target region of a bladder wall to provide therapy to the target region; and ~~one or more~~ 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 ~~convey~~ 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; wherein at least one of the sensing tips includes one or more electrodes on a tissue-interfacing surface thereof and a degradable support structure configured to dissolve in the presence of a liquid; and wherein the degradable support structure is arranged relative to the tissue-interfacing surface of the at least one sensing tip such that the degradable support structure may be placed beside the bladder wall and wetted to dissolve the degradable support structure causing one or more of the electrodes on the tissue-interfacing surface of the at least one sensing tip to contact the bladder wall.

[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 <u>is</u> configured to condition the signal. In aspects, ~~the microcircuit is embedded into the surgical tool and~~ at least a portion of the electrical coupling <u>of the microcircuit</u> 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 a~~n~~ <u>surface</u> area of less than 5000 μm^2, less than 1000 μm^2, less than 250 μm^2, less than 100 μm^2, 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 bladder-treating drug substance, a neuromodulating substance, a neuroblocking substance, a~~n~~ bladder-treating acid, a bladder-treating base, a denervating agent, or a combination thereof, 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, 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, urinary frequency, pain, nocturia, or bladder capacity, and/or configured to modulate neural activity in at least a portion of the bladder wall.

[0026A] In aspects, at least one of the sensing tips includes a hook-shaped structure having one or more of the electrodes placed on an inner surface of the hook-shaped structure.

[0026B] In aspects, the one or more electrodes are configured to monitor a local electromyographic (EMG) signal at a given portion of the tissue surface of the bladder wall.

[0026C] In aspects, the tissue-interfacing surface of the at least one sensing tip 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.

[0026D] In aspects, the tissue-interfacing surface of the at least one sensing tip comprises a bioadhesive configured to bond the tissue-interfacing surface to the bladder wall, the bioadhesive being biodegradable such that the tissue-interfacing surface bonds to the bladder wall for a limited period of time.

[0026E] In aspects, 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.

[0026F] In aspects, at least one of the sensing tips comprises one or more electrodes and one or more whisker structures extending from the electrodes.

[0026G] In aspects, at least one of the whisker structures comprises a carbon structure, the carbon structure comprising one of a carbon fiber and a carbon nanotube.

[0026H] In aspects, said at least one whisker structure is insulated along a portion of its length and has an electrically exposed region at a tip thereof.

[0026I] In aspects, said at least one whisker structure is configured with sufficient strength to penetrate into the tissue surface 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.

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;

wherein at least one of the sensing tips comprises one or more electrodes on a tissue-interfacing surface thereof and a degradable support structure configured to dissolve in the presence of a liquid; and

wherein the degradable support structure is arranged relative to the tissue-interfacing surface of the at least one sensing tip such that the degradable support structure may be placed beside the bladder wall and wetted to dissolve the degradable support structure causing one or more of the electrodes on the tissue-interfacing surface of the at least one sensing tip to contact the bladder wall.

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 surgical 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 ~~a~~an surface area of less than 5000μm^2, less than 1000μm^2, less than 250μm^2, or less than 100μm^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 bladder-treating drug substance, a neuromodulating substance, a neuroblocking substance, a bladder-treating~~n~~ acid, a bladder-treating 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, urinary frequency, pain, nocturia, or bladder capacity.

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

18. The ~~apparatus~~ surgical tool in accordance with claim ~~17~~1, 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~~ surgical tool in accordance with claim 1~~7 or claim 18~~, wherein the ~~hook-shaped structure~~tissue-interfacing surface of the at least one sensing tip 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~~ surgical tool 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~~ tissue-interfacing surface of the at least one sensing tip comprises a bioadhesive configured to bond the tissue-interfacing surface to the bladder wall, the bioadhesive being biodegradable such that the tissue-interfacing surface bonds to the bladder wall for a limited period of time.

21. The ~~apparatus~~ surgical tool in accordance with any of the preceding claims, 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~~ surgical tool 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~~ surgical tool 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~~ surgical tool 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~~ surgical tool 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.