

[54] **DEVICE FOR OCCLUSION OF AN OVIDUCT**

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[51] Int. Cl. **A61b 19/00**

[58] Field of Search **128/1 R, 127, 130, 131, 341, 128/343, 303**

[56] **References Cited**

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[57] **ABSTRACT**

An occluding member, for being lodged in an oviduct where it narrows, e.g. at the junction between the ampulla and the isthmus, includes a tapered base portion and a narrowed forward portion. A suture attached to the occluding member is passed through an opening in the wall of the oviduct and is wrapped about the oviduct to occlude its walls against the forward portion of the occluding member. For inserting the occluding member, a separable rod passes the member through the inlet of the oviduct until it is lodged. Over the forward portion of the occluding member is temporarily positioned a suture guide, which holds the suture forward of the occluding member forward portion during positioning the occluding member and forms the opening in the wall of the oviduct. After the suture is drawn out of the oviduct through the opening in its wall, the suture guide is removed through the same opening in the oviduct wall.

19 Claims, 8 Drawing Figures

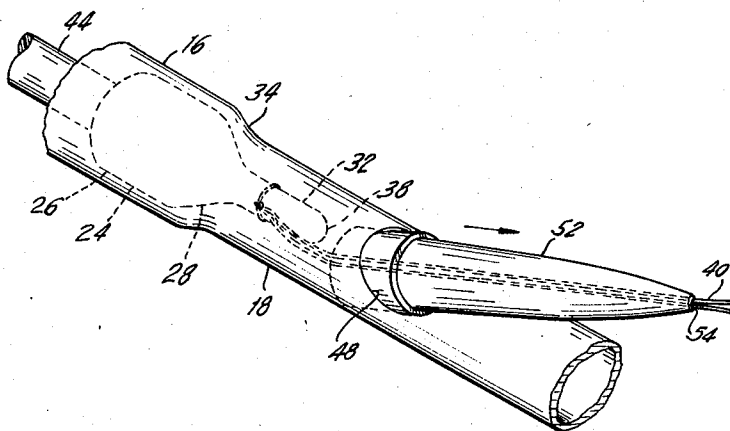


FIG. 1.

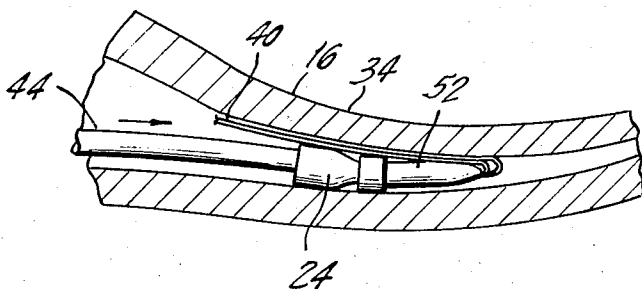
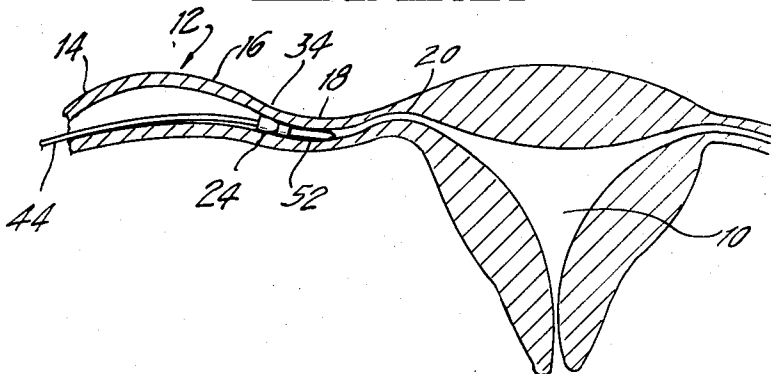


FIG. 2.

FIG. 3.

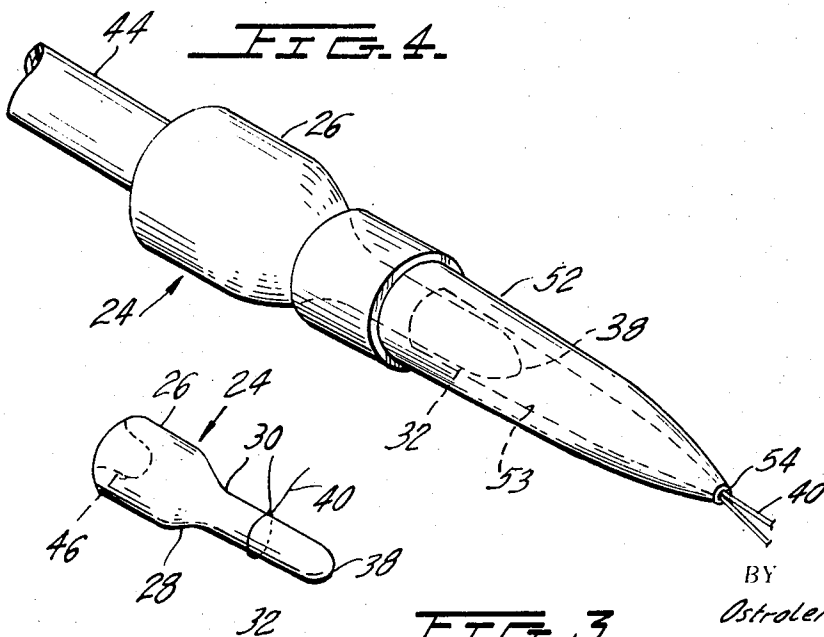
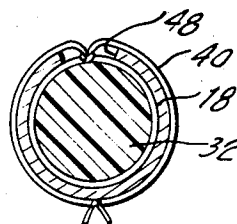
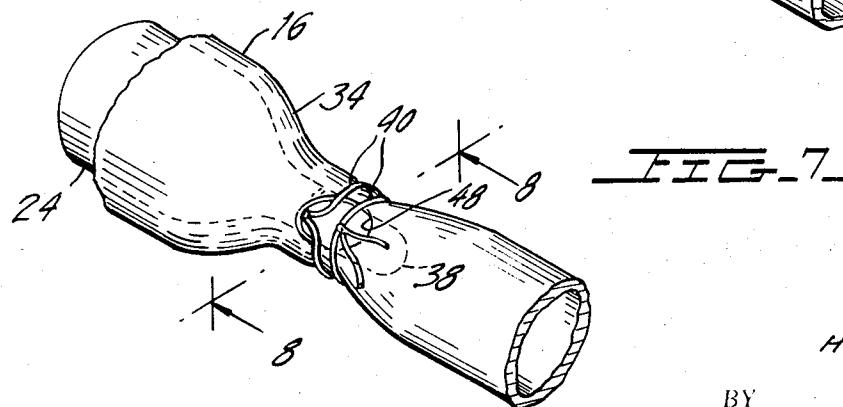
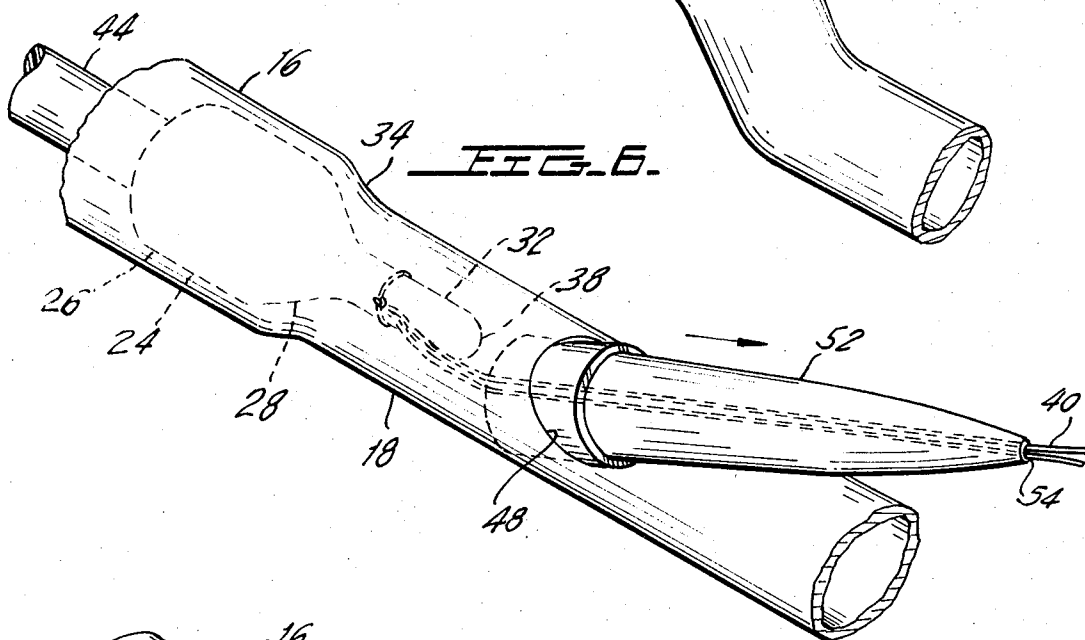
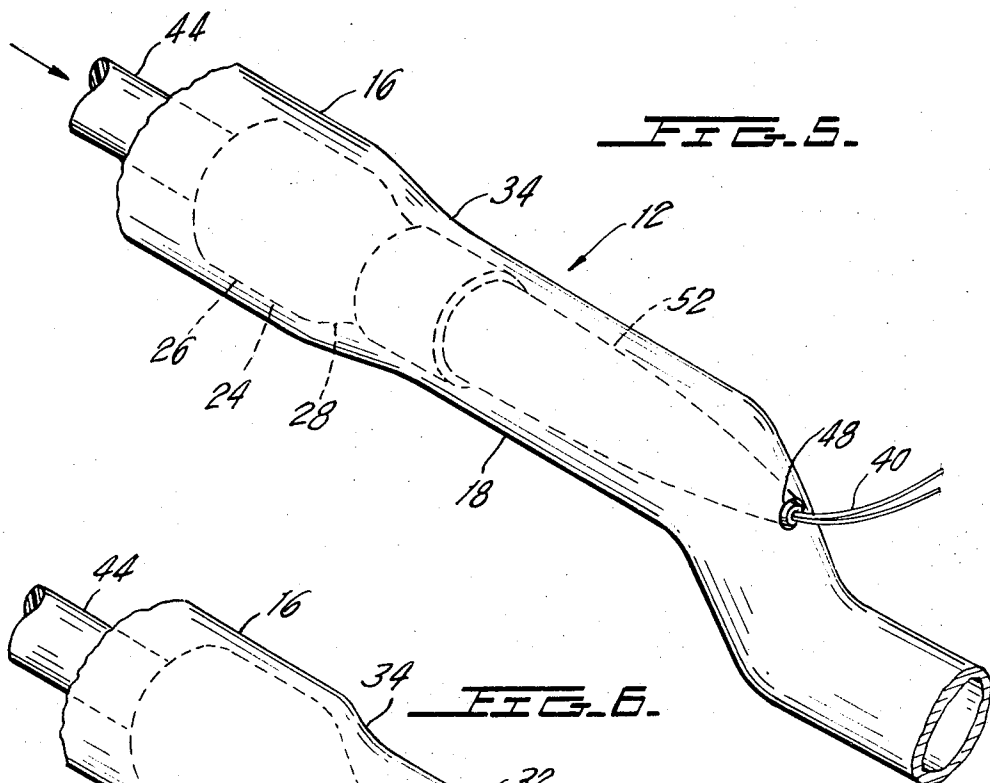


FIG. 4.

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DEVICE FOR OCCLUSION OF AN OVIDUCT

The present invention relates to temporary sterilization of a female, and more particularly to a device for occluding an oviduct and to a method of installation of a device for occluding an oviduct. While many mechanical devices are known for temporary sterilization of a female, including intra-uterine contraceptive devices, most of these devices are not held in the body of the female and may fall out without her knowledge. Furthermore, devices placed within the uterus may damage its sensitive walls or cause discomfort.

Another common technique for female contraception is to occlude or tie off the Fallopian Tubes or oviducts to prevent ova and sperm from passing therethrough. However, when an oviduct is occluded, its interior surfaces may adhere to each other, and the oviduct may be permanently and irrevocably sealed.

The present invention provides a mechanical means for temporarily sterilizing a female, which means cannot shift out of place without the female's knowledge. Furthermore, the device does not contact the uterus.

The temporary sterilization device comprises an occluding member to be located in the oviduct for blocking the passage of ova and sperm. The occluding member is so shaped as to be able to be lodged in a fixed position within the oviduct and is provided with a securing means, like a suture, which secures the interior walls of the oviduct against the occluding member, but not against each other, thereby preventing undesired irreversible oviduct wall adhesion.

The invention also comprises a novel method of inserting an occluding member in the oviduct. The occluding member is positioned on an insertion device. When the female's abdominal cavity has been surgically opened, e.g. after a Caesarian birth, the entire length of the oviduct is exposed to the surgeon. The insertion element is passed through the entrance of the oviduct, and the occluding member is moved through the relatively wide ampulla of the oviduct toward the narrower and more muscular isthmus of the oviduct. The occluding member is shaped so as to lodge in the oviduct where it narrows. It is intended that the occluding member usually lodge at the junction between the ampulla and the isthmus.

Secured to the occluding member is an occluding member securing means, e.g. a surgical suture, which is passed through an opening that has been formed by the surgeon in the wall of the oviduct. The securing means is then manipulated to occlude the walls of the oviduct about the forward portion of the occluding member.

A guide means for the occluding member securing means may be removably mounted on the occluding member, e.g. by being positioned over the narrowed forward portion of the occluding member. The securing means is held forward of the occluding member by the guide means. The above described opening through the wall of the oviduct is made at the forward position where the guide means holds the occluding member securing means. The forward end of the guide means is sufficiently sharp to be manipulated to punch the opening through the wall of the oviduct. First, the securing means, and then the guide means therefor, are pulled through the opening in the wall of the oviduct. The securing means then tightens the walls of the oviduct, as noted above. With the securing means having been carried forward by the guide means therefor, the act of

tightening the securing means about the occluding member draws the occluding member further into the oviduct and thereby ensures that the occluding member will be securely lodged in position.

After the occluding member has been moved into and lodged in position in the tube, the insertion element may be removed by being drawn out through the entrance to the oviduct.

For later removal of the occluding member, it is necessary to surgically open the female's abdominal cavity, to cut the securing means, which is holding the occluding member in position, and to then remove the occluding member by squeezing the walls of the oviduct against the occluding member to force it out through the oviduct until it appears at the open end of the oviduct.

Accordingly, it is a primary object of the present invention to provide an effective means for temporarily sterilizing a female.

It is another object of the present invention to provide such a device, which minimizes damage and discomfort to the user.

It is a further object of the present invention to provide such a mechanical device, which will not accidentally fall out of place.

It is a further object of the present invention to provide a means for occluding an oviduct without causing permanent blockage thereof.

It is a further object of the present invention to provide a method of occluding an oviduct.

These and other objects of the present invention will become apparent from the following description of the accompanying drawings, in which:

FIG. 1 is a schematic view of a portion of the female reproductive system, illustrating the invention in conjunction therewith;

FIG. 2 is an enlarged view of a portion of FIG. 1;

FIG. 3 is a perspective view of an occluding member in accordance with the invention;

FIG. 4 is a further enlargement of a portion of FIG. 2;

FIGS. 5-7 show three stages in the emplacement of an occluding member; and

FIG. 8 is a view of a secured occluding member in the direction of arrows 8 of FIG. 7.

Turning to the drawings, the relevant portions of the female reproductive system are schematically illustrated in FIGS. 1 and 2. Uterus 10 has Fallopian Tube or oviduct 12 leading into it. As is well known, an ovum (not shown) passes from the ovary (not shown) into the abdominal cavity (not shown) where it is sucked into the inlet, interstitial or intramural portion 14 of oviduct 12. From there, it passes through ampulla 16 and isthmus 18 and out the infundibulum 20 into uterus 10. Fertilization of an ovum will occur during its passage through oviduct 12. In order to prevent fertilization of the ovum, it is necessary to prevent sperm from travelling through the oviduct to meet an ovum and to prevent the ovum from travelling through the oviduct to meet sperm.

The present invention provides a novel occluding member 24 (FIG. 3) for occluding oviduct 12 so as to block the passage of both ova and sperm. Occluding member 24 is intended to be lodged and permanently held within the oviduct 24. Accordingly, it is comprised of a biologically inert material, such as a plastic materi-

al, like polytetrafluoroethylene, which is distributed under the trademark "TEFLON." Alternatively, the material might comprise a filled rubber material, based upon trifluoropropylmethylsiloxane units, a proprietary product marketed under the trademark "SILASTIC" by Dow-Corning Company, U.S.A. The occluding member must also be sufficiently rigid so that the oviduct walls can be occluded against it, as described below.

Member 24 has a substantially circular cross-section along its entire length and includes a base portion 26, which gradually inwardly tapers at neck 28 to merge at 30 into a thin, elongated forward portion 32. The width of base portion 26 is such that member 24 will lodge in the pathway through oviduct 12. A convenient location for such lodging is the junction 34 between ampulla 16 and isthmus 18, where the oviduct naturally narrows.

Secured to occluding member 24, back from its forward end 28, is a securing means 40 for securing member 24 within the oviduct and for also occluding the walls of the oviduct against the occluding member, so as to block the oviduct while preventing adhesion of its interior walls. The securing means is back from forward end 38 so that when the means is tightened, as described below, this will more securely lodge member 24 in position. Securing means 40 may comprise a biologically inert conventional surgical suture which is used, as described below, to securely tie the walls of the oviduct against the occluding member. The suture may be embedded in, wrapped about a groove around or merely tied securely to the occluding member.

For inserting occluding member 24, the abdomen of the female must be conventionally surgically opened. An insertion element, such as elongated rod 44 (FIGS. 1, 2, 4, 5), has occluding member 24 mounted on it. Most simply, occluding member 24 has a depression 46 (FIG. 3) in its base, which depression is so dimensioned as to frictionally receive and hold occluding member 24 on the end of rod 44. Rod 44 is semi-rigid. Occluding member 24 is passed through oviduct inlet 14 and is transmitted by rod 44 to its lodgement position (FIG. 2). The semi-rigid, straight rod temporarily straightens the curved oviduct, while rod 44 is within it. When member 24 has been moved to its lodgement position, rod 44 is separated from member 24 and is withdrawn through the entrance to the oviduct. (See FIG. 7). The removal may be immediately after insertion of member 24, but as illustrated in sequential drawings FIGS. 5-7, it is preferred that removal of rod 40 be deferred until after member 24 has been secured. The oviduct then reassumes its normally curved orientation.

For securing occluding member 24 within oviduct 12, suture 40 is passed through an opening 48 that has been cut in the wall of the isthmus in a manner described below. The suture is then pulled tight and wrapped about the exterior of the oviduct, as shown in FIGS. 7 and 8, and squeezes the interior walls of the oviduct securely about forward portion 32 of occluding member 24.

It is necessary that suture 40 be available to be grasped by the surgeon emplacing occluding member 24 after the occluding member has been lodged in the oviduct. Opening 48 through which suture 40 is passed is preferably slightly forward of the lodgement location of occluding member 24, whereby when suture 40 is

pulled, occluding member 24 is drawn securely into junction 34 of oviduct 12 and blocks the passage. To hold suture 40 forward of occluding member 24, guide means 52, comprising a hollow tube through which suture 40 is passed, has its hollow opening 53 fitted over forward portion 32 of occluding member 24 and seats upon tapering portion 28 of member 24. The suture extends out of and is held by the open narrowed forward end 54 of guide means 52. Forward end 54 is sufficiently rigid and sharpened as to be able to punch through the thin, relatively soft wall of the isthmus. End 54 cannot be so sharp, however, that it will accidentally cut through the wall at a location where this is not desired.

The procedure for effecting temporary sterilization includes the previously described steps of opening the abdominal cavity to expose the oviduct, mounting occluding member 24 on insertion rod 44, passing suture 40 through guide means 52, mounting the guide means on member 24 and moving member 24 into the oviduct.

Once occluding member 24 has been lodged in position at junction 34, opening 48 is formed in the wall of the oviduct. Either or both of the oviduct and guide means 52 within the oviduct is grasped and manipulated, by manipulation of rod 44 or twisting of oviduct 12, until guide means forward end 54 punches opening 48. (See FIG. 5)

Suture 40, which has been held forward by guide means 52, and forward end 54 of guide means 52 are drawn out of oviduct 12 through opening 48. (See FIG. 6). Guide means 52 is then shifted off forward portion 32 of occluding member 24, is drawn out of opening 48 and is then slipped off the suture. The suture is then wrapped about the oviduct and tied into position, as shown in FIGS. 7 and 8.

At some time after occluding member 24 has been lodged in position and suture 40 has been drawn through opening 48 and preferably before the suture is wrapped about the oviduct, insertion rod 44 is released from member 24 and removed from the oviduct.

When the walls of the oviduct are securely tightened about the forward portion of the occluding member, the oviduct is blocked against the passage of ova and sperm.

Since occluding member 24 is permanently lodged in the oviduct, to reestablish fertility, it is necessary to remove occluding member 24. The abdominal cavity of the female must be opened. Securing means 40 is released. Occluding member 24 is then removed by squeezing the walls of the oviduct against the tapered neck 28 of member 24 which shifts member 24 toward and eventually out of the open entrance into the oviduct, the same insertion rod 44 being passed through the oviduct and engaging the occluding member to facilitate its removal. Opening 48 is closed. Because the walls of oviduct 12 were never secured against each other, no adhesion of the walls will have occurred and full fertility should be readily restored.

Although this invention has been described with respect to the embodiments of the apparatus and method of the invention, it should be understood that many variations and modifications will now be obvious to those skilled in the art, and it is preferred, therefore, that the scope of the invention not be limited by the

specific disclosure herein, but only by the appended claims.

I claim:

1. A device for occluding an oviduct comprising, an occluding member having a base portion of a first width contoured to lodge in the oviduct and to be engaged by the walls thereof;

a securing means attached to said occluding member for being secured to said oviduct and for holding said occluding member in position;

a narrowed width forward portion narrower than said first width for extending into the oviduct; a forward end of said occluding member forward of said forward portion; said securing means being positioned and adapted to occlude the oviduct about said forward portion of said occluding member.

2. The occluding device of claim 1, wherein said occluding member is comprised of an inert material.

3. In combination, the occluding device of claim 1 and an insertion element for inserting said occluding member into the oviduct; said insertion element being removably secured to said occluding member and being separable therefrom upon completion of insertion.

4. The combination of claim 3, wherein said insertion element comprises an elongated rod of sufficient length to extend from the inlet of the oviduct to the location at which said occluding member is to be lodged.

5. The occluding device of claim 1, wherein said occluding member base portion has a tapering neck leading into said occluding member forward portion, whereby said occluding member lodges in the oviduct at the junction between the ampulla and the isthmus.

6. The occluding device of claim 1, wherein said securing means comprises a suture secured to said occluding member.

7. In combination, the occluding device of claim 1, and a securing means guide device removably secured to said occluding member;

said securing means being carried by said guide device into the oviduct so as to be positioned thereby for later securement of the securing means so as to enable said securing means to occlude the oviduct about said occluding member forward portion.

8. The combination of claim 7, wherein said guide device is structured and positioned to carry said securing means forward of said occluding member forward portion.

9. The combination of claim 8, wherein said guide device comprises a hollow tube which fits over said occluding member forward portion and includes a forward opening which is forward of said occluding member forward portion;

said securing means comprising a suture secured to said occluding member; said suture being passed through said guide device tube, and extending out of said forward opening for being held forward of said occluding member forward portion.

10. The combination of claim 9, wherein said guide device forward opening is defined by a forward end, which is sufficiently rigid and sharp to punch through the wall of the oviduct.

11. The combination of claim 9 and an insertion element for inserting said occluding member into the oviduct; said insertion element being securable to said occluding member and being separable therefrom upon completion of insertion.

12. A method of occluding an oviduct comprising the steps of:

passing an occluding member into the oviduct through its entrance; and

lodging the occluding member in the oviduct at the narrowing junction between the ampulla and the isthmus of the oviduct and blocking the oviduct with the occluding member.

13. The method of occluding an oviduct of claim 12, comprising the further step of securing the occluding member in the oviduct where it has lodged.

14. The method of occluding an oviduct of claim 13, wherein before being passed into the oviduct, the occluding member is positioned on an insertion rod;

the occluding member is passed into the oviduct by the rod being passed into the oviduct;

the insertion rod is separated from the occluding member after the occluding member has been lodged in the oviduct.

15. The method of occluding an oviduct of claim 13, wherein before being passed into the oviduct, the occluding member is provided with a securing means; and

after the occluding member is lodged in the oviduct, the securing means is secured to hold the occluding member in the oviduct.

16. The method of occluding an oviduct of claim 15, wherein the securing means is a suture;

an opening is made in the wall of the oviduct forward of the location where the occluding member is to be lodged;

after the occluding member is lodged in the oviduct, the suture is passed through the opening in the wall and is then wrapped about the oviduct to occlude the oviduct about the occluding member.

17. The method of occluding an oviduct of claim 16, wherein the suture is passed through a guide device which carries the free end of the suture forward of the occluding member as the occluding member is passed into the oviduct;

after the occluding member has been lodged in the oviduct, both the guide device and the suture are drawn through the opening in the oviduct wall, the guide device is then removed from the suture, and the suture is then wrapped about the oviduct to occlude it.

18. The method of occluding an oviduct of claim 17, wherein after the occluding member has been lodged in the oviduct, the oviduct and guide device are manipulated with respect to each other to cause the guide device to form the opening in the wall of the oviduct.

19. In combination, the method of occluding an oviduct of claim 15 and a method of removal of the occluding member;

the method of removal comprising the steps of releasing the securing means; and

squeezing the walls of the oviduct against the occluding member to force the member to shift out of the oviduct.

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