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(71) Applicant(s)  
Boston Scientific Limited

(72) Inventor(s)  
Charles D Lennox; Ronald B Lamport; Andrew H. Levine ; Douglas E. Godshall; Aaron Perlmutter; Steven Nordstrom

(74) Agent/Attorney  
DAVIES COLLISON CAVE, 1 Little Collins Street, MELBOURNE VIC 3000

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(71) Applicant: SCIMED LIFE SYSTEMS, INC. (US/US); One Seimed Place, Maple Grove, MN 55311-1566 (US).			
(72) Inventors: LENNOX, Charles, D.; 17 Williams Drive, Hudson, NH 03051 (US). LAMPORT, Ronald, B.; 4 Benoit Avenue, Pelham, NH 03076 (US). LEVINE, Andrew, H.; 16 Daniel Street, Newton Center, MA 02459 (US). GODSHALL, Douglas, E.; 34 Town Line Road, Franklin, MA 02038 (US). PERLMUTTER, Aaron; Room 918, 525 East 68th Street, New York, NY 10021 (US). NORDSTROM, Steven; 1 Huckleberry Lane, Franklin, MA 02038 (US).			
(74) Agent: BLUNDELL, Isabelle, A., S.; Testa, Hurwitz & Thibeault, LLP, High Street Tower, 125 High Street, Boston, MA 02110 (US).			
(71) <b>Boston Scientific Limited,</b> The Corporate Centre, Bush Hill, Bay Street, St. Michael, Barbados, West Indies.			
(54) Title: TREATING URINARY RETENTION			
(57) Abstract <p>A urethral prosthesis provides relief of urinary retention and has first and second tubular elements with an interposed bridge segment. A valve can be disposed in the second tubular element to control the flow of urine therethrough.</p>			

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## TREATING URINARY RETENTION

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### Technical Field

The invention relates generally to urethral prostheses and methods of insertion into a body. More particularly, the invention relates to a urethral prosthesis having a bladder/prostate segment and a penile urethra segment connected by a bridge segment, which crosses the urinary sphincter.

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### Background Information

Urinary retention in males is often caused by neurological disorders or by obstructions in the urinary tract. Neurogenic urinary retention is a condition in which a person is unable to empty his urinary bladder voluntarily due to a neurological dysfunction of the urinary bladder and/or of the urinary sphincter. Neurogenic urinary retention is due to an inability of the bladder 15 to contract and/or of the urinary sphincter to relax. Patients with spinal cord injuries, multiple sclerosis, Parkinson's disease, or trauma to the pelvic region may suffer from neurogenic urinary retention on a permanent or transient basis.

Patients suffering from neurogenic urinary retention generally have limited options for draining their bladders. These include using a Foley catheter, intermittent catheterization, and a 20 suprapubic drainage tube. All three options have high infection rates, are inconvenient for the patient and/or care giver, are uncomfortable for the patient, and cause the patient emotional distress.

Urinary retention is also caused by obstructions in the urethra, such as prostatic obstructions. The prostate gland encircles the urethra immediately below the urinary bladder. A

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common affliction among older males is benign prostatic hyperplasia (BPH), or the nonmalignant enlargement of the prostate. When the prostate becomes enlarged, it may restrict the urethra and thereby obstruct the flow of urine from the bladder.

A common treatment of BPH is surgical resection of the prostate and urethral tissue, but 5 this option is not suitable for many patients. BPH afflicts primarily older males, so other health problems, such as cardiovascular disease, may prevent surgical intervention. Furthermore, potential complications associated with surgery, such as urinary infection, dysuria, and incontinence, may make a patient unwilling to undergo the surgery.

Summary of the Invention

It is an object of the invention to relieve the symptoms of urinary retention in males without the high infection rates and other potential complications associated with current treatments. It is another object of the invention to provide a urethral prosthesis that resides 5 within a bladder and urethra of a patient and that provides the patient control over drainage of the bladder without the discomfort and emotional distress associated with conventional treatments.

In one aspect, the invention provides a urethral prosthesis, comprising:

- (a) a first tubular element having a first diameter and including a distal portion 10 with at least one drainage hole for receiving urine, a proximal end, and a lumen extending from the hole through the first tubular element to the proximal end, at least a portion of the first tubular element for residing in a urethra of a patient;
- (b) a bridge segment having a diameter smaller than the first diameter, 15 extending from the proximal end of the first tubular element, and for passing through a urinary sphincter of the patient, the bridge segment including a lumen extending from the lumen of the first tubular segment and through the bridge segment to provide a permanent urine flow channel across and through the urinary sphincter;
- (c) a second tubular element for residing in a penile urethra of the patient, the second tubular element extending from an end of the bridge segment opposite the proximal 20 end of the first tubular element and including a lumen extending from the permanent urine flow channel through the second tubular element; and
- (d) a valve disposed within the lumen of the second tubular element for controlling a flow of urine through the lumen of the second tubular element.

Embodiments according to this aspect of the invention can include the following

- 25 additional features. The first and second tubular elements and the bridge segment may all be made of a pliable, biocompatible material, such as silicone rubber, for example. In another embodiment, the bridge segment comprises a spring disposed within the pliable, biocompatible material. In another embodiment, the proximal end of the second tubular element contains a suture wire to aid in removing the prosthesis from the urethra of a
- 30 patient. The first and second tubular elements may also have an external surface coated with a coating including a plurality of gas bubbles therein.

In this aspect of the invention, the valve may be a magnetically-actuated valve. In this embodiment, the valve includes a ferromagnetic valve seat, which has an aperture for the passage of fluid therethrough, and a valve element. The valve element includes a magnet encapsulated in a non-magnetic capsule. The capsule has a top portion and a base portion, which is wider than the top portion. The valve element is magnetically attracted to the valve seat so that it blocks the flow of fluid through the aperture in the valve seat.

The invention also provides a system for use in treating urinary retention, comprising:

- (a) a urethral prosthesis, comprising:
  - (i) a first tubular element having a first diameter and including a distal portion with at least one drainage hole for receiving urine, a proximal end, and a lumen extending from the hole through the first tubular element to the proximal end, at least a portion of the first tubular element for residing in a urethra of a patient;
  - (ii) a bridge segment having a diameter smaller than the first diameter, extending from the proximal end of the first tubular element, and for passing through a urinary sphincter of the patient, the bridge segment including a lumen extending from the lumen of the first tubular segment and through the bridge segment to provide a permanent urine flow channel across and through the urinary sphincter;
  - (iii) a second tubular element for residing in a penile urethra of the patient, the second tubular element extending from an end of the bridge segment opposite the proximal end of the first tubular element and including a lumen extending from the permanent urine flow channel through the second tubular element; and
  - (iv) a valve disposed within the lumen of the second tubular element for controlling a flow of urine through the lumen of the second tubular element;
- (b) an inflation cannula having a proximal end, a distal end, and a lumen; and
- (c) an inflatable balloon attached to the distal end of said inflation cannula and 30 in communication with the lumen of said inflation cannula, said balloon being inflatable over said second tubular element.

Embodiments according to this aspect of the invention can include the following additional features. The first and second tubular element may also have an external surface coated with a coating including a plurality of gas bubbles. The first and second tubular elements may be composed of a pliable, biocompatible material, such as silicone rubber, 5 for example. The second tubular element may include a suture wire attached to its proximal end to aid in removing the prosthesis from the patient.

The invention also provides a method of inserting a urethral prosthesis, comprising the steps of:

- (a) providing a urethral prosthesis, comprising:
  - 10 (i) a first tubular element having a first diameter and including a distal portion with at least one drainage hole for receiving urine, a proximal end, and a lumen extending from the hole through the first tubular element to the proximal end, at least a portion of the first tubular element for residing in a urethra of a patient;
  - 15 (ii) a bridge segment having a diameter smaller than the first diameter, extending from the proximal end of the first tubular element, and for passing through a urinary sphincter of the patient, the bridge segment including a lumen extending from the lumen of the first tubular segment and through the bridge segment to provide a permanent urine flow channel across and through the urinary sphincter;
  - 20 (iii) a second tubular element for residing in a penile urethra of the patient, the second tubular element extending from an end of the bridge segment opposite the proximal end of the first tubular element and including a lumen extending from the permanent urine flow channel through the second tubular element; and
  - 25 (iv) a valve disposed within the lumen of the second tubular element for controlling a flow of urine through the lumen of the second tubular element;
- (b) inserting said prosthesis in a urethra of a patient so that the drainage hole is positioned in a bladder of the patient; and
- 30 (c) withdrawing said prosthesis until a resistance is felt, the resistance indicating that the bridge segment is positioned within the urinary sphincter of the patient.

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The foregoing and other objects, aspects, features, and advantages of the invention will become more apparent from the following description and from the claims.

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Brief Description of the Drawings

In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

5 FIG. 1 is an illustration of an embodiment of a urethral prosthesis of the invention for use in treating neurogenic urinary retention.

FIG. 2 shows the urethral prosthesis of FIG. 1 residing in a urethra of a patient.

FIG. 3A is an illustration of a valve for use in a urethral prosthesis of the invention in its closed state.

10 FIG. 3B is an illustration of a valve for use in a urethral prosthesis of the invention in its open state.

FIG. 4 is an illustration of an embodiment of a urethral prosthesis of the invention for use in treating urinary retention due to obstructions in the urethra.

FIG. 5 shows a urethral prosthesis of FIG. 4 residing in a urethra of a patient.

15 FIG. 6 is a cross-sectional view of a second tubular element of a prosthesis of the invention containing an optical lens embedded in its wall.

FIG. 7 is an illustration of a configuration for use in inserting a urethral prosthesis of the invention.

20 FIG. 8A is an illustration of a configuration for inserting a urethral prosthesis of the invention using an inflatable balloon that covers the second tubular element.

FIG. 8B is an illustration of the configuration of FIG. 8A in which the balloon is inflated.

FIG. 8C is an illustration of a positioning stylet for use in methods of the invention.

FIGS. 9A-9D are illustrations of a method of inserting a urethral prosthesis of the invention using a system of FIGS. 8A-8C.

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FIG. 10A is an illustration of a configuration for inserting a urethral prosthesis of the invention using an inflatable balloon that covers at least a portion of the first tubular element.

FIG. 10B is an illustration of the configuration of FIG. 10A in which the balloon is inflated.

5 FIGS. 11A-11C are illustrations of a method of inserting a urethral prosthesis of the invention using a system of FIGS. 10A-10B.

FIG. 12 is an illustration of a system for use in inserting a urethral prosthesis of the invention using a transducer to monitor changes in pressure of the balloon.

10 FIG. 13A is an illustration of a configuration for inserting a urethral prosthesis of the invention using an endoscope.

FIG. 13B is a cross-sectional view, taken along line 13B-13B in FIG. 13A, of the urethral prosthesis which has an external groove for accommodating the endoscope.

FIG. 14 is an illustration of a positioning stylet having fluid delivery ports.

15 FIG. 15A is a cross-sectional view of a second tubular element of a urethral prosthesis of the invention having an optical lens embedded in its wall and a positioning stylet positioned within its lumen, such as the stylet of FIG. 14.

FIG. 15B is a cross-sectional view of a second tubular element of a urethral prosthesis of the invention having an endoscope and a positioning stylet positioned within its lumen.

Description

20 The invention relates to a urethral prosthesis for providing relief of urinary retention. A urethral prosthesis of the invention includes first and second tubular elements with an interposed bridge segment. The first and second tubular elements both have lumens extending therethrough. The bridge segment can be a generally non-compressible section with a diameter smaller than the diameter of each of the first and second tubular elements. Alternatively, the bridge segment can 25 comprise at least one suture extending between the two tubular elements. A valve can be

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disposed in the lumen of the second tubular element, so as to control the flow of urine through the second tubular element.

When inserted into a patient, a drainage hole in the first tubular element resides within or near the patient's bladder, the remainder of the first tubular element resides within the prostatic urethra, the bridge segment passes through the urinary sphincter, and the second tubular element resides within the penile urethra. A urethral prosthesis of the invention therefore provides a channel for the flow of urine from the bladder out of the patient's body.

Systems and methods are also provided for the treatment of urinary retention using a urethral prosthesis, such as the types of prostheses described above. A system and method of the 10 invention provides for the use of an inflatable balloon to locate the urinary sphincter and thereby ensure proper positioning of the urethral prosthesis of the invention. Other methods ensure proper positioning by detecting resistance or by viewing the urinary sphincter with an optical lens during insertion.

An embodiment of a urethral prosthesis of the invention for use in treatment of 15 neurogenic urinary retention is illustrated in FIG. 1. The prosthesis 9 includes a first tubular element 10, a bridge segment 12, and a second tubular element 14. The first tubular element 10 and the second tubular element 14 may be composed of any pliable biocompatible material, such as silicone rubber, for example. In one embodiment, the first tubular element 10 and the second tubular element 14 each has a lumen that is circular in cross-sectional shape. In an alternative 20 embodiment, the lumen of the first tubular element 10 and the lumen of the second tubular element 14 are not circular in cross-sectional shape and may comprise a C-shape or a semi-circular shape, for example. The external surfaces of the first tubular element 10 and the second tubular 14 may be modified accordingly in order to create the non-circular shapes.

In some embodiments, the external surfaces of both the first tubular element 10 and the 25 second tubular element 14 are coated with a plastic coating, such as a silicone coating, which is impregnated with gas bubbles. This coating makes the prosthesis echogenic, so that ultrasound may be used to ensure proper positioning of the prosthesis during insertion or to confirm proper placement of the prosthesis after it is inserted.

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The first tubular element 10 and the second tubular element 14 both have lumens and are open at their proximal ends. The second tubular element 14 is also open at its distal end. The distal end of the first tubular element 10 is closed, but a drainage hole 16 is provided near the distal end. The bridge segment 12 has a reduced diameter as compared to the first tubular element 10 and the second tubular element 14. Disposed within the bridge segment 12 is a spring 18. The second tubular element 14 includes a valve 20 and suture wires 22. These suture wires 22 aid in removal of the prosthesis from the urethra of the patient. The prosthesis may be removed by pulling on suture wires 22. The suture wires 22 can be made of thin strands of a polymeric material, of silicone, metal, plastic, or rubber. The suture wires 22 may also be 5 braided or monofilaments.

The separate sections of the urethral prosthesis 9 shown in FIG. 1 are adapted for positioning within different segments of the urethra and the bladder. FIG. 2 is an illustration of the urethral prosthesis 9 in a urethra of a patient. The first tubular element 10 is inserted so that the drainage hole 16 resides within the bladder 24 of the patient. The remainder of the first 10 tubular element 10 spans the prostatic urethra, which is identified as that portion of the urethra surrounded by the prostate 26. The bridge segment 12 spans the urinary sphincter 28, so as to provide a permanently open channel through which urine from the bladder can flow into the second tubular element 14, which resides in the penile urethra 30.

In one embodiment, the bridge segment 12 is non-compressible so as to hold the urinary 15 sphincter in an open position and thereby provide a permanently open channel for the flow of urine from the bladder 24. The bridge segment 12 may be composed of any pliable biocompatible material, such as silicone rubber, for example. Patients suffering from neurogenic urinary retention are unable to control the opening and closing of the urinary sphincter and/or are 20 unable to contract the bladder. By providing an open channel for the flow of urine across the urinary sphincter, these problems are alleviated. Furthermore, the bridge segment 12 includes the spring 18, which imparts flexibility to the bridge segment 12, thereby increasing the comfort 25 level of the patient. The suture wires 22 extend into the penile urethra 30, where they may be grasped and pulled in order to remove the prosthesis 9 from the urethra of the patient.

To control the flow of urine through the second tubular element 14 and out of the body, a 30 valve 20 is disposed within the second tubular element 14. A suitable valve for use in a urethral

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prosthesis, as described above, is as described in U.S. Patent No. 5,366,506, the entire disclosure of which is hereby incorporated by reference herein. In one embodiment, as shown in FIG. 3A, a valve includes a ferromagnetic valve seat 32, which includes apertures 34 and 34'. The valve 20 also includes a valve element 38, which includes a magnet 36. The walls of the valve element 38 are non-magnetic. As shown in FIG. 3A, the bottom portion of the valve element 38 is wider than the top portion of the valve element 38. Absent any external force, the valve element 38 is magnetically attracted to the valve seat 32, thereby blocking the aperture 34. The valve 20 is therefore in its closed position and fluid cannot flow through it. When an external magnetic force is applied to the valve 20, such as by contacting an exterior of a penis in which such a valve resides with a magnet, the valve element 38 is displaced so as to open the aperture 34, as is shown in FIG. 3B. In the open position, fluid flows into the valve 20 through the aperture 34' and then through the aperture 34 to the remainder of the penile urethra 30, and then out of the body.

An embodiment of a urethral prosthesis 39 of the invention for use in treating urinary retention due to an obstruction in the urethra is shown in FIG. 4. In this embodiment, the first tubular element 10 and the second tubular element 14 are as described above. The first tubular element 10 has a closed distal end, except for a drainage hole 16. In this embodiment of the invention, the bridge segment 12 includes suture wires 40.

In the case of urinary retention due to an obstruction in the urethra, patients have the ability to control their urinary sphincters and bladder contractions. A bridge segment that maintains a permanent flow channel is therefore not required. This embodiment of the invention therefore allows the patient to control the urinary sphincter, while the prosthesis otherwise maintains an open channel in the urethra. An illustration of a prosthesis 39 in a patient is shown in FIG. 5. Obstructions of the urethra commonly occur when the prostate 26 becomes enlarged and restricts the prostatic urethra, thereby blocking it. As can be seen in FIG. 5, the first tubular element 10 resides with its drainage hole 16 in the bladder 24, and with the remainder of the first tubular element 10 spanning the prostatic urethra. The first tubular element 10 therefore serves to maintain an open channel for the flow of urine through the prostatic urethra. When the urinary sphincter 28 is closed, the suture wires 40 are compressed. When the urinary sphincter 28 is

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open, urine flows into the second tubular element 14 and through the penile urethra 30 to the exterior of the body.

In one embodiment of the urethral prosthesis 39, as shown in FIG. 4, the first tubular element 10 and the second tubular element 14 are composed of a pliable, biocompatible material, such as silicone rubber. In another embodiment, the first tubular element 10 and the second tubular element 14 have external surfaces coated with a plastic coating including a plurality of gas bubbles. As described above, this echogenic coating provides for ultrasound imaging of the device during or after insertion. The prosthesis 39 also contains suture wires 22, which aid in removing the prosthesis 39 from the patient, also as described above.

10 In an alternative embodiment of a urethral prosthesis for relieving urinary retention due to obstructions in the urethra, an optical lens is embedded within the wall of the second tubular element 14. FIG. 6 shows a cross-sectional view of a second tubular element 14 having an optical lens 42 embedded within its wall. The optical lens 42 may be used to ensure proper placement of the prosthesis during insertion. In one embodiment, the optical lens 42 is disposed 15 at the distal end of the second tubular element 14, so that the urinary sphincter 28 may be viewed during the insertion procedure. (This insertion procedure is described in more detail below.) The first and second tubular elements of a urethral prosthesis containing an optical lens embedded within the wall of the second tubular element may or may not have external surfaces coated with an echogenic coating, as described above.

20 Methods of the invention relate to the insertion of a urethral prosthesis in a urethra and bladder of a patient. Methods the invention may include the use of any of the urethral prostheses described above. One such configuration for inserting a urethral prosthesis is shown in FIG. 7. The configuration in FIG. 7 includes the urethral prosthesis 9, the insertion sleeve 44, and the retractor 46. The insertion sleeve 44 is disposed over the second tubular element 14 and the 25 bridge segment 12, and is partially disposed over the first tubular element 10. The retractor 46 is releasably attached to the proximal end of the second tubular element 14. The configuration of FIG. 7 is shown with the prosthesis 9 by way of example only. The kit may also be used in conjunction with the prosthesis 39, or any of the above-described embodiments of prostheses 9 and 39.

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A method of insertion of a urethral prosthesis involves inserting the prosthesis 9, the insertion sleeve 44, and the retractor 46 into a urethra of a patient. The distal end of the first tubular element 10 is inserted first. The prosthesis 9 is inserted so that the drainage hole 16 resides in the bladder 24 of the patient, as shown in FIG. 2. If the first tubular element has an 5 echogenic coating, the first tubular element 10 with the drainage hole 16 in the bladder 24 may be imaged with ultrasound, as described above. Alternatively, the placement of the prosthesis 9 may be imaged by inserting an ultrasound transducer into the lumen of the second tubular element 14. The ultrasound transducer may also be advanced through the bridge segment 12 of the prosthesis 9 and into the lumen of the first tubular element 10, so as to view the placement of 10 the first tubular element within the bladder 24. The insertion sleeve 44 is then removed, and the retractor 46 is used to pull the prosthesis 9 back toward the opening of the urethra until a resistance is felt by the user. This resistance indicates that the bridge segment 12 is properly positioned in the urinary sphincter 28, as shown in FIG. 2. The retractor 46 is then disengaged from the second tubular element 14 and removed from the urethra. Proper positioning of the 15 prosthesis may be confirmed with urethroscopy or ultrasound, as described above.

A system of the invention is shown in FIGS. 8A-8C. The system contains the prosthesis 39, a pusher 48, a positioning stylet 50, an inflation cannula 52, and an inflatable balloon 54. The pusher 48 is sized and shaped for butting up against the proximal end of the second tubular element 14, so that it pushes against the second tubular element 14 and thereby advances the 20 prosthesis 39 into a urethra of a patient. The pusher 48 has a lumen for insertion of the positioning stylet 50 therein. An illustration of the positioning stylet 50 is shown in FIG. 8C. The positioning stylet 50 is adapted to reside within the lumens of the pusher 48, the second tubular element 14, and the first tubular element 10, so as to maintain the prosthesis 39 in its 25 extended position during the insertion procedure. Without the stylet 50, suture wires 40 may become bent, twisted, or collapsed during insertion.

The inflation cannula 52 of FIG. 8A also has a lumen, which is in communication with the inflatable balloon 54. To inflate the balloon 54, fluid or gas is delivered through the lumen of the inflation cannula 52. The balloon 54 is disposed over the second tubular element 14. In FIG. 8A, the balloon 54 is not inflated. FIG. 8B is an illustration of the system in which the balloon 30 54 is inflated over the second tubular element 14. The balloon 54 may be compliant or non-

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compliant. Balloons are standardized so that the injection of a known amount of fluid within the balloon induces inflation of the balloon to a specific diameter. Balloons may also be standardized with respect to diameter and pressure. Once the system of FIGS. 8A-8C is closed, a relation exists between the pressure within the system and the diameter of the balloon. The 5 system is shown with the prosthesis 39 by way of example only. The system may also be used in conjunction with the prosthesis 9, or any of the above-described embodiments of prostheses 9 and 39.

A method for inserting a prosthesis using the system shown in FIGS. 8A-8C is shown in FIGS. 9A-9D. In this method, the prosthesis 39, the positioning stylet 50, the pusher 48, the 10 inflation cannula 52, and the balloon 54 are inserted into a urethra of a patient, with the distal end of the first tubular element 10 being inserted first. The prosthesis 39 is pushed by the pusher 48, along with the positioning stylet 50, until a first resistance is felt. This first resistance indicates that the distal end of the first tubular element 10 has contacted the urinary sphincter 28, as shown in FIG. 9A. The balloon 54 is then inflated by delivering fluid or gas via the inflation cannula 52 15 to the interior of the balloon 54. The balloon 54 inflates over the second tubular element 14, as shown in FIG. 9B. The prosthesis 39 is then pushed farther into the urethra until a second resistance is felt. This second resistance indicates that the balloon 54 has contacted the urinary sphincter 28, as shown in FIG. 9C. The pusher 48 and the inflation cannula 52 are removed from the urethra so as to deflate the balloon 54. At this point, the prosthesis 39 is properly positioned 20 within the urethra of the patient, such that the drainage hole 16 is residing in the bladder 24 and the bridge segment 12 spans the urinary sphincter 28, as shown in FIG. 9D. Proper placement of the prosthesis may be confirmed by urethroscopy or ultrasound, as described above.

An alternative system of the invention is shown in FIGS. 10A-10B. The system shown in FIG. 10A contains the prosthesis 39, a pusher 48, an inflation cannula 49, and an inflatable 25 balloon 51. The pusher 48 is sized and shaped for butting up against the proximal end of the second tubular element 14, so that it pushes against the second tubular element 14 and thereby advances the prosthesis 39 into a urethra of a patient. The pusher 48 has a lumen for insertion of the inflation cannula 49 therein. The inflation cannula is adapted to reside within the lumens of the pusher 48, the second tubular element 14, and the first tubular element 10. The inflation 30 cannula 49 also has a lumen, which is in communication with the inflatable balloon 51 so as to

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deliver a volume of fluid or gas to the balloon 51 and thereby inflate the balloon 51. As shown in FIG. 10B, the balloon 51 covers at least a portion of the first tubular element 10 when it is inflated. The balloon 51 is inflated at a position on the first tubular element 10 that resides in the bladder of a patient just above the prostate gland when inserted.

5 A method for inserting a prosthesis using the system shown in FIGS. 10A-10B is shown in FIGS. 11A-11C. In this method, the prosthesis 39, the pusher 48, the inflation cannula 49, and the balloon 51 are inserted into a urethra of a patient, with the distal end of the first tubular element 10 being inserted first, as shown in FIG. 11A. The prosthesis is pushed by the pusher 48, along with the inflation cannula 49, until the drainage hole 16 of the first tubular element 10  
10 is positioned within the bladder 24, as shown in FIG. 11B. The balloon 51 is then inflated by delivering a volume of fluid or gas via the inflation cannula 49 to the interior of the balloon 51. The balloon 51 inflates over at least a portion of the first tubular element 10, as shown in FIG. 11C. The prosthesis 39 is then withdrawn (such as, for example, by using a retractor, as in FIG. 7) until a resistance is felt. This resistance indicates that the balloon 51 is contacting the opening  
15 53 of the bladder 24 just above the prostate 26. This indicates that the prosthesis is properly positioned so that the bridge segment 12 spans the urinary sphincter 28. Proper placement of the prosthesis may be confirmed by urethroscopy or ultrasound, as described above.

In an alternative embodiment of the system of FIGS. 8A-8C, as shown in FIG. 12, a transducer (not shown) is disposed within the balloon 54. The location of the transducer within  
20 the closed system is unimportant as long as it is located within and senses changes in pressure within the area containing the fluid or gas. The transducer is in electrical communication via the connecting wire 51 with the controller 53. The controller 53 monitors variations in pressure. The controller 53 includes an indicator 55, which displays a plot 59 of the changes in pressure as a function of time or as a function of distance of insertion into the urethra. Indicator 55 may be a  
25 video monitor or a print-out display, for example. A marked increase in pressure 57, indicates that the balloon 54 has contacted the urinary sphincter 28. Detection of the location of the urinary sphincter 28 is then made by a visual reading of the plot 59, so as to ensure accurate placement of the prosthesis 39. Alternatively, when the balloon used is a compliant balloon, the plot 59 may be standardized to yield a defined pressure for a specific diameter for a known  
30 volume of inflation fluid. Alternatively, the embodiment of the system shown in FIGS. 10A-10B

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may be similarly adapted. For example, a transducer may be disposed within balloon 51 and may indicate placement of the prosthesis 39 by detecting marked increases in pressure as the prosthesis 39 is withdrawn from the urethra.

In an alternative embodiment, the system shown in FIG. 12 is used to measure the competency of the sphincter or detrusor muscles. This is accomplished by passing the balloon 54 with a known freestanding pressure-volume curve into the desired location and incrementally inflating it with known volumes of fluid. After each inflation of the balloon 54, a pressure measurement is taken and a pressure volume curve generated. By calculating the area difference between the curves, the net amount of work done by the sphincter is obtained.

In another alternative embodiment, the system of FIG. 12 is used to determine adequate bulking pressures or volumes used during bulking procedures to remediate sphincter incontinence, for example. The system may be used to monitor the injection of agents typically used to bulk sphincters and create constrictions, such as to treat stress incontinence (AUS, Collagen products) or GERD. By placing a balloon 54 with the transducer in the desired position to be bulked, one can then monitor the compliance of the restriction created with the agent as it is injected. Clinical outcomes can be correlated to the compliance measured with this device to determine how much bulking agent is needed for the desired outcome.

The system of FIG. 12 may also have applications in urodynamic measurements, such as, compliance of body tissues within the urinary tract, arterial stenosis, aneurysm detection, or other areas where stricture, enlargement, or body tissue compliance quantification is pertinent.

Another configuration for insertion of a urethral prosthesis is shown in FIGS. 13A-13B. This configuration includes the prosthesis 39, the pusher 48, the positioning stylet 50, and an endoscope 56. The positioning stylet 50 has a lumen and contains fluid delivery ports 58, which are positioned to deliver fluid through the bridge segment 12 during the insertion procedure. Irrigating the insertion site during the insertion procedure is necessary to keep the optical lens 42 of the endoscope 56 clear for viewing. The positioning stylet 50 with delivery ports 58 is illustrated in FIG. 14.

In the configuration of FIGS. 13A-13B, the second tubular element 14 and the pusher 48 both have external grooves to allow the endoscope 56 to slide along the external surface of both

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the second tubular element 14 and the pusher 48. A cross-sectional view of the second tubular element 14 having an external groove is shown in FIG. 13B. As shown in FIG. 13B, the endoscope 56 fits within the external groove of the second tubular element 14. Also shown in the lumen of the second tubular element 14 is the positioning stylet 50. The configuration is 5 shown with the prosthesis 39 by way of example only. The configuration may also be used in conjunction with the prosthesis 9, or any of the above-described embodiments of prostheses 9 and 39.

In alternative embodiments of this configuration, the optical lens 42 is embedded within the wall of the second tubular element 14, as shown in FIG. 15A. FIG. 15A is a cross-sectional 10 view of the second tubular element 14. In this embodiment, the second tubular element 14 and the pusher 48 do not have external grooves. Also shown in FIG. 15A is the positioning stylet 50 within the lumen of the second tubular element 14. In another alternative embodiment, both the endoscope 56 and the positioning stylet 50 are adapted to fit within the lumen of the second tubular element 14, as shown in FIG. 15B.

15 A method of inserting a urethral prosthesis 39 using such a configuration include inserting the prosthesis 39, the pusher 48, the positioning stylet 50, and the endoscope 56 into a urethra of a patient. The distal end of the first tubular element 10 is inserted first, and the prosthesis 39 is advanced farther into the urethra by pushing against the proximal end of the second tubular element 14 with the pusher 48 and by pushing with the positioning stylet 50. 20 While pushing the prosthesis 39 into the urethra, the endoscope 56 is used to view the bridge segment 12. In one embodiment, the urethra is irrigated by delivering a fluid through the lumen of the positioning stylet 50 and through the fluid delivery ports 58. The fluid may be any biological compatible fluid, such as saline, for example.

25 In this method of insertion, the bridge segment 12 is viewed with the endoscope 56 to determine when the bridge segment 12 is positioned such that it spans the urinary sphincter 28, as shown in FIG. 5. The positioning stylet 50, the pusher 48, and the endoscope 56 are then removed from the urethra. If the second tubular element 14 includes the optical lens 42 embedded within its wall, the method does not require use of the endoscope 56 for viewing. The bridge segment 12 is viewed with the embedded optical lens 42. Proper placement of the 30 prosthesis may be confirmed by urethroscopy or ultrasound, as described above.

The above described systems and methods provide the patient control over the draining of the bladder. Urethral prostheses of the invention may also be used in situations where it is not desirable or possible for the patient to have control over the draining of the bladder. In such circumstances, the distal end of the first tubular element of the prosthesis 5 may be open, and a catheter, such as a Foley catheter, for example, may be inserted through the lumens of the second tubular element, bridge segment, and first tubular element of the prosthesis. The catheter can then be attached to a urine collection bag and meter. This embodiment allows for the monitoring of urine production by the patient.

Variations, modifications, and other implementations of what is described herein 10 will occur to those of ordinary skill in the art without departing from the spirit and the scope of the invention as claimed. Accordingly, the invention is to be defined not by the preceding illustrative description but instead by the spirit and scope of the following claims.

The reference to any prior art in this specification is not, and should not be taken 15 as, an acknowledgment or any form of suggestion that that prior art forms part of the common general knowledge in Australia.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group 20 of integers or steps but not the exclusion of any other integer or step or group of integers or steps.



THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A urethral prosthesis, comprising:
  - (a) a first tubular element having a first diameter and including a distal portion with at least one drainage hole for receiving urine, a proximal end, and a lumen extending from the hole through the first tubular element to the proximal end, at least a portion of the first tubular element for residing in a urethra of a patient;
  - (b) a bridge segment having a diameter smaller than the first diameter, extending from the proximal end of the first tubular element, and for passing through a urinary sphincter of the patient, the bridge segment including a lumen extending from the lumen of the first tubular segment and through the bridge segment to provide a permanent urine flow channel across and through the urinary sphincter;
  - (c) a second tubular element for residing in a penile urethra of the patient, the second tubular element extending from an end of the bridge segment opposite the proximal end of the first tubular element and including a lumen extending from the permanent urine flow channel through the second tubular element; and
  - (d) a valve disposed within the lumen of the second tubular element for controlling a flow of urine through the lumen of the second tubular element.
- 20 2. The prosthesis of claim 1, wherein an external surface of said first tubular element comprises a coating including a plurality of gas bubbles disposed therein.
3. The prosthesis of claim 1, wherein an external surface of said second tubular element comprises a coating including a plurality of gas bubbles disposed therein.
- 25 4. The prosthesis of claim 1, wherein said bridge segment comprises a spring disposed within a pliable, biocompatible material.
5. The prosthesis of claim 4, wherein said pliable, biocompatible material is silicone rubber.

6. The prosthesis of claim 1, wherein said valve comprises a magnetically-actuatable valve.

7. The prosthesis of claim 6, wherein said magnetically-actuatable valve, comprises:

5 (a) a ferromagnetic valve seat having an aperture for passage of fluid therethrough; and

(b) a valve element, comprising a magnet encapsulated in a non-magnetic capsule, said capsule having a top portion and a base portion, said base portion being adjacent said valve seat and being wider than said top portion, and said valve element 10 being magnetically attractive to said valve seat to block a flow of fluid through said aperture.

8. The prosthesis of claim 1, wherein said first and second tubular elements comprise a pliable, biocompatible material.

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9. The prosthesis of claim 8, wherein said pliable, biocompatible material is silicone rubber.

10. The prosthesis of claim 1, further comprising at least one suture wire attached to 20 the proximal end of said second tubular element to aid in removing the prosthesis from the patient.

11. A system for use in treating urinary retention, comprising:

(a) a urethral prosthesis, comprising:

25 (i) a first tubular element having a first diameter and including a distal portion with at least one drainage hole for receiving urine, a proximal end, and a lumen extending from the hole through the first tubular element to the proximal end, at least a portion of the first tubular element for residing in a urethra of a patient;

30 (ii) a bridge segment having a diameter smaller than the first diameter, extending from the proximal end of the first tubular element, and for

passing through a urinary sphincter of the patient, the bridge segment including a lumen extending from the lumen of the first tubular segment and through the bridge segment to provide a permanent urine flow channel across and through the urinary sphincter;

5 (iii) a second tubular element for residing in a penile urethra of the patient, the second tubular element extending from an end of the bridge segment opposite the proximal end of the first tubular element and including a lumen extending from the permanent urine flow channel through the second tubular element; and

10 (iv) a valve disposed within the lumen of the second tubular element for controlling a flow of urine through the lumen of the second tubular element;

(b) an inflation cannula having a proximal end, a distal end, and a lumen; and

(c) an inflatable balloon attached to the distal end of said inflation cannula and in communication with the lumen of said inflation cannula, said balloon being inflatable

15 over said second tubular element.

12. The system of claim 11, further comprising a transducer disposed within said inflatable balloon for monitoring pressure within said balloon.

20 13. The system of claim 11, wherein an external surface of said first tubular element comprises a coating including a plurality of gas bubbles disposed therein.

14. The system of claim 11, wherein an external surface of said second tubular element comprises a coating including a plurality of gas bubbles disposed therein.

25 15. A method of inserting a urethral prosthesis, comprising the steps of:

(a) providing a urethral prosthesis, comprising:  
(i) a first tubular element having a first diameter and including a distal portion with at least one drainage hole for receiving urine, a proximal end, and a lumen extending from the hole through the first tubular element to the proximal end, at least a portion of the first tubular element for residing in a

urethra of a patient;

(ii) a bridge segment having a diameter smaller than the first diameter, extending from the proximal end of the first tubular element, and for passing through a urinary sphincter of the patient, the bridge segment

5 including a lumen extending from the lumen of the first tubular segment and through the bridge segment to provide a permanent urine flow channel across and through the urinary sphincter;

(iii) a second tubular element for residing in a penile urethra of the patient, the second tubular element extending from an end of the bridge

10 segment opposite the proximal end of the first tubular element and including a lumen extending from the permanent urine flow channel through the second tubular element; and

(iv) a valve disposed within the lumen of the second tubular element for controlling a flow of urine through the lumen of the second tubular element;

15 (b) inserting said prosthesis in a urethra of a patient so that the drainage hole is positioned in a bladder of the patient; and

(c) withdrawing said prosthesis until a resistance is felt, the resistance indicating that the bridge segment is positioned within the urinary sphincter of the patient.

20 16. The method of claim 15, wherein an external surface of said first tubular element comprises a coating including a plurality of gas bubbles disposed therein.

17. The method of claim 16, further comprising the step of imaging said first tubular element by ultrasound.

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18. The method of claim 15, wherein an external surface of said second tubular element comprises a coating including a plurality of gas bubbles disposed therein.

20 19. The method of claim 18, further comprising the step of imaging said second tubular element by ultrasound.

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20. A urethral prosthesis substantially as hereinbefore described with reference to the accompanying drawings.

21. A system for use in treating urinary retention substantially as hereinbefore  
5 described with reference to the accompanying drawings.

22. A method of inserting a urethral prosthesis substantially as hereinbefore described with reference to the accompanying drawings.

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DATED this 13th day of March 2003

15 BOSTON SCIENTIFIC LIMITED

By its Patent Attorneys

DAVIES COLLISON CAVE

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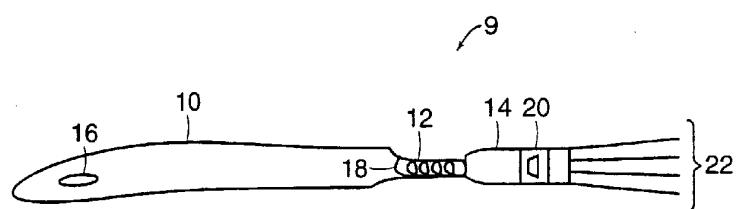


FIG. 1

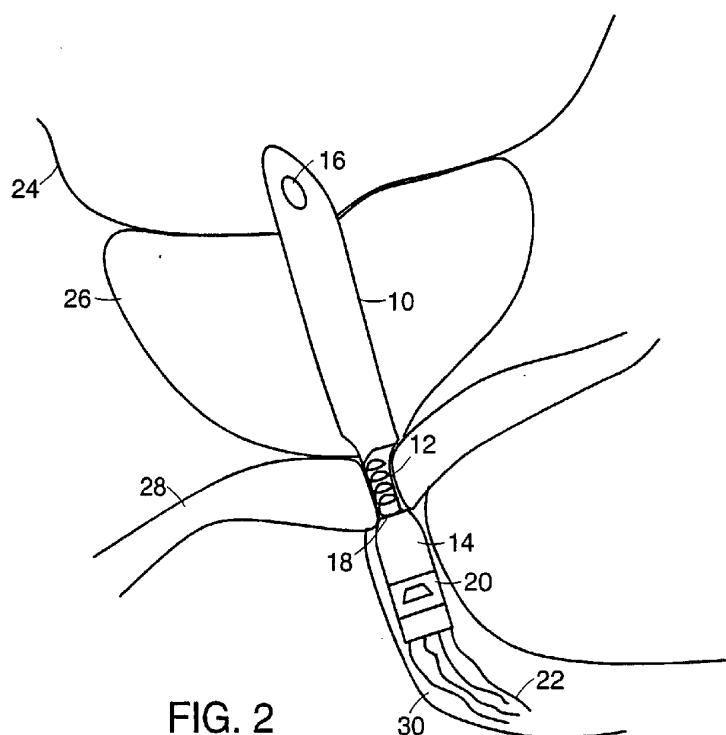


FIG. 2

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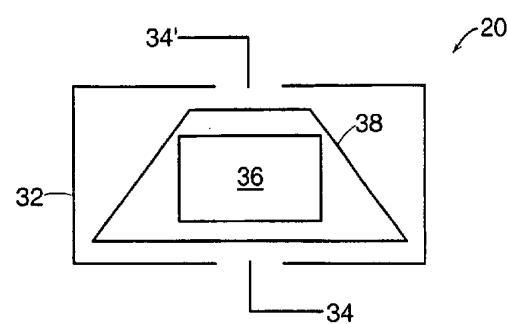


FIG. 3A

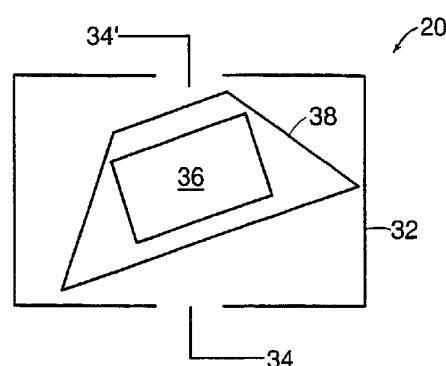


FIG. 3B

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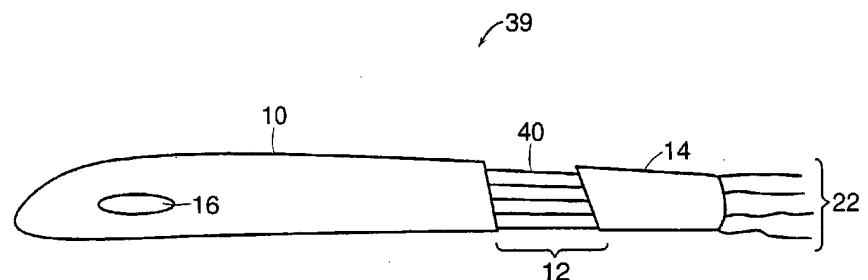


FIG. 4

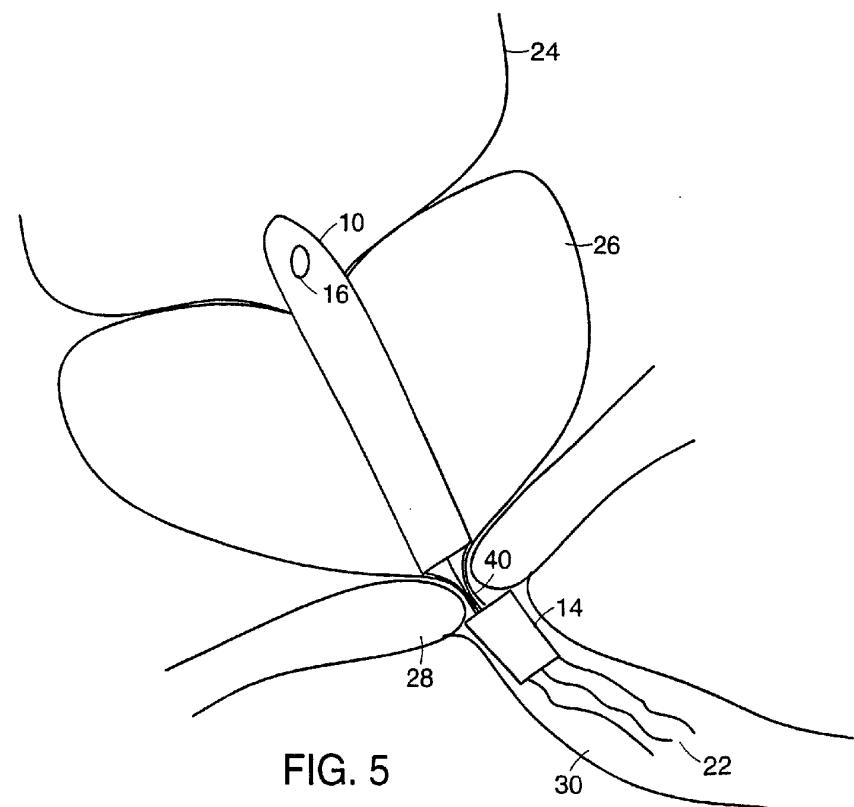


FIG. 5

**SUBSTITUTE SHEET (RULE 26)**

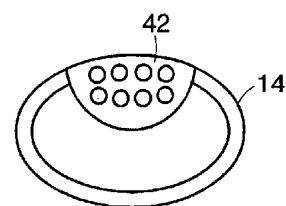


FIG. 6

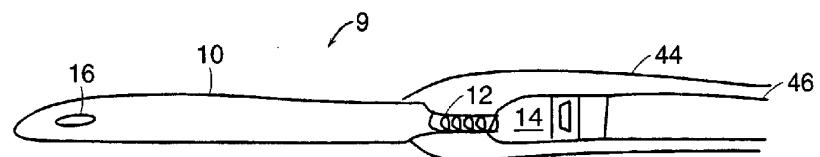
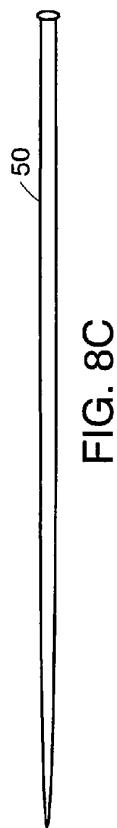
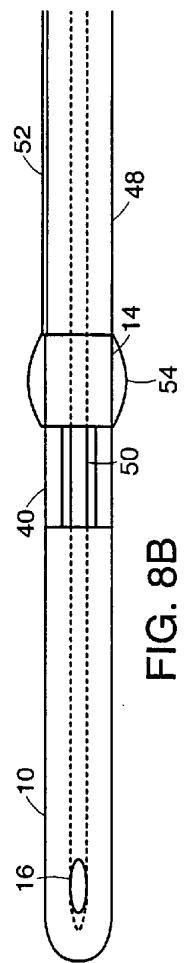
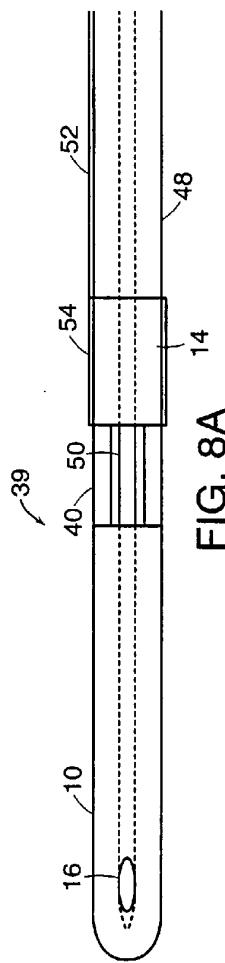


FIG. 7



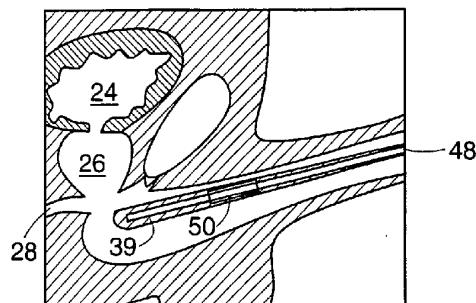


FIG. 9A

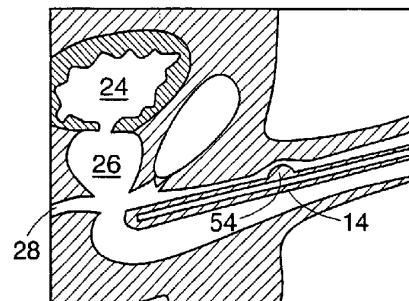


FIG. 9B

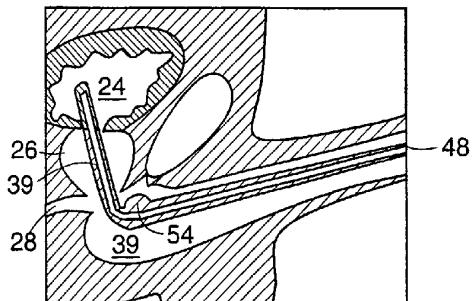


FIG. 9C

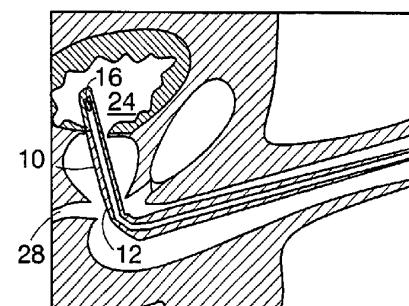


FIG. 9D

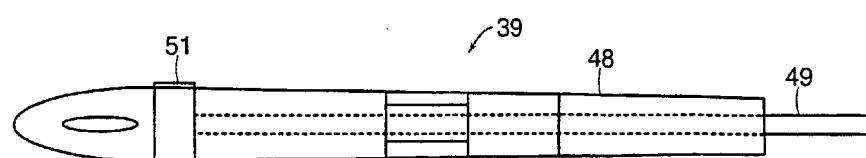


FIG. 10A

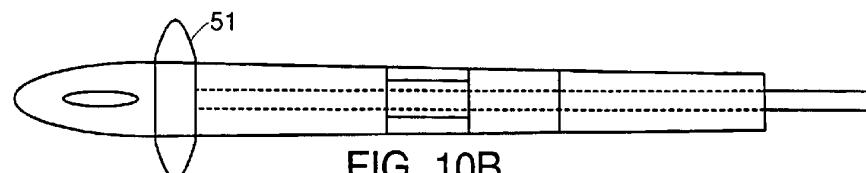


FIG. 10B

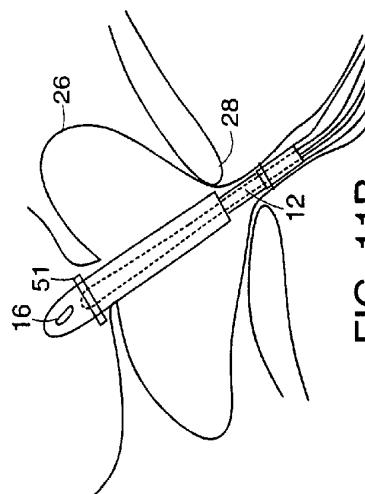


FIG. 11B

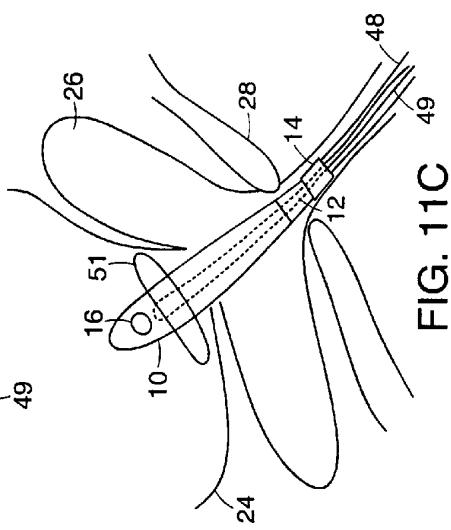


FIG. 11C

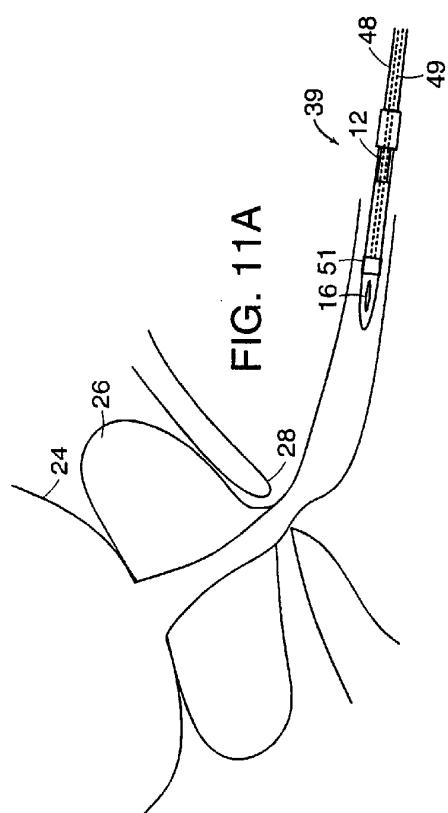
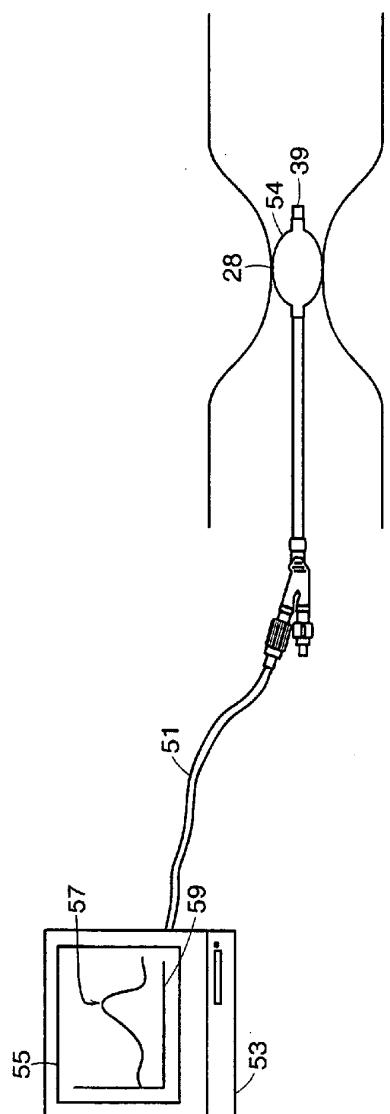


FIG. 11A

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FIG. 12



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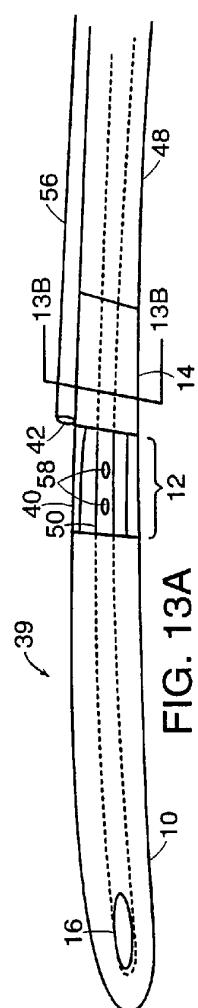


FIG. 13A

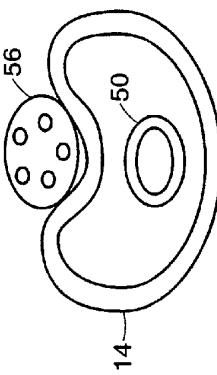


FIG. 14

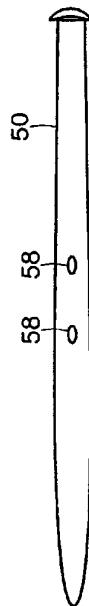


FIG. 13B

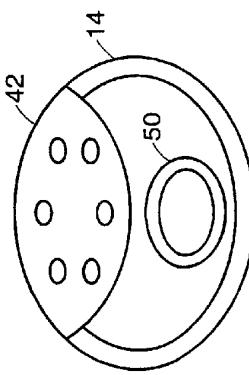


FIG. 15A  
FIG. 15B