

AN INTRAUTERINE SYSTEM WITH A LOCKING PART

TECHNICAL FIELD

The present disclosure relates generally to long-acting reversible
5 contraception systems, and more specifically to intrauterine systems.
Furthermore, the present disclosure relates to kits comprising an
intrauterine system and an inserter.

BACKGROUND

An intrauterine system (IUS) or an intrauterine device (IUD) is usually
10 positioned into the uterus using an inserter for preventing unwanted
pregnancies, family planning or treatment of a medical condition. In the
following, the abbreviation IUS is used, and covers both IUS's and IUD's.
The proper functioning of the IUS depends on the configuration of the
IUS and the accurate placement of the IUS in the uterus.

15 A conventional IUS requires an insertion tube that is passed through the
cervix during insertion. Indeed, in conventional IUS's available on the
market and disclosed in the prior art, the drug (hormone) containing
capsule is inside the insertion tube during the insertion procedure. As a
consequence, the cross-sectional diameter of what needs to pass through
20 the cervix is the diameter of the capsule and twice the wall thickness of
the insertion tube.

Furthermore, during insertion of a conventional IUS with its inserter,
there exists a risk of uterus penetration during insertion. Indeed, if an
unexperienced physician performs the insertion procedure or the
25 dimensions of the uterus have been wrongly determined in the sounding
step, the inserter may penetrate the uterine wall or even perforate it.

It is assumed that the pain and discomfort caused by insertion procedure is caused by stretching of the cervix channel. Therefore, in light of the foregoing discussion, there exists a need to overcome the aforementioned drawbacks associated with the conventional IUS.

5 SUMMARY

The present disclosure seeks to provide an intrauterine system (IUS). The present disclosure also seeks to provide a kit comprising an IUS and an inserter. The present disclosure seeks to provide a solution to the existing problem of pain and discomfort experienced by a subject during the
10 placement of the IUS. It is also one object of the current invention to diminish the diameter of the parts which have to pass the cervix channel during the IUS insertion process. It is a further object of the invention to provide a new IUS and its inserter which reduces the risk of uterus penetration during insertion.

15 An aim of the present disclosure is to provide a solution that overcomes at least partially the problems encountered in prior art, and provides an improved IUS that is highly flexible to enhance patient acceptability, and provides a relatively more comfortable experience during the insertion of the IUS through the cervical canal and final placement into the uterus, as
20 compared to existing systems.

In one aspect, an embodiment of the present disclosure provides an intrauterine system comprising

- a frame having a first end, a second end and a length L defined as a distance from the first end to the second end;
- 25 - a removal thread attached to the first end of the frame; and
- at least one pharmaceutically active agent;

wherein the first end of the frame comprises a first locking part and the second end of the frame comprises a second locking part, the first locking part and the second locking part being arranged to form a lock, the

removal thread being configured to guide the first locking part to the second locking part.

In another aspect, an embodiment of the present disclosure provides a kit comprising an intrauterine system and an inserter, wherein the inserter comprises

- a handle body having a distal end, a proximal end and a length L_H defined as the distance between the distal end and the proximal end;
- a measurement tube having a distal end and a proximal end, its proximal end being movably attached to the distal end of the handle body, provided the measurement tube is arranged to remain outside a cervix channel during insertion;
- a plunger having a distal end, a proximal end, a length L_P defined as the distance between the distal end and the proximal end, the plunger being movably arranged inside the handle body and the measurement tube, wherein the length L_P is greater than the length L_H ;
- a flange movably arranged to surround the measurement tube;
- a finger holder movably arranged to surround the handle body; and
- means for reversibly locking a removal thread of an intrauterine system, arranged on the handle body.

Embodiments of the present disclosure substantially eliminate or at least partially address the aforementioned problems in the prior art, and enable the disclosed IUS to be efficiently and conveniently inserted into the uterine cavity. The disclosed IUS has a small cross-sectional area, which minimizes discomfort and pain during its insertion through the cervix. The disclosed IUS is adaptable for a variety of drug loads and doses opening avenues for its use beyond just means of contraception. The disclosed IUS is also suitable for insertion without the need for any part of the inserter that has a larger cross-sectional diameter than the capsule to pass through the cervix, thus decreasing the diameter of what actually passes through cervix.

The IUS according to the present invention can be inserted without requiring that the capsule with the drug is pulled into an insertion tube. Therefore, the diameter of the object which has to pass the cervix channel during the insertion procedure of the current invention is reduced by two
5 times the wall thickness of the insertion tube of the conventional inserters. Indeed, for the insertion of the present IUS, the inserter can be such that no part of the inserter having a cross-sectional diameter larger than the IUS's largest diameter is entered into the cervical canal (and in consequence into the uterus).

10 A further advantage of an IUS according to the current invention is that the risk of uterus penetration during the insertion procedure is minimized as there is no insertion tube which could penetrate the uterus muscle if inserted too deep. Also, the IUS as such cannot penetrate as it starts to immediately form the final shape after passage of the cervix channel.

15 Additional aspects, advantages, features and objects of the present disclosure would be made apparent from the drawings and the detailed description of the illustrative embodiments construed in conjunction with the appended claims that follow.

It will be appreciated that features of the present disclosure are
20 susceptible to being combined in various combinations without departing from the scope of the present disclosure as defined by the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The summary above, as well as the following detailed description of
25 illustrative embodiments, is better understood when read in conjunction with the appended drawings. For the purpose of illustrating the present disclosure, exemplary constructions of the disclosure are shown in the drawings. However, the present disclosure is not limited to specific

methods and instrumentalities disclosed herein. Moreover, those skilled in the art will understand that the drawings are not to scale. Wherever possible, like elements have been indicated by identical numbers.

Embodiments of the present disclosure will now be described, by way of example only, with reference to the following diagrams wherein:

FIG. 1 is a perspective view of an IUS in a loaded configuration, in accordance with an embodiment of the present disclosure;

FIG. 2 is a schematic view of the IUS of FIG. 1, in accordance with an embodiment of the present disclosure;

10 FIG. 3 is a schematic view of an IUS, in accordance with another embodiment of the present disclosure;

FIG. 4A is a schematic view of an IUS in a loaded configuration, in accordance with yet another embodiment of the present disclosure;

15 FIG. 4B is a perspective view of the IUS of FIG. 4A in a loaded configuration, in accordance with an embodiment of the present disclosure;

FIG. 4C is a cross-sectional view of the IUS of FIG. 4A in a deployed state, in accordance with an embodiment of the present disclosure;

20 FIG. 4D is a perspective view of the IUS of FIG. 4A in a deployed state, in accordance with various embodiments of the present disclosure;

FIG. 5 is a perspective view of an IUS, in accordance with still another embodiment of the present disclosure;

FIGs. 6A-6D are schematic illustrations of a frame and of an IUS according to an embodiment;

25 FIGs. 7A-7C are perspective views of an inserter in an assembled and unassembled states, respectively, as well as details of an IUS, in accordance with an embodiment of the present disclosure;

FIG. 8A illustrates a perspective view of a piston and plunger subassembly of an inserter, in accordance with an embodiment of the present disclosure;

FIG. 8B illustrates a cross-sectional view of a piston and plunger subassembly with engagement parts of a piston of an inserter, in accordance with an embodiment of the present disclosure;

FIGs. 9A-9C illustrate a schematic view of an inserter with enlarged views that depicts internal structure of different sections of the inserter, in accordance with an embodiment of the present disclosure;

FIGs. 10A-10I illustrate different views of an inserter depicting various operational stages to position an IUS into a uterus, in accordance with various embodiments of the present disclosure; and

FIGs. 11A and 11B illustrate an inserter in an assembled and unassembled states, respectively, in accordance with another embodiment of the present disclosure.

In the accompanying drawings, a non-underlined number relates to an item identified by a line linking the non-underlined number to the item. When a number is non-underlined and accompanied by an associated arrow, the non-underlined number is used to identify a general item at which the arrow is pointing.

DETAILED DESCRIPTION OF EMBODIMENTS

The following detailed description illustrates embodiments of the present disclosure and ways in which they can be implemented. Although some modes of carrying out the present disclosure have been disclosed, those skilled in the art would recognize that other embodiments for carrying out or practicing the present disclosure are also possible.

In one aspect, an embodiment of the present disclosure provides an intrauterine system comprising

- a frame having a first end, a second end and a length L defined as a distance from the first end to the second end;
 - a removal thread attached to the first end of the frame; and
 - at least one pharmaceutically active agent;
- 5 wherein the first end of the frame comprises a first locking part and the second end of the frame comprises a second locking part, the first locking part and the second locking part being arranged to form a lock, the removal thread being configured to guide the first locking part to the second locking part.
- 10 In another aspect, an embodiment of the present disclosure provides a kit comprising an intrauterine system and an inserter, wherein the inserter comprises
- a handle body having a distal end, a proximal end and a length L_H defined as the distance between the distal end and the proximal end;
 - 15 - a measurement tube having a distal end and a proximal end, its proximal end being movably attached to the distal end of the handle body, provided the measurement tube is arranged to remain outside a cervix channel during insertion;
 - a plunger having a distal end, a proximal end, a length L_P defined as
 - 20 the distance between the distal end and the proximal end, the plunger being movably arranged inside the handle body and the measurement tube, wherein the length L_P is greater than the length L_H ;
 - a flange movably arranged to surround the measurement tube;
 - a finger holder movably arranged to surround the handle body; and
 - 25 - means for reversibly locking a removal thread of an intrauterine system, arranged on the handle body.

The present disclosure provides the aforementioned IUS and the aforementioned kit comprising the IUS and the inserter, which enables efficient and convenient insertion of the IUS into the uterus. The IUS is

30 straightened when loaded in the inserter (by the manufacturer) and

regains its desired shape upon insertion into the uterine cavity (i.e. when in a deployed state), with the help of the locking parts. Moreover, the disclosed IUS attains a smooth shape, such as a triangular-shape, an annular-shape or a rounded-shape in the deployed state. Such smooth
5 shape of the IUS not only ensures a proper fit of the IUS within the uterus but also reduces the risk of potential perforation of the uterus lining. Moreover, the frame segments, the bending segments, and the locking parts of the IUS enable the IUS to attain a desired continuous smooth shape in its deployed state. Beneficially, the aforementioned IUS provides
10 an intuitive insertion experience for a health care professional. Additionally, the aforementioned inserter of the kit enables an increase in an overall rate of successful insertion of the IUS without causing any or only minimal discomfort to the subject. Furthermore, the risk of uterus penetration during insertion is minimized as the inserter does not include
15 an insertion tube that enters the uterine cavity.

The IUS comprises a frame. The frame has a flexible tubular structure designed to adapt to the anatomical structure of the cervix region as well as the uterine cavity. The flexible structure enables the frame to bend easily into a shape and to withstand strain and stress associated with that
20 shape. For example, the frame may be stretched to almost a straight-line (i.e. a straightened configuration) during insertion of the IUS using the aforementioned inserter (or another suitable inserter), and attains a prespecified shape when placed within the uterine cavity, with the help of the locking parts. Optionally, the frame may have a triangular-shape,
25 an annular-shape, an oval-shape, a circular-shape, a polygonal-shape or an almond-shape in the deployed state.

Optionally, the frame mainly has an essentially round cross-section and the width W is the diameter of the frame. The frame preferably has a smooth cross-section. More optionally, the frame may have oval, or
30 elliptical cross-section to prevent any injuries in the uterine cavity. The

width W of the frame may be in a range of 1.5-3.5 mm. The width W is typically from 1.5, 1.7, 1.9, 2.1, 2.3, 2.5, 2.7, 2.9, 3.1 or 3.3 mm up to 1.7, 1.9, 2.1, 2.3, 2.5, 2.7, 2.9, 3.1, 3.3 or 3.5 mm. Beneficially, a smooth round-like cross-section and a small diameter of the frame
5 facilitate frictionless and nearly painless insertion of the IUS into and out of the cervical canal and uterus, and minimises any risk of perforation of the fundus of the uterus. Moreover, the fabrication material of the frame provides the required resilience to the IUS while in use. The resilience of the frame prevents expulsion of the IUS out of the uterine cavity and
10 displacement inside the uterine cavity due to uterine contractions, as the flexible frame balances out the stress caused by the uterine contractions.

Optionally, the frame is manufactured from a material selected from polyethylene, polypropylene, polyether ether ketone and thermoplastic polyurethane. Typically, the frame is made of an inert biocompatible
15 material of an elastomeric composition.

The bending segments, such as the first bending segment and the second bending segment, allow the frame to bend adequately to attain the desired shape. Moreover, the aforementioned removal thread guides the first locking part and the second locking part to lock with each other,
20 which in turn provides the desired shape. In the present description, by a removal thread it is also meant threads in plural. The removal thread is attached in any suitable manner, such as with a knot or by glue.

Optionally, the frame may comprise at least one diagnostic means for locating the IUS in the uterine cavity without a physical intervention. In
25 an example, the at least one diagnostic means may be an X-ray opaque agent, such as barium sulphate, for example, up to 20 wt-% (weight percentage) of the polymeric/elastomeric material of the frame. In another example, the at least one diagnostic means may be a ferromagnetic agent or an agent detectable by ultrasound or fluoroscopic
30 imaging of the IUS in the deployed state. Optionally, the at least one

diagnostic means is provided as an inert metal, either coated on at least a part of the frame of the IUS, or provided as a partial metal ring, e.g. made from silver embedded in the IUS.

The frame has a first end, a second end and a length L defined as a distance from the first end to the second end. Typically, the term "*first end*" refers to the end that is closer to the uterus of a subject during the insertion of the IUS (also called distal end), and the term "*second end*" refers to the end opposite to the first end, i.e. the end that is closer to the user, such as a health care professional, during the insertion of the IUS by use of an inserter (also called proximal end). Optionally, the length L of the frame ranges from 50-110 millimetre (mm) in a straightened configuration (i.e. when loaded in an inserter). The length L may be typically from 50, 60, 70, 80, 90 or 100 mm up to 60, 70, 80, 90, 100 or 110 mm. The frame of the IUS once deployed in a desired position in the uterine cavity may attain a prespecified configuration (length $\times$ width) in a range of 25 $\times$ 23 mm to 31 $\times$ 28 mm, preferably 26 $\times$ 25 mm. In the deployed state, the length is typically from 25, 27 or 29 mm up to 27, 29 or 31 mm. Similarly, in the deployed state, the breadth is typically from 23, 25 or 27 up to 24, 26 or 28 mm. In an example, the configuration of a frame of a triangular-shaped IUS in the deployed state may be 26.6 $\times$ 24.5 mm (length $\times$ width). In another example, the configuration of a frame of a triangular-shaped IUS in the deployed state may be 26.2 $\times$ 24.3 mm (length $\times$ width).

Furthermore, the first end of the frame comprises a first locking part and the second end of the frame comprises a second locking part, the first locking part and the second locking part being arranged to form a lock. The first locking part and the second locking part extend as overhangs from the first end and the second end of the frame respectively. Optionally, the first locking part and the second locking part are geometrically complementary structures, such as for example, a hook

and a loop, a pin and a loop (or slot), or a clamp and a column. It will be appreciated that the first locking part and the second locking part having the geometrically complementing structures comes in contact with each other in the deployed state in the uterus to engage with each other. The first locking part mechanically interacts with the second locking part for locking of the frame for suitable placement of the IUS into the uterus. While locking, the first locking part is directly held in a non-displaceable manner with the second locking part, consequently locking the frame in a desired shape. While unlocked, the first locking part and the second locking part exist in a disengaged state, for example in a straightened configuration at least partly inside the inserter or in a configuration when the IUS is not yet completely inserted (or released) into the uterine cavity. It will be appreciated that external influences, such as uterine contractions, do not affect the locking of the frame when the first locking part is locked to the second locking part. In an embodiment, the width of the first locking part and the second locking part may be more than the width W of the frame. The width of the first locking part and the second locking part may be in a range of 1.5-4 mm. The width of each of the first locking part and the second locking part is typically from 1.5, 2, 2.5, 3 or 3.5 mm up to 2, 2.5, 3, 3.5 or 4 mm. Notably, the fabrication material of the first locking part and the second locking part makes the IUS including the first locking part, the second locking part highly malleable, and thus the effective width and the largest outer diameter of the IUS is less than 3.7 mm, preferably 2.9 mm.

Optionally, the first locking part is a pin and the second locking part is a loop, wherein the pin is arranged to be irremovably inserted into the loop. The pin and loop engagement ensure a substantial portion of the pin to be engaged in the loop. Preferably, the pin has a knob-like structure and the loop has a complementary recess or opening-like structure for more efficient pin-loop engagement. The pin and loop engagement provide a desired shape to the frame in the deployed state inside the uterus.

- Optionally, the first locking part is a hook and the second locking part is a loop, wherein the hook is arranged to be irremovably inserted into the loop. The hook engages with the loop to lock the frame in the desired shape in the deployed state of the IUS inside the uterus. Optionally, the
- 5 first locking part and the second locking part are made from the same material that is used to make the frame. Optionally, the first locking part is a clamp and the second locking part is a column. The geometrically complimentary structures of the clamp and the column lock with each other in the deployed state inside the uterus.
- 10 According to an embodiment, the second locking part is designed to completely contain the first locking part, when the locking parts are locked together. Such an embodiment, when combined with the below discussed inserter, would ensure that the first locking part is not in contact with a plunger of the inserter.
- 15 Optionally, the frame comprises a first, a second and a third frame segment having a width W defined as a dimension perpendicular to the length, the first and the second frame segment being connected via a first bending segment and the second and third frame segments being connected via a second bending segment. The width W of the first, the
- 20 second and the third frame segment is essentially same as the width of the frame. The width W of the first, the second and the third frame segment may be in a range of 1.5-3.5 mm. The width W is typically from 1.5, 1.7, 1.9, 2.1, 2.3, 2.5, 2.7, 2.9, 3.1 or 3.3 mm up to 1.7, 1.9, 2.1, 2.3, 2.5, 2.7, 2.9, 3.1, 3.3 or 3.5 mm. The first bending segment and the
- 25 second bending segment enable the frame to bend at predefined distances to enable the frame to attain the desired triangular-shape in a deployed state in the uterus. Typically, the bending segments are thinner in at least one dimension than the frame segments, in order to allow them to efficiently bend during insertion, so that the IUS obtains its correct
- 30 shape. The bending segments (as the whole IUS) however needs to stand

forces when the IUS is pulled out, and typically this force is defined as 12 N. Thus, it may be beneficial to make the bending segments wider than the frame segments, in a direction that is perpendicular to the direction when the bending segments are thinner than the frame segments.

- 5 According to an embodiment, the first and third frame segments are slightly curved, i.e. they are not completely straight. The radius can be for example 120-155 % of the largest dimension of the IUS when it is locked into shape. The radius can thus be for example from 120, 125, 130, 135 or 140 % up to 130, 135, 140, 145, 150 or 155 % of the largest
10 dimension, such as about 45 mm. This helps the IUS to correctly turn during the insertion, thus minimising discomfort to the patient and uterine wall penetration.

Optionally, the first bending segment is arranged at a first distance D1 from the first end, and the second bending segment is arranged at a
15 second distance D2 from the first end, wherein the first distance D1 is 25-40 % of the length L and the second distance D2 is 55-80 % of the length L. The first distance D1 is typically from 25, 30 or 35 % up to 30, 35 or 40 % of the length L. The first distance D1 may be typically from 12.5 to 44 mm, preferably 17.5 to 28 mm. In an example, the first
20 distance D1 is 32-34 % of the length L of the frame, i.e. 16 to 37.4 mm. Similarly, the second distance D2 is typically from 55, 60, 65, 70 or 75 % up to 60, 65, 70, 75 or 80 % of the length L. In an example, the first distance D2 may be from 27.5 to 88 mm, and preferably 38.5 to 56 mm. In an example, the second distance D2 is 65-67 % of the length L of the
25 frame, i.e. 32.5 to 73.7 mm.

The first bending segment has a first width W1 and the second bending segment has a second width W2, and the first width W1 may be 5-50 % of the width W and the second width W2 may be 5-50 % of the width W. More optionally, the first width W1 is 20-30 % of the width W and the
30 second width W2 is 20-30 % of the width W. The width W1 is typically

from 5, 10, 15, 20, 25, 30, 35, 40 or 45 % up to 10, 15, 20, 25, 30, 35, 40, 45 or 50 % of the width W. In an example, the width W1 may be from 0.1 to 2 mm, and preferably 0.4 to 1.2 mm. Similarly, the width W2 is typically from 5, 10, 15, 20, 25, 30, 35, 40 or 45 % up to 10, 15, 20, 25, 30, 35, 40, 45 or 50 % of the width W. For example, the width W2 may be from 0.1 to 2 mm, and preferably 0.4 to 1.2 mm. Thus, the first width W1 and the second width W2 may be substantially identical.

In another embodiment, the first width W1 of the first bending segment and the second width W2 of the second bending segment are larger than the width W of the frame segment. For example, W1 can be 100-150 % of W and W2 can independently be 100-150 % of W. Indeed, W1 and W2 can be independently selected to be from 100, 105, 110, 115, 120, 125, 130, 135 or 140 % up to 105, 110, 115, 120, 125, 130, 135, 140, 154 or 150 % W.

Optionally, the cross-section of the frame at the first bending segment and at the second bending segment has an essentially concave shape wherein the first width W1 and the second width W2 is the smallest dimension of the cross-section. The concave shape of the cross-section of the frame at the first bending segment and at the second bending segment allows bending of the IUS. In an embodiment, the cross-section of the frame at the first bending segment and at the second bending segment may have a different shape as long as it allows the frame to bend into the desired shape. For example, a notch may be present on at least one side of each of the first, the second, or the third bending segments and the second bending segment, to allow bending of the frame into the desired shape.

Optionally, the frame comprises a bending point allowing the IUS to be removed. The bending point is a weaker part as compared to the other parts of the frame. In one embodiment, the bending point is provided in a middle section of the frame that does not have locking parts at its end,

such as in the middle portion of the second frame segment. Alternatively, the bending point may be provided in any other part of the frame, as long as it facilitates bending or breaking of the frame of the IUS. In an embodiment, during the removal of the IUS from the IUS, when the
5 removal thread is pulled, the IUS is thus bent at the bending point and the circular or triangular shape of the frame thus collapses which allows the removal of the "folded" frame through the cervix channel. The bending point should be designed such that the IUS does not bend in a wrong direction during insertion. In another embodiment, the IUS breaks
10 at the bending point when the removal thread is pulled.

The IUS comprises a removal thread attached to the first end of the frame. The term "*removal thread*" as used herein refers to a thread (namely a string) attached to the IUS at one end and used for removing the IUS at the end of the wearing period (which is about 3-10 years,
15 preferably 5-7 years). The removal thread is not only used for removal and/or replacement of the IUS at a later time during the wearing period, but also to detect (e.g. as an indication) whether the IUS is in a correct position within the uterine cavity once the IUS is deployed in the uterus. Still further, the removal thread is typically used to hold the IUS in place
20 with respect to the inserter, when in a sales package.

The removal thread is furthermore configured to guide the first locking part to the second locking part. The removal thread guides the first locking part to come in contact to the second locking part and further to engage the first locking part with the second locking part to provide a
25 desired shape to the IUS inside the uterine cavity. Alternatively stated, the removal thread guides the first locking part to the second locking part to engage and lock together when the removal thread is pulled. The strain while pulling the removal thread results in the first locking part to be immovably inserted into the second locking part, consequently locking
30 the frame in the desired shape. Optionally, the first end of the frame has

a means for attachment for coupling the removal thread. Examples of the means for attachment include, but are not limited to an opening, a perforation, a recess, a protrusion, and a notch.

The IUS comprises at least one pharmaceutically active agent. In an example, the pharmaceutically active agent may be a hormone, a drug or drug analogue, an active pharmaceutical ingredient, or a health-promoting substance having contraceptive or other curative properties. Such pharmaceutically active agent functions by either thickening cervical mucus, changing the endometrium making it unsuitable for egg implant, stopping ovulation, or acting as COX1/COX2 inhibitors. In an example, the pharmaceutically active agent may provide and/or enhance protection against various microbial infections, such as a bacterial infection, a fungal infection, and/or a sexually transmitted infection. The IUS may also comprise more than one pharmaceutically active agent.

Optionally, the pharmaceutically active agent is selected from progesterone and its derivatives, oestrogen, progestin, levonorgestrel, cyproterone acetate, desogestrel, etonogestrel, lynestrenol, medroxyprogesterone acetate, norethisterone, norethisterone acetate, norgestimate, drospirenone, gestodene, 19-nor-17-hydroxyprogesterone esters, 17 α -ethinyltestosterone and derivatives thereof, 17 α -ethinyl-19-nortestosterone and derivatives thereof, ethynodiol diacetate, dydrogesterone, norethynodrel, allylestrenol, medrogestone, norgestrienone, ethisterone and dl-norgestrel; and androgenic steroids, such as danazol and gestrinone; naproxen, ibuprofen, mefenamic acid, flurbiprofen, indomethacin, diclofenac, piroxicam, meloxicam, ketoprofen, gonadotropin-releasing hormone agonists, progesterone receptor antagonists such as mifepristone (11 β -4-dimethylaminophenyl-17 β -hydroxy-17 α -propinyl-4, 9-estradiene-3-one); ulipristale acetate, (11 β ,17 β)-17-Hydroxy-11-[4-(methylsulphonyl)phenyl]-17-(pentafluoroethyl)-estra-4,9-dien-3-one, 17 α -acetoxy-11 β -[4-(*N,N*-

dimethylamino)phenyl]-21-methoxy-19-norpregna-4,9-diene-3,20-dione, 17 α -acetoxy-11 β -(4-*N,N*-dimethylaminophenyl)-19-norpregna-4,9-diene-3,20-dione, 11 β -(4-acetylphenyl)-17 β -hydroxy-17 α -(1,1,2,2,2-pentafluoroethyl)-4,9-estradiene-3-one, asoprisnil (benzal
5 dehyde-4-[(11 β ,17 β)-17-methoxy-17-(methoxymethyl)-3-oxoestra-4,9-dien-11-yl])-1-oxime).

As hormones, for example levonorgestrel can be used, and as COX inhibitor, indomethacin may be used. It will be appreciated that the pharmaceutically active agent is administered at a suitable amount, for
10 example in a maximum feasible amount suitable to a subject. Moreover, the amount (i.e. dosage) of the pharmaceutically active agent varies depending on the particular pharmaceutically active agent, intended use, action time, release rate and therapy period as well as the age and medical condition of the subject. Furthermore, the pharmaceutically
15 active agent typically has a pH level that is suitable for the uterus. Thus, the IUS functions not only as a long-acting reversible contraceptive method but may be used for a variety of other applications, such as treating a medical condition, swelling, pain in the uterus, depending upon the pharmaceutically active agent supplied via the IUS.

20 Optionally, at the least one pharmaceutically active agent is arranged in the frame. In an example, the at least one pharmaceutically active agent is dispersed or dissolved in the material of the frame before its manufacturing. In an embodiment, the at least one pharmaceutically active agent is provided in one of the three frame segments, i.e. the first,
25 the second, or the third frame segment. In another embodiment, the at least one pharmaceutically active agent is provided in all the three frame segments.

Optionally, the at least one pharmaceutically active agent is arranged in at least one capsule, the capsule being arranged to surround the frame
30 on at most a part of its length L. Specifically, the at least one capsule is

a drug container comprising the pharmaceutically active agent. The at least one capsule arranged to surround the frame may also provide a required stiffness to the frame of the IUS at such part of the frame's length. The at least one capsule is arranged to surround at least one of the first, the second, or the third frame segment, leaving the first locking part, the first bending segment, the second bending segment and the second locking part free from the at least one capsule.

Optionally, the at least one capsule is arranged to surround the frame along its whole length with the exception of the first locking part and the second locking part. The at least one capsule is arranged to surround the first, the second, and the third frame segments. In such a case, the at least one capsule is flexible enough to bend at the bending segments.

Optionally, the at least one capsule is manufactured from poly(dimethyl silicone), siloxane based elastomer, a thermoplastic polyurethane, a thermoplastic polyurethane elastomer, ethyl vinyl acetate, a polyolefin-based elastomer, a silicone containing thermoplastic, polyurethane, polylactic acid and polycaprolactone. More optionally, the at least one capsule is manufactured from a biocompatible polymer matrix. Examples of the biocompatible polymer matrix include, but are not limited to copolymers of dimethylsiloxanes and methylvinylsiloxanes, polyethylene, polypropylene, polybutadiene, polyisoprene, acrylic acid polymers, ethylene/propylene copolymers, ethylene/ethyl acrylate copolymers, poly(methacrylate), polymethyl methacrylate, styrene-butadiene-styrene block copolymers, styrene-isobutylene-styrene copolymers, poly(hydroxyethylmethacrylate), polyethers, polyacrylonitriles, polyethylene glycols, polymethylpentene, polyhydroxy alkanoates, polyorthoesters, hydrophilic polymers (such as hydrophilic hydrogels), cross-linked polyvinyl alcohol, polytetrafluoroethylene, polyvinyl chloride, polyvinyl acetate, neoprene rubber, and butyl rubber.

In an embodiment, the at least one capsule is selected from a matrix system and a core-membrane system. In an example, the matrix system may be a polymer matrix, such as a siloxane-based elastomer, with the pharmaceutically active agent dispersed or dissolved therein. In another
5 example, in the core-membrane system, the at least one capsule may comprise a pharmaceutically active agent core, and a membrane encasing the pharmaceutically active agent core. The core may be a hollow tube-like structure assembled on the frame (surrounding the frame on at most a part of its length L) to deliver the pharmaceutically
10 active agent at a controlled rate in the uterus. The membrane may be a permeable layer, made up of an inert material, that prevent direct contact between the pharmaceutically active agent and the biological fluid in the uterus. Furthermore, the membrane layer may adjust the release rate of the pharmaceutically active agent by acting as a diffusion layer
15 surrounding the pharmaceutically active agent core. In an embodiment, the membrane may surround the at least one capsule from all directions, resulting in a closed capsule. In another embodiment, the at least one capsule is not completely surrounded by the membrane. In an embodiment, the membrane is more permeable and allows the
20 pharmaceutically active agent to contact the biological fluids as compared to the pharmaceutically active agent core.

Optionally, a cross-section of the at least one capsule is selected from circular and oval. For example, the capsule may have a round, circular, an oval or an elliptical cross-section as long as the shape is suitable to be
25 inserted into the cervical canal and into the uterus. Optionally, the outer diameter of the capsule is in a range of 2-3.5 mm, and preferably about 2.9 mm. The outer diameter of the capsule is typically from 2, 2.1, 2.3, 2.5, 2.7, 2.9, 3.1, or 3.3 mm up to 2.1, 2.3, 2.5, 2.7, 2.9, 3.1, 3.3 or 3.5 mm.

Optionally, the IUS comprises at least two capsules. In an example, the at least two capsules are placed at a predefined distance from each other on the frame. Preferably, the at least two capsules are not in contact with each other once the IUS is inserted into the uterine cavity. Optionally,
5 the number of capsules may be 3, 4, and so forth, depending on the different types of therapeutic agents to be administered.

Optionally, the IUS comprises a first capsule arranged to surround the first frame segment, a second capsule arranged to surround the second frame segment and a third capsule arranged to surround the third frame
10 segment, wherein the first locking part, the first bending segment, the second bending segment and the second locking part are free from capsules. In this embodiment, the first capsule, the second capsule and the third capsule may impart sufficient stiffness to the frame during the insertion process and further help the IUS to attain a desired continuous
15 smooth shape (i.e. a prespecified configuration) in its deployed state. The first locking part, the first bending segment, the second bending segment and the second locking part are void of capsules in order to cause necessary bends in and/or shaping of the frame of the IUS.

Optionally, the capsules comprise different pharmaceutically active
20 agents. Optionally, the first capsule, the second capsule and the third capsule may be identical or different in structure, and may contain same or different pharmaceutically active agents. In an example, the first capsule may include a first pharmaceutically active agent, such as progestin, the second capsule may include a second pharmaceutically
25 active agent, such as diclofenac, and the third capsule may include a third pharmaceutically active agent, such as levonorgestrel. Furthermore, the release of the pharmaceutically active agents from the at least two capsules may be carried out simultaneously or one after another depending upon a rate of release of the pharmaceutically active agents

to be achieved and their respective interactions with the biological fluid in the uterus.

Optionally, a first pharmaceutically active agent is arranged in a capsule, the capsule being arranged to surround the frame on at most a part of its length L, and a second pharmaceutically active agent is arranged in the frame. The capsule affects the rate of release of the pharmaceutically active agent in the uterus. The at least one pharmaceutically active agent dispersed or dissolved in the fabrication material of the frame has a rate of release of the pharmaceutically active agent different from the rate of release of the pharmaceutically active agent arranged in the capsule. It will be appreciated that the rate of release of the pharmaceutically active agent depends upon the permeability of the fabrication material of the frame and/or the capsule.

According to an embodiment, the frame is obtained by an injection moulding process. One capsule is arranged to surround a part of the frame that forms a capsule-frame assembly. However, in cases where there is more than one capsule, the capsules may be arranged anywhere on the frame, leaving at least the first locking part and the second locking part free from the capsule, depending on the desired shape of the IUS to be achieved.

In another exemplary aspect, an embodiment of the present disclosure provides an intrauterine system comprising

- a frame having a first end, a second end and a length L defined as a distance from the first end to the second end;
- a removal thread attached to the first end of the frame; and
- a copper wire arranged around at least a part of the frame;

wherein the first end of the frame comprises a first locking part and the second end of the frame comprises a second locking part, the first locking part and the second locking part being arranged to form a lock, the

removal thread being configured to guide the first locking part to the second locking part.

According to this embodiment, the copper wire arranged around at least a part of the frame functions as a contraceptive by preventing fertilization
5 of an egg by sperm. The copper IUS (i.e. the IUS comprising copper) is hormone free and therefore a good option for women who prefer or are advised a non-hormonal birth control method due to medical reasons.

The present disclosure also provides a kit comprising an intrauterine system and an inserter. The IUS of the kit is as described above.
10 According to an embodiment, the IUS is pre-installed (or preloaded) in the inserter in a sterile sales package. The sales package protects the contents of the kit from environmental and mechanical factors. The various embodiments and variants described above for the IUS apply *mutatis mutandis* to the IUS of the kit.

15 The present disclosure thus provides the kit for efficiently and conveniently performing the IUS insertion into the uterus. The inserter enables insertion of the IUS in a stable position in the uterus. The inserter is easy-to-use and enables direct entry of the IUS into the cervical canal instead of insertion of any part of the inserter into the cervical canal, to
20 reduce the pain associated with the IUS placement into the uterus. Moreover, a small cross-sectional area of the IUS makes the insertion of the IUS into the uterus almost painless or at least less painful than with conventional IUS's and inserters. Furthermore, the various parts of the inserter are released at a specific time during the IUS insertion process,
25 thereby providing an intuitive and enhanced experience to a healthcare professional while operating the inserter in the IUS insertion process. The use of the kit therefore may enable an increase in an overall rate of successful insertion of the IUS without causing any or only minimal discomfort to the subject.

In the present description, a proximal end is the end that is closest to the user (the medical practitioner) during insertion of the IUS, and a distal end is the opposite end, furthest away from the user.

The inserter comprises a handle body having a distal end, a proximal end
5 and a length L_H defined as the distance between the distal end and the proximal end. The handle body is preferably designed for easy handling of the inserter with a single hand. Moreover, the handle body is preferably designed to be devoid of any handedness preferences. Alternatively stated, the inserter works equally when held using the handle body either
10 with a right hand or a left hand.

According to an embodiment, the handle body is fabricated from a polymeric material (e.g. medical-grade plastics material) and is employable for a single use for hygienic purpose. The handle body may have various shapes and sizes. The handle body is typically a hollow
15 elongated structure, for example, tubular, cylindrical, elliptical, oval, cuboidal, or the like. The handle body acts as a housing and a support structure for various components of the inserter. Moreover, the handle body may be designed to conform to a palm of a medical practitioner. In an example, the handle body has a first cover portion and a second cover
20 portion. Each of the first cover portion and the second cover portion may have a geometrically complementary structure to attach to each other in the assembled state of the inserter. According to an embodiment, the length L_H is 70-110 mm. Optionally, the length L_H of the handle body is around 94 mm. The length L_H is typically from 70, 75, 80, 85, 90, 95 or
25 100 mm up to 80, 85, 90, 95, 100, 105 or 110 mm.

The inserter further comprises a measurement tube having a distal end and a proximal end. The proximal end of the measurement tube is movably attached to the distal end of the handle body. The measurement

tube is a hollow tube-like structure. Optionally, the measurement tube has a circular or oval cross-section.

Optionally, the proximal part of the measurement tube comprises insertion depth indicators, for example on its outer surface. In an example, the insertion depth indicators may refer to calibrated lines with corresponding numerical values marked on the outer surface of a proximal part of the measurement tube. Such insertion depth indicators are used to correctly set the aforementioned flange at a correct position on the measurement tube at the beginning of the IUS insertion process, after the insertion length (i.e. length of the uterus and of the cervical canal) has been measured.

Optionally, the measurement tube is fabricated from a medical grade polymeric material, such as polyethylene, polypropylene, silicone, and the like, or metal. Optionally, the measurement tube may be made of polyether ether ketone, thermoplastic polyurethane, thermoplastic polyurethane elastomer, and the like. It may comprise reinforcing material such as glass fibres.

The inserter further comprises a plunger having a distal end, a proximal end, and a length L_p defined as the distance between the distal end and the proximal end. The plunger is movably arranged inside the handle body and the measurement tube. The length L_p is greater than the length L_h . According to an embodiment, the length L_p is 50-90 mm. The length L_p is typically from 50, 55, 60, 65, 70, 75 or 80 mm up to 60, 65, 70, 75, 80, 85 or 90 mm.

According to an embodiment, the plunger is hollow so as to allow the removal thread of the aforementioned intrauterine system to pass through the plunger. The plunger can thus be a thin hollow tube-like structure that allows the removal thread to pass through the plunger. It

will be appreciated that the term "*removal thread*" as used herein refers to one or more threads (namely strings) attached to the IUS at one end and used for removing the IUS at the end of a wearing period (which can be for example 5-7 years). The removal thread is not only used for
5 removal of the IUS, but also to detect whether the IUS is in a correct position within the uterine cavity once the IUS is deployed in the uterus. In an example, the IUS may be preloaded in the inserter in a sales package. In the preloaded state of the IUS, one end of the removal thread remains coupled to the aforementioned first locking part of the IUS,
10 whereas the other end of the removal thread passes through the plunger.

According to an embodiment, the distal end of the plunger is configured to cooperate with the second locking part. Optionally, a portion of the plunger at the distal end may have a form that is geometrically complementary as of the second locking part. Optionally, the plunger is
15 made of a medical grade polymeric material, such as polyethylene, polypropylene, silicone, and the like, or metal.

According to an embodiment, the plunger comprises means for preventing its removal from inside the handle body. The plunger may comprise these means for preventing its removal from inside the handle
20 body at the proximal end of the plunger. In an embodiment, the means has a circumference that is greater than the circumference of the remaining portion of the plunger. Optionally, the means is in the form of a ring or a polygonal shaped part that retains the plunger inside the piston as well as the handle body. The plunger is attached to the distal end
25 inside the piston. Specifically, the plunger is locked between engagement parts of the piston. In an example, the engagement parts of the piston may be small protrusions extending inwards from geometrically opposite directions from the inner surface of the distal part of the piston.

The inserter further comprises a flange movably arranged around the
30 measurement tube. In an embodiment, the insertion depth indicators on

the measurement tube allows setting the position of the flange by a user. In the beginning of the IUS insertion procedure, the flange is manually moved to a specified position on the measurement tube with the help of the insertion depth indicators on outer surface of the proximal part of the measurement tube. The specified position refers to the length of the
5 uterine cavity plus the length of the cervical canal measured previously during uterine sounding. Once set on the measurement tube of the inserter, a firm grip of the flange is established with respect to the measurement tube, thereby preventing an unwanted movement of the
10 flange from its initial set position when the inserter is used in the IUS insertion process.

Optionally, the flange comprises a gripping surface on two diametrically opposing sides at an outer portion of the flange. In an example, the gripping surface has a waved structure to enable a firm grip of fingers of
15 a single hand and for pressing an outer part of the flange towards an inner part of the flange for adjusting the flange at a correct position by sliding it over the measuring tube. In such case, the release of the grip then sets the flange in place, and the friction between the flange and the measurement tube allows the flange to remain in its place.

20 Optionally, the flange has a length L_r . The length L_r is 2-10 %, preferably 4-8 % of the length L of the measurement tube of the inserter. In an example, L_r may be from 2, 3, 4, 5, 6, 7 or 8 up to 4, 5, 6, 7, 8, 9 or 10 % of L . Optionally, the flange is made of a polymeric material, such as low-density polyethylene, high-density polyethylene, polypropylene,
25 thermoplastic polyurethane, thermoplastic polyurethane elastomer, polyether ether ketone and/or a combination thereof. The flange may have various shapes, for example, a rounded rectangular shape, oval, elliptical, round, or the like.

The inserter may further comprise a tip cover having a distal end and a
30 proximal end and arranged to withdraw inside the distal end of the

measurement tube, provided the tip cover is arranged to remain outside the cervix channel during insertion. The distal end of the tip cover has a round bulbous-like structure to prevent the measurement tube from entering into the cervical canal of the subject. The proximal end of the tip cover is movably arranged within an inner surface of the measurement tube at the distal end of the measurement tube. During the insertion of the IUS, when the inserter is pushed towards the subject, the tip cover slides backwards (i.e. towards the handle body), and locks itself on the inner surface of the measurement tube. Optionally, the tip cover is movably attached on the outer surface of the measurement tube and slides over the measurement tube.

The inserter further comprises a finger holder movably arranged to surround the handle body. The finger holder may be used as a support for fingers (e.g. two fingers) to conveniently press the piston towards the distal end of the handle body during the IUS insertion process. According to an embodiment, in the assembled state of the inserter, only the optional tip cover, the flange, and the means (e.g. a thread lock) for reversibly locking the removal thread are movable, and other parts of the inserter are locked. The other parts of the inserter are only released at a specific time during use (i.e. during the IUS insertion process). For example, the finger holder is initially locked in the inserter. Optionally, the finger holder comprises one or more hooks that locks the movement of the finger holder in the inserter. In an embodiment, the finger holder comprises two hooks, such as a first hook and a second hook, which may be locked in corresponding recesses provided in the distal end of the handle body. During the IUS insertion process, once the piston has completely entered the handle body, the finger holder becomes unlocked and moves towards the proximal end of the handle body. Moreover, after the finger holder moves to the proximal end of the handle body, the lock that holds a movement of the measurement tube with respect to the handle body is also released. In an example, one or more clamps may be

used to lock the movement of the measurement tube with respect to the handle body. A proximal part of the measurement tube moves inside the handle body until the flange abuts the distal end of the handle body. Thus, the various parts of the inserter are released at a specific time
5 during the IUS insertion process, thereby providing an intuitive and enhanced experience to a healthcare professional as well as a comfortable experience to the subject in the IUS insertion process.

The finger holder may be arranged on the proximal end of the handle body. The finger holder may have one or two ring-shaped or half ring-shaped structure to provide grip for at least two fingers. Alternatively
10 shaped structure to provide grip for at least two fingers. Alternatively stated, the finger holder may be in the form of circles extending outwards from diametrically opposite sides of the outer surface of the handle body at its proximal end. In such embodiment, the finger holder is movably arranged on the handle body. Optionally, the finger holder is fixedly
15 arranged on the handle body.

The inserter further comprises means for reversibly locking the removal thread of the intrauterine system, arranged on the handle body. According to an embodiment, the means for reversibly locking the removal thread comprises a rotatable knob arranged, in a first position,
20 to lock the removal thread between the handle and the knob and in a second position, to allow the removal thread to be moved with respect to the handle body. Optionally, the knob and the handle body comprise corresponding forms allowing the removal thread to be locked when the knob is in the first position.

25 In another embodiment, the means for reversibly locking the removal thread may be a roller-like mechanism on which the removal thread is rolled. The rolling of the roller-like mechanism in one direction (e.g. in a forward direction) may lock the removal thread, and the rolling of the roller-like mechanism in another direction (e.g. in a reverse direction)
30 may release the removal thread. In an example, the roller-like

mechanism may be a pinion arranged in an opening of the handle body and having a corresponding counterpart.

According to an embodiment, the inserter further comprises a piston attached to the plunger and arranged to move the plunger, the piston
5 being movably arranged inside the handle body. The piston is arranged at the proximal end of the handle body. Moreover, the proximal end of the piston comprises a press member. The press member is provided, for example, for a thumb of the user of the inserter. When the press member of the piston is pushed, the piston enters inside the handle body, and
10 further moves forward towards the distal end of the handle body. In an example, the press member may be integrated to the piston during an injection moulding process. Additionally, the plunger locks between the aforementioned engagement parts of the piston. In the IUS insertion process, the plunger is pushed into the cervical canal and partially into
15 the uterine cavity when the piston is pushed forward towards the distal end of the handle body.

According to an embodiment, the piston is hollow so as to allow the removal thread of the intrauterine system to pass through the piston. The piston is a hollow tube-like structure that allows the removal thread to
20 pass therethrough. In an example, the IUS may be preloaded in the inserter in a sales package. In the preloaded state of the IUS, one end of the removal thread remains coupled to the aforementioned first locking part of the IUS, whereas the other end of the removal thread passes through the plunger and the piston, and emerges from the handle body
25 around the means for reversibly locking the removal thread.

According to an embodiment, the piston comprises means for preventing its removal from inside the handle body. The piston may comprise the means for preventing its removal from inside the handle body at the distal end of the piston. In an example, the means for preventing the removal
30 of the piston from inside the handle body may be at least one protrusion

extending from an outer surface of the piston at the distal end of the piston. The at least one protrusion prevents an accidental removal of the piston from the handle body. In another example, two protrusions may be attached to or arranged on the outer surface of the piston. The two
5 protrusions may extend from the outer surface of the piston in two geometrically opposite directions. Optionally, the means for preventing the removal of the piston from inside the handle body may be in the form of a ring that conforms to the inner diameter of the handle body.

According to an embodiment, the IUS insertion process into the uterus
10 (namely, operational stages of the aforementioned inserter when used) is described by taking an example of the IUS having locking parts, and is as follows.

Typically, before insertion, the IUS is at least partly within the inserter (i.e. preloaded in the inserter) and stored in a sales package. The removal
15 thread (which is also the guiding tread) is attached at the first end of the frame of the IUS (i.e. the end that enters the uterus first), and the other end of the removal thread is attached to the handle body. According to an embodiment, the IUS is preloaded on the inserter in such a manner that a small part of the IUS protrudes from the inserter, the rest of the
20 IUS is surrounded and protected by the tip cover. In an example, about 10 mm of the frame is left outside the inserter (i.e. outside the tip cover of the measurement tube) in the preloaded state. The inserter is used in aseptic conditions with a pair of sterile gloves put on by a user (e.g. a health care professional). The insertion process then starts with the
25 adjustment of flange.

A) Flange adjustment: the flange is manually moved at a specified position on the measurement tube with the help of the insertion depth indicators on the outer surface of the measurement tube. The specified position refers to the length of the uterine cavity plus the length of the
30 cervical canal measured previously during uterine sounding. In an

example, the gripping surface provided on the two diametrically opposing sides of the flange may be used to press an outer part towards an inner part of the flange.

After the adjustment of flange, the steps slightly vary depending on whether the inserter comprises a tip cover or not. Below, both variants are disclosed (step B for a device without a tip cover, step B'' for a device with a tip cover).

B) First IUS insertion stage: the measurement tube is passed through vagina towards the cervix. The inserter is positioned such that the distal end of the measurement tube reaches the cervix opening (i.e. external orifice) and the first end (i.e. the tip) of the IUS is positioned inside the cervix opening. At this stage, the piston is in an extended state and the aforementioned press member of the piston is away from the proximal end of the handle body.

B') First IUS insertion stage: the measurement tube is passed through vagina towards the cervix. The inserter is positioned such that the tip cover reaches the cervix opening (i.e. external orifice) and the first end (i.e. the tip) of the IUS is positioned inside the cervix opening. Thereafter, the whole inserter is gently pushed towards the subject, which makes the tip cover move backwards (i.e. towards the handle body), and a part of the frame (for example about 30 mm) is released from the inserter in the cervical canal. When the tip cover moves backwards, the tip cover locks itself inside the measurement tube. Alternatively stated, the cervix opening prohibits the tip cover from moving forward together with the inserter, and instead forces the tip cover to enter inside the measurement tube, and lock itself in the inner surface of the distal part of the measurement tube. The inserter is gently pushed towards the subject until a resistance from the inserter, typically a physical pressure, is felt by the user. The measurement tube itself is not passed into the cervical canal at any operational stages during the IUS insertion process, thereby

decreasing discomfort during the IUS insertion process. At this stage, the piston is in an extended state and the aforementioned press member of the piston is away from the proximal end of the handle body.

- C) Second IUS insertion stage: while maintaining a firm contact of the measurement tube (in the case a tip cover is used, a contact of the tip cover, i.e. the tip of inserter) to the portio of the cervix, the piston is pressed from its proximal end towards the distal end of the handle body. The finger holder may be used as a support for fingers (e.g. two fingers) to conveniently press the piston towards the distal end of the handle body. The IUS starts to exit the inserter and to form a loop, under the effect of the removal thread that is held tightly (as it is attached to the handle body). The movement of the piston moves the plunger attached to the piston, which in turn pushes an end (i.e. the aforementioned second locking part) of the frame and thus more frame is released from the inserter into the uterine cavity. Before the piston is entirely inside the handle body, the piston opens a lock of the finger holder, thus allowing its movement. Movement of the finger holder (while the piston and plunger are not moved) makes the IUS to form its final form, but does not move the IUS further inside the uterus. The finger holder also opens a lock of the plunger and piston, where after the action of the user on the piston (pushing it towards the distal end of the handle body) locks the IUS into final shape. The user thus pushes on the piston while maintaining a firm grip on the finger holder, and the locking parts inside the handle ensure the above movements.
- Thus, when the finger holder meets the proximal end of the handle body (and also the movement of the piston inside the handle body stops), the IUS is outside the inserter and the locking parts (i.e. the first locking part and the second locking part) of the IUS lock. The piston is locked inside the handle body by finger holder snap hooks, so that a user cannot pull

it back. The measurement tube's locking is opened, allowing its movement.

D) Third IUS insertion stage: the whole inserter is pushed towards the patient until the flange meets the handle body. In this stage, a part of
5 the measurement tube moves inside the handle body (i.e. towards the health care professional). This pushes the IUS into correct position in the uterus. In other words, the IUS moves into its fundal position and the whole IUS is accurately positioned within the uterine cavity.

E) Removal thread release and removal of the inserter: the removal
10 thread is released. The removal thread is released by turning the means for reversibly locking the removal thread. In an embodiment, the means for reversibly locking the removal thread comprises a rotatable knob, which is rotated from a first position to the second position, to allow the removal thread to be moved with respect to the handle body, and further
15 allow the release of the removal thread. Optionally, the removal thread is released by pushing a thread cutting button provided on the handle body. When the thread cutting button is pushed, a cutter blade inside the handle body cuts the removal thread. The inserter is positioned such that the removal thread is cut to leave about 2-3 cm visible outside the cervix
20 (i.e. outside the external orifice and about 2-3 cm into vagina to be detectable by touch). The inserter is then pulled out from the subject denoting the completion of the IUS insertion process by the inserter.

It is to be understood that instead of the piston, a different means for moving the plunger may be used in the IUS insertion process, as
25 described above, although the use of the piston makes the operation of the inserter much more convenient. For example, a slider arranged on the handle body may be used to move the plunger. Moreover, in another embodiment, instead of the tip cover moving inside the measurement tube (e.g. in the first IUS insertion stage as described above), the tip
30 cover slides over the distal end of the measurement tube, and locks itself

on the outer surface of the measurement tube. In such a case, the tip cover may be required to be made from two parts instead of one part (i.e. in a case where the tip cover withdraws inside the measurement tube, the tip cover is made in one part). Moreover, an additional welding
5 may be required to assemble the two parts of the tip cover on the measurement tube. The present inserter is also suitable for other types of IUS's than what are described here.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to FIG. 1, there is shown a perspective view of an IUS **100** in
10 a loaded configuration, in accordance with an embodiment of the present disclosure. As shown, the IUS **100** comprises a frame **102** having a first end **104**, a second end **106** and a length **L** defined as a distance from the first end **104** to the second end **106**. The frame **102** is straightened and stretched when loaded in an inserter before inserting the IUS **100**
15 into the uterus. The first end **104** of the frame **102** comprises a first locking part **108** and the second end **106** of the frame **102** comprises a second locking part **110**. In this embodiment, the first locking part **108** is a hook and the second locking part **110** is a loop. Further, shown is an outer diameter **112** (i.e. the largest outer diameter) of the IUS **100**. The
20 IUS **100** further comprises a pharmaceutically active agent arranged in the frame **102**.

FIG. 2 shows a schematic view of the IUS **100** of FIG. 1, in accordance with an embodiment of the present disclosure. In this embodiment, the frame **102** of the IUS **100** is a triangular-shaped frame. The first locking
25 part **108** at the first end **104** of the frame **102** and the second locking part **110** at the second end **106** of the frame **102** are arranged to form a lock **202** in the deployed state in the uterus.

The frame **102** further comprises a first frame segment **204**, a second frame segment **206** and a third frame segment **208**. The first frame

segment **204** and second frame segment **206** are connected with each other via a first bending segment **210**. The second frame segment **206** and third frame segment **208** are connected with each other via a second bending segment **212**. The width **W** of the first frame segment **204**, the
5 second frame segment **206** and the third frame segment **208** is the same as the width of the frame **102**. Further, shown is the first bending segment **210** having a first width **W1** and the second bending segment **212** having a second width **W2**. In this embodiment, the cross-section of the frame **102** at the first bending segment **210** and at the second
10 bending segment **212** has an essentially concave shape **214**. The first width **W1** and the second width **W2** is the smallest dimension of the cross-section of the frame **102**. In this embodiment, the first width **W1** is essentially identical to the second width **W2**, and each of the first width **W1** and the second width **W2** is about 25 % of the width **W**. The smaller
15 cross-section (i.e. a localized thinning) at the first bending segment **210** and the second bending segment **212** as compared to the other portions of the frame **102** facilitate bending of the frame **102** into the triangular-shape. The frame **102** further comprises a bending point **216** that facilitates removal of the IUS **100** when required.

20 The IUS **100** further comprises a removal thread **218** attached to the first end **104** of the frame **102**. Specifically, the removal thread **218** is coupled to an opening **220** in the first locking part **108** at the first end **104** of the frame **102**. The removal thread **218** is configured to guide the first locking part **108** towards the second locking part **110**. Further,
25 shown is a length **222** and a width **224** of a frame **102** of the triangular-shaped IUS **100** in the deployed state in the uterus.

Now referring to FIG. 3, shown is a schematic view of an IUS **300**, in accordance with another embodiment of the present disclosure. The IUS **300** comprises a frame **302** having a first end **304** and a second end
30 **306**. In this embodiment, the frame **302** is a triangular-shaped frame.

The first end **304** of the frame **302** comprises a first locking part **308** and the second end **306** of the frame **302** comprises a second locking part **310**. The first locking part **308** and the second locking part **310** are arranged to form a lock **312**. The first locking part **308** is a hook and the
5 second locking part **310** is a loop, and the hook is arranged to be irremovably inserted into the loop.

The frame **302** further comprises a first frame segment **314**, a second frame segment **316** and a third frame segment **318**. The first frame segment **314** is connected to the second frame segment **316** via a first
10 bending segment **320**. Similarly, the second frame segment **316** is connected to the third frame segment **318** via a second bending segment **322**. In this embodiment, the frame **302** further comprises two bending points **324** allowing the IUS **300** to be removed. The region between the two bending points **324** is a weaker part of the frame **302** as compared
15 to other parts of the frame **302**.

The IUS **300** further comprises a removal thread **326** attached to the first end **304** of the frame **302**. The removal thread **326** is received in an opening **328** provided in the first locking part **308**. The removal thread **326** is configured to guide the first locking part **308** towards the
20 second locking part **310**. The IUS **300** further comprises four capsules, a first capsule **330**, a second capsule **332**, a third capsule **334** and a fourth capsule **336**. The first capsule **330** is shorter in length as compared to other capsules **332**, **334**, and **336**. The capsules **330**, **332**, **334** and **336** comprise same or different pharmaceutically active agents.

25 FIG. 4A shows a schematic view of an IUS **400** in a loaded configuration, in accordance with yet another embodiment of the present disclosure. As shown, the IUS **400** comprises a frame **402** having a first end **404** and a second end **406**, and a length **L** is defined as a distance from the first end **404** to the second end **406**. The frame **402** is straightened and
30 stretched when loaded in an inserter (i.e. in the loaded configuration)

before inserting the IUS **400** into the uterus. The first end **404** of the frame **402** comprises a first locking part **408** and the second end **406** of the frame **402** comprises a second locking part **410**. In this embodiment, the first locking part **408** is a pin and the second locking part **410** is a loop. The first locking part **408** and the second locking part **410** have complementary structures to enable the pin to be irremovably inserted into the loop. The first locking part **408** of the IUS **400** comprises an opening **412** for receiving a removal thread.

The frame **402** further comprises a first capsule **414**, a second capsule **416**, a third capsule **418**, and a fourth capsule **420**. The first capsule **414** and the second capsule **416** are arranged to surround a first frame segment **422** and a second frame segment **424** respectively. The third capsule **418** and the fourth capsule **420** are arranged to surround a third frame segment **426** of the frame **402**. Further, shown is a first bending segment **428** and a second bending segment **430**. The first frame segment **422** is connected to the second frame segment **424** via the first bending segment **428**, and the second frame segment **424** is connected to the third frame segment **426** via the second bending segment **430**.

FIG. 4B shows a perspective view of the IUS **400** of FIG. 4A, in accordance with an embodiment of the present disclosure. As shown, the first locking part **408** is a pin and the second locking part **410** is a loop, i.e. having geometrically complementing structures, such that the pin substantially engages in the loop in the deployed state of the IUS **400** in the uterus.

FIG. 4C shows a schematic cross-sectional view of the IUS **400** in a deployed state, in accordance with an embodiment of the present disclosure. In the deployed state, the frame **402** of the IUS **400** attains a triangular-shape when the first locking part **408** and the second locking part **410** engages to form a lock **432**. The frame **402** further comprises a bending point **434** allowing the IUS **400** to be removed. In this

embodiment, the bending point **434** is provided in a middle section of the second bending segment **424**, and is a weaker part as compared to the other parts of the frame **402**. Further, shown is the first capsule **414** arranged to surround the first frame segment **422**, the second capsule **416** arranged to surround the second frame segment **424**, the third capsule **418** arranged to surround a part of a third frame segment **426** and a fourth capsule **420** arranged to surround another part of the third frame segment **426** of the frame **402** respectively. The first locking part **408** comprises an opening **412** for receiving a removal thread **436**. The removal thread **436** guides the first locking part **408** to come in contact to the second locking part **410** and further to engage the first locking part **408** with the second locking part **410** to provide the desired triangular-shape to the frame **402** in the uterus in the deployed state.

FIG. 4D shows a perspective view of the IUS **400** of the FIG. 4C in a deployed state, in accordance with an embodiment of the present disclosure. As shown, the first locking part **408** and the second locking part **410** have geometrically complementing structures, such that the first locking part **408** substantially engages in the second locking part **410** and form the lock **432** in the deployed state in the uterus.

FIG. 5 shows a schematic view of an IUS **500**, in accordance with still another embodiment of the present disclosure. The IUS **500** comprises a frame **502** having a first end **504** and a second end **506**. The first end **504** of the frame **502** comprises a first locking part **508** and the second end **506** of the frame **502** comprises a second locking part **510**. The first locking part **508** and the second locking part **510** have geometrically complementing structures in a clamp and column arrangement to allow the first locking part **508** to be locked to the second locking part **510**. The first locking part **508** comprises an opening **512** for receiving a removal thread. The frame **502** further comprises a first capsule **514**, a second capsule **516** and a third capsule **518** that are spaced apart and

arranged to surround a part of the frame **502**. In this embodiment, the frame **502** has a rounded rectangular tube-like cross-section. In the deployed state in the uterus, the frame **502** bends at two bending segments **520** and **522** that are devoid of the capsules, i.e. the first capsule **514**, the second capsule **516**, and the third capsule **518**.

FIGs. 6A-6D are schematic illustrations of a frame of an IUS and of the IUS according to an embodiment, as well as show how the IUS is locked into shape. Indeed, FIG. 6A shows the frame **602** of the IUS . The Figure also shows a first end **604** of the frame and a second end **606** of the frame. The first end **604** of the frame **602** comprises a first locking part **608** and the second end **606** of the frame **602** comprises a second locking part **610**. In this embodiment, the first locking part **608** is a knob and the second locking part **610** is a loop.

The frame **602** further comprises a first frame segment **612**, a second frame segment **614** and a third frame segment **616**. The first frame segment **612** and second frame segment **614** are connected with each other via a first bending segment **618**. The second frame segment **614** and third frame segment **616** are connected with each other via a second bending segment **620**. The width of the first frame segment **612**, the second frame segment **614** and the third frame segment **616** is smaller than the width of the locking parts **608** and **610**. In this embodiment, the cross-section of the frame **602** at the first bending segment **618** and at the second bending segment **620** has an essentially concave shape. Moreover, the width of the bending segments is larger than the width of the frame segments. The frame **602** further comprises a bending point **622** that facilitates removal of the IUS **600** when required.

FIG. 6B shows the IUS in the form it can be stored in the sales package, i.e. before it is inserted inside the inserter, including a capsule **624** and a removal thread **626**. FIGs. 6C and 6D illustrate the steps of closing and locking into shape of the IUS, once it is released inside the uterus. Figure

6B shows how the frame **602** is bent by pulling on the removal thread **624**. In FIG. 6C, the first end **604** of the frame **602** is in contact with the second end **606** of the frame, and in FIG. 6D, the first end **604** has been pulled through the second end **606**, thus locking the IUS **600** into
5 shape.

Referring to FIG. 7A, there is shown a perspective view of an inserter **1100** in an assembled state preloaded with an IUS **1102**, in accordance with an embodiment of the present disclosure. The inserter **1100** comprises a handle body **1104** having a proximal end **1106** and a distal
10 end **1108**. The inserter **1100** further comprises a measurement tube **1110** having a proximal end **1112** and a distal end **1114**. The proximal end **1112** of the measurement tube **1110** is movably attached to the distal end **1108** of the handle body **1104**. The inserter **1100** further comprises a tip cover **1116** having a distal end **1118** and a proximal end
15 **1120**. The tip cover **1116** is arranged to withdraw inside the distal end **1114** of the measurement tube **1110**. The inserter **1100** further comprises a flange **1122** movably arranged around the measurement tube **1110**. A finger holder **1124** is movably arranged to surround the handle body **1104**. The inserter **1100** further comprises a means **1126**
20 for reversibly locking a removal thread of the IUS **1102**. The means **1126** for reversibly locking the removal thread is arranged on the handle body **1104**. The inserter **1100** further comprises a piston **1130** that is movably arranged inside the handle body **1104**.

Referring to FIG. 7B, there is shown a perspective view of the inserter
25 **1100** of FIG. 7A in an unassembled state with the IUS **1102**, in accordance with an embodiment of the present disclosure. The inserter **1100** further comprises a plunger **1132** having a distal end **1134**, a proximal end **1136**, and a length L_p defined as the distance between the distal end **1134** and the proximal end **1136**. In the assembled state of
30 the inserter **1100**, the plunger **1132** is movably arranged inside the

handle body **1104** and the measurement tube **1110**. Further, shown is a first cover portion **1138A** and a second cover portion **1138B** of the handle body **1104**. The handle body **1104** has a length L_h defined as the distance between the distal end **1108** and the proximal end **1106**.
5 Notably, the length L_p is greater than the length L_h . Further, shown is a first part **1140A** and a second part **1140B** of the measurement tube **1110**, a first part **1142A** and a second part **1142B** of the finger holder **1124**, and a first part **1144A** and a second part **1144B** of the piston **1130**. Further, shown is the flange tip cover **1116** and the means **1126**
10 for reversibly locking the removal thread of the IUS **1102**. In the assembled state of the inserter **1100**, the tip cover **1116** accommodates the frame **1146** of the IUS **1102** in the straightened configuration (i.e. in a preloaded state of the IUS **1102** in the inserter **1100** before the insertion of the IUS **1102** into the uterus). Further, shown is the flange
15 **1122**, the finger holder **1124**, and the means **1126** for reversibly locking a removal thread of the IUS **1102**.

Further, FIG. 7C shows an enlarged view of the IUS **1102**. The IUS **1102** comprises a frame **1146** having a first end **1148** and a second end **1150**, and a length L is defined as a distance from the first end **1148** to the
20 second end **1150**. The frame **1146** is straightened and stretched when loaded in the inserter **1100** in the assembled state, before inserting the IUS **1102** into the uterus. The first end **1148** of the frame **1146** comprises a first locking part **1152** and the second end **1150** of the frame **1146** comprises a second locking part **1154**. In this embodiment,
25 the first locking part **1152** is a pin and the second locking part **1154** is a loop. The first locking part **1152** and the second locking part **1154** have complementary structures to enable the pin to be irremovably inserted into the loop. The first locking part **1152** at the first end **1148** of the frame **1146** comprises an opening **1156** for receiving the removal
30 thread **1128**.

Referring to FIG. 8A, there is shown a perspective view of a piston and plunger subassembly **1200** of an inserter, in accordance with an embodiment of the present disclosure. In the piston and plunger subassembly **1200**, there is shown an arrangement of a plunger **1202** within a piston **1204**. The plunger **1202** comprises a means **1206** for preventing its removal from inside a handle body and the piston **1204** of the inserter.

Referring to FIG. 8B, there is shown a cross-sectional view of a piston and plunger subassembly **1200** of an inserter, in accordance with an embodiment of the present disclosure. In the piston and plunger subassembly **1200**, the plunger **1202** is attached to the piston **1204**. Further shown, is an enlarged view of a distal portion of the piston and plunger subassembly **1200** to depict engagement parts **1208** of the piston **1204**. The plunger **1202** locks between the engagement parts **1208** of the piston **1204**.

Referring to FIG. 9A, there is shown a schematic view of an inserter **1300** with an enlarged view of a first section **1302** of the inserter **1300** to depict a piston **1304** that is movably arranged inside a handle body **1306**, in accordance with an embodiment of the present disclosure. The piston **1304** comprises a means **1308** for preventing the removal of the piston **1304** from inside the handle body **1306**. Further, shown is an enlarged view of a second section **1310** of the inserter **1300** to depict a first hook **1312** of a finger holder **1314** that is locked in a first recess **1316** of the handle body **1306**, and which are opened during the insertion process, when the piston is moved towards the distal end of the handle body, for a first part of the movement.

Referring to FIG. 9B, there is shown a schematic view of the inserter **1300** with an enlarged view of a fourth section **1324** of the inserter **1300** to depict clamps **1326** that secures a measurement tube **1328**, in accordance with an embodiment of the present disclosure. The clamps

1326 secures the measurement tube **1328** in such a manner that the measurement tube **1328** is movably attached inside a distal end **1330** of the handle body **1306**. The clamps are opened by the piston towards the end of the insertion, when the IUS is fully inside the uterus and the
5 locking parts are locked together.

Referring to FIG. 9C, there is shown a schematic view of an inserter **1300** with an enlarged view of a fifth section **1332** of the inserter **1300** to depict an arrangement of a tip cover **1334** within the measurement tube **1328**. In the fifth section **1332**, an IUS **1336** is shown preloaded in the
10 inserter **1300** in such a manner that a small part of a frame **1338** of the IUS **1336** protrudes from the inserter **1300**, and the rest of the frame **1338** is surrounded and protected by the tip cover **1334**. Further, shown is an enlarged view of the IUS **1336**. The frame **1338** of the IUS **1336** has a first end **1340** and a second end **1342**. The frame **1338** is
15 straightened and stretched when loaded in the inserter **1300** before inserting the IUS **1336** into the uterus. The first end **1340** of the frame **1338** comprises a first locking part **1344** and the second end **1342** of the frame **1338** comprises a second locking part **1346**. In this embodiment, the first locking part **1344** is a pin and the second locking
20 part **1346** is a loop. The IUS **1336** further comprises a pharmaceutically active agent arranged in the frame **1338**. The frame **1338** further comprises a first frame segment **1348**, a second frame segment **1350** and a third frame segment **1352**. The first frame segment **1348** and the second frame segment **1350** are connected with each other via a first
25 bending segment **1354**. The second frame segment **1350** and third frame segment **1352** are connected with each other via a second bending segment **1356**. A removal thread **1358** is attached to an opening in the first locking part **1344**. In the fifth section **1332**, there is further shown a distal end **1360** of a plunger **1362** that is configured to cooperate with
30 the second locking part **1346**. The plunger **1362** is hollow so as to allow

the removal thread **1358** of the IUS **1336** to pass through the plunger **1362**.

FIGs. 10A-10H illustrates different views of an inserter **1400** depicting various operational stages to position an IUS **1402** into a uterus, in accordance with an embodiment of the present disclosure. With reference to FIG. 10A, there is shown an adjustment of a flange **1404** on a measurement tube **1406** of the inserter **1400**, in accordance with an embodiment of the present disclosure. The flange **1404** is manually moved at a specified position on the measurement tube **1406** with the help of insertion depth indicators **1408** on the outer surface of the measurement tube **1406**. The specified position refers to the length of the uterine cavity plus the length of the cervical canal measured previously during uterine sounding. The flange **1404** once set does not move during the insertion process of the IUS **1402**. Further, shown is a part of a frame **1412** of the IUS **1402** that is outside the inserter **1400** in a preloaded state. Moreover, in the preloaded state, removal thread **1414** is coupled to one end (i.e. a first end) of the frame **1412**, and passes through the inserter **1400** and a portion of the removal thread **1414** emerges from a handle body **1416** of the inserter **1400**. A rotatable knob **1418** is arranged in a first position to lock the removal thread **1414** between the handle body **1416** and the rotatable knob **1418**.

FIGs. 10B and 10C show one embodiment of the flange **1404** in more detail. In this embodiment, the flange **1404** comprises a snap lock **1410** which is originally in an "open" position, where the snap lock **1410** is in an open state, and the flange can be easily moved. Once the flange is in its correct position (on the insertion depth indicators **1408**), the snap lock **1410** is closed by pressing the flange, and thus the snap lock will be in a "closed" position.

FIG. 10D, shows a first insertion stage of the IUS **1402** using the inserter **1400**, in accordance with an embodiment of the present disclosure. In this stage, there is shown a transition from a first state **1424** (on the left) to a second state **1426** (on the right) of the inserter **1400**. In the first state **1424** (on the left), a tip cover **1422** is shown in an extended position. The measurement tube **1406** is passed through vagina **1428** towards the cervix. The inserter **1400** is positioned such that the tip cover **1422** reaches the cervix opening and the first end (i.e. the tip) of the IUS **1402** is positioned inside the cervix opening. At this stage, the whole inserter **1400** is gently pushed towards the subject, which makes the tip cover **1422** to move backwards inside the handle body **1416**.

In the second state **1426** (on the right), the tip cover is withdrawn inside the handle body **1416**, and a part of the frame **1412** is released from the inserter **1400** into the cervical canal **1430** and partially into the uterine cavity **1432**. In the second state **1426**, further shown is a distal end **1434** of the tip cover that has a round bulbous-like structure to prevent the measurement tube **1406** to enter into the cervical canal **1430**. At this stage, a press member **1436** of a piston **1438** is still away from a proximal end **1440** of the handle body **1416** (i.e. the piston **1438** is in an extended state).

With reference to FIG. 10E, there is shown a second insertion stage of the IUS **1402** using the inserter **1400**, in accordance with an embodiment of the present disclosure. In this stage, at operation **1442** (on the left), while maintaining a firm contact of the distal end **1434** of the tip cover (i.e. the tip of the inserter **1400**) to the portio of the cervix, the piston **1438** is pressed on the press member **1436** from a proximal end of the piston **1438**. A finger holder **1446** is used as a support for fingers (e.g. two fingers in this case) to conveniently press the piston **1438** towards the handle body **1416**.

The piston **1438** is pressed from the proximal end until the piston **1438** is completely inside the handle body **1416**, and a further movement of the piston **1438** is not allowed (i.e. the movement of the piston **1438** stops). The IUS **1402** starts to exit the inserter **1400** and to form a loop into the uterine cavity **1432**. The movement of the piston **1438** moves a plunger **1450** attached to the piston **1438**, which in turn pushes an end of the frame and thus more frame is released from the inserter **1400** to form the loop into the uterine cavity **1432**.

At operation **1448** (on the right), after the piston has fully entered the handle body **1416**, the finger holder **1446** is unlocked and moves towards the proximal end of the handle body **1416**. At this stage, the IUS **1402** is outside the inserter **1400**, while the IUS **1402** is at the entrance of the uterine cavity **1432**. At this stage, the plunger also locks itself inside the inserter **1400** and cannot be moved further by pressing the piston.

FIG. 10F shows a step where the locking parts of the IUS **1402** lock, while the IUS **1402** is at the entrance of the uterine cavity **1432**. The measurement tube **1406** is released and can thus move again.

With reference to FIG. 10G, there is shown a third insertion stage of the IUS **1402** using the inserter **1400**, in accordance with an embodiment of the present disclosure. In this stage, the inserter **1400** is pushed towards the patient until the flange **1404** meets the handle body **1416** (i.e. a part of the proximal end of the measurement tube **1406** enters inside a distal end **1454** of the handle body **1416**). During this stage, the IUS **1402** moves into its fundal position and the whole IUS **1402** is accurately positioned into the uterine cavity **1432**.

With reference to FIG. 10H, there is shown a release of the removal thread **1414** using the inserter **1400** after the IUS **1402** is deployed in the uterine cavity, in accordance with an embodiment of the present

disclosure. In this stage, the removal thread **1414** is released using the rotatable knob **1418**. The rotatable knob **1418** is moved to a second position from its initial first position to allow the removal thread **1414** to be moved with respect to the handle body **1416**, and finally get released.

- 5 With reference to FIG. 10I, there is shown removal of the inserter **1400** from a subject, in accordance with an embodiment of the present disclosure. The inserter **1400** is pulled out from the vagina **1428** denoting the completion of the insertion process of the IUS **1402** by the inserter **1400**.
- 10 Referring to FIG. 11A, there is shown a schematic view of an inserter **1500** in an assembled state preloaded with an IUS **1502**, in accordance with another embodiment of the present disclosure. The inserter **1500** comprises a handle body **1504** having a proximal end **1506** and a distal end **1508**. The inserter **1500** further comprises a measurement tube
- 15 **1510** having a proximal end **1512** and a distal end **1514**. The proximal end **1512** of the measurement tube **1510** is movably attached to the distal end **1508** of the handle body **1504**. The inserter **1500** further comprises a flange **1522** movably arranged around the measurement tube **1510**. A finger holder **1524** is arranged on the handle body **1504**.
- 20 In this embodiment, the finger holder **1524** is in a ring shape, i.e. in the form of circles extending outwards from diametrically opposite sides of the outer surface of the handle body **1504** at its proximal end **1506**. The inserter **1500** further comprises a means **1526** for reversibly locking a removal thread of the IUS **1502**. The means **1526** for reversibly locking
- 25 a removal thread is arranged on the handle body **1504**. The inserter **1500** further comprises a piston **1530** that is movably arranged inside the handle body **1504**.

Referring to FIG. 11B, there is shown a perspective view of the inserter **1500** of FIG. 11A in an unassembled state, in accordance with an

30 embodiment of the present disclosure. The inserter **1500** further

comprises a plunger **1532** plunger having a distal end **1534** and a proximal end **1536**. In the assembled state of the inserter **1500**, the plunger **1532** is movably arranged inside the handle body **1504** and the measurement tube **1510**. The handle body **1504** has a first cover portion
5 **1538A** and a second cover portion **1538B**. Further, shown is a first part **1540A** and a second part **1540B** of the measurement tube **1510**, and a first part **1542A** and a second part **1542B** of the piston **1530**. Further, shown is the means **1526** for reversibly locking the removal thread of the IUS **1502**, as well as a flange **1550**.

10 Modifications to embodiments of the present disclosure described in the foregoing are possible without departing from the scope of the present disclosure as defined by the accompanying claims. Expressions such as "including", "comprising", "incorporating", "have", "is" used to describe
and claim the present disclosure are intended to be construed in a non-
15 exclusive manner, namely allowing for items, components or elements not explicitly described also to be present. Reference to the singular is also to be construed to relate to the plural.