PLEATED MEMBRANE INTRAUTERINE CONTRACEPTIVE DEVICE

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ABSTRACT
A pleated membrane intrauterine contraceptive device, adapted to be non-surgically placed into the uterus to protect against accidental conception, consists of a series of accordion-like folded pleats of flexible material. The large surface area due to these pleats allows this intrauterine contraceptive device to be impregnated with such an amount of a biochemically active chemical as to have a significant contraceptive effect.

6 Claims, 4 Drawing Figures
PLEATED MEMBRANE INTRAUTERINE CONTRACEPTIVE DEVICE

FIELD OF THE INVENTION

The present invention relates to an intrauterine contraceptive device which will fold-up for insertion and deploy into the desired shape after it is introduced into the uterus. The endometrium of the uterus molds itself to the shape of the IUD due to the action of the opposing endometrial surface exposed to the pleated IUD keying into the folds.

BACKGROUND OF THE INVENTION

Intrauterine contraceptive devices have evolved through many stages of empirical development and have achieved a significance of performance over the earlier devices developed by Richter and Grafenberg. However, due to the increasing awareness of the world population explosion problem, as well as the concern of unwanted pregnancy, a device which is more effective than the prior art devices in preventing conception is desired.

In addition, many of the IUDs now available cause pain and abnormal bleeding to the user due to the pressure of the inner end of the device at the fundus. This bleeding is also due to the fact that most of the devices available today are substantially rigid in a longitudinal direction, and thus do not conform to the size and shape of each individual uterus. Thus, a device which would adjust to a change in the uterus size due to muscle activity is needed.

SUMMARY OF THE INVENTION

It is, accordingly, an object of the present invention to overcome the defects of the prior art, such as indicated above.

Another object of the invention is to provide for improved contraception.

Another object is to provide a device of large surface area in contact with the endometrium to improve contraceptive efficacy.

A further object is to develop a device which has the ability to fit into a large or small uterine lumen thus reducing the problems associated with miscarriage.

Yet another object is to improve the contraceptive efficacy by keeping the IUD in the portion of the uterine lumen where impregnation of the blastocyst is favored, while reducing expulsion by avoiding uterine motility induced by the IUD contact near the inner os.

Still another object is to provide a device which is both soft and flexible and will reduce and/or eliminate pain and abnormal bleeding.

Another object is to provide a thick and convoluted surface contour to improve the efficacy of the device and to reduce expulsion.

A further object is to provide a biochemically active IUD, whose increased surface area provides a greater latitude in the selection of materials to give the desired rate of release for drugs impregnated into the IUD.

For a better understanding of the invention a possible embodiment thereof will now be described with reference to the attached drawings, it being understood that this embodiment is to be intended as merely exemplary and in no way limitative.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a plan view of the fully deployed IUD; FIG. 2 is a cross-section taken along line 2—2 of FIG. 1;

FIG. 3 is a front elevation view of the inserter and the interuterine contraceptive device folded for insertion; FIG. 4 is a side elevation view of the inserter.

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 shows an intrauterine contraceptive device in accordance with the present invention as it looks when it is fully deployed inside the uterus. The membrane is made up of a series of generally horizontally disposed and angularly extending accordion pleats, folded substantially into the shape of a plurality of "V's" along vertically disposed crease lines. The membrane, creased in such a manner, will easily allow the device to be folded up for insertion and then deployed into the desired shape in the uterus, much better than any currently available IUD.

The membrane, when fully opened is in the general shape of a heart, containing about four to seven and preferably five rows of pleats, each pleat having a V-shape in cross-section as shown in FIG. 2, and each having a height and width of approximately ¼ to ½ cms. preferably about 1 cm. In use, this device has approximately seven to 15 square centimeters of surface area, preferably about 12 cm², all of which is in contact with the endometrium, and which constitutes an area of about five times greater than most IUD configurations. Due to the pleating of the membrane, this IUD is compliant enough to conform to nearly any normal uterine shape. The IUD has a plastic string extending from its bottom.

Examination of excised uteri removed with IUDs in place has consistently revealed that the endometrium has molded itself to the shape of the IUD. Thus, the opposing endometrial surface exposed to the pleated IUD will key into the folds. This conformity locks the IUD in place. Under the influence of uterine motility, the IUD has a distinct tendency to move in only the funicular direction, thereby remaining in the portion of the uterine lumen where impregnation of the blastocyst is favored. This also reduces the chance of expulsion due to muscle activity of the uterus.

The membrane is preferably fabricated from flexible polyethylene or polypropylene film about 100 microns thick, although other materials of this type may be used. This enables it to be both soft and flexible, yet allows it to withstand great resistance to bending and buckling in the longitudinal direction because of the high bending modulus of the V-shaped pleats in this direction. The softness and the shape of the pleated IUD makes migration through the uterine wall unlikely. If it should be inserted into the peritoneal cavity, its closed configuration allows it to remain there without harmful effects. Even so, the pleated IUD is more flexible in the longitudinal direction than many IUDs made of solid structural elements. This feature relieves the pain and abnormal bleeding which is associated with IUDs presently available.

While this device may operate mechanically without any chemical agents whatsoever, the high surface area and low diffusion distance of the pleated membrane IUD are distinct advantages for releasing certain com-
pounds which may be impregnated within the membrane material. For example, since the area of this IUD is about five times greater than that of most IUD configurations, a pleated polyethylene IUD impregnated with copper compounds, will release copper ions at a rate large enough to have significant contraceptive effect. The IUD may also be infused with anti-bleeding agents, such as progestin to prevent unpleasant bleeding from occurring.

FIG. 3 shows the intrauterine contraceptive device which is folded for insertion into the uterus. As with other IUDs, conventional procedures should be followed in preliminary examinations to check the normality and position of the uterus, including a bimanual examination, speculum examination of the cervix and vagina, and performance of a Pap smear and test for gonorrhea. If these tests prove negative, then after the cervix is cleansed with an antiseptic solution, the IUD may be inserted.

A hook-like instrument such as a tenaculum is initially secured to the anterior lip of the cervix. While traction is applied to the tenaculum to straighten the canal and stabilize the uterus, the uterus is sounded by any known means or by use of an inserter 10, i.e., the corresponding distance is noted on a uterine depth scale 28 embossed or otherwise marked on the surface of the inserter 10, which is later used to assist in the insertion of the IUD 12 into the uterus. The inserter 10, comprising a hollow cylinder of about 10 cms. in length and 1½ cm. in diameter and formed of any suitable material such as polyethylene or polypropylene, is molded to a funnel 16, made of a similar material as the inserter 10, which aids in the insertion of the IUD 12 into the inserter 10. This funnel 16 is approximately 15 cm. in length, and increases in cross sectional area from where it is joined to the inserter 10 at 32 to its base 30. The inserter 10 terminates at its IUD feeding end 26.

The IUD 12 is placed in the base 30 of the inserter 10, with the string 14 placed through a narrow slot 34 extending through the wall of the funnel section 16. An ejector rod 18, constructed of material similar to the inserter, being about 30 cm. in length and containing a small bulb 20 one cm. from its posterior end, is provided to advance the IUD 12 from the funnel 16 into the inserter as shown in FIG. 3 and then, in use, through the inserter 10 and into the uterus to deploy the IUD properly within the uterus. FIG. 3 shows the ejector rod 18 partly in phantom disposed within the inserter 10. Both the end 26 and the curvature of the inserter 10 will provide aid in orienting the tube so the plane of the IUD 12 will correspond with the plane of the uterine lumen.

The inserter 10 in use is advanced into the uterus until the distal end reaches the fundus, care being taken to assure that the inserter is properly aligned so that the pleated membrane will be deployed properly. To deploy the pleated membrane, the inner push rod 18 should be held steady while the outer tube 10 is withdrawn until it is stopped by the enlarged section 20 of the inner rod 18. To insure that the fundally placed IUD may not be displaced, the inner rod 18 must be removed before the inserter 10. The total length of the IUD is 10 cm.; thus, high fundal positioning can be checked by comparing the length of string protruding from the outer end with the sounded distance.

The device may easily be removed by applying a tenaculum to the anterior lip of the cervix and traction used to stabilize the uterus and align the canal. The string 14 is gripped with a sponge forceps or another suitable non-serrated instrument, and then extracting the IUD with steady, even traction. If the string 14 has become disengaged from the IUD 12, then cystoscopic or other forceps suitable for gripping within the uterus can be used for removing the IUD.

It will be obvious to those skilled in the art that various changes may be made without departing from the scope of the invention and the invention is not to be considered limited to what is shown in the drawings and described in the specification.

What is claimed is:

1. An intrauterine contraceptive device adapted to be placed in the uterus comprising a soft flexible membrane containing a plurality of pleats arranged in a herringbone pattern along at least one vertical line of intersection, wherein each pleat situated on the same side of said vertical line of intersection is parallel to another pleat and wherein each pleat slopes in the opposite direction with respect to an adjacent pleat located on the opposite side of said vertical line of intersection, whereby said contraceptive device is contractable laterally without buckling allowing said membrane to conform to the shape of uterine cavities smaller in width than the width of the uncontracted device and whereby said membrane can compress laterally into a configuration having a substantially rectangular cross-section to facilitate placement in the uterus.

2. An intrauterine contraceptive device according to claim 1 further comprising a removal string disposed at one end of the flexible material.

3. An intrauterine contraceptive device according to claim 1 wherein said flexible membrane is polyethylene or polypropylene.

4. An intrauterine contraceptive device according to claim 1, wherein said soft flexible material is impregnated with a biochemically active compound to reduce the likelihood of conception.

5. An IUD in accordance with claim 1 having an area of about 12 cm.² for contact with the endometrium.

6. A device in accordance with claim 1, wherein the pleats abutting the lateral edge of said membrane intersect the lateral edge at an angle enabling said device to resist expulsion against the action of the uterine muscles.

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