



(22) Date de dépôt/Filing Date: 1998/07/16

(41) Mise à la disp. pub./Open to Public Insp.: 1999/01/18

(45) Date de délivrance/Issue Date: 2007/11/06

(30) Priorité/Priority: 1997/07/18 (US08/897,069)

(51) Cl.Int./Int.Cl. *A61F 6/22* (2006.01),
A61F 6/24 (2006.01)

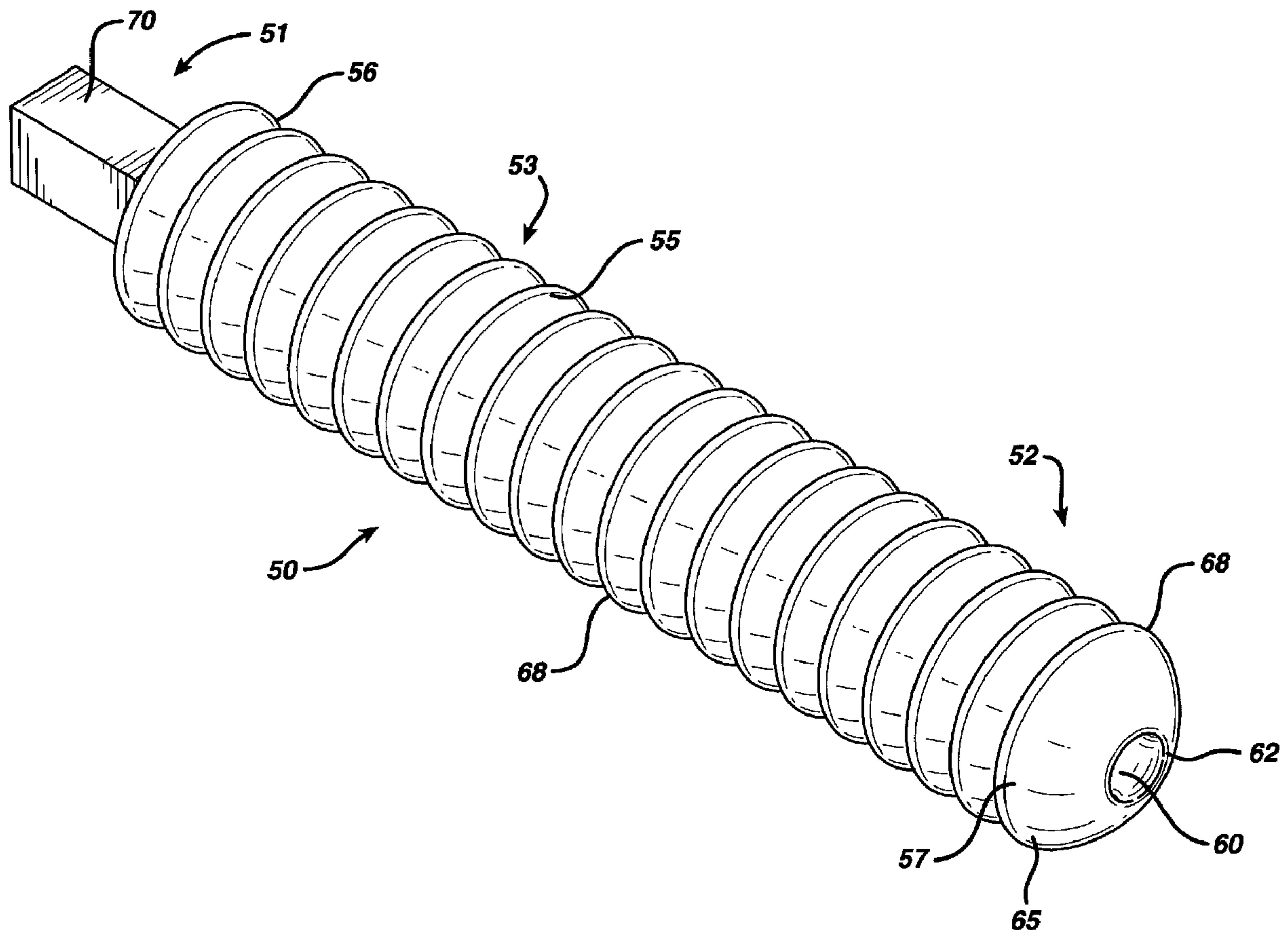
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(54) Titre : DISPOSITIF DE STERILISATION TUBAIRE

(54) Title: TUBULAR FALLOPIAN STERILIZATION DEVICE



(57) Abrégé(suite)/Abstract(continued):

flexible ribs configured to provide a plurality of seals within the interstitial portion of a Fallopian tube. A valve member is preferably disposed within the lumen of the tubular member. The occlusive device may further include a plurality of copper rings disposed between the ribs of the tubular member, or ribs may be coated with a material containing copper. The method includes placing the occlusive device within a delivery catheter having a lumen and placing the distal end of the delivery catheter within the uterus. After the occlusive device and distal end of the delivery catheter are placed in the Fallopian tube, the occlusive device is removed from the delivery catheter and ejected into the Fallopian tube. In addition, a guide wire may be inserted through the vagina and into a Fallopian tube of the uterus such that the occlusive device and the delivery catheter are threaded over the guide wire.

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ABSTRACT

An apparatus and method for human female sterilization. The apparatus includes an occlusive device configured from an elongate tubular member having a central lumen and a flange formed at the proximal end. The occlusive device is formed with a plurality of flexible ribs configured to provide a plurality of seals within the interstitial portion of a Fallo-
5 pian tube. A valve member is preferably disposed within the lumen of the tubular member. The occlusive device may further include a plurality of copper rings disposed between the ribs
10 of the tubular member, or ribs may be coated with a material containing copper. The method includes placing the occlusive device within a delivery catheter having a lumen and placing the distal end of the delivery catheter within the uterus.
15 After the occlusive device and distal end of the delivery catheter are placed in the Fallopian tube, the occlusive device is removed from the delivery catheter and ejected into the Fallopian tube. In addition, a guide wire may be inserted through the vagina and into a Fallopian tube of the uterus such
20 that the occlusive device and the delivery catheter are threaded over the guide wire.

TITLE

TUBULAR FALLOPIAN STERILIZATION DEVICE

BACKGROUND OF THE INVENTION

5 The present invention relates generally to an apparatus and method for female sterilization and more particularly to a system for occlusion of the Fallopian tubes of a human uterus having a tubular blockage device insertable with a catheter in which the blockage device is disposed prior to deployment.

10 The following terms as used herein have the meaning given below:

"Endometrium" is that portion of the inner lining of the uterus to which an embryo normally attaches and is responsible for the menstrual cycles.

15 "Proximal" is that portion closest to the physician or furthest outside the patient.

"Distal" is that portion furthest from the physician or furthest inside the patient.

20 "Interstitial segment" is the portion of the Fallopian tube which is immediately distal to the opening of the tube into the uterine cavity.

"Isthmic segment" is the portion of the Fallopian tube which is distal to the interstitial segment.

25 "Fimbrial segment" is the portion of the Fallopian tube which is distal to the isthmic segment.

It has been widely recognized that the explosive growth in the world population, creates a serious problem for the future of our society. Thus, there is a need to develop a safe and effective contraceptive device and/or method. Although the surgical sterilization of women may be the most effective and widely used method of contraception known, current procedures, such as radical hysterectomy, is not always warranted or desirable. Consequently, a need exists for the development of a nonsurgical method for effecting sterilization which can be performed by a gynecologist within a non-hospital setting and which does not require extensive facilities or equipment.

35 The ideal sterilization procedure should be safe, as well as effective. The method and/or device should be applicable to

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ambulatory patients with the use of local anesthesia or without anesthesia, since many of the complications that relate to sterilization procedures are complications that occur with the use of anesthetic agents. It should be socially and personally acceptable; it should be inexpensive and applicable to large numbers of patients; and it should be potentially reversible in the event of a change in desire for fertility potential on the part of the patient.

Although many techniques of female sterilization have been described, tubal sterilization shows increasing acceptance for providing safe and effective contraception. A wide range of transcervical techniques for female sterilization have been documented. Previous efforts to achieve this goal have included the infusion of various scarifying and necrotizing agents, tissue glues and tubal plugs into the uterus for the purpose of effecting an occlusion of the oviducts or Fallopian tubes. The use of a hysteroscope for direct visual approach to the tubal ostia has been suggested to enhance such a procedure. The female reproductive anatomy presents natural barriers to sterilization.

The oviducts are paired, hollow, seromuscular organs that extend from the superior-lateral aspect of the uterine fundus to the ovaries. Each oviduct is supported throughout its length by a peritoneal fold, the mesosalpinx, and is bordered anteriorly by the round ligament and posteriorly by the ovarian ligament and mesovarium. The oviduct is attached medially to the uterine fundus and laterally to the infundibular pelvic ligament and ovary by way of an elongated mucosal fold, the fimbria ovarica.

The extrauterine oviduct is sheathed throughout its length by a serosal covering consisting of a layer of loose connective tissue covered by a single layer of mesothelium continuous with the mesosalpinx. Beneath the mesothelial layer, smooth muscle fibers, distinct from those of the tubal muscularis are present. The connective tissue is highly vascular and contains numerous lymphatic vessels. These originate primarily along the mesosalpingeal border, extend parallel to the oviduct, and

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branch extensively, penetrating into the muscular and mucosal layers of the oviduct.

Because of the arrangement of muscle fibers in layers oriented in circular and longitudinal fashion, the oviduct is capable of generating a variety of contractile patterns, including peristaltic, antiperistaltic, and segmental contractions. Unlike the alimentary tract, the oviduct does not generate regular peristaltic contractions. Instead, it demonstrates segmental contractions that propagate simultaneously in opposite directions over short distances. Ovum transport, therefore, assumes a discontinuous pattern of reciprocal movements in which the ovum is forced out of areas of contraction into inactive regions. Thus, ovum transport appears to occur in a series of random movements that, over several days, acquire a gradual net bias toward the uterus.

Whether "blind" or hysteroscopically directed, transcervical sterilization procedures can be divided into three categories based upon the mechanism of tubal occlusion. Sterilization can be effected by (1) destruction of the interstitial portion of the oviduct by thermal energy (electro-coagulation or cryosurgery); (2) injection techniques for the delivery of sclerosing substances or tissue adhesives; and (3) mechanical occlusive devices or plugs to block the oviduct.

In the early 1970's, a number of investigators developed experience with electrocoagulation as a technique for hysteroscopic sterilization. Tubal occlusions were performed by applying a coagulating current to the interstitial portion of the Fallopian tube with a metal ball-tip electrode to coagulate the tubal epithelium. Alternatively, a silastic tipped electrode was introduced into the interstitial or isthmic portion of the tube to a depth to avoid unnecessary complications. Tubal electrocoagulation under hysteroscopic control was performed on uteri using different coagulation times and intensities of current. A coagulation current was applied to the tubal epithelium until the tissue became white and small air bubbles were seen while the coagulation current was applied. The electrode was then removed from the tube and the

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procedure repeated on the contralateral Fallopian tube. Another approach to transcervical sterilization utilized cryosurgical techniques to produce necrosis of the endometrium and subsequent scar formation of the cornual areas of the uterus. Such cryosurgery caused coagulation necrosis of the tissue, due to severe biochemical and biophysical changes produced by the sub-freezing temperatures.

Several injection techniques for the delivery of sclerosing substances or tissue adhesives have been attempted. One such technique includes passing a nitric acid-coated probe through a woman's cervix to chemically stricture the tubal ostia. Another procedure comprised hysteroscopically controlled quinacrine infusion in the tubal ostia. Another procedure utilized an assembly for positioning and guidance of a hypodermic needle for blind injection of an inflammatory or sclerosing agent at the cornual portion of the tubal lumen on opposite sides of the uterus. However, the failure rate with such techniques was so high that such techniques have been generally abandoned.

Alternate chemical blocking procedures include infusing catalyzed viscous silicone rubber into the uteri of animals. Similarly, occlusion of the oviducts with silicone rubber was tried for sterilization. The procedure comprised a system and application technique for a nonincisional method for blocking the Fallopian tubes with medical-grade silicone rubber. Under hysteroscopic control, catalyzed liquid silicone polymer flows into the oviduct through a silicone rubber obturator tip positioned at the tubal ostium. The formed-in-place plug becomes bonded to the obturator tip. The resulting flexible structure is larger in diameter at both ends than it is in the isthmus and thus remains in place to achieve tubal occlusion. One major disadvantage is the need for sophisticated equipment and technology. Another limitation is the time demand on the physician and assistant. An additional concern is the potential for inadvertent disruption of the plugs at the time of a diagnostic dilatation and curettage, should this be indicated at some later date.

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Recent attention has focused on the concept of mechanically blocking or occluding the oviducts with intratubal devices. Such devices include an inert cornual plug designed to obstruct entry to the Fallopian tubes having an overall bullet configuration having a cone-shaped forward portion that cooperates with the uterine walls. The device included a wire anchoring means extending from about the mid-portion of the plug to secure the plug in position by anchoring it to the cornual area of the uterus. The cornual plug is optionally provided with a pendant string or cord for removal of the device.

Also known is a spherical device that is inserted in the Fallopian tube to plug the passageway and prevent the passage of an egg or ovum from the Fallopian tubes into the uterus. Also described is an intrauterine contraceptive device that is generally V-shaped having a pair of slender divergent arms formed with bulbous extremities that are said to tend to become located in the Fallopian region of the uterus when the stem portion of the device is in the os. Others have developed a hydrogelic tubal blocking device fixed on a firm nylon skeleton. In addition, the tubal occlusion properties of ceramic plugs has been studied.

Other known tubular occlusive devices included a polyethylene plug that measured approximately ten millimeters in length with a diameter of one millimeter at the tip and two millimeters at the base. Further, plugs formed from inert, radiopaque, surgical nylon were placed in the tubal ostia with the use of the colpomicrohysteroscope. The nylon device has an open loop with elastic "memory" at each extremity to prevent migration within the Fallopian tube. The midpiece, measuring twenty-three millimeters in length and one millimeter in diameter, is flexible and permits negotiation of the interstitial portion of the tube. Removal of the plug is easily effected by traction on the proximal loop.

Still another intratubal device was made of preformed silicone rubber and is packed in advance into an introducer made of Teflon tubing 1.5 millimeters in diameter. The plug

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was generally tubular having a segmented body and a proximal portion configured to engage the tubular ostia and for removal of the device. An obturator wire pushes the plug out of the introducer into the tubal ostia under direct hysteroscopic visualization. Such a device was reported in Fertility Control, Corson et al. Eds., 2d edition 1994, Goldin Publishers, London, Ont., p. 369 (see Fig. 6 re Sugimoto device). Placement of some such occlusive plugs were reportedly accomplished during an outpatient visit, utilizing no anesthesia. Carbon dioxide was utilized for uterine distention in certain techniques.

Although the prior art has attempted various means of female human sterilization, many such methods have proven ineffective over time. Thus, heretofore, there has been a need for a minimally invasive female sterilization system that ensures complete, but reversible, blockage of the Fallopian tubes to provide safe and effective sterilization.

SUMMARY OF THE INVENTION

The present invention relates generally to an apparatus and method for female sterilization and more particularly to a system for occlusion of the Fallopian tubes of a human uterus having a tubular blockage device insertable with a catheter in which the blockage device is disposed prior to deployment. The present invention includes a tubular blockage device having a size and shape configured to be removably implanted into the Fallopian tubes of a human uterus. The blockage device has a distal end configured in a conical tip and a plurality of arcuate ribs forming a body. The proximal end is configured with a peg-like flange for securing to a removal device. A central lumen traverses from the proximal end to the distal end of the blockage device body for insertion of a guide wire or for alternative functions, such as reversibility of sterilization.

One embodiment of the present invention includes a sealing core in the lumen of the blockage device body. Another embodiment of the present invention further includes a hydrogel seal-

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ing core in the lumen of the blockage device body. In another embodiment of the present invention, the blockage device body includes a lumen for retaining a guide wire. Such a lumen may also include duck bill valves disposed in the proximal end and
5 the distal end of the lumen of the blockage device. Yet another embodiment of the present invention includes a plurality of bristles disposed within the lumen of the blockage device body.

The method of use of the device of the present invention
10 includes inserting a guide wire into the Fallopian tube. A blockage device is inserted over the guide wire. A sheath or delivery catheter is used to push the blockage device into place. The uterine cavity and Fallopian tube are examined with
15 a hysteroscope, with x-ray imaging or with a similar visualization system so as to estimate the position of the blockage device. Once the blockage distal is in the desired position, the guide wire is withdrawn while keeping the blockage device in position using the sheath. The device is then left in place within the interstitial or isthmus segment of the Fallopian
20 tube.

The occlusive device of the present invention configured for human female sterilization includes an elongate tubular member having a central lumen therethrough. The device is configured with a flange formed at the proximal end of the
25 elongate tubular member and a plurality of ribs formed between the proximal end and the distal end of the tubular member. A valve member is preferably disposed within the lumen of the tubular member. The ribs of the tubular member are preferably constructed of an elastomeric material. The occlusive device
30 may further include a plurality of copper rings disposed between the ribs of the tubular member, or ribs may be coated with a material containing copper.

The method for human female sterilization of the present invention includes inserting an occlusive device of the present
35 invention into a Fallopian tube of human female uterus. The method further includes placing the occlusive device within a delivery catheter having a lumen and placing the distal end of

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the delivery catheter within the uterus. After the occlusive device and distal end of the delivery catheter are placed in the Fallopian tube, the occlusive device is removed from the delivery catheter and ejected into the Fallopian tube. In addition, a guide wire may be inserted through the vagina and into a Fallopian tube of the uterus. The occlusive device and the delivery catheter are then threaded over the guide wire.

Another aspect of the present invention is a system for human female sterilization comprising the device described above and a delivery catheter having a proximal end, a distal end, and a lumen therethrough, wherein the distal end is configured for removably retaining said tubular member.

Another aspect of the present invention is a use of the device or system described above for human female sterilization.

These and other features and advantages of the present invention will become apparent from the following more detailed description, when taken in conjunction with the accompanying drawings which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is perspective view of one embodiment of the Fallopian tube blockage device of the present invention.

FIG. 2 is a partial cross-sectional of a blockage device of the present invention disposed within a Fallopian tube of a human uterus.

FIG. 3 is an enlarged side sectional view of the portion of the Fallopian tube containing the blockage device of the present invention as shown along circle A-A in FIG. 2.

FIG. 4 is a sectional perspective view of the blockage device of an embodiment of the present invention having a sealing core in the lumen of the blockage device body.

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FIG. 5 is a sectional perspective view of the blockage device of an embodiment of the present invention having a hydrogel sealing core in the lumen of the blockage device body.

5 FIG. 6 is a side cross-sectional view of an embodiment of the present invention having a plurality of bristles disposed within the lumen of the blockage device body.

FIG. 7 is a perspective view of a guide wire retained in a duck bill valve formed in the distal end of an embodiment of
10 the blockage device of the present invention.

FIG. 8 is a perspective view of a pinhole valve formed from an elastomeric material suitable for use in the blockage device of the present invention.

