Devices, Systems, and Methods for Diagnosis and Treatment of Overactive Bladder

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application is a national stage application of ~~an international application~~International Application No. PCT/2013/045605 which claims benefit of and priority to U.S. Provisional Application Ser. No. 61/659,463 filed on June 14th, 2012, entitled "Devices, systems, and methods for diagnosis and treatment of overactive bladder", by Landy Toth et al., the entire contents of which are both incorporated by reference herein for all purposes.

BACKGROUND

Technical Field

[0002] The present disclosure is directed to systems, devices, and methods for assessing, treating, and monitoring an internal surface of a body (e.g. an organ wall, a tissue site, etc.). The present disclosure is further directed to systems, devices, and methods for diagnosing and treating neurological diseases of the bladder.

Background

[0003] Urine storage symptoms (e.g. urgency, frequency, and nocturia), with or without associated urge incontinence are characterized as overactive bladder (OAB). In subjects with OAB, smooth muscle in the unstable bladders often shows enhanced spontaneous contractile activity. In addition, altered responses to electrical stimulation and/or agonists are seen from the unstable detrusor. The bladder smooth muscle from patients suffering from unstable bladder demonstrates increased myogenic activity along with fused tetanic contractions and changes in morphological structure (increased connective tissue between muscle fascicles often associated with local trauma). Sensitization of bladder afferents may lead to enhanced signal transmission along associated neurons. Furthermore, in genomically predisposed patients (e.g. patients with familial urge incontinence or chronic pain syndromes), or patients with long-term environmental changes (e.g. following spinal cord injury, obstruction, inflammation, ~~etc.), nerve growth factor (NGF) may alter afferents irreversibly. Such conditions often lead to a long term chronic condition for patients that can be difficult to manage.~~

etc.), nerve growth factor (NGF) may alter afferents irreversibly. Such conditions often lead to a long term chronic condition for patients that can be difficult to manage.

[0004] The overactive bladder (OAB) and urinary incontinence (UI) marketplace for drug and device based therapies in the United States is an over $12 billion a year industry. Prevalence based modeling analyses have shown the OAB-attributable expenditures in the US to be $65.9B per year. The conditions affect over 16 percent of all Americans (projected prevalence is between 15% and 38%), resulting in approximately 37 million men and women living with the OAB in the US. Due to social stigmas attached to OAB and UI, as well as misunderstanding of the signs and symptoms associated with OAB and UI, only 40 percent of those affected (13.6M) seek treatment. Of those 13.6 million individuals, nearly 30 percent are unsatisfied with their current therapy.

[0005] Currently, a range of OAB treatment options are available for patients or currently under development. Such treatments include anticholinergic agents (antimuscarinic agents), β_3 agonists (sensory inhibition), vanilloid receptor agents (desensitization of C-fiber-afferent neurons), neurokinin-1 receptor antagonists (pathophysiologic sensory signaling interference), phosphodiesterase-5 inhibitors (symptom relief), botulinum toxin (neuromuscular blocking agents), sacral neuromodulation (surgically implanted stimulation devices), and posterior tibial nerve stimulation (externally applied stimulation devices). Treatments to date have been met with limited success and, as mentioned previously, a large subset of the patient population is currently unsatisfied with their current therapy.

SUMMARY

[0006] ~~One objective of t~~The present disclosure ~~is to~~may provide systems, devices, and methods to for treatment of a disease state in a body (e.g. to treat overactive bladder). ~~Another objective is to~~The present disclosure may provide a system for performing sympathectomy and/or parasympathectomy on a compliant structure within a body (e.g. a bladder wall, an intestinal wall, etc.). Yet another objective is to provide systems, devices, and methods to map, monitor, and/or study electrophysiology of a structure within a body (e.g. a bladder wall, an intestinal wall, etc.).

[0007] ~~Another objective is to~~The present disclosure may provide devices, systems, and methods for monitoring local neurological activity along an organ wall and/or to extract spatially fine electrophysiological characteristics from amongst one or more macroscopic biosignals (e.g. to extract local neurological signals from potentially overwhelming electrocardiographic and/or electromyographic signals), and to predict the spatial origin of neurological signals (e.g. as part of a neuronal locating and/or mapping system, etc.).

[0008] ~~Yet another objective is to~~The present disclosure may provide devices, systems, and methods for determining the directivity of local neurological activity, directivity of signal propagation, and/or assessing neurological behavior (e.g. regular behavior versus rogue behavior) along a surface in a body (e.g. along a bladder wall, an intestinal wall, etc.).

[0009] ~~Another objective is to~~ The present disclosure may provide devices, systems, and methods for determining the location (i.e. along a surface, depth into a surface, etc.) of one or more anatomical features (e.g. sensory receptor, a neuron, a nerve plexus, etc.) along an organ or cavity wall within a body.

[0010] ~~Another~~ The present disclosure may ~~objective is to~~ provide devices, systems, and methods for ablating local anatomy within a body with physiological feedback before, during, and/or after the procedure to assess the state of completion thereof.

[0011] The present disclosure may ~~Another objective is to~~ provide devices, systems, and methods for combined urinary bladder urodynamic testing, neurological assessment, treatment, and/or urodynamic follow up. Such systems, devices, and methods may be advantageous for substantially optimally treating diseased tissue states such as those associated with overactive bladder.

~~[0012] The above objectives are wholly or partially met by devices, systems, and methods described herein. In particular, features and aspects of the present disclosure are set forth in the appended claims, following description, and the annexed drawings.~~

~~[0013]~~[0012] According to a first aspect there is provided, a surgical tool for neuromodulating bladder function, including an elongate delivery member configured and dimensioned to be inserted into a bladder through a urethra, a therapy delivery element coupled with the delivery member, configured to interface with a tissue in a

target region of a bladder wall to provide therapy to the target region; and one or more sensing tips electrically and mechanically coupled with the delivery member, configured to interface with one or more tissue surfaces of the bladder wall and/or the urethra, the sensing tips configured to convey one or more electrophysiological signals associated with the tissue surfaces before, during, and/or after the therapy.

[0013] In aspects, the electrophysiological signals may be related to one or more of water concentration, tissue tone, evoked potential, remotely stimulated nervous activity, a pressure stimulated nervous response, an electrically stimulated movement, sympathetic nervous activity, an electromyographic signal [EMG], a mechanomyographic signal [MMG], a local field potential, an electroacoustic event, vasodialation, bladder wall stiffness, muscle sympathetic nerve activity [MSNA], central sympathetic drive, nerve traffic, or combinations thereof, or the like.

[0014] In aspects, one or more of the sensing tips comprise the therapy delivery element. In aspects, at least one of the tissue surfaces is substantially coincident with the target region.

[0015] In aspects, one or more sensing tips may include one or more electrodes in accordance with the present disclosure configured to interface with the associated tissue surface. In aspects, one or more of the electrodes may include embossed, plated, and/or filament loaded structures thereupon configured to protrude into the associated tissue surface when biased there against. In aspects, one or more of the sensing tips may be electrically coupled with a microcircuit in accordance with the present disclosure, the microcircuit configured to condition the signal. In aspects, the microcircuit is embedded into the surgical tool and at least a portion of the electrical coupling is provided via the delivery member. In aspects, one or more sensing tips may include one or more needle electrodes and/or one or more whiskers each of which having a characteristic length and a tip, the needle electrode and/or whiskers arranged so as to extend from the sensing tip into the associated tissue surface.

[0016] In aspects, one or more sensing tips may include a mechanomyographic (MMG) sensing element configured to generate a mechanomyographic signal (MMG) from the associated tissue surface, a compliance sensor, configured to generate a tissue

tone signal, and/or a microelectrode configured to interface with the associated tissue surface, the microelectrode having an area of less than 5000 μm^2~~squm~~, less than 1000 μm^2~~squm~~, less than 250 μm^2~~squm~~, less than 100 μm^2~~squm~~, etc.

[0017] In aspects, one or more sensing tips and/or the therapy delivery element may be configured to stimulate (e.g. electrically stimulate, mechanically stimulate, rub,

vibrate, pinch, pressurize, provide a current to, etc.) and/or ablate (e.g. thermally ablate, apply RF current thereto, cyroablate, ultrasonically ablate, radiosurgically ablate, etc.) the associated tissue surface and/or target region respectively. In aspects, one or more sensing tips may be configured so as to monitor the effect of the stimulation and/or ablation on the tissue surface and/or target region.

[0018] In aspects, the therapy delivery element may be configured for delivering a therapeutic substance in accordance with the present disclosure to the target region. In aspects, one or more of the sensing tips may be configured to monitor the effect of the therapeutic substance on the target region.

[0019] In aspects, some non-limiting examples of therapeutic substances are a chemical, a drug substance, a neuromodulating substance, a neuroblocking substance, an acid, a base, a denervating agent, or a combination thereof, a ~~neutotoxin~~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, a combination thereof, or the like.

[0020] In aspects, the delivery member may include a lumen for providing fluid communication between the bladder and a fluid source located outside of the bladder. In aspects, a therapeutic fluid (i.e. for performing hyperthermia based chemotherapy, etc.) may be provided via the lumen.

[0021] In aspects, the surgical tool may include a balloon mechanically coupled to the delivery member, configured and dimensioned to interface with the bladder wall when filled with a fluid. In aspects, one or more of the sensing tips and/or the therapy delivery element may be attached to the balloon and arranged so as to interface with the associated tissue surface and/or target region upon filling of the balloon. In aspects, the delivery member comprising a lumen, arranged so as to provide fluid communication between the balloon and a fluid source positioned outside of the bladder. In aspects, the lumen may be coupled in fluid communication with the balloon, the tool may include a pressure sensor in fluid communication with the balloon, configured to measure the balloon fill pressure during a procedure, and/or one or more sensing tips may be

configured to measure an interfacial pressure between the balloon and the associated tissue surface.

[0022] In aspects, the therapy delivery element may be configured to deliver thermal energy, radio frequency energy, etc. to the target region.

[0023] In aspects, the surgical tool may include a microfinger in accordance with the present disclosure having a substantially elongate structure and a length, electrically and mechanically coupled with the delivery member, configured so as to bias at least a portion thereof against the bladder wall upon deployment from within the bladder. In aspects, the microfinger may include one of the sensing tips, configured to bias the sensing tip towards the bladder wall upon deployment from within the bladder. In aspects, the microfinger may include an electrically conducting core extending along the length thereof and an electrically insulating clad layer surrounding the core. In aspects, the system may include more than 100 microfingers, more than 500 microfingers, more than 1,000 microfingers, etc.

[0024] In aspects, the tool may be configured to deliver a tissue visualizing medium in accordance with the present disclosure to the target region and/or one or more of the tissue surfaces. In aspects, the tool may be coupled to a display, configured to convey a visualization of the signals, the target region, or one or more of the tissue surfaces to a user.

[0025] In aspects, the tool may be configured to perform a urodynamic study on the bladder, one or more of the sensing tips configured to monitor the effect of urodynamic study on the associated tissue surfaces and/or the target region. In aspects, the tool may include a processor, configured to analyze the signals to generate the target region.

[0026] In aspects, the therapy delivery element may be configured to modulate at least one of micturition, incontinence, frequency, pain, nocturia, or bladder capacity, and/or configured to modulate neural activity in at least a portion of the bladder wall.

[0027] According to aspects there is provided, use of a surgical tool in accordance with the present disclosure, to modulate electrophysiological activity in at least a portion of the bladder or urethra.

[0028] According to aspects there is provided, use of a surgical tool in accordance with the present disclosure, to perform a surgical procedure on a subject.

[0029] According to aspects there is provided, use of a microsurgical tool in accordance with the present disclosure, to treat overactive bladder (OAB), interstitial cystitis (IC), bladder cancer, or ureteral stent pain/voiding dysfunction.

[0030] According to aspects there is provided, a method for determining the electrophysiological function of a bladder, including monitoring electrophysiological activity at a plurality of sites within the bladder during a urodynamic test, monitoring one or more of bladder fill pressure or volume during the urodynamic test, and comparing the monitored activity with the fill pressure or volume.

[0031] In aspects, the method may include generating a metric from the monitored electrophysiological activity and bladder fill pressure or volume, the metric being representative of electrophysiological function of the bladder, comparing activity measured at one of the sites to the metric to determine if the site exhibits abnormal activity, generating a map of the electrophysiological functionality of the bladder from the monitored activity alone or in combination with the metric, and/or determining if one or more of the sites would benefit from therapy.

[0032] In aspects, the method may include applying a neural block to one or more of the sites and re-evaluating electrophysiological function of the bladder. In aspects, the method may include comparing activities before and after the neural block to determine if a permanent surgical procedure is warranted.

[0033] In aspects, one or more one or more of the steps of the method may be performed using a surgical tool in accordance with the present disclosure.

[0034] According to aspects there is provided, a method to modulate bladder function, including monitoring a first electrophysiological activity at one or more sites within the bladder, applying ~~therapy~~ a stimulus to a target region of the bladder, monitoring a second electrophysiological activity at one or more sites within the bladder, and comparing the first monitored activity and the second monitored activity to determine if the ~~therapy~~ stimulus was successful in modulating bladder function.

[0035] In aspects, the method may include applying additional therapy to the target region and/or applying therapy to an alternative target region if the therapy was determined to be unsuccessful, selecting the target region based upon the first monitored activity, selecting an alternative target region based at least in part upon the second monitoring activity.

[0036] In aspects, the monitored electrophysiological activity may include one or more of water concentration, tissue tone, evoked potential, remotely stimulated nervous activity, a pressure stimulated nervous response, an electrically stimulated movement, sympathetic nervous activity, an electromyographic signal [EMG], a mechanomyographic signal [MMG], a local field potential, an electroacoustic event, vasodialation, bladder wall stiffness, muscle sympathetic nerve activity [MSNA], central sympathetic drive, nerve traffic as measured in the vicinity of the bladder, urethra, spine, uterus, or rectum, combinations thereof, or the like.

[0037] In aspects, the method may include mapping electrophysiological activity in the bladder using the first monitored activity, and/or applying a stimulus to a tissue in neurological and/or neuromuscular communication with the bladder. In aspects, the method may include recording electrophysiological activity before, during, and/or after the stimulus to determine the effects thereof on the bladder.

[0038] In aspects, the method may include applying a neural block to a region of the bladder. In aspects, the method may include recording electrophysiological activity before, during, and/or after the neural block to determine the effects thereof on the bladder, and/or assessing if the change in electrophysiological activity caused by the neural block is desirable, if so, delivering sufficient therapy to the region so as to form a substantially irreversible neural block.

[0039] In aspects, the ~~therapy~~ stimulus may be delivered in the form of a radio frequency current, cryoablation, an ultrasonic wave, a microwave, a chemical agent, or thermal energy.

[0040] In aspects, one or more one or more of the steps of the method may be performed using a surgical tool in accordance with the present disclosure.

[0041] According to aspects there is provided, an implantable device for monitoring electrophysiological activity within a bladder, including a housing including a microcircuit configured to acquire and communicate signals and a power supply or energy harvesting element to provide power to the microcircuit, the housing configured and dimensioned for placement within and attachment to a wall of the bladder, and one or more sensing tips electrically coupled with the microcircuit configured to interface with the wall of the bladder, the sensing tips configured to convey one or more electrophysiological signals associated with the activity to the microcircuit.

[0042] In aspects, the electrophysiological signals may be related to one or more of water concentration, tissue tone, evoked potential, remotely stimulated nervous activity, a pressure stimulated nervous response, an electrically stimulated movement, sympathetic nervous activity, an electromyographic signal [EMG], a mechanomyographic signal [MMG], a local field potential, an electroacoustic event, vasodialation, bladder wall stiffness, muscle sympathetic nerve activity [MSNA], central sympathetic drive, nerve traffic, combinations thereof, or the like.

[0043] In aspects, the implantable device may include a pressure sensor electrically coupled with the microcircuit configured to measure a fill pressure within the bladder.

[0044] In aspects, one or more sensing tips may include a microelectrode configured to interface with the associated wall of the bladder, the microelectrode having an area of less than 5000 μm^2~~squm~~, less than 1000 μm^2~~squm~~, less than 250 μm^2~~squm~~, or less than 100 μm^2~~squm~~, and/or one or more stimulating electrodes, electrically coupled with the housing, arranged so as to interface with the wall of the bladder, the stimulating electrodes configured to provide a stimulating and/or ablating current to the wall of the bladder.

[0045] In aspects, the implantable device may include a plurality of stimulating electrodes, each stimulating electrode electrically coupled with the microcircuit configured to coordinate stimulating and/or ablating currents between two or more of the stimulating electrodes via the wall of the bladder.

[0046] In aspects, one or more of the sensing tips may be configured so as to monitor the effect of the stimulating and/or ablating current(s) on the wall of the bladder.

[0047] In aspects, the implantable device may be configured to deliver a therapeutic substance in accordance with the present disclosure to the wall of the bladder. In aspects, one or more of the sensing tips may be configured to monitor the effect of the therapeutic substance on the bladder. In aspects, the 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. In aspects, 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. In aspects, the therapeutic substance may be included within a restraining matrix in accordance with the present disclosure. In aspects, the restraining matrix is at least partially biodegradable.

[0048] According to aspects there is provided, use of one or more devices, systems, and/or methods in accordance with the present disclosure to treat overactive bladder (OAB), interstitial cystitis (IC), bladder cancer, ureteral stent pain/voiding dysfunction, and the like.

BRIEF DESCRIPTION OF THE DRAWINGS

[0049] Figs. 1a-b show aspects of a surgical tool placed within a urinary bladder in accordance with the present disclosure.

[0050] Fig. 2 shows aspects of a surgical tool in accordance with the present disclosure.

[0051] Fig. 3 shows a non-limiting example of a balloon wall in accordance with the present disclosure.

[0052] Figs. 4a-c show aspects of substrates in accordance with the present disclosure.

[0053] Figs. 5a-b show aspects of a surgical tool with flexible wire elements in accordance with the present disclosure.

[0054] Fig. 6 shows aspects of a surgical tool with a deployable substrate in accordance with the present disclosure.

[0055] Fig. 7a-d show aspects of a surgical tool with deployable mesh in accordance with the present disclosure.

[0056] Fig. 8 shows aspects of a surgical tool with a counter electrode in accordance with the present disclosure.

[0057] Fig. 9 shows aspects of a surgical tool with one or more remote monitoring sites in accordance with the present disclosure.

implantable device in place during the postoperative recovery period but yet sufficiently biodegradable such that retention is only maintained for a reasonable period of time. In the case of a urodynamic monitoring application, the implantable device may be retained for up to 3 weeks, 2 weeks, 1 week, 3 days, or 1 day.

[00358] In aspects, the housing 2510, 2550 may include one or more eyelets adapted so as to accept a suture or staple. Such sutures or staples may be biodegradable for easy detachment after a known period of retention. Some examples of suitable materials include amino acid based families, polyester urethanes, polyester amides, polyester ureas, polythioesters, and polyesterurethanes.

[00359] In aspects, the implantable device or the housing 2510, 2550, may include a coating, a chamber, a release layer, etc. for sustained release of a neuromodulating substance in accordance with the present disclosure into the surrounding tissues of the bladder 2. In aspects, the implantable device may include a neuromodulating substance, perhaps confined in a retaining medium (i.e. a hydrogel matrix, etc.) and the substance may leach into the surrounding tissues over time, after placement during a surgical procedure. In aspects, the neuromodulating substance may be a potent denervating agent (i.e. a ~~neutotoxin~~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, etc.), a neuroblocking agent (i.e., capaicin, an anesthetic, lidocaine, tetanus toxin, quaternary ammonium salts, a pachycurare, a leptocurare, acetylcholine, aminosteroids, etc.).

[00360] In aspects, the retaining medium may be configured so as to crosslink via a radial polymerization procedure (i.e. photopolymerization), a click polymerization procedure (i.e. an oxime click chemistry based hydrogel), or the like. Such form-in-place hydrogels known in the art of bioscaffold formation and bioadhesives may be adapted for use in this application.

[00361] In aspects, the retaining medium may be configured with one or more biodegradable aspects, such that over time (i.e. in a controlled fashion), the retaining medium may breakdown and further neuromodulating substance may be released into the surrounding tissues.

WHAT IS CLAIMED IS:

1 A surgical tool for neuromodulating bladder function, comprising:

an elongate delivery member configured and dimensioned to be inserted into a bladder through a urethra;

a therapy delivery element coupled with the delivery member, configured to interface with a tissue in a target region of a bladder wall to provide therapy to the target region; and

one or more sensing tips electrically and mechanically coupled with the delivery member, configured to interface with one or more tissue surfaces of the bladder wall and/or the urethra, the sensing tips configured to convey one or more electrophysiological signals associated with the tissue surfaces before, during, and/or after the therapy.

2 The surgical tool in accordance with claim 1, wherein the electrophysiological signals are related to one or more of water concentration, tissue tone, evoked potential, remotely stimulated nervous activity, a pressure stimulated nervous response, an electrically stimulated movement, sympathetic nervous activity, an electromyographic signal [EMG], a mechanomyographic signal [MMG], a local field potential, an electroacoustic event, vasodialation, bladder wall stiffness, muscle sympathetic nerve activity [MSNA], central sympathetic drive, nerve traffic, or combinations thereof.

~~3~~ The surgical tool in accordance with claim 1 or 2, wherein: one or more of the sensing tips comprise the therapeutic delivery element and~~.~~

43. ~~The surgical tool in accordance with claim 3, wherein~~ at least one of the tissue surfaces is substantially coincident with the target region.

~~5.~~ The surgical tool in accordance with any preceding claim, wherein one or more of the sensing tips comprises one or more electrodes configured to interface with the associated tissue surface and.

64. ~~The surgical tool in accordance with claim 5,~~ wherein one or more of the electrodes comprises embossed, plated, and/or filament loaded structures thereupon configured to protrude into the associated tissue surface when biased there against.

~~75.~~ The microsurgical tool in accordance with any preceding claim, wherein one or more of the sensing tips are electrically coupled with a microcircuit, the microcircuit configured to condition the signal.

86. The surgical tool in accordance with claim ~~75~~, wherein the microcircuit is embedded into the surgical tool and at least a portion of the electrical coupling is provided via the delivery member.

~~97.~~ The surgical tool in accordance with any preceding claim, wherein one or more sensing tips comprise one or more needle electrodes and/or one or more whiskers each of which having a characteristic length and a tip, the needle electrode and/or whiskers arranged so as to extend from the sensing tip into the associated tissue surface.

~~10.~~ The surgical tool in accordance with any preceding claim, wherein one or more sensing tips comprise at least one of a mechanomyographic (MMG) sensing element configured to generate a mechanomyographic signal (MMG) from the associated tissue surface and.

~~118~~ ~~The surgical tool in accordance with any preceding claim, wherein one or more sensing tips comprise~~ a compliance sensor, configured to generate a tissue tone signal.

~~129~~ The surgical tool in accordance with any preceding claim, wherein one or more sensing tips comprise a microelectrode configured to interface with the associated tissue surface, the microelectrode having an area of less than 5000squm, less than 1000squm, less than 250squm, or less than 100squm.

~~1310~~ The surgical tool in accordance with any preceding claim, wherein one or more sensing tips and/or the therapy delivery element are configured to electrically stimulate and/or ablate the associated tissue surface and/or target region respectively.

~~14 The surgical tool in accordance with claim 13, wherein one or more of the sensing tips and/or the therapy delivery element are configured to electrically stimulate and/or ablate the associated tissue surface and/or target region respectively.~~

~~1511~~ The surgical tool in accordance with claim 13, wherein one or more of the sensing tips and/or the therapy delivery element are configured to mechanically stimulate and/or ultrasonically ablate the associated tissue surface and/or target region respectively.

~~16 The surgical tool in accordance with any one of claims 13 – 15, wherein one or more sensing tips are configured so as to monitor the effect of the stimulation and/or ablation on the tissue surface and/or target region.~~

~~1712~~ The surgical tool~~apparatus~~ in accordance with any preceding claim wherein: the therapy delivery element configured to deliver a therapeutic substance to the target region.

~~18~~13 The surgical tool in accordance with claim ~~17~~12 wherein one or more of the sensing tips are configured to monitor the effect of the therapeutic substance on the target region.

~~19~~14 The surgical tool in accordance with claim ~~17~~12 or ~~18~~13, wherein the 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.

~~20~~15 The surgical tool in accordance with any one of claims ~~17~~12 – ~~19~~15, wherein the therapeutic substance is a selected from a ~~neutotoxin~~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.

~~21 The surgical tool in accordance with any preceding claim, wherein the delivery member comprises a lumen for providing fluid communication between the bladder and a fluid source located outside of the bladder.~~

~~22 The surgical tool in accordance with any preceding claim, comprising a balloon mechanically coupled to the delivery member, configured and dimensioned to interface with the bladder wall when filled with a fluid, one or more of the sensing tips and/or the therapy delivery element attached to the balloon and arranged so as to interface with the associated tissue surface and/or target region upon filling of the balloon.~~

~~23. The surgical tool in accordance with claim 22, the delivery member comprising a lumen, arranged so as to provide fluid communication between the balloon and a fluid source positioned outside of the bladder.~~

~~24. The surgical tool in accordance with claim 22 or 23, comprising a pressure sensor in fluid communication with the balloon, configured to measure the balloon fill pressure.~~

~~25. The surgical tool in accordance with any one of claims 22 – 24, wherein one or more sensing tips is configured to measure an interfacial pressure between the balloon and the associated tissue surface.~~

~~26. The surgical tool in accordance with any preceding claim, wherein the therapy delivery element is configured to deliver thermal energy to the target region.~~

~~27. The surgical tool in accordance with any one of claims 1 – 25, wherein the therapy delivery element is configured to deliver radio frequency energy to the target region.~~

~~28. The surgical tool in accordance with any preceding claim, comprising a microfinger having a substantially elongate structure and a length, electrically and mechanically coupled with the delivery member, configured so as to bias at least a portion thereof against the bladder wall upon deployment from within the bladder.~~

~~29. The surgical tool in accordance with claim 28, wherein the microfinger comprises one of the sensing tips, configured to bias the sensing tip towards the bladder wall upon deployment from within the bladder.~~

~~30. The surgical tool in accordance with claim 28 or 29, wherein the microfinger comprises an electrically conducting core extending along the length thereof and an electrically insulating clad layer surrounding the core.~~

~~31. The surgical tool in accordance with any one of claims 28 – 30, comprising more than 100 microfingers, more than 500 microfingers, or more than 1,000 microfingers.~~

~~32. The surgical tool in accordance with any preceding claim, configured to deliver a tissue visualizing medium to the target region and/or one or more of the tissue surfaces.~~

~~33. The surgical tool in accordance with any preceding claim, coupled to a display, configured to convey a visualization of the signals, the target region, or one or more of the tissue surfaces to a user.~~

~~34. The surgical tool in accordance with any preceding claim, configured to perform a urodynamic study on the bladder, one or more of the sensing tips configured to monitor the effect of urodynamic study on the associated tissue surfaces and/or the target region.~~

~~35. The surgical tool in accordance with any preceding claim, comprising a processor, configured to analyze the signals to generate the target region.~~

~~36~~16. The surgical tool in accordance with any preceding claim, wherein the therapy delivery element is configured to modulate at least one of micturition, incontinence, frequency, pain, nocturia, or bladder capacity.

~~37 The surgical tool in accordance with any preceding claim, wherein the therapy delivery element is configured to modulate neural activity in at least a portion of the bladder wall.~~

~~38 Use of a surgical tool in accordance with any one of claims 1 37, to modulate electrophysiological activity in at least a portion of the bladder or urethra.~~

~~39 Use of a surgical tool in accordance with any one of claims 1 37, to perform a surgical procedure on a subject.~~

~~40 Use of a microsurgical tool in accordance with any one of claims 1 37, to treat overactive bladder (OAB), interstitial cystitis (IC), bladder cancer, or ureteral stent pain/voiding dysfunction.~~

~~41~~17 A method for determining the electrophysiological function of a bladder, comprising:

- monitoring electrophysiological activity at a plurality of sites within the bladder during a urodynamic test;
- monitoring one or more of bladder fill pressure or volume during the urodynamic test; and
- comparing the monitored activity with the fill pressure or volume.

~~42~~18 The method in accordance with claim ~~41~~17, comprising generating a metric from the monitored electrophysiological activity and bladder fill pressure or volume, the metric being representative of electrophysiological function of the bladder.

~~43 The method in accordance with claim 42, comprising comparing activity measured at one of the sites to the metric to determine if the site exhibits abnormal activity.~~

~~44~~19 The method in accordance with ~~any one of claims 41—43~~claim 17 or 18, comprising generating a map of the electrophysiological functionality of the bladder from the monitored activity alone or in combination with the metric.

~~45 The method in accordance with any one of claims 41—43, comprising determining if one or more of the sites would benefit from therapy.~~

~~46 The method in accordance with any one of claims 41—45, comprising applying a neural block to one or more of the sites and re-evaluating electrophysiological function of the bladder.~~

~~47 The method in accordance with claim 46, comprising comparing activities before and after the neural block to determine if a permanent surgical procedure is warranted.~~

~~48 The method in accordance with any one of claims 41—47, wherein one or more of the steps are performed using a surgical tool in accordance with any one of claims 1—37.~~

~~49~~20 A method to modulate bladder function, comprising:

- ~~Monitoring~~ monitoring a first electrophysiological activity at one or more sites within the bladder;
- applying ~~therapy~~ a stimulus to a target region of the bladder;
- monitoring a second electrophysiological activity at one or more sites within the bladder; and
- comparing the first monitored activity and the second monitored activity to determine if the ~~therapy~~ stimulus was successful in modulating bladder function.

~~The method in accordance with claim 49, comprising:~~

~~applying additional therapy to the target region and/or applying therapy to an alternative target region if the therapy was determined to be unsuccessful.~~

~~50~~21 The method in accordance with claim ~~49 or 50~~20, comprising selecting the target region based upon the first monitored activity.

~~51 The method in accordance with any one of claims 49 – 51, comprising selecting an alternative target region based at least in part upon the second monitoring activity.~~

~~52~~22 The method in accordance with any one of claims 49 – 52, wherein the monitored electrophysiological activity comprises one or more of water concentration, tissue tone, evoked potential, remotely stimulated nervous activity, a pressure stimulated nervous response, an electrically stimulated movement, sympathetic nervous activity, an electromyographic signal [EMG], a mechanomyographic signal [MMG], a local field potential, an electroacoustic event, vasodialation, bladder wall stiffness, muscle sympathetic nerve activity [MSNA], central sympathetic drive, nerve traffic as measured in the vicinity of the bladder, urethra, spine, uterus, or rectum.

~~53~~23 The method in accordance with any one of claims 49 – 53, comprising mapping electrophysiological activity in the bladder using the first monitored activity.

~~54 The method in accordance with any one of claims 49 – 54, comprising applying a stimulus to a tissue in neurological and/or neuromuscular communication with the bladder.~~

~~55 The method in accordance with claim 55, comprising recording electrophysiological activity before, during, and/or after the stimulus to determine the effects thereof on the bladder.~~

~~56~~24 ~~The method in accordance with any one of claims 49 56, comprising~~ applying a neural block to a region of the bladder.

~~57~~25 The method accordance with claim 57, comprising recording electrophysiological activity before, during, and/or after ~~the~~ a neural block is applied to a region of the bladder to determine the effects thereof on the bladder.

~~58 The method in accordance with one of claims 57 58, comprising assessing if the change in electrophysiological activity caused by the neural block is desirable, if so, delivering sufficient therapy to the region so as to form a substantially irreversible neural block.~~

~~59~~26 The method in accordance with any one of claims ~~49 59~~20 to 25, wherein ~~therapy~~ stimulus is delivered in the form of a radio frequency current, cryoablation, an ultrasonic wave, a microwave, a chemical agent, or thermal energy.

~~60 The method in accordance with any one of claims 49 60 wherein one or more of the steps are performed using a microsurgical tool in accordance with any one of claims 1 37.~~

~~61 An implantable device for monitoring electrophysiological activity within a bladder, comprising:~~

~~a housing comprising a microcircuit configured to acquire and communicate signals and a power supply or energy harvesting element to provide power to the microcircuit, the housing configured and~~

~~dimensioned for placement within and attachment to a wall of the bladder; and~~

~~one or more sensing tips electrically coupled with the microcircuit configured to interface with the wall of the bladder, the sensing tips configured to convey one or more electrophysiological signals associated with the activity to the microcircuit.~~

~~62. The implantable device in accordance with claim 62, wherein the electrophysiological signals are related to one or more of water concentration, tissue tone, evoked potential, remotely stimulated nervous activity, a pressure stimulated nervous response, an electrically stimulated movement, sympathetic nervous activity, an electromyographic signal [EMG], a mechanomyographic signal [MMG], a local field potential, an electroacoustic event, vasodialation, bladder wall stiffness, muscle sympathetic nerve activity [MSNA], central sympathetic drive, nerve traffic, or combinations thereof.~~

~~63. The implantable device in accordance with claim 62 or 63, comprising a pressure sensor electrically coupled with the microcircuit configured to measure a fill pressure within the bladder.~~

~~64. The implantable device in accordance with any one of claims 62—64, wherein one or more sensing tips comprise a microelectrode configured to interface with the associated wall of the bladder, the microelectrode having an area of less than 5000squm, less than 1000squm, less than 250squm, or less than 100squm.~~

~~65. The implantable device in accordance with any one of claims 62—65, comprising one or more stimulating electrodes, electrically coupled with the housing,~~

arranged so as to interface with the wall of the bladder, the stimulating electrodes configured to provide a stimulating and/or ablating current to the wall of the bladder.

66 The implantable device in accordance with any one of claims 62 – 66, comprising a plurality of stimulating electrodes, each stimulating electrode electrically coupled with the microcircuit configured to coordinate stimulating and/or ablating currents between two or more of the stimulating electrodes via the wall of the bladder.

67 The implantable device in accordance with any one of claims 62 – 67, one or more of the sensing tips configured so as to monitor the effect of the stimulating and/or ablating current(s) on the wall of the bladder.

68 The implantable device in accordance with any one of claims 62 – 68, configured to deliver a therapeutic substance to the wall of the bladder.

69 The implantable device in accordance with any one of claims 62 – 69, wherein one or more of the sensing tips are configured to monitor the effect of the therapeutic substance on the bladder.

70 The implantable device in accordance with any one of claims 62 – 70, wherein the 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.

71 The implantable device in accordance with any one of claims 62 – 71, wherein the therapeutic substance is a selected from a neutotoxin, 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.~~

~~72. The implantable device in accordance with any one of claims 62—72, wherein the therapeutic substance is comprised within a restraining matrix.~~

~~74. The implantable device in accordance with any one of claims 62—73, wherein the restraining matrix is at least partially biodegradable.~~