United States Patent

[11] 3,522,803

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[54] **INSERTER FOR INTRA-UTERINE DEVICE**
9 Claims, 8 Drawing Figs.

[52] **U.S. Cl.** **128/127,** 128/130
[51] **Int. Cl.** **A61f 5/46**
[50] **Field of Search** 128/127, 128, 129, 130

[56] **References Cited**

UNITED STATES PATENTS

2,086,344	7/1937	Weiner	128/127
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905,173	9/1962	Great Britain	128/130

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ABSTRACT: An insertion apparatus string method for inserting an intra-uterine device which has a string associated therewith into a uterus is provided, the apparatus having a hollow tube member open at both ends and a rod member having string securing means at one end thereof. The rod member is moveable in the hollow member from a first position in which the string is secured to the rod member and a second position in which the string is pulled through the hollow member to seat the intra-uterine device therein. The hollow member is then inserted into the uterus and moved relative to the rod member to cause expulsion of the intra-uterine device from the hollow member into the uterus.

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FIG. 1

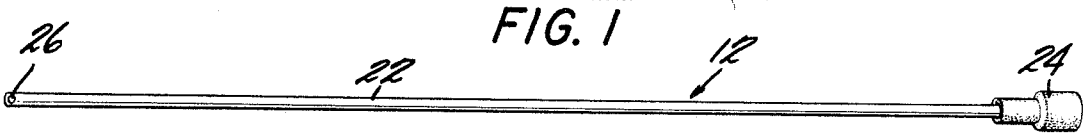


FIG. 2

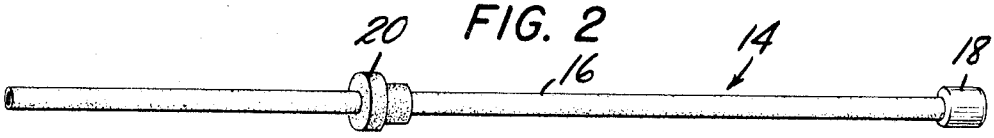


FIG. 6

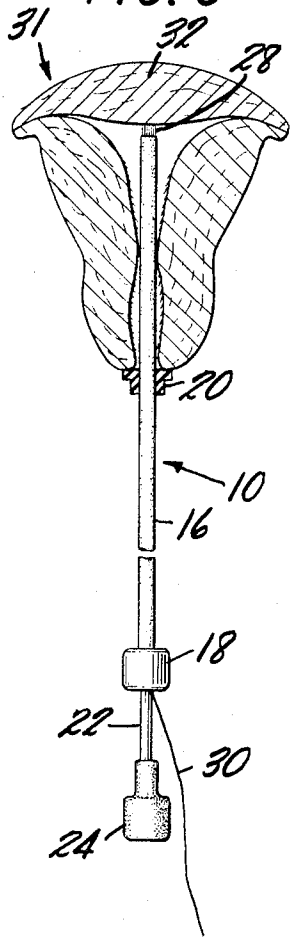


FIG. 7

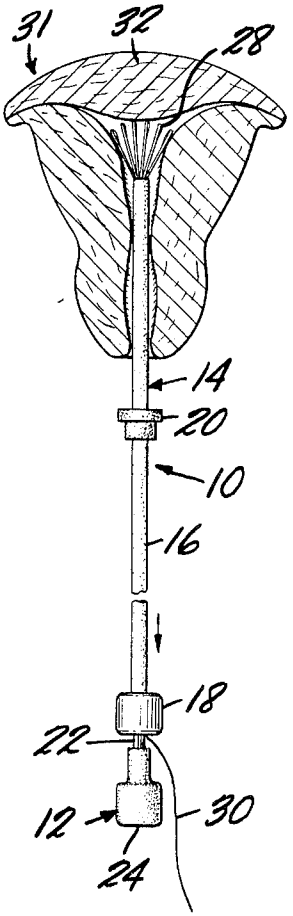
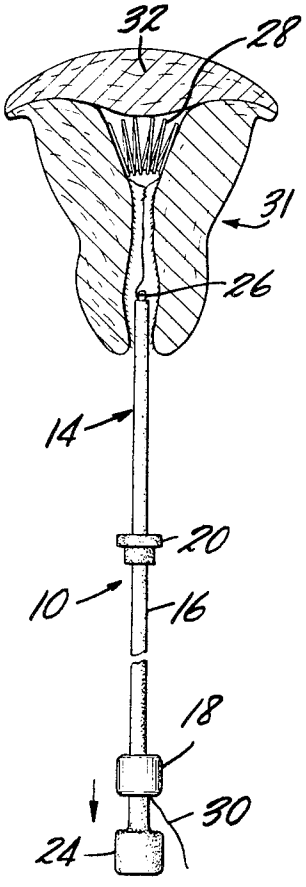


FIG. 8



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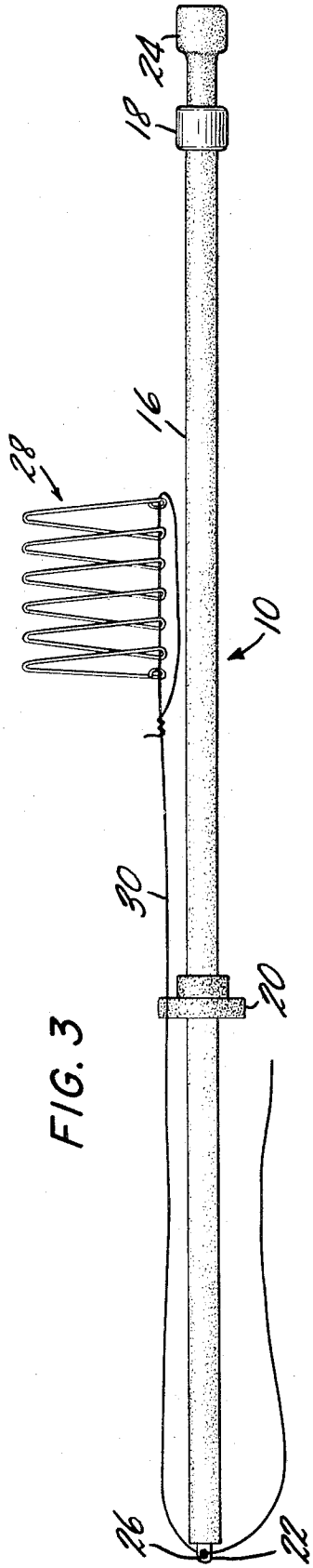

FIG. 3

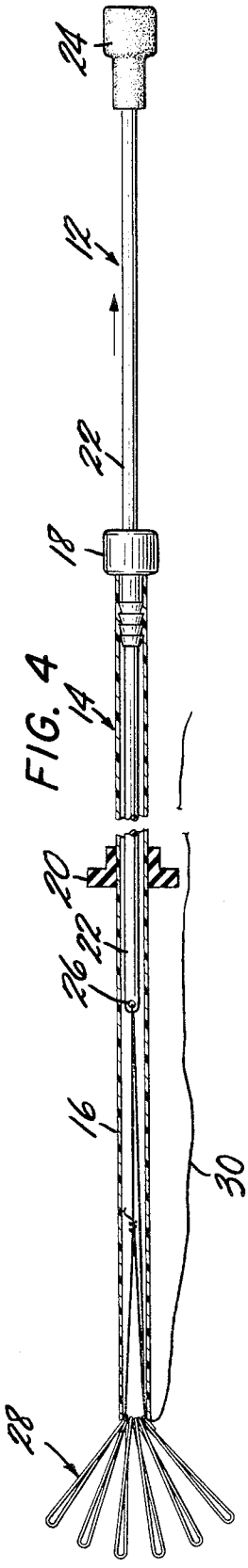

FIG. 4

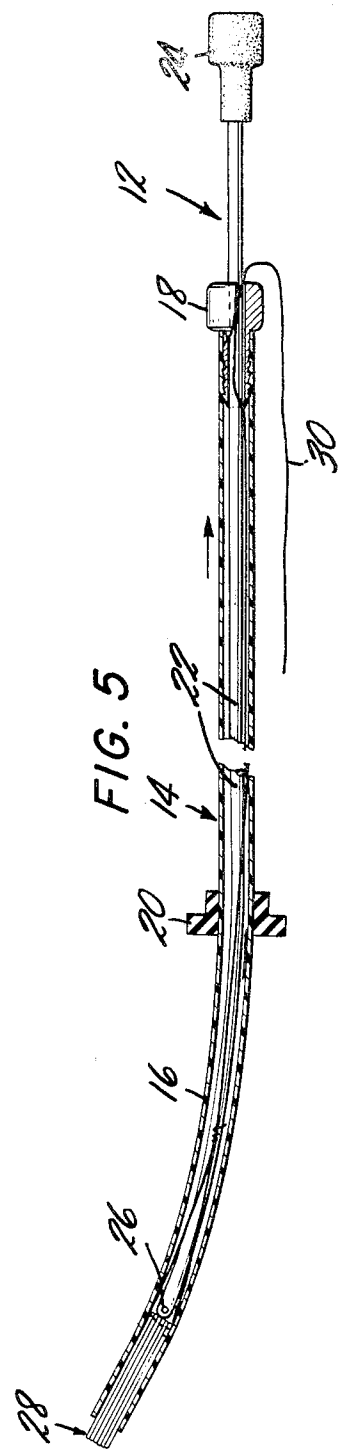

FIG. 5

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INSERTER FOR INTRA-UTERINE DEVICE

The present invention relates to an improved inserter for placing an intra-uterine device within the uterus and more specifically to an inserter apparatus which can be readily loaded with an intra-uterine device with a minimum of handling and inserted within the uterus without the risk of perforation of the uterine walls.

Heretofore, the standard inserter for placing intra-uterine devices within the uterus consisted of a cannula with plunger.

However one of the major drawbacks of this inserter is the difficulty in loading the intra-uterine device within the cannula. An intra-uterine device of the type of applicant's co-pending application Serial No. **554,765**, filed on June **2**, **1966**, requires the device to be collapsed by hand and forced into the cannula which is difficult and time consuming. The intra-uterine device of the type devised by Dr. Lippes requires that the device be stretched out into a straight line and then pushed into the cannula, which is also difficult to do and time consuming. These handling problems are of further disadvantage since they result in contamination of the intra-uterine device and require that the device, after loading on the cannula, be resterilized before insertion into the uterus.

The present invention overcomes the foregoing problems in that the inserter of the invention can readily be loaded with an intra-uterine device without requiring the doctor to touch the device itself and the sterile condition of the device is maintained.

The inserter of the present invention comprises a tube member and a rod member slidably seated in the tube member. At one end of the rod member a small eyelet is provided to receive a string attached to the intra-uterine device. The string is usually provided with all intra-uterine devices as a check to be sure the device is still in place and for easy removal of the device from the uterus when it is no longer desired.

The string is threaded through the eyelet in the rod member and the rod member is then drawn down and out from the tube. This draws the string completely through and out from the tube and fixes the intra-uterine device in place at the opposite end of the tube member. The rod member is then reinserted into the tube up against the loaded intra-uterine device. The loaded inserter is now ready to be placed in the uterus.

The rod member can be made of any sterilizable metal or plastic material which is deformable and yet has sufficient rigidity to force the intra-uterine device out of the tube without losing its shape. It has been found that rod members made from copper or brass are particularly useful since a doctor can bend the rod into a shape which conforms with the cervical canal of the patient. The tube member can be made from any plastic material such as but not limited to nylon and polyethylene. Again the material used for the tube must be able to withstand sterilization.

Another advantage of applicant's invention is the method of inserting the intra-uterine device into the uterus. With existing inserters, the loaded inserter is placed within the uterine cavity and the plunger pushed up to force the intra-uterine device out of the cannula into the cavity. This rapid expulsion of the device from the cannula can cause the device to perforate the uterine walls or cause a wrong orientation of the device in the uterus. In applicant's invention, the loaded inserter is placed in the uterus so that the intra-uterine device is up against the fundus. The tube is then drawn down upon the rod which will release the intra-uterine device very slowly into the uterine cavity. This method insures that the device will always be correctly oriented in the uterus and thereby prevents accidental expulsion of the device from the uterus or perforation of the uterine walls.

These and other features of the present invention are best understood by reference to the following drawings which show a preferred embodiment of the invention and of which:

FIGURE 1 shows the rod member of the improved inserter;

FIGURE 2 shows the tube member of the improved inserter having an adjustable stop member;

FIGURE 3 shows the assembled inserter having the string of the intra-uterine device threaded through the eyelet in the rod member;

FIGURE 4 shows a cross sectional view of the assembled inserter with the intra-uterine device being pulled into the tube member;

FIGURE 5 shows a cross sectional view of the inserter with the intra-uterine device in place in the tube member;

FIGURE 6 shows an inserter with an intra-uterine device placed within the uterus;

FIGURE 7 shows the intra-uterine device being released from the inserter; and

FIGURE 8 shows the intra-uterine device in place, within the uterine cavity.

Referring to **FIGURES** 1, 2 and 3, the inserter **10** comprises a rod member **12** and a tube member **14**.

The tube member **14**, consists of a sleeve **16** and a collar **18** which can be made of metal such as stainless steel or a plastic such as nylon. The collar **18** is affixed to one end of the sleeve **16** by conventional means, and forms the bottom of the tube member **14**. The other end of the sleeve **16** is smoothed to prevent any sharp edges being exposed to tissue when the inserter is placed in the uterus and forms the top of the tube member **14**. A stop member **20** is slidably seated on the sleeve **16** the importance of which will be discussed below.

The rod member **12** consists of a shaft **22** and a base **24** affixed to the shaft at one of its ends. An eyelet **26** is provided adjacent the other end of the shaft **22** as seen in **FIGURE** 1.

Referring to **FIGURES** 3and 5, the method of loading an intra-uterine device **28** into the inserter **10** can best be seen. The intra-uterine device shown in the drawings is the type described in applicant's co-pending application Serial No. **554,765**, filed on June **2**, **1966**. However, it should be understood that other types of intra-uterine devices can be placed within the uterine cavity with the present invention.

The inserter **10** is loaded by first seating the rod member **12** within the tube member **14** so that the base **24** abuts the collar **18** as shown in **FIGURE** 3. The rod member **12** is made slightly longer than the tube member **14** in order that the eyelet **26** extends beyond the end of the sleeve **16** (See **FIGURE** 3). A string **30** forming part of the intra-uterine device is threaded through the eyelet **26**. The rod member **12** is then withdrawn from the tube member **14** to draw the string **30** through and out the bottom of the tube member **14**. The string **30** is then pulled to seat the intra-uterine device **28** in the top portion of the tube member **14**. It is preferred that the intra-uterine device **28** is not completely seated within the tube **14** but that a small portion of the intra-uterine device **28** is protruding above the top of the tube member **14** as shown in **FIGURE** 5. This will prevent the natural tendency of the plastic sleeve **16** from enclosing the intra-uterine device **28** which results when the device is seated below the top of the sleeve **16**. The rod member **12** is then reinserted into the tube member **14** being sure that the string **30** remains in an extended position shown in **FIGURE** 4. If the string **30** is not completely extended it may be difficult to force the rod member **12** through the tube member **14**. The rod member **12** is pushed through the tube member **14** until it is up against the intra-uterine device **28** as shown in **FIGURE** 5. The inserter **10** is now loaded and ready for use. Before loading the inserter **10**, it has been found that if the unloaded inserter is first placed in the uterus the rod member can be bent to approximate the shape of the cervical canal and the stop member **20** positioned on the sleeve **16** so that the inserter **10** can only be moved into the uterus a specified distance. The above procedure will expedite the insertion of the intra-uterine device with a loaded inserter with almost no discomfort to the patient.

The method of placing the intra-uterine device **28** within the uterine cavity can best be seen from **FIGURES** 6 through 8. Referring to **FIGURE** 6 the inserter **10** is placed within the uterus **31** until the intra-uterine device **28** touches the fundus **32**. The stop member **20** also prevents the inserter from being moved any further. The tube member **14** is then moved down

upon the rod member **12** until the collar **18** meets the base **24**. As the tube member **14** is moved down upon the rod member **13**, the intra-uterine device **28** will be released slowly into the uterine cavity as shown in **FIGURE 7**, but without any movement of the device coaxially with the longitudinal axes of the tube and rod members. The device remains stationary in the coaxial direction and the edge of the tube member slowly moves coaxially away from the device until the device has been completely released out of the tube member. After the intra-uterine device **28** is free of the inserter **10**, which will occur when the collar **18** is in contact with the base **24**, the inserter is removed from the uterus **31** leaving the intra-uterine device in place within the uterine cavity. The string **30** is then cut to the proper size completing the process. Because the intra-uterine device is placed up against the fundus and remains stationary in the coaxial direction during its gradual release from the inserter, there is no tendency for the device to assume an improper orientation within the uterine cavity. This is in marked contrast to conventional inserters in which the device is moved coaxially up out of a cannula into the space of the uterine cavity without restraint of any kind and hence the device frequently assumes improper positions which allow its expulsion by the contractions of the uterine walls.

It will be clear from the foregoing description that the invention provides an improved inserter for placement on intra-uterine devices within the uterine cavity with a minimum of effort and time and a method for inserting an intra-uterine device within the uterus with maximum safety against perforation of the uterus wall and insures proper orientation of the intra-uterine device within the uterus. It is intended to cover all changes and modifications of the preferred form of structure herein chosen for the purpose of illustration which do not constitute departures from the spirit and scope of the invention.

I claim:

1. An apparatus for inserting an intra-uterine device into a uterus, said device having a string associated therewith for easy removal of said device from the uterus, the apparatus comprising a hollow elongated member open at both ends and a rod member, said rod member having string securing means at one end thereof and being adapted for movement within said hollow member from a first position in which said string securing means extends out from one end of said hollow member to receive said string and to a second position in which the string securing means is removed from the other end of said hollow member to pull both said string through said hollow member and conjointly pull and compress said device into the one end of said hollow member, and to a third position in contact with said device to cause the ejection of said device into the uterus upon relative movement of said rod member further toward the first position.

2. The apparatus specified in Claim **1** further comprising a stop member slideably mounted on said hollow member for limiting the depth of insertion of said hollow member into the uterus.

3. The apparatus specified in Claim **1** wherein said hollow member is made of a flexible material and said rod member is made of a material which is deformable.

4. The apparatus specified in Claim **1** further comprising a base member mounted on one end of said rod member, said base member being adapted for engaging said other end of the hollow member when said rod member is in said first position.

5. The apparatus specified in Claim **1** wherein said rod member is made of copper.

6. The apparatus specified in Claim **1** in which said rod member is made of brass.

7. A method for inserting an intra-uterine device which has a string associated therewith into a uterus by use of a push rod and a hollow insertion apparatus open at both ends comprising the steps of:

a) inserting said device into one end of said apparatus with the string extending out of the second end thereof, and then

b) inserting one end of said push rod into the second end of said apparatus,

c) inserting said apparatus into the uterus, and

d) pushing said device out of said insertion apparatus and into the uterus.

8. The method specified in Claim **7** further including the steps of:

a) moving said device into the uterus until it contacts the fundus of the uterus,

b) maintaining said device in position against the fundus, and

c) moving the insertion apparatus out of said uterus to release said device into said uterus.

9. The method specified in Claim **7** further including the step of conforming the insertion apparatus to the shape of the cervical canal prior to inserting said device.