

[54] **INSERTER FOR INTRAUTERINE DEVICE**

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Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 308,596, Nov. 21, 1972, Pat. No. 3,880,156.

- [52] U.S. Cl. 128/130
- [51] Int. Cl.² A61F 5/46
- [58] Field of Search..... 128/127, 130, 260

[56] **References Cited**

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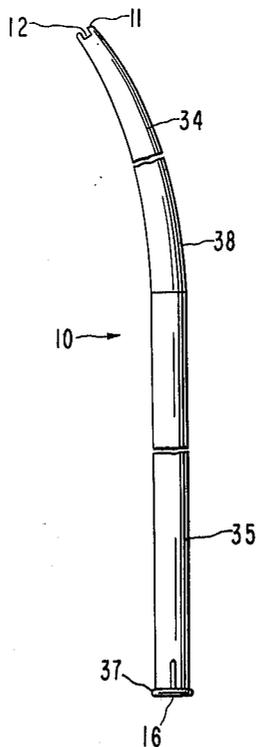
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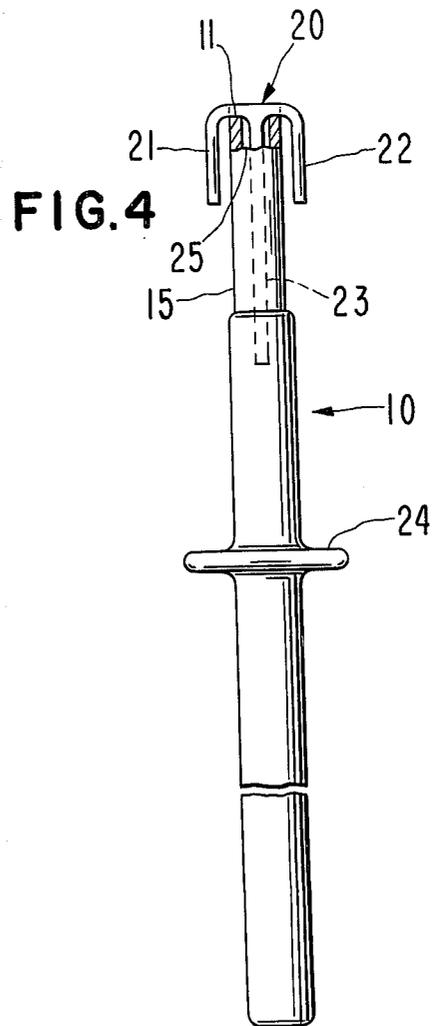
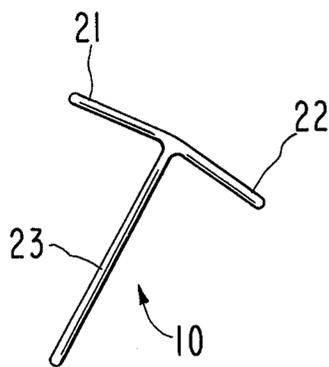
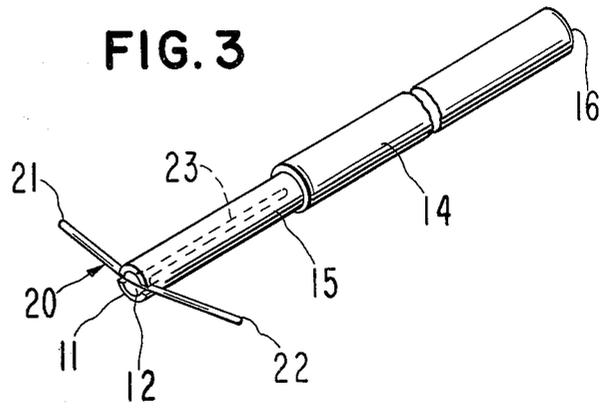
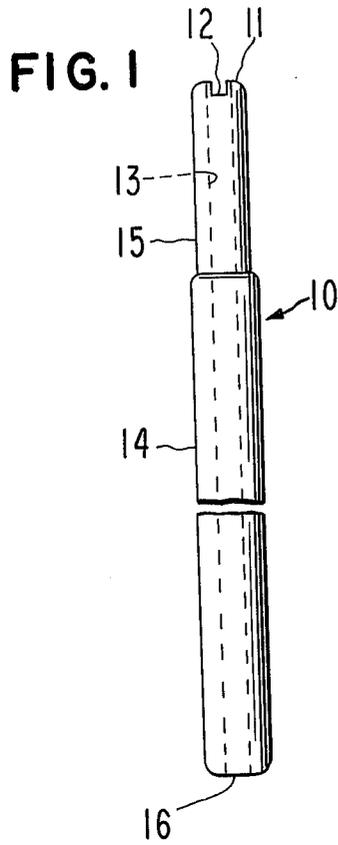
Primary Examiner—Lawrence W. Trapp
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[57] **ABSTRACT**

An inserter for an intrauterine device is disclosed. The inserter is comprised of a leading end and a trailing end with the leading end formed as a tapered section or a section having a smaller cross-sectional area than the trailing end. The leading end is notched and has a hollowed internal area for receiving a part of a device in cooperation with the notch and the exterior of the tapered or smaller section that is adapted to receive in axial alignment the remainder of the device in nested relation with the inserter. The inserter-intrauterine device combination provides an assembly of reduced volume that permits easy movement through the cervical canal into the uterus for effectively positioning the device.

11 Claims, 13 Drawing Figures





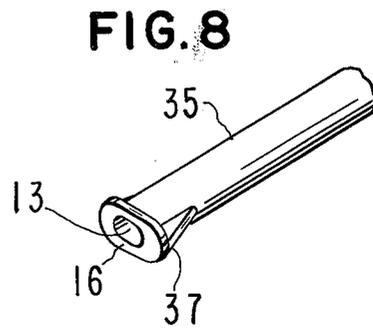
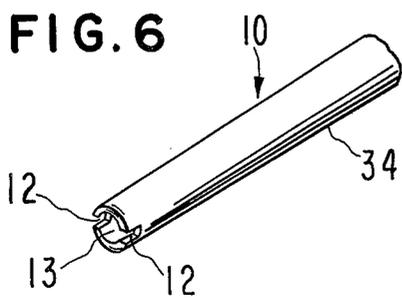
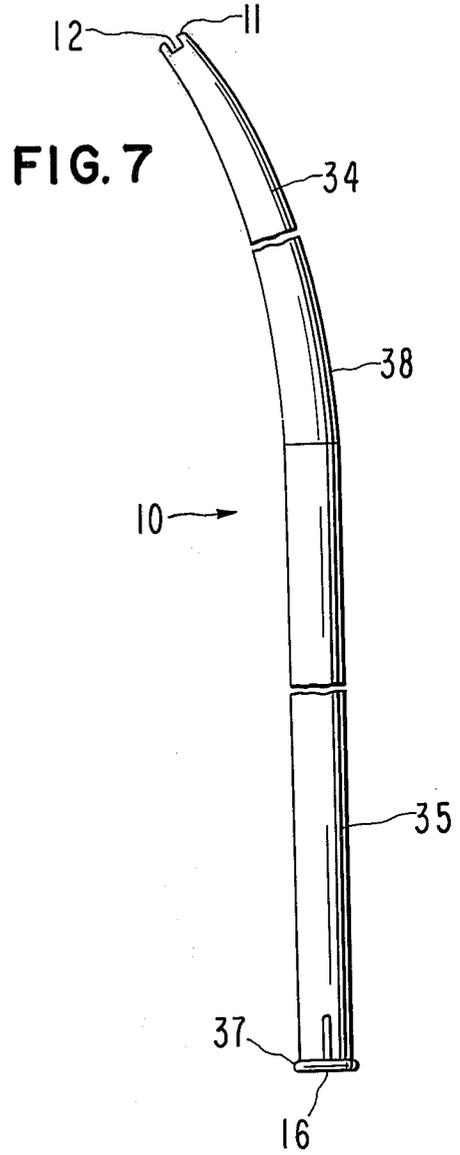
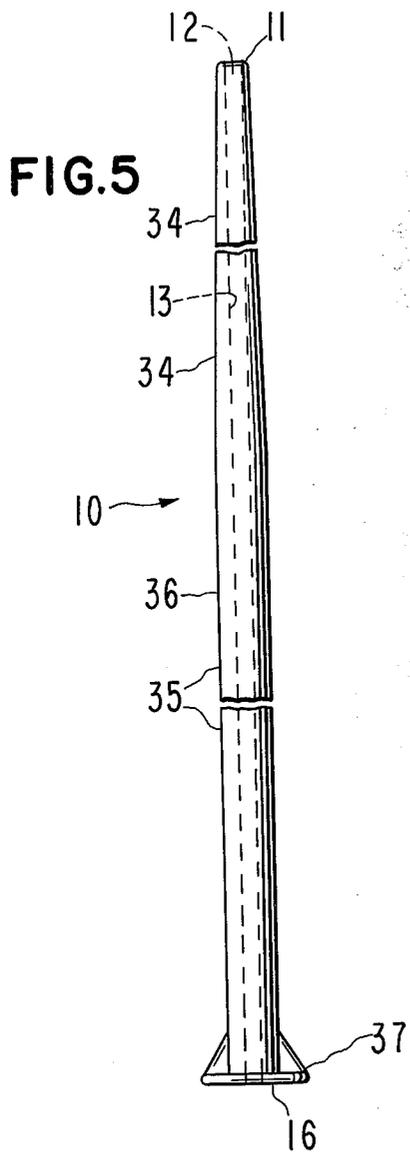


FIG. 9

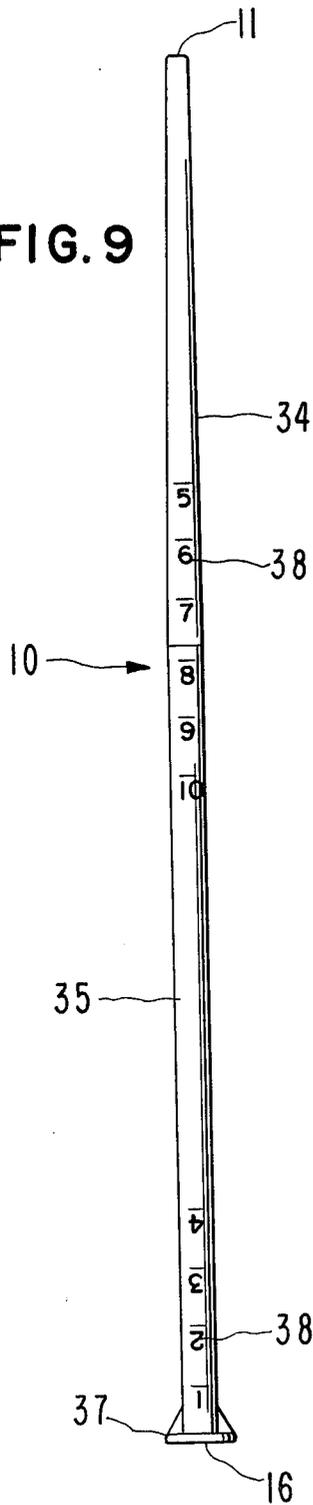


FIG. 10

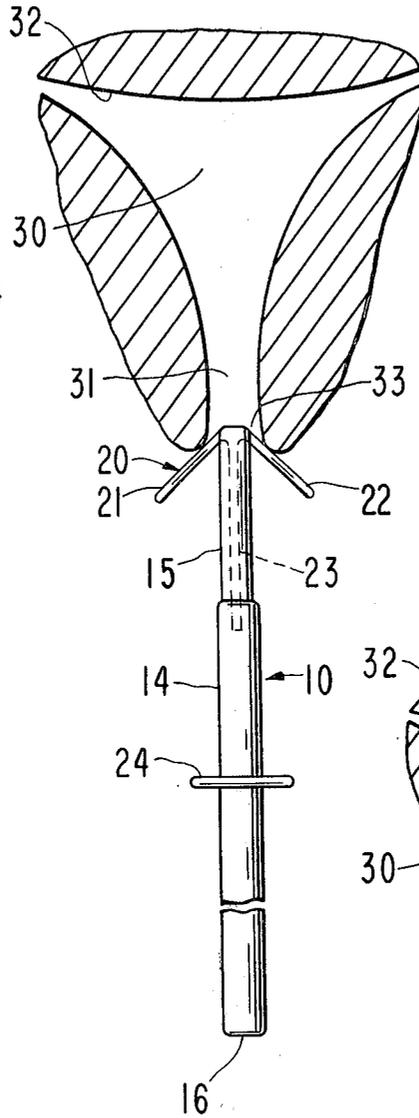
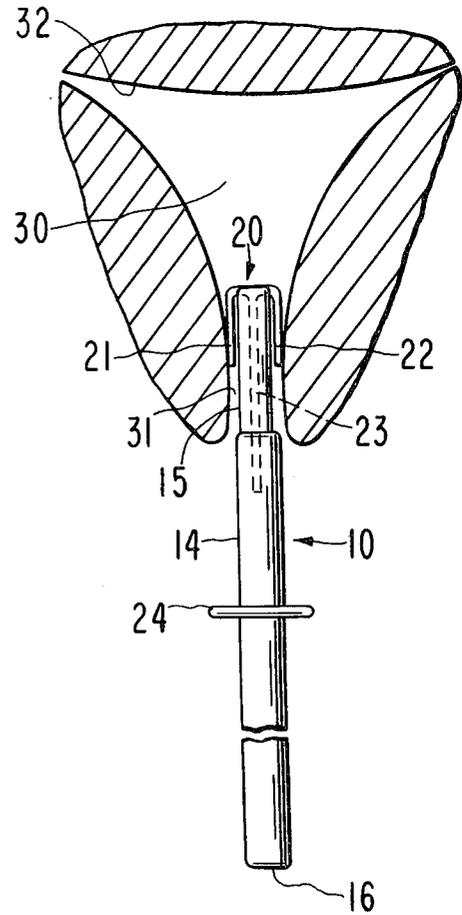


FIG. 11



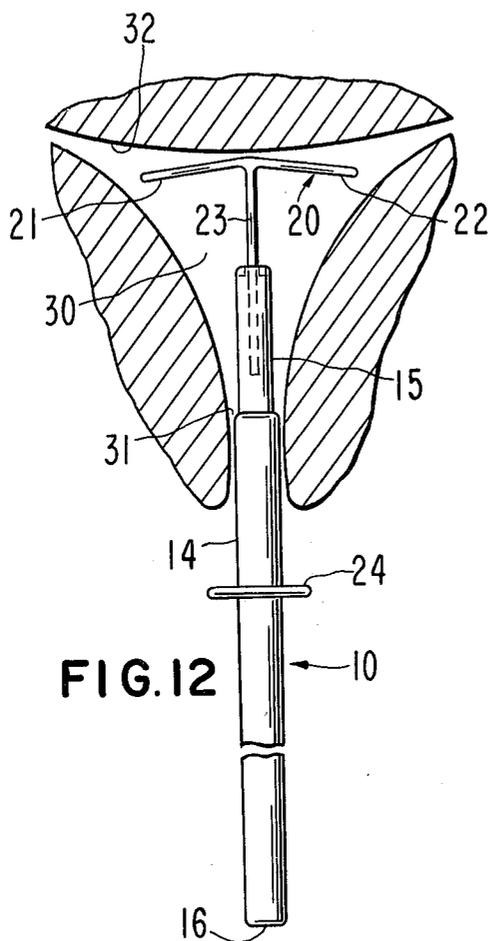
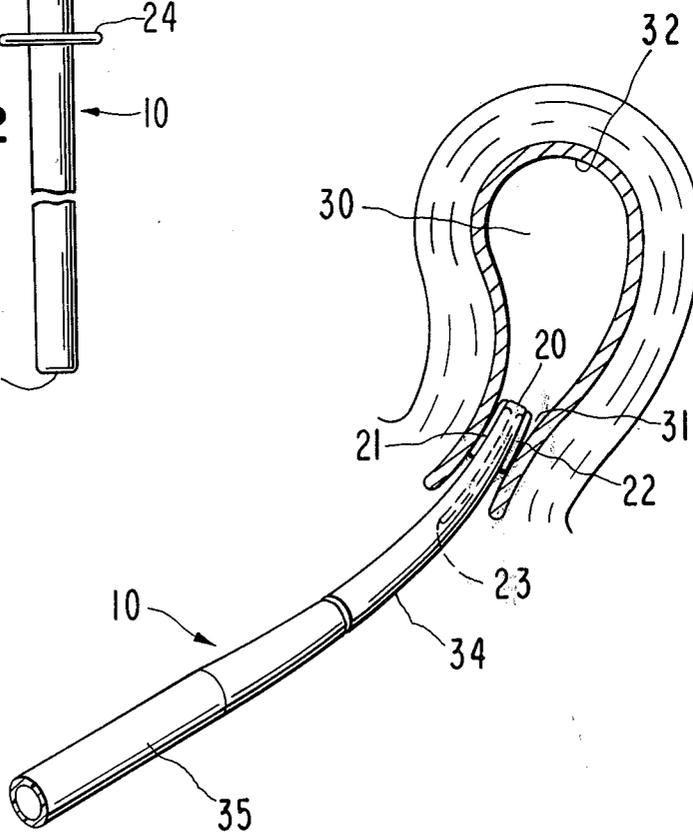


FIG. 12

FIG. 13



INSERTER FOR INTRAUTERINE DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Pat. application Ser. No. 308,596, filed Nov. 21, 1972 now U.S. Pat. No. 3,880,156, which application was assigned to the same assignee as this application.

BACKGROUND OF THE INVENTION

The present invention relates to a novel and useful inserter for placing an intrauterine device within a uterus. More specifically, the invention relates to an improved inserter which can be easily loaded with an intrauterine device with little handling and inserted within the uterus for easily positioning an intrauterine device in the uterus with both a minimum of trauma and risk of perforation of the uterine wall.

Inserters for placing an intrauterine device in a uterus are known to the prior art. Generally, these inserters were of various shapes and they consisted of two pieces: a tube or cannula and a plunger or rod. While these inserters have enjoyed wide usage, several major disadvantages were associated with their use. For example, one disadvantage is that the inserters were hard to load because they required that the intrauterine device be collapsed and completely forced into the cannula which is often time-consuming and difficult. Another disadvantage inherent in the two-piece inserters is that they require a high degree of manual dexterity to assure that the intrauterine device is effectively pushed from the cannula without changing the preselected shape of the device. The major disadvantage associated with the use of a two-piece inserter is that they do not provide for the automatic self-release of the device from the inserter in the uterus. That is, with a two-piece inserter, it is always necessary that the device be pushed from the inserter with the rod. Frequently, the rod is pushed too far which leads to perforation of the uterine wall. Additionally, these prior art assemblies comprised of an inserter and device, have a large volume, and when they are presented to the cervical canal and the uterus, there is a resultant unwanted incident of pain and trauma accompanying their use.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide an inserter for placing an intrauterine device in the uterus that overcomes the disadvantages associated with the prior art.

It is a further object of the invention to provide an inserter for placing an intrauterine contraceptive device in a mammalian uterus which inserter is easily loaded, is easy to handle, and easy to use for positioning the intrauterine device in the uterus.

Another object of the invention is to provide an inserter for holding an intrauterine contraceptive device which inserter self-releases the device in the uterus as the inserter is withdrawn therefrom.

Yet still another object of the invention is to make available to the art a novel and useful inserter that can be used with safety and with a minimum of risk of perforation of the uterine wall.

Still a further object of the invention is to provide an inserter that can be easily manufactured from either a disposable material or from a material that lends itself to repeated use.

It is another object of the invention to provide an inserter that can be easily removed after placing a device in the uterus.

Yet another object of the invention is to provide an inserter that has a smaller volume thereby requiring a space smaller than the cervical os and the cervical canal to substantially lessen the incident of pain and trauma associated with placing within the uterus an intrauterine device.

Still another object of the invention is to provide an inserter having a tapered lead section to reduce the dimensions presented to the cervical os and canal during insertion of an intrauterine device.

These objects, as well as other objects, features and advantages will become more readily apparent from the following detailed description, the drawings and the accompanying claims.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, which are not drawn to scale, but rather are set forth to illustrate various embodiments of the invention, the figures are as follows:

FIG. 1 is a view illustrating the improved inserter of the invention.

FIG. 2 is an illustration of one type of intrauterine device that can be placed in a uterus with the inserter of the invention.

FIG. 3 illustrates an intrauterine device nested in a notch located in the leading end of an inserter.

FIG. 4 illustrates an intrauterine contraceptive device nested in the inserter.

FIG. 5 shows a side view of an inserter having a tapered lead section.

FIG. 6 depicts the lead end of a tapered inserter with a pair of notches.

FIG. 7 is another side view of a tapered inserter with a curved lead section.

FIG. 8 illustrates the trailing end of an inserter.

FIG. 9 illustrates a tapered inserter with numbers.

FIG. 10 depicts a method of placing an intrauterine contraceptive device in a uterus illustrating an inserter intrauterine contraceptive device combination with the arms of the device moving toward the smaller area of the inserter as the combination enters the cervical os.

FIG. 11 illustrates in combination an inserter and intrauterine device with part of the device nested in the inserter and the remainder thereof linearly received by the smaller end of the inserter.

FIG. 12 is a sketch of the inserter of the invention positioning an intrauterine contraceptive device in a uterus as the inserter is withdrawn therefrom.

FIG. 13 illustrates in combination a tapered inserter and intrauterine device as the combination moves through the cervical os and canal.

In the drawings and specification, like parts in related figures are identified by like numbers. The terms appearing earlier in the specification and in the description of the drawings, as well as embodiments thereof, are further described elsewhere in the disclosure.

DETAILED DESCRIPTION OF THE INVENTION

Turning now to the drawings in detail, which are examples of the article of manufacture of the invention and which are not to be construed as limiting, one embodiment of an inserter is indicated in FIG. 1 by the numeral 10. Inserter 10 is a tubular member or rod member having a leading end 11 and a trailing end 16. Inserter 10 at leading end 11 has a receiving area 12,

shaped like a notch, a half square, a half rectangle, a half circle, or other geometric configuration suitable for holding and freely releasing an intrauterine device. Inserter 10 at end 11 has an internal hollowed area 13 continuous with recess area 12 for slidably receiving within the inserter an intrauterine device not shown in FIG. 1. Hollowed area 13 is seen in dashed lines and it can have various embodiments. For example, in an inserter manufactured from a tubular material hollowed area 13 can extend the length of the inserter, as seen in FIG. 1, or in an inserter manufactured from a rod-like material hollowed area 13 internally extends at least a distance continuous from the recess area, not shown in FIG. 1, sufficient to internally house and easily release an intrauterine device.

Inserter 10 in FIG. 1 is further uniquely characterized as comprised of two integrally formed sections with each section having a different diameter. That is, inserter 10 has a section of larger diameter 14 and a section of smaller diameter 15 that merge to form a single-piece inserter 10. Larger diameter 14 extends substantially throughout the length of the inserter from the trailing end 16 to the point where it merges with the section of smaller diameter 15. Smaller diameter 15 is of a smaller circumference and occupies a lesser amount of space since it is designed for closely receiving parts of an intrauterine device, not seen in FIG. 1. This closeness or effective use of space facilitates the advance of the device through the cervical os and the cervical canal with positioning in the uterus of the intrauterine device, while at the same time it minimizes the likelihood of injury or pain which frequently occurs with prior art devices. That is, inserter 10, at area 15, has smaller dimensions, thereby requiring a smaller space as the inserter travels through the cervical os, the cervical canal into the uterus.

FIG. 2 illustrates a conventional intrauterine device that can be easily and efficiently positioned in a uterus with inserter 10 of the invention. In FIG. 2, there is depicted an intrauterine device 20 shaped like a T, and it is similar to the T described in U.S. Pat. No. 3,533,406. The T is comprised of a top crossbar having a left and right member identified by 21 and 22, with the bar about 2 to 5 cm in length and a depending member or leg 23 of about 2 to 5 cm in length. The inserter of the invention can be used for inserting a T of the solid filament type or for inserting a T intrauterine device that contains at least one antifertility agent that is administered from the T. While the T is a presently preferred embodiment for use with inserter 10, it is to be understood that inserter 10 can be used with other intrauterine devices for placing them in a uterus; that is, intrauterine devices shaped like an arrow, the number seven, and devices having a part that can be housed in the hollowed area and a part that can rest in the notch.

FIG. 3 illustrates another view of inserter 10 of the invention. In FIG. 3 there is seen inserter 10, formed of a single, unit piece of biologically acceptable material. Inserter 10 is comprised of notch 12 holding an intrauterine device 20 comprised of cross members 21 and 22 continuous with shaft 23. Shaft 23 is slidably housed in the leading end and hollowed section 13 of inserter 10. Device 20 is positioned in notch 12 and the smaller section 15 of inserter 10.

FIG. 4 illustrates an intrauterine device 20 housed in an inserter 10. Inserter 10 is similar to the inserter of FIG. 1 and it has an additional embodiment illustrated

in FIG. 4 of a stop member or collar 24. Inserter 10 in FIG. 4 is about 20 to 30 cm long and member 24 is spaced about 4 to 8 cm from lead end 11. Member 24 aids in preventing unnecessary penetration beyond the cervical canal and this reduces the likelihood of injury to a warm blooded uterus. In FIG. 4 at leading end 11, a section of wall 25 is removed for illustrating device 20 received in notch 12. Top crossbars 21 and 22 of device 20 are seen nested against smaller area 15 for decreasing the volume of the inserter 10 intrauterine device 20 assembly. Top crossbars 21 and 22 nested against smaller area 15 in side-by-side generally linear relation present a smaller volume to the cervical os and the cervical canal during insertion and positioning of intrauterine device 20. The smaller section 15, which uniformly extended along a part of the inserter, is a means adapted for receiving the intrauterine device has in the embodiment shown a length of about 1 to 3 cm. Depending member 23 of device 20 is illustrated by dashed lines and it is housed in hollowed area 13 as seen in FIG. 1. Device 20 is freely nested therein, and it is easily, slidably released from inserter 10.

Turning now to FIG. 5, there is seen an inserter 10 comprising a tubular member having a leading end 11 and a flanged 37 trailing end 16. Inserter 10 at leading end 11 has a pair of notches 12, not shown in FIG. 5, for receiving, holding and freely releasing an intrauterine device therefrom. Inserter 10 is hollowed, 13, for receiving within inserter 10 an intrauterine device, not shown in FIG. 5.

Inserter 10 of FIG. 5 is further characterized as comprised of two sections, a tapered section 34 and a non-tapered section 35. Tapered section 34 starts at lead end 11 and extends towards non-tapered section 35 and trailing or rear end 16. Non-tapered section 35 is of uniform diameter and it extends from trailing end 16 towards leading end 11 to the point where it merges with tapered section 34. Tapered section 34 occupies a lesser amount of space than non-tapered section 35 and it is designed for closely receiving parts of an intrauterine device, not seen in FIG. 5, in close, intimate contact to inserter 10. This closeness or effective use of the exterior space facilitates the advance of device 10 through the cervical canal with subsequent placement of an intrauterine device in the uterus, while simultaneously reducing the possibility of injury and pain which frequently occurs with prior art devices.

FIG. 6 illustrates another view of inserter 10 of FIG. 5. In FIG. 6 there is seen the top portion of tapered section 34 comprised of a pair of receiving notches 12 leading to hollowed area 13. Notches 12 are in the wall of tubular member 10 at the terminus of tapered section 34, and they are in faced relation or laterally positioned, and of sufficient depth to engage and orient the transverse member of an intrauterine device. FIG. 7 illustrates tapered inserter 10 curved at its leading section for easier insertion into a uterine cavity. Curved, tapered inserter 10 of FIG. 7 corresponds to the straight, tapered inserter of FIG. 5 as it too is made of non-toxic, uterine acceptable materials and adapted to present a small inserter to the reproductive area. FIG. 8, taken through 8-8 of FIG. 7 illustrates trailing end 16 comprised of a flanged member 37 and a hollowed area 13. Flanged member 37 is optionally used to receive a butter-fly plug, not shown, when a plug is inserted into hollowed area 13 to secure a thread, not shown, that travels through inserter 10 from an intrauterine device in leading end 11. FIG. 9 illustrates a tapered inserter

10 with indicia 38, or numbers, used for sounding a uterus for determining by art known techniques if an intrauterine device is properly positioned therein.

FIGS. 10, 11, 12 and 13 collectively illustrate a method for using inserter 10 for positioning intrauterine contraceptive device 20 in a uterine cavity 30. In FIG. 10, inserter 10 is seen loaded with intrauterine device 20 and inserter 10 carries device 20 in nested relation to inserter 10. In actual operation, inserter 10 is first gently moved against the cervical os 33 that blends and leads into cervical canal 31. Members 21 and 22 of intrauterine device 20 initially are spread in open T formation and abuts inserter 10. As inserter 10 enters cervical os 33, members 21 and 22 move toward smaller area 15 of inserter 10 to eventually position in axial alignment with inserter 10.

In FIG. 11, inserter 10 slidably carrying intrauterine contraceptive device 20 is seen traveling through cervical canal 31 in route to uterus 30. In FIG. 11, members 21 and 22 are now positioned in side-by-side linear relation with inserter 10. Members 21 and 22 are in proximate contact with the wall of inserter 10 in smaller area 15 which area 15 is a means adapted for receiving members 21 and 22. This novel design of the invention, comprised of the inserter-intrauterine device combination presents a smaller volume to the cervical canal and substantially reduces the incident of pain and trauma. Members 21 and 22 are held in smaller area 15 by the walls of the cervical canal until the inserter enters uterus 30. In uterine cavity 30 members 21 and 22, free from the influence of the cervical wall return to their original T spaced relation.

In FIG. 12, there is seen inserter 10 positioning an intrauterine contraceptive device 20 in uterus 30. In this illustration, members 21 and 22 are now in their original open spaced T form. In actual insertion of an intrauterine device, inserter 10 is gently moved through uterus 30 until intrauterine device 20 contacts fundus uteri 32. Then, inserter 10 is easily withdrawn from uterus 30, while simultaneously slidably self-releasing and positioning intrauterine device 20 in uterus 30. Inserter 10 is finally, totally withdrawn from the host.

In FIG. 13, there is seen a curved and tapered inserter 10 carrying intrauterine device 20 through cervical canal 31 to uterus 30. In FIG. 13, members 21 and 22 are positioned in side-by-side mated relation with the exterior, tapered section of inserter 10. Members 21 and 22 are in close contact with the wall of inserter 10 at its tapered section which is a means adapted for receiving 21 and 22. The novel, curved and tapered inserter preferably has a curved and tapered section corresponding to the female, mammalian reproductive system including multiparous, primiparous and nulliparous uteri. The combination inserter-intrauterine device presents a diminished volume to the system to reduce the incident of pain and trauma. Members 21 and 22 are held in tapered section 34 by the walls of cervical canal 31 until inserter 10 enters uterus 30. In uterine cavity 30, members 21 and 22 are freed from the influence of the cervical wall and they return to their original T shaped relation. Inserter 10 is withdrawn as described in FIG. 12.

Inserter 10 of the invention can be manufactured from any suitable material, and the material can be of naturally occurring or synthetic origin. Exemplary materials include poly(olefins) such as poly(ethylene), poly(propylene), nylon, or any suitable commercially available plastic, surgical steel, or the like. The inserter

can be made by techniques standard in the art such as parison forming, extrusion, casting and the like. Inserter 10 is about 20 to 50 cm long with the larger section having a diameter of about 4 to 8 mm, and the smaller and tapered section having a diameter of 2 to 3.5 mm, with the length of the smaller or tapered section about 12 to 20 mm. Of course these dimensions are representative of presently preferred inserters, and other inserters of larger or smaller dimensions in like proportions and like structure are within the scope of the invention.

It will be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in carrying out the above method and in the article set forth without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying figures shall be interpreted as illustrative and not in a limiting sense.

I claim:

1. An inserter for an intrauterine device comprising a transverse member and a leg member depending therefrom, the inserter comprising:

- a. an elongated tapered tubular member having a leading section and a trailing section distant from the leading section;
- b. a pair of notches in the terminus of the tubular member at its leading section, said notches adapted to orient and engage the transverse member of the device;
- c. a hollowed area extended within the tubular member of dimension such that the leg portion of the device can be introduced and positioned therein; and
- d. wherein the taper extends along the leading section of the member to exteriorly form a surface adapted to mate with the transverse member of the device when in collapsed configuration during the insertion of the device within the cervical canal and when the device is housed within the inserter.

2. An inserter according to claim 1 wherein the inserter has a stop on the member for limiting the depth of uterine penetration.

3. An inserter according to claim 1 wherein the inserter is curved along the leading tapered section.

4. An inserter according to claim 1 wherein the inserter is flanged at the trailing section.

5. An inserter according to claim 1 wherein the inserter has indicia on the trailing section thereof.

6. An inserter according to claim 1 wherein the inserter has indicia on its leading section thereof.

7. An inserter for an intrauterine device and an intrauterine device comprising in combination:

- a. a tubular member having a leading section and a trailing section and made from a biologically inert acceptable material;
- b. a pair of notches laterally positioned in the tubular member at the terminus of the leading section as a means for positioning and housing a part of the device;
- c. a hollowed area in the tubular member extended from the terminus of the leading section for internally receiving in cooperation with the notches a part of the device;
- d. a tapered section extended from the terminus of the leading section for exteriorly receiving in cooperation with the notches and the hollowed area a

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part of the device, and wherein the inserter houses;
 e. a device having a transverse member and a leg member depending therefrom with the leg member in the hollowed area and the transverse member in the notches.
 8. An inserter according to claim 7 wherein the transverse member is in the notches and downwardly positioned in nested relation along the tapered section of

the inserter.

9. An inserter according to claim 7 wherein the device is substantially in the shape of a T.

10. An inserter according to claim 7 wherein the taper increases in diameter towards the trailing end.

11. An inserter according to claim 7 wherein the taper is curved.

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