

[54]	INTRAUTERINE DEVICE WITH LOCATOR MEANS FOR INDICATING UTERINE POSITION OF DEVICE	3,448,737	6/1969	Huck	128/130 X
		3,515,132	6/1970	McKnight	128/130
		3,516,403	6/1970	Courhut	128/130
		3,533,406	10/1970	Tatum	128/130

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[52]	U.S. Cl.	128/130
[51]	Int. Cl. ²	A61F 5/46
[58]	Field of Search	128/127-131, 128/260, 267

[57] ABSTRACT

Intrauterine device with locator is disclosed. The locator is a means for indicating the position of an intrauterine device for effectively interfering with the reproductive process.

[56] References Cited

UNITED STATES PATENTS

3,250,271	5/1966	Lippes	128/130
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8 Claims, 3 Drawing Figures

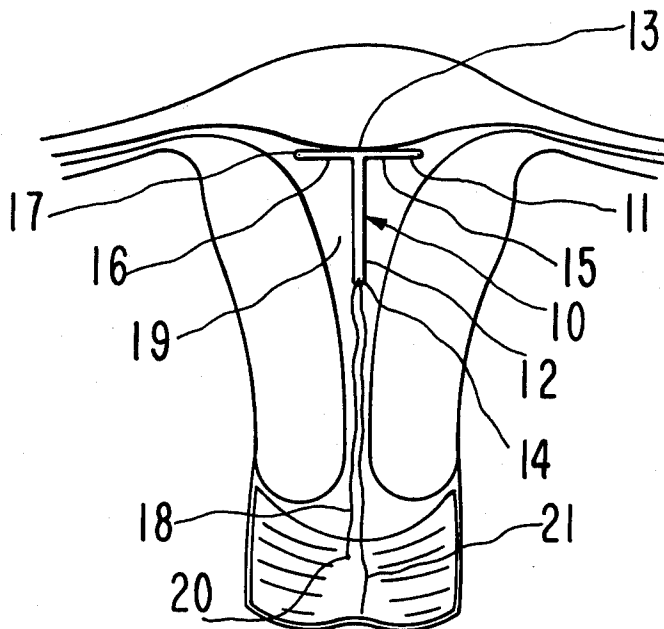


FIG. 1

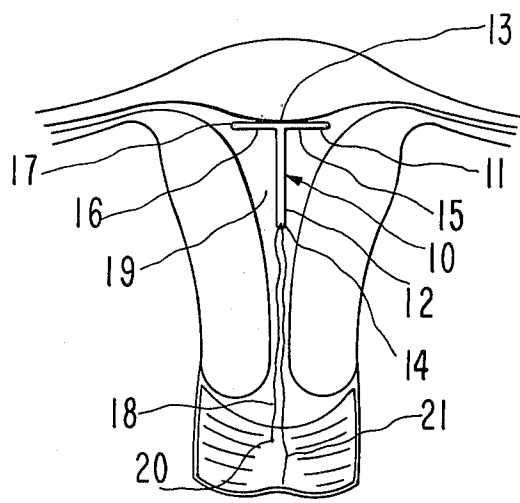


FIG. 2

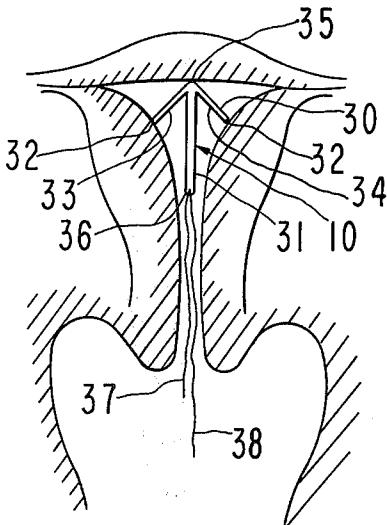
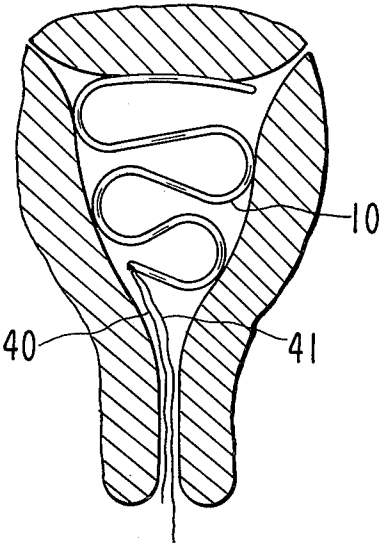


FIG. 3



INTRAUTERINE DEVICE WITH LOCATOR MEANS FOR INDICATING UTERINE POSITION OF DEVICE

BACKGROUND OF THE INVENTION

The present invention pertains to intrauterine devices. More particularly, the invention relates to intrauterine devices having a means for determining that a device when in the uterus is properly positioned for continuously interfering with the reproductive process. The invention also concerns a method for ascertaining if a device in the uterus is correctly positioned therein.

It is known to medical science that an intrauterine device when placed within a fertile uterus can be used for interfering with the reproductive process. This knowledge has been used for the intentional prevention of pregnancy by placing into the uterus devices having a T-shape, spiral, sinuous, open-ring, arrow and the like shapes.

The use of the above described and other devices for effective and continuous contraception requires that they be properly placed in the uterus. This includes high fundal positioning and any displacement therefrom, such as involuntary movement of the device into the upper cervical canal, often results in unwanted pregnancies. While medical science is aware of this critical requirement, prior to this invention it lacked an easy to use and reliable means for verifying that the device is correctly positioned and has not undergone invisible displacement. Thus, in view of the foregoing, it will be readily appreciated by those knowledgeable in the subject science, that if a means were made available for verifying the uterine position of a device, such means would increase the usefulness of the device and also represent a valuable contribution to reproductive science.

SUMMARY OF THE INVENTION

Accordingly, it is an immediate object of the present invention to provide an improved intrauterine contraceptive device that overcomes the difficulties associated with the prior art.

Another object of the invention is to provide a means for an intrauterine device for verifying that the device is correctly positioned in the uterine cavity.

Another object of the invention is to provide an improvement in intrauterine devices that is inexpensive to manufacture and easy to use for ascertaining if the device is properly positioned in the uterine cavity.

Yet another object of the invention is to provide an intrauterine contraceptive device having an article of manufacture fixed thereto, which article in cooperation with the device is reliable for verifying that a positioned device has not undergone invisible displacement in the uterus.

Yet another principal object of the invention is to make available to the art an intrauterine device having a leading end and a trailing end with a locator thread attached thereto. The device and the locator thread, when placed in the uterus abutting the fundus, have a combined length that is equal to or greater than the length from the fundus to the external cervical os. The device and locator thread are for determining the uterine position of a device.

Still a further object of the invention is to provide an intrauterine device consisting of two threads, a locator

or short thread for verifying the uterine position of the device and/or for removing the device from the uterus, and a reserve or longer thread optionally for verifying the position of the device and/or for manually removing the device. The two threads can be used separately or together for removing the device.

The above and other objects of the present invention will become more apparent from a reading of the following description, taken in conjunction with the drawings which illustrate the invention and the accompanying claims.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, which are not drawn to scale, but are set forth to illustrate various embodiments of the invention, the drawings are as follows:

FIG. 1 is a sectional view of the uterine cavity showing an intrauterine device having a transverse member and a perpendicular dependent member with means attached to the dependent member for ascertaining that the device is properly positioned in a uterus;

FIG. 2 is a partly diagrammatical frontal elevational view of an intrauterine contraceptive device having a wedged-shaped transverse member and a dependent member with two strings of different lengths in a uterine cavity;

FIG. 3 is an elongated frontal view of another intrauterine device in sinuous form with means for locating the device shown in an uterine cavity.

In the drawings and specification, like parts in related Figures are identified by like numbers. The terms appearing earlier in the specification and in the description of the drawings, as well as embodiments thereof, are further described elsewhere in the disclosure.

DETAILED DESCRIPTION OF THE DRAWINGS

Turning now to the drawings in detail, which are examples of improved intrauterine contraceptive devices of the invention, and which examples are not to be construed as limiting, one embodiment of a novel intrauterine device is indicated in FIG. 1 by the number 10. In FIG. 1, device 10 is comprised of a transverse member 11 suitably fixed to a dependent member 12. Member 12 has a front end 13 and a distant end 14. Member 11 interconnects with dependent member 11 at front end 13 with member 11 extended outwards in two directions from member 12 to define arm 15 and arm 16, a right and left arm respectively. Arms 15 and 16 each terminate in a rounded end 17 to prevent any possible damage to uterine cavity 19. Device 10 is substantially T-shaped and it is sized and shaped to fit all uterine cavities. Its dimensions can be made to conform to the nulliparous, and multiparous adult, female uterine cavities. Generally, members 11 and 12 have a length of 20 to 40 millimeters and a diameter of 1 to 4 millimeters. For household pets, farm and sport animals, device 10 can of course, be dimensioned to appropriate size. An intrauterine device similar to the above described device is disclosed in U.S. Pat. No. 3,533,406.

A locator thread 18 is fixed to device 10 on end 14 of dependent member 12. Thread 18 is a locator or indicator thread usable as a means for indicating correct uterine positioning such as fundal placement of device 10. In the embodiment shown in FIG. 1, locator thread 18 extends 9 centimeters from front 13, the top of device 10, to tip 20, the distant end of thread 18. Thread 18 serves as a reliable indicator for verifying that de-

vice 10, when in situ, is correctly positioned in uterine cavity 19. Generally, high fundal positioning is indicated for effective and continuous contraception.

Locator 18 is indicated for determining if device 10 is properly positioned in uterus 19 as follows: first, the uterus is sounded with a commercially available calibrated sounder to determine uterine depth. This is accomplished by introducing the sound as a simple probe through the cervical canal and isthmus into the endometrial cavity until the fundus is reached. A reading is then taken on the centimeter calibrations at the external cervical os. This depth corresponds to the measured distance from the fundus to the external cervical os, for example about 7 cm. Next, device 10 is placed into an inserter having calibrations aligned exactly with those on the uterine sound. Then, device 10 is gently inserted to full depth in the plane of the uterine cavity and the depth of insertion measured on the inserter by various means, such as the length of exposed thread or by other indication on the inserter, for example, calibration marks that are visible during the insertion procedure. This dimension is noted and the inserter withdrawn leaving the exposed locator thread extended from the cervix into the vagina. This exposed thread is then measured to verify proper placement of the intrauterine device for effective reproduction control.

The distance between the external cervical os and the tip of the locator thread should remain constant through the medical history of the device. On follow-up visits, the distance is again measured to verify that the device is correctly positioned high in the uterine cavity. If the measured distance from the external os to the tip of the thread is still the same, this indicates the device has remained in place. However, if the measured distance has changed, the locator indicates that the device has undergone invisible displacement or movement.

Locator thread 18 also can be used for removing device 10 from uterus 19. Device 10 optionally has an additional or reserve thread 21 attached at end 14 of member 12. Reserve thread 21 is longer than locator thread 18 and thread 21 can be used for removing the device, and for maintaining device 10 in an inserter during placement. Threads 18 and 21 each can be used alone or they can be used together for pulling device 10 from uterus 21. In another embodiment, according to the invention, threads 18 and 21 are made from a single thread tied to end 14 of member 12. In this embodiment, both thread 18 and thread 21 have the length and function as above described.

In FIG. 2 there is depicted another novel intrauterine contraceptive device 10 prepared according to the spirit of the invention. The device of FIG. 2 possesses a specifically different configuration and advantage than the device of FIG. 1. Intrauterine device of FIG. 2 is comprised of a wedged-shaped member 30 fixed to a dependent member 31 to generally define an arrow. Member 30 and 31 can be joined anywhere along member 30 from within ends 32 to the mid-point of member 30. Wedged-shaped member 9 is comprised of two arms 33 and 34 which project slightly downward from a straight member 14 formed with a rounded end in a coplanar non-perpendicular arrangement. Arms 33 and 34 also terminate at rounded ends 32. Member 31 has a lead end 35 and a distant end 36 with a locator thread 37 and a reserve thread 38 attached at end 36. As in FIG. 1, locator thread 37 and device 10 have a com-

bined length of about 7 to 9 cm, while reserve thread 38 is longer by about 1 to 4 cm.

FIG. 3 illustrates another improved intrauterine device 10 made according to the invention. In this embodiment, device 10 is comprised of an elongated body arranged in sinuous form. Device 10 is substantially in one plane within imaginary boundaries of an isosceles trapezoid. The device of FIG. 3 is an improvement of the device disclosed in U.S. Pat. No. 3,250,271 wherein the improvement consists essentially of a locator thread 40 attached to the end of device 10. In this embodiment, device 10 and locator 40, when device 10 is placed in a uterus with the top of device 10 abutting the fundus, have a combined length that is equal to or greater than the length from the fundus to the external cervical os. Device 10 optionally is equipped with a reserve thread 41 having a longer length than locator thread 40 that extends further into the vaginal cavity. Either thread or both threads together can be used for pulling device 10 from uterus 19.

The intrauterine devices of the invention can also be a source of an antifertility agent. In one embodiment, the agent is a wire made of a member selected from the group consisting of copper and zinc and mixtures thereof wrapped around the device. These metals and alloys also can be applied on the device by coating, encasing the arms in a metal sleeve, or the like. The use of copper and zinc as a contraceptive agent is disclosed in U.S. Pat. No. 3,563,235. The amount of agent on the exposed surface of a device is about 25 to 400 mm², for releasing a contraceptively effective amount of copper ion, zinc ion or a mixture thereof when placed in a fertile uterine cavity.

The improved intrauterine device of the invention also can be fabricated with a reservoir housed in the device. The reservoir contains a carrier and an antifertility agent. The material suitable for use as the carrier is permeable to the passage of the agent and it contains an agent or a mixture of agents. The wall of this kind of device is formed of a material permeable to the passage of the antifertility agent but at a lower rate than through the carrier. In operation, agent dissolved in the carrier is released from the device by diffusion through the wall at a rate controlled by the wall.

Carriers suitable for the present purpose include propylene glycol, silicone oil, glycerin, corn oil and the like. Materials suitable for the wall of a reservoir device include vinylchloride diethyl fumarate, poly(dimethylsiloxane), cross-linked partially hydrolyzed insoluble poly(vinyl alcohol), and the like. Antifertility agents suitable for use with these devices include progestational agents and estrogenic agents, such as, pregn-4-ene-3,20-dione; 19-nor-pregn-4-ene-3,20-dione; dl-11 β -ethyl-17-ethinyl-17- β -hydroxygn-4-ene-3-one; 17 β -estradiol; ethynyl estradiol; and the like. The amount of the above agent present in a reservoir is usually 20 mg to 300 mg for release at a rate of 20 μ g to 300 μ g per day for 3 months to 3 years, to a fertile uterus of a potential child-bearing, adult woman.

It will be understood by those versed in the art in the light of the present specification, drawings and accompanying claims that this invention makes available to the art both a novel and useful intrauterine device endowed with a means for verifying that an intrauterine device is correctly positioned in a uterus. And, while the means can be used with devices that release an antifertility agent and with nonreleasing devices, it will be

further understood by those versed in the art that many different embodiments of this invention can be made without departing from the scope of the invention. Accordingly, it is to be understood the invention is not to be construed as limited, but it embraces all equivalents inherent therein.

We claim:

1. An improved intrauterine device adapted for easy insertion and prolonged retention in a viable uterine cavity, the device having a transverse member, a leg dependent from the member and suitably fixed thereto, the device having a lead end and a distant end with the lead end formed where the member and leg meet, the improvement consisting essentially of a locator thread for indicating the position of the device when in the uterus, the locator thread fixed to the distant end and having a free end, said device and locator thread having a combined length from the lead end of the device to the end of the thread of from 6 to 10 centimeters, a reserve thread fixed to the distant end and having a free end, said device and reserve thread having a combined length greater than the combined length of the device and the locator thread.

2. The intrauterine device according to claim 1 wherein the transverse member and the leg meet to form a T-shaped device with the device from its lead end to the locator thread end having a combined length of 9 centimeters.

3. The intrauterine device according to claim 1 wherein the transverse member and the leg form an arrow-shaped device with the device from the lead end to the locator thread end having a combined length of 9 centimeters.

4. An improved intrauterine device according to claim 3 wherein the device and the locator thread have a combined length of 6 to 10 centimeters.

5. An improved intrauterine device having a configuration shaped and adapted for easy insertion and prolonged retention in a viable uterine cavity, the device having a leading end and a trailing end, the improvement consisting essentially of a locator thread fixed to the trailing end and having an end free, said device and

locator thread having a combined length that corresponds to the length from the fundus to the external cervical os, a reserve thread fixed to the trailing end and having an end free, said device and reserve thread having a combined length greater than the combined length of the device and the locator thread, and wherein the locator thread verifies the device when in the uterus, has acceptable fundal positioning by the exposed length of the locator thread free end measured from the external cervical os to the end of the thread.

6. An improved method for verifying that an intrauterine device is correctly positioned in a uterine cavity, the intrauterine device having a configuration shaped and adapted for easy insertion and prolonged retention in the cavity, the device having a leading end and a trailing end, a locator thread fixed to the trailing end and having a free end, a reserve thread fixed to the trailing end and having a free end, said device and reserve thread having a combined length greater than the combined length of the device and the locator thread, the improvement consisting of the steps of measuring the uterine cavity for determining its uterine depth measured from the fundus to the external cervical os, inserting the device with the locator thread having a combined length at least corresponding to the uterine depth into high fundal position in the uterus, comparing the uterine depth with the corresponding position of the free end of the locator, thereby verifying the device is correctly positioned in the uterine cavity.

7. A method for verifying the position of the intrauterine device in the uterine cavity according to claim 6, wherein the device consists essentially of a transverse member with a leg dependent therefrom, a lead end formed where the member and the leg meet, a trailing end formed by the leg distant from the lead end with a locator thread fixed to the trailing end, and where the device and the locator thread have a combined length of —6 to 10 centimeters.

8. A method according to claim 7, wherein the device and the locator thread have a combined length of 9 centimeters.

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