



(51) International Patent Classification:

A61F 6/18 (2006.01) A61K 9/00 (2006.01)
A61F 6/14 (2006.01)

(21) International Application Number:

PCT/US2017/023738

(22) International Filing Date:

23 March 2017 (23.03.2017)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/312,728 24 March 2016 (24.03.2016) US
15/460,849 16 March 2017 (16.03.2017) US

(71) Applicant: **MEDICINES360** [US/US]; 353 Sacramento St., Suite 300, San Francisco, CA 94111 (US).

(72) Inventors: **DECKMAN, Rob**; 353 Sacramento St., Suite 300, San Francisco, CA 94111 (US). **CARSON, Craig**; 353 Sacramento St., Suite 300, San Francisco, CA 94111 (US). **GUYER, Curt**; 353 Sacramento St., Suite 300, San Francisco, CA 94111 (US). **NETT, David**; 353 Sacramento St., Suite 300, San Francisco, CA 94111 (US). **CREININ, Mitchell**; 353 Sacramento St., Suite 300, San Francisco, CA 94111 (US).

(74) Agents: **O'REGAN, Cecily Anne** et al.; Shartsis Fries LLP, One Maritime Plaza-18th Floor, San Francisco, CA 94111 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

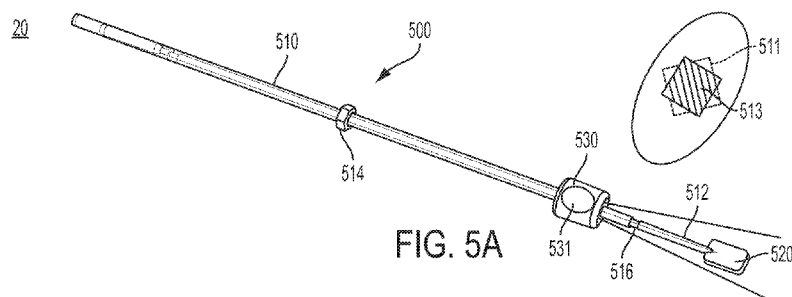
Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

Published:

- with international search report (Art. 21(3))

(54) Title: IUD INSERTION DEVICES, AND RELATED METHODS AND KITS THEREFOR



(57) Abstract: Disclosed are two-handed IUD insertion devices for positioning an intrauterine device (IUD) in the uterus which includes a plunger, a sheath, a grip and a handle where the axial movement of the plunger is controlled via features along the length of the plunger in communication with a grip feature.

IUD INSERTION DEVICES, AND RELATED METHODS AND KITS THEREFOR

CROSS-REFERENCE

[0001] This application claims priority to U.S. Patent Application 15/460,849 filed March 16, 2017, which claims the benefit of U.S. Provisional Application No. 62/312,728, filed March 24, 2016, entitled IUD Insertion Devices, and Related Methods and Kits Therefor, which applications are incorporated herein by reference.

BACKGROUND

[0002] Field of the Invention: The disclosure relates to intrauterine systems (IUS), intrauterine devices (IUDs), insertion devices, methods of use, and kits therefor.

[0003] Background of the Invention: An intrauterine device (IUD) is an object that, when placed in the uterus of a female, acts as a birth control device to prevent pregnancy. Two types of IUDs are commonly available, copper-containing devices and hormone-containing devices that release a progestogen. Hormone containing devices are considered to be a different form of birth control and may be distinguished in the literature by the term intrauterine system (IUS).

[0004] Copper IUDs work by negatively affecting the mobility of sperm and preventing the sperm from joining an egg. Additionally, the copper body positioned within the uterus irritates the lining of the uterus and uterine wall making it difficult for an embryo to plant in the wall if the egg is fertilized by the sperm. IUS devices, such as the hormonal IUD Mirena® (marketed by Bayer) reduce or prevent menstrual bleeding. The Mirena® device releases levonorgestrel (a progestogen).

[0005] IUDs have been previously disclosed in a variety of shapes and sizes. See, for example, U.S. Patent and Publications:

[0006] **US 2005/0045183 A1** to Callister et al. for *Methods and Devices* issued March 3, 2005;

[0007] US 3,407,806 A to Hulka et al for *Contraceptive Intra-Uterine Devices* issued October 29, 1968;

[0008] US 3,902,483 A to Seymour et al. for Intrauterine Device with Locator Means for Indicating Uterine Position of Device issued September 2, 1975;

[0009] US 3,937,217 A to Kosenen for *Intrauterine Contraceptive Device* issued February 10, 1976;

[0010] US 4,353,363 A to Quesada for *Intrauterine Spermicide* issued October 12, 1982;

[0011] US 4,359,046 A to Shaw Jr. for *IUD Arrangement* issued November 16, 1982;

[0012] US 4,372,302 A to Akerlund for Instrument for Retrieval of Retracted Threads of Intrauterine Contraceptive Devices issued February 8, 1983;

[0013] US 4,381,001 to Shaw Jr. for *IUD Arrangement* issued April 26, 1983;

[0014] US 4,495,934 A to Shaw Jr. for *IUD Arrangement* issued January 29, 1985;

[0015] US 4,830,025 A to Gainutdinova et al. for *Intrauterine Contraceptive Device* issued May 16, 1989;

[0016] US 4,957,119 A to de Nijs for *Contraceptive Implant* issued September 18, 1990;

[0017] US 5,088,505 A to de Nijs for *Contraceptive Implant* issued February 18, 1992;

[0018] US 6,039,968 A to Nabahi for *Intravaginal Drug Delivery Device* issued March 21, 2000; and

[0019] US 7,862,552 B2 to McIntyre et al. for *Medical Devices for Treating Urological and Uterine Conditions* issued January 4, 2011.

[0020] IUDs are typically inserted using an insertion device or instrument. See, for example, U.S. Patents and publications:

[0021] US 3,794,025 A to Lerner for Intrauterine Device Saddle Insertor issued February 26, 1974;

[0022] US 4,920,727 A to Ristimaki et al. for Cassette System and Apparatus for Manufacturing an Active Agent Liberating Capsule for Subcutaneous Use issued May 1, 1990;

[0023] US 4,949,732 A to Spoon et al. for Apparatus for Insertion and Fixation of an Intra Uterine Contraceptive Device to the Uterine Fundus issued August 21, 1990;

- [0024] US 5,084,004 A to Ranoux for Process for Intra-Uterine Fertilization in Mammals and Device for Implementation Thereof issued January 28, 1992;
- [0025] US 5,370,129 A to Diaz et al. for IUD Inserting Apparatus issued December 6, 1994;
- [0026] US 5,400,804 A to Helle et al. for Method and Equipment for Installing a Medicine Capsule on a Support issued March 28, 1995;
- [0027] US 5,785,053 A to Macandrew et al. for Inserter for the Positioning of an Intrauterine Device issued July 28, 1998; and
- [0028] US 3,783,861 A to Abramson for Inserter for Intrauterine Devices issued January 8, 1974.
- [0029] Other references of interest in the IUS and IUD field include, for example, U.S. Patents and publications:
- [0030] US 6,056,976 A to Markkula et al. for Elastomer, Its Preparation and Use issued May 2, 2000;
- [0031] US 6,063,395 A to Markkula et al. for Drug Delivery Device Especially for the Delivery of Progestins and Estrogens issued May 16, 2000;
- [0032] US 6,103,256 A to Nahabi for Intravaginal Drug Delivery Device issued August 15, 2000;
- [0033] US 6,117,442 A to Markkula et al. for Drug Delivery Device, Especially for the Delivery of Androgens issued September 12, 2000;
- [0034] US 2008/0095825 A1 to LaFont for Method for Making a Reservoir Containing an Active Substance Diffused through the Reservoir and Installation Therefor published April 24, 2008; and
- [0035] US 2013/0014762 A1 to Deckman et al. for Intrauterine Systems, IUD Insertion Devices, and Related Methods and Kits Therefor, published January 17, 2013.
- [0036] Conventional insertion devices used with IUDs (which includes devices used for IUSs) can cause pain and even loss of consciousness to a patient during the insertion procedure as a result of induction of a vagal reflex response. Conventional insertion devices lack smooth operability and exhibit issues with ease of use. Thus, there exists a need for an insertion device adaptable and configurable for use with

IUDs and related methods and kits which reduce patient pain and trauma during the insertion procedure and provides a simple, high-quality, easy-to-use, smoothly operating, economical solution.

SUMMARY

[0037] Disclosed are two-handed IUD insertion devices. The two-handed IUD insertion devices comprise: an elongated sheath having a proximal end and a distal end and a lumen extending between the proximal end and the distal end; a plunger having a proximal end and a distal end with a plurality of notches along its length wherein the plunger is configured to move axially within the lumen of the elongated sheath; a grip secured to the proximal end of the elongated sheath wherein the grip has an interior surface and an exterior surface and a centrally translating member configured to move without rotation towards a central axis to engage one of the plurality of notches on the plunger and an external button that engages the centrally translating member to disengage the centrally translating member away from an engaged notch; a proximally positioned tab handle secured to the proximal end of the plunger. In some configurations, the tab handle has a hinge and/or a textured surface. A flange can be positioned about an exterior of the elongated sheath and visible markings can be provided on the sheath. The two-handed IUD insertion device operates in combination with an intrauterine device (IUD). An elongate member of the IUD comprises a core part containing a polymeric reservoir with an active agent around which a rate limiting polymer membrane has been fitted. The active agent in the reservoir can be a hormone used for the treatment of menopausal troubles or for contraception.

[0038] Yet another aspect of the disclosure is directed to two-handed IUD insertion devices comprising: an elongated sheath having a proximal end and a distal end and a

lumen extending between the proximal end and the distal end; a plunger having a proximal end and a distal end with a plurality of notches along its length at the proximal end wherein the plunger is configured to move axially within the lumen of the elongated sheath; a grip secured to the proximal end of the elongated sheath; a proximally positioned tab handle having a first member and a second member with a hinge along one edge between the first member and the second member wherein the tab handle is secured to the proximal end of the plunger. In some configurations, the tab handle has a hinge and/or a textured surface. A flange can be positioned about an exterior of the elongated sheath and visible markings can be provided on the sheath. The two-handed IUD insertion device operates in combination with an intrauterine device (IUD). An elongate member of the IUD comprises a core part containing a polymeric reservoir with an active agent around which a polymeric rate controlling membrane has been fitted. The active agent in the reservoir can be a hormone used for the treatment of menopausal troubles or for contraception.

[0039] Still another aspect of the disclosure is directed to methods of delivering an IUD comprising: providing a two-handed IUD insertion device having an elongated sheath having a proximal end and a distal end and a lumen extending between the proximal end and the distal end, a plunger having a proximal end and a distal end with a plurality of notches along its length at the proximal end wherein the plunger is configured to move within the lumen of the elongated sheath, a grip secured to the proximal end of the elongated sheath wherein the grip has an interior surface and an exterior surface and a centrally translating member configured to engage one of the plurality of notches on the plunger and an external button that engages the centrally translating member to disengage the centrally translating member away from an engaged notch, and a proximally positioned tab handle secured to the proximal end of

the plunger with a t-shaped IUD having two arms positioned within the distal end of the elongated sheath of the two-handed IUD insertion device; advancing the two-handed insertion device into a cervix of a patient until a flange positioned around the elongated sheath is from 1.5 cm to 2.0 cm from an external opening of the cervix; pulling the sheath proximally to release the arms of the IUD; advancing the two-handed insertion device proximally into the cervix until a fundal resistance is detected; and releasing the IUD from the two-handed insertion device. The method can also comprise the step of delivering an active agent used for the treatment of menopausal troubles or for contraception from the IUD.

[0040] Yet another aspect of the disclosure is directed to methods of delivering an IUD comprising: providing a two-handed IUD insertion device having an elongated sheath having a proximal end and a distal end and a lumen extending between the proximal end and the distal end; a plunger having a proximal end and a distal end with a plurality of notches along its length wherein the plunger is configured to move axially within the lumen of the elongated sheath; a grip secured to the proximal end of the elongated sheath wherein the grip has an interior surface and an exterior surface and a centrally translating member configured to move without rotation towards a central axis to engage one of the plurality of notches on the plunger and an external button that engages the centrally translating member to disengage the centrally translating member away from an engaged notch; a proximally positioned tab handle secured to the proximal end of the plunger. In some configurations, the tab handle has a hinge and/or a textured surface; advancing the two-handed insertion device into a cervix of a patient until a flange positioned around the elongated sheath is from 1.5 cm to 2.0 cm from an external opening of the cervix; pulling the sheath proximally to release the arms of the IUD; advancing the two-handed insertion device proximally

into the cervix until a fundal resistance is detected; and releasing the IUD from the two-handed insertion device. The method can also comprise the step of delivering an active agent used for the treatment of menopausal troubles or for contraception from the IUD.

[0041] Another aspect of the disclosure is directed to two-handed IUD insertion devices comprising: an elongated sheath having a proximal end and a distal end and a lumen extending between the proximal end and the distal end; a rotatable plunger having a proximal end and a distal end with a first cross-section at a first orientation, a second cross-section at a second orientation different than the first cross-section orientation and a third cross-section at a third orientation along its length wherein the plunger is configured to move axially within the lumen of the elongated sheath until the cross-section of the plunger changes orientation; a grip secured to the proximal end of the elongated sheath wherein the grip has an aperture shaped to receive the rotatable plunger; a proximally positioned tab handle secured to the proximal end of the plunger. In some configurations, the tab handle has a hinge and/or a textured surface. A flange can be positioned about an exterior of the elongated sheath and visible markings can be provided on the sheath. The two-handed IUD insertion device operates in combination with an intrauterine device (IUD). An elongate member of the IUD comprises a core part containing a polymeric reservoir with an active agent around which a polymeric rate controlling membrane has been fitted. The active agent in the reservoir can be a hormone used for the treatment of menopausal troubles or for contraception.

[0042] Yet another aspect of the disclosure is directed to methods of delivering an IUD comprising: providing a two-handed IUD insertion device having an elongated sheath having a proximal end and a distal end and a lumen extending between the

proximal end and the distal end; a rotatable plunger having a proximal end and a distal end with a first cross-section at a first orientation, a second cross-section at a second orientation different than the first cross-section orientation and a third cross-section at a third orientation along its length wherein the plunger is configured to move axially within the lumen of the elongated sheath until the cross-section of the plunger changes orientation; a grip secured to the proximal end of the elongated sheath wherein the grip has an aperture shaped to receive the rotatable plunger; a proximally positioned tab handle secured to the proximal end of the plunger; advancing the two-handed insertion device into a cervix of a patient until a flange positioned around the elongated sheath is from 1.5 cm to 2.0 cm from an external opening of the cervix; pulling the sheath proximally to release the arms of the IUD; advancing the two-handed insertion device proximally into the cervix until a fundal resistance is detected; and releasing the IUD from the two-handed insertion device. The method can also comprise the step of delivering an active agent used for the treatment of menopausal troubles or for contraception from the IUD.

[0043] Disclosed are two-handed IUD insertion devices. The two-handed IUD insertion devices comprise: an elongated sheath means having a proximal end and a distal end and a lumen extending between the proximal end and the distal end; a plunger means having a proximal end and a distal end with a plurality of notches along its length wherein the plunger means is configured to move axially within the lumen of the elongated sheath means; a grip means secured to the proximal end of the elongated sheath means wherein the grip means has an interior surface and an exterior surface and a centrally translating member configured to move without rotation towards a central axis to engage one of the plurality of notches on the plunger means and an external button means that engages the centrally translating member to

disengage the centrally translating member away from an engaged notch; a proximally positioned tab handle means secured to the proximal end of the plunger means. In some configurations, the tab handle means has a hinge and/or a textured surface. A flange means can be positioned about an exterior of the elongated sheath means and visible markings can be provided on the sheath. The two-handed IUD insertion device operates in combination with an intrauterine device (IUD). An elongate member of the IUD comprises a polymeric reservoir with an active agent around which a jacket-like rate controlling polymeric membrane has been fitted. The active agent in the reservoir can be a hormone used for the treatment of menopausal troubles or for contraception.

[0044] Yet another aspect of the disclosure is directed to two-handed IUD insertion devices comprising: an elongated sheath means having a proximal end and a distal end and a lumen extending between the proximal end and the distal end; a plunger means having a proximal end and a distal end with a plurality of notches along its length at the proximal end wherein the plunger means is configured to move axially within the lumen of the elongated sheath means; a grip means secured to the proximal end of the elongated sheath means; a proximally positioned tab handle means having a first member and a second member with a hinge along one edge between the first member and the second member wherein the tab handle means is secured to the proximal end of the plunger means. In some configurations, the tab handle means has a hinge and/or a textured surface. A flange means can be positioned about an exterior of the elongated sheath means and visible markings can be provided on the sheath. The two-handed IUD insertion device operates in combination with an intrauterine device (IUD). An elongate member of the IUD comprises a polymeric reservoir with active agent in which a rate controlling membrane has been fitted. The active agent in

the reservoir can be a hormone used for the treatment of menopausal troubles or for contraception.

[0045] Still another aspect of the disclosure is directed to methods of delivering an IUD comprising: providing a two-handed IUD insertion device having an elongated sheath means having a proximal end and a distal end and a lumen extending between the proximal end and the distal end, a plunger means having a proximal end and a distal end with a plurality of notches along its length at the proximal end wherein the plunger means is configured to move within the lumen of the elongated sheath means, a grip means secured to the proximal end of the elongated sheath means wherein the grip means has an interior surface and an exterior surface and a centrally translating member configured to engage one of the plurality of notches on the plunger means and an external button means that engages the centrally translating member to disengage the centrally translating member away from an engaged notch, and a proximally positioned tab handle means secured to the proximal end of the plunger means with a t-shaped IUD having two arms positioned within the distal end of the elongated sheath means of the two-handed IUD insertion device; advancing the two-handed insertion device into a cervix of a patient until a flange means positioned around the elongated sheath means is from 1.5 cm to 2.0 cm from an external opening of the cervix; pulling the sheath proximally to release the arms of the IUD; advancing the two-handed insertion device proximally into the cervix until a fundal resistance is detected; and releasing the IUD from the two-handed insertion device. The method can also comprise the step of delivering an active agent used for the treatment of menopausal troubles or for contraception from the IUD.

[0046] Yet another aspect of the disclosure is directed to methods of delivering an IUD comprising: providing a two-handed IUD insertion device having an elongated

sheath means having a proximal end and a distal end and a lumen extending between the proximal end and the distal end; a plunger means having a proximal end and a distal end with a plurality of notches along its length wherein the plunger means is configured to move axially within the lumen of the elongated sheath means; a grip means secured to the proximal end of the elongated sheath means wherein the grip means has an interior surface and an exterior surface and a centrally translating member configured to move without rotation towards a central axis to engage one of the plurality of notches on the plunger means and an external button means that engages the centrally translating member to disengage the centrally translating member away from an engaged notch; a proximally positioned tab handle means secured to the proximal end of the plunger means. In some configurations, the tab handle means has a hinge and/or a textured surface; advancing the two-handed insertion device into a cervix of a patient until a flange means positioned around the elongated sheath means is from 1.5 cm to 2.0 cm from an external opening of the cervix; pulling the sheath proximally to release the arms of the IUD; advancing the two-handed insertion device proximally into the cervix until a fundal resistance is detected; and releasing the IUD from the two-handed insertion device. The method can also comprise the step of delivering an active agent used for the treatment of menopausal troubles or for contraception from the IUD.

[0047] Another aspect of the disclosure is directed to two-handed IUD insertion devices comprising: an elongated sheath means having a proximal end and a distal end and a lumen extending between the proximal end and the distal end; a rotatable plunger means having a proximal end and a distal end with a first cross-section at a first orientation, a second cross-section at a second orientation different than the first cross-section orientation and a third cross-section at a third orientation along its length

wherein the plunger means is configured to move axially within the lumen of the elongated sheath means until the cross-section of the plunger means changes orientation; a grip means secured to the proximal end of the elongated sheath means wherein the grip means has an aperture shaped to receive the rotatable plunger means; a proximally positioned tab handle means secured to the proximal end of the plunger means. In some configurations, the tab handle means has a hinge and/or a textured surface. A flange means can be positioned about an exterior of the elongated sheath means and visible markings can be provided on the sheath. The two-handed IUD insertion device operates in combination with an intrauterine device (IUD). An elongate member of the IUD comprises a polymeric reservoir containing an active agent around which a rate limiting polymeric membrane has been fitted. The active agent in the reservoir can be a hormone used for the treatment of menopausal troubles or for contraception.

[0048] Yet another aspect of the disclosure is directed to methods of delivering an IUD comprising: providing a two-handed IUD insertion device having an elongated sheath means having a proximal end and a distal end and a lumen extending between the proximal end and the distal end; a rotatable plunger means having a proximal end and a distal end with a first cross-section at a first orientation, a second cross-section at a second orientation different than the first cross-section orientation and a third cross-section at a third orientation along its length wherein the plunger means is configured to move axially within the lumen of the elongated sheath means until the cross-section of the plunger means changes orientation; a grip means secured to the proximal end of the elongated sheath means wherein the grip means has an aperture shaped to receive the rotatable plunger means; a proximally positioned tab handle means secured to the proximal end of the plunger means; advancing the two-handed

insertion device into a cervix of a patient until a flange means positioned around the elongated sheath means is from 1.5 cm to 2.0 cm from an external opening of the cervix; pulling the sheath proximally to release the arms of the IUD; advancing the two-handed insertion device proximally into the cervix until a fundal resistance is detected; and releasing the IUD from the two-handed insertion device. The method can also comprise the step of delivering an active agent used for the treatment of menopausal troubles or for contraception from the IUD.

INCORPORATION BY REFERENCE

[0049] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0050] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0051] FIGS. 1A-1C illustrate a conventional IUD insertion device;

[0052] FIG. 2 illustrates a conventional T-shaped IUD;

[0053] FIGS. 3A-B illustrates a two handed IUD inserter with a tab; **FIG. 3C**

illustrates a cross-section of the grip;

[0054] FIG. 4 illustrates a two-handed IUD inserter with detents along the length to allow threads to be secured;

[0055] **FIGS. 5A-H** illustrate a two-handed IUD inserter with a tab and a retractable grip;

[0056] **FIGS. 6A-E** illustrate details of the tab plunger of the two-handed IUD inserter of **FIG. 5**;

[0057] **FIGS. 7A-C** illustrate a single-handed IUD inserter;

[0058] **FIGS. 8A-C** illustrate another configuration of a single-handed IUD inserter;

[0059] **FIGS. 9A-C** illustrate another configuration of a single-handed IUD inserter;

[0060] **FIGS. 10A-B**, and **11** illustrate another configuration of a single-handed IUD inserter; and

[0061] **FIG. 12** illustrates a plurality of mechanical features for the proximal end of an IUD inserter.

DETAILED DESCRIPTION

[0062] Conventional intrauterine insertion devices include an inserter or insertion device **100** such as the device shown in **FIGS. 1A-1C**, which includes a sheath **110** or insertion tube having a proximal end **10** and a distal end **20** and a lumen extending between the proximal end and the distal end of the sheath **110** for housing the IUD (shown in **FIG. 2**), a plunger **112** for pushing the IUD through the sheath **110**, and a user interface such as a handle **120** for holding the insertion device. The device shown in **FIGS. 1A-1C** requires a two-handed operation, whereby the operator or user holds the handle **120** in one hand and the sheath **110** in another hand.

[0063] The disclosed insertion devices can, for example, be used with a T-shaped IUD **200**, such as the IUD as shown in **FIG. 2**. IUDs typically have a length of from about 31.90 mm to about 32.22 mm and a width of from about 31.81 mm to about 32.13 mm when the IUD is in the fully deployed position. As will be appreciated by those skilled in the art, the length does not include the knot or strings that may

accompany the IUD. The T-shaped IUD **200** comprises an elongated body **202** having a proximal end **10** and a distal end **20**. The elongated body **202** can include a coating such as a time-release drug or hormone. The elongated body can be formed from any suitable material, including, but not limited to plastic or copper. At the distal end **20** of the IUD (i.e., the end positioned away from the physician's hand), arms **206a**, **206b** are attached to or integrally formed with the elongated body **202**. The arms **206a**, **206b** are configurable to fold upward **u** or downward **d** to minimize the IUD cross-section such that the IUD can fit into a lumen of the sheath of the insertion device or a tube for insertion through the cervix and into the uterus. Additionally, either or both of the arms **206a**, **206b** are configurable so that the ends of the tips **208a**, **208b** are enlarged or bulbous, which can, for example, have a curved, spherical or semi-spherical shape. The tips **208a**, **208b** of the arms **206a**, **206b** can be formed such that the arms, when folded upward and pushed together, form a smooth and rounded distal tip. At the proximal end **10** of the t-shaped IUD **200**, the t-shaped IUD **200** can further include one or more strings **210a**, **210b** attached to the IUD. The strings are connectable to the IUD at a connection point **212**, e.g., tied in a knot as illustrated.

[0064] Although the insertion device is generally described herein with regard to a T-shaped IUD such as the t-shaped IUD **200** shown in **FIG. 2**, it should be noted that the insertion devices of the present disclosure are adaptable to facilitate insertion of other IUD configurations, as would be appreciated by a person of skill in the art. Moreover, insertion device operation and IUD insertion procedures can include any number of steps corresponding to a desired IUD position. In addition to the features described below, the insertion devices of the present disclosure include IUD position control features which may be advantageous for insertion of IUDs having a variety of

configurations. For example, while the IUD insertion procedure described below refers to a three-phase procedure corresponding to three different IUD positions, the insertion device operation procedure can include less than three or more than three steps. Accordingly, the insertion devices can include any number of position control features corresponding to the desired IUD positions. The insertion device of the present disclosure can be used with various conventional IUDs available on the market, including such devices as the T-frame LNG-20 IUD, marketed as Mirena® by Bayer®, as well as the Neo-Safe CuT 380A™ available from Mona-Lisa™.

[0065] Insertion device disclosed herein are configurable to operate according to procedural steps which generally mimic commonly known and used procedures for IUD insertion. However, the insertion device of the present disclosure includes improvements in device structure and operation. In another aspect of the disclosed devices, procedural steps for IUD insertion include: (i) pre-insertion insertion device preparation procedures, (ii) a first phase of IUD insertion (also referred to herein as phase 1, position 1, or step 1), (iii) a second phase of IUD insertion (also referred to herein as phase 2, position 2, or step 2), (iv) a third phase of IUD insertion (also referred to herein as phase 3, position 3, or step 3), and (v) post-insertion procedures.

[0066] Pre-insertion insertion device preparation procedures can include loading an IUD, such as the IUD illustrated in **FIG. 2**, into an insertion device, aligning the IUD in-plane with a patient, positioning the IUD in a correct longitudinal position along the length of a sheath of the insertion device, and locking the IUD into a position for insertion. Such pre-insertion insertion device preparation procedures are described in further detail below.

[0067] A contraceptive device, which is available on the market and which releases levonorgestrel, consists of a T-shaped IUD **200** having an elongated body **202**

fabricated of polyethylene equipped with a reservoir adjusted around it and containing the hormone levonorgestrel. The IUD comprises a polymeric reservoir containing an active agent around which a rate controlling polymeric membrane has been fitted. The active agent includes hormones used for the treatment of menopausal troubles or for contraception. The IUD is sold in sterile packaging together with the inserter with the plunger contained within the protecting tube. The T-shaped IUD **200** is positioned at the forward end of the plunger with the hormone-containing elongate member protected by the tube. The arms **206a**, **206b** of the transverse member, on the other hand, are expanded in order to prevent fatigue. The strings by which the T-shaped device is retracted towards the outside run between the plunger and the protective tube and end at the end of the handle. The strings **210a**, **210b** remain attached to the IUD **200** after the IUD has been inserted into the uterus. The strings are trimmed so that the strings extend into the vagina from the opening of the cervix.

[0068] FIGS. 3A-C illustrates a two handed IUD inserter **300** with a tab handle **320** having a proximal end **10** and a distal end **20**. The two handed IUD inserter **300** has a sheath **310** which defines a lumen, with a flange **314**. The sheath **310** is configured to hold a t-shaped IUD **200** within its lumen at a proximal end **10** prior to insertion and a plunger **312** within the lumen. The plunger **312** acts as a plunger and can be locked in place until the user squeezes a button **332** on a grip **330** that is affixed to a proximal end of the sheath **310** to release the plunger **312**. Once the plunger **312** is released the plunger **312** can be pushed into or withdrawn from the lumen of the sheath **310**. The tab handle **320** can be hinged **322** to allow the tab handle **320** to fold closed (as shown from **FIG. 3A** to **FIG. 3B**). Additionally, texturing **324** can be provided on a surface of the tab handle **320** to engage the IUD threads **210** of the t-shaped IUD **200**. In some configurations, the tab handle **320** need not be hinged. Where the tab handle **320**

is not hinged, the texturing **324** can be on any or all surfaces of the tab handle **320**. Markings can be applied to the plunger **312** or the sheath **310**, such as ink markings (shown in **FIG. 5H**), to provide the user information on depth during the insertion procedure. Flange **314** movement can be achieved using different materials, geometry or processing.

[0069] Turning to **FIG. 3C**, a cut-away of the grip **330** engaging the sheath **310** and plunger **312** is shown. The plunger **312** has two or more notches **316**, **316'** along its length which are configured to engage a lever **334** within the body of the grip **330**. When the lever **334** engages one of the two or more notches **316** as the plunger **312** is moved (proximally or distally) through the sheath **310**, the lever **334** translates up and into one of the two or more notches **316** which results restricting the movement of the plunger **312**. To release the plunger **312**, the user presses the button **332** on a surface of the grip **330** which then translates the lever **334** downward and away from one of the two or more notches **316**, thereby allowing the plunger **312** to move within the sheath **310**. While pressure is applied to the button **332**, the sheath can freely move proximally or distally. Once pressure is released from the button **332**, the sheath can freely move until the lever **334** engages another notch of the two or more notches **316** on the plunger **312**.

[0070] **FIG. 4** illustrates a two-handed IUD inserter **400** with one or more indentations **412**, **414** along the length of the sheath **410**. The indentations **412**, **414** allow IUD threads **210** (from **FIG. 2**) to be secured while the IUD is being deployed.

[0071] **FIGS. 5A-H** illustrate configurations for two-handed IUD inserter **500** with a tab handle **520** at the proximal end of the plunger **512**, a grip **530** and a flange **514** positioned around a sheath **510**.

[0072] FIGS. 5A-D show the two-handed IUD inserter 500 at various stages of inserting the t-shaped IUD 200 with the tab handle 520 rotating about an axis **a** corresponding to a length of the two-handed IUD inserter 500. The tab handle 520 rotates (FIG. 5B) to align a cross-section 511 of the sheath 510 with the cross-section 513 of the plunger 512. Once the shapes are aligned or keyed, the plunger 512 can be advanced distally into the lumen of the sheath 510. As the plunger 512 is advanced into the lumen of the sheath 510, the arms of the t-shaped IUD 200 is released from the distal end 20 of the two-handed IUD inserter 500 as shown in FIG. 5C, and then the t-shaped IUD 200 is released entirely from the distal end 20 of the two-handed IUD inserter 500. Twisting the tab handle 520 clockwise or counter-clockwise allows the cross-section 511 of the sheath 510 to line up with the cross-section 513 of the plunger 512 to allow the plunger 512 to be advanced into the sheath 510. As will be appreciated by those skilled in the art, the cross-sectional shape of the plunger 512 can vary along its length to provide a stopping mechanism for advancement of the plunger 512 through the sheath 510 at discrete times during the insertion process. A depression 531 can be provided on the grip 530 to improve the user's engagement with the device during use.

[0073] In use, the two-handed IUD inserter 500 of FIGS. 5A-D with a tab handle 520 is advanced into the cervix with the IUD positioned with the arms positioned within the distal end of the sheath. The two-handed IUD inserter 500 is inserted into the cervix until the flange 514 is 1.5-2.0 cm from the cervix. At this point the cross-section of the plunger 512 changes to cause distal motion of the plunger to stop. The tab handle 520 is then rotated to align the cross-section of the plunger 512 with the aperture of the grip 530 and the plunger 512 is advanced to release the arms of the IUD. At this point the cross-section of the plunger 512 changes to cause continued

distal motion of the plunger to stop. The tab handle **520** is then rotated again to align the cross-section of the plunger **512** with the aperture of the grip **530** and the plunger **512** is advanced until the flange meets the cervix and the user feels fundal resistance. At this point, the IUD is released and the inserter is withdrawn from the cervix. As shown in the call-out, the cross-section of the plunger is square along its length, but the square cross-section changes relative to a square cross-section at another location along the length of the plunger.

[0074] **FIGS. 5E-G** show additional details of the interaction between the plunger **512**, the grip **530**, the flange **514**, and the tab handle **520**, with the finger **30** of a user on the grip **530** of the cross-section shown in **FIGS. 3A-C** and discussed above.

Instead of the oval shaped depression shown in **FIGS. 5A-D**, a button **532** is provided. Depressing the button **532** allow the plunger **512** to be advanced into the sheath **510**. As with the design shown in **FIGS. 5A-D**, the tab handle is rigidly affixed to the plunger **512** and the grip **530** is rigidly affixed to the sheath **510**. The cross-section of the plunger and grip is rounded at one end and flat at a second end.

[0075] In use, the two-handed IUD inserter **500** of **FIGS. 5E-G** with a tab handle **520** is advanced into the cervix with the IUD positioned with the arms positioned within the distal end of the sheath. The two-handed IUD inserter **500** is inserted into the cervix until the flange **514** is 1.5-2.0 cm from the cervix. At this point distal motion of the plunger stops. The button **532** on the tab handle **520** is then depressed which allows the plunger **512** to be advanced distally until the arms of the IUD **200** are released. Continued distal motion of the plunger then stops. The button **532** on the tab handle **520** is then depressed again and the plunger **512** is advanced until the flange meets the cervix and the user feels fundal resistance. At this point, the IUD is released and the inserter is withdrawn from the cervix.

[0076] Turning to **FIG. 5H**, additional features of the sheath **510** can include markings **516** along its length to indicate distance (e.g., 1 cm, 2cm, 3 cm ... 10 cm).

[0077] **FIGS. 6A-E** illustrate additional configuration options for the plunger **512** of the two-handed IUD inserter of **FIGS. 5A-D**. The grip **630** is connected to the sheath **610** and is configured with keyhole indentions which are shaped to receive a corresponding detents on the plunger **612** and allow for axial movement of the plunger **612** when the orientation of the detents on the plunger and the keyhole of the aperture in the grip **630** are aligned.

[0078] **FIGS. 7A-C** illustrate a single-handed IUD inserter **700**. The single-handed IUD inserter **700** has a sheath **710**, a flange **714**, a handle **720**, and a button **732** that moves within a recess formed in the handle to control release of the t-shaped IUD **200**. The button moves, for example, from position 1, to position 2, to position 3. The button **732** can have a variety of shapes **732a**, **732b**, **732c**, **732d** and can include various styles of surface texturing **734**, **736** to facilitate engaging a user's finger during operation. The single-handed IUD inserter **700** can come in different sizes **700a**, **700b**, **700c**.

[0079] **FIGS. 8A-C** illustrate another configuration of a single-handed IUD inserter **800** for use with an IUD **200**. The single-handed inserter **800** has a sheath **810**, a flange **814**, and a handle **820**. The handle **820** has an elongated frame **822** which defines an open space **824**, and a first cross-member **826** which is positioned midway along the length of a proximal end and a distal end and an elongated central cross-member which is positioned in alignment with the axis formed by the sheath **810**. The handle **810** is affixed to the plunger and the button **832** engages the sheath **810** so that the handle can move towards and away from the button in operation.

[0080] FIGS. 9A-C illustrate another configuration of a single-handed IUD inserter **900** for use with an IUD **200**. The single-handed inserter **900** has a sheath **910**, a flange **914**, and a handle **920**. The handle **920** has an elongated flat upper end which defines an open space between the elongated flat upper end and the curved lower member. The handle **910** is affixed to the plunger and the button **932** engages the sheath **910** so that the handle can move towards and away from the button in operation.

[0081] FIGS. 10A-B, and 11 illustrate another configuration of a single-handed IUD inserter **1000, 1100** for use with an IUD **200**. The single-handed inserters **1000, 1100** have a sheath **1010, 1110**, a flange **1014, 1114**, and a handle **1020, 1120**. The handle **1020** in **FIG. 10** has an elongated central member with two curved members extending away from the proximal end of the central member and then passing adjacent the elongated central member such that the handle **1020** has an M shape in one plane. A corresponding open space exists between the central member and the two curved member. Additionally, the two curved members can curve towards a central axis formed by the central member. The handle **1010** is affixed to the plunger and the button **1032** engages the sheath **1010** so that the handle can move towards and away from the button in operation.

[0082] The handle **1120** in **FIG. 11** has an elongated central member with two curved members extending away from the proximal end of the central member and then passing adjacent the elongated central member such that the handle **1120** has an M shape in one plane. A corresponding open space exists between the central member and the two curved member. Additionally, the two curved members can curve towards a central axis formed by the central member. The handle **1110** is affixed to the plunger and the button **1132** engages the sheath **1110** so that the handle can move

towards and away from the button in operation. A series of notches can be provided along the length of the central member to control the movement of the handle relative to the sheath during operation.

[0083] FIG. 12 illustrates a plurality of mechanical features for the proximal end of an IUD inserter **1200**. A variety of shapes of the proximal most portion of the handle can be provided. In a first handle **1220a** the handle is elongated with two sides and an aperture formed along a portion of its length. The second handle **1220b** can be configured similar to the first handle **1220a** with the addition of cross members in the aperture. The cross-members can be perpendicular or positioned at an angle. The third handle **1220c** has a similar configuration to the first handle **1220a** but is twisted about an axis corresponding to the sheath. The fourth handle **1220d** has a solid bulbous end with a small aperture positioned proximally. The fourth handle **1220d** can further be bent away from an axis corresponding to the sheath as shown in the fifth handle **1220e**.

[0084] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

CLAIMS

WHAT IS CLAIMED IS:

1. A two-handed IUD insertion device comprising:
 - an elongated sheath having a proximal end and a distal end and a lumen extending between the proximal end and the distal end;
 - a plunger having a proximal end and a distal end with a plurality of notches along its length wherein the plunger is configured to move axially within the lumen of the elongated sheath;
 - a grip secured to the proximal end of the elongated sheath wherein the grip has an interior surface and an exterior surface and a centrally translating member configured to move without rotation towards a central axis to engage one of the plurality of notches on the plunger and an external button that engages the centrally translating member to disengage the centrally translating member away from an engaged notch;
 - a proximally positioned tab handle secured to the proximal end of the plunger.
2. The two-handed IUD insertion device of claim 1 wherein the tab handle has a hinge.
3. The two-handed IUD insertion device of claim 1 wherein the tab handle has a textured surface.
4. The two-handed IUD insertion device of claim 1 further comprising a flange positioned about an exterior of the elongated sheath.

5. The two-handed IUD insertion device of claim 1 further comprising visible markings on the sheath.
6. The two-handed IUD insertion device according to claim 1, in combination with an intrauterine device (IUD).
7. The two-handed IUD insertion device according to claim 6, wherein an elongate member of the IUD comprises a polymeric reservoir containing an active agent around which a rate controlling polymeric membrane has been fitted.
8. The combination according to claim 7, wherein the active agent is a hormone used for the treatment of menopausal troubles or for contraception.
9. A two-handed IUD insertion device comprising:
 - an elongated sheath having a proximal end and a distal end and a lumen extending between the proximal end and the distal end;
 - a plunger having a proximal end and a distal end with a plurality of notches along its length at the proximal end wherein the plunger is configured to move axially within the lumen of the elongated sheath;
 - a grip secured to the proximal end of the elongated sheath;
 - a proximally positioned tab handle having a first member and a second member with a hinge along one edge between the first member and the second member wherein the tab handle is secured to the proximal end of the plunger.

10. The two-handed IUD insertion device of claim **9** wherein the tab handle has a hinge.
11. The two-handed IUD insertion device of claim **9** wherein the tab handle has a textured surface.
12. The two-handed IUD insertion device of claim **9** further comprising a flange positioned about an exterior of the elongated sheath.
13. The two-handed IUD insertion device of claim **9** further comprising visible markings on the sheath.
14. The two-handed IUD insertion device according to claim **9**, in combination with an intrauterine device (IUD).
15. The two-handed IUD insertion device according to claim **14**, wherein an elongate member of the IUD comprises a core part around which a jacket-like polymeric reservoir containing an active agent has been fitted.
16. The combination according to claim **14**, wherein the active agent is a hormone used for the treatment of menopausal troubles or for contraception.
17. A method of delivering an IUD comprising:
providing a two-handed IUD insertion device having an elongated sheath having a proximal end and a distal end and a lumen extending between the proximal

end and the distal end, a plunger having a proximal end and a distal end with a plurality of notches along its length at the proximal end wherein the plunger is configured to move within the lumen of the elongated sheath, a grip secured to the proximal end of the elongated sheath wherein the grip has an interior surface and an exterior surface and a centrally translating member configured to engage one of the plurality of notches on the plunger and an external button that engages the centrally translating member to disengage the centrally translating member away from an engaged notch, and a proximally positioned tab handle secured to the proximal end of the plunger with a t-shaped IUD having two arms positioned within the distal end of the elongated sheath of the two-handed IUD insertion device;

advancing the two-handed insertion device into a cervix of a patient until a flange positioned around the elongated sheath is from 1.5 cm to 2.0 cm from an external opening of the cervix;

pulling the sheath proximally to release the arms of the IUD;

advancing the two-handed insertion device proximally into the cervix until a fundal resistance is detected; and

releasing the IUD from the two-handed insertion device.

18. The method of claim 17 further comprising the step of delivering an active agent used for the treatment of menopausal troubles or for contraception from the IUD.

19. A two-handed IUD insertion device comprising:

an elongated sheath having a proximal end and a distal end and a lumen extending between the proximal end and the distal end;

a rotatable plunger having a proximal end and a distal end with a first cross-section at a first orientation, a second cross-section at a second orientation different than the first cross-section orientation and a third cross-section at a third orientation along its length wherein the plunger is configured to move axially within the lumen of the elongated sheath until the cross-section of the plunger changes orientation;

a grip secured to the proximal end of the elongated sheath wherein the grip has an aperture shaped to receive the rotatable plunger;

a proximally positioned tab handle secured to the proximal end of the plunger.

20. The two-handed IUD insertion device of claim **19** wherein the tab handle has a hinge.

21. The two-handed IUD insertion device of claim **19** wherein the tab handle has a textured surface.

22. The two-handed IUD insertion device of claim **19** further comprising a flange positioned about an exterior of the elongated sheath.

23. The two-handed IUD insertion device of claim **19** further comprising visible markings on the sheath.

24. The two-handed IUD insertion device according to claim **19**, in combination with an intrauterine device (IUD).

25. The two-handed IUD insertion device according to claim **24**, wherein an elongate member of the IUD comprises a core part around which a jacket-like polymeric reservoir containing an active agent has been fitted.

26. The combination according to claim **25**, wherein the active agent is a hormone used for the treatment of menopausal troubles or for contraception.

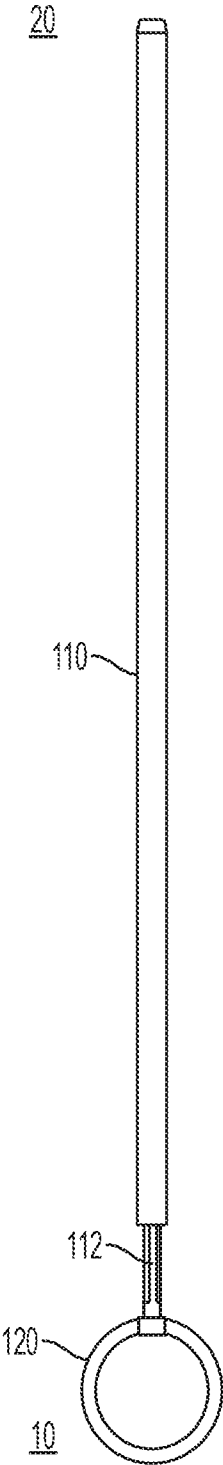


FIG. 1A
PRIOR ART

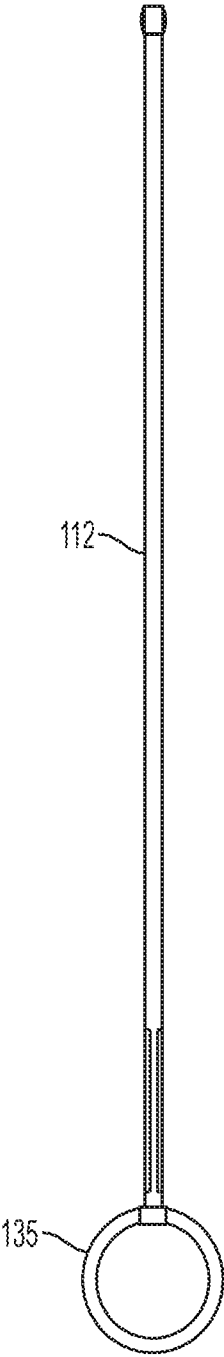


FIG. 1B
PRIOR ART

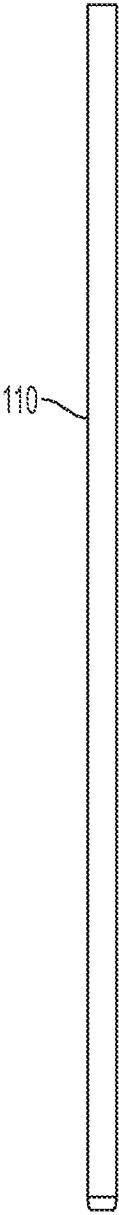


FIG. 1C
PRIOR ART

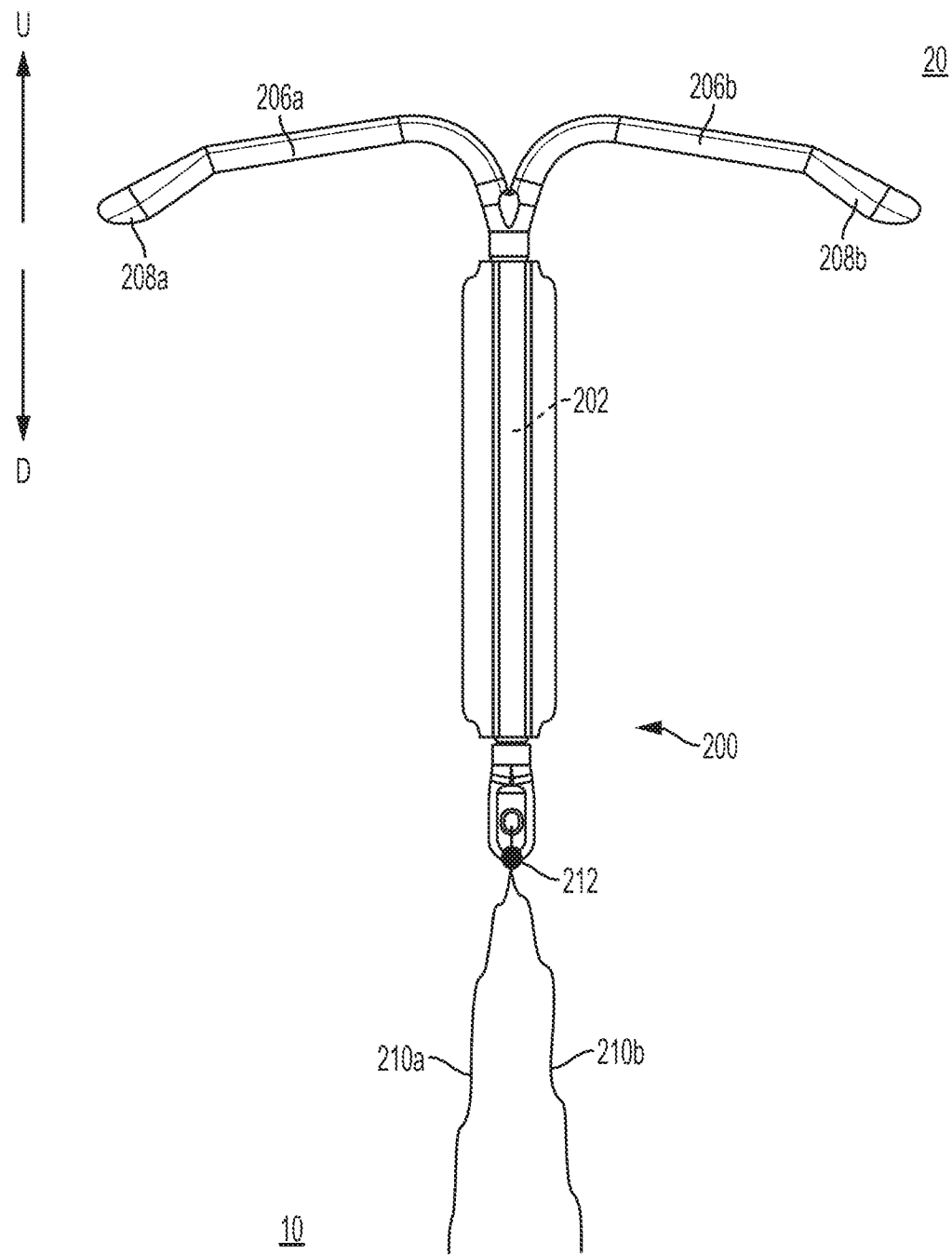


FIG. 2
PRIOR ART

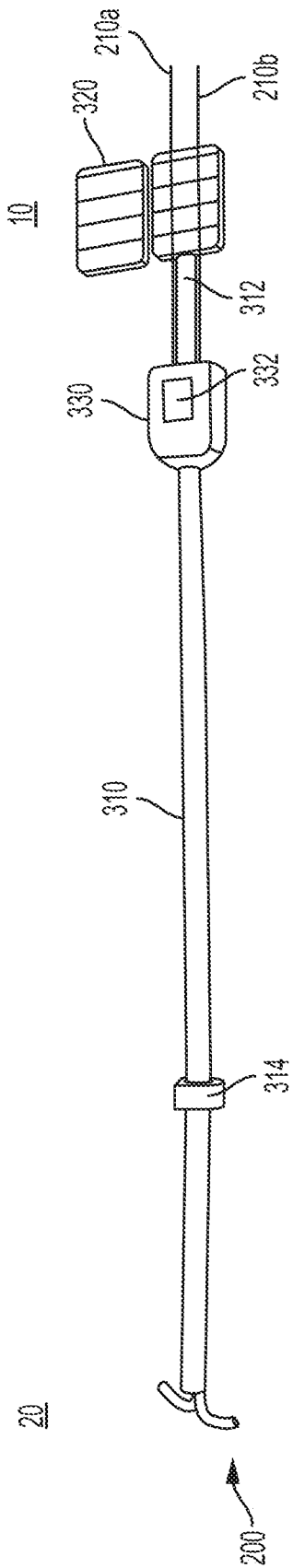


FIG. 3A

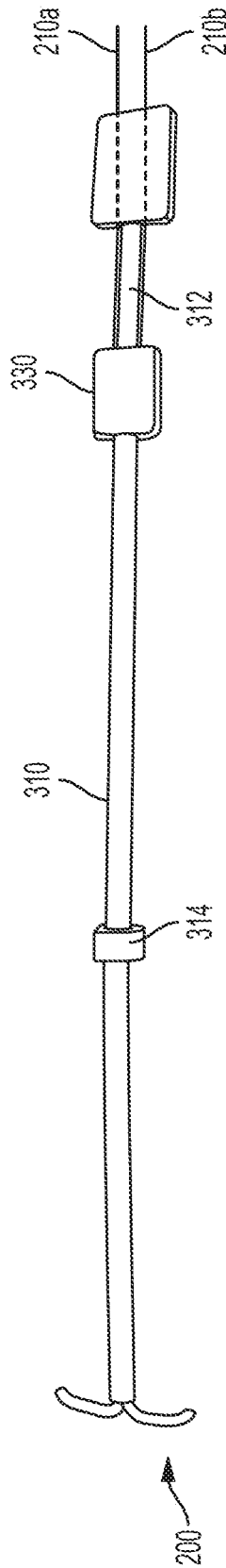


FIG. 3B

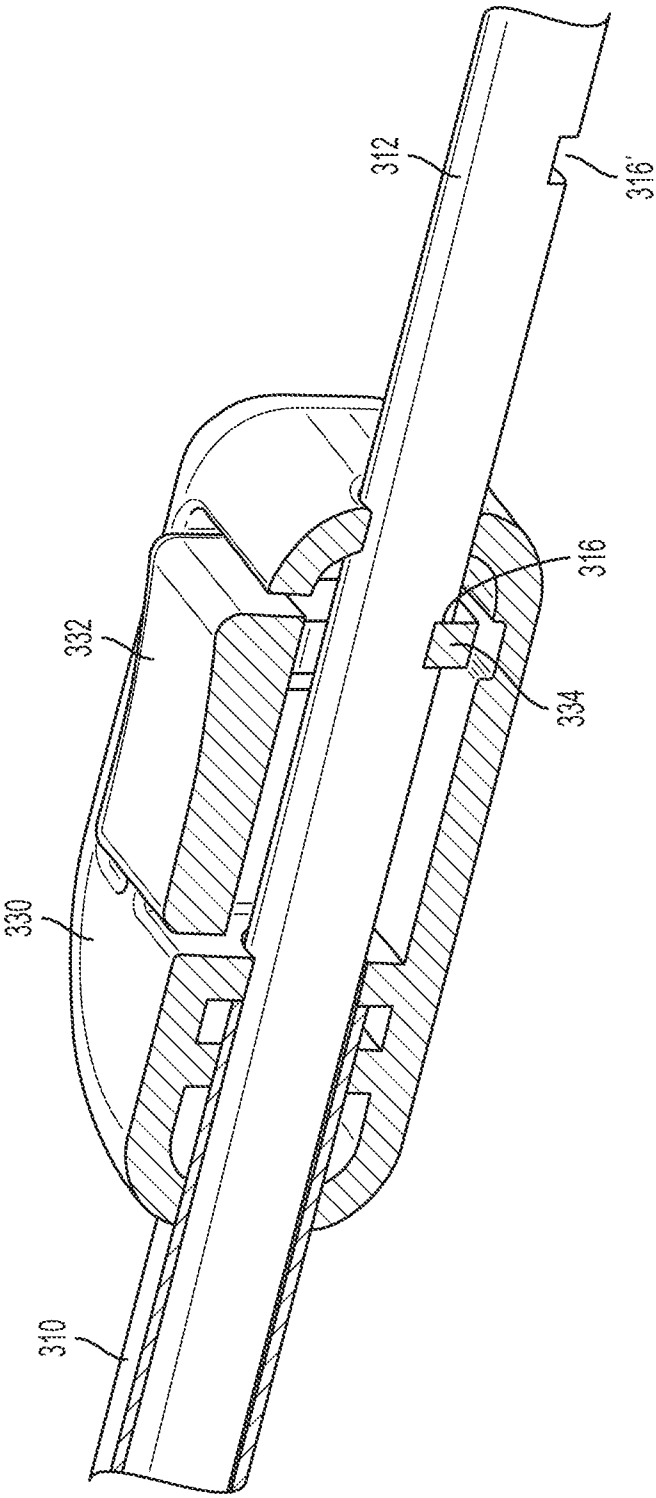


FIG. 3C

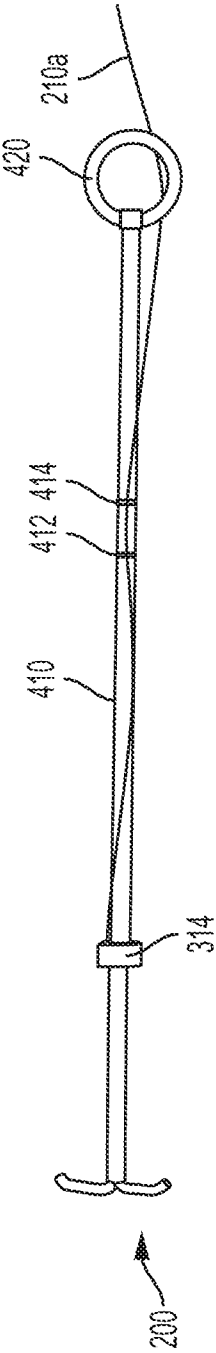
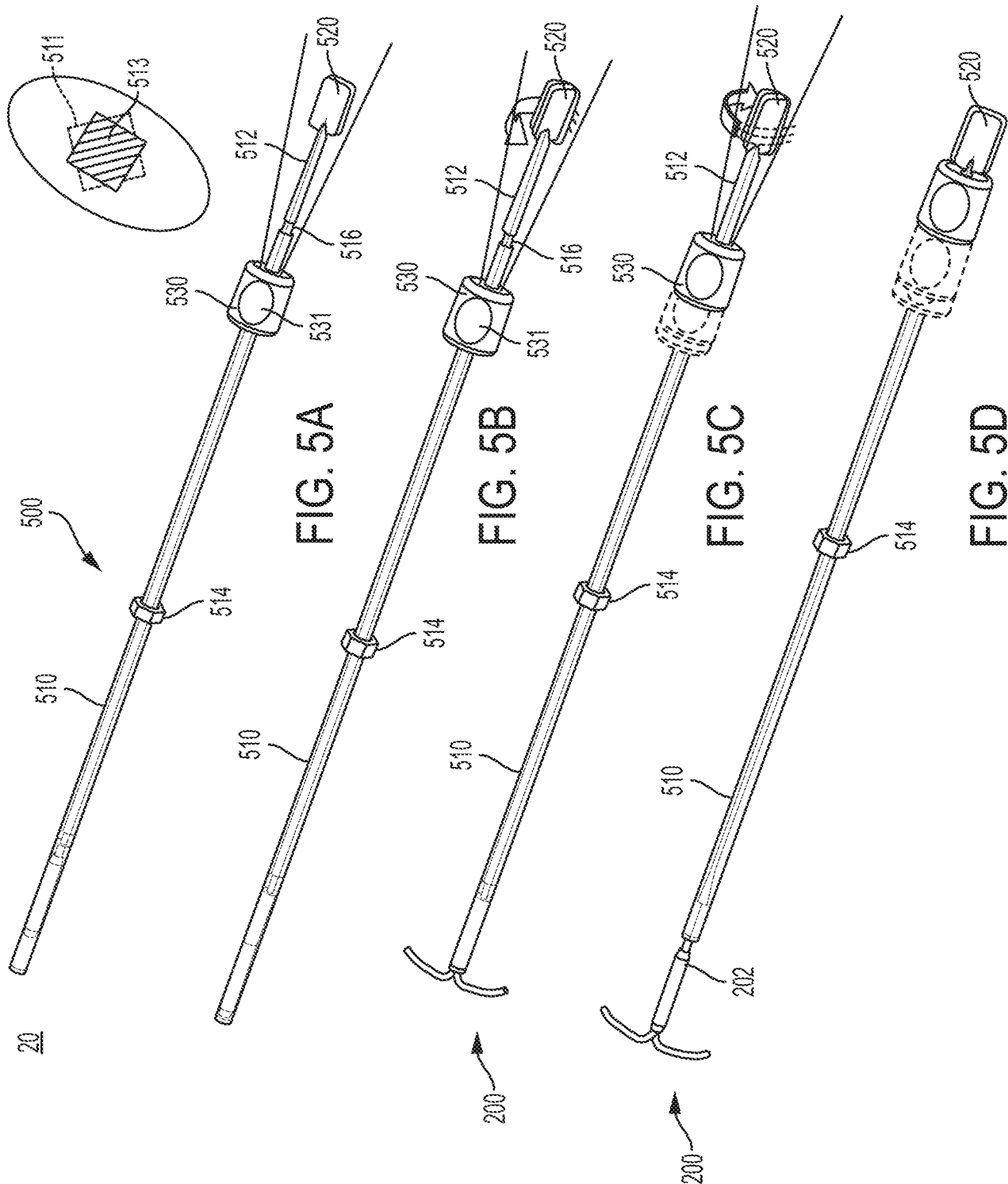
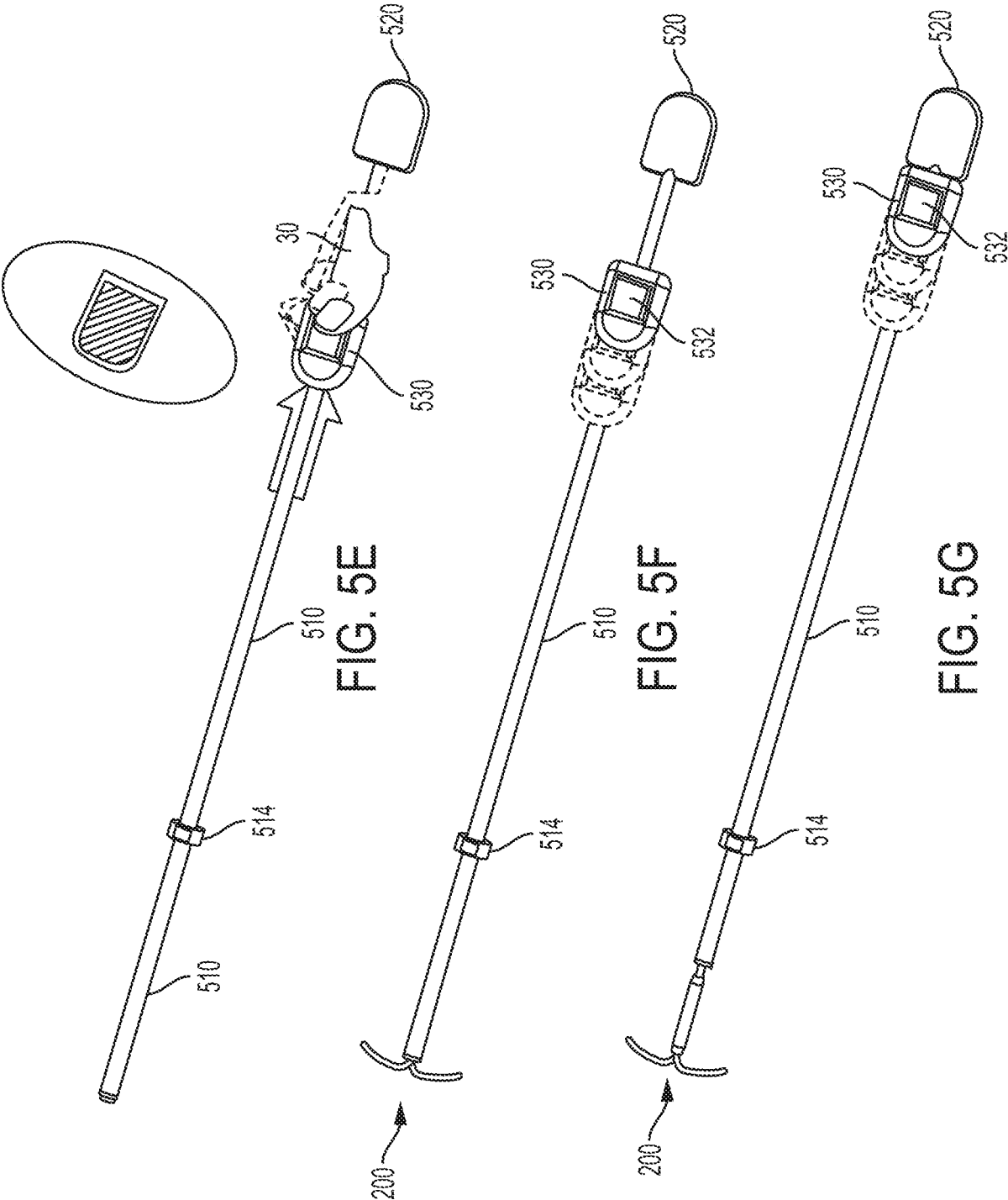


FIG. 4





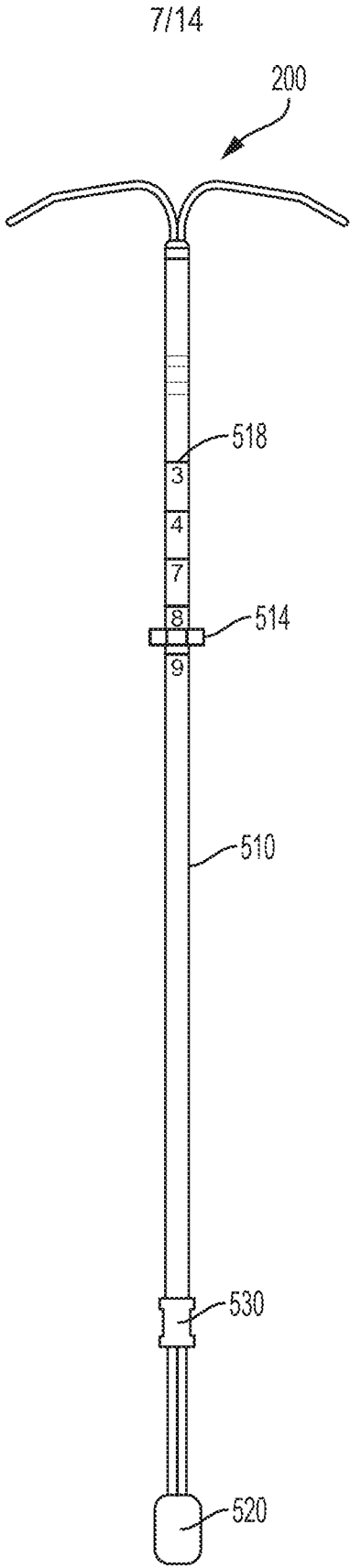


FIG. 5H

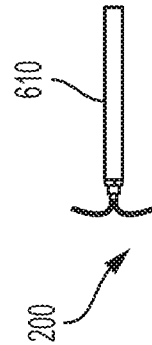


FIG. 6A

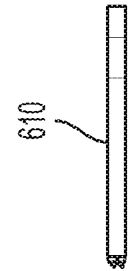


FIG. 6B

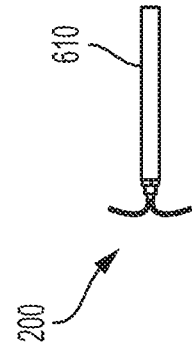


FIG. 6C

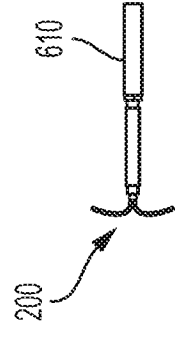


FIG. 6D

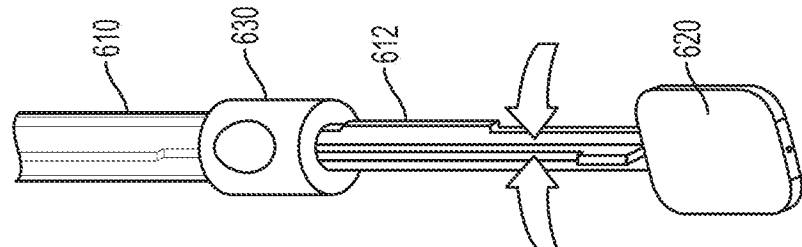
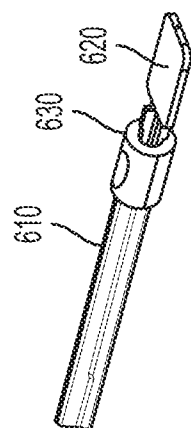
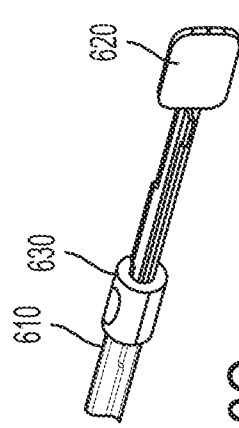
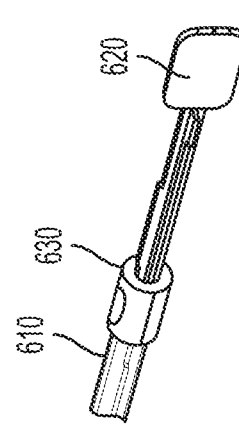


FIG. 6E

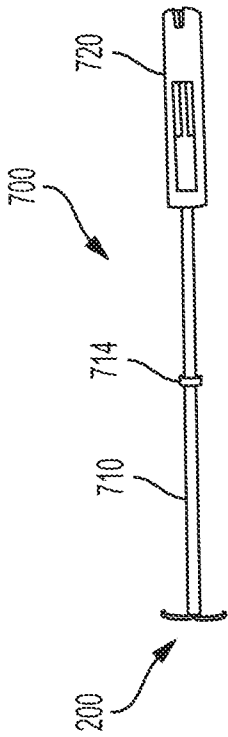


FIG. 7A

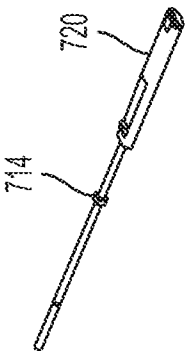


FIG. 7B

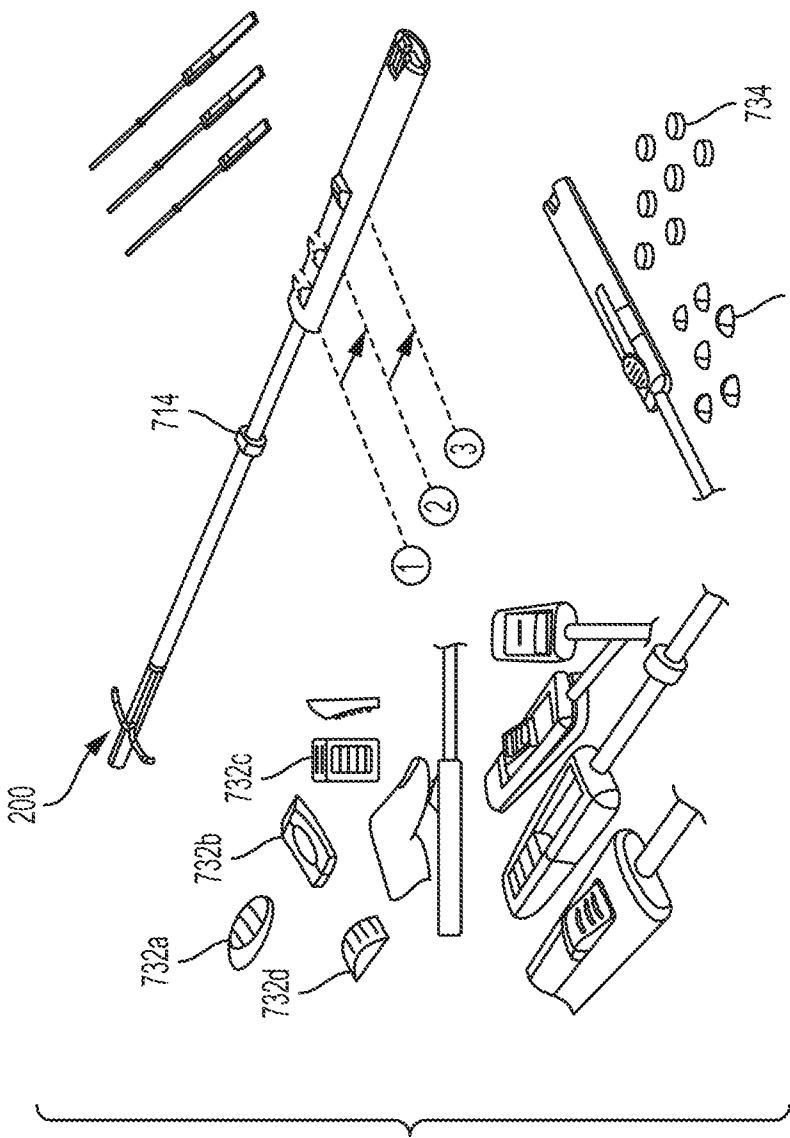
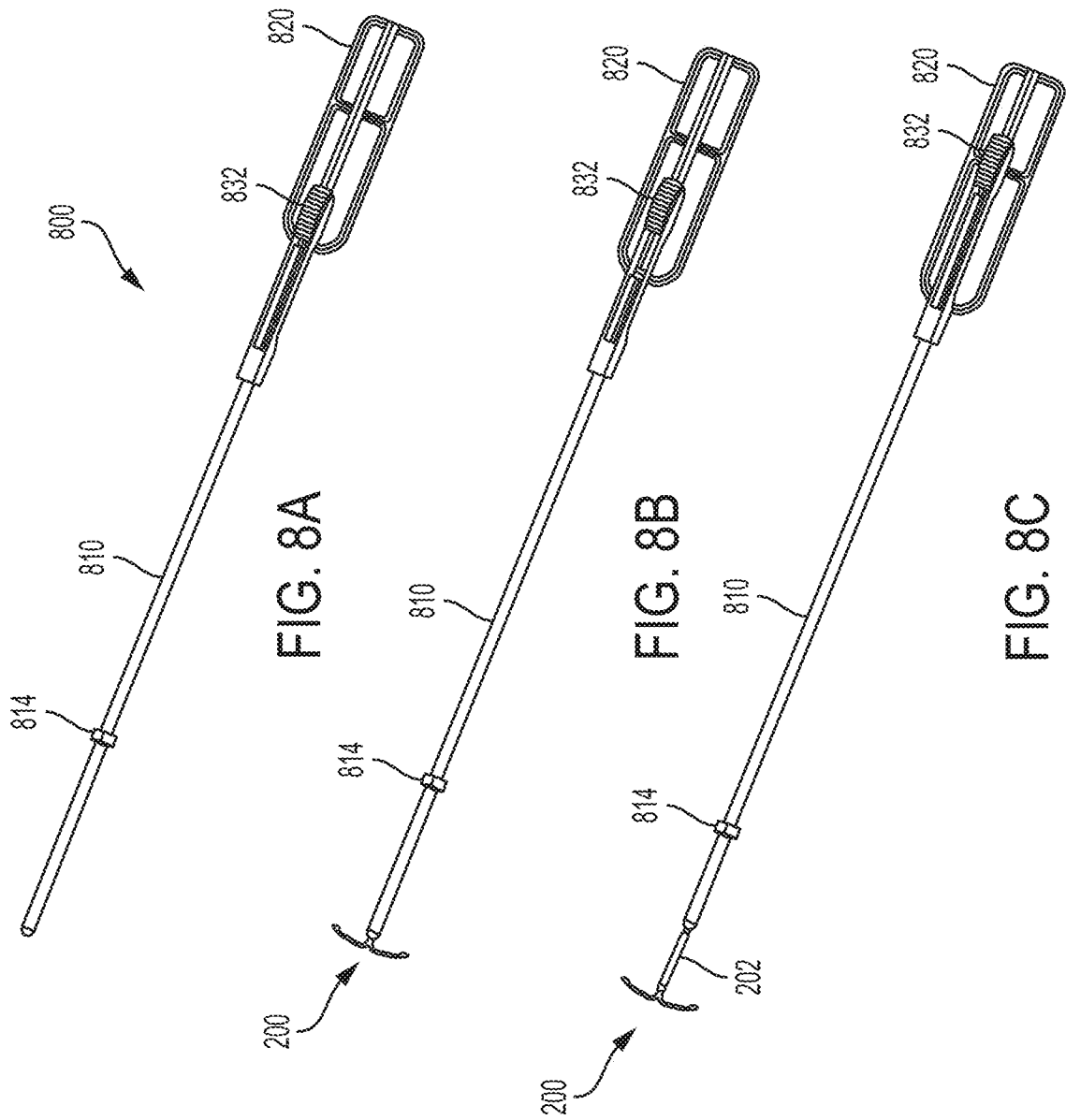
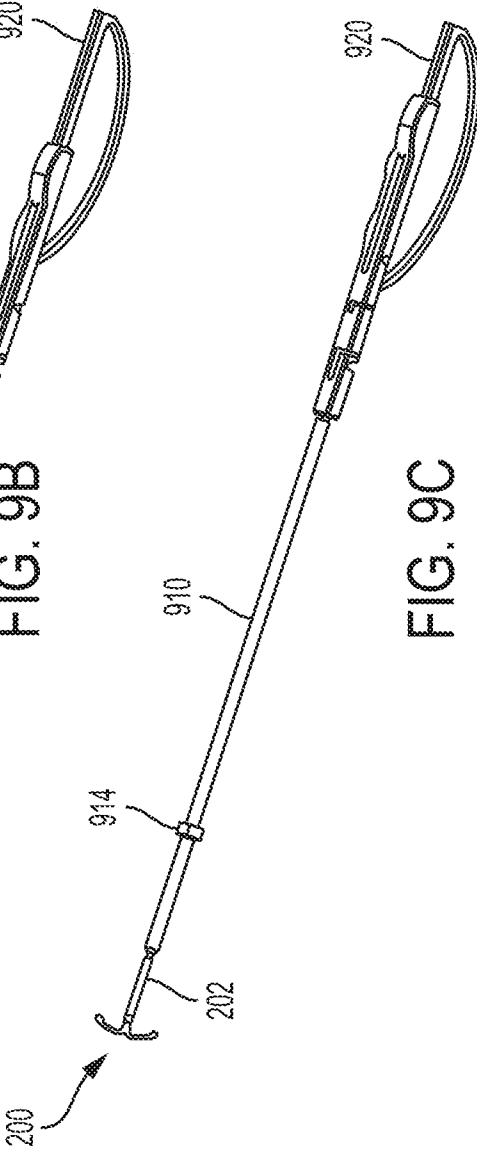
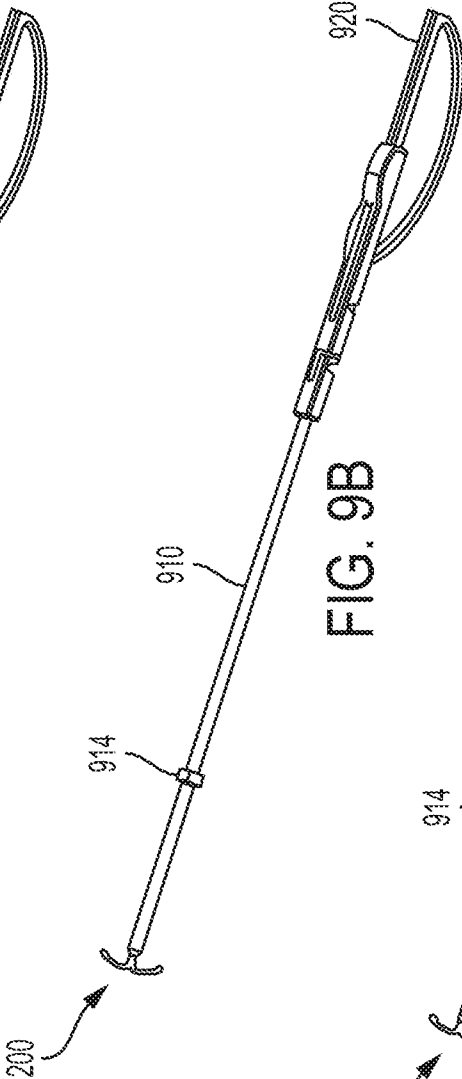
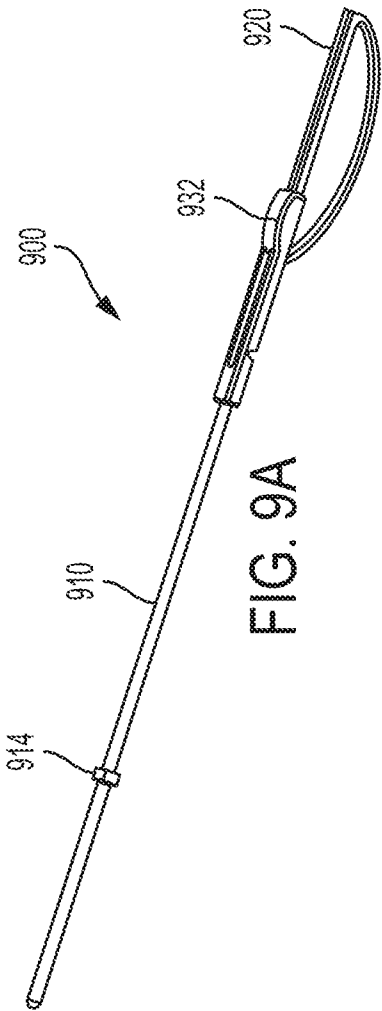


FIG. 7C





12/14

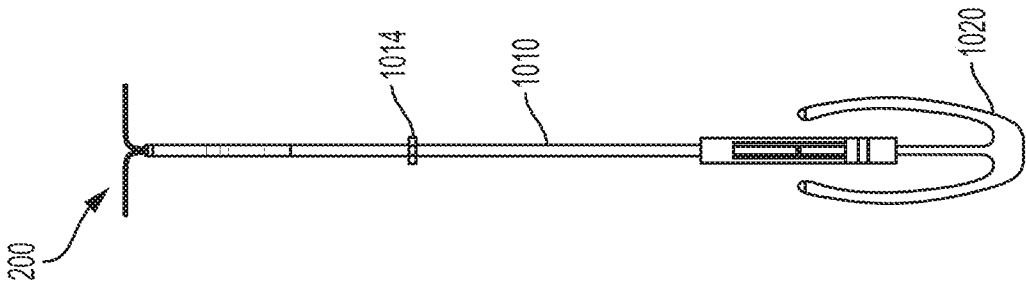


FIG. 10B

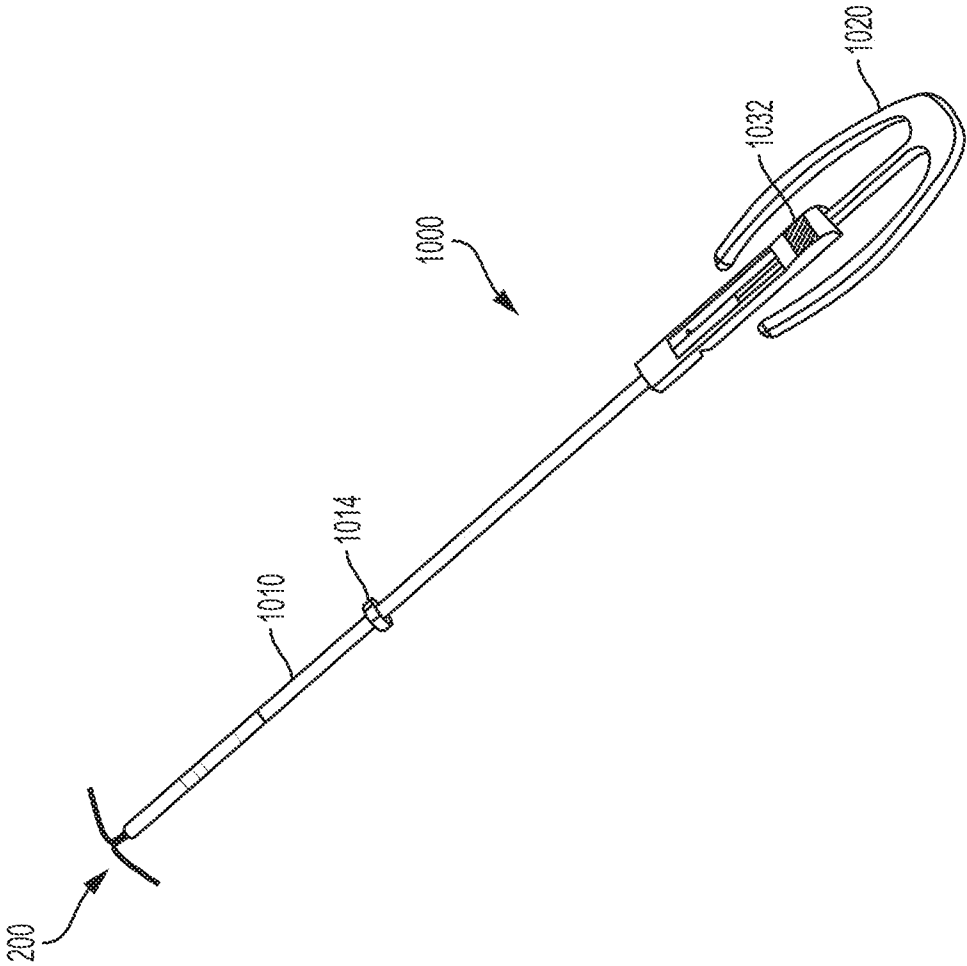
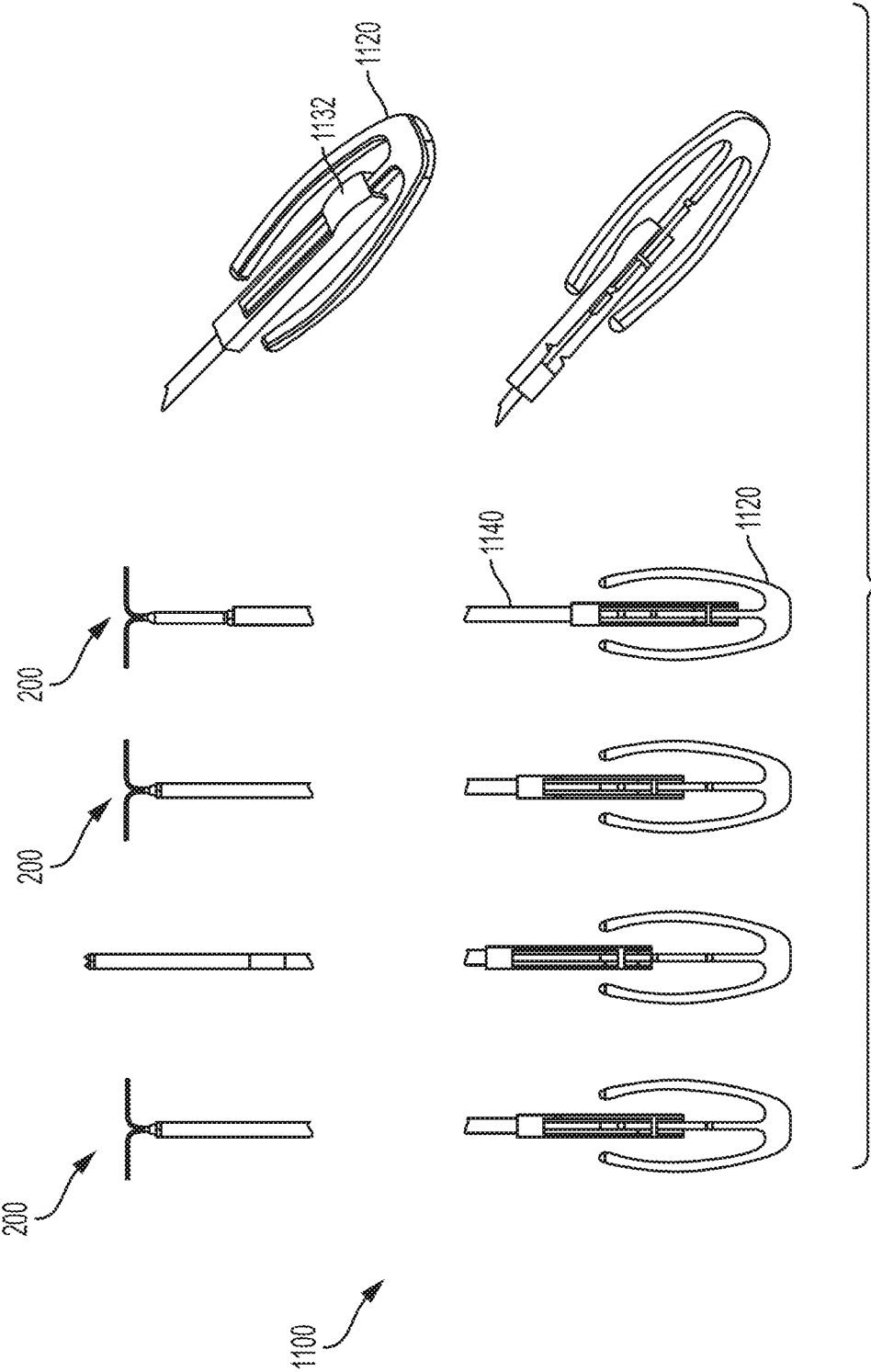


FIG. 10A



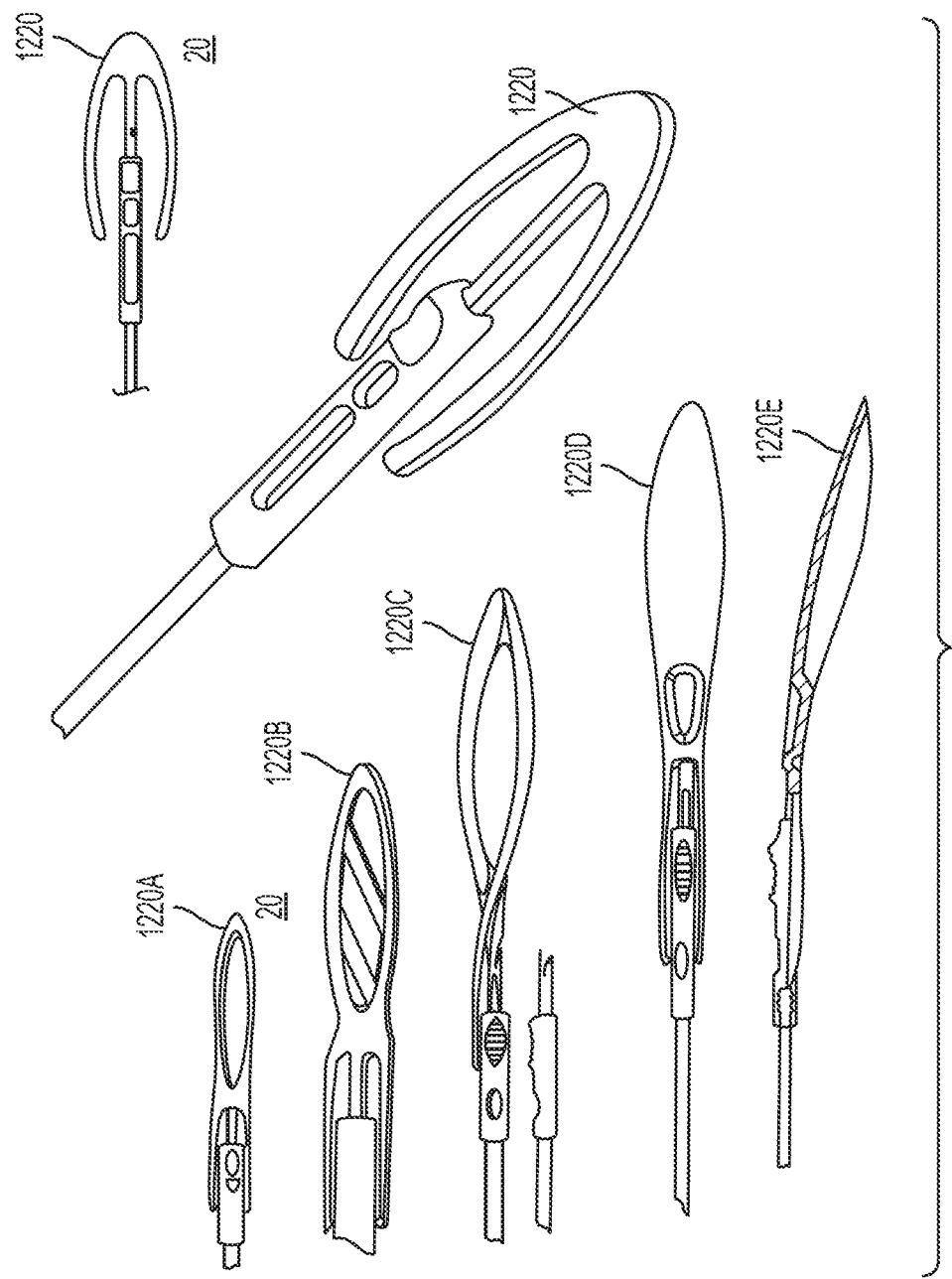


FIG. 12

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/US2017/023738**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.: 17,18
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 17,18 pertain to the treatment methods of the human body and thus relate to a subject-matter which this International Searching Authority is not required, under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv), 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 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 an additional fees, this Authority did not invite payment of any 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.:

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/US2017/023738**A. CLASSIFICATION OF SUBJECT MATTER****A61F 6/18(2006.01)i, A61F 6/14(2006.01)i, A61K 9/00(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)

A61F 6/18; A61F 6/06; A61M 31/00; A61F 6/14; A61K 9/00

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: IUD insertion, plunger, tab, handle, hinge, rotation

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6588429 B1 (WILDEMEERSCH, D.) 08 July 2003 See claims 1-5; figures 1-10.	1-16, 19-26
A	WO 2015-036465 A1 (BAYER OY) 19 March 2015 See the whole document.	1-16, 19-26
A	US 2009-0270835 A1 (KUSHNER, D. M.) 29 October 2009 See the whole document.	1-16, 19-26
A	US 2013-0014762 A1 (DECKMAN, R. et al.) 17 January 2013 See the whole document.	1-16, 19-26
A	US 2013-0213406 A1 (FRANKENNE, F. et al.) 22 August 2013 See the whole document.	1-16, 19-26



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

03 July 2017 (03.07.2017)

Date of mailing of the international search report

04 July 2017 (04.07.2017)

Name and mailing address of the ISA/KR

International Application Division

Korean Intellectual Property Office

189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea



Facsimile No. +82-42-481-8578

Authorized officer

HAN, Inho

Telephone No. +82-42-481-3362



INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2017/023738

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6588429 B1	08/07/2003	AU 2000-39505 A1 CN 1184937 C CN 1344141 A EP 1175191 A1 WO 00-62725 A1	02/11/2000 19/01/2005 10/04/2002 30/01/2002 26/10/2000
WO 2015-036465 A1	19/03/2015	CA 2923691 A1 CN 105579000 A EP 3043757 A1 JP 2016-530577 A US 2016-0217707 A1	19/03/2015 11/05/2016 20/07/2016 29/09/2016 28/07/2016
US 2009-0270835 A1	29/10/2009	None	
US 2013-0014762 A1	17/01/2013	AU 2012-282832 A1 AU 2012-282832 B2 CA 2841855 A1 CN 104023681 A CN 104023681 B EP 2731562 A2 JP 2014-523780 A KR 10-2014-0051296 A WO 2013-009674 A2 WO 2013-009674 A3	17/01/2013 02/07/2015 17/01/2013 03/09/2014 31/08/2016 21/05/2014 18/09/2014 30/04/2014 17/01/2013 21/03/2013
US 2013-0213406 A1	22/08/2013	AU 2011-322726 A1 AU 2011-322726 B2 EP 2632399 A2 EP 2632399 B1 JP 2013-544121 A JP 6068350 B2 WO 2012-055766 A2 WO 2012-055766 A3	02/05/2013 26/03/2015 04/09/2013 17/12/2014 12/12/2013 25/01/2017 03/05/2012 27/09/2012