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[54] **MULTI-FUNCTIONAL VALVE FOR USE IN THE URETHRA**

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[51] Int. Cl. **A61b 19/00, A61m 25/00**

[58] Field of Search **128/349 R, 349 B, 349 BV, 128/1 R, DIG. 25, 285, 129, 344, 325; 251/5**

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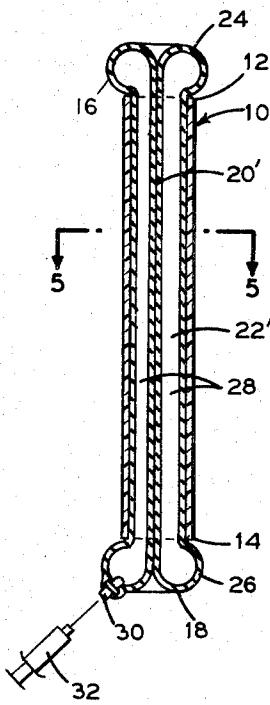
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Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—Edward F. Costigan

[57] **ABSTRACT**

A valve adapted to be positioned in the channel of the urethra for the maintenance of such channel at a predetermined size in a substantially sterilized condition relative to bacteria, such valve controlling the flow of urine from the bladder through the channel of the urethra to the atmosphere.

6 Claims, 6 Drawing Figures



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FIG.1

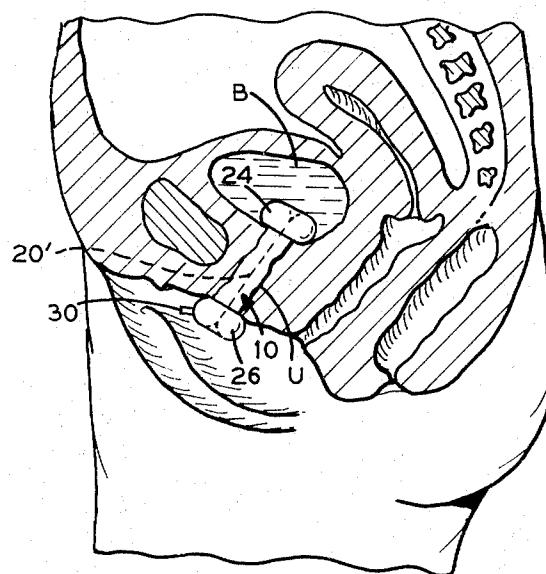


FIG.2

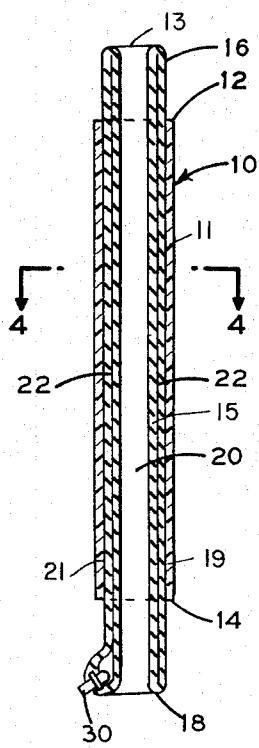


FIG.3

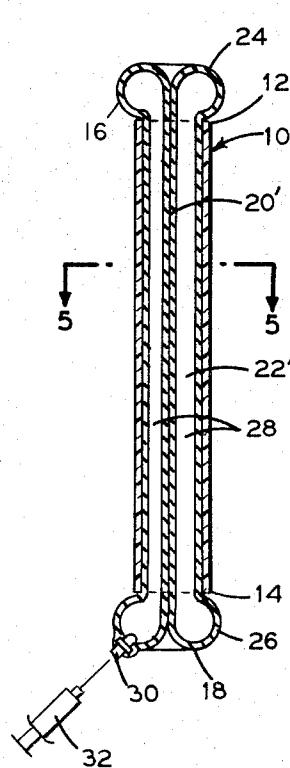


FIG.4

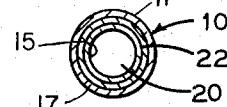


FIG.5

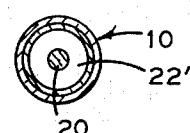
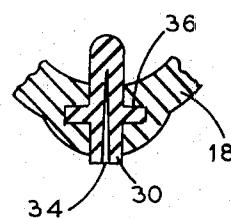


FIG.6



MULTI-FUNCTIONAL VALVE FOR USE IN THE URETHRA

This invention relates to the flow of urine from the bladder of a female patient through the channel of the urethra to the atmosphere.

More particularly, this invention relates to a valve for use in the control of the aforesaid flow of urine.

In the past, it has been found that in some patients, the channel of the urethra is subject to diminishment in size through natural traumatic or disease processes. As a result, this process leads to a condition which not only restricts the flow of urine through the channel but may lead to discomfort and even a dangerous condition relative to infection if the bladder is not properly voided. In other conditions, the patient may have no voluntary control over the process of voiding urine. Urinary leakage through the urethra in such cases may be constant or intermittent.

In situations such as that described above, the Practitioner usually dilates the channel of the urethra through the use of successive insertions of sounds of a progressively increasing circumference. When the desired circumference is attained through such dilation, the channel will maintain this size for a time until the process of dilation must be repeated again to bring the channel to the desired size. If, perchance, the channel was blocked for any appreciable period of time, a pool of stagnant urine would form in the bladder and might produce an infection in situ which could be transmitted to the channel of the urethra.

What is needed in the art is a device which would maintain the channel of the urethra at the circumference desired for a relatively extended period of time without any attendant susceptibility to infection while naturally controlling the flow of urine from the bladder to the atmosphere through such channel, and preventing uncontrolled urinary leakage.

The subject invention answers the needs of the art with special emphasis on a device which may be positively placed and securely held in position in the channel of the urethra but which may be easily removed when so desired.

It is therefore an object of this invention to provide a device of improved construction which functions as a valve when placed in a fixed position in the channel of the urethra.

Another object of this invention is to provide the aforesaid device with the ability to substantially maintain the channel of the urethra at a predetermined size.

An still another object is to provide the aforesaid device with the propensity to maintain the channel in a relatively clear state relative to bacteria when in place in the channel.

A still further object is to provide such device with the ability to control the flow of urine from the bladder to the atmosphere through the channel by functioning as a naturally controlled valve.

Other objects and many of the attendant advantages of this invention will become more apparent to those skilled in the art upon reading the following detailed specification accompanied by the drawings, wherein:

FIG. 1 is a sectional side elevation of the female torso.

FIG. 2 is a sectional side elevation of the device of this invention.

FIG. 3 is a sectional side elevation of the device of FIG. 1 in the inflated condition.

FIG. 4 is a plan view taken along line 4—4 of FIG. 2.

FIG. 5 is a plan view taken along line 5—5 of FIG. 3.

FIG. 6 is a side view of the inflation means provided on the device of FIGS. 2 and 3.

Similar numerals refer to similar parts throughout the several views.

For a better understanding, refer to FIG. 1 where a cross-sectional view is shown of the device 10 in place in the body of a patient. As may be seen from this view, the device 10 is held in a substantially stationary position in the channel of the urethra u by inflated collars 24 and 26 at each extremity of the device. However, a rupture of the inflated collar 26 at the extremity of the device 10 which is adjacent the outer surface of the body will completely void both collars 24 and 26 and the device 10 may then be easily removed from the channel of the urethra u.

As shown in FIG. 2, the device 10 is in condition for insertion into the urethra u of the female patient by the specialist. The aforesaid device 10 is provided with a hollow plastic cylinder 11 of the flexible variety having an upper end 12 and a lower end 14 both of which are in open-end construction. A longitudinal tube 13 of the elastical variety such as rubber is fitted into the cylinder 11 with extremal end portions 16 and 18 extending beyond the ends 12 and 14 of the cylinder 11.

The longitudinal tube 13 consists of two abutting walls 15 and 17 of closed end construction forming an inflatable annular ring which circumscribes area 20 when the device is in the deflated state. This may be clearly seen in FIG. 4. Referring again to FIG. 2, the lower end 18 of the tube 13 is fitted with a valve 30 of the needle type punctural variety for use in the inflation of the area 22 formed by the abutment of walls 15 and 17 of the tube 13. The longitudinal tube 13 may be inserted in the cylinder 11 and the inner surface 19 of the cylinder 11 may be secured or affixed to the outer surface 21 of the tube 13 by conventional procedures.

As may now be seen from FIGS. 1 and 3, the device 10 is in the inflated state. This may be accomplished by injecting a fluid through valve 20 by means of a syringe 32. The fluid may be sterilized distilled water. Note should be taken that the extremal ends 16 and 18 of the tube 13 by its unique construction within cylinder 11 form two hollow inflatable collars 24 and 26 which maintain the device in position in the urethra u. It may also be seen from a comparison of FIGS. 2 and 3 that the space 22 between the walls 15 and 17 is now in the form of a longitudinal annular chamber 22 within the cylinder 11. Further, as may be seen from FIGS. 1, 2 and 5, the former area 20 of relatively large size circumscribed by the wall 15 is diminished in size to that shown in FIGS. 3 and 5 by inflation of annular chamber 28.

Referring to FIG. 6, the body of the valve 30 is provided with a longitudinal channel 34 of closed-end construction within the inflated area of the collar 26. The valve 30 is provided with a flange 36 upon which a force is exerted by the adjacent lining 18 of such a magnitude that the channel 34 is forced closed even after the insertion and withdrawal of syringe 32. However, the valve 30 may be of the self-sealing needle type valve or pressure-type valve.

In operation, the device of FIG. 2 is inserted into the urethra ^u of the female as shown in FIG. 3. After insertion, a syringe 32 is inserted into channel 34 of the valve 30 until the tip penetrates the area adjacent thereto. The longitudinal tube 13 is then inflated to form an annular ring 28 within the cylinder 11 and the portions 16 and 18 of the tube 13 extending beyond the cylinder 11 are inflated into the form of an annular collar 24 and 26. The latter collars maintain the device 10 in position in the urethra ^u.

When it is desired to remove the device 10, the inflated collar 26, which communicates with the longitudinal area 28 and collar 24, is ruptured or serrated. As a result, the inner tube 13 collapses and the device may be easily removed from the body channel. However, in an improvement of the above the valve 30 may be of inflatable and deflatable variety which may be more economical to the Practitioner when fitting a device of the proper size to the patient.

The cylinder 11 is relatively flexible but when in the urethra, it is securely fixed in place. In the initial stage of the process of extruding this cylinder, bactericidal metallic solids or cations or other bacteriostatic or bactericidal substances tolerated by human tissues may be introduced in the melting pot. Cations such as Cu or Ag have been found to kill bacteria of even the most stubborn variety. As a result, the urethra may be maintained bacteria free when the device of the present invention is placed therein.

The volume of liquid necessary to inflate the device will be such that the pressure exerted by the fluid will approximate a force of approximately 90 cm to the linear passageway 20' of FIG. 3. When such force is exceeded the urinating process takes place. And, the patient after a relatively short period of time may find it easy to control the voiding of the bladder by natural processes.

The external circumference of the cylinder 11 of FIG. 2 may be manufactured in individual sizes from 10 mm to 36 mm, in this manner, the device is customized to the channel of the individual patient. Also, the device may be manufactured in individual lengths between 2 cm to 4 cm as a means of customization of the device to individual patients.

What is claimed is:

1. A valving device adapted for placement in the

channel of the urethra of a female for use in controlling the flow of urine from a bladder to the atmosphere by way of such channel,

consisting essentially of:

- a. a first flexible tube having solid sidewalls, an exterior surface and an interior surface of open-end construction,
- b. a second flexible tube having sidewalls provided with an exterior surface and an interior surface of open-end construction,
- 10 1. said sidewalls of said second tube being hollow between the latter surfaces,
2. said second tube inserted into said first tube and extending beyond both ends of said first tube,
- 15 3. said second tube secured in position in said first tube, and
- c. means provided on the portion of said second tube which extends beyond the end of said first tube for the inflation of the hollow area of such second tube,

Whereby, (1) said second tube when inflated substantially closes the area circumscribed by the interior surface of said second tube except for a relatively thin longitudinal passageway formed by the abutting surface of said interior surface of said second tube, and

Whereby, (2) said second tube when inflated forming a circular collar surrounding each end of said first tube, said collars adapted to maintain said first tube in position in said urethra.

- 20 2. The device of claim 1 wherein said first flexible tube is provided with sidewalls impregnated with bactericidal cations.
3. The device of claim 2 wherein said sidewalls are made from a flexible plastic such as polyvinyl ethylene.

- 30 4. The device of claim 3 wherein said second tube is made of inflatable material, such as plastic or rubber.

- 40 5. The device of claim 1 wherein the exterior circumference of said first tube in individual units lies uniformly between 10 mm and 36 mm in circumference.

- 45 6. The device of claim 1 wherein the uniform length of said first tube lies between 2 cm to 4 cms.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,797,478 Dated 19, May 1974

Inventor(s) Michael A. Walsh & Edward F. Costigan

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

In Claim 2, as set forth in Column 4, lines 32 to 33, the word "bactericdal" is deleted and the word-----bactericidal-----is substituted therefor.

Signed and sealed this 17th day of September 1974.

(SEAL)

Attest:

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Attesting Officer

C. MARSHALL DANN
Commissioner of Patents