PROSTHETIC URINARY SPHINCTER

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References Cited

U.S. PATENT DOCUMENTS
2,455,859 12/1948 Foley 128/346
2,533,924 12/1950 Foley 128/346
3,854,469 12/1974 Giori et al. 128/1 R
3,863,622 2/1975 Buuck 128/1 R
4,064,882 12/1977 Johnson et al. 128/349 BV

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 typically include an inflatable cuff surrounding the urethral tube, an inflating pump connected to the cuff for pressurizing the cuff, and a separate deflating pump for removing fluid from the cuff enabling relief of the bladder. A reservoir containing a suitable fluid solution such as a saline solution is connected to the inflating and deflating pumps and check valves are used to control the flow direction. However, this device is not used in extensive application due to the frequent failure of the device and the extensive surgery required for implanting the device, the failure rate being caused primarily by the pump structure and the existence of numerous check valves in the fluid lines. A similar device is shown in U.S. Pat. No. 3,744,063 including separate inflating and deflation pumps wherein the pumps and valves are arranged so that the inflation and deflation are carried out in incremental steps whereby pressure is graduated and controlled.

U.S. Pat. Nos. 3,903,894 and 3,854,469 disclose other implantable devices utilizing bulb reservoirs and flap and slit valves, respectively, which are simple requiring minimum surgery but which do not afford highly accurate pressure control and relief.

U.S. Pat. Nos. 2,455,859 and 2,533,924 typify a second type of artificial 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.

BRIEF DESCRIPTION OF THE DRAWING

The construction designed to carry out the invention will be hereinafter described, together with other features thereof.

The invention will be more readily understood from a reading of the following specification and by reference to the accompanying drawing forming a part thereof, wherein an example of the invention is shown and wherein:

FIG. 1 is an elevation illustrating the implant of a prosthetic sphincter device according to the invention;

FIG. 2 is an elevation of a pump/valve unit constructed according to the invention for inflating and deflating a urethral collar of a prosthetic sphincter device;

FIG. 3 is a top plan view of the device of FIG. 2; and

FIG. 4 is an enlarged elevation in cutaway form illustrating in detail a pump/valve unit constructed in accordance with the invention.

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 19 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 12 which enclosing the components thereof. The housing 12 is illustrated as being cylindrical in shape consisting of a cap portion 13 and a base portion 14 received within a flange portion 15 of the cap which may be bonded or welded. The reservoir bulb material 10 is made integral with the housing 12 preferably by bonding at 10a and 10b by any suitable bonding agent which is biocompatible. The cap 13 includes a bulb fitting 16 and boss 18 providing a fluid port for interfacing with the pressurization tubing 19 connected to the urethral collar B. The pressurization tubing 19 may be made of any suitable tubing material such as expanded Teflon.

Internally of the housing 12, the device D has as its components a main body portion 20 which may be of stainless steel and provides a member for retaining the shape of the device generally. The body 20 includes two upstanding leg portions 21 and 22 and a central upstanding stem portion 23 which serves as a valve stem. A fluid port 24 is provided in the upstanding leg portion 21 communicating with the fluid reservoir 10.

A reciprocating valve member 25 is included within the housing and includes a depressible button member 26 which serves as a valve actuator and a valve body 27 attached to the button 26 by means of pin 26a. The housing 12 is made from a suitable resilient material such as silicone elastomer such that the center of cap portion 13 is depressible to manually operate valve 27 when implanted.

The valve body 27 includes a fluid port 27a, a valve seat 27b defining a second fluid port, and a bore 27c connecting the two ports. A valve element is provided in the form of a ball poppet 28 maintained on the seat.
button member

adjusted by adding or subtracting shims

27b

valve element thus has a first position off the seat per-

path exists between the reservoir

body

valve element

valve bore

one end between the retainer body

33

action against the diaphragm will allow the valve mem-

37

once again. inflatable collar and in response to said operation

phagm

position wherein flange

A spring

23.

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 be-
tween said stem and valve element, and

biasing means carried between said base means and
said valve member urging said valve member away
from said base means.

4. The structure of claim 1 wherein said valve mem-

ber 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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