INTRA-UTERINE CONTRACEPTIVE DEVICE AND METHOD OF USING SAME

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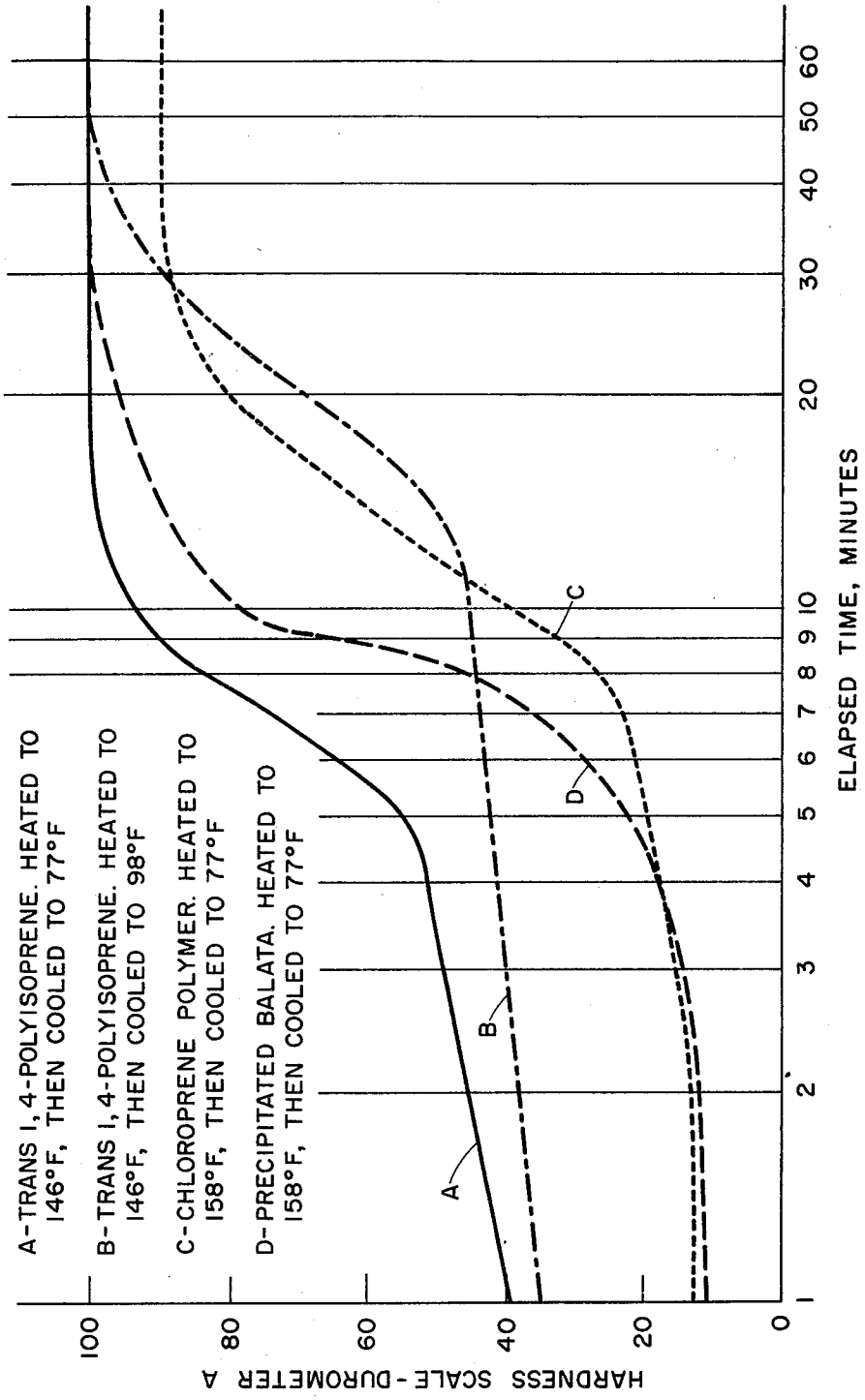


Fig. 6

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INTRA-UTERINE CONTRACEPTIVE DEVICE AND METHOD OF USING SAME

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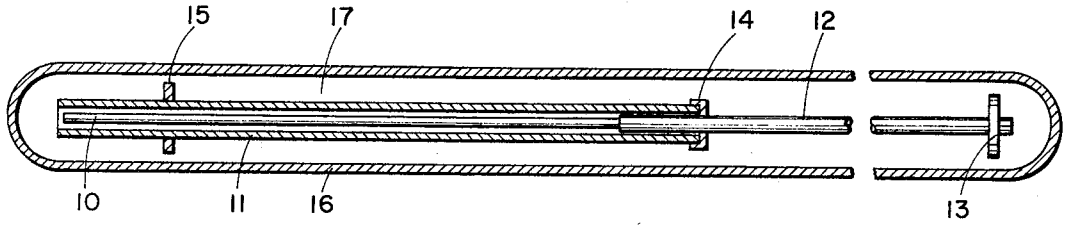


Fig. 1

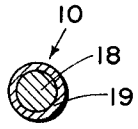


Fig. 2

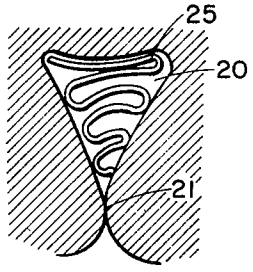


Fig. 5

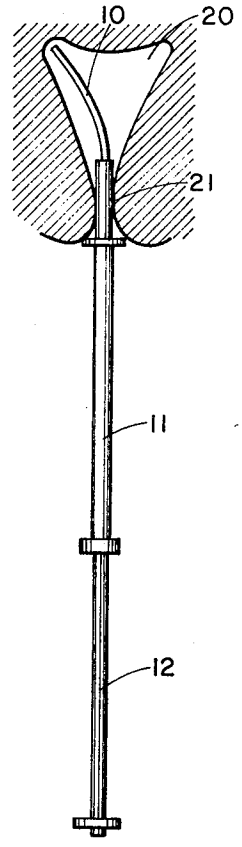


Fig. 3

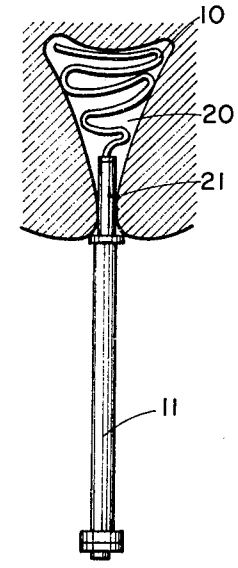


Fig. 4

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INTRA-UTERINE CONTRACEPTIVE DEVICE AND METHOD OF USING SAME

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U.S. Cl. 128—130 10 Claims

ABSTRACT OF THE DISCLOSURE

An intra-uterine contraceptive device in the form of a rod of a crystalline thermoplastic material which may be softened by heat decrystallization and inserted at a comfortable temperature into the uterine cavity in the plastic state to assume a random configuration substantially corresponding to the size and shape of the uterine cavity, thus making it particularly effective. Subsequent to insertion the crystalline thermoplastic material recrystallizes to retain its random configuration making it less subject to expulsion than preformed devices.

The use of intra-uterine devices to prevent pregnancy has recently received a great deal of attention, and a number of preformed configuration have been suggested for such devices. Among these prior art devices may be listed the Lippes "loop," the Margulies "spiral," the Birnberg "bow," and various ring configurations (e.g., USP 3,312,214). Concurrent with the development and use of intra-uterine devices has come a realization that they must be designed with consideration being given to uterine morphology. It has now become apparent that the human uterus is not a standard object with respect to size and contour. (See, for example, the cavity measurements tabulated by Davis and Israel in "Uterine Cavity Measurements in Relation to Design of Intra-Uterine Contraceptive Devices," Intra-Uterine Conception, Proceedings of the Second International Conference, October 1964, New York, N.Y., at p. 139).

The rather large variations in size and contour have made it impossible to design a single preformed configuration which will avoid unduly distending some uterine cavities while not being subject to expulsion from others. In the above-identified article, Davis and Israel made the following observation: "An ideal intra-uterine contraceptive device should probably allow for the very considerable variations observed in cavity size among normal multiparous uteri. An ideal Incon should also combine two mechanically contradictory characteristics; ease of insertion and resistance to expulsion."

There is, therefore, indicated a need for an improved intra-uterine contraceptive device and method for positioning such a device in the uterine cavity.

It is, therefore, a primary object of this invention to provide an improved intra-uterine contraceptive device, the improvement being reflected in its ability to adjust for variations in the size and contours of the normal uterine cavity. It is another object of this invention to provide a device of the character described which is easy to insert and which, once inserted, is less subject to involuntary expulsion. It is yet another object of this invention to provide an improved method of positioning an intra-uterine device within the uterine cavity. Other objects of the invention will in part be obvious and will in part be apparent hereinafter.

The invention accordingly comprises the several steps and the relation of one or more of such steps with repect to each of the others, and the article possessing the features, properties, and the relation of elements, which are exemplified in the following detailed disclosure,

and the scope of the invention will be indicated in the claims.

For a fuller understanding of the nature and objects of the invention, reference should be had to the following detailed description taken in connection with the accompanying drawings in which

FIG. 1 is a side elevational view, partly in cross section, of the intra-uterine device of this invention;

FIG. 2 is a cross section of a modification of the rod showing the use of a physiologically inert coating;

FIGS. 3 and 4 illustrate the steps in the insertion of the device;

FIG. 5 is a longitudinal section of a uterine cavity showing the final position of the intra-uterine device lodged therein; and

FIG. 6 is a plot of increase in hardness with elapsed time for several exemplary materials suitable for the device of this invention.

The intra-uterine device of this invention combines the two mechanically contradictory characteristics heretofore considered impossible to achieve in one device by being formed originally as a substantially straight rod and by being inserted in a plastic condition so as to be finally lodged in a random configuration which conforms substantially to the shape and size of the individual uterine cavity. The crystalline thermoplastic material has physical characteristics which permit it to be softened by heat and then inserted in a softened plastic state at no greater than body temperature. Subsequent to insertion the thermoplastic material gradually returns to its original crystalline state before heating, thus "setting up" the configuration in permanent form. Although the device is not normally subject to expulsion, it exhibits sufficient flexibility to permit ready removal.

The intra-uterine device of this invention is illustrated in detail in FIG. 1. It will be seen to comprise a substantially straight rod **10** of a crystalline thermoplastic material (described in detail below) contained within a thin-walled cannula **11**. Extending a short distance into the cannula **11** is a pusher member **12** adapted as a means to impart a forward motion to rod **10**. The pusher member **12** may have a flange **13** located at or near its exposed end to serve to limit its forward motion so that no appreciable length of the pusher member can extend beyond the outlet or forward end of cannula **11**. The pusher member **12** may be tempararily sealed to the cannula by means of a removable sealing ring **14**. The cannula has a collar **15** spaced about one inch back from the inserting end to prevent its insertion beyond the cervical canal.

If desired, the device may be packaged for use in a presterilized condition by enclosing it in a sheath **16** adapted to maintain aseptic condition in the volume **17** surrounding the cannula. Alternatively, the sheath may be omitted and the assembly, without the sheath, sterilized just prior to use.

FIGS. 3–5 illustrate the method by which the intra-uterine device is lodged in the uterine cavity. The assembly of FIG. 1 is heated such as by immersing it in hot water to a sufficiently high temperature to decrystallize the rod material and render it plastic, soft and pliable while still retaining its rod configuration. Since this heating may raise the rod and cannula to a temperature above that which can be tolerated, the assembly is allowed to cool to body temperature or even room temperature before insertion. As explained before, the rod material must be such as to exhibit a delay in recrystallization to permit insertion at a comfortable temperature but in a plastic state.

As shown in FIG. 3, the cannula is then inserted into the uterine cavity **20** through the cervical canal **21**, and the rod is given a forward motion by means of the pusher

member **12**. As the rod **10** enters the uterine cavity **20**, it contacts a wall thereof; and as it is inserted further, it is twisted and turned to conform substantially to the contours of the cavity as shown in FIG. 4. With the withdrawal of the cannula, the rod remains lodged in its random configuration to become the intra-uterine device **25** of FIG. 5.

It will be seen from FIG. 5 that once the thermoplastic material forming the device has returned to its crystalline state there is little opportunity for the device to be expelled. Moreover, since the device is molded in situ to conform to the particular configuration of the uterine cavity, it will normally cause no damage to the cavity walls.

As indicated previously, the material from which the rod, and ultimately the intra-uterine device, is formed must meet certain requirements. First, the material should be physiologically inert under the normal chemical and physical conditions existing within the uterine cavity. If, however, a material fulfills all of the other requirements described but is not physiologically inert, then, as illustrated in FIG. 2, the rod **18** may have a coating **19** which is inert. Such a coating may be polytetrafluoroethylene (sold as Teflon), a suitable silicone rubber, or any other inert material which may be deposited in the form of a thin flexible coating. Tests on coated materials have shown that the coating does not influence the desired properties of the rod material.

The rod material may be characterized as a crystalline thermoplastic which is decrystallized through heating at a temperature above body temperature, i.e., above about 100° F. It is desirable that decrystallization take place at a temperature no higher than the temperature of boiling water (212° F.) and it is preferable that it take place over a range between about 120 and 170° F. It is also necessary that the material in its decrystallized state be soft and pliable while retaining its physical integrity, i.e., its rod-like structure. It is also necessary that the crystalline thermoplastic material be capable of exhibiting a crystallization rate, subsequent to heat decrystallization, such that it remains soft and pliable for a brief period of time (e.g., at least several minutes) after its temperature is reduced to that which is suitable for contact with the human body.

Finally, the thermoplastic material should exhibit a degree of flexibility and springiness in the form of a relatively small diameter, elongated member in its crystallized state and should have a hardness no greater than about 100 on the Durometer A scale which will allow easy withdrawal from the uterus when removal is desired.

A number of crystalline thermoplastic materials are known, and they include naturally occurring as well as synthetic materials. FIG. 6 illustrates the rate of recrystallization of three typical materials suitable for the practice of this invention. As noted in FIG. 6, the materials were heated, either to 146° F. or 158° F., and then cooled to approximately room temperature or to body temperature. The hardness on the Durometer A scale (see ASTM Standard Method of Test D 1706–61) was then measured for each sample for a period of time. Since hardness is a function of degree of crystallinity, the curves of FIG. 6 may be considered to represent the rate of crystallinity experienced by the materials after they had been cooled to the indicated temperatures. The trans 1,4-polyisoprene used in these tests was a synthetic material. It is known, however, to occur naturally in balata, a natural rubber. The chloroprene polymer was that sold by E. I. du Pont de Nemours & Co., under the trade name Neoprene HC. It is characterized as having a relatively fast rate of crystallization when compared to other related polymers. The precipitated balata is one form of nautral rubber.

FIG. 6 indicates that crystallization of the trans 1,4-polyisoprene increases rapidly after about 5 minutes when cooled to 77° F. and after about 12 minutes when cooled to 98° F. For the chloroprene rapid crystallization sets in after about 8 minutes at 77° F. and for the precipitated balata, after about 5 to 6 minutes.

Such materials as these are ideally suited for the intra-uterine device of this invention, for they permit decrystallization to be achieved at a temperature below 212° F., and they remain soft and pliable for a finite period of time, typically in the order of at least four minutes, after they have been cooled to a temperature which is comfortable for insertion.

The rod of crystalline thermoplastic material which is to form the intra-uterine device of this invention will typically have a diameter between about 0.1 and 0.12 inch and a length between about 2 and 2.5 times the length of the normal average uterine canal. Within these dimension ranges it is possible to provide protection for a majority of the cases.

Inasmuch as it is necessary to heat the rod in the cannula, it is necessary that the cannula **11**, pusher member **12** and sheath **16** be formed of materials which are capable of withstanding the temperature required to effect this heating. The cannula is preferably made of a plastic material, such as polyethylene, which has some degree of flexibility.

If the assembly of FIG. 1 is not distributed with the protective sheath or in a sterilized condition, then sterilization can be effected simultaneously with heating, or after heating such as by immersing in a suitable sterilizing fluid which is at a temperature which does not substantially accelerate the crystallization rate of the rod material.

It will be seen from the above discussion that the intra-uterine contraceptive device of this invention meets the two primary requirements for such a device, namely, ease of insertion and resistance to expulsion; moreover, it minimizes through its configuration the possibility of complications brought about through damage to the uterine cavity.

It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in carrying out the above method and in the article set forth without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawing shall be interpreted as illustrative and not in a limiting sense.

I claim:

1. An intra-uterine contraceptive device, comprising in combination:

(a) a cannula;

(b) a substantially straight rod positioned within said cannula, said rod having a diameter ranging between about 0.1 and 0.12 inch and a length equivalent to from about 2 to 2.5 times the length of the normal uterine canal, said rod being formed of a physiologically inert material capable of being decrystallized at a temperature below about 212° F. and above normal body temperature to an inelastically soft and pliable state which it will maintain for a finite period upon being cooled to near said body temperature, and after which period said material will recrystallize into a stable, hard, elastic state in whatever configuration it then finds itself; and

(c) means to apply a forward motion to said rod whereby said rod may be inserted into the uterine cavity in said softened, pliable state and assume a random configuration essentially conforming in size and shape to said uterine cavity.

2. An intra-uterine device in accordance with claim **1** wherein said rod is formed of trans 1,4-polyisoprene.

3. An intra-uterine device in accordance with claim **1** wherein said rod is formed of a polymer of chloroprene.

4. An intra-uterine device in accordance with claim **1** wherein said rod is formed of precipitated balata.

5. An intra-uterine device in accordance with claim 1 wherein said rod is covered with a physiologically inert material.

6. An intra-uterine device in accordance with claim 1 wherein said cannula in which said rod is positioned and said means to apply a forward motion to said rod are encased in an aseptic casing adapted to be heated to said decrystallization temperature of said rod material.

7. A method of positioning an intra-uterine contraceptive device within the uterine cavity, characterized by the step of inserting into the uterine cavity a rod of a physiologically inert material in a soft pliable, decrystallized state whereby in the process of said insertion said rod is bent into a random configuration to conform substantially to the shape of said uterine cavity, said rod being formed of a material capable of being decrystallized at a temperature below about 212° F. and above normal body temperature to said soft state which it will maintain for a finite period of time upon being cooled to near said body temperature and after which said material will re-

crystallize into a stable, hard, elastic state in whatever configuration it then finds itself.

8. A method in accordance with claim 7 wherein said rod material is trans 1,4-polyisoprene.

9. A method in accordance with claim 7 wherein said rod material is a polymer of chloroprene.

10. A method in accordance with claim 7 wherein said rod material is precipitated balata.

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ADELE M. EAGER, Primary Examiner

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