An artificial urethral valve for implantation in the bladder or urethra of an incontinent person comprising a movable valve occluding means which is retained in the closed position by means of a spring that requires a relatively high opening force and then substantially collapses to allow the passage of bladder contents through the valve. The valve occluding member retaining spring requires a relatively high breakaway or opening force to open. Thereafter the normal outflow of bladder contents through the valve is sufficient to substantially keep the valve open. After the contents of the bladder have been voluntarily evacuated, the valve occluding member is automatically returned to the valve seat to again close the valve to a leakproof seal.
IMPLANTABLE ARTIFICIAL URETHRAL VALVE

This is a division of an application for U.S. Pat. Ser. No. 849,720, filed Aug. 13, 1969 and now abandoned. Voluntary control over the discharge of bladder contents has long been a serious and distressing problem for persons whose natural urethral valve is no longer capable of completely controlling the outflow of urine from the bladder for such reasons as advanced age, surgery, disease, or malformation of the natural urethral valve. Persons with this problem have attempted other means of control or correction which have proved to be uncomfortable, inconvenient, unsanitary, offensive, and inadequate.

One such method of caring for involuntary bladder emissions consists of the incontinent person wearing a pad of absorbent material in close proximity to the external opening of the urethra to absorb all the fluid that escapes past the malfunctioning natural urethral valve. This method is very undesirable in that the wearer is continually confronted with the embarrassment of having to wear a bulky pad of absorbent material that can create skin irritations and offensive odors. A person thus equipped will of necessity feel unduly restricted in his activities since he must always be aware of the problems associated with urination, used pad removal and disposal, and pad replacement.

Another method of caring for involuntary urinary emissions has been for the incontinent person to wear a receiving container attached to the leg or suspended from the waist and connected to the external opening of the urethra in such a manner as to allow the urine to flow by the force of gravity into the receiving container. Such a device is disclosed by Snyder, U. S. Pat. No. 3,447,536. Not only is such a device cumbersome, but it can be odoriferous and has on occasion been known to spill or otherwise accidently discharge its contents.

Neither of the foregoing methods is directed towards solving the underlying problem of the incontinent person nor do they attempt to return the evacuation of bladder contents to the completely voluntary control of the afflicted person.

Beliveau et al., U. S. Pat. No. 3,372,695, propose a device that is inserted up the urethra until a retaining portion resides inside the bladder and an appendage thereto or plug passes out of the bladder into the urethra such that the plug resides within the confines of the urethral sphincter muscle. The appendage or plug portion of their device that passes out through the urethral sphincter muscle is smaller in diameter than the internal diameter of the urethra but of sufficient diameter to form a fluids barrier when the urethral sphincter muscle is closed about it. Their invention is adaptable only for those persons who are able to partially close the urethral sphincter muscle sufficiently to completely restrict the urethra when the plug is located within the confines of the muscle and thus overcome incontinence of urination. Their invention would not be usable in a person who was unable to exercise any form of voluntary control over the urethral sphincter muscle or in a person whose urethral sphincter muscle has been damaged by disease such that the plug portion would not completely seal when acted upon by the muscle. Nor would it be operable in a person whose urethral sphincter muscle has been surgically removed for one reason or another. Also, it is well known in the medical field that an unstrained foreign object in the urethra is a source of irritation to the lining of the urethra and substantially increases the dangers of infection of the urethra. The cord in their invention, which extends out the urethra (see column 4, lines 32-36), is such a source of irritation to the urethra since it would reside within the urethra while the appliance is in place as a method of overcoming incontinence.

The apparatus of the present invention does not require the use of any external appliances as disclosed by Snyder or the adaptation of other voluntary muscles to the task of supplying motive power to a urethral closure device located externally of the urethra as disclosed by Berry, U. S. Pat. No. 3,066,667. Berry discloses an inert and rigid body that is pressed against the urethra to pinch it closed or otherwise cause the urethra to be kinked in such a manner as to prevent the passage of bladder contents through the urethra. From the foregoing, a serious question arises as to whether the pinching of the living tissue will tend to cause necrosis of that section of tissue.

The present invention completely replaces the natural urethral sphincter muscle as the urethra closure means and utilizes only the normal muscles used in urination to create sufficient pressure upon the bladder contents to overcome the spring tension force that holds the occluding member to the valve seat to form the leakproof seal. Once the initial spring tension force is overcome, the valve will remain open under the normal flow of the bladder contents with very little pressure required to be exerted upon the bladder to keep the valve open and the bladder contents flowing.

After the bladder contents have been evacuated, there is sufficient spring tension in the resilient member to return the occluding member to the closed position to form again a leakproof seal.

It is an object of this invention to provide an artificial urethral valve suitable for implantation in the urethra or bladder of an incontinent person for the purpose of returning the evacuation of bladder contents to the voluntary control of the user.

A further object of this invention is to provide an artificial urethral valve that requires an opening force greater than the static pressures normally exerted on the bladder and thereafter remains open under a minimal force such as the gravitational flow of urine from the bladder.

A still further object of this invention is to provide an artificial urethral valve that automatically returns to the closed position when the contents of the bladder have been voluntarily evacuated.

These and other objects and advantages of the present invention will become apparent from the following drawing and accompanying descriptions of the drawing.

FIG. 1 is a schematic of one embodiment of the artificial urethral valve with a spherical occluding member.

FIG. 2 is a schematic of another embodiment of the artificial urethral valve with a conical occluding member.

FIG. 3 is an end view of both embodiments set forth in FIGS. 1 and 2.

Referring to FIG. 1, an artificial urethral valve is shown generally at 10 and comprises a fluids occluding member 11 in the shape of a sphere which occludes the distal end of the inlet portion 12 of a tunnel through the body of the valve when held by the spring tension force of a spring 17 against a valve seat 14. Valve seat 14 is
formed circumferentially about the distal end of the inlet tunnel 12. When dislodged from the valve seat 14 by the voluntary exertion of force upon the bladder and its contents sufficient to initiate urination, occluding member 11 is forced away from valve seat 14 whereupon the spring tension force of spring 17 tending to return occluding member 11 to valve seat 14 rapidly collapses. Once dislodged from valve seat 14, occluding member 11 is held away from the valve seat by the force of the flow of bladder contents through inlet tunnel 12 of valve 10.

The diameter of occluding member 11 is less than the internal diameter of the cavity or tunnel within which it resides to allow the passage of bladder contents through the valve once the occluding member has been dislodged from the valve seat 14.

After the bladder contents have been voluntarily evacuated, the spring tension force of spring 17 acting upon occluding member 11 is sufficient to return occluding member 11 to valve seat 14 and again form a leakproof seal. In this manner, the artificial urethral valve very closely approximates the functions of a normally functioning natural urethral valve.

Spring 17 is in the form of a spring that has relatively high resistance to movement up to a certain point but no movement beyond that point causes the spring to substantially collapse to a condition of weaker resilience. Such a spring is similar to the common noisemaker or "cricket" which has a leaf of spring metal with a depression or dimple formed therein which creates the high resistance to movement up to a point after which the spring collapses with a loud noise to the condition of weaker resilience. Spring 17 is also similar in principle to the commercially available Belleville spring wherein opposing compressive and tensile forces within the body of the spring create the condition of relatively high resistance to movement up to a certain point and any movement beyond that point causes the spring to substantially collapse to a condition of weaker resistance.

Utilizing this type of spring, occluding member 11 is held against valve seat 14 until forced away by the voluntary exertion of force sufficient to cause urination at which time spring 17 substantially collapses and allows occluding member 11 to move away from valve seat 14 to allow the bladder contents to be evacuated through the valve. The flow of the bladder contents through the valve is sufficient to overcome the resilience of spring 17 in its substantially collapsed state. After the flow has ceased, the remaining resilience of the substantially collapsed spring 17 is sufficient to return occluding member 11 to the closed position against valve seat 14 whereupon the spring again requires a relatively high force to open the valve.

It would be obvious to one skilled in the surgical arts that an artificial urethral valve as shown is designed for implantation in the bladder over the bladder outlet to the urethra in such a manner as to completely control the outflow of bladder contents into the urethra and subsequently from the body.

Referring to FIG. 2, occluding member 11 is generally in the form of a right circular cone with a blunted apex and gently rounded corners. The apex of the cone resides within the inlet tunnel 12 and the sloping sides of the cone contact valve seat 14 to form a leakproof seal. This cone shape of the occluding member causes it to act as a lifting body under the flow of bladder contents in that the flow of fluids around the cone shape in a direction generally parallel to the axis of the cone will tend to create an area of decreased pressure behind the cone. This area of decreased pressure will in turn assist in the movement of the occluding member 11 further from the valve seat 14 and in overcoming the resistance of spring 17.

The cone shape is merely one suggested embodiment of the occluding member 11. Other forms or shapes could easily be adapted for use as an occluding member for the artificial urethral valve.

FIG. 3 is an end view of the valves shown in FIGS. 1 and 2 and serves to illustrate how openings 15 between restraining members 16 allow the passage of bladder contents from the valve into the urethra. In all embodiments, restraining members 16 prevent the downstream travel of occluding member 11.

In all embodiments of the artificial urethral valve all materials of construction in contact with living tissue are inert and non-irritating to living tissue in addition to being inert to urine wherever the materials come into actual contact with the bladder contents.

The artificial urethral valve shown could be surgically implanted in the appropriate position in the lower urinary tract of the incontinent person; however, it could also be constructed of such a small external diameter that it could be inserted through the external opening of the urethra and up the urethra until in a position proximal to the natural urethral valve muscle such that the natural urethral valve muscle would retain the artificial urethral valve in place. As an alternative, the artificial urethral valve could be bonded in place by means of tissue compatible adhesives or by means of expandable bars that could be expanded when the valve is in place to engage the inner wall of the urethra sufficient to hold the valve in place in the urethra against the pressures of the bladder contents.

We claim:

1. In an artificial urethral valve for implantation in the lower urinary tract of an incontinent person for the purpose of allowing the incontinent person to regain voluntary control over the evacuation of bladder contents, said valve comprising a body of a size for wholly implanting and blocking the lower urinary tract of the incontinent person and having a tunnel which extends therethrough for the passage of bladder contents through said valve body wherein the internal diameter of a first downstream portion of the inlet section of said tunnel is of a lesser diameter than an adjacent second downstream section of said tunnel, the downstream face of said lesser diameter portion being located in a plane generally transverse to the longitudinal axis of said tunnel and serving as a valve seat for an occluding member of said valve tunnel, which occluding member resides within the second section of the tunnel downstream of said valve seat, said occluding member being held in the occluding position against said valve seat by the resilience of a spring means, said spring means having a first greater resiliency to movement to a predetermined position away from said seat and thereafter substantially collapses to a condition of lesser resiliency under a force exerted upon the bladder contents sufficient to initiate urination wherein said occluding member is held away from said occluding position by the force of the outflow of bladder contents from the bladder through said valve body until said outflow of said bladder contents has substantially ceased where-
upon the residual resilience of said spring is sufficient to return said occluding member to said occluding position.

2. In an artificial urethral valve as defined in claim 1 wherein said occluding member is in the shape generally of an apex of a blunted cone wherein the blunted tip of said cone resides within the center of said valve seat and the sloping sides of said cone serve as a liquid proof contact between said valve seat and said occluding member said occluding member acting as a lifting body under a flow of bladder contents through said tunnel, said lifting body action serving to assist in overcoming any remaining resistive force tending to return said occluding member to said valve seat.

3. An artificial urethral valve as defined in claim 1 wherein all materials of construction exposed to living tissue are inert to and compatible with living tissue.

4. An artificial urethral valve as defined in claim 1 wherein all materials of construction exposed to bladder contents are inert to said bladder contents.

5. An implantable artificial urethral valve comprising valving means operable under a first, greater pressure to open said valve and retained in said open position under a second, lesser, pressure, said valving means comprising a body of a size to be implanted wholly within the lower urinary tract, a tunnel extending through said body having a valve seat therein, an occluding member engaging said seat, and a spring engaging said occluding member to normally retain said occluding member against said valve seat in a sealing relationship until opened by said first greater pressure, said spring having a first greater resiliency to movement to a predetermined position away from said seat and a second lesser resiliency to movement beyond said predetermined position.