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.
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 the bladder functions such as shown in U.S. Pat. No. 3,863,622 which 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 10 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 encloses the components thereof. The housing 12 is illustrated as being cylindrically shaped in the shape 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 25.

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
mitting flow through the valve member and a second
position on the seat blocking flow therethrough. A flow
path exists between the reservoir 10 and collar B when
valve element 28 is in its first position through port 24,
valve bore 27c, and port 16 of the valve unit.

A pair of outwardly extending flanges 32 cooperate
with a cylindrical retainer body portion 33 of the main
body 20 to limit the upward vertical movement of the
valve member 25. A flexible diaphragm 34 is attached
to one end between the retainer body 33 and main body 20
and is partially carried by valve member 25 by attach-
ment at a diaphragm seat member 35 integral with mem-
ber 25.

The diaphragm 34 divides the interior of housing 12
into a first compartmented section 12a in fluid commu-
nications with collar B and a second compartmented
section 12b in fluid communication with reservoir 10.
The outwardly extending flanges 32 include openings
36 through which the pressure of the fluid in section 12a
and hence collar B is transmitted for relieving the pres-
sure should it exceed a predetermined value. Action of
the excessive pressure against the diaphragm 34 causes
the valve member 25 to move downwardly engaging
the ball poppet against the plunger 23 to open the valve
and allow the excessive pressure to be relieved, the
action against the diaphragm will allow the valve mem-
ber to raise back to its normal position abutting the
retaining member 33 allowing the ball poppet to seat
once again.

A spring 37 biases the valve body 27 in its normal
position wherein flange 32 abuts the retaining member
33 away from the base 20. The amount of bias of spring
37 may be adjusted by adding or removing annular shims
38 received over stem 23.

The amount of pressure differential across the dia-
aphragm 34 required to unseat ball poppet 28 being a 40
function of the combination of spring bias force pro-
vided by springs 31 and 37 whereby the amount of spring bias may be adjusted so as to relieve a desired,
predetermined excess of pressure in section 12a and
hence collar B. The amount of pressure being limited to
that value necessary to close off the urethral passage
while avoiding deterioration of the tissue cells as can
result from poor blood circulation due to maintenance
of an excess pressure on the urethra.

Thus, it can be seen that an advantageous construc-
tion 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 sphinc-
ter device which is simple and reliable, requiring a mini-
imum of implant area and surgery and which automati-
cally 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 de-
parting from the spirit or scope of the following claims.

What is claimed is:
1. In a prosthetic sphincter device for controlling
urinary incontinence of the type having an inflatable
urethral collar for surrounding the urethra and prevent-
ing 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 inte-
rior space defining a fluid reservoir;
a valve unit integral with said bulbous pump means
which includes:
a valve housing having a resilient depressible por-
tion;
said valve housing having a first port communicat-
ing 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 dis-
posed in said fluid flow path having a valve actu-
ator element operable by depression of said resil-
ient portion of said valve valve;
said valve member including a valve element hav-
ing a first position permitting fluid flowthrough
said valve member and a second position block-
ing fluid flow therethrough; and
said 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 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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