ABSTRACT
A pump/valve unit for controlling the inflation and deflation of a urethral collar in a prosthetic urinary sphincter device is disclosed including a compressible bulb pump defining a reservoir made integral with a valve unit for implant wherein the valve unit includes a movable valve member operable by depression of a flexible portion of the valve unit housing for controlling fluid flow between the reservoir and collar and a pressure sensing means which operates the valve member to relieve an excess pressure in the collar should too much pressure be applied by the patient.

4 Claims, 4 Drawing Figures
PROSTHETIC URINARY SPHINCTER

ORIGIN OF THE INVENTION

The invention described herein was made by employees of the United States Government and may be manufactured and used by or for the Government for governmental purposes without the payment of any royalties thereon or therefor.

BACKGROUND OF THE INVENTION

The invention relates to a prosthetic urinary sphincter device for controlling the bladder function in the situation where a person has lost bladder control. Implantable devices have been used before for controlling this situation where a person has lost bladder control. Implantable devices utilizing bulb reservoirs and flap valves, respectively, which are simple requiring minimum surgery but which do not afford highly accurate rate pressure control and relief.

Another important object is a simplified device whose implant requires a minimum amount of surgery. The device includes a compressible bulbous pump means C, having a press bulb made from a soft synthetic material such as a silicon elastomer which provides a reservoir for a suitable fluid solution which is used as a pressurizing fluid, such as a saline solution and an integral valve unit D, having a housing which encloses the components thereof. The housing is illustrated as being cylindrical in shape consisting of a cap portion and a base portion received within a flange portion of the cap which may be bonded or welded. The reservoir bulb material is made integral with the housing preferably by bonding at any suitable bonding agent which is biocompatible. The cap includes a bulb fitting and boss providing a fluid port for interfacing with the pressurization tubing connected to the urethral collar. The pressurization tubing may be made of any suitable tubing material such as expanded Teflon.

DESCRIPTION OF A PREFERRED EMBODIMENT

The drawing illustrates a device, designated generally as A, for pressurizing and relieving the collar B, of a urinary prosthetic sphincter device. The device includes a compressible bulbous pump means C, having a press bulb made from a soft synthetic material such as a silicon elastomer which provides a reservoir for a suitable fluid solution which is used as a pressurizing fluid, such as a saline solution and an integral valve unit D, having a housing which encloses the components thereof. The housing is illustrated as being cylindrical in shape consisting of a cap portion and a base portion received within a flange portion of the cap which may be bonded or welded. The reservoir bulb material is made integral with the housing preferably by bonding at any suitable bonding agent which is biocompatible. The cap includes a bulb fitting and boss providing a fluid port for interfacing with the pressurization tubing connected to the urethral collar. The pressurization tubing may be made of any suitable tubing material such as expanded Teflon.

Internally of the housing, the device D has as its components a main body portion which may be of stainless steel and provides a member for retaining the shape of the device generally. The body includes two upstanding leg portions and a central upstanding stem portion which serves as a valve stem. A fluid port is provided in the upstanding leg portion communicating with the fluid reservoir.

A reciprocating valve member is included within the housing and includes a depressible button member which serves as a valve actuator and a valve body attached to the button by means of a pin. The housing is made from a suitable resilient material such as silicone elastomer such that the center of cap portion is depressible to manually operate valve defining a second fluid port, and a bore communicating with the fluid reservoir.

Another important object of the present invention is to provide a prosthetic sphincter device for controlling urinary incontinence in which the device for controlling inflation of the urethral cuff is not implanted, thus permitting a more conventional construction.

Accordingly, an important object of the present invention is to provide a prosthetic sphincter device for controlling urinary incontinence which is reliable and does not require replacement following implant.

Another important object is a simplified device whose implant requires a minimum amount of surgery.

Still another important object of the present invention is to provide a prosthetic sphincter device which has an improved pump/valve unit for controlling pressurization of the urethral collar.

Yet another important object is the provision of a prosthetic urinary sphincter device having automatic and highly accurate relief of an excess pressure exerted on the urethra due to over pressurization by the user avoiding tissue damage thereto.

SUMMARY OF THE INVENTION

The invention provides a novel unitary press bulb pump/valve device which eliminates the use of two pumps. The device includes a press bulb which acts as a reservoir for containing the fluid and an integral valve unit for controlling the flow direction and manual relief for patient urination. The device further includes a relief feature for controlling the maximum pressure exerted by the urethral collar against the urethra.
In a prosthetic sphincter device for controlling urinary incontinence of the type having an inflatable urethral collar for surrounding the urethra and preventing flow in the urethral passage when inflated while permitting flow when deflated, a pump/valve unit for inflating and deflating said collar comprising:

1. A compressible bulbous pump means having an interior space defining a fluid reservoir;
2. A valve unit integral with said bulbous pump means which includes:
   - a valve housing having a resilient depressible portion;
   - said valve housing having a first port communicating with said fluid reservoir and a second port adapted for connection to said inflatable collar;
3. Said valve housing having a second port permitting fluid flow therethrough; and
4. A valve actuator element operable by depression of said resilient portion of said valve housing;

said valve member including a valve element having a first position permitting fluid flow therethrough said valve member and a second position blocking fluid flow therethrough; and
5. A valve element occupying said first position in response to the compression of said pump means allowing fluid to flow from said reservoir to said inflatable collar and in response to said operation of said actuator element allowing fluid to flow from said collar to said reservoir.

2. The structure of claim 1 wherein said valve unit includes pressure sensing and relief means for sensing the pressure of said fluid in said inflatable collar and causing said valve element to move to said first position in the event said fluid pressure in said collar exceeds a predetermined amount.

3. The structure of claim 1 wherein said valve unit includes:
   - base means having an upstanding stem,
   - said valve member being carried for movement toward said base means affording engagement between said stem and valve element, and
   - said valve member being urged away from said base means.

4. The structure of claim 1 wherein said valve member includes:
   - a valve body having a fluid port,
   - a valve seat formed in said valve body remote from said fluid port defining a second fluid port;
   - a bore formed in said valve body connecting said first and second ports,
   - said valve element carried in said bore seatable on said valve seat in said second position, and
   - said valve actuator element carried by an end of said valve body opposite said valve seat.

Thus, it can be seen that an advantageous construction for an implantable pump/valve device can be had according to the invention for controlling the inflation and deflation of a urethral collar in an artificial sphincter device which is simple and reliable, requiring a minimum of implant area and surgery and which automatically and accurately relieves an excess of pressure placed upon the urethra by over inflation of the collar by the user avoiding permanent damage to the tissue of the urethra.

While a preferred embodiment of the invention has been described using specific terms, such description is for illustrative purposes only, and it is to be understood that changes and variations may be made without departing from the spirit or scope of the following claims.

What is claimed is:

1. A prosthetic sphincter device for controlling urinary incontinence of the type having an inflatable urethral collar for surrounding the urethra and preventing flow in the urethral passage when inflated while permitting flow when deflated, a pump/valve unit for inflating and deflating said collar comprising:
   - a compressible bulbous pump means having an interior space defining a fluid reservoir;
   - a valve unit integral with said bulbous pump means which includes:
     - a valve housing having a resilient depressible portion;
     - said valve housing having a first port communicating with said fluid reservoir and a second port adapted for connection to said inflatable collar;
     - a fluid flow path in said valve housing between said first and second ports;
     - a valve member enclosed within said housing disposed in said fluid flow path having a valve actuator element operable by depression of said resilient portion of said valve housing;
     - said valve member including a valve element having a first position permitting fluid flow therethrough said valve member and a second position blocking fluid flow therethrough; and
     - a valve element occupying said first position in response to the compression of said pump means allowing fluid to flow from said reservoir to said inflatable collar and in response to said operation of said actuator element allowing fluid to flow from said collar to said reservoir.

2. The structure of claim 1 wherein said valve unit includes pressure sensing and relief means for sensing the pressure of said fluid in said inflatable collar and causing said valve element to move to said first position in the event said fluid pressure in said collar exceeds a predetermined amount.

3. The structure of claim 1 wherein said valve unit includes:
   - base means having an upstanding stem,
   - said valve member being carried for movement toward said base means affording engagement between said stem and valve element, and
   - said valve member being urged away from said base means.

4. The structure of claim 1 wherein said valve member includes:
   - a valve body having a fluid port,
   - a valve seat formed in said valve body remote from said fluid port defining a second fluid port;
   - a bore formed in said valve body connecting said first and second ports,
   - said valve element carried in said bore seatable on said valve seat in said second position, and
   - said valve actuator element carried by an end of said valve body opposite said valve seat.

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