sensing tip 465 in accordance with the present disclosure. In aspects, the electrical traces 455 and/or regions of the substrate may be covered with an insulating layer 460 to isolate them from the adjacent environment, etc.

[00281] Fig. ~~4c~~ 4d shows aspects of a substrate 470 including an electrode with a plurality of whiskers 495 in accordance with the present disclosure. The substrate 470 may include one or more whisker-like structures 495 extending from an electrode element 490 included or exposed on the surface of the substrate 470 (i.e. collectively forming a sensing tip in accordance with the present disclosure). The electrode element 490 may be electrically interconnected 480 with a circuit element elsewhere in the tool, perhaps a local microcircuit, etc. Such electrical interconnects 475 may be provided by a flexible circuit, wiring, cabling, etc. The substrate 470 may be configured such that one or more of the electrical interconnects 475 may be situated substantially at the neutral axis of the tool (i.e. so as to minimize stress thereupon during bending of the substrate 470). The tool may include insulating regions 485 configured for similar purposes, and/or as ways to define the extent of the electrode element 490 on the substrate 470 surface.

[00282] In aspects, one or more of the whiskers 495 may be formed from microfibers, nanofibers, microneedles, nanoneedles, etc. In aspects, one or more whiskers 495 may be formed from a carbon structure, e.g. a carbon fiber, a carbon nanotube, etc. In aspects, the whiskers 495 may be insulated along a portion of their length, with an electrically exposed region at the tip there upon.

[00283] The whiskers 495 may be configured with sufficient strength so as to penetrate into a tissue structure when biased there against. The whiskers 495 may be configured such that the tips may penetrate into an adjacent nerve structure, a nerve bundle, a nerve cell body (often called the soma), a dendrite, an axon, a cable-like bundle of neural axons, the endoneurium, a fascicle, an epineurium, and/or a perineurium during a procedure. Such a configuration may be advantageous for monitoring a neuronal signal from a more highly selective tissue site, than would be achievable with an associated macroscopic electrode.

[00284] Figs. 5a-b show aspects of a surgical tool with flexible wire elements in accordance with the present disclosure. Fig. 5a shows a surgical tool including a delivery

adjacent orifice of the body, a vagina, a rectum, etc. to facilitate communication with the surgical tool 800 during a procedure.

[00297] In aspects, a sensing tip in accordance with the present disclosure including one or more piezoresistive materials may be configured to measure a local contact pressure between the balloon and the wall of the organ. Such measurements may be performed in conjunction with the monitoring so as to relate local stresses (i.e. embodied in local tissue strains, etc.) with electrophysiological activity in the related tissues. Such relationships may be used in the formation of a metric for diagnosing a disease state, determining if a tissue site is a candidate for therapy, determining if a therapy has been successful, etc.

[00298] Fig. 9 shows aspects of a surgical tool 900 in conjunction with one or more remote monitoring sites 920a-d placed upon a subject 6 in accordance with the present disclosure. The surgical tool 900 may be placed within the subject 6 (i.e. so as to access at least a portion of an organ within the subject 6) as part of a surgical procedure. The surgical tool 900 may be configured to communicate 910 with a controller, a connector, a microcircuit (not explicitly shown) and to monitor and/or treat one or more adjacent tissues within the body in conjunction with the remote monitoring sites 920a-d. The remote monitoring sites 920a-d may be coupled 930 in electrical communication with the same controller, or microcircuit in order to provide a reference, a counter electrode, etc. for a procedure performed on the subject 6.

[00299] Such remote monitoring sites 920a-d may be arranged so as to monitor one or more electromyographical signals associated with pelvic muscles, the bladder, abdominal muscles, a peripheral nerve signal, etc. as part of a procedure in accordance with the present disclosure.

[00300] In aspects, such a configuration may be advantageous for general monitoring of a subject 6 (i.e. as part of a diagnostic procedure, part of a follow up procedure, etc.), as part of a urodynamic test performed on the subject 6, etc.

[00301] Fig. 10 shows a urinary bladder 2 with non-limiting examples of treatment patterns 1010~~a-e~~, 1020, 1030, 1040 thereupon. The patterns 1010~~a-e~~, 1020, 1030, 1040 may be formed with a system, surgical tool, and/or one or more sensing tips in

accordance with the present disclosure. The bladder wall 2 may be treated with one or more spot treatment patterns 1010~~a-e~~ so as to treat reasonably confined regions of abnormal tissue behavior. In aspects, the bladder wall 2 may be treated with one or more track-like patterns 1020 so as to disconnect a region of abnormal electrophysiological behavior from a region of normally functioning tissues, from an associated neural circuit, etc. In aspects, the bladder wall 2 may be treated with a through-wall pattern 1030 of controlled depth into the wall of the organ. In aspects, the through-wall patterned 1030 treatment site may be controlled, so as to limit damage to the mucosal and adventitial layers of the organ wall (i.e. focused so as to affect primarily the muscular layers of the organ wall). Such control may be obtained with coolant mitigated RF ablation currents, a bolus of chemical agent delivery into the wall, etc.

[00302] In aspects, one or more regions 1040 around the bladder neck and/or the urethra 1 may be treated so as to form substantially circumferential treatment pattern there-around.

[00303] In aspects, the regions 1010~~a-e~~, 1020, 1030, 1040 treated during a procedure in a particular subject may be compared with regions previously treated in that subject, across a patient population, etc. so as to determine typical areas of abnormal behavior, outcomes, etc.

[00304] Fig. 11 shows a graphical display of the relationship between local neurological activity and bladder fill volume before 1110, during 1120, and after 1130 treatment with a device in accordance with the present disclosure. The relationship shows micturition onset for a pretreated 1140 and post treated 1150 subject, demonstrating the effect of the surgical procedure on the bladder storage capacity thereof. In aspects, a procedure in accordance with the present disclosure may include assessing the micturition volume for a subject at intervals during a surgery to determine whether to continue with a surgery, to stop, to adjust the treatment site, etc.

[00305] Figs. 12a-d show aspects of methods for using a surgical tool in accordance with the present disclosure. Fig. 12a shows a method for treating a tissue site within a subject including inserting 1201 one or more electrodes and/or sensing tips into the subject, biasing 1203 the electrodes and/or sensing tips against the wall of an organ in the

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.

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

3 at least one of the tissue surfaces is substantially coincident with the target region.

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 4 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.

5 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.

6 The surgical tool in accordance with claim 5, wherein the microcircuit is embedded into the surgical tool and at least a portion of the electrical coupling is provided via the delivery member.

7 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.

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

8 a compliance sensor, configured to generate a tissue tone signal.

9 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.

10 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.

11 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.

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

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

14 The surgical tool in accordance with claim 12 or 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.

15 The surgical tool in accordance with any one of claims 12 – 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.

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.

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.

18 The method in accordance with claim 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.

19 The method in accordance with 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.

20 A method to modulate bladder function, comprising:

- monitoring a first electrophysiological activity at one or more sites within the bladder;
- applying 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 stimulus was successful in modulating bladder function.

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

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.

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

24

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

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

Claims

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

a plurality of sensing tips arranged in a networked array and 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 measure one or more electrophysiological signals associated with the tissue surfaces before, during, and/or after the therapy; and

a microcircuit embedded in the elongate delivery member, the microcircuit being electrically coupled to the networked array of sensing tips, the microcircuit being configured to multiplex signals from the networked array of sensing tips prior to conveying the measured electrophysiological signals to an extracorporeal system.

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 at least one of the tissue surfaces is substantially coincident with the target region.

4. 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 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.

5. The tool in accordance with any preceding claim, wherein the microcircuit is configured to condition the signal.

6. The surgical tool in accordance with claim 5, wherein at least a portion of the electrical coupling of the microcircuit is provided via the delivery member.

7. 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.

8. 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 a compliance sensor, configured to generate a tissue tone signal.

9. 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 $5000\mu m^2$, less than $1000\mu m^2$, less than $250\mu m^2$, or less than $100\mu m^2$.

10. 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.

11. The surgical tool in accordance with any preceding claim, 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.

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

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

14. The surgical tool in accordance with claim 12 or 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.

15. The surgical tool in accordance with any one of claims 12 – 14, 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.

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.

17. The apparatus in accordance with claim 1, wherein at least one of the sensing tips comprises a hook-shaped structure having one or more tissue-interfacing electrodes placed on inner surface of the hook-shaped structure.

18. The apparatus in accordance with claim 17, wherein the one or more tissue-interfacing electrodes of the hook-shaped structure are configured to monitor a local electromyographic (EMG) signal at a given portion of the tissue surface of the bladder wall.

19. The apparatus in accordance with claim 17 or claim 18, wherein the hook-shaped structure contours to the given portion of the tissue surface to read local neurological signals without interfering mechanically with signal transmission of the local neurological signals.

20. The apparatus in accordance with any one of claims 17-19, wherein the hook-shaped structure comprises a degradable support structure, the degradable support structure being configured to dissolve in the presence of a liquid such that the degradable structure may be placed beside the bladder wall and wetted to dissolve the degradable support structure and cause the remaining portion of the hook-shaped structure to contact the bladder wall.

21. The apparatus in accordance with any preceding claim, wherein the microcircuit is locally placed proximate to the networked array of sensing tips and configured to communicate with the networked array of sensing tips and the extracorporeal system via digital means such that the microcircuit is configured to exchange data pertaining to selected ones of the plurality of sensing tips in the networked array, switch data, control data and radio frequency pulse routing.

22. The apparatus in accordance with claim 1, wherein at least one of the sensing tips comprises one or more electrodes and one or more whisker structures extending from the electrodes.

23. The apparatus in accordance with claim 22, wherein at least one of the whisker structures comprises a carbon structure, the carbon structure comprising one of a carbon fiber and a carbon nanotube.

24. The apparatus in accordance with claim 22 or claim 23, wherein said at least one whisker structure is insulated along a portion of its length and has an electrically exposed region at a tip thereof.

25. The apparatus in accordance with any one of claims 22-24, wherein said at least one whisker structure is configured with sufficient strength to penetrate into the tissue surface of the bladder wall.