

[54]	IMPLANT METHODS AND DEVICES FOR INFLUENCING BODY FLUIDS	3,416,530	12/1968	Ness.....	128/260
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[75]	Inventor: Louis Bucalo, Holbrook, N.Y.	3,704,704	12/1972	Gonzales.....	128/1 R
[73]	Assignee: Investors In Ventures, Inc., New York, N.Y.	3,742,933	7/1973	Bucalo	128/1 R

[22] Filed: July 2, 1973

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[21] Appl. No.: 375,359

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 155,141, June 21, 1971, Pat. No. 3,742,933.

[52] U.S. Cl. 128/1 R, 128/260

[51] Int. Cl. A61b 19/00

[58] Field of Search..... 128/1 R, 303 R, 260, 268;
3/1

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[57]

ABSTRACT

An implant method according to which an implant which comes in contact with a body fluid is placed in communication with a reservoir having a relatively large supply of an agent for influencing a component of the body fluid. The device has a tubular portion which receives the body fluid and which communicates with a reservoir which contains the agent for influencing the component of the body fluid.

16 Claims, 6 Drawing Figures

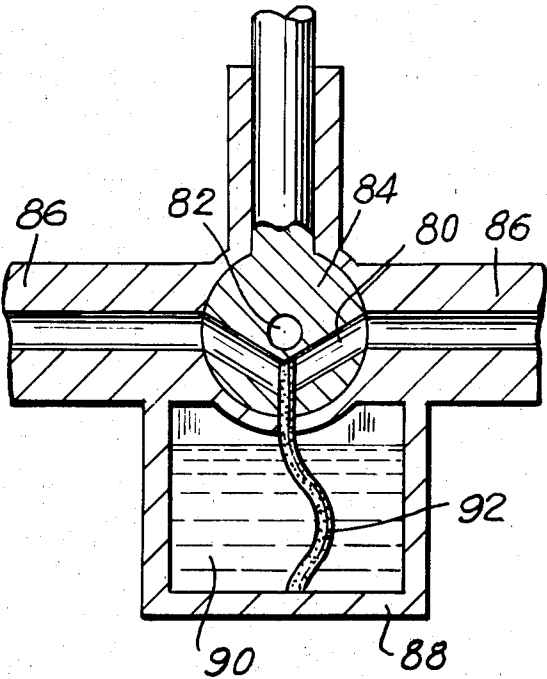


FIG. 1

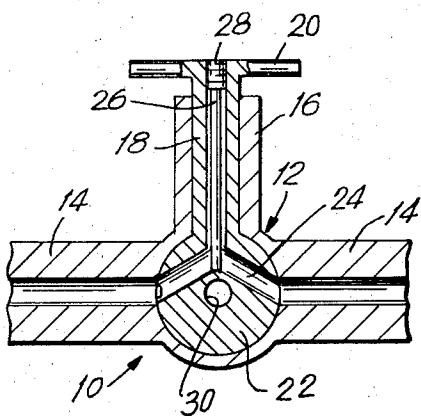


FIG. 2

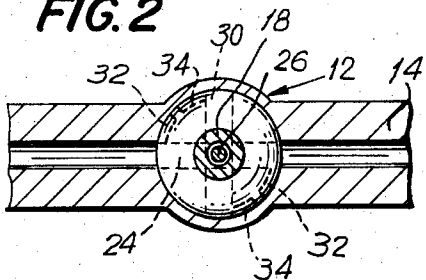


FIG. 3

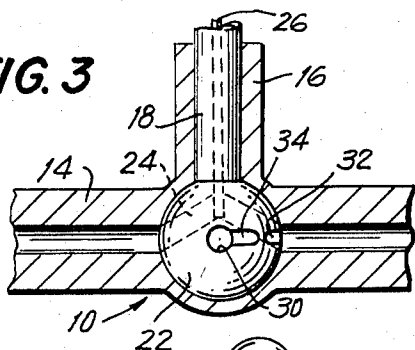


FIG. 6

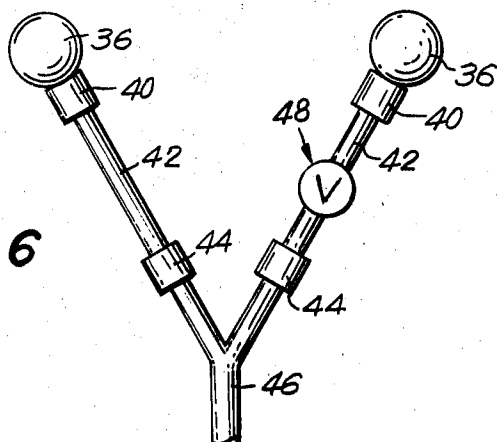


FIG. 4

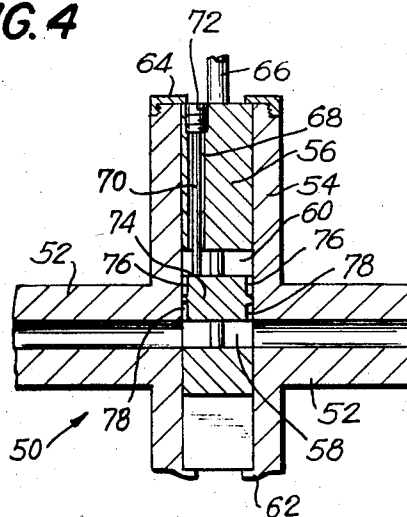
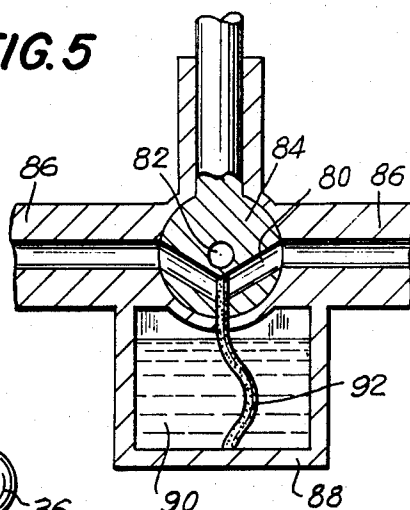


FIG. 5



IMPLANT METHODS AND DEVICES FOR INFLUENCING BODY FLUIDS

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of copending application Ser. No. 155,141, filed June 21, 1971 and entitled "DEVICE FOR CONTROLLING FLUID FLOW IN LIVING CREATURES", now U.S. Pat. No. 3,742,933, which issued July 3, 1973.

BACKGROUND OF THE INVENTION

The present invention relates to implant methods and devices for influencing body fluids in living beings.

It has been proposed to include in methods and devices of this type an agent for influencing at least a component of the body fluid. However, with methods and devices of this nature there is a problem of maintaining a sufficient supply of the agent in the body for assuring the desired influence over a long period of time.

A further problem encountered with methods and devices of the above type is in connection with achieving a desired precise control of the influence on the component of the body fluid. Thus, while it has been proposed to provide arrangements according to which it is possible to place a body fluid either in communication with an agent which will influence a component thereof or completely out of communication with such an agent, it has not been possible heretofore to control the extent of the influence of the agent on the component of the body fluid.

SUMMARY OF THE INVENTION

It is accordingly a primary object of the present invention to provide methods and devices which will solve the above problems.

Thus, it is one of the important objects of the present invention to provide a method and device which will enable a body fluid to be maintained in contact with an agent for influencing a component of the body fluid over as long a period as might practically be desired in any given living being such as a human being, with the assurance that the influence of the agent on the component of the body fluid will be maintained effective throughout the long period which may be throughout the life of a given living being such as a human being.

It is also an object of the present invention to provide a method and device of the above type which is capable of controlling the extent to which a component of a body fluid is influenced by an agent, so that in this way excessive control from an agent can be reduced and instead a precise selection of the extent of influence of a given agent on a component of the body fluid can be achieved.

A more specific object of the present invention is to solve the above problems in connection with semen of a human male by influencing the sperm suspended in the semen.

Thus, in accordance with the present invention an implant is situated in a body cavity to come in contact with a body fluid, and the implant is placed in communication with a reservoir having a supply of an agent for influencing at least a component of the body fluid, this supply of the agent being sufficiently large to assure the

desired influence from the agent over as long a period as desired.

Also, according to the invention the device includes a tubular means having a hollow interior for receiving the body fluid, this tubular means communicating with a reservoir means which contains an agent for influencing at least a component of the body fluid which is received in the interior of the tubular means. The reservoir means is capable of containing a supply of this agent which is great enough to assure the effective influence thereof on the component of the body fluid for as long as may be desired.

BRIEF DESCRIPTION OF DRAWINGS

The invention is illustrated by way of example in the accompanying drawings which form part of this application and in which:

FIG. 1 is a schematic longitudinal sectional elevation of one embodiment of a device and method of the present invention;

FIG. 2 is a sectional plan view of the device of FIG. 1 showing in section the housing of the illustrated valve and the reservoir mean which communicates with the movable valve member;

FIG. 3 is a sectional elevation similar to FIG. 1 but showing only the valve housing section;

FIG. 4 is a schematic sectional elevation of another embodiment of a device and method according to the invention;

FIG. 5 is a schematic sectional elevation of a still further embodiment of a device and method according to the present invention; and

FIG. 6 is a schematic illustration of a further embodiment of a method according to the invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring first to FIG. 1, there is illustrated therein an implant 10 according to the present invention. This implant 10 is shown as including a valve housing 12 having a pair of elongated tubular portions 14 which form, respectively, an inlet and outlet for the valve. The valve housing 12 has an upwardly extending tubular portion 16, as viewed in FIG. 1, and this portion receives a rotary stem 18 capable of being turned in any suitable way as by the handle portion 20. The stem 18 is connected with a rotary valve member 22 seated fluid-tightly in the housing 12 and formed with a passage 24 of substantially V-shaped configuration which forms a tubular means for receiving a body fluid.

In the illustrated example the elongated rotary stem 18 is itself hollow and forms a reservoir means for containing an agent 26 for influencing at least a component of the body fluid. This agent 26 in the example of FIG. 1 is a solid in the form of an elongated rod which is retained in the hollow interior of the reservoir means 18 by any suitable means such as the threaded plug 28. It will be noted that the rod 26 extends with clearance through the hollow interior of the reservoir means 18 from the latter into the tubular means 24 so that the body fluid received in the tubular means 24 will also be received in the interior of the reservoir means 18 to come into engagement with a relatively large area of the agent 26.

The rotary valve member 22 is formed with a second passage 30 extending transversely through the rotary valve member 22 in a direction perpendicular to that of the passage 24. Thus, when it is desired to terminate

the influence of the agent 26 on the body fluid, the rotary valve member is turned by way of the element 20 to place the passage 30 in communication with the inlet and outlet portions 14 and to terminate communication of the passage 24 with the inlet and outlet portions 14.

However, according to a present feature of the invention the passage 24 communicates at its opposed ends with a pair of relatively short grooves 32 which respectively extend in opposite directions from the ends of the passage 24 along the exterior surface of the rotary valve member 22 in the manner most clearly apparent from FIGS. 2 and 3. In the same way the opposed ends of the passage 30 respectively communicate with a pair of relatively short grooves 34 which respectively extend in opposite directions from the opposed ends of the passage 30 along the exterior surface of the rotary valve member 22 in the manner shown most clearly in FIGS. 2 and 3. Thus, it will be noted that the relatively short grooves 32 and 34 extend toward each other at the lower right and upper left portions of FIG. 2. The passages 32 and 34 are situated in a plane which contains the axis of the tubular portions 14 and which is perpendicular to the axis of the reservoir means 18. The angular distance through which all of the grooves 32 and 34 extend are the same, this angular distance being somewhat less than 45°.

As a result of this feature when the part 20 is manipulated to adjust the angular position of the rotary valve member 22, it becomes possible not only to place either the passage 24 alone or the passage 30 alone in communication with the tubular inlets and outlets 14, but in addition it is possible to situate the pairs of adjoining grooves 32 and 34 simultaneously in communication with the tubular inlet and outlet portions 14 with the angular position of the rotary valve member 22 controlling the extent to which passages 22 and 24 communicate with the tubular inlet and outlet portions 14. In this way it becomes possible to control the extent to which the component of the body fluid is influenced by the agent 26.

One of the specific uses for an implant method and device as described above in connection with FIGS. 1-3 is in the case of a human male where the implant may be situated in a body cavity formed by a vas deferens and where the agent 26 is a spermicidal agent. For example, in the case where the agent is a solid in the form of a rod as shown in FIGS. 1-3, this agent 26 may take the form of a copper rod or a rod made of any solid material which will have a spermicidal capability, such as a rod of an alloy of copper with materials such as zinc and nickel. Thus, these latter metals are also known to be spermicidal agents, and of course in addition it is known that tin, silver, and magnesium have spermicidal properties. Also, certain plastics such as celluloid may be used as the spermicidal agent.

The principle according to which the influence of the agent on a component of a body fluid is controlled is illustrated according to a further method of the invention in FIG. 6. Thus, referring to FIG 6, there are schematically illustrated therein the testes 36, each adjoining an epididymis 40, with the latter respectively communicating with the extensions forming the pair of vas deferentia 42. The vas deferentia 42 in turn respectively communicate with the schematically illustrated seminal vesicles 44 beyond which is located the ejacu-

latory duct or urethra 46 in which the fluids of the vas deferentia 42 join.

In accordance with the method of the invention which is illustrated in FIG. 6, an implant such as a valve 48 is situated only in one of the pair of vas deferentia 42. A number of advantages flow from this particular method of the invention. For example, in the case of an implant similar to that of FIGS. 1-3 where a spermicidal agent is placed by the implant 48 in communication with the semen in only one of the vas deferentia, the influence of the spermicidal agent may be strong enough to prevent conception even though the semen flows in a completely unobstructed fully natural manner through the left vas deferens 42 of FIG. 6. In other words the spermicidal effect of the agent may be so strong that when the fluids from the pair of vas deferentia 42 join each other in the duct 46, the spermicidal effect is sufficiently great on the fluid received from the left vas deferens 42 of FIG. 6 to prevent the number of viable sperm in the ejaculated semen from resulting in conception. Therefore, when the implant 48 is adjusted so as to terminate the effect of the spermicidal agent, even if there should be any problems in reestablishing the flow of semen through the right vas deferens 42 of FIG. 6, there would be no problem with respect to the left vas deferens 42 of FIG. 6, so that the sperm in the semen flowing through the left vas deferens 42 of FIG. 6 would be fully viable when the influence of the spermicidal agent is terminated and thus reestablishment of the capability of conception by the male would be assured to an even greater degree with the method as illustrated in FIG. 6.

Furthermore, an implant such as the implant 48 may take other forms. For example, instead of having a spermicidal agent, it may be used simply to terminate the flow of semen through the right vas deferens of FIG. 2 while leaving the flow of semen through the left vas deferens of FIG 6 unaffected. Such an arrangement is of particular utility in a case where it is suspected by a physician that a patient having faulty sperm has the source of the faulty sperm from only one of the testes 36, so that by terminating the flow in only one of the vas deferentia it becomes possible to effect a suitable cure. In addition, it is to be noted that it may be suspected that sperm having one type of characteristic is derived from one of the vas deferentia, while sperm having another characteristic is derived from the other of the vas deferentia, so that with a method as shown in FIG. 6 it becomes possible to prevent sperm having particular characteristics from reaching the duct 46. Controls of this nature also may be provided with an arrangement as shown in FIG. 6.

It is to be noted that the specific details of the invention are not limited to arrangements as shown in FIGS. 1-3 and described above. Thus, FIG. 4 shows an implant 50 in the form of a valve also having tubular inlet and outlet portions 52, similar to the portions 14. However, in this case the valve housing has an elongated tubular portion 54 perpendicular to the portions 52 and supporting for sliding movement a spool valve member 56 having a pair of valve passages 58 and 60. In the position shown in FIG. 4 the passage 58 is in communication with the inlet and outlet portions 52. However, by displacing the spool 56 until it engages the flange 62, the passage 60 will be placed in communication with the tubular inlet and outlet portions 52. The housing portion 54 threadedly carries a ring 64 which deter-

mines the position of position of the spool valve 56 shown in FIG. 4, and this spool valve may be maintained in any desired position by frictional engagement with the housing and it may be moved to the desired position by way of the adjusting rod 66.

As may be seen from FIG. 4, the spool valve 56 is formed with an elongated tubular portion 68 housing a rod 70 which may be the same as the rod 26 and which is held in the position shown in FIG. 4 by any suitable means such as a threaded plug 72. Thus, when the passage 60 is placed in communication with the tubular portions 52, the effect of the agent 70 on the component of the body fluid will be provided, and in this case also it is clear that the axially bored part of the spool valve 56 forms a reservoir means which contains the agent 70 which communicates with the tubular means 60 which forms a passage for the body fluid.

It is to be noted that in this case also the spool part 74 situated between the tubular passages 58 and 60 is formed with a pair of axial grooves 76 and 78 which respectively communicate with the passages 60 and 58, so that the valve member 56 also may have either positions where only the tubular passage 58 or the tubular passage 60 communicates with the tubular inlet and outlet portions 52 or where both of the passages 58 and 60 simultaneously communicate with the tubular inlets and outlets so that in the same way as with the embodiment of FIGS. 1-3 it is possible to regulate the extent of the influence of the agent 70 on the component of the body fluid.

Furthermore, the use of a solid spermicidal agent is not essential. Thus, FIG. 5 shows an embodiment of the

invention similar to that of FIGS. 1-3 except that in this case a tubular means 80 of the rotary valve member extends downwardly beneath the transverse passage 82 of the rotary valve member 84, this passage 82 of course corresponding in all respects to the passage 30. Thus, the pair of inlet and outlet portions 86 are capable of being in communication either with the passage 80 or the passage 82 by turning the rotary valve member 84 in the manner described above.

With the embodiment of FIG. 5, the device includes a reservoir means 88 in the form of a container which may contain a liquid agent 90 in the illustrated example. A wick 92 of the reservoir means extends into the liquid 90 and extends through a suitable opening in the valve housing into the passage 80 as illustrated in FIG. 5, so that through this wick 92 of the reservoir means the agent is supplied to the interior of the tubular means 80. Thus, in this way contact between the body fluid in the passage 80 and the agent 90 is assured, and it becomes possible to use liquid agents with a method and device as shown in FIG. 5.

Of course, the agent, which may be a spermicidal agent in the specific case of a vas valve, need not be completely liquid in the case of FIG. 5 but can have a non-solid condition such as, for example, a semisolid paste or jelly.

The following are examples of various types of spermicidal agents which may be used as the agents 26 and 90 or as semisolid agents for spermicidal purposes in the specific case where the implant is situated in a body cavity formed by a vas deferens.

Nature and Properties of Chemical Contraceptives		
Type	Example	Action
Heavy Metals	Hg ⁺⁺	SH inhibitor
Surfactants	Nonionic and anionic detergents; Cationic detergents; Vitamin A-OH	Membrane solubilizers
Antibiotics	Bacitracin Spiromycin Filipin Antimycin	Energy metabolism blockers; Membrane disrupters
Cations	CA ⁺⁺ K ⁺ Zn	Interference with motile mechanisms of sperm
Enzyme inhibitors (Anti-acrosome enzymes)	Inhibition of hyaluronidase and/or neuraminidase (DF)	—
Antibodies	Antibodies to purified sperm specific antigens or to acrosomal proteins	Agglutinators
Seminal plasma	Seminal spermine plus diamine oxidase gives rise to unknown oxidation products (probably aldehydes)	—

Jellies Name	Ingredients	Type
1. Ortho-Gynol Jelly	ricinoleic acid, p-diisobutyl phenoxypolyethanol, boric acid	detergent
2. Lancen-jelly (Esta prods.)	ricinoleic acid, hexylresorcinol, chlorothymol, glycerin, sodium benzoate	surface active
3. Trimo san Therapeutic jelly (used as antifungus agent)	phenylmercuric acetate, sodium lauryl sulfate	heavy metal detergent

Continued

Jellies Name	Ingredients	Type
4. Lurophyn suppositories and jelly	phenylmercuric acetate, polyethylene glycol	heavy metal nonionic surfactant
5. Preceptin gel (Ortho)	ricinoleic acid, p-diisobutyl phenoxypolyethoxy ethanol	surface active nonionic surfactant
6. Contral Paste (Jelly, Egypt)	phenylmercuric nitrate	heavy metal inhibitor
7. O.A.K. Jelly (Denmark)	hexyl resorcinol, propylene glycol, sodium alginate	—
8. Dupree Jelly	phenylmercury borate, oxyquinoline sulfate, lactate, borate	heavy metal redox inhibitor acid (surfactant) redox poison
9. Genoson Jelly	ricinoleate, oxyquinoline sulfate, merthiolate	acid redox block anionic surfactant
10. Kemi Jelly	lactate, borate, oxyquinoline sulfate	surface active redox inhibitor
11. M. Lex Crescent Jelly	sodium lauryl sulfonate	redox inhibitor heavy metal (SH inhibitor)
12. Milex Crescent Jelly	ricinoleic acid, glycerol, oxyquinoline sulfate	—
13. Natogel Jelly	oxyquinoline sulfate	—
14. Safetycin Jelly (Taiwan)	phenylmercuric acetate	—
Creams		
1. Ortho-creme	ricinoleic acid, sodium lauryl sulfate, boric acid, nonoxynol-9	anionic detergent nonionic detergent
2. Creemox creme	nonylphenoxy polyoxyethylene, beta naphthol, phenol	nonionic detergent acid
3. Kemi-creme	trioxymethylene paraformaldehyde oleate	oxidizing agent protein inactivator surfactant
4. Tutus Creme (East Germany)	p-hydroxybenzoate aluminum subacetate "Letio-Lanette Wax"	heavy metal
Foams Name	Ingredients	Type
Delphen Vaginal Foam	nonoxynol-9 (oil-H ₂ O emulsion) pH 4.5	nonionic surfactant

What is claimed is:

1. In a method for controlling body fluid in a body cavity of a living being, the steps of situating in the body cavity of the living being an implant which receives the body fluid which is to be controlled and which has in its interior an agent which is contacted by the body fluid and which influences at least a component of the body fluid, and placing in communication with the implant a reservoir containing a relatively large supply of said agent for replenishing the latter, so that the influence of the agent on the component of the body fluid can be maintained effective over a long period of time.

2. In a method as recited in claim 1 and wherein the agent is a solid.

3. In a method as recited in claim 2 and wherein the agent is a metal.

4. In a method as recited in claim 1 and wherein the agent is a non-solid.

5. In a method as recited in claim 4 and wherein the agent is a liquid.

6. In a method as recited in claim 1 and wherein the body cavity is a vas deferens and the agent is a spermicidal agent.

7. In a method as recited in claim 1 and including the

step of adjusting the extent to which the component of the body fluid is exposed to the agent.

8. In a method for controlling semen in a male being having a pair of vas deferentia, the step of connecting an implant with only one of the vas deferentia.

9. In a method as recited in claim 8 and wherein the implant is a valve.

10. An implant comprising tubular means having a hollow interior for receiving a body fluid, an agent in said hollow interior of said tubular means for influencing at least a component of the body fluid, and reservoir means operatively connected with said tubular means and communicating with the hollow interior thereof, said reservoir means containing said agent for replenishing the latter in the hollow interior of said tubular means.

11. The combination of claim 10 and wherein said reservoir means forms an extension of the hollow interior of said tubular means and said agent is in the form of a solid body situated in said extension and said tubular means.

12. The combination of claim 10 and wherein said agent is a liquid, said reservoir means including a container which contains said liquid and a wick extending

from the interior of said container to the interior of said tubular means and extending into the liquid.

13. The combination of claim 10 and wherein a valve means includes a housing having an inlet and an outlet and also includes a movable valve member situated between said inlet and outlet and formed with a passage which forms said tubular means, said valve member having at least one position where said passage communicates with said inlet and outlet so that in the latter position of said valve member the agent in said reservoir means is effective to influence the component of a body fluid which is received in the valve means.

14. The combination of claim 13 and wherein said valve member is formed with a second passage which does not communicate with said reservoir means and which can selectively be placed in communication with

the inlet and outlet to eliminate the influence of the agent.

15. The combination of claim 14 and wherein both of said passages have configurations for mutually exclusive or simultaneous communication with said inlet and outlet, and said valve member being adjustable for providing only communication with one or the other of the passages or for providing a selected extent of communication of the inlet and outlet with both of said passages for controlling the influence of the agent on the component of the body fluid.

16. The combination of claim 15 and wherein the valve housing is adapted to be received in a vas deferens and the agent is a spermicidal agent.

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