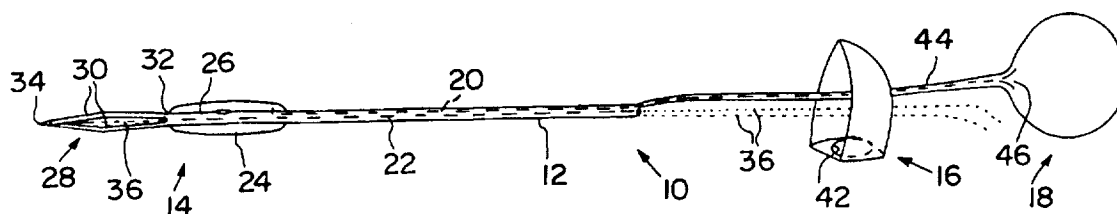




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(54) Title: APPARATUS FOR TREATING INCONTINENCE IN FEMALES



(57) Abstract

An apparatus for treating incontinence in females includes an elongate body member (12) having a first end and a second end; an internal plug member (28) positioned at the first end of the body member; an external retaining member (16) positioned at the second end, at least one member of the internal plug member, and the external retaining member being movable longitudinally with respect to the other member of the internal plug member and the retaining member; and a member for longitudinally securing at least one member relative to the other member, whereby the elongate body member can be positioned in a urethra with the plug member positioned at an interior opening of the urethra, and with the retaining member positioned at an exterior opening of the urethra.

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APPARATUS FOR TREATING INCONTINENCE IN FEMALES**BACKGROUND OF THE INVENTION**

The invention relates to an apparatus and method for treating incontinence in females, especially for treating urinary incontinence.

Urinary incontinence is a common problem in women. This is, in large part, due to laxity of bladder support structures brought on by pregnancy and/or aging. The magnitude of this problem is evidenced by increasingly large expenditures each year on products such as incontinence diapers and other protective clothing. Surgical correction is possible in some cases, but is an invasive and costly procedure. Foley-type catheters are another solution, but require the wearing of a urine collection bag, and this type of catheter is associated with frequent infections. Urethral catheters with valves have been designed, but have not been widely used.

U.S. Patent No. 5,090,424 to Simon et al. discloses a conformable urethral plug which has an inflatable element and which is removed each time the patient wishes to urinate, and then is reinserted. This device has the disadvantage of needing to be physically entirely removed and reinserted several times a day, leading to inconvenience, and the potential for irritation and/or infection.

It is clear that the need remains for an apparatus and method for treating urinary incontinence in women which does not require the use of collection bags, or repeated insertion and removal, and which does not lead to excessive irritation and/or infection.

It is therefore the primary object of the present invention to provide an apparatus for treating urinary incontinence in women which is indwelling and easy to operate.

It is a further object of the present invention to provide an apparatus which is easily inserted by a doctor or a patient.

It is a still further object of the present invention to provide an apparatus which is reliable and inexpensive, and simple in use.

It is a further object of the present invention to provide an apparatus the use of which does not lead to irritation and/or frequent infections.

It is a still further object of the present invention to provide a method for treating urinary incontinence in women using an apparatus according to the present invention.

Other objects and advantages will appear hereinbelow.

SUMMARY OF THE INVENTION

In accordance with the present invention, the foregoing objects and advantages are readily attained.

According to the invention, an apparatus is provided for treating incontinence in females, comprising: an elongate body member having a first end and a second end; an internal plug member positioned at the first end of the body member; an external retaining member positioned at the second end, at least one member of the internal plug member and the external retaining member being moveable longitudinally with respect to the other member of the internal plug member and the retaining member; and means for longitudinally securing the at least one member relative to the other member, whereby the elongate body member can be positioned in a urethra with the plug member positioned at an interior opening of the urethra and with the retaining member positioned at an exterior opening of the urethra.

In further accordance with the invention, the internal plug member is preferably an inflatable balloon for substantially blocking flow of urine into the urethra.

In accordance with a preferred embodiment, the apparatus of the present invention preferably further comprises means for selectively inflating and deflating the balloon between an inflated position wherein a flow of urine into the urethra is substantially blocked and a deflated position wherein flow into the urethra is substantially unblocked.

According to an alternative embodiment of the invention, the apparatus preferably further comprises a flexible member extending from the second end of the elongate body member, the retaining member being slidably positioned on the flexible

member, and wherein the means for longitudinally securing comprises means for securing the retaining member relative to the body member.

In further accordance with the invention, a method is provided for treating incontinence in females which comprises the steps of providing an apparatus comprising an elongate body member having a first end and a second end; an internal plug member positioned at the first end of the body member; an external retaining member positioned at the second end, at least one member of the internal plug member and the external retaining member being movable longitudinally with respect to the other member of the internal plug member and the retaining member; and means for longitudinally securing the at least one member relative to the other member, wherein the internal plug member comprises an inflatable balloon in a deflated condition; positioning the elongate body member in the urethra with the internal plug member positioned at an interior opening of the urethra; moving the retaining member relative to the plug member so as to position the retaining member at the exterior opening of the urethra; securing the retaining member relative to the plug member at the exterior opening of the urethra; and selectively inflating and deflating the balloon between an inflated condition wherein the plug member substantially seals the interior opening of the urethra and the deflated condition wherein the plug member does not substantially seal the interior opening of the urethra.

BRIEF DESCRIPTION OF THE DRAWINGS

A detailed description of preferred embodiments of the present invention follows, with reference to the attached drawings wherein:

Figure 1 is a side schematic view of an apparatus for treating incontinence in females in accordance with the present invention;

Figure 2 is a side schematic view of the apparatus of Figure 1, with a retaining member and balloon both in an expanded position;

Figure 3 is an end view of the apparatus of Figure 2 showing the expanded retaining structure of same;

Figure 4 is an end view of a retaining structure of the embodiment of Figures 1-3;

5 Figure 5 is a side schematic view of an alternative embodiment of the present invention;

Figure 6 is a side schematic view of the alternative embodiment of Figure 5 with the balloon in an inflated condition and the retaining member engaged on a knob structure;

10 Figure 7 is an end view showing the retaining structure of the apparatus of Figure 6;

Figure 8 is a side view of a further embodiment of the present invention;

15 Figure 9 is a side view of the embodiment of Figure 8 with struts and balloon in an inflated position;

Figure 10 is a side view of a further alternative embodiment of the present invention;

Figure 11 is a side view of the embodiment of Figure 10 with struts and balloon in an expanded condition;

20 Figure 12 is an end view of the embodiment of Figures 10-11;

Figure 13 is a side view of a portion of an apparatus in accordance with the present invention;

25 Figures 14A and 14B illustrate an alternative embodiment for operating a portion of the present invention;

Figures 15A and 15B illustrate a further alternative embodiment of the present invention;

Figure 16 illustrates a further embodiment of the present invention;

30 Figures 17A-17C further illustrate a valve structure in accordance with an embodiment of the present invention; and

Figures 18A and 18B illustrate a further alternative embodiment of a valve structure in accordance with the present invention.

35 DETAILED DESCRIPTION

In accordance with the invention, a method and apparatus are provided for treating incontinence, especially urinary

incontinence, in females. In accordance with the invention, an apparatus is provided which is an indwelling apparatus having structure allowing the patient and/or attendant to the patient to selectively block and unblock the flow of urine from the bladder into the urethra for voiding as desired.

Referring now to the drawings, Figure 1 shows an apparatus 10 having a substantially elongate body member 12, a plug structure 14, retaining structure 16 and a bulb structure 18 for selectively expanding plug structure 14 as will be thoroughly discussed below.

Body member 12 is preferably a substantially elongate tube structure which is preferably substantially rigid and resilient so as to adapt to angles which may be required during use. Body member 12 preferably defines two lumens or passages which are shown schematically by dashed lines 20, 22. Body member 12 preferably has a length of about 3 to about 6 centimeters, typically about 4 centimeters, and preferably has a relatively narrow diameter, sufficient to accommodate lumens 20, 22 and yet sufficiently small to allow flow through the urethra external to body member 12.

Plug member 14 preferably includes an inflatable balloon 24 positioned at a first or distal end 26 of body member 12. Balloon 24 is preferably inflated and deflated to an expanded position (FIG. 2) wherein balloon 24 is sufficiently large to seal an interior opening of a urethra, and a deflated position (as shown in FIG. 1) wherein balloon 24 is sufficiently small that apparatus 10 can be readily inserted through the urethra so as to position balloon 24 at the interior opening of the urethra, preferably at the vesico-urethral opening. Balloon 24 may be provided of any suitable material so as to provide desired expansion or inflation responsive to a reasonable influx of inflation fluid as will be further discussed below.

Plug member 14 preferably further includes an internal retaining structure 28 also positioned at distal end 26 of body member 12. As shown in FIG. 1-3, internal retaining structure 28 preferably includes a plurality of flexible struts 30 having first ends 32 connected to or extending from distal end 26 and having second ends 34 extending away from first ends 32 so that

struts 30 are generally longitudinally aligned with elongate body member 12. In accordance with the invention, struts 30 are preferably flexible and biased toward a substantially straight position as shown in FIG. 1. Struts 30 arranged as shown in FIG. 1 form a compressible member which, upon compression, expands to a radially expanded position as shown in FIGS. 2 and 3. As will be discussed below, this is advantageous in that during use of apparatus 10, balloon 24 is deflated to allow flow from the bladder into the urethra. When balloon 24 is deflated, struts 30 in the radially expanded position shown in FIGS. 2 and 3 serve to hold apparatus 10 in position so that, when desired, balloon 24 can be re-inflated in the desired position so as to sealingly engage the interior opening of the urethra as desired.

Struts 30 may suitably be compressed to the radially expanded position through any means, but are preferably operated by elongate members such as ligatures 36 which are preferably slidably arranged in lumen 22, and are connected at one end to second or distal ends 34 of struts 30, and which extend through body member 12 and retaining structure 16 for use in securing structure 16 at a desired position relative to plug member 14 as will be thoroughly discussed below. In this way, ligatures 36 can be tensioned so as to assert compressive force on distal ends 34 of struts 30 and thereby cause an outward flexing of each strut 30 to the radially expanded position shown in FIGS. 2 and 3.

Retaining structure 16 is preferably a substantially hemispherical, dome or cone-shaped molded rubber or other flexible material structure which is slidably mounted on body member 12 so as to be longitudinally movable with respect to plug structure 14. Referring to FIG. 4, retaining structure 16 preferably has one centrally located aperture 38 for slidably receiving body member 12, and may also suitably have a pair of substantially centrally located apertures 40 for receiving ligatures 36. As shown in FIGS. 2 and 4, when retaining structure 16 is positioned as desired, ligatures 36 may suitably be tied on the proximal end of apertures 40 so as to secure retaining structure 16 in position against movement away from plug structure 14. Referring to FIGS. 1 and 2, retaining

structure 16 also preferably includes an opening 42 arranged to be positioned downwardly away from body member 12. Opening 42 advantageously serves to direct flow from the urethra during use of apparatus 10 away from the longitudinal axis of body member 12 and, thereby, away from the hands of the user as desired.

Still referring to FIGS. 1 and 2, bulb structure 18 is preferably provided and communicates with balloon 24 through lumen 20 so as to provide inflation fluid as desired. Bulb structure 18 in accordance with the invention is preferably a flexible bulb structure containing liquid or air or some other suitable inflation fluid medium. Bulb structure 18 may suitably be connected to lumen 20 through tube 44 as shown. In further accordance with the invention, bulb structure 18 preferably also includes a check valve 46 for releasably preventing backflow from tube 44 into bulb 18. In this manner, bulb structure 18 can be compressed so as to drive inflation fluid through tube 44 and lumen 20 into balloon 24 for inflation of same. When it is desired to deflate balloon 24 and thereby allow flow from the bladder into the urethra, check valve 46 is manually actuated so as to allow inflation fluid to return into bulb 18, thereby deflating balloon 24 and allowing flow into the interior opening of the urethra.

It should be noted that although the present embodiment is described in terms of a bulb structure which is compressed to drive fluid into balloon 24, numerous other means for selectively inflating and deflating balloon 24 with inflation fluid could of course be provided.

Referring collectively to FIGS. 1-4, the method for implanting and operating apparatus 10 in accordance with the present invention will be described.

The apparatus is provided initially in the condition shown in FIG. 1, with retaining structure 16 loosely and slidably supported on body member 12, with balloon 24 in a deflated condition, and with struts 30 in a substantially straight or radially withdrawn position. In this condition, it is readily apparent that apparatus 10 has a narrow profile and can be readily inserted into the urethra of the patient to be treated as desired. Once the body member 12 is sufficiently inserted

into the urethra that plug structure 14 extends beyond the interior opening of the urethra, fluid from bulb structure 18 is driven through tube 44 and lumen 20 into balloon 24 as desired so as to inflate balloon 24 to the inflated condition as shown in FIG. 2. Check valve 46 serves to releasably hold fluid within tube 44, lumen 20 and balloon 24 as desired. Next, by pulling on ligatures 36, inflated balloon 24 may be sealably engaged with the interior opening of the urethra, and retaining structure 16 can then be slidably positioned along body member 12 so as to snugly engage the exterior opening of the urethra as desired. At this position, slight additional tension on ligatures 36 results in the inward compression of struts 30, thereby flexing same to the radially expanded position as shown in FIGS. 2 and 3. Ligatures 36 are then preferably tied across apertures 40 as shown in FIG. 4 so as to releasably hold body member 12 with plug structure 14 positioned at the interior opening of the urethra, and with retaining structure 16 located at the exterior opening of the urethra. Also at this point, balloon 24 has sealably engaged the interior opening of the urethra and thereby substantially prevents flow from the bladder into the urethra as desired.

When it is desired to allow flow through the urethra and thereby void the bladder, the patient or attending personnel can manually release check valve 46 so as to allow fluid to flow from balloon 24 through lumen 20 and tube 44 back into bulb structure 18. This deflates balloon 24 to the deflated condition in FIG. 1, and thereby allows flow from the bladder into the urethra, into retaining structure 16 and through opening 42 as desired. During this process, radially expanded struts 30 serve to prevent apparatus 10 from being ejected from the urethra while balloon 24 is deflated. When sufficient fluid has been removed from the bladder, bulb structure 18 can then suitably be used to again drive inflation fluid back through tube 44 and lumen 20 into balloon 24 so as to inflate balloon 24 into the inflated condition as shown in FIG. 2, thereby once again substantially sealing the interior opening of the urethra as desired.

It should be readily appreciated that apparatus 10 according to the invention provides an indwelling apparatus which can be operated as desired by the patient or attending personnel, and which clearly does not require frequent insertion and removal. Further, this apparatus is simple and efficient in structure and easy to operate.

Referring now to FIGS. 5-7, an alternative embodiment of the present invention will be described, and like reference numerals will be used to indicate similar elements. Referring to FIG. 5, elongate body member 12 of this embodiment is preferably provided having a single lumen 20a communicating with balloon 24 of plug structure 14 so as to allow inflation and deflation of same. Body member 12 is preferably also provided with a knob structure 48 at proximal or second end 50 of body member 12. A nylon string or other suitable ligature 52 is preferably attached to and extends from proximal end 50 of body member 12 as shown, and retaining structure 16 is slidably positioned along nylon string 52. A retaining knob or bead 54 is preferably provided at a position along nylon string 52 so as to limit the maximum movement of retaining structure 16 away from balloon 24 in accordance with the invention.

Body member 12 preferably further includes a portion 58 communicated with lumen 20a which is made from a self-sealing material for use in connection with an inflation needle to charge balloon 24 with an inflation fluid, and automatically seal upon removal of the inflation needled as desired. Self-sealing portion 58 may suitably be made of self-sealing rubber or like material which seals or substantially seals after a puncturing member is removed.

In operation, the embodiment of FIGS. 5-7 is positioned within the urethra as desired, balloon 24 is inflated, and retaining structure 16 is engaged with knob 48 so as to hold same in place with inflated balloon 24 sealingly engaging the interior opening of the urethra. FIG. 6 shows apparatus 10 in accordance with this embodiment of the invention with balloon 24 in an inflated condition and with retaining structure 16 engaging knob 48.

Referring to FIG. 7, an end view of retaining structure 16 according to this embodiment is shown, wherein structure 56 is provided for releasably engaging knob 48 as desired. As shown in FIGS. 5-7, retaining structure in accordance with this
5 embodiment also has opening 42 for directing flow as desired in accordance with the invention.

In further accordance with this embodiment of the invention, knob 48 is preferably longitudinally adjustable or positionable with respect to plug structure 14 so as to
10 accommodate various positions which may be required for engaging retaining structure 16. In this manner, advantageously, apparatus 10 can readily be adjusted to various lengths or distances between plug structure 14 and retaining structure 16 as may be required by various patients. Knob 48 may suitably be
15 adjustable relative to plug structure 14 through any longitudinally adjustable connection or mounting of knob 48 relative to body member 12 and/or nylon string 52. For example, releasable stop means (not shown) could be provided for releasably secured knob 48 along nylon string 52.
20 Alternatively, knob 48 could be structurally movable with respect to body member 12, for example through a threaded engagement. Of course, numerous other means may be provided for accomplishing the desired releasable positioning of knob 48 in accordance with the invention.

25 Retaining structure 16 in accordance with this embodiment is preferably sufficiently flexible that engaging structure 56 such as a cruciate slit as shown in the drawings can be securely engaged and released from knob 48 as desired.

Referring collectively to FIGS. 5-7, apparatus 10 in
30 accordance with this embodiment is installed and used as follows. For installation, apparatus 10 is provided in the condition illustrated in FIG. 5, with balloon 24 deflated and retaining structure 16 disengaged from knob structure 48. Body member 12 is preferably positioned within the urethra, with
35 balloon structure 24 extending to and preferably slightly beyond the interior opening of the urethra. Inflation fluid is then driven from a source (not shown in FIGS. 5-7) through lumen 20a so as to inflate balloon 24 to the inflated condition as shown

in FIG. 6. Body member 12 is then positioned so as to snugly engage balloon 24 with the interior opening of the urethra, and knob 48 is then preferably longitudinally adjusted with respect to body member 12 and balloon 24 for proper positioning so as to engage retaining structure 16. Once knob 48 is properly located, retaining structure 16 is then positioned along nylon string 52 toward balloon 24 so as to engage knob 48 with engaging structure 56. In this position, body member 12 is securely held within the urethra with balloon 24 sealingly engaging the interior opening of the urethra and retaining structure 16 snugly positioned with respect to the exterior opening of the urethra. When it is desired to void fluids from the bladder, retaining structure 16 is disengaged from knob 48, allowing body member 12 to migrate slightly inwardly, thereby removing inflated balloon 24 from sealing engagement with the interior opening of the urethra and allowing flow into the urethra to retaining structure 16 and out of opening 42 as desired. When sufficient fluids have been removed from the bladder, nylon string 52 can be pulled gently proximally, while retaining structure 16 is pressed gently distally so as to re-engage engaging structure 56 with knob structure 48, thereby again sealingly positioning inflated balloon 24 with respect to the interior opening of the urethra.

In accordance with this embodiment, it should be appreciated that balloon 24 is inflated upon installation of apparatus 10, and can remain inflated until apparatus 10 needs to be removed. Thus, advantageously, no inflating and deflating structure is required to be permanently associated with apparatus 10 in accordance with the use and operation of this embodiment.

Referring now to Figures 8 and 9, an alternative embodiment of the invention is illustrated which is similar to the embodiment of Figures 1-4. In this embodiment, however, balloon 24 is actually positioned within struts 30 as shown. In this embodiment, rather than ligatures 36 for compressing struts 30 as in the above-described embodiments, struts 30 are alternatively provided of a suitable material preferably having shape memory to the expanded position of Figure 9, wherein the

material is sufficiently soft that struts 30 can be radially compressed for insertion and removal. Alternatively, struts 30 could be provided having shape memory to the radially withdrawn position of Figure 1, and balloon 24 could thereby be used to expand struts 30 to a retaining position as desired.

Still referring to Figures 8 and 9, apparatus 10 in accordance with this embodiment may suitably be provided with an additional retaining balloon 60 preferably positioned toward retaining structure 16 from balloon 24 and struts 30.

Additional retaining balloon 60 is preferably positioned so as to correspond with the urethral meatus of a patient, and additional retaining balloon 60 is connected, preferably through lumen 20, to the source of inflation fluid such that balloons 24, 60 can be inflated and deflated simultaneously. Additional retaining balloon 60 serves, in accordance with the invention, to be secured in the bladder neck of a patient and thereby help to insure secure placement of apparatus 10 for use in accordance with the present invention.

Still referring to Figures 8 and 9, as well as Figures 1-4, these figures show apparatus 10 in accordance with the invention having balloon 24 positioned in a particular location with respect to struts 30. Although this may be one preferred embodiment of the present invention, it should of course be noted that apparatus 10 could be provided using only balloon 24, and without struts 30, all within the scope of the present invention. In this embodiment, balloon 24 could advantageously be inflated for sealing the bladder, and deflated to allow flow from the bladder, while holding apparatus 10 in place by external pressure on retaining structure 16 or bulb 18 while balloon 24 is deflated.

Additionally, the embodiment of Figures 8 and 9 could also be provided without retaining structure 16, and in such a configuration that balloons 24, 60 are used to hold apparatus 10 in position as desired during use.

Referring now to Figures 10, 11 and 12, a further embodiment of the present invention will be illustrated. As shown, retaining member 16 may be provided having a different structure, and this embodiment including a collar portion 62 for

slidably engaging elongate member 12, a rim portion 64 for engaging against structure of the body so as to hold apparatus 10 in place during use, and a plurality of spokes or struts 66 for connecting rim portion 64 to collar portion 62, preferably with rim portion positioned distally or toward balloon 24 from collar portion 62. In accordance with this alternative embodiment of retaining structure 16, a simpler structure is provided which also allows for less restricted flow past apparatus 10, if desired, albeit without the control of direction of flow as provided with the embodiment of retaining member 16 as shown in Figures 1 and 2.

As discussed above, struts 30 may suitably be provided having shape memory to an expanded position. Figure 10 shows an embodiment of the present invention wherein struts 30 are held in a radially compressed position for insertion of the device by a dissolvable sleeve 68 which, advantageously, serves to bias struts 30 against their natural tendency to expand, and which sleeve 68 is provided of physiologically for example by heat or contact with urine, dissolvable and non-toxic material such that sleeve 68 relatively rapidly dissolves once apparatus 10 is positioned within the urethra of a patient as desired. In this way, apparatus 10 can be inserted in the condition of Figure 10, and upon dissolution of sleeve 68, struts 30 expand so as to secure apparatus 10 in place. Sleeve 68 may suitably be provided from any physiologically dissolving material as is well known to a person of ordinary skill in the art. A key advantage of this embodiment is that apparatus 10 can be inserted by the patient, rather than medical personnel, which greatly expands the applicability of apparatus 10 according to this embodiment.

Still referring to Figures 10 and 11, struts in accordance with this embodiment of the invention are preferably provided with distal end 34 having a smooth or blunted tip 70 so as to further facilitate insertion of apparatus 10 with minimized discomfort. This feature is also further illustrated in Figure 12.

Figures 10-12 further illustrate an alternative embodiment of bulb structure 18 for inflating and deflating balloon 24 as desired. As shown, bulb structure 18 in this embodiment is

positioned between two compressing members 72, 74 which are movable relative to each other between the spaced position of Figure 10 and the closed position of Figure 11. In the spaced position of Figure 10, fluid is contained within bulb portion 18, and balloon 24 is deflated as shown. When it is desired to inflate balloon 24, compressible members 72, 74 are manually compressed to the closed position of Figure 11, which in turn compresses bulb 18 and forces fluid through lumen 20, so as to inflate balloon 24 as desired. Compressible members 72, 74 are preferably further provided with a snap or latch structure 76 for releasably holding compressible members 72, 74 in the closed position of Figure 11. Thus, when apparatus 10 is installed for use, compressible members 72, 74 can readily be snapped together so as to inflate balloon 24, and when deflation of balloon 24 is desired, latch structure 76 can be released so as to allow compressible members 72, 74 to expand so that fluid passes into bulb 18 and out of balloon 24, thereby allowing flow into the urethra external of body member 12.

Figure 13 shows, partially schematically, a portion of apparatus 10 in accordance with the present invention, wherein retaining structure 16 is held in place through frictional engagement with elongate member 12, rather than by being tied in position using ligatures 36. As shown, retaining member 16 is preferably provided having collar portion 62 frictionally engaging elongate member 12, and elongate member 12 may be provided with an at least partially treated surface 78 so as to enhance the frictional grip of retaining structure 16 thereon. Partially treated surface 78 may suitably be a material selected to provide a desired level of friction with retaining structure 16, or could be provided as a mechanical structure such as suitably sized and spaced ratchet teeth and the like so as to provide secure but adjustable positioning of retaining structure 16 relative to elongate member 12 as desired in accordance with the present invention.

Referring now to Figures 14A and 14B, an alternative embodiment for compressing and decompressing bulb 18 is shown. In this embodiment, compressible members 72, 74 are provided in similar manner to the embodiment of Figures 10 and 11. However,

compressible members 72, 74 in this embodiment are biased toward a compressing position (Figure 14B) wherein bulb 18 is compressed and balloon 24 is inflated. In accordance with this embodiment, compressible members 72, 74 preferably have crossed extension members 80, 82 each preferably having a pressing surface 84, 86. Pressing surfaces 84, 86 can be squeezed together to the position shown in Figure 14A, thereby opening compressible members 72, 74 and allowing fluid to flow from balloon 24 into bulb 18 as desired. When it is desired to re-inflate balloon 24, releasing pressing surfaces 84, 86 allows compressible members 72, 74 to return to the rest position as shown in Figure 10, thereby compressing bulb 18 and inflating balloon 24 as desired.

Referring now to Figures 15A and 15B, a further alternative embodiment of the structure for inflating and deflating balloon 24 is illustrated. In this embodiment, bulb 18 is provided within an enclosure or sleeve member 88, and a plunger 90 is positioned within sleeve 88 for compressing bulb 18 as shown. In this manner, advantageously, plunger 90 can suitably be pressed against bulb 18 so as to compress bulb 18 and inflate balloon 24. In the apparatus of Figures 15A and 15B, plunger 90 is preferably provided with selective latch structure 91 for holding plunger 90 in the position of Figure 15B as desired. This structure 91, shown schematically in Figures 15A and 15B, could suitably be similar to the latching structure included, for example, in button-retractable pens and the like, and could be adapted to selectively latch plunger 90 in the compressed position of Figure 15B and the released position of Figure 15A.

Referring now to Figure 16, the embodiment of Figure 10 including dissolving sleeve 68 is further illustrated in a configuration corresponding to the embodiment of Figure 1, wherein balloon 24 is mounted serially adjacent to struts 30 as shown. This embodiment is in all other respects identical to the dissolving sleeve 68 which is discussed in connection with Figure 10 above and serves to provide apparatus 10 which could be inserted by the patient.

Referring now to Figures 17A-17C, an alternative embodiment of the valve structure 46 of the present invention is

illustrated. In this embodiment, a valve seat 92 is positioned, preferably between lumen 20 and the interior space of bulb 18, and for example at the neck portion 94 of bulb 18 as shown. A valve body or ball valve 96 is also preferably provided, and is suitably biased into sealing engagement with valve seat 92, for example by spring 98 as shown. In accordance with the present invention, valve seat 92 is preferably provided of a material which is distortable from the closed and sealed position of Figure 17B to the distorted and open position of Figure 17C. Advantageously, this material is selected such that, upon removal of forces distorting valve seat 92, valve seat 92 will return to the sealing position of Figure 17B.

In accordance with this embodiment, ball valve 96 serves suitably to confine fluid within balloon 24 and lumen 20 so as to insure inflation and, thereby, sealing of the bladder as desired. When it is required to deflate balloon 24 so as to allow flow from the bladder, the exertion of a laterally compressing force such as is illustrated by arrows A in Figure 17C serves to distort valve seat 92 as desired in accordance with the invention so as to open spaces 100 between ball valve 96 and the opening 102 of valve seat 92.

Referring now to Figures 18A and 18B, still another alternative embodiment of the valve structure 46 of the present invention is provided. In accordance with this embodiment, a valve seat 104 is provided, preferably also at the neck portion 94 of bulb 18 as shown, and a valve body or ball valve 106 is preferably biased into sealing engagement with valve seat 104, for example by spring 108 as shown. In this embodiment, valve seat 104 may suitably be a substantially rigid structure, and a compressible member 110 is preferably provided substantially adjacent to ball valve 106 and adapted such that the application of a compressing force such as is illustrated by arrows A in Figure 18B results in a lengthening of compressible member 110 so as to displace ball valve 106 from valve seat 104 as shown in Figure 18B, thereby allowing flow through valve 46 as desired. In this embodiment, compressible member 110 is shown as a series of struts 112 being bowed centrally outwardly such that a compressible force, when exerted thereupon, lengthens this

structure as desired. Of course, alternative structure could be provided so as to accomplish the desired displacement of ball valve 106 from valve seat 104 as desired in accordance with the present invention.

5 In accordance with this embodiment of the invention, it should be readily apparent that an apparatus 10 has been provided for relatively long-term or permanent installation and treatment of incontinence in females, which apparatus avoids the need for several daily insertions and removals, and which allows
10 for a convenient and relatively simple procedure for removing fluids from the bladder.

It is to be understood that the invention is not limited to the illustrations described and shown herein, which are deemed to be merely illustrative of the best modes of carrying out the
15 invention, and which are susceptible of modification of form, size, arrangement of parts and details of operation. The invention rather is intended to encompass all such modifications which are within its spirit and scope as defined by the claims.

WHAT IS CLAIMED IS:

1. An apparatus for treating incontinence in females, comprising:
 - an elongate body member having a first end and a second end;
 - an internal plug member positioned at the first end of the body member;
 - an external retaining member positioned at the second end, at least one member of the internal plug member and the external retaining member being moveable longitudinally with respect to the other member of the internal plug member and the retaining member; and
 - means for longitudinally securing the at least one member relative to the other member, whereby the elongate body member can be positioned in a urethra with the plug member positioned at an interior opening of the urethra and with the retaining member positioned at an exterior opening of the urethra.
2. An apparatus according to claim 1, wherein the internal plug member comprises an inflatable balloon for substantially blocking flow of urine into the urethra.
3. An apparatus according to claim 2, further comprising means for inflating the balloon with the elongate body member positioned in the urethra.
4. An apparatus according to claim 3, wherein the means for inflating comprises a fluid passage associated with the elongate body member and communicated at one end with the balloon and communicated at the other end with a source of inflation fluid for inflating the balloon.
5. An apparatus according to claim 4, wherein the fluid passage comprises a lumen running lengthwise along the elongate body member.
6. An apparatus according to claim 5, wherein the lumen is defined within the elongate body member.

7. An apparatus according to claim 4, wherein the source of inflation fluid comprises a bulb communicated with the fluid passage and containing inflation fluid whereby compression of the bulb drives the inflation fluid through the fluid passage into the balloon to inflate the balloon.

8. An apparatus according to claim 7, further comprising means for selectively compressing and releasing the bulb to inflate and deflate the balloon.

9. An apparatus according to claim 8, wherein the means for compressing comprises first and second compression members disposed on substantially opposite sides of the bulb, at least one of the first and second compression members being movable relative to the other of the first and second compression members between a closed position wherein the first and second members compress the bulb, and an opened position wherein the first and second members are at least partially spaced from each other to at least partially decompress the bulb.

10. An apparatus according to claim 9, wherein the first and second compression members are biased toward the open position and further comprising latch means for selectively locking the first and second compression members in the closed position.

11. An apparatus according to claim 9, wherein the first and second compression members are biased toward the closed position, and further comprising means for manually moving the first and second compression members to the open position.

12. An apparatus according to claim 8, wherein the means for selectively compressing comprises a support member for holding the bulb, a plunger movably disposed in the support member between a closed position wherein the plunger compresses the bulb and an open position wherein the bulb is at least partially decompressed, and latch means for selectively latching the plunger in the closed position.

13. An apparatus according to claim 7, further comprising a valve member associated with the bulb for releasably blocking flow of inflation fluid into the bulb whereby the balloon is selectively inflatable for blocking flow of urine into the urethra.

14. An apparatus according to claim 13, wherein the valve member comprises a deformable resilient valve seat and a valve body member in sealing engagement with the valve seat in a non-deformed position, wherein deforming the valve seat at least partially opens the valve seat relative to the valve body to allow flow therethrough, and releasing the valve seat allows the valve seat to return to a non-deformed position in sealing engagement with the valve body member.

15. An apparatus according to claim 13, wherein the valve member comprise a valve seat and a valve body member biased into sealing engagement with the valve seat, and further comprising means for displacing the valve body relative to the valve seat.

16. An apparatus according to claim 15, wherein the means for displacing comprises a compressible structure positioned substantially adjacent to the valve body member and compressible to a deformed position wherein the compressible member displaces the valve body member from the valve seat.

17. An apparatus according to claim 2, further comprising means for selectively inflating and deflating the balloon between an inflated position wherein flow of urine into the urethra is substantially blocked and a deflated position wherein flow of urine into the urethra is substantially unblocked.

18. An apparatus according to claim 17, further comprising interior retaining means positioned at the first end for retaining the elongate body member within the urethra when the balloon is deflated.

19. An apparatus according to claim 18, wherein the interior retaining means comprises expandable means expandable to a radially expanded position for holding the elongate body member within the urethra.

20. An apparatus according to claim 19, further comprising means for expanding the expandable means with the elongate body member positioned in the urethra.

21. An apparatus according to claim 20, wherein the means for expanding comprises means extending through the elongate body member and secured to the expandable means at one end, and passing through the retaining member at the other end, for exerting a longitudinally compressive force on the expandable means so as to expand the expandable means to the radially expanded position.

22. An apparatus according to claim 21, wherein the expandable means comprises a plurality of flexible struts having first ends and second ends, wherein the first ends are fixed relative to the elongate body member and the second ends extend longitudinally away from the first ends and the elongate body member, wherein the flexible struts are biased toward a substantially straight radially withdrawn position, and wherein the means for expanding is secured to the second ends for exerting the longitudinally compressive force on the second ends to flex the struts and expand the expandable means to the radially expanded position.

23. An apparatus according to claim 20, wherein the elongate body member defines a lumen and wherein the means for expanding is accommodated in the lumen.

24. An apparatus according to claim 20, wherein the elongate body member defines a first lumen and a second lumen, wherein the first lumen accommodates the means for selectively inflating and deflating and the second lumen accommodates the means for expanding.

25. An apparatus according to claim 1, further comprising interior retaining means positioned at the first end for retaining the elongate body member within the urethra.

26. An apparatus according to claim 25, wherein the interior retaining means comprises expandable means expandable to a radially expanded position for holding the elongate body member within the urethra.

27. An apparatus according to claim 26, further comprising means for expanding the expandable means with the elongate body member within the urethra.

28. An apparatus according to claim 27, wherein the means for expanding comprises means extending through the elongate body member and secured to the expandable means at one end, and passing through the retaining member at the other end, for exerting a longitudinally compressive force on the expandable means so as to expand the expandable means to the radially expanded position.

29. An apparatus according to claim 28, wherein the expandable means comprises a plurality of flexible struts having first ends and second ends, wherein the first ends are fixed relative to the elongate body member and the second ends extend longitudinally away from the first ends and the elongate body member, wherein the flexible struts are biased toward a substantially straight radially withdrawn position, and wherein the means for expanding is secured to the second ends for exerting the longitudinally compressive force on the second ends to flex the struts and expand the expandable means to the radially expanded position.

30. An apparatus according to claim 29, wherein the elongate body member defines a lumen and wherein the means for expanding is accommodated in the lumen.

31. An apparatus according to claim 25, wherein the interior retaining means comprises a compressible radially expanded member, and means for radially compressing the radially expanded member to a radially compressed position, whereby insertion of the apparatus into a urethra is facilitated.

32. An apparatus according to claim 31, wherein the means for radially compressing comprises a dissolvable sleeve positioned over the radially expanded member whereby, after insertion, the sleeve dissolves and the radially expanded member expands.

33. An apparatus according to claim 25, wherein the internal plug member is positioned within the interior retaining means.

34. An apparatus according to claim 1, wherein the retaining means comprises a substantially hemispheric member slidably positioned on the elongate body member and having means for directing flow at an angle with respect to a longitudinal axis of the elongate body member.

35. An apparatus according to claim 34, wherein the means for directing flow comprises an opening positioned in a side wall of the substantially hemispheric member.

36. An apparatus according to claim 34, wherein the means for longitudinally securing comprises at least one flexible member fixed relative to the plug member and securably passing through the hemispheric member, whereby securing the flexible member to the hemispheric member fixes the hemispheric member against longitudinal movement away from the plug member.

37. An apparatus according to claim 1, wherein the means for longitudinally securing comprises a frictional engagement between the external retaining member and the elongate body member.

38. An apparatus according to claim 1, wherein the retaining member comprises a hub for engaging the elongate body member, a retaining rim for contacting exterior opening of the urethra, and means for connecting the hub and the rim with the rim spaced distally of the hub.

39. An apparatus according to claim 38, wherein the means for connecting comprises a plurality of spokes connected between the rim and the hub.

40. An apparatus according to claim 1, further comprising a flexible member extending from the second end, the retaining member being slidably positioned on the flexible member, and wherein the means for longitudinally securing comprises means for securing the retaining member relative to the body member.

41. An apparatus according to claim 40, wherein the means for securing comprises knob means positioned at the second end of the elongate body member, and wherein the retaining member has knob engaging means for releasably engaging the knob means in a blocking position wherein the plug member is substantially sealingly positioned in the interior opening of the urethra.

42. An apparatus according to claim 41, wherein the knob means is longitudinally positionable relative to the elongate body member whereby a distance between the plug member and the retaining member in the blocking position can be adjusted.

43. An apparatus according to claim 40, further comprising stop means positioned on the flexible member for limiting a maximum movement of the retaining member away from the plug member along the flexible member.

44. An apparatus according to claim 40, wherein the elongate body member is a rod and the flexible member is a string.

45. An apparatus according to claim 40, wherein the retaining member comprises a substantially dome shaped member having the flexible member passing therethrough, and having an opening in a side wall of the dome shaped member for directing flow out of the dome shaped member.

46. An apparatus according to claim 40, wherein the internal plug member comprises an inflatable balloon.

47. An apparatus according to claim 46, further comprising means for inflating the balloon with the elongate body member positioned in the urethra.

48. An apparatus for treating incontinence in females, comprising:

- an elongate body member having a first end and a second end;

- an inflatable internal plug member positioned at the first end of the body member; and

- an inflatable retaining member spaced toward the second end from the first end and position, when inflated, to prevent migration of the apparatus into the bladder;

wherein the inflatable internal plug member is inflatable to an inflated condition wherein the inflatable internal plug member blocks flow from the bladder, and a deflated condition wherein flow from the bladder, and through the urethra outside the elongate body member is allowed.

49. A method for treating incontinence in females, comprising the step of:

- providing an apparatus comprising an elongate body member having a first end and a second end; an internal plug member positioned at the first end of the body member; an external retaining member positioned at the second end, at least one member of the internal plug member and the external retaining member being movable longitudinally with respect to the other member of the internal plug member and the retaining member; and means for longitudinally securing the at least one member

relative to the other member, wherein the internal plug member comprises an inflatable balloon in a deflated condition;

positioning the elongate body member in the urethra with the internal plug member positioned at an interior opening of the urethra;

moving the retaining member relative to the plug member so as to position the retaining member at the exterior opening of the urethra;

securing the retaining member relative to the plug member at the exterior opening of the urethra; and

selectively inflating and deflating the balloon between an inflated condition wherein the plug member substantially seals the interior opening of the urethra and the deflated condition wherein the plug member does not substantially seal the interior opening of the urethra.

50. A method for treating incontinence in females, comprising the steps of:

providing an apparatus comprising an elongate body member having a first end and a second end; an internal plug member positioned at the first end of the body member; an external retaining member positioned at the second end, at least one member of the internal plug member and the external retaining member being movable longitudinally with respect to the other member of the internal plug member and the retaining member; and means for longitudinally securing the at least one member relative to the other member, wherein the internal plug member comprises an inflatable balloon in a deflated condition;

positioning the elongate body member in the urethra with the internal plug member positioned at an interior opening of the urethra;

inflating the balloon; and

selectively moving the retaining member relative to the plug member between a sealing position wherein the balloon is sealingly positioned at the interior opening of the urethra and a voiding position wherein the balloon is at least partially spaced from the interior opening of the urethra.

51. A method according to claim 50, wherein the apparatus further includes knob means associated with the second end of the elongate body member; and wherein the retaining member further comprises knob engaging means for releasably engaging the knob means; and further comprising the step of engaging the knob engaging means with the knob in the sealing position.

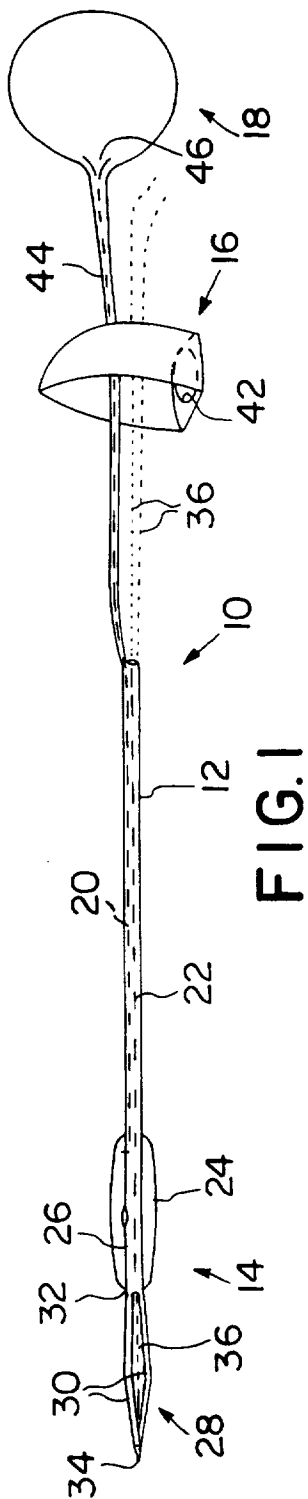


FIG. 1

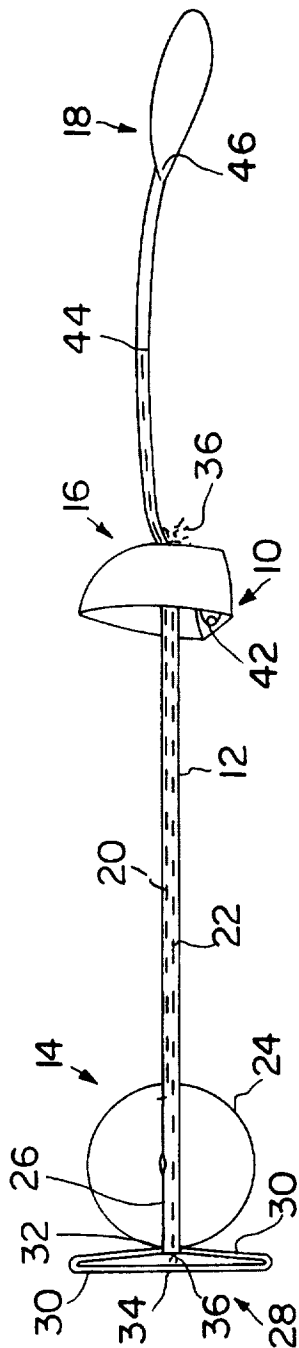


FIG. 2

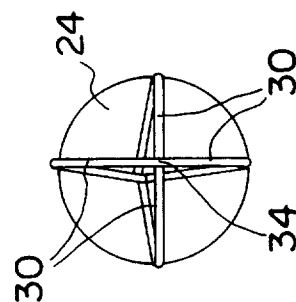


FIG. 3

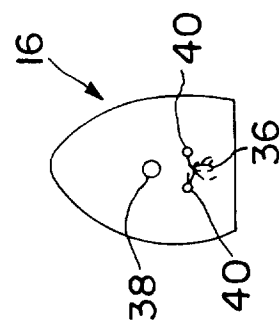


FIG. 4

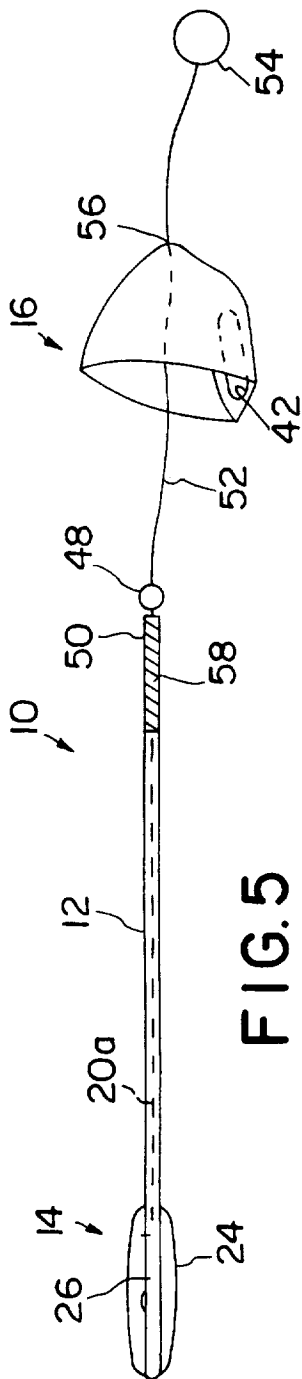


FIG. 5

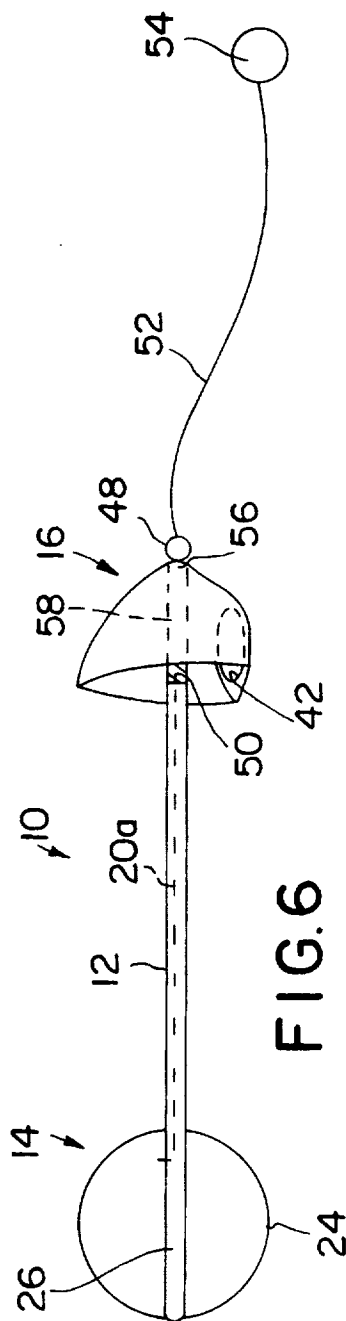


FIG. 6

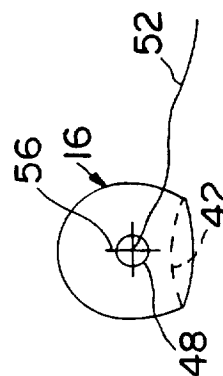


FIG. 7

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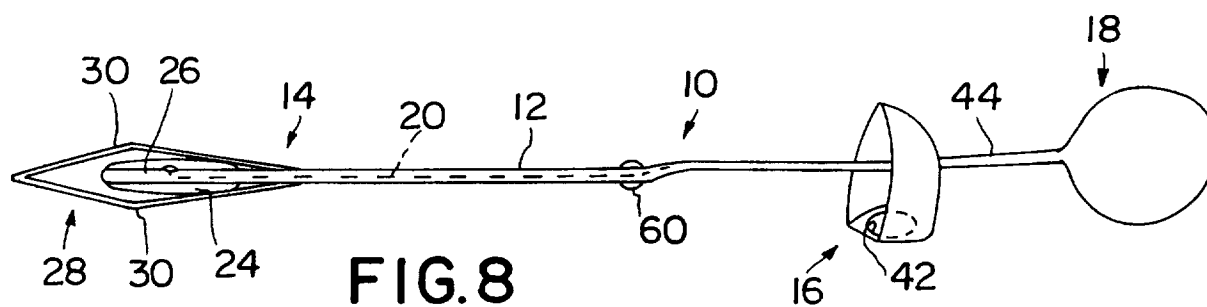


FIG. 8

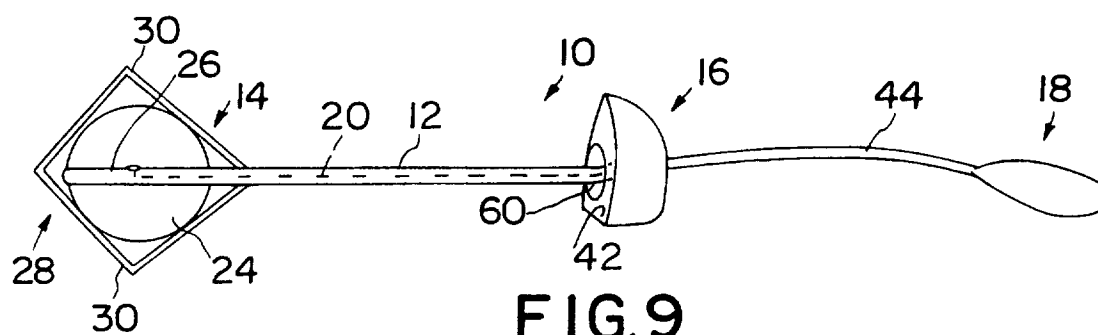


FIG. 9

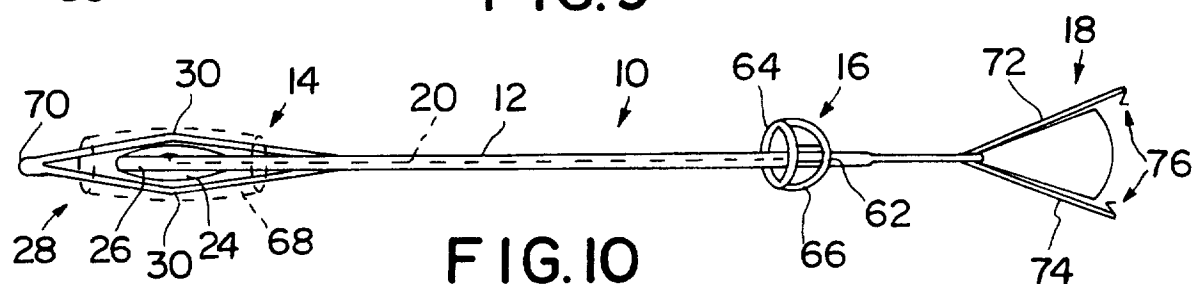


FIG. 10

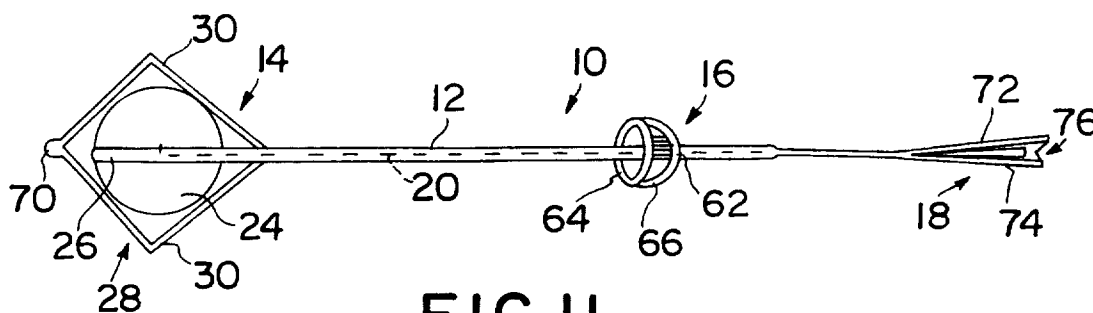


FIG. 11

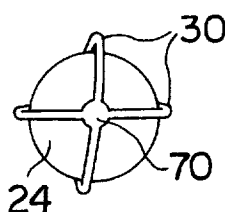


FIG. 12

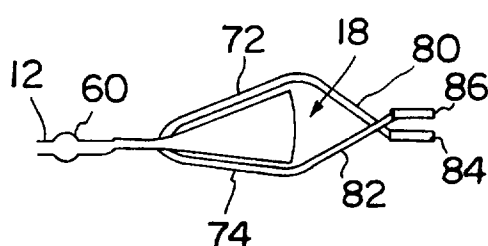


FIG. 14A

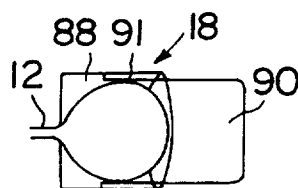


FIG. 15A

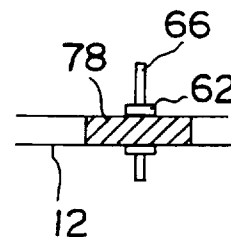


FIG. 13

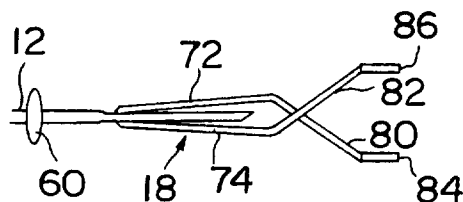


FIG. 14B

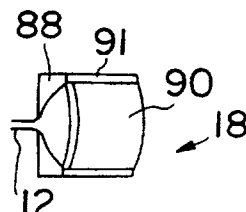


FIG. 15B

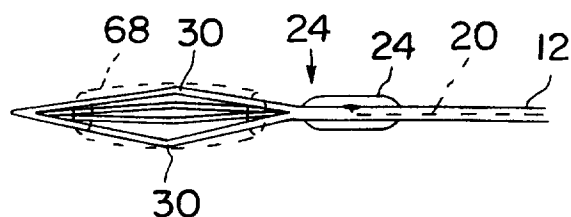


FIG. 16

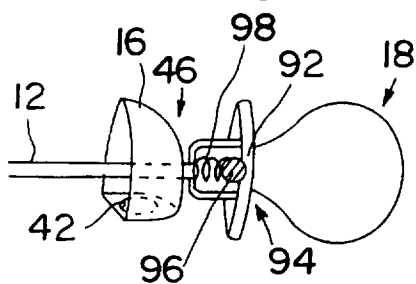


FIG. 17A

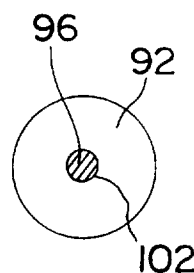


FIG. 17B

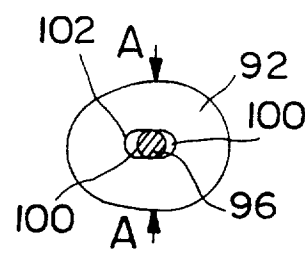


FIG. 17C

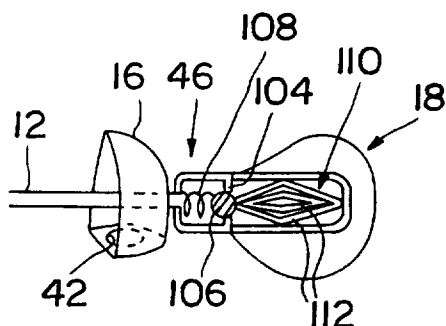


FIG. 18A

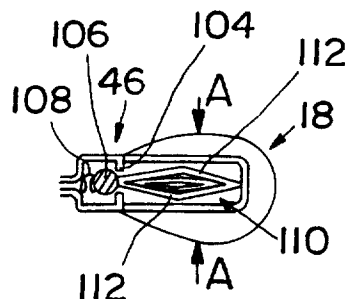


FIG. 18B

INTERNATIONAL SEARCH REPORT

 International application No.
PCT/US97/13830

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/DIG. 25, 834-836; 600/029-032

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.
X --- Y	US 3,841,304 A (JONES) 15 October 1974, entire document.	1-8, 13, 17, 37, 40, 46, 47, 49- 51 ----- 9, 38
Y	US 5,234,409 A (GOLDBERG et al.) 10 August 1993, col. 4, lines 36-46.	14-16
Y	US 4,909,785 A (BURTON et al.) 20 March 1990, Fig. 1.	48

☐ 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)	"G" 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

11 SEPTEMBER 1997

Date of mailing of the international search report

06 OCT 1997

 Name and mailing address of the ISA/US
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