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[Continued on next page]

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(54) Title: DEVICE FOR INSTILLATION OF A CHEMICAL AGENT INTO THE ENDOMETRIAL CAVITY FOR PURPOSE OF GLOBAL ENDOMETRIAL ABLATION

(57) Abstract: A device for chemical endometrial ablation comprising an outer tube, a moveable cervical collar surrounding a portion of the outer tube and located near the distal end of the outer tube, an inner tube movable in a distal-proximal direction within the lumen of the outer tube, a porous and/or sponge-like material on the distal end of the inner tube within the lumen of the distal end of the outer tube having a size, shape, and expandability so that when the distal end of the inner tube within the distal end of the outer tube is moved in a distal direction in relation to the outer tube, the porous and/or sponge-like material expands to the approximate size of a uterus so as to contact the endometrium, a source of cauterizing agent, and means to cause the cauterizing agent to flow through the lumen of the inner tube onto the porous and/or sponge-like material. In operation, the cervical collar can be moved or advanced along the outer tube to the cervix and secured tightly around the external portio in order to prevent chemical cauterizing agent from entering the vagina.

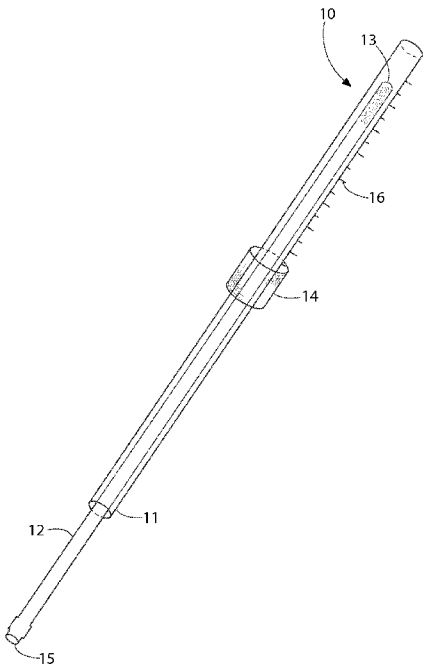

FIG. 1

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

DEVICE FOR INSTILLATION OF A CHEMICAL AGENT INTO THE ENDOMETRIAL CAVITY FOR PURPOSE OF GLOBAL ENDOMETRIAL ABLATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] Benefit of U.S. provisional application Serial Number 61/659,151 filed June 13, 2012, is claimed.

BACKGROUND OF THE INVENTION

[0002] This invention relates to the field of endometrial ablation. More specifically the invention relates to devices and methods for performing endometrial ablations with chemical cauterizing agents.

[0003] According to current insurance company policies, endometrial ablation is considered medically necessary for women who meet certain selection criteria, including A. menorrhagia unresponsive to either 1. dilation and currettage or 2. hormonal therapy or other pharmacotherapy; and B. endometrial sampling has excluded cancer, pre-cancer, or structural abnormalities that require surgery; and C. pap smear and gynecologic examination have excluded significant cervical disease. Chemical ablation with trichloroacetic acid, cryoablation, electrosurgical ablation, laser, microwave endometrial ablation, radiofrequency ablation, and thermoablation are alternative approaches are considered by certain insurance companies to be medically appropriate and established.

[0004] Kucukozkan, *et al.*, *Chemical ablation of endometrium with trichloroacetic acid*, Int J Gynaecol Obstet., 84(1):41-6, Jan. 2004, concluded that endometrial ablation by trichloroacetic acid (TCA) may readily be performed as an alternative treatment method in the management of dysfunctional uterine bleeding (DUB).

[0005] However, except for the aforementioned Kucukozkan, *et al.*, experiments in Turkey, the use of chemical cauterizing agent for endometrial ablation has not been carried out in clinical settings and has not been adopted by clinicians at all in the U.S. It is believed that Kucukozkan, *et al.*, used cotton swabs to apply the chemical cauterizing agent to the endometrium in their experiments. To the inventor's knowledge, no special

devices have been proposed or used by others to deliver a chemical cauterizing agent into the endometrial cavity.

[0006] There are numerous advantages to delivering a chemical cauterizing agent to the endometrial surface as a method of global endometrial ablation rather than currently available devices that require various energy sources, significant anesthesia, and/or direct visualization with hysteroscopy in order to ablate the endometrium.

SUMMARY OF THE INVENTION

[0007] In one aspect, the invention comprises a device for chemical endometrial ablation comprising an outer tube, a cervical collar surrounding a portion of the outer tube on the outer tube and moveable in relation to the outer tube, an inner tube movable in a distal-proximal direction within the lumen of the outer tube, a porous and/or sponge-like material on the distal end of the inner tube within the lumen of the distal end of the outer tube having a size, shape, and expandability property so that when the distal end of the inner tube within the distal end of the outer tube is moved in a distal direction in relation to the outer tube, the porous and/or sponge-like material exits the outer tube and expands to the approximate size of a uterus so as to contact the endometrium, a source of cauterizing agent, and means to cause the cauterizing agent to flow through the lumen of the inner tube onto the porous and/or sponge-like material.

[0008] In the retracted, or insertion position, the porous and/or sponge-like material is compressed within the lumen of the outer tube. In the expanded position, when the inner tube is moved distally in relation to the outer tube, the porous and/or sponge-like material expands to fill the uterine cavity and contact the endometrium to apply the chemical cauterizing agent.

[0009] The volume of the sponge when expanded can be 3 to 12 cc in preferred embodiments. The volume of the sponge when expanded can be different, depending on operator preference or expected volume of the uterus to be chemically ablated.

[0010] Preferably, the device comprises an outer tube having a lumen, a proximal end, a distal end, and an inner diameter, a cervical collar surrounding a portion of the outer tube on the outer tube and moveable in relation to the outer tube, an inner tube having an outer diameter less than the inner diameter of the outer tube, the inner tube

movable in a distal-proximal direction within the lumen of the outer tube, the inner tube having a proximal end and a distal end, a porous and/or sponge-like material on the distal end of the inner tube within the lumen of the distal end of the outer tube, the porous and/or sponge-like material having a size, shape, and expandability so that when the distal end of the inner tube within the distal end of the outer tube is moved in a distal direction in relation to the outer tube, the porous and/or sponge-like material expands to the approximate size of a uterus having an endometrium so as to contact the endometrium of the uterus, a source of cauterizing agent at the proximal end of the inner tube, and means to cause the cauterizing agent to flow through the lumen of the inner tube onto the porous and/or sponge-like material.

[0011] The preferred cauterizing agent is trichloroacetic acid. Derivatives of trichloroacetic acid such as bichloroacetic acid, silver nitrate, and derivatives of silver nitrate can also be used in certain embodiments.

[0012] The porous and/or sponge-like material preferably conforms to the contours of the uterus so that the cauterizing agent will effectively contact the endometrium when it is received by the porous and/or sponge-like material from the cauterizing agent source such as a syringe.

[0013] In embodiments where the source is a syringe, the syringe can be pre-filled with the cauterizing agent or it can be filled with cauterizing agent by the operator. It is preferred to have a pre-filled syringe attached to the proximal end to avoid the need to attach it by the operator but in embodiments wherein the syringe is pre-filled, a valve or other device is preferably provided to prevent cauterizing agent from exiting the syringe until the distal end of the device is inserted into a uterus and the porous and/or sponge-like material has expanded.

[0014] The outer tube can have markings to allow the operator to gauge the depth of insertion into the uterine cavity.

[0015] The moveable cervical collar is designed to prevent leakage of chemical cauterizing agent from the uterus and to retain the chemical within the uterus. In operation, the cervical collar is moved or advanced along the outer tube to the cervix and can be secured tightly around the external portio in order to prevent chemical cauterizing agent from entering the vagina. The collar can comprise means to tighten it on the external portio of the cervix such as a drawstring or the like.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] **FIG. 1** is a perspective view of one embodiment of a device according to the invention in a retracted state.

[0017] **FIG. 2** is a perspective view of the embodiment of Fig. 1 in an expanded state.

DETAILED DESCRIPTION OF THE INVENTION

[0018] Referring to Fig. 1, an embodiment of the device 10 is illustrated which consists of an outer tube 11, an inner tube 12 within the lumen of the outer tube, a sponge-like material 13 at the distal end of the inner tube 12 and fluidly connected thereto. A syringe (not shown) is separately provided to fit into the opening 15 at the proximal end of the inner tube shown in this embodiment. The syringe is filled with trichloroacetic acid (not shown), although other sources and species of chemical can be used, for example derivatives of trichloroacetic acid such as dichloroacetic acid, silver nitrate, or derivatives of silver nitrate.

[0019] The device is designed to be passed through the cervix into the endometrial cavity (17 in Fig. 2). The plastic and porous and/or sponge-like material used in the device are of the type which are approved for human contact.

[0020] A collection collar 14 is then advanced along the shaft of the catheter to the cervix and can be approximated tightly around the external portion to accommodate variations in cervical size and anatomy in order to minimize the possibility of runback. The collar may also be lined with an absorptive fiber, in the event of any small amount of leakage.

[0021] The sponge-like material 13 may have a single or multiple openings so as to allow adequate diffusion of the chemical cauterant to spread evenly through the endometrial cavity 17, thus insuring uniform adequate ablation. The proximal end 15 of the catheter receives a syringe (not shown) either by screwing into the proximal end 15 of inner tube 12 or by pressure fitting into proximal end 15. The syringe, which fits into opening 15, is pre-filled with the chemical cauterant to obviate any operator handling of the caustic material. A drawstring (not shown) can be used to tighten the collar 14.

[0022] The outer tube 11 has one half cm markings 16 in the illustrated embodiment to allow the operator to gauge the depth of insertion into the uterine cavity.

[0023] The pre-filled syringe securely locks on to the catheter, with a snug adherence of the delivery system to the portion of the cervix and no reliance upon power source for completion of the ablation.

[0024] The porous sponge like material 13 is "swedged-on" to the distal end of the inner tube 12.

[0025] Referring now to Fig. 2, when the outer tube 11 is retracted proximately and/or the inner tube 12 is moved distally in relation to the outer tube 11, the sponge-like material 13 springs open, conforming to the contours of the endometrial surface of the uterus 17. The chemical cauterant is contained within a pre-loaded, closed syringe system 13. A pre-calculated volume of chemical cauterant is injected to adequately saturate the sponge which is in direct contact with the endometrial surface for a specified period of time.

[0026] After application of the cauterant chemical to the endometrial surface, the porous and/or sponge-like material 13 is then pulled back to be retracted into the outer sheath, the cervical collar loosened slightly, withdrawn and then further cinched closed to prevent any liquid from escaping during final removal through the vagina.

[0027] The distal tip of the device may have a single or multiple openings so as to allow adequate diffusion of the chemical cauterant to spread evenly through the endometrial cavity, thus insuring uniform adequate ablation. The proximal end of the catheter attaches to a syringe pre-filled with the chemical cauterant to obviate any operator handling of the caustic material.

[0028] The insertion catheter has one half cm 16 markings to allow the operator to gauge the depth of insertion into the uterine cavity.

[0029] The unique features of this device include the safety-designed catheter, pre-filled syringe that securely locks on to the catheter, the snug adherence of the delivery system to the portio of the cervix and no reliance upon power source for completion of the ablation.

[0030] The present invention, therefore, is well adapted to carry out the objects and attain the ends and advantages mentioned, as well as others inherent therein. While the invention has been depicted and described and is defined by reference to particular preferred embodiments of the invention, such references do not imply a limitation on the invention, and no such limitation is to be inferred. The invention is capable of

considerable modification, alteration and equivalents in form and function, as will occur to those ordinarily skilled in the pertinent arts. The depicted and described preferred embodiments of the invention are exemplary only and are not exhaustive of the scope of the invention. Consequently, the invention is intended to be limited only by the spirit and scope of the appended claims, giving full cognizance to equivalents in all respects.

CLAIMS

What is claimed is:

1. A device for chemical endometrial ablation comprising an outer tube having a lumen, a proximal end, a distal end, and an inner diameter, a cervical collar surrounding a portion of the outer tube on the outer tube and moveable in relation to the outer tube, an inner tube having an outer diameter less than the inner diameter of the outer tube, the inner tube movable in a distal-proximal direction within the lumen of the outer tube, the inner tube having a proximal end and a distal end, a porous and/or sponge-like material on the distal end of the inner tube within the lumen of the distal end of the outer tube, the porous and/or sponge-like material having a size, shape, and expandability so that when the distal end of the inner tube within the distal end of the outer tube is moved in a distal direction in relation to the outer tube, the porous and/or sponge-like material expands to the approximate size of a uterus having an endometrium so as to contact the endometrium of the uterus, a source of cauterizing agent at the proximal end of the inner tube, and means to cause the cauterizing agent to flow through the lumen of the inner tube onto the porous and/or sponge-like material.

2. The device of claim 1 wherein the cauterizing agent is trichloroacetic acid or its derivatives or silver nitrate or its derivatives.

3. The device of claim 1 wherein the uterus has contours and the porous and/or sponge-like material conforms to contours.

4. The device of claim 1 wherein the source of cauterizing agent is a syringe fluidly connected to the proximal end of the inner tube so that when operated, the syringe causes cauterizing agent to flow through the lumen of the inner tube and to exit through the pores of the porous and/or sponge-like material.

5. The device of claim 1 wherein the outer tube has markings to allow the operator to gauge depth of insertion into a uterine cavity.

6. The device of claim 1 wherein the cervical collar is lined with an absorptive fiber.

7. The device of claim 1 wherein the cervical collar surrounding a portion of the outer tube on the outer tube and moveable in relation to the outer tube comprises

means to secure the collar on a cervix to prevent chemical cauterizing agent from entering the vagina.

8. The device of claim 7 wherein the means to secure or lock the collar comprises a drawstring.

9. The device of claim 1 wherein the cauterizing agent is trichloroacetic acid.

10. A method for chemical endometrial ablation of a uterus comprising providing a device according to claim 1, moving the distal end of the inner tube in a distal direction in relation to the outer tube, causing the porous and/or sponge-like material to expand to the approximate size of a uterus having an endometrium so as to contact the endometrium of the uterus, and causing the cauterizing agent to flow through the lumen of the inner tube onto the porous and/or sponge-like material.

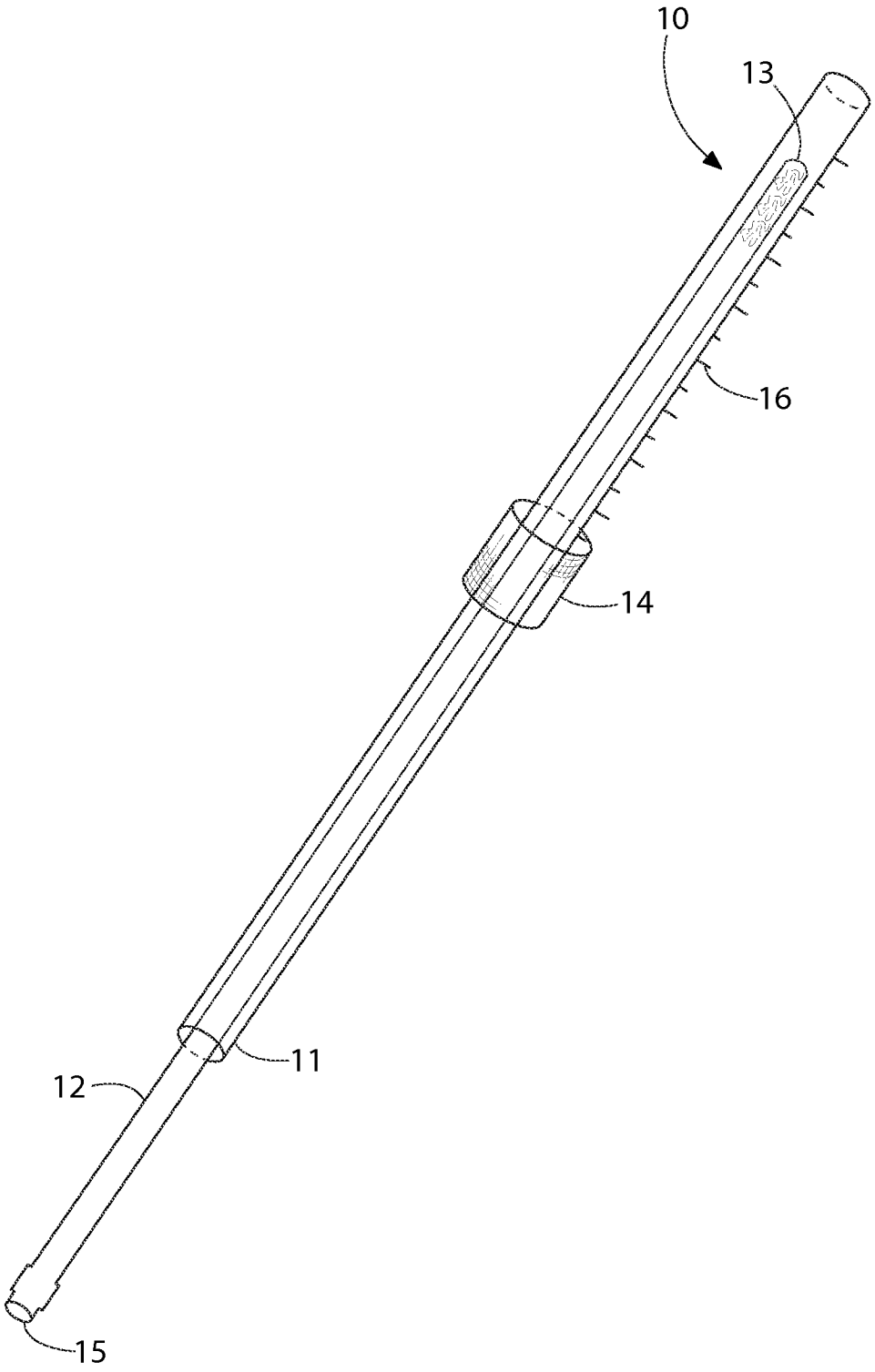

FIG. 1

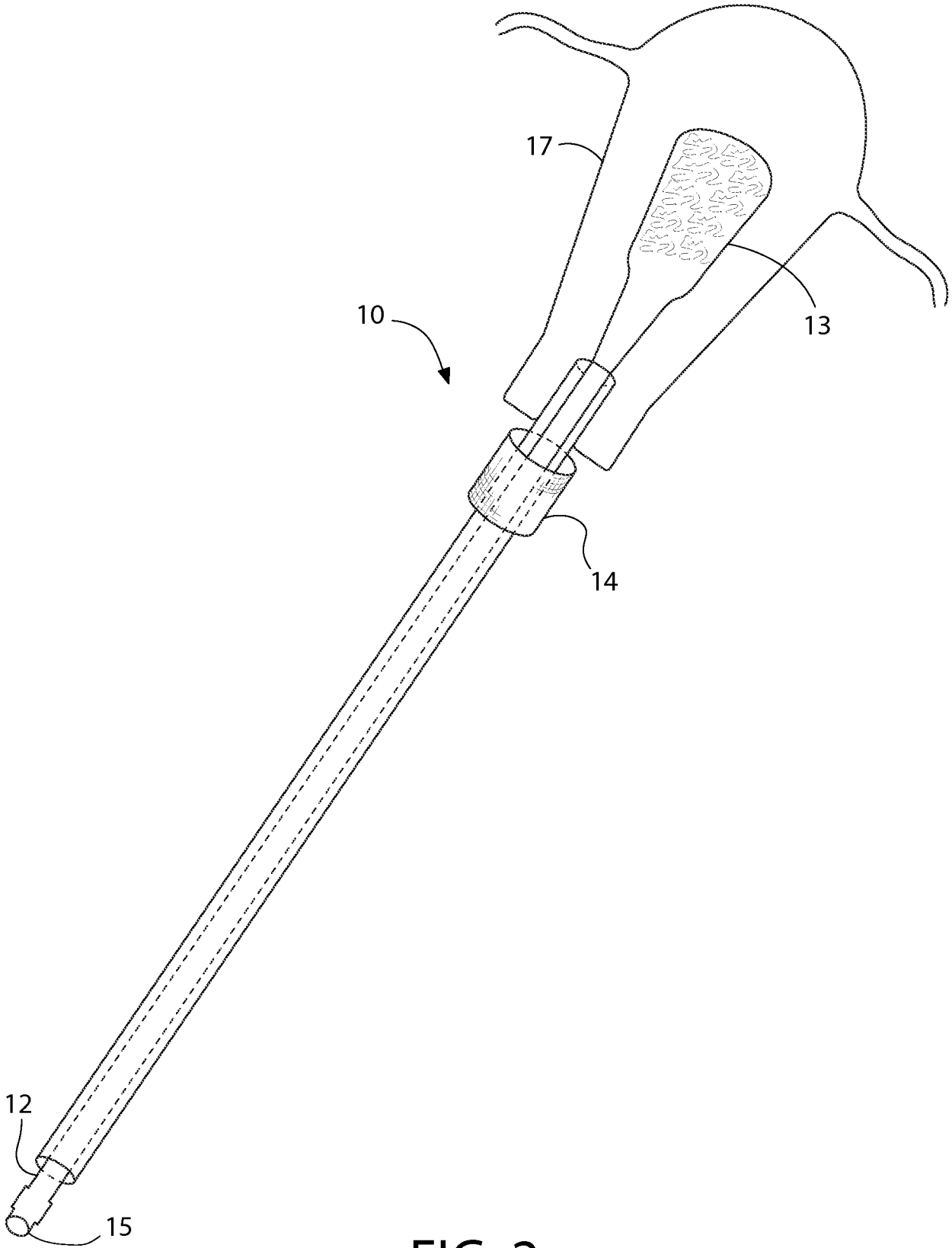

FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/045566

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/3205(2006.01)i, A61B 17/42(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 17/3205; A61F 6/06; A61M 31/00; A61M 25/10; A61B 18/04; A61F 2/82; A61B 18/18; A61B 18/02; A61B 17/42

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: chemical, infusion, uterus, ablation, sponge, porous, expand, lining

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5891457 A (NEUWIRTH, R. S.) 06 April 1999 See abstract; column 6 - column 7; figure 1.	1-9
A	US 2009-0069883 A1 (DING, N. and ANDRUS, W. S.) 12 March 2009 See abstract; paragraphs [0008]-[0010], [0022]-[0028]; figures 1a-3.	1-9
A	US 2008-0058797 A1 (RIOUX, R. F.) 06 March 2008 See abstract; claims 15-22; figure 1.	1-9
A	US 6066132 A (CHEN, C and SKULA, E. R.) 23 May 2000 See abstract; claims 1-4; figures 4, 5.	1-9
A	US 2009-0138000 A1 (VANCELETTE, D. W. et al.) 28 May 2009 See abstract; claims 1-14; figure 8.	1-9

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 August 2013 (27.08.2013)	**02 September 2013 (02.09.2013)**

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/045566

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 10
because they relate to subject matter not required to be searched by this Authority, namely:
Claim 10 pertains to a method for treatment of the human body and thus relates to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulation under the PCT, to search.

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/045566

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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