United States Patent

Osthagen et al.

[15] **3,642,004**

[45] **Feb. 15, 1972**

[54] URETHRAL VALVE

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[73] Assignee: **Life Support Equipment Corp,** Burlington, Mass.

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[21] Appl. No.: **525**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 652,916, July 12, 1967.

[52] **U.S. Cl.** .....**128/349 R,** 128/DIG. 25, 128/349 B

[51] **Int. Cl.** **A61m 25/00**

[58] **Field of Search** .....128/239— 241, 348–350

[56] **References Cited**

UNITED STATES PATENTS

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[57] **ABSTRACT**

A valved drainage-control device adapted to be retained in the urinary canal, comprising a slim, elongate, flexible catheter tube at one end connected to both a valve housing and a collapsible enlargement or bulb which latter is adapted to be inflated and to occupy the bladder for retaining the catheter tube in place. At its inner end, the catheter tube is closed and contains an electromagnetic valve comprising a magnet coil and a magnetic core of permanent magnet material. A flexible corrugated diaphragm spans the interior of the flexible tube adjacent the magnetic valve, said diaphragm forming with the closed end of the tube a sealed chamber in which the magnet coil and magnetic core are located. Adjoining the diaphragm and exterior to the sealed chamber is an annular valve seat which is engageable by a valve facing carried by the diaphragm. The diaphragm is connected with the magnetic core to be actuated thereby, for opening and closing the valve. Openings in the sidewall of the flexible tube communicate with the valve, to provide for a controlled drainage of the bladder. Extending along the flexible tube is a channel which communicates with the inflatable bulb for the purpose of providing an inflating fluid therein. The connecting wires for the electromagnet extend in said fluid channel and are brought out at the other or exterior end of the flexible tube, for connection to a battery and switch whereby the valve may be actuated from the exterior of the user's body.

10 Claims, 4 Drawing Figures

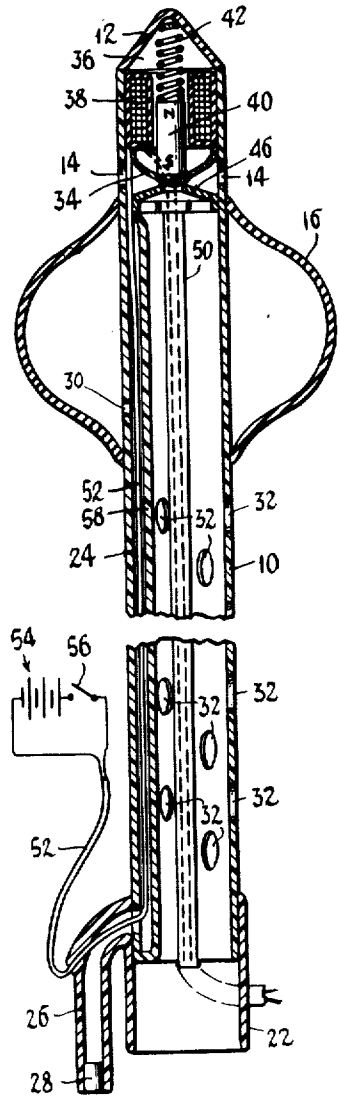


Fig. 3

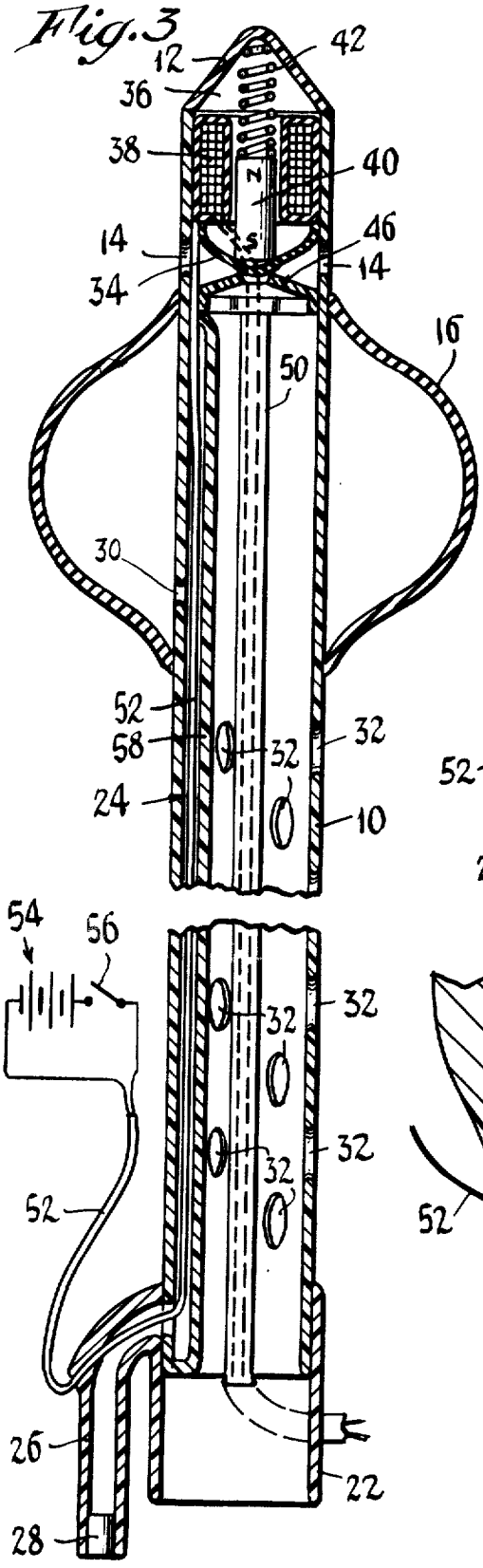


Fig. 1

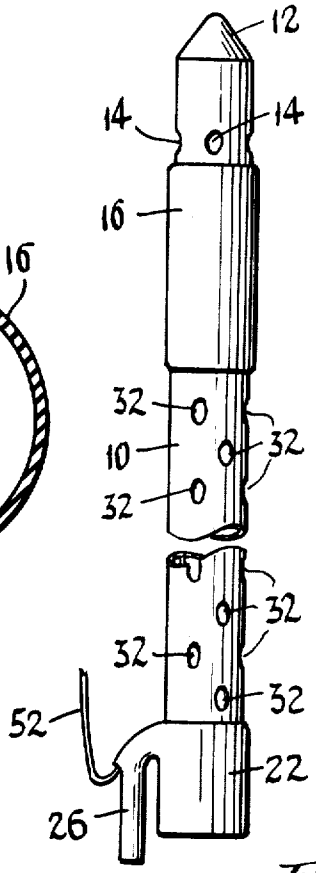


Fig. 4

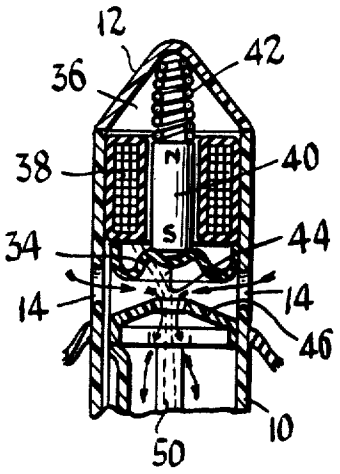
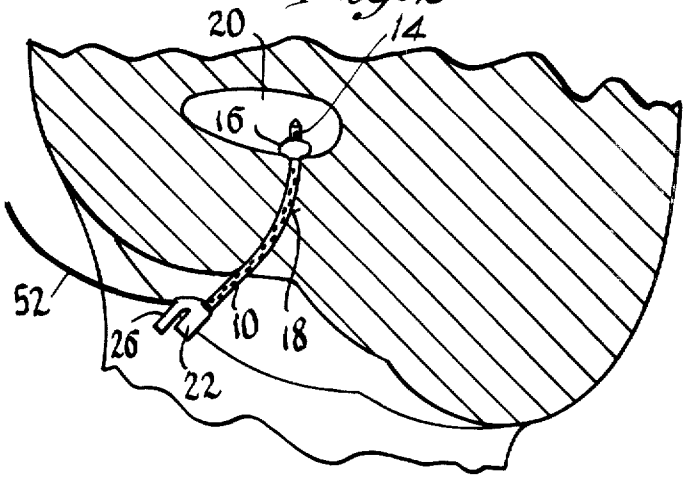


Fig. 2



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URETHRAL VALVE

The present application is a continuation-in-part of our above identified copending application, Ser. No. 652,916, filed July 12, 1967 and entitled, "Urethral Valve."

CROSS-REFERENCE TO RELATED COPENDING APPLICATIONS

1. Copending application of Sven M. Osthagen, et al., Ser. No. 652,916, filed July 12, 1967, entitled "Urethral Valve," and having common ownership with the present application, now U.S. Pat. No. 3,503,400, issued Mar. 31, 1970.

PRIOR ART REFERENCES

1. U.S. Pat. No. 396,754.
2. U.S. Pat. No. 1,878,671
3. U.S. Pat. No. 1,920,006
4. U.S. Pat. No. 2,024,982
5. U.S. Pat. No. 2,616,429.

BACKGROUND

This invention relates to drainage devices intended to be implanted in a living body, and more particularly to devices of this type which are valve controlled and intended to be retained in the bladder and urethral canal for the purpose of controlling drainage therefrom.

Heretofore, various kinds of drainage devices, commonly known as catheters, draining probes, dilators, surgical instruments, etc., have been proposed and/or produced to cope with problems involving obstruction, operative procedures, examination of tissue, removal of fluids and the like. These prior devices were as a rule restricted in their use to the specific purpose originally in mind, and none could be satisfactorily utilized, for instance, as a fairly long term implant in the urethra or urinary tract to permit drainage of urine at will from the bladder. Such a long term drainage control device, moreover, is greatly needed and would find widespread use and acceptance.

It is known that patients who have neurogenic bladders due to congenital spinal cord defects, spinal cord or brain injury, or other neurologic diseases present a major economic problem because of persistent incontinence.

Also, patients who have incontinence of urination caused either by muscle weakness or postoperative surgical damage to the urinary sphincter, are candidates for a satisfactory, long term drainage device which could provide controlled periodic emptying of the bladder. Many such patients are not suitable for surgical correction of incontinence.

In addition, patients who have lower urinary tract obstruction, whose physical condition does not permit operative relief of this obstruction, can greatly benefit by having their bladder drained periodically by use of a long term drainage control implant, until such time as operative intervention is permitted.

Efforts to meet and solve this longstanding problem have in general been directed toward the provision of an externally carried reservoir or bag, in which the urine collected, to be periodically removed at the user's convenience. This type of device was, at the very best, a poor solution to the problem, for many quite obvious reasons not considered necessary to enumerate in connection with the present invention.

SUMMARY

The above disadvantages and drawbacks of prior devices are obviated by the present invention, and one object of the invention is to provide a novel and improved self-operated, internally contained valved drainage control device which can be implanted in the urinary tract and readily retained therein for extended periods of time so as to effect urinary continence, thereby to successfully cope with the above-mentioned urinary problems arising from various causes. Another object is to provide a readily operated valved drainage implant suitable for extended periods of use, which can be utilized in various, different locations in the body for the indicated purpose, being not restricted to the urinary tract.

These objects are accomplished by the provision of a novel valve means adapted to be disposed in the body, actuator means for the valve which includes at least one flexible wire, which either extends through or along the inside of an elongate novel pervious means comprising a slim flexible catheter tube having multiple perforations in its walls to permit a flushing of the walls of the body passage, particularly when the valve is actuated to the open position. The control cable or wire extends through the perforated tube to the external orifice, and the perforations of the tube enable an exchange and passage of liquids to occur, facilitating drainage and the natural functioning of the surrounding tissues whereby the likelihood of irritation, infection and incompatibility is greatly minimized, to the extent that the implant can be well tolerated without giving rise to undesired side effects.

The novel valve means comprises an electromagnet and a permanent magnet core disposed in a sealed chamber at the inner end of the catheter tube. One wall of the chamber comprises a corrugated diaphragm which spans the interior of the tube and which constitutes the valve element that is actuated by the magnetic core. Adjoining the diaphragm is an annular valve seat which is engaged by a valve facing of the diaphragm, for the purpose of controlling fluid flow.

Other objects of the invention are to provide an improved long term drainage implant as above set forth, which is especially simple in construction, economical to fabricate and produce, small and compact, readily adaptable to both male and female patients, safe to use, and effective and reliable in operation.

Yet other features and advantages will hereinafter appear.

In the drawings:

FIG. 1 is a side elevational view of a valved drainage control device as provided by the invention.

FIG. 2 is a fragmentary sagittal median section through a female pelvis showing the present improved valved drainage control device in its implanted operative position extending through the urethra.

FIG. 3 is an axial sectional view, enlarged, of the valve drainage control device of the invention, shown with the valve in its closed condition.

FIG. 4 is a fragmentary axial sectional view of the valve portion of the drainage control device, with the valve in the open position.

Referring first to FIG. 1, the drainage control device of the invention as shown therein comprises a slim, flexible catheter tube **10** of inert plastic material, said tube having a closed and pointed forward or inner end portion **12** provided at a distance from its tip with a plurality of inlet openings **14**. Adjacent the inlet openings **14** is a collapsible and inflatable enlargement or bulb **16** adapted to be expanded or inflated to a position such as is shown in FIG. 3.

The catheter device of FIG. 1 is intended to be inserted into and retained in the urethral canal **18** of a living person, as illustrated in FIG. 2, with the inflated retainer bulb **16** occupying the bladder **20**, the other end of the catheter being located at the exterior of the body and having a discharge orifice fitting **22**. It will be understood that during the insertion of the catheter the bulb **16** is in the deflated condition as shown in FIG. 1, and that after insertion the bulb is inflated by a suitable fluid such as water, in the manner of the well-known Foley catheter.

Referring to FIG. 3, for the purposes of inflation of the bulb, the tube **10** is provided with an internal channel **24** which communicates with an inflation fitting **26** provided with a plug or check valve **28** at its end. The wall of the catheter tube **10** has an opening **30** through which fluid introduced into the inflation fitting **10** can enter the bulb **16** and expand it to the position shown in FIGS. 2 and 3 for purposes of retaining the device in the desired position.

In accordance with the present invention, the catheter tube **10** is provided with multiple perforations or apertures **32** to facilitate a flushing of the walls of the body passage or urethra when drainage of the bladder **20** is occurring through the tube **10**. The provision of such perforations tends to reduce the

likelihood of irritation of the walls of the urethral canal, since there is minimized the possibility of accumulation of any discharge with accompanying discomfort and possible infection. Instead, the walls of the urethral canal have communication with the interior of the catheter tube **10** at a large number of locations, enabling a drainage to occur which tends to improve the condition of the urethral wall.

Also in accordance with the invention, a novel and improved valve arrangement is provided at the innermost end of the catheter tube **10**. Considering FIGS. **3** and **4** there is shown flexible circular diaphragm **34** which spans the interior of the tube **10** adjacent the inner, closed end portion **12** thereof, said diaphragm forming with said closed end portion a sealed chamber **36**. Located in the chamber **36** is a DC electromagnet coil **38** and also a magnetic core **40** constituted of permanent magnet material. The core **40** is biased away from the end wall of the tube **10** by a helical compression spring **42**, and is able to move vertically in the coil **38** as viewed in FIGS. **3** and **4**. The magnet core **40** is secured to the inner face of the central portion of the diaphragm **34**, as by a suitable adhesive. The outer face **44** of the central portion of the diaphragm **34** constitutes the valve element, being cooperable with an annular valve seat **46** which is disposed in the tube **10** to span the interior thereof adjacent the diaphragm **34**. Above the valve seat **46** are the inlet openings **14** of the tube.

Considering FIG. **3**, when the electromagnet coil **38** is not energized, the biasing spring **42** will maintain the magnet core **40** and valve facing **44** of the diaphragm in a lowered position wherein the opening of the valve seat **46** is closed, preventing drainage of liquid from the bladder **20**. When the electromagnet coil **38** is energized with proper polarity, it will pull upward the core **40** and the diaphragm **34**, uncovering the central opening of the valve seat **46** whereby drainage from the bladder **20** can occur through the openings **14**, valve seat **46**, and then through the catheter tube **10**.

Energization of the coil **38** can be effected by means of lead wires **48** carried in a flat tape **50** which is adhered to the interior of the catheter tube **10**.

In place of the wire-containing tape **44**, the lead wires from the coil **38** may be brought through the inflation channel for the bulb **16**. Thus, as seen in FIGS. **3** and **4**, a second set of lead wires **52** is shown as extending through the channel **24**, such wires being brought out at the inflation fitting **26** and being connected with a battery **54** and with a manually operable on-off switch **56**. For such arrangement, the channel **24** will extend closely adjacent the annular valve seat **46**. The channel **24** is formed by an interior beadlike wall portion **58** which is either molded in the tube **10** or attached to the tube after the latter has been initially formed. The entrance and exit arrangements of the lead wires **52** are done in such a manner that a fluidtight seal is had, thereby to not impair the inflation of the bulb **16**, as will now be understood. By having the lead wires **52** brought through the inflation channel **24**, the flat tape **50** with the wires **48** may be dispensed with; or such tape may be retained and constitute an alternative conductor for effecting energization of the coil **38** if the conductor **52** should fail or break for some unforseen reason.

The sealed valve arrangement which is shown in FIG. **4** has considerable advantage, since the locating of the movable core **40** in the sealed chamber **36** prevents contamination of the core and the spring **42**, and the formation of deposits or caked material which might impair the functioning of the valve.

The diaphragm **34** is formed of an inert, flexible rubberlike material such as silicone rubber, neoprene rubber or the like. The valve seat **46** can be formed of a tough resilient plastic such as polytetrafluorethylene, known commercially as "-Teflon." The bulb **16** and catheter tube **10** are formed of inert resilient plastic or rubberlike material. The sealed tip portion **12** of the catheter tube **10** may be constituted as a separate part to facilitate insertion of the electromagnetic valve in the inner end of the tube. After placement of the valve mechanism, the tip portion **12** may be sealed to the tube **10** by a suitable heat-sealing or cementing procedure. The flexible nature of the diaphragm **34** tends to prevent caking and deposits from forming on it, to impair the functioning thereof. Also, the slippery surface characteristics of the Teflon valve seat **46** will similarly prevent the adhering of deposits whereby the valve mechanism is not likely to malfunction during an extended period of use.

Referring to FIGS. **3** and **4** it will be noted that the openings **14** and the drainage openings **32** in the tube **10** are provided with well-rounded edges, thereby to prevent any possibility of irritation to the walls of the urethral canal at the time that the drainage device is being inserted, retained or removed, and this is an important feature of the invention.

It will now be understood from the foregoing that I have provided a novel and improved drainage catheter which may remain for extended periods of time in the urethral canal for the purpose of controlling and preventing incontinence, said device being so constituted as to provide for improved drainage from and around the walls of the urethral canal to minimize the likelihood of irritation thereof. Further, the drainage device has a novel sealed electromagnetic valve mechanism by which remote control is had in a reliable and convenient manner, such valve mechanism being especially constituted by location in a sealed chamber and utilizing a flexible diaphragm valving element, to minimize the likelihood of malfunctioning or jamming of the valve.

Variations and modifications are possible without departing from the spirit of the invention.

We claim:

1. A valved drainage-control device adapted to be implanted in a cavity and passage of a living body for the purpose of shutting off or allowing the flow of liquid from the cavity through said passage, comprising in combination:

a. valve means adapted to be disposed in said body cavity for controlling liquid flow therefrom through said passage, said valve means including a valve housing having a valve seat and a movable valve cooperable with said seat,

b. actuator means for said valve, including at least one slender, flexible wire adapted to extend through said body passage to the exterior of the body,

c. means providing a collapsible enlargement, attached to said valve housing for retaining the housing in said body cavity during normal movements of the body,

d. a slim elongate flexible tube at one end connected to said valve housing and collapsible enlargement means and adapted for disposition in said body passage to provide for the flow of liquid therethrough, said flexible wire extending through the flexible tube to the exterior of the body and having a fluidtight seal with said tube to prevent loss of pressure from the tube,

e. the other end of said tube being disposed outside of the body and constituting a discharge orifice.

2. A valved drainage-control device as in claim **1**, wherein:

a. the flexible tube has multiple perforations in its walls, to permit a flushing of the walls of the body passage when the valve is actuated to the open position.

3. A valved drainage-control device as in claim **2**, wherein:

a. the flexible tube comprises an inert plastic,

b. said wall perforations having rounded edges.

4. A valved drainage-control device as in claim **1**, wherein:

a. the actuator means comprises an electromagnet connected to the valve, and a circuit therefor comprising the said slender, flexible wire.

5. A valved drainage-control device as in claim **4** and further including:

a. means providing a channel extending longitudinally along said flexible tube,

b. said tube and channel-providing means being constituted of inert plastic,

c. said retainer means comprising an inflatable bulb surrounding said flexible tube and communicating with said channel to receive an inflating fluid therefrom,

d. said slender wire extending through said channel.

6. A valved drainage-control device as in claim 4, wherein:
a. the valve comprises a permanent magnet,
b. said electromagnet being adapted for battery energization.

7. A valved drainage-control device as in claim 4, wherein:
a. the movable valve comprises a magnetic core, and
b. one end of the flexible tube being closed and containing said valve means and electromagnet,
c. said movable valve comprising a flexible and resilient deflectable diaphragm spanning the interior of the flexible tube at the location of the valve means, and forming a sealed chamber at the closed end of the tube,
d. said magnetic core and electromagnet being disposed in said sealed chamber.

8. A valved drainage-control device as in claim 7, wherein:
a. said movable valve further comprises a facing carried by said diaphragm,
b. said diaphragm and facing being attached to said magnetic core.

9. A valved drainage-control device as in claim 4, and further including:
a. a flat tape extending along the inside wall of the flexible tube,
b. said slender wire being disposed in said flat tape.

10. A valved drainage-control device as in claim 8, wherein:
a. said valve seat comprises polytetrafluorethylene plastic,
b. said diaphragm comprising a rubberlike plastic material.

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