

[72] Inventor **Jerome Schwartz**  
**1321 Club Drive, Hewlett Harbor, N.Y.**  
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 [45] Patented **Dec. 21, 1971**

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*Primary Examiner*—Dalton L. Truluck

*Attorney*—Leonard H. King

[54] **INTRAUTERINE DEVICE FOR CONTRACEPTION**  
**18 Claims, 9 Drawing Figs.**

[52] U.S. Cl. .... **128/130**

[51] Int. Cl. .... **A61f 05/46**

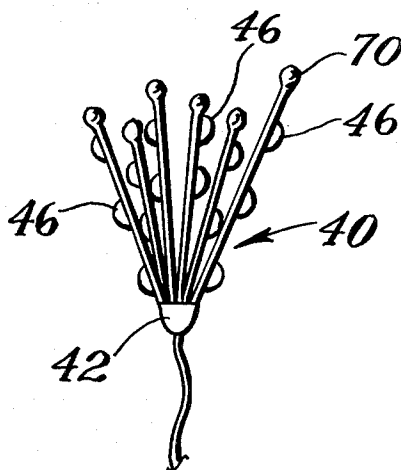
[50] Field of Search ..... **128/128,**  
**129, 130, 131**

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**ABSTRACT:** An intrauterine device (I.U.D.) for contraception is provided which is comprised of a plurality of rodlike members made of a soft, inert plastic. One end of each of the rodlike members is joined at a common junction to define, in an expanded condition, an upwardly diverging cone having an envelope that is oval shaped in transverse cross section. The rodlike members may be of equal or unequal lengths and may have irregularly spaced nodules formed thereon. A heat soluble gelation cap may be used to hold the rodlike members in a collapsed condition prior to insertion of the I.U.D.



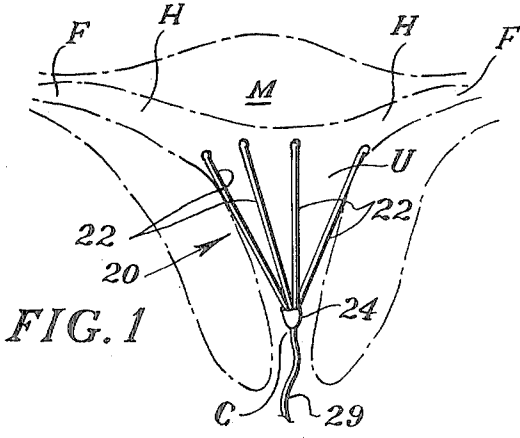


FIG. 1

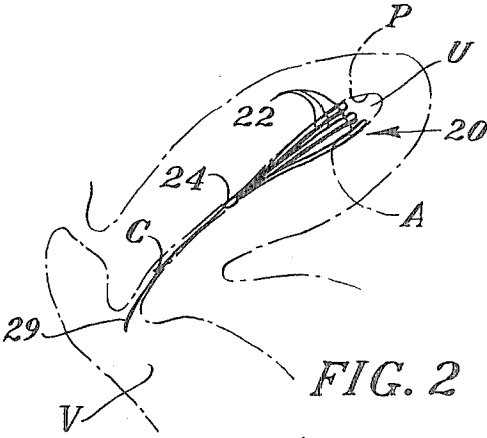


FIG. 2

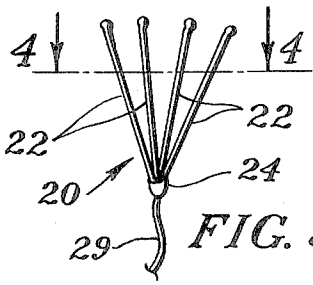


FIG. 3

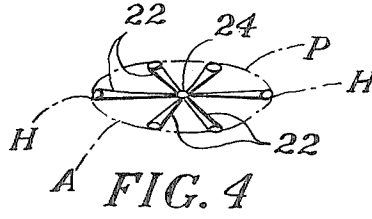


FIG. 4

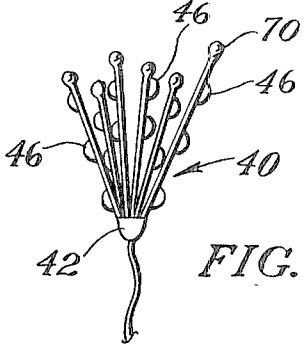


FIG. 6

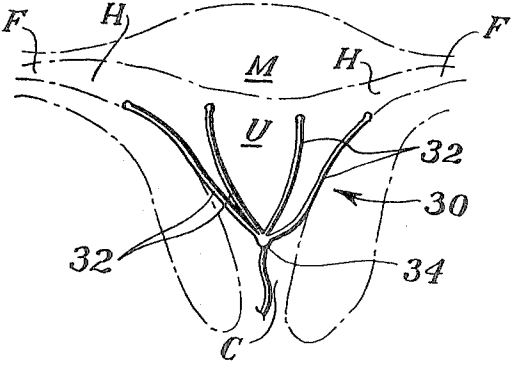


FIG. 5

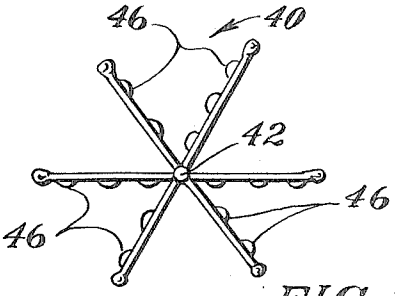


FIG. 7

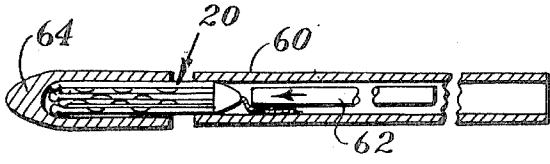


FIG. 9

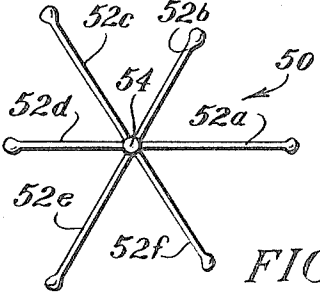


FIG. 8

INVENTOR.  
JEROME SCHWARTZ  
BY  
Leonard H. King  
ATTORNEY

## INTRAUTERINE DEVICE FOR CONTRACEPTION

The present invention relates generally to I.U.D.'s and more particularly to an improved I.U.D. that, in transverse cross section defines a shallow oval.

### BACKGROUND OF THE INVENTION

I.U.D.'s used for the purpose of contraception are old in art, having been popularized by the development of Dr. Ernst Grafenberg's silver ring. Since that time, almost forty years ago, there have been many improvements in both the configuration and the material of the device as well as in the efficiency and the public acceptance of the device. The configuration of the I.U.D.'s most frequently used today may be categorized generally as coils, loops, rings and bows, the best known examples being those devices developed by Margulies, Lippes, Ota and Birnberg, respectively. Still another, structurally different form of I.U.D. is described in U.S. Pat. No. 3,353,533 granted on Nov. 21, 1967 to Atsumi Ishihama. The materials most frequently used today in I.U.D.'s are semirigid, inert, medium density plastics such as polyethylene, polypropylene, polytetrafluoroethylene, polyvinyls, silicones etc. Frequently, a radio opaque compound such as barium sulfate is combined with the plastic to permit subsequent radiologic detection. Alternatively, a ferrous metal insert has been used to facilitate magnetic detection or detection by means of electronic apparatus.

While I.U.D.'s are presently considered to be one of the better forms of contraception, the manner in which they function is not fully understood. It has been suggested that I.U.D.'s increase the functional activity of the endometrium but it is not believed that I.U.D.'s prevent ovulation. Nor is it believed that the I.U.D. interferes with fertilization. The I.U.D. does, however, prevent implantation of the ovum in the uterine wall due, it is suspected to a simulated foreign body reaction. In any event, I.U.D.'s are statistically very effective and are widely accepted.

It has long been recognized that even though I.U.D.'s are safe, reliable and efficient, there are still several very important structural aspects that can be improved. For example, the I.U.D. must be capable of insertion using a thin-walled cannula and a push rod without the need for dilation of the cervix. Or, if dilation of the cervix is required, then it should be kept to an absolute minimum. The I.U.D. must also be readily removable and yet must be capable of resisting expulsion caused by the involuntary uterine contractions exhibited by the fundus muscle. These are, of course, diametrically opposite conditions, but which must nevertheless be met for the I.U.D. to be effective.

Another functionally important aspect of I.U.D. design is the ultimate effectiveness for contraception. In this regard there is a body of opinion to the effect that the degree of protection is dependent upon the size of the I.U.D. This may very well mean that the greater area of the uterine wall that is contacted by the I.U.D., the less likelihood there will be of an unwanted pregnancy. There are, of course, practical size limitations and it is absolutely essential that the device is not made too large. If the I.U.D. is not properly sized and shaped, there is the danger that it will embed itself in the endometrial tissue or will perforate the uterus.

The prior art patents that are the closest to the present invention will now be discussed in limited detail. The closest is the aforementioned Ishihama patent wherein there is disclosed a plurality of elongated members secured to each other at a common joint. When inserted, the I.U.D. due to its inherent elasticity, opens up to form a single plane sector. The free end of each of the two outboard elongated members is located adjacent one of the uterine horns leading to the fallopian tubes. The free end of each of the remaining elongated members is positioned in opposition to the fundus muscle. Ishihama recognized the need to cover as much as the uterine cavity as possible but since his device is disposed solely in a single plane then only one wall in the frontal plane of the

uterus will be contacted. The drawing of Ishihama shows, and he claims, contact of only two elongated members with the anterior wall and not the posterior wall as well.

Other patents, for example, U.S. Pat. No. 3,077,879 issued on Feb. 19, 1963 to M. H. Knoch, U.S. Pat. No. 3,312,214 issued on Apr. 4, 1967 to C. L. Burdick and U.S. Pat. No. 3,306,286 issued on Feb. 28, 1967 to M. A. Ahmed all disclose generally triangular configurations but it is apparent that only a single plane of usage is contemplated, as in the Ishihama patent. Accordingly, even though these patentees recognized the need for a device that will maximize contact with the uterine wall, which will be readily insertable and removable and which will resist involuntary expulsion, they have failed to provide the optimum configuration, namely a device that will contact both the anterior wall as well as the posterior wall of the uterus.

The Margulies coil, the Lippes loop, the Ota ring and the Birnberg bow all exhibit the same single plane construction that is both structurally and functionally different from the present invention. The same may be said for H. H. Hall ring U.S. Pat. No. 3,323,520 and the construction shown by G. Mazlin in U.S. Pat. No. 3,397,690.

### SUMMARY OF THE INVENTION

In its most basic form the present invention is characterized by a plurality of soft plastic, rodlike members that are connected to each other at a common joint. When inserted the device of this invention assumes a conical shape which, in transverse cross section, defines a shallow oval that permits both the anterior and posterior walls of the uterus to be contacted. One of the several embodiments disclosed herein teaches the use of unequal lengths for the rodlike members while another embodiment teaches the use of irregularly spaced nodules formed integrally with the rodlike members. It is also contemplated that the scope of the present invention includes a heat soluble gelation cap used to hold the rodlike members in a collapsed condition prior to insertion as well as detection means, for example, a compound such as barium sulfate or barium chloride or a ferrous metal integral with the plastic.

Accordingly, it is the primary object of the present invention to provide an improved I.U.D. for contraception.

Another important object of this invention is to provide an improved I.U.D. which, when inserted, assumes a conical shape.

Still another important object of this invention is to provide an improved I.U.D. which, when inserted, assumes an oval shape in transverse cross section.

Yet another important object of this invention is to provide an improved I.U.D., as described above, that is comprised of a plurality of rodlike members secured to each other at a common joint.

It is a particular object of this invention to provide an improved I.U.D., as described above, wherein the rodlike members are of unequal length.

An additional object of this invention is to provide an improved I.U.D., as described above, wherein the rodlike members include a plurality of irregularly spaced modules.

A further object of this invention is to provide an improved I.U.D., as described above, including a heat soluble gelatin cap arranged to hold the rodlike members in a collapsed condition prior to the insertion thereof into the uterus by means of a thin-walled cannula and a push rod.

Still another object of this invention is to provide an improved I.U.D., as described above, including means for detecting the presence thereof after it is inserted into the uterus.

It is a feature of this invention that the improved I.U.D. disclosed herein will, after it is inserted, have portions contacting both the anterior and posterior walls of the uterine cavity.

An advantage of the present invention is that the improved I.U.D. will resist involuntary contractions of the muscles adjacent the uterus and yet will still readily be removable.

These and other features, objects and advantages of the invention will, in part, be pointed out with particularity and will, in part, become obvious from the following, more detailed description of the invention taken in conjunction with the accompanying drawing, which forms an integral part thereof.

#### BRIEF DESCRIPTION OF THE DRAWING

In the various figures of the drawing, like reference characters designate like parts.

In the drawing:

FIG. 1 is a diagrammatic, sectional view in the frontal plane illustrating a human uterus and cervix with one embodiment of the present invention properly placed therein;

FIG. 2 is a diagrammatic side elevational view in section showing the embodiment of FIG. 1 together with a human uterus and cervix;

FIG. 3 is an enlarged elevational view of the embodiment of FIG. 1;

FIG. 4 is a sectional plan view taken along line 4—4 of FIG. 3;

FIG. 5 is an enlarged elevational view of an alternative embodiment of this invention;

FIG. 6 is an enlarged elevational view of another alternative embodiment of this invention;

FIG. 7 is a developed plan view of the embodiment shown in FIG. 6.

FIG. 8 is a developed plan view of still another embodiment of this invention; and

FIG. 9 is an elevational view of one of the embodiments of this invention shown prior to insertion.

Referring now to the drawings, FIGS. 1—4 will be used to describe and illustrate the present invention in its most basic form. A human uterus U, a cervix C and a vagina V are shown in dot and dash outline with the improved I.U.D. 20 properly placed. The I.U.D. 20 is comprised of a plurality of rodlike members 22 secured to each other at one end to define a common junction 24. FIG. 1 illustrates that the free ends of the outboard rodlike members 22 are positioned proximate the uterine horns H that lead to the fallopian tubes F while the free ends of the remaining, rodlike members are positioned in opposition to the fundus muscle M. In FIGS. 2 and 4 it will be seen that several of the rodlike members 22 are in contact with the anterior wall A of the uterus U, while several of the rodlike members are in contact with the posterior wall P of the uterus U. FIG. 3 illustrates the generally conical shape of the I.U.D. 20.

Nylon strings 29 attached to the junction 24 extend from the cervix and can be manually detected to verify the presence of the I.U.D. The device of the present invention can include other means for detecting the presence of the I.U.D. after insertion. The detection means may take the form of a radio opaque compound such as barium sulfate or barium chloride, for example, which lends itself to subsequent radiologic detection or, like the barium compound, a metal may be formed integrally with the I.U.D. so that its presence can be verified after insertion by suitable electronic apparatus.

The single plane prior art devices are generally fabricated from a semirigid polyethylene material which can perforate the tissues of the uterus. On the other hand, one of the advantages of the configuration of this invention is that soft plastic, such as ethylene-vinyl acetate copolymers, may be employed. Such materials approach rubber in softness and flexibility and are unlikely to damage surrounding tissues.

Where cost is an important factor, polyethylene may be used as the plastic. The thin configuration of the arms make it flexible even when polyethylene is employed, minimizing the danger of perforation.

The second embodiment shown in FIG. 5 is functionally similar to the first embodiment just described. That is, I.U.D. 30 is comprised of a plurality of rodlike members 32 that are secured to each other at a common junction 34. The second embodiment 30 is also substantially conical in elevation and is

oval shaped in transverse cross section. However, in the I.U.D. 30 of the second embodiment, the rodlike members 32 are gently curved so that at least the lower portion of the cone that is adjacent joint 34 is convex. This construction permits contact over a greater area of the uterus and, in accordance with one widely held theory, will more effectively inhibit conception. It is also less likely to be expelled.

Turning now to FIGS. 6 and 7, there is shown a construction that may be used with either of the first two embodiments of the invention just described. I.U.D. 40 is substantially cone shaped in elevation and oval shaped in transverse cross section. A plurality of rodlike members 42 are provided and are secured to each other at a common junction 44. In addition, the rodlike members 42 are each provided with a plurality of nodules 46 formed integrally thereon. The nodules 46 serve to make positive contact with the anterior and posterior walls A and P respectively, of the uterus U. Preferably, the nodules are irregularly spaced with respect to the juncture 44, as shown in the developed plan view of FIG. 7. This arrangement provides greater compactness of the device 40 in the collapsed condition. That is, the nodules 46 will tend to nest between each other when the I.U.D. 40 is being inserted thereby minimizing the need for dilation of the cervix C.

FIG. 8 illustrates still another construction of the present invention that may be used in combination with any of the previously described embodiments. An I.U.D. 50 is provided and is comprised of a plurality of rodlike members 52a—52f that are secured to each other at a common joint 54. In this embodiment, the rodlike members 52a—52f are of unequal length as is clearly shown in the developed plan view of FIG. 8. This construction also provides greater compactness in the collapsed condition so that the need for dilation of the cervix C is minimized.

Means for inserting the I.U.D. of this invention is shown in FIG. 9 and for purposes of illustration only the I.U.D. 20 is shown. A thin-walled cannula 60 and a push rod 62 of conventional design are employed in the usual manner that is well known to the medical profession and need not be described in greater detail. A nontoxic, heat soluble gelation cap 64 is formed about the free ends of the rodlike members 22. Within a short time after insertion, the gelation cap 64 will dissolve permitting the I.U.D. 20 to assume its expanded or oval shape. Until that time the gelation cap 64 holds the rodlike members 22 in a relatively tight and compact bundle thus permitting usage of the thin-walled cannula 60 and the push rod 62. In place of a cap, the bundle could be dipped into liquid gelatin, while clamped in a closed position, removed, until gelation occurs, to bond the rodlike members together. The resulting gelatin mass will melt in the body cavity.

All of the embodiments described hereinabove have, as a common factor, a conical shape that defines an oval in transverse cross section. The conical shape is made up of a plurality of soft plastic rodlike members that may be of equal or unequal length and, as desired, the rodlike members may be either straight or at least a portion thereof may be curved convexly in the frontal plane. Irregularly spaced nodules may also be provided on the rodlike members of any of the embodiments and means integral with the I.U.D. may be included to facilitate subsequent verification of the placement of the I.U.D. Preferably, a gelation cap that is nontoxic and heat soluble is used to hold the rodlike members in a collapsed condition prior to insertion of the device in the uterus.

It is preferred to have enlarged tip portions 70 to minimize the likelihood that the end of the rod member may perforate the uterus wall.

There has been disclosed heretofore the best embodiment of the invention presently contemplated. However, it is to be understood that various changes and modifications may be made by those skilled in the art without departing from the spirit of the invention.

I claim:

1. An intrauterine device for contraception comprising a plurality of flexible rodlike members, juncture means securing

said rodlike members at one end thereof to each other at a common joint, each member terminating in an enlarged portion at the free end thereof, said rodlike members further having included thereon a plurality of nodules formed integrally along the said rodlike members, said nodules being irregularly spaced relative to said juncture means, and said device being substantially conical in elevation and oval shaped in transverse cross section.

2. The device in accordance with claim 1 wherein said rodlike members are substantially straight.

3. The device in accordance with claim 1 wherein at least the portion of said rodlike members adjacent said juncture means is convex.

4. The device in accordance with claim 1 wherein said rodlike members are of equal length.

5. The device in accordance with claim 1 wherein said rodlike members are of unequal length.

6. The device in accordance with claim 1 wherein there is further included means for detecting the presence of said device subsequent to the insertion thereof.

7. The device in accordance with claim 6 wherein said detecting means comprises a metal insert.

8. The device in accordance with claim 1 wherein said detecting means comprises a ferrous metal insert.

9. The device in accordance with claim 6 wherein said de-

tecting means comprises a radio opaque substance.

10. The device in accordance with claim 9 wherein said radio opaque substance is barium chloride.

11. The device in accordance with claim 1 wherein there is further included a nontoxic, soluble retaining member positioned about the end of said rodlike members opposite said juncture means to thereby maintain said rodlike members in a collapsed condition prior to insertion thereof.

12. The device in accordance with claim 11 wherein said retaining member is a heat soluble gelation cap.

13. The device in accordance with claim 1 wherein at least said rodlike members are fabricated from a nontoxic, soft plastic material.

14. The device in accordance with claim 13 wherein said material is ethylene-vinyl acetate copolymer.

15. The device in accordance with claim 13 wherein said material is polyethylene.

16. The device of claim 1 including a presence-detecting means.

17. The device of claim 16 wherein said presence-detecting means is a flexible filament extending from said juncture means.

18. The device of claim 16 wherein said presence-detecting means is a radiant energy opaque material.

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