

Nov. 12, 1968

M. E. CHAFT
INTRA-UTERINE CONTRACEPTIVE DEVICE AND
DEVICE FOR INSERTING THE SAME

3,410,265

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2 Sheets-Sheet 1

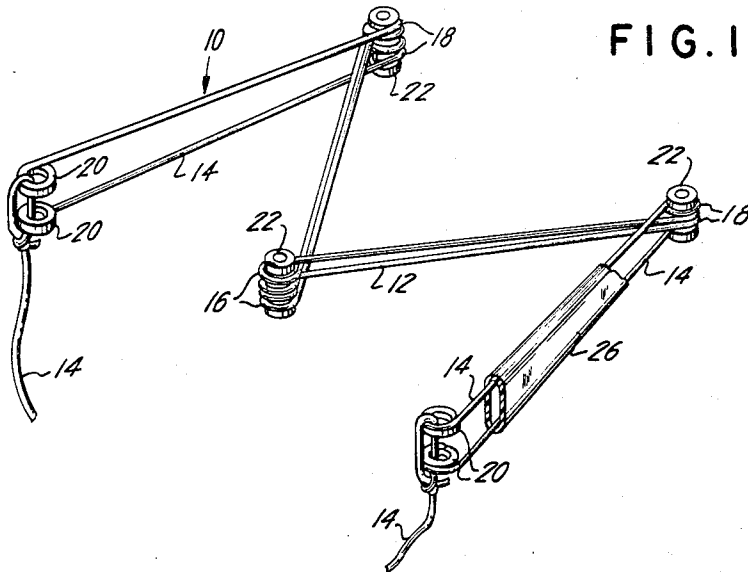


FIG. 1

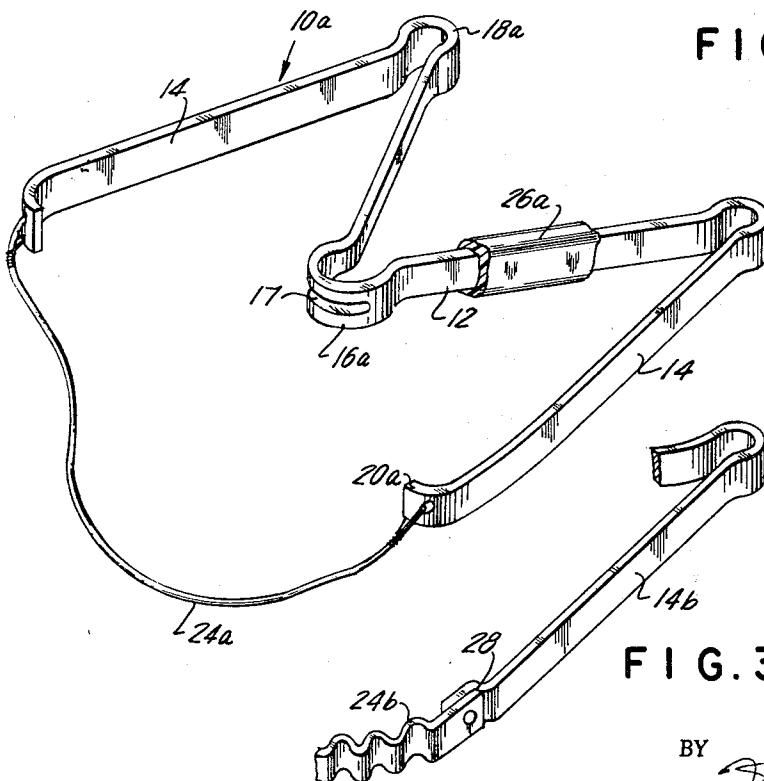


FIG. 2

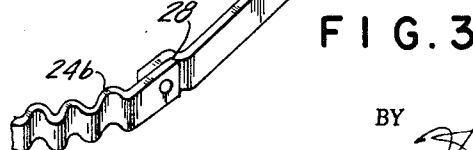


FIG. 3

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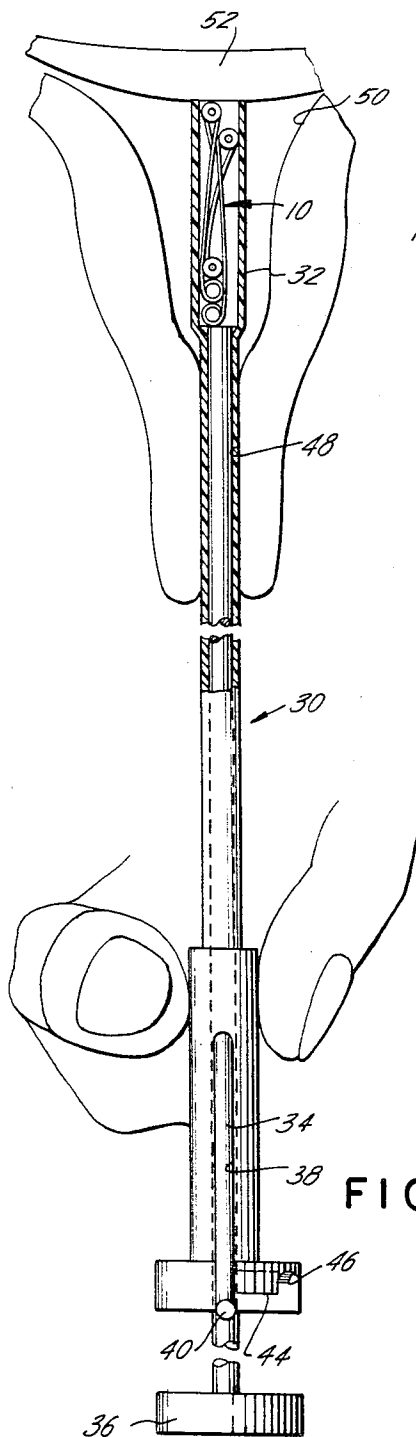


FIG. 4

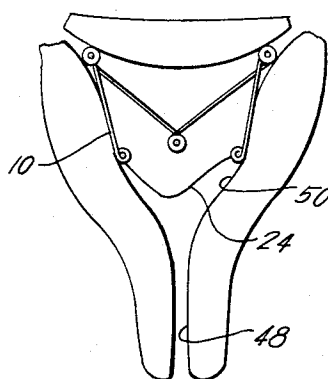


FIG. 5

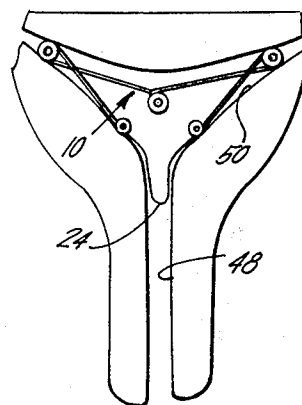


FIG. 6

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3,410,265

INTRA-UTERINE CONTRACEPTIVE DEVICE AND DEVICE FOR INSERTING THE SAME

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ABSTRACT OF THE DISCLOSURE

An intra-uterine contraceptive device consisting of a plurality of substantially straight elements hingedly interconnected at their ends by flexibly resilient joints, said elements normally disposed in divergent relation to one another, in accordion arrangement, and compressible at their joints, to be disposed in substantially parallel and substantially contacting relation; and an insertion device consisting of a tube and plunger with one of the ends of the tube adapted to receive the device when in compressed state.

The present invention relates to an intra-uterine contraceptive device and, more particularly, to such device which is wholly disposed within the uterine cavity, and to the device by which it may be inserted into the uterine cavity.

Intra-uterine contraceptive devices that are used by disposing them wholly within the uterine cavity have been known for some time, in various forms. These forms include multi-strand rings or wads of silkworm gut, multi-strand rings of gold or silver wire, rigid rings of stainless steel, and compressible rings of stainless steel wire coil. More recently, devices have been introduced which are formed of synthetic plastic material arranged in spirals or in multiple re-entrantly connected convolutions. All of the foregoing, heretofore known forms of intra-uterine contraceptive devices, while used for their purposes to varying degrees have presented certain shortcomings and disadvantages. Thus, the bulkier and more rigid of the devices required extensive dilation of the cervical passage for their insertion into the uterine, which, even when performed with anaesthesia, had a substantial incidence of injury to the cervical passage and prolonged pain and discomfort after insertion. Some of such devices were not only difficult to insert, but difficult to remove when required. Some intra-uterine devices have been known to injure the walls of the uterine cavity.

The prior intra-uterine contraceptive devices, which were of pliable character, were also prone to be discharged from the uterine cavity by reason of the physiologic contractile action of the uterine musculature, frequently without even the knowledge of the user.

As to the more recent devices formed of spiraled or convoluted plastic rods, while they may, generally, be inserted without the need for dilation, they present other difficulties of insertion. They are generally inserted by means of a urether tube into which a pre-spiraled or pre-convoluted plastic rod is inserted in straightened form, an end of the tube then being inserted into the uterine cavity and the straightened rod discharged from the tube into the cavity by means of a plunger applied through the other end of the tube. However, the straightened spiral or convoluted rod exerts high pressure and a great deal of friction against the inner wall of the tube, so that great pressure must be applied on the plunger to effect discharge of the straightened plastic rod from the tube, and such discharge is accomplished with great difficulty in the management of the tube and plunger, and with the possibility of damage or perforation of the uterine wall in the course of such operation. Further, the coiled or convoluted plastic rod may be softened during heat sterili-

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zation and, particularly if such sterilization is prolonged, may lose its "memory" during the straightening within the tube and may, therefore, not assume its original shape upon insertion into the uterine cavity.

It is the general objective of the present invention to provide an intra-uterine contraceptive device, of the character described, which avoids all of the foregoing shortcomings and disadvantages of the devices of the prior art, while at the same time presenting additional advantages and superiorities over the devices of the prior art.

It is, thus, an object of the present invention to provide an intra-uterine contraceptive device, of the character described, which may be quickly and easily inserted into the uterine cavity without the need for dilation of the cervical canal and with a minimum of effort.

It is another object of the present invention to provide an intra-uterine contraceptive device, of the character described, which may be positively, accurately positioned within the uterine cavity, in the fundus, where it is most effective, and be physically retained therein.

It is still another object of the present invention to provide an intra-uterine contraceptive device, of the character described, which will retain its shape within the uterus for an indefinitely long period of time.

It is yet another object of the present invention to provide an intra-uterine contraceptive device, of the character described, which will not injure or otherwise adversely affect the wall of the uterine cavity.

It is a further object of the present invention to provide an intra-uterine contraceptive device, of the character described, which may be easily and readily removed from the uterine cavity, likewise without dilation, and without injury to it or to its passage.

It is a still further object of the present invention to provide an intra-uterine contraceptive device, of the character described, which may be mass-produced at relatively low cost.

It is a collateral object of the present invention to provide an instrument for inserting the device of the present invention which is of sufficiently small diameter that it may serve, at one and the same time, as a flexible sound to locate direction of insertion; which will deposit the device directly against the fundus wall; and which may require such little effort in its operation that it may be operated with one hand.

The foregoing and other objects and advantages of the intra-uterine contraceptive device of the present invention will become more readily apparent to those skilled in the art from the embodiment thereof shown in the accompanying drawings, and from the description following. It is to be understood, however, that such embodiment is shown by way of illustration only, to make the principles and practice of the invention more readily comprehensible, and without any intent of limiting the invention to the specific details therein shown.

In the drawings:

FIG. 1 is a perspective view, on an enlarged scale, of one embodiment of an intra-uterine contraceptive device of the present invention, partly broken away to illustrate details of construction;

FIG. 2 is a view similar to that of FIG. 1 of another embodiment of the same;

FIG. 3 is a fragmentary, perspective view of a modified embodiment of the device of FIG. 2;

FIG. 4 is an elevational and partly sectional view, on an enlarged scale, of one embodiment of a device for inserting a contraceptive device of the present invention into a uterine cavity;

FIG. 5 is a more or less diagrammatic view, showing the device in position within the uterine cavity, at rest; and

FIG. 6 is a view similar to that of FIG. 5, showing the effect of the contraction of the uterine wall muscles on the position of the device within the uterine cavity.

Generally stated, the contraceptive device of the present invention comprises an even-numbered plurality of elongated rectangular elements or sides, interconnected at their ends in accordion pleated arrangement to form a sigmoid or M-shaped structure, the elements being relatively rigid and connected to one another by resiliently flexible joints, whereby the sides of the device may be compressed against one another into compact arrangement for disposal into one end of an insertion tube for ready and painless insertion by means of the tube and a plunger reciprocating therein, through the cervical passageway into the uterine cavity and released therein to expand into normal position; with the open end of the center V portion of the device facing the fundus of the uterine cavity, and the free ends of the outer sides facing the outer end thereof. The device may have its two outer sides diverge and may be of a size that the free ends of the outer sides will be in continuous contact with the walls of the uterine cavity.

Referring now, in greater detail, to the embodiment of the invention illustrated in the drawing, which particular reference to the form of the device illustrated in FIG. 1 thereof, the device, generally designated as 10, is shown to consist of two spaced, congruous, sigmoid or M-shaped members formed of preferably continuous lengths of relatively stiff resilient wire of chemically inert character that will not react with body tissues and fluids, as of stainless steel. Each of the two members comprises a center, energizing section, 12, formed of two elements or sides connected in V-shape, and outer uterine wall contacting elements or sides, 14, which are connected to the ends of the sides of the center section 12, in preferably divergent relation to one another.

The sides of the central V-shaped section 12 of each of the wire members are connected to one another, at the vertex, by an integrally-formed, torsion coil, 16, and are similarly, connected at their other ends to the sides 14 by integrally-formed torsion coils, 18, and the sides 14 may, preferably, be formed with inwardly-offset loops, 20, at their free ends. The two M-shaped wire members, thus formed, may be connected, in spaced parallel relation, to one another, by eyelets, 22, engaged through torsion coils, 16 and 18, and a flexible or pliable band or thread, 24, of an inert material, preferably synthetic plastic material, such as nylon, may be tied, by its ends, to the registering pairs of loops 20. If desired, a covering of an inert synthetic plastic material may be provided over the two wires of the device, between torsion coils, to cover them and to form a continuous web between them. Such covering, 26, may comprise any suitable inert, synthetic plastic material, which may be boiled, for sterilization, such as nylon, or Teflon, or the like.

In FIG. 2 there is illustrated a modified embodiment of the invention in which the contraceptive device, 10a, is formed of a continuous length of leaf spring of appreciable width, preferably of an inert metal, such as stainless steel, which is bent into sigmoid shape to provide, similarly, a central V-section, 12a, and outer sides, 14a; the resilient joints between the sides comprise the bellied circular connection or bights, 16a, at the vertex of the V, 12a, and similar connection joints, 18a, between the ends of the sides of the V and the outer sides 14a. Such bights may preferably be of an arc greater than a half-circle, and the bight 16a may preferably be of greater resilience or lesser stiffness than bights 18a, effect attainable, in one way, by making it of larger diameter or by a longitudinally-extending slit, 17 through the bight 15a. If desired, a slit such as 17 may be provided in the other bight, 18a, making possible the use of thicker stock for the device 10a.

The free ends of sides 14a of the device 10a may be inwardly curved, toward one another as at 20a, to elimi-

nate any sharp, uterus wall contacting ends, and may be provided with openings in their ends wherethrough the ends of a thread or band, 24a, may be engaged. If desired, the device may also be covered with a layer or sleeve, 26a.

In the embodiment of FIG. 3, the free end portions of the outer sides, 14a, of the device, instead of being curved, are inwardly offset a short distance, to form the narrow shoulders, 28, and a band, 24b, of a thickness and width equal substantially to the depth of a shoulder 28, is secured by its ends, to such offset ends against their outer surfaces below shoulders 28, so that band 24b forms a continuous surface with the outer surface of sides 14b and covers the relatively sharp ends of such sides to prevent their contacting the uterine wall. If desired, the band 24b, which may be formed of an inert, synthetic plastic material, such as nylon, may be formed with transverse corrugations, so that its normal length is shortened and may be extended, by pulling against it.

For inserting either of the devices, 10, 10a, or 10b, within the uterus, I provide a relatively thin, elongated tube, generally designated as 30, preferably of synthetic plastic material, that may be sterilized by boiling, such as polyethylene or nylon, one end of which may be slightly enlarged, as at 32, to be capable of receiving one of the devices, 10, 10a, or 10b, as the case may be, in compacted state, and an elongated plunger, 34, of a length greater than the length of tube 30, adapted to be inserted into the tube 30 through its other end and to project therefrom. The plunger 34 may be provided with a knob or handle, 36, at its projecting end. Releasable means may be provided whereby inward movement of the inner end of plunger 34 into the contraceptive-holding end 32 of tube 30.

In FIG. 4 of the drawings, such inhibiting means is shown to comprise an axially-extending slot, 38, formed in the wall of the tube 30, opening into its edge at its other end, of a length substantially equal to the depth of the contraceptive receiving end 32, and of a pin, 40, set into the plunger 34, at a distance from its inner end not greater than the length of tube 30 from the inner end of portion 32 to its other end and at a distance from its projecting end or knob 36 not less than the length of slot 38. If desired, a collar, 42, may be provided at the plunger end of tube 30, through which slot 38 may extend, part of which extending a distance from one side of slot 38, may be cut away to form an end indentation, 44, whose sides will limit rotational movement of pin 40, and a further detent recess 46 may be formed in the inner wall of indentation 44, in spaced relation to the opening of slot 38, in which pin 40 is disposed and held while tube 30 is being inserted into the uterine cavity, to prevent premature discharge of the contraceptive device from the opposed end of the tube. If desired, the slotted end portion of tube 30 may be thickened as illustrated.

In use, a device 10 or 10a, or 10b, is compressed to bring its sides together in substantially compact, parallel relation, and is fitted into the wider end 32 of the tube 30, with the open end of its center V 12 outwardly facing, until it is substantially completely enclosed within tube portion 32. Plunger 34 is then inserted into tube 30, with pin 40 disposed in detent recess 46, to prevent further inward displacement of the plunger and consequent dislodgment of the contraceptive device. The assembly of the device, tube and plunger, may then be sterilized as a unit. When sterilization is completed, the tube, with its wider end 32 farthest, may be pushed through the uterine passageway, 48, and into the uterine cavity, 50, until the end of the tube portion 32 contacts the inner end wall or fundus, 52, of the uterine cavity. As the end 32 of the tube may be as thin as not to exceed one-quarter-inch in diameter, such insertion operation involves little, if any, pain or discomfort and obviously requires no anaesthesia. When the operator feels that the tube end 32 has reached and is disposed

against the inner end wall or fundus 52 of the uterus, the pin 40 is displaced from detent recess 46 and moved opposite the opening of slot 38, and, holding the plunger 34 steady, the tube 30 is engaged by collar 42 and gradually pulled outwardly over plunger 34, to gradually release the tube from the device and permit the device to expand and assume its normal form at the inner end of the uterus, with the ends of its sides 14, 14a, or 14b, as the case may be, resiliently engaging against the wall of the uterine cavity 50 at diametrically opposed points, as shown in FIG. 5 of the drawings. Thereafter, both tube and plunger are completely withdrawn from the uterus and from the uterine passageway.

It may here be stated that, while the contraceptive device has been described as being formed of metal, it will be readily understood that said device, particularly the forms thereof illustrated in FIGS. 2 and 3, may readily be formed of suitable synthetic plastic material capable of flexibility resilient bights.

This completes the description of the contraceptive device of the present invention, and the device inserting mechanism, and the manner in which the device is inserted and used.

It will be readily apparent that the device and inserting implement, of the present invention, may be mass-produced at relatively low cost. It will also be apparent that such device may be inserted in position with maximum ease for the physician and minimum pain and discomfort for the host.

It will likewise be apparent that the device of the present invention may be inserted in accurate position by means of the inserting implement of the present invention and that, once inserted into position, the device, by reason of the construction and arrangement of its hinged parts, will be actively and positively maintained in proper position, within the uterus, by the muscular action of its walls.

It will be further apparent that numerous variations and modifications may be made in the contraceptive device of the present invention and in the implement by which it is inserted, by anyone skilled in the art, in accordance with the principles of the invention hereinabove set forth and without the exercise of any inventive ingenuity. I desire, therefore, to be protected for any and all such modifications and variations that may be made within the spirit of the invention and the scope of the claims hereto appended.

What I claim is:

1. An intra-uterine contraceptive device comprising a substantially M-shaped body, including a center portion formed of sides convergent to V-shape and outer sides divergently connected to the diverged ends of said sides of said center portion, said sides each connected to each adjacent side by a resiliently flexible joint, whereby said sides may be compressed toward one another to lie substantially flatly against one another.

2. The contraceptive device of claim 1, wherein the said outer sides are divergent relative to one another.

3. The contraceptive device of claim 1, wherein said body is coated with a film of synthetic plastic material inert to body fluids.

4. The contraceptive device of claim 1, wherein said body comprises a pair of stiffly resilient wire units, bent into M-shape, and wherein said sides of said M-shaped wire units are connected to one another by torsion coils, said wire units connected to one another in spaced parallel relation by eyelets engaged through corresponding of their said torsion coils.

5. The contraceptive device of claim 4, wherein said outer sides of each said wire units is formed with an inwardly offset circular loop at its free end, and a string is engaged by one of its ends in each corresponding pair of said loops.

6. The contraceptive device of claim 1, wherein said body comprises a leaf spring bent into M-shape and said resiliently flexible joints comprise circular bights formed between the connected ends of the sides thereof.

7. The contraceptive device of claim 6, wherein the free ends of said outer sides curve inwardly toward one another.

8. The contraceptive device of claim 6, wherein the free ends of said outer sides are offset toward one another.

9. The contraceptive device of claim 8, wherein a narrow shoulder is formed between said outer sides and said offset ends thereof and a flexible band of an inert material of a thickness equal to the depth of said shoulder is secured to said offset ends against their outer surfaces outwardly of said shoulders.

10. The contraceptive device of claim 9, wherein said flexible band is formed of a synthetic plastic material capable of being boiled and is transversely corrugated.

11. The contraceptive device of claim 6, wherein longitudinally extending slits are formed in at least one of said bights to increase its flexibility.

12. An intra-uterine contraceptive device comprising an accordion-pleated body formed of a plurality of stiffly resilient sides, said sides connected to one another by enlarged resiliently flexible joints; said sides normally disposed in divergent relation to one another and compressible to close, substantially parallel relation to each other.

13. The intra-uterine contraceptive device of claim 12, wherein said sides are of even number.

14. The intra-uterine contraceptive device of claim 12, wherein said sides comprise integrally connected wire sections and said enlarged joints comprise coils formed at the connected ends of said wire sections.

15. The intra-uterine contraceptive device of claim 12, wherein said sides comprise integrally connected leaf spring sections, and said enlarged joints comprise bights formed at the connected ends of said leaf spring sections.

16. An intra-uterine contraceptive device, comprising a center, V-shaped section formed of elongated, relatively rigid, rectangular elements connected at their vertex, and an elongated, relatively rigid element connected to the free end of each of said first-named elements in re-entrant, divergent relation thereto, said elements connected to one another by resiliently flexible, circular joints of a circumference greater than half a circle, whereby said device may be compressed into compact shape, with said elements in parallel, substantially contacting relation, for insertion into a uterine cavity through the passageway thereinto, and resume normal, expanded position when released from said compression within the uterine cavity.

17. The contraceptive device of claim 16, wherein said elements and said resiliently compressible joints are integrally formed.

18. An intra-uterine contraceptive device comprising an elongated, relatively thin, stiffly resilient body folded re-entrantly into a plurality of interconnected sections divergent to one another and connected to one another by flexible joints, said body normally disposed in extended position with said sections in divergent relation to one another and responsive to pressure applied at its ends to be compressed to have said sections disposed in substantially parallel, juxtaposed relation to one another for insertion through the uterine passageway into the uterus.

19. The device of claim 18, wherein means are provided on the ends of the end-most sections of said body for securing the ends of a drawstring thereto.

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ADELE M. EAGER, *Primary Examiner*.