United States Patent [19]

Nolan

[11] **3,842,826**

[45] **Oct. 22, 1974**

[54] **INTRAUTERINE CONTRACEPTIVE DEVICE AND INSERTER THEREFOR**

[76] Inventor: **John L. Nolan,** c/o Hollister Incorporated, 211 E. Chicago Ave., Chicago, Ill. 60611

[22] Filed: **Oct. 25, 1972**

[21] Appl. No.: **300,748**

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

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

[58] **Field of Search** 128/127, 128, 129, 130, 128/330, 260, 263, 264, 265, 345, 5; 81/15.5, 15.7

[56] **References Cited**

UNITED STATES PATENTS

3,241,554	3/1966	Coanda	128/350
3,374,788	3/1968	Rosenthal	128/130
3,467,089	9/1969	Hasson	128/130
3,511,231	5/1970	Robinson	128/130
3,515,132	6/1970	McKnight	128/130
3,777,748	12/1973	Abramson	128/130

Primary Examiner—Richard A. Gaudet
Assistant Examiner—G. F. Dunne
Attorney, Agent, or Firm—Hofgren, Wegner, Allen, Stellman & McCord

[57] **ABSTRACT**

An assembly of a resiliently collapsible intrauterine contraceptive device (IUD) and a disposable inserter for positioning the device in the uterus of a patient, including a flexible plastic tube for holding the IUD in relaxed expanded condition before use and for holding the IUD in collapsed linear form for insertion, a rod reciprocable in the tube for ejecting the IUD from the tube, a severable string connecting the rod and the IUD, a sleeve on the tube, and a scale on the tube for cooperation with the sleeve to indicate the depth of penetration of the sleeve into the uterus.

7 Claims, 9 Drawing Figures

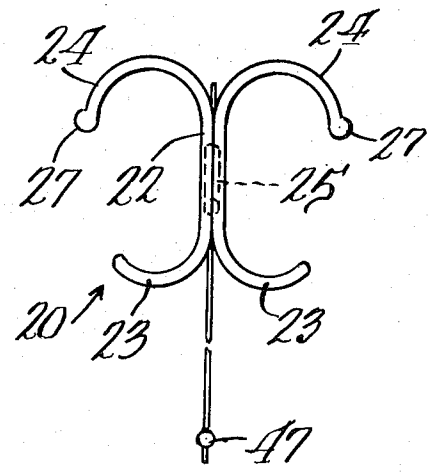


Fig. 1.

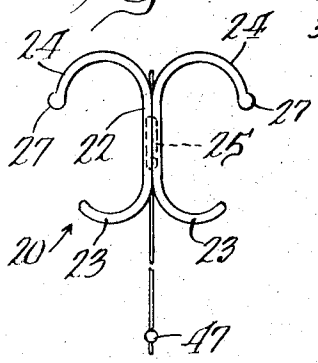


Fig. 2.

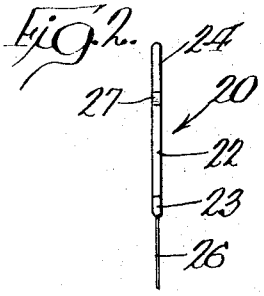


Fig. 3.

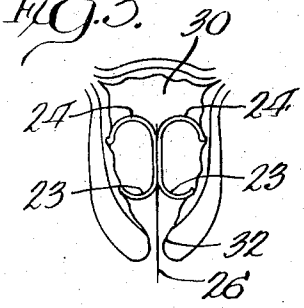


Fig. 4.

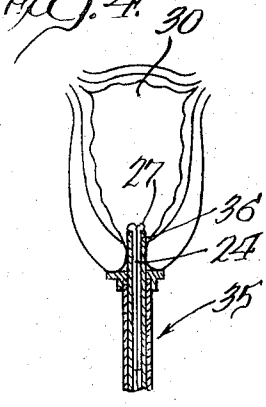


Fig. 5.

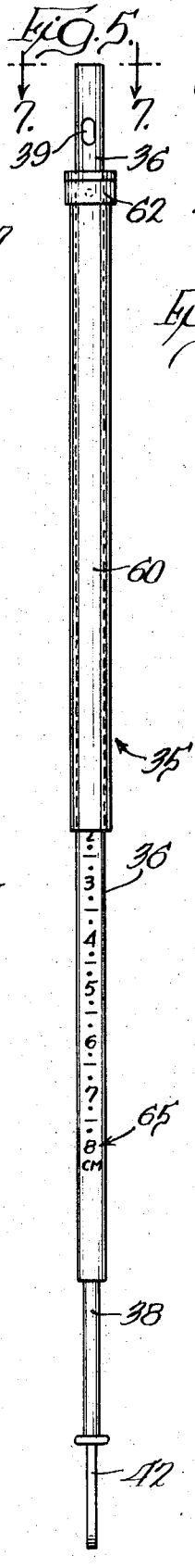


Fig. 6.

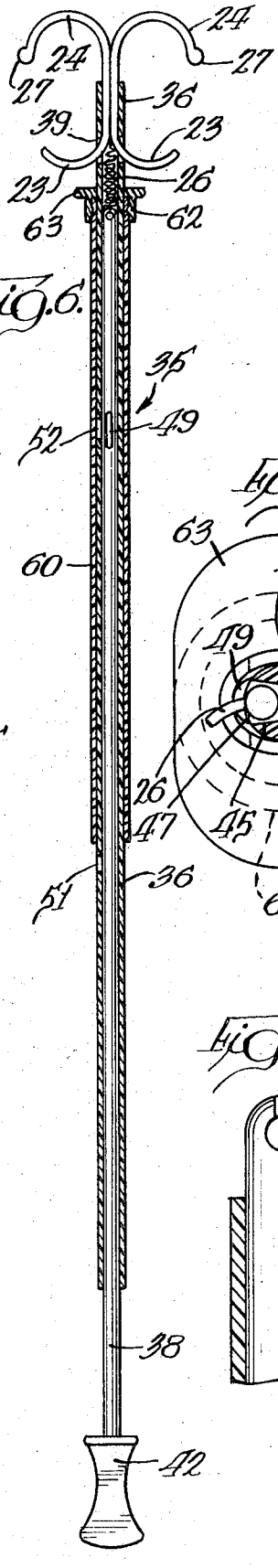


Fig. 7.

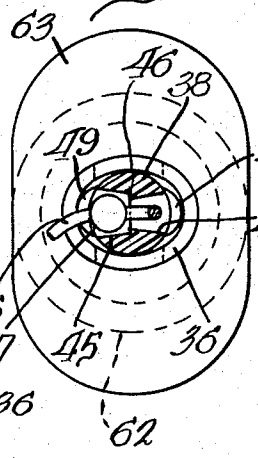


Fig. 8.

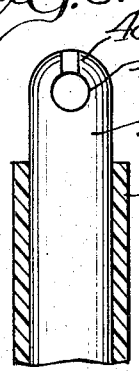
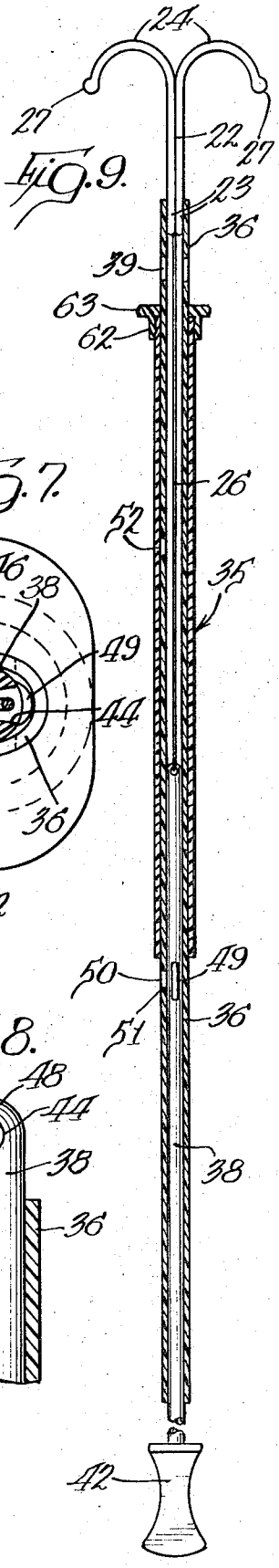


Fig. 9.



INTRAUTERINE CONTRACEPTIVE DEVICE AND INSERTER THEREFOR

BACKGROUND OF THE INVENTION

This invention relates to an intrauterine contraceptive device (IUD) in association with an inserter for positioning the IUD in a uterus.

In recent years, the growth of population throughout the world has been the subject of considerable discussion. For various reasons, it has been the position of many that the rate of births ought to be planned in a way such that the welfare of all people is improved. As a result, much attention has been directed toward various birth control methods and means.

Among birth control devices, the interauterine contraceptive device (IUD) has become established as a reasonably reliable and relatively inexpensive device. It has a long life in place, and after installation it requires no forethought in use, and is not subject to failure due to inaction on the part of the patient. It is thought that the function of such devices is to influence the uterus to assume an attitude of rejection. In any event, pregnancy is prevented. In order to obtain the desired results, IUD's have been made in various shapes and various materials have been utilized.

Among the problems encountered in use of IUD's are the problem of initial insertion, the possibility of inadvertent expulsion, the problem of host intolerance, and penetration of the device into the surrounding tissues of the uterus. Prior U.S. Pat. No. 3,467,089 relates to an IUD including an elongated stem with a pair of resilient wings at each end of the stem and an inert plastic exterior surface. The device is resiliently collapsible for initial insertion, after which it expands in a manner to prevent inadvertent expulsion. A wire core is utilized for desired rigidity, and the plastic exterior surface is nontoxic.

It is desirable to simplify the process of insertion of the IUD into the uterus.

SUMMARY OF THE INVENTION

The present invention relates to an improved intrauterine contraceptive device which is particularly constructed to simplify insertion into the uterus, together with an inexpensive inserter which may be provided with the IUD and discarded after use.

The IUD is made of flexible plastic material and includes a central stem portion and a pair of flexible outwardly extending wings at each end of the stem, together with a string having one end molded into the stem portion and extending from one end thereof to facilitate use of the IUD with an inserter and later serve as a means for indicating the presence of the IUD in the uterus.

In a preferred form, the IUD is made of resilient plastic material and includes a central relatively stiff stem portion and a pair of flexible wings at opposite ends of the stem extending laterally to opposite sides.

The improved inserter includes an elongate tube adapted to receive an IUD in collapsed linear form, an elongate rod reciprocable in the tube to expel the contraceptive device, and opposed apertures in the tube adjacent one end of the rod for permitting extension of resilient wings of a contraceptive device outwardly of the tube in relaxed condition during storage prior to use.

Preferably, the tube has an oval-shaped cross section and the rod in the tube has an approximately complementary cross section.

In the preferred embodiment illustrated, the tube is comprised of resilient material and permits the collapsed contraceptive device to be turned in the tube so that the wings are not aligned with the opposed apertures, and the IUD may be retracted almost completely into the tube.

The wings at one end of the IUD each have an enlargement at the free end thereof for limiting movement of the collapsed device into the inserter tube.

A sleeve is slidable on the tube, and a scale is provided in association with the sleeve to indicate the depth of penetration of the tube into the uterus preparatory to insertion of the IUD.

The improved contraceptive device and inserter are assembled into a unitary package in which a string connects the reciprocable rod and the contraceptive device for purposes of retracting the device into the tube. After the IUD is inserted into the uterus, the string is severed and the short portion may be retained for indicating the presence of the IUD in the uterus and for facilitating removal when that is desirable.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a plan view of an improved intrauterine contraceptive device according to the principles of the present invention;

FIG. **2** is a side elevation of the device illustrated in FIG. **1**;

FIG. **3** is a view illustrating the IUD in position in a uterine cavity;

FIG. **4** is a view showing the inserter positioned in the uterine cervix;

FIG. **5** is an elevational view of an inserter embodying the principles of the present invention;

FIG. **6** is a longitudinal sectional view of an assembly including the inserter and IUD of the present invention;

FIG. **7** is an enlarged end elevational view taken at about the line 7—7 of FIG. **5**, with an end portion of the rod shown in cross section;

FIG. **8** is an enlarged elevational view of an end portion of the rod; and

FIG. **9** is a longitudinal sectional view showing the inserter and the IUD preparatory to retraction of the IUD into the inserter in collapsed linear form.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENT

Referring now to the drawings in more detail, an intrauterine device **20** embodying the principles of the present invention includes a central stem portion **22** and laterally extending reversely curved wings **23** and **24** at opposite ends of extruded resiliently flexible plastic material such as polyethylene. The intermediate stem portion **22** is formed with similar wings **23** at one end and a pair of similar wings **24** at the opposite end. A relatively rigid molded line as stiffener **25** is secured on a flexible string **26** and molded in place in the extruded stem portion **22** so as to be incorporated in the device. The string may be comprised of flexible plastic material, such as twisted Dacron fibers, and functions as described presently. The stiffener **25** is made of relatively rigid plastic material, such as polyethyleneterephthalate (Dacron), and functions to stiffen the

stem portion and provide rigidity which assists in maintaining the shape of the device.

The wings **23** and **24** may be of generally circular cross-sectional configuration such that each wing has the shape of a curved strand or filament on the order of 1/16 of an inch in diameter. As seen in FIGS. **1, 6** and **9,** the ends of the wings **24** are formed with enlarged tips **27** which function to limit retraction of the collapsed device into the inserter, as will appear as the description proceeds. The wings **23** are shorter than the wings **24** in order to better fit in the narrower portion of the uterine cavity. While the IUD is described herein as an extruded unitary structure with the stiffener **25** and string **26** molded therein, it will be understood that the device may be made in other ways if desired.

Referring now to FIG. **3,** the IUD is intended to be utilized in a uterine cavity **30** where the relatively wide wings **24** are positioned deepest in the cavity near the point of entry of the fallopian tubes where the cavity is widest, while the narrower wings **23** are near the cervix **32.** Initially, the string **26** has a relatively great length, as seen in FIG. **9,** for example, for use in connection with the inserter, as will appear hereinbelow. After the IUD is positioned in the uterus, the string is severed to a desired length to provide an end portion immediately outside the entrance to the uterus, so that the string is indicative that the IUD is in place. It also serves as an aid in removing the device from the uterus.

The material of the IUD and the string embodied therein is nontoxic and compatible with the body tissues with which it comes in contact, as a result of which there is no problem of intolerance of the body to the material of the IUD.

As best seen in FIG. **4,** the IUD is inserted into the uterus in a collapsed linear form in which the wings **23** and the wings **24** are held in an inserter **35,** with only the enlarged tips **27** of the wings **24** projecting outwardly from the inserter. The inserter **35** includes a tube **36** which holds the IUD in collapsed form, and a rod **38** which is reciprocable in the tube **36** for forcing the IUD out of the tube and into the uterus while the tube is positioned in the cervix. The inserter tube **36** and rod **38** are preferably of plastic material with a moderate degree of resilient flexibility, such as polyethylene.

As seen best in FIG. **7,** the tube **36** has an oval cross section, and in the relatively flat sides of the tube near the distal end, there are opposed apertures as at **39** (FIG. **5**). As shown in FIG. **6,** the end portion of the tube **36** beyond the apertures **39** is adapted to receive the central stem portion of the intrauterine device, with the wings **23** of the device projecting outwardly through the apertures **39,** and the wing portions **24** located outwardly from the end of the tube **36.** In this manner, the IUD may be stored in the inserter for an indefinite period of time before use, with the wing portions **23** and **24** in relaxed extended positions where the resilience of the wings will be preserved. The IUD is positioned in the inserter as illustrated in FIG. **6** by first pressing the ends of the wings **23** together, manually for example, so they may be inserted into the tube **36** as shown in FIG. **9.** With the wings **23** in the tube **36,** and aligned with the apertures **39,** the IUD may be retracted from the position of FIG. **9** to the position of FIG. **6,** during which movement the wings **23** slide through the apertures **39** into the position of FIG. **6.** Alternatively, if the IUD is turned 90° in the tube **36** to the place where the wings **23** are no longer aligned with the apertures **39,** then the IUD may be completely retracted into the tube **36** to the position illustrated in FIG. **4,** where only the enlarged tips **27** of the wings **24** remain outside and limit further movement.

In order to eject the IUD from the tube **36** when the tube **36** is positioned in the cervix as illustrated in FIG. **4,** the plunger **38** is reciprocable in the tube **36** and includes an end portion outside of the tube with a handle as at **42.** The rod **38** is slightly longer than the tube **36,** and when the handle **42** abuts the lower end of the tube, viewed in FIGS. **5** and **6,** for example, the upper end of the rod **38** projects slightly outwardly of the upper end of the tube, as illustrated best in FIG. **8.** Thus, the rod is long enough to eject the IUD from the tube **36.** In order to facilitate retraction of the IUD into the tube to the position of FIG. **4,** preparatory to placement of the IUD in the uterus, the IUD is connected to the upper end of the rod by means of the string **26.** In order to facilitate attachment of the free end of the string to the upper end of the rod **38,** when the tip is positioned as shown in FIG. **8,** the end of the rod includes a transverse passage including a tapered entrance portion **44,** a relatively larger recess **45,** and a shoulder **46** between the recesses **44** and **45.** The free end of the string carries a small hard ball **47** molded thereon which may be forced through the entrance portion **44** and drawn back to the recess **45** against the shoulder **46** to retain the end of the string in the end of the rod **38.** So that the string may proceed axially in line with the rod **38,** the end of the rod is slotted at **48** so that the entrance portion **44** communicates with the end of the rod.

The rod **38** has a generally circular cross sectional configuration as illustrated best in FIG. **7,** but in order to yieldably restrain the rod against rotation in the tube **36,** it is provided with a pair of ridges at opposite sides as at **49.** The ridges **49** fit into the wide portions of the tube **36.** In order to releasably restrain the rod **38** against longitudinal movement in the tube **36,** the rod is formed with the projection **50** between the ribs **47.** When the IUD is to be pulled outwardly of the tube **36** from the position shown in FIG. **6** to the position shown in FIG. **9** for purposes of retraction thereafter to the position of FIG. **4,** the rod **38** is positioned in the tube **36** with the projection **50** in a recess **51** in the tube **36** so that the rod and string serve to restrain movement of the IUD beyond the position of FIG. **9.** In this manner, the wings **23** are retained in the tube against inadvertent removal, which would require careful manipulation to replace the device in the tube. With the IUD in the storage position illustrated in FIG. **6,** the rod **38** may be retained in a storage position with the projection **50** positioned in a second recess **52** in the tube **36** so that the rod is stored compactly.

In use, the IUD **20** and the inserter **35** may be assembled as shown in FIG. **6** for distribution as a unitary package. When the IUD is to be positioned in the uterus of a patient, the rod **38** is retracted from the storage position of FIG. **6** to the position of FIG. **9** where the projection **50** is disposed in recess **51** in tube **36.** At this time, stem portion **22** of the IUD may be grasped to pull the IUD outwardly of the tube **36** from the position of FIG. **6** to the position of FIG. **9** so that wings **23** are collapsed in the tube. Movement of the IUD outwardly is restrained by the string **26** and the rod **38,** with the projection **50** in recess **51.** With the

IUD positioned as shown in FIG. **9**, it may be turned 90° in the tube **36** so that the wings **23** are out of alignment with apertures **39**. Now, the rod **38** may be retracted still further to draw the IUD into the tube **36** to the position of FIG. **4**, where the wings **24** are collapsed and the enlarged tips **27** prevent further retraction. With the IUD thus fully collapsed into substantially linear form, it may be easily inserted into the uterus through the cervix by placing the end of the tube **36** in the cervix as shown in FIG. **4**, and ejecting the IUD by pushing the rod **38**. After insertion, the IUD is separated from the inserter by severing the string **26**, which thereafter serves to indicate the presence of the IUD and to aid in its removal when desired.

In order to aid in properly positioning the IUD in the uterus, a sleeve **60** is slidably mounted on the tube **36**. The sleeve includes a collar **62** at the end of the tube adjacent the IUD and the collar includes enlarged flanges **63** adapted to engage the tissue adjacent the cervix. In cooperation with the sleeve **60**, a scale is provided at **65** on the tube, and the scale begins at a place spaced from the distal end of the tube by an amount corresponding to the length of the sleeve. Thus, the remote end of the sleeve indicates a value on the scale **65** corresponding to the distance of the flanges **63** from the end of the tube **36**. In this manner, the scale indicates the depth of penetration of the tube into the uterus, so that the physician is able to position the contraceptive device properly in the uterus. The depth to which the tube should be inserted may be properly determined by use of the uterine sound described in the copending application of Hasson, Ser. No. 53,084, filed July 8, 1970, and assigned to the assignee of this application.

I claim:

1. A combined assembly including an intrauterine contraceptive device and inserter therefor comprising,

a. an intrauterine contraceptive device including a central elongated stem and a pair of outwardly extending resilient wings at each end thereof collapsible into linear alignment with the stem,

b. an elongate tube positionable in a uterine cervix and having an interior passage at one end thereof to receive the collapsed contraceptive device,

c. an elongate rod reciprocable in the tube having one end adapted to engage the contraceptive device in collapsed linear form for ejecting the device and an opposite end projecting from the tube for manual access,

d. a pair of opposed apertures in opposite sides of said tube adjacent said one end thereof for receiving a pair of resilient wings at one end of said stem extending outwardly in relaxed condition while the resilient wings at the opposite end of the stem extend outwardly from said one end of the tube, so that the contraceptive device may be stored in relaxed condition,

e. a string connecting the contraceptive device and said one end of the rod said tube being of resilient material and having an opening therein spaced from said opposed apertures, and

f. a lateral protrusion on said rod positionable in said opening for maintaining the rod in a position in which the string prevents complete removal of the contraceptive device from the tube, whereby said device may be pulled outwardly toward said one end of the tube to linearly align the first-mentioned pair of resilient wings, the device rotated 90° to misalign the said pair of wings with the apertures whereupon said rod may be moved outwardly of the tube to draw said device into said tube to align all of the wings linearly and position the device for insertion in the uterus.

2. For positioning an intrauterine contraceptive device including a central elongated stem with a pair of outwardly extending resilient wings at each end of the stem, an inserter comprising,

a. an elongate tube adapted to receive an intrauterine contraceptive device in collapsed linear form,

b. opposed apertures in said tube spaced from one end thereof approximately the length of the stem of the contraceptive device for permitting extension of resilient wings at one end of the stem outwardly in relaxed condition while resilient wings at the opposite end of the stem extend outwardly from said one end of the tube,

c. an elongate rod having one end reciprocable in the tube and an opposite end projecting from the tube and having a handle accessible for manipulation of the rod,

d. cooperating stop means on the rod and the tube to releasably hold the rod in a storage position,

e. flexible means secured to said device and to said rod having a length less than the distance between said one end of the rod with the rod in storage position and said one end of the tube to prevent the device from being withdrawn completely from the tube thereby limiting the outward movement of said device, said limited outward movement of the device serving to flex the wings at said one end from said relaxed position to linear alignment with said stem, said flexible means being operable on movement of said rod outwardly from the tube to draw said device into the tube to flex the wings at said opposite end into linear alignment with the stem, said rod being movable inwardly of the tube to eject the linearly aligned device into the uterus.

3. For positioning an intrauterine contraceptive device including a central elongated stem with a pair of outwardly extending resilient wings at each end of the stem, an inserter comprising,

a. an elongate tube oval in cross-section and adapted to receive an intrauterine contraceptive device in collapsed linear form,

b. opposed apertures in said tube spaced from one end thereof approximately the length of the stem of a contraceptive device for permitting extension of resilient wings at one end of the stem outwardly in relaxed condition while resilient wings at the opposite end of the stem extend outwardly from said one end of the tube,

c. an elongate rod round in cross-section and having one end reciprocable in the tube to eject a contraceptive device and an opposite end projecting from the tube and having a handle accessible for manipulation of the rod, and

d. a plurality of lateral projections on the rod generally conforming to the interior of the tube to oppose relative rotation between the rod and the tube.

4. An inserter as defined in claim **3**, wherein the tube is comprised of resilient material and has an opening

spaced from said opposed apertures, and said rod has a lateral protrusion positionable in said opening for maintaining the rod in the tube in storage position.

5. An inserter as defined in claim **3,** wherein the tube is comprised of resilient material which permits the linearly aligned contraceptive device to be turned in the tube so that the wings at said one end of the stem are not aligned with said opposed apertures and said device may be retracted into the tube.

6. For positioning an intrauterine contraceptive device including a central elongated stem with a pair of outwardly extending resilient wings at each end of the stem, an inserter comprising,

a. an elongate tube of flexible plastic material of oval cross section adapted to receive an intrauterine contraceptive device in collapsed linear form,

b. opposed apertures in said tube spaced from one end thereof approximately the length of the stem of a contraceptive device for permitting extension of resilient wings at one end of the stem outwardly in relaxed condition while resilient wings at the opposite end of the stem extend outwardly from said one end of the tube,

c. an elongate rod having cross section portions approximately fitting the tube and one end reciprocable in the tube to eject a contraceptive device and an opposite end projecting from the tube and having a handle accessible for manipulation of the rod, said tube having an opening therein spaced from said apertures, and

d. a protrusion on said rod positionable in the opening for releasably holding the rod in storage position in the tube, a measuring sleeve on said one end of the tube, and an indicating scale on the tube beginning at a position spaced from said one end of the tube by the length of the sleeve.

7. A combined assembly including an intrauterine contraceptive device and inserter therefor comprising,

a. an intrauterine contraceptive device including a central elongaged stem and a pair of outwardly extending resilient wings at each end thereof collapsible into linear alignment with the stem,

b. an elongate tube of flexible plastic positionable in a uterine cervix and having an interior passage at one end thereof adapted to receive the collapsed contraceptive device,

c. an elongate rod reciprocable in the tube having one end adapted to engage the contraceptive device in collapsed linear form for ejecting the device and an opposite end projecting from the tube for manual access,

d. a pair of opposed apertures in opposite sides of said tube adjacent said one end thereof for receiving a pair of resilient wings at one end of said stem extending outwardly in relaxed condition while the resilient wings at the opposite end of the stem extend outwardly from said one end of the tube, so that the contraceptive device may be stored in relaxed condition,

e. a string connecting the contraceptive device and said one end of the rod to retract the contraceptive device into the tube,

f. enlargements on the wings at said opposite end of the contraceptive device engageable with the tube to limit movement of the device into the tube, said tube having a first opening spaced from said opposed apertures and a second opening spaced from said first opening,

g. a protrusion on said rod engageable in the first opening for holding the rod in storage position and engageable in said second opening for maintaining the rod in a position in which the string prevents removal of the contraceptive device, and

h. a sleeve on said one end of the tube and a scale on the tube spaced from said one end by the length of the sleeve.

* * * * *