PATENT SPECIFICATION

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COMPLETE SPECIFICATION

DRAWINGS ATTACHED

Intra-Uterine Contraceptive

We, THE MOUNT SINAI HOSPITAL RESEARCH FOUNDATION, INC., a membership corporation under the laws of the State of New York with offices at One East 100th Street, New York 29, New York, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to intra-uterine birth control devices and more particularly relates to an object that may be introduced through the cervix although having a diameter *in situ* considerably larger than the normal cervical canal.

Birth control or contraception has been practiced by innumerable methods to various degrees of effectiveness for centuries and in modern times has become the subject of organised study and even actively encouraged by certain governments in the world. However, no fully satisfactory method of preventing pregnancy has been developed, it being desirable that a method be effective, safe, cheap, simple, physically and phychologically acceptable and permanently applicable without repeated regimen, but subject to cancellation at will.

In 1929 Graefenberg reported on the celebrated ring which bears his name and which became the subject of dispute among gynecologists all over the world. This ring was about one inch in diameter, flexible and formed of silver originally and subsequently of other metals that are presumably inert. It required dilation of the cervix to about 10 mm. to permit passage of the ring when folded which was extremely painful unless anaesthesia were utilised. Ota in Japan added a central element to the ring and formed it of gold, gilt silver or polyethylene with a nylon coil around the outer circle, to overcome certain objections that had been raised, but the dilation of the cervical canal remained a disadvantage as before. A report (10 Yokohama Medical Bulletin 89-105 1959) on the Ota device describes almost 20,000 cases having a frequency of conception of about 2.2% in two years. The rate of conception of a portion of the cases were determined by the Stix-Notestein method and showed 96.5% effectiveness, this being equivalent to one pregnancy in 40 years of exposure.

A silkwork gut ring had also been developed which is preferred by some writers because of the insertion difficulty of the Graefenberg ring. As described by Oppenheimer, this is a ring formed of three or four intertwined threads of silkworm gut, each about 14 cm. long with a knot at each end. These threads and the resultant ring are very stiff and must be dipped into hot water to avoid cracking of the threads and permit knotting of the ends so that end points or cracked threads will not pierce the uterine wall. Furthermore, this ring must be formed just before use, as otherwise it will lose its elasticity properties which are essential. A report (78 Am. J. Obst. & Gynec. 446-454 1959) primarily on the silkwork gut ring describes over 1,000 insertions (a few were the Graefenberg silver ring) on 329 patients with an effectiveness of about one pregnancy in 40 years of exposure. This report points out that the rings are 25 times as effective as rubber caps (diaphragms). Diaphragms, although having certain psychological disadvantages and being inconvenient, are generally considered the most effective method in general use in the United States.

Halton also coiled silkworm gut in individual pieces and placed two or three in the uterus via capsules but they caused considerable uterine disturbances.

[Price 4s. 6d.]

The Graefenberg rings were involved in heated controversy when first reported which apparently precluded any substantial use of the devices at that time. However, the two aforementioned reports, based on over 20,000 cases, show the devices to be effective and safe, and particularly when inert materials are used.

Thus, the intra-uterine rings already meet several of the criteria for an ideal contraceptive as they are (1) by far the most effective, (2) cheap to manufacture, (3) permanently applicable but subject to removal at any time (4) offer no physical or phychological interference with intercourse, and (5) safe to use. However, the plastic or metal rings are either very painful to insert and remove or must be transferred with anaesthesia and the silkworm gut ring must be formed immediately before insertion and must be critically treated with hot water to avoid cracking and subsequent piercing of the uterine wall, all of which are time consuming and detract from the universal acceptance of intra-uterine rings, particularly on a mass basis as is desired in certain over-populated areas of the world.

Therefore, it is an object of this invention to provide an improved intra-uterine device for contraceptive purposes.

It is also an object of this invention to provide an intra-uterine coil that may be cheaply fabricated in mass quantities prior to the time for inserting same.

It is an additional object of this invention to provide such an intra-uterine coil that may be painlessly and simply inserted and removed through the normal cervical canal without dilation.

It is a further object of this invention to provide an intra-uterine coil that permits placement within the frontal plane of the uterus to avoid any discomfort from the device.

According to the present invention, there is provided an intra-uterine contraceptive comprising an elongated strand having two free ends and a free shape as a coil in substantially one plane, the said strand being readily deformable to a straight line by application of force and always returning to the said coil shape when free of the said force. The device is sufficiently flexible that it can be straightened to a strand by slight force, but is rigid enough to return to its original shape immediately the force is removed, *i.e.*, it exhibits perfect elasticity. This permits the painless insertion of the device through the cervical canal through a cannula into the uterus where it will immediately regain its original shape on being pushed out of the cannula.

In the accompanying drawings:

Fig. 1 is a frontal section through the uterus showing an intra-uterine coil being placed in the uterine cavity;

Fig. 2 is a section through line 2-2 of Fig. 1;

Fig. 3 is a sagittal section through the uterus after placement of the coil of Fig. 1;

Fig. 4 is a perspective view of the coil in Figs. 1 to 3; and

Figs. 5 to 8 are perspective views of modified intra-uterine devices in accordance with this invention.

This invention as illustrated in the drawing shows the placement of an intra-uterine contraceptive coil and several alternative modified forms or shapes that the coil may have when free, although in each instance the coil has two free ends which may be pulled apart to form an elongated strand.

The various coils shown in Figs. 4 to 8 all have two free ends, are made of flexible material and thus may be lengthened into a straight strand by application of slight force. Moreover, many other shapes can be made having the same properties, it being within the scope of this invention to have a shape which is deformable to an elongated straight strand, but when free returns to define a shape in substantially one plane and of substantial area relative to the cross-section of the strand and preferably in which the total curvature is more than 360°, preferably at least 720°, the curvature being all in one direction as in coil 13, Fig. 4, in two directions as in Figs. 5, 6 and 7 or in several directions as in Fig. 8.

These coils may be formed of any inert material which exhibits the proper elasticity to reform the coil from a straight strand and is sufficiently inert to be considered safe for intra-uterine application. It is preferred to use plastics that have been tested and found inert to the human body such as polyethylene, polypropylene, polyethylene glycol terephthalate, polytetrafluoroethylene, polyvinyls or silicones. Metals coated with plastics or otherwise inert may also be used. It is preferred to use polyethylene and an excellent formulation has been found to be 80% polyethylene and 20% barium sulphate which are mixed as powders and then moulded into any of the various shapes by injection moulding under pressure. The barium sulphate is desirable, but not necessary, so that the position and presence of the coil may be noted at any time by radiology. Other radio opaque materials can, of course, be used.

As pointed out hereinbefore, the placement of the Graefenberg ring and other devices has created a difficult problem in the past. As will be appreciated from Fig. 3, the uterine cavity is largely a potential cavity, but does not exist as an actual cavity unless and until there is something within the uterus. Therefore, to avoid irritation and other inconveniences, it is essential that the primary

plane of the coil lie within the frontal plane of the uterus as is shown in Figs. 1 and 3. Thus, the placement of the coil assumes importance.

The placement of these coils is accomplished through a cannula 11 provided with an internal plunger 12, such cannulas generally having a diameter of less than 4.5 mm. if they are to be inserted painlessly through the cervical canal without dilation. Any of the coils of Figs. 4 to 8 (but preferably Fig. 4) are inserted into the cannula 11, and the end of the cannula then passed through the cervix 14 of the uterus 16 until the inner oval flange 17 contacts the cervix. This flange which is approximately 2 inches from the end of the cannula, is not necessary, of course, but serves as a convenient measurement to insure that the end of the cannula has passed sufficiently high into the uterine cavity 18 to permit discharge of the coil and also to indicate the plane of the coil to the operator.

The cannula, if metal, will generally be slightly curved in the sagittal plane for ease and convenience of insertion and if made of plastic will also be slightly forced into this position by the tendency of the coil to return to its curved shape and by the natural curve of the uterus and cervix. In any event, the coil will be ready to curve itself on release in the same plane as the curvature of the cannula and since it is highly desirable that the coil lie in the frontal plane, the cannula should be rotated 90° and then the plunger 12 placed in position (if not before) and pushed to force out the coil 13 which will then take the position shown in Figs. 1 and 3. It is also preferred that inner end 15 of the coil enter the cavity first (and outer end 20 last) because the free inner end makes little movement, whereas if outer end 20 enters first, there is relatively extensive movement of free end 20 which may rub against the cavity wall. Outer oval flange 19 is preferably provided near the exterior end of the cannula to aid the operator to determine the plane of the cannula at any time, but the inner flange 17 is far more important for this purpose. If the flanges were circular, they could be marked to indicate the cannula plane but the oval shape is convenient for both visual and tactile sensing.

For convenience in placement of the coil in a specific plane, it has been found desirable that the cannula and coil have an oval (or rounded rectangular) cross-section (see Fig. 2) rather than a circular one as the latter would permit rotation of the coil within the cannula and the operator would not know in which plane he was placing the coil. Thus if the long dimension shown in Fig. 2 is in the frontal plane of the original insertion of the cannula the operator by a mere 90° rotation, which will be obvious from observing flange 17 or 19, will be in a position to discharge the coil into the frontal plane in the manner shown in Figs. 1 and 3. In addition, the oval cross-section helps retain the curvature in the plane transverse to the shorter dimension.

One of the reasons that coil 13 of Fig. 4 is preferred is the fact that it is very adept at being positioned in the frontal plane, inasmuch as the direction of curvature never changes while the coil is being discharged. However, the other patterns shown do change direction of curvature which means rotation of the entire unit discharged prior to the change. Thus these patterns are more apt to become caught in the uterine walls on discharge from the cannula without taking up the desirable frontal plane and this may thereafter cause irritation for the patient. Thus the simple coil 13 of Fig. 4 has been found highly satisfactory for easy insertion into the uterus

In view of the fact that the largest cannulas for cervical insertion without dilation are not more than 4.5 mm. in their longest transverse dimension, the longest transverse dimension of the coil should not be more than 4 mm. and it has been found, in fact, that a preferred dimension is about 2.25 by 1.25 mm. and 11 cm. long, having a diameter or largest dimension across the coil of about 2.5 cm., the preferred range being 2 to 3 cm.

As will be noted, the coil of Fig. 6 is provided with thickened areas 21 which aid the elastic properties of the coil. All of the coils are preferably provided with thick ends (15 and 20 on Fig. 4) to prevent piercing or irritation of the uterine wall.

These various designs shown in Figs. 4 to 8 have been inserted in various patients for periods of several months and have resulted in complete absence of pregnancies with no side effects, except for slight cramps and spotting for a few days after insertion and occasionally some pre- and post-menstrual staining for a few months. The preferred time for insertion is the end of the second week of the menstrual cycle, *i.e.*, around ovulation time and not sooner than two cycles after a delivery or abortion.

The coils are easily and painlessly removed by inserting a hook through the cervix, securing the coil and pulling it back through the cervix. The coil can be left in the uterus for several years and should be removed only if there is a disturbance in the uterus, after menopause, or a decision to resume exposure to pregnancy.

When the word "coil" is used in the specification and claims, it is intended to cover any device, such as shown in Fig. 4 to 8, which are formed from a strand having two free ends, but is curved more or less

continually in one or more directions.

WHAT WE CLAIM IS:—

1. An intra-uterine contraceptive comprising an elongated strand having two free ends and a free shape as a coil in substantially one plane, the said strand being readily deformable to a straight line by application of force and always returning to the said coil shape when free of the said force.

2. A contraceptive as claimed in claim 1 wherein the curvature of the coils exceeds 360°.

3. A contraceptive as claimed in either of the preceding claims wherein the strand is made of metal.

4. A contraceptive as claimed in either of claims 1 or 2 wherein the said strand is of moulded plastic.

5. A contraceptive as claimed in claim 4 wherein the strand is moulded polyethylene.

6. A contraceptive as claimed in claim 4 wherein the strand is moulded polyethylene with barium sulphate incorporated therein.

7. A contraceptive as claimed in any of claims 1 to 5 wherein the strand is radio-opaque.

8. A contraceptive as claimed in any preceding claim wherein the said coil is curved in one direction only.

9. A contraceptive as claimed in any of claims 1 to 7 wherein the said coil is curved in one direction only for at least 720°.

10. A contraceptive as claimed in any preceding claim wherein the transverse section of the said strand has one dimension greater than the other.

11. A contraceptive substantially as described with reference to any of the figures of the accompanying drawings.

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