United States Patent [19]

Chabon

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[45] **May 7, 1974**

[54] **INTRAUTERINE CONTRACEPTIVE DEVICE**

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[52] **U.S. Cl.** **128/130**
[51] **Int. Cl.** **A61t 5/46**
[58] **Field of Search** ..... 128/127–131, 128/132 R; 24/90 TA

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Primary Examiner—Richard A. Gaudet
Assistant Examiner—G. F. Dunne
Attorney, Agent, or Firm—Wolder & Gross

[57] **ABSTRACT**

An intrauterine contraceptive device having a closed perimeter and an interior opening of limited size to prevent catching of a loop of bowel in the event that the device perforates the uterus. The device is of a thin wafer, disc design and is made of silicone rubber elastomer. A steel band may be impressed into the perimeter.

9 Claims, 12 Drawing Figures

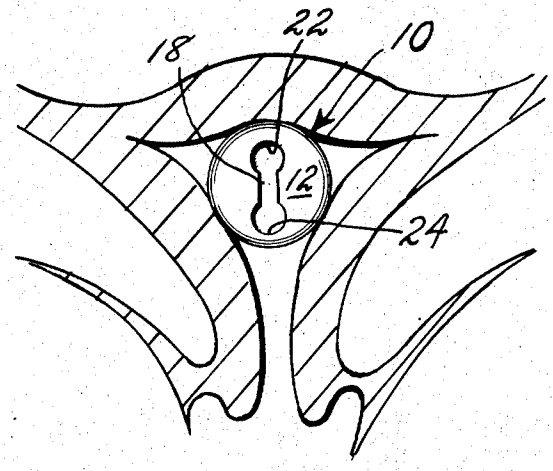


Fig.1

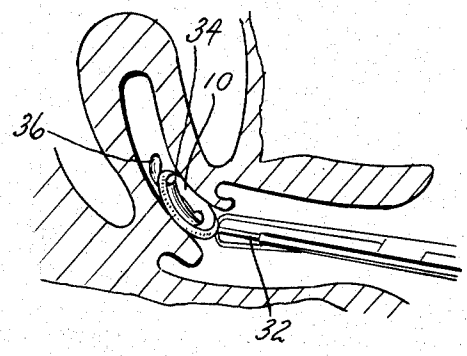


Fig.2

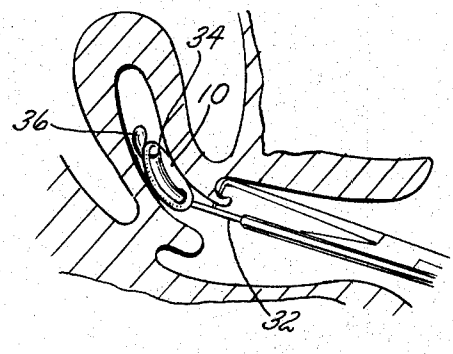


Fig.3

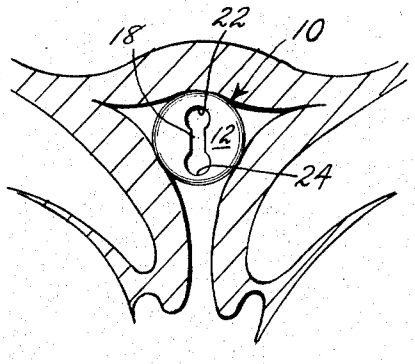


Fig.4

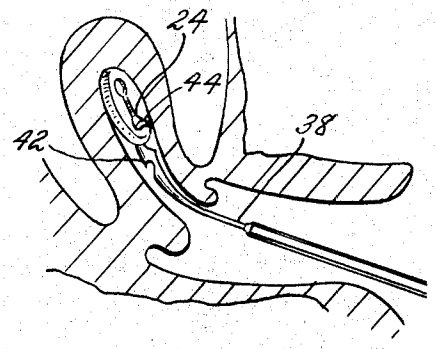


Fig.5

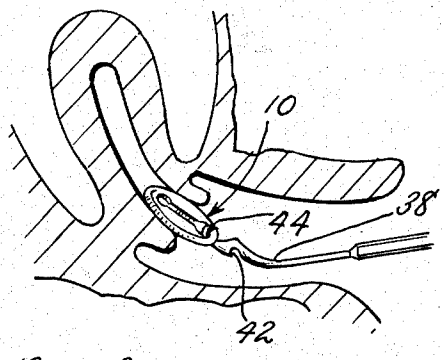


Fig.6

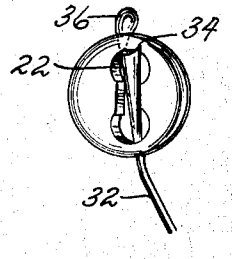
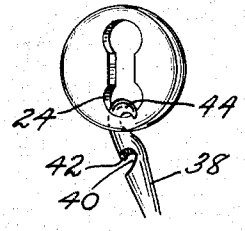


Fig.7



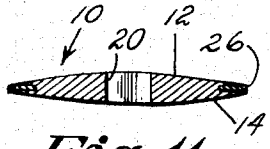


Fig.11

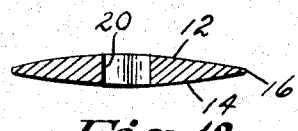


Fig.12

Fig.8

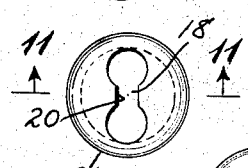
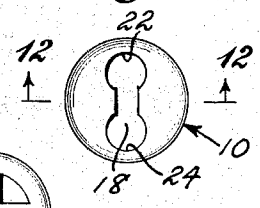


Fig.9



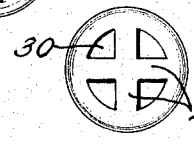


Fig.10

INTRAUTERINE CONTRACEPTIVE DEVICE

PRIOR ART

Intrauterine contraceptive devices are well known in the art and have taken many different shapes, but the most promising devices have been of a closed perimeter construction, such as disclosed in the Hall U.S. Pat. No. 3,323,520. This device consists of a helical spring forming a circle with a steel band passing through the interior thereof. However, at least four major disadvantages have been observed with its use.

The spread of the helices predisposes the uterine lining to laceration because of scraping. The thickness of the coils distends the uterine cavity causing cramps. The wide open design results in minimal contact of the surface area as well as retention of a bowel if the lining is perforated. And since the device is made of stainless steel, it is not possible to use an electronic locator, and the position of the device must be determined by physical probing.

Accordingly, it is among the principal objects of the present invention to provide an intrauterine contraceptive device embodying the present invention which will provide maximal coverage of the endometrium with minimum distention.

Still another object of the present invention is to provide a device of the character described which eliminates the necessity for having appendages extruding through the cervix.

Still another object of the present invention is to provide a contraceptive device which will be relatively easy to place within the uterus, adjust its position therein, and remove it.

Yet a further object of the present invention is to provide a contraceptive device having a small cut-out which will not permit any loop of bowel to be caught inside should the device enter the abdominal cavity.

Yet a further object of the present invention is to provide a device of the character described which is fabricated from a material which is easily grasped by the introducer and extractor tools, and yet is tolerated by the body.

Still yet a further object is to provide a device of the character described which may be fabricated from a material which can be sterilized by standard autoclave.

Still yet another object is to provide an intrauterine device which may be fabricated from insulating materials, thus allowing use of electronic detection.

Still a further object of the present invention is to provide a new and novel intrauterine contraceptive device which makes use of standard introducer and extractor tools already available.

SUMMARY OF INVENTION

The present invention contemplates an improved intrauterine contraceptive device which is wafer thin and shaped in the form of a disc, thus presenting a closed perimeter. In cross-section the unit is somewhat elliptical having a greater thickness at the central portion than at the perimeter. Centrally located within the device is a cut-out which may be a dumbbell shape or oppositely disposed cordal sections, resembling a closed maltese cross. The actual openings are small enough so that if the device should pass through the uterus into the abdominal cavity, it would be impossible for a loop of bowel to get caught within the opening. The openings are designed to be engaged by introducer or extractor tools, which are well known in the art, and may easily engage the openings along their edges.

In order to provide strengthening to the unit, a steel band may be inserted along the perimeter. Instead of the steel bands, silicon rubber rodding may be used.

Additional objects and advantages of the present invention will become apparent from a consideration of the following detailed description when taken in conjunction with the accompanying drawings in which:

FIG. 1 is a cross-sectional view of a vagina and uterine cavity with the introducer tool placing an intrauterine contraceptive device embodying the present invention into position within the uterine cavity;

FIG. 2 is a view similar to FIG. 1 with the device moved further along in the uterine cavity;

FIG. 3 is a top plan cross-sectional view of the uterine cavity showing the device in porper position therein;

FIG. 4 is a view similar to FIG. 1, showing the extractor tool engaging the device just prior to its removal from the cavity;

FIG. 5 is a view similar to FIG. 4 with the device being removed from the cavity and passing through the cervix;

FIG. 6 is a plan view of the device engaged by the introducer tool;

FIG. 7 is a view similar to FIG. 6 with the device being engaged by the extractor tool;

FIG. 8 is a plane view of the device having a steel or silicone rubber rodding band embedded proximate the perimeter;

FIG. 9 is a view similar to FIG. 8 without the band;

FIG. 10 is a plane view of the device with a modified cut-out design;

FIG. 11 is a view taken along the lines 11—11 of FIG. 8; and

FIG. 12 is a cross-sectional view taken along the lines 12—12 of FIG. 9.

Referring in detail to the drawings, and in particular to FIGS. 8 and 11, there is shown an intrauterine contraceptive device 10 having a disc design and being of a very thin wafer type shape. The unit may be fabricated from silicone rubber, such as SILASTIC, which is available from Dow Corning. This material is used because it may be easily engaged by the introducer and extractor tools, is well tolerated by the human body, can be easily sterilized by autoclaving, and is an insulating material so it allows the use of electronic detection to locate the position of the device.

As seen from FIG. 9, this device is circular or disc like in plane view and as seen in FIG. 11 in cross-sectional configuration it is somewhat elliptical in shape. The device is defined by an upper surface 12, a lower surface 14, and a perimeter 16. It has been found that the device may have a diameter of 22 mm. and be no more than 2 mm. thick at its midpoint.

Centrally located within the device is a cut-out 18 in a dumbbell shape defined by parallel side edges 20 and circular end edges 22, 24. This opening is limited in size so that if the device should pass into the abdominal cavity, it would not be possible for any loop of bowel to get caught therein, as has happened with prior art devices.

The device is very flexible and may be folded prior to its introduction into the cervix. In order to provide some additional rigidity to the otherwise resilient mem-

ber, a stiffening band **26** (FIGS. **8, 11**) may be placed within the device proximate the perimeter **16.** The band may be 2 mm in width and approximately 1/10,000 of an inch in thickness, and made of surgical stainless steel.

In order to further minimize the problem of interior body sections becoming entangled within the opening in the device, a different internal opening pattern may be utilized, as such is shown in FIG. **10.** In this embodiment a circular opening with perpendicular elements **28** have been designed leaving four oppositely disposed chordal openings **30.** These openings leave a much less cross-sectional area than the opening **18,** and yet are capable of receiving the operable sections of the tools.

FIG. **5** shows the device with the introducer tool **32** having a lower lip projection **34** and a bulbous end **36.** The bulbous end passing through the portion of the opening defined by the edge **22,** with the lip **34** catching on the edge as shown. The tool, together with the device, is then placed within the vagina and folded so as to more easily pass through the cervix (FIG. **1**). The device is then continually moved inwardly and passes into (FIG. **2**) the interior of the uterus until it is placed in position as shown in FIG. **3.** In this position there is maximal coverage of the endometrium with minimal distention of the uterus. This is extremely important since one of the major objects of the device is to prevent distention of the uterus.

Periodically, examinations are made to insure that the device remains in proper position within the uterus. If the device must be repositioned, it may be done with the extractor tool **38.**

This tool has a slight cavity **40** and an upper lip **42** and an end lip **44.** These lips may engage the lower edge **24** of the opening **18** as shown in FIG. **5.** Utilizing the lips **42, 44** or the lip **34,** the device may be properly repositioned within the uterine cavity (FIG. **3**). In addition, the device may be removed by engaging the lip **44** on the edge **24** and withdrawing the device from the uterine cavity, allowing it to pass through the cervix (FIG. **4**).

In a like manner, the embodiment shown in FIG. **10** can be easily engaged by the lips **34, 42, 44** and positioned within the uterus and removed as previously shown.

The terms and expressions which have been employed here are used as terms of description and not of limitation, and there is no intention in the use of such terms and expressions, of excluding equivalents of the features shown and described, or portions thereof, it being recognized that various modifications are possible within the scope of the invention claimed.

What is claimed is:

1. An intrauterine contraceptive device comprising:

a. a wafer, disc shaped body, formed of an elastomeric material compatible with retention in the uterus said body having a substantially symmetrically taped cross-section such that a relatively thick central portion gradually tapers to a thin perimeter portion, the body being flexible in any orientation, sufficient to allow passage from the vagina into the uterus; and

b. an interior opening defined in the face of the body and passing therethrough, said body containing a small cut out portion facilitating engagement of introducer-extractor devices, the size of the opening being restricted to prevent passage of a loop of bowel from passing therethrough in the event of uterine perforation.

2. The invention according to claim **1,** the body being circular in plane view and somewhat elliptical in side elevational view.

3. The invention according to claim **2,** the body having a diameter of 22 mm. and a thickness of no more than approximately 2 mm. at its midpoint.

4. The invention according to claim **1,** a stiffening band located within the body and proximate the perimeter.

5. The invention according to claim **4,** the band being made of surgical stainless steel.

6. The invention according to claim **4,** the band being **2** mm. in width and approximately 1/10,000 of an inch in thickness.

7. The invention according to claim **1,** the body being made of silicone rubber.

8. The invention according to claim **1,** the cut out portion defined by parallel central edges and circular end edges, resembling a dumbbell shape.

9. The invention according to claim **1,** the cut out portion having a circular outer edge with intersecting elements therein defining opposingly disposed chordal openings.

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