Systems and Methods for Regulating Organ and/or Tumor Growth Rates, Function, and/or Development

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application is national phase ~~an international~~ application of International Application PCT/US2013/073844, which claims benefit of and priority to U.S. Provisional Application Ser. No. 61/735,056 filed on December 9th, 2012, entitled "Systems and Methods for Regulating Organ Growth Rates and Development", by Landy Toth et al., the entire contents of which are incorporated by reference herein for all purposes.

BACKGROUND

Technical Field

[0002] The present disclosure relates to the field of neuromodulation. The present disclosure also relates to methods and systems for use in nerve and/or receptor monitoring, electrophysiological monitoring, and/or surgical procedures, in particular related to the systems and mechanisms that regulate prostate and/or tumor growth. The present disclosure further relates to systems and methods for modulating neurological traffic to and from the prostate, the testis, and/or organs of the lower urinary tract.

Background

[0003] As men age, there is an associated increase in the frequency of pathologic diseases affecting the genitourinary tract. The prevalence of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH), chronic prostatitis (CP), hypogonadism (HG), nocturia, prostate cancer (PrCa), and erectile dysfunction (ED) continue to rise in the western world.

[0004] Relating to one contributor to LUTS, the prevalence of BPH increases with age, with initial development usually after 40 years of age. More than half of men in their 60s and up to 90% of men in their 70s and 80s have some symptoms of BPH. The

direct costs of medical services provided in hospital inpatient and outpatient settings, emergency departments, and physician offices for BPH management in the US exceeded

[0011] Yet another objective is to provide systems, devices, and methods for regulating the autonomic, sympathetic, and/or parasympathetic traffic to/from, and/or so as to affect the growth rate, hormone secretion rates, or development of an organ (e.g. a prostate, a testicle, etc.), or a tumor (e.g. a prostate cancer tumor, a perineural invading cancerous tumor, etc.).

[0012] Another objective is to provide systems, devices, and methods for treating a disease of the lower urinary tract (LUT).

[0013] The above objectives are wholly or partially met by devices, systems, and methods according to the appended claims in accordance with the present disclosure. Features and aspects are set forth in the appended claims, in the following description, and in the annexed drawings in accordance with the present disclosure.

[0014] According to a first aspect there is provided, a surgical tool for monitoring and/or altering electrophysiological activity within the vicinity of a prostate within a body, the surgical tool comprising:

- an elongate member with a distal tip, the distal tip shaped and dimensioned so as to fit within a lumen of the body, the elongate member shaped and dimensioned so as to extend from outside the body, through an entry site on the body and into the lumen; and

- the distal tip comprising a plurality of elements arranged there upon and coupled to the distal tip such that biasing of the distal tip towards the prostate, engages one or more of the elements with a wall of the lumen;

wherein the plurality of elements comprises an array of electrodes arranged on a face of the distal tip such that biasing of the distal tip towards the wall of the lumen brings the electrodes into intimate contact with the prostate through the wall of the lumen;

wherein the array of electrodes arranged on the face of the distal comprises one or more imaging elements, one or more sensing elements and a plurality of energy delivery elements; and

wherein the plurality of energy delivery elements are configured to be individually controlled based on feedback from one or more of the imaging elements and

sensing elements to direct energy into surrounding tissues with a desired pattern and desired penetration depth.

[0015] In aspects, the surgical tool may include one or more imaging elements coupled to the distal tip, configured to couple with tissues in the vicinity of the prostate upon biasing of the distal tip towards the prostate. Some non – limiting examples of imaging elements include one or more of an ultrasound transducer array, an ultrasound element, a transducer, a piezoelectric element, an optical coherence tomography (OCT) element, a capacitive micromachined ultrasound transducer, a camera, an infrared camera, a near infrared camera, a deep tissue penetrating imaging element, a fiber optic array, a combination thereof, or the like.

[0016] In aspects, the imaging element may be configured to convey information about a neural structure in the vicinity of the prostate to an operator during operation of

the surgical tool. Some non-limiting examples of information include~~s~~ the location, health state, a quantity, blood flow to, blood flow through, temperature, a stiffness, and/or changes therein, of an artery, a vein, a nerve, a neural plexus, a prostatic plexus, a prostatic artery, a dorsal nerve, a cavernous nerve, a vesical plexus, a hypogastric nerve, a splanchnic nerve, a pudendal nerve, an organ, a urethra, the prostate, a reference point, a combination thereof, or the like.

[0017] In aspects, one or more of the sensing elements may be configured to monitor one or more physiological signals associated with a tissue in the vicinity of the prostate while engaged with the wall, the electrophysiological signals related to one or more of water concentration, tissue tone, evoked potential, remotely stimulated nervous activity, sympathetic nervous activity, an electromyographic signal [EMG], a mechanomyographic signal [MMG], a local field potential, an electroacoustic event, vasodialation, vessel wall stiffness, muscle sympathetic nerve activity [MSNA], central sympathetic drive, nerve traffic, a combination thereof, or the like.

[0018] In aspects, one or more of the sensing elements may include an electrode for monitoring one or more of the physiological signals, and/or may be electrically coupled with a microcircuit, the microcircuit configured to condition one or more of the signals conveyed therefrom.

[0019] In aspects, the microcircuit may be embedded into the surgical tool and at least a portion of the electrical coupling may be provided via the elongate member.

[0020] In aspects, one or more of the sensing elements may include a microelectrode configured to interface with an adjacent tissue volume within or beyond the wall of the lumen while engaged with the wall, the microelectrode having an area of less than 5000μm^2~~squm~~, less than 1000μm^2~~squm~~, less than 250μm^2~~squm~~, or less than 100μm^2~~squm~~.

[0021] In aspects, the surgical tool may include a plurality of sensing elements arranged upon and coupled to the distal tip, the sensing elements configured to collectively map electrophysiological activity in the vicinity of the prostate while engaged with the wall.

[0022] In aspects, one or more of the energy delivery elements may be configured to provide a radio frequency current, a microwave current, thermal energy, cryoablating action, ultrasound energy, a combination thereof, or the like to a volume of tissue in the vicinity of the prostate while engaged with the wall.

[0023] In aspects, one or more energy delivery elements may include one or more stimulating electrodes electrically and mechanically coupled to the distal tip and/or the elongate member, the stimulating electrodes configured to provide a stimulating and/or ablating current to a tissue site in the vicinity of the prostate while engaged with the wall. In aspects, one or more of the stimulating electrodes may have an area of greater than 0.1sqmm^2, 0.5sqmm^2, 1sqmm^2, 2sqmm^2, or 10sqmm^2.

[0024] In aspects, a surgical tool in accordance with the present disclosure may include a fluid delivery means for providing a coupling fluid to the distal tip to enhance the engagement of one or more of the sensing elements, imaging elements, and/or energy delivery elements with the wall when biased there against, and/or to protect the wall during the passage of energy there through.

[0025] In aspects, one or more chemical delivery elements may include one or more probes mechanically, fluidly, and/or electrically coupled with the distal tip, arranged so as to penetrate through the wall upon engagement there with or upon a deployment procedure, one or more of the probes including a lumen configured to deliver a diagnostic and/or therapeutic substance to a tissue site beyond the wall of the lumen, and/or including one or more electrodes each in accordance with the present disclosure.

[0026] In aspects, one or more of the sensing elements may be configured to monitor the effect of the diagnostic and/or therapeutic substance on the tissue site and/or tissues related thereto.

[0027] In aspects, the diagnostic and/or therapeutic substance may be selected from a chemical, a drug substance, a neuromodulating substance, a neuroblocking substance, an acid, a base, a denervating agent, a combination thereof, or the like.

[0028] In aspects, the therapeutic substance may include a neutotoxin, a botulinum toxin, a tetrodotoxin, a tetraethylammonium, a chlorotoxin, a curare, a conotoxin, a

[0034] In aspects, one or more of the feedback signals may be related to an electrode impedance, a bioimpedance, a local electrical field, and/or an electrophysiological response to the pulsatile and/or radio frequency signal, an analyte level, a hormone level, water concentration, tone, blood oxygen saturation of local tissues, evoked potential, stimulation/sensing of nervous activity, electromyography, temperature, blood pressure, vasodilation, vessel wall stiffness, muscle sympathetic nerve activity (MSNA), central sympathetic drive (e.g. bursts per minute, bursts per heartbeat, etc.), tissue tone, blood flow (e.g. through an artery, through a renal artery), a blood flow differential signal (e.g. a significantly abnormal ~~and~~ and/or sudden change in blood flow within a structure of the body, a vessel, an organ, etc.), blood perfusion (e.g. to an organ, an eye, etc.), a blood analyte level (e.g. a hormone concentration, norepinephrine, catecholamine, renine, angiotensin II, an ion concentration, a water level, an oxygen level, testosterone, etc.), a state of inflammation within an organ, a change in growth rate of an organ, nerve traffic (e.g. post ganglionic nerve traffic in the peroneal nerve, celiac ganglion, superior mesenteric ganglion, aorticorenal ganglion, renal ganglion, carotid body, splanchnic nerve, hypogastric nerves, testicular plexus, vesical plexus, prostatic plexus, and/or related nervous system structures), combinations thereof, and the like.

[0035] In aspects, the control unit may be configured to locate a target treatment site with respect to one or more components of the surgical tool based upon one or more of the signals, and/or to exclude an anatomical site from a surgical procedure based upon one or more of the signals.

[0036] According to aspects there is provided, a method for altering the physiological function of a tissue site in the vicinity of a prostate of a subject including altering the function of one or more nerves or neural receptors belonging to and/or coupled to a prostatic plexus of the subject.

[0036A] According to aspects there is provided a method for altering a recording of electrophysiological signals generated by one or more nerves or neural receptors belonging to and/or coupled to a prostatic plexus of a subject, comprising: delivering energy and/or a chemical substance to a tissue site in the vicinity of a prostate of the subject; and recording one or more electrophysiological signals in the vicinity of the

nerves, the neural receptors, the prostatic plexus, the prostate, a penis, a testicle, or a neural structure related thereto.

[0037] In aspects, the altering of function may be accomplished via delivery of energy, and/or delivery of a chemical substance to the nerves, the receptors, the prostatic plexus, or a neural structure coupled thereto.

[0038] In aspects, the altering of function may be accomplished via an ablation, an excision, a cut, a burn, a radio frequency ablation, a cryoablation, a radiosurgical

[0085] As used herein, the term "treating" a medical condition encompasses therapeutically regulating, preventing, improving, alleviating the symptoms of, reducing the effects of and/or diagnosing the medical condition. As used herein, the term "medical condition" encompasses any condition, disease, disorder, function, abnormality, or deficit influenced by the autonomic nervous system. Further, the systems and methods of the present disclosure can be used to treat more than one medical condition concurrently. Non-limiting examples of medical conditions that can be treated according to the present disclosure include genetic, skeletal, immunological, vascular or hematological, muscular or connective tissue, neurological, ocular, auditory or vestibular, dermatological, endocrinological, olfactory, cardiovascular, genitourinary, psychological, gastrointestinal, respiratory/pulmonary, neoplastic, or inflammatory medical conditions. Further, the medical condition can be the result of any etiology including vascular, ischemic, thrombotic, embolic, infectious (including bacterial, viral, parasitic, fungal, abscessal), neoplastic, drug-induced, metabolic, immunological, collagenic, traumatic, surgical, idiopathic, endocrinological, allergic, degenerative, congenital, or abnormal malformational causes.

[0086] The present systems and methods also encompass~~es~~ enhancing the therapeutic effects of other therapies, such as methods and systems working in conjunction with a pharmaceutical agent or other therapies to augment, enhance, improve, or facilitate other therapies (adjunctive therapies) as well as reducing/minimize and counteracting side effects, complications and adverse reactions for any therapies involved in treating the above-mentioned medical conditions. For example, the methods and systems of the present disclosure may be used for a cancer patient undergoing chemotherapy utilizing stimulation and/or sympathectomy to minimize the adverse effects of chemotherapy, influence the development of a tumor, etc. In contrast, the methods and systems can be used to enhance chemotherapy.

[0087] In aspects, one or more organs or target tissue sites to be treated in accordance with the present disclosure may be accessed via incision, via rectum, transurethral access, transcutaneous access, interventionally (e.g. access via the femoral artery, access to nerve plexuses running along arteries serving one or more of the organs in question, etc.).

nerve/nerve plexus coupled thereto and injecting a chemical denervation agent in accordance with the present disclosure into the tissues so as to provide the desired denervation. The method may include directing the delivery device into the organ / nerve (such as with an imaging probe, via an imaging modality (e.g. via CT, MRI, PET, etc.).

[0098] In aspects, a method in accordance with the present disclosure may include cutting through tissue to reach the selected anatomy, inspecting the selected anatomy, visualizing which tissues are to be treated, which are to be preserved, and the like, and applying the appropriate surgical procedures to treat the tissues.

[0099] In aspects, the method may include treating the LUT organ, and/or nerves coupled thereto via a radiosurgical approach, etc. (e.g. such as by using a CyberKnife™ to thermally / radiosurgically affect the target tissues), as identified in images created by an associated imaging system (e.g. an MRI, CT, PET scan, etc.).

[00100] In aspects, one or more steps of a method and/or one or more aspects of a surgical tool each in accordance with the present disclosure may be accomplished by and/or coupled to a robotic surgical system (e.g. a DaVinci system™, etc.).

[00101] In aspects, a method in accordance with the present disclosure may include considering nerve locations, imaging nerves, mapping nerves, etc.

[00102] In aspects, a method may include diagnosing and/or treatment of one or more neurological structures. Such diagnostics may be performed with an ultrasonic probe (e.g. an ultrasonic probe to assess the state of the organ, if the organ is large, if the organ has changed since the last checkup, etc.), an electrophysiological~~electrophysiolgical~~ monitor (e.g. an electrode array configured to monitor neural traffic in the vicinity of the organ, to determine a baseline activity, etc.). The method may include performing a surgical procedure in accordance with the present disclosure if the diagnostic step indicates that such a procedure is necessary (e.g. the organ growth rate is abnormally high, excess neural traffic is present around the organ, an abnormally high degree of innervation is visualized around the organ, etc.).

[00103] A method in accordance with the present disclosure may include assessing one or more properties of the organ (e.g. size, diameter, change in anatomy, urethral

vicinity thereof, to map, locate, identify, monitor, and/or evaluate function of the prostate 1, and/or nerves 3a, 3b, 3c.

[00108] The surgical tool 100 may be coupled 120 to a controller and/or one or more circuits each in accordance with the present disclosure. The controller and/or circuits may be configured to interface with one or more of the energy delivery elements 110, imaging elements, probes, electrodes, or the like included in the distal tip of the surgical tool 100.

[00109] In aspects, the surgical tool 100 may include one ~~of~~ or more imaging elements in accordance with the present disclosure, such as an ultrasound transducer. The imaging element may be configured to send energy 140 towards or receive energy from the prostate 1, or the nerves 3a, 3b, 3c, so as to image one or more aspects thereof, as part of a procedure.

[00110] In aspects, the surgical tool 100 may include a means for delivering fluid to the face 130 during a procedure. Such a configuration may be advantageous to cool the wall of the rectum 5 during energy delivery to the surrounding tissues, but may also be advantageous for improving electrical, mechanical, ~~and~~ and/or acoustic coupling of the energy delivery elements 110, imaging elements, probes, electrodes, or the like with the wall of the rectum 5 during a procedure.

[00111] Fig. 2 shows aspects of a system configured for a combination of transrectal and transurethral therapy in accordance with the present disclosure. The system includes a transrectally insert able surgical tool 200 sized and shaped so as to be inserted into the rectum 5 of a subject, the transrectally insert able tool including one or more faces 205 arranged along the tip of the transrectally insert able tool 200 such that it can be biased against a wall of the rectum 5 to interface with one or more organs (e.g. prostate 1, urethra 2, bladder, nerves 3a, 3b, 3c) during a surgical procedure, a diagnostic test, a follow-up procedure, or the like. The face 205 may include one or more electrodes 210 or probes configured for interfacing with tissues in the vicinity thereof during a surgical procedure. The transrectally insert able surgical tool 200 may be coupled to a controller 220 or one or more circuits in accordance with the present disclosure, the controller 220 or circuits coupled to one or more of the electrodes 210, configured to delivery energy to

fiber optic array, or the like to image, locate, and interface with one or more tissues in the vicinity of the target organ or nerves.

[00120] In aspects, the electrodes 415 may be provided in accordance with the present disclosure, configured to deliver energy to the tissues as part of a surgical procedure, etc.

[00121] In aspects, the electrodes 415, and imaging head 410 may be coupled 405 to a controller or circuit each in accordance with the present disclosure.

[00122] Fig. 4b illustrates a distal tip of a transrectally insert able surgical tool 420 including a contoured surface for easy placement into the rectum of a subject as part of a surgical procedure. The surgical tool 420 includes an array 430 of electrodes 435 each in accordance with the present disclosure configured to interface with adjacent tissues during a procedure. One or more electrodes 435 may include a non-stick coating, be coupled to a cooling element, etc. in order to assist with the flow or energy and/or protect the surrounding tissues during a procedure.

[00123] One or more of the electrodes 435 may be coupled 425 to a controller in accordance with the present disclosure. Energy may be directed into the surrounding tissues via electrodes 435 in the array 430, the pattern, penetration depth, etc. being a function of the enlisted electrodes 435, control of current flow through the electrodes, completion of the circuit with a counter electrode arranged elsewhere on the body (e.g. transurethrally, within the bladder, on the skin, etc.), between electrodes, etc. In aspects, the controller may include a switching array, and optionally feedback to assist with the management of current flow through the electrodes.

[00124] The system may include or be coupled to a display to summarize and assist with visualization of current flow for an operator (i.e. so as to assist with ensuring only the target tissues are treated with a procedure, etc.).

[00125] Fig. 4c shows a schematic of a distal tip of a transrectally insert able surgical tool 440 in accordance with the present disclosure. The surgical tool ~~404~~ 440 includes dual tips 441, 442 and a deployment mechanism such that the dual tips 441, 442, may be closely packed during delivery to the surgical site and may be actuated 445 so as to form a cupping surface. Such a configuration may be advantageous for providing a simple

monitor electrophysiological activity near to a tip of the probe 600a, the larger electrode 605a located along the shank of the probe 600a may be configured to provide a counter electrode function, a reference electrode function, or the like. In aspects, energy may be delivered in the form of an RF current from the tip electrode 605b into the surrounding tissues, perhaps using the larger electrode 605a as a return path for the current. In aspects, the probe 600a includes a lumen for delivery of a fluid 610a in accordance with the present disclosure into the treatment zone 615a. Fig. 6a also shows a probe 600b including a lumen configured to facilitate delivery of a fluid 610b to a treatment zone 615b in accordance with the present disclosure.

[00139] In aspects, one or more of the probes 605a, 605b~~652a, 652b~~ may be transcutaneously inserted into the body in order to access one or more of the treatment zones ~~656a,b~~615a,b. Alternatively, additionally, or in combination one or more of the probes 605a, 605b ~~652a, 652b~~ may be delivered along an artery or vein in the subject to reach the treatment zones ~~656a,b~~615a,b.

[00140] In aspects, one or more of the probes 600a, 600b may be guided towards a corresponding treatment zone 615a,b through guidance with an imaging system, an ultrasound guided insertion imaging system, or the like.

[00141] In aspects, the fluid 610a,b may be a temporary neural blocking agent, a receptor selective neuroblocking and/or neurotoxic agent, etc. In aspects, the fluid 610a,b may be a neural agonistic agent to increase receptor activity at an associated site.

[00142] Fig. 6b shows a prostate 1, a urethra 2, and a plurality of treatment zones 640a,b located near the surface of the prostate 1. A transurethrally insert able surgical tool 620 in accordance with the present disclosure is shown placed within the urethra 2 with the distal tip thereof located within the boundaries of the prostate 1. The transurethrally insert able surgical tool 620 may include a plurality of probes 624a – e, deploy ably coupled to an elongate member 638 of the transurethrally insert able surgical tool 620. The probes 624a – e may be slidingly deployed 628 into the prostate 1 from the elongate member of the transurethrally insert able surgical tool 620 during a deployment procedure. The tips of the probes 624a – e may be inserted into or placed near to one or more intended treatment zones 640a,b. The elongate member 638 may include one or

more lumens 626 along which the probes 624a – e may be located within the transurethrally insert able surgical tool 620.

[00143] A first probe 624d is shown with a plurality of electrodes 632a,b configured for monitoring electrophysiological activity in the vicinity thereof before, during, and/or after a procedure. In aspects, the electrodes 632a,b may be configured to delivery energy in the form of an RF current into the surrounding tissues, one of the electrodes 632~~b,a~~a,b, an electrode 636 on the elongate member 638 or a remotely placed electrode may act as a return path for the current. In aspects, one or more of the probes 624b or the elongate member 638 may include a lumen and/or port 634 for delivery of a fluid 630 in accordance with the present disclosure into the treatment zone 640b.

[00144] In aspects, one or more of the probes 624a – e may be guided towards a corresponding treatment zone 640a,b through guidance with an imaging system, an ultrasound guided insertion imaging system, or the like. In aspects, a surgical planning session may be used to determine a distance d through which the probes 624a – e may be deployed 628 during a procedure to best interface with the treatment zones 640a,b. Such a distance may be used when selecting the transurethrally insert able surgical tool 620. Each of the probes 624a – e may be configured with a stop in order to control the distance into the prostate 1 that they may be deployed during a procedure.

[00145] In aspects, the fluid 630 may be a temporary neural blocking agent, a receptor selective neuroblocking and/or neurotoxic agent, etc. In aspects, the fluid 630 may be a neural agonistic agent to increase receptor activity at an associated site.

[00146] Fig. 6c shows a prostate 1, a urethra 2, and a plurality of treatment zones 656a,b located near the surface of the prostate 1. Multiple probes 652a, 652b are shown along with a transurethrally insert able surgical tool 650, each in accordance with the present disclosure, the probes 652a, 652b having been advanced 654 into the vicinity of the prostate 1 and the transurethrally insert able surgical tool 650 inserted into the urethra 2 and positioned with a corresponding electrode region 662 arranged within the prostate 1 for the purpose of interfacing with tissues therein. A first probe 652a is shown with a plurality of electrodes 658a, 658b, configured for monitoring electrophysiological activity in the vicinity thereof before, during, and/or after a procedure. In aspects, the tip

electrode 658b may be configured as a microelectrode to monitor electrophysiological activity near to a tip of the probe 652a, the larger electrode 658a located along the shank of the probe 652a may be configured to provide a counter electrode function, a reference electrode function, or the like. In aspects, energy may be delivered in the form of an RF current 660a,b from the tip electrode 658b, into the surrounding tissues (i.e into a treatment zone 656b), optionally using the larger electrode 658a as a return path for the current 660a, or using ~~communicating~~ communication with the transurethrally insert able surgical tool 650 for the return path of the current 660b.

[00147] Fig. 6c also shows a probe 652b including a lumen configured to facilitate delivery of a fluid 655 to a treatment zone 656a in accordance with the present disclosure.

[00148] In aspects, one or more of the probes 652a, 652b may be transcutaneously inserted into the body in order to access one or more of the treatment zones 656a,b. Alternatively, additionally, or in combination one or more of the probes 652a, 652b may be delivered along an artery or vein in the subject to reach the treatment zones 656a,b.

[00149] In aspects, one or more of the probes 652a, 652b may be guided towards a corresponding treatment zone ~~615a,b~~656a,b through guidance with an imaging system, an ultrasound guided insertion imaging system, communication with the transurethrally insert able surgical tool 650, or the like.

[00150] In aspects, the transurethrally insert able surgical tool 650 may include one or more electrodes 662 (optionally for sensing, energy delivery, etc.), or fluid delivery means 664 for purposes of cooling the urethra 2, interfacing with adjacent tissues, etc.

[00151] In aspects, the fluid 655 may be a temporary neural blocking agent, a receptor selective neuroblocking and/or neurotoxic agent, etc. In aspects, the fluid 655 may be a neural agonistic agent to increase receptor activity at an associated site.

[00152] In aspects, one or more of the probes 652a, 652b, and/or the transurethrally insert able surgical tool 650 may be coupled 668, 666, 670 with a controller in accordance with the present disclosure, to facilitate the interaction with the surrounding tissues, etc.

member 740 includes one or more sensors, electrodes 745, or the like, configured to interface with a surrounding tissue, and/or the transrectally insert able surgical tool 700 during a surgical procedure. The elongate member 740 may include an actuatable region 752 configured such that upon advance of the tip into a bladder 4, the tip may be bent 755 so as to bias the sensors, electrodes 745, or the like against the bladder wall 8 as part of a placement, nerve locating, or monitoring procedure, or the like.

[00158] In aspects, the elongate member 740 may include a lumen for providing a fluid, a cooling agent, a medication, a denervating agent, a diagnostic fluid, etc. to the bladder 4 as part of a diagnostic test, a surgical procedure, a monitoring procedure, etc.

[00159] In aspects, the face 705 may include one or more probes in accordance with the present disclosure, the probes arranged in a protruding configuration from the face 705, one or more probes configured to bias into, or penetrate through the wall of the rectum 5 during a procedure.

[00160] In aspects, the elongate member 740 may include one or more probes in accordance with the present disclosure, slidingly attached thereto, the probes being configured and arranged so as to be deployably inserted into the wall of the bladder, and/or tissues of the prostate 1 during a procedure.

[00161] In aspects, the transrectally insert able surgical tool 700 may include one ~~of~~ or more imaging elements in accordance with the present disclosure (situated along the face 705), such as an ultrasound transducer. The imaging element may be configured to send energy ~~760~~ 770 towards or receive energy from the prostate 1, urethra 2, bladder 4, or the nerves 3a, 3b, 3c, so as to image one or more aspects thereof, as part of a procedure.

[00162] Figs. 8a-d show aspects of methods for treating an organ in accordance with the present disclosure.

[00163] Fig. 8a shows aspects of a method for treating a target tissue including accessing and locating the target tissue 801, optionally monitoring one or more electrophysiological signals from at least a region of the target tissue and assessing if the ranges are normal or abnormal. If the ranges are normal, accessing an alternative region of the target tissues and monitoring again, or aborting the procedure. The act of

accessing alternative regions of the target tissues may include orienting or reorienting the tool 803. Once the correct target tissue has been located, and/or if the electrophysiological activity in the measured tissues is abnormal, the method may include treating the tissue, forming one or more ablations 805 in the vicinity of the tissue (e.g. stimulate, ablate, administer a chemical, etc.), or the like. Optionally, after performing a treatment, the region of the target tissue may be monitored to determine if the electrophysiological activity has changed, is now within a normal range, if a block has occurred, etc. (i.e. ~~a~~ determine if there has been a successful outcome for the treatment), or if the signals are still abnormal and require further treatment, alternative treatment, or the like.

[00164] In aspects, the method may include reorienting the tool 803 to adjust a contact pressure, adjust an electrode placement against a tissue site (such as along a bowel wall, along an artery coupled to the target organ, etc.), testing another region of the target tissue, treating one or more regions of the target tissue, including one or more steps from a method in accordance with the present disclosure, performing any step of the procedure with a system in accordance with the present disclosure, or the like.

[00165] Fig. 8b shows aspects of a method for treating a target tissue including biasing an energy delivery element and/or sensing element towards a prostate 809, locating the nerves to be treated 811 (e.g. the nerves of the prostatic plexus, receptors located on or near the surface of the prostate, etc.), and selectively treating 813 the nerves, receptors, tissues, etc. In aspects, the selectively treating 813 includes sparing nerves that are meant to be preserved during the treatment (such as the pudendal nerves, the dorsal nerves of the penis, etc.). Such selectivity may be provided by one or more sensors in accordance with the present disclosure, one or more imaging elements, a sensation felt by the subject during a stress test, or the like.

[00166] In aspects, the method may include accessing the target tissue, and testing at least a region of the accessed tissue with a stimulus in accordance with the present disclosure, while monitoring the response thereof. If the response to the stimulus indicates that the accessed tissue is not the intended target of the therapy (e.g. if the local receptors do not respond to the stimulus, the local receptors respond within a normal

cervicothoracic ganglia, spinal cord segments T1 to L3 (explicitly shown in FIG. 9 are segments T10-L4); sympathetic ganglia (including paravertebral ganglia and prevertebral ganglia), paravertebral sympathetic chain, thoracic and lumbar sympathetic ganglia, nerve plexuses in communication with sympathetic ganglia, dorsal roots, ventral roots, dorsal root ganglia, dorsal rami, ventral rami, white rami communicans, gray rami communicans, and recurrent meningeal branches, all emerging from spinal cord segments T1 to L3; T1 to L3 spinal nerves; and any combination of the above from one or both of the sympathetic nerve chains. Thoracic and lumbar ganglia and prevertebral ganglia and their associated sympathetic structures include the cardiac, celiac, mesenteric (superior and inferior), renal, hypogastric, and intermesenteric (abdominal aortic) ganglia as well as ganglia associated with glands such as hepatic or adrenal glands. Nerve plexuses include prevertebral plexuses such as the superior and inferior hypogastric (pelvic) plexus. Target sites also include the thoracic, lumbar, and sacral splanchnic nerves.

[00173] The spermatic plexus (or testicular plexus) is derived from the renal plexus, receiving branches from the aortic plexus. It accompanies the internal spermatic artery 19 to the testis.

[00174] The prostatic plexus of the male is derived from the larger nerves of the anterior portion of the inferior hypogastric plexus and lies alongside the prostate gland. It supplies the prostate gland, the prostatic urethra and the ejaculatory duct. The prostatic plexus also gives rise to the cavernous nerves of the penis, which are mainly parasympathetic and responsible for relaxation of smooth muscle allowing blood to flow into cavernous spaces in the corpora of the penis resulting in erection. Sympathetic stimulation causes ejaculation and vasoconstriction resulting in remission of an erection. Relating to the treatment of a disease of the prostate, nerves coupled with the prostatic plexus, arranged along a branch thereof, or the like, may be treated in accordance with the present disclosure. Such treatment may result in a decrease of neurotransmitter release within the prostate, a decrease in inflammation within the prostate, may alter the growth-rate of the prostate, may favorably alter the microenvironment of a prostate tumber, or the like.

1013, actuating one or more aspects of the surgical tool 1010, deploying one or more probes, etc.

[00184] Fig. 10 shows a probe 1020 in accordance with the present disclosure, having been transcutaneously inserted into a body so as to access one or more potential treatment sites. The probe 1020 may include one or more electrodes 1021a,b each in accordance with the present disclosure, and may include one or more lumens to deliver a chemical substance 1022 as part of a treatment, diagnostic, stimulation, ablation, surgical procedure, etc. in accordance with the present disclosure. Some non-limiting examples of target sites 1016, 1017, 13, 9, 11 are shown for treating one or more aspects of the testis, prostate, epididymis, etc.

[00185] Fig. 10 shows schematic diagrams for a plurality of distal tips 1013, each in accordance with the present disclosure. A distal tip 1024, including an array of probes 1027, each with an electrode 1028 situated at the tip thereof, is shown, with the array 1027 being confined by a collar 1026, the exposure of which may be used to deploy the array 1027 at a surgical site within a subject. The distal tip 1024 includes a microcircuit 1025 embedded therein and coupled with the electrodes 1028 of the array 1027. The microcircuit 1027 may include one or more preamplifiers for amplifying signals measured at one or more of the electrodes 1028, one or more switches for directing stimulating and/or ablating current flow to one or more of the electrodes 1028, one or more multiplexing circuits, analog to digital converters, digital communication circuits, or the like to communicate between the distal tip 1024 and a controller 1015.

[00186] A double cage distal tip 1030 is shown including an array of wire probes 1036a-b, each wire probe 1036a-b mechanically bound at a tip 1035. The wire probes 1036a-b may include one or more electrodes 1032a-f, each configured to interface with a wall of a lumen adjacent thereto, for communicating a stimulating or ablating current 1034 there between, for monitoring electrophysiological signals, or the like. The distal tip 1030 may include a sleeve, the retraction 1031 of which may be suitable for deploying the double cage wire probes 1036a-b and interfacing the electrodes 1032a-f with the wall of a lumen into which it has been placed.

[00187] Fig. 10 shows a balloon catheter based distal tip 1040 including a balloon 1042 with a plurality of electrodes 1044 or fluid delivery aspects. The balloon 1042 may be deployed 1050 within a lumen in a body in order to bring the electrodes 1044 into intimate contact with a potential treatment site. The balloon tip ~~1035~~ 1046 of the balloon catheter based distal tip 1040 may be suitable for safely advancing the distal tip 1040 through the lumen without puncturing the wall thereof during deployment to a target treatment site.

[00188] Fig. 10 shows a deploy able probe based distal tip 1052 including one or more probes 1054 each in accordance with the present disclosure. Collectively the probes 1055 may be deployed 1056 so as to bias against, or penetrate through an adjacent lumen wall during a procedure to access a potential target treatment site.

[00189] Fig. 10 shows a single cage distal tip 1060 including a sheath 1062 arranged along the length thereof, retraction 1068 of the sheath 1062 exposing/deploying one or more arms 1064 of a cage, each arm 1064 including one or more sensing elements, electrodes 1066, etc.

[00190] Fig. 10 shows a guidewire based distal tip 1070 including a shape changing region 1072 (e.g. a region that may be controllably deployed via an actuation, retraction of a core element 1076, actuation of an electroactive material, etc.), which may transition from a substantially straight shape to a "deployed" shape, suitable for biasing 1078 one or more electrodes, sensing elements, energy delivery elements, or the like against the wall of a lumen into which the guidewire based distal tip 1070 has been placed. The guidewire based distal tip 1070 may include one or more electrodes 1074, sensing elements, etc. for applying energy to a tissue, monitoring the effect thereof, monitoring electrophysiological information in the vicinity of the surgical site, etc.

[00191] Fig. 11 shows a schematic of aspects of a system in accordance with the present disclosure. The system includes a surgical tool 1115 in accordance with the present disclosure, which may be connected to a controller 1110 in accordance with the present disclosure. The controller 1110 may include one or more signal conditioning circuits, RF generation units, fluid delivery aspects, and/or pulse generators, configured

to facilitate one or more methods in accordance with the present disclosure. The controller 1110 may be coupled to a feedback subsystem 1105.

[00192] The feedback subsystem 1105 may be configured to display data associated with a surgical procedure, physiological data associated with a monitoring session, graphically display data associated with a mapping process, audibly display data associated with electrophysiological activity, etc.

[00193] Figs. 12a-b show aspects of methods in accordance with the present disclosure.

[00194] Fig. 12a shows aspects of a method for treating a target tissue including inserting a surgical tool into a lumen within a body 1210 such as an artery, a vein, a ureter, a duct, or the like, locating and interfacing one or more elements of the tool with the target tissue along the lumen wall or a branch thereof, and optionally monitoring one or more physiological signals from at least a region of the target tissue or site related. The act of accessing the target tissues may include deploying one or more elements of the tool. Once the target tissue has been located and interfaced with, the method may include treating the tissue, forming one or more ablations in the vicinity of the tissue (e.g. stimulate, ablate, administer a chemical, etc.), modulating neural traffic 1220 in the vicinity of the target tissue, or the like, and after completion of the procedure, removing the tool from the body 1230. The act of neuromodulating may include ablating, stimulating, delivering a stimulant or depressant to the target tissues, or the like.

[00195] Fig. 12b shows aspects of a method for treating a target tissue including inserting a tool into a lumen within the body 1240 and delivering one or more elements of the tool to the target tissue located in the vicinity of the lumen or a branch thereof, measuring one or more electrophysiological signals 1250 associated with the adjacent organ or neural plexus, target tissue, tissues associated therewith, and modulating 1260 the electrophysiological signals, ~~829~~ the nerves, receptors, tissues, etc. The method may include further monitoring 1270 to determine the extent of the procedure, the state of tissues or nerves surrounding the site that are meant to be spared, etc. and determining if further treatment is necessary, or if the treatment is sufficient. If the treatment is

sufficient the method includes completing the procedure 1280, withdrawing tools from the body, etc.

[00196] In aspects, the further monitoring 1270 may include monitoring tissues in the vicinity of the surgical site that are meant to be preserved during the treatment (such as the pudendal nerves, the dorsal nerves of the penis, etc.). Such monitoring may be provided by one or more sensors in accordance with the present disclosure, one or more imaging elements, feedback relating to a sensation felt by the subject during a stress test, or the like.

[00197] Figs. 13a-b show aspects of methods in accordance with the present disclosure. Fig. 13a shows aspects of a method for treating a target tissue including accessing the target tissue 1301, optionally monitoring one or more electrophysiological signals from at least a region of the target tissue, applying a temporary treatment 1303 in the vicinity of the tissue (e.g. stimulate, ablate, administer a chemical, etc.)~~. D~~, and determining if the temporary treatment was effective (e.g. by monitoring, evaluating the state of the subject, querying the subject, monitoring nerve traffic, etc.). If the temporary treatment was effective, durably treating 1307 the target tissue. If the temporary treatment was ineffective, the method may include adjusting the positioning and/or setting on the tool and/or the therapy 1305 and applying another temporary treatment 1303 to the target tissue or a site related thereto.

[00198] In aspects, the method may include testing another region of the target tissue, treating one or more regions of the target tissue, including one or more steps from a method in accordance with the present disclosure, performing any step of the procedure with a system in accordance with the present disclosure, or the like.

[00199] Fig. 13b shows aspects of a method for treating a target tissue including accessing the target tissue 1331, optionally monitoring one or more electrophysiological signals from at least a region of the target tissue, applying a temporary treatment 1333 in the vicinity of the tissue (e.g. stimulate, ablate, administer a chemical, etc.). Monitoring one or more physiological signals 1335 from the target site or a site related thereto in accordance with the present disclosure to determine if the treatment was effective (e.g. by monitoring, evaluating the state of the subject, querying the subject, monitoring nerve

aspects, the feedback may be used to control the bias force of the distal tip 1400 against the adjacent tissues. Such bias force may contribute to an altering of local electrophysiological function. By controlling the force or the effects thereof, a potentially improved image of the local electrophysological signals may be captured. In aspects, the force may be altered so as to modify a "depth of activity" whereby tissues nearest to the face 1405 may be rendered temporarily inoperative by the force of the bias force, and the measured electrophysiological signals may be characteristic of tissues further way from the face 1405 than otherwise.

[00203] Fig. 14b shows an image 1430 obtained from a collection of contact points 1440 created by an array of sensing elements 1435 in accordance with the present disclosure in contact with an anatomical site in the body. The image demonstrates propagation of a wave 1460 across the contact points 1440 and illustrates the direction of travel of the wave 1450, 1445 to one or more future sites 1455, 1465. The image and location of the contact points 1440 within the image may be determined from the known positioning of sensing elements on a distal tip in accordance with the present disclosure (e.g. along a face of a distal tip, along a surface of a balloon coupled with a distal tip, etc.). In aspects, the positioning of the sensing elements against the wall may not be known a priori (i.e. in an arrangement with freely moving probes protruding from a distal tip, etc.). In aspects, the positioning of sensing elements within the array may be, at least partially determined from the sensed signals, through correlation of wave propagation throughout the array during a monitoring session. In aspects, a wave propagation algorithm may be used to approximate the positioning of one or more sensing elements against the wall during the monitoring, etc. Other aspects of such configurations are discussed throughout this disclosure.

[00204] Fig. 15 shows aspects of a stimulator in accordance with the present disclosure. Aspects relating to two non-limiting examples of stimulators 1510, 1550 are shown. The first stimulator 1510 may include a power source (e.g. such as a battery, an energy harvesting circuit, etc.), a processor, a pulse generator, etc. in order to communicate one or more stimulating pulses via one or more cables 1520, to one or more electrodes 1530 so as to apply a stimulating pulse in accordance with the present disclosure to one or more neural structures in accordance with the present disclosure.

the probe through a target tissue, precisely placing one or more regions of the probe within a target tissue, etc.

[00223] In aspects, one or more probes may include a microneedle electrode, configured such that at least a portion thereof (e.g. a tip, a shank, a region, a plurality of regions, etc.) may be configured so as to facilitate electrical communication with one or more target tissues adjacent thereto, one or more probes, and/or one or more external electrodes as part of a deployment, monitoring, or treating procedure.

[00224] In aspects, a probe may include an array of electrodes, configured so as to assist with determination of a local field gradient, configured so as to monitor a plurality of sites along the length of the probe, to provide a configurable electrode arrangement for sensing, stimulation, ablation, etc.

[00225] In aspects, one or more electrodes may be arranged with an active area (i.e. area available to electrically interface with adjacent tissues) of less than $10mm^2$, less than $1mm^2$, less than $0.1mm^2$, less than 10,000μm^2~~um^2~~, less than 1,000μm^2~~um^2~~, less than 100μm^2~~um^2~~, less than 1μm^2~~um^2~~, etc. Alternatively, one or more electrodes may be configured so as to form electrical impedance in normal saline of greater than 100ohm, greater than 1kohm, greater than ~~100kokm~~100kohm, greater than 1Mohm, greater than 10Mohm, greater than 50Mohm, etc.

[00226] In aspects, one or more probes may be configured with a characteristic width (i.e. a dimension perpendicular to a length measurement thereof, for example, a diameter), of less than 1mm, less than 200μm~~um~~, less than 100μm~~um~~, less than 50μm~~um~~, less than 12μm~~um~~, less than 3μm~~um~~, etc. Such characteristic width may vary along the length of the probe. In aspects, one or more probes may be tapered to a fine tip (e.g. a tip with less than 5μm~~um~~ radius of curvature, less than 1um radius of curvature, etc.) so as to more easily be advanced through tissues during a procedure.

[00227] In aspects, one or more regions of a probe or elongate member in accordance with the present disclosure may be coated with a substance and/or treated so as to be lubricious in the presence of water. Some non-limiting examples of such coatings include a hydrophilic coating, a silicone coating, a PTFE coating, parylene, a ceramic, PEBAX, a hydrogel, etc. Some non-limiting examples of such treatments include vapor

deposition of a ceramic, a polymer, an ion treatment process, an electroplating process, dip process, etc. Such coating may provide for easier deployment as part of a surgical procedure in accordance with the present disclosure.

[00228] In aspects, one or more probes may include a tip fashioned with a tip electrode (e.g. an exposed region of the probe suitable for electrically interfacing with a surrounding tissue, with one or more probes, an external electrode, etc.). In aspects, the tip electrode may be arranged so as to provide a microscopic interface over a length at an end of the probe less than 150μm~~um~~, less than 50μm~~um~~, less than 20μm~~um~~, less than 10μm~~um~~, less than 1μm~~um~~, and the like. Such a configuration may be suitable for spatially precise monitoring of local field potentials during a procedure (e.g. during monitoring of electrophysiological activity, during a denervation procedure, during placement of the probe, etc.). In aspects, the tip electrode may be arranged so as to provide an intermediately sized interface along the length of the probe, greater than 50μm~~um~~ but less than 1mm, greater than 100μm~~um~~ but less than 500μm~~um~~, or the like. Such an arrangement may be suitable for stimulating local tissues, for monitoring overall electrophysiological activity around a volume of tissue, to act as a reference electrode, and the like. In aspects, the tip electrode may be configured along a length of the probe greater than 100μm~~um~~, greater than 500μm~~um~~, greater than 1mm, greater than 2mm, and the like. Such an arrangement may be advantageous for providing a sufficiently high current to surrounding tissues in the vicinity of the electrode, for example, during a hyperpolarizing stimulation, during an ablation procedure, to substantially affect tissues in the vicinity of the tip electrode, and the like.

[00229] In aspects an electrode in accordance with the present disclosure may be formed from an electrically and/or ionically conductive material. Some non-limiting examples of electrode materials include gold, platinum, platinum iridium, stainless steel, tungsten, iridium, palladium, rhodium, organic conducting polymer modified materials, poly(acetylene)s, poly(pyrrole)s, poly(thiophene)s, poly(terthiophene)s, poly(aniline)s, poly(fluorine)s, poly(3-alkythiophene)s, polytetrathiafulvalenes, polynapthalenes, poly(p-phenylene sulfide), poy(para-phenylenevinylene)s, poly(3,4-ethylenedioxy thiophene) (PEDOT), poly(3,4-ethylenedioxythiophe)/poly(styrenesulfonate)(PEDOT/PSS), polyfuran, polyindole, polycarbazole, nanorods, nanotubules, carbon nanotubes, carbon

probes, and/or one or more probes and an external electrode (e.g. a patch electrode, an electrode placed elsewhere in the body, etc.).

[00247] In aspects, one or more of the circuits may be configured to administer a current pulse and/or radiofrequency signal to one or more regions of the target tissue for a period of 250seconds, 100seconds, 10seconds, 1second, less than 1second, etc. via one or more energy delivery elements (e.g. electrodes). In aspects, the current pulse and/or radiofrequency signal may be administered with sufficiently high current, so as to heat one or more regions of the target tissue to a predetermined value within the designated time period. Due to the placement of the probes into the target tissue, a rapid heating pulse may be administered to effectively heat the target tissues to a therapeutic level (e.g. to a temperature above 40°C, above 50°C, above 60°C, above 70°C, etc.). Such heating may be applied with a duty cycle, such that the mean temperature rise in the vicinity of the electrode may be approximately 40°C, 50°C, 60°C, etc. while the transient temperatures and electric fields experienced by adjacent tissues may vary with modulation thereof.

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[00248] In aspects, one or more circuits may be configured to administer one or more stimulatory pulses to the surrounding tissue during use. Such stimulatory pulses may be configured with amplitude, pulse width, repetition rates, etc. at significant values so as to generate a response in the target tissues without causing substantial damage thereto.

[00249] Radiofrequency current may be applied with a frequency of greater than 50kHz, greater than 500kHz, greater than 1MHz, greater than 300MHz (i.e. into the microwave spectrum), etc. Radiofrequency signals may be modulated with a predetermined and/or variable duty cycle, managed by a user, by an automatic control algorithm, etc.

[00250] In aspects, one or more of the circuits may be configured to administer a pulse (e.g. a current controlled pulse, a voltage controlled pulse, a trailing edge pulse, etc.) to one or more regions of the target tissue. In aspects, the circuits may be configured to administer a hyperpolarizing pulse to one or more regions of the target tissue. Such a pulse may be advantageous for suppressing neuronal activity from one or more nerves in the vicinity of the target tissue. Such a configuration may be advantageous for reducing

lumen. In aspects, the system may be configured to monitor muscular sympathetic nerve activity (MSNA) in a wall of a lumen, an artery, a vein, a nerve plexus, etc. Related activity may be monitored in the vicinity of one or more sensory afferent nerves, motor efferent nerves, sympathetic, and/or parasympathetic nerves in the vicinity thereof. Thus a correlation between associated nerve traffic may be related to the firing rate of sensory afferents may be directly determined from stimulation of receptors, whether in muscles, tendons, or skin. The same may be true for efferent signals travelling to smooth muscle located within a lumen wall.

[00255] In aspects, the system may be configured to monitor nerve traffic along a nerve and/or nerve plexus (e.g. part of ~~a~~ the sympathetic nervous system, autonomic nervous system, parasympathetic nervous system, celiac plexus, a renal nerve plexus, a carotid plexus, an enteric plexus, a vagus nerve plexus, nerve associated with the LUT, prostatic plexus, testicular plexus, hypogastric plexus, pancreatic plexus, a nerve fiber terminating within the pancreas, and the like), near to a nerve ganglion (e.g. a celiac ganglion, a mesenteric ganglion, lumbosacral plexus, sphenopalatine ganglion, etc.), within a nerve ganglion, near to a receptor, amongst collections thereof, and the like. Such a configuration may be advantageous to monitor electrophysiological activity of a subject as part of a patient selection process (e.g. as part of a patient selection process for an implant, as part of a device function, a pre-surgical procedure, a denervation procedure, etc.), during a surgical procedure (e.g. so as to assess changes in electrophysiological activity associated with one or more aspects of the surgical procedure), as follow-up to a surgical procedure (e.g. as an assessment of the completeness of the surgical procedure, of the durability of the surgical procedure, so as to schedule for a follow-on surgical procedure, etc.).

[00256] In aspects, a system in accordance with the present disclosure may be placed for chronic monitoring of electrophysiological activity in the wall of the lumen, within tissue of the organ (e.g. the prostate, the bladder wall, etc.). Such a configuration may be advantageous for monitoring trends in electrophysiological activity (e.g. parasympathetic activity, sympathetic activity, nerve traffic, MSNA, related afferent/efferent traffic, etc.) over a prolonged period of time, and/or within environments unsuitable for acute study (e.g. for a period following a surgical procedure, as part of a long-term follow-up

procedure, as part of a clinical study, etc.). Such a configuration may be advantageous in systems for inferring the stress state of a subject, for contribution to a system for managing the stress state of a subject, for feedback into a neuro-activity modulation system, or the like.

[00257] In aspects, one or more probes (e.g. flexible elements, needles, or the like) may be oriented into an arch, an anchor, a spiral, etc. so as to provide an interlocking action with the wall of the lumen. Such a configuration may be advantageous for anchoring and/or orienting one or more aspects of one or more probes to the wall of the lumen. Such anchoring may be advantageous for retaining one or more aspects of the system during a procedure, during monitoring, etc. Such anchoring may be advantageous for aligning one or more aspects of the system during a treatment, during a chronic monitoring session, etc.

[00258] In aspects, a system in accordance with the present disclosure may be configured and used to alter the sensitivity of one or more regions of an organ in a body to a stimulus. A non-limiting list of organs for which such a procedure may be performed include a gall bladder, a kidney, a small intestine, a stomach, a large intestine, a spleen, a pancreas, a bladder, an adrenal gland, a prostate, a lung, a uterus, or the like. In aspects, such alteration may be achieved through substantially controlled ablation of one or more regions of the organ, one or more sensory nerves, and/or one or more receptors associated therewith coupled with the organ, or the like. In aspects, such a procedure may be completed at least in part with a system in accordance with the present disclosure.

[00259] In aspects, a system in accordance with the present disclosure may be used to alter a physiological function within the body. Some non-limiting examples of functions which may be altered by the system include a sensation (e.g. a hunger sensation, an urge to urinate, etc.), a tremor, altering release/secretion of a chemical substance (e.g. one or more acids, neurotransmitters, hormones, toxins, bile, enzymes, surfactants, sebum, renin, etc. from a secretory cell), or the like. Such a system may be used to treat a disease of the LUT, gall bladder, intestines, to augment hunger sensation, reduce sympathetic tone (e.g. overall, and/or related to one or more sympathetic branches, etc.), altering the local

the vicinity thereof (e.g. such as a region of tissue on or near a prostate, a length of nerves in the vicinity of the lumen into which the guidewire has been placed, etc.). In aspects, the guidewire may be coated with a substantially non-conducting material (such as PTFE, silicone, polyurethane, PEBAX™, etc.), one or more internal wires of the guidewire exposed near the tip thereof to provide an electrode via which energy may be delivered to a surrounding tissue (e.g. as part of a surgical procedure, etc.). In aspects, the guidewire tip may include a monopolar electrode, and the system may include an additional electrode configured for placement on the skin of, within the urethra of, within the rectum of, the subject so as to provide a counter electrode for the guidewire tip. An RF or MW current passed between the guidewire tip electrode and the additional electrode may be as part of the surgical procedure, etc.

[00266] In aspects, the system may include one or more guard electrodes, coupled to the elongate member or a secondary member, coupled with one or more circuits so as to direct a current thereby/through. One or more circuits may be configured so as to communicate/control an electrical signal between one or more of the guard electrodes and one or more of the probes/electrodes. Such communication may be advantageous for controlling an electric field generated thereby, to control current flow through one or more probes/electrodes and one or more guard electrodes, to minimize current flow through tissues adjacent to the guard electrodes, etc.

[00267] In aspects, the system may include one or more stabilizing members (e.g. a balloon, an anchor, a curved leg, etc.) coupled to the elongate member, configured to brace and/or position one or more regions of the elongate member near to or against the wall of a lumen during use (e.g. so as to stabilize the elongate member within a rectum, within an artery, etc.). One or more of the stabilizing members may be configured so as to be deploy able during use (e.g. so as to move from a first, stored position, to a second deployed position upon actuation).

[00268] In aspects, one or more stabilizing members may include a balloon, the balloon configured so as to take on a shape when actuated (i.e. when a fluid bolus is delivered into the balloon). The balloon may be configured to brace and/or orient at least

a region of the elongate member with respect to the wall of a lumen during a procedure. In

aspects, the balloon may be shaped so as to allow for fluid passage thereby even when it is deployed. Some non-limiting shapes (i.e. cross sections oriented along a plane substantially perpendicular to the elongate member) of balloons include a rectangular shape, a ring, a toroid, a gear-like, a flower-like shape, a quatrefoil, an oval, an ellipse, a crescent, a star, a blunted star, a hypocycloid, a hypotrochoid, a rose, a cardiod, a vane, a ribbon, combinations thereof, and the like.

[00269] In aspects, one or more of the stabilizing members may include a flexible member, coupled to the elongate member, optionally deploy able therefrom during use (e.g. via use of a retractable sheath, by an actuation mechanism in accordance with the present disclosure, etc.). Some non-limiting examples of flexible members include coils, hooks, clips, leaf spring elements, mesh, netting, bistable forms, cantilever beams, and the like. The flexible member may be maintained in close proximity to the elongate member in a stored position (e.g. retractably stored within the elongate member, stored between the elongate member and a sheath, etc.) and configured so as to bias away from the elongate member (i.e. deploy) during use (e.g. through actuation of the flexible member, push actuation of the flexible member, retraction of an associated sheath, sliding of the flexible member along the length of the elongate member, etc.).

[00270] In aspects, one or more stabilizing members and/or probes may include an active material element. Control signals delivered to the active material element may help to bias the stabilizing members and/or probes towards the lumen wall, towards the target tissues, actively control the bias force between the stabilizing member and a lumen wall, etc. Some non-limiting examples of active materials that may be suitable for application to one or more probes and/or stabilizing members include shape memory materials (e.g. shape memory alloys, polymers, combinations thereof), electroactive polymers (e.g. conjugated polymers, polypyrrole, dielectric elastomers, piezoelectric polymers, electrets, liquid crystals, graft elastomers, polyvinylidene fluoride, combinations thereof, derivatives thereof, etc.), piezoceramics (e.g. amorphous piezoceramics, single crystals, composites, etc.). In addition the active material may be used as a vibratory exciter and/or mechanical probe, for use in monitoring the tone of the adjacent tissues. Alternatively, in addition or in combination, such active materials may be used to cause vibratory/ultrasonic ablation and/or local heating to the tissues during a

procedure. In aspects, one or more stabilizing members and/or probes may be configured so as to actuate (e.g. in this case, to change shape, alter a bias force, etc.) so as to bias and/or orient one or more aspects of the system against a wall of an associated lumen (i.e. a lumen into which the at least a portion of the system is deployed during a surgery) and/or reorient the component with respect to the target tissue.

[00271] In aspects, one or more stabilizing members may be actuate-able so as to cling to the wall of an associated lumen during use. In one non-limiting example, the stabilizing member may be configured so as to close the tip thereof in a pinch-like configuration, as a pincer like configuration, etc. so as to fasten to the wall of an associated lumen during use. In one non-limiting example, a stabilizing member includes a shape memory alloy (e.g. a Nitinol® material) configured so as to undergo shape change when placed inside the body of a subject (i.e. so as to transition between a first shape and a second shape upon increase in temperature due to placement within a warm body). In aspects, a stabilizing member including a shape memory alloy may be configured to change shape (e.g. curl, twist, bend, etc.) upon heating with a control current (i.e. as provided by one or more circuits coupled thereto). Such a configuration may be advantageous for controllably fastening one or more aspects of a system in accordance with the present disclosure to a wall of an associated lumen.

[00272] In aspects, one or more probes may include an active material configured so as to assist with orientation during passage into/through the wall of a lumen during surgery. Such a configuration may be advantageous for guiding a probe through the wall of a lumen, towards a target tissue. Additionally, alternatively, or in combination one or more of the probes may include a radiopaque (i.e. radiodense) material (e.g. a titanium, tungsten, zirconium oxide, metal filled polymers, barium sulfate, bismuth compounds, platinum, gold, palladium, combinations thereof, and the like). Such a configuration may be advantageous for visualizing one or more aspects of a probe (e.g. shape, orientation, position with respect to a target tissue, etc.) during a procedure within a body.

[00273] In aspects, a system in accordance with the present disclosure may include a plurality of probes, the probes configured so as to protrude at least somewhat radially from an associated elongate member, such that one or more of the probes may bias

against and/or penetrate into the wall of an adjacent lumen during use. The system may include one or more circuits configured to interface with one or more of the probes, such that a current (e.g. a radiofrequency current, a modulated current, a microwave current, etc.) may be passed between two or more probes and/or between one or more probes and an additional electrode (i.e. an electrode placed elsewhere on/in the body). Such a configuration may be advantageous for treating regions of target tissue in the vicinity of the lumen. In aspects, current may be passed through two or more probes so as to treat target tissues along the length of the lumen (i.e. in a direction substantially longitudinal to the lumen), along a path substantially circumferential to the lumen (i.e. in a path arching around the center of the lumen), radially out from the lumen (i.e. in a path directed substantially outwardly from the center of the lumen), combinations thereof, or the like. A longitudinal treatment may be advantageous for treating a collection of target tissues (e.g. nerve fibers, etc.) along the length thereof, so as to controllably limit the rate of reinnervation after the procedure.

[00274] In aspects, one or more circuits and/or processors included in a system in accordance with the present disclosure may be coupled to a sensory electrode and may be configured to assess functionality of one or more regions of target tissue in the vicinity of the sensory electrode before, during, and/or after a treatment. The circuits and/or processors may be configured to monitor nerve activity in the vicinity of the sensory electrode and to ~~extract~~ extract/distinguish between changes in such activity before, during, and/or after a process. In aspects, the circuits and/or processors may be configured to extract one or more metrics of signal activity from the monitored signals, some non-limiting examples of such activity include spectral power density thereof, spike count rates, integrated signal strength, and the like. Such metrics may be used to determine the effect of a procedure on the local electrophysiological activity in the vicinity of the sensory electrode, to control a surgical procedure (i.e. the extent of a denervation process), to predict the outcome of a procedure, and the like.

[00275] In aspects, one or more probes may be moved (e.g. retracted, nudged, etc.) during a procedure (i.e. during an ablation procedure). Such movement may be used to controllably increase the region of treatment during a procedure.

[00285] In aspects, the method may include administering a fluid bolus to one or more regions of the target tissue. In aspects, the method may include monitoring neurological activity in the vicinity of one or more electrodes to determine a change in activity after administration of the bolus.

[00286] In aspects, the method may include tracking the position of one or more aspects of a probe with an imaging system such as an MRI, fMRI, PET, CT scanner, with an ultrasonic probe, or the like.

[00287] In aspects, the method may include robotically steering one or more of the probes to access the target tissue.

[00288] In aspects, the method may include ablating at least a region of the target tissue. In aspects, the method may include monitoring a change in neurological activity after at least a portion of the ablation procedure.

[00289] In aspects, the method may include placement of a probe substantially near to a receptor within the target tissue (e.g. within 2mm, within 1mm, within 100μm~~um~~, etc.).

[00290] In aspects, the method may include passing a therapeutic current longitudinally along the length of the lumen, radially out from the lumen, and/or circumferentially around the lumen. Such therapeutic current may be passed between one or more probes in accordance with the present disclosure.

[00291] In aspects, a system in accordance with the present disclosure may include a probe with a bent and/or twisted tip. Such a probe may be suitable for steerable guidance through a tissue, so as to controllably advance the probe towards the target tissue. The system may include one or more controls (e.g. manual controls, levers, knobs, mechanized/servo controls, actuators, motors, etc.) coupled to the probe so as to enable advancement, retraction, and/or rotation thereof during a procedure in accordance with the present disclosure.

[00292] In aspects, one or more probes may be bendable, so as to flexibly access one or more regions of the target tissue during a procedure.

[00293] In aspects, a system in accordance with the present disclosure may be used to automatically locate a target tissue and/or electrophysiologically rich region within a

[00298] In aspects, the system may include a plurality of probes (e.g. 3 or more, 5 or more, 8 or more, etc.), arranged along the elongate member both circumferentially (i.e. around the circumference of the elongate member) as well as along the length thereof (e.g. advancing from the elongate member from one or more regions along the length thereof, a first region near the tip of the elongate member and a second region within 30mm, within 20mm, within 10mm of the first region). In aspects, the probes may be arranged such that deployment thereof outwardly from the elongate member will result in orientation of the elongate member within the lumen (i.e. substantially stabilizing the elongate member within the lumen during deployment). In aspects, the elongate member may include 1 or more deployment regions, each deployment region including 3 or more probes equally spaced around the circumference thereof (e.g. 3 probes 120°~~deg~~, 4 probes 90°~~deg~~, etc.). Such a configuration may be advantageous to maintain the orientation of the elongate member during a deployment process of the probes into an adjacent lumen wall.

[00299] A system/surgical tool in accordance with the present disclosure may be used to access and to treat one or more sensory receptors: Ampullae of Lorenzini (respond to electric field, salinity, temperature, etc.), baroreceptors, chemoreceptors, hydroreceptors, mechanoreceptors, nociceptors, osmoreceptors (osmolarity sensing), photoreceptors, proprioceptors, thermoreceptors, combinations thereof, and the like.

[00300] In aspects, a surgical tool in accordance with the present disclosure may include the capability to sense one or more physiological parameters at one or more points around a surgical site, as well as include the capability to stimulate and/or ablate tissues at one or more of the same points and/or an alternative point around a surgical site. The nerve ablation system may be configured so as to access vessels and/or surgical sites in the body. The non-limiting examples disclosed herein may be directed towards such configurations (e.g. so as to controllably ablate renal nerves along a renal artery via an endoscopic procedure, to ablate nerves coupled with a prostate along a prostatic artery, branch thereof, to ablate nerves coupled with a prostate from a transrectally placed probe, to ablate nerves coupled with a prostate from a transcutaneously delivered needle, etc.).

[00301] In aspects, one or more electrodes in accordance with the present disclosure may be configured to apply/receive an RF current to/from the surrounding tissue. The RF current may be provided locally between two ~~of~~ or more electrodes, or alternatively between one or more electrodes and a macroelectrode placed elsewhere on the body (e.g. on a large skin patch over the surgical site, an electrode placed on another organ, as selected from multiple patches placed over the body, in an associated catheter electrode, etc.). In a non-limiting example where current is restricted to being applied between electrodes, the path for current flow may be well controlled, yet may be highly localized. Alternatively, in an example where RF current is passed between one or more electrodes and one or more macroelectrodes, the current flow may be more challenging to control, but may be used to access tissues more remote from the sensing elements (e.g. farther into the adjacent tissues, deeper into a region of target tissue, from a monopolar guidewire electrode, from a microelectrode configuration, etc.).

[00302] In aspects, a system in accordance with the present disclosure may include one or more circuits to simultaneously engage one or more electrodes with the flow of an RF current during an ablation process. In aspects, the local impedance measured between electrodes may be monitored and/or controlled so as to better optimize the current delivered thereto. Additionally, alternatively, or in combination, the local current flow through each electrode may be monitored so as to determine the path of the RF current flow, to ensure no leakage currents are detected, etc. Such information may be used to better control the delivery of RF currents to the target tissues during an ablation procedure.

[00303] In aspects, an externally placed (e.g. onto the body of the subject) light source (e.g. infrared, near infrared, visible, etc.) may be directed into the body towards the surgical site, target tissues, and/or lumen. The light source may optionally be modulated to provide a more easily detected signal within the subject. One or more probes may be equipped with optical microsensors that may sense light emitted from the light source. The mapping of received light may be used to locate~~d~~ anatomical features such as nerves near to one or more of the optical microsensor equipped probes during a procedure.

[00310] In aspects, one or more probes may be sufficiently hyper elastic (e.g. formed from a memory alloy material, a superelastic material, etc.) so as to effectively deploy from a very small deployment tube and expand outward to larger tissue areas over which to monitor/treat. Such a configuration may be advantageous in so far as a small number of unit sizes may be suitable for treating a wide range of anatomical structures. In addition, the designed curvature and form of a probe may be substantially chosen so as to further enable a wide deploy able range of movement during a procedure.

[00311] One or more aspects of a probe may be formed from a polymer, a thermoplastic, a polyurethane, a silicone, an elastomer, silk fibroin materials, combinations thereof, or the like. Inclusion of microporous or fibrous substrates, may be advantageous to allow one or more regions of the probe to adhere to the adjacent tissues via capillary effects (i.e. tendencies to wick fluid from adjacent tissues into the substrate). The thickness of films formed from the material may be less than 30μm~~um~~ thick, less than 20μm~~um~~, less than 10μm~~um~~, less than 4μm~~um~~, less than 1μm~~um~~. Composites of somewhat stiffer materials (such as polyimide, PET, PEN, etc.) and somewhat softer materials (e.g. silicones, polyurethanes, thermoplastic elastomers, etc.) maybe used to compromise between overall structural stiffness and conformal capabilities.

[00312] Patterned overcoats and/or composite layers may also be used to expose electrode materials and/or probe tips to the surrounding tissues in the vicinity of measurement regions, etc.

[00313] In one non-limiting example, one or more elements of a probe may be formed from a silk material (e.g. Bombyx mori cocoons). The material may be processed to remove sericin (which may cause undesirable immunological response) using methods known in the art. The resulting material can be solvent cast into shapes and crystallized to form self-supporting structures or insulation along a probe, a structural support for a probe, etc.

[00314] Alternatively, additionally or in combination the ascribed sensing techniques may be combined with stimulation from local sources. Such stimulation and sensing may be advantageous in determining functionality of local nerves without the need to listen to complex biologically generated nervous activity. Furthermore, combined stimulation and

[00351] In aspects, some non-limiting examples of remote physiological parameters that may be monitored during before, during, and/or after a procedure include water concentration, tone, blood oxygen saturation of local tissues, evoked potential, stimulation/sensing of nervous activity, electromyography, temperature, blood pressure, vasodilation, vessel wall stiffness, muscle sympathetic nerve activity (MSNA), central sympathetic drive (e.g. bursts per minute, bursts per heartbeat, etc.), tissue tone, blood flow (e.g. through an artery, through a renal artery), a blood flow differential signal (e.g. a significantly abnormal ~~and~~ and/or sudden change in blood flow within a structure of the body, a vessel, an organ, etc.), blood perfusion (e.g. to an organ, an eye, etc.), a blood analyte level (e.g. a hormone concentration, norepinephrine, catecholamine, renine, angiotensin II, an ion concentration, a water level, an oxygen level, testosterone, etc.), a state of inflammation within an organ, a change in growth rate of an organ, nerve traffic (e.g. post ganglionic nerve traffic in the peroneal nerve, celiac ganglion, superior mesenteric ganglion, aorticorenal ganglion, renal ganglion, carotid body, splanchnic nerve, hypogastric nerves, testicular plexus, vesical plexus, prostatic plexus, and/or related nervous system structures), combinations thereof, and the like.

[00352] The updated remote physiological signal and/or reference remote physiological signal may be combined and/or compared with one or more reference signals, and/or one or more updated signals in order to determine the extent of completion.

[00353] The method may include selecting a surgical location. The step of selection may depend upon one or more monitoring steps, proximity to an alternative surgical location (e.g. a previously treated surgical location, a new location, etc.). The step of selecting may include stimulating local tissues and determining if the stimulation results in excitation of a neural structure, the function of which is to be preserved (such as a pudendal nerve function, etc.), which may be assessed via querying sensation of a subject, etc. and altering the stimulation location until the sensation is no longer felt (i.e. such that the treatment site is sufficiently remote from a neural structure that is to be preserved).

in blood pressure, a blockage of blood flow, etc.). Such a system may be advantageous for assessing the responsiveness and/or sensitivity of one or more tissue regions to the stimulus.

[00386] The system may be configured to treat one or more of the tissue regions, to subsequently apply the stimulus and assess a change in the response thereto.

[00387] According to aspects there is provided, a method for altering the growth rate of an organ, including denervating and/or altering (e.g. increasing, decreasing, oscillating, etc.) the functionality of one or more neurons and/or neurological structures (e.g a nerve plexus, a ganglion, etc.) coupled to the organ or a hormone releasing organ associated therewith.

[00388] In aspects, the organ may be a prostate gland, a testicle, an ovary, an organ of the lower urinary tract, or the like.

[00389] In aspects, one or more of the neurons may belong to a corresponding sympathetic or parasympathetic nervous system, or afferent nerves associated with the organ.

[00390] In aspects, the step of denervating and/or altering the functionality may be accomplished via a surgical procedure (e.g. a denervation procedure, a partial denervation procedure, an ablation, an ultrasonic ablation, a chemical denervation, a radiological denervation, a dissection, a thermal treatment, a mechanical disruption, combinations thereof, or the like).

[00391] In aspects, the method may include one or more of insertion of a surgical tool in accordance with the present disclosure into the rectum of a subject, insertion of a surgical tool in accordance with the present disclosure into the urethra of a subject, biasing the surgical tool towards the organ, scanning the surface of the organ to locate one or more target tissues/features (e.g. nodules, nerves, lymphnodes, or the like) thereupon, ~~the~~ directing energy towards one or more of the target tissues/features, locating one or more of the nerves, marking one or more of the target tissues/features, monitoring one or more of the target tissues/features, displaying and/or mapping one or more of the target tissues/features, combinations thereof, and the like.

[00392] In aspects, the method may include insertion of a surgical tool in accordance with the present disclosure transcutaneously into the tissues surrounding the organ.

[00393] In aspects, the method may include insertion of a surgical tool in accordance with the present disclosure transurethrally so as to position it against the organ.

[00394] In aspects, the method may include directing energy between a first surgical tool and a second surgical tool each in accordance with the present disclosure, the first surgical tool having been positioned within the urethra and the second surgical tool having been positioned within the rectum of the subject.

[00395] In aspects, the method may include mapping and/or imaging one or more regions of the organ, so as to locate and/or identify one or more of the target tissues/features. The step of mapping and/or imaging may be accomplished using ultrasound (transcutaneous, transrectal, transurethral, etc.), radiological imaging, magnetic resonant imaging, PET imaging, electrophysiological mapping, combinations thereof, or the like, etc.

[00396] In aspects, the method may include monitoring electrophysiological activity in, on, or near to the organ, and/or one or more nerves coupled thereto. The step of monitoring electrophysiological activity may be accomplished with one or more surgical tools in accordance with the present disclosure.

[00397] In aspects, the step of ~~a~~ monitoring may include, monitoring one or more electrophysiological signals in a tissue included in and/or coupled to the organ to establish one or more characteristics thereof, applying a therapy to the organ and/or tissue coupled thereto, and monitoring the electrophysiological signals again to assess if there was a change in one or more of the characteristics. The step of monitoring may include performing the treatment until the electrophysiological signals have been altered so as to reach a predetermined level (e.g. reduced to a predetermined activity level, reduced by a percentage of an initially measured activity level, etc.).

[00398] The method may include testing the response of target tissue to a stimulus to determine if the target tissue is that which is intended for treatment, if not, adjusting the placement of one or more probes and repeating the test.

WHAT IS CLAIMED IS:

1. A surgical tool for monitoring and/or altering electrophysiological activity within the vicinity of a prostate within a body, the surgical tool comprising:

- an elongate member with a distal tip, the distal tip shaped and dimensioned so as to fit within a lumen of the body, the elongate member shaped and dimensioned so as to extend from outside the body, through an entry site on the body and into the lumen; and
- the distal tip comprising one or more sensing elements, energy delivery elements, and/or chemical delivery elements arranged there upon and coupled to the distal tip such that biasing of the distal tip towards the prostate, engages one or more of the elements with a wall of the lumen.

2. The surgical tool in accordance with claim 1, comprising one or more imaging elements coupled to the distal tip, configured to couple with tissues in the vicinity of the prostate upon biasing of the distal tip towards the prostate.

3. The surgical tool in accordance with claim 2, wherein the imaging element comprises one or more of an ultrasound transducer array, an ultrasound element, a transducer, a piezoelectric element, an optical coherence tomography (OCT) element, a capacitive micromachined ultrasound transducer, a camera, an infrared camera, a near infrared camera, a deep tissue penetrating imaging element, a fiber optic array, or a combination thereof.

4. The surgical tool in accordance with claim 2 or 3, wherein the imaging element is configured to convey information about a neural structure in the vicinity of the prostate to an operator during operation of the surgical tool.

5. The surgical tool in accordance with claim 4, wherein the information pertains to the location, health state, a quantity, blood flow to, blood flow through, temperature, a stiffness, and/or changes therein, of an artery, a vein, a nerve, a neural plexus, a prostatic plexus, a prostatic artery, a dorsal nerve, a cavernous nerve, a vesical plexus, a hypogastric nerve, a splanchnic nerve, a pudendal nerve, an organ, a urethra, the prostate, a reference point, or a combination thereof.

6. The surgical tool in accordance with any preceding claim, wherein one or more of the sensing elements are configured to monitor one or more physiological signals associated with a tissue in the vicinity of the prostate while engaged with the wall, the electrophysiological signals related to one or more of water concentration, tissue tone, evoked potential, remotely stimulated nervous activity, sympathetic nervous activity, an electromyographic signal [EMG], a mechanomyographic signal [MMG], a local field potential, an electroacoustic event, vasodialation, vessel wall stiffness, muscle sympathetic nerve activity [MSNA], central sympathetic drive, nerve traffic, or a combination thereof.

7. The surgical tool in accordance with claim 6, wherein one or more of the sensing elements comprises an electrode for monitoring one or more of the physiological signals.

8. The surgical tool in accordance with any preceding claim, wherein one or more of the sensing elements are electrically coupled with a microcircuit, the microcircuit configured to condition one or more of the signals conveyed therefrom.

9. The surgical tool in accordance with claim 8, wherein the microcircuit is embedded into the surgical tool and at least a portion of the electrical coupling is provided via the elongate member.

10. The surgical tool in accordance with any preceding claim, wherein one or more of the sensing elements comprises a microelectrode configured to interface with an adjacent tissue volume within or beyond the wall of the lumen while engaged with the wall, the microelectrode having an area of less than 5000squm, less than 1000squm, less than 250squm, or less than 100squm.

11. The surgical tool in accordance with any preceding claim, comprising a plurality of sensing elements arranged upon and coupled to the distal tip, the sensing elements configured to collectively map electrophysiological activity in the vicinity of the prostate while engaged with the wall.

12. The surgical tool in accordance with any preceding claim, wherein one or more of the energy delivery elements is configured to provide a radio frequency current, a microwave current, thermal energy, cryoablating action, and/or ultrasound energy, to a volume of tissue in the vicinity of the prostate while engaged with the wall.

13. The surgical tool in accordance with any preceding claim, one or more energy delivery elements comprises one or more stimulating electrodes electrically and mechanically coupled to the distal tip and/or the elongate member, the stimulating electrodes configured to provide a stimulating and/or ablating current to a tissue site in the vicinity of the prostate while engaged with the wall.

14. The surgical tool in accordance with any preceding claim, comprising a fluid delivery means for providing a coupling fluid to the distal tip to enhance the

engagement of one or more of the sensing elements, imaging elements, and/or energy delivery elements with the wall when biased there against, and/or to protect the wall during the passage of energy there through.

15. The surgical tool in accordance with any preceding claim, wherein one or more chemical delivery elements comprises one or more probes mechanically, fluidly, and/or electrically coupled with the distal tip, arranged so as to penetrate through the wall upon engagement there with or upon a deployment procedure, one or more of the probes comprising a lumen configured to deliver a diagnostic and/or therapeutic substance to a tissue site beyond the wall of the lumen.

16. The surgical tool in accordance with any one of claims 16 or 17, wherein the diagnostic and/or therapeutic substance is selected from a chemical, a drug substance, a neuromodulating substance, a neuroblocking substance, an acid, a base, a denervating agent, or a combination thereof.

17. The surgical tool in accordance with any one of claims 16 – 18, wherein the therapeutic substance is a selected from a neurotoxin, a botulinum toxin, a

tetrodotoxin, a tetraethylammonium, a chlorotoxin, a curare, a conotoxin, a bungarotoxin, arsenic, ammonia, ethanol, hexane, nitric oxide, glutamate, resiniferatoxin, alchohol, phenol, capaicin, an anesthetic, lidocaine, tetanus toxin, quaternary ammonium salts, a pachycurare, a leptocurare, acetylcholine, aminosteroids, or a combination thereof.

18. The surgical tool in accordance with any preceding claim, wherein the lumen is a rectum, a urethra, an artery, a vein, or a duct.

19.

20. A method for altering the physiological function of a tissue site in the vicinity of a prostate of a subject comprising: altering the function of one or more nerves or neural receptors belonging to and/or coupled to a prostatic plexus of the subject.

21. A method for altering a recording of electrophysiological signals generated by one or more nerves or neural receptors belonging to and/or coupled to a prostatic plexus of a subject, comprising: delivering energy and/or a chemical substance to a tissue site in the vicinity of a prostate of the subject; and

recording one or more electrophysiological signals in the vicinity of the nerves, the neural receptors, the prostatic plexus, the prostate, a penis, a testicle, or a neural structure related thereto.

22. The method in accordance with claim 19 or 20, wherein the alteration is accomplished via delivery of energy, and/or delivery of a chemical substance to the nerves, the receptors, the prostatic plexus, or a neural structure coupled thereto.

23. The method in accordance with any one of claims 19 to 21, wherein the alteration is accomplished via an ablation, an excision, a cut, a burn, a radio frequency ablation, a cryoablation, a radiosurgical procedure, an ultrasonic ablation, an abrasion, delivery of a substance, or a combination thereof.

24. The method in accordance with any one of claims 19 to 22, comprising accessing the nerves, the receptors, or the prostatic plexus with a

guidewire or surgical tool inserted into a prostatic artery or an artery coupled thereto, and/or a prostatic venous plexus or vein coupled thereto.

25. The method in accordance with claim 19, comprising recording one or more electrophysiological signals in the vicinity of the nerves, the neural receptors, the prostatic plexus, the prostate, a penis, a testicle, or a neural structure related thereto.

26. The method in accordance with claim 20 or 24, comprising confirming, and/or determining the extent of the altering of function based upon the recording.

27. The method in accordance with any one of claims 20, 24 and 25, comprising determining an adverse effect of the altering of function on one or more of the related neural structures based upon the recording, the adverse effect being related to a change in function of the related neural structures.

CLAIMS

1. A surgical tool for monitoring and/or altering electrophysiological activity within the vicinity of a prostate within a body, the surgical tool comprising:

- an elongate member with a distal tip, the distal tip shaped and dimensioned so as to fit within a lumen of the body, the elongate member shaped and dimensioned so as to extend from outside the body, through an entry site on the body and into the lumen; and

- the distal tip comprising a plurality of elements arranged there upon and coupled to the distal tip such that biasing of the distal tip towards the prostate, engages one or more of the elements with a wall of the lumen;

wherein the plurality of elements comprises an array of electrodes arranged on a face of the distal tip such that biasing of the distal tip towards the wall of the lumen brings the electrodes into intimate contact with the prostate through the wall of the lumen;

wherein the array of electrodes arranged on the face of the distal comprises one or more imaging elements, one or more sensing elements and a plurality of energy delivery elements; and

wherein the plurality of energy delivery elements are configured to be individually controlled based on feedback from one or more of the imaging elements and sensing elements to direct energy into surrounding tissues with a desired pattern and desired penetration depth.

2. The surgical tool in accordance with claim 1, wherein the one or more imaging elements are configured to couple with tissues in the vicinity of the prostate upon biasing of the distal tip towards the prostate, wherein information obtained from the one or more imaging elements is utilized to control energy delivery from the plurality of energy delivery elements to focus energy delivery on a target tissue in the vicinity of the prostate while minimizing energy delivery to an adjacent tissue site.

3. The surgical tool in accordance with claim 2, wherein the one or more imaging elements comprises one or more of an ultrasound transducer array, an ultrasound

element, a transducer, a piezoelectric element, an optical coherence tomography (OCT) element, a capacitive micromachined ultrasound transducer, a camera, an infrared camera, a near infrared camera, a deep tissue penetrating imaging element, a fiber optic array, or a combination thereof.

4. The surgical tool in accordance with claim 2 or 3, wherein the one or more imaging elements are configured to convey information about a neural structure in the vicinity of the prostate to an operator during operation of the surgical tool.

5. The surgical tool in accordance with claim 2 or 3, wherein the one or more imaging elements are configured to convey information to an operator during operation of the surgical tool, the information pertaining to the location, health state, a quantity, blood flow to, blood flow through, temperature, and/or a stiffness, and/or changes therein, of an artery, a vein, a nerve, a neural plexus, a prostatic plexus, a prostatic artery, a dorsal nerve, a cavernous nerve, a vesical plexus, a hypogastric nerve, a splanchnic nerve, a pudendal nerve, an organ, a urethra, the prostate, a reference point, or a combination thereof.

6. The surgical tool in accordance with any preceding claim, wherein one or more of the sensing elements are configured to monitor one or more physiological signals associated with a tissue in the vicinity of the prostate while engaged with the wall, the electrophysiological signals related to one or more of water concentration, tissue tone, evoked potential, remotely stimulated nervous activity, sympathetic nervous activity, an electromyographic signal [EMG], a mechanomyographic signal [MMG], a local field potential, an electroacoustic event, vasodialation, vessel wall stiffness, muscle sympathetic nerve activity [MSNA], central sympathetic drive, nerve traffic, or a combination thereof.

7. The surgical tool in accordance with any preceding claim, wherein one or more of the sensing elements are electrically coupled with a microcircuit, the microcircuit configured to condition one or more of the signals conveyed therefrom.

8. The surgical tool in accordance with claim 7, wherein the microcircuit is embedded into the surgical tool and at least a portion of the electrical coupling is provided via the elongate member.

9. The surgical tool in accordance with any preceding claim, wherein one or more of the sensing elements comprises a microelectrode configured to interface with an adjacent tissue volume within or beyond the wall of the lumen while engaged with the wall, the microelectrode having an area of less than 5000sqμm, less than 1000sqμm, less than 250sqμm, or less than 100sqμm.

10. The surgical tool in accordance with any preceding claim, comprising a plurality of sensing elements arranged upon and coupled to the distal tip, the plurality of sensing elements configured to collectively map electrophysiological activity in the vicinity of the prostate while engaged with the wall.

11. The surgical tool in accordance with any preceding claim, wherein one or more of the energy delivery elements is configured to provide a radio frequency current, a microwave current, thermal energy, cryoablating action, and/or ultrasound energy, to a volume of tissue in the vicinity of the prostate while engaged with the wall.

12. The surgical tool in accordance with any preceding claim, one or more of the energy delivery elements comprise one or more stimulating electrodes electrically and mechanically coupled to the distal tip and/or the elongate member, the stimulating electrodes configured to provide a stimulating and/or ablating current to a tissue site in the vicinity of the prostate while engaged with the wall.

13. The surgical tool in accordance with any preceding claim, comprising a fluid delivery means for providing a coupling fluid to the distal tip to enhance the engagement of one or more of the sensing elements, imaging elements, and energy delivery elements with the wall when biased there.

14. The surgical tool in accordance with any preceding claim, further comprising one or more chemical delivery elements comprising one or more probes mechanically, fluidly, and/or electrically coupled with the distal tip, arranged so as to penetrate through the wall upon engagement there with or upon a deployment procedure, one or more of the probes comprising a lumen configured to deliver a diagnostic and/or therapeutic substance to a tissue site beyond the wall of the lumen.

15. The surgical tool in accordance with claim 14, wherein the diagnostic and/or therapeutic substance is selected from a chemical, a drug substance, a neuromodulating substance, a neuroblocking substance, an acid, a base, a denervating agent, or a combination thereof.

16. The surgical tool in accordance with claim 14 or 15, wherein the therapeutic substance is a selected from a neurotoxin, a botulinum toxin, a tetrodotoxin, a tetraethylammonium, a chlorotoxin, a curare, a conotoxin, a bungarotoxin, arsenic, ammonia, ethanol, hexane, nitric oxide, glutamate, resiniferatoxin, alchohol, phenol, capaicin, an anesthetic, lidocaine, tetanus toxin, quaternary ammonium salts, a pachycurare, a leptocurare, acetylcholine, aminosteroids, or a combination thereof.

17. The surgical tool in accordance with any preceding claim, wherein the lumen is a rectum, a urethra, an artery, a vein, or a duct.

18. The surgical tool in accordance with any preceding claim, wherein the plurality of energy delivery elements are configured to be individually controlled by selectively applying energy to a subset of the plurality of energy delivery elements.

19. The surgical tool in accordance with any preceding claim, wherein the plurality of energy delivery elements are configured to be individually controlled by adjusting current flow to respective ones of the plurality of energy delivery elements.

20. The surgical tool in accordance with claim 18 or 19, further comprising a microcircuit embedded in the distal tip comprises one or more switches for directing current flow to respective ones of the energy delivery elements.

21. The surgical tool in accordance with any preceding claim, wherein the distal tip comprises a dual tip and the surgical tool further comprises a deployment mechanism which when actuated adjusts a positioning of the dual tips to cup a target organ.

22. The surgical tool in accordance with claim 21, wherein each of the dual tips comprises:

a first region arranged on a face thereof comprising one or more imaging elements and one or more sensing elements; and

a second region arranged on the face thereof comprising one or more energy delivery elements.

23. The surgical tool in accordance with claim 22, wherein the deployment mechanism when actuated moves one or more of the first and second regions on one or more of the dual tips towards a target location.

24. The surgical tool in accordance with claim 23, wherein movement of the first and second regions on one or more of the dual tips comprises in-plane and out-of-plane movement.

25. The surgical tool in accordance with any preceding claim, further comprising a cooling subsystem comprising:

one or more temperature sensors arranged on the face of the distal tip to monitor temperature rise during energy delivery via the plurality of energy delivery elements; and

one or more fluid delivery elements arranged on the face of the distal tip configured to deliver fluid to one or more portions of the face of the distal tip to cool a wall of the rectum during energy delivery via the plurality of energy delivery elements

based on feedback from one or more of the temperature sensors arranged on the face of the distal tip.

26. The surgical tool in accordance with any preceding claim, wherein one or more of the electrodes comprises a non-stick coating.