CLAIMS

1. An intravaginal device comprising:

a) a substantially ring-shaped form having an outer edge configured to contact the vaginal wall and an internal diameter sized to substantially circumferentially surround a cervix or a vaginal cuff; and

b) at least one sensor ~~within the substantially ring shaped form~~ that is capable of detecting an upward lifting movement of a pelvic floor muscle of ~~an individual~~ a subject; wherein the at least one sensor is within the substantially ring shaped form or is within a tether attached to the substantially ring-shaped form.

~~2. An intravaginal device comprising:~~

~~a) a substantially ring-shaped form having an outer edge configured to contact the vaginal wall and an internal diameter sized to substantially circumferentially surround a cervix or a vaginal cuff; and~~

~~b) a tether comprising at least one sensor that is capable of detecting an upward lifting movement of a pelvic floor muscle of an individual.~~

2 ~~3~~. The intravaginal device of claim 1 ~~claim 1 or 2~~, wherein:

i) the intravaginal device further comprises one or more of: ~~further comprising~~

a) a microcontroller configured within the substantially ring shaped form for receiving and non-transiently storing data from the at least one sensor;

b) a transmitter and receiver within the substantially ring shaped form for communicating wirelessly with an electronic device;

c) a transmitter and receiver located in an external housing connected to the intravaginal device by a detachable cable;

d) a power source connected to the sensor;

e) a Bluetooth and/or Wi-Fi enabled electronic device configured for use with the transmitter and receiver; and

f) a detachable cable connected to the sensor; and/or

ii) the tether is exchangeable and/or modular.

~~4. The intravaginal device of any one of claims 1-3, further comprising a transmitter and receiver within the substantially ring shaped form for communicating wirelessly with an electronic device.~~

~~5. The intravaginal device of any one of claims 1-3, further comprising a transmitter and receiver located in an external housing connected to the intravaginal device by a detachable cable.~~

~~6. The intravaginal device of claim 4 or 5, wherein the transmitter and receiver are configured for use with a Bluetooth and/or Wi-Fi enabled electronic device.~~

3 ~~7~~. The intravaginal device of ~~any one of claims 4-6~~ claim 2, wherein the electronic device:

a) is a computer, tablet, and/or smartphone;

b) receives and/or processes data measured by the at least one sensor;

c) is configured to communicate with a database; and/or

d) comprises a user interface configured to display data and/or instructions for use of the intravaginal device.

~~8. The intravaginal device of any one of claims 4-7, wherein the electronic device receives and/or processes data measured by the at least one sensor.~~

~~9. The intravaginal device of any one of claims 4-8, wherein the electronic device is configured to communicate with a database.~~

~~10. The intravaginal device of any one of claims 4-9, wherein the electronic device comprises a user interface.~~

~~11. The intravaginal device of claim 10, wherein the user interface is programmed to display data and/or instructions for use of the intravaginal device.~~

~~12. The intravaginal device of any one of claims 1-11, further comprising a power source connected to the sensor.~~

4 ~~13~~. The intravaginal device of claim 2 ~~12~~, wherein the power source is a battery and/or is connected to the transmitter or receiver.

~~14. The intravaginal device of claim 5, wherein the external housing further comprises a power source connected to the transmitter or receiver.~~

~~15. The intravaginal device of any one of claims 1-4 or 6-14, further comprising a detachable cable connected to the sensor.~~

5 ~~16~~. The intravaginal device of ~~claim 15~~ claim 2, wherein the detachable cable is configured to:

a) connect the intravaginal device to an electronic device;

b) connect the sensor to the power source; and/or

c) assist in the removal of the intravaginal device.

~~17. The intravaginal device of claim 15, wherein the detachable cable is configured to connect the sensor to a power source.~~

~~18. The intravaginal device of any one of claims 5 and 15-17, wherein the detachable cable is configured to assist in the removal of the intravaginal device.~~

6 ~~19~~. The intravaginal device of ~~any one of claims 1-18~~ claim 1, wherein the at least one sensor is configured to detect a pelvic floor lift and/or pelvic floor relaxation.

~~20. The intravaginal device of any one of claims 1-19, wherein the at least one sensor is configured to detect a pelvic floor relaxation.~~

7 ~~21~~. The intravaginal device of ~~any one of claims 1-20~~ claim 1, wherein the at least one sensor is selected from the group consisting of a movement sensor, accelerometer, gyroscope, micro-electro-mechanical (MEM) sensor, G-sensor, tilt sensor, rotation sensor, a light detecting sensor, such as a light detecting and ranging (LiDAR) sensor, and electrical impedance myography (EIM) sensor.

~~22. The intravaginal device of claim 21, wherein the at least one sensor is an accelerometer.~~

8 ~~23~~. The intravaginal device of ~~claim 22~~ claim 7, wherein:

a) the accelerometer is a multiple-axis accelerometer;

b) the gyroscope is a multiple-axis gyroscope; and/or

c) the EIM sensor is a localized biological transfer impedance (LBTI) sensor.

~~24. The intravaginal device of claim 21, wherein the at least one sensor is a gyroscope.~~

~~25. The intravaginal device of claim 24, wherein the gyroscope is a multiple-axis gyroscope.~~

~~26. The intravaginal device of claim 23, wherein the at least one sensor is a MEM sensor.~~

~~27. The intravaginal device of claim 21, wherein the at least one sensor is an EIM sensor.~~

~~28. The intravaginal device of claim 27, wherein the EIM sensor is a localized biological transfer impedance (LBTI) sensor.~~

9 ~~29~~. The intravaginal device of ~~any one of claims 1-28~~ claim 1, further comprising:

a) at least one additional sensor within the substantially ring-shaped form selected from the group consisting of a pressure sensor, a muscle quality sensor, a muscle strength sensor, a pH sensor, a humidity sensor, a temperature sensor, a hormone sensor, and a toxin sensor; and/or

b) a permeable or semi-permeable membrane, a mesh, and/or a perforated barrier.

10 ~~30~~. The intravaginal device of ~~any one of claims 1-29~~ claim 1, further comprising within the substantially ring-shaped form a sensory output component for providing biofeedback to the ~~individual~~ subject.

11 ~~31~~. The intravaginal device of ~~claim 30~~ claim 10, wherein the biofeedback relates to at least one performance metric as measured by the at least one sensor and/or wherein the sensory output component is configured to produce a visual, vibrational, and/or auditory signal as the biofeedback.

12 ~~32~~. The intravaginal device of ~~claim 31~~ claim 11, wherein the performance metric is:

a) proper execution of a pelvic floor lift and/or a pelvic floor relaxation;

b) duration of time in which the intravaginal device has been in use; and/or

c) selected from a measurement of pressure, muscle quality, muscle strength, humidity, temperature, a hormone level, a toxin level, and/or pH.

~~33. The intravaginal device of claim 31, wherein the performance metric is duration of time in which the intravaginal device has been in use.~~

~~34. The intravaginal device of claim 31, wherein the performance metric is selected from a measurement of pressure, muscle quality, muscle strength, humidity, temperature, a hormone level, a toxin level, and/or pH.~~

~~35. The intravaginal device of any one of claims 30 to 34, wherein the sensory output component is configured to produce a visual, vibrational, and/or auditory signal as the biofeedback.~~

13 ~~36~~. The intravaginal device of ~~any one of claims 1 to 35~~ claim 1, wherein the substantially ring-shaped form is cup-shaped, comprises a non-continuous ring, or is a horseshoe form.

~~37. The intravaginal device of any one of claims 1 to 36, further comprising a permeable or semi-permeable membrane, a mesh, and/or a perforated barrier.~~

14 ~~38~~. The intravaginal device of ~~any one of claims 1 to 37~~ claim 1, wherein the intravaginal device has a diameter of about 20 mm to about 80 mm, 55 mm to about 75 mm, or 22 mm to about 30 mm, and/or a thickness of about 0.1 mm to about 1 mm.

~~39. The intravaginal device of any one of claims 1 to 38, wherein the intravaginal device has a diameter of about 55 mm to about 75 mm.~~

~~40. The intravaginal device of any one of claims 1 to 38, wherein the intravaginal device has a diameter of about 22 mm to about 30 mm.~~

~~41. The intravaginal device of any one of claims 38 to 40, wherein the intravaginal device has a thickness of about 0.1 mm to about 1 mm.~~

15 ~~42~~. The intravaginal device of ~~any one of claims 1 to 41~~ claim 1, further comprising at least one feature for the purpose of stabilizing, orienting, and/or positioning the device within the body of the ~~individual~~ subject.

16 ~~43~~. The intravaginal device of claim 15 ~~42~~, wherein the feature is selected from the group consisting of a coating, a protrusion, and a texture.

17 ~~44~~. The intravaginal device of ~~any one of claims 1 to 43~~ claim 1, wherein the device is made from a flexible, biocompatible material.

~~45. The intravaginal device of claim 44, wherein the material is selected from the group consisting of silicone, polyethylene, polypropylene, polystyrene, polyester, polycarbonate, polyvinyl chloride, polyethersulfone, polyacrylate, hydrogel, polysulfone, polyetheretherketone, thermoplastic elastomers, poly-p-xylylene, fluoropolymers, rubber, and latex.~~

~~46. The intravaginal device of claim 45, wherein the material is silicone.~~

18 ~~47~~. The intravaginal device of ~~any one of claims 1 to 46~~ claim 1, wherein the intravaginal device is configured for use with a tool for insertion.

19 ~~48~~. The intravaginal device of claim 18 ~~47~~, wherein the tool for insertion is capable of deforming the intravaginal device and/or deploying the intravaginal device within the vagina of the individual and at an orientation substantially parallel to the surface of the upper vagina adjacent to the pelvic floor.

20 ~~49~~. The intravaginal device of ~~any one of claims 1 to 48~~ claim 1, wherein the intravaginal device:

a) is configured to notify the ~~individual~~ subject when to remove the intravaginal device from the subject ~~individual~~; and/or

b) comprises and/or is configured to administer at least one pharmaceutical agent.

~~50. The intravaginal device of any one of claims 1 to 49, wherein the intravaginal device is configured to administer at least one pharmaceutical agent.~~

~~51. The intravaginal device of claim 50, wherein the device comprises the at least one pharmaceutical agent.~~

21 ~~52~~. The intravaginal device of ~~claim 51~~ claim 20, wherein the at least one pharmaceutical agent is:

a) evenly distributed throughout the substantially ring-shaped form ~~material comprising the main body~~ and/or the tether of the intravaginal device;

b) is applied to the surface of the substantially ring-shaped form and/or tether of the intravaginal device as a coating, layer, and/or gel; and/or

c) is selected from the group consisting of a muscarinic receptor agonist, a anticholinesterase inhibitor, an alpha-adrenergic agonist, an alpha-adrenergic antagonist, a beta-adrenoceptor agonist, an anticholinergic agent, an antispasmodic agent, an antidepressant, a hormone, such as a vasopressin, a toxin, such as a botulinum toxin, a muscle relaxant, a muscle stimulant, an agent that prevents muscle mass loss, a microbicide, a contraceptive agent, an estrogen receptor modulator, an antiviral agent, an antibacterial agent, an anticancer agent, a therapeutic peptide or protein, a benzodiazepine, and an analgesic.

~~53. The intravaginal device of any one of claims 50 to 52, wherein the at least one pharmaceutical agent is applied to the surface of the main body and/or tether of the intravaginal device as a coating, layer, and/or gel.~~

22 ~~54~~. The intravaginal device of ~~any one of claims 1 to 53~~ claim 1, wherein the intravaginal device comprises at least one inner core, reservoir, or other delivery module.

23 ~~55~~. The intravaginal device of claim 22 ~~54~~, wherein the at least one inner core, reservoir, or other delivery module:

a) is located within the main body and/or the tether of the intravaginal device;

b) comprises the at least one pharmaceutical agent; and/or

c) comprises 2, 3, 4, 5, 6, 7, 8, 9, or 10 pharmaceutical agents.

~~56. The intravaginal device of claim 54 or 55, wherein the at least one inner core, reservoir, or other delivery module comprises the at least one pharmaceutical agent.~~

~~57. The intravaginal device of claim 56, wherein the at least one inner core, reservoir, or other delivery module comprises 2, 3, 4, 5, 6, 7, 8, 9, or 10 pharmaceutical agents.~~

~~58. The intravaginal device of any one of claims 50 to 57, wherein the at least one pharmaceutical agent is selected from the group consisting of a muscarinic receptor agonist, a anticholinesterase inhibitor, an alpha-adrenergic agonist, an alpha-adrenergic antagonist, a beta-adrenoceptor agonist, an anticholinergic agent, an antispasmodic agent, an antidepressant, a hormone, such as a vasopressin, a toxin, such as a botulinum toxin, a muscle relaxant, a muscle stimulant, an agent that prevents muscle mass loss, a microbicide, a contraceptive agent, an estrogen receptor modulator, an antiviral agent, an antibacterial agent, an anticancer agent, a therapeutic peptide or protein, a benzodiazepine, and an analgesic.~~

24 ~~59~~. The intravaginal device of ~~any one of claims 1 to 58~~ claim 1, wherein the intravaginal device is configured to treat, or inhibit or reduce the development or progression of, a pelvic floor disorder in the ~~individual~~ subject, wherein the pelvic floor disorder is selected from the group consisting of urinary incontinence, stress urinary incontinence, urge incontinence, mixed stress and urge urinary incontinence, fecal incontinence, pelvic organ prolapse, pelvic pain, sexual dysfunction, weak or impaired pelvic floor muscle function, post-labor issues or damage, pain and/or incontinence caused by damage to a lumbosacral nerve, nonrelaxing pelvic floor dysfunction, and vaginismus.

25 ~~60~~. The intravaginal device according to claim 1 for use in ~~A method of~~ treating, ~~or~~ inhibiting, or reducing the development or progression of[[,]] a pelvic floor disorder in ~~an individual~~ a subject, wherein the use comprises ~~comprising~~ inserting the intravaginal device ~~of any one of claims 1 to 59 or 99~~ into the vagina of the ~~individual~~ subject and monitoring the engagement of, or relaxation of, a pelvic floor muscle of the ~~individual~~ subject with the intravaginal device, and wherein the ~~treatment~~ use reduces the frequency of occurrence and/or severity of at least one symptom of a pelvic floor disorder.

26 ~~61~~. The intravaginal device for use according to claim 25, wherein the use further comprises releasing ~~A method of treating, or inhibiting or reducing the development or progression of, a pelvic floor disorder or a disease or condition of the vaginal tissues or female urogenital system in an individual comprising inserting the intravaginal device of any one of claims 1 to 59 or 99 into the vagina of the individual, wherein the intravaginal device comprises~~ at least one pharmaceutical agent useful in treating the [[a]] pelvic floor disorder ~~PFD~~ or ~~the~~ symptoms thereof.

27 ~~62~~. The intravaginal device for use according to claim 26 ~~method of claim 61~~, wherein the at least one pharmaceutical agent:

a) is selected from the group consisting of a muscarinic receptor agonist, a anticholinesterase inhibitor, an alpha-adrenergic agonist, an alpha-adrenergic antagonist, a beta-adrenoceptor agonist, an anticholinergic agent, an antispasmodic agent, an antidepressant, a hormone, a vasopressin analogue, a botulinum toxin, a muscle relaxant, a muscle stimulant, an agent that prevent muscle mass loss, a microbicide, a contraceptive agent, an estrogen receptor modulator, an antiviral agent, an antibacterial agent, an anticancer agent, a therapeutic peptide or protein, a benzodiazepine, and an analgesic; and/or

b) treats, inhibits, or reduces the frequency of occurrence and/or severity of the pelvic floor disorder, or at least one symptom thereof.

~~63. The method of claim 61 or 62, wherein the pharmaceutical agent treats, inhibits, or reduces the frequency of occurrence and/or severity of a PFD, or at least one symptom thereof.~~

28 ~~64~~. The intravaginal device for use according to claim 25 ~~method of any one of claims 60 to 63~~, wherein:

a) the pelvic floor disorder is selected from the group consisting of urinary incontinence, stress urinary incontinence, urge incontinence, mixed stress and urge urinary incontinence, fecal incontinence, coital incontinence, pelvic organ prolapse, pelvic pain, sexual dysfunction, weak or impaired pelvic floor muscle function, post-labor issues or damage, pain and/or incontinence caused by damage to a lumbosacral nerve, muscle pain, nonrelaxing pelvic floor dysfunction, and vaginismus;

b) the at least one symptom of the pelvic floor disorder is selected from the group consisting of muscle tone, muscle strength, bladder leakage, fecal leakage, pain, frequency, and urgency;

c) the monitoring is performed more than once during a treatment period; and/or

d) the use further comprises performing a treatment program.

~~65. The method of any one of claims 60 to 64, wherein the at least one symptom of pelvic floor disorder is selected from the group consisting of muscle tone, muscle strength, bladder leakage, fecal leakage, pain, frequency, and urgency.~~

~~66. The method of any one of claims 60 to 65, wherein the monitoring is performed more than once during a treatment period.~~

29 ~~67~~. The intravaginal device for use according to claim 25 ~~method of any one of claims 60 to 66~~, wherein:

a) the intravaginal device remains inside the subject ~~patient~~ during the treatment period;

b) the treatment period is about one week to about three months or about 2 weeks to about 8 weeks;

c) the treatment program comprises performing a series of one or more pelvic floor lifts and/or relaxations;

d) the treatment program is performed at least once per day, twice per day, or three times per day;

e) the treatment program is determined by, or evaluated by, a medical practitioner;

f) the treatment program is determined by the subject; and/or

g) during the treatment program, the subject engages a user interface of an electronic device that is connected to the intravaginal device and is programmed to display data and/or instructions for using the intravaginal device.

~~68. The method of claim 66 or 67, wherein the treatment period is about one week to about three months.~~

~~69. The method of claim 68, wherein the treatment period is about 2 weeks to about 8 weeks.~~

~~70. The method of any one of claims 60 to 69, further comprising performing a treatment program.~~

~~71. The method of claim 70, wherein the treatment program comprises performing a series of one or more pelvic floor lifts and/or relaxations.~~

30 ~~72~~. The intravaginal device for use according to claim 29 ~~method of claim 71~~, wherein:

a) each series occurs in about 1 second ~~seconds~~ to about 10 minutes;

b) the series is repeated five times, wherein the series comprises performing the pelvic floor lifts and/or relaxations for 15 seconds and then resting for 15 seconds;

c) the series occurs in about 2.5 minutes;

d) the electronic device provides instructions that coach the subject through the treatment program;

e) the electronic device generates a readout of results on the quality and quantity of the pelvic floor lifts and/or pelvic floor relaxation in substantially real time or after completion of the treatment program;

f) the electronic device instructs the subject to perform a pelvic floor lift or to relax the pelvic floor muscles;

g) the electronic device collects data on the symptoms experienced by the subject during use of the intravaginal device and provides recommendations for adjusting the treatment program to improve efficacy; and/or

h) the electronic device notifies the subject when to remove the intravaginal device.

~~73. The method of claim 71 or 72, wherein the series is repeated five times, and wherein the series comprises an individual performing pelvic floor lifts and/or relaxations for 15 seconds and then resting for 15 seconds.~~

~~74. The method of any one of claims 70 to 73, wherein the series occurs in about 2.5 minutes.~~

~~75. The method of any one of claims 70 to 74, wherein the treatment program is performed at least once per day.~~

~~76. The method of claim 75, wherein the treatment program is performed twice per day.~~

~~77. The method of claim 75, wherein the treatment program is performed three times per day.~~

~~78. The method of any one of claims 70 to 77, wherein the treatment program is determined by, or evaluated by, a medical practitioner.~~

~~79. The method of any one of claims 70 to 77, wherein the treatment program is determined by the individual.~~

~~80. The method of any one of claims 70 to 79, wherein, during the treatment program, the individual engages a user interface of an electronic device that is connected to the intravaginal device and is programmed to display data and/or instructions for using the intravaginal device.~~

~~81. The method of claim 80, wherein the electronic device provides instructions that coach the individual through the treatment program.~~

~~82. The method claim 80 or 81, wherein the electronic device generates a readout of results on the quality and quantity of pelvic floor lifts and/or pelvic floor relaxation in substantially real time or after completion of the treatment program.~~

31 ~~83~~. The intravaginal device for use according to claim 30 ~~method ofany one of claims 80 to 82~~, wherein the electronic device instructs the individual to perform a pelvic floor lift or to relax the pelvic floor muscles.

~~84. The method of claim 83, wherein the electronic device instructs the individual to repeat the pelvic floor lift or to relax the pelvic floor muscles two or more times.~~

~~85. The method of any one of claims 80 to 84, wherein the electronic device collects data on the symptoms experienced by the individual during use of the intravaginal device and provides recommendations for adjusting the treatment program to improve efficacy.~~

~~86. The method of any one of claims 80 to 85, wherein the electronic device notifies the individual when to remove the intravaginal device.~~

32 ~~87~~. The intravaginal device for use according to claim 25 ~~method of any one of claims 60 to 86~~, wherein the intravaginal device is configured to administer the at least one pharmaceutical agent continuously, periodically, in response to a change in a ~~the~~ condition of the vagina, in response to sensor data obtained by the intravaginal device, and/or in response to a delivery command from the user.

33 ~~88~~. The intravaginal device for use according to claim 32 ~~method of claim 87~~, wherein the sensor data indicates the performance of a pelvic floor lift, a pelvic floor relaxation, a change in muscle quality, a change in muscle strength, and/or a change in vaginal pH.

34. The intravaginal device for use according to claim 25, wherein the intravaginal device comprises an exchangeable and/or modular tether, and wherein the tether:

a) comprises at least one delivery module or component, inner core, reservoir, coating layer, and/or gel, and wherein the intravaginal device is configured to administer a therapeutically effective amount of the at least one pharmaceutical agent to the subject during a treatment period; and/or

b) comprises at least one sensor selected from the group consisting of a movement sensor, accelerometer, gyroscope, micro-electro-mechanical system (MEMs) sensor, G-sensor, tilt sensor, rotation sensor, a light detecting sensor, such as a light detecting and ranging (LiDAR) sensor, and electrical impedance myography (EIM) sensor, a pressure sensor, a pH sensor, a humidity sensor, a temperature sensor, a hormone sensor, and a toxin sensor; and/or

c) may be exchanged one or more times during the treatment period.

35 ~~89~~. A method of calibrating an intravaginal device for treating, ~~or~~ inhibiting, or reducing the development or progression of, a pelvic floor disorder in a subject ~~an individual~~ comprising:

(a) inserting the intravaginal device of ~~any one of claims 1 to 59 or 99~~ claim 1 into the vagina of the ~~individual~~ subject and monitoring the engagement of, or relaxation of, a pelvic floor muscle of the ~~individual~~ subject with the intravaginal device over a calibration period; and

(b) using the data collected over the calibration period to calculate a baseline score for at least one performance metric of the engagement of, or relaxation of, a pelvic floor muscle of the ~~individual~~ subject and/or at least one characteristic of the pelvic floor disorder of the subject.

36 ~~90~~. The method of claim 35 ~~claim 89 or 103~~, wherein the at least one performance metric of the engagement of, or relaxation of, [[a]] the pelvic floor muscle of the ~~individual~~ subject and/or the at least one characteristic of the pelvic floor disorder is selected from the group consisting of the maximum number of pelvic floor lifts and/or the maximum number of pelvic floor relaxations performed, the maximum strength of a pelvic floor lift and/or a pelvic floor relaxation performed, and muscle quality, muscle strength, and/or vaginal pH.

37 ~~91~~. A system comprising the intravaginal device of ~~any one of claims 1 to 59 or 99-102~~ claim 1 and one or more of ~~the following~~:

a) a transmitter and receiver;

b) a detachable cable;

c) a tool for insertion of the intravaginal device;

d) an electronic device;

e) a database; and/or

f) a user interface.

~~92. The system of claim 91 for treating or reducing the progression of a pelvic floor disorder in an individual.~~

~~93. The system of claim 92, wherein the pelvic floor disorder is selected from the group consisting of urinary incontinence, stress urinary incontinence, urge incontinence, mixed stress and urge urinary incontinence, fecal incontinence, pelvic organ prolapse, pelvic pain, sexual dysfunction, weak or impaired pelvic floor muscle function, post-labor issues or damage, pain and/or incontinence caused by damage to a lumbosacral nerve, nonrelaxing pelvic floor dysfunction, and vaginismus.~~

38 ~~94~~. A kit for treating or reducing the progression of a pelvic floor disorder in a subject ~~an individual,~~ comprising the intravaginal device of ~~any one of claims 1 to 59 or 99-102~~ claim 1 or a system comprising the intravaginal device and one or more of a transmitter and receiver, a detachable cable, a tool for insertion of the intravaginal device, an electronic device, a database, and a user interface ~~or the system of any one of claims 91 to 93~~, and instructions for use thereof.

~~95. The kit of claim 94, wherein the pelvic floor disorder is selected from the group consisting of urinary incontinence, stress urinary incontinence, urge incontinence, mixed stress and urge urinary incontinence, fecal incontinence, pelvic organ prolapse, pelvic pain, sexual dysfunction, weak or impaired pelvic floor muscle function, post-labor issues or damage, pain and/or incontinence caused by damage to a lumbosacral nerve, nonrelaxing pelvic floor dysfunction, and vaginismus.~~

39 ~~96~~. The kit of claim 38 ~~claim 94 or 95~~, further comprising one or more of a lubricant, ~~and/or~~ a biomaterial, and a pharmaceutical agent, or wherein the pharmaceutical agent is incorporated into the device.

~~97. The kit of any one of claims 94 to 96, further comprising a pharmaceutical agent.~~

~~98. The kit of claim 97, wherein the pharmaceutical agent is in a separate container or is incorporated into the device.~~

40 ~~99~~. The intravaginal device of claim 17 ~~any one of claims 1 to 59~~, wherein all or at least a portion of the intravaginal device, delivery module or component, inner core, reservoir, coating layer, and/or gel is comprised of a material selected from the group consisting of a thermoplastic elastomer, an ethylene-vinyl acetate (EVA) copolymer, a fluorocarbon-based polymer, a hydrogel, a hydrophilic elastomer, a latex polymer, a low-melting point wax, a neoprene rubber, a nitrile rubber, a non-swellable elastomer, a drug permeable elastomer, a poly(isobutylene) copolymer, a poly(acrylic acid) copolymer, a poly(ethylene-co-vinyl acetate) copolymer, a poly(hydroxyethylmethacrylate) copolymer, a poly(isoprene) copolymer, a poly(vinyl alcohol) copolymer, a polyacrylate polymer, a polyacrylonitrile polymer, a polyamide polymer, a polybutadiene polymer, a polycarbonate polymer, a polyester polymer, a polyetheretherketone polymer, a polyether polymer, a polyethersulfone polymer, a polyethylene glycol polymer, a polyethylene vinyl acetate (PEVA) polymer, a polyethylene polymer, a polymethylpentene polymer, a polyphosphazene polymer, a polypropylene polymer, a poly-p-xylylene polymer, a polysiloxane polymer, a polystyrene polymer, a polysulfone polymer, a polyurethane polymer, a polyvinyl chloride polymer, a rubber, a semi-synthetic glyceride of a saturated fatty acid, a silicone polymer, a stearyl alcohol polymer, a styrene-butadiene-styrene block copolymer, a cellulose, a polysaccharide, a protein, a polyhydroxy acid polymer, a polymethacrylic acid polymer, a derivatives thereof, and a mixture thereof.

~~100. The intravaginal device of claim 1, further comprising an exchangeable and/or modular tether which comprises at least one sensor.~~

41 ~~101~~. The intravaginal device of claim 12 ~~34~~, wherein the hormone level is a level of a hormone selected from the group consisting of gonadotropin-releasing hormone (GnRH), follicle-stimulating hormone (FSH), lutenizing hormone (LH), estrogen, progesterone, human chorionic gonadotropin (HCG), and derivatives thereof and/or the toxin level is a level of a toxin selected from the group consisting of bacterial toxins, fungal toxins, and viral toxins.

~~102. The intravaginal device of claim 34, wherein the toxin level is a level of a toxin selected from the group consisting of bacterial toxins, fungal toxins, and viral toxins.~~

~~103. The method of any one of claims 60-65, wherein the intravaginal device comprises an exchangeable and/or modular tether, and wherein the tether comprises at least one delivery module or component, inner core, reservoir, coating layer, and/or gel, and wherein the intravaginal device is configured to administer a therapeutically effective amount of the at least one pharmaceutical agent to the individual.~~

~~104. The method of any one of claims 60-65 and 103, wherein the intravaginal device comprises an exchangeable and/or modular tether which comprises at least one sensor selected from the group consisting of a movement sensor, accelerometer, gyroscope, micro-electro-mechanical system (MEMs) sensor, G-sensor, tilt sensor, rotation sensor, a light detecting sensor, such as a light detecting and ranging (LiDAR) sensor, and electrical impedance myography (EIM) sensor, a pressure sensor, a pH sensor, a humidity sensor, a temperature sensor, a hormone sensor, and a toxin sensor.~~

~~105. The method of claim 69, wherein the tether, or a modular component of the tether, may be exchanged one or more times during the treatment period.~~

42 ~~106~~. A method of monitoring the health and/or safety status of the urogenital system and/or pelvic floor in a female subject ~~an individual~~ comprising:

(a) inserting the intravaginal device of ~~any one of claims 1 to 59 or 99-102~~ claim 1 into the vagina of the ~~individual~~ subject;

(b) calibrating the intravaginal device by monitoring the engagement of, or relaxation of, a pelvic floor muscle and/or monitoring at least one characteristic of the urogenital system of the subject with the intravaginal device over a calibration period;

(c) using the data collected over the calibration period to calculate a safety score for at least one performance metric of the engagement of, or relaxation of, a pelvic floor muscle of the ~~individual~~ subject and/or at least one characteristic of the urogenital system of the subject;

(d) monitoring the engagement of, or relaxation of, a pelvic floor muscle and/or monitoring at least one characteristic of the urogenital system of the ~~individual~~ subject during the performance of her daily activities with the intravaginal device; and

(e) providing feedback to the ~~individual~~ subject in substantially real-time upon the performance of an activity or upon the detection of a characteristic that exceeds the established safety score or that alters her urogenital system and/or pelvic floor health.

~~107. A method of real-time monitoring the health of the urogenital system and/or pelvic floor in an individual comprising:~~

(a) inserting the intravaginal device of any one of claims 1 to 59 or 99-102 into the vagina of the individual;

(b) calibrating the intravaginal device by monitoring the engagement of, or relaxation of, a pelvic floor muscle and/or monitoring at least one characteristic of the urogenital system of the subject with the intravaginal device over a calibration period;

(c) using the data collected over the calibration period to calculate a safety score for at least one performance metric of the engagement of, or relaxation of, a pelvic floor muscle of the individual and/or at least one characteristic of the urogenital system of the subject;

(d) monitoring the engagement of, or relaxation of, a pelvic floor muscle and/or monitoring at least one characteristic of the urogenital system of the individual during the performance of her daily activities in real-time with the intravaginal device; and

(e) providing feedback to the individual in substantially real-time upon the performance of an activity or upon the detection of a characteristic that alters her urogenital system and/or pelvic floor health.

108. The intravaginal device of any one of claims 1-59, or 99-102, wherein the substantially ring-shaped form is non-continuous.

109. The intravaginal device of claim 108, wherein the substantially ring-shaped form is a horseshoe form.

110. The intravaginal device of claim 1, further comprising a transmitter and receiver within the substantially ring shaped form for communicating wirelessly with an electronic device.

111. The intravaginal device of claim 1, further comprising a transmitter and receiver located in an external housing connected to the intravaginal device by a detachable cable.

112. The intravaginal device of claim 110, wherein the transmitter and receiver are configured for use with a Bluetooth and/or Wi-Fi enabled electronic device.

113. The intravaginal device of claim 110, wherein the electronic device is a computer, tablet, and/or smartphone.

114. The intravaginal device of claim 110, wherein the electronic device receives and/or processes data measured by the at least one sensor.

~~115. The intravaginal device of claim 110, wherein the electronic device is configured to communicate with a database.~~

~~116. The intravaginal device of claim 110, wherein the electronic device comprises a user interface.~~

~~117. The intravaginal device of claim 116, wherein the user interface is programmed to display data and/or instructions for use of the intravaginal device.~~

~~118. The intravaginal device of claim 1, further comprising a power source connected to the sensor.~~

~~119. The intravaginal device of claim 118, wherein the power source is a battery.~~

~~120. The intravaginal device of claim 111, wherein the external housing further comprises a power source connected to the transmitter or receiver.~~

~~121. The intravaginal device of claim 1, further comprising a detachable cable connected to the sensor.~~

~~122. The intravaginal device of claim 121, wherein the detachable cable is configured to connect the intravaginal device to an electronic device.~~

~~123. The intravaginal device of claim 121, wherein the detachable cable is configured to connect the sensor to a power source.~~

~~124. The intravaginal device of 111, wherein the detachable cable is configured to assist in the removal of the intravaginal device.~~

~~125. The intravaginal device of claim 1, wherein the at least one sensor is configured to detect a pelvic floor lift.~~

~~126. The intravaginal device of claim 1, wherein the at least one sensor is configured to detect a pelvic floor relaxation.~~

~~127. The intravaginal device of claim 1, wherein the at least one sensor is selected from the group consisting of a movement sensor, accelerometer, gyroscope, micro-electro-mechanical (MEM) sensor, G-sensor, tilt sensor, rotation sensor, a light detecting sensor, such as a light detecting and ranging (LiDAR) sensor, and electrical impedance myography (EIM) sensor.~~

~~128. The intravaginal device of claim 127, wherein the at least one sensor is an accelerometer.~~

~~129. The intravaginal device of claim 128, wherein the accelerometer is a multiple-axis accelerometer.~~

~~130. The intravaginal device of claim 127, wherein the at least one sensor is a gyroscope.~~

~~131. The intravaginal device of claim 130, wherein the gyroscope is a multiple-axis gyroscope.~~

~~132. The intravaginal device of claim 129, wherein the at least one sensor is a MEM sensor.~~

~~133. The intravaginal device of claim 127, wherein the at least one sensor is an EIM sensor.~~

~~134. The intravaginal device of claim 133, wherein the EIM sensor is a localized biological transfer impedance (LBTI) sensor.~~

~~135. The intravaginal device of claim 1, further comprising at least one additional sensor within the substantially ring-shaped form selected from the group consisting of a pressure sensor, a muscle quality sensor, a muscle strength sensor, a pH sensor, a humidity sensor, a temperature sensor, a hormone sensor, and a toxin sensor.~~

~~136. The intravaginal device of claim 1, further comprising within the substantially ring-shaped form a sensory output component for providing biofeedback to the individual.~~

~~137. The intravaginal device of claim 136, wherein the biofeedback relates to at least one performance metric as measured by the at least one sensor.~~

~~138. The intravaginal device of claim 137, wherein the performance metric is proper execution of a pelvic floor lift and/or a pelvic floor relaxation~~

~~139. The intravaginal device of claim 137, wherein the performance metric is duration of time in which the intravaginal device has been in use.~~

~~140. The intravaginal device of claim 137, wherein the performance metric is selected from a measurement of pressure, muscle quality, muscle strength, humidity, temperature, a hormone level, a toxin level, and/or pH.~~

141. The intravaginal device of claim 136, wherein the sensory output component is configured to produce a visual, vibrational, and/or auditory signal as the biofeedback.

142. The intravaginal device of claim 1, wherein the substantially ring-shaped form is cup-shaped.

143. The intravaginal device of claim 1, further comprising a permeable or semi-permeable membrane, a mesh, and/or a perforated barrier.

144. The intravaginal device of claim 1, wherein the intravaginal device has a diameter of about 20 mm to about 80 mm.

145. The intravaginal device of claim 1, wherein the intravaginal device has a diameter of about 55 mm to about 75 mm.

146. The intravaginal device of claim 1, wherein the intravaginal device has a diameter of about 22 mm to about 30 mm.

147. The intravaginal device of claim 144, wherein the intravaginal device has a thickness of about 0.1 mm to about 1 mm.

148. The intravaginal device of claim 1, further comprising at least one feature for the purpose of stabilizing, orienting, and/or positioning the device within the body of the individual.

149. The intravaginal device of claim 148, wherein the feature is selected from the group consisting of a coating, a protrusion, and a texture.

150. The intravaginal device of claim 1, wherein the device is made from a flexible, biocompatible material.

151. The intravaginal device of claim 150, wherein the material is selected from the group consisting of silicone, polyethylene, polypropylene, polystyrene, polyester, polycarbonate, polyvinyl chloride, polyethersulfone, polyacrylate, hydrogel, polysulfone, polyetheretherketone, thermoplastic elastomers, poly-p-xylylene, fluoropolymers, rubber, and latex.

152. The intravaginal device of claim 151, wherein the material is silicone.

153. The intravaginal device of claim 1, wherein the intravaginal device is configured for use with a tool for insertion.

154. The intravaginal device of claim 153, wherein the tool for insertion is capable of deforming the intravaginal device and/or deploying the intravaginal device within the vagina of the individual and at an orientation substantially parallel to the surface of the upper vagina adjacent to the pelvic floor.

155. The intravaginal device of claim 1, wherein the intravaginal device is configured to notify the individual when to remove the intravaginal device from the individual.

156. The intravaginal device of claim 1, wherein the intravaginal device is configured to administer at least one pharmaceutical agent.

157. The intravaginal device of claim 156, wherein the device comprises the at least one pharmaceutical agent.

158. The intravaginal device of claim 157, wherein the at least one pharmaceutical agent is evenly distributed throughout the material comprising the main body and/or the tether of the intravaginal device.

159. The intravaginal device of claim 156, wherein the at least one pharmaceutical agent is applied to the surface of the main body and/or tether of the intravaginal device as a coating, layer, and/or gel.

160. The intravaginal device of claim 1, wherein the intravaginal device comprises at least one inner core, reservoir, or other delivery module.

161. The intravaginal device of claim 160, wherein the at least one inner core, reservoir, or other delivery module is located within the main body and/or the tether of the intravaginal device.

162. The intravaginal device of claim 160, wherein the at least one inner core, reservoir, or other delivery module comprises the at least one pharmaceutical agent.

163. The intravaginal device of claim 162, wherein the at least one inner core, reservoir, or other delivery module comprises 2, 3, 4, 5, 6, 7, 8, 9, or 10 pharmaceutical agents.

164. The intravaginal device of claim 157, wherein the at least one pharmaceutical agent is selected from the group consisting of a muscarinic receptor agonist, a anticholinesterase inhibitor, an alpha-adrenergic agonist, an alpha-adrenergic antagonist, a beta-adrenoceptor agonist, an anticholinergic agent, an

antispasmodic agent, an antidepressant, a hormone, such as a vasopressin, a toxin, such as a botulinum toxin, a muscle relaxant, a muscle stimulant, an agent that prevents muscle mass loss, a microbicide, a contraceptive agent, an estrogen receptor modulator, an antiviral agent, an antibacterial agent, an anticancer agent, a therapeutic peptide or protein, a benzodiazepine, and an analgesic.

165. The intravaginal device of claim 1, wherein the intravaginal device is configured to treat, or inhibit or reduce the development or progression of, a pelvic floor disorder in the individual, wherein the pelvic floor disorder is selected from the group consisting of urinary incontinence, stress urinary incontinence, urge incontinence, mixed stress and urge urinary incontinence, fecal incontinence, pelvic organ prolapse, pelvic pain, sexual dysfunction, weak or impaired pelvic floor muscle function, post-labor issues or damage, pain and/or incontinence caused by damage to a lumbosacral nerve, nonrelaxing pelvic floor dysfunction, and vaginismus.

166. A method of treating, or inhibiting or reducing the development or progression of, a pelvic floor disorder in an individual comprising inserting the intravaginal device of claim 1 into the vagina of the individual and monitoring the engagement of, or relaxation of, a pelvic floor muscle of the individual with the intravaginal device, wherein the treatment reduces the frequency of occurrence and/or severity of at least one symptom of a pelvic floor disorder.

167. The method of claim 166, wherein the intravaginal device comprises at least one pharmaceutical agent useful in treating a PFD or the symptoms thereof.

168. The method of claim 167, wherein the at least one pharmaceutical agent is selected from the group consisting of a muscarinic receptor agonist, a anticholinesterase inhibitor, an alpha-adrenergic agonist, an alpha-adrenergic antagonist, a beta-adrenoceptor agonist, an anticholinergic agent, an antispasmodic agent, an antidepressant, a hormone, a vasopressin analogue, a botulinum toxin, a muscle relaxant, a muscle stimulant, an agent that prevent muscle mass loss, a microbicide, a contraceptive agent, an estrogen receptor modulator, an antiviral agent, an antibacterial agent, an anticancer agent, a therapeutic peptide or protein, a benzodiazepine, and an analgesic.

169. The method of claim 167, wherein the pharmaceutical agent treats, inhibits, or reduces the frequency of occurrence and/or severity of a PFD, or at least one symptom thereof.

170. The method of claim 166, wherein the pelvic floor disorder is selected from the group consisting of urinary incontinence, stress urinary incontinence, urge incontinence, mixed stress and urge urinary incontinence, fecal incontinence, coital incontinence, pelvic organ prolapse, pelvic pain, sexual dysfunction, weak or impaired pelvic floor muscle function, post-labor issues or damage, pain and/or

~~incontinence caused by damage to a lumbosacral nerve, muscle pain, nonrelaxing pelvic floor dysfunction, and vaginismus.~~

~~171. The method of claim 166, wherein the at least one symptom of pelvic floor disorder is selected from the group consisting of muscle tone, muscle strength, bladder leakage, fecal leakage, pain, frequency, and urgency.~~

~~172. The method of claim 166, wherein the monitoring is performed more than once during a treatment period.~~

~~173. The method of claim 166, wherein the intravaginal device remains inside the patient during the treatment period.~~

~~174. The method of claim 172, wherein the treatment period is about one week to about three months.~~

~~175. The method of claim 174, wherein the treatment period is about 2 weeks to about 8 weeks.~~

~~176. The method of claim 166, further comprising performing a treatment program.~~

~~177. The method of claim 176, wherein the treatment program comprises performing a series of one or more pelvic floor lifts and/or relaxations.~~

~~178. The method of claim 177, wherein each series occurs in about 1 seconds to about 10 minutes.~~

~~179. The method of claim 177, wherein the series is repeated five times, and wherein the series comprises an individual performing pelvic floor lifts and/or relaxations for 15 seconds and then resting for 15 seconds.~~

~~180. The method of claim 177, wherein the series occurs in about 2.5 minutes.~~

~~181. The method of claim 177, wherein the treatment program is performed at least once per day.~~

~~182. The method of claim 181, wherein the treatment program is performed twice per day.~~

~~183. The method of claim 181, wherein the treatment program is performed three times per day.~~

~~184. The method of claim 177, wherein the treatment program is determined by, or evaluated by, a medical practitioner.~~

~~185. The method of claim 177, wherein the treatment program is determined by the individual.~~

~~186. The method of claim 177, wherein, during the treatment program, the individual engages a user interface of an electronic device that is connected to the intravaginal device and is programmed to display data and/or instructions for using the intravaginal device.~~

~~187. The method of claim 186, wherein the electronic device provides instructions that coach the individual through the treatment program.~~

~~188. The method claim 186, wherein the electronic device generates a readout of results on the quality and quantity of pelvic floor lifts and/or pelvic floor relaxation in substantially real time or after completion of the treatment program.~~

~~189. The method of claim 186, wherein the electronic device instructs the individual to perform a pelvic floor lift or to relax the pelvic floor muscles.~~

~~190. The method of claim 189, wherein the electronic device instructs the individual to repeat the pelvic floor lift or to relax the pelvic floor muscles two or more times.~~

~~191. The method of claim 186, wherein the electronic device collects data on the symptoms experienced by the individual during use of the intravaginal device and provides recommendations for adjusting the treatment program to improve efficacy.~~

~~192. The method of claim 186, wherein the electronic device notifies the individual when to remove the intravaginal device.~~

~~193. The method of claim 167, wherein the intravaginal device is configured to administer the at least one pharmaceutical agent continuously, periodically, in response to a change in the condition of the vagina, in response to sensor data obtained by the intravaginal device, and/or in response to a delivery command from the user.~~

~~194. The method of claim 193, wherein the sensor data indicates the performance of a pelvic floor lift, a pelvic floor relaxation, a change in muscle quality, a change in muscle strength, and/or a change in vaginal pH.~~

195. A method of calibrating an intravaginal device for treating, or inhibiting or reducing the development or progression of, a pelvic floor disorder in an individual comprising:
(a) inserting the intravaginal device of claim 1 into the vagina of the individual and monitoring the engagement of, or relaxation of, a pelvic floor muscle of the individual with the intravaginal device over a calibration period; and
(b) using the data collected over the calibration period to calculate a baseline score for at least one performance metric of the engagement of, or relaxation of, a pelvic floor muscle of the individual and/or at least one characteristic of the pelvic floor disorder of the subject.

196. The method of claim 195, wherein the at least one performance metric of the engagement of, or relaxation of, a pelvic floor muscle of the individual and/or the at least one characteristic of the pelvic floor disorder is selected from the group consisting of the maximum number of pelvic floor lifts and/or the maximum number of pelvic floor relaxations performed, the maximum strength of a pelvic floor lift and/or a pelvic floor relaxation performed, and muscle quality, muscle strength, and/or vaginal pH.

197. A system comprising the intravaginal device of claim 1 and one or more of the following:
a) a transmitter and receiver;
b) a detachable cable;
c) a tool for insertion of the intravaginal device;
d) an electronic device;
e) a database; and/or
f) a user interface.

198. The system of claim 197 for treating or reducing the progression of a pelvic floor disorder in an individual.

199. The system of claim 198, wherein the pelvic floor disorder is selected from the group consisting of urinary incontinence, stress urinary incontinence, urge incontinence, mixed stress and urge urinary incontinence, fecal incontinence, pelvic organ prolapse, pelvic pain, sexual dysfunction, weak or impaired pelvic floor muscle function, post-labor issues or damage, pain and/or incontinence caused by damage to a lumbosacral nerve, nonrelaxing pelvic floor dysfunction, and vaginismus.

200. A kit for treating or reducing the progression of a pelvic floor disorder in an individual, comprising the intravaginal device of claim 1, and instructions for use thereof.

201. The kit of claim 200, wherein the pelvic floor disorder is selected from the group consisting of urinary incontinence, stress urinary incontinence, urge incontinence, mixed stress and urge urinary incontinence, fecal incontinence, pelvic organ prolapse, pelvic pain, sexual dysfunction, weak or impaired pelvic floor muscle function, post-labor issues or damage, pain and/or incontinence caused by damage to a lumbosacral nerve, nonrelaxing pelvic floor dysfunction, and vaginismus.

202. The kit of claim 200, further comprising a lubricant and/or a biomaterial.

203. The kit of claim 200, further comprising a pharmaceutical agent.

204. The kit of claim 203, wherein the pharmaceutical agent is in a separate container or is incorporated into the device.

205. The intravaginal device of claim 1, wherein all or at least a portion of the intravaginal device, delivery module or component, inner core, reservoir, coating layer, and/or gel is comprised of a material selected from the group consisting of a thermoplastic elastomer, an ethylene-vinyl acetate (EVA) copolymer, a fluorocarbon-based polymer, a hydrogel, a hydrophilic elastomer, a latex polymer, a low-melting point wax, a neoprene rubber, a nitrile rubber, a non-swellable elastomer, a drug permeable elastomer, a poly(isobutylene) copolymer, a poly(acrylic acid) copolymer, a poly(ethylene-co-vinyl acetate) copolymer, a poly(hydroxyethylmethacrylate) copolymer, a poly(isoprene) copolymer, a poly(vinyl alcohol) copolymer, a polyacrylate polymer, a polyacrylonitrile polymer, a polyamide polymer, a polybutadiene polymer, a polycarbonate polymer, a polyester polymer, a polyetheretherketone polymer, a polyether polymer, a polyethersulfone polymer, a polyethylene glycol polymer, a polyethylene vinyl acetate (PEVA) polymer, a polyethylene polymer, a polymethylpentene polymer, a polyphosphazene polymer, a polypropylene polymer, a poly-p-xylylene polymer, a polysiloxane polymer, a polystyrene polymer, a polysulfone polymer, a polyurethane polymer, a polyvinyl chloride polymer, a rubber, a semi-synthetic glyceride of a saturated fatty acid, a silicone polymer, a stearyl alcohol polymer, a styrene-butadiene-styrene block copolymer, a cellulose, a polysaccharide, a protein, a polyhydroxy acid polymer, a polymethacrylic acid polymer, a derivatives thereof, and a mixture thereof.

206. The intravaginal device of claim 1, further comprising an exchangeable and/or modular tether which comprises at least one sensor.

207. The intravaginal device of claim 140, wherein the hormone level is a level of a hormone selected from the group consisting of gonadotropin-releasing hormone (GnRH), follicle-stimulating hormone (FSH), lutenizing hormone (LH), estrogen, progesterone, human chorionic gonadotropin (HCG), and derivatives thereof.

208. The intravaginal device of claim 140, wherein the toxin level is a level of a toxin selected from the group consisting of bacterial toxins, fungal toxins, and viral toxins.

209. The method of claim 166, wherein the intravaginal device comprises an exchangeable and/or modular tether, and wherein the tether comprises at least one delivery module or component, inner core, reservoir, coating layer, and/or gel, and wherein the intravaginal device is configured to administer a therapeutically effective amount of the at least one pharmaceutical agent to the individual.

210. The method of claim 166, wherein the intravaginal device comprises an exchangeable and/or modular tether which comprises at least one sensor selected from the group consisting of a movement sensor, accelerometer, gyroscope, micro-electro-mechanical system (MEMs) sensor, G-sensor, tilt sensor, rotation sensor, a light detecting sensor, such as a light detecting and ranging (LiDAR) sensor, and electrical impedance myography (EIM) sensor, a pressure sensor, a pH sensor, a humidity sensor, a temperature sensor, a hormone sensor, and a toxin sensor.

211. The method of claim 175, wherein the tether, or a modular component of the tether, may be exchanged one or more times during the treatment period.

212. A method of monitoring the safety status of the urogenital system and/or pelvic floor in an individual comprising:
(a) inserting the intravaginal device of claim 1 into the vagina of the individual;
(b) calibrating the intravaginal device by monitoring the engagement of, or relaxation of, a pelvic floor muscle and/or monitoring at least one characteristic of the urogenital system of the subject with the intravaginal device over a calibration period;
(c) using the data collected over the calibration period to calculate a safety score for at least one performance metric of the engagement of, or relaxation of, a pelvic floor muscle of the individual and/or at least one characteristic of the urogenital system of the subject;
(d) monitoring the engagement of, or relaxation of, a pelvic floor muscle and/or monitoring at least one characteristic of the urogenital system of the individual during the performance of her daily activities with the intravaginal device; and
(e) providing feedback to the individual in substantially real-time upon the performance of an activity or upon the detection of a characteristic that exceeds the established safety score.

213. A method of real-time monitoring the health of the urogenital system and/or pelvic floor in an individual comprising:
(a) inserting the intravaginal device of claim 1 into the vagina of the individual;

~~(b) calibrating the intravaginal device by monitoring the engagement of, or relaxation of, a pelvic floor muscle and/or monitoring at least one characteristic of the urogenital system of the subject with the intravaginal device over a calibration period;~~

~~(c) using the data collected over the calibration period to calculate a safety score for at least one performance metric of the engagement of, or relaxation of, a pelvic floor muscle of the individual and/or at least one characteristic of the urogenital system of the subject;~~

~~(d) monitoring the engagement of, or relaxation of, a pelvic floor muscle and/or monitoring at least one characteristic of the urogenital system of the individual during the performance of her daily activities in real-time with the intravaginal device; and~~

~~(e) providing feedback to the individual in substantially real-time upon the performance of an activity or upon the detection of a characteristic that alters her urogenital system and/or pelvic floor health.~~

~~214. The intravaginal device of claim 1, wherein the substantially ring-shaped form is non-continuous.~~

~~215. The intravaginal device of claim 214, wherein the substantially ring-shaped form is a horseshoe form.~~

43 ~~216~~. An insertion tool comprising an upper body and a lower body, wherein the upper body and lower body are configured to detachably engage with the intravaginal device of claim 1.