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(54) SYSTEM AND METHOD FOR PRECISELY IDENTIFYING A CONFIGURATION OF AN ANATOMICAL SPACE IN REAL TIME

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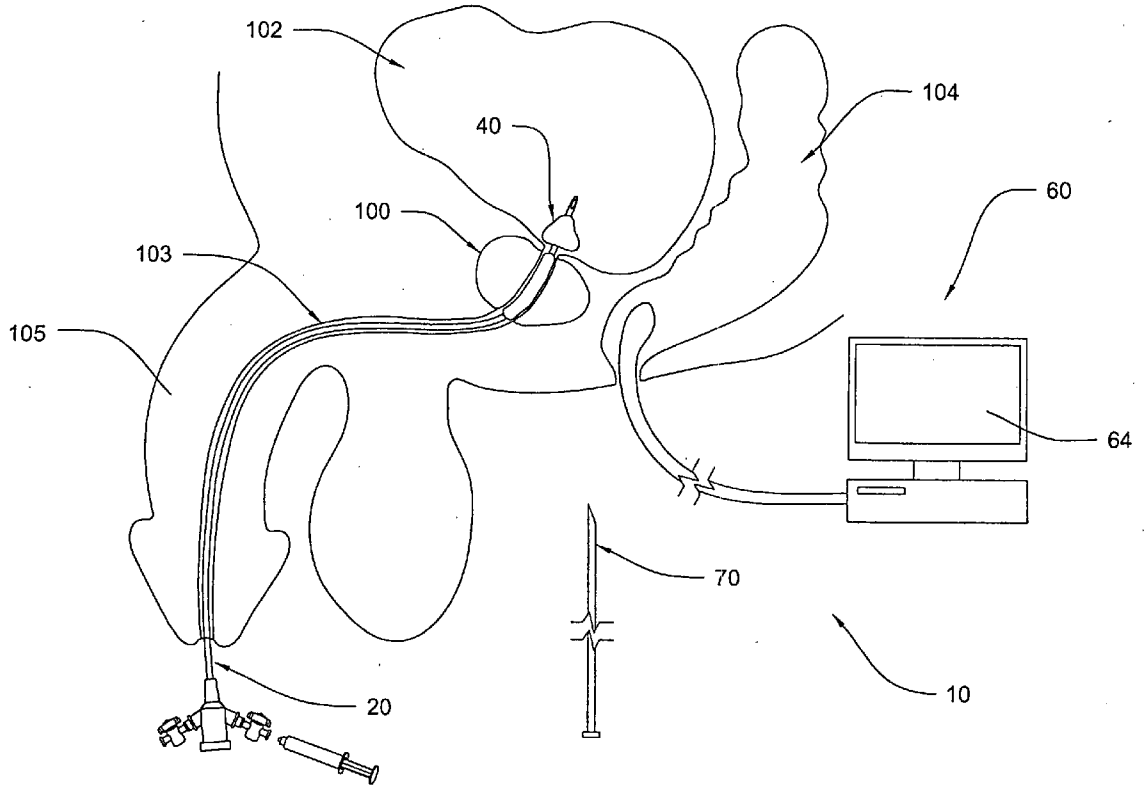
(57) **ABSTRACT**

A method of identifying a configuration of an anatomical space within a patient in real-time for the precise performance of a procedure at a site of medical interest associated with the anatomical space, wherein a catheter containing an external, inflatable imaging bladder is introduced into the patient until the image bladder is generally aligned with the site of medical interest, an imaging probe of an imaging device is operatively positioned relative to the site of medical interest and is activated so as to obtain a real-time image of the site of medical interest, the imaging bladder being filled when needed to essentially turn on and define a visible and discernable interface between the interior of the imaging bladder and a boundary of the anatomical space. Preferably, the method is employed utilizing an identification system that includes a catheter having an imaging bladder disposed in spaced relation from the tip of the catheter and structured to be filled with a fluid such as air through an inflation conduit so that the imaging bladder contacts the patient and defines a visible interface at a boundary therebetween that is visible utilizing an imaging device.



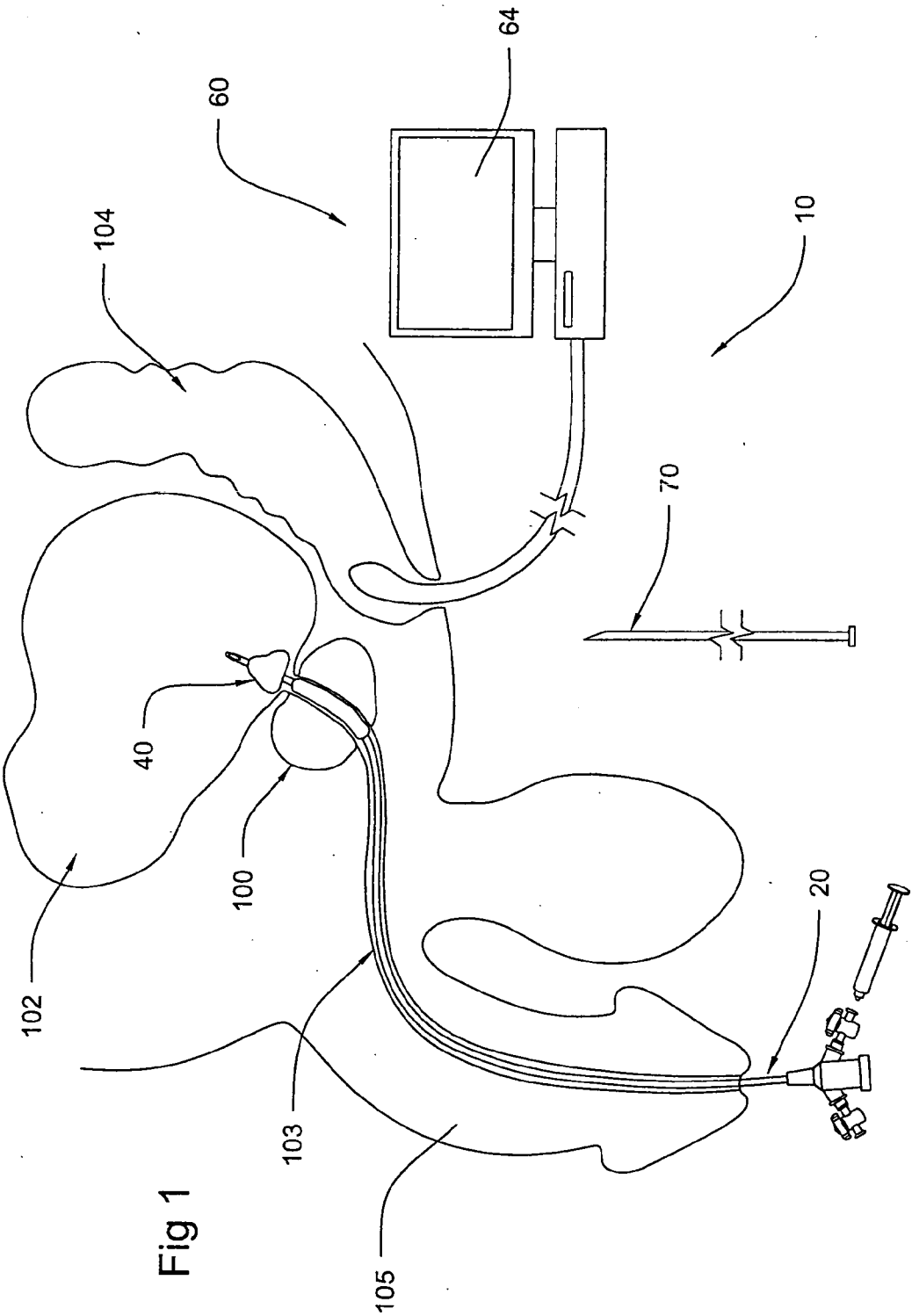


Fig 1

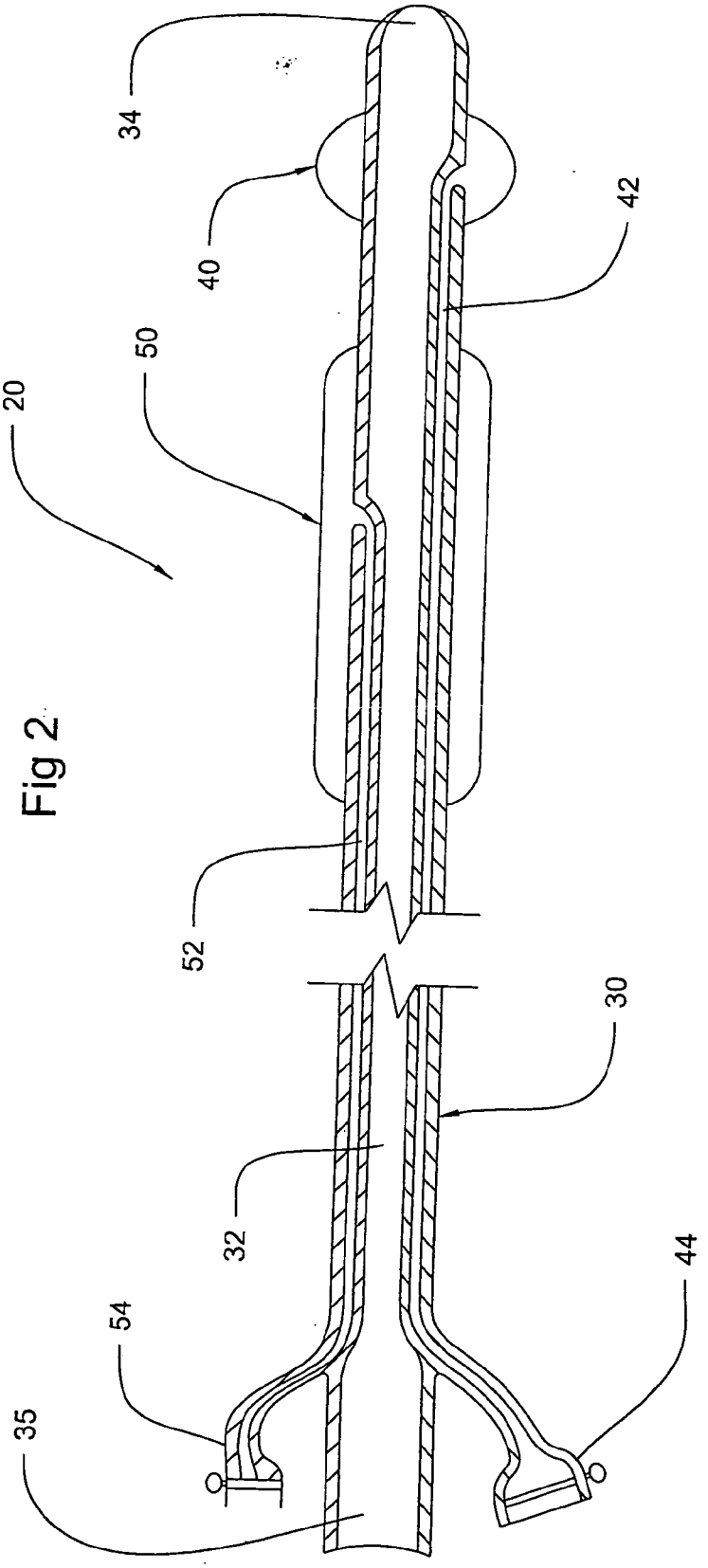


Fig 2

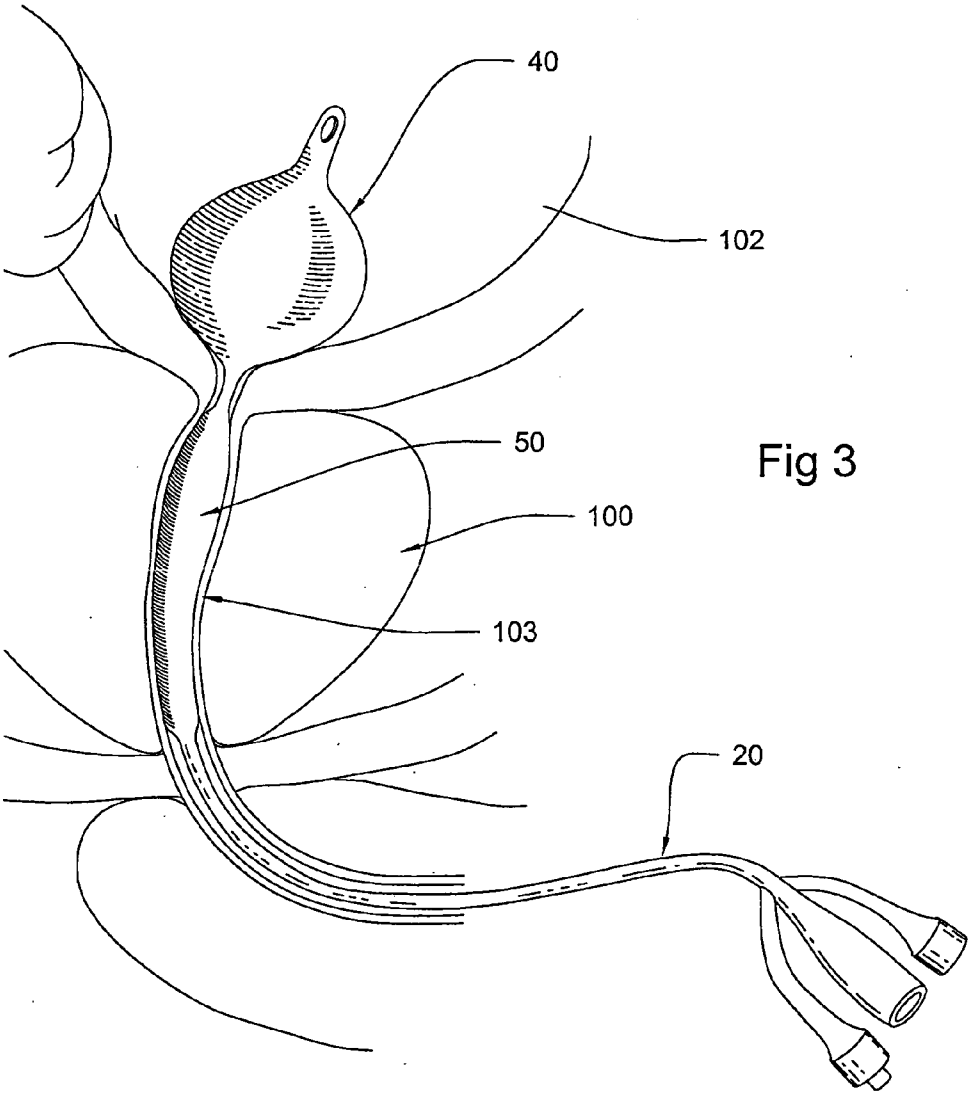


Fig 3

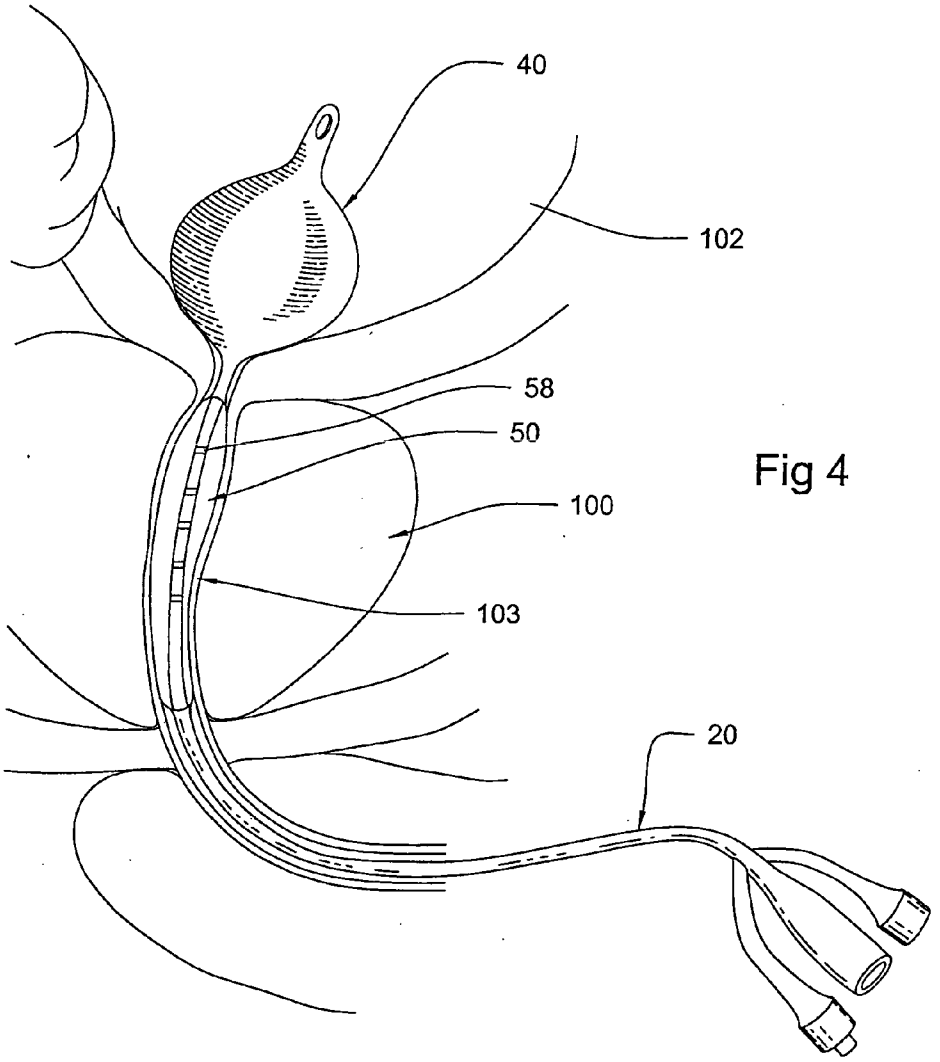


Fig 4

SYSTEM AND METHOD FOR PRECISELY IDENTIFYING A CONFIGURATION OF AN ANATOMICAL SPACE IN REAL TIME

CLAIM OF PRIORITY

[0001] The present application is a continuation-in-part application of previously filed, now pending application having Ser. No. 10/439,271, filed on May 15, 2003, which claims priority to now expired provisional patent application having Ser. No. 60/469,213 and a filing date of May 10, 2003.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to a method of identifying a configuration of an anatomical space within a patient so as to significantly facilitate the performance of a diagnostic, treatment or other procedure at a site of medical interest associated with the anatomical space being identified. For example, one such anatomical space may be a patient's urethral anatomic course, the accurate identification of a location and boundaries of that course being especially suited for accurately locating a brachytherapy or cryoablation treatment element into a patient's prostate in a manner that allows a practitioner to achieve optimal spacing between the treatment element and the urethra, while still effectively positioning the treatment element in effective and operative proximity to a tumor, Benign Prostatic Hyperplasia (BPH) tissue, or other desired treatment site within the prostate. In this regard, the present invention is further directed towards a system for precisely identifying the configuration of an anatomical space which substantially enhances the identifyability of a boundary of the anatomical space by generating, on demand, a maintainable, discernable interface with the boundary of the anatomical space that is visible utilizing an imaging device. For example, an acoustic, radiographic or other interface can be achieved depending upon a medium utilized within the system, and is visible using corresponding ultrasound, radiographic or other appropriate equipment. As a result, utilizing the present system and method, a practitioner can safely take into account the precise configuration of the anatomical space when performing procedures at a site of medical interest associated with that anatomical space.

[0004] 2. Description of the Related Art

[0005] The human body includes a variety of organs, regions, internal boundaries and other anatomical spaces whose precise configuration and/or boundaries can vary from patient to patient. When performing diagnostic, treatment or other procedures related to these anatomical spaces, however, it is often critical to be able to identify boundaries of that anatomical space with significant and readily identifiable precision, and preferably in a minimally invasive manner that can be viewed externally of the patient. For example, it is often necessary, in connection with a variety of procedures, to identify the specific anatomical course or boundaries of anatomical spaces such as the fallopian tubes, biliary tree, endometrial cavity, and/or elements of the vascular anatomy. Moreover, by way of example, one such organ for which precision identification is often critical, is the prostate.

[0006] The prostate is a male accessory sex organ located inferior to the urinary bladder and anterior to the rectum. Roughly the size of a walnut, the prostate is located in generally close proximity to the urinary bladder and surrounds and/or encircles an upper part of the urethra, the tube that is connected to the urinary bladder and empties urine therefrom. Prostate cancer is potentially aggressive and is the second leading cause of cancer deaths among men in the United States. When diagnosed at an early, localized stage and when the disease is organ confined, prostate cancer is also often considered one of the most treatable and curable forms of cancer. As a result, early detection and effective treatment is of a critical nature.

[0007] Over the years a variety of different techniques and procedures have been developed in an effort to effectively treat prostate cancer, as well as other disorders associated with the prostate, including, but not limited to Benign Prostatic Hyperplasia (BPH). Specifically, in addition to traditional radiation/chemotherapy treatments which are commonly employed for a variety of different types of cancer, due to the localized nature of prostate cancer, if detected sufficiently early, a variety of additional techniques to treat prostate tumors have been developed.

[0008] Of the existing treatments, one procedure involves the complete removal of the prostate from the patient and/or the resection of affected portions of the prostate. Given the nature of a malignant tumor, when surgery is the elected course of treatment, complete removal of the prostate is generally undertaken. However, in many circumstances surgery for the removal of a prostate may not be desirable for a variety of reasons. Among these are the post operative risks of urinary incontinence and erectile dysfunction, and co-morbid medical conditions which may increase a patient's morbidity and/or intra-operative mortality. The anatomic location of the prostate, in relation to the external urinary sphincter and the lateral neurovascular bundles, mandates that extirpative surgical procedures for the prostate, maintain the integrity of the external urinary sphincter and preserve the neural erectile pathways. Therefore, it may be preferable to leave the prostate intact. As a result, alternative minimally invasive techniques which treat prostatic malignancies, but do not require removal of the prostate may ultimately be the preferred course of treatment, and such treatment protocols are continuously being perfected.

[0009] In particulars there exist a variety of novel techniques which do not require a patient to be subjected to excessive doses of radiation, but which perform substantially localized treatment directly to the prostate. One such technique known as transperineal interstitial brachytherapy ("brachytherapy") is commonly utilized when managing localized prostate cancer. Specifically, brachytherapy involves the transperineal delivery of radioactive implants, sometimes referred to as seeds, into the stroma of the prostate and in substantially close proximity to the tumor, for an extended period of time. In this regard, the one or more radioactive seeds can directly and/or locally treat a malignant tumor, often ultimately destroying the tumor, with limited effects to the rest of the patient's body.

[0010] Still another technique of localized treatment of a malignant tumor in the prostate, as well as the treatment of BPH, a condition whereby prostatic hypertrophy can result

in an impediment to the evacuation of urine through the urethra, involve a treatment method known as cryoablation of the prostate. Under such cryoablation techniques, one or more cryo-probes and temperature sensing probes are introduced into the prostate into operative proximity with the malignant tumor or the desired treatment site. Specifically, the cryo-probes often include small gauge needles that can be effectively inserted into the prostate from the exterior of the patient. Through these cryo-probes, a cold temperature is effectively delivered at the treatment site, such as the site of the tumor, such as through the delivery of a cryogen gas including argon gas. Once the cryogen is delivered, a field of cold temperature is generated that forms essentially an ice ball to contain a majority of the lethal portions of the tumor, and/or to shrink the prostate. Subsequently, these ice balls are allowed to thaw, and then one or more subsequent freeze/thaw cycles can be performed in an effort to effectively cure the malignancy of the tumor and/or relieve the pressure resulting from the BPH.

[0011] In addition to the above techniques for localized treatment of a tumor and/or BPH and/or other aliments of the prostate, it is also recognized that other techniques are continuously being developed, refined and/or tested in an effort to achieve directed and localized treatment of tumors or other disorders within the prostate. Generally in such techniques, and especially in the techniques of brachytherapy and cryoablation, it is of significant importance for a practitioner to obtain an effective image of the prostate in order to identify a deposit location of the treatment element, be it radioactive seeds and/or cryo-probes, without performing highly invasive procedures. Traditionally, such imaging of the prostate is achieved utilizing transrectal ultrasonography.

[0012] In particular, transrectal ultrasonography requires that a practitioner insert an ultrasound probe into the rectum, and utilizing the probe, direct ultrasound towards the prostate. When employing such an ultrasound system, the practitioner is thereby able to visualize an image of the prostate, on a monitor, in real-time during the positioning of a treatment element. Unfortunately, while such techniques are generally effective for viewing the exterior shape and location of the walnut sized prostate; due to the inherent physical nature of the prostate and its circumferential orientation around the proximal urethra, practitioners typically cannot obtain any meaningful, sustained, and standardized imaging of the urethra, and more specifically the anatomic course of the prostatic urethra. There currently exist some techniques for achieving a fleeting and inconsistent viewing of the urethra. Such techniques include the manual manipulation of a Foley catheter within the urethra or the introduction of an aerated gel into the catheter. Such techniques, however, cannot be readily controlled into a standardized and manageable on and off position, and generally provide merely a temporary, variable glimpse of the urethra, if any. Furthermore, based upon the previous, traditionally accepted practice, it was not necessary for the practitioner to be able to view and/or recognize the urethral boundaries within the prostate, as the primary item of importance related to appropriate viewing of the shape, size and location of the prostate so as to effectively achieve proper positioning of the treatment element within the prostate. Also, given the general desire to minimize the potential negative impact of the treatment elements, and especially the radioactivity from the radioactive seeds on the surrounding tissue and/or organs, the treatment elements have traditionally been implanted substantially into the prostate, such that the prostate itself would act as a shield for the external tissues and/or organs.

[0013] Although such practices had been traditionally accepted, more recent studies in brachytherapy have concluded that positioning of a treatment element in substantially close proximity to the urethra, such that the urethra is exposed to higher radiation doses, can correlate with urethral toxicity. The subsequent detrimental effects to the urethra may be clinically experienced as irritative voiding symptoms, urinary retention, and/or recto-urethral fistulas. Therefore, determining the precise location for the placement of the treatments element, such as radioactive seeds, relative to the urethra, can impact the nature, location, and quantity of treatment to be employed. As a result of these discoveries, it would be highly beneficial to provide a method and system which can effectively provide for the identification of the urethral course through the prostate, thereby allowing a practitioner, in real-time, to effectively identify not only the external boundaries of the prostate, but also the urethral boundary, thereby taking both boundaries into consideration when appropriately positioning a treatment element, such as radioactive seeds and/or cryo-probes. In particular, ideal techniques may call for a positioning of the treatment element in substantially close proximity to a malignant tumor, while maintaining a maximum possible spacing from the urethral boundary. As indicated, however, presently available systems and methods do not permit for the effective viewing and/or distinguishing of the urethra relative to the prostate so as to substantially aid in treatment, and no identification systems and/or techniques which provide for a clearly visible, on demand on/off, and standardized visualization are known to be implemented. As a result, the method and system of the present invention can provide a substantial enhancement in the field of art associated with localized treatment of tumors and other disorders, such as BPH, within the prostate in a manner which reduce urethral exposure to the treatment element and thereby reduce post operative complications to the urethra. Moreover, utilizing the system and method of the present invention, certain configurations and/or boundaries of other anatomical spaces can also be readily identified in connection with a variety of precision procedures associated therewith, including, but not limited to assessment of the thickness of the endometrium in the assessment and treatment of endometrial carcinoma, placement of a nasogastric tube, placement of a PEG device, etc.

SUMMARY OF THE INVENTION

[0014] The present invention relates to a system and method of identifying a configuration of an anatomical space of patient in real-time, in order to facilitate the precision performance of a procedure at a site of medical interest. One such example of the use of the present system and method relates to identifying the location of the prostate in order to A facilitate placement of a treatment element within the prostate in a desired location relative to the urethral boundary. In particular, the present identification system may include an elongate catheter. This elongate catheter includes a primary lumen and a tip structured to be inserted into an anatomical space of a patient. In the case of use for treatment of prostate cancer, the elongate catheter is introduced into the urethra into fluid flow communication with a urinary bladder of the patient, the primary lumen being configured

to allow fluid to flow from the urinary bladder. Further, the elongate catheter will preferably have a sufficient length such that a tip of the catheter will actually extend into the urinary bladder of the patient, and in a preferred embodiment, a tip bladder is provided generally at the tip of the elongate catheter. The tip bladder is structured to be inflated, once introduced into an anatomical space, such as the urinary bladder of the patient, so as to effectively resist removal of the catheter from the anatomical space.

[0015] Additionally, the elongate catheter of the urethral identification system also includes an imaging bladder. The imaging bladder is at least partially, but preferably completely disposed about the elongate catheter in spaced relation from a tip of the catheter. Preferably, the spaced relation from the tip of the catheter will be a distance which appropriately positions the imaging bladder relative to another boundary in the anatomical space associated with the site of medical interest. In the case of treatment of the prostate, the spacing is preferably such as to place the imaging bladder within the portion of the urethra which is surrounded by a prostate of the patient. Furthermore, connected in fluid flow communication with the imaging bladder is an inflation conduit. The inflation conduit, which may in some embodiments define the primary lumen, is structured to direct a fluid, and preferably a gas such as air, into the imaging bladder. The fluid, which is preferably introduced into the imaging bladder once the imaging bladder has been appropriately positioned in a desired location within the patient's anatomical space, causes the imaging bladder to be inflated and to engage, at least somewhat, and substantially conform to at least a portion of a boundary of the anatomical space, such as the urethral wall. Also, in a preferred embodiment, the imaging bladder has a substantially thin walled construction so as to minimally interfere with imaging, as will be described.

[0016] Further provided as a part of the identification system is an imaging device. Preferably, the imaging device is configured to correspond to the type of fluid introduced into the imaging bladder so as to provide the best visibility, and in one preferred embodiment includes an ultrasound type device. The imaging device preferably includes an imaging probe that is disposed in operative proximity to the imaging bladder such that through the use of the imaging probe, the imaging device is structured to provide a real-time image of a vicinity of the imaging probe and is structured to effectively view and identify an interface, such as an acoustic interface when the fluid is air, that is defined between the fluid disposed in the imaging bladder and the boundary of the anatomical space, such as the urethral wall. This interface is substantially visible utilizing the corresponding imaging device and based upon the inflation of the imaging bladder and its close proximity with a wall of site of medical interest is able to effectively identify a boundary at the air/liquid interface therebetween. As a result, in the case of prostate treatment, a practitioner is effectively able to identify the urethral boundary and/or the wall of the urethra, as well as being able to view the prostate both before and during introduction of a treatment element. Moreover, the practitioner has substantial control over the viewing process since inflation and/or deflation of the image bladder can provide an on demand, on/off type imaging that can generate a meaningful, manageable and standardized display for an extended period of time as needed by the practitioner.

[0017] From the preceding, it is seen that the present identification system may be the preferred implements to be utilized within a method of identifying a configuration of an anatomical space within a patient in real time, such as a patient's urethral anatomic course, for the precision performance of a procedure at a site of medical interest associated with the anatomical space. In particular, the method preferably includes an initial step of inserting a catheter that contains an external inflatable imaging bladder into the anatomical space, such as the urethra, of the patient until the imaging bladder is generally aligned with a site of medical interest, such as a treatment site of the prostate. Additionally, an imaging probe is operatively positioned relative to the site, such that when activated, it provided a real-time image of a boundary of the anatomical space, such as on an associated monitor which may be viewed by a practitioner.

[0018] With the imaging bladder appropriately positioned within the patient, the imaging bladder-is inflated, preferably by a fluid such as air, until the imaging bladder engages a boundary of the anatomical space and an acoustic interface is defined between the interior of the imaging bladder and the engaged surface. In this regard, it is noted that this engagement may include a close spacing therebetween so long as effective definition of the boundary within a required degree of certainty for the procedure can be achieved. As a result, a boundary of the site of medical interest at that acoustic interface can be thereafter identified during conducting of the procedure.

[0019] These and other features and advantages of the present invention will become more clear when the drawings as well as the detailed description are taken into consideration.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] For a fuller understanding of the nature of the present invention, reference should be had to the following detailed description taken in connection with the accompanying drawings in which:

[0021] **FIG. 1** is a detailed schematic illustration of one preferred embodiment of the identification system of the present invention operatively disposed relative to a patient in the context of prostate treatment;

[0022] **FIG. 2** is a partial cross section view of one embodiment of the elongate catheter of the present invention;

[0023] **FIG. 3** is an operative view of one embodiment of the elongate catheter of the present invention; and

[0024] **FIG. 4** is an operative view of an alternative embodiment of the elongate catheter of the present invention.

[0025] Like reference numerals refer to like parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0026] The present invention is directed towards a system for precisely identifying a configuration of an anatomical space, generally indicated as **10**, and further to a method of identifying a configuration of an anatomical space within a patient in real time to facilitate precision performance of a

procedure at a site of medical interest associated with the anatomical space. In this context, it is recognized that an anatomical space may be defined as any open or openable area of a patient into which the elongate catheter of the present system can be introduced. For example, an exterior or interior boundary of an internal organ, passage, cavity, skeletal element, potential space, etc. may define the anatomical space, the present invention providing for effective imaging of a boundary thereof in connection with an associated procedure so that a practitioner can see that boundary in an identifiable and if desired, controllable fashion during performance of the procedure. Moreover, some specific examples of an anatomical space for which the present system and method could be used, said examples not considered to be limiting and/or exhaustive, include the fallopian tubes, the biliary tree, the endometrial cavity, elements of the vascular anatomy, a urethral anatomical course (such as for location of the prostate), etc. Furthermore, the procedure to be performed utilizing the present system and method can also vary between a diagnostic, exploratory, and/or treatment procedure, such as including, but not limited to, placement of a nasogastric tube, placement of a PEG device, assessment of the thickness of the endometrium in the assessment and treatment of endometrial carcinoma, placement of a brachytherapy radioactive seed and/or a cryoablation cryo-probe, etc. Despite each of these varied uses and applications of the present system and method, however, for purposes of clarity in explanation, the following description will focus on the use of the present system and method in connection with the identification of the prostate and/or urethral anatomical course to aide in the precise placement of a treatment element into the patient's prostate **100**, such as the effective placement of a brachytherapy radioactive seed and/or a cryoablation cryo-probe, with precision, at a desired location within the patent's prostate **100**.

[**0027**] Looking first to the illustrated embodiments of the identification system **10**, it includes an elongate catheter, generally **20**. In particular, the catheter **20** is generally elongate and of an appropriate length to extend into the corresponding anatomical space associated with the procedure to be performed. In the illustrated embodiment, the elongate catheter **20** is similar in length to that of a traditional use Foley catheter, the elongate catheter **20** being structured to be introduced into the urethra **103** of a patient through the penis **105** until a proximate tip **34** thereof extends into a urinary bladder **102** of the patient so as to drain urine from the urinary bladder **102**. Furthermore, the elongate catheter **20** also includes a primary lumen **32** that extends generally from the tip **34** that in the illustrated embodiment is inserted into the patient's urinary bladder **102** to an exterior, open end **35**. In this manner, and through this primary lumen **32**, urine may be drained from the patient's urinary bladder **102** during the performance of this and other procedures as necessary, and/or after the procedure. Of course, in alternate uses of the present system wherein drainage and/or ventilation is not necessary, the primary lumen need not extend completely through the catheter, being open at both ends, but may itself merely define an inflation conduit as will be described subsequently. Further provided in a preferred embodiment of the catheter **20** is a tip bladder **40**. In particular, the tip bladder **40** is formed of a flexible balloon type material and is structured to be effectively expanded upon the introduction of a fluid therein. In order to aid the inflation of the tip bladder **40**, the primary lumen **32** and/or a secondary lumen **42** is provided in fluid flow communication between the tip bladder **40** and an inlet port **44**. The inlet port **44** may include any desirable valve construction so as to effectively allow for the introduction of a fluid while regulating the escape of a fluid. In use in the preferred embodiment, the elongate catheter **20** is introduced into the patient's urethra **103** until the tip bladder **40** extends into the urinary bladder **102** of the patient. Once inserted into the urinary bladder **102** of the patient, the tip bladder **40** may thereafter be effectively inflated. By inflating the tip bladder **40**, and as illustrated in the figures, the catheter **20** is essentially maintained in its operative and fluid flow connection with the urinary bladder **102** of the patient, and or in the context of other procedures may be effectively 'locked' in place to provide necessary positioning, drainage and/or ventilation. Specifically, the larger size of the tip bladder **40** relative to an opening, such as the opening to the urethra **103** from the urinary bladder **102** is such that removal of the catheter **20** is generally resisted. Furthermore, it noted that although the tip bladder **40** is not a prerequisite for the catheter **20** and identification system **10** of the present invention, it may be preferred as it will often help provide a precise positioning of the catheter **20** within the patient. For example, once the tip bladder **40** is inflated, the catheter can be carefully pulled out from the urethra **103** until the tip bladder **40** engages the urinary bladder wall. As a result, a base of the tip bladder **40** will always be disposed at the entrance way to the urethra **103** from the urinary bladder **102**.

[**0028**] Looking further to the preferred catheter **20**, it also preferably includes an imaging bladder **50**. In particular, the imaging bladder **50** is at least partially, and preferably completely; disposed about an exterior surface of the catheter, although it is recognized that internal placement with appropriate open or flexible construction of the catheter wall can also be achieved. Further, the imaging bladder **50** may be completely cylindrical, helical, fluted, cone shaped or another symmetrical or non-symmetrical shape. A further auxiliary lumen and/or the primary lumen may define an inflation conduit **52** communicatively disposed between the imaging bladder **50** and an inlet port **54** that preferably includes an appropriate flow control valve structure. As a result, in use, a fluid may be passed through this auxiliary lumen **52** into inflating position within the imaging bladder **50**, such as using a proximately integrated inflation device or a separate device such as a syringe.

[**0029**] Looking to the preferred embodiments of the imaging bladder **50**, it is preferably structured to be a low pressure bladder inflated by a fluid, and preferably air, for reasons to be subsequently described. Furthermore, the imaging bladder **50** is preferably formed of a flexible material which may be made of latex or be latex-free material such as including but not limited to silicone, polyurethane, polyethyleneteraphalete or another latex-free material, so as to allow for appropriate inflation thereof. The preferred material construction of the imaging bladder **50** is achieved so as to minimize the potential obstruction to be generated by the imaging bladder **50** to an imaging device **60**, to be described in greater detail subsequently. Furthermore, to aide and/or minimize the obstruction of the imaging, to allow maximum conformance of the imaging bladder **50** to the configuration of the anatomical space, if desired, and to provide a clearly visible indicator, the imaging

bladder **50** will preferably be formed of a substantially thin wall thickness in the range of 0.0001 inches to 0.5 inches depending upon the application, and in the preferred, illustrated embodiments a wall thickness of between 0.001 to 0.005 inches. Further an inflated diameter of approximately 1 Fr (French)-50 Fr may be provided, again depending upon the procedure. For example, in the preferred, illustrated embodiment, the diameter may be between 14 Fr-30 Fr, whereas in a cardiac context it may be closer to 2 Fr, in neurosurgical or biliary procedures closer to 4 Fr and/or for thoracic or rectal procedures closer to 36 Fr, each of these dimensions being of course approximations that may vary from case to case. Further, the imaging bladder may also include a non-inflated dimension of between approximately 1 Fr-35 Fr and/or be configured to increase 100× from its baseline or non-inflated external circumference or internal diameter, and when a tip bladder is included, the imaging bladder to tip bladder capacity rations may also vary between 1:0.1, 1:1, 1:2, 1:5, 1:10, 1:20, 1:50, etc. or any increment therebetween. In use, and as will be described in greater detail subsequently, the imaging bladder **50** is structured to be inflated under low pressure only until it engages, at least partially, and exerts a mild outward pressure on the patient, such as at the urethral wall. As a result, a thick wall, high volume/high pressure structure of the imaging bladder **50** is not required, and indeed in some embodiments may actually be detrimental due to its imaging obstruction. Furthermore, a thin wall thickness and flexible material provides a greater degree of conformity with the urethral wall, if so desired, so that a more accurate image is defined. Moreover, because the practitioner has substantial control over the inflation and/or deflation of the imaging bladder **50** in an on demand type system, the practitioner has substantial control over the viewing process as well, essentially being able to turn on optimized, continuous and manageable imaging of the urethral course, as needed, and until no longer needed.

[**0030**] As can be seen from the Figures, the imaging bladder **50**, when operatively disposed with the catheter **20** in the patient, is preferably positioned as close as possible to the anatomical space and in the illustrated embodiment is aligned with at least a portion and in many embodiments all of the prostate **100**. Specifically, the prostate which is the walnut sized sex organ that wraps around an upper portion of the urethra **103** substantially near the urinary bladder **102** typically has a somewhat standard range of dimensions, at least with regard to the length of the urethra **103** overlapped thereby. Moreover, through various imaging techniques a general determination of the length of the prostate **100** or other site of interest may be determined to select an appropriate sized imaging bladder. As a result, the imaging bladder **50** preferably extends through a substantial portion of the urethra **103** that is encased by the prostate **100**, and, in the preferred embodiment the imaging bladder **50** is preferably about 4 cm in length. Of course, it is understood that varying lengths of the imaging bladder **50** may also be provided if greater precision and/or larger coverage area is desired, and depending upon the procedure in connection with which it will be employed.

[**0031**] Also, the imaging bladder **50** is preferably, although not necessarily, disposed a desired spaced apart distance from the tip bladder **50** in order to be appropriately positioned. In the illustrated embodiment, the imaging bladder **50** may be closely spaced from the base of the tip bladder **40**, that spacing generally positioning the imaging bladder **50** in an appropriately aligned position relative to the prostate **100** when the tip bladder **40** has been inflated and is engaging the walls of the urinary bladder **102**. Accordingly, it is seen that ultimately, depending upon the procedure and the part of the body into which the catheter **20** will be introduced, the spacing can be between 1 mm and 50 cm.

[**0032**] Further provided as part of the urethral identification system **10** of the present invention is an imaging device, generally **60**. Although the imaging device **60** may include any of a number of different types of imaging devices which provide an accurate, real-time view of internal organs, including yet to be developed imaging devices, in the preferred, illustrated embodiments the imaging device **60** includes an ultrasound type system. Of course, in an embodiment wherein an alternate fluid is introduced into the imaging bladder, such as a radio-opaque material, and/or if the imaging bladder itself is formed in whole or in part from a radio-opaque material, alternate radiographic, fluoroscopy, or x-ray equipment may be utilized as the imaging device, and indeed, as new contrast agents or other fluids are developed or seen to provide effective results, an MRI or PET scan system may be used as the imaging device. Still the preferred fluid is air so as to provide an acoustic interface visivle using ultrasound equipment. In this embodiment, an imaging probe **62** is preferably provided and is structured to emit sound waves in a conventional fashion towards the prostate so as to generate ultrasound images on an associated monitor **64** and processor assembly. In use, the imaging probe **62** is preferably inserted into the rectum **104** of the patient as that provides a substantially close proximity to the prostate **100**, and as a result, to the imaging bladder **50** that is located within the prostate **100**.

[**0033**] As previously recited, the imaging bladder **50** is preferably inflated with a fluid, and preferably air or another appropriate fluid such as a radio-opaque contrast agent, through any conventional means such as through the utilization of a syringe at the inlet port **54** or a proximately integrated inflation/deflation device. With the imaging bladder **50** generally inflated such that it at least partially and preferably substantially contacts, conforms to and engages a boundary of the anatomical space, such as the urethral wall, an effective image can be achieved by the imaging device **60**. In particular, it is noted that although the urethra **103** is generally not visible and/or readily discernable within the prostate **100** utilizing ultrasound and/or other standard imaging techniques, by inflating the imaging bladder **50** with air, an acoustic interface that is clearly visible utilizing the imaging device **60** is generated and defined. Specifically, the contrast between the fluid disposed within the imaging bladder **50** and the urethral wall defines the acoustic interface, thus allowing a practitioner utilizing the image device **60** to readily view, on their monitor **64**, a boundary of the urethra as the contrast point. This boundary of the urethra **103** may then be monitored during performance of a necessary procedure, such as the effective location of a treatment element **70** in the prostate **100**. Again, as mentioned, the fluid utilized to inflate the imaging bladder may include a radio-opaque material or other contrast medium that can be viewed using ancillary imaging modalities including fluoroscopy as the imaging device, and/or if desired, the imaging bladder may be pre-inflated partially and/or completely.

[0034] As previously recited, in the preferred embodiment the treatment element **70** may include a brachytherapy probe that introduces one or more radioactive seeds into the prostate **100** of the patient. Alternatively, the treatment element **70** may include one or more cryo-probes and/or temperature sensing probes that are inserted into the prostate **100** of the patient in order to achieve effective cryoablation of a tumor that may be contained within the prostate **100** or treatment for BPH. In either such instances, however, effective positioning of the treatment element **70** within the prostate **100**, taking into account a desired optimal spacing with the urethral wall can be achieved. Moreover, such placement may also impact the nature and/or extent of treatment, such by helping in the determination of the number of radioactive seeds to be used and/or the determination of the progress of BPH treatment.

[0035] Looking to **FIG. 4**, in an alternative embodiment of the catheter **20** of the present invention, in addition to the imaging bladder **50**, it is also seen that one or more hyperechoic or radio-opaque rings **58** may also be provided and disposed completely or partially around a periphery of the catheter. These rings **58** may be defined on an exterior of the catheter, such as using an echogenic coating on or in the surface material of the catheter, as may be desired. Specifically the rings **58** will exhibit visible landmark images when utilizing the imaging device **60**, those landmarks also being potentially helpful for performance of a procedure, such as the selection of a treatment element **70** and/or the effective and appropriate positioning of a treatment element **70**, as needed. In the illustrated embodiment, the rings **58** are preferably formed of an echogenic material and spaced **1** cm from one another. Of course, it is understood that other hyperechoic or radio-opaque materials and/or varied spacing and/or numbering of the rings **58** may also be employed if the rings **58** are ultimately utilized in the imaging catheter **20**.

[0036] As indicated, utilizing the preceding identification system **10** and the catheter **20**, it is further seen that the present invention may be directed towards a method of identifying a configuration of an anatomical space within a patient in real time to facilitate precision performance of a procedure at a site of medical interest associated with the anatomical space, such as in the illustrated embodiment a patient's urethral anatomic course for the precise placement of a treatment element **70** into the patient's prostate **100**. In use, the present method may include an initial step of introducing a catheter that has at least an external imaging bladder **50**, and in some preferred embodiments a tip bladder **40** into the anatomical space, such as the urethra **103**, of the patient until the image bladder **50** is generally aligned with the site of medical interest, and in some embodiments until the tip bladder **40** is disposed within the urinary bladder **102**. When appropriate, the tip bladder **40** may be effectively inflated thereby securing the catheter within the patient, such as within the urethra **103** of the patient. Furthermore, also when appropriate, the imaging bladder **50** is preferably inflated, preferably utilizing a fluid such as air, and preferably until the exterior wall of the imaging bladder **50** generally abuts and/or engages at least a portion of a boundary of the anatomical space. In this regard, it may be preferred that the imaging bladder **50**, which as previously recited may have a substantially thin wall thickness, will generally conform to the anatomic course and/or configuration of that boundary and will only exert a mild pressure on the patient, although minimal contact is also possible.

[0037] The present method further includes the step of placing an imaging probe **62** in operative proximity to the imaging bladder **50**, and generally in operative proximity to the anatomical space that is preferably aligned therewith. This step in the method preferably includes the insertion of an ultrasound probe **62** into the patient, and ultimately activating the imaging device **60** so as to produce a real-time image of the boundary of the anatomical space of the patient. Additionally, it is noted that either prior to or subsequent to the activation of the imaging device **60**, the imaging bladder **50** is filled with the fluid such as air. The imaging bladder **50** is filled until a visible and discernible interface is defined between the interior of the imaging bladder **50** and the boundary being engaged, this interface being achieved generally when a sufficient pocket of fluid, such as air, is defined next to the boundary. A practitioner may then, preferably utilizing the imaging device **60**, appropriately identify and view a boundary at the interface, and effective placement of a treatment element **70** or performance of another procedure, can thereafter proceed. Indeed, it is this flexibility of activation/inflation that gives the practitioner substantial control over the imaging process. For example, by achieving inflation and/or deflation of the imaging bladder **50** in an on demand type system, the practitioner has substantial control and can turn on an optimized, continuous image of the anatomical space course as needed and until no longer needed. Moreover, the process can be generally standardized from one case to another.

[0038] In one embodiment of the present method the effective placement of the treatment element **70** comprises the insertion of one or more elongate brachytherapy probes which allow for the positioning of radioactive seeds in operative proximity to a tumor located within the prostate **100**. Utilizing the image that is identified and viewed utilizing the imaging device **60**, appropriate relative positioning of the radioactive seeds between the exterior of the prostate **100**, the urethral boundary and the tumor to be treated can appropriately be achieved. Further, in an alternative embodiment of the present method the treatment element **70** may include one or more cryoablation cryo-probes, as well as potentially one or more temperature sensing probes. In use, the temperature sensing probes and/or cryo-probes are introduced into the prostate **100** in effective operative proximity to a tumor or other treatment site within the prostate **100**. As previously recited, this appropriate spacing utilizing the imaging of the urethral boundary can take into account both the urethral boundary and the exterior of the prostate **100**. Once the one or more cryoablation probes are effectively positioned a series of freezing and thawing cycles may then take place, such as through the introduction of a cryogenic gas, like argon gas, to create an ice ball at the tumor located within the prostate **100** and/or to treat the BPH. As a result, in either such embodiment and/or in any other embodiment wherein a treatment element, such as a microwave or other heating element to treat BPH or another ailment associated with the prostate, must be effectively placed within the prostate **100**, a practitioner need not unduly sacrifice the health and integrity of the urethra **103** in positioning a treatment element **70**, but rather can now take into account the

appropriate location, size and orientation of the urethra **103** within the prostate **100** when determining an ideal location for a treatment element **70**.

[**0039**] Since many modifications, variations and changes in detail can be made to the described preferred embodiment of the invention, it is intended that all matters in the foregoing description and shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense. Thus, the scope of the invention should be determined by the appended claims and their legal equivalents, and may extend to alternate imaging needs outside of the prostate context.

What is claimed is:

1. A method of identifying a configuration of an anatomical space within a patient in real time to facilitate precision performance of a procedure at a site of medical interest associated with the anatomical space, said method comprising:

a) introducing a catheter containing an external imaging bladder into the anatomical space of the patient until said image bladder is generally aligned with the site of medical interest;

b) operatively positioning an imaging probe of an imaging device relative to the site of medical interest and proximate portions of the anatomical space;

c) activating said imaging device so as to obtain a real time image of the site of medical interest;

d) filling said imaging bladder on demand until said imaging bladder defines an acoustic interface between the interior of said imaging bladder and the anatomical space; and

e) identifying and viewing a boundary of the anatomical space at said acoustic interface during performance of said procedure so as to identify proper positioning relative to the anatomical space.

2. The method of claim 1 further comprising:

a) introducing said catheter containing a tip bladder and said external, inflatable imaging bladder positioned a determined spacing therefrom into the anatomical space of the patient until said tip bladder enters a known anatomical chamber of the patient;

b) inflating said tip bladder so as to prevent removal thereof from the patient's known anatomical chamber; and

c) withdrawing said catheter from the patient's anatomical space until said tip bladder engages the patient's known anatomical chamber in proximity to an entrance to the anatomical site so as to position said image bladder in generally aligned relation with the site of medical interest.

3. The method of claim 1 further comprising inflating said imaging bladder with a fluid.

4. The method of claim 3 further comprising inflating said imaging bladder with air as said fluid.

5. The method of claim 1 further comprising at least partially filling said imaging bladder with a radio-opaque material.

6. The method of claim 1 further comprising inflating said imaging bladder until said imaging bladder begins to contact and minimally expand the anatomical space.

7. The method of claim 1 further comprising introducing said catheter having said imaging bladder formed of a substantially thin walled construction.

8. The method of claim 1 further comprising introducing said catheter having said imaging bladder with a wall thickness of approximately 0.0001 inches to 0.5 inches.

9. The method of claim 1 further comprising introducing said catheter having said imaging bladder with a wall thickness of approximately 0.001 inches to 0.5 inches.

10. The method of claim 1 further comprising introducing said catheter having said imaging bladder with a filled diameter of approximately 1 Fr-50 Fr.

11. The method of claim 1 further comprising introducing said catheter having said imaging bladder formed of a latex free material.

12. The method of claim 1 further comprising introducing said catheter having said imaging bladder formed of a latex material.

13. The method of claim 1 further comprising introducing a brachytherapy treatment element into the anatomical space within a vicinity of the site of medical interest and at a determined spacing from the boundary of the anatomical space so as to minimize adverse affects on the patient.

14. The method of claim 1 further comprising introducing a cryoablation treatment element into the patient at a determined spacing from the boundary of the anatomical space so as to minimize adverse affects on the patient.

15. The method of claim 1 wherein said step of operatively positioning said imaging probe of said imaging device relative to the site of medical interest and proximate portions of the anatomical space further comprises operatively positioning an ultrasonography probe into the patient until said probe is in imaging proximity to the site of medical interest.

16. The method of claim 1 further comprising introducing a PEG device into the patient at a precise location relative to the anatomical space.

17. A system for precisely identifying a configuration of an anatomical space comprising:

a) an elongate catheter having a primary lumen and a tip structured to be inserted into an anatomical space of a patient;

b) an imaging bladder at least partially disposed about said elongate catheter in spaced relation from said tip of said catheter;

c) an inflation conduit disposed in fluid flow communication with said imaging bladder and structured to direct a fluid into said imaging bladder;

d) said imaging bladder structured to be inflated upon receipt of said fluid, and to engage and substantially conform to at least a portion of a boundary of said anatomical space;

e) an imaging device including an imaging probe structured to be disposed in operative proximity to said imaging bladder; and

f) said imaging device structured to provide a real time image of a vicinity of said imaging probe, said fluid disposed in said imaging bladder structured to define a maintainable, discernable interface with the boundary

of the anatomical space visible utilizing said imaging device so as to precisely identify a location of said boundary.

18. An identification system as recited in claim 17 wherein said imaging bladder is formed from a latex free flexible material structured to minimize impedance of said real time image provided by said imaging probe.

19. An identification system as recited in claim 17 wherein said imaging bladder is formed from a flexible latex material.

20. An identification system as recited in claim 17 wherein said imaging bladder includes a wall thickness of between approximately 0.0001 inches to 0.5 inches.

21. An identification system as recited in claim 17 wherein said imaging bladder includes a wall thickness of between approximately 0.001 inches to 0.5 inches.

22. An identification system as recited in claim 17 wherein an inflated diameter of said imaging bladder is approximately 1 Fr-50 Fr.

23. An identification system as recited in claim 17 wherein said fluid is air.

24. An identification system as recited in claim 17 wherein said fluid is a radio-opaque material which defines a radiographic interface.

25. An identification system as recited in claim 17 further comprising at least one radio opaque ring disposed on said catheter.

26. An identification system as recited in claim 17 wherein said imaging bladder is approximately 4 cm in length.

27. An identification system as recited in claim 17 wherein said catheter further comprises a tip bladder disposed generally at said tip of said catheter, said tip bladder structured to be inflated once disposed in the patient to a size greater than a dimension of an entrance to an anatomical chamber so as to resist removal of said catheter.

28. An identification system as recited in claim 17 wherein said imaging device comprises an ultrasound imaging device.

29. An identification system as recited in claim 28 wherein said imaging probe comprises an ultrasonography probe structured to be inserted into the patient.

30. An identification system as recited in claim 17 wherein said inflation conduit comprises said primary lumen.

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