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[54] INTRA-UTERINE CONTRACEPTIVE DEVICE

14 Claims, 3 Drawing Figs.

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[50] Field of Search. **128/130,**
215, 127, 128, 129, 131; 273/106.5; 43/43.16,
42.44, 44.82

[56] **References Cited**

UNITED STATES PATENTS

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ABSTRACT: A contraceptive device has retaining means comprising a barb arranged to penetrate into the muscular wall of the uterus, to prevent accidental loss or ejection of the device. The device may also have an elongated shaft which is slotted transversely to receive a flexible vane. The vane is rolled on the shaft for insertion, and thereafter unrolls to engage the uterine walls. A ball-and-socket connection of the barb and the shaft permits the vane to unroll. The vane may be made of polyethylene, or a silico-organic rubber impregnated with contraceptive hormone chemicals. The vane is transversely slidable in the slot of the shaft to permit proper self-alignment with the form of the individual uterus.

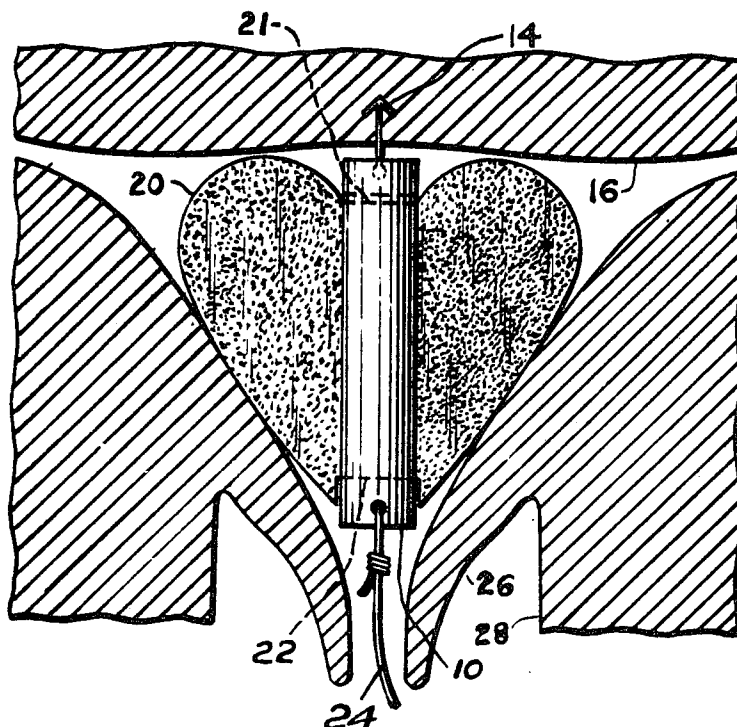


Fig. 1.

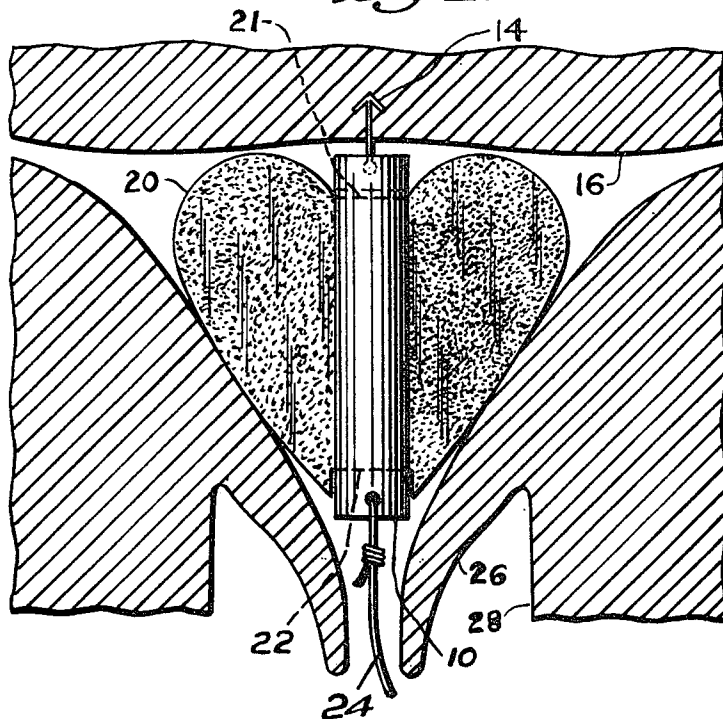


Fig. 3.

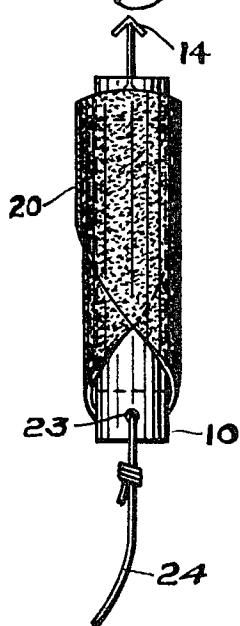
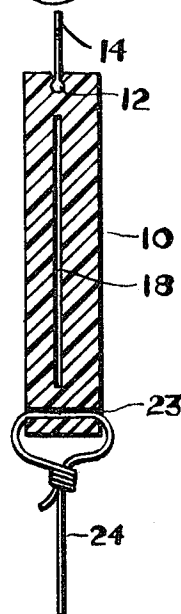


Fig. 2.



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INTRA-UTERINE CONTRACEPTIVE DEVICE

BACKGROUND AND BRIEF DESCRIPTION OF THE INVENTION

A variety of coils, loops, and devices of other shapes for intrauterine placement have been designed for contraceptive purposes. It is well established that the presence of a foreign body produces a change in the mucous uterine lining which inhibits nidation. A large percentage of patients can tolerate the presence of such a device for an extended period of time, and present devices, if tolerated, are perhaps 97 percent effective in preventing pregnancies.

The greatest difficulty that has been encountered is that such devices have depended on the support of the internal OS of the cervix to hold them in place. They are sometimes ejected from the uterus accidentally, for example by normal contractions of the organ. A coil or loop device must be inserted in an elongated uncoiled form through a small-diameter tube passed into the cervix, which requires the services of a physician. The user may not immediately become aware of an ejection of the device, and may even then experience delay in securing the services of a doctor. This difficulty is magnified in those underdeveloped nations which have the greatest need for this inexpensive and automatic method of contraception.

It is the primary object of my invention to provide an intrauterine contraceptive device which has improved means for retaining the device securely in place within the uterine cavity. It is another object to provide an improved intrauterine device which is both compatible with the physiology of the uterus, and effective. It is still another object to provide an intrauterine device which affords chemical as well as mechanical contraceptive action. Further objects and advantages will appear as the following description proceeds.

Briefly stated, according to a preferred embodiment of the invention, I mount a barb, preferably of stainless steel, at the forward end of an elongated cylindrical shaft. When the shaft is inserted in the uterus the barb pierces into, but not through the muscular wall and retains the device securely in place. I have discovered that the uterine lining does not reject such a barb, but will retain it for an indefinite period of time without adverse effect. Nor does the piercing of the uterine lining or muscle produce noticeable pain. This barb is quite effective in preventing expulsion of the device from the uterus.

I form a slot longitudinally through the shaft, and insert a transverse vane which is made of a plastic compatible with retention in the uterus, such as polyethylene or a silico-organic rubber. The vane is formed with two enlarged lobes and generally conforms to the shape of a frontal cross section of the uterus. The vane is notched at its lower end to form a pivotal connection with the slot, and is slidably received in the slot so that it may move laterally to align itself with the uterus in the event the shaft is not accurately centered.

The vane may be impregnated with a contraceptive hormone chemical or synthetic progestagen, such as megestrol acetate; this is disseminated at a slow rate. The impregnated vane may be coated with a further layer of silico-organic rubber to control the dissemination rate.

For insertion, the vane is rolled about the shaft so that the entire device assumes a cylindrical shape; it is inserted by means of a tube of conventional construction, which is passed through the cervical passage into the uterine cavity. After insertion, the plastic memory of the vane causes it to unroll and flatten out to conform to the uterine cavity, which is normally flattened when viewed in a sagittal cross section. The barb is rotatably mounted in the shaft by a ball-and-socket joint to allow the shaft to turn as the vane unrolls. A tail or string is attached to the rear end of the shaft for subsequent removal whenever this may be desired.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a view in frontal section through the uterus, showing the improved contraceptive device inserted in place and unrolled;

FIG. 2 is a sectional view in side elevation of the device; and FIG. 3 is a view in front elevation showing the device before insertion in the uterus, with the vane rolled up.

In the drawings, a preferred embodiment of the improved intrauterine device includes an elongated shaft or member 10 of polyethylene, or a silico-organic rubber, one of which is available under the trademark Silastic from the Dow Corning Company, or other inert plastic material. At its forward end, the shaft is provided with a socket to receive an enlarged end or ball 12 formed on the barb 14. This connection provides freedom of the barb to rotate relative to the shaft 10. The barb is preferably made of stainless steel and includes two hooks as shown, but may have any desired form which allows it to penetrate muscular tissue but resists withdrawal.

The shaft 10 is formed with a longitudinal slot 18 extending transversely to the frontal elevation, and a flat vane 20 is inserted therein. The vane may be made of the same material as the shaft. The vane is formed with two lobes generally conforming to the frontal cross section of the uterine cavity. The lobes are joined by a central portion fitting in the slot; the central portion is preferably of slightly shorter length than the slot, terminating at a forward edge 21. The rear edge is formed by a notch 22 slightly wider than the shaft 10. This permits the vane to slide transversely and also to pivot about the rear end of the slot 18, that is, the lower end as viewed in FIG. 1, but prevents separation of the parts. The vane can therefore assume the centered position in the uterus even though the shaft may not be accurately centered.

The vane engages the mucous uterine lining, and thereby induces a change whose nature is not clearly known, but which is detrimental to the adherence of a conceptus to the lining. It is through this reaction mechanism of the uterus that a contraceptive effect is obtained.

In addition, the vane may be used as a means for disseminating contraceptive hormone chemicals at a slow and controlled rate. I prefer to impregnate a vane of silico-organic rubber with megestrol acetate, or other chemicals known to inhibit pregnancy, and to coat the impregnated vane with a thin layer of plain silico-organic rubber. I have found that megestrol acetate can be disseminated at a controlled rate of about 0.02 mcg. per day by this type of vane. This chemical tends to render the mucus within the passage of the cervix 26 hostile to sperm, thereby preventing the entry of sperm into the uterine cavity. Barium sulfate may also be added to the vane to render it visible to X-ray examination.

At the rear end of the shaft 10, a tail or string 24, which can be made of nylon or other material that will not deteriorate with long exposure to body chemicals, is tied through a transverse hole 23. The tail extends through the cervix into the vagina 28, and is used for removing the device when desired.

To insert the device, the vane 20 is rolled around the shaft 10 to form a generally cylindrical package, which is then placed in a suitable insertion tube of a conventional and well-known type. The tube is then inserted into the uterus; care must be taken that the barb 14 is projected into the muscular wall, as shown in FIG. 1. A very slight application of force should be adequate to do this if the barb is properly shaped. This does not entail any severe pain to the patient, and is generally not noticeable. The insertion tube is then withdrawn. The vane unrolls because of its plastic memory, while the ball-and-socket joint 12 allows the shaft 10 to rotate freely.

I have found that the improved device is highly resistant to accidental loss or ejection by uterine contractions, and that it is entirely compatible with that organ, so that it may remain in place for an indefinite period.

While I have illustrated and described a preferred embodiment of my invention, it will be understood by those skilled in

the art that various changes and modifications may be made therein without departing from the true spirit and scope of the invention. For example, the barb may be used in combination with various known types of coils, loops, springs or other intrauterine devices to retain them in place.

What I claim is:

1. An intrauterine contraceptive device comprising an elongated member adapted to fit within the human uterus and formed of a material compatible with retention therein, and a barb connected to a forward end of said member and projecting therefrom for penetration into the muscular wall of the uterus to retain the device in place against accidental loss through the cervix, together with a vane attached to said member and having lobes projecting therefrom for engaging the uterine lining, said vane being formed of a flexible material compatible with retention in the uterus, and being foldable about said member to facilitate insertion into the uterus.

2. A device as recited in claim 1, in which said member is formed with a transverse slot extending longitudinally therethrough and receiving said vane.

3. A device as recited in claim 2, in which said lobes of the vane are longer than said slot in a direction longitudinal to said member, said vane having a central portion shorter than said slot and received therein, whereby said vane is transversely slidable in said member but is retained in said slot.

4. A device as recited in claim 2, in which said vane is formed with a notched central portion received in said slot, whereby said vane is tiltable relative to said member.

5. A device as recited in claim 1, in which said vane is of a plastic material impregnated with a contraceptive chemical.

6. A device as recited in claim 5, in which said plastic

material is a silico-organic rubber.

7. A device as recited in claim 5, in which said chemical is a synthetic progestagen.

8. An intrauterine contraceptive device comprising a shaft-like member adapted to fit within the human uterus and formed of a material compatible with retention therein, and a vane attached to said member and having enlarged, thin, and normally planar lobes projecting from opposite sides thereof for engaging the uterine lining, the lobes comprising a large surface area, tapering to conform to the frontal cross section of the uterus, said vane being formed of a flexible material compatible with retention in the uterus, and being foldable by rolling said lobes about the axis of said member to facilitate insertion into the uterus.

9. A device as recited in claim 8, in which said member is formed with a transverse slot extending longitudinally therethrough and receiving said vane.

10. A device as recited in claim 9, in which said lobes of the vane are longer than said slot in a direction longitudinal to said member, said vane having a central portion shorter than said slot and received therein, whereby said vane is transversely slidable in said member but is retained in said slot.

11. A device as recited in claim 8, in which said vane is formed of a plastic material.

12. A device as recited in claim 11, in which said vane is impregnated with a contraceptive chemical.

13. A device as recited in claim 11, in which said plastic material is a silico-organic rubber.

14. A device as recited in claim 12, in which said chemical is a synthetic progestagen.

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