Jan. 20, 1970 M. SLONĚK ET AL 3,490,446

CONTRACEPTIVE

Filed April 6, 1967

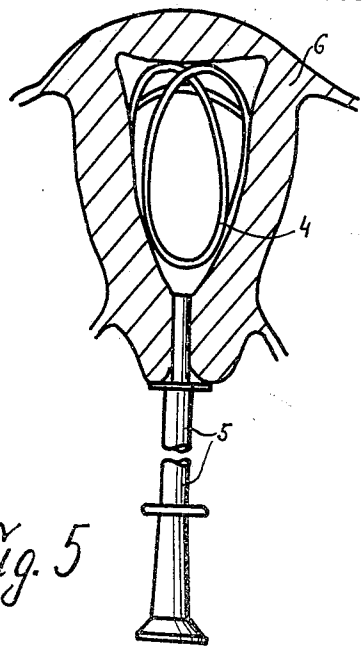

Fig. 5

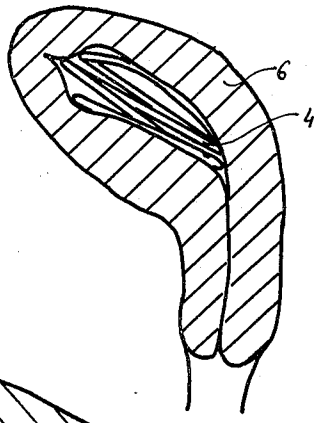

Fig. 6

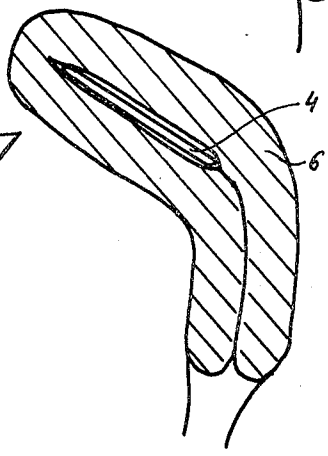

Fig. 7

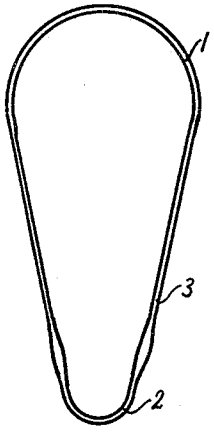

Fig. 1

Fig. 3

Fig. 4

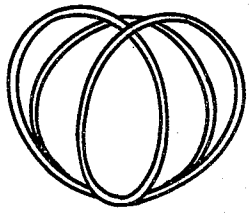

Fig. 2

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CONTRACEPTIVE

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U.S. Cl. 128—130 24 Claims

ABSTRACT OF THE DISCLOSURE

A mechanical intra-uterine contraceptive in form of an endless body of elastically deformable wirelike material having a plurality of loop portions disposed in different planes and each being deformable in the respective plane as well as transversely thereof.

BACKGROUND OF THE INVENTION

The present invention relates to contraceptives in general, and more particularly to mechanical contraceptives. Still more specifically, the present invention relates to mechanical intra-uterine contraceptive devices.

The idea of preventing undesired conception by introducing a mechanical device into the uterus to guard against deposition and growth of the ovum in the membrane which lines the interior of the uterus is by no means new. The concept can, in fact, be traced as far back as the writings of Hippocrates and has since that time been abandoned and revived repeatedly.

However, this method of mechanical prevention of pregnancies has never become accepted because no suitable materials were found from which to manufacture the devices which were to be introduced into the uterus. Many different types of metals were tried, but because of their hardness, poor resiliency, and excessive tissue reaction resulting therefrom the devices invariably were found to produce serious complications.

With the advent of plastics technology all of this has changed. There are now available many types of plastic substances which are not possessed of the disadvantages inherent in the previously used materials, and with this in mind the concept of a mechanical device to be introduced into the uterus was revived and, this time, was found to be safe and reliable. Accordingly, there are now available various different type of intra-uterine devices, all made from plastics, and in particular certain types of polyethylene substances which are harmless to the living organism and which do not cause inflammations or malignant tumors. Polyethylene and its copolymer vinyl acetate have been found particularly suitable, and it has also been proposed that to facilitate location of the once-inserted device the basic polymer be filled with barium sulphate so that the device will more readily show up on X-ray examination or be locatable by the acoustic frequency method.

A considerable variety of different devices of the type in question is now available world-wide. However, all of these devices can be classified as belonging to one of three basic types, namely the type which has the shape of an Archimedean spiral, the type which has the shape of a loop, and the type which has the shape of a bow. The spiral-shaped type of device is the one which is most effective in the prevention of conception. But it is so easily expelled from the uterus, and has other disadvantages, that it finds very little practical use. The type of device in form of a loop is only slightly less effective for its intended purpose but it, also, is frequently expelled. The bow-shaped device, which might also be said to have

the shape of an hour glass, has a lower efficiency in preventing unwanted pregnancy than either the spiral or the loop types, but by virtue of its shape it provides the best protection against expulsion. It should be mentioned here that such expulsion can occur entirely without knowledge of the wearer, leaving her therefore completely unaware that she is devoid of the protection the device is intended to furnish.

The spiral and loop-shaped devices cover, when deformed within the uterus, the greatest area of the walls bounding the uterine cavities. However, as already stated, their open shape renders them susceptible to being easily expelled. The bow device, when deformed, covers substantially smaller areas of the wall bounding the uterine cavity, so that gravidity may occur in portions of the wall which are not covered by the device. Generally speaking it may be said that mechanical intra-uterine contraceptive devices of the "open" and "closed" types as just described above, cover the walls bounding the uterine cavity in two dimensions while the uterus is in idle state. By idle state it is meant that the uterine is not undergoing muscular contractions. Such contractions are, however, characteristic of the uterus and occur rather frequently. When they take place the shape of the uterine cavity changes and the uterine walls move so that the aforementioned types of devices cannot cover the desired seventy five percent of the uterine cavity area in the third dimension brought about by the contractions.

SUMMARY OF THE INVENTION

The present invention overcomes the disadvantages set forth above with respect to the previously existing state of the art.

More particularly, the present invention provides a mechanical intra-uterine contraceptive device which has the capacity to conform itself and to modify its shape in the variously-configurated three-dimensional volumes of space which are defined within the uterus during changes in the latter in response to muscular contraction.

The mechanical intra-uterine contraceptive device in accordance with the present invention is possessed of inherent recovery ability subsequent to deformation resulting from shifts in the uterine walls.

Furthermore, the device according to the present invention is simple and inexpensive to construct, and has a wide range of applicability for the prevention of unwanted pregnancies and as a treatment for therapeutic indications.

The device disclosed here is applicable not only for use on human beings, but can also be utilized in veterinary practice.

In accordance with one feature of our invention we provide a mechanical intra-uterine contraceptive device which is an endless body of elastically deformable wire-like material. This body has a plurality of loop portions which are disposed in different planes and each of which is deformable in the respective plane as well as transversely thereof.

Another aspect of our invention resides in a method of making such a mechanical intra-uterine device, and this method comprises the steps of forming a blank which consists of an endless length of elastic material which is disposed in a single plane, and in the subsequent conversion of the thus obtained blank into a series of loops which are respectively located in different planes from one another, so that the inherent elasticity of the material tends to increase the distance between the two outermost ones of these loops.

The novel features which are considered as characteristic for the invention are set forth in particular in the appended claims. The invention itself, however, both as to its construction and its method of operation, together

with additional objects and advantages thereof, will be best understood from the following description of specific embodiments when read in connection with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a diagrammatic showing of a blank for an intra-uterine contraceptive device in accordance with the present invention;

FIG. 2 is a top view of the contraceptive device which results from coiling the blank of FIG. 1 into an endless spatial spiral;

FIG. 3 is a side view of the device as shown in FIG. 2, showing the loops of the spiral in abutting state;

FIG. 4 is a side view of the device with the spatial arrangement apparent;

FIG. 5 is a frontal view of the device inserted in a uterus;

FIG. 6 is a sagittal section of a uterus in idle or normal state, having the present device inserted therein; and

FIG. 7 is the same view as shown in FIG. 6, but showing the uterus while undergoing uterine contractions.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Discussing now the drawing in detail, and firstly FIG. 1 thereof, it will be seen that a blank for making the novel device in accordance with the present invention consists of an endless strip of wire-like material. It has been found that polyethylene or its co-polymers, which if desired may be filled with barium or other substances to provide X-ray contrast, are particularly suitable and make possible a device having the desired elasticity and shape-recovery characteristics. The blank of FIG. 1 is preferably made by injection molding, but need not necessarily be made by the method.

As clearly seen in FIG. 1 the plastic strip or wire has a cross section which is different at different points of the material and, although this is not specifically shown, this cross section varies from circular to oval or elliptic shape. The material thickness of the blank ranges between 0.8 and 2.5 mm. and this provides the device with better resistance to mechanical strains which it undergoes, particularly when it is pulled into an intertergite prior to being introduced into the uterine cavity. This will be discussed later on.

The blank shown in FIG. 1 is a planar body consisting of two integral portions located on opposite sides of a plane of symmetry coinciding with the longitudinal axes of the blank. FIG. 1 shows that the blank consists of two arcuate end portions of which the larger one is identified with reference numeral **1** whereas the smaller one is identified with reference numeral **2**. The end portions **1** and **2** are connected to one another by a pair of integral side or leg portions **3** which in FIG. 1 are shown to be linear but which, it will be understood, may also be curved or bowed.

The larger end portion **1** has a radius which is preferably four times greater than the radius of the shorter or smaller end portion **2**. Of course, in FIG. 1 the end portions are shown to be of semi-circular configuration and in such case the diameter of the larger end portion **1** will be four times that of the smaller end portion **2**. Having just stated that the relationship is four to one it should be pointed out that this is only an exemplary figure. Actually, the ratio of the radii or, if the end portions are semi-circular, of the diameters can vary within a range of 1:2.5 and 1:5.5.

In the illustrated embodiment the overall longitudinal extension of the blank is assumed to be 12 cm. and this is assumed to be approximately 2.5 times the diameter of the larger end portion **1**. This ratio, also, can vary within a range of 1:1.8 and 1:3. By suitably choosing these basic dimensions, the desired ratio between the end portions **1** and **2** and the legs **3** is obtained so that, after coiling the blank into the form shown in FIG. 2, an endless spatial spiral **4** is obtained, as clearly shown in FIG. 2.

The device which is obtained by coiling the blank of FIG. 1, for instance about the finger of the person who will insert the contraceptive device into the uterus, is a three-dimensional body comprising egg-shaped and oval loops which are formed from the end portions **1** and **2** as well as from the legs **3**. FIG. 3 shows the form of the device after the blank of FIG. 1 has been coiled about a finger of the inserter and has then been removed from the finger. In this view the coils are abutted against one another. FIG. 4 shows what happens when the person releases his hold on the device as illustrated in FIG. 3, and how the inherent elasticity of the device causes the loops to move apart from one another. It will be clearly evident that all of the loops are now located in different planes.

FIG. 2 shows a device according to the invention as it appears when inserted into the uterine cavity. It is clearly evident that the device forms a three-dimensional body wherein each loop is located in a different plane, and whereof each loop can be deformed in its own plane as well as transversely thereof independently of the other loops formed by the spatial spiral. It is this three-dimensional shape which is responsible for the high efficiency which has been found in the novel device, and which also prevents the expulsion of the device during uterine contractions. This configuration in form of a three-dimensional body, in which the loops formed from the larger and smaller end portions **1** and **2** form two opposite arches and contact the frontal and lower uterine cavities, is not known from the prior art.

FIG. 5 shows that the spiral which is formed by winding the body or blank of FIG. 1 about the fingers of the inserter, and which has a configuration as shown in FIG. 3, is inserted or pulled into an inserting device **5** by means of which it is introduced into the uterine cavity **6**. Therein the device is expelled or released from the inserting device **5** and opens into the configuration shown in FIG. 2 and FIG. 5, that is into an endless spatial spiral **4**. Once introduced into the uterine cavity **6** the spiral **4** covers the desired maximum area of the uterine cavity and, unlike devices of the type known from the prior art, it is capable of conforming itself to the shape of the uterine cavity. This is illustrated in FIGS. 6 and 7, which respectively show cross sections of the uterus in the idle state and during uterine contractions. The capacity of the device to conform itself and to modify its shape in the three-dimensional space defined within the uterus is clearly evident from these figures and is an outstanding property of the novel device which is responsible for the effective performance of the device.

Because of the coiling of the blank shown in FIG. 1 into an endless spatial spiral the plastic strip or wire-like material of the blank, that is of the basic planar body, is prestressed whereby its recovery ability after deformation is greatly enhanced. This ability, it is to be noted, is further supported by the local reinforcement provided by increases in the cross section of the device at predetermined points on the basic body, such section being reinforced or increased at points which are dynamically strained during contractions of the uterine cavity in which the device is to be located.

As has already been pointed out, the use of the device in accordance with the present invention is not limited to applications for human beings, but can also be extended to veterinary practice. Furthermore, the novel device need not be limited in its application to contraceptive uses per se, but can also be employed for therapeutic indications.

It will be understood that each of the elements described above, or two or more together, may also find a useful application in other types of applications differing from the types described above.

While the invention has been illustrated and described as embodied in a mechanical intra-uterine contraceptive device, it is not intended to be limited to the details shown, since various modifications and structural changes may be made without departing in any way from the spirit of the present invention.

Without further analysis, the foregoing will so fully reveal the gist of the present invention that others can by applying current knowledge readily adapt it for various applications without omitting features that, from the standpoint of prior art, fairly constitute essential characteristics of the generic or specific aspects of this invention and, therefore, such adaptations should and are intended to be comprehended within the meaning and range of equivalence of the following claims.

What is claimed as new and desired to be protected by Letters Patent is set forth in the appended claims.

I claim:

1. A mechanical intra-uterine contraceptive device, comprising an endless body of elastically deformable wire-like material, said body having a longitudinal as well as a transverse extension and being provided with a plurality of loop portions of different sizes disposed in different planes respectively and whose major loop sections are out of contact in direction of said longitudinal extension so that each of said loop portions is deformable in the respective plane as well as transversely thereof.

2. A device as defined in claim **1**, wherein said body defines an endless spatial spiral.

3. A device as defined in claim **1**, wherein said body is of other than constant cross section.

4. A device as defined in claim **1**, wherein the wire-like material of said body is of rounded cross-sectional contour.

5. A device as defined in claim **1**, wherein said wire-like material is a synthetic plastic material.

6. A device as defined in claim **2**, wherein said loop portions are disposed in a plurality of adjoining planes.

7. A device as defined in claim **2**, wherein said planes intersect each other.

8. A device as defined in claim **1**, wherein each of said loop portions is deformable independently of the remaining loop portions.

9. A device as defined in claim **1**, wherein the thickness of said wire-like material of said body at different points of the body varies between 0.8 and 2.5 mm.

10. As a novel article of manufacture, a blank for producing a mechanical intra-uterine device, said blank comprising an endless body of wire-like material having a first loop portion of a relatively large radius of curvature, a second loop portion of a smaller radius of curvature than that of said first loop portion, and a pair of elongated leg portions elongated between and each connecting one end of said first loop portion with a corresponding end of said second loop portion.

11. An article as defined in claim **10**, wherein said body is elongated and said first and second loop portions are respectively provided at opposite ends of said body.

12. An article as defined in claim **10**, wherein said wire-like material of said body is of other-than-constant cross section.

13. An article as defined in claim **10**, wherein said body consists of synthetic plastic material.

14. An article as defined in claim **10**, wherein said wire-like material of said body is of rounded cross-sectional configuration.

15. An article as defined in claim **10**, wherein said body is elongated and comprises two substantially identical halves located at opposite sides of a longitudinal symmetry plane.

16. An article as defined in claim **10**, wherein said loop portions are rounded.

17. An article as defined in claim **16**, wherein the difference in the radii of curvature of said two loop portions ranges from a ratio of 1:2.5 to a ratio of 1:5.5.

18. An article as defined in claim **16**, wherein one of said loop portions has a radius of curvature which is four times greater than the radius of curvature of the other of said loop portions.

19. An article as defined in claim **10**, wherein said body has an overall length of substantially 12 cm.

20. An article as defined in claim **10**, wherein the overall length of said body is substantially 2.5 times the doubled radius of curvature of the first loop portion.

21. An article as defined in claim **10**, wherein a predetermined ratio exists between the overall length of said body and double the radius of curvature of said first loop portions, and wherein said ratio ranges between 1:1.8 and 1:3.

22. An article as defined in claim **10**, wherein the cross-sectional configuration of the material of said wire-like body ranges from circular to elliptic outline at different points along said body.

23. A method of making a mechanical intra-uterine device, comprising the steps of forming a blank consitsing of an endless length of elastic material disposed in a single plane; and converting said blank into a body composed of a series of loops of different sizes respectively located in different planes from one another, whereby the inherent elasticity of the material tends to increase the distance between the two outermost loops and impart to said body a length determined by the maximum distance between said two outermost loops.

24. A method as defined in claim **23**, wherein said step of converting said blank includes twisting said blank into the shape of an endless spatial spiral.

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