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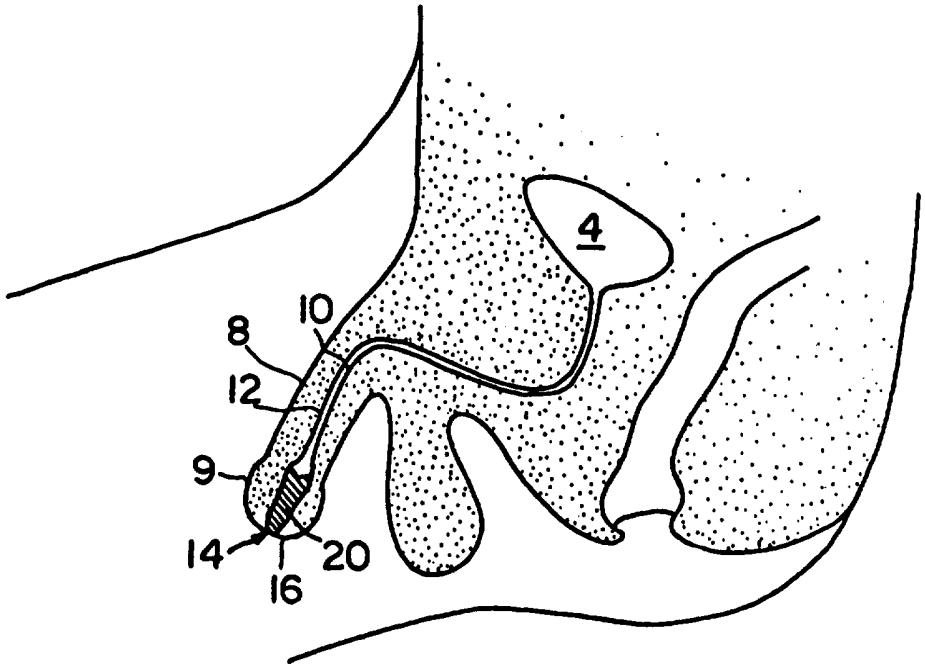
(54) Title: DEVICE AND METHOD FOR CONTROL OF URINARY INCONTINENCE

(57) Abstract



This invention features a urethral occlusion device and a method for controlling urinary incontinence. The method includes providing an occluding medium (20) that exhibits little or no tendency to flow when subjected to a shear stress less than a specified value. The user dispenses the occluding medium (20) into the urethra (10) by actuating a fluid reservoir (32) (e.g., squeezes a tube-like structure) of the medium. The occluding medium's (20) coaptation with the urethral walls (12) and the medium's non-flowing characteristic at low shear stress forms a seal, thereby blocking the unintentional discharge of urine. The occluding medium (20) is also resistant to expulsion from pressure of urine accumulating in the urethra (10) as well as body stress induced bladder pressure spikes. The method further includes removing the occluding medium (20) by the user manipulating the urethra (10) to force the occluding medium (20) out of the urethra (10) or by the user contracting the bladder (4), so the sustained increased pressure forces the occluding medium (20) out of the urethra (10). In addition, the occluding medium (20) may be vibrated to aid the removal of the occluding medium (20) when removing by contracting the bladder (4). After the occluding medium is removed, the user can void the bladder (4). In another embodiment, a removal device is provided which is used to remove at least a portion of the occluding medium (20) from the urethra (10).

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DEVICE AND METHOD FOR CONTROL OF URINARY INCONTINENCE

FIELD OF INVENTION

This invention relates to occlusion devices and methods for controlling incontinence and more particularly to urethral occlusion devices and methods for controlling urinary incontinence.

BACKGROUND OF THE INVENTION

Urinary stress incontinence is the involuntary loss of urine when the pressure within the urethra exceeds the urethral sphincter pressure available for maintaining continence. The problem of urinary incontinence occurs in men and women, although it is an affliction especially common in women of child bearing age and beyond.

There are in existence many methods used to address the problem of incontinence including surgical corrective techniques (e.g., bladder neck suspension surgery), surgically implanted indwelling devices, and physician prescribed and inserted indwelling devices. There are numerous risks associated with surgery, notwithstanding the expense and for some patients, corrective surgery is not recommended for medical or other reasons. Nor is it an appropriate solution for those with mild incontinence.

Surgically implanted devices are described in United States Patent Nos. 4,019,499, 3,789,828, 4,428,365 and No. 4,846,784. Some adverse affects associated with surgically implanted indwelling devices include encrustation, irritation, infection, toxic reactions to materials and tissue necrosis. Also, it may be necessary to perform additional surgery to remove the device due to device failure or complications. For non-manipulative type of surgically implanted devices severe tissue damage may result, and for manipulative type of surgically implanted devices, thickening and scarring of surrounding tissue often results. Indwelling devices that are inserted by a physician, without involving surgical

implantation, are described in United States Patent Nos. 4,850,963, No. 4,457,299, 4,553,533, 3,797,478, and 3,841,304. These devices are often cumbersome and uncomfortable to the wearer and often cause numerous complications such as encrustation, irritation and infection as well as having other limitations such as component migration and inserting a separate wire to remove the device.

There also are devices that are capable of being inserted by the wearer into the urethra. Such devices are removed for voiding, and then reintroduced into the urethra upon completion of bladder evacuation. Examples of such devices are described by Nielsen, Kurt K. et al., in "The Urethral Plug: A New Treatment Modality for Genuine Urinary Stress Incontinence in Women" J. Urology, vol. 44, p. 1100 (1990) and in United States Patent No. 5,090,424. There are also certain external devices that do not require insertion into the urethra, such as the urine absorbing pad described in U.S. Patent No. 5,074,855. Such pads are susceptible to migration and often lack effectiveness in preventing leakage. These pads may include a gel like material to absorb urine discharges.

Other external devices include those which use catheters and clamps. For a male, a clamping device is disposed about the penis so actuation of the device compresses the urethra thereby preventing the unintentional discharge of urine. The devices using a catheter involve collecting discharges from the urethra (e.g., using a condom type of mechanism about the penis) and transporting the collected urine to a storage bag or device.

These devices are uncomfortable for the users as well as making the voiding process complicated and cumbersome (e.g., clamping device has to be removed and re-secured for each voiding). The catheter devices, because they involve collecting urine external to the body, create the potential for undesirable odors and spillage as well as requiring the collected urine to be separately discharged. There is also the potential for irritation and maceration of tissue when

using the catheter devices such as the condom catheter. For clamping devices, there is also the potential for tissue necrosis in the clamp area.

As evidenced by the above discussion, the indwelling incontinence devices and associated methodologies involve devices that are uniquely constructed for insertion into and occlusion of the urethra. These occlusion devices are generally sized for a given user and generally include a means for retaining the device within the urethra (i.e., prevent migration). These devices also require a means to be provided to remove the device from within the urethra.

There is, therefore, a need for a urinary occlusion device that is comfortable and that is useable by any individual (i.e. without requiring the device to be sized for each application/ user) as well as a methodology for occluding the urethra using such a device.

SUMMARY OF THE INVENTION

It is, therefore, an object of the present invention to provide a method and means for controlling urinary incontinence that occludes the urethra using a medium such as gel, paste or non-Newtonian type of fluid.

It is another object of the present invention to provide a urethral occlusion device that does not require sizing for a given user.

It is a further object of the present invention to provide an occlusion medium that enhances coaptation with the mucosal tissue and urethra to seal the device within the urethra.

It is yet another object of the present invention to provide a means for comfortably and easily inserting the occluding medium into the urethra by the user.

It is yet a further object of the present invention to provide a means for removing the occluding medium disposed within the urethra.

This invention features a method and device for

controlling urinary incontinence. The method for controlling incontinence includes providing an occluding device comprising an occluding medium that exhibits little tendency to flow when subjected to a shear stress less than a specified value and dispensing a quantity of the occluding medium within the urethra. The quantity of the occluding medium being dispensed is sufficient to block the unintentional discharge of urine from a bladder. The occluding medium also may exhibit no tendency to flow when subjected to a shear stress less than the specified value. For another embodiment, the occluding medium being provided behaves as a solid material at applied shear stresses below the specified value and which behaves as a fluid when subjected to shear stresses above the specified value.

In further embodiments, the occluding medium is a bio-compatible gel or a bio-compatible non-Newtonian fluid. The specified shear stress below which the medium acts as a solid or exhibits little or no tendency to flow is at least 500 dynes per cm^2 and more particularly is at least 1000 dynes per cm^2. At least about 0.1 cc of occluding medium is dispensed into the urethra to block the flow of urine. Preferably, the amount dispensed is about .5 cc and more particularly an amount in the range of about 0.1 to about 5 cc is dispensed into the urethra.

The method further comprises the step of removing the occluding medium from within the urethra so the user can void their bladder. In one embodiment, the removing step includes having the user manipulate the urethra so as to cause the occluding medium therein to pass out of the natural urethral opening. In another embodiment, the removing step includes contracting the bladder thereby establishing a sustained elevated pressure within the bladder. This sustained elevated bladder pressure causes the occluding medium within the urethra to pass out of the natural urethral opening. Alternatively, the occluding medium is vibrated at least before, and may be vibrated during, the contraction of the bladder.

In an alternate embodiment, the occluding device being provided further includes a removal device having a first member. In this embodiment, the removal mechanism and occluding medium are dispensed so the occluding medium is disposed within the urethra so as to be between the first member and the natural urethral opening. For removal of the occluding medium, the first member is withdrawn from the urethra (i.e., out the natural urethral opening) so as to remove at least a portion of or essentially all of the occluding medium residing in the urethra. To accomplish this, the first member is appropriately configured (i.e., sized and shaped) to remove the desired amount of the occluding medium.

When removing a portion of the occluding medium, the amount being removed preferably is sufficient so the user easily voids through the urethra and any remnants of the occluding medium are washed away by the flowing urine. Otherwise, the user contracts the bladder thereby establishing a sustained elevated pressure within the bladder. This sustained elevated bladder pressure causes any occluding medium remaining within the urethra, after the first member is withdrawn, to pass out of the natural urethral opening.

The removal mechanism further includes a flexible second member, such as a string, that is attached to the first member. When dispensed, a portion of the second member lies within the urethra and another portion extends out from the natural urethral opening. For removal, the user pulls on or applies an outward force to the second member which causes the first member to be withdrawn from within the urethra as well as causing removal of the occluding medium.

In either of the foregoing methods, an applicator may be provided that is adapted for storing and dispensing the occluding device being provided for the above described embodiments. In use, the user positions the applicator so it is proximate to the natural urethral opening and more particularly disposes the applicator tip within the urethra. After appropriately locating the applicator the user dispenses the occluding device as hereinabove described.

Also featured herein is a device for controlling urinary incontinence. As hereinabove described, in one embodiment the device includes a sufficient quantity of an occluding medium that exhibits no or little tendency to flow when subjected to shear stresses below a pre-specified value. Alternatively, the device further includes a removal mechanism having a first member that is used to remove occluding medium from within the urethra. Reference should be made to the foregoing discussion for further details concerning these occlusion devices.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1-2 are cross sectional views of the urinary tract of a male and female respectively, where the occluding medium of the instant invention is disposed in the urethra;

FIG. 3 is a cross sectional view of the urinary tract and a device that dispenses the occluding medium into the urethra;

FIG. 4 is a cross sectional view of the urinary tract of a male, using an alternate occluding device according to the instant invention;

FIGS. 5-6 are views of two embodiments of the occluding medium removing device of FIG. 4;

FIGS. 7-8 are diagrammatic illustrations of the removal of the occluding device of FIGS. 4-6;

FIGS. 9-11 are views of applicators for storing and dispensing an occluding medium; and

FIGS. 12A-C are views of an applicator for storing and dispensing the occluding device of FIGS. 4-6.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The instant invention is most clearly understood with reference to the following definitions:

Newtonian fluids shall be understood to mean a fluid that deforms on the application of the smallest force or stress or, in other words, the smallest force or stress causes the fluid to flow. Newtonian fluids also generally exhibit a linear relationship between the shearing stress being applied to the fluid and the resultant rate of strain or deformation.

Non-Newtonian fluid shall be understood to mean a fluid that does not exhibit a linear proportionality or relationship between shear stress and rate of strain or deformation and/or a fluid that does not go through the origin of zero stress-zero rate of strain (i.e., characteristic curve intercepts shear stress axis). In general, a non-Newtonian fluid is a fluid whose viscosity or ability to flow depends on the shear stress being applied to the fluid. For example, in some cases the fluid does not flow at all, but rather acts essentially as a solid or semi-solid until the force or shear stress being applied exceeds some threshold value, characteristic of the fluid.

Coaptate and coaptation generally mean the adjustment or adaptation of things, parts and the like to each other or their fitting together. In the instant invention, such terms shall be understood to mean or describe the automatic adjustment, adaptation or fitting together of the occluding medium 20 to the urethra, bladder neck, mucosal tissue and bladder as well as the removal device of the instant invention.

There is shown in FIGS. 1-2, the urinary tract of a male (FIG. 1) and a female (FIG. 2), where the urethra 10 is occluded by an occluding medium 20. The occluding medium 20 is preferably a material, such as a gel or a non-Newtonian fluid, that shows or exhibits very little or no tendency to flow when a shear stress, below a given value, is applied to the material. The occluding medium 20 also preferably exhibits a time dependent behavior in response to applied stress so the material exhibits little or no tendency to flow from a shear stress that is applied over a short time period. The shear stress versus rate of strain property of the bio-compatible material, however, is also such that the user can consciously cause the material to flow sufficiently easily out of the urethra 10, such as for urination. The term material for the occluding medium 20 shall be understood to include combinations of separate constituents or materials.

There are two broad groupings of materials that are useable as an occluding medium 20 of the instant invention. The first material grouping generally includes those materials which exhibit no tendency to flow when a shear stress below a given value is being applied to the material. The characteristic curve for shear stress versus rate of strain for these materials intercepts the shear stress axis. Thus, at very low shear stress values the rate of strain for these materials remains zero until the applied shear stress exceeds a given characteristic or value (hereinafter "yield stress"), the point of intercept. Until this yield stress value is exceeded, the material does not flow but rather it behaves as a visco-elastic solid. When the applied shear stress exceeds the given yield stress characteristic or value, then the material starts to flow and behave as a fluid.

The second material grouping generally includes those materials which exhibit little tendency to flow when a shear stress below a given value is applied to the material. For these materials, the characteristic curve of shear stress versus rate of strain approaches the shear stress axis closely before curving sharply downward towards the zero-zero point. Thus, at very low shear stress values, which are also below a given value or characteristic, the material exhibits an extraordinarily high (e.g., near infinite but nonetheless finite) apparent viscosity. As such, these materials flow or deform very, very slowly when subjected to a low applied shear stress over a long time period (i.e. very little tendency to flow). Since the typical time period between urination is short in comparison to this "long time," the material, when it is disposed within the urethra 10, essentially does not flow. Essentially, at very low shear stress values, these materials behave, in practice, as though they had a yield stress.

The occluding medium 20 is a bio-compatible material that minimizes, avoids or does not exacerbate irritation, risk of urinary infection and /or carcinogenesis. The bio-compatible material is osmotically balanced so as to avoid excessive dehydration of the urethral mucosa when the occluding medium

is disposed within the urethra 10. Some dehydration of the mucous versus the mucosal tissue is acceptable, since it increases the ability of the boundary between the occluding medium 20 and the urethral walls 12 to withstand the forces to which it is subjected as hereinafter discussed. Thus, coaptation between the occluding medium 20 and the urethral walls is thereby improved. Also, the bio-compatible material minimizes diffusion or permeation of the urine accumulating within the urethra 10 so the urine does not diffuse or permeate into the occluding medium, softening it and allowing it to pass out through the natural urethral opening 14.

In addition, the bio-compatible material should be water soluble so remnants of the occluding medium 20 that may remain within the urethra 10 are cleared or washed away when the bladder 4 is being voided. This also assures that the occluding medium 20 that is expelled from the urethra 10 does not accumulate in the toilets and/or plumbing used for receipt and discharge of waste products. Thus, there is no special provisions needed for the disposal of the spent or expelled occluding medium 20 which makes it easy to use.

As indicated above, the occluding medium 20 of the instant invention includes a material composition made from a number of constituents. For example, a thickening agent such as fumed silica is mixed with a fluid such as water to yield a composition where, at low shear stress values, the composition behaves as a solid and where the composition behaves as a fluid when a shear stress value is exceeded. Another example of such a composition is arrived at by mixing polyethylene glycol in the liquid and powdered forms with water. A surfactant can also be added to any composition, as is known in the art, to improve the characteristics of the composition for its intended function as an occluding medium.

Other thickening agents that can be used alone or in combination to provide a composition having the desired physical characteristics include, but are not limited to: cellulose including methylcellulose, powdered cellulose and hydroxyethyl cellulose; polysaccharides including guar gum,

gellan gum, karaya gum, rhamsan gum, welan gum and xanathan gum; polyethylene glycol in either liquid or powdered form; propylene glycol; silicon dioxide; carbamide peroxide; carbopols; collagen; glycerin; kaolin; lanolin; mineral oil; and monoglycerides. The fluid or base material may be water, a fluid thickening agent such as polyethylene glycol, or any other bio-compatible fluid known in the art which is capable of being combined with a thickening agent to form a composition with the desired physical characteristics. The surfactants referred to above include polysorbate, sapponen, tween and triton.

When in the urethra 10, the occluding medium 20 coaptates with the walls 12 of the urethra so as to form a seal between the occluding medium and the mucosal tissue of the urethra. The seal between the occluding medium 20, the mucous layer and the urethral walls 12 in conjunction with the non-flowing characteristic (i.e., resistance to flow at low shear stress) of the occluding medium, establishes a barrier to the inadvertent discharge of urine. The occluding medium 20, when it is disposed within the urethra 10, also resists expulsion from the urethra due to the slow build-up of pressure from the urine, as it escapes from the bladder 4 into the urethra 10 through the incompetent sphincter, as well as being able to resist the momentary pressure spikes attributable to physical body stress such as that caused by coughing, sneezing, laughing or jogging. Simply, the physical properties of the occluding medium 20, i.e., no flow until reaching the true or effective yield stress value of the bio-compatible material, are such that it does not flow back out through the natural urethral opening 14 as a result of the fluid pressure (e.g., 50 cm of water) of the urine accumulating in the urethra 10 or as a result of pressure spikes (e.g., 200 cm of water) induced by body stress. The time dependent nature of the above described property of such bio-compatible materials also assures that the material does not become flowable until after a shear stress has been applied for a time period that is long in comparison to the time period of the pressure spike.

The occluding medium 20 of the instant invention and the method for using the occluding medium to occlude the urethra 10 of an individual can be further understood from the following discussion and with reference to FIGS. 1-3. In the following discussion, a syringe type applicator 30 is used, however, this is not a limitation as any means known in the art for dispensing the occluding medium 20 within the urethra 10, including those described hereinafter in connection with FIGS. 9-11 may be used. Reference should also be made to the discussion regarding FIG. 9, for further details regarding the syringe type applicator 30.

As preparation, the user removes the syringe applicator 30 from the sterile shipping packaging (not shown) and any other protective wrappings and/or covers, such as that protecting and sealing the tip 34 of the syringe applicator. For example, the user would twist or screw off a cap 45 (FIG. 10) that goes over the tip 34. Preferably, the occluding medium 20 is loaded into the body 32 of the syringe applicator 30 prior to shipment to simplify and ease in dispensing the occluding medium 20.

After preparing the applicator, the user locates the tip 34 at the natural urethral opening 14 and pushes on the plunger 38, thereby dispensing the occluding medium out of the tip 34 and into the urethra 10. Alternatively, the user inserts the so located tip 34 through the natural urethral opening 14 and into the urethra 10 until the applicator flange 36 rests or abuts the meatus 16 (i.e., fully inserting the tip 34). After fully inserting the tip 34 within the urethra 10, the user pushes on the plunger 38 to dispense the occluding medium 20 into the urethra 10. As indicated above, since the occluding medium 20 is a highly viscous gel, paste or non-Newtonian type of fluid, the occluding medium must be forced out of the fluid reservoir 32 and tip 34 into the urethra 10. To occlude the urethra, at least about 0.1 cc of the occluding medium 20 is dispensed; more particularly, the occluding medium being dispensed is in the range of from about 0.1 to about 5 cc; and preferably about 0.5 cc of the occluding

medium is dispensed. The amount of occluding medium 20 being dispensed to occlude the urethra 10 is dependent upon a number of factors including the sex of the user as well as the severity and type of incontinence.

After dispensing the occluding medium 20, the user removes and disposes of the applicator 30. If the tip 34 was inserted into the urethra 10, such removing includes removing the tip from within the urethra. Following removal, the user may manipulate the urethra 10, in a fashion similar to that described hereinafter (e.g., squeezing the corona 9 of the penis 8), so as to force the occluding medium 20 further along the urethra 10 away from the natural urethral opening 14.

While FIGS. 1-3 illustrate the occluding medium 20 as being dispensed so it is proximal the natural urethral opening 14, this is not a limitation as the occluding medium 20 may be dispensed so as to be in the urethra 10 at a distance from the natural urethral opening 14. Also, while the foregoing describes dispensing the occluding medium 20 while the applicator tip 34 is in a fixed relation with respect to the meatus, the occluding medium 20 may be dispensed while removing the applicator 30/ tip 34 from within the urethra 10.

Once dispensed, the occluding medium 20 remains within the urethra 10 until the user wants to void the bladder 4 or otherwise remove the occluding medium 20 from the urethra. Using one technique, the user manipulates the urethra 10 so as to cause the occluding medium 20 to pass out of the natural urethral opening 14. For example, a male would manipulate the penis 8 and a female would manipulate the urethra 10 through the vagina 6. Alternatively, the user pushes down on or contracts the bladder 4 so as to create and sustain an increased fluid pressure within the bladder. This sustained increased bladder pressure forces the occluding medium 20 out of the urethra 10.

Using yet another technique, a vibration source, such as a mechanical vibration device, is disposed proximal the urethra 10 so as to impose a cyclical or vibratory stress on the occluding medium 20. This cyclical or vibratory stress

induces a fluid behavior in the bio-compatible material so it will flow responsive to normal urination pressures. For females, the vibration source is inserted into the vagina 6 proximate the vaginal wall near the urethra and for males, the vibration source is disposed on the underside of the penis 8 adjacent the urethra 10.

Once the occluding medium 20 is essentially removed from within the urethra 10, the user voids the bladder 4. The voiding action, should clear out any remnants of the occluding medium 20 that may be left within the urethra 10 following the above described removal actions. Following voiding, the user repeats the above as and when needed to occlude the urethra 10 and/or to void the bladder 4.

There is shown in FIG. 4 a cross sectional view of the urinary tract of a male, in which an alternate occluding device embodiment occludes the urethra 10. As shown in FIGS 7-8, this occluding device is also useable to occlude the urethra 10 of a female. The alternate occluding device includes an occluding medium 20, as hereinabove described, and a removal device 22.

Referring also to the exemplary embodiments of the removal device 22 shown in FIGS. 5-6, the removal device 22 includes a head portion 26a,b and a string 24 being attached thereto. The string 24 is a flexible material having sufficient strength so the head portion 26a,b can be withdrawn from a urethra occluded with the occluding medium 20. The string 24 and head portion 26a,b are made from a bio-compatible material such as thermoplastic elastomer, plastic or foam material. The string 24 also may be cotton, dacron or nylon. The head portion 26a,b may be provided with any geometric shape. Preferably, the head portion 26a,b is configured and sized with a shape that is atraumatic and easy to insert into the urethra 10 using any of a number of applicator devices, including those described hereinafter.

There is shown in FIG. 5 one embodiment of a head portion 26a which is essentially spherical in shape. Alternatively the head portion may have a generally conical shape with a

rounded tip and more particularly, as shown in FIG. 6, the head portion 26b may be configured so, in cross section, it forms an arrow headed shape. As discussed hereinafter, these two head portions 26a,b may be sized differently to effect different levels of removal of the occluding medium 20 from within the urethra 10.

Referring back to FIG. 4, when the occluding medium 20 and the removal device 22 are disposed within the urethra 10, the head portion 26a,b (FIGS. 5-6) is distal from the natural urethral opening 14 so the occluding medium 20 is disposed between the head portion 26a,b and the natural urethral opening. The string 24 passes through the occluding medium 20 and out of the natural urethral opening 14 so a portion of the string extends out from the natural urethral opening.

In this embodiment, the occluding medium 20 coaptates with the urethral walls 12, the string 24 disposed within the urethra 10, and the head portion 26a,b so as to form a seal between the occluding medium 20, the removal device 22 and the mucosal tissue of the urethra. This seal, in conjunction with the non-flowing characteristic of the occluding medium 20, establishes a barrier to the inadvertent discharge of urine. As described hereinabove, this seal and the non-flowing characteristic of the occluding medium at low shear stress, also makes the occluding medium 20 resistant to expulsion from the urethra 10 due to the slow pressure buildup from the urine accumulating in the urethra 10 and due to transient bladder pressure conditions. Although the head portion 26a,b also coaptates with the urethral walls 12 and thereby forms a seal to block the flow of urine, the primary urine blocking mechanism is the occluding medium 20.

The occluding device of the instant invention and the method for using this occluding device can be further understood from the following discussion and with reference to FIGS. 3-8, 12A. In the following discussion, a syringe type applicator 60 (FIG. 12A) dispenses the occluding medium 20 and the removal device 22 comprising the occluding device.

However, this is not a limitation as any means known in the art may be used for dispensing the occluding medium 20 and the removal device 22 into the urethra 10, including that described in connection with FIGS. 12A-C. Reference should also be made to the discussion above regarding FIGS. 1-3, for additional details regarding the method of use as well as to the following discussion concerning FIGS. 12A-C for additional details concerning the syringe type applicator 60.

As preparation, the user removes the syringe applicator 60 from the sterile shipping packaging (not shown) and the user removes any other protective wrappings and/or covers such as the cover protecting and sealing the tip 64 of the syringe applicator 60. For example, the user could break off a break away tip 55 (FIG. 11) sealing the tip 64. Typically the occluding medium 20 and removal device 22 are loaded into the syringe applicator 60 prior to shipment to simplify and ease dispensing them into the urethra 10.

After preparing the applicator, the user locates the tip 64 at the natural urethral opening 14 and pushes on the plunger 68, thereby dispensing the occluding medium 20 and the part of the removal device 22 (e.g., the head portion 26a,b) out of the tip 64 and into the urethra 10. Alternatively, the user inserts the so located tip 64 through the natural urethral opening 14 and into the urethra 10 until the applicator flange 66 rests or abuts the meatus 16 (i.e., fully inserting the tip 64). After fully inserting the tip 64 within the urethra 10, the user pushes on the plunger 68 to dispense the occluding medium 20 and a part of the removal device 22 into the urethra 10. Once dispensed, the removal device 22 and the occluding medium 20 lie in the urethra as shown in FIG. 4. Reference should be also made to the discussion above regarding FIGS. 1-3 for other details regarding dispensing the occluding medium 20 including the amount of occluding medium 20 being dispensed.

After dispensing the occluding medium 20 and a part of the removal device, the user removes the remaining portion of the removal device 22 from the applicator 60 and disposes of

the applicator. If the tip 64 was inserted into the urethra 10, such removing includes removing the tip from within the urethra. Following removal, the user may manipulate the urethra 10, in a fashion similar to that described hereinabove (e.g., squeezing the corona 9 of the penis 8), so as to force the occluding medium 20 further along the urethra 10 away from the natural urethral opening 14. As also discussed above, the occluding medium 20 and removal device 22 may be dispensed within the urethra 10 so as to be at a distance from the natural urethral opening 14 and they may be dispensed while removing the applicator 60 from the urethra 10.

Once dispensed, the occluding medium 20 and the removal device 22 remain disposed within the urethra 10 until the user wishes to void the bladder 4 or otherwise remove the occluding medium 20 from the urethra. As diagrammatically illustrated in FIGS 7-8, to void the user preferably pulls on the portion of the string 24 extending from natural urethral opening 14 to withdraw the head portion 26a,b out the natural urethral opening 16 and thereby remove at least a portion of the occluding medium 20 disposed within the urethra 10.

Preferably, withdrawing the head portion 26a,b removes at least a sufficient amount of the occluding medium 20 so the urine flows relatively unimpeded from the bladder 4 and through the urethra 10 (e.g., a channel or passage is formed in the occluding medium). As indicated above (see FIGS. 1-3 discussion), any occluding medium remnants in the urethra 10 should be cleared out when voiding the bladder 4. Alternatively, the head portion may be sufficiently sized and appropriately shaped, such as the illustrated arrow-headed shaped head portion 26b, so withdrawal of the head portion removes substantially all of the occluding medium 20 so the urethra 10 is considered essentially free of the occluding medium 20. However, the head portion 26a,b is sized and shaped to remove at least a portion of the occluding medium 20 from the urethra 10 so the user easily ejects or expels any remaining occluding medium by pushing down on or contracting the bladder 4. The described head portions 26a,b (FIGS. 5-8)

are exemplary as the head portion may be provided with any geometric shape that can be easily and comfortably inserted into the urethra 10 and which removes the occluding medium 20, as hereinabove described, when the head portion 26a,b is withdrawn from the urethra.

In yet another embodiment, the removal device 22 may be a string like member having a size and configuration such that at least a portion of the occluding medium is removed from the urethra 10 when the string like member is removed. A part of the string like member also may be configured, such as with a knot, so this portion provides a greater cross section for the removal of the occluding medium than other portions of the string like member. The string like member may be a circular string, a flat ribbon, or similarly constructed materials. The string like member, when it is withdrawn from the urethra 10, removes a portion of the occluding medium 20 so urine flows relatively unimpeded through the urethra 10 or so the occluding medium 20 remaining within the urethra is easily expelled or ejected by the user by contracting the bladder 4.

The above described process is repeated as and when needed to void the bladder, to remove the occluding medium 20 and/or to occlude the urethra 10.

The occluding medium 20 provides a means for occluding the urethra 10 that is easily disposed of following use, that does not create a condition that is conducive to generating undesirable odors, and that does not involve a cumbersome process for urination. In contrast to known indwelling device, the occluding medium 20 of the instant invention can be discharged or disposed directly into the vessel (e.g., toilet) that receives the urine. Known remove to void devices must be collected after removal and separately disposed of by the user.

Since there are no cumbersome devices (e.g., clamps) that have to be removed or operated for voiding, the occluding device of the instant invention yields a simple and comparatively normal urination procedure for voiding one's bladder 4. In contrast, known remove to void devices

generally require the user to follow a set procedure for removing the device from the urethra 10 and inserting a new device or reusing the indwelling device. Similarly there is a set procedure that must be followed to operate a void through device. In addition for known remove to void devices, removing and disposing of the device requires the user to contend with the privacy issue attendant with voiding in public restrooms (e.g., the device being removed is observable by others).

The occluding device of the instant invention avoids conditions which can create undesirable odors since it occludes the urethra to prevent inadvertent discharges of urine. In contrast, some known devices (e.g., pads, condom catheters) do not prevent inadvertent discharges but rather collect urine discharges outside of the body. This creates the potential for undesirable odors as well as the potential for accidental releases of the urine (e.g., the pad becomes saturated, collection bag leaks or is dropped).

Also, since the occluding device, e.g., the occluding medium 20, of the instant invention is contained within the urethra 10, the device is relatively unobservable to others. In contrast, some known occluding devices such as clamps, catheters and pads can alter the physical appearance of an individual, even if only slightly, so the user is self-conscious about their appearance.

It should be recognized that the materials of the occluding medium 20 are such that the occluding device of the instant invention automatically conforms to the urethra 10 of a given individual without involving any external action on the part of the user. This is in contrast to some known occlusion devices where the urethra 10 must conform to the shape of the device as well as conforming to any outwardly extending projections of the device. These known devices also have fixed preestablished configurations within the urethra and, as such, they cannot be optimized for a given user without requiring the device to be sized or customized for the particular use.

There is shown in FIGS. 9-11 a syringe type applicator 30, a squeeze tube type applicator 40, and a squeeze bulb type applicator 50) respectively, where each dispenses an occluding medium 20 into the urethra 10. The illustrated applicators are not exhaustive of the types and designs of applicators or devices that may be used to dispense the occluding medium 20 of the instant invention, but rather are exemplary and are intended to generally describe the characteristics such devices should include.

The syringe type applicator 30, also discussed in connection with FIGS. 1-3, includes a body 32, a tip 34, a flange 36 and a plunger 38. Preferably, the body 32, tip 34 and the flange 36 are formed as an integral structure. The body 32 is hollow and sized to provide a reservoir or storage location for at least the required volume of the occluding medium 20 to be dispensed within the urethra 10 (FIG. 1). The interior of the body 32 is in fluid communication with the tip 34 so the occluding medium 20 is dispensed out through the aperture in the tip 34 when the user pushes on the plunger 38. The plunger 38 may be spring actuated, trigger actuated or operated or actuated using any of a number of techniques known in the art.

As illustrated in FIG. 9, the tip 34 projects upward from the inside surface 37 of the flange 36. In one embodiment, as discussed above, the tip 34 projects a specified distance above the flange 36 so the tip 34 is inserted beyond the natural urethral opening 14 (FIG. 1) into the urethra 10 when the flange inside surface 37 abuts the meatus urinarius 16. Alternatively, the tip 34 and the flange 36 are arranged so the tip 34 is positioned at the natural urethral opening 14 when the flange inside surface 37 abuts the meatus urinarius 16 (FIG. 1).

The end of the tip 34 is atraumatic to minimize damage and injury to the mucosal tissue of the urethra 10 when inserted therein. The tip 34 is also cylindrical in shape, however, the tip 34 may be configured with any geometric shape

that minimizes mucosal tissue damage and which makes insertion of the tip 34 easy and comfortable for the user.

For shipment, the tip 34 of the applicator 30 is typically sealed to prevent the inadvertent release of the stored occluding medium 20, to maintain the sterility of the occluding medium in the body 34 and to protect the tip 34. As such, the tip 34 is configured with a means that closes or seals off the aperture for storage and shipment and that is removed by the user as part of preparing the applicator 30 to dispense the occluding medium 20. In one embodiment, as shown in FIG. 11, the tip end sealing means is a break away portion 55 that is broken off or removed from the tip 34 by the user before insertion. Alternatively, as shown in FIG. 10, the tip end sealing means is a cap 45 that is pulled, twisted or screwed off the tip 34.

The flange 36 preferably is circular and generally configured to conform to the meatus 16 and to locate the tip 34 at the natural urethral opening 14. Alternatively, the flange 36 and tip 34 are configured so as to locate the tip 34 at the desired distance in the urethra 10 for dispensing the occluding medium 20. The flange 36 also may be configured with a three dimensional shape for better conformance with the meatus 16 of the user. For example, the flange 36 may be given a concave shape so the flange 36 conforms better to the meatus of a penis 8 (FIG. 1).

It is within the scope of the instant invention for the flange 36 to be configured with any geometric shape and any size that will allow the applicator tip 34 to be at least positioned at the natural urethral opening 16 so the occluding medium is dispensed within the urethra 10 and more particularly so the tip 34 is disposed at the desired location within the urethra. Also while providing the applicator 30 with a flange 36 is preferred, it is within the scope of the present invention for an applicator 30 to be configured without a flange. In this case, the user locates the tip 34 at the natural urethral opening 16, as well as inserting the

tip so it is within the urethra 10, before dispensing the occluding medium 20.

The applicator 30, including, the body 32, tip 34, flange 36 and plunger 38 are made from bio-compatible materials such as polypropylene, polyethylene or a thermoplastic elastomer such as polyurethane using any of a number of manufacturing techniques known in the art such as injection molding, blow molding or thermoforming. The material of construction for these components of the applicator 30 also maintains the sterility of the occluding medium 20 during shipment and storage. In general, the selected material and thicknesses of the applicator components (e.g., body 32, plunger 38) is such that the components have the required strength and material characteristics for the intended use.

There is shown in FIG. 10 a squeeze tube type applicator 40 having a body 42, a tip 44, and a flange 46 and where the body 42, the tip 44 and the flange 46 are preferably formed as an integral structure. The body 42 is hollow and sized to provide a reservoir or storage location for at least the required volume of the occluding medium 20 to be dispensed. The body 42 is also a flexible tube like structure that is manipulated (e.g., squeezed) by the user to force the occluding medium 20 out of the body 42, through the aperture in the tip 44 and into the urethra 10. As aforementioned, the tip 44 is sealed using any of a number of means or techniques including a cap 45 or a break away portion 55 (FIG. 11). Reference should be made to the FIG. 9 discussion above for other details of such an applicator 40 (e.g., materials of construction).

There is shown in FIG. 11 a squeeze bulb type applicator 50 having a body 52, a tip 54, and a flange 56, where the body 52, the tip 54 and the flange 56 are preferably formed as an integral structure. The body 52 is hollow and sized to provide a reservoir or storage location for at least the required volume of the occluding medium 20 to be dispensed. The body 52 is also a flexible bulb like structure that is manipulated (e.g., squeezed) by the user to force the

occluding medium 20 out of the body 52, through the aperture in the tip 54 and into the urethra 10. As aforementioned, the tip 54 is sealed using any of a number of means or techniques including a cap 45 (FIG. 10) or a break away portion 55. Reference should be made to the discussion above concerning FIGS. 9-10 for other details of such an applicator 50 such as the materials of construction.

The above described applicators 30,40,50 provide a means by which a user can easily and comfortably dispense the required volume of the occluding medium 20 so as to occlude the urethra 10 and block unintentional discharges of urine. These applicators are compact and light weight so a user can easily bring the applicator along on vacation trips, shopping and in social settings. Since the constructions and materials of these applicators 30,40,50, as well as the occluding medium 20, are not bio-hazardous, it is relatively easy for the user to dispose of the applicator after dispensing the occluding medium as well as disposing of the used occluding medium.

There is shown in FIGS. 12A-C an applicator 60, also discussed in connection with FIGS. 4-8, that dispenses into the urethra 10 (FIG. 4) the occluding medium 20 and the removal device 22 of either removal device shown in FIGS. 5-6. The illustrated applicator is not exhaustive of the types and designs of applicators or devices that may be used to dispense the occluding medium 20 and removal device 22, but rather is exemplary and is intended to generally describe the characteristics such devices should include for dispensing these items 20,22.

The applicator 60 is a syringe type of applicator, having a body 62, a tip 64, a flange 66 and a plunger 68. Preferably, the body 62, tip 64 and the flange 66 are formed as an integral structure. The body 62 is hollow and sized to provide a reservoir or storage location for at least the required volume of the occluding medium 20 to be dispensed within the urethra and the head portion 26a,b of the removal device 22. The body interior is also in fluid communication

with the tip 64, in particular the through aperture of the tip.

The plunger 68 includes a hollow portion 69 in which a portion of the string 24 of the removal device 22 is located, the portion of the string 24 which extends from the natural urethral opening 14 after the removal device 22 is inserted into the urethra 10. The plunger 68 may be spring actuated, trigger actuated or operated/ actuated using any of a number of techniques known in the art.

The head portion 26a of the removal device 22, as shown in FIG. 12B, is partially disposed in the tip 64 or alternatively, as shown in FIG. 2C, the head portion 26b is disposed within the tip. This is not a limitation, however, as the head portion 26a,b may be disposed within the applicator tip 64 or the applicator body 62 as well as extending from the tip 64 to any degree. In this way, when the applicator 60 is loaded, the occluding medium 20 is located between the head portion 26a and the end of the plunger 68 that is disposed in the body 62.

When the plunger 68 is actuated or operated, the head portion 26a exits the aperture in the tip 64 and travels on top, or on the leading edge, of the occluding medium 20 that is being dispensed from the applicator 60. As indicated above, a portion of the string 24 is dispensed along with occluding medium 20 and head portion 26a,b and the remaining portion of the string is removed from the applicator 60 so it extends from the natural urethral opening 16.

As aforementioned, the tip 64 is preferably sealed and protected using any of a number of means or techniques including a cap 45 (FIG. 10) or a break away portion 55 (FIG. 11). Reference should be made to the discussions above about FIGS. 9-11 for other details of such an applicator 60 (e.g., materials of construction, tip design).

This applicator 60 provides a means by which a user can easily and comfortably dispense the required volume of the occluding medium 20 to occlude the urethra 10 along with a removal device 22 that is used to remove at least a portion of

the so dispensed occluding medium 20 for voiding. Since the constructions and materials of the applicator 60, as well as the occluding medium 20 and removal device 22, are not bio-hazardous, it is relatively easy for the user to dispose of the applicator after dispensing the occluding medium as well as dispensing of the spent occluding medium and removal device.

The lower urinary tract as well as the urethra and bladder are subject to a variety of disorders and/or bacterial infections. These disorders/infections are treatable using either described urinary occlusion device of the instant invention as a medicine delivery system for patients suffering from lower urinary tract infections or other urinary disorders, and disorders of the urethra and bladder. Accordingly, in a yet further embodiment of the instant invention, the medicine to be delivered to the urinary tract and/or bladder is dispersed within the occluding medium 20. Further, the occluding medium 20 can be so configured to deliver medicine to those having known disorders/ illnesses as well as to deliver medicine to minimize the risk of the onset of urinary tract infections and such disorders/illnesses.

Infections involving bacteria and other disorders in the urine and/or in the superficial regions of the urethral and bladder tissues are in most situations, highly amenable to treatment by the direct release of antibiotics or other compounds into the urine in the bladder or into the urethral walls. The antibiotics or other compounds include sulfonamides, tetracycline, ampicillin or amoxicillin, trimethoprim, trimethoprim/ sulfamethoxazole, or ciprofloxacin hydrochloride. These antibiotics or treatment compounds are dispersed alone or in combination in the occluding medium 20 of the instant invention.

In addition to antibiotics, a pain medicant such as benzocaine and lidocaine can be dispersed in the occluding medium alone, in combination with other pain medicants, or in combination with the antibiotics hereinabove described. Such pain medication is used primarily to numb mucosal tissue

within the urethra 10 during and following the insertion of the occluding medium 20 as well as the removal device 22 into the urethra.

Alternatively, or in combination with dispersing the medicine in the occluding medium 20, the head portion 26a,b of the removal device 22 may be configured with a medicine containing pellet that is attached to a part (e.g., the tip) of the head portion. For example, the medicine containing pellet is bonded to the tip of the arrow-headed head portion 26b (FIG. 6) using cyanoacrylate glue. Thus, when the head portion 26a,b of the removal device 22 is disposed in the urethra, the medicine containing pellet is in fluid communication with at least the bladder 4 so the medication is dispersed into the urine. Preferably, the medicine containing pellet is applied or affixed to the head portion 26a,b when the occlusion device is being packaged by the manufacturer.

While a preferred embodiment of the invention has been described using specific terms, such description is for illustrative purposes only, and it is to be understood that changes and variations may be made without departing from the spirit or scope of the following claims, giving due regard for those changes that are obvious to those skilled in the art, including other antibiotics or compounds not identified herein that can be used for treatment of urinary infections or disorders as well as other techniques for delivering the medicine using the urinary occlusion device of the instant invention.

CLAIMS

What is claimed is:

1. A method for controlling urinary incontinence by occluding a urethra, comprising the steps of:

providing an occluding medium that exhibits little tendency to flow when subjected to a shear stress less than a specified value; and

dispensing a quantity of occluding medium within the urethra, where the quantity being dispensed is sufficient to block the unintentional discharge of urine from a bladder.

2. The method for controlling urinary incontinence of claim 1, wherein the occluding medium being provided exhibits no tendency to flow when subjected to a shear stress less than the specified value.

3. The method for controlling urinary incontinence of claim 1, wherein the occluding medium being provided behaves as a solid material at applied shear stresses below the specified value and which behaves as a fluid when subjected to shear stresses above the specified value.

4. The method for controlling urinary incontinence of claim 1, wherein the specified shear stress value is at least 500 dynes per square centimeter.

5. The method for controlling urinary incontinence of claim 1, wherein the quantity of occluding medium being dispensed is at least about 0.1 cc.

6. The method for controlling urinary incontinence of claim 1, further comprising the step of removing the occluding medium from the urethra to void.

7. The method for controlling urinary incontinence of claim 6, wherein said removing step includes manipulating the urethra so as to cause the occluding medium therein to pass

out of the natural urethral opening, where said manipulating is performed by the user.

8. The method for controlling urinary incontinence of claim 6, wherein said removing step includes contracting the bladder thereby establishing a sustained elevated pressure within the bladder, and wherein the sustained elevated pressure causes the occluding medium within the urethra to pass out of the natural urethral opening.

9. The method for controlling urinary incontinence of claim 8, wherein said removing step further includes vibrating the occluding medium dispensed within the urethra at least before said contracting the bladder step.

10. The method for controlling urinary incontinence of claim 1, wherein the occluding medium being provided is a bio-compatible gel.

11. The method for controlling urinary incontinence of claim 1, wherein said providing step further includes providing an applicator adapted for storing and dispensing the occluding medium into the urethra; and wherein said dispensing step includes dispensing the occluding medium from the applicator into the urethra.

12. The method for controlling urinary incontinence of claim 1, further comprising the step of dispersing a medicinal compound in the occluding medium being provided.

13. A method for controlling urinary incontinence by occluding a urethra, comprising the steps of:

providing an occluding device including an occluding medium, that exhibits little tendency to flow when subjected to a shear stress less than a specified value and a removal device having a first member;

dispensing the occluding medium and the removal device so the occluding medium is disposed within the urethra between the first member and the natural urethral opening; and

wherein said dispensing step dispenses a quantity of occluding medium within the urethra, where the quantity being dispensed is sufficient to block the unintentional discharge of urine from a bladder.

14. The method for controlling urinary incontinence of claim 13, wherein the occluding medium being provided exhibits no tendency to flow when subjected to a shear stress less than the specified value.

15. The method for controlling urinary incontinence of claim 13, wherein the occluding medium being provided behaves as a solid material at applied shear stresses below the specified value and which behaves as a fluid when subjected to shear stresses above the specified value.

16. The method for controlling urinary incontinence of claim 13, wherein the specified shear stress value is at least 500 dynes per square centimeter.

17. The method for controlling urinary incontinence of claim 13, wherein the quantity of occluding medium being dispensed is at least about 0.1 cc.

18. The method for controlling urinary incontinence of claim 13, further comprising the step of removing at least a portion of the occluding medium from the urethra to void.

19. The method for controlling urinary incontinence of claim 18, wherein the first member being provided is configured to remove at least a portion of the occluding medium from the urethra and wherein said removing step includes withdrawing the first member from the urethra.

20. The method for controlling urinary incontinence of claim 19, wherein the first member being provided is configured to remove essentially all the occluding medium from the urethra.

21. The method for controlling urinary incontinence of claim 19, wherein the removal device being provided further includes a flexible second member attached to the first member, wherein said dispensing step includes dispensing the second member so a portion thereof extends from the natural urethral opening and wherein said withdrawing step further includes applying a force to the portion of the second member outside the natural urethral opening, thereby withdrawing the first member from the urethra.

22. The method for controlling urinary incontinence of claim 19, wherein said removing step further includes contracting the bladder thereby establishing a sustained elevated pressure within the bladder, where the sustained elevated pressure causes the occluding medium remaining within the urethra to pass out of the natural urethral opening.

23. The method for controlling urinary incontinence of claim 13, wherein the fluid being provided is a bio-compatible gel.

24. The method for controlling urinary incontinence of claim 13, wherein said providing step further includes providing an applicator adapted for storing and dispensing the occluding medium and the removal device; and wherein said dispensing step includes dispensing the occluding medium and removal device.

25. The method for controlling urinary incontinence of claim 13, further comprising the step of dispersing a medicinal compound in the occluding medium being provided.

26. A method for controlling urinary incontinence by occluding the urethra, comprising the steps of:

providing an applicator having a tip and a reservoir of an occluding medium;

locating the applicator tip at the natural urethral opening;

actuating the fluid reservoir so as to dispense the occluding medium from the tip into the urethra to block the unintentional discharge of urine from a user's bladder; and

removing the applicator tip from the natural urethral opening after dispensing the occluding medium.

27. The method for controlling urinary incontinence of claim 26, wherein the occluding medium being provided exhibits little tendency to flow when subjected to a shear stress less than a specified value.

28. The method for controlling urinary incontinence of claim 26, wherein the occluding medium being provided exhibits no tendency to flow when subjected to a shear stress less than the specified value.

29. The method for controlling urinary incontinence of claim 26, wherein the occluding medium being provided behaves as a solid material at applied shear stresses below the specified value and which behaves as a fluid when subjected to shear stresses above the specified value.

30. The method for controlling urinary incontinence of claim 27, wherein the specified shear stress value is at least 500 dynes per square centimeter.

31. The method for controlling urinary incontinence of claim 26, wherein the quantity of occluding medium being dispensed is at least about 0.1 cc.

32. The method for controlling urinary incontinence of claim 26, further comprising the step of removing the occluding medium from the urethra to void.

33. The method for controlling urinary incontinence of claim 26, wherein the tip of the applicator being provided is adapted for insertion into the urethra; and in which the method further comprises the step of inserting the tip through the natural urethral opening until an end of the tip lies a specified distance within the urethra.

34. The method for controlling urinary incontinence of claim 33, wherein the applicator being provided includes a flange portion proximate the tip and wherein said inserting step further includes inserting the tip until the flange abuts the meatus.

35. The method for controlling urinary incontinence of claim 26, further comprising the step of dispersing a medicinal compound in the occluding medium being provided.

36. A method for controlling urinary incontinence by occluding a urethra, comprising the steps of:

providing an applicator containing an occluding medium, and a removal device having a first member;

wherein the occluding medium being provided exhibits little tendency to flow when subjected to a shear stress less than a specified value;

dispensing the occluding medium and the removal device from the applicator so the occluding medium is disposed within the urethra between the first member and the natural urethral opening;

wherein said dispensing step dispenses a quantity of occluding medium within the urethra, where the quantity being dispensed is sufficient to block the unintentional discharge of urine from a bladder; and

withdrawing the first member from the urethra, thereby removing at least a portion of the occluding medium disposed in the urethra.

37. The method for controlling urinary incontinence of claim 36, wherein the occluding medium being provided behaves as a solid material at applied shear stresses below the specified value and which behaves as a fluid when subjected to shear stresses above the specified value.

38. The method for controlling urinary incontinence of claim 36, wherein the specified shear stress value is at least 500 dynes per square centimeter.

39. The method for controlling urinary incontinence of claim 36, wherein the quantity of occluding medium being dispensed is at least about 0.1 cc.

40. The method for controlling urinary incontinence of claim 36, wherein said step of withdrawing removes essentially all the occluding medium disposed within the urethra.

41. The method for controlling urinary incontinence of claim 36, further comprising the step of dispersing a medicinal compound in the occluding medium being provided.

42. A device for controlling urinary incontinence by occluding a urethra, comprising an occluding medium that exhibits little tendency to flow when subjected to a shear stress less than a specified value and being a sufficient quantity so as to block the unintentional discharge of urine from the urethra.

43. The device for controlling urinary incontinence of claim 42, wherein the occluding medium exhibits no tendency to flow when subjected to a shear stress less than the specified value.

44. The device for controlling urinary incontinence of claim 42, wherein the occluding medium behaves as a solid material at applied shear stresses below the specified value and behaves as a fluid when subjected to shear stresses above the specified value.

45. The device for controlling urinary incontinence of claim 42, wherein the specified shear stress value is at least 500 dynes per square centimeter.

46. The device for controlling urinary incontinence of claim 42, wherein said occluding medium is a bio-compatible gel.

47. The device for controlling urinary incontinence of claim 42, wherein the quantity of said occluding medium is at least about 0.1 cc.

48. The device for controlling urinary incontinence of claim 42, further including an applicator that stores and dispenses said occluding medium into the urethra.

49. The device for controlling urinary incontinence of claim 42, wherein said occluding medium includes a medicinal compound.

50. A device for controlling urinary incontinence by occluding a urethra, comprising an occluding medium and a removal mechanism having a first member; wherein said occluding medium exhibits little tendency to flow when subjected to a shear stress less than a specified value and being a sufficient quantity so as to block the unintentional discharge of urine from the urethra; and wherein said occluding medium and said removal mechanism are arranged so said occluding member in the urethra is disposed between said first member and the natural urethral opening.

51. The device for controlling urinary incontinence of claim 50, wherein the occluding medium exhibits no tendency to flow when subjected to a shear stress less than the specified value.

52. The device for controlling urinary incontinence of claim 50, wherein the occluding medium behaves as a solid material at applied shear stresses below the specified value and behaves as a fluid when subjected to shear stresses above the specified value.

53. The device for controlling urinary incontinence of claim 50, wherein the specified shear stress value is at least 500 dynes per square centimeter.

54. The device for controlling urinary incontinence of claim 50, wherein said occluding medium is a bio-compatible gel.

55. The device for controlling urinary incontinence of claim 50, wherein the quantity of said occluding medium is at least about 0.1 cc.

56. The device for controlling urinary incontinence of claim 50, wherein said first member is configured to remove at least a portion of the occluding medium disposed in the urethra, when said first member is withdrawn from the urethra.

57. The device for controlling urinary incontinence of claim 56, wherein said first member is configured so withdrawal removes essentially all the occluding medium disposed in the urethra.

58. The device for controlling urinary incontinence of claim 50, wherein the removal mechanism further includes a flexible second member attached to said first member, wherein

a portion of said second member extends from the natural urethral opening when said device is inserted into the urethra; and wherein said second member is configured so a force applied to the second member portion outside the natural urethral opening causes said first member to be withdrawn from the urethra.

59. The device for controlling urinary incontinence of claim 50, further including an applicator that stores and dispenses said occluding medium into the urethra.

60. The device for controlling urinary incontinence of claim 50, wherein said occluding medium includes a medicinal compound.

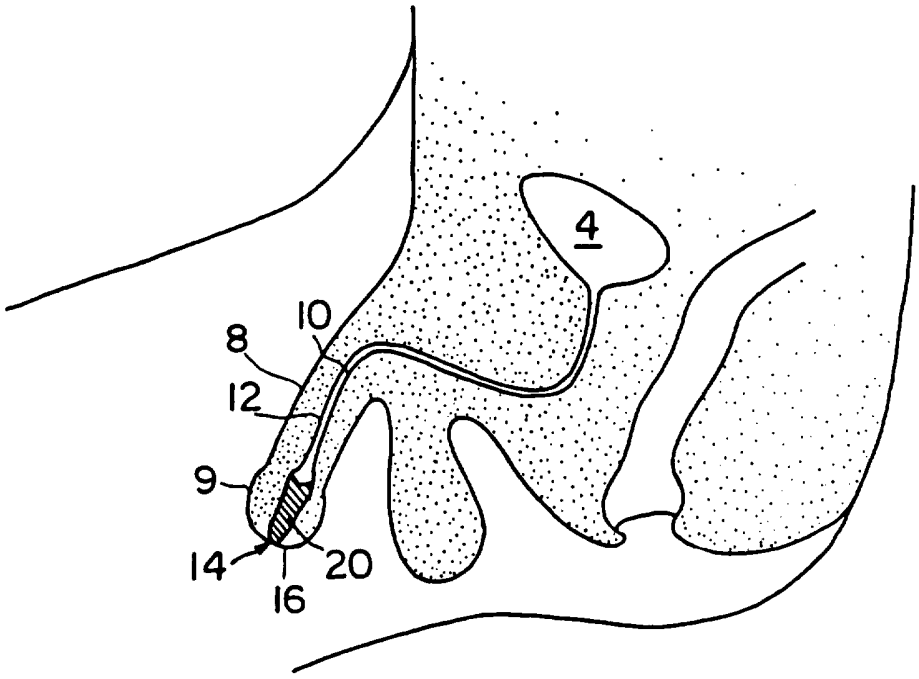

FIG. 1

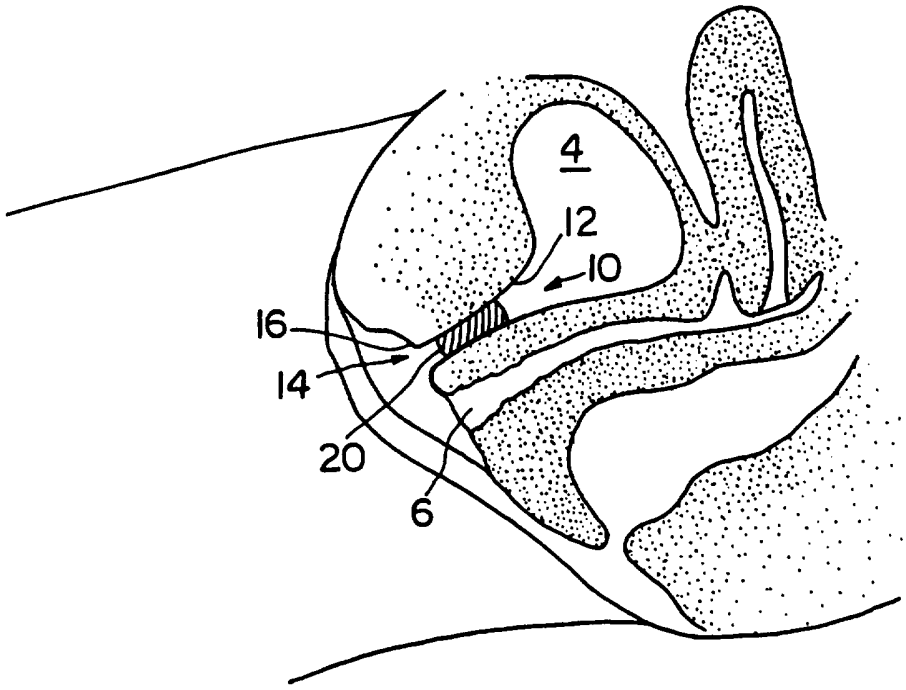

FIG. 2

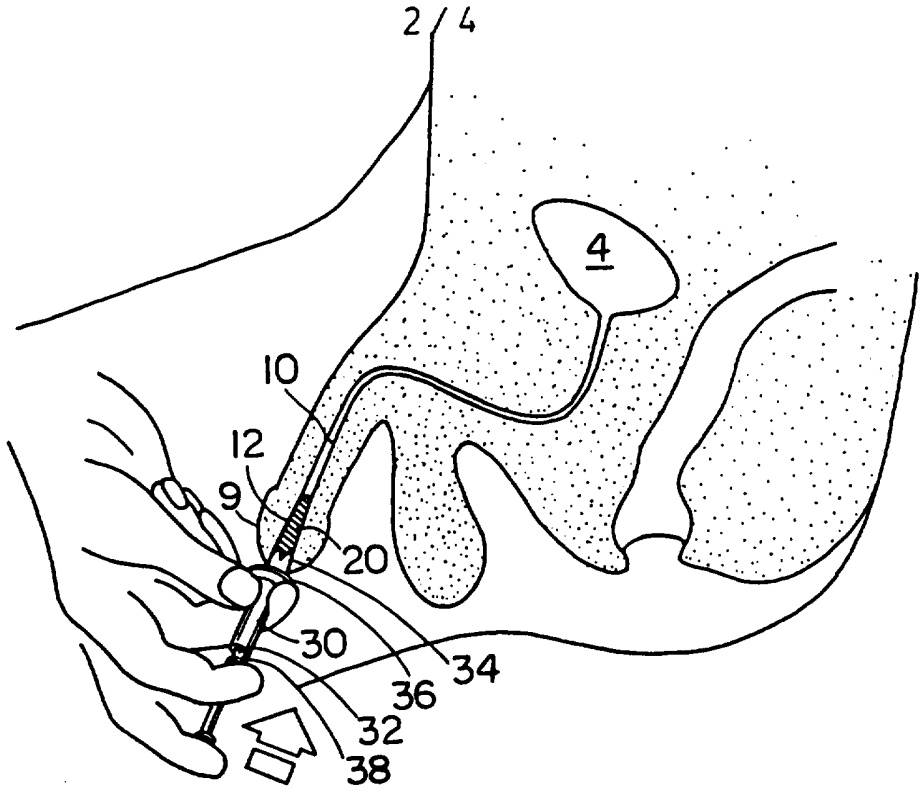

FIG. 3

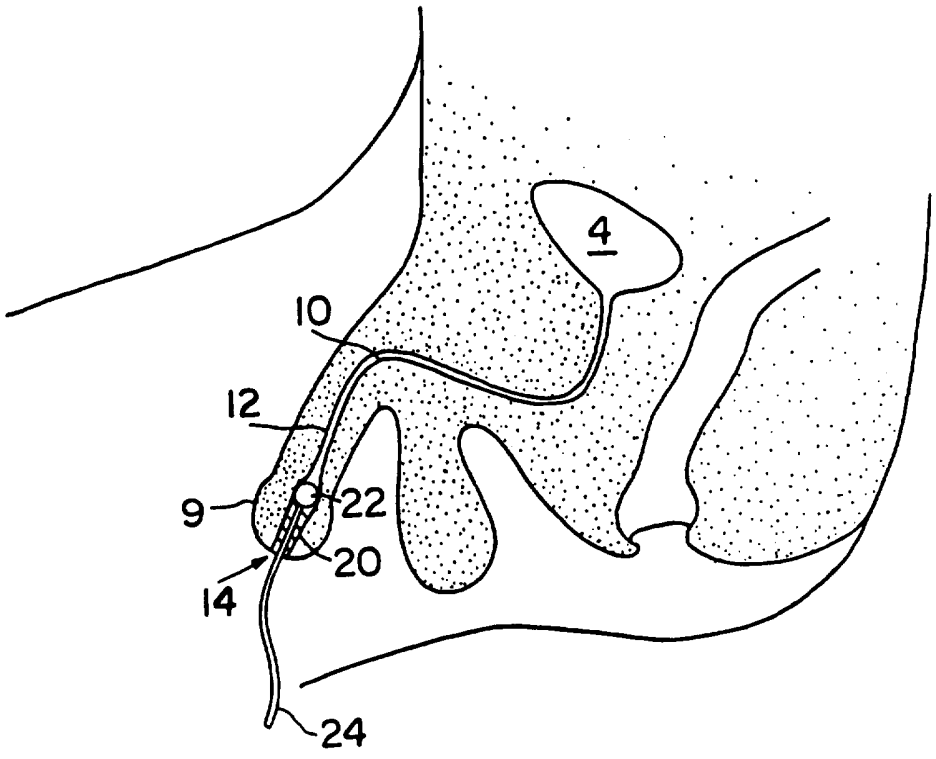

FIG. 4

FIG.5

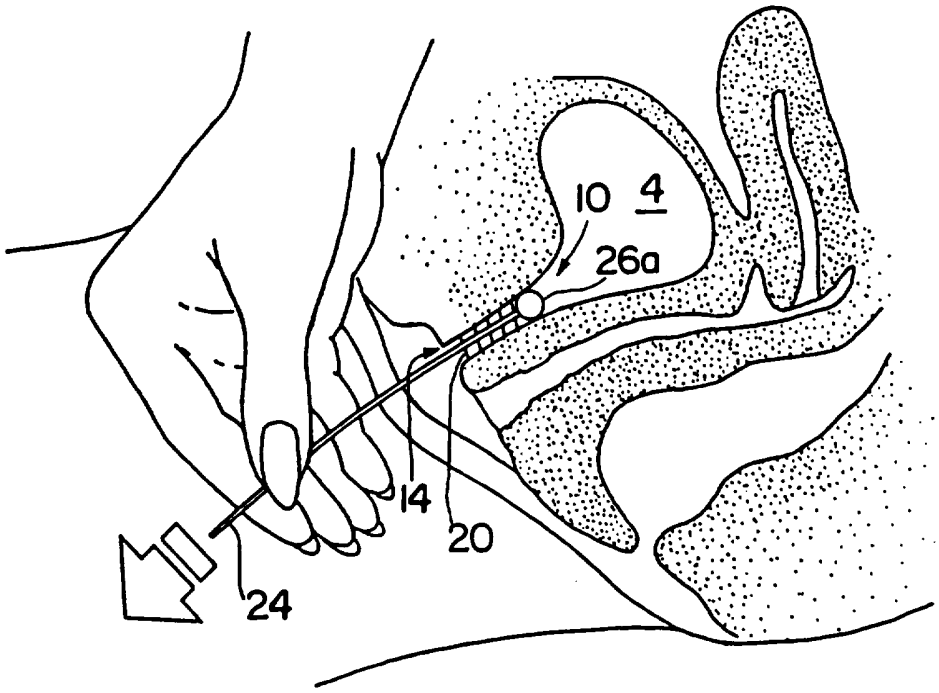

FIG.7

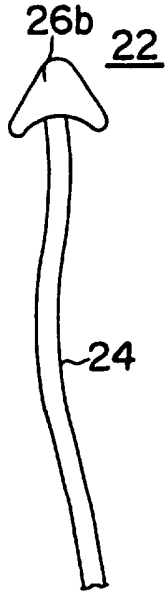

FIG.6

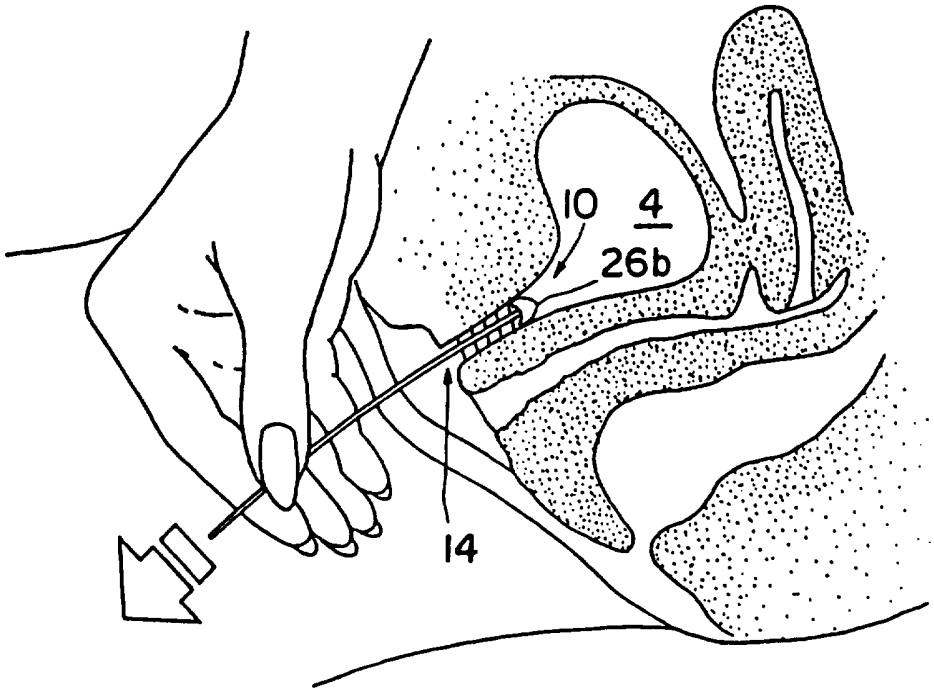

FIG.8

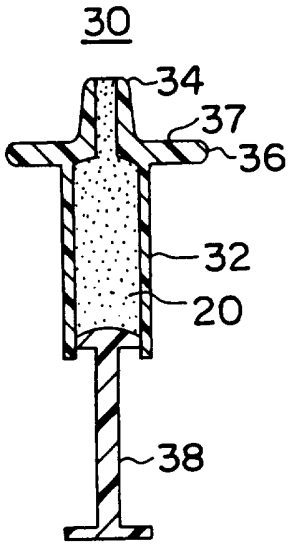

FIG.9

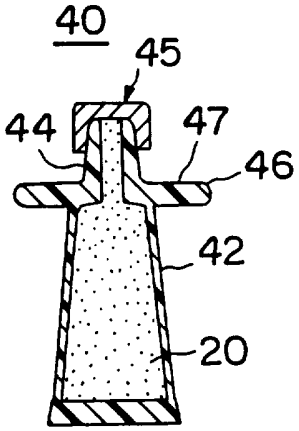

FIG.10

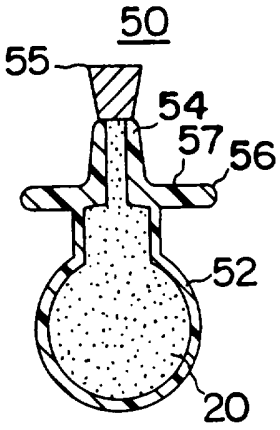

FIG.11

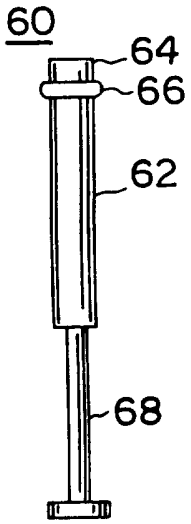

FIG.12A

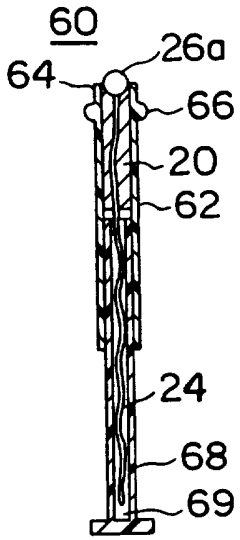

FIG.12B

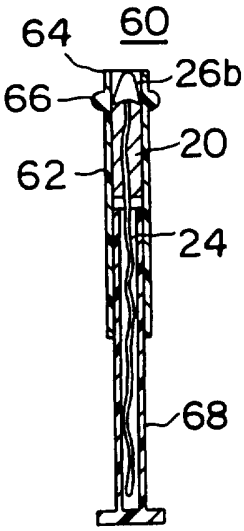

FIG.12C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/16057

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/00
US CL :600/029
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/885, DIG. 25; 600/29-31

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y, E	US 5,562,599 A (BEYSCHLAG) 08 October 1996, entire document.	1-60
Y, P	Us 5,483,976 A (MCLAUGHLEN et al) 16 January 1996, entire document.	1-60
Y, P	US 5,513,660 A (SIMON et al) 07 May 1996, entire document.	1-60
Y	US 5,123,428 A (SCHWARZ) 23 June 1992, entire document.	1-60
Y	5,417,226 A (JUMA) 23 May 1995, entire document.	1-60

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search 08 NOVEMBER 1996	Date of mailing of the international search report 27 DEC 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3590	Authorized officer RYAN CARTER Telephone No. (703) 308-2990

Form PCT/ISA/210 (second sheet)(July 1992)*