

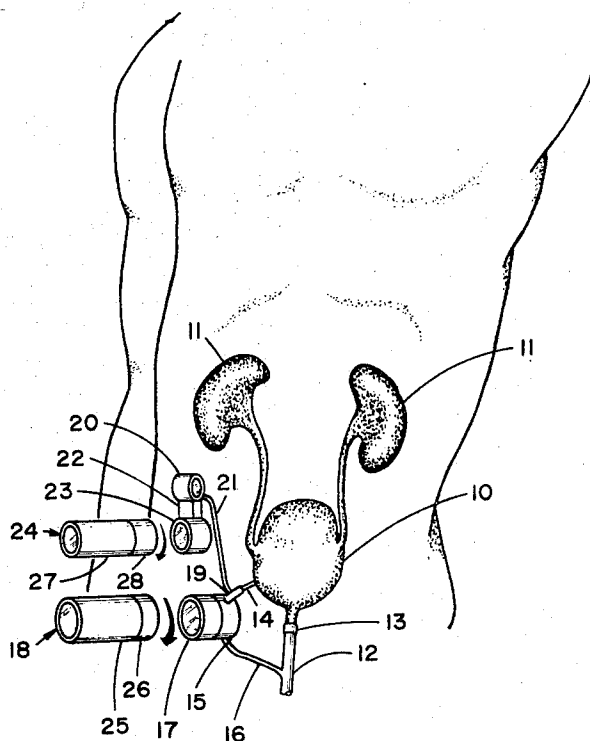
[21] Appl. No.: 348,644

UNITED STATES PATENTS

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3,585,648	6/1971	Suroff	3/1

An implantable urinary control apparatus for controlling the flow of urine from the bladder including a pump adapted to be connected to the bladder for pumping urine out of the bladder and into a natural or artificial channel so that it can be from the from the body. The apparatus also includes a sensor adapted to be connected to the natural or to an artificial urinary bladder for detecting the pressure in the bladder as it fills with urine, and an alarm unit connected to the sensor for giving warning that the bladder is filling with urine when the sensor detects the pressure caused by urine in the bladder.

7 Claims, 3 Drawing Figures



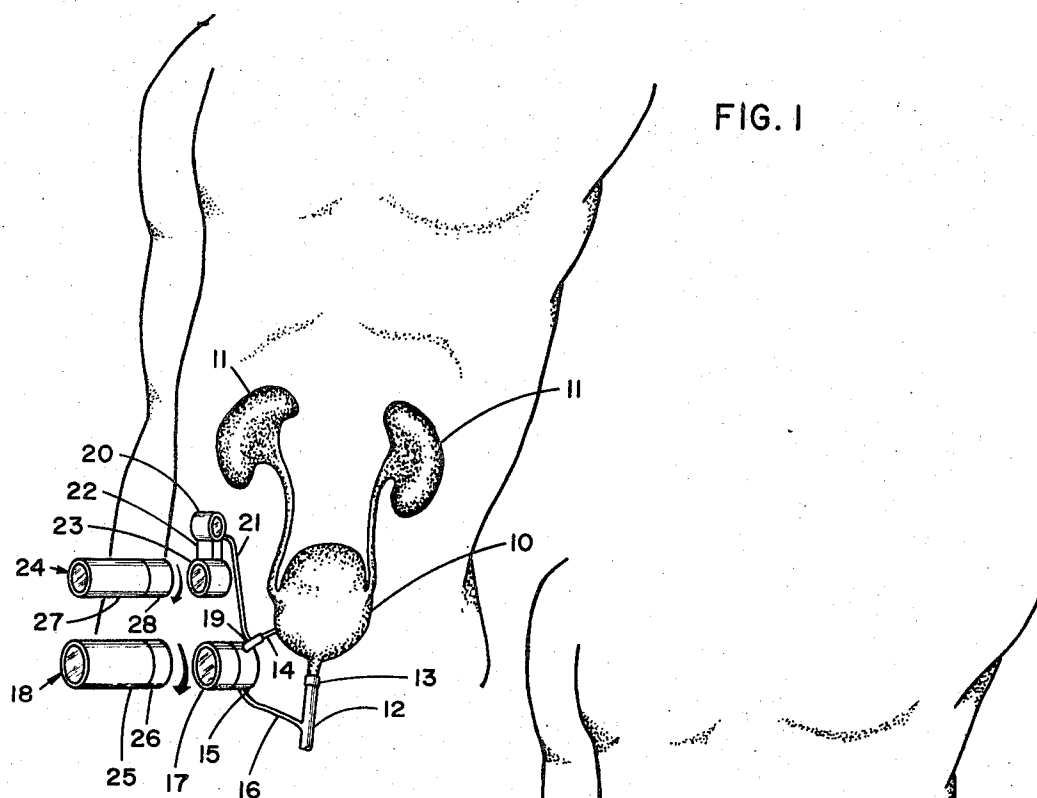


FIG. 2

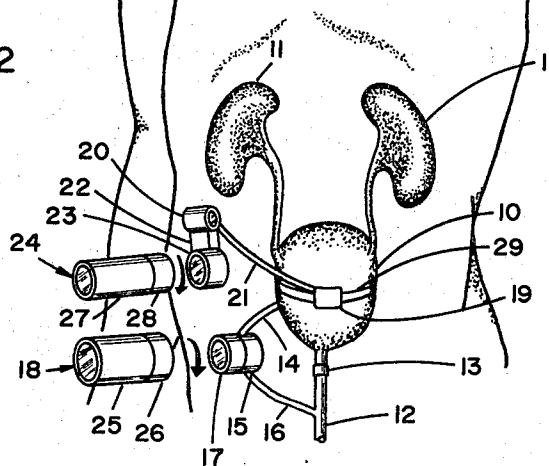
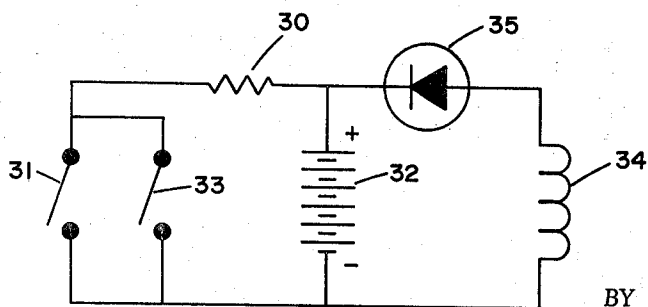


FIG. 3



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IMPLANTABLE URINARY CONTROL APPARATUS

This application is a continuation of application, Ser. No. 109,308, filed Jan. 25, 1971, now abandoned, which in turn is a division of application Ser. No. 842,921, filed July 18, 1969, now U.S. Pat. No. 3,575,158.

This invention relates to an implantable control apparatus, more particularly, this invention relates to an implantable control apparatus for controlling the discharge of urine from the urinary bladder.

The failure to discharge urine from the bladder can cause urine to back up into the kidneys and this can result in serious medical consequences such as uremia and infections. Present techniques for medically relieving the failure of urine to flow from the urinary bladder through the urethra and to outside the body depend in part on the cause of failure. In some cases the bladder wall no longer functions either from failure of the motor nerve pathways leading to the bladder, from deterioration of the bladder wall or muscle, or from a neoplastic growth interfering with normal function. In such cases, the usual medical treatment is to insert a catheter through the urethra and into the bladder. Flow is then controlled by opening or closing a portion of the catheter external to the body. This process leads to infection of the urethra and/or the urinary bladder in most patients when the catheter is left in place for more than a few days. Often this infection is difficult to control or cure with antibiotics, especially when the catheter remains in the body. Additionally, uric acid crystals and other matter may form or collect in the catheter, leading to restricting or stopping fluid flow.

Another cause of failure of urine flow is the inability of the patient to voluntarily cause the sphincters (constricting muscles) around the urethra to relax. Again in this case a catheter may be used. A more recent technique has been tried which consists of an implanted electrical stimulator attached to the sphincters or their afferent nerves. Powered and controlled in one of several ways, the electrical current supplied can cause sphincter relaxation. However, the system has not always proved useful over a period of time as the sphincters require increasingly large values of current and/or voltage. Finally a point may be reached when either pain or burn will occur before sphincter relaxation.

In cases of urinary incontinence in which there is continuous or intermittent involuntary voiding of urine, present management techniques include wearing of absorbent diaper-like clothing and the collection of urine in watertight bags. Unfortunately, these techniques are inconvenient to use and can cause considerable discomfort to the patient.

Reference is made to the device described in my co-pending application Ser. No. 814,760 filed Apr. 9, 1969, now U.S. Pat. No. 3,672,352, which describes the use of implantable sensors for detecting body conditions in connection with implantable signal means and means for transmitting energy into the body and receiving signals from inside the body.

It is therefore an object of the present invention to provide an implantable urinary control apparatus for controlling the discharge of urine from the urinary bladder.

Another object of this invention is to provide an implantable urinary control apparatus that is capable of detecting the pressure in the urinary bladder caused by the filling of the bladder with urine.

Another object of the present invention is to provide an implantable urinary control apparatus that is capable of giving a warning when the bladder is filling with urine.

Another object of the present invention is to provide an implantable urinary control apparatus having a pump that is capable of being powered and controlled from outside the body.

The present invention provides an implantable urinary control apparatus for controlling the discharge of urine from the urinary bladder in a body which includes implantable pump means for pumping urine from the bladder out of the body, implantable inlet means connected to the implantable pump means for connecting the bladder to the implantable pump means for permitting urine to flow from the bladder to the implantable pump means and implantable outlet means connected to the implantable pump means for connecting the implantable pump means to an artificial or natural body channel that leads out of the body for permitting urine to flow from the implantable pump means to the artificial or natural body channel. Means capable of being operatively coupled to the pump means for operating the pump means, implantable sensing and alarm means, and a power source for the alarm means are also provided.

In order that the invention may be more clearly set forth and better understood, reference is made to the accompanying drawings in which:

FIG. 1 is a diagrammatic view showing typically how the invention would be implanted within the body of a human;

FIG. 2 is a diagrammatic view of an alternative embodiment of the invention implanted within the body of a human; and

FIG. 3 is a circuit diagram of the alarm unit, battery and charging circuit used in the preferred embodiment of the invention.

Referring first to FIG. 1, there is shown a bladder 10 connected to the kidneys 11. The bladder 10 may be the natural urinary bladder or an implanted artificial urinary bladder and any reference to the word bladder in the specification and claims is meant to include both natural or artificial urinary bladders, except where an artificial bladder is specified as an element in the claims. Connected to the bladder 10 is the urethra and/or artificial urethra 12 that is surrounded by the sphincters 13 which are muscles that are normally closed so that urine cannot flow out of the bladder through the urethra. In the normal body these sphincters 13 are opened or closed by voluntary controlled nerve impulses. It should be understood that any reference to the word urethra in the specification and claims is meant to include both the natural or artificial urethra or other suitable natural or artificial channel or tube that leads outside the body. An implanted tube 14 is connected to the bladder 10 and to the inlet of an implanted pump 15 to permit passage of urine from the bladder to the pump. An implanted tube 16 is connected to the outlet of the pump 15 and to the urethra 12 below the sphincters 13 to permit the passage of urine from the pump to the urethra when the pump is activated. An implanted pump driving unit 17 that is responsive to energy received from outside the body is operably connected to the pump 15 and is controlled and powered by an external pump activating unit 18 that transmits energy from outside the body through

the skin and into the body to the pump driving unit to drive the pump.

A pressure sensor 19 is connected to the implanted tube 14 and detects pressure in the bladder 10 when it fills with urine. An implanted alarm unit 20 is connected to the pressure sensor 19 by means of an implanted electrical connection 21 that transmits a signal to activate the alarm unit when the bladder is full of urine. A rechargeable implanted power source 22 is connected to the implanted alarm unit 20 for supplying power to the alarm unit. An implanted recharging unit 23 is connected to the power source 22 to permit recharging of the power source. The implanted recharging unit 23 is energized by means of an external energy transmitter 24 that transmits energy from outside the body through the skin and into the body to the recharging unit. This energy causes the recharging unit 23 to recharge the power source 22.

In the preferred embodiment of the invention the pump 15, the pump driving unit 17, and the external pump activating unit 18 are similar in construction to the magnetically driven pump and accessories described in an article entitled "A New Miniature Pump for the Treatment of Hydrocephalus" by Summers and Matthews in the May/June 1967 issue of *The Journal of the Association for the advancement of Medical Instrumentation* and to the device described in my co-pending application Ser. No. 741,117 filed June 27, 1968, now U.S. Pat. No. 3,527,220. In the preferred embodiment the implanted pump driving unit 17 consists of a suitable rotatable magnet operably connected to the pump 15 so that the rotation of the magnet will cause the pump to operate. In the preferred embodiment the external pump activating unit 18 that is used to control and operate the pump 15 by transmitting energy into the body consists of a motor 25 that is operably connected to a rotatable magnet 26. When the motor 25 is turned on, this causes rotation of the magnet 26. The rotation of the magnet 26 causes the implanted magnet in the driving unit 17 to rotate due to the action of the magnetic field between the external magnet 20 and the implanted magnet within the driving unit 17. The rotation of the magnet within the pump driving unit 17 causes the pump 15 to operate and pump urine from the bladder 10 through the implanted tube 14, through the pump, and through the implanted tube 16 into the urethra 12 at a point below the sphincters 13.

Other types of pumps can be employed; however, a magnetically driven pump is highly desirable since once it has been implanted, it can be powered from outside the body without having to penetrate the skin. An alternative type of pump that could be employed would be driven by implanted batteries that could be recharged by the action of a rotating magnetic field located outside the body. Activation of this alternative type of pump could be achieved by a suitable electromagnetic signal from outside the body.

In the preferred embodiment of this invention the external energy transmitter 24 consists of a motor 27 that is operably connected to a rotatable magnet 28. When the motor 27 is turned on, this causes the magnet 28 to rotate which results in the generation of a moving magnetic field within the implanted recharging unit 23 that causes the recharging unit to recharge the power source 22. Through the proper selection of circuitry it is possible that the pump activating unit 18 can also

serve as the external energy transmitter 24. Alternatively, the implanted recharging unit 23 can be energized by means of an energy transmitter 24 that includes an rf generator.

In FIG. 2 an alternative embodiment of the invention is shown in which the implanted pressure sensor 19 is connected to an implanted restraining band 29 that partially or totally surrounds the urinary bladder 10. This pressure sensor 19 is pressed against the wall of the urinary bladder 10 as the bladder increases in size as a result of its being filled with urine. When the pressure sensor 19 detects pressure resulting from the distention of the urinary bladder 10 as it is filled with urine, the sensor energizes the implanted alarm unit 20 through implanted electrical connection 21 as previously described with respect to the embodiment shown in FIG. 1.

FIG. 3 illustrates a circuit diagram of the preferred embodiment of the implanted alarm unit 20, the implanted power source 22 and the implanted recharging unit 23. The alarm unit includes a resistive heating element 30 and a switch 31 that is closed by a signal from the sensor 19 when the sensor detects pressure resulting from the filling of the bladder with urine. When the switch 31 is closed, the resistive heating element 30 becomes heated by the action of the electrical current generated by the battery 32 in the power source 22. The resistive heating element 30 must become hot enough to be sensed by the patient, but not hot enough to cause damage to the tissue surrounding the implanted resistor. The switch 31 opens and the heat sensation that results from the resistive heating element 30 is relieved when the implanted pump 15 is activated and urine is pumped out of the bladder 10 since the pressure sensor 19 no longer detects pressure in the bladder and thus is not transmitting a signal to keep the switch 31 in its closed position.

A test switch 33 that is normally open is connected in parallel with the switch 31 to permit testing of the alarm unit. This test switch 33 can be of a type that is magnetically activated so that it can be closed by a suitable means such as a magnetic source (not shown) located outside of the body. The battery 32 should be rechargeable and recharging is accomplished by means of the implanted recharging unit 23 and the external energy transmitter 24. In the preferred embodiment the recharging unit 23 has an induction coil 34 that is connected in parallel with the battery 32 and a diode 35 that is connected in series with the induction coil. The recharging unit is energized from outside the body by the energy transmitter 24 which in the preferred embodiment has a motor 27 that is used to drive a rotatable magnet 28. A current is generated in the induction coil by means of a moving magnetic field by placing the rotating magnet 28 at a point outside the body that is close to the induction coil in the implanted recharging unit 23. The ac current that is generated in the induction coil 34 by this moving magnetic field is rectified by the diode 35 and the rectified current charges the battery 32. The diode 35 also serves the purpose of preventing the battery 32 from discharging through the coil 34. Alternatively, a mechanical vibrator, an optical source that is visible through the skin, an rf source or an externally interrogated telemetry unit can be employed as the alarm unit 20.

The alarm unit 20, the power source 22, the recharging unit 23 and the pump 15 including the driving unit

17 must be covered by a suitable inner layer such as standard latex rubber over a suitable case to protect these implanted devices. This inner layer must then be coated by a suitable outer layer of material that is compatible with body tissue. Various types of silicone rubber compositions are suitable for this outer layer. Some examples of these suitable compositions are presented in U.S. Pat. No. 3,279,996. These protective layers also protect the body by electrically insulating these devices from the body. In a similar manner, the electrical connection 21 and the pressure sensor 19 must be covered by a suitable insulating material and by a material such as silicone rubber that is compatible with body tissue. In addition the tubes 14 and 16 must consist of some material that will not permit diffusion of urine through their walls and the outside of the tubes must be coated with silicone rubber or some other such material that will be compatible with the body tissue.

In some cases it will not be necessary to employ an implanted alarm unit 20 and associated devices. In this situation the implanted alarm unit 20, the implanted power source 22, the implanted recharging unit 23, the implanted pressure sensor 19 and the implanted electrical connection 21 can be omitted. In this situation it will also be unnecessary to utilize any sort of external energy transmitter 24.

To utilize this invention the pump 15 including the connected pump driving unit 17, the alarm unit 20, the rechargeable power source 22, and the recharging unit 23 are implanted into the body so that they are located close to the skin. Appropriate anchoring devices such as wings or tabs of a silicone net-like material can be attached to these devices to maintain them in their desired locations within the body. Body tissue will grow through this net-like material and thus anchor the implanted devices within the body. The inlet of the pump 15 must also be connected to the bladder 10 preferably by implanting the tube 14 and connecting it to the bladder and the pump inlet. The outlet of the pump 15 must also be connected to a natural or artificial channel 12 that leads out of the body at a point below the sphincters 13 preferably by implanting the tube 16 and connecting it to the pump outlet and the channel. Alternatively the pump outlet can be connected to some other suitable natural or artificial channel that can be used to discharge urine from the body. In some cases where the patient suffers urinary incontinence, in which there is involuntary voiding of urine, it may be desirable to close the urethra 12 surgically at some point above where the tube 16 connects to the urethra.

The pressure sensor 19 is also implanted into the body and operably connected to the bladder 10 for detecting the pressure in the bladder as it fills with urine. If it is desired to practice the embodiment of the invention shown in FIG. 1, then the pressure sensor 19 is implanted and operably connected to the bladder 10 by connecting it to the implanted tube 14 that is connected to the bladder. If it is desired to practice the embodiment of the invention shown in FIG. 2 then the restraining band 29 that can partially or completely surround the bladder is implanted into the body around the bladder and the pressure sensor 19 is implanted and connected to the restraining band. The implanted pressure sensor 19 is also connected to the alarm unit 20 by implanting the electrical connection 21 and connecting it to the pressure sensor and the alarm unit.

After the urinary control apparatus has been implanted within the body, the filling of the bladder 10 with urine will activate the pressure sensor 19 which, in turn, will activate the alarm unit 20. In the preferred embodiment activation of the alarm unit will cause the resistive heating element 30 to generate heat that will be sensed by the patient. When the patient feels this heat, he will know that his bladder is full and should be emptied. The patient can accomplish the emptying of his bladder by activating the pump 15 by means of the implanted pump driving unit 17 and the external pump activating unit 18. If the motor 25 and the magnet 26 are employed, the patient places the magnet over the implanted pump driving unit 17 and starts the motor. The resulting moving magnetic field causes the implanted magnet in the driving unit 17 to rotate and this activates the pump 15 to pump urine from the bladder 10 and out of the body. As soon as the patient has pumped sufficient urine from his bladder 10, the pressure sensor 19 will no longer detect pressure in the bladder and this will result in deactivation of the alarm unit 20 and stop the resistive heating element 30 from generating heat.

In the event that the patient is unable to sense the heat from the resistive heating element 30 or to use the external rotatable magnet 26 and motor 25 himself, a suitable heat sensor (not shown) can be taped on the outside of his skin near the implanted alarm unit 20 so that it will detect the heat generated by the resistive heating element 30 when the bladder 10 is full of urine. This heat sensor can be connected to a suitable external signalling system to call for assistance in pumping out the bladder. The battery 32 in the power source 22 can be periodically recharged by use of the external energy transmitter 24 which can consist of a motor 27 and a rotatable magnet 28. To recharge the battery 32 with this device the patient places the magnet 28 over the coil 34 in the recharging unit 23 and activates the motor to magnetically induce an electric current in the coil that will recharge the battery. The patient may also test the alarm unit by activating the test switch 33 which in the preferred embodiment will simulate the closing of the switch 31 by a signal from the pressure sensor 19 and result in current flowing in the resistive heating element 30. Thus the patient should feel heat after the switch is closed if the alarm unit is operating properly and the battery is charged.

In the event that the patient should develop an infection in his bladder and it should be desirable to irrigate the bladder, this can be accomplished through the use of this implanted urinary control apparatus by merely causing the pump 15 to operate in reverse to pump a suitable irrigating solution from outside the body into the bladder 10. When the implanted urinary apparatus is used for this purpose, the pressure sensor 19 and the alarm unit 20 can serve the purpose of warming the patient when the bladder 10 is full of the irrigating solution so that the solution will not be forced up into the kidneys and of preventing undue distention of the bladder. The pump can also be operated in reverse to cleanse the implanted apparatus by pumping a suitable solution through the apparatus from outside the body in the event the apparatus becomes clogged with uric acid crystals or other matter.

In some cases such as when it is planned to pump urine from the bladder 10 at preset time intervals by means of the pump 15 and the associated devices that

have been previously described, it will be unnecessary to utilize the alarm unit 20. In such cases it will be unnecessary to implant the alarm unit 20, the power source 22, the recharging unit 23, the electrical connection 21, the pressure sensor 19, and any associated restraining band 29. In these cases it is also unnecessary to use any external energy transmitter 24. When the alarm system 20 is not implanted and utilized, the pump 15 must be activated according to some schedule to insure that the bladder 10 does not fill with urine to the extent that it would bring undesirable results.

This invention has been previously described primarily in relation to its use within the body of a human, however, it can also be implanted within the body of an animal to control the animal's urinary functions.

Although the invention has been described in considerable detail with reference to certain preferred embodiments, it will be understood that variations and modifications may be made within the spirit and scope of the invention as defined in the appended claims.

What is claimed is:

1. An implantable urinary control apparatus for controlling the discharge of urine from the urinary bladder in a body comprising implantable pump means for pumping urine from said urinary bladder out of the body, implantable inlet means connected to said implantable pump means for connecting said urinary bladder to said implantable pump means for permitting urine to flow from said bladder to said implantable pump means, implantable outlet means connected to said implantable pump means for connecting said implantable pump means to an artificial or natural body channel that leads out of the body to permit urine to flow from said implantable pump means to said artificial or natural body channel, means capable of being operatively coupled to said implantable pump means for causing the operation thereof, implantable sensing means adapted to be operatively associated with said bladder for sensing pressure in said bladder as said bladder is filling with urine, implantable alarm means operatively connected to said implantable sensing means for providing an alarm when said sensing means

senses pressure in said bladder as said bladder is filling with urine, and implantable power source means operatively connected to said alarm means for supplying power to said implantable alarm means.

2. The implantable urinary control apparatus of claim 1 wherein said alarm means comprises a resistive heating element.

3. The implantable urinary control apparatus of claim 1 wherein said sensing means is connected to said implantable inlet means.

4. The implantable urinary control apparatus of claim 1 further comprising implantable recharging means operatively connected to said implantable power source means and means locatable outside the body for transmitting energy into the body to cause said implantable recharging means to recharge said implantable power source means.

5. The implantable urinary control apparatus of claim 1 further comprising securing means connected to said sensing means for securing said sensing means to said urinary bladder.

6. The implantable urinary control apparatus of claim 5 wherein said securing means comprises a strap.

7. An implantable urinary control apparatus for controlling the discharge of urine from a body comprising an artificial implantable urinary bladder, implantable pump means for pumping urine from said implantable bladder out of the body, implantable inlet means connected to said implantable pump means and to said implantable bladder for permitting urine to flow from said implantable bladder to said implantable pump means, implantable outlet means connected to said implantable pump means for connecting said implantable pump means to an artificial or natural body channel that leads out of the body for permitting urine to flow from said implantable pump means to said artificial or natural body channel, and means capable of being operatively coupled to said pump means for operating said implantable pump means.

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