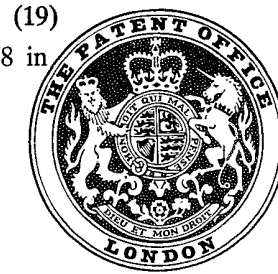


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(54) AN INTRAUTERINE DEVICE

(71) We, FUJI LATEX COMPANY LIMITED, of 19-1, 3-chome, Kanda Nishi-ki-cho Chiyoda-ku, Tokyo, Japan; a Company organised and existing under the laws of Japan, 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 intrauterine devices.

Heretofore various intrauterine devices for conception control have been of two basic types; one relying upon pharmacological properties for contraception, and the other being devoid of pharmacological properties and relying upon a physical relationship with the uterus. Within the former category certain devices have been adapted to emit hormones, while other have incorporated copper for bringing about an inter-reaction with the uterine wall. The present invention falls within the second class and thus is devoid of reaction in a pharmacological sense with the uterus.

With non-pharmacological active uterine devices the fundamental effort has been to effect a relatively increased contact between the devices and the uterine endometrium. Contact may be achieved by direct engagement, as well as by the provision of means for covering relatively wide zones of the endometrium, such as through the medium of wires or networks. However, it is manifest that the quality of the contact between the devices and the endometrium is of extreme criticality, so as to avoid any injury to the uterine wall with the potential for infection. Accordingly, effective, but limited contact of a non-injurious nature is desired.

In addition to the structure of the device itself there is always the problem of providing means, such as by a tool or implement, for effecting insertion of the device within

the uterus. Thus, in addition to the desired characteristics of the device for bringing about contraception, the passage of the same through the cervical canal must be considered, to prevent injury to the tissues. Certain devices heretofore known have been of tubular character for relatively facile insertion within the cervical canal and permitting the intrauterine device to be moved through the tube as by a plunger for expulsion into the uterus. Other efforts have involved the detachable mounting of a device upon the inner end of an inserting bar so that release may be effected upon withdrawing of the bar from the canal. With the tubular tool the intrauterine devices have been consistently formed of a relatively hard plastic and have thus, with undesired frequency, caused a piercing of the uterine wall upon expulsion. With the more readily detachable types of uterine devices the same have consistently caused a relative expansion of the cervical canal upon insertion, which, in addition to causing discomfort, has also brought about injury to the canal as well as to the external uterine orifice.

According to the invention there is provided an improved intrauterine device comprising a stem, a plurality of arms projecting from opposite sides of said stem and being flexible about the junction therewith, said arms being biased for presenting the longitudinal axes thereof at an angle of less than 90° with the longitudinal axis of said stem, and said stem incorporating a relatively thin elongate portion extending in a direction remote from said arms, said stem in the portion thereof adjacent said arms having opposed side faces, said arms extending from said opposite side faces, and each of said arms being relatively flat, said arms being in paired relationship with there being a multiplicity of such pairs and said paired arms being so related that the same are of increasing extent progressing from said

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elongate stem portion.

With such an intrauterine device the inserting portion can easily bend in conformity with the configuration of the cervical canal and go into the uterus without giving any pain to the user.

A suitable tool for inserting such an intrauterine device is the subject of our co-pending application number 7941481 (Serial No. 1600318).

Preferably, the intrauterine device is formed of relatively soft, limitedly flexible plastic and incorporates a stem having a plurality of parallel branches or arms of decreasing extent projecting from the stem at a predetermined angle, which branches or arms, though inherently biased outwardly, may be folded snugly inwardly toward the stem during inserting movement through the cervical canal and are easily reversely bent for promoting smooth, non-discomfort withdrawal through the canal. These arms ensure sufficient contact with the uterine wall to inhibit implantation of a fertilized ovum within the uterus endometrium and thereby promote the expulsion of the same.

However, the intrauterine device is also adapted for minimal contact with the uterine wall so as to relatively diminish any potential for irritation or the like of the wall.

Further advantages are:

The intrauterine device will maintain operative condition over long periods of time without undesired deformation or displacement.

The intrauterine device is adapted for facile withdrawal from the uterus without requiring the utilization of invasive instruments.

The intrauterine device which is most economically manufactured and which is reliable and durable in usage; and being so cheaply produced to be clearly of discardable character.

Figure 1 is a front view of an intrauterine device constructed in accordance with and embodying the present invention and mounted upon a tool for inserting same as shown in Figure 4.

Figure 2 is another view of the device and tool as shown in Figure 1.

Figure 3 is a vertical transverse sectional view of the device shown in Figure 1 fitted to a tool as shown in Figure 4.

Figure 4 is a vertical sectional view of a tool for insertion of the intrauterine device constructed in accordance with and embodying the present invention.

Figure 5 is a front view of the intrauterine device alone.

Figure 6 is a vertical transverse sectional view taken on the line II-II of Figure 5.

Figure 7 is a front view of the intrauterine device, but with the branches or arms being reversely bent in withdrawing position.

Figure 8 is a side view of the intrauterine device.

Figure 9 is a vertical sectional view of the uterus having disposed therein, in operative position, an intrauterine device embodying the present invention.

The present invention will be further explained by reference to the numerals of the drawings.

A tool for inserting an intrauterine device according to the invention comprises an elongated narrow body A formed of a material such as synthesized resin, said body A having at its top end an intrauterine inserting portion 1 and at its lower end a handle 2. In order that intrauterine inserting portion 1 may have flexibility enough to bend freely in conformity with the curvature or configuration of the cervical canal while intrauterine device B is being inserted into the uterus, said portion 1 is made thin and narrow relative to the other parts of body A, or is formed of a flexible material such as synthesized resin, rubber or the like.

Spacedly from the opposite end of said tool A there is an integral, relatively short cross piece 7 perpendicular to the axis of said tool B which cross piece 7 is so located as to limit the extent of insertion of tool B being engageable with the upper vaginal wall adjacent external uterine orifice *d* so that any further insertion is effectively inhibited, although as will be shown hereinbelow said cross piece is presented merely for precautionary purposes as the distance between same and the proximate end of tool A is such that in normal operation said cross piece will be disposed spacedly below the upper vaginal wall.

At the front portion of cross piece 7 is provided intrauterine inserting portion 1. And the top end of portion 1 is provided with aperture 3 where end portion 26 of intrauterine device B is engaged and held. In the longitudinal direction of intrauterine insertion portion 1 is provided a channel 4 as a passage of a thread portion 23 of device B.

The intrauterine inserting portion 1 is hollowed to provide a continuous elongated channel 4 which is defined by side walls 8,8', a base 9, and a top wall 10. Said top wall 10 is cut away throughout the major portion of its length to define a slot-like opening 12 communicating with channel 4 and with base 9 being provided in its rearwardmost portion with a narrow opening 6 of limited extent which latter is longitudinally offset from opening 12. At its forward end channel 4 communicates with the normally inner or forward end of tool A through an end aperture 3 which latter has a diameter of but slightly greater extent than that of intermediate stem portion 27 of device B for purposes presently appearing.

The section of intrauterine inserting por-

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tion 1 may be of any shape so long as it is convenient to carry intrauterine device B into the uterus; for example, triangular, quadrilateral, polygonal, circular, oval or of a section incorporating a slit 5 therein. As will be stated hereinafter, it makes the handling of the intrauterine device B easy to provide slit 5 on intrauterine inserting portion 1, as thread portion 23 of device B can easily pass through it.

The inner section of aperture 3 is substantially as large as that of end portion 26 of intrauterine device B, so that end portion 26 may be engaged and held there. As shown in Figure 3, for example, aperture 3 is provided, at its upper part, with slit 5, through which thread portion 23 of intrauterine device B can easily pass into thread passage 4.

Thread passage 4 is a channel provided to prevent thread portion 23 of intrauterine device B from going out of intrauterine inserting portion 1. Such channel may be the one that has the same sectional shape as inserting portion 1, the one that is only deep enough for thread 23 to trail, or the one that lessens its depth towards the handle. Thread passage 4 need not be long enough to cover full length of thread 23 of device B. Further, thread passage 4 can be of a channel only. However, as shown in Figure 4, it is preferable to provide an opening 6 at the opposite side of thread passage 4, to pass thread portion 23 of intrauterine device B.

An intrauterine device according to the present invention is of a molded flexible plastic having a central elongated stem 21 which in its normally lower end portion 22 is of relatively reduced diameter so as to provide a generally thread-simulative section 23 having a short hook forming a terminal 24 substantially axially perpendicular to section 23. The upper portion of stem 21 is of substantially greater thickness than thread portion 23, as at 25, incorporating a shoulder 26 constituting the upper limit of a section 27 between upper and lower portions 25, 22, respectively, and being of intermediate thickness with respect thereto. Said upper portion 25 comprehends planar parallel side walls 28,28' from each of which laterally project in opposite directions a plurality of arms or branches 29, 30, 31, 32 and 29', 30', 31', 32', respectively; the arms projecting from stem side wall 28 corresponding to, and being symmetrical with, the related arms extending from side wall 28'. Arms 32,32' which are located at the upper end of device B are of greater length than the adjacent arms 31,31' which, in turn, slightly exceed the length of arms 30,30', and which latter correspondingly are of greater extent than arms 29,29', whereby an outward diverging edge contour is developed by the arms as one progresses from

forwardmost arms 29,29' to outer arms 32,32'. Such relationship thus presents an edge conformity to the diverging nature of the uterus, as at U in Figure 9, wherein *l* designates the endometrium and the myometrium is indicated *m*, as the same proceeds upwardly from the interior uterine orifice *o* (see Figure 9). The spacing between the adjacent arms is substantially uniform from utilitarian as well as economic standpoints although such spacing is not crucial since the disposition of the arms or branches 29,29' - 32,32' is dictated by the need to effect requisite engagement of the outer ends thereof with the uterine endometrium *e*. Each of the aforesaid arms or branches are axially flexible about their engagement with stem 21 as to be easily bendable in reverse directions for purposes appearing more fully hereinbelow.

With reference being made particularly to Figure 6 it will be seen that the arms or branches 29,29' through 32,32', inclusive, are inherently biased so that their longitudinal axes form an angle of less than 90° with the axis of stem 21 whereby such axes normally project laterally and downwardly. By reason of the inherent slight downward bias of said arms or branches and in view of their flexibility, the same are readily bent or folded inwardly in the general direction toward stem 1 as the intrauterine device is introduced into the confining wall of the human cervical canal *c* (see Figure 9) and held by such wall during transit there-through so that negligible, if any, discomfort is accorded the individual during insertion. As the intrauterine device passes through the interior uterine orifice *o* and thus introduced into the upwardly expanding or diverging uterus U the arms or branches commencing from the upper end of device B are progressively freed from the restriction embodied by the cervical canal *c* and, thus, allowed to return to normal bias condition as shown in Figure 6.

The overall length of each arm 29,29' - 32,32', inclusive, is slightly greater than the minimum distance between upper stem portion 25 and the proximate zone of the intrauterine wall so that the said arms or branches in their normally biased condition will cause their outer end edges to make firm, but non-injurious, contact with the uterine wall and thereby through such engagement be securely retained in operative position.

It is to be further particularly noted that the line of integration or jointure of each arms or branches 29,29' - 32,32' with stem portion 25 is at an angle of less than 90° to the longitudinal axis of stem portion 25, such angle being indicated at $\angle \theta$ in the drawings (see Figure 6), and being within the range of approximately 30° to 50°. This

angulation is productive of an enhanced stabilization of the device in operative position, resisting any tendency of the device to twist, tilt, or become distorted, as well as to be displaced vertically, so as to effect a loss of contact with one or more of the arms of the uterine wall or to provide an unbalanced engagement. This angle presents a marked advance in the art, assuring of efficacious retention of the device in operative position. The novel angular relationship of the arms or branches to the stem conduces to relatively less inhibited menstrual flow than was occasioned by devices incorporating arms extending perpendicularly from a central portion and furthermore the inclusion of the stated angle has been found to permit of a reduced thickness of such arms or branches without any diminution in strength or effectiveness for both insertion and withdrawal purposes as well as retentiveness in engaged condition. The permitted relative slenderization of such arms or branches brings about a still further unusual result and that is in enhancing the sensitivity of such arms or branches to the normal continuous flexing or alternate contractile and expanding action of the uterus U so that on contracting said arms or branches are correspondingly flexed inwardly and upon expansion of such wall said arms return outwardly whereby requisite contact is at all times maintained without injury to the uterus U and without displacement of device B.

By reference to Figure 9 it will be seen that lower stem portion 32 is of such length that when device B is in mounted condition, terminal 24 will be located within the vagina *v* downwardly of the external uterine orifice *d* for ready accessibility for purposes of withdrawal of device B.

Referring to Figure 7 it will be seen that when device B is withdrawn from uterus U as by being pulled through canal *c* by the application of a pulling force upon hook 24, arms or branches 29,29' - 32,32' will be progressively subjected to a restricting path through the uterus as device B follows the downwardly tapering nature of the walls thereof causing said arms and branches to be folded or bent in what may be considered an upward condition as suggested in Figure 7 and with such folding being further increased as device B transits canal *c*. Thus the relative thickness and flexibility of said arms and branches permits same to readily assume such reversely folded condition and present an overall compact relationship to permit of a smooth facile passage through canal *c* with negligible, if any, discomforting contact with the canal walls. Thereby device B is uniquely contrived to allow for quick, easy, and noninjurious removal.

Inserting tool A and intrauterine device B conceived as above are combined for use in

the following manner. After tool A and device B are sterilized separately, end portions 26 of device B is inserted into aperture 3 of tool A and then the thread portion 23 is directed through aperture 3 and then directed along channel 4 with said device being suitably manipulated so as to feed hook 24 through opening 6 as into the position shown in Figures 1 and 2. Said hook 24 will thus abut against the adjacent edge of opening 6. As pointed out above intermediate stem portion 27 of device A is of substantially like diameter as aperture 3 for relatively snug acceptance therein.

Intrauterine device B is, therefore, firmly held without any disengagement during the operation. Further, as slit 5 is provided at aperture 3, a rather troublesome work as of running thread portion 23 through aperture 3 is saved at the time of inserting lower end portion 26 of device B. This brings about an easy operation of device B. Still further, it becomes unnecessary to sterilize, or with the device set on tool A, as in the case of the known arts concerned. In other words, according to the known arts, such a device and a tool have been used as a set. According to the present invention, however, the attachment of device B to tool A is very simple and can be effected, for example, at the time of mounting the device B to the user, so that they can be handled separately. This also means that one inserting tool A can be used repeatedly after sterilization.

Cleansing of the uterus as well as the measurement of its size should be done before insertion of device B into it. It is preferable to give a scale along intrauterine inserting portion 1 so that the inserting of device B may be operated by reference to the measured length of the uterus. This brings about a safe, successful and highly efficient operation.

It will thus be seen that device B and tool A are uniquely coordinated so that device B is sufficiently securely retained by tool A to permit of suitable manipulation of the latter for device-inserting purposes without danger of accidental or premature displacement of device B therefrom. It should be particularly noted that the combined length of device B as engaged by tool A and the outer or cross piece adjacent extremity of opening 6 is slightly greater than the normal distance between the upper wall of the uterus U and the external uterine orifice *d* so that said stem hooked portion 24 will be presented immediately below said orifice *d* for ready accessibility.

The operation of tool A should be apparent from the foregoing since with device B engaged thereon as described the inner end portion of said tool A is inserted into the cervical canal through the external uterine orifice *d* and gently directed therethrough

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with the walls of said canal *c* having a compressing effect upon the arms or branches of device A causing same to be bent downwardly or toward the normally outer end of tool A. After tool A has been moved so as to introduce the said arms or branches of device B into the uterus the said arms or branches are thus permitted through the inherent bias to return to normal condition and with their edges firmly but gently abutting the confronting portions of the uterine wall for retention thereby. The movement of tool A is continued until the upper end of device B is brought into contact with the endometrium at the upper end of uterus U and all such inserting movement is then discontinued. At this juncture device B is firmly held by the gripping effect of the uterine walls upon said arms or branches so that a tilting movement as directed toward the rear of the uterus frees tool A for withdrawing action as the same is moved outwardly relatively along stem 21 with reverse passage through cervical canal *c*. During such removing action thread portion 23 of stem 21 travels relatively along channel 4, through opening 3, with hook 24 being thus presented within the vagina below orifice *d*.

It will accordingly be seen that the curvature of the normally upper or inner end of tool A is such as to permit of but limited axial tilting of tool B to bring about the requisite disengagement between same and device B so as to free tool A for facile and nondiscomforting withdrawal.

The ultimate withdrawing of device B from the uterus after serving the intended function, such as, for instance, producing expulsion of a fertilized ovum, is easily brought about by the simple procedure of gripping hook 24 and pulling device A through uterus U and cervical canal *c* with such passage being facilitated as described by the upper or reverse folding of arms or branches 29, 29', etc. as within the condition shown in Figure 7.

WHAT WE CLAIM IS:-

1. An improved intrauterine device comprising a stem, a plurality of arms projecting from opposite sides of said stem and being flexible about the junction therewith, said arms being biased for presenting the longitudinal axes thereof at an angle of less than 90° with the longitudinal axis of said stem, and said stem incorporating a relatively thin elongate portion extending in a direction remote from said arms, said stem in the portion thereof adjacent said arms having opposed side faces, said arms extending from said opposite side faces, and each of said arms being relatively flat, said arms being in paired relationship with there being a multiplicity of such pairs, and said paired arms being so related that the same

are of increasing extent progressing from said elongate stem portion.

2. An intrauterine device as claimed in Claim 1 and further characterised in that the said arms having maximum extent are located at the end extremity of said stem remote from said elongate stem portion, said stem further having a zone of thickness reduced relative to the portion adjacent to said arms between said portion and the thin elongate portion.

3. An intrauterine device as claimed in Claim 2 and further characterised by a hook formed at the end of said elongate stem portion.

4. An intrauterine device, substantially as hereinbefore described with reference to, and as shown in, the accompanying drawings.

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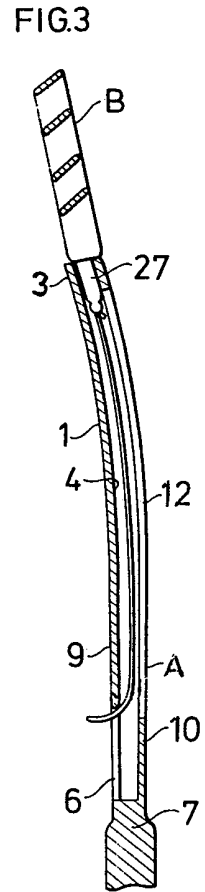
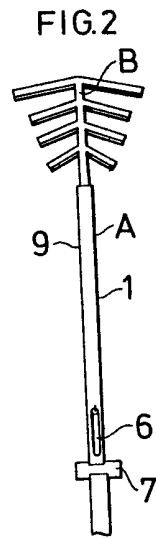
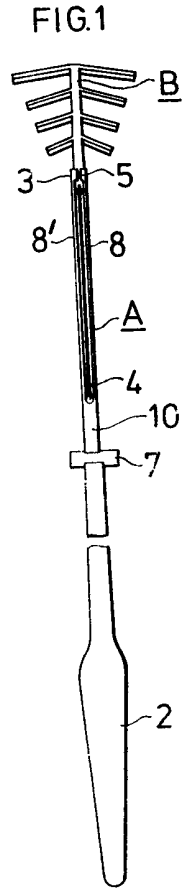


FIG.4

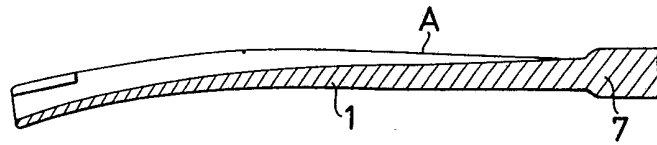


FIG.5

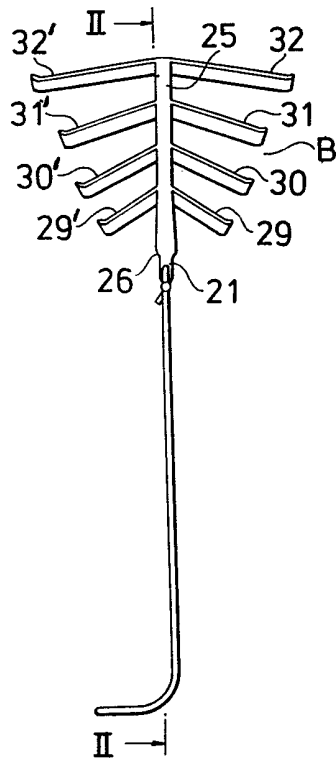


FIG.6

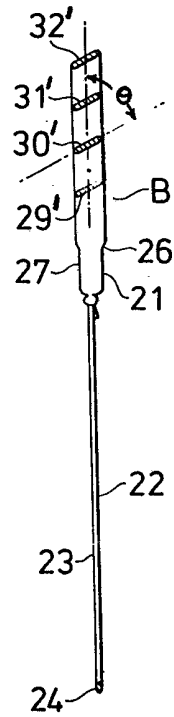


FIG.7

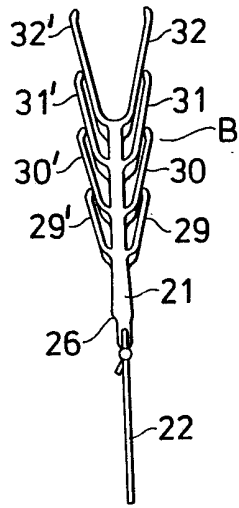


FIG.8

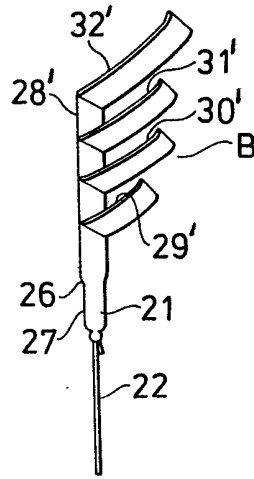


FIG.9

