

# PATENT SPECIFICATION

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## DRAWINGS ATTACHED

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## (54) INTRAUTERINE CONTRACEPTIVE DEVICE

(71) We, A. H. ROBINS COMPANY, INCORPORATED, of 1407 Cummings Drive, Richmond, Virginia, United States of America; a corporation organised and existing under the laws of the State of Virginia, United States of America do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates generally to contraceptive devices and particularly those designed for intrauterine insertion.

Intrauterine contraceptive devices have a very long history. In recent years, however, increased attention has been focused on such devices because of the rapid rate of population increase and the resulting recognition of a need for better contraceptive methods. The mode of operation of intrauterine devices has not yet been definitely ascertained, but enough data has been collected to verify their contraceptive efficacy, and to reveal some of the problems associated with such devices.

One of these problems is that the devices are often expelled through the cervical os, probably as a result of the natural muscular activity of the uterus. Preventing such expulsion is difficult, since a device may be prone to this difficulty as a result of its being either too flexible or too inflexible.

For example some prior art devices are highly flexible, and in fact are designed to stretch out into an elongated linear configuration for greater ease of insertion. After insertion, these devices coil themselves into a convoluted configuration in situ. Unfortunately such devices are sometimes expelled through the cervical os by the reverse process; the device is fed back out through the cervical os linearly in response to uterine contraction.

On the other hand, it is believed that some devices which respond less flexibly may be pushed out through the cervical os precisely because they fail to deform sufficiently when

under compressive stress, and act as a dilating wedge.

Another problem caused by devices of too little flexibility is that they tend to generate cramps and pain in the patient because of their unwillingness to yield and deform in response to muscular activity of the uterus. As a result, the less flexible devices require manufacture in different sizes so as to adequately fill uteri of varying sizes.

Another problem encountered with intrauterine devices has been the difficulty of fitting them to different different size uteri. Usually the devices are mass produced in a single size, and must therefore be large enough to maintain appropriate contact with a large uterus, but flexible enough so that it deforms sufficiently to accommodate itself to a small uterus without undue pain or cramps.

According to the present invention an intrauterine contraceptive device comprises a ring (as herein below defined), a membrane (as herein below defined), attached to said ring along opposite edge parts of the internal periphery thereof and extending therebetween, and means distributed around said ring and extending outwardly from the external periphery thereof for engaging the wall of the uterus and for impeding expulsion of the device therefrom after insertion of the device in a patient.

It should be noted that the term "ring" used throughout the specification and claims, is intended to include within its scope any generally elliptical or oval shaped, closed band of material.

In a preferred embodiment of the invention, the contraceptive device is coated with a suitable film of material which minimizes the accumulation of calcium deposits thereon after the device has been in the uterus for a length of time, and thus enhances its effectiveness.

Preferably the means for engaging the wall of the uterus comprises a plurality of spurs extending outwardly from opposed points on the outer periphery of the ring, in the plane of the ring, and are inclined relative to the

major axis of the ring so as to impede expulsion movement of the device, after insertion into a patient.

5 The intrauterine contraceptive devices in accordance with the invention and described below actively resist expulsion through the cervical os and readily accommodate themselves to a range of uterine sizes with comfort to the patient. Further these embodiments  
10 are easier to insert than prior art devices and acts to avoid the possibility of strangulation of a loop of bowel in an open loop of such prior art device in the event that it protrudes or escapes into the peritoneal cavity.

15 Embodiments of the invention will be further described, purely by way of example, with reference to the accompanying drawings, in which:—

20 Fig. 1 is a plan view of an intrauterine contraceptive device in accordance with the present invention;

Fig. 2 is a sectional view of the ring of the intrauterine device, taken at one side thereof, along the line 2—2 of Fig. 1;

25 Fig. 3 is a sectional view rotated through 90° of the same ring taken at a tail end of the contraceptive device, along the line 3—3 of Fig. 1;

30 Fig. 4 is another sectional view rotated through 90° of the ring taken at a head end of the device, along the line 4—4 of Fig. 1.

FIG. 5 is a longitudinal section of the tip of a typical spur of the contraceptive device, taken along the line 5—5 of FIG. 1;

35 FIG. 6 is a transverse section of a typical spur, taken along the line 6—6 of FIG. 1;

FIG. 7 is a sectional view of the intrauterine contraceptive device, taken along the line 7—7 of FIG. 1;

40 FIG. 8 is a perspective view of a modified embodiment of a contraceptive device in accordance with this invention;

FIG. 9 is a fragmentary plan view of another modification of the device;

45 FIG. 10 is a fragmentary plan view of yet another modification of the device;

FIG. 11 is a sectional view rotated through 90° and taken along the line 11—11 in FIG. 10; and

50 FIG. 12 is a plan view of still a further modification of the device. (It should be noted that the various figures, and in particular Figs. 2 to 6 are not drawn to a constant scale).

55 As seen in FIG. 1, an intrauterine contraceptive device 10 in accordance with this invention generally comprises an outer ring 12, a membrane 14 extending across and closing a major portion of the centre of the ring, and a plurality of spurs 16-1 through 20-1  
60 on one side of the ring and 16-2 through 20-2 on the opposite side thereof. Preferably, but not necessarily, the membrane 14 is provided with an opening 22 at the head end of the device and another opening 24 at the tail  
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end. While it is presently preferred that membrane 14 be a continuous (albeit apertured) film of the same material as ring 12, as used herein the word "membrane" is intended to additionally include screening, grids and other perforated sheets or one or more cross bars extending across ring 12. A small opening 26 may optionally extend transversely through the ring 12 to communicate with the membrane opening 24, providing a convenient  
75 place for securing a telltale string, which may also be used to aid in removing the device. As described and as preferred, the membrane 14 is not connected to ring 12 along its entire periphery. However, the membrane 14 may be continuously peripherally connected to ring 12 without departing from the present concepts.

In greater detail, the device 10 comprises a single piece of integrally molded plastics material which preferably has been mixed with a suitable amount of radio-opaque material to permit the device to be located by X-ray or fluoroscope techniques if necessary. A preferred plastics material is "Ultrathene" (R.T.M.), a copolymer of ethylene, and a vinyl monomer material, catalogue listing UE633 of U.S. Industries, with 10% by weight of barium sulfate as a radio-opaque ingredient. While the proportions just mentioned are preferred, the range of barium sulfate may be anywhere from 0 to 40%. Alternative plastics materials which may be employed are polyethylene, polypropylene, ethylene, propylene, copolymers, and terpolymers, e.g., polyvinyl acetate, copolymers of vinyl acetate with another ethylenically unsaturated monomer copolymerizable therewith, silicone rubber, polyfluoroethylenes, e.g. Teflon (R.T.M.), Kel-F (R.T.M.).  
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In accordance with a preferred embodiment of this invention, the molded device 10 may be provided with a thin coating of a suitable material to inhibit the deposition of calcium upon the surface of the device after it has been in the uterus for a period of time and thus to enhance its effectiveness. Such materials include gold, platinum, silver, copper, tantalum, and alloys of these metals or of these metals with other metals. The coating may be vapor-deposited to a preferred thickness of approximately  $5 \times 10^{-6}$  inch. A preferred range of coating thickness is from  $2 \times 10^{-6}$  to  $40 \times 10^{-6}$  inch.

The outer ring 12 forms the structural framework of the device 10, and in that respect functions similarly to other ringlike structures found in some prior art devices. However, the present ring 12 has a configuration which is designed, in accordance with this invention, to maximize the likelihood that the intrauterine device 10 will be retained in place after insertion in the uterus. Specifically, the ring 12 is designed to make the device flexible enough so that it yields when  
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placed in hoop compression by the natural muscular activity of the uterus. If the device resisted such pressures unyieldingly, it might be moved in the direction of the cervical os, act as a dilating wedge, and eventually be expelled.

In addition, the ring 12 is designed to deform in a particular manner, so as to further minimize the chances of expulsion. Specifically, the cross-section of the ring 12 is somewhat heavier at region 12-4 (the head end of the device 10) than it is at regions 12-2 (along the side of the device) and also than it is at region 12-3 (at the tail end thereof). As seen in FIG. 4, the cross-section of the ring at region 12-4 is substantially rectangular with rounded corners, and its thickness in the direction perpendicular to the plane of the ring 12 is somewhat less than it is in the direction parallel to the plane of the ring. Preferred dimensions are a .07 inch parallel to the plane of the ring, and .066 inch perpendicular to that plane, at region 12-4.

The cross-section of the ring 12 remains substantially rectangular with rounded corners throughout the length of the ring, but in the head and tail regions 12-4 and 12-3 respectively the ring thickness is greater in the direction parallel to the plane of the ring than it is in the direction perpendicular to that plane, while in the side regions 12-2 the opposite is true, i.e. the ring thickness is greater in the direction perpendicular to the plane of the ring than in the direction parallel to it. As a result, the ring 12, when subjected to hoop compression applied to the side regions 12-2 by the adjacent uterine walls, buckles first in the side regions.

One advantage of this is that the intra-uterine device 10 tends to deform in response to such compression, rather than to be cammed longitudinally relative to the uterine wall. If the ring 12 buckled first at the head region 12-4, it would be subject to a camming force tending to move it toward the cervical os, with expulsion as a possible consequence. Thus the tendency of the ring 12 to buckle preferably in the side region 12-2 helps to prevent expulsion. A second advantage resulting from such side buckling has to do with deformation of the central membrane 14, and is discussed below.

The cross-section at the tail region 12-3 (see FIG. 3) has preferred thickness dimensions of 0.5 inch perpendicular to the plane of the ring by .06 inch parallel to that plane. Note that the cross-section of the ring 12 is smaller in both directions in the tail regions 12-3 than it is in the head region 12-4.

As a result, if sufficient compressive stress is exerted upon the side regions 12-1 of ring 12 to buckle either the head or tail regions, the tail region 12-3 will buckle first, thus insuring that the camming force then exerted on the device 10 will tend to move it in the

direction of the head region 12-4 rather than in the direction of the tail region 12-3. It is only the latter direction of motion which can result in expulsion through the cervical os.

The cross-section at either of the side regions 12-2 (the device 10 is symmetrical about its longitudinal or head-to-tail axis) has preferred thickness dimensions of .066 inch perpendicular to the plane of the ring by .05 inch parallel to that plane. As previously mentioned, the perpendicular dimension preferably exceeds the parallel dimension in these regions, to promote buckling of the sides 12-2 in the direction parallel to the plane of the ring.

A preferred range of the various ring thicknesses mentioned extends from .05 inch for the smallest dimension to an upper limit of .13 inch for the largest, while preserving the same relative proportions which give the device its flexibility in preferred directions to prevent expulsion. At the same time, the device 10 does not suffer from the opposite disadvantage of the "long line" type of intra-uterine device which is so flexible that it can be deformed by uterine contractions into a linear shape and thus expelled through the cervical os by a reversal of the insertion process.

However, while the cross sectional area and the dimensions of the various regions around the ring have been carefully selected so as to respond to external forces on the perimeter by deforming the entire device in a non-planar manner, the addition of the membrane 14 produces the desired deformation regardless of the relative dimensions of height and width of the ring walls, and in fact the cross-section may be rectangular or round or almost any geometric shape. When the device is subjected to external forces around its perimeter, the spurs deflect initially in response to these forces and the transmit these forces to the ring. As the ring tends to collapse, portions of the membrane respond to the compressional forces by becoming non-planar and other portions of the membrane have a resultant force in tension causing the ring to deflect in a non-planar manner in the region where the membrane in tension is attached to the ring.

To make the above behaviour more clearly obvious, consider a flat washer of a given outside diameter and an inner concentric hole, the thickness of the washer being considerably less than the overall diameter of the washer. If forces are applied to the perimeter of the washer it will tend to buckle non-planarly by folding along a central axis, flat faces tending to come together. Consider now a barrel hoop with a height (perpendicular to the face of the hoop) greater than the wall thickness parallel to the plane of the hoop. The response of the barrel hoop to side forces on its periphery is to fold so as to bring the inner surfaces of the hoop toward each other with

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the hoop remaining essentially coplanar with its original position. Now by attaching a flexible membrane to the inner wall of the barrel hoop, external compression forces on the hoop will transmit tensile forces to the membrane so as to tend to make the barrel hoop distort out of its original plane.

The performance of the present device may thus be likened to the action of the barrel hoop with a membrane. Side forces on the device cause non-planar deformation of the device and, in particular, will cause the tail region to deflect away from the exit cervical os. However, to enhance the effect of non-planar collapse, it is preferred to proportion ring 12 as above described so that the ring would collapse non-planarly even without the presence of membrane 14.

The ring 12 also has carefully calculated overall dimensions which are designed to correspond to the midrange of normal uterine sizes, while at the same time making sufficiently firm contact with any size uterus to be firmly retained in place. Specifically, the ring 12 is of a generally elliptical configuration in that the outside diameter of the ring along the head-to-tail axis is greater than the maximum outside diameter along an axis transverse thereto. The preferred outside diameter of the ring 12 along the head-to-tail or major axis is .775 inch, and a preferred range of outside diameters is from .75 to 1.25 inch.

The preferred outside diameter of the ring 12 in a direction transverse to the major axis is .76 inch, although a preferred range of outside diameter is from .56 to 1.12 inch. The maximum transverse width of the ring 12 is reached at a location somewhat closer to the head end of the device, region 12-4, than to the tail end, region 12-3. This is related to the fact that the curvature of the ring 12 at the head of the device is somewhat more blunt, compared to the ring curvature at the tail end which is somewhat more pointed. The resulting trilobite, or buglike shape of the ring further increases the tendency of the device 10 to resist being expelled tailward through the cervical os, since, apart from any considerations of buckling, an object under compression tends to be cammed toward its wider end, in this case the head region 12-4.

The outside diameters referred to so far in this detailed description have to do with the dimensions of the ring 12 alone. The dimensions of the entire intrauterine contraceptive device 10 are somewhat greater, taking into account the length of the spurs 16-1 through 20-1 and 16-2 through 20-2. In the preferred embodiment of FIG. 1, there are five such spurs on each side of the ring 12. The longest ones 16-1 and 16-2 are located nearest to the head end of the device, and the spurs decrease progressively in length as they approach the tail end. Moreover, the spurs preferably do not extend outwardly from the ring in a

normal direction to the ring periphery but slant toward the tail end of the device 10 so as to form an acute angle with the major axis of the ring. The value of that angle preferably decreases progressively from the foremost spurs 16-1 and 16-2 through the rearmost 20-1 and 20-2. While it is preferred that the spurs extend outwardly from ring 12 in the plane of the ring, this is not necessary and the spurs may extend away from ring 12 at angles to the plane of the ring.

The foremost spurs 16-1 and 16-2 are preferably about .25 inch long, measured from the outermost tip of the spur to the point at the base of the spur where its longitudinal axis intersects the extrapolated surface of the ring 12. A preferred range for this dimension is from about .125 inch to .375 inch. The spurs 16-1 and 16-2 are swept back at preferred angles of about 50° to the major axis of device 10. Fillets 28 of plastics material may be provided at the roots of all the spurs to control the stiffness of the spurs.

The second spurs 17-1 and 17-2 have preferred lengths of about .18 inch, although this value may vary widely. A preferred range of length is from about .09 to .27 inch. These spurs are swept back at preferred angles of about 42° to the major axis.

The third spurs 18-1 and 18-2 have preferred lengths of about .148 inch. A preferred range of length is from about .075 to .3 inch, although wider variation is acceptable, and they are swept back at preferred angles of about 34° to the major axis.

The fourth spurs 19-1 and 19-2 have preferred lengths of about .135 inch. A range of about .065 to .2 inch is preferred although lengths outside of this range are useful. Spurs 19-1 and 19-2 are swept back at preferred angles of about 26° to the major axis.

The fifth and last spurs 20-1 and 20-2 have preferred lengths of only about .1 inch, and a preferred range of .05 to .15 inch, although other lengths may be used. Spurs 20-1 and 20-2 are swept back preferably at an angle of about 20° relative to the major axis of the ring 12.

All of the dimensions above and hereafter set forth are merely preferred dimension and ranges. Wide variations in any given dimension and in relative dimensions, even beyond the limits of the preferred ranges, may be employed. Further, specifically, the relative lengths of spurs 16-1 through 20-1 and 16-2 through 20-2, while preferred as described, are not critical and spurs of higher reference character number can even be longer than those of smaller reference character number.

The preferred angular orientations given for the spurs 16-1 through 20-1 and 16-2 through 20-2 may be varied over a wide range but, preferably, they should all intersect the longitudinal axis at an acute angle, so that

they extend outwardly toward the tail end and most preferably at progressively more acute angles from head to tail.

The spurs serve more than one function. They flex closer to the ring 12 in response to the natural muscular contractions of the uterus, and thus help the overall device 10 to yield to such contractions rather than resisting and thereby increasing the chances of expulsion through the cervical os. The flexibility of these spurs also permits the device 10 to fit a greater range of uterine sizes, since the spurs can either remain spread out to contact a larger uterine cavity or can flex inwardly to accommodate a smaller one, while still helping to retain the device 10 in place.

Additionally, because the spurs are resilient cantilevers, they will yield to muscular contractions transverse to their length and by so yielding, apply a self-restoring force against the uterine wall to maintain the device in its position.

Most significantly, however, the spurs have a preferential direction of slant towards the tail end of the device 10 which serves to impede retrograde movement of the device 10 in the direction of the cervical os. The device is inserted head first; i.e. the region 12-4 enters the uterus first, followed by the tail region 12-3. As a result, reverse movement of the device 10 goes against the "grain" of the spurs 16-1 through 20-1 and 16-2 through 20-2. In order to move in the reverse direction the spurs would have to be flexed outwardly from the ring 12, which is not easily accomplished. Thus by resisting such deformation the spurs impede reverse movement of the device. In contrast, upon initial insertion of the device the spurs are more easily flexed rearwardly, i.e. bent closer to the ring 12, so that they offer considerably less resistance to movement in the direction of insertion.

FIG. 5 is a longitudinal section taken through the tip of a typical one of the spurs, and shows that the tip shape is preferably generally hemi-spherical so as to avoid injury to adjacent tissue.

FIG. 6 is a transverse section through a typical spur illustrating that the projections are preferably substantially thicker in the direction perpendicular to the plane of the ring 12 than they are in the direction parallel to the plane. The preferred dimensions are about .066 inch and .035 inch respectively, but these dimensions are not critical and could be widely varied, could be increased or decreased, keeping in mind the need for flexibility. Thus these dimensions are a function of material properties as well as other dimensions of the spurs themselves.

As a result of this preferred difference in the thickness in the two directions, the spurs flex readily toward the ring 12, while it is relatively more difficult to deflect them out of the plane of the ring 12. Thus the spurs

can easily yield during initial insertion of the device 10, but it is undesirable that they be deflected too far out of the plane of the ring since that would make them less effective in impeding reverse movement of the device.

One function of the membrane 14 is to substantially block the interior of the ring 12 so as to prevent intrusion of intestinal tissue thereinto in the event that the device 10 should be partially or completely perforated into the peritoneal cavity. The membrane 14 is attached to the inner periphery of the ring 12 over most of the length of that ring, in contrast to prior art device lacking a central barrier or having a barrier attached only at a few points. Thus the present device is more effective in preventing the possible intrusion of intestinal tissue into the ring opening.

Moreover, the membrane 14 is thin enough to be very flexible, the preferred thickness being only about .006 inch and the preferred range of thickness being from about .002 to .06 inch. The result of such flexibility is that, when the ring 12 is under hoop compression by uterine muscles, the membrane has a tendency to buckle out of the plane of the ring 12 and consequently to bear against the internal wall of the uterus. This additional contact against the uterine wall is a further factor in resisting expulsion of the device 10 when muscular contractions take place.

In order to enable the membrane 14 to buckle more easily in this manner, it is not attached to the ring 12 at preferably two locations 30 and 32 adjacent to the head region 12-4 and tail region 12-3 respectively. Freeing the membrane 14 from the ring 12 at these locations increases the likelihood that it will buckle along a line roughly corresponding to the major axis of the device. In addition, since the ring 12 itself yields preferentially in the side regions 12-2 where the membrane 14 is primarily attached, it carries the attached edges of membrane 14 along with it, causing the membrane to deform outwardly from the plane of ring 12 to make contact with the uterine wall.

The relieving of the membrane 14 at locations 30 and 32 is preferably carried to the extent of providing the two distinct openings 22 and 24, previously mentioned as among the general features of the device 10. These openings are not essential, but opening 22 is useful for cooperation with certain types of uterine insertion devices, while opening 24 is useful for cooperation with an extracting hook. The latter can be inserted through the opening 24 at the tail end of the device 10 for withdrawing it through the cervical os.

At the tail end of the device 10 there may be provided a telltale string 50 which extends out through the cervical os so that the presence of the intrauterine device can be verified by vaginal examination. The telltale string 50 may, if desired, be inserted through

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the opening 24 and tied around the ring 12 in the region 12-3. However, the hole 26 approximately .02 inch in diameter may be provided for the purpose of securing string 50. If hole 26 is provided the telltale string may be inserted through the hole 26 and thereby tied to the ring 12 as shown in FIG. 1. Another way of securing string 50 is to mold string 50 integral with the remainder of device 10 to thereby eliminate the connection problem and the costs incurred therein, as shown in FIG. 9.

In an alternative embodiment of the invention, an intrauterine contraceptive device 100 as seen in FIG. 8 includes a ring 112, and spurs 116-1 through 120-1 and 116-2 through 120-2 which are similar to their counterparts in the device 10 discussed earlier. However, the central membrane 114 of this embodiment differs in that it is formed with accordion pleats 140 which fold upwardly out of the plane of the ring 112, and alternate accordion pleats 142 which fold downwardly out of that plane. In addition, the membrane 114 is completely separated from the ring 112 for a considerable length thereof at the head end 112-1 and the tail end 112-3. This configuration of the membrane 114 allows it to buckle out of the plane of the ring 112 and particularly easily in response to compressive forces exerted on the ring 112, and the pleats 140 and 142 provide definite fold lines along which such buckling takes place preferentially. Furthermore, the pleats 140 fold upwardly to contact one wall of the uterus, while the alternative pleats 142 simultaneously fold downwardly to engage the opposite wall. Thus the membrane 114 engages both walls of the uterus simultaneously, the better to impede reverse motion of the intrauterine contraceptive device 100. In this embodiment a telltale string 150 is shown tied around the tail section 112-3 of the ring 112.

Another feature of the accordion folding membrane is that the entire device can be compressed into a compact configuration with the membrane neatly folded within the configuration so as to provide no obstruction or impediment to its introduction through the cervical os into the uterus.

Referring now to FIGS. 10 and 11 a further modification of the device is shown. The main body of the device can be substantially identical to the embodiments of FIGS. 1, 8 or 9. However, a dilator in the form of a round or oval ball 52 may be molded integrally with the ring 12 at the head end 12-4 thereof whereby to permit insertion of the device with the dilator ball or sphere 52 preceding the remainder of the device to gently spread the uterine wall during insertion whereby to prevent injury thereto.

As best shown in FIG. 12, the membrane need not be apertured as heretofore described. That is to say the membrane can enclose the

entire central passage of the ring 12 as does the membrane 214 for the ring 212 of device 210 of FIG. 12.

However, it has been found that insertion of the device is facilitated by the inclusion of one or more apertures 22 and 24. Accordingly, the embodiment of FIG. 1 is preferred.

Irrespective of the form of the membrane, be it continuous or apertured, a film, a grid, or one or more cross-members, an advantage of the membrane is that it prevents tissue growth which would entrap the device as by growing around the ring through the open center thereof if the membrane were not present. So long as apertures 22 and 24 are sized sufficiently small, they will not adversely interfere with this function of the membrane.

The skilled gynecological clinician will recognize that there are a number of suitable instruments for inserting and withdrawing any of the devices of the present invention. One suitable inserter which may be used in connection herewith is described in U.S. Patent No. 2,176,559.

It will now be appreciated that the above intrauterine contraceptive devices according to the invention provide significant advantages over prior art devices of this kind. The contraceptive devices when suitably coated, resist the deposition of calcium on the surface thereof even after they have been in the uterus for some time, and also fit a wide variety of uterine sizes, resist expulsion, and prevent possible intestinal strangulation by filling a major portion of the centre of the ring in the event of partial or complete uterine perforation.

#### WHAT WE CLAIM IS:—

1. An intrauterine contraceptive device comprising: a ring (as hereinbefore defined), a membrane (as hereinbefore defined) attached to said ring along opposite edge parts of the internal periphery thereof and extending therebetween, and means distributed around said said ring and extending outwardly from the external periphery thereof for engaging the wall of the uterus and for impeding expulsion of the device therefrom after insertion of the device in a patient.

2. A device as claimed in claim 1 in which the wall engaging means comprise a plurality of spurs of extending outwardly from the external periphery of the ring on opposite edge parts thereof.

3. A device as claimed in claim 2, in which the spurs and the ring lie in the same plane and slant towards a tail region of the ring.

4. A device as claimed in any of claims 1 to 3, which is molded of a plastics material, and further comprises a film coating on the surface of said plastics material for preventing the formation of calcium deposits thereon.

5. A device as claimed in any of claims 1 to 4, in which the membrane is unattached

the opening 24 and tied around the ring 12 in the region 12-3. However, the hole 26 approximately .02 inch in diameter may be provided for the purpose of securing string 50. If hole 26 is provided the telltale string may be inserted through the hole 26 and thereby tied to the ring 12 as shown in FIG. 1. Another way of securing string 50 is to mold string 50 integral with the remainder of device 10 to thereby eliminate the connection problem and the costs incurred therein, as shown in FIG. 9.

In an alternative embodiment of the invention, an intrauterine contraceptive device 100 as seen in FIG. 8 includes a ring 112, and spurs 116-1 through 120-1 and 116-2 through 120-2 which are similar to their counterparts in the device 10 discussed earlier. However, the central membrane 114 of this embodiment differs in that it is formed with accordian pleats 140 which fold upwardly out of the plane of the ring 112, and alternate accordian pleats 142 which fold downwardly out of that plane. In addition, the membrane 114 is completely separated from the ring 112 for a considerable length thereof at the head end 112-1 and the tail end 112-3. This configuration of the membrane 114 allows it to buckle out of the plane of the ring 112 and particularly easily in response to compressive forces exerted on the ring 112, and the pleats 140 and 142 provide definite fold lines along which such buckling takes place preferentially. Furthermore, the pleats 140 fold upwardly to contact one wall of the uterus, while the alternative pleats 142 simultaneously fold downwardly to engage the opposite wall. Thus the membrane 114 engages both walls of the uterus simultaneously, the better to impede reverse motion of the intrauterine contraceptive device 100. In this embodiment a telltale string 150 is shown tied around the tail section 112-3 of the ring 112.

Another feature of the accordian folding membrane is that the entire device can be compressed into a compact configuration with the membrane neatly folded within the configuration so as to provide no obstruction or impediment to its introduction through the cervical os into the uterus.

Referring now to FIGS. 10 and 11 a further modification of the device is shown. The main body of the device can be substantially identical to the embodiments of FIGS. 1, 8 or 9. However, a dilator in the form of a round or oval ball 52 may be molded integrally with the ring 12 at the head end 12-4 thereof whereby to permit insertion of the device with the dilator ball or sphere 52 preceding the remainder of the device to gently spread the uterine wall during insertion whereby to prevent injury thereto.

As best shown in FIG. 12, the membrane need not be apertured as heretofore described. That is to say the membrane can enclose the

entire central passage of the ring 12 as does the membrane 214 for the ring 212 of device 210 of FIG. 12.

However, it has been found that insertion of the device is facilitated by the inclusion of one or more apertures 22 and 24. Accordingly, the embodiment of FIG. 1 is preferred.

Irrespective of the form of the membrane, be it continuous or apertured, a film, a grid, or one or more cross-members, an advantage of the membrane is that it prevents tissue growth which would entrap the device as by growing around the ring through the open center thereof if the membrane were not present. So long as apertures 22 and 24 are sized sufficiently small, they will not adversely interfere with this function of the membrane.

The skilled gynecological clinician will recognize that there are a number of suitable instruments for inserting and withdrawing any of the devices of the present invention. One suitable inserter which may be used in connection herewith is described in U.S. Patent No. 2,176,559.

It will now be appreciated that the above intrauterine contraceptive devices according to the invention provide significant advantages over prior art devices of this kind. The contraceptive devices when suitably coated, resist the deposition of calcium on the surface thereof even after they have been in the uterus for some time, and also fit a wide variety of uterine sizes, resist expulsion, and prevent possible intestinal strangulation by filling a major portion of the centre of the ring in the event of partial or complete uterine perforation.

#### WHAT WE CLAIM IS:—

1. An intrauterine contraceptive device comprising: a ring (as hereinbefore defined), a membrane (as hereinbefore defined) attached to said ring along opposite edge parts of the internal periphery thereof and extending therebetween, and means distributed around said said ring and extending outwardly from the external periphery thereof for engaging the wall of the uterus and for impeding expulsion of the device therefrom after insertion of the device in a patient.

2. A device as claimed in claim 1 in which the wall engaging means comprise a plurality of spurs of extending outwardly from the external periphery of the ring on opposite edge parts thereof.

3. A device as claimed in claim 2, in which the spurs and the ring lie in the same plane and slant towards a tail region of the ring.

4. A device as claimed in any of claims 1 to 3, which is molded of a plastics material, and further comprises a film coating on the surface of said plastics material for preventing the formation of calcium deposits thereon.

5. A device as claimed in any of claims 1 to 4, in which the membrane is unattached



to said internal ring periphery at two opposed locations.

6. A device as claimed in claim 5, in which said two locations lie at head and tail regions on the medial internal periphery of the ring.

7. A device as claimed in any of claims 1 to 6, in which the ring lies substantially in a single plane and the flexibility of the membrane substantially exceeds that of said ring, whereby said member buckles out of the plane of said ring in response to hoop compression of said ring.

8. A device as claimed in claim 7 in which the membrane has a plurality of pleats to facilitate such buckling.

9. A device as claimed in any of claims 1 to 8 including a biologically inactive metal coating on the surface of the ring for preventing the formation of calcium deposits thereon.

10. A device as claimed in any one of claims 1 to 9, in which the ring thickness in the direction perpendicular to the plane in which the ring lies exceeds the ring thickness in the direction parallel to said plane at locations adjacent said opposite internal peripheral edge parts of said ring; and the ring thickness in the direction perpendicular to said plane is less than the ring thickness in the direction parallel to said plane at opposed head and tail regions of said ring between said opposite internal peripheral edge parts thereof, whereby said ring buckles preferentially at locations adjacent said opposite internal peripheral edge parts in response to hoop compression of the ring.

11. A device as claimed in any of claims 1 to 10 in which the ring thickness parallel to the plane of the ring is less at locations adjacent said opposite internal peripheral edge parts thereof than at opposed head and tail regions of said ring between said opposite internal peripheral edge parts.

12. A device as claimed in claim 10, in which the ring thickness in any given direction at said tail region is less than the thickness in said direction at said head region.

13. A device as claimed in any of claims 1 to 12, in which the combined membrane and ring are proportioned so as to be distortable in three dimensions when the ring is subjected to a hoop compression force.

14. A device as claimed in any of claims 1 to 12 in which the thickness of portions of the ring by itself are such that the ring is collapsible in three dimensions when subjected to a hoop compression force.

15. A device as claimed in claim 14 in which the membrane is planar when said ring is unstressed.

16. A device as claimed in any of claims 1 to 15, in which an elongate flexible tail extends from the tail region of the ring; said tail being attached or integrally moulded with the ring.

17. An intra-uterine contraceptive device substantially as herein described and illustrated with reference to the accompanying drawings.

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