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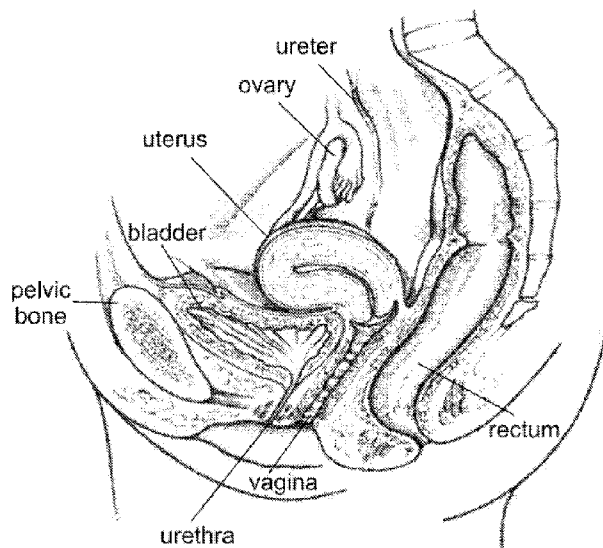


Figure 1A

(57) Abstract: A device and method may include a wire having a portion capable of forming an elastically deformable three-dimensional structure, wherein the three-dimensional structure. A device and method may include a device that (a) is elastically deformable to a partially collapsed configuration and (b) is configured to elastically contract and expand in response to contraction and expansion of the uterine cavity. A device and method may include a sensor arrangement comprising: at least one sensor configured to measure at least one parameter, wherein the at least one sensor is positioned on at least portion of the wire, wherein the at least one sensor is configured to measure at least one parameter of uterine cavity.



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## INTRAUTERINE SENSOR DEVICE AND METHOD OF TREATMENT THEREOF

Field of the Invention

**[0001]** The exemplary embodiments relate to a device positionable in the uterine cavity. More particularly, the exemplary embodiments relate to a device and method of treatment using the sensor device positionable in the uterine cavity and including a sensor arrangement.

Background

**[0002]** An intrauterine device (IUD) is a small device which is implanted in the uterine cavity and can be used for birth control. There are two general types of contraceptive IUDs, Copper IUDs and hormonal IUDs.

**[0003]** Copper IUDs (e.g., Paragard) are the most commonly used IUDs. Copper IUDs force the uterus and fallopian tubes to produce a fluid that contains white blood cells, copper ions, enzymes, and prostaglandins which are toxic to sperm.

**[0004]** Hormonal IUDs (e.g., Mirena or Skyla), release a form of the hormone progestin. Hormonal IUDs prevent fertilization by damaging or killing sperm, preventing sperm migration into the uterus (by making the mucous viscous and sticky) and by preventing implantation and growth of the fertilized egg (by preventing thickening of the endometrium). Hormonal IUDs can also reduce menstrual bleeding and cramping.

**[0005]** Both copper and hormonal IUDs are effective at preventing pregnancy (hormonal IUDs might be slightly more effective than copper IUDs), however, both suffer from several inherent limitations. Copper IUDs may increase menstrual bleeding or cramps, while hormonal IUDs may lead to side effects similar to those caused by oral contraceptives, such as breast tenderness, mood swings, headaches, and acne. Hormonal IUDs may also increase the risk of ovarian cysts.

[0006] In addition to the above, both types of IUDs can also cause uterine wall perforations and are susceptible to expulsion. In about 1 out of 1,000 women, an IUD will lodge in, or perforate the uterus wall, typically during insertion. About 2 to 10 out of 100 IUDs are expelled from the uterus into the vagina during the first year. Expulsion is more likely when the IUD is inserted right after childbirth or in women who have not carried a pregnancy or are 20 years old or younger.

[0007] Another limitation of presently used IUDs is mal position. An IUD which is not positioned correctly or migrates out of its optimal position during use can be less effective in preventing a pregnancy. If pregnancy does occur, the presence of the IUD increases the risk of miscarriage, particularly during the second trimester. Removal of the IUD at the beginning of the pregnancy still carries a risk for premature delivery.

#### Brief Description of the Figures

[0008] Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

[0009] Figure 1A shows a uterine cavity in its relaxed state.

[0010] Figure 1B shows a prior art T-shaped IUD disposed within a relaxed uterine cavity.

[0011] Figure 2 illustrates an exemplary embodiment of an intrauterine device in a three-dimensional configuration.

[0012] Figure 3 illustrates the exemplary device of Figure 2 as partially compressed by the forces of the relaxed uterine walls.

**[0013]** Figure 4 illustrates a configuration of the exemplary device of Figure 2 that further includes sensor beads disposed on a wire thereof.

**[0014]** Figure 5 illustrates an exemplary delivery guide utilizable for delivering an exemplary intrauterine device into a uterine cavity.

**[0015]** Figures 6A-6C illustrate stepwise formation of the three-dimensional structure of an exemplary intrauterine device as it is pushed out of an exemplary delivery guide and into the uterine cavity.

**[0016]** Figure 7 illustrates a schematic view of elements of an exemplary sensor bead that may form a portion of the exemplary intrauterine device of Figure 4.

#### Summary of the Invention

**[0017]** In some embodiment, the techniques described herein relate to an intrauterine device including: a wire having a portion capable of forming an elastically deformable three-dimensional structure; wherein the three-dimensional structure: (a) is elastically deformable to a partially collapsed configuration; (b) is configured to elastically contract and expand in response to contraction and expansion of the uterine cavity, a sensor arrangement including: at least one sensor configured to measure at least one parameter, wherein the at least one sensor is positioned on at least portion of the wire; wherein the at least one sensor is configured to measure at least one parameter of uterine cavity when the at least one sensor for a time period sufficient to provide such measurement.

**[0018]** In some embodiment, the techniques described herein relate to an intrauterine device wherein the sensor arrangement is a microsensor arrangement.

[0019] In some embodiment, the techniques described herein relate to an intrauterine device wherein the sensor arrangement includes at least two sensors.

[0020] In some embodiment, the techniques described herein relate to a method of sensing at least one parameter within the uterine cavity including: (a) providing an intrauterine device including: a wire having a portion capable of forming an elastically deformable three-dimensional structure; wherein the three-dimensional structure: (a) is elastically deformable to a partially collapsed configuration; (b) is configured to elastically contract and expand in response to contraction and expansion of the uterine cavity, a sensor arrangement including: at least one sensor configured to measure at least one parameter, wherein the at least one sensor is positioned on at least portion of the wire; wherein the at least one sensor is configured to measure at least one parameter of uterine cavity when the at least one sensor for a time period sufficient to provide such measurement.; and (b) delivering the device through a hollow sleeve into a uterine cavity to thereby form said three dimensional configuration in the uterine cavity wherein the elongate conformable member is linearized into a single straight elongate conformable member in the hollow sleeve with the proximal end at one end of the sleeve and the caudal end at the other end of the sleeve and introduced proximal-end first from the sleeve into the uterine cavity to assume the predetermined three dimensional configuration; wherein said three dimensional configuration is capable of elastically contracting and expanding in response to contraction and expansion of said uterine cavity thereby enabling said three dimensional configuration to maintain its position within said uterine (c) measuring at least one parameter using the at least one sensor; and (d) communicating the at least one parameter and recording the at least one parameter.

[0021] In some embodiment, the techniques described herein relate to a method, wherein the measuring step measures uterine health.

[0022] In some embodiment, the techniques described herein relate to a method, wherein the measuring step measures parameters related to properties of, or changes in, the endometrial lining.

[0023] In some embodiment, the techniques described herein relate to a method, wherein the measuring step measures parameters indicative of uterine spotting.

[0024] In some embodiment, the techniques described herein relate to a method, wherein the measuring step measures parameters indicative of fertility.

[0025] In some embodiment, the techniques described herein relate to a method, wherein the measuring step measures parameters related to the microbiome within the uterus.

[0026] In some embodiment, the techniques described herein relate to a method, wherein the measuring step measures uterine health.

[0027] In some embodiment, the techniques described herein relate to a method, wherein the measuring step measures uterine health..

#### Detailed Description of the Invention

[0028] A device may include a wire having a portion capable of forming an elastically deformable three-dimensional structure, wherein the three-dimensional structure. A device may include (a) is elastically deformable to a partially collapsed configuration. A device may include (b) is configured to elastically contract and expand in response to contraction and expansion of the uterine cavity. A device may include a sensor arrangement comprising: at least one sensor configured to measure at least one parameter, wherein the at least one sensor is positioned on at least portion of the wire, wherein the at least one sensor is configured to measure at least one parameter of uterine cavity when the at least one sensor for a time period sufficient to provide such measurement.

[0029] The exemplary embodiments relate to an implantable device which can be used to prevent pregnancy or treat uterine-related disorders. Specifically, the exemplary embodiments relate to an

intrauterine device capable of releasing an active agent suitable for preventing pregnancy, release hormones for menopausal treatment, treatment of intrauterine infections or treating endometrial disorders and myometrial disorders.

**[0030]** The principles and operation of the exemplary embodiments may be better understood with reference to the drawings and accompanying descriptions.

**[0031]** Before explaining at least one exemplary embodiment in detail, it is to be understood that the present invention is not limited in its application to the details set forth in the following description or exemplified by the Examples. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

**[0032]** In its relaxed state, the cavity of the uterus is a mere slit having substantially no volume (Figure 1A). During uterine contractions, the uterine walls relax and contract upon each other. When relaxed, the uterine walls exert an inward force of 10 mmHg (about 13.5 grams/cm<sup>2</sup>), however, under contractions, inward forces exerted by the uterine walls can rise to as much as 50-60 mmHg (about 67-82 grams/cm<sup>2</sup>) and higher (Gestel et al. Human Reproduction Update, Vol. 9, No. 2 pp. 131-138, 2003).

**[0033]** The overall design of presently used IUDs has not changed in decades since it is dictated by the anatomical space constraints of the relaxed uterus. Thus, the most widely used IUDs are configured as flat T-shaped devices (Figure 1B) that minimize forcible contact between the IUD and the relaxed uterine walls although its 3 pointed sharp edges may sting and irritate the contracting walls. Although such a design is effective in preventing pregnancies, it can lead to perforation, malposition and expulsion since any device-stabilizing forces provided by the relaxed uterine walls are substantially reduced during uterine contractions.

**[0034]** In addition, due to its flat T-shaped design, presently used IUDs are difficult to deliver and may cause tissue wall perforations during insertion because of forward arrow like motion when coming out of the insertion device.

**[0035]** In order to solve these problems of flat IUDs, some IUDs are formed from a single wire during delivery into the uterine cavity and is capable of contracting and expanding along with uterine wall movement while assuming a substantially flat configuration when the uterus is in a relaxed state.

**[0036]** Experiments conducted with this breakthrough design have shown a reduced incidence of migration and a high level of comfort among tested subjects. Although this design was shown to be less susceptible to migration than flat IUDs, improvements to the device that increase device stability in the uterus, especially when relaxed were pursued.

**[0037]** The exemplary embodiments described herein relate to an intrauterine device that is not completely flattened by the relaxed uterine walls but rather applies a slight counterforce to the uterine walls is less likely to migrate, malposition and expel from the uterus. Without being bound to a theory, it is believed that a completely flattened device composed of a single (multi-loop) wire is susceptible to “device creeping” (e.g., undesired movement of the device within the uterus) caused by movement of the relaxed uterine walls.

**[0038]** In some embodiments, a three-dimensional device which is characterized by a specific crush force and diameter range is prevented from completely flattening under the forces applied by the walls of a relaxed uterus while enabling the device to contract and expand along with an active uterus.

**[0039]** As is further described in the Example section which follows, these characteristics provide the present intrauterine device with substantial advantages over the device described in U.S. Patent Application Publication No. 2011/0271963, especially with respect to device stability.

**[0040]** Thus, in some embodiments, an intrauterine device is provided. As used herein "an intrauterine device" refers to any device implantable within the uterine cavity. In some embodiments, an intrauterine device is implantable via delivery through the vaginal cavity and cervix. In some embodiments, such a device is configured for releasing an active agent capable of preventing pregnancy (contraceptive or birth control IUD) or treating a uterine disorder such as menorrhagia or medical or surgical therapy to endometrium or myometrium for any length of time including minutes, hours, days, weeks, months or years.

**[0041]** The present device includes a wire having a portion capable of forming an elastically deformable three-dimensional structure.

**[0042]** The wire can be composed of an elastic material selected capable of being pre-shaped into the three-dimensional structure and being linearized by a pulling force on the ends of the wire. Such a transition between three dimensional and linear configurations can be affected repeatedly due to the elastic nature of the material and its ability to maintain the three dimensional shape in the absence of any pulling force on the ends of the wire (e.g., shape memory).

**[0043]** Examples of materials suitable for such purposes include alloys such as stainless steel, nickel-titanium, copper-aluminum-nickel and other copper containing alloys or polymers such as polyurethanes, polyols, polyethylene terephthalates and acrylates.

**[0044]** The wire can be 50-100 mm long with the portion forming the three-dimensional structure being 50-100% of the overall length (10-100 mm).

**[0045]** The three-dimensional structure of the present device is formed by two or more contiguous loops of the wire which are angled with respect to each other. The loops can be 12-18 mm in diameter and are arranged (in a two-loop configuration) such that one loop is positioned within the plane of the second loop and is angled 60-120 degrees with respect thereto (the angle is measured at the wire portion interconnecting the loops). In some embodiments, the angle is 80-100 degrees.

Thus, the loops form a loop-in-loop structure that “traps” a roughly spherical volume of 0.9-3.0 cm<sup>3</sup> (e.g., 1-1.5 cm<sup>3</sup>) with a surface area of 4.5-10.1 cm<sup>2</sup> (e.g., 6-8 cm<sup>2</sup>). Further description of the three-dimensional structure and formation of the loops from the linear/linearized wire is provided hereinbelow.

**[0046]** As is described hereinabove, the present device was designed in order to improve the stability of a previous design. In order to provide the requisite stability, the exemplary embodiments include a wire diameter of 0.3-1.0 mm combined with a device overall diameter of 12-20 mm, resulting in elastic resistance to wall forces of a relaxed uterus and a slight device shape change under such forces, while enabling the device to contract and expand along with an active uterus (and nearly completely flatten under strong contractions). Although the present device applies a counter force to the relaxed uterine walls, such a counterforce does not result in tissue irritation and does not lead to any discomfort.

**[0047]** As is mentioned hereinabove, the present device can be used as a birth control device or as a device suitable for treating a uterine disorder such as menorrhagia, or other endometrial or myometrial disorders.

**[0048]** Thus, the present device can be configured to release a metal ion or a hormone (e.g., progesterone, estrogen, menotropin hormones, LH and/or FSH), antibiotics, anti-inflammatory drugs, silver nitrate and/or other chemicals suitable for preventing pregnancy or treating uterine related disorders and conditions.

**[0049]** The active agent can be released from the wire, a coating disposed thereupon or from structures such as beads disposed on the wire.

**[0050]** For example, in the case of copper, the present device can include copper beads 1.5-6.0 mm in diameter mounted on the wire. The beads can be composed from pure copper, gold or silver or any other metal having contraceptive activity.

[0051] The beads can be threaded over the wire and freely move thereon in which case the beads include a central through-hole (0.4-1.1 mm in diameter), and/or they can be fixed to the wire via an adhesive, or crimping. A configuration of the present device which includes fixed and freely moving beads is illustrated in Figure 4 which is described in greater detail hereinbelow.

[0052] Copper ions can also be released from a copper-containing coating bonded to, or formed on the wire, via, for example, printing, vapor deposition, spray coating and the like.

[0053] Hormones such as estrogen, progesterone, menotropins and others can be released from hormone-containing beads or coatings made of hormone-containing polymers such as silicones or polyvinyl alcohol (PVA).

[0054] Ablating agents such as trichloroacetic acid, silver nitrate, cantharidin, vitamin A derivatives or other chemically tissue destructive agents can be released from abating agent-containing beads or coatings. The beads or coatings can include the agent and optionally carrier material. The beads can be fixedly attached to the wire or slidably mounted thereupon.

[0055] Referring now to the drawings, Figure 2 illustrates one embodiment of the present device which is referred to herein as device 10. The device 10 includes a wire 12 forming a three-dimensional structure 14 from a first loop 16 contiguous with a second loop 18. The ends of wire 12 (indicated by E) are turned inward in the direction of the volume defined by loops 16 and 18 of device 10. Any of ends E can be connected to a pull string 57 (Figures 3 and 5) for loading device 10 into a delivery guide and for removing device 10 from the body. Such a pull string can be fabricated from nylon, polypropylene or polyethylene attached to wire 12 via gluing crimping etc. The function of pull string 57 is described hereinbelow.

[0056] Loops 16 and 18 are connected via a contiguous segment 20 which forms an angle "A" between loops 16 and 18; angle "A" can be 80-100 degrees.

[0057] The overall diameter of device 10 (D) can be 12-15 mm. In some embodiments, the diameter of the device 10 is 13 mm. Loops 16 and 18 are substantially of equal diameter (d) of 12-18 mm. In some embodiments, the diameter of the loops 16 and 18 is 13 mm. The diameter of wire 12 (wd) can be 0.4-1.0 mm. In some embodiments, the diameter of the wire 12 is 0.6 mm.

[0058] As is mentioned hereinabove, device 10 is configured to partially compress under the forces applied by the walls of a relaxed uterine cavity.

[0059] For example, a device 10 having an overall diameter of 13 mm constructed from a Nitinol wire (0.5 mm in diameter) formed into two contiguous loops (13 mm in diameter) an angled at 90 degrees with respect to each other would partially collapse under a force of 13.6 grams/cm<sup>2</sup> to form a roughly oval shape (Figure 3) with a height of 10 mm. When partially collapsed, device 10 applies an elastic counterforce to the walls of the uterine cavity thus firmly securing device 10 in position. Near flattening of this configuration of device 10 would require about 50-60 grams/cm<sup>2</sup>.

[0060] Collapse of device 10 under such forces is influenced by two separate or combined mechanisms, change in angle A (elastic bending at segment 20) and shape change (round to oval) in each of loops 16 and 18 (elastic bending of the loops).

[0061] Collapse along one axis of device 10 is primarily mediated by segment 20 which can bend under relatively lower forces (exerted by relaxed uterine walls). Such collapse enables device 10 to assume the oval-shaped configuration described above. Collapse along other axis requires a larger force (uterine contractions) since it necessitates a shape-change (round to oval) in loops 16 and 18 (as well as further bending of segment 20). Collapse through a combination of axis is also possible and will depend on the orientation of device 10 in the uterine cavity and type of contractions.

[0062] Figure 4 illustrates a configuration of device 10 which includes beads 22 disposed over wire 12. As is mentioned hereinabove, beads 22 can be fixed to, and/or they can freely move upon

wire 12. In the configuration shown in Figure 4, beads 24 and 26 are fixed to ends of wire 12, while the beads 22 in-between freely move along wire 12.

**[0063]** Fixing beads 24 and 16 while allowing beads 22 (in-between beads 24 and 26) to freely slide upon wire 12 provides several advantages. Beads 24 and 26 protect (and blunt) the ends of wire 12 thus minimizing the chances of tissue perforation during delivery and precludes any sharp edges from irritating or piercing tissue during the course of use.

**[0064]** Allowing beads 22 (in-between beads 24 and 26) to freely slide on wire 12 optimizes contact between beads 22 and the uterine wall thus maximizing contact between the active agent contained therein and the tissue wall as well as reducing potential irritation that may be caused by a stationary bead during the course of use.

**[0065]** In addition, since device 10 periodically contracts and expands, beads fixed along wire 12 might snag on one another and interfere with device expansion or contraction. By allowing beads 22 to slide along wire 12, the chances of bead-snagging are reduced. This is particularly important when device 10 is removed, since linearization of the wire can be hampered by bead snagging.

**[0066]** Device 10 can be fabricated by winding a wire (e.g., Nitinol) around a mold (e.g., mandrel) capable of maintaining the wire in the desired form. The mold and wound wire are then heated or chemically treated for a specified time to set the wire in the molded shape and the shaped wire is removed from the mold. The formed wire structure can then be coated and/or beads can be threaded thereupon with a leading and trailing bead permanently attached to the wire via soldering. Any excess wire protruding past the leading or trailing bead can then be trimmed.

**[0067]** As is mentioned hereinabove, in some embodiments, device 10 is implanted in the uterine cavity to release an active agent therein with one or more beads, in addition, to having one or more sensor beads.

**[0068]** In some embodiments, delivery and implantation of device 10 in the uterine cavity is carried out using a dedicated delivery guide. Figure 5 illustrates one configuration of such a delivery guide which is referred to herein as guide 50.

**[0069]** Guide 50 includes a hollow tube 52 having a distal opening 53 and a proximal opening 55 defining a lumen therebetween. Wire 12 with mounted beads 22 and attached pull string 57 is linearized and positioned within the lumen of tube 52. Device 10 can be loaded into the lumen by threading pull string 57 into lumen and pulling it through thereby linearizing the three-dimensional structure formed by wire 12 as it is pulled into the lumen. A typical pulling force required for such linearization can be 100-150 grams.

**[0070]** Guide 50 also includes a plunger 54 having a shaft 58 fitted with a handle 56. Plunger shaft 58 fits into the lumen of tube 52 through proximal opening 55. Handle 56 is used to advance shaft 58 within the lumen of tube 52 thus advancing wire 12 with fitted beads 22 out of distal opening 53 incrementally forming the two-loop three-dimensional structure of the present device.

**[0071]** Figures 6A-6C illustrate delivery of device 10 into a uterine cavity using delivery guide 50.

**[0072]** Distal opening 53 of guide 50 is positionable in the uterine cavity by measuring uterine depth prior to insertion using a hysteroscope (sound). The measured depth from the fundus to the external ostium of the cervical canal is marked on tube 52 as reference to the insertion depth of guide 50.

**[0073]** Plunger 54 (shown in Figure 5) is then used to advance wire 12 and attached beads 22 out of distal opening 53 as is shown in Figures 6A-6C, thereby forming the first loop (Figure 6B) and contiguous second loop (Figure 6C) of the 3D structure of device 10 from the linear wire. Delivery guide 50 is then removed from the body leaving behind device 10 in the uterus and attached pull string 57, the proximal end of which is positioned at the vaginal canal.

**[0074]** Delivery guide 50 can also include an attached light source (e.g., LED or fiber optic light) in order to illuminate the uterine cavity with white light or light of a specific wavelength (e.g., blue light). Delivery guide can also include a camera for imaging the uterine cavity in 3D instead of using a hysteroscope.

**[0075]** In some embodiments, one or more of the beads 22, 24, and/or 26 of the device 10 includes a sensor (e.g., a microsensor, such as a sensor having a size that is on the order of between 10 microns and 5 millimeters). In some embodiments, by inclusion of a sensor on one or more of the beads 22, 24, and/or 26, the device 10 is configured as a sensor device that enables monitoring of various conditions within the uterus and detection of events occurring within the uterus. For example, in some embodiments, a sensor device as described herein is operable to identify changes in the endometrial cells for purposes of detecting conditions such as uterine cancer. In some embodiments, a sensor device as described herein is operable to detect the presence and concentration of vitamins, minerals, or other substances within the uterus. In some embodiments, a sensor device as described herein is operable to detect conditions or occurrences relating to fertilization, such as ovulation or other relevant conditions.

**[0076]** Figure 7 schematically illustrates a sensor bead 70. It is understood that the term “beads,” can include different shapes (e.g. round, oval, spherical, oblong and non-symmetrical) In some embodiments, the device 10 includes one bead 22, 24, or 26 that is a sensor bead 70. In some embodiments, the device 10 includes two or more of the beads 22, 24, and/or 26 that are sensor beads 70. In some embodiments, the device includes between two and 50 of the beads 22, 24, and/or 26 that are sensor beads 70. In some embodiments, all of the beads 22, 24, and/or 26 are sensor beads 70, and in such embodiments the device 10 performs only a sensing function as described herein and does not perform other functions such as hormone delivery. Figure 7 illustrates the sensor bead 70 including various elements that will be described hereinafter, but the sensor bead 70 may include some subset of the elements to be described hereinafter that is less than all of these elements.

[0077] In some embodiments, the sensor bead 70 includes a sensor arrangement 72. In some embodiments, the sensor arrangement 72 includes one sensor. In some embodiments, the sensor arrangement 72 includes more than one sensor. In embodiments wherein the sensor arrangement 72 includes more than one sensor, the term “sensor arrangement” should not be interpreted to require that such sensors must be collocated within the sensor bead 70; rather, such sensors may be distributed within the sensor bead 70. In some embodiments, the sensor arrangement 72 includes at least one sensor that is positioned on an exterior surface of the sensor bead 70 so as to be exposed to bodily fluids. In some embodiments, the sensor arrangement 72 includes a physical sensor. In some embodiments, the physical sensor is configured to sense a physical parameter such as fluid flow within the uterus, size of the uterus, thickness of the uterine wall, temperature within the uterus, etc. In some embodiments, the sensor arrangement 72 includes a chemical sensor. In some embodiments, the chemical sensor is configured to sense a chemical parameter such as pH within the uterus, a level of oxygenation within the uterus, a level of glucose within the uterus, a level of iron within the uterus, etc. In some embodiments, the sensor arrangement 72 includes an imaging sensor. In some embodiments, the imaging sensor is capable of obtaining images in the visible spectrum, the infrared spectrum, and/or the ultraviolet spectrum. In some embodiments the sensor arrangement 72 includes another type of a sensor (e.g., a bio-potential sensor configured to sense bio-potential within tissue of the uterus).

[0078] In some embodiments, the sensor arrangement 72 is operative to measure levels of analytes that are typically monitored during blood testing. In some embodiments, the sensor arrangement 72 is operative to measure parameters related to uterine health. In some embodiments, the sensor arrangement 72 is operative to measure parameters related to disease progression. In some embodiments, the sensor arrangement 72 is operative to measure parameters related to properties of, or changes in, the endometrial lining (e.g., the physical parameters or composition thereof). In some embodiments, the sensor arrangement 72 is operative to measure parameters indicative of uterine spotting. In some embodiments, the sensor arrangement 72 is operative to measure parameters indicative of fertility. In some embodiments, the sensor arrangement 72 is operative to measure parameters indicative of the menstrual cycle. In some embodiments, the sensor arrangement 72 is operative to measure parameters indicative of contraception.

**[0079]** In some embodiments, the sensor arrangement 72 is operative to measure parameters related to the microbiome within the uterus. It will be known to those of skill in the art that a healthy uterine microbiome includes a combination of bacteria, viruses, yeasts, and fungi. For example, a healthy uterus may include commensals such as several species of *Escherichia* (such as *E. coli*), *Ureaplasma parvum*, *Fusobacterium nucleatum*, *Prevotella tanneriae*, several species of *Bacteroides*, *Streptomyces avermitilis*, several species of *Mycoplasma*, *Neisseria lactamica*, *Neisseria polysaccharea*, Epstein-Barr virus, Respiratory-Syncytial virus, Adenovirus, and several species of *Candida*. In some cases, certain organisms present in the uterine microbiome may produce negative birth outcomes. In some cases, certain organisms present in the uterine microbiome may cause microbial dysbiosis (e.g., an imbalance in microbiota within the uterine microbiome) that may cause gynecological disorders such as endometriosis, chronic endometritis, dysfunctional menstrual bleeding, endometrial cancer, and infertility. In some embodiments, the sensor arrangement 72 of one or more of the sensor beads 70 is operative to measure presence and/or concentration of one or more type of bacterium, virus, yeast, or fungus that may be present within the uterus.

**[0080]** In some embodiments, the sensor arrangement 72 is operative to measure parameters related to fertilization. For example, in some embodiments, the sensor arrangement 72 is operative to identify the occurrence of ovulation. In some embodiments, the sensor arrangement 72 is operative to identify conditions within the uterus that are indicative of ovarian health. In some embodiments, the sensing of parameters related to ovulation by the sensor arrangement can improve the safety and/or the efficacy of in vitro fertilization (“IVF”); for example, by sensing the timing of ovulation, IVF procedures may be optimally timed.

**[0081]** In some embodiments, the sensor arrangement 72 is operative to monitor health of the cells of the endometrium. For example, in some embodiments, the sensor arrangement 72 includes an imaging sensor or other type of sensor that is operable to monitor the color of the cells of the endometrium. In some embodiments, the sensor arrangement 72 includes a physical sensor that is operable to monitor the consistency of the cells of the endometrium. In some embodiments,

detection of changes in the endometrial cells may enable identification of conditions such as uterine cancer.

**[0082]** As discussed above, in some embodiments, the device 10 includes a plurality of the sensors 70. In some such embodiments, the device 10 includes a plurality of sensors -- e.g. more than one of the sensor beads 70 having a same sensor arrangement 72 as one another (for example, two of the sensor beads 70 both having the sensor arrangement 72 that is a chemical sensor configured to sense pH at two respective positions within the uterus). In some such embodiments, the device 10 includes more than one of the sensor beads 70 having different sensor arrangements 72 than one another (for example, one of the sensor beads having the sensor arrangement 72 that is a chemical sensor configured to sense pH within the uterus, and another of the sensor beads having the sensor 72 that is a physical sensor configured to sense temperature within the uterus).

**[0083]** In some embodiments, the sensor 70 includes a communication interface 74 allowing data from the sensor(s) to be conveyed to a device outside the uterus. In some embodiments, the communication interface 74 includes an RFID communication link. In some embodiments, the communication interface 74 includes a personal area networking (e.g., Bluetooth) communication link. In some embodiments, the communication interface 74 includes a different type of communication link. In some embodiments, the sensor bead 70 is operatively coupled to the wire 12 such that the material of the wire 12 acts as an antenna to improve performance (e.g., transmission range, transmission quality, etc.) of the communication interface 74. In some embodiments, the communication interface 74 is passively powered (e.g., a passive RFID tag that is powered by energy transmitted from an RFID reader that is outside the body of the patient). In some embodiments, the communication interface 74 is actively powered (e.g., is powered by an onboard power supply, as will be described hereinafter). In some embodiments, the communication interface 74 is operative to transmit data captured by the sensor arrangement 72 to an external device in order to thereby facilitate analysis of the data and treatment of the patient.

**[0084]** In some embodiments, the sensor bead 70 includes a light source 76 that is configured to facilitate operation of embodiments of the sensor arrangement 72 including an imaging sensor. In some embodiments, the light source 76 is selectively illuminated (e.g., is controllable via the communication interface 74). In some embodiments, the light source 76 is periodically illuminated (e.g., at predetermined intervals). In some embodiments, the light source 76 is constantly illuminated.

**[0085]** In some embodiments, the sensor bead 70 includes data storage 78. In some embodiments, the data storage 78 is communicatively coupled to the sensor arrangement 72. In some embodiments, the data storage 78 includes any type of data storage known in the art (e.g., flash memory, solid state memory, etc.) operable to store data sensed by the sensor arrangement 72. In some embodiments, the data storage 78 is configured to store a predefined amount of data (e.g., data for the most recent day, the most recent week, etc.). In some embodiments, the data storage 78 is communicatively coupled to the communication interface 74 so as to allow stored data to be retrieved when the communication interface 74 is active.

**[0086]** In some embodiments, the sensor bead 70 includes a power supply 80. In some embodiments, the power supply 80 is operatively coupled to the remaining elements of the sensor bead 70 (e.g., the sensor arrangement 72, the communication interface 74, etc.) so as to enable such other elements to operate. In some embodiments, the power supply 80 includes a battery (e.g., a rechargeable battery). In some embodiments, the power supply 80 includes an inductive charging element.

**[0087]** In some embodiments, the sensor bead 70 lacks the power supply 80. In some such embodiments, the sensor bead 70 is powered by an external device (e.g., a wearable device), such as by radio energy in a manner similar to the operation of a passive radio frequency identification (“RFID”) device, as described above with reference to the communication interface 74.

**[0088]** In some embodiments, the sensor bead 70 includes an identification element 82. In some embodiments, the identification element 82 includes a computing element (e.g., including a combination of hardware and software). In some embodiments, the identification element 82 is operable to authenticate a patient who is carrying the device 10 having the sensor bead 70 including the identification element (e.g., biometric authentication). In some embodiments, the identification element 82 is operable to associate any data captured by the sensor bead 70 including the identification element, or any other sensor beads 70 of the device, with patient-identifying information.

**[0089]** In some embodiments, device 10 includes two or more of the beads 22, 24, and/or 26 that are sensor beads 70, and the sensor beads 70 are spaced apart from one another within the device 10. In some embodiments, the sensor beads 70 are spaced apart from one another so as to enable the sensor beads 70 to measure the difference in properties between two locations within the uterus.

**[0090]** In some embodiments, one or more of the sensor beads 70 are coupled to the wire 12 in a manner such that the sensor beads 70 may freely slide along the wire 12. In such embodiments, the movability of the sensor beads 70 results in the sensor beads 70 collecting sensed data across a variety of locations within the uterus, resulting in a representative sampling of data.

**[0091]** In some embodiments, one or more of the sensor beads 70 are coupled to the wire 12 in a manner such that the sensor beads 70 are fixed at specific locations along the wire 12. In such embodiments, the fixed location of the sensor beads 70 results in the time series of data collected by the sensor beads 70 to be of increased significance due to various data points within the time series being directly comparable to one another.

**[0092]** In some embodiments, the sensor beads 70 are physically configured (e.g., sufficiently sealed, made of suitable material(s), etc.) so as to be capable of operation over a suitable period of time (e.g., minutes, hours, days, weeks, months or years) within the uterine environment. For example, in some embodiments, the sensor beads 70 are configured so as to be capable of operation

within the uterine environment for a time period that is between one minute and ten years. In some embodiments, the sensor beads 70 are sufficiently designed so as not to be damaged by moisture levels within the uterine environment. In some embodiments, the sensor beads 70 are sufficiently designed so as not to be damaged by acidity levels within the uterine environment (e.g., at a normal vaginal pH value of about 4.5). In some embodiments, the sensor beads 70 include a casing that is sufficiently designed so as to be operable within the uterine environment, and only a sensing element of the sensor arrangement 72 is positioned so as to be in contact with the uterine environment, with the remainder of the elements of the sensor beads 70 fully contained within the casing.

**[0093]** The exemplary sensor beads 70 described above with reference to Figure 7 have been described with reference to the incorporation of such sensor beads 70 into a generally spherical intrauterine device such as the device 10 shown in Figure 4. However, in other embodiments, the sensor beads 70 are equally suitable for incorporation into a differently shaped intrauterine device, such as a generally T-shaped intrauterine device, a generally Y-shaped intrauterine device, or any other shape that is known to be suitable for an intrauterine device.

**[0094]** As used herein the term "about" refers to  $\pm 10\%$ .

**[0095]** While a number of embodiments of the present invention have been described, it is understood that these embodiments are illustrative only, and not restrictive, and that many modifications may become apparent to those of ordinary skill in the art. For example, all dimensions discussed herein are provided as examples only, and are intended to be illustrative and not restrictive.

What is claimed:

1. An intrauterine device comprising:

a wire having a portion capable of forming an elastically deformable three-dimensional structure;

wherein the three-dimensional structure:

- a) is elastically deformable to a partially collapsed configuration;
- b) is configured to elastically contract and expand in response to contraction and expansion of the uterine cavity,

a sensor arrangement comprising:

at least one sensor configured to measure at least one parameter,

wherein the at least one sensor is positioned on at least portion of the wire;

wherein the at least one sensor is configured to measure at least one parameter of uterine cavity when the at least one sensor for a time period sufficient to provide such measurement.

2. The intrauterine device of claim 1 wherein the sensor arrangement is a microsensor arrangement.

3. The intrauterine device of claim 2 wherein the sensor arrangement comprises at least two sensors.

4. A method of sensing at least one parameter within the uterine cavity comprising:

(a) providing an intrauterine device comprising:

a wire having a portion capable of forming an elastically deformable three-dimensional structure; wherein the three-dimensional structure:

- a) is elastically deformable to a partially collapsed configuration;
- b) is configured to elastically contract and expand in response to contraction and expansion of the uterine cavity,

a sensor arrangement comprising: at least one sensor configured to measure at least one parameter, wherein the at least one sensor is positioned on at least portion of the wire; wherein the at least one sensor is configured to measure at least one parameter of uterine cavity when the at least one sensor for a time period sufficient to provide such measurement.; and

- (b) delivering the device through a hollow sleeve into a uterine cavity to thereby form said three dimensional configuration in the uterine cavity wherein the elongate conformable member is linearized into a single straight elongate conformable member in the hollow sleeve with the proximal end at one end of the sleeve and the caudal end at the other end of the sleeve and introduced proximal-end first from the sleeve into the uterine cavity to assume the predetermined three dimensional configuration; wherein said three dimensional configuration is capable of elastically contracting and expanding in response to contraction and expansion of said uterine cavity thereby enabling said three dimensional configuration to maintain its position within said uterine

- (c) measuring at least one parameter using the at least one sensor; and

- (d) communicating the at least one parameter and recording the at least one parameter.

5. The method of claim 4, wherein the measuring step measures uterine health.

6. The method of claim 4, wherein the measuring step measures parameters related to properties of, or changes in, the endometrial lining.
7. The method of claim 4, wherein the measuring step measures measure parameters indicative of uterine spotting.
8. The method of claim 4, wherein the measuring step measures parameters indicative of fertility.
9. The method of claim 4, wherein the measuring step measures parameters related to the microbiome within the uterus
10. The method of claim 4, wherein the measuring step measures uterine health.
11. The method of claim 4, wherein the measuring step measures uterine health.

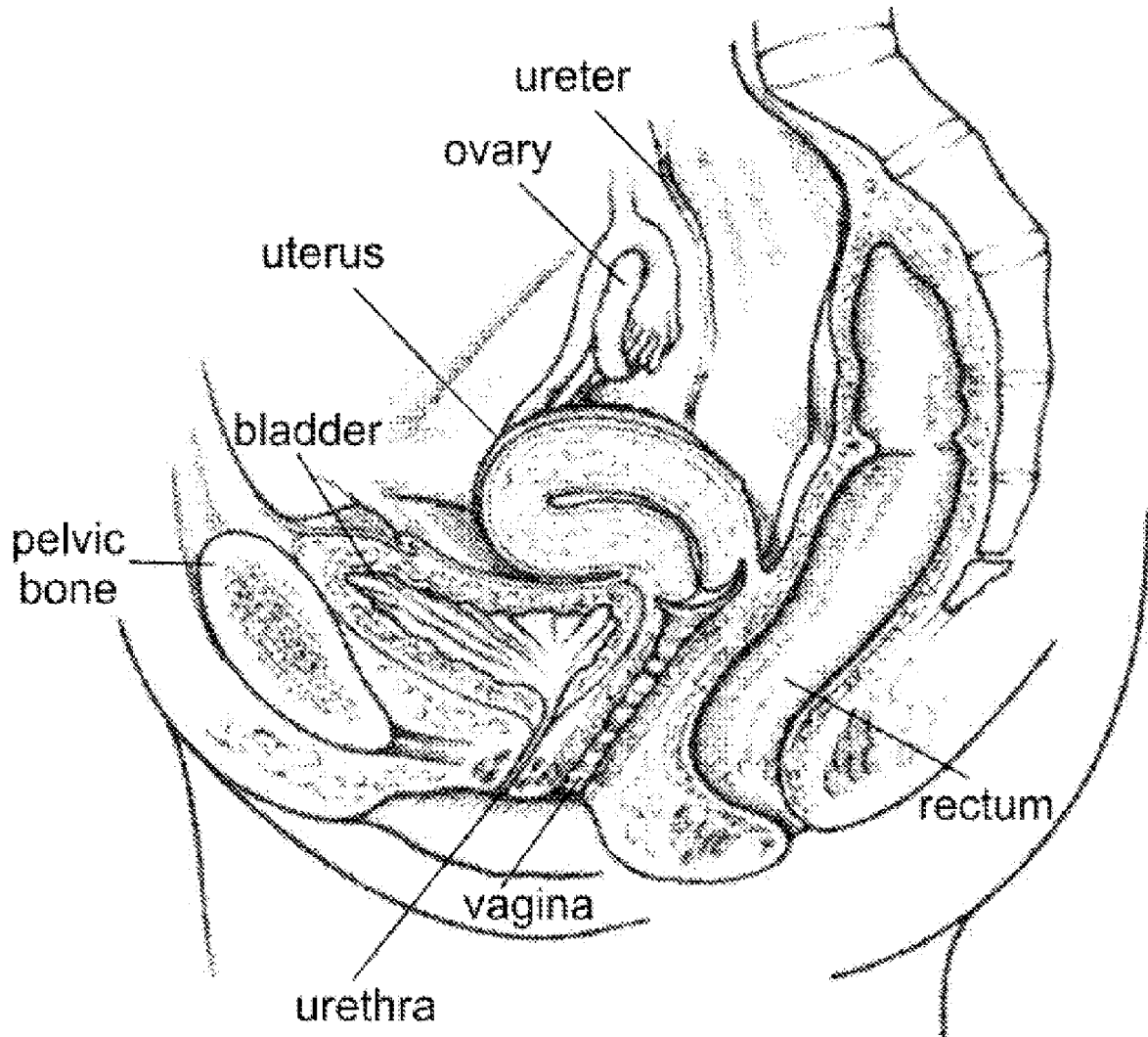


Figure 1A

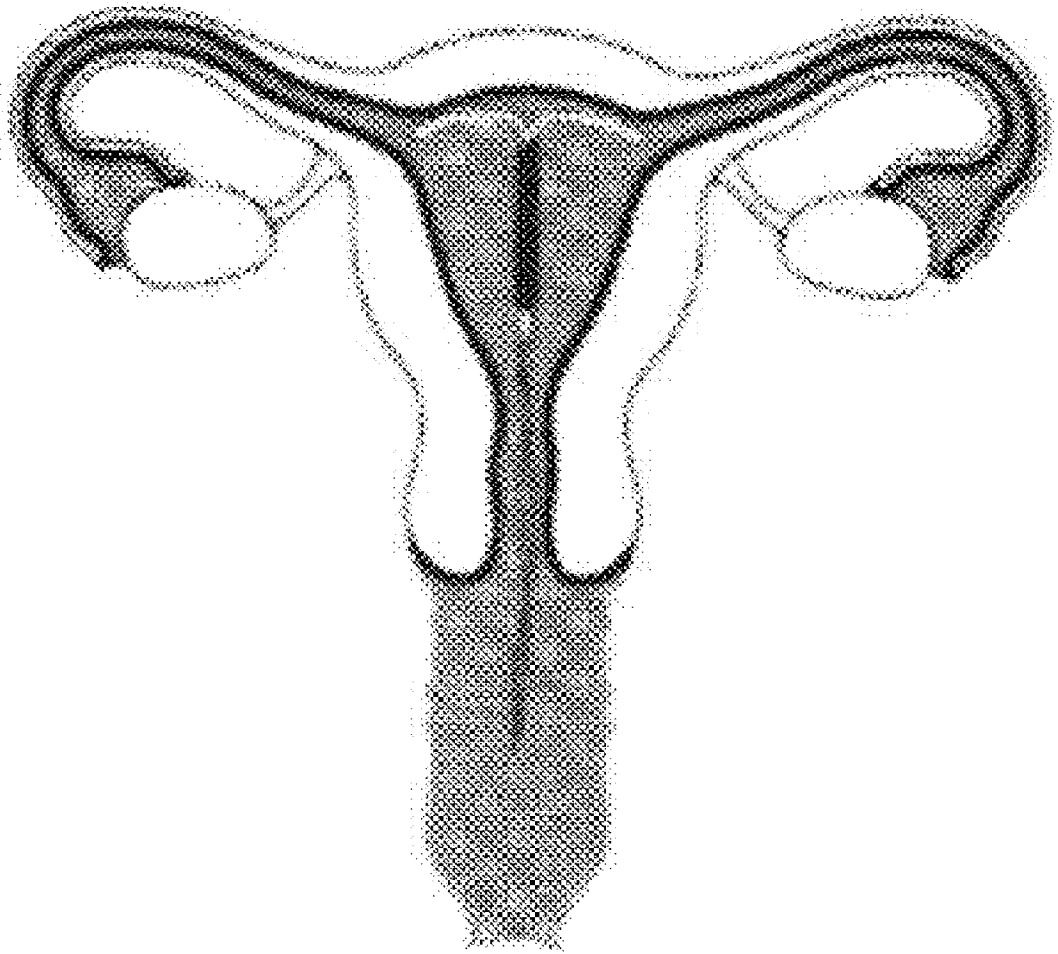


Figure 1B

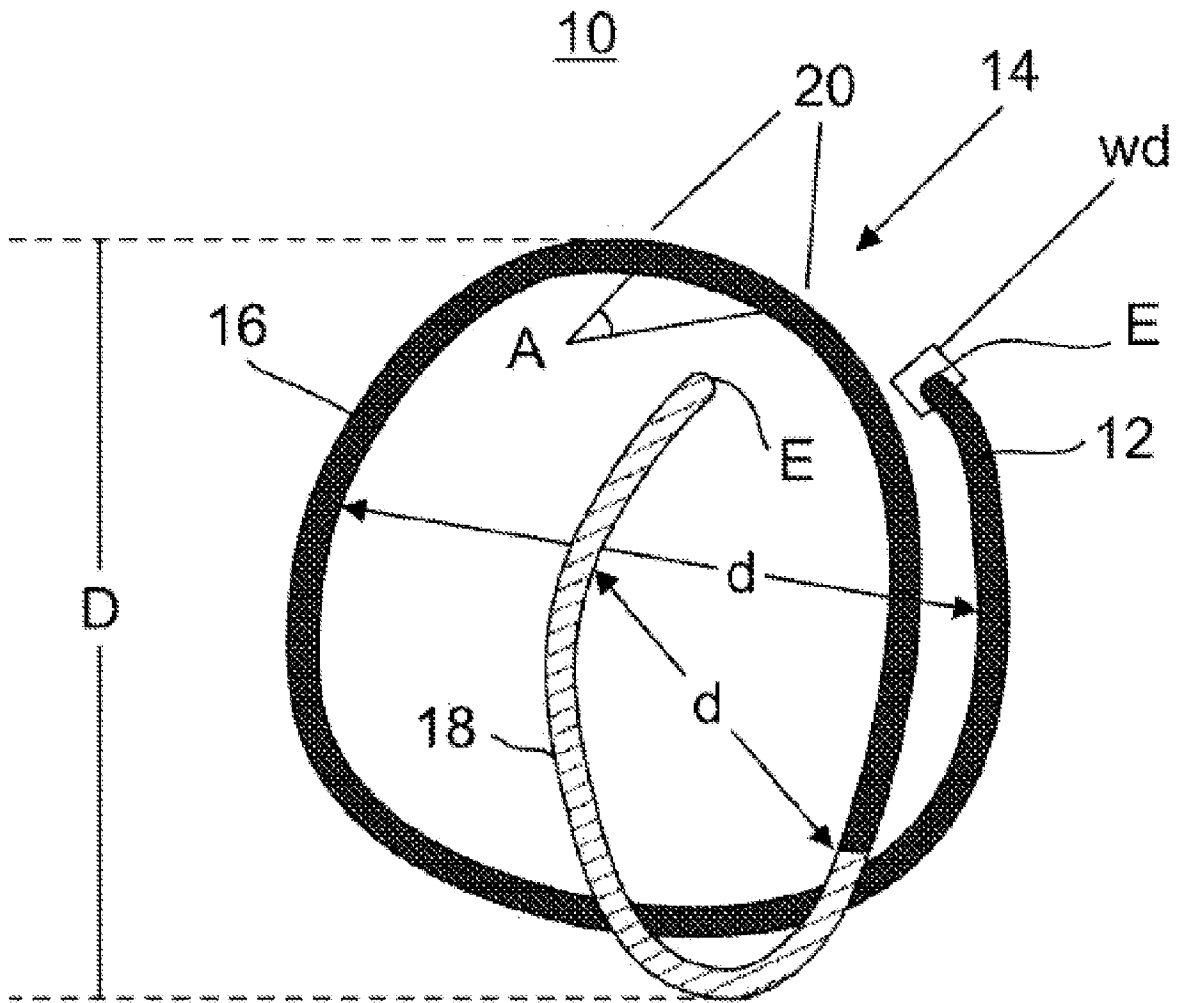


Figure 2

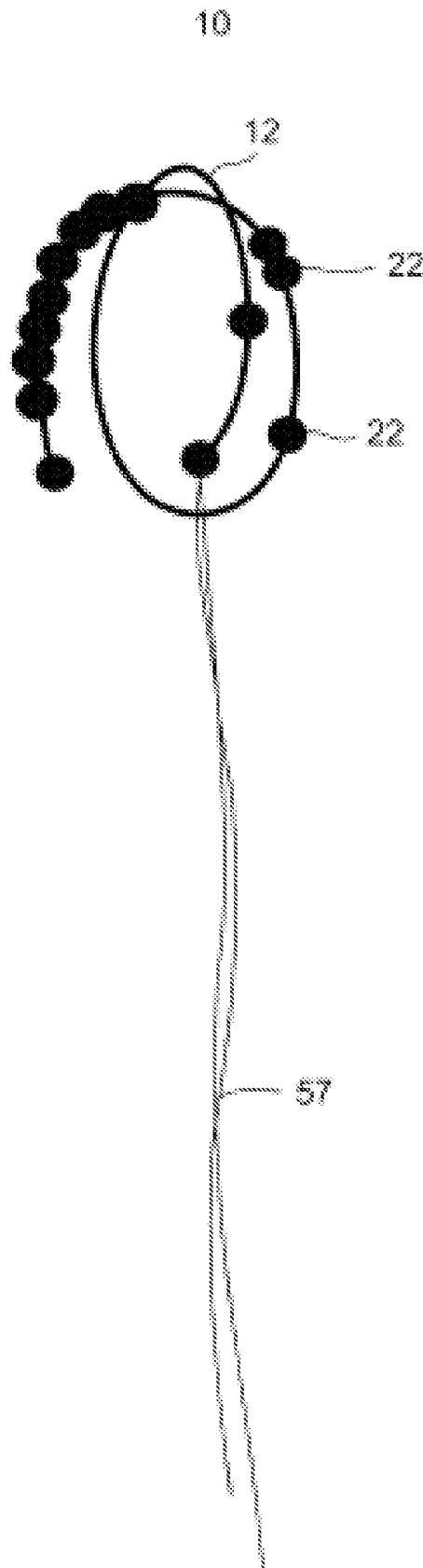


Figure 3

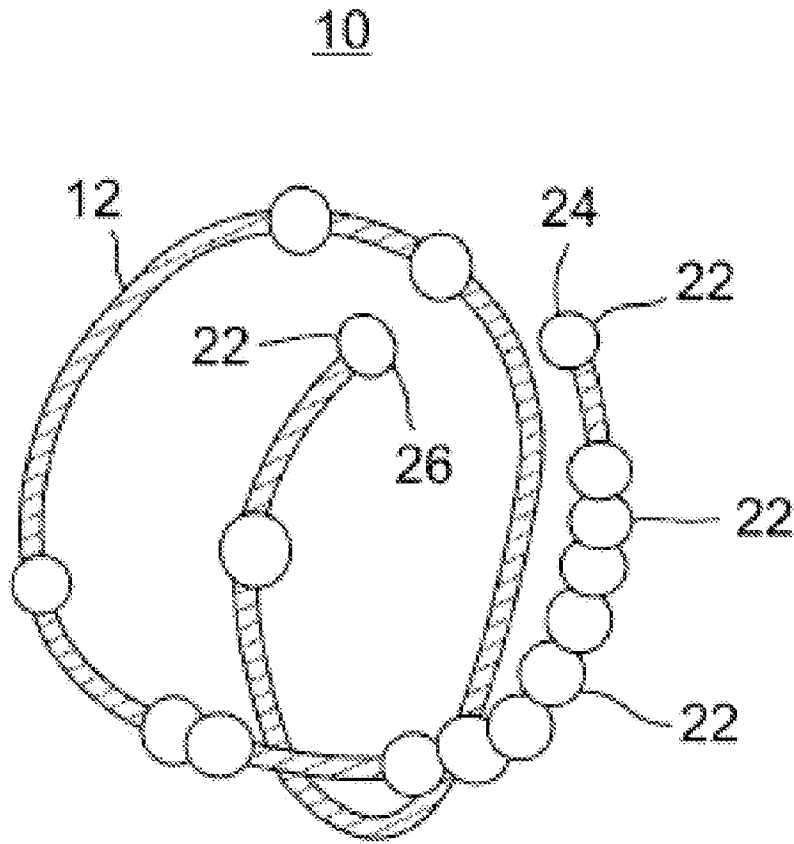


Figure 4

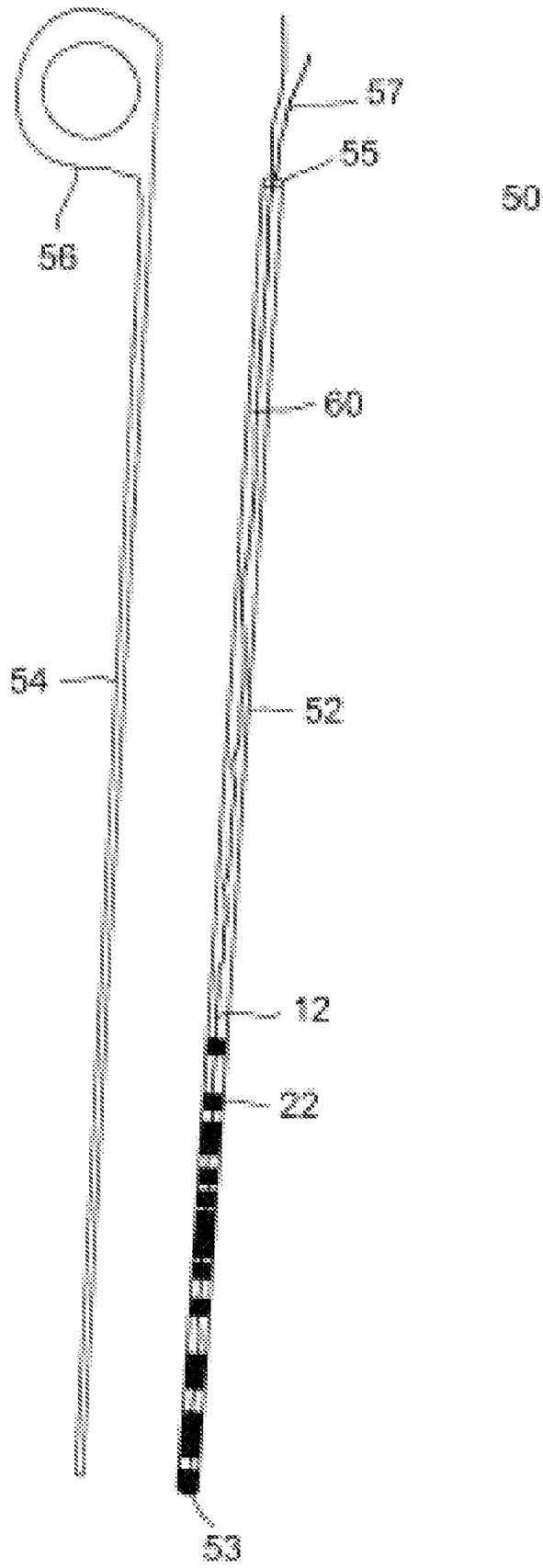


Figure 5

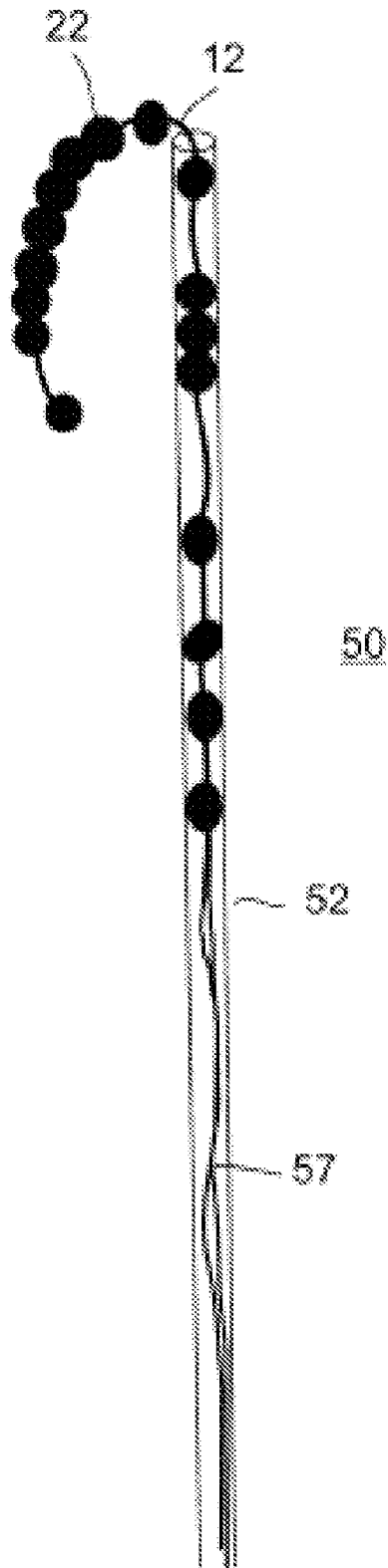


Figure 6A

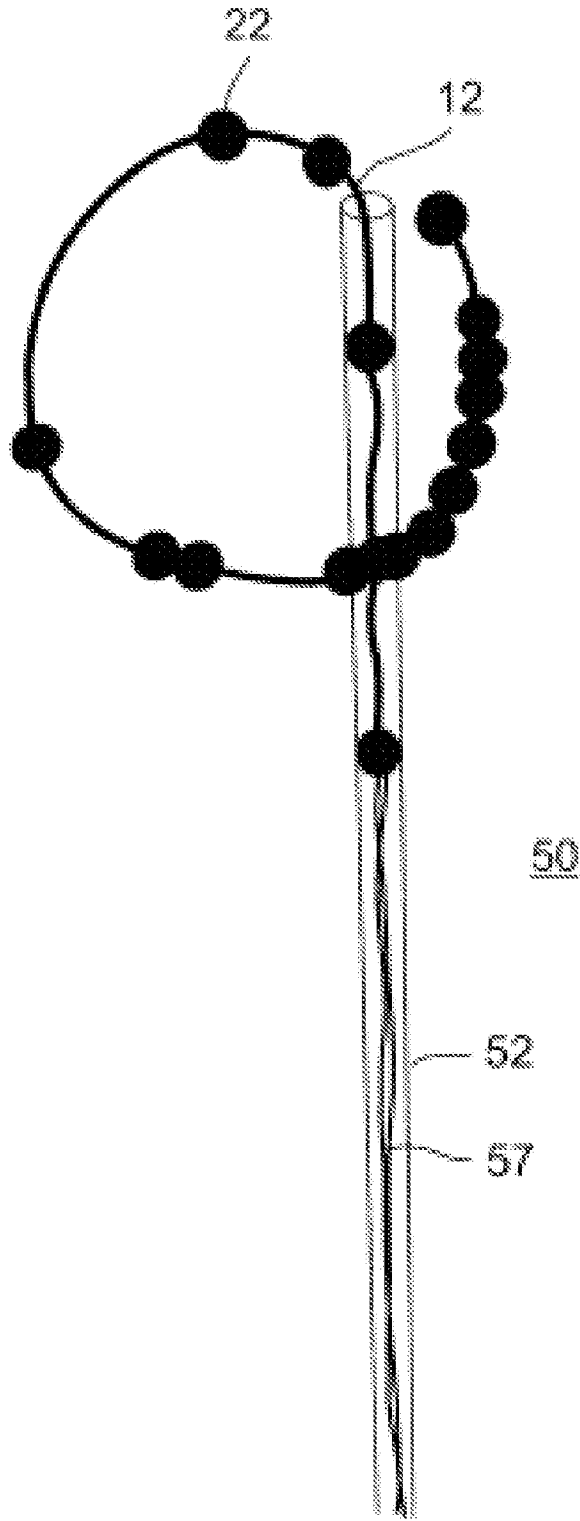


Figure 6B

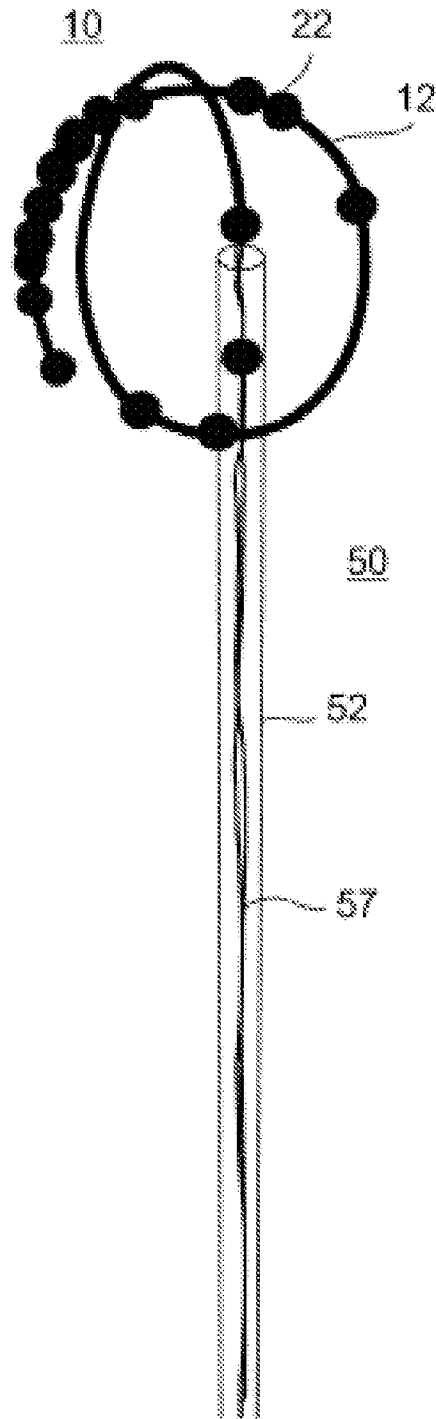


Figure 6C

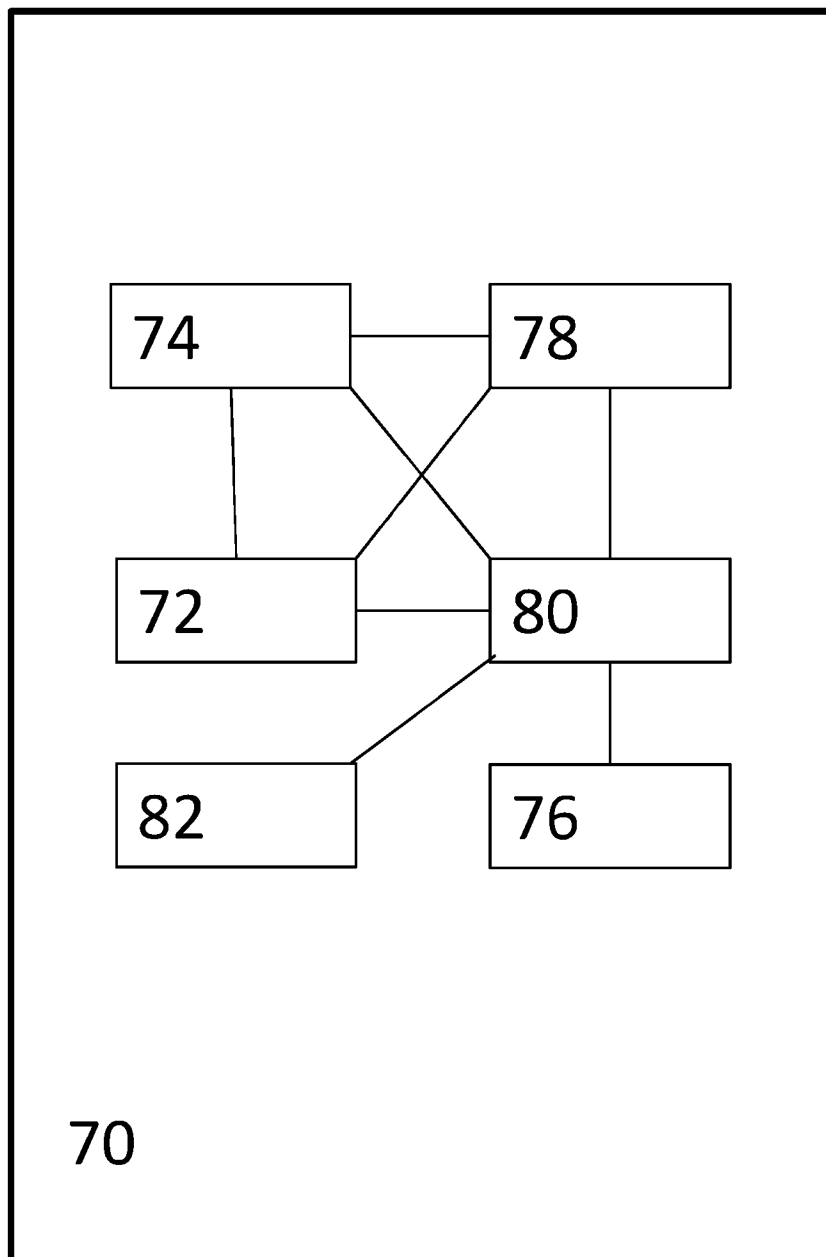


Figure 7

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>194517-010501/PCT</b>		<b>FOR FURTHER ACTION</b> see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. <b>PCT/IB2024/000320</b>	International filing date ( <i>day/month/year</i> ) <b>14 June 2024 (14.06.2024)</b>	(Earliest) Priority Date ( <i>day/month/year</i> ) <b>14 June 2023 (14.06.2023)</b>
Applicant <b>OCON MEDICAL LTD.</b>		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

the international application in the language in which it was filed.

a translation of the international application into \_\_\_\_\_ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b.  This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c.  With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2.  **Certain claims were found unsearchable** (see Box No. II).

3.  **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 1A

as suggested by the applicant.

as selected by this Authority, because the applicant failed to suggest a figure.

as selected by this Authority, because this figure better characterizes the invention.

b.  none of the figures is to be published with the abstract.

## INTERNATIONAL SEARCH REPORT

International application No.

**PCT/IB2024/000320**

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
IPC: <b>A61B 5/11</b> (2024.01); <b>A61F 6/14</b> (2024.01); <b>A61B 10/00</b> (2024.01); <b>A61B 17/12</b> (2024.01); <b>A61B 17/42</b> (2024.01) CPC: <b>A61B 5/4325</b> ; <b>A61F 6/142</b> ; <b>A61B 5/1107</b> ; <b>A61B 5/4356</b> ; <b>A61B 5/6875</b> ; <b>A61B 10/0012</b> ; <b>A61B 17/12145</b> ; <b>A61B 17/42</b>		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) See Search History Document		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched See Search History Document		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) See Search History Document		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2020/0060607 A1 (UNIVERSITY OF SOUTHAMPTON) 27 February 2020 (27.02.2020) entire document	1-3
Y	entire document	4-11
Y	US 2021/0154044 A1 (OCON MEDICAL LTD.) 27 May 2021 (27.05.2021) entire document	4-11
A	US 2020/0315593 A1 (GEORGIU et al.) 08 October 2020 (08.10.2020) entire document	1-11
A	US 2019/0282397 A1 (GYRUS ACMI, INC. D.B.A OLYMPUS SURGICAL TECHNOLOGIES AMERICA) 19 September 2019 (19.09.2019) entire document	1-11
A	US 2020/0163579 A1 (OSAKA UNIVERSITY) 28 May 2020 (28.05.2020) entire document	1-11
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents: “A” document defining the general state of the art which is not considered to be of particular relevance “D” document cited by the applicant in the international application “E” earlier application or patent but published on or after the international filing date “L” document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) “O” document referring to an oral disclosure, use, exhibition or other means “P” document published prior to the international filing date but later than the priority date claimed “T” later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention “X” document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone “Y” document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art “&” document member of the same patent family		
Date of the actual completion of the international search <b>04 November 2024 (04.11.2024)</b>		Date of mailing of the international search report <b>08 November 2024 (08.11.2024)</b>
Name and mailing address of the ISA/US <b>COMMISSIONER FOR PATENTS MAIL STOP PCT, ATTN: ISA/US P.O. Box 1450 Alexandria, VA 22313-1450 UNITED STATES OF AMERICA</b>		Authorized officer  <b>TAINA MATOS</b>
Facsimile No. <b>571-273-8300</b>		Telephone No. <b>571-272-4300</b>