

- [54] **CONTRACEPTIVE DEVICE AND METHOD OF EMPLOYING SAME**
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- [51] Int. Cl. .... **A61b 19/00**
- [58] Field of Search..... **128/1 R, 127, 303 R, 334 R, 128/348, 274; 3/1**

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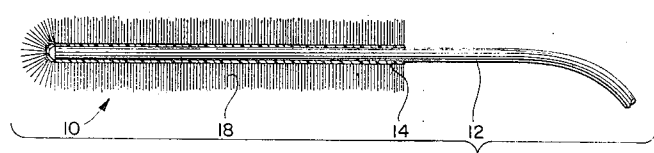
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[57] **ABSTRACT**

A male contraceptive device which comprises a plug having a coating of fabric on its outer walls. The plug is inserted in the vas deferens. The fabric coating allows for the ingrowth of cells from the wall of the vas deferens into the fabric. This provides for complete occlusion of the vas deferens to prevent passage of the sperm therethrough.

**34 Claims, 5 Drawing Figures**



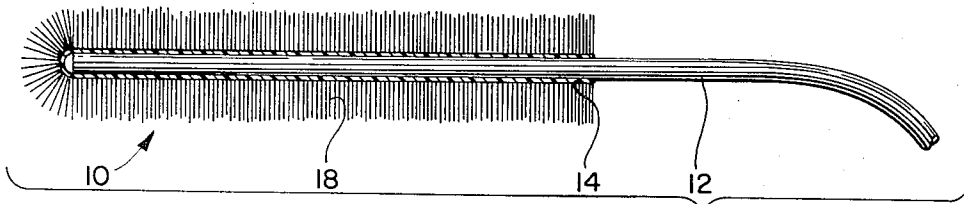


FIG. 1

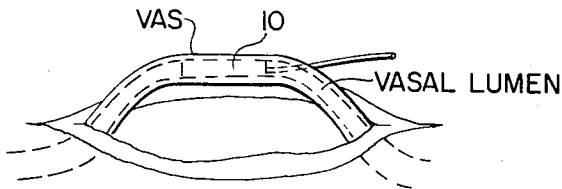


FIG. 2

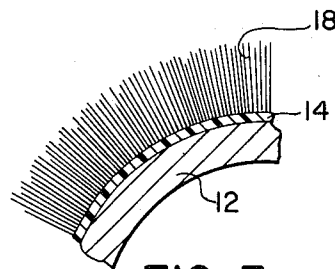


FIG. 3

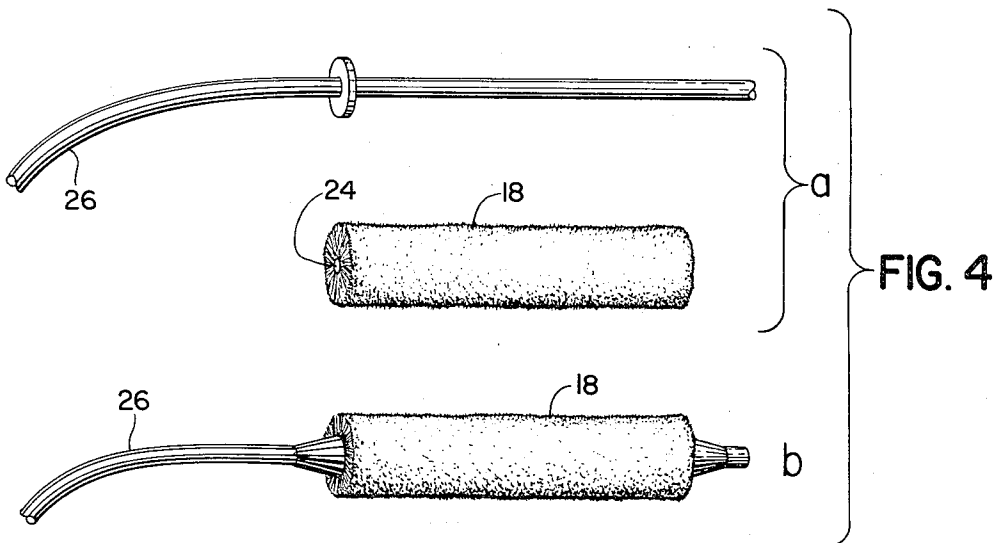


FIG. 4

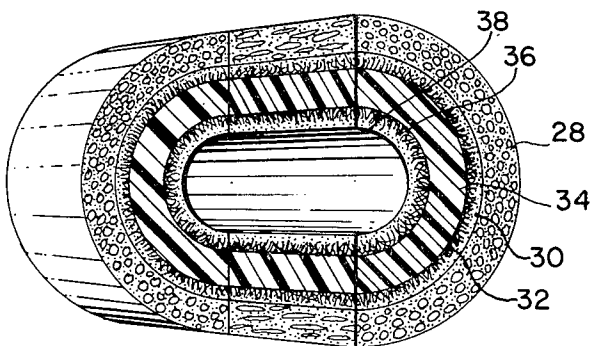


FIG. 5

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## CONTRACEPTIVE DEVICE AND METHOD OF EMPLOYING SAME

### BACKGROUND OF THE INVENTION

Many approaches are currently in use for the prevention of conception. These have been very aptly summarized in the report on Population/Family Planning, issued by the Population Control and International Institute for the Study of Human Reproduction. Briefly, the methods are: coitus interruptus, postcoital douche, prolonged lactation, condom, vaginal diaphragm, spermicides, rhythm method, oral contraceptives, intrauterine devices, and surgical sterilization. During the past decade, interest in family planning and birth control has intensified as the result of the rapid rise in world population and increased use of its natural resources. It is now believed that only through population control and management of resources can the ratio of resources to man be kept within an acceptable level. The sterilization of the male has received increased attention as a method for family planning. However, vasectomy is primarily an irreversible method of sterilization and accordingly is performed on a permanent basis. Although it is a simple surgical procedure, vasectomy has not become popular since it is difficult to ensure that fecundity can be restored if desired.

Attempts have been made, primarily in animals, to achieve reversible male sterilization by vas occlusion using various techniques, such as insertion of a piece of plastic material, electrocoagulation, chemical cauterization, nonoperative vasoligature and placement of nonreactive suture material. Of these, the last named application has proved to be the most satisfactory.

Although the passage of sperm may be blocked by placing various sizes of surgical nylon thread or surgical silk thread into the vas deferens as an intravasal thread and the luminal patency of the vas could be restored by removing the thread, this method is not entirely satisfactory. The surgical thread in a small portion of the experiments conducted revealed that the vas dilated probably because of the increased intravasal pressure caused by continued deposition of sperm due to imbalance between the spermatogenesis and spermatolysis in the testis.

To avoid the vasal dilatation around the intravasal thread and to enhance the restoration of patency of the vasal lumen, certain steps were taken to overcome these drawbacks. The insertion of the intravasal, which in effect blocked passage of the sperm, inhibited the passage of the sperm in a majority of cases. However, the dilation caused by the occlusion allowed the sperm to flow through the outer portion of the intravasal thread and the inner wall of the vas. Also, in some cases tissue reaction was noted.

### BRIEF SUMMARY OF THE INVENTION

My invention is directed to a vas occlusive plug for use as a male contraceptive device. As stated above, currently plugs are being made with a smooth surface, such as the intravasal thread. When they are implanted in the vas deferens, they may not react with the tissue; however, they do not permit growth of the tissue. Since their wall is very smooth and since the sperm is very small, it can travel between the wall of the plug and the intimal wall of the vas. In my invention, the plug is

coated with a material which will permit the ingrowth of tissue therein, thereby preventing a slippage of the sperm at the material tissue junction. The plug is coated with a very fine layer or flock, such as non-woven nylon fabric and/or flocking the surface with a fine layer of nylon or polyester or other type of flock. In this way, the plug may be implanted in the vas deferens, the tissue will grow into the fabric coating thereby fixing the plug in place.

In a preferred embodiment, the head of the plug rather than the entire outer wall is characterized by having bonded thereto a very fine layer of flock or fabric. In addition to the flock, the head may be made by attaching to the device fabric structures which are useful for the ingrowth of tissue, such as woven, non-woven, knitted, etc., fabric structures.

In the selection of the plug material, the primary consideration is the choice of an appropriate material which is compatible with the tissue of the host vessel. For example, organic materials, such as polymeric materials which would include silicones, fluorinated polymers, cellulose and its derivatives, polyesters, polyolefins, vinyls, polyamides, etc., may be used. Inorganic materials and metallic materials, such as stainless steel, etc., also may be used. The plug may be of any structure, either solid or hollow, cylindrical, oval, elliptical, etc. The advantage of using a hollow plug is that it may be saturated or filled with hormones or other drugs which may influence the rate of tissue ingrowth or may be spermicidal or may have some other physiological action.

A further advantage of using a hollow plug for the main body of the device is that it would facilitate the reversibility of the device if at a future date it is decided to allow the sperm to pass through the vas and therefore establish fertility. By having a hollow plug for the main body, the passage initially sealed could be reopened such as by cutting across the plug at both ends in order to open up a channel for the passage of spermatozoa, or by removing a pin from the passage. This would greatly facilitate the surgical procedure and reduce the traumatic effect at the site of implantation.

Accordingly, my device overcomes some of the difficulties of vas occlusion by providing a plug which would eliminate clotting and infection, and provides for fixation of the device in reference to the vas deferens.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic illustration of a plug having a fabric coating on a portion thereof;

FIG. 2 is a schematic illustration of the device inserted in the vas deferens;

FIG. 3 is an enlarged sectional view of the flock attached to the device;

FIGS. 4a and b are schematic illustrations of an alternative embodiment of the device; and

FIG. 5 is a sectional view of the hollow plug having a fabric coating on the outer wall and a fabric lattice on the inner wall.

### DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 shows in schematic form a device 10 which is composed of a plug or filament 12 which varies from 50 to 400 microns in diameter, say for example 100 to 200

microns in diameter. The filament as shown is solid and is composed of a polymeric material such as a polyester, for example DACRON (a trademark of E.I. du Pont de Nemours & Co., Inc.). The head 12 of the plug 10 is composed of a layer of adhesive coating 16 covering a portion of the outer wall of the entire plug body. To overcome infection, but primarily to enhance fixation, bonded into this adhesive layer is a very fine layer of flock 18, such as a DACRON flock.

The outer wall of the device may also be coated with a fabric, such as a velour fabric. This allows for the ingrowth of surrounding tissue into the fabric and fixes the device permanently in the host vessel. The material which form the fabric or fabric layers may be either woven or nonwoven and formed from a variety of organic polymers and also from inorganic compounds which offer the advantages of inertness, complete stability, and a wide range of surface properties. The fabric may be prepared from hot melt polymer extrusion apparatus capable of producing filaments as fine as 0.1 to 2 microns, say for example from 0.1 to 1.0 microns, from various thermoplastic materials. The fabric may also be prepared using polyblend membranes and matting processes.

The plug may be inserted in the vas by making two incisions at either end of an exposed vas and then drawing the plug through the vasal lumen as shown in FIG. 2 until positioned where desired.

A plug similar to that shown in FIG. 1 of approximately 2 centimeters in length having a DACRON flocking thereon was bonded to a silicone polycarbonate rubber filament through the use of a silicone rubber adhesive. The adhesive coated filament was flocked with the DACRON flock, such as electrostatically. The plugs were implanted in 16 humans. After a period of 20 days there was no sperm reappearance in any of the 16 cases. After an average implantation period of 80 days, there was no sperm reappearance and no inflammation signs, pain, or discomfort. After a period of 80 days, in three cases the plugs were removed and there was sperm reappearance after twenty days. The sperm count after reappearance was 10 to 50 million sperms per milliliter.

Referring to FIGS. 4a and b, an alternative embodiment of the plug is shown. This particular plug incorporates a removable pin 26, which is adapted to be placed inside the hollow fiber 24 and anchored on one side thereof with adhesive. The fiber may be comprised of a cellulose resin such as cellulose acetate. The pin may be made of stainless steel or other suitable polymer. After implantation in the vas, tissue will grow and anchor the filamentous flock on the hollow fiber surface. If at a future date it is desired to open this duct, the pin may be removed leaving a straight hollow tube approximately 0.25 millimeters in diameter for the flow of sperm therethrough. This reversibility feature eliminates the problem of rejoining a severed vas which may only be 20 to 30 percent successful. Also, if the coated plug of my invention is used as a solid plug, then its removal would require more delicate surgery and shear the wall of the vas. Another feature of the removable pin is that if sterilization is to be effected again, this may be accomplished by reinserting a pin, such as 26, into the passage thus occluding the flow of sperm therethrough.

In the formation of fabrics to permit cell growth, the matting process is particularly useful for the inorganic materials which are now available in extremely fine diameter filaments. In a selection of materials to produce the fabric the most important consideration is one that will permit good cell attachment. Among some of the parameters considered are: ionic functionality of the polymer (anionic and cationic); varying exchange capacity; surface-free energy; and chemical treatment of surfaces to effect surface-free energy in wetting properties (and probably self-spreading qualities). In the preparation of the fabric, if the hot melt polymer extrusion method is used, fibers may be prepared from a variety of thermoplastic materials including nylon, polyesters, polyethylene, polystyrene, polymethacrylate and others.

In addition to the hot melt polymer extrusion process for forming the lattices, there is a wide range of organic and inorganic fibers which are inert and stable and may be used as viable, compatible materials, for example carbon, the glasses, etc. For these materials, the mats, particularly nonwoven mats, may be prepared by filtering dilute suspensions or filaments or fine screens or filters. The mats may then be attached directly to the fibers which form the device, either by direct bonding or by lamination. Still another method of producing a cell-holding surface is via an open-cell "sponge".

In bonding the fabric to a substrate, depending upon the thickness of the fabric desired, there are various methods which may be employed. For example, vapor phase bonding where exposure of a cold polymer surface to hot concentrated solvent vapor produces a very thin solvent deposit on the surface. This deposit will in turn dissolve the polymer and make the surface tacky. If the two surfaces are brought in contact and held together until the solvent is removed, they will adhere. Also, solvent etching is advantageous for polymer webs and mats that are of a greater thickness than the fine fabric produced by vapor phase bonding, but which still possesses the desired filaments diameter and fabric geometry.

In the technique of controlled solvent etching the fabric is completely embedded in a polymer matrix, for example nylon, acrylic, etc., to form a fabric film laminate. The laminate is then treated with a solvent which removes the matrix film gradually from the surface until the desired thickness of the fabric lattice is exposed. Excess matrix polymers may be removed from the fabric web with a diluted solvent and a nonsolvent.

Heat bonding may also be employed, and one of the more important factors in heat bonding of fabric web in mats to a sheet of polymer is, of course, temperature control. A very rapid rise in the polymer temperature results in complete melting of the film and subsequent total embedding of the fabric in the melted polymer. This point becomes immediately apparent during the determination of the melting point of an organic compound. A gradual rise in temperature is necessary in order to ensure only softening of the polymer surface. The fabric is then impressed on the soft surface with an embossed press to ensure the formation of cell-trapping loops. This technique lends itself particularly to the fabrication of composites from fiber mats of carbon and glass wool. These fibers possess a very high melting point and therefore any suitable thermoplastic

polymer used as a substrate will have a lower melting point. The applicability of the technique is enhanced by using a substrate polymer whose melting point is lower than the fabric material.

A further technique is negative casting wherein a fabric mat, particularly a very thin fabric mat, is rolled into a layer of suitable adhesive having a predetermined thickness. Onto this composite is poured a layer of medical grade silicone rubber adhesive or polyurethane which vulcanizes at room temperature. When the polymer is cured, the soluble adhesive layer is removed by washing in a solvent which does not dissolve the cured polymer layer. This exposes a fabric lattice having a thickness equivalent to the soluble adhesive. The process depends primarily on the selection of an adhesive which is soluble and remains tacky and gelatinous for at least ten minutes after casting onto a flat surface.

A still further method is adhesive bonding which includes a direct bonding of fiber mats and webs to substrate material and is particularly applicable for bonding thicker mats to desirable substrates. For very sheer lattices or fabrics, the adhesive is applied by spraying the composite with a dilute solution of the adhesive in a volatile solvent.

The plug device has been described primarily in reference to the application of a fabric lining on the outer wall of the plug. When a hollow plug is used as shown in FIG. 4, it is also possible to coat the inner wall of the hollow tube with a fine fabric lattice to promote cell growth thereon. This would be applicable when the pin 26 of FIG. 4 is removed to provide the reversibility as desired. Upon the removal of the pin and the resumption of the flow of the sperm through the passageway left therein, the fine fabric lattice on the inside wall would then promote the growth of a cellular layer thereon.

As is generally known, the number of cellular layers supported by the lattice is related to the original thickness of the lattice. If desired to facilitate growth of cells, the lattice may be seeded with a cellular suspension obtained from the host vessel. The fabric lattice would support the growth on endothelial cells such as would be found on the inner wall of the vasal lumen. Referring to FIG. 5, a sectional view is shown of the hollow fiber where the plug has been removed. The vasal lumen is shown at 28, the cell ingrowth into the fabric layer shown as 30, the fabric layer shown as 32, the inner wall of the hollow fiber shown as 34, the fabric lattice shown as 36 and the endothelial cells coating said fabric layer are shown at 38. Accordingly, by coating the outer wall of the reversible plug with a fabric, this provides the cell ingrowth into the fabric to provide fixation of the plug. If reversibility is desired, once the pin 26 of FIG. 4a is removed, then the fabric lattice on the inside of the hollow fiber will permit the growth of the endothelial cells thereon as shown in FIG. 5. The webs which form the fabric lattice may be either woven or preferably nonwoven and formed from a variety of organic polymers and from inorganic compounds which offer the advantages of inertness, complete stability, and a wide range of surface properties. The selection of the fabric, velour or flock, inner lining for the hollow tube is made bearing similar considerations in mind as were made for the fabric coating

on the outer wall of the device. That is, the material should be compatible with the cell structure or type of cells in the surrounding tissue which will grow into and attach to the fabric lattice. Also, similar materials on construction as were used for the outer fabric may also be used for the inner fabric. The lamination or preparation of the inner wall of the device may be accomplished in any of several ways such as outlined for the preparation of the fabric on the outer wall. Further, additives which would control the growth of the cells may be incorporated into the fabric material. Additionally, the fabric velours or flocks may be woven or nonwoven and made from material similar to those used in the preparation of the outer fabric and may be incorporated onto or within the polymer surface or wall surface in a manner similar to that as the fabric.

In another embodiment, the entire plug, either solid or hollow, may be made out of a soluble suture material such as cat gut, collagen, gelatin, starches, such as cross-linked polysaccharides, which are essentially materials adapted to be dissolved by tissue enzymes. Depending upon how long an individual such as a male, was to be sterilized, the degree of tanning or cross-linking of the plug material can be varied whereby it may dissolve from two weeks to three years by the tissue enzymes. In this situation if sterilization is only required say for a period of 2 years, then such a plug as shown in FIG. 1 may be inserted, the outer fabric wall will provide the fixation desired, and then at the end of the 2 year period enough of the plug will have dissolved to provide a passageway for the sperm therethrough. In another embodiment as shown in FIG. 4, a hollow tube may be used with the inner wall either coated or uncoated with a lattice and the pin may be constructed of suitable material whereby it will dissolve within the prescribed time.

Additionally, material may be used for which the solid plug, hollow plug, or pin may be composed, which materials would dissolve upon the introduction of a dissolving agent into the vas deferens. For example, the pin 26 of FIG. 4 may be composed of a material noninjurious to the body, such as a cellulose. When it is desired to restore fecundity, a dissolving agent noninjurious to body tissue, such as an enzyme, for example a cellulase enzyme, may be added dissolving the pin thus freeing the passage for the flow of sperm therethrough.

Accordingly, the invention provides a very simple and effective method of male sterilization which can be reversed. Although described in connection with a vas plug, it is of course obvious that the same concept and device may be used for a fallopian plug. Recent studies with silicone rubber implants in the fallopian tube have shown that such plugs are readily dislodged by normal tubular motility and can be extruded intraabdominally. Of course, if such a plug is made from the device of my invention, that is a flock hollow fiber packed with a removable pin, it will be anchored by the adjoining tissue and may be reversed by removing the pin. This could be accomplished by injecting a fluid into the fallopian tube to dilate the tube, inserting the plug, and when the tube retracts, the plug would be held in place until such time as the tissue commences to grow into the fabric wall.

Having described my invention, what I now claim is:

1. A device for the reversible occlusion of a body cavity, such as a vas deferens or fallopian tube, which device comprises:

- a. a plug-like structure adapted to be inserted into a body cavity to provide occlusion of the cavity, the structure characterized by an outer surface;
- b. a fabric means disposed on and secured to at least a portion of the outer surface of the plug-like structure to provide for fixation of tissues to the fabric means through the growth of cells therein; and
- c. all or a part of the device composed of a material adapted to be dissolved by enzymes while in the body cavity within a predetermined period of time, thereby permitting removal of the occlusion of the body cavity by the device.

2. The device of claim 1 wherein the plug-like structure is composed of a material adapted to be dissolved by the tissue enzymes.

3. The device of claim 1 wherein the fabric means is composed of a material adapted to be dissolved by the tissue enzymes.

4. The device of claim 1 wherein the device is composed of a material adapted to be dissolved by the introduction of a dissolving agent.

5. The device of claim 1 wherein the plug is generally cylindrically shaped and composed of solid polymeric material.

6. The device of claim 1 wherein the plug comprises a hollow tube-like structure, and wherein said plug is sealed at either end thereof.

7. The device of claim 1 wherein the plug comprises a hollow tube-like structure, and includes a removable pin disposed therein and adapted to seal said plug.

8. The device of claim 7 wherein the pin is composed of a material adapted to be dissolved by the action of enzymes within a predetermined period of time.

9. The device of claim 1 wherein the device is composed of a material comprising catgut, collagen, gelatin, starch, cellulose and cross-linked polysaccharides dissolvable by enzymes.

10. The device of claim 1 wherein the fabric means comprises a flock material.

11. The device of claim 1 wherein the plug-like structure comprises a silicone rubber, and the fabric means comprises a polyester or nylon material.

12. A contraceptive device for the reversible occlusion of a vas deferens, which device comprises:

- a. a hollow tube-like structure adapted to be inserted into the lumen of the vas deferens to provide occlusion of the sperm through the lumen, the tube-like structure characterized by an outer and inner surface;
- b. a fabric means disposed on and secured to at least a portion of the outer surface to provide for fixation of the tissues from the inner wall of the lumen to the fabric means through the growth of cells therein;
- c. a removable pin disposed within the tube-like structure and adapted to seal said structure; and
- d. all or part of the device composed of a material adapted to be dissolved within a predetermined period of time, thereby permitting removal of the occlusion caused by the device in the vasal lumen.

13. A method for sterilization which comprises:

a. inserting a plug-like structure having a fabric-like material covering a portion of the outer surface of the plug-like structure into the vasal lumen to provide occlusion to the passage of sperm through the lumen, the plug-like structure composed at least in part of a material adapted to be dissolved within a predetermined period of time, while in the vasal lumen;

b. allowing the growth of cells into the fabric fabric-like material to secure the plug-like structure in the vasal lumen and to preclude the passage of sperm between the outer surface of the plug and the inner wall of the lumen; and

c. dissolving all or part of the dissolvable material through the use of enzymes so as to provide a passageway for the sperm through the vasal lumen after a predetermined period of time.

14. The method of claim 13 wherein the material adapted to be dissolved comprises catgut, collagen, gelatin, starch, cellulose and cross-linked polysaccharides.

15. The method of claim 13 wherein the material to be dissolved is dissolved through action of the tissue enzymes.

16. The method of claim 13 wherein the dissolvable material is dissolved by adding a dissolving agent into the vasal lumen.

17. The method of claim 13 wherein the dissolvable material is composed of cellulose, and wherein the dissolving agent is an enzyme which dissolves the cellulose.

18. The method of claim 13 wherein the plug-like structure is a hollow tube-like structure which includes a removable pin disposed therein and adapted to seal said tube-like structure, and which method includes the step of providing a pin material made of a dissolvable material, and dissolving the pin after a predetermined period of time.

19. A device for the reversible occlusion of the vas deferens, which device comprises:

a. a hollow tube-like structure characterized by having an outer surface, the structure adapted to be inserted into the vasal lumen of the vas deferens;

b. means sealing either end of the tube-like structure prior to insertion in the vasal lumen, which means can be removed at a later period of time to permit the passage of sperm through the interior of the tube-like structure without removal of the structure from the lumen; and

c. a fabric means disposed and secured to at least a portion of the outer surface of the tube-like structure to provide for fixation of tissue to the fabric means through the growth of cells therein, thereby preventing the passage of sperm between the outer surface and the inner wall of the vasal lumen.

20. The device of claim 19 wherein the sealing means of the tube-like structure includes a removable pin disposed within the tube-like structure and adapted to seal said structure.

21. The device of claim 19 wherein the fabric means disposed on the outer surface comprises a flock material.

22. The device of claim 19 wherein the fabric means comprises a polyester or nylon material and the tube-like structure comprises a silicone rubber.

23. The device of claim 19 wherein the tube-like structure is a hollow tube-like structure characterized by an inner wall, and wherein the fabric means is also disposed on and secured to at least a portion of the inner wall.

24. The device of claim 19 wherein the tube-like structure contains therein a material which influences the rate of tissue growth.

25. The device of claim 19 wherein the tube-like structure contains therein a material which is spermicidal.

26. A reversible method of male sterilization, which method comprises:

- a. inserting a hollow tube-like structure having a fabric-like material covering a portion of the outer surface into the vasal lumen, the tube-like structure sealed at either end thereof;
- b. allowing the growth of tissue into the fabric to fix the sealed tube-like structure in the vasal lumen and to occlude the passage of the sperm through the vasal lumen; and
- c. removing the seal from the tube-like structure when occlusion of the passage of sperm is no longer desired, thereby permitting sperm to pass again through the interior of the tube-like structure and through the vasal lumen.

27. The method of claim 26 wherein the tube-like structure is sealed by inserting a removable pin in the tube-like structure, and wherein the seal is removed by removing said pin.

28. The method of claim 26 which includes covering a portion of the inner surface of the hollow tube-like structure with a fabric-like material, and after removal of the seal of the tube-like structure, permitting the growth of cells into said fabric material on the inner surface.

29. The method of claim 26 which includes reopening the vasal lumen by cutting across the sealed tube-

like structure at both ends in order to open a channel for the passage of spermatozoa.

30. A contraceptive device for occlusion of a vas deferens which comprises:

- a. a plug-like structure adapted to be inserted into the vasal lumen to provide occlusion of the sperm through the vasal lumen;
- b. the plug-like structure characterized by an outer surface, which surface is adapted to engage the inner wall of the vasal lumen; and
- c. fabric means disposed on and secured to at least a portion of the outer surface to provide for fixation of tissue to said fabric means through the growth of cells from the walls of the vasal lumen into the fabric so that passage of sperm between the outer surface of the plug-like structure and the inner wall of the vasal lumen is prevented by such tissue growth.

31. The device of claim 30 wherein the plug is generally cylindrically shaped and composed of solid polymeric material, and wherein the fabric means is composed of a polymeric material compatible with the body tissues.

32. The device of claim 30 wherein the plug is composed of silicone resin and the fabric means is composed of nylon or polyester material.

33. The device of claim 30 wherein the fabric means comprises a flock material.

34. A method of male sterilization which comprises:

- a. inserting a plug-like structure into the vasal lumen, the plug-like structure characterized by an outer surface having a fabric material thereon; and
- b. allowing the growth of tissue from the inner wall of the vasal lumen into the fabric material to occlude the passage of sperm between the outer wall of the plug-like structure and the inner wall of the vasal lumen.

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