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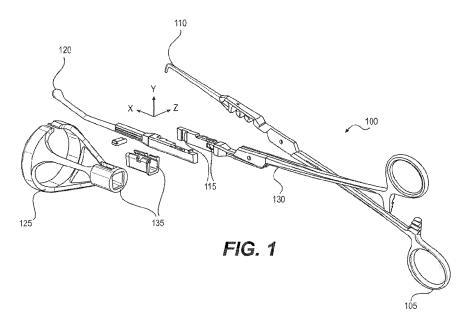
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(54) Title: UTERINE MANIPULATOR ARRANGEMENT



(57) Abstract: An exemplary apparatus, according to an exemplary embodiment of the present disclosure, can include, for example, a uterine manipulator having a clamp arrangement having a first tip(s) and a second tip(s), and a colpotomy ring arrangement coupled to the clamp arrangement on or at the first tip(s), and including an opening(s) in an outer surface thereof for insertion of the second tip(s) therethrough when the clamp arrangement is in a closed position. In some exemplary embodiments of the present disclosure, the clamp arrangement can include a uterine manipulator. The first tip(s) can include a plurality of removable tips, where each of the tips can have a different length from one another. In certain exemplary embodiments of the present disclosure, the first tip(s) can have a variable length.



UTERINE MANIPULATOR ARRANGEMENT CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This application relates to and claims priority from U.S. Patent Application No. 62/278,149, filed on January 13, 2016, the entire disclosure of which is incorporated herein by reference.

[0002]

FIELD OF THE DISCLOSURE

[0003] The present disclosure relates generally to a medical device, and more specifically, to exemplary embodiments of an exemplary uterine manipulator.

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BACKGROUND INFORMATION

Uterine manipulators are medical devices that are used to hold the uterus in [0004] place during surgery (e.g., during a hysterectomy). Current devices are made of plastic, are of inferior quality and often slip out during surgery, which can cause complications. For example, various uterine manipulators are available such as the Jarcho cannula or a tenaculum, both of which are essentially sponge sticks. There are also more complex manipulators available, such as the VCare® Uterine Manipulator/Elevator. However, uterine manipulators - in a stick form - have the disadvantage in that they can easily slip out. Currently-available devices are also complicated to use. For example, currently-available devices require two separate components (a colpotomy ring and a cannula) in order to perform the surgery. While such instruments may be capable when performing the specific task they are designed for, their drawbacks do not easily facilitate complex interactions often required between tool interactions in the uterine environment. The separate devices can be unwieldy to use, and can be difficult to place and maintain during surgery. Specifically, independently manipulating a separate colpotomy ring and a uterine cannula is non-optimal in a real world surgical setting. Thus, it may be beneficial to provide an exemplary uterine manipulator arrangement, which can overcome at least some of the deficiencies described herein above.

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SUMMARY OF EXEMPLARY EMBODIMENTS

[0006] An exemplary apparatus, according to an exemplary embodiment of the present disclosure, can include, for example, a uterine manipulator having a clamp arrangement having a first tip(s) and a second tip(s), and a colpotomy ring arrangement

coupled to the clamp arrangement on or at the first tip(s), and including an opening(s) in an outer surface thereof for insertion of the second tip(s) therethrough when the clamp arrangement is in a closed position. In some exemplary embodiments of the present disclosure, the clamp arrangement can include a tenaculum manipulator. The first tip(s) can include a plurality of removable tips, where each of the tips can have a different length from one another. In certain exemplary embodiments of the present disclosure, the first tip(s) can have a variable length.

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[0007] In some exemplary embodiments of the present disclosure, the first tip(s) can be coupled to the clamp arrangement using a key arrangement. The second tip(s) can include a hook tip, and the second tip(s) can be fixed to the clamp arrangement. A locking lug(s) can be configured to be inserted over the first tip(s) in order to secure the first tip(s) to the clamp arrangement. The colpotomy ring arrangement can be coupled to the clamp arrangement using the locking lug(s). In certain exemplary embodiments of the present disclosure, the colpotomy ring arrangement can include a ring shelf provided on the outer surface thereof or a groove provided on the outer surface thereof. In some exemplary embodiments of the present disclosure, the uterine manipulator can be configured to be inserted into a vagina of a patient.

[0008] Exemplary embodiments of the present disclosure can also include a colpotomy ring, which can include, for example, a first end configured to be coupled to a clamp arrangement, and a second end opposite the first end that can include a first circular portion and a second circular portion. The first circular portion can have a first outer surface that can have a first diameter and the second circular portion can have a second outer surface that can have a second diameter. The second diameter can be smaller than the first diameter.

25 **[0009]** Exemplary embodiments of the present disclosure can also include a colpotomy ring, which can include, for example, a first end configured to be coupled to a clamp arrangement, and a second end opposite the first end that can include a circular portion having a groove.

[0010] These and other objects, features and advantages of the exemplary embodiments of the present disclosure will become apparent upon reading the following detailed description of the exemplary embodiments of the present disclosure, when taken in conjunction with the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

- **[0011]** Further objects, features and advantages of the present disclosure will become apparent from the following detailed description taken in conjunction with the accompanying Figures showing illustrative embodiments of the present disclosure, in which:
- **[0012]** Figure 1 is an exemplary diagram of an exploded view of an exemplary device extending in a first direction according to an exemplary embodiment of the present disclosure;

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- **[0013]** Figure 2 is an exemplary diagram showing a perspective view of the exemplary device from Figure 1 extending in a second direction according to an exemplary embodiment of the present;
 - **[0014]** Figure 3 is an exemplary diagram showing a side view of the exemplary device from Figure 1 according to an exemplary embodiment of the present disclosure;
- [0015] Figure 4 is an exemplary diagram showing a front view of the exemplary device from Figure 1 according to an exemplary embodiment of the present disclosure;
- **[0016]** Figure 5 is an exemplary diagram showing a top-down view of the exemplary device from Figure 1 according to an exemplary embodiment of the present disclosure;
- [0017] Figures 6A-6C are exemplary diagrams illustrating exemplary connection between the variable length tip and the clamp according to an exemplary embodiment of the present disclosure;
 - **[0018]** Figures 7A-7C are exemplary close-up diagrams of a distal end of the exemplary device from Figure 1 according to an exemplary embodiment of the present disclosure;
- 25 **[0019]** Figures 8A-8C are further exemplary close-up diagrams of the distal end of the exemplary device from Figure 1 according to an exemplary embodiment of the present disclosure;
 - **[0020]** Figure 9A is an exemplary close-up diagram of the colpotomy ring placed over the locking lug with the tenaculum clamp in the open position according to an exemplary embodiment of the present disclosure;
 - **[0021]** Figure 9B is an exemplary close-up diagram of the colpotomy ring placed over the locking lug with the tenaculum clamp in the closed position according to an exemplary embodiment of the present disclosure;

[0022] Figure 10 is an exemplary close-up perspective diagram of the colpotomy ring according to an exemplary embodiment of the present disclosure;

- [0023] Figure 11 is an exemplary close-up front view of the colpotomy ring according to an exemplary embodiment of the present disclosure;
- 5 **[0024]** Figure 12 is an exemplary diagram showing a side view of the exemplary device from Figure 1 according to an exemplary embodiment of the present disclosure; and
 - [0025] Figure 13 is an exemplary perspective view of the exemplary device from Figure 1 according to an exemplary embodiment of the present disclosure.
- 10 **[0026]** Throughout the drawings, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components or portions of the illustrated embodiments. Moreover, while the present disclosure will now be described in detail with reference to the figures, it is done so in connection with the illustrative embodiments and is not limited by the particular embodiments illustrated in the figures and the appended claims.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

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[0027] According to an exemplary embodiment of the present disclosure, the exemplary device described herein can be used for performing laparoscopic and/or robotic hysterectomies. For example, the exemplary uterine manipulator arrangement can be a device that can facilitate laparoscopic and/or robotic hysterectomies. Placement of the exemplary device can be used to position the uterus in such a manner that the entire procedure can be easily performed. In contrast, current instruments that are used for the same procedure are unreliable (e.g., they are plastic, disposable and can slip out of the uterine cavity), and also can be difficult to place and to use. The exemplary device can combine a tenaculum clamp that can hold on to the cervix of the uterus, as well as a colpotomy ring that can aid in delineating the cervico-vaginal junction, to enable the hysterectomy to be performed. In an exemplary embodiment of the present disclosure, the colpotomy ring can be placed separately, and then attached to the clamp.

[0028] The exemplary device can integrate the utility of the tenaculum clamp and a colpotomy ring, while also being rigid. Various colpotomy ring sizes can be included, as well as various tip lengths. An exemplary pneumo-retaining balloon can be used to facilitate particular positioning of the exemplary device.

[0029] As shown in the diagrams of Figures 1-11C, an exemplary device or clamp 100 (e.g., including but not limited to a tenaculum clamp) can include a proximal end 105 and a distal end 110. The distal end 110 can include a mating surface 115 (e.g., a primary key and a secondary key for tip mating), which can be used to lock a tip 120 (e.g., a removable tip) in place (e.g., attached to the uterine manipulator). As shown in the diagrams of Figures 6A-6C, the removable tip 120 can vary in length (e.g., there can be multiple removable tips 605 and 610 each having its own length). Alternatively, or in addition, a single removable tip can be used that can have an adjustable length. Additionally, the tip 120 can be permanently attached to the distal end and can be adjustable in length. The tip 120 can be connected to the clamp 100 at location 615 using any suitable connection, including an interference fit as shown in the diagrams of Figures 6B and 6C.

[0030] The variable length tips can facilitate positive locking of the colpotomy ring 125 to the handle 130 when the clamp 100 is shut, regardless of the position of the colpotomy ring 125. The removable tip 120 can be locked in one of a plurality of positions (e.g., 3 positions as shown in the diagram of Figure 2), and it can be coupled to, and moved through, the colpotomy ring 125 assembly using a docking station that can have a docking position locking tab 205. The colpotomy ring 125 can include a lug 135 that can be keyed for single orientation fit and the exemplary colpotomy ring 125 can be formed from, or machined from, a single piece of material (e.g., from a single piece of metal such as stainless steel).

[0031] As shown in the diagram of Figure 1, the locking lug 135 can be used to further lock the variable length tip 120 to the clamp 100. This can facilitate the prevention of the variable length tip 120 from detaching during use. As shown in Figures 7A-7C, the colpotomy ring 125 can be placed in a plurality of positions (e.g., three positions as shown, although not limited thereto), and the placement of the colpotomy ring 125 can be dependent on the length of the tip 120 chosen and/or on the locking lug 135, although not limited thereto. For example, the colpotomy ring 125 can be placed in a first position that facilitates the hook tip of the tenaculum clamp 705 to extend a particular amount (e.g., distance) out of the colpotomy ring 125. (See, e.g., diagram shown in Figure 7A). Various other positions for the colpotomy ring 125 can be selected, which can affect the distance that hook tip of the tenaculum clamp 705 extends from the colpotomy ring 125. (See, e.g., diagram shown in Figure 7B). At a

particular position of the colpotomy ring 125 (see, e.g., diagram shown Figure 7C), the hook tip of the tenaculum clamp 705 may not extend at all past the colpotomy ring.

[0032] In some exemplary embodiments of the present disclosure, the distance between the hook tip of the tenaculum clamp 705 and the variable length tip 120 can be selected and/or changed, for example, based on the patient. Alternatively, the exemplary device can be configured such that the distance between the hook tip of the tenaculum clamp 705 and the variable length tip 120 can be approximately constant (e.g., about 0.5cm, about 1cm, about 2cm, about 3cm, etc.) regardless of the position that the colpotomy ring 125 is locked in. (See, e.g., diagrams shown in Figures 8A-8C).

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This can be accomplished, for example, using variable-length teeth 805 provided on the clamp, which can affect the height of the locking lug 135 with respect to the clamp.

[0033] As shown in the diagrams of Figures 9A and 9B, the colpotomy ring 125 can then be placed over the locking lug 135, while the clamp 100 is in the open position (see, e.g., diagram shown Figure 9A), and the colpotomy ring 125 can be locked in place when the clamp 100 is in the closed position. (See, e.g., diagram shown Figure 9B).

[0034] As shown in the diagram of Figure 10, the colpotomy ring 125 can include a ring shelf or a groove 1005 that can facilitate use as a guide for the surgeon when the exemplary device is inserted into the cervix. During use of the exemplary device, for example, the exemplary device can be inserted into the cervix through the vagina, and the surgeon can access the other side of the vagina through an incision in the abdominal wall of the patient. The surgeon can then feel the vaginal wall for the ring shelf or groove 1005 in the colpotomy ring 125, which can serve as a guide from which the surgeon can get tactile feedback about the location of the exemplary device. The surgeon can use this guide to cut the tissue around the cervix. The ring shelf or groove 1005 can also be used as a guide for an electric cutting tool (e.g., to cauterize around the cervix).

[0035] In order to facilitate the closing of the exemplary device (e.g., clamping the hook tip of the tenaculum clamp 705 to the variable length tip 120), the colpotomy ring 125 can include a ring slot 1105 that can facilitate the hook tip of the tenaculum clamp 705 to enter through the outer portion of the colpotomy ring 125. (See, e.g., diagram shown Figure 11). Thus, the colpotomy ring 125 does not block, or otherwise interfere with, the clamping, or scissor action, of the exemplary device. In order to ensure that the ring slot 1105 always substantially lines up with the hook tip of the tenaculum

clamp 705, the locking lug 135 can have a structure and/or configuration such that the colpotomy ring 125 can only be placed over the locking lug 135 at a particular orientation (e.g., an orientation that can facilitate the hook tip of the tenaculum clamp 705 to align with the ring slot 1105).

5 **[0036]** The exemplary device can include a mechanism for which the cup can be placed over the clamp and secured together (e.g., by screwing it in place).

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[0037] As shown in the diagrams of Figures 12 and 13, the exemplary device can have a reduced cradle length as compared to previous uterine manipulators. A reduced cradle length can reduce the bulk of the colpotomy ring 125 and the exemplary device while still maintaining the functionality and strength compared to other uterine manipulators.

[0038]The foregoing merely illustrates the principles of the disclosure. Various modifications and alterations to the described embodiments will be apparent to those skilled in the art in view of the teachings herein. It will thus be appreciated that those skilled in the art will be able to devise numerous systems, arrangements, and procedures which, although not explicitly shown or described herein, embody the principles of the disclosure and can be thus within the spirit and scope of the disclosure. Various different exemplary embodiments can be used together with one another, as well as interchangeably therewith, as should be understood by those having ordinary skill in the art. In addition, certain terms used in the present disclosure, including the specification, drawings and claims thereof, can be used synonymously in certain instances, including, but not limited to, for example, data and information. It should be understood that, while these words, and/or other words that can be synonymous to one another, can be used synonymously herein, that there can be instances when such words can be intended to not be used synonymously. Further, to the extent that the prior art knowledge has not been explicitly incorporated by reference herein above, it is explicitly incorporated herein in its entirety. All publications referenced are incorporated herein by reference in their entireties.

WHAT IS CLAIMED IS:

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- 1. A uterine manipulator, comprising:
- a clamp arrangement having at least one first tip and at least one second tip; and a colpotomy ring arrangement coupled to the clamp arrangement on or at the at least one first tip, and including at least one opening in an outer surface thereof for insertion of the at least one second tip therethrough when the clamp arrangement is in a closed position.
- 10 2. The uterine manipulator of claim 1, wherein the clamp arrangement includes at least one of a uterine manipulator or a tenaculum.
 - 3. The uterine manipulator of claim 1, wherein the at least one first tip includes a plurality of removable tips, each of the tips having a different length from one another.
 - 4. The uterine manipulator of claim 1, wherein the at least one first tip has a variable length.
- 5. The uterine manipulator of claim 1, wherein the at least one first tip is removablefrom the clamp arrangement, and wherein the at least one first tip has a variable length.
 - 6. The uterine manipulator of claim 1, wherein the at least one first tip is coupled to the clamp arrangement using a key arrangement.
- 7. The uterine manipulator of claim 1, wherein the at least one second tip includes a hook tip.
 - 8. The uterine manipulator of claim 1, wherein the at least one second tip is fixed to the clamp arrangement.
 - 9. The uterine manipulator of claim 1, wherein the at least one second tip extends a particular distance out of the colpotomy ring arrangement when the clamp arrangement is provided in a closed position.

10. The uterine manipulator of claim 1, wherein the at least one second tip does not extend out of the colpotomy ring arrangement when the clamp arrangement is provided in a closed position.

- 5 11. The uterine manipulator of claim 1, further comprising at least one locking lug configured to be inserted over the at least one first tip in order to secure the at least one first tip to the clamp arrangement.
- 12. The uterine manipulator of claim 11, wherein the colpotomy ring arrangement is10 coupled to the clamp arrangement using the at least one locking lug.
 - 13. The uterine manipulator of claim 1, wherein the colpotomy ring arrangement includes at least one of a ring shelf provided on the outer surface thereof or a groove provided on the outer surface thereof.

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- 14. The uterine manipulator of claim 1, wherein the uterine manipulator is configured to be inserted into a vagina of a patient.
- 15. The uterine manipulator of claim 1, wherein a distance between a first end of the at least one first tip and a second end of the at least one second tip is variable.
 - 16. The uterine manipulator of claim 1, wherein a distance between a first end of the at least one first tip and a second end of the at least one second tip is fixed.
- 25 17. A uterine ring, comprising:
 - a first end configured to be coupled to a clamp arrangement; and
 - a second end opposite the first end and including a first circular portion and a second circular portion;

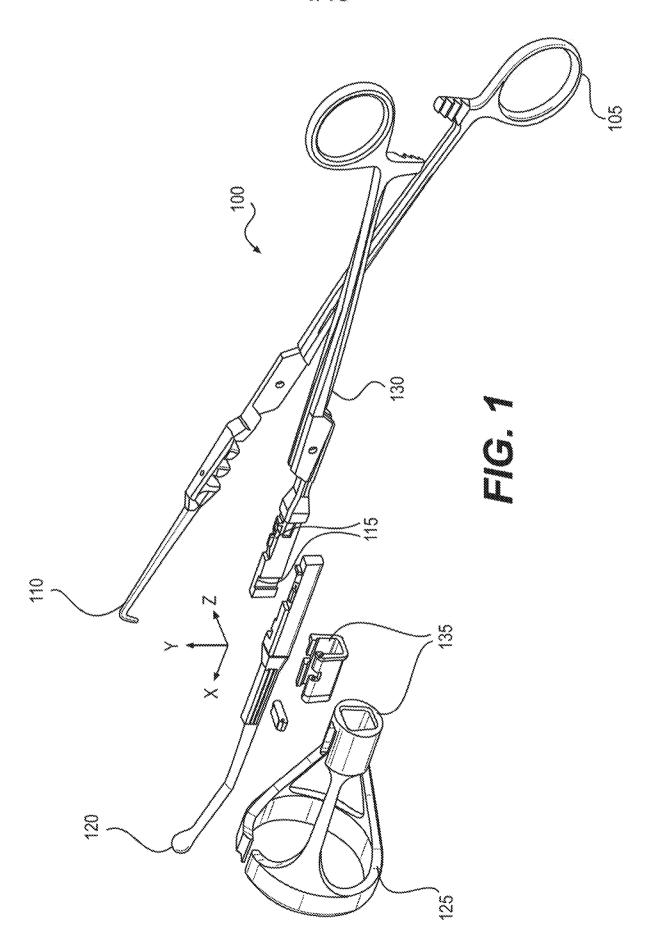
wherein the first circular portion has a first outer surface having a first diameter and the second circular portion has a second outer surface having a second diameter; and

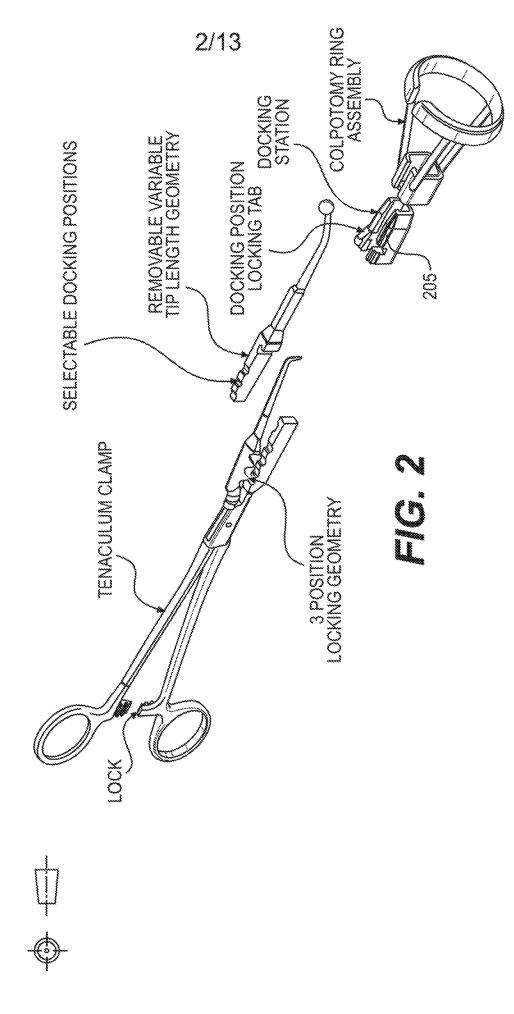
wherein the second diameter is smaller than the first diameter.

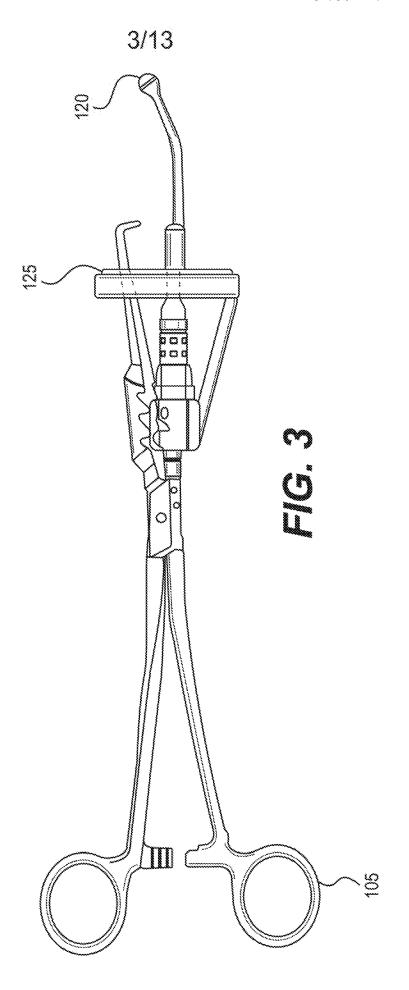
18. The uterine ring of claim 17, wherein the second end includes at least one opening in an outer surface thereof for an insertion of at least one tip from the clamp arrangement when the clamp arrangement is provided in a closed position.

- 5 19. A uterine ring, comprising:
 - a first end configured to be coupled to a clamp arrangement; and a second end opposite the first end and including a first circular portion having a groove.
- 10 20. The uterine ring of claim 19, wherein the second end includes at least one opening in an outer surface thereof for an insertion of at least one tip from the clamp arrangement when the clamp arrangement is provided in a closed position.

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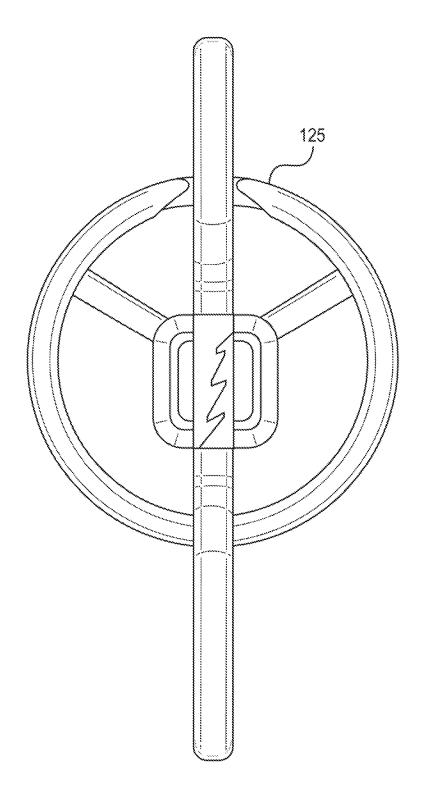
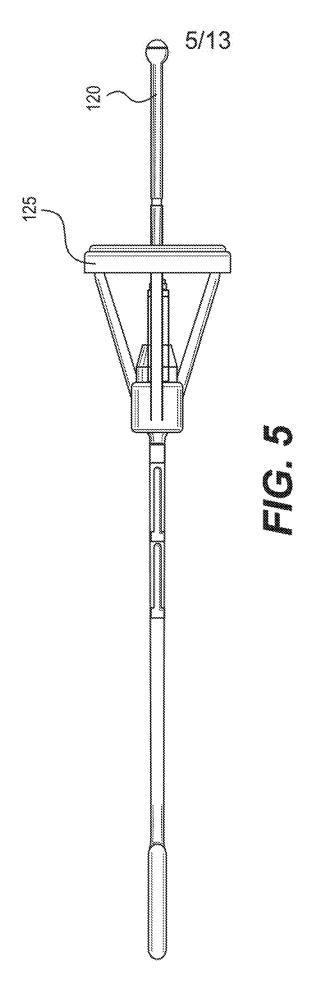
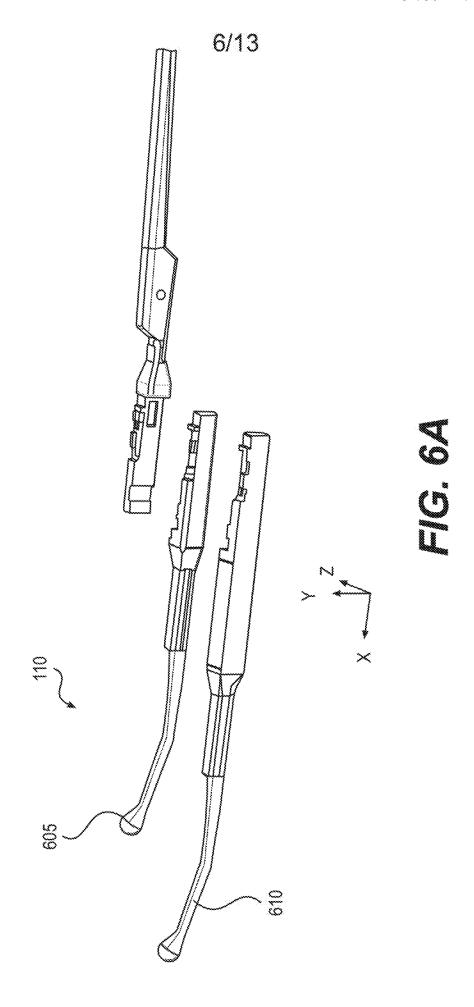


FIG. 4





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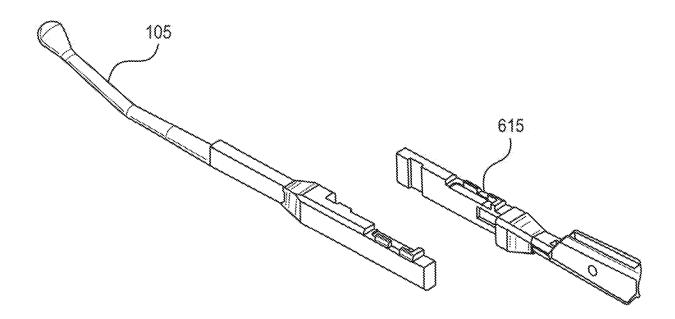
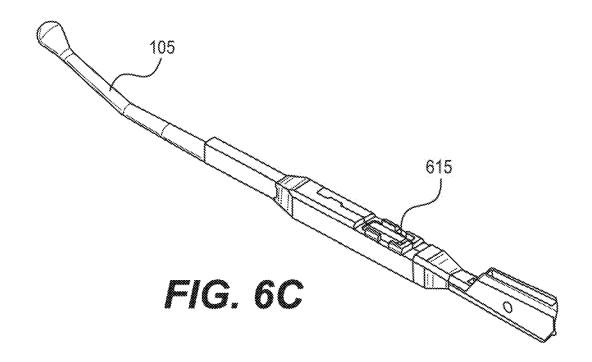


FIG. 6B



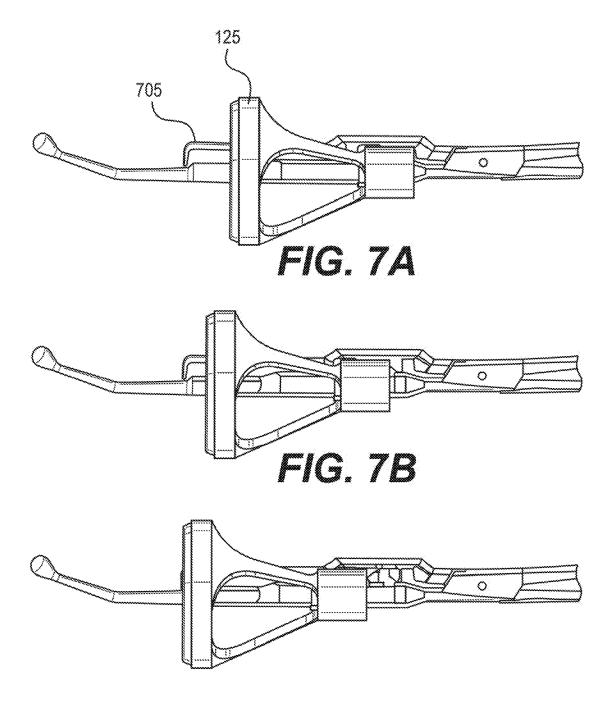
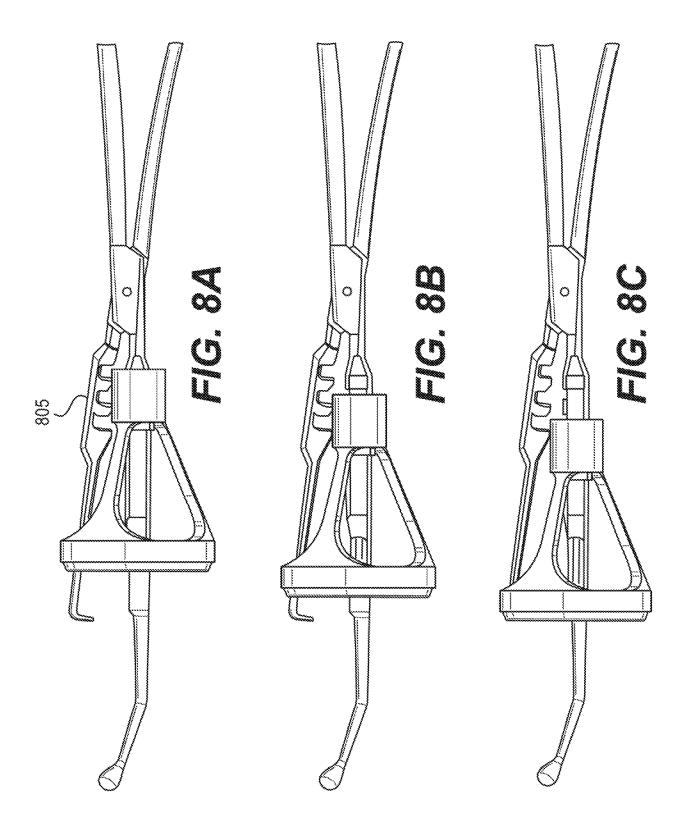
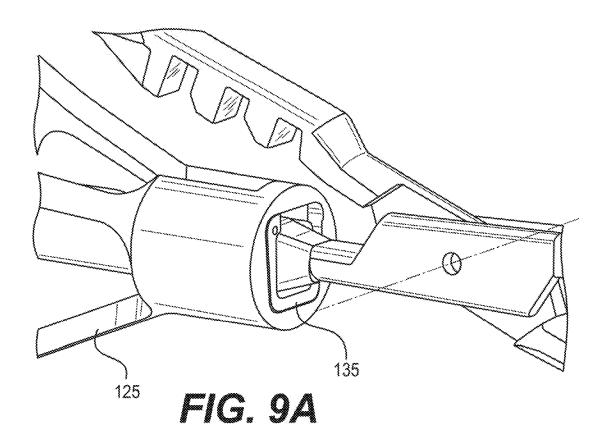
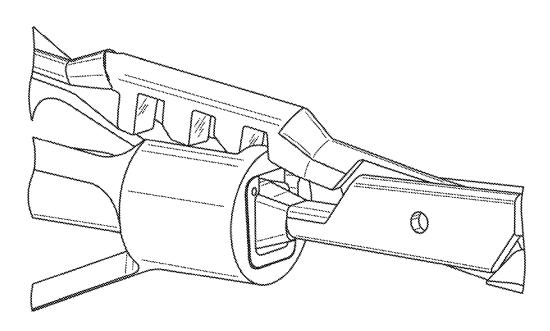


FIG. 7C

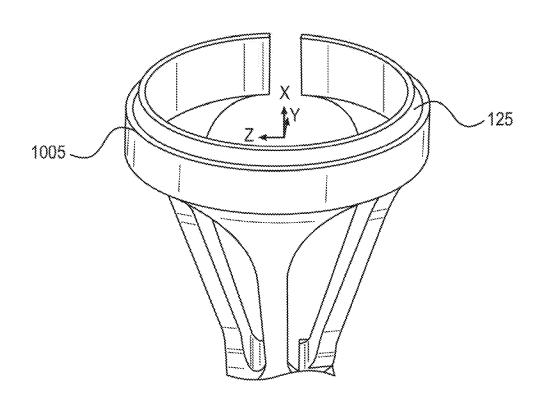


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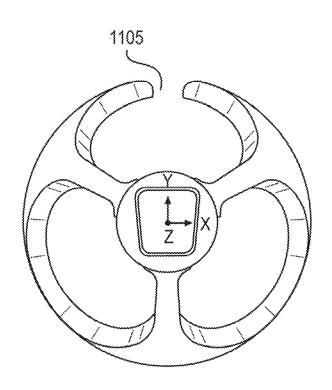
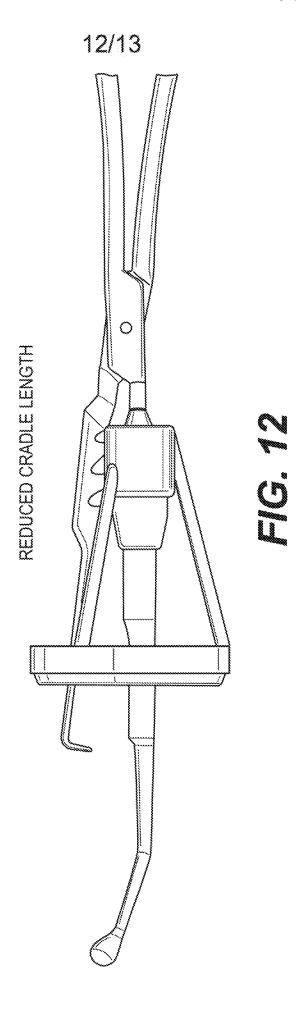
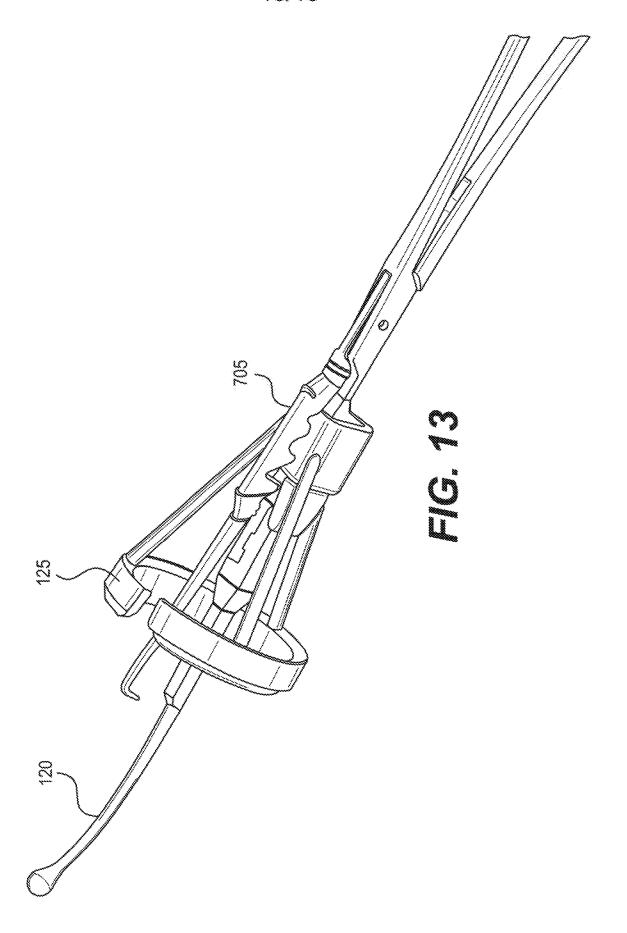


FIG. 11





INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 17/13365

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61B 17/42, A61B 17/44 (2017.01) CPC - A61B 17/4241, A61B 17/44, A61B 17/42, A61B 17/44								
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Category*	Citation of document, with indication, where ap		Relevant to claim No.					
X 	US 2012/0109147 A1 (AUERBACH et al.) 03 May 2012 (03.05.2012) Entire document, especially Abstract, para[0051]- para[0055] and FIGS. 1-9.		1-2, 7-8, 10, 13-14, 16					
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A	CN 202843741 U (PENGMU) 03 April 2013 (03.04.201	13) Entire document.	1-16					
Α	WO 2013/151512 A1 (TOMAZEVIC) 10 October 2013	(10.10.2013) Entire document.	1-16					
Furthe	er documents are listed in the continuation of Box C.	See patent family annex.						
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08 May 2017		2 5 MAY 2017						
	nailing address of the ISA/US	Authorized officer:						
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450		Lee W. Young PCT Helpdesk: 571-272-4300						
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Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 17/13365

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.: 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: 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.: 1-16						
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 17/13365

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Box No. III - Observations where unity of invention is lacking

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 1-16: a clamp arrangement having at least one first tip and at least one second tip; and a colpotomy ring arrangement coupled to the clamp arrangement on or at the at least one first tip, and including at least one opening in an outer surface thereof for insertion of the at least one second tip therethrough when the clamp arrangement is in a closed position.

Group II: Claims 17-20: directed towards uterine rings a second end opposite the first end and including a first circular portion and a second circular portion; wherein the first circular portion has a first outer surface having a first diameter and the second circular portion has a second outer surface having a second diameter; and wherein the second diameter is smaller than the first diameter. a second end opposite the first end and including a first circular portion having a groove

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

Special Technical Features See Above

Common Technical Features

Groups I-II generally share the technical features of a clamp member arranged to hold a uterine/colpotomy ring member. However, these common technical features are anticipated by US 2012/0109147 A1 to Auerbach et al. (hereinafter: Auerbach). Auerbach discloses a clamp member (tenaculum 40, FIGS. 1-9; para[0051]) arranged to hold a uterine/colpotomy ring member (colpotomizer cup 20, FIGS. 1-9; para[0051]).

Accordingly, Groups I-II lack unity under PCT Rule 13.