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Okamoto et al.

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[54] **INSERTER FOR INTRA-UTERINE DEVICE (IUD)**

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[21] Appl. No.: **462,582**

[30] **Foreign Application Priority Data**

Feb. 26, 1974 Japan 49-21984

[52] **U.S. Cl.** **128/130**

[51] **Int. Cl.²** **A61F 5/46**

[58] **Field of Search** 128/127–131, 128/263, 264, 270, 271; 206/306, 307, 363, 438, 439, 63.3, 485, 817

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Primary Examiner—Lawrence W. Trapp
Attorney, Agent, or Firm—McGlew and Tuttle

[57] **ABSTRACT**

The inserter is designed to receive and hold an intra-uterine device (IUD), as well as to insert the IUD in the uterus, and comprises two opposed holding members, which are U-shape in cross-section, which conjointly define an elongated tubular element which preferably is slightly bowed. At a zone intermediate the ends of the inserter, and substantially at its mid-point, the two holding members are spread apart or opened to form an IUD receiving and holding portion. In use, a cervix shield portion of the inserter is inserted into the uterus, the cervix shield portion extending from the receiving and holding portion to the inner end of the inserter, and the inner end is tapered. A plunger is then inserted in the outer end of the inserter to engage the IUD and move it through the cervix shield portion out the inner end of the inserter and into the uterus, after which the inserter is withdrawn. Elastic bands or the like hold the U-shape members in engagement with each other, to form the tubular inserter, while allowing the holding members, in the cervix shield portion, to expand to facilitate movement of the IUD therethrough. The spread apart portion of the inserter may be provided with supporting surfaces for an IUD and may have the shape of a flat trumpet.

8 Claims, 17 Drawing Figures

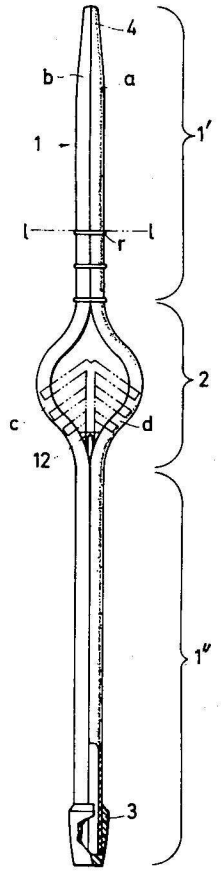


FIG. 1

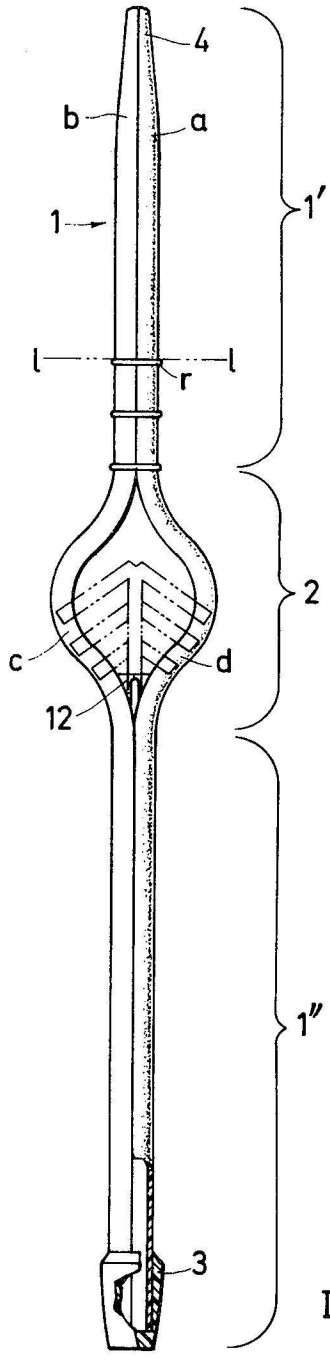


FIG. 2

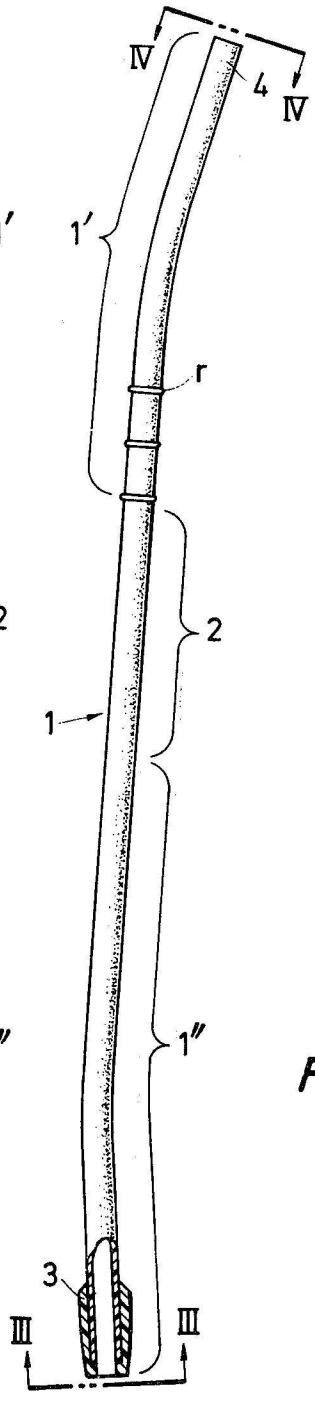


FIG. 4

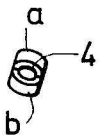


FIG. 3

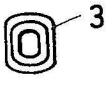


FIG. 5

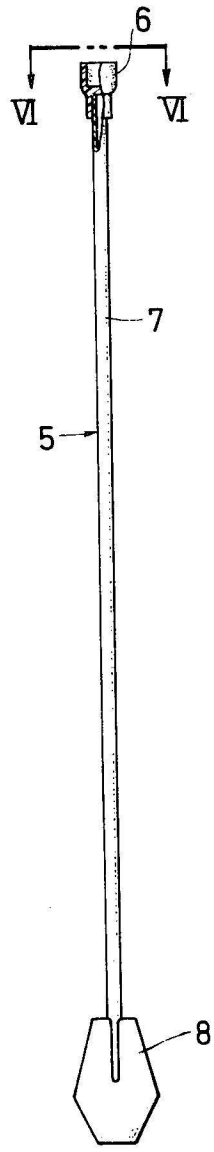


FIG. 6

FIG. 7

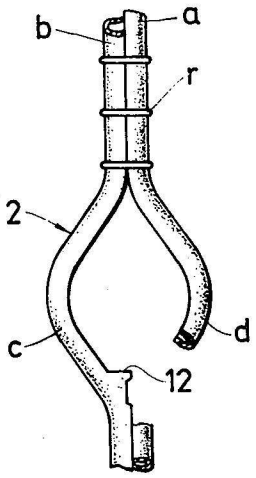


FIG. 8

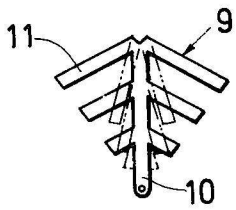


FIG. 14

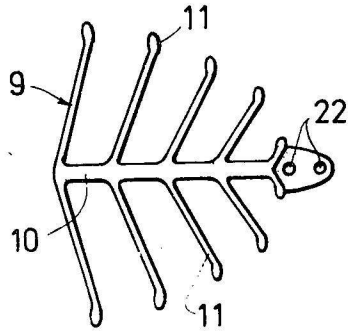


FIG. 15

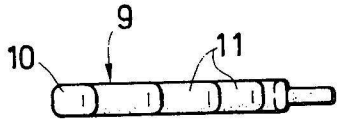


FIG. 16

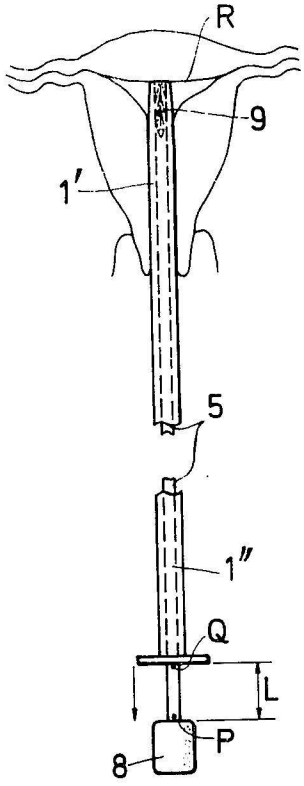


FIG. 17

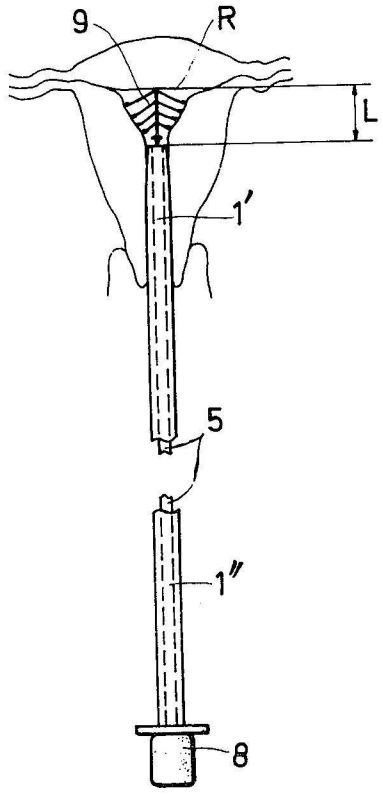


FIG. 9

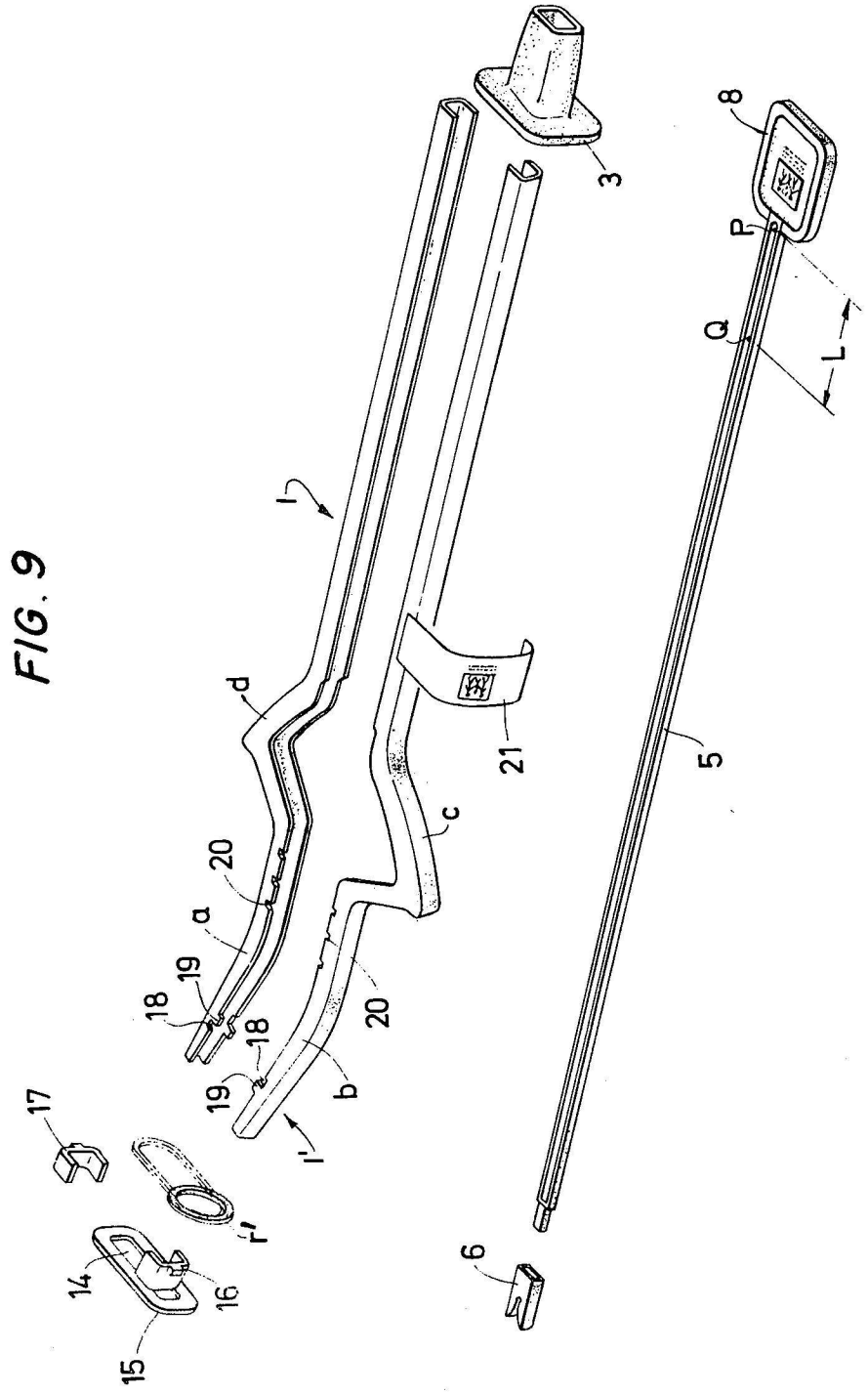


FIG. 10

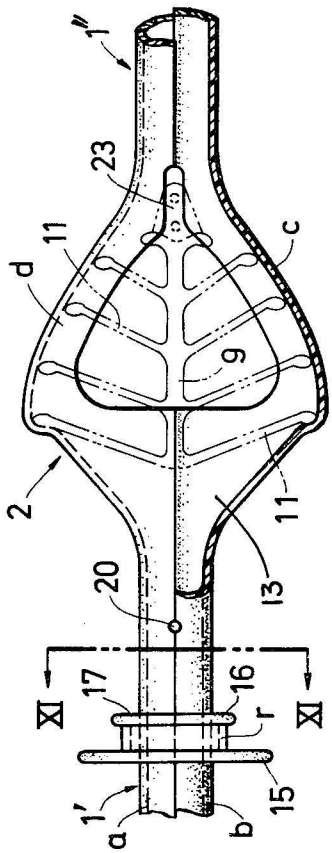


FIG. 11

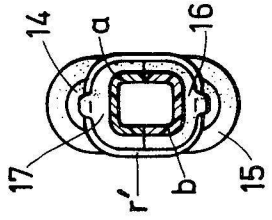


FIG. 12

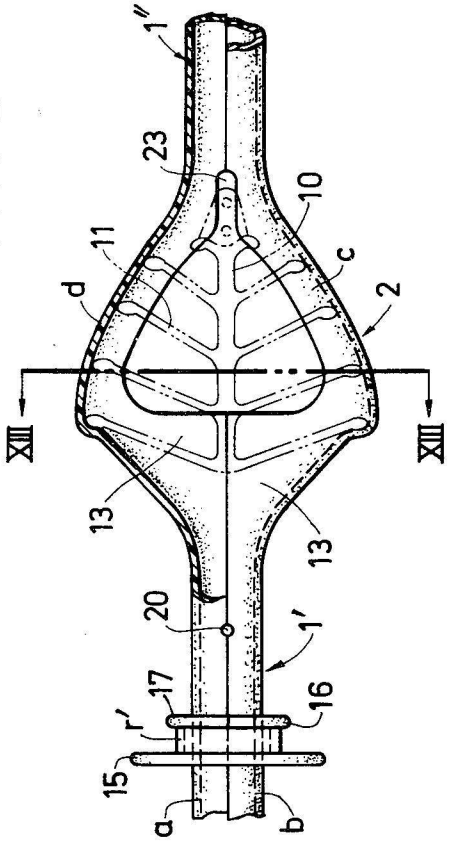
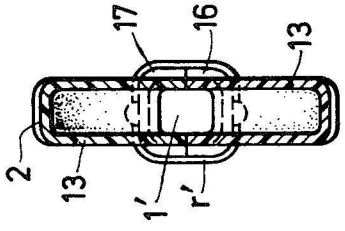


FIG. 13



INSERTER FOR INTRA-UTERINE DEVICE (IUD)

FIELD AND BACKGROUND OF THE INVENTION

This invention relates to contraceptive appliances for preventing the fertilized ovum from being deposited on the bed of the uterus by inserting an intra-uterine device (IUD) made of synthetic resin into the uterus and, more particularly, to a novel and improved inserter enabling a user to insert and set the IUD in the uterus by setting the IUD in the inserter beforehand and using a plunger to push the IUD through the inserter and out the inner end thereof into the uterine cavity.

There are conventional devices of this kind, such as loop and Dalkon types, in a ring form. For inserting such contraceptive devices into the uterus, the cervix must be expanded and the cervix tends to be harmed often by such expansion. As a consequence, many users may suffer from such harmful effects as pain and bleeding.

There are some other improved devices which are not in a ring form, and which are still incapable of storing an IUD beforehand, due to lack of full restoration of the original shape of the synthetic resin IUD. Thus, an IUD must be set, just before insertion into the uterus, into the tube of such a device by pulling threads attached to the IUD. The IUD is then inserted and set in the uterine cavity by means of a cylinder.

SUMMARY OF THE INVENTION

The invention is directed to an inserter for an intrauterine device (IUD) for contraceptive use, in which the inconveniences of prior art devices are eliminated. For the sake of brevity the term "IUD" will be used, hereinafter, to designate an "intra-uterine device."

An objective of the invention is to provide an IUD inserter by means of which it is possible to insert an IUD into the uterus instantly without mechanical harm to the cervix, merely by introducing a plunger into the inserter in which the IUD has already been set.

Another objective is to provide an inserter into which an IUD may be set and kept in its original form, so as to be used without undesired deformation even after a long period of storage.

In further accordance with the invention, the inserter has a cervix shield portion at its leading end formed of two opposed members, of U-shape cross-section arranged in facing engagement in such a manner as to be freely spread apart to some extent for feeding an IUD through the cervix shield portion, with the IUD being expanded as it passes through the cervix shield portion without causing any mechanical injury to the cervix.

For the purpose of receiving an IUD, the inserter has, intermediate its ends, a spread apart or open IUD receiving and holding portion shaped and adapted to hold various types of IUDs, different in shape and size, firmly therein and permitting easy insertion of the IUD into the cervix shield portion of the inserter.

A further object of the invention is to provide such an inserter which enables a user to insert an IUD properly in the uterus without the use of any probe, by making good use of an interrelation in length between the inserter and a plunger for inserting the IUD.

For an understanding of the principles of the invention, reference is made to the following description of typical embodiments thereof as illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. **1** is a front elevational view, partly cut away, of an inserter embodying the invention;

FIG. **2** is a side view, partly cut away, of the inserter shown in FIG. **1**;

FIG. **3** is an end elevation view taken along the line III—III of FIG. **2**, looking in the direction of the arrows;

FIG. **4** is an end elevation view, taken along the line IV—IV of FIG. **3**, looking in the direction of the arrows;

FIG. **5** is a front elevation view, partly broken away, of a plunger for use with the inserter;

FIG. **6** is an end elevation view, taken along the line VI—VI of FIG. **5**, looking in the direction of the arrows;

FIG. **7** is a front elevation view, partly cut away, of a spread or open portion of the inserter;

FIG. **8** is a front elevation view of an IUD;

FIG. **9** is an exploded perspective view of another inserter embodying the invention, and its associated plunger;

FIG. **10** is a front elevation view, partly broken away, of the spread or open portion of the inserter shown in FIG. **9**;

FIG. **11** is a transverse sectional view taken on the line XI—XI of FIG. **10** and looking in the direction of the arrows;

FIG. **12** is a front elevation view, partly broken away, of the spread or open portion of still another inserter embodying the invention;

FIG. **13** is a transverse sectional view, taken along the line XIII—XIII of FIG. **12**, looking in the direction of the arrows;

FIG. **14** is a front elevational view of another form of IUD;

FIG. **15** is a side elevation view of the IUD shown in FIG. **14**;

FIG. **16** is an explanatory view illustrating the use of the inserter and showing an IUD just before the setting thereof in the utuerus; and

FIG. **17** is a view similar to FIG. **16** and illustrating the setting of the IUD in the uterus.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As previously mentioned, the present invention is directed to an inserter for an IUD, such as a contraceptive ring. In conventional inserters, such a ring device must be set therein at each time a ring device is to be inserted, and in practice, this is very troublesome. The invention is accordingly directed to an inserter which provides for previous setting of an IUD in the inserter, before use of the IUD, and immediate setting of the IUD into the uterus simply by inserting a plunger through the inserter to move the IUD out of the inner end of the inserter and into the uterus.

In accordance with the invention, as shown in FIGS. **1** through **8**, an inserter **1** for an IUD, such as a contraceptive ring, has a spread or open portion **2** provided at about its midportion, this spread or open portion being formed by two holding members *c* and *d* arranged in opposition to each other and U-shape in cross-section for holding the IUD, such as a contraceptive ring. With the inserter of the invention, an IUD **9**, shown in FIG. **8**, can be set beforehand or stored in the

spread portion 2 of the inserter 1. Inserter 1 has the general form of a tube, being formed by two members *a* and *b* arranged in facing opposition so as to form the tube, the members *a* and *b* having a U-shape cross-section. These members are maintained in firm but releasable engagement with each other by rubber rings *r*, while, at the entrance for a plunger, the two members are maintained in firm engagement with each other by means of a holding ring 3. The setting exit portion 4 of the inserter is tapered so as to be inserted easily into the vagina.

As best seen in FIG. 2, inserter 1 preferably is slightly arcuate, so as to make a user's posture, during insertion of the IUD, easy for the insertion. In order to insert the IUD into the uterus, the inserter is put into the vagina up to the line 1—1 in FIG. 1, whereby the exit or inner end of the inserter will contact the fundus uteri. A plunger 5, shown more particularly in FIGS. 5 and 6, is introduced into the inserter through the holding ring 3 so as to push the IUD 9 on the tip of the plunger into the uterus. Plunger 5 has a support 6, for the IUD, on the leading end of a bar 7, the support 6 receiving a vertical shaft portion 10 of the IUD 9. The IUD 9 is inserted into the uterus with the assistance of a grip 8 on the outer end of the plunger 5.

The IUD 9 used with the inserter shown in FIGS. 1 through 7 is illustrated, in FIG. 8, as shaped like an inverted unfolded fan, preferably including the vertical shaft 10 having branches 11 extending therefrom. However, the structure of the IUD is not limited to the shape shown in FIG. 8, but the IUD may have any other form so long as it can be held between the holding members *c* and *d* of the spread portion 2 of the inserter 1, and can be pushed out by means of plunger 5.

When the IUD is pushed by the plunger through the forward or inner portion of the inserter 1, the branches 11 are folded inwardly as shown by the dotted lines in FIG. 8. When the IUD is forced out of the setting exit 4 and inserted into the uterus, the branches 11 spread apart and are set stably in the uterus to conform substantially to the uterine shape as shown by solid lines in FIG. 8.

Upon completion of the insertion of the IUD into the uterus, inserter 1 is withdrawn from the vagina and the IUD is left in the uterus. For removing the IUD from the uterus, there are used threads which have been previously attached to the IUD.

The IUD inserter embodying the invention has numerous advantages. Thus, inserter 1, containing an IUD beforehand, may be sold as a composite article, permitting simple insertion of the IUD into the uterus by just inserting plunger 5 into the inserter. Furthermore, the IUD is maintained safe against deformation before its sale due to the shape of the spread portion 2, which is adapted to that of the IUD. If an IUD formed of synthetic resin is stored in a cylindrical case, not conforming to the shape of the IUD, the IUD may be deformed, after the lapse of some time, due to permanent deformation of the synthetic resin material, and may not resume its original shape or form. This means a failure of the essential function of the IUD.

In a prior art IUD inserter having a tubular inserting portion, an IUD, when used, is set in the cervix shield portion of the inserter by pulling or pushing the IUD thereinto while deforming the IUD. Under these conditions, the inserter is placed into the uterus, and the IUD is pushed into the uterus from the inserter with a bar, from under the shield portion.

By contrast, with the present invention, an IUD can be previously carried in a position outwardly of the cervix shield portion of the inserter and without deformation, and the plunger may be easily inserted into the inserter when it is desired to use the IUD. Thus, an advantage of the invention arrangement is that it is very convenient to use the inserter as it does not require troublesome setting by pulling or pushing an IUD thereinto each time an IUD is to be used.

A further advantage of the invention is that, when an IUD is being inserted into the uterus, the cervix is protected from any mechanical injury which otherwise might occur, as a result of the passing of the IUD through the interior of the cervix shield portion and into the uterus.

In accordance with a further feature of the invention, a supporting surface 12, as shown in FIGS. 1 through 7, is provided at the location where the holding members *c* and *d*, forming the spread portion 2, engage each other, this supporting surface having a proper area for supporting the IUD. Supporting surface 12 extends in a plane from the inner side of either of the holding members forming the spread portion 2, so as to hold an IUD more positively. Portion 12 further serves to protect stored IUDs, which may be different in shape and size, against accidentally falling out of the inserter. The area of the supporting face 12 may be defined as such as to span the space between holding members *c* and *d*, with the supporting surface 12 extending from either of these holding members.

Furthermore, in other embodiments of the invention as shown in FIGS. 12 and 13, an IUD can be guided into the cervex shield portion of the inserter more positively. In these figures, guide plates 13 are provided in the form of a flat trumpet at the joining positions of the holding members *c* and *d*. The guide plates 13 are formed at the entrance into the shield portion 1', so as to hold an IUD 9, set in spread portion 2, with the leading end engaged with the cervix shield portion, and thereby protecting the IUD from slipping as well as keeping it secured in position independent of its size and shape. The guide plates 13 also serve as an effective means for guiding and pushing an IUD 9, when used, into cervix shield portion 1', smoothly and without fail by engaging the leading end 6 of the plunger 5 with the stem portion of the IUD.

As shown in the embodiments of the invention illustrated in FIGS. 1, 9 and 12, shield portion 1' is formed like a tube by engaging the two opposed members *a* and *b*, and these members are elastically retained into engagement so as to be expandable or spreadable to a certain extent. In the embodiment of FIG. 2, the opposed members *a* and *b* are retained in engagement by means of rubber rings *r*, so as to permit some spreading thereof and smooth passage of an IUD, in accordance with the form and size of the IUD.

On the other hand, in the embodiment of the invention shown in FIGS. 9 and 12, shield portion 1' is inserted slidably through a slot 14 on a frame 15 which has a fixed bearing piece 16 extending therefrom and cooperable with an opposed movable bearing piece 17. Bearing pieces 16 and 17 are elastically retained in engagement with each other by a rubber band *r'* so that movable bearing piece 17 is elastically displaceable relative to fixed bearing piece 16. Bearing pieces 16 and

17 are engaged and supported in such a manner as to embrace the two opposed members *a* and *b*. An IUD may pass through the tubular cervix shield portion thus formed by the members *a* and *b*.

In conventional inserters, which are of a simple tubular form, use of different IUD's is limited by the diameter of the shield portion. In accordance with the present invention, the shield portion is spreadable or expandable laterally, so that limitation due to the difference in size between IUD's is eliminated. It is thus possible to set an IUD in the uterus without mechanical harm to the cervix uteri by inserting the shield portion of the inserter through the cervix, with the shield portion compressed, feeding the IUD from the rear or outer end of the shield portion, and passing the IUD through the shield portion while the latter is expanded or spread. Thus, the inserter embodying this invention has a wider and more useful application.

In the embodiment of the invention shown in FIG. **9**, the opposed members *a* and *b* are provided, at their respective leading ends, with a recess **18** and a protrusion **19**, each protrusion on one member being engageable into a recess on the other member. This reinforces the shield portion, as well as prevents the shield portion from undesired distortion or axial misengagement as a result of the spreading of the shield portion at the time of insertion of the IUD into the uterus.

In this embodiment of the invention, marks **20** are provided for measuring the length of the insertion. In the embodiment of FIG. **1**, on the other hand, the mark to indicate the insertion depth is the position of the rubber ring *r* furthest from the spread portion **2**. In the embodiment of FIG. **9**, an indication plate **21** is wound around the inserter.

As illustrated in FIGS. **14** and **15**, an IUD of synthetic resin has holes **22** for the pulling threads, and these are positioned in a recessed portion **23** of the inserter shown in FIG. **10**, for drawing the pulling threads outside.

A further object of the present invention is to provide an inserter which permits proper spreading of an IUD in the uterine cavity without the use of any probe. FIGS. **9**, **16** and **17** illustrate how this is accomplished in practice. In FIG. **9**, a point P, close to grip **8** on plunger **5**, is used as a reference point, plunger **5** having the same length as inserter **1**, and a point Q is marked, at a position spaced from point P, by the length L of an IUD and in the forward axial direction.

In practical use, the shield portion of inserter **1** is inserted toward the uterus until its inner or leading end strikes against the fundus uteri R, illustrated in FIGS. **16** and **17**, and plunger **5** is introduced into the inserter **1** until point Q is aligned with the outer end of inserter **1**. At this time, the leading or inner end of plunger **5** has pushed an IUD **9** to the inner end of shield portion **1'**, where the leading end of the IUD is brought into contact with the fundus uteri R. Inserter **1** is now drawn back to the point or marking P on plunger **5**, so that shield portion **1'** is retracted from the fundus uteri R by the length L with plunger **5** being maintained stationary. As a result, the IUD is released from the setting exit **4** of the inserter **1** and remains in the uterus.

By contrast with the present invention, for setting an IUD properly in the uterus, that is, right against the fundus uteri, in conventional inserters, the distance must be measured by the use of a probe before insertion of the IUD, after which the IUD is inserted so as to engage against the fundus uteri. Such an operation cannot be carried out with external direct perception.

On the other hand, with the arrangement of the present invention and its operation as described above, it is possible to operate the inserter quite in the same way and with visual perception of the actual state inside the shield portion, and to set the IUD in proper position in the uterine cavity.

While specific embodiments of the invention have been described in detail to illustrate the application of the principles of the invention, the invention may be embodied otherwise without departing from such principles.

What is claimed is:

1. An inserter for an intra-uterine device for contraceptive use comprising, in combination, a pair of elongated continuous and facing substantially U-shape cross-section members forming an elongated intra-uterine device holding and guiding element, said members being spaced apart only at a relatively short zone intermediate their ends to form a widened receiving and holding portion for an expanded IUD, said receiving and holding portion being constituted by two opposed and laterally spaced coextensive and uninterrupted intermediate portions of said continuous U-shape cross-section members which latter are otherwise in contact with each other throughout the length of said holding and guiding element.

2. An inserter, as claimed in claim **1**, including a cervix shield portion extending from said receiving and holding portion and communicating therewith; said cervix shield portion being constituted by uninterrupted portions of said two U-shape cross-section members forming a tube; and means retaining said last-named portions of said members in engagement with each other.

3. An inserter, as claimed in claim **2**, in which said retaining means comprises at least one resilient member embracing said cervix shield portion forming portions of said members to provide for elastic lateral spreading thereof to some extent.

4. An inserter, as claimed in claim **3**, including a tubular plunger guiding portion extending outwardly from said receiving and holding portion to receive and guide a plunger into engagement with an intra-uterine device received and held in said receiving and holding portion to move the intra-uterine device into, through and out of said cervix shield portion.

5. An inserter, as claimed in claim **4**, in which said receiving and holding portion includes a supporting surface extending thereacross between said spaced apart portions of said members.

6. An inserter, as claimed in claim **4**, in which the junction between said receiving and holding portion and said cervix shield portion is shaped like a flattened trumpet.

7. An inserter, as claimed in claim **4**, including an elongated plunger inserted through said holding and guiding element to engage an intra-uterine device to move the device from said receiving and holding portion into, through and out of said cervix shielding portion; said plunger having an outer manipulating end and an inner end engageable with an intra-uterine device in said receiving and holding portion; said plunger having, adjacent its outer end and at a point spaced from its inner end by a distance equal to the length of said holding and guiding element, a first reference

mark, and having, at a distance inwardly from said first reference mark equal to the length of an intra-uterine device, a second reference mark; said plunger being inserted through said holding and guiding element up to said first reference mark.

8. An inserter, as claimed in claim 4, in which said cervix shield portion has thereon at least one reference mark indicating the depth of insertion.

* * * * *