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(54) Title: FEMALE URINARY INCONTINENCE CATHETER

(57) Abstract: A catheter for treating urinary incontinence in a female individual is provided. The catheter including: (a) a catheter body having an open proximal end and a distal end and being of a length such that when positioned within a urinary tract of the individual the proximal end resides within a bladder of the individual and the distal end extends out of the individual’s meatus urinarius, at least a portion of the catheter body being of a sufficiently thin material so as to be in a collapsed state when substantially void of urine, and in an expanded state when filled with urine; (b) a permanent or openable seal being integrally formed with, or attached to, a distal portion of the catheter body, the seal being for controlling urine flow out of the distal end; and (c) an elastic anchor integrally formed with, or attached to the proximal end of the catheter body, the elastic anchor being of a diameter wider than that of an opening of the bladder and being for positioning and anchoring the catheter body within the urinary tract of the individual.

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FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to a urinary incontinence catheter, system and method utilizing same and, more particularly, to a catheter which when positioned within the urethra via a dedicated catheter guide, assumes a collapsed state and as such causes minimal patient discomfort. Upon urinary incontinence the catheter fills with urine and expands against the urethra thus preventing the loss of urine between the catheter and the urethra.

Urinary incontinence is characterized by the involuntary loss of urine in individuals. Urinary incontinence affects approximately 13 million people in the United States alone, 85% of them women. Urinary incontinence can be caused by physical stress (stress incontinence) typically brought on by heavy object lifting, coughing, laughing or sneezing, an overactive bladder (typically referred to as urge incontinence) or by an uncontrollable slow leak which is termed flow incontinence, and which is often experienced when complete bladder emptying can not be achieved by an individual. Additional but less common types of urinary incontinence include functional incontinence and unconscious or reflex incontinence.

Of the above causes for urinary incontinence, stress incontinence and urge incontinence are considered the most prevalent. Stress incontinence can be caused by anatomic abnormalities in the positioning of the bladder or bladder neck or by sphincter dysfunction. Urine loss occurs when the intravesicle pressure (i.e. pressure within the urinary bladder) exceeds, even by a small amount of pressure, the maximum urethral pressure (i.e. pressure on the urethra to maintain closure). While the problem of stress incontinence occurs in both men and women, it predominantly occurs in women of childbearing age and beyond. The frequency of incontinence
in women is approximately four times that of men. Less than one-third of women with moderate to severe incontinence are treated for the problem. While 25 to 41% of all women suffer some form of incontinence, 6 to 8% are troubled by the problem to the extent that they must wear diapers or sanitary napkins constantly.

There are several methods and devices which can be used to alleviate 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 bladder neck is suspended such that the bladder assumes a normal position. However, often a surgically suspended bladder neck recedes to its original and unwanted position and as such surgical procedures do not always provide a permanent solution to the incontinence problem. In addition, there are numerous risks associated with this surgical procedures on top of the risks normally associated with any invasive surgical procedure. For some patients, surgery is not recommended due to medical or other reasons, and for those with mild incontinence surgery is presently not the solution of choice. In addition, the expense of surgical procedure, followed by hospitalization and/or recovery is also a factor to be considered.

Incontinence can also be treated with various medications as well as exercises although with only a limited success. A more common approach to treating incontinence involves the use of a device.

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.
To try and solve the leakage problems associated with diapers in females an external seal was devised and is marketed under the name IMPRESS SOFTPATCH. This seal is placed externally at the female meatus urinarius, and is effective in cases where mild to moderate stress urinary incontinence is experienced. More severe cases of incontinence cannot be effectively prevented with this device.

For women, vaginal devices which function to support the urethra, are also utilized. Such devices must be inserted into the vagina to support the urethra by pushing against the vaginal wall. For example, International Patent Application No. PCT/GB88/00464 by Prosthex, Ltd., teaches an incontinence device for use by women. This device is a sponge tampon which is inserted into the vagina. The sponge tampon is supposed to exert pressure on the urethra, but it does not stop or plug the urethral opening. This device evidently limits the patient from engaging in intercourse while the device is implanted.

Yet another approach to alleviate incontinence involves the use of prosthetic urethral valves, which require undesirable surgical implantation which can lead to complications normally associated with invasive surgical procedures.

The size of the incontinent population and the relatively unattractive treatment options described hereinabove has led to the development of numerous products for the treatment of incontinence which do not necessitate surgery and which are minimally invasive.

U.S. Pat. No. 4,457,299 to Corewell teaches an internally prestressed capsule device which is inserted into the urethra. This device can be used by both men and women. The prestressed capsule deforms the lower interior of the urethra into a broadly elliptical shape, and the capsule is set at a prestressed pressure slightly above the involuntary pressure. When the urine pressure exceeds the preset pressure of the capsule, the capsule
deforms allowing the urine to flow around the device. When voiding ceases, the device returns to its prestressed position and configuration. As an indwelling device, the device faces the problems of encrustation and infection. Also, no mechanism for anchoring the device in place is described, and it is not clear that one could anchor this device in place, seal off the urine and leave the urethra unharmed. In addition, there is a need to measure the diameter of the patient's urethra and perform pressure testing before this device can be used. Different sizes are therefore required.

U.S. Pat. No. 4,553,533 to Leighton teaches a prosthetic urethral sphincter valve which is placed in the urethra and anchored in the bladder. The valve is composed of a spring, an annular guide, a diaphragm and a grease filled bag member. The patient increases his bladder pressure by means of a valsalva maneuver, and holds this pressure while the valve activates. The urine passes through the valve, and then the spring returns to its collapsed position when the bladder pressure is released. This device is relatively expensive and complicated, requiring that it be used for a relatively long time in order to make it economically feasible. It appears that this device would be uncomfortable for the patient. Furthermore, no means for anchoring the device to prevent its migration into the bladder is provided. As an indwelling device, it is subject to infection, encrustation and irritation. Due to the complexity and location of the device, it must be inserted under the guidance of a physician.

Nielsen, Kurt K. et al. in their paper entitled "The Urethral Plug: A New Treatment Modality for Genuine Urinary Stress Incontinence in Women", published in J. Urology, Vol. 44, p. 1199-202 at 1990, describe a device to be used by women which includes one or two solid spheres of 7 mm in diameter, located along a 3 mm soft shaft. A thin and soft plate is used to anchor the device at the meatus urinarius. The mental plate is located normal to the end of the device to prevent the plug from being
drawn into the urethra. One sphere is located upstream of the maximum urethral closing pressure point, corresponding to the location of the sphincter. In the two sphere embodiment, the second sphere is located with its midpoint at the bladder neck, and is used to assist in reducing urinary flow and pressure transmission to the urethra such that the sphincter can operate. When the patient wants to void, the plug is removed and then a new one inserted.

One problem with this device is that the patient must have three urethral closure pressure profiles performed before the device is inserted in addition to various other examinations. This is done in order to locate the urinary sphincter. The device is then custom made for each patient based on the profiles and according to their individual anatomy. This device is made from KRATON G, a non-toxic thermoplastic elastomer. Additional problems are associated with the use of this device. Patients often lost the plug showing inadequate anchoring. Some could not learn how to insert it and there were difficulties with the placement of the distal sphere. In addition, there is no sealing mechanism to prevent urine outflow, so that the device must depend on the body's own sealing mechanism. This presents a problem, because there is a significant population without such capabilities.

U.S. Pat. No. 5,090,424 to Simon et al. describes a flexible urethral plug which has two components: a molded soft inflatable plastic catheter and a transportable fluid. The fluid can be moved from an external bellows, through a check valve to inflate and distend the device within the urethra, the bladder neck or the bladder causing the device to block the flow of urine through the urethra and assist the natural function of the sphincter in closing the urethra. Although this device is relative simple in design, the use of an externally provided bellows limits the patient from engaging in intercourse while the device is implanted.
U.S. Pat. No. 5,637,091 to Hakky et al. describes a collapsible catheter for irrigation or aspiration of the urinary bladder with fluid. The catheter consists of a collapsible hollow elastomeric tube which is open at the proximal end. The distal end portion has at least one stiffened aperture. A plurality of channels are provided along the length of the tube which contain removable wires or rods which stiffen the tube for insertion into the bladder. A balloon means is provided to hold the catheter in place.

U.S. Pat. No. 5,713,829 also to Hakky, describes a female urinary incontinence catheter including a hollow plastic tube which can be collapsible provided with a mushroom shaped anchor to maintain the device within the urethra.

Although the use of a collapsible catheter body substantially increases patient comfort, the use of an anchoring balloon and wire rod fittings for positioning substantially described in U.S. Pat. No. 5,637,091 or a mushroom shaped anchor described in U.S. Pat. No. 5,713,829, complicates both the manufacturing of such a catheter and the positioning thereof in a patient.

There is thus a widely recognized need for, and it would be highly advantageous to have, a urinary incontinence catheter which is devoid of the above limitations and yet which causes minimal patient discomfort when positioned and utilized.

SUMMARY OF THE INVENTION

According to one aspect of the present invention there is provided a catheter for treating urinary incontinence in a female individual, the catheter comprising: (a) a catheter body having an open proximal end and a distal end and being of a length such that when positioned within a urinary tract of the individual the proximal end resides within a bladder of the individual and the distal end extends out of the individual's meatus urinarius, at least a
portion of the catheter body being of a sufficiently thin material so as to be in a collapsed state when substantially void of urine, and in an expanded state when filled with urine; (b) a permanent or openable seal being integrally formed with, or attached to, a distal portion of the catheter body, the seal being for controlling urine flow out of the distal end; and (c) an elastic anchor integrally formed with, or attached to the proximal end of the catheter body, the elastic anchor being of a diameter wider than that of an opening of the bladder and being for positioning and anchoring the catheter body within the urinary tract of the individual.

According to another aspect of the present invention there is provided a catheter system comprising: (a) a catheter including: (i) a catheter body having an open proximal end and a distal end and being of a length such that when positioned within a urinary tract of the individual the proximal end resides within a bladder of the individual and the distal end extends out of the individual's meatus urinarius, at least a portion of the catheter body being of a sufficiently thin material so as to be in a collapsed state when substantially void of urine, and in an expanded state when filled with urine; (ii) a permanent or openable seal being integrally formed with, or attached to, a distal portion of the catheter body, the seal being for controlling urine flow out of the distal end; and (iii) an elastic anchor integrally formed with, or attached to the proximal end of the catheter body, the elastic anchor being of a diameter wider than that of an opening of the bladder and being for positioning and anchoring the catheter body within the urinary tract of the individual; and (b) a guiding element being releasably attachable to the elastic anchor and being for positioning the catheter within the urinary tract.

According to yet another aspect of the present invention there is provided a method of alleviating urinary incontinence in a female individual, the method comprising the steps of: (a) attaching the catheter described
hereinabove to a guiding element; (b) using the guiding element to position the catheter within the urinary tract of an individual; and (c) pulling the guiding element out of the urinary tract so as to position the catheter and at the same time release the catheter from the guiding element.

According to further features in preferred embodiments of the invention described below the at least a portion of the catheter body is configured such that when expanded the at least a portion of the catheter body tightly seals against the walls of the urethra so as to prevent loss of urine between the urethra walls and the at least a portion of the catheter body.

According to still further features in the described preferred embodiments, the walls of the at least a portion of the catheter body are selected of a thickness between 0.1-0.3 mm.

According to still further features in the described preferred embodiments, the walls of the at least a portion of the catheter body are selected of a Shore hardness of 30-70 Shore A.

According to still further features in the described preferred embodiments, the walls of at least a portion of the catheter body are composed of a material selected from the group consisting of silicon, latex, polyurethane and butyl rubber.

According to still further features in the described preferred embodiments, at least a proximal portion of the guiding element includes a receptacle element suitable for releasably receiving at least a portion of the elastic anchor.

According to still further features in the described preferred embodiments the elastic anchor is an elastic ring element.

According to still further features in the described preferred embodiments the elastic anchor is an elastic malecot element.
According to still further features in the described preferred embodiments the seal is removably attached to the distal portion of the catheter body.

According to still further features in the described preferred embodiments the seal is an elastic member formed with a biasing slit in a relaxed state, which slit is deformed into an wider opening in a tensed state of the member.

According to still further features in the described preferred embodiments the seal is positionable around the distal portion of the catheter body.

According to still further features in the described preferred embodiments the distal portion of the catheter body is self-sustained.

According to still further features in the described preferred embodiments the seal is positionable within the distal portion of the catheter body.

According to still further features in the described preferred embodiments the seal is formed by a permanently sealed distal end of the catheter body.

According to still further features in the described preferred embodiments the seal includes a valve mechanism so as to allow the individual control over urine flow.

According to still further features in the described preferred embodiments the distal portion of the catheter body includes at least one stoppage element for preventing the catheter body from displacing in a direction of the bladder once positioned within the urinary tract.

According to still further features in the described preferred embodiments the elastic anchor includes a engaging element, the engaging element being for attaching the catheter to a guiding element.
According to still further features in the described preferred embodiments the elastic anchor is deformable so as to be attached to a guiding element, the elastic anchor resumes its relaxed shape when detached from the guiding element.

According to still further features in the described preferred embodiments the catheter body is cylindrical in shape.

According to still further features in the described preferred embodiments the catheter body is cone shaped, progressively narrowing towards the distal end.

The present invention successfully addresses the shortcomings of the presently known configurations by providing a catheter for treating urinary incontinence which substantially minimizes the discomfort of an individual and yet which is of a simple design and construction.

**BRIEF DESCRIPTION OF THE DRAWINGS**

The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.
Referring to the drawings wherein:

FIG. 1a is a cross sectional view of one embodiment of a catheter according to the present invention;

FIG. 1b is a cross sectional view of another embodiment of a catheter according to the present invention;

FIG. 1c is a cross sectional view of yet another embodiment of a catheter according to the present invention;

FIG. 1d is a cross sectional view of still another embodiment of a catheter according to the present invention;

FIG. 2a is a cross sectional view of a catheter according to the present invention positioned within a female urinary tract, with the bladder filled with urine, depicting the collapsed state of the catheter body prior to an incontinence episode;

FIG. 2b depicts the expanded state of the catheter of Figure 2a following an incontinence episode;

FIG. 3a is a perspective view of a valved seal utilizable in the catheter of the present invention;

FIG. 3b is a cross sectional view of a relaxed or closed state of the seal depicted in Figure 3a;

FIG. 3c is a cross sectional view of a compressed or open state of the seal depicted in Figure 3a;

FIG. 4a is a top view of an elastic anchor element depicting one embodiment of an engaging element according to the present invention;

FIG. 4b is a top view of an elastic anchor element depicting another embodiment of an engaging element according to the present invention;

FIG. 5 is a cross sectional view of a guiding element according to the present invention;

FIG. 6a is a cross sectional view of the guiding element of Figure 5 attached to the catheter of Figure 1c or 1d;
FIG. 6b is a cross sectional view of the guiding element of Figure 5 attached to the catheter of Figures 1a-d;

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of a catheter and a catheter system which can be used to treat urinary incontinence in a female individual. Specifically, the present invention can be used to treat female urinary incontinence by providing a soft, thin walled catheter which is open at the bladder end and permanently or reversibly sealed at the meatus urinarius end. The catheter of the present invention normally assumes a collapsed state when positioned within the urinary tract. During an incontinence episode, excess bladder urinary pressure over urethral urinary pressure results in urine outflow from the bladder which expands and seals the catheter against the urethra and as such prevents urine loss between the catheter and the urethra.

The principles and operation of the present invention may be better understood with reference to the drawings and accompanying descriptions.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

According to one aspect of the present invention and as illustrated in Figures 1a-2b there is provided a catheter which serves for treating urinary incontinence in a female individual and which is referred to hereunder as catheter 10.
To effect treatment, catheter 10 is positioned (as further described hereinbelow) within the urinary tract of the individual, the urinary tract including the urinary bladder and the entire length of the urethra which spans from the meatus urinarius to the bladder opening. As used herein the phrase "bladder opening" refers to the opening of the bladder neck towards the urethra. As used herein in the specification and in the claims section that follows, and in relation to the urinary tract positioning of the catheter or guiding element according to the present invention, the terms "proximal" and "proximally" denote towards the urinary bladder and the terms "distal" and "distally" denote towards the meatus urinarius.

Catheter 10 includes a catheter body 12 having an open proximal 14 end and a distal 16 end. As specifically shown in Figures 2a and 2b catheter 10 is constructed of a length such that when positioned within a urinary tract of the female individual proximal end 14 resides within the urinary bladder (indicated by 18) of the individual and distal end 16 extends out of the individual's meatus urinarius (indicated by 20). As such catheter 10 is preferably 3-10 cm in length, more preferably 3-8 cm in length. It will be appreciated that since female urethral lengths vary, several catheter lengths can be constructed so as to provide adequate coverage for various urethral lengths. Catheter body 12 can be of any shape suitable for positioning within the individuals urinary tract. For example, body 12 can be of a cylindrical shape or a cone shape which narrows towards distal end 16.

As specifically shown in Figure 2a-b, at least a portion 22 of catheter body 12 is constructed of a sufficiently soft and thin material so as to be in a collapsed state when substantially void of urine (Figure 2a), and in an expanded state when filled with urine (Figure 2b). As such the diameter of body 12 can vary according to it's state. When collapsed the measurable diameter of body 12 is preferably within the range of 6-10 mm, more
preferably 7-9 mm and when expanded it is preferably within the range of 7-11 mm.

It will be appreciated that catheter 10 of the present invention fills with urine only when the pressure difference between the urinary bladder and the urethral pressure exceeds a value beyond which incontinence ensues. This is the case for stress and urge incontinence wherein a sudden rise in pressure within the bladder combined with the inability of the urethra to resist this pressure rise causes a flow of urine from the bladder into the urethra (this is further described by Thind et al. in "Urethral pressure increment preceding and following bladder pressure elevation during stress episode in healthy and stress incontinent women" (1991) Neurology and Urodynamics 10:177-183 and in "Initial urethral pressure increase during stress episodes in genuine stress incontinent women" (1992) British journal of Urology 69:137-140 both of which are incorporated herein by reference).

This momentary flow of urine and an increased pressure in the bladder expands catheter 10 or portion 22 thereof such that walls 24 seal against the urethral walls to prevent urine loss between the urethra and catheter 10. It will be appreciated in this case that for catheter 10 to expand as described distal end 16 must be sealed. Various sealing mechanisms are further described hereinbelow. To enable this expansion of walls 24 of catheter 10 or portion 22 and to ensure that when sufficiently expanded optimal contact between walls 24 and the urethra is maintained, wall 24 of catheter 10 or portion 22 thereof are preferably constructed of a material with a Shore hardness value of 20-80 Shore A more preferably 30-70 Shore A, and a thickness of 0.05-0.40 mm more preferably 0.1-0.3 mm. Examples of appropriate materials include but not limited to silicone rubber, polyurethane, butyl rubber, latex rubber or any other suitable medically approved material which falls within the indicated Shore hardness values indicated above. Using these shore hardness and thickness values ensures
that a pressure rise and a resultant inflow of urine expands catheter 10 or portion 22 thereof in a manner which provides tight sealing against the urethral walls to prevent urine loss between catheter 10 and the urethra. It will be appreciated that although prior art catheters which assume a collapsed state when applied have been described these catheters are typically constructed of materials with a thickness and/or Shore hardness higher than that of the catheter of the present invention. As such these catheters cannot rely on expansion as a sealing mechanism since under small excess of bladder pressure over urethral pressure, which is experienced during an incontinence episode, expansion of the catheter is either not effected or alternatively an adequate seal between the catheter and the urethra cannot be achieved. In fact, such a sealing function is not an intended feature of these catheters which are designed to be in a collapsed state in order to increase patient comfort only. Thus, these prior art catheters typically rely on adequate sealing at the bladder opening in order to prevent urine loss.

It will be appreciated that although Figures 1a-d depict catheter 10 in the expanded state this is done for the purposes of demonstration only since normally when void of urine, catheter 10 or portion 22 thereof is in a shapeless collapsed state. As used herein and in the claim section which follows the phrase "collapsed state" refers to a substantially structureless state which is the result of the inability of catheter body 12 to self sustain a structure due to a lack of rigidity in walls 24. It will be appreciated that since catheter 10 cannot self support a structure, when positioned within the urinary tract, catheter 10 assumes the shape of the collapsed urethra.

Catheter 10 of the present invention also includes a seal 26 which is integrally formed with, or attached to, a distal portion 28 of catheter body. Seal 26 serves for preventing urine flow out of distal end 16 so as to enable the expansion of catheter 10 or portion 22 when incontinence occurs.
According to one preferred embodiment of the present invention and as specifically shown in Figures 1a-b, seal 26 can be a permanent seal. As such, seal 26 is integrally formed with, or permanently attached to distal portion 28. As such to allow urination, catheter 10 shown in Figures 1a-b must be removed by the individual and replaced following urination. To facilitate removal this embodiment of catheter 10 also includes an element 30 (specifically shown in figure 1a) which can be, for example, a draw string such that catheter 10 can easily be pulled out of the urinary tract.

According to another preferred embodiment of the present invention and as specifically shown in Figures 1c-d and 2a-b, catheter 10 includes an openable seal 26. In this case, urination is facilitated by simply removing seal 26 to allow urine flow. In this case walls 25 of distal portion 28 are preferably constructed such that portion 28 sustains a structure. For example walls 25 of distal portion 28 can be fabricated of a thickness so as to allow distal portion 28 rigidity. As such the walls 25 of distal portion 28 are selected 0.5-1.5 mm thick, more preferably 0.7-1 mm thick. Alternatively to achieve rigidity walls 25 of distal portion 28 can also be constructed of a material with a Shore hardness value above 80 Shore A. Examples of such materials include but are not limited to the abovementioned materials. It will be appreciated that a self sustaining structure can more easily facilitates the insertion and removal of seal 26 than a collapsed structure.

Although seal 26 is depicted as a stopper in Figures 1c-d and 2a-b any mechanism which allows control over urination can also be utilized by the present invention. For example a valve mechanism can be implemented within seal 26 so as to allow the individual control over urination.

Thus according to another preferred embodiment of the present invention and as specifically shown in Figure 3a-c, seal 26 is an elastic member formed around distal portion 28 which in this case is constructed of a soft and thin collapsible material. As specifically shown in Figure 3a-b
Seal 26 is formed with a biasing slit 33 which applies a force on distal portion 28 such that urine flow therefrom is blocked. As specifically shown in Figure 3c when seal 26 is compressed by an individual, slit 33 is deformed into an opening 32 thus allowing for urine flow. It will be appreciated that once compression pressure is relieved seal 26 reshapes to form slit 33 and as such distal end 16 is blocked again. It will be appreciated that slit 33 of seal 26 can also be configured such that during incontinence it remains closed as described above while voluntary urination pressure forces slit 33 to deform and open so as to allow urination. In this case no manual manipulation of seal 26 is required.

Seal 26 is formed of medical grade elastic material such as but not limited to silicon, butyl rubber, polyurethane, latex and the like. This embodiment of seal 26 is particularly advantageous since this seal which can also act as a stoppage element (further described hereinbelow) can be positioned anywhere on distal portion 28 and as such a single length size of catheter 10 can be used with varying urethral lengths.

According to a preferred embodiment of the present invention catheter 10 also includes a stoppage element 34. Stoppage element 34 serves for preventing catheter body 12 from displacing in a direction of the bladder once positioned within the urinary tract. Stoppage element 34 can be provided on distal portion 28 (specifically shown in Figure 1d), or provided as part of seal 26 (shown in Figures 1b-c).

According to the present invention catheter 10 further includes an elastic anchor 36 integrally formed with, or attached to proximal end 14 of catheter body 12. Elastic anchor 36 is selected of a diameter wider than that of an opening of the bladder. In addition anchor 36 is formed of a substantially elastic material such that anchor 36 can be reversibly compacted so as to be inserted through the individuals urinary tract. Anchor 36 serves for positioning and anchoring catheter body 12 within
the urinary tract of the individual. To position catheter 10 within the urinary tract anchor 36 is constructed such that it can be reversibly attached to a guiding element which is further detailed hereinbelow with respect to Figures 5-6b.

According to one preferred embodiment anchor 36 includes an engaging element 38. Engaging element 38 serves for attaching anchor 36 and as such catheter 10 to a guiding element.

According to one preferred embodiment engaging element 38 is formed of a portion of anchor 36 which is elastically deformable so as to be attached to a guiding element. In this case anchor 36 resumes its relaxed shape when detached from the guiding element.

According to another preferred embodiment of the present invention and as seen in Figures 1a-d and 4a, engaging element 38 is a protrusion, which is designed to be inserted into an accepting guiding element as further described hereinbelow. Although Figures 1a-d and 4a depict engaging element 38 as protruding outwards from anchor 36, it will be appreciated that any direction of protrusion (inward, upward, etc) can be implemented.

According to another preferred embodiment of the present invention and as seen in Figures 4b, engaging element 38 is an elastic bar which is appropriately positioned within anchor 36 and designed for attaching to a guiding element which is further described hereinbelow.

It will be appreciated that although engaging element 38 is depicted as a part of a ring shaped anchor 36 which is further described hereinbelow, engaging element 38 can also be incorporated into other anchoring means.

According to another and presently preferred embodiment shown in Figures 1a-2b and 4a-b, anchor 36 is an elastic ring element. Utilizing a ring element for anchoring is particularly advantageous since such a ring can easily be co-fabricated as part of proximal end 14 of catheter body 12. It will
be appreciated that as used herein and in the claim section that follows, the term "ring" refers to an element which surrounds at least a portion of proximal end 14. As such ring shaped anchor 36 can be of any shape which is largely dependent on the cross sectional shape of proximal end 14.

According to another aspect of the present invention and as seen in Figures 5-6b there is provided a system utilizable for treating urinary incontinence in an individual which is referred to hereunder as system 50.

As specifically shown in Figure 6a-b, system 50 includes catheter 10 which is described hereinabove and a guiding element 52. Guiding element 52 which is specifically shown in Figure 5, is constructed so as to be releasably attachable to engaging element 38 of catheter 10 which is further described hereinabove as such at least a proximal portion 53 of guiding element 52 includes a receptacle element 54 which can be reversibly attached to engaging element 38. For example, receptacle element 54 can include a hollow which is of an inner diameter suitable for releasably receiving the protrusion embodiment of engaging element 38.

In an alternative embodiment anchor 36 is directly attached to guiding element 52. It will be appreciated that since anchor 36 is elastic it can be compacted into a shape which would be suitable for insertion into this hollow. Once released from guiding element 52 anchor 36 can reform its normal shape. Alternatively, receptacle element 54 can include a notch attachable to the bar embodiment of engaging element 38. It will further be appreciated that numerous other types of attachment methods between anchor 36 and guiding element 52 can also be realized as part of the present invention.

To position catheter 10 via guiding element 52, engaging element 38 is first attached to guiding element 52. This attachment is strong enough to be maintained when the catheter is maneuvered into position within the
urinary tract but on the otherhand reversible such that guiding element 52 can be removed once catheter 10 is positioned and self anchored.

The configurations of attachment depend on the type of catheter 10 attached. As specifically shown in Figure 6a, when catheter 10 which includes a reversible seal such as the catheter depicted in Figures 1c-d is positioned, guiding element 52 can be inserted through catheter body 12 and contacted to engaging element 38 positioned into open proximal end 14. If a permanently sealed catheter 10 is used such as catheter 10 depicted in Figures 1a-b, then guiding element 52 is provided alongside catheter 10 (specifically shown in Figure 6b) and attached to engaging element 38. It will be appreciated that this guiding element attachment configuration can also be utilized for the catheter depicted in Figures 1c-d.

In any case it will be appreciated that since most if not all of catheter body 12 is of a substantially thin material in a collapsed state, catheter 10 is of a minimal bulk and as such can easily be guided via guiding element 52 through the urethra and into the urinary bladder. In addition and as already mentioned hereinabove since anchor 36 is elastic and as such compressible it can easily be forced through the urethra and into the bladder.

As such, once attached, catheter 10 is navigated through the urethra until anchor 36 reaches the urinary bladder. At this point a substantial decrease in resistance is felt by the individual positioning catheter 10, since most of the resistance to movement is provided by the pressure of the urethral walls against the compressed anchor 36. Finally, to position catheter 10, guiding element 52 is slowly pulled in the direction of the meatus urinarius. The now expanded anchor 36 is of a diameter larger than that of the bladder opening and as such resists movement in this direction. This resistance causes the disengagement of guiding element 52 from catheter 10 while at the same time positions anchor 36 against the bladder
opening and as such positions and anchors catheter 10 within the urinary tract.

It will be appreciated that guiding element 52 can also be provided with a release mechanism operable by the individual. Such a release mechanism can be for example, a rod element which is of a size and girth which fits into hollow 54 such that an attached engaging element 38 can be pushed out by the individual via this rod.

Thus the present invention provides a catheter system which is utilizable for treating urinary incontinence in a female individual. The catheter system of the present invention presents several advantages over prior art catheters.

It is of a simple design and construction and as a result can be fabricated from a single mold.

When positioned in the urinary tract it assumes a collapsed state of minimal bulk and as such minimizes discomfort in the individual. It will be appreciated in this case that the urethra of an individual is normally in a collapsed state when void of urine. In addition the female urethra twists along its axis from the bladder to the meatus urinarius. As such substantially rigid prior art catheters can be extremely uncomfortable when applied.

Since the catheter of the present invention is selected of a material with a substantially low Shore hardness value and minimal wall thickness, a momentary inflow of urine into the catheter combined with increased bladder pressure enables tight sealing of the catheter walls against the urethral walls and as such tight sealing against urine loss. This feature is not provided by prior art catheters which assume a collapsed state when applied.
In addition, since such prior art devices force open the urethra an individual utilizing such devices is more susceptible to urinary tract infections.

Furthermore, the catheter of the present invention can also utilize a relatively small anchor which provides a minimal anchoring force. This is possible because when incontinence occurs a rush of urine into the catheter expands the catheter body against the urethral walls and as such provides an additional anchoring force. The use of a relatively small anchor is particularly advantageous since relatively large and often complicated prior art bladder anchors such as balloons are often a source of irritation and infections.

Finally, the use of a simple guiding element attachment means further simplifies the construction of the catheter of the present invention, negating the need for complicated construction schemes such as the plurality of channels running along the length of the catheter described in U.S. Pat. No. 5,637,091 which channels serve to accommodate wires or rods utilizable for catheter positioning.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

All publications cited herein are incorporated by reference in their entirety.
WHAT IS CLAIMED IS:

1. A catheter for treating urinary incontinence in a female individual, the catheter comprising:
   
   (a) a catheter body having an open proximal end and a distal end and being of a length such that when positioned within a urinary tract of the individual said proximal end resides within a bladder of the individual and said distal end extends out of the individual's meatus urinarius, at least a portion of said catheter body being of a sufficiently thin material so as to be in a collapsed state when substantially void of urine, and in an expanded state when filled with urine;

   (b) a permanent or openable seal being integrally formed with, or attached to, a distal portion of said catheter body, said seal being for controlling urine flow out of said distal end; and

   (c) an elastic anchor integrally formed with, or attached to said proximal end of said catheter body, said elastic anchor being of a diameter wider than that of an opening of the bladder and being for positioning and anchoring said catheter body within the urinary tract of the individual.

2. The catheter of claim 1, wherein said at least a portion of said catheter body is configured such that when expanded said at least a portion of said catheter body tightly seals against the walls of the urethra so as to prevent loss of urine between the urethra walls and said at least a portion of said catheter body.
3. The catheter of claim 1, wherein the walls of said at least a portion of said catheter body are selected of a thickness between 0.1-0.3 mm.

4. The catheter of claim 1, wherein the walls of said at least a portion of said catheter body are selected of a Shore hardness of 30-70 Shore A.

5. The catheter of claim 1, wherein the walls of at least a portion of said catheter body are composed of a material selected from the group consisting of silicon, latex, polyurethane and butyl rubber.

6. The catheter of claim 1, wherein said elastic anchor is an elastic ring element.

7. The catheter of claim 1, wherein said elastic anchor is an elastic malecot element.

8. The catheter of claim 1, wherein said seal is removably attached to said distal portion of said catheter body.

9. The catheter of claim 8, wherein said seal is an elastic member formed with a biasing slit in a relaxed state, which slit is deformed into an wider opening in a tensed state of said member.

10. The catheter of claim 9, wherein said seal is positionable around said distal portion of said catheter body.
11. The catheter of claim 1, wherein said distal portion of said catheter body is self sustained.

12. The catheter of claim 11, wherein said seal is positionable within said distal portion of said catheter body.

13. The catheter of claim 1, wherein said seal is formed by a permanently sealed distal end of said catheter body.

14. The catheter of claim 1, wherein said seal includes a valve mechanism so as to allow the individual control over urine flow.

15. The catheter of claim 1, wherein said distal portion of said catheter body includes at least one stoppage element for preventing said catheter body from displacing in a direction of the bladder once positioned within the urinary tract.

16. The catheter of claim 1, wherein said elastic anchor includes an engaging element, said engaging element being for attaching the catheter to a guiding element.

17. The catheter of claim 1, wherein said elastic anchor is deformable so as to be attached to a guiding element, said elastic anchor resumes its relaxed shape when detached from said guiding element.

18. The catheter of claim 1, wherein said catheter body is cylindrical in shape.
19. The catheter of claim 1, wherein said catheter body is cone shaped, progressively narrowing towards said distal end.

20. A catheter system comprising:
   (a) a catheter including:
       (i) a catheter body having an open proximal end and a distal end and being of a length such that when positioned within a urinary tract of the individual said proximal end resides within a bladder of the individual and said distal end extends out of the individual’s meatus urinarius, at least a portion of said catheter body being of a sufficiently thin material so as to be in a collapsed state when substantially void of urine, and in an expanded state when filled with urine;
       (ii) a permanent or openable seal being integrally formed with, or attached to, a distal portion of said catheter body, said seal being for controlling urine flow out of said distal end; and
       (iii) an elastic anchor integrally formed with, or attached to said proximal end of said catheter body, said elastic anchor being of a diameter wider than that of an opening of the bladder and being for positioning and anchoring said catheter body within the urinary tract of the individual; and
   (b) a guiding element being releasably attachable to said elastic anchor and being for positioning said catheter within the urinary tract.
21. The system of claim 20, wherein the walls of said at least a portion of said catheter body are selected of a thickness between 0.1-0.3 mm.

22. The system of claim 20, wherein the walls of said at least a portion of said catheter body are selected of a Shore hardness of 30-70 Shore A.

23. The system of claim 20, wherein the walls of at least a portion of said catheter body are composed of a material selected from the group consisting of silicon, latex, polyurethane and butyl rubber.

24. The system of claim 20, wherein said elastic anchor is an elastic ring element.

25. The system of claim 20, wherein said elastic anchor is an elastic malecot element.

26. The system of claim 20, wherein said seal is removably attached to said distal portion of said catheter body.

27. The system of claim 26, wherein said seal is an elastic member formed with a biasing slit in a relaxed state, which slit is deformed into an wider opening in a tensed state of said member.

28. The system of claim 27, wherein said seal is positionable around said distal portion of said catheter body.
29. The system of claim 20, wherein said distal portion of said catheter body is self sustained.

30. The system of claim 29, wherein said seal is positionable within said distal portion of said catheter body.

31. The system of claim 20, wherein said seal is formed by a permanently sealed distal end of said catheter body.

32. The system of claim 20, wherein said seal includes a valve mechanism so as to allow the individual control over urine flow.

33. The system of claim 20, wherein said distal portion of said catheter body includes at least one stoppage element for preventing said catheter body from displacing in a direction of the bladder once positioned within the urinary tract.

34. The system of claim 20, wherein said elastic anchor includes an engaging element, said engaging element being for reversibly attaching the catheter to said guiding element.

35. The system of claim 20, wherein said elastic anchor is deformable so as to be attached to said guiding element, said elastic anchor resumes its relaxed shape when detached from said guiding element.

36. The system of claim 20, wherein said catheter body is cylindrical in shape.
37. The system of claim 20, wherein said catheter body is cone shaped, progressively narrowing towards said distal end.

38. The system of claim 20, wherein at least a proximal portion of said guiding element includes a receptacle element suitable for releasably receiving at least a portion of said elastic anchor.

39. The system of claim 20, wherein at least a portion of said catheter body is configured such that when expanded said at least a portion of said catheter body tightly seals against the walls of the urethra so as to prevent loss of urine between the urethra walls and said at least a portion of said catheter body.

40. A method of treating urinary incontinence in a female individual, the method comprising the steps of:
   (a) attaching the catheter of claim 1 to a guiding element;
   (b) using said guiding element to position said catheter within the urinary tract of an individual; and
   (c) pulling said guiding element out of the urinary tract so as to position said catheter and at the same time release said catheter from said guiding element.