biased such that,

when in a resting state, the spring members are positioned in the fully resting condition shown in Fig. 11. Such spring members would spring to the resting condition upon withdrawal of the sheath 32 from the RF applicator head 2.

Alternatively, a pair of inflatable balloons 52 may be arranged inside the electrode carrying means 12 as shown in Fig. 20 and connected to a tube (not shown) extending through the shaft 10 and into the balloons 52. After insertion of the apparatus into the organ and following retraction of the sheath 32, the balloons 52 would be inflated by introduction of an inflation medium such as air into the balloons via a port similar to port 38 using an apparatus similar to the suction/insufflation apparatus 40.

Structural integrity may also be added to the electrode carrying means through the application of suction to the proximal end 22 of the suction/insufflation tube 17. Application of suction using the suction/insufflation device 40 would draw the organ tissue towards the electrode carrying means 12 and thus into better contact with the electrodes 14.

Figs. 12 and 13 show an alternative embodiment of an ablation device according to the present invention. In the alternative embodiment, an electrode carrying means 12a is provided which has a shape which is generally tubular and thus is not specific to any particular organ shape. An ablation device having a general shape such as this may be used anywhere within the body where ablation or coagulation is needed. For example, the alternative embodiment is useful for bleeding control during laparoscopic surgery (Fig. 14),

tissue ablation in the prostate gland (Fig. 17), and also intrauterine ablation (Figs. 15 and 16).

First Exemplary Embodiment - Operation

Operation of the first exemplary embodiment of an ablation device according to the present invention will next be described.

Referring to Fig. 1, the device is initially configured for use by positioning the introducer sheath 32 distally along the shaft 10, such that it compresses the electrode carrying means 12 within its walls.

At this time, the electrical connector 21 is connected to the RF generator 16, and the fiberoptic cable 48 and the illumination cable 50 are connected to the illumination source, monitor, and camera, 54, 56, 45. The suction/insufflation unit 40 is attached to suction/insufflation port 38 on the handle rail 35. The suction/insufflation unit 40 is preferably set to deliver carbon dioxide at an insufflation pressure of 20 - 200 mmHg.

Next, the distal end of the apparatus is inserted through the vaginal opening V and into the uterus U as shown in Fig. 6, until the distal end of the introducer sheath 32 contacts the fundus F of the uterus. At this point, carbon dioxide gas is introduced into the tube 17 via the port 38, and it enters the uterine cavity, thereby expanding the uterine cavity from a flat triangular shape to a 1-2 cm high triangular cavity. The physician may observe (using the camera 45 and monitor 56) the internal cavities using images detected by a fiberoptic cable 48 inserted through lumen 42. If, upon observation, the physician determines that a tissue biopsy or other procedure is

needed, the required instruments may be inserted into the uterine cavity via the instrument channel 46.

Following insertion, the handle 34 is withdrawn until it abuts the collar 13. At this point, the sheath 32 exposes the electrode carrying member 12 but the electrode carrying member 12 is not yet fully expanded (see Fig 9), because the spring members 15, 19 have not yet been moved to their open condition. The handle 34 is withdrawn further, causing the shaft 10 to move proximally relative to the suction/insufflation tube 17, causing the passive spring members 15 to pull the active spring members 19, causing them to open into the opened condition shown in Fig. 10.

The physician may confirm proper positioning of the electrode carrying member 12 using the monitor 56, which displays images from the fiberoptic cable 48.

Proper positioning of the device and sufficient contact between the electrode carrying member 12 and the endometrium may further be confirmed using the contact sensors 25a, 25b. The monitoring module of the RF generator measures the impedance between these sensors using conventional means. If there is good contact between the sensors and the endometrium, the measured impedance will be approximately 20 - 180 ohm, depending on the water content of the endometrial lining.

The sensors are positioned on the distal portions of the bicornual shaped electrode carrying member 12, which during use are positioned in the regions within the uterus in which it is most difficult to achieve good contact with the endometrium. Thus, an indication from the sensors 25a, 25b that there is sound contact

between the sensors and the endometrial surface indicates that good electrode contact has been made with the endometrium.

Next, insufflation is terminated. Approximately 1 - 5 cc of saline may be introduced via suction/insufflation tube 17 to initially wet the electrodes and to improve electrode electrical contact with the tissue. After introduction of saline, the suction/insufflation device 40 is switched to a suctioning mode. As described above, the application of suction to the RF applicator head 2 via the suction/insufflation tube 17 collapses the uterine cavity onto the RF applicator head 2 and thus assures better contact between the electrodes and the endometrial tissue.

If the generally tubular apparatus of Figs. 12 and 13 is used, the device is angled into contact with one side of the uterus during the ablation procedure. Once ablation is completed, the device (or a new device) is repositioned in contact with the opposite side and the procedure is repeated. See. Figs. 15 and 16.

Next, RF energy at preferably about 500 kHz and at a constant power of approximately 30 W is applied to the electrodes. As shown in Fig. 5a, it is preferable that each electrode be energized at a polarity opposite from that of its neighboring electrodes. By doing so, energy field patterns, designated F1, F2 and F4 in Fig. 18, are generated between the electrode sites and thus help to direct the flow of current through the tissue T to form a region of ablation A. As can be seen in Fig. 18, if electrode spacing is increased such by energizing, for example every third or fifth electrode rather than all electrodes, the energy patterns will extend more deeply into the tissue. (See, for example, pattern F2 which results from

energization of electrodes having a non-energized electrode between them, or pattern F4 which results from energization of electrodes having two non-energized electrodes between them).

Moreover, ablation depth may be controlled as described above by providing low surface density electrodes on areas of the electrode carrying member which will contact tissue areas at which a smaller ablation depth is required (see Fig. 19A). Referring to Fig. 19B, if multiple, closely spaced, electrodes 14 are provided on the electrode carrying member, a user may set the RF generator to energize electrodes which will produce a desired electrode spacing and active electrode area. For example, alternate electrodes may be energized as shown in Fig. 19B, with the first three energized electrodes having positive polarity, the second three having negative polarity, etc.

As another example, shown in Fig. 19C, if greater ablation depth is desired the first five electrodes may be positively energized, and the seventh through eleventh electrodes negatively energized, with the sixth electrode remaining inactivated to provide adequate electrode spacing.

As the endometrial tissue heats, moisture begins to be released from the tissue. The moisture permeates the electrode carrying member 12 and is thereby drawn away from the electrodes. The moisture may pass through the holes 17a in the suction/insufflation tube 17 and leave the suction/insufflation tube 17 at its proximal end via port 38 as shown in Fig. 7. Moisture removal from the ablation site may be further facilitated by the

application of suction to the shaft 10 using the suction/insufflation unit 40.

Removal of the moisture from the ablation site prevents formation of a liquid layer around the electrodes. As described above, liquid build-up at the ablation site is detrimental in that provides a conductive layer that carries current from the electrodes even when ablation has reached the desired depth. This continued current flow heats the liquid and surrounding tissue, and thus causes ablation to continue by unpredictable thermal conduction means.

Tissue which has been ablated becomes dehydrated and thus decreases in conductivity. By shunting moisture away from the ablation site and thus preventing liquid build-up, there is no liquid conductor at the ablation area during use of the ablation device of the present invention. Thus, when ablation has reached the desired depth, the impedance at the tissue surface becomes sufficiently high to stop or nearly stop the flow of current into the tissue. RF ablation thereby stops and thermal ablation does not occur in significant amounts. If the RF generator is equipped with an impedance monitor, a physician utilizing the ablation device can monitor the impedance at the electrodes and will know that ablation has self-terminated once the impedance rises to a certain level and then remains fairly constant. By contrast, if a prior art bipolar RF ablation device was used together with an impedance monitor, the presence of liquid around the electrodes would cause the impedance monitor to give a low impedance reading regardless of the depth of ablation which had already been carried out, since current would continue to travel through the low-impedance liquid layer.

Other means for monitoring and terminating ablation may also be provided. For example, a thermocouple or other temperature sensor may be inserted to a predetermined depth in the tissue to monitor the temperature of the tissue and terminate the delivery of RF energy or otherwise signal the user when the tissue has reached a desired ablation temperature.

Once the process has self terminated, 1 - 5 cc of saline can be introduced via suction/insufflation tube 17 and allowed to sit for a short time to aid separation of the electrode from the tissue surface. The suction/insufflation device 40 is then switched to provide insufflation of carbon dioxide at a pressure of 20 - 200 mmHg. The insufflation pressure helps to lift the ablated tissue away from the RF applicator head 2 and to thus ease the closing of the RF applicator head. The RF applicator head 2 is moved to the closed position by sliding the handle 34 in a distal direction to fold the spring members 15, 19 along the axis of the device and to cause the introducer sheath 32 to slide over the folded RF applicator head. The physician may visually confirm the sufficiency of the ablation using the monitor 56. Finally, the apparatus is removed from the uterine cavity.

Second Exemplary Embodiment - Structure

A second embodiment of an ablation device 100 in accordance with the present invention is shown in Figs. 21 - 37B. The second embodiment differs from the first embodiment primarily in its electrode pattern and in the mechanism used to deploy the electrode applicator head or array. Naturally, aspects of the first and

second exemplary embodiments and their methods of operation may be combined without departing from the scope of the present invention.

Referring to Figs. 21 and 22, the second embodiment includes an RF applicator head 102, a sheath 104, and a handle 106. As with the first embodiment, the applicator head 102 is slidably disposed within the sheath 104 (Fig. 21) during insertion of the device into the uterine cavity, and the handle 106 is subsequently manipulated to cause the applicator head 102 to extend from the distal end of the sheath 104 (Fig. 22) and to expand into contact with body tissue (Fig. 33).

RF Applicator Head

Referring to Fig. 23, in which the sheath 104 is not shown for clarity, applicator head 102 extends from the distal end of a length of tubing 108 which is slidably disposed within the sheath 104. Applicator head 102 includes an external electrode array 102a and an internal deflecting mechanism 102b used to expand and tension the array for positioning into contact with the tissue.

Referring to Figs. 25A and 25B, the array 102a of applicator head 102 is formed of a stretchable metallized fabric mesh which is preferably knitted from a nylon and spandex knit plated with gold or other conductive material. In one array design, the knit (shown in Figs. 26A and 26B) is formed of three monofilaments of nylon 109a knitted together with single yarns of spandex 109b. Each yarn of spandex 109b has a double helix 109c of five nylon monofilaments coiled around it.

This knit of elastic (spandex) and inelastic (nylon) yarns is beneficial for a number of reasons. For example, knitting elastic and relatively inelastic yarns allows the overall deformability of the array to be pre-selected.

The mesh is preferably constructed so as to have greater elasticity in the transverse direction (T) than in the longitudinal direction (L). In a preferred mesh design, the transverse elasticity is on the order of approximately 300% whereas the longitudinal elasticity is on the order of approximately 100%. The large transverse elasticity of the array allows it to be used in a wide range of uterine sizes.

Another advantage provided by the combination of elastic and relatively inelastic yarns is that the elastic yarns provide the needed elasticity to the array while the relatively inelastic yarns provide relatively non-stretchable members to which the metallization can adhere without cracking during expansion of the array. In the knit configuration described above, the metallization adheres to the nylon coiled around the spandex. During expansion of the array, the spandex elongates and the nylon double helix at least partially elongates from its coiled configuration.

One process which may be used to apply the gold to the nylon/spandex knit involves plating the knit with silver using known processes which involve application of other materials as base layers prior to application of the silver to ensure that the silver will adhere. Next, the insulating regions 110 (described below) are etched onto the silver, and afterwards the gold is plated onto the silver. Gold is desirable for the array because of it has a relatively smooth surface,

is a very inert material, and has sufficient ductility that it will not crack as the nylon coil elongates during use.

The mesh may be configured in a variety of shapes, including but not limited to the triangular shape S1, parabolic S2, and rectangular S3 shapes shown in Figs. 27A, 27B and 27C, respectively.

Turning again to Figs. 25A and 25B, when in its expanded state, the array 102a includes a pair of broad faces 112 spaced apart from one another. Narrower side faces 114 extend between the broad faces 112 along the sides of the applicator head 102, and a distal face 116 extends between the broad faces 112 at the distal end of the applicator head 102.

Insulating regions 110 are formed on the applicator head to divide the mesh into electrode regions. The insulated regions 110 are preferably formed using etching techniques to remove the conductive metal from the mesh, although alternate methods may also be used, such as by knitting conductive and non-conductive materials together to form the array.

The array may be divided by the insulated regions 110 into a variety of electrode configurations. In a preferred configuration the insulating regions 110 divide the applicator head into four electrodes 118a - 118d by creating two electrodes on each of the broad faces 112. To create this four-electrode pattern, insulating regions 110 are placed longitudinally along each of the broad faces 112 as well as along the length of each of the faces 114, 116. The electrodes 118a-118d are used for ablation and, if desired, to measure tissue impedance during use.

Deflecting mechanism 102b and its deployment structure is enclosed within electrode array 102a. Referring to Fig. 23, external hypotube 120 extends from tubing 108 and an internal hypotube 122 is slidably and co-axially disposed within hypotube 120. Flexures 124 extend from the tubing 108 on opposite sides of external hypotube 120. A plurality of longitudinally spaced apertures 126 (Fig. 28) are formed in each flexure 124. During use, apertures 126 allow moisture to pass through the flexures and to be drawn into exposed distal end of hypotube 120 using a vacuum source fluidly coupled to hypotube 120.

Each flexure 124 preferably includes conductive regions that are electrically coupled to the array 102a for delivery of RF energy to the body tissue. Referring to Fig. 29, strips 128 of copper tape or other conductive material extend along opposite surfaces of each flexure 124. Each strip 128 is electrically insulated from the other strip 128 by a non-conductive coating on the flexure. Conductor leads (not shown) are electrically coupled to the strips 128 and extend through tubing 108 (Fig. 23) to an electrical cord 130 (Fig. 21) which is attachable to the RF generator.

During use, one strip 128 on each conductor is electrically coupled via the conductor leads to one terminal on the RF generator while the other strip is electrically coupled to the opposite terminal, thus causing the array on the applicator head to have regions of alternating positive and negative polarity.

The flexures may alternatively be formed using a conductive material or a conductively coated material having insulating regions formed thereon to divide the flexure surfaces into multiple

conductive regions. Moreover, alternative methods such as electrode leads independent of the flexures 124 may instead be used for electrically connecting the electrode array to the source of RF energy.

It is important to ensure proper alignment between the conductive regions of the flexures 124 (e.g. copper strips 128) and the electrodes 118a - 118d in order to maintain electrical contact between the two. Strands of thread 134 (which may be nylon) (Fig. 23) are preferably sewn through the array 102a and around the flexures 124 in order to prevent the conductive regions 128 from slipping out of alignment with the electrodes 118a - 118d. Alternate methods for maintaining contact between the array 102a and the conductive regions 128 include using tiny bendable barbs extending between the flexures 124 and the array 102a to hook the array to the conductive regions 128, or bonding the array to the flexures using an adhesive applied along the insulating regions of the flexures.

Referring again to Fig. 23, internal flexures 136 extend laterally and longitudinally from the exterior surface of hypotube 122. Each internal flexure 136 is connected at its distal end to one of the flexures 124 and a transverse ribbon 138 extends between the distal portions of the internal flexures 136. Transverse ribbon 138 is preferably pre-shaped such that when in the relaxed condition the ribbon assumes the corrugated configuration shown in Fig. 23 and such that when in a compressed condition it is folded along the plurality of creases 140 that extend along its length. Flexures 124,

136 and ribbon 138 are preferably an insulated spring material such as heat treated 17-7 PH stainless steel.

The deflecting mechanism is preferably configured such that the distal tips of the flexures 124 are sufficiently flexible to prevent tissue puncture during deployment and/or use. Such an atraumatic tip design may be carried out in a number of ways, such as by manufacturing the distal sections 124a (Fig. 28) of the flexures from a material that is more flexible than the proximal sections 124b. For example, flexures 124 may be provided to have proximal sections formed of a material having a modulus of approximately 28 x 10^6 psi and distal sections having a durometer of approximately 72D.

Alternatively, referring to Fig. 30, the flexures 124 may be joined to the internal flexures 136 at a location more proximal than the distal tips of the flexures 124, allowing them to move more freely and to adapt to the contour of the surface against which they are positioned (see dashed lines in Fig. 30). Given that uterine sizes and shapes vary widely between women, the atraumatic tip design is further beneficial in that it allows the device to more accurately conform to the shape of the uterus in which it is deployed while minimizing the chance of injury.

The deflecting mechanism formed by the flexures 124, 136, and ribbon 138 forms the array into the substantially triangular shape shown in Fig. 23, which is particularly adaptable to most uterine shapes. As set forth in detail below, during use distal and proximal grips 142, 144 forming handle 106 are squeezed towards one another to withdraw the sheath and deploy the applicator head.

This action results in relative rearward motion of the hypotube 120 and relative forward motion of the hypotube 122. The relative motion between the hypotubes causes deflection in flexures 124, 136 which deploys and tensions the electrode array 102a.

Measurement Device

The ablation device according to the second embodiment includes a measurement device for easily measuring the uterine width and for displaying the measured width on a gauge 146 (Fig. 21). The measurement device utilizes non-conductive (e.g. nylon) suturing threads 148 that extend from the hypotube 122 and that have distal ends attached to the distal portion of the deflecting mechanism (Fig. 23). As shown in Fig. 24, threads 148 are preferably formed of a single strand 150 threaded through a wire loop 152 and folded over on itself. Wire loop 152 forms the distal end of an elongate wire 154 which may be formed of stainless steel or other wire.

Referring to Fig. 31, wire 154 extends through the hypotube 122 and is secured to a rotatable bobbin 156. The rotatable bobbin 156 includes a dial face 158 preferably covered in a clear plastic. As can be seen in Fig. 32, dial face 158 includes calibration markings corresponding to an appropriate range of uterine widths. The bobbin is disposed within a gauge housing 160 and a corresponding marker line 162 is printed on the gauge housing. A torsion spring 164 provides rotational resistance to the bobbin 156.

Expansion of the applicator head 102 during use pulls threads 148 (Fig. 23) and thus wire 154 (Fig. 24) in a distal direction. Wire 154 pulls against the bobbin 156 (Fig. 31), causing it to rotate.

Rotation of the bobbin positions one of the calibration markings on dial face 158 into alignment with the marker line 162 (Fig. 32B) to indicate the distance between the distal tips of flexures 124 and thus the uterine width.

The uterine width and length (as determined using a conventional sound or other means) are preferably input into an RF generator system and used by the system to calculate an appropriate ablation power as will be described below. Alternately, the width as measured by the apparatus of the invention and length as measured by other means may be used by the user to calculate the power to be supplied to the array to achieve the desired ablation depth.

The uterine width may alternatively be measured using other means, including by using a strain gauge in combination with an A/D converter to transduce the separation distance of the flexures 124 and to electronically transmit the uterine width to the RF generator.

Control of Ablation Depth

The most optimal electrocoagulation occurs when relatively deep ablation is carried out in the regions of the uterus at which the endometrium is thickest, and when relatively shallower ablation is carried out in areas in which the endometrium is shallower. A desirable range of ablation depths includes approximately 2 - 3 mm for the cervical os and the cornual regions, and approximately 7 - 8 mm in the main body of the uterus where the endometrium is substantially thicker.

As discussed with respect to the first embodiment, a number of factors influence the ablation depth that can be achieved using a

given power applied to a bipolar electrode array. These include the power supplied by the RF generator, the distance between the centers of adjacent electrodes ("center-to-center distance"), the electrode density (i.e., the porosity of the array fabric or the percent of the array surface that is metallic), the edge gap (i.e. the distance between the edges of adjacent electrode poles), and the electrode surface area. Other factors include blood flow (which in slower-ablating systems can dissipate the RF) and the impedance limit.

Certain of these factors may be utilized in the present invention to control ablation depth and to provide deeper ablation at areas requiring deeper ablation and to provide shallower regions in areas where deep ablation is not needed. For example, as center-to-center distance increases, the depth of ablation increases until a point where the center to center distance is so great that the strength of the RF field is too diffuse to excite the tissue. It can been seen with reference to Fig. 33 that the center to center distance d1 between the electrodes 118a, 118b is larger within the region of the array that lies in the main body of the uterus and thus contributes to deeper ablation. The center to center distance d2 between electrodes 118a, 118b is smaller towards the cervical canal where it contributes to shallower ablation. At the distal end of the device, the shorter center to center distances d3 extend between top and bottom electrodes 118b, 118c and 118a, 118d and again contribute to shallower ablation.

Naturally, because the array 102a expands to accommodate the size of the uterus in which it is deployed, the dimensions of the array 102a vary. One embodiment of the array 102a includes a

range of widths of at least approximately 2.5 - 4.5 cm, a range of lengths of at least approximately 4 -6 cm, and a density of approximately 35% - 45%.

The power supplied to the array by the RF generator is calculated by the RF generator system to accommodate the electrode area required for a particular patient. As discussed above, the uterine width is measured by the applicator head 102 and displayed on gauge 146. The uterine length is measured using a sound, which is an instrument conventionally used for that purpose. It should be noted that calibration markings of the type used on a conventional sound device, or other structure for length measurement, may be included on the present invention to allow it to be used for length measurement as well.

The user enters the measured dimensions into the RF generator system using an input device, and the RF generator system calculates or obtains the appropriate set power from a stored look-up table using the uterine width and length as entered by the user. An EPROM within the RF generator system converts the length and width to a set power level according to the following relationship:

$$P = L \times W \times 5.5$$

Where P is the power level in watts, L is the length in centimeters, W is the width in centimeters, and 5.5 is a constant having units of watts per square centimeter.

Alternatively, the user may manually calculate the power setting from the length and width, or s/he may be provided with a table of suggested power settings for various electrode areas (as determined by the measured length and width) and will manually set the power on the RF generator accordingly.

Handle

Referring again to Figs. 21 and 22, the handle 106 of the RF ablation device according to the second embodiment includes a distal grip section 142 and a proximal grip section 144 that are pivotally attached to one another at pivot pin 166.

The proximal grip section 144 is coupled to the hypotube 122 (Fig. 23) via yoke 168, overload spring 170 and spring stop 172, each of which is shown in the section view of Fig. 34. The distal grip section 142 is coupled to the external hypotube 120 via male and female couplers 174, 176 (see Figs. 32A and 32B). Squeezing the grip sections 142, 144 towards one another thus causes relative movement between the external hypotube 120 and the internal hypotube 122. This relative sliding movement results in deployment of the deflecting mechanism 102b from the distal end of the sheath and expansion of the array 102a to its expanded state.

Referring to Figs. 32A and B, rack 180 is formed on male coupler 174 and calibration markings 182 are printed adjacent the rack 180. The calibration markings 182 correspond to a variety of uterine lengths and may include lengths ranging from, for example, 4.0 to 6.0 cm in 0.5 cm increments.

A sliding collar 184 is slidably disposed on the tubing 108 and is slidable over male coupler 174. Sliding collar 184 includes a rotating collar 186 and a female coupler 176 that includes a wedge-shaped heel 188. A locking spring member 190 (Figs. 32B and 35) extends across an aperture 192 formed in the proximal grip 144 in alignment with the heel 188. When the distal and proximal handle sections are squeezed together to deploy the array, the heel 188 passes into the aperture 192. Its inclined lower surface gradually depresses the spring member 190 as the heel moves further into the aperture 192. See Figs. 36A and 36B. After passing completely over the spring member, the heel moves out of contact with the spring member. The spring member snaps upwardly thereby engaging the heel in the locked position. See Fig. 36C.

A release lever 194 (Fig. 35) is attached to the free end of the spring member 190. To disengage the spring lock, release lever 194 is depressed to lower spring member 190 so that the inclined heel can pass over the spring member and thus out of the aperture 192.

Referring again to Figs. 32A and 32B, sliding collar 184 is configured to allow the user to limit longitudinal extension of the array 102a to a distance commensurate with a patient's predetermined uterine length. It does so by allowing the user to adjust the relative longitudinal position of male coupler 174 relative to the female coupler 176 using the rotating collar 186 to lock and unlock the female coupler from the rack 180 and the male coupler 174. Locking the female coupler to the rack 180 and male coupler 174 will limit extension of the array to approximately the

predetermined uterine length, as shown on the calibration markings 182.

Once the uterine length has been measured using a conventional sound, the user positions sliding collar 184 adjacent to calibration marks 182 corresponding to the measured uterine length (e.g. 4.5 cm). Afterwards, the user rotates the collar section 186 to engage its internally positioned teeth with the rack 180. This locks the longitudinal position of the heel 188 such that it will engage with the spring member 190 on the proximal grip when the array has been exposed to the length set by the sliding collar.

The handle 106 includes a pair of spring assemblies which facilitate controlled deployment and stowage of the array 102a. One of the spring assemblies controls movement of the grips 142, 144 to automatically stow the array 102a into the sheath 104 when the user stops squeezing the grips 142, 144 towards one another. The other of the spring assemblies controls the transverse movement of the spring flexures 124 to the expanded condition by limiting the maximum load that can be applied to the deployment mechanism 102b.

Fig. 34 shows the distal and proximal grips 142 and 144 in partial cross-section. The first spring assembly for controlled stowage includes a handle return mandrel 196 that is slidably disposed within the proximal grip 144. A compression spring 198 surrounds a portion of the return mandrel 196, and a retaining ring 200 is attached to the mandrel 196 above the spring 198. A spring stop 202 is disposed between the spring 198 and the retaining ring.

The lowermost end of the return mandrel 196 is pivotally engaged by a coupling member 204 on distal grip 142. Relative movement of the grips 142, 144 towards one another causes the coupling member 204 to pull the return member downwardly with the proximal grip 144 as indicated by arrows. Downward movement of the mandrel 196 causes its retaining ring 200 and spring stop 202 to bear downwardly against the compression spring 198, thereby providing a movement which acts to rotate the grips 142, 144 away from one another. When tension against the grips 142, 144 is released (assuming that heel 188 is not locked into engagement with spring member 190) the grips rotate apart into the opened position as the compression spring 198 returns to the initial state, stowing the applicator head inside the sheath.

The second spring assembly for controlling array deployment is designed to control separation of the flexures. It includes a frame member 178 disposed over yoke 168, which is pivotally attached to proximal grip 144. Tubing 108 extends from the array 102a (see Fig. 23), through the sheath 104 and is fixed at its proximal end to the frame member 178. Hypotube 122 does not terminate at this point but instead extends beyond the proximal end of tubing 108 and through a window 206 in the frame member. Its proximal end 208 is slidably located within frame member 178 proximally of the window 206 and is fluidly coupled to a vacuum port 210 by fluid channel 212. Hypotube 120 terminates within the frame. Its proximal end is fixed within the distal end of the frame.

A spring stop 214 is fixed to a section of the hypotube within the window 206, and a compression spring 170 is disposed around

the hypotube between the spring stop 172 and yoke 168. See Figs. 32B and 34.

When the distal and proximal grips are moved towards one another, the relative rearward motion of the distal grip causes the distal grip to withdraw the sheath 104 from the array 102a. Referring to Figs. 37A and 37B, this motion continues until female coupler 176 contacts and bears against frame member 178. Continued motion between the grips causes a relative rearward motion in the frame which causes the same rearward relative motion in external hypotube 120. An opposing force is developed in yoke 168, which causes a relative forward motion in hypotube 122. The relative motion between the hypotubes causes deflection in flexures 124, 136 which deflect in a manner that deploys and tensions the electrode array. Compression spring 170 acts to limit the force developed by the operator against hypotubes 120, 122, thus limiting the force of flexures 124, 136 acting on the array and the target tissue surrounding the array.

Referring to Fig. 21, collar 214 is slidably mounted on sheath 104. Before the device is inserted into the uterus, collar 214 can be positioned along sheath 104 to the position measured by the uterine sound. Once in position, the collar provides visual and tactile feedback to the user to assure the device has been inserted the proper distance. In addition, after the applicator head 102 has been deployed, if the patient's cervical canal diameter is larger than the sheath dimensions, the collar 214 can be moved distally towards the cervix, making contact with it and creating a pneumatic seal between the sheath and cervix.

Second Exemplary Embodiment - Operation

In preparation for ablating the uterus utilizing the second exemplary embodiment, the user measures the uterine length using a uterine sound device. The user next positions sliding collar 184 (Fig. 32B) adjacent to calibration marks 182 corresponding to the measured uterine length (e.g. 4.5 cm) and rotates the collar section 186 to engage its internally positioned teeth with the rack 180. This locks the longitudinal position of the heel 188 (Fig. 32A) such that it will engage with the spring member 190 when the array has been exposed to the length set by the sliding collar.

Next, with the grips 142, 144 in their resting positions to keep the applicator head 102 covered by sheath 104, the distal end of the device 100 is inserted into the uterus. Once the distal end of the sheath 104 is within the uterus, grips 142, 144 are squeezed together to deploy the applicator head 102 from sheath 104. Grips 142, 144 are squeezed until heel 188 engages with locking spring member 190 as described with respect to Figs. 36A through 36C.

At this point, deflecting mechanism 102b has deployed the array 102a into contact with the uterine walls. The user reads the uterine width, which as described above is transduced from the separation of the spring flexures, from gauge 146. The measured length and width are entered into the RF generator system 250 (Fig. 21) and used to calculate the ablation power.

Vacuum source 252 (Fig. 21) is activated, causing application of suction to hypotube 122 via suction port 210. Suction helps to draw uterine tissue into contact with the array 102.

Ablation power is supplied to the electrode array 102a by the RF generator system 250. The tissue is heated as the RF energy passes from electrodes 118a-d to the tissue, causing moisture to be released from the tissue. The vacuum source helps to draw moisture from the uterine cavity into the hypotube 122. Moisture withdrawal is facilitated by the apertures 126 formed in flexures 124 by preventing moisture from being trapped between the flexures 124 and the lateral walls of the uterus.

If the RF generator 250 includes an impedance monitoring module, impedance may be monitored at the electrodes 118a-d and the generator may be programmed to terminate RF delivery automatically once the impedance rises to a certain level. The generator system may also or alternatively display the measured impedance and allow the user to terminate RF delivery when desired.

When RF delivery is terminated, the user depresses release lever 194 to disengage heel 188 from locking spring member 190 and to thereby allow grips 142, 144 to move to their expanded (resting condition). Release of grips 142, 144 causes applicator head 102 to retract to its unexpanded condition and further causes applicator head 102 to be withdrawn into the sheath 104. Finally, the distal end of the device 100 is withdrawn from the uterus.

Two embodiments of ablation devices in accordance with the present invention have been described herein. These embodiments have been shown for illustrative purposes only. It should be understood, however, that the invention is not intended to be limited to the specifics of the illustrated embodiments but is defined only in terms of the following claims.

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Expr ss Mailing Label: EM503277278US

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We Claim:

1. A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the electrode carrying member and away from the tissue.

2. The method of claim 1 wherein the fluid permeable elastic member includes metallized fabric.

3. The method of claim 1 wherein the array is expandable and wherein step (b) further includes the step of moving the array to an expanded condition.

4. The method of claim 3 wherein the array is carried by a pair of elongate flexures and wherein the step of moving the array to the expanded condition includes the step of expanding the flexures.

5. The method of claim 4 wherein each flexure includes at least one opening and wherein step (d) includes allowing at least a portion of the moisture to pass through the openings in the flexures.

6. The method of claim 1 wherein step (d) includes permitting at least a portion of the moisture to pass from the array into the tubular member.

7. The method of claim 3 wherein step (d) includes the step of applying suction to draw the moisture through the tubular member.

8. The method of claim 1 wherein the method further includes the step of

(e) monitoring impedance using the electrode array and automatically terminating the flow of current into the tissue once impedance has approximately reached a predetermined level.

9. The method of claim 1 wherein the method further includes the step of measuring the approximate length and width of the organ and wherein step (c) includes the steps of selecting an ablation power corresponding to the measured length and width and delivering the RF energy to the tissue at approximately the selected power.

10. The method of claim 9 wherein the array is carried by a pair of elongate flexures and wherein the step of measuring the

approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

11. The method of claim 9 wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

12. The method of claim 2 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

13. The method of claim 12 wherein the metallized fabric includes yarns of spandex and nylon.

14. The method of claim 2 wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

15. The method of claim 1 including the step of applying suction through the tubular member to draw the tissue into contact with the electrode array.

16. An ablation and/or coagulation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising:

an electrode array carried by an elongate member, the array including a fluid permeable elastic member having insulating and conductive regions thereon, the electrode array configured to permit moisture generated during ablation to pass actively and/or passively into the electrode array and away from underlying tissue;

a source of radio frequency energy electrically coupled to the conductive regions of the array.

17. The ablation and/or coagulation apparatus of claim 16 further including an elongate tube having at least one opening adjacent to the array and a vacuum source fluidly coupled to the elongate tube.

18. The apparatus of claim 16 wherein the fluid permeable elastic member includes metallized fabric.

19. The apparatus of claim 18 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

20. The apparatus of claim 18 wherein the metallized fabric includes yarns of spandex and nylon.

21. The apparatus of claim 16 wherein the array has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

22. The apparatus of claim 16 wherein the electrode array is carried by a deflecting mechanism moveable between a retracted position and an expanded position.

23. The apparatus of claim 22 wherein the deflecting mechanism includes a pair of elongate flexures.

24. The apparatus of claim 23 wherein the flexures include at least one fluid opening.

25. The apparatus of claim 22 wherein the deflecting mechanism includes electrically conductive regions electrically coupled to conductive regions of the electrode array.

26. The apparatus of claim 23 wherein the flexures include electrically conductive regions electrically coupled to conductive regions of the electrode array.

27. The apparatus of claim 16 further comprising:

width measurement means for measuring the approximate width of the organ.

28. The apparatus of claim 27 further comprising:

length measurement means for measuring the approximate length of the organ.

29. The apparatus of claim 27 further comprising means for determining an ablation power using the measured approximate width.

30. The apparatus of claim 28 further comprising means for determining an ablation power using the measured approximate width and length.

31. An ablation and/or coagulation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising:

an elongate member;

a deployment mechanism carried by the elongate member, the deployment mechanism moveable between a retracted position and a plurality of laterally expanded positions;

an electrode array carried by the deployment mechanism;

a sheath slidably disposed over the electrode array;

a handle coupled to the sheath and deployment mechanism, the handle moveable between an insertion position in which the sheath is disposed over the electrode array and the array is in an unexpanded condition, and a deployment position in which the electrode array extends from the distal end of the sheath and is in one of its expanded positions;

limiting means for selectively limiting lateral expansion of the deployment mechanism and for selectively limiting longitudinal extension of the array from the sheath; and

a source of radio frequency energy electrically coupled to the array.

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ABSTRACT OF THE DISCLOSURE

An apparatus and method for use in performing ablation or coagulation of organs and other tissue includes a metallized fabric electrode array which is substantially absorbent and/or permeable to moisture and gases such as steam and conformable to the body cavity. The array includes conductive regions separated by insulated regions arranged to produce ablation to a predetermined depth. Following placement of the ablation device into contact with the tissue to be ablated, an RF generator is used to deliver RF energy to the conductive regions and to thereby induce current flow from the electrodes to tissue to be ablated. As the current heats the tissue, moisture (such as steam or liquid) leaves the tissue causing the tissue to dehydrate. Suction may be applied to facilitate moisture removal. The moisture permeability and/or absorbency of the electrode carrying member allows the moisture to leave the ablation site so as to prevent the moisture from providing a path of conductivity for the current.

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Applicant or Patentee: Csaba Tr[redacted]et al.
Appln. or Patent No.: NEW
Filed or Issued: HEREWITH
For: A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

Attorney's
Docket No.: ENVS-220

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(c)) - SMALL BUSINESS CONCERN

I hereby declare that I am
[] the owner of the small business concern identified below:
[X] an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN Novacept
ADDRESS OF CONCERN 1047 Elwell Court, Palo Alto, CA 94303

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION by inventor(s) Csaba Truckai et al. described in

[X] the specification filed herewith with title as listed above.
[] application no. , filed .
[] patent no. , issued .

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27).

NAME _____
ADDRESS _____
[ ] Individual [ ] Small Business Concern [ ] Nonprofit Organization

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[ ] Individual [ ] Small Business Concern [ ] Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time or paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Csaba Truckai
TITLE OF PERSON OTHER THAN OWNER Vice Pres. of Research and Development
ADDRESS OF PERSON SIGNING 1047 Elwell Court, Palo Alto, CA 94303

SIGNATURE: _____ DATE: _____

Atty Docket No. ENVS-220 []

DECLARATION FOR CIP PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship ar as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

the specification of which (check one) _X_ is attached hereto or ___ was filed on ____ as Application No. __ and was amended on ____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed Yes	No
Number	Country	Day/Month/Year Filed		
Number	Country	Day/Month/Year Filed		

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) below.

60/084,791	May 8, 1998
Application Number	Filing Date
Application Number	Filing Date

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

08/632,516 [Patent No. 5,769,880]	April 12, 1996	Patented
Application Number	Filing Date	Status: Patented, Pending, Abandoned
Application Number	Filing Date	Status: Patented, Pending, Abandoned

Attorney Dock. No. ENVS-220

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are beli ved to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fin or imprisonment or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Csaba Truckai

Inventor's signature _____ Date

Residence 627 Alberta Avenue, Sunnyvale, CA 94087

Citizenship USA

Post Office Address 627 Alberta Avenue, Sunnyvale, CA 94087

Full name of second joint inventor, if any, Russel Mahlon Sampson

Inventor's signature _____ Date

Residence 271 Diablo Ave, Mountain View, CA 94043

Citizenship USA

Post Office Address 271 Diablo Ave, Mountain View, CA 94043

Full name of third joint inventor, if any, Stephanie Squarcia

Inventor's signature _____ Date

Residence 411 California Ave, Apt. 14, Palo Alto, CA 94306

Citizenship USA

Post Office Address 411 California Ave, Apt. 14, Palo Alto, CA 94306

Full name of fourth joint inventor, if any, Alfonzo Lawrence Ramirez

Inventor's signature _____ Date

Residence 2911 Betsy Way, San Jose, CA 95133

Citizenship USA

Post Office Address 2911 Betsy Way, San Jose, CA 95133

Full name of fifth joint inventor, if any, Estela Hilario

Inventor's signature _____ Date

Residence 887 Altos Oaks Dr., Los Altos, CA 94024

Citizenship USA

Attorney Docket No. ENVS-220 II

ASSIGNMENT

WHEREAS, WE, Csaba Truckai, Russel Mehlon Sampson, Stephanie Squarcia, Alfonzo Lawrence Ramirez and Estela Hilario hereinafter referred to as "ASSIGNORS", have invented certain new and useful improvements as described and set forth in the below-identified application for United States Letters Patent:

Title of Invention: **A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION**

Application (Declaration/Oath) Execution Date: July 31, 1998 and August 4, 1998

Filing Date: June 23, 1998 Application No.: 09/103,072

WHEREAS, Novacept, a corporation of the State of California, 1047 Elwell Court, Palo Alto, CA 94303 hereinafter referred to as "ASSIGNEE", is desirous of acquiring the entire right, title and interest in the said invention and application and in any Letters Patent which may be granted on the same;

NOW, THEREFORE, TO ALL WHOM IT MAY CONCERN: Be it known that, for One Dollar ($1.00) and other good and valuable consideration, receipt of which is hereby acknowledged by Assignors, Assignors have sold, assigned and transferred, and by these presents do sell, assign and transfer unto the said Assignee, and Assignee's successors and assigns, all right, title and interest in and to the said invention, said application for United States Letters Patent, and any Letters Patent which may hereafter be granted on the same in the United States and all countries throughout the world including any divisions, renewals, continuations in whole or in part, substitutions, conversions, reissues, prolongations or extensions thereof, said interest to be held and enjoyed by said Assignee as fully and exclusively as it would have been held and enjoyed by said Assignors had this assignment and transfer not been made, to the full end and term of any such Letters Patent.

Assignors further agree that they will, without charge to said Assignee, but at Assignee's expense, cooperate with Assignee in the prosecution of said application and/or applications, execute, verify, acknowledge and deliver all such further papers, including applications for Letters Patent and for the reissue thereof, and instruments of assignment and transfer thereof, and will perform such other acts as Assignee lawfully may request, to obtain or maintain Letters Patent for said invention and improvement in any and all countries, and to vest title thereto in said Assignee, or Assignee's successors and assigns.

IN TESTIMONY WHEREOF, Assignor has hereunto signed his/her name to this assignment on the date indicated below.

Date: 8/5/98

Csaba Truckai

State of CA

County of SANTA CLARA

On 8/5/98 before me, ANN FOSTER,

personally appeared _____ personally known to me or proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

ANN FOSTER
Comm. # 1159470
NOTARY PUBLIC - CALIFORNIA
County of Santa Clara
My Comm. Expires Oct. 25, 2001

SEAL

WITNESS my hand and official seal.

Signature of Notary

Attorney Docket No. ENVS-220

IN TESTIMONY WHEREOF, Assignor has hereunto signed his/her name to this assignment on the date indicated below.

Date: 08-05-98

Russel Mahlon Sampson

State of CA

County of Santa Clara

On 8/5/98 before me, ANN FOSTER,

personally appeared RUSSEL MAHLON SAMPSON personally known to me or proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

ANN FOSTER
Comm. # 1159470
NOTARY PUBLIC - CALIFORNIA
County of Santa Clara
My Comm. Expires Oct. 25, 2001

SEAL

Signature of Notary

IN TESTIMONY WHEREOF, Assignor has hereunto signed his/her name to this assignment on the date indicated below.

Date: 8/5/98

Stephanie Squarcia

State of CA

County of Santa Clara

On 8/5/98 before me, ANN FOSTER,

personally appeared Stephanie Squarcia, personally known to me or proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

ANN FOSTER
Comm. # 1159470
NOTARY PUBLIC - CALIFORNIA
County of Santa Clara
My Comm. Expires Oct. 25, 2001

SEAL

Signature of Notary

Attorney Docket No. ENVS-220

IN TESTIMONY WHEREOF, Assignor has hereunto signed his/her name to this assignment on the date indicated below.

Date: 8-5-98

Alfonzo Lawrence Ramirez

State of CA

County of Santa Clara

On 8/5/98 before me, ANN FOSTER,

personally appeared Alfonzo L. Ramirez personally known to me or proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

SEAL

ANN FOSTER
Comm. # 1159470
NOTARY PUBLIC - CALIFORNIA
County of Santa Clara
My Comm. Expires Oct. 25, 2001

Signature of Notary

IN TESTIMONY WHEREOF, Assignor has hereunto signed his/her name to this assignment on the date indicated below.

Date: 8-5-98

Estela Hilario

State of CA

County of Santa Clara

On 8/5/98 before me, ANN FOSTER,

personally appeared _____, personally known to me or proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

ANN FOSTER
Comm. # 1159470
NOTARY PUBLIC - CALIFORNIA
County of Santa Clara
My Comm. Expires Oct. 25, 2001

Signature of Notary

PATENT APPLICATION FEE DETERMINATION RECORD

Effective October 1, 1997

Application or Docket Number: 09/103072

CLAIMS AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA
BASIC FEE		
TOTAL CLAIMS	31 minus 20 =	* 11
INDEPENDENT CLAIMS	3 minus 3 =	*
MULTIPLE DEPENDENT CLAIM PRESENT		

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐	RATE	FEE	OR	OTHER THAN SMALL ENTITY	RATE	FEE
BASIC FEE		395.00	OR	BASIC FEE		790.00
TOTAL CLAIMS	x$11=		OR	TOTAL CLAIMS	x$22=	242.00
INDEPENDENT CLAIMS	x41=		OR	INDEPENDENT CLAIMS	x82=	
MULTIPLE DEPENDENT CLAIM PRESENT	+135=		OR	MULTIPLE DEPENDENT CLAIM PRESENT	+270=	
	TOTAL		OR		TOTAL	1032.00

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 68	Minus	** 31	= 37
Independent	* 4	Minus	*** 3	= 1
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY	RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY	RATE	ADDITIONAL FEE
Total	x$11=	333	OR	Total	x$22=	666
Independent	x41=	41	OR	Independent	x82=	82
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM	+135=		OR	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM	+270=	
	TOTAL ADDIT. FEE	374	OR		TOTAL ADDIT. FEE	748

PL 6/23/03 PL 6/23/03

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY	RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY	RATE	ADDITIONAL FEE
Total	x$11=		OR	Total	x$22=	
Independent	x41=		OR	Independent	x82=	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM	+135=		OR	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM	+270=	
	TOTAL ADDIT. FEE		OR		TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY	RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY	RATE	ADDITIONAL FEE
Total	x$11=		OR	Total	x$22=	
Independent	x41=		OR	Independent	x82=	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM	+135=		OR	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM	+270=	
	TOTAL ADDIT. FEE		OR		TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-875 (Rev. 8/97) *U.S. Government Printing Office: 1997 - 430-571/69194 Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

HOL-MIN_146901

CLAIMS ONLY

SERIAL NO.	FILING DATE
APPLICANT(S)	

CLAIMS

	AS FILED		AFTER 1st AMENDMENT		AFTER 2nd AMENDMENT	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
1						
2						
3						
4						
5			1			
6			1			
7			1			
8						
9						
10						
11						
12						
13						
14						
15			1			
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33						
34				1		
35				1		
36				1		
37				1		
38				1		
39				1		
40				1		
41				1		
42				1		
43				1		
44				1		
45				1		
46				1		
47				1		
48				1		
49				1		
50				1		
TOTAL IND.			4			
TOTAL DEP.			64			
TOTAL CLAIMS			68			

	*		*		*	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
51				1		
52				1		
53				1		
54				1		
55				1		
56				1		
57				1		
58				1		
59				1		
60				1		
61				1		
62				1		
63				1		
64				1		
65				1		
66				1		
67				1		
68				1		
69				1		
70				1		
71				1		
72				1		
73				1		
74				1		
75				1		
76				1		
77				1		
78				1		
79				1		
80				1		
81				1		
82				1		
83				1		
84				1		
85				1		
86				1		
87				1		
88				1		
89				1		
90				1		
91				1		
92				1		
93				1		
94				1		
95				1		
96						
97						
98						
99						
100						
TOTAL IND.						
TOTAL DEP.						
TOTAL CLAIMS						

* MAY BE USED FOR ADDITIONAL CLAIMS OR ADMENDMENTS

FORM PTO-2022 (1-98)

U.S.DEPARTMENT OF COMMERCE
Patent and Trademark Office

*U.S. GPO: 1998-443-593/89152

SECTOR

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	Group Art Unit: 3736
Csaba Truckai et al.	Examiner: Unknown
Appln. No. 09/103,072	**RESPONSE TO NOTICE TO FILE MISSING PARTS OF APPLICATION AND SUBMISSION OF SMALL ENTITY STATUS, POWER OF ATTORNEY, AND DECLARATION**
Filed: June 23, 1998	
For: **MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION**	2001 Ferry Building San Francisco, CA 94111 415/433-4150

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on August 13, 1998.

LIMBACH & LIMBACH L.L.P. Date: 8/13/98

By: Beryl Anne Keys

Name: Beryl Anne Keys

Box Missing Parts
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Notice to File Missing Parts of Application mailed July 17, 1998 (copy enclosed), applicant submits the enclosed Declaration for Patent Application and Verified Statement Claiming Small Entity Status-Small Business Concern.

Also enclosed is a Power of Attorney by Assignee.

A check in the amount of $581.00 is enclosed herewith to cover the $65.00 surcharge for filing missing parts of an application, and the basic filing fee of $516.00.

The Commissioner is hereby authorized to charge payment of any **additional** fees associated with this communication or credit any overpayment to Deposit Account No. 12-1420. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

LIMBACH & LIMBACH L.L.P.

08/20/1998 SCARMICH 00000076 09103072

01 FC:201 395.00 OP
02 FC:205 65.00 OP
03 FC:203 21.00 OP

August 13, 1998
(Date)

By: Kathleen A. Frost
Kathleen A. Frost
Registration No. 37,326

ENVS-220

Attorneys for Applicant(s)

PATENTS\MISSPART.MRG

Rev. 03/06/98

HOL-MIN_146903

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO./TITLE
09/103,072	06/23/1998	TRUCKAI	ENVS-220

AUG 17 1998

0242/0717

KATHLEEN A FROST
LIMBACH & LIMBACH
2001 FERRY BUILDING
SAN FRANCISCO CA 94111

NOT ASSIGNED

DATE MAILED: 3736

NOTICE TO FILE MISSING PARTS OF APPLICATION

07/17/98

Filing Date Granted

An Application Number and Filing Date have been assigned to this application. The items indicated below, however, are missing. Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). **If any of items 1 or 3 through 5 are indicated as missing, the SURCHARGE set forth in 37 CFR 1.16(e) of ☐ $65.00 for a small entity in compliance with 37 CFR 1.27, or ☐ $130.00 for a non-small entity, must also be timely submitted in reply to this NOTICE to av id abandonment.**

If all required items on this form are filed within the period set above, the total amount owed by applicant as a ☐ small entity (statement filed) ☐ non-small entity is $ 1162.

☑ 1. The statutory basic filing fee is:
- ☑ missing.
- ☐ insufficient.

Applicant must submit $ 790 to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27).

☐ 2. Additional claim fees of $ 372 including any multiple dependent claim fees, are required.

$ _____ for _____ independent claims over 3.

$ 242 for 11 dependent claims over 20.

$ _____ for multiple dependent claim surcharge.

Applicant must either submit the additional claim fees or cancel additional claims for which fees are due.

☐ 3. The oath or declaration:
- ☑ is missing or unexecuted.
- ☐ does not cover the newly submitted items.
- ☐ does not identify the application to which it applies.
- ☐ does not include the city and state or foreign country of applicant's residence.

An oath or declaration in compliance with 37 CFR 1. 63, including residence information and identifying the application by the above Application Number and Filing Date is required.

☐ 4. The signature(s) to the oath or declaration is/are by a person other than inventor or person qualified under 37 CFR 1.42, 1.43 or 1.47.

A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:

_____

An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

☐ 6. A $50.00 processing fee is required since your check was returned without payment (37 CFR 1.21(m)).

☐ 7. Your filing receipt was mailed in error because your check was returned without payment.

☐ 8. The application does not comply with the Sequence Rules.

See attached "Notice to Comply with Sequence Rules 37 CFR 1.821-1.825."

☐ 9. OTHER

Direct the reply and any questions about this notice to "Attention: Box Missing Parts."

A copy of this notic MUST b returned with the reply.

K. Carol Smith

Customer Service Center
Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE

HOL-MIN_146904

Applicant or Patentee: Csaba [redacted] et al.

Attorney's

Appln. No.: 09/103,072

Docket No.: ENVS-220

Filed: June 23, 1998

For: A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(c)) - SMALL BUSINESS CONCERN

I hereby declare that I am

[ ] the owner of the small business concern identified below:

[X] an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN Novacept

ADDRESS OF CONCERN 1047 Elwell Court, Palo Alto, CA 94303

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled **A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION** by inventor(s) Csaba Truckai et al. described in

[X] the specification filed herewith with title as listed above.

[ ] application no. , filed .

[ ] patent no. , issued .

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27).

NAME _____

ADDRESS _____

[ ] Individual [ ] Small Business Concern [ ] Nonprofit Organization

NAME _____

ADDRESS _____

[ ] Individual [ ] Small Business Concern [ ] Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time or paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Csaba Truckai

TITLE OF PERSON OTHER THAN OWNER Vice Pres. of Research and Development

ADDRESS OF PERSON SIGNING 1047 Elwell Court, Palo Alto, CA 94303

SIGNATURE: _____ DATE: 08-05-98

Atty Dock t No. ENVS-220 []

DECLARATION FOR CIP PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship ar as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

the specification of which (check one) ___ is attached hereto or __X__ was filed on June 23, 1998 as Application No. 09/103,072 and was amended on ___ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed Yes	No
Number	Country	Day/Month/Year Filed		
Number	Country	Day/Month/Year Filed		

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) below.

60/084,791	May 8, 1998
Application Number	Filing Date
Application Number	Filing Date

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

08/632,516 [Patent No. 5,769,880]	April 12, 1996	Patented
Application Number	Filing Date	Status: Patented, Pending, Abandoned
Application Number	Filing Date	Status: Patented, Pending, Abandoned

Attorney Dock. No. ENVS-220

I hereby d clare that all statements made h rein of my own knowledg are true and that all statements made on information and beli f are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so mad are punishable by fine or imprisonment or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Csaba Truckai

Inventor's signature _____ 07.31.98 Date

Residence 627 Alberta Avenue, Sunnyvale, CA 94087

Citizenship USA

Post Office Address 627 Alberta Avenue, Sunnyvale, CA 94087

Full name of second joint inventor, if any, Russel Mahlon Sampson

Inventor's signature _____ 07.31.98 Date

Residence 271 Diablo Ave, Mountain View, CA 94043

Citizenship USA

Post Office Address 271 Diablo Ave, Mountain View, CA 94043

Full name of third joint inventor, if any, Stephanie Squarcia

Inventor's signature _____ 8/4/98 Date

Residence 411 California Ave, Apt. 14, Palo Alto, CA 94306

Citizenship USA SJS 8/4/98

Post Office Address 411 California Ave, Apt. 14, Palo Alto, CA 94306

SJS 8/4/98

Full name of fourth joint inventor, if any, ~~Alfonzo~~ Alfonso Lawrence Ramirez

Inventor's signature _____ 8-4-98 Date

Residence 2911 Betsy Way, San Jose, CA 95133

Citizenship USA

Post Office Address 2911 Betsy Way, San Jose, CA 95133

Full name of fifth joint inventor, if any, Estela Hilario

Inventor's signature _____ 8-4-98 Date

Residence 887 Altos Oaks Dr., Los Altos, CA 94024

Citizenship USA

Post Office Address 887 Altos Oaks Dr., Los Altos, CA 94024

Attorney Docket No. ENVS-220

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES PATENT

In re Patent Application of	Group Art Unit: Unknown
Csaba Truckai et al.	**POWER OF ATTORNEY BY ASSIGNEE AND CERTIFICATE BY ASSIGNEE UNDER 37 CFR § 3.73(b)**
Appln. No. 09/103,072	
Filed: June 23, 1998	
For: **A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION**	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Novacept, assignee of the entire right title and interest in the above-identified application by assignment dated 8/5/98, which assignment is [ ] recorded in the Patent and Trademark Office at Reel , frame , [X] attached hereto, hereby appoints the members of the firm of LIMBACH & LIMBACH L.L.P., a firm composed of:

Karl A. Limbach	18,689	W. Patrick Bengtsson	32,456	Kyla L. Harriel	P-41,816
George C. Limbach	19,305	Mark A. Dalla Valle	34,147	Mayumi Maeda	40,075
John K. Uilkema	20,282	Charles P. Sammut	28,901	Kent J. Tobin	39,496
Neil A. Smith	25,441	Mark C. Pickering	36,239	Christine S. Ring	P-42,106
Veronica C. Devitt	29,375	Kathleen A. Frost	37,326	Michael R. Ward	38,651
Ronald L. Yin	27,607	Alan S. Hodes	38,185	Steven M. Santisi	40,157
Gerald T. Sekimura	30,103	Patricia Coleman James	37,155	Charles L. Hamilton	P-42,624
Michael A. Stallman	29,444	Alan A. Limbach	39,749	Andrew V. Smith	P-43,132
Philip A. Girard	28,848	Douglas C. Limbach	35,249	Heath W. Hoglund	41,076
Michael J. Pollock	29,098	Brian J. Keating	39,520	J. Thomas McCarthy	22,420
Stephen M. Everett	30,050	Seong-Kun Oh*			
Alfred A. Equitz	30,922	Cameron A. King	P-41,897		

* Recognition under 37 CFR 10.9(b)

as its attorneys with full power of substitution to prosecute this application and to transact all business in the Patent and Trademark Office in connection therewith.

The assignee certifies that it has reviewed the assignment and to the best of the assignee's knowledge and belief, title is in the assignee.

Please direct all correspondence regarding this application to the following:

LIMBACH & LIMBACH L.L.P.
Attn: Kathleen A. Frost
2001 Ferry Building
San Francisco, CA 94111

Telephone: (415) 433-4150
Facsimile: (415) 433-8716

Dated: 8/10/98

Novacept

By: _____ 8-10-98
Name: Csaba Truckai
Title: Vice Pres. of Research and Development

PATENTS\PWR&ASN.MRG

Rev. 03/25/98

HOL-MIN_146908

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A list of the patent(s) or publication(s) is set forth on the attached Form PTO-1449 (Modified).

A copy of the items on PTO-1449 (Modified) is supplied herewith:

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached form PTO-1449 (Modified) are not supplied because they were previously cited by or submitted to the Office in a prior application no. , filed and relied upon in this application for an earlier filing date under 35 U.S.C. § 120.

A concise explanation of relevance of the items listed on form PTO-1449 (Modified) is:

(k) [x] not given

(l) [] given for each listed item

(m) [] given for only non-English language listed item(s) [Required]

(n) [] is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references [copy attached].

The Examiner is reminded that a "concise explanation of the relevance" of the submitted items "may be nothing more than identification of the particular figure or paragraph of the patent or publication which has some relation to the claimed invention," MPEP § 609.

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR § 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein

is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR § 1.56(a) exists. It is submitted that the Information Disclosure Statement is in compliance with 37 CFR § 1.98 and MPEP § 609 and the Examiner is respectfully requested to consider the listed references.

[x] The Commissioner is hereby authorized to charge our Deposit Account No. 12-1420 for any fees required in connection with the filing of this Information Disclosure Statement. **A duplicate copy of this Notice is enclosed for this purpose.** In particular, in the event that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is authorized to charge the above-named deposit account for any fees required pursuant to CFR §§ 1.17(p) or 1.17(i)(1).

Respectfully submitted,
LIMBACH & LIMBACH L.L.P.

Dated: 10-16-98

By: Kathleen A. Frost
Kathleen A. Frost
Reg. No. 37,326
Tel. No. 415/433-4150

Our File: ENVS-220

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/103,072	06/23/98	TRUCKAI	C ENVS-220

EXAMINER

QM31/0621

KATHLEEN A FROST
LIMBACH & LIMBACH
2001 FERRY BUILDING
SAN FRANCISCO CA 94111

ART UNIT	PAPER NUMBER
3762	6

DATE MAILED: 06/21/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 6/23/98

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-31 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 1-4, 6, 7, 8-14, 16, 18-23, 25-31 is/are rejected.
☑ Claim(s) 5-7, 15, 17, 24 is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☑ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5
☐ Interview Summary, PTO-413
☑ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

Drawings

1. Since allowable subject matter has been indicated, applicant is encouraged to submit formal drawings in response to this Office action. The early submission of formal drawings will permit the Office to review the drawings for acceptability and to resolve any informalities remaining therein before the application is passed to issue. This will avoid possible delays in the issue process.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1, 3, 8, 16, 22, 25 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Stern et al '470.

Stern et al '460 discloses the invention substantially as claimed including an expansible member constructed of open-cell, porous material which do to its structure will act to absorb moisture when this surface is not coated with a paste or gel.

4. Claim 31 is rejected under 35 U.S.C. 102(e) as being anticipated by Edwards.

Edwards discloses an elongate member (15), a deployment mechanism (12), an electrode array (40), a sheath (14), a handle (16), a limiting means (20, 22, 23, 24) and a source of RF energy is supplied to the electrodes (column 4, line 46).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2, 9-14, 18-22 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al '470.

Stern et al '470 discloses the invention substantially as claimed except for the fluid permeable member including a variety of fabrics, the step of measuring the length and width of the organ being treated and width measurment means. The material used in the construction of the

permeable member would have been an obvious design choice in the absence of any new or unobvious results, the material being used being dependent upon its absorption properties and biocompatibility with the body. It would be obvious to one of ordinary skill in the art to survey the organ being treated as to its size, shape etc. as a preliminary step in the treatment proceedure. Measurment means is accomplished by comparing the dimensions of the organ to the known measurments of the treatment mechanism.

7. Claims 4, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al '470 in view of Chin (WO 95/07664).

Stern et al. '470 discloses the invention substantially as claimed except for the use of spring members to assist in the deployment of the electrode carrying member. Chin discloses spring members (50, 52) which assist in the deployment of the balloon (10) into proper configuration in the uterus during organ ablation. It would have been obvious to one of ordinary skill in the art to provide similar additional support means in the balloon structure of Stern et al. In order to assist in the proper placement of the device in the uterus for the ablation proceedure.

Allowable Subject Matter

8. Claims 5-7, 15, 17 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record does not teach openings in elements of the device for actively withdrawing moisture from the treatment site.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kent Gring whose telephone number is (703) 308-2214. The examiner can normally be reached on Monday - Friday from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Kent Gring

June 18, 1999

CORRINE McDERMOTT
PRIMARY EXAMINER

Form PTO 948 (Rev. 8-98) U.S. DEPARTMENT OF COMMERCE - Patent and Trademark Office Application No. 103072

NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW

The drawing(s) filed (insert date) 6/23/98 are:

A. ☐ approved by the Draftsperson under 37 CFR 1.84 or 1.152.

B. ☒ objected to by the Draftsperson under 37 CFR 1.84 or 1.152 for the reasons indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawing must be sumitted according to the instructions on the back of this notice.

1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings: Black ink. Color.
   - ___ Color drawings are not acceptable until petiton is granted. Fig(s) _____
   - ___ Pencil and non black ink not permitted. Fig(s) _____
2. PHOTOGRAPHS. 37 CFR 1.84 (b)
   - ___ 1 full-tone set is required. Fig(s) _____
   - ___ Photographs not properly mounted (must use brystol board or photographic double-weight paper). Fig(s) _____
   - ___ Poor quality (half-tone). Fig(s) _____
3. TYPE OF PAPER. 37 CFR 1.84(e)
   - ___ Paper not flexible, strong, white, and durable. Fig(s) _____
   - ___ Erasures, alterations, overwritings, interlineations, folds, copy machine marks not accepted. Fig(s) _____
   - ___ Mylar, velum paper is not acceptable (too thin). Fig(s) _____
4. SIZE OF PAPER. 37 CFR 1.84(f): Acceptable sizes:
   - ___ 21.0 cm by 29.7 cm (DIN size A4)
   - ___ 21.6 cm by 27.9 cm (8 1/2 x 11 inches)
   - ___ All drawing sheets not the same size. Sheet(s) _____
   - ___ Drawings sheets not an acceptable size. Fig(s) _____
5. MARGINS. 37 CFR 1.84(g): Acceptable margins:

   Top 2.5 cm Left 2.5cm Right 1.5 cm Bottom 1.0 cm SIZE: A4 Size

   Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm SIZE: 8 1/2 x 11

   Margins not acceptable. Fig(s) 21 26 32 4B 36A, 37B
   - ☒ Top (T) ☒ Left (L)
   - ___ Right (R) ☒ Bottom (B)
6. VIEWS. 37 CFR 1.84(h)

   REMINDER: Specification may require revision to correspond to drawing changes.

   Partial views. 37 CFR 1.84(h)(2)
   - ___ Brackets needed to show figure as one entity. Fig(s) _____
   - ___ Views not labeled separately or properly. Fig(s) _____
   - ☒ Enlarged view not labeled separetely or properly. Fig(s) 27
7. SECTIONAL VIEWS. 37 CFR 1.84 (h)(3)
   - ___ Hatching not indicated for sectional portions of an object. Fig(s) _____
   - ___ Sectional designation should be noted with Arabic or Roman numbers. Fig(s) _____
8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)
   - ___ Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s) _____
9. SCALE. 37 CFR 1.84(k)
   - ___ Scale not large enough to show mechanism without crowding when drawing is reduced in size to two-thirds in reproduction. Fig(s) _____
10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(i)
    - ☒ Lines, numbers & letters not uniformly thick and well defined,clean, durable, and black (poor line quality). Fig(s) 21-36
11. SHADING. 37 CFR 1.84(m)
    - ___ Solid black areas pale. Fig(s) _____
    - ___ Solid black shading not permitted. Fig(s) _____
    - ___ Shade lines, pale, rough and blurred. Fig(s) _____
12. NUMBERS, LETTERS, & REFERENCE CHARACTERS. 37 CFR 1.84(p)
    - ___ Numbers and reference characters not plain and legible. Fig(s) _____
    - ___ Figure legends are poor. Fig(s) _____
    - ___ Numbers and reference characters not oriented in the same direction as the view. 37 CFR 1.84(p)(1) Fig(s) _____
    - ___ English alphabet not used. 37 CFR 1.84(p)(2) Figs _____
    - ___ Numbers, letters and reference characters must be at least .32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3) Fig(s) _____
13. LEAD LINES. 37 CFR 1.84(q)
    - ___ Lead lines cross each other. Fig(s) _____
    - ___ Lead lines missing. Fig(s) _____
14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(t)
    - ___ Sheets not numbered consecutively, and in Arabic numerals beginning with number 1. Sheet(s) _____
15. NUMBERING OF VIEWS. 37 CFR 1.84(u)
    - ___ Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s) _____
16. CORRECTIONS. 37 CFR 1.84(w)
    - ___ Corrections not made from prior PTO-948 dated _____
17. DESIGN DRAWINGS. 37 CFR 1.152
    - ___ Surface shading shown not appropriate. Fig(s) _____
    - ___ Solid black shading not used for color contrast. Fig(s) _____

COMMENTS

REVIEWER _____ DATE 8/24/01 TELEPHONE NO. _____

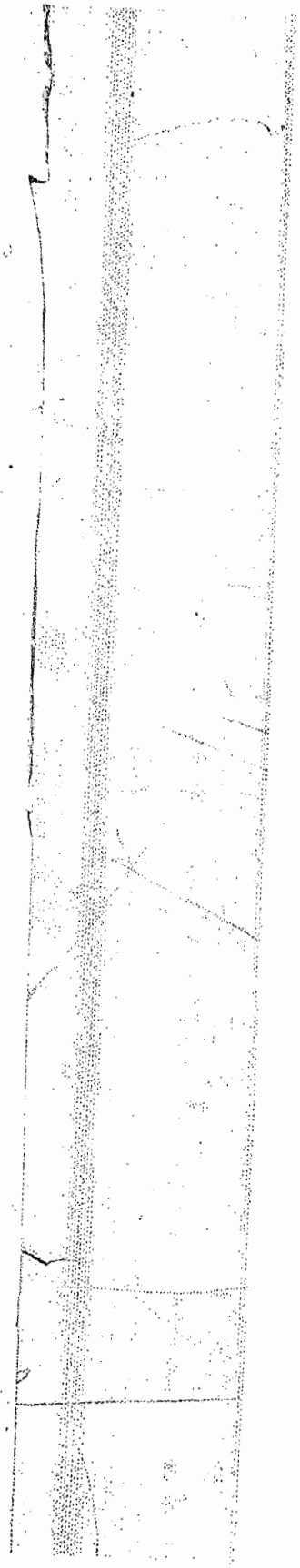
ATTACHMENT TO PAPER NO. _____

Attachment 6

The drawings submitted with this application were declared informal by the applicant. Accordingly they have not been reviewed by a draftsperson at this time. When formal drawings are submitted, the draftsperson will perform a review.

Direct any inquires concerning drawing review to the Drawing Review Branch (703) 305-8404.

Substitute PTO-948



HOL-MIN_146919

PATENT

Sheet 1 of 2

FORM PTO-1449 (Modified) (Rev. 7-80)	U.S Dept. of Commerce Patent and Trademark Office	Atty Docket No. ENVS-220	Serial No. 09/103,072
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)		Applicant(s) Csaba Truckai ET AL.	
		Filing Date 06/23/98	Group 3736

OIPE OCT 26 1998 PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

*Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	AA	1,620,929	03/15/27	Wallerich	—	—	02/05/25
	AB	1,827,306	10/13/31	Chapman et al.	—	—	09/14/25
	AC	2,190,383	02/13/40	Newman	128	401	08/29/36
	AD	2,466,042	04/05/49	Reich et al.	128	401	08/26/47
	AE	3,645,265	02/29/72	Majzlin	128	303.13	06/25/69
	AF	3,840,016	10/08/74	Lindemann	128	303.17	03/07/73
	AG	3,924,628	12/09/75	Droegemueller et al.	128	303.1	12/01/72
	AH	3,948,270	04/06/76	Hasson	128	348	10/15/74
	AI	4,057,063	11/08/77	Gieles et al.	128	303.17	02/27/76
	AJ	4,601,698	07/22/86	Moulding, Jr.	604	55	09/17/84
	AK	4,960,133	10/02/90	Hewson	128	784	11/21/88
	AL	4,662,383	05/05/87	Sogawa et al.	128	784	09/23/83
	AM	4,676,258	06/30/87	Inokuchi et al.	128	804	06/05/86
	AN	4,832,048	05/23/89	Cohen	128	786	10/29/87
	AO	4,865,047	09/12/89	Chou et al.	128	784	06/30/88
	AP	4,949,718	08/21/90	Neuwirth et al.	128	401	09/09/88
	AQ	4,961,435	10/09/90	Kitagawa et al.	128	788	10/17/88
	AR	4,979,948	12/25/90	Geddes et al.	606	33	04/13/89
	AS	5,057,106	10/15/91	Kasevich et al.	606	33	07/09/90
	AT	5,084,044	01/28/92	Quint	606	27	07/14/89
	AU	5,105,808	04/21/92	Neuwirth et al.	128	401	08/09/90
	AV	5,147,353	09/15/92	Everett	606	15	03/23/90
	AW	5,159,925	11/03/92	Neuwirth et al.	128	401	01/28/91
	AX	5,186,181	02/16/93	Franconi et al.	128	804	07/27/90
	AY	5,188,122	02/23/93	Phipps et al.	128	788	06/20/90
	AZ	5,188,602	02/23/93	Nichols	604	113	06/08/92
	BA	5,248,312	09/28/93	Langberg	606	28	06/01/92

Examiner	Date Considered
Greg Lee	6/15/99 8/24/01

* Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PATENT

Sheet 2 of 2

FORM PTO-1449 (Modified) (Rev. 7-80)	U.S Dept. of Commerce Patent and Trademark Office	Atty Docket No. ENVS-220	Serial No. 09/103,072
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)		Applicant(s) Csaba Truckai ET AL.	
		Filing Date 06/23/98	Group 3736

OIPE OCT 26 1998 PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

*Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	BB	5,277,201	01/11/94	Stern	607	98	05/01/92
	BC	5,308,327	05/03/94	Heaven et al.	604	96	11/25/91
	BD	5,334,193	08/02/94	Nardella	606	41	11/13/92
	BE	5,433,708	07/18/95	Nichols et al.	604	113	06/07/93
	BF	5,437,629	08/01/95	Goldrath	604	21	04/14/94
	BG	5,443,470	08/22/95	Stern et al.	607	98	04/14/93
	BH	5,364,393	11/15/94	Auth et al. (abstract only)	606	34	12/30/93
	BI	5,505,730	04/09/96	Edwards	606	41	06/24/94 -
	BJ	5,797,903	08/25/98	Swanson et al.	606	34	04/12/96
	BK	4,691,703	09/08/87	Auth et al. (abstract only)	606	31	04/25/86
	BL	4,582,057	04/15/86	Auth et al. (abstract only)	606	31	11/21/83
	BM	4,532,924	08/06/85	Auth et al.	606	50	04/30/82
	BN	4,492,231	01/08/85	Auth (abstract only)	606	42	09/17/82
	BO	4,449,528	05/22/84	Auth et al. (abstract only)	606	31	07/20/81

FOREIGN PATENT DOCUMENTS

*Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation YES	Translation NO
	BP	WO 92/19145	11/12/92	PCT	A61B	—	X	
	BQ	WO 94/07445	04/14/94	PCT	A61F		X	
	BR	0584930A1	03/02/94	EPO	A61B		X	
	BS	WO 95/07664	03/23/95	PCT	A61B		X	
	BT	WO 95/10326	04/20/95	PCT	A61N		X	
	BU	WO 94/10948	05/26/94	PCT	A61F		X	
	BV	WO 94/23794	10/27/94	PCT	A61N		X	
	BW	WO 95/05869	03/02/95	PCT	A61N		X	
	BX	WO 95/04385	02/09/95	PCT	H01Q		X	

Examiner	Date Considered
	8/24/01 6/15/99

* Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PATENT

V. Douglas #8/a 1-4-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

CSABA TRUCKAI , et al.

Application No. 09/103,072

Filed: June 23, 1998

For: MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

Group Art Unit: 3736

Examiner: Gring, N

RESPONSE TO OFFICIAL ACTION MAILED JUNE 21, 1999

2001 Ferry Building
San Francisco, CA 94111
(415) 433-4150

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: , Assistant Commissioner for Patents, Washington, DC 20231, on December 21, 1999.

LIMBACH & LIMBACH LLP Date: 12/21/99

By: Pat Gamble
Pat Gamble

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Applicants make the following amendments and remarks in response to the official action mailed June 21, 1999:

In the Claims:

Please amend Claims 5-7, 15, 17 and 24:

5. (AMENDED) A method of ablating and/or coagulating tissue, comprising the steps of: [The method of claim 4 wherein each flexure includes]

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member and a pair of elongate flexures wherein each flexure includes at least one opening, the

Rev. 09/15/99

GP3736 $

LIMBACH & LIMBACH L.L.P.
2001 Ferry Building
San Francisco, CA 94111
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Attorney Docket No. ENVS-220

In re Patent Application of: Csaba Truckai et al.

Application No.: 09/103,072

Filed: June 23, 1998

For: **MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

The fee has been calculated as shown below.

	(Col. 1) CLAIMS REMAINING AFTER AMENDMENT		(Col. 2) HIGHEST NO. PREVIOUSLY PAID FOR	(Col. 3) PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL	* 33	MINUS	** 31	= 2	x 18 =	$ 36
INDEP.	* 11	MINUS	*** 3	= 8	x 78 =	$ 624
FIRST PRESENTATION OF MULTIPLE DEP CLAIM					+260 =	
					TOTAL	$ 670.00
Small Entity 50% Filing Fee Reduction (if applicable)						$ 335.00

* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.
The "Highest Number Previously Paid For" (Total or Independent is the highest number found from the equivalent box in Col. 1 of a prior amendment or the number of claims originally filed.)

1. ___ No additional fee is required.

2. _X_ A check in the amount of $770.00 is attached to cover additional claims fee and three month extension of time.

3. _x_ Please charge any additional fees, including any fees necessary for extensions of time, or credit overpayment to Deposit Account No. 12-1420.
A duplicate copy of this sheet is enclosed.

4. _x_ Petition for extension of time. The undersigned attorney of record hereby petitions for an extension of time pursuant to 37 C.F.R. § 1.136(a), as may be required, to file this response.

LIMBACH & LIMBACH L.L.P.

Dated: December 21, 1999 By: _____
Kathleen A. Frost
Registration No. 37,326
Attorneys for Applicant(s)

CERTIFICATE OF MAILING

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Dated: December 21, 1999 By: _____

electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition by expanding the flexures;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the electrode carrying member and away from the tissue and allowing at least a portion of the moisture to pass through the openings in the flexures.

6. (AMENDED) A method of ablating and/or coagulating tissue, comprising the steps of: [The method of claim 1 wherein step (d) includes]

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the electrode carrying member and away from tissue and

permitting at least a portion of the moisture to pass from the array into the tubular member.

7. (AMENDED) A method of ablating and/or coagulating tissue, comprising the steps of: [The method of claim 3 wherein step (d) includes the step of]

(a) providing an ablation device including an expandable electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated and moving the array to an expanded condition;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the electrode carrying member and away from the tissue, including applying suction to draw the moisture through the tubular member.

15. (AMENDED) A method of ablating and/or coagulating tissue, comprising the steps of: [The method of claim 1 including the step of]

(a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid

permeable elastic member having insulating regions and conductive regions thereon;

(b) positioning the electrode array into contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate;

(d) permitting moisture generated during the dehydration of step (c) to pass into the electrode carrying member and away from the tissue and

(e) applying suction through the tubular member to draw the tissue into contact with the electrode array.

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17. (AMENDED) An ablation and/or coagulation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising:

[The ablation and/or coagulation apparatus of claim 16 further including an elongate tube having at least one opening adjacent to the array and a vacuum source fluidly coupled to the elongate tube]

an electrode array carried by an elongate member, the array including a fluid permeable elastic member having insulating and conductive regions thereon, the electrode array configured to permit moisture generated during ablation to pass actively and/or passively into the electrode array and away from underlying tissue;

a source of radio frequency energy electrically coupled to the conductive regions of the array;

an elongate tube having at least one opening adjacent to the array;

and a vacuum source fluidly coupled to the elongate tube.

24. (AMENDED) An ablation and/or coagulation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising:

[The apparatus of claim 23 wherein the flexures include at least one fluid opening]

an electrode array carried by a deflecting mechanism moveable between a retracted position and an expanded position wherein the deflecting mechanism includes a pair of elongate flexures that include at least one fluid opening, the array including a fluid permeable elastic member having insulating and conductive regions thereon, the electrode array configured to permit moisture generated during ablation to pass actively and/or passively into the electrode array and away from underlying tissue;

a source of radio frequency energy electrically coupled to the conductive regions of the array.

Please add new Claims 32 and 33:

--32. (NEW) A method of ablating and/or coagulating tissue, comprising the steps of:

(a) providing an ablation device including an electrode array carried by an elongate member, the electrode array including a fluid permeable metallized fabric member having insulating regions and conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be ablated;

(c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of step (c) to pass into the electrode carrying member and away from the tissue.

--33. (NEW) An ablation and/or coagulation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising:

an electrode array carried by an elongate member, the array including a fluid permeable metallized fabric member having insulating and conductive regions thereon, the electrode array configured to permit moisture generated during ablation to pass actively and/or passively into the electrode array and away from underlying tissue;

a source of radio frequency energy electrically coupled to the conductive regions of the array.--

REMARKS

Claims 5-7, 15, 17, and 24 have been amended. New Claims 32 and 33 are added. Claims 1 – 33 are now pending.

I. Prior Art Rejections

A. *Rejections Under U.S.C. §102*

Claims 1, 3, 8, 16, 22, 25 and 26 have been rejected under 35 U.S.C. §102 as being anticipated by Stern et al, U.S. Patent 5,433,470.

Applicants respectfully submit that the Stern reference fails to disclose or fairly suggest the step of permitting moisture generated during the dehydration of tissue to pass into an electrode carrying member and away from the tissue, as recited in Claims 1, 3 and 8. The

open-cell, porous material mentioned at Stern Col. 5, lines 47-53 is described as being filled with gel or foam, which is critical to the Stern device's ability to deliver energy to the underlying tissue. The reference appears to include no mention or suggestion for permitting, either actively or passively, moisture to pass into the material and away from the tissue.

Likewise, there is no disclosure in Stern of a fluid permeable elastic member configured to permit moisture generated during ablation to pass into the electrode carrying member and away from underlying tissue, as is recited in Claims 16, 22, 25 and 26. For this reason, Claims 1, 3, 8, 16, 22, 25 and 26 are not anticipated by Stern.

Claim 31 stands rejected as being anticipated by Edwards. However, as far as Applicants can see Edwards lacks teaching of "limiting means for selectively limiting lateral expansion of the deployment mechanism and for selectively limiting longitudinal extension of the array from the sheath." Edwards' switch 20 rotates the viewing optics. Switch 21 controls movement of sleeve 14. Switch 22 causes hinge 18 to pivot the balloon 12. Switch 23 controls RF delivery. Switch 24 controls flow of electrolytic solution. As far as Applicant can see, there is no mechanism that allows longitudinal extension of Edwards' electrode from the sheath to be selectively limited so as to be, for example, commensurate with the measured length of a patient's uterus. Accordingly, Claim 31 is not anticipated by Edwards.

B. Rejections Under U.S.C. § 103

Claims 2, 9-14, 18-22 and 27-30 have been rejected as being made obvious by Stern.

As discussed, Stern fails to teach of the step of permitting moisture generated during the dehydration of tissue to pass into an electrode carrying member and away from the tissue, as is recited in Claims 2, 9-14. It also fails to teach the use of a fluid permeable elastic member configured to permit moisture generated during ablation to pass into the electrode carrying member and away from underlying tissue, as is recited in Claims 18-22 and 27-30. Moreover, Applicants can find no suggestion for modifying the Stern method/apparatus to utilize the recited steps/features. Thus Claims 2, 9-14, 18-22 and 27-30 are not made obvious by the teachings of Stern.

With respect to Claims 2, 12 - 14, 18-21, an additional basis for the patentability of the claims resides in the recitation of metallized fabric in the array. Applicants can find no fair suggestion for the utilization of a metallized fabric in the Stern device, and respectfully submit that one of skill in the art would not have considered the metallized fabric to be an obvious design choice on the Stern device.

C. Rejection based on Stern in View of Chin

Claims 4, 23 and 26 have been rejected as being made obvious by Stern in view of Chin. As discussed, Stern fails to teach of the step of permitting moisture generated during dehydration to pass into an electrode

carrying member and away from the tissue, as is recited in Claim 4, and it lacks any teaching of the use of a fluid permeable elastic member configured to permit moisture generated during ablation to pass into the electrode carrying member and away from underlying tissue, as is recited in Claims 23 and 26. These teachings are likewise missing from Chin, which discloses the use of an inflatable balloon that is filled with heated liquid and used for thermal ablation.

Thus, Claims 4, 23 and 26 are not made obvious by the combined teachings of these references.

II. Allowable Subject Matter

Applicants note with appreciation the Examiner's indication that Claims 5-7, 15, 17, and 24 would be allowable if rewritten in independent form. These claims are now independent of the rejected base claims and their allowance is respectfully requested.

III. New Claims 32 and 33

New Claims 32 and 33 recite the use of metallized fabric and thus are allowable on this basis.

IV. Conclusion

For the foregoing reasons, Applicants respectively submit that

the application is in condition for allowance. Early reconsideration and allowance of the claims is respectfully requested.

Respectfully submitted,

LIMBACH & LIMBACH L.L.P.

Dated: 12-21-99 By: Kathleen A Frost

Kathleen A. Frost
Reg. No. 37,326

Attorneys for Applicant(s)

Attorney Docket No. ENVS-220 []

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trad mark Offic
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SM

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/103,072	06/23/98	TRUCKAI C	ENVS-220

QM32/1003

KATHLEEN A FROST
LIMBACH & LIMBACH
2001 FERRY BUILDING
SAN FRANCISCO CA 94111

EXAMINER	
LAM, A	
ART UNIT	**PAPER NUMBER**
3763	12

DATE MAILED: 10/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

U.S. G.P.O. 2000 ; 465-166/25266

1- File Copy

HOL-MIN_146944

Office Action Summary	Application No.	Applicant(s)	
	09/103,072	TRUCKAI ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	3763	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *21 December 1999* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5-7,15,17,24 and 31* is/are allowed.

6)☒ Claim(s) *1-4,8-14,16,18-23,25-30,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☐ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3, 8, 16, 22, 25, 26, 32 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Stern et al., 5,433,470, as described in office action dated June 18, 1999. New claims 32 and 33 are same as claims 1 and 16, respectively, and thus are rejected for the same reasons as claims 1 and 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 9-14, 18-22 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al '470, as described in office action dated June 18, 1999.

Claims 4, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. '470 in view of Chin (WO 95/07664) as described in office action dated June 18, 1999.

Response to Arguments

Applicant's arguments filed December 21, 1999 have been fully considered but they are not persuasive. Stern '470 discloses the open-cell, porous material as capable of permitting fluid to pass into it, see column 5, lines 47-53. The porous material is the fluid permeable elastic member. As to Edwards, 5,505,730,

Allowable Subject Matter

Claims 5-7, 15, 17, 24 and 31 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Seidel Richard can be reached on (703)305-3009. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.
September 29, 2000

Sharon Kennedy
Primary Examiner

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

CSABA TRUCKAI , et al.

Application No. 09/103,072

Filed: June 23, 1998

For: MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

Group Art Unit: 3763

Examiner: LAM, A

PRELIMINARY AMENDMENT RESPONSIVE TO FINAL ACTION MAILED OCTOBER 3, 2000

121 Spear Street, Suite 290
San Francisco, CA 94105
(415) 512-1312

CERTIFICATE OF EXPRESS MAIL

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee": Express Mail Label No. EL816893930US addressed to: Commissioner for Patents, Washington, DC 20231, on March 5, 2001.

STALLMAN & POLLOCK LLP Date: 3/5/01

By: Georgia K. Stith
Georgia Stith

Commissioner for Patents
Washington, DC 20231

Sir:

Applicants submit this preliminary amendment in connection with the CPA application filed herewith. The CPA application is filed to permit consideration of a supplemental Information Disclosure Statement being submitted in order to disclose new references submitted in a Request for Reexamination filed against Applicants' U.S. Patent 5,769,880 (of which the present application is a CIP). To date two such Requests have been filed against the '880 patent. Copies of the Requests are also listed on the IDS and enclosed herewith.

In the Claims

Please cancel Claims 1-4, 8-14, 16, 18-23, 25-30, 32 and 33.

Please add new Claims 34 - 108:

--34. The method of claim 5 wherein the fluid permeable elastic member includes metallized fabric.

35. The method of claim 5, wherein step (d) includes the step of applying suction to draw the moisture through the tubular member.

36. The method of claim 5 wherein step (b) includes the step of causing the electrode array to conform to the shape of the tissue surface.

37. The method of claim 5 wherein the method further includes the step of

(e) monitoring impedance using the electrode array and automatically terminating the flow of current into the tissue once impedance has approximately reached a predetermined level.

38. The method of claim 5 wherein the tissue to be ablated is within an organ, wherein the method further includes the step of measuring the approximate length and width of the organ and wherein step (c) includes the steps of selecting an ablation power corresponding to the measured length and width and delivering the RF energy to the tissue at approximately the selected power.

39. The method of claim 38 wherein the step of measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

40. The method of claim 39 wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

41. The method of claim 34 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

42. The method of claim 41 wherein the metallized fabric includes yarns of spandex and nylon.

43. The method of claim 5 wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

44. The method of claim 5 wherein at least one of the flexures includes an electrically conductive region in contact with a conductive region of the electrode array.

45. The method of claim 6 wherein the fluid permeable elastic member includes metallized fabric.

46. The method of claim 6, wherein step (d) includes the step of applying suction to draw the moisture through the tubular member.

47. The method of claim 6 wherein step (b) includes the step of causing the electrode array to conform to the shape of the tissue surface.

48. The method of claim 6 wherein the method further includes the step of

(e) monitoring impedance using the electrode array and automatically terminating the flow of current into the tissue once impedance has approximately reached a predetermined level.

49. The method of claim 6 wherein the tissue to be ablated is within an organ, wherein the method further includes the step of measuring the approximate length and width of the organ and wherein step (c) includes the steps of selecting an ablation power corresponding to the measured length and width and delivering the RF energy to the tissue at approximately the selected power.

50. The method of claim 49 wherein the providing step provides the electrode array to be carried by a pair of elongate flexures, and wherein the step of

measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

51. The method of claim 50 wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

52. The method of claim 45 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

53. The method of claim 52 wherein the metallized fabric includes yarns of spandex and nylon.

54. The method of claim 6 wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

55. The method of claim 6 wherein the array is expandable and wherein step (b) further includes the step of moving the array to an expanded condition.

56. The method of claim 55 wherein the array is carried by a pair of elongate flexures and wherein the step of moving the array to the expanded condition includes the step of expanding the flexures.

57. The method of claim 56 wherein at least one of the flexures includes an electrically conductive region in contact with a conductive region of the electrode array.

58. The method of claim 7 wherein the fluid permeable elastic member includes metallized fabric.

59. The method of claim 7, wherein the step of applying suction further includes applying suction to draw tissue into contact with the electrode array.

60. The method of claim 7 wherein step (b) includes the step of causing the electrode array to conform to the shape of the tissue surface.

61. The method of claim 7 wherein the method further includes the step of

(e) monitoring impedance using the electrode array and automatically terminating the flow of current into the tissue once impedance has approximately reached a predetermined level.

62. The method of claim 7 wherein the tissue to be ablated is within an organ, wherein the method further includes the step of measuring the approximate length and width of the organ and wherein step (c) includes the steps of selecting an ablation power corresponding to the measured length and width and delivering the RF energy to the tissue at approximately the selected power.

63. The method of claim 62 wherein the providing step provides the electrode array to be carried by a pair of elongate flexures, and wherein the step of measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

64. The method of claim 63 wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

65. The method of claim 58 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

66. The method of claim 65 wherein the metallized fabric includes yarns of spandex and nylon.

67. The method of claim 7 wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

68. The method of claim 7 wherein the array is expandable and wherein step (b) further includes the step of moving the array to an expanded condition.

69. The method of claim 68 wherein the array is carried by a pair of elongate flexures and wherein the step of moving the array to the expanded condition includes the step of expanding the flexures.

70. The method of claim 69 wherein at least one of the flexures includes an electrically conductive region in contact with a conductive region of the electrode array.

71. The method of claim 15 wherein the fluid permeable elastic member includes metallized fabric.

72. The method of claim 15, wherein step (d) includes the step of applying suction to draw the moisture through the tubular member.

73. The method of claim 15 wherein step (b) includes the step of causing the electrode array to conform to the shape of the tissue surface.

74. The method of claim 15 wherein the method further includes the step of

(e) monitoring impedance using the electrode array and automatically terminating the flow of current into the tissue once impedance has approximately reached a predetermined level.

75. The method of claim 15 wherein the tissue to be ablated is within an organ, wherein the method further includes the step of measuring the approximate length and width of the organ and wherein step (c) includes the steps of selecting an ablation power corresponding to the measured length and width and delivering the RF energy to the tissue at approximately the selected power.

76. The method of claim 15 wherein the step of measuring the approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

77. The method of claim 15 wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

78. The method of claim 71 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

79. The method of claim 78 wherein the metallized fabric includes yarns of spandex and nylon.

80. The method of claim 15 wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

81. The method of claim 15 wherein the array is expandable and wherein step (b) further includes the step of moving the array to an expanded condition.

82. The method of claim 81 wherein the array is carried by a pair of elongate flexures and wherein the step of moving the array to the expanded condition includes the step of expanding the flexures.

83. The method of claim 15 wherein at least one of the flexures includes an electrically conductive region in contact with a conductive region of the electrode array.

84. The apparatus of claim 17 wherein the fluid permeable elastic member includes metallized fabric.

85. The apparatus of claim 84 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

86. The apparatus of claim 84 wherein the metallized fabric includes yarns of spandex and nylon.

87. The apparatus of claim 17 wherein the array has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

88. The apparatus of claim 17 wherein the electrode array is carried by a deflecting mechanism moveable between a retracted position and an expanded position.

89. The apparatus of claim 88 wherein the deflecting mechanism includes a pair of elongate flexures.

90. The apparatus of claim 88 wherein the deflecting mechanism includes electrically conductive regions electrically coupled to conductive regions of the electrode array.

91. The apparatus of claim 89 wherein the flexures include electrically conductive regions electrically coupled to conductive regions of the electrode array.

92. The apparatus of claim 17 further comprising:

width measurement means for measuring the approximate width of the organ.

93. The apparatus of claim 92 further comprising:

length measurement means for measuring the approximate length of the organ.

94. The apparatus of claim 92 further comprising means for determining an ablation power using the measured approximate width.

95. The apparatus of claim 93 further comprising means for determining an ablation power using the measured approximate width and length.

96. The apparatus of claim 92, wherein the measurement means includes a pair of elongate flexures, the flexures carrying the electrode array.

97. The apparatus of claim 24 wherein the fluid permeable elastic member includes metallized fabric.

98. The apparatus of claim 97 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

99. The apparatus of claim 97 wherein the metallized fabric includes yarns of spandex and nylon.

100. The apparatus of claim 24 wherein the array has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

102. The apparatus of claim 24 wherein the deflecting mechanism includes electrically conductive regions electrically coupled to conductive regions of the electrode array.

103. The apparatus of claim 24 wherein the flexures include electrically conductive regions electrically coupled to conductive regions of the electrode array.

104. The apparatus of claim 24 further comprising:

width measurement means for measuring the approximate width of the organ.

105. The apparatus of claim 104 further comprising:

length measurement means for measuring the approximate length of the organ.

106. The apparatus of claim 104 further comprising means for determining an ablation power using the measured approximate width.

107. The apparatus of claim 105 further comprising means for determining an ablation power using the measured approximate width and length.

108. The apparatus of claim 104, wherein the width measurement means includes the elongate flexures.--

REMARKS

Claims 1-4, 8-14, 16, 18-23, 25-30, 32 and 33 are cancelled. Applicants reserve the right to resubmit these or similar claims in a continuation application.

Claims 5-7, 15, 17, 24 and 31 remain in the case. **These claims were allowed in the Final Office Action mailed October 3, 2000.**

Claims 34 - 108 are new. Claims 5-7, 15, 17, 24, 31 and 34 - 108 are now pending.

All of the new claims are dependent on an allowed claim. Specifically:

Claims 34 - 44 are dependent on Claim 5.

Claims 45 - 57 are dependent on Claim 6.

Claims 58 - 70 are dependent on Claim 7.

Claims 71 - 83 are dependent on Claim 15.

Claims 84 - 96 are dependent on Claim 17.

Claims 97 - 108 are dependent on Claim 24.

Support for the subject matter in each of the new claims is found in the original claims and disclosure.

Given that all new claims are dependent on an allowed claim, allowance of all claims is requested.

Respectfully submitted,

STALLMAN & POLLOCK L.L.P.

Dated: 3-5-2001 By: Kathleen A Frost

Kathleen A. Frost
Reg. No. 37,326

Attorneys for Applicant(s)

Attorney Docket No. ENVS-220

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/103,072	06/23/98	TRUCKAI	C ENVS-220

QM12/0522

KATHLEEN A. FROST
STALLMAN & POLLOCK LLP
121 SPEAR STREET
SUITE 290
SAN FRANCISCO CA 94105

EXAMINER	
LAM, A	
ART UNIT	PAPER NUMBER
3763	14

DATE MAILED: 05/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev.11/00)

1- File Copy

HOL-MIN_146971

Offic Action Summary	Application N . 09/103,072	Applicant(s) TRUCKAI ET AL.	
	Examiner Ann Y. Lam	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7,15,17,24,31 and 34-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *5-7, 15, 17, 24, 31 and 34-108* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 5-7, 15, 84-108, drawn to a method of ablating and/or coagulating tissue, classified in class 604, subclass 509.

II. Claims 31, 34-83, 17 and 24, drawn to an apparatus for ablating and/or coagulating, classified in class 607, subclass 101.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product, such as using the product to determine the length and width of an organ for medical treatment purposes other than to select an ablation power which is proportional to the measured length times the measured width.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Seidel can be reached on (703)308-5115. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.
May 20, 2001

ANHTUAN T. NGUYEN
PRIMARY EXAMINER
5/24/01

3763

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

6-12-01

In re Patent Application of

CSABA TRUCKAI , et al.

Application No. 09/103,072

Filed: June 23, 1998

For: MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

Group Art Unit: 3763

Examiner: LAM, A

RESPONSE TO RESTRICTION REQUIREMENT MAILED MAY 22, 2001

121 Spear Street, Suite 290
San Francisco, CA 94105
(415) 512-1312

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope, addressed to: Commissioner for Patents, Washington, DC 20231 on June 5, 2001.

STALLMAN & POLLOCK LLP

Dated: 6/5/01 By: Chanti Appling

Commissioner for Patents
Washington, DC 20231

Sir:

Applicants request that the Patent and Trademark Office withdraw the Restriction Requirement mailed May 22, 2001.

This application is a CPA application filed to permit consideration of a supplemental Information Disclosure Statement. Before the CPA was filed, Claims 5-7, 15, 17, 24 and 31 were **allowed in the Final Office Action mailed October 3, 2000.** These claims have been pending for nearly three years - since the application was filed in June 1998 - and were addressed in a substantive office action in June 1999 before they were indicated allowable in October 2000. Thus, search and examination of both method and apparatus claims has already been conducted by the Examiner. For this reason, it would not unduly burden the PTO to have these claims remain pending in the case.

The addition of new Claims 34-108 does not present additional burden, in that **ach of th new claims is d pend nt on a claim that has b n allow d.** Specifically:

Claims 34 - 44 are dependent on Claim 5.
Claims 45 - 57 are dependent on Claim 6.
Claims 58 - 70 are dependent on Claim 7.
Claims 71 - 83 are dependent on Claim 15.
Claims 84 - 96 are dependent on Claim 17.
Claims 97 - 108 are dependent on Claim 24.

Given that Claims 5-7, 15, 17, 24 and 31 have been allowed, and further given that each of Claims 34-108 is dependent on an allowed claim, Applicant respectfully requests withdrawal of the Restriction Requirement.

In the event the Restriction Requirement is not withdrawn, Applicant provisionally elects the method claims, Claims 5-7, 15, 84-108, with traverse.

Respectfully submitted,

STALLMAN & POLLOCK L.L.P.

Dated: 6-5-01 By: Kathleen A. Frost

Kathleen A. Frost
Reg. No. 37,326

Attorneys for Applicant(s)

Attorney Docket No. ENVS-220

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/103,072	06/23/98	TRUCKAI C	ENVS-220

EXAMINER

QM32/0829

LAM, A

KATHLEEN A. FROST
STALLMAN & POLLOCK LLP
121 SPEAR STREET
SUITE 290
SAN FRANCISCO CA 94105

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 08/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev.11/00)

1- File Copy

Offic Action Summary	Application N .	Applicant(s)	
	09/103,072	TRUCKAI ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	3763	

-- The MAILING DATE of this communication app ars on the cov r sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7,15,17,24, 31 and 34-108* is/are pending in the application.

4a) Of the above claim(s) *1-4,8-14,16,18-23,25-30,32 and 33* is/are withdrawn from consideration.

5)☒ Claim(s) *5-7,15 and 34-83* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *5-7,15,17,24,31 and 34-108* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the method claims, in Paper No. 18 is acknowledged. The traversal is on the ground(s) that search and examination of both method and apparatus claims has already been conducted by the Examiner before the CPA was filed, and that the new claims are dependent on a claim that has been previously allowed. Thus Applicant alleges that it would not unduly burden the PTO to have these claims remain pending in the present case. This is not found persuasive because a CPA requires further search and consideration of all the claims, even if they have been previously searched, considered and allowed. Moreover, the method claims and the apparatus claims are directed to different embodiments of Applicant's invention, and thus a search of the method claims does not require a search in all the same classes and subclasses as would be required for the apparatus claims. The requirement is still deemed proper and is therefore made FINAL.

Furthermore, Applicant elected the method claims in Paper No. 18, but indicated that the method claims are Claims 5-7, 15, and 84-108, see page 2, line 14, of Applicant's response. Examiner would like to point out that this is incorrect, and that the method claims are actually Claims 5-7, 15 and 34-83.

Allowable Subject Matter

Claims 5-7, 15 and 34-83 are allowed.

Conclusion

This application is in condition for allowance except for the following formal matters:

Claims 17, 24, 31 and 84-108, as being directed to non-elected claims with traverse in Paper number 18, must be canceled by Applicant before the method claims may be allowed.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Seidel can be reached on (703)308-5115. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

A.L.
August 25, 2001

ANHTUAN T. NGUYEN
PRIMARY EXAMINER
8/27/01.

Notice of References Cited	Application/Control No. 09/103,072	Applicant(s)/Patent Under Reexamination TRUCKAI ET AL.	
	Examiner Ann Y. Lam	Art Unit 3763	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification	
	A	US-6,159,207	12-2000	Yoon	606	41
	B	US-				
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification	
	N						
	O						
	P						
	Q						
	R						
	S						
	T						

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

ATTY DOCKET NO.	SERIAL NO.
ENVS-220	09/103,072
Csaba Truckai	
FILING	GROUP
June 23, 1998	3763

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A	5,797,903	8/25/98	Swanson et al.	606	34	4/12/96
	B	5,879,348	3/9/99	Owens et al.	606	41	4/12/96
	C	5,891,136	4/6/99	McGee et al.	606	41	4/8/96
	D	5,078,717	7/7/92	Parins et al.	606	48	9/10/90

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

		E	D. E. Haines and A. F. Verow, Observations on Electrode-Tissue Interface Temperature and Effect on Electrical Inpendance During Radiofrequency Ablation of Ventricular Myocardium. Circulation Vol. 82, No. 3, Sept. 1990
		F	Abstracts Fron the 67th Scientific Sessions Dallas Convention Center Dallas, Texas November 14-17, 1994. Circulation Vol. 90, No. 4, Part 2, October 1994

EXAMINER	DATE CONSIDERED
	6/11/02

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Docket Number (Optional)	Application Number
ENVS-220	09/103,072
Applicant(s) Csaba Truckai	
Filing Date June 23, 1998	**Group Art Unit** 3763

*EXAMINER INITIAL		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	G	W. M. Jackman et al. Radiofrequency Current Directed Across the Mitral Anulus with a Bipolar Epicardial-Endocardial Catheter Electrode Configuration in Dogs. Circulation Vol. 78, No. 5, November 1988.
	H	First Request for Reexamination of U. S. 5,769,880, Reexamination Control Number 90/005,435
	I	Second Request for Reexamination of U. S. 5,769,880, Reexamination Control Nuimber 90/005,866

EXAMINER	DATE CONSIDERED
	6/11/02

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of

CSABA TRUCKAI , et al.

Application No. 09/103,072

Filed: June 23, 1998

For: MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

Group Art Unit: 3763

Examiner: LAM, A

RESPONSE TO OFFICE ACTION

121 Spear Street, Suite 290
San Francisco, CA 94105
(415) 512-1312

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope, addressed to: Commissioner for Patents, Washington, DC 20231 on February 28, 2002.

STALLMAN & POLLOCK LLP

Dated: 2/28/02 By: _____
Janet Chan

Commissioner for Patents
Washington, DC 20231

Sir:

Applicant makes the following amendments and remarks in response to the Official Action mailed August 29, 2001.

In the Claims

Please cancel Claims 17, 24, 31 and 84-108 without prejudice.

REMARKS

I. Cancellation of Claims 17, 24, 31 and 84-108

Claims 5-7, 15 and 34-83 were allowed in the Official Action mailed August 29, 2001. In view of the cancellation of Claims 17, 24, 31 and 84-108, only allowed claims remain in the case. Since only allowed claims remain in the case, Applicants respectfully request issuance of a Notice of Allowance.

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PATENT

II. IDS Filed March 5, 2001

Applicant requests acknowledgment of the IDS filed (with copies of all references) on March 5, 2001. A copy of that IDS is attached.

III. New IDS

A Supplemental Information Disclosure Statement is attached for the Examiner's consideration.

Respectfully submitted,

STALLMAN & POLLOCK L.L.P.

Dated: February 28, 2002 By: Kathleen A. Frost

Kathleen A. Frost
Reg. No. 37,326

Attorneys for Applicant(s)

Attorney Docket No. ENVS-220

US005443470A

United States Patent [19]

Stern et al.

[11] Patent Number: 5,443,470

[45] Date of Patent: * Aug. 22, 1995

[54] **METHOD AND APPARATUS FOR ENDOMETRIAL ABLATION**

[75] Inventors: **Roger A. Stern**, Cupertino; **Vincent N. Sullivan**; **Robert L. Marion**, both of San Jose, all of Calif.

[73] Assignee: **Vesta Medical, Inc.**, Palo Alto, Calif.

[*] Notice: The portion of the term of this patent subsequent to Jan. 11, 2011 has been disclaimed.

[21] Appl. No.: **46,683**

[22] Filed: **Apr. 14, 1993**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 877,567, May 1, 1992, Pat. No. 5,277,201.

[51] **Int. Cl.**[6] **A61N 5/00**

[52] **U.S. Cl.** **607/98**; 607/99; 607/113; 607/138; 606/32; 606/41

[58] **Field of Search** 606/27, 28, 32, 33, 606/40, 41, 45, 49; 607/98, 99, 113, 116, 138, 148

[56] **References Cited**

U.S. PATENT DOCUMENTS

1,827,306	10/1931	Chapman et al. .	
3,324,847	6/1967	Zoumboulis .	
3,369,549	2/1968	Armao .	
3,750,653	8/1973	Simon .	
3,789,829	2/1974	Hassen .	
3,840,016	10/1974	Lindemann .	
3,901,224	8/1975	Bucalo .	
3,924,628	12/1975	Droegemueller et al. .	
3,934,580	1/1976	Cournut .	
4,014,988	3/1977	Pharriss et al. .	
4,016,270	4/1977	Pharriss et al. .	

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

0115420	8/1984	European Pat. Off. .	
0407057	1/1991	European Pat. Off. .	
8527331.7	9/1985	Germany .	
3516830	11/1986	Germany	607/116
WO87/01276	3/1987	WIPO .	

OTHER PUBLICATIONS

"Hyperthermia Overview Using Microwave Antennas", Invited Lectures, Thomas P. Ryan, M.D. Thermoradiotherapy, C. T. Coughlin, M.D.

"Devices: Replaceing the Roto-Rooter", Trends, Michael Dolan.

(List continued on next page.)

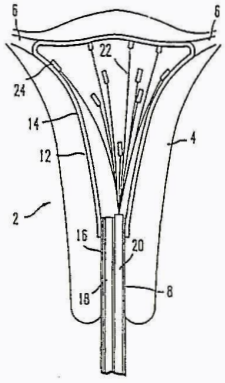
Primary Examiner—Lee S. Cohen

Attorney, Agent, or Firm—Oblon, Spivak, McClelland, Maier & Neustadt

[57] **ABSTRACT**

An endometrial ablation apparatus and method wherein an RF current having a frequency of between 250 kHz and 100 MHz is passed through the entire surface of an endometrium in order to provide heating of the endometrium. An electroconductive expandable member such as a balloon is used as the medium for passing the current and causing the heating of the endometrium. The temperature of the endometrium is raised to a temperature between 45° C. and 90° C. and preferably not above 70° for a time sufficient to destroy the cells of the lining while maintaining the average temperature of the myometrium at a temperature below approximately 42° C. The expandable balloon is connected to a power source which provides the radio frequency power having the desired characteristics to selectively heat the endometrial lining to the desired temperature. The balloon can be constructed with an electroconductive elastomer such as a mixture of polymeric elastomer and electroconductive particles or can be a non-extensible bladder having a shape and a size, in its fully expanded form, which will extend the organ and effect contact with the endometrial lining to be destroyed. The electroconductive member may consist of a plurality of electrode area segments having a thermistor associated with each electrode segment whereby the temperature from each of said plurality of segments is monitored and controlled by a feedback arrangement from the thermistors.

22 Claims, 13 Drawing Sheets



U.S. PATENT DOCUMENTS

4,072,147	2/1978	Hett .	
4,102,342	7/1978	Akiyama et al. .	
4,160,455	7/1979	Law .	
4,198,981	4/1980	Sinnreich .	
4,292,960	10/1981	Paglione .	
4,296,760	10/1981	Carlsson et al. .	
4,311,154	1/1982	Sterzer et al. .	
4,349,033	9/1982	Eden .	
4,375,220	3/1983	Matvias .	
4,377,168	3/1983	Rzasa et al. .	
4,409,993	10/1983	Furihata .	
4,469,103	9/1984	Barrett .	
4,491,131	1/1985	Vassiliadis .	
4,494,539	1/1985	Zenitani et al. .	
4,549,533	10/1985	Cain et al. .	
4,552,127	11/1985	Schiff .	
4,572,190	2/1986	Azam et al. .	
4,622,972	11/1986	Giebeler, Jr. .	
4,638,436	1/1987	Badger et al. .	
4,658,836	4/1987	Turner .	
4,662,383	5/1987	Sogawa et al. .	
4,674,481	6/1987	Boddie, Jr. et al. .	
4,676,258	6/1987	Inokuchi et al. .	
4,692,452	9/1987	Cerny et al. .	
4,700,701	10/1987	Montaldi .	
4,754,752	7/1988	Ginsburg et al. .	
4,754,757	7/1988	Feucht .	
4,758,592	7/1988	Horrobin et al. .	
4,771,778	9/1988	Mar .	
4,773,899	9/1988	Spears .	
4,776,349	11/1988	Nashef et al. .	
4,818,954	4/1989	Flachenecker et al. .	
4,823,812	4/1989	Eshel et al. .	
4,836,189	6/1989	Allred, III et al. .	
4,852,579	8/1989	Gilstad et al. .	
4,860,752	8/1989	Turner .	
4,865,047	9/1989	Chou et al. .	
4,927,413	5/1990	Hess .	
4,935,003	6/1990	Gainutdinova et al. .	
4,938,217	7/1990	Lele .	
4,946,440	8/1990	Hall .	
4,949,718	8/1990	Newwirth et al. .	
4,955,377	9/1990	Lennox et al. .	
4,960,109	10/1990	Lele .	
4,961,435	10/1990	Kitagawa et al. .	
4,967,765	11/1990	Turner et al. .	
4,974,587	12/1990	Turner et al. .	
4,979,948	12/1990	Geddes et al. .	
4,985,027	1/1991	Dressel .	
4,993,430	2/1991	Shimoyama et al. .	
4,997,653	3/1991	Igarashi .	
4,998,930	3/1991	Lundahl .	
5,003,991	4/1991	Takayama et al. .	
5,006,119	4/1991	Acker et al. .	
5,026,959	6/1991	Ito et al. .	
5,032,124	7/1991	Menton .	
5,035,694	7/1991	Kazprzyk et al. .	
5,041,089	8/1991	Mueller et al. .	
5,045,056	9/1991	Behl .	
5,050,597	9/1991	Daikuzono .	
5,057,106	10/1991	Kasevich et al.	606/33
5,059,191	10/1991	Beyer et al. .	
5,084,044	1/1992	Qunit .	
5,092,841	3/1992	Spears .	
5,098,429	3/1992	Sterzer .	
5,100,388	3/1992	Behl et al. .	
5,188,122	2/1993	Phipps et al.	607/138
5,248,312	9/1993	Langberg	607/113
5,277,201	1/1994	Stern	607/98

OTHER PUBLICATIONS

"Endometrial Ablation", Therapeutic Hysteroscopy: Indications and Techniques, pp. 148–163, W. W. Babcock et al.

"Uterine Resectoscopes for Endometrial Ablation and Resection", Karl Storz.

"Treatment of Menorrhagia by Radiofrequency Heating", Int. J. Hyperthermai, 1991, vol. 7, No. 2, 213–220, M. V. Prior et al.

"Treatment of Functional Menorrhagia by Radiofrequency-Induced Thermal Endometrial Ablation", The Lancet, Feb. 17, 1990, pp. 374–376, J. H. Phipps et al.

"Resectoscopes for the Gynecologist", Contemporary OB/GYN, Philip G. Brooks, M.D., pp. 51–57.

"New Techniques in Operative Hysteroscopy", Audio-Digest Obstetrict/Gynecology, vol. 37, No. 10, May 15, 1990, Bruce McLucas et al.

"New Concepts in Hysteroscopy", Symposium, Contemporary OB/GYN, pp. 84–103, Michael S. Baggish, M.D. et al.

"Microwave Applicator for Transurethral Hyperthermia of Benign Prostatic Hyperplasia", Int. J. Hyperthermia, 1989, vol. 5, No. 3, 283–296, M. A. Astrahan et al.

"Endometria Ablatin: An Alterative to Hysterectomy", The American Journal of Gynecologic Health, vol. V, No. 3, Thierry G. Vancaillie, M.D.

"A Technique for Combining Microwave Hyperthermia with Intraluminal Brachytherapy of the Oesophagus", Int. J. Hyperthermia, 1989, vol. 5, No. 1, 37–51, N. A. Astrahan et al.

U.S. Patent Aug. 22, 1995 Sheet 1 of 13 5,443,470

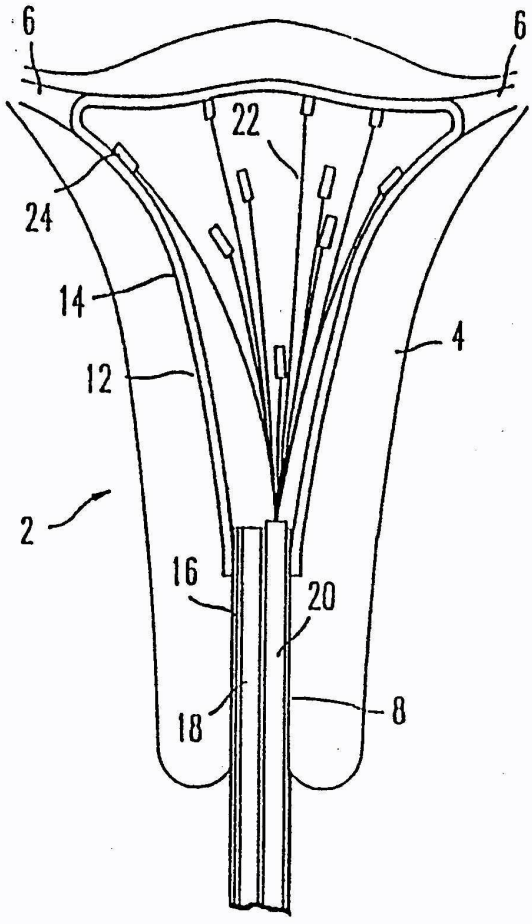


FIG. 1

FIG. 2

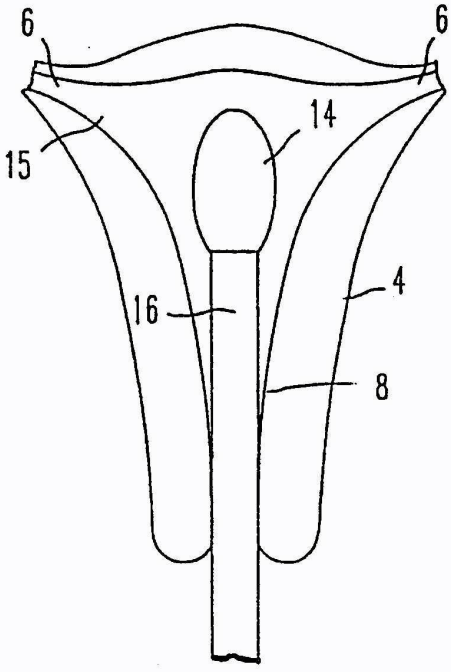
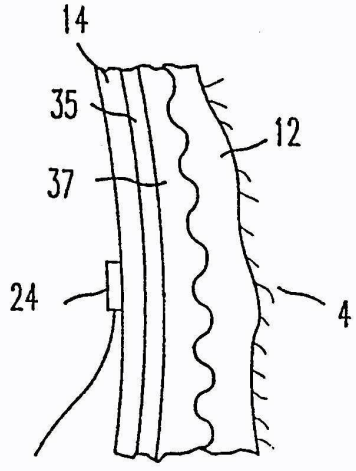


FIG. 3



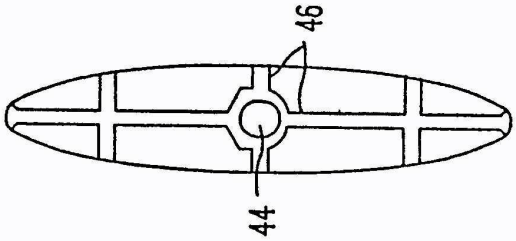


FIG. 4b

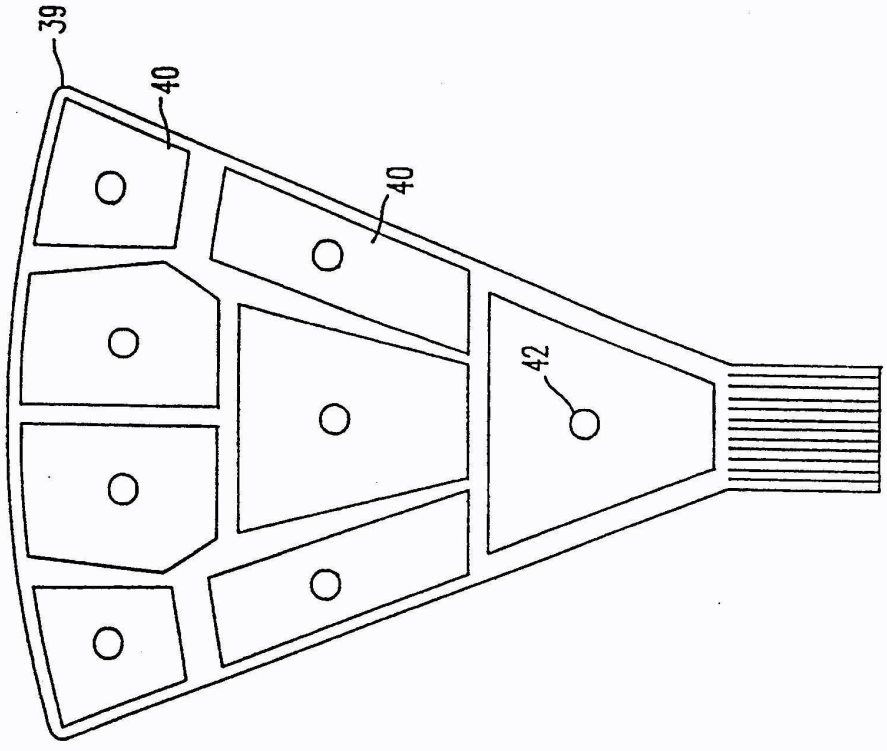
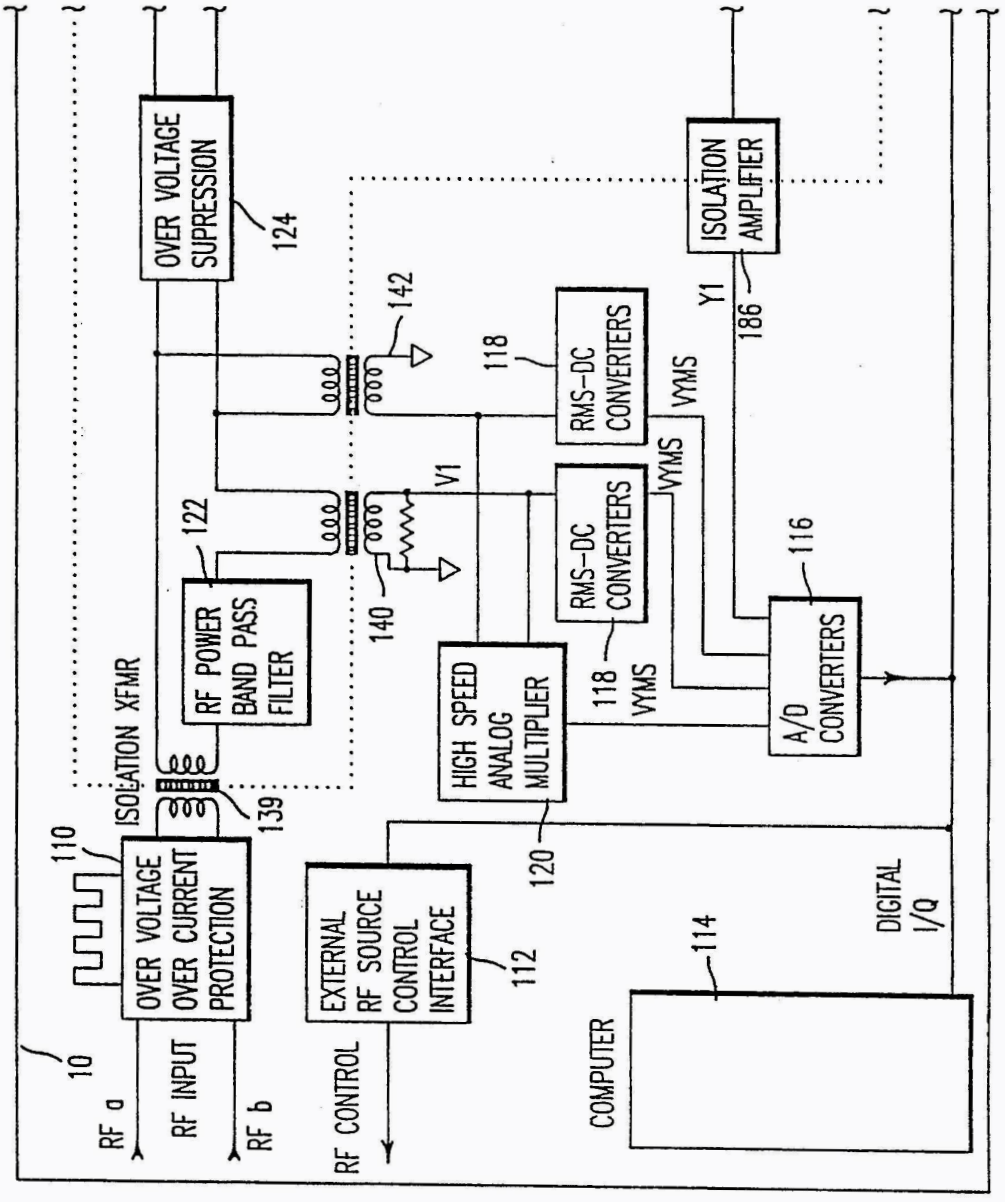


FIG. 4a

FIG. 5a


10
RF a
RF INPUT
RF b
RF CONTROL
110
OVER VOLTAGE OVER CURRENT PROTECTION
ISOLATION XFMR
139
EXTERNAL RF SOURCE CONTROL INTERFACE
112
120
HIGH SPEED ANALOG MULTIPLIER
RF POWER BAND PASS FILTER
122
140
V1
142
OVER VOLTAGE SUPRESSION
124
118
RMS-DC CONVERTERS
VYMS
118
RMS-DC CONVERTERS
VYMS
ISOLATION AMPLIFIER
Y1
186
116
A/D CONVERTERS
DIGITAL I/Q
114
COMPUTER

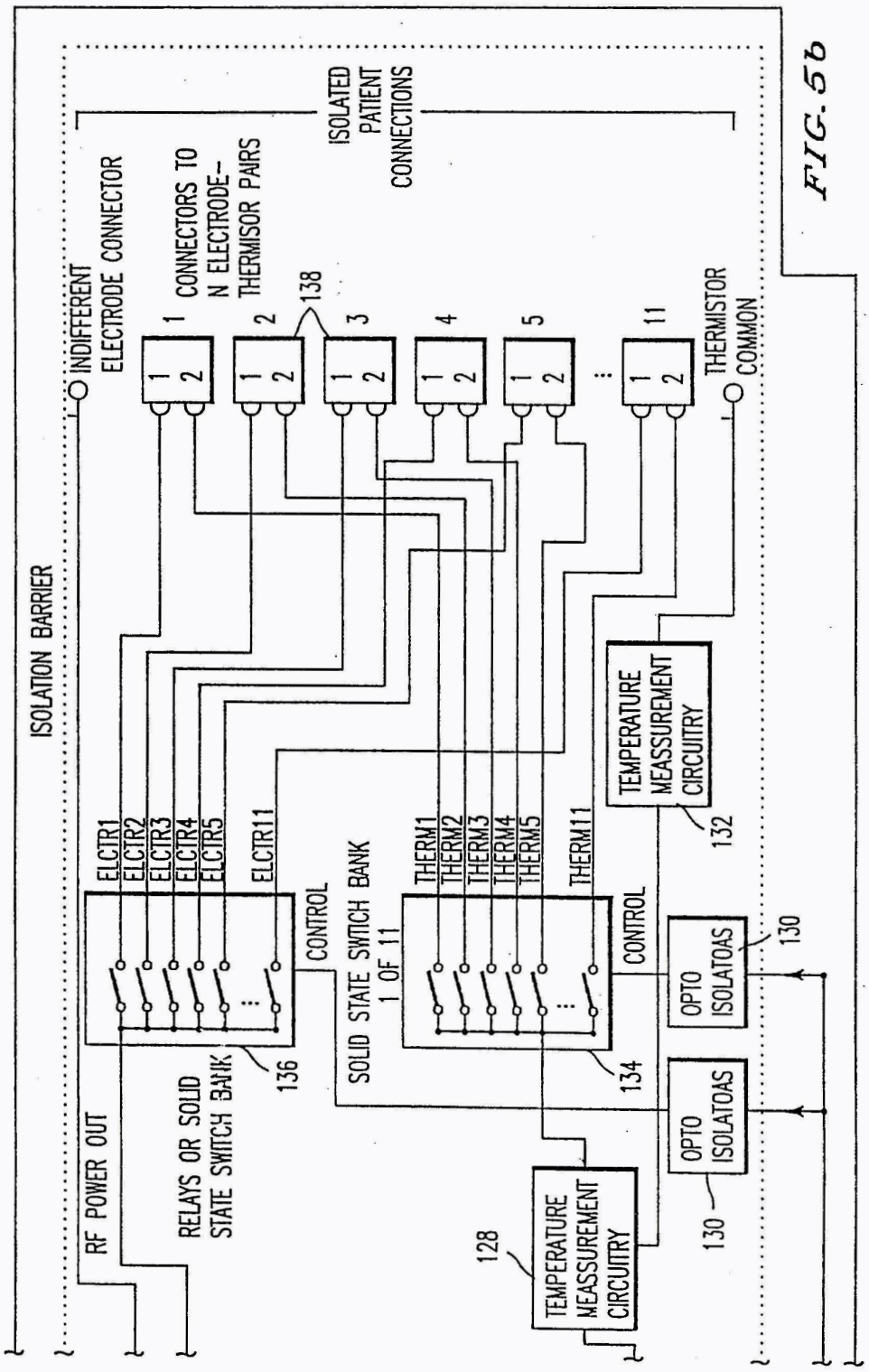


FIG. 5b

MSI00171145

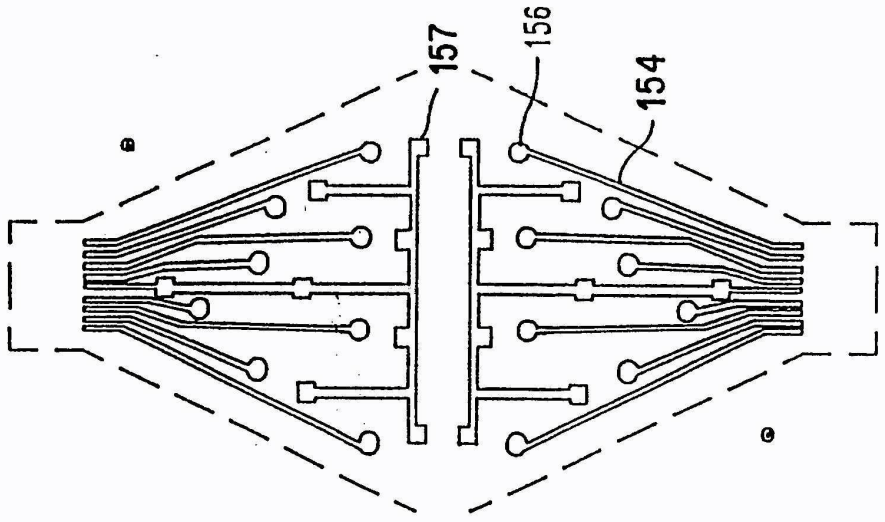


FIG. 7

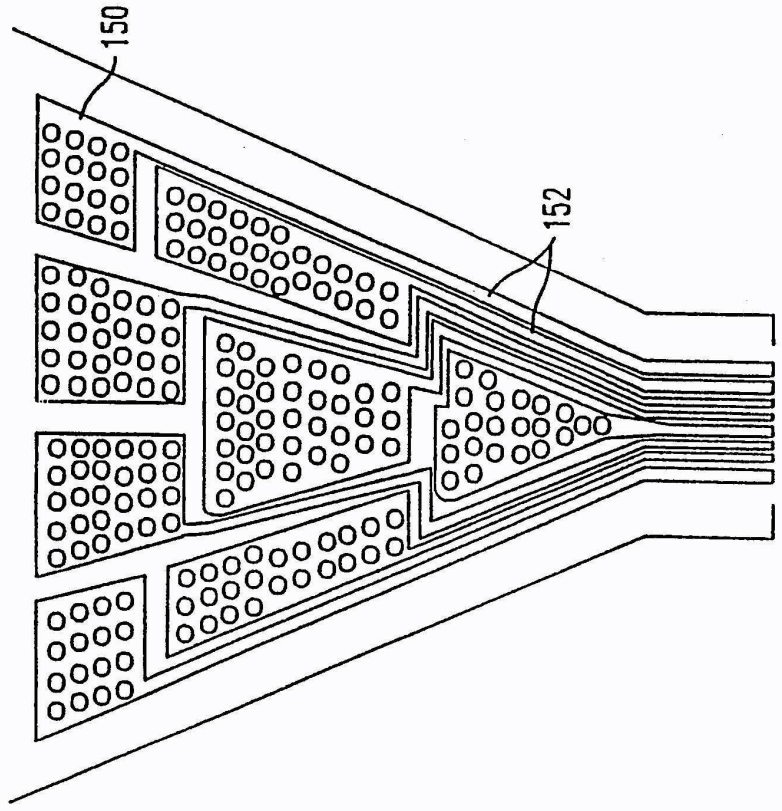


FIG. 6

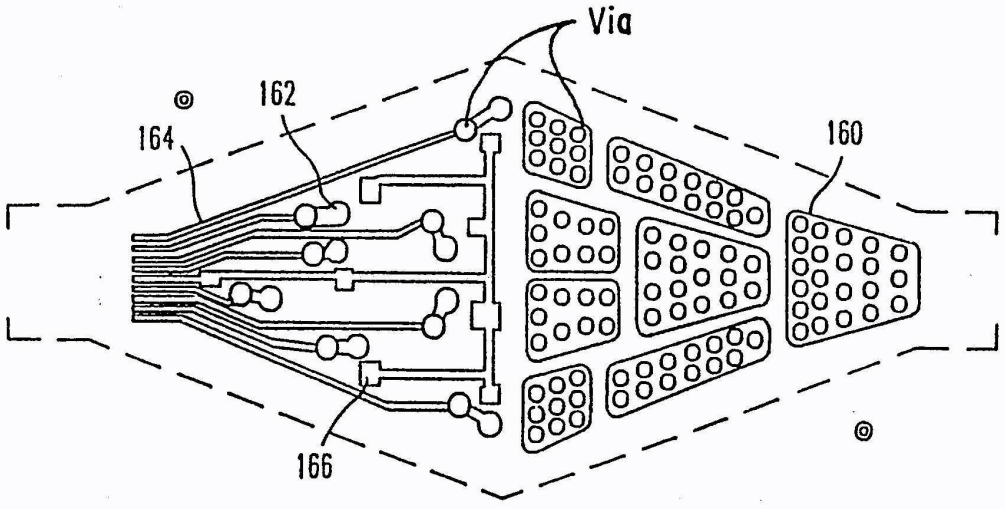


FIG. 8a

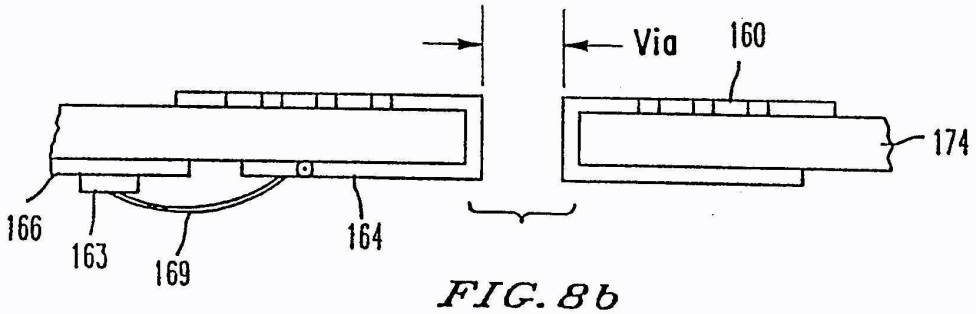


FIG. 8b

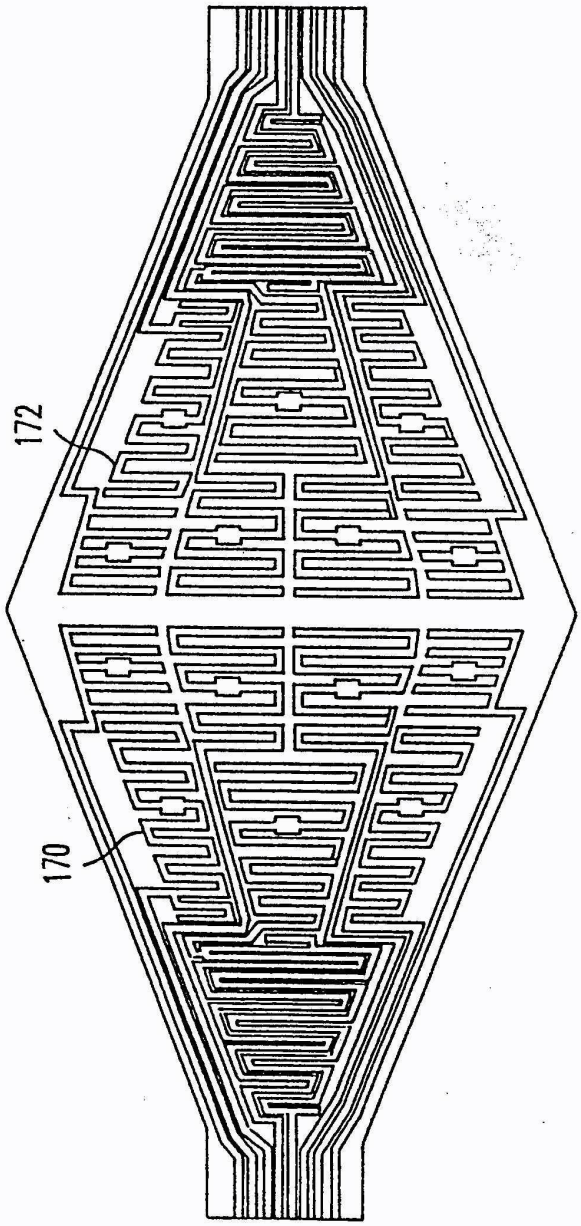


FIG. 9

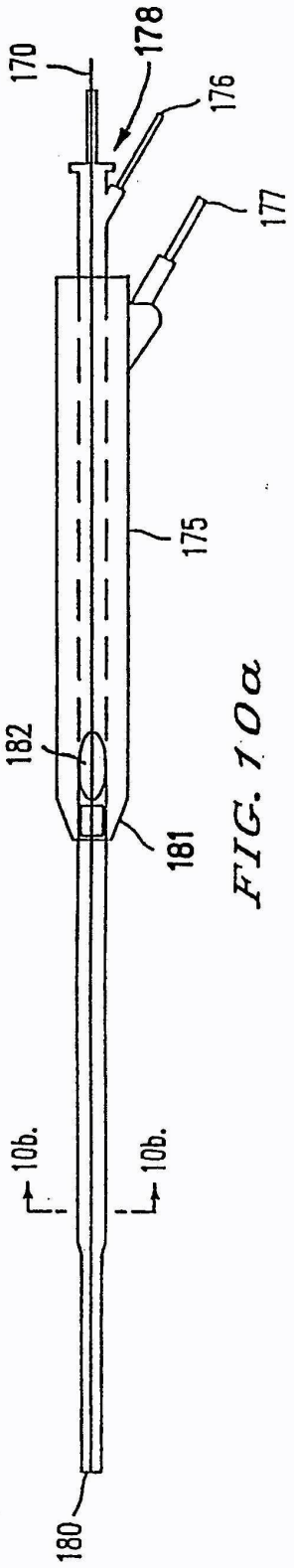


FIG. 10a

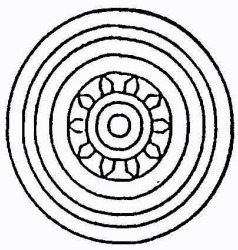


FIG. 10b

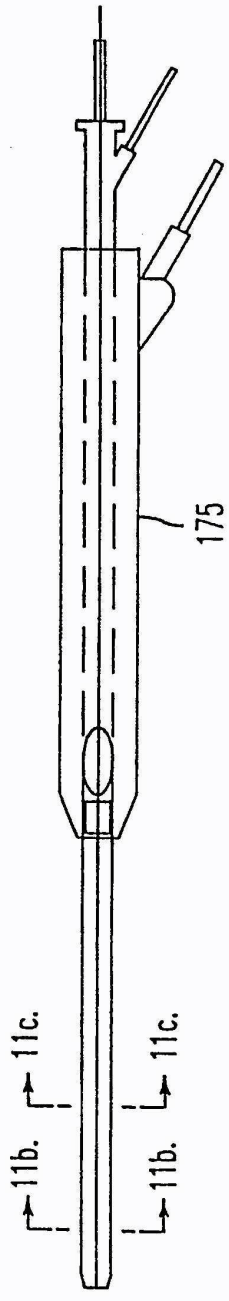


FIG. 11a

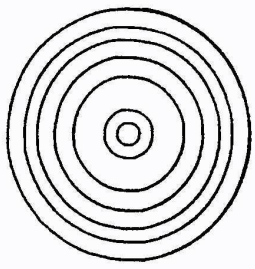


FIG. 11c

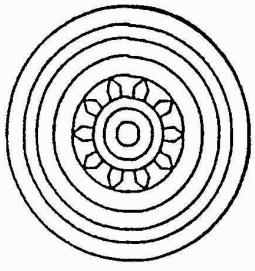


FIG. 11b

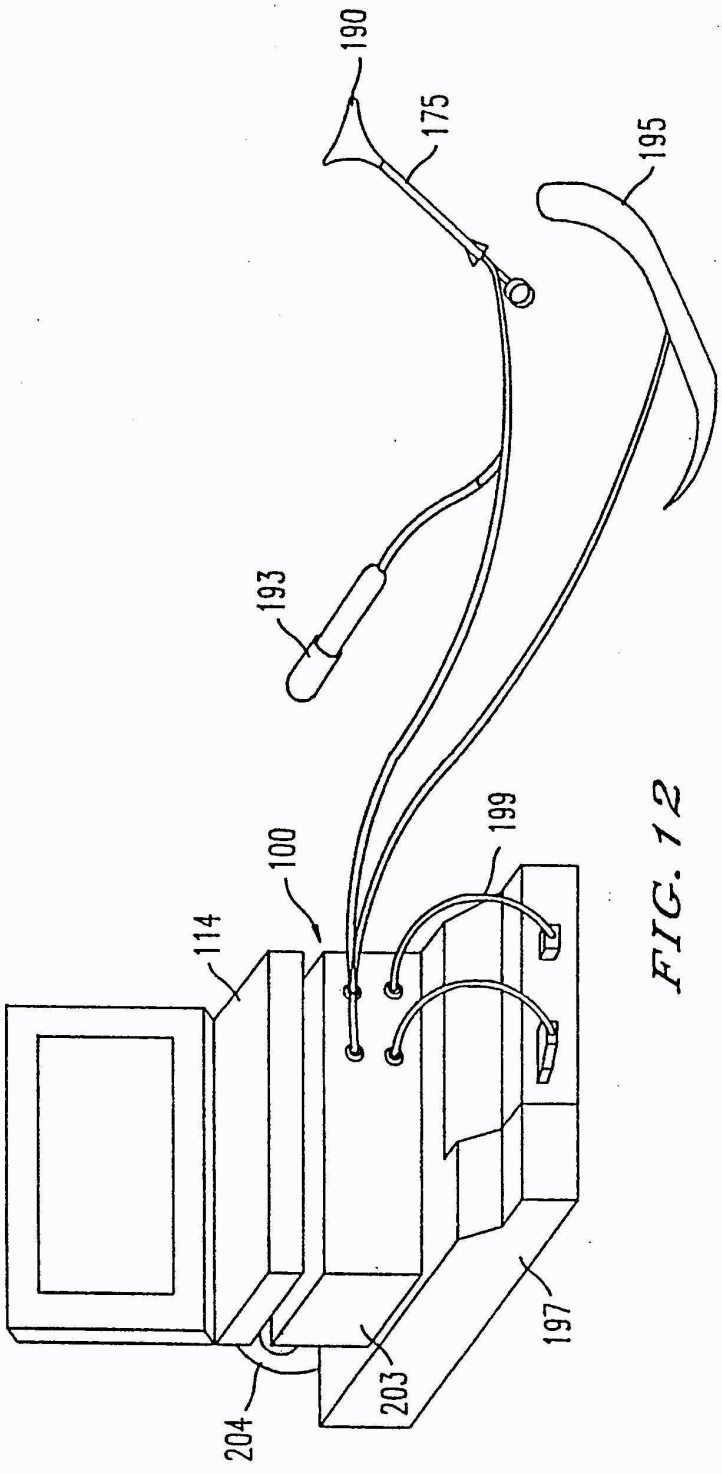


FIG. 12

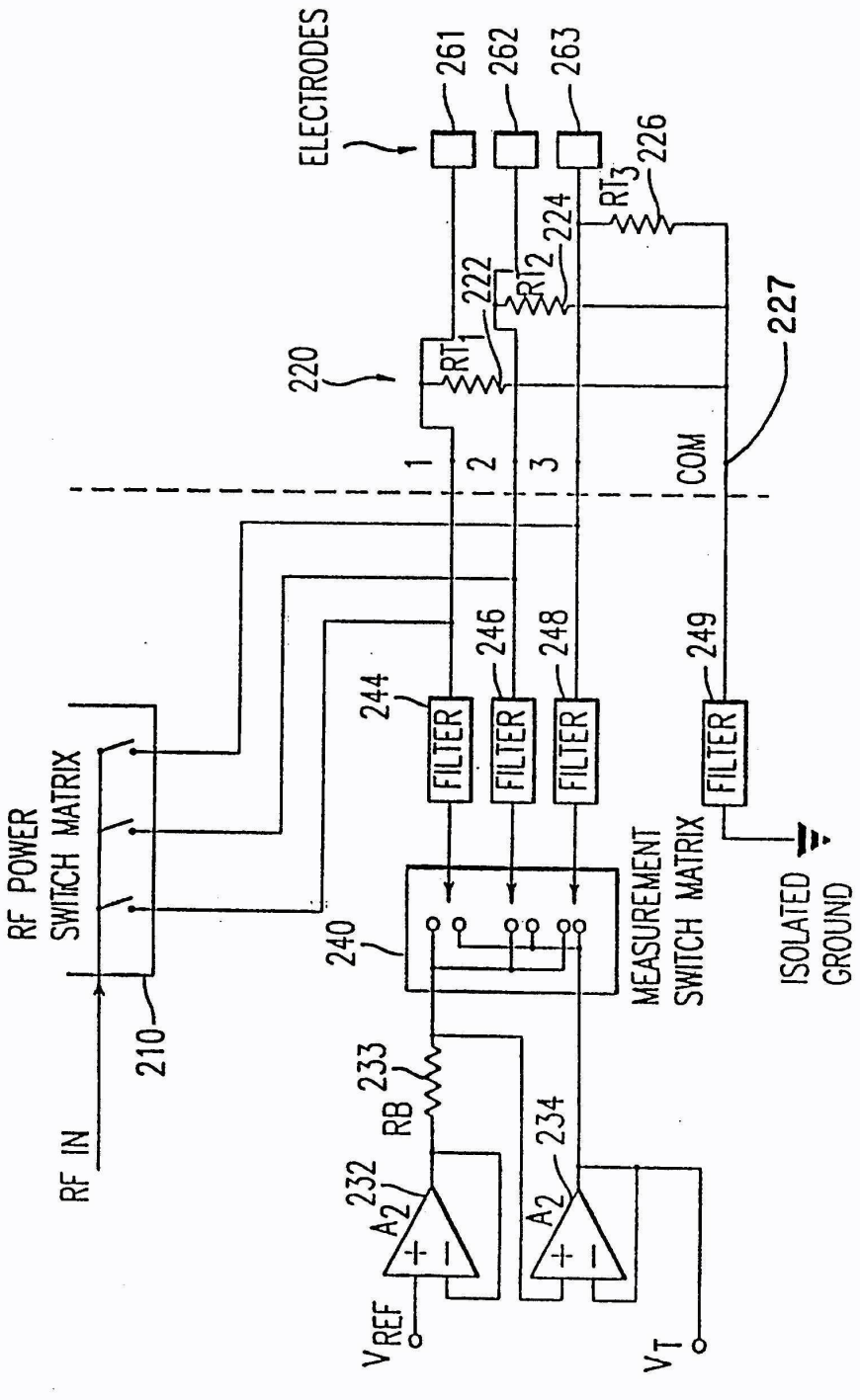

ELECTRODES
261
262
263
226
RT3
224
RT2
222
RT1
220
227
1
2
3
COM
246
248
249
244
FILTER
FILTER
FILTER
FILTER
RF POWER SWITCH MATRIX
MEASUREMENT SWITCH MATRIX
ISOLATED GROUND
240
210
RF IN
233
RB
232
234
A2
A2
VREF
VT

FIG. 13

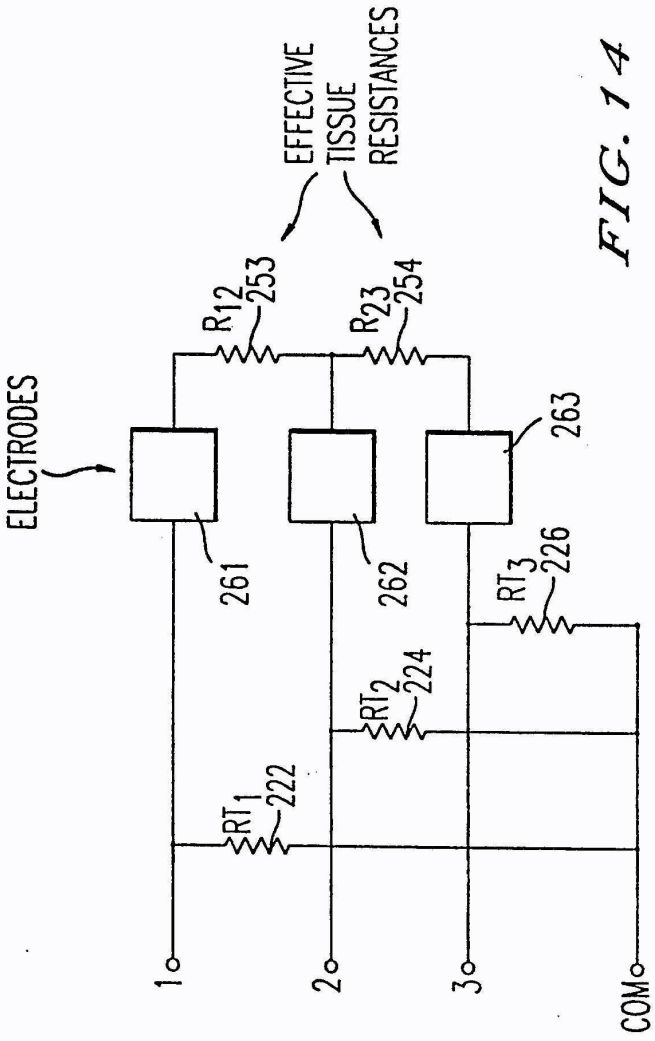

EFFECTIVE TISSUE RESISTANCES
R12 253
R23 254
ELECTRODES
261
262
263
RT3 226
RT2 224
RT1 222
1
2
3
COM

FIG. 14

METHOD AND APPARATUS FOR ENDOMETRIAL ABLATION

CROSS-REFERENCE TO RELATED APPLICATION

This is a continuation-in-part of application Ser. No. 07/877,567 filed May 1, 1992, now U.S. Pat. No. 5,277,201.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a method and an apparatus for in situ destruction of the inner lining of body organs, and more particularly the providing of a selective destruction of the endometrium as an alternative to hysterectomy for treatment of uterine bleeding.

2. Discussion of Background

Prior techniques for removing or destroying the inner lining of body organs have been explored in order to provide for an alternative to surgical removal of the body organs for treatment of diseases and other abnormal conditions. Prior techniques involved the destructive treatment of the inner linings with chemicals and with various forms of thermal energy such as radio frequency, microwave heating, cryotherapy, laser surgery and electrosurgery. Radio frequency and microwave energies have also been applied directly to the linings to generate heat in situ.

One type of thermal destruction is described in U.S. Pat. No. 4,979,949 wherein thermal ablation of the mucosal layer of a gall bladder is accomplished by resistive heating with an RF balloon electrode. Electric current is delivered from the balloon by a conductive expansion liquid filling the balloon. This device has power loss which occurs in the conductive fluid and it cannot be adapted for anything but a single electrode arrangement and it lacks a complete individual power control and/or temperature sensor.

In another example of prior art treatment, balloon catheters have been supplied with a heated fluid for thermal ablation of hollow body organs as described in U.S. Pat. No. 5,045,056. Furthermore, application of microwave and high frequency RF energy to body areas to destroy body tissue, using single electrodes enclosed in expanded balloons have been described in U.S. Pat. No. 4,662,383 and U.S. Pat. No. 4,676,258.

The disadvantage of the procedures occurring in the prior art such as described above include a lack of uniform large area treatment because these procedures involve a lack of uniform control or temperature sensing ability to ensure complete ablation.

Other procedures developed to date involve manual applications of small treatment tools to successive areas of the lining which is an expensive operating room procedure and which, similar to the other previous heat balloon treatments, involve limited assurance of uniform results.

SUMMARY OF THE INVENTION

Accordingly, one object of the present invention is to provide a novel method and apparatus for performing safe and rapid endometrial ablation without the need for visual contact during the ablation of the lining.

It is a further object to provide an apparatus and a method for endometrial ablation which can be carried out on an out-patient basis without requiring the use of an operating room.

The objects of the invention are carried out by a method which utilizes an electrically conductive or conductively coated expandable member conforming to the inner surface of the endometrium. The expandable member is filled with an electrically non-conductive medium and a RF current is passed through substantially the entire surface of the endometrium. The current is sufficient to resistively heat the endometrium in a single Operation to a temperature within a range of between 45° C. to 90° C. for a time sufficient to destroy the cells of the lining while maintaining the average temperature of the myometrium at a temperature of substantially 42° C. or less. The RF current has a frequency of at least 250 kHz and less than 100 MHz.

The method according to the present invention involves the insertion of a conductive, expandable member in its unexpanded state into the uterine cavity through the cervical opening and subsequently expanding the member to establish surface contact with the endometrial surface and applying the RF current to the member in its expanded condition.

It is a further object of the present invention to provide that the electroconductive expandable member includes a thin bladder having an array of separate electrodes on one surface and further having a temperature sensor associated with each separate electrode in order to provide a feedback temperature sensor for each electrode. The plurality of separate electrodes are independently and sequentially energized with thermistor temperature feedback to bring the endometrial temperature to a desired level.

It is further an object of the present invention to provide electrodes having a specific configuration so that the heating is not concentrated at the edges of the electrode and so that uniform heating is achieved over the entire electrode surface by providing a plurality of throughholes throughout the electrode or by forming the electrode in a pattern of lines, thereby creating a uniform density of edges and equalizing the current density across the surface area of the electrode.

It is a further object of the present invention to provide an electronic control means capable of controlling the output of a conventional electrosurgical power source and delivering power from the power source sequentially, and in a controlled manner, to the electrodes of the balloon.

It is a further object of the present invention to provide a disposable handheld applicator and electrode assembly combination to deliver the ablation device to the uterus and to retract the device upon completion of the ablation.

It is a further object of the present invention to provide an array of separate electrodes and associated separate thermistors on an expandable member with a series of power leads with each power lead delivering power to a single electrode and to its associated thermistor to provide a temperature feedback for temperature regulation of the endometrial ablation.

It is a further object of the present invention to provide an inner lumen having the ability to contain a fiber optic image conduit which serves as a visual aid when placing the device.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete appreciation of the invention and many of the attendant advantages thereof will be

readily obtained as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, wherein:

FIG. **1** is a cross-sectional representation of an electroconductive balloon as an expandable member in an expanded format in place in a uterus;

FIG. **2** is a representation of the apparatus of FIG. **1** in an unexpanded condition;

FIG. **3** is an enlarged cross-section illustrating the relationship between a small segment of the uterine endometrium and the expanded member;

FIGS. **4***a–b* is a representation of an embodiment of an expandable member which uses a plurality of surface segments with each surface segment having a separate conductive surface and a temperature sensor;

FIGS. **5***a–b* is a schematic representation of the power control system for the multi-segment element shown in FIG. **4**;

FIG. **6** illustrates an embodiment of the multi-segment element having perforated electrodes with illustrated power traces on the outside surface of the expandable member;

FIG. **7** illustrates thermistor traces and circular wiring jumper mounting pads on the interior of the expandable member;

FIGS. **8***a* and **8***b* illustrates the double-sided electrode/thermistor traces on the respective inside and outside portions of the expandable member of FIGS. **6** and **7**;

FIG. **9** illustrates an embodiment utilizing flat metallized stock material to be adhesively bonded to the expandable member with the material being arranged in a serpentine configuration;

FIGS. **10***a–b* show the bladder device for delivering the expandable member to the uterus;

FIGS. **11***a–c* show the bladder device of FIG. **10** in a retracted position and illustration of the deflated expandable member;

FIG. **12** schematically represents the connection of the bladder device to the power generation source and testing structure;

FIG. **13** is a schematic of an embodiment of the temperature measurement circuitry of FIG. **5**; and

FIG. **14** is an equivalent of FIG. **13** showing effective tissue shunting.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, wherein like reference numerals designate identical or corresponding parts throughout the several views, and more particularly to FIG. **1** thereof, a cross-sectional representation of the invention utilizes an electroconductive balloon as the expandable member with FIG. **2** representing the same apparatus as FIG. **1** prior to inflation of the balloon element. The uterus **2** consists of myometrial tissue **4** surrounding the uterine cavity. The normal uterine cavity or envelope is a flat cavity having approximately the shape of an inverted triangle with the two upper corners communicating with the ovaries by way of the fallopian tubes **6** in the bottom corner opening into the cervical canal **8**. The entire surface of the envelope includes the entrance of the fallopian tubes **6** and the cervical canal **8** which is covered with a thin layer of tissue known as uterine endometrium. The selective destruction of the endometrial cells is the goal of the improved method and apparatus disclosed in this present invention.

The monopolar electrode system developed in conjunction with FIG. **1** expands to conform to the endometrial surface to be treated and this in turn dilates and stretches the endometrium to reduce surface folds. Radio frequency electric current passes through the dilated endometrial surface for a time sufficient to destroy the endometrial cells by elevating the temperature of the endometrium to between 45° C. and 90° C., and preferably within 10 seconds. The temperature is maintained until the endometrial tissue is destroyed which is optimally accomplished by a temperature between 55° C. to 65° C. for up to 10 minutes.

The electric current passes through or along the surface of the expandable member and the interior of the expandable member is filled with an electrically non-conductive substance such as a fluid or gas. The expandable member can be any material or article which can be compressed or otherwise prepared in a small diameter configuration for insertion through the cervix and expanded or inflated after insertion to provide the dilation. This expandable member establishes direct electrical connection or capacitive coupling with the endometrium. A second electrical contact can occur by way of grounding plates or patches which contact a large area of the patient's skin in order to complete the electrical circuit.

Electric current flowing through the tissue causes resistive heating. The power density diminishes with distance from the electrode as the reciprocal of the fourth power of the distance. Thus, any heat generated is focused in the endometrium and the immediately surrounding muscular tissue which in the particular case of the present invention is the portion of the myometrium in contact with the lining. Because the myometrium **4** is highly vascularized, heat removal occurs rapidly. As a result, the temperature of the endometrium **12** can be heated to a destructive temperature faster than the myometrium **4** and the rest of the uterus. Therefore, because of this temperature relationship, endometrial ablation can be safely accomplished as a simple medical procedure using local anesthesia. Furthermore, it can be a service made available at a fraction of the cost of prior art systems with less hazard than other endometrial ablations.

The inflatable balloon or bladder **14** is inserted into the uterine cavity **15** as shown in FIG. **2** and subsequently the inflation of the balloon occurs with a gas or a non-conductive liquid so that it extends and fills the uterine cavity conforming to the expanded surface as shown in FIG. **1**. Portions of the balloon **14** extend into the entrance to the fallopian tubes **6** and extend along the entire endometrial surface **12** to the cervix **8**. The balloon is attached to and forms a fluid-tight seal with the tube **16** which encloses a smaller fluid delivery tube **18** as well as an electrical cable **20** containing leads for the conductor as well as additional leads for the sensors. A plurality of temperature sensors **24** are shown attached to the inner surface of the balloon. Alternatively, this lead configuration can be replaced by lead pairs **22** for each sensor. The temperature sensors **24** are conventional thermistors or thermocouples and are positioned on zones of the balloon which will contact areas of the endometrial surface which are most sensitive to overheating. The temperature sensors can also be fiber optic temperature sensors. The fluid delivery tube **18** is connected to a source of gas or liquid through a conven-

tional fluid control system which will be later illustrated in conjunction with FIG. **13**.

The FIG. **3** is an enlarged cross-section illustrating the relationship between a small segment of uterine endometrium and the expandable balloon element of the FIG. **1**. The endometrial lining **12**, supported on the myometrium **4**, is typically an irregular surface even after it is extended by the inflated balloon **14**. Electrical contact between the conductive surface **35** on the outer surface of the balloon **14** and the endometrium **12** can be improved by covering the outer surface of the balloon **14** with a conventional electroconductive solution, paste or gel **37** which is physiologically non-toxic and non-irritating. Suitable electroconductive media including the known types of gels and pastes used as surface coatings for defibrillators may be used. Examples of suitable conductive gels are carboxymethylcellulose gels made from aqueous electrolyte solutions such as physiological saline solutions and the like. The electroconductive solution, paste or gel enhances electrical contact between the balloon and the endometrium by filling the pores of the balloon surface and the irregularities in the endometrial surface.

The expandable balloon or bladder can be an elastomeric polymer such as a natural or synthetic rubber made conductive by mixing the polymer with electroconductive particles such as carbon or conductive metal particles. Alternately, it may be made conductive by a surface coating of electroconductive material such as an electroconductive gel, or a conductive metal coating on the outer or inner surface of the balloon or bladder wall. Electroconductive coating can be applied to organic polymer surfaces by conventional vapor deposition, electrical depositions, sputtering and the like.

A preferred balloon comprises a thin, non-extensible polymer film such as a polyester or other flexible thermoplastic or thermosetting polymer film, for example, having a conductive metal coating on the outer or inner surface thereof. The films form a non-extensible bladder having a shape and size, in its fully expanded form, which will extend the organ and effect contact with the endometrial lining to be destroyed. The inner surface of the non-extensible bladder can be coated with electroconductive material which will capacitively couple to the endometrium provided that the bladder wall thickness is less than approximately 0.25 mm.

The surface of the expandable member can be an open-cell, porous material such as a foam or similar caged network of material which can hold a quantity of the electroconductive solution, paste or gel required to secure satisfactory electrical contact with the opposed endometrial surface. The surface can be coated with or impregnated with the electroconductive substance.

FIG. **4** illustrates an embodiment using a balloon with a plurality of surface segments as the expandable bladder **39**. Each of the surface segments has a conductive surface and a temperature sensor. In this particular embodiment, the balloon has a segmented electrode coating of electroconductive metal on either the inner or the outer surface to permit controlled delivery of power to each segment. Each segment **40** is electrically connected through conventional leads to a power source (not shown in FIG. **4**). Each conductive segment **40** also has a thermistor **42** which is connected through conventional leads to a switch matrix. FIG. **4B** illustrates a top view of the bladder **39** and particularly features a lumen **44** extending through the center of the bladder **39**. The lumen allows for light guides to be inserted through the center of the electrode. In other words, there is an inner lumen tube **44** attached to the center of the flat film.

FIG. **5** is a schematic representation of the power source controller and the switch matrix for the multi-segment balloon discussed above in conjunction with, for example, FIG. **4**. The electrical leads connect to the electro-thermistor pairs of the bladder of FIG. **4** by way of connectors **138** as shown in FIG. **5**. The thermistor leads are connected to the matrix switch bank **134** and the electrode leads are connected to the switch bank **136**. Each thermistor (FIG. **4***a*) **42** is sampled by means of the temperature measurement circuitry **128** and the isolation amplifier **126** before being converted in the converter **116** and fed to the computer **114**. The temperature measurement circuitry compares the measured temperature with a thermistor reference voltage **132**. The electrode switch **136** is controlled in response to the output of the computer **114** by means of the opto-isolators **130**. Input power from the RF input passes through the overvoltage and overcurrent protector **110** and is filtered by the bandpass filter **122** before being subjected to overvoltage suppression by the suppression unit **124**. The voltage is isolated by means of the transformers **139**, **140** and **142** with the transformer voltages V_i and V_v from the transformers **140** and **142** being converted by the RMS-DC converters **118** into an RMS voltage to be fed to the converters **116**. Prior to conversion, the signals V_i and V_v are also fed to a high-speed analog multiplier **120** RF control from computer **114** is provided through interface **112**.

A variation of the electrode structure of FIG. **4** is shown in FIG. **6** wherein there are perforated electrodes **150** illustrated with their power traces **152**. This particular electrode bladder of FIG. **6** is shown with the perforated electrode **150** on the exterior of the bladder.

FIG. **7** illustrates thermistor common-side traces **154** on the interior of the bladder with circular wiring jumping pads **156** with mounting sites **157** serving as the base for the thermistors. The common-side traces provide power for both the electrodes and the associated thermistor. The FIG. **7** illustrates both interior sides of the bladder.

FIGS. **8***a–b* illustrates both the outside and the inside of a double-sided electrode with thermistor traces having perforated electrodes **160** on the outside and thermistor wiring pads **162** and electrode power leads **164** as well as thermistor mounting sites **166** on the inside. The connection between the inside and outside of the bladder is shown by the continuity labeled Via in the FIGS. **8***a* and **8***b*. FIG. **8***b* specifically shows a cross-sectional view of the bladder with the electrode **160** on the top or outside surface and the power traces **164** and thermistor wiring pad and mounting site **166** on the lower or inside surface. FIG. **8***b* illustrates the mounting of the thermistor **163** on the mounting site **166** with a connection between the power trace **164** and the thermistor **163** being made by the thermistor lead **169**. FIG. **8***b* clearly illustrates that all except one of the holes in the perforated electrode **160** have a depth which reaches to the substrate or bladder **174**. The one hole labelled Via extends through the entirety of the bladder as an electrical connection between the perforated electrode **160** and the power trace **164** on the bottom or inside surface. The FIG. **8***a* embodiments corresponds to a combination of the inside illustration of the power traces and the bonding surfaces from FIG. **7** along with the perforated electrode of FIG. **6** with the exception that FIG. **8***a* has

the power traces on the inside surface whereas the embodiment of FIG. **6** has the power traces for the perforated electrodes on the outside surface.

Each of the views of FIGS. **6**, **7** and **8**, whether on the inside or the outside must be understood to represent only two surfaces of a bladder which must necessarily have four surfaces. The bladder, prior to inflation, can be envisioned as triangular with two outside triangular surfaces (top and bottom) and two inside triangular surfaces prior to inflation.

A further variation of the electrode structure is shown in FIG. **9** which illustrates a flat metallized stock material adhesively bonded as electrodes **170** and **172** to the outside of both the top and the bottom of the bladder. The electrodes, which are metallized and adhesively bonded, form a serpentine electrode pattern in order to promote uniform heating of the area.

FIGS. **10***a* and **10***b* illustrate the bladder application device which is used to insert the bladder electrode constructed in accordance with any one of the embodiments discussed above. FIG. **10***b* is a side view of the application device illustrating a sheath applicator with a main tube and a shrink wrap covering the wiring leads. A fiber bundle is located in the center of the applicator which would be connected through the lumen illustrated in FIG. **1**, for example. The applicator device **175** has an inflation inlet **176** and an electrode wiring insertion port **177** as well as the optical viewing fiber inlet **178** through a lumen. Movement of the bladder electrode **180** is controlled by the alignment guide and the sheath retraction knob **181** acting in conjunction with a thumb detent **182**. The applicator of FIG. **10***a* shows the bladder electrode in an extended but unexpanded position.

The FIGS. **11***a–c* illustrate the bladder device of FIG. **10** in a retracted position with FIGS. **11***b* and **11***c* being taken at the cross sections titled A—A′ and B—B′ respectively. FIG. **11***c* illustrates the position of the deflated bladder with respect to the main tube in the retracted position at line B—B′. The remaining features of the applicator **175** remain as indicated with respect to FIG. **10**.

An illustration of the connection of the application device **175** and the electrode balloon **190** in accordance with any one of the embodiments of the FIGS. **6–9** is illustrated in FIG. **12**. An inflation pump **193** provides the medium for the expansion of the balloon **190** while the electrode belt **195** provides the reference electrode for connection to the control system **100**. RF generator **197** serves as the RF input power for the control system schematic of FIG. **5** by means of electrosurgical interface cables **199**. The control module **203** and interface control **204** connect with computer **114**.

Once the electrode system and the control system of FIG. **12** and FIG. **5** are connected, the RF electrodes are separately, independently and sequentially energized with thermistor temperature feedback to bring the endometrial temperature up to a desired level. The system accomplishes this in an automated manner based upon the output from the RF generator **197** which is a conventional electrosurgical power supply. As discussed previously, the electrodes may have a variety of specific configurations and heating is concentrated in the endometrium at the surfaces of the electrodes due to the various illustrated electrode configurations in order to provide uniform heating. An example of the concentration of the heat over the entire surface of the electrode is available from the embodiment wherein holes are provided through the electrode as shown in FIGS. **6** and **8**. Uniform heating is also obtained by extending the electrodes in a pattern of lines such as the serpentine pattern structure of FIG. **9**.

As a result of these kinds of constructions, the treatment method of the present invention as well as the electrode elements provide an increased current density as a function of the "electrode edge length" available for heating. Furthermore, as discussed previously, the electrodes can be on the outer surface of the bladder while the power traces, thermistors, and thermistor leads can be on the other surface of the bladder.

In the embodiments of FIGS. **6–9**, the various electrode pattern feature common power traces for both the electrodes and the associated thermistors. That is, one power lead provides the power for an individual electrode as well as its associated thermistor thereby saving in the construction of the bladder electrodes by reducing the number of required thermistor leads by one-half. In such embodiments, each electrode has a corresponding thermistor lead in common with the RF power lead. The second leads from all thermistors are then connected together to form a thermistor common as shown for example in the FIGS. **7** and **8***a*. This arrangement provides the advantage that it only requires N+1 leads to drive an ablation balloon with N electrodes and N thermistors. Because of this construction, however, the temperature measurement circuitry **128** of FIG. **5** has additional requirements beyond the construction with a separate power lead for each thermistor and for each individual electrode. The construction with separate power leads for the electrodes and the thermistor are well known and any one of a variety of temperature measurements schemes for individual electrodes could be utilized.

The specialized requirements brought about by using a common power lead for each electrode and each thermistor are met by the embodiment shown in the FIG. **13**. In FIG. **13**, RF power is selectively applied through switch matrix **210** so that it can be applied to selected electrodes. The electrode/thermistor circuitry is represented on the right hand side of the Figure generally as **220** with a particular example being given by three electrodes and three thermistors represented by resistors **222**, **224** and **226**. A reference voltage Vref is buffered by an operational amplifier follower **232** and passes through resistor **233** before entering the measurement switch matrix **240**. The output of resistor **233** is buffered by operational amplifier **234**. Outputs of the measurement switch matrix **240** are fed through the filters **244**, **246** and **248** which represent low pass filters which block high frequency RF but pass DC and very low frequency voltages.

The balloon thermistor common lead **227** passes through the filter **249** to ground.

During operation, RF power is applied to a particular desired electrode or electrodes by operations of the RF power switch matrix **210**. Measurement of thermistor resistance **222**, **224** or **226** is independent of the particular electrodes connected to the RF power. In order to provide a measurement of RT**1** (**222**), measurement switch matrix **240** is set up to connect lead **1** to the right hand side of resistor **233** while all other leads are set to be connected to the output of the follower **234**. This particular set up and arrangement forces the voltage VT to be equal to V_{REF} RT1/(Rb+RT1). Therefore this allows the measurement of RT**1** due to the known value of Rb and V_{REF}. Because the other leads **2**, **3** from

the circuitry **220** are held at the same voltage by the follower **234**, there are no voltage differences between any of these leads and therefore no current will flow between them.

This lack of a current between leads is extremely important because the tissue which contacts the electrodes cause an effective shunt current path that would otherwise affect the measured voltage VT, without the circuitry of FIG. **13**.

This effective shunting by the tissue is illustrated by the equivalent circuit of FIG. **14** which shows effective tissues resistances **253** and **254** connected between electrodes **261**, **262** and **263**.

The bladder electrodes are constructed in accordance with a method wherein a double-sided thin flat film is plated on one side to increase the electrode thickness and a deposit mask is provided for an electrode pattern on the thick side using lithographic techniques. Then a mask is deposited for the conductors which lead to the temperature sensing elements on a second side. Subsequently, non-masked conductors are etched away leaving the desired pattern. In an alternate embodiment, the conductive patterns for the electrodes and conductors leading to the temperature sensing elements could be directly deposited using vapor or other deposition techniques.

The thermistors (FIG. **4***a*) **42** are provided using surface mounting techniques and the attached inner lumen is provided at the center of the flat film. The balloon is then folded and sealed to the main tube at the proximal end with the inner and outer concentric tubes sliding with respect to each other as illustrated in the FIG. **10**. Subsequently, conductors are brought to the outside of the main tube to the end of the device near the handle of the applicator. The outer tube is placed over the conductor and heat-shrunk as shown in FIG. **10***b*. Finally, the handle of the applicator of FIG. **10** or FIG. **11** is assembled.

Other forms of providing an electrode balloon may be used such as utilizing a blow molded preform or the formation of the balloon with copper on polyimide conductive elements on the surface of a compliant balloon. Furthermore, this balloon may be formed as a "sock" to fit over the inner latex balloon with the sock being a compliant device. Other anticipated forms of an electrode balloon structure include the use of the plated or etched wiring all the way from the balloon itself down to the handle.

Utilizing the present invention allows for the use of low accuracy thermistors wherein calibrations can be stored in memory chips in the handles of the device. The attachment of the electrodes to the bladder can be accomplished by conductive adhesive or by soldering.

The applicator of FIGS. **10** and **11** can be deployed by pulling the front end of the balloon back inside and collapsing the balloon around it. In order to expedite the deployment, the pattern can be formed with particular kinds of spines for the sheath in order to aid in the folding of the patterned electrode within the applicator.

Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

What is claimed and desired to be secured by Letters Patent of the United States is:

1. An endometrial ablation apparatus for selectively destroying the endometrial lining of a body organ, said apparatus comprising:

an electroconductive, expandable electrode means for effecting electrical contact with said endometrial lining to be destroyed, said expandable electrode means containing an electrically non-conductive expansion medium for extending said electrode means to provide said effected electrical contact with said organ;

a radio frequency power means connected to said expandable electrode means at a frequency greater than 250 kHz for selectively providing current to said electrode means to heat said endometrial lining to a uniform temperature of between 45° C. to 90° C.

2. An endometrial ablation apparatus according to claim **1** wherein said frequency is in a range between 250 kHz and 100 MHz.

3. An endometrial ablation apparatus according to claim **1** wherein said expandable electrode means include an electroconductive balloon and an expansion fluid inlet which is connected to the electroconductive balloon and wherein said balloon is filled with said electrically non-conductive expansion medium.

4. An endometrial ablation apparatus according to claim **3** wherein said balloon is an electroconductive elastomer.

5. An endometrial ablation apparatus according to claim **1** wherein said expandable electrode means is a non-extensible bladder coated with electroconductive material.

6. An endometrial ablation apparatus according to claim **5** wherein an inner surface of said non-extensible bladder is coated with electroconductive material and the bladder wall thickness is less than 0.25 mm.

7. The apparatus according to claim **1** wherein said expandable electrode means includes at least one temperature sensing means.

8. The apparatus according to claim **1** wherein the radio frequency power means includes an output and the apparatus further includes a control means for controlling the output of said radio frequency power means to said expandable electrode means.

9. The apparatus according to claim **8** wherein said control means includes at least one thermistor, having an output, for measuring a temperature of said expandable electrode means and wherein said control means includes means for comparing the output of said at least one thermistor with a reference value and wherein said control means provides an output in response to said means for comparing in order to control the output of said radio frequency power means.

10. The apparatus according to claim **1** wherein said expandable electrode means includes an expandable member and a flat metallized electrode, said expandable member having an outside, said flat metallized electrode being attached to said outside, and wherein said metallized electrode is arranged in a serpentine manner to form a patterned electrode.

11. The apparatus according to claim **1** wherein said radio frequency power means provides current to said electrode means to heat said endometrial lining to a uniform temperature of between 45° C. to 90° C. for a period of ten minutes or less.

12. The apparatus according to claim **1** wherein said expandable electrode means is provided with a plurality of separate electrodes and a thermistor associated with

each of said plurality of separate electrodes and further including a plurality of electrode power leads each one of said leads being electrically connected to a respective one of said plurality of separate electrodes and a respective one of said thermistors.

13. The apparatus according to claim **12** further including a temperature measurement circuitry including a first switch matrix means for selectively applying RF power to at least one of said plurality of electrode power leads, a first reference voltage point, a second reference voltage point and a second switch matrix means for connecting a selected one of said plurality of electrode power leads to said first reference voltage point while simultaneously connecting all other ones of said electrode leads to said second reference voltage point.

14. An endometrial ablation apparatus for selectively destroying the endometrial lining of a body organ, said apparatus comprising:

an electroconductive, expandable electrode means for effecting electrical contact with said endometrial lining to be destroyed, said expandable electrode means containing an electrically non-conductive expansion medium for extending said electrode means to provide said effected electrical contact with said organ, said expandable electrode means being a non-extensible bladder provided with a plurality of separate electrodes; and

a radio frequency power means connected to said expandable electrode means at a frequency greater than 250 kHz for selectively providing current to said electrode means to heat said endometrial lining to a uniform temperature of between 45° C. to 90° C., said radio frequency power means having an output.

15. The apparatus according to claim **14** wherein each of said electrodes includes a thermistor.

16. The apparatus according to claim **15** further including a control means responsive to an output of each of said thermistors for controlling the output of the said radio frequency power means to said expandable electrode means.

17. An electrically conductive expandable electrode assembly for providing electrical contact with an endometrial lining of a uterus for the purpose of destroying said endometrial lining, said assembly comprising:

an expandable bladder having an-inner surface and an outer surface, one of said inner and said outer surface being provided with a plurality of separate electrodes and the other of said inner and outer surface being provided with a plurality of thermistors corresponding to each of said plurality of electrodes;

each of said plurality of electrodes further comprising a plurality of holes with one of said plurality of holes of each electrode extending through said bladder from said outside surface to said inside surface and said extended holes providing electrical continuity between said electrodes and said other surface;

said other surface further including a plurality of power leads, each lead being electrically connected to a corresponding one of said electrodes, said leads each extending from one extremity of said bladder to a respective one of said extended holes, each said power lead also extending to a respective one of said thermistors,

whereby the relationship between the plurality of holes in each of said electrodes and said power leads provides for uniform heating on a surface of each of the respective electrodes.

18. The expandable electrode assembly according to claim **17** wherein each of said thermistors is further connected to a common ground lead on said other surface.

19. An ablation method for selectively destroying the lining of a body organ having a supporting mass under the lining, said method comprising the steps of:

passing a radio frequency current having a frequency of at least 250 kHz from an expandable member conforming to the lining and filled with an electrically non-conductive medium, wherein said current is passed through a portion of the lining to resistively heat in a single operation the lining to a temperature within a range from 45° C. to 90° C. for a time sufficient to destroy the cells of the lining while maintaining an average temperature of the supporting mass at a temperature below approximately 42° C.;

monitoring the temperature of the lining and reducing said current when said monitored temperature exceeds a predetermined value.

20. The method of claim **19** wherein the body organ is a uterus, the lining is the endometrium of the uterus, and the supporting mass is a myometrium of the uterus.

21. The method of claim **19** wherein said portion of the lining includes the entire inner surface of the lining.

22. An ablation method of claim **19** wherein the method comprises an endometrial ablation method for selectively destroying the endometrial lining of a uterus having a myometrium layer under the endometrial lining, said endometrial ablation method comprising the steps of:

passing a radio frequency current having a frequency of at least 250 kHz from an expandable member conforming to an inner surface of the lining and filled with an electrically non-conductive medium, wherein said current is passed through substantially the entire inner surface of the lining to resistively heat in a single operation said lining to a temperature within a range from 45° C. to 90° C. for a time sufficient to destroy the cells of the lining while maintaining an average temperature of the myometrium at a temperature below approximately 42° C.;

monitoring the temperature of the surface of said lining and reducing said current when said monitored temperature exceeds a predetermined value.

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