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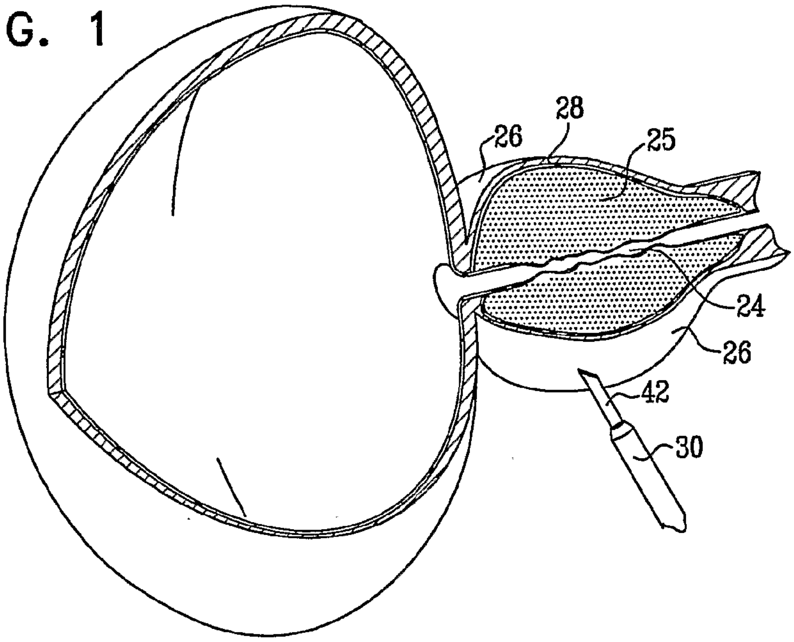
(54) Title: PROSTATIC CAPSULOTOMY FOR TREATMENT OF CONDITIONS

FIG. 1



(57) Abstract: Apparatus is described including an elongate element (922) for inserting into a subject's body, there being a joint (911) at a distal end of the elongate element. An arm (912) has a proximal end and a distal end (913). The distal end of the arm is articulatable at the joint with the elongate element. In a closed position of the arm with respect to the elongate element, a portion of the arm faces a portion of the elongate element. A cutting element (921) is coupled to at least one of the portions. Other embodiments are also described.

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PROSTATIC CAPSULOTOMY FOR TREATMENT OF CONDITIONS

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application claims the benefit of (a) US Provisional Patent Application 61/005,637 to Goldwasser, filed December 5, 2007, (b) US Provisional Patent Application 61/050,628 to Goldwasser, filed May 6, 2008, and (c) US Provisional Patent Application 61/080,258 to Goldwasser, filed July 13, 2008, all of which applications are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention generally relates to medical apparatus and methods for treating the prostate. Specifically, the present invention relates to medical apparatus and methods for the treatment of benign prostatic hyperplasia.

BACKGROUND OF THE INVENTION

Benign prostatic hyperplasia is a condition in which the prostate enlarges to the point where it constricts the urethra and impedes the flow of urine, making urination difficult and painful, and in extreme cases completely impossible.

US Patent 6,491,672 to Slepian et al. describes a process that has been developed to reduce or relieve prostatic obstruction. The steps involved in the TUVOR Process include: 1. Transurethral Incision; 2. De-bulking and Intra-Prostatic Volume Reduction; 3. Intra-prostatic void exclusion and space filling with adhesive and/or therapeutic polymeric materials, alone or in combination with bioactive agents and/or mechanical means for closure; 4. Endourethral compression and prostatic mass remolding; 5. Endourethral Polymer Liner Layer. This liner formed from structurally supportive, yet eventually biodegradable, polymers is described as further bolstering and supporting the urethra and periurethral tissue during healing, eliminating the need for postprocedure catheter drainage. This step may be optional in specific clinical circumstances. The process is described as being designed to allow outpatient treatment under local anesthesia for BPH.

Valleylab (Colorado, USA) manufactures the following products:

LigaSure™ V, which is described as being capable of performing sealing and cutting in laparoscopic procedures;

LigaSure Atlas™, which is described as being for use in laparoscopic surgery;

The LigaSure Atlas™ is described as being capable of grasping and holding sealed tissue for easy transection; and

LigaSure™ Lap, which is described as a laparoscopic 5 mm instrument for sealing and fine dissection of structures in small surgical spaces.

InterVentional Technologies Inc. (CA, USA) manufactures The Cutting Balloon®.

Covidien (USA) manufactures the SPACEMAKER™ PLUS Dissector System, which is described as a dissection balloon that is available in 2 shapes (round or oval).

Johnson and Johnson (NJ, USA) manufactures the Harmonic Scalpel®, which is described as an ultrasonic cutting and coagulating surgical device.

SUMMARY OF THE INVENTION

In some embodiments of the present invention, a subject is identified as suffering from benign prostatic hyperplasia (BPH), and typically (but not necessarily) has not been diagnosed with prostate cancer. For some applications, the subject is identified as having a prostatic urethra obstruction that is not based on BPH, and the obstruction is treated (i.e., reduced, or removed), using the methods and apparatus described herein. An instrument incises the prostatic capsule surrounding the prostate, to relieve pressure in the prostate. Following the incising, the prostate is more free to expand, for example, in response to the presence and/or growth of the BPH, reducing the pressure that the BPH exerts on the urethra. Typically, the pressure is relieved without removing the BPH itself, or in some embodiments, without even touching the BPH. (For some applications, a portion of the prostate may be cut or removed, as described herein.)

Typically, a physician makes one or more incisions in the prostatic capsule, e.g., between two and eight incisions. In some embodiments, the incisions in the prostatic capsule are in the superior-inferior direction or in the medial-lateral direction. Alternatively, the physician incises and/or excises the prostatic capsule, in whole or in part, using, for example, laser-induced vaporization of the capsule, radiofrequency (RF) energy, or a cold knife.

Typically, an imaging device (e.g., an endoscopic imaging device, an ultrasound device, a CT imaging device, an MRI imaging device, a cystourethroscope, or a laparoscope) is used by the physician to facilitate the passage of the instrument to the prostatic capsule.

In an embodiment of the present invention, the instrument gains access to the capsule via passage through the abdominal wall. In another embodiment, the instrument accesses the capsule via passage through the urethra. In yet another embodiment, the instrument gains access to the prostatic capsule via passage through the perineum.

In some embodiments, access of the instrument to the prostatic capsule is aided by the inflation of a balloon at the distal end of a longitudinal surgical introduction tool, such as a trocar, a delivery catheter, or an endoscope, that places the instrument near the capsule. In one embodiment of the present invention, inflation of the balloon pushes the prostate in the posterior direction and/or pushes the urinary bladder in the superior direction. On deflation of the balloon, the space where the balloon had been inflated is insufflated with air or carbon dioxide, to provide additional room for the instrument to gain access to the prostatic capsule. As appropriate, the balloon may surround the distal end of the introduction tool, or be passed through a channel of the introduction tool, for example, through a channel of an endoscope.

For some applications, the instrument incises the prostatic capsule from within the capsule, gaining access to the capsule transurethrally, transperineally, or transabdominally.

In some embodiments, a balloon device is used for treating BPH, the balloon device including at least one incision or excision element designed to incise or excise the prostate capsule, with or without incision/excision of the prostate tissue.

In some embodiments, the balloon is filled with a compressible and/or a non- compressible fluid, such as air, carbon dioxide, or water, to create a space near the prostate, thus facilitating the procedure. The space may be, for example, between the anterior surface of the prostate and the posterior surface of the pubic bone.

In some embodiments, following balloon expansion, the balloon is attached to the prostate, and the prostate capsule is incised and/or excised at one or more locations.

In some embodiments, the incision/excision elements ("cutting elements") are capable of incising or excising soft tissue, such as the prostate capsule and the underlying prostatic tissue. The cutting method may include use of, for example, a knife, a sharp edge, diathermia, a harmonic scalpel (e.g., a Harmonic Scalpel® manufactured by Johnson and Johnson), a monopolar or bipolar device (e.g., a LigaSure™ device manufactured by Valleylab), or a laser, such as a green laser.

In an embodiment, two cutting elements are incorporated into the balloon. Optionally, the balloon comprises more cutting elements, for example, three, four, or a greater number of such elements. In an embodiment of the invention, longitudinal cutting elements are used. For some applications, the cutting elements are parallel to each other. In some embodiments, two or more parallel cutting elements are spaced from each other by a distance of between 10 mm and 100 mm, for example, between 20 mm and 70 mm, or between 45 and 55 mm. Alternatively the parallel cutting elements are spaced from each other by a different distance. For some applications, two cutting elements are oriented such that the cutting elements incise and/or excise the prostate and/or prostate capsule at the 2 o'clock and 10 o'clock positions (the pubis defining the 12 o'clock position, as is known in the art). Alternatively or additionally, the cutting elements are oriented or spaced differently with respect to each other, and/or, in general, in order to facilitate the creation of a different cutting pattern along the prostate capsule.

In some embodiments, the cutting element(s) are mounted on a wire or similar construction, and are movable, to allow their movement along a predefined path.

In an embodiment of the invention, the balloon has a rectangular shape. Alternatively, the balloon may be shaped differently, for example, the balloon may be spherical, oval, trapezoid, square, or a different shape.

In an embodiment, the balloon has a width and/or length of between 20 mm and 70 mm, for example, between 30 mm and 60 mm, or between 40 mm and 50 mm. Alternatively the balloon has different dimensions.

In an embodiment, the balloon is guided by an imaging device, for example, an endoscopic imaging device, an ultrasound imaging device (e.g., a transrectal or a transabdominal ultrasound probe), a CT imaging device, and/or an MRI imaging device. In an embodiment, the imaging device and balloon are introduced into the subject body via a single access port. Alternatively, different access ports are used for the introduction of the balloon and the imaging device.

In some embodiments, a single port access imaging device is used, for example, for treating BPH. In an embodiment, the single port access imaging device allows the surgeon to complete an entire procedure through a single access point, located, for example, near the umbilicus or at a small distance from it, for example, 10 mm to 30 mm from the umbilicus, or at a location between the upper border of the pubic symphysis and the umbilicus.

In an embodiment, a single port access imaging device, for instance an endoscope, comprises:

a lighting source, such as a white LED;

a camera; and

a working channel, through which a soft tissue cutting device, such as a diathermia device, a harmonic scalpel (e.g., the Harmonic Scalpel® manufactured by Johnson and Johnson), a monopolar or bipolar device (e.g., a LigaSure™ device manufactured by Valleylab), a laser (e.g., green laser) device, and or a scalpel is introduced and used.

For some applications, the endoscope contains additional lumens, for example, a lumen that is used for the introduction of air and/or another fluid, the air or other fluid being utilized for camera lens cleaning, and/or for inflating a space such as one created between the prostate and pubic symphysis.

In an embodiment, the endoscope body is made of metal. Alternatively, the endoscope body may be made of polymeric rigid construct. For some applications, the endoscope includes a multi-lumen endoscope, as is known in the art.

In some embodiments, the imaging device is a single use instrument. Alternatively, the imaging device is reusable.

In some embodiments, an access needle that also serves as a working channel is used, for example, for the treatment of BPH.

In an embodiment of the invention, the needle is used with a stylet, to facilitate insertion of the needle through soft tissue. In an embodiment of the invention, a blunt-edged stylet is used.

In an embodiment of the invention, the needle and/or stylet are manufactured from a relatively flexible material, for example, a metal such as Nickel-Titanium ("nitinol"), or a polymer. Alternatively, the needle is shaped to be curved. For some applications, the flexibility and/or the shape of the needle facilitates insertion of the needle in a curved or straight path, or a path that includes a curved portion and a straight portion. For example, the needle, and/or another instrument, may be inserted along a path that closely follows the pubic symphysis towards the prostate (this being an embodiment of a retropubic approach).

In an embodiment of the invention, the needle outer diameter is less than 1mm, 2mm, 3mm, 4mm, 5mm, 6mm, 7mm, 8mm, 9mm, or 10mm. Alternatively, the needle has different dimensions.

In an embodiment of the present invention, following positioning of the needle, the stylet is removed and a cutting instrument is introduced via the needle, to allow incision(s) or excision(s) of the prostate capsule. The cutting instrument may comprise, for example, a stylet with a cutting element at its distal tip, and may be made of a flexible material, for example, a metal, such as nitinol, and/or a polymeric material. In some embodiments, prior to the introduction of the cutting instrument, a balloon device is inserted via the needle and inflated, to create a space in a vicinity of the prostate.

In an embodiment, the cutting instrument is curved or bent. For example, the cutting instrument may be curved and/or bent in one or more locations. In an embodiment, the cutting instrument has a curved arc having a length of between about 20mm and 100mm. In some embodiments, the shape of the cutting instrument facilitates insertion of the cutting instrument, such that the cutting instrument follows the outer surface of the prostate during the insertion. In some embodiments, the cutting instrument has a bent cutting element at its distal end, located, for example, 2 mm to 10 mm from the device distal tip, that provides for the cutting function. The bent portion may be bent with respect to the longitudinal axis of a portion of the device immediately proximal to the bent portion by an angle of between 10 degrees and 20 degrees, for example, about 15 degrees.

In an embodiment of the invention, the cutting element may include a knife, a scalpel, a diathermia device, a harmonic scalpel (e.g., the Harmonic Scalpel® manufactured by Johnson and Johnson), a monopolar or bipolar device (e.g., a LigaSure™ device manufactured by Valleylab), a laser (e.g., a green laser), and/or different device for cutting soft tissue that is known in the art.

In accordance with respective embodiments of the invention, the distal tip of the cutting instrument has a sharp tip or a wide tip, the tip having a width of 2 mm to 15 mm, for example. In some embodiments, the cutting tip is made of a nitinol core, covered with a polymer layer having a thickness of 0.02 mm to 2 mm.

In an embodiment of the present invention, a limiting structure/device is incorporated onto the cutting instrument to limit the penetration of the cutting element to a pre-defined depth. For some applications, the limiting device is a small balloon device or a pulley device.

In an embodiment of the present invention, an imaging device, such as an endoscope, ultrasound, CT or MRI imaging device, is used in combination with the access needle, to guide the needle positioning and incision and/or excision of the prostate capsule. In an embodiment of the invention, a transrectal or transabdominal ultrasound imaging device is used.

In an embodiment of the invention, a balloon is used and filled with a compressible fluid, a non-compressible fluid, and/or with an ultrasound opaque substance to create a working space near the prostate. In some embodiments, the balloon is introduced via the access needle. The balloon may have, for example, a round shape or a rectangular shape.

In an embodiment of the invention, more than one access needle is introduced, for example, two access needles are introduced, optionally, parallel to each other, and the cutting procedure is performed via the two ports.

In an embodiment of the invention, an access stylet and/or the cutting instrument have non-round cross sections, for example square, triangular, or rectangular-shaped cross sections, in order to facilitate accurate orientation of these devices relative to the prostate outer surface.

In some embodiments, following incision and/or excision ("cuts") of the prostate capsule for the treatment of BPH, a method and apparatus are used to prevent the cuts from re-closing.

In an embodiment of the invention, a device is implanted around at least a portion of the circumference of the prostate capsule, to cover the cuts, following incision(s)/excision(s) of the prostate capsule and/or prostate tissue. In an alternative embodiment of the present invention, the device is implanted without previous incision of the prostate capsule or prostate tissue.

In an embodiment of the invention, the device(s) may be implanted so that it is anchored in deeper prostate tissue. For some applications, the device has an omega shape.

In an embodiment of the present invention, the device is flexible (e.g., made of nitinol), and is configured such that following its implantation it works as a spring to preserve the cuts and prevent their closure.

In an embodiment of the present invention, the spring-like device exerts continuous radial force against the prostate tissue to reduce the constrictive force on the prostate urethra and/or bladder neck.

In an embodiment of the present invention, one or more spring-like devices are placed along each cut of the prostate capsule to prevent the cuts from re-closing. For example, three flexible devices may be implanted along each cut.

In an embodiment of the invention, the device(s) is implanted via the access needle described hereinabove. For some applications, the implantation is guided by an imaging device.

In an embodiment of the invention, subsequent to accessing the prostate, for example, transperineally or transabdominally (e.g., a retropubic approach), at least a portion of the prostate tissue is excised in order to relieve pressure in the prostate, without damaging the urethra. For some applications, the prostate capsule is also incised or excised. Alternatively, the prostate capsule remains intact (except for a small access port to the prostate), and only prostate tissue is removed.

In an embodiment, an imaging device is used to enable visualization of the procedure. In an embodiment, the imaging device includes at least one imaging device selected from the group consisting of: an endoscopic imaging device, an ultrasound device, such as a transrectal ultrasound device, a CT imaging device, an MRI imaging device, a cystourethroscope, and a laparoscope.

In an embodiment of the invention, the removal of prostate tissue is performed with at least one instrument selected from the group consisting of: a cold knife, a cauterizing tool, a laser, a morcellation device, and an ablation device. Examples of such devices include: a diathermia device, a harmonic scalpel (e.g., as manufactured by Johnson and Johnson), a monopolar or bipolar device (e.g., a LigaSure™ device manufactured by Valleylab), a green laser device, a red laser device, a laser device the laser having a wavelength in the range of 500 nm to 2100 nm, and/or a plasma device.

In an embodiment of the invention, incision and/or excision of the prostatic capsule is performed extraurethrally, from within the prostate. In an embodiment of the invention, access into the prostate is gained, for example, perineally. For some applications, an instrument used to cut the prostate capsule is positioned at the anterior portion of the prostate, to cut the capsule from inside the prostate. Alternatively, a perineal approach is used to cut the prostate capsule, for example, at its anterior portion, from outside of the capsule.

In an embodiment, an imaging device is used to enable visualization of the procedure. In an embodiment, the imaging device includes at least one imaging device selected from the group consisting of: an endoscopic imaging device, an ultrasound device, such as transrectal ultrasound, a CT imaging device, an MRI imaging device, a cystourethroscope, and a laparoscope.

In an embodiment of the invention, incision and/or excision of the prostatic capsule may be performed with at least one instrument selected from the group consisting of: a cold knife, a cauterizing tool, a laser, a morcellation device, and an ablation device. Examples of such devices include a diathermia device, a harmonic scalpel (e.g., the Harmonic Scalpel® manufactured by Johnson and Johnson), a monopolar or bipolar device (e.g., a LigaSure™ device manufactured by Valleylab), a green laser device, a red laser device, a laser device the laser having a wavelength in the range of 500 nm to 2100 nm, and/or a plasma device. In an embodiment of the invention, a device capable of tissue cutting and coagulating is used.

In an embodiment of the invention, a cutting device, including a pair of clips and a cutting element (such as scissors or blade) in between the clips, is used for prostate capsule incision. Using the clips, the tissue of the prostate capsule is grasped in two locations, and capsule incision is performed between these clips, by the cutting element.

In an embodiment of the invention, one or more of the procedures described herein is used to treat prostate cancer, for example, when a focal malignant growth is diagnosed. In such cases, the cancerous tissue is removed extraurethrally (i.e., without urethral access), using one of the methods described herein.

In an embodiment, the procedures described herein are computer-aided and/or robot-aided. For example, introduction and/or operation of the instrumentation may be computer-aided and/or robot-aided.

There is therefore provided, in accordance with an embodiment of the present invention, apparatus, including:

an elongate element for inserting into a subject's body;

a joint at a distal end of the elongate element;

an arm having a proximal end and a distal end, the distal end of the arm articulatable at the joint with the elongate element, wherein in a closed position of the arm with respect to the elongate element, a portion of the arm faces a portion of the elongate element; and

a cutting element coupled to at least one of the portions.

In an embodiment, the cutting element is slidably coupled to the elongate element.

In an embodiment, the cutting element includes a cutting element selected from the group consisting of: a knife, a sharp edge, a diathermia device, a harmonic scalpel, an RF device, a plasma device, and a laser.

In an embodiment, the cutting element includes one or more blades disposed on the arm.

In an embodiment, the joint includes a plastic hinge.

In an embodiment, the cutting element is configured to sequentially cut tissue of the subject at successively more proximal cutting sites, by the distal end of the elongate element being moved to the successively more proximal cutting sites.

In an embodiment, the apparatus further includes two balloons disposed on opposing sides of the elongate element at the distal end of the elongate element, the balloons being configured to create a space distal to the balloons and distal to the elongate element, by being inflated.

In an embodiment, the apparatus further includes at least one coagulation electrode configured to coagulate tissue of the subject.

In an embodiment, the coagulation electrode includes two or more bipolar coagulation electrodes.

In an embodiment, the coagulation electrode includes a monopolar coagulation electrode.

In an embodiment, the cutting element includes a coagulation electrode configured to coagulate tissue of the subject.

In an embodiment, the cutting element further includes a mechanical cutting element.

In an embodiment, the coagulation electrode includes two or more bipolar coagulation electrodes.

In an embodiment, the coagulation electrode includes one monopolar coagulation electrode.

In an embodiment, the electrode is coated with a coating produced by an alodine process and a hard anodization process.

In an embodiment, the coating has a thickness of less than 100 microns.

In an embodiment, the arm includes a penetration element configured to penetrate tissue of the subject.

In an embodiment, the penetration element is disposed at the proximal end of the arm.

In an embodiment, the penetration element includes a sharp edge.

In an embodiment, the arm is configured to grasp tissue of the subject by being at least partially closed with respect to the elongate element.

In an embodiment, the cutting element is configured to cut the grasped tissue, and the apparatus further includes a coagulation electrode configured to coagulate the grasped tissue.

In an embodiment, the cutting element is configured to cut the grasped tissue.

In an embodiment, the cutting element is configured to cut and coagulate the grasped tissue.

In an embodiment, the distal end of the elongate element is configured to be inserted to a vicinity of an anterior side of a prostate of the subject, and the cutting element is configured to cut a prostate capsule of the prostate.

In an embodiment, the distal end of the elongate element is configured to be inserted to inside the subject's prostate, and the cutting element is configured to cut the prostate capsule from inside the prostate.

In an embodiment, the distal end of the elongate element is configured to be inserted to outside the subject's prostate, and the cutting element is configured to cut the prostate capsule from outside the prostate.

In an embodiment, the elongate element is configured to be transperineally inserted to the vicinity of the anterior side of the subject's prostate.

In an embodiment, the elongate element is configured to be transabdominally inserted to the vicinity of the anterior side of the subject's prostate.

In an embodiment, the elongate element is shaped to define a curved distal region and a straight proximal region of the elongate element, the curved shape of the distal region of the elongate element facilitating retropubic insertion of the distal end of the elongate element.

There is further provided, in accordance with an embodiment of the present invention, apparatus, including:

an elongate element for inserting into a subject's body, the elongate element having a proximal-facing portion at a distal end of the elongate element,

the proximal-facing portion including a cutting element, the cutting element configured to sequentially cut tissue of the subject at successively more proximal cutting sites, by the distal end of the elongate element being moved to the successively more proximal cutting sites.

In an embodiment, the cutting element includes a cutting element selected from the group consisting of: a knife, a sharp edge, a diathermia device, a harmonic scalpel, an RF device, a plasma device, and a laser.

In an embodiment, the apparatus further includes two balloons disposed on opposing sides of the elongate element at the distal end of the elongate element, the balloons being configured to create a space distal to the balloons and distal to the elongate element, by being inflated.

In an embodiment, the cutting element is a sharp tip of the proximal-facing portion.

In an embodiment, the proximal-facing portion is a continuation of the elongate element.

In an embodiment, the proximal-facing portion and the elongate element are formed as one integral body, in which the proximal-facing portion includes a curved aspect that makes the proximal-facing portion face in a proximal direction.

In an embodiment, the cutting element includes an electrode and a mechanical cutting element, the cutting element being configured to cut the tissue by applying pressure to the tissue, and to coagulate the tissue by driving a current into the tissue.

In an embodiment, at least a portion of the proximal-facing portion includes a shape memory material.

In an embodiment, the apparatus further includes an elongate-element introduction-device that defines a lumen, the elongate element is inserted via the lumen, and the proximal-facing portion is configured to open with respect to the elongate element, due to the shape memory material, when the proximal-facing portion passes out of a distal end of the lumen.

There is additionally provided, in accordance with an embodiment of the present invention, apparatus for treating an obstruction of a prostatic urethra of a subject, including:

a balloon that during inflation of the balloon is configured to expand in a first direction by more than 200% of an expansion of the balloon in each of second and third directions, the first, second and third directions being mutually perpendicular to each other;

one or more cutting elements coupled to a surface of the balloon, at least a portion of the surface being disposed in a plane that is defined by the second and third directions;

an elongate element configured to place the balloon in a vicinity of an anterior side of a prostate of the subject; and a balloon control unit configured to create a space in the vicinity by inflating the balloon.

In an embodiment, during inflation of the balloon, the balloon is configured to expand in the first direction by more than 400% of the expansion of the balloon in each of the second and third directions.

In an embodiment, the one or more cutting elements protrude from the surface.

In an embodiment, the cutting elements include a cutting element selected from the group consisting of: a knife, a sharp edge, a diathermia device, a harmonic scalpel, an RF device, a plasma device, and a laser.

In an embodiment, the length of the balloon in the second and third directions is less than 60 mm, when the balloon is maximally inflated.

In an embodiment, the cutting elements include one or more cutting elements that are substantially mobile with respect to the surface of the balloon in the plane that is defined by the second and third directions.

In an embodiment, the cutting elements include one or more cutting elements that are substantially immobile with respect to the surface of the balloon in the plane that is defined by the second and third directions.

In an embodiment, the balloon is configured to be in a folded disposition during insertion of the balloon into the vicinity, and each of the cutting elements are disposed on a respective fold of the folded balloon.

In an embodiment, an outer surface of the balloon is shaped to match a shape of the anterior side of the prostate.

In an embodiment, the outer surface of the balloon is shaped concavely when maximally inflated.

There is further provided, in accordance with an embodiment of the present invention, a method, including:

inserting a tool into a subject's body via a perineum of the subject; and while the tool is inside the subject's body, performing minimally invasive surgery on the subject using the tool.

There is further provided, in accordance with an embodiment of the present invention, a method for treating an obstruction of a prostatic urethra of a subject, including:

identifying that the subject has a constricted urethra due to the prostatic urethra obstruction; and

relieving pressure on the urethra caused by the prostatic urethra obstruction, by performing an action on at least a portion of a capsule of a prostate of the subject, the action being selected from the group consisting of: incising, and excising.

In an embodiment, performing the selected action includes grasping the portion and cutting the grasped portion.

In an embodiment, relieving pressure on the urethra includes performing at least one surgical access selected from the group consisting of:

transabdominally accessing the capsule,

transperineally accessing the capsule,

transurethrally accessing the capsule, and

non-transurethrally accessing the capsule.

In an embodiment, relieving pressure on the urethra includes performing at least one surgical access selected from the group consisting of:

transabdominally accessing the capsule, and

transperineally accessing the capsule,

In an embodiment, relieving pressure on the urethra includes performing the selected action on at least the portion of the capsule from a site within the prostate.

In an embodiment, performing the selected action on at least the portion of the capsule includes performing the selected action on at least the portion of the capsule with at least one instrument selected from the group consisting of: a cold knife, a cauterizing tool, and a laser.

In an embodiment, performing the selected action on at least the portion of the capsule includes performing the selected action on at least the portion of the capsule with at least one instrument selected from the group consisting of: a sharp edge, a diathermia device, a harmonic scalpel, and an RF device.

In an embodiment, performing the selected action on at least the portion of the capsule includes forming at least one incision in a superior-inferior direction in the prostatic capsule.

In an embodiment, performing the selected action on at least the portion of the capsule includes forming at least one incision in a medial-lateral direction in the prostatic capsule.

In an embodiment, performing the selected action on at least the portion of the capsule includes excising the prostatic capsule.

In an embodiment, performing the selected action on at least the portion of the capsule includes incising the prostatic capsule.

In an embodiment, the method further includes inserting a cutting element into the subject's body, and performing the selected action on the portion of the capsule includes sequentially cutting the capsule at successively more proximal cutting sites by moving the cutting element to the successively more proximal cutting sites.

In an embodiment, the method further includes:

inserting a balloon into a body of the subject, to a vicinity of an anterior side of the subject's prostate;

creating space in the vicinity by inflating the balloon such that the balloon expands in a first direction by more than 200% of an expansion of the balloon in each of second and third directions, the first, second and third directions being mutually perpendicular to each other; and

performing the selected action on the portion of the capsule includes cutting the capsule with one or more cutting elements that are coupled to a surface of the balloon, the surface being disposed at least partially in a plane that is defined by the second and third directions.

In an embodiment, performing the selected action on the portion of the capsule includes moving the cutting elements with respect to the surface of the balloon in the plane that is defined by the second and third directions.

In an embodiment, performing the selected action on the portion of the capsule includes substantially not moving the surface of the balloon during performance of the selected action.

In an embodiment, performing the selected action on the portion of the capsule includes moving the balloon with respect to the capsule.

In an embodiment, performing the selected action on the portion of the capsule includes, during the performance of the selected action, substantially not moving the cutting elements with respect to the surface of the balloon in the plane that is defined by the second and third directions.

In an embodiment, performing the selected action on at least the portion of the capsule includes forming a plurality of incisions in the prostatic capsule.

In an embodiment, performing the selected action on at least the portion of the capsule includes forming 1-3 incisions in the capsule.

In an embodiment, performing the selected action on at least the portion of the capsule includes forming 4-10 incisions in the capsule.

In an embodiment, performing the selected action on at least the portion of the capsule includes forming a plurality of incisions in the prostatic capsule in different directions.

There is additionally provided, in accordance with an embodiment of the present invention, apparatus for treating an obstruction of a prostatic urethra of a subject, including:

an instrument, configured to perform an action on at least a portion of a capsule of a prostate of the subject to an extent that is sufficient to relieve pressure in the prostate due to the prostatic urethra obstruction, the action being selected from the group consisting of: incising, and excising; and

an imaging device, configured to facilitate guiding of the instrument to the prostatic capsule of the subject.

In an embodiment, the imaging device includes at least one imaging device selected from the group consisting of: an endoscopic imaging device, an ultrasound device, a CT imaging device, an MRI imaging device, a cystourethroscope, and a laparoscope.

In an embodiment, the instrument is configured to access the capsule via passage through at least one site selected from the group consisting of: an abdominal wall of the subject, a urethra of the subject, and a perineum of the subject.

In an embodiment, the instrument includes at least one instrument selected from the group consisting of: a cold knife, a cauterizing tool, and a laser.

In an embodiment, the instrument is configured to make at least one incision in a superior-inferior direction, in the prostatic capsule.

In an embodiment, the instrument is configured to make at least one incision in a medial-lateral direction, in the prostatic capsule.

In an embodiment, the instrument is configured to make a plurality of incisions in the prostatic capsule.

In an embodiment, the instrument is configured to make a plurality of incisions, at least some of which are in different directions.

In an embodiment, the instrument is configured to excise at least a portion of the prostatic capsule.

In an embodiment, the instrument is configured to incise the prostatic capsule.

There is additionally provided, in accordance with an embodiment of the present invention, apparatus for treating an obstruction of a prostatic urethra of a subject, including:

a balloon device having a balloon; and

at least one cutting element coupled to the balloon and configured to perform an action on a prostate capsule of the subject, the action being selected from the group consisting of: incising and excising.

In an embodiment, the at least one cutting element is movable with respect to the balloon.

There is further provided, in accordance with an embodiment of the present invention, a method for treating an obstruction of a prostatic urethra of a subject, including:

accessing a prostate of the subject with an access device;

introducing a balloon to a vicinity of the prostate via the access device, the balloon having cutting elements coupled thereto;

inflating the balloon to create a space near the prostate; and

performing an action on a capsule of the prostate using the cutting elements, the action being selected from the group consisting of: incising and excising.

In an embodiment, the method further includes imaging the balloon introduction, and the performing of the selected action, with an imaging device.

There is additionally provided, in accordance with an embodiment of the present invention, a single port access apparatus, including:

a lighting source; and

a camera;

the apparatus defining at least one working channel, and the apparatus being configured to treat an obstruction of a prostatic urethra of a subject.

In an embodiment, the apparatus further includes camera-lens cleaning equipment, and the apparatus defines a lumen configured such that the camera-lens cleaning equipment can be inserted through the lumen.

In an embodiment, the apparatus further includes a fluid, and the apparatus defines a lumen configured such that the fluid insufflates a space between a prostate and a pubis of the subject by being passed through the lumen.

There is further provided, in accordance with an embodiment of the present invention, a method for treating an obstruction of a prostatic urethra of a subject, including executing a procedure via only one access port, wherein executing the procedure includes:

accessing a prostate of the subject with an endoscope by inserting the endoscope via the access port, the endoscope having at least one working channel; and

performing an action on a prostate capsule of the prostate via the at least one working channel of the endoscope, the action being selected from the group consisting of: incising and excising.

In an embodiment, the method further includes creating a space in a vicinity of the prostate by inflating a balloon in the vicinity prior to performing the selected action.

There is additionally provided, in accordance with an embodiment of the present invention, apparatus for treating an obstruction of a prostatic urethra of a subject, including:

an access needle; and

a cutting instrument, configured to perform an action on a prostate capsule of the subject, via the access needle, the action being selected from the group consisting of: incising, and excising.

In an embodiment, the apparatus further includes a stylet configured to facilitate introduction of the needle into the subject.

There is further provided, in accordance with an embodiment of the present invention, a method for treating an obstruction of a prostatic urethra of a subject, including:

introducing at least one access needle from a lower abdomen of the subject toward an anterior surface of a prostate of the subject by following a retropubic approach; and

performing an action on a capsule of the prostate, via the at least one access needle, the action being selected from the group consisting of: incising, and excising.

In an embodiment, the method further includes imaging the performing of the selected action, using an imaging device selected from the group consisting of:

an ultrasound imaging device, an endoscopic imaging device; an MRI imaging device; and a CT imaging device.

In an embodiment, the method further includes inserting a balloon to a vicinity of the anterior surface via the access needle, and creating a space in the vicinity by inflating the balloon.

There is further provided, in accordance with an embodiment of the present invention, apparatus for treating an obstruction of a prostatic urethra of a subject, including a flexible device configured to be placed inside a prostate of the subject and to reduce a constrictive force on a portion of a body of the subject, by exerting a radial force on the prostate, the portion being selected from the group consisting of: a urethra and a bladder neck.

In an embodiment, the device is configured to be implanted inside the subject's body.

There is further provided, in accordance with an embodiment of the present invention, a method for treating an obstruction of a prostatic urethra of a subject, including reducing a constrictive force on a portion of a body of the subject, by exerting a radial force on a prostate of the subject, by non-transurethrally placing a flexible device inside the prostate, the portion being selected from the group consisting of: a urethra and a bladder neck.

In an embodiment, non-transurethrally placing the flexible device inside the prostate includes introducing the device from a lower abdomen of the subject toward an anterior surface of the prostate by following a retropubic approach.

There is additionally provided, in accordance with an embodiment of the present invention, a method for treating an obstruction of a prostatic urethra of a subject, including creating a lesion in a prostate capsule of a prostate of the subject, the lesion being selected from the group consisting of: an incision and an excision, and preventing the lesion from closing by exerting a radial force on the prostate, by placing a flexible device inside the prostate, subsequent to creating the lesion.

There is additionally provided, in accordance with an embodiment of the present invention, a method for treating an obstruction of a prostatic urethra of a subject, including creating a lesion in a prostate capsule of the subject, the lesion being selected from the group consisting of: an incision and an excision, and preventing the lesion from closing by placing at least one flexible device in a vicinity of the lesion.

There is additionally provided, in accordance with an embodiment of the present invention, a method, including performing an action on tissue of a subject by transperineally accessing the tissue, the action being selected from the group consisting of: incising, and excising, the tissue being selected from the group consisting of: prostate capsule tissue and prostate tissue of the subject.

In an embodiment, performing the selected action on the tissue includes treating an obstruction of a prostatic urethra of the subject.

In an embodiment, the method further includes imaging the performing of the action using transrectal ultrasound imaging.

In an embodiment, performing an action selected from the group consisting of: accessing the tissue, excising the tissue, and incising the tissue, includes performing the selected action using an aid selected from the group consisting of: a computer-aid and a robotic-aid.

There is additionally provided, in accordance with an embodiment of the present invention, a method including performing an action on tissue of a subject by extra-urethrally accessing the tissue, the action being selected from the group consisting of: incising, and excising, the tissue being selected from the group consisting of: prostate capsule tissue and prostate tissue of the subject.

In an embodiment, accessing the tissue includes accessing the tissue without damaging the urethra.

In an embodiment, accessing the tissue includes accessing the tissue without puncturing the urethra.

In an embodiment, the method further includes imaging the performing of the selected action using transrectal ultrasound imaging.

In an embodiment, performing the selected action on the tissue includes using an incision technique selected from the group consisting of: laser incision, RF incision, plasma incision, ultrasound incision and electrical incision.

There is further provided, in accordance with an embodiment of the present invention, apparatus including a shaft having a sharp distal end, the apparatus being configured to facilitate an extraurethral action on the tissue by penetrating the tissue, the action being selected from the group consisting of: incising, and excising, the tissue being selected from the group consisting of: prostate capsule tissue and prostate tissue.

In an embodiment, the apparatus further includes a movable arm at a distal portion of the shaft.

In an embodiment, the arm is configured to press tissue located between the arm and the distal portion of the shaft, by the arm being at least partially closed with respect to the distal portion of the shaft.

In an embodiment, the apparatus is configured to apply a pressing force to the tissue and to perform coagulation and cutting of the tissue subsequently to applying the pressing force to the tissue.

In an embodiment, the apparatus includes a device configured to perform the selected action on the tissue, the device being selected from the group consisting of: a laser, an RF device, a plasma device, an ultrasound device, and an electrical device.

The present invention will be more fully understood from the following detailed description of embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic illustration of a tool for incising the capsule of the prostate, in accordance with an embodiment of the present invention;

Fig. 2 is a schematic illustration of the capsule of the prostate after incision, in accordance with an embodiment of the present invention;

Fig. 3A is a schematic illustration of a Y-shaped incision into the prostatic capsule, in accordance with an embodiment of the present invention;

Fig. 3B is a schematic illustration of the prostatic capsule after the Y-shaped incision, in accordance with another embodiment of the present invention;

Figs. 4-5 are schematic illustrations of an incision device inserted into the body of the subject, in accordance with respective embodiments of the present invention;

Fig. 6A is a schematic illustration of a balloon prior to inflation thereof, inserted into the body of the subject, in accordance with an embodiment of the present invention;

Fig. 6B is a schematic illustration of the balloon of Fig. 6A, now inflated, inserted into the body of the subject, in accordance with an embodiment of the present invention;

Fig. 6C is a schematic illustration of an incision device inserted into the body of a subject, after withdrawal of the balloon, in accordance with an embodiment of the present invention;

Fig. 7A is a schematic illustration of a balloon prior to the inflation thereof, inserted into the body of a subject in accordance with another embodiment of the present invention;

Fig. 7B is a schematic illustration of the balloon of Fig. 7A, now inflated, inserted into the body of a subject, in accordance with an embodiment of the present invention;

Fig. 7C is a schematic illustration of a balloon, in accordance with an alternative embodiment of the present invention;

Figs. 8A-F are schematic illustrations of a balloon for inserting into a vicinity of the anterior side of the subject's prostate, in accordance with an embodiment of the present invention;

Figs. 9A-C are schematic illustrations of a balloon which comprises cutting elements, in accordance with an embodiment of the present invention;

Figs. 10A-C are schematic illustrations of a balloon that unfolds, in accordance with an embodiment of the present invention;

Figs. 11A-D are cross-sectional schematic illustrations of balloon cutting elements, in accordance with respective embodiments of the present invention;

Figs. 12A-D are cross-sectional schematic illustrations of dynamic cutting elements, in accordance with respective embodiments of the present invention;

Fig. 13 is a schematic illustration of a single port access endoscope, in accordance with an embodiment of the present invention;

Figs. 14A–B are schematic illustrations of an access needle which serves as a working channel, in accordance with an embodiment of the present invention;

Figs. 15A-B are schematic illustrations of a balloon, in accordance with an embodiment of the present invention;

Fig. 16 is schematic illustration of a cutting instrument, in accordance with an embodiment of the present invention;

Figs. 17A-C are schematic illustrations of the tip of the cutting element shown in Fig. 16, in accordance with respective embodiments of the present invention;

Figs. 18A-B are schematic illustrations of the introduction of an access needle, a balloon, and a cutting instrument to the anterior side of the subject's prostate, in accordance with an embodiment of the present invention;

Figs. 19-20 are schematic illustrations of a flexible device designed to prevent closure of the cuts in the prostate capsule, in accordance with respective embodiments of the present invention;

Figs. 21A-B are schematic illustrations of apparatus for cutting and/or coagulating soft tissue, in accordance with an embodiment of the present invention;

Fig. 22 is a schematic illustration of a plastic hinge used with the apparatus shown in Figs. 21A-B, in accordance with an embodiment of the present invention;

Figs. 23A-B are schematic illustrations of apparatus used for cutting and/or coagulating soft tissue, in accordance with an alternative embodiment of the present invention;

Figs. 24A-E are schematic illustrations of a procedure for performing prostate capsulotomy, in accordance with an embodiment of the present invention; and

Fig. 25 is a schematic illustration of a laser device for cutting and/or coagulating soft tissue, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Reference is now made to Fig. 1, which is a schematic illustration of an incision device 42, that has been introduced via an introduction device 30, incising or excising at least a portion of a capsule 26 of a prostate 28 of a subject, in accordance with an embodiment of the present invention. A benign prostatic hyperplasia (BPH) 25 in prostate 28, or an obstruction, causes the constriction of a urethra 24 of the subject. Incision of prostatic capsule 26 by incision device 42 relieves pressure on the constricted portion of urethra 24, because it allows the expansion of prostate 28 in an outward direction.

Introduction device 30 typically comprises an endoscopic imaging device, an ultrasound device, a CT imaging device, an MRI imaging device, a cystourethroscope, or a laparoscope, in order to facilitate the passage of incision device 42 to prostatic capsule 26. The incision device typically comprises a cold knife, a cauterizing tool, a laser, or another cutting tool that is suitable for incising the prostatic capsule, for example, as described hereinbelow. In some embodiments, a multi-lumen endoscope, or an access needle is used for introduction device 30, as described hereinbelow. In some embodiments, the incision device is not inserted via an introduction device.

Reference is now made to Fig. 2, which is a schematic illustration of prostatic capsule 26 after an incision 29 has been made, in accordance with an embodiment of the present invention. Incision device 42 typically incises prostatic capsule 26 one or more times, for example, to create one to three or four to ten incisions. Fig. 2 shows prostatic capsule 26 after a single incision has been made, thereby relieving the urethral constriction, as shown.

In some embodiments, incision device 42 incises prostatic capsule 26 in a superior-inferior direction. In other embodiments, incision device 42 incises prostatic capsule 26 in a medial-lateral direction. In yet another embodiment, incision device 42 incises prostatic capsule 26 multiple times. In some embodiments the incisions are in the same direction, and in other embodiments, the incisions are in different directions. Alternatively, incision device 42 excises at least a portion of prostatic capsule 26.

Reference is now made to Fig. 3A, which is a schematic illustration of prostatic capsule 26 with a Y-shaped incision, created to relieve pressure within prostate 28, in accordance with an embodiment of the present invention.

Reference is now made to Fig. 3B, which is a schematic illustration of prostatic capsule 26 following creation of the Y-shaped incision shown in Fig. 3A, in accordance with an embodiment of the present invention.

Reference is now made to Figs. 4-5, which are schematic illustrations of incision device 42 inserted into the body of the subject, in accordance with respective embodiments of the present invention. Fig. 4 schematically illustrates transabdominal access by incision device 42 to prostatic capsule 26. Fig. 5 schematically illustrates transperineal access of incision device 42 to prostatic capsule 26. (It is noted that introduction device 30 is introduced such that the introduction device does not traverse the subject's urethra.) In some embodiments, incision device 42 is inserted toward prostatic capsule 26 transurethrally.

Reference is now made to Fig. 6A, which is a schematic illustration of a balloon 40 prior to inflation thereof, inserted into the body of a subject, in accordance with an embodiment of the present invention. Balloon 40 is typically advanced transabdominally to prostate 26, via introduction device 30. In some embodiments, the balloon passes around pubic bone 36, i.e., a retropubic approach. Alternatively, the balloon is inserted transperineally, or via a different approach. In some embodiments, the balloon is not inserted via an introduction device.

Reference is now made to Fig. 6B, which is a schematic illustration of balloon 40 of Fig. 6A inflated, in accordance with an embodiment of the present invention. On inflation, balloon 40 pushes prostate 28, surrounded by prostatic capsule 26, in a posterior direction, and/or pushes a bladder 32 of the subject in a superior direction, creating a space to facilitate capsulotomy. Although balloon 44, when maximally inflated, is shown to have a generally spherical shape, the scope of the present invention includes having a differently-shaped balloon, such as a balloon having a shape as described herein.

Reference is now made to Fig. 6C, which is a schematic illustration of incision device 42 incising capsule 26 after deflation of balloon 40, in accordance with another embodiment of the present invention. After deflation of the balloon, the space created by inflating balloon 40 is insufflated with air or carbon dioxide, providing and maintaining additional space for incision device 42 to perform the capsulotomy. While the space is maintained (typically by ongoing application of air or CO2), incision device 42 is used to make one or more incisions into prostatic capsule 26.

Reference is now made to Fig. 7A, which is a schematic illustration of a balloon 44 prior to inflation thereof, inserted into the body of a subject, in accordance with another embodiment of the present invention. Balloon 44 surrounds the distal end of introduction device 30 (e.g., an endoscope, an access needle, or another suitable introduction device) and is advanced transabdominally to prostate 26 during advancement of introduction device 30. Alternatively, the balloon is inserted transperineally, or via a different approach.

Reference is now made to Fig. 7B, which is a schematic illustration of balloon 44 of Fig. 7A inflated, in accordance with an embodiment of the present invention. On inflation, balloon 44 pushes bladder 32 in a superior direction and/or pushes prostate 28 surrounded by capsule 26 in a posterior direction (as shown in Fig. 7B), creating a space to facilitate capsulotomy by incision tool 42. Although balloon 44 is shown having a generally spherical shape, when maximally inflated, the scope of the present invention includes having a different shaped balloon, such as balloons having shapes as described herein. Subsequently, the balloon is deflated and the prostate capsule is incised, in accordance with the techniques described with reference to Fig. 6C.

Reference is now made to Fig. 7C, which is a schematic illustration of two balloons 43 and 45 disposed on opposing sides of introduction device 30, for example, a left-balloon 43 and a right-balloon 45, in accordance with an alternative embodiment of the present invention. In some embodiments, the left and right balloons are inflated on the left and right sides of the distal end of introduction device 30. While the balloons are inflated, one or more working spaces 41 are created in the vicinity of the distal end, and the prostate and/or prostate capsule is incised and/or excised using an instrument that is inserted into the working space, using techniques described herein. For some applications the working space is created distal to the balloons and to the introduction device. Fig. 7C includes a sagittal view of balloons 43 and 45 inserted in the subject's body, therefore a greater portion of left-balloon 43 is seen, than of right balloon 45. From an anterior or posterior perspective, one would observe the left and right balloons, respectively to the left and right of the distal end of the introduction device.

Reference is now made to Figs. 8A-F, which are schematic illustrations of a balloon 50 for inserting into the vicinity of the anterior side of the subject's prostate, in accordance with an embodiment of the present invention. In some embodiments, balloon 50 is inflated so as create a space to facilitate capsulotomy by incision tool 42, using generally similar techniques to those described with reference to Figs. 6A-C. Alternatively or additionally, cutting edges that are coupled to the balloon cut the prostate capsule while the balloon is in an inflated state, for example, as described with reference to Figs. 9A-C.

The balloon is typically inserted into the vicinity of the anterior side of the subject's prostate, via introduction device 30, using an insertion technique described herein. The balloon is inflated by balloon control unit 60, such that the balloon creates a space in the vicinity of the anterior side of the prostate. Typically when the balloon is maximally inflated in the x and z directions the balloon has maximal lengths Lx and Lz, in each of the x and z directions, of less than 60 mm, and a maximal length Ly of 30 mm to 100 mm in the y direction, the x, y, and z directions being mutually perpendicular to each other.

Fig. 8A shows balloon 50 in an uninflated state, and Fig. 8B shows the balloon in a maximally-inflated state. In some embodiments, during inflation of the balloon, the balloon expands predominantly in the y direction. For example, the expansion of the balloon in the y direction (as measured by dividing maximal length Ly when the balloon is maximally inflated by maximal length Ly when the balloon is uninflated) is typically more than 200%, or more than 400% (e.g., 200% to 500%) of the expansion of the balloon in each of the x and z directions (expansion in the x and z directions being measured similarly). In some embodiments, using a balloon that expands predominantly in the y direction facilitates accurate placement of cutting elements on the balloon, with respect to the balloon, in the x-z plane. Since the balloon expands predominantly in the y direction, the position with respect to the balloon in the x-z plane, of the cutting elements which are fixed to the balloon, does not vary by a substantial amount. In this manner, the cutting elements are advanced in the y direction upon inflation of the balloon. The cutting elements having substantially fixed positions with respect to the balloon in the x-z plane allows the cutting elements to be aimed at and moved toward target tissue.

In some embodiments, balloon 50 has a round shape in the x-z plane, as shown in Fig. 8C. Alternatively the balloon has a rectangular shape in the x-z plane, as shown in Fig. 8D, or the balloon has a different shape in the x-z plane.

In some embodiments, the balloon is inserted into the vicinity of the anterior side of prostate 26 via an elongate element, for example, introduction device 30. For example, the balloon may be inserted via the abdomen (as shown in Fig. 8E), or transperineally, using the techniques described herein. When the balloon is in the vicinity of the prostate, the balloon is inflated (typically, by balloon control unit 60), such that it creates space in the vicinity of the anterior side of the prostate.

Fig. 8F is a schematic illustration of a cross section of balloon 50 in the x-y plane while the balloon is in an inflated state, in accordance with an embodiment of the present invention. In some embodiments, the balloon is curved, as shown, to facilitate contact between the surface of the balloon and the anterior surface of the prostate. Typically, the balloon is configured to be curved upon being inflated by shaping the balloon in a mold, using techniques that are known in the art. In some embodiments, techniques that are used with The Cutting Balloon® manufactured by InterVentional Technologies Inc. (CA, USA) are practiced in combination with balloon 50.

Reference is now made to Figs. 9A-B, which are schematic illustrations of balloon 50, or a different balloon, comprising one or more cutting elements 102 and/or 104, for example, cutting wires, or cutting blades, in accordance with respective embodiments of the present invention. The cutting elements incise or excise the prostate capsule and, in some embodiments, the cutting elements additionally incise or excise prostate tissue. Although Figs. 9A-B show specific numbers and orientations of cutting elements, the scope of the present invention includes using different numbers of cutting elements and cutting elements that are oriented differently. In some embodiments, balloon 50 is introduced, transabdominally (for example, retropubically), towards the prostate of a patient, for example, via introduction device 30. Alternatively, the balloon is inserted transperineally. When the balloon is positioned in a vicinity of the anterior side of the subject's prostate, the balloon is filled with a compressible or non-compressible fluid, such as air, carbon dioxide or water, via tube 105. In some embodiments, balloon control unit 60 controls the inflation of the balloon. Typically, the inflation of the balloon creates space on the anterior side of the prostate, for example, between the anterior surface of the prostate and the posterior surface of the pubic bone. Following balloon inflation, balloon 50 is typically substantially in contact with the anterior surface of the prostate. Cutting element 102 and/or 104, which is coupled to a surface 107 of the balloon, is used to incise and/or excise the prostate capsule using techniques that are known in the art, and/or techniques as described herein. In some embodiments, the cutting element protrudes from surface 107 of the balloon. Alternatively, the cutting element is disposed beneath surface 107. For some applications, the cutting element is substantially immobile with respect to surface 107, in the x-z plane. In such embodiments, the prostate capsule is typically cut by moving the balloon with respect to the prostate capsule. In some embodiments, one or more of the following cutting techniques or instruments are used to incise and/or excise the prostate capsule: a knife, a sharp edge, diathermia, a harmonic scalpel (for example, the Harmonic Scalpel® manufactured by Johnson and Johnson), a monopolar or bipolar device (e.g., a LigaSure™ device manufactured by Valleylab), or laser, such as green laser.

Reference is now made to Fig. 9C, which is a schematic illustration of balloon 50, or a different balloon, including one or more dynamic cutting elements 106 and/or 108 mounted on a wire(s) 110, 112 or similar construction(s), in accordance with an embodiment of the present invention. The dynamic cutting elements are substantially mobile with respect to surface 107, in the x-z plane. In such embodiments, the prostate capsule is cut by moving the cutting elements with respect to surface 107, in the x-z plane, typically while surface 107 remains substantially stationary. The wires typically facilitate movement of the cutting elements during the incision and/or excision of the prostate capsule. In some embodiments, a cutting element control unit 62 controls the motion of the cutting elements.

In some embodiments, insertion of balloon 50, as shown in Figs. 9A-C, is guided by an imaging device, for example, an endoscopic, ultrasound (e.g., transrectal ultrasound), CT and/or MRI imaging device. For some applications, balloon 50 and the imaging device are introduced into the subject's body via a single access port, for example, access needle 300 described hereinbelow.

Reference is now made to Figs. 10A-C, which are schematic illustrations of balloon 50, in accordance with an embodiment of the present invention. In some embodiments, balloon 50 is in a folded disposition during insertion of the balloon into the subject's body. When the balloon emerges from the distal end of the insertion tool (for example, introduction device 30), the balloon is inflated. Inflation of the balloon initially, predominantly results in the unfolding of the balloon in the x-z plane (Fig. 10B). Subsequently, inflation of the balloon expands the balloon, for example, predominantly in the y direction (Fig. 10C), as described hereinabove. In some embodiments, using a folded balloon facilitates accurate placement of cutting elements on the balloon with respect to the balloon, in the x-z plane. For example, each of the cutting elements is disposed on a respective fold of the folded balloon. The placement of a cutting element on a given fold will result in the element having a specific position with respect to the balloon in the x-z plane, subsequent to the unfolding of the balloon. The element having a specific position with respect to the balloon in the x-z plane allows the cutting element to be aimed at and moved toward a target.

Reference is now made to Figs. 11A-11D, which are schematic cross-sectional illustrations of cutting elements 102 and/or 104 shown in Figs. 9A-B, in accordance with respective embodiments of the present invention. In respective embodiments, one or more of the cutting elements has:

a round cross section 120 (Fig. 11A);

a triangle cross section 130 (Fig. 11B), configured, for example, such that a sharp cutting edge faces the prostate;

a rectangular cross section 140 (Fig. 11C), that typically allows a surgeon to create a cut, the width and depth of the cut being in accordance with the width and depth of cutting element 140; and/or

a generally semi-circular cross section 150 (Fig. 11D), that typically allows a surgeon to create a relative wide cut, the cut edges being substantially spaced from each other. Typically, this reduces the risk of cut closing. The semi-circle is oriented such that the closed portion of the semi-circle faces the prostate.

Reference is now made to Figs. 12A-D, which are schematic cross-sectional illustrations of dynamic cutting elements 106 and/or 108, shown in Fig. 9C, in accordance with respective embodiments of the present invention. Wires 110 and 112, shown in Fig. 9C, are typically shaped in accordance with the cross section of the cutting elements. In respective embodiments, one or more of the dynamic cutting elements has:

a round cross section 160 (Figure 12A);

an oval shape cross section 170 (Figure 12B);

a square cross section 180 (Figure 12C); and/or

a triangle cross section 190 (Figure 12D).

Reference is made now to Figure 13, which is a schematic illustration of a single port endoscope 200, which, typically, allows a surgeon to perform an entire procedure as described herein, using a single access port, in accordance with an embodiment of the present invention. The endoscope comprises several lumens, for example, a lumen 202 for a camera and dedicated light source, a working channel 204, through which prostate capsule and optionally prostate tissue are cut using a soft-tissue cutting instrument, and an irrigation/suction lumen 206 for camera lens cleaning. In some embodiments, the device comprises an additional working lumen 208, for example, for the insertion of gas for insufflating the space near the prostate. Device 200 comprises a handle 210 at its proximal section. The endoscope shaft typically has a diameter of 6 mm to 8 mm.

Reference is made now to Figs. 14A-B, which are schematic illustrations of an access needle 300 that serves as a working channel, in accordance with respective embodiments of the present invention. In some embodiments, access needle 300 is used as introduction device 30, described herein. In Figure 14A, a straight needle 300 is shown. For some applications, needle 300 is constructed from a flexible material (e.g., nitinol, and/or a polymeric material) to allow its introduction via a straight and/or a curved path within the patient's body. Figure 14B illustrates needle 300, in accordance with an alternative embodiment. The needle shown in Fig. 14B has a proximal straight section 302 and a curved distal section 304 that is designed to comply with the lower abdomen anatomy, for example. Typically, a length L302 of the straight portion is 30 mm to 100 mm, and a length L304 of the straight portion is 20 mm to 100 mm. Introduction of access needle 300 may be facilitated by the use of a stylet (not shown). For example, a flexible and blunt tip stylet is inserted and, subsequently, the needle is passed over the stylet during needle introduction. Following the insertion of the needle, the stylet is removed.

Reference is now made to Figs. 15A-B, which are schematic illustrations of a balloon device 400 or 402, that is introduced via needle 300, to create a void near the prostate, for example between the anterior surface of the prostate and the posterior surface of the pubic bone, in accordance with respective embodiments of the present invention. The balloon may have, for example, a round or elliptical shape 400 (Fig. 15A) or a trapezoid shape 402 (Fig. 15B). In some embodiments, the dimensions of balloon 400, and/or balloon 402 (and/or balloon 50, described hereinabove), are selected in accordance with the anatomy of the subject. For some applications, a diameter D400 of elliptical balloon 400 when inflated is 8 mm to 20 mm, and a length of the balloon L400 is less than 60 mm. For some applications, a height H402 of the larger parallel side of a trapezoidal balloon when inflated is 8 mm to 20 mm, a height h of the smaller parallel side of the trapezoidal balloon is 3 mm to 15 mm, and a length of the balloon L402 is less than 60 mm. In some embodiments, balloon 50 described hereinabove is inserted via access needle 300. During a procedure, balloon 400 is filled with a compressible fluid, a non-compressible fluid, and/or an ultrasound opaque substance in order to create a working space in a vicinity of the prostate. Following expansion of balloon 400, balloon 400 is deflated and removed. In some embodiments, an incision device cuts the prostate capsule, while the balloon is inflated. Alternatively, the balloon is deflated (and, optionally, the space in which the balloon was disposed is insufflated with a fluid) and, subsequently, an incision device cuts the prostate capsule.

Reference is now made to Fig. 16, which is a schematic illustration of a cutting instrument 500, that is introduced via access needle 300, or via a different introduction device, in order to cut the prostate capsule, in accordance with an embodiment of the invention. Cutting instrument 500 comprises a proximal straight section 502 and a curved distal section 504. In some embodiments, the lengths of the straight and curved sections comply with the lengths of the straight and curved sections of access needle 300. Typically, the shape of the device facilitates introduction of the device by complying with the lower abdomen anatomy, for example. A cutting element 506 is disposed at the distal end of the instrument. In some embodiments, the cutting element is disposed at an angle with respect to the portion of the device immediately proximal to the cutting element (as shown). In some embodiments, the disposition of the cutting element facilitates the cutting function. In some embodiments, a limiting structure 508 at the distal end of the device, for example, a balloon (as shown), or a pulley, limits the penetration into tissue of cutting element 506 to a pre-defined depth.

In accordance with an embodiment of the invention, cutting instrument 500 comprises a flexible stylet with a cutting element at its distal tip. Reference is now made to Figs. 17A-C, which are schematic illustrations of a stylet cutting tip, in accordance with respective embodiments of the invention. In accordance with respective embodiments, the stylet has:

a conical tip 602 (Fig. 17A);

a blunt cutting tip 604 (Fig. 17B); and/or

a curved edge 606 (Fig. 17C) that typically removes a wide section of soft tissue. For some applications, other cutting tips and/or cutting techniques (e.g., diathermia and green laser) are used.

In accordance with an embodiment of the present invention, an imaging device, such as an endoscope, an ultrasound probe (e.g., a transrectal ultrasound probe), and/or a CT or MRI imaging device, is used in combination with needle 300 shown in Figs. 14A-B, to guide needle 300 and to facilitate incision of the prostate capsule.

Reference is now made to Figs. 18A-B, which are schematic illustrations of respective steps of a surgical procedure, in accordance with an embodiment of the present invention. Fig. 18A shows an entry point 700 of an access needle 702 above the pubic bone 704. In some embodiments, access needle 702 is generally similar to access needle 300 described hereinabove. In some embodiments, access needle includes a flexible stylet (not shown). Needle 702 follows the pubis until the needle reaches the retropubic space 706, anterior to the prostate 708 (i.e., a retropubic approach). Following positioning of needle 702, the stylet is removed and, optionally, a balloon device 710 is introduced and inflated. In some embodiments, balloon 710 is generally similar to balloon 50, 400, and/or 402 described hereinabove. Fig. 18B shows the introduction of a cutting instrument 712 via needle 702. Cutting instrument 712, which is typically a cutting instrument as described herein, creates one or more incisions and/or excisions at designated locations in the prostate capsule (with or without incising or excising prostate tissue). In some embodiments, the procedure is guided by an imaging device, as described hereinabove.

Reference is now made to Fig. 19, which is a schematic illustration of apparatus 800 that is used following the creation of one or more cuts 801 and/or 802 by incision and/or excision of the prostate capsule 804, in accordance with an embodiment of the present invention. In some embodiments, apparatus 800 prevents the cuts from re-closing. Fig. 19 is an inferior-superior view, thus only the ends of the relatively anterior cuts 801, 802 are shown in Fig. 19. Urethra 803 is also shown. In some embodiments, a flexible, generally circular, oval, or (as shown) omega-shaped implant 800 is placed around at least a portion of the circumference of the prostate. Ends 806 and 808 of the element are anchored in the prostate such that cuts 801, 802 are enclosed by the element. Device 800 is configured such that an outward radial force F forces the device toward an open configuration. For example, the device may comprise a shape-memory alloy, such as nitinol. Force F typically prevents closure of the cuts. In some embodiments, device 800 is non-transurethrally implanted in the subject's prostate without the prostate being incised (apart from incisions that are necessary for the implantation of device 800). The device exerts an outward radial force, as described, thus reducing the constrictive force on the prostatic urethra. In some embodiments, the device is implanted via a transabdominal, e.g., a retropubic, approach.

Reference is now made to Figure 20, which is a schematic illustration of apparatus 900, that is used following the production of one or more cuts 901 and/or 902 by incision and/or excision of the prostate capsule 904, in accordance with an embodiment of the present invention. Fig. 20 is an anterior view of the prostate. In some embodiments, apparatus 900 prevents the cuts from re-closing. In some embodiments, at least one flexible, generally circular, oval, or (as shown) omega-shaped implant 900, is placed in a vicinity of each cut 901 and/or 902, so that its ends 906, 908 are anchored in the prostate. Implant 900 prevents the cuts from reclosing in a generally similar manner to omega-shaped implant 800 described with reference to Fig. 19.

Reference now is made to Figs. 21A-B, which are schematic illustrations of a device 910 intended for cutting and/or coagulating soft tissue ("a cutting device"), such as prostate capsule and/or prostate tissue, in accordance with an embodiment of the present invention. Cutting device 910 includes a joint 911 at a distal portion of the device. An arm 912 articulates with shaft 922 of the cutting device at the joint, at a distal end 913 of the arm, as shown in Fig. 21B. For example, joint 911 may include a pin, as shown. In a closed position of the arm with respect to the shaft, a portion of the arm faces a portion of the shaft. Shaft 922 typically has a diameter of 3 mm to 6 mm, e.g., 4 mm to 5 mm.

Arm 912 typically includes a penetration element 929 at a proximal portion thereof, as shown in Fig. 21B. For some applications, penetration element includes a sharp edge, as shown. Device 910 typically has a handle 914 at its proximal end. In some embodiments, arm 912 also includes one or more protrusions 930, as shown in Fig. 21B. Typically, an electrode 919 and/or a cutting element 921 are disposed on the shaft. For example, the cutting element may be a blade, and/or other cutting elements as described herein, or as are known in the art. For some applications, the cutting element is slidable coupled to the shaft. In some embodiments, one or more of protrusions 930 on arm 912 include a cutting element (e.g., a blade) 932, and/or monopolar or bipolar electrodes.

Optionally, the distal tip 916 of device 910 is pointed to facilitate introduction of device 910 through soft tissue. Alternatively, distal tip 916 may be blunt (not shown in Fig. 21A), and device 910 is introduced, for example, via a needle (such as access needle 300 described hereinabove) following the introduction of a trocar and/or stylet. Typically, device 910 is advanced toward the prostate using techniques described herein, for example, transabdominally or transperineally.

In some embodiments, arm 912 is connected to a connection element 918, for example, a cable, a rod, or a tube, which is connected at its proximal end to an activating mechanism, such as a button 920. During introduction of device 910 toward the prostate, arm 912 is in a closed configuration, within the device shaft 922, to prevent damage to the tissue, as shown in Fig. 21A. Following introduction and positioning of device 910, button 920 is pressed and arm 912 protrudes from a slot or a lumen at the distal end of device shaft 922 into an open configuration (Fig. 21B). The opening of the arm facilitates the penetration (for example, by penetration element 929) and, optionally, the mechanical incision of tissue, for example, tissue of the prostatic capsule. In an embodiment, following the penetration (through, for example, tissue of the prostatic capsule), the tissue to be cut is positioned in the space between open arm 912 and device shaft 922. When the tissue is positioned in the space the arm is at least partially closed. In embodiments according to which cutting elements 932 are blades, the tissue is cut by closing the arm.

In some embodiments, device 910 coagulates tissue (using, for example, RF energy, plasma and/or laser technology), to reduce tissue bleeding due to the cut. Typically, the tissue is coagulated prior to cutting the tissue, although, in some embodiments, the tissue is first cut and then coagulated. Typically, an electrode 919 is disposed within shaft 922. When arm 912 is closed, the tissue between the arm and the shaft is grasped and is pressed against the electrode and coagulated, by the electrode driving a current into the tissue. Device 910 is connected (typically via a cable 926) to a generator 940, for example, a bipolar or a monopolar generator. In some embodiments, electrode 919 is a monopolar electrode and is connected to a monopolar generator. For some applications, when a monopolar generator is used, a ground (return) plate is placed against the patient (e.g., between a bed on which the patient lies and the patient's leg) (not shown). For some applications, connection element 918 is an electrical conductor that is electrically connected to arm 912, and that is isolated from device shaft 922. Arm 912 and electrode 919 act as bipolar electrodes. Activation of the coagulation function may be achieved by, for example, pressing a button 928 or a foot pedal (not shown).

In some embodiments, electrode 919, and, optionally, connection element 918, are aluminum electrodes. For some applications, one or more of the electrodes are coated using two processes: the alodine process, and hard anodization. In some embodiments, coating the electrodes in the aforementioned manner results in the electrodes having a coating that is less than 100 microns, for example, less than 60 microns thick. For some applications, the electrodes are coated in a polymer (e.g., epoxy, and/or polyester), using techniques that are known in the art.

In some embodiments, the prostate capsule is cut in accordance with the following procedure: The distal portion of shaft 922 is positioned adjacent to a first cutting site of the prostate capsule, while arm 912 is in a closed position. The arm is opened and the capsule is penetrated by penetration element 929. Tissue of the capsule is then grasped between the arm and shaft 922. The arm is partially closed in order to coagulate the tissue, as described hereinabove. Subsequently to the coagulation of the tissue, a cutting element (e.g., blade 921) is advanced distally, (for example, by sliding the blade distally with respect to the shaft) thereby cutting the coagulated tissue. The arm is typically in a closed position during the cutting of the tissue and the blade advances into the slot in arm 912 between protrusions 930. In some embodiments, the grasped tissue is cut by blade 921 without the tissue first being coagulated. For some applications, a blade disposed in a different portion, for example, on protrusions 930 of arm 912 cuts the grasped tissue. For some applications, a different cutting element, as described herein, is used to cut the grasped tissue. Subsequently to the tissue being cut, the distal portion of shaft 922 is moved adjacent to a more proximal cutting site. The cutting (and/or the coagulation procedure) is repeated at the more proximal cutting site. The device cuts tissue of the prostate capsule sequentially at successively more proximal cutting sites by the distal portion of shaft 922 being moved to successively more proximal cutting sites, and the cutting (and/or the coagulation procedure) being repeated.

In accordance with respective embodiments, device 910 is inserted transperineally or transabdominally. When inserted transperineally, the device cuts tissue of the prostate capsule from a position that is either inside or outside the prostate. Typically, when the device is inserted transabdominally, the device cuts the prostate capsule from a position that is outside the prostate.

For some applications, shaft 922 is shaped in a similar shape to the shape of access needle 300, described with reference to Figs. 14A-B.

Reference is now made to Fig. 22, which is a schematic illustration of a plastic hinge 941, which is used for joint 911 of device 910, in accordance with an embodiment of the present invention. In some embodiments, using a plastic hinge for joint 911, enables arm 912 to be coupled to shaft 922 at a position that is closer to distal tip 916 of device 910, than if a pin is used for joint 911, as is shown in Figs. 21A-B.

Reference is now made to Fig. 23A-B, which are schematic illustrations of a prostate capsule cutting device 980, in accordance with an embodiment of the present invention. In some embodiments, the cutting device is made of a shape-memory material, such as nitinol. The device is configured such that during insertion through introduction device 30, a proximal-facing distal portion 982 of the device is constrained by the introduction device. Upon passing out of the distal end of the introduction device, distal portion 982 opens automatically, based on material properties of the distal portion, as shown in Fig. 23B. A penetration element 984 of the distal portion, for example, a sharp tip of the proximal facing portion penetrates tissue, for example, tissue of the prostate capsule. In some embodiments, the penetration element penetrates the tissue automatically by the distal portion opening while the distal portion is adjacent to the tissue. Subsequent to the penetration of the tissue, a cutting element 983 (for example, a sharp edge of the proximal–facing portion, and/or a monopolar or bipolar electrode) is used to cut the prostate capsule or the prostate, typically, in accordance with the techniques described herein. In particular, cutting element 983 cuts tissue as cutting device 980 is pulled in a proximal direction. In some embodiments, the cutting element, or a different region of proximal-facing distal portion 982, is configured to coagulate the tissue. For example, the proximal-facing distal portion may comprise a single monopolar electrode, or bipolar electrodes for coagulating, and/or cutting the tissue.

Reference is now made to Figs. 24A-E, which are schematic illustrations of device 910 incising and/or excising the prostate capsule and/or prostate tissue, in accordance with an embodiment of the present invention. In an embodiment of the present invention, the procedure is performed while the patient is in the lithotomy position, under general/spinal/local anesthesia, and/or sedated. In some embodiments, the procedure is imaged, using, for example, transrectal ultrasound. Although embodiments are described with respect to Figs. 24A-E according to which device 910 is used, the scope of the present invention includes using device 980, and/or other devices described herein, to practice the described techniques, *mutatis mutandis*. Although embodiments are described with respect to Figs. 24A-E according to which a device is inserted transperineally, the scope of the present invention includes practicing the described techniques using a transabdominal, and/or a transurethral approach, *mutatis mutandis*.

In Fig. 24A, device 910 is shown being introduced into prostate 930 transperineally, while its arm 912 is closed. In an embodiment of the invention, two access ports 931 are formed (although only one port can be seen in Fig. 22A, since Fig. 22A shows a lateral view). One or more devices 910 are positioned in an upper, anterior portion of the prostate, close to capsule 934, for example, 1 mm to 10 mm, e.g., 1 mm to 4 mm, from the interior portion of capsule 934. In some embodiments, each access port 931 is of 2 mm to 6 mm diameter. Typically, in accordance with such embodiments, the outer diameter of the shaft of device 910 is between 1 mm and 5 mm. For some applications, two devices 910 are placed approximately parallel to each other. For some applications, two devices 910 are located at "10 o'clock" and at "2 o'clock" positions. Alternatively, a different number of access ports (and, accordingly, or otherwise, a different number of capsule incisions) are used. In some embodiments, one or more devices 910 are positioned differently with respect to the prostate.

Subsequent to positioning device 910 (as is verified by an imaging device, in accordance with some embodiments), button 920 (shown in Fig. 21A) of device 910 is pressed, and arm 912 protrudes from device shaft 922, into the prostate capsule 934 (i.e., from the prostate tissue into and through the capsule), as shown in Fig. 24B. At this stage, while prostate capsule tissue (and, optionally, a small amount of prostate tissue) is located in the space between the open arm 912 and device shaft 922, arm 912 is at least partially re-closed, to grasp the tissue, as shown in Fig. 22C.

Subsequently, the physician retracts device 910, thereby cutting the capsule tissue from within the prostate, as shown in Fig 24D. In some embodiments, coagulation is provided to seal blood vessels, thus reducing bleeding, for example, by a physician pressing a button and/or foot-pedal, as described hereinabove. For some applications, cutting and coagulating are performed in steps – firstly, while penetrating/cutting element 912 is pressed against the tissue, the physician presses the coagulation button, and then slightly pulls back device 910 to cut the capsule. Alternatively, subsequent to coagulating the tissue, the capsule is cut using a blade, such as blade 921, described with reference to Fig. 21A. This operation is typically repeated a few times, until sufficient tissue has been incised. In some embodiments, the incisions are performed along the prostate capsule curvature, from the upper prostate part towards its apex. For some applications, incisions are made to a depth of 1 mm to 10 mm.

Excision and/or incision of prostate capsule is achieved with or without a guiding stylet, in accordance with respective embodiments of the present invention. When a guiding stylet is used, it may be introduced, for example, perineally, up to the distal (upper) part of the anterior prostate, under image guidance. Following stylet positioning, device 910 is advanced over the guiding stylet. In some embodiments, a device is introduced into the lower part of the prostate, and the incision direction is from the prostate apex towards the upper part of the prostate, device 910 being modified appropriately to facilitate the forward motion during cutting.

In some embodiments, device 910 is inserted transperineally (or via a different approach), and the capsule is approached from the outside of the capsule, as shown in Fig. 24E. The cutting and coagulation device 910 is operated similarly to the procedure described with respect to Figs. 24A-D.

Reference is now made to Fig. 25, which is a schematic illustration of a laser device 950 for cutting and coagulating soft tissue, in accordance with an embodiment of the present invention. For example, device 950 may be based on green laser, red laser, or Nd:YAG technology. In some embodiments, the laser wavelength is in the range of 500 nm to 2,100 nm. A laser light guide 952 passes through the device shaft 954. In some embodiments, a distal end 956 of laser light guide 952 is angled, for example, upwards, thereby enabling incision of the prostate capsule from within the prostate. For some applications, device distal end 958 is pointed, to facilitate advancement of the device, and/or to prevent damage to tissue, while the device is introduced toward the prostate. For some applications, device 950 incorporates a handle 960 at its proximal part, and/or a button/foot pedal (not shown in Fig. 25) for device operation. In some embodiments, device 950 comprises a hook 962 at the distal end of the device. The hook is closed during device introduction toward the prostate. Following positioning of device 950, the hook is opened to penetrate the capsule tissue from within the prostate (or from outside of the prostate), in accordance with techniques described herein. In some embodiments, the hook is then at least partially re-closed, so that the tissue to be cut and/or ablated is gripped between hook 962 and a device shaft 954 (for example, using techniques described herein), in order to position the tissue in the path of the laser light guide distal end 956. For some applications, hook 962 shields surrounding tissue from the laser.

In an embodiment, device 950 comprises a drainage tube or tubing system, for draining out of the patient's body vapors generated during the operation of device 950. Alternatively or additionally, device 950 comprises a tube or tubing system, which circulates water in the surrounding tissue, thereby cooling the surrounding tissue (not shown in Fig. 25).

It is to be understood that although some embodiments of the present invention are described with respect to the use of an imaging device to facilitate capsulotomy or capsulectomy, the scope of the present invention includes performing the capsulotomy or capsulectomy without such an imaging device.

It is noted that whereas some embodiments of the present invention are described herein with respect to the use of an endoscope, the scope of the present invention includes the use of another longitudinal surgical introduction tool, such as a trocar or a delivery catheter, in place of or in addition to an endoscope. The scope of the invention further includes the insertion of cutting devices and/or balloons without the use of an introduction tool.

It is noted that whereas some embodiments of the present invention are described herein with respect to treating a constriction of the prostatic urethra due to BPH, the scope of the present invention includes using the methods and apparatus described herein to treat a constriction of the urethra due to other causes, such as an obstruction of the prostatic urethra.

It is noted that all embodiments described herein that are not specifically described as being carried out in a transurethral fashion are performed without puncturing the urethra.

It is further noted that whereas some embodiments are described hereinabove with respect to incising the prostatic capsule, the scope of the present invention includes excising at least a portion of the capsule, whether by energy-based excision techniques or using a cold knife. It is still further noted that although embodiments are described with respect to cutting the prostate, and/or the prostatic capsule, the scope of the present invention includes performing an incision and/or an excision in the prostate capsule with or without incising or excising the prostate tissue.

The terms "cutting" and "incising," as used in the present application and in the appended claims, are to be understood to mean cutting, incising, and/or excising.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

CLAIMS

1. Apparatus, comprising:

an elongate element for inserting into a subject's body;

a joint at a distal end of the elongate element;

an arm having a proximal end and a distal end, the distal end of the arm articulatable at the joint with the elongate element, wherein in a closed position of the arm with respect to the elongate element, a portion of the arm faces a portion of the elongate element; and

a cutting element coupled to at least one of the portions.

2. The apparatus according to claim 1, wherein the cutting element is slidably coupled to the elongate element.

3. The apparatus according to claim 1, wherein the cutting element comprises a cutting element selected from the group consisting of: a knife, a sharp edge, a diathermia device, a harmonic scalpel, an RF device, a plasma device and a laser.

4. The apparatus according to claim 1, wherein the cutting element comprises one or more blades disposed on the arm.

5. The apparatus according to claim 1, wherein the joint comprises a plastic hinge.

6. The apparatus according to claim 1, wherein the cutting element is configured to sequentially cut tissue of the subject at successively more proximal cutting sites, by the distal end of the elongate element being moved to the successively more proximal cutting sites.

7. The apparatus according to claim 1, further comprising two balloons disposed on opposing sides of the elongate element at the distal end of the elongate element, the balloons being configured to create a space distal to the balloons and distal to the elongate element, by being inflated.

8. The apparatus according to any one of claims 1-7, further comprising at least one coagulation electrode configured to coagulate tissue of the subject.

9. The apparatus according to claim 8, wherein the coagulation electrode comprises two or more bipolar coagulation electrodes.

10. The apparatus according to claim 8, wherein the coagulation electrode comprises a monopolar coagulation electrode.

11. The apparatus according to any one of claims 1-7, wherein the cutting element comprises a coagulation electrode configured to coagulate tissue of the subject.

12. The apparatus according to claim 11, wherein the cutting element further comprises a mechanical cutting element.

13. The apparatus according to claim 11, wherein the coagulation electrode comprises two or more bipolar coagulation electrodes.

14. The apparatus according to claim 11, wherein the coagulation electrode comprises one monopolar coagulation electrode.

15. The apparatus according to claim 11, wherein the electrode is coated with a coating produced by an alodine process and a hard anodization process.

16. The apparatus according to claim 15, wherein the coating has a thickness of less than 100 microns.

17. The apparatus according to any one of claims 1-7, wherein the arm comprises a penetration element configured to penetrate tissue of the subject.

18. The apparatus according to claim 17, wherein the penetration element is disposed at the proximal end of the arm.

19. The apparatus according to claim 17, wherein the penetration element comprises a sharp edge.

20. The apparatus according to any one of claims 1-7, wherein the arm is configured to grasp tissue of the subject by being at least partially closed with respect to the elongate element.

21. The apparatus according to claim 20, wherein the cutting element is configured to cut the grasped tissue, and further comprising a coagulation electrode configured to coagulate the grasped tissue.

22. The apparatus according to claim 20, wherein the cutting element is configured to cut the grasped tissue.

23. The apparatus according to claim 22, wherein the cutting element is configured to cut and coagulate the grasped tissue.

24. The apparatus according to any one of claims 1-7, wherein the distal end of the elongate element is configured to be inserted to a vicinity of an anterior side of a prostate of the subject, and wherein the cutting element is configured to cut a prostate capsule of the prostate.

25. The apparatus according to claim 24, wherein the distal end of the elongate element is configured to be inserted to inside the subject's prostate, and wherein the cutting element is configured to cut the prostate capsule from inside the prostate.

26. The apparatus according to claim 24, wherein the distal end of the elongate element is configured to be inserted to outside the subject's prostate, and wherein the cutting element is configured to cut the prostate capsule from outside the prostate.

27. The apparatus according to claim 24, wherein the elongate element is configured to be transperineally inserted to the vicinity of the anterior side of the subject's prostate.

28. The apparatus according to claim 24, wherein the elongate element is configured to be transabdominally inserted to the vicinity of the anterior side of the subject's prostate.

29. The apparatus according to claim 28, wherein the elongate element is shaped to define a curved distal region and a straight proximal region of the elongate element, the curved shape of the distal region of the elongate element facilitating retropubic insertion of the distal end of the elongate element.

30. Apparatus, comprising:

an elongate element for inserting into a subject's body, the elongate element having a proximal-facing portion at a distal end of the elongate element,

the proximal-facing portion comprising a cutting element, the cutting element configured to sequentially cut tissue of the subject at successively more proximal cutting sites, by the distal end of the elongate element being moved to the successively more proximal cutting sites.

31. The apparatus according to claim 30, wherein the cutting element comprises a cutting element selected from the group consisting of: a knife, a sharp edge, a diathermia device, a harmonic scalpel, an RF device, a plasma device and a laser.

32. The apparatus according to claim 30, further comprising two balloons disposed on opposing sides of the elongate element at the distal end of the elongate element, the balloons being configured to create a space distal to the balloons and distal to the elongate element, by being inflated.

33. The apparatus according to claim 30, wherein the cutting element is a sharp edge of the proximal-facing portion.

34. The apparatus according to claim 30, wherein the proximal-facing portion is a continuation of the elongate element.

35. The apparatus according to claim 30, wherein the proximal-facing portion and the elongate element are formed as one integral body, in which the proximal-facing portion includes a curved aspect that makes the proximal-facing portion face in a proximal direction.

36. The apparatus according to claim 30, wherein the proximal-facing portion further comprises a penetration element configured to penetrate the tissue.

37. The apparatus according to claim 30, wherein the cutting element comprises an electrode and a mechanical cutting element, the cutting element being configured to cut the tissue by applying pressure to the tissue, and to coagulate the tissue by driving a current into the tissue.

38. The apparatus according to any one of claims 30-37, wherein at least a portion of the proximal-facing portion comprises a shape memory material.

39. The apparatus according to claim 38, further comprising an elongate-element introduction-device that defines a lumen, wherein the elongate element is inserted via the lumen, and wherein the proximal-facing portion is configured to open with respect to the elongate element, due to the shape memory material, when the proximal-facing portion passes out of a distal end of the lumen.

40. Apparatus for treating an obstruction of a prostatic urethra of a subject, comprising:

a balloon that during inflation of the balloon is configured to expand in a first direction by more than 200% of an expansion of the balloon in each of second and third directions, the first, second and third directions being mutually perpendicular to each other;

one or more cutting elements coupled to a surface of the balloon, at least a portion of the surface being disposed in a plane that is defined by the second and third directions;

an elongate element configured to place the balloon in a vicinity of an anterior side of a prostate of the subject; and

a balloon control unit configured to create a space in the vicinity by inflating the balloon.

41. The apparatus according to claim 40, wherein during inflation of the balloon, the balloon is configured to expand in the first direction by more than 400% of the expansion of the balloon in each of the second and third directions.

42. The method according to claim 40, wherein the one or more cutting elements protrude from the surface.

43. The apparatus according to claim 40, wherein the cutting elements comprise a cutting element selected from the group consisting of: a knife, a sharp edge, a diathermia device, a harmonic scalpel, an RF device, a plasma device, and a laser.

44. The apparatus according to claim 40, wherein the length of the balloon in the second and third directions is less than 60 mm, when the balloon is maximally inflated.

45. The apparatus according to claim 40, wherein the cutting elements comprise one or more cutting elements that are substantially mobile with respect to the surface of the balloon in the plane that is defined by the second and third directions.

46. The apparatus according to claim 40, wherein the cutting elements comprise one or more cutting elements that are substantially immobile with respect to the surface of the balloon in the plane that is defined by the second and third directions.

47. The apparatus according to claim 40, wherein the balloon is configured to be in a folded disposition during insertion of the balloon into the vicinity, and wherein each of the cutting elements are disposed on a respective fold of the folded balloon.

48. The apparatus according to any one of claims 40-47, wherein an outer surface of the balloon is shaped to match a shape of the anterior side of the prostate.

49. The apparatus according to claim 48, wherein the outer surface of the balloon is shaped concavely when maximally inflated.

50. A method, comprising:

inserting a tool into a subject's body via a perineum of the subject; and

while the tool is inside the subject's body, performing minimally invasive surgery on the subject using the tool.

51. A method for treating an obstruction of a prostatic urethra of a subject, comprising:

identifying that the subject has a constricted urethra due to the prostatic urethra obstruction; and

relieving pressure on the urethra caused by the prostatic urethra obstruction, by performing an action on at least a portion of a capsule of a prostate of the subject, the action being selected from the group consisting of: incising, and excising.

52. The method according to claim 51, wherein performing the selected action comprises:

creating a space in a vicinity of the prostate, by inflating two balloons at a distal end of an elongate element, the space being distal to the balloons and distal to the elongate element; and

accessing the capsule of the prostate via the space.

53. The method according to claim 51, wherein performing the selected action comprises grasping the portion and cutting the grasped portion.

54. The method according to claim 51, further comprising coagulating tissue of the capsule in a vicinity of the portion on which the selected action is performed.

55. The method according to claim 51, wherein relieving pressure on the urethra comprises performing at least one surgical access selected from the group consisting of:

transabdominally accessing the capsule,
transperineally accessing the capsule,
transurethrally accessing the capsule, and
non-transurethrally accessing the capsule.

56. The method according to claim 51, wherein relieving pressure on the urethra comprises performing at least one surgical access selected from the group consisting of:

transabdominally accessing the capsule, and
transperineally accessing the capsule.

57. The method according to claim 51, wherein relieving pressure on the urethra comprises performing the selected action on at least the portion of the capsule from a site within the prostate.

58. The method according to claim 51, wherein performing the selected action on at least the portion of the capsule comprises performing the selected action on at least the portion of the capsule with at least one instrument selected from the group consisting of: a cold knife, a cauterizing tool, and a laser.

59. The method according to claim 51, wherein performing the selected action on at least the portion of the capsule comprises performing the selected action on at least the portion of the capsule with at least one instrument selected from the group consisting of: a sharp edge, a diathermia device, a harmonic scalpel, a plasma device, and an RF device.

60. The method according to claim 51, wherein performing the selected action on at least the portion of the capsule comprises forming at least one incision in a superior-inferior direction in the prostatic capsule.

61. The method according to claim 51, wherein performing the selected action on at least the portion of the capsule comprises forming at least one incision in a medial-lateral direction in the prostatic capsule.

62. The method according to claim 51, wherein performing the selected action on at least the portion of the capsule comprises excising the prostatic capsule.

63. The method according to claim 51, wherein performing the selected action on at least the portion of the capsule comprises incising the prostatic capsule.

64. The method according to any one of claims 51-63, further comprising inserting a cutting element into the subject's body, wherein performing the selected action on the portion of the capsule comprises sequentially cutting the capsule at successively more proximal cutting sites by moving the cutting element to the successively more proximal cutting sites.

65. The method according to claim 64, wherein inserting the cutting element comprises inserting the cutting element inside the subject's prostate, and wherein performing the selected action on the portion comprises performing the selected action on the portion from inside the prostate, subsequently to inserting the cutting element inside the subject's prostate.

66. The method according to claim 64, wherein inserting the cutting element comprises inserting the cutting element to a site outside the subject's prostate, and wherein performing the selected action on the portion comprises performing the selected action on the portion from the site outside the prostate.

67. The method according to claim 64, wherein inserting the cutting element comprises transperineally inserting the cutting element.

68. The method according to claim 64, wherein inserting the cutting element comprises transabdominally inserting the cutting element.

69. The method according to any one of claims 51-63, further comprising:

inserting a balloon into a body of the subject, to a vicinity of an anterior side of the subject's prostate;

creating space in the vicinity by inflating the balloon such that the balloon expands in a first direction by more than 200% of an expansion of the balloon in each of second and third directions, the first, second and third directions being mutually perpendicular to each other; and wherein performing the selected action on the portion of the capsule comprises cutting the capsule with one or more cutting elements that are coupled to a surface of the balloon, the surface being disposed at least partially in a plane that is defined by the second and third directions.

70. The method according to claim 69, wherein performing the selected action on the portion of the capsule comprises cutting the capsule with one or more cutting elements that protrude from the surface of the balloon.

71. The method according to claim 69, wherein creating the space in the vicinity comprises inflating the balloon such that the balloon expands in the first direction by more than 400% of the expansion of the balloon in each of the second and third directions.

72. The method according to claim 69, wherein inserting the balloon comprises inserting the balloon while the balloon is in a folded disposition, and unfolding the balloon when the balloon is in the vicinity.

73. The method according to claim 69, wherein performing the selected action on the portion of the capsule comprises moving the cutting elements with respect to the surface of the balloon in the plane that is defined by the second and third directions.

74. The method according to claim 73, wherein performing the selected action on the portion of the capsule comprises substantially not moving the surface of the balloon during performance of the selected action.

75. The method according to claim 69, wherein performing the selected action on the portion of the capsule comprises moving the balloon with respect to the capsule.

76. The method according to claim 75, wherein performing the selected action on the portion of the capsule comprises, during the performance of the selected action, substantially not moving the cutting elements with respect to the surface of the balloon in the plane that is defined by the second and third directions.

77. The method according to any one of claims 51-63, wherein performing the selected action on at least the portion of the capsule comprises forming a plurality of incisions in the prostatic capsule.

78. The method according to claim 77, wherein performing the selected action on at least the portion of the capsule comprises forming 1-3 incisions in the capsule.

79. The method according to claim 77, wherein performing the selected action on at least the portion of the capsule comprises forming 4-10 incisions in the capsule.

80. The method according to claim 77, wherein performing the selected action on at least the portion of the capsule comprises forming a plurality of incisions in the prostatic capsule in different directions.

81. Apparatus for treating an obstruction of a prostatic urethra of a subject, comprising:

an instrument, configured to perform an action on at least a portion of a capsule of a prostate of the subject to an extent that is sufficient to relieve pressure in the prostate due to the prostatic urethra obstruction, the action being selected from the group consisting of: incising, and excising; and

an imaging device, configured to facilitate guiding of the instrument to the prostatic capsule of the subject.

82. The apparatus according to claim 81, wherein the imaging device comprises at least one imaging device selected from the group consisting of: an endoscopic imaging device, an ultrasound device, a CT imaging device, an MRI imaging device, a cystourethroscope, and a laparoscope.

83. The apparatus according to claim 81, wherein the instrument is configured to access the capsule via passage through at least one site selected from the group consisting of: an abdominal wall of the subject, a urethra of the subject, and a perineum of the subject.

84. The apparatus according to claim 81, wherein the instrument comprises at least one instrument selected from the group consisting of: a cold knife, a cauterizing tool, and a laser.

85. The apparatus according to claim 81, wherein the instrument is configured to make at least one incision in a superior-inferior direction, in the prostatic capsule.

86. The apparatus according to claim 81, wherein the instrument is configured to make at least one incision in a medial-lateral direction, in the prostatic capsule.

87. The apparatus according to claim 81, wherein the instrument is configured to make a plurality of incisions in the prostatic capsule.

88. The apparatus according to claim 81, wherein the instrument is configured to make a plurality of incisions, at least some of which are in different directions.

89. The apparatus according to claim 81, wherein the instrument is configured to excise at least a portion of the prostatic capsule.

90. The apparatus according to claim 81, wherein the instrument is configured to incise the prostatic capsule.

91. Apparatus for treating an obstruction of a prostatic urethra of a subject, comprising:

a balloon device having a balloon; and

at least one cutting element coupled to the balloon and configured to perform an action on a prostate capsule of the subject, the action being selected from the group consisting of: incising and excising.

92. Apparatus according to claim 91, wherein the at least one cutting element is movable with respect to the balloon.

93. A method for treating an obstruction of a prostatic urethra of a subject, comprising:

accessing a prostate of the subject with an access device;

introducing a balloon to a vicinity of the prostate via the access device, the balloon having cutting elements coupled thereto;

inflating the balloon to create a space near the prostate; and

performing an action on a capsule of the prostate using the cutting elements, the action being selected from the group consisting of: incising and excising.

94. The method according to claim 93, further comprising imaging the balloon introduction, and the performing of the selected action, with an imaging device.

95. A single port access apparatus, comprising:

a lighting source; and

a camera;

the apparatus defining at least one working channel, and the apparatus being configured to treat an obstruction of a prostatic urethra of a subject.

96. The apparatus according to claim 95, further comprising camera-lens cleaning equipment, wherein the apparatus defines a lumen configured such that the camera-lens cleaning equipment can be inserted through the lumen.

97. The apparatus according to claim 95, further comprising a fluid, wherein the apparatus defines a lumen configured such that the fluid insufflates a space between a prostate and a pubis of the subject by being passed through the lumen.

98. A method for treating an obstruction of a prostatic urethra of a subject, comprising executing a procedure via only one access port, wherein executing the procedure comprises:

accessing a prostate of the subject with an endoscope by inserting the endoscope via the access port, the endoscope having at least one working channel; and

performing an action on a prostate capsule of the prostate via the at least one working channel of the endoscope, the action being selected from the group consisting of: incising and excising.

99. A method according to claim 98, further comprising creating a space in a vicinity of the prostate by inflating a balloon in the vicinity prior to performing the selected action..

100. Apparatus for treating an obstruction of a prostatic urethra of a subject, comprising:

an access needle; and

a cutting instrument, configured to perform an action on a prostate capsule of the subject, via the access needle, the action being selected from the group consisting of: incising, and excising.

101. The apparatus according to claim 100, further comprising a stylet configured to facilitate introduction of the needle into the subject.

102. A method for treating an obstruction of a prostatic urethra of a subject, comprising:

introducing at least one access needle from a lower abdomen of the subject toward an anterior surface of a prostate of the subject by following a retropubic approach; and

performing an action on a capsule of the prostate, via the at least one access needle, the action being selected from the group consisting of: incising, and excising.

103. The method according to claim 102, further comprising imaging the performing of the selected action, using an imaging device selected from the group consisting of: an ultrasound imaging device, an endoscopic imaging device; an MRI imaging device; and a CT imaging device.

104. The method according to claim 102, further comprising inserting a balloon to a vicinity of the anterior surface via the access needle, and creating a space in the vicinity by inflating the balloon.

105. Apparatus for treating an obstruction of a prostatic urethra of a subject, comprising a flexible device configured to be non-transurethrally placed inside a prostate of the subject and to reduce a constrictive force on a portion of a body of the subject, by exerting a radial force on the prostate, the portion being selected from the group consisting of: a urethra and a bladder neck.

106. The apparatus according to claim 105, wherein the device is configured to be implanted inside the subject's body.

107. A method for treating an obstruction of a prostatic urethra of a subject, comprising reducing a constrictive force on a portion of a body of the subject, by

exerting a radial force on a prostate of the subject, by non-transurethrally placing a flexible device inside the prostate, the portion being selected from the group consisting of: a urethra and a bladder neck.

108. The method according to claim 107, wherein non-transurethrally placing the flexible device inside the prostate comprises introducing the device from a lower abdomen of the subject toward an anterior surface of the prostate by following a retropubic approach.

109. A method for treating an obstruction of a prostatic urethra of a subject, comprising creating a lesion in a prostate capsule of a prostate of the subject, the lesion being selected from the group consisting of: an incision and an excision, and preventing the lesion from closing by exerting a radial force on the prostate, by placing a flexible device inside the prostate, subsequent to creating the lesion.

110. A method for treating an obstruction of a prostatic urethra of a subject, comprising creating a lesion in a prostate capsule of the subject, the lesion being selected from the group consisting of: an incision and an excision, and preventing the lesion from closing by placing at least one flexible device in a vicinity of the lesion.

111. A method, comprising performing an action on tissue of a subject by transperineally accessing the tissue, the action being selected from the group consisting of: incising, and excising, the tissue being selected from the group consisting of: prostate capsule tissue and prostate tissue of the subject.

112. The method according to claim 111, wherein performing the selected action on the tissue comprises treating an obstruction of a prostatic urethra of the subject.

113. The method according to claim 111, further comprising imaging the performing of the action using transrectal ultrasound imaging.

114. The method according to claim 111, wherein performing an action selected from the group consisting of: accessing the tissue, excising the tissue, and incising the tissue, comprises performing the selected action using an aid selected from the group consisting of: a computer-aid and a robotic-aid.

115. A method comprising performing an action on tissue of a subject by extra-urethrally accessing the tissue, the action being selected from the group consisting of: incising, and excising; the tissue being selected from the group consisting of: prostate capsule tissue and prostate tissue of the subject.

116. The method according to claim 115, wherein accessing the tissue comprises accessing the tissue without damaging the urethra.

117. The method according to claim 115, wherein accessing the tissue comprises accessing the tissue without puncturing the urethra.

118. The method according to claim 115, further comprising imaging the performing of the selected action using transrectal ultrasound imaging.

119. The method according to claim 115, wherein performing the selected action on the tissue comprises using an incision technique selected from the group consisting of: laser incision, RF incision, plasma incision, ultrasound incision and electrical incision.

120. Apparatus comprising a shaft having a sharp distal end, the apparatus being configured to facilitate an extraurethral action on the tissue by penetrating the tissue, the action being selected from the group consisting of: incising, and excising, the tissue being selected from the group consisting of: prostate capsule tissue and prostate tissue.

121. The apparatus according to claim 120, wherein the apparatus is configured to apply a pressing force to the tissue and to perform coagulation and cutting of the tissue subsequently to applying the pressing force to the tissue.

122. The apparatus according to claim 120, wherein the apparatus comprises a device configured to perform the selected action on the tissue, the device being selected from the group consisting of: a laser, an RF device, a plasma device, an ultrasound device, and an electrical device.

123. The apparatus according to any one of claims 120-122, further comprising a movable arm at a distal portion of the shaft.

124. The apparatus according to claim 123, wherein the arm is configured to press tissue located between the arm and the distal portion of the shaft, by the arm being at least partially closed with respect to the distal portion of the shaft.

FIG. 1

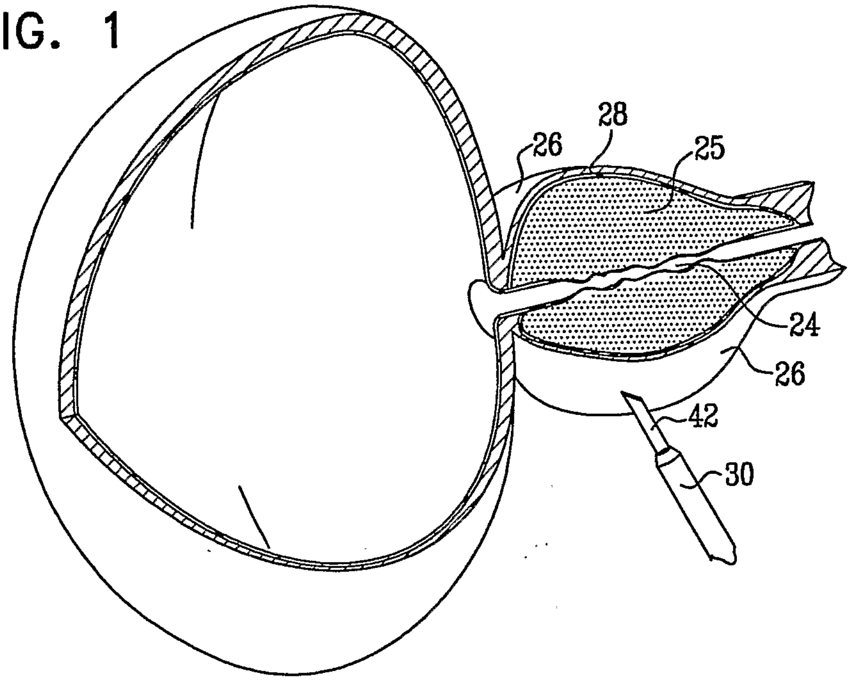
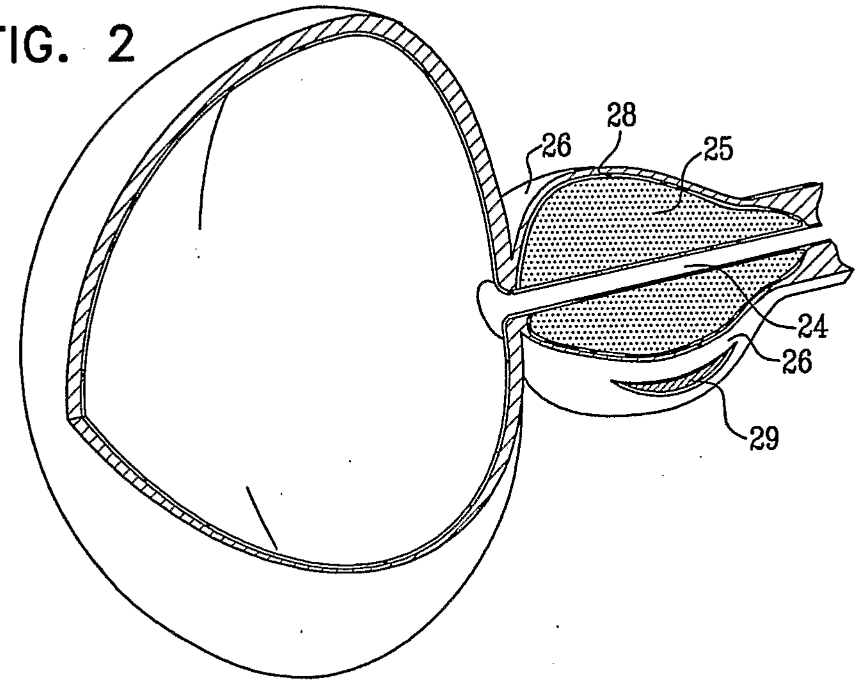


FIG. 2



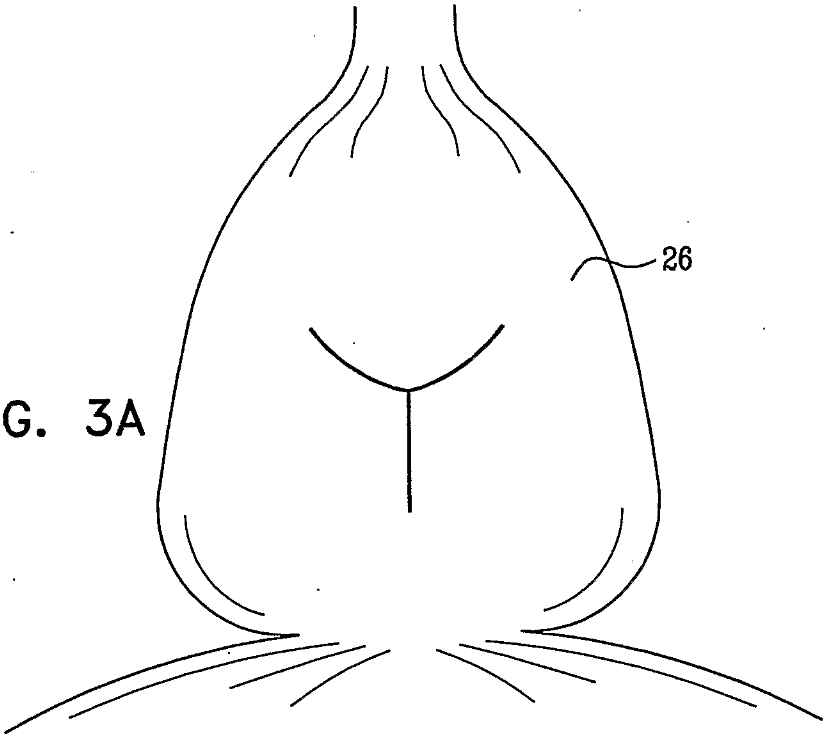


FIG. 3A

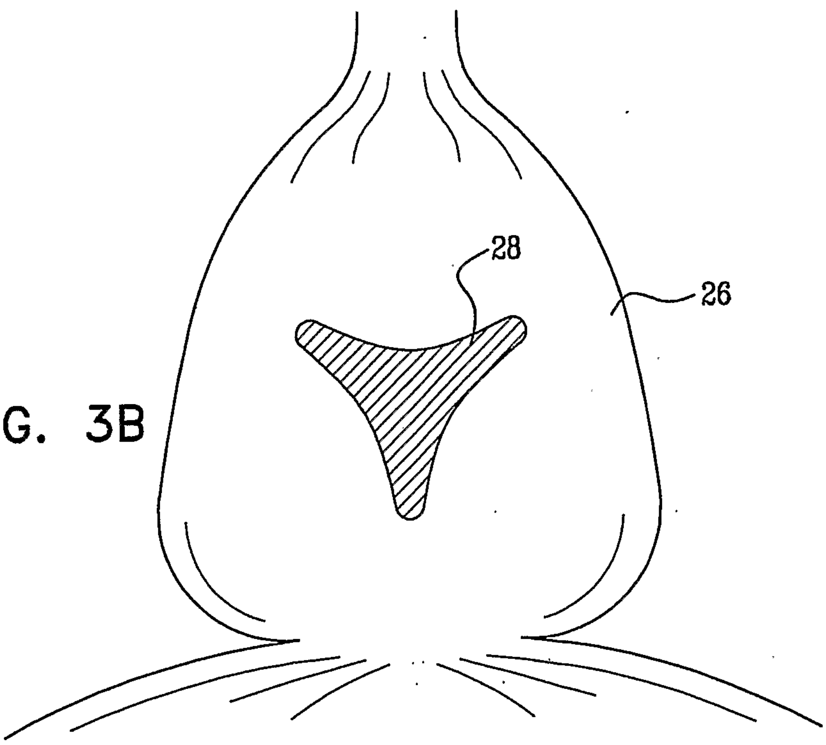


FIG. 3B

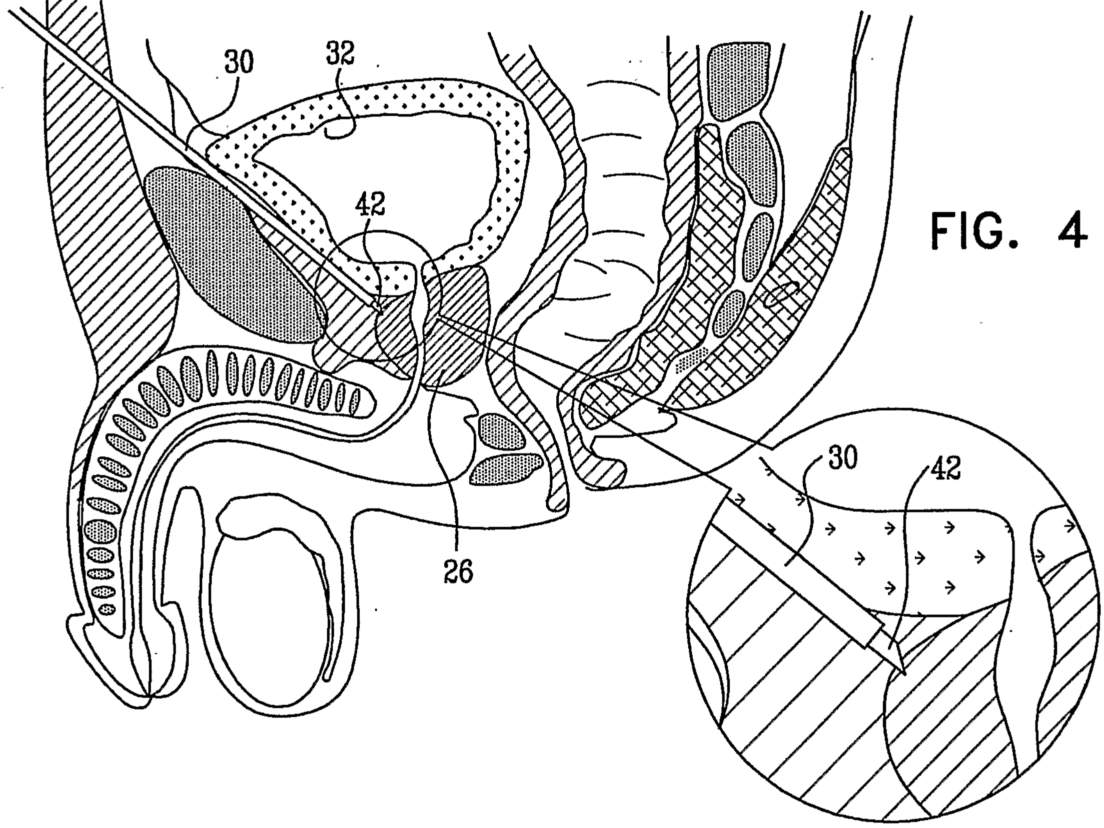


FIG. 4

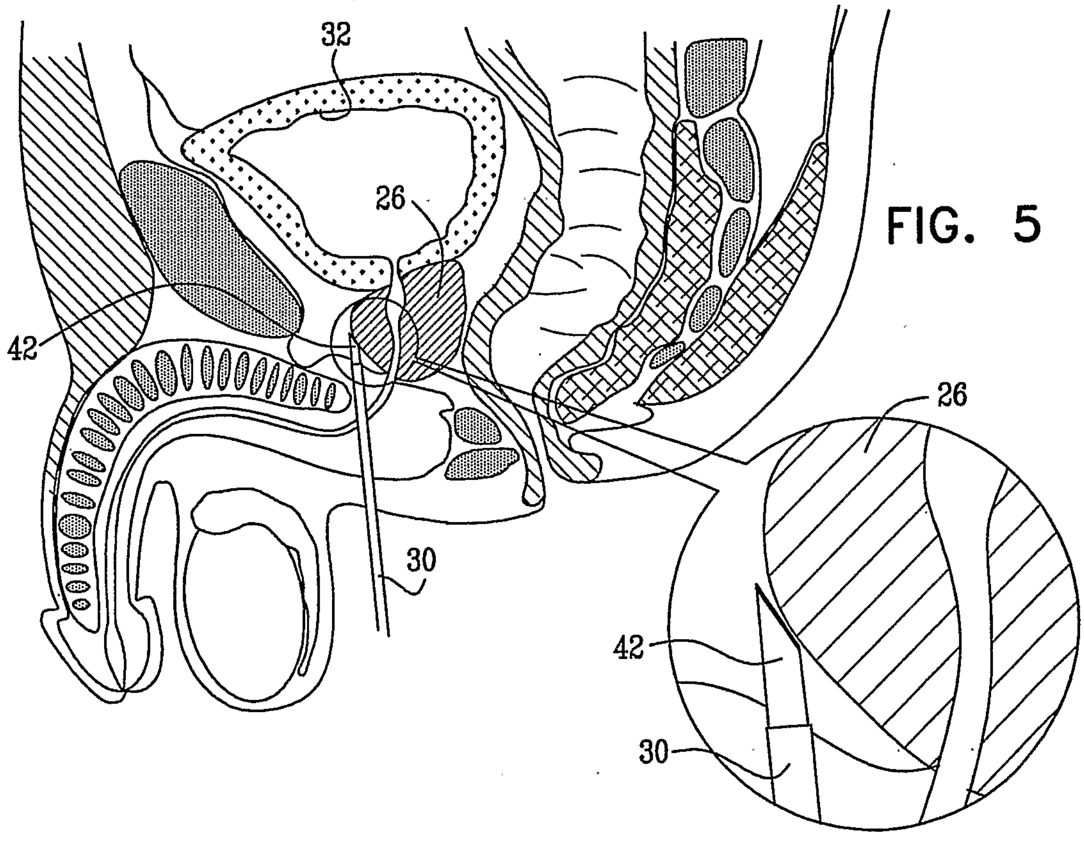


FIG. 5

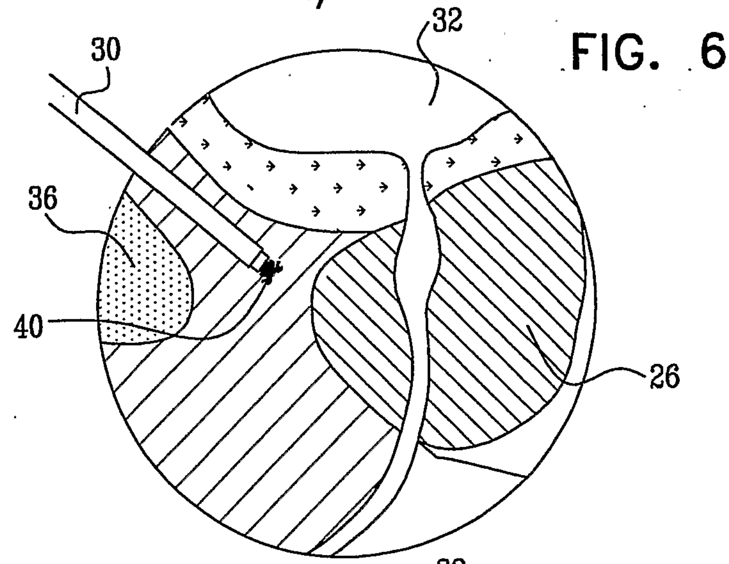


FIG. 6A

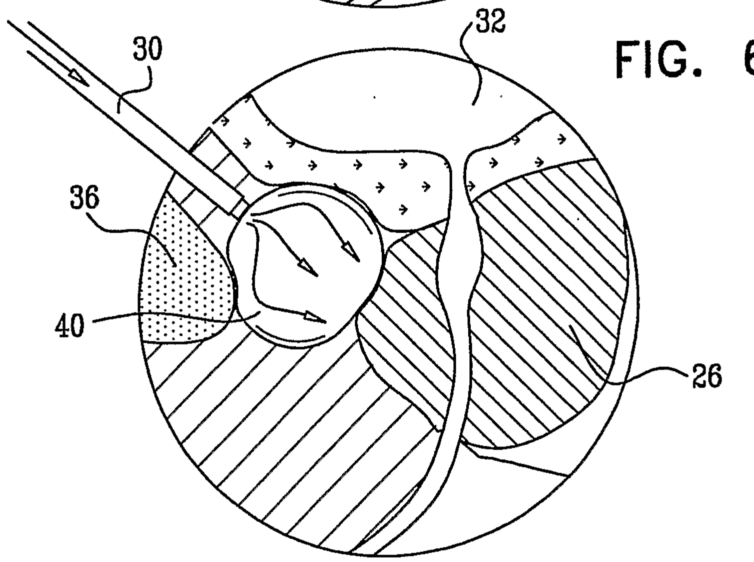


FIG. 6B

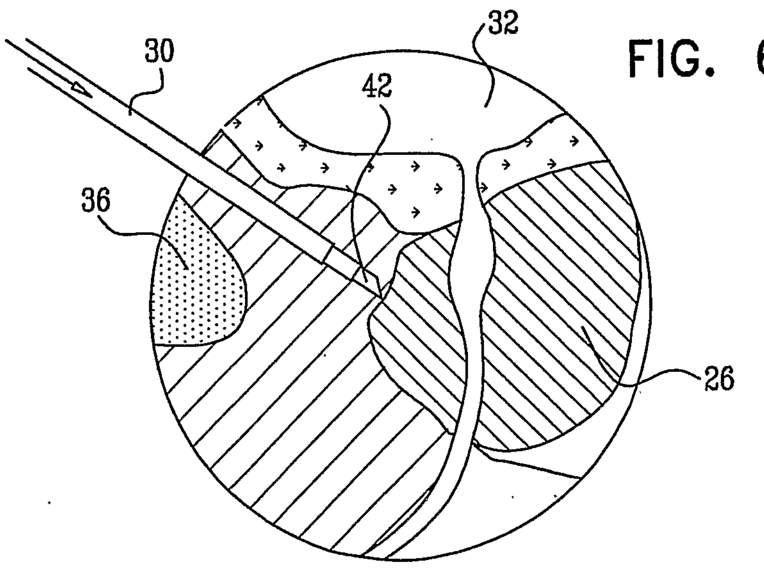


FIG. 6C

FIG. 7A

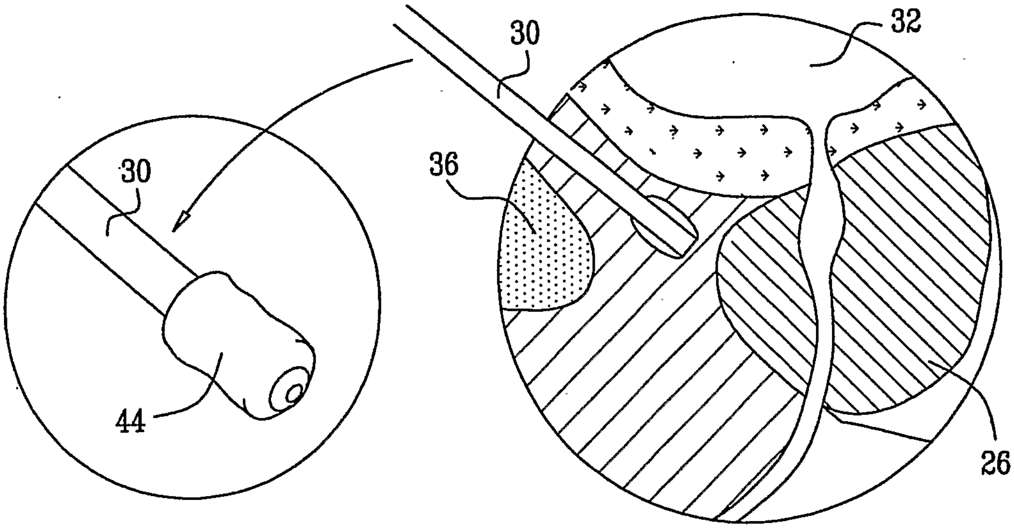


FIG. 7B

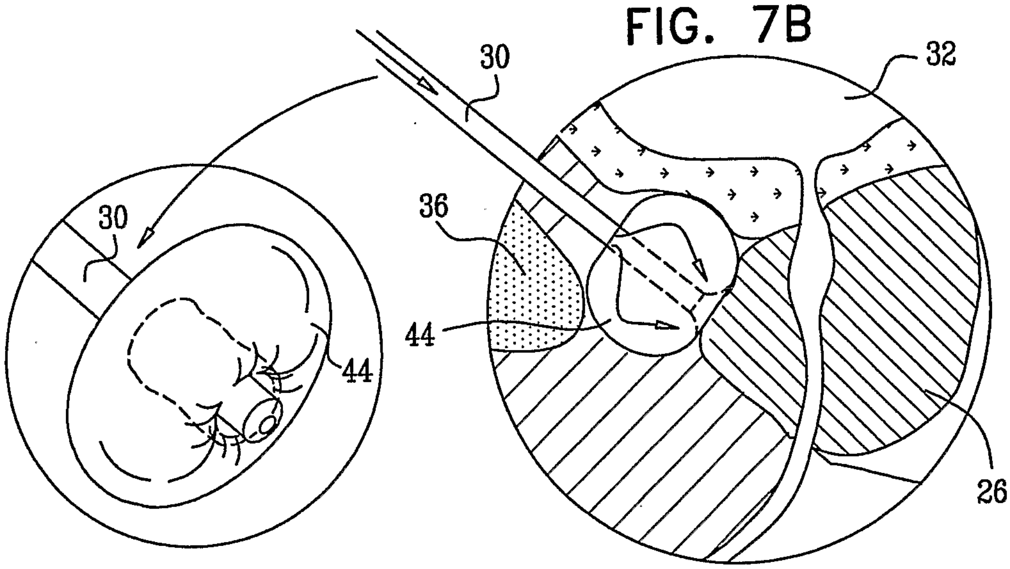


FIG. 7C

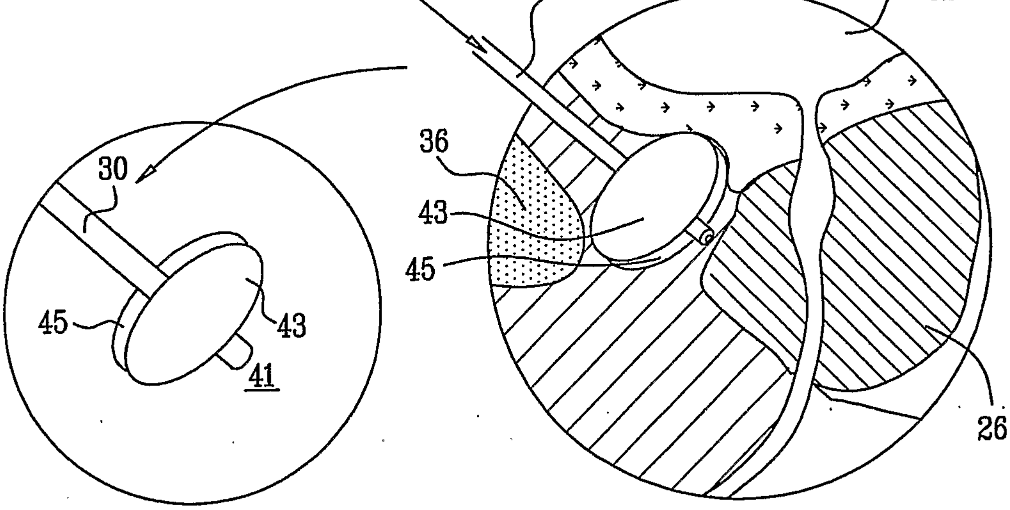


FIG. 8A

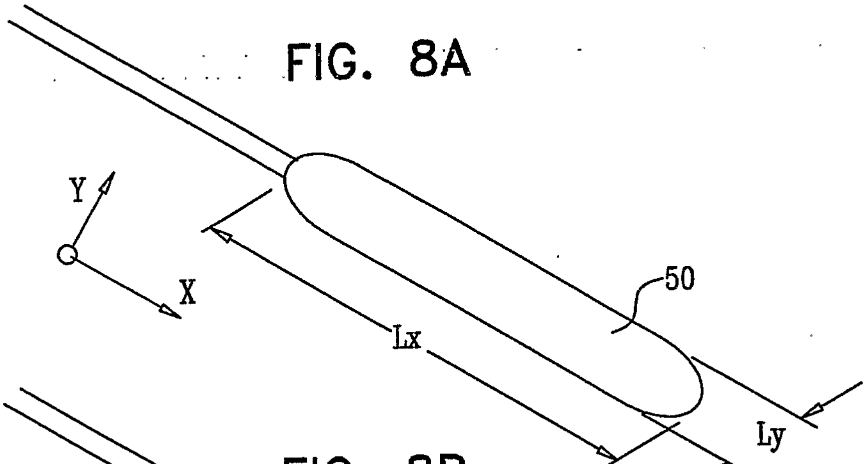


FIG. 8B

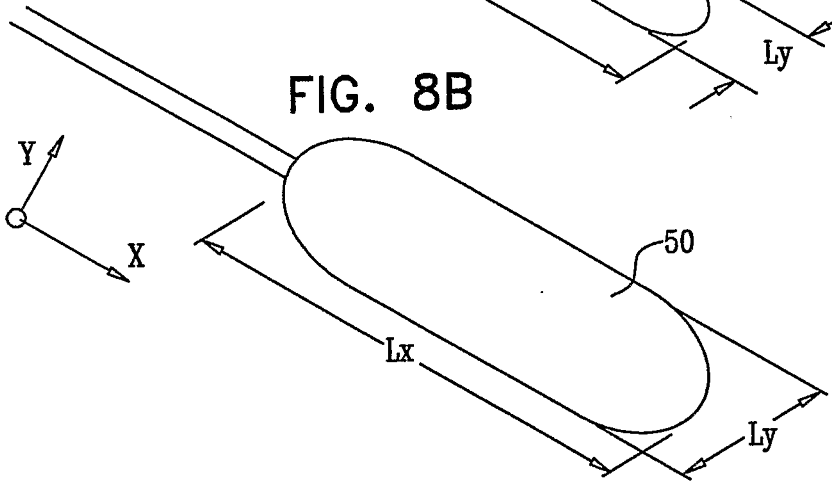


FIG. 8C

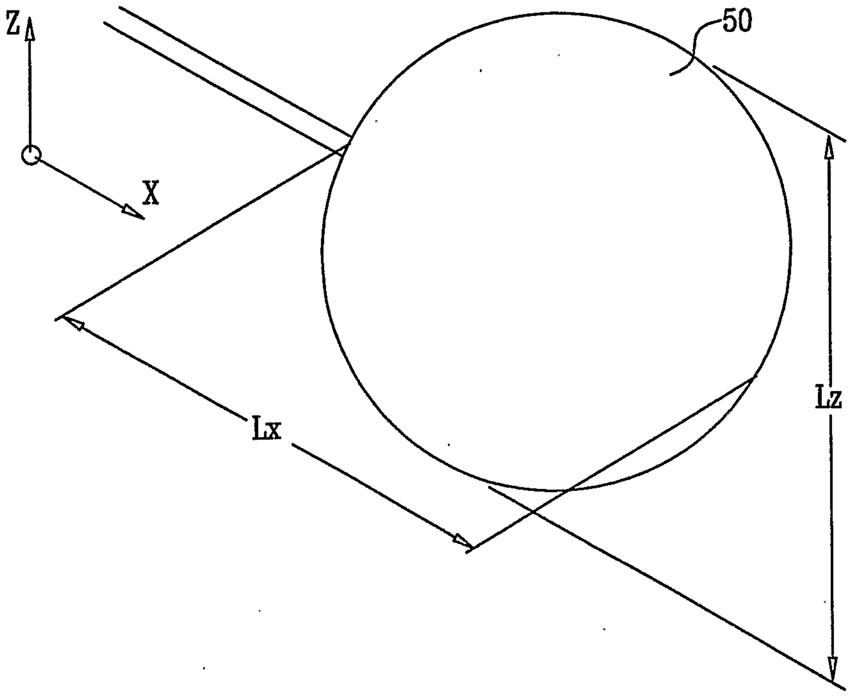
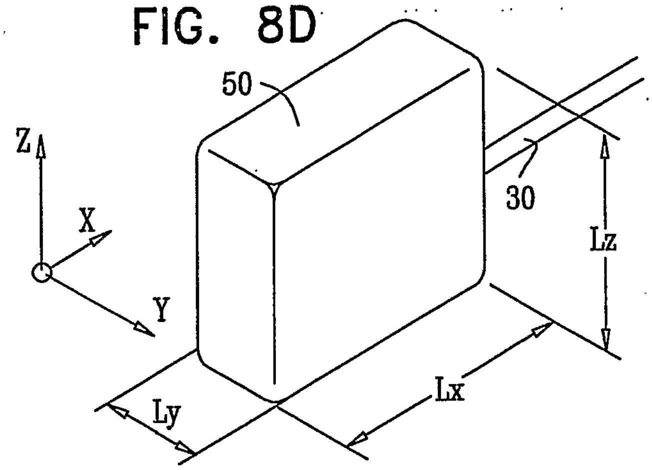


FIG. 8D



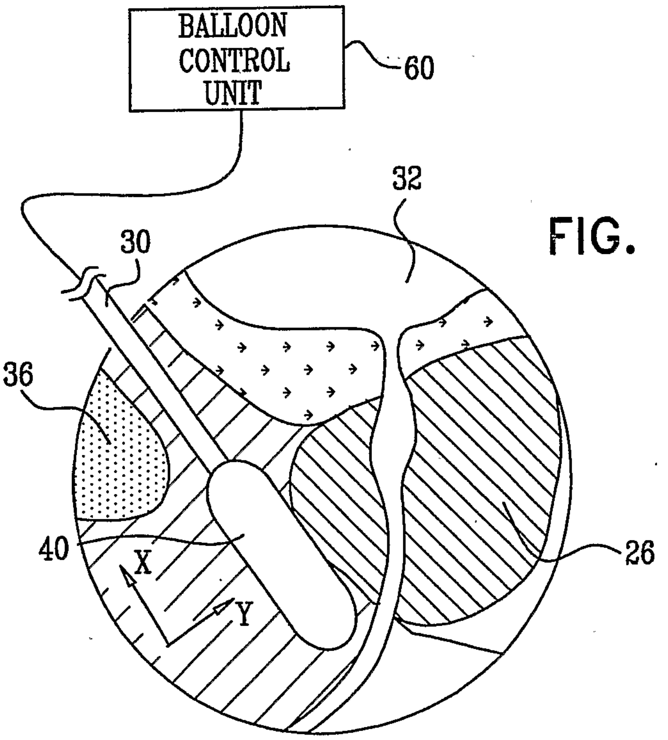


FIG. 8E

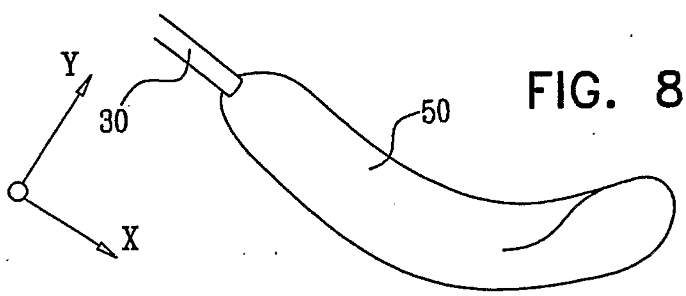


FIG. 8F

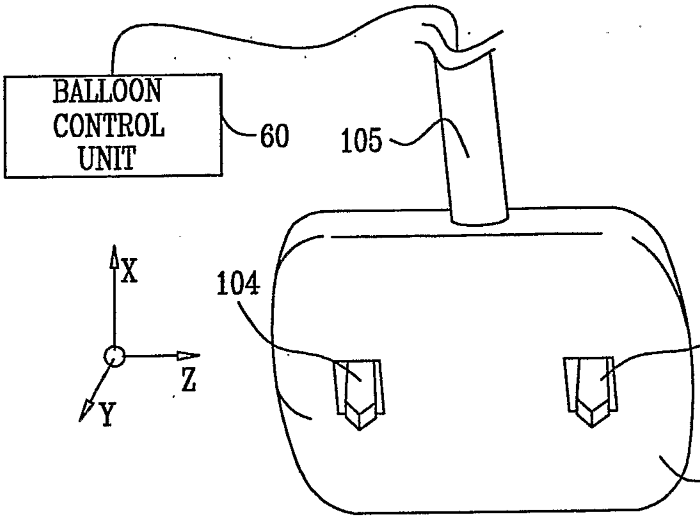


FIG. 9A

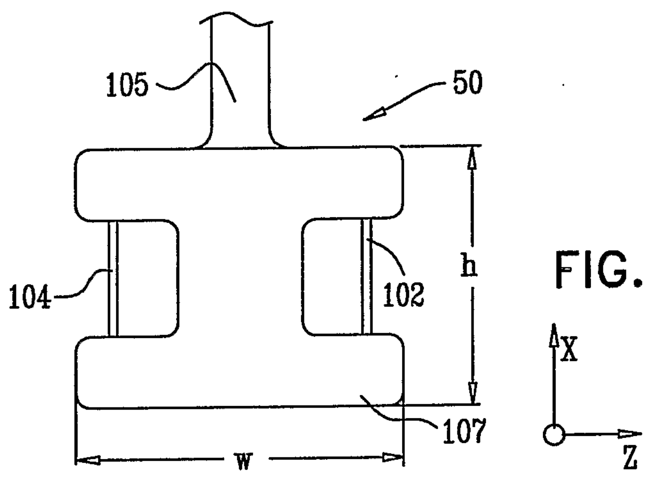


FIG. 9B

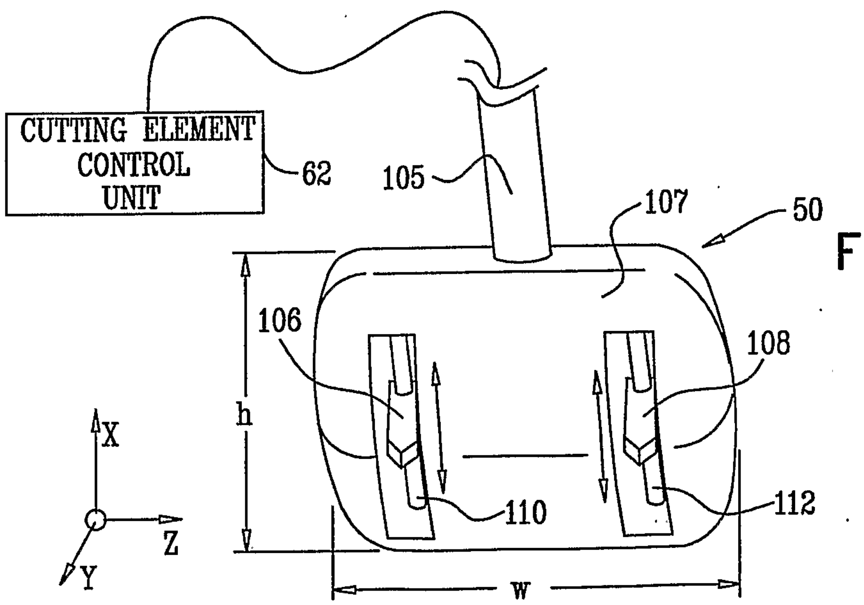


FIG. 9C

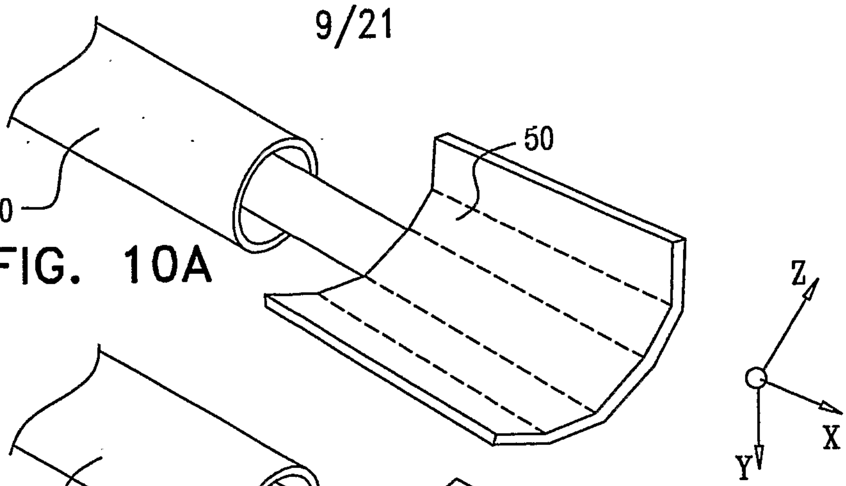


FIG. 10A

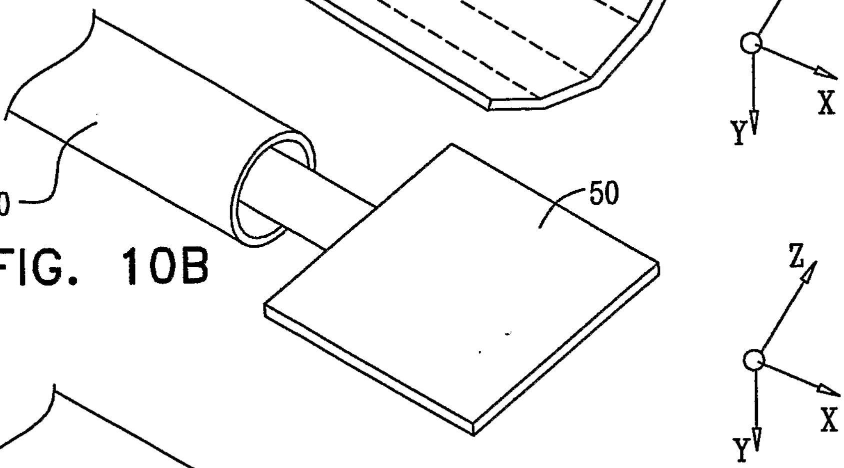


FIG. 10B

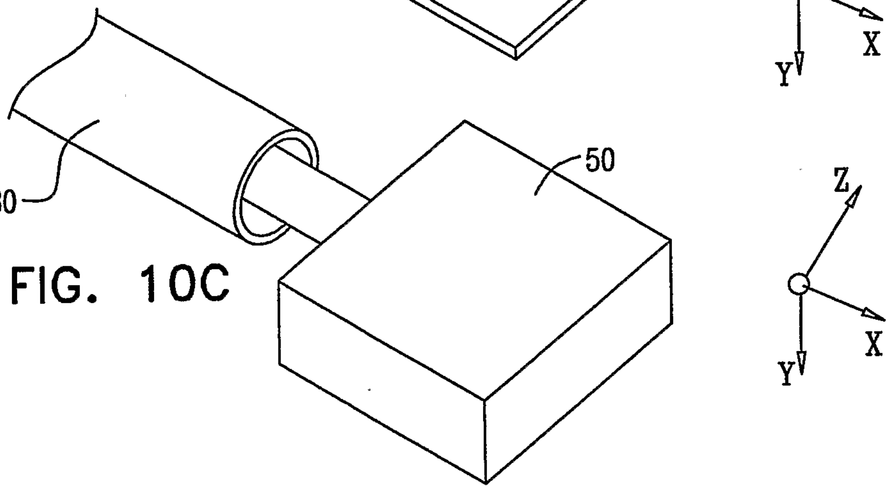


FIG. 10C

FIG. 11A

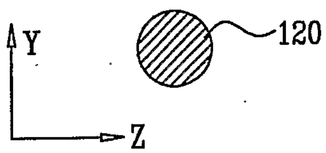


FIG. 11B

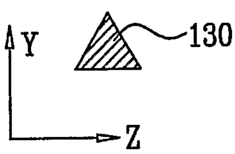


FIG. 11C

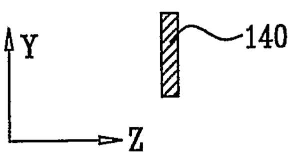


FIG. 11D

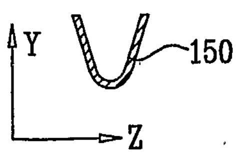


FIG. 12A

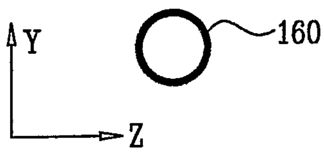


FIG. 12B

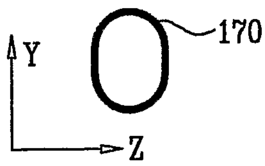


FIG. 12C

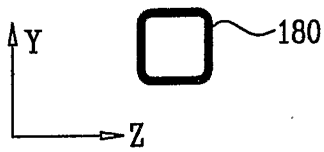


FIG. 12D

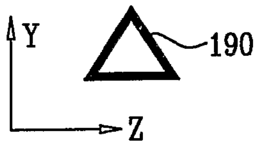


FIG. 13

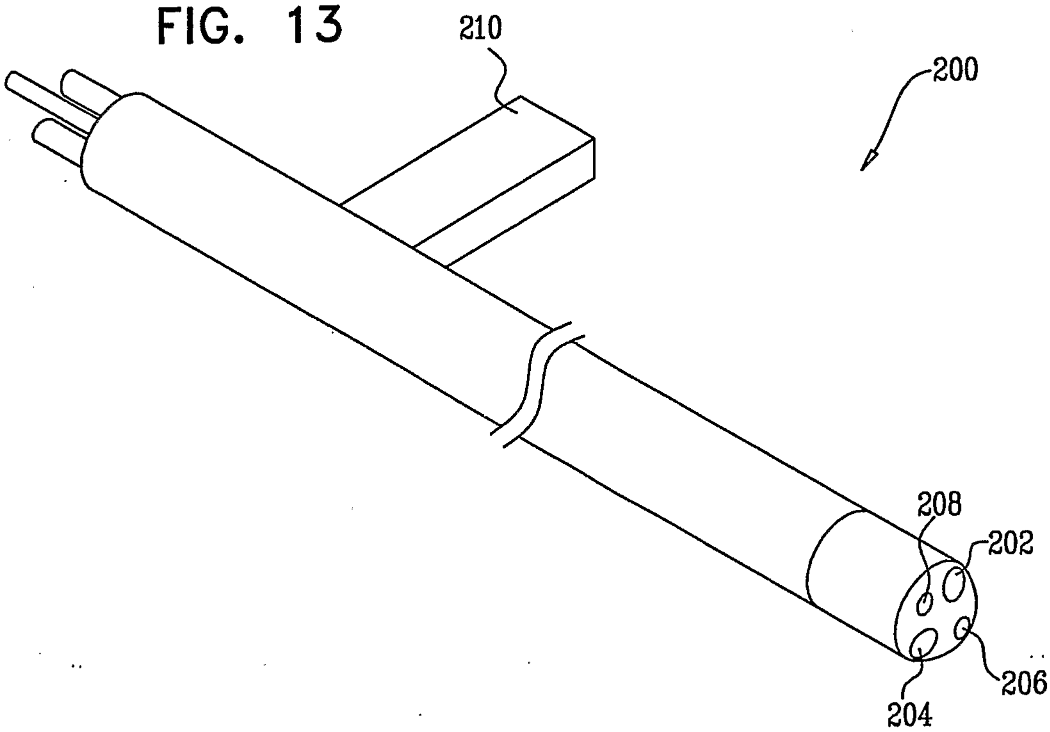


FIG. 14A

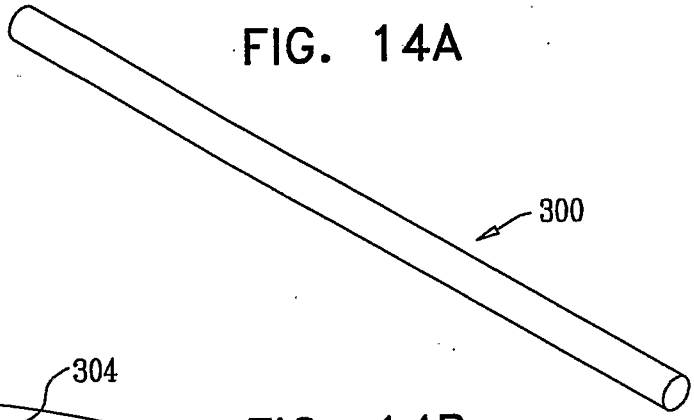


FIG. 14B

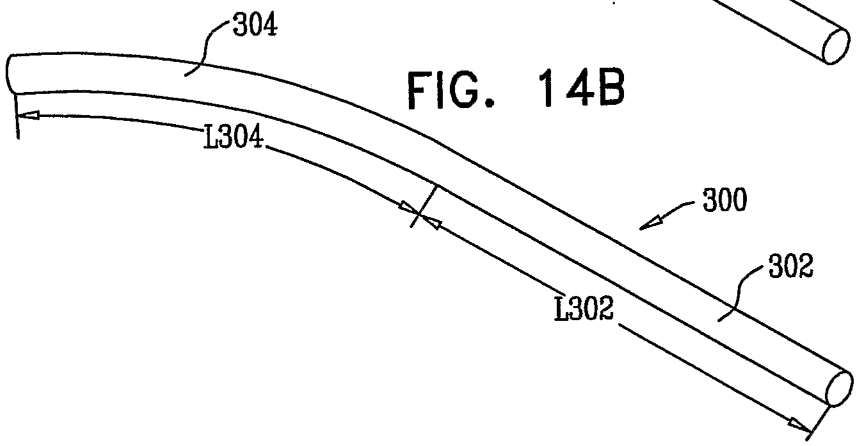


FIG. 15A

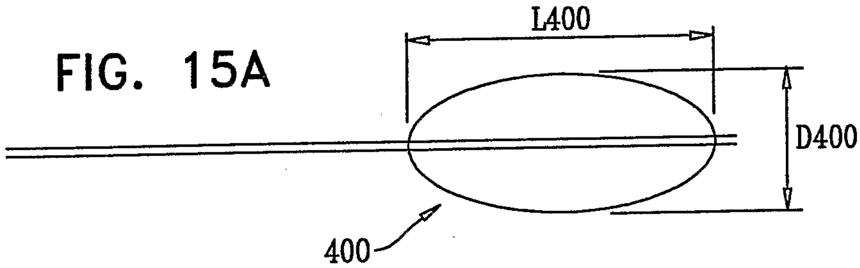
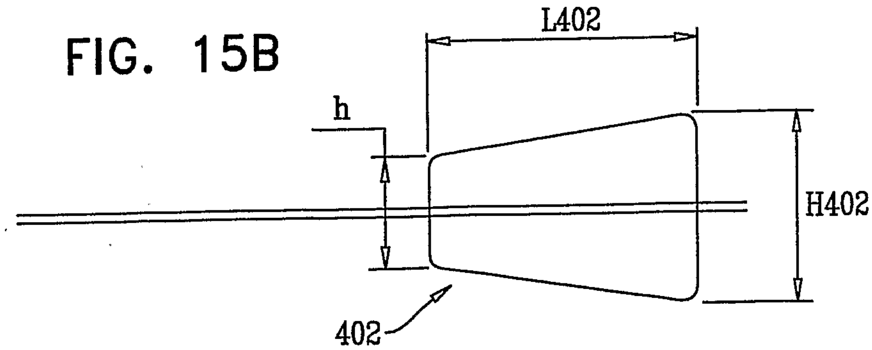


FIG. 15B



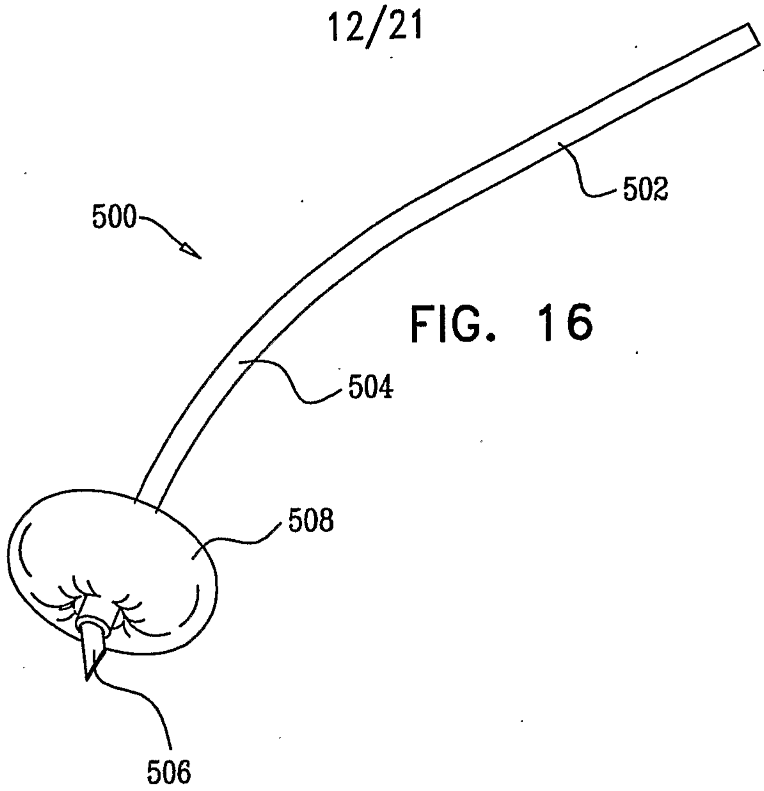


FIG. 16

FIG. 17A

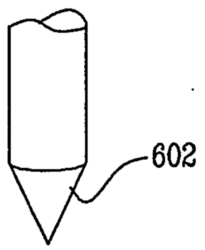


FIG. 17B

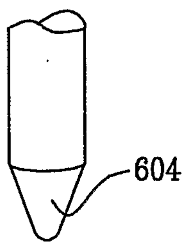


FIG. 17C

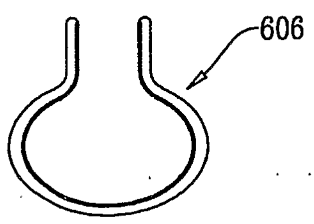


FIG. 18A

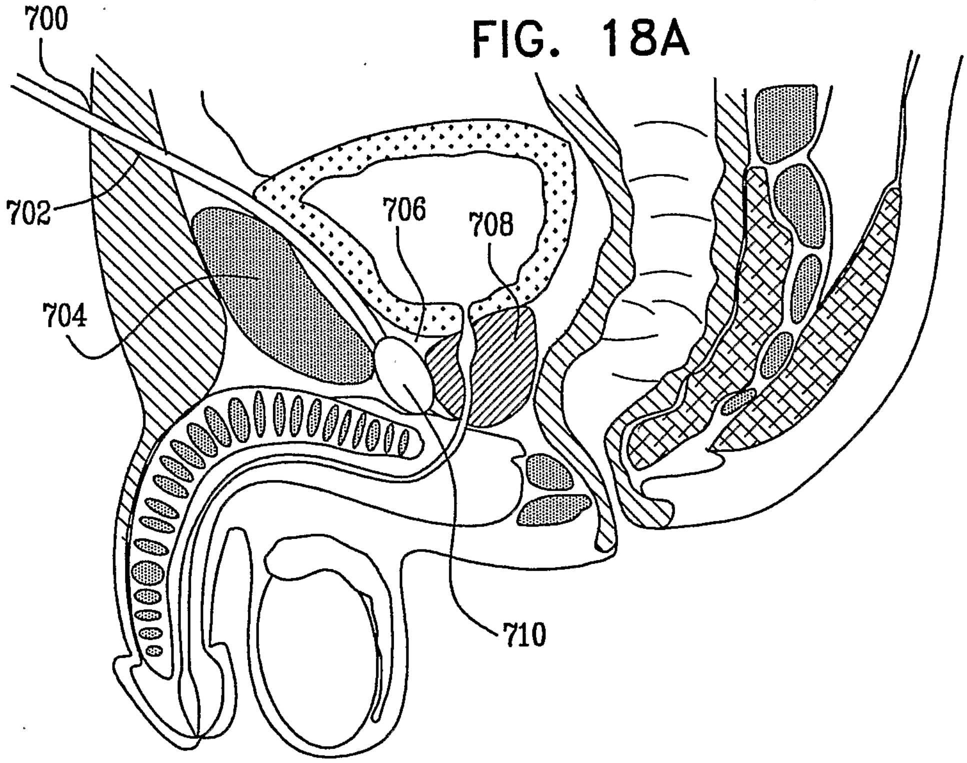


FIG. 18B

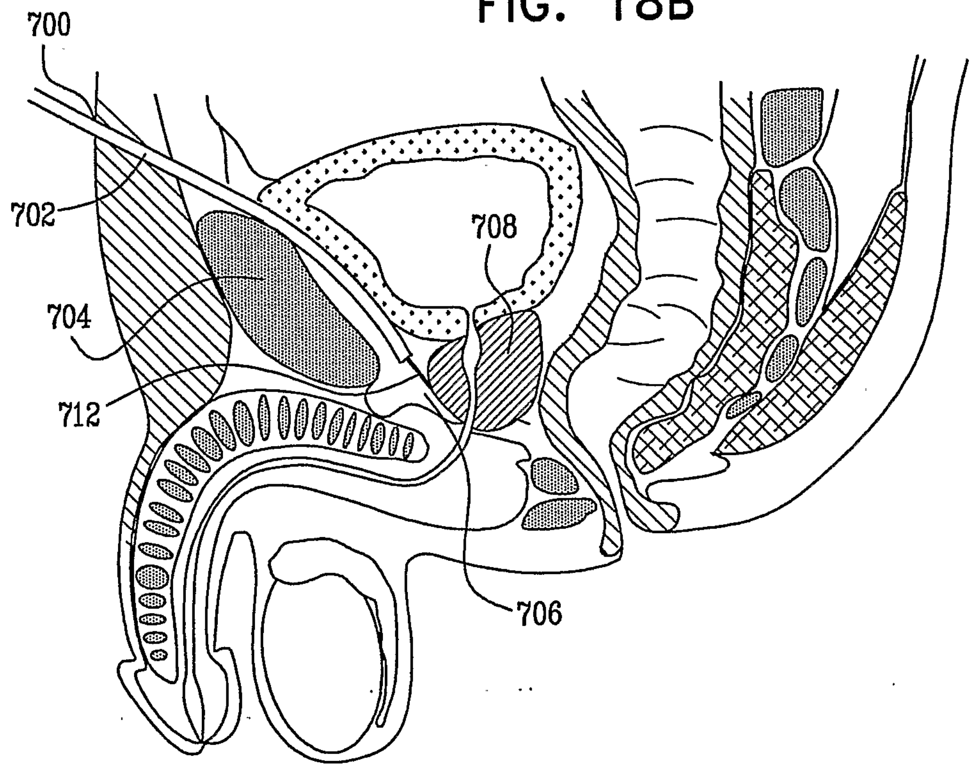


FIG. 19

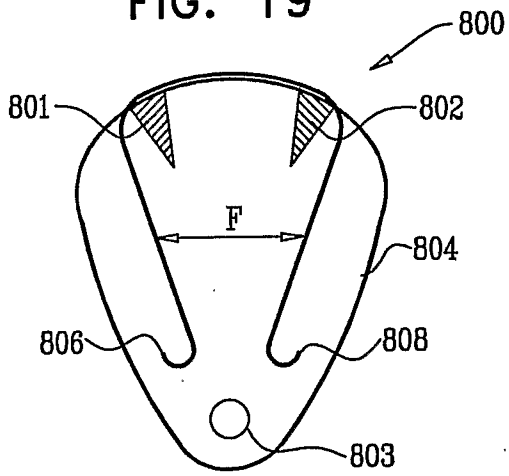
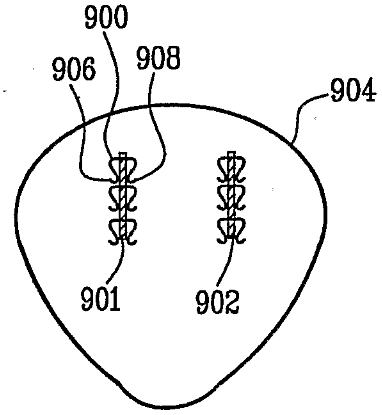


FIG. 20



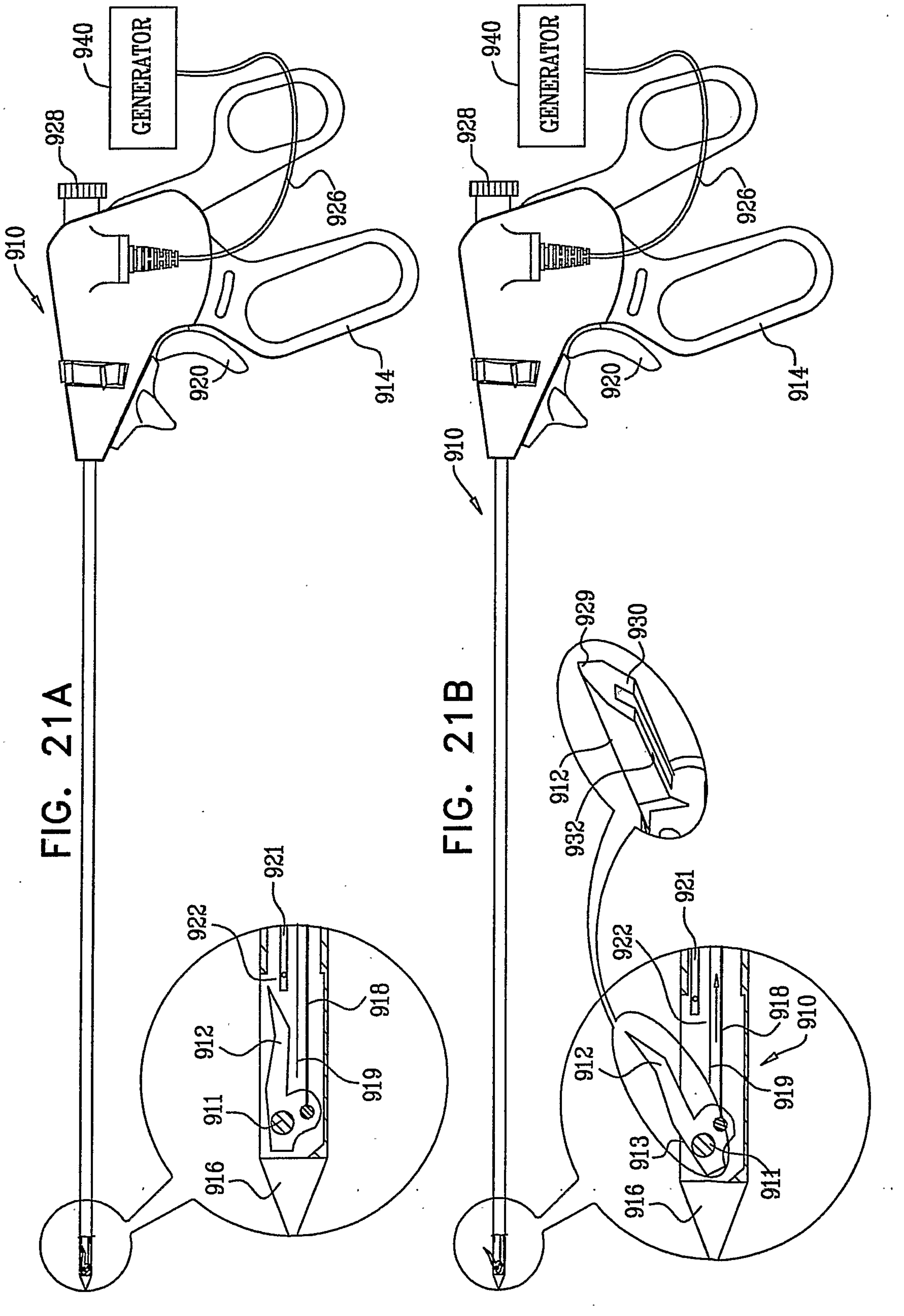


FIG. 21A

FIG. 21B

FIG. 22

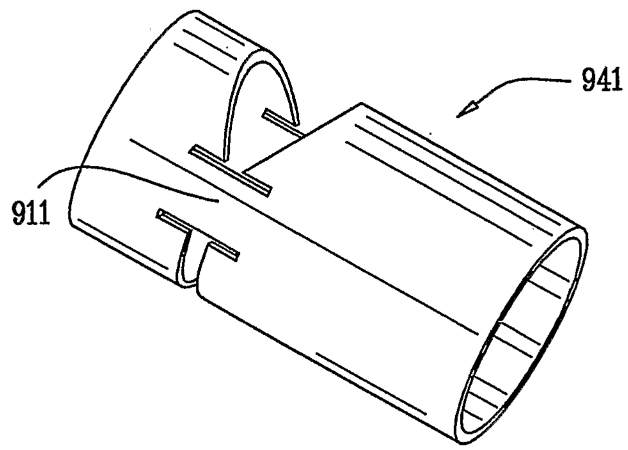


FIG. 23A

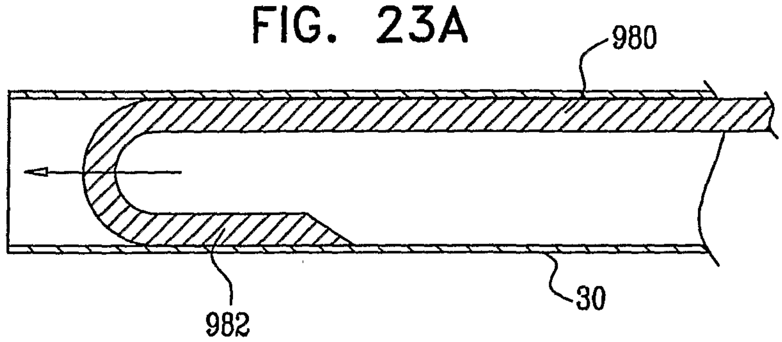


FIG. 23B

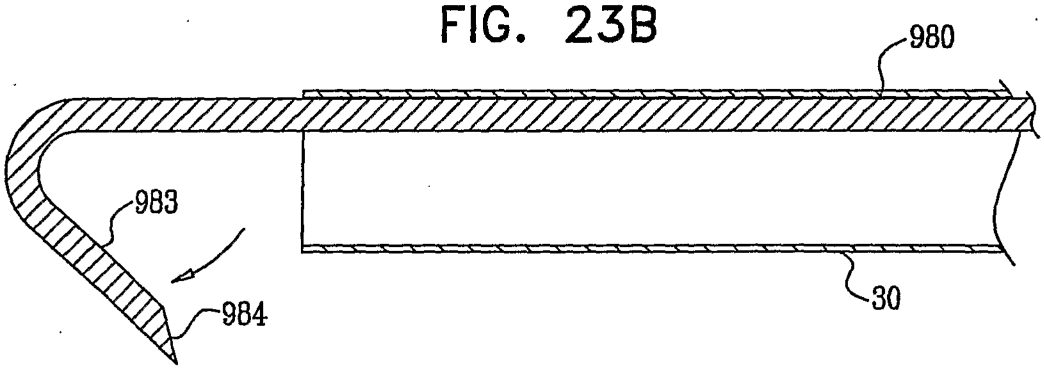


FIG. 24A

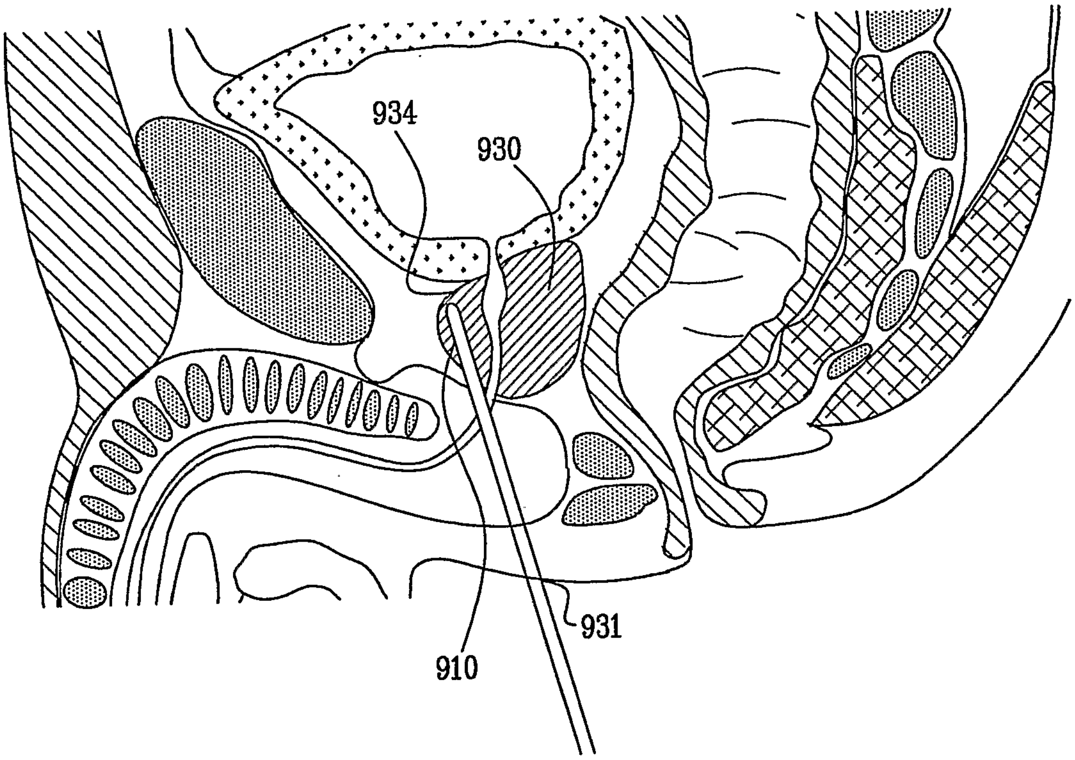


FIG. 24B

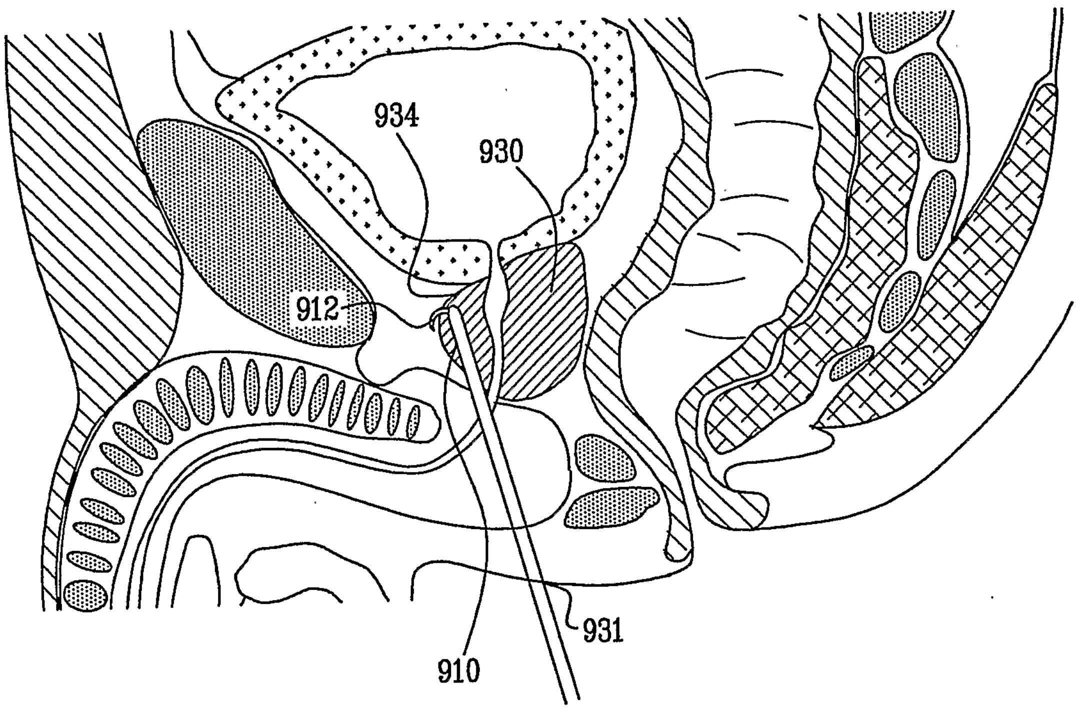


FIG. 24C

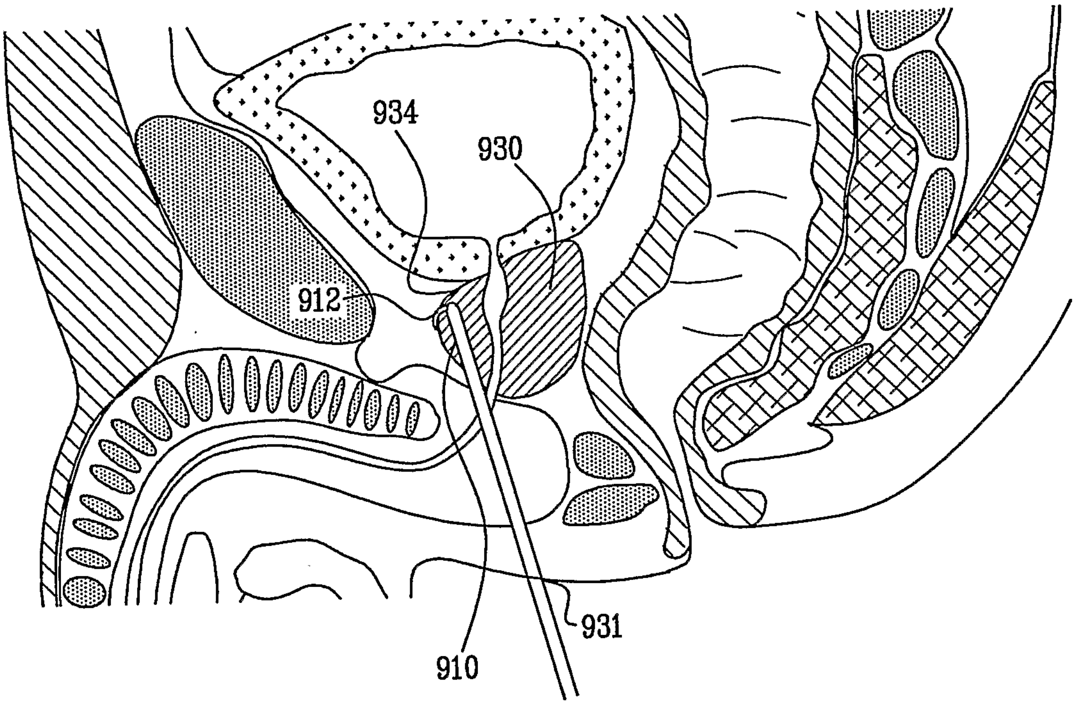


FIG. 24D

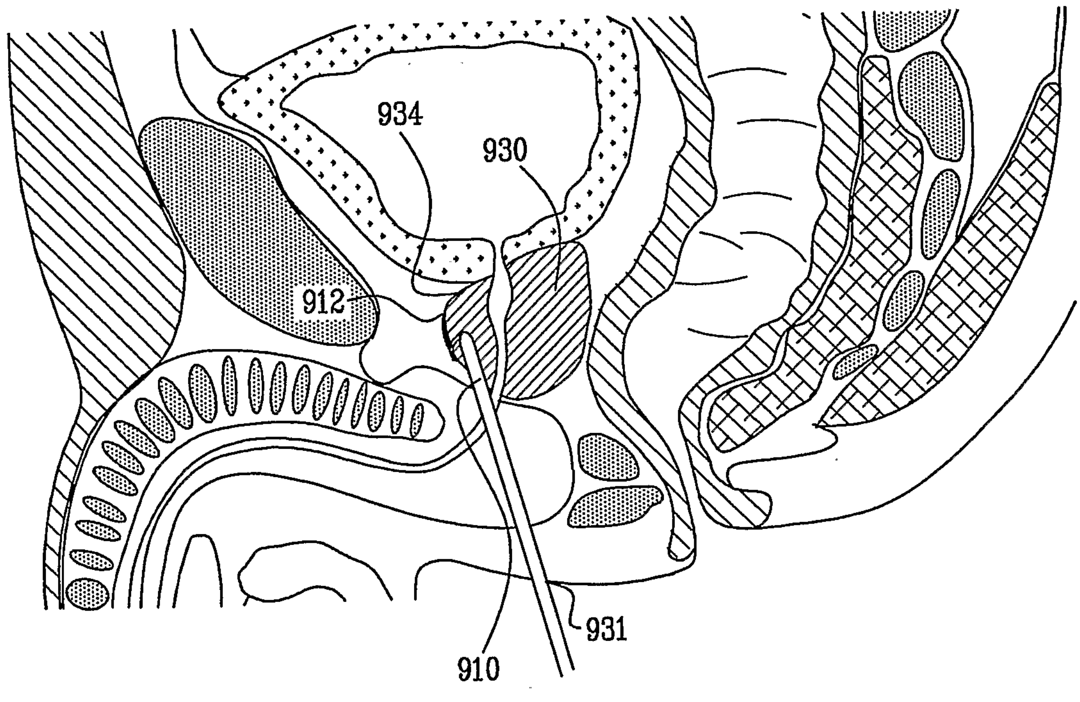
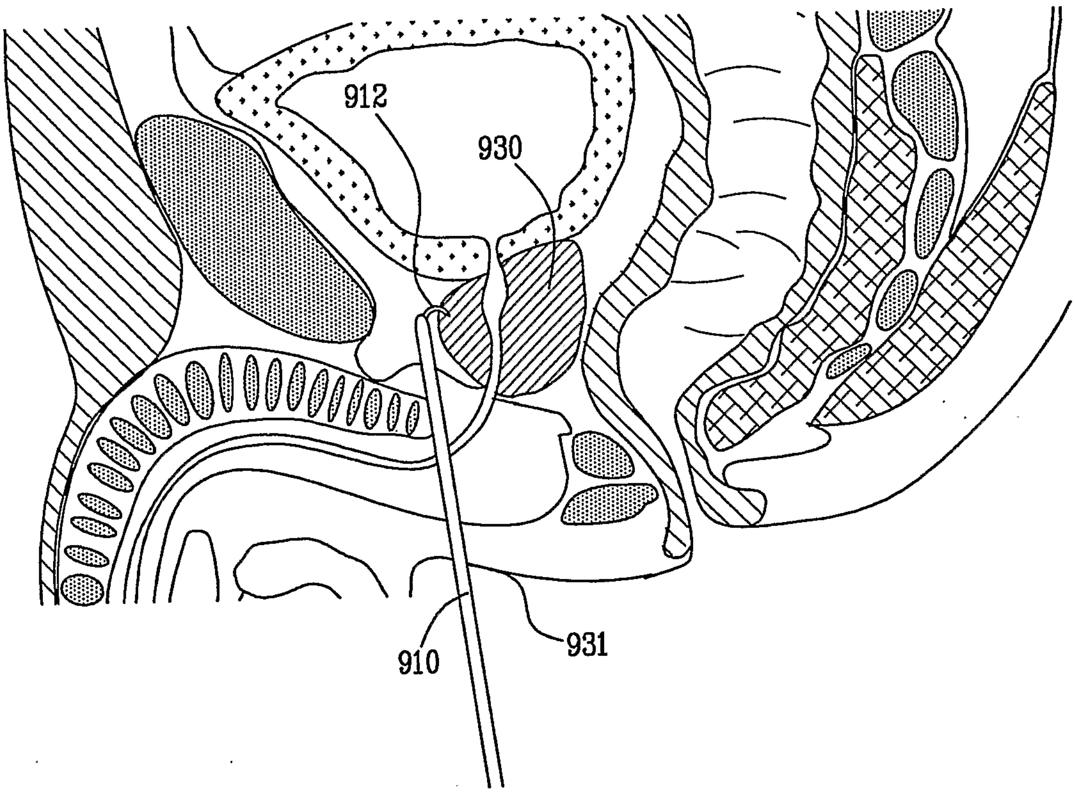


FIG. 24E



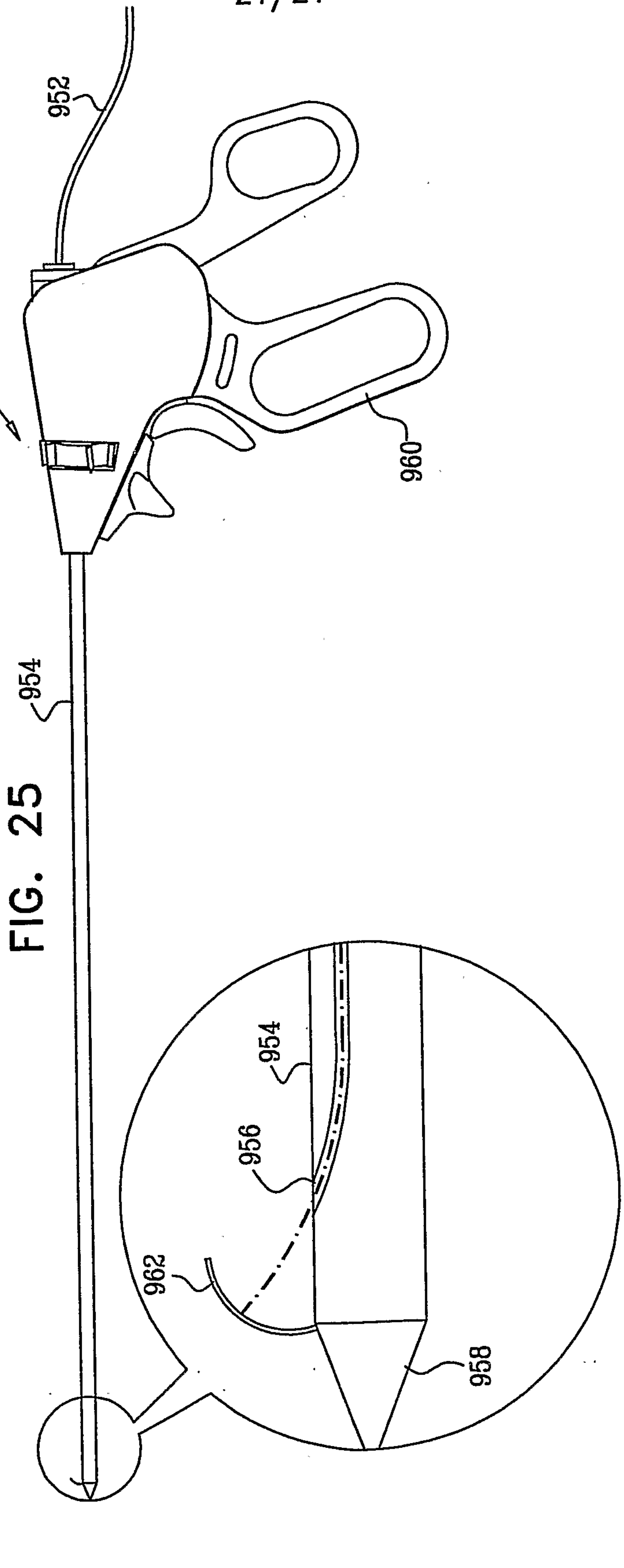


FIG. 25