

[54] **INTRA-UTERINE DEVICE**
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Yorkshire, England
[22] Filed: **Oct. 30, 1970**
[21] Appl. No.: **85,395**

[30] **Foreign Application Priority Data**
Nov. 4, 1969 Great Britain 54,094/69

[52] U.S. Cl. **128/130**
[51] Int. Cl. **A61f 5/46**
[58] Field of Search..... 128/130, 127, 131,
128/128, 129; 24/10 PB, 201 C, 208;
277/204, 222; 49/482, 498; 285/321, 340; 215/37

[56] **References Cited**
UNITED STATES PATENTS
3,659,597 5/1972 Wolfers..... 128/130

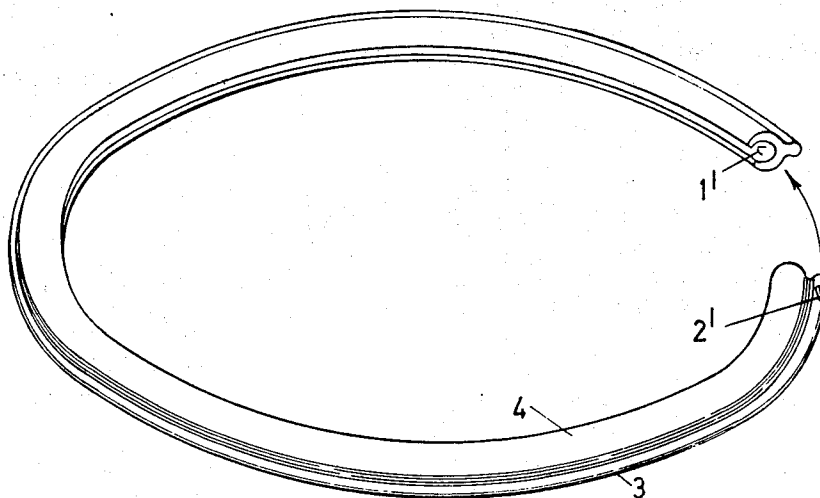
3,518,727	7/1970	Eberle et al.....	24/16 PB
1,100,182	6/1914	Hettinger.....	277/204
2,827,320	3/1958	Kane.....	288/20
3,553,793	1/1971	Long et al.....	24/16 PB
3,200,815	8/1965	Margulies.....	128/130
3,382,869	5/1968	Rigney et al.....	128/130

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[57] **ABSTRACT**

A post-partum intra-uterine contraceptive in the form of a uniform profiled strip with complementary cross-sectional areas which can interlock so that the strip can be coiled with continuous turns slidable along one another to accommodate uterine involution.

6 Claims, 13 Drawing Figures



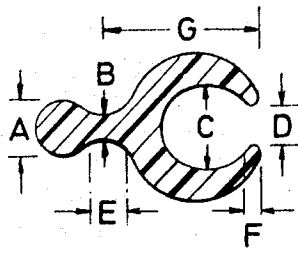


FIG. 1.

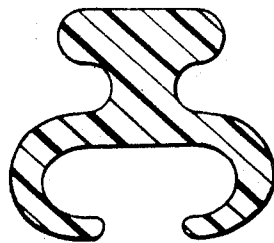


FIG. 4.

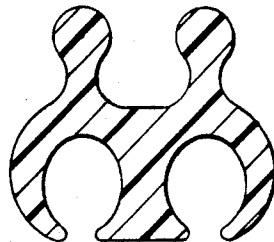


FIG. 5.

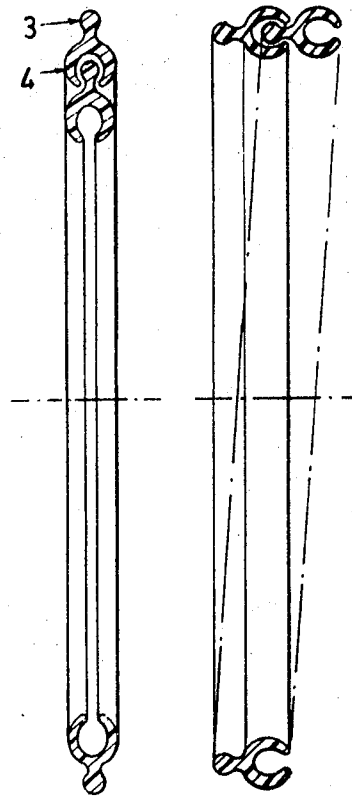


FIG. 2.

FIG. 3.

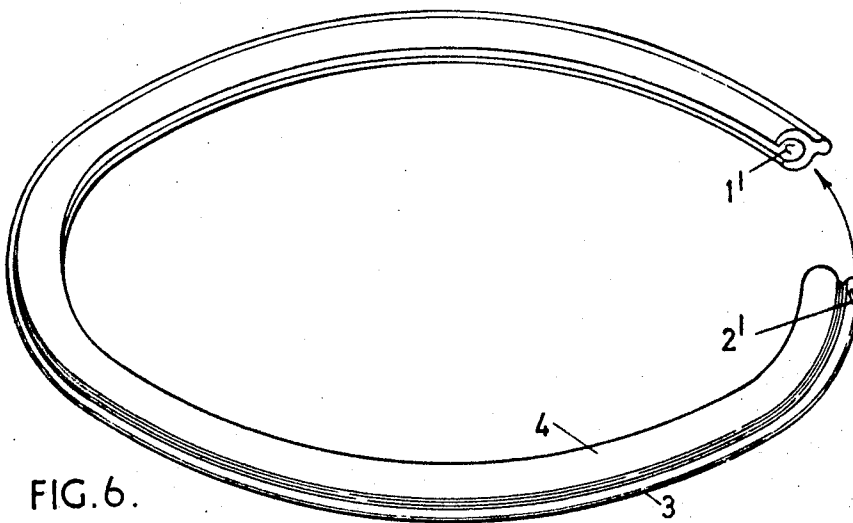


FIG. 6.

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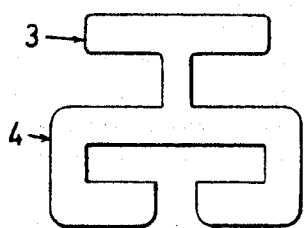


FIG. 7a.

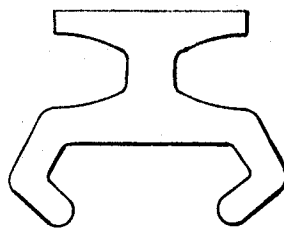


FIG. 7b.

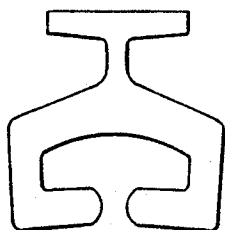


FIG. 7c.

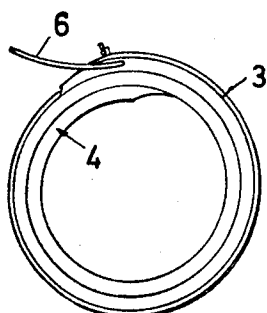


FIG. 9b.

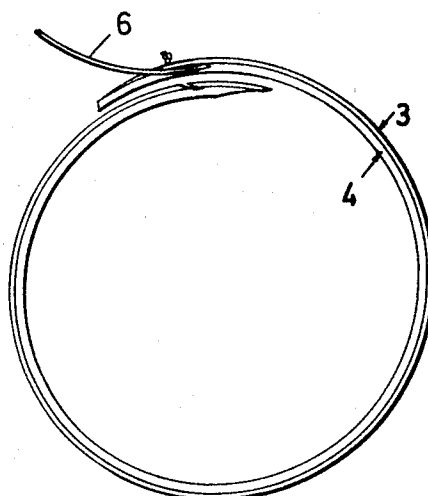


FIG. 9a.

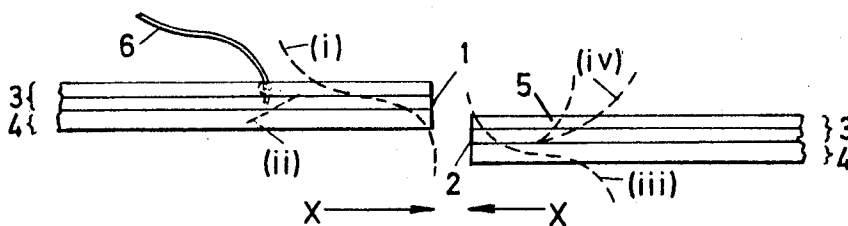


FIG. 8.



FIG. 10.

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INTRA-UTERINE DEVICE

This invention relates to an intra-uterine contraceptive device capable of being inserted in the uterine cavity of the human female in the early puerperium.

In many developing countries the only contact which a majority of women have with trained medical personnel is at the time of childbirth. It would clearly be of advantage therefore if an intra-uterine contraceptive device could be inserted at that time after delivery of the child, especially since a psychological effect of labour and delivery is to heighten suggestibility and feelings of dependence so as to favour acceptance of contraceptive service.

Although there have been some proposals to use known commercial contraceptive devices in this fashion, these have not found favour since there is a high expulsion rate (20 - 40 percent) as the parturient uterus changes in size and shape in the weeks following delivery.

There is known to the applicants a proposal to provide a contraceptive device the object of which is to fit the parturient uterus and to accommodate gradually the involutionary process. This device is in the form of a tube of flexible material coiled with one end of the tube engaged and telescopically slidable in the other end of the tube, the device being of size shape and flexibility as to be insertable into the human uterine cavity so as to abut the lateral walls and fundus of the uterus, and the coefficient of friction of the material of the device being low enough to ensure that as the uterine cavity contracts the inner end of the tube will travel further into the lumen of the tube so that the device will remain the correct size in any stage of uterine involution. Certain preferred features of such a proposed device are also known to the present applicants; thus it is preferred for the inner periphery of the tube to have a continuous slot to allow the escape of any undesirable fluids such as unclotted blood. It is also preferred for the tubes to be a thin-walled tapering tube and for the slot to occupy about one quarter of its circumference. Moreover, it is preferred that the tube includes some form of tongue and cooperating notch to prevent it from being completely uncoiled.

The present applicants make no claim to the invention as described in the preceding paragraph involving the use of such a tube, and are concerned specifically with a device fulfilling the same functions but having a different construction.

The present invention therefore provides an intra-uterine contraceptive device comprising a longitudinally extending flexible member of a cross-section uniform over essentially the whole length which cross-section exhibits complementary areas which are capable of mechanical interaction to maintain contiguous interconnection of portions of the member as these are slid progressively along each other in either direction in relation to the length of the material to provide a visibly spiral or helical configuration with interconnected contiguous turns.

It is more particularly envisaged to provide for this purpose a longitudinally extending strip or like body of material,

a. of a uniform cross-section which has (1) at least one re-entrant cavity and (2) at least one complementary projection of shape and dimensions capable of fitting and being retained within said cavity,

b. the whole having an elastic memory such that the position of minimum stress occurs when the member is in the form of a loop,

c. the material and cross-section of the strip or like body being such as to ensure that when a projection or projections is brought into a corresponding cavity or cavities by looping the material it or they can readily be slid along within the cavity or cavities to coil the member into a spiral or helical coil,

d. the member being of such a size shape and flexibility that when looped it can be deformed to a configuration insertable into the human uterine cavity and thereafter can adopt a configuration so as to abut the lateral walls and fundus of the uterus.

In particular, the invention is concerned with such a device formed of a strip of synthetic material, preferably about 7 to 11 inches long, and having in cross-section a projection; complementary retaining jaws with an internal re-entrant cavity somewhat larger than said projection, but a jaw opening somewhat smaller than said projection; and a neck between the projection and the jaws somewhat narrower than the jaw opening and longer than the thickness of the jaw extremities. The effect of these various size relationships is to provide a loose but secure fit. The present invention is concerned with (i) the flexible member which has been programmed into a looped form, (ii) with such a loop of material wherein the projection is engaged within the jaws and the loop is closed (iii) with such a loop of material which has been formed into a helix or, preferably, a spiral by progressively reducing the overall diameter of the loop and allowing or causing the projection to slide along within the cavity and (iv) with such a loop occupying a configuration in which it can be inserted into the human uterine cavity. It will be practical to provide a stop to prevent the two ends of the loop from becoming freed in use.

As is conventional in this field, the device may incorporate radio-opaque or magnetically detectable material and be formed from non-toxic thermoplastic synthetic material or the like which can be sterilised before, during or (preferably) after packaging. Suitable plastics will be capable of being sterilized by one or more of steam, chemical or radiation sterilisation and include polypropylene, nylon, polyethylenes or especially ethylene/vinyl acetate copolymer (EVA) which is less stiff than the others (and so lends itself more readily to being formed into a coil or loop) and is suitable for electron or gamma irradiation.

So that the loop does not become disengaged in use it will be preferable to provide complementary retaining means one at or towards each end of the longitudinally extending member to hold the loop closed. For instance, the retaining means may be such that a catch is formed at or towards one end of the member and a complementary flap at or towards the other end.

It is not generally suitable to insert the device as in the expanded form or as a simple tightly coiled loop, since in practice the overall width of the device as inserted should be less than one-half inch. Thus, the device can be folded back on itself in several folds, or possibly can be a single flattened loop, or can be inserted in a twisted configuration. The device should normally be inserted via the vagina, i.e., not by surgical operation unless after caesarean section and the use of an introducer utilising the effect of a plunger within the suitably shaped tube is envisaged.

Thus, an aspect of the invention consists in a device as described above constrained into the tube of an introducer especially when the introducer tube is disposable and of not more than one-half inch outside diameter. Also, the sterile packaged loop forms an aspect of the invention.

The invention will be further described with reference to the accompanying drawings, wherein:

FIG. 1 is a cross section of a typical flexible strip of material according to the invention;

FIGS. 2 and 3 show in cross section a spiral coil and a helical coil of such a strip respectively;

FIGS. 4 and 5 show alternative cross sections of flexible strip;

FIG. 6 shows one possible stop arrangement for the device;

FIG. 7a shows a die orifice and FIGS. 7b and 7c of extrudate produced from such a die orifice;

FIG. 8 shows how the ends of the loop may be kept inter-engaged;

FIGS. 9a and 9b show the loop, in unengaged and a tightly coiled form respectively;

FIG. 10 shows an introducer which can be used to introduce the loop into a post-partum uterus.

FIG. 1 shows a flexible uniform section of a shape which will interlock with and slide along itself, progressively reducing its diameter, as a spiral or helical coil. This will be appreciated from the examination of the Figure, where the dimension A is sufficiently less than dimension C and dimension B is sufficiently less than dimension D to permit easy sliding, even when the strip is curved to a tight radius. For example, if the strip is 7 inches long it is possible to coil it into a coil of overall diameter as small as 1 inch. It will also be noted from the drawing that dimension A is greater than dimension D to prevent the projection from becoming disengaged from the jaws, and that dimension E is greater than dimension F further to facilitate easy sliding. Dimension G is for example about one-sixteenth of an inch.

As will be seen from FIGS. 2 or 3, the coil can be a spiral coil or a helical coil. As a consequence of the shape shown in FIG. 1 a flat spiral configuration is most likely to be adopted. To ensure ready coiling it will be preferred to provide some form of heat and/or cooling treatment upon the extruded section while it is bent into the desired configuration. The spiral of FIG. 2 appears to be preferable in use.

FIGS. 4 and 5 show alternative cross section of flexible strip, FIG. 4 showing a cross section with a relatively wide projection and FIG. 5 showing a cross section having two projections and two corresponding pairs of jaws.

FIG. 6 shows a possible form of stop which prevents the device becoming uncoiled. The oblique cuts 1' and 2' (only single cuts are shown but several of each can be provided) interengage and prevent uncoiling. Of course, other stop arrangements such as a decrease in radius of the jaws and increase in radius of the projection possibly effected after engagement, can be envisaged.

In a specific example, ethylene/vinyl acetate copolymer loaded with 20 percent of barium sulphate as a radio-opaque filler was extruded on a Bone Brothers extruder with zone 1 at 130° C, zone 2 at 180° C and the extrusion die at 200° C. Screw speed was 48 r.p.m. and the extrusion was hauled off at 80 feet per minute

through a water bath 5 feet long at a die-bath separation of 1½ inches.

With a die shaped as shown in FIG. 7a, the die slot being ¼ inch deep, and other dimensions being (in inches) A six-sixty fourth B eight six-fourth C twenty-eight sixty-fourth D twelve sixty-fourth D thirty three sixty-fourth this embodiment produced a continuous length of extrudate where the cross-sectional dimensions (because of draw-down) were one-third of the die dimension. The shape could be varied to some extent if the extrudate were drawn into the water bath at an angle to the die extrusion axis; drawing at an angle away from the open jaws tends to open the jaws (FIG. 7b) which is generally preferable as facilitating sliding interengagement) while drawing at an angle on the side of the jaws produces a section as in FIG. 7c. The shape could also be varied to some extent by changing the die-bath separation.

Lengths of the extrudate were wrapped around glass cylinders of 2 inches diameter and heat treated at about 80° C for 90 minutes, then cut into one-turn lengths. In commercial production a heated rotating mandrel could be utilised.

To provide a suitable retaining means suitable cuts were made at each end, bearing initial end faces 1 and 2 as shown in FIG. 8. The "spine" region is shown at 3 and the "jaws" region at 4. Cut (i) generally tapers one end away from the top of the spine; Cut (ii) from inside the jaws forms an internal flap extending transversely across the inner surface of the jaws opposite the mouth and part-way up into the spine; cut (iii) tapers the other end away from the jaws; and cut (iv) forms a ratchet 5 to catch in the flap. The two ends could then be interengaged as shown by arrows X.

It will be appreciated that the device could be made, with the retaining means already formed, by injection moulding of the member in substantially looped form. Since the material is flexible the loop could possibly be drawn out of the mould from one end, but it will be generally more convenient to locate the plane of the loop at the parting surface of the mould with a removable metal insert (inside the loop as it is being moulded) from which the loop can be peeled off after moulding. One or more loops can be made at a time by this method.

A nine-inch surgical thread was passed through the spine and knotted, at a position where it would tend to unwind the loop when pulled, in order that the device can be removed as an unlooped length of material.

Although the body fluids will exert a lubricating effect, the ease of sliding engagement was in this embodiment further facilitated by the application of a known non-toxic silicon lubricant fluid (for example that sold by Midland Silicones under the trade designations MS 200, of viscosity 12,500 centistokes) to a surface coating of about 1 mg/cm².

FIG. 9a shows a typical device according to the invention with the end adjacent but not inter-engaged but prior to being coiled to its maximum extent, while FIG. 9b shows the device in tightly coiled form.

FIG. 10 shows a curved polypropylene introducer tube 7 of outside diameter one-half inch and length 11 inches having a slight overall curve (about 5 feet radius) and an enlarged end 8. This is used in conjunction with an anodised aluminum rod 9 having a hook at one end 10 and a loosely fitting piston end 11. Alternatively

the rod could be a rigid synthetic plastic material e.g. polyamide.

The I.U.C.D. according to the invention is conveniently packed with ends interengaged in a polyethylene/cellophane envelope for radiation sterilization, and it will be found convenient to provide a medical kit consisting of the packed I.U.C.D., the introducer tube and rod and a disposable surgical glove or gloves.

In use the pack is opened, and the rod 9 placed in tube 8 with the hook end 10 protruding from the enlarged tube end 8. The hook 10 is engaged with the loop at a point remote from the thread connection and is used to remove the loop from its pack and draw it into, and to the other end of the tube. Then the hook is freed, the said other end of the tube is inserted into the cervix and the loop is pushed out of the tube into the uterus by the piston end of the rod, thereby leaving the thread trailing. When the tube is removed the face end of the thread therefore lies in such a position as to provide an indication that the loop is in place, and a means for removing the loop when desired. It will be appreciated that the enlarged end 8 ensures that no attempt is made to draw the loop into the tube and then push it out of the same end; this would generally speaking deform and probably disengage at the ends. In practice, anyone using this tube would always use the enlarged end to draw the loop, and never use the enlarged end for insertion into the cervix.

I claim:

1. An intra-uterine contraceptive device comprising an elongate flexible member of a predetermined uniform cross-section disposed in a continuous coil wherein one side in each convolution confronts the opposite side in the adjacent convolution and wherein the one side contains spaced parallel grooves of a predetermined configuration having restricted openings in communication therewith at said side and the opposite side has spaced parallel ribs complementary in configuration to the grooves disposed through said restricted openings, said grooves being of larger cross-section than said ribs such that there are clearance spaces of uniform width between the interior surfaces of the grooves and the exterior surfaces of the ribs which per-

mit the interengaged lengths thereof to move longitudinally relative to each other and hence to contract and expand with changes in the dimensions of the uterine cavity, said member being prestressed to take up a closed coiled configuration in which the external convolution is at least as great as the maximum dimension of the uterine cavity.

2. An intra-uterine contraceptive device adapted to be disposed in the uterine cavity comprising an elongate flexible member of a predetermined uniform cross-section disposed in a continuous coil of overlapping convolutions such that one side of each convolution confronts the opposite side of the adjacent convolution and wherein the one side contains a continuous groove of predetermined internal configuration having a restricted opening in communication therewith at said side, and the other side has a continuous rib complementary in configuration to the groove disposed through said constrictive opening, said rib being slightly larger in cross-section than said restricted opening and appreciably smaller in cross-section than said groove such that there is an appreciable clearance between the interior surface of the groove and the exterior surface of the rib throughout the interengaged lengths thereof which permits longitudinal movement of the rib within the groove in either direction, and said member being elastically stressed to maintain its contact with the walls of the uterine cavity within which it is confined with changes in the dimensions of the uterine cavity.

3. A device according to claim 2, wherein the convolutions are arranged in a spiral.

4. A device according to claim 2, wherein the convolutions are arranged in a helix.

5. A device according to claim 2, comprising interengageable means on the confronting sides of the device near the ends cooperable to prevent complete uncoiling of the flexible member.

6. A device according to claim 2, wherein there is a cord attached to the end of the external convolution operable to unwind the device when pulled.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,744,489 Dated July 10, 1973

Inventor(s) Graham Donald Munro

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Please change the assignee's name from "T.J. & Nephew Limited" to --T.J. Smith & Newpew Limited--.

Signed and sealed this 29th day of January 1974.

(SEAL)
Attest:

EDWARD M. FLETCHER, JR.
Attesting Officer

RENE D. TEGTMEYER
Acting Commissioner of Patents

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,744,489 Dated July 10, 1973

Inventor(s) GRAHAM DONALD MUNRO

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

On the cover sheet [73], the assignee should read
as follows: -- T. J. Smith & Nephew Limited, Hull,
Yorkshire, England -- .

This certificate supersedes Certificate of Correction
issued January 29, 1974.

Signed and sealed this 13th day of August 1974.

(SEAL)
Attest:

MCCOY M. GIBSON, JR.
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents