United States Patent

[11] 3,590,816

[72] Inventor **Gerald S. Rosenthal**
Ogden, Utah

[21] Appl. No. **715,256**
[22] Filed **Mar. 22, 1968**
[45] Patented **July 6, 1971**

[73] Assignee **Julius Schmid, Inc.**
New York, N.Y.

Continuation-in-part of application Ser. No. 461,281, June 4, 1965, now abandoned, and a continuation of application Ser. No. 515,284, Oct. 24, 1965, now Patent No. 3,374,788.

[54] **PLACEMENT UNIT FOR INTRAUTERINE CONTRACEPTIVE DEVICES**
9 Claims, 29 Drawing Figs.

[52] **U.S. Cl.** **128/130, 128/263**

[51] **Int. Cl.** **A61f 5/46**
[50] **Field of Search** 128/167, 128, 130, 129, 263

[56] **References Cited**

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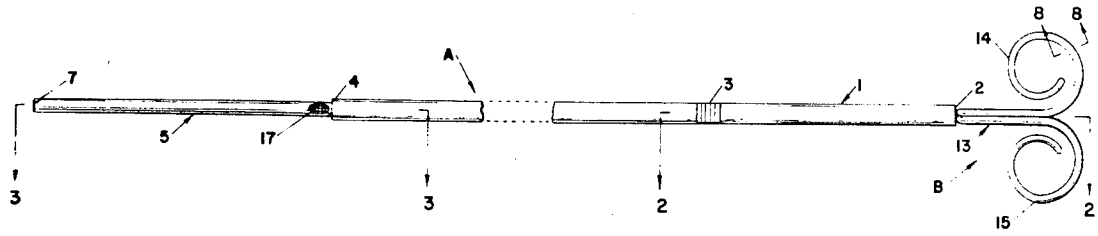
Primary Examiner—Adele M. Eager
Attorney—Darby & Darby

ABSTRACT: A unit for correctly placing an intrauterine contraceptive device (IUCD) in the female uterine cavity while preserving the sterility of the IUCD, the unit comprising a plunger attached at its leading end to one end of the IUCD for manipulation of the IUCD into and out of a tubular inserter by manual control exerted upon the trailing end of the plunger which projects beyond the trailing end of the tubular inserter.



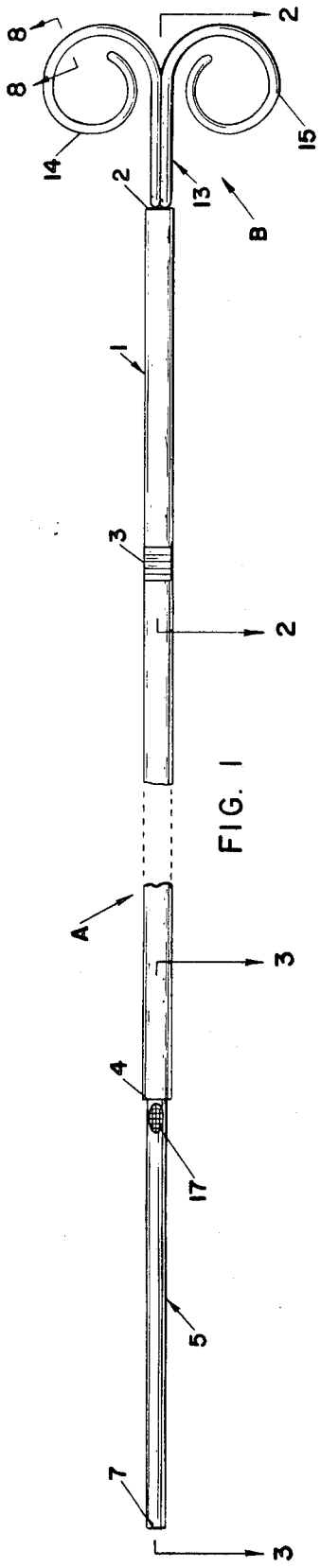


FIG. 1

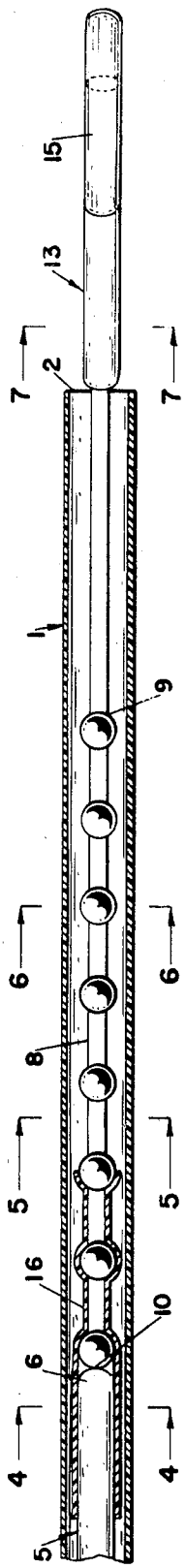


FIG. 2

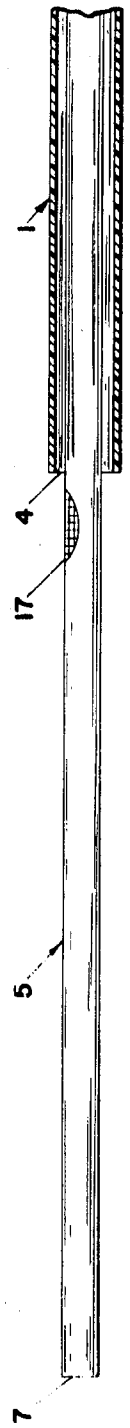
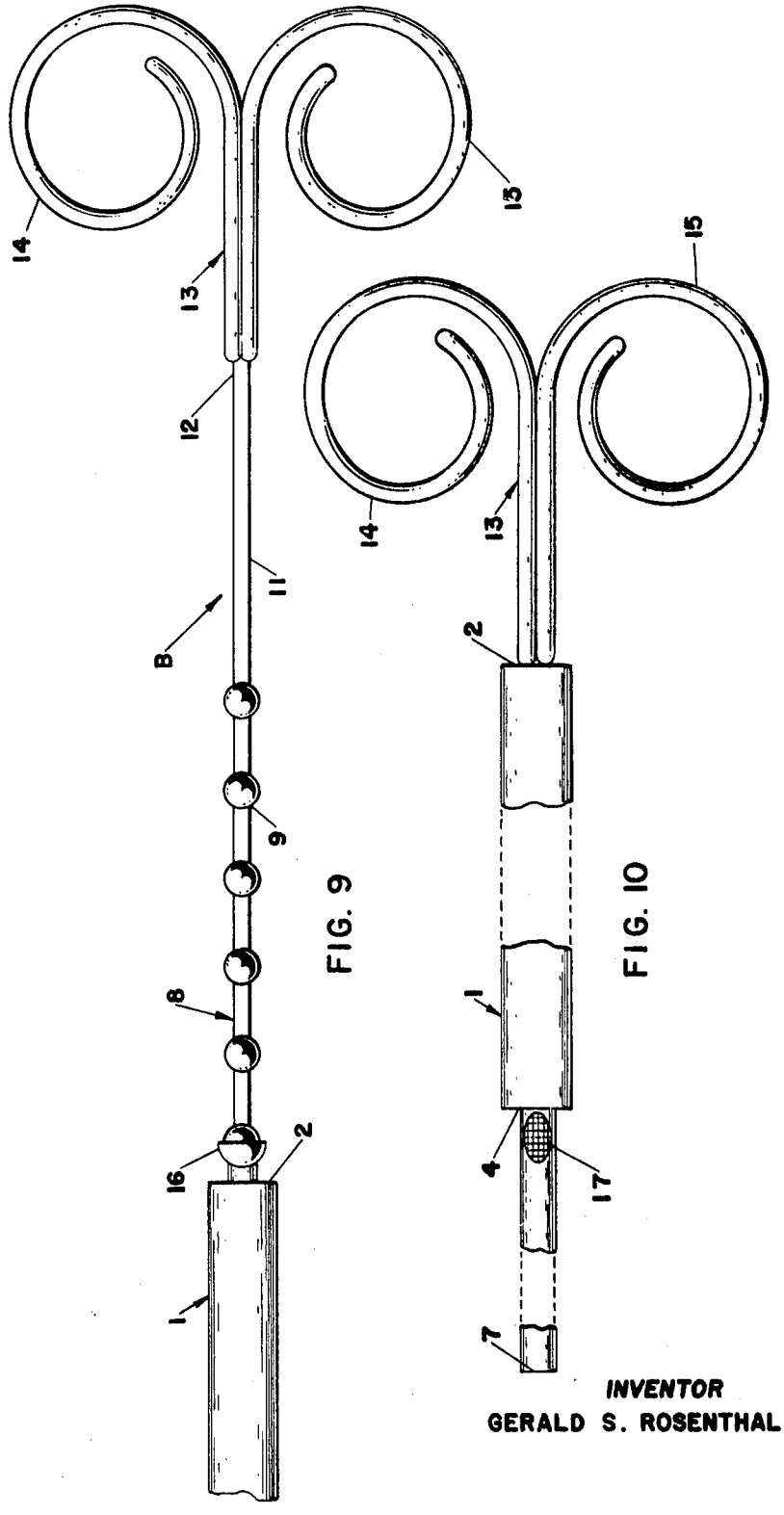


FIG. 3

INVENTOR
GERALD S. ROSENTHAL



INVENTOR
GERALD S. ROSENTHAL

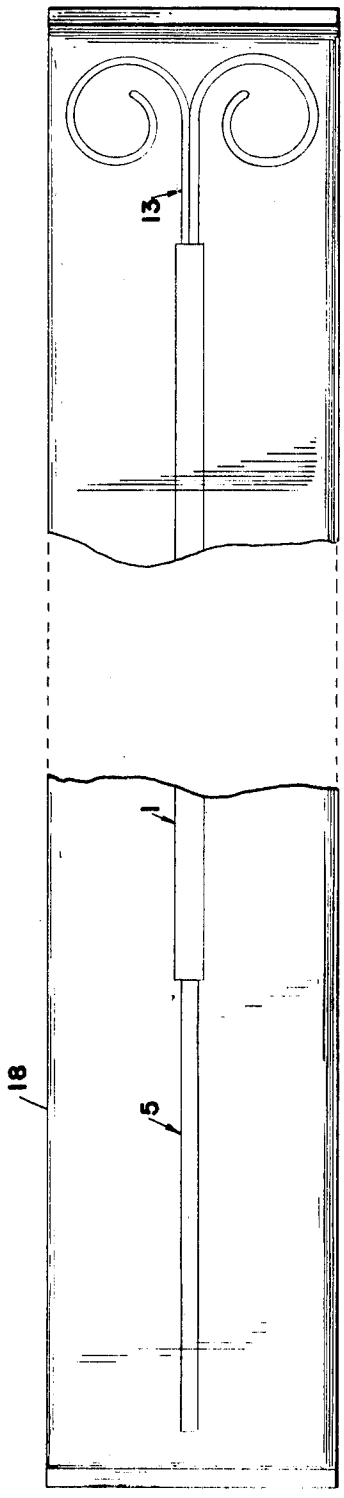


FIG. 11

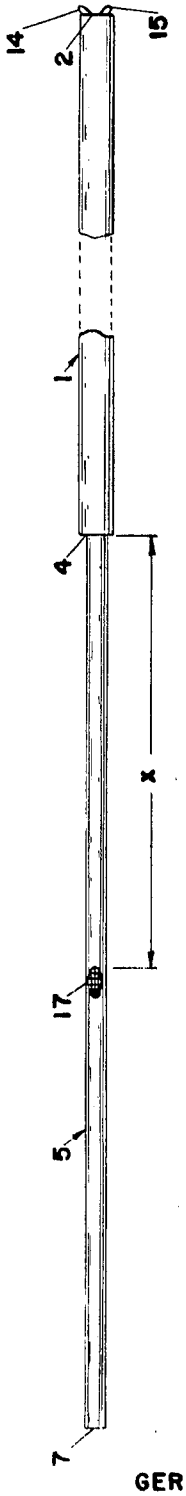


FIG. 12

INVENTOR
GERALD S. ROSENTHAL

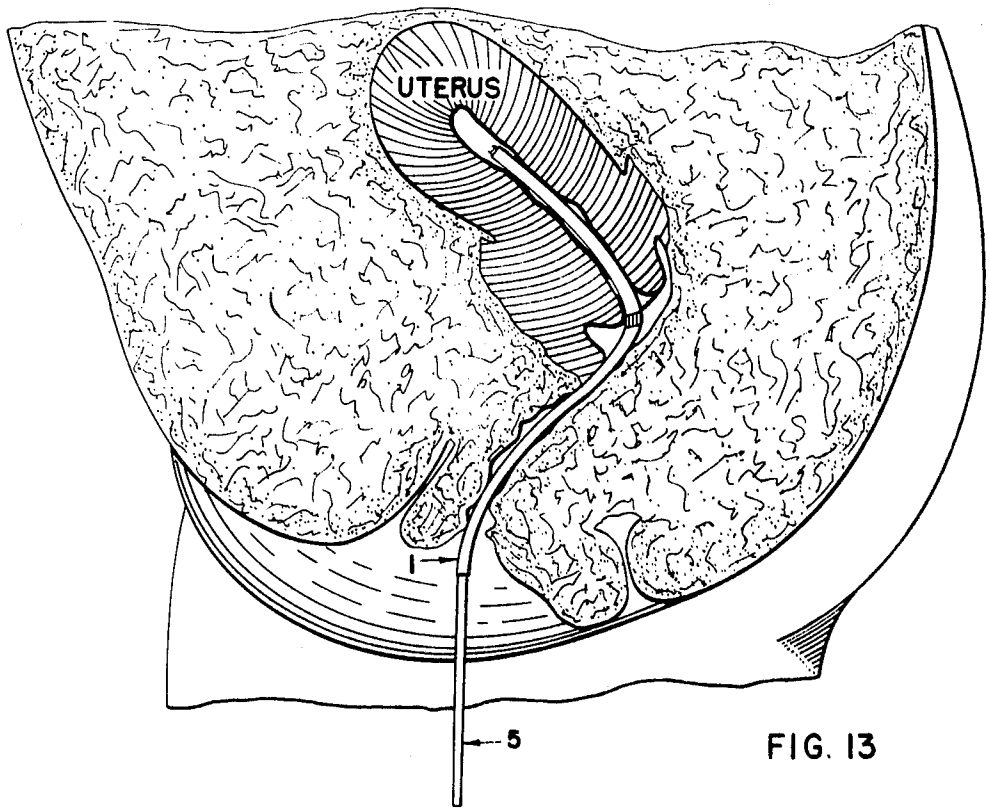


FIG. 13

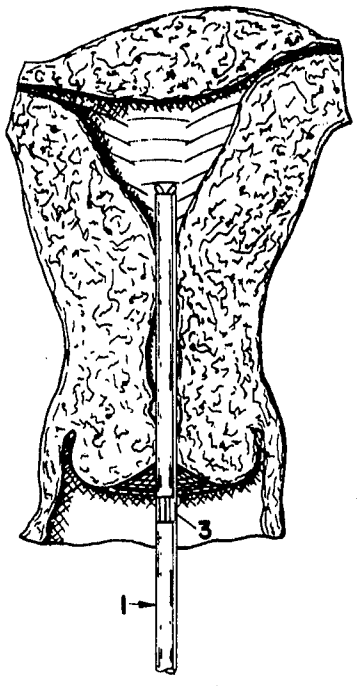


FIG. 14

INVENTOR
GERALD S. ROSENTHAL

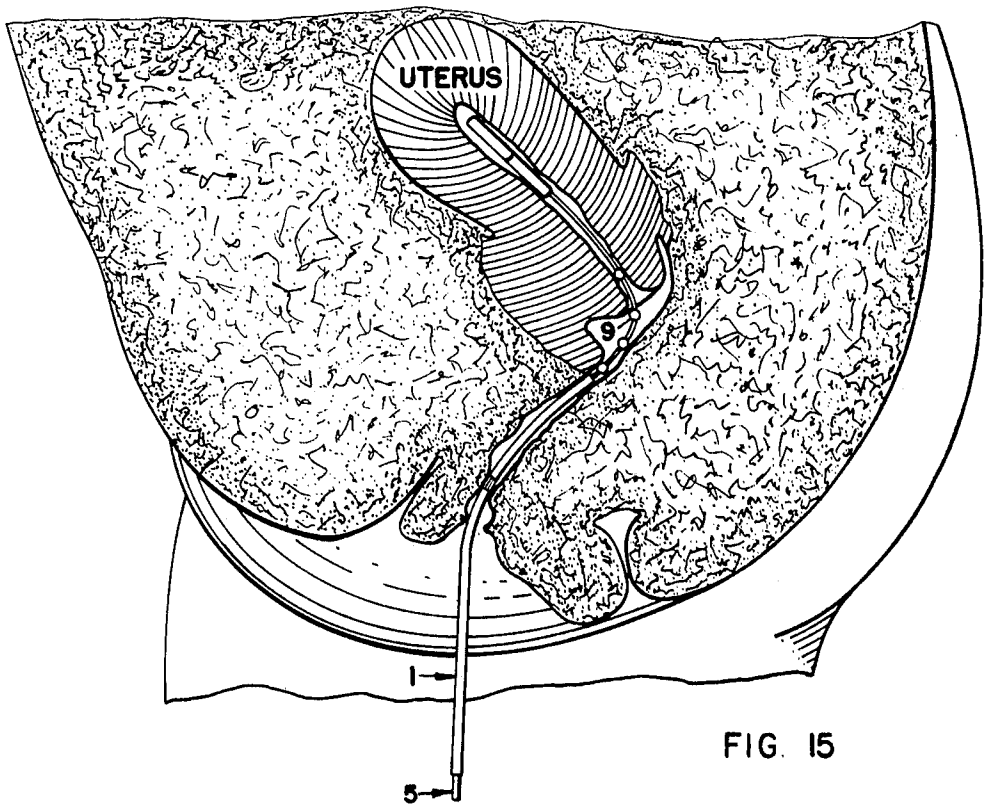


FIG. 15

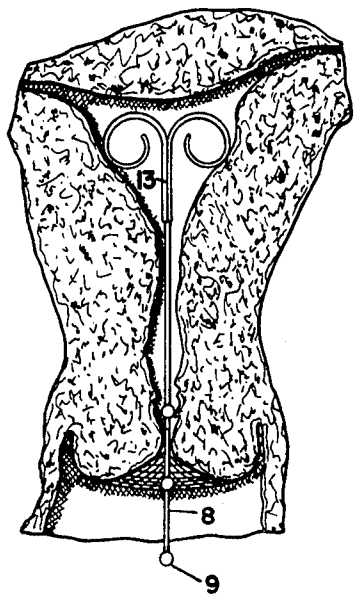


FIG. 16

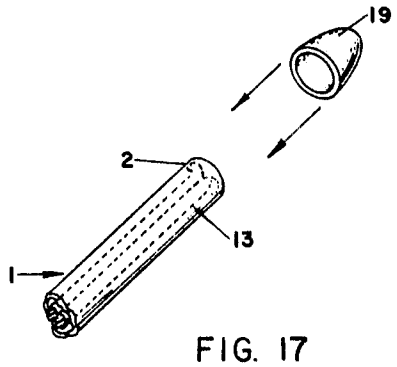


FIG. 17

INVENTOR
GERALD S. ROSENTHAL

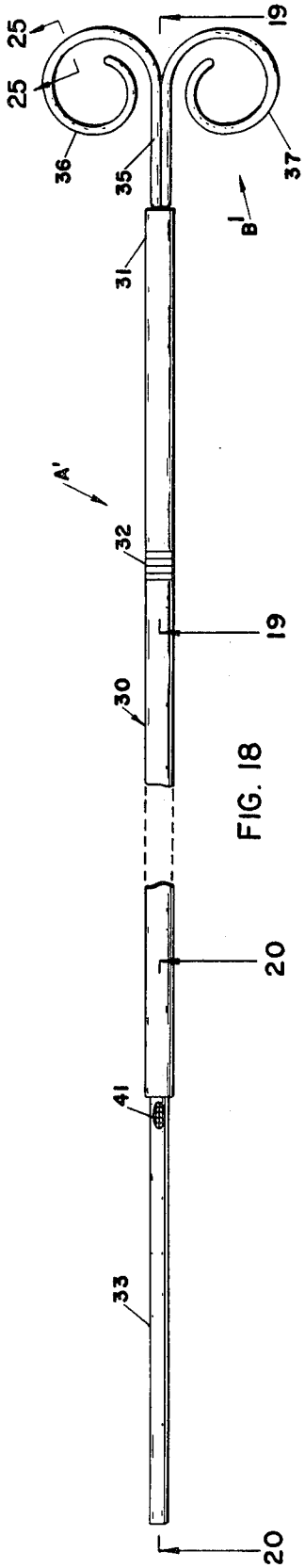


FIG. 18

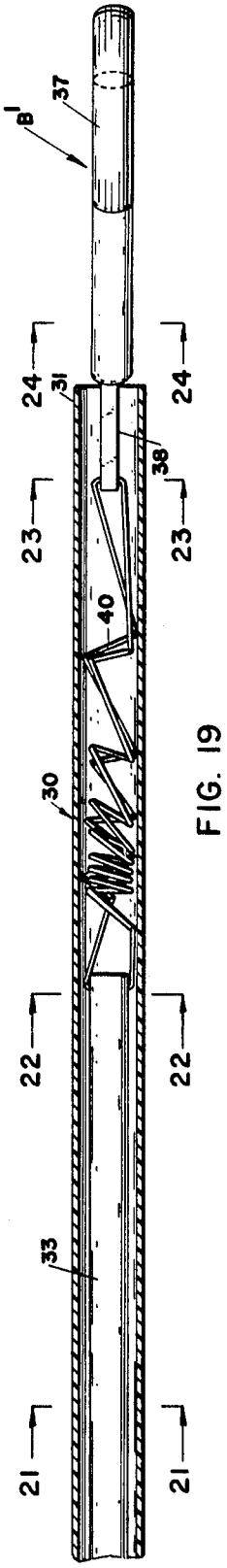


FIG. 19

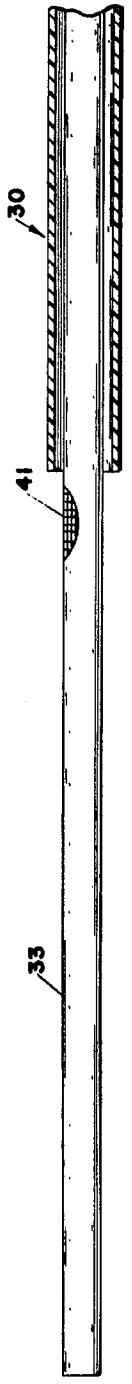


FIG. 20

INVENTOR
GERALD S. ROSENTHAL

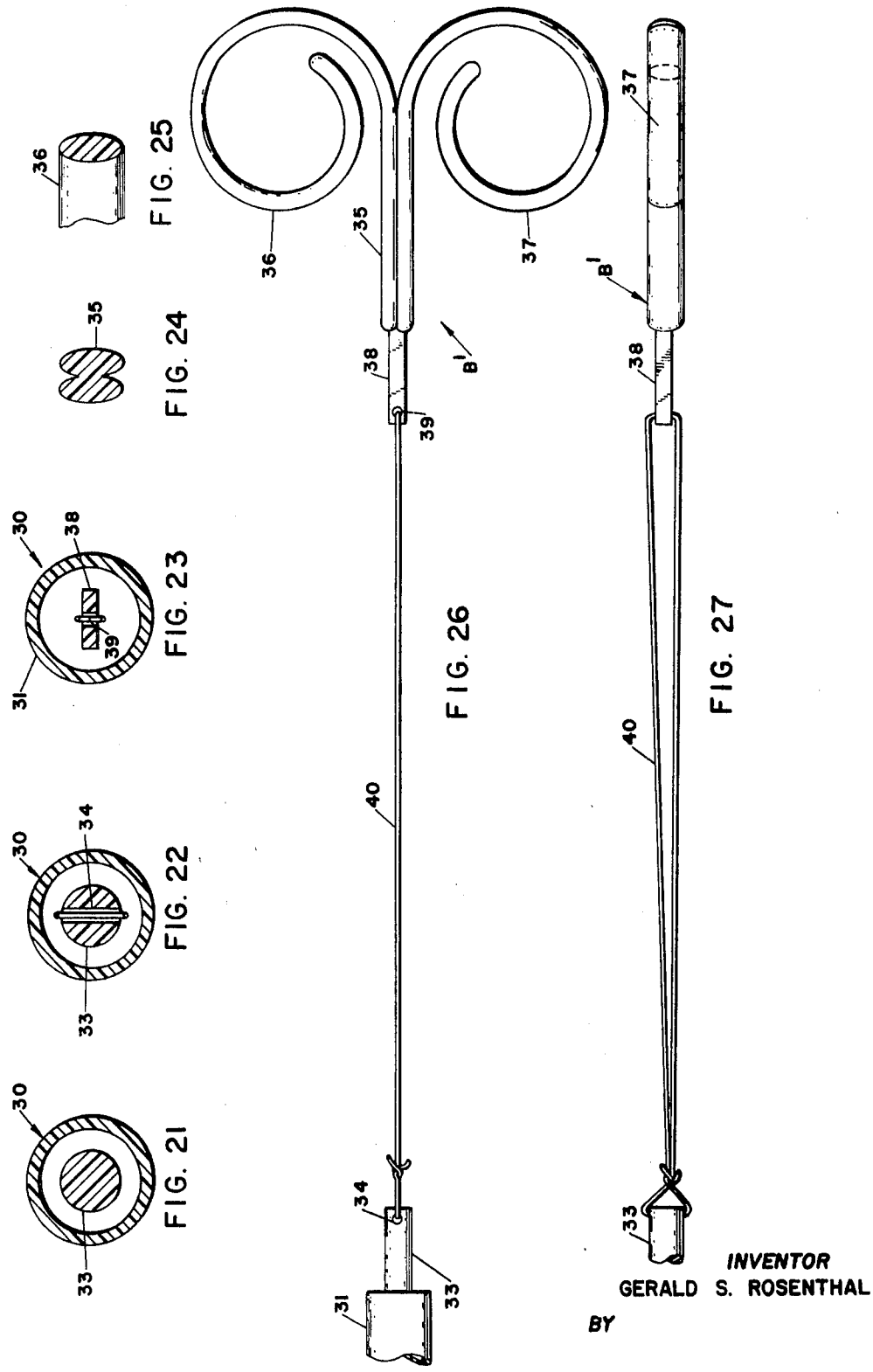


FIG. 25

FIG. 24

FIG. 23

FIG. 22

FIG. 21

FIG. 26

FIG. 27

INVENTOR
GERALD S. ROSENTHAL
BY

ATTORNEY

PLACEMENT UNIT FOR INTRAUTERINE CONTRACEPTIVE DEVICES

This invention relates in general to a new and useful improvement means for installing intrauterine contraceptive devices. This application is a continuation-in-part of my application Ser. No. 461,281, filed June 4, 1965, now abandoned, and a continuation of my copending application Ser. No. 515,284, filed Oct. 24, 1965, now U.S. Pat. No. 3,374,788.

It is the primary object of the present invention to provide a unit for correctly placing an initially sterile intrauterine contraceptive device within the female uterus without destroying the initial sterility.

It is another object of the present invention to provide a unit for aseptically placing an intrauterine device into the uterus with a minimum of discomfort to the patient.

These and other objects and features of the present invention will become more fully apparent from the following description and appended claims taken in conjunction with the accompanying drawings wherein:

FIG. 1 is a top plan view of a combined intrauterine insert and insertion means constructed in accordance with and embodying the present invention;

FIGS. 2 and 3 are enlarged fragmentary sectional views taken along lines 2–2 and 3–3, respectively, of FIG. 1;

FIGS. 4, 5, 6 and 7, are transverse sectional views taken along lines 4–4, 5–5, 6–6 and 7–7, respectively, of FIG. 2;

FIG. 8 is a fragmentary transverse sectional view taken along line 8–8 of FIG. 1;

FIG. 9 is an enlarged fragmentary plan view of the insert connected to the inserter rod or plunger;

FIG. 10 is an enlarged fragmentary plan view of the combined insert and insertion means with the insert partially projected therefrom preparatory to enclosure in a sterile outer envelope;

FIG. 11 is a plan view of the entire sterilized unit prior to use by the physician;

FIG. 12 is an enlarged fragmentary sectional view showing the insert withdrawn or loaded into the insertion device preparatory to implantation with the uterus;

FIG. 13 is a diagrammatic transverse view of the female pelvic region, illustrating the first stage of installing the intrauterine insert of the present invention;

FIG. 14 is a diagrammatic frontal view of the female pelvic region showing the second stage of installing said intrauterine insert;

FIG. 15 is a diagrammatic transverse view of the female pelvic region showing the third stage of installing said intrauterine insert;

FIG. 16 is a diagrammatic frontal view of the female pelvic region showing the final stage of installing said intrauterine insert;

FIG. 17 is a fragmentary perspective view showing the distal end of an insertion tube and a gelatine cap forming part of the present invention;

FIG. 18 is a top plan view of a modified intrauterine device constructed in accordance with and embodying the present invention;

FIGS. 19 and 20 are enlarged fragmentary sectional views taken along lines 19–19 and 20–20, respectively, of FIG. 18;

FIGS. 21, 22, 23 and 24 are transverse sectional views taken along lines 21–21, 22–22, 23–23 and 24–24, respectively, of FIG. 19;

FIG. 25 is a fragmentary transverse sectional view taken along line 25–25 of FIG. 18;

FIGS. 26 and 27 are enlarged plan and elevational views, respectively, of the insert forming part of the modified intrauterine device illustrated in FIG. 18; and

FIGS. 28 and 29 are top plan views of modified forms of intrauterine devices equipped with placement units constructed in accordance with and embodying the present invention.

Corresponding reference characters indicate corresponding parts throughout the several views of the drawings.

Corresponding reference characters indicate corresponding parts throughout the several views of the drawings.

Referring now in more detail and by reference characters to the drawings, which illustrate practical embodiments of the present invention, A designates an intrauterine device comprising an elongated insertion tube 1 formed preferably of polyethylene or a similar biologically inert synthetic resin which is of sufficient overall thickness and polymeric density so as to be resiliently flexible so that it will readily bend in conformity with the contours of the vagina and cervical canal, but is nevertheless sufficiently rigid so that it can be inserted into the cervical canal and will not collapse under the contractile muscular pressure of the walls thereof. The overall dimensions of the insertion tube 1 are not critical but it has been found as a matter of practical experience that the insertion tube or tubular inserter 1 should preferably have a length of approximately 10 or 14 inches, an outside diameter of approximately three-eighths of an inch and a wall thickness of approximately 80 mils. Inwardly from its distal tip 2, the insertion tube 1 is provided externally with a red annular indicator band 3. Actually, this indicator band 3 may be of any desired color but, on the basis of practical experience, it has been found that red is readily visible and serves very well to afford the physician or gynecologist some means of determining the distance to which the distal tip 2 has been inserted into the cervical canal, as will be presently more fully discussed. In this connection, it should also be noted that the indicator band 3 is located approximately 6 centimeters or 2½ inches from the distal tip 2 of the insertion tube which is considered to be the normal internal length between the external cervical os and the fundus of the uterus for the average human female. Loosely and slidably disposed within the insertion tube 1 and extending for a substantial distance axially outwardly from the proximal end 4 thereof is an inserter rod or plunger 5 having a distal end 6 and a proximal end 7. The inserter rod 5 is preferably of circular cross-sectional shape and is formed of semirigid somewhat flexible polyethylene or other suitable material.

As a matter of fact, the insertion tube 1 and the inserter rod 5 do not remain within the body of the patient and therefore the material used in fabricating them is not particularly critical provided it has the necessary combination of rigidity and flexibility to perform its mechanical function.

Provided for cooperation with the insertion tube 1 and inserter rod 5 is an intrauterine insert or device B molded or otherwise suitably formed from high molecular weight polyethylene or other similar biologically inert synthetic resin, which is substantially rigid but is nevertheless resiliently flexible and can be deformed under moderate manually applied force but will nevertheless resume its initial shape when released. The intrauterine insert B integrally includes a relatively flexible tail portion 8 of ribbonlike or rectangular cross-sectional shape having a plurality of spherical beads or knoblike protuberances 9 integrally formed at uniformly spaced intervals therealong. As a result of observation and experimentation, it has been found preferable to employ eight such spherical beads 9 spaced by a center-to-center distance of five-sixteenths of an inch, with the first bead 9 being directly adjacent to the proximal end 10 of the tail portion 8, the entire length of the tail portion 8 being approximately 3¾ inches in length. Thus the tail portion 8 will have a smooth uninterrupted section 11 at its distal end 12, all as best seen in FIG. 9. Formed integrally upon and extending axially outwardly from the distal end 12 of the tail portion 8 is a retention head !13 having an uninterrupted cross-sectional shape somewhat resembling a "figure eight" and separating at its outer end into two spirally curled terminal portions 14, 15, which are, in turn, of somewhat oval or elliptical cross-sectional shape, as best seen in FIG. 8.

The proximal end 10 of the tail portion 8 is connected or fixed by joining structure to the distal end 6 of the inserter rod or plunger 5 by means of a tubular sleeve 16 formed preferably of heat-shrinkable synthetic resin. The sleeve 16 is initially slid, for a substantial distance at one of its ends, over

the distal end 6 of the inserter rod 5 and the proximal end 10 of the tail portion 8 is, in turn, slid into the other end, the sleeve 16 being of sufficient length so as to extend for a substantial distance along the tail portion 8 and embrace at least one of the spherical beads 9. The sleeve 16 is thereupon subjected to a moderate degree of elevated temperature sufficient to cause it to shrink tightly down around and embrace the adjacent ends of the tail portion 8 and the inserter rod 5, thereby holding them tightly and securely together. It will be evident to one skilled in the art that the tail portion 8 and the inserter rod 5 can be joined in any suitable manner such as by a split metal sleeve or by fusing the two together through the application of heat. In the latter instance, the rod and tail portion, of course, would have to be formed from compatible plastics. Finally, the inserter rod 5 is provided approximately 3¼ inches from its proximal end 7 with a plainly visible black dot 17, this distance being substantially equal to the length of the entire retention head 13 of the insert B when the latter is sheathed within the insertion tube 1, as indicated by the reference letter x in FIG. 12.

The proximal end 7 of the inserter rod 5 is then slid into the distal end of the insertion tube 1 and pushed entirely through the length thereof until the connected end of the insert B is also pulled into the insertion tube 1 and the proximal end 7 of the inserter rod 5 will project from the proximal end 4 of the insertion tube 1 with the black dot 17 visible. In this position the retention head 13 will still be completely outside of the insertion tube 1 and the region of juncture between the tail portion 8 and the retention head 13 will be located approximately at the distal end 2 of the insertion tube 1, all as best seen in FIG. 10. In this relative position, the combined insertion tube 1, the inserter rod 5 and insert B are enclosed within a flat rectangular envelope 18 preferably made of heat-sealable transparent synthetic resin sheathing. The envelope 18 is then heat sealed and the entire unit sterilized in any suitable conventional manner. The sterilization can be performed in a number of different ways and can be carried out after packaging but initial sterilization does not constitute part of the present invention and, therefore, need not be specifically described in detail herein. It is sufficient for present purposes merely to point out that the intrauterine device A and the interior of the envelope 18 are surgically sterile and the envelope 18 serves to preserve the intrauterine device A in such sterile condition during subsequent storage and handling of the sealed envelope.

The sterile intrauterine device A and sterile insertion unit are then removed from the sterile envelope 18 and the proximal, trailing or protruding end of the inserter rod 5 is pulled slowly outwardly through the proximal or trailing end of the insertion tube 1 so that the circuitously shaped retention head 13 of the insert B is drawn into in essentially linear relation and sheathed in such disposition within the distal end of the insertion tube 1. As this occurs the coiled convolutions of the terminal portions 14, 15, straighten out until, when fully sheathed, they assume the position shown in FIG. 12. Thus, the device A is aseptically loaded into the tubular inserter solely by manipulation of the proximal end of the plunger and no human contact is made with the device A.

Thereupon, with reference to FIGS. 13—16, the distal tip 2 of the loaded insertion tube 1 is gently inserted into the cervical os and the insertion tube 1 is slowly but firmly advanced through the cervical canal and uterus until it contacts the fundus. At this point in the procedure, usually both the patient and the gynecologist will feel the pressure of contact with the fundus. As has been above mentioned, the red band 3 is approximately 2½ inches or 6 centimeters from the distal tip 2 of the insertion tube 1, this length being assumed to be the average anatomical distance between the external cervical os and fundus. From this position, the insertion tube 1 is pulled back about ½ inch or 1 centimeter and the entire device A is rotated if necessary about its longitudinal axis until the black dot on the inserter rod 5 is facing upward. This orients the insert B in the frontal plane of the uterus. Thereupon the inserter rod 5 is advanced slowly and gently until the black dot on the inserter rod 5 reaches the proximal end 7 of the insertion tube 1. Sometimes, in a patient with a very small uterus, pressure will be felt by the patient within the uterus before the black dot fully reaches the proximal end 7 of the insertion tube 1 and in such case the inward pushing movement will be terminated. Obviously, as the inserter rod 5 is pushed inwardly the retention head 13 of the insert B will be progressively unsheathed and the terminal portions 14, 15, will return to their original coiled shape or position for retentive lodgment within the cavum uteri. Thus, the sterility of the device A and the leading portion of the plunger and insertion tube will be preserved as no human contact therewith is made during placement.

Thereupon, the insertion tube 1 is gently withdrawn from the cervical canal while the inserter rod 5 is held stationary. As this occurs the tail portion 8 of the insert B will be unsheathed and left within the cervical canal. As has been above indicated, the tail portion 8 is usually longer than the cervical canal and therefore the proximal end 10 thereof will now depend loosely and in exposed position within the interior chamber of the vagina below the cervix. The insertion tube 1 and the inserter rod 5 are then manually shifted in a lateral direction so as to bring the downwardly protruding end of the tail portion 8 somewhat to one side. A scissors or cutting forceps can then be inserted into the vagina and the downwardly protruding end of the tail portion 8 can be severed or cut loose from the inserter rod 5. Preferably all but one or two of the beads 9 protruding from the cervix should be clipped off and the cutting should preferably be done very close to the underside of the lowermost bead 9 which is left in place. By this means rough edges are avoided. As soon as the clipping or cutting operation has been completed, the insertion tube 1 and inserter rod 5 can be entirely withdrawn and discarded.

It is possible to fit a gently contoured gelatin cap 19 over the distal end 2 of the insertion tube 1 once the retention head 13 has been completely drawn into it, all as best seen in FIG. 17. The cap 19 prevents chafing of and irritation to the cervical canal as the insertion tube 1 is advanced therethrough and into the uterus. In fact, by fitting the cap 19 over the distal end 2, it is possible for the gynecologist to insert the tube 1 without previously dilating the cervical canal. The cap 19 is, of course, nontoxic and dissolves within the uterus in a matter of minutes allowing the gynecologist to perform subsequent procedures as hereinbefore described.

As will be seen by reference to FIGS. 18 through 27, it is possible to provide a modified intrauterine contraceptive device A^1 including an insertion tube or tubular inserter 30 having a distal tip 31, the tube 30 being provided inwardly from its distal tip 31 at a distance of about 2½ inches with an indicator band 32 which is similar to the indicator band 3 of the intrauterine device A. Slidably fitted within the tube 30 is a flexible inserter rod or plunger 33 provided with a transversely extending hole 34 at its distal end.

Provided for cooperation with the insertion tube 30 and inserter rod 33 is an intrauterine insert B^1 integrally including a retention head 35 which separates at one end into two spirally curled terminal portions 36, 37, and is otherwise similar to the retention head 13 of intrauterine insert B. Extending from the opposite end of the retention head 35 is a relatively short tail portion 38 of ribbonlike or rectangular cross-sectional shape, the tail portion 38 being provided with an aperture 39. Interconnecting the inserter rod 33 and the retention head 35 is joining structure comprising a nylon or other suitable biologically inert string 40 which is fixed to the inserter rod or plunger 33 by being passed through the hole 34 of the inserter rod 33 and is fixed to the device by being passed through the aperture 39 of the tail portion 38 and is tied therebetween. Finally, the inserter rod 33 is provided with a plainly visible black dot 41 which, when the circuitously shaped retention head 35 is completely drawn into generally linear relation within the tube 30 and the distal end of the inserter rod 33 is brought into endwise abutment with such retention head, is

located at a distance from the proximal end of the insertion tube **30** equal to the sheathed length of the insert B^1. The gynecologist, of course, can use the black dot **41** to determine when the retention head **35** is fully unsheathed in the patient's uterus. In other words, when the black dot **41** reaches the proximal end of the insertion tube **30**, the intrauterine insert B^1 will be fully unsheathed within the patient's uterus.

Intrauterine device A^1 is utilized for emplacing the intrauterine insert B^1 within the patient's uterus in a manner similar to that described in conjunction with intrauterine device A. Specifically, the device is aseptically loaded solely by pulling upon the proximal end of the plunger or rod **33** and the device is properly implanted in the uterus solely by pushing on the proximal end of the plunger or rod so that the distal end of the rod forces against the proximal end **38** of the device and forces the device out of the insertion tube, all without subjecting the device to human contact.

After the insertion tube **30** is withdrawn, the string **40** instead of a beaded tail portion is cut with a scissors or cutting forceps and removed leaving the intrauterine insert B^1 emplaced within the patient's uterus. Of course, a gelatine cap **19** can be fitted over the distal end of the insertion tube **30** so that the insertion tube **30** can be passed through the cervical canal.

It is also possible to use the various embodiments of the present placement unit with modified forms of intrauterine devices, for example, with device B^2, as shown in FIG. **28**. The overall assembly A^2 comprises the device B^2 and one of the described inserters or placement units comprising an insertion tube, a plunger and joining structure fixed to the leading end of the plunger and fixed to the trailing end of the device B^2, such as, for example, the described structure identified by numeral **16** in FIG. **2** or by numeral **40** in FIG. **19**. Device B^2 differs primarily from the earlier-described devices in that it is provided with a retention head **19** comprising a single spiral coil **20**.

Similarly, it is possible to use the various embodiments of the present inserters or placement units with device B^3, as shown in FIG. **29**. The overall assembly A^3 comprises the device B^3 and one of the described inserters or placement units comprising an insertion tube, a plunger and joining structure fixed to the leading end of the plunger and fixed to the trailing end of the device B^3, such as, for example, the described structure identified by numerals **16** or **40** in FIGS. **2** and **40**, respectively. Device B^3 differs from the earlier-described devices in that it is provided with a retention head **21** comprising a sinuous or serpentine terminal portion **22**.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore to be embraced therein.

What I claim and desire to be secured by United Stated Letters Patent is:

1. An intrauterine assembly comprising:

an intrauterine device of a flexible material with a retentive memory having a curved portion and a trailing end portion,

placement apparatus for placing said device within the uterine cavity, said apparatus comprising:

a. a plunger,

b. severable means connecting the leading end portion of the plunger to the device,

c. a tubular inserter having an internal diameter of a size within which the plunger, said connecting means and said device can be disposed, the combined lengths of the connecting means and the plunger being so related to the length of the inserter that the trailing end portion of the plunger can extend beyond the trailing end of the inserter with a portion of the device extending beyond the leading end of the inserter, whereby the trailing end portion of the plunger can be pulled further out of the inserter to pull the device through force carried by said severable connecting means further into said inserter to assume a more linear configuration for said device curved portion, the device being expelled out of the inserter to assume its normal shape by pushing on the exposed trailing end portion of the plunger to move it back into the inserter.

2. A placement unit as claimed in claim **1** further comprising a sealed package with the tubular inserter, the plunger and the intrauterine device therein, with the plunger and intrauterine device situated in a beginning position with the trailing end portion of the plunger extending beyond the trailing end of the inserter so that the trailing end portion of the plunger can be grasped.

3. An intrauterine assembly as in claim **1** wherein the said severable connecting means is located outside of said inserter when the device has been expelled from the inserter into the uterus in a position where said connecting means can be severed.

4. A combination according to claim **3** further comprising an enlargement comprising a free leading end of the device.

5. A combination according to claim **4** wherein the enlargement rests upon and projects beyond the leading portion of the inserter when in the loaded position.

6. A combination according to claim **3** wherein the severable connecting means comprises a tension-transmitting thread.

7. A combination according to claim **3** wherein the severable connecting means comprises an elongated coupling piece adapted to transfer both tensile and compressing forces between the device and the plunger without appreciable deflection.

8. A combination according to claim **3** wherein the severable connecting means comprises a relatively thin cord of material which transmits tension to enable the plunger to load the device within the inserter by pulling upon the plunger and buckles under compression so that the force of ejection caused by pushing upon the plunger will first collapse and gather the cord and thereafter cause the device to be displaced.

9. An intrauterine assembly as in claim **1** wherein said severable connecting means joins the leading end portion of the plunger to a trailing end portion of the device.