

[54] INTRAUTERINE DEVICE SADDLE
INSERTER

3,253,590 5/1966 Birnberg 128/130

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[57] ABSTRACT

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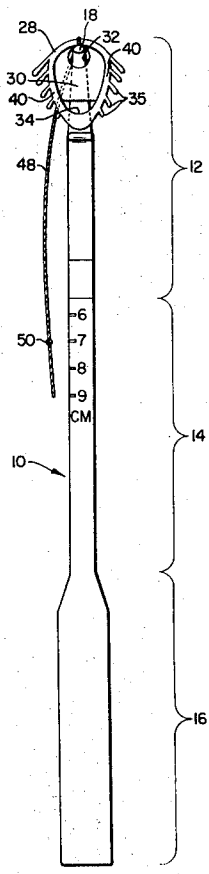
[58] Field of Search 128/127, 128, 129, 130, 260

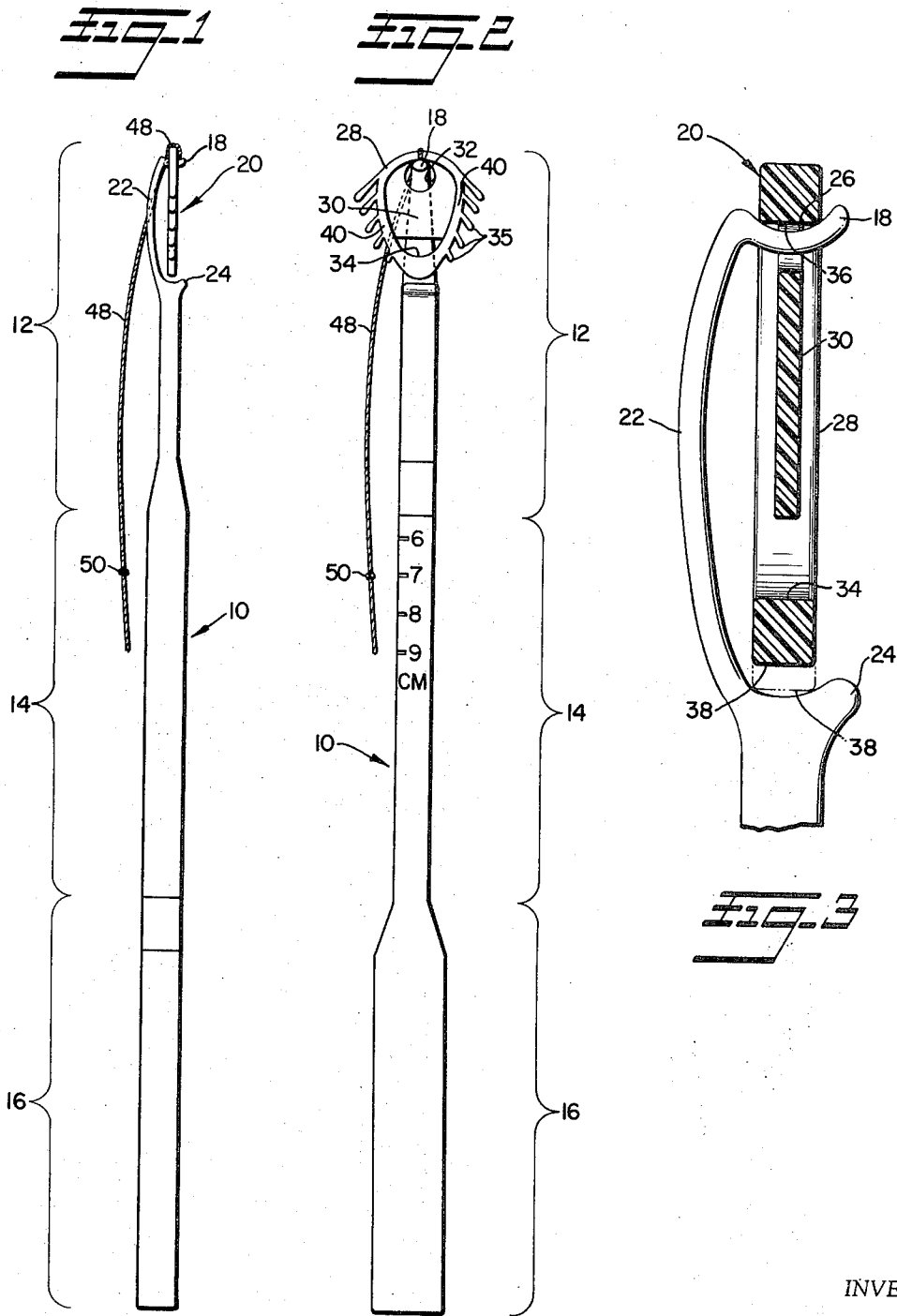
An improved inserter for an intrauterine contraceptive device, or IUD, comprising an elongated body having a saddle shaped IUD retainer at the outer end thereof to firmly retain the IUD on the inserter for proper, high fundal positioning of the IUD yet permit easy disengagement and withdrawal of the inserter after IUD positioning by rotation and withdrawal along a line co-incident with the path of insertion.

[56] References Cited
UNITED STATES PATENTS

2,714,886 8/1955 Castelli 128/127

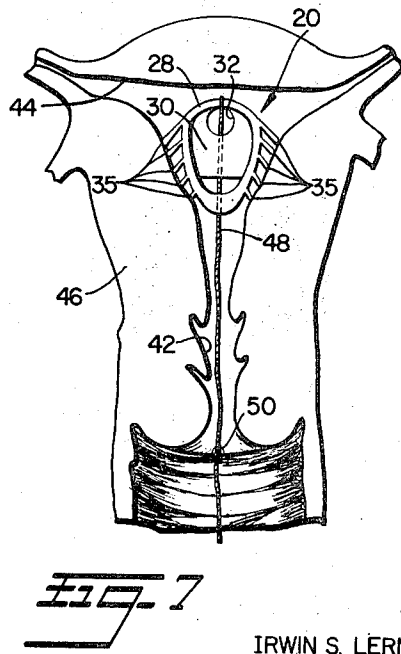
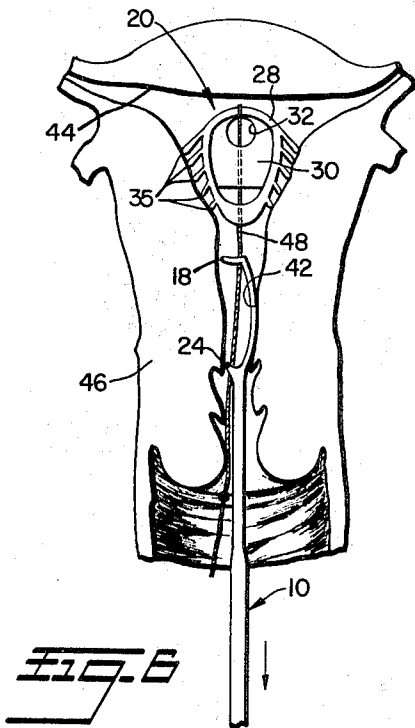
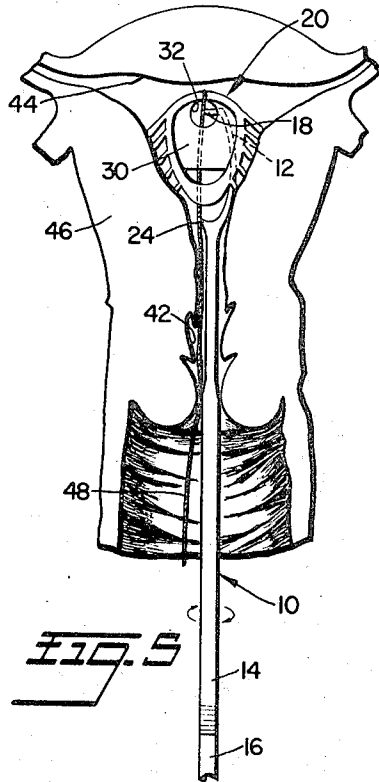
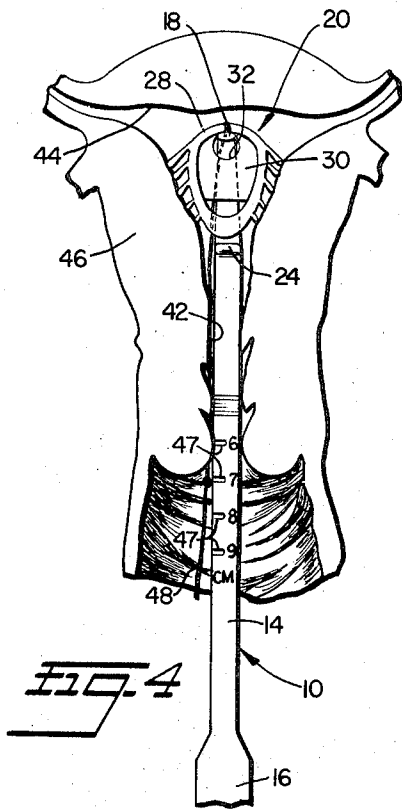
5 Claims, 7 Drawing Figures





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INTRAUTERINE DEVICE SADDLE INSERTER**CROSS REFERENCE TO RELATED APPLICATIONS**

The present invention relates to improvements in the inserter disclosed and claimed in my prior co-pending application Ser. No. 87,663, filed Nov. 9, 1970.

BACKGROUND OF THE INVENTION**1. FIELD OF THE INVENTION**

The invention relates to the art of intrauterine contraceptive devices, now popularly known as "IUD's" and specifically to an improved device for properly positioning an IUD in the fundal region of the uterus.

2. DISCUSSION OF PRIOR ART

Of the wide variety of female contraceptive agents available, the intrauterine contraceptive device has assumed extremely significant importance, particularly in view of recent highly sophisticated improvements which have virtually eliminated historical difficulties and complications formerly attendant to the use of the intrauterine device or, as it is more popularly known, the "IUD". Other agents, such as the diaphragm, spermicidal gels and foams, and oral contraceptives, both sequential and combined, still possess inherent disadvantages not encountered with the IUD. Specifically, barrier types of contraceptives such as the diaphragm require user manipulation to be effective. Gels and foams require application prior to each act of sexual intercourse. Use of both the diaphragm and spermicidal gels and foams yield unacceptably high pregnancy rates. Oral contraceptives require ingestion by the user, which may cause harmful physical and physiological side effects, and such contraceptives must be taken on a regular basis, usually daily during the month between menstrual cycles. Thus the user must employ a reminder system for maximum effect of this type of contraceptive.

In contradistinction, the IUD, once in place, provides long term contraceptive assurance for a period of time up to two years or more without need of device manipulation by the user or ingestion of any medicinal product. It has been found that the pregnancy rate from use of the IUD is entirely within acceptable parameters. Once in place, the IUD may be "forgotten" by the user, save for periodic checks to assure that dislodgement has not occurred.

Of significance is the fact that insertion of the IUD may be performed either by the physician or paramedical personnel, with only a slight chance of inconvenience and/or discomfort to the user. Experience has shown that the experience of insertion of the IUD remains as primarily the only factor in the way of even more widespread use and acceptance of this contraceptive device. An important contribution to this end is the development of satisfactory insertion means for properly locating the IUD within the uterine cavity, in high fundal position. The insertion means must firmly engage the IUD during insertion through the uterine canal and positioning in the fundus, yet must easily disengage therefrom for withdrawal of the inserter. Additionally, the inserter should be readily manipulable by one hand only, since the other hand of the physician or medical person performing the insertion will be employed in moving the uterus from its normal, anteflexed position to a state of traction whereby the IUD may be inserted;

this is done by grasping and exerting a pulling force on the cervical anterior lip with a tenaculum.

Such an inserter for an IUD is shown, described and claimed in my above mentioned application Ser. No. 87,663, filed Nov. 9, 1970. The instant application relates to specific improvements in a modified embodiment of such an inserter as is set forth below. In the case of both applications, the inserter is particularly adapted for use with an IUD of the type shown and described in a prior co-pending application Ser. No. 775,729 filed Nov. 14, 1968 now U. S. Pat. No. 3,633,574, dated Jan. 11, 1972 and assigned to the same assignee as is the present invention. Briefly stated, this IUD comprises a ring having a membrane across the central portion thereof and a plurality of spurs extending from lateral edges of the ring which prevent expulsion of the IUD from the uterus.

Prior art inserters are numerous. Two examples thereof are disclosed in prior U.S. Pat. Nos. 2,176,559 issued to Louis W. Mecksroth and 3,077,879 issued to Max H. Knoch. In both patents, a curved inserter is shown having a slotted terminal head for engaging and retaining a loop type of IUD. The IUD interengaging means of the present invention, utilizing a different principle of IUD retention on the inserter, provides more positive engagement yet easier disengagement from the IUD than these prior art devices.

SUMMARY OF THE INVENTION

It is a principal object of this invention to provide an inserter for high fundal positioning of an IUD having IUD interengaging means which firmly grasp the IUD during insertion yet permit easy disengagement therewith and withdrawal of the inserter from the uterus once the IUD is properly positioned.

It is another object of the invention to provide an IUD inserter wherein the operator thereof need only use one hand in inserting and positioning the IUD properly.

It is yet another object of the invention to provide an IUD inserter which virtually eliminates the possibilities of discomfort and inconvenience to the user.

A further object of the invention is to provide an IUD inserter having means thereon indicating disposition of the IUD within the uterus to the operator during insertion and positioning of the IUD.

Another object of the invention is to provide an IUD inserter combined with an IUD, the inserter being adapted for one use only, being readily disposable after use.

Yet another object of the invention is to provide an IUD inserter made of readily flexible material which will conform itself to the natural contours of the uterus during insertion of the IUD.

Further novel features and other objects of this invention will become apparent from the following detailed description, discussion and the appended claims taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF DRAWINGS

A preferred structural embodiment of this invention is disclosed in the accompanying drawings in which:

FIG. 1 is a side elevational view of the invention having an IUD thereon;

FIG. 2 is a plan view of the invention as illustrated in FIG. 1;

FIG. 3 is an enlarged partial sectional side view of the upper portion of FIG. 1; and

FIGS. 4 through 7 are sequential views illustrating completion of insertion of an IUD, disengagement, withdrawal, and insertion depth confirmation of the IUD after withdrawal of the inserter.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The inserter 10 comprises a slender elongate body having an upper, forward IUD interengagement portion 12, an intermediate body 14, and a lower handle 16 manipulable by the operator during insertion and positioning of the IUD. The inserter 10, as illustrated, is of uniplanar, straight configuration but it may be curved in the vicinity of interengagement portion 12 so as to readily conform to the natural curvature of the uterus, as is the inserter in my prior co-pending application Ser. No. 87,663. Alternatively, inserter 10 may be formed of a somewhat flexible material such as polyurethane so as to naturally follow the contours of the uterus; such contours may vary significantly from individual to individual.

Inserter 10 is of reduced segmental configuration from handle 16 to portion 12 with respect to transverse planes drawn through the instrument thereby providing sufficient structural rigidity at the lower end of the inserter yet enabling some flexibility, particularly at its upper end 12 to permit easy insertion into the cervical canal and fundus. To this end, reduced tapers may be provided as illustrated between handle 16 and intermediate body 14 and IUD interengagement portion 12.

The upper terminal end of the IUD interengagement portion 12 is configured as a saddle shape with an IUD retention seat 18 arranged to support an upper peripheral rim portion of an IUD 20 and a neck 22 extending from the retention seat 18 with a gradual concave curvature and tapering to a reflex curved terminal portion 24 which is disposed beneath the lower peripheral part of IUD 20. The upper side of retention seat 18 is formed into a saddle 26 which in combination with lower curved terminal portion 24 retains the IUD 20 in place on inserter 10, yet permits ready disengagement of inserter 10 from IUD 20 upon rotation of inserter 10, as will be explained in detail below.

The IUD illustrated is of the type shown, described and claimed in prior co-pending application Ser. No. 775,729. Basically it comprises a somewhat pear-shaped perimetral ring 28 the larger end being the nose and the smaller end the tail. An integral thin membrane 30 is disposed laterally across the central portion of the ring to define an upper IUD opening 32 and a lower opening 34. As shown in FIG. 2 a plurality of downwardly extending spurs 35 are formed on lateral edges of ring 28 and aid in preventing expulsion of the IUD from the uterus.

FIG. 3 best illustrates placement of IUD 20 on interengagement portion 12 of the inserter prior to insertion, and during the insertion and positioning of IUD 20 within the uterus. The inner edge of ring 28 adjacent upper opening 32 engages saddle 26 of retention seat 18, at 36. Simultaneously, the lower terminal periphery of ring 28 is disposed slightly spaced from lower curved terminal seat 24, at 38. During insertion of IUD 20, the lateral side portions 40, 40 (FIG. 2) of ring 28 will be slightly deflected toward one another, thereby causing slight elongation of the IUD 20 so that lower periphery

38 of IUD 20 is urged against seat 24, as indicated by dot and dash lines in FIG. 3. Thus, during insertion, IUD 20 will be firmly engaged by both seat 24 and saddle 26. After insertion, (FIG. 4), IUD 20 will return to a normal, unelongated shape due to its inherent resilient characteristics, or to the state illustrated by solid lines in FIG. 3, so that lower periphery 38 of IUD 20 unseats from lower seat 24. Therefore, once insertion is completed, only saddle 26 will need to be disengaged from IUD 20.

The process of insertion of IUD 20 in the uterus and withdrawal of the inserter from the uterus will be discussed, with particular reference to FIGS. 4 through 7, which sequentially illustrate the inserter withdrawal process. Prior to insertion of the IUD, the vagina of the user is dilated with a speculum followed by a gentle cleansing of the cervix (not shown). Then the exterior os of the cervix is grasped with a tenaculum to draw the uterus from its normal, anteflexed position into a state of traction so that the axis of the uterus is generally aligned with the axis of the vagina, to ease insertion of the IUD into the cervical canal and uterus (not shown). A sounder is then employed to measure depth and determine the particular axis and contour of the uterus. The IUD is inserted through cervical canal 42 and positioned against fundus 44 of uterus 46 as illustrated in FIG. 4. Once in place as shown in FIG. 4, IUD 20 returns to a normal, uncompressed state wherein portion 38 of ring 28 becomes unseated from seat 24. A series of gradations 47 may be affixed on central body 14 which indicate the distance from the upper terminal edge of inserter 10 to the point where a gradation appears on central body 14. As is usual in gynecological practice, such measurements are demarcated in centimeters and tell the operator how deep the inserter is within uterus 46, proper depth of insertion having previously been determined from the sounding step set forth above. Additionally, the broad flat profile of handle 16 will indicate to the operator the axial disposition of IUD 20 within uterus 46 for final proper positioning as illustrated in FIGS. 4 through 7.

Once positioned, IUD 20 is disengaged from inserter 10 through rotating inserter 10 through about a one-quarter turn as shown in FIG. 5. During this step, disengagement is enhanced by the curved configuration of saddle 26 which tends to force the inserter 10 downwardly and out of the uterus, thereby disengaging the saddle shaped IUD interengaging portion 12 from IUD 20. Withdrawal of inserter 10 is continued as illustrated in FIG. 6 and completed (FIG. 7).

IUD 20 may include a talisman and withdrawal cord 48 which is attached to ring 28 adjacent upper opening 32. The IUD 20 may be withdrawn with minimal discomfort in that pulling the cord 48 will cause IUD 20 to invert within the uterus so that spurs 35 slope away from the path of withdrawal of IUD 20 through cervical canal 42. A knot 50 near the lower end of cord 48 is used to confirm proper insertion depth of IUD 20 and is usually located about 7 cm. from the upper end of IUD 20.

Inserter 10 may be formed of a molded plastic and is readily adapted to be packaged and dispensed with an IUD 20 properly positioned thereon as shown in FIGS. 1 and 2 as a unitary structure within a sealed, sterilized envelope or container (not shown). In this manner, it can be assured that IUD 20 is properly located on inserter 10 while a sterile environment for both inserter

10 and IUD 20 is provided, just prior to insertion into the uterus.

This invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiment is therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed and desired to be secured by Letters Patent is:

1. In combination, an intrauterine device and an inserter for high fundal positioning thereof, said intrauterine device comprising perimetral ring means having an integral membrane formed thereacross so as to define at least an upper and a lower opening therein between portions of said perimetral ring means and membrane, said inserter comprising a body of extended length and releasable intrauterine device retention means adjacent one end thereof, said retention means comprising a reduced diameter neck extended therefrom, a saddle configured into a retention seat on the end of the neck, the saddle being arranged to engage a portion of said ring adjacent said upper opening and to disengage therefrom upon rotation of said body

about its long axis with respect to said intrauterine device and a second seat formed at the junction of said neck and body, and arranged to support a portion of said ring adjacent said lower opening.

2. The combination of claim 1 wherein said saddle and second seat comprise upwardly facing surfaces arranged generally in parallel planes of curvature, and having terminal portions extending slightly beyond the edges of said intrauterine device being retained thereon.

3. The combination of claim 1 wherein said second seat is arranged to contact and support said intrauterine device lower opening ring portion only during insertion of the inserter and device into the female uterus, said second seat and saddle being spaced apart a distance greater than the major length of said intrauterine device.

4. The combination of claim 1, wherein said intrauterine device further comprises removal means attached to a ring portion adjacent said upper opening for withdrawal of said intrauterine device after high fundal insertion.

5. The combination of claim 4, wherein said removal means comprises an elongate cord having means adjacent a free end thereof indicating distance thereof from said ring portion adjacent said upper opening.

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