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F. E. B. FOLEY
ARTIFICIAL SPHINCTER
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2,533,924

FIG 1

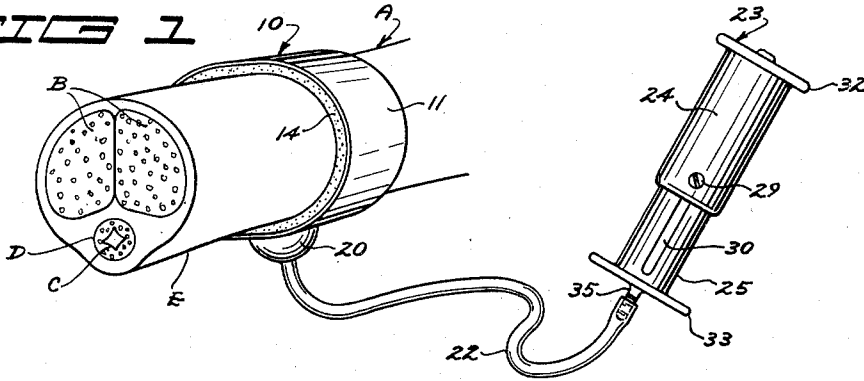


FIG 2

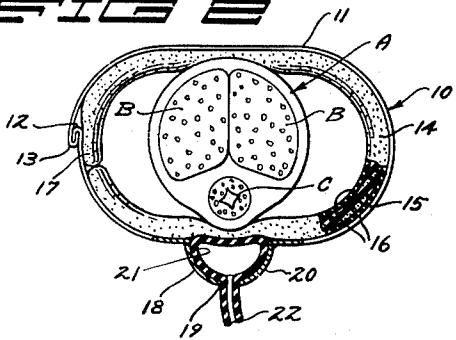


FIG 3

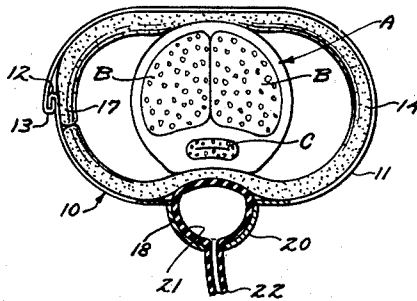


FIG 4

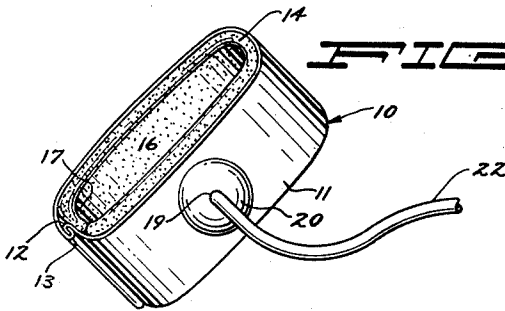
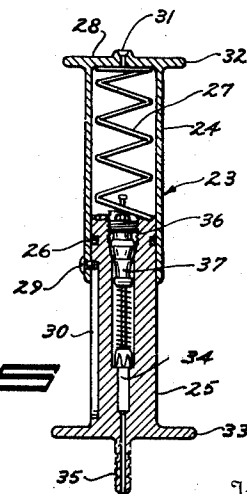


FIG 5



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ARTIFICIAL SPHINCTER

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5 Claims. (Cl. 128—346)

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This invention relates to improvements in artificial sphincters for controlling the involuntary escape of urine in the male and the primary object is to provide means for this purpose which is simple, practical and sanitary and which admirably meets the problems of persons suffering from this affliction.

The term involuntary escape of the urine is here used generically to describe both the permanent or temporary urinary incontinence resulting from anatomic or neurologic incompetence of the sphincter muscles and the nocturnal enuresis of childhood. Previous means for caring for these problems have been devised among which are my own method and apparatus disclosed in co-pending application Serial No. 669,218, filed May 13, 1946, now Patent No. 2,454,859, issued December 7, 1948. The present invention provides an apparatus such that it may be easily applied to and removed from the organ and used to mechanically compress and close the contained urethra under remote control, thus making it particularly useful where the condition is a temporary one, or does not justify more technical or complicated procedures, or possibly surgery, for its care.

As an example of such devices, applicable without surgery, the most widely known heretofore is probably the so-called Cunningham incontinence clamp which comprises hinged jaws which are placed across the penis and operate to compress all of the structures therein, including its erectile bodies as well as the contained urethra. This device is, however, objectionable as to size, difficulty of operation and the discomfort which it causes the wearer. It is particularly undesirable due to its tendency to cause partial erection distal to the site of application.

In accordance with my invention I provide a sphincter, which may also be applied to the intact penis, with an inflatable, or rather distensible, element located in intimate contact with the ventral area immediately about the contained urethra, and tubularly connected to an inflating means which may be carried in a trouser's pocket or other convenient location. Said distensible element may then be normally expanded or distended as necessary by fluid pressure, to compress the urethra and completely close its lumen to positively prevent the escape of the urine. In this connection and in furtherance of the objects of my invention the location of the distensible element on the ventral area, proximate to the urethra itself, results in exertion of the maximum pressure per unit of area at and about this desired point and minimum pressure on the cir-

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cumferential quadrants of the organ and particularly about the cavernous bodies thereof. Thus the tendency towards partial erection, distal to the location of the artificial sphincter, is to a large extent eliminated. Of course, the pressure of the fluid may be released whenever required and in practice it is found that the patient may exercise control over his urine equally well, if not better, than the person not afflicted, and with the very minimum of discomfort in the wearing of the device.

These and other more detailed and specific objects will be disclosed in the course of the following specification reference being had to the accompanying drawings, in which—

Fig. 1 is a perspective view of my improved artificial sphincter as applied to the penile organ, including the remotely operable inflating means and tubular connecting means.

Figs. 2 and 3 are elevations of the sphincter element in its applied position, showing it respectively in inoperative and operative, or urethra closing, conditions.

Fig. 4 is a perspective view of the sphincter alone.

Fig. 5 is an enlarged detail cross sectional view of the inflation pump and control element alone.

Referring now more particularly and by reference characters to the drawing A designates generally a section of the penile organ, wherein are the corpora cavernosa B and the urethra C contained within the corpus spongiosum D, the whole being within the outer surrounding skin E.

The artificial sphincter of my present invention is designated generally at 10 and comprises a parted ring or clamp 11 of spring material having oppositely turned lips or flanges 12 and 13 at its ends adapted to hook together and hold the clamp closed as clearly shown in Figs. 2 and 3. When unhooked the clamp will spring apart to facilitate its removal as will be readily understood. The clamp has a lining designated at 14 on its inner side and while this lining is yieldable to provide maximum comfort to the wearer it is not, however, inflatable. In its preferred form the lining is made of a strip of soft sponge rubber 15 which is enclosed in a thin cover 16 of latex or the like, the purpose being to protect the spongy center portion, necessary for softness, with a smoother outer surface which may be readily kept in a sanitary condition. The lining thus formed is cemented to the inside of the clamp to hold them together and it will be noted that the lining terminates short of one of the clamp ends and projects loosely past the

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other as indicated at 17 to completely cover the inside of the clamp while allowing the lips 12 and 13 to be manipulated in applying or removing the device.

While I herein use the term "clamp" in describing my device, for convenience in description, it is to be understood that it does not act as a clamp in the sense that it compresses the organ with sufficient pressure to close the contained urethra C as does the Cunningham clamp previously mentioned. Instead my clamp is made of such size and is so shaped and arranged as merely to hold itself in position on the particular organ to which it is applied.

On the lower part of the clamp, or the part which in use will be applied across the ventral quadrant of the organ there is formed a downwardly or outwardly rounded distension bag seat or socket 18 having a centrally located distension tube opening 19, this seat being here shown as formed by means of a hemispherical shell 20 soldered or otherwise secured about an opening in the clamp. See Figs. 2 and 3. The aforesaid lining 14 traverses this opening into the seat and protects against contact with the edge thereof.

For use with this clamp I provide a distension bag 21 formed of latex at the end of a flexible distension tube 22 of the same material and the bag is in its uninflated condition also substantially hemispherical in shape to thus fit nicely into its seat 18 with the tube 22 extending out through the opening 19. The distension bag is thus outside or below the lining 14 as clearly shown in the drawing. The distension tube 22 leads to a control unit designated generally at 23 which is attached to the other end of the tube and due to the flexibility and length of the tube this unit may be carried in a trouser's pocket (not shown) or other location prepared for it and where it may be operated by one hand as will presently appear.

The control unit 23 includes a pump for supplying a fluid (air in this case) under pressure to the distension bag and valve means for holding the air in the bag or exhausting it therefrom as the case may be. Referring particularly to Fig. 5 it will be seen that this unit comprises a barrel or cylinder 24 telescopically fitted over a plunger 25 around which is placed a small conventional "O-ring" 26 to make an air tight circumferential seal between these parts. An expansion coil spring 27 is placed inside the cylinder 24 and braced between its closed end 28 and the end of the plunger 25 thus to normally urge them apart to the position shown. A stop screw 29 is threaded inwardly through the cylinder wall and plays in a longitudinal groove 30 in the plunger to limit the relative motion between the parts. Air may enter the chamber inside the cylinder 24 through an opening 31 in its end 28 and it will be noted that this end of the cylinder is diametrically enlarged or flanged as indicated at 32, as is also the opposite end of the plunger as designated at 33.

The plunger 25 has an axially extending passageway 34 from end to end and a projecting needle portion 35 on the exposed end permits the convenient application of the distension tube 22 thereto in communication with said passageway. The opposite end portion of the passageway is enlarged and is threaded at 36 to receive a conventional pneumatic tire inflation valve 37 which operates to open upon the building up of sufficient pressure within the cylinder 24.

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In the use and operation of the device, with the sphincter clamp or ring in place the wearer operates the control unit 23 by hooking two fingers over the plunger flange 33 and placing the thumb over the flanged cylinder end 32 covering the opening 31. Then by squeezing the fingers and thumb together the cylinder 24 and plunger 25 will be telescoped and the air trapped in the chamber of the cylinder will be compressed until it reaches a point at which it will open or unseat the valve 37. The air will then pass through the distension tube 22 into the distension bag 21 which will be expanded to the bulbous shape shown in Fig. 3. When pressure on the control unit is relieved by the hand operating it the air will be held in the distension tube and bag by the valve 37 without further effort. As clearly shown this distension of the bag 21 forces the lining 14 immediately thereadjacent against the ventral part of the penile organ to squeeze the urethra closed, and completely obliterates its lumen to positively prevent the unwanted escape of the urine. When urination is necessary the user again grasps the control unit and telescopes it, but this time with his thumb not covering the air opening 31, it being the purpose of the flange 32 to provide purchase space for the thumb in this operation. The end of the cylinder will now strike and mechanically open the valve 37 so that the air may escape in a rush from the distension bag allowing it to collapse and the urethra to open and start the flow. When urination is completed the bag is again distended as described above.

It is an important feature of my invention that the urethra is compressed by the distension bag 21 only and this bag being small and located intimate to the ventral surface of the organ below the urethra delivers the maximum pressure per unit of area at this point with a minimum pressure upon the other circumferential areas of the organ. See Fig. 3 particularly. The liner engaging or pressure wall of the bag has a transverse dimension of about 10% of the circumference of the clamp shown and, no matter how small a clamp is used, in any case the transverse dimension of the wall should be less than 25% of the circumferential dimension of the clamp. The pressure on the erectile bodies of the organ is thus minimized and the tendency towards partial erection, distal to the location of the device is largely if not completely eliminated. In this connection it will be noted that the sphincter is not circular but is elongated laterally and engages only the dorsal and ventral areas of the organ. Lateral pressure on the cavernous bodies B is thus eliminated. Actually since the distension bag 21 is enclosed by its seat except for its normally flat end it is the distension of this end which develops the pressure against the ventral area of the organ, thus limiting the pressure area to that strictly necessary for my purpose. All of these factors contribute to the comfort of the patient and to the elimination of the tendency toward erection as will be readily appreciated.

It is understood that suitable modifications may be made in the structure as disclosed, provided such modifications come within the spirit and scope of the appended claims. Having now therefore fully illustrated and described my invention, what I claim to be new and desire to protect by Letters Patent is:

1. Apparatus for controlling involuntary escape of urine, comprising a clamp for the penile organ and having a soft and comfortable yield-

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able lining, and a fluid actuated distension bag separate from the said lining but operative between the lining and the clamp to urge only a circumferentially small portion of the former into pressure engagement with the organ.

2. Apparatus for controlling involuntary escape of urine, comprising in combination, a clamp for application to the male organ, a yieldable lining for the inside of the clamp, the said clamp having a seat, a bulbous fluid actuated distension bag positioned in said seat, and means for inflating the bag to distend it and force the immediate area of the said lining against the ventral quadrant of the organ.

2. Apparatus for controlling involuntary escape of urine, comprising in combination, a clamp for application to the male organ, a yieldable lining for the inside of the clamp, the said clamp having a seat forming means and an opening therein, a distension bag seated in the seat forming means and a distension tube leading from the bag out through the said opening, and means attached to the tube for distending the bag.

4. An apparatus for controlling involuntary escape of urine comprising a clamp for the male organ, said clamp having a seat adjacent the ventral portion of the organ, a bulbous distensible element positioned in the seat, and a disten-

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sion means on the apparatus for distending the element towards said ventral portion.

5. A device for controlling the involuntary escape of urine from the male organ which comprises a member adapted to encircle the organ and engage the ventral portion thereof, a distensible element on said member adjacent the point of ventral engagement, said element having a pressure wall adapted to be moved radially inward toward the ventral portion of the organ as the element is distended, said wall being less in transverse dimension than 25% of the circumferential dimension of the member whereby the upper side portions of the organ will not be compressed by said distension, and means on the device for distending the element.

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20 The following references are of record in the file of this patent:

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