Oct. 29, 1968 J. F. HULKA ET AL 3,407,806

CONTRACEPTIVE INTRA-UTERINE DEVICES

Filed Aug. 24, 1966

Fig. 1

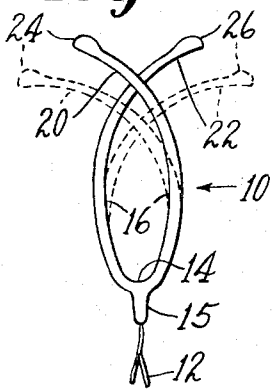


Fig. 4

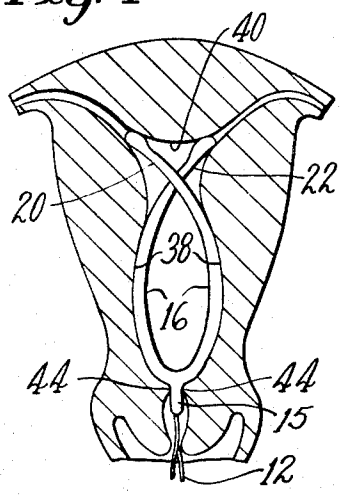


Fig. 6

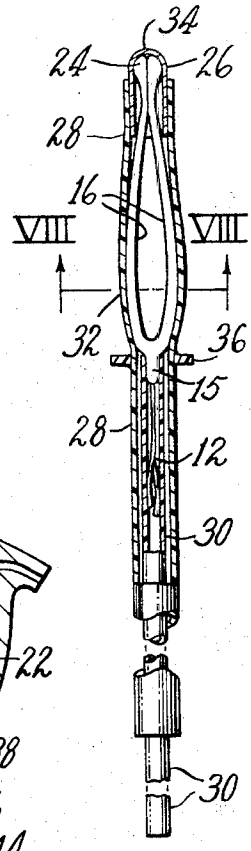


Fig. 2

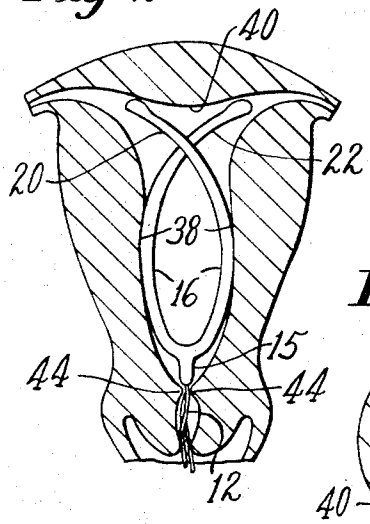


Fig. 5

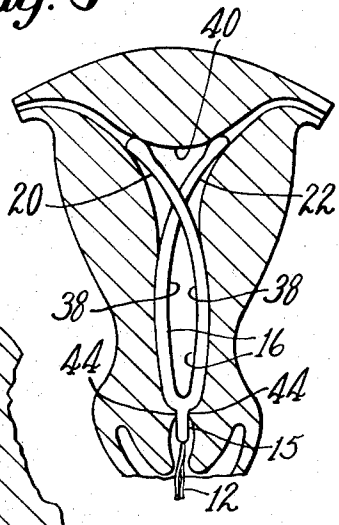


Fig. 7

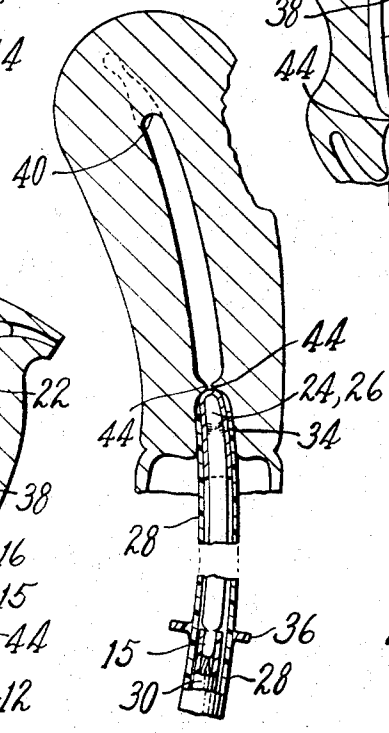


Fig. 8

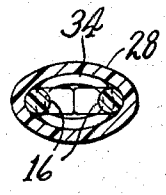
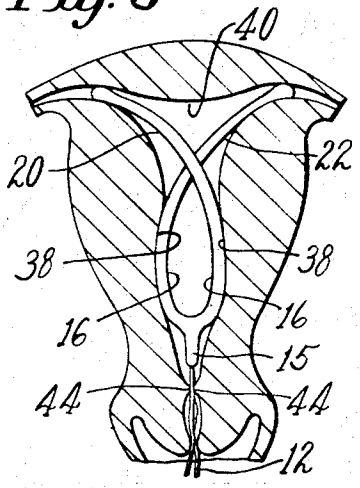


Fig. 3



Inventors

Jaroslav F. Hulka

Richard A. Butler Jr.

Alan W. Burke

By their Attorney

Maurice R Bouteau

United States Patent Office 3,407,806 Patented Oct. 29, 1968

3,407,806

CONTRACEPTIVE INTRA-UTERINE DEVICES

Jaroslav F. Hulka, Pittsburgh, Pa., and Richard A. Butler, Jr., Brookline, and Alan W. Burke, Newton, Mass.; said Butler and said Burke assignors to Butler Automatic Machine, Inc., Canton, Mass., a corporation of Massachusetts

Filed Aug. 24, 1966, Ser. No. 574,608
8 Claims. (Cl. 128—130)

This invention relates to improvements in contraceptive intra-uterine devices. A secondary aspect of the invention relates to a combination of an intra-uterine device in a disposable tool for inserting the device into position within the uterus.

Various forms of contraceptive intra-uterine devices are already well known but these various forms have not enjoyed full acceptance because of several disadvantages. Some devices are relatively complex in form and consequently expensive to manufacture. Others are so shaped that complicated instruments and skilled procedures are required for their insertion into the uterine cavity.

A more important disadvantage of prior intra-uterine devices is the fact that the wearer may unknowingly and unwittingly expel the device from the uterine cavity and thus render herself subject to impregnation under conditions that are believed to offer a high degree of safety.

It is accordingly an object of the present invention to provide an intra-uterine device which is securely locked in the uterine cavity against expulsion by contraction and relaxation of the walls of the cavity.

Another object is to provide such a device which is both simple and inexpensive to manufacture so that widespread distribution can be undertaken at moderate cost.

Still another object is to provide such a device in a form and with a tool necessary for its insertion by one having limited training. A related object is to provide a device prepared in a sterile manner in a disposable tool for inserting the device, thereby minimizing the efforts required by trained physicians or other personnel while at the same time assuring the highest degree of sterility at the time of insertion.

A further object is to provide such a device, the position of which may be accurately checked in the uterus and which may be readily removed when conception is desired.

In the achievement of the foregoing objects one feature of the invention relates to the configuration of the device as a unitary body of resilient material including a pair of flexible flanks rising from a base and defining a closed ovoid loop. The flanks overlie one another and a pair of projections extend beyond the overlying area. When the device according to the invention is positioned within the uterine cavity normal contractions and relaxations of the walls of the cavity cause interrelated deformations in the device which result in locking the device securely against the walls of the cavity to resist expulsion.

Another feature of the invention relates to a simple and economical tool which may be packaged in a sterile manner and loaded with a device ready for insertion into the uterine cavity by one having only limited training. The tool comprises a thin flexible shell and preferably a tubular plunger adapted to slide loosely in the shell and to receive in its central opening a connector formed integrally with the intra-uterine device. The connector is detachably fitted into the opening in the plunger so as to provide to the user of the tool tactile information concerning the condition under which the device is entering the uterine cavity.

The foregoing objects and features of the present invention will be more fully understood by reference to a detailed description of an illustrative embodiment taken in connection with the accompanying drawings, in which:

FIG. 1 is a view of an intra-uterine device according to the present invention;

FIG. 2 is a longitudinal sectional view of a uterine cavity in which the device of FIG. 1 has been inserted and in which the device is in its relatively unstressed passive state;

FIGS. 3, 4 and 5 are views similar to FIG. 2 but showing the device resisting expulsion by reaction to three of the more common forms of movement of the walls of the uterine cavity;

FIG. 6 is a view on a somewhat enlarged scale of the device of FIG. 1 positioned in an inserting tool according to the invention for insertion of the device into the uterine cavity;

FIG. 7 is a longitudinal section of the uterine cavity taken in a plane essentially normal to that shown in FIGS. 2–5 inclusive and showing the entry of the device into the uterine cavity when inserted by the tool of FIG. 6; and

FIG. 8 is a view in cross section taken along the line VIII—VIII of FIG. 7.

Turning now to the drawings, the intra-uterine device according to the present invention comprises a unitary resilient body indicated at **10**, to which is connected a loop **12** of flexible strand which serves as a means of withdrawal and of identification within the body. The body **10** is advantageously moldable of a synthetic polymeric material such as various polyolefins represented by polyethylene and polypropylene, as well as other materials such as polystyrene or similar materials. In order to permit checking by X-ray examination of the position of the body **10** within the uterine cavity, the resin composition of which the body is molded may be filled with barium sulfate or another well known equivalent substance which is opaque to X-rays. Either additionally or alternatively, the filler may be barium ferrite or another magnetic alloy so that the presence of the body **10** may also be checked magnetically in the uterine cavity.

The body **10** comprises a base portion **14** from the center of which depends an integral cylindrical connector **15**. The strand **12** is connected to the base portion **14** preferably by being embedded during molding within the connector **15**. A pair of arcuate flanks **16** extends from the ends of the base portion **14** to a cross-over or overlapping area **18** and projections **20** and **22** continue in diverging relationship from the cross-over area. Each of the projections **20** and **22** terminates in a half-tear shaped end **24** and **26** respectively, the ends being so oriented relatively that when contiguously positioned as shown in FIG. 6 they together present a smooth leading surface for ease of entry into the uterine cavity.

It has already been suggested that the body **10** may be molded of synthetic polymeric material for example. One advantage of molding is that greater uniformity may be obtained in the body and also that a molded product may easily be designed with suitable characteristics in its different portions, for example, with a relatively stiff base portion by means of an appropriately thick cross sectional area while the flanks **16** are molded with a cross section of gradually decreasing area toward the projections **20** and **22** to obtain the desired flexibility. In any event the flanks **16** of the overlapping area **18** merely overlie one another without being interconnected so that, for example, pressure applied to the flanks tending to bring them together causes deformation of the body from the solid line position in FIG. 1 to the dash line position in which the ends **24** and **26** are more widely separated. The body defines an unclosed ovoid loop in which the flanks **16** extend from the base portion **14** to the overlapping area **18** wherever it may be located depending upon the stresses applied to the body **10**. The

loop varies in size depending upon the stresses applied to the flanks 16.

There is shown on a slightly enlarged scale in FIG. 6 a tool for inserting the device according to the invention into the uterine cavity. The device comprises a thin flexible outer shell 28 and a losely fitted relatively thick wall tubular plunger 30. The interior passage in the plunger 30 provides a snug slip fit for the connector 15 and the loop 12 is loosely contained in the passage when the device is loaded in the tool. Because the shell 28 is thin-walled and of readily pliable material the shell 28 is deformed at 32 above the level of the base 14 of the device loaded within the shell as seen in FIG. 6. This occurs because of the relative stiffness of the base 14 but the wall thickness and pliability of the shell 28 are such as to cause minimal distortion to the base portion during extended periods of storage. The ends 24 and 26 are brought together within the shell 28 and covered by a gelatin cap 34 to facilitate entry of the device into the uterus. After the device has entered the uterine cavity the cap 34 melts and frees the projections 20 and 22 to assume various positions in response to movements of the walls of the uterus which will be described in greater detail below. As seen in FIG. 7 the shell 28 and plunger 30 are preferably curved on a large radius to facilitate entry of the tool into the uterus. Prior to expelling the device from the tool, the tool is inserted into the uterine cervix until the shell 28 contacts the internal cervical os, a contact which may readily be sensed after little training and practice. Although the internal os presents an obstruction to entry of the shell into the uterine cavity, a stop collar 36 is secured to the shell in a position to abut the external cervical os and thus automatically to prevent any substantial penetration of the shell into the uterine cavity. Unlimited penetration coupled with unskilled manipulation of the tool could otherwise result in a puncture of the wall of the uterus. The distance from the end of the shell to the collar 38 is accordingly slightly greater than that normally separating the internal from the exetrnal os.

The fit of the connector 15 in the passage of the plunger 30 provides a connection which causes the device itself to act as an integral part of the plunger during insertion of the device by means of the tool already described. As a result the physician or technician inserting the device in this way receives tactile sensations transmitted from the intrauterine device through the plunger 30 in a manner similar to that experienced when an ordinary intrauterine sound is used for exploring the uterine cavity. The connection thus provides means whereby the physician or technician may detect difficulties such as anatomical variaitons and obstructions within the uterus and otherwise for more skilled insertion than is possible with conventional devices and tools. After the device has been inserted into the cavity the plunger 30 is readily decoupled from the connector 15 by slight twist of the plunger 30.

Although the plunger 30 of the inserting tool has been described above and is illustrated as tubular, it may alternatively be in the form of a slightly curved solid rod. In this form the plunger, particularly if formed to match the cap 34 in diameter and contour, is also useful as a disposable probe for performing such functions as probing the location of the internal os and the direction of the uterine cavity as well as for dilating the internal os if necessary to facilitate subsequent entry of the device. As a further alternative the plunger may be formed with a tubular end to receive the connector 15 and a solid end useful as a probe. In order to improve the accuracy in using the plunger 30 as a probe and to assist in positioning the tool, both the plunger and the shell 28 may bear similar linear measure graduations.

The shell 28, the plunger 30 as well as the body 10 and the strand 12 are of materials which readily withstand a sterilizing procedure. After sterilization the entire assembly is most conveniently packaged in a sterile envelope for distribution. Since the insertion tool is adapted to economical production it may be considered a disposable element. Alternatively, the insertion tool may be constructed for greater durability and thus be used indefinitely.

The manner in which the device according to the invention resists expulsion by uterine contraction and relaxation will be best understood from FIGS. 2–5. When the device is subjected to approximately equal forces from the side walls 38 and the upper portion of the uterus 40, the body 10 is only slightly deformed from its normal configuration as shown in FIG. 2. The projections 20 and 22 are slightly spread apart and fit into the fundal portion 42 of the uterus thereby to retain the device in position. When the lower portion of the side walls 38 contract as shown in FIG. 3, the projections 20 and 22 are spread apart as the flanks are brought closer together. The projections are thus pushed firmly into the fundal portion 42 of the uterus anchoring themselves high in the uterus and thereby resisting dislodgement during such a contraction. A contraction of the fundal portions 42 as shown in FIG. 4 causes the projections 20 and 22 to move closer together and the loop defined by the flanks 16 and the base 14 to grow larger than while the device is in its unstressed condition. This increase in the size of the loop prevents expulsion of the device through the uterine os 44. During a simultaneous contraction of the fundal portions 42 and the lower portion of the uterus just above the os 44 as shown in FIG. 5 the body 10 assumes the shape of an elongated Y and in conforming to the new configuration of the cavity engages the side walls with a slightly greater force because of the greater deformation. The projections 20 and 22 still remain in the fundal portions 42 and upon relaxation of the uterus return the device to the position of FIG. 2. It is thus seen that by a combination of reactions to the forces imposed by the uterus the device is transformed into different shapes most optimally suited to retain its position within the uterine cavity.

It will be appreciated from the foregoing detailed description of an illustrative embodiment of a device and tool according to the invention that the objects initially stated are thereby economically and conveniently achieved.

Having thus disclosed our invention, what we claim as new and desire to secure by Letters Patent of the United States is:

1. An intra-uterine device comprising arcuate flanks of resilient material rising from a base to an overlying area and defining a closed ovoid loop, each of the flanks having a projection extending in divergent relationship with the other beyond the overlying area whereby a force exerted by the uterus tending to bring the projections closer together causes the flank to be spread apart and a force tending to bring the flanks closer together causes the projections to be spread apart.

2. A device according to claim 1 further characterized in that a flexible strand is attached to the base for detecting the presence of the device within the uterine cavity.

3. A device according to claim 1 further characterized in that it consists of a unitary body of a synthetic polymeric material.

4. A device according to claim 3 in which the polymeric material contains a filler which is opaque to X-rays.

5. A device according to claim 3 further characterized in that it contains a filler of magnetic material.

6. A device according to claim 1 further comprising a shell in which the body is positioned and a plunger slidable in the shell for expelling the body from the shell and into the uterine cavity.

7. A device according to claim 1 further comprising a cylindrical connector extending from a position between

the flanks, a shell in which the body is positioned and a tubular plunger slidable in the shell for expelling the body from the shell and into the uterine cavity, the passage in the plunger being fitted to the connector for providing tactile sensations through the plunger during insertion of the device into the uterine cavity.

8. A device according to claim **6** further comprising a stop collar secured to the exterior of the shell.

References Cited

UNITED STATES PATENTS

533,120	1/1895	Ferguson	128—130
759,342	1/1904	Brunig	128—130
2,176,559	10/1939	Meckstroth	128—130
3,291,125	12/1966	Robinson	128—130

ADELE M. EAGER, *Primary Examiner.*