

[54] **DISPOSABLE DIAPHRAGM AND INSERTION-REMOVAL UNIT THEREFOR**

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[58] Field of Search ... **128/128, 264, 127, 129, 130, 128/260**

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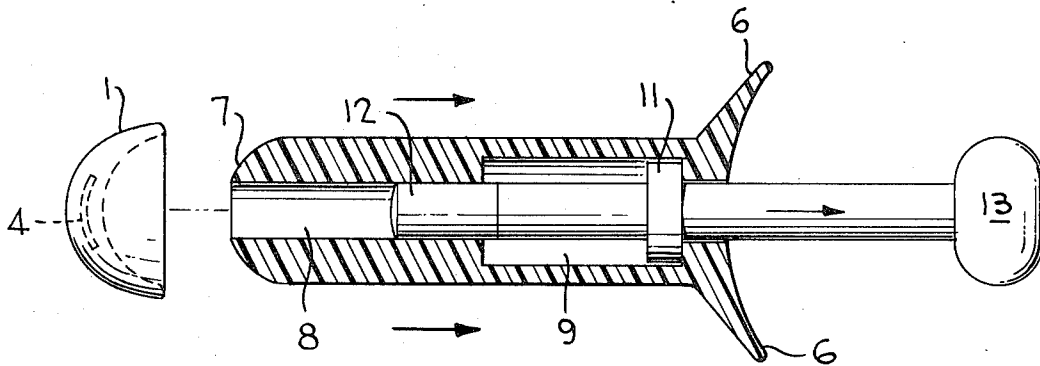
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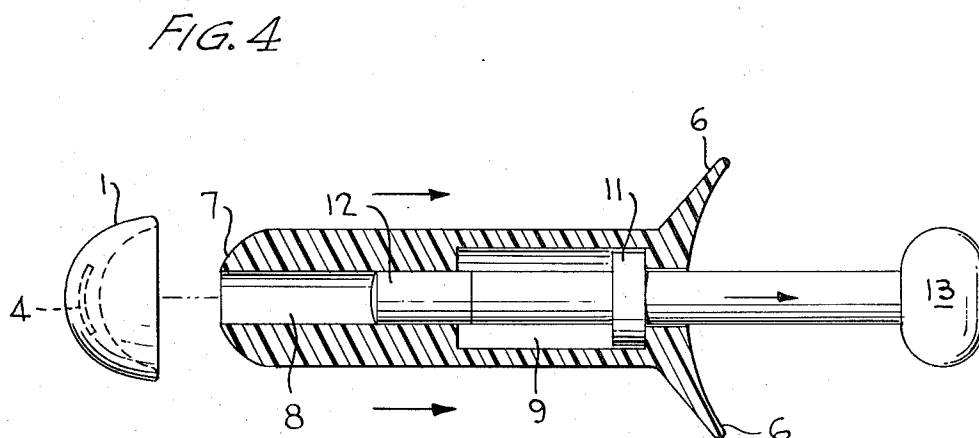
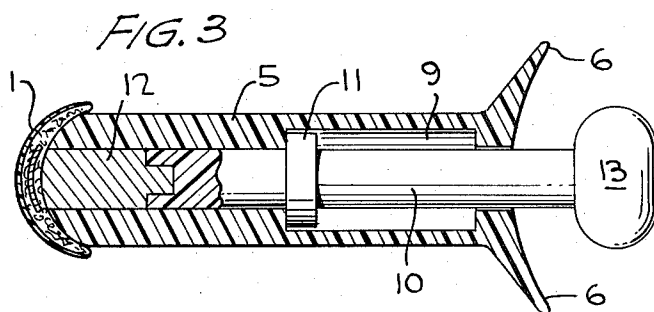
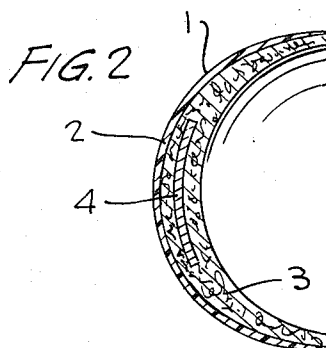
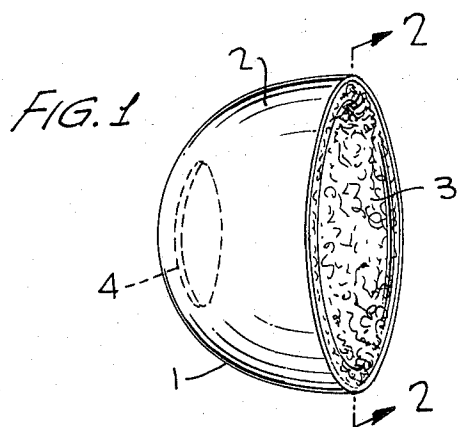
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[57] **ABSTRACT**

A disposable diaphragm and reusable insertion-removal unit which enables the user to easily insert, position and remove the diaphragm. The diaphragm includes a magnetically attractable object embedded in absorbent material, such magnetically attractable object being attracted to or released from the tip of an insertion-removal unit, the insertion-removal unit having a magnet at the end of a plunger-rod. When the plunger-rod is advanced forward, it attracts and holds the diaphragm and when it is retracted it releases the diaphragm.

9 Claims, 4 Drawing Figures





DISPOSABLE DIAPHRAGM AND INSERTION-REMOVAL UNIT THEREFOR

BACKGROUND OF THE INVENTION

In light of present day thinking with respect to the problem of the crowded world population and the great need for stable and healthy family units in our society, various birth control methods have been proposed.

One widely known method is the oral administration of birth control pills. This systematic suppression of conception through the use of hormones, while being a particularly effective means of birth control, often has undesirable side effects on the user. A further problem which limits the wide acceptance of contraceptive pills is the unknown long range physical effects of hormone injection on the human body.

More recently, the introduction of the intra-uterine device has provided an alternative to birth control pills, such intra-uterine devices affording effective contraception while not causing the undesirable physical side effects. However, since these devices are permanently placed in the uterus to provide a mechanical obstacle to insemination, they are not easily tolerated by the tissue and mucous membrane which surround them, a condition which often results in deterioration or dislodgement of the intra-uterine device.

It has further been known to use a flexible nonpermeable diaphragm as a method of contraception whereby the flexible non-permeable membrane is lodged crosswise in the vaginal canal at the base of the cervix and is retained in this position by virtue of the surrounding contractal wall tissues. One problem common to this method has been the assurance of proper positioning of the contraceptive diaphragm. The importance of such proper positioning is, of course, obvious since the prevention of insemination cannot be accomplished unless the diaphragm covers the end of the cervix. The use, therefore, of applicator instruments have been known to aid in the ease and accuracy of placing the contraceptive diaphragm into the vaginal canal and assisting its proper positioning near the cervix where it is deposited.

BRIEF SUMMARY OF THE INVENTION

This invention is directed generally to improvements in a disposable contraceptive diaphragm and an instrument for the insertion and removal of a diaphragm. This invention further relates to improved combination of diaphragm and insertion-removal unit therefor.

It is therefore an object of this invention to provide a contraceptive diaphragm which can be easily inserted and positioned in the vaginal canal.

It is also an object of the present invention to provide an apparatus which enables one to easily insert or remove the contraceptive diaphragm.

It is a further object of this invention to provide a combination contraceptive diaphragm and insertion-removal unit which work together to facilitate easy insertion, positioning and removal of the diaphragm.

It is a still further object of the present invention to provide a magnetically attracted, disposable contraceptive diaphragm.

It is yet another object of this invention to provide a magnetic insertion and removal unit for contraceptive diaphragms.

BRIEF DESCRIPTION OF THE DRAWINGS

The above brief description as well as further objects, features and advantages of the present invention will be more fully appreciated by reference to the accompanying drawings in which:

FIG. 1 is a perspective view of the disposable contraceptive diaphragm of the present invention;

FIG. 2 is a cross-sectional view of the disposable contraceptive diaphragm along lines 2—2' of FIG. 1;

FIG. 3 is a vertical section of the insertion removal device with the diaphragm attached in a position ready for insertion; and

FIG. 4 is a vertical section of the insertion-removal unit in the depositing position, i.e., with the magnet out of the range of the diaphragm.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring more particularly to the drawings, there is illustrated in FIG. 1 the disposable diaphragm 1 consisting of a soft plastic cover 2 in a bowl-shape, with a soft compact absorbent material 3, e.g., cotton, lining the inside of the plastic cover. Embedded within the end of the diaphragm is a stainless steel disc 4 covered above and below with the soft absorbent material.

The insertion-removal unit 5 shown in FIG. 3 has a hollow cylindrical shape with flanged edges 6 at one end thereof and a smooth rounded tip 7 at the opposite end. The hollow core 8 of this unit has a widened central bore 9 which permits the movement of the cylindrical plunger-rod 10 and its attached annular limiting rim 11 of increased circumference. The plunger-rod 10 in FIG. 3 is in a position ready for the insertion of the diaphragm 1 which is attached at the rounded tip 7 of the insertion unit and which is held in place by means of a magnet 12 which is attached to the tip of plunger-rod 10.

The depositing position as shown in FIG. 4 demonstrates the plunger-rod 10 with handle means 13 in a drawn back position so that the magnet 12 at the tip of the unit is not sufficiently near to attract the stainless steel disc 4 of the diaphragm (shown now at a distance from the insert-removal unit). This position is easily obtained by simple retraction of plunger-rod 10 as far as possible. Movement of the annular limiting rim 11 within the widened central bore 9 prevents the complete removal of the plunger-rod when it is pulled back and also limits the movement of the rod forward so that it cannot be pushed in too far.

The outwardly extending flanges 6 of the insertion removal unit, as shown in FIGS. 3 and 4, enable the user to adequately determine the proper positioning of the diaphragm. These extending flanges limit the insertion of the unit itself into the vagina. The length of the insertion-removal unit is such that when the unit with diaphragm attached is inserted into the vagina up to the outwardly extending flanges, the diaphragm will be deposited in proper position.

The insertion of the diaphragm is an easy maneuver when the insertion-removal unit is used. The cylindrical plunger-rod 10 is advanced so that the magnet 12 at the end of the plunger-rod is flush with the head of the unit. This position is easily determined by advancing the plunger-rod 10 as far as the annular limiting rim 11 allows. The bowl-shaped diaphragm 1 is placed over the end of the unit 7 and the magnet 12 immedi-

ately attracts and holds the diaphragm 1 to the end of the unit. The diaphragm is then introduced into the vagina and carried to the deep end of the vagina where it is deposited. Once inserted to this position, the plunger handle 13 of the insertion-removal unit is pulled back with the insertion-removal unit remaining in place. This results in the drawing of the magnet 12 out of the range of the stainless steel disc 4 in the diaphragm 1. Then, the entire insertion-removal unit is removed leaving the diaphragm 1 in place.

For removal of the diaphragm, the insertion-removal unit is prepared by merely advancing the plunger-rod so that the head of the magnet 12 is flush with the head of the unit 7 and inserting the unit into the vagina as far as the outwardly extending flanges 6 allows. The magnet thereby approximates the steel disc 4 in the diaphragm 1 and likewise causes the diaphragm 1 to attach to the head of the unit 7 to permit the removal of the diaphragm 1 with insertion-removal unit.

The insertion-removal unit and cylindrical plunger rod 10 may be made of any suitable form retaining material. A plastic material which is smooth, essentially rigid and inexpensively manufactured is preferred. However, other materials such as metal or natural occurring fibrous material may be molded or manufactured into the desired form for the insertion-removal unit. In the event a metal is used for the insertion-removal unit, it is understood that the magnetic properties of the metal must be such that interference with the magnetic end of the cylindrical rod is prevented.

The magnet may be attached to the cylindrical rod by the use of an adhesive or by any other suitable means which does not interfere with the movement of the rod inside the hollow cylinder.

While the metallic material which is embedded in the diaphragm is shown to be a stainless steel disc, it is understood that any ferrous material subject to attraction by magnetism and of any convenient shape which can easily be embedded in the thin absorbent lining is suitable. The preferred use of stainless steel, however, enables easy sterilization of the disposable diaphragm. Also, the preferred disc shape provides the maximum surface area which is necessary for optimum magnetic attraction.

The particular bowl-shaped construction of the diaphragm itself allows for the secure attachment to the tip of the insertion unit. The outer smooth plastic surface of the diaphragm enables smooth painless insertion, but may additionally be wetted or lubricated to assist in the insertion. Once inserted, the diaphragm covers the end of the cervix preventing the entrance of sperm during intercourse. The cotton or soft fiber consistency of the diaphragm absorbs the sperm after ejaculation preventing insemination while the plastic backing prevents the semen from leaking through the diaphragm. While cotton has been illustrated as a suitable absorbent material, other absorbent materials such as woven and non-woven natural and synthetic fibers, plastic foams and the like may be used. As noted above, the plastic backing is a non-permeable membrane and therefore may consist of any suitable plastic material such as natural or synthetic soft rubber. It is further necessary that the backing material be sufficiently strong so that a smooth, thin membrane of sufficient strength is provided which forms a shell for the absorbent material and embedded metal disc and will not break or rupture during insertion, use and re-

moval. The absorbent material may be secured to the non-permeable backing membrane by any suitable means such as an adhesive, thermal welding or the like or by means of an overlapping portion of the backing membrane.

In another embodiment of the invention, the absorbent material may contain a dried medicating or spermicidal agent. The use of a diaphragm containing a medicinal agent provides for an effective method of treating infections in the vaginal cavity. The use of a spermicidal agent increases the contraceptive qualities of the diaphragm.

The particular improvement of this invention, that is, the construction and cooperation of a magnetic insertion-removal unit and a magnetically attracted diaphragm allows for a simple inexpensive and yet effective means of birth control which enables the user to insert or remove the contraceptive means when desired and when convenient and eliminates the need for any skillful placement or removal by a physician.

What is claimed is:

1. A disposable diaphragm comprising a soft, non-permeable backing member in a bowl-shaped configuration, an absorbent means for retaining a spermicidal agent, said absorbent means positioned within the inner side of said backing member, and a magnetically attractable disc embedded in said absorbent means.

2. A disposable diaphragm as defined by claim 1 wherein said non-permeable backing member is a thin synthetic rubber.

3. A disposable diaphragm as defined by claim 1 wherein said absorbent means is cotton.

4. A disposable diaphragm as defined by claim 1 wherein said absorbent means is a non-woven fibrous material.

5. A disposable diaphragm as defined by claim 1 wherein said magnetically attractable disc is a stainless steel disc.

6. An insertion-removal unit for diaphragms comprising a hollow cylinder having a widened central bore over a portion of the length thereof, said cylinder having outwardly extending flanges at one end thereof and a rounded tip at the opposite end; a cylindrical plunger-rod movably located within said hollow cylinder and extending beyond said cylinder at said flanged end; handle means at the end of said plunger-rod extending beyond said cylinder; a magnet forming the end of said plunger-rod opposite said handle means, said plunger-rod having a fixed annular rim located between said magnet and handle means, said rim being of a circumference lesser than said widened central bore and greater than the remainder of the bore of said hollow cylinder, thereby defining the limit of movement of said plunger-rod within said hollow cylinder.

7. An insertion-removal unit as defined by claim 6 wherein the hollow cylinder with outwardly extending flanges is comprised of a smooth, essentially rigid plastic material.

8. An insertion-removal unit as defined by claim 6 wherein the magnet is adhesively attached to said plunger-rod.

9. The combination of a disposable diaphragm and an insertion-removal unit wherein the diaphragm comprises a soft non-permeable backing member in a bowl-shaped configuration; an absorbent lining material positioned within to the inner side of the backing member and embedded in the absorbent lining, a mag-

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netically attractable disc and wherein the insertion-removal unit comprises a hollow cylinder having widened central bore over a portion of the length thereof, said cylinder having outwardly extending flanges at one end thereof and a rounded tip at the opposite end; a cylindrical plunger-rod movably located within said hollow cylinder and extending beyond said cylinder at said flanged end; handle means at the end of said plunger-rod extending beyond said cylinder, a magnet

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forming the end of said plunger-rod opposite said handle means, said plunger-rod having a fixed annular rim located between said magnet and handle means, said rim being of a circumference lesser than said widened central bore and greater than the remainder of the bore of said hollow cylinder, thereby defining the limit of movement of said plunger-rod within said hollow cylinder.

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