

[54] **INCONTINENCE SYSTEM AND METHODS OF IMPLANTING AND USING SAME**

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[51] Int. Cl. .... **A61f 1/00**, A61b 17/00

[58] Field of Search ..... 128/1 R, 325-327, 128/346, DIG. 25; 3/1

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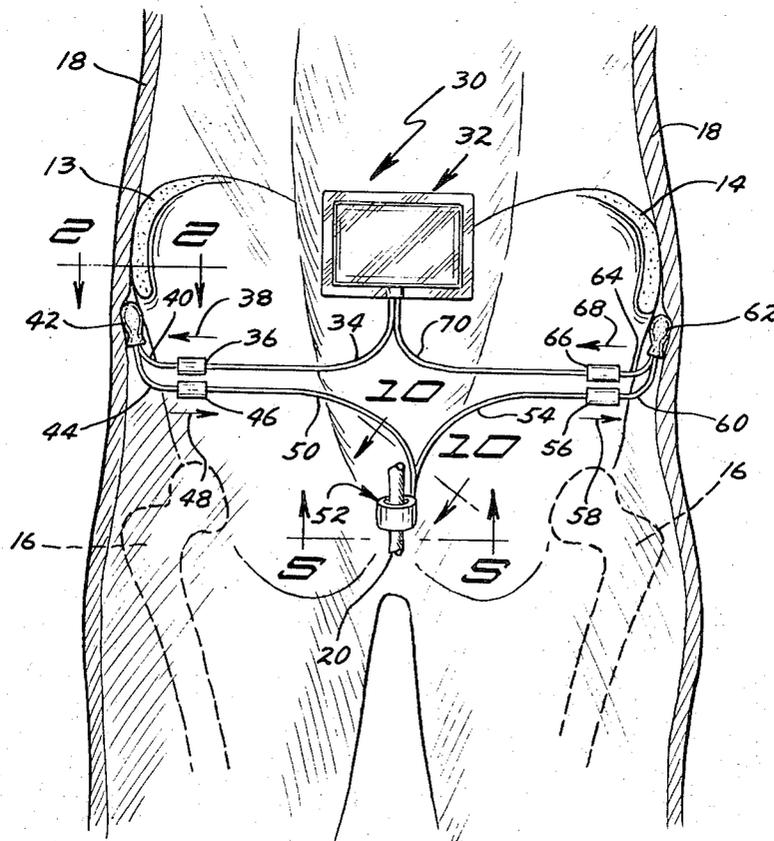
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Primary Examiner—Dalton L. Truluck  
Attorney, Agent, or Firm—Stuart R. Peterson

[57] **ABSTRACT**

An inflatable cuff unit has an expansible chamber formed by a readily deformable wall and a relatively rigid wall. The relatively rigid wall contains a number of threads or cords embedded therein with projecting end portions that are tied together when the cuff is implanted in an encircling relation with an excretory vessel within a person's body. The deformable wall is placed against the vessel to be controlled. Also implanted is a reservoir containing a radio-opaque fluid. Strategically located elastomeric bulbs are disposed innerjacent the skin, together with internally located check valves and appropriate connecting tubes, enable the user to squeeze the proper bulb, doing so through his skin, so as to pump fluid to and from the cuff. When the cuff is under pressure, it acts in a manner resembling the sphincter surrounding the urethra when the urethra constitutes the vessel to be controlled. A basically similar cuff may be used for gastro intestinal tract control.

**6 Claims, 15 Drawing Figures**



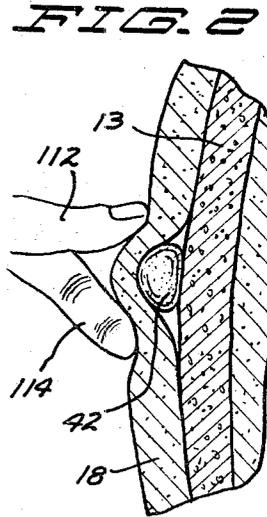
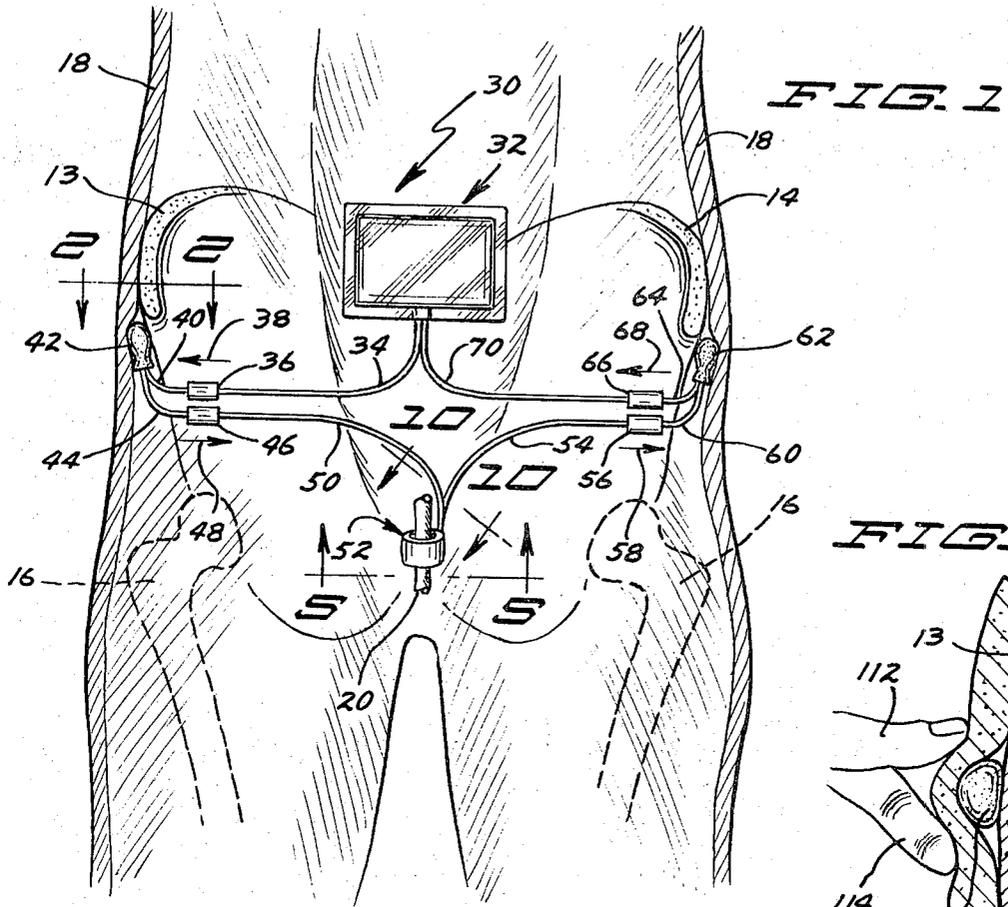


FIG. 3

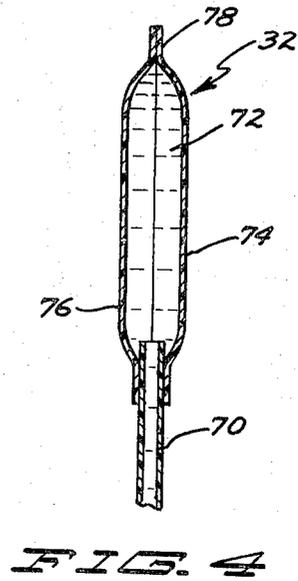
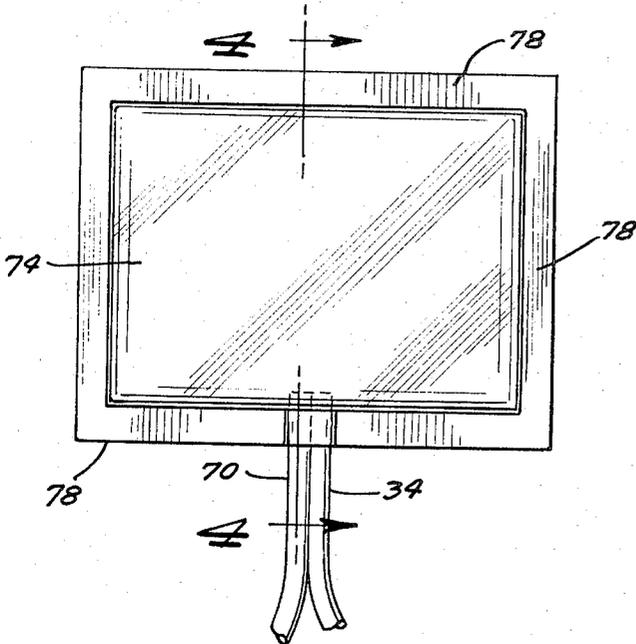


FIG. 5

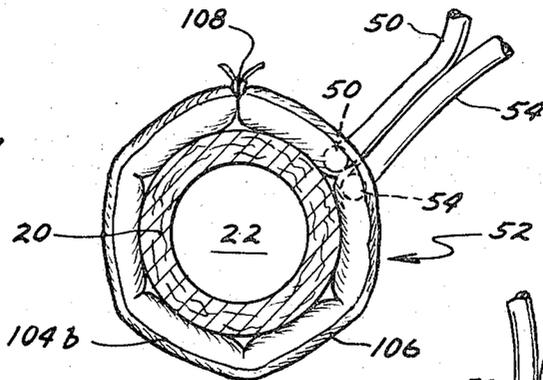


FIG. 6

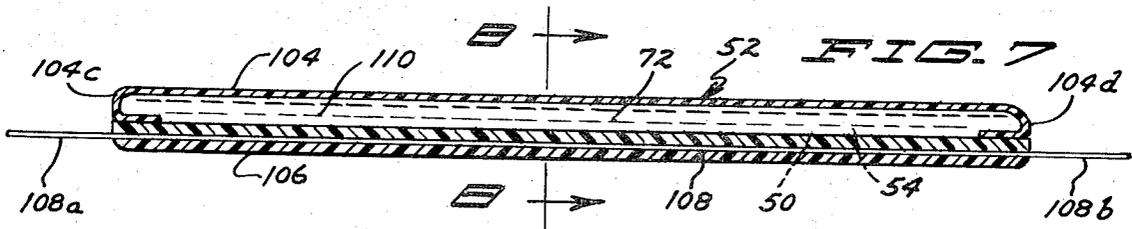
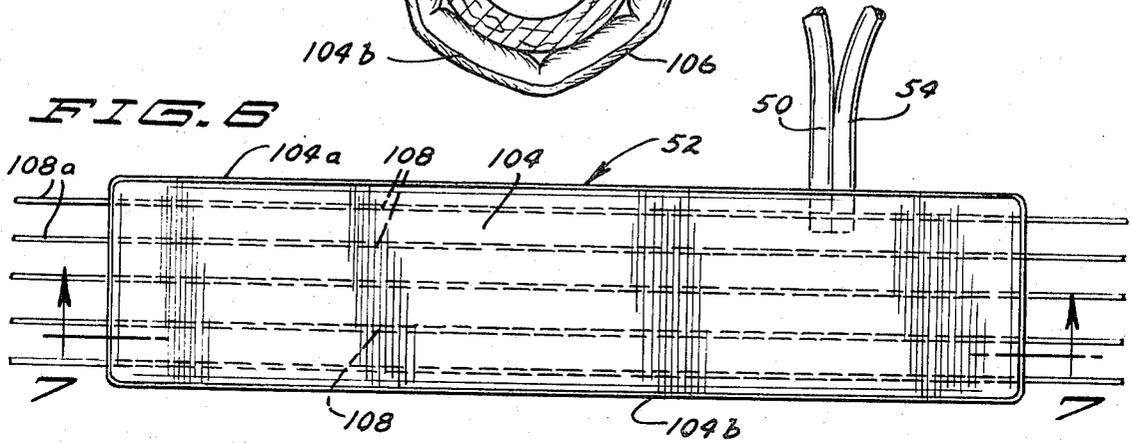


FIG. 7

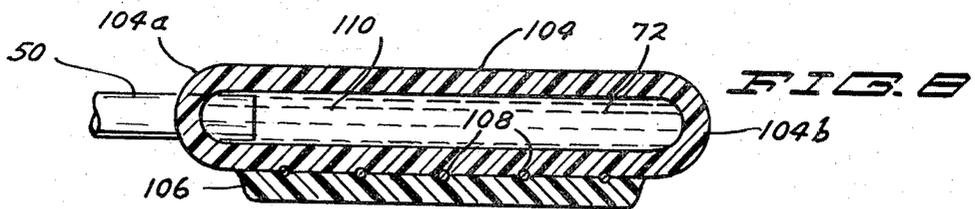


FIG. 8

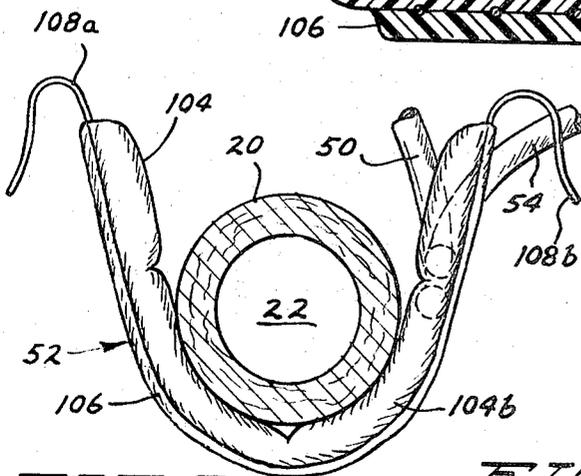


FIG. 9

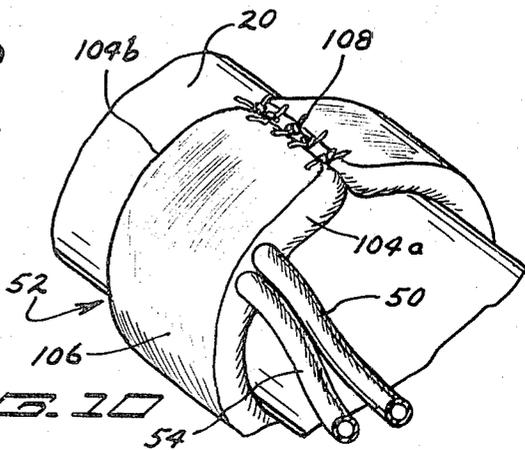


FIG. 10

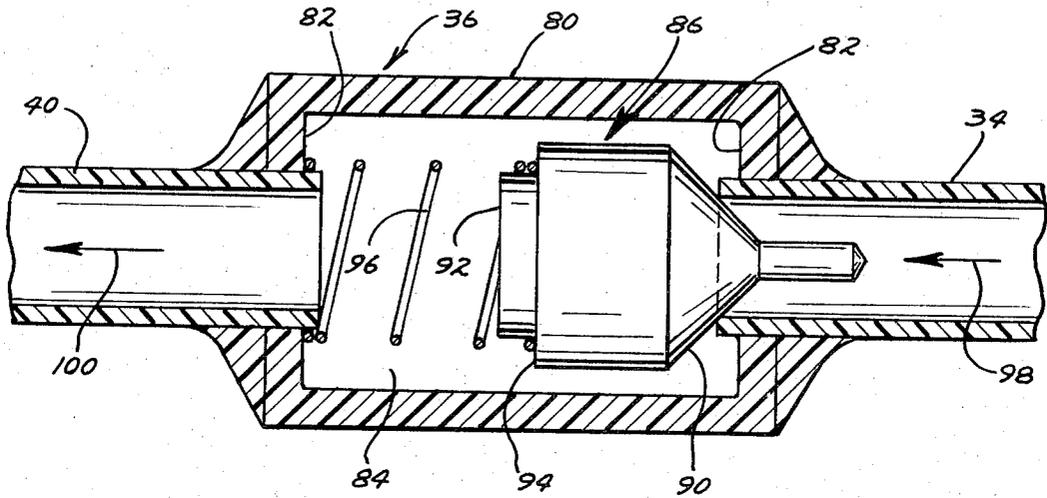
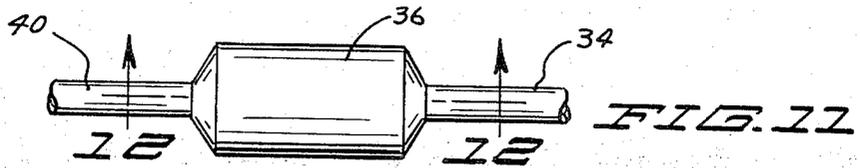


FIG. 12

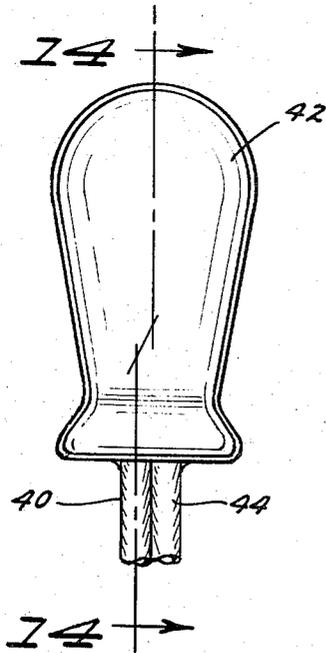


FIG. 13

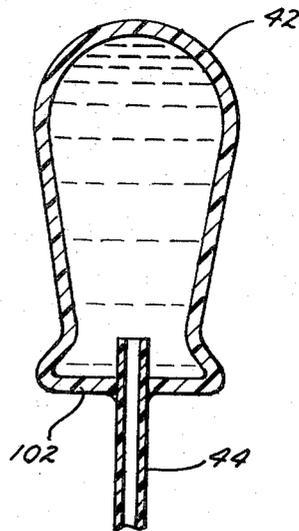
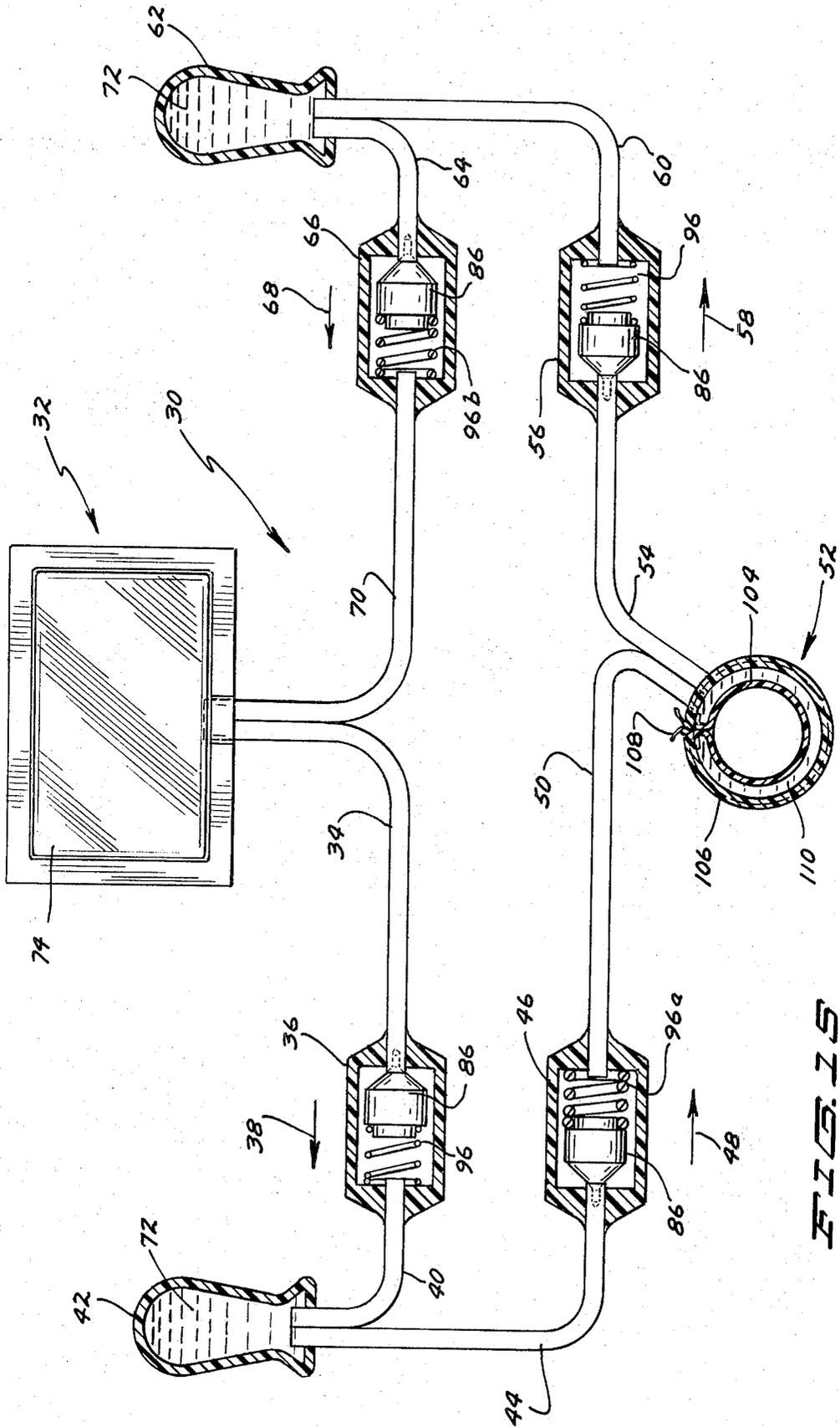


FIG. 14



**F I G. 15**

## INCONTINENCE SYSTEM AND METHODS OF IMPLANTING AND USING SAME

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

This invention relates generally to a system functioning as an artificial muscle, such as a sphincter muscle, and pertains more particularly to a system that can be completely implanted within an animal body and controlled exteriorally.

#### 2. Description of the Prior Art

Artificial sphincters are not completely new. Owing to the rather large number of persons afflicted with the vexing problem of incontinence, it is no wonder that various attempts have been made to simulate artificially the action that should be performed by the natural muscles within an animal body. One such attempt is portrayed in U.S. Pat. No. 2,455,959, granted on Dec. 7, 1948 to Frederic E. B. Foley titled "ARTIFICIAL SPHINCTER AND METHOD" and also in the same patentee's U.S. Pat. No. 2,533,924, issued on Dec. 12, 1950. In both instances, the artificial sphincter is only suitable for external use, thereby further restricting it to employment solely by males. Both of these patents, however, provide a detailed description of the malady and the prior art up to that time period, the two patent disclosures emphasizing the difficulties experienced from the use of the so-called rather common Cunningham incontinence clamp.

Various modifications of the Cunningham clamp have been devised. Such clamps carry the same shortcomings of the Cunningham clamp in that they are cumbersome, large and relatively uncomfortable.

Other efforts in the past have resorted to valve mechanisms that are inserted directly into the canal or passage to be controlled. Also, various blockage schemes, both external and internal, have been tried on at least an experimental basis, especially in an effort to correct for rectal incontinence.

Prior art devices have been designed for both internal and external application. The implanted devices have in common the fact that the integrity of the outflow tract is disrupted, thereby damaging the biological content therein. The external devices are inherently bulky and cumbersome, and can only be applied to males.

### SUMMARY OF THE INVENTION

One important object of the present invention is to provide an incontinence system that is contained completely within an animal body, but external to the outflow tract itself.

Another object is to provide a system of the foregoing character for use by humans that will be devoid of cosmetic detraction. In this regard, not only will the system be completely concealed from view, and thereby unnoticeable when the user is unclothed, but its operation will be virtually imperceptible, thereby eliminating any possible embarrassment or adverse social reaction from others.

Another object is to provide a system requiring no source of power other than that furnished by the user himself. Stated more specifically, the pumping is achieved manually from outside, there being a pair of elastomeric bulbs innerjacent the individual's skin that can be squeezed or kneaded to produce the requisite operating pressure.

A further object is to provide an incontinence system in which the pressural condition necessary to simulate the muscular action is easily achieved and then automatically maintained without further attention or effort from the user. An additional aim is to enable an equally facile reduction in pressure to be realized when the passage is to be opened to allow flow therethrough.

Yet another object of the invention is to provide an incontinence system that can be employed by both males and females. For instance, our system can be installed in the scrotum, although not restricted to this region, of a male or the major labia of a female, also not necessarily restricted to this area, in the correction of an urethral malfunction.

Also, an object is to provide a versatile system generally suited to controlling either the flow of urine or fecal waste.

Still another object is to provide a system that can be implanted in various types of animals, particularly humans, without difficulty and without injury to neighboring organs and tissue. Equally readily, should circumstances so dictate, the entire system can be removed without damage to the body.

Further, our system has the capability of performing for prolonged periods, even during the remaining life of a patient, without either professional or user attention. As mentioned above, while it is expected that the system will function as intended without difficulty, the system, even though completely contained within the body, lends itself readily to utilizing a radiation-impermeable fluid which will obstruct the passage of X-rays or other radiant energy so as to enable detection and localizing of an improperly performing part or member of the system. An aim of the invention, however, is to provide a system so simple that it is not apt to get out of order in the first place, all as mentioned above.

Still another object is to provide an implantable system which can be constructed, at least as far as its tissue-contacting surfaces are concerned, of non-toxic material which the body can tolerate and will not reject. The integrity of the outflow tract is maintained since the incontinence system is external to it.

Briefly, our invention involves the implanting of a self-contained system within an animal body by making an incision through the skin in the region of the affected vessel and then exposing a section of the vessel for application of an inflatable cuff having a deformable wall that is flexed against the vessel in a constrictive fashion so as to prevent fluid flow therethrough. In the case of humans, pressure is developed by the person himself, a simple repetitive squeezing through the person's skin of one of two elastomeric bulbs being all that is necessary in order to force fluid into the interior or expansion chamber of the cuff. Each time the squeezing is stopped fluid is withdrawn automatically from the reservoir, which is implanted at the same time that the cuff is implanted, in preparation for the next squeezing of the bulb. Squeezing of the second bulb returns fluid back to the reservoir to reduce the pressure within the cuff sufficiently to open the vessel and allow fluid flow therethrough.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front sectional view depicting the trunk of a human body having our incontinence system implanted therein in an encircling relation with a section of that person's urethra;

FIG. 2 is an enlarged sectional detail taken in the direction of line 2—2 of FIG. 1 for the purpose of demonstrating how one of the elastomeric bulbs is squeezed through the skin to pump fluid into the inflatable cuff that encircles the urethra in FIG. 1;

FIG. 3 is an enlarged front elevational view of the reservoir appearing in the abdominal cavity, as suggested in FIG. 1;

FIG. 4 is a sectional view taken in the direction of line 4—4 of FIG. 3 for the purpose of illustrating the construction of the reservoir;

FIG. 5 is a side view of the inflatable cuff that circumscribes the fragmentarily shown urethra depicted in FIG. 1, the view being taken in the direction of line 5—5 of FIG. 1 but being on a considerably larger scale;

FIG. 6 is a plan view of the cuff before it is implanted, the end portions of the threads or cords which are used in tying the cuff in place projecting from the opposite ends of the cuff;

FIG. 7 is a sectional view taken in the direction of line 7—7 of FIG. 6 for the purpose of showing to better advantage how the threads or cords are embedded in one wall of the cuff;

FIG. 8 is a sectional view taken in the direction of line 8—8 of FIG. 7;

FIG. 9 is a view corresponding generally to FIG. 5 but illustrating an intermediate step in the implanting of the cuff around the urethra;

FIG. 10 is a perspective view taken generally in the direction of line 10—10 of FIG. 1 picturing the manner in which the ends of the threads or cords are tied together to maintain the circumscribed relationship, the view being opposite in direction to FIG. 5, showing to better advantage the two flexible tubes via which fluid is introduced and withdrawn from the cuff;

FIG. 11 is an enlarged elevational view of one of the check valves appearing in FIG. 1;

FIG. 12 is a greatly enlarged sectional view taken in the direction of line 12—12 of FIG. 11;

FIG. 13 is an enlarged elevational view of one of the elastomeric pump bulbs of FIG. 1;

FIG. 14 is a sectional view taken in the direction of line 14—14 of FIG. 13, and

FIG. 15 illustrates on a larger scale the system appearing in FIG. 1, the pump bulbs, check valves and cuff being shown in cross section.

## DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring first to FIG. 1, the trunk of a human body has been denoted generally by the reference numeral 10. More specifically, the region selected therein for exemplifying the invention is the pelvic cavity labeled 12. Within the pelvic cavity 12 are the right and left hip bones 13, 14 and, for the sake of completion, upper ends of the thigh bones 16 have also been illustrated. The person's skin has been assigned the reference numeral 18. The reference numeral 20 represents an excretory vessel biologically provided within the body 10. To illustrate the invention, the urethra has been selected as the collapsible vessel 20, a section thereof

having been pictured. However, it will be recognized that the vessel 20 might very well constitute the gastro intestinal tract where fecal control is needed. In any event, it will be appreciated that a broad objective of the present invention is to provide an artificial sphincter that acts to close a canal or passage 22 extending through the vessel 20. Thus, when the vessel 20 constitutes the urethra, the function of the present invention is to collapse the urinary tract to prevent undesired discharge of urine from the person's bladder. In other words, the cross section of the tubular vessel 20, being open in FIGS. 5 and 9, is reduced or collapsed to such an extent that its passage 22 is completely closed.

The system exemplifying our invention is shown in its entirety in FIG. 1, and also in FIG. 15, being denoted by the reference numeral 30. It is believed helpful to refer to the system in a broad sense initially and then describe the various components with greater particularity hereinafter. Accordingly, it will be observed that the system 30 includes a reservoir 32 which is implanted in the lower portion of the patient's abdominal cavity or the upper portion of the pelvic cavity 12 as illustrated in FIG. 1.

A first flexible tube 34 extends from the reservoir 32 to a check valve 36, the check valve 36 permitting flow only in the direction of the arrow 38. Another tube 40 leads from the check valve 36 to an elastomeric bulb 42 that functions as a first pump. Still another tube 44 extends from the bulb 42 to a second check valve 46 which allows fluid flow only in the direction of the arrow 48.

A tube 50 connects with an inflatable cuff unit or device denoted generally by the reference numeral 52. The cuff 52 circumscribes the excretory vessel 20 in FIG. 1 which in the illustrated situation constitutes the urethra as already explained. The cuff 52, being toroidal, functions to constrict the urethra and thereby close its passage 22 to prevent the flow or discharge of urine from the bladder. Inasmuch as the cuff 52 is contained wholly within the body of the person or other animal, it lends itself to being installed in either a male or female. Hence, it will be appreciated that the cuff 52 is located before the penis as far as the male is concerned and also before the vaginal orifice as far as a female is concerned. It can also be appreciated that the cuff 52 is exterior to the excretory vessel being regulated so that any potential complications or hazards resulting from foreign materials in contact with sensitive biologic substances are not adversely affected.

An additional tube 54 extends from the cuff 52 to still another check valve 56 which permits fluid flow only in the direction of the arrow 58. From the check valve 56 there extends a tube 60 having communication with another elastomeric bulb 62 which functions as a second pump. There is still another tube 64 leading from the bulb 62 to a fourth check valve 66 allowing fluid to flow only in the direction of the arrow 68. A final tube 70 connects the fourth check valve 66 to the earlier-mentioned reservoir 32.

As best understood from FIG. 15, the system is initially filled with a fluid under slight pressure, more specifically a liquid 72 containing a radio-opaque dye therein. Quite obviously, the fluid that is selected must be physiologically compatible with the body tissue and its organs in case a leak should develop in the system. By rendering the fluid 72 opaque to radiation, such as X-rays, the flow of fluid can be readily traced with the

result that any malfunctioning of the system 30 or impairment of the individual components comprising the system can be easily detected and surgical correction then made if need be.

At this time, the reservoir 32 will be referred to in greater detail. From FIG. 4 it will be discerned that the reservoir 32 is formed with two flexible panels labeled 74, 76. The marginal edges 78 of the panels 74, 76 form a lap joint, being sealed together with a suitable adhesive so as to prevent leakage from the reservoir. The two tubes 34, 70 connecting with the bottom of the reservoir 32 are also sealed in place. It might be explained that the panels 74, 76 do not have to be resilient or elastic. Consequently, when silicone rubber, which is the preferred material, is used for the panels 74, 76 it can be reinforced with polyester fibers.

With respect to the various tubes that have been referred to, these tubes can be also of silicone rubber. An implantable grade of adhesive can be employed to assure a liquid tight connection of the tubes 34, 70 with the reservoir 32. Type A adhesive, manufactured by Dow Corning Corporation of Midland, Mich., is an example of one adhesive that has proved satisfactory.

Similarly, a liquid-tight connection is made between the tubes 34, 40, 44, 50, 54, 60, 64, 70 and the various check valves 36, 46, 56, 66. FIG. 11 elevationally shows the check valve 36 and FIG. 12 sectionally illustrates this same check valve 36 on a greatly expanded scale. Thus, the end portions of the two tubes 34, 40 are sealed within the ends of this check valve 36. More specifically, it will be noted that the check valve 36 comprises a cylindrical housing or casing denoted by the reference numeral 80 and that the two tubes extend through its end walls 82 into the chamber assigned the reference numeral 84. Within the chamber 84, as can be seen from FIG. 12, there is a plug member 86 having a cylindrical body 88. One end portion is tapered or conical at 90 and seats against the end of the attached tube 34. The other end has a cylindrical boss 92 integral therewith, the boss being of lesser diameter than the body 88 so as to form a shoulder 94. A stainless steel coil spring 96 is confined between the shoulder 94 and the other right end wall 82. Thus, the plug member 86 is biased to the right or against the end of the tube 34, this being by reason of the coil spring 96 which is always under a slight amount of compression within the chamber 84.

Consequently, it should be clear from FIG. 12 that the check valve 36 permits fluid to flow only in the direction of the arrow 38 in FIGS. 1 and 15 and also only in the direction of the subsidiary arrows 98 and 100 applied to FIG. 12. In other words, fluid 72 can flow from the reservoir 32 through the tube 34 (as indicated by the arrow 98 in FIG. 12), past the plug 86 contained within the chamber 84, the spring 96 yielding sufficiently to permit passage, and then through the tube 44 (in the direction of the arrow 100 in FIG. 12).

Passing now to a description of the elastomeric bulb 42 appearing at the left (the right side of the user's body) in FIGS. 1 and 15, and shown on an enlarged scale in FIGS. 13 and 14, it will be appreciated from FIG. 14 that this bulb constitutes a resilient, and readily compressible, envelope. More specifically, the bulb 42 is fabricated from silicone rubber that is thin and elastic, yet readily creates a negative internal pressure when not being compressed so that it readily refills, the two tubes 40 and 44 extending into the interior of the

bulb 42 through its bottom wall 102. As with the components 32 and the various check valves 36, 46, 56 and 66, the tubes 40, 44 are retained in a sealed relationship with the wall 102 of the bulb 42.

The check valve 46, although consisting of the same basic components or parts as the check valve 36 has a much stronger spring 96a than the spring 96. In other words, the spring 96a has a spring constant much greater than that of the spring 96 so that the plug 86 of the check valve 46 seats firmly against the end of the tube 46 to prevent any leakage back through the tube 44, yet permitting flow in the direction of the arrow 48 appended to FIGS. 1 and 15.

Playing a very important role in the practicing of our invention is the cuff unit 52. While the cuff 52 has been referred to as inflatable, it does not have to be elastic as the term is normally understood. It is necessary, though, that the cuff 52 have a readily deformable portion. Thus, as can be discerned from FIGS. 7 and 8, the cuff 52 has a deformable wall 104 which is considerably thinner than the opposite wall indicated by the reference numeral 106. Actually, the more rigid wall 106 is approximately twice the thickness of the deformable wall 104, being composed of two layers of rubber adhered together. The wall 106 has embedded therein a number of polyester threads or cords 108. The end portions 108a, 108b of these strings project from the opposite ends of the cuff 52. The cuff can be made of the same material as the reservoir 32 and bulb 42, but when silicone rubber reinforced with polyester sheeting is used, the cuff material contains a more pliable polyester mesh. It is further formed with curved side walls 104a and 104b, being integral continuations of the layer or wall 104; continuations 104c and 104d are inturned at the ends of the cuff 52 and are appropriately sealed to the bottom layer of the wall 106. In this way, an expansion chamber 110 is formed therewithin into which some of the opaque fluid 72 is pumped. It will be appreciated that the various walls forming the cuff 52 can be of adhered layers or laminations which are simply sealed together as best understood from FIG. 7 or the difference in thickness between the walls 104 and 106 can be achieved by molding techniques. Thus, the deformable wall 104 may constitute a single thickness or layer, whereas the more rigid wall 106, as illustrated, can constitute two layers that are adhered together with the cords 108 therebetween. The ends of the tubes 50 and 54 are in fluid communication with the chamber 110, entering through the side wall 104a in a sealed relation therewith.

The check valve 56 can be of identical construction with the check valve 36 in that it contains a spring having the same spring strength as the spring 96; consequently its spring carries the same reference numeral. Likewise, the bulb 62 can be identical with the other bulb 42 that has already been described in considerable detail. While the fourth check valve is basically similar to the three check valves 36, 46 and 56, it differs by reason of a coil spring 96b (FIG. 15) having a greater spring constant than the springs 96 contained in the check valves 36 and 56 but a lesser spring constant than the spring 96a. An effort has been made to pictorially demonstrate the relative spring strengths in FIG. 15 by showing a spring having convolutions possessing a greater cross section than that of the springs 96 and a smaller cross section than the spring 96a; also a fewer number of convolutions are depicted so as to make it

graphically clear that the spring 96b does not compress as readily as the springs 96 housed in the check valves 36 and 56. It is not deemed necessary to show the valve on the scale used for showing the valve 36 in FIG. 12 inasmuch as only a heavier coil spring is substituted for the particular coil spring 96 appearing in FIG. 12. As the description progresses, the manner in which the spring 96b is selected will become clearer. However, at this stage it can be pointed out that it governs or limits the maximum pressure that can be built up within the cuff chamber 110.

The system 30 is quite compact, being constructed with components of small size, thereby occupying little space within the body 10. To provide some idea as to the physical dimensions and volumetric capacities the following illustrative data is presented:

reservoir 32	30-40 cc
bulbs 42, 62	1-2 cc each
cuff 52	3-5 cc
tubes 34, 40 etc	3.2 mm O.D. 1.6 mm I.D.

The volume or capacity of the reservoir 32, it can be explained, is approximately 10 times that of each pump bulb 42, 62, whereas the cuff 52, more specifically its chamber 110, has a volume of one to three times the volume of the bulb 42 or 62. The width (FIG. 6) or cylindrical length of the toroidal configuration (FIGS. 1 and 10) is approximately one to one and one-half times the diameter of the vessel 20 (FIG. 5).

#### OPERATION

For the moment it will be assumed that the system 30 has already been implanted within the trunk 10 of the body appearing in FIG. 1 and that it has been filled with fluid 72, actually under a slight initial pressure. From FIG. 2 it will be perceived that the user himself can squeeze the particular bulb 42 through the portion of the skin 18 overlying the bulb on the right side of the patient. In other words, the innerjacency of the bulb 42 with respect to the skin enables the user to apply squeezing pressure through the skin (and any intervening tissue). Hence, fingers 112, 114 have been shown in FIG. 2 which simply knead or squeeze the bulb 42 to force fluid 72 therefrom under pressure through the check valve 46 containing the strongest spring of the four check valves, the valve 46 being located between said bulb 42 and the cuff 52 as earlier pointed out. In other words, when the bulb 46, which itself functions as an expansion chamber device, is compressed, the fluid is forced therefrom through the tube 44, the check valve 46 and the tube 50 into the cuff 52. In so doing, the plug 86 in the check valve 46 is forced to the right or away from the end of the tube 44 as viewed in FIG. 15, the coil spring 96 of this particular valve 46 compressing enough to permit flow of fluid in the direction of the arrow 48. Due to its heavy construction, though, the spring 96a is effective to prevent any fluid leakage to the left or back to the bulb 42 when the bulb 42 is allowed to return to its normal or uncompressed size as explained below.

When pressure applied through the skin 18 against the bulb 42 is relaxed, the bulb 42 immediately returns to its normal shape and volume, the resiliency of the rubber constituting this bulb being such as to assure such return to its original, uncompressed state. In the process of doing this, it draws fluid from the reservoir

32 via the tubes 34 and 40 as well as through the check valve 36 connected in fluid circuit therewith. In other words, the plug 86 of the check valve 36 is drawn away from the inwardly projecting end of the tube 34, the particular coil spring 96 housed within the casing 80 of this valve being compressed sufficiently to allow fluid flow therethrough in the direction of the arrow 38. However, whenever the bulb 42 is squeezed, the check valve 36 prevents flow in a reverse direction from the bulb 42 back to the reservoir 32. Thus, when the squeezing operation or manipulation is successively repeated, each time the bulb 42 is compressed there is more fluid forced into the cuff 52 and thus the pressure within the cuff is incrementally increased by this manipulative action because the spring 96a prevents any reverse flow by forcibly seating the plug 86 of the valve 46 against the end of the tube 44.

It should be apparent that the increase in fluid pressure within the cuff 52 causes the cuff to be expanded or inflated. Inasmuch as the wall 104 is readily deformable, it is forced inwardly against the vessel 20 and thus applies a constrictive force against this vessel to collapse its walls and thus close the passage 22 therein. It should be equally apparent that there cannot be any reverse flow from the cuff 52 back to the reservoir 32 through the check valves 46 and 36 (and also the bulb 42) because the plugs 86 housed therein simply abut or seat against the ends of the tubes 44 and 34, respectively, that extend into the casings 80 of these two check valves.

It should also be obvious that while flow might be expected to take place through the check valves 56, 66 in the direction of the arrows 58, 68, any such flow from the cuff 52 under these conditions is effectively resisted by the fourth check valve 66. It will be recalled that the coil spring 96b housed within the casing 80 of the check valve 66 is stronger than the springs 96 within the casings of the check valves 36, 56 (but weaker than the spring 96a in the check valve 46). Consequently, a maximum pressure can be built up in the cuff 52 which is determined by the spring strength of the spring 96b in the check valve 66. The specific spring 96b in the check valve 66 is selected so as to enable the appropriate pressure to be developed within the cuff 52, the pressure being sufficient so as to produce the sufficient deformation of the wall 104 to effect only enough constriction of the vessel 20 to close or block its passage 22, yet not enough pressure to cause discomfort to the patient or user. Stated somewhat differently, the check valve 66 acts as a directional safety or relief valve, yielding to the proper pressure in the direction of the arrow 68 (but blocking flow in a reverse direction). The increased pressure, that is the pressure determined by the valve 66, will be maintained automatically owing to the prevention of reverse flow back to the reservoir 32 due to the checking action provided by the valves 36, 46.

The foregoing has dealt with the closing of the vessel 20. When the user wishes to open, actually reopen, the vessel 20, he must manipulate the bulb 62 located at his left side (at the right in FIGS. 1 and 15), doing so in the same fashion that he manipulated the bulb 42 located at his right side (at the left in FIGS. 1 and 15 and also in FIG. 2).

What transpires is that when the bulb 62 is squeezed, there can be no flow of fluid 72 through the check valve 56 in a direction opposite to the arrow 58. This

result occurs because the plug 86 in this particular check valve 56 is forced against the tube 54 to block any reverse flow. However, when the bulb 62 is squeezed, the plug 86 in the check valve 66 moves to the left or in the direction of the arrow 68 to open the tube 64, the coil spring 96b, even though heavier than the other coil springs 96, compressing to permit this. Under these conditions, fluid 72 contained in the bulb 62 is forcibly returned to the reservoir 32.

The repeated kneading or squeezing of the bulb 62 will withdraw fluid from the cuff 52, owing to the inherent resiliency of the rubber constituting the bulb 62, with the consequence that the deformable wall 104 no longer is forced inwardly against the vessel 20. Hence, flow can take place through the now open passage 22.

When the vessel 20 is to be closed again, the system 30 is operated once more in the same manner outlined above. Thus, the bulb 62 at the left in FIGS. 1 and 15 is repeatedly squeezed and the cuff 52 is again inflated so that its deformable wall 104 presses radially inwardly against the vessel 20 to close its passage 22. The passage 22 can be reopened again by manipulating the pump bulb 62 as already described. It will be appreciated, though, that the pressure (and closure of the passage 22) developed by manipulating the bulb 42 is maintained automatically until the bulb 62 is manipulated.

#### IMPLANTING PROCEDURE

Inasmuch as the system 30 is to be installed completely within an animal body, surgical procedures are resorted to. Assuming that the system 30 is to be implanted in the trunk 10 as illustrated in FIG. 1, an abdominal incision is made through the skin 18 so as to provide access to the pelvic cavity 12. With the pelvic cavity open, the particular section of the urethra or vessel 20 to be encircled is exposed by further cutting and forcing overlying tissue to one side. The entire system 30 can be laid within the trunk 10. In this particular type of operation, the left end labeled 104c of the cuff 52 is advanced from the right to the left beneath the urethra 20 as viewed in FIG. 1, assuming the patient to be in a prone position. More specifically, the surgeon positions the cuff 52 so that its ends 104c and 104d are substantially equidistant from the urethra 20.

FIG. 9 exemplifies the next step of raising the ends 104c and 104d of the cuff 52, thereby partially wrapping the cuff about the vessel 20. The encircling or wrapping procedure is completed by bringing the cuff ends in juxtaposition with each other. Then, the surgeon ties each of the projecting end portions of the polyester threads or cords 108a and 108b so as to assure that the circumscribed toroidal relationship appearing in FIGS. 5 and 10, and also in FIG. 1, will be maintained. Care is exercised, though, to not draw the cuff 52 too tightly around the vessel 20, for no initial constrictive force is to be applied to the vessel 20 as the passage 22 should remain fully open under these conditions.

It will be fully appreciated, it is thought, that FIG. 1 is only exemplary of the installation, being generic to both males and females. In most cases, the system 30 will be implanted within the scrotum of the male and in the major labia of the female. Our system is sufficiently versatile to allow implanting in various regions of the body. In this regard, it has already been mentioned that the system is applicable to fecal control and

in such a situation it would be installed with the cuff circumscribing the intestine.

We claim:

1. A method of implanting an incontinence system in an animal body comprising the steps of placing at one location within said body a cuff device having a deformable wall so that said wall resides in a proximal relation with a vessel having a passage extending there-through which passage is to be opened and closed, placing at a second location within said body a pump bulb having fluid communication with said cuff device, said second location being spaced from said first location and sufficiently near the inner surface of the animal's skin so that said bulb can be squeezed through the skin to force fluid under pressure into said cuff device, placing at a third location within said body spaced from said second location a reservoir having fluid communication with said pump bulb for storing at least some of said fluid which is to be pumped into said cuff device by the squeezing of said bulb, placing a first check valve between said reservoir and said pump bulb and a second check valve between said pump bulb and said cuff device, said first check valve permitting fluid flow only from said reservoir to said pump bulb and said second check valve permitting fluid flow only from said pump bulb to said cuff device, placing within said body a second pump bulb at still another location spaced from said cuff device and from said first pump bulb, and also third and fourth check valves, said third check valve being between said cuff device and said second pump bulb and said fourth check valve being between said pump bulb and said reservoir, said third check valve permitting fluid flow only from said cuff to said second pump bulb and said fourth check valve permitting fluid flow only from said second pump bulb to said reservoir, each check valve including a plug member and a coil spring urging its said plug member in a direction to prevent fluid flow, the coil spring in said second check valve having a greater strength than the spring in said fourth check valve, and said spring in said fourth valve having a greater strength than the springs in said first and third check valves.

2. The method set forth in claim 1 in which each plug member has a generally cylindrical portion against which its said coil spring acts and a tapered end portion for preventing said fluid flow.

3. The method set forth in claim 2 in which each check valve has a generally circular seat against which a tapered end portion bears to prevent said fluid flow.

4. A method of implanting an incontinence system in the body of an animal in order to thereafter control the opening and closing of a biologically provided urethra comprising the steps of applying a cuff unit having an inwardly deformable wall and a relatively rigid outer wall in a circumscribing relationship with the urethra, implanting pump means including a pair of elastomeric bulbs within said body at locations innerjacent the skin so that fluid under pressure can thereafter be delivered into said cuff unit in order to cause said deformable wall to be flexed inwardly to reduce the cross section of said urethra, implanting in said animal body reservoir means for storing some of the fluid to be delivered to and withdrawn from said cuff unit by said pump means, and also implanting valve means for controlling the direction of fluid flow when said pump means is later actuated, said valve means including a first check valve for permitting fluid to flow only from said reser-

voir to one of said bulbs, a second check valve for permitting fluid to flow only from said one bulb to said cuff unit, a third check valve for permitting fluid to flow only from said cuff unit to the other of said bulbs, and a fourth check valve for permitting fluid to flow only from said other bulb to said reservoir means, said fourth check valve providing a greater resistance to flow than said third check valve, said second check valve providing a greater resistance to flow than said fourth check valve, and said first and third check valves providing a lesser resistance to fluid flow to both said second and fourth check valves.

5. An incontinence system for implanting within an animal body comprising an inflatable cuff unit for circumscribing the vessel to be opened and closed, a reservoir for storing at least some of the fluid to be supplied to said cuff unit, a pair of elastomeric bulbs, a first check valve connected between said reservoir and one of said pump bulbs for permitting fluid flow only from said reservoir to said one pump bulb, a second check valve between said one pump bulb and said cuff unit for permitting fluid flow only between said one pump bulb and said cuff unit, a third check valve for permitting fluid flow only between said cuff unit and the other of said pump bulbs, a fourth check valve for permitting fluid flow only from said other pump bulb to said reservoir, a coil spring contained in each of said check valves, said fourth check valve containing a coil spring having a greater spring constant than the coil springs contained in said first and third check valves, and the coil spring in said second check valve having a greater spring constant than the coil spring contained in said fourth check valve.

6. An incontinence system for implanting within an animal body comprising a cuff unit for circumscribingly engaging the vessel to be opened and closed, said cuff unit having an inwardly deformable wall and a relatively rigid outer wall to form a chamber therebetween, a reservoir for storing at least some of the fluid to be supplied to the chamber of said cuff unit, a pair of elastomeric bulbs, a first check valve including therein a plug member having a tapered end portion, a first flexible tube connected to said reservoir and to said check valve, said first check valve including a coil spring having one spring constant for biasing said plug member in a direction to cause its tapered end portion to seat against the end of said first flexible tube which is connected to said first check valve to prevent fluid flow from said first check valve to said first flexible tube, a second flexible tube connected to said first check valve and to one of said elastomeric bulbs, a second check valve including therein a plug member having a tapered end portion, a third flexible tube connected to said one elastomeric bulb and to said second check valve, said second check valve including a coil spring having a spring constant which is greater than that of the spring included in said first check valve, said last-mentioned spring biasing the plug member of said second check valve in a direction to cause its tapered end portion to seat against the end of said third flexible tube which is connected to said second check valve to prevent fluid flow from said second check valve to said third flexible tube, a fourth flexible tube connected to said second check valve and to said cuff unit, a third check valve including therein a plug member having a tapered end portion, a fifth flexible tube connected to said cuff unit and to said third check valve, said third check valve in-

cluding a coil spring having a spring constant corresponding to that of the spring included in said first check valve, said last-mentioned spring biasing the plug member of said third check valve in a direction to cause its tapered end portion to seat against the end of said fifth flexible tube which is connected to said third check valve to prevent fluid flow from said third check valve to the said cuff unit, a sixth flexible tube connected to said third check valve and to the other of said pair of elastomeric bulbs, a fourth check valve including therein a plug member having a tapered end portion, a seventh flexible tube connected to said other elastomeric bulb and to said fourth check valve, said fourth check valve including a coil spring having a spring constant greater than the spring included in said first and third check valves but less than that of the spring included in said second check valve, said last-mentioned spring biasing the plug member of said fourth check valve in a direction to cause its tapered end portion to seat against the end of said seventh flexible tube which is connected to said fourth check valve to prevent fluid flow from said fourth check valve to said seventh tube, and an eighth flexible tube connected to said fourth check valve and to said reservoir, whereby manipulation or squeezing of said one elastomeric bulb will cause the tapered end portion of the plug member included in said first check valve to seat more tightly against said first flexible tube and to cause fluid to be forced from said one elastomeric bulb through said third flexible tube to overcome the biasing action of the coil spring included in the second check valve, thereby causing the tapered end portion of the plug member included in said second check valve to unseat to permit fluid to flow through said second check valve into the chamber of said cuff unit, the unsqueezing of said one elastomeric bulb causing fluid to be drawn from said reservoir through said first and second tubes, the coil spring included in said first check valve at this time yielding to permit the unseating of the tapered end portion of the plug member included in said first check valve, the tapered end portion of the plug member included in said second check valve at this time seating against the third tube to prevent fluid flow from said cuff unit back through said second check valve into the said one elastomeric bulb, the coil spring included in said fourth check valve during the squeezing of said one bulb determining the amount of pressure that can be built up in the chamber of said cuff unit, and whereby squeezing of the other of said elastomeric bulbs overcomes the biasing action of the coil spring included in said fourth check valve to cause the tapered end portion of the plug member included in said fourth check valve to unseat from said seventh flexible tube, the tapered end portion of the plug member included in said third check valve during this period seating against said fifth flexible tube to prevent fluid flow from the said other elastomeric bulb back through said sixth and fifth tubes, the unsqueezing of said other elastomeric bulb causing the tapered end portion of the plug member included in said third check valve to unseat and permit fluid to flow from said cuff unit into said other elastomeric bulb and the coil spring included in said fourth check valve biasing the plug member included in said fourth check valve in a direction to cause its tapered end portion to seat against said seventh tube, the repetitive squeezing and unsqueezing of said one elastomeric bulb thus causing said cuff unit to in-

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flate with said inner wall portion being deformed against the vessel in a constricting manner to thereby close said vessel and the repetitive squeezing and un-squeezing of said other elastomeric bulb permitting said inner wall portion causing said cuff unit to deflate with said inner wall then releasing its constrictive action against said vessel and thereby open said vessel, the spring included in said second check valve which has the greatest spring constant of the four springs, bi-

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asing the plug member included in said second check valve in a direction to cause its tapered end portion to seat against said third flexible tube and thus prevent fluid from flowing from said third tube through said second check valve into said fourth tube and thus prevent fluid from flowing into the chamber of said cuff unit when said cuff unit is deflated.

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