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Shubeck

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[54] **INTRA-UTERINE CONTRACEPTIVE DEVICES**

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

[51] **Int. Cl.** **A61f 5/46**

[58] **Field of Search** ..... 128/130, 127, 128, 128/129, 131, 132 R, 275, 295; 150/10; 229/55, 85

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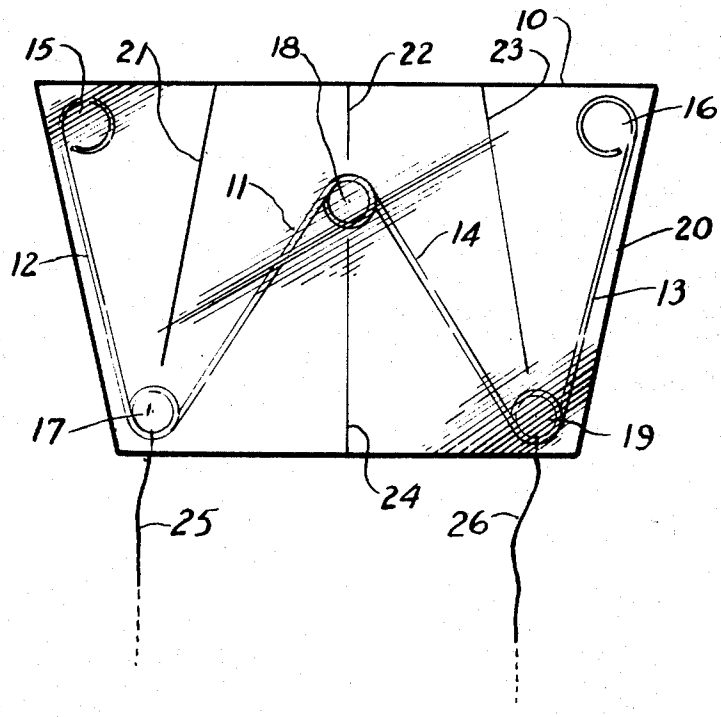
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Primary Examiner—Richard A. Gaudet
Assistant Examiner—G. F. Dunne
Attorney—Thomas B. Graham

[57] **ABSTRACT**

An improvement in linear, compressible, uniplanar intra-uterine devices which comprises sealing the device in fixed position between two layers of plastic membrane and then slitting the membrane to allow compression of the device, and, in particular, a W-shaped wire frame sealed in said slitted membrane.

17 Claims, 8 Drawing Figures



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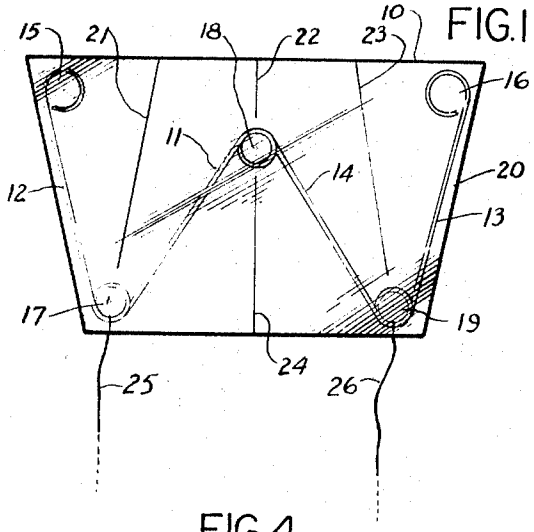


FIG.1

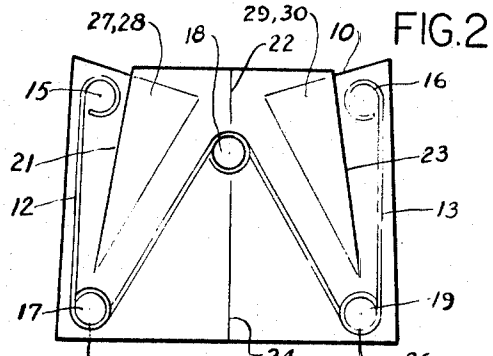


FIG.2

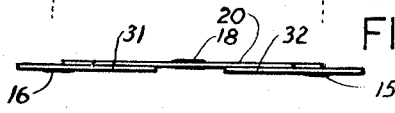


FIG.3

FIG.4

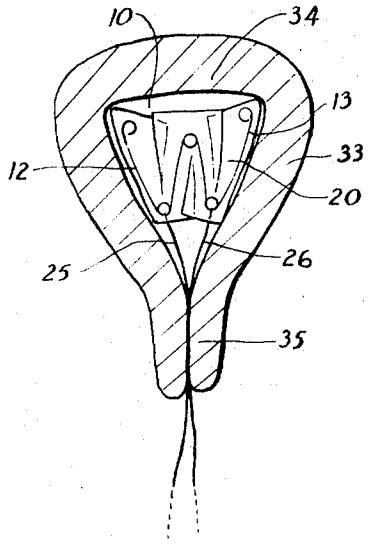


FIG.6

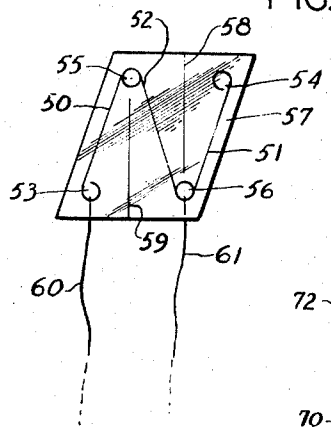


FIG.7

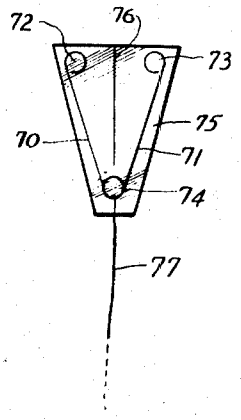


FIG.5

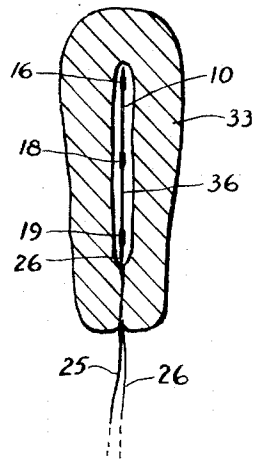
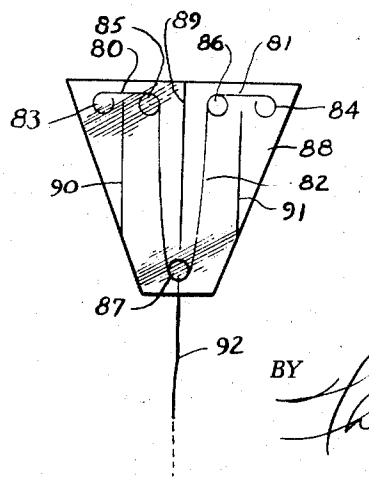


FIG.8



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INTRA-UTERINE CONTRACEPTIVE DEVICES

BACKGROUND OF THE INVENTION

It has been known for many years that the presence of mechanical inserts in the uterus will prevent contraception. Such intra-uterine devices have assumed a wide variety of shapes, sizes and configurations, e.g. the Margulies spiral, the Lippes loop, the Birnberg bow and the Ota ring.

There are, however, certain disadvantages with the presently available intra-uterine devices. These include spontaneous expulsion of the device, excessive pain and/ or bleeding, perforation and/or migration through tissue, local inflammation, and reactivity or toxicity with body tissues.

Several of these difficulties stem from the fact that the devices exert substantial pressure against the endometrium, the tissue which lines the interior of the uterus, and the myometrium, the mass of smooth muscle lying adjacent to the endometrium through which course a system of blood vessels. Since these blood vessels of the endometrium have very little supportive elements in their walls, the mere insertion of the device ruptures the blood vessels, endometrial glands and interstitial cells. Those devices which exhibit greater volume and greater movement through the endometrium tend to cause greater damage. Likewise, those devices which have numerous leading edges or ends also cause greater damage since they are more prone to migration and since movement by the edge has the potential of producing a shearing stress against the endometrial vessels, glands and cells. In addition, those devices which have free ends may embed themselves in the myometrial tissue and may actually perforate the uterus.

SUMMARY OF THE INVENTION

It is the primary object of this invention to provide intra-uterine devices of novel configuration.

It is a further object to provide a technique for minimizing the physiological complications arising from the insertion and continued presence of intra-uterine devices.

It is still another object to provide a preferred intra-uterine contraceptive device which is adaptive to the uterine interior for enhancement of contraceptive effectivity.

Various other objects and advantages of this invention will become apparent from the following detailed description thereof.

I have now discovered that the difficulties inherent in the use of prior art intra-uterine devices, and particularly linear, compressible, uniplanar devices, may be substantially minimized by enclosing the device between two layers of plastic film which are heat sealed to maintain the device in a fixed position and then selectively slit from the periphery inward to allow for compression of the total assembly. In this manner, it is seen that there is a substantial increase in the surface area of the device without a comparable increase in its volume. This is a beneficial relationship inasmuch as it is generally accepted that the incidence of pregnancy is inversely related to the surface area of the device. Furthermore, the plastic membrane reduces the number of leading edges and free ends, thereby minimizing the likelihood of spontaneous expulsion, migration into the peritroneal cavity, and rupture of blood vessels and/or endometrial cells. The incidence of bleeding is also reduced inasmuch as only a thin flexible membrane is in contact with the uterine walls. The absence of free ends also removes the possibility of their becoming embedded in the myometrial tissue.

The slits in the membrane enable the device to be compressed for insertion into the uterus and to respond to uterine contractile forces while still maintaining the device in substantially a single plane. The overlap of the membrane on the opposite sides of the slit is significant inasmuch as a substantial reduction in the exposed surface area and an increase in the thickness and volume of the device are avoided.

The invention is more specifically defined in the appended claims read together with the following description and accompanying drawings in which

FIG. 1 is a plan view of the preferred embodiment of an intra-uterine contraceptive device according to the invention;

FIG. 2 is a plan view of the device of FIG. 1 in compressed form;

FIG. 3 is an end view of the compressed device of FIG. 2 illustrating the overlapped membrane;

FIG. 4 is a frontal section through the uterus showing the placement of the device of FIG. 1;

FIG. 5 is a cross sectional view of the uterus showing the device of FIG. 1;

FIGS. 6–8 are plan views of other embodiments of the subject invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

With regard to the structural frames that can be utilized with the unique plastic membranes of this invention, they should be linear, compressible, substantially uniplanar bodies. For purposes of this invention, the term "linear" is intended to define structural frames which exhibit an open perimeter, and which contain at least two accessible free ends. The necessity for exhibiting an open perimeter will be evident from the discussion appearing, hereinbelow, relating to the plastic membrane. The compressibility is required such that the device may be placed in a compacted state for disposal into one end of an inserter for ready and painless insertion into the uterine interior and subsequent expansion into normal position. The substantially uniplanar structure insures that the volume of the device will not be overly excessive so as to exert substantial pressure against the uterine wall.

The structural frame will generally comprise at least two outer arms which are connected at the ends thereof. Such connection may be directly effected as in a V-shaped device, or it may be accomplished by means of a connecting member as noted in W- and M-shaped devices. The frame will generally be prepared from continuous lengths of relatively stiff resilient wire of a chemically inert nature, such as stainless steel, that will not react with body tissues and fluids. It should be noted, however, that the structural frame may also be prepared from a synthetic plastic material which exhibits the desired flexibility and chemical inertness.

The free ends of the structural frame are formed into loops of generally one turn in order to eliminate potentially harmful projections. Likewise, any angular intersections which form part of the frame structure are formed into loops of generally one and a half or two and a half turns in order to provide the spring-like action required for the flexibility of the frame structure

as well as to further eliminate the presence of potentially harmful projections.

In enclosing the frame structure in the plastic membrane, it is merely necessary to place the frame between two layers of plastic film and subject the laminate to sufficient heat to cause the films to adhere to one another in the areas of contact, thereby substantially forming a single plastic membrane with the frame sealed therein in fixed position. The plastic membrane utilized for this purpose may be prepared from any heat sealable, physiologically inert, flexible synthetic plastic material, including polyurethanes, polyethylenes, polypropylenes, polytetrafluoroethylene, and the like.

While the dimensions of the frame structure and the plastic membrane may be determined by the practitioner in accordance with his particular needs, it is desirable that the height, i.e. thickness of the total assembly not exceed about 0.020 inch and that the thickness of the heat sealed membrane not exceed about 0.008 inch. In this manner, the total volume of the device is kept at a minimum, thereby avoiding excessive contact with and pressure on the uterine wall. Needless to say, the other dimensions of the membrane will be dependent upon the dimensions of the frame structure utilized therewith, it being necessary that no portion of the frame be exposed and that the outer edges of the membrane provide a closed perimeter for the frame.

The heat sealed membrane is provided with slits in order to insure that the device, when in a compressed state, maintains its substantially uniplanar configuration. These slits are cut into the membrane from its periphery inward and extend toward the frame structure without contacting it and thereby exposing it. The slits are positioned so that they substantially bisect the open areas between adjacent segments of the frame structure, thereby forming substantially triangular sectors bounded by the frame, the slit and the periphery of the membrane. For example, a V-shaped frame (FIG. 7) merely requires a single slit bisecting the area between the arms of the V, while the preferred W-shaped device of this invention (FIG. 1) requires four slits which bisect, respectively, the area between each outer arm and the sides of the inverted V-shaped central segment, the area inside the inverted V-shaped segment, and the area between the outer arms will lie above the center segment.

Thereafter, when the device is compressed, the portions of membrane on each side of the the slit in the line of compression overlap. The overlap does not significantly reduce the surface area of the device. Since it only consists of two layers of membrane in the area of the overlap, there is no significant increase in the thickness of the device. Furthermore, since buckling of the membrane is avoided, due to the potential for overlap and the pressure exerted against the membrane by the uterine surfaces and fluid, there is no undesirable increase in the total volume of the device.

It should also be noted, that inasmuch as peripheral slits extending into the area of the frame structure are required in order to achieve the overlap, frame structures which exhibit a closed perimeter, such as rings, loops and spirals, are not applicable to the present invention. Thus, any compression of these configurations would necessarily result in the undesirable buckling of the membrane.

At least one tail in the form of one or more strands of a strong, chemically inert material, such as nylon, silk, and the like, may be suspended from the device to project through the cervix and facilitate removal of the device from the uterus. The tail will generally be tied to a loop in the lower section of the device through a hole in the membrane provided for that purpose.

Referring now to the drawings, the preferred embodiment of the invention is illustrated in FIG. **1.** The device **10** is shown to consist of a continuous wire frame structure **11** in a general "W-shape" having two outer arms **12, 13** divergently connected to a center inverted V-shaped section **14.** It is seen that the outer arms **12, 13** are formed into loops **15, 16** at the free ends thereof in order to blunt the protruding ends of the device and thereby substantially reduce the pressure exerted upon the uterine wall and the potential for damage of the uterine wall. The center section **14** also exhibits loops **17, 18, 19** at its angular intersection points, these loops **17, 18, 19** providing the spring-like action required for the flexibility of the frame structure **11** as well as eliminating potentially harmful projections.

The wire frame structure **11** is sealed in place in plastic membrane **20.** It is seen that the frame **11** is entirely enclosed within membrane **20,** the membrane **20** extending slightly beyond the periphery of frame **11.** The membrane **20** is provided with slits **21, 22, 23, 24** which extend from the outer edge of membrane **20** inwardly toward frame **11** but stop short of the frame **11** so as not to expose any portion thereof. The slits **21, 22, 23, 24** are positioned at each opening in the perimeter of frame **11.** For purposes of removing the intra-uterine device **10,** strings **25, 26** are tied to the device through loops **17, 19.**

FIG. **2** and FIG. **3** depict the compressed state of device **10** which will exist during insertion of the device or in response to contractions of the uterine muscles. Thus, it is seen that as outer arms **12, 13** are compressed toward each other, the sections of membrane **20** lying adjacent to slit **21** (sections **27, 28**) and slit **23** (sections **29, 30**) are caused to overlap. Although not shown, any pressure exerted against loops **17, 19** will result in the overlap of the sections of membrane **20** lying adjacent to slit **24.** It is to be noted that the overlapped sections **27, 28, 29** and **30** do not substantially reduce the overall surface area of membrane **20.** Likewise, as seen in FIG. **3,** the overlap does not appreciably increase the thickness of membrane **20** inasmuch as a double layer of membrane **20** is only evident in the areas of overlap **31, 32.** Since the overlap also prevents the buckling of the membrane, an undesirable increase in the volume of device **10** is avoided.

FIG. **4** depicts the positioning of device **10** in uterus **33,** with the closed end of the inverted V section **14** facing the fundus or inner end wall **34** of the uterine cavity **33.** It is seen that the extended surface area of device **10** as provided by membrane **20** provides a continuous cover for a substantial cross-section of the uterus **33,** thereby significantly increasing the contraceptive effectiveness. The outer arms **12, 13** resiliently engage the wall of the uterine interior **33,** thereby insuring that the device **10** will be positively maintained in proper position within the uterus, despite the muscular action of the uterine walls. Overlap of several sections of membrane **20** is seen in response to this muscular activity. The removal strings **25, 26** extend through the cervix **35** of the uterus **33** in order to provide ready accessibility.

The side view of device **10** as positioned in uterus **33** (FIG. 5) is clearly illustrative of the negligible amount of surface area of device **10** which impinges on the uterine wall and exerts pressure thereon. Thus, it is primarily the thin flexible edge **36** of the membrane **20** which contacts the wall, thereby exerting minimal pressure on the wall and significantly reducing the physiological effects which may be encountered.

FIGS. **6–8** depict additional embodiments of the subject invention. The N-shaped frame structure of FIG. **6** is shown to consist of two outer arms **50, 51** obliquely connected by central member **52.** The outer arms are formed into loops **53, 54** at the free ends thereof, while loops **55, 56** are formed at the intersections of outer arms **50, 51** and connecting member **52.** The frame structure is sealed in place in membrane **57** and entirely enclosed thereby. Slits **58, 59** are positioned at each opening in the perimeter of the N-shaped frame extending from the outer edge of membrane **57** inwardly toward the frame but stopping short thereof. Compression of outer arms **50, 51** toward each other will cause overlap of the sections of membrane **57** lying adjacent to slits **58, 59.** For purposes of removing the intra-uterine device, strings **60, 61** are tied to the device through loops **53, 56.**

The V-shaped frame structure in FIG. **7** is shown to consist of two outer arms **70, 71,** the ends of which are directly connected to each other by means of spring-like loop **74.** The free ends of outer arms **70, 71** are formed into loops **72, 73** in order to blunt the protruding ends. The frame structure is sealed in a fixed position in membrane **75** which encompasses the entire frame structure. A single slit **76** extending inwardly from the outer edge of membrane **75** and bisecting the area between arms **70, 71** is sufficient, in this construction, to provide the desired overlap characteristics. String **77** is tied to the device through loop **74** to facilitate efficient removal of the device from the uterus.

The T-shaped frame structure in FIG. **8** is shown to consist of crossbar extensions **80, 81** connected to a center U-shaped section **82.** The free ends of extension **80, 81** are formed into loops **83, 84** in order to blunt the protruding ends. Loops **85, 86, 87** are provided at the angular intersection points in order to provide the flexibility necessary to adjust to external pressure regardless of the direction in which it is exerted. The frame structure is sealed in place in membrane **88** and entirely enclosed thereby. Slit **89,** which extends inwardly from the outer edge of membrane **88** and bisects the interior area of the center U-shaped section **82,** is positioned to respond to pressure exerted substantially against the sides of the device.

Since the perimter of the T-shaped frame is a triangle formed by drawing imaginary lines between loops **83, 84** and **87,** slits **90, 91** extending into the other open areas of the perimeter are required in order to respond to pressure exerted on extensions **80, 81** in a downward and/or oblique direction. String **92** is attached to the device through loop **87** to facilitate efficient removal of the device.

It is to be noted that the devices of this invention may be inserted in position with maximum ease for the physician and minimum pain for the host by the use of virtually any conventional inserter known in the art. Thus, any elongated tube capable of receiving the device, in compressed state, fitted with a suitable plunger and release means may be adapted for use.

Summarizing, this invention is seen to provide a novel construction for intra-uterine devices which enhances its contraceptive effectiveness while minimizing the adverse physiological effects resulting therefrom. It should be understood that the present invention is not limited to the embodiments specifically described herein but extends to equivalent embodiments utilizing the principles herein disclosed as defined by the following claims.

What is claimed is:

1. An intra-uterine contraceptive device comprising a flexible, uniplanar non-continuous frame structure adapted to fit within a uterine cavity in fixed position within a plastic membrane resulting from the intimate, face-to-face sealing of two flexible biologically inert plastic films, said membrane totally enclosing said frame structure and forming peripheral edge portions slightly larger than said frame structure, said membrane containing at least one slit extending inwardly from its periphery into an open sealed space within the area defined by said frame structure.

2. The contraceptive device of claim **1,** wherein said frame structure comprises at least two outer arms connected at the ends thereof such that each arm exhibits a connected end and an accessible free end.

3. The contraceptive device of claim **2,** wherein said outer arms are connected to one another by means of a connecting member.

4. The contraceptive device of claim **1,** wherein said frame structure is prepared from a continuous length of relatively stiff, resiliently flexible, inert wire.

5. The contraceptive device of claim **4,** wherein said wire is stainless steel.

6. The contraceptive device of claim **2,** wherein the free ends of said outer arms are formed into circular loops.

7. The contraceptive device of claim **3,** wherein each member of the frame structure is connected to its adjacent member by means of a resiliently flexible loop joint, whereby said frame structure may be compressed into compact form for insertion into a uterine interior and may resume its expanded position when released from said compression within said uterine cavity.

8. The contraceptive device of claim **1,** wherein said plastic membrane is prepared from two layers of a heat sealable, inert, synthetic plastic material.

9. The contraceptive device of claim **1,** wherein said slit substantially bisects the open area between adjacent segments of the frame structure, thereby forming substantially triangular sectors bounded by a segment of the frame structure, the slit and the periphery of the membrane.

10. The contraceptive device of claim **1,** wherein at least one string is affixed to said frame structure to project through the cervix and facilitate removal of said contraceptive device.

11. The contraceptive device of claim **2,** wherein said frame structure is a substantially V-shaped body.

12. The contraceptive device of claim **3,** wherein said frame structure is a substantially N-shaped body.

13. The contraceptive device of claim **3,** wherein said frame structure is a substantially T-shaped body, the connecting member thereof formed of sides convergent to a U-shape.

14. A uniplanar non-continuous frame structure adapted to fit within a uterine cavity as an intra-uterine contraceptive device comprising (1) a substantially W-

shaped body, including a center connecting member formed of sides convergent to an inverted V-shape and outer arms divergently connected to the diverged sides of said center member, the free ends of said outer arms formed into circular loops, said outer arms connected to the sides of said center member and said sides of said center member connected to one another by means of resiliently flexible loop joints, whereby said body may be compressed into compact form; said substantially W-shaped body being enclosed in a fixed position within (2) a plastic membrane resulting from the intimate, face-to-face sealing of two flexible biologically inert plastic films, said membrane containing four slits extending inwardly from the periphery thereof and substantially bisecting, respectively, the area between each outer arm and a side of the inverted V-shaped center member, the area between the converging sides of the inverted V-shaped center members, and the area between the length of outer arms which extend above point of convergence of the inverted V-shaped center member, said member totally enclosing said frame structure and forming peripheral edge portions slightly larger than said frame structure.

15. The contraceptive device of claim **14,** wherein said W-shaped body is formed from a continuous length of stainless steel wire.

16. The contraceptive device of claim **14,** wherein said plastic membrane is prepared from two layers of a synthetic plastic material selected from the group consisting of polyurethanes, polyethylenes, polypropylenes and polytetrafluoroethylene.

17. The contraceptive device of claim **14,** wherein a string is tied to each flexible loop joint connecting said outer arms to the sides of said center member.

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