CLAIMS

1. An intravaginal device comprising 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 a tether attached to the substantially ring-shaped form, wherein the tether comprises a plurality of accelerometers positioned along a length of the tether that are capable of detecting an upward lifting movement of a pelvic floor muscle of a subject.

2. The intravaginal device of claim 1, wherein the device comprises a plurality of accelerometers positioned throughout the substantially ring-shaped form.

3. The intravaginal device of claim 1, wherein:

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

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

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 accelerometers;

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 accelerometers; and/or

ii) the tether is exchangeable and/or modular.

4. The intravaginal device of claim 3, wherein the electronic device:

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

b) receives and/or processes data measured by the accelerometers;

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.

5. The intravaginal device of claim 3, wherein the power source is a battery and/or is connected to the transmitter or receiver.

6. The intravaginal device of claim 3, wherein the detachable cable is configured to:

a) connect the intravaginal device to an electronic device;

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

c) assist in the removal of the intravaginal device.

7. The intravaginal device of claim 1, wherein at least one of the accelerometers is configured to detect a pelvic floor lift and/or pelvic floor relaxation and/or is a multiple-axis accelerometer.

8. The intravaginal device of claim 1, wherein the device further comprises at least one additional sensor 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.

9. The intravaginal device of claim 8, wherein:

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

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

10. The intravaginal device of 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.

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

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

13. The intravaginal device of claim 12, 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.

14. The intravaginal device of claim 1, wherein the substantially ring-shaped form is cup-shaped, comprises a non-continuous ring, or is a horseshoe form.

15. The intravaginal device of claim 1, wherein the intravaginal device has a diameter of 20 mm to 80 mm, 55 mm to 75 mm, or 22 mm to 30 mm, and/or a thickness of 0.1 mm to 1 mm.

16. 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 subject.

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

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

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

20. The intravaginal device of claim 19, 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.

21. The intravaginal device of claim 1, wherein the intravaginal device:

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

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

22. The intravaginal device of claim 21, wherein the at least one pharmaceutical agent is:

a) evenly distributed throughout the substantially ring-shaped form 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.

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

24. The intravaginal device of claim 23, 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.

25. 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 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.

26. The intravaginal device according to claim 1 for use in treating, inhibiting, or reducing the development or progression of a pelvic floor disorder in a subject, wherein the use comprises inserting the intravaginal device into the vagina of the subject and monitoring the engagement of, or relaxation of, a pelvic floor muscle of the subject with the intravaginal device, and wherein the use reduces the frequency of occurrence and/or severity of at least one symptom of a pelvic floor disorder.

27. The intravaginal device for use according to claim 26, wherein the use further comprises releasing at least one pharmaceutical agent useful in treating the pelvic floor disorder or symptoms thereof.

28. The intravaginal device for use according to claim 27, 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.

29. The intravaginal device for use according to claim 26, 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.

30. The intravaginal device for use according to claim 26, wherein:

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

b) the treatment period is one week to three months or 2 weeks to 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.

31. The intravaginal device for use according to claim 30, wherein:

a) each series occurs in 1 second to 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 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.

32. The intravaginal device for use according to claim 31, wherein the electronic device instructs the individual to perform a pelvic floor lift or to relax the pelvic floor muscles.

33. The intravaginal device for use according to claim 26, wherein the intravaginal device is configured to administer the at least one pharmaceutical agent continuously, periodically, in response to a change in a 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.

34. The intravaginal device for use according to claim 33, 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.

35. The intravaginal device for use according to claim 26, 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.

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

(a) self-inserting the intravaginal device of claim 1 into the vagina of the subject and monitoring the engagement of, or relaxation of, a pelvic floor muscle of the 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 subject and/or at least one characteristic of the pelvic floor disorder of the subject.

37. The method of claim 36, wherein the at least one performance metric of the engagement of, or relaxation of, the pelvic floor muscle of the 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.

38. A system comprising the intravaginal device of claim 1 and one or more of:

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.

39. A kit for treating or reducing the progression of a pelvic floor disorder in a subject comprising the intravaginal device of 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, and instructions for use thereof.

40. The kit of claim 39, further comprising one or more of a lubricant, a biomaterial, and a pharmaceutical agent, or wherein the pharmaceutical agent is incorporated into the device.

41. The intravaginal device of claim 18, 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.

42. The intravaginal device of claim 13, 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.

43. A method of monitoring the health and/or safety status of the urogenital system and/or pelvic floor in a female subject comprising:

(a) self-inserting the intravaginal device of claim 1 into the vagina of the 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 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 subject during the performance of her daily activities with the intravaginal device; and

(e) providing feedback to the 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.