

INTRAUTERINE ADHESION BARRIER DEVICE AND METHOD OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 62/325,125 filed April 20, 2016, which is hereby incorporated by reference in its entirety.

BACKGROUND

A. Field

[0002] This disclosure relates generally to intrauterine adhesion barrier (IUAB) devices and more particularly to an IUAB device for preventing adhesion reformation.

B. Description of Related Art

[0003] Asherman's syndrome refers to symptomatic intra-uterine adhesions that form most commonly as a result of gravid or non-gravid curettage or infection, and is a significant source of infertility and recurrent miscarriages. Uterine curettage ("D&C") is the most common cause of Asherman's syndrome, particularly when performed shortly after a pregnancy.

[0004] The treatment for Asherman Syndrome is hysteroscopic adhesiolysis. The uterine cavity is distended with fluid media and the adhesions are divided with scissors. The uterine cavity is generally in the shape of a triangle. It is a virtual space since the anterior and posterior walls are in direct contact.

[0005] Because the anterior and posterior walls are again in direct contact immediately after lysis of adhesions, recurrence of the adhesions during subsequent healing is common. In an effort to prevent recurrence, it is recommended that a mechanical barrier be placed into the uterus for a number of days immediately after lysis of intrauterine adhesions.

Clinicians frequently insert a "stent" into the uterine cavity to keep the anterior and posterior walls separated immediately following lysis of adhesions. Several different stents are currently used to reduce recurrence.

[0006] In the past, an intrauterine device (IUD) was used as a stent. However, because of the profile of IUDs, none of them prevented contact between the majority of the anterior and posterior wall of the uterus.

[0007] Currently, balloons catheters are the most common intrauterine stents used for prevention of reformation of intrauterine adhesions after hysteroscopic lysis. One example is the Foley catheter, which is an elastic balloon catheter designed for continuous drainage of the urinary bladder. However, because of the spherical shape of the Foley balloon, it does not effectively separate the uterine walls in the upper areas of the triangle shaped uterine cavity. In addition, distension of the uterine cavity by the balloon often results in significant uterine cramping and occasionally extrusion of the catheter. Further, the 4-5 mm diameter of the catheter extending through the cervix into the vagina is associated with an increased risk of ascending infection.

[0008] To improve upon this, a heart-shaped balloon uterine stent was developed for preventing post-operative recurrence of intrauterine adhesions. The heart shape is designed to more effectively separate the uterine walls both in the lower and upper areas. However, because of the shape, it is more difficult to place into the uterus than a Foley catheter, and is relatively painful to remove. Like the Foley catheter, the heart-shaped balloon stent is associated with uterine cramping in many women due to uterine distension. The 3 mm stem is likely to increase the risk of ascending infection, and thus prophylactic antibiotics are recommended while in place.

[0009] Thus, it would be desirable to provide an improved intrauterine stent to prevent reformation of intrauterine adhesions after hysteroscopic lysis. Specifically, the

intrauterine stent should be relatively easy to insert, prevent apposition of the majority of the anterior and posterior uterine walls, minimally distend the uterine cavity to decrease discomfort and the risk of being expelled, minimize the risk of ascending intrauterine infection, and minimize discomfort during removal.

SUMMARY

[0010] The following embodiments and aspects thereof are described and illustrated in conjunction with systems, tools and methods which are meant to be exemplary and illustrative, not limiting in scope.

[0011] In one aspect, an intrauterine adhesion barrier (IUAB) device is disclosed. The IUAB device includes a frame having a vertical member and a horizontal member, and at least one flexible member attached to the vertical member and to the horizontal member. The vertical member has a first end and a second end, and the horizontal member has a first end, a second end, and a middle portion. The first end of the vertical member extends from the middle portion of the horizontal member, and the first end and the second end of the horizontal member extend outwardly from the vertical member.

[0012] In another aspect, an intrauterine adhesion barrier (IUAB) device includes a frame including a vertical member and a horizontal member, a first flexible member attached to the vertical portion at two attachments points and to the horizontal portion at one attachment point, a second flexible member attached to the vertical portion at two attachments points and to the horizontal portion at one attachment point, and a retrieval element. The vertical member having a first end and a second end, and the horizontal member having a first end, a second end, and a middle portion. The retrieval element is attached to the second end of the vertical member. The first end of the vertical member extends from the middle portion of the horizontal member, and the first end and the second end of the horizontal member extend outwardly from the vertical member.

[0013] In yet another aspect, a method of inserting an intrauterine adhesion barrier device into a patient is provided. The method includes providing an intrauterine adhesion barrier device having a frame with a vertical member and a horizontal member, and at least one flexible member attached to the vertical member and to the horizontal member. The vertical member has a first end and a second end, and the horizontal member has a first end, a second end, and a middle portion. The first end of the vertical member extends from the middle portion of the horizontal member, and the first end and the second end of the horizontal member extend outwardly from the vertical member. The method further includes providing an insertion tube with an internal diameter equal to or larger than that of an external diameter of the IUAB device, inserting the insertion tube into a uterus of a patient, pushing the IUAB device through the insertion tube, removing the insertion tube from the patient, and ensuring that the device is securely in place.

[0014] In yet another embodiment, a method of removing an intrauterine adhesion barrier device from a patient is disclosed. The method includes providing an intrauterine adhesion barrier device having a frame with a vertical member and a horizontal member, and at least one flexible member attached to the vertical member and to the horizontal member. The vertical member has a first end and a second end, and the horizontal member has a first end, a second end, and a middle portion. The first end of the vertical member extends from the middle portion of the horizontal member, and the first end and the second end of the horizontal member extend outwardly from the vertical member. The method further includes applying a downward force to the vertical member, thereby causing the horizontal member to fold upwardly.

[0015] In another embodiment, a kit including the intrauterine adhesion barrier (IUAB) device described above is disclosed. The kit is enclosed in sterile packaging, and also includes an insertion tube with an internal diameter equal to or larger than that of an

external diameter of the IUAB device, and instructions for insertion of the IUAB device into the uterus of a patient. The IUAB device is positioned within the insertion tube.

[0016] In addition to the exemplary aspects and embodiments described above, further aspects and embodiments will become apparent by reference to the drawings and by study of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Exemplary embodiments are illustrated in the drawings. It is intended that the embodiments and figures disclosed herein are to be considered illustrative rather than restrictive.

[0018] Figure 1A is a front view of an intrauterine adhesion barrier device of the present application including a retrieval element;

[0019] Figure 1B is a front view of another embodiment of an intrauterine adhesion barrier device of the present application including a retrieval element;

[0020] Figure 2A is the intrauterine adhesion barrier device shown in Figure 1A without the retrieval element;

[0021] Figure 2B shows the intrauterine adhesion barrier device with arms folded upward;

[0022] Figure 2C shows the intrauterine adhesion barrier device with arms folded downward;

[0023] Figure 3A is the intrauterine adhesion barrier device shown in Figure 1B without the retrieval element;

[0024] Figure 3B shows the intrauterine adhesion barrier device of Figure 3A with arms folded upward;

[0025] Figure 4 shows the intrauterine adhesion barrier device of Figure 1A inserted in a proper uterine position;

[0026] Figure 5 shows the intrauterine adhesion barrier device of Figure 1A being removed from a uterus with arms folded upward attached to material; and

[0027] Figure 6 shows the intrauterine adhesion barrier device of Figure 1A being removed from a uterus with arms folded upward detached from material.

DETAILED DESCRIPTION

[0028] An intrauterine adhesion barrier (IUAB) device that aids in the prevention of adhesion reformation in a patient is disclosed. The IUAB device is easy to insert and remove, minimizes uterine cramping, minimizes the risk of being expelled, and minimizes the risk of ascending uterine infection. In some embodiments, the device comprises a T-shaped frame that supports one large or two smaller triangle shaped pieces of impervious flexible adhesion preventing material, and that prevents contact of the anterior and posterior walls of the uterine cavity during healing. The IUAB device may be inserted into a patient's uterus in its folded state using an insertion tube similar to, but of slightly greater diameter than that used for contemporary IUD insertion. The IUAD has a flat profile which minimizes uterine cramping and the risk of being expelled. Moreover, the risk of ascending uterine infection is minimized by the utilization of a retrieval means, such as a monofilament string, instead of a thick stem. Removal is relatively easily and painless because the arms of the frame extend and fold with traction.

[0029] Figures 1A and 1B show an example IUAB device 100 of the present application. The IUAB device 100 includes a frame 102, which may have a T-shape. The frame 102 has a first, vertical member 104 and a second, horizontal member 110. The vertical and horizontal members 104, 110 may be constructed of a soft, flexible plastic material, for example. It should be understood that other suitable materials may be used as well. In one embodiment, the vertical member 104 and horizontal member 110 are constructed as a single piece. In an alternate embodiment, the vertical member 104 and

horizontal member 110 may be constructed as two separate pieces which are connected together by a thread, for example. In other embodiments, the vertical and horizontal members may be connected together by any suitable fastening device.

[0030] The vertical member 104 has a first end 106 located adjacent the horizontal member 110, and a second end 108 located opposite the first end 106. The horizontal member 110 includes a first end 112, a second end 114 which is opposite the first end, and a middle portion 116 located between the first end 112 and the second end 114. The first end 106 of the vertical member 104 extends from the horizontal member 110 at the middle portion 116. Additionally, the first end 112 and the second end 114 of the horizontal member 110 extend outwardly from the vertical member 104.

[0031] As shown in Figure 1A, the IUAB device 100 further comprises one or two flexible members 130, 132 attached to both the vertical member 104 and to the horizontal member 110. The flexible members 130, 132 may comprise any shape such that when inserted into the uterus, the IUAB device 100 is of a sufficient size to prevent contact of the anterior and posterior walls of the uterine cavity. In some embodiments, the flexible members 130, 132 comprise triangle-shaped pieces of a flexible material. In an alternative embodiment, shown in Figure 1B, a single flexible member 131, which may be a triangle-shaped flexible material, is connected to the frame 102. In other embodiments, the flexible material may take alternate shapes.

[0032] The flexible material may comprise, for example, an inert flexible material that does not adhere to healing human tissue, and thus acts as an adhesion barrier, such as expanded polytetrafluoroethylene material. In alternate embodiments, the flexible material may comprise other similar suitable materials as well.

[0033] Referring again to Figure 1A, the flexible members 130, 132 are attached to the IUAB device 100 via at least two respective attachment points, the first attachment point

134 positioned on the vertical member 104 and the second attachment point 136 positioned on the horizontal member 110. In some embodiments, the flexible members 130, 132 are attached to the frame 102 at three respective attachment points. In an example embodiment, the first attachment point 134 is at the first end 106 of the vertical member 104, the second attachment point 136 is at one end of the horizontal member 110, and the third attachment point 138 is at the second end 108 of the vertical member 104. In another embodiment, the second flexible member 132 is attached to the horizontal member 110 by an additional fourth attachment point 140. In other embodiments, alternate attachment configurations are possible.

[0034] In the case where a single flexible member 131 is used, the flexible member 131 may be attached to the horizontal member 110 at two attachment points 142, 144, as shown in Figure 1B. In one embodiment, two layers of flexible material can be secured together around the vertical member 104 to create openings. Alternatively, the flexible member 131 may be securely attached to the vertical member 104 via a suitable fastening mechanism.

[0035] The flexible members 130, 132, or 131, may be firmly affixed to the IUAB frame 102 so that they do not become completely detached from the frame 102 during insertion or removal of the IUAB device 100 from the uterus. In some embodiments, the flexible members 130, 132, or 131 may be attached to the vertical and/or horizontal members 104, 110 by one or more of threads, staples, sleeves, or an adhesive, such as glue, or a combination thereof. In the case where only one flexible member 131 is used, two layers of flexible material can be secured together around the vertical member using adhesive, staples, or thread, for example.

[0036] In one embodiment, the flexible members 130, 132, or 131 may be attached to the horizontal member 110 using a structure that is intended to break when pulled into

tension, such as a pop-off mechanism, fine thread or suture, an adhesive, or other similar structure. This type of structure will detach or break when a force is applied that folds the horizontal member 110 upwardly past perpendicular. In this embodiment, the flexible members 130, 132, or 131 will be firmly affixed to the vertical member 104 in such a manner that will not detach, thereby ensuring that the flexible members 130, 132, or 131 do not become completely detached from the frame 102.

[0037] The IUAB device 100 may further include a retrieval element 150 attached to the second end 108 of the vertical member 104. In some embodiments, the retrieval element 150 comprises a string, such as a monofilament string made of a durable material such as polyethylene or isotactic polypropylene, for example. It should be understood that other suitable retrieval elements and materials may be used as well. The retrieval element 150 facilitates removal of the IUAB device 100 from the uterus, which is described in more detail below.

[0038] Referring now to Figures 2A-2C, the IUAB device 100 is adapted to be folded in order to fit inside an insertion tube 200 for delivery to a patient. In one embodiment, the IUAB device 100 folds at one or more hinge points on the horizontal member 110 of the IUAB frame 102. In one example, the horizontal member 110 folds at two hinge points 118, 120. The first hinge point 118 is positioned between the first end 112 of the horizontal member 110 and the middle portion 116, and the second hinge point 120 is positioned between the second end 114 of the horizontal member 110 and the middle portion 116. When folded, the horizontal member 110 is divided into a first arm 111 and a second arm 113. The first arm 111 extends from the first end 112 of the horizontal member 110 to the first hinge point 118, and the second arm 113 extends from the second end 114 of the horizontal member 110 and the second hinge point 120.

[0039] The arms 111, 113 of the IUAB device 100 may also fold during removal in order to allow for the device to slide through the cervix and out of the patient. For example, in one embodiment, the flexible material is firmly affixed to the horizontal member 110 with a breakable component (e.g., a thread) that remains attached when the arms 111, 113 are flexed downward for insertion, but breaks during removal when the arms 111, 113 are flexed upward. In an alternate embodiment, the connection between the flexible material and the horizontal member 110 may be in the form of one or more sleeves that slide along the horizontal member so that the flexible material can stay attached when the arms 111, 113 are flexed either upwards or downward for insertion and upward for removal. The insertion and removal of the IUAB device 100 is described in more detail below.

[0040] Figure 2B shows the IUAB device 100 with the flexible material 130, 132 folded upwardly. In this embodiment, the flexible material of the flexible members 130, 132 is folded upwardly by sliding or moving the third attachment 138, which may be in the form of a sleeve, upward on the vertical member 104. Figure 2C shows the IUAB device 100 with the flexible material of the flexible members 130, 132 folded downwardly. In this embodiment, the flexible material of the flexible members 130, 132 is folded downwardly by the first and fourth attachment points 136, 140, which may also be in the form of sleeves, sliding or moving along the horizontal member 110.

[0041] Similarly, in the case where only one flexible member 131 is used, the flexible material of the flexible member 131 folds as the two attachment points 142, 144 slide along the horizontal member 110, as shown in Figures 3A and 3B. In one example, the flexible member 131 can comprise two layers of flexible material secured together around the vertical member 104 to create openings, allowing the connections or attachment points 142, 144 to slide along the horizontal member 110 when the frame folds upward, as shown in Figure 3B.

It should be understood that the single flexible member 131 may fold downward as well, in a similar manner as described above with respect to Figure 2C.

[0042] When folded, the IUAB device 100 will fit into an insertion tube 200, as shown in Figures 2B, 2C, and 3B, similar to that used for IUD insertion, but of a slightly larger diameter to accommodate the bulk of the flexible members 130, 132. The insertion tube 200 facilitates insertion of the IUAB device 100 into a patient. When folded, the diameter of the IUAB device 100 measures in the range of about 5 mm to about 7 mm. Thus, the diameter of the insertion tube 200 may be in the range of about 7 mm to about 9 mm, for example.

[0043] Another aspect of the present disclosure provides a kit including the intrauterine adhesion barrier device 100. The kit may include, under sterile packaging, an inserter made up of a tube, such as tube 200 described above, having an internal diameter equal to or slightly larger than the external diameter of the intrauterine adhesion barrier (IUAB) device 100 described above. The kit further includes the IUAB device 100 positioned within the tube 200, and instructions for inserting the IUAB device 100 into the uterus of a patient.

[0044] In operation, the IUAB device 100 may be prepared for insertion into a patient by being collapsed into a folded state. The IUAB device 100 may be folded by pulling downward on the retrieval element 150, allowing the arms 111, 113 of the horizontal member 110 to fold upwardly, as described above. In one embodiment, the IUAB device 100 is then placed into an inserter such as insertion tube 200. In some embodiments, the cervix of the patient is dilated prior to inserting the tube 200. For example, the cervix of the patient may be dilated to accommodate an operative hysteroscope with a diameter of about 5.5mm to about 8mm. The tube 200 containing the IUAB device 100 is then inserted into the uterus of the patient through the vagina. The tube 200 is placed at the mouth of the cervix, and the

IUAB device 100 is then pushed through the tube 200 to fully insert the IUAB device 100 into the uterus of the patient. The IUAB device 100 is considered to be securely in place within the uterus when the arms 111, 113 fully extend so that they are perpendicular to the horizontal member 110, resulting in the triangle configuration. In one embodiment, the IUAB device is inserted into the uterus immediately following hysteroscopic lysis of adhesions to prevent adhesion reformation.

[0045] Referring to Figure 4, once inserted into the uterus 300, the tube 200 is removed from the patient, which causes the folded arms 111, 113 of the horizontal member 110 to expand outwardly about 90 degrees from the vertical member 104, and spread out the flexible members 130, 132. The retrieval element 150 may extend downwardly from the vertical member 104 into the vagina. Due to the substantially flat configuration of the IUAB device 100, there is minimal distention of the uterus.

[0046] To remove the IUAB device 100, the arms 111, 113 of the horizontal member 110 are once again folded by pulling downwardly on the retrieval element 150, as shown in Figure 5. In this embodiment, the flexible material of the flexible members 130, 132 slides at the third attachment 138 to the vertical member 104, and folds upwardly with the arms 111, 113 when the IUAB device 100 is pulled into the tubular uterine cervix. The third attachment 138 may therefore be in the form of a sleeve.

[0047] Figure 6 shows an alternative embodiment of the folding of the IUAB device 100 for removal. In this embodiment, the arms 111, 113 of the horizontal member 110 are folded by pulling downwardly on the retrieval element 150 as in Figure 5. The downward force bends the arms 111, 113 upwardly past perpendicular, which causes the attachments 136, 140 to break, and therefore fully detach from the horizontal member 110. As mentioned above, the attachments 136, 140 may be any type of known mechanism, such as a pop-off mechanism, a fine suture or thread, or an adhesive, for example. The attachments 134, 138 to

the vertical member 104 remain, and the IUAB device 100 can be fully removed from the patient. Example

[0048] In one embodiment, the IUAB device 100 may be inserted into the uterus immediately following hysteroscopic lysis of adhesions to prevent adhesion reformation. Because of the generally flat profile of the IUAB device 100, placement of the device does not result in uterine distension. Further, a thick stem does not protrude into the vagina.

[0049] While a number of exemplary aspects and embodiments have been discussed above, those of skill in the art will recognize that still further modifications, permutations, additions and sub-combinations thereof of the features of the disclosed embodiments are still possible. It is therefore intended that the following appended claims and claims hereafter introduced are interpreted to include all such modifications, permutations, additions and sub-combinations as are within their true spirit and scope.

CLAIMS

1. An intrauterine adhesion barrier (IUAB) device comprising:
a frame including a vertical member and a horizontal member, the vertical member having a first end and a second end, and the horizontal member having a first end, a second end, and a middle portion; and
at least one flexible member attached to the vertical member and to the horizontal member;
wherein the first end of the vertical member extends from the middle portion of the horizontal member, and the first end and the second end of the horizontal member extend outwardly from the vertical member.
2. The intrauterine adhesion barrier device of claim 1 wherein the at least one flexible member comprises a first flexible member and a second flexible member being positioned opposite the first flexible member, and wherein the second flexible member is attached to the vertical portion and to the horizontal portion.
3. The intrauterine adhesion barrier device of any preceding claim wherein each at least one flexible member is attached at three respective positions along the vertical portion and the horizontal portion.
4. The intrauterine adhesion barrier device of any preceding claim wherein each at least one flexible member is attached to the vertical portion and the horizontal portion via at least one of adhesive, threads, staples, or sleeves.
5. The intrauterine adhesion barrier device of any preceding claim wherein the frame further comprises a retrieval element attached to the second end of the vertical member.
6. The intrauterine adhesion barrier device of claim 5 wherein the retrieval element comprises a monofilament string.
7. The intrauterine adhesion barrier device of any preceding claim wherein the horizontal member includes a first hinge point and a second hinge point, the first hinge point being positioned between the first end of the horizontal member and the middle portion, and the second hinge point being positioned between the second end of the horizontal member and the middle portion.
8. The intrauterine adhesion barrier device of claim 7 wherein the horizontal member folds at the first hinge point and at the second hinge point upon a downward force.

9. The intrauterine adhesion barrier device of any preceding claim wherein the at least one flexible member detaches from the horizontal member upon removal of the IUAB device.

10. The intrauterine adhesion barrier device of any preceding claim further comprising an insertion tube, the insertion tube having an internal diameter larger than or equal to an external diameter of the intrauterine adhesion barrier device, the intrauterine adhesion barrier device being configured to fit within the insertion tube in a folded state.

11. An intrauterine adhesion barrier (IUAB) device comprising:

- a frame including a vertical member and a horizontal member, the vertical member having a first end and a second end, and the horizontal member having a first end, a second end, and a middle portion;

- a first flexible member attached to the vertical portion at two attachment points and to the horizontal portion at one attachment point;

- a second flexible member attached to the vertical portion at two attachment points and to the horizontal portion at one attachment point; and

- a retrieval element attached to the second end of the vertical member;

- wherein the first end of the vertical member extends from the middle portion of the horizontal member, and the first end and the second end of the horizontal member extend outwardly from the vertical member.

12. The intrauterine adhesion barrier device of claim 11 wherein the horizontal member includes a first hinge point and a second hinge point, the first hinge point being positioned between the first end of the horizontal member and the middle portion, and the second hinge point being positioned between the second end of the horizontal member and the middle portion.

13. The intrauterine adhesion barrier device of claim 12 wherein the horizontal member folds at the first hinge point and at the second hinge point upon application of a downward force to the retrieval member.

14. The intrauterine adhesion barrier device of any preceding claim wherein the first flexible member and the second flexible member are each attached at three positions along the vertical portion and the horizontal portion.

15. A method of inserting an intrauterine adhesion barrier device into a patient comprising:

- providing an intrauterine adhesion barrier device as claimed in claim 1 or claim 11;

providing an insertion tube with an internal diameter equal to or larger than that of an external diameter of the IUAB device;
inserting the insertion tube into a uterus of a patient;
pushing the IUAB device through the insertion tube;
removing the insertion tube from the patient; and
ensuring that the device is securely in place.

16. The method of claim 15 further comprising dilating a cervix of the patient prior to insertion of the insertion tube.

17. The method of claim 15 wherein the at least one flexible member is folded upwardly within the insertion tube.

18. The method of claims 15 wherein the at least one flexible member is folded downwardly within the insertion tube.

19. A method of removing an intrauterine adhesion barrier device from a patient comprising:

providing an intrauterine adhesion barrier device as claimed in claim 1 or claim 11; and

applying a downward force to the vertical member, thereby causing the horizontal member to fold upwardly.

20. The method of claim 19 wherein the at least one flexible member remains secured to the horizontal member as the horizontal member folds upwardly.

21. The method of claim 19 wherein the at least one flexible member detaches from the horizontal member as the horizontal member folds upwardly.

22. A kit comprising the intrauterine adhesion barrier (IUAB) device as described in any of claims 1-14, the kit being enclosed in sterile packaging, and further comprising:

an insertion tube with an internal diameter equal to or larger than that of an external diameter of the IUAB device, the IUAB device being positioned within the insertion tube;
and

instructions for insertion of the IUAB device into the uterus of a patient.

1/7

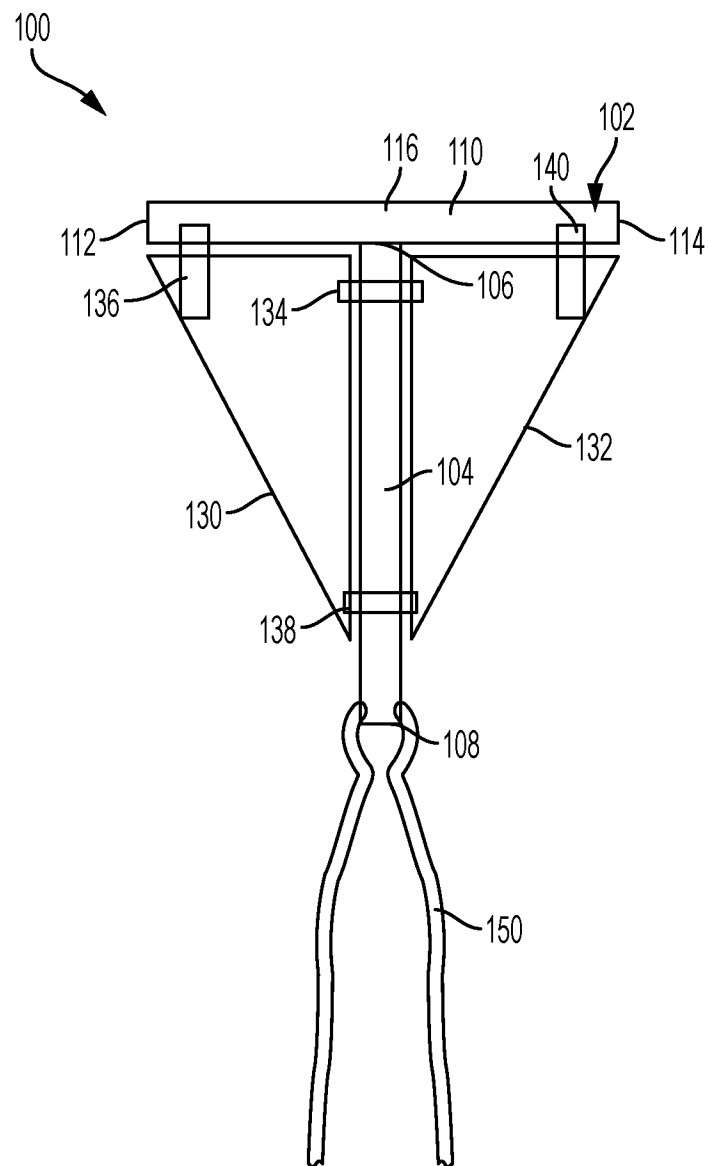


FIG. 1A

2/7

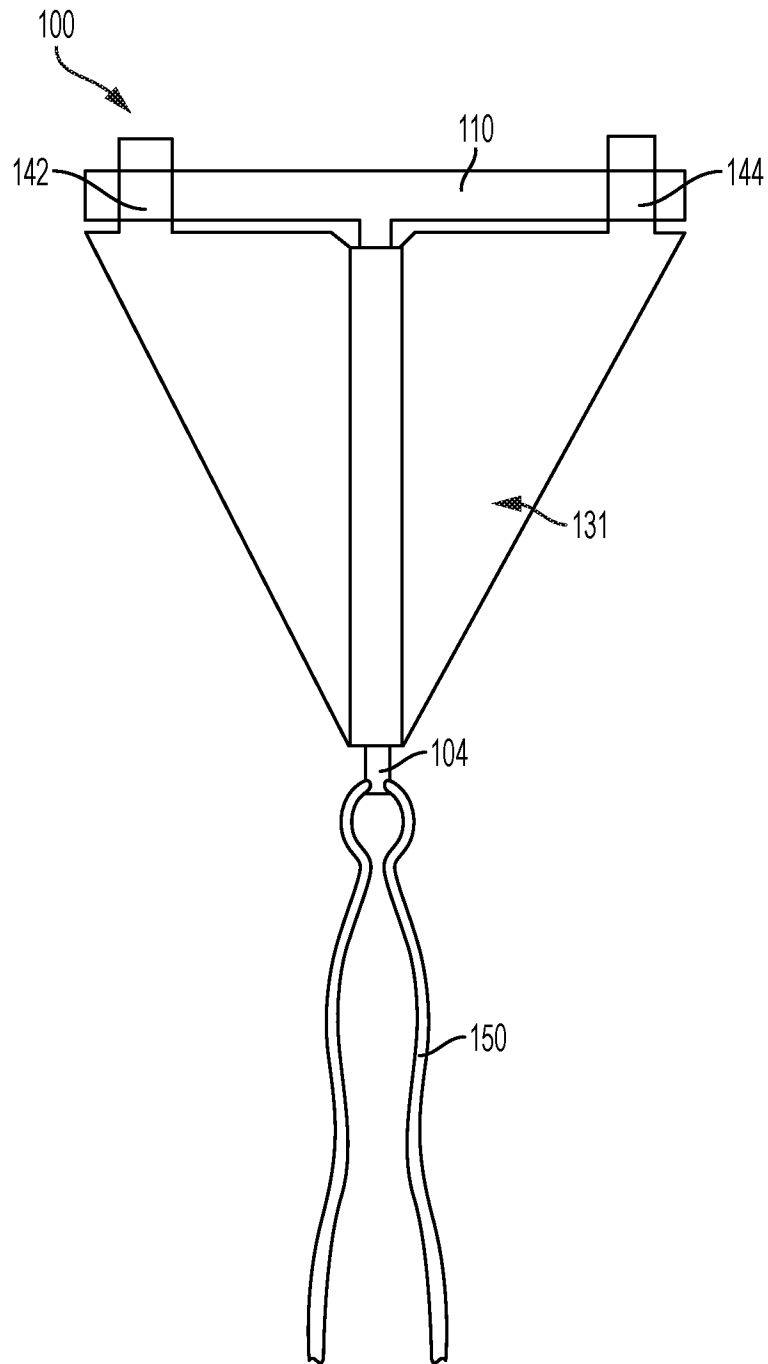


FIG. 1B

3/7

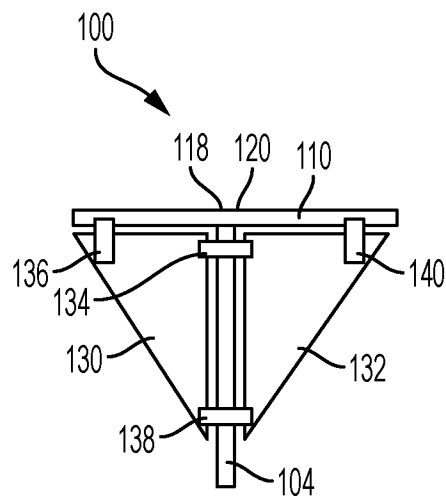


FIG. 2A

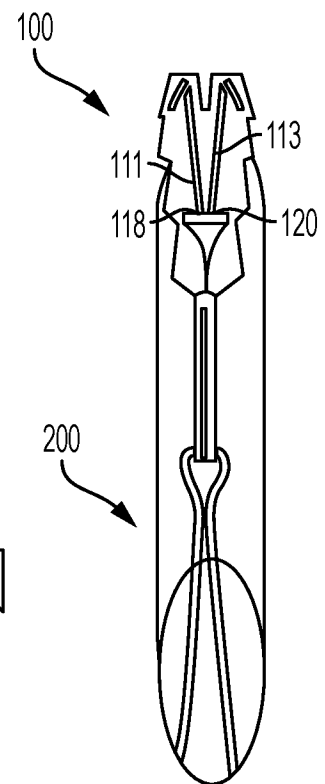


FIG. 2B

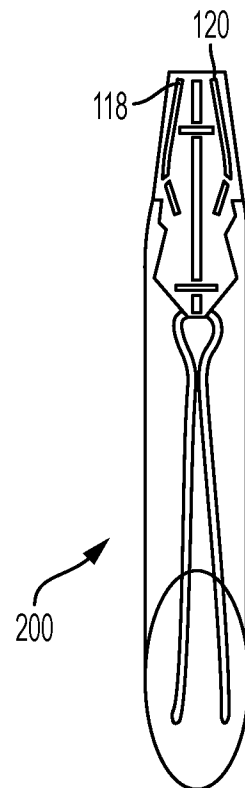


FIG. 2C

4/7

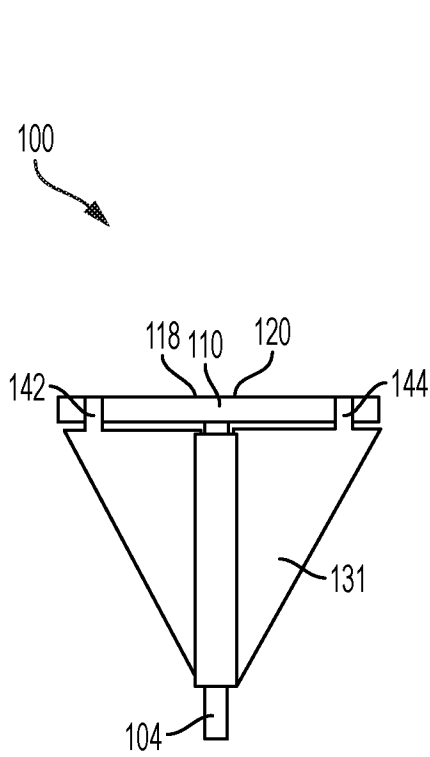


FIG. 3A

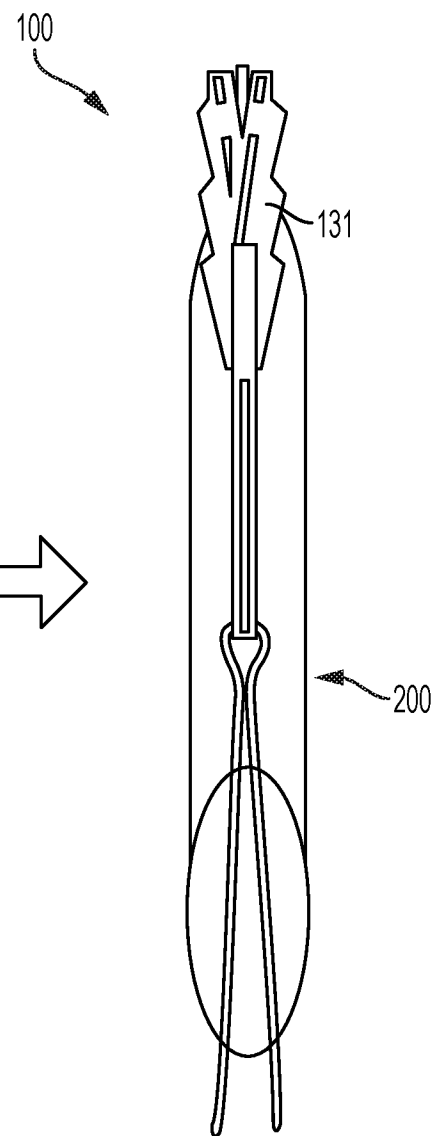
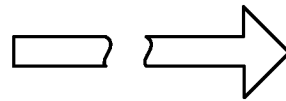


FIG. 3B

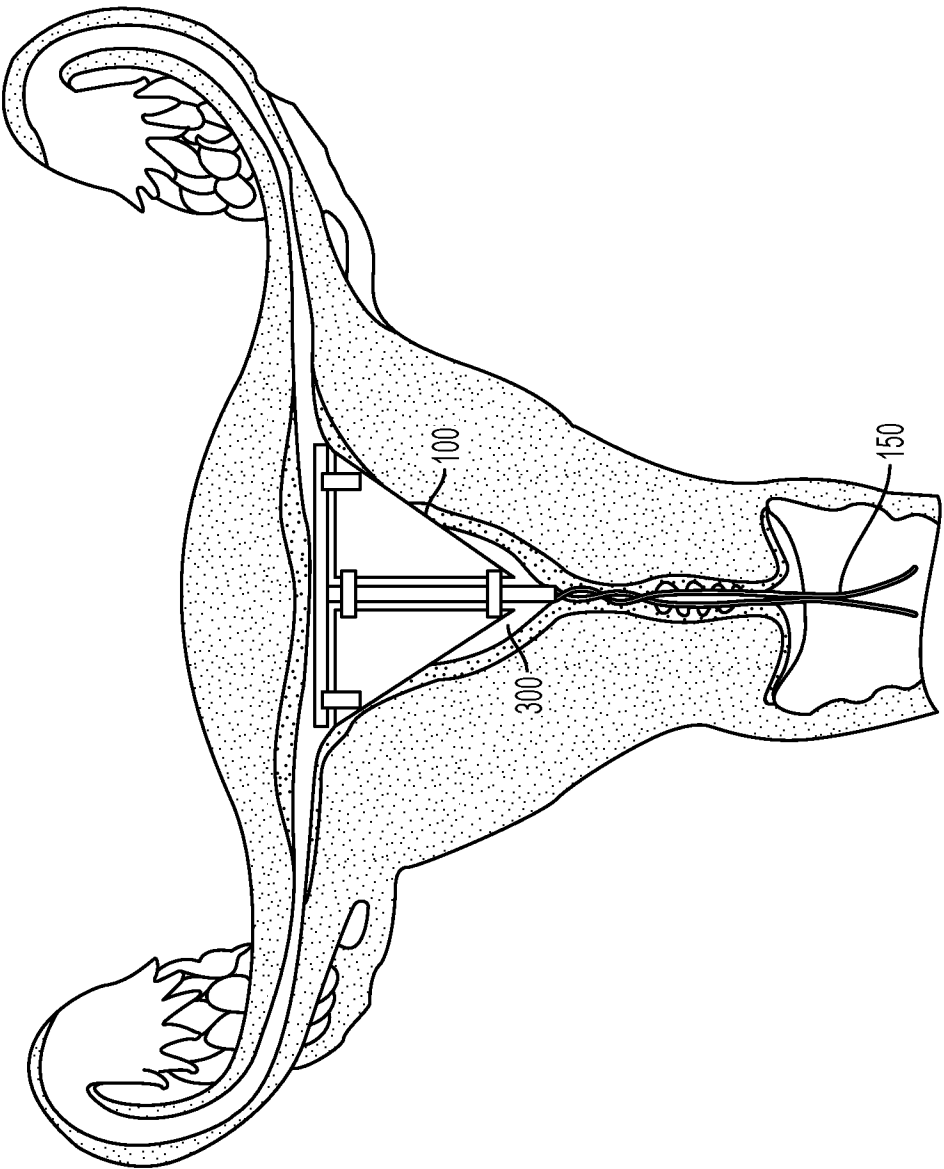


FIG. 4

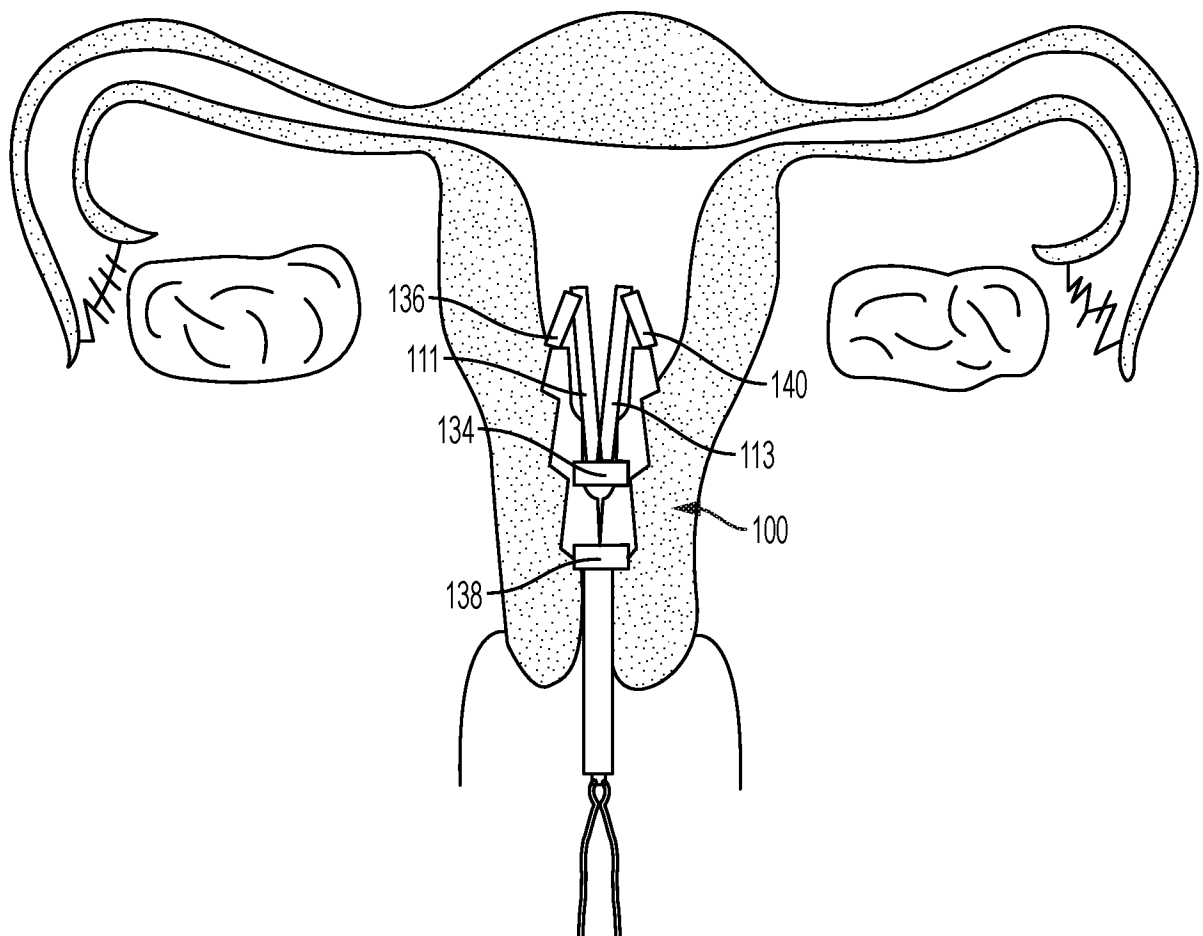


FIG. 5

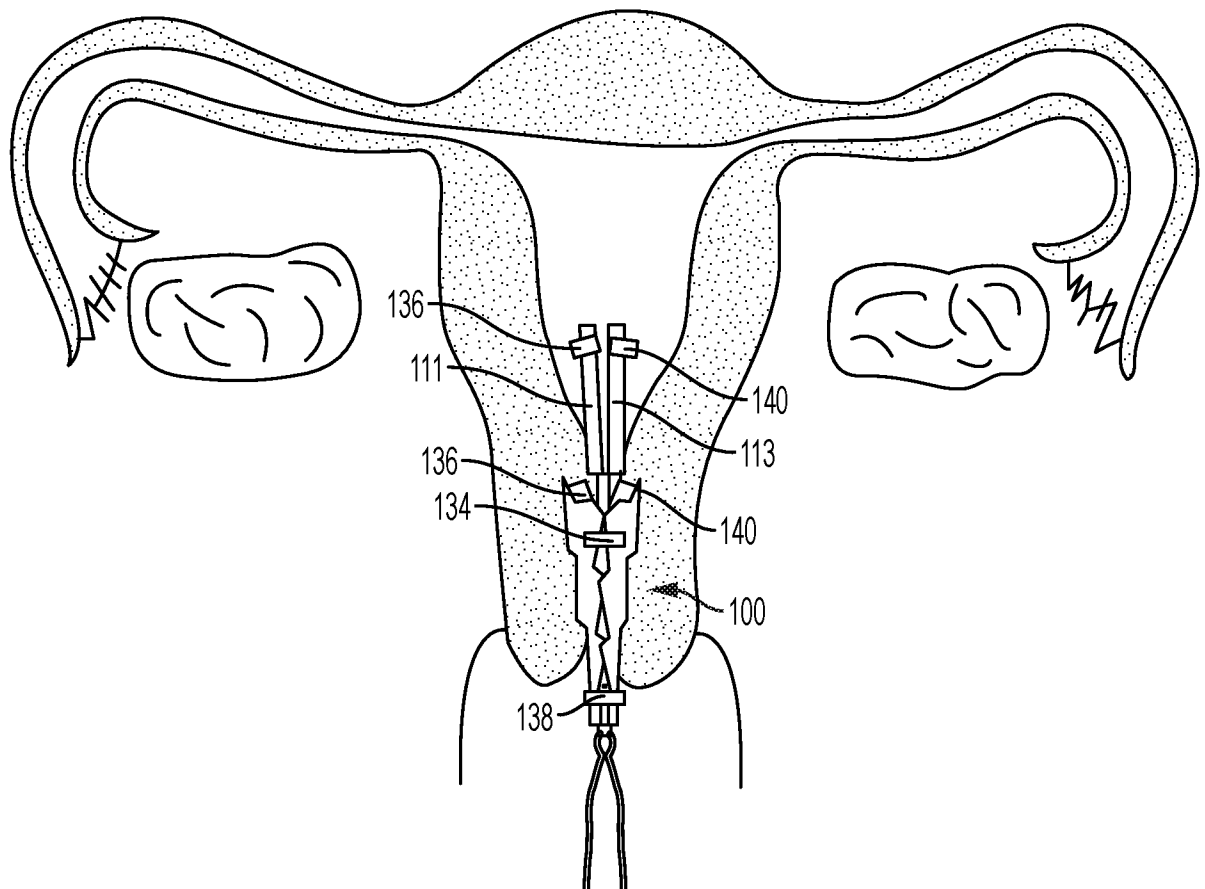


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 17/28250

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/42 (2017.01)

CPC - A61B 2017/4216, A61B 17/42, A61B 17/12022, A61F 6/144

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)

See Search History Document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2014/106315 A1 (RAO YONG) 10 July 2014 (10.07.2014) Entire document, especially Abstract, p6, para2, p9, para20 and FIG. 8.	1
X -- Y	CN 104771210 A (LING ANDONG) 15 July 2015 (15.07.2015) Entire document, especially Abstract, p2, para7- p3, para3 and FIG. 1.	1-3, 11 ----- 12-13
Y	US 3,935,860 A (HOFF) 03 February 1976 (03.02.1976) Entire document, especially Abstract, col 2, ln 63- col 3, ln 61 and FIGS. 1-2.	12-13
A	US 3,645,258 A (MASSOURAS) 29 February 1972 (29.02.1972) Entire document.	1-3, 11-13
A	CN 102120059 A (SOUTHEAST UNIVERSITY) 13 July 2011 (13.07.2011) Entire document.	1-3, 11-13
A	CN 103637836 A (NANYANG MEDICAL COLLEGE) 19 March 2014 (19.03.2014) Entire document.	1-3, 11-13
A	CN 102648868 A (XU DABAO) 29 August 2012 (29.08.2012) Entire document.	1-3, 11-13
A	CN 104323829 A (NIV FUDAN SHANGHAI CANCER CT) 04 February 2015 (04.02.2015) Entire document.	1-3, 11-13
A	US 3,820,535 A (MARCO) 28 June 1974 (28.06.1974) Entire document.	1-3, 11-13
A	US 6,708,056 B2 (DUCHON et al.) 16 March 2004 (16.03.2004) Entire document.	1-3, 11-13

☐ 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 another 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

08 August 2017

Date of mailing of the international search report

29 AUG 2017

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 17/28250

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.:
because they relate to subject matter not required to be searched by this Authority, namely:

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.: 4-10, 14, 22
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:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: claims 1-3, 11-13, drawn to an intrauterine adhesion barrier device

Group II: claims 15-21, drawn to method of inserting and method of removing intrauterine adhesion barrier devices

The inventions listed as Groups I - II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

----- see extra sheet -----

1. ☐ As all required additional 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 additional fees, this Authority did not invite payment of additional fees.
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.: 1-3, 11-13

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

International application No.

PCT/US 17/28250

----- Continuation of Box III: Observations where unity of invention is lacking (Continuation of item 3 of first sheet) -----

Group II includes the special technical features of method steps including particular use steps (Claim 15) providing an insertion tube with an internal diameter equal to or larger than that of an external diameter of the IUAB device; inserting the insertion tube into a uterus of a patient; pushing the IUAB device through the insertion tube; removing the insertion tube from the patient (Claim 19) applying a downward force to the vertical member, thereby causing the horizontal member to fold upwardly, not required by Group I.

Group I-II are related to an apparatus (Group I) and method(s) of using the apparatus (Group II). These groups therefore share the technical features of the apparatus of claims 1 and 11, however, these shared technical features fail to provide a contribution over the prior art of CN 104771210 A (LING ANDONG). LING ANDONG describes an intrauterine adhesion barrier (IUAB) device (Abstract) comprising: a frame (elastic/resilient support 1, FIG. 1; Abstract, p2, para7) including a vertical member (vertical portion of 1, FIG. 1; Abstract, p2, para7) and a horizontal member ('T-shaped' i.e. horizontal portion of 1, FIG. 1; Abstract, p2, para7), the vertical member having a first end and a second end (top/bottom, FIG. 1), and the horizontal member having a first end, a second end, and a middle portion (left/right/middle, FIG. 1); and at least one flexible member attached to the vertical member and to the horizontal member (expanded films 2, FIG. 1; Abstract, p2, para7- p3, para3: note elastic and entire device is flexible/foldable); wherein the first end of the vertical member extends from the middle portion of the horizontal member, and the first end and the second end of the horizontal member extend outwardly from the vertical member (FIG. 1; i.e. 'T-shape' p2, para7). LING ANDONG describes an intrauterine adhesion barrier (IUAB) device (Abstract) comprising: a frame (elastic/resilient support 1, FIG. 1; Abstract, p2, para7) including a vertical member (vertical portion of 1, FIG. 1; Abstract, p2, para7) and a horizontal member ('T-shaped' i.e. horizontal portion of 1, FIG. 1; Abstract, p2, para7), the vertical member having a first end and a second end (top/bottom, FIG. 1), and the horizontal member having a first end, a second end, and a middle portion (left/right/middle, FIG. 1); a first flexible member attached to the vertical portion [at two attachment points] and to the horizontal portion [at one attachment point] ('expanded films (2)', p3, para3; i.e. one of left/right films 2, FIG. 1); a second flexible member attached to the vertical position [at two attachment points] and to the horizontal portion [at one attachment point] ('expanded films (2)', p3, para3; i.e. one of left/right films 2, FIG. 1); and a retrieval element attached to the second end of the vertical member (wire 3, FIG. 1; Abstract, p4, para1); wherein the first end of the vertical member extends from the middle portion of the horizontal member, and the first end and the second end of the horizontal member extend outwardly from the vertical member (FIG. 1; i.e. 'T-shape' p2, para7), but fails to describe the attachment points of the flexible members to the vertical and horizontal portions, specifically: at two attachment points, at one attachment point (to the vertical/horizontal portions respectively). LING ANDONG discloses the attachment of flexible films to a collapsible/expandable elastic frame (Abstract, p2, para7- p3, para3), but doesn't explicitly disclose how/where. It would have been obvious to one skilled in the art, through routine experimentation, to provide any number and size of attachment points so as to securely maintain the film on the frame while minimizing manufacturing costs.

Thus, Groups I-II lack unity of invention because they do not share a same or corresponding special technical feature providing a contribution over the prior art.