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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :		(11) International Publication Number:	WO 92/11826
A61F 5/48	A1	(43) International Publication Date:	23 July 1992 (23.07.92)

(21) International Application Number: PCT/US91/09664

(22) International Filing Date: 24 December 1991 (24.12.91)

(30) Priority data:

636,285	31 December 1990 (31.12.90)	US
746,364	16 August 1991 (16.08.91)	US
811,571	20 December 1991 (20.12.91)	US

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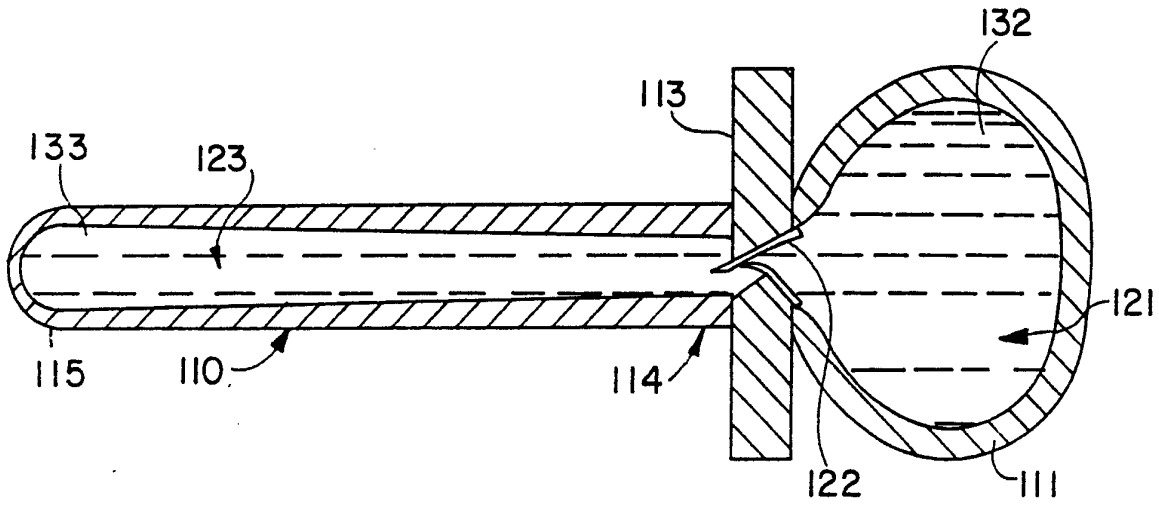
(81) Designated States: AT (European patent), AU, BE (European patent), BR, CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), GR (European patent), HU, IT (European patent), JP, KR, LU (European patent), MC (European patent), NL (European patent), NO, SE (European patent).

Published
With international search report.

(54) Title: A METHOD AND A REMOVABLE DEVICE WHICH CAN BE USED FOR THE SELF-ADMINISTERED TREATMENT OF URINARY TRACT INFECTIONS OR OTHER DISORDERS AND AS A URETHRAL PLUG



(57) Abstract

The present invention is a removable drug delivery system used by patients suffering from lower urinary tract infections. Infections involving bacteria in the urine and/or in the superficial regions of the urethral and bladder tissues should be highly amenable to treatment by the release of antibiotics into the urine in the bladder, or onto the walls of the urethra. The present invention comprises the delivery of antibiotics to the infected areas utilizing a modified urethral plug. The urethral plug individually can be used to treat incontinence by plugging the urethra thus preventing the unwanted discharge of urine. The device comprises a balloon (12) at the proximal end and means to inflate and deflate the balloon. The patient simply inserts the plug (10) into the urethra and inflates the balloon (12) to achieve continence or to deliver the antibiotics coated on the plug (10) to the infected areas.

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A METHOD AND A REMOVABLE DEVICE WHICH CAN BE USED FOR THE SELF-ADMINISTERED TREATMENT OF URINARY TRACT INFECTIONS OR OTHER DISORDERS AND AS A URETHAL PLUG

BACKGROUND OF THE INVENTION

Field of Invention

The present invention is a novel urethral plug which in addition to serving as removable plug for the prevention of incontinence can be used also as a medicine delivery system by patients suffering from lower urinary tract infections or other urine disorders and disorders of the urethra and bladder.

The lower urinary tract is subject to a variety of bacterial illnesses and other disorders, which can be further characterized as renal, ureteral, bladder, urethral and urinary. For example, bacteria infections of the lower urinary tract are very common, and after infancy occur about ten times more often in women than in men. The main route of infections in women ascends from the vagina through the urethra to the bladder. The majority of urinary tract infections (UTIs) are caused by gram negative bacteria such as Escherichia coli (up to 85% of UTIs), Klebsiella sp., Proteus sp., Enterobacter (Aerobacter) aerogenes, and Pseudomonas aeruginosa. Occasionally gram positive pathogens may be involved, including Staphylococcus epidermis (albus), and Staphylococcus aureus. The most common UTI is bacteriuria, or the proliferation of bacteria within the urine; as many as 10% of adolescent girls have this condition, often in asymptomatic form. The condition is considered deserving of treatment at bacterial counts above 100,000 per ml, and acute at counts above 500,000 per ml or more. Bacteriuria may lead to, or stem from, infections of the urethra and/or bladder. Most such conditions involve urea-splitting bacteria which render the

urine alkaline and favor the formation of calcified deposits and urinary stones, which in turn harbor and protect the proliferating bacteria.

Infections involving bacteria in the urine and/or in the superficial regions of the urethral and bladder tissues should be highly amenable to treatment by the release of antibiotics into the urine in the bladder, or onto the walls of the urethra. The present invention comprises the delivery of antibiotics to the infected areas utilizing modified urethral plugs.

The drug delivery aspect of this invention is equally applicable to and intended for use in treating urine disorders and, other disorders of the bladder, or urethra such as (e.g.) interstitial cystitis which can be treated chemically, by the action of a drug. However the novel plug itself is intended primarily for removable insertion into the urethra to prevent incontinence.

Prior Art

The principal therapy for UTIs involves antibiotics such as sulfonamides, tetracycline, ampicillin or amoxicillin, trimethoprim, or trimethoprim/sulfamethoxazole. Oral doses typically on the order of a gram per day are usually maintained for 7-10 days, though 1-3 days is often effective. Recurrent infections are common and may be treated with additional medicines such as cephalosporins, nalidixic or oxolinic acid, or nitrofurantoin. Although this antibacterial therapy has markedly improved the prognosis for most UTIs, current methods of administering antibiotics have certain disadvantages which can be overcome by the present invention. The same can be said of using oral means to deliver medicines for other disorders.

Oral administration of antibiotics for the treatment of lower UTIs involves high doses, because the medicine must pass through the stomach, be absorbed by the intestines, survive first pass metabolism in the liver, accumulate in the blood, and finally accumulate in the urine and urinary tract in sufficiently high concentration to kill pathogenic organisms. This method is a very indirect means of administration, and leads to prolonged high systemic concentration of antibiotics. Under such conditions, many antibiotics have harmful side-effects such as ototoxicity and nephrotoxicity. The side effects limit the selection of antibiotics, and under the best of circumstances still expose the patient to small but undesirable risks.

Urinary medicines can also be administered by means of inserting conventional Foley catheters up the urethra to the bladder and instilling solutions via the Foley urine tube. Although this method delivers medication to where it is most needed, it is rarely used, and is almost never used unless the infection occurs in an already catheterized patient. Indwelling catheters tend to hinder free movement by the patient, and they preserve stagnant urethral conditions favorable to bacterial growth. Effort to address the problems of indwelling catheters by repeated insertion and removal, introduces more bacteria into the infected urinary tract and may actually aggravates the infection. Moreover, existing catheters are expensive and not designed for easy self-administration. In addition, existing catheters have an open lumen for draining urine; this lumen would also drain out any antibiotic, limiting the effectiveness of any instillation.

There are in existence many methods and devices used to address the problem of involuntary loss of urine in people suffering from incontinence. Surgery is perhaps the most desirable method in cases of severe incontinence in younger

patients. The surgical alternative often involves a procedure whereby the neck of the bladder is reduced by suspending the bladder. However, there are numerous well known risks associated with this as well as any surgical procedure. For some patients, surgery is not recommended for medical or other reasons and for those with mild incontinence surgery is not an appropriate solution. The expense of surgery is also a factor to be considered.

Incontinence can also be treated with various medications as well as exercises, these methods varying depending whether the patient is male or female. The most commonly used device for both sexes is the diaper which simply catches and absorbs the urine involuntarily voided. This device obviously does not alleviate the problem of incontinence and has many hygienic and aesthetic drawbacks. Leakage occurs frequently and there is no control over the voiding of urine. For women, rigid devices, such as tampons, were suggested. Such rigid devices must be inserted into the vagina to support the urethra. These types of rigid devices are difficult to fit and thus require medical assistance in fitting. There are also in existence prosthetic urethral valves, which require surgical implantation and invite numerous complications. Foley drainage catheters and drainage bags are also known but these devices have many disadvantages.

SUMMARY OF THE INVENTION

One important embodiment of the present invention is a device for the treatment of incontinence in men and women and a method for using the device to stop unwanted flow of urine and is particularly useful for stress incontinence.

The urethra plug is a soft, flexible device which is inserted into the patient's urethra. It conforms to the shape and size of the urethra, especially upstream of the sphincter, toward the bladder neck. There is no need to custom make the device for each individual, although the device may be manufactured in several lengths and sizes. The patient's urethra length is measured by a physician to ensure that the proper size plug is used. The plug is designed in accordance with the present invention to be inserted or diseased and removed by the patient.

The medicine delivery system for use by patients suffering from lower urinary tract infections or other disorders effecting the urine, urethra and bladder is a removable delivery system which does not have an open lumen in connection with an external drainage bag; hence it maintains therapeutic effect without risking contamination. The system comprises an improved urethral plug (delivery device), a solution of antibiotics or other therapeutic compound and soluble binder and a method of delivering the medicine to the infected urinary tract.

Infections involving bacteria or other disorders in the urine and/or in the superficial regions of the urethral and bladder tissues should be highly amenable to treatment by the direct release of antibiotics or other compound into the urine in the bladder, or onto the walls of the urethra. The antibiotics or other compound are adhered to the urethral plug or delivery device with the help of a soluble binder. The antibiotics or other compound are dispersed in the soluble binder, and the solution is coated on the exterior surface of the delivery device. The solution can be coated onto the entire outer surface or on portions of the outer surface. Different types of antibiotics or other compound can be coated onto different portions of the outer surface.

Therefore, a variety of antibiotics or other compound can be delivered to the infected or diseased areas. The delivery system is then inserted into the infected or diseased urethra or bladder.

The delivery device can be a simple plug. One preferred plug for the drug delivery system is a modified urethral plug for the treatment of incontinence. Disclosed herein and in Simon et al, U.S. Serial No. 07/746,364 referred to herein as Simon '364. Simon '364 is a urethral plug configured to fit within the urethra, bladder neck or bladder with a balloon at the proximal end, and a cap defining an aperture at the distal end. The urethral plug can easily be inserted and removed by the patient. The balloon is inflated by injecting fluid through the aperture at the distal end into the hollow plug whose lumen communicates with the interior of the balloon. Fluid may be injected through the plug by a syringe. After inflation, the balloon plugs the bladder neck and the urethra, and the antibiotics or other compound then dissolve into the infected or diseased areas. The balloon is deflated by pulling on a deflation string projecting outwardly from inside the plug through the aperture on the cap. After the balloon is deflated, the plug may be removed.

Another preferred embodiment of the insertable urethral plug is disclosed herein and in Simon et al, U.S. Serial No. 07/636,285, referred to hereafter as Simon '285 . Simon '285 is a conformable urethral plug which has two components: a molded soft inflatable plastic catheter and a transportable fluid. After insertion, the fluid can be moved from an external bellows, through a check valve to inflate and distend the device within the urethra, bladder neck or bladder causing the device to plug the urethra and

bladder neck. The antibiotics or other compound dissolve into the infected or diseased areas. The device is deflated and removed by intentionally misaligning the check valve.

The medicine can also be delivered by means of a medicated pellet attached to the proximal end of the urethral plugs. The antibiotic or other compound and binder solution can be covered by a permeable membrane to control the rate of discharge of antibiotics or other compound to the infected or diseased areas. With this delivery system, the medicine can be delivered quickly and directly to the infected or diseased areas in high dosage. A further advantage is that the delivery can be halted immediately by removing the device.

Accordingly an object of the present invention is to provide a removable plug which treats urinary tract infections or other diseases.

Another object of the present invention to provide a urethral plug which is inserted and removed by the patient and which prevents involuntary voiding of urine.

It is another object of the present invention to provide a method of using a urethra plug by patients suffering from urinary incontinence.

Another object of the present invention is to provide a removable urethral plug which delivers the medicine to the infected or diseased urinary tract.

Another object of the present invention is to administer the medicine directly to the infected or diseased urinary tract.

Another object of the present invention is to provide a treatment for the infected or diseased urinary tract that requires less medicine than oral dosage.

Another object of the present invention is to provide a treatment for the infected or diseased urinary tract that results in lower systemic medicine levels and fewer side effects than oral dosage.

Another object of the present invention is to provide a greater freedom of choice of medicine in treating urinary tract infection or diseases.

Another object of the present invention is to provide a medicine delivery system that can be easily used by the patients.

A further object of the present invention is to a provide fast acting method for the treatment of urinary tract infection or other diseases.

Still a further object of the present invention is to provide a fast acting method for the treatment of urinary tract that can be easily and quickly halted.

Still another object of the present invention is to provide highly concentrated but brief pulses of antibiotics or other medication.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view of a plug in accordance with the present invention in a pre-insertion configuration;

FIG. 2 is a cross-sectional view of the plug of Fig. 1 in an inserted and inflated configuration;

FIG. 3 is a cross-sectional view of a plug of Fig. 1 in an inserted and holding configuration;

FIG. 4 is a cross-sectional view of a plug of Fig. 1 in a deflated and removable configuration;

FIG. 5 is a cross-sectional view of available plug in a deflated insertable configuration;

FIG. 6 is a cross-sectional view of the plug of Fig. 5 in an inflated configuration;

FIG. 7 is a diagrammatic representation of a plug of Fig. 5

FIG. 8 is a cross-sectional view of the check valve of the plug of Fig.5 in a closed position;

FIG. 9 is a cross-sectional view of the check valve of Fig. 8 in an open position;

FIG. 10 is a cross-sectional view of a drug delivery system of the present invention in a pre-insertion configuration showing a medicated pellet attached to the proximal end of the present invention;

FIG. 11 is a cross-sectional view of a drug delivery system of the present invention in an inflated and holding position showing a medicated pellet attached to the proximal end of the present invention;

FIG. 12 is a cross-sectional view of a drug delivery system of the present invention in a pre-insertion configuration showing a medicated coating attached to the proximal balloon of the present invention;

FIG. 13 is a cross-sectional view of a drug delivery system of the present invention in an inflated and holding position showing a medicated coating attached to the proximal balloon of the present invention;

FIG. 14 is a cross-sectional view of a drug delivery system of the present invention in a pre-insertion configuration showing a medicated coating attached to the shaft of the present invention;

FIG. 15 is a cross-sectional view of a drug delivery system of the present invention in an inflated and holding position showing a medicated coating attached to the shaft of the present invention;

FIG. 16 is a cross-sectional view of a drug delivery system of the present invention in a pre-insertion configuration showing a medicated coating attached to the proximal balloon and the shaft of the present invention;

FIG. 17 is a cross-sectional view of a drug delivery system of the present invention in an inflated and holding position showing a medicated coating attached to the proximal balloon and the shaft of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

At the outset, the invention is described in its broadest overall aspects with a more detailed description following.

The present invention is a plug which can be used to prevent incontinence and/or as a medicine delivery system for the treatment of urinary tract infections (UTIs) or other disorders. The drug delivery system of the present invention utilizes a urethral plug as the delivery device, and a solution of antibiotics or other therapeutic compounds and soluble binder. The antibiotics or other therapeutic compounds are delivered directly to the infected or diseased area by the delivery device. The antibiotics or other therapeutic compounds are attached to the plug with the help of a soluble binder. A solution of antibiotics or other therapeutic compounds and binder is coated onto the outer surface of the delivery device. The coated delivery device is then inserted by the patient into the infected or diseased urinary tract. Inside the urinary tract, said solution dissolves into the urine or onto the wall of the urethra and thereby releases the antibiotics or other therapeutic compounds to treat the infection or disease.

The rate of discharge can be controlled by covering the coated solution of antibiotics and binder with a permeable membrane. The membrane slows down the rate of discharge by forcing the dissolving antibiotics or other therapeutic compounds to first pass through the membrane. Further, the membrane can also be selectively perforated to allow more control over the rate of discharge. The antibiotics or other compound can also be delivered by means of a medicated pellet attached to the proximal end of the urethral plug.

I. URETHAL PLUGS

A. Simon et al U.S. Serial No. 07/746,364

Simon '364 is a urethral plug comprising a balloon at its proximal end, a hollow main body which is in fluid communication with the balloon and with a fluid receiving

port at the distal end of the main body. To deliver the antibiotics or other compound to the infected or diseased areas, the patient simply inserts the coated plug into the urethra and inflates the balloon. The balloon is inflated by injecting fluid into the hollow main body through the fluid receiving port. Fluid can be injected into the device with a syringe or other means. To remove the urethral plug the patient pulls on a string attached to the distal end of the device which deactivates a seal to deflate the balloon enabling the plug to be withdrawn.

Fig. 1 is a cross-sectional view of a preferred embodiment of Simon '364 in its pre-insertion configuration. At the distal end, urethral plug 10 has distal cap 24. Distal cap 24 is used to anchor urethral plug 10 at the meatus urinarius or orifice of the urethra, preventing the migration of urethral catheter 10 into the bladder. Distal cap 24 defines aperture 26, which is located in the center of distal cap 24 and has a truncated cone shape with the larger opening facing outward. The fluid receiving port for the hollow main body of urethral plug 10 includes aperture 26 with which it is in fluid communication.

The main body of plug 10 is a fluid tight lumen for fluid to travel from the fluid receiving port to balloon 12, and comprises lumen 30 and balloon shaft 13. Lumen 30 is defined as the space between sheath 52 and plunger 18, which is located inside of sheath 52. Lumen 30 also includes the space within the two springs 14 and 16 affixed to each end of plunger 18. The springs 14 and 16 are used to keep plunger 18 in a predetermined static position. Force applied to plunger 18 can move it distally or proximally. When plunger 18 is moved, one spring is compressed, and the other is stretched storing energy in both springs. After the applied force is removed, the springs release the stored energy and return plunger 18 to its static position.

Balloon shaft 13 has a distal end and a proximal end and comprises three sections: hollow base section 42, hollow section 44 and solid section 46. Hollow base section 42 and hollow section 44 define tunnel 38. Balloon 12 is secured to balloon shaft 13 by means of affixing balloon 12 to glue joints 25 and 27. Only the ends of balloon 12 are affixed to glue joints 25 and 27 by means of epoxy adhesive. The middle part of balloon 12 is unattached and is free to expand or contract.

Plunger 18 is a cylinder interrupted by groove 17, and has a proximal end and a distal end. Return spring 16 is affixed to distal cap 24 and to the distal end of plunger 18. Return spring 14 is affixed to the proximal end of plunger 18 and to the distal end of balloon shaft 13. O-ring 22 is secured to groove 17, and is large enough to protrude out of groove 17. In the static position groove 17 is aligned with internal ridge 20 forming passageway 34 which is shown in Fig. 2. In this position, O-ring 22 squashes against ridge 20 forming a seal, and seals off passageway 34. The seal keeps fluid from escaping when balloon 12 is inflated. Sheath 52 circumferentially covers urethral catheter 10 from base section 42 of balloon shaft 13 to return spring 16, inclusive. Sheath 52 abuts distal cap 24 and balloon 12. Ridge 20 is a part of sheath 52, and may be located approximately in the middle of sheath 52.

Now referring specifically to the fluid path, lumen 30 has three sections: distal lumen 32, passageway 34 and proximal lumen 36, as shown in Fig. 2. Distal lumen 32 is in communication with ambient via aperture 26, and is connected to passageway 34. Passageway 34 connects distal lumen 32 to proximal lumen 36. Distal lumen 32 and proximal lumen 36 are in fluid communication when passageway 34 is open. Passageway 34 is open when O-ring 22 is not aligned

with ridge 20. O-ring 22 may be misaligned with ridge 22 by pushing plunger 18 proximally or pulling it distally until O-ring 22 is no longer in contact with ridge 20.

Lumen 36 is connected to tunnel 38. Tunnel 38 runs through the centers of base section 42 and hollow section 44, until it connects with nozzle 40 (Fig. 2). Nozzle 40 is orthogonal to tunnel 38. Fluid entering or exiting balloon 12 passes through nozzle 40.

Fluid may be injected by means of a syringe. Syringe 50 (Fig. 1) may be of any conventional design, but nose 51 should have a conical shape. During fluid injection, nose 51 should form a tight fluid seal with the conical shaped aperture 26 so that injected fluid can inflate balloon 12 and not leak outside. If the syringe does not form a seal with aperture 26, the fluid injected would spill back out through aperture 26 instead of filling up balloon 12, because spilling outward is the least resistance path for the fluid.

Now referring to the method for using urethral plug 10, a preferred embodiment as shown in Fig. 1 is inserted up the urethra until distal cap 24 abuts the orifice of the urethra. Fig. 2 shows urethral catheter 10 as it would be inserted in the urethra and in the process of inflation. Syringe 50 is introduced into aperture 26. Nose 51 pushed plunger 18 proximally, compressing return spring 14 and extending return spring 16. Energy is stored in both return springs 14 and 16. When O-ring 22 is pushed until it is no longer in contact with ridge 20, passageway 34 is open. Syringe 50 expels filling fluid into distal lumen 32. Filling fluid is then pushed through passageway 34 into proximal lumen 36, and into tunnel 38. Filling fluid then enters balloon 12 through nozzle 40. After balloon 12 is inflated, syringe 50 is withdrawn. Energy stored in return

springs 14 and 16 is released, and pushes plunger 18 distally back to its static position. O-ring 22 is once again in contact with ridge 20, and seals off passageway 34 preventing filling fluid from escaping. Inflated balloon 12 plugs up the urethra, bladder neck or bladder. Fig. 3 shows urethral catheter 10 in its inflated holding position with deflation string 15 threading through aperture 26 and hanging outside of urethral catheter 10.

Fig. 4 describes the preferred embodiment in its deflated removable position. Filling fluid may be released by means of pulling on deflation string 15. When the patient wishes to deflate and remove urethral catheter 10 from the urethra, the patient simply pulls on string 15. Return spring 16 is compressed, and return spring 14 is extended. When O-ring 22 is no longer aligned with ridge 20, passageway 34 is open. Filling fluid is forced out through a path reversed from the path that it had entered, and balloon 12 deflates. After balloon 12 has been fully deflated, urethral catheter 10 may be removed. Urethral catheter 10 may be re-inserted and inflated as described above.

B. Simon et al, U.S. Serial No. 07/636,285

The urethral plug disclosed in Simon'285 is a soft, flexible device which is inserted into the patient's urethra. It conforms to the shape and size of the urethra, especially upstream of the sphincter, toward the bladder neck. There is no need to custom make the device for each individual, although the device may be manufactured in several lengths and sizes. The patient's urethral length is measured by a physician to ensure that the proper size plug is used.

The plug has a hollow inner core with an increasing internal diameter toward the bladder neck. At the proximal end of the device there is an expandable sack, and at the distal end there is an inflatable bellows with a check valve. The check valve is located within a meatal plate, and said plate will anchor the plug at the meatus urinarius. The device is inserted into the urethra, so that the inflatable bellows is left outside the body, and the sack remains in the urethra, bladder neck or bladder.

The hollow inner core is filled with a fluid. When the device is inserted, the patient squeezes the inflatable balloon filled with the fluid, thus moving the fluid through the check valve into the sack at the proximal end. The inflated sack forms a plug by blocking the passage in the urethra, the bladder neck or the bladder itself. When the patient wishes to remove the plug, a gentle tug on the external part of the device will cause misalignment of the valve, and the fluid will move back down out of the sack into the balloon. Then, the device can be removed.

One embodiment of the device of the present invention is shown in FIG. 5 where a urethral plug 110 is shown. A bellows 111 defines cavity 121, and is used to transport fluid 132 contained in cavity 121 through a check valve 122 which is located within meatal plate 113. The bellows is made from a material which makes it conformable to the body and comfortable for the patient when the urethral plug is in place. The fluid 132 is transported to cavity 123 located within plug 110 becoming fluid 133. The wall of the plug is relatively constant in outer diameter allowing the device to be easily inserted. However, the wall thickness varies from the meatal plate 113, beginning at location 114 to the proximal end 115 where the wall is thinnest, allowing the

greatest inflation. The fluid 132 can be any fluid which can be pumped from cavity 121 to cavity 123 through check valve 122.

Check valve 122, shown in FIGS. 8 and 9, is designed to be asymmetric, functioning as a normal check valve. When bellows 111 is squeezed, fluid 132 is pumped from cavity 121 through valve 122. FIG. 6 shows cavity 123 inflated to a new configuration 123'. When it is desired to deflate cavity 123', the patient simply tugs on bellows 111 causing valve 122 to intentionally misalign, allowing fluid 133 to substantially return to cavity 121 such that there is pressure equilibrium between cavity 121 and cavity 123 as shown in FIG. 7.

FIG. 8 shows the intentional misalignment which is caused by leaf 124 being connected to meatal plate 113 such that it deflects minimally. On the other hand, leaf 125 is relatively flexible such that it moves in response to a patient-initiated tug on bellows 111, causing leaf 125 to separate from leaf 124. FIG. 9. shows leaf 125 separated from leaf 124. Thus, fluid may pass reversibly from cavity 123 back to cavity 121 through check valve 122 when bellows 111 is tugged upon.

II. ANTIBIOTIC OR OTHER COMPOUND COATING FOR PLUGS

Antibiotic or other compound by itself could be coated onto the outer surface of the delivery device; however, in this embodiment the antibiotics are dissolved in solution with a binder such as polyvinylpyrrolidone, carboxymethylcellulose, gelatin, or a lactide-glycolide copolymer, the task can be accomplished. Following this step, the solution then can be coated onto one or more portions of the outer surface of the delivery device. The solution can be coated on the shaft to treat infection or

disease of the urethra, on the proximal distensible balloon to treat infection or disease in the bladder, on any portion of the balloon or on any combination thereof. Further, different solutions containing different types of antibiotics or compounds can be coated onto different portions of the surface of the delivery device.

The solution can also be coated onto the inside surface of a permeable elastic or heat-shrinkable silicone tubular membrane. The membrane is slipped over the shaft of the delivery device and warmed or allowed to contract in place trapping the solution of antibiotics and binder between the membrane and the delivery device.

Once inserted the antibiotics or other compound are dissolved into the urine in the bladder or released onto the wall of the urethra. The rate of dissolution can be controlled by means of the permeable membrane. The membrane reduces the rate of dissolution by forcing the antibiotics or other compound and binder to pass through the permeable membrane. The rate of dissolution can be controlled further by perforating the membrane to allow higher rate.

A similar tubular antibiotic or other compound-loaded membrane can then be applied over the extended proximal shaft of the delivery device, or alternatively the proximal tip of the device can be dip-coated with a dispersion of the antibiotics or other compounds and binder. Alternatively, a medicated pellet can be attached to the proximal end of the delivery device.

Figures 10 and 11 show external insertion and holding views for a Simon '364 urethral plug improved by attaching an active medicated pellet 60 affixed to the proximal end of the delivery device, where it can dissolve into the urine. Figures 12 and 13 show the same end achieved by a medicated

coating 61 over the outer the inflatable balloon. Figures 14 and 15 show similar views of a urethral plug modified by a medicated coating 62 on the wall of the shaft of the plug, where it can combat infection or other diseases in the walls of the urethra. Figures 16 and 17 illustrate that more than one outer surface can be utilized on a single delivery device. In any of these versions, an outer membrane may be useful for controlling and mediating the rate of dissolution of the solution of binder and antibiotics or other compound.

All of the modifications of Simon '364 are also applicable to Simon '285 (not shown).

In other embodiments, modes of delivering antibiotics on a modified urethral plug include: diffusion of medicine solution stored in the annulus between two concentric balloons through the permeable walls of the outer balloon, effusion of medicine solution from a concentric balloon through a small orifice, and osmotic effusion through an orifice from a chamber behind a semipermeable membrane.

It is understood that the preceding description is given merely by way of illustration and not in limitation of the invention, and that various modifications may be made thereto without departing from the spirit of the invention as claimed. The scope of the invention should be construed in accordance with the accompanying claims, having due regard for changes that are obvious to those skilled in the art.

CLAIMS:

1. A removable device for blocking unwanted flow of urine comprising:

an expandable housing forming a plug portion of the device which conforms to the shape of the urethra and defines an inner core which can accept a fluid;

a means for the wearer to insert the device to achieve continence including means for introducing fluid into the inner core to cause the configuration of the outer housing to distend sufficiently to reduce the flow of urine from a bladder when the device is inserted into a urethra by the wearer; and

a means for the wearer to remove the device to void including means for removing fluid in the core of the plug portion of the device so that the plug can be removed from the urethra by the wearer.

2. The device as set forth in claim 1 wherein the means for introducing fluid into the inner core includes a check valve in fluid communication with the inner core which permits flow of fluid through the check valve into the inner core.

3. The device as set forth in claim 2 wherein the means for introducing fluid into the inner core includes a bellows filled with fluid in fluid communication through the check valve with the inner core.

4. A method for preventing an unwanted discharge of urine comprising the following steps:

providing an expandable plug which can be inserted into the urethra;

inserting the expandable plug into the urethra;
expanding the plug in the urethra to restrict the flow of urine from the bladder through the urethra; and
deflating and removing the plug from the urethra when discharge of urine is desired.

5. A method for preventing an unwanted discharge of urine without first determining the location of the urinary sphincter comprising:
selecting an expandable plug which has been determined to conform to the length of the urethra;
inserting the expandable plug into the urethra
expanding the plug in the urethra to restrict the flow of urine from the bladder through the urethra; and
deflating and removing the plug from the urethra when discharge of urine is desired

6. A removable device for blocking unwanted flow of urine comprising:
an expandable housing forming a plug portion of the device which conforms to the shape of the urethra and defines an inner core which can accept a fluid;
a means for the wearer to insert the device to achieve continence including means for introducing fluid into the inner core to cause the configuration of the outer housing to distend sufficiently to reduce the flow of urine from a bladder when the device is inserted into a urethra by the wearer wherein the means for introducing fluid into the inner core includes a check valve in fluid communication with the inner core which permits flow of fluid through the check valve into the inner core, and a bellows

filled with fluid in fluid communication through the check valve with the inner core;

a means for the wearer to remove the device to void including means for removing fluid in the core of the plug portion of the device so that the plug can be removed from the urethra by the wearer; and

a meatal plate which is used to anchor the device at the meatus urinarius, and is attached to the bellows with the check valve positioned within the meatal plate.

7. The device as set forth in claim 6 wherein the means for removing fluid in the inner core includes two leaves which comprise the check valve which separate when the check valve is misaligned so the fluid returns through the check valve into the bellows.

8. The device as set forth in claim 6 wherein the means for removing fluid in the inner core further includes a distended portion which tends to return to its original undistended shape.

9. A removable device having a proximal end and a distal end for controlling passage of urine comprising:

a balloon affixed to the proximal end forming the plug portion;

a means for introducing fluid to inflate the balloon; and

a means for removing fluid to deflate the balloon.

10. The device as set forth in claim 9 wherein the means for introducing fluid into the balloon includes an interior balloon shaft defining a tunnel in fluid communication with the balloon.

11. The device as set forth in claim 10 wherein the means for introducing fluid into the balloon includes a lumen having a distal end and a proximal end, and in fluid communication with the balloon through the tunnel.

12. The device as set forth in claim 11 wherein the lumen has a fluid receiving port at the distal end.

13. The device as set forth in claim 12 wherein the lumen is defined as the space bounded externally by the balloon shaft, a sheath containing an internal ridge, a distal cap defining a conical aperture, and internally by a plunger having a proximal end, a distal end, and a cylindrical shape interrupted by a groove.

14. The device as set forth in claim 13 wherein
the balloon shaft is affixed to one end of a proximal spring;
the proximal end of the plunger is affixed to the other end of the proximal spring;
the distal end of the plunger is affixed to one end of a distal spring;
the distal cap is affixed to the other end of the distal spring;
the sheath circumferentially covers the plunger, the proximal spring, the distal spring, and a portion of the balloon shaft;
the sheath abuts the balloon and the distal cap; and
the internal ridge and the groove define a passageway.

15. The device as set forth in claim 14 wherein the fluid receiving port includes the aperture defined by the distal cap.

16. The device as set forth in claim 15 wherein the lumen includes a means for opening and closing the lumen.

17. The device as set forth in claim 16 wherein the means for opening and closing the lumen includes a means for sealing the passageway between the internal ridge of the sheath and the groove on the plunger.

18. The device as set forth in claim 17 wherein the means for sealing the passageway can be an O-ring secured to the groove.

19. The device as set forth in claim 18 wherein when the internal ridge is aligned with the O-ring, the O-ring quashes against the internal ridge and seals the passageway, and when the internal ridge is not aligned with the O-ring, the passageway is open.

20. The device as set forth in claim 19 wherein the means for introducing fluid into the balloon includes injecting fluid in the fluid receiving port.

21. The device as set forth in claim 20 wherein the fluid can be injected by means of a syringe through the aperture defined by the distal cap, and said syringe forms a seal with the aperture.

22. The device as set forth in claim 21 wherein the means for removing fluid includes a string attached to the distal end of the plunger.

23. The device as set forth in claim 22 wherein the means for removing fluid includes pulling the string.

24. A method for preventing unwanted discharge of urine comprising the following steps:

providing a removable device including an expandable balloon which can be inserted into the urethra, bladder neck or bladder;

inserting the removable device into the urethra, bladder neck or bladder;

inflating the balloon to restrict flow of urine from the bladder;

deflating the balloon by pulling on a means of deflating the balloon; and

removing the device from the urethra when voiding is desired.

25. The method as set forth in claim 24 wherein the means for deflating the balloon is a string attached to the device.

26. The method as set forth in claim 25 wherein the balloon of said removable device is deflated by pulling on a string.

27. The method as set forth in claim 26 wherein the balloon of said removable device is inflated by a separate applicator.

28. The method as set forth in claim 27 wherein the separate applicator is a syringe.

29. A method for delivering antibiotics or other therapeutic compound to an infected or diseased urinary tract comprising the following steps:

providing a removable delivery device having exterior surface and including an expandable proximal portion which can be inserted into the urethra, bladder or bladder neck;

adhering antibiotics or other therapeutic compound onto the delivery device;

inserting a system consisting of the delivery device and the antibiotics or other therapeutic compound into the urethra;

inflating the expandable portion of the device;

allowing the antibiotics or other therapeutic compounds to dissolve into the urine and/or onto the inner wall of the urethra;

deflating the expandable portion of the device;

removing the device from the urethra.

30. The method as set forth in claim 29 wherein the antibiotics or other therapeutic compound are adhered onto the delivery device by means of coating the exterior surface or portions of the exterior surface with a solution of antibiotics or other therapeutic compound and urine-soluble binder.

31. The method as set forth in claim 29 wherein the antibiotics or other therapeutic compound are adhered onto the delivery device by means of attaching a urine-soluble pellet containing antibiotics or other therapeutic compound to the proximal end of the delivery device.

32. The method as set forth in claim 29 wherein the antibiotics or other therapeutic compound are adhered onto the delivery device by means of coating the exterior surface or portions of the exterior surface with a solution of antibiotics or other compound and urine-soluble binder or by attaching a urine-soluble pellet containing antibiotics or other compound, or both.

33. The method as set forth in claim 32 wherein the rate of dissolution of antibiotics into the urine is controlled by covering the solution of antibiotics or other compound and urine-soluble binder with a permeable membrane.

34. The method as set forth in claim 33 wherein the rate of dissolution of antibiotics or other compound into the urine is further controlled by perforating the permeable membrane.

35. A method of treating a diseased urinary tract comprising inserting a plug coated with an effective amount of therapeutic agent into the urethra enabling the release of the agent while in place and thereafter removing the plug at the end of the treatment.

36. A device for the use in applying medical treatment to the urethra comprising a plug having a configuration such that it can be inserted and maintained in the urethra, said plug being coated with a binder, said binder being capable of binding it to a therapeutic agent to effect treatment.

37. The device according to claim 36 wherein said plug is coated with a binding agent selected from the group consisting of polyvinylpyrrolidone, carboxymethlcellulose, gelatin, or a lactide-glycolide copolymer.

38. A device for the use in applying medical treatment to the urethra comprising a plug having a configuration such that it can be inserted and maintained in the urethra, said plug being coated with a binder, said binder binding to a therapeutic agent.

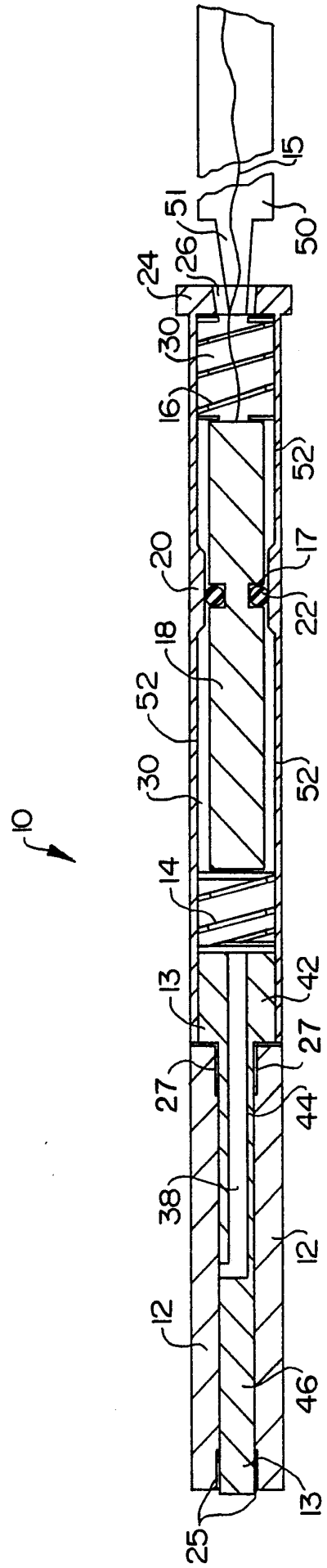
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FIG. 1

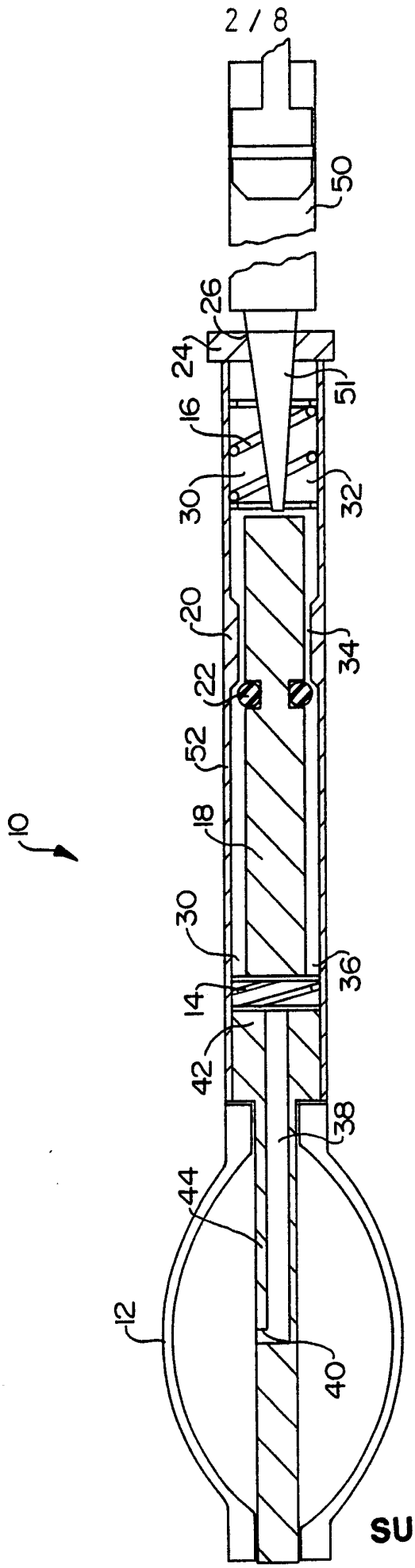

FIG. 2

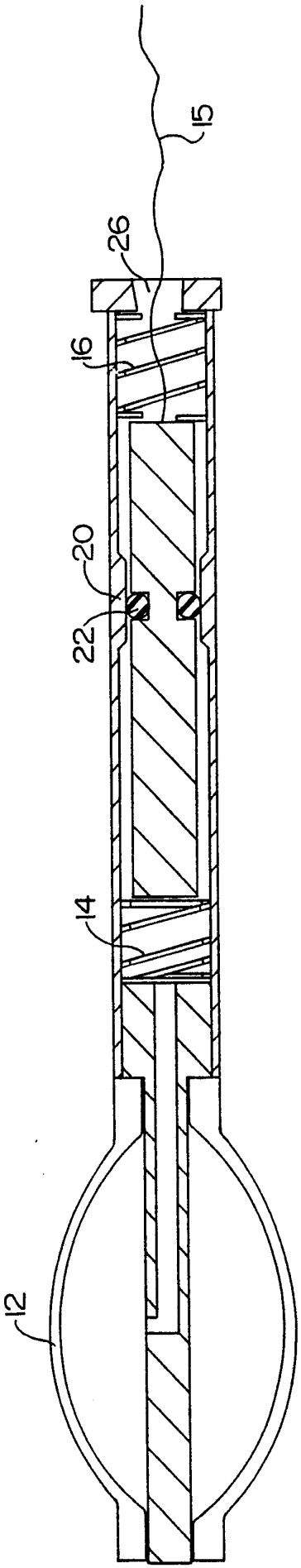

FIG. 3

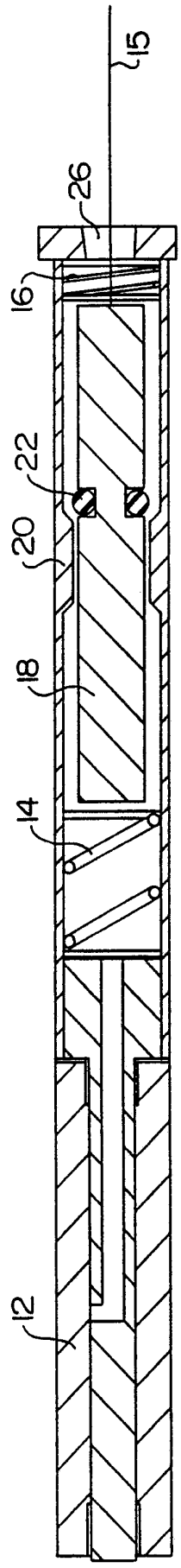

FIG. 4

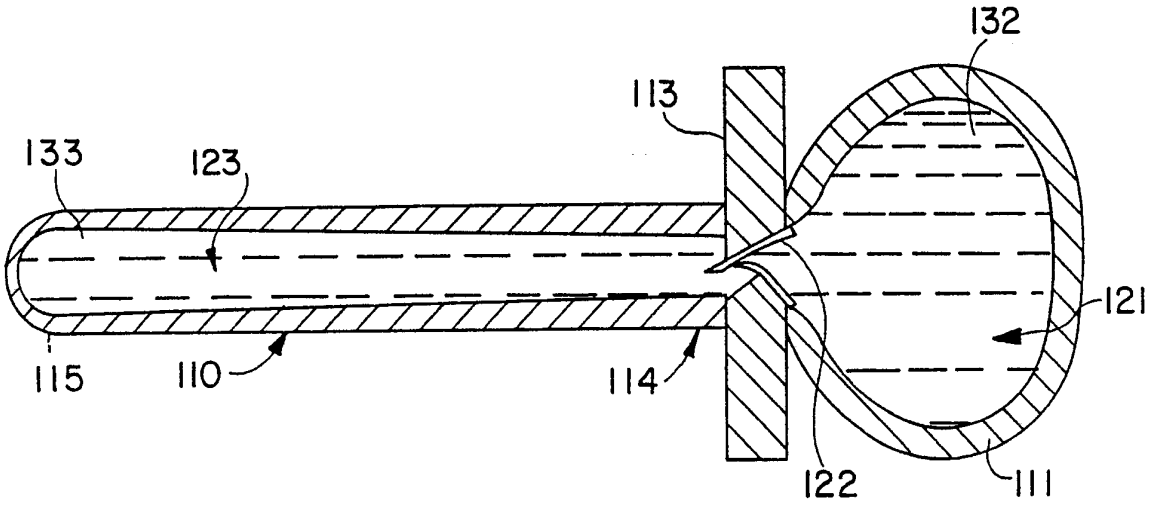

FIG. 5

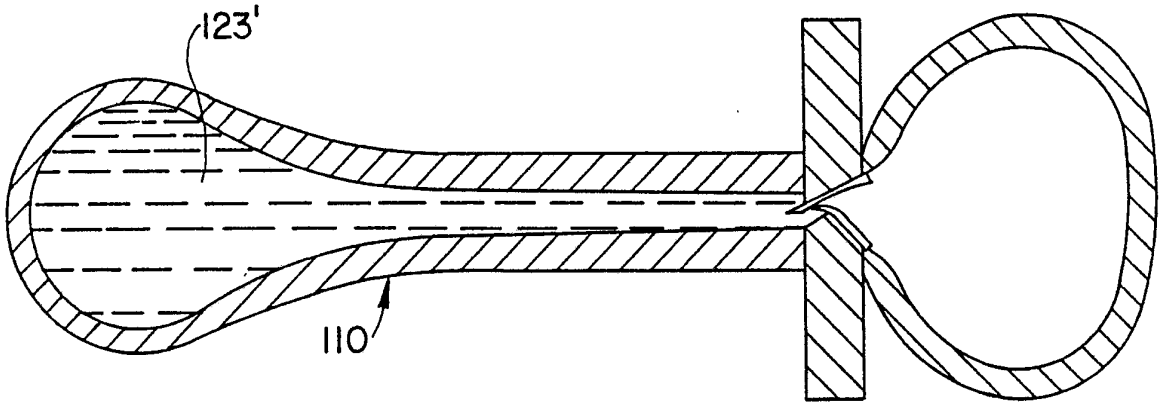

FIG. 6

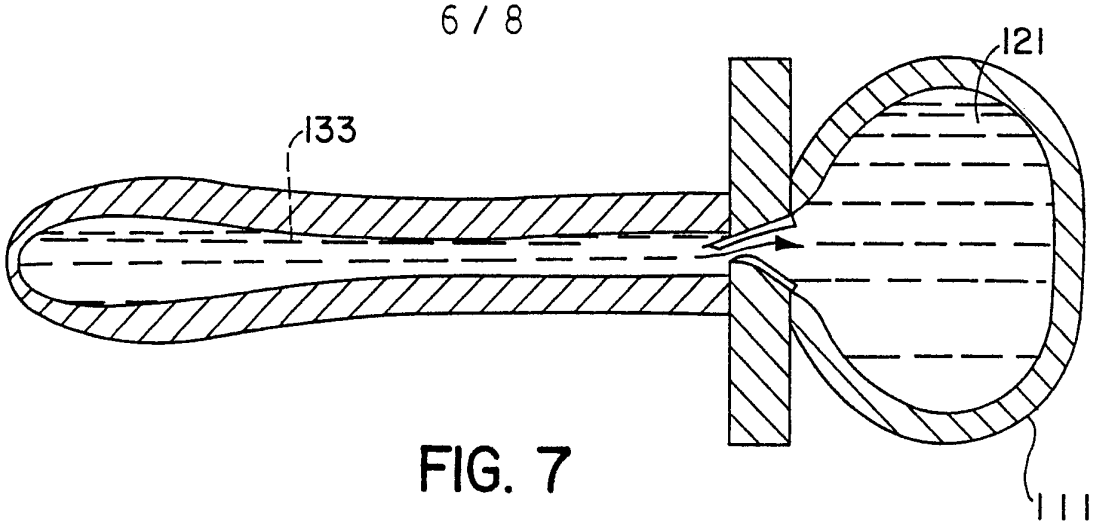

FIG. 7

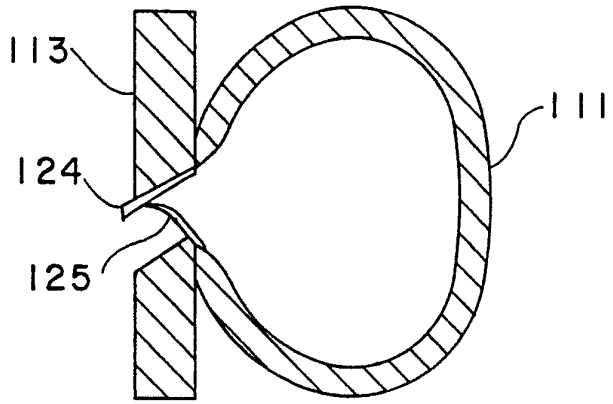

FIG. 8

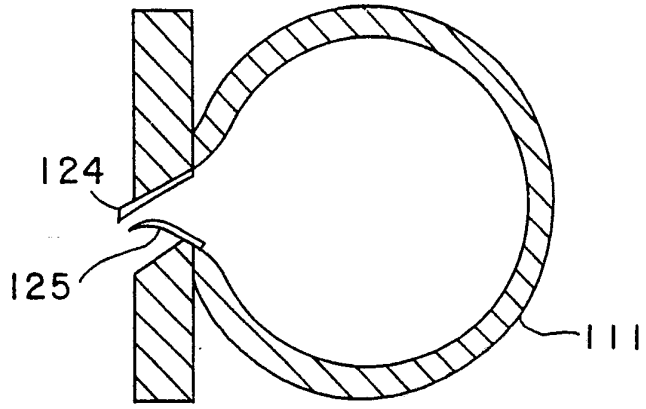

FIG. 9

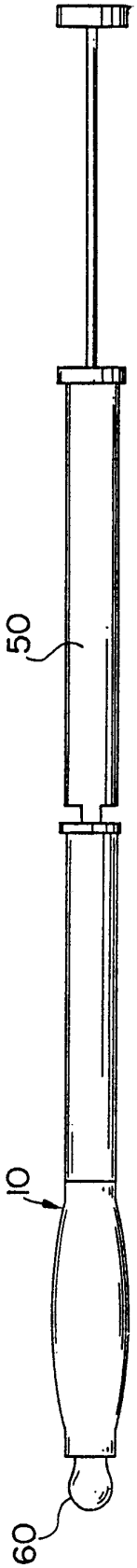

FIG. 10

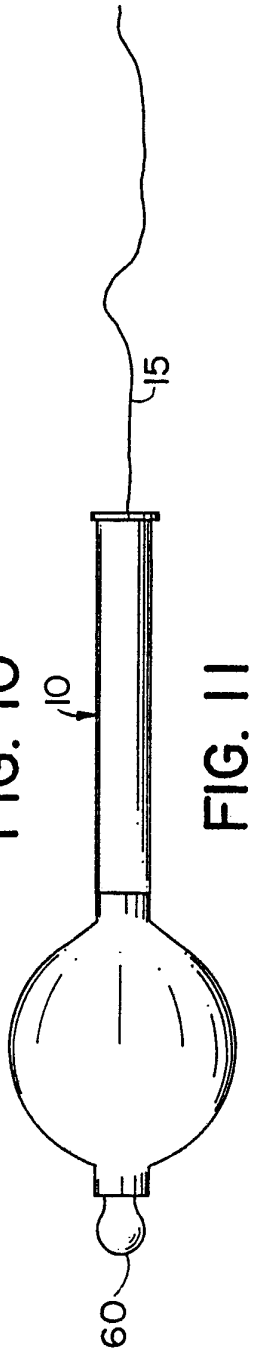

FIG. 11

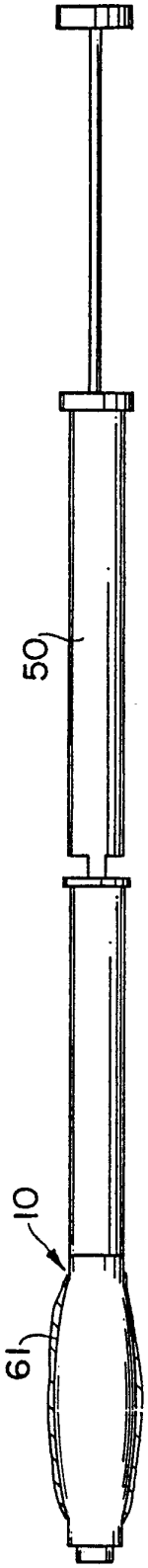

FIG. 12

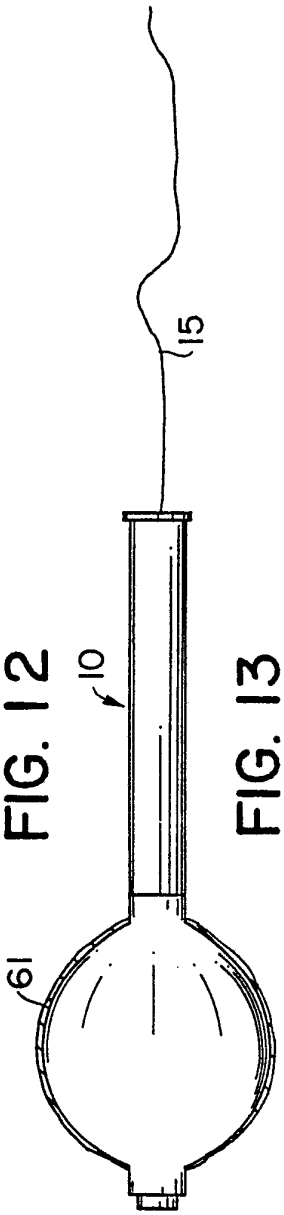

FIG. 13

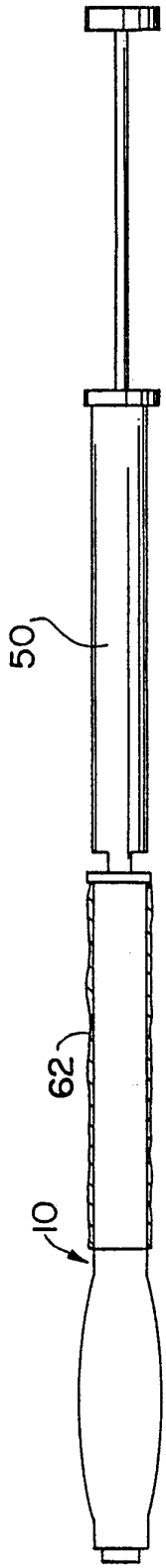

FIG. 14

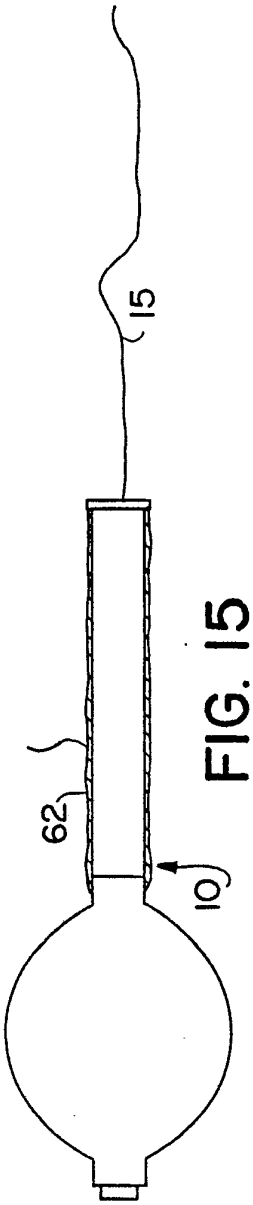

FIG. 15

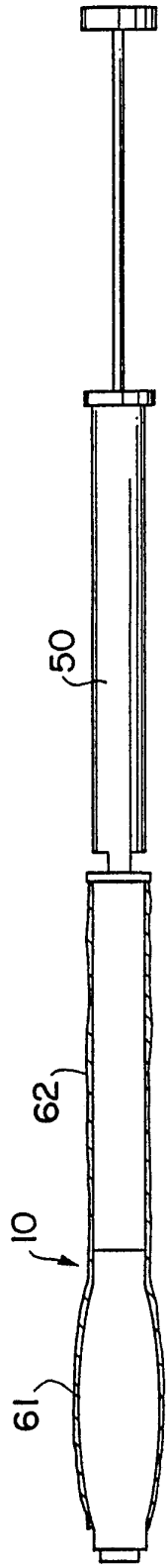

FIG. 16

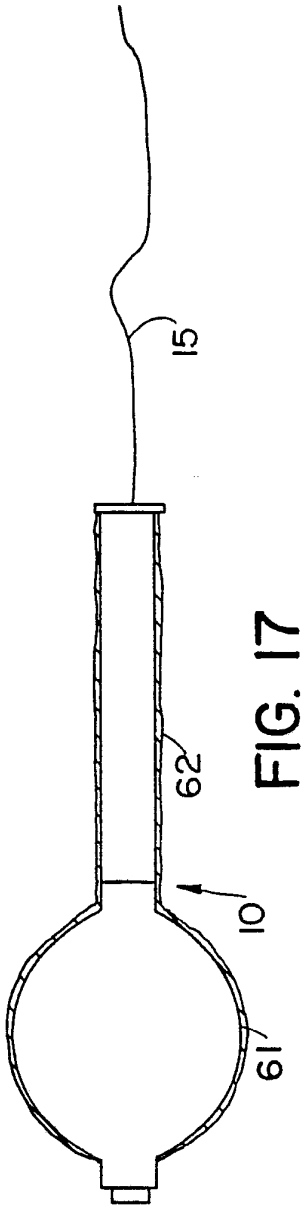

FIG. 17

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/09664

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61F 5/48

U.S. CL.: 128/885

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S. CL.	128/885, dig. 25; 600/29-31, 604/809.1, 96

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A X	US,A, 4,846,784 (HABER) 11 JULY 1989 See the entire document	1-8,25-38 9-11,24
A X	US,A, 2,494,393 (LAMSON) 10 JANUARY 1950 See the entire document	1-8,25-38 9-11,24
A X	US,A, 3,646,929 (BONNAR) 07 MARCH 1972 See the entire document	1-8,25-38 9-11,24
A X	US,A, 4,428,365 (HAKKY) 31 JANUARY 1984 See the entire document	1-8,25-38 9-11,24
A X	US,A, 3,841,304 (JONES) 15 OCTOBER 1974 See the entire document	1-8,25-38 9-11,24
A X	US,A, 2,638,093 (KULICK) 12 MAY 1953 See the entire document	1-8,25-38 9-11,24

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
23 MARCH 1992	16 APR 1992
International Searching Authority	Signature of Authorized Officer
ISA/US	For MICHAEL A. BROWN NGUYEN NGOC-HO INTERNATIONAL DIVISION

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers . . , because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

3. ☐ Claim numbers_____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

I-Claims 1-8 drawn to a removable device for blocking unwanted flow.
II- Claims 9-28 drawn to device for controlling the flow of urine.
III-Claims 29-34 drawn to a method for delivering antibiotics.
IV-Claims 35-78 drawn to a device and method used to treat a urinary tract.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest. .

☐ No protest accompanied the payment of additional search fees.