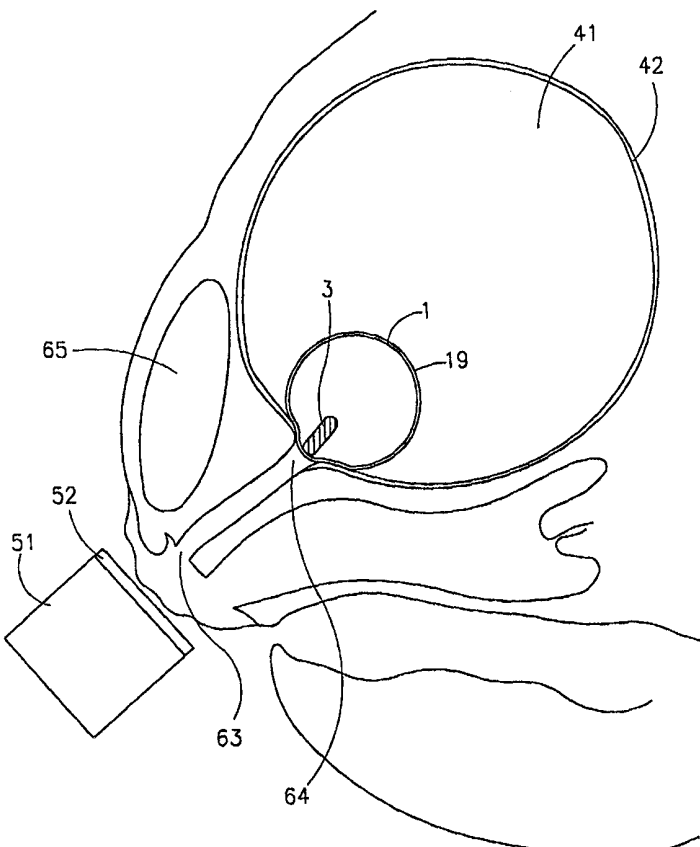


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁷ : A61F 2/00, A61M 31/00</p>	<p>A1</p>	<p>(11) International Publication Number: WO 00/54701</p> <p>(43) International Publication Date: 21 September 2000 (21.09.00)</p>
<p>(21) International Application Number: PCT/IL00/00160</p> <p>(22) International Filing Date: 15 March 2000 (15.03.00)</p> <p>(30) Priority Data: 09/268,109 15 March 1999 (15.03.99) US</p> <p>(71) Applicant (for all designated States except US): INNOVENTIONS INC. [US/US]; c/o C.T. Corporation Systems, P.O. Box 4349, Carol Stream, IL 60197-4349 (US).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): YACHIA, Daniel [IL/IL]; Yehuda Maccabi Street 17-B, 46762 Herzliya on Sea (IL). HIRSZOWICZ, Eran [IL/IL]; Aluf David Street 171, 52236 Ramat-Chen (IL).</p> <p>(74) Agent: REINHOLD COHN AND PARTNERS; P.O. Box 4060, 61040 Tel-Aviv (IL).</p>		<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: INTRAVESICULAR BALLOON</p>		
<p>(57) Abstract</p> <p>A system for treating a urinary bladder of an individual. The system comprises a balloon for insertion into the urinary bladder. The balloon can be filled with a fluid such that after filling the balloon has a specific gravity less than or equal to that of urine. The system also comprises an applicator for inserting the balloon into the urinary bladder or for removing the balloon from the urinary bladder. The balloon is useful in treating the urinary bladder, in monitoring the urinary bladder and in the treatment of urinary incontinence.</p> 		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

INTRAVESICULAR BALLOON

FIELD OF THE INVENTION

The invention is in the field of medical devices. More specifically, the invention relates to devices for the treatment of urinary bladder disorders.

BACKGROUND OF THE INVENTION

5 Several disorders of the urinary tract are known. Among these are urinary incontinence, chronic urinary tract infections, urinary bladder tumors.

SUMMARY OF THE INVENTION

Urinary incontinence mostly affects women (approximately 10 million in the U.S.A. alone) primarily after childbirth or due to old age. In men, urinary
10 incontinence often occurs as a complication of surgery or old age (approximately 3 million in the U.S.A.).

Incontinence has serious economic, health, social and psychological consequences. Its estimated cost to the health system in the United States in 1993 was US \$16 billion. It leads to chronic and severe skin irritation in the genital area,
15 an increase in urinary infections and urosepsis. Fear of incontinence and odors in public cause incontinent people to severely restrict their social activities. The impact on the mental health of the affected people may be even more devastating than the social and health consequences. They suffer severe embarrassment, loss of self-esteem, depression and anxiety.

Urinary incontinence can be divided into 4 groups:

Stress Incontinence - is the involuntary release of urine due to a sudden increase in the intraabdominal pressure caused by laughing, sneezing, coughing, running, etc.

5 This is the most common type of incontinence and in women may be the result of childbirth, estrogen deficiency, unsuccessful surgical repairs for incontinence or pelvic irradiation. In men, it often happens after surgery for benign enlargement of the prostate gland or after radical removal of the prostate.

10 ***Total Incontinence*** – is the continuous leak of urine entering the bladder due to failure of the sphincteric muscles.

Urge Incontinence – is involuntary loss of urine due to involuntary bladder contractions. This type of incontinence mostly affects the elderly who leak until
15 they reach a toilet.

Mixed Incontinence – is a combination of stress and urge incontinence. This condition is more common in elderly women than men.

20 Ideally, treatment of incontinence should provide permanent dryness and is easy to perform.

Pharmacological treatments of bladder dysfunctions are based either on estrogen replacement for treating post-menopausal vaginal and urethral atrophy or on agents affecting the tonus of the bladder muscle. Since affected elderly women
25 suffer from both hormonal deficiency and urge incontinence, both types of agents are usually prescribed simultaneously.

Surgical treatments are based on restoring the anatomical changes causing the incontinence. Although in the short-term most surgical procedures restore continence, the long-term prognosis is usually unsatisfactory. Moreover, surgery
30 entails morbidity and high expenses.

Conservative/behavioral treatments are based on pelvic floor muscle exercises, bladder training, biofeedback, vaginal cones, low-frequency electrostimulation of pelvic floor muscles, intravaginal bladder neck support pessaries, urethral meatus suction cups and intraurethral devices. Conservative
5 treatments are time consuming and require the patients' understanding, cooperation and persistence.

Devices which have been used to obtain almost immediate dryness in incontinent people can be divided into two groups:

10 (1) Urethral Plugs/Inserts

These comprise a flexible rod having a 14 Ch. (approximately 4.5 mm) diameter and a length adjusted to fit the length of the patient's urethra. The rod has an inflatable balloon on its bladder end and a flange at other end. After insertion of the device, the balloon is inflated in the bladder. The balloon and the flange
15 maintain the device in its proper position within the urethra. The balloon and rod form a mechanical barrier to retain the urine within the bladder. The balloon must be deflated and the device removed and discarded prior to voiding. Such inserts are known in the art, for example, the device known as RELIANCE™ produced by UroMed Corp., U.S.A.

20 Since inserts are discarded after each voiding and replaced with a new one by the patient, manual dexterity of the patient is required. Insertion of an insert into a female has the risk of pushing vaginal and perineal bacteria into the bladder and insertion of an insert a few times a day increases this risk. The inconvenience of removing and inserting a new device and its costs, in addition to the infection risk,
25 are the major disadvantages of these devices.

(2) Valve Catheters

These comprise a tube with a valve at one end. The bladder end of the device typically has a balloon or flanges for retaining the device in place and a
30 flange at the other end to prevent migration into the bladder. The valve is opened

- 4 -

for voiding through the lumen of the catheter with the help of an external magnet. The tube typically has a 18 Ch. (6 mm.) to 20 Ch. (approximately 7 mm) diameter and a length adjusted to fit the patient's urethra. For male incontinence, an active intraurethral Foley-type catheter is used. This device has a retaining balloon at its
5 bladder end and another smaller balloon under the prostate for fixing the device in place. The magnet activated valve is situated at the end of the device near the distal end of the urethra. Active inserts are typically left indwelling up to 4 weeks and are then replaced. Examples of such catheters are disclosed in U.S. Patent Nos. 5,030,199 and 5,234,409.

10 Valve catheters are more convenient for the patient than the inserts. However, in females they cause ascending infection because they connect the bladder with the vulva which is rich in pathogenic bacteria, especially *Escherichia Coli*. Even with continuous use of antibiotics, infection is unpreventable in the majority of cases.

15 During prolonged use of catheters or inserts in female patients, a relaxation of the urethra occurs and the patients may start to leak around the device. Unfortunately valve catheters and inserts are unavailable in increasing diameters.

A significant disadvantage of both the inserts and the valve catheters is the discomfort felt by the patient especially when sitting and during sexual intercourse
20 (felt by the patient and the partner). The present invention therefore provides a device for the treatment of urinary incontinence in which the disadvantages of the prior art devices are substantially reduced or eliminated.

(3) Urinary Bladder Plugs

U.S. Patent No. 4,850,963 to Sparks *et al.* discloses a bolus for insertion in
25 to a urinary bladder for the treatment of urinary incontinence. The bolus contains a ferromagnetic material and has a specific gravity greater than that of urine. The bolus is maintained at the urinary bladder outlet to the urethra under the influence of gravity so as to prevent the flow of urine into the urethra. For voiding, the bolus is displaced from the opening using an external magnet.

Urinary Tract Infections

Nearly half of all women experience urinary tract infection (UTI) at some point in their lifetime and most of these infections are confined to the bladder. Isolated UTIs can be treated by short and effective antibiotic treatment. However, 5 recurrent UTIs often occur in women due to antibiotic resistant bacteria . In this case complicated infections often exhibit multidrug resistance and necessitate longer antimicrobial drug administrations.

Treatment of UTI often requires urinary levels of antimicrobial drugs that are several hundred times greater than those allowable in the blood. Many 10 antibacterials cannot be used in UTI because, when taken orally or intravenously, they do not attain the required concentration in the urine, without exceeding the allowable limit in the blood. It would therefore be desirable to be able to continuously introduce antimicrobial drugs continuously and directly into the bladder.

15

Bladder tumors

Even after resection, bladder tumors may not only recur but may also invade deeper in the bladder wall. Due to the heterogeneity of these tumors (from low-grade tumors showing a benign course to highly malignant high-grade tumors), 20 there does not exist a single approach to the surveillance and treatment of these tumors. Intravesical drug therapies are often used for reducing tumor recurrence. In this approach, an immunotherapeutic or chemotherapeutic agent is inserted into the bladder through a catheter. This treatment is typically repeated once a week for 6 weeks and then once a month for a period of 6-12 months. However, periodic 25 treatment has not been established as being effective in altering the progression of the tumor. Continuous local treatment with chemotherapeutic or radioactive materials may treat or prevent not only superficial tumors but also deep tumors as well. It would therefore be desirable to be able to introduce antitumoral drugs continuously and directly into the bladder.

30

Bladder dysfunction

During filling, the bladder muscle relaxes for keeping the intravesical pressure low while it contracts for voiding. Certain diseases such as spinal cord injuries, diabetes, multiple sclerosis, or hormonal changes after menopause or old
5 age in both sexes may cause a hypo-contraction or, paradoxically, hyper-contraction of the muscle. In atonic bladder, pharmacological treatment is not very effective. In hyperreflexic bladder, drugs for relaxing the bladder cause constipation and mouth dryness and are therefore not tolerated well by the patients.

Diagnosis of bladder dysfunction requires continuously monitoring various
10 bladder parameters during filling and/or voiding. These measurements usually are made by inserting a catheter connected to a measuring device into the bladder. This is done, for example, in uroflowmetry (measurement of urinary flow rate) which is non-invasive, simple and inexpensive. However, its sensitivity and specificity are low. Cystometry is an invasive technique for measuring bladder capacity,
15 compliance and muscle tonus. Pressure-flow study is an invasive and costly test for distinguishing patients with low urinary flow due to obstruction or bladder antonia, from those with high intravesical pressure and high urinary flow. It is therefore a need in the art for a simple and inexpensive technique for intravesicular monitoring.

20 In the diagnostic procedure known as "urodynamics", the bladder is filled through a catheter, and the response of the bladder is monitored. Available 24 hour urodynamic monitors have catheters or wires passing through the urethra, connecting sensors inserted into the bladder to a recorder. The connecting wires and catheters inadvertently introduce pathogenic bacteria from the genital areas into
25 the bladder. It is therefore desirable to be able to monitor bladder function over several cycles of filling and voiding without the need for such wires or catheters.

Diagnosis of some intravesical pathological conditions often involves inserting an endoscope into the bladder and optically scanning the bladder walls. In cases of bleeding in the ureters or the kidneys, the observation of blood coming
30 through the ureteral orifices allows determination of the origin of the bleeding.

However, if the bleeding has temporarily stopped at the time of the examination, or if the blood concentration in the urine is insufficient to make the urine red or pink, endoscopy is of little value in reaching a diagnosis. In such cases more invasive procedures are performed in order to enter the upper urinary tract. It is therefore
5 desirable to be able to monitor the bladder over long periods of time.

Bladder shape during filling and its contraction during voiding is important for the diagnosis of certain bladder pathologies. These functions can be followed in fluoroscopy and by sonography. These techniques however are not accurate and cannot be used for monitoring changes in bladder shape over long periods of time.

10 It would therefore be desirable to be able to continuously image the bladder interior over long periods of time.

The present invention therefore provides a device for continuous monitoring of the bladder interior and for the treatment of bladder disorders in which the disadvantages of the prior art devices are substantially reduced or eliminated.

15 SUMMARY OF THE INVENTION

The present invention provides a system for treating a urinary bladder. The system comprises a balloon having a specific gravity less than or equal to that of urine suitable for insertion into a urinary bladder. Preferably, the specific gravity of the balloon is less than that of urine. The system also comprises an applicator for
20 inserting the balloon into the bladder and for removing it. After insertion into the urinary bladder, the balloon experiences a buoyant force due to urine in the bladder having a magnitude greater than that of any counter forces acting on it (e.g. a gravity or a hydrostatic pressure). Thus, in the absence of an externally applied force, the balloon spontaneously floats in the urine irrespective of the person's
25 position.

The invention may be used for the intermittent sealing of the urinary bladder outlet for the prevention of involuntary urine leakage. Sealing the urinary bladder outlet involves applying an external force such as a magnetic force in order to position the balloon in the outlet so as to seal it. Unsealing the outlet to allow

voiding of the bladder involves removing the externally applied force so as to allow the balloon to float away from the outlet thus unsealing the outlet. The balloon is preferably coated with a hydrophilic coating to reduce frictional forces between the balloon and the wall of the bladder. This facilitates release of the balloon from the
5 outlet upon removal of the external force.

The invention may also be used for such purposes as for example, delivery of drugs, imaging the urinary bladder, and measuring intravesicular parameters such as pressure in the urinary bladder. When used for such purposes, the balloon may be, for example, positioned in the urinary bladder outlet, immobilized in a
10 desired location in the bladder, freely floating in the urine in the bladder, etc.

The invention is entirely confined to the urinary bladder and has no urethral parts. As will become apparent in the description below, the balloon is easily inserted and removed. It may be left in the bladder for prolonged periods of time without encrusting or causing infections and is displaced within the bladder at will
15 using a hand held magnet. The invention is comfortable for the patient and does not interfere with the daily activities of the patient including sitting, jogging, riding, or sexual intercourse.

Thus, in its first aspect, the invention provides a urological medicinal system for use in medical procedures within a urinary bladder of an individual, comprising:

- 20 (a) a balloon for insertion into the urinary bladder, the balloon having a lumen and a wall, the wall having an outer surface, the balloon being configured so that the lumen may be filled with a fluid such that, after filling, the balloon has a specific gravity less than or equal to that of urine; and
- 25 (b) an applicator for inserting the balloon into the urinary bladder or for removing the balloon from the urinary bladder, the applicator fitted at an end thereof with a gripping device for releasably gripping the balloon.

In its second aspect, the invention provides a method for treating urinary incontinence in an individual comprising the steps of:

- 9 -

- (a) inserting into a urinary bladder of the individual a balloon having a specific gravity less than or equal to that of urine and formed with a magnetizable portion;
- (b) expanding the balloon in the urinary bladder;
- 5 (c) displacing the balloon into a sealing position for sealing the urinary bladder; and
- (d) displacing the balloon within the urinary bladder into an unsealing position for voiding the urinary bladder.

In its third aspect, the invention provides a method for releasing one or more
10 substances into a urinary bladder comprising the steps of:

- (a) loading the one or more substances into a balloon;
- (b) inserting the balloon into the individual's urinary bladder;
- (c) expanding the balloon in the urinary bladder so that after expanding, the balloon has a specific gravity less than or equal to that of urine;
15 and
- (d) displacing the balloon within the urinary bladder to a desired location.

In its fourth aspect, the invention provides a method for monitoring the interior of a urinary bladder comprising the steps of:

- 20 (a) inserting into the urinary bladder a balloon including one or more monitoring devices for sampling a morphological or physiological parameter of the urinary bladder and for emitting a signal indicative of a quality or quantity of a sampled parameter;
- (b) expanding the balloon in the urinary bladder so that after expanding,
25 the balloon has a specific gravity less than or equal to that of urine and;
- (c) displacing the balloon within the urinary bladder to a desired location; and
- (d) in a monitoring apparatus, recording and optionally processing the
30 signals emitted from the one or more monitoring devices.

In its fifth aspect, the invention provides a method for imaging the interior of a urinary bladder comprising the steps of:

- 5 (a) inserting into the urinary bladder a balloon including a device for imaging the urinary bladder and for emitting a signal indicative of an image of the urinary bladder;
- (b) expanding the balloon in the urinary bladder so that after expanding, the balloon has a specific gravity less than or equal to that of urine and;
- 10 (c) displacing the balloon within the urinary bladder to a desired location within the urinary bladder; and
- (d) transmitting signals from the imaging device to a receiver.

In its sixth aspect, the invention provides a method for releasing one or more substances into a urinary bladder comprising steps of:

- 15 (a) providing a balloon comprising a pump fed by a reservoir and configured for pumping the content of the reservoir to the balloon's exterior;
- (b) loading the reservoir with the one or more substances;
- (c) inserting the balloon into the urinary bladder;
- (d) expanding the balloon in the urinary bladder so that after expanding, the
20 balloon has a specific gravity less than or equal to that of urine; and
- (d) activating the pump so as to release the one or more substances into the bladder.

In its seventh aspect, the invention provides a balloon for insertion into the urinary bladder, the balloon having a lumen and a wall, the wall having an outer
25 surface, the balloon being configured so that the lumen may be filled with a fluid such that, after filling, the balloon has a specific gravity less than or equal to that of urine.

BRIEF DESCRIPTION OF THE DRAWINGS:

In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

5 **Fig. 1** shows various embodiments of the balloon according to the invention;

Fig. 2 shows a portion of a balloon according to the invention having a duck-bill valve;

Fig. 3 shows a portion of a balloon according to the invention having a ball
10 valve;

Fig. 4 shows a balloon filled after have been inserted into the urinary bladder;

Fig. 5 shows a balloon filled before being inserted into the urinary bladder;

Fig. 6 shows a balloon comprising diffusible substances within its wall or
15 lumen;

Fig. 7 shows a balloon comprising an imaging device;

Fig. 8 shows a balloon comprising devices for measuring urinary bladder parameters;

Fig. 9 shows use of an applicator for inserting a balloon into the urinary
20 bladder of a female individual;

Fig. 10 shows use of an applicator for inserting a balloon into the urinary bladder of a male individual;

Fig. 11 shows a retrieval device for retrieving a balloon;

Fig. 12 shows use of a displacing member to displace a balloon into a
25 sealing position within the urinary bladder;

Fig. 13 shows use of a displacing member to displace a balloon from a sealing position in the urinary bladder;

Fig. 14 shows use of an immobilizing member; and

Fig. 15 shows a balloon comprising a pump.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

Reference is now made to Fig. 1 which shows several embodiments of the invention. An expandable hollow balloon generally designated as **1**, for use in the system of the invention, has a wall **2** made of an elastic biocompatible material enclosing a lumen **4**. The balloon **1** may be coated on its outer surface with a hydrophilic coating **19**. The balloon **1** may further comprise a magnetizable portion which may consist for example, of one or more metal particles which may be free in the lumen **3a** (as in Fig. 1b), attached to the inner surface **3b** (as in Fig. 1c) or embedded in the wall **3c** of the balloon (as in Fig. 1d). The lumen **4** of balloon **1** may be filled with a biocompatible fluid which may be presterilized such as air, water, saline or an oil such as liquid paraffin, or a mixture thereof, so that the balloon has an overall specific gravity less than or equal to that of urine.

A self-sealing valve **5** in the wall of the balloon is used to fill the balloon. The valve **5** may be for example a duck-bill type valve as shown in Fig. 2 or a ball valve as shown in Fig. 3 in which a ball **8** may be in a sealing position (Fig. 3a) or an unsealing position (Fig. 3c). The canula **6** of a syringe **7** is inserted through the valve **5** into the lumen **4** of the balloon. The fluid injected into the lumen **4** causes the balloon to expand. After filling, the syringe needle **6** is withdrawn, and the valve **5** seals itself. After filling, the balloon may adopt a predetermined shape, for example, a sphere, ellipsoid, or an irregular shape. Since the inflated balloon has a specific gravity less than or equal to that of urine, the balloon floats in urine.

As shown in Fig. 4, the balloon may first be inserted into the bladder by means of an applicator **20** to be described below in detail (Fig. 4a), filled with fluid **24** from a syringe **7** (Fig. 4b) and then released from the applicator into the bladder. Alternatively, as shown in Fig. 5a, the balloon **1** may be filled and compressed before being inserted into the bladder by means of applicator **20**. The prefilled balloon is clutched by the flanges **23** which are initially kept closed by constraining sleeve **26** (Fig. 5a). After insertion of the applicator **20** with the prefilled balloon **1** into the urinary bladder, ring **25** is pulled as indicated by

arrow 21 in Fig. 5b to urge the constraining sleeve 26 away from the flanges 23, allowing flanges 23 to open and release the prefilled balloon 1 into the bladder.

Fig. 6 shows a balloon 1 constructed so as to have one or more diffusible substances contained within its wall 2 or lumen 4. Such substances could be, for example, drugs, antibiotics immunoglobulins, or radioactive substances, etc. After insertion of the balloon 1 into the lumen of the urinary bladder, the substances diffuse from the balloon 1 into the bladder (arrows 9) in order to achieve a desired effect.

Fig. 7 shows a balloon 1 constructed so as to comprise a microvideo camera 19 for imaging the interior of the bladder. The video camera 19 may have associated with it a transmitter 10 for transmitting images to a remote receiver 11. Such microvideo cameras and transmitters are known in the art, for example, as disclosed in U.S. Patents 5,604,531, 5,579,781 and 5,188,109. The receiver 11 may be connected to a processing unit 12 for processing the images, or a display 13 for displaying images.

Fig. 8 shows a balloon 1 constructed so as to comprise one or more devices 14 for measuring one or more parameters associated with the urinary bladder, for example, bladder pressure, urine temperature, urine density, urine conductivity or urine composition. The devices 14 may be affixed to the outer surface of the balloon 14a, embedded within the wall 2 of the balloon 14b or affixed to the inner surface of the balloon 14c. The measuring devices 14 may have associated with them a transmitter 15 for transmitting measurements to a remote receiver 16. The receiver may be connected to a processing unit 17 for processing the measurements or to a display 18 for displaying results. Such measuring devices are known in the art, for example as disclosed in U.S. Patents 5,579,781 and 5,188,109.

Fig. 9 shows use of an applicator 20 for inserting the balloon 1 into the lumen 41 of the urinary bladder 42 of a female individual, and Fig. 10 shows use of the applicator 20 inserting the balloon 1 into the lumen of the urinary bladder 42 of

a male individual. In either case the balloon **1** is initially grasped by the closed flanges **23a** at the distal end of the applicator **20** (Figs. 9a and 10a). The distal end of the applicator-balloon combination is inserted into the urethra until it reaches the lumen **41** of the bladder **42**. The balloon **1** is filled and then released from the applicator by opening the flanges **23b** by pulling on ring **25** while holding the constraining sleeve **26**. The applicator **20** is then removed from the body, leaving the balloon **1** in the bladder lumen **41**.

Fig. 11 shows a retrieval device generally designated as **30** for removing the balloon from the bladder. A catheter **27** has at its distal end **28** a magnetizable portion **29** so as to hold the balloon **1** at the distal tip **28** by means of the magnetizable particles **3** associated with the balloon **1**.

The retrieval device is inserted into a full bladder. After opening the flanges **31** of the retrieval device, the engaging probe **32** with magnetizable portion **29** in its tip is inserted into the lumen of the full bladder so as to engage the magnet **3** of the balloon. The probe **32** is then pulled so as to bring the balloon **1** into the grip of flanges **31** of the retrieval device. A piercer **33** is inserted into the balloon to drain the fluid contained in its lumen **4** into an attached syringe (not shown) or into the bladder lumen. The applicator **20** is then withdrawn from the patient together with the deflated balloon **1**.

Figs. 12 and 13 show use of a displacing member **51** to position the balloon **1** at a desired location within the lumen **41** of an individual's urinary bladder **42**. The displacing member **51** is located outside the individual's body and comprises a magnetizable portion **52**. The displacing member **51** is placed at a location on the surface of the individual's body so as to draw the balloon **1** from its initial location to the desired location.

Fig. 12 shows use of the balloon **1** for sealing the urinary bladder outlet in a female subject. Displacing member **51** is placed over the urethral meatus **63** such that, due to the magnetizable portion **52** associated with the displacing member **51** and the magnetizable portion **3** associated with balloon **1**, the balloon is drawn into

the bladder outlet **64**. The balloon thus becomes positioned in the outlet and seals it. The invention is used similarly for sealing the urinary bladder outlet in male subjects.

As seen in Fig. 13, in order to open the urinary bladder for voiding, the magnetic displacing member **51** is distanced from the individual's body. Due to the buoyant force acting on the balloon **1** by the urine, the balloon **1** spontaneously floats in the urine thus opening the bladder outlet **64** so as to allow voiding of urine as indicated by arrow **66**. The presence of a hydrophilic coating **19** coating the external surface of the balloon **1** facilitates the release of the balloon **1** from the sealing position, as shown in Fig. 12 to the non-sealing position shown in Fig. 13. The magnetic displacing member may optionally be used to maintain the balloon away from the outlet during voiding, as shown in Fig. 13. After voiding, the balloon is redrawn into the bladder outlet **64** by the displacing member **51** so as to seal the outlet again as shown in Fig. 12.

Fig. 14 shows use of an immobilizing member **71** comprising a magnetizable portion **72** affixed to the surface **73** of the individual's body so as to maintain the balloon **1** at the desired location in the lumen **41** of the urinary bladder **42**. The magnetizable portion **72** of immobilizing member **71** may be enclosed in a coating **75** so as to form, for example, a hygienic pad. The immobilizing member **71** may be affixed to the surface **73** by means of tape, or by pressure applied to it by the individual's underwear.

Fig. 15 shows a balloon **1** constructed so as to comprise a pump **50** for the controlled release of one or more substances into the bladder. The pump **50** has a reservoir **51** for storing the one or more substances. The pump **50** may have a receiver **52** for receiving signals from a remote control **53**. The rate of release of the substance may thus be varied at will using the remote control.

The invention has been described with a certain degree of particularity only for the sake of clarity. However, several variations and modifications in the invention are possible without exceeding the scope and spirit of the invention as defined in the following set of claims.

CLAIMS:

1. A urological medicinal system for use in medical procedures within a urinary bladder of an individual, comprising:
 - (a) a balloon for insertion into the urinary bladder, the balloon having a lumen and a wall, the wall having an outer surface, the balloon being configured so that the lumen may be filled with a fluid such that, after filling, the balloon has a specific gravity less than or equal to that of urine; and
 - (b) an applicator for inserting the balloon into the urinary bladder or for removing the balloon from the urinary bladder, the applicator fitted at an end thereof with a gripping device for releasably gripping the balloon.
2. The system according to Claim 1, wherein the balloon has a specific gravity less than that of urine.
3. The system according to Claim 1, wherein the balloon is formed with a magnetizable portion.
4. The system according to Claim 3, wherein the magnetizable portion of the balloon comprises one or more magnetizable particles in the lumen of the balloon, attached to the wall of the balloon, or embedded in the wall of the balloon.
5. The system according to Claim 1, wherein the balloon is coated on its outer surface with a hydrophilic coating.
6. The system according to Claim 1, wherein the balloon is capable of storing one or more substances and releasing them into the urinary bladder.
7. The system according to Claim 6, wherein the one or more substances are stored in the lumen or in the wall of the balloon.
8. The system according to Claim 6, wherein at least one substance is selected from the group consisting of radioactive substances, drugs, antibiotics, anti-microbial agents, contrast agents, and substances having a local or systemic effect on cells or tissues of the individual.

9. The system according to Claim 1 wherein the balloon comprises a device which can emit or absorb a signal detectable by an apparatus for imaging the urinary bladder.

10. The system according to Claim 9, wherein said device comprises a transmitter transmitting signals to a receiver within said apparatus.

11. The system according to Claim 10, further comprising one or more components selected from the list comprising:

- (a) a processing unit processing signals received by the receiver;
- (b) a display for displaying signals received by the receiver;
- 10 (c) a display for displaying an output produced by the processing unit.

12. The system according to Claim 1, wherein the balloon comprises one or more monitoring devices for sampling a morphological or physiological parameter of the urinary bladder and for emitting a signal indicative of a quality or quantity of a sampled parameter.

13. The system according to Claim 12, wherein said one or more devices monitors a parameter of the urinary bladder selected from the group consisting of bladder pressure, urine temperature, urine density, urine conductivity and urine composition.

14. The system according to Claim 12, further comprising a transmitter transmitting signals from the monitoring device to a receiver.

15. The system according to Claim 12, further comprising one or more components selected from the list comprising:

- (a) a processing unit processing signals received by the receiver;
- (b) a display for displaying signals received by the receiver;
- 25 (c) a display for displaying an output produced by the processing unit.

16. The system according to Claim 1, further comprising an immobilizing member comprising a magnetizable portion, the immobilizing member being fitted for securing onto the individual's body for immobilizing the balloon at a desired location in the individual's urinary bladder.

17. The system according to Claim 16, wherein the immobilizing member is in the form of a hygienic pad adapted to be placed in the individual's underwear.
18. The system according to Claim 1 for use in the treatment of a disorder selected from the group consisting of urinary incontinence, urinary bladder
5 infections, urinary bladder tumors and bladder dysfunction.
19. The system according to Claim 1, wherein the balloon further comprises a self-sealing valve in the wall leading to the lumen.
20. The system according to Claim 1 further comprising:
- (a) an expanding device for expanding the balloon in the individual's
10 urinary bladder; and
 - (b) a magnetizable displacing member for displacing the balloon within the urinary bladder.
21. The system of Claim 1, wherein the gripping device comprises flanges for releasably gripping the balloon.
- 15 22. The system of Claim 1, wherein the gripping device comprises a magnetizable portion for securing the balloon thereto during application by means of a magnetic interaction.
23. The system of Claim 1, further comprising an injector for injecting a fluid into the balloon so as to expand the balloon.
- 20 24. The system of Claim 1 further comprising a decompressor for decompressing a previously compressed balloon so as to expand the balloon.
25. The system according to Claim 9 for use in imaging a urinary bladder.
26. The system according to Claim 6 for releasing one or more substances in a urinary bladder.
- 25 27. The system according to Claim 12 for monitoring a urinary bladder.
28. The system according to Claim 1 wherein the balloon comprises a pump having a reservoir for releasing a substance into the bladder.
29. The system according to Claim 28 wherein the pump further comprises a receiver for receiving signals from a remote control.
- 30 30. The system according to Claim 29 further comprising a remote control.

31. A method for treating urinary incontinence in an individual comprising the steps of:

- 5 (a) inserting into a urinary bladder of the individual a balloon having a specific gravity less than or equal to that of urine and formed with a magnetizable portion;
- (b) expanding the balloon in the urinary bladder;
- (c) displacing the balloon into a sealing position for sealing the urinary bladder; and
- 10 (d) displacing the balloon within the urinary bladder into an unsealing position for voiding the urinary bladder.

32. The method according to Claim 31 wherein the balloon is coated on its outer surface with a hydrophilic coating.

33. A method for releasing one or more substances into a urinary bladder comprising the steps of:

- 15 (a) loading the one or more substances into a balloon;
- (b) inserting the balloon into the individual's urinary bladder;
- (c) expanding the balloon in the urinary bladder so that after expanding, the balloon has a specific gravity less than or equal to that of urine; and
- 20 (d) displacing the balloon within the urinary bladder to a desired location.

34. The method of Claim 33 wherein said one or more substances are selected from the group consisting of radioactive substances, drugs, antibiotics, anti-microbial agents, contrast agents, and substances having a local or systemic
25 effect on cells or tissues of the individual.

35. A method for monitoring the interior of a urinary bladder comprising the steps of:

- (a) inserting into the urinary bladder a balloon including one or more monitoring devices for sampling a morphological or physiological

parameter of the urinary bladder and for emitting a signal indicative of a quality or quantity of a sampled parameter;

- (b) expanding the balloon in the urinary bladder so that after expanding, the balloon has a specific gravity less than or equal to that of urine and;
- (c) displacing the balloon within the urinary bladder to a desired location; and
- (d) in a monitoring apparatus, recording and optionally processing the signals emitted from the one or more monitoring devices.

10 **36.** The method of Claim 35, further comprising one or more steps selected from the list comprising:

- (a) storing the signals in a computer memory;
- (b) displaying the signals on a display;
- (c) processing the signals in a computer processing unit;
- 15 (d) storing results of the processing in a computer memory; and
- (e) displaying results of the processing on a display.

37. A method for imaging the interior of a urinary bladder comprising the steps of:

- (a) inserting into the urinary bladder a balloon including a device for
20 imaging the urinary bladder and for emitting a signal indicative of an image of the urinary bladder;
- (b) expanding the balloon in the urinary bladder so that after expanding, the balloon has a specific gravity less than or equal to that of urine and;
- 25 (c) displacing the balloon within the urinary bladder to a desired location within the urinary bladder; and
- (d) transmitting signals from the imaging device to a receiver.

38. The method of Claim 37, further comprising one or more steps selected from the list comprising:

- 30 (a) storing the signals in a computer memory;

- 21 -

- (b) displaying the signals on a display;
 - (c) processing the signals in a computer processing unit;
 - (d) storing results of the processing in a computer memory; and
 - (e) displaying results of the processing on a display.
- 5 **39.** A method for releasing one or more substances into a urinary bladder comprising steps of:
- (a) providing a balloon comprising a pump fed by a reservoir and configured for pumping the content of the reservoir to the balloon's exterior;
 - 10 (b) loading the reservoir with the one or more substances;
 - (c) inserting the balloon into the urinary bladder;
 - (d) expanding the balloon in the urinary bladder so that after expanding, the balloon has a specific gravity less than or equal to that of urine; and
 - (e) activating the pump so as to release the one or more substances into the
 - 15 bladder.
- 40.** The method according to Claim 39 wherein the pump is activated by a remote control.
- 41.** A balloon for insertion into the urinary bladder, the balloon having a lumen and a wall, the wall having an outer surface, the balloon being configured so that
- 20 the lumen may be filled with a fluid such that, after filling, the balloon has a specific gravity less than or equal to that of urine.
- 42.** A balloon according to Claim 41, comprising one or more magnetizable portions.
- 43.** A balloon according to Claim 41, wherein the magnetizable portion
- 25 comprises one or more magnetizable particles in the lumen of the balloon, attached to the walls of the balloon, or embedded in the wall of the balloon.
- 44.** A balloon according to Claim 41, coated on its outer surface with a hydrophilic coating.
- 45.** A balloon according to Claim 41, capable of storing one or more substances
- 30 and releasing them into the urinary bladder.

– 22 –

46. A balloon according to Claim 41, wherein the one or more substances are stored in the lumen or in the walls of the balloon.
47. A balloon according to Claim 41, comprising a device, which can emit or absorb a signal detectable by an apparatus for imaging the urinary bladder.
- 5 48. A balloon according to Claim 41, comprising one or more monitoring devices for sampling a morphological or physiological parameter of urinary bladder and for emitting a signal indicative of a quality or quantity of a sampled parameter.

1/14

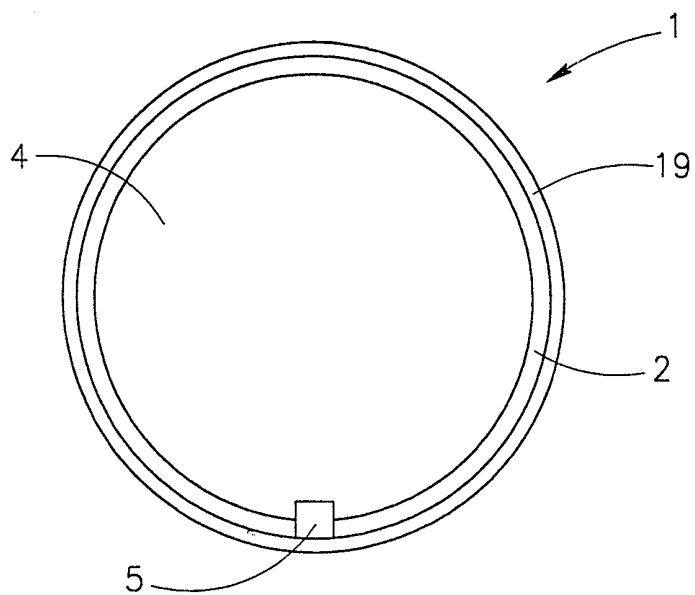


FIG. 1A

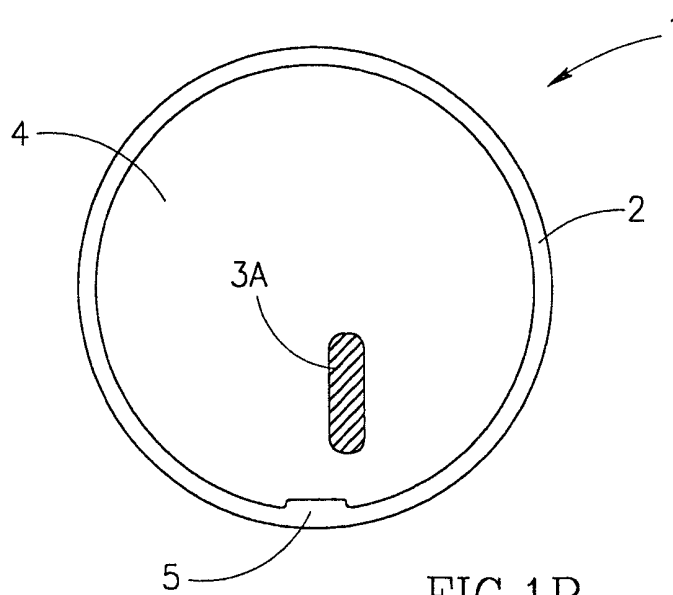


FIG. 1B

2/14

FIG.1C

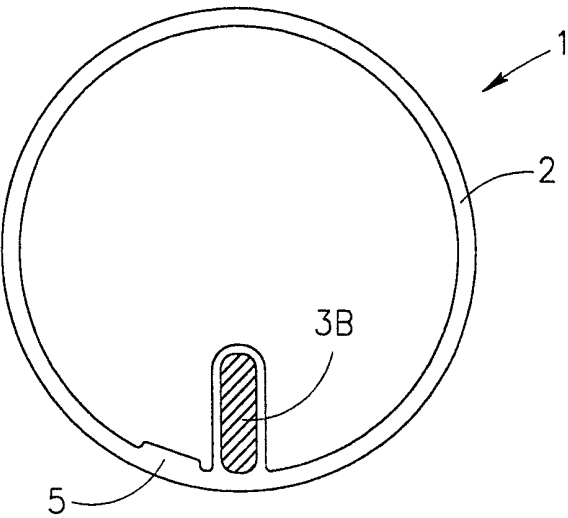


FIG.1D

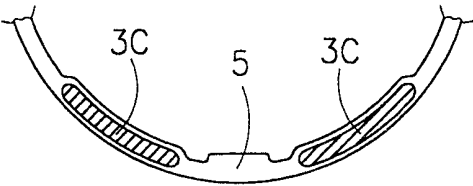
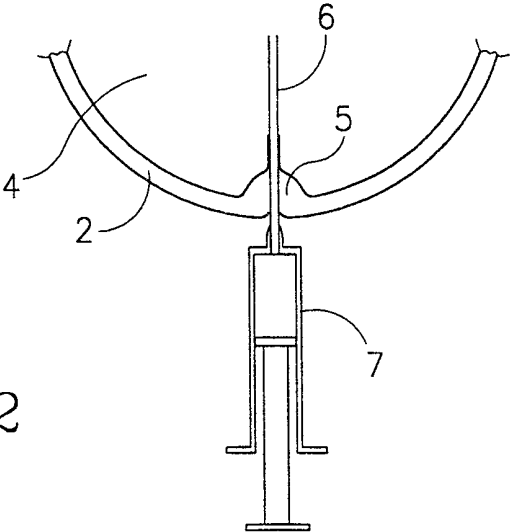


FIG.2



3/14

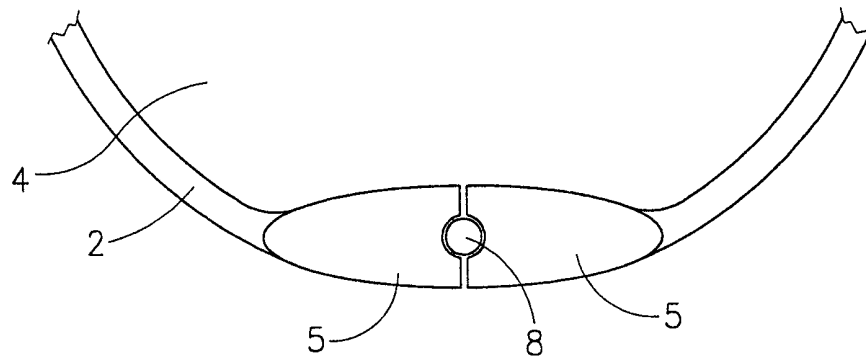


FIG.3A

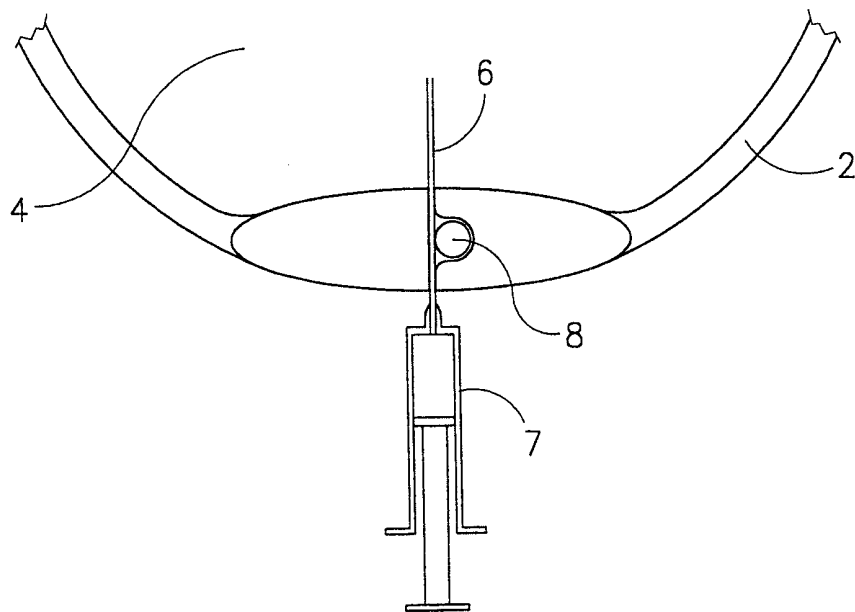


FIG.3B

4/14

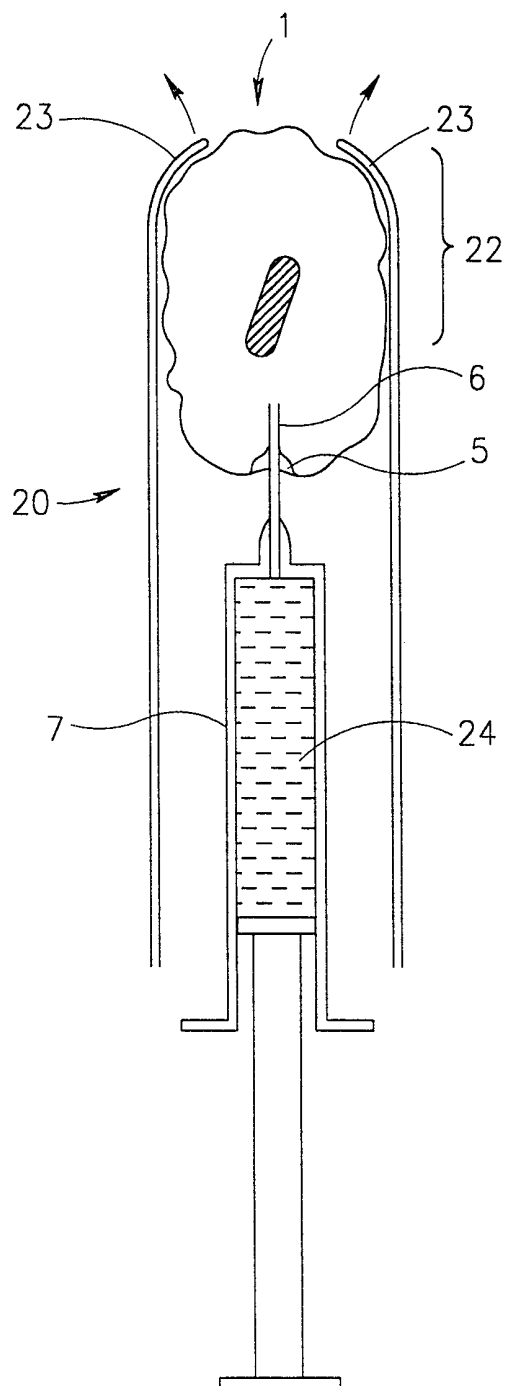


FIG. 4A

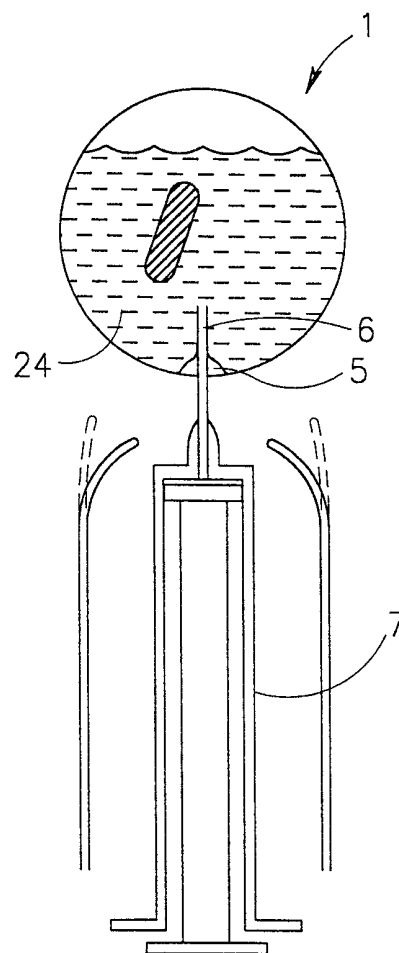


FIG. 4B

5/14

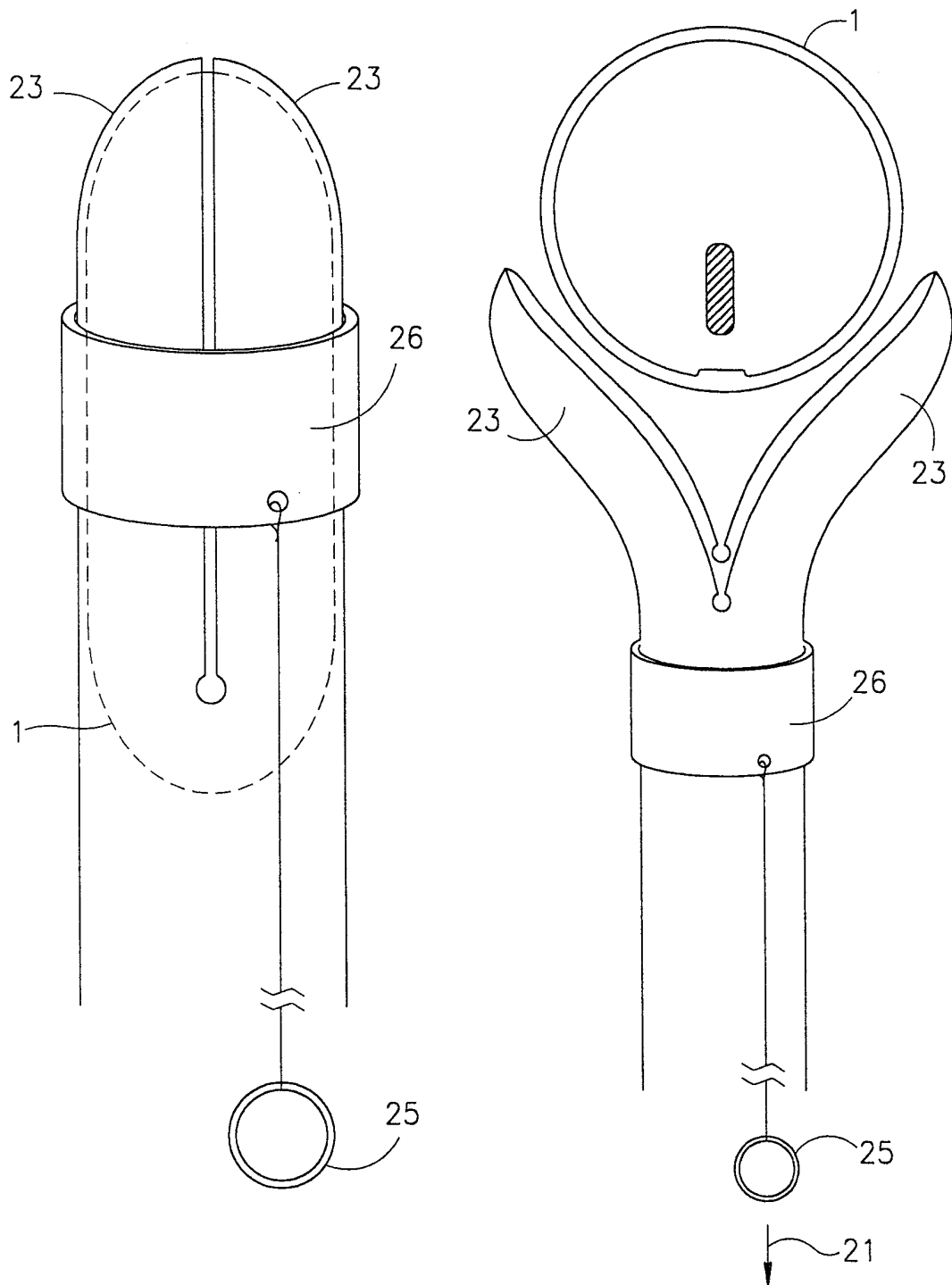


FIG.5A

FIG.5B

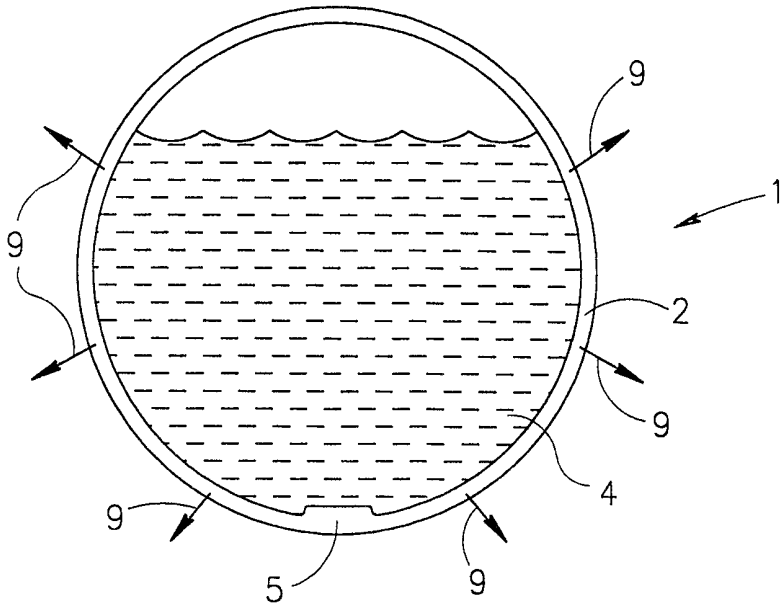


FIG. 6

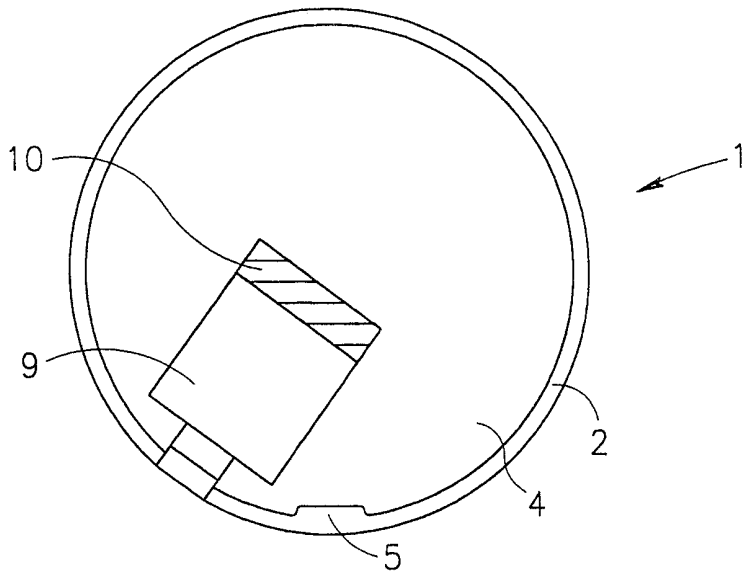
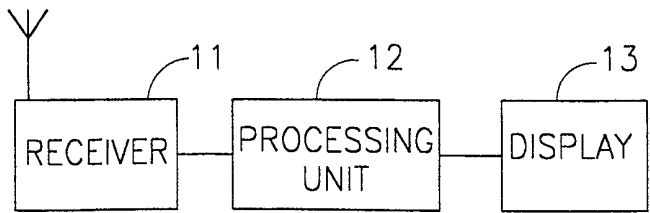


FIG. 7



7/14

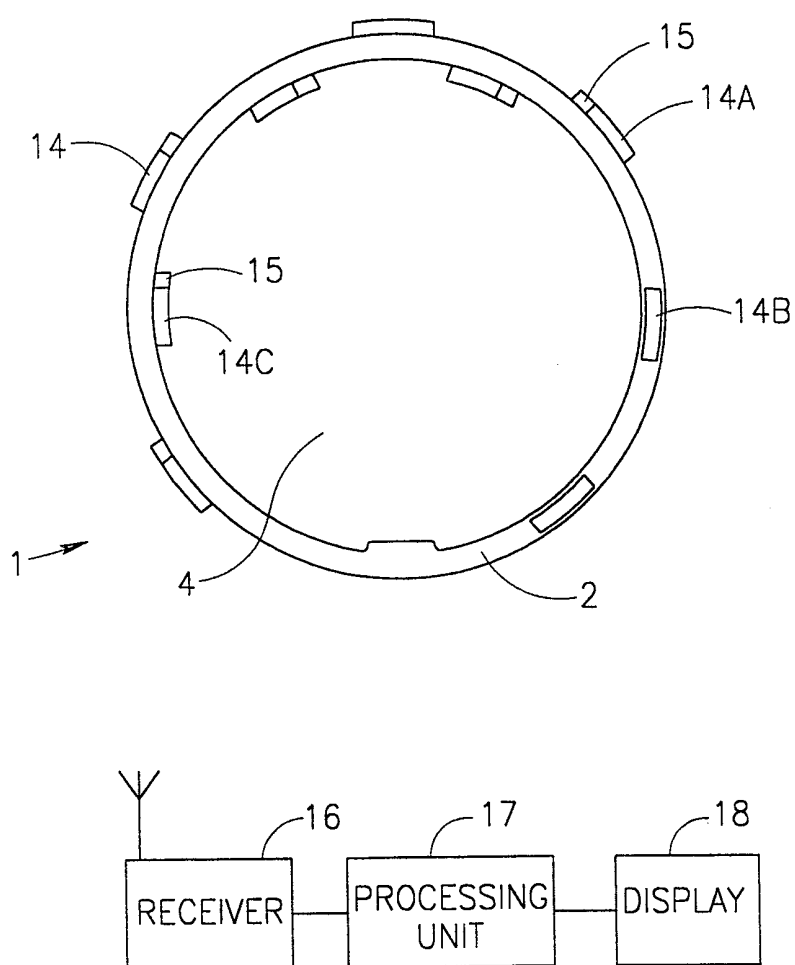


FIG. 8

8/14

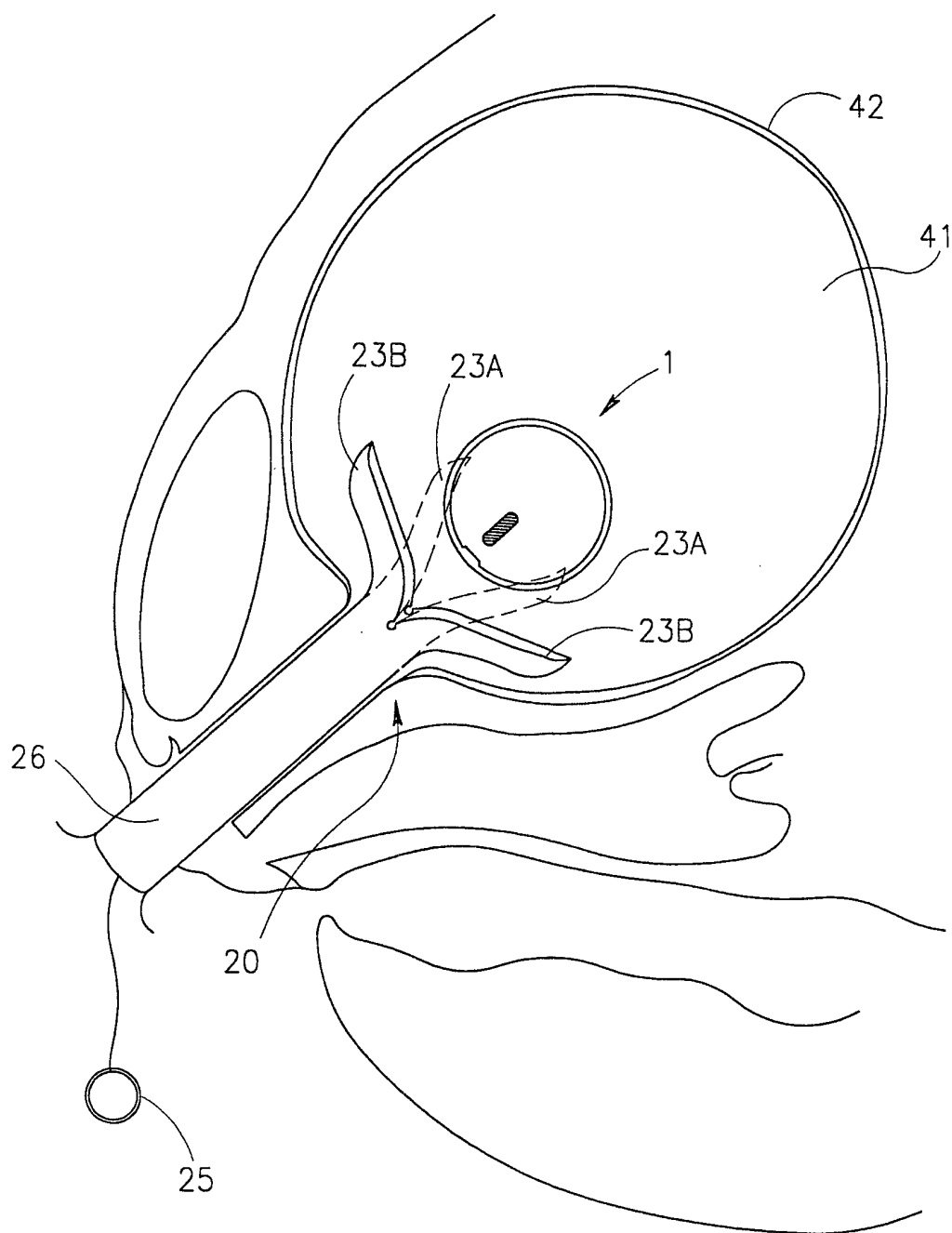
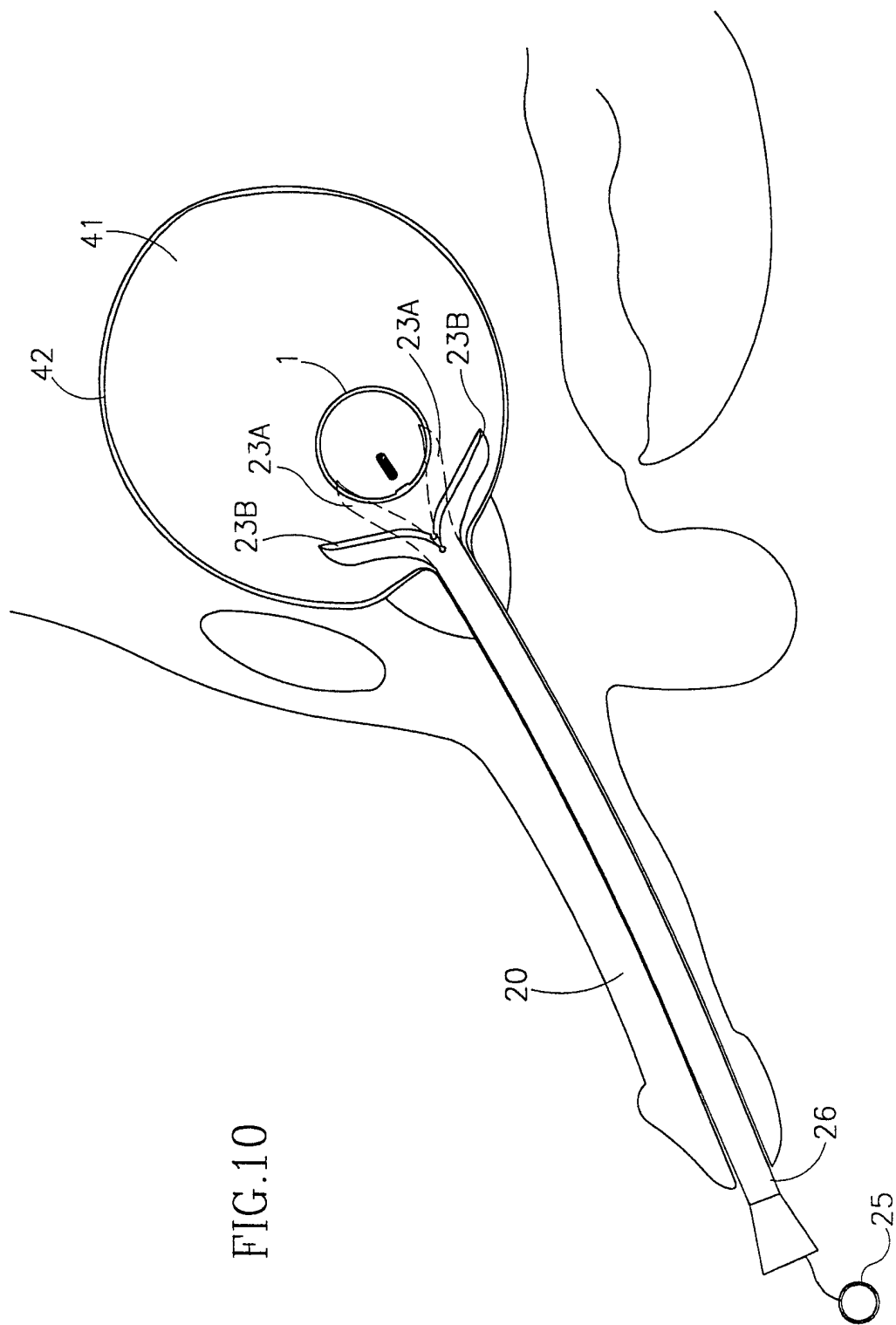


FIG. 9

9/14



10/14

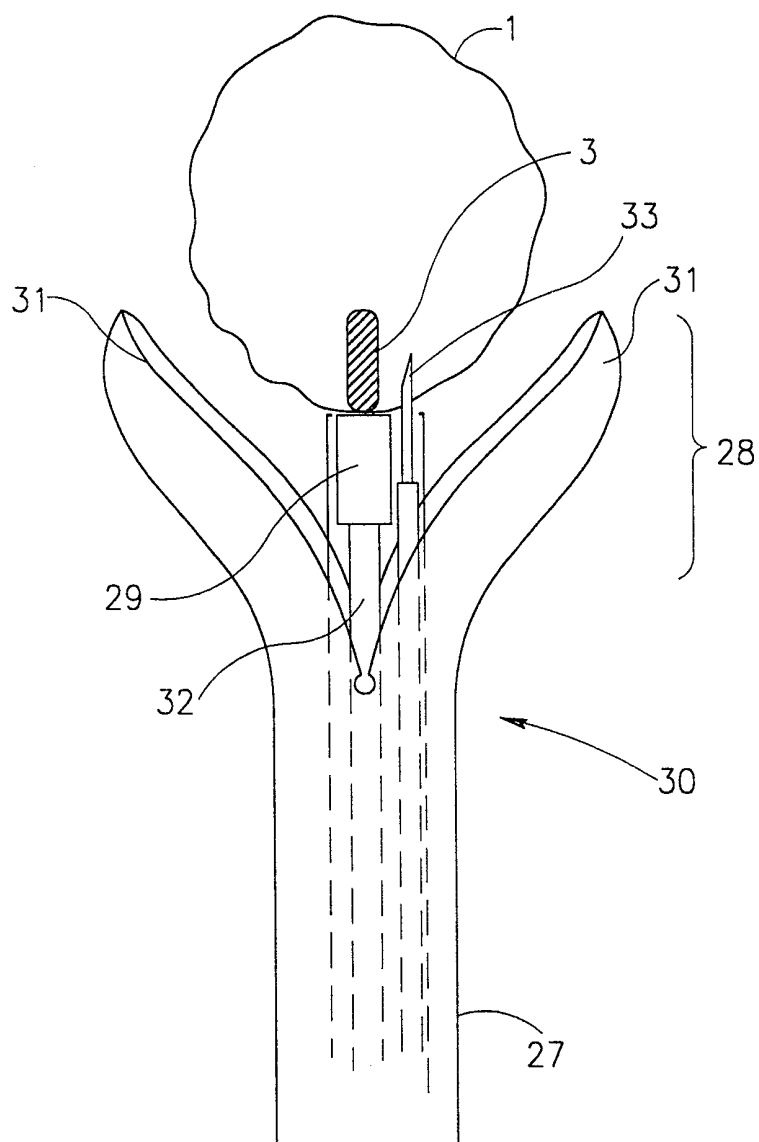


FIG.11

11/14

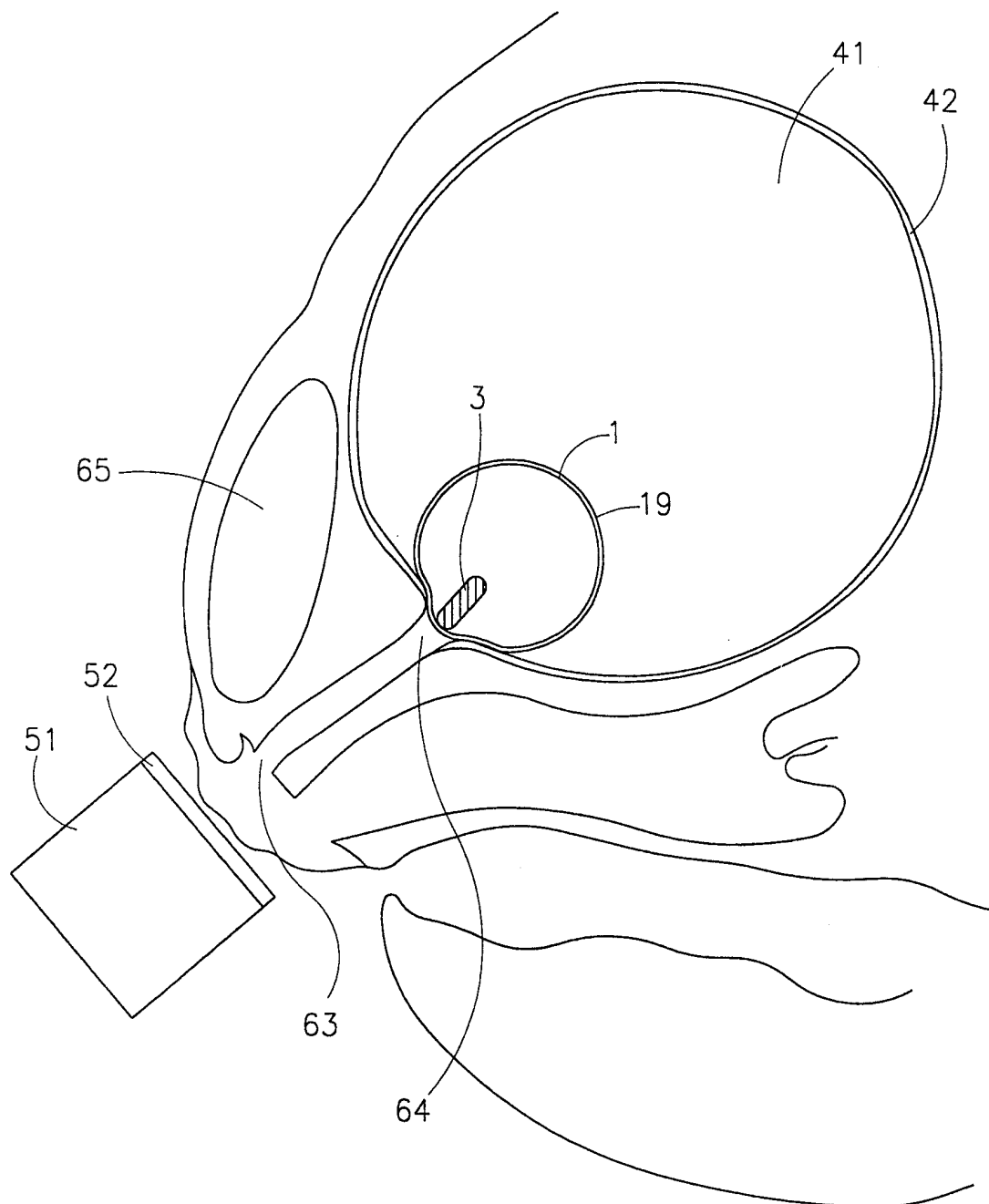


FIG.12

12/14

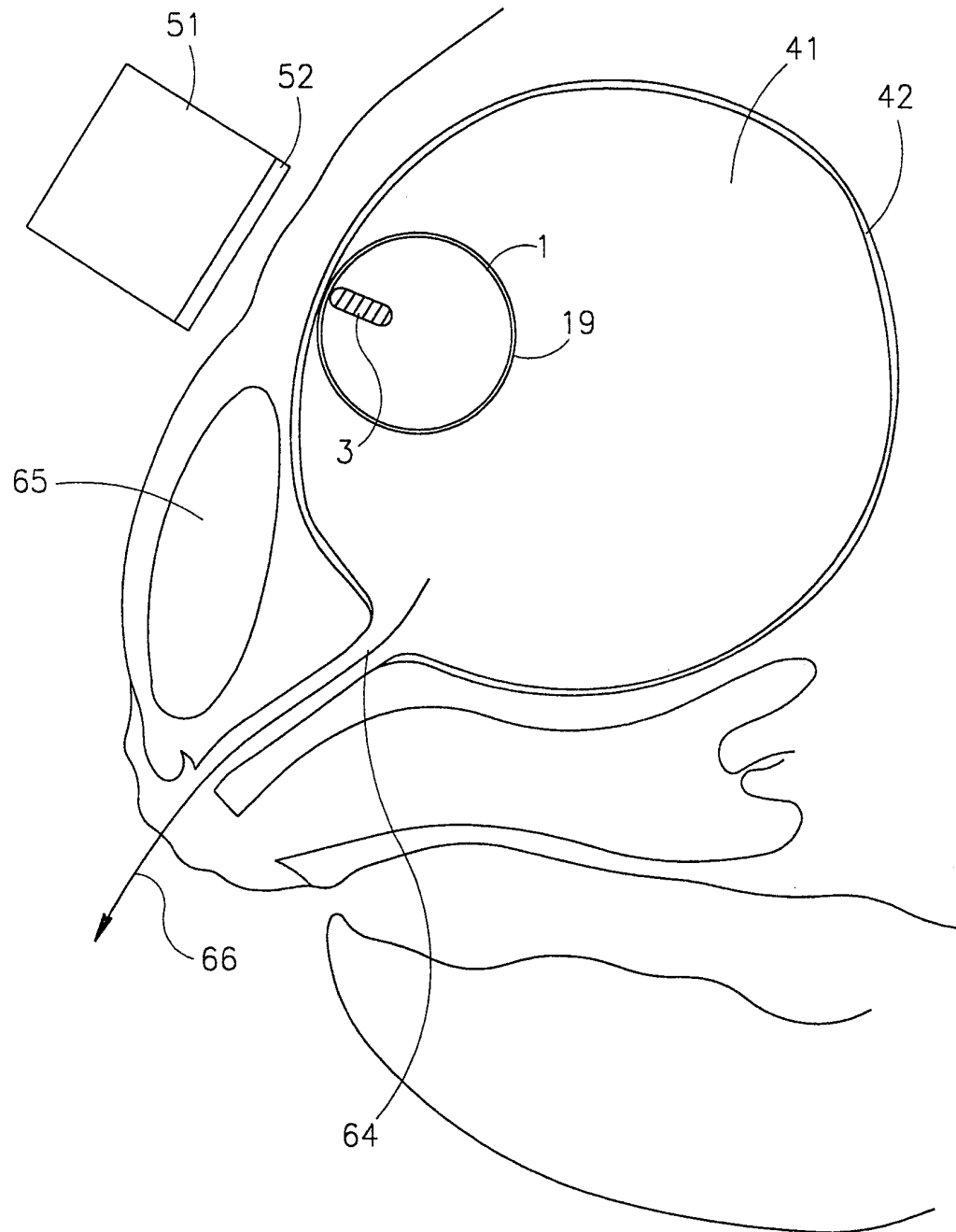


FIG.13

13/14

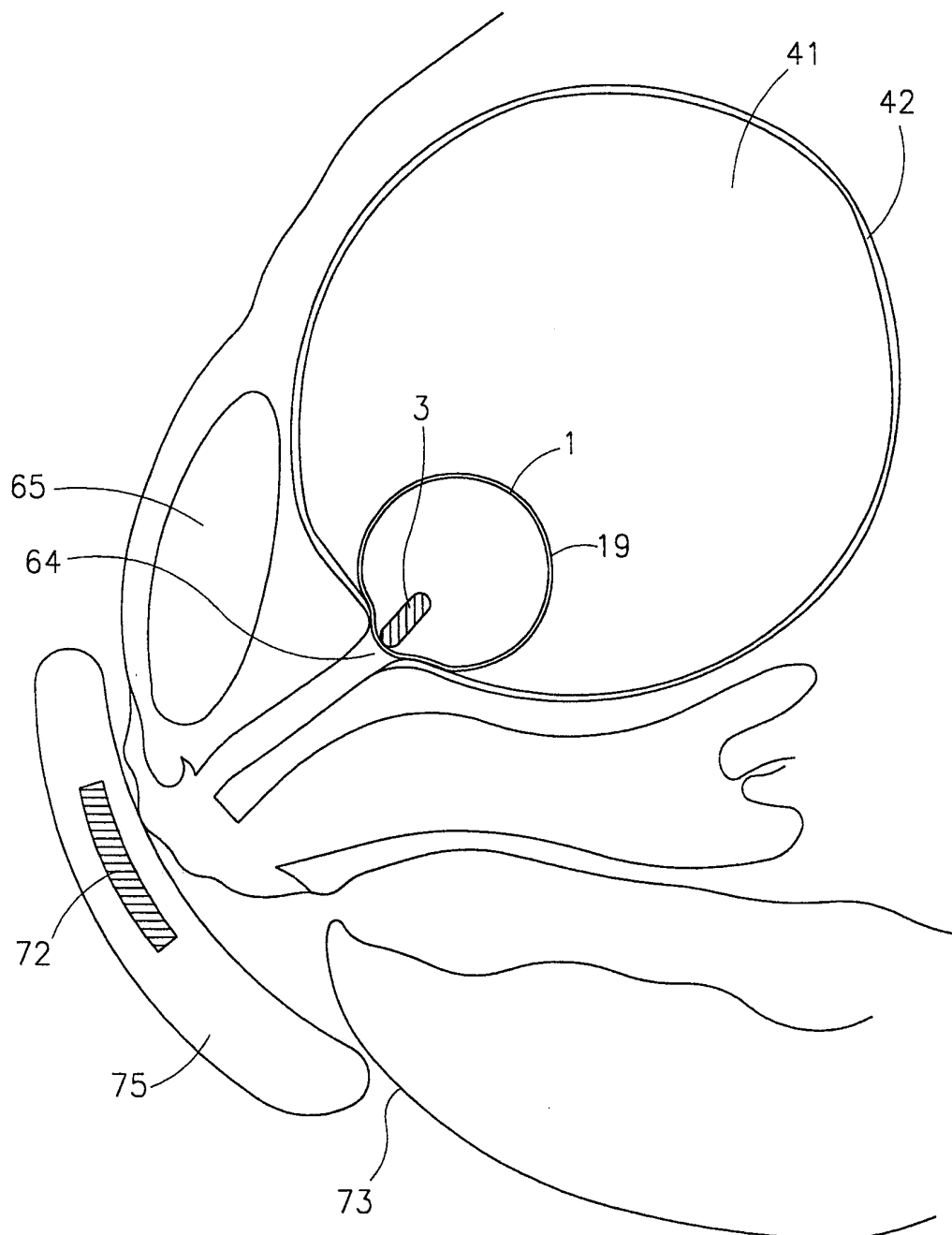


FIG. 14

14/14

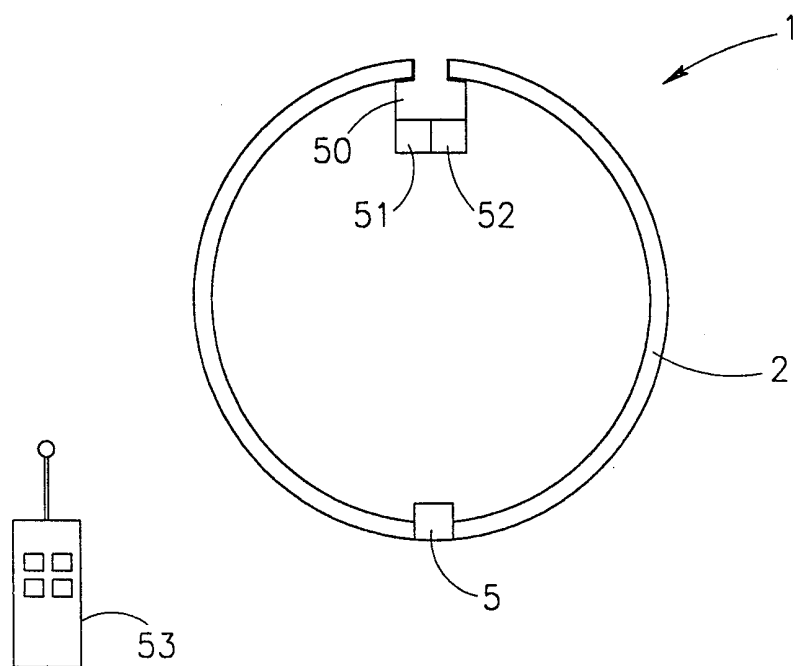


FIG.15

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 00/00160

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/00 A61M31/00

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)

IPC 7 A61F A61M

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 practical, search terms used)

WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 850 963 A (SPARKS ET AL) 25 July 1989 (1989-07-25) cited in the application the whole document ---	1,41
A	US 4 871 542 A (VILHARDT) 3 October 1989 (1989-10-03) the whole document -----	1,41

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

3 July 2000

Date of mailing of the international search report

10/07/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Smith, C

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IL 00/00160

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4850963 A	25-07-1989	AU 612692 B	18-07-1991
		AU 2177388 A	09-11-1989
		JP 1285263 A	16-11-1989
		EP 0357846 A	14-03-1990
US 4871542 A	03-10-1989	AU 622877 B	30-04-1992
		AU 2685088 A	02-08-1990
		EP 0372137 A	13-06-1990
		IN 168149 A	09-02-1991