

United States Patent

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[54] INTRAUTERINE DEVICE

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[51] Int. Cl.....A61f 5/46

[58] Field of Search.....128/128-131, 270

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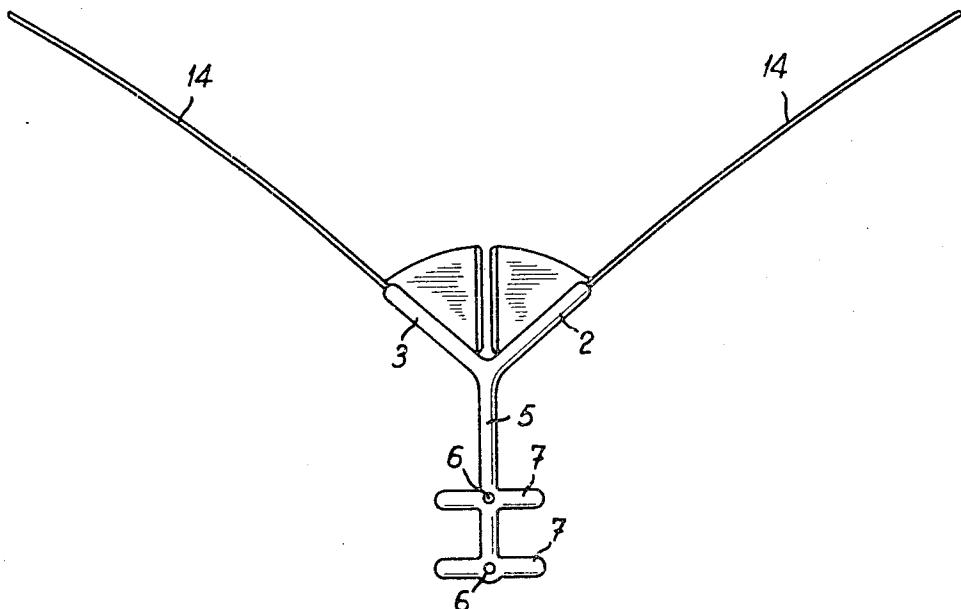
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[57]

ABSTRACT

The invention concerns a gynaecological device for insertion in a woman's womb, i.e., an intrauterine device. This device includes a Y-shaped flexible support means, the branches of which are each provided with a fanlike, inwardly extending membrane covering at least part of the space between the two branches. This intrauterine device has the advantage of enabling its part which penetrates into the uterus to unfold after introduction therein so as to cover up practically the whole internal wall of the uterus.

20 Claims, 8 Drawing Figures



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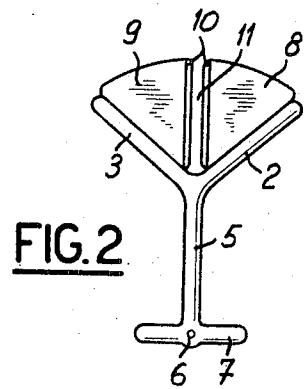
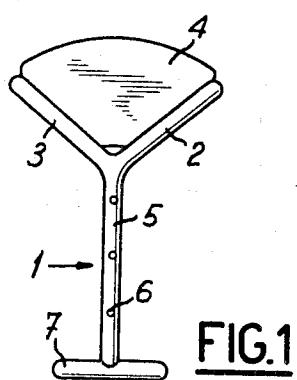


FIG.1

FIG.2

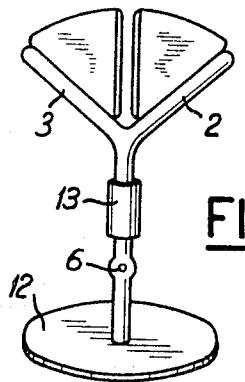


FIG.4

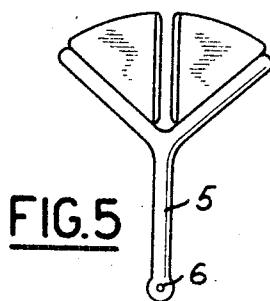


FIG.5

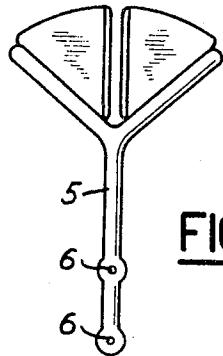


FIG.6

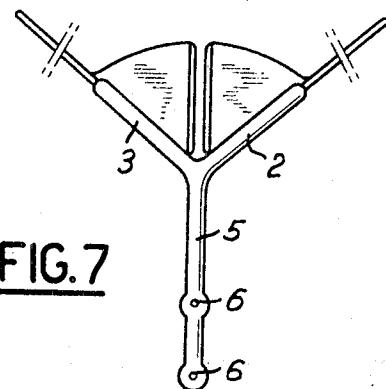


FIG.7

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FIG. 3

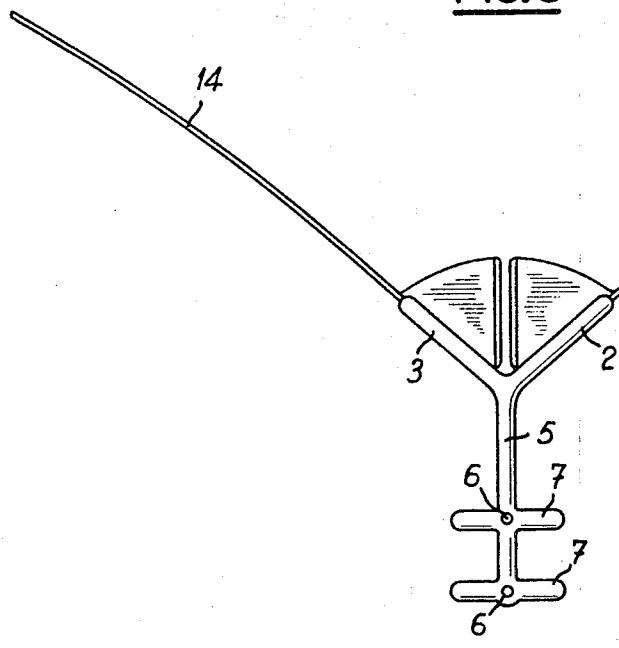
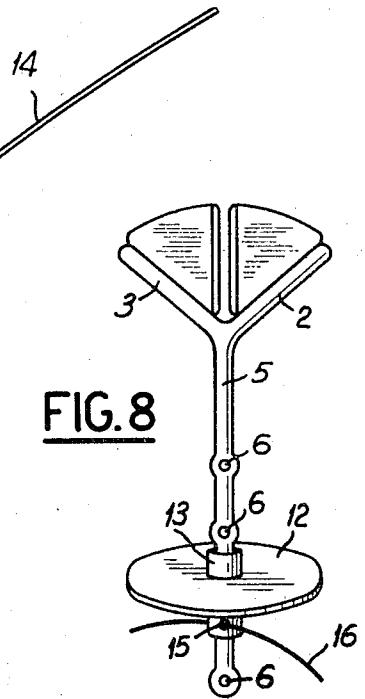


FIG. 8



INTRAUTERINE DEVICE

Gynaecological devices, so-called intrauterine devices are increasingly used, following surgery, in cases of polypectomy, curettting, therapeutic abortion, etc. They are also used as feminine contraceptives provided to avoid the nesting of fecundated ovules in the uterus.

The gynaecological device provided for introduction into a woman's womb according to the invention, has the advantage of enabling its part which penetrates into the uterus to unfold after introduction therein so as to cover up practically the whole internal wall of the uterus.

The device is characterized in that it includes a Y-shaped flexible support, the branches of which are each provided with a fanlike, inwardly extending membrane covering at least part of the space between the two branches.

The attached drawing shows by way of example three embodiments of the device according to the invention and variants thereof.

FIG. 1 is a front elevation of the first embodiment.

FIG. 2 is a view similar to FIG. 1 of the second embodiment.

FIGS. 4, 5, 6 and 8 are variants of the second embodiment.

FIGS. 3 and 7 are respectively views of the third embodiment and of a variant thereof.

The device shown in FIG. 1 includes a Y-shaped flexible support 1 the branches 2 and 3 of which are each secured to one of the edges of a fanlike membrane extending between the said branches 2 and 3. The leg 5 of the Y is provided with spaced holes 6 which may receive a thread and with a crossbar 7 extending, at its lower end, in the same plane as the branches 2 and 3.

This device is preferably made by injection molding of polyethylene or other soft plastic material including as an X-ray opacifier a barium sulfate filler.

The use of the device is as follows:

After curetting, therapeutic abortion, intrauterine specimen taking, excision of polyps etc., the part of the device provided with membrane 4 may be introduced into the uterus by folding together, by means of surgical pliers, the branches 2 and 3 thereof so as to permit their introduction into the cervix and their subsequent unfolding within the uterus itself. According to the length of the uterine duct it may be possible either to insert the whole device into the uterus, the crossbar 7 bearing then against the edge of the cervix in order to avoid that the device penetrates more deeply therein, or to shorten the leg 5 of the Y from the bottom thereof in order to avoid that the lower end of the leg 5 of the Y protrudes exaggeratedly into the vaginal cavity once the device has been introduced into the uterus. In this case it is preferable to provide the hole 6 most distant from the branches 2 and 3 of the Y with a thread permitting later on an easy extraction of the device. Alternatively the device may be produced in three sizes: small, medium and large.

Provided the device is left at least 10 consecutive days inside the uterus, following the above-mentioned types of surgery, one avoids the occurrence of adhesions between the anterior and posterior walls of the uterus in view of the insertion between them of membrane 4.

Risks of sterility, oligomenorrhea, amenorrhea etc., following such surgery are therefore prevented.

After Strassmann's operations or the excision of fibromyomas, the device may be introduced from above, that is through the cut wall of the uterus before it is restitched. In this case the crossbar 7 of the device must be taken off in order to permit the introduction of leg 5 into the uterine duct from above and one usually provides one of the holes 6 with a thread in order to permit the extraction of the device from the womb through the cervix 10 or 50 days later.

The device thus inserted into the womb avoids that, when stitching the cut wall thereof, one stitches the anterior wall to the posterior wall, since the needle is deflected by membrane 4 of the inserted device. It further avoids adhesions which may occur during the healing period and maintains the womb in shape during that time. It further avoids that adhesions which were excised by surgery are reformed.

The embodiment of FIG. 2 and its variants of FIGS. 4, 5 and 6 are more advantageous when introducing the device into the womb through the cervix. The membrane 4 is replaced therein by two half membranes 8 and 9 respectively attached to branches 2 and 3 of the Y by one of their edges and provided along their opposed free edges with bulging stiffening ridges 10 defining between them a slit 11 coaxial with leg 5. This makes it possible to use a single device for every size of uterus since the two half membranes 8 and 9 overlap when branches 2 and 3 are pressed together in the womb. It makes also the introduction of the device into the uterus easier and avoids an exaggerated crumpling or a deterioration of membranes 8, 9 as a result of this crumpling, which is frequently the case for the membrane 4 of FIG. 1. The other parts of the device remain unchanged and it may be provided at the bottom of leg 5 with a crossbar and a hole 6. It may be provided with only one hole 6 (FIG. 5) or two holes 6 (FIG. 6) in locations of leg 5 showing a bulge.

In the variant of FIG. 4 the crossbar is replaced by an oval plate 12, the diameters of which are at a right angle with leg 5, in order to secure a better bearing on the edge of the cervix. A tubular sliding block 13 may further be provided to help folding the branches 2 and 3 together for their introduction into the cervix. Thereafter the sliding block 13 may be slit longitudinally and taken off by means of pliers.

In the sophisticated variant of FIG. 8, the oval plate 12 instead of being fastened to the bottom of leg 5 as shown in FIG. 4, is secured at a right angle to a tubular sliding block 13 traversing the oval plate 12 concentrically. Sliding block 13 is further provided with a crosswise perforation 15 which may be positioned in line with any one of holes 6 of leg 5 to permit its fastening at the corresponding height on leg 5 by means of a nylon thread 16 engaging the said perforation 15 and hole 6 and tied up around sliding block 13. Any part of leg 5 protruding underneath sliding block 13 may then be severed. That sliding block 13 may be used initially to help folding up to the branches 2 and 3 of the device for their introduction into the cervix and subsequently to adjust the position of oval plate 12 at the desired height on leg 5 depending on the size of the cervix. The length of leg 5 in this case is preferably of 5 to 10 cm., in order to facilitate the introduction of the device into the cervix through the vagina, any excess length of leg 5 being severed thereafter.

It is evident that in addition to their stiffening function the bulging ridges 10 avoid any risk of cutting the walls of the cervix when introducing the device or extracting it therethrough.

Preferably membranes 4, 8 and 9 have a thickness of 0.3 mm. The leg 5 is preferably cylindrical, 2 to 5 cm. long (except in the variant of FIG. 8) and 2.7 mm. thick. The crossbar 7 is preferably 2 to 3 cm. long and 2.7 mm. thick. The branches 2 and 3 are preferably 2 to 2.5 cm. long and 2.7 mm. thick; they form preferably between themselves an angle of 75° to 120°.

In the embodiment of FIG. 3 and its variant of FIG. 7 each branch 2 and 3 of the device is provided at its free end with a filamentary or flagellate extension 14 made of the same material and preferably 12 cm. long and 1 mm. thick. These extensions are to be introduced into the Fallopian tubes when

60 performing a Strassmann operation with or without salpingostomy or implantation etc. so as to avoid occlusion of the Fallopian tubes during the healing period. Preferably in this case the variant of FIG. 7 is used and after surgery the extensions 14 are inserted into the Fallopian tubes or their equivalent obtained by salpingoplasty or salpingostomy to avoid the formation of internal adhesion which may block or reblock them.

65 Thereafter leg 5 is inserted into the cervix from the inside of the womb, while membranes 8 and 9 are unfolded between the front and back walls of the womb to avoid, as with the device of FIGS. 1 or 5 the formation of the intrauterine adhesions.

Prior to introducing leg 5 into the cervix, one of its holes 6 is provided with a nylon thread permitting subsequently the extraction of the device through the vagina.

Since it is easy to cut off unwanted parts of the device, the 75 embodiment of FIG. 3 may be considered as a universal in-

trauterine device which may be used in surgery for insertion after a laparotomy of the womb (the two crossbars 7 are then cut off and the leg 5 may further be shortened) or as a contraceptive to be inserted from the vagina through the cervix (the extensions 14 and one of the two crossbars 7 are then cut off).

Obviously one could provide the device of FIG. 3 with three crossbars 7 to permit to adapt the length of leg 5 to three dimensions of the uterus (and three holes 6 at the intersection of the said crossbars 7 with leg 5) or else to substitute oval plates such as 12 (see FIG. 4) for these cross-bars 7 and provide leg 5 with a sliding block 13 to facilitate the insertion of the device into the womb from the vagina through the cervix.

Preferably the polyethylene chosen should have a sufficiently high softening temperature to permit sterilization of the device in boiling water before its use. However, a sterilization by means of antiseptic surgical liquids or gamma rays for example is preferred.

Preferably the insertion through the vagina is made under general anesthesia after dilatation of the cervix by means of Hegar bougies up to No. 7. The branches of the Y of the device are pressed together by means of Knight's forceps for example and the device is inserted into the womb through the cervix up to the first bulge or crossbar of leg 5. The forceps is then withdrawn and branches 2 and 3 of the device unfold inside the womb by means of their own elasticity in order to insert membrane 4 or membranes 8 and 9 between the front and back wall of the womb. Should a deeper penetration be required the device may be pushed further forward up to the second bulge, crossbar 7 or oval plate 12. Leg 5 is of course curtailed in an appropriate manner for each particular case.

The device may remain inside the womb without major harm up to 1 year since it is well tolerated by the organism.

I claim:

1. An intrauterine device comprising a Y-shaped flexible support having a pair of branches, each of said branches having an inwardly extending membrane covering at least a part of the space between the two branches, the membranes being separate from each other.

2. A device as claimed in claim 1, and a reinforcing flange along the free edge of each membrane.

3. A device as claimed in claim 1, the support having a cen-

tral leg having at least one hole therethrough.

4. A device as claimed in claim 3, said hole being located in the free end of said leg.

5. A device as claimed in claim 3, and a thread extending through said hole for retrieving said device.

6. A device as claimed in claim 1, said support having a central leg having at least one crossbar thereon.

7. A device as claimed in claim 6, said crossbar being disposed at the free end of said leg.

10 8. A device as claimed in claim 1, said support having a central leg and having a plate carried by said leg at a right angle to said leg.

9. A device as claimed in claim 1, said branches extending beyond the membranes in flexible filamentary extensions.

15 10. A device as claimed in claim 9, said extensions being substantially thinner than said branches.

11. A device as claimed in claim 1, said support having a central leg and a sliding block slidably mounted on said leg to fold together the branches of the support.

20 12. A device as claimed in claim 3, and a tubular sliding block slidably mounted on said leg to fold said branches toward each other, and a plate secured to said tubular sliding block at a right angle to said leg, said tubular sliding block having a crosswise perforation that may be aligned with said hole to fix the position of the sliding block and plate along said leg upon insertion of a member through the holes of said leg and tubular sliding block.

25 13. A device as claimed in claim 12, there being a plurality of said holes through said leg for selective positioning of said tubular sliding block and plate along said leg.

14. A device as claimed in claim 8, said plate being oval.

15. A device as claimed in claim 12, said plate being oval.

16. A device as claimed in claim 1 made of soft plastic material.

30 17. A device as claimed in claim 16, said material being polyethylene.

18. A device as claimed in claim 16 in which said material includes a filler of barium sulfate.

19. A device as claimed in claim 1 of molded construction.

40 20. A device as claimed in claim 1 of injection molded construction.

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