

L016.047

PATENT SPECIFICATION

DRAWINGS ATTACHED

L016.047



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COMPLETE SPECIFICATION

Intra-Uterine Device

I, JACK LIPPES a citizen of the United States of America, of 64 Curtis Parkway, Tonawanda, State of New York, United States of America, do hereby declare the invention for which I pray that a patent may be granted to me 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 device, and more particularly to such a device useful for contraceptive purposes.

It is a known medical fact that a foreign object in the uterus will prevent conception. Heretofore, different types of intra-uterine devices for contraceptive purposes have been proposed but none has been fully satisfactory.

According to the present invention we provide an intra-uterine device comprising an elongated body arranged in sinuous form in substantially one plane within the imaginary boundaries of an isosceles trapezoid including a pair of opposite non-parallel boundary sides, such sinuous body having a pair of nodes on each of two opposite sides thereof, one of said non-parallel boundary sides being tangent to one node pair and the other of said non-parallel boundary sides being tangent to the other node pair.

The intra-uterine device may be readily inserted into the uterus with aid of a simple instrument and may be worn with comfort for months, and even years, and thereafter simply and readily removed without discomfort to the wearer. The intra-uterine device does not prevent or interfere with menstruation or in any other way adversely affect the well-being of the wearer. Any undesired displacement of the device from the uterus following proper insertion therein can be detected. The intra-uterine device is also simple in construction, easy to manufacture and relatively inexpensive.

Other features of the present invention will be apparent from the following detailed de-

scription of a preferred embodiment illustrated in the accompanying drawing in which:

Fig. 1 is a side elevational view, partly in section, of an instrument in operative position for inserting into an uterus the intra-uterine device, also shown in substantially straightened out form and arranged on the instrument;

Fig. 2 is a view similar to Fig. 1 insofar as illustration of the uterus in concerned and showing the intra-uterine device in operative position therewithin following its insertion and withdrawal of the inserting instrument, a portion of the tail forming part of the device which is cut off following insertion being illustrated in broken lines;

Fig. 3 is a side elevational view of the intra-uterine device in the operative sinuous configuration which it normally assumes, and showing the critical dimensions of the isosceles trapezoid within whose imaginary boundaries the device in its normal sinuous form is confined;

Fig. 4 is an enlarged transverse sectional view of the inserting instrument with the intra-uterine device arranged thereon, and taken on line 4—4 of Fig. 1;

Fig. 5 is a left end elevational view of the intra-uterine device shown in Fig. 3; and

Fig. 6 is an enlarged sectional view thereof taken on line 6—7 of Fig. 3.

The intra-uterine device is shown as comprising an elongated or bar-like body 10 of flexible material arranged in sinuous or serpentine form substantially in one plane within the imaginary boundaries of an isosceles trapezoid having a short side 11, a parallel long side 12, and a pair of non-parallel sides 13 and 14 of equal length. The dimensions of such sides are critical. The short side 11 has a length falling in the range of from about 15 to about 18 millimetres. The long side 12 has a length falling in the range of from about 25 to about 30 millimeters. Each of the long



sides 13 to 14 has a length falling in the range of from about 23 to about 25 millimeters. As shown, the device has two nodes or reverse curves on each end.

5 The body 10 may be round or non-round such as oblong in cross-section as shown in Fig. 6 and preferably has a major dimension in cross-section of about 0.080 inch, and a length when straightened out of about 4.5 inches.

10 The intra-uterine device also comprises a thread-like tail 15 of flexible material connected at one end to that end of the body 10 at the short side 11 of the aforementioned trapezoid. Preferably, the tail 15 is provided by inserting a length of a single thread through a hole 101 in the end portion of the body 10 until about half the length of the thread has passed through the hole. Then the two thread portions are tied into a knot indicated at 150 leaving two strands 151 and 152. However, a single strand tail may be used and it may be suitably attached to the body 10 other than by being tied thereto.

25 The tail 15 may be round or non-round in cross-section and is preferably smaller in cross-section than the body 10. The length of the tail 15 is about 2.5 inches.

30 The intra-uterine device may be made of any suitable flexible material. While the body portion 10 and the tail portion 15 may be made of different materials, it is preferred that they be made of the same material. It is preferred to make the device of polyethylene with the body portion 10 composed of low density, polyethylene and the tail portion 15 composed of polyethylene. I have found a surgical thread having a thickness of about 0.007 inch particularly useful to provide the tail. If a single strand tail is employed it may be molded integrally with or fused to the body of the device.

45 Regardless of what material the device is made of, it is essential that the body 10 provides a resilient member capable of being substantially straightened out and upon release thereafter returning to its sinuous form as illustrated. In the case of polyethylene, this can be conveniently achieved by moulding the body 10 in its sinuous form so that when straightened out, it has "memory" or a resistance to cold flow which causes it to return to its sinuous configuration.

50 If desired about 20% by volume of barium sulphate may be mixed with the plastics material to render the resilient devices molded therefrom visible to X-ray examination.

60 The reason why the aforementioned resilient characteristic of the body portion 10 of the intra-uterine device is important will be apparent when the mode of inserting the device into an uterus is considered.

Referring to Figs. 1 and 2, an uterus is represented at U having a cavity 16 in the inner portion or fundus of the uterus which com-

municates with the vagina (not shown) by a neck portion or isthmus 17.

The inserting instrument represented generally by the numeral 18 is shown as comprising a sleeve or tube 19 and a plunger 20 freely slidably arranged therein. The sleeve or tube 19 has a gradually turning or curved inner portion as indicated at 21, and while it may be made of a rigid material it is preferably made of a flexible plastics material such as one of the long chain fluorinated polymers of ethylene such as tetrafluoroethylene, known under the trademark "Teflon". In cross-section, the sleeve or tube 19 may be round, or non-round such as being oblong.

The plunger 20 is made of a flexible material since it must follow the contour of the passage in the sleeve or tube 19, and is also preferably made of "Teflon". The cross-section of the plunger 20 corresponds generally to that of the sleeve or tube 19, except that the plunger is provided with a longitudinal groove 22.

In use of the instrument 18, the sleeve 19 or tube 19 and plunger 20 are first separated. The body portion 10 of the intra-uterine device is then fed into the sleeve or tube 19, with the free end remote from the tail portion 15 being inserted into the end of the sleeve or tube remote from the curved portion 21. In the course of so inserting the body portion 10, it is straightened out against its natural urging of assuming its sinuous form. When the body portion has been substantially completely inserted within the sleeve or tube 19, the tail portion 15 is placed in the groove 22 in the plunger 20, such groove being large enough to receive the tail portion. The end of the plunger 20 adjacent the trailing end of the straightened out body portion 10 is then inserted into the sleeve or tube 19. Partial insertion of the tail portion within the groove 22 is depicted in Fig. 1, in which the partial insertion of the plunger 20 within the sleeve or tube 19 is also illustrated. The leading end of the plunger 20 thrustingly bears against the rearwardly facing shoulder 23 formed by the trailing end of the body portion 10 due to the difference in thickness of the tail portion 15.

With the intra-uterine device so arranged on the instrument 18, the assembly is inserted into the vagina (not shown) and partially into the uterine cavity 16 through the isthmus 17 as illustrated in Fig. 1. Thereafter, the plunger 20 with the tail portion arranged within the groove 22, is gradually pushed into the sleeve or tube 19.

As the body portion 10 enters the uterine cavity 16, it returns to its sinuous form, as shown in Fig. 2. The plunger 20, which is longer than the sleeve or tube 19, is continued to be pushed inwardly thereof until the entire body portion 10 is accommodated within the uterine cavity 16 and the tail por-

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tion 15 is left extending through the isthmus 17. Thereafter the instrument 18 is withdrawn and the portion of the tail 15 extending outwardly of the isthmus 17 may be cut off. Such cut-off portion is shown at 15a in Fig. 2.

Instead of utilizing an inserting instrument for the intra-uterine device in which the plunger has a groove such as the groove 22, the plunger may have enough clearance between its periphery and the internal surface of the guide sleeve or tube as will accommodate the tail portion 15 of the device and still be freely slidable within the sleeve or tube.

Clinical studies have shown that the intra-uterine device remains in the operative position shown in Fig. 2 and does not rotatively move within the uterine cavity so as to draw thereinto the tail 15. The device may be left within the uterus for months or years and will remain in its operative position during such time. In case it is desired to remove the device, this is readily accomplished by grasping the free end of the tail 15 with a suitable instrument such as forceps (not shown) and thereafter gradually pulling the device outwardly of the uterus through the isthmus 17. In being so removed, the body portion 10 straightens out substantially to pass through the isthmus 17 without discomfort.

WHAT WE CLAIM IS:—

1. An intra-uterine device, comprising an elongated body arranged in sinuous form in substantially one plane within the imaginary boundaries of an isosceles trapezoid including a pair of opposite non-parallel boundary sides, such sinuous body having a pair of nodes on each of two opposite sides thereof, one of said non-parallel boundary sides being tangent to one node pair and the other of said non-parallel boundary sides being tangent to the other node pair.

2. An intra-uterine device according to

claim 1, wherein the sinuous body has short, long and non-parallel sides, said short side having a length falling in the range of from about 15 to about 18 millimeters, said long side having a length falling in the range of from about 25 to about 30 millimeters and said non-parallel sides having a length falling in the range of from about 23 to about 25 millimeters.

3. An intra-uterine device according to claim 2, wherein a flexible tail is connected to the end of the sinuous body at the short side.

4. An intra-uterine device according to claim 1, 2 or 3, wherein the flexible body is moulded in its sinuous form so that when straightened out, it has "memory" or a resistance to cold flow which causes it to return to its sinuous configuration.

5. An intra-uterine device according to any one of claims 1 to 4, wherein about 20% by volume of barium sulphate is mixed with the synthetic plastics material to render the resilient device moulded therefrom visible to X-ray examination.

6. An intra-uterine device according to any one of claims 1 to 5, also comprising a flexible sleeve or tube with a freely slidable plunger for inserting the flexible body in the uterus.

7. An intra-uterine device according to claim 6, wherein the plunger has a longitudinal groove to accommodate the flexible tail attached to the flexible body.

8. An intra-uterine device according to claim 7, wherein the flexible tube, and the plunger are made from tetrafluoroethylene.

9. An intra-uterine device constructed and arranged substantially as herein described with reference to the accompanying drawing.

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