

[54] **VAS PROSTHESIS FOR REVERSIBLE
STERILIZATION**
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[51] Int. Cl. **A61b 19/00**
[58] Field of Search **128/1 R, 127, 303 R, 274;**
251/4, 9

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[57] **ABSTRACT**
A prosthetic device for reversibly blocking semen flow through the vas deferens including a cannula for sealed coupling with severed portions of the vas and a reversible valve associated with the cannula having a closed position for blocking fluid flow and an open position for permitting fluid flow. Microcavities may be incorporated externally or internally on the surfaces of the cannula for compatibility with living tissue. The valve types include mechanical clamps or plugs and a hydraulically actuated expandible cuff.

6 Claims, 6 Drawing Figures

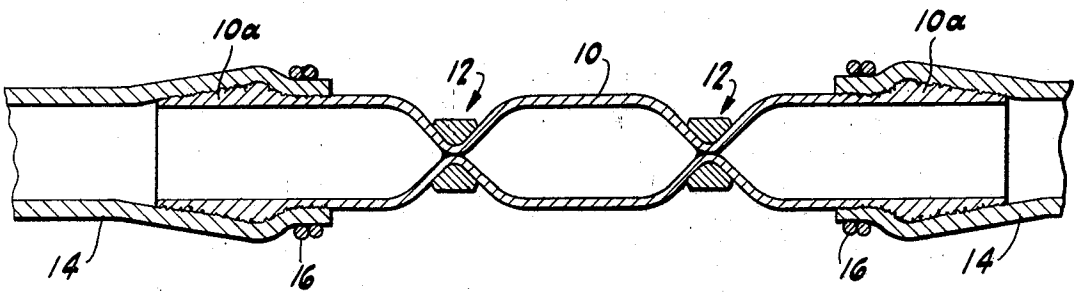


FIG-1

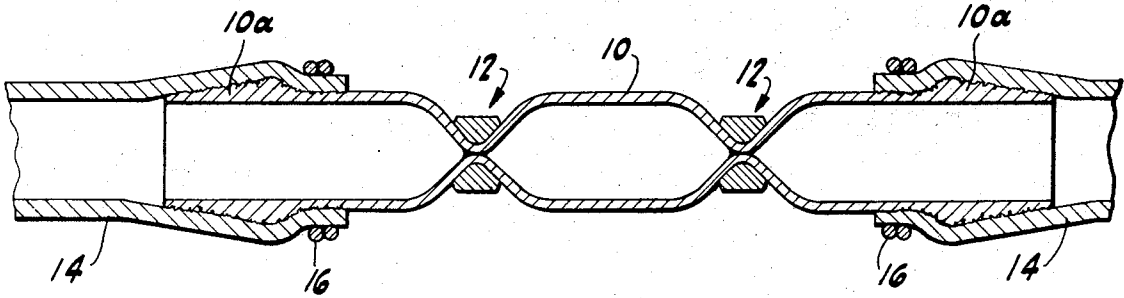


FIG-2

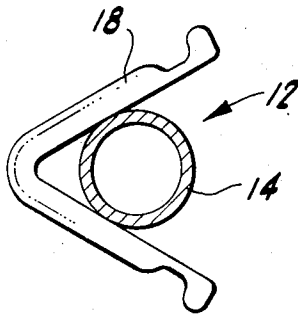


FIG-3

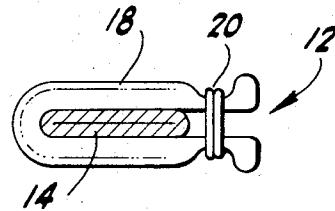
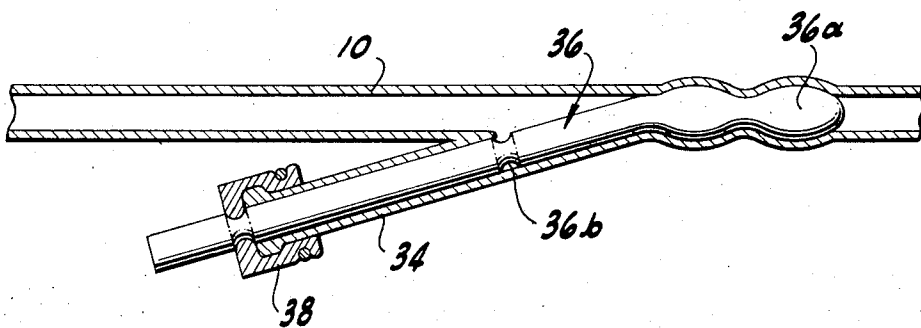


FIG. 6



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FIG. 4

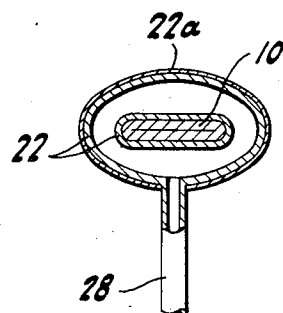
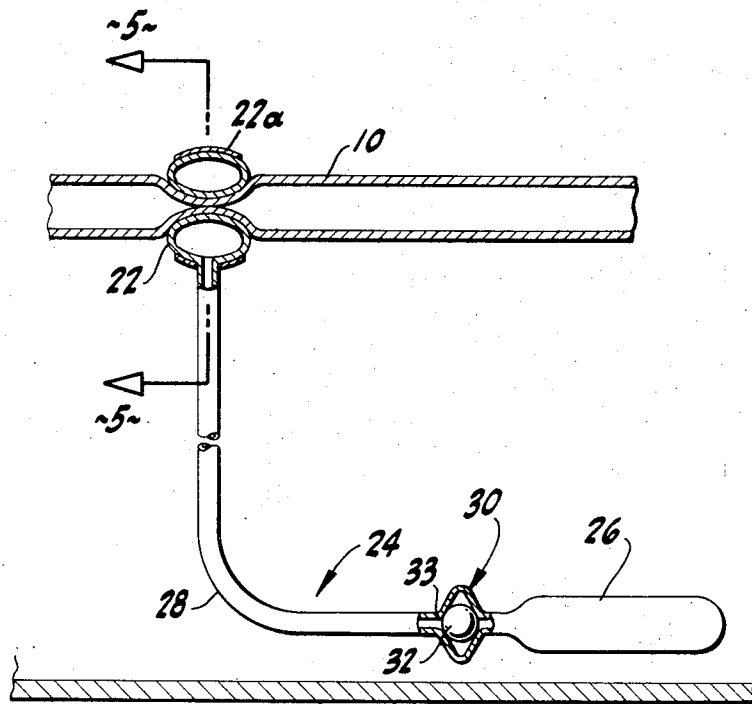


FIG. 5

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VAS PROSTHESIS FOR REVERSIBLE STERILIZATION

BACKGROUND OF THE INVENTION

The present invention relates to method and means for reversible sterilization of the male.

A well-known technique for sterilization of the male is by vasectomy, the removal of a section of the vas deferens, or semen-carrying duct, and the ligation of each end of the tube. This is a comparatively safe procedure accomplished in a matter of minutes with local anesthesia. However, reversing the sterilization procedures by reuniting the severed portions of the vas is surgically complex and is frequently unsuccessful. Accordingly, although a vasectomy offers a highly effective sterilization method with extremely small risk to physical health only those males who are certain that they do not desire more children are generally willing to be so operated upon.

Various devices for reversible sterilization have been attempted by blocking the vas deferens such as by direct clamping or plugging of the same. However, these methods are not successful in complete blockage of semen flow over long periods of time. This is apparently due to the tendency of the vas tissue to provide paths around the blockage through which the semen is able to flow. In fact, because of this tendency, during a vasectomy extensive precautions are taken to avoid the possibility of this natural tunnelling phenomenon by the vas tissue. For example, in a typical vasectomy, a portion of the vas is severed and removed and the remaining extremities are either tied off and cauterized with an electric needle, or wrapped in tissue for sealing. Even in those cases when anastomosis of the severed vas portions is successful in the reformation of the vas to carry semen, certain serious complications frequently arise due to sperm leakage from the vas at the connection. Such complications include granulomas, tumors, infections, and general discomfort to the patient.

SUMMARY OF THE INVENTION AND OBJECTS

In accordance with the present invention, a prosthetic device is provided for reversibly blocking semen flow through the vas deferens. The device includes a cannula which is inserted into severed portions of the vas to provide a continuous fluid passageway. The cannula extremities may include surface portions having a plurality of microcavities for compatibility with living tissues so that the vas forms an adherent tissue with the cannula extremities upon coupling.

A reversible valve is associated with the cannula with positions for blocking or unblocking fluid passage through the cannula in a relatively simple manner. The valve may be mechanically, hydraulically, magnetically, or electromagnetically actuated. In one embodiment, a cannula is formed of a flexible material and the valve means includes a pinch clamp. Or the valve may include a side arm in communication with the cannula passage with a plug slidably received in sealing engagement within the side arm so that in one position the plug projects into the cannula passage in fluid sealing engagement and is retractable to another position to unblock the cannula but prevent leakage. In still another embodiment, the valve includes an inflatable cuff mounted about a flexible cannula with a hydraulic

mechanism for expanding the cuff by filling it with hydraulic fluid or collapsing the same by withdrawing the fluid.

After insertion of the prosthetic device, the valve means may be actuated by either another incision to obtain access to the valve, or by external manipulation without the necessity of incision. An example of the latter method is by manual operation of the aforementioned hydraulic mechanism.

In general, it is an object of the present invention to provide a method and means for highly reliable reversible male sterilization.

It is a particular object of the invention to provide for periodic blocking and unblocking of semen flow without the necessity of vas ligation or anastomosis at each occurrence.

The foregoing and other objects will become apparent from the following description when taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an enlarged view of the severed end portions of a vas with a prosthetic device according to the invention in a closed position.

FIGS. 2 and 3 are cross-sectional views of the valve and prosthetic device in open and closed positions, respectively.

FIG. 4 is an enlarged cross-sectional view of another valve for the prosthetic device of the invention in a closed position.

FIG. 5 is a cross-sectional view taken along the lines 5—5 of an inflatable cuff portion of FIG. 4.

FIG. 6 is another view of the valve and the prosthetic device of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIGS. 1-3, one embodiment of the prosthetic device includes a cannula 10 and an operatively associated valve means 12. The cannula extremities 10a are adapted for insertion within two severed end portions of the vas deferens 14 for sealing engagement therewith. For this purpose, extremities 10a are formed from or supported by a generally rigid material such as a metal (e.g., stainless steel) or a rigid plastic (e.g. nylon or polyvinyl chloride) to provide support for ties 16, of a normal suture material such as polymer thread. The ties are wound about the external surface of the vas to provide a fluid seal and also to retain the cannula within the vas. Tissue adhesion and fixation subsequently improve this seal and cannula retention. As a further retention feature, extremities 10a are provided with a tapered portion which includes a slip-resistant shoulder. The central portion of the cannula is formed of a flexible material such as an elastomer (e.g., silicon rubbers and polyurethanes) which is compressible to seal against itself and is sufficiently resilient to return to its initial shape when compression is relieved. In a particularly effective means for providing a tissue-adherent fluid sealed interface between the cannula extremities and the vas, the outer wall may contain a plurality of microcavities such as formed in accordance with the method set forth in copending application Ser. No. 77,289, filed Oct. 1, 1971. These microcavities allow the vas tissue to grow around the outside walls

and become permanently affixed or anchored to the same by tissue ingrowth.

A surface containing a plurality of microcavities may also be applied internal to the prosthesis to improve tissue adhesion and compatibility.

Referring again to FIGS. 1-3, valve means 12 is illustrated as a pair of clamps 18 having a pivotal central portion for two extending side arms. Ties 20 are provided to tie the clamp into a closed position as shown in FIG. 3. Clamps 18 should be formed of a material which is capable of repeated flexure and prolonged stress, such as an elastomer or metal. It is noted that, in a closed position, clamps 18 provide sufficient compression to flatten the cannula between the arms so that there is essentially no fluid bypass. Although two clamps are illustrated as a double blocking device, it should be understood that a single clamp could be used if it were sufficiently reliable in blocking semen passage.

The aforementioned prosthetic device is inserted by making an incision to provide access to the vas, severing the vas deferens, and then inserting cannula extremities 10a at the severed end portions of the vas to form a continuous passageway. When clamps 18 are in open position as shown in FIG. 2, semen is permitted to pass through the linking channel formed within the cannula. When the valve is in a closed position as shown in FIG. 3, semen is blocked from passage. It is apparent that in this type of an incision to provide access for opening or closing the valve. This is a procedure that requires relatively minor surgical precision.

Referring to FIGS. 4 and 5, a hydraulically actuated valve means is provided comprising an inflatable cuff 22 mounted about cannula 10 and in fluid communication with a hydraulic fluid flow means 24. The valve is closed by expansion of the cuff to force the cannula inwardly to provide a fluid seal as shown in FIG. 4. The cuff is of a generally elliptical and annular configuration so that upon expansion, it will form two opposing surfaces which will flatten out the corresponding inner surfaces of the cannula to provide a long sealing edge. To prevent outward expansion of the cuff as it fills with fluid and to thereby direct the expansion of the cuff inwardly, the outer, non-engaging portion 22a of the cuff is formed of a material which does not substantially stretch. This is suitably accomplished by adhering a rigid backing to the cuff or thickening the elastic material in that area. The inner cuff material may be formed of any elastic material which is reversibly expandible and collapsible.

Hydraulic fluid flow means 24 generally includes a reservoir 26, a fluid duct 28 to provide fluid communication between the reservoir and cuff, and a fluid duct valve 30 disposed along duct 28. Reservoir 26 may be formed of any flexible material which is capable of transmitting fluid from the reservoir upon the application of pressure and of receiving the same fluid upon pressure release. Valve 30 is of a type that includes an open position in which the hydraulic fluid is permitted to flow between reservoir 26 and cuff 30 for inflation or deflation of the same depending upon the flow direction and a closed position in which passage of the hydraulic fluid is completely blocked in both directions. A suitable valve of this type, illustrated in

FIG. 4, is of a ball-check type including a ball 32 in valve seat 33 formed of flexible, annularly projecting portion of duct 28. In a closed position, ball 32, is seated to block hydraulic fluid passage in either direction. The valve is opened to permit bypass of fluids by squeezing the valve seat 33.

The cannula portion of the prosthetic device and method of insertion is the same as that described with respect to FIGS. 1-3. After initial cannula insertion, there is no need to repeat incisions in the scrotum to provide access for changing the valve setting since the hydraulic fluid flow means is actuatable by external manipulation. The valve 30 may be pressed for opening to permit bypassing of fluid by compressing the valve seat 33 through the skin. In like manner, the cuff is expandible by finger pressure against reservoir 26 causing fluid to pass through the open valve 30 into the cuff. When desired to permit semen passage through the cannula, the valve seat 33 is again compressed and pressure created on the walls of the flexible cuff causes the same to collapse and release fluid under pressure into the reservoir. Valve 30 is then closed and semen is permitted to flow continuously through the cannula.

Referring to FIG. 6, another embodiment of a valving means of the invention is provided including a hollow side arm 34 in communication with the main passage of cannula 10 and a plug means 36 slidably received in fluid sealing engagement within the side arm. Plug means 36 is formed of a generally flexible material and includes a plug tip 36a, of a configuration to provide a fluid seal with a portion of the flexible cannula when projecting into the cannula passage, and an annular plug recess groove 36b. This closed valve position is illustrated in FIG. 6. Side arm 34 is provided with a suitable plug retainer 38 having inwardly projecting portions for seating accommodating groove 36b when the plug is withdrawn sufficiently to open the main channel of cannula 10 but not enough to break the semen seal in the side arm. The outer end of the plug 36 projects from the side arm when the valve is in a closed position so that it may be manually engaged for sliding the plug into an open or closed position.

It is apparent from the foregoing that a prosthetic device for reversibly blocking semen flow through the vas deferens had been provided which includes a cannula which is inserted within severed portions of the vas and a valve having a closed position for blocking fluid flow and an open position for permitting flow. Certain embodiments of the valve mechanism have been illustrated. It should be apparent that any reversible valve may be employed along with a vas-insertable cannula to function within the scope of the present invention.

I claim:

1. A prosthetic device for reversibly blocking semen flow through the vas deferens comprising a cannula including surface portions at both extremities including a plurality of adjacent substantially discrete pockets with the walls of said pockets being of a shape and size for receiving living cells of said vas deferens for sealed firm coupling with severed portions of the vas deferens to provide a continuous fluid passageway therewith and form a semen seal and reversible valve means associated with said cannula having a closed position for blocking fluid flow and an open position for permitting flow.

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2. A prosthetic device as in claim 1 in which the cannula extremities are essentially rigid and are adapted for insertion into the vas portions.

3. A prosthetic device as in claim 1 in which said cannula is formed of a flexible material and said reversible valve means includes a clamp which compresses portions of the cannula together in said closed valve position.

4. A prosthetic device as in claim 1 in which said reversible valve means includes a side arm in communication with the cannula passage and a plug means slidably received in fluid sealing engagement with said side arm, said plug means projecting into the cannula passage in fluid sealing engagement therewith in a closed valve position and retracting to unblock the cannula passageway but prevent leakage therefrom in open valve position.

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5. A prosthetic device as in claim 1 in which said cannula if formed of flexible material and said reversible valve means comprises an inflatable cuff mounted about said cannula and hydraulic fluid flow means for expanding said cuff by filling the same with hydraulic fluid and for collapsing the cuff by withdrawing the fluid.

6. A prosthetic device as in claim 4 in which said hydraulic fluid flow means includes a hydraulic fluid reservoir, a fluid duct in communication with said fluid reservoir and cuff, and a fluid duct valve operably associated with said duct having an open position in which the hydraulic fluid is permitted to flow between said reservoir and said cuff for inflation or deflation of the same and a closed position in which passage of the hydraulic fluid is blocked.

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