

994,160



PATENT SPECIFICATION

DRAWINGS ATTACHED

994,160

Date of Application and filing Complete Specification: July 6, 1962.

No. 26020/62.

Application made in United States of America (No. 191,674) on April 24, 1962.

(Patent of Addition to No. 986,000 dated Oct. 24, 1961.)

Complete Specification Published: June 2, 1965.

© Crown Copyright 1965.

Index at acceptance:—A5 RB35

Int. Cl.:—A 61 f 5/46

COMPLETE SPECIFICATION

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 an intra-uterine birth control device that may be painlessly introduced through the cervix, although having a diameter *in situ* considerably larger than the normal cervical canal and is an improvement in or modification of the invention set forth in co-pending patent application No. 38046/61 (Serial No. 986,000).

It is an object of the present invention to improve the earlier device by adding an integral follower thereto which extends from the cervix through the cervical canal into the vagina for a short distance, where it may be sensed with the fingers through the vagina, its position determined and the entire unit easily removed if desired. The present device is inserted in the same manner as the earlier ones.

In the accompanying drawings:

Figure 1 is a perspective view of a coil with a sensing follower;

Figure 2 is a frontal section through the uterus showing the coil of Figure 1 being placed; and

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

The improved embodiment of the invention shows a coil 25 similar to coil 13 of Figure 4 of the parent specification, except that the leading end 26 of coil 25 is of a slightly reduced diameter and the trailing end has attached thereto a follower 27 which has a plurality of enlarged areas or beads 29

spaced along its trailing end zone 28. The reduced diameter of leading end 26 aids the unit to start curling immediately on its release from the cannula.

The coil has two free ends, is made of flexible material and thus may be lengthened into a straight strand by application of slight force. It preferably has a total curvature of more than 360°. The coil may be curved in one direction only for at least 720°.

The coil 25 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 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 shown in Figure 2, a cannula 30 is longer and a plunger 31 about the same length as the corresponding elements 11 and 12 in Figure 1 of the parent specification. The longer cannula 30 is required to house the additional length of follower 27 therein. The leading end of cannula 30 is placed similar to 11 and the plunger 31 pushed to its limit as shown, at which point coil 25 is within the uterine cavity 18, but the follower 27 remains in the cannula. The cannula is then removed and follower 27 and beads 29 (both of less diameter than the trailing portion of coil 25) assume the position in the cervical



improved

[Price 4s. 6d.]

canal with the beads extending partly out into the vagina. The extra beads are severed to leave the placement of the unit as shown in Figure 3.

As shown in Figure 3, when coil 25 is in position in the uterus, the coil portion occupies the same position as coil 13 in Figure 3 of the main patent but the follower 27 extends through the cervical canal of the uterus with the beads or thickened areas 29 being positioned near the opening of the cervix. In fact, since the cervical canal is of variable length in different patients, the coil of Figure 1 has an elongated zone 28 of spaced beads 29, but after positioning the coil in the uterus, the extra length of beads may be severed so that only one or two beads are extending into the vagina, the follower being pliable and harmless.

This follower serves three functions, the first and most important being that the presence and relative position of the coil within the uterus may readily be determined with the fingers by merely feeling for and counting the beads. This is important because the primary fault of coil 13 of the parent specification has been its passage from the uterus on a few occasions without the knowledge of the patient.

The second important function is that the entire coil can be readily removed by merely grasping beads 29 and pulling the coil from the uterus by hand and thus avoiding the insertion of a hooked device into the uterus as is required with coil 13 of the main patent.

A further function of the follower is dependent upon the fact that the unthickened portion of the follower is not round, but is oval or flat-shaped. Thus, by feeling the follower, the doctor will immediately know whether the coil 25 is laying in the proper plane as shown in Figure 2 or whether it may be lying at an angle to that plane which would tend to irritate the uterine walls.

Although the coils of the parent specification have been found to give excellent results as a contraceptive as long as they remain in position, they may be lost without the knowledge of the patient, are more difficult to remove than coil 25 and cannot be observed in position without radiology and accordingly coil 25 is to be preferred.

The following data has been accumulated on different sizes and modifications of the coils, Nos. 1 to 4 being patterned after coil 13 of the parent specification and No. 5 after coil 25 herein:

No.	Diameter mm.	Patients	Ejections	Months Exposure	
				Total	Per Pregnancy
1	23	49	23%	330	80
2	27	58	23%	840	130
3	30	156	10%	1,200	200
4	33	106	6.5%	550	infinite
5	33	264	2.2%	1,050	infinite

Thus the larger size coils are preferred as they reduce both the ejections and pregnancies, there having been no pregnancies with the 33 mm. coils. Ejections may lead readily to pregnancies when the woman is unaware of the ejection and is falsely relying on the presence of the coil.

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 coil's longest transverse dimension should not be more than 4 mm. and it has been found, in fact, that a preferred dimension is about 2 by 3 mm. and 16 cm. long, the follower of Figure 9 being an additional 10 cm., including the distal 5 cm. having beads 29. The preferred diameter, i.e. largest dimension, across the coil *per se* is about 3.3 cm., the range being 2 to 4 cm. The smaller sizes are, of course, ejected more,

but some women with a small uterus cannot receive a 3.3 cm. coil so that a 2.5 cm. coil is generally provided for them. The follower described herein may obviously be added to any of the coils of the parent specification.

WHAT WE CLAIM IS:—

1. An intra-uterine contraceptive comprising an elongated strand having two free ends, a free shape as a coil in substantially one plane and a substantially straight follower, 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 said force.

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

3. A contraceptive as claimed in claim 1 wherein the said strand is made of metal.

4. A contraceptive as claimed in claim 1



canal with the beads extending partly out into the vagina. The extra beads are severed to leave the placement of the unit as shown in Figure 3.

5 As shown in Figure 3, when coil 25 is in position in the uterus, the coil portion occupies the same position as coil 13 in Figure 3 of the main patent but the follower 27 extends through the cervical canal of the uterus with the beads or thickened areas 29 being positioned near the opening of the cervix. In fact, since the cervical canal is of variable length in different patients, the coil of Figure 1 has an elongated zone 28 of spaced beads 29, but after positioning the coil in the uterus, the extra length of beads may be severed so that only one or two beads are extending into the vagina, the follower being pliable and harmless.

20 This follower serves three functions, the first and most important being that the presence and relative position of the coil within the uterus may readily be determined with the fingers by merely feeling for and counting the beads. This is important because the primary fault of coil 13 of the parent specification has been its passage from the uterus on a few occasions without the knowledge of the patient.

The second important function is that the entire coil can be readily removed by merely grasping beads 29 and pulling the coil from the uterus by hand and thus avoiding the insertion of a hooked device into the uterus as is required with coil 13 of the main patent.

A further function of the follower is dependent upon the fact that the unthickened portion of the follower is not round, but is oval or flat-shaped. Thus, by feeling the follower, the doctor will immediately know whether the coil 25 is laying in the proper plane as shown in Figure 2 or whether it may be lying at an angle to that plane which would tend to irritate the uterine walls.

Although the coils of the parent specification have been found to give excellent results as a contraceptive as long as they remain in position, they may be lost without the knowledge of the patient, are more difficult to remove than coil 25 and cannot be observed in position without radiology and accordingly coil 25 is to be preferred.

The following data has been accumulated on different sizes and modifications of the coils, Nos. 1 to 4 being patterned after coil 13 of the parent specification and No. 5 after coil 25 herein:

No.	Diameter mm.	Patients	Ejections	Months Exposure	
				Total	Per Pregnancy
1	23	49	23%	330	80
2	27	58	23%	840	130
3	30	156	10%	1,200	200
4	33	106	6.5%	550	infinite
5	33	264	2.2%	1,050	infinite

60 Thus the larger size coils are preferred as they reduce both the ejections and pregnancies, there having been no pregnancies with the 33 mm. coils. Ejections may lead readily to pregnancies when the woman is unaware of the ejection and is falsely relying on the presence of the coil.

65 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 coil's longest transverse dimension should not be more than 4 mm. and it has been found, in fact, that a preferred dimension is about 2 by 3 mm. and 16 cm. long, the follower of Figure 9 being an additional 10 cm., including the distal 5 cm. having beads 29. The preferred diameter, i.e. largest dimension, across the coil *per se* is about 3.3 cm., the range being 2 to 4 cm. The smaller sizes are, of course, ejected more,

but some women with a small uterus cannot receive a 3.3 cm. coil so that a 2.5 cm. coil is generally provided for them. The follower described herein may obviously be added to any of the coils of the parent specification.

WHAT WE CLAIM IS:—

1. An intra-uterine contraceptive comprising an elongated strand having two free ends, a free shape as a coil in substantially one plane and a substantially straight follower, 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 said force.

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

3. A contraceptive as claimed in claim 1 wherein the said strand is made of metal.

4. A contraceptive as claimed in claim 1

wherein the said strand is made of moulded plastic.

5 5. A contraceptive as claimed in claim 1 wherein the said strand is made of moulded polyethylene.

6. A contraceptive as claimed in claim 1 wherein the said strand is made of moulded polyethylene with barium sulphate incorporated therein.

10 7. A contraceptive as claimed in claim 1 wherein the said strand is radio-opaque.

8. A contraceptive as claimed in claim 1 wherein the said coil is curved in one direction only.

15 9. A contraceptive as claimed in claim 1 wherein the said coil is curved in one direction only for at least 720°.

10. A contraceptive as claimed in claim 1 wherein the transverse section of the said

strand has one dimension greater than the other. 20

11. A contraceptive as claimed in claim 1 wherein the free end of the said follower includes spaced beads.

12. A contraceptive as claimed in claim 1 25 wherein the transverse section of said follower has one dimension greater than the other.

13. The improvement in or modification of the invention set forth in patent application No. 38046/61 (Serial No. 986,000) substantially as described with reference to the accompanying drawings. 35

ELKINGTON AND FIFE,
Chartered Patent Agents,
Bank Chambers, 329, High Holborn,
London, W.C.1,
Agents for the Applicants.

Leamington Spa: Printed for Her Majesty's Stationery Office, by the Courier Press (Leamington) Ltd.—1965. Published by The Patent Office, 25 Southampton Buildings, London, W.C.2, from which copies may be obtained.

