

[54] **FORCE TRANSMITTING INTRAUTERINE DEVICE**

[76] Inventors: **Erick-Pierre Fournier**, 30 Park Ave., New York, N.Y. 10016;
Alberto Lomeo, 200 E. End Ave., New York, N.Y. 10028

[22] Filed: **Feb. 19, 1971**

[21] Appl. No.: **116,867**

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

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

[58] Field of Search 128/127-131, 261,
128/263, 260; 24/81, 252

3,683,906 8/1972 Robinson 128/130
2,484,449 10/1949 Fetterman 24/81 C X
3,678,927 7/1972 Soichet 128/130

FOREIGN PATENTS OR APPLICATIONS

9,546 7/1899 Great Britain 24/252 PC

OTHER PUBLICATIONS

A. H. Robins Co. Advertising Booklet, "Dalkon Shield," A. H. Robins Co., Richmond, Va., Nov. 1970.

Primary Examiner—Richard A. Gaudet

Assistant Examiner—J. C. McGowan

Attorney, Agent, or Firm—Morgan, Finnegan, Durham & Pine

[56] References Cited

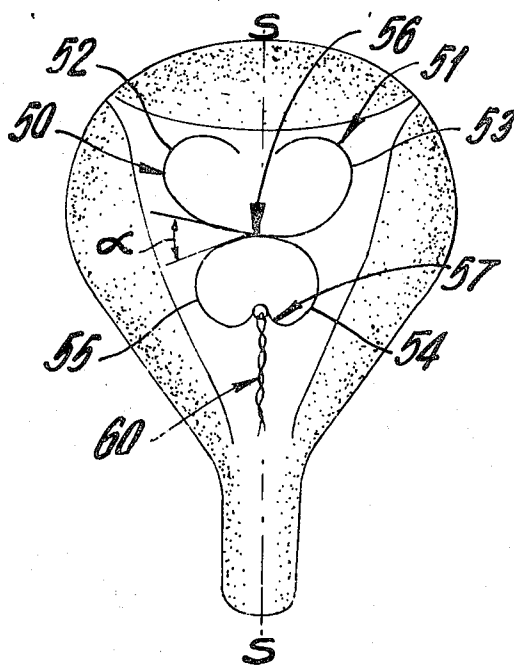
UNITED STATES PATENTS

3,492,990	2/1970	Clarke	128/130
3,633,574	1/1972	Lerner	128/130
30,410	10/1860	Kleinwort	128/127
3,312,214	4/1967	Burdick	128/130
2,256,602	9/1941	Edwards	128/127
2,176,559	10/1939	Meckstroth	128/130
3,537,445	11/1970	Burnhill	128/130
3,077,879	2/1963	Knoch	128/130
3,397,690	8/1968	Majzlin	128/130
496,711	5/1893	Thompson	128/127
1,407,102	2/1922	Viden	15/210 R
3,407,806	10/1968	Hulka et al.	128/130

[57] ABSTRACT

An intrauterine contraceptive device having substantial surface area for contact with the endometrium and capable of being releasably contracted to a size and shape for ready passage into the uterus and, when released, of expanding to conformably engage the walls of the uterine cavity in the mid-uterine area above the level of the internal os to resist expulsion, and thereafter of being readily removed, together with an introducer implement for releasably contracting the device in the proper orientation for insertion are disclosed.

16 Claims, 47 Drawing Figures



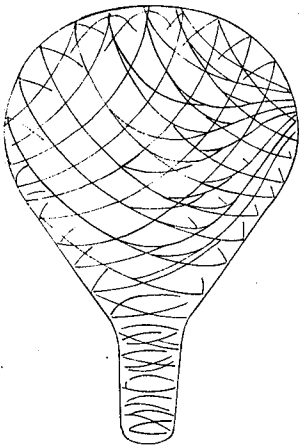


FIG. 1

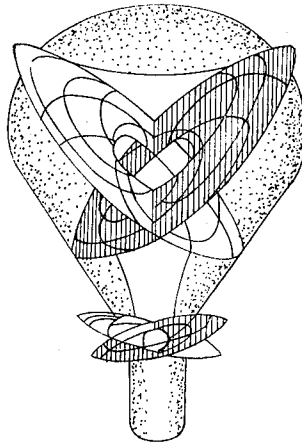


FIG. 2

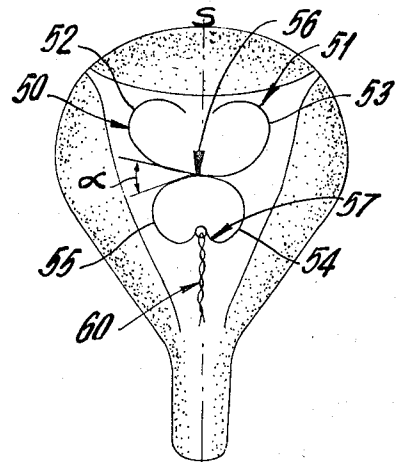


FIG. 3

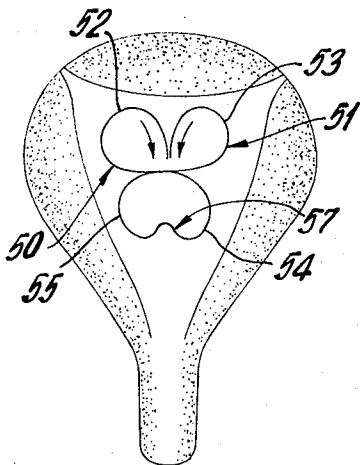


FIG. 4

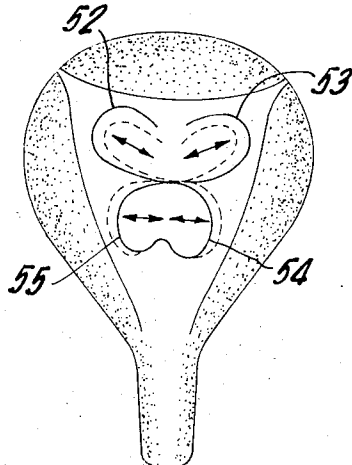


FIG. 5

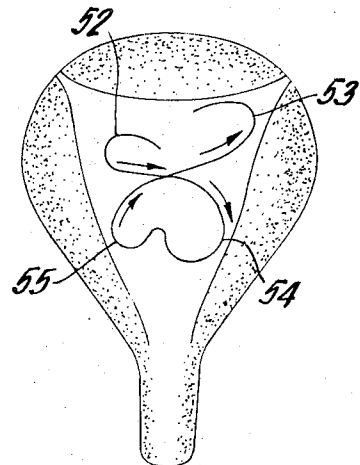


FIG. 6

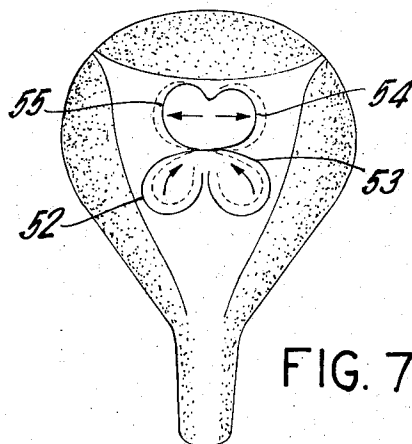


FIG. 7

INVENTORS
ERICK-PIERRE FOURNIER
BY ALBERTO LOMEO

Morgan, Finnegan, Durham & Pine
ATTORNEYS



FIG. 11

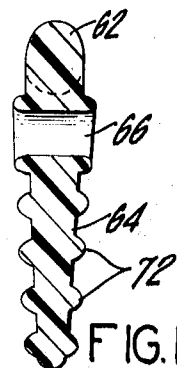


FIG. 10A

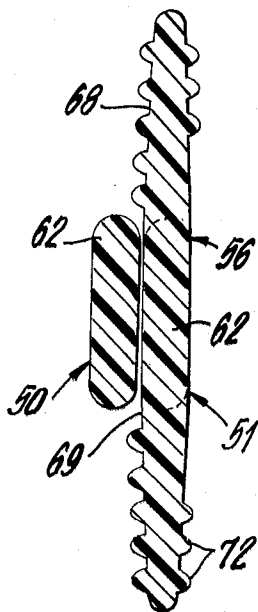


FIG. 9

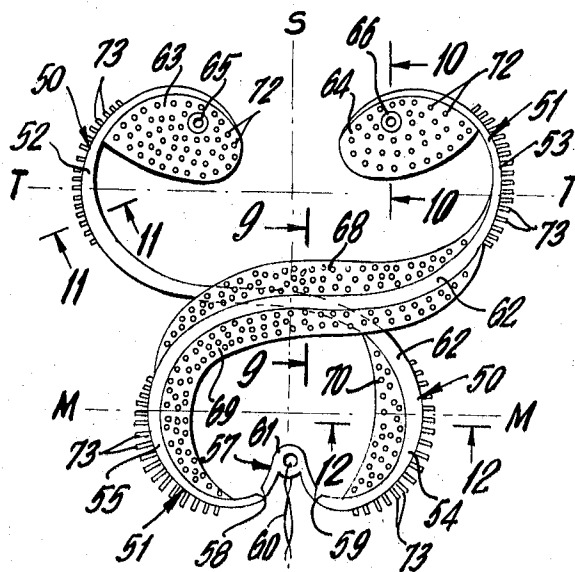


FIG. 8

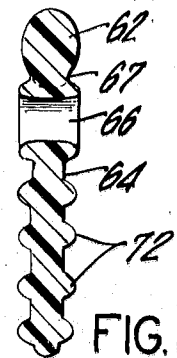


FIG. 10

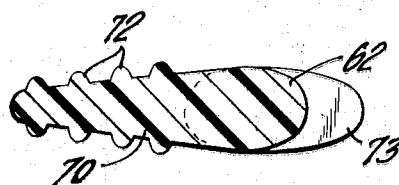


FIG. 12A

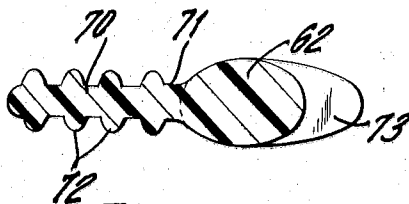


FIG. 12

INVENTORS
ERICK-PIERRE FOURNIER
BY ALBERTO LOMELO

Morgan, Finnegan, Durham & Line
ATTORNEYS

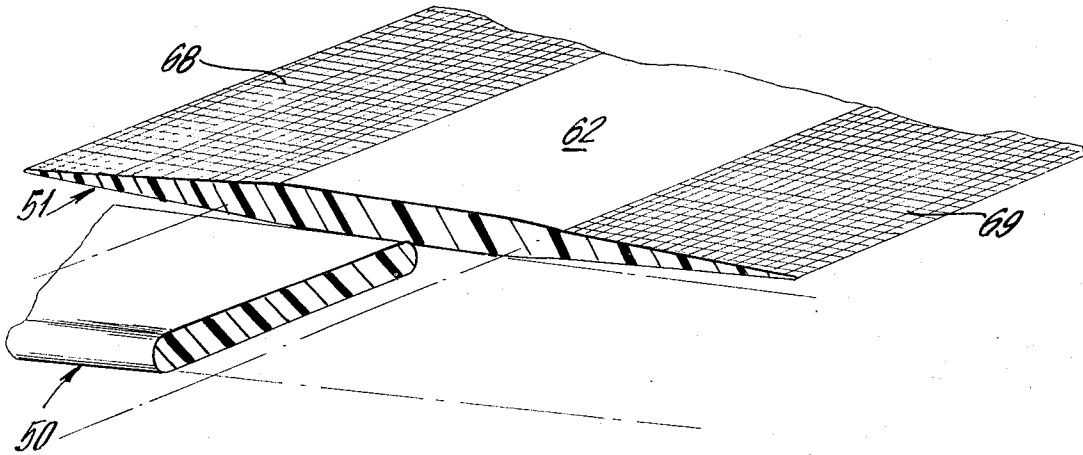


FIG. 13

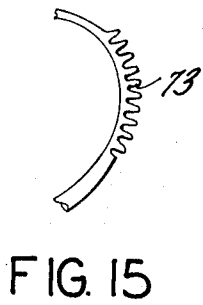


FIG. 15

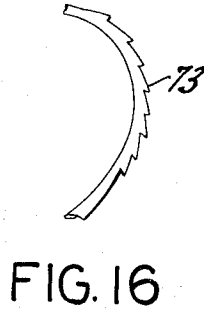


FIG. 16

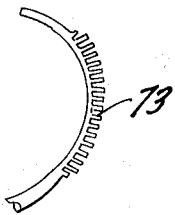


FIG. 17



FIG. 18

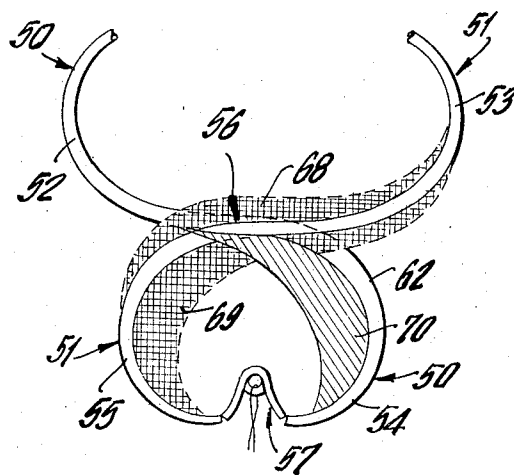


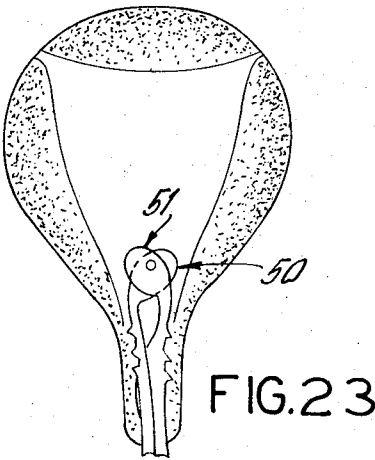
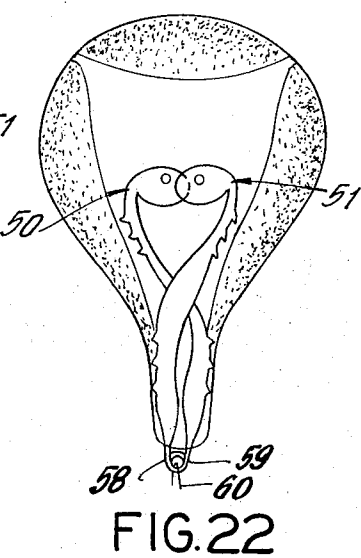
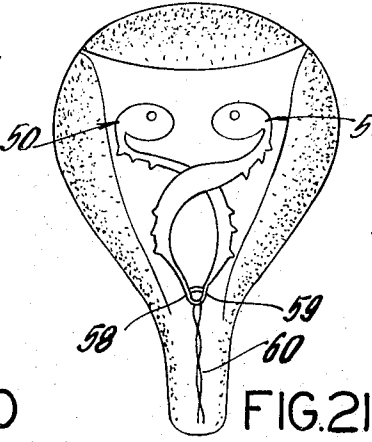
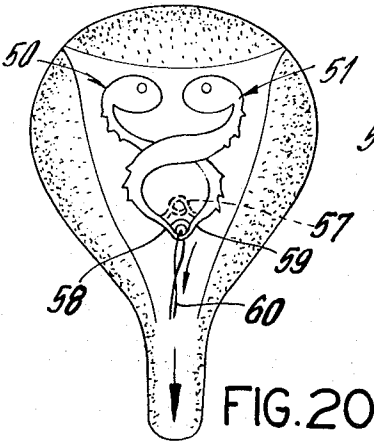
FIG. 14

INVENTORS
ERICK-PIERRE FOURNIER
BY ALBERTO LOMEO

Morgan, Finnegan, Durham & Line
ATTORNEYS

TYPES	TOP VIEWS	CROSS-SECTION (TYPICAL)	PROFILE (TYPICAL)
MOUNDS, CRATERS or PERFORATIONS			
RIDGES and GRIDS			
CIRCLES, STARS, CROSSES and SQUARES			
PEAKS			

FIG.19



INVENTORS
ERICK-PIERRE FOURNIER
BY ALBERTO LOMELO
Morgan, Finnegan, Ducham & Line
ATTORNEYS

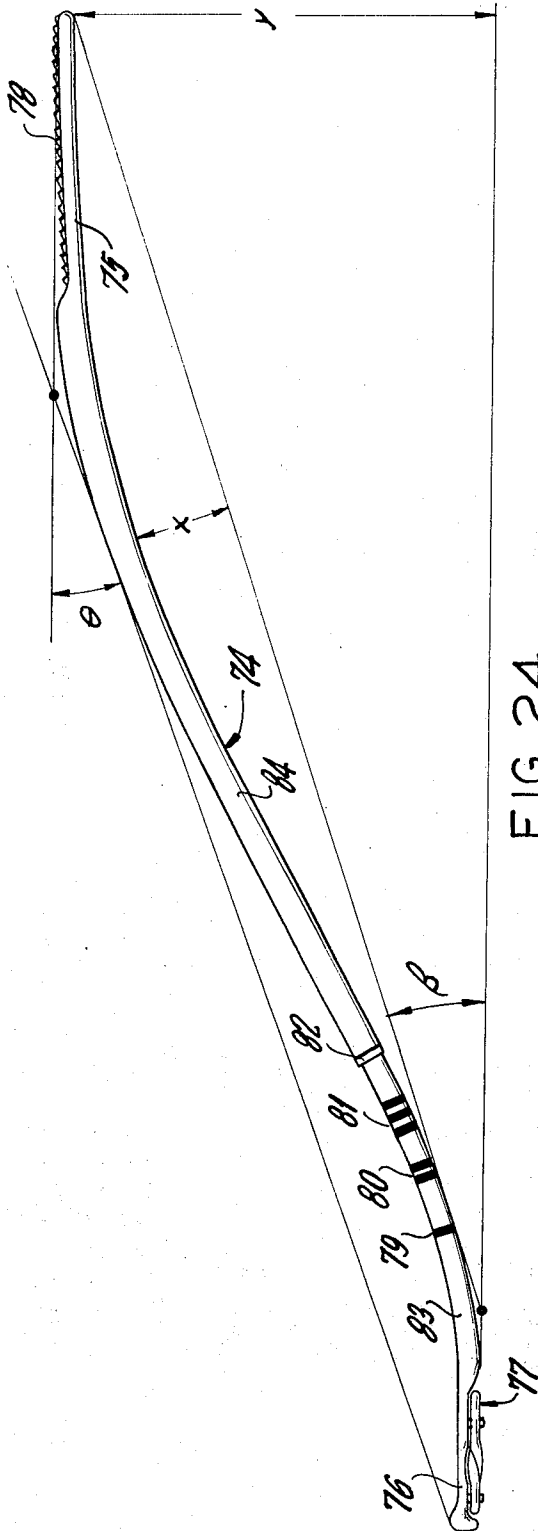


FIG. 24

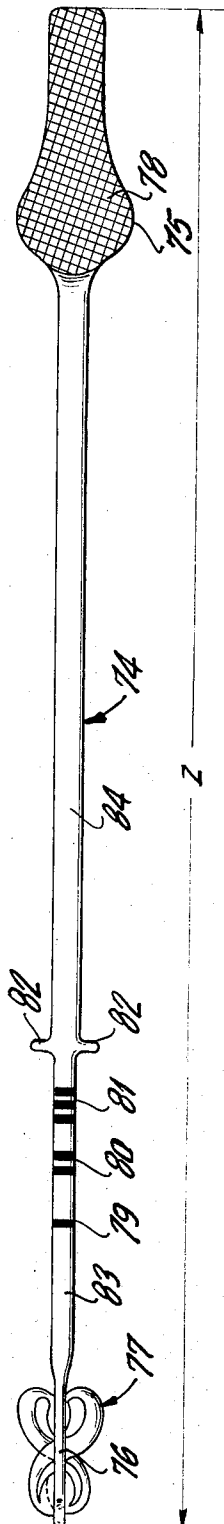
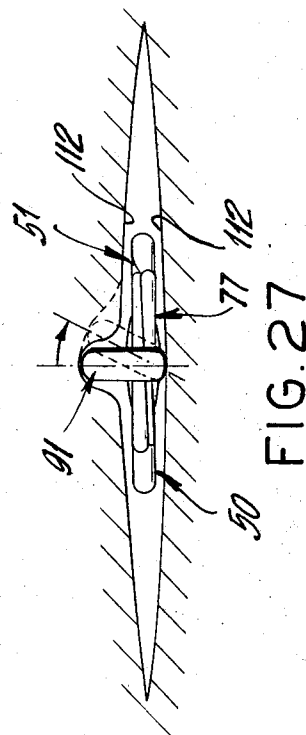
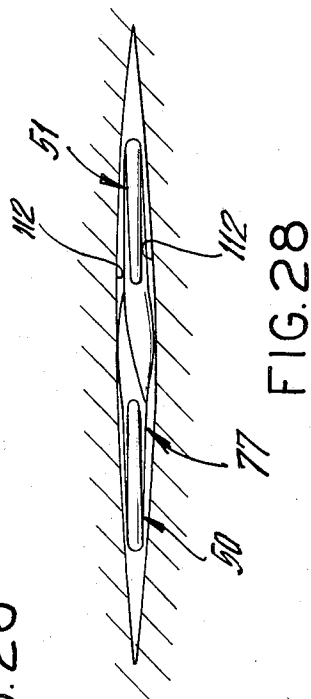
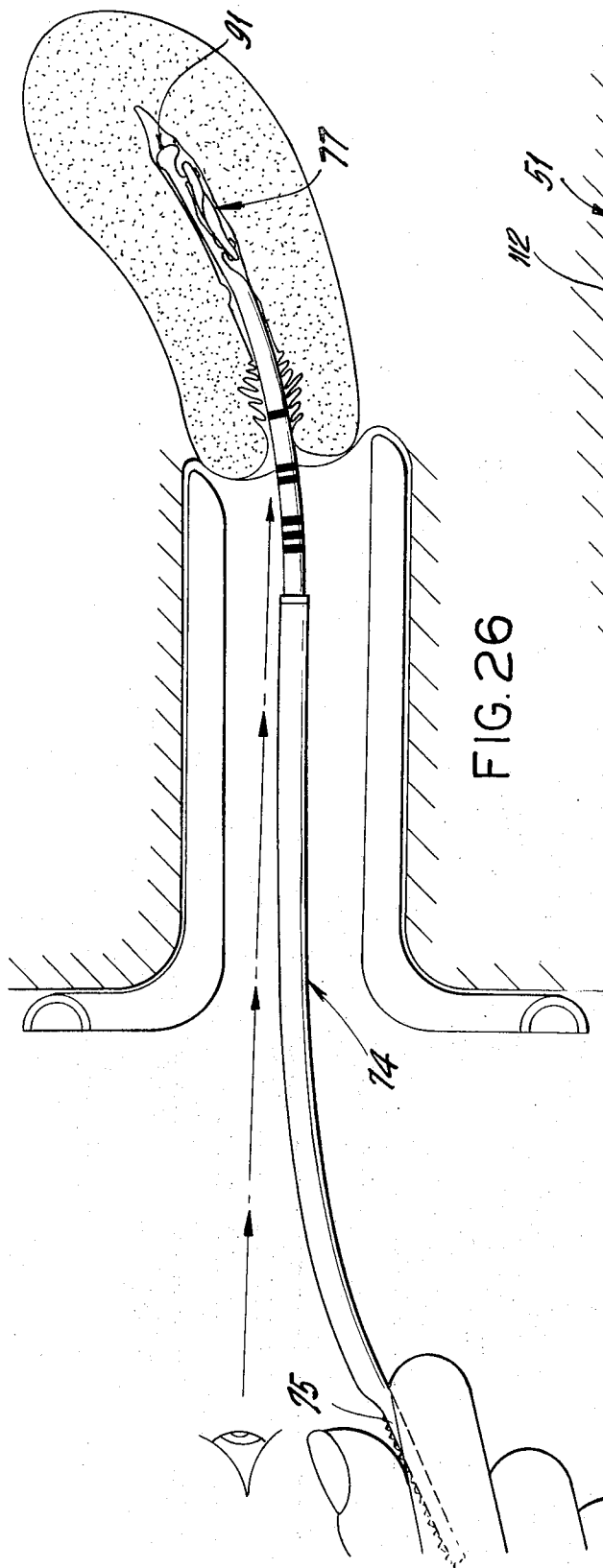


FIG. 25

INVENTORS

ERICK-PIERRE FOURNIER
BY ALBERTO LOMEO

Morgan, Finnegan, Durkam & Line
ATTORNEYS



INVENTORS
ERICK-PIERRE FOURNIER
BY ALBERTO LOMELO

Morgan, Finnegan, Durham & Line
ATTORNEYS

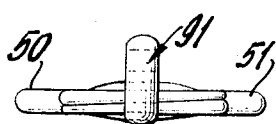


FIG. 30

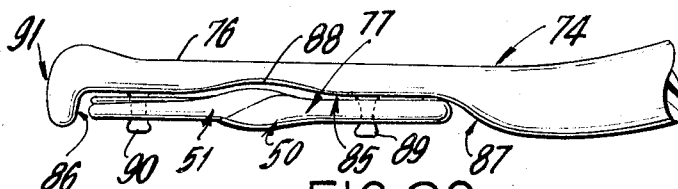


FIG. 29

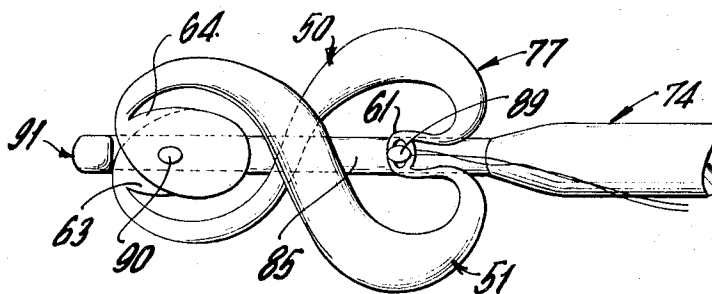


FIG. 31

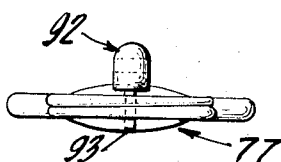


FIG. 33

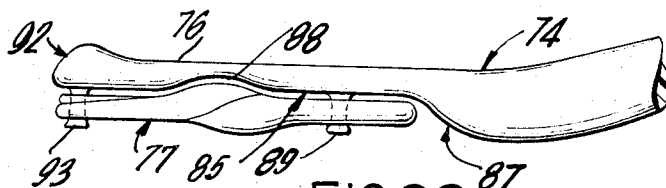


FIG. 32

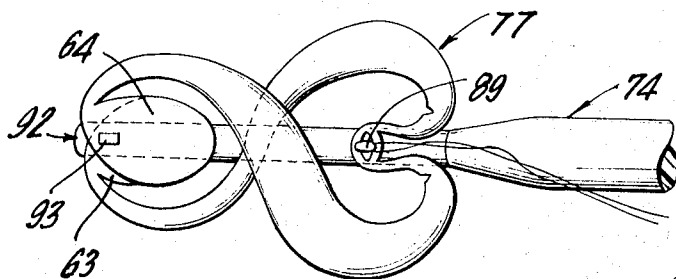


FIG. 34

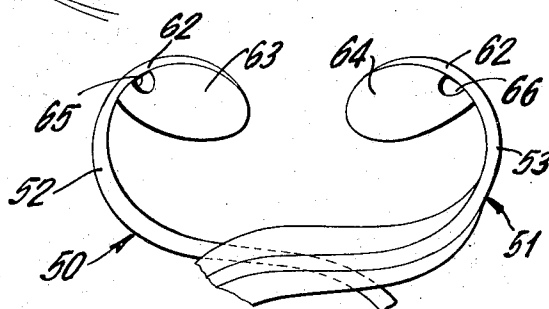


FIG. 45

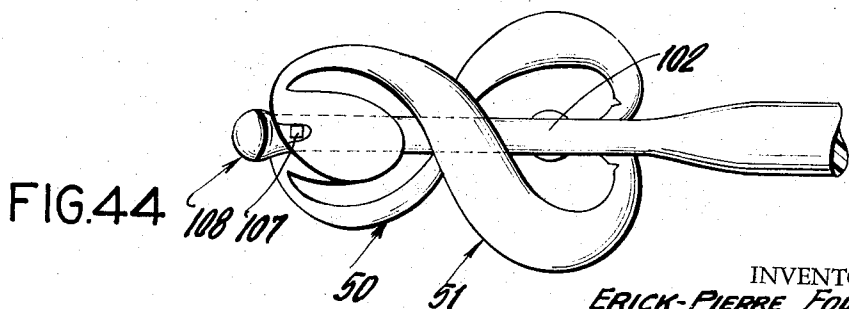
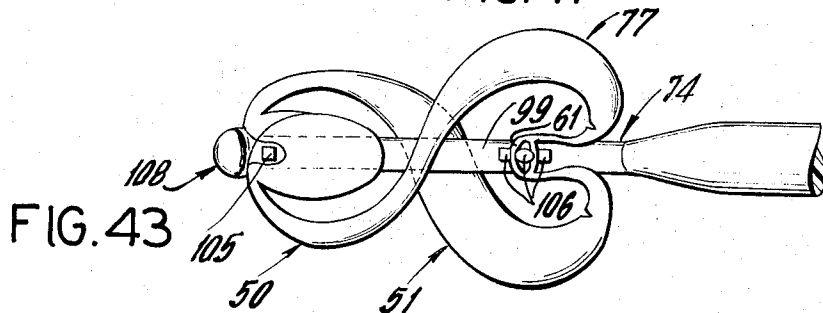
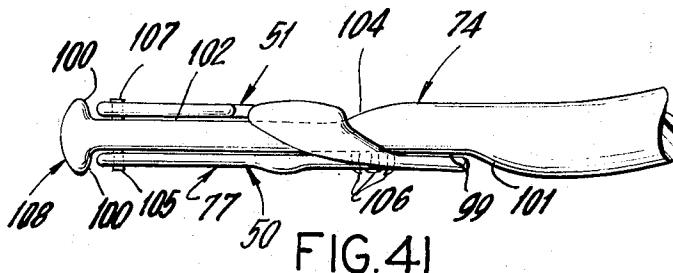
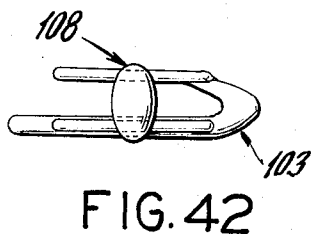
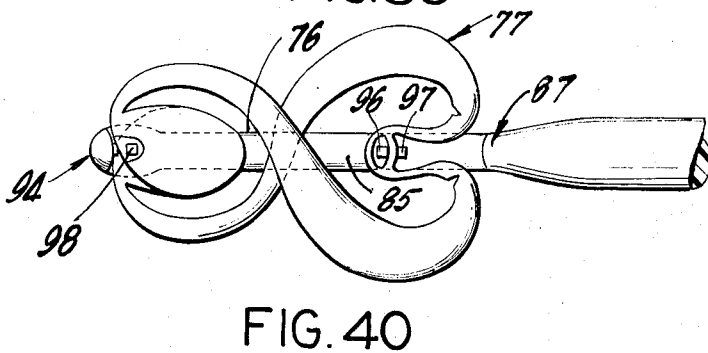
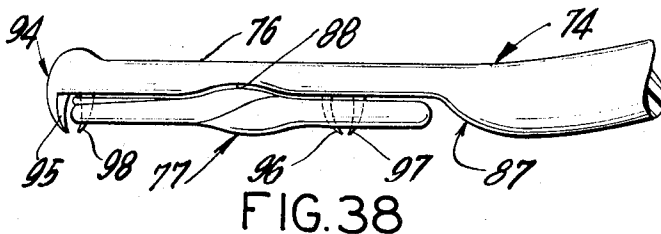
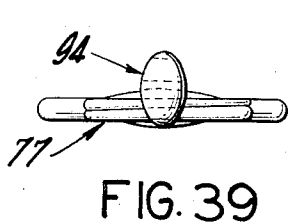
FIG. 35 T

FIG. 36 T

FIG. 37 T

INVENTORS
ERICK-PIERRE FOURNIER
BY ALBERTO LOMEO

Morgan, Finnegan, Durham & Line
ATTORNEYS



INVENTORS
ERICK-PIERRE FOURNIER
BY ALBERTO LOMEO

Morgan, Finnegan, Durham & Pine
ATTORNEYS

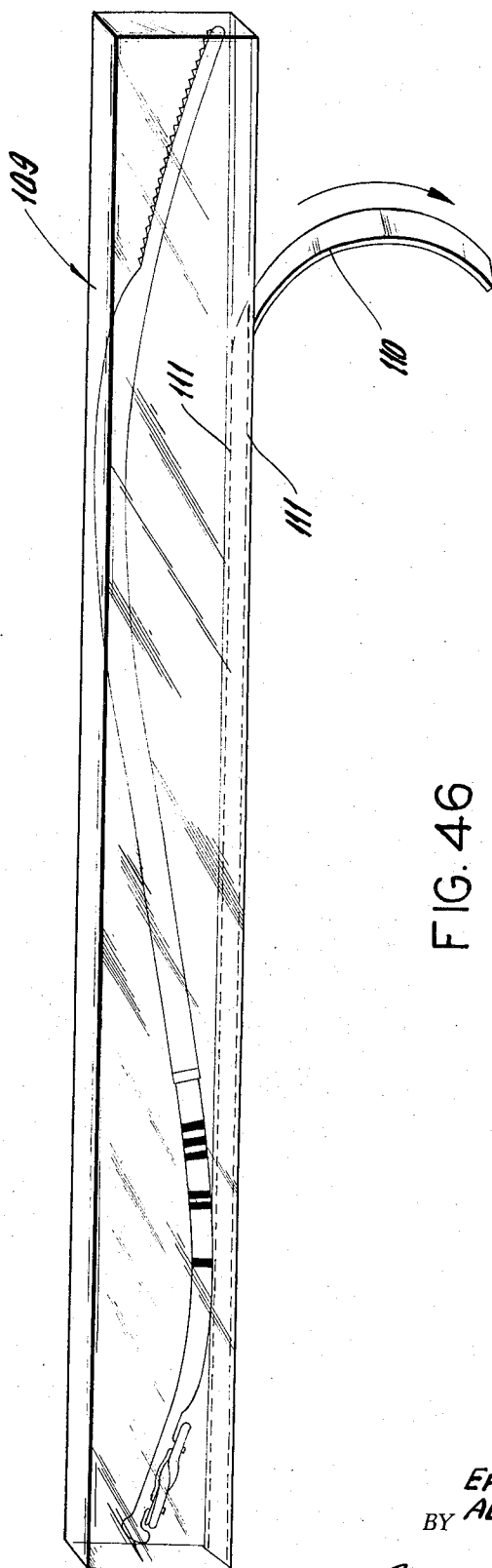


FIG. 46

INVENTORS
ERICK-PIERRE FOURNIER
BY ALBERTO LOMEO

Morgan, Finnegan, Durham & Line
ATTORNEYS

FORCE TRANSMITTING INTRAUTERINE DEVICE
BACKGROUND AND SUMMARY OF THE
INVENTION

Overpopulation presents such potentially disastrous socio-economic and ecological consequences that safe, effective, convenient and readily accessible means of curbing the world's birth rate other than through sterilization and abortion must be developed and massively implemented in the not-too-distant future.

Currently available modes of contraception fall broadly into three categories. Physical and/or chemical barriers interposed between the sperm and the ovum such as condoms, diaphragms, spermicidal foams, creams and jellies. Hormonal interference with ovulation and/or implantation of the fecundated ovum which can be either of the oral, injectable or implantable type. Intrauterine contraceptive devices which, according to current theory, are believed to activate and to attract the presence of phagocytic cells through irritation of the endometrial cavity, thereby isolating the blastocyst and preventing its implantation, although the exact contraceptive mechanism involved has yet to be fully understood.

All these methods have not been without varying forms and degrees of drawbacks. Let alone the fact that low incidence of pregnancy with condoms, diaphragms and sperm-killing chemicals is heavily related to the skill and care of the user, they are generally regarded as clumsy and inconvenient. Besides their relatively high cost, they require, in order to be beneficial, a definite amount of sophistication and sustained individual motivation which inhibit their wide-spread usage, particularly among lower socio-economic groups.

Although rated the most effective to date, any hormonal treatment demands continuous periodic supervision by highly qualified medical personnel for the assessment and evaluation of its systemic effects, which constitutes a definite limiting factor. In addition, they still imply on the part of the user a measurable degree of self-discipline, particularly among highly mobile population groups resorting to "one-a-day" oral contraceptives.

In contrast to the other modes of contraception, the intrauterine device at least theoretically represents potentially the ideal method of mass population control for both developed and developing countries. This contraceptive approach is basically inexpensive and convenient, and requires a minimum of attention and supervision all of which militate in favor of its use-effectiveness. Furthermore, clinical experience with such devices has indicated the potential effectiveness and reliability of this approach to contraception without the need to alter natural hormonal balances.

Any intrauterine contraceptive device, before it can expect to meet with a full measure of success, should ideally satisfy the following objectives:

The pregnancy rate should match or closely approach the low incidence level of hormonal contraceptives.

The rate of spontaneous expulsion should be very low.

Side effects such as pain, cramps, bleeding and other discomfort must be minimal so as to encourage the user to continue.

The design of the intrauterine device and of its introducer implement as well as the insertion procedure,

should be such that uterine perforation is made virtually impossible during insertion of the device.

The structural design of the device should be such as to comfortably fit the uterine cavity of all women, especially nulligravidas.

The introduction of the device, as well as its removal, should be painless, easy and relatively fast to perform by either physicians or paramedical personnel after a short period of training.

The material composition of the device must be such that it causes no harm to the human body.

The device should be able to be mass produced at a low manufacturing cost.

Heretofore, this mode of contraception has not attained the level of reliability and acceptance indicated by theoretical considerations, the available devices having been found lacking in one or more of the foregoing areas. The principal shortcoming has been in an inability to control the rate of spontaneous expulsion with accompanying side effects such as pain and bleeding.

On the basis of the body of current clinical knowledge, the relationships between some of the physical characteristics of a device and its wanted and unwanted effects can be summarized in the following table where a plus sign indicates an increase as a direct function of a physical factor, a minus sign a decrease and a zero no significant change.

Physical Characteristics	Physiological Effects			
	Pain	Bleeding	Expulsion	Pregnancy
Resilience	+	+	-	0
Stiffness	+	+	-	0
Size	+	+	-	0
Surface Contact	0	+	-	-
Roughness	+	+	0	-
Irritation	0	0	0	-

As can be observed, for instance, the rate of pregnancy and expulsion is inversely proportional to the extent of surface contact of the device with the endometrial tissues, but with the disadvantage of increased bleeding; whereas a high degree of resilience and stiffness tends to lower the expulsion rate while causing at the same time the unwanted effects of greater pain and bleeding. Similarly, too large a size in the dimensions of a device will lower the expulsion rate without too much effect on the pregnancy rate while increasing bleeding and pain due to the distention caused to the uterine cavity.

Having in mind the foregoing, the present invention has as its general object the provision of an intrauterine contraceptive device which eliminates the shortcomings and drawbacks of the prior art. More particularly, the invention has as its object the provision of a device and means for inserting same which embodies all of the objectives set forth above, especially one which couples low incidence of pregnancy with high resistance to spontaneous expulsion and ease of insertion and removal.

Briefly and generally, the invention in its broad aspects comprises a device having a substantially planar deformable but resilient body capable of being releasably contracted for ready passage in to the uterus and, when released, of expanding to conformably engage the uterine walls in the mid-uterine area substantially above the average level of the internal os to resist ex-

pulsion. In accordance with a basic principle of the invention, the device has a substantially lobate outer contour including upper and lower pairs of structural uterine wall bearing lobes disposed in substantially symmetrical relation about a longitudinal axis extending therebetween with diagonally opposed upper and lower lobes of said lobe pairs directly coupled in contralateral force transmitting relation by structural force transmitting means extending in crossed relation diagonally across said axis, the device being adapted for proper orientation in the uterus with its longitudinal axis substantially coaxial with the cervical canal.

In one preferred form of the invention, the device has substantially the configuration of a figure 8, open at the top, the operative elements including two substantially similar resilient S-shaped force transmitting members having upper and lower arcuate lobe forming sections and arranged in overlapped mirror-image relation with their said arcuate sections outwardly disposed with respect to a symmetrical axis longitudinally extending therebetween as aforesaid. In accordance with a further principle of the invention, the terminal portions of the lower arcuate sections located nearest the cervical canal when the device is properly oriented in the uterus are resiliently joined via spring-hinge means resiliently resisting inward compression of the members towards the longitudinal axis, and externally accessible withdrawal means is provided for deactuating the spring-hinge means to permit the members to be readily contracted for removal.

In a preferred embodiment, the spring-hinge means comprises a filamentary extension of the force transmitting members having the form of an "inverted-V" expansion joint with an apex substantially coincident with the longitudinal axis, the withdrawal means comprising zones of weakness formed at the junctions of the members with the V joint and filament means affixed to the apex of the joint and readily externally accessible whereby the manual application of a force for removal of the device will result in the joint being inverted and a deactuation of its spring energy normally resisting contraction of the force transmitting members towards the longitudinal axis.

In accordance with a further and preferred feature of the invention, the device is formed with a series of plastic membranous regions which, still more preferably, incorporate minute regularly distributed surface protuberances or asperities giving the device substantial surface area for contact and surface irritation of the endometrium.

In accordance with still another aspect of the invention, the arcuate sections of the force transmitting members are provided on their outer wall bearing lobe surfaces with knurl forming protuberances for gripping the uterine wall to provide stability and resistance to downward displacement of the device.

Means in accordance with the invention for introducing the contraceptive device into the uterus comprises a shaft having handle means formed in one end and means formed in the other end having a bulbous searching head for releasably holding the device in a properly oriented contracted condition, the shaft being formed with a curvilinear profile intermediate its ends having a double reverse curvature whereby the handle section and holding section oppositely extend in axially offset substantially parallel relation. This means for holding the device comprises a linear section of the

shaft defining a cavity having a back wall and locating pin means operatively associated with the cavity for cooperating with pin engaging means formed in the device whereby the device is releasably retained within the cavity with its longitudinal axis parallel to the axis of the shaft and its force transmitting members contracted towards the longitudinal axis with their normally free ends held in fixed spatial relation.

Preferred dimensional and geometrical parameters in accordance with the invention are that the outer wall bearing surfaces of the upper arcuate sections be normally spaced apart a substantially greater distance than the corresponding surfaces of the lower arcuate sections, that the force transmitting members cross over one another at substantially the mid-point of the device taken along the longitudinal axis and that they extend in relation to one another at an angle of about 0°-30°, and that the lowermost extremity of the device when positioned in the uterus lies substantially above the average level of the internal os, the device being adapted to lie in the mid-uterine area.

Having summarized the invention, a detailed description follows with reference for illustrative purposes to the accompanying drawings which form part of the specification, of which:

FIG. 1 is a diagrammatical view of the uterus illustrating its muscular structure;

FIG. 2 is a diagrammatical view illustrating the muscular dynamics of the uterus including the two major centers of concentric forces;

FIG. 3 is a diagrammatical view of an intrauterine contraceptive device embodying the invention in its elemental concept illustrating same unstressed within the uterine cavity;

FIGS. 4, 5 and 6 are diagrammatical views similar to FIG. 3 illustrating the device conforming to the physiology of the uterine cavity under various contractive forces and the force transmitting and diffusing mechanism of the device to prevent expulsion;

FIG. 7 is a diagrammatical view similar to FIG. 3 illustrating the device conforming to the uterine cavity in the event that it accidentally assumes an upside-down position;

FIG. 8 is an elevational view, partially diagrammatical, of a preferred embodiment of the invention;

FIG. 9 is a cross-sectional view of the device of FIG. 8 taken along line 9-9 thereof;

FIG. 10 is a cross-sectional view of the device of FIG. 8 taken along line 10-10 thereof;

FIG. 10A is a cross-sectional view of the device illustrating an alternate cross-sectional configuration to that of FIG. 10;

FIG. 11 is a cross-sectional view of the device of FIG. 8 taken along line 11-11 thereof;

FIG. 12 is a cross-sectional view of the device of FIG. 8 taken along line 12-12 thereof;

FIG. 12A is a cross-sectional view illustrating an alternate cross-sectional configuration to that of FIG. 12;

FIG. 13 is a fragmentary cross-sectional view of the device taken in perspective at the cross-over region of the force transmitting members of the device;

FIG. 14 is a diagrammatical elevational view illustrating in accordance with the invention an alternate membranous configuration to that of FIG. 8;

FIGS. 15-18 are fragmentary diagrammatical views illustrating, in accordance with the invention, four al-

ternate lobate knurl configurations for the arcuate sections of the device;

FIG. 19 is a chart illustrating various possible membrane asperity configurations in accordance with the invention;

FIGS. 20-23 are diagrammatical elevational views illustrating a contraceptive device in accordance with the invention being removed from the uterine cavity;

FIG. 24 is an elevational view of an introducer implement in accordance with the invention releasably holding a contraceptive device similar to that of FIG. 8;

FIG. 25 is a top plan view of the introducer and device combination of FIG. 24;

FIG. 26 is a diagrammatical elevational view illustrating the technique for inserting a contraceptive device utilizing the introducer implement of FIG. 24;

FIG. 27 is a sectional view taken transversely of the uterine cavity illustrating the contraceptive device held in its contracted state by the introducer as in FIG. 26 and further illustrating the manner by which the device is disengaged;

FIG. 28 is a view similar to FIG. 27 illustrating the contraceptive device fully expanded after disengagement from the introducer conformably engaging the walls of the uterine cavity;

FIGS. 29, 30 and 31 are enlarged side and end elevational and bottom plan views, respectively, of the contraceptive device and introducer combination of FIG. 24;

FIGS. 32, 33 and 34 are views similar to FIGS. 29, 30 and 31, respectively, illustrating an introducer implement of alternate construction in accordance with the invention releasably holding a contraceptive device similar to that of FIG. 8;

FIGS. 35-37 are diagrammatical views of three alternate introducer locating pin configurations in accordance with the invention for releasably engaging a contraceptive device as herein illustrated.

FIGS. 38, 39 and 40 are views similar to FIGS. 29, 30 and 31, respectively, illustrating still another alternate introducer construction in accordance with the invention releasably holding a contraceptive device similar to that of FIG. 8;

FIGS. 41, 42 and 43 are views similar to FIGS. 29, 30 and 31, respectively, illustrating in combination with a contraceptive device as herein illustrated yet another introducer construction in accordance with the invention;

FIG. 44 is an enlarged top plan view of the contraceptive device and introducer combination of FIG. 41;

FIG. 45 is a fragmentary diagrammatical view of a contraceptive device in accordance with the invention having alternate pin engaging locations to that of FIG. 8 for use with the introducers of FIGS. 32, 38 and 41; and

FIG. 46 is a perspective view of an intrauterine contraceptive device and introducer combination in accordance with the invention prepackaged for use.

Turning now to the drawings in detail wherein like reference characters are employed to designate like parts throughout, an intrauterine device embodying the invention in its elemental concept is illustrated diagrammatically in FIG. 3, the device being shown in unstressed condition within the uterine cavity.

In accordance with the invention, the device comprises a substantially filamentary compressible resilient

body having a longitudinal axis S—S which extends substantially coaxially with the cervical canal when the device is properly positioned within the uterine cavity as shown in FIG. 3. The operative elements of the illustrative embodiment include two substantially similar S-shaped resilient force transmitting members 50 and 51 having upper arcuate arm sections 52 and 53, respectively, and lower arcuate arm sections 54 and 55, respectively, members 50 and 51 being disposed in overlapped mirror-image relation with respect to the longitudinal axis S—S to form a substantially planar body. The lower arcuate arm sections 54 and 55 at their terminal portions are joined via spring-hinge means 57 whereas the terminal portions of the upper arcuate arm sections 52 and 53 are normally disposed in overhanging spaced apart movable relation, as shown. The force transmitting members cross intermediate their upper and lower arcuate sections at a point 56 substantially coinciding with axis S—S.

The configuration of the device thus defined when unstressed can be seen to markedly resemble the contour of a numeral 8, unclosed at the top, whose overlapping members 50, 51 intersect almost tangentially and are free to slide past one another in any direction and to independently withstand deformations due to their plasticity. The overhanging terminal portions of arms 50 and 51 are normally spaced apart as shown when the device is unstressed and curve slightly inwardly toward the open center of the upper section of the device away from the sensitive zones of the cornua.

The outer contour of the device can be characterized as having upper and lower pairs of wall bearing lobes formed by the arcuate sections of the force transmitting arms 50, 51 which are laterally disposed in symmetrical relation with respect to axis S—S to define two transverse axes T—T and M—M. The cross-bar sections of the arms 50, 51 serve to interconnect in force transmitting relation diagonally opposed upper and lower lobes to provide contralateral transmission and diffusion of the forces exerted on the lobe regions by the uterine walls.

The spring-hinge means 57 preferably comprises a filamentary extension of the force transmitting members 50, 51 having the form of an inverted V expansion joint having an apex substantially coincident with axis S—S, as illustrated. The spring-hinge joint serves, in accordance with the invention, as the source of spring energy to the force transmitting members 50, 51 resiliently resisting compression of the members towards the longitudinal axis S—S when under stress of uterine contractions. The ability of the device to resist contraction under such conditions is an important feature of the invention as will hereinafter more fully appear.

In accordance with a further feature of the invention, the device is provided with withdrawal means for deactuating the spring-hinge joint 57 to permit the device to be contracted towards its longitudinal axis S—S in order to facilitate withdrawal. As presently illustrated, the withdrawal means comprises zones of weakness 58 and 59 (See FIG. 8) formed in the filamentary structure at the junctions of the members 50 and 51 with the base of joint 57, and a monofilament 60 affixed to the apex of joint 57 by suitable means such as by ring 61. By simply pulling with sufficient force on filament 60, which is adapted to be externally accessible through

the cervical canal, the zones of weakness can be sufficiently stressed, as lower arcuate lobe forming sections 54, 55 press against the uterine walls, to cause joint 57 to invert thereby losing its spring energy and permitting the device to be readily contracted.

Dimensions for parous cavities should preferably not exceed 25 millimeters when the device is unstressed along its longitudinal axis S—S and 24 millimeters at its upper major transverse axis T—T. (See FIG. 8) More preferably, the geometry of the device should obey a number of constant ratios for optimal results. The spacing between upper arcuate arm sections 52 and 53 should be substantially greater and ideally on the order of 1 ½ times greater than the spacing between lower arcuate sections 54 and 55, while the overlapping force transmitting arms should cross at substantially the midpoint of the device when measured along longitudinal axis S—S. In addition, the angle between the tangents taken on the two intersecting arms 50 and 51 at the point of intersection 56 denoted as angle α in FIG. 3 should preferably not exceed 30°.

The importance of these dimensional parameters can best be understood in light of the theoretical considerations underlying the invention and the manner in which the device reacts to intrauterine contractions to avoid spontaneous expulsion.

The muscular structure of the uterus follows the configuration of its pear-like shape. As diagrammatically represented in FIG. 1, the concentric pattern of cross-laid muscular fibers assumes from the top to the mid-section of the uterus a direction generally inclined at a 45° angle. From the mid-section down to the isthmus, the inclination of the muscular fibers becomes progressively less angulated to a point where the muscles form horizontal rings from the level of the isthmus down to the cervix.

Thus, the muscular dynamics of the uterus can be reduced for practical purposes to two major centers of concentric forces as shown in the planar representation of FIG. 2:

first, two cross-lines of forces intersecting at a 90° angle and extending from the cornua down to about the mid-portion of the uterus, and

second, a series of minor lines of forces generated by the ring muscles encircling the cervical canal.

However, the uterine muscular structure is so dense that it can produce on stimulation an almost infinite variety of deformations of the uterine cavity. Taking into consideration the classic segments of the uterus, contractions can originate at three levels: at the level of the fundus in one or both cornua regions, at the mid-uterus, or at the isthmus which for practical and functional reasons will hereinafter be referred to as the area of the internal os.

Contractions starting in a circular fashion at the level of one of the cornua regions will cause distortion of the cavity with a resulting contralateral and diagonally downward displacement of any uterine content. A bilateral or in toto fundal contraction will produce with or without dilation of the uterine mid-portion or of the internal os area, a remarkable reduction in size of the volume of the uterine cavity placed just above and just below the tubal insertion with the displacement of any uterine content almost vertically downward. A separate, almost horizontal contraction at the mid-portion of the uterus will tend to deform the cavity in the shape of an hour-glass acting as an ejecting force against any

uterine content that offers resistance at that level. A contraction at the level of the internal os and, for that matter, at the level of the isthmus, can produce a dual effect: a restrictive distortion of the lower part of the uterus and, possibly simultaneously, a widening in the diameter of the internal os with a resultant downward ejection reaction.

In any event, the essential aspect to consider is that these various forms of contractions seem to originate chiefly at the level of the cornua and in the particularly sensitive area of the internal os. Considering further that the volumetric dimensions of the uterine cavity are far from being static but vary with the different phases of the menstrual cycle, we are led to believe that any intrauterine device primarily designed to exert pressure on the periphery of the uterine cavity or to resist compression from the uterine walls in order to resist expulsion is unphysiological. In addition, the foregoing suggests that the configuration of any such device should be such as to avoid stimulating the sensitive contraction triggering points of the cornua and of the internal os by evading contact with these areas as much as can practically be done.

In accordance with the invention, prevention of expulsion is accomplished in three separate ways: minimal contact of the device with uterine walls, compressibility of the device, and contralateral transmission and diffusion of uterine contraction forces.

The size of the device is not intended to cover the entire periphery of the uterine cavity, least of it the area of the internal os, where unwanted stimulations associated with pain and bleeding would necessarily be generated. Rather, the device is designed to fit in the middle section of the uterine cavity where fecundated ova tend to implant themselves most frequently and to stay away from the contraction triggering zones of the cornua, the area of the internal os and the extreme lateral ends of the uterine cavity.

To that effect, the curvature of the overhanging terminal portions of arms 50 and 51 is smooth and oriented inward, away from both cornua: the 24 millimeter width of the device along its major transverse axis T—T can be comfortably accommodated by most uterine cavities whose average width from cornu to cornu is in the extremity of 33 millimeters while the lowermost extremity of the device lies at least 10 millimeters substantially above the average level of the internal os.

In the event of minor uterine contractions, the device first acts like a cushioning spring and absorbs the initial shock from the uterine walls at its four lobate regions defined by the transverse axes T—T and M—M. Contraction forces may then cause the device to constrict and to adapt itself to the restricted dimensions of the uterine cavity, particularly in its uppermost transverse plane where the upper overhanging arcuate sections 52, 53 can simultaneously fold inward toward the open center of the device and overlap each other, depending upon the direction of the contractions (See FIG. 4).

As a whole, the structural design of the device is such that its original geometry can ultimately withstand a total size reduction in the order of 40 percent and spring back to its normal shape once uterine contractions cease. In accordance with the principles enunciated above, this device is primarily designed not to fight against the physiology of the uterus but to conform to it.

In case of strong contractions, as can happen during menstruation, the device utilizing uterine muscular forces will anchor itself against the walls of the uterine cavity in order to keep from being expelled. The anchoring effect is achieved through the cross-bar relationship of the force transmitting arms 50, 51 whereby the multi-directional forces exerted by the uterine walls against one or both sides of the device are transmitted and diffused contralaterally to the opposite sides.

Referring to FIGS. 4-7 inclusive to illustrate, a bilateral contraction exerted at the level of the fundus causes the upper arcuate sections 52 and 53 to be compressed inwardly with the forces being transmitted contralaterally to the lower diagonally opposed arcuate sections 54 and 55 respectively, as shown in FIG. 5. As a result, the lower arcuate sections 54 and 55 bulge outwardly resisting downward displacement toward the area of the internal os. Should the contractions occur at the mid-section of the uterus, the reverse occurs: sections 54 and 55 are compressed inwardly while their corresponding diagonally opposed arcuate sections 52 and 53 expand and anchor themselves in the upper part of the uterine cavity. Muscular forces generated by a partial contraction at the level of the fundus and acting unilaterally on the upper arcuate section 52 of arm 50 (See FIG. 6) are entirely directed toward lower arcuate section 54 of arm 50 causing the device to deform and tilt on its longitudinal axis S-S and to subsequently diffuse some of the forces to arm 51 whose upper arcuate section 53 tends to anchor itself up with an ascending motion. In the remote event that the uterine contractions force the device in an upside-down position as shown in FIG. 7, the structural design is such that the cross-bar mechanism can still operate effectively and prevent the device from engaging into the area of the internal os as well as from being expelled.

In order to increase the adherence and anchoring ability of the device against the uterine walls, minute knurl-forming protuberances such as hereinafter described can be formed in the outer lobate wall bearing surfaces of the four arcuate sections of the device.

On the basis of the foregoing, the importance of the interaction between the shape and the dimensions of the device can be appreciated: the spring-hinge joint 57 acts as a fulcrum permitting each force transmitting member to react independently whereby forces are diffused to the points of least resistance through the device. In turn, this spring-hinge mechanism constitutes an important complement to the cross-bar mechanism of the members, the effectiveness of which is directly related to the amount of built-in leverage available.

In order that the force transmitting arms 50 and 51 can develop sufficient torque to properly transmit and direct forces against the uterine walls, the dimensional and geometric parameters hereinabove described should be followed.

It is to be appreciated that the invention in its broad aspects is not limited to the figure 8 configuration herein illustrated and described, but the cross-bar mechanism and its advantages can be achieved in accordance with the invention by any other suitable configuration and orientation.

A preferred embodiment of the invention is illustrated in FIGS. 8-12. In the preferred form illustrated, the plastic body of the device comprises a substantially filamentary structural frame 62 describing the basic geometrical configuration illustrated in FIG. 3 and con-

stituting the areas of maximum cross-section of the device, and membrane means is integrally formed with the frame to provide substantial surface contact with the endometrium.

While the cross-section of the frame 62 varies according to the specific functions to be performed by its various segments, in general, the cross-section is preferably ovoid having a major axis in the plane of the device which is greatest at the overlapping sections of the members 50, 51.

Since the main function of the cross-bar mechanism of members 50 and 51 is to transmit contraction forces, the major cross-sectional axis of the frame is at its greatest in this region to provide structural strength. In order to keep the bulk of the device down as much as possible to avoid bleeding and discomfort, the frame in this region is also substantially flattened. (See FIGS. 9 and 13) Moving upwardly towards the terminal portions of upper arcuate sections 52, 53 where flexibility is required, the shape of the frame gradually takes on a more rounded cross-section and the major cross-sectional axis lying in the plane of the device undergoes a progressive diminution (See FIGS. 10 and 11). Similarly, the frame progressively regains an ovoidal section and undergoes a slight reduction in its major axis in the lower arcuate sections 54, 55 in a direction towards their terminal portions (See FIG. 12). At junctions 58 and 59 at the base of spring-hinge joint 57, the frame illustratively undergoes a major decrease in section to form zones of weakness so that the joint can be readily inverted prior to removal of the device as will hereinafter be described. The optimum cross-sectional shape and dimensions of the frame can be determined through use, as will also be the case with the geometrical parameters of the inverted-V joint 57.

An important feature of the invention resides in the provision of plastic inwardly deformable membranous regions which are strategically located so as to maximize contact with the endometrium without interfering with the dynamic mechanism and flexural ability of the device and without creating sources of pain and bleeding.

It has been empirically verified that the extent of surface contact with the endometrium is directly related to low pregnancy rate. At this state of the art, the exact contraceptive process involved is still a matter of conjecture but, on the basis of recent investigations, the most probable reason appears to be the accumulation of macrophages around the surfaces of the device. Thus, the greater the endometrial area covered, the larger the accumulation of macrophages and the lower the probability of conception. In order to maximize their effectiveness, this accumulation of macrophages should preferably be made to occur at the level of the fundus as well as in the mid-uterine area wherein implantation takes place most frequently.

To that end, the body of the device is preferably formed as illustrated in FIG. 8 with thin pliable plastic membrane-like regions operatively associated with the structural frame at the overhanging terminal portions of the upper arcuate sections 52 and 53, at their mid-sections in the region of overlap and at their lower arcuate sections 54 and 55.

Referring specifically to FIG. 8, a pair of elliptically shaped membranous regions 63 and 64 extend inwardly from the overhanging terminal portions of upper arcuate sections 52 and 53 where they are free to bend

downwardly toward the open center of the device in the event of fundal contractions. The membranous regions 63 and 64 are formed with two similarly located pin engaging openings 65 and 66 respectively which can be reinforced as shown. Openings 65 and 66 comprise the means in conjunction with ring 61 at the apex of joint 57 by which the device is releasably secured in a contracted state onto a suitable introducer implement for and during insertion into the uterus, all of which is hereinafter described.

FIGS. 10 and 10A illustrate two possible cross-sectional forms that membranous regions 63, 64 can take. In FIG. 10, the membrane structure is substantially uniform in cross-section from a narrowed neck 67 at its junction with frame 62 to its free edge. Alternatively, FIG. 10A shows a membrane section which gradually diminishes in thickness. In any event, the membrane regions should be formed so that they do not interfere with the ability of the upper arcuate arm sections to flex downwardly under fundal contractions.

Referring to FIG. 8 and FIG. 13, a second set of membranous areas 68 and 69 illustratively extend from the opposite sides of member 51 substantially above and below its region of overlap with the opposite member 50. Upper membrane area 68 extends from the inner surface of upper arcuate arm section 53 substantially at the transverse axis T—T and gradually increases in width as it approximates the curvature of the frame until it reaches the overlapping cross-bar region where it is at a maximum, and then tapers down until its point of termination on the outer surface of lower arcuate section 55 somewhat above transverse axis M1—M. Lower membrane area 69, which extends in the opposite direction to membrane area 68, has a similar tapered configuration as it follows the contour of the frame from the outer surface of upper arcuate section 53 to traverse substantially the entire inner extent of lower arcuate section 55 terminating close to spring-hinge joint 57.

FIGS. 9 and 13 illustrate one possible cross-sectional shape that the membrane areas 68 and 69 can take. As in FIG. 10A, the membrane structures are tapered from their junctions with the central frame member 62 with which they are integrally formed.

Still referring to FIG. 8, the crescent-shaped membranous area 70 is located at the inner surface of lower arcuate section 54. The lower terminal point of this membrane region is located similarly to that of the opposed membrane area 69, being in a substantially proximal relation to the spring-hinge joint 57, whereas its upper terminal point is located just about where the membranous area 69 crosses over arm 50 below the mid-point of intersection 56.

The cross-section of the membrane area 70 can, as in the case of membrane areas 63, 64 illustrated in FIGS. 10 and 10A, take on a uniform thickness from a narrowed neck 71 junction with frame member 62 as in FIG. 12, or can have a tapered configuration as in FIG. 12A. Again, the primary consideration is that the membranous structures are inwardly compressible upon themselves so as not to interfere with the ability of the plastic body to flex and conformably engage the uterine walls in response to contractions.

An alternate embodiment having a different membranous configuration is illustrated in FIG. 14. As shown therein, the crescent-shaped membranous re-

gion 70 is greater in area than its counterpart in FIG. 8, as is also true with the lower portion of membrane 69 extending from arcuate arm section 55. In addition, membrane region 70 extends upwardly substantially higher than in FIG. 8 to a point above the mid-point of intersection 56, the purpose being to increase the total surface area available for contact with the endometrium.

Due to their relative thinness and their locations, the membranous regions above described should not materially affect the flexibility of the plastic body or the ability of the frame to transmit contraction forces.

It should be evident that the foregoing description pertains to the most likely configuration of membranous regions, and variations therefrom to provide increased surface area are within the scope of the invention so long as the flexibility and contractability of the device are not materially affected.

In accordance with a further aspect of the invention, pluralities of substantially regularly distributed minute surface irregularities, or what can be called asperities 72, are preferably formed in the membrane surfaces front and back substantially across their entire extent. The asperities provide an extremely slight controlled degree of irritation over the surface of the endometrium which should result in an increased presence of phagocytic cells in the uterine cavity and a consequent further reduction in the incidence of pregnancy.

The key features of these asperities are twofold and equally important, comprising other for

First, they are minute in terms of height and width as their dimensions are not likely to exceed fractions of a millimeter and,

Second, their profile must avoid any sharp, rough or jagged edges which, no matter how small, could possibly cause bleeding.

As long as these two criteria are met, the shape of the asperities can assume any number of basic designs such as circles, ridges and grids, stars, crosses, mounds or peaks and the like, as shown in FIG. 19.

In accordance with a further feature of the invention, the outer lobate wall bearing surfaces of the four arcuate sections of the force transmitting members are preferably formed at and adjacent the transverse axes T—T and M—M with pluralities of low profile protuberances 73 to create knurled gripping surfaces.

The knurl-forming protuberances have a dual purpose: to increase the stability of the device and prevent its migration in the uterine cavity and to enhance the ability of the frame to anchor against the uterine walls in case of strong uterine contractions so that the device can better resist being pushed down toward the area of the internal os.

To illustrate and referring again to FIG. 5, under a bilateral contraction at the level of the fundus, the device will transmit forces contralaterally via its cross-bar mechanism causing the lower arcuate sections 54, 55 to expand outwardly against the uterine walls. Conversely, contractions at the level of the mid-uterus will compress arcuate segments 54 and 55 which, in turn, will cause the upper arcuate sections 52, 53 to expand outwardly and to anchor themselves in the upper portion of the cavity. To maximize their gripping ability, the knurl-forming protuberances are deployed at the four lateral lobate regions where contraction forces tend to exert most of their thrust.

The actuator contour of the protuberances 73 is not limited to any particular shape and, as is illustrated in FIGS. 15-18, they can be embodied in any number of suitable shapes. For example, rows of thin pliable fins of rounded contour extending from the frame 62 a few millimeters as shown in FIGS. 11, 12, and 12A can be employed, as can a series of saw tooth notches or indentations in the frame itself as in FIGS. 16 and 18. Whatever their precise shape, it is important that the protuberances 73 define a low profile having a substantially non-jagged edge to avoid injury without sacrificing gripping ability.

Recent clinical investigations of the use of metallic copper as an adjunct to intrauterine contraceptive devices have yielded promising results, although it is too early to pass any definite judgement on the long term effects of copper on the endometrium.

In the event that such an adjunct is found to be desirable, a device in accordance with the present invention would be wholly compatible with the use of copper or any other metal, compound or bicomponent able to duplicate the anti-fertility mechanism of copper which has yet to be precisely determined. Should the ionic or electrical properties of copper be largely responsible for such mechanism, other metals could conceivably include silver, gold or any other metal of low electrical resistivity.

The membrane surfaces of the device would provide a convenient carrier for the metals which, if in wire form, can readily be stitched into the thin plastic membranes or, if in ultra-thin plate form, can be tacked onto both surfaces of the membrane structure and interconnected. Still, among other possibilities, the entire device or parts thereof could be coated with a metallic film which would not affect its flexibility.

The device can be constructed from a wide variety of synthetic polymer resins such as polyethylene, polypropylene, nylon, polyester or teflon among others, or any other suitable resilient material proven to be non-allergenic and inert to human body tissue. Preferably, the material should have good molding properties and be suitable for injection molding. Although one single polymeric component is seen as preferable for the device, a bicomponent can also be used such as an inner core of polyester coated with teflon or silicon or even an inner frame of metal such as stainless steel or a high molecular memory alloy such as nitinol covered with a polymer. In any event, since the position of the device in the uterine cavity may in some cases have to be checked, any of the well-known radiopaque substances such as a barium sulphate can be added to the resin.

As indicated, the device can be made by molding or by any other suitable forming process.

Referring to FIGS. 20-23, removal of the device from the uterine cavity is easily accomplished by the physician and with a minimum of discomfort for the user, the key procedural step consisting of deactuating the spring-hinge joint 57. Referring specifically to FIG. 20, the physician first pulls monofilament 60 connected to the apex of V joint 57 which should be adapted to be easily externally accessible through the cervical canal. With the lower arcuate sections 54 and 55 of the force transmitting members pressing against the walls of the uterine cavity, a sufficient downward pull causes the lower arcuate sections to spread apart and the expansion V joint 57 to pivot downwardly about its zones of weakness 58 and 59. As soon as the V joint is in-

verted, the source of spring energy to the force transmitting members 50 and 51 is deactuated and the force transmitting members offer a minimum resistance to further pulling.

Channelled by the narrowing walls of the uterine cavity, further downward force exerted on the filament causes the joint 57 to elongate (FIG. 21) and, in turn, forces the collapse of the entire bottom section of the device whereby the lower arcuate arm sections 54, 55 are forced to assume a parallel arrangement with respect to longitudinal axis S-S. The elongated shape and rounded contour taken by the V joint is quite important in that it progressively opens the cervical canal and dilates it to facilitate the outward passage of the device.

In the following FIGS. 22 and 23, the force transmitting members 50, 51 along their entire extent are shown reduced to a fully parallel arrangement, thus presenting a minimum of surface resistance to their introduction in and passage through the cervical canal.

As has already been stated above, the procedure and means for inserting the contraceptive device into the uterus must insure against perforation of the uterine wall. In addition, the introduction of the device should be a painless procedure and one which is easy and relatively fast to accomplish even by paramedical personnel after only a brief period of orientation and training. In accordance with a further aspect of the invention, an introducer implement is provided which meets these requirements and which constitutes a major departure from the prevalently used cannulae or tubes, although the latter can be used if so desired.

Referring to FIGS. 24 and 25, the introducer comprises a cylindrical shaft 74 of biologically inert and relatively stiff material having a curvilinear profile with a handle 75 formed in one end and means comprising a rectilinear shaft section 76 formed in the other end of releasably holding a contraceptive device 77 of the type herein illustrated and described in proper orientation and contracted condition for passage into the uterine cavity.

The handle illustratively comprises a flattened section of the shaft at the end preferably having a knurled surface 78 to facilitate gripping. As illustrated in FIG. 26, the handle is designed to be held by the user between thumb and index finger and can be suitably contoured with a widened area at its junction with the bowed portion of the shaft, as shown, to maximize surface contact with the thumb to facilitate control and manipulation of the implement during insertion.

An important feature of the introducer resides in its curvilinear profile illustrated in FIGS. 24 and 26. As shown, the shaft 74 describes a curve which angles downwardly from its end having the handle 75 to an intermediate point on the shaft where it reverses its direction of curvature. The effect created by this double reverse curvature of the shaft is that the rectilinear section of the shaft 76 holding the contraceptive device extends in axially offset substantially parallel relation with the handle 75 of the implement.

As can best be seen in FIG. 26, the curvature of the shaft in the region of the device holding section 76 conforms to the general angulation of the longitudinal section of the uterine cavity when the patient is properly positioned on the examining table, while the reverse curvature at the opposite end near the handle 75 should be such as to prevent the fingers from interfer-

ing with the physician's line of vision and also to permit the forward end of the introducer to be lowered in a way that the obstacle of the perineum is overcome.

Referring again to FIG. 24, the angle β formed between the axis of the rectilinear section 76 of the shaft and the tangent to the shaft drawn from the handle extremity at the opposite end should be substantially similar to the angle θ formed between the horizontal and the tangent to the shaft drawn from the forward extremity of the shaft. Both angles should preferably range between about 15° and 25°, primarily to conform to the angulation of the uterine cavity.

Both angles being equal or substantially equal permits the forward forces exerted on the shaft at the handle end by the user to be transmitted on a parallel plane to the forward end of the shaft holding the device with little or no loss of force. This provides greater sensitivity to the hand and better judgement as to the amount of force to be applied, which is particularly important in cases of unrecognized retroflexed uteri assuring greater safety against perforation.

Another important feature of the invention assuring against perforation of the fundus are the groups of thin annular bands 79, 80 and 81 formed on the shaft which provide a means for gauging the depth reached by the forward end of the introducer in the uterus. The three reference levels can for illustration be spaced one centimeter apart representing the 5, 6 and 7 centimeter marks measured from the tip of the forward end 76.

As can be seen, the first or 5 centimeter reference level 79 is represented by a single band, the second or 6 centimeter level 80 by two spaced apart bands and the third or 7 centimeter level 81 by an arrangement of three bands. These illustrative dimensions have been empirically determined and should cover the full range of uterine depths from the external cervical os to the fundus. The sequential groups of bands where each succeeding group has an additional band is judged preferable over numbers imprinted on the introducer which are sometimes used but difficult to decipher during insertion of the device.

Preferably, the bands are in a color providing a sharp contrast with the color of the shaft and readily distinguishable from the color environment of the vaginal walls. By way of example, bright green colored bands on a white introducer shaft should provide the contrast desired.

A final safeguard against perforation of the fundus are the flanges 82 preferably formed on the shaft 8 centimeters from the tip of the forward end 76. Flanges 82 prevent the introducer from being pushed into the uterus any deeper, although a uterine cavity of such depth is rather rare.

The introducer shaft 74 is preferably circular in cross-section intermediate its ends and is formed with segments 83 and 84 of different diameter for reasons of structural strength. Segment 83 which extends from the rectilinear section of the shaft 76 to the flanges 82 can illustratively have a diameter in the order of 4 millimeters. Segment 84, which illustratively can be 5 millimeters in diameter, extends from flanges 82 to the junction with handle 75. This stepped increase in diameter is intended to provide sufficient strength in the major portion of the shaft to withstand the force necessary for the introduction of the device and at the same time to provide a certain degree of desired flexibility in the similar portion of the shaft in the region to be inserted.

Illustrative of suitable overall shaft dimensions are the following:

$x \approx 1.7$ cm.

$y \approx 7.5$ cm.

$z \approx 26$ cm.

In accordance with the invention, reference being had to FIGS. 29-31 in particular, the means for releasably holding the contraceptive device 77 comprises a cavity formed in the rectilinear shaft section 76 having a substantially flat back support wall 85, and two end walls 86 and 87, the cavity being open on the sides. As can readily be seen, the length and profile of the cavity are contoured to conform to the shape of the device 77 when held in contracted condition for insertion, the back wall having a recessed area 88 substantially midway between end walls 86, 87 to accommodate the double thickness of the overlapped force transmitting arms 50, 51 to avoid any potentially harmful protrusion.

In accordance with the invention, locating pin means operatively associated with the cavity is provided for cooperating with the pin engaging openings formed in the device 77 to releasably position the device for insertion. In the illustrative embodiment of FIGS. 29-31, two locating pins 89 and 90 depend substantially perpendicularly from back wall 85 into the cavity. Pins 89 and 90 are situated on the axis of the shaft and are spaced apart, as shown, to cooperate with the pin engaging openings 65 and 66 of the upper arms of the device 77 and with the pin engaging opening in ring 61 at the apex of joint 57 in the lower portion of the device.

As is clearly shown in FIG. 31, the device 77 is releasably mounted on the introducer in a contracted condition with its normally movable force transmitting members 59 and 51 held in fixed relation and its longitudinal axis S—S parallel to the axis of the shaft 74. The rear locating pin 89 is disposed within and extends through the ring 61 thereby releasably engaging the lower end of the device. The upper end of the device is similarly releasably engaged by forward locating pin 90 which is disposed within and extends through the openings formed in the upper membrane regions 63 and 64, the upper arcuate sections of arms 50 and 51 being contracted so that the membrane regions 63 and 64 are overlapped with their pin engaging openings superimposed.

Preferably, the locating pins 89 and 90 are axially spaced apart so that the device when thus engaged is also compressed along its longitudinal axis S—S, the overall length of the compressed device being reduced by a few millimeters from its unstressed dimension. As will hereinafter become apparent, this constitutes an important safety factor against fundal perforation.

In the embodiment of FIGS. 29-31, the locating pins 89 and 90 are designed to have a force fit engagement with their cooperating pin engaging openings in the device 77. As can be seen, each pin is shaped with a rounded enlarged terminus and a tapered stem.

An additional feature of the introducer is the bulbous searching head 91 formed in the forward or leading end of the shaft. Extending out front of the leading edges of the device 77 by a few millimeters, it performs during insertion the triple function of dilating the narrow lumen of the cervical canal, of deflecting some of the stress exerted onto the leading edges of the device and, most importantly, of serving as a guide to the physician

in the initial portion of the cervical canal which is lined with the glandular cavities of the arbor vitae (See FIG. 26). If the forward tip of the introducer were too sharp, one of these cavities could be mistaken for the cervical canal leading to possible uterine perforation.

Illustrated in FIGS. 32-34 is an introducer having an alternate configuration in accordance with the invention, FIG. 45 illustrating alternate membrane opening locations suitable for use therewith. As shown, the introducer of FIG. 32 differs from that of FIG. 29 in two respects.

In order to minimize the length of the implement, the searching head 92 while retaining a bulbous configuration is modified so that the forward end of the contracted contraceptive device 77 is exposed, the cavity formed in the shaft 74 having only a rear end wall 87 and no front end wall. To compensate for the increased stress exerted on the leading edges of the arcuate arms of the device, the pin engaging openings 65 and 66 in the membrane regions 63 and 64 are located at the junctions of the membranes with the frame 62 as shown in FIG. 45. Engagement with the locating pin 93, illustratively having a modified shape from the corresponding pin 90 of FIG. 29, thus occurs at the very edge of the structural frame 62 imparting greater strength and resistance to distortion than would be the case if the opening locations were as shown in FIG. 31.

It should, of course, be understood that the locating pins can have a variety of force fit shapes such as shown in FIGS. 35 and 36, and can have a hook or clamp configuration such as shown in FIG. 37 and embodied in the introducer of FIGS. 38-40. The introducer shown in FIGS. 38-40, adapted for use with a membrane opening configuration such as in FIG. 45, constitutes still another possible variation to that of FIGS. 29-31 within the scope of the invention.

As best illustrated in FIG. 38, there is provided a bulbous searching head 94 having a forward contour substantially similar to that of head 91 of FIG. 29. As contrasted from the embodiment of FIG. 32, the cavity formed in the linear section 76 of the shaft of FIG. 38 has both a rear end wall 87 and a forward end wall 95 formed by the searching head 94. The locating pin means for releasably engaging the contraceptive device comprises a pair of mirror-image hook shaped rear locating pins 96 and 97 cooperating to form a spring-like two prong clamp, and a forward hook shaped locating pin 98 similarly cooperating with the searching head 94 which can be seen to have a hook-like configuration as well.

Yet another introducer embodying the principles of the invention is illustrated in FIGS. 41-44. This type of introducer differs markedly from the other three embodiments herein disclosed. As illustrated, the linear section 76 is formed with a pair of cavities on opposite sides of the shaft. The lower cavity having a substantially flat rear support wall 99 and two end walls 100 and 101 differs from the similarly located cavities of the other illustrative embodiments in that it is shallower and does not have a recessed area designated 88 in FIGS. 29, 32 and 38. The upper cavity, which is substantially of the same depth but substantially shorter in length than the lower cavity, has a flat rear wall 102 and two end walls 103 and 104.

The lower cavity has locating pin means 105 and 106 depending from rear wall 99, pin means 106 comprising three locating pins in the nature of a triple prong

clamp, as shown. The upper cavity has a single locating pin 107 substantially coaxially aligned with pin 105 of the lower cavity. As can be seen, the searching head 108 has a bulbous contour similar to the contour of head 91 of the embodiment of FIG. 29.

The contraceptive device 77 is affixed to the introducer in a manner different from that previously described. The device is mounted with its force transmitting members 50 and 51 disposed in different planes, member 50 being disposed in the lower cavity and engaged by locating pin 105 and member 51 being bent around the shaft and disposed in the upper cavity engaging locating pin 107. The ring 61 located at the lower axial end of the device is disposed in the lower cavity in the same plane as member 50 and is held by pin means 106.

It is preferred that the device and introducer be sold fully assembled and prepackaged in a sterilized condition. Referring to FIG. 46, the package can comprise a transparent heat-sealable plastic casing 109 of rectangular configuration and having a removable cardboard base 110. Illustratively, the base is provided with two rows of perforations running along its entire length. One end of the base can be made to extend beyond the edge of the enclosure to provide a pull tab. With such a construction, the base can be readily removed providing access to the contents.

Although the foregoing implies that the device is mounted in its contracted condition on the introducer ready for insertion, alternatively the device may come attached only via its lower ring 61 with the upper arcuate arms in their relaxed extended position. This may be desirable in the event that a synthetic resin of low resilience and weak molecular memory is used to injection-mold the device. In such case, the physician need only bend the upper arcuate arm sections of the device so that their membrane openings superimpose and then snap them onto the forward locating pin of the introducer. Of course, sterile gloves will be used during assembly.

Insertion of the device is relatively simple. Referring back to FIG. 26, the bulbous forward end of the introducer shaft is gently inserted into the cervical os with the device disposed downwardly and is slowly advanced through the cervical canal until a definite snap is felt through the introducer shaft. This snap occurs shortly after the device, constricted during passage through the narrow cervical canal, has passed through the constrictive ring formed by the internal os where it expands back to its normal contracted condition as mounted on the introducer. At this point, the device is ready to be released.

It should be apparent that by virtue of its pliability the device upon entering the narrow cervical canal can be simultaneously squeezed inwardly and elongated reducing its resistance and permitting easy insertion. In the event that any partially inserted device has to be withdrawn, the locating pins are such that the device will remain attached to the introducer and, therefore, safely retrievable even though resistance is met by the lower edges of the device.

The release technique can best be understood by reference to FIGS. 27 and 28. In its normal state, the uterine cavity has the form of a flat, collapsed envelope. When an object is introduced therein, the muscular layers will "give" but will nevertheless stay in close contact with the object due to their tight elasticity.

Thus, the uterine walls exert a certain amount of pressure onto the surface of the device shown ready for release in FIG. 27 preventing it from being rotated about its longitudinal axis which extends perpendicularly to the plane of FIG. 27.

To release the device, the introducer is rotated until the force exerted by the uterine walls on the device causes the locating pins to disengage their cooperating pin engaging openings. Thus disengaged, the spring-hinge joint 57 causes the force transmitting members of the device to spring back to their normal extended configuration represented in FIG. 28. As shown in FIG. 28, the device is held in close contact by the surfaces of the endometrium 112 without contacting the extreme lateral ends of the cavity.

The relative position of the searching head 91 with respect to the fundus at the point of release is illustrated in FIG. 26. Since the overall length of the device is 25 millimeters for parous (20 millimeters for nulliparous), the total extent of the introducer engaged in the uterus will very rarely exceed 60 millimeters in parous and 55 millimeters in nulli-parous women. These depth levels are at least 10 millimeters below the normal level of the fundus so that there is no fundal contact during insertion. This represents a major safety factor assuring in conjunction with the bulbous searching head and depth control bands on the shaft that fundal perforation will not occur.

The relationships between the various physical features of the device embodying the present invention and the four major uterine physiological effects mentioned earlier can be summarized in tabular form where a plus sign indicates an increase as a function of a physical factor, a minus sign a decrease and a zero, no significant change.

Physical Features	Physiological Effects			
	Pain	Bleeding	Expulsion	Pregnancy
Size	-	-	-	-
Shape	-	-	-	0
Membranes	0	0	0	-
Asperities	0	0	0	0
Contralateral Force Distrib. (Cross-bar Mechanism)	-	-	-	-
Knurled Lobate Surfaces	0	0	-	-

Thus, based on theoretical considerations, reduction in pregnancy rate in the present device is seen to be primarily due to the irritation generated by the membrane surfaces and their minute asperities while the size of the device and the knurled lobate regions can be regarded as ancillary factors since both features essentially contribute to keeping the device in the strategic implantation ground of the middle portion of the uterine cavity. And whereas the size, shape, cross-bar mechanism and lobate regions of the device should result in a measurably lower expulsion rate than has previously been attainable, these physical elements are also seen for the most part to reduce pain and bleeding, or at worst to cause no significant change, since they are designed to conform to the uterine physiology.

What is claimed is:

1. An intrauterine contraceptive device comprising a substantially membranous readily deformable and inwardly contractible but resilient planar body having an outer substantially lobate contour including upper and lower pairs of resilient, structural uterine wall bearing

lobes laterally disposed in substantial mirror-image relation with respect to a common symmetrical axis extending longitudinally therebetween when in unstressed condition, said planar body further comprising a pair of diagonally extending crossed structural force transmitting members operatively interconnecting in direct force transmitting relation diagonally opposed lobes of said upper and lower lobe pairs whereby forces exerted on said lobes by said uterine walls are contralaterally transmitted and diffused through said body and inward compression of a lobate region by uterine wall forces being thereon causes the diagonally associated lobate region to exert increased outward pressure on said uterine wall.

2. An intrauterine contraceptive device capable of being readily compressed for passage into the uterine cavity and, when released, of expanding to conformably engage the uterine walls to resist expulsion, said device comprising a substantially planar, readily deformable, pliable but resilient body of a resilient substantially filamentary frame having an outer substantially lobate contour including upper and lower pairs of resilient, structural uterine wall bearing lobes laterally, outwardly disposed in mirror-image relation defining a common longitudinal axis of symmetry when in unstressed condition, said device being adapted by location within said uterine cavity such that said axis is substantially aligned with the cervical canal, said filamentary frame of said body also having a pair of resilient, structural force transmitting members diagonally extending in crossed relation across said axis operatively interconnecting in force transmitting relation diagonally opposed lobes of said upper and lower pairs, said force transmitting members being independently freely rotationally and translationally movable relative to each other, said upper and lower structural lobes and said pair of structural force transmitting members defining a configuration having two free ends and being continuously traceable between said two ends, whereby forces exerted on said lobes by said uterine walls are contralaterally transmitted and diffused through said body and inward compression of any one of said four lobate regions by uterine wall forces bearing thereon causes the diagonally associated lobate region to exert increased outward pressure on said uterine wall, said resilient body further comprising membrane means operatively associated with said frame providing substantial surface area for contact with the endometrium when said device is positioned within said uterine cavity.

3. A device as defined in claim 2, said membrane means forming membranous surfaces having asperities substantially regularly distributed thereon.

4. An interuterine contraceptive device capable of being readily compressed for passage into the uterine cavity and, when released, of expanding to conformably engage the uterine walls to resist expulsion, said device comprising a substantially planar readily deformable pliable but resilient body having an outer substantially lobate contour including upper and lower pairs of resilient, structural uterine wall bearing lobes laterally, outwardly disposed in mirror-image relation defining a common longitudinal axis of symmetry when in unstressed condition, said device being adapted for location within said uterine cavity such that said axis is substantially aligned with the cervical canal, said resilient body further comprising a pair of resilient, struc-

tural force transmitting members diagonally extending in crossed relation across said axis operatively interconnecting in force transmitting relation diagonally opposed lobes of said upper and lower pairs, said force transmitting members being independently freely rotationally and translationally movable relative to each other, said upper and lower structural lobes and said pairs of structural force transmitting members defining a configuration having two free ends and being continuously traceable between said two ends, whereby forces exerted on said lobes by said uterine walls are contralaterally transmitted and diffused through said body and inward compression of any one of said four lobate regions by uterine wall forces bearing thereon causes the diagonally associated lobate region to exert increased outward pressure on said uterine wall, and knurl forming means disposed on the outer wall bearing surfaces of said lobes for gripping the uterine wall to provide stability and resistance to downward displacement of the device.

5. An intrauterine contraceptive device capable of being readily compressed for passage into the uterine cavity and, when released, of expanding to conformably engage the uterine walls to resist expulsion, and thereafter of being readily contracted for removal, said device comprising two substantially similar resilient S-shaped force transmitting members having respective upper and lower arcuate sections, said members in unstressed conditions being arranged in substantially planar overlapped mirror-image relation with their said upper and lower arcuate sections outwardly disposed with respect to a symmetrical axis extending longitudinally therebetween, said device being adapted for location within said uterine cavity with said axis substantially aligned with the cervical canal and said upper and lower arcuate sections forming lateral uterine wall bearing lobes, said device further comprising spring-hinge means normally resiliently joining the terminal portions of said lower arcuate sections and manually operable withdrawal means operatively associated therewith for deactuating the resilient forces of said hinge means to permit said force transmitting members to be non-resiliently readily contracted towards said longitudinal axis for removal of the device, said upper arcuate sections of said members terminating in free ends, and said spring-hinge means comprising a substantially filamentary extension of said force transmitting members forming an inverted-V expansion joint having an apex substantially coincident with said longitudinal axis.

6. A device as defined in claim 5, said withdrawal means comprising zones of weakness formed in said force transmitting members at their junctions with the base of said inverted-V joint and means for inverting said joint, said means comprising filament means connected to said apex of said joint and adapted to be readily externally accessible for exerting a downward force thereon.

7. An intrauterine contraceptive device capable of being readily compressed for passage into the uterine cavity and, when released, of expanding to conformably engage the uterine walls to resist expulsion, and thereafter of being readily contracted for removal, said device comprising two substantially similar resilient S-shaped force transmitting members having respective upper and lower arcuate sections, said members in unstressed condition being arranged in substantially planar overlapped mirror-image relation with their said upper and lower arcuate sections outwardly disposed with respect to a symmetrical axis extending longitudinally therebetween, said device being adapted for location within said uterine cavity with said axis substantially aligned with the cervical canal and said upper and lower arcuate sections forming lateral uterine wall bearing lobes, said device further comprising spring-hinge means normally resiliently joining the terminal portions of said lower arcuate sections and manually operable withdrawal means operatively associated therewith for deactuating the resilient forces of said hinge means to permit said force transmitting members to be non-resiliently readily contracted towards said longitudinal axis for removal of the device, said upper arcuate sections of said members terminating in free ends, and knurl forming means disposed on the outer wall lobe bearing surfaces of said arcuate sections of said force transmitting members for gripping the uterine wall to provide stability and resistance to downward displacement of the device.

nar overlapped mirror-image relation with their said upper and lower arcuate sections outwardly disposed with respect to a symmetrical axis extending longitudinally therebetween, said device being adapted for location within said uterine cavity with said axis substantially aligned with the cervical canal and said upper and lower arcuate sections forming lateral uterine wall bearing lobes, said device further comprising spring-hinge means normally resiliently joining the terminal portions of said lower arcuate sections and manually operable withdrawal means operatively associated therewith for deactuating the resilient forces of said hinge means to permit said force transmitting members to be non-resiliently readily contracted towards said longitudinal axis for removal of the device, aid upper arcuate sections of said members terminating in free ends, and membrane means secured to said force transmitting members providing substantial surface area for frictional contact with the endometrium when said device is positioned within said uterine cavity.

8. A device as defined in claim 7, said membrane means forming membranous surfaces having asperities substantially regularly distributed thereon.

9. A device as defined in claim 7, said membrane means comprising a membranous region secured to the lower terminal portion of each of said upper arcuate sections of said force transmitting members.

10. A device as defined in claim 7, said membrane means comprising a membranous region operatively associated with said force transmitting members at their area of overlap.

11. A device as defined in claim 7, said membrane means comprising a membranous region secured to each of said lower arcuate sections of said force transmitting members.

12. An intrauterine contraceptive device capable of being readily compressed for passage into the uterine cavity and, when released, of expanding to conformably engage the uterine walls to resist expulsion, and thereafter of being readily contracted for removal, said device comprising two substantially similar resilient S-shaped force transmitting members having respective upper and lower arcuate sections, said members in unstressed condition being arranged in substantially planar overlapped mirror-image relation with their said upper and lower arcuate sections outwardly disposed with respect to a symmetrical axis extending longitudinally therebetween, said device being adapted for location within said uterine cavity with said axis substantially aligned with the cervical canal and said upper and lower arcuate sections forming lateral uterine wall bearing lobes, said device further comprising spring-hinge means normally resiliently joining the terminal portions of said lower arcuate sections and manually operable withdrawal means operatively associated therewith for deactuating the resilient forces of said hinge means to permit said force transmitting members to be non-resiliently readily contracted towards said longitudinal axis for removal of the device, said upper arcuate sections of said members terminating in free ends, and knurl forming means disposed on the outer wall lobe bearing surfaces of said arcuate sections of said force transmitting members for gripping the uterine wall to provide stability and resistance to downward displacement of the device.

13. An intrauterine contraceptive device capable of being readily compressed for passage into the uterine

cavity and, when released, of expanding to conformably engage the uterine walls to resist expulsion, and thereafter of being readily contracted for removal, said device comprising two substantially similar resilient S-shaped force transmitting members having respective upper and lower arcuate sections, said members in unstressed condition being arranged in substantially planar overlapped mirror-image relation with their upper and lower arcuate sections outwardly disposed with respect to a symmetrical axis extending longitudinally therebetween and wherein the overall unstressed transverse extent of said device between said pair of upper arcuate sections is substantially greater than between said pair of lower arcuate sections, and said force transmitting members overlap one another substantially mid-way along said longitudinal axis and extend thereat in relation to one another at an angle within the range of about 0° to 30°, said device being adapted for location within said uterine cavity with said axis substantially aligned with the cervical canal and said upper and lower arcuate sections forming lateral uterine wall bearing lobes, said device further comprising spring-hinge means normally resiliently joining the terminal portions of said lower arcuate sections and manually operable withdrawal means operatively associated therewith for deactuating the resilient forces of said hinge means to permit said force transmitting members to be non-resiliently readily contracted towards said longitudinal axis for removal of the device, said upper arcuate sections of said members terminating in free ends, said device having an overall dimension such that when in position within the uterus, its lower extremity is at a level substantially above the average level of the internal os and its lateral extremities are substantially spaced apart from the extreme lateral ends of said uterine cavity.

14. In an intrauterine contraceptive device having a longitudinal axis substantially aligned with the cervical canal when said device is properly positioned in the uterus and having two substantially filamentary arms normally substantially symmetrically disposed with respect to said axis in movable spaced apart relation and extending upwardly away from the cervical canal, spring-hinge means joining the terminal portions of said arms nearest said cervical canal when said device is properly positioned in the uterus resiliently resisting inward contraction of said arms towards said axis, and withdrawal means operatively associated with said

spring-hinge means for deactuating the resilient forces of said hinge means to permit said arms to be non-resiliently readily inwardly contracted towards said longitudinal axis for removal of the device, said spring-hinge means comprising a substantially filamentary extension of said arms forming an inverted-V expansion joint having an apex substantially coincident with said longitudinal axis and displaced with respect to the lowermost extremities of said arms upwardly away from said cervical canal when said device is properly positioned in the uterus, said withdrawal means comprising zones of weakness formed in said arms at their junctions with the base of said inverted-V joint and filament means affixed to said apex for inverting said joint upon exertion of a downward force thereon, said filament means being adapted to be readily externally accessible through the cervical canal.

15. In a device as defined in claim 14, said inverted-V joint having a substantially rounded contour at its apex serving as a means for dilating the cervical canal during removal of said device.

16. In an intrauterine contraceptive device having a longitudinal axis substantially aligned with the cervical canal when said device is properly positioned in the uterus and having two substantially filamentary arms normally substantially symmetrically disposed with respect to said axis in movable spaced apart relation and extending upwardly away from the cervical canal, spring-hinge means joining the terminal portions of said arms nearest said cervical canal when said device is properly positioned in the uterus resiliently resisting inward contraction of said arms towards said axis, said spring-hinge means comprising a filamentary extension of said arms forming a reversible inverted-V expansion joint having an apex substantially coincident with said longitudinal axis and displaced with respect to the lowermost extremities of said arms upwardly away from said cervical canal when said device is properly positioned in the uterus, means accessible externally of the uterus for inverting said inverted-V joint so that its said apex is substantially coincident with said longitudinal axis and displaced with respect to the lowermost extremities of said arms downwardly towards said cervical canal, said joint having a substantially rounder contour at its said apex when inverted whereby said joint serves to dilate the cervical canal during removal of said device.

* * * * *

50

55

60

65

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,789,838

Dated February 5, 1974

Inventor(s) Erick-Pierre Fournier and Alberto Lomeo

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

In the Claims

Column 19, line 65, after "body" and before "having" insert -- capable of insertion into the uterine cavity and --; line 66 after "contour" and before "including" insert -- for conformably engaging the uterine walls to resist expulsion --.

Column 20, line 4, after "condition," and before "said" insert -- the upper pair of said lobes comprising gently rounded inwardly turned filamentary arms having free ends inwardly directed towards said longitudinal axis,--; line 11, after "a" and before "lobate" insert -- lower --; line 12, "being" should be -- bearing --; line 13, after "associated" and before "lobate" insert -- upper --; line 14, after "on said uterine wall " insert -- in the upper portion of the uterine cavity while keeping the free end of said upper lobe away from the opening of the fallopian tube. --; line 54, "intera uterine" should be -- intrauterine --.

Column 21, line 8, "pairs" should be -- pair --; line 29, "conditions" should be -- condition --.

Column 22, line 15, "aid" should be -- said --.

Column 24, line 19, after "its" and before "apex" insert -- said --.

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,789,838 Dated February 5, 1974

Inventor(s) Erick-Pierre Fournier and Alberto Lomeo

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Cover Page

Abstract, line 7, "so" should be -- os --.

In the Specification

Column 7, line 45, "cervial" should be -- cervical --.

Column 8, line 45, "extremity" should be -- order --.

Column 9, line 29, "aruate" should be -- arcuate --.

Column 12, line 30, delete "comprising other for".

Column 13, line 1, "actuator" should be -- actual --.

Column 14, line 36, "comprisin" should be -- comprising --;
line 37, "othe end of" should be -- other end for --.

Column 15, line 31, "leve" should be -- level --; line 67, "th"
should be -- the --.

Column 16, line 33, "devic" should be -- device --.

Signed and sealed this 9th day of July 1974.

(SEAL)
Attest:

McCOY M. GIBSON, JR.
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents