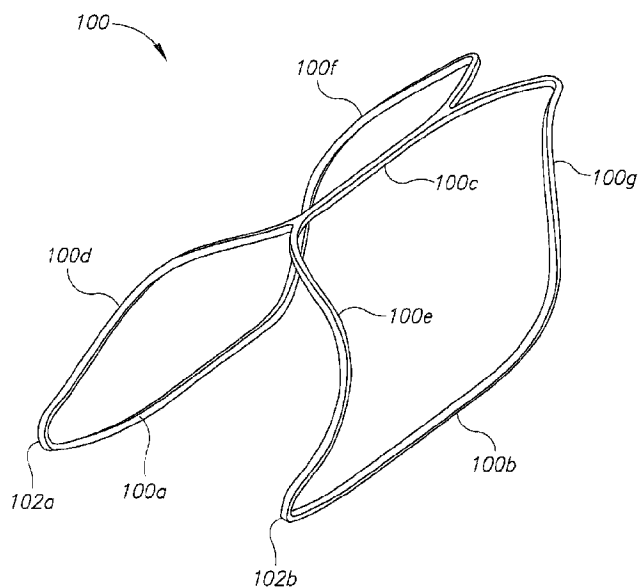




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(54) Title: A DILATING DEVICE FOR PROSTATIC URETHRA



(57) Abrégé/Abstract:

A dilating device for the prostatic urethra comprising: at least three, laterally connected ridges, wherein each ridge is configured to longitudinally engage with a different substantially longitudinal groove of the prostatic urethra of a patient, and wherein the at least three laterally connected ridges are configured to laterally compress to enable insertion into the prostatic urethra in a compressed configuration, and wherein the at least three laterally connected ridges are configured to laterally expand to a normally-open configuration upon deployment within the prostatic urethra, to exert a radially outwards force that dilates the prostatic urethra.

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(54) Title: A DILATING DEVICE FOR PROSTATIC URETHRA

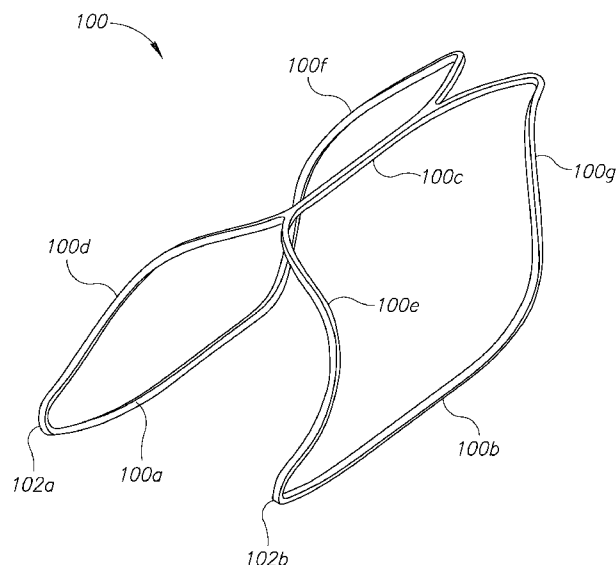


FIG.1A

(57) Abstract: A dilating device for the prostatic urethra comprising: at least three, laterally connected ridges, wherein each ridge is configured to longitudinally engage with a different substantially longitudinal groove of the prostatic urethra of a patient, and wherein the at least three laterally connected ridges are configured to laterally compress to enable insertion into the prostatic urethra in a compressed configuration, and wherein the at least three laterally connected ridges are configured to laterally expand to a normally-open configuration upon deployment within the prostatic urethra, to exert a radially outwards force that dilates the prostatic urethra.

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A DILATING DEVICE FOR PROSTATIC URETHRA

FIELD OF THE INVENTION

The invention relates to the field of urological medical devices.

10

BACKGROUND

Benign prostate hyperplasia (BPH), also known as benign prostatic hypertrophy, is a urological disease in which the prostate enlarges and constricts the urethra. BPH affects a majority of the male population over 50 years of age, and is thus of great medical and commercial importance.

15

Surgical treatment of hypertrophy of the prostate has been a routine procedure for many years. One method of such surgical treatment is open prostatectomy wherein the gland is totally or partially removed. Another method of surgical treatment is transurethral resection of the prostate (TURP). However, surgical treatment is an extremely invasive procedure which is debilitating, painful and often traumatic to the patient. Various complications including impotence, incontinence, bleeding, infection and other undesirable problems attendant with such surgery can result.

20

Another procedure to treat prostatic hypertrophy is to place a catheter at the external opening of the urethra and into the obstructed portions of the urethra, allowing urine to pass from the bladder by way of the catheter lumen. These urinary catheters typically employ a positioning or retention balloon at the distal tip which inflates at the bladder neck and prevents the expulsion of the catheter from the body.

25

Heat, such as produced by microwave or laser energy, may be provided in combination with such catheters for treating the enlarged portion of the prostate. However, this procedure may result in pain and discomfort to the patient

30

The foregoing examples of the related art and limitations related therewith are intended to be illustrative and not exclusive. Other limitations of the related art will become apparent to those of skill in the art upon a reading of the specification and a study of the figures.

SUMMARY

The following embodiments and aspects thereof are described and illustrated in conjunction with systems, tools and methods which are meant to be exemplary and illustrative, not limiting in scope.

There is provided, in accordance with an embodiment, a dilating device for the prostatic urethra, the device comprising: at least three, laterally connected longitudinal ridges, wherein each ridge is configured to longitudinally engage with a different substantially longitudinally groove of the prostatic urethra of a patient, and wherein the at least three laterally connected ridges are configured to laterally compress to enable insertion into the prostatic urethra in a compressed configuration, and wherein the at least three laterally connected ridges are configured to laterally expand to a normally-open configuration upon deployment within the prostatic urethra, to exert a radially outwards force that dilates the prostatic urethra.

In some embodiments, the at least three laterally connected ridges comprise two peripheral ridges that are each configured to engage with a different postero-lateral groove of the prostatic urethra, and a central ridge that is configured to engage with the anterior inter-lobar groove of the prostatic urethra.

In some embodiments, there is further provided one or more connectors that laterally connect each peripheral ridge to the central ridge.

In some embodiments, the one or more connectors laterally connect each peripheral ridge to the central ridge at a point on each ridge that lies between the distal and proximal ends of the peripheral and central ridges.

In some embodiments, the one or more connectors comprise two distal connectors that laterally connect a distal end of each peripheral ridge to a distal end of the central ridge, and two proximal connectors that laterally connect a proximal end of each peripheral ridge to a proximal end of the central ridge, thereby forming two closed forms joined at the central ridge.

In some embodiments, the two closed forms comprise lengthwise oriented ovoid loops that together form a figure-eight shape in the normally-open configuration.

In some embodiments, the two closed forms form two substantially rectangular shapes that span two substantially non-parallel planes in the normally-open configuration.

In some embodiments, the two distal connectors are substantially S-shaped, and are configured to span a portion of a cylinder in the normally-open configuration, thereby dilating the prostatic urethra at the bladder neck.

5 In some embodiments, the two proximal connectors are substantially S-shaped, forming a butterfly shape by the device in the normally-open configuration.

In some embodiments, all the at least three laterally connected ridges and one or more connectors are configured to maintain intimate contact with the prostate urethra mucosa.

10 In some embodiments, there is further provided two or more distally positioned protrusions that are configured to impinge against the postero-lateral side of the bladder neck, thereby preventing a migration of the device into the urinary bladder.

In some embodiments, the at least three laterally connected ridges are composed of wire.

15 In some embodiments, the at least three laterally connected ridges are composed of cut foil.

In some embodiments, the at least three laterally connected ridges are composed of super-elastic alloy.

In some embodiments, the at least three laterally connected ridges are composed of super-elastic polymer.

20 In some embodiments, the super-elastic polymer is a biodegradable polymer.

In some embodiments, the device is configured to allow free passage of a liquid when deployed in the prostatic urethra.

In some embodiments, the shape of the device is configured to reside within the prostate urethra.

25 In some embodiments, the at least three, laterally connected ridges are further configured to: laterally compress for fitting within a deployment lumen, laterally expand to a normally-open configuration upon extraction from the deployment lumen, and exert the outwards radial force upon deployment within the prostatic urethra.

30 In some embodiments, the deployment lumen is configured to be housed within a work channel of a cystoscope.

In some embodiments, the deployment lumen is further provided with a fluid delivery lumen and balloon that are configured to deliver a fluid to the bladder to allow deploying the device within the prostatic urethra via the bladder.

In some embodiments, the at least three, laterally connected ridges are provided with one or more proximally disposed protrusion that are configured to releasably connect the device to an alignment mechanism housed within the deployment lumen.

5 In some embodiments, the alignment mechanism comprises a releasable string that loops through the protrusions and runs through an alignment lumen.

In some embodiments, the device is configured for alignment within the prostatic urethra via a torque that is transferred from the alignment mechanism.

10 There is provided, in accordance with an embodiment, a method for dilating a prostatic urethra, the method comprising: inserting a dilating device into the urethra of a patient; aligning the dilating device within the prostatic urethra; positioning the dilating device within the prostatic urethra of the patient; and deploying the dilating device within the prostatic urethra, thereby causing the dilating device to: expand to a normally-open configuration, engage with the grooves of the prostatic urethra, exert a radially outwards force on the prostatic urethra, and dilate the prostatic urethra.

15 In some embodiments, positioning comprises extracting the device from a deployment lumen and inserting the device into the urinary bladder of the patient.

In some embodiments, positioning comprises drawing the device from the bladder into the prostate urethra.

20 In some embodiments, aligning comprises transferring a torque applied to an alignment mechanism connected to the device.

In some embodiments, the torque is applied by rotating an alignment lumen that is connected to the device.

25 In some embodiments, aligning comprises positioning a central ridge of the device for engaging with the anterior inter-lobar groove of the prostatic urethra and positioning two peripheral ridges of the device to each engage with a different postero-lateral groove of the prostatic urethra.

In some embodiments, the method further comprises causing the device to laterally compress and retreat within the deployment lumen if the alignment or position of the device is incorrect.

30 In some embodiments, the method further comprises causing the device to impinge against the postero-lateral side of the bladder neck, thereby preventing a migration of the device into the urinary bladder.

In some embodiments, the method further comprises disconnecting the device from a deployment lumen provided to deploy the device.

In some embodiments, the method further comprises applying a positioning balloon to secure the position of the deployed device.

There is provided, in accordance with an embodiment, a kit for dilating a prostatic urethra, the kit comprising: a deployment lumen; and a dilating device which
5 comprises: at least three, laterally connected ridges, wherein each ridge is configured to vertically engage with a different substantially vertical groove of the prostatic urethra of a patient, and wherein the at least three laterally connected ridges are configured to laterally compress to enable insertion into the prostatic urethra, in a compressed configuration, through said deployment lumen, and wherein the at least
10 three laterally connected ridges are configured to laterally expand to a normally-open configuration upon deployment from said deployment lumen into the prostatic urethra, to exert a radially outwards force that dilates the prostatic urethra,

In some embodiments, the at least three, laterally connected ridges are provided with one or more proximally disposed protrusion that are configured to releasably
15 connect the device to an alignment mechanism housed within the deployment lumen.

In some embodiments, the alignment mechanism comprises a releasable string that loops through the protrusions and runs through an alignment lumen.

In some embodiments, the device is configured for alignment within the prostatic urethra via a torque that is transferred from the alignment mechanism.

20 In some embodiments, the deployment lumen is configured to be housed within a work channel of a cystoscope.

In some embodiments, the deployment lumen is further provided with a balloon that is configured to position the device within the within the prostatic urethra.

In some embodiments, the at least three laterally connected ridges comprise two
25 peripheral ridges that are each configured to engage with a different postero-lateral groove of the prostatic urethra, and a central ridge that is configured to engage with the anterior inter-lobar groove of the prostatic urethra.

In some embodiments, the kit further comprises one or more connectors that laterally connect each peripheral ridge to the central ridge.

30 In some embodiments, the one or more connectors laterally connect each peripheral ridge to the central ridge at a point on each ridge that lies between the distal and proximal ends of the peripheral and central ridges.

In some embodiments, the one or more connectors comprise two distal connectors that laterally connect a distal end of each peripheral ridge to a distal end of

the central ridge, and two proximal connectors that laterally connect a proximal end of each peripheral ridge to a proximal end of the central ridge, thereby forming two closed forms joined at the central ridge.

5 In some embodiments, the two closed forms comprise lengthwise oriented ovoid loops that together form a figure-eight shape in the normally-open configuration.

In some embodiments, the two closed forms form two substantially rectangular shapes that span two substantially non-parallel planes in the normally-open configuration.

10 In some embodiments, the two distal connectors are substantially S-shaped, and are configured to span a portion of a cylinder in the normally-open configuration, thereby dilating the prostatic urethra at the bladder neck.

In some embodiments, the two proximal connectors are substantially S-shaped, forming a butterfly shape by the device in the normally-open configuration.

15 In some embodiments, all the at least three laterally connected ridges and one or more connectors are configured to maintain intimate contact with the prostate urethra mucosa.

In some embodiments, the kit further comprises two distally positioned protrusion that are configured to impinge against the postero-lateral side of the bladder neck, thereby preventing a migration of the device into the urinary bladder.

20 In some embodiments, the at least three laterally connected ridges are composed of wire.

In some embodiments, the at least three laterally connected ridges are composed of cut foil.

25 In some embodiments, the at least three laterally connected ridges are composed of super-elastic alloy.

In some embodiments, the at least three laterally connected ridges are composed of super-elastic polymer.

In some embodiments, the super-elastic polymer is a biodegradable polymer.

30 In some embodiments, the device is configured to allow free passage of a liquid when deployed in the prostatic urethra.

There is provided, in accordance with an embodiment, a dilating device for the prostatic urethra, the device comprising: at least two dilating means of the prostate urethra, wherein the dilating means are connected by ridges that are configured to fix the dilating means in place within the prostate urethra and prevent their movements or

dislodgement and wherein the dilating means are configured to laterally expand to a normally-open configuration upon deployment within the prostatic urethra, to exert a lateral outwards force that dilates the prostatic urethra.

5 In some embodiments, the dilating means comprise arcs that exert lateral forces on the lateral lobes.

In some embodiments, the dilating means comprise rings.

In some embodiments, the shape of the device in a normally open configuration is configured to reside within a delimiting surface of a longitudinally oriented tube.

In some embodiments, the device is shaped to reside within the prostate urethra.

10 In some embodiments, the dilating means and connecting ridges of the device are configured to maintain intimate contact with the prostate urethra mucosa.

In addition to the exemplary aspects and embodiments described above, further aspects and embodiments will become apparent by reference to the figures and by study of the following detailed description.

15

BRIEF DESCRIPTION OF THE FIGURES

Exemplary embodiments are illustrated in referenced figures. Dimensions of components and features shown in the figures are generally chosen for convenience and clarity of presentation and are not necessarily shown to scale. The figures are
20 listed below.

Fig. 1A-B illustrates a dilating device for the prostatic urethra from a perspective view and a top view, respectively, in accordance with an embodiment;

Fig. 1C shows a profile view of the device of Fig. 1A, according to an embodiment;

25 Fig. 1D shows a frontal view of the device of Fig. 1A, according to an embodiment;

Figs. 2A-B, together show an exemplary deployment of a device for dilating a prostatic urethra, according to an embodiment;

30 Figs. 3A-B together illustrate a deployment apparatus for a dilating device for the prostatic urethra, in accordance with an embodiment;

Figs. 4A-B show a cystoscope configured to deploy a dilating device for the prostatic urethra, in accordance with an embodiment; and

Fig. 5 shows a flowchart of a method for dilating the prostatic urethra, according to an embodiment.

DETAILED DESCRIPTION

Disclosed herein is a device that is configured to dilate the prostatic urethra by engaging with the three grooves of the prostatic urethra and exerting a radially outwards force upon deployment within the urethra. The device may be normally open, and made of a resilient material allowing it to laterally compress for fitting within a deployment lumen, and to laterally expand to a normally-open configuration upon extraction from the deployment lumen, and exert the outwards radial force that dilates the prostatic urethra upon deployment.

Figs. 1 through 5, wherein like parts are designated by like reference numerals throughout, illustrate a dilating device for the prostatic urethra, and a method of use according to the present invention. Although the present invention will be described with reference to the figures, it should be understood that many alternative forms can embody the present invention. One of ordinary skill in the art will additionally appreciate different ways to alter the parameters disclosed, such as the size, shape, or type of elements or materials, in a manner still in keeping with the spirit and scope of the present invention.

Reference is now made to Figs. 1A-B which illustrates a dilating device **100** for the prostatic urethra, from a perspective view and a top view, respectively, in accordance with an embodiment. Device **100** may comprise at least three laterally connected ridges **100a**, **100b**, **100c**, each of which is configured to longitudinally engage with a different substantially longitudinal groove of the prostatic urethra of a patient. Device **100** may be normally-open, and may be configured to laterally compress, causing the distance between ridges **100a**, **100b**, **100c** to decrease, thereby enabling the insertion of device **100** into the prostatic urethra in a compressed configuration, and to laterally expand to its normally-open configuration, causing the distance between ridges **100a**, **100b**, **100c** to increase, upon deployment within the prostatic urethra. The lateral expansion of device **100** when deployed within the prostatic urethra may exert a radially outward force that causes ridges **100a**, **100b**, **100c** to engage with the grooves of the urethra and push them outwards, thereby dilating the prostatic urethra, and allowing a free flow of a liquid, such as urine, to pass from the bladder through the urethra and out of the patient's body.

Peripheral ridges **100a**, **100b** may each be configured to engage with a different postero-lateral groove of the prostatic urethra, and central ridge **100c** may be configured to engage with the anterior inter-lobar groove of the prostatic urethra.

Two distal connectors **100d**, **100e** may branch out from a V-shaped distal end of central ridge **100c** and laterally connect to the distal ends of peripheral ridges **100a** and **100b**, respectively. Additionally, two proximal **100f**, **100g** may branch out from a proximal end of central ridge **100c** and laterally connect to the proximal ends of peripheral ridges **100a**, and **100b**, thereby forming two closed forms that are joined at central ridge **100c**. In one embodiment, proximal connectors **100f** and **100g** may branch out from a V-shaped proximal end of central ridge **100c**, as illustrated in Fig. 1A. In the embodiment of Fig. 1A, connectors **100d**, **100e**, **100f**, and **100g** may be substantially S-shaped, forming a butterfly shape by device **100** when in the normally-open configuration, where proximal connectors **100f**, and **100g** may be configured for positioning towards the distal end of the prostate urethra. .

Device **100** may be provided with two, or more distally positioned protrusions **102a** and **102b** that are configured to impinge against the postero-lateral side of the bladder neck, and prevent a migration of device **100** into the urinary bladder. Protrusions **102a** and **102b** may be integrally formed with distal connectors **100d**, **100e**, such as forming a portion of the S-shape of distal connectors **100d**, **100e** that are shown in Figs. 1A, 2.

Device **100** may additionally be configured for alignment within the prostatic urethra via two proximally disposed protrusions that are provided with device **100** to releasably connect device **100** to an alignment mechanism provided with the deployment lumen, and which will be described in greater detail below. Protrusions may be integrally formed with proximal connectors **100f**, **100g**.

For example, an operator may be guided by an external marker provided with device **100**, and apply a torque that is transferred to device **100** and that causes it to rotate, thereby aligning central ridge **100c** with the anterior inter-lobar groove of the prostatic urethra.

Device **100** may be integrally formed, and may be made of a suitably flexible material, such as wire or cut foil made of a super-elastic alloy such as Nitinol. Alternatively, device may be made of a super-elastic polymer or biodegradable polymer.

This memory-retaining flexibility may allow distal connectors **100d** and **100e** and proximal connectors **100f** and **100g** to bend in a manner that decreases the distance between ridges **100a**, **100b** and **100c**, thereby compressing device **100** to enable its insertion into the prostatic urethra. Additionally, distal connectors **100d** and **100e** and proximal connectors **100f** and **100g** may be normally unbent, and may revert to their normally unbent configuration upon deployment within the prostatic urethra, thereby increasing the distance between ridges **100a**, **100b** and **100c** and expanding device **100** to enable dilating the prostatic urethra.

Reference is made to Fig. 1C, which shows a profile view of the device of Figs. 1A-B, according to an embodiment. The closed form that is formed by peripheral ridge **100b**, central ridge **100c**, distal connector **100e**, and proximal connector **100g** resembles a 'butterfly wing'. An identical and symmetric butterfly wing (not shown) is formed by peripheral ridge **100a**, central ridge **100c**, distal connector **100d**, and proximal connector **100f**.

Reference is now made to Fig. 1D, which shows a frontal view of the device of Figs. 1A-B, according to an embodiment. When normally-open, S-shaped distal connectors **100d**, **100e**, comprising a distal end of device **100**, may be configured to span an arc, such as a portion of a circle to dilate the prostatic urethra at the bladder neck.

In one embodiment, the shape of the device in the normally-open configuration may reside within the delimiting surface of a longitudinally oriented tube, such as a free-form longitudinally-oriented lumen. The shape of the lumen may be a cylinder, prism, or trunk-conical shape, to name a few, and may comprise a combination of shapes. For example, the lumen may have a cylindrical shape at the tubular ends, and a triangular prism shape at the midsection. The profile, or cross section of such shape may be circular ovoid, triangular, and may be uniform or may change in size and/or shape along the axial length. In the example given above, the cross-section at the ends of the open device may be circular due to the normally-open circular arc-shape of connector pairs **100d**, **100e**, and **100f**, **100g**, whereas the cross-section at the middle of the device may be triangular due to the three ridges **100d**, **100e**, **100c** that are 'pulled apart' by the normally open connectors. The device may have a varying cross-sectional size. For example, a portion of the device may reside within a fraction, such as 50%, 66%, or 75% of the longitudinally oriented tube.

Similarly, in the normally-open configuration, S-shaped proximally connectors **100f**, **100g**, comprising a proximal end of device **100** may be configured to reside within the circular delimiting surface of a cylinder to dilate the prostatic urethra at the proximal end of device **100**.

5 The device may be shaped for residing within the prostate urethra and for positioning on the longitudinal axis between the external sphincter of the urethra distally and the bladder neck proximally.

10 In an embodiment, connectors **100d**, **100e** with ridge **100c** may, in the normally-open configuration, may create an arc that exerts a lateral force on the lateral prostate lobes and dilates the prostate. Similarly, connectors **100f**, **100g** with **100c** may create another arc that exerts a lateral force on the lateral prostate lobes and may dilate the prostate at a region situated distally. Thus, the device may provide two or more arcs that each exert a lateral force on a different region of the lateral prostate lobes.

15 In another embodiment additional connectors (not shown), similar and substantially parallel to connectors **100d**, **100e**, **100f**, and **100g**, may be provided to laterally connect each peripheral ridge **100a**, **100b**, to the central ridge **100c** at a point on each ridge that lies between the distal and proximal ends of the peripheral and central ridges **100a**, **100b**, **100c**, such as at a midpoint along the ridge. The distance along the long axis of the device between any such pair of connectors may be between
20 0.5 cm to 3 cm, or more explicitly between 1 cm to 2 cm. The shape of the device in the normally-open configuration may reside within the delimiting surface of an longitudinally oriented tube, such as a free-form longitudinally-oriented lumen.

In an embodiment, the length of the device may range between 1cm to 7 cm. There may be different sizes suitable for different lengths of prostate urethra.

25 In an embodiment, the diameter of the expanded device may be between 10 mm to 30 mm, and more explicitly between 15 mm and 25 mm.

In an embodiment, the device may be compressed to a minimal diameter of 0.5 mm to 3 mm and more explicitly of 1mm to 2 mm.

30 In an embodiment, in case of a Nitinol device, the wire or ribs size may range from 0.2 to 0.8 mm and more explicitly between 0.3mm to 0.6 mm.

In an embodiment, the dilating action of the device on the prostate urethra may be performed by the radial outward force exerted by the longitudinally oriented ridges on the prostate grooves and by an additional force exercised on the lateral lobes by the

arc formed by the connection of components **100d**, **100c**, **100e**, and the arc formed by the connection of components **100f**, **100c**, **100g**.

In an embodiment, the components of the device, such as the ridges and connectors, or alternatively, the dilating means and connecting ridges of the device
5 may be configured to maintain intimate contact with the mucosa of the prostate urethra when the device is in the open configuration.

Alternatively, the arcs formed by connectors **100d**, **100e**, **100f**, and **100g** of device **100** may comprise at least two dilating means of the prostate urethra. Connectors **100d**, **100e**, **100f**, and **100g** may be connected with longitudinally oriented
10 ridges **100a**, **100b**, and **100c** that may be configured to fix the dilating means in place within the prostate urethra and prevent their movement or dislodgement.

In one embodiment, any of connectors **100d**, **100e**, **100f**, and **100g** may comprise closed rings, and any of connecting ridges may have an oblique or sinusoidal orientation.

Reference is now made to Figs. 2A-B, which together show an exemplary
15 deployment of a device for dilating a prostatic urethra, according to an embodiment. Fig. 3A shows a cross-section of prostatic urethra **200** that is obstructed by an enlarged prostate **202**. Fig. 3B shows the cross-section of the prostatic urethra of Fig. 3A upon deploying a dilating device, in accordance with an embodiment of the invention. The
20 three laterally connected ridges of the device that are illustrated at a midsection view along the axially oriented device and labeled as points **204a**, **204b**, and **204c**, are shown in the normally-open configuration and engaged within the grooves of prostatic urethra **200**, thereby dilating urethra **200** to allow a free passage of fluid therethrough.

Reference is now made to Figs. 3A-B which together illustrate an apparatus for
25 deploying a dilating device for the prostatic urethra, in accordance with an embodiment. Fig. 3A shows a dilating device **300** in the normally-open configuration such as after deployment, and Fig 3B shows device **300** in the compressed configuration while housed within a deployment lumen **308**, prior to deployment. The apparatus for deployment and the dilating device may be jointly referred to as a "kit".

Turning to Fig. 3B, to deploy device **300**, deployment lumen **308** may be
30 retracted relative to device **300** to expose device **300** from the distal end **314** of lumen **308**, allowing device **300** to protrude from lumen **308** and expand to its normally-open configuration, as shown in Fig. 4A. Upon protruding from lumen **308** and during the expansion of device **300**, the ridges of device **300** may engage with the grooves of the

prostatic urethra and cause it to dilate, as described above. To reposition device **300** within the prostatic urethra after its exposure from lumen **308**, device **300** may be retracted relative to lumen **308**, such as by pulling a string **312** that is releasably attached to device **300** and that is exposed from a proximal end of deployment lumen **308**. The distal opening **314** of lumen **308** may press on the expanded ridges of device **300**, causing device **300** to compress and allowing its retreat into lumen **308** where it may be housed for subsequent redeployment.

The retraction of either deployment lumen **308** or device **300** in relation to each other may be performed mechanically by a practitioner, such as via a work channel of a cystoscope, and which will be described in greater detail below.

Dilating device **300** may be provided with one or more proximally disposed protrusions **304a** and **304b** that are that may be integrally formed with the proximal end of device **300** and that are configured to releasably connect device **300** to an alignment mechanism **306** that is configured for being housed within deployment lumen **308**.

Alignment mechanism **306** may comprise an alignment lumen **310** concentrically housed within deployment lumen **308**, as well as releasable string **312**. String **312** may loop through protrusions **304a** and **304b** of device **300** and may run through alignment lumen **310** and may be exposed from a proximal end of alignment lumen **310** for subsequent removal upon deployment of device **300**. Device **300** may be configured for alignment within the prostatic urethra via a torque that is transferred from alignment mechanism **306** to device **300**. For example, an operator may rotate alignment lumen **310** to align alignment lumen **310** with an externally provided alignment mark, thereby applying a torque to alignment lumen **310** that is transferred by alignment mechanism **306** to device **300** and causes device **300** to be aligned within the prostatic urethra.

Alternatively, referring to Figs. 4A-B a cystoscope **420** disposed with a work channel **422** may be used for deploying device **300** of Figs. 3A-B from the distal end **428** of cystoscope **420**. Device **300** housed within deployment lumen **308** and optionally with alignment lumen **310** may be inserted into work channel **422**. The deployment and alignment of device **300** may be controlled from a proximal end **428** of work channel **422**.

In an embodiment, cystoscope **420** may be provided with a fluid delivery lumen and a balloon (not shown) that are configured to deliver a fluid to inflate the patient's

bladder. The device may be configured for delivery into the inflated bladder, where it may be extracted from the deployment lumen to expand within the bladder, and then retracted for final deployment within the prostate urethra.

Reference is made to to Fig. 4B which shows a close-up view of distal end **428** of cystoscope **420**, a camera **424** and illuminator **426** provided with cystoscope **420** may be utilized, in an embodiment, for aligning and deploying device **300** using conventional techniques. Deployment lumen **308** housing device **300** and alignment mechanism **306**, and optionally the fluid delivery lumen and balloon, may be inserted into work channel **422** of cystoscope **420** and may be manipulated from a proximal end **428** of work channel **422** to deploy device **300** within the prostatic urethra. The patient's bladder may be filled via the fluid delivery lumen and balloon, allowing deployment of device **300** within the prostatic urethra via the bladder.

Reference is now made to Fig. 5 which is a flowchart of a method for deploying a dilating device into a prostatic urethra.

The laterally compressed dilating device may be inserted into the urethra of a patient via a deployment lumen that is releasably connected to the device (Step **500**). The patient's bladder may be filled according to conventional techniques, such as via a fluid delivery lumen disposed with a balloon (Step **502**). The device may be extracted from the deployment lumen and inserted into the urinary bladder, such as by retracting the deployment lumen relative to the device, and, upon exiting from the deployment lumen, the dilating device may expand to a normally-open configuration in the partially filled urinary bladder of the patient (Step **504**). A torque may be applied to align the device via an alignment mechanism connected to the device, such as by rotating an alignment lumen of the alignment mechanism and transferring the torque to the device, where alignment may comprise aligning a central ridge of the device for engaging with the anterior inter-lobar groove of the prostatic urethra and aligning two peripheral ridges of the device to each engage with a different postero-lateral groove of the prostatic urethra (Step **506**). The application of the torque may be guided via a cystoscope, or alternatively, via an external mark indicating that the device is aligned.

The aligned device may be positioned in the prostate urethra, such as by pulling on the deployment mechanism to draw the device in from the bladder into the prostate urethra (Step **508**). Two protrusions disposed at the distal end of the device may be caused to impinge against the postero-lateral side of the bladder neck, thereby securing the position of the device, and preventing a migration of the device into the urinary

bladder (Step **510**). The device, thus deployed and aligned within the prostatic urethra, may exert an outwards radial force that pushes the inter-lobar grooves of the urethra outwards, and dilate the urethra (Step **512**).

5 If the positioning or alignment of the device is incorrect, the device may be retracted relative to the deployment lumen, causing the device to laterally compress and retreat within the deployment lumen (Step **514**). The retreated device may be repositioned or realigned within the prostatic urethra and redeployed (Steps **504-512**). If the positioning and alignment of the device is correct, The device may be disconnected from the deployment and alignment lumens (Step **518**), such as by
10 removing a string that releasably connects the device to the alignment lumen.

Numerous modifications and alternative embodiments of the present invention will be apparent to those skilled in the art in view of the foregoing description. Accordingly, this description is to be construed as illustrative only and is for the purpose of teaching those skilled in the art the best mode for carrying out the present
15 invention. Details of the structure may vary substantially without departing from the spirit of the present invention, and exclusive use of all modifications that come within the scope of the appended claims is reserved. Within this specification embodiments have been described in a way which enables a clear and concise specification to be written, but it is intended and will be appreciated that embodiments may be variously
20 combined or separated without parting from the invention. It is intended that the present invention be limited only to the extent required by the appended claims and the applicable rules of law.

It is to be understood that the following claims are to cover all generic and specific features of the invention described herein, and all statements of the scope of
25 the invention which, as a matter of language, might be said to fall therebetween.

CLAIMS

What is claimed is:

1. A system for dilating a prostatic urethra, the system comprising:
a dilating device including
two dilating means symmetrically interconnected on opposite postero-lateral sides of the dilating device,
two longitudinally oriented peripheral ridges configured to fix the dilating means in place within the prostate urethra and prevent their movements or dislodgement,
wherein the two dilating means are configured to laterally expand said two longitudinally oriented peripheral ridges to a normally-open configuration upon deployment within the prostatic urethra, to exert a lateral outwards force that dilates the prostatic urethra and
protrusions on opposite postero-lateral sides of the dilation device, each of said protrusions protruding distally from a respective peripheral ridge of said two longitudinally oriented peripheral ridges, said protrusions protruding distally beyond the rest of the device configured to impinge against opposite postero-lateral sides of a bladder neck of the prostatic urethra, thereby preventing a migration of the device into a urinary bladder.
2. The system of claim 1, wherein the dilating means comprise arcs that exert lateral forces on lateral lobes of the prostatic urethra.
3. The system of claim 1, wherein the dilating means comprise rings.
4. The system of claim 1, wherein a shape of the dilating device in a normally open configuration is configured to reside within a delimiting surface of a longitudinally oriented tube.

5. The system of claim 1, wherein the dilating device is shaped to reside within the prostate urethra.
6. The system of claim 1, wherein the dilating means and peripheral ridges of the device are configured to maintain intimate contact with prostate urethra mucosa.
7. The system of any one of claims 1 to 6, wherein said two dilating means branch out from a distal end of a central ridge of the device.
8. The system of claim 7, wherein said two dilating means branch out from said distal end of said central ridge in a V-shape.
9. The system of any one of claims 1 to 8, wherein said protrusions are integral to said two dilating means.
10. The system of claim 9, wherein said two dilating means are S-shaped.
11. The system of any one of claims 1 to 10, wherein said two peripheral ridges are included in two closed forms symmetrically positioned on opposite sides of the device.
12. The system of claim 11, wherein said two closed forms are lengthwise ovoid loops.
13. The system of claim 12, wherein said protrusions are integral to said two closed forms.
14. The system of any one of claims 1 to 13, wherein a posterior side of the dilating device is open.
15. The system of claim 1, wherein the two dilating means comprise two peripheral ridges that are each configured to engage with a different postero-lateral groove of the prostatic urethra.

16. The system of any one of claims 1 to 13, wherein the two longitudinal ridges are composed of wire.
17. The system of any one of claims 1 to 13, wherein the two longitudinal ridges are composed of cut foil.
18. The system of any one of claims 1 to 13, wherein the two longitudinal ridges are composed of super-elastic alloy.
19. The system of any one of claims 1 to 13, wherein the two longitudinal ridges are composed of super-elastic polymer.
20. The system of claim 19, wherein the super-elastic polymer is a biodegradable polymer.
21. The system of any one of claims 1 to 13, wherein the dilating device is configured to allow free passage of a liquid when deployed in the prostatic urethra.
22. The system of any one of claims 1 to 13, wherein the dilating device is configured to reside within the prostate urethra.
23. The system of any one of claims 1 to 13, further comprising:
 - a deployment lumen from which the dilating device is deployed into the urethra, and
 - wherein the two longitudinal ridges are further configured to:
 - laterally compress for fitting within the deployment lumen,
 - laterally expand to a normally-open configuration upon extraction from the deployment lumen, and
 - exert the lateral outwards force upon deployment within the prostatic urethra.

24. The system of claim 23, wherein the deployment lumen is configured to be housed within a work channel of a cystoscope.
25. The system of claim 23, wherein the deployment lumen is further provided with a fluid delivery lumen and balloon that are configured to deliver a fluid to the bladder to allow deploying the device within the prostatic urethra via the bladder.
26. The system of claim 23, wherein the two longitudinal ridges are provided with one or more proximally disposed protrusion that are configured to releasably connect the device to an alignment mechanism housed within the deployment lumen.
27. The system of claim 26, wherein the alignment mechanism comprises a releasable string that loops through the protrusions and runs through an alignment lumen.
28. The system of claim 26, wherein the device is configured for alignment within the prostatic urethra via a torque that is transferred from the alignment mechanism.
29. The system of any one of claims 1 to 13, further comprising an alignment mechanism configured for aligning the dilating device within the prostatic urethra via a torque that is transferred from the alignment mechanism to the dilating device.
30. The system of claim 29, wherein the two longitudinal ridges are provided with one or more proximally disposed protrusion that are configured to releasably connect the dilating device to said alignment mechanism housed within a deployment lumen.
31. The system of claim 29, wherein the alignment mechanism comprises a releasable string that loops through the dilating device and runs through an alignment lumen.
32. The system of claim 29, further comprising a deployment lumen and wherein the deployment lumen is configured to be housed within a work channel of a cystoscope.
33. The system of claim 32, wherein the deployment lumen is further provided with a balloon that is configured to position the device within the prostatic urethra.

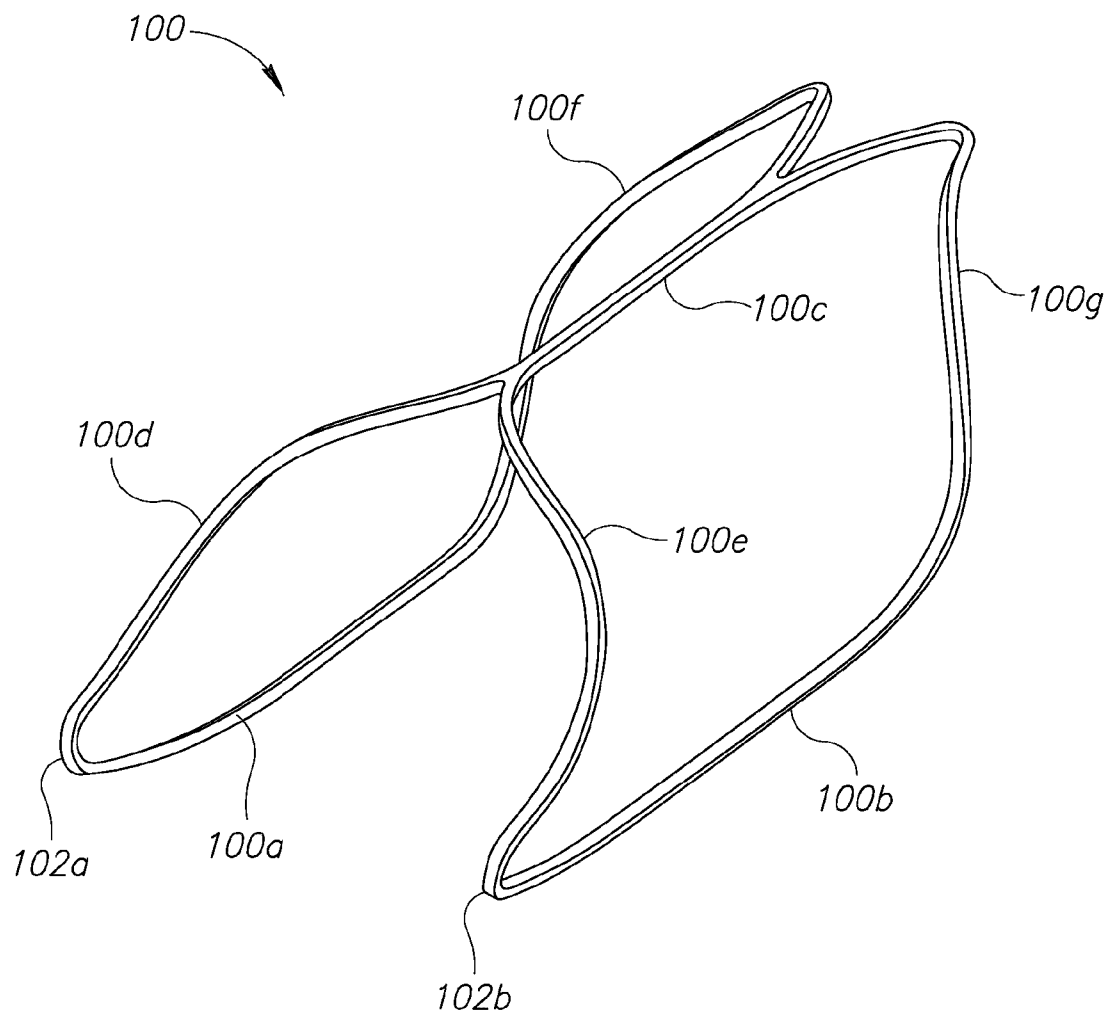
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FIG.1A

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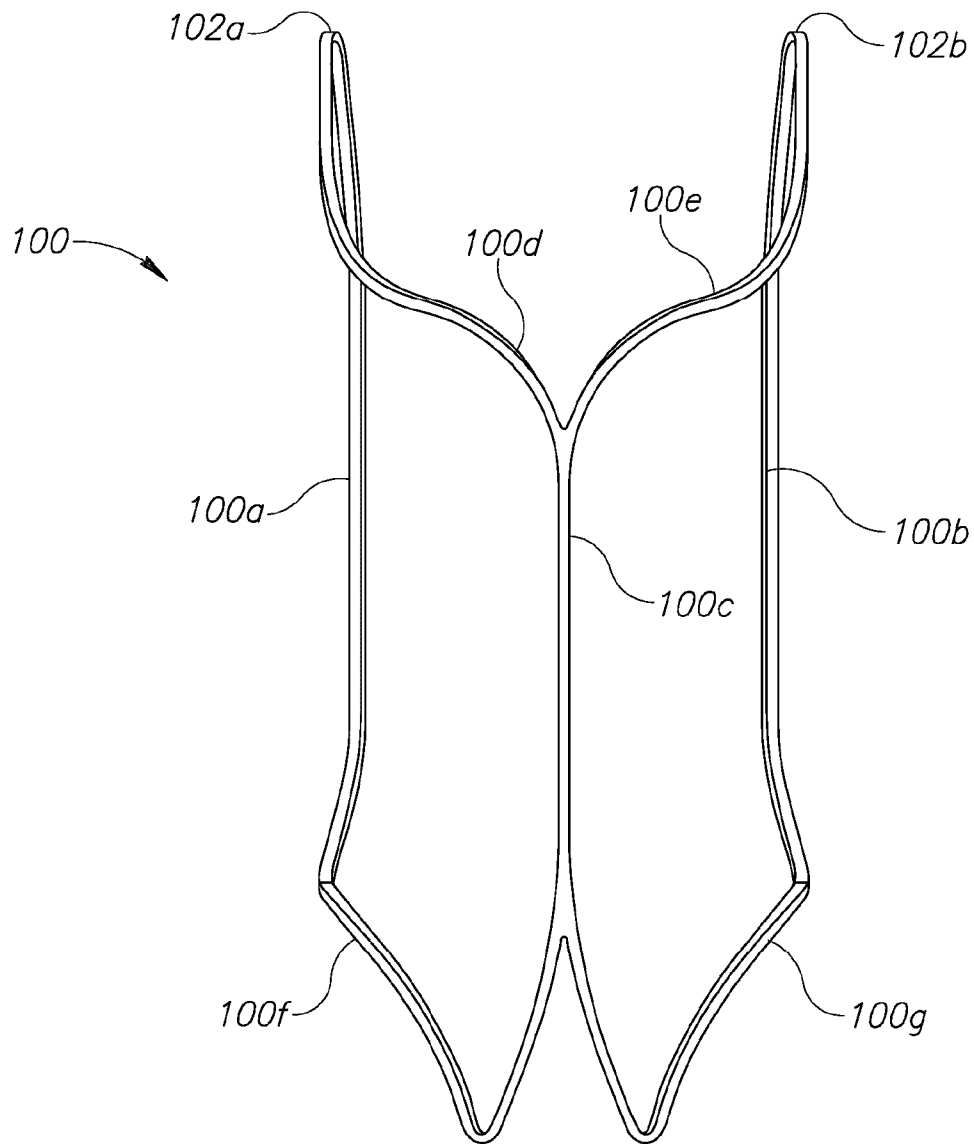


FIG.1B

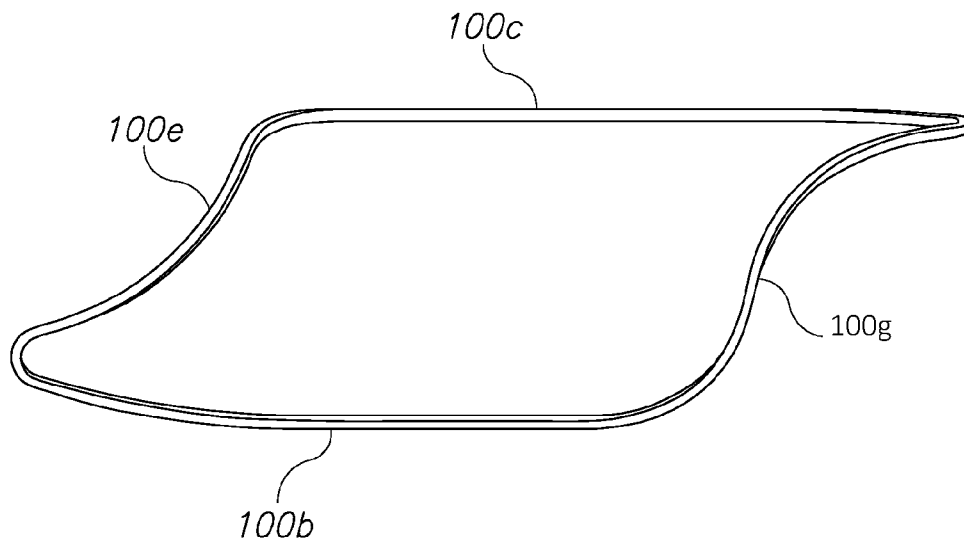


FIG. 1C

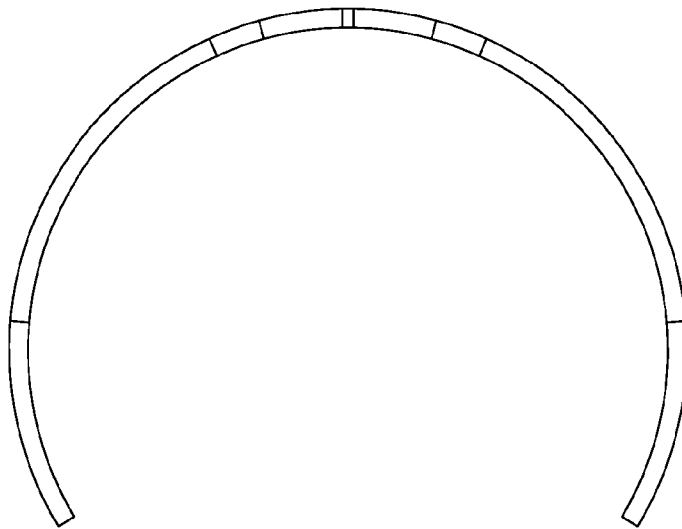


FIG. 1D

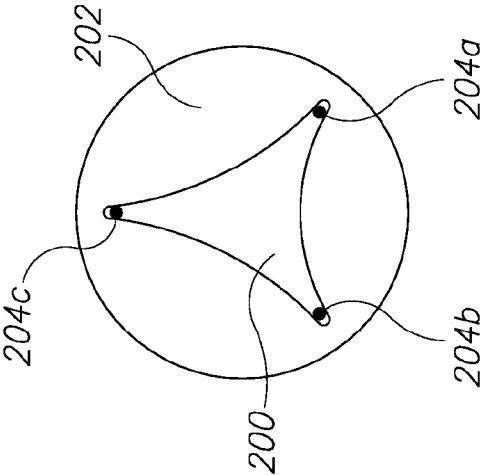


FIG. 2B

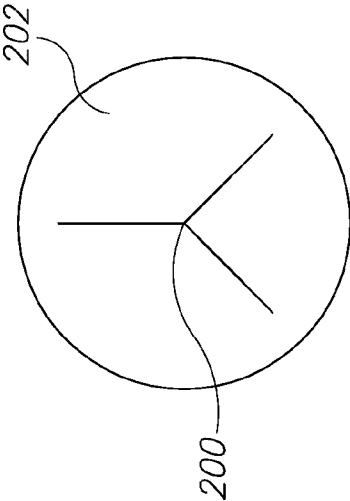


FIG. 2A

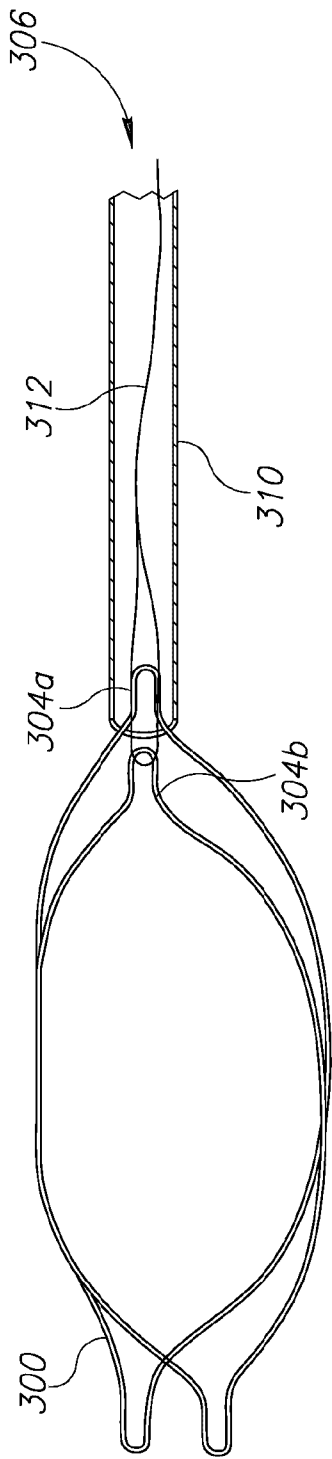


FIG. 3A

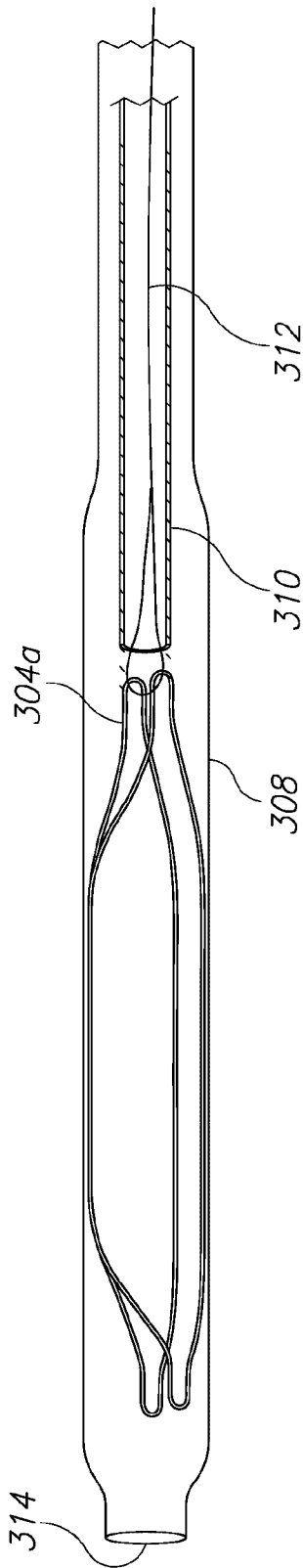
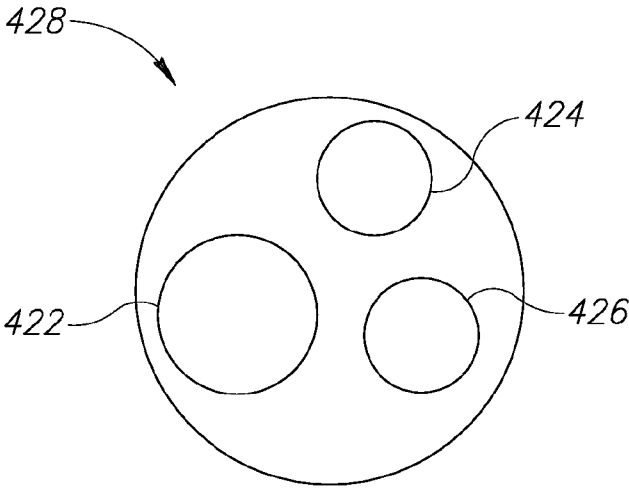
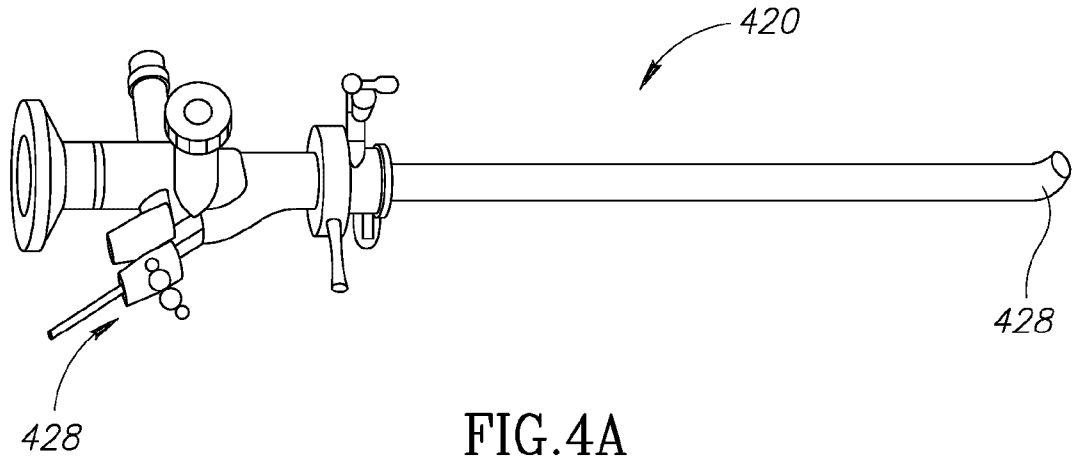


FIG. 3B

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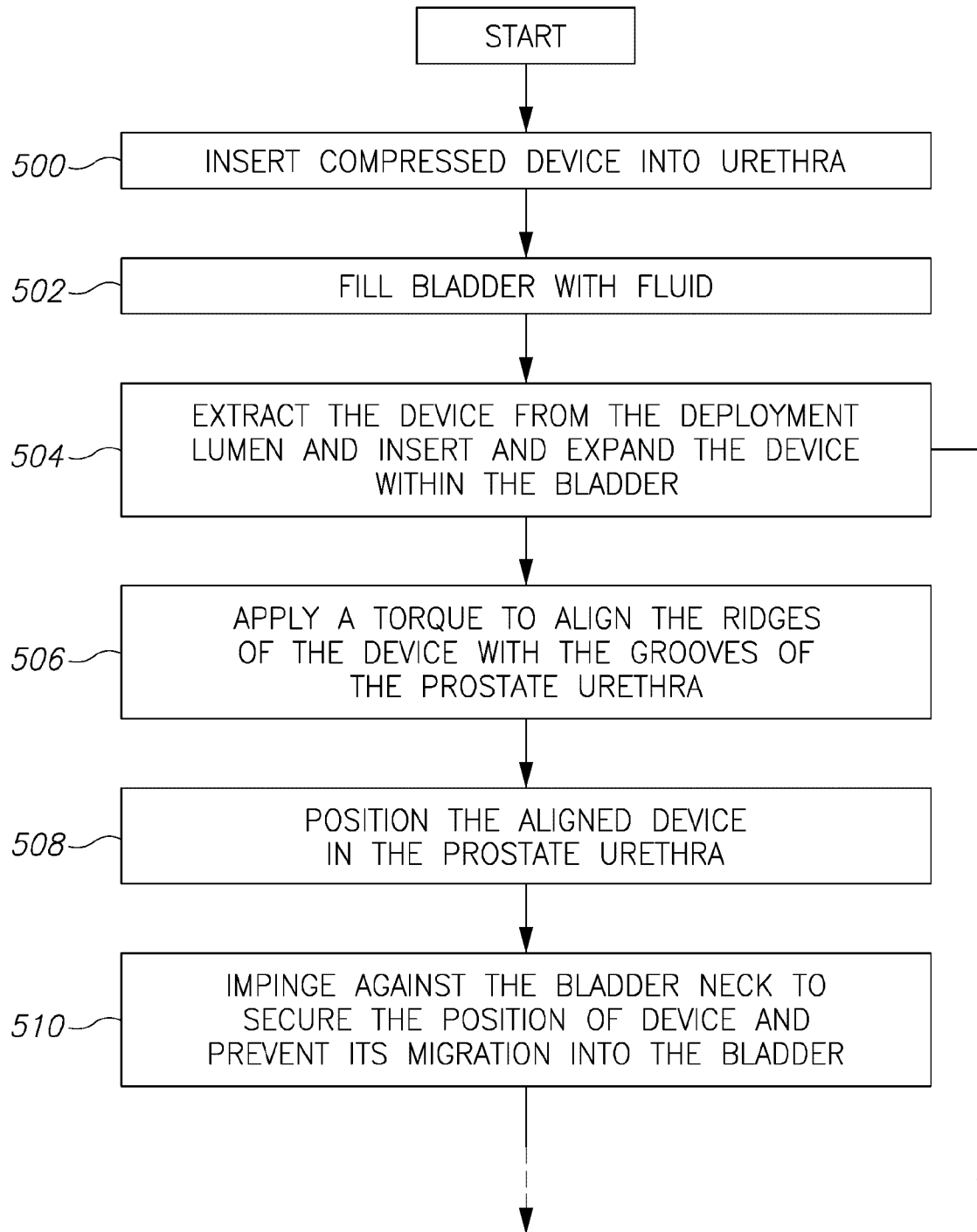


FIG.5

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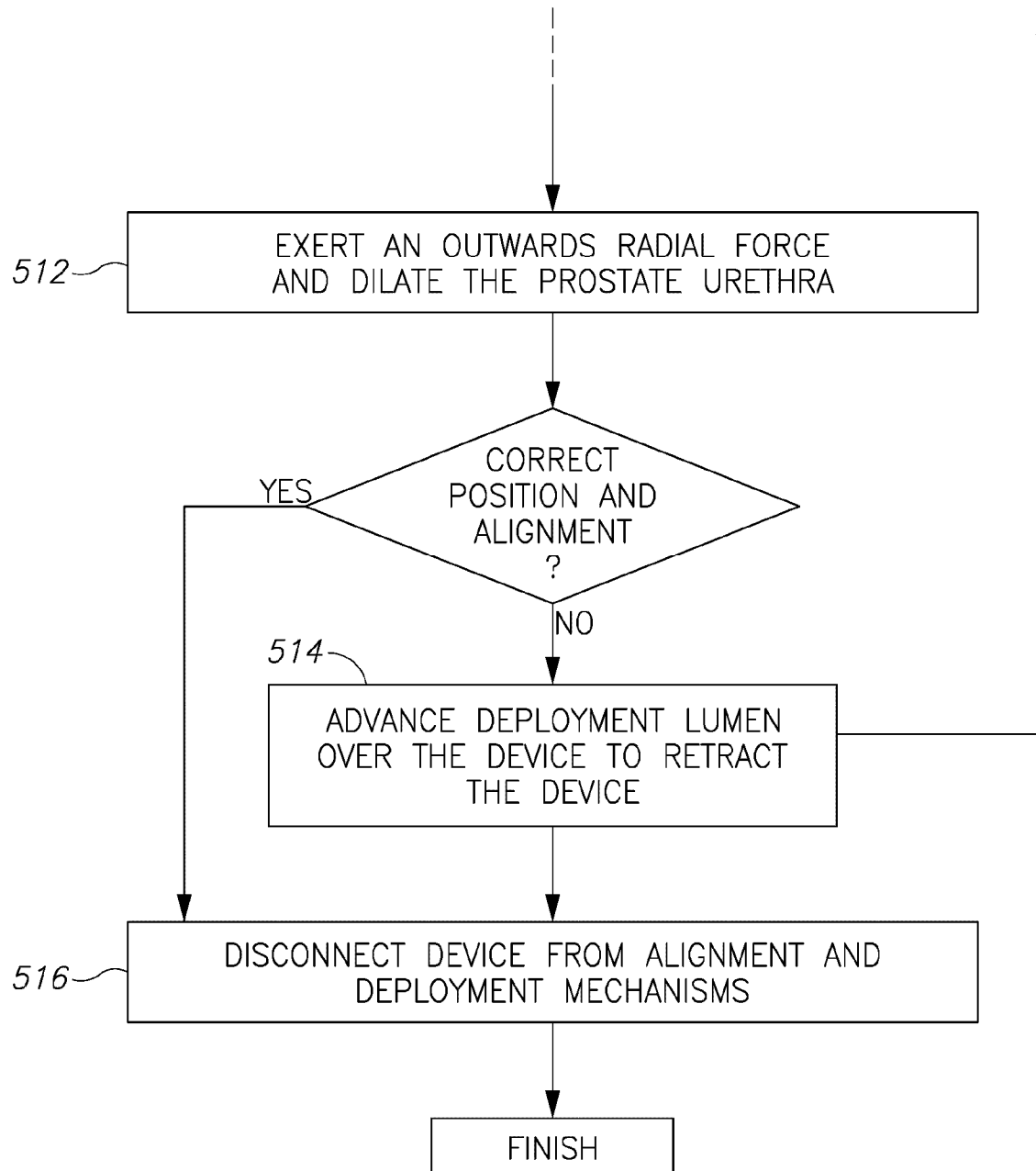


FIG.5 (cont. 1)

