

[54] **INTRAUTERINE CONTRACEPTIVE
DEVICE**

[72] Inventors: **Bruce B. Pharriss**, Cupertino; **Max An-
liker**, Portola Valley, both of Calif.

[73] Assignee: **Alza Corporation**

[22] Filed: **Aug. 5, 1970**

[21] Appl. No.: **61,069**

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

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

[58] Field of Search **128/130, 127**

[56] **References Cited**

UNITED STATES PATENTS

3,516,403 6/1970 Cournot.....128/130

3,454,004 7/1969 Leininger.....128/130

Primary Examiner—Richard A. Gaudet

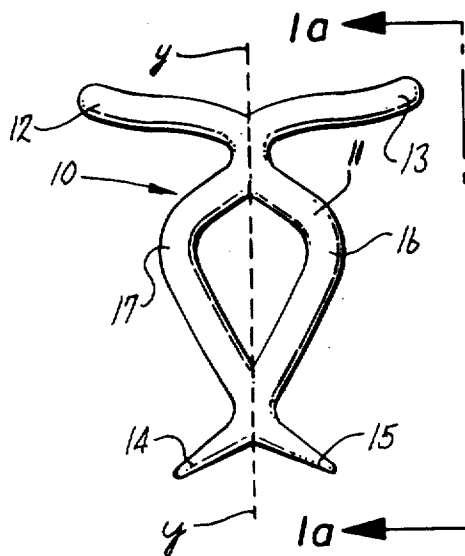
Assistant Examiner—C. F. Dunne

Attorney—Steven D. Goldby and Paul L. Sabatine

[57] **ABSTRACT**

Intrauterine contraceptive device is an integral filamentary body with a flexible closed ovoid loop stem. At its leading end, the stem terminates in a pair of laterally extending flexible arms and, at its trailing end, terminates in a pair of laterally and axially rearwardly extending relatively inflexible arms, shorter in length than the arms at the leading end. Trailing arms serve to anchor the device relative to the cervix while the leading arms, as well as the stem, are free to conform to changes in position caused by muscular contractions of the uterus.

8 Claims, 4 Drawing Figures



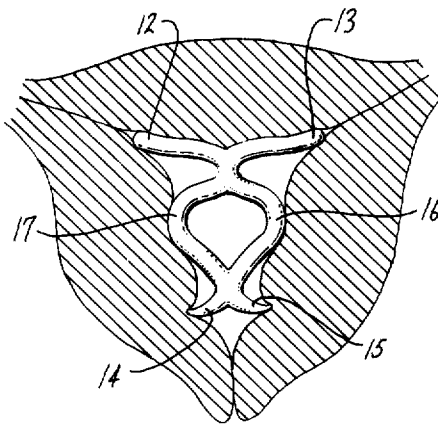
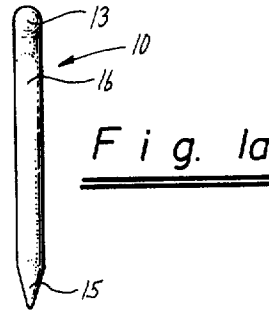
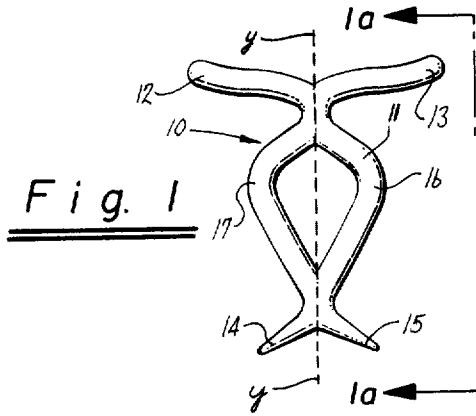


Fig. 3

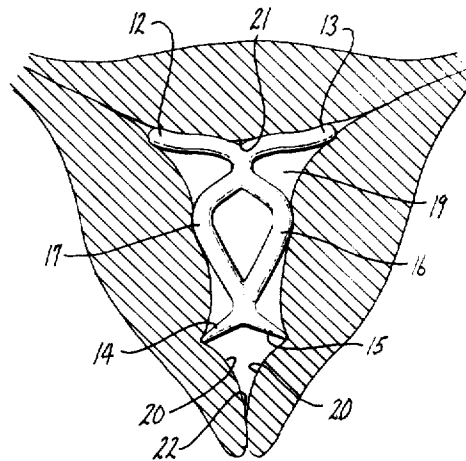


Fig. 2

INVENTORS
 Bruce B. Pharriss
 BY Max Anliker
Steven D. Goldby
 Attorney

INTRAUTERINE CONTRACEPTIVE DEVICE

BACKGROUND OF THE INVENTION

This invention relates an intrauterine contraceptive device, and more especially, to a device adapted for comfortable retention in the uterus and resistance to expulsion.

Intrauterine contraceptive devices have become an increasingly more important means of birth control. Widely known devices include the Lippe's Loop, Margulie's Spiral, Birnberg Bow, and Grafenberg Ring. In general, these devices are integral filamentary bodies formed of thin rods or tubes of polymeric material bent to a shape which will abut against the walls of the uterus.

Low cost, relatively long useful life, and freedom from regular intervening acts by the user are significant theoretical advantages of an intrauterine contraceptive device, as contrasted with other techniques of birth control. Thus, such devices are fabricated by simple molding procedures from inexpensive polymeric materials. When properly inserted by a physician or paramedical technician, the device should remain in place until removed and provide an effective birth control means during that period. Conscious periodic acts by the user, such as taking a daily pill, are avoided and failures due to patient inadvertence should be slight.

Despite these advantages, intrauterine contraceptive devices have not achieved their full potential in population control or family planning. Even in developing nations, where low cost is vital, these devices have not been an unqualified success. This unhappy result is due in large part to the high failure rate or large number of unwanted pregnancies by users. Undoubtedly, the leading cause of such failure is expulsion of the device by large numbers of females. Often this expulsion goes undetected and the female unknowingly has no birth control protection.

Because of the increasing problem of overpopulation and the benefits which would flow from an effective intrauterine device, a vast amount of research has been conducted to improve the retention of these devices. Numerous shapes have been proposed including rings, loops, "T" and "M" shapes. Recently, devices have been described which are provided with arms at either end to resist expulsion. Thus, U. S. Pat. No. 3,467,089 describes an intrauterine device having an elongated straight stem and a pair of elongated arms, of identical length and nature, extending from either end thereof. In the patented device, the two pairs of arms are stiffened with wire springs to provide anchoring means at either end of the device. Because the trailing arms of this device are quite long, there is a substantial dilation of the uterus which stimulates uterine muscular contractions. Because of its shape, the patented device cannot give with these forces but reacts against them. Another related intrauterine device is described in U. S. Pat. No. 3,454,004. That device has an elongated straight stem connecting an elongated leading end strand having an outwardly bowed curvature and a trailing end strand having an inwardly bowed curvature. This device too has a shape which prevents the device from fully adapting to muscular contractions of the uterus without being expelled therefrom.

SUMMARY OF THE INVENTION

Accordingly, it is a primary object of this invention to provide an intrauterine contraceptive device of improved configuration which will resist expulsions resulting from muscular contractions of the uterus.

Another object of this invention is to provide an intrauterine device which can adapt itself to the shape of the uterine lumen during muscular contractions of the uterus and, in doing so, assume a configuration which makes it more difficult to be expelled.

In accomplishing these objects, one feature of this invention resides in an intrauterine contraceptive device comprising an integral filamentary body having a flexible closed ovoid loop stem. At its leading end, the stem terminates in a pair of

laterally extending flexible arms and terminates at its trailing end in a pair of laterally and axially rearwardly extending relatively inflexible arms which are shorter in length than the arms at the leading end.

Other objects, features and advantages of this invention will be apparent to those skilled in the art from the detailed description of the invention which follows and from the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 is a frontal view of the improved intrauterine contraceptive device of the invention;

FIG. 1a is a side view of the intrauterine contraceptive device of the invention;

FIG. 2 is a schematic representation, partially in cross-section, of the device of the invention in place in a relaxed uterus; and

FIG. 3 is a schematic representation, partially in cross-section, of the device of the invention in place in the uterus and temporarily distorted by muscular contractions of the uterus.

DETAILED DESCRIPTION OF THE INVENTION

As illustrated in FIGS. 1 and 1a, the intrauterine contraceptive device 10 of the invention has a flexible closed ovoid loop stem 11. Stem 11 terminates at its leading end in a pair of laterally extending flexible arms 12 and 13. At its trailing end, stem 11 terminates in a pair of laterally and axially rearwardly extending relatively inflexible arms 14 and 15.

Preferably and as illustrated in FIG. 1, stem 11 is symmetrical about its longitudinal axis $y-y$. Also, it is preferred that the area circumscribed by the closed ovoid loop be greater toward the leading end than toward the trailing end of stem 11. Thus, the widest portion of closed ovoid loop stem 11 preferably is at curved sections 16 and 17 toward the leading end.

Leading arms 12 and 13 extend laterally from stem 11 and advantageously these arms extend axially forwardly of stem 11. Thus, arms 12 and 13 preferably subtend an angle of 120° to 180° with respect to each other, which angle is bisected in equal parts by axis $y-y$. Arms 12 and 13 are of the same length and are substantially longer than trailing arms 14 and 15. Typically, each of arms 12 and 13 is from 40 to 80 percent of the axial length of stem 11; that is, of the length of axis $y-y$. These arms are of uniform rounded or elliptical cross-section and have rounded or blunt end portions. Arms 12 and 13 act to provide a physiologically acceptable surface to receive the force of muscular contractions of the uterus. Their primary function is not to anchor or secure the intrauterine device in the uterine lumen but rather to yieldingly receive the forces and transmit such forces to stem 11.

Trailing arms 14 and 15 are smaller in size and less flexible than leading arms 12 and 13. Typically, each of trailing arms 14 and 15 is from 10 to 40 percent of the axial length of stem 11. They extend both laterally and axially rearwardly and preferably are subtend an angle of from 90° to 180° with respect to each other, which angle is bisected in equal parts by axis $y-y$. Trailing arms 14 and 15 can be of uniform rounded cross-section but preferably are tapered toward their extremities, as illustrated in FIG. 1. These arms serve to provide a fixed trailing anchor point for the intrauterine device within the uterus.

In use and as illustrated in FIG. 2, device 10 is disposed within lumen 19 of a uterus schematically represented as being defined by side-walls 20, top wall 21, and cervix 22. Device 10 is disposed within lumen 19 with leading arms 12 and 13 abutting against uterine top wall 21 and the ends of trailing arms 14 and 15 abutting against and anchoring the device toward the lower portion of uterine side-walls 20. Crests of curved stem sections 16 and 17 also abut against side-walls 20 of the uterus.

During muscular contractions of the uterus, device 10 is not expelled, but rather, temporarily distorts in shape in response to the forces applied. Important to the invention is that trailing arms 14 and 15 abut against and partially embed within uterine side-walls 20 providing a fixed anchoring point for the device. Thus, as a generally downward uterine muscular contraction begins at the upper uterine wall 21, leading arms 12 and 13 are forced downwardly, compressing and shortening the axial length of closed ovoid stem 11. As stem 11 shortens axially, curved sections 16 and 17 are extended outwardly thereby providing additional anchoring points for the device and further resisting expulsion. As force from a side-wall 20 is applied to curved sections 16 and 17, stem 11 will tend to elongate and trailing arms 14 and 15 will be further secured against the lower portion of side-walls 20. Because the trailing arms provide a fixed anchoring point, the device will not be expelled. FIG. 3 illustrates device 10 in a temporarily compressed or stressed configuration during a contraction of the uterus. When the uterus relaxes, device 10 resumes its original unflexed configuration, illustrated in FIG. 2.

Thus, the intrauterine contraceptive device of this invention is specially designed to adapt itself to the various forces which can be applied by uterine muscular contractions and to assume a stressed shape that resists expulsion. Individual elements of the device act in concert to ensure that the device will remain in the uterus until intentionally removed. Leading arms of the device provide a receiving surface for forces of uterine contractions but do not restrict downward mobility of the device. Closed ovoid stem can shorten axially in response to axial forces transmitted from the leading arms and the crests of its curved sections spread outwardly to provide further anchoring points and then to return the device to its unflexed condition when lateral forces are applied thereto. Trailing arms provide a fixed anchor point for the device and prevent expulsion through the cervix. Because the trailing arms are relatively short, they do not substantially dilate the uterus which can result in unwanted stimulation of muscular contractions.

Devices of the invention are provided in different sizes to accommodate various size uterine lumens. One typical device is of the shape illustrated in FIG. 1 and has leading arms each 2 cm. in length, an axial stem length of 3 cm., a closed ovoid loop stem with an interior area of 6 cm.², trailing arms each 0.7 cm. in length, and is formed of filamentary polymeric material having a diameter of 0.2 cm. However, these dimensions are not critical and the individual elements can be smaller or larger depending on the needs of the particular patient. In this specification and the appended claims, all dimensions, relative dimensions, and angles are set forth for the device in an unflexed condition.

One can insert the device of the invention into the uterine lumen through the cervix in the conventional manner. Leading arms can be disposed forwardly, trailing arms disposed rearwardly and the device loaded in an extended configuration into a conventional cylindrical inserter whose upper end is entered into the cervix. Upon discharge of the device into the uterine lumen by force of a plunger, the device assumes the configuration illustrated in FIG. 2. By grasping and disposing rearwardly the trailing arms, the device can be withdrawn from the uterus in a simple manner.

Various biologically acceptable flexible, resilient, polymeric materials can be used to form the intrauterine device of the invention. Illustrative materials include polyethylene, ethylene-vinyl acetate copolymers, silicone rubbers, ethylene-ethyl acrylate copolymers, polybutylmethacrylate, plasticized nylon, and plasticized polyvinyl chloride. With these materials, the device can be readily fabricated by conventional molding techniques. Because trailing arms 14 and 15 are shorter in length than leading arms 12 and 13, the trailing arms are inherently less flexible, even when formed of the same material. However, numerous means, well known in themselves, can be used to further stiffen trailing arms 14 and 15, when desired. In one embodiment of the invention, arms 14 and 15 can be

stiffened with wires embedded in and constituting their axial cores and totally encased in the biologically acceptable polymeric coating. In another embodiment, the polymeric material in arms 14 and 15 can be cross-linked to a greater degree than that in the remainder of the device, thereby rendering arms 14 and 15 relatively non-resilient in respect to the remainder of the device. This can be accomplished, for example, by cross-linking arms 14 and 15 using electromagnetic radiation or heat, while suitably shielding the remainder of the device from these cross-linking initiators. Alternatively, arms 14 and 15 can be formed from a different and stiffer material than the stem and leading arms 12 and 13 and then adhesively secured to the trailing end of stem 11. By "relatively inflexible" used to describe trailing arms 14 and 15 is meant that these arms are less flexible than leading arms 12 and 13 and stem 11.

Intrauterine contraceptive device of the invention is of unique shape to adapt itself to the shape and muscular contractions of the uterus without being expelled. In addition, the device is of sufficient surface area to provide contraceptive efficacy. Besides being used as a mechanical intrauterine contraceptive device, the device of this invention can be employed as a drug container to release antifertility agents or other drugs to the uterus. When this is desired, the device will incorporate the antifertility agent or other drug within its interior and be formed of a suitable polymeric membrane to release the antifertility agent or drug to the uterus at a predetermined therapeutically effective level. One suitable means of construction for such a drug releasing intrauterine device is disclosed in copending application Ser. No. 42,786, filed June 2, 1970 for an invention of A. Zaffaroni, assigned to the assignee of this invention. The disclosure of that copending application is relied upon and incorporated herein by reference.

While the invention has been described and illustrated with reference to certain preferred embodiments thereof, those skilled in the art will appreciate that various modifications, changes, omissions and substitutions can be made without departing from the spirit of the invention. It is intended, therefore, that the invention be limited only by the scope of the following claims.

What is claimed is:

1. An intrauterine contraceptive device, non-irritating to the uterus, adapted for comfortable retention therein and resistant to expulsion therefrom, and which does not cause erosion or perforation of the uterine walls, said device being comprised of an integral filamentary body having a flexible closed ovoid loop stem, said stem terminating at one end in a pair of opposed laterally extending flexible leading arms adapted to abut against the fundus of the uterus and which define a physiologically acceptable surface to receive the force of muscular contractions of the said uterus, and terminating at its other end in a pair of opposed laterally and axially rearwardly extending relatively inflexible trailing arms which are shorter in length than the said leading arms, said trailing arms adapted to provide a fixed anchor point for the intrauterine device within the uterus, said closed ovoid loop stem between said leading and trailing arms having a lateral extent at least equal to that of said trailing arms; and whereby, when inserted in the uterus, said device can adapt itself to the shape of the uterine lumen during muscular contractions of the said uterus without being expelled therefrom.

2. The intrauterine device of claim 1 wherein the said leading arms subtend an angle of 120° to 180° with respect to each other and the said trailing arms subtend an angle of 90° to 180° with respect to each other.

3. The intrauterine device of claim 1 wherein the said trailing arms are tapered toward their extremities.

4. The intrauterine device of claim 1 wherein each of the leading arms has a length of 40 to 80 percent the axial length of the stem and each of the trailing arms has a length of 10 to 40 percent the axial length of the stem.

5

5. The intrauterine device of claim 1, wherein the leading arms each are about 2 cm. in length, the trailing arms each are about 0.7 cm. in length, and the longitudinal axial stem length is about 3 cm.

6. The intrauterine device of claim 1 wherein the stem is symmetrical about its longitudinal axis.

7. The intrauterine device of claim 6 wherein the area circumscribed by the closed ovoid loop stem is greater toward the end bearing the trailing arms than toward the end bearing the trailing arms.

8. The intrauterine contraceptive device of claim 1 comprising

a flexible closed ovoid loop stem which is symmetrical

6

about its longitudinal axis and circumscribes an area greater toward one end than toward the other end, said stem terminating at the one end in a pair of flexible leading arms extending laterally and subtending an angle of 120° to 180° with respect to each other and each of the leading arms having a length of 40 to 80 percent axial length of the stem, and

said stem terminating at its other end in a pair of relatively inflexible trailing arms extending laterally and axially rearwardly and subtending an angle of 90° to 180° with respect to each other and each of the trailing arms having a length of 10 to 40 percent the axial length of the stem.

* * * * *

15

20

25

30

35

40

45

50

55

60

65

70

75