Title: MALE URETHRAL SPHINCTER PROSTHESIS

Abstract: The present invention provides a urethral prosthesis (10) including a substrate (20), an inflatable pillow (30) attached to the substrate (20), a pressurized reservoir (110) in fluid communication with the pillow and a restrictor (70). Upon compression of the inflatable pillow (30), inflating agent is transferred from the inflatable pillow (30) to the pressurized reservoir (110). Upon terminating compression, inflating agent returns to the inflatable pillow (30). The urethral prosthesis (10) may be implanted such that the inflatable pillow (30) prevents unintentional voiding of a patient's bladder.
MALE URETHRAL SPHINCTER PROSTHESIS

BACKGROUND OF THE INVENTION

Urinary incontinence is a condition characterized by involuntary loss of urine beyond the individual's control. One cause for this loss of control is damage to the urethral sphincter caused by, for example, prostatectomy, radiation therapy or pelvic accidents. Other causes of incontinence include bladder instability, over-flowing incontinence and fistulas.

Currently, there are a few known surgical treatments for male incontinence, including the implantation of an Artificial Urinary Sphincter (e.g. AMS Sphincter 800 available from American Medical Systems, Minnetonka, MN), the implantation of a bone-screw fixated male sling (e.g. AMS InVance, available from American Medical Systems), and a few other procedures. Other procedures that have been largely discontinued include the implantation of a Kaufman III Prosthesis beneath the urethra. All of these prostheses exert a force on the urethra to prevent unintentional voiding of the bladder.

An improved urethral prosthesis has also been reported, in which a fluid filled chamber is incorporated into the prosthesis to provide improved treatment of incontinence. For example, U.S. Patent No. 6,502,578 and U.S. Patent Application 2001/0023356, both to Raz et al. report an apparatus and method for treatment of male incontinence in which a "hammock-like" prosthesis is positioned between the descending rami of the pubic bone. The prosthesis includes an inflatable balloon device positioned to provide passive compression on the bulbar urethra to prevent voiding of the bladder. The
volume of the balloon may be adjusted after implantation in a patient with a needle and syringe device.

PCT Published Application No. WO 00/74633 A2 reports a urethral prosthesis including a tape having an expandable pillow adapted to be positioned between the tape and the urethra after implantation. The pillow may be expanded by injecting bulking agent into the pillow, resulting in a vertical lifting against the urethra.

U.S. Patent No. 3,789,828 to Schulte reports a urethral prosthesis including a capsule having a liquid filled cavity and two flexible prosthesis ties.

U.S. Patent No. 4,019,499 to Fitzgerald reports a compression implant for urinary incontinence including a cap with an external planar pressure face, a base with an external bearing face and a wall connecting the cap and the base. The cap, base and wall form a cavity that may be filled with an adjustable amount of fluid to adjust the force exerted against the urethra after implantation.

U.S. Patent No. 6,117,067 to Gil-Vernet reports a device for adjusting the height of internal anatomical organs. The device includes a chamber with a volume that may be adjusted by varying the amount of fluid in the chamber. A capsule connected to the chamber via a tube may be used to increase or decrease the amount of fluid in the chamber. Each end of a thread is connected to an end of the chamber, and the thread is adapted to surround an organ. By adjusting the volume of the chamber the thread lifts or lowers the organ as desired.
PCT Application 00/18319 reports a prosthesis including a flexible elongate member, a distensible portion, a conduit and a valve. The distensible portion is bonded to the elongate member and may be filled with a fluid. The conduit provides fluid communication between the distensible portion and the valve. Fluid may be injected into the valve to adjust the pressure of the distensible portion.

Although urethral prostheses that incorporate adjustable fluid-filled chambers may reduce unintentional voiding of the bladder, current chambers may suffer from one or more drawbacks. For example, if the chambers are not sufficiently inflated before implantation, a clinician must inject additional fluid into the chamber to place sufficient force against the patient's urethra. However, this fluid puts additional strain on the prosthesis material, which is generally anchored to an anatomical structure in the body. Such strain may cause patient discomfort, or may even cause the prosthesis to fail. In another example, if the chamber exerts too much pressure on a patient's urethra, then the patient may be unable to void the bladder. This too would require a clinician to perform an additional procedure to adjust the fluid level in the chamber, which would subject the patient to additional risk of infection and may make the procedure more costly. Further yet, such devices have little tolerance for improvement or deterioration in the patient's incontinence condition. Thus, it would be advantageous to provide a male urethral prosthesis that overcomes one or more of these drawbacks.
SUMMARY OF THE INVENTION

The present invention provides a urethral prosthesis including a biocompatible implantable substrate, an inflatable pillow attached to the substrate that is adapted to house an inflating agent, a pressurized reservoir in fluid communication with the inflatable pillow and a restrictor to regulate transfer of the inflating agent between the pressurized reservoir and the inflatable pillow. Upon compression of the inflatable pillow, the inflating agent is adapted to transfer from the pillow to the pressurized reservoir. However, upon terminating compression of the inflatable pillow, the inflating agent is adapted to transfer from the pressurized reservoir to the pillow. The prosthesis may further include a conduit to facilitate transfer of the inflating agent between the inflatable pillow and the pressurized reservoir.

In another embodiment, the present invention provides a urethral prosthesis including an implantable substrate, an inflatable pillow attached to the substrate that has an inflated mode and a deflated mode, and a pressurized reservoir in fluid communication with the inflatable pillow that is adapted to house a portion of the inflating agent. Upon compression of the inflatable pillow when in the inflated mode, the inflatable pillow adjusts to the deflated mode. However, upon terminating compression of the inflatable pillow, the inflatable pillow returns to the inflated mode after a sufficient period of time to allow voiding of a patient's bladder.

In yet another embodiment, the present invention provides a method for treating urinary incontinence in which an embodiment of the urethral prosthesis
described above is implanted in a patient. An inflatable pillow attached to a substrate is implantably secured in the patient such that the inflatable pillow is positioned to exert a force on a portion of the patient's urethra when in an inflated mode. After implantation, a pressure may be exerted on the inflatable pillow to deflate the pillow to reduce the force exerted on the portion of the patient's urethra. The pressure exerted on the inflatable pillow is then reduced to allow the inflatable pillow to inflate. Before the inflatable pillow returns to the inflated mode, a patient's bladder may be voided without resistance against the urethra from the inflatable pillow. However, the inflatable pillow may adjust to the inflated mode prior to a subsequent, unintentional voiding of a patient's bladder.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 schematically illustrates a top view of an embodiment of the present invention.

Fig. 2 schematically illustrates a side view of an embodiment of the present invention in an inflated mode.

Fig. 3 schematically illustrates a side view of the embodiment of Fig. 2 in a deflated mode.

Fig. 4 schematically illustrates a partial cross-section of a restrictor portion suitable for use with an embodiment of the present invention.
DETAILED DESCRIPTION

As illustrated in Figures 1-3, one embodiment of the urethral prosthesis 10 of the present invention includes a substrate 20, an inflatable pillow 30, a conduit 50, a restrictor 70 and a pressurized reservoir 110.

The substrate 20 in this embodiment may be a length of flexible, longitudinally extendable material. The material may be inelastic or elastic, longitudinally extendable or non-extendable and may be patterned, for example in a mesh pattern, which may encourage tissue in-growth. Suitable materials for the substrate may include, but are not limited to materials such as polyester, polypropylene, nylon, polyethylene terephthalate, polytetrafluorethylene, expanded polytetrafluorethylene (e.g. Gortex), polyvinylidene fluoride, polyamides and silk. Preferably, at least the end portions of the substrate 20 may be configured, for example configured as a mesh, to promote tissue in-growth. Alternatively, the substrate 20 may be at least partially formed from a bioabsorbable material such as polylactic acid or polyglycolic acid. Suitable materials are also reported in U.S. Published Patent Application No. 2002/0147382. Still further, the substrate 20 may be coated with a suitable bioactive material having a desired physiological effect. For example, suitable bioactive materials may be selectively coated on desired areas or portions of the urethral prosthesis 10 to reduce inflammation, encourage tissue in-growth and/or to prevent infection in specific areas of a patient.

In one embodiment, the substrate 20 is a polymeric mesh coated with a silicone material or other suitable material, such as an elastomer, polyethylene,
polypropylene, polyester or polyurethane, or a derivative or combination thereof. In another embodiment, an insertion sheath 21 may be optionally used. For example, insertion sheath 21 may be used when the substrate 20 is formed from a longitudinally extending mesh. Suitable materials for the sheath 21 include polyethylene, polypropylene, nylon, polyester, and polytetrafluoroethylene. Other suitable sheaths are reported in co-pending U.S. Patent Application No. 10/335,119, filed December 31, 2002.

Optionally, the substrate 20 may also include a tensioning member, such as a tensioning suture or filament. Suitable tensioning members are disclosed in U.S. Published Patent Application Nos. 2002/0107430-A1 and 2003/0065402 A1, and U.S. Patent Application No. 10/335,119. Additionally, the substrate 20 may include suitable connectors or dilators to facilitate implantation in a patient with guide instruments as reported in further detail below.

The substrate 20 may be sized and shaped for implantation and attachment in the vicinity of a patient's descending rami. In one embodiment, the substrate 20 may have a length between about 5 and about 25 cm, more particularly between about 10 and about 15 cm. The substrate 20 may have a width of between about 0.5 and about 5 cm, more particularly between about 1.5 and about 2.5 cm. The width along the substrate 20 may vary.

The inflatable pillow 30 may be attached to the substrate 20 in any suitable manner. For example, inflatable pillow 30 may be attached by a suitable adhesive. Alternatively, the urethral prosthesis 10 may have an
intermediate layer (not shown) to facilitate attachment between the substrate 20 and the inflatable pillow 30.

The inflatable pillow 30 may be attached approximately at a center point of the substrate 20. A variety of shapes may be used for the inflatable pillow 30. In the illustrated embodiment, the inflatable pillow 30 is a generally oblong shape having rounded edges. From the side perspective of Figure 2, inflatable pillow 30 possesses a concave upper face 35, however, other embodiments may possess a comparatively flat or convex upper face 35 to provide maximum surface area for contact with a urethra of a patient. The size of inflatable pillow 30 may vary widely, however, in one embodiment, the inflatable pillow 30 has a major dimension between about 1 and about 10 cm and a minor dimension between about 0.5 and about 3 cm. In another embodiment, the inflatable pillow 30 may be positioned transverse with respect to the length of the substrate 20.

The inflatable pillow 30 may be formed from any suitable material capable of withstanding a sufficient volume of pressurized fluid to prevent unintentional voiding of a patient's bladder. Suitable materials may include, but are not limited to include elastomers, silicones, polypropylenes, polyesters, polyurethanes, polyvinyl chlorides and polyamides. The inflatable pillow 30 also generally includes an opening 120 to facilitate the delivery and receipt of inflating agent from the pressurized reservoir 110.

The pressurized reservoir 110 is in fluid communication with the inflatable pillow 30 and is capable of pressurizing varying amounts of inflating
agent such that the entire fluid system (i.e., the reservoir, inflatable pillow, conduit and restrictor) is pressurized. The pressurized reservoir 110 may be an expandable material having a generally spherical shape. The pressurized reservoir 110 may be formed from any suitable material capable of delivering and receiving inflating agent. Suitable materials may include, but are not limited to elastomers, silicones, polypropylanes, polyesters and polyurethanes. The pressurized reservoir 110 also includes an opening 130 to facilitate the receipt and delivery of inflating agent.

The inflatable pillow 30 and the pressurized reservoir 110 fluidly communicate via conduit 50. Conduit 50 includes a tube 55 having a first end 60 and a second end 65. The first end 60 communicates with opening 120 of the inflatable pillow 30. The tube 55 may be formed from a flexible polymeric material that is resistant to kinks. Suitable materials for the tube 55 may include, but are not limited to, flexible polymeric materials such as elastomers, silicones, polypropylanes, polyesters, polyurethanes and polyvinyl chlorides. The tube 55 may be reinforced with a variety of suitable materials to impart additional kink resistant properties.

Restrictor 70 is attached to tube 55 at an opening 135, and is attached reservoir 110 at an opening 131. The restrictor 70 is adapted to regulate the flow of inflating agent between the inflatable pillow 30 and the pressurized reservoir 110. More particularly, the restrictor 70 allows inflating agent to flow from the inflatable pillow 30 to the pressurized reservoir 110 during
compression of the inflatable pillow, but resists flow of inflating agent from the pressurized reservoir 110 to the inflatable pillow 30.

As illustrated in Fig. 4, restrictor 70 may include a housing 140, a channel 170, a spring 80, a fluid resistor 90, a ball 100 and a valve seat 105. The fluid resistor provides a narrow channel or orifice through which inflating agent may travel. The ball 100, spring 80 and valve seat 105 cooperate to allow inflating agent to travel from the inflatable pillow 30 to the pressurized reservoir 110, but to prevent the inflating agent from traveling in the reverse direction except through the fluid resistor 90.

In an alternative embodiment, the fluid resistor 90 may include a valve or other means to provide regulated flow from the pressurized reservoir 110 to the inflatable pillow 30. For example, the fluid resistor 90 may be combined with the ball 100, and spring 80 such that the inflating agent only travels along a single path while in the restrictor 70. More particularly, the valve seat 105 for the ball 100 could have small holes to duplicate the action of the resistor 90 and thus eliminate the separate fluid resistor 90 from the restrictor 70.

In the illustrated embodiment, the restrictor 70 is adjacent to the pressurized reservoir 110. Other configurations are possible that place the restrictor at different proximities to the pressurized reservoir 100 and the inflatable pillow 30. In one embodiment, for example, the restrictor may be positioned between the inflatable pillow 30 and the pressurized reservoir 110 with conduits attached to openings 131 and 135 to provide fluid communication. In another embodiment, the restrictor housing may be
positioned 140 adjacent to the inflatable pillow 30 with the opening 135 of the restrictor 70 communicating with the opening 120 of the inflatable pillow 30. In this embodiment, the opening 131 of the restrictor 70 would fluidly communicate with the opening 130 of the pressurized reservoir 110 via conduit 50. In one embodiment, the urethral prosthesis may also include a compression region 40. The compression region 40 provides a tactile locator for operating the prosthesis as described below. The compression region 40 may be attached to, or in communication with the inflatable pillow 30, and may be located on a lower face of the inflatable pillow 30. Alternatively, the compression region may be attached to a portion of the substrate 20 upon which the inflatable pillow 30 is attached.

The inflating agent used in the urethral prosthesis 10 may be any material consistent with the function of the present invention. Suitable inflating agents are generally fluids, such as gasses or aqueous solutions. The viscosity of the fluid may range from 0.2 centipoise to 1000 centipoise.

In operation, the inflatable pillow 30 is adapted to adjust between an inflated mode 150 shown in Fig. 2 and a deflated mode 160, exemplified in Fig. 3. When fluid is transferred to the reservoir 110 from the inflatable pillow 30, the pressure within the pressurized reservoir 110 forces fluid back to the pillow 30 through the restrictor 70. This process continues until the pillow 30 and reservoir 110 have reached fluid equilibrium. The amount of fluid transferred to the pillow 30 is dependent on the amount of fluid required for the reservoir 110 and pillow 30 to reach equilibrium.
When the internal pressure between the pressurized reservoir 110 and the inflatable pillow 30 is at equilibrium, sufficient amounts of the inflating agent are present in the inflatable pillow 30 such that the inflatable pillow 30 is in the inflated mode 150. In the inflated mode 150, the inflatable pillow 30 may have an internal "physiological" pressure sufficient to prevent unintentional voiding of a patient's bladder, without causing necrosis of the urethra. In one embodiment the pressure of the inflatable pillow may be between about 50 and about 300 cm H₂O, more particularly, between about 50 and about 140 cm H₂O, even more particularly, between about 50 and about 70 cm H₂O.

When a sufficient force is exerted on the inflatable pillow 30 when in the inflated mode 150, inflating agent transfers from the inflatable pillow 30, through the conduit 50 and restrictor 70 and into the pressurized reservoir 110. In this embodiment, the inflatable pillow 30 may be compressed from an inflated mode 150 as shown in Figure 2 to a deflated mode 160 as shown in Figure 3. As used herein, the term "deflated mode" refers to the inflatable pillow after sufficient compression is exerted on the inflatable pillow to transfer inflating agent to the reservoir 110 and to allow voiding of a patient's bladder.

When the compression is reduced or terminated, the inflating agent transfers from the pressurized reservoir 110 to the inflatable pillow 30. The transfer of the inflating fluid to the inflatable pillow 30 may be regulated by several factors. First, the pressurized reservoir 110 is adapted to exert sufficient pressure on the inflating fluid such that inflating agent transfers to the inflatable
pillow 30 without requiring a pump system. However, the restrictor 70 regulates the rate of transfer of the inflating agent between the pressurized reservoir 110 and the inflatable pillow 30. More particularly, upon reducing or terminating compression on the inflatable pillow 30, the restrictor 70 resists transfer of inflating fluid from the pressurized reservoir 110 to the inflatable pillow 30, such that the inflatable pillow 30 does not adjust to the inflated mode 150 instantaneously, but rather, inflation occurs over a sufficient period of time to allow a patient's bladder to be voided. For example, after terminating compression of the inflatable pillow 30, the inflatable pillow 30 may return to the inflated mode 150 over a period of between about 30 seconds and about 7 minutes, more particularly between about 1 and about 4 minutes, even more particularly between about 2 and about 3 minutes.

The urethral prosthesis 10 of the present invention may be implanted in a patient by a variety of suitable methods. Suitable implantation methods are reported, for example in U.S. Patent No. 6,502,578 to Raz et al., incorporated herein by reference. In one embodiment, a small scrotal incision is made. The urethral prosthesis 10 is then positioned in the vicinity of a patient's descending rami of the pubic bone such that the inflatable pillow 30 exerts a sufficient force on a portion of a patient's urethra, particularly the bulbular urethra, to prevent unintentional voiding of the bladder. The pressurized reservoir 110 may be implanted in the scrotum of a male patient.

In an alternate embodiment, a small transverse scrotal incision and one or two small horizontal suprapubic incisions are made. A suitable guide needle,
similar to the needles reported in U.S. Published Patent Application Nos. 2002/0147382, 2002/0099259 A1, 2002/0099258 A1 and 2001/0161382 may be inserted into the first suprapubic incision and passed either anterior or superior to the pubic symphysis and towards the scrotal incision. Once a first guide needle has been successfully guided and/or positioned, a second guide needle may be inserted through the optional second suprapubic incision and positioned and/or guided in a similar manner, in opposition to the first needle. The distal ends of the guide needles may then be secured to the optional dilators or connectors attached to the ends of substrate 20, and the urethral prosthesis 10 may be pulled up through the suprapubic incisions. During the implantation procedure, the substrate may be at least partially covered with one or more heat sealed plastic sheaths (not shown), which are removed prior to completing the procedure.

The urethral prosthesis 10 may then be positioned in the vicinity of a patient's descending rami of the pubic bone such that the inflatable pillow 30 contacts a portion of the patient's urethra. The pressure exerted on the urethra may be adjusted during implantation. For example, the pressure may be increased by pulling on the ends of the substrate 20 until a sufficient force is exerted on the urethra. Alternatively, the pressure may be reduced by exerting downward tension in the vicinity of the inflatable pillow 30. The optional tensioning members may facilitate adjustments to the urethral prosthesis 10.

The urethral prosthesis 10 may be secured internally within the patient in a variety of suitable manners. In one embodiment, the urethral prosthesis 10
may be secured solely by tissue in-growth and/or tissue encapsulation. More specifically, portions of the substrate 20 may be configured, for example, in a mesh configuration, to encourage tissue in-growth. Other portions of the prosthesis 10, such as the inflatable pillow 30, may be configured in a manner that does not promote tissue in-growth, but may allow for tissue encapsulation. During the weeks and months after implantation, portions of the urethral prosthesis 10 may become increasingly secured within the patient by tissue in-growth and/or tissue encapsulation. In this manner, portions that are in-grown with tissue secure the urethral prosthesis 10, while portions that are encapsulated in tissue allow for some movement of portions of the urethral prosthesis 10 during use. Advantageously, this embodiment does not require (but may include) additional bone or soft tissue anchors to further secure the urethral prosthesis 10.

In an alternate embodiment, the substrate 20 may be secured to a soft tissue region, such as at the obturator internus muscles or the gracilis muscles, with a combination of suitable soft tissue anchors and sutures. In an additional embodiment, a combination of tissue in-grown portions and suitable anchors may secure the urethral prosthesis 10.

In yet another embodiment, the urethral prosthesis 10 may be secured to the pelvic origin of the gracilis tendon. For example, a tissue anchor may be implanted in the most proximal position to the inferior pubic ramus, where the gracilis tendon attaches to the bone. After the tissue anchor is inserted lateral to the tendon, a suture may be passed medial through the tendon to secure the
prosthesis in place. This technique may be used on both sides of the body in opposition to secure the urethral prosthesis 10. A variety of suitable tissue anchor designs and materials may be used for securing the urethral prosthesis 10 in this embodiment. In one embodiment, for example, a "T" shaped tissue anchor may be formed from titanium, plastic, or stainless steel and may be deployed with a suitable deployment tool and attached to a suture to secure the sling to the tissue.

In an alternate embodiment, one or more tissue anchors may be used to secure the urethral prosthesis to the obturator internus muscles. The anchor may be deployed through the obturator foramen and pass through the obturator externus muscle to the obturator internus muscle. The anchor may then be positioned in the anterior recess of the ischio-anal fossa, just anterior to the obturator internus muscle. At least one anchor in each obturator internus muscle in opposition may be used to secure the sling in place. In a further embodiment, the urethral prosthesis 10 may be secured in this position by screwing a bone screw proximal to the gracilis tendon into the inferior pubic ramus. Alternatively, the urethral prosthesis may be secured to the superior or inferior pubic rami with a bone screw.

Once implanted, the inflatable pillow 30 may be deflated by exerting tactile pressure on the patient's skin at a region that is in the vicinity of the inflatable pillow 30, more particularly, the optional compression region 40. The inflatable pillow 30 then deflates, reducing the force on a portion of the patient's urethra to allow the patient's bladder to be intentionally voided. After
reducing or terminating pressure on the inflatible pillow 30 (normally prior to voiding) the inflatible pillow 30 returns to the inflated mode 150 over a period of time sufficient to allow voiding of the patient's bladder without allowing a subsequent unintentional voiding of the bladder.

In embodiments in which the urethral prosthesis 10 is secured at least partially by tissue in-growth, it may be desirable to maintain the inflatible pillow 30 in a deflated mode until sufficient tissue in-growth has occurred, and then "activating" the urethral prosthesis such that the inflatible pillow 30 is in the inflated mode 150 absent compression. This activation feature may be accomplished by several methods. For example, the urethral prosthesis may be implanted without the pressurized reservoir 110 being pressurized with inflating agent by, for example, injecting inflating agent into the pressurized reservoir 110. After sufficient tissue in-growth has occurred, the pressurized reservoir 110 may then be pressurized with inflating agent. Alternately, the urethral prosthesis may include a lock-out valve (not shown) that prevents inflating agent from filling the inflatible pillow 30. After sufficient tissue in-growth has occurred, the lock-out valve may be released to allow the inflatible pillow to expand to the inflated mode 150 to place additional pressure on a portion of a patient's urethra.

Advantageously, after initial implantation, the patient may perform the method reported herein without the assistance of a clinician. Further, compression and inflation of the inflatible pillow 30 places no additional stress on the substrate 20 because compressing the pillow actually reduces stress on
the substrate. Thus, the urinary prosthesis 10 may be implanted in such a manner that voiding of a patient's bladder is not possible without deflating the inflatable pillow 30. Furthermore, the pillow allows a consistent pressure to be maintained on a portion of the urethra over time regardless of any changes that may occur in the space between the substrate 20 and the urethra. This may significantly reduce the adjustments required in conventional fluid filled devices to determine the precise pressure at which the patient's bladder may be intentionally voided while still preventing unintentional voiding.
CLAIMS

WE CLAIM:

1. A urethral prosthesis comprising:

   an implantable substrate;

   an inflatable pillow attached to the substrate that is adapted to house an
   inflating agent;

   a pressurized reservoir in fluid communication with the inflatable
   pillow, the pressurized reservoir also being adapted to house the inflating agent;
   and

   a restrictor to regulate transfer of the inflating agent between the
   pressurized reservoir and the pillow,

   wherein upon compression of the inflatable pillow, the inflating agent is
   adapted to transfer from the inflatable pillow to the pressurized reservoir and
   wherein upon terminating compression of the inflatable pillow, the inflating
   agent is adapted to transfer from the pressurized reservoir to the inflatable
   pillow.

2. The urethral prosthesis of claim 1 wherein the implantable substrate
   comprises an elongate strip of flexible material.

3. The urethral prosthesis of claim 1 wherein the implantable substrate
   comprises a polymeric material.
4. The urethral prosthesis of claim 1 wherein the implantable substrate comprises polyester, polypropylene, polyethylene terephthalate, polytetrafluorethylene, expanded polytetrafluorethylene or polyvinylidene fluoride.

5. The urethral prosthesis of claim 1 wherein the implantable substrate comprises a mesh material.

6. The urethral prosthesis of claim 1 wherein the implantable substrate comprises a coated substrate.

7. The urethral prosthesis of claim 6 wherein the coating comprises an elastomer, silicone, polypropylene, polyester, polyurethane, or derivatives or combinations thereof.

8. The urethral prosthesis of claim 1 wherein the implantable substrate has a width between about 0.5 and about 5 cm.

9. The urethral prosthesis of claim 1 wherein the implantable substrate has a width between about 1.5 and about 2.5 cm.

10. The urethral prosthesis of claim 1 wherein the implantable substrate has a length between about 5 and about 25 cm.
11. The urethral prosthesis of claim 1 wherein the implantable substrate has a length between about 10 and about 15 cm.

12. The urethral prosthesis of claim 1 wherein the inflatatable pillow comprises an elastomeric material.

13. The urethral prosthesis of claim 1 wherein the inflatatable pillow comprises a polypropylene, polyester, silicone or polyurethane material.

14. The urethral prosthesis of claim 1 wherein the inflatatable pillow comprises a silicone material.

15. The urethral prosthesis of claim 1 wherein the inflatatable pillow comprises an aperture for fluidly communicating with the pressurized reservoir.

16. The urethral prosthesis of claim 1 wherein the inflatatable pillow is adapted to have a pressure of between about 50 and about 140 cm H₂O in an inflated mode.

17. The urethral prosthesis of claim 1 wherein the inflatatable pillow is adapted to have a pressure between about 50 and about 70 cm H₂O in an inflated mode.
18. The urethral prosthesis of claim 1 wherein the pressure in the inflatable pillow and the pressurized reservoir are in fluid equilibrium when the inflatable pillow is in an inflated mode.

19. The urethral prosthesis of claim 1 wherein the inflatable pillow is permanently or removably attached to the substrate.

20. The urethral prosthesis of claim 19 wherein the inflatable pillow is attached by adhesive to the substrate.

21. The urethral prosthesis of claim 19 wherein the inflatable pillow is attached to the substrate by an intermediate layer of material.

22. The urethral prosthesis of claim 1 wherein the pressurized reservoir is expandable.

23. The urethral prosthesis of claim 1 wherein the pressurized reservoir comprises an elastomeric material.

24. The urethral prosthesis of claim 1 wherein the pressurized reservoir comprises polypropylene, polyester, silicone, polyurethane, polyvinyl chloride, nylon or combinations or derivatives thereof.
25. The urethral prosthesis of claim 1 wherein the pressurized reservoir comprises a silicone material.

26. The urethral prosthesis of claim 1 wherein the restrictor provides passive resistance to the transfer of inflating agent from the pressurized reservoir to the pillow.

27. The urethral prosthesis of claim 1 wherein the restrictor regulates the transfer of the inflating agent such that after terminating compression, the inflating agent transfers to the inflatable pillow over a sufficient amount of time to allow voiding of a patient's bladder prior to the inflatable pillow adjusting to an inflated mode.

28. The urethral prosthesis of claim 1 wherein the restrictor comprises a valve.

29. The urethral prosthesis of claim 28 wherein the valve further comprises a ball and spring.

30. The urethral prosthesis of claim 28 wherein the valve comprises a ball and spring in communication with a valve seat.
31. The urethral sling of claim 1 wherein the restrictor comprises a fluid resistor.

32. The urethral sling of claim 31 wherein the resistor is a small orifice fluid resistor.

33. The urethral sling of claim 1 wherein the restrictor is attached adjacent to the pressurized reservoir.

34. The urethral sling of claim 1 wherein the restrictor is attached adjacent to the inflatable pillow.

35. The urethral sling of claim 1 wherein the restrictor is attached to the substrate.

36. The urethral sling of claim 1 wherein the restrictor is in fluid communication with the pressurized reservoir and the pillow via at least one conduit.

37. The urethral prosthesis of claim 1 further comprising a conduit adapted to transfer the inflating agent between the pillow and the pressurized reservoir.
38. The urethral prosthesis of claim 37 wherein the conduit comprises a flexible tube having a first end adapted to communicate with the inflatable pillow.

39. The urethral prosthesis of claim 38 wherein the conduit has a second end adapted to communicate with the pressurized reservoir or the restrictor.

40. The urethral cling of claim 37 wherein the conduit comprises a flexible polymer material.

41. The urethral prosthesis of claim 37 wherein the conduit comprises a kink-resistant material.

42. The urethral prosthesis of claim 1 further comprising a compression region in communication with the inflatable pillow that is adapted to be contacted to compress the inflatable pillow.

43. The urethral prosthesis of claim 42 wherein the compression region is formed on the inflatable pillow.

44. The urethral prosthesis of claim 42 wherein the compression region is attached to a portion of the flexible substrate in contact with the inflatable pillow.
45. The urethral prosthesis of claim 1 further comprising a first connector
attached to a first end of the flexible substrate and a second connector attached
to a second end of the flexible substrate, wherein the connectors are adapted to
removably attach to a guide instrument.

46. The urethral prosthesis of claim 45 wherein the first and second
connectors are removably attached to the respective first and second ends.

47. The urethral prosthesis of claim 1 wherein the inflating agent comprises
a fluid.

48. The urethral prosthesis of claim 47 wherein the inflating agent
comprises an aqueous solution or a gas.

49. The urethral prosthesis of claim 1 wherein the inflating agent has a
viscosity between about 0.5 and 1.0 centipoise.

50. The urethral prosthesis of claim 1 further comprising a lockout valve
adapted to prevent transfer of inflating agent into the inflatable pillow.

51. The urethral prosthesis of claim 50 wherein the restrictor includes the
lockout valve.
52. A urethral prosthesis comprising
an implantable substrate;
a pillow attached to the substrate having an inflated mode and a deflated
mode, and
a pressurized reservoir in fluid communication with the pillow and
adapted to house an inflating agent;
wherein upon compression of the pillow when in the inflated mode, the
pillow adjusts to a deflated mode, and wherein upon terminating compression
of the pillow, the pillow returns to the inflated mode after a sufficient period of
time to allow voiding of a patient's bladder.

53. The urethral prosthesis of claim 52 wherein the pillow has a first
pressure in the inflated mode and a second pressure in the deflated mode.

54. The urethral prosthesis of claim 52 wherein the first pressure is higher
than the second pressure.

55. The urethral prosthesis of claim 52 wherein the first pressure is between
about 50 and about 140 cm H₂O.

56. The urethral prosthesis of claim 52 wherein the pillow is adapted to
house inflating agent in the inflated mode.
57. The urethral prosthesis of claim 52 wherein the pillow and the pressurized reservoir are at fluid equilibrium when the pillow is in the inflated mode.

58. The urethral prosthesis of claim 52 further comprising a conduit adapted to provide transfer of inflating agent between the pillow and the pressurized reservoir.

59. The urethral prosthesis of claim 52 further comprising a restrictor adapted to provide resistance to the transfer of inflating agent between the pillow and the pressurized reservoir.

60. A method of treating urinary incontinence in a patient comprising implanting into the patient a urethral prosthesis comprising:

an implantable substrate adapted to be secured to body tissue in the patient,

an inflatable pillow attached to the substrate that is adapted exert a force on a portion of the patient's urethra in an inflated mode,

a pressurized reservoir in fluid communication with the pillow and adapted to house inflating agent, and

a restrictor to regulate transfer of an inflating agent between the pressurized reservoir and the pillow;
exerting pressure on the inflatable pillow to deflate the inflatable pillow to reduce the force exerted on the portion of the patient's urethra; terminating the pressure exerted on the inflatable pillow to allow inflation of the inflatable pillow to the inflated mode; and
voiding the bladder prior to the inflatable pillow inflating to the inflated mode.

61. The method of claim 60 wherein the inflatable pillow is adapted to contact a portion of the patient's bulbar urethra.

62. The method of claim 60 wherein the pressurized reservoir is adapted to be implanted in a scrotum of a male patient.

63. The method of claim 60 wherein the urethral prosthesis further comprises at least one connector, and the urethral prosthesis is implanted using at least one guide instrument that is removably attachable to the at least one connector.

64. The method of claim 60 wherein portions of the substrate are positioned anterior to the pubic symphysis.

65. The method of claim 60 wherein portions of the substrate are positioned posterior to the pubic symphysis.
66. The method of claim 60 wherein portions of the substrate are positioned transobturator relative to the pubic symphysis.

67. The method of claim 60 wherein the substrate is secured to soft tissue in a patient.

68. The method of claim 60 wherein the substrate is secured by at least one tissue anchor.

69. The method of claim 60 wherein the substrate is secured by at least one soft tissue anchor.

70. The method of claim 60 wherein the substrate is secured by at least one suture.

71. The method of claim 60 wherein the substrate is at least partially secured by tissue in-growth.

72. The method of claim 60 wherein the substrate is secured to the patient's gracilis tendon.

73. The method of claim 60 wherein the substrate is secured to the patient's obturator muscles.
74. The method of claim 60 further comprising after implantation, activating the urethral prosthesis to allow inflating agent to transfer into the inflatable pillow.

75. The method of claim 74 wherein activating the urethral prosthesis comprises opening a lockout valve to allow inflating agent to transfer into the inflatable pillow.
Fig. 4
A. CLASSIFICATION OF SUBJECT MATTER

IPC 7  A61F2/00

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7  A61F

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

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>US 4 587 954 A (HABER TERRY M) 13 May 1986 (1986-05-13) column 2, line 17 - line 43 column 3, line 57 - column 4, line 61 column 10, line 38 - column 14, line 66 claims; figures 1,5,6,11-14,18-26</td>
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Further documents are listed in the continuation of box C.

Date of the actual completion of the international search

24 August 2004

Date of mailing of the international search report

01/09/2004

### INTERNATIONAL SEARCH REPORT

#### DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>US 6 117 067 A (VILA JOSE MA GIL-VERNET) 12 September 2000 (2000-09-12) cited in the application claims; figures</td>
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## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. **X** Claims Nos.: 60-75
   - because they relate to subject matter not required to be searched by this Authority, namely:
     Rule 39.1(iv) PCT – Method for treatment of the human or animal body by surgery

2. □ Claims Nos.: because they relate to parts of the international Application that do not comply with the prescribed requirements to such an extent that no meaningful international Search can be carried out, specifically:

3. □ Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. □ As all required additional search fees were timely paid by the applicant, this international Search Report covers all searchable claims.

2. □ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. □ As only some of the required additional search fees were timely paid by the applicant, this international Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. □ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims, it is covered by claims Nos.:

### Remark on Protest
- □ The additional search fees were accompanied by the applicant’s protest.
- □ No protest accompanied the payment of additional search fees.
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