INTRA-UTERINE CONTRACEPTIVE
DEVICE

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ABSTRACT
An intra-uterine contraceptive device having a pair of loops extending in opposite directions from a common stem. Each loop has a free end. The character and thickness of the material forming the loops and the shape of the loops are such as to permit the loops to more readily conform to the walls of the uterine cavity of the patient and thereby be better retained.

6 Claims, 4 Drawing Figures
INTRA-UTERINE CONTRACEPTIVE DEVICE

Intra-uterine contraceptive devices which are inserted into the uterus of a patient to prevent conception are well-known in the art. The presence of the device in the uterus, through some phenomenon not entirely proved, prevents conception.

Modern day intra-uterine devices normally are formed of suitable biologically inert plastic material having a retentive memory. These devices rely upon the application of a force, due to the springiness and/or shape of the device, acting against the walls of the uterine cavity. The plastic material is made sufficiently thick and the device is shaped so that the device engages the walls of the uterus at or near predetermined points of the device. The material and shape of the device are made such that its active portions engaging the uterus wall are relatively rigid. The devices are also sufficiently "still", though resilient, such that they will retain substantially their original shape, before insertion into the patient, against the forces exerted by the moving walls of the uterine cavity. That is, if force is applied to the device by the walls of the uterine cavity at the points of contact with the device, the device itself will always be exerting a counter force which will restore it to its original shape.

Intra-uterine devices have suffered, to some extent, from the problems of discomfort and expulsion from the uterus of the patient. Expulsion is due to several factors, for example, anatomical features of the patient which are incompatible with the material and/or shape of the device, physiological and psychological incompatibility, etc. The expulsion rate, variable with different types of devices, still presents a problem for, if the device is expelled or is not retained in the uterus properly, it cannot prevent conception in the intended manner.

It is believed that the expulsion and discomfort problem is due in some measure to the trauma accompanied with the insertion of the device into the uterine cavity. While this trauma is relatively minor in nature, it still presents a problem since it is believed to set in motion those physiological and psychological factors which cause expulsion. This is particularly true in so-called nullipara patients (patients who have not previously borne children). It is known that the tolerance of nullipara patients for retaining intra-uterine devices is substantially lower than in patients who have borne children. Therefore, the expulsion rate of nullipara patients is considerably higher than those of other patients with the same device.

It has been found that the comfortable seating of the device and the ability of the device to conform to the uterine cavity reduces the incidence of cramping, excess bleeding and other discomforts normally associated with these devices following their insertion. This is particularly true following the insertion of the presently available devices for the nullipara patients.

The present invention is directed to an intra-uterine contraceptive device and improvements therein which reduces the trauma accompanying the insertion of the device, and raises the tolerability of acceptance and retention by a patient. This results in a lower expulsion and higher acceptance rate.

In accordance with the invention, the intra-uterine device is of the double loop type, for example, that shown in U.S. Pat. No. 3,590,816, issued to Gerald S. Rosenthal, which is assigned to the assignee of the subject application. This device is currently being marketed by Julius Schmid, Inc., the assignee of the subject application, under the trademark SAF-T-COIL. The device of the subject invention is suitably shaped and made of material having dimensions such that the device is capable of easily deforming within the uterus of the patient to more closely conform to the particular configuration or shape of the patient's uterus. Unlike prior art intra-uterine devices, the device of the subject invention does not depend upon a completely retentive memory which enables it to spring back to its original shape.

It is therefore an object of the present invention to provide an intra-uterine contraceptive device which can be more easily inserted into the patient and retained.

Another further object is to provide an intra-uterine contraceptive device which is suitable for use by nullipara patients.

Another object is to provide an intra-uterine contraceptive device which, though having a partially retentive memory, is still capable of substantial deformation.

Other objects and advantages of the present invention will become more apparent upon reference to the following specification and annexed drawings, in which:

FIG. 1 is a plan view of the intra-uterine contraceptive device according to the subject invention;
FIG. 2 is a view of the intra-uterine contraceptive device and a portion of the inserter system therefor;
FIG. 3 is a view of a cross-section of the uterus of a patient, in the frontal plane, showing a device of the subject invention implanted therein; and
FIG. 4 is another cross-sectional view of the uterus of FIG. 3 taken along the medial plane thereof.

Referring to FIG. 1, the intra-uterine contraceptive device 10 of the present invention includes a stem 12 which is formed at its lower end with an enlarged portion 13 having a hole 14. A double thread 16 has one end passed through hole 14. The thread is tied at the hole or just passed through and a portion doubled back. The other end of the double thread 16 is inserted through a hole 18 in the leading end of a plunger 20. Here again, the thread is tied or merely passed through and a portion doubled back. Plunger 20 fits within the leading end of a tubular inserter 22 and the rilling end of the plunger projects from the trailing end of the tubular inserter 22. The inserter system formed by the combination of thread 16, rod 20 and the tubular member 22 are more fully described in the aforesaid patent to Rosenthal, and below.

The upper end of the stem opposite hole 14 has two loops 30a and 30b originating therefrom. Each loop has a free terminal end. With the exception of the terminal end of loop 30b, the material for the loop is of uniform shape and cross-section. In the original, undeformed state of the device, the two loops lie in the same plane, that is, they are coplanar.

Considering first loop 30a, this is formed by upper and lower sections 31a and 32a. Sections 31a and 32a are sectors of a generally circular configuration which are joined by a straight portion 33a. The two sections 31a and 32a are, essentially, semi-circular in shape. The mid-point, or center, of the upper semi-circular section 31a is shown at point A, and the mid-point for the lower semi-circular section 32a is shown at point B.
The radii originating from points A and B, to the inner or outer edge of the sections are different with the former being slightly greater, for example, 0.150 versus 0.200 inches to the outer edge of the respective section.

The outer arm of loop 31a, which contains straight portion 33a will normally engage the uterus wall. Having a straight-side wall 33a, it will engage the uterus wall over a greater area of contact than would be possible if the loop 33a were a continuous curve or series of curves. Also, as explained below, the loops 30a and 30b are highly deformable and conformable to the shape of the uterine cavity walls and their movement.

It should be noted that, with respect to the lower section 32a of the loop 30a, its free end terminates on the diameter line of the lower loop section 32a extending through point B. That is, the lower section 32a having the radius originating at point B is only a semi-circle and does not comprise an arc of more than 180°. This permits a relatively high degree of flexibility and deformability of the bottom portion 32a.

If the free end of lower section 32a were continued for more than 180°, beyond the diameter line, or to start to form a spiral, the free end would have a greater tendency to spring the loop 30a back into its original, undeformed shape when force is applied to the device.

Considering now the other loop 30b, the upper section 31b is of the same configuration as section 31a of loop 30a, and has the same radius and mid-point A. The lower loop section 32b has a first radius, the same as the lower section 32a of the loop 30b, originating from point B forming an approximately 90° sector of a circle and a second somewhat smaller radius originating from point C. The upper and lower sections 31b and 32b are joined together by the straight side wall piece 33b.

Instead of terminating in a free end of the same diameter as the other portion of the loop 31b, as in the case of loop 30a, loop 31b terminates the sector formed by radius C in a head 36 extending from a shank portion 38. Head 36 is of substantially increased diameter as compared to the remainder of loop 31b and terminates in a larger bulbous end 39. The bulbous end 39 of head 36 prevents the device from being drawn into the tubular inserter 22 when the device is placed in a position in the inserter tube such as to be inserted in the patient.

Considering now the material and dimensions of the device of FIG. 1, the material is primarily an ethylene-vinyl acetate (EVA) copolymer. Materials of this type are flexible and rubber-like in character. They are also resilient and have "snap-back" action, or a retentive memory. The material can be molded, such as by injection molding, to form the device. The plastic molding resin used in the molding preferably has a radio opaque material, such as barium sulphate mixed therein. Preferably, up to about (Ten) 10 percent of the radio opaque material is used. If desired, processing aids or lubricants can be mixed with the material.

In accordance with the present invention, the cross-section of the portion of the device forming the two loops 31a and 31b, with the exception of the bulbous end 39 of head 36 on loop 31b, is made relatively thin. For example, it has a cross-section of approximately 0.050 inches in the plane shown, that is, between points X and Y of FIG. 1, and a dimension of about 0.060 in a plane transverse thereto. The use of such a relatively thin cross-section, while in part detracting from the retentive memory characteristic of the intra-uterine device as compared to a device of the same general shape having a thicker cross-section material, is deliberately selected since it permits the high degree of flexibility of the loops 30a and 30b and their better conformity to the walls of the uterus. It should be understood that the two dimensions for the cross-section given above can vary within a range, for example, between about 0.045 and 0.055 inches for the first dimension given, and between about 0.055 and 0.065 inches for the second dimension given. A more circular or fully circular cross-section also can be used.

The device shown in FIG. 1 is in overall shape similar to another type of device, Model 32-S, which is marketed under the trademark SAF-T-COIL by the assignee of the subject application. However, it differs in several respects which affect its operation. First of all, the material forming the loops 30a and 30b has a cross-section approximately one-half the thickness, thereby giving the desired characteristics of flexibility both in the final shape of the loops in the uterus and, also, to permit the two loops to depart from their original co-planar relationship when in the undeformed state. This results in some loss of the "springiness" of retentive memory characteristics of the material which, in accordance with the invention, is desired. As a second difference, the free end of the loop 30a, which does not have the head 36, terminates at the diameter line rather than extending thereabove as in the Model 32S. This also retracts somewhat from the springiness of loop 30a to permit the loop to more readily conform to the shape of the uterus wall, that is, the loop 30a has less of a tendency to spring back when deflected toward the stem of the device.

Considering now the use of the device, referring to FIG. 2, the device is shown withdrawn within the tubular inserter 22. This is accomplished by the person installing the device grasping the free trailing end of the plunger and pulling it out of the trailing end of the inserter. This applies tension through the thread 16 to draw first the stem of the device into the inserter tube and then the two loops 30a and 30b. The loops are stretched out in the tubular inserter into a more linear shape.

After the device has been placed in the position shown in FIG. 2, it is ready for insertion into the uterus. The person installing the device advances the leading end of the system, with the device sheathed in the tubular inserter, into the uterus through the vaginal opening. Prior to doing this, the uterus may be inspected with a sound to determine its position and tilt, if any. A suitable sound for accomplishing this is shown, for example, in U.S. Pat. No. 3,630,190 to Samuel Baker, issued Dec. 28, 1971, which is assigned to the assignee of the same application.

After the inserter tube has been oriented in the proper position in the uterine cavity, the person installing the device pushes the plunger. The leading end of the plunger engages the end of the stem of the device and pushes it out of the inserter tube. The inserter tube is then withdrawn through the vaginal opening and the thread is cut off. A length of the thread is left for inspection purposes.

The act of withdrawing the device into the tubular inserter and then unsheathing it, distorts the device from its original shape shown in FIG. 1. Due to the fact that the material of the loops does not have a fully re-
tendent memory. This distortion normally would result in the loops 30a, 30b being rotated upwardly somewhat from the position shown in FIG. 1. This distortion is unimportant since the shape of the uterine cavity varies from patient to patient.

FIG. 3 shows the device located within the uterus. The drawing depicts the loops 30 of the device being deformed to conform to the general shape of the walls of the uterine cavity. As seen, the loops are distorted from their original shape of FIG. 1. This is characteristic of the device of the subject invention. That is, the relative "softness" of the loop material, due to its relatively small cross-section, and reduction in springiness makes the loops of the device more conformable to the uterus wall than prior art devices. The latter rely more heavily on the springiness characteristic of the material and also make a smaller area of contact with the uterus walls, where the device has a curved configuration. The straight wall portion 33 of the device of FIG. 1, which joins the upper and lower loop sections 31, 32, also presents a larger area of wall contact than if the loop were made fully arcuate or curved.

FIG. 4 shows a view taken transverse to that of FIG. 3. This shows a slight shift of the two loops out of their original coplanar relationship. This shifting, which occurs readily due to the relative softness of the material, is also desirable since it permits better conformation of the device to the shape of the uterine cavity. It should be understood that the uterus can change its shape somewhat depending upon the position and muscular activity. Therefore, by making the device in such a way that it better conforms to the shape of the uterine cavity and soft enough to move with the uterus walls as they move, the device has a higher acceptance and lower expulsion rate. Further, the relative softness of the material reduces the trauma when the device is inserted. While a quantitative measurement of trauma is impossible, patients, particularly nulliparas, having the device of the subject invention inserted, report very little discomfort during the insertion process. This also is believed to aid in the reduction of the expulsion rate.

What is claimed is:

1. An intra-uterine contraceptive device comprising a substantially straight stem portion from which extends at one end thereof a pair of oppositely disposed loops which are generally coplanar with the stem, at least the loops of said device being of a soft plastic material and having a partially retentive memory to permit the loops of the device to deform and more readily conform to the walls of the uterine cavity into which the device is to be inserted, each loop having a first arch with a respective first radius and commencing in one direction from one end of the stem and curved to extend and terminate in a second direction opposite from said first direction; (a) an elongated straight section commencing at the termination of said first semi-circular section and extending for a distance in said second direction and generally parallel to the stem, and a second arch each of (a smaller) respective second radius (than) which is smaller than the radius of said first arch commencing at the termination of said elongated straight section extending in said second direction and then curving back to terminate with a free end extending toward said first direction; the cross-section of the loop material having a maximum dimension in one direction in the range of from about 0.055 to about 0.065 inches and a maximum dimension in a direction generally transverse to said one direction in the range of from about 0.045 to about 0.055 inches.

2. A device as in claim 1 wherein the cross-section of each of said loops is substantially uniform throughout.

3. A device as in claim 1 wherein each of said arches of a said loop is a substantially semi-circular section.

4. A device as in claim 3 wherein the free end of the second semi-circular section of one of said loops terminates at a point no higher than a diameter line of substantially a semi-circle located between the terminating end of the straight section of the loop and the free end of said loop.

5. An intra-uterine contraceptive device comprising a substantially straight stem portion from which extends at one end thereof a pair of oppositely disposed loops which are generally coplanar with the stem, at least the loops of said device being of a soft plastic material and having a partially retentive memory to permit the loops of the device to deform and more readily conform to the walls of the uterine cavity into which the device is to be inserted, each loop having a first arch with a respective first radius and commencing in one direction from one end of the stem and curved to extend and terminate in a second direction opposite from said first direction; (a) an elongated straight section commencing at the termination of said first semi-circular section and extending for a distance in said second direction and generally parallel to the stem, and a second arch each of (a smaller) respective second radius (than) which is smaller than the radius of said first arch commencing at the termination of said elongated straight section extending in said second direction and then curving back to terminate with a free end extending toward said first direction; the free end of the second semi-circular section of one of said loops terminating at a point no higher than a diameter line of substantially a semi-circle located between the terminating end of the straight section of the loop and the free end of said loop with said diameter line being spaced from all portions of the first section of the loop, the cross-section of the loop material having a maximum dimension in one direction in the range of from about 0.055 to about 0.065 inches on a maximum dimension in a direction generally transverse to said one direction in the range of from about 0.045 to about 0.055 inches.

6. A device as in claim 5 wherein the cross-section of each of said loops is substantially uniform throughout.

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