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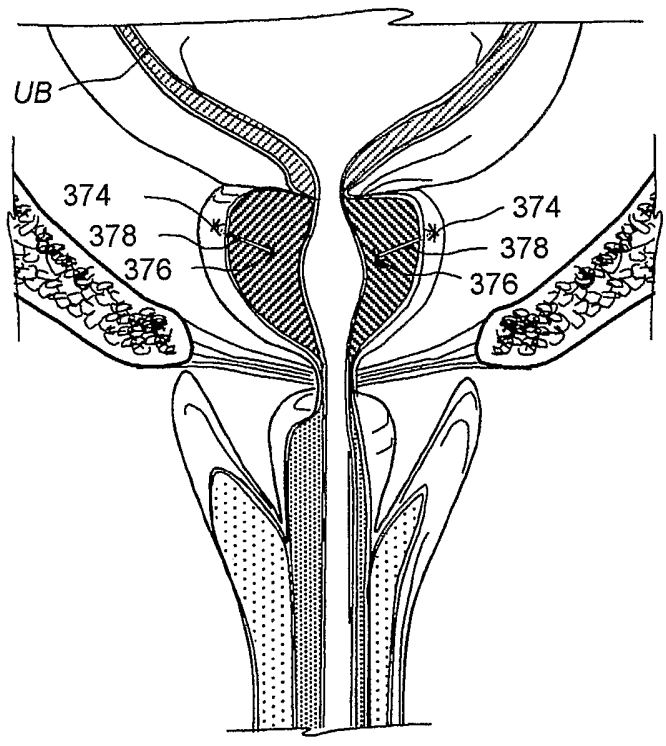
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(54) Title: DEVICES, SYSTEMS AND METHODS FOR TREATING BENIGN PROSTATIC HYPERPLASIA AND OTHER CONDITIONS



(57) Abstract: Devices, systems and methods for compressing, cutting, incising, reconfiguring, remodeling, attaching, repositioning, supporting, dislocating or altering the composition of tissues or anatomical structures to alter their positional or force relationship to other tissues or anatomical structures. In some applications, the invention may be used to used to improve patency or fluid flow through a body lumen or cavity (e.g., to limit constriction of the urethra by an enlarged prostate gland).

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DEVICES, SYSTEMS AND METHODS FOR TREATING BENIGN PROSTATIC HYPERPLASIA AND OTHER CONDITIONS

FIELD OF THE INVENTION

The present invention relates generally to medical devices and methods and more particularly to devices, systems and methods for treating conditions wherein a tissue (e.g., the prostate gland) has a) become enlarged and/or b) undergone a change in form, position, structure, rigidity or force exertion with respect to another anatomical structure and/or c) has begun to impinge upon or compress an adjacent anatomical structure (e.g., the urethra).

BACKGROUND OF THE INVENTION

There are numerous pathological and nonpathological conditions in which a tissue (e.g., a gland, tumor, cyst, muscle, fascia, skin, adipose, mucous membrane, etc.) becomes enlarged, changed form or position and/or causes unwanted impingement, obstruction, occlusion, stretching, sagging, caving, expulsion and/or collapse of an adjacent body lumen or anatomical structure (e.g., the urethra). Examples of specific conditions which illustrate these medical problems include tissue relaxation or collapse (loose skin, fat or muscle folds, vaginal, rectal, or bladder prolapse,, incontinence, etc.), tissue remodeling (scar formation, bladder stiffness secondary to chronic overexertion, infiltrative lung disease), traumatic injury, surgical manipulation (i.e. removal of supportive tissues, removal of tumors, reattachment of ligaments, etc.), tissue growth or enlargement (i.e. benign growths, cancers, angiomas, bone spurs, etc.), luminal obstruction or occlusion (coronary artery disease, peripheral vascular disease, stroke, non-communicating hydrocephalus, infertility secondary to non-patent fallopian tubes, urinary tract obstruction, etc.), tissue impingement (slipped spinal disks, degenerative joint disease, etc.), and ptosis.

In particular, Benign Prostatic Hyperplasia (BPH) is one of the most common medical conditions that affect men, especially elderly men. It has been reported that, in the United Sates, more than half of all men have histopathologic evidence of BPH by age 60 and, by age 85, approximately 9 out of 10 men suffer from the condition. Moreover, the incidence and prevalence of BPH are expected to increase as the average age of the population in developed countries increases.

The prostate gland enlarges throughout a man's life. In some men, the prostatic capsule around the prostate gland may prevent the prostate gland from enlarging further. This causes the inner region of the prostate gland to squeeze the urethra. This compression of the urethra increases resistance to urine flow through the region of the urethra enclosed by the prostate. Thus the urinary bladder has to exert more pressure to force urine through the increased resistance of the urethra. Chronic over-exertion causes the muscular walls of the urinary bladder to remodel and become stiffer. This combination of increased urethral resistance to urine flow and stiffness and hypertrophy of urinary bladder walls leads to a variety of lower urinary tract symptoms (LUTS) that may severely reduce the patient's quality of life. These symptoms include weak or intermittent urine flow while urinating, straining when urinating, hesitation before urine flow starts, feeling that the bladder has not emptied completely even after urination, dribbling at the end of urination or leakage afterward, increased frequency of urination particularly at night, urgent need to urinate etc.

In addition to patients with BPH, LUTS may also be present in patients with prostate cancer, prostate infections, and chronic use of certain medications (e.g. ephedrine, pseudoephedrine, phenylpropanolamine, antihistamines such as diphenhydramine, chlorpheniramine etc.) that cause urinary retention especially in men with prostate enlargement.

Although BPH is rarely life threatening, it can lead to numerous clinical conditions including urinary retention, renal insufficiency, recurrent urinary

tract infection, incontinence, hematuria, and bladder stones.

In developed countries, a large percentage of the patient population undergoes treatment for BPH symptoms. It has been estimated that by the age of 80 years, approximately 25% of the male population of the United States will have undergone some form of BPH treatment. At present, the available treatment options for BPH include watchful waiting, medications (phytotherapy and prescription medications), surgery and minimally invasive procedures.

For patients who choose the watchful waiting option, no immediate treatment is provided to the patient, but the patient undergoes regular exams to monitor progression of the disease. This is usually done on patients that have minimal symptoms that are not especially bothersome.

Medications for treating BPH symptoms include phytotherapy and prescription medications. In phytotherapy, plant products such as Saw Palmetto, African Pygeum, Serenoa repens (sago palm) and South African star grass are administered to the patient. Prescription medications are prescribed as first line therapy in patients with symptoms that are interfering with their daily activities. Two main classes of prescription medications are alpha-1a-adrenergic receptors blockers and 5-alpha-reductase inhibitors. Alpha-1a-adrenergic receptors blockers block that activity of alpha-1a-adrenergic receptors that are responsible for causing constriction of smooth muscle cells in the prostate. Thus, blocking the activity of alpha-1a-adrenergic receptors causes prostatic smooth muscle relaxation. This in turn reduces urethral resistance thereby reducing the severity of the symptoms. 5-alpha-reductase inhibitors block the conversion of testosterone to dihydrotestosterone. Dihydrotestosterone causes growth of epithelial cells in the prostate gland. Thus 5-alpha-reductase inhibitors cause regression of epithelial cells in the prostate gland and hence reduce the volume of the prostate gland which in turn reduces the severity of the symptoms.

Surgical procedures for treating BPH symptoms include Transurethal Resection of Prostate (TURP), Transurethral Electrovaporization of Prostate

(TVP), Transurethral Incision of the Prostate (TUIP), Laser Prostatectomy and Open Prostatectomy.

Transurethal Resection of Prostate (TURP) is the most commonly practiced surgical procedure implemented for the treatment of BPH. In this procedure, prostatic urethral obstruction is reduced by removing most of the prostatic urethra and a sizeable volume of the surrounding prostate gland. This is carried out under general or spinal anesthesia. In this procedure, a urologist visualizes the urethra by inserting a resectoscope, that houses an optical lens in communication with a video camera, into the urethra such that the distal region of the resectoscope is in the region of the urethra surrounded by the prostate gland. The distal region of the resectoscope consists of an electric cutting loop that can cut prostatic tissue when an electric current is applied to the device. An electric return pad is placed on the patient to close the cutting circuit. The electric cutting loop is used to scrape away tissue from the inside of the prostate gland. The tissue that is scraped away is flushed out of the urinary system using an irrigation fluid. Using a coagulation energy setting, the loop is also used to cauterize transected vessels during the operation.

Another example of a surgical procedure for treating BPH symptoms is Transurethral Electrovaporization of the Prostate (TVP). In this procedure, a part of prostatic tissue squeezing the urethra is desiccated or vaporized. This is carried out under general or spinal anesthesia. In this procedure, a resectoscope is inserted transurethrally such that the distal region of the resectoscope is in the region of the urethra surrounded by the prostate gland. The distal region of the resectoscope consists of a rollerball or a grooved roller electrode. A controlled amount of electric current is passed through the electrode. The surrounding tissue is rapidly heated up and vaporized to create a vaporized space. Thus the region of urethra that is blocked by the surrounding prostate gland is opened up.

Another example of a surgical procedure for treating BPH symptoms is Transurethral Incision of the Prostate (TUIP). In this procedure, the resistance to urine flow is reduced by making one or more incisions in the prostrate gland

in the region where the urethra meets the urinary bladder. This procedure is performed under general or spinal anesthesia. In this procedure, one or more incisions are made in the muscle of the bladder neck, which is the region where the urethra meets the urinary bladder. The incisions are in most cases are deep enough to cut the surrounding prostate gland tissue including the prostatic capsule. This releases any compression on the bladder neck and causes the bladder neck to spring apart. The incisions can be made using a resectoscope, laser beam etc.

Another example of a surgical procedure for treating BPH symptoms is Laser Prostatectomy. Two common techniques used for Laser Prostatectomy are Visual Laser Ablation of the Prostate (VLAP) and the Holmium Laser Resection/Enucleation of the Prostate (HoLEP). In VLAP, a neodymium:yttrium-aluminum-garnet (Nd:YAG) laser is used to ablate tissue by causing coagulation necrosis. The procedure is performed under visual guidance. In HoLEP, a holmium: Yttrium-aluminum-garnet laser is used for direct contact ablation of tissue. Both these techniques are used to remove tissue obstructing the urethral passage to reduce the severity of BPH symptoms.

Another example of a surgical procedure for treating BPH symptoms is Photoselective Vaporization of the Prostate (PVP). In this procedure, laser energy is used to vaporize prostatic tissue to relieve obstruction to urine flow in the urethra. The type of laser used is the Potassium-Titanyl-Phosphate (KTP) laser. The wavelength of this laser is highly absorbed by oxyhemoglobin. This laser vaporizes cellular water and hence is used to remove tissue that is obstructing the urethra.

Another example of a surgical procedure for treating BPH symptoms is Open Prostatectomy. In this procedure, the prostate gland is surgically removed by an open surgery. This is done under general anesthesia. The prostate gland is removed through an incision in the lower abdomen or the perineum. The procedure is used mostly in patients that have a large (greater than approximately 100 grams) prostate gland.

Minimally invasive procedures for treating BPH symptoms include Transurethral Microwave Thermotherapy (TUMT), Transurethral Needle Ablation (TUNA), Interstitial Laser Coagulation (ILC), and Prostatic Stents.

In Transurethral Microwave Thermotherapy (TUMT), microwave energy is used to generate heat that destroys hyperplastic prostate tissue. This procedure is performed under local anesthesia. In this procedure, a microwave antenna is inserted in the urethra. A rectal thermosensing unit is inserted into the rectum to measure rectal temperature. Rectal temperature measurements are used to prevent overheating of the anatomical region. The microwave antenna is then used to deliver microwaves to lateral lobes of the prostate gland. The microwaves are absorbed as they pass through prostate tissue. This generates heat which in turn destroys the prostate tissue. The destruction of prostate tissue reduces the degree of squeezing of the urethra by the prostate gland thus reducing the severity of BPH symptoms.

Another example of a minimally invasive procedure for treating BPH symptoms is Transurethral Needle Ablation (TUNA). In this procedure, heat induced coagulation necrosis of prostate tissue regions causes the prostate gland to shrink. It is performed using local anesthetic and intravenous or oral sedation. In this procedure, a delivery catheter is inserted into the urethra. The delivery catheter comprises two radiofrequency needles that emerge at an angle of 90 degrees from the delivery catheter. The two radiofrequency needles are aligned are at an angle of 40 degrees to each other so that they penetrate the lateral lobes of the prostate. A radiofrequency current is delivered through the radiofrequency needles to heat the tissue of the lateral lobes to 70-100 degree Celsius at a radiofrequency power of approximately 456 KHz for approximately 4 minutes per lesion. This creates coagulation defects in the lateral lobes. The coagulation defects cause shrinkage of prostatic tissue which in turn reduces the degree of squeezing of the urethra by the prostate gland thus reducing the severity of BPH symptoms.

Another example of a minimally invasive procedure for treating BPH symptoms is Interstitial Laser Coagulation (ILC). In this procedure, laser induced necrosis of prostate tissue regions causes the prostate gland to

shrink. It is performed using regional anesthesia, spinal or epidural anesthesia or local anesthesia (periprostatic block). In this procedure, a cystoscope sheath is inserted into the urethra and the region of the urethra surrounded by the prostate gland is inspected. A laser fiber is inserted into the urethra. The laser fiber has a sharp distal tip to facilitate the penetration of the laser scope into prostatic tissue. The distal tip of the laser fiber has a distal-diffusing region that distributes laser energy 360° along the terminal 3 mm of the laser fiber. The distal tip is inserted into the middle lobe of the prostate gland and laser energy is delivered through the distal tip for a desired time. This heats the middle lobe and causes laser induced necrosis of the tissue around the distal tip. Thereafter, the distal tip is withdrawn from the middle lobe. The same procedure of inserting the distal tip into a lobe and delivering laser energy is repeated with the lateral lobes. This causes tissue necrosis in several regions of the prostate gland which in turn causes the prostate gland to shrink. Shrinkage of the prostate gland reduces the degree of squeezing of the urethra by the prostate thus reducing the severity of BPH symptoms.

Another example of a minimally invasive procedure for treating BPH symptoms is implanting Prostatic Stents. In this procedure, the region of urethra surrounded by the prostate is mechanically supported to reduce the constriction caused by an enlarged prostate. Prostatic stents are flexible devices that are expanded after their insertion in the urethra. They mechanically support the urethra by pushing the obstructing prostatic tissue away from the urethra. This reduces the constriction of the urethra and improves urine flow past the prostate gland thereby reducing the severity of BPH symptoms.

Although existing treatments provide some relief to the patient from symptoms of BPH, they have significant disadvantages. Alpha-1a-adrenergic receptors blockers have side effects such as dizziness, postural hypotension, lightheadedness, asthenia and nasal stuffiness. Retrograde ejaculation can also occur. 5-alpha-reductase inhibitors have minimal side effects, but only a modest effect on BPH symptoms and the flow rate of urine. In addition, anti-androgens, such as 5-alpha-reductase, require months of therapy before

LUTS improvements are observed. Surgical treatments of BPH carry a risk of complications including erectile dysfunction; retrograde ejaculation; urinary incontinence; complications related to anesthesia; damage to the penis or urethra, need for a repeat surgery etc. Even TURP, which is the gold standard in treatment of BPH, carries a high risk of complications. Adverse events associated with this procedure are reported to include retrograde ejaculation (65% of patients), post-operative irritation (15%), erectile dysfunction(10%), need for transfusion (8%), bladder neck constriction (7%), infection (6%), significant hematuria (6%), acute urinary retention (5%), need for secondary procedure (5%), and incontinence (3%) Typical recovery from TURP involves several days of inpatient hospital treatment with an indwelling urethral catheter, followed by several weeks in which obstructive symptoms are relieved but there is pain or discomfort during micturition.

The reduction in the symptom score after minimally invasive procedures is not as large as the reduction in symptom score after TURP. Up to 25% of patients who receive these minimally invasive procedures ultimately undergo a TURP within 2 years. The improvement in the symptom score generally does not occur immediately after the procedure. For example, it takes an average of one month for a patient to notice improvement in symptoms after TUMT and 1.5 months to notice improvement after ILC. In fact, symptoms are typically worse for these therapies that heat or cook tissue, because of the swelling and necrosis that occurs in the initial weeks following the procedures. Prostatic stents often offer more immediate relief from obstruction but are now rarely used because of high adverse effect rates. Stents have the risk of migration from the original implant site (up to 12.5% of patients), encrustation (up to 27.5%), incontinence (up to 3%), and recurrent pain and discomfort. In published studies, these adverse effects necessitated 8% to 47% of stents to be explanted. Overgrowth of tissue through the stent and complex stent geometries have made their removal quite difficult and invasive.

Thus the most effective current methods of treating BPH carry a high risk of adverse effects. These methods and devices either require general or

spinal anesthesia or have potential adverse effects that dictate that the procedures be performed in a surgical operating room, followed by a hospital stay for the patient. The methods of treating BPH that carry a lower risk of adverse effects are also associated with a lower reduction in the symptom score. While several of these procedures can be conducted with local analgesia in an office setting, the patient does not experience immediate relief and in fact often experiences worse symptoms for weeks after the procedure until the body begins to heal. Additionally all device approaches require a urethral catheter placed in the bladder, in some cases for weeks. In some cases catheterization is indicated because the therapy actually causes obstruction during a period of time post operatively, and in other cases it is indicated because of post-operative bleeding and potentially occlusive clot formation. While drug therapies are easy to administer, the results are suboptimal, take significant time to take effect, and often entail undesired side effects.

Thus there remains a need for the development of new devices, systems and methods for treating BPH as well as other conditions in which one tissue or anatomical structure impinges upon or compresses another tissue or anatomical structure.

SUMMARY OF THE INVENTION

The present invention provides devices, systems and methods for compressing, cutting, incising, reconfiguring, remodeling, attaching, repositioning, supporting, dislocating or altering the composition of tissues or anatomical structures to alter their positional or force relationship to other tissues or anatomical structures. In some applications, the invention may be used to improve patency or fluid flow through a body lumen or cavity. Examples of body lumens through which flow may be facilitated using the present invention include the urethra, ureter, trachea, bronchus, bronchiole, other respiratory passageway, stomach, duodenum, small intestine, jejunum, illium, colon, cystic duct, hepatic duct, common bile duct, pancreatic duct, the alimentary canal, an endocrine passageway, a lymphatic, etc. Examples of

tissues and anatomical structures that may be compressed, cut, incised, reconfigured, remodeled, attached, repositioned, supported, dislocated or compositionally altered by the present invention include the prostate gland, other glands and organs, neoplasms, benign growths, cancerous growths, tumors, cysts, other masses, congenital deformities, structures that have become enlarged due to hypertrophy, hyperplasia, edema, fluid build up, fluid retention, excess fluid production, impeded fluid outflow, etc.

In accordance with the invention there are provided devices, systems and methods for implanting devices within the body to compress tissue in a manner that relieves pressure exerted on or interference with an adjacent anatomical structure. The implantable devices useable for this purpose generally comprising anchoring elements and tensioning elements that extend between the anchoring elements. The anchoring elements are implanted at selected locations and the tensioning elements then draw or pull the anchoring elements toward one another, thereby compressing tissue between the anchoring elements. In applications where these devices are implanted to treat prostatic enlargement, anchoring and tensioning element(s) are implanted and tensioned to compress or reposition prostatic tissue thereby lessening prostate induced constriction of the urethra. In at least some applications, this invention may be used to treat prostatic enlargement without causing substantial damage to the urethra (e.g., forming an opening in the urethra no larger than about 2 mm in its greatest cross-dimension). As used herein, the term "compress" includes not only actual compression of the tissue but also any application of pressure or force upon the tissue that causes the intended therapeutic effect by reconfiguring, remodeling, repositioning or altering the tissue.

Still further in accordance with the invention there are provided devices, systems and methods for cutting tissue(s) of the body in a manner that relieves pressure exerted on or interference with an adjacent anatomical structure. In some applications of the invention, one or more working devices may be inserted into the body and used to incise the capsule of an encapsulated organ, tumor, mass or other structure, thereby relieving the

capsule's constraint of the encapsulated organ, tumor, mass or other structure and allowing the encapsulated organ, tumor, mass or other structure to expand, herniate, evulse, splay, spread apart, reconfigure or move in a way that results in decreased pressure on, or decreased interference with, the adjacent anatomical structure. In applications where the invention is used to treat prostatic enlargement, a cutting device may be anchoring and tensioning element(s) are implanted and tensioned to compress or reposition prostatic tissue thereby lessening prostate induced constriction of the urethra.

Additional and more specific aspects, elements, steps, applications, embodiments and examples of the invention will be understood by those of skill in the art upon reading of the detailed description and claims set forth herebelow.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A is a sagittal sectional view of a male human body through the lower abdomen showing the male urinary tract.

Figure 1B is a coronal sectional view through the lower abdomen of a human male showing a region of the male urogenital system.

Figure 2A is a coronal sectional view through the prostate gland and adjacent structures showing a first trans-urethral approach that may be used to implant tissue compression devices(s) (e.g., clips, compression elements, anchoring elements, etc.) to compress or modify the shape of the prostate gland.

Figure 2B is a coronal sectional view through the prostate gland and adjacent structures showing a second trans-urethral approach that may be used to implant tissue compression devices(s) (e.g., clips, compression elements, anchoring elements, etc.) to compress or modify the shape of the prostate gland.

Figure 2C is a coronal sectional view through the prostate gland and

adjacent structures showing a third trans-urethral approach that may be used to implant tissue compression devices(s) (e.g., clips, compression elements, anchoring elements, etc.) to compress or modify the shape of the prostate gland.

Figure 2D is a coronal sectional view through the prostate gland and adjacent structures showing a transperineal approach that may be used to implant tissue compression devices(s) (e.g., clips, compression elements, anchoring elements, etc.) to compress or modify the shape of the prostate gland.

Figure 2E is a coronal sectional view through the prostate gland and adjacent structures showing a percutaneous approach that may be used to implant tissue compression devices(s) (e.g., clips, compression elements, anchoring elements, etc.) to compress or modify the shape of the prostate gland.

Figure 2F is a coronal sectional view through the prostate gland and adjacent structures showing a percutaneous trans-osseus approach that may be used to implant tissue compression devices(s) (e.g., clips, compression elements, anchoring elements, etc.) to compress or modify the shape of the prostate gland.

Figure 2G is a coronal sectional view through the prostate gland and adjacent structures showing a percutaneous suprapubic approach that may be used to implant tissue compression devices(s) (e.g., clips, compression elements, anchoring elements, etc.) to compress or modify the shape of the prostate gland.

Figure 2H is a sagittal sectional view through the prostate gland and adjacent structures showing a percutaneous infrapubic approach that may be used to implant tissue compression devices(s) (e.g., clips, compression elements, anchoring elements, etc.) to compress or modify the shape of the prostate gland.

Figure 2I is a sagittal sectional view through the prostate gland and adjacent structures showing a trans-rectal approach that may be used to implant tissue compression devices(s) (e.g., clips, compression elements, anchoring elements, etc.) to compress or modify the shape of the prostate gland.

Figures 3A to 3H show various components of a system for treating prostate gland disorders by compressing a region of the prostate gland. Figure 3A shows the perspective view of an introducer device.

Figure 3B shows a perspective view of an injecting needle that may be used for injecting one or more diagnostic or therapeutic agents in the anatomy.

Figure 3C shows a perspective view of an introducing sheath.

Figure 3D shows a perspective view of a trocar.

Figure 3E shows a perspective view of an anchor delivery device.

Figure 3F shows an enlarged view of the distal region of the device in figure 3E.

Figure 3G shows a perspective view of deployed anchors showing radially expanded splayable arms of proximal anchor and distal anchor.

Figure 3H shows a perspective view from the proximal direction of a particular embodiment of the attachment mechanism of figure 99E.

Figures 4A through 4H show a coronal section through the prostate gland showing the various steps of a method of treating prostate gland disorders by compressing a region of the prostate gland using the kit shown in figures 3A through 3H.

Figures 4G' through 4H' show the final steps of an embodiment of method of treating prostate gland disorders by deploying a proximal anchor in the urethra.

Figure 4H" shows a coronal section through the prostate gland showing a final deployed configuration of an embodiment of bone anchoring devices for treating prostate gland disorders by compressing a region of the prostate gland.

Figures 4I and 4J is a crossectional view through the prostatic urethra (i.e., the portion of the urethra that passes through the prostate gland) showing the appearance of the urethral lumen before and after performing the method shown in figures 4A through 4H.

Figures 5A through 5I show perspective views of some designs of the tension elements that can be used in the embodiments disclosed elsewhere in this patent application.

Figure 5A shows a perspective view of a tension element comprising a single strand of an untwisted material.

Figure 5B shows a perspective view of a tension element comprising one or more serrations or notches.

Figure 5C shows a perspective view of a tension element comprising multiple filaments of a material twisted together.

Figure 5D shows a perspective view of a tension element comprising a flexible, elastic, spiral or spring element.

Figure 5E shows a perspective view of a tension element comprising a screw threading on the outer surface of tension element.

Figure 5F shows a perspective view of a tension element comprising a hollow shaft comprising one or more collapsible regions.

Figure 5G shows a perspective view of an anchoring device 522 comprising a tension element and two anchors.

Figure 5H shows a perspective view of a tensioning element device comprising a detachable region.

Figure 5I shows a perspective view of a tensioning element comprising telescoping tubes.

Figures 6A through 11B show various examples of anchor designs and/or anchoring device designs.

Figures 6A and 6B show perspective views of two states of a crumpling anchor.

Figures 7A and 7B show sectional views of an undeployed configuration and a deployed configuration respectively of a deployable anchor.

Figures 8A and 8B show sectional views of an undeployed configuration and a deployed configuration respectively of a "T" shaped deployable anchor.

Figures 9A through 9D show various alternate configurations of the anchoring arms in figures 7A and 7B.

Figure 10A and 10A' show a distal view and a perspective view respectively of an anchor comprising a spiral element having a three dimensional shape.

Figure 10B and 10B' show a distal view and a side view respectively of an anchor comprising a spiral element having a two dimensional shape.

. Figure 10C and 10C' show a distal view and a perspective view respectively of an anchor comprising one or more circular elements.

Figure 10D shows a perspective view of an embodiment of an anchoring device comprising an outer ring.

Figure 10E shows a partial perspective view of an anchoring device comprising a hemostatic element.

Figure 11A shows a perspective view of a device having a set of

anchors comprising a curved sheet.

Figure 11B shows a perspective view of a device having a detachable region located on a tensioning element.

Figures 12A through 17I show further examples of anchor designs and/or anchoring device designs. Figure 12A shows a perspective view of an anchor comprising an arrowhead.

Figure 12B shows a crossectional view of an anchor comprising a cup-shaped element that encloses a cavity.

Figure 12C shows a perspective view of an anchor comprising a screw.

Figure 13A and 13B show perspective views of an uncollapsed state and a collapsed state respectively of an anchor comprising a collapsible region.

Figures 13C and 13D show perspective views of an undeployed state and a deployed state respectively of an anchor comprising radially spreading arms.

Figure 13E shows perspective views of an alternate embodiment of an undeployed state of an anchor comprising radially spreading arms.

Figures 14A and 14B show perspective views of anchoring devices comprising an adhesive delivering element.

Figures 15A and 15B show two configurations of an anchoring device comprising a ratcheted tension element.

Figure 16 shows a perspective view of an anchor comprising a trocar lumen.

Figure 17A shows a perspective view in the undeployed state of an anchor comprising a rigid or partially flexible T element and a crumpling element.

Figures 17B and 17C show various steps of a method to deploy the anchoring device shown in figure 17A.

Figures 17D and 17E show perspective views of an undeployed and deployed configuration of an anchor comprising a rigid or partially flexible T element with one or more openings or perforations.

Figures 17F and 17G show perspective views of an undeployed and deployed configuration of an anchor comprising a stent.

Figures 17H and 17I show perspective views of an undeployed and deployed configuration of an anchor comprising a spring.

Figures 18A through 22E show various embodiments of mechanisms to deploy one or more anchors. Figure 18A and 18B show a crossection of an anchor deploying mechanism comprising a screw system.

Figures 19A and 19B show a crossectional view of an anchor deploying system comprising an electrolytic detachment element.

Figure 20 shows a perspective view of an anchor deploying system comprising a looped ribbon.

Figures 21A shows a crossectional view of an anchor deploying system comprising a locked ball.

Figures 21B and 21C show a method of deploying an anchor comprising a locked ball.

Figures 22A through 22C show various views of an anchor deploying system comprising two interlocking cylinders.

Figures 22D and 22E show the steps of a method of unlocking the two interlocking cylinders from the anchor deploying systems of figures 22A through 22C.

Figure 23A shows a perspective view of a distal end of an anchoring

device that has an imaging modality.

Figures 23B through 23G show various steps of a method for compressing an anatomical region using the anchoring device of figure 23A.

Figures 24A through 24C' show the device and various steps of a method of compressing an anatomical region using a device with deploying arms deployed through a trocar.

Figure 24D shows a crossection through the deployed anchoring device of figure 24A.

Figure 25A shows a perspective view of a spring clip that can be used to spread the anatomy.

Figures 25B through 25F show various steps of a method of spreading an anatomical region or regions using the spring clip of figure 25A.

Figures 26A and 26B show a crossectional view and a perspective view respectively of a mechanism of cinching a tension element or tether to an anchor.

Figures 26C and 26D show a partial section through a cinching mechanism comprising a cam element.

Figure 26E shows a sectional view of an embodiment of a cinching mechanism comprising a locking ball.

Figure 26F shows a side view of an embodiment of a cinching mechanism comprising multiple locking flanges.

Figure 26G shows an end view of body of figure 26F.

Figure 26H shows a side view of an embodiment of a cinching mechanism comprising a single locking flange.

Figure 26I shows an end view of body of figure 26H.

Figure 26J shows an end view of a cinching mechanism comprising a crimping lumen.

Figures 26K and 26L show crossections of an embodiment of a cinching mechanism comprising a crimping anchor in the undeployed and deployed configurations respectively.

Figure 26M shows a perspective view of an embodiment of a cinching mechanism comprising an element providing a tortuous path to a tension element.

Figure 26N shows a crossectional view of an embodiment of a locking mechanism comprising a space occupying anchor securely attached to a tension element.

Figures 26O and 26P shows a partial sectional view and a perspective view of an embodiment of a cinching mechanism comprising a punched disk.

Figures 26Q and 26R show a perspective view of a first embodiment of a cutting device before and after cutting an elongate element.

Figure 26S show a crossectional view of a second embodiment of a cutting device for cutting an elongate element.

Figures 27A through 27D show axial sections through the prostate gland showing various configurations of anchoring devices comprising distal anchors and a tension element.

Figure 28 and 28A show perspective views of an embodiment of an anchoring device comprising an elongate element comprising multiple barbs or anchors.

Figures 28B through 28E show a coronal section through the prostate gland showing various steps of a method of treating the prostate gland using the device of figure 28.

Figure 29A shows an axial section of the prostate gland showing a pair

of implanted magnetic anchors.

Figures 29B through 29D show a coronal section through the prostate gland showing the steps of a method of implanting magnetic anchors of figure 29A.

Figure 30A is a coronal sectional view of a portion of the male urogenital system showing a transurethral approach that may be used to perform a prostate cutting procedure of the present invention.

Figure 30B is a coronal sectional view of a portion of the male urogenital system showing another transurethral approach that may be used to perform a prostate cutting procedure of the present invention.

Figure 30C is a coronal sectional view of a portion of the male urogenital system showing a transurethral/transvesicular approach that may be used to perform a prostate cutting procedure of the present invention.

Figure 30D is a coronal sectional view of a portion of the male urogenital system showing another transurethral approach that may be used to perform a prostate cutting procedure of the present invention, wherein a device advances from the urethra, through the prostate gland, and thereafter accesses the prostate capsule from its outer surface.

Figure 31 is a coronal sectional view of a portion of the male urogenital system showing a percutaneous/infrapubic approach that may be used to perform a prostate cutting procedure of the present invention.

Figure 32 is a coronal sectional view of a portion of the male urogenital system showing a percutaneous/transvesicular approach that may be used to perform a prostate cutting procedure of the present invention.

Figures 33A-33E shows perspective views of various devices that may be included in a system for performing a prostate cutting procedure in accordance with the present invention.

Figure 33A shows a perspective view of an introducer device comprising a first tubular element having a working device lumen.

Figure 33B shows a perspective view of an injecting needle that may be used for injecting one or more diagnostic or therapeutic substances.

Figure 33C shows a perspective view of a guiding device comprising an elongate body comprising a sharp distal tip.

Figure 33D shows a perspective view of a RF cutting device

Figure 33E shows a perspective view of an embodiment of a plugging device to plug an opening created during a procedure.

Figures 33F through 33N show various alternate embodiments of the electrosurgical cutting device in figure 33D.

Figures 33F and 33G show perspective views of the distal region of a first alternate embodiment of an electrosurgical cutting device in the undeployed and deployed states respectively.

Figures 33H and 33I show perspective views of the distal region of a second alternate embodiment of an electrosurgical cutting device in the undeployed and deployed states respectively.

Figures 33J through 33L show perspective views of the distal region of a second alternate embodiment of an electrosurgical cutting device showing the steps of deploying the electrosurgical cutting device.

Figures 33M through 33N show perspective views of the distal region of a third alternate embodiment of an electrosurgical cutting device showing the steps of deploying the electrosurgical cutting device.

Figure 34 shows a perspective view of the distal region of a balloon catheter comprising a balloon with cutting blades.

Figure 35 shows a perspective view of the distal region of a balloon catheter comprising a balloon with cutting wires.

Figures 36A and 36B series show perspective views of an undeployed state and a deployed state respectively of a tissue displacement device.

Figures 36C and 36D show a coronal view and a lateral view respectively of a pair of deployed tissue displacement devices of figures 36A and 36B implanted in the prostate gland.

Figures 36E through 36H show an axial section through a prostate gland showing the various steps of a method of cutting or puncturing the prostate gland and lining or plugging the cut or puncture.

Figures 37A through 37K show an embodiment of a method of treating prostate gland disorders by cutting a region of the prostate gland using the devices described in Figure 33A through 33E.

Figures 38A to 38D show various components of a kit for treating prostate gland disorders by compressing a region of the prostate gland. Figure 38A shows the perspective view of an introducer device.

Figure 38B shows a perspective view of a bridge device

Figure 38C shows a perspective view of a distal anchor deployment device

Figure 38D shows the proximal anchor delivery tool

Figure 38E shows a close-up perspective view of proximal anchor 3833 mounted on proximal anchor delivery tool of figure 38D.

DETAILED DESCRIPTION

The following detailed description and the accompanying drawings are intended to describe some, but not necessarily all, examples or embodiments of the invention only and does not limit the scope of the invention in any way.

The following detailed description and the accompanying drawings are intended to describe some, but not necessarily all, examples or embodiments of the invention only and does not limit the scope of the invention in any way.

A number of the drawings in this patent application show anatomical structures of the male reproductive and/or urinary system. In general, these anatomical structures are labeled with the following reference letters:

Urethra	UT
Urethral Lumen	UL
Urethral Opening	UO
Urinary Bladder	UB
Ureters	UR
Prostate Gland	PG
Capsule of Prostate Gland	CP
Testis	TS
Vas Deferens	VD

Figure 1A shows a sagittal section of a male human body through the lower abdomen showing the male urinary tract. The male urinary tract comprises a pair of tubular organs called ureters (UR) that conduct urine produced by the kidneys. The ureters empty into the urinary bladder. The urinary bladder is a hollow muscular organ that temporarily stores urine. It is situated posterior to the pubic bone. The inferior region of the urinary bladder

has a narrow muscular opening called the bladder neck which opens into a soft, flexible, tubular organ called the urethra. The muscles around the bladder neck are called the internal urethral sphincter. The internal urethral sphincter is normally contracted to prevent urine leakage. The urinary bladder gradually fills with urine until full capacity is reached, at which point the sphincter relaxes. This causes the bladder neck to open, thereby releasing the urine stored in the urinary bladder into the urethra. The urethra begins at the bladder neck, terminates at the end of the penis, and allows for urine to exit the body.

The region of the urethra just inferior to the urinary bladder is completely surrounded by the prostate gland. The prostate gland is part of the male reproductive system and is usually walnut shaped. Clinically, the prostate is divided into lobes. The lateral lobes are located lateral to the urethra; the middle lobe is located on the dorsal aspect of the urethra, near the bladder neck. Most commonly in BPH, the lateral lobes become enlarged and act like curtains to close the urethral conduit. Less commonly, the middle lobe grows in size and becomes problematic. Because of its superior location near the bladder neck with respect to the urethra, an enlarged middle lobe acts like a ball valve and occludes fluid passage.

Figure 1B shows a coronal section through the lower abdomen of a human male showing a region of the male urinary system. The prostate gland (PG) is located around the urethra at the union of the urethra and the urinary bladder.

Figures 2A through 2H show various alternate approaches to deploy implantable tissue compression device(s) (e.g., one or more clips, anchoring elements, tensioning members, etc.) to compress the prostate gland PG, thereby relieving constriction of the urethra. Specific examples of implantable tissue compression device(s) (e.g., one or more clips, anchoring elements, tensioning members, etc.) useable in this invention are shown in other figures of this patent application and are described more fully herebelow.

Figure 2A shows a first trans-urethral approach that may be used to

implant tissue compression devices(s) to compress the prostate gland PG. In Figure 2A, an introducing device 200 is introduced in the urethra through the urethral opening of the penis. Introducing device 200 comprises an elongate body 202 comprising a lumen that terminates distally in a distal opening 204. One or more working device(s) 206 is/are then introduced through distal opening 204 into the urethra. The working device(s) 206 penetrate the urethral wall and thereafter one or more lobes of the prostate gland. In some applications of the method, working device(s) 206 may further penetrate the prostate capsule and enters the pelvic cavity. Working device(s) 206 are also used to deploy and implant implantable tissue compression device(s) (e.g., one or more clips, anchoring elements, tensioning members, etc.) to compress the prostate gland PG, thereby relieving constriction of the urethra.

Figure 2B shows a second trans-urethral approach that may be used to implant tissue compression devices(s) to compress the prostate gland PG. In Figure 2B, an introducing device 210 is introduced in the urethra through the urethral opening UO of the penis. Introducing device 210 comprises an elongate body 212 comprising a lumen that terminates distally in a distal opening 214. One or more working device(s) 216 is/are insertable through distal opening 214 into the urethra. Working device(s) 216 penetrate(s) the urethral wall inferior to the prostate gland and enters the pelvic cavity. Thereafter, working device(s) 216 penetrate(s) the prostate capsule CP and thereafter one or more lobes of the prostate gland. In some applications of the method the working device(s) 216 may further penetrate the urethral wall enclosed by the prostate gland EG and enters the urethral lumen. Working device(s) 216 may then be used to deploy and implant implantable tissue compression device(s) (e.g., one or more clips, anchoring elements, tensioning members, etc.) to compress the prostate gland PG, thereby relieving constriction of the urethra.

Figure 2C shows a third trans-urethral approach that may be used to implant tissue compression devices(s) to compress the prostate gland PG. In Figure 2C, an introducing device 220 is introduced in the urethra through the

urethral opening UO of the penis. Introducing device 220 comprises an elongate body 222 comprising a lumen that terminates distally in a distal opening 224. Introducing device 220 is positioned such that distal opening 224 is located in the urinary bladder UB. Thereafter, a one or more working device(s) 226 is/are introduced through distal opening 224 into the urinary bladder UB. Working device(s) 226 penetrate(s) the wall of the urinary bladder UB and thereafter penetrate(s) one or more lobes of the prostate gland PG. In some applications of the method, the working device(s) 226 may further penetrate the prostate capsule and enter the pelvic cavity. Working device(s) 226 may then be used to deploy and implant implantable tissue compression device(s) (e.g., one or more clips, anchoring elements, tensioning members, etc.) to compress the prostate gland PG, thereby relieving constriction of the urethra.

Figure 2D shows a transperineal approach that may be used to implant tissue compression devices(s) to compress the prostate gland PG. In Figure 2D, an introducing device 230 is introduced in the pelvic cavity percutaneously through the perineum. Introducing device 230 comprises an elongate body 232 comprising a lumen that terminates distally in a distal opening 234. Introducing device 230 is positioned such that distal opening 234 is located in the pelvic cavity adjacent to prostate gland. Thereafter, one or more working device(s) 236 is/are introduced through distal opening 234 into the prostate gland PG. Working device(s) 236 penetrate(s) the prostate capsule CP and thereafter penetrate(s) one or more lobes of the prostate gland PG. In some applications of the method, the working device(s) 236 may further penetrate the urethral wall surrounded by the prostate gland PG and enter the urethral lumen. Working device 236 may then be used to deploy and implant implantable tissue compression device(s) (e.g., one or more clips, anchoring elements, tensioning members, etc.) to compress the prostate gland PG, thereby relieving constriction of the urethra.

Figure 2E shows a percutaneous/transvesicular approach that may be used to implant tissue compression devices(s) to compress the prostate gland PG. In Figure 2E, an introducing device 240 is introduced percutaneously

through the abdominal wall. Introducing device 240 comprises an elongate body 242 comprising a lumen that terminates distally in a distal opening 244. After passing through the abdominal wall, introducing device 240 is advanced through the wall of the urinary bladder UB such that distal opening 244 is located in the urinary bladder UB. Thereafter, one or more working device(s) 246 is/are introduced through distal opening 244 into the urinary bladder UB. One ore more working device(s) 246 are advanced through the wall of the urinary bladder UB and into the prostate gland PG. In some applications of the method, working device(s) 246 may further penetrate through the prostate gland capsule and enter the pelvic cavity. Working device(s) 246 is/are then used to deploy and implant implantable tissue compression device(s) (e.g., one or more clips, anchoring elements, tensioning members, etc.) to compress the prostate gland PG, thereby relieving constriction of the urethra.

Figure 2F shows a percutaneous trans-osseus approach that may be used to implant tissue compression devices(s) to compress the prostate gland PG. In Figure 2F, an introducing device 250 is introduced percutaneously through the abdominal wall. Introducing device 250 comprises an elongate body 252 comprising a lumen that terminates distally in a distal opening 254. Introducing device 250 is used to penetrate a pelvic bone (e.g. the pubic bone PB). Thereafter, introducing device 250 is positioned such that distal opening 254 is located adjacent to the prostate gland PG. Thereafter, one or more working device(s) 256 is/are introduced through distal opening 254 into the prostate gland PG. Working device(s) 256 penetrate the prostate capsule and thereafter penetrate one or more lobes of the prostate gland PG. In some applications of the method, working device(s) 256 may further penetrate the urethral wall surrounded by the prostate gland and enter the urethral lumen. Working device(s) 256 is/are then used to deploy and implant implantable tissue compression device(s) (e.g., one or more clips, anchoring elements, tensioning members, etc.) to compress the prostate gland PG, thereby relieving constriction of the urethra. .

Figure 2G shows a percutaneous suprapubic approach that may be used to implant tissue compression devices(s) to compress the prostate gland

PG. In Figure 2G, an introducing device 260 is introduced in the pelvic cavity percutaneously in a trajectory that passes superior to the pubis bone. Introducing device 260 comprises an elongate body 262 comprising a lumen that terminates distally in a distal opening 264. Introducing device 260 is then positioned such that distal opening 264 is located in the pelvic cavity adjacent to prostate gland. Thereafter, one or more working device(s) 266 is/are introduced through distal opening 264 into the prostate gland PG. Working device(s) 266 penetrate the prostate capsule CP and thereafter penetrate one or more lobes of the prostate gland PG. In some applications of the method, working device(s) 266 may further penetrate the urethral wall surrounded by the prostate gland and enter the urethral lumen. Working device(s) 266 is/are then used to deploy and implant implantable tissue compression device(s) (e.g., one or more clips, anchoring elements, tensioning members, etc.) to compress the prostate gland PG, thereby relieving constriction of the urethra. Figure 2H shows a percutaneous infrapubic approach that may be used to implant tissue compression devices(s) to compress the prostate gland. In Figure 2H, an introducing device 270 is introduced in the pelvic cavity percutaneously in a trajectory that passes inferior to the pubis bone. Introducing device 270 comprises an elongate body 272 comprising a lumen that terminates distally in a distal opening 274. Introducing device 270 is introduced percutaneously in the pelvic cavity in a trajectory that passes inferior to the pubic bone. Introducing device 270 is then positioned such that distal opening 274 is located in the pelvic cavity adjacent to prostate gland. Thereafter, one or more working device(s) 276 is/are introduced through distal opening 274 into the prostate gland PG. Working device(s) 276 penetrate the prostate capsule CP and thereafter penetrate one or more lobes of the prostate gland PG. In some applications of the method, working device(s) 276 may further penetrate the urethral wall surrounded by the prostate gland PG and enter the urethral lumen. Working device(s) 276 is/are then used to deploy and implant implantable tissue compression device(s) (e.g., one or more clips, anchoring elements, tensioning members, etc.) to compress the prostate gland PG, thereby relieving constriction of the urethra.

Figure 2I shows a trans-rectal approach that may be used to implant

tissue compression devices(s) to compress the prostate gland PG. In Figure 2I, an introducing device 280 is introduced in the rectum. Introducing device 280 comprises an elongate body 282 comprising a lumen that terminates distally in a distal opening 284. Introducing device is then advanced such that it penetrates the rectal wall and enters the pelvic cavity. Introducing device 280 is then positioned such that distal opening 284 is located in the pelvic cavity adjacent to prostate gland. Thereafter, one or more working device(s) 286 is/are introduced through distal opening 284 into the prostate gland PG. Working device(s) 286 penetrate the prostate capsule CP and thereafter penetrate one or more lobes of the prostate gland. In some applications of the method, working device(s) 286 may further penetrate the urethral wall surrounded by the prostate gland and enter the urethral lumen. Working device(s) 286 is/are then used to deploy and implant implantable tissue compression device(s) (e.g., one or more clips, anchoring elements, tensioning members, etc.) to compress the prostate gland PG, thereby relieving constriction of the urethra.

Figures 3A to 3F show various examples of devices and systems that are useable to treat conditions where the prostate gland PG is compressing a region of the urethra such that the urethra does not expand normally during micturition and urine outflow is impeded. .

Figure 3A shows the perspective view of an introducer device 300. Introducer device 300 comprises an outer body 301 constructed from suitable biocompatible materials including, but not limited to Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, metals like stainless steel and fluoropolymers like PTFE, PFA, FEP, EPTFE etc. Body 301 comprises a working device lumen 302. Distal end of working device lumen 302 emerges out of the distal end of body 301. In one embodiment, distal end of working device lumen 302 has a bent or curved region. Proximal end of working device lumen 302 emerges out of a first flexible tube 304. The proximal end of first flexible tube 304 comprises a stasis valve 306. Body 301 further comprises a cystoscope lumen 308. Distal end of cystoscope lumen 308 emerges out of the distal end of body 301.

Proximal end of cystoscope lumen 308 emerges out of a second flexible tube 310. The proximal end of second flexible tube 310 comprises a stasis valve 312. Cystoscope lumen 308 may comprise one or more side ports e.g. a first side port 318 for the introduction or removal of one or more fluids. Working device lumen 302 may comprise one or more side ports e.g. a second side port 320 for the introduction or removal of one or more fluids.

Figure 3B shows a perspective view of an injecting needle. Injecting needle 330 is used for injecting one or more diagnostic or therapeutic substances. In some applications of the invention, the injecting needle 330 may be used to inject local anesthetic in the urethra, prostate gland and/or tissues near the prostate gland. Specific examples of target areas for injecting local anesthetics are the neurovascular bundles, the genitourinary diaphragm, the region between the rectal wall and prostate, etc. Examples of local anesthetics that can be injected by injecting needle 330 are anesthetic solutions e.g. 1% lidocaine solution; anesthetic gels e.g. lidocaine gels; combination of anesthetic agents e.g. combination of lidocaine and bupivacaine; etc. Injecting needle 330 comprises a hollow shaft 332 made of suitable biocompatible materials including, but not limited to stainless steel 304, stainless steel 306, Nickel-Titanium alloys, titanium etc. In this example, the distal end of hollow shaft 332 comprises a sharp tip 334. The proximal end of hollow shaft 332 has a needle hub 336 made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel 304, stainless steel 306, Nickel-Titanium alloys, titanium etc.; polymers e.g. polypropylene, Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, PTFE, PFA, FEP, EPTFE etc. In one embodiment, needle hub 336 comprises a luer lock.

Figure 3C shows an example of an introducing device or introducing sheath 340. Introducing sheath 340 comprises a hollow, tubular body 342 made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel 304, stainless steel 306, Nickel-Titanium alloys, titanium etc. or polymers e.g. Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, PTFE, PFA, FEP, EPTFE etc. Tubular

body 342 further comprises two marker bands: a proximal marker band 344 and a distal marker band 346. The marker bands can be seen by a cystoscope. In one embodiment, proximal marker band 344 and distal marker band 346 are radiopaque. The position of proximal marker band 344 and distal marker band 346 is such that after introducing sheath 340 is placed in an optimum location in the anatomy, proximal marker band 344 is located in the urethra where it can be seen by a cystoscope and distal marker band 346 is located in the prostrate gland or in the wall of the urethra where it cannot be seen by a cystoscope. Tubular body 342 further comprises a series of distance markers 348 on the outer surface of tubular body 342. The proximal end of tubular body 342 further comprises a hub 350 made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel 304, stainless steel 306, Nickel-Titanium alloys, titanium etc. or polymers e.g. Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, PTFE, PFA, FEP, EPTFE etc. In one embodiment, hub 350 comprises a luer lock.

Figure 3D shows a perspective view of a trocar. Trocar 360 comprises a tubular trocar body 362. The proximal end of trocar body 362 comprises a hub 364. Trocar body 362 and hub can be constructed from suitable biocompatible materials including, but not limited to metals e.g. stainless steel 304, stainless steel 306, Nickel-Titanium alloys, titanium etc. or polymers e.g. Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, PTFE, PFA, FEP, EPTFE etc. Distal end of trocar body 362 ends in a sharp trocar tip 366.

Figure 3E shows a perspective view of an anchor delivery device. Anchor delivery device 370 comprises a body 372 having a distal opening 373. A section of the distal region of body 372 has been removed to show a view of the anchor assembly. Body 372 encloses a distal anchor 374 and a proximal anchor 376. Proximal anchor 376 and distal anchor 374 can have a variety of designs including, but not limited to the designs disclosed elsewhere in this patent application. Proximal anchor 376 and distal anchor 374 can be constructed from suitable biocompatible materials including, but not limited to

metals e.g. stainless steel 304, stainless steel 306, Nickel-Titanium alloys, titanium etc. or polymers e.g. Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, PTFE, PFA, FEP, EPTFE etc. In one embodiment, shown in Figures 3F and 3G, proximal anchor 9976 and distal anchor 9974 comprise splayable elements that expand in a radially outward direction when a radial compression force, as enacted by body lumen 9972, on proximal anchor 9976 and distal anchor 9974 is removed. The splayable elements can be made of suitable super-elastic materials such as Nickel-Titanium alloys etc. Proximal anchor 9976 and distal anchor 9974 are connected to each other by a tension element 9978. Tension element 9978 can be made of suitable elastic or non-elastic materials including, but not limited to metals e.g. stainless steel 304, stainless steel 306, Nickel-Titanium alloys, suture materials, titanium etc. or polymers such as silicone, nylon, polyamide, polyglycolic acid, polypropylene, Pebax, PTFE, ePTFE, silk, gut, or any other braided or mono-filament material. Tension element 9978 can have a variety of designs including the designs shown in figures 5A through 5F. As shown in Figure 3E, the proximal end of proximal anchor 9976 is connected by an attachment mechanism 9980 to a torquable shaft 9982. The proximal end of torquable shaft 9982 is attached to a control button 9984. Control button 9984 can be used to deploy proximal anchor 9976 by sliding control button 9984 along groove 9985 in the distal direction. Control button 9984 is then used to deploy distal anchor 9974 by turning control button 9984 in the circumferential direction along groove 9985.

Figure 3H shows a perspective view from the proximal direction of a particular embodiment of the attachment mechanism of figure 3E. Attachment mechanism 380 comprises a circular plate 386 made from suitable biocompatible materials including, but not limited to metals e.g. stainless steel 304, stainless steel 306, Nickel-Titanium alloys, titanium etc. or polymers e.g. Polycarbonate, PVC, Pebax, Polyimide, Polyurethane, Nylon, Hytrel, HDPE, PEEK, PTFE, PFA, FEP etc. The proximal face of circular plate 386 is connected to torquable shaft 382. Circular plate 386 further comprises a semicircular groove 388. One end of semicircular groove 388 comprises an enlarged region 390. A knob 392 located on the proximal portion of proximal

anchor 376 slides on semicircular groove 388. The size of knob 322 is larger than the size of semicircular groove 388 but smaller than size of enlarged region 390. This keeps proximal anchor 376 attached to circular plate 386. When control button 384 is turned in the circumferential direction along groove 385, torquable shaft 382 is turned. This turns circular plate 386 causing knob 392 to slide on the groove 388. Ultimately, knob 392 reaches enlarged region 390. This releases knob 392 from circular plate 386 thereby releasing proximal anchor 376 from anchor delivery device 370.

Figures 4A through 4H show a coronal section through the prostate gland showing the various steps of a method of treating prostate gland disorders by compressing a region of the prostate gland using the kit shown in Figures 3A through 3F. In Figure 4A, introducer device 300 is introduced in the urethra through the urethral opening at the tip if the penis. A cystoscope is inserted in introducer device 300 through cystoscope lumen 308 such that the lens of the cystoscope is located in the distal opening of cystoscope lumen. The cystoscope is used to navigate introducer device 300 through the urethra such that the distal region of introducer device 300 is located in a target region in the prostatic urethra. Thereafter in Figure 4B, injecting needle 330 is advanced through working device lumen 302 such that the distal tip of injecting needle 330 penetrates into a region of the urethral wall or the prostate gland. Injecting needle 330 is then used to inject one or more diagnostic or therapeutic agents into the urethral wall or the prostate gland. This step may be repeated one or more times to inject one or more diagnostic or therapeutic agents in one or more regions of the urethral wall and/or the prostate gland. In one method embodiment, injecting needle 330 is used to inject an anesthetic in one or more regions of the urethral wall and/or the prostate gland. In another embodiment, injecting needle 330 is used to deliver energy in the form of radiofrequency energy, resistive heating, laser energy, microwave energy etc. In another embodiment, injecting needle 330 is used to deliver alpha antagonist agents, such as phenoxybenzamine, prazosin, doxazosin, terazosin, tamsulosin, alfuzosin etc. In another embodiment, injecting needle 330 is used to deliver anti-androgen, such as flutamide or 5-alpha reductase inhibitors, such as finasteride, dutasteride, 3-oxosteroid

compounds, 4-aza-3-oxosteroid derivatives of testosterone etc. In another embodiment, injecting needle 330 is used to deliver anti-inflammatory agents, such as rapamycin, paclitaxel, ABT-578, everolimus, taxol etc. In another embodiment, injecting needle 330 is used to deliver ablative agents such as methyl alcohol etc.

In another embodiment, injecting needle 330 is used to deliver energy in the form of radiofrequency energy, resistive heating, laser energy, microwave energy etc. In another embodiment, injecting needle 330 is used to deliver alpha antagonist agents, such as phenoxybenzamine, prazosin, doxazosin, terazosin, tamsulosin, alfuzosin etc. In another embodiment, injecting needle 330 is used to deliver anti-androgen, such as flutamide or 5-alpha reductase inhibitors, such as finasteride, dutasteride, 3-oxosteroid compounds, 4-aza-3-oxosteroid derivatives of testosterone etc. In another embodiment, injecting needle 330 is used to deliver anti-inflammatory agents, such as rapamycin, paclitaxel, ABT-578, everolimus, taxol etc. In another embodiment, injecting needle 330 is used to deliver ablative agents such as methyl alcohol etc.

In step 4C, injecting needle 330 is withdrawn from introducer device 300. Thereafter, introducer sheath 340 and trocar 360 are advanced through working device lumen 302. In the example shown, introducer sheath 340 and trocar 360 are advanced till the distal tip of trocar 360 penetrates the capsule of the prostate gland and the distal end of introducer sheath 340 is located outside the prostate gland in the pelvic cavity. Thereafter, trocar 360 is withdrawn from working device lumen 302 leaving introducer sheath 340 in place. In Figure 4D, anchor delivery device 370 is introduced through the lumen of introducer sheath 340 till the distal end of body 372 protrudes through the distal tip of introducer sheath 340. In step 4E, distal anchor 374 is deployed. It should be noted that the anchor may be carried to the site and deployed from within an introducer, on the outside of an introducer, or it may be the distal tip of the introducer itself. Thereafter, anchor deliver device 370 is pulled in the proximal direction along with introducer sheath 340 so that distal anchor 374 is anchored on the outer surface of the prostate capsule.

This step may be used to create tension in the tension element 378. In one method embodiment, anchor deliver device 370 is pulled in the proximal direction along with introducer sheath 340 such that the distal end of anchor delivery device 370 is located in the prostate gland. In another method embodiment, anchor deliver device 370 is pulled in the proximal direction along with introducer sheath 340 till the distal end of anchor delivery device 370 is located in the urethral wall or the urethral lumen. In step 4F, proximal anchor 376 is deployed. Proximal anchor 376 may be deployed in the prostate gland, in the urethral wall or in the urethral lumen. Proximal anchor 376 is still attached by attachment mechanism 380 to anchor delivery device 370. The proximal anchor may be pre-loaded on the tension element, or may subsequently be loaded by the operator on the tension element. Figures 4G through 4H show the steps of deploying proximal anchor 376 in the prostate gland. In Figure 4G, proximal anchor 376 is separated from anchor delivery device 370. This separation may be achieved via numerous means including cutting, melting, un-locking a link, or breaking the tensioning element at a desired location. Ideally this residual end of the tensioning element will not protrude substantially into the lumen of the urethra. Thus proximal anchor 376 and distal anchor 374 are anchored in the anatomy. Thereafter, anchor delivery device 370 and introducer sheath 340 are both pulled in the proximal direction and are withdrawn into introducer device 300. Thereafter, introducer device 300 is pulled in the proximal direction to pull it out of the urethra. In Figure 4H, the steps from Figure 4A through 4G are repeated in a second region of the prostate gland if desired to implant two or more sets of anchoring devices.

Alternatively, Figures 4G' through 4H' show the steps of deploying proximal anchor 376 in the urethra. After the step in Figure 4F, in Figure 4G', proximal anchor 376 is separated from anchor delivery device 370 in the urethra. Thus proximal anchor 376 and distal anchor 374 are anchored in the urethra and the prostate capsule respectively. Thereafter, anchor delivery device 370 and introducer sheath 340 are both pulled in the proximal direction and are withdrawn into introducer device 300. Thereafter, introducer device 300 is pulled in the proximal direction to pull it out of the urethra. In Figure

4H', the steps from Figure 4A through 4G' are repeated optionally in a second region of the prostate gland to implant two or more sets of anchoring devices. It should be understood that this method and devices may be applied to any lobe (middle or lateral lobes) of the prostate and further more may be used multiple times in the same lobe to achieve the desired effect.

Figure 4H" shows a coronal section through the prostate gland showing the final deployed configuration of an embodiment of bone anchoring devices for treating prostate gland disorders by compressing a region of the prostate gland. In the method of deploying this device, introducer sheath 340 and trocar 360 are advanced till the distal tip of trocar 360 penetrates a bone in the abdomen (e.g. the pelvic bone, etc.) and the distal end of introducer sheath 340 is located outside the bone. Thereafter, trocar 360 is withdrawn from working device lumen 302 leaving introducer sheath 340 in place. Thereafter, anchor delivery device 370 is introduced through the lumen of introducer sheath 340 until the distal end of body 372 touches the bone through the distal tip of introducer sheath 340. Thereafter, distal anchor 374 is implanted in the bone. Distal anchor 374 may comprise a variety of designs including, but not limited to designs of distal tips of Kirschner wires. Examples of such Kirschner wire distal tips are spiral drill tips, lancer tips, threaded trocar tips, lengthwise knurled tips, 3-sided trocar tips, 4-sided trocar tips, Thereafter, anchor deliver device 370 is pulled in the proximal direction along with introducer sheath 340. This step creates tension in the tension element 378. In another method embodiment, anchor deliver device 370 is pulled in the proximal direction along with introducer sheath 340 till the distal end of anchor delivery device 370 is located in the urethral wall or the urethral lumen. The remaining method steps are similar to steps 4F through 4H.

One or more anchors disclosed in this patent application may be implanted in anatomical locations that include, but are not limited to:

a location within prostatic lobe;

a location within peripheral zone of prostate;

a location within prostatic capsule;

a location between prostatic capsule and pubic fascia;

a location within the pubic fascia;

a location within the levator ani muscle

a location within the obturator internus muscle;

a location within the pelvic bone;

a location within the periostium of pelvic bone;

a location within the pubic bone;

a location within the periostium of pubic bone;

a location within the symphysis pubica;

a location within the urinary bladder wall;

a location within the ischiorectal fossa;

a location within the urogenital diaphragm; and

a location within the abdominal fascia.

Figures 4I and 4J show a crossection of the urethra through the prostate gland PG showing the appearance of the urethral lumen before and after performing the method shown in Figures 4A through 4H. Figure 4I shows a crossection of the urethra through the prostate gland showing the appearance of the urethral lumen in a patient with BPH. Figure 4J shows a crossection of the urethra through the prostate gland PG showing the appearance of the urethral lumen after performing the procedure shown in Figures 4A through 4H. The urethral lumen shown in Figure 4I is larger than the urethral lumen in Figure 4J.

Figures 5A through 5F show perspective views of some designs of the tension elements that can be used in the embodiments disclosed elsewhere in this patent application. Figure 5A shows a perspective view of a tension element 500 comprising a single strand of an untwisted material. Examples of materials that can be used to manufacture tension element 500 include but are not limited to synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; natural fibers e.g. cotton, silk etc.; rubber materials e.g. various grades of silicone rubber etc. Figure 5B shows a perspective view of a tension element 502 comprising one or more serrations 504 or notches. Serrations 504 may be aligned in a particular direction to allow relatively easy movement of an outer body along tension element 502 in one direction and offer significant resistance to movement of the outer body along the tension element in the other direction. Figure 5C shows a perspective view of a tension element 506 comprising multiple filaments 507 of a material twisted together. Examples of materials that can be used include to manufacture multiple filaments 507 include but are not limited to synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; natural fibers e.g. cotton, silk etc.; rubber materials e.g. various grades of silicone rubber etc. multiple filaments 507 may be coated with a coating 508 including, but not limited to a lubricious coating, antibiotic coating, etc. It is also possible for the tension element to comprise a composite braided structure in a plastic/metal or plastic/plastic configuration to reduce profile and increase strength. Such materials could have preset levels of elasticity and non-elasticity. Figure 5D shows a perspective view of a tension element 509 comprising a flexible, elastic, spiral or spring element. Examples of materials that can be used include to manufacture tension element 509 include but are not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc. Figure 5E shows a perspective view of a tension element 510 comprising a screw threading 511 on the outer surface of tension element 510. Screw threading 511 enables tension element 510 to be screwed

through an outer element to advance or withdraw tension element through the outer element. Figure 5F shows a perspective view of a tension element 512 comprising a hollow shaft 514 comprising one or more collapsible regions 516. A collapsible region 516 comprises one or more windows 518. Windows 518 are cut in hollow shaft 514 in such a way that several thin, collapsible struts 520 are created between adjacent windows 518. When tension element 512 is compresses along its length, collapsible struts 520 are deformed in the radially outward direction to create one or more anchoring regions.

Figure 5G shows a perspective view of an anchoring device 522 comprising a tension element and two anchors. Distal end of a tension element 524 is attached to a distal anchor 526. Proximal end of tension element 524 is attached to a proximal anchor 528.

Figure 5H shows a perspective view of a tensioning element device comprising a detachable region. Anchoring device 530 comprises a first anchor 532 and a second anchor 534. First anchor 532 and second anchor 534 may comprise a variety of anchor designs disclosed elsewhere in this patent application. In one embodiment, one or both of first anchor 532 and second anchor 534 comprise a substantially flat plate. The substantially flat plate may be made from various materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc.; synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; natural fibers e.g. cotton, silk etc.; rubber materials e.g. various grades of silicone rubber etc. First anchor 532 and second anchor 534 are connected to a tensioning element. The tensioning element comprises two flexible members: a first tensioning member 536 and a second tensioning member 538. The distal end of first tensioning member 536 is connected to first anchor 532 and the proximal end of second tensioning member 538 is connected to second anchor 534. Proximal end of first tensioning member 536 and distal end of second tensioning member 538 are connected to a releasable member 540. Releasable member 540 can be releasably connected to a deploying device. In one embodiment of a method using

anchoring device 530, first anchor 532 is deployed out of an anatomical tissue (e.g. the prostate gland) into a first anatomical cavity (e.g. the pelvic cavity). Thereafter, second anchor 534 is deployed into a second anatomical cavity (e.g. the urethral lumen). Thereafter, releasable member 540 is released from the deploying device to deliver anchoring device 530 in a target region.

Figure 5I shows a perspective view of a tensioning element comprising telescoping tubes. Tensioning element 544 may comprise two or more telescoping tubes. In this example, tensioning element 544 comprises three telescoping tubes: a first telescoping tube 546, a second telescoping tube 548 and a third telescoping tube 550. Second telescoping tube 548 slidably fits into a lumen of first telescoping tube 546. Similarly third telescoping tube 550 slidably fits into a lumen of second telescoping tube 548. The telescoping tubes have a locking mechanism to prevent a telescoping tube from completely disengaging from another telescoping tube. The telescoping tubes may be made from a variety of biocompatible materials including, but not limited to plastics, metals etc.

All the components of the systems disclosed herein (including but not limited to the tensioning elements, inner and outer anchor members) may be coated or embedded with therapeutic or diagnostic substances (e.g., drugs or therapeutic agents) or such therapeutic or diagnostic substances may be introduced into or near the prostate or adjacent tissue through a catheter, cannula needles, etc. Examples of therapeutic and diagnostic substances that may be introduced or eluted include but are not limited to: hemostatic agents; antimicrobial agents (antibacterials, antibiotics, antifungals, antiprotozoals; antivirals; antimicrobial metals (e.g., silver, gold, etc.); hemostatic and/or vasoconstricting agents (e.g., pseudoephedrine, xylometazoline, oxymetazoline, phenylephrine, epinephrine, cocaine, etc.); local anesthetic agents (lidocaine, cocaine, bupivacaine,); hormones;anti-inflammatory agents (steroidal and non-steroidal); hormonally active agents; agents to enhance potency; substances to dissolve, degrade, cut, break, weaken, soften, modify or remodel connective tissue or other tissues; (e.g., enzymes or other agents such as collagenase (CGN), trypsin, trypsin/EDTA,

hyaluronidase, and tosyllysylchloromethane (TLCM)); chemotherapeutic or antineoplastic agents; substances that prevent adhesion formation (e.g., hyaluronic acid gel); substances that promote desired tissue ingrowth into an anchoring device or other implanted device; substances that promote or facilitate epithelialization of the urethra or other areas; substances that create a coagulative lesion which is subsequently resorbed causing the tissue to shrink; substances that cause the prostate to decrease in size; phytochemicals that cause the prostate to decrease in size; alpha-1a-adrenergic receptor blocking agents; 5-alpha-reductase inhibitors; smooth muscle relaxants; agents that inhibit the conversion of testosterone to dihydrotestosterone, etc. Specific examples of antitumor agents (e.g., cancer chemotherapeutic agents, biological response modifiers, vascularization inhibitors, hormone receptor blockers, cryotherapeutic agents or other agents that destroy or inhibit neoplasia or tumorigenesis) that may be delivered in accordance with the present invention include but are not limited to; alkylating agents or other agents which directly kill cancer cells by attacking their DNA (e.g., cyclophosphamide, isophosphamide), nitrosoureas or other agents which kill cancer cells by inhibiting changes necessary for cellular DNA repair (e.g., carmustine (BCNU) and lomustine (CCNU)), antimetabolites and other agents that block cancer cell growth by interfering with certain cell functions, usually DNA synthesis (e.g., 6 mercaptopurine and 5-fluorouracil (5FU), antitumor antibiotics and other compounds that act by binding or intercalating DNA and preventing RNA synthesis (e.g., doxorubicin, daunorubicin, epirubicin, idarubicin, mitomycin-C and bleomycin) plant (vinca) alkaloids and other anti-tumor agents derived from plants (e.g., vincristine and vinblastine), steroid hormones, hormone inhibitors, hormone receptor antagonists and other agents which affect the growth of hormone-responsive cancers (e.g., tamoxifen, herceptin, aromatase inhibitors such as aminoglutethamide and formestane, trriazole inhibitors such as letrozole and anastrazole, steroidal inhibitors such as exemestane), antiangiogenic proteins, small molecules, gene therapies and/or other agents that inhibit angiogenesis or vascularization of tumors (e.g., meth-1, meth-2, thalidomide), bevacizumab (Avastin), squalamine, endostatin, angiostatin, Angiozyme, AE-941 (Neovastat), CC-5013 (Revimid), medi-522 (Vitaxin), 2-methoxyestradiol

(2ME2, Panzem), carboxyamidotriazole (CAI), combretastatin A4 prodrug (CA4P), SU6668, SU11248, BMS-275291, COL-3, EMD 121974, IMC-1C11, IM862, TNP-470, celecoxib (Celebrex), rofecoxib (Vioxx), interferon alpha, interleukin-12 (IL-12) or any of the compounds identified in Science Vol. 289, Pages 1197-1201 (August 17, 2000) which is expressly incorporated herein by reference, biological response modifiers (e.g., interferon, bacillus calmette-guerin (BCG), monoclonal antibodies, interluken 2, granulocyte colony stimulating factor (GCSF), etc.), PGDF receptor antagonists, herceptin, asparaginase, busulphan, carboplatin, cisplatin, carmustine, cchlorambucil, cytarabine, dacarbazine, etoposide, flucarbazine, flurouracil, gemcitabine, hydroxyurea, ifosphamide, irinotecan, lomustine, melphalan, mercaptopurine, methotrexate, thioguanine, thiotepa, tomudex, topotecan, treosulfan, vinblastine, vincristine, mitoazitrone, oxaliplatin, procarbazine, streptocin, taxol, taxotere, analogs/congeners and derivatives of such compounds as well as other antitumor agents not listed here.

Additionally or alternatively, in some applications such as those where it is desired to grow new cells or to modify existing cells, the substances delivered in this invention may include cells (mucosal cells, fibroblasts, stem cells or genetically engineered cells) as well as genes and gene delivery vehicles like plasmids, adenoviral vectors or naked DNA, mRNA, etc. injected with genes that code for anti-inflammatory substances, etc., and, as mentioned above, macrophages or giant cells that modify or soften tissue when so desired, cells that participate in or effect the growth of tissue.

Figures 6A through 11B show various examples of anchor designs and/or anchoring device designs. Figures 6A and 6B show examples of a crumpling anchor 600. In Figure 6A, crumpling anchor 600 comprises a substantially flattened body 602. Body 602 can be made of a variety of materials including, but not limited to synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; natural fibers e.g. cotton, silk etc.; rubber materials e.g. various grades of silicone rubber etc. Further, in any of the

implantable tissue compression devices, any or all of the anchors, the tensioning element(s) and any other components may be coated, impregnated, embedded or otherwise provided with substance(s) (e.g., drugs, biologics, cells, etc.) to reduce the likelihood of infection, inflammation, treat the prostatic adenoma directly or enhance the likelihood of endothelialization, deter adhesion formation, promote healing or otherwise improve the likelihood or degree of success of the procedure. Such substance(s) may be released primarily at the time of delivery or may be released over a sustained period. Examples of such substances are listed above and include but are not limited to certain metals with bacteriostatic action (i.e. silver, gold, etc.), antibiotics, antifungals, hemostatic agents (i.e. collagen, hyaluronic acid, gelfoam, cyano-acrylate, etc.), anti-inflammatory agents (steroidal and non-steroidal), hormonally active agents, stem cells, endothelial cells, genes, vectors containing genes, etc. Body 602 may be non-woven or woven. Body 602 may have a variety of shapes including, but not limited to square, rectangular, triangular, other regular polygonal, irregular polygonal, circular etc. Body 602 may have a substantially one dimensional, two dimensional or three dimensional shape. The material chosen for this device may have hemostatic properties to reduce bleeding from the implantation tract or site. Distal end of body 602 is connected to the distal end of tension element 604. Body 602 further comprises one or more attachment means 606. Attachment means are used to create a channel in the body 602 through which tension element 604 passes. Crumpling anchor 600 is introduced through a region of tissue (e.g. through prostate gland tissue) into a cavity or lumen e.g. pelvic cavity, urethral lumen etc. In Figure 6B, tension element 604 is pulled in the proximal direction. The causes crumpling (e.g., collapsing) of the crumpling anchor 600 between the tissue and the distal end of tension element 604. This process prevents tension element 604 in the tissue and prevents further movement of tension element 604 in the proximal direction.

Figures 7A and 7B show an example of a deployable anchor 700 in an undeployed configuration and a deployed configuration, respectively. This deployable anchor 700 comprises one or more anchoring arms 702. Anchoring arms 702 may be made from a variety of elastic, super-elastic or

snape memory materials etc. Typical examples of such materials include but are not limited to metals e.g. stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc. Anchoring arms 702 are connected to a central hub 704. Central hub in turn is connected to the distal end of a tension element 706. In Figure 7A, anchoring arms 702 are folded inside a hollow deploying sheath 708. This reduces the undeployed diameter of anchoring arms 702 and also prevents unwanted anchoring of anchoring arms 702. In Figure 7B, deploying sheath 708 is pulled in the proximal direction. This releases anchoring arms 702 from the distal end of deploying sheath 702. This causes anchoring arms 702 to open in the radially outward direction. Anchor 700 can then anchor to tissue and resist movement of tension element 706 in the proximal direction.

Figures 8A and 8B show sectional views of an undeployed configuration and a deployed configuration respectively of a "T" shaped deployable anchor. Anchor 8110 comprises an elongate region 802. Elongate region 802 may be made from a variety of elastic, super-elastic or shape memory materials etc. Typical examples of such materials include but are not limited to metals e.g. stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc; polymers e.g. polypropylene, Teflon etc. Middle section of elongate region 802 is connected to the distal end of a tension element 804 to form a "T" shaped anchor. In one embodiment, middle section of elongate region 802 is connected to the distal end of a tension element 804 by a hinge. In Figure 8A, elongate region 802 is folded inside a hollow deploying sheath 806. This reduces the undeployed diameter of the distal region of anchor 8110 and also prevents unwanted anchoring of elongate region 802 to tissue. In Figure 8B, deploying sheath 806 is pulled in the proximal direction. This releases elongate region 802 from the distal end of deploying sheath 806. This in turn causes elongate region 802 to twist and orient itself perpendicular to the distal end of a tension element 804. Anchor 800 can then anchor to tissue and resist movement of tension element 804 in the proximal direction.

Anchoring arms 702 in Figures 7A and 7B can have a variety of

configurations including, but not limited to configurations shown in Figures 9A through 9D. Figure 9A shows a distal end view of an embodiment of an anchor comprising two triangular arms. Anchor 900 comprises two anchor arms 902. Anchor arms 902 can be made of a variety of materials including, but not limited to metals e.g. stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc; polymers e.g. polypropylene, Teflon etc. Anchor arms 902 are connected to a tension element 904. In one embodiment, anchor arms 902 are connected to a central hub, which in turn is connected to tension element 904. The arms in each of these devices may be folded or contained prior to deployment through the use of a sheath or grasping or mounting device. Figure 9B shows a distal end view of an embodiment of an anchor comprising four rectangular arms. Anchor 906 comprises four anchor arms 908. Anchor arms 908 can be made of a variety of materials including, but not limited to metals e.g. stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc; polymers e.g. polypropylene, Teflon etc. Anchor arms 908 are connected to a tension element 910. In one embodiment, anchor arms 908 are connected to a central hub, which in turn is connected to tension element 910. Figure 9C shows a distal end view of an embodiment of an anchor comprising a mesh or a woven material. Anchor 912 comprises four anchor arms 914. Anchor arms 914 can be made of a variety of materials including, but not limited to metals e.g. stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc; polymers e.g. polypropylene, Teflon etc. Anchor arms 914 are connected to a tension element 916. In one embodiment, anchor arms 914 are connected to a central hub, which in turn is connected to tension element 916. A layer of porous material 918 is located between anchor arms 914. Porous material 918 comprises a plurality of pores that allow for tissue ingrowth. Porous material 918 may also help to distribute the pressure on anchor arms 914 over a wider area. Porous material 918 can be made of variety of materials including, but not limited to synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; natural fibers e.g. cotton, silk etc.; rubber materials e.g. various grades of silicone rubber etc. Porous material 918 may

be non-woven or woven. Any of the arms or struts in one or more anchoring devices may comprise bent or curved regions. For example, Figure 9D shows a distal end view of an embodiment of an anchor comprising four curved arms. Anchor 920 comprises four curved anchor arms 922. Curved anchor arms 922 can be made of a variety of materials including, but not limited to metals e.g. stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc; polymers e.g. polypropylene, Teflon etc. Curved anchor arms 922 are connected to a tension element 924. In one embodiment, curved anchor arms 922 are connected to a central hub which in turn is connected to tension element 924.

Figure 10A shows a distal end view of an anchor comprising a spiral element having a three dimensional shape. Anchor 1000 comprises a three dimensional spiral element 1002. Diameter of spiral element 1002 may be substantially constant or may substantially vary along the length of spiral element 1002. Spiral element 1002 may be made of an elastic, super-elastic or shape memory materials. Spiral element 1002 may be made of a variety of materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc.; synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; natural fibers e.g. cotton, silk etc.; rubber materials e.g. various grades of silicone rubber etc. Spiral element 1002 is connected to a central hub 1004, which in turn is connected to a tension element. In one embodiment, spiral element 1002 is directly connected to a tension element without using central hub 1004. Figure 10A' shows a side view of the anchor in Figure 10A. Figure 10A' shows anchor 1000 comprising spiral element 1002 connected to central hub 1004 which in turn is connected to a tension element 1006. Figure 10B shows a distal end view of an anchor comprising a spiral element having a two dimensional shape. Anchor 1000 comprises a two dimensional spiral element 1010. Spiral element 1010 may be made of an elastic, super-elastic or shape memory materials. Spiral element 1010 may be made of a variety of materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.;

polymers e.g. polypropylene, Teflon etc.; synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; natural fibers e.g. cotton, silk etc.; rubber materials e.g. various grades of silicone rubber etc. Spiral element 1010 is connected to a central hub 1012 which in turn is connected to a tension element. In one embodiment, spiral element 1010 is directly connected to a tension element without using central hub 1012. Figure 10B' shows a side view of the anchor in Figure 10B. Figure 10B' shows anchor 1008 comprising spiral element 1010 connected to central hub 1012 which in turn is connected to a tension element 1014. Figure 10C shows a distal end view of an anchor comprising one or more circular elements. In Figure 10C, anchor 1016 comprises an inner circular element 1018 and an outer circular element 1020. A series of radial arms or struts 1022 connect inner circular element 1018 to outer circular element 1020 and to a central hub 1024. Central hub 1024 may have a lumen 1026. Anchor 1016 may be substantially two dimensional or three dimensional. Figure 10C' shows a perspective view of the anchor in Figure 10C. Figure 10C' shows an anchor 1016 comprising an inner circular element 1018, an outer circular element 1020 and series of radial arms or struts 1022 connecting inner circular element 1018 to outer circular element 1020 and to a central hub 1024. Central hub 1024 is connected to a tension element.

Figure 10D shows a perspective view of an embodiment of an anchoring device comprising an outer ring. Anchor 1040 comprises a central hub 1042 and an outer ring 1044. In one embodiment, central hub 1042 acts as a plug to plug an opening in the anatomy to reduce or prevent bleeding or leakage of fluids. Central hub 1042 is connected to outer ring 1044 by one or more bars or struts 1046. In one embodiment, central hub 1042 is connected to an inner ring 1048 which in turn is connected to outer ring 1044 by one or more bars or struts 1046. Central hub 1042 further comprises a locking element 1050. Locking element 1050 comprises a lumen 1052 through which a tension element can slide. After positioning anchor 1040 in a desired position with respect to the tension element, locking element 1050 is used to securely attach anchor 1040 on the tension element. Locking element 1050 may comprise a design disclosed including various locking designs disclosed

elsewhere in this patent application. Anchor 1040 may be made from a variety of materials including, but not limited to synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; natural fibers e.g. cotton, silk etc.; rubber materials e.g. various grades of silicone rubber etc.

Figure 10E shows a partial perspective view of an anchoring device comprising a hemostatic element. Anchor 1060 comprises a central hub 1062. In one embodiment, central hub 1062 acts as a plug to plug an opening in the anatomy to reduce or prevent bleeding or leakage of fluids. Central hub 1062 comprises a cinching mechanism to allow central hub 1062 to cinch on to a tension element 1064 passing through central hub 1062. The free end 1066 of tension element 1064 is severed to minimize the presence of tension element 1064 in the anatomy. Anchor 1060 further comprises an outer ring 1068. Central hub 1062 is connected to outer ring 1068 by one or more struts 1070. Anchor 1060 further comprises a mesh or porous element 1072 between outer ring 1068 and struts 1070. The mesh or porous element 1072 may be concave shaped as shown in Figure 10E. Mesh or porous element 1072 allows for tissue ingrowth over a period of time thus providing additional securing of anchor 1060 to tissue.

Figure 11A shows a perspective view of a device having a set of anchors comprising a curved sheet. Anchoring device 1100 may comprise one or more anchors comprising a curved sheet. In this example, anchoring device 1100 comprises a first anchor 1102 and a second anchor 1104. First anchor 1102 and second anchor 1104 may comprise elastic, super elastic or shape memory materials. First anchor 1102 and second anchor 1104 may be made from various materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc.; synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; natural fibers e.g. cotton, silk etc.; rubber materials e.g. various grades of silicone rubber etc. The concave surface of first anchor 1102 is connected to

a first end of a tension element 1106. Second end of tension element 1106 is connected to the convex surface of second anchor 1104. In one embodiment of a method to deploy anchoring device 1106, first anchor 1102 is deployed out of an anatomical tissue (e.g. the prostate gland) into a first anatomical cavity (e.g. the pelvic cavity). Thereafter, second anchor 1104 is deployed into a second anatomical cavity (e.g. the urethral lumen). This method embodiment has the advantage of using the natural curvature of first anchor 1102 and second anchor 1104 to distribute pressure on first anchor 1102 and second anchor 1104 over a large area.

Figures 12A through 17I show further examples of anchor designs and/or anchoring device designs. Figure 12A shows a perspective view of an anchor comprising an arrowhead. Anchor 1200 comprises an arrowhead 1202. Arrowhead 1202 may be made from various materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc.; rubber materials e.g. various grades of silicone rubber etc. Arrowhead 1202 may comprise a sharp distal tip. Arrowhead 1202 may have a three dimensional or a substantially two dimensional design. Proximal region of arrowhead 1202 is wider that the distal region of arrowhead 1202 to resist motion of arrowhead 1202 along the proximal direction after it is deployed in a tissue. Proximal region of arrowhead 1202 is connected to a tension element 1204. Figure 12B shows a crossectional view of an anchor comprising a cup-shaped element that encloses a cavity. Anchor 1208 comprises a cup-shaped element 1210. Proximal, concave surface of cup-shaped element 1210 encloses a cavity. Cup-shaped element 1210 may be made from various materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc.; rubber materials e.g. various grades of silicone rubber etc. Proximal region of cup-shaped element 1210 is connected to a tension element 1212. Figure 12C shows a perspective view of an anchor comprising a screw. Anchor 1216 comprises a screw 1218. Screw 1218 may be made from various materials including, but not limited to metals e.g. various grades of stainless steel,

titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc. Screw 1218 may comprise a sharp distal tip. Proximal region of screw 1218 may be wider that the distal region of screw 1218 to resist motion of screw 1218 along the proximal direction after it is deployed in a tissue. Screw 1218 comprises a thread rolled thread including, but not limited to wood screw style thread, double lead thread, tapping style thread, tapered wood thread etc. Proximal region of arrowhead 1202 is connected to a tension element 1204.

Figure 13A and 13B show perspective views of an uncollapsed state and a collapsed state respectively of an anchor comprising a collapsible region. In Figure 13A, anchor element 1300 is in an uncollapsed state. Anchor element 1300 comprises a hollow shaft 1302 comprising one or more collapsible regions. A collapsible region comprises one or more windows 1304. Windows 1304 are cut in hollow shaft 1302 in such a way that several thin, collapsible struts 1306 are created between adjacent windows 1304. In Figure 13B, anchor element 1300 is in a collapsed state. When anchor element 1300 is compresses along its length, collapsible struts 1306 are deformed in the radially outward direction to create one or more anchoring regions.

Figures 13C and 13D show perspective views of an undeployed state and a deployed state respectively of an anchor comprising radially spreading arms. In Figure 13C, anchor 1312 comprises a hollow tube 1314. Hollow tube 1314 is made from suitable elastic, super-elastic or shape memory materials such as metals including, but not limited to titanium, stainless steel, Nitinol etc.; suitable elastic polymers etc. U-shaped slots 1316 are cut in hollow tube 1314 in such a way that arms 1318 are created within U-shaped slots 1316. In this embodiment, U-shaped slots are substantially parallel to the axis of hollow tube 1314. In absence of an external force, arms 1318 tend to spread in a radially outward direction. Anchor 1312 is kept in an undeployed state by enclosing anchor 1312 in a sheath. Anchor 1312 is deployed by removing the sheath to allow arms 1318 to spread in a radially outward direction as shown in Figure 13D.

Hollow tube 1314 may comprise one or more cinching elements. Cinching elements may be located on the proximal region, distal region or a middle region of hollow tube 1314. The cinching element or elements may comprise cinching mechanisms including, but not limited to cinching mechanisms disclosed in figures 26A through 29P.

Figure 13E shows perspective views of an alternate embodiment of an undeployed state of an anchor comprising radially spreading arms. In Figure 13C, anchor 1320 comprises a hollow tube 1322. Hollow tube 1322 is made from suitable elastic, super-elastic or shape memory materials such as metals including, but not limited to titanium, stainless steel, Nitinol etc.; suitable elastic polymers etc. U-shaped slots 1324 are cut in hollow tube 1322 in such a way that arms 1326 are created within U-shaped slots 1324. In this embodiment, U-shaped slots are at an angle to the axis of hollow tube 1322 as shown in Figure 13E.

Figures 14A and 14B show perspective views of anchoring devices comprising an adhesive delivering element. Figure 14A shows a perspective view of an anchoring device 1400 comprising a hollow shaft 1402 with a shaft lumen. Hollow shaft 1402 can be made of suitable biocompatible materials including, but not limited to Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, metals like stainless steel and fluoropolymers like PTFE, PFA, FEP and EPTFE etc. Distal end of shaft lumen ends in a delivery opening 1404. When an adhesive is injected through the shaft lumen, it emerges out of anchoring device 1400 through delivery opening 1404. Hollow shaft 1402 may also comprise an attachment element 1406 such as a porous woven or non-woven circular sleeve securely attached to hollow shaft 1402. The circular sleeve may be made of a variety of materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc.; synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; natural fibers e.g. cotton, silk etc.; rubber materials e.g. various grades of silicone rubber etc. The adhesive flowing out through delivery opening comes into contact

with attachment element 1406 and securely attaches attachment element 1406 to surrounding tissue. Figure 14B shows a perspective view of an anchoring device 1408 comprising a hollow shaft 1410 with a shaft lumen. Hollow shaft 1410 can be made of suitable biocompatible materials including, but not limited to Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, metals like stainless steel and fluoropolymers like PTFE, PFA, FEP and EPTFE etc. Distal end of shaft lumen ends in a delivery opening 1412. When an adhesive is injected through the shaft lumen, it emerges out of anchoring device 1408 through delivery opening 1412. Hollow shaft 1410 may also comprise an attachment element 1414 such as porous foam securely attached to hollow shaft 1410. The porous foam may be made of a variety of materials including, but not limited to polymers e.g. polypropylene, Teflon etc.; synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; rubber materials e.g. various grades of silicone rubber etc. The adhesive flowing out through delivery opening comes into contact with attachment element 1414 and securely attaches attachment element 1414 to surrounding tissue. Typical examples of adhesives that can be used with anchoring device 1400 and anchoring device 1408 include but are not limited to cyanoacrylates, marine adhesive proteins, fibrin-based sealants etc.

Figures 15A and 15B show two configurations of an anchoring device comprising a ratcheted tension element. Anchoring device 1500 comprises a distal anchor. Distal anchor may comprise a design selected from the variety of designs disclosed elsewhere in this document. In this particular example, distal anchor comprises a series of radial arms 1502 connected to a central hub 1504. The proximal end of central hub is attached to a ratcheted tension element 1506. A proximal anchor is located on ratcheted tension element 1506 proximal to the distal anchor. Proximal anchor may comprise a design selected from the variety designs disclosed elsewhere in this document. In this particular example, distal anchor comprises a series of radial arms 1508 connected to a central hub 1510. Central hub 8368 has a central lumen through which ratcheted tension element 1506 can slide. Ratcheted tension element 1506 has ratchets arranged such that proximal anchor can slide

easily over ratcheted tension element 1506 in the distal direction but cannot slide easily in the proximal direction. In Figure 15B, proximal anchor slides over ratcheted tension element 1506 in the distal direction. This causes a compression of tissue between distal anchor and proximal anchor. The compression of tissue can be maintained since proximal anchor cannot slide easily in the proximal direction. In one embodiment of a method using anchoring device 1500, distal anchor is introduced via an anatomical lumen (e.g. the urethral lumen) and through a tissue (e.g. the prostate gland) into an anatomical cavity (e.g. the pelvic cavity). Thereafter, proximal anchor is advanced along ratcheted tension element 1506 till it encounters a wall (e.g. the urethral wall) of the anatomical lumen. Anchoring device 1500 may be made from various materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc.

Figure 16 shows a perspective view of an anchor comprising a trocar lumen. Anchor 1600 comprises a hollow shaft 1602 comprising a lumen. A trocar 1604 or a penetrating device can pass through hollow shaft 1602 such that the distal tip of trocar 1604 emerges out through the distal end of hollow shaft 1602. Distal end of hollow shaft 1602 comprises a tapering region 1606 with a smaller distal diameter and a larger proximal diameter. Tapering region 1606 further comprises a series of sharp projections 1608 located on the proximal end of tapering region 1606. Projections 1608 may be projecting in the proximal direction, radially outward direction etc. Projections 1608 prevent the movement of anchor 1600 in the proximal direction after it has penetrated through a tissue. Anchor 1600 may also comprise a sleeve 1610 located proximal to tapering region 1606. Sleeve 1610 is made of a porous material that has a plurality of pores that allow for tissue ingrowth thus anchoring sleeve 1610 firmly in tissue. Sleeve 1610 may also help to distribute the pressure on tapering region 1606 over a wider area. Sleeve 1610 may be non-woven or woven. Sleeve 1610 can be made of variety of materials including, but not limited to synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium

alloys, tantalum etc.; natural fibers e.g. cotton, silk etc.; rubber materials e.g. various grades of silicone rubber etc.

Figure 17A shows a perspective view in the undeployed state of an anchor comprising a rigid or partially flexible T element and a crumpling element. In Figure 17A, anchoring device 1700 comprises a distal, T element 1702. The T element 1702 may be made of a variety of materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc.; rubber materials e.g. various grades of silicone rubber etc. Further it may be a composite material or have cut out sections to allow it to be flexible in certain dimensions but rigid in other dimensions. In this example, T element 1702 is in the form of a hollow cylinder. The proximal end of T element 1702 is in contact with the distal end of a delivery rod 1704. Delivery rod 1704 is hollow and is used to deliver T element 8266 in a target anatomical region. A trocar 1705 can pass through delivery rod 1704 and through T element 1702 such that the distal tip of trocar emerges through the distal end of rigid element 1702. The T-element could also be contained within a lumen of the trocar or may be the trocar itself. of the T element 1702 is connected to the distal end of a flexible tension element 1706. Various connection means are possible such as the tension element being tied or crimped to the T element, or passing through a loop in the T element, or being adhered by adhesive or weld, or by being made of a continuous material which becomes the T element. Although the T element is shown as a T, any shape which is larger in at least one dimension compared to its other dimensions could appropriately be released and cause to change it's orientation to produce an anchoring effect. Examples of materials that can be used to manufacture tension element 1706 include but are not limited to synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; natural fibers e.g. cotton, silk etc.; rubber materials e.g. various grades of silicone rubber etc. A substantially flattened body 1708 is located on the distal region of tension element 1706. Tension element 1706 is threaded through body 1708 in such

a way that tension element 1706 can slide through body 1708. Body 1708 may be non-woven or woven. Body 1708 can be made of a variety of materials including, but not limited to synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; natural fibers e.g. cotton, silk etc.; rubber materials e.g. various grades of silicone rubber etc. Body 1708 may have a variety of shapes including, but not limited to square, rectangular, triangular, other regular polygonal, irregular polygonal, circular etc. Body 1708 may have a substantially one dimensional, two dimensional or three dimensional shape. Figures 17B and 17C show various steps of a method to deploy the anchoring device shown in Figure 17A. In Figure 17B, anchoring device 1700 is introduced in an anatomical cavity (e.g. the pelvic cavity) through a tissue (e.g. the prostate gland). Thereafter, trocar 1705 is withdrawn by pulling trocar 1705 in the proximal direction. Thereafter, delivery rod 1704 is withdrawn by pulling delivery rod 1704 in the proximal direction. Thereafter, tension element 1706 is pulled in the proximal direction. Tension element 1706 in turn pulls T element 1702 in the proximal direction. In Figure 17C, rigid element 1702 is pulled against a wall of the tissue (e.g. the prostate gland) but is unable to penetrate the tissue because of its size. This causes body 1708 to crumple because of compression of body 1708 between the wall of the tissue and rigid element 1702. Crumpled body 1708 may be designed to cause tissue ingrowth or epithelialization in body 1708 as well as healing, hemostasis or a more even force distribution.

Figures 17D and 17E show perspective views of an undeployed and deployed configuration of an anchor comprising a rigid or partially flexible T element with one or more openings or perforations. Figure 17D shows a perspective view of an anchoring device 1720 comprising an anchor 1722. Anchor 1722 comprises a tubular body. The tubular body may comprise one or more openings or perforations 1724 in the tubular body. Openings or perforations 1724 increase the flexibility of anchor 1722. This makes it easier to navigate anchoring device 1720 through the anatomy before reaching its target location. Further it enables anchoring device 1720 to be passed

through a tight bend in the anatomy or through a delivery device. Within tubular body of anchor 1722 is trocar tip 1727 that is fixedly attached to tensioning element 1728. In the embodiment shown in figure 17D, anchor 1722 comprises a lumen. A length of the distal end of deployment element 1726 passes through the proximal end of the lumen and abuts trocar tip 1727 that enables anchor 1722 to puncture tissue. In an alternate embodiment trocar tip is fixedly attached to elongate deployment element 1726 and is retracted fully into element 1729 upon anchor deployment. In an alternate embodiment, distal tip of deployment device 1726 is not exposed through the distal end of anchor 1722. Distal end of anchor 1722 comprises a sharp tip to enable anchor 1722 to puncture tissue. Anchoring element 1720 further comprises a tension element 1728 attached to tubular body 1722. In this embodiment, distal end of tension element 1728 attached to the inner surface of the trocar tip 1727. Proximal region of tension element 1728 passes through deployment element 1726. Anchor 1722 is deployed by pushing in a distal direction one elongate deployment element 1726, that runs within lumen of anchor 1722 abutting trocar tip 1727 distally, in tandem with another elongate deployment element 1729 that abuts the proximal end of anchor 1722. Anchoring device 1720 punctures tissue to transport anchor 1722 through a first anatomical location (e.g. a prostate gland) to a second anatomical location (e.g. the pelvic cavity, urethra etc.). Thereafter, deployment element 1726 is withdrawn by pulling deployment element 1726 in the proximal direction. Thereafter, tension element 1728 is pulled in the proximal direction. This causes anchor 1722 to anchor in tissue as shown in figure 17E. Proximal portion of tension element 1728 emerges out of anchor 1722 through a lengthwise groove in anchor 1722 to create a T shaped anchor as shown in figure 17E. Tension on tensioning element 1728 causes trocar tip 1727 to retract into lumen 1722. In the example shown, the first anatomical location is the prostate gland PG and the second anatomical location is the pelvic cavity. Anchoring device 1720 can be made from a variety of materials including, but not limited to metals such as synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; natural fibers e.g. cotton, silk

etc.; rubber materials e.g. various grades of silicone rubber etc. Tension element 1728 may then be connected to any one of the other anchoring elements such as anchor 10D.

Figures 17F and 17G show perspective views of an undeployed and deployed configuration of an anchor comprising a stent. Anchor 1730 comprises a self-expanding stent 1732 and a tension element 1734. Distal end of tension element 1734 is attached to stent 1732. In one embodiment, distal end of tension element 1734 is attached on the mid section of stent 1732. Stent 1732 may comprise various designs including, but not limited to metallic tube designs, polymeric tube designs, spiral designs, chain-linked designs, rolled sheet designs, single wire designs etc. Stent 1732 may have an open celled or closed celled structure. A variety of fabrication methods can be used for fabricating stent 1732 including but not limited to laser cutting a metal or polymer element, welding metal elements etc. A variety of materials can be used for fabricating stent 1732 including but not limited to metals, polymers, foam type materials, super elastic materials etc. A variety of features can be added to stent 1732 including but not limited to radiopaque coatings, drug elution mechanisms etc. Anchor 1730 is introduced through a sheath 1736 into a target anatomy. Thereafter, sheath 1736 is withdrawn. This causes stent 1732 to revert to its natural shape as shown in Figure 17G and act as an anchor.

Figures 17H and 17I show perspective views of an undeployed and deployed configuration of an anchor comprising a spring. Anchor 1740 comprises an elastic spring 1742 and a tension element 1744. Distal end of tension element 1744 is attached to spring 1742. In one embodiment, distal end of tension element 1744 is attached on the mid section of spring 1742. A variety of materials can be used for fabricating spring 1742 including but not limited to metals, polymers, foam type materials, super elastic materials etc. A variety of features can be added to spring 1742 including but not limited to radiopaque coatings, drug elution mechanisms etc. Anchor 1740 is introduced through a sheath 1746 into a target anatomy to reduce the profile of spring

1742. Thereafter, sheath 1746 is withdrawn. This causes spring 1742 to revert to its natural shape as shown in Figure 17I and act as an anchor.

Figures 18A through 22E show various embodiments of mechanisms to deploy one or more anchors. Figure 18A shows a crossection of an anchor deploying mechanism comprising a screw system. Figure 18A shows an anchor deploying mechanism comprising an anchor 1800 comprising an anchor body 1802 and anchoring elements 1804 attached to anchor body 1802. Anchor body 1802 comprises an inner lumen. Inner lumen of anchor body 1802 comprises screw threading. Anchoring elements 1804 may have various designs including, but not limited to anchor designs disclosed elsewhere in this document. Anchor body 1802 and anchoring elements 1804 may be made of a variety of materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc.; rubber materials e.g. various grades of silicone rubber etc. The anchor deploying mechanism further comprises a deploying shaft 1806. Distal region of deploying shaft 1806 comprises a screw threading such that deploying shaft 1806 can be screwed into anchor body 1802. Figure 18B shows the method of deploying an anchor comprising a screw mechanism. Deploying shaft 1806 is rotated to release the distal region of deploying shaft 1806 from anchor body 1802 after positioning anchor 1800 in a desired location. Such a mechanism can be used to deploy one or more anchors. In one embodiment, more than one anchors are located on deploying shaft 1806. The anchors can be sequentially deployed by rotating deploying shaft 1806. Deploying shaft 1806 may be made of a variety of materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc. In one embodiment, the anchor deploying mechanism is located inside an outer sheath.

Figures 19A and 19B show a crossectional view of an anchor deploying system comprising an electrolytic detachment element. Figure 19A shows a crossection of an anchor deploying mechanism comprising a

deployable anchor 1900. Deployable anchor 1900 comprises an anchor body 1902 and anchoring elements 1904 attached to anchor body 1902. Anchoring elements 1904 may have various designs including, but not limited to anchor designs disclosed elsewhere in this document. Anchor body 8402 and anchoring elements 8404 may be made of a variety of materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc.; rubber materials e.g. various grades of silicone rubber etc. Proximal region of deployable anchor 1900 further comprises an electrolyzable element 1906. Electrolyzable element 1906 is made of a length of metallic wire e.g. steel wire. Proximal region of electrolyzable element 1906 is electrically connected to a deploying shaft 1908. Proximal region of deploying shaft 1908 is further connected to a first electrode. The anchor deploying system further comprises a second electrode 1910 connected to a bodily region of the patient to be treated. In Figure 19B, the first electrode is connected to a positive terminal of a power supply and the second electrode is connected to the negative terminal of the power supply to form an electrical circuit. Electrical current flowing between electrolyzable element 1906 and second electrode 1910 causes metallic ions from electrolyzable element 1906 to dissolve into surrounding anatomy. This causes electrolyzable element 1906 to detach from deploying shaft 1908.

Figure 20 shows a perspective view of an anchor deploying system comprising a looped ribbon. The anchor deploying system comprises a deployable anchor 2000. Deployable anchor 2000 comprises an anchor body 2002 and anchoring elements 2004 attached to anchor body 2002. Anchoring elements 2004 may have various designs including, but not limited to anchor designs disclosed elsewhere in this document. Anchor body 2002 and anchoring elements 2004 may be made of a variety of materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc.; rubber materials e.g. various grades of silicone rubber etc. Proximal region of deployable anchor 2000 further comprises a looping lumen 2006. A looped ribbon 2008 is looped through looping lumen

2006. Looped ribbon 2008 may be made of a variety of materials including, but not limited to synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; natural fibers e.g. cotton, silk etc.; rubber materials e.g. various grades of silicone rubber etc. looped ribbon 2008 extends to a proximal region where it can be cut by a user. In a method of deploying deployable anchor 2000, a single cut is made in looped ribbon 2008 at a proximal region. This turns looped ribbon 2008 into a straight ribbon. The straight ribbon can then be pulled in the proximal direction to remove it from deployable anchor 2000. Looped ribbon 2008 may also be in the form of a looped monofilament or multifilament wire or suture.

Figures 21A shows a crossectional view of an anchor deploying system comprising a locked ball. The anchor deploying system comprises a deployable anchor 2100. Deployable anchor 2100 comprises an anchor body 2102. Deployable anchor 2100 may have various designs including, but not limited to anchor designs disclosed elsewhere in this document. Proximal end of anchor body 2102 is connected to a thin shaft 2104. Proximal end of thin shaft 2104 comprises a locking ball 2106. Anchor body 8428, thin shaft 2104 and locking ball 2106 may be made of a variety of materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc.; rubber materials e.g. various grades of silicone rubber etc. The anchor deploying system further comprises an outer locking sheath 2108. Distal end of locking sheath 2108 comprises an opening 2110. Diameter of opening 2110 is greater than the diameter of thin shaft 2104 but greater than diameter of locking ball 2106. Thus, locking ball 2106 is locked in locking sheath 2108. The anchor deploying system further comprises a deploying shaft 2112 located within locking sheath 2108. Deploying shaft 2112 can be pushed in the distal direction within locking sheath 2108 by a user. Locking sheath 2108 and deploying shaft 2112 may be made of a variety of materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys,

tantalum etc.; polymers e.g. polypropylene, Teflon etc. In one embodiment, distal region of locking sheath 2108 comprises one or more longitudinal grooves or windows to allow distal region of locking sheath 2108 to expand easily in the radial direction. Figures 21B and 21C show a method of deploying an anchor comprising a locked ball. In Figure 21B, deploying shaft 2112 is pushed in the distal direction by a user. This causes distal end of deploying shaft 2112 to push locking ball 2106 in the distal direction. This in turn causes locking ball 2106 to exert a force on the distal end of locking sheath 2108. This force causes opening 2110 to enlarge and release locking ball 2106. In Figure 21C, locking ball 2106 is released by locking sheath 2108 thus releasing deployable anchor 2100.

Figures 22A through 22C show various views of an anchor deploying system comprising two interlocking cylinders. The anchor deploying system comprises a proximal interlocking cylinder and a distal interlocking cylinder. The distal interlocking cylinder is located on an anchor to be deployed. Figure 22A shows a perspective view of a proximal interlocking cylinder 2200 comprising a locking element 2202 located on the distal end of proximal interlocking cylinder 2200. In this example, locking element 2202 comprises a solid cylinder with a ninety degree bend. Proximal interlocking cylinder 2200 and locking element 2202 may be made of a variety of materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc. Figure 22B shows a crossectional view of the anchor deploying system comprising proximal interlocking cylinder 2200 interlocked with a distal interlocking cylinder 2204. Distal interlocking cylinder 2204 comprises a groove 2206 which locks locking element 2202. Locking element 2202 can be unlocked from distal interlocking cylinder 2204 by turning proximal interlocking cylinder 2200. distal interlocking cylinder 2204 may be made of a variety of materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; polymers e.g. polypropylene, Teflon etc.; rubber materials e.g. various grades of silicone rubber etc. Figure 22C shows a crossectional view through plane A-A in Figure 22B. Figure 22C shows

distal interlocking cylinder comprising groove 2206. Also shown is locking element 2202 located in groove 2206. Turning proximal interlocking cylinder 2200 turns locking element 2202. At a particular orientation, distal region of locking element 2202 can pass easily through groove 2206 unlocking proximal interlocking cylinder 2200 from distal interlocking cylinder 2204.

Figures 22D and 22E show the steps of a method of unlocking the two interlocking cylinders from the anchor deploying systems of Figures 22A through 22C. In Figure 22D, locking element 2202 of proximal interlocking cylinder 2200 is locked in groove 2206 of distal interlocking cylinder 2204. In Figure 22E, proximal interlocking cylinder 2200 is turned in a clockwise or counterclockwise direction to unlock locking element 2202 from groove 2206. Thereafter, proximal interlocking cylinder 2200 is pulled in the proximal direction to separate proximal interlocking cylinder 2200 from distal interlocking cylinder 2204.

Figure 23A shows a perspective view of a distal end of an anchoring device that has an imaging modality. Anchoring device 2300 comprises an elongate shaft 2302 comprising a lumen. Elongate shaft 2302 can be made of suitable biocompatible materials such as metals, polymers etc. The lumen of shaft 2302 terminates in a window 2304 located on the distal region of shaft 2302. Anchoring device further comprises an imaging modality such as a cystoscope, an ultrasound imaging system etc. In this example, the imaging modality is a cystoscope 2306. Distal end of cystoscope 2306 is located in window 2304 to allow visualization of the anatomy adjacent to window 2304. In one embodiment, cystoscope 2306 is permanently fixed to anchoring device 2300. In another embodiment, cystoscope 2306 can be introduced through the proximal region of anchoring device 2300. Anchoring device 2300 further comprises a puncturing device 2308. Puncturing device 2308 comprises a sharp distal tip and a lumen that holds an anchor. Anchoring device 2300 further comprises an anchor deployment device 2310. Distal end of anchor deployment device 2310 is detachably attached to the anchor.

Figures 23B through 23G show various steps of a method for compressing an anatomical region using the anchoring device of Figure 23A.

In Figure 23B, Anchoring device 2300 is introduced in an anatomical region such that distal end of anchoring device 2300 is located adjacent to a target anatomical region to be treated. In one method embodiment, anchoring device 2300 is introduced transurethrally into the prostatic urethra. Thereafter, puncturing device 2308 is advanced to puncture the anatomical region. In this example, puncturing device 2308 punctures the prostate gland PG such that distal end of puncturing device 2308 is located in the pelvic cavity. Puncturing device comprises an anchor located in the lumen of puncturing device 2308. The anchor comprises a distal anchor 2312, a tension element 2314 connected at one end to distal anchor 2312 and a proximal anchor 2316 that can slide over tension element 2314. Puncturing device 2308 comprises a groove at the distal end such that tension element exits puncturing device 2308 through the groove. Puncturing device 2308 further comprises a pusher 2318 that can push distal anchor 2312 out of puncturing device 2308. Proximal anchor 2316 is detachably attached to the distal region of anchor deployment device 2310. Proximal anchor 2312, distal anchor 2316 and tension element 2314 may comprise designs including, but not limited to the designs disclosed elsewhere in this patent application. The imaging modality may be used to verify the accurate placement and working of anchoring device 2300. In Figure 23C, pusher 2318 is pushed in the distal direction to push distal anchor 2312 out of puncturing device 2308. Distal anchor 2312 is thus deployed in the anatomy e.g. in the pelvic cavity surrounding the prostate gland PG. Thereafter, in step 23D, Puncturing device 2308 is withdrawn by pulling it in the proximal direction. In step 23E, tension element 2314 is pulled in the proximal direction through anchor deployment device 2310. Thereafter, in step 23F, tension element 2314 is pulled further in the proximal direction such that the anatomical region between proximal anchor 2316 and distal anchor 2312 is compressed. Thereafter, in step 23G, proximal anchor 2316 is securely locked on to tension element 2314. Further in step 23G, proximal anchor 2316 is detached from anchor deployment device 2310. The detachment can be performed by a variety of mechanisms including, but not limited to the anchor detachment mechanisms disclosed elsewhere in this patent application. Further in step 23G, excess length of tension element 2314 is removed. This removal can be done using a variety of methods

including, but not limited to the methods disclosed elsewhere in this patent application such as cutting, delinking, melting, and breaking. Thereafter, anchoring device 2300 is withdrawn from the anatomy. It should be understood that these deployment steps may be repeated in the same, opposing or neighboring tissues to essentially tack up the encroaching tissue (i.e. prostatic tissue, tumor, relaxed tissue, expanded tissue or growth). It may be desired that over time both anchors become completely embedded within the tissue and covered to prevent encrustation, clotting or other tissue or body-fluid interaction – this may be facilitated by the processes, therapeutic agents and coatings described elsewhere in the application. Although these anchors are shown on either side of the tissue, it may be possible to deploy either or both of them within the body of the tissue itself to help bury them and eliminate the possibility that they may interact with other parts of the body. It should further be noted that in the case of application to the prostate, that this technique may be used on any of the lateral or middle lobes to compress or hold the prostate gland PG away from the lumen of the urethra.

If removal of the intra or para luminal anchor is required, it may be possible to resect that region completely, capturing the anchor embedded within the tissue and removing it en-bloc, severing the tether in the process. In the case of prostate applications, such removal may be accomplished with a standard resectoscope system. In other regions, and energized RF or sharp curette or blade may be used to resect the anchor minimally invasively. Alternatively if engagement with the locking mechanism is still achievable, it may be possible to simply unlock the tether, releasing the anchor. Lastly, if applying additional tension at some point after the procedure is required, it may be possible to engage and grasp the tether as it exits the locking device in the anchor and apply additional tension.

Figures 24A through 24C' show various steps of a method of compressing an anatomical region using a device with deploying arms deployed through a trocar. In Figure 24A, an anchoring device 2400 is introduced in an anatomical region. Anchoring device 2400 comprising a distal anchor 2402 is introduced in the anatomy. Distal anchor 2402 comprises a

hollow shaft. Distal end of distal anchor 2402 comprises one ore more outwardly curling or spreading arms 2404. Curling or spreading arms 2404 are made of an elastic, springy, super-elastic or shape memory material such that they tend to curl or spread in a radially outward direction in absence of an external force. Anchoring device 2400 further comprises a proximal anchor comprising a variety of designs including, but not limited to the designs disclosed elsewhere in this patent application. In this example, proximal anchor is designed similar to anchor 1040 in Figure 10D. Anchor 1040 can slide along proximal region of distal anchor 2402. Anchor 1040 can also be attached to distal anchor 2402 after a desired positioning between anchor 1040 and distal anchor 2402 is achieved. Anchoring device 2400 is delivered through a trocar 2406. Trocar 2406 comprises a sharp distal tip 2408 that can penetrate through tissue. The proximal region of distal tip 2408 comprises one ore more grooves or notches such that distal ends of curling or spreading arms 2404 can be temporarily held together by distal tip 2408 to allow for easy introduction into a target anatomy. Anchoring device 2400 is introduced into a target tissue to be compressed such that curling or spreading arms 2404 are distal to the target tissue and anchor 1040 is proximal to the target tissue. Figure 24A' shows the distal end view of the anchoring device 2400. In Figure 24B, trocar 2406 is pushed in the distal direction relative to proximal anchor 2402. This releases the distal ends of curling or spreading arms 2404 causing them to curl or spread outwards. Figure 24A' shows the distal end view of the anchoring device 2400 with released curling or spreading arms 2404. In Figure 24C, anchor 1040 is pushed in the distal direction over distal anchor 2402 to compress tissue between anchor 1040 and distal anchor 2402. Thereafter, anchor 1040 is attached to the hollow shaft of distal anchor 2402. Thereafter trocar 2406 is withdrawn from the anatomy. In the above embodiment, the tethering function is performed by the shaft of the distal anchor, and the force is created by the curling arms. This tension may be pre-set into the arms through heat forming. It should be noted that any mechanism capable of expanding from within a tubular shape and capable of applying retrograde forces on the tissue are within the scope of this invention such as expandable flanges, balloons, cages, molly-bolt-like structures, stent-like structures and springs.

Figure 24D shows a crossection through the deployed anchoring device 2400 of Figure 24A.

In one anchoring device embodiment, anchoring device 2400 comprises a distal anchor such as the distal anchor described in figure 17A instead of distal anchor 2412.

Figure 25A shows a perspective view of a spring clip that can be used to spread the anatomy. Clip 2500 comprises two or more spreading arms 2502. Spreading arms 2502 may be curved or straight. Distal ends of spreading arms 2502 may comprise a flattened region. The proximal ends or curved arms 2502 are connected to each other by a heel region 2504. Heel region 2504 may be made from the same material as curved arms 2502. In an undeployed configuration, spreading arms 2502 are held close to each other. When clip 2500 is deployed, spreading arms 2502 tend to expand away from each other thus spreading the anatomical region or regions between spreading arms 2502. Clip 2500 can be made of suitable elastic, super-elastic or shape memory biocompatible materials including, but not limited to synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid etc.; metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, etc.

Figures 25B through 25F show various steps of a method of spreading an anatomical region or regions using the spring clip of Figure 25A. In Figure 25B, a delivery tool 2506 comprising a clip 2500 is introduced in the anatomy and positioned near the target anatomy to be spread. Delivery tool 2506 comprises an elongate hollow body 2508 comprising a lumen. Distal end of body 2508 may comprise a blunt, atraumatic end. Distal region of body 2508 comprises a slot 2510 that is in fluid communication with the lumen of body 2508. Delivery tool may further comprise an outer sheath 2512 and an imaging modality 2514. Imaging modality 2514 may be permanently attached to delivery tool 2506 or may be introduced into delivery tool 2506 by a user. In this example, imaging modality 2514 is a cystoscope. In Figure 25C, clip 2500 is introduced into the anatomy by pushing clip 2500 out of slot 2510 such that the distal ends of spreading arms 2502 emerge first. Slot 2510 is designed

such that spreading arms 2504 are biased towards each other as they emerge out of slot 2510. In Figure 25D, clip 2500 is further advanced such that distal tips of spreading arms 2502 penetrate into the tissue to be spread. In Figure 25E, clip 2500 is advanced further such that the biasing forces on spreading arms 2502 are removed. Spreading arms 2502 tend to spread away from each other thus spreading the tissue between them. Clip 2500 is detachably attached to delivery tool 2506 by a detaching mechanism 2516 including, but not limited to the several detaching mechanisms disclosed elsewhere in this patent application. In Figure 25F, detaching mechanism 2516 is used to detach clip 2500 from delivery tool 2506 or deploy clip 2500 in the target anatomy. In this example, distal region of delivery tool 2506 is inserted transurethrally into the prostatic urethra. Clip 2500 is then delivered into the anterior commissure to spread the two lateral lobes of the prostate gland PG apart. In one method embodiment, an opening in the commissure is made prior to the method of Figures 25B through 25G. In another embodiment, the spreading force exerted by spreading arms 2502 cause cutting of the anterior commissure. Clip 2500 may be placed completely sub-urethrally or a small amount of heel region 2504 remains in the urethra.

The embodiments of anchoring devices wherein a sliding anchor is slid over a tension element may comprise one or more cinching elements. These cinching elements may be present on the sliding anchors, on the tension elements etc. A cinching element may be a separate device that cinches to a tension element. In doing so, it increases the effective diameter of that region of the tension element and prevents the tension element from sliding through a sliding anchor. Cinching elements may allow only unidirectional motion of the sliding anchor over the tension element or may prevent any substantial motion of the sliding anchor over the tension element. Typical examples of such cinching mechanisms include, but are not limited to mechanisms described in the Figure 26 series. For example, Figures 26A and 26B show a crossectional view and a perspective view respectively of a mechanism of cinching a tension element or tether to an anchor. In Figure 26A, cinching mechanism 2600 comprises an outer base 2602. Outer base 2602 comprises one or more grooves created by the presence of two or more leaflets 2604.

Leaflets 2604 are biased along a first axial direction as shown in Figure 26A. When a tension element 2606 is located in the one or more grooves, cinching mechanism 2600 allows motion of tension element 2606 only along the first axial direction and prevents substantial movement of tension element 2606 in the opposite direction.

Figures 26C and 26D show a partial section through a cinching mechanism comprising a cam element. In Figure 26C, cinching mechanism 2610 comprises an outer body 2612 made of suitable biocompatible metals, polymers etc. Body 2162 comprises a cam 2614 located on a pivot 2616. Cam 2614 may comprise a series of teeth to grip a tension element 2618 passing through body 2612. In one embodiment, body 2162 comprises an opening 2620 located proximal to cam 2614. Proximal region of tension element 2618 passes out of body 2612 through opening 2620. Cinching mechanism 2610 allows movement of body 2162 over tension element 2618 in the proximal direction. In Figure 26D, body 2162 is moved over tension element 2618 in the distal direction. Motion of tension element 2618 over cam 2614 causes cam 2614 to turn in the anti-clockwise direction. This causes tension element 2618 to be pinched between cam 2614 and body 2612. This in turn prevents further motion of body 2162 over tension element 2618.

Figure 26E shows a sectional view of an embodiment of a cinching mechanism comprising a locking ball. Cinching mechanism 2630 comprises an outer body 2632 comprising a lumen. A tension element 2634 passes through the lumen of outer body 2632. The lumen of outer body gradually reduces in the proximal direction as shown in Figure 26E. A locking ball 2636 is present in the lumen. Motion of outer body 2632 over tension element 2634 in the distal direction pushes locking ball 2636 in the proximal region of outer body 2632. A proximal end region 2638 of a small diameter prevents locking ball 2636 from falling out of outer body 2632. The large lumen diameter in the proximal region of outer body 2632 allows free motion of locking ball 2636. Thus, presence of locking ball 2636 does not hinder the motion of outer body 2632 over tension element 2634 in the proximal direction. When outer body 2632 is moved over tension element 2634 in the proximal direction, locking

ball 2636 is pushed in the distal region of outer body 2632. The small lumen diameter in the proximal region of outer body 2632 constricts motion of locking ball 2636. This causes a region of tension element 2634 to be pinched between anchoring ball 2636 and outer body 2632. This in turn prevents further motion of outer body 2632 over tension element 2634 in the proximal direction. This mechanism thus allows unidirectional motion of outer body 2632 is over tension element.

Figure 26F shows a side view of an embodiment of a cinching mechanism comprising multiple locking flanges. In this embodiment, cinching mechanism 2644 comprises a body 2646 comprising a lumen lined by a first locking flange 2648 and a second locking flange 2650. First locking flange 2648 and second locking flange 2650 are biased in the proximal direction as shown. A tension element 2652 passes through the lumen of body 2646. First locking flange 2648 and second locking flange 2650 together allow the movement of body 2646 over tension element 2652 in the distal direction, but prevent movement of body 2646 over tension element 2652 in the proximal direction. Similar cinching mechanisms may be designed comprising more than two locking flanges. Figure 26G shows an end view of body 2646 comprising a lumen lined by first locking flange 2648 and second locking flange 2650. Body 2646 may be made of suitable biocompatible metals, polymers etc.

Figure 26H shows a side view of an embodiment of a cinching mechanism comprising a single locking flange. In this embodiment, cinching mechanism 2656 comprises a body 2658 comprising a lumen lined by a locking flange 2660. Locking flange 2660 is biased in the proximal direction as shown. A tension element 2662 passes through the lumen of body 2658. Locking flange 2660 allows the movement of body 2658 over tension element 2662 in the distal direction, but prevents movement of body 2658 over tension element 2662 in the proximal direction. Figure 26I shows an end view of body 2658 comprising a lumen 2662 lined by locking flange 2660. Body 2658 may be made of suitable biocompatible metals, polymers etc.

Figure 26J shows an end view of a cinching mechanism comprising a

crimping lumen. Cinching mechanism 2670 comprises a body 2672 comprising a crimping lumen 2674. Crimping lumen 2674 is in the form of an arc with a gradually reducing size as shown in Figure 26J. A tension element 2676 passes through crimping lumen 2674. In Figure 26J, tension element 2676 is locked in a region of crimping lumen 2674 of a diameter smaller than the diameter of tension element 2676. Tension element 2676 can be unlocked from crimping lumen 2674 by rotating body 2672 in the anti-clockwise direction. Similarly, rotating body 2672 in the clockwise direction causes an unlocked tension element 2676 to be locked into crimping lumen 2674.

In an alternate embodiment, cinching mechanism comprises a disk shaped body comprising a central lumen. Central lumen is large enough to allow a tension element to slide easily through the central lumen. One or more radially oriented slits emerge from the central lumen. The radially oriented slits have a diameter that is of the same size or is slightly smaller than the diameter of the tension element. To lock cinching mechanism to the tension element, the tension element is forced through one of the radially oriented slits. The friction between the disk shaped body and the tension element prevents or resists sliding of tension element through the disk shaped body. To unlock cinching mechanism from the tension element, the tension element is moved back to the central lumen.

In another alternate embodiment, cinching mechanism comprises a disk shaped body comprising a small central lumen. The central region of the body comprises three or more triangular flaps biased together out of the plane of the body. The ends of the triangular flaps together form the central lumen that is of the same size or is slightly smaller than the diameter of the tension element. Tension element can pass easily through the central lumen in the direction of the bias of the triangular flaps. But, tension element cannot pass or encounters substantial resistance when the tension element is pulled through the central lumen in the opposite direction.

Figures 26K and 26L show crossections of an embodiment of a cinching mechanism comprising a crimping anchor in the undeployed and deployed configurations respectively. Cinching mechanism 2680 comprises a

crimping anchor 2680 comprising a lumen. Crimping anchor 2680 can be made of a variety of biocompatible materials including, but not limited to metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc., polymers, etc. A tension element 2684 passes through the lumen of crimping anchor 2680. The lumen of an undeployed crimping anchor 2680 is larger than the diameter of tension element 2684. In Figure 26L, crimping anchor 2680 is deployed by compressing the middle section of crimping anchor 2680 such that crimping anchor 2680 compresses tension element 2684. Friction between crimping anchor 2680 and tension element 2684 prevents relative motion between crimping anchor 2680 and tension element 2684. Crimping anchor 2680 may be a component of a sliding anchor or may be a stand-alone device used to prevent or restrict motion of a sliding anchor over a tension element.

Figure 26M shows a perspective view of an embodiment of a cinching mechanism comprising an element providing a tortuous path to a tension element. In this example, cinching mechanism 2686 comprises a spring 2688. A tension element 2690 is passed through spring 2688 such that the path of tension element 2690 through spring 2688 is tortuous. When spring 2688 is moved over tension element, motion of tension element 2690 through the tortuous path generates high frictional forces that prevent or reduce motion of spring 2688 over tension element 2690. The frictional forces are strong enough to resist motion of spring 2688 over tension element 2690 after deploying cinching mechanism 2686 in the anatomy. A user can move spring 2688 over tension element 2690 by applying a force that overcomes the resistive frictional forces that prevent movement of spring 2688 over tension element 2690. Similarly, other cinching mechanisms comprising a tortuous path can be used instead of spring 2688. Examples of such mechanisms are solid elements comprising tortuous lumens, elements comprising multiple struts or bars that provide a tortuous path etc. In another embodiment the cinching mechanism comprises a knot on one or more tensioning element. Said knot can be advanced fully tightened or can be loose when advanced and tightened in situ.

Figure 26N shows a crossectional view of an embodiment of a locking mechanism comprising a space occupying anchor securely attached to a tension element. Locking mechanism 2692 comprises a hollow element 2694 comprising a lumen. Hollow element 2694 is a component of a sliding anchor that slides over tension element 2696. Tension element 2696 comprises a space occupying anchor 2698 comprising a tapering distal end 2699. Anchor 2698 is securely attached to tension element 2696. Diameter of anchor 2698 is larger than the diameter of the lumen of hollow element. Due to this, anchor 2698 cannot pass through hollow element 2694 effectively locking the position of tension element 2696 with respect to the position of hollow element 2694.

Figures 26O and 26P shows a partial sectional view and a perspective view of an embodiment of a cinching mechanism comprising a punched disk. Cinching mechanism 2602' comprises a disk 2604' comprising a punched hole 2606'. Punched hole 2606' is made by punching disk 2604' along the proximal direction such that the punching action leaves an edge that is biased along the proximal direction as shown in Figure 26O. Disk 2604' can slide over a tension element 2608' along the distal direction. However, motion of disk 2604' over tension element 2608' along the proximal direction is substantially resisted by the proximally biased edges of punched hole 2606'.

Excess lengths of tension elements or other severable regions of one or more devices disclosed in this patent application may be cut, severed or trimmed using one or more cutting devices. For example, Figures 26Q and 26R show a perspective view of a first embodiment of a cutting device before and after cutting an elongate element. In Figure 26Q, cutting device 2610' comprises an outer sheath 2612' comprising a sharp distal edge 2614'. Outer sheath 2612' encloses an inner sheath 2616'. Inner diameter of outer sheath 2612' is slightly larger than outer diameter of inner sheath 2616' such that inner sheath 2616' can slide easily through outer sheath 2612'. Inner sheath 2616' comprises a lumen that terminates distally in an opening 2618'. An elongate severable device passes through the lumen and emerges out of opening 2618'. An example of an elongate severable device is a tension element 2620'. In the method of cutting or trimming tension element 2620' the

desired area of tension element 2620' to be cut or severed is positioned near opening 2618' by advancing or withdrawing cutting device 2610' over tension element 2620'. Thereafter, outer sheath 2612' is advanced over inner sheath 2616' to cut tension element 2620' between sharp distal edge 2614' and an edge of opening 2618'. Inner sheath 2616' and outer sheath 2612' may be substantially rigid or flexible. They may be made of suitable materials including, but not limited to Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, metals like stainless steel and fluoropolymers like PTFE, PFA, FEP and EPTFE etc.

Figure 26S show a crossectional view of a second embodiment of a cutting device for cutting an elongate element. Cutting device 2622' comprises an outer sheath 2624' comprising a lumen that opens in an opening 2626' in outer sheath 2624'. Outer sheath 2624' encloses an inner sheath 2628' that comprises a lumen and a sharp distal edge 2630'. Inner diameter of outer sheath 2624' is slightly larger than outer diameter of inner sheath 2628' such that inner sheath 2628' can slide easily through outer sheath 2624'. An elongate severable device passes through the lumen of inner sheath 2628' and emerges out of distal end of inner sheath 2628' and out of outer sheath 2624' through opening 2626'. An example of an elongate severable device is a tension element 2632'. In the method of cutting or trimming tension element 2632' the desired area of tension element 2632' to be cut or severed is positioned near opening 2626' by advancing or withdrawing cutting device 2622' over tension element 2632'. Thereafter, inner sheath 2628' is advanced through outer sheath 2624' to cut tension element 2632' between sharp distal edge 2630' and an edge of opening 2626'. Inner sheath 2628' and outer sheath 2624 may be substantially rigid or flexible. They may be made of suitable materials including, but not limited to Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, metals like stainless steel and fluoropolymers like PTFE, PFA, FEP and EPTFE etc.

In a third embodiment of a cutting device for cutting an elongate element, the cutting device comprises an outer hollow sheath. Outer hollow sheath has a distal end plate comprising a window. An elongate severable

device passes through the window. An example of an elongate severable device is a tension element. An inner shaft can slide and rotate within outer hollow sheath. Distal end of inner shaft comprises a blade that is usually located away from the window and adjacent to the distal end plate of the outer hollow sheath. In the method of cutting or trimming tension element the elongate severable device, the desired area of the elongate severable device to be cut or severed is positioned near the window. This is done by advancing or withdrawing the cutting device over the elongate severable device. Thereafter, the inner shaft is rotated within outer hollow sheath such that the blade cuts the elongate severable device between a sharp edge of the blade and an edge of the window. Inner shaft and outer hollow sheath may be substantially rigid or flexible. They may be made of suitable materials including, but not limited to Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, metals like stainless steel and fluoropolymers like PTFE, PFA, FEP and EPTFE etc. The end plate and the blade are preferentially rigid. They may be made of suitable materials including, but not limited to metals like stainless steel, polymers like Polycarbonate, Polyimide, PVC, Hytrel, HDPE, PEEK and fluoropolymers like PTFE, PFA, FEP etc.

The anchoring devices disclosed herein may be used in a variety of configurations depending on the location of the disease process, ease of procedure etc. Figures 27A through 27D show axial sections through the prostate gland PG showing various configurations of anchoring devices comprising distal anchors 2700 and a tension element 2702 that is anchored at a suitable location such that a sufficient tension exists in tension element 2702.

Figure 28 and 28A show perspective views of an embodiment of an anchoring device comprising an elongate element comprising multiple barbs or anchors. Figure 28 shows a perspective view of anchoring device 2800 comprising an elongate element 2802. Elongate element 2802 can be made of several biocompatible materials including, but not limited to synthetic fibers e.g. various grades of Nylon, polyethylene, polypropylene, polyester, Aramid

etc.; metals e.g. various grades of stainless steel, titanium, nickel-titanium alloys, cobalt-chromium alloys, tantalum etc.; natural fibers e.g. cotton, silk etc.; rubber materials e.g. various grades of silicone rubber etc. Elongate element 2802 may comprise natural or artificial suture materials. Examples of such materials include but are not limited to Polyamide (Nylon), Polypropylene, Polyglycolic Acid (PGA), polylactic acid (PLA) and copolymers of polylactic acid, polyglycolic acid and copolymers of polyglycolic acid, copolymers of PLA and PGA, Silk, Polyester, silicone, collagen, Polymers of Glycolide and Lactide. A particular example of a suture is the Nordstrom suture which is a highly elastic silicone suture. In one embodiment, the suture material is bioabsorbable. Elongate element 2802 comprises two sets of projections such as barbs, anchors or hooks. In the example shown, elongate element 2802 comprises a set of distal barbs 2804 and a set of proximal barbs 2806. Distal barbs 2804 are oriented in the proximal direction and proximal barbs 2806 are oriented in the distal direction as shown in Figure 25. Figure 28A shows a magnified view of the region 28A of anchoring device 2800 showing proximal barbs 2806.

Figures 28B through 28E show a coronal section through the prostate gland PG showing various steps of a method of treating the prostate gland PG using the device of Figure 28. In Figure 28B, introducer device 300 of Figure 3A comprising a working device lumen and a cystoscope lumen 308 is introduced into the urethra such that the distal end of introducer device 300 is located in the prostatic urethra. Thereafter, a hollow puncturing device 2808 is inserted in the working device lumen of introducer device. Puncturing device 2808 is advanced such that distal end of puncturing device 2808 penetrates the prostate gland PG. In Figure 28C, anchoring device 2800 is introduced through puncturing device 2808 into the prostate gland PG. Thereafter, puncturing device 2808 is pulled in the proximal direction. Simultaneously, anchoring device 2800 is pulled in the proximal direction to anchor distal barbs 2804 in the anatomy. In Figure 28D, puncturing device 2808 is pulled further in the proximal direction to expose the entire anchoring device 2800. Thereafter, in step 28E, the proximal end of anchoring device 2800 is detached to deploy anchoring device 2800 in the anatomy. Thus, tissue

between distal barbs 2804 and proximal barbs 2806 is anchored to anchoring device 2800.

Figure 29A shows an axial section of the prostate gland PG showing a pair of implanted magnetic anchors. In Figure 29A, a first magnetic anchor 2900 and a second magnetic anchor 2902 are implanted in the prostate gland PG on either side of the urethra. Like poles of first magnetic anchor 2900 and second magnetic anchor 2902 face each other such that there is magnetic repulsion between first magnetic anchor 2900 and second magnetic anchor 2902. This causes the urethral lumen to widen potentially reducing the severity of BPH symptoms.

Figures 29B through 29D show a coronal section through the prostate gland PG showing the steps of a method of implanting magnetic anchors of Figure 29A. In Figure 29B, a deployment device 2904 is advanced trans-urethrally. Deployment device 2904 comprises a sharp distal tip 2906 and first magnetic anchor 2900. Distal tip 2906 of deployment device 2904 penetrates prostatic tissue and implants fist magnetic anchor 2900 in the prostate gland PG. Similarly, another deployment device 2908 comprising a sharp distal tip 2920 is used to implant second magnetic anchor 2902 in the prostate gland PG. First magnetic anchor 2900 and second magnetic anchor 2902 are implanted on opposite sides of the urethra such that like poles of first magnetic anchor 2900 and second magnetic anchor 2902 face each other. This causes magnetic repulsion between first magnetic anchor 2900 and second magnetic anchor 2902. This causes the urethral lumen to widen potentially reducing the severity of BPH symptoms. In one embodiment, deployment device 2904 can be used to deploy multiple magnetic anchors.

Figure 30A shows a coronal section of a region of the male urinary system showing the general working environment of a method of treating prostate disorders by cutting prostrate tissue using a device inserted into the prostate gland PG from the urethra. Cutting device 3000 comprises an outer body 3002 comprising a side port 3004. Outer body 3002 can be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, Nickel-Titanium alloys, titanium etc.; polymers e.g. etc. Cutting

device 3000 further comprises an access device 3006 that can be deployed out of side port 3004. Access device 3006 can be retracted back into side port 3004. Typical examples of elements that can be used as access device 3006 are needles, trocars etc. Access device 3006 may be made from suitable biocompatible materials including, but not limited to metals e.g. stainless steel, Nickel-Titanium alloys, titanium etc.; polymers e.g. etc. Access device 3006 penetrates the walls of the urethra and enters the prostate gland PG by creating an access channel in the prostate gland PG. Cutting device 3000 further comprises a cutting element 3008 that is introduced into the prostate gland PG through the access channel in the prostate gland PG. In one embodiment, cutting element 3008 enters the prostate gland PG through access device 3006. Cutting element 3008 comprises one or more cutting modalities such as electrosurgical cutter, Laser cutter, mechanical cutter e.g. a knife edge etc. Cutting element 3008 may be moved through prostate tissue by several mechanisms including one or more deflecting or bending elements located on cutting element 3008; one or more articulating elements located on cutting element 3008; motion of cutting device 3000 along the urethra etc. Cutting element 3008 is used to cut one or more regions of the prostate gland PG including peripheral zone, transition zone, central zone or prostatic capsule. After the desired region or regions of the prostate gland PG are cut, cutting element 3008 and access device 3006 are withdrawn into cutting device 3000. Thereafter, cutting device 3000 is withdrawn from the urethra. In one device embodiment, cutting device 3000 comprises an endoscope or means for inserting an endoscope.

Figure 30B shows a coronal section of a region of the male urinary system showing the general working environment of a method of treating prostate disorders by cutting prostrate tissue using a device that accesses outer surface of the prostate gland PG by passing through the walls of the urethra distal to the prostate gland PG. Cutting device 3020 comprises an outer body 3022 comprising a side port 3024. Outer body 3022 can be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, Nickel-Titanium alloys, titanium etc.; polymers e.g. etc. Cutting device 3020 is advanced into the urethra such that side port 3024 is located

distal to the prostate gland PG. Cutting device 3020 further comprises an access device 3026 that can be deployed out of side port 3024. Access device 3026 can be retracted back into side port 3024. Typical examples of elements that can be used as access device 3026 are needles, trocars etc. Access device 3026 may be made from suitable biocompatible materials including, but not limited to metals e.g. stainless steel, Nickel-Titanium alloys, titanium etc.; polymers e.g. etc. Access device 3026 is deployed from side port 3024 in a desired orientation such that access device 3026 penetrates the wall of the urethra. Access device 3026 is advanced further such that distal end of access device 3026 is located near the prostate gland PG. Thereafter, a cutting element 3028 is introduced through access device 3026 to the outer surface of the prostate gland PG. Cutting element 3028 comprises one or more cutting modalities such as electrosurgical cutter, Laser cutter, mechanical cutter e.g. a knife edge etc. Cutting element 3028 is used to cut one or more regions of the prostate gland PG including prostatic capsule, peripheral zone, transition zone or central zone. Cutting element 3028 may be moved relative to prostate tissue by several mechanisms including one or more deflecting or bending elements located on cutting element 3028; motion of cutting element 3028 along access device 3026 etc. In one method embodiment, cutting element 3028 cuts prostatic capsule while being withdrawn into access device 3026. After the desired region or regions of the prostate gland PG are cut, cutting element 3028 and access device 3026 are withdrawn into cutting device 3020. Thereafter, cutting device 3020 is withdrawn from the urethra. In one device embodiment, cutting device 3020 further comprises an endoscope or means for inserting an endoscope.

Figure 30C shows a coronal section of a region of the male urinary system showing the general working environment of a method of treating prostate disorders by cutting prostrate tissue using a device that accesses outer surface of the prostate gland PG by passing through the wall of the urinary bladder. Cutting device 3040 comprises an outer body 3042 comprising a side port 3044. Outer body 3042 can be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, Nickel-Titanium alloys, titanium etc.; polymers e.g. etc. Cutting device

3040 is advanced into the urethra such that side port 3044 is located inside the urinary bladder. Cutting device 3040 further comprises an access device 3046 that can be deployed out of side port 3044. Access device 3046 can be retracted back into side port 3044. Typical examples of elements that can be used as access device 3046 are needles, trocars etc. Access device 3046 may be made from suitable biocompatible materials including, but not limited to metals e.g. stainless steel, Nickel-Titanium alloys, titanium etc.; polymers e.g. etc. Access device 3046 is deployed from side port 3044 in a desired orientation such that access device 3046 penetrates the wall of the urinary bladder. Access device 3046 is advanced further such that distal end of access device 3046 is located near the prostate gland PG. Thereafter, a cutting element 3048 is introduced through access device 3046 to the outer surface of the prostate gland PG. Cutting element 3048 comprises one or more cutting modalities such as electrosurgical cutter, Laser cutter, mechanical cutter e.g. a knife edge etc. Cutting element 3048 is used to cut one or more regions of the prostate gland PG including prostatic capsule, peripheral zone, transition zone or central zone. Cutting element 3048 may be moved relative to prostate tissue by several mechanisms including one or more deflecting or bending elements located on cutting element 3048; motion of cutting element 3048 along access device 3046 etc. In one method embodiment, cutting element 3048 cuts prostatic capsule while being withdrawn into access device 3046. After the desired region or regions of the prostate gland PG are cut, cutting element 3048 and access device 3046 are withdrawn into cutting device 3040. Thereafter, cutting device 3040 is withdrawn from the urethra. In one device embodiment, cutting device 3040 further comprises an endoscope or means for inserting an endoscope.

Figure 30D shows a coronal section of a region of the male urinary system showing the general working environment of a method of treating prostate disorders by cutting prostrate tissue using a device that accesses outer surface of the prostate gland PG by passing through the walls of the urethra enclosed to the prostate gland PG. Cutting device 3060 comprises an outer body 3062 comprising a side port 3064. Outer body 3062 can be made of suitable biocompatible materials including, but not limited to metals e.g.

stainless steel, Nickel-Titanium alloys, titanium etc.; polymers e.g. etc. Cutting device 3060 is advanced into the urethra such that side port 3064 is located in the region of the urethra enclosed by the prostate gland PG. Cutting device 3060 further comprises an access device 3066 that can be deployed out of side port 3064. Access device 3066 can be retracted back into side port 3064. Typical examples of elements that can be used as access device 3066 are needles, trocars etc. Access device 3066 may be made from suitable biocompatible materials including, but not limited to metals e.g. stainless steel, Nickel-Titanium alloys, titanium etc.; polymers e.g. etc. Access device 3066 is deployed from side port 3064 in a desired orientation such that access device 3066 penetrates the prostate. Thereafter, a cutting element 3068 is introduced through access device 3066 such that the distal region of cutting element can access the outer surface of the prostate gland PG. Cutting element 3068 comprises one or more cutting modalities such as electrosurgical cutter, Laser cutter, mechanical cutter e.g. a knife edge etc. Cutting element 3068 is used to cut one or more regions of the prostate gland PG including prostatic capsule, peripheral zone, transition zone or central zone. Cutting element 3068 may be moved relative to prostate tissue by several mechanisms including one or more deflecting or bending elements located on cutting element 3068; motion of cutting element 3068 along access device 3066 etc. In one method embodiment, cutting element 3068 cuts prostatic capsule while being withdrawn into access device 3066. After the desired region or regions of the prostate gland PG are cut, cutting element 3068 and access device 3066 are withdrawn into cutting device 3060. Thereafter, cutting device 3060 is withdrawn from the urethra. In one device embodiment, cutting device 3060 further comprises an endoscope or means for inserting an endoscope.

Figure 31 shows a coronal section of a region of the male urinary system showing the general working environment of a method of treating prostate disorders by cutting prostrate tissue by a percutaneous device that accesses the prostate gland PG through an incision in the abdomen. In this

method, a cannula 3100 is introduced percutaneously into the lower abdomen. Cannula 3100 can be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, Nickel-Titanium alloys, titanium etc.; polymers etc. Cannula 3100 is advanced into the abdomen such that it passes below the pubic bone. The distal end of cannula 3100 is positioned near the prostate gland PG. Thereafter, a cutting device 3102 is advanced through distal end of cannula 3100 to the outer surface of the prostate gland PG. Cutting device 3102 can be retracted back into cannula 3100. Cutting device 3102 comprises one or more cutting modalities such as electrosurgical cutter, Laser cutter, mechanical cutter e.g. a knife edge etc. Cutting device 3102 is used to cut one or more regions of the prostate gland PG including prostatic capsule, peripheral zone, transition zone or central zone. Cutting device 3102 may be moved relative to prostate tissue by several mechanisms including one or more deflecting or bending elements located on cutting device 3102; motion of cutting device 3102 along cannula 3100 etc. In one method embodiment, cutting device 3102 cuts prostatic capsule while being withdrawn into cannula 3100. After the desired region or regions of the prostate gland PG are cut, cutting device 3102 is withdrawn into cannula 3100. Thereafter, cannula 3100 is withdrawn from the urethra. In one device embodiment, cannula 3100 further comprises an endoscope or means for inserting an endoscope.

Figure 32 shows a coronal section of a region of the male urinary system showing the general working environment of a method of treating prostate disorders by cutting prostrate tissue by a percutaneous device that penetrates the urinary bladder and accesses the outer surface of the prostate gland PG through an incision in the urinary bladder. In this method, a cannula 3200 is introduced percutaneously into the lower abdomen. Cannula 3200 can be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, Nickel-Titanium alloys, titanium etc.; polymers etc. Cannula 3200 is advanced into the abdomen such that it passes above the pubic bone. The distal end of cannula 3200 enters the urinary bladder. Thereafter, an access device 3202 is advanced through cannula 3200 such that access device 3202 penetrates the urinary bladder wall as shown in

Figure 4. Thereafter, a cutting device 3204 is advanced through distal end of access device 3202 to the outer surface of the prostate gland PG. Cutting device 3202 can be retracted back into access device 3202. Cutting device 3202 comprises one or more cutting modalities such as electrosurgical cutter, Laser cutter, mechanical cutter e.g. a knife edge etc. Cutting device 3202 is used to cut one or more regions of the prostate gland PG including prostatic capsule, peripheral zone, transition zone or central zone. Cutting device 3202 may be moved relative to prostate tissue by several mechanisms including one or more deflecting or bending elements located on cutting device 3202 or access device 3202; motion of cutting device 3202 along access device 3202 etc. In one method embodiment, cutting device 3202 cuts prostatic capsule while being withdrawn into access device 3202. After the desired region or regions of the prostate gland PG are cut, cutting device 3202 is withdrawn into access device 3202. Access device 3202 is then withdrawn into cannula 3200. Thereafter, cannula 3200 is withdrawn from the urinary bladder. In one device embodiment, cannula 3200 further comprises an endoscope or means for inserting an endoscope.

Figure 33 series shows a perspective view of a prostate treatment kit to cut prostate tissue. Figure 33A shows a perspective view of an introducer device. Introducer device 3300 comprises a first tubular element 3302 enclosing a working device lumen 3304. First tubular element 3302 can be made of suitable biocompatible materials such as Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, metals like stainless steel and fluoropolymers like PTFE, PFA, FEP and EPTFE etc. The proximal end of working device lumen 3304 comprises a first stasis valve 3306. The distal end of working device lumen 3304 comprises a deflection mechanism. The deflection mechanism is used to bend the distal region of working device lumen 3304. One example of deflection mechanism is a pull wire and a deflection dial 3310 to adjust the magnitude and/or the direction of deflection caused by the pull wire. Similarly, other deflection mechanisms can be used in the introducer device instead of a pull wire. Introducer device 3300 further comprises a second tubular element 3312 which encloses a cystoscope lumen 3314. A cystoscope can be introduced through cystoscope

lumen 3314 into the urethra. Typical examples of cystoscopes that can be used with introducer device are those manufactured by Olympus, Pentax, Storz, Wolf, Circon-ACMI, etc. These may have pre-set angles (i.e. 0, 30, 70, 120 degrees) or may be flexible scopes where in the tip may be deflectable. The proximal end of cystoscope lumen 3314 comprises a second stasis valve 3316. The cystoscope is inserted through the proximal end of cystoscope lumen 3314 and emerges out into the urethra from the distal end of cystoscope lumen 3314. The cystoscope can then be used to visualize the anatomy and various instruments during a procedure. Working device lumen 3314 may comprise one or more side ports e.g. a first side port 3318 for the introduction or removal of one or more fluids. Cystoscope lumen 3314 may comprise one or more side ports e.g. a second side port 3320 for the introduction or removal of one or more fluids.

Figure 33B shows a perspective view of an injecting needle. Injecting needle 3330 is used for injecting one or more diagnostic or therapeutic agents in the anatomy. In one method embodiment, injecting needle 3330 is used to inject local anesthetic in the urethra and/or prostate gland PG. Specific examples of target areas for injecting local anesthetics are the neurovascular bundles, the genitourinary diaphragm, the region between the rectal wall and prostate, etc. Examples of local anesthetics that can be injected by injecting needle 3330 are anesthetic solutions e.g. 1% lidocaine solution; anesthetic gels e.g. lidocaine gels; combination of anesthetic agents e.g. combination of lidocaine and bupivacaine; etc. Injecting needle 3330 comprises a hollow shaft 3332 made of suitable biocompatible materials including, but not limited to stainless steel 304, stainless steel 306, Nickel-Titanium alloys, titanium etc. The length of hollow shaft 3332 can range from to centimeters. The distal end of hollow shaft 3332 comprises a sharp tip 3334. The proximal end of hollow shaft 3332 has a needle hub 3336 made of suitable biocompatible materials including, but not limited to metals e.g. like stainless steel 304, stainless steel 306, Nickel-Titanium alloys, titanium etc.; polymers e.g. polypropylene etc. In one embodiment, needle hub 3336 comprises a luer lock.

Figure 33C shows a perspective view of a guiding device. Guiding

device 3338 comprises an elongate body 3340 comprising a sharp distal tip 3342. In one embodiment, guiding device 3338 is a guidewire. Distal end of elongate body 3340 may comprise an anchoring element to reversibly anchor guiding device 3338 into tissue. Examples of suitable anchoring elements are barbs, multipronged arrowheads, balloons, other mechanically actuable members (e.g. bendable struts), screw tips, shape memory elements, or other suitable anchor designs disclosed elsewhere in this patent application.

Figure 33D shows a perspective view of a RF cutting device. Cutting device 3343 comprises an inner sheath 3344 and an outer sheath 3346. Inner sheath 3344 comprises a lumen of a suitable dimension such that cutting device 3343 can be advanced over guiding device 538. Outer sheath 3346 can slide on inner sheath 3344. Outer sheath 3346 also comprises two marker bands: a proximal marker band 3348 and a distal marker band 3350. The marker bands can be seen by a cystoscope. In one embodiment, proximal marker band 3348 and distal marker band 3350 are radiopaque. The position of proximal marker band 3348 and distal marker band 3350 is such that after cutting device 3343 is placed in an optimum location in the anatomy, proximal marker band 3348 is located in the urethra where it can be seen by a cystoscope and distal marker band 3350 is located in the prostrate gland PG or in the wall of the urethra where it cannot be seen by the cystoscope. Cutting device 3343 further comprises a cutting wire 3352 that is capable of delivering electrical energy to the surrounding tissue. The distal end of cutting wire 3352 is fixed to the distal region of outer sheath 3344. The proximal end of cutting wire 3352 is connected to a distal region of outer sheath 3346 and is further connected to a source of electrical energy. In Figure 33D, cutting wire 3352 is in an undeployed configuration. Figure 33D' shows the distal region of cutting device 3343 when cutting wire 3352 is in a deployed configuration. To deploy cutting wire 3352, inner sheath 3344 is moved in the proximal direction with respect to outer sheath 546. This causes cutting wire 3352 to bend axially outward thus deploying cutting wire 3352 in the surrounding anatomy.

Figure 33E shows a perspective view of an embodiment of a plugging device to plug an opening created during a procedure. Plugging device 3354

comprises a tubular shaft 3356 comprising a distal opening 3358. Distal opening 3358 is used to deliver one or more plugging materials 3360 in the adjacent anatomy. Plugging material 3360 may comprise a porous or non-porous matrix formed of a biodegradable or non-biodegradable material such as a flexible or rigid polymer foam, cotton wadding, gauze, hydrogels, etc. Examples of biodegradable polymers that may be foamed or otherwise rendered porous include but are not restricted to polyglycolide, poly-L-lactide, poly-D-lactide, poly(amino acids), polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, polyorthoesters, polyhydroxybutyrate, polyanhydride, polyphosphoester, poly(alpha-hydroxy acid) and combinations thereof. In one embodiment, plugging material 3360 comprises biocompatible sealants including but not limted to fibrin sealants, combination of natural proteins (e.g. collagen, albumin etc.) with aldehyde cross-linking agents (e.g. glutaraldehyde, formaldehyde) or other polymeric, biological or non-polymeric materials capable of being implanted with the body, etc. Plugging device 3354 may be introduced in the anatomy by various approaches including the approaches disclosed elsewhere in this patent application. Plugging device 3354 may be introduced in the anatomy through a cannula, over a guiding device such as a guidewire etc. In the embodiment shown in Figure 33E, plugging material 3360 is preloaded in plugging device 3354. Plugging material 3360 is introduced through distal opening 3358 by pushing plunger 3362 in the distal direction. In another embodiment, plugging device 3354 comprises a lumen that extends from the proximal end to distal opening 3358. Plugging material 3360 may be injected through the proximal end of the lumen such that it emerges out through distal opening 3358.

Figures 33F through 33N show various alternate embodiments of the electrosurgical cutting device in Figure 33D. Figures 33F and 33G show perspective views of the distal region of a first alternate embodiment of an electrosurgical cutting device in the undeployed and deployed states respectively. Figure 33F show an electrosurgical cutting device 570 comprising an elongate shaft 3372. Shaft 3372 is made of an electrically insulating material. Electrosurgical cutting device 3370 further comprises an

electrosurgical cutting wire 3374. Electrosurgical cutting wire 3374 can be made of a variety of materials including, but not limited to tungsten, stainless steel, etc. Distal end of cutting wire 3374 is attached to distal region of shaft 3372. The proximal region of cutting wire 3374 can be pulled in the proximal direction by an operator. In one embodiment, electrosurgical cutting device 3370 is introduced in the target anatomy through a sheath 3376. In Figure 33F, electrosurgical cutting device 3370 is deployed by pulling cutting wire 3374 in the proximal direction. This causes distal region of shaft 3372 to bend. Thereafter, electrical energy is delivered through cutting wire 3374 to cut tissue. This may be accompanied by motion of electrosurgical cutting device 3370 along the proximal or distal direction.

Figures 33H and 33I show perspective views of the distal region of a second alternate embodiment of an electrosurgical cutting device in the undeployed and deployed states respectively. Electrosurgical cutting device 3380 comprises an elongate sheath 3382 comprising a lumen. Distal region of sheath 3382 has a window 3384. Electrosurgical cutting device 3380 further comprises an electrosurgical cutting wire 3386 located in the lumen. Distal end of cutting wire 3386 is fixed to the distal end of sheath 3384. Proximal end of cutting wire 3386 can be pushed in the distal direction by a user. In Figure 33I, cutting wire 3386 is deployed by pushing cutting wire 3386 in the distal direction. This causes a region of cutting wire 3386 to bend in the radially outward direction and thus emerge out of window 3384. Thereafter, electrical energy is delivered through cutting wire 3386 to cut tissue. This may be accompanied by motion of electrosurgical cutting device 3380 along the proximal or distal direction.

Figures 33J through 33L show perspective views of the distal region of a second alternate embodiment of an electrosurgical cutting device showing the steps of deploying the electrosurgical cutting device. Electrosurgical cutting device 3390 comprises an elongate sheath 3391 comprising a lumen 3392. In Figure 33J, an electrosurgical cutting wire 3394 is introduced through lumen 3392 such that it emerges out through the distal opening of lumen 3392. In Figure 33K, cutting wire 3394 is further advanced in the distal

direction. Distal end of cutting wire 3394 has a curved region so that cutting wire 3394 starts to bend as it emerges out of lumen 3392. IN Figure 33L, cutting wire 3394 is further advanced in the distal direction to fully deploy cutting wire 3394. Thereafter, electrical energy is delivered through cutting wire 3394 to cut tissue. This may be accompanied by motion of electrosurgical cutting device 3390 along the proximal or distal direction.

Figures 33M through 33N show perspective views of the distal region of a third alternate embodiment of an electrosurgical cutting device showing the steps of deploying the electrosurgical cutting device. Electrosurgical cutting device 3395 comprises an elongate sheath 3396 comprising a lumen. Cutting device 3395 further comprises a cutting wire 3398 located in the lumen of elongate sheath 3396. The proximal end of cutting wire 3398 is connected to a source of electrical energy. Distal end of cutting wire 3398 is connected to the inner surface of the distal region of elongate sheath 3396. Cutting wire 3398 may be made from suitable elastic, super-elastic or shape memory materials including but not limited to Nitinol, titanium, stainless steel etc. In Figure 33N, Electrosurgical cutting device 3395 is deployed by pushing the proximal region of cutting wire 3398 in the distal direction. This causes a distal region of cutting wire 3398 to emerge from the distal end of elongate sheath 3396 as a loop. Thereafter, electrical energy is delivered through cutting wire 3398 to cut tissue. This may be accompanied by motion of electrosurgical cutting device 3395 along the proximal or distal direction. Electrosurgical cutting device 3395 can be used to cut multiple planes of tissue by withdrawing cutting wire 3398 in elongate sheath 3396, rotating elongate sheath 3396 to a new orientation, redeploying cutting wire 3398 and delivering electrical energy through cutting wire 3398. The devices 33H through 33N may be introduced by one or more access devices such as guidewires, sheaths etc.

Figure 34 shows a perspective view of the distal region of a balloon catheter comprising a balloon with cutting blades. Balloon catheter 3400 can be introduced into a lumen or in the tissue of an organ to be treated using one or more of the introducing methods disclosed elsewhere in this patent

application. Balloon catheter 3400 comprises a shaft 3402. Shaft 3402 may comprise a lumen to allow balloon catheter 3400 to be introduced over a guidewire. In one embodiment, shaft 3402 is torquable. Shaft 3402 comprises a balloon 3404 located on the distal end of shaft 3402. Balloon 3404 can be fabricated from materials including, but not limited to polyethylene terephthalate, Nylon, polyurethane, polyvinyl chloride, crosslinked polyethylene, polyolefins, HPTFE, HPE, HDPE, LDPE, EPTFE, block copolymers, latex and silicone. Balloon 3404 further comprises one or more cutter blades 3406. Balloon catheter 3400 is advanced with balloon 3404 deflated, into a natural or surgically created passageway and positioned adjacent to tissue or matter that is to be cut, dilated, or expanded. Thereafter, balloon 3404 is inflated to cause cutter blades 3406 to make one or more cuts in the adjacent tissue or matter. Thereafter balloon 3404 is deflated and balloon catheter 3400 is removed. Cutter blades 3406 may be energized with mono or bi-polar RF energy. Balloon catheter 3400 may comprise one or more navigation markers including, but not limited to radio-opaque markers, ultrasound markers, light source that can be detected visually etc.

Figure 35 shows a perspective view of the distal region of a balloon catheter comprising a balloon with cutting wires. Balloon catheter 3500 can be introduced into a lumen or in the tissue of an organ to be treated using one or more of the introducing methods disclosed elsewhere in this patent application. Balloon catheter 3500 comprises a shaft 3502. Shaft 3502 may comprise a lumen to allow balloon catheter 3500 to be introduced over a guidewire. In one embodiment, shaft 3502 is torquable. Shaft 3502 comprises a balloon 3504 located on the distal end of shaft 3502. Balloon 3504 can be fabricated from materials including, but not limited to polyethylene terephthalate, Nylon, polyurethane, polyvinyl chloride, crosslinked polyethylene, polyolefins, HPTFE, HPE, HDPE, LDPE, EPTFE, block copolymers, latex and silicone. Balloon 3504 further comprises one or more radiofrequency wires 3506. Balloon catheter 3500 is advanced with balloon 3504 deflated, into a natural or surgically created passageway and positioned adjacent to tissue or matter that is to be cut, dilated, or expanded. Thereafter, balloon 3504 is inflated and an electrical current is delivered through

radiofrequency wires 3506 to make one or more cuts in the adjacent tissue or matter. Thereafter the electrical current is stopped, balloon 3504 is deflated and balloon catheter 3500 is removed. Radiofrequency wires 3504 may be energized with mono or bi-polar RF energy. Balloon catheter 3500 may comprise one or more navigation markers including, but not limited to radio-opaque markers, ultrasound markers, light source that can be detected visually etc.

Figures 36A and 36B series show perspective views of an undeployed state and a deployed state respectively of a tissue displacement device. Figure 36A shows a tissue anchoring device 3600 in the undeployed state. Anchoring device 3600 comprises an elongate body having a proximal end 3602 and a distal end 3604. Anchoring device 3600 may be made of a variety of elastic or super-elastic materials including, but not limited to Nitinol, stainless steel, titanium etc. Anchoring device 3600 is substantially straight in the undeployed state and has a tendency to become substantially curved in the deployed state. Anchoring device 3600 is maintained in the undeployed state by a variety of means including, but not limited to enclosing anchoring device 3600 in a cannula or sheath, etc. Figure 36B shows tissue anchoring device 3600 in the deployed state. Anchoring device 3600 comprises a curved region. When anchoring device 3600 changes from an undeployed state to a deployed state, the anatomical tissue adjacent to the central region of anchoring device 3600 is displaced along the direction of motion of the central region. Anchoring device 3600 can be deployed by a variety of methods including, but not limited to removing anchoring device 3600 from a sheath or cannula, etc. In one embodiment, anchoring device 3600 is made from a shape memory material such as Nitinol. In this embodiment, anchoring device 3600 is maintained in the undeployed state by maintaining anchor device 3600 in a temperature lower than the transition temperature of the super-elastic material. Anchoring device 3600 is converted to the deployed state by implanting anchoring device 3600 in a patient such that the device is warmed to the body temperature which is above the transition temperature of the super-elastic material.

Figures 36C and 36D show a coronal view and a lateral view respectively of a pair of deployed tissue displacement devices of Figures 36A and 36B implanted in the prostate gland PG. In Figure 36C, two anchoring devices are implanted in the prostate gland PG near the prostatic urethra in a patient with BPH. A first anchoring device 3600 is introduced on a first side of the urethra and is deployed there as shown. Similarly, a second anchoring device 3606 comprising a proximal end 3608 and a distal end 3610 is introduced on the other side of the urethra and is deployed there as shown. First anchoring device 3600 and second anchoring device 3606 change into the deployed curved configuration. This causes prostate gland PG tissue near the central regions of first anchoring device 3600 and second anchoring device 3606 to be displaced radially away from the urethra. This displacement of prostate gland PG tissue can be used to eliminate or reduce the compression of the urethra by an enlarged prostate gland PG. Figure 36D shows a lateral view of the urethra enclosed by the prostate gland PG showing deployed first anchoring device 3600 and second anchoring device 3606.

The various cuts or punctures made by one ore more cutting devices disclosed in this patent application may be plugged or lined by a plugging or space filling substance. Figures 36E through 36H show an axial section through a prostate gland showing the various steps of a method of cutting or puncturing the prostate gland and lining or plugging the cut or puncture. Figure 36E shows a section of the prostate gland showing the urethra, the lateral lobes and the middle lobe surrounded by the prostatic pseudocapsule. In figure 36F, one or more cuts are made in a region of the prostatic pseudocapsule. In addition, one or more cuts may be made in a region of between two lobes of the prostate gland. In figure 36G, a plugging material 3619 is introduced in the one or more regions of the prostate gland that are cut or punctured. Plugging material 3619 may be delivered through one or more delivery devices including, but not limited to the device disclosed in figure 33E. Plugging material 3619 may comprises a material such as plugging material 3360.

The various cuts or punctures made by one ore more cutting devices disclosed in this patent application may be spread open by a clipping device. For example, figure 36H shows an axial section through a prostate gland showing a clip for spreading open a cut or punctured region of the prostate gland. Spreading device 3620 comprises a body having a central region and two distal arms. Spreading device 3620 may be made of a variety of elastic or super-elastic materials including, but not limited to Nitinol, stainless steel, titanium etc. Spreading device 3620 has a reduced profile in the undeployed state by maintaining distal arms close to each other. Spreading device 5000 is maintained in the undeployed state by a variety of means including, but not limited to enclosing spreading device 3620 in a cannula or sheath, etc. When spreading device 3620 changes from an undeployed state to a deployed state, the distance between the two distal arms increases. This causes any anatomical tissue between two distal arms to spread along the straight line between two distal arms Spreading device 3620 can be deployed by a variety of methods including, but not limited to removing spreading device 3620 from a sheath or cannula, etc. In one embodiment, spreading device 3620 is made from a shape memory material such as Nitinol. In this embodiment, spreading device 3620 is maintained in the undeployed state by maintaining anchor device 3620 in a temperature lower than the transition temperature of the super-elastic material. Spreading device 3620 is converted to the deployed state by implanting spreading device 3620 in a patient such that the device is warmed to the body temperature which is above the transition temperature of the super-elastic material. Stretching of prostate gland tissue can be used to eliminate or reduce the compression of the urethra by an enlarged prostate gland or to prevent cut edges of a cut from rejoining.

More than one spreading device 3620 may be used to treat the effects of an enlarged prostate or to eliminate or reduce the compression of the urethra by an enlarged prostate gland or to prevent cut edges of a cut from rejoining.

Figures 37A through 37K show an embodiment of a method of treating prostate gland disorders by cutting a region of the prostate gland using the

devices described in Figure 33A through 33E. In Figure 37A, introducer device 3300 is introduced in the urethra. It is advanced through the urethra such that the distal tip of introducer device 3300 is located in the prostatic urethra. Thereafter, injecting needle 3330 is introduced through introducer device 3300. The distal tip of injecting needle 3330 is advanced such that injecting needle 3330 penetrates the prostate gland. Injecting needle 3330 is then used to inject a substance such as an anesthetic in the prostate gland. Thereafter, in Figure 37B, injecting needle 3330 is withdrawn from the anatomy. The distal region of introducer device 3300 is positioned near a region of the prostate gland to be punctured. Thereafter, in Figure 37C, first tubular element 3302 is bent or deflected with a bending or deflecting mechanism such as the bending mechanism in Figures 37C" and 37C"' to align the distal region of first tubular element 3302 along a desired trajectory of puncturing the prostate gland.

Figure 37C' shows the proximal region of introducer device 3300. A cystoscope 3700 is introduced through second stasis valve 3316 such that the distal end of cystoscope 3700 emerges through the distal end of introducer device 3300. Cystoscope 3700 is then used to visualize the anatomy to facilitate the method of treating prostate gland disorders.

Figure 37C" shows a perspective view of the distal region of an embodiment of introducer device 3300 comprising a bending or deflecting mechanism. In this embodiment, first tubular element 3302 comprises a spiral cut distal end and a pull wire. In Figure 37C"', the pull wire is pulled by deflection dial 3310. This deflects the distal tip of first tubular element 3302 as shown.

After the step in Figure 37C, guiding device 3338 is introduced through first tubular element 3302. Guiding device 3338 is advanced through first tubular element 3302 such that the distal tip of guiding device 3338 penetrates into the prostate gland. In one method embodiment, guiding device 3338 is further advanced such that the distal tip of guiding device 3338 penetrates through the prostate gland and enters the urinary bladder. In one embodiment, distal region of guiding device 3338 comprises an anchoring

element 3702. Anchoring element 3702 is deployed as shown in figure 37E. Thereafter, guiding device 3338 is pulled in the proximal direction till anchoring element 3702 is snug against the wall of the urinary bladder. Cystoscope 3700 can be used to visualize the steps of penetrating the prostate gland by guiding device 3338 and deploying anchoring element 3702. If guiding device 3338 is not positioned in a satisfactory position, guiding device 3338 is pulled back in introducer device 3300. The deflection angle of distal end of first tubular lumen 3302 is changed and guiding device 3338 is re-advanced into the urinary bladder. Figure 37E' shows a perspective view of an embodiment of anchoring element 3702. Anchoring element comprises a hollow sheath 3704. Distal region of hollow sheath 3704 is attached to distal region of guiding device 3338. A number of windows are cut in the distal region of hollow sheath 3704 such that several thin, splayable strips are formed between adjacent windows. Pushing hollow sheath 3704 in the distal direction causes splayable strips to splay in the radially outward direction to form an anchoring element. In Figure 37F, cutting device 3343 is advanced over guiding device 3338 into the prostate gland. In Figure 37G, cutting device 3343 is positioned in the prostate gland such that proximal marker band 3348 can be seen by cystoscope 3700 but distal marker band 3350 cannot be seen.

Thereafter, in Figure 37H, relative motion between outer sheath 3343 and inner sheath 3344 causes cutting wire 3352 to deploy outward in the axial direction. In one embodiment, this step is carried out by moving outer sheath 3343 in the distal direction while the inner sheath 3344 is stationary. In another embodiment, this step is carried out by moving inner sheath 3344 in the proximal direction while outer sheath 3343 is kept stationary. Also during step, electrical energy is delivered through cutting wire 3352 to cut tissue. In figure 37I, cutting device 3343 is pulled in the proximal direction such that the deployed cutting wire 3352 slices through tissue. Thereafter, cutting wire 3352 is withdrawn again in cutting device 3343. Cutting device 3343 is then removed from the anatomy.

In Figure 37J, plugging device 3354 is introduced over guiding device

3338 through the puncture or opening in the prostate gland. Thereafter, in Figure 37K, anchoring element 3702 is undeployed and guiding device 3343 is withdrawn from the anatomy. Thereafter, plugging device 3354 is used to deliver one or more plugging materials in the adjacent anatomy. The plugging materials can be used to plug or line some or all of the cuts or punctures created during the method.

Figures 38A to 38D show various components of a kit for treating prostate gland disorders by compressing a region of the prostate gland. Figure 38A shows the perspective view of an introducer device 3800. Introducer device 3800 comprises an outer body 3801 constructed from suitable biocompatible materials including, but not limited to metals like stainless steel, Nichol plated brass, polymers like Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK and fluoropolymers like PTFE, PFA, FEP, EPTFE etc. Body 3801 comprises a working device lumen 3802. Distal end of working device lumen 3802 emerges out of the distal end of body 3801. Proximal end of working device lumen 3802 incorporates lock thread 3803 such that introducer device may join with other devices. Device lumen 3802 may comprise one or more side ports e.g. a first side port 3804 and a second side port 3805 for the introduction or removal of one or more fluids.

Figure 38B shows a perspective view of a bridge device 3806 constructed from suitable biocompatible materials including, but not limited to metals like stainless steel, Nichol plated brass, polymers like Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK and fluoropolymers like PTFE, PFA, FEP, EPTFE etc. Bridge device may insert into introducer lumen 3802 and lock into place by threadably mating thread lock 3807 with thread 3803. Bridge may incorporate port 3808 for cystoscope with locking means 3809 that joins to cystoscope when inserted. Bridge device may incorporate one or more working lumens. Working lumen 3810 emerges out of the distal end of body 3806. In one embodiment, distal end of working device lumen 3810 has a bent or curved region. Proximal end of lumen 3810 emerges from port 3811 that may

incorporate fluid stasis valve 3812 and a luer lock. Working lumen 3813 emerges distally in straight fashion through blunt obturator 3814 at distal end of body 3806 and emerges proximally through second port that may incorporate fluid stasis valve and luer lock.

Figure 38C shows a perspective view of a distal anchor deployment device 3815 constructed from suitable biocompatible materials including, but not limited to polymers like Polycarbonate, PVC, Pebax, Polyimide, Braided Pebax, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, metals like stainless steel, Nichol plated brass, and fluoropolymers like PTFE, PFA, FEP, EPTFE etc. Deployment device 3815 comprises handle 3816, which incorporates movable thumb ring pusher 3817 and anchor deployment latch 3818; and distal shaft 3819 which has trocar point 3820 at distal end. Mounted on distal shaft 3819 is distal anchor 3821 that incorporates tether 3822. Tether 3822 can be made of suitable elastic or non-elastic materials including, but not limited to metals e.g. stainless steel 304, stainless steel 306, Nickel-Titanium alloys, suture materials, titanium etc. or polymers such as silicone, nylon, polyamide, polyglycolic acid, polypropylene, Pebax, PTFE, ePTFE, silk, gut, or any other monofilament or any braided or mono-filament material. Proximal end of tether 3822 may incorporate hypotube 3823. Distal anchor 3821 is constructed from suitable biocompatible materials including, but not limited to metals e.g. stainless steel 304, stainless steel 306, Nickel-Titanium alloys, titanium etc. or polymers e.g. Pebax, Braided Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, PTFE, PFA, FEP, EPTFE etc. Deployment device 3815 is inserted into bridge working lumen 3810. Advancement of thumb ring 3817 extends distal shaft 3819 through distal end of working lumen 3810, preferably into tissue for deployment of distal anchor 3821. Depth of distal shaft deployment can be monitored on cystoscope by visualizing depth markers 3824. Once distal shaft 3819 is deployed to desired depth, anchor deployment latch 3818 is rotated to release distal anchor 3821. Retraction of thumb ring 3817 then retracts distal shaft 3819 while leaving distal anchor 3821 in tissue. Bridge 3806 is then disconnected from introducer device 3800 and removed.

Figure 38D shows the proximal anchor delivery tool 3825 constructed from suitable biocompatible materials including, but not limited to polymers like Polycarbonate, PVC, Pebax, Polyimide, Braided Pebax, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, metals like stainless steel, Nichol plated brass, and fluoropolymers like PTFE, PFA, FEP, EPTFE etc. Proximal anchor delivery tool 3825 comprises handle 3826, which incorporates anchor deployment switch 3827 in slot 3828 and tether cut switch 3829; and distal shaft 3830 which houses hypotube 3831. Lumen of hypotube 3831 emerges proximally at port 3832 which may incorporate a luer lock. Mounted on the hypotube and distal shaft is the proximal anchor 3833 with cinching hub 3834. Proximal anchor 3833 is constructed from suitable biocompatible materials including, but not limited to metals e.g. stainless steel 304, stainless steel 306, Nickel-Titanium alloys, titanium etc. or polymers e.g. Pebax, Braided Pebax, Polyimide, Braided Polyimide, Polyurethane, Nylon, PVC, Hytrel, HDPE, PEEK, PTFE, PFA, FEP, EPTFE or biodegradable polymers e.g. polyglycolic acid, poly(dioxanone), poly(trimethylene carbonate) copolymers, and poly (ε-caprolactone) homopolymers and copolymers etc. Figure 38E shows a close-up perspective view of proximal anchor 3833 mounted on hypotube 3831 and distal shaft 3830 of proximal anchor delivery tool 3825. Hypotube 3831 biases open the cinching lock 3835 of cinching hub 3834. In order to deploy proximal anchor 3833, hypotube 3823 is loaded into hypotube 3831 until it exits proximal port 3832. Hypotube 3823 is then stabilized while proximal anchor delivery tool 3825 is advanced into introducer device lumen 3802 and advanced to tissue target. Because hypotube 3831 biases open cinching lock 3835, the proximal anchor delivery tool travels freely along tether 3822. Once proximal anchor 3833 is adequately apposed to urethral wall of prostate, anchor deployment switch 3827 is retracted. During retraction of switch 3827, hypotube 3831 is retracted proximal to cinching hub 3834 and tether 3822 is tightened. When switch 3827 is fully retracted or desired tension is accomplished, tether 3822 is cut within cinching hub 3834 by advancing cutting switch 3829.

Any of the anchoring devices disclosed herein may comprise one or more sharp distal tips, barbs, hooks etc. to attach to tissue.

Various types of endoscopes can be used in conjunction with the devices disclosed herein such as flexible scopes that are thin, flexible, fibre-optic endoscopes and rigid scopes that are thin, solid, straight endoscopes. The scopes may have one or more side channels for insertion of various instruments. Further they may be used with in conjunction with standard and modified sheaths intended for endoscopic and transurethral use.

Local or general anesthesia may be used while performing the procedures disclosed herein. Examples of local anesthetics that can be used are anesthetic gels e.g. lidocaine gels in the urethra; combination of anesthetic agents e.g. combination of lidocaine and bupivacaine in the urethra; spinal anesthetics e.g. ropivacaine, fentanyl etc.; injectable anesthetics e.g. 1% lidocaine solution injected into the neurovascular bundles, the genitourinary diaphragm, and between the rectal wall and prostate; etc.

An optional trans-rectal ultrasound exam may be performed before and/or during the procedures disclosed herein. In this exam, a device called ultrasound transducer is inserted into the rectum. The ultrasound transducer is then used to image the prostate gland PG using ultrasound waves. The devices may be modified so that they are more visible under ultrasound such as etched surfaces. Other imaging devices may also be optionally used such as MRI, RF, electromagnetic and fluoroscopic or X-ray guidance. The anchoring devices or delivery devices may contain sensors or transmitters so that certain elements may be tracked and located within the body. The tethering devices may be used as cables to temporarily transmit energy to the distal and/or proximal anchors during deployment.

The invention has been described hereabove with reference to certain examples or embodiments of the invention but various additions, deletions, alterations and modifications may be made to those examples and embodiments without departing from the intended spirit and scope of the invention. For example, any element or attribute of one embodiment or example may be incorporated into or used with another embodiment or

example, unless to do so would render the embodiment or example unsuitable for its intended use. Also, where the steps of a method or process are described, listed or claimed in a particular order, such steps may be performed in any other order unless to do so would render the embodiment or example un-novel, obvious to a person of ordinary skill in the relevant art or unsuitable for its intended use. All reasonable additions, deletions, modifications and alterations are to be considered equivalents of the described examples and embodiments and are to be included within the scope of the following claims.

CLAIMS

What is claimed is:

1. A method for treating a condition in a human or animal subject wherein tissue located adjacent to that anatomical structure is exerting undesired pressure on the anatomical structure, said method comprising the step of:

A) implanting at least one tissue compressing device in the body of the subject to compress the tissue so as to relieve at least some of the pressure exerted by the tissue on the anatomical structure.

2. A method according to claim 1 wherein the anatomical structure is the urethra and the tissue comprises the prostate.

3. A method according to claim 2 wherein the prostate is enlarged.

4. A method according to claim 3 wherein the subject suffers from benign prostatic hypertrophy.

5. A method according to claim 1 wherein Step A comprises:

placing a first anchor at a first location on, in or adjacent to the prostate;

placing a second anchor at a second location on, in or adjacent to the prostate; and

placing a connecting member between the first and second anchors, said connecting member drawing at least one of said first and second anchors toward the other thereby compressing at least a portion of the prostate.

6. A method according to claim 5 wherein one of the first and second anchors is placed within the lumen of the urethra adjacent to the prostate.

7. A method according to claim 5 wherein one of the first and second anchors is placed within the wall of the urethra adjacent to the prostate.

8. A method according to claim 5 wherein one of the first and second anchors is placed within the prostate adjacent to the wall of the urethra.

9. A method according to any of claim 6, 7 or 8 wherein the other of said first and second anchors is placed within the prostate.

10. A method according to any of claim 6, 7 or 8 wherein the other of said first and second anchors is placed within the prostate adjacent to the inner surface of the prostatic capsule.

11. A method according to any of claims 6, 7 or 8 wherein the other of said first and second anchors is placed outside of the prostate.

12. A method according to claim 6, 7 or 8 wherein the other of said first and second anchors is placed adjacent to the outer surface of the prostatic capsule.

13. A method according to claim 6, 7 or 8 wherein the other of said first and second anchors is placed on or in a bone.

14. A method according to claim 13 wherein the other of said first and second anchors is placed on or in the pubic bone.

15. A method according to claim 6, 7 or 8 wherein the other of said first and second anchors is placed on or in a muscle.

16. A method according to claim 6, 7 or 8 wherein the other of said first and second anchors is placed on or in fascia.

17. A method according to claim 6, 7 or 8 wherein the other of said first and second anchors is placed at a location selected from the group consisting of:

a location within prostatic lobe;

a location within peripheral zone of prostate;

a location within prostatic capsule;

a location between prostatic capsule and pubic fascia;

a location within the pubic fascia;

a location within the levator ani muscle

a location within the obturator internus muscle;

a location within the pelvic bone;

a location within the periostium of pelvic bone;

a location within the pubic bone;

a location within the periostium of pubic bone;

a location within the symphysis pubica;

a location within the urinary bladder wall;

a location within the ischiorectal fossa;

a location within the urogenital diaphragm; and

a location within the abdominal fascia.

18. A method according to claim 2 wherein Step A comprises advancing an introducer device into the subject's urethra and using said introducer device to introduce the tissue compression device.

19. A method according to claim 18 wherein the introducer device comprises an elongate body having a scope lumen through which a scope may be inserted and a working lumen through which the tissue compression device may be introduced.

20. A method according to claim 2 wherein an opening is formed in the urethra adjacent to the prostate and at least a portion of said device is advanced through that opening in the urethra.

21. A method according to claim 2 wherein an opening is formed in the urethra and an introducer is advanced through the opening on the urethra to a position where it is used to implant the first anchor.

22. A method according to claim 21 wherein the introducer is then retracted to another position where it is used to implant the second anchor.

23. A method according to claim 20 wherein the opening formed in the urethra is no more than 2 mm in its greatest cross dimension.

24. A method according to claim 20 wherein at least one device is advanced into the urethra and used to i) form the opening in the urethra, ii) place the first anchor, iii) place the second anchor and iii) place the connecting member.

25. A method according to claim 20 wherein at least one device is advanced through the subject's lower abdominal wall and used to i) place the first anchor, ii) place the second anchor and ii) place the connecting member.

26. A method according to claim 20 wherein said at least one device is advanced percutaneously to a position adjacent to or within the prostate.

27. A method according to claim 25 wherein at least one device is advanced percutaneously into the subject's urinary bladder and through the wall of the urinary bladder to a location adjacent to or within the prostate.

28. A method according to claim 25 wherein the first anchor is placed within the urethra adjacent to the prostate, the second anchor is placed within the bladder adjacent to the wall of the bladder and the connecting member is placed such that it extends through the prostate between the first and second anchors.

29. A method according to claim 2 wherein a first device is advanced transurethrally into the subject's urinary balder and at least one other device is then advanced through the wall of the urinary bladder to a location adjacent to or within the prostate where said at least one other device is then used to place at least one of the first and second anchors and the connecting member.

30. A method according to claim 29 wherein the first anchor is placed within the urethra adjacent to the prostate, the second anchor is placed within the bladder adjacent to the wall of the bladder and the connecting member is placed such that it extends through the prostate between the first and second anchors.

31. A method according to claim 2 wherein the connecting member is elastic.

32. A method according to claim 31 wherein the first and second locations are spaced apart such that the elastic connecting member is in a stretched state.

33. A method according to claim 2 wherein the length of the connecting member is adjustable.

34. A method according to claim 33 wherein the wherein the step of placing the connecting member comprises adjusting the length of the connecting member.

35. A method according to claim 34 wherein the method further comprises the step of:

B) subsequently readjusting the length of the connecting member at least one time.

36. A method according to claim 1 wherein the at least one device implanted within the body comprises i) a first anchor, ii) a second anchor and iii) a tensioning member that extends between the first and second anchors, and wherein the method comprises:

causing the first anchor to be anchored at a first location;

causing the second anchor to be anchored at a second location; and

causing the tensioning member to be under sufficient tension to compress tissue between the first and second anchors.

37. A method according to claim 1 wherein Step A comprises placing at least first, second and third anchors at least first second and third locations on, in or adjacent to the prostate and placing at least one connecting member to connect said first second and third anchors and to compress at least a portion of the prostate.

38. A method according to claim 1 wherein Step A causes ischemia of at least a portion of the tissue.

39. A method according to claim 1 further comprising the step of:

forming a lesion within the tissue which subsequently causes shrinkage of the tissue.

40. A method according to claim 39 wherein a coagulative lesion is formed by heating the tissue.

41. A method according to claim 39 wherein the coagulative lesion subsequently becomes resorbed thereby causing the tissue to shrink.

42. A method according to claim 39 wherein the creation of the coagulative lesion within the tissue causes swelling of the tissue and wherein the at least

one device is positioned to compress the tissue in a manner that limits the affect of such swelling on the adjacent anatomical structure.

43. A method according to claim 39 wherein the tissue comprises prostate tissue and wherein the coagulative lesion causes the prostate to shrink.

44. A method according to claim 1 wherein the compression created by Step A causes necrosis of at least a portion of the tissue.

45. A method according to claim 2 wherein Step A comprises forming at least one opening in the wall of the urethra and wherein the method further comprises the step of:

treating the opening formed in the urethra to facilitate closure of that opening without substantial constriction or blockage of the lumen of the urethra.

46. A method according to claim 20 further comprising the step of:

implanting an epithelialization promoter to facilitate epithelialization over the anchor placed within the urethra without substantial constriction or blockage of the lumen of the urethra.

47. A method according to claim 5 wherein one of said first and second anchors is placed substantially within the lumen of the urethra.

48. A method according to claim 5 wherein one of said first and second anchors is placed substantially within the wall of the urethra.

49. A method according to claim 20 further comprising the step of:

implanting a substance that prevents or deters the formation of adhesion, scars or tissue within the lumen of the urethra.

50. A method according to claim 46 wherein the step of implanting an epithelialization promoter comprises seeding or sodding the wall of the urethra with epithelial cells.

51. A method according to claim 2 wherein said method further comprises the step of:

B) incising the capsule of the prostate.

52. A method according to claim 51 wherein Step B comprises inserting a cutting device transurethrally, advancing the cutting device through an opening formed in the wall of the urethra and using the cutting device to incise the capsule of the prostate.

53. A method according to claim 51 wherein Step B comprises inserting a cutting device percutaneously, advancing the cutting device to allocation within or near the prostate and using the cutting device to incise the capsule of the prostate.

54. A method according to claim 51 wherein Step B comprises inserting a cutting device percutaneously into the urinary bladder, advancing the cutting device through the wall of the urinary bladder to a location within or near the prostate and using the cutting device to incise the capsule of the prostate.

55. A method according to claim 51 wherein Step B comprises inserting a cutting device percutaneously into the rectum, advancing the cutting device through the wall of the rectum to a location within or near the prostate and using the cutting device to incise the capsule of the prostate.

56. A method according to claim 51 wherein Step B comprises inserting a cutting device percutaneously through the perineum, advancing the cutting device through the wall of the urinary bladder to a location within or near the prostate and using the cutting device to incise the capsule of the prostate.

57. A method according to claim 1 further comprising the step of:

B) delivering a therapeutic substance to a location within or near the tissue.

58. A method according to claim 57 wherein the therapeutic substance comprises a substance that weakens or modifies tissue.

59. A method according to claim 57 wherein the substance is selected from the group consisting of:

hemostatic agents; antimicrobial agents; antibiotics; antifungals; antiprotozoals; antivirals; antimicrobial metals; hemostatic and/or vasoconstricting agents; pseudoephedrine; xylometazoline; oxymetazoline; phenylephrine; epinephrine; cocaine; local anesthetic agents; lidocaine; cocaine; bupivacaine; hormones; anti-inflammatory agents; corticosteroids; non-steroidal anti-inflammatory agents; hormonally active agents; agents that enhance potency; substances that dissolve, degrade, cut, break, weaken, soften, modify or remodel connective tissue or other tissue; enzymes; collagenase; trypsin; EDTA; trypsin combined with EDTA; hyaluronidase; tosyllysylchloromethane (TLCM)); chemotherapeutic or antineoplastic agents; substances that prevent adhesion formation; hyaluronic acid gel; space occupying substances; substances that promote desired tissue ingrowth into an anchoring device or other implanted device; substances that promote or facilitate epithelialization; substances that create a coagulative lesion which is subsequently resorbed causing the tissue to shrink, substances that cause the prostate to decrease in size; phytochemicals that cause the prostate to decrease in size; alpha-1a-adrenergic receptor blocking agents; 5-alpha-reductase inhibitors; smooth muscle relaxants and agents that inhibit the conversion of testosterone to dihydrotestosterone.

60. A method according to claim 1 comprising:

providing a system that comprises i) an introducer that is insertable to a position within or near the prostate gland, ii) an implantable device for compressing the prostate gland and iii) delivery apparatus advanceable through the introducer and useable to implant the implantable device such that it compresses the prostate gland;

inserting the introducer to a position within or near the prostate gland;

advancing the delivery apparatus through the introducer; and

using the delivery apparatus to implant the implantable device such that the implantable device compresses the prostate gland.

61. A method according to claim 60 wherein the introducer has a scope lumen and a working lumen and wherein a scope is inserted into the scope lumen and the delivery apparatus is advanced through the working lumen.

62. A method according to claim 61 further comprising the step of using the scope to view at least a portion of the performance of the method.

63. A method according to claim 60 wherein the introducer comprises a scope and a working lumen and wherein the delivery apparatus is advanced through the working lumen and the scope is used to view at least a portion of the performance of the method.

64. A method according to claim 60 wherein the step of inserting the introducer to a position within or near the prostate gland comprises inserting the introducer percutaneously through the abdominal wall.

65. A method according to claim 60 wherein the step of inserting the introducer to a position within or near the prostate gland comprises inserting the introducer percutaneously through the perineum.

66. A method according to claim 60 wherein the step of inserting the introducer to a position within or near the prostate gland comprises inserting the introducer percutaneously through the abdominal wall, through the wall of the urinary bladder and to a position within the urinary bladder.

67. A method according to claim 60 wherein the step of inserting the introducer to a position within or near the prostate gland comprises inserting the introducer into the urethra and advancing the introducer to a position within the urethra where the urethra is substantially surrounded by the prostate gland.

68. A method according to claim 60 wherein the step of inserting the introducer to a position within or near the prostate gland comprises inserting the introducer into the urethra and advancing the introducer to a position within the urethra distal to the prostate gland.

69. A method according to claim 60 wherein the step of inserting the introducer to a position within or near the prostate gland comprises inserting the introducer into the urethra and advancing the introducer into the urinary bladder.

70. A method according to claim 60 wherein the step of inserting the introducer to a position within or near the prostate gland comprises percutaneously inserting the introducer through the abdominal wall and though an opening formed in a bone of the pelvis.

71. A method according to claim 60 wherein the step of inserting the introducer to a position within or near the prostate gland comprises inserting the introducer into the rectum and advancing either the introducer or the delivery device through an opening formed in the rectal wall.

72. A method according to claim 71 wherein the method further comprises closing the opening formed in the rectal wall.

73. A method according to claim 60 wherein the introducer is positioned within the urethra and wherein the step of using the delivery apparatus to implant the implantable device such that the implantable device compresses the prostate gland comprises advancing either the introducer or the delivery apparatus though an opening formed in the wall of the urethra.

74. A method according to claim 73 wherein the opening formed in the wall of the urethra is no greater than 2 mm in its greatest cross-dimension.

75. A method according to claim 72 further comprising the step of closing the opening formed in the urethra.

76. A method according to claim 72 wherein the delivery device is advanced outwardly through the capsule of the prostate gland to a position outside the prostate gland.

77. A method according to claim 60 wherein the introducer is positioned within the pelvic cavity outside of the prostate gland and wherein the step of using the delivery apparatus to implant the implantable device such that the implantable device compresses the prostate gland comprises advancing either the introducer or the delivery apparatus through the capsule of the prostate gland.

78. A method according to claim 77 wherein the delivery device is advanced through the wall of the urethra to a position within the urethra.

79. A method according to claim 60 wherein the implantable device comprises a first anchor, a second anchor and a tensioning member that extends between the first anchor and the second anchor.

80. A method according to claim 79 wherein the step of using the delivery apparatus to implant the implantable device such that the implantable device compresses the prostate gland comprises:

advancing the delivery apparatus to a first location and causing the first anchor to be implanted at said first location;

moving the delivery device to a second location and causing the second anchor to be implanted at the second location; and

causing the tensioning member to be under sufficient tension to cause compression of prostate tissue between the first anchor and the second anchor.

81. A method according to claim 80 wherein the step of causing the tensioning member to be under sufficient tension to cause compression of prostate tissue between the first anchor and the second anchor comprises causing the distance between the first location and the second location to be sufficient to result in said sufficient tension on said tensioning member.

82. A method according to claim 80 wherein the step of causing the tensioning member to be under sufficient tension to cause compression of prostate tissue between the first anchor and the second anchor comprises shortening the tensioning member after the first and second anchors have been implanted.

83. A method according to claim 80 wherein the step of causing the tensioning member to be under sufficient tension to cause compression of prostate tissue between the first anchor and the second anchor comprises cinching at least one of the first and second anchors to the tensioning member.

84. A method according to claim 80 further comprising the step of adjusting the tension on the tensioning member at least one time subsequent to implantation of the implantable device.

85. A method according to claim 83 wherein the tension on the tensioning member is adjustable by non-invasive means and wherein the step of adjusting the tension on the tensioning member at least one time subsequent to implantation of the implantable device is carried out by non-invasive means.

86. A method for compressing at least one region of the prostate in a manner that relieves constriction of the urethra, said method comprising the steps of

placing a first member in an anatomical structure outside of the urethra;

placing a second member in the lumen or wall of the urethra;

bringing the first member closer to the second member in a manner that relieves constriction of the urethra.

87. A device for compressing at least one region of the prostate comprising

a first element configured to communicate force to an anatomical structure outside of the urethra;

a second element configured to communicate force to the urethra; and

a tethering element capable of linking the first and second elements.

88. A method for relieving an obstruction of a lumen in the body of a human or animal subject due to encroachment of a tissue within or outside the lumen comprising

placing at least one first element such that it can maintain a force communicating relationship with the inner surface of the lumen;

placing at least one second element such that it can maintain a force communicating relationship with a structure outside of the lumen;

bring the first element closer to the second element thereby displacing tissue and relieving the obstruction.

89. A device for relieving an obstruction of a lumen in the body due to encroachment of a tissue within or outside the lumen comprising;

at least one first element capable of communicating force to an anatomical structure outside of the lumen;

at least one second element capable of communicating force to the inner surface of the lumen;

a tethering element capable of linking the first and second elements.

90. A method of relieving obstruction of the urethra by the prostate, said method comprising the steps of:

delivering at least one device through the wall of the urethra;

using said at least one device to performing at least one action on the prostate which changes the force exerted by the prostate on the urethra without removing or destroying prostatic tissue.

91. A device for relieving a urethral obstruction caused by the prostate gland, said device comprising

an implant that modifies at least one property of the tissue beyond the prostatic urethra without destroying or removing tissue.

92. A system for altering the crossectional morphology of a lumen within the body of a human or animal subject, said system comprising:

an introduction device positionable within the lumen;

a device that is introduceable through the introduction device into an opening

in the lumen, said device being useable to modifying the forces exerted on the lumen by tissue outside of the lumen, thereby resulting in a change of the crossectional morphology of the lumen.

93. A system according to claim 92 wherein the lumen within the body comprises the urethra and the device modifies forces exerted by the prostate gland on the urethra.

94. A system according to claim 92 wherein the lumen within the body comprises a blood vessel and the device modifies forces exerted on the blood vessel by tissue adjacent thereto.

95. A system according to claim 92 wherein the lumen within the body comprises a lumen of the trachea, bronchus, bronchiole or other respiratory passageway and the device modifies forces exerted on that trachea, bronchus, bronchiole or other respiratory passageway by tissue adjacent thereto.

96. A system according to claim 92 wherein the lumen within the body comprises a lumen of the stomach, duodenum, small intestine, jejunum, illium, colon, cystic duct, hepatic duct, common bile duct, pancreatic duct or other alimentary or endocrine passageway and the device modifies forces exerted on that trachea, stomach, duodenum, small intestine, jejunum, illium, colon, cystic duct, hepatic duct, common bile duct, pancreatic duct or other alimentary or endocrine passageway by tissue adjacent thereto.

97. A system according to claim 92 wherein the lumen within the body comprises a lumen of a lymphatic passageway and the device modifies forces exerted on that lymphatic passageway by tissue adjacent thereto.

98. A system according to claim 92 wherein the tissue comprises an organ.

99. A system according to claim 92 wherein the tissue comprises a neoplasm, benign growth, cancerous growth, tumor, cyst or other mass.

100. A system according to claim 92 wherein the tissue comprises congenital deformity.

101. A system according to claim 92 wherein the tissue comprises an anatomical structure that has become enlarged due to hypertrophy, hyperplasia, edema, fluid build up, fluid retention, excess fluid production, impeded fluid outflow, a tumor.

102. A method for decompressing a compressed lumen within the body of a human or animal subject, said method comprising the steps of:

forming an opening in the wall of the lumen;

placing a first attachment element in or near the lumen,

placing a second attachment element in the subject's body at a location farther away from the lumen than the first attachment element;

placing a tensioning element between the first attachment element and

the second attachment element said tensioning element being under sufficient tension to decompress the lumen.

103. A method according to claim 102 wherein the lumen within the body comprises the lumen of the urethra and the first attachment element, second attachment element and tensioning element are placed so as to modify forces exerted on the urethra.

104. A method according to claim 102 wherein the lumen within the body comprises the lumen of a blood vessel and the first attachment element, second attachment element and tensioning element are placed so as to modify forces exerted on that blood vessel.

105. A method according to claim 102 wherein the lumen within the body comprises the lumen of the trachea, bronchus, bronchiole or other respiratory passageway and the first attachment element, second attachment element and tensioning element are placed so as to modify forces exerted on that trachea, bronchus, bronchiole or other respiratory passageway.

106. A method according to claim 102 wherein the lumen within the body comprises a lumen of the trachea, stomach, duodenum, small intestine, jejunum, ileum, colon, cystic duct, hepatic duct, common bile duct, pancreatic duct or other alimentary or endocrine passageway and the first attachment element, second attachment element and tensioning element are placed so as to modify forces exerted on that trachea, stomach, duodenum, small intestine, jejunum, ileum, colon, cystic duct, hepatic duct, common bile duct, pancreatic duct or other alimentary or endocrine passageway.

107. A system for treating a condition where a tissue or anatomical structure causes constriction or interferes with an adjacent tissue or anatomical structure in the body of a human or animal subject, said system comprising:

a first anchor;

a second anchor; and

a tensioning member that extends between the first and second anchors.

108. A system according to claim 107 wherein at least one of the first and second anchors comprises a crumpling anchor.

109. A system according to claim 107 wherein at least one of the first and second anchors comprises T shaped anchor.

110. A system according to claim 107 wherein at least one of the first and second anchors comprises a bow shaped anchor.

111. A system according to claim 107 wherein at least one of the first and second anchors comprises a cross shaped anchor.

112. A system according to claim 107 wherein at least one of the first and second anchors comprises a woven fabric, screen, textile, paper or other porous material.

113. A system according to claim 107 wherein at least one of the first and second anchors comprises an adhesive.

114. A system according to claim 107 wherein at least one of the first and second anchors comprises a plurality of arms extending outwardly from a central hub.

115. A system according to claim 107 wherein at least one of the first and second anchors comprises a spiral anchor.

116. A system according to claim 107 wherein at least one of the first and second anchors is configured to generally conform to the shape of an anatomical structure against which it is intended to rest.

117. A system according to claim 107 wherein at least one of the first and second anchors comprises a screw.

118. A system according to claim 107 wherein at least one of the first and second anchors comprises a plurality of splayable members.

119. A system according to claim 107 wherein at least one of the first and second anchors comprises a molly bolt anchor.

120. A system according to claim 107 wherein at least one of the first and second anchors comprises a compressible structure that engages tissue when compressed.

121. A system according to claim 107 wherein at least one of the first and second anchors comprises at least one tissue engaging flange.

122. A system according to claim 107 wherein at least one of the first and second anchors comprises at least one tissue engaging barb.

123. A system according to claim 107 wherein at least one of the first and second anchors comprises a cylinder.

124. A system according to claim 107 wherein at least one of the first and second anchors comprises a tube.

125. A system according to claim 107 wherein at least one of the first and second anchors comprises a slotted tube.

126. A system according to claim 107 wherein at least one of the first and second anchors is constructed to receive a trocar during insertion of the anchor.

127. A system according to claim 107 wherein at least one of the first and

second anchors comprises a mesh.

128. A system according to claim 107 wherein at least one of the first and second anchors comprises a helix.

129. A system according to claim 107 wherein at least one of the first and second anchors comprises a device that is a) implantable in tissue before it is connected to the tensioning member and b) is configured to facilitate connection of the tensioning member thereto after it has been implanted in tissue.

130. A system according to claim 107 wherein at least one of the first and second anchors comprises a spring.

131. A system according to claim 107 wherein at least one of the first and second anchors comprises a screw.

132. A system according to claim 107 wherein at least one of the first and second anchors is configured to engage bone.

133. A system according to claim 107 wherein at least one of the first and second anchors is configured to engage soft tissue.

134. A system according to claim 107 wherein at least one of the first and

second anchors is configured to engage or rest upon a surface of an anatomical structure.

135. A system according to claim 107 wherein the tensioning member comprises a monofilament.

136. A system according to claim 107 wherein the tensioning member comprises an elongate member having at least one toothed surface.

137. A system according to claim 107 wherein the tensioning member comprises a multifilament.

138. A system according to claim 107 wherein the tensioning member comprises a helical member.

139. A system according to claim 107 wherein the tensioning member comprises a threaded member.

140. A system according to claim 107 wherein the tensioning member has one or more regions that engage surrounding tissue to deter unwanted movement of the tensioning member after implantation.

141. A system according to claim 107 wherein the tensioning member comprises a telescoping member.

142. A system according to claim 107 wherein the tensioning member comprises a first elongate portion, a second elongate portion and a connecting body, the first elongate portion being connected to and extending from the connecting body in a first direction and the second elongate portion being connected to and extending from the connecting body in a second direction.

143. A system according to claim 107 wherein the tensioning member is elastic.

144. A system according to claim 107 wherein the tensioning member is capable of being shortened after at least one of the anchors has been implanted.

145. A system according to claim 107 further comprising apparatus for placing the tensioning member under a desired amount of tension.

146. A system according to claim 145 wherein the apparatus for placing the tensioning member under a desired amount of tension comprises apparatus for shortening the tensioning member.

147. A system according to claim 145 wherein the apparatus for placing the tensioning member under a desired amount of tension comprises apparatus for compressing the tensioning member.

148. A system according to claim 145 wherein the apparatus for placing the tensioning member under a desired amount of tension comprises apparatus for cinching at least one of the anchors on the tensioning member.

149. A system according to claim 145 wherein the apparatus for placing the tensioning member under a desired amount of tension comprises apparatus for changing the shape of the tensioning member.

150. A system according to claim 145 wherein the apparatus for placing the tensioning member under a desired amount of tension comprises apparatus for collapsing at least a portion of the tensioning member.

151. A system according to claim 107 further comprising a delivery device for delivering the system into the subject's body.

152. A system according to claim 151 wherein the delivery device comprises an elongate member having a lumen and wherein the system is initially disposed within the lumen of the elongate member and wherein the system is expellable out of the lumen of the elongate member.

153. A system according to claim 152 wherein the system is to be implanted near a body lumen or body cavity and the elongate member is sized and configured to be advanced into that body lumen or body cavity and then into a tissue or anatomical structure adjacent to that body lumen or body cavity.

154. A system according to claim 153 wherein the body lumen or body cavity is the urethra and wherein delivery device is constructed to implant the first and second anchors and the tensioning member in a manner that relieves constriction of the urethra caused by the prostate gland.

155. A system according to claim 151 wherein the delivery device is attached to at least one of said first anchor, second anchor and tensioning member and wherein the system further comprises apparatus for severing that attachment.

156. A system according to claim 155 wherein the apparatus for severing that attachment comprises an electrolytic detachment element.

157. A system according to claim 155 wherein the apparatus for severing that attachment comprises a looped ribbon.

158. A system according to claim 155 wherein the apparatus for severing that attachment comprises a locked ball.

159. A system according to claim 155 wherein the apparatus for severing that attachment comprises interlocking cylinders.

160. A system according to claim 152 further comprising an introducer device that has a lumen through which the delivery device may be advanced.

161. A system according to claim 160 wherein the body lumen or body cavity is the urethra and wherein the delivery device and the introducer device are constructed to be useable to implant the first and second anchors and the tensioning member in a manner that relieves constriction of the urethra caused by the prostate gland.

162. A system according to claim 161 wherein the introducer is advanceable into the urethra and the delivery device is then advanceable from the introducer device to a location within or near the prostate gland.

163. A system according to claim 161 wherein the introducer is advanceable percutaneously into the subject's body and the delivery device is then advanceable from the introducer device to a location within or near the prostate gland.

164. A system according to claim 161 wherein the introducer is advanceable into the subject's urinary bladder and the delivery device is then advanceable from the introducer device to a location within or near the prostate gland.

165. A system according to claim 160 or 161 wherein the introducer device further comprises an endoscope.

166. A system according to claim 160 or 161 wherein the introducer device further comprises a scope lumen into which an endoscope may be inserted.

167. A system according to claim 166 wherein the introducer device further comprises a holding apparatus that holds the endoscope in a substantially fixed position within the scope lumen.

168. A system according to claim 165 wherein the introducer device further comprises endoscope adjustment apparatus for adjusting the view obtained by the endoscope.

169. A system according to claim 166 wherein the introducer device further comprises endoscope adjustment apparatus for adjusting the view obtained by an endoscope disposed within the scope lumen.

170. A system according to claim 165 wherein the introducer device further comprises apparatus for controlling the trajectory on which the delivery device advances from the introducer device.

171. A system according to claim 170 wherein the apparatus for controlling the trajectory on which the delivery device advances from the introducer device comprises a preformed or steerable guide member through which or over which the delivery device is advanceable.

172. An introducer device that is useable to facilitate insertion of a working device into the prostate gland of a human or animal subject, said introducer device comprising:

an elongate body that is insertable into the subject's urethra;

a scope lumen configured to receive a cystoscope or other endoscopic device; and

a working lumen through which at least one working device may be advanced, said working lumen having an outlet through which the working device may exit the introducer device and advance through the wall of the urethra and to a position within or near the prostate gland.

173. An introducer device according to claim 172 further comprising apparatus for holding a cystoscope or other endoscopic device in a substantially fixed position in the scope lumen.

174. An introducer device according to claim 172 further comprising apparatus for adjusting the view obtained by a cystoscope or other endoscopic device disposed in the scope lumen.

175. An introducer device according to claim 172 further comprising apparatus for adjusting the view obtained by a cystoscope or other endoscopic device disposed in the scope lumen.

176. An introducer device according to claim 172 further comprising apparatus for controlling the trajectory on which the delivery device advances from the introducer device.

177. An introducer device according to claim 176 wherein the apparatus for controlling the trajectory on which the delivery device advances from the introducer device comprises a preformed or steerable guide member through which or over which the delivery device is advanceable.

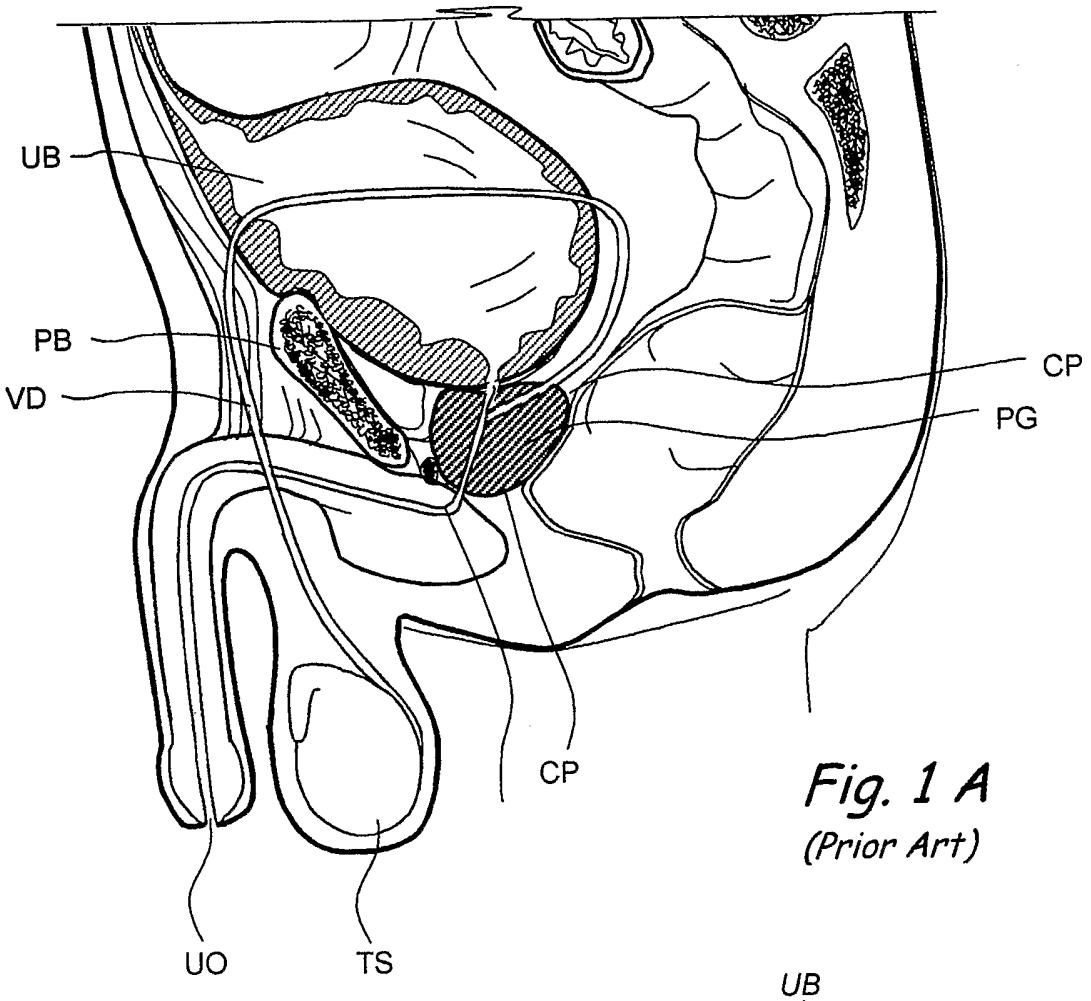


Fig. 1 A
(Prior Art)

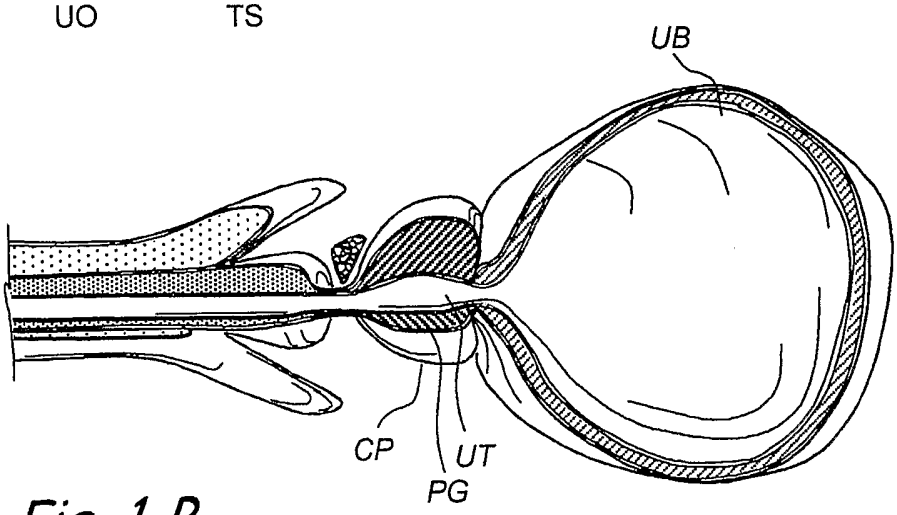


Fig. 1 B
(Prior Art)

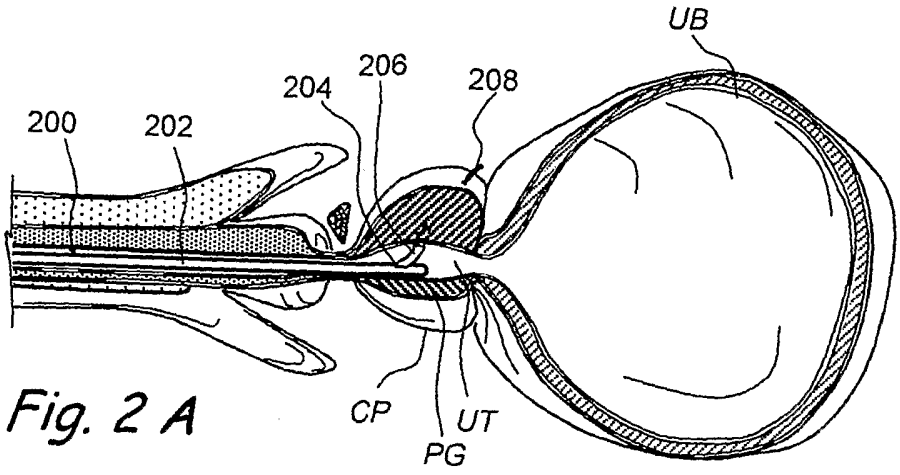


Fig. 2 A

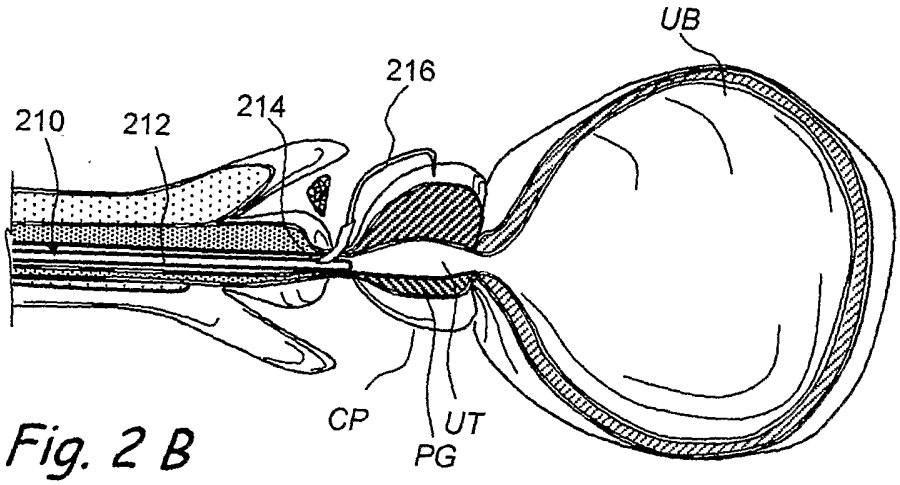


Fig. 2 B

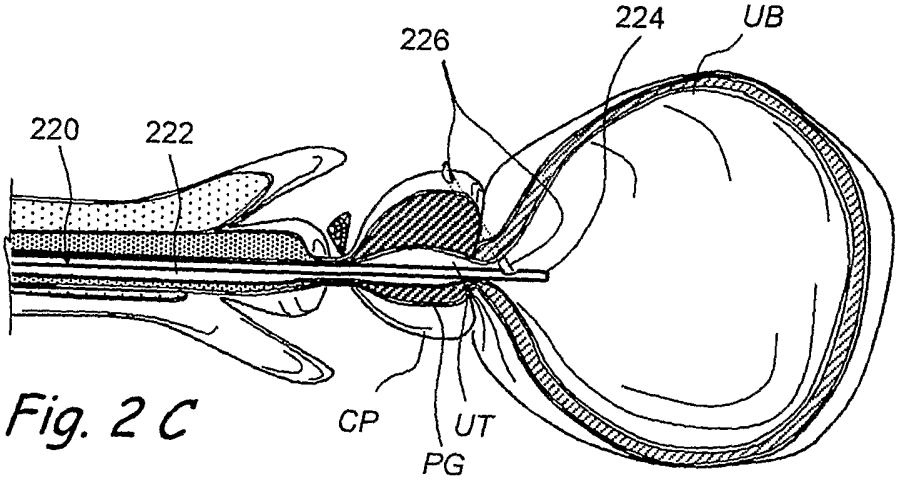


Fig. 2 C

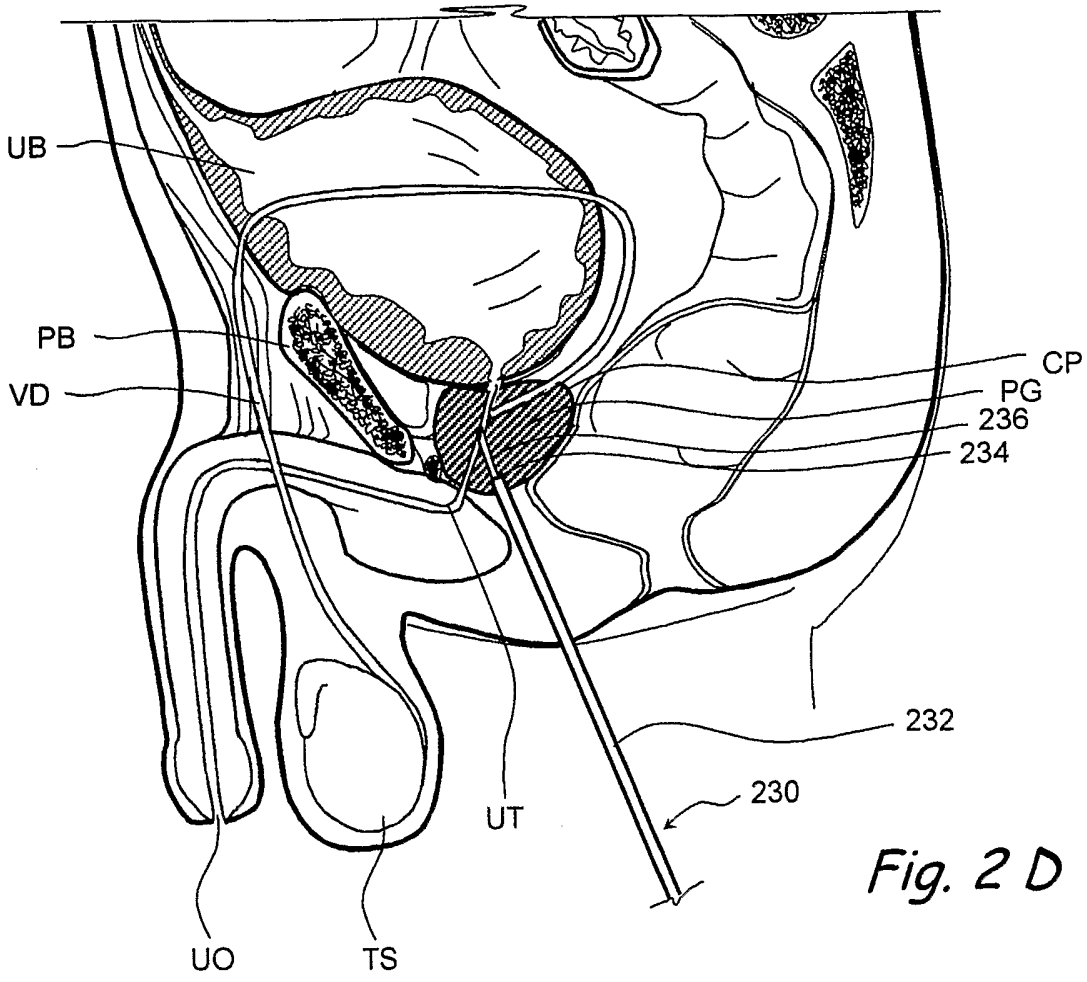

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Fig. 2 D

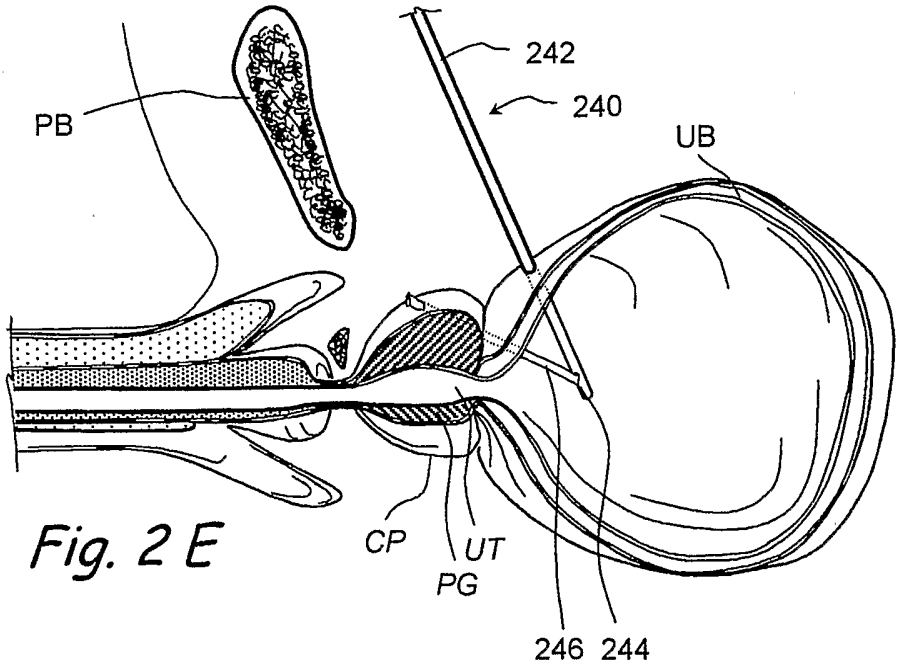

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Fig. 2 E

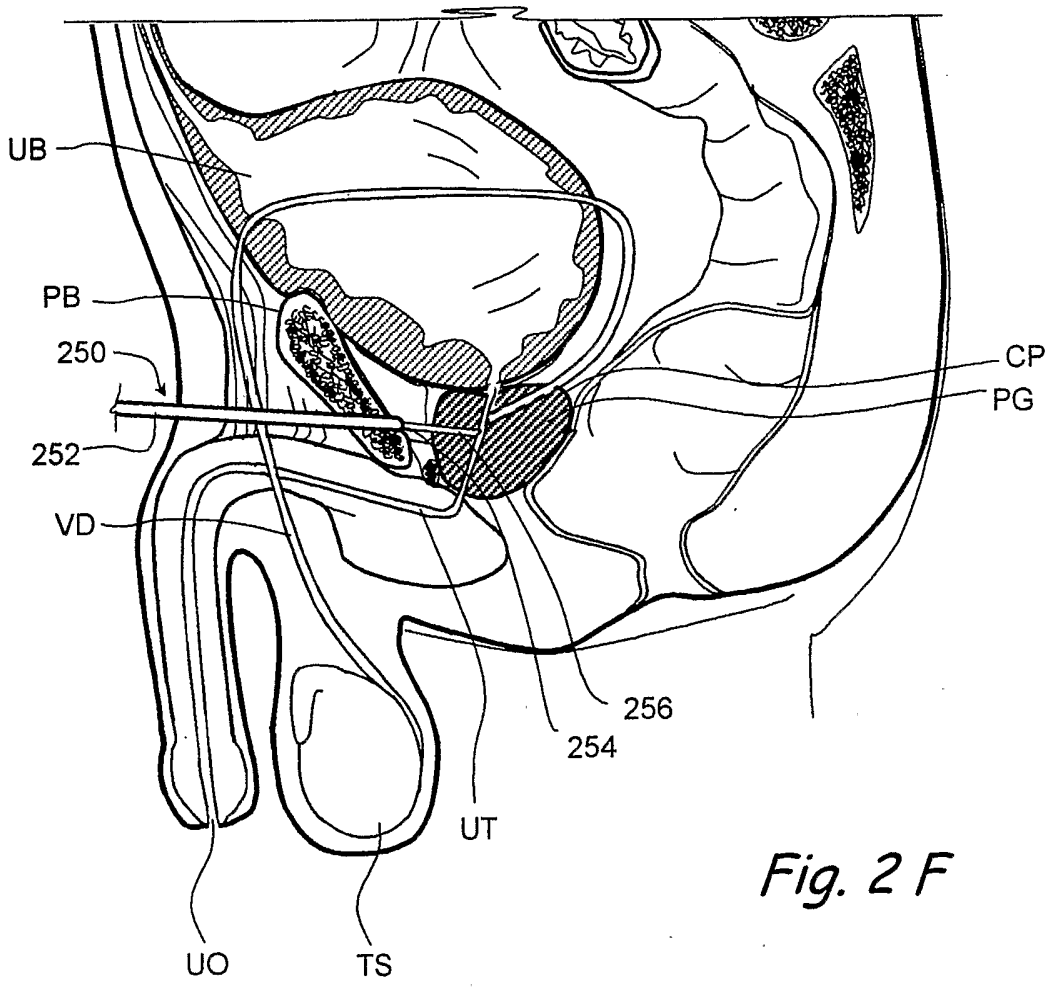


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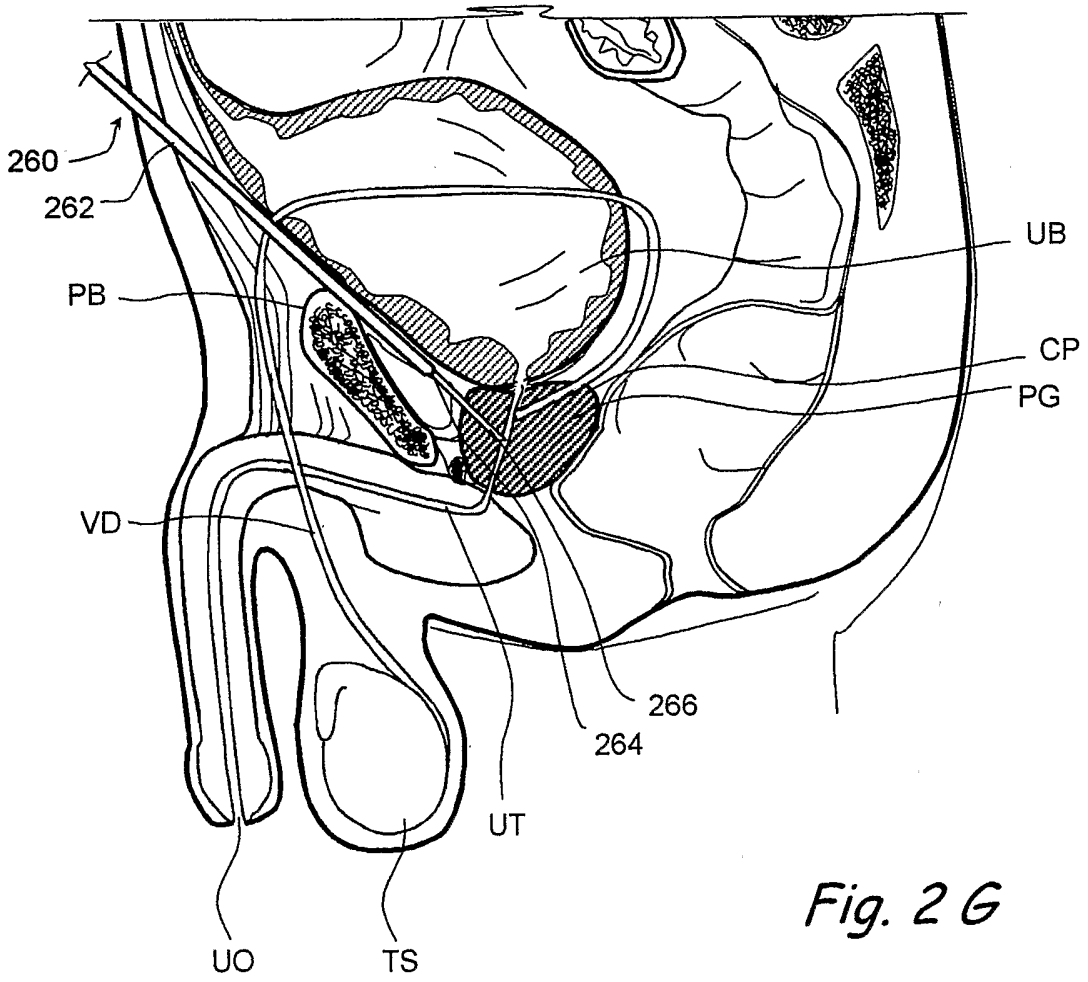


Fig. 2 G

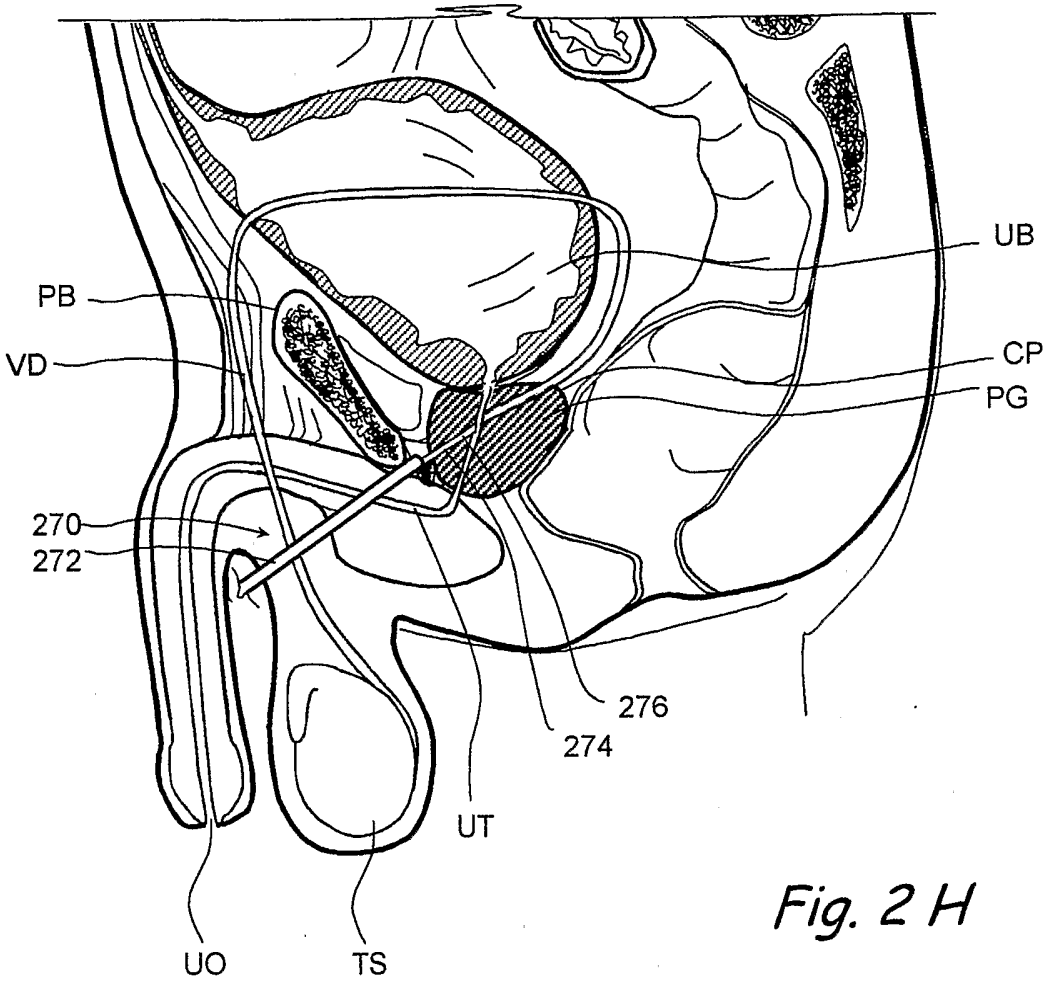


Fig. 2 H

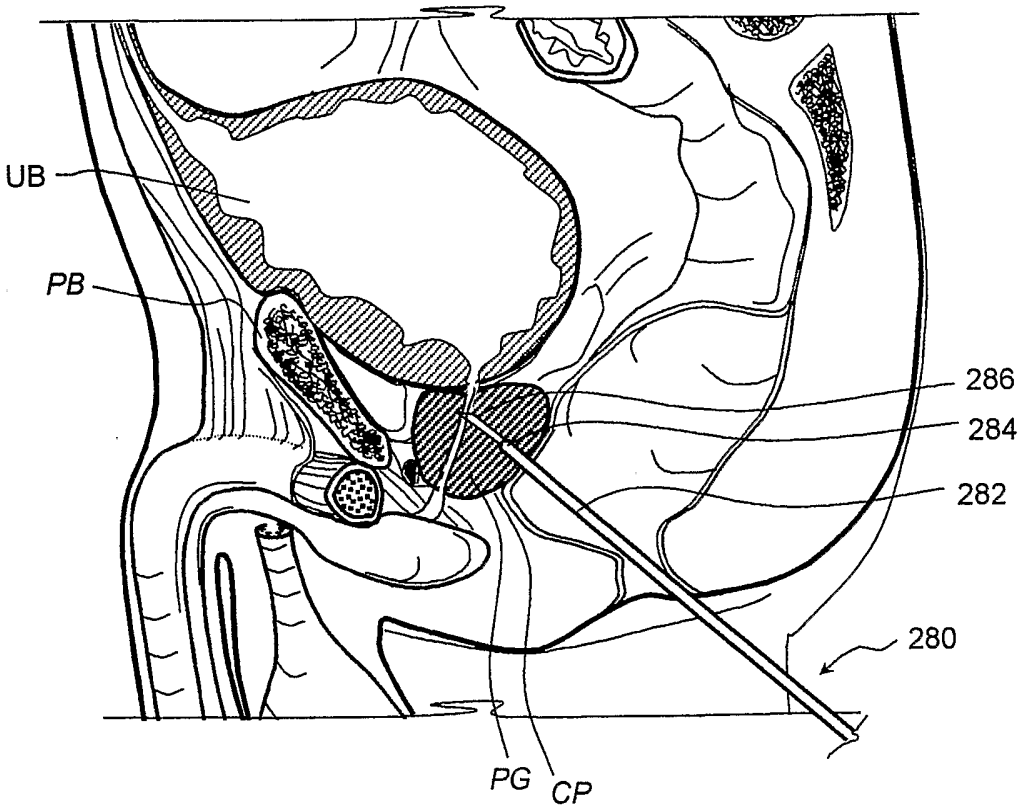


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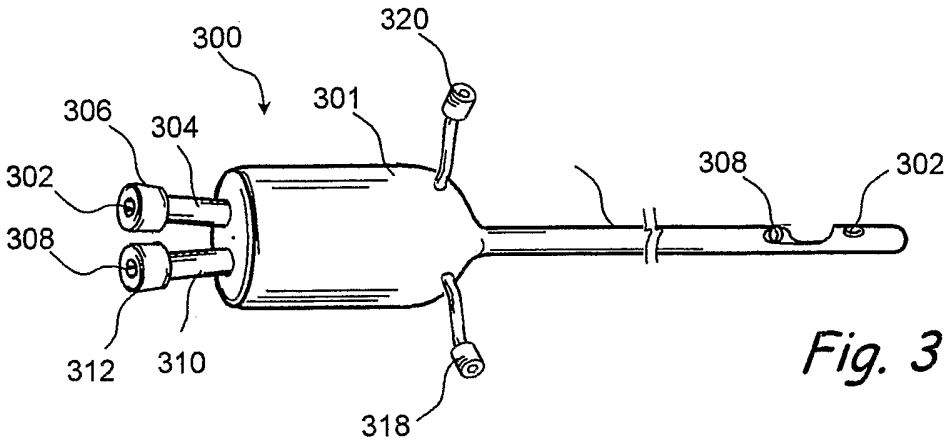


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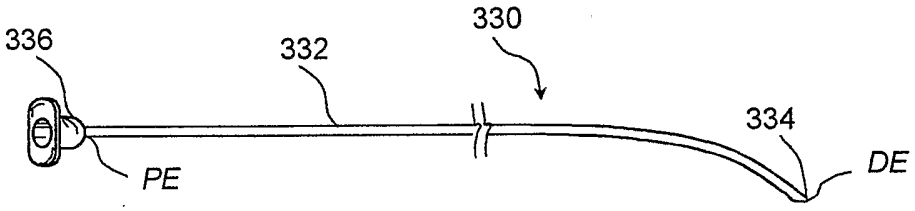


Fig. 3 B

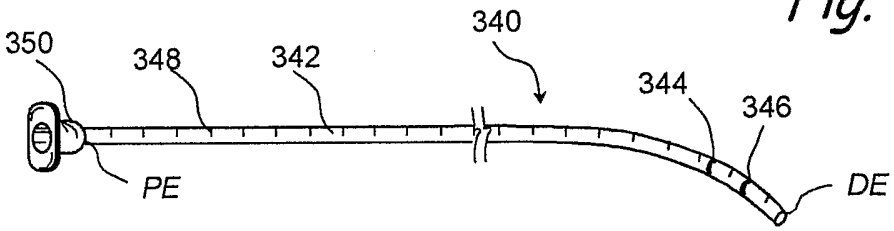


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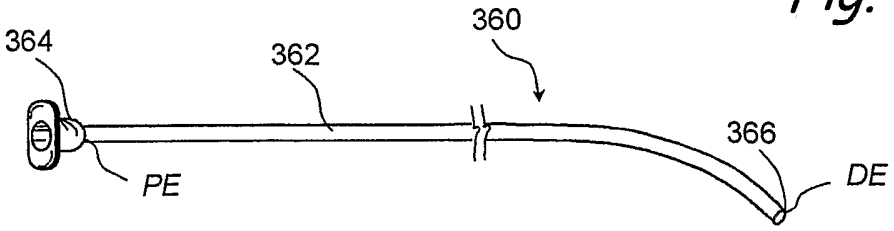


Fig. 3 D

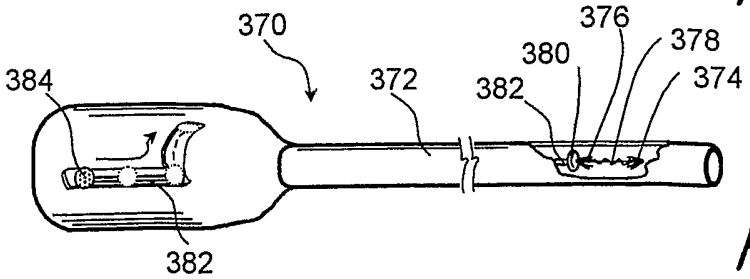


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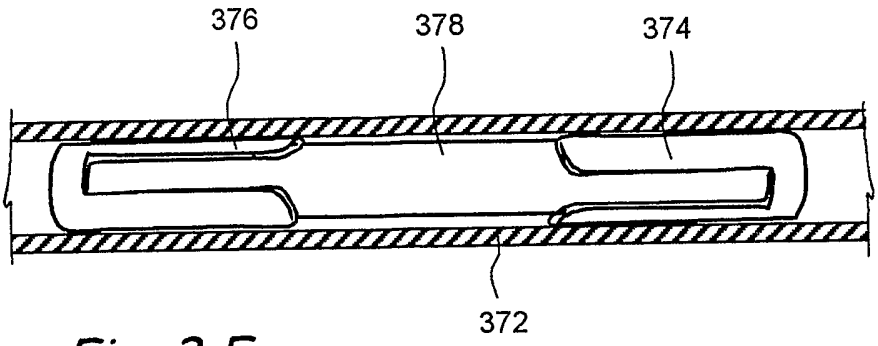


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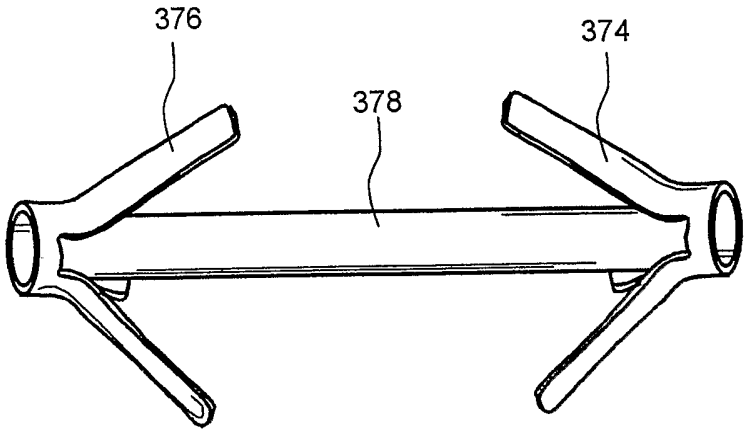


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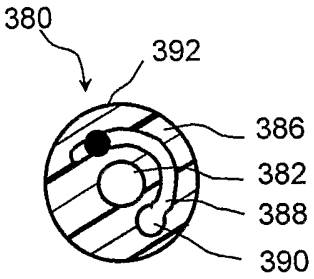


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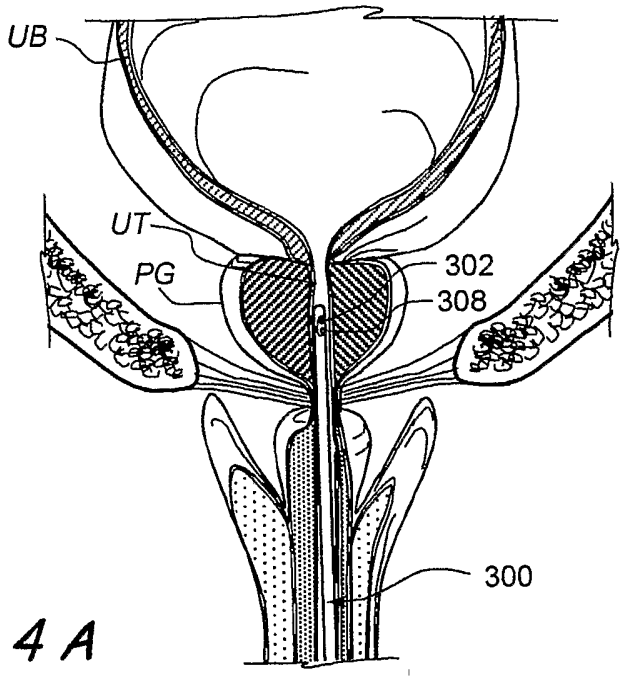


Fig. 4 A

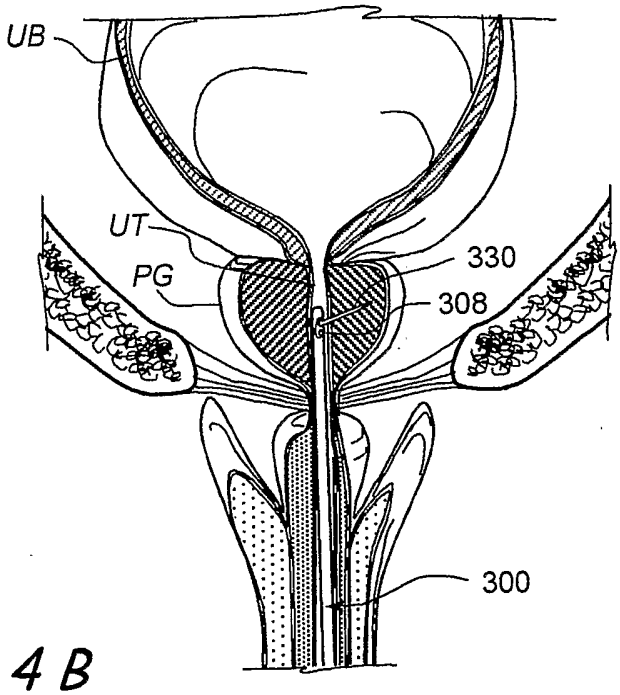


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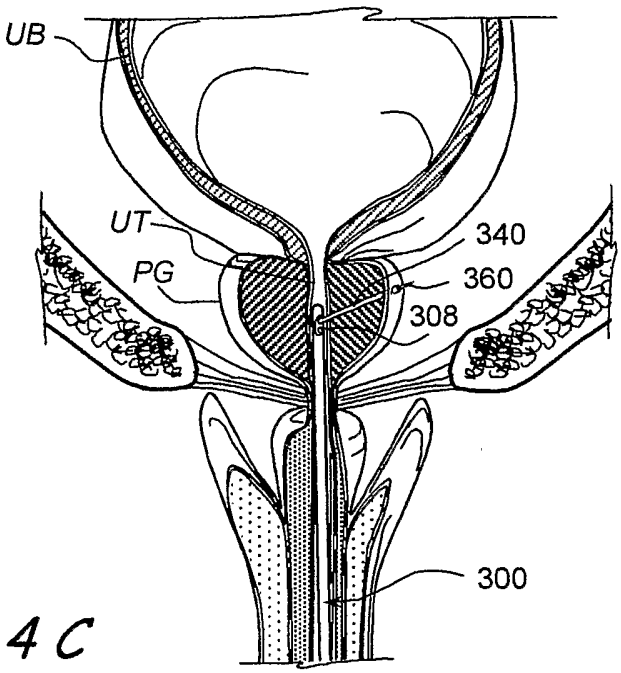


Fig. 4 C

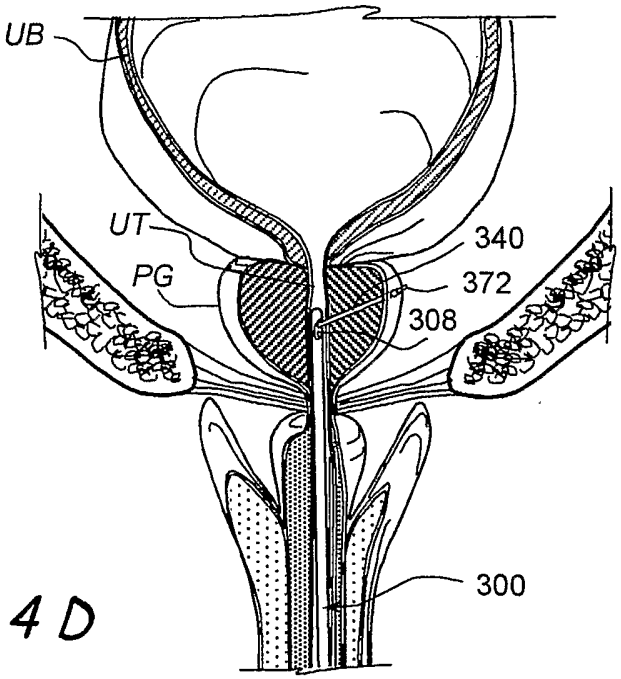


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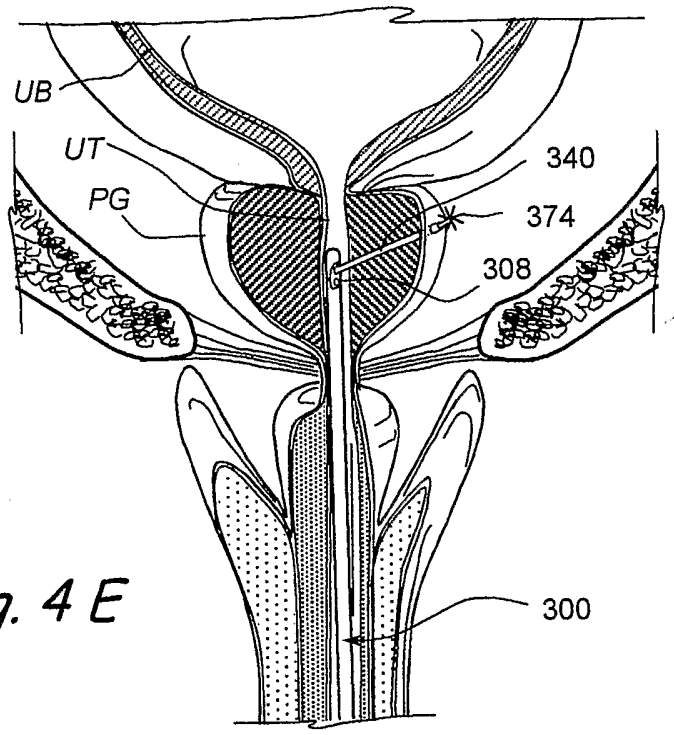


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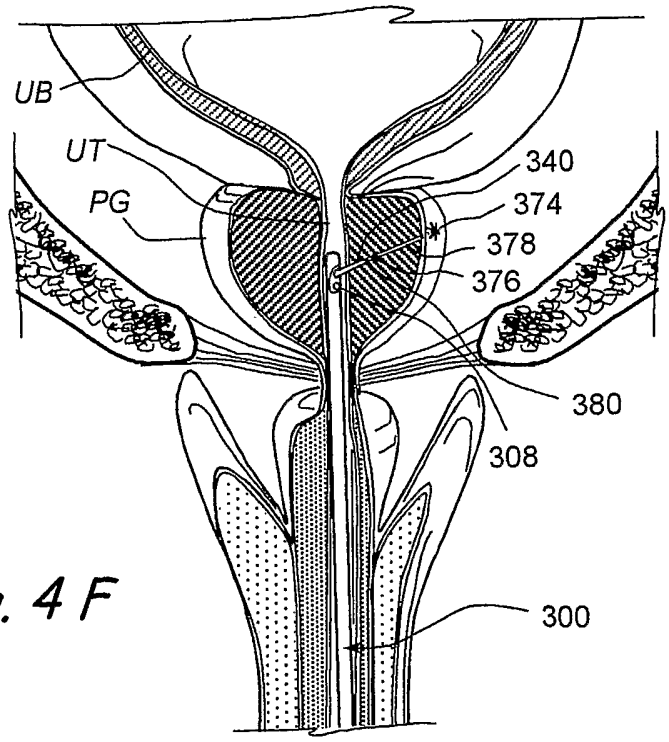


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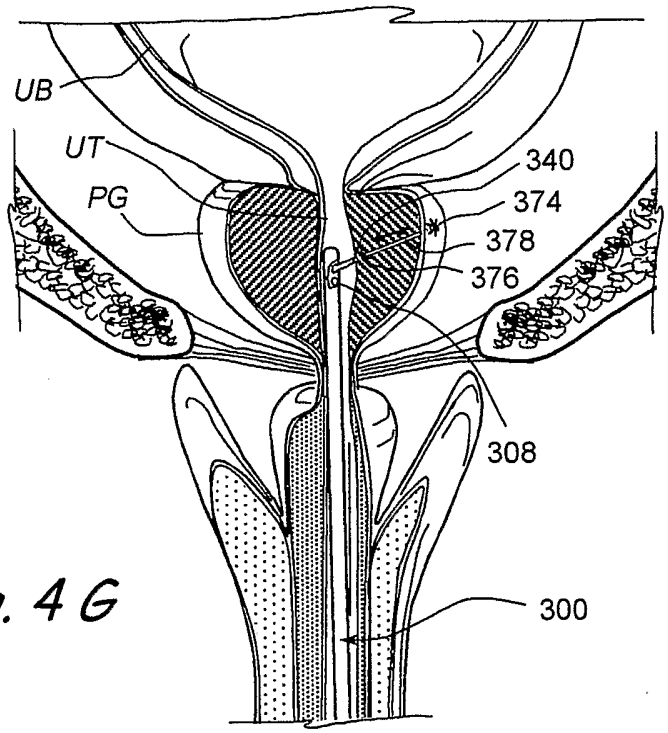


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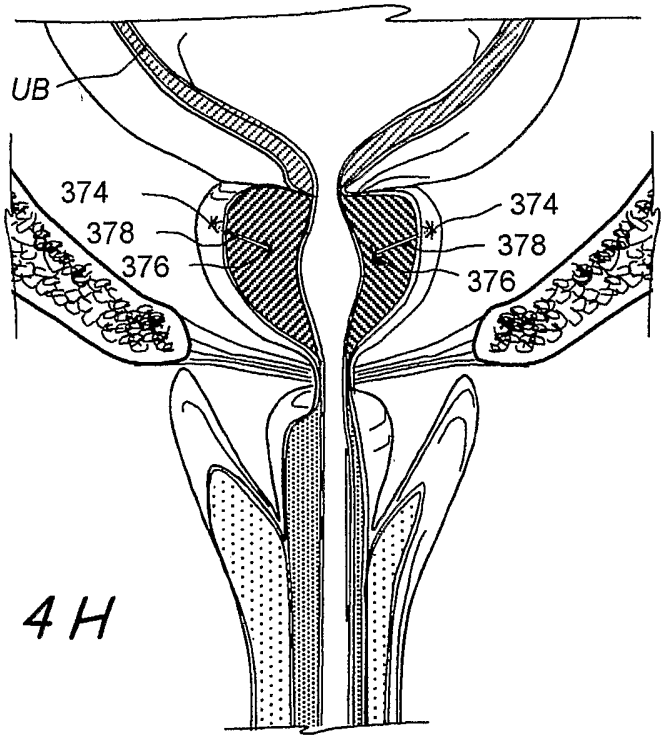


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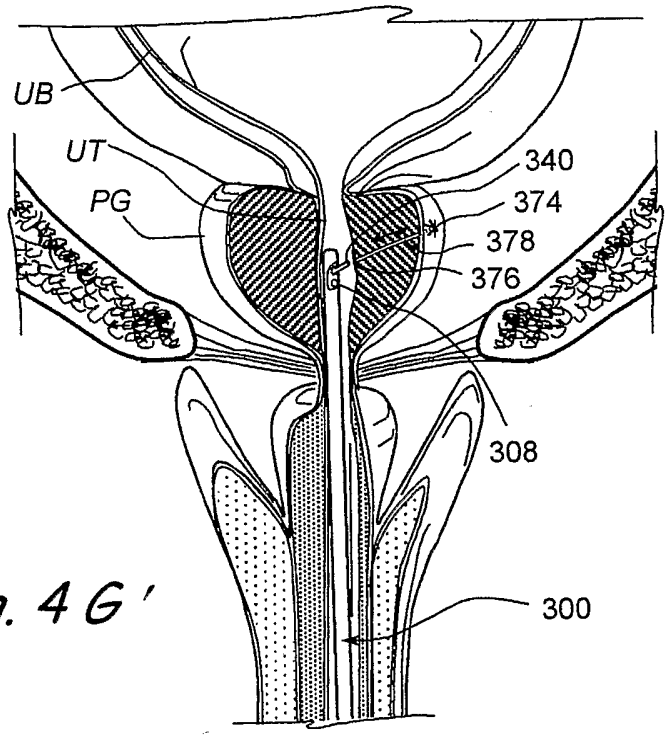


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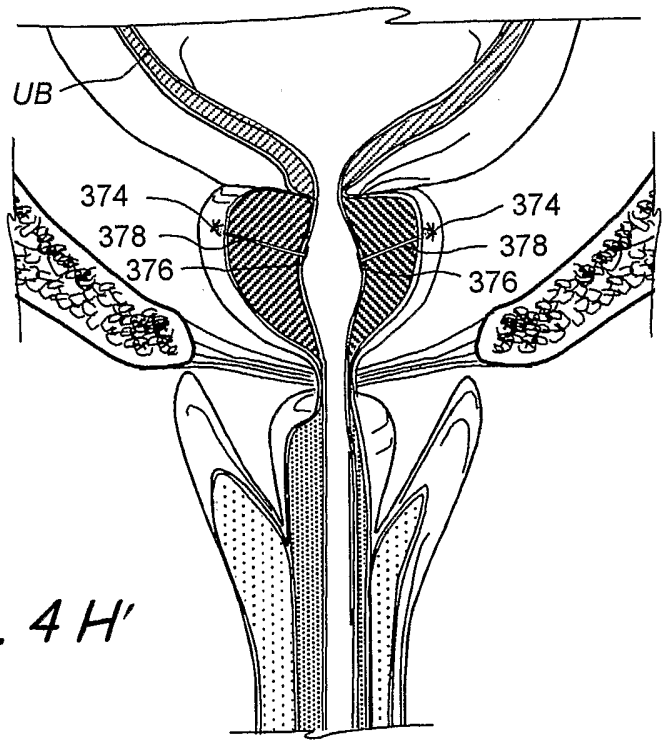


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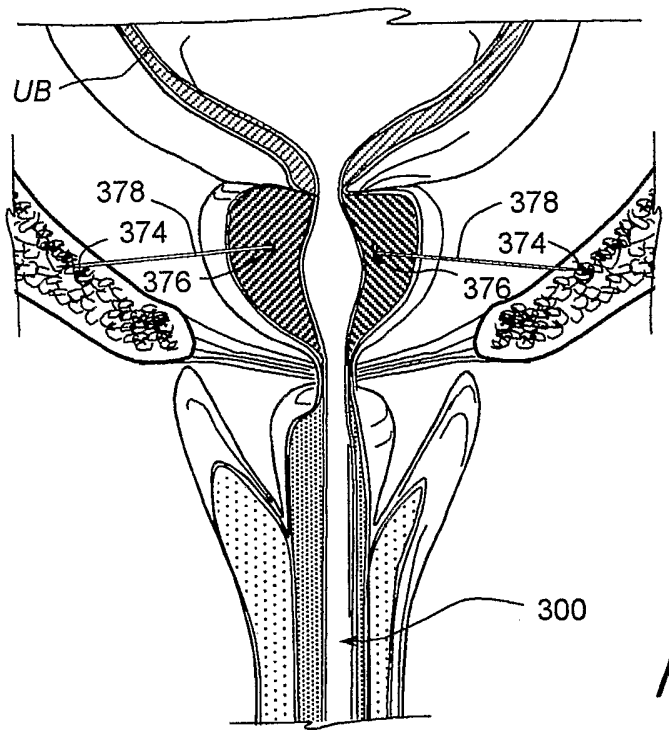


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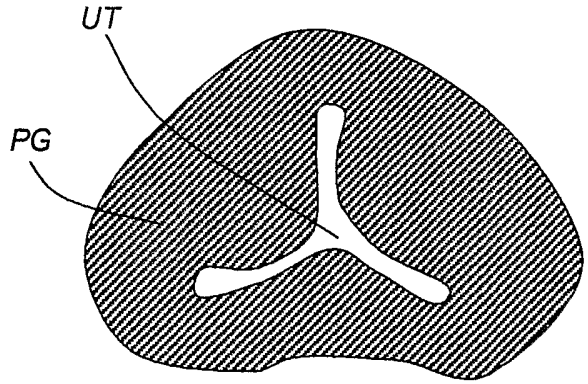


Fig. 4 I

PRIOR ART

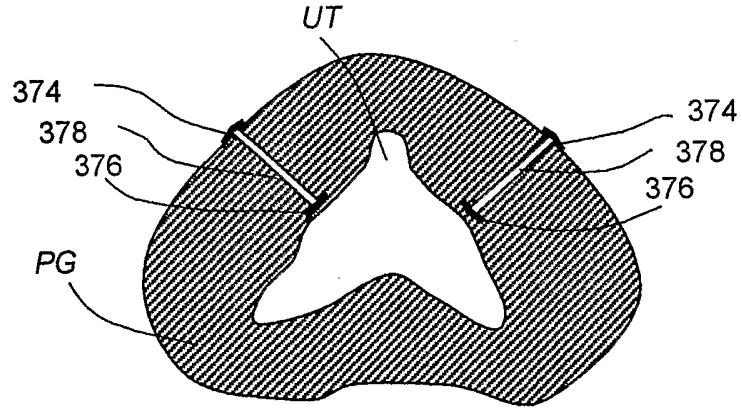


Fig. 4 J

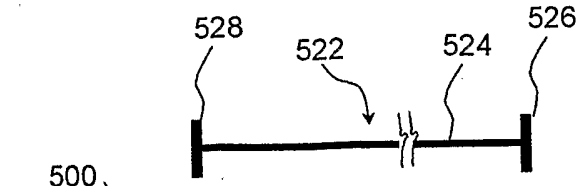


Fig. 5 G

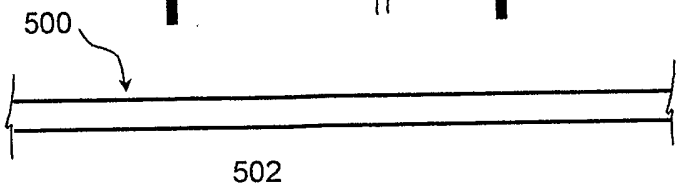


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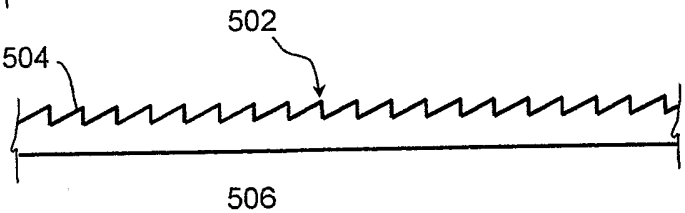


Fig. 5 B

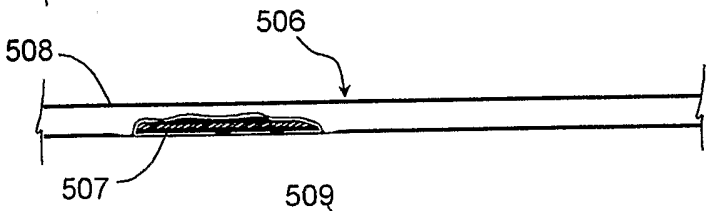


Fig. 5 C

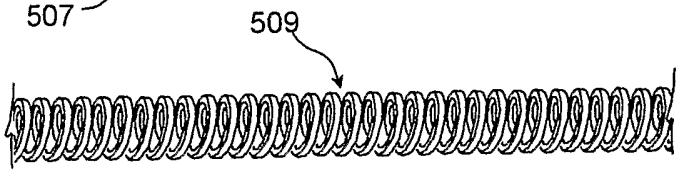


Fig. 5 D

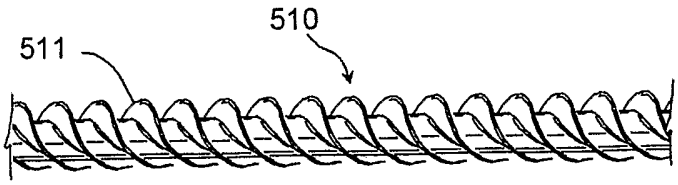


Fig. 5 E

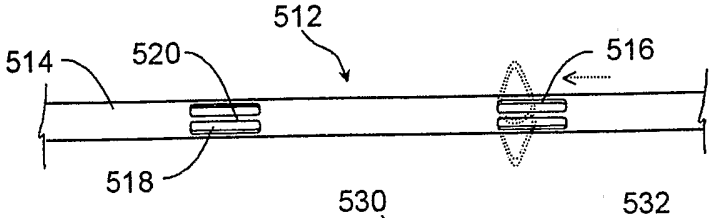


Fig. 5 F

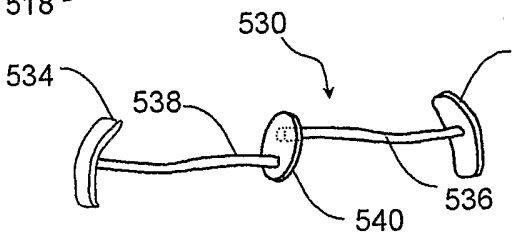


Fig. 5 H

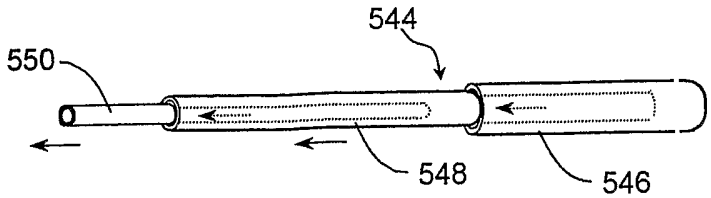


Fig. 5 I

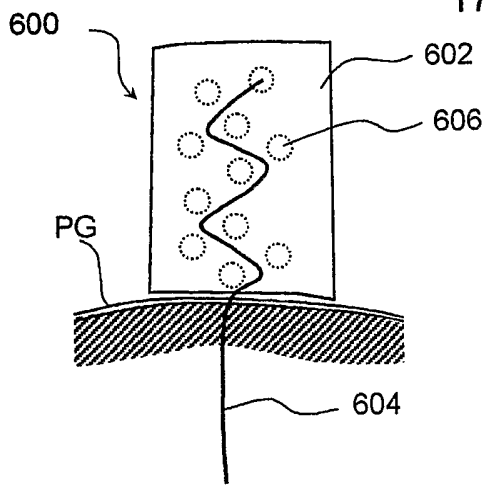


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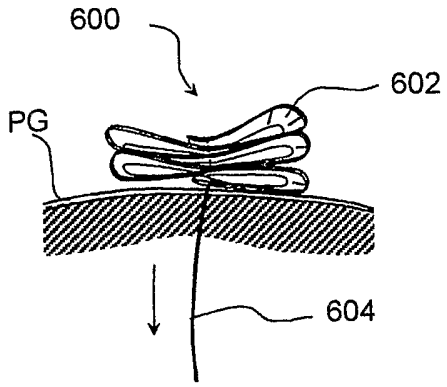


Fig. 6 B

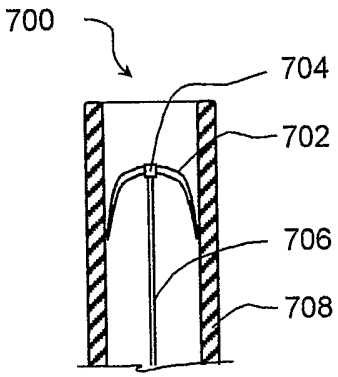


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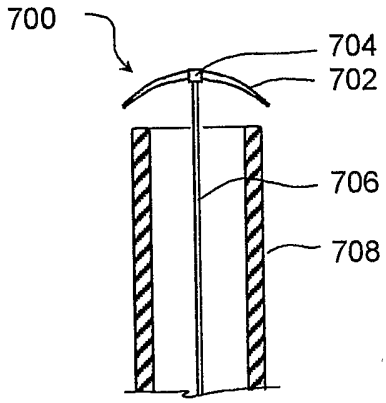


Fig. 7 B

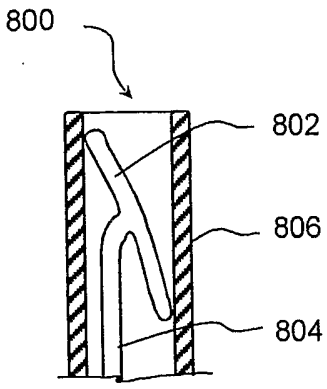


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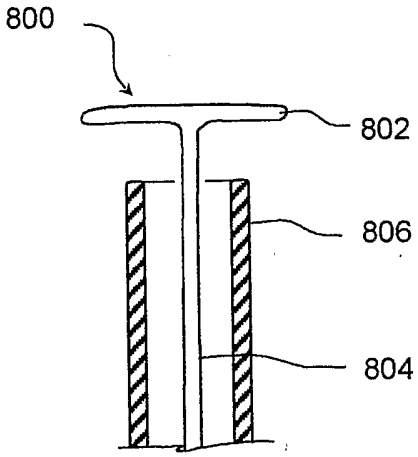


Fig. 8 B

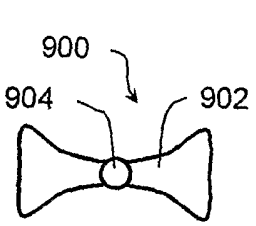


Fig. 9 A

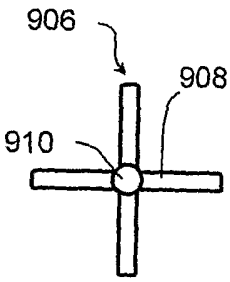


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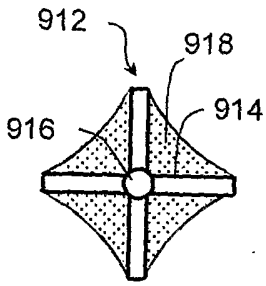


Fig. 9 C

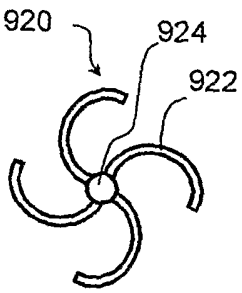


Fig. 9 D

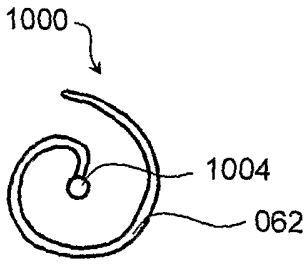


Fig. 10 A

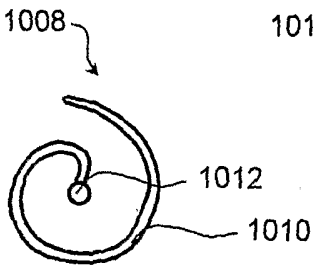


Fig. 10 B

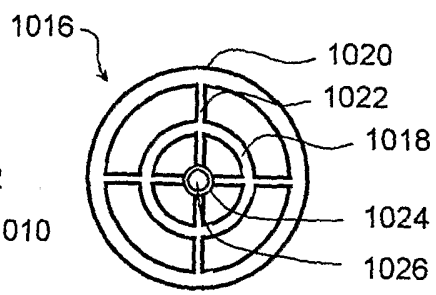


Fig. 10 C

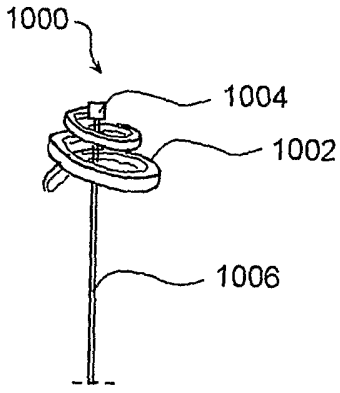


Fig. 10 A'

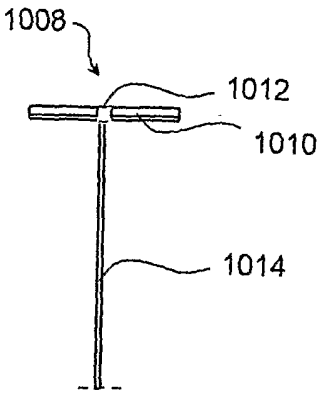


Fig. 10 B'

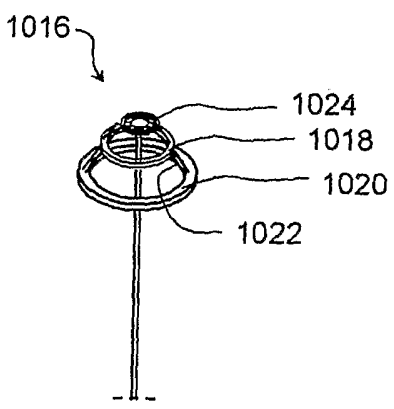


Fig. 10 C'

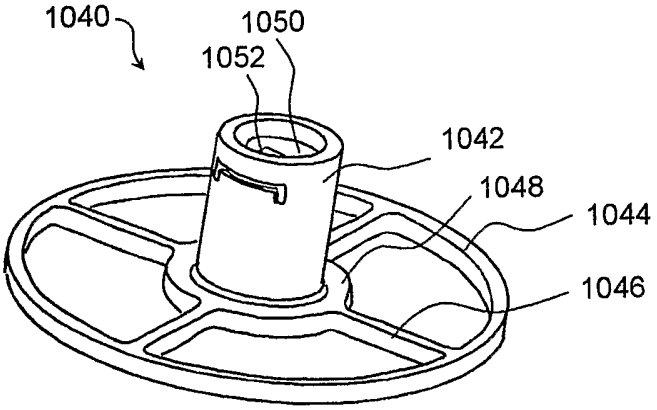


Fig. 10 D

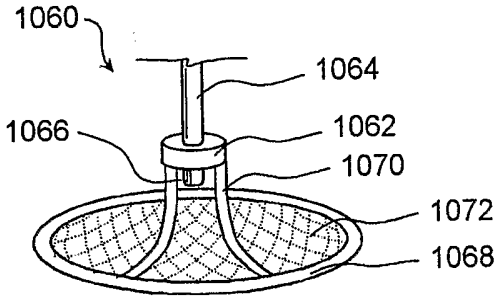


Fig. 10 E

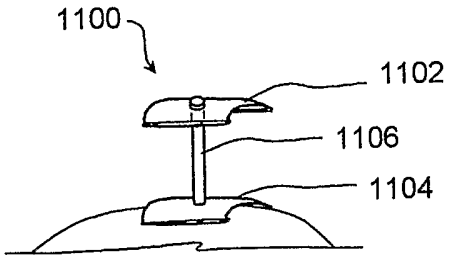


Fig. 11 A

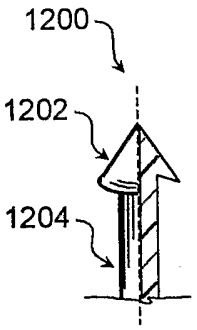


Fig. 12 A

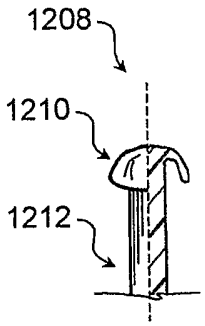


Fig. 12 B

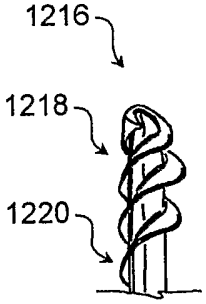


Fig. 12 C

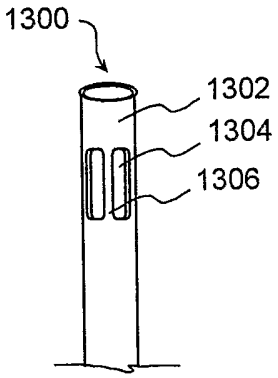


Fig. 13 A

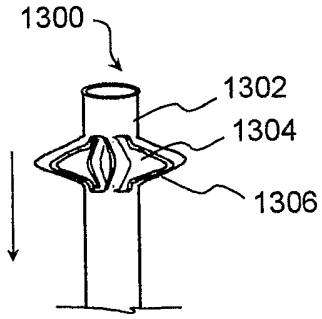


Fig. 13 B

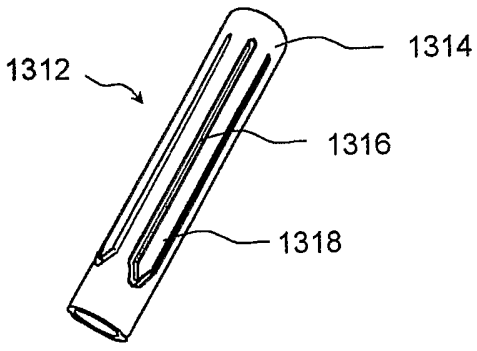


Fig. 13 C

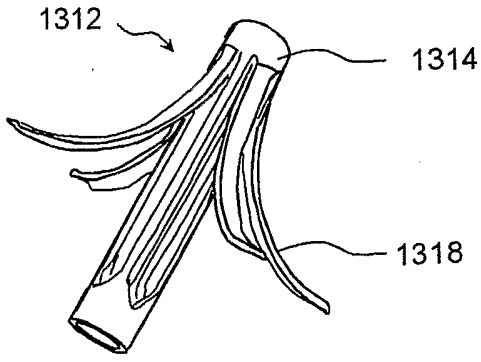


Fig. 13 D

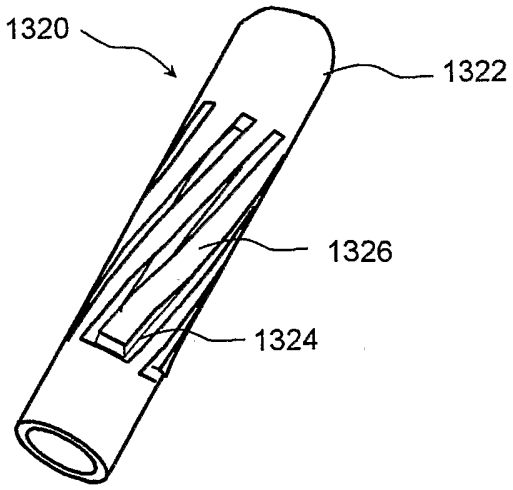


Fig. 13 E

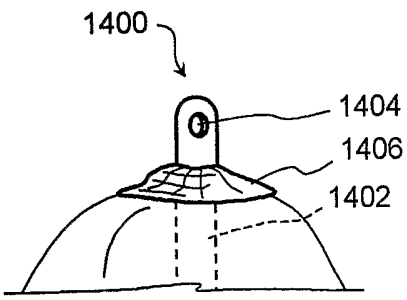


Fig. 14 A

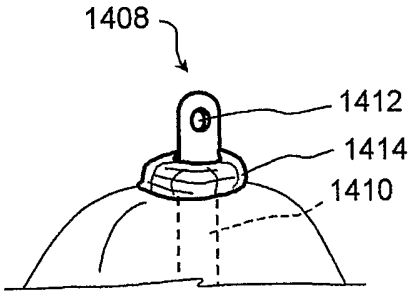


Fig. 14 B

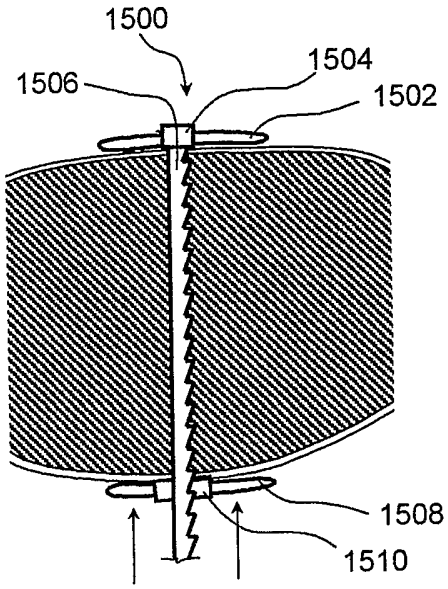


Fig. 15 A

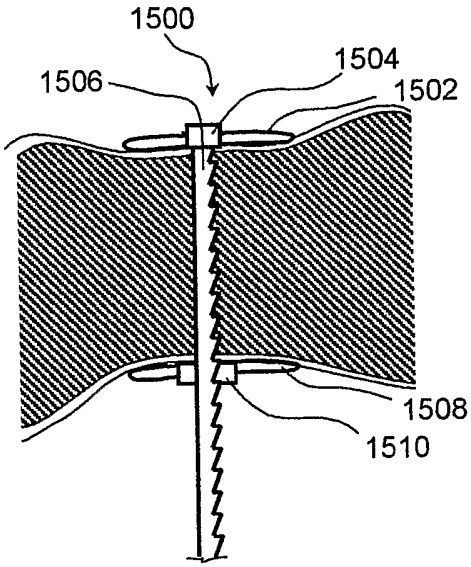


Fig. 15 B

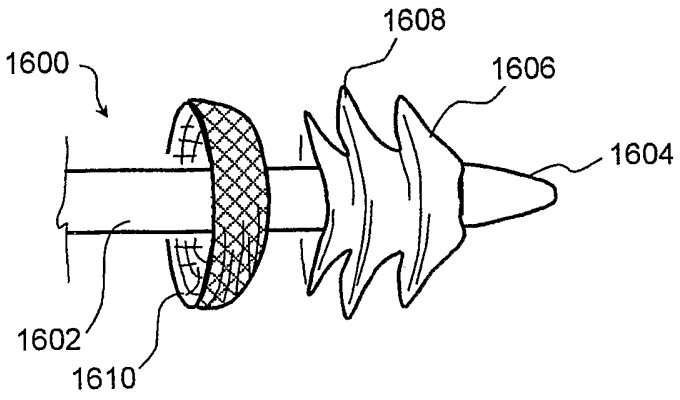


Fig. 16

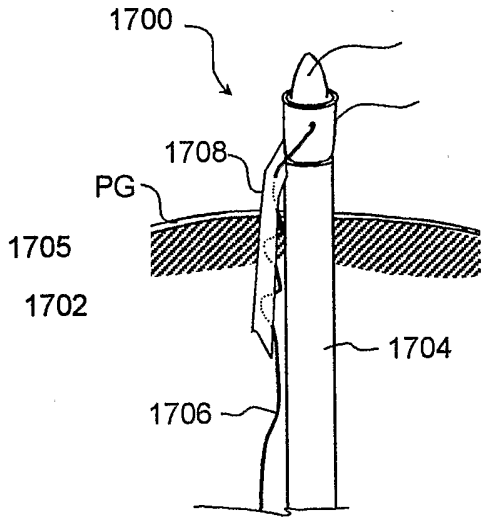


Fig. 17 A

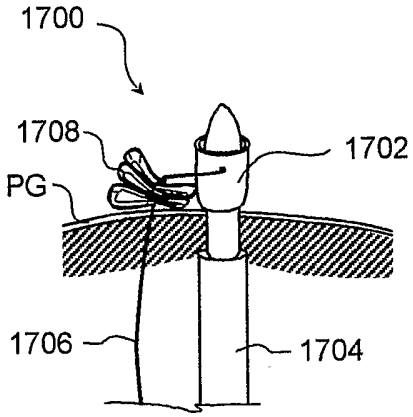


Fig. 17 B

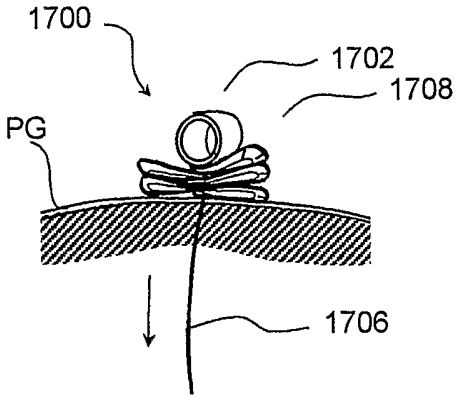


Fig. 17 C

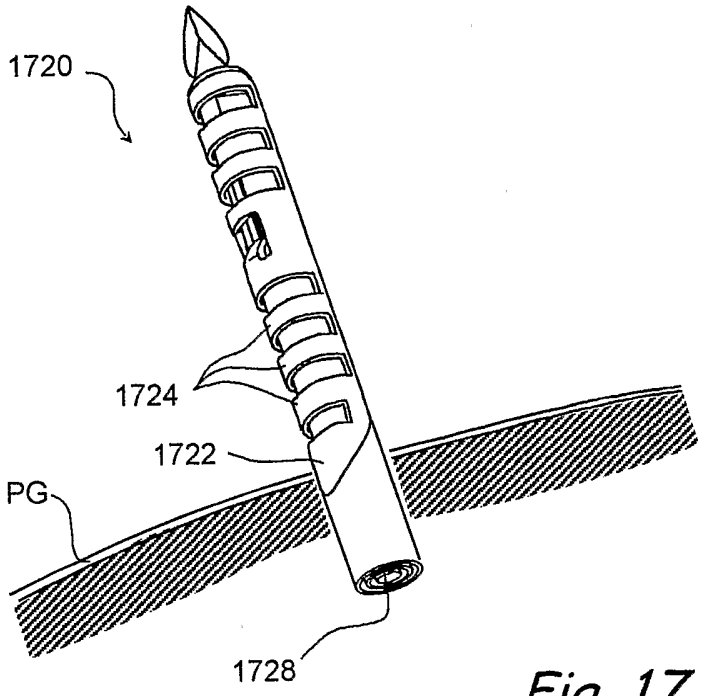


Fig. 17 D

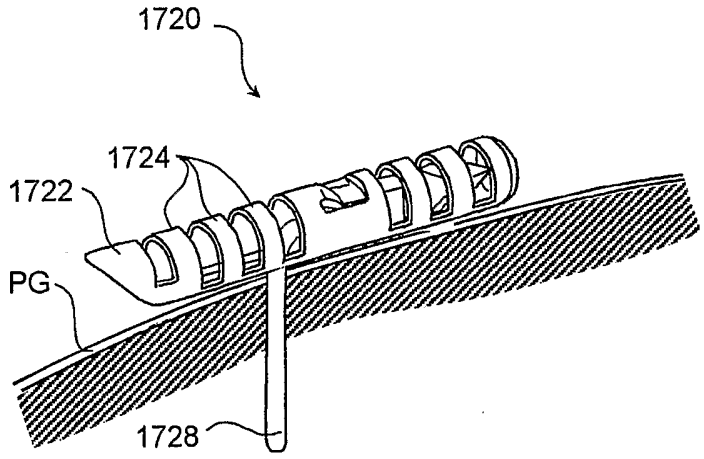


Fig. 17 E

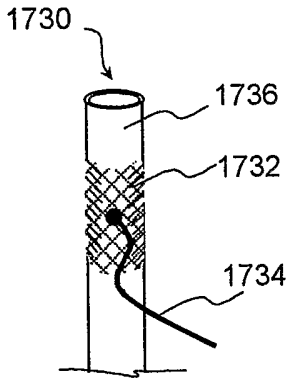


Fig. 17 F

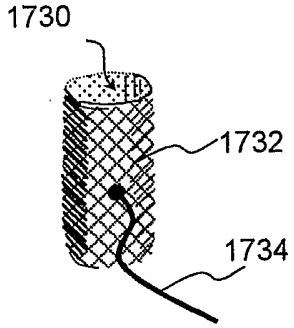


Fig. 17 G

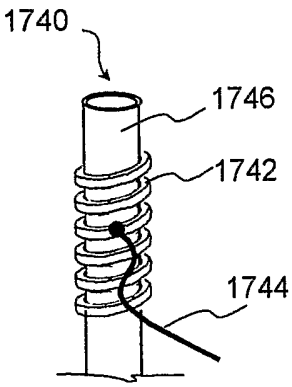


Fig. 17 H

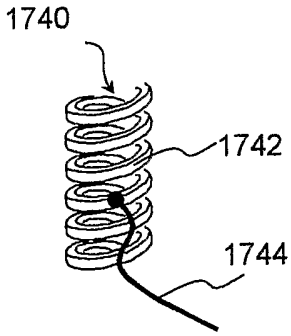


Fig. 17 I

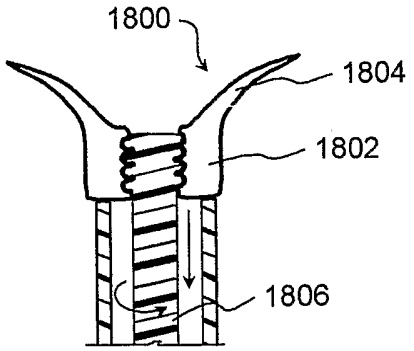


Fig. 18 A

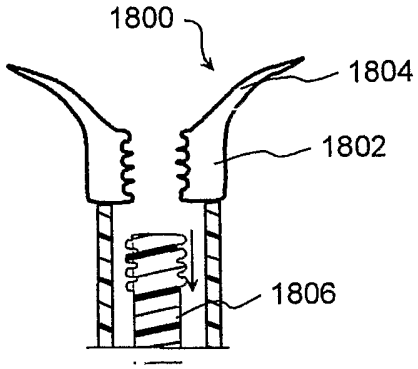


Fig. 18 B

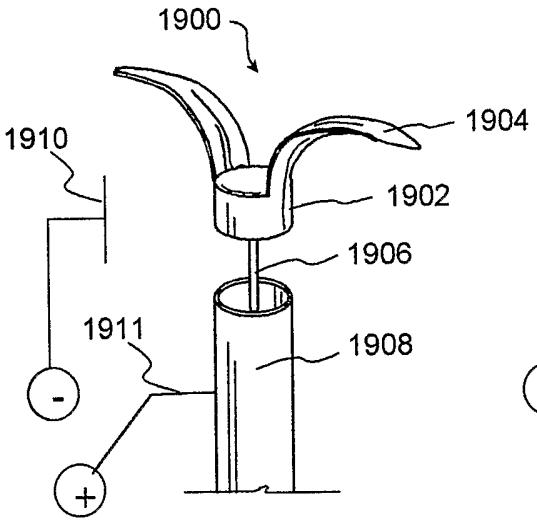


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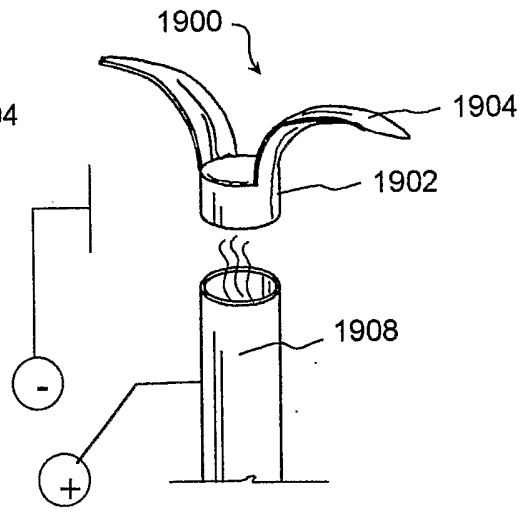


Fig. 19 B

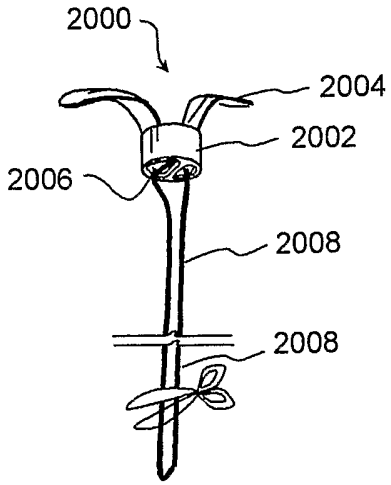


Fig. 20

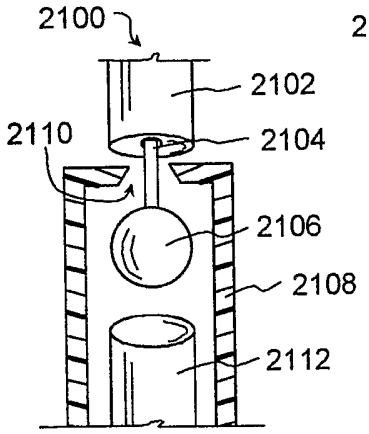


Fig. 21 A

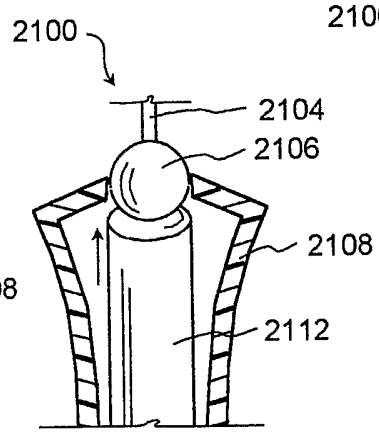


Fig. 21 B

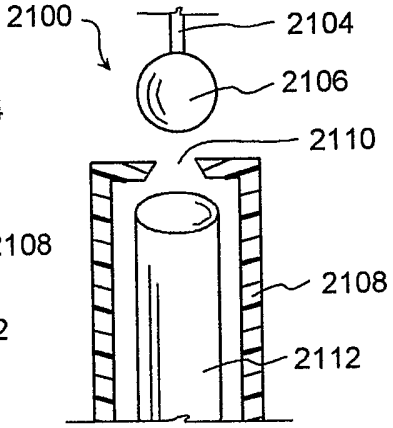


Fig. 21 C

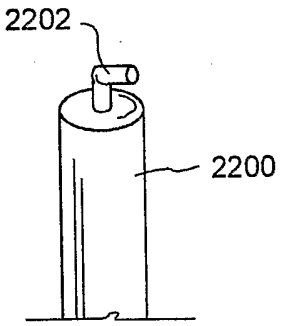


Fig. 22 A

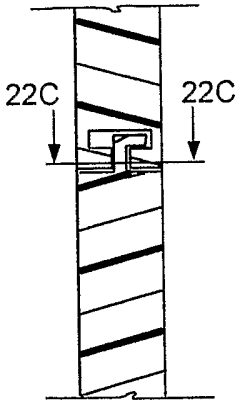


Fig. 22 B

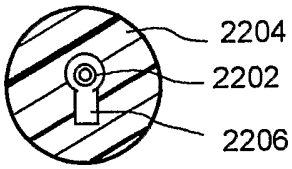


Fig. 22 C

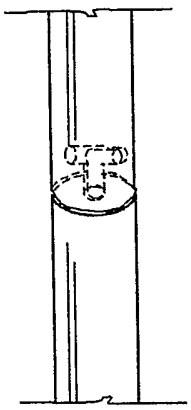


Fig. 22 D

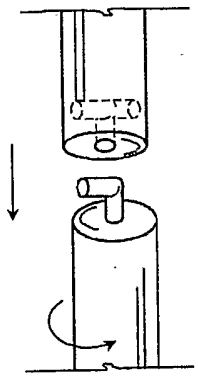


Fig. 22 E

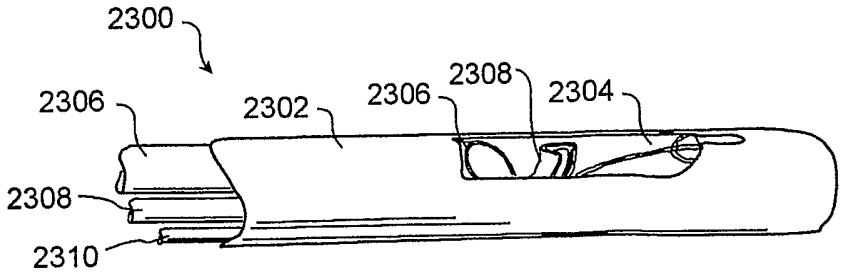


Fig. 23 A

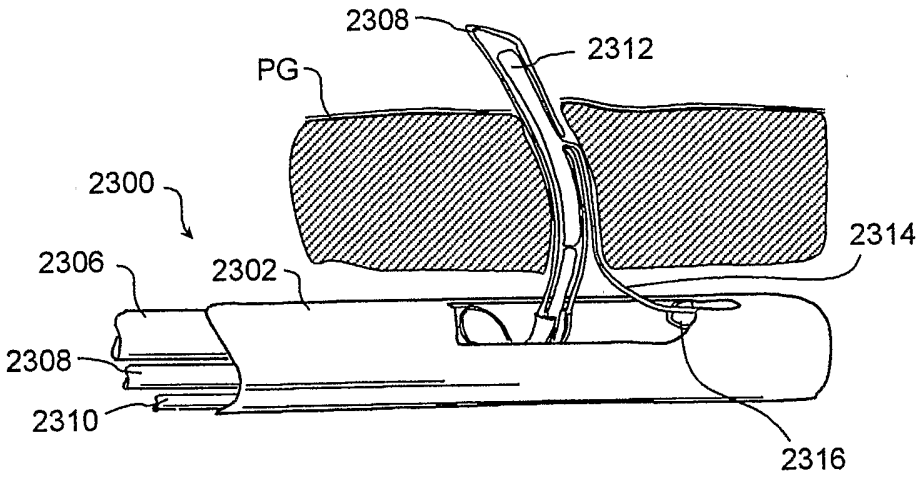


Fig. 23 B

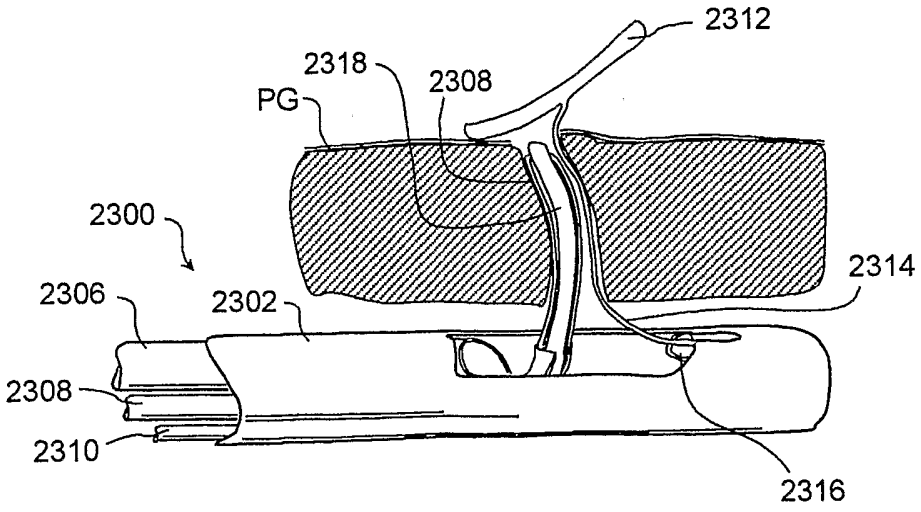


Fig. 23 C

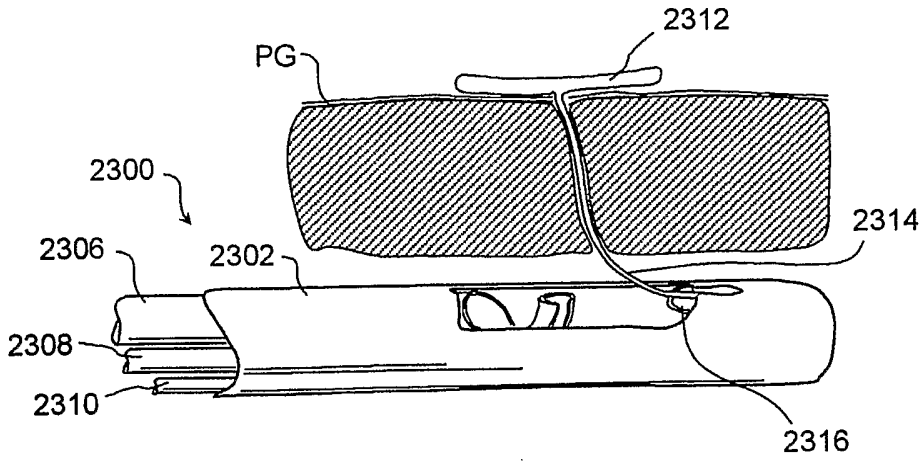


Fig. 23 D

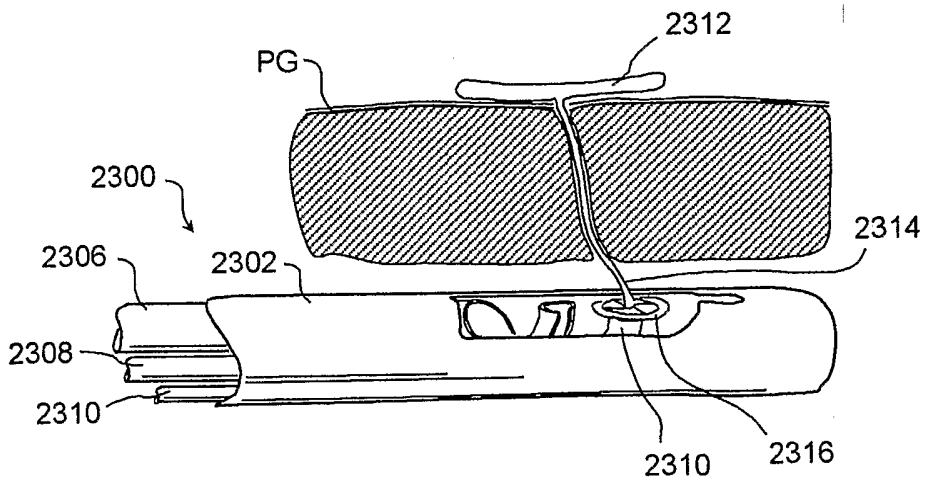


Fig. 23 E

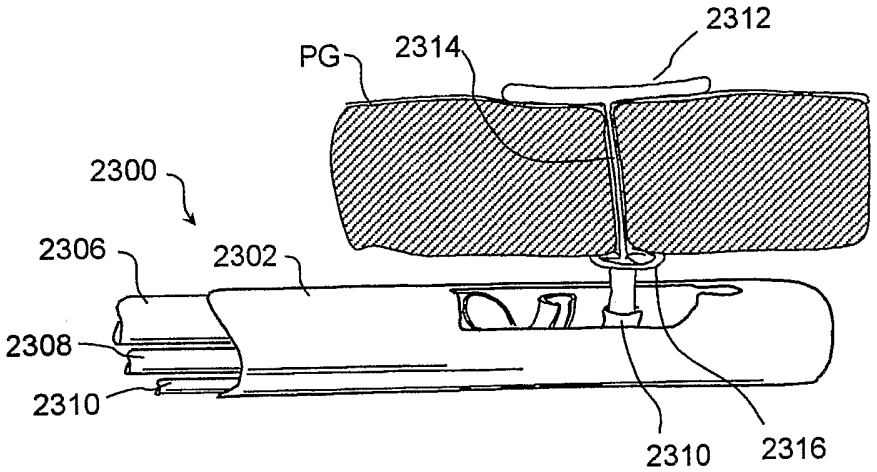


Fig. 23 F

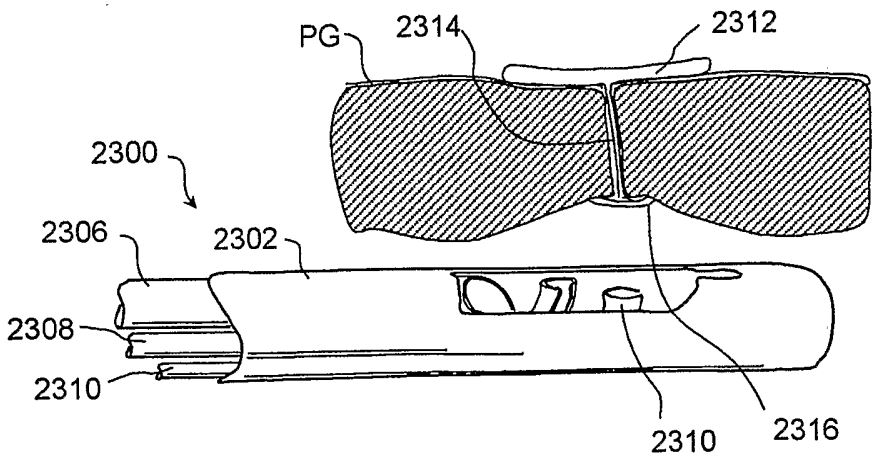


Fig. 23 G

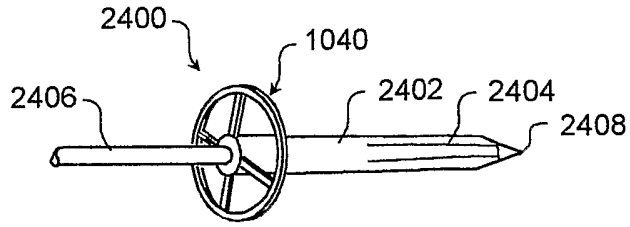


Fig. 24 A

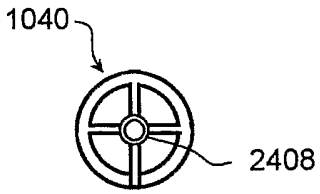


Fig. 24 A'

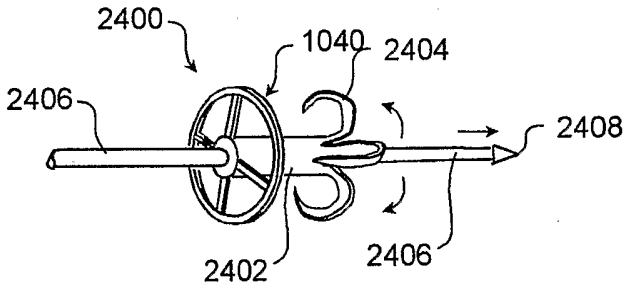


Fig. 24 B

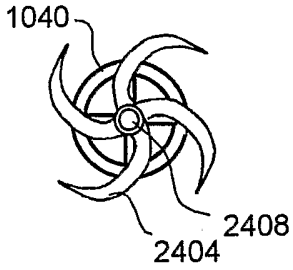


Fig. 24 B'

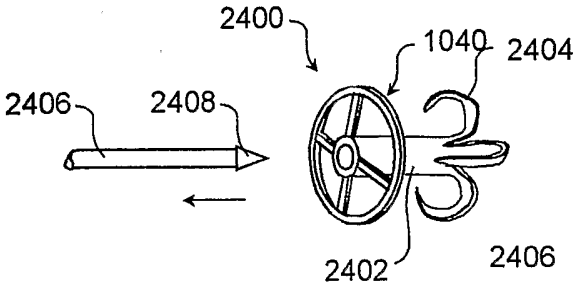


Fig. 24 C

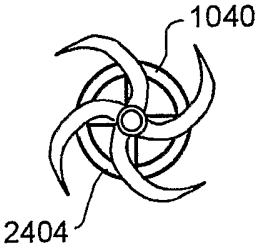


Fig. 24 C'

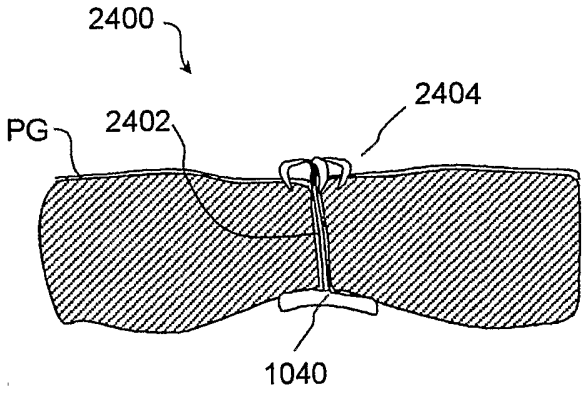


Fig. 24 D

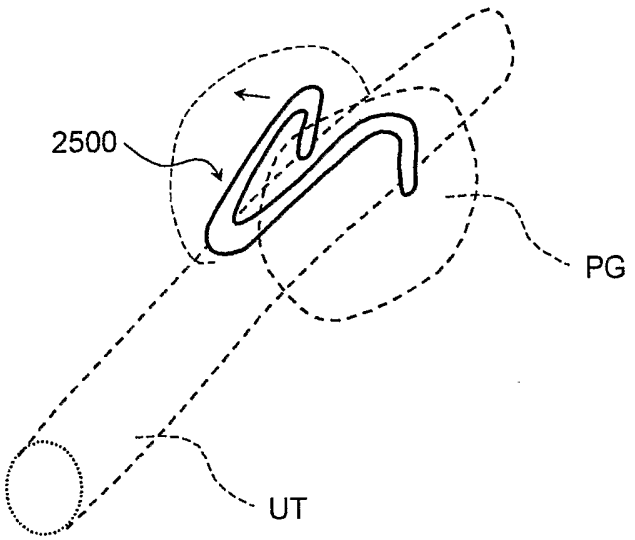


Fig. 25 F

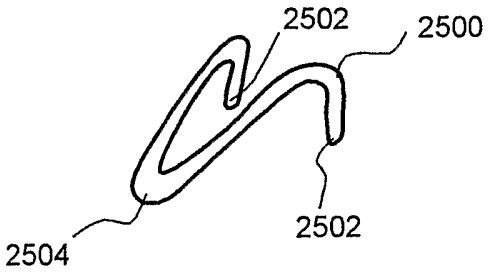


Fig. 25 A

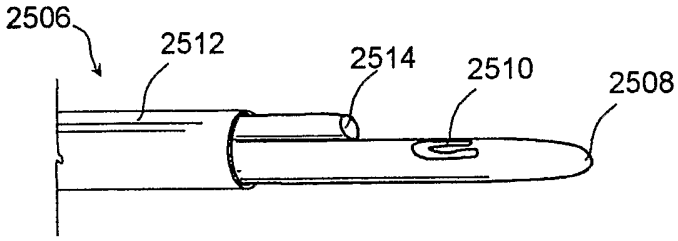


Fig. 25 B

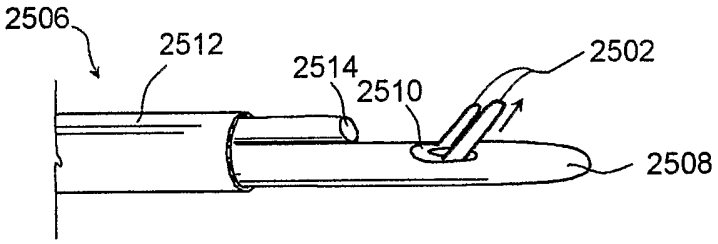


Fig. 25 C

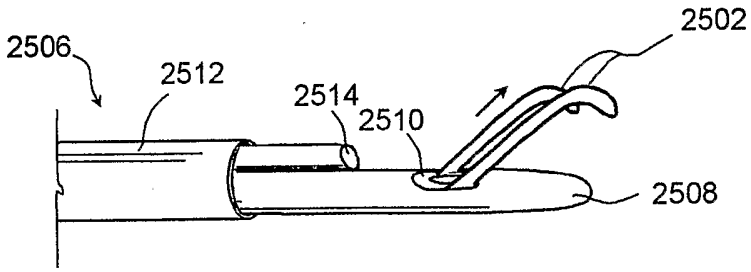


Fig. 25 D

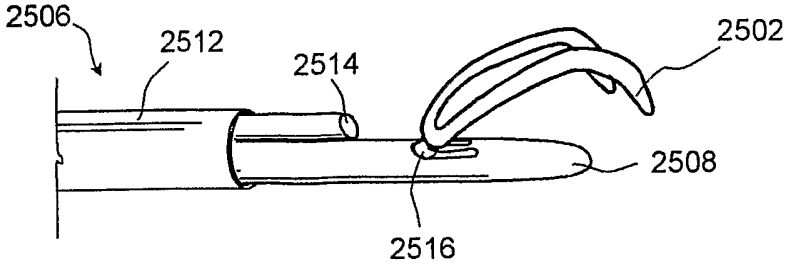


Fig. 25 E

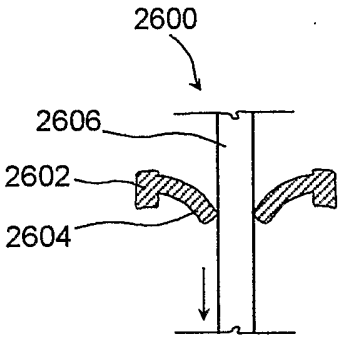


Fig. 26 A

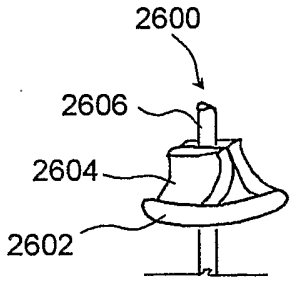


Fig. 26 B

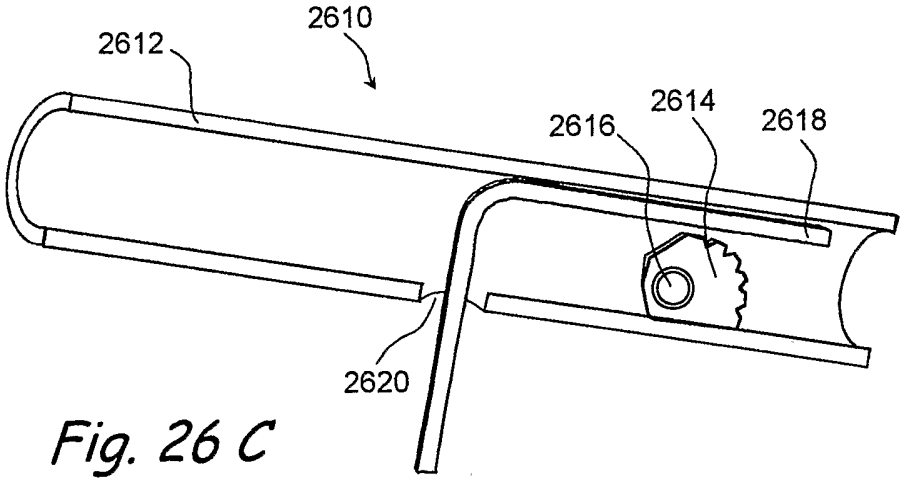


Fig. 26 C

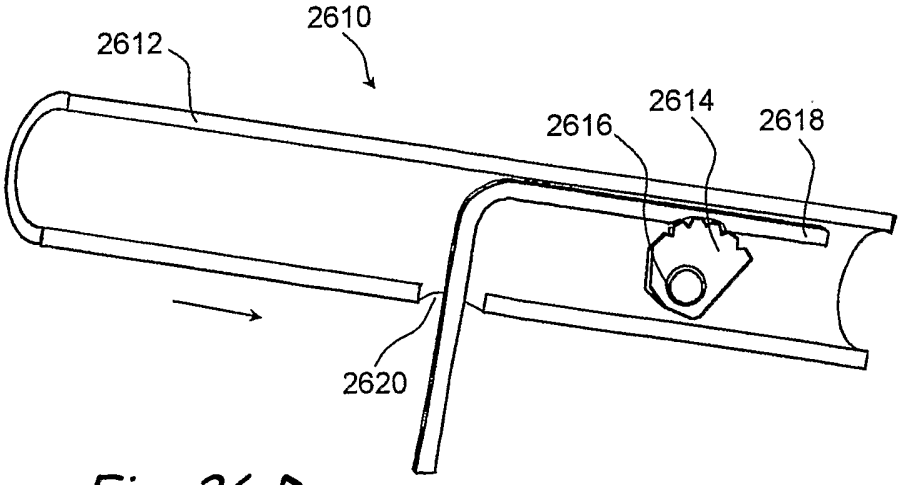


Fig. 26 D

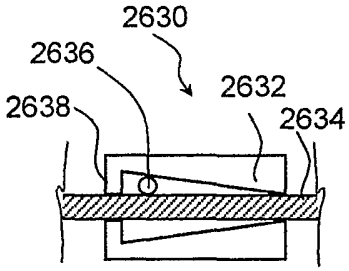
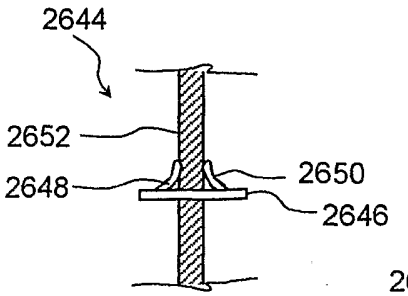


Fig. 26 E



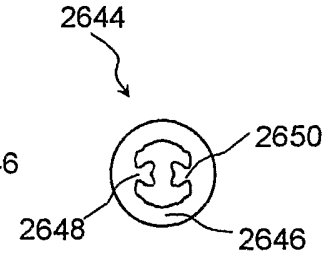


Fig. 26 G

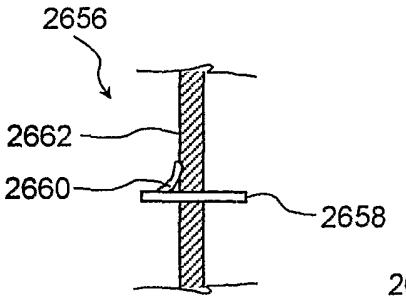


Fig. 26 H

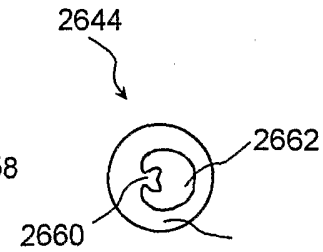


Fig. 26 I

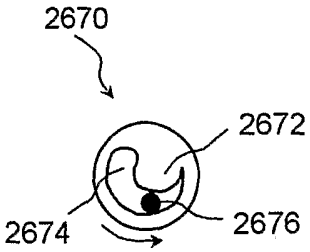


Fig. 26 I

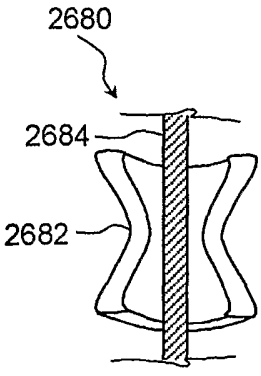


Fig. 26 K

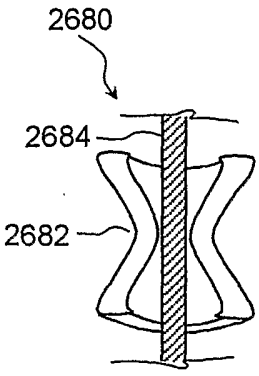


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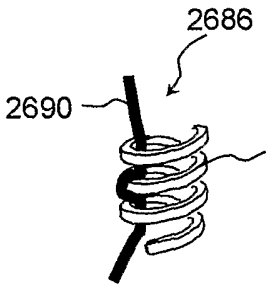


Fig. 26 M

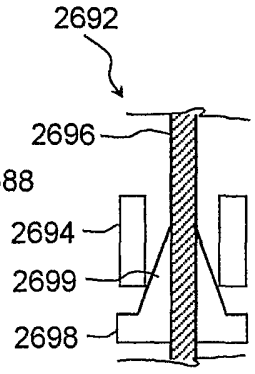


Fig. 26 N

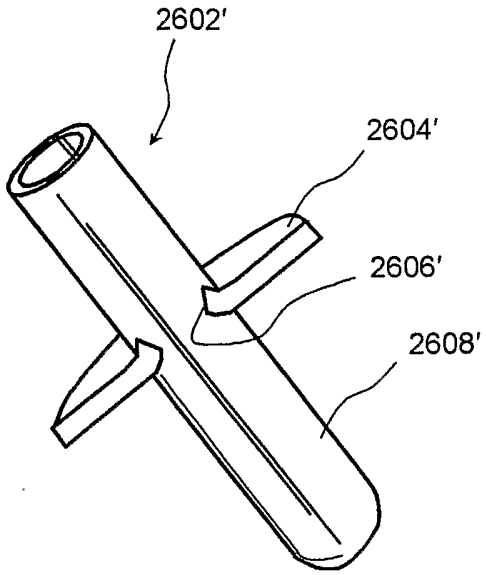


Fig. 26 O

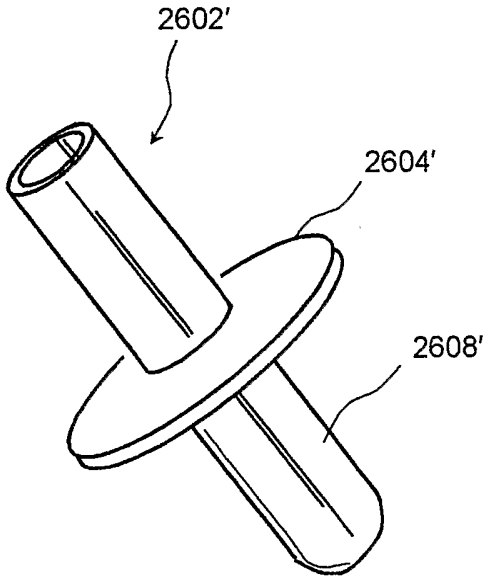


Fig. 26 P

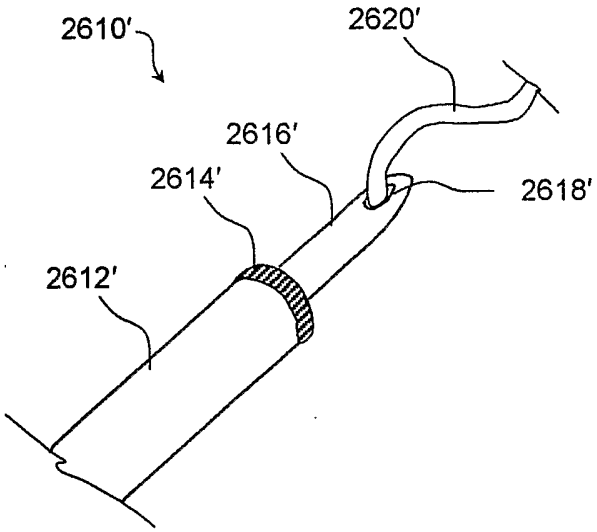


Fig. 26 Q

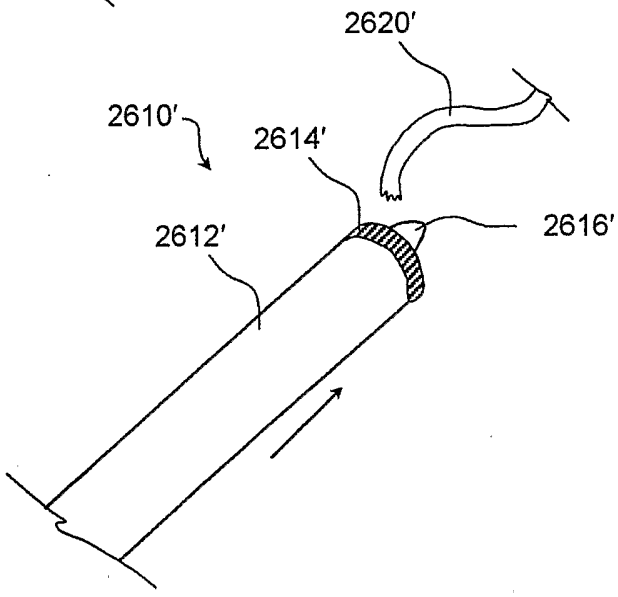


Fig. 26 R

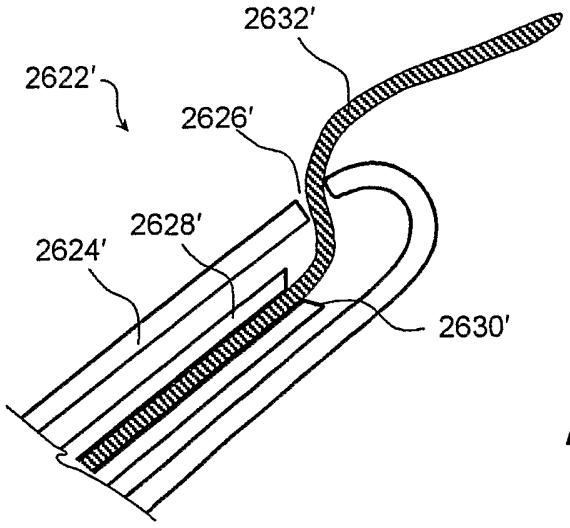


Fig. 26 S

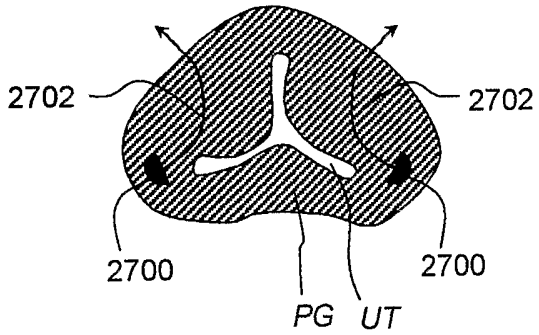


Fig. 27 A

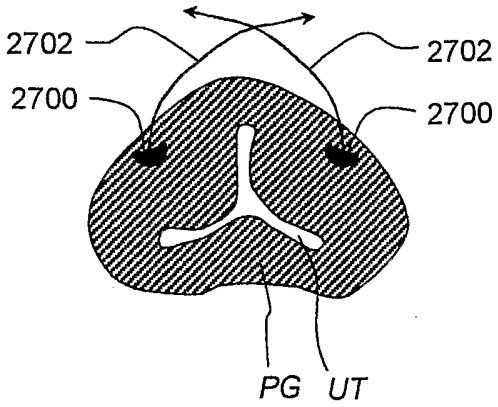


Fig. 27 B

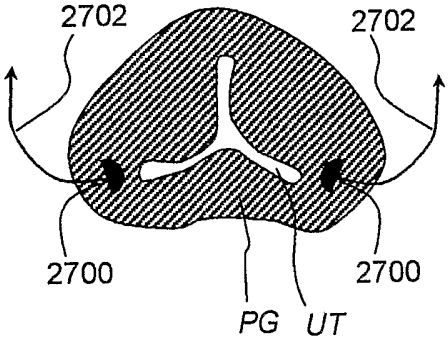


Fig. 27 C

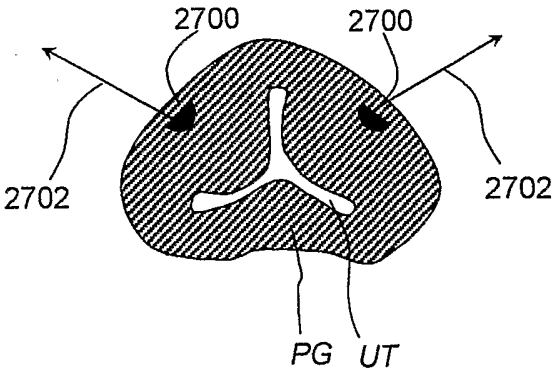


Fig. 27 D

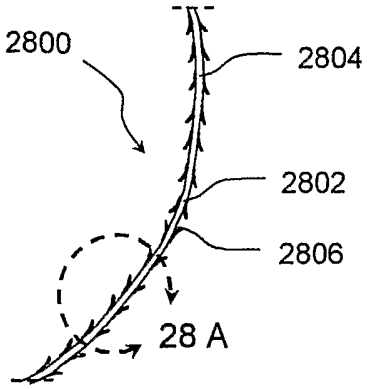


Fig. 28

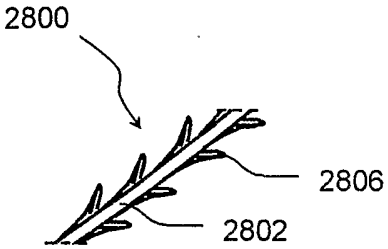


Fig. 28 A

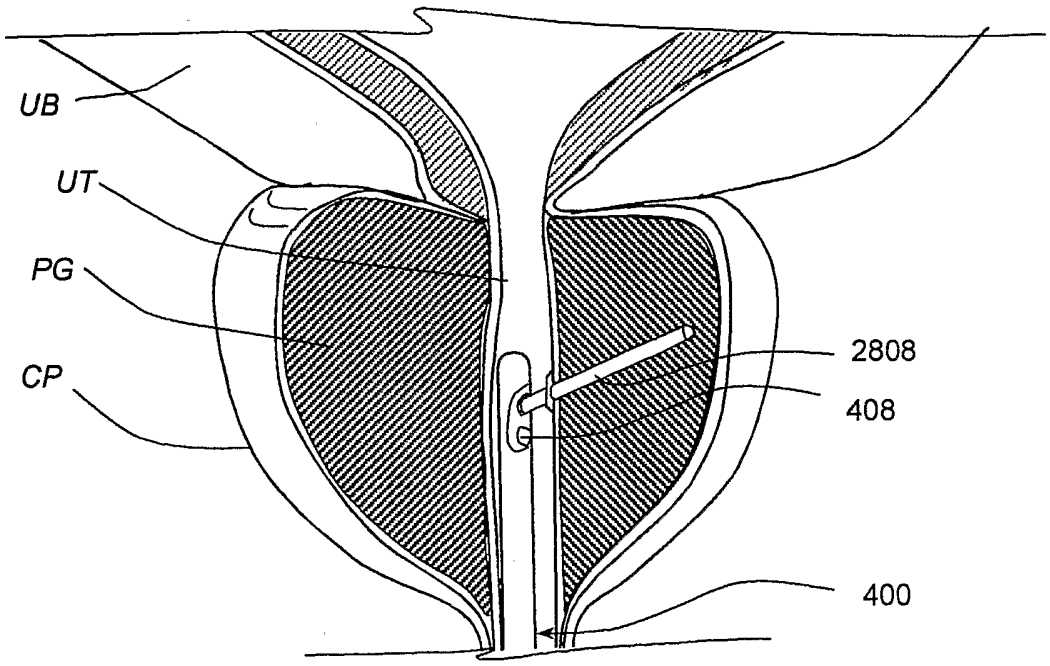


Fig. 28 B

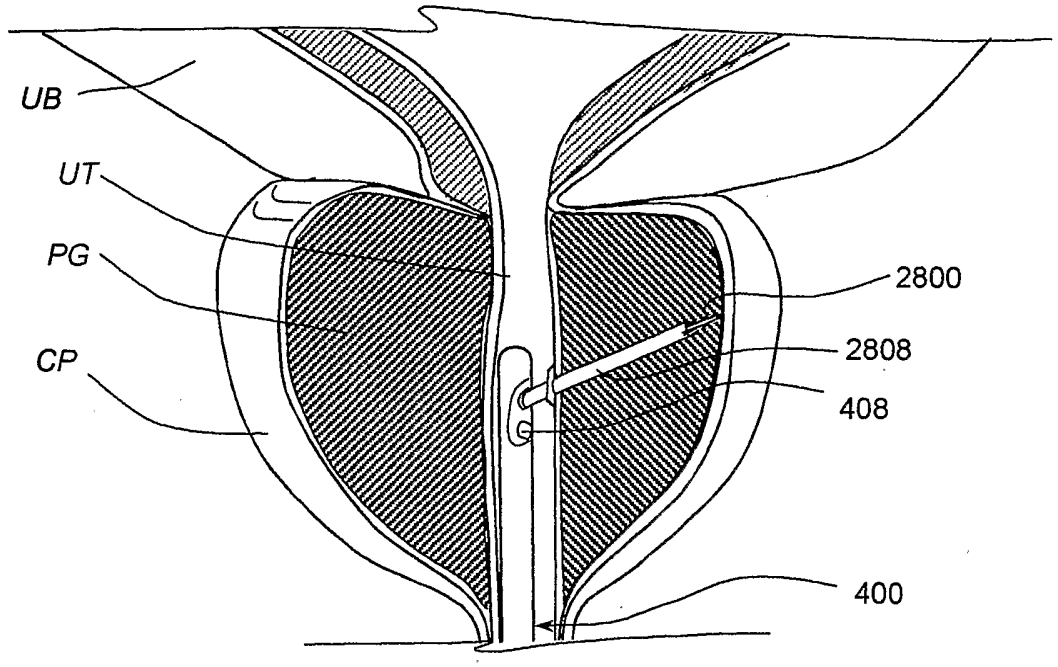


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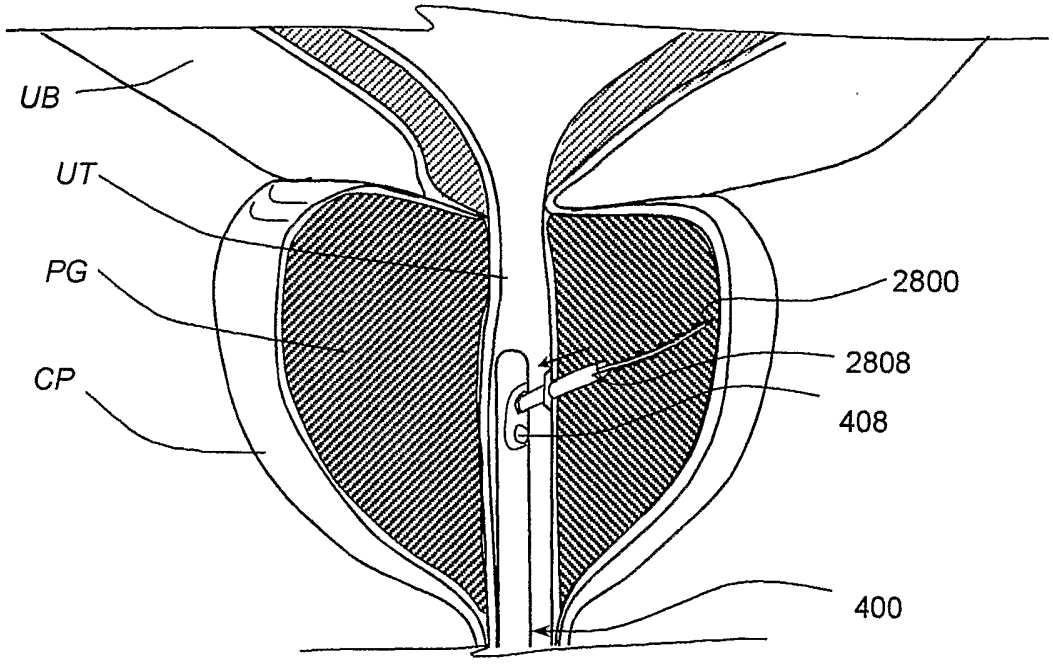


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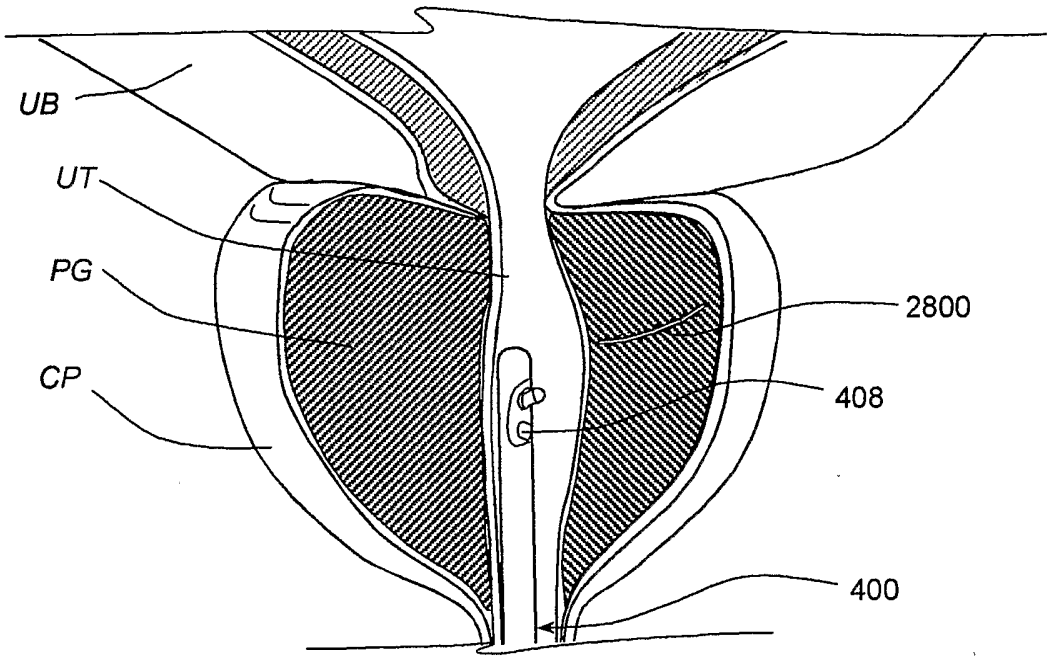


Fig. 28 E

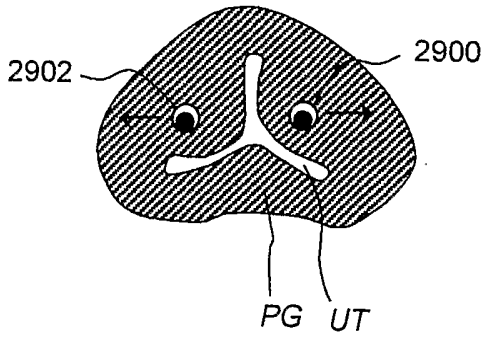


Fig. 29 A

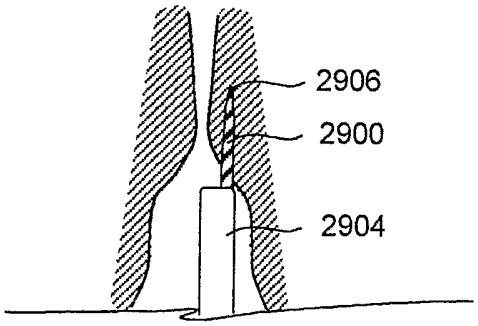


Fig. 29 B

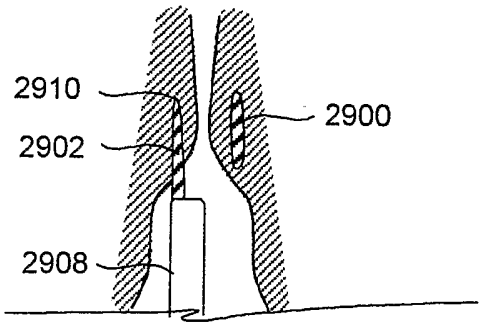


Fig. 29 C

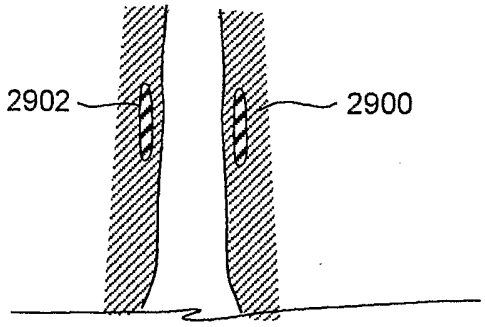


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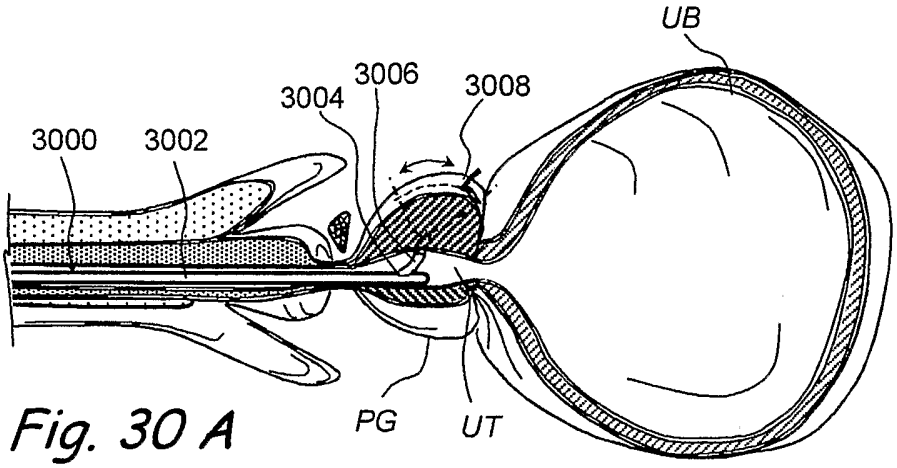


Fig. 30 A

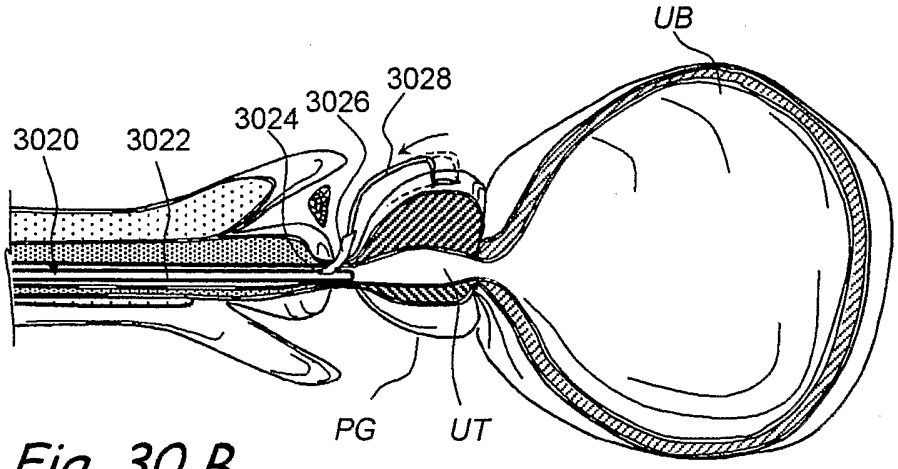


Fig. 30 B

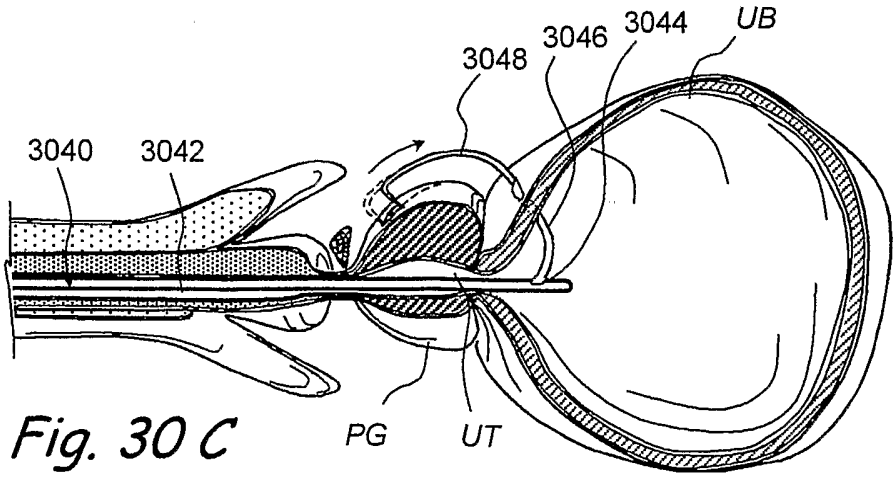


Fig. 30 C

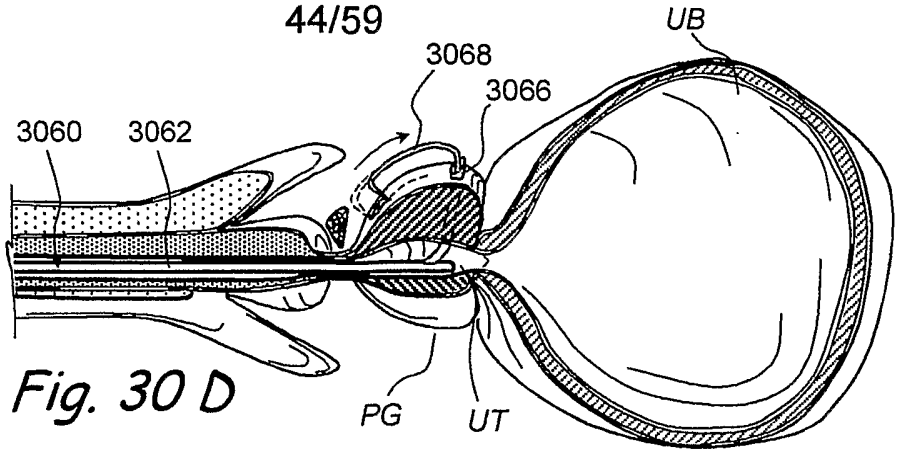


Fig. 30 D

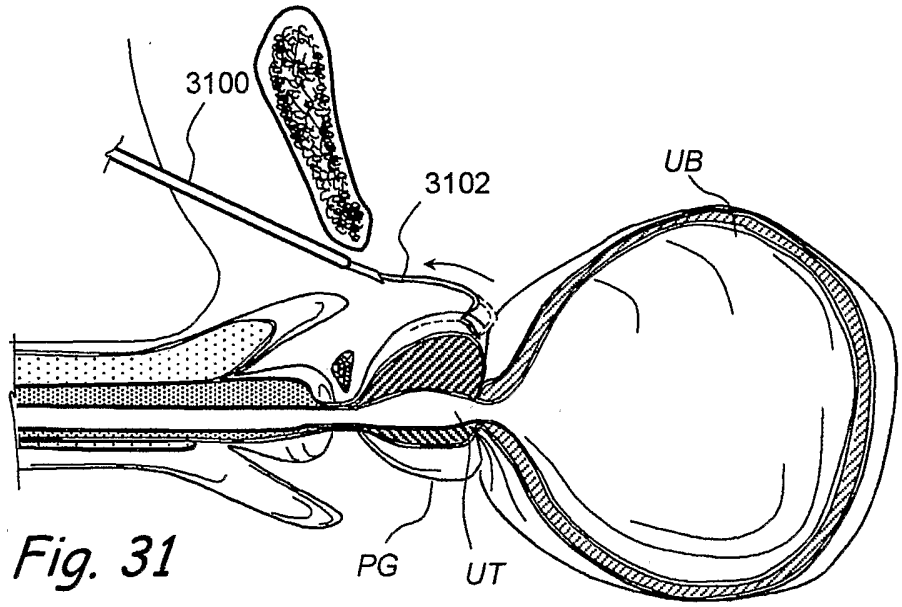


Fig. 31

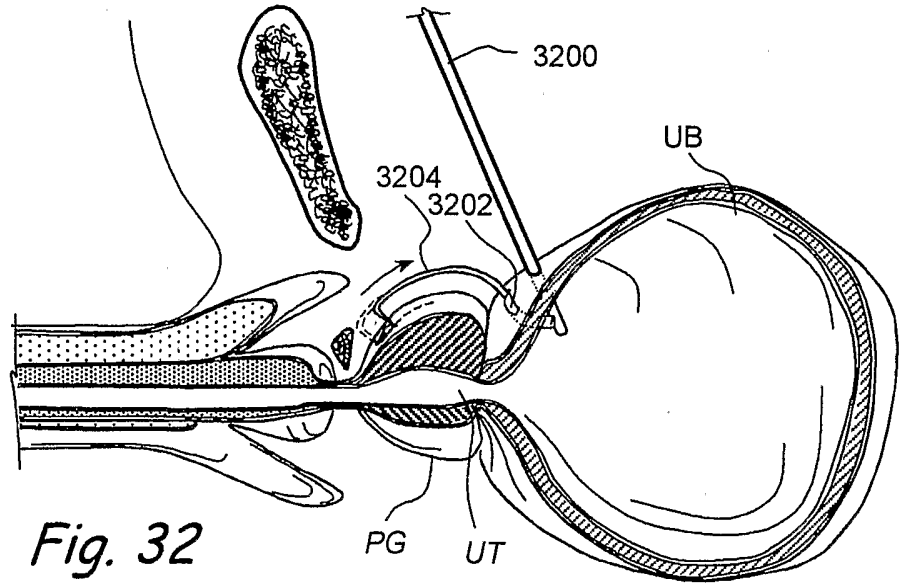


Fig. 32

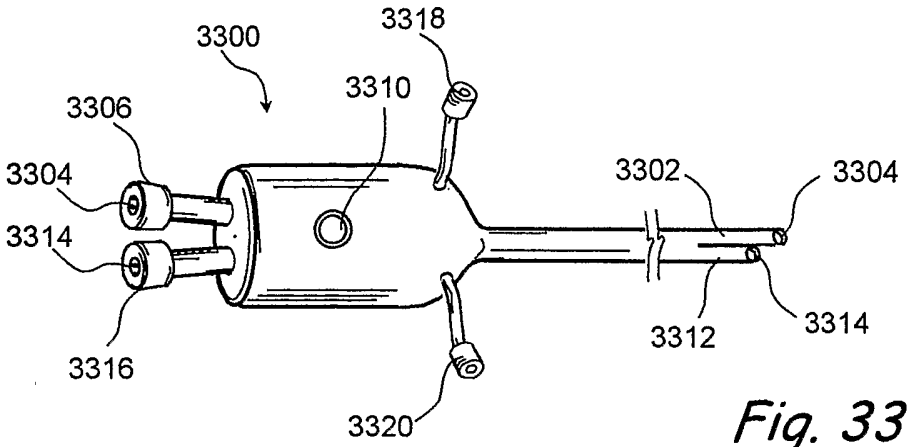


Fig. 33 A

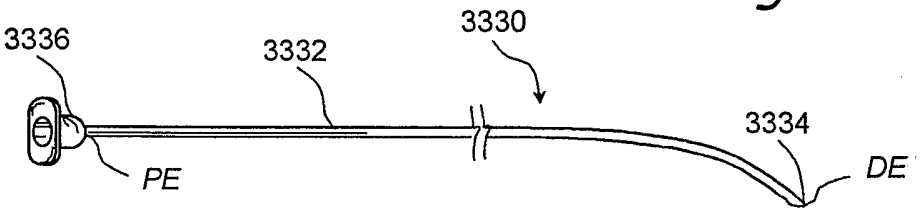


Fig. 33 B

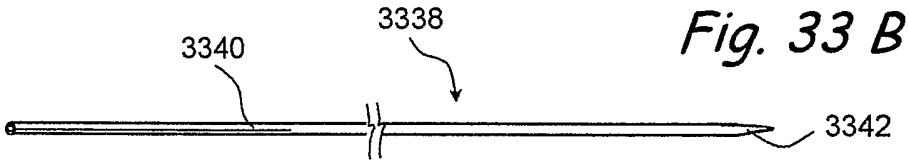


Fig. 33 C

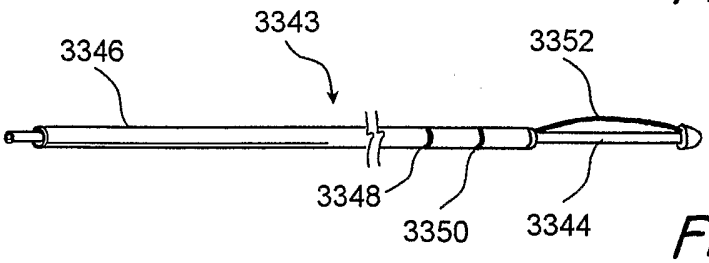


Fig. 33 D

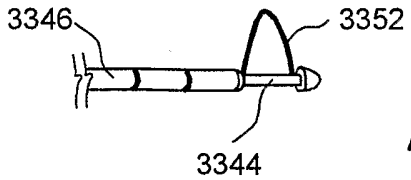


Fig. 33 D'

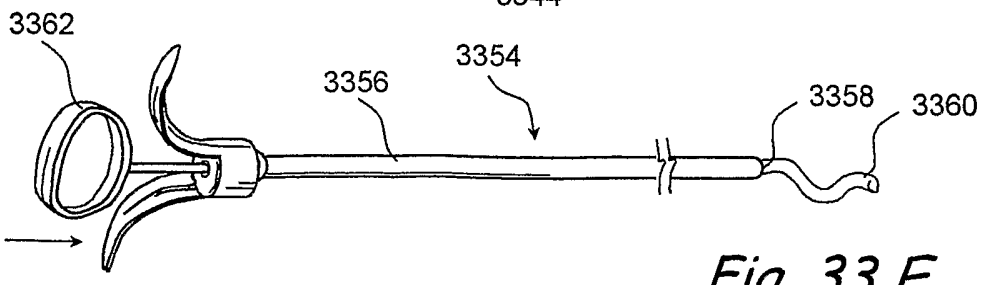


Fig. 33 E

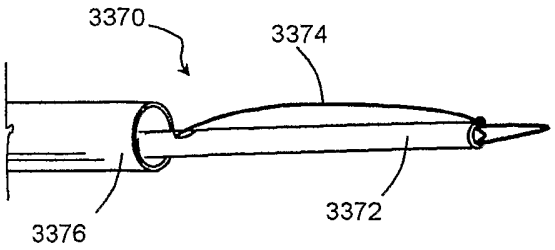


Fig. 33 F

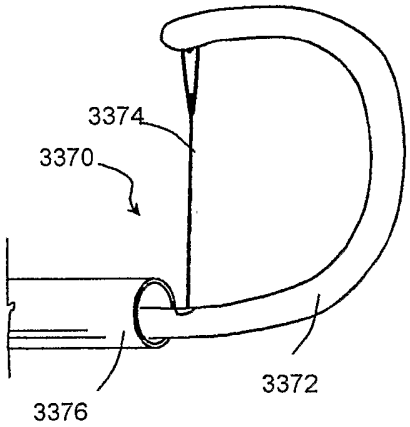


Fig. 33 G

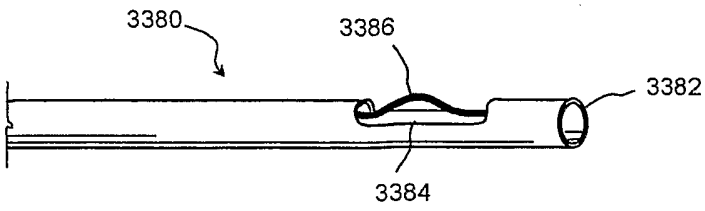


Fig. 33 H

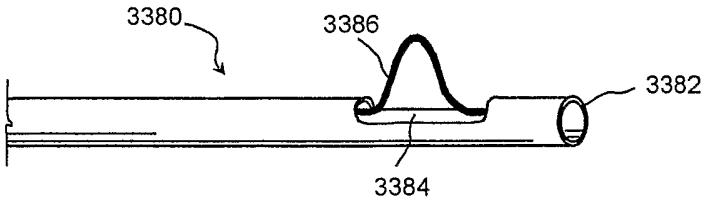


Fig. 33 I

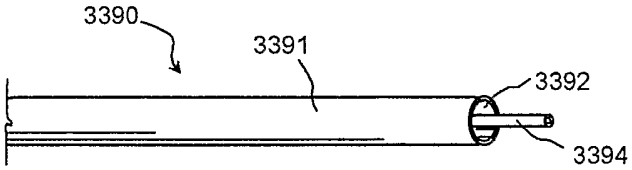


Fig. 33 J

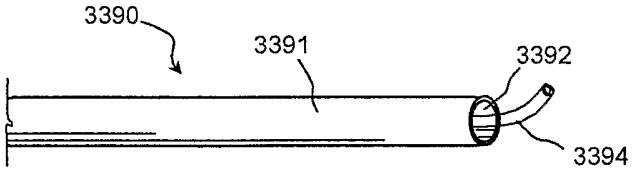


Fig. 33 K



Fig. 33 L



Fig. 33 M

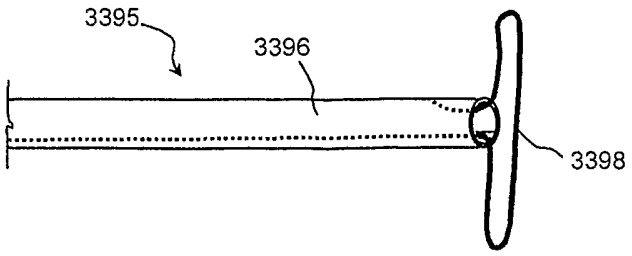


Fig. 33 N

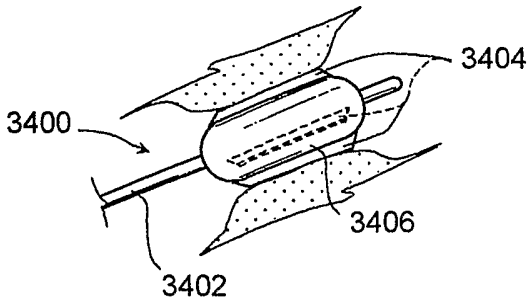


Fig. 34

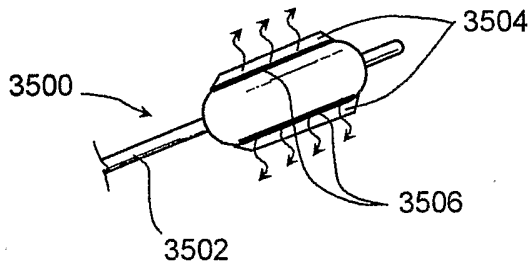


Fig. 35

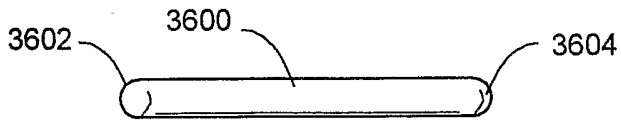


Fig. 36 A

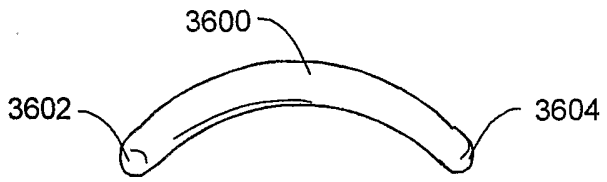


Fig. 36 B

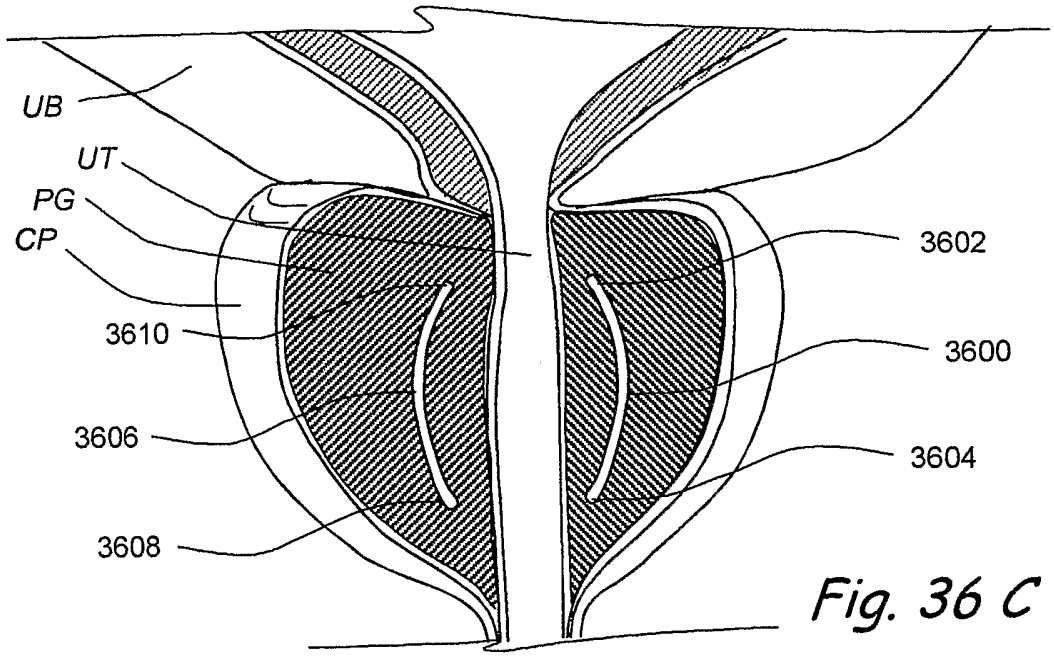


Fig. 36 C

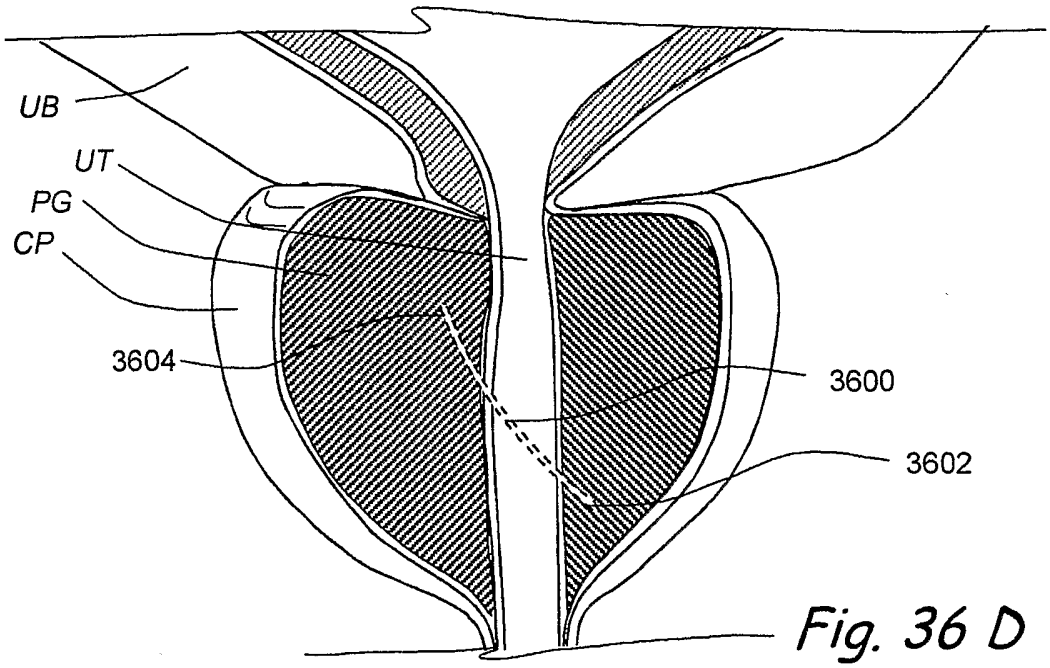


Fig. 36 D

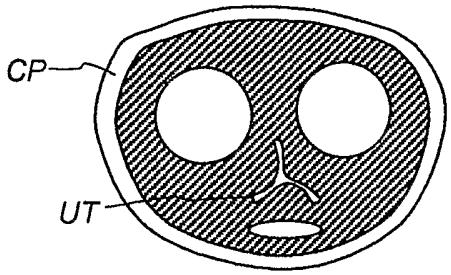


Fig. 36 F

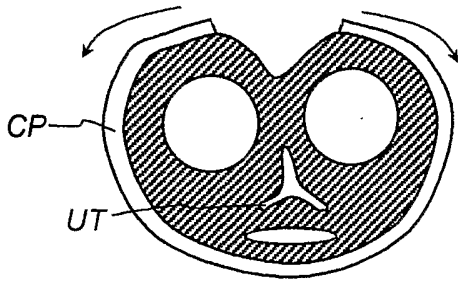


Fig. 36 G

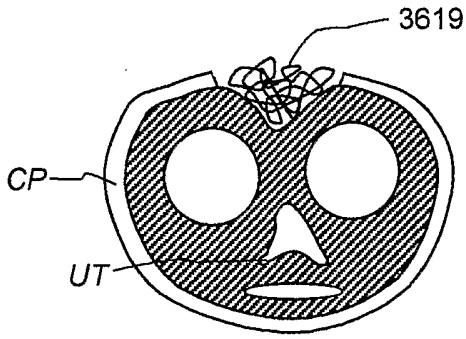


Fig. 36 H

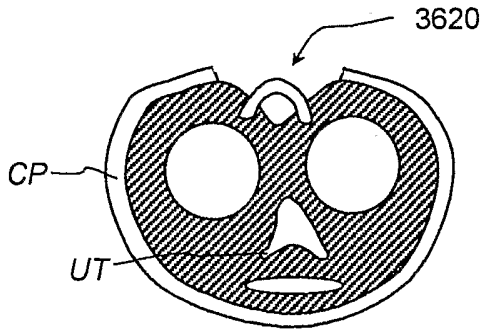


Fig. 36 I

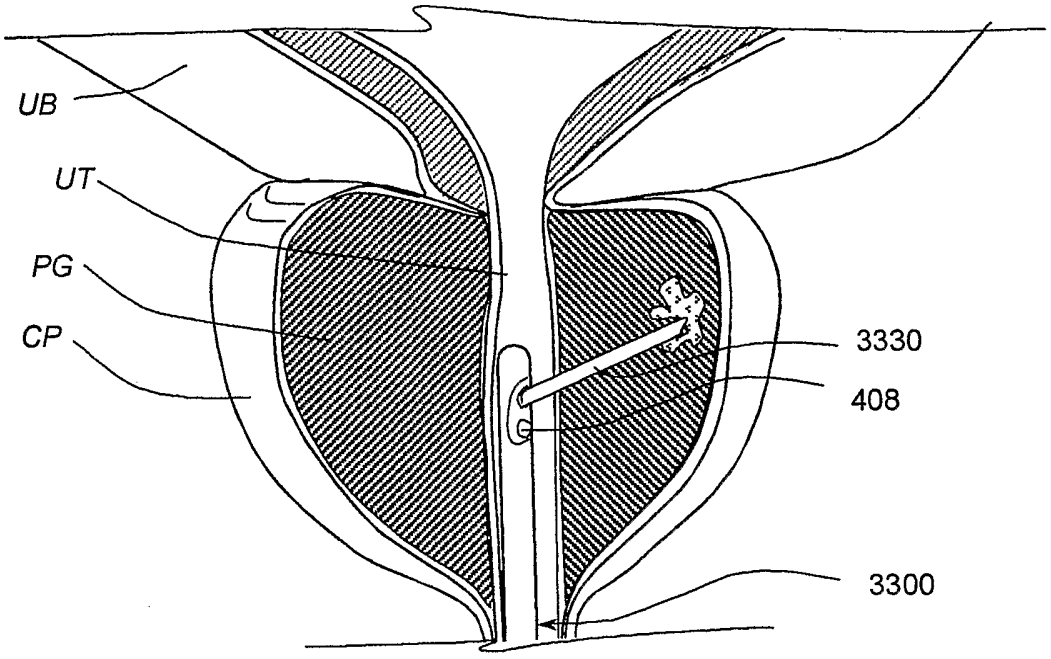


Fig. 37 A

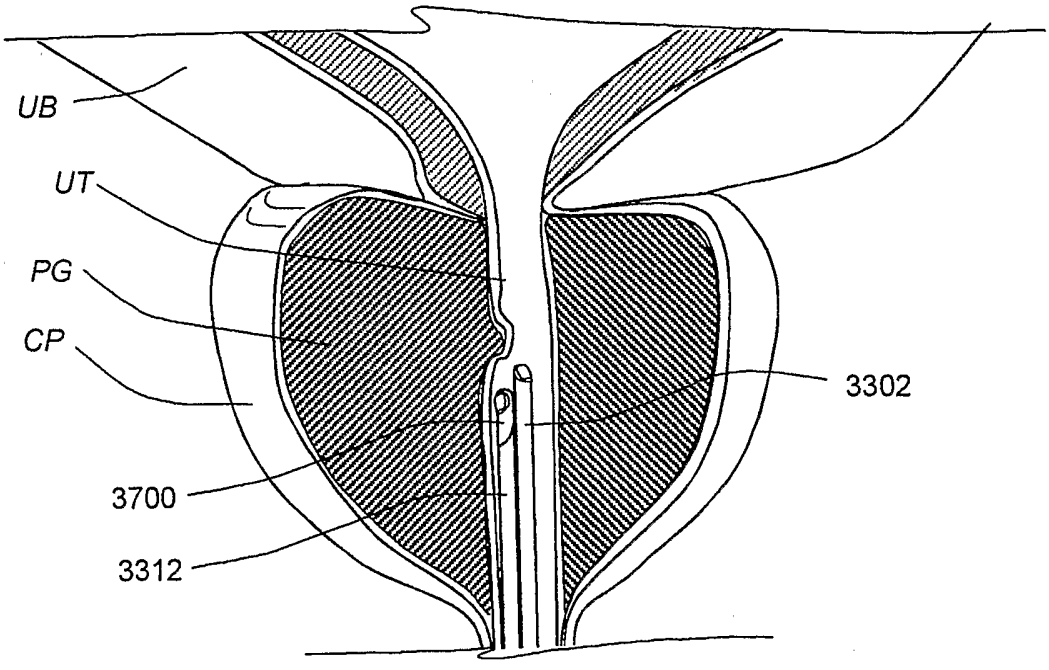


Fig. 37 B

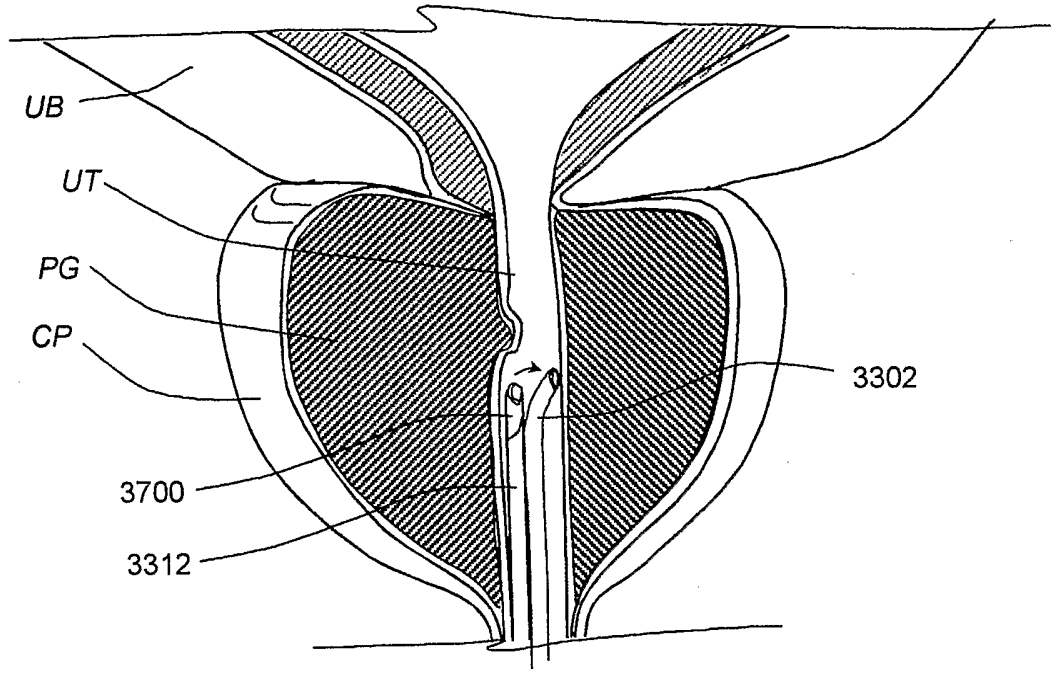


Fig. 37 C

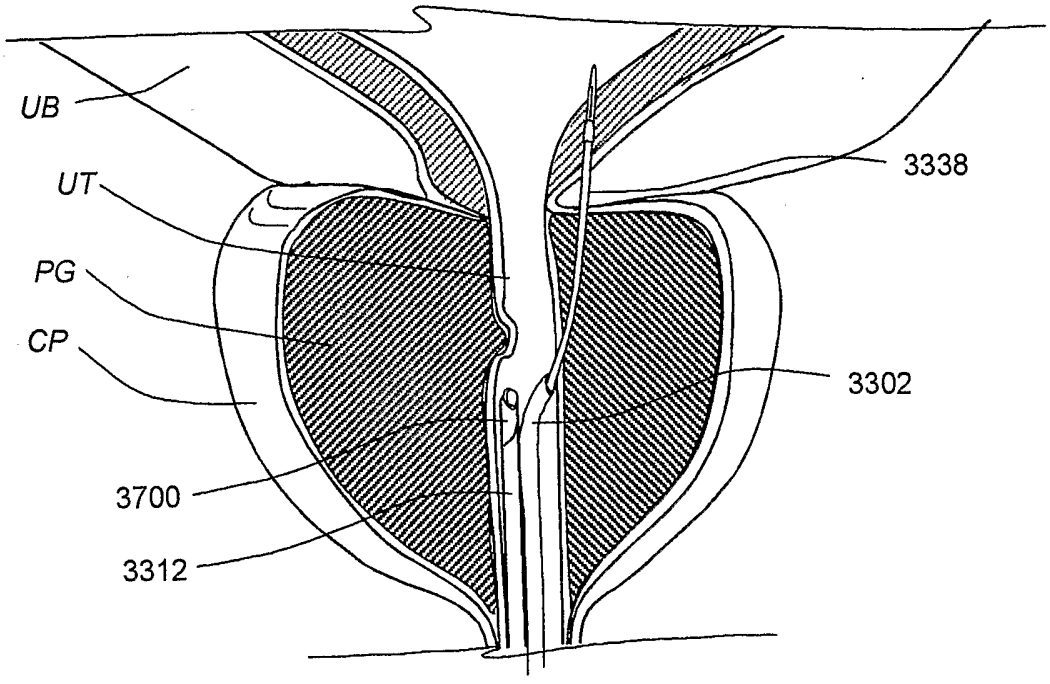


Fig. 37 D

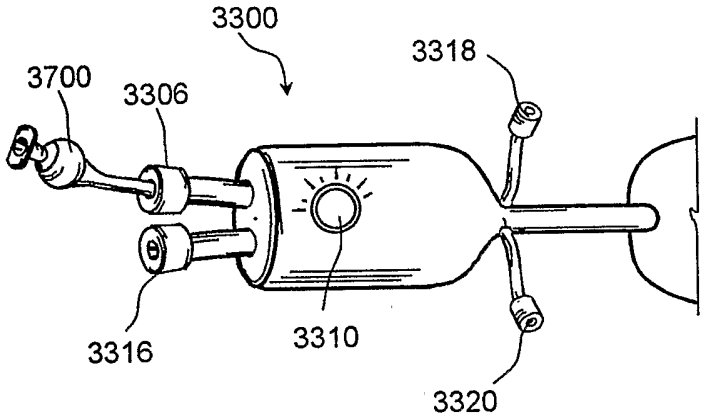


Fig. 37 C'

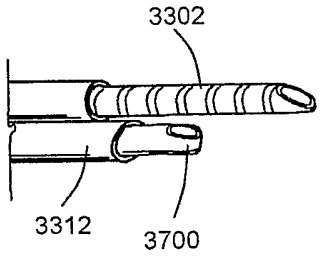


Fig. 37 C"

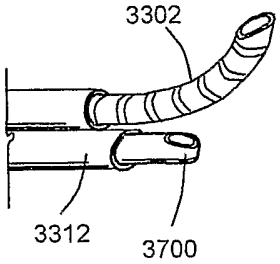


Fig. 37 C'''

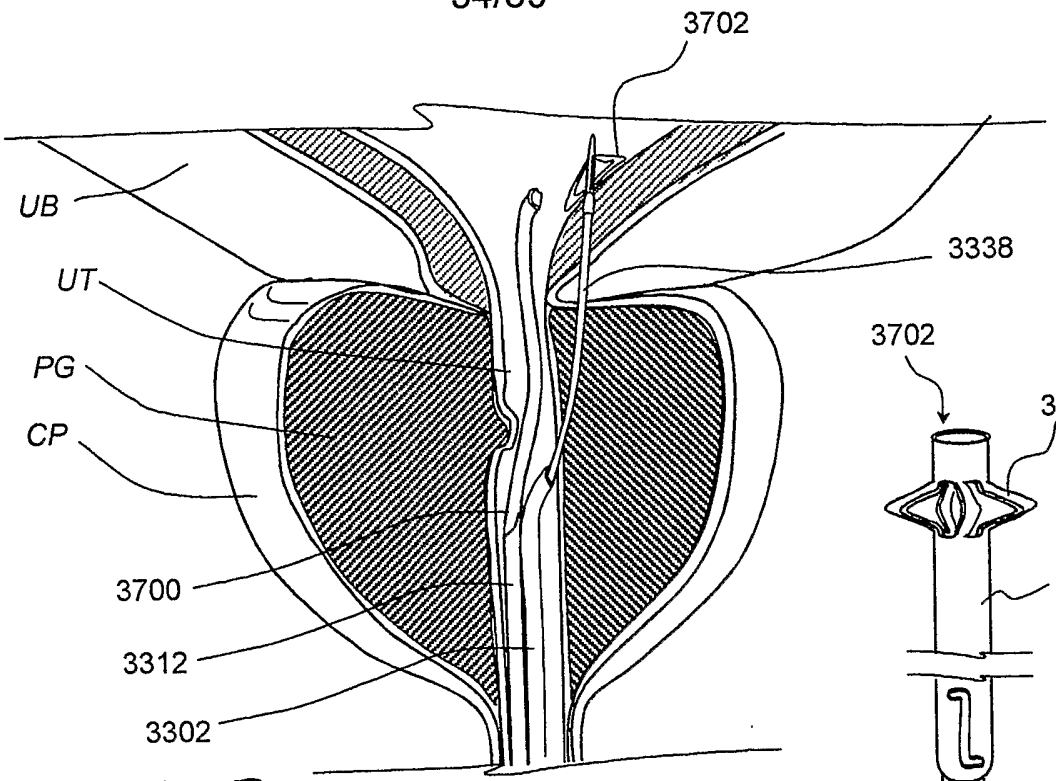


Fig. 37 E

Fig. 37 E'

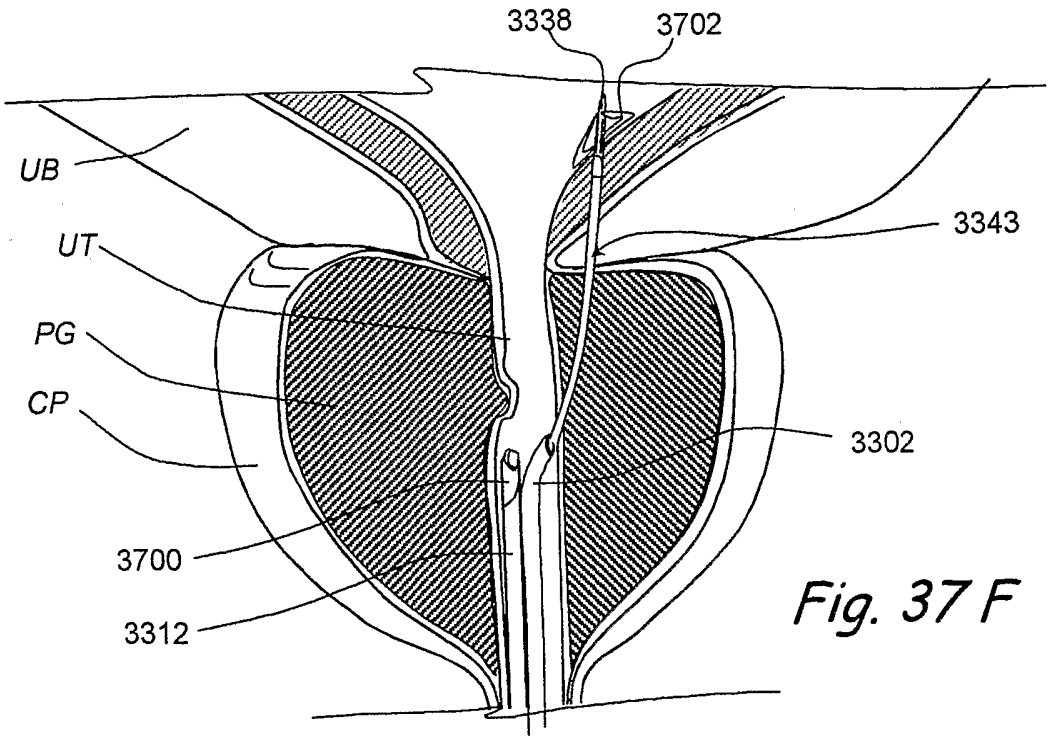


Fig. 37 F

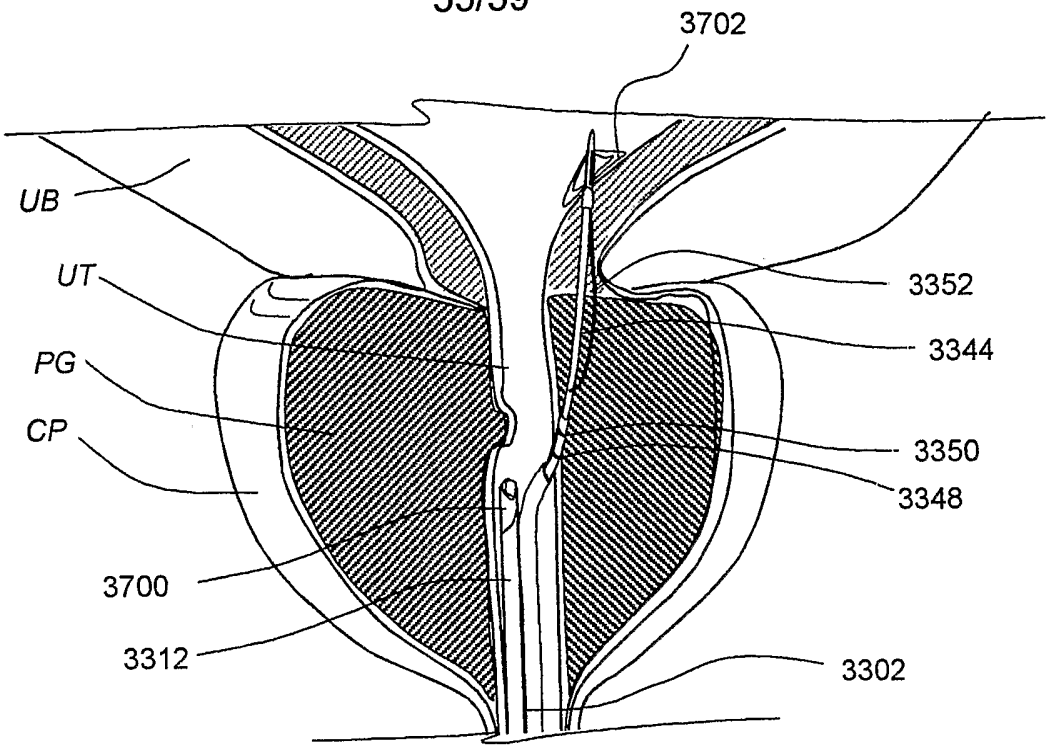


Fig. 37 G

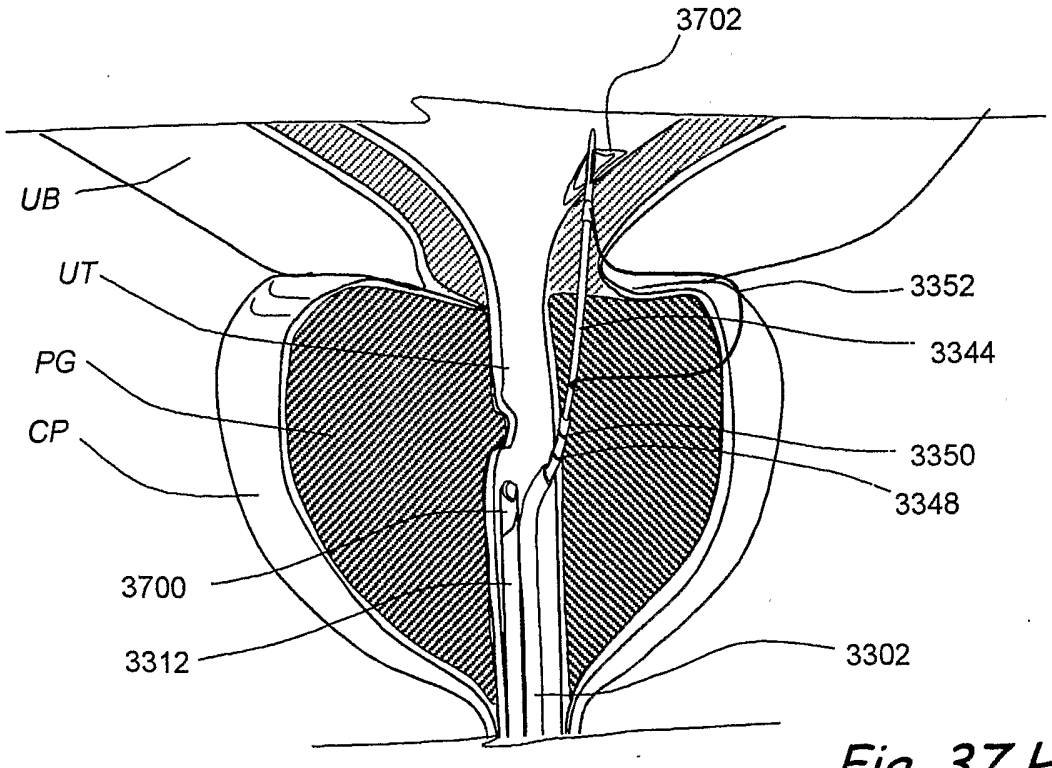


Fig. 37 H

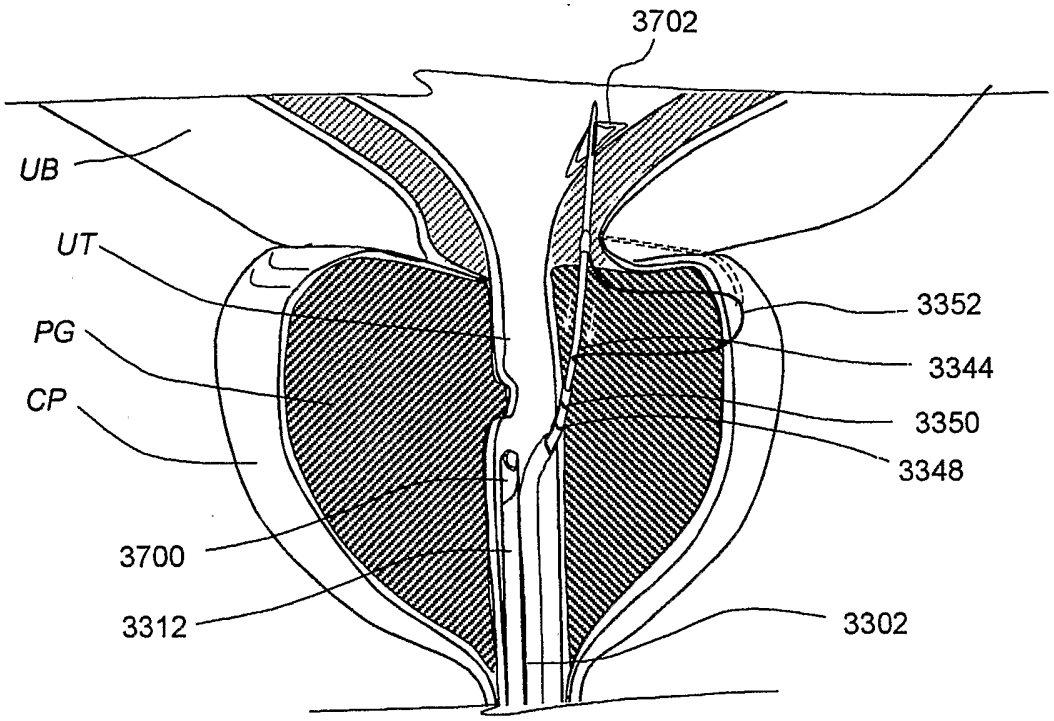


Fig. 37 I

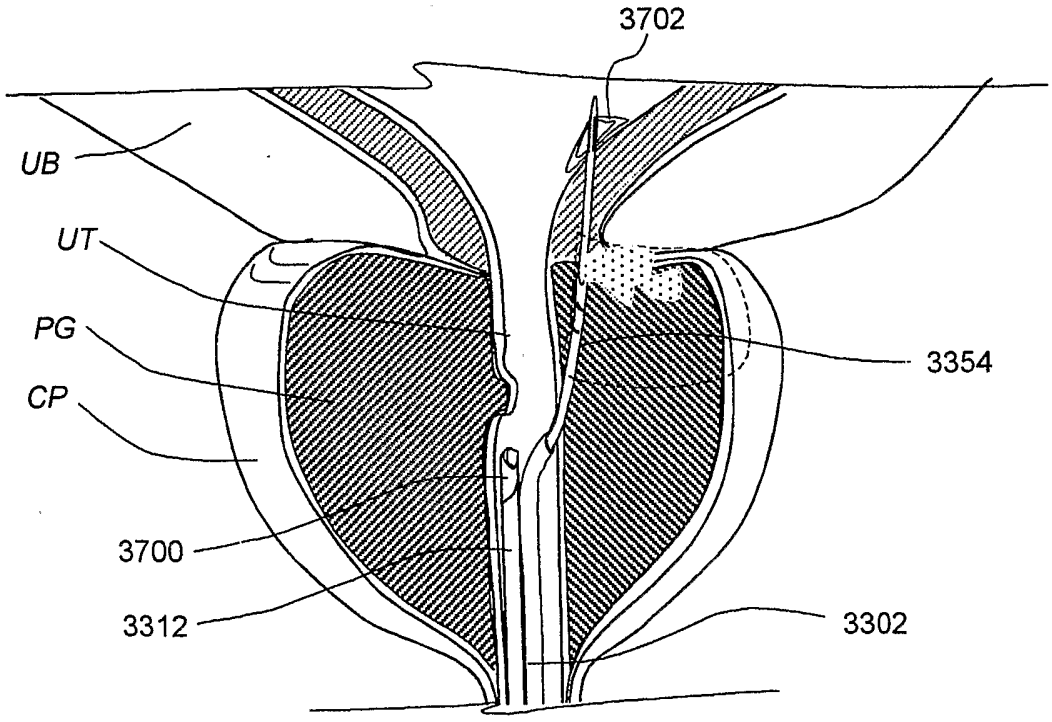


Fig. 37 J

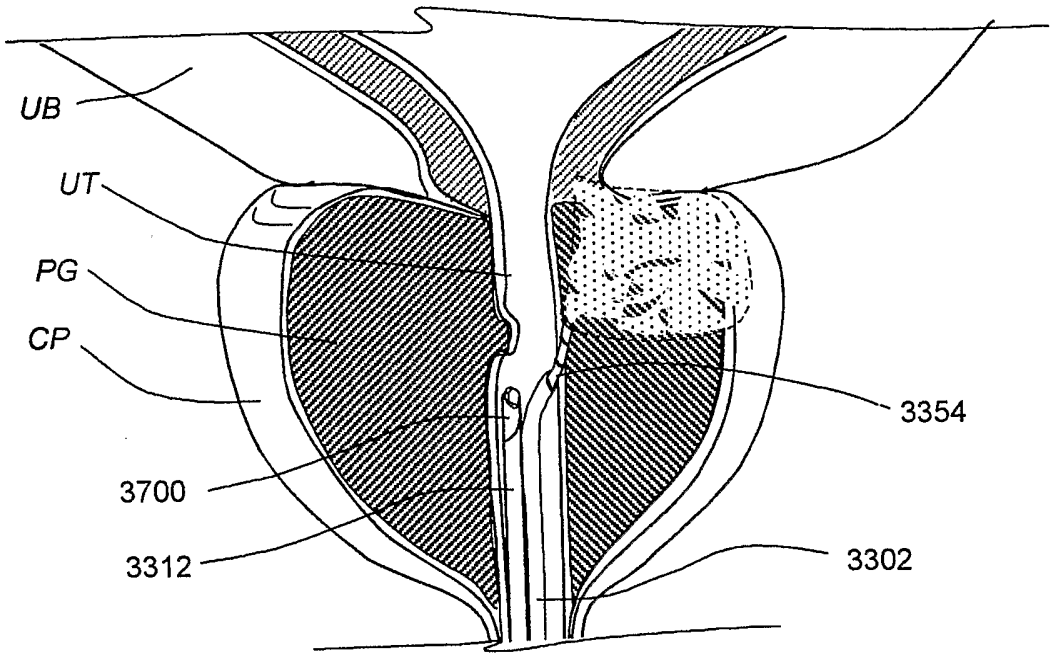


Fig. 37 K

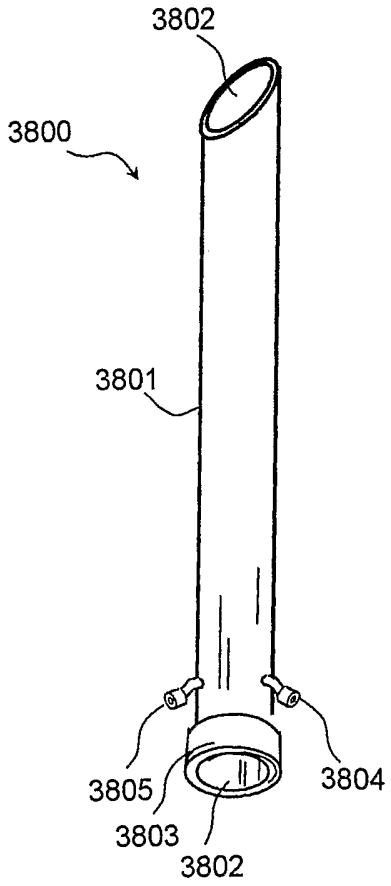


Fig. 38 A

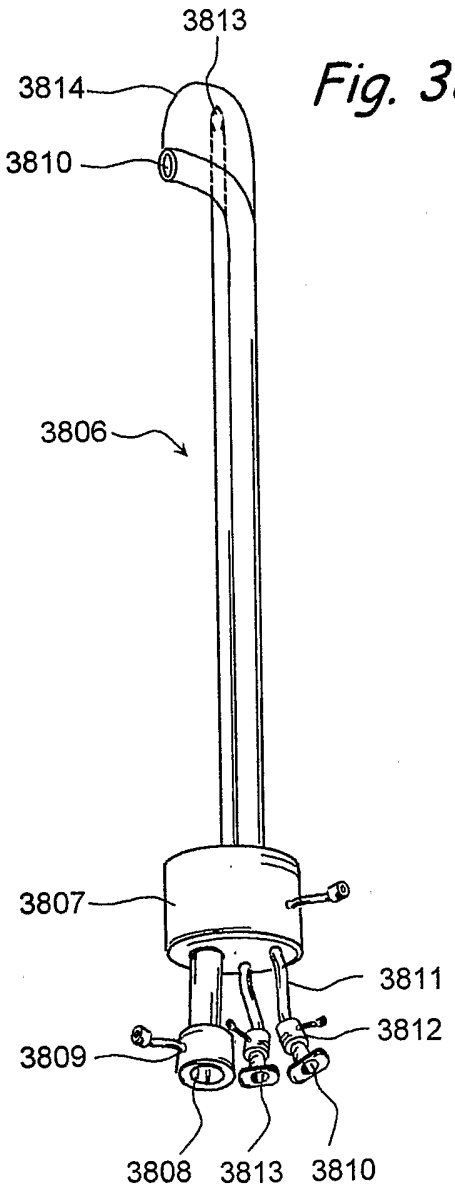


Fig. 38 B

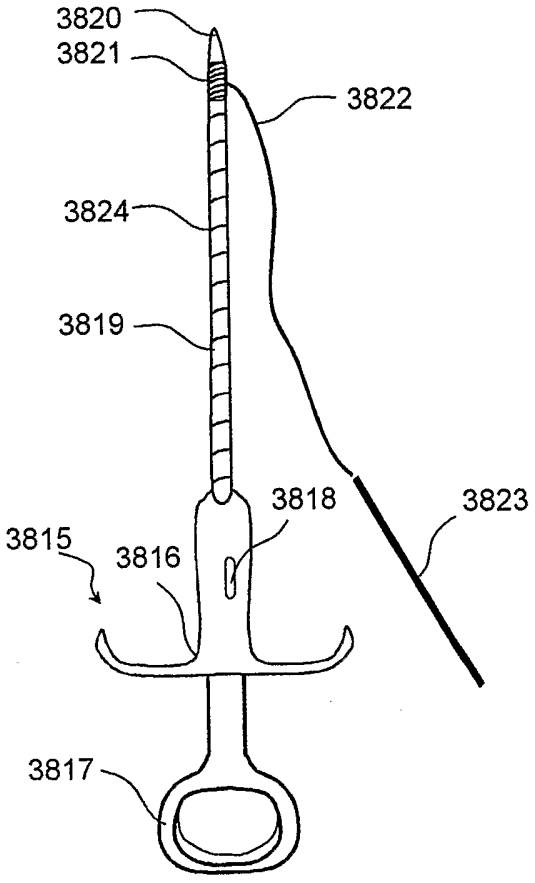


Fig. 38 C

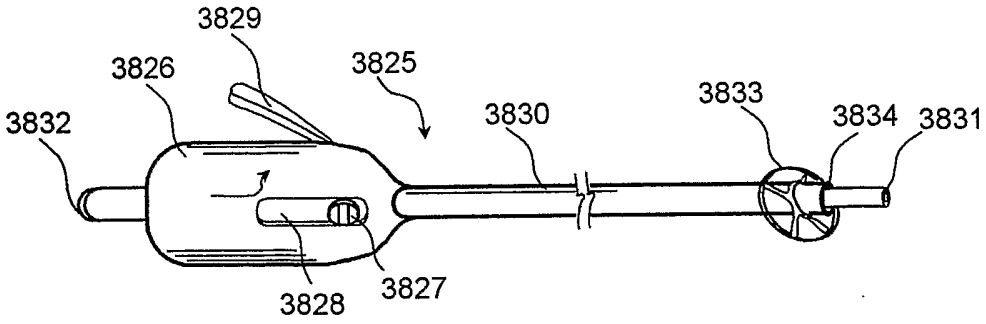


Fig. 38 D

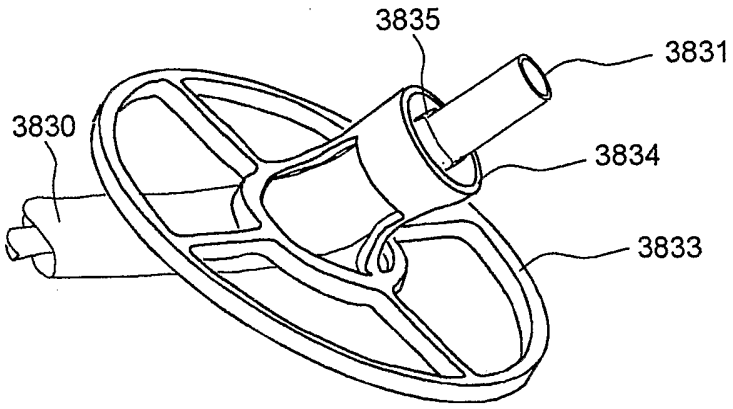


Fig. 38 E