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(54) Title: CONTRACEPTIVE SYSTEM AND METHOD OF USE

(57) Abstract

A device and method of using the device for contraception or sterilization and particularly for reversible contraception by occluding a reproductive lumen to prevent the passage of reproductive cells through the lumen for a desired period of time until the patient wishes to become fertile again and then be reopened. The occluding member preferably comprises a tubular framework formed from a shape memory material configured to be implanted in a reproductive lumen. The occluding member is implanted within a body lumen, secured to the wall of the reproductive lumen and then collapsed to collapse the wall and occlude the lumen. Alternatively, the occluding member may be collapsed upon a solid plug. The closure of the reproductive lumen may be reversed by introducing a balloon catheter and by a series of inflations of the balloon reexpanding the collapsed occluding member or by removing the plug. The occluding member and the plug may be configured to facilitate endothelialization, to provoke an inflammatory response or to deliver a drug.

CONTRACEPTIVE SYSTEM AND METHOD OF USE

FIELD OF INVENTION

This invention relates to the field of contraceptive and sterilization devices and more particularly to reversible contraceptive devices and the methods of using such devices.

BACKGROUND OF THE INVENTION

Conventional contraceptive strategies generally fall within three categories: physical barriers, drugs and surgery. While each have certain advantages, they also suffer from various drawbacks. Barriers such as condoms and diaphragms are subject to failure due to breakage and displacement. Drug strategies, such as the pill and Norplant™, which rely on artificially controlling hormone levels, suffer from known and unknown side-effects from prolonged use. Finally, surgical procedures, such as tubal ligation and vasectomy, involve the costs and attendant risks of surgery, and are frequently not reversible. Thus, there remains a need for a safe, effective method of contraception, particularly a non-surgical method which is reversible.

SUMMARY OF THE INVENTION

The present invention is directed to a contraceptive or sterilization system for occluding a reproductive tract or lumen to prevent the passage of reproductive cells through the tract or lumen. The invention includes an occluding member expandable within the body lumen from a first configuration suitable for introduction into the body lumen to a second larger configuration to facilitate securing the expanded occluding member to at least a portion of a wall which defines the reproductive body lumen. The invention also includes means to facilitate securing the expanded occluding member to the wall of the body lumen and means to contract the expanded occluding member and the wall portion secured to the

occluding member to occlude the reproductive body lumen sufficiently to prevent the passage of reproductive cells therethrough.

One presently preferred embodiment of the invention comprises a reversible contraceptive system which can be used to occlude either the fallopian tubes of a female patient, the vas deferens of a male patient or other reproductive tract. A key feature of the contraceptive system is a occluding member which is first secured to the wall defining the reproductive tract in an expanded condition and then is collapsed to smaller transverse cross-sectional dimensions to cause the collapse of the secured portion of the wall and thereby block the vessel passageway to prevent the passage of reproductive cells. The occluding member may be reopened by any number of suitable means. For example, by collapsing the occluding member about a plug or mandrel which can be left in place to effectively blocking the passageway until the patient wishes to reverse the procedure. The plug can be removed by suitable means such as conventional laparoscopic or other instruments to reopen the passageway. A balloon dilatation catheter may be used to further expand the opening once the plug is removed Other ways of reopening the reproductive lumen include leaving the proximal portion of the occluding member open when the member is collapsed so that an expandable member such a balloon on a catheter can be inserted and expanded. By means of a series of expansions and stepped advancements, the entire passageway can be reopened.

Preferably, the occluding member comprises a tubular member formed from a shape-memory alloy material and has a primary configuration which is relatively small in transverse dimensions to facilitate the insertion of the member into the desired body lumen. Once in place, the occluding member is then expanded to a second configuration with transverse dimensions roughly corresponding to or slightly larger than the body lumen so that the occluding member can be secured to the wall defining the body lumen . With the open, lattice-like framework of the occluding member expanded within the body lumen, endotherlialization through the open structure secures the occluding member to the wall defining the body lumen. By heating the occluding member formed of shape-memory alloy material to a

temperature at or above the transition temperature of the shape-memory material, it transforms to a remembered closed or collapsed configuration which causes the wall secured to the occluding member to close down so that the passageway therethrough is occluded. The occluding member may be delivered to the desired location within the body lumen by suitable means such as a conventional balloon catheter similar to those used for delivering stents, aortic grafts and various types of prosthesis.

In one presently preferred embodiment, the occluding member has an open or lattice-like framework so that the growth of endothelial tissue through the openings of lattice-like framework so as to interconnect the occluding member and the wall of the body lumen. The surface of the occluding member may be treated to promote the endothelialization.

Once the occluding member is implanted into the body lumen and it has been sufficiently endothelialized to secure it to the body wall (which may take a week or more), it may be activated by warming the occluding member to a temperature at or above the transition temperature of the shape-memory material so it may revert to its remember constricted shape. Since the endotheliaization has secured the occluding member to the wall of the body lumen, the contraction of the occluding member to its remembered collapsed shape, causes the wall defining the body lumen to collapse along with the occluding member, effectively blocking the passageway. Alternatively, a plug may be located within the interior of the occluding member prior to heat activation so that the occluding member collapses onto the plug to block the lumen.

The occluding member may be mounted onto the exterior of a balloon of a dilatation balloon catheter in the first configuration with small transverse dimensions, and then be introduced and positioned within the region of the reproductive lumen to be occluded. The balloon is inflated to expand the occluding member, preferably with the outer diameter slightly larger than the inner dimensions of the reproductive lumen to which it is secured. The occluding member will remain in the open

configuration until heated to a temperature at or above its martensite to austenite transition temperature which causes it to revert to its collapsed state. If the occluding member is collapsed about a plug, the plug may be extracted to reopen the passageway when the patient wishes to become fertile again.

The present invention provides effective sterilization or contraception for both males and females and importantly it is easily reversed. Moreover, the implantation and activation of the occluding member as well as the subsequent restoration of vessel patency requires easily used minimally invasive devices such as catheters, guidewires, guiding catheters and the like. These and other advantages of the invention will become more apparent from the following detailed description of the invention when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates a catheter with an occluding member embodying features of the invention mounted on an expandable member on a distal section of the catheter.

Figures 2 and 3 show one embodiment of the occluding member in expanded and contracted or closed configurations respectively.

Figures 4 and 5 show another embodiment of the occluding member in expanded and closed configurations respectively.

Figures 6 and 7 show yet another embodiment of an occluding member in expanded and closed configurations respectively.

Figure 8 depicts the occluding member on a delivery catheter as shown in Figure 1 within a reproductive tract or lumen.

Figure 9 illustrates the expansion of the occluding member within the reproductive tract or lumen.

Figure 10 illustrates the female reproductive anatomy and shows the occluding member positioned within one of the patient's fallopian tubes.

Figure 11 illustrates the male reproductive anatomy and depicts an expanded occluding member within a vas deferens of a male patient.

Figure 12 illustrates the occluding member secured to the wall of the reproductive tract by endothelial tissue.

Figure 13 is a transverse cross-sectional view of the expanded endotherlized occluding member as shown in Figure 12 taken along the lines 13-13.

Figure 14 shows the occluding member in a collapsed state after being activated by warmed saline.

Figure 15 is a transverse cross-sectional view of the collapsed occluding member as shown in Figure 14 taken along the lines 15-15.

Figure 16 is similar to Figure 14 and illustrates the occluding member collapsed about an elongated removable plug or mandrel.

Figure 17 shows the occluding member being activated in a location distal to the proximal extremity thereof in order to keep the proximal end partially open to facilitate reopening the passageway.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 illustrates a catheter 10 useful in the practice of the invention, which comprises an elongated shaft 12 having an inflation lumen 14 which is in fluid communication with inflatable member 16 mounted on a distal section of the catheter shaft and adapter 18. Occluding member 20, a self-supporting metallic member of shape-memory material, closely conforms to the diameter of the uninflated inflatable member 16 to facilitate introduction into the desired body lumen. Occluding member 20 is formed so that it has a remembered collapsed configuration with relatively small transverse dimensions. The occluding member 20 may be

deformed to facilitate mounting onto the inflatable member 16 and is expanded by the inflatable member to an open expanded configuration within a body lumen. Upon heating to a transition temperature it will revert to the remembered configuration. In this embodiment the occluding member 20 has an open, lattice-type structure facilitating endothelialization which secures the occluding member to the wall defining the body lumen. Preferably, occluding member 20 can be deformed to an expanded diameter, preferably equal to or slightly larger than the dimensions of the body lumen within which the occluding member is to be disposed. For disposition within a female patient's fallopian tubes the expanded transverse dimensions should be about 0.1 mm to about 5 mm.

The occluding member may have a number of suitable configurations as shown in schematically in Figs. 2-7. Figures 2 illustrates occluding member 22 in an open configuration and Fig. 3 its relatively small dimensioned configuration for introduction and advancement into the patient's body lumen. Occluding member 22 may be constructed from a length of shape memory hypodermic tubing. Slots 24 cut into the wall of the tubing allow expansion of the occluding member into an open configuration as shown in Figure 2. Likewise, in Figures 4 and 5, occluding member 26 is a coil 28 of shape-memory wire or ribbon. Figures 6 and 7 show occluding member 30, which comprises a braided tube of shape-memory wire or ribbon 32. Finally, in Figs. 1 and 8 occluding member 20 comprises a number of closed sinusoidal rings of shape-memory wire or ribbon and is mounted onto an inflatable member 16 of catheter 10.

Inflation of inflatable member 16 expands occluding member 20 in a reproductive tract 38 to an open, relatively large diameter configuration as shown in Figure 9.

In each of these embodiments, the shape memory material of the occluding member should have a transition temperature sufficiently above the normal variation of human body temperature to prevent accidental activation which might prematurely collapse the occluding member. On the other hand, the transition temperature

should be high enough so that thermal activation of the occluding member does not cause undesirable thermal damage to the surrounding tissue. The shape memory-material is preferably a shape memory, nickel-titanium alloy such as NITINOL and preferably has a transition temperature of between about 43° C to about 70° C.

In each of the embodiments described above, certain conventional refinements may be employed. For example, the surface of the occluding member's framework may be designed to facilitate endothelial growth. Such modifications generally comprise providing the occluding member with an open or lattice-like framework to promote endothelial growth into as well as around the member to ensure it secure attachment to the wall of the body lumen. Suitable surface techniques include EDM machining, laser drilling, photo etching, scintering and the like. Additionally, increasing the surface area of the occluding member can also provide greater adhesion for the endothelial tissue. Suitable surface treatments include plasma etching, sand blasting, machining and other treatments to roughen the surface. In other embodiments, the shape-memory material may be coated or seeded to spur endothelialization. For example, the occluding device can be coated with a polymer having impregnated therein a drug, enzyme or protein for inducing or promoting endothelial tissue growth. In yet another refinement, the occluding member could be plated with or otherwise incorporate copper to produce an inflammatory response in the tissue of the wall defining the body lumen, which further contributes to the obstruction of the lumen. Other inflammatory materials my be suitable as well. For example, the occluding member could be radioactive, emitting alpha, beta or gamma particles.

The practice of the invention comprises the following general steps. An occluding member 20 having relatively small transverse dimension is mounted onto the exterior of balloon 16 of catheter 10 as shown in Figure 1. The catheter 10 is advanced under fluoroscopic or endoscopic visualization until occluding member 20 is positioned within one of the female patient's fallopian tubes 34, as shown in Figure 10. Inflation fluid is introduced through adapter 18 to inflate inflatable member 16. As shown in Figures 9-10, inflation of inflatable member 16 expands

occluding member 20 to an open configuration and lodging it in body lumen 38. Catheter 10 is removed, leaving the expanded occluding member 20 implanted in body lumen 38 as shown in Figure 12. Another expandable member is delivered to the patient's other fallopian tube and expanded therein in the same manner. Alternatively, the occluding member may be expanded into positioned within the vas deferens 36 of a male patient as shown in Figure 11 to provide male contraception using the same procedures.

Over a period of a week or more endothelial cells lining the lumen will proliferate, growing around the open framework of occluding member 20 as shown in Figures 12 and 13 thereby securing the wall defining the body lumen 38 to the expanded occluding member 20. After the expanded occluding member 20 is sufficiently endothelialized within the patient's reproductive tract 38, it is thermally activated to return it to its remembered collapsed configuration. The occluding member may be activated by several means, including warmed fluid, RF energy, laser energy, or other suitable energy sources. A suitable activation system is shown in Figure 14 where the distal end of catheter 40 is positioned adjacent to the occluding member 20, saline fluid somewhat above the transition temperature is introduced to bathe occluding member 20, raising its temperature to the transition point or higher, causing occluding member 20 to collapse to its closed, reduced-diameter configuration. The layer of endothelial tissue that forms within the lattice-like structure of the occluding member helps block and seal the lumen so as to prevent the passage of reproductive cells, eggs or sperm cells.

In an alternative embodiment of the invention is shown in Figure 16 where a plug 42 is positioned inside occluding member 20 in the expanded condition so that upon activation the occluding member 20 collapses onto plug 42, blocking the lumen 38. The plug is preferably formed from an inert material such as a fluoropolymer, e.g. PTFE. Other suitable materials include high density polyethylene and silicone rubber. A number of modifications to the plug may also be suitable. For example, the plug could be used as a drug delivery device, similar to the Norplant™ device. The plug could also be used to provoke an inflammatory response as described

above to augment the occlusion of the lumen. In such embodiments, plug 42 preferably has an outer diameter from about 0.25 mm to about 4 mm. The plug 42 may also have holes, deep grooves or which help to preserve at least part of the natural lining of the reproductive tract.

The occlusion of the lumen may be reversed simply by removing the plug 42. If a passageway larger than passageway left by the removed plug 42 is desired, a balloon catheter can be advanced within the body lumen until the balloon is within the lumen left by the removal of the plug and then the balloon on the catheter is inflated to expanded the occluding member 20, deforming it into an open configuration. It may be desirable when activating the expanded occluding member to the collapsed configuration to leave the proximal end of the occluding member somewhat open or in an expanded condition to facilitate the introduction of dilatation balloon on a catheter to facilitate the opening of the body lumen. As shown in Figure 15, the catheter 40 used to activate the occluding member may be positioned within the proximal end of the occluding member, so that the proximal end is unable to completely revert to its closed configuration. The reproductive tract could be subsequently close should contraception again be desired by heating the occluding member 20 so as to activate the transformation thereof to the collapsed configuration.

In embodiments of the invention employing the plug 40, various other strategies are suitable to reverse the occlusion. For example, the plug 40 can simply be removed, restoring the lumen 38 to patency. Alternatively, the plug 40 may be hollow with a removable core (not shown). This core may be formed from a softer material, such as silicone, or could be threaded, in order to facilitate its removal. Similarly, the plug itself may be threaded so that removal would comprise a twisting motion, minimizing the stress on the tissue in which the occluding member is located.

In still other embodiments, mechanical, adhesive or other means may be employed to secure the expanded occluding member 20 to the vessel wall defining

the reproductive passageway 38. For example, the means to secure a stent or prosthetic device to an aortic or arterial wall described in U.S. Patent No. 4,140,126; U.S. Patent No. 4,562,596 ; U.S. Patent No. 4,577,631; U.S. Patent No. 4,787,899; U.S. Patent No. 5,104,399; U.S. Patent No. 5,167,614; U.S. Patent No. 5,275,622; U.S. Patent No. 5,456,713; and U.S. Patent No. 5,489,295 may be used with the present invention to interconnect the wall defining the reproductive tract and the expandable member. These patents are incorporated herein in their entireties by reference.

Various modifications and improvements may be made to the present invention without departing from the scope thereof. For example, a mechanical expandable member such as described in U. S. Patent No. 4, 585,000, which is incorporated herein by reference, may be used to expand the expandable member within the reproductive tract to engage the wall thereof. Moreover, although individual features of embodiments of the invention may be shown in some of the drawings and not in others, those skilled in the art will recognize that individual features of one embodiment of the invention can be combined with any or all the features of one or more of the other embodiments.

WHAT IS CLAIMED IS:

1. A contraceptive or sterilization system for occluding a reproductive body lumen to prevent the passage of reproductive cells therethrough, comprising:

a) an occluding member which is at least in part expandable within the reproductive body lumen from a first configuration to a second larger configuration to facilitate securing the expanded portion of the occluding member to a wall portion which defines at least in part the reproductive body lumen;

b) means to secure the expanded portion of the occluding member to the wall portion; and

c) means to contract the expanded portion of the occluding member so that the wall portion secured thereto likewise contracts to occlude the reproductive body lumen sufficiently to prevent the passage of reproductive cells therethrough.

2. The contraceptive system of claim 1 including an expanding means to expand at least a portion of the occluding member.

3. The contraceptive system of claim 2 wherein the expanding means is an elongated catheter having an inner lumen extending within the elongated catheter from a proximal portion of the catheter to a location within a distal portion, an inflatable member on a distal portion thereof with an interior in fluid communication with the inner lumen to facilitate the delivery of inflation fluid to the interior of the inflatable member.

4. The contraceptive system of claim 1 including a mandrel configured to be disposed within an expanded portion of the occluding member so that the occluding member contracts onto the mandrel to occlude the reproductive body lumen sufficiently to prevent the passage of reproductive cells therethrough.

5. The contraceptive system of claim 1 wherein the occluding member has a tubular open-wall structure to facilitate the ingrowth of endothelial cells thereby securing the expanded portion of the occluding member to the wall portion.

6. The contraceptive system of claim 5 wherein the tubular structure has an lattice-like framework.

7. The occluding member of claim 6 wherein the lattice-like framework comprises a thin walled metallic tube having a pattern of cuts configured to allow the occluding member to be expanded to an open-walled, relatively large diameter configuration.

8. A contraceptive member formed of shape memory alloy which has a stable martensite phase at body temperature, has a first small dimensioned configuration facilitating the introduction thereof into a lumen of a patient's reproductive system, is expandable to a second larger configuration facilitating securing a least a portion of the contraceptive member to a wall portion defining at least in part the lumen of the patient's reproductive system, has an open lattice-like framework facilitating the ingrowth of endothelial cells thereby securing the expanded portion of the contraceptive member to the wall portion and has a contracted remembered shape in an austenite phase at temperatures higher than body temperature with a remembered configuration having smaller transverse dimensions than the second larger configuration.

9. An contraceptive system installed within a lumen of the patient's reproductive system comprising a collapsed occluding member having at least a portion thereof which is secured to a body wall portion defining at least in part the lumen of the patient's reproductive system and which occludes the lumen sufficiently to prevent the passage of reproductive cells therethrough.

10. The installed contraceptive system of claim 9 wherein the occluding member has a tubular structure.

11. The installed contraceptive system of claim 10 wherein the tubular structure of the occluding member has a lattice-like framework.

12. The contraceptive system of claim 9 including a mandrel disposed within the collapsed occluding member.

13. An occluding member for body lumens formed of a shape memory alloy exhibiting a martensitic metallurgical structure at body temperature and an austenitic metallurgical structure at temperatures above body temperature having a remembered reduced diameter configuration, having an expanded open configuration to facilitate securing itself to a wall portion defining the body lumen.

14. The occluding member of claim 13 wherein the occluding member comprises a lattice-like framework.

15. The occluding member of claim 14 wherein the lattice-like framework comprises a thin walled metallic tube having a pattern of cuts configured to allow the occluding member to be expanded to the open, relatively large diameter configuration.

16. The occluding member of claim 14 wherein the lattice-like framework comprises a plurality of interconnected closed wire rings.

17. The occluding member of claim 14 wherein the lattice-like framework comprises a helical coil of wire.

18. The occluding member of claim 14 wherein the lattice-like framework comprises a braid of wire.

19. The occluding member of claim 13 wherein the shape memory material comprises a nickel-titanium alloy.

20. The occluding member of claim 13 wherein the surface of the occluding member is configured to promote endothelialization.

21. The occluding member of claim 13 further comprising a material capable of provoking an inflammatory response.

22. The occluding member of claim 21 wherein the inflammatory material comprises copper or copper alloy.

23. An occluding assembly comprising an occluding member having a tubular metallic framework with an inner lumen extending therein and having a plug within the lumen, wherein the occluding member has a closed configuration about the plug disposed within the inner lumen thereof, so that the occluding member may be expanded to an open, relatively large diameter configuration by removal of the plug, and then may be heated to the transition temperature to cause the occluding member to revert to the closed, minimal-diameter configuration.

24. The occluding assembly of claim 23 wherein the occluding member is configured to promote endothelialization.

25. The occluding assembly of claim 23 wherein the plug is formed from a material capable of provoking an inflammatory response.

26. The occluding assembly of claim 23 wherein the plug has a threaded configuration.

27. The occluding assembly of claim 23 wherein the plug comprises a hollow tube and removable core.

28. A method of contraception comprising the steps of:

a) inserting within a desired body lumen an occluding member;

b) expanding the occluding member within the body lumen;

c) securing the expanded occluding member to a wall portion defining at least in part the body lumen; and

d) collapsing the occluding member and the wall portion secured thereto to occlude the body lumen.

29. The method of claim 28 further comprising the step of positioning an elongated plug within the expanded occluding member before collapsing the occluding member.

30. The method of claim 28 wherein the occluding member comprises a metallic framework of shape memory material having a phase transition from martensite to austenite at a temperature above body temperature and having a remembered shape in the austenite phase which is a collapsed configuration so that the tubular occluding member may be deformed to the open configuration and then reverted to the closed configuration when heated to a temperature at or above the transition temperature.

31. The method of claim 28 wherein the expanded occluding member is disposed within the body lumen for sufficient time for it to be endothelialized within the body lumen and thereby secured to the wall portion.

32. The method of claim 30 wherein the step of heating the occluding member comprises bathing the occluding member with fluid at a temperature at or above the transition temperature.

33. The method of claim 30 wherein the occluded member is heated by one means of the group consisting of inductive heating, RF heating, laser application and ultrasound.

34. The method of claim 28 wherein the occluding member has a proximal end and a distal end, further comprising the step of collapsing the occluding member so that the proximal end has a relatively larger diameter than the distal end to facilitate the insertion of a catheter into the lumen of the occluding member

35. A kit for performing a reversible sterilization procedure comprising:

a) a catheter having an inflatable member; and

b) an occluding member comprising a tubular metallic framework which has a closed, minimal-diameter configuration and is formed from a shape-memory material having a transition temperature above body temperature, so that the occluding member may be expanded to an open, relatively large diameter configuration, and then heated to or above the transition temperature to cause the occluding member to revert to the closed, small diameter configuration within a desired body-lumen.

36. The kit of claim 35 further comprising a plug configured to be positioned within the occluding member prior to activation of the occluding member.

37. The kit of claim 35 wherein the plug is radioactive.

38. The kit of claim 35 wherein the plug is provided with one or more depressions or grooves to minimize damage to tissue lining the reproductive tract.

39. The kit of claim 35 wherein the plug is formed of material which produces an inflamatory response within the reproductive tract.

40. The kit of claim 39 wherein the plug is formed at least in part of copper or a copper alloy.

41. The kit of claim 37 wherein the plug has incorporated therein or coated thereon a drug or other therapeutic agent which infuses out of the plug into the reproductive tract.

42. The kit of claim 41 wherein thetherapeutic agent is a growth hormone to promote endothelial cell growth.

43. The kit of claim 36 wherein the plug is formed of polymer material selected from the group consisting of fluoropolymers, high density polyethylene and silicone rubber.

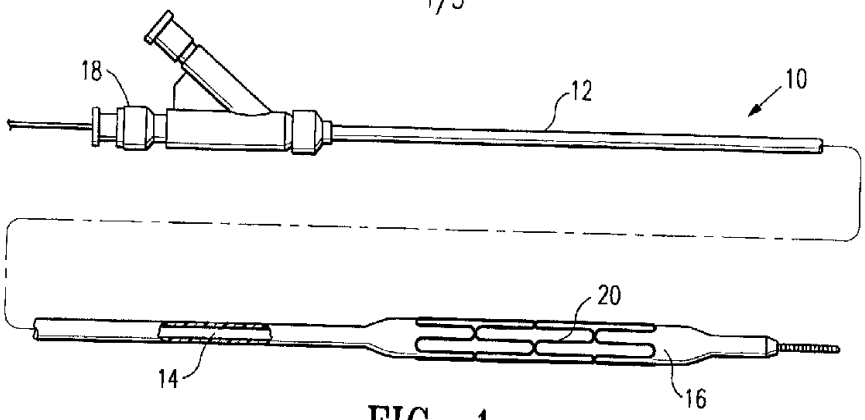


FIG. 1

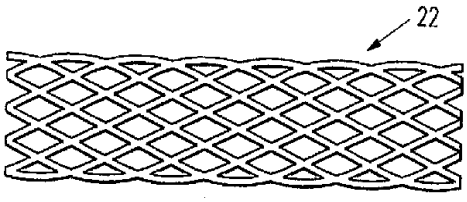


FIG. 2

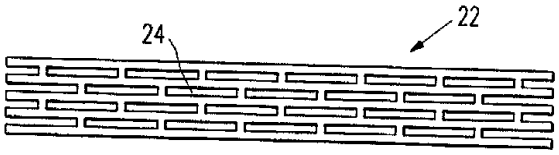


FIG. 3

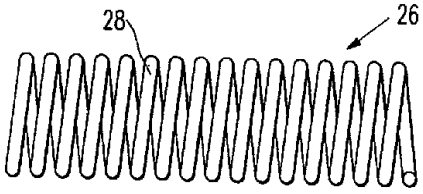


FIG. 4

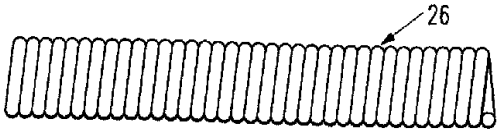


FIG. 5

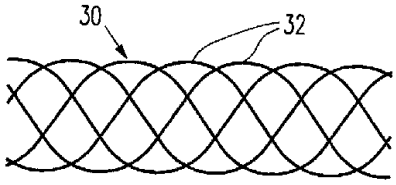


FIG. 6

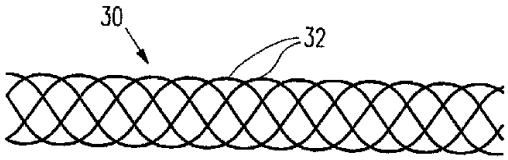


FIG. 7

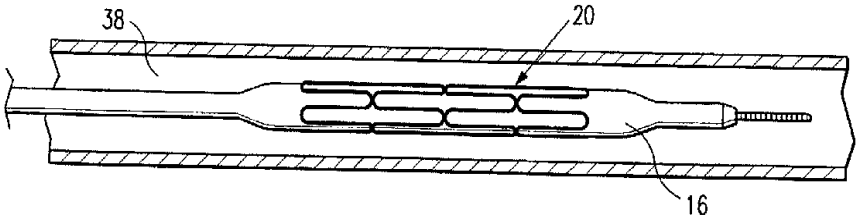


FIG. 8

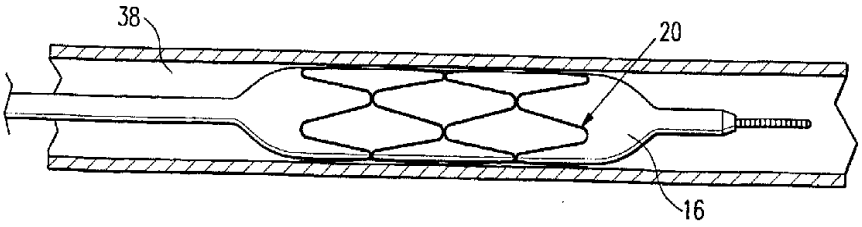


FIG. 9

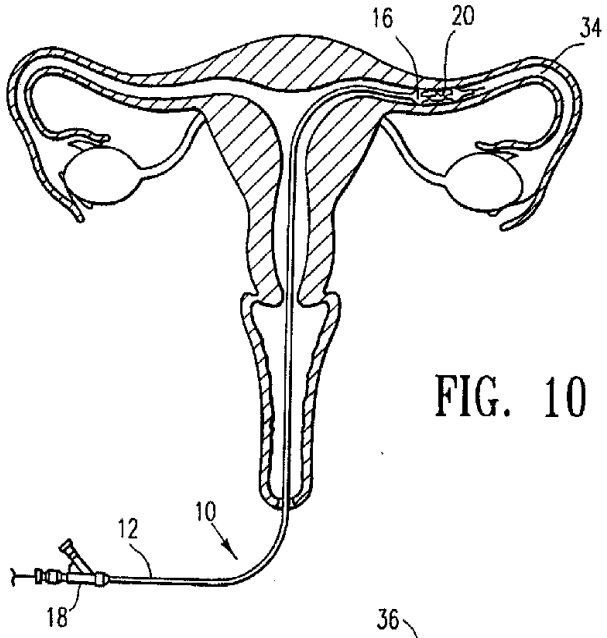


FIG. 10

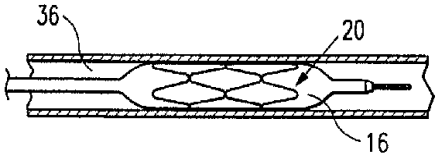


FIG. 11A

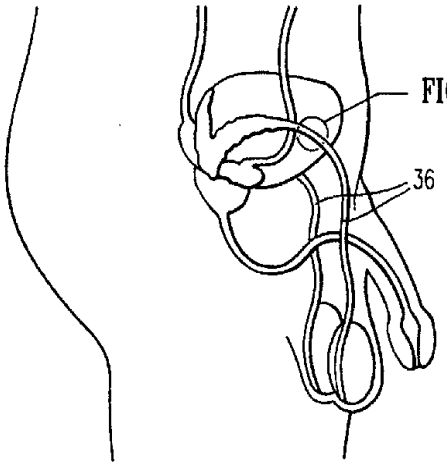


FIG. 11

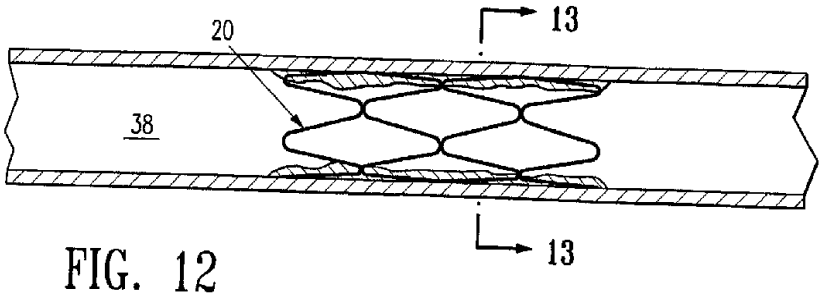


FIG. 12

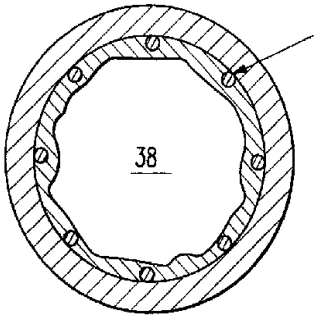


FIG. 13

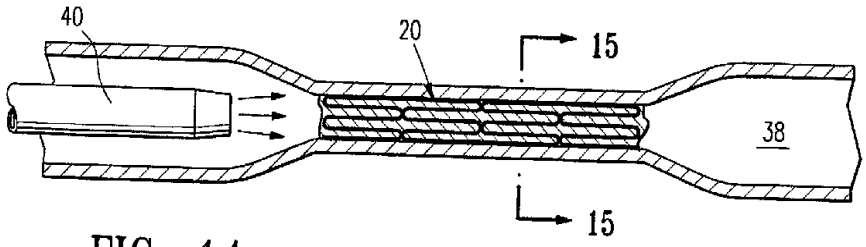


FIG. 14

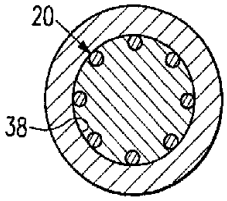


FIG. 15

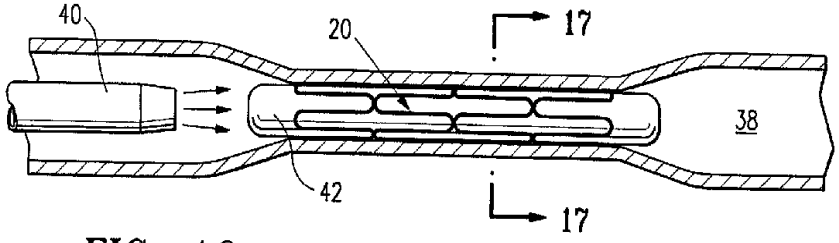


FIG. 16

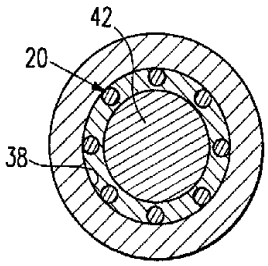


FIG. 17

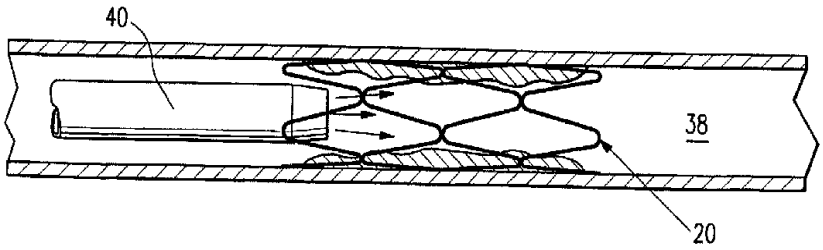


FIG. 18