

PATENT SPECIFICATION

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(54) A VALVE ADAPTED TO BE LOCATED IN A HUMAN VAS DEFERENS

(71) We, INVESTORS IN VENTURES, INC., of 140 Broadway, New York, State of New York, United States of America; a corporation organized and existing under the laws of the State of New York, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to a valve adapted to be located in a human vas deferens.

In particular, the present invention relates to a valve which is constructed so that it can be inserted into a human vas deferens and remain permanently therein.

As is well known, vasectomies are performed in order to achieve sterility in the adult human male. While such operations are simple and effective, they suffer from the extremely serious drawback of being irreversible, for all practical purposes. Once a vasectomy is performed it is almost impossible to reestablish flow through the vas. It is theoretically possible to perform a second operation re-establishing communication in the vas at the location where the original surgical excision took place, but the initial vasectomy is invariably performed with a view toward achieving permanent sterility, and at best reestablishing flow through the vas would involve extremely complex, expensive, and delicate procedures.

At present there is no known way to close the vas temporarily and again conveniently open it in the event that flow therethrough is again desired.

It is accordingly a primary object of the present invention to provide the possibility of conveniently and with simple surgical procedures closing the vas reliably in a manner which will enable convenient open-

ing thereof at any future time, if so desired.

In particular, it is an object of the invention to provide a valve which can conveniently be inserted into the vas and which can be manipulated for closing the vas and for subsequently reopening the vas.

Thus, it is an object of the present invention to provide a valve which is on the one hand small enough to be accommodated within the vas without any substantial distention thereof while on the other hand it is large enough to provide unrestricted flow through the vas when the valve is opened.

It is especially an object of the present invention to provide a valve of this nature which will have relatively movable components coacting in a fully fluid-tight manner while at the same time assuring the movability of one component relative to the other without undesirable resistance to this movement.

Also, it is an object of the invention to provide a valve of this nature the possibility of reliably locking the valve releasably in its closed position.

Furthermore, it is an object of the present invention to provide a valve of this type which is capable of forming an intimate union with that part of a vas wall through which the valve structure extends to the exterior of the vas.

According to the present invention there is provided a valve for reversibly interrupting the flow of sperm in a human vas deferens which is small enough to be implantable in a human vas deferens, the valve carrying, at its exterior surface, means capable of forming an intimate union with the wall of the vas deferens when the valve is implanted therein, such that, in use, a seal is formed between said means and the wall of the vas deferens which prevents the passage of sperm along the vas deferens along

[Price 25p]

the exterior surface of the valve.

The invention will be further described by way of example with reference to the accompanying drawings, in which:—

5 Fig. 1 is a longitudinal sectional elevation showing the valve in its closed position and schematically illustrating the part of the vas deferens which receives the valve of the invention;

10 FIG. 2 is a transverse section, at a scale enlarged as compared to FIG. 1, taken along line 2-2 of FIG. 1 in the direction of the arrows;

15 FIG. 3 is a longitudinal sectional elevation of another embodiment of a valve of the invention, also illustrated within a schematically represented vas deferens;

20 FIG. 4 is a longitudinal sectional elevation of another embodiment of a valve of the invention, also shown in a schematically represented vas deferens;

25 FIG. 5 is a transverse section at a scale which is enlarged as compared to FIG. 4, taken along line 5-5 of FIG. 4 in the direction of the arrows; and

FIG. 6 is an enlarged representation of another embodiment of a handle which may be mounted on the outer operating end portion of the valve stem.

30 Referring now to FIG. 1, there is schematically represented therein a human vas deferens 12 surrounded by tissue 14. Situated within the vas deferens 12 is the valve 16 of the present invention. This valve 16 includes an inner component 18 and an outer component 20. The inner component 18 has at one end a valve body 22 which is of a spherical configuration in the illustrated example and which is formed with a bore 24 passing therethrough. As is apparent particularly from FIG. 2, the bore 24 extends perpendicularly across the axis of an elongated stem 26 of the inner component 18. The outer component 20 houses the valve body 22 and part of the stem 26 adjacent to the valve body. The stem 26 and valve body 22 are affixed to one another, and the entire inner component 18 can rotate about the axis of the stem 26 thereof within the outer portion. The stem 26 terminates distant from the valve body 22 in an outer operating end portion 28 situated beyond the vas deferens 12 and formed with a bore 30 passing there-
55 through.

60 This bore 30 receives part of a wire handle 32 which projects from the operating end portion of the stem and is accessible beyond the vas deferens for manual turning of the inner component 18 between the illustrated closed position and an open position angularly displaced about the axis of the stem 26 through 90° with respect to the closed position. In the open position of the valve the axis of bore 24 coincides with

the axis of the hollow tubular interior of the vas 12 while in the closed position the valve the axis of the bore 24 extends perpendicularly to the axis of the hollow interior of the vas deferens. The handle 32 is curved laterally in the manner shown in FIG. 2 so that it can be swung in a counter-clockwise direction, as viewed in FIG. 2, from the position shown in FIG. 2 into an inoperative rest position where it will be situated directly alongside the vas 12. 70 75

The outer component 20 of the valve consists of integrated molecular layers of a material which is compatible with the human vas deferens. The inner component 18 is also made of such material. For example, the valve components may be made of gold, although other materials such as platinum or rhodium may be used. 80

The valve of the present invention may be constructed in a manner shown in the inventor's United States Patent No. 3,616,520, issued November 2, 1971. Thus, the outer component is deposited by gas vapor deposition, by electrolytic deposition, by electroless deposition, or the like, on suitable cores which are subsequently removed as well as directly on the valve body 22 and the part of stem 26 located directly next to the valve body 22. This deposition of molecular layers one upon the other is continued until the wall thickness of the outer component 20 has reached a desired magnitude. Upon removal of the cores the component 20 will have the hollow, open-ended tubular extensions 34 and 36 which communicate with the bore 24 when the inner component is in its open position and which extend along the axis of the vas deferens in opposite directions away from the valve body 22. In the position of the parts shown in FIG. 1 the tubular extension 34 which is longer than the extension 36 forms the upstream extension of the outer component 20. This extension 34 is formed with a series of annular constrictions 36' distributed along the extension 34 in order to enhance the mounting of the valve in the vas deferens. 85 90 95 100 105 110

The part 38 of the stem 26, which is directly adjacent to the valve body 22, is of a lesser diameter than the outer operating end portion 28 of the stem 26, and this part 38 is surrounded by a tubular portion 40 of the outer component 20. As a result of the deposition of the integrated molecular layers which form the component 20, the innermost molecular layer forms the inner surface of the component 20 and has a fluid-tight engagement with the exterior surface of inner component 18 at its part 38 as well as at the entire exterior surface of valve body 22 except the portions of this latter surface which communicate with the tubular extensions 34 and 36. This inner 115 120 125 130

surface of the outer component 16 is pre-
sely complementary to the exterior surface
of the inner component which it engages,
and as a result of the deposition of the inte-
grated molecular layers a reliable fluid-
tightness is achieved while at the same time
the inner component 18 can be turned with
respect to the outer component 16 without
the requirement of overcoming an undesir-
ably large force of friction. Thus, with
this particular construction a perfectly reli-
able fluid-tightness is achieved with the pos-
sibility of conveniently turning the valve
between its open and closed positions.

The valve is inserted into the vas deferens
after a relatively short longitudinal slit 42
is formed in the vas deferens. This slit is
schematically represented in FIGS. 1, 3,
and 4. After the slit 42 is formed, the
surgeon can readily introduce the extension
34 into the interior of the vas deferens into
the position shown in FIG. 1, and then the
rest of the valve can be introduced into the
vas deferens until it assumes the position
shown in FIG. 1. The wall of the vas de-
ferens will of course heal at the slit 42 so
as to close the latter.

In order to form an intimate union with
the wall of the vas deferens a suitable
means surrounds the tubular portion 40 of
the outer component 16. In the illustrated
example this means 44 takes the form of a
fine gold wire which is simply wound
directly around the tubular portion 40 of
the outer component 16 so as to provide the
valve at the exterior of the tubular portion
40 with an irregular exterior surface struc-
ture having many interstices into which the
tissue can grow for the purpose of achiev-
ing the desired intimate bond or union with
the valve.

The size of the valve components is
chosen so that the valve is small enough to
be introduced into the vas deferens without
substantially distending the vas deferens.
On the other hand, the hollow interiors of
the tubular extensions 34 and 36 as well as
the bore 24 have diameters large enough to
provide for substantially unrestricted flow
through the valve and along the tubular in-
terior of the vas deferens when the valve is
turned to its open position.

In an actual construction of the valve of
the invention the spherical valve body 22
has a diameter of 0.040 inch while the
tubular extensions have an internal dia-
meter of 0.020 inch. Thus, the diameter of
each tubular extension may be considered
as being roughly equal to one-half the dia-
meter of the spherical valve body 22.

After the above-described valve of the
invention has been introduced into the vas
in the manner described above, the valve is
initially situated in its closed position shown
in FIGS. 1 and 2, and then the handle 32

is turned down to the dot-dash line position
indicated in FIG. 2. If at any future time
it is desired to open the valve, the surgeon
need only provide access to the handle 32
which can again be turned up to the solid
line position shown in FIG. 2, whereupon
the inner component 18 can be turned
through 90° from the position shown in
FIGS. 1 and 2, so as to provide communica-
tion of the tubular extensions 34 and 36
through the bore 24. The handle 32 can
now be turned to a position extending
across and located closely adjacent the vas
deferens and whenever it is desired to close
the valve the parts can be returned readily
to the position shown in the drawings.

The embodiment of the invention which
is illustrated in FIG. 3 is identical with that
of FIGS. 1 and 2, except for the following
differences, and the identical components
are designated by the same reference
characters. Thus, in the embodiment of
FIG. 3 the exterior surface of the outer
component 20 is covered with a coating 46
which is a plastics coating. This coating
may be a silicone rubber coating, preferably
silastic (R.T.M.) which is known to be com-
patible with human tissue.

Also, in the embodiment of FIG. 3, in-
stead of a handle 32, there is an elongated
resilient wire handle 48 having one end
received in the bore 30 and having an
opposed tapered enlarged end 52. This
handle is more compact in that it does not
extend to the same distance from the oper-
ating end portion of inner component 18
and can just as readily be turned down to
an inoperative position. Also, if desired it
can be removed and simply connected with
the operating end portion of the inner com-
ponent 18 whenever it is desired to change
the position of the valve. Except for these
differences the embodiment of FIG. 3 is
identical with that of FIGS. 1 and 2. The
wire handles 32 or 48 may be made of a
metal such as tantalum.

The embodiment of FIGS. 4 and 5 is
identical with that of FIG. 3 except that this
embodiment includes an elongated longi-
tudinally split, resilient, tubular plastics
shroud 54 which can be expanded at its
axially extending slit 56 so that it can
readily be placed around the vas. The
shroud 54 is formed with a bore 58 through
which the stem 26 extends with the operat-
ing end portion 28 thereof and handle 48
situated beyond the shroud. After the
shroud is placed in its position surrounding
the vas and received the stem 26 through
the bore 58, the end 50 of the handle 48 is
introduced into the bore 30. At its upper
surface, as viewed in FIG. 4, the shroud 54
is formed with an axially extending groove
60 which acts as a locking recess extending
along the shroud to the right from the bore

58 thereof, as viewed in FIG. 4. The width of the groove 60 is just great enough to receive the resilient enlarged end 52 which acts as a locking portion. With this end 52 in the groove 60, the shroud acts as a lock releasably locking the inner component in its closed position. However, due to the resilient nature of the handle 48, the enlarged end 52 thereof can be displaced beyond the locking recess 60 of the lock means which is formed by the shroud 54, and thus it is possible to displace the valve between its open and closed positions. FIG. 6 shows a variation where the outer end portion of the stem 26', which corresponds to the stem 26, is formed with an axially extending notch receiving an oval-shaped handle 62. A cross pin 64 is provided for retaining the handle 62 in its operative position in the slit or notch which extends through the stem 26' in a diametral plane thereof. Thus, through this simple expedient it is also possible to provide a handle for the valve invention.

Thus, with the present invention surgical excision as required in a conventional vasectomy with resulting permanent sterility is completely avoided. All that is required is a simple incision 42 in order to enable the valve of the invention to be introduced, and then this valve of the invention can remain as long as desired in its closed position to provide the desired sterility until such time as it may be desired to open the valve so as to reestablish flow through the vas deferens.

WHAT WE CLAIM IS:—

1. A valve for reversibly interrupting the flow of sperm in a human vas deferens which is small enough to be implantable in a human vas deferens, the valve carrying, at its exterior surface, means capable of forming an intimate union with the wall of the vas deferens when the valve is implanted therein such that, in use, a seal is formed between said means and the vas deferens which prevents the passage of sperm along the vas deferens along the exterior surface of the valve.

2. A valve as claimed in claim 1 wherein the valve comprises an inner rotary component having a valve body and a valve stem integral with and extending from said body, and an outer component rotatably housing said valve body and part of said stem adjacent to said valve body, said outer component consisting of molecular layers deposited successively one upon another, one of said layers forming an inner surface of said outer component fluid-tightly engaging and complementing an exterior surface area of said inner component, said outer component having hollow, open-ended tubular extensions extending in opposite directions away from said valve body and

said body being formed with a bore providing communication between said extensions when said inner component is in an open position, said stem terminating distant from said body in an outer operating end portion accessible for turning said inner component with respect to said outer component between the open position and a closed position where said bore is out of communication with said tubular extensions and said body cuts off communication therebetween, said components being made of materials compatible with a human vas deferens and having a size small enough to be implantable into the tubular interior of a human vas deferens without substantial distention thereof such that, when implanted, said stem of said inner component extends laterally through a wall of the vas deferens and the operating end portion is accessible at the exterior of the vas deferens, so that the inner component can be turned between its open and closed positions, said tubular extensions and bore all having an inner diameter great enough to provide normal unrestricted flow through the vas deferens when said inner component is in its open position.

3. A valve as claimed in claim 2 wherein said outer component has a tubular portion surrounding and fluid-tightly engaging that part of said stem which is directly adjacent said body of said inner component, the means capable of forming an intimate union with the wall of the vas deferens surrounding said tubular portion.

4. A valve as claimed in claim 3 wherein said means is in the form of a wire wound around said tubular portion of said outer component.

5. A valve as claimed in claim 4 wherein said wire is a gold wire.

6. A valve as claimed in any one of claims 2 to 5 wherein one of said tubular extensions is formed with a series of annular constrictions distributed therealong.

7. A valve as claimed in any one of claims 2 to 6 wherein a handle is operatively connected with said operating end portion of said stem.

8. A valve as claimed in claim 7 wherein said operating end portion of said stem is formed with a bore receiving part of said handle, such that, when implanted in a vas deferens, said handle is turnable in said bore between an inoperative position wherein the handle is parallel to the longitudinal axis of the vas deferens and substantially adjacent the outer surface of the vas deferens and an operative position projecting from said operating end portion of said stem.

9. A valve as claimed in claim 7 or 8 wherein a lock coacts with said handle for releasably locking the latter at a position



58 thereof, as viewed in FIG. 4. The width of the groove 60 is just great enough to receive the resilient enlarged end 52 which acts as a locking portion. With this end 52 in the groove 60, the shroud acts as a lock releasably locking the inner component in its closed position. However, due to the resilient nature of the handle 48, the enlarged end 52 thereof can be displaced beyond the locking recess 60 of the lock means which is formed by the shroud 54, and thus it is possible to displace the valve between its open and closed positions. FIG. 6 shows a variation where the outer end portion of the stem 26', which corresponds to the stem 26, is formed with an axially extending notch receiving an oval-shaped handle 62. A cross pin 64 is provided for retaining the handle 62 in its operative position in the slit or notch which extends through the stem 26' in a diametral plane thereof. Thus, through this simple expedient it is also possible to provide a handle for the valve invention.

Thus, with the present invention surgical excision as required in a conventional vasectomy with resulting permanent sterility is completely avoided. All that is required is a simple incision 42 in order to enable the valve of the invention to be introduced, and then this valve of the invention can remain as long as desired in its closed position to provide the desired sterility until such time as it may be desired to open the valve so as to reestablish flow through the vas deferens.

WHAT WE CLAIM IS:—

1. A valve for reversibly interrupting the flow of sperm in a human vas deferens which is small enough to be implantable in a human vas deferens, the valve carrying, at its exterior surface, means capable of forming an intimate union with the wall of the vas deferens when the valve is implanted therein such that, in use, a seal is formed between said means and the vas deferens which prevents the passage of sperm along the vas deferens along the exterior surface of the valve.

2. A valve as claimed in claim 1 wherein the valve comprises an inner rotary component having a valve body and a valve stem integral with and extending from said body, and an outer component rotatably housing said valve body and part of said stem adjacent to said valve body, said outer component consisting of molecular layers deposited successively one upon another, one of said layers forming an inner surface of said outer component fluid-tightly engaging and complementing an exterior surface area of said inner component, said outer component having hollow, open-ended tubular extensions extending in opposite directions away from said valve body and

said body being formed with a bore providing communication between said extensions when said inner component is in an open position, said stem terminating distant from said body in an outer operating end portion accessible for turning said inner component with respect to said outer component between the open position and a closed position where said bore is out of communication with said tubular extensions and said body cuts off communication therebetween, said components being made of materials compatible with a human vas deferens and having a size small enough to be implantable into the tubular interior of a human vas deferens without substantial distention thereof such that, when implanted, said stem of said inner component extends laterally through a wall of the vas deferens and the operating end portion is accessible at the exterior of the vas deferens, so that the inner component can be turned between its open and closed positions, said tubular extensions and bore all having an inner diameter great enough to provide normal unrestricted flow through the vas deferens when said inner component is in its open position.

3. A valve as claimed in claim 2 wherein said outer component has a tubular portion surrounding and fluid-tightly engaging that part of said stem which is directly adjacent said body of said inner component, the means capable of forming an intimate union with the wall of the vas deferens surrounding said tubular portion.

4. A valve as claimed in claim 3 wherein said means is in the form of a wire wound around said tubular portion of said outer component.

5. A valve as claimed in claim 4 wherein said wire is a gold wire.

6. A valve as claimed in any one of claims 2 to 5 wherein one of said tubular extensions is formed with a series of annular constrictions distributed therealong.

7. A valve as claimed in any one of claims 2 to 6 wherein a handle is operatively connected with said operating end portion of said stem.

8. A valve as claimed in claim 7 wherein said operating end portion of said stem is formed with a bore receiving part of said handle, such that, when implanted in a vas deferens, said handle is turnable in said bore between an inoperative position wherein the handle is parallel to the longitudinal axis of the vas deferens and substantially adjacent the outer surface of the vas deferens and an operative position projecting from said operating end portion of said stem.

9. A valve as claimed in claim 7 or 8 wherein a lock coacts with said handle for releasably locking the latter at a position



locating said inner component in its closed position.

10. A valve as claimed in claim 9 wherein said lock includes an elongated tubular longitudinally split shroud formed with a bore through which said stem extends and beyond which said operating end portion of said stem and handle are located, said handle having a resilient locking portion and said shroud being formed in its exterior with a locking recess releasably receiving said resilient locking portion of said handle for releasably locking said inner component.

11. A valve as claimed in claim 1 wherein an elongated tubular longitudinally split shroud is additionally provided which, when the valve is implanted in a vas deferens sur-

rounds said vas deferens, said shroud being formed with a bore through which said stem extends and beyond which said operating end portion of said stem is located.

12. A valve as claimed in any one of claims 2 to 11 wherein said outer component has an exterior surface covered with a coating.

13. A valve as claimed in claim 12 wherein said coating contains silicone.

14. A valve for reversibly interrupting the flow of sperm in a human vas deferens constructed and arranged to operate substantially as hereinbefore described with reference to and as illustrated in the accompanying drawings.

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