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Isaacson

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[54] **URETHRA MAGNETIC VALVE STRUCTURE**

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[52] **U.S. Cl.**..... **128/1 R,** 128/DIG. 25, 128/349 R, 251/65

[51] **Int. Cl.**..... **A61b 19/00**

[58] **Field of Search**..... 128/1 R, 273, 274, 349 R, 128/349 B, 350 R, DIG. 25; 251/65

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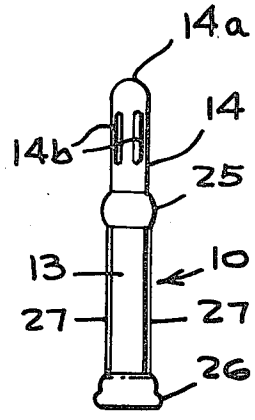
[57] **ABSTRACT**

A urethra magnetic valve structure comprising an implantable tubular valve housing to be located in the urethra at its juncture with the bladder. The valve housing has a pair of spaced, inflatable retention collars to be inflated for supporting the valve unit in proper position with a slotted head portion of the housing in the bladder. A valve member is resiliently biased to closed position against an apertured valve seat, and a magnetic core is connected to the valve member, to be moved by a force field generated by an electromagnet activating device external of the patient's body to open the valve and void the bladder.

12 Claims, 11 Drawing Figures



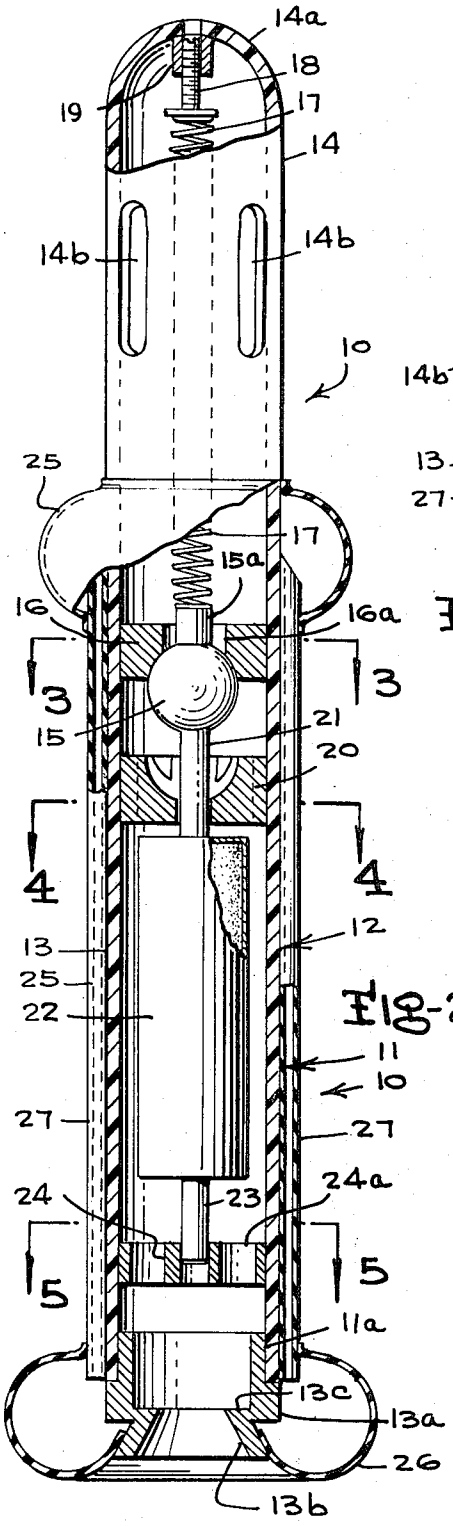


Fig-2

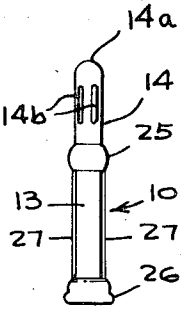


Fig-1

Fig-3

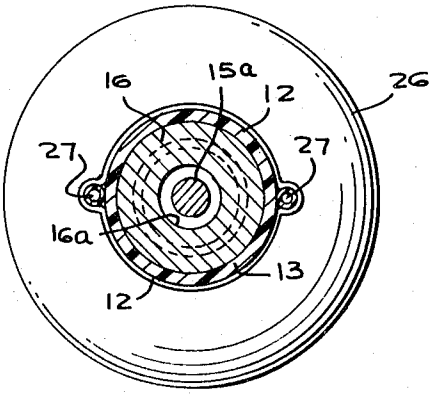


Fig-4

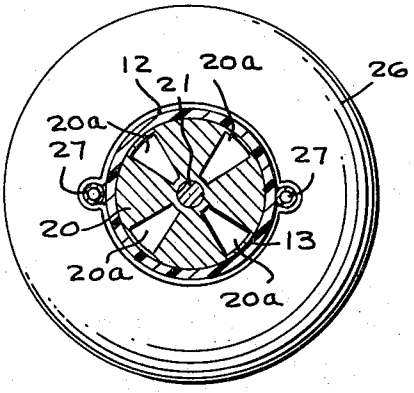


Fig-5

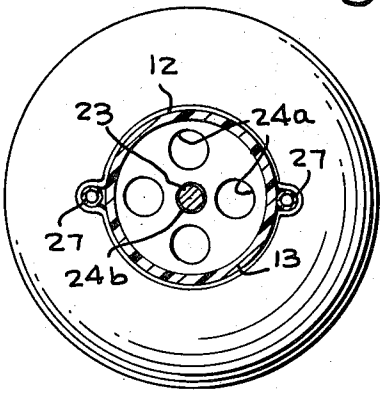


FIG-6

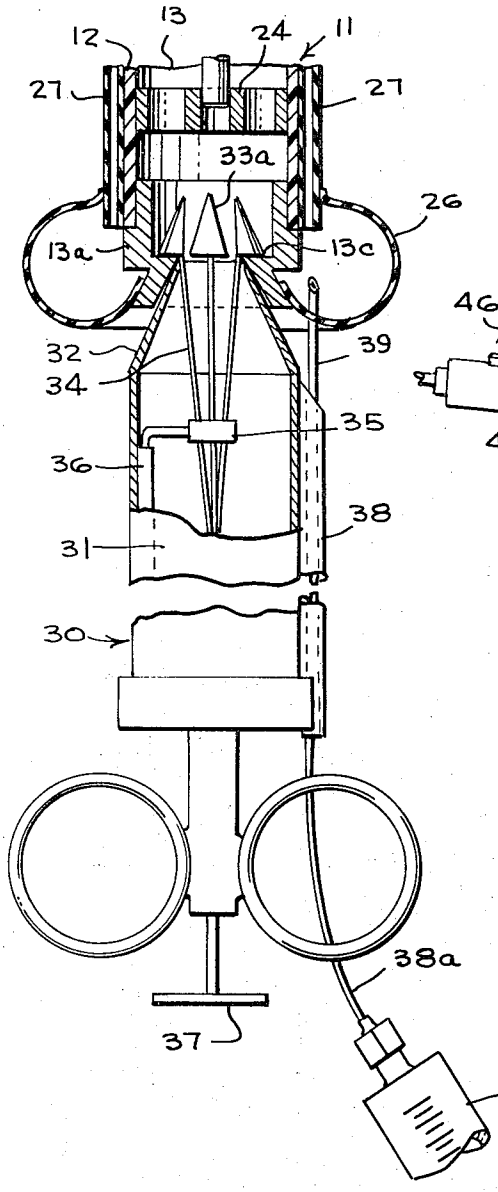


FIG-7

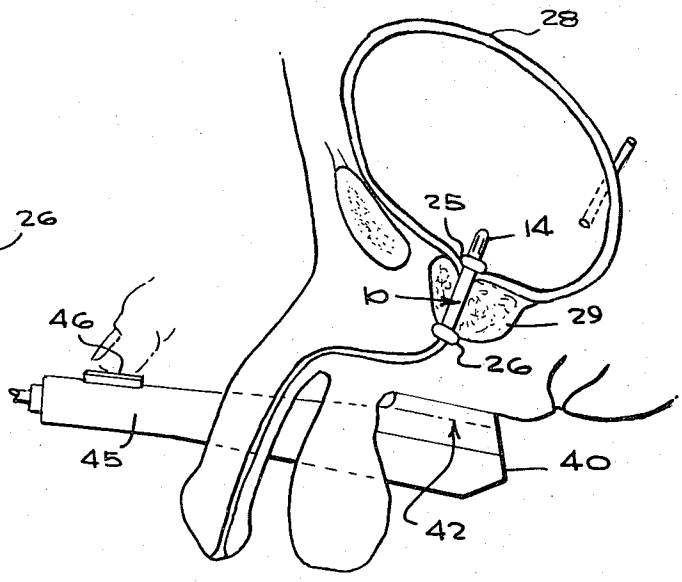


FIG-8

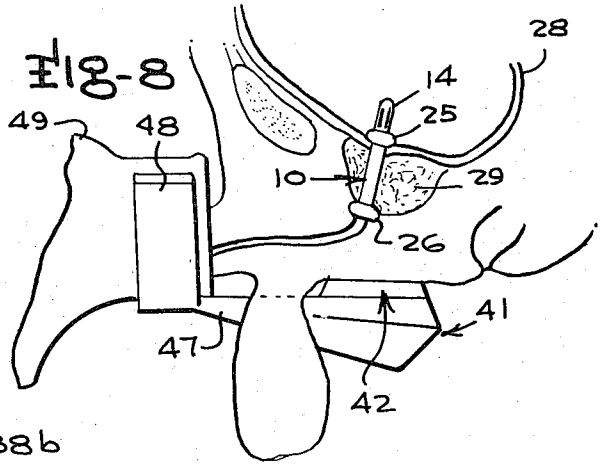
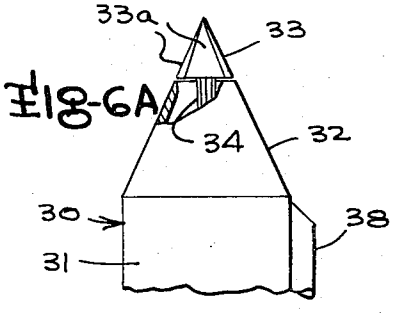


FIG-6A



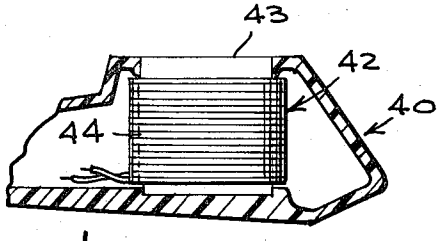
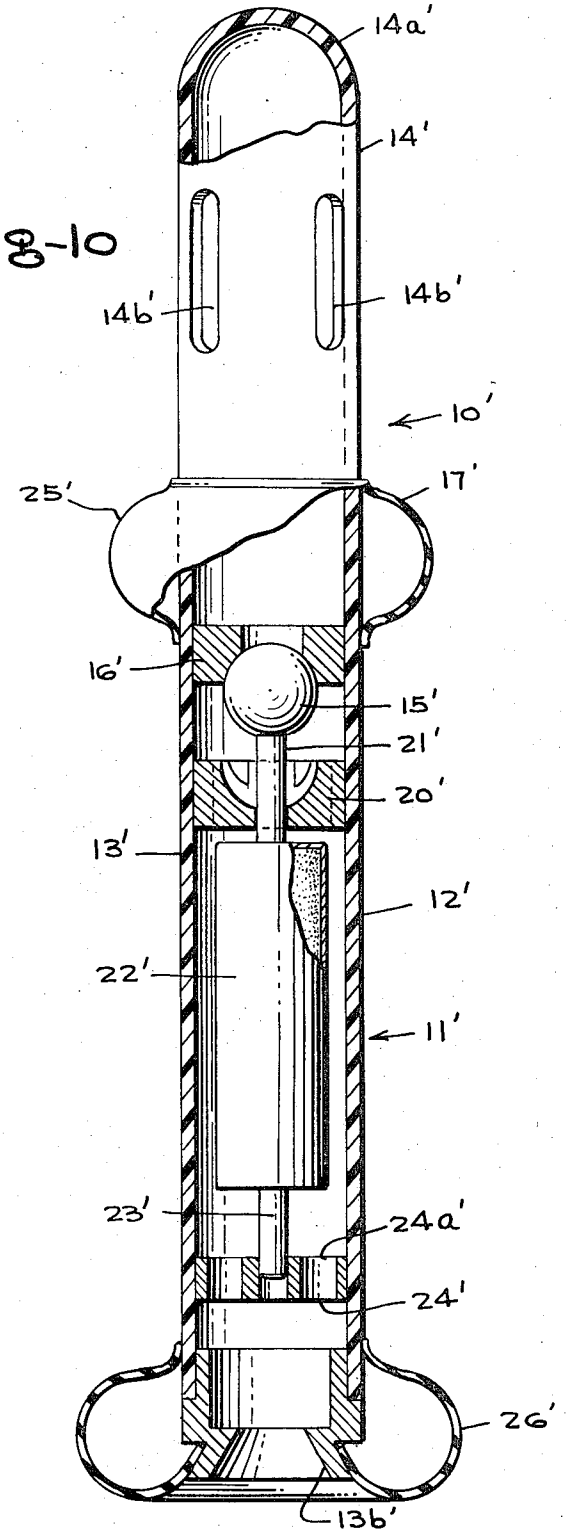


FIG-9

FIG-10



URETHRA MAGNETIC VALVE STRUCTURE

BACKGROUND AND OBJECTS OF THE INVENTION

The present invention relates in general to an implantable control valve for controlling discharge of fluid from the urethra, and more particularly to an implantable valve device having magnetic movable parts which will respond to a magnetic field produced by an external device to control the flow of urine in patients without physical control capabilities.

Urinary incontinence is a long recognized problem in the medical field to which much effort has been directed in providing devices for handling of this problem in some way. Urinary incontinence, which is defined as the inability to control automatically or under command the elimination function of the bladder, is a widespread disorder which results from some form of neurological disfunction, usually incurable, which effects either or both the ability to sense an over capacity condition which causes involuntary forced elimination, or to control the bladder sphincters. Such incontinence may be caused by birth defects, disease, injury or aging, frequently resulting from infection in the urinary tract, and sometimes resulting after prostate removel. Waste water is discharged from the body through the urethra which leads from the bladder and is controlled by the sphincter associated with the urethra in the area of its junction with the bladder. When the sphincter becomes disabled or incapacitated, the incontinence and loss of control of the passage of waste liquids through the urethra is a circumstance which is common but quite embarrassing, awkward, uncomfortable and inconvenient.

While many methods and expedients have been employed and proposed to control and alleviate such urinary incontinence, these have possessed numerous drawbacks and disadvantages and have done little to solve this problem. The usual medical treatment has been to insert a catheter through the urethra into the bladder with an exterior water-tight collecting bag connected to the catheter tube and a flow control clamp or similar device associated with the catheter and located externally of the body. Other management techniques have included wearing of absorbent diaperlike clothing or plastic pants, but such devices present a continuing and distressing problem of odor. Also, penile clamps have been proposed, for exerting enough pressure to occlude the urethra, but extreme care must be taken in the use of such devices to prevent forces that would impair circulation or cause edema. Also, use of such a device over a long period of time may cause a urethral diverticulum at the point of pressure, and skin irritations may also develop.

An object of the present invention is the provision of an implantable magnetic valve device which serves as a semipermanent implant in the urethra to control the flow of urine by creation of a magnetic field eminating from an external device when it is desired to open the valve, and thus replace the use of catheters, urinal bags and similar devices usually employed to manage the urinary incontinence problem.

Another object of the present invention is the provision of a novel urethra valve structure of magnetic character which can be conveniently inserted in the urethra to alleviate problems of urinary incontinence,

which has inflatable retention collars to keep the device in position, and which is of such design that it may be inserted in a convenient manner.

Other objects, advantages and capabilities of the present invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings illustrating preferred embodiments of the invention.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 is an elevation view of the urethra magnetic valve of the present invention, shown to approximate full scale;

FIG. 2 is an enlarged longitudinal section view of the urethra magnetic valve, illustrating the device at a scale enlargement of about 4 to 1;

FIG. 3 is a transverse section view of the urethra valve, taken along the line 3—3 of FIG. 2;

FIG. 4 is a transverse section view through the urethra valve, taken along the line 4—4 of FIG. 2;

FIG. 5 is a transverse section view through the urethra valve, taken along the line 5—5 of FIG. 2;

FIG. 6 is an elevation view of an insertion and removing instrument for implanting and removing the valve in the urethra, with parts of the instrument broken away to reveal the interior thereof and showing adjacent portions of the urethra valve in section;

FIG. 6A is a fragmentary elevation view of the working end portion of the insertion instrument, showing the chuck or collet in collapsed condition;

FIG. 7 is a somewhat diagrammatic view illustrating the urethra valve in implanted position and illustrating the electromagnetic activator in a position of use to activate the urethra valve;

FIG. 8 is a diagrammatic view of a modified form of electromagnetic activator for the valve;

FIG. 9 is an enlarged fragmentary section view of the magnetic head portion of the activating device; and

FIG. 10 is an enlarged sectional view, similar to FIG. 2, showing a modified form of my urethra magnetic valve.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to the drawings, wherein like reference characters designate corresponding parts throughout the several figures, and referring particularly to FIGS. 1 through 6, the urethra magnetic valve unit of the present invention is a small implantable device, indicated by the reference character **10**, formed of an elongated, generally cylindrical housing tube **11**, molded for example from a slightly flexibly deformable plastic material and having a cylindrical tubular outer wall **12** defining an elongated lower main body portion **13** and a head portion **14**. The head portion **14** extends over, for example, approximately one third of the axial length of the tube **11** and terminates at its upper end in a spherically configurated closed leading end or inner end **14*a***. The head portion **14** also is provided with a plurality of axially elongated slots or holes **14*b*** for admitting fluid into the interior of the housing tube **11**. The trailing or lower end of the main body portion **13** of the housing tube **11** is indicated at **11*a***, and has fixed therein a coupling ring **13*a*** defining a constricted, upwardly converging and conically tapering throat portion **13*b*** and an annular restraining shoulder **13*c***. Within the housing tube **11** in the intermediate or cen-

tral zone thereof is a valve structure formed by a valve member **15** which may be of spherical or conical configuration. The valve member **15** is normally held against a valve seat **16** by a coiled tension spring **17**, secured for example to the valve member stem portion **15***a* extending through the valve opening **16***a* in the valve seat **16** and secured at its other end to an adjustment screw **18** threaded into a threaded anchor sleeve **19** at the closed end of the head portion **14**. By adjusting the screw **18** and therefore the tension of the spring **17**, the tension of the valve may be controlled as required to accommodate to bladder volume and pressure and to enable the valve to weep if the pressure gets too great and the bladder has not been emptied at periodic intervals, as may be necessary for paraplegics, who have no sensation.

A valve retainer member **20** is also fixed in the housing tube **11** spaced toward the lower end **11***a* thereof from the valve, this being a slotted collar member having slots **20***a* for passage of fluid and having a central opening which assists in guiding the valve member **15** by means of a connecting stem or rod **21** extending from the valve member **15** to a magnetic core member **22**, for example an Alnico magnetic core of cylindrical configuration. Another guide rod **23** extends from the opposite end of magnetic core **22** along the center axis of the core and the valve member and into a guide opening in a guide collar **24** fixed in the lower region of the housing tube **11** near the lower end **11***a* thereof.

It will be noted that the valve retainer **20** is slotted as indicated at **20***a* in FIG. **4**, and the guide collar **24** has a series of circumferentially spaced apertures **24***a* spaced outwardly from the center guide aperture **24***b* thereof, the slots and the apertures being provided to permit free passage of fluid which is allowed to enter the head portion **14** through the slots **14***a* and pass through the opening of the valve seat **16** and through the lower section of the housing tube **11**.

Mounted on the external surface of the housing tube **11**, near the lower end **11***a* thereof and adjacent the lower end of the head portion **14**, are a pair of upper and lower inflatable retention collars **25** and **26** interconnected by one or more interconnecting inflation tubes **27** extending between the collars **25** and **26**. The interconnecting tubes **27**, shown here as a pair of tubes located at diametrically opposite parts of housing tube **11**, form a unitary inflation chamber with the interior chamber portions of the collars **25** and **26** to facilitate inflation of both collars upon inflating of the lower collar **26**. It is intended that the inflation chamber portions defined by the collars **25** and **26** and the inflation tubes **27** be inflated with some liquid, such as saline solution, or other desired solution, to which may be added, if desired, anitbiotics to retard possible infection and possibly desensitising drugs. The inflatable collars should be constructed of self-sealing material forming a semipermeable membrane through which the osmotic process might function to permit the collar fluids to leak at a very slow rate and thereby permit any drug used in the solution to accomplish the desired physiological effect.

The inflatable collars **25, 26** are spaced apart an appropriate distance so that the upper collar, upon inflation, will be disposed at the site where the urethra enters the bladder and thus form a restraining collar against the bladder wall or the top of the prostate gland. while the lower collar **26** is located at the position where the urethra leaves the prostate gland. Upon implanting of the urethra valve and inflation of the collars **25** and **26**, the inflatable collars thus form enlarged rings or restraining collars at the approximate positions illustrated in FIGS. **7** and **8** where the urethra emerges from opposite portions of the prostate gland, to hold the valve in desired position in the urethra with the head portion **14** disposed within the bladder. In the drawings, the bladder is indicated by the reference character **28** and the prostate gland by the reference character **29**. It will be noted from FIG. **7** that a slight curvature is imparted to the body portion **13** of the urethra valve **10**, which is permitted by reason of the slightly flexibly deformable character of the plastic material forming the cylindrical housing **11** and valve member, or by preforming of the valve housing and valve member to this configuration.

The urethra valve **10** is conveniently inserted into the urethra and advanced to the appropriate site by a suitable insertion and removing instrument, indicated generally by the reference character **30** in FIG. **6** and shown in decoupled, contracted condition in FIG. **6A**. This insertion and removing instrument **30** has an elongated cylindrical instrument tube or body **31** terminating at its forward end in a tapered leading end portion **32** of truncated conical configuration having a conical expansion collet or chuck **33** at the leading end thereof. The collet or chuck **33** is formed of a plurality of split segments **33***a* which, when contracted into tightly nested condition, define a conical surface which is an extension of the truncated conical surface of the end portion **32**. The segments **33**a of the expansion collet or expanding chuck are spring biased to the outwardly extended position illustrated in FIG. **6** by means of the spring wires **34** which support the chuck segments **33**, the spring wires **34** and chuck segments **33***a* being contractable to the closed position illustrated in FIG. **6A** by forward movement of the contracting ring **35** surrounding the spring wires **34** and coupled by connecting rod **36** to the activator or plunger **37** at the outer end of the insertion and removing instrument **30**.

When the plunger **37** and the ring **35** connected thereto is moved to its forwardmost position, the spring wires **34** are contracted toward each other by the ring **35** from their normal diverging positions, disposing the chuck segments **33***a* in the nested conical position illustrated in FIG. **6A**. When the plunger **37** of the instrument **30** is retracted to its outermost position, the ring **35** occupies the position illustrated in FIG. **6**, allowing the spring wires **34** to resiliently move the chuck setments **33***a* radially outwardly from the axis of the instrument **30** to engage the shoulder on the segments against the annular restraining shoulder **14***c* of the ring **14***a*, thereby coupling the valve **10** to the insertion and removing instrument **30**. The insertion and removing instrument **30** also preferably contains a guide sleeve **38** extending along the length thereof fixed to the external surface of the cylindrical body **31** through which a flexible syringe needle **39** may be inserted to puncture the lower retention collar **26**. A tubular conduit **38***a*, such as plastic tubing, connects the syringe needle **39** to a supply container, such as a collapsible syringe **38***b*, filled with saline solution or any other antibiotic solution to inflate the collars **25, 26.**

With the collars **25, 26** in deflated condition, the complete urethra magnetic valve **10** may be implanted

in the urethra by locking the valve unit **10** to the insertion and removing instrument **30** through use of the expanding chuck segments **33***a* inserted into the throat portion **13***b* of the coupling ring **13***a* to interlock with the restraining shoulder **13***c*. The valve unit **10** is then inserted in the urethra and advanced by the insertion and removing instrument **30** to the proper position in the zone of the prostate gland **29**, whereupon the flexible syringe needle **39** is inserted through the guide sleeve **38** to puncture the lower retention collar **26** and inflate the two interconnected retention collars **25** and **26** with the fluid in the syringe **38***b*. The needle **39** is then withdrawn from the guide sleeve and the plunger or actuator **37** of the instrument **30** pushed inwardly, advancing the contracting ring **35** along the spring wires **34** to cause the chuck to collapse to the condition illustrated in FIG. **6**A, so that the insertion tool can be withdrawn from interlocking relation with the ring **13**a to leave the valve in the urethra as a temporary implant.

The valve seat member **16**, in one preferred embodiment, may be a teflon valve seat designed to accommodate the valve member **15**, either of spherical ball shape or of conical shape, with the opening **16***a* in the valve seat sized so that when the valve is activated and the urine begins to flow, the increased surface of the exposed valve member should permit hydrostatic pressure to assist in keeping the valve open. The design and the tension on the spring **17** should be of such nature so that under normally full bladder pressure, the valve will weep sufficiently to warn the patient that he has exceeded the normal void time, for example if the patient is a paraplegic.

The valve is designed to be controlled by the patient to open the valve and achieve voiding, by the use of an external electromagnetic device creating a magnetic force field of sufficient strength to penetrate the distance between the valve and the external surface back of the scrotum. Examples of such magnetic activating devices are illustrated in FIGS. **7** and **8** and indicated generally by the reference characters **40** and **41**. The magnetic activating devices **40** and **41** each include a magnetic head **42** formed for example of a metallic core **43** of any desired configuration and windings indicated generally at **44** creating a force field of sufficient strength to attract the magnetic core member **22** of the valve structure and cause the valve member **15** to be drawn open to permit the fluid to flow freely from the bladder. Power for the windings of the magnetic head can be a standard DC battery or array of batteries, or a small step-down transformer operating off of a standard 110 volt 60 cycle supply and having a full wave DC rectifying bridge formed of diodes to produce the supply current of proper voltage, for example about 15 volts, across the windings of the magnetic head. In the form illustrated in FIG. **7**, the external electromagnetic device **40** is shown to have an elongated curved handle portion **45** shaped to extend forwardly around the scrotum from the electromagnetic head to a convenient access position and having, for example, a pushbutton switch **46** thereon to be operated by the thumb of the patient. In the form shown in FIG. **8**, the external electromagnetic device **41** has a curved portion **47** projecting forwardly from the head **42** to extend around the scrotum and terminates in a C-shaped clamp portion **48** adapted to releasibly clamp about the neck of a bottle or receptacle **49** to collect the fluid voided from the bladder upon electromagnetic activation of the valve to withdraw the valve member **15** to open position.

A modified form of the implantable device of the present invention is illustrated in FIG. **10**, indicated by reference character **10'**, formed of an elongated generally cylindrical housing tube **11'**, head portion **12'** and a pair of retention collars **25'**, **26'**. The components of this embodiment corresponding to parts of the first-described embodiment are indicated by reference characters which are primes of the reference characters used in describing the first embodiment. One or both of the collars **25'**, **26'** in this second embodiment are formed of highly resilient soft rubber or plastic material whose elastic memory normally urges them to the relatively radially enlarged annular configuration shown. The collars **25'**, **26'** are deformed inwardly by unyielding wall regions of the urethra during insertion, to approach substantially conformation to the cylindrical configuration and diameter of the exterior surface of the housing tube **11'**, but spring back to their enlarged condition when they reach the implant site astride the prostate gland. In this way, the need for the inflation tube **27** and for inflating means is eliminated. Also, need for the spring **17** is eliminated by making the valve seat **16'** of magnetic material magnetized to produce a North or South magnetic pole adjacent the ball valve **15'**, and the ball valve **15'** is made of magnetic material of opposite polarity to be permanently attracted to the valve seat. The valve is opened by the magnetic activator device **40** or **41** creating a force field of sufficient strength to move the magnet core **22'**, and the valve **15'** connected thereto, with such force as to overcome the attractive force of the valve seat **16'** and retract the valve member **15'** to open position. When the field of the activator device **40** or **41** collapses upon deenergization of its electro-magnet, the ball valve member **15'** is again attracted magnetically to closed position against the valve seat **16'**.

The implant valve assembly **10** or **10'** need not be especially formed to be coupled to the insertion and removing instrument **30**, but may be inserted in the urethra by other known urethra examination devices, such as the telescoping tubes of known urethrascopes.

What is claimed is:

1. A valve unit to be implanted in the urethra of a patient at the juncture of the urethra with the bladder to be operated by a magnetic force field generated by an external electromagnetic device for controlling the flow of urine through the urethra, the valve comprising an axially elongated hollow tubular housing of substantially cylindrical configuration having an upper spherical end and a lower open end, a valve assembly in the intermediate region of said housing including a centrally apertured annular valve seat member, a movable valve member below said valve seat member normally urged toward said valve seat member to closed position, a magnetic core member connected to said valve member and guided for movement in said housing to retract the valve member to open position responsive to a magnetic force field generated externally of the patient's body, and a pair of radially inwardly deformable annular collars located on the exterior surface of said housing at axially spaced locations to assume relatively enlarged condition upon implanting of the valve unit in the urethra and provide retaining collars at the opposite ends of the urethra portion passing through the prostate gland to restrain the valve unit in implanted

position, and the portion of said housing above the uppermost collar, defining a head portion having openings for passage of urine from the bladder into the interior of the housing, and a coupling ring at the lower end of said housing having an upwardly converging throat adjoining an upwardly facing annular restraining shoulder for removable coupling of an insertion and removing instrument therewith.

2. A valve unit as defined in claim **1,** said collars being normally collapsed inflatable collars which are inflated after insertion to assume such relatively enlarged condition.

3. A valve unit as defined in claim **2,** including conduit means interconnecting said pair of inflatable collars whereby inflating fluid may be introduced into and withdrawn from the lowermost collar for inflating or deflating both collars, said lowermost collar being self-sealing and being puncturable by a syringe needle for inflating and deflating the same.

4. A valve unit as defined in claim **1,** including a centrally apertured valve retainer member below said valve seat member having openings for passage of urine therethrough when the valve is in open position, said movable valve member being located between said valve seat member and said valve retainer member.

5. A valve unit as defined in claim **4,** wherein said collars are normally collapsed inflatable collars, and conduit means interconnecting said pair of inflatable collars whereby inflating fluid may be introduced into and withdrawn from the lowermost collar for inflating or deflating both collars, said lowermost collar being self-sealing and being puncturable by a syringe needle for inflating and deflating the same.

6. A valve unit as defined in claim **5** including tension spring means coupled at one end thereof through the aperture in said valve seat member to said valve member and adjustably fastened at its other end to said housing for adjustment of the spring tension force tending to close said valve member against said valve seat member prior to implanting of the valve unit in the urethra.

7. A valve unit to be implanted in the urethra of a patient at the juncture of the urethra with the bladder to be operated by a magnetic force field generated by an external electromagnetic device for controlling the flow of urine through the urethra, the valve comprising an axially elongated hollow tubular housing of substantially cylindrical configuration having an upper spherical end and a lower open end, a valve assembly in the intermediate region of said housing including a centrally apertured annular valve seat member, a movable valve member below said valve seat member normally urged toward said valve seat member to closed position, a magnetic core member connected to said valve member and guided for movement in said housing to retract the valve member to open position responsive to a magnetic force field generated externally of the patient's body, and a pair of radially inwardly deformable annular collars located on the exterior surface of said housing at axially spaced locations to assume relatively enlarged condition upon implanting of the valve unit in the urethra and provide retaining collars at the opposite ends of the urethra portion passing through the prostate gland to restrain the valve unit in implanted position, and the portion of said housing above the uppermost collar defining a head portion having openings for passage of urine from the bladder into the interior of said housing, a coupling ring at the lower end of said housing having an upwardly converging throat adjoining an upwardly facing annular restraining shoulder for removable coupling of an insertion and removing instrument therewith, an insertion and removing instrument including an elongated instrument tube having a convergently tapering leading end of truncated conical configuration, an expandable chuck at said leading end releasably coupled to said coupling ring and defining a cone which is an extension of said tapering leading end when in contracted condition and which is made up of conic segments which are radially outwardly movable to expanded position in said valve housing interlocking against said annular restraining shoulder of said coupling ring, spring wires in said instrument tube supporting said conic segments and normally urging them to said expanded position, and a contracting ring in said instrument tube surrounding said wires and mounted for reciprocation axially of the tube by a plunger to expand and contract the conic segments.

8. A valve unit as defined in claim **7,** wherein said collars are normally collapsed inflatable collars which are inflated after insertion to assume such relatively enlarged condition.

9. A valve unit as defined in claim **8,** including conduit means interconnecting said pair of inflatable collars whereby inflating fluid may be introduced into and withdrawn from the lowermost collar for inflating or deflating both collars, said lowermost collar being self-sealing and being puncturable by a syringe needle for inflating and deflating the same.

10. A valve unit as defined in claim **7,** wherein said collars are formed of resiliently deformable material normally elastically urged to selected radially enlarged annular formations and resiliently contractible to approximately flat condition adjacent the surface of said tubular housing.

11. A valve unit as defined in claim **7,** including a centrally apertured valve retainer member below said valve seat member having openings for passage of uring therethrough when the valve is in open position, said movable valve member being located between said valve seat member and said valve retainer member.

12. A valve unit as defined in claim **11,** wherein said collars are normally collapsed inflatable collars, conduit means interconnecting said pair of inflatable collars whereby inflating fluid may be introduced into and withdrawn from the lowermost collar for inflating or deflating both collars, said lowermost collar being self-sealing and being puncturable by a syringe needle for inflating and deflating the same, and tension spring means coupled at one end of the valve unit through the aperture in said valve seat member to said valve member and adjustably fastened at its other end to said housing for adjustment of the spring tension force tending to close said valve member against said valve seat member prior to implanting of the valve unit in the urethra.

* * * * *