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(54) **Title:** LESS TRAUMATIC METHOD OF DELIVERY OF MESH-BASED DEVICES INTO HUMAN BODY

(57) **Abstract:**

LESS TRAUMATIC METHOD OF DELIVERY OF MESH-BASED DEVICES INTO HUMAN BODY

Related Application

[0001] This application claims priority to and the benefit of U.S. Provisional Patent Application Serial No. 61/289,898, filed on December 23, 2009, entitled, "Less Traumatic Method of Delivery of Mesh-Based Devices Into Human Body," which is incorporated herein by reference in its entirety.

Background

[0002] The disclosed invention relates generally to medical devices and more particularly to implants and less traumatic methods for delivering implants within a pelvic region of a patient to treat various pelvic dysfunctions.

[0003] A variety of medical procedures are performed to treat various female pelvic dysfunctions, including procedures to treat urinary incontinence, and correcting various prolapse conditions such as uterine prolapse, cystoceles, rectoceles, and vaginal vault prolapse.

[0004] Women often experience vaginal prolapses due to age or other factors. For example, women may experience a cystocele, a rectocele and/or a hysterocele. A cystocele occurs when the bladder bulges into the vagina, and a rectocele occurs when the rectum bulges into the vagina. A hysterocele occurs when the uterus descends into the vagina. An enterocele (small bowel prolapse) can also occur, when the small bowel pushes through the upper wall of the vagina. It is relatively common for a hysterocele and cystocele or hysterocele and rectocele, or other combinations thereof to occur at the same time. It is also common for different types of prolapse to occur in relatively quick succession.

[0005] Treatment has included suturing procedures or the use of implants for support or suspension. A hysterocele is often treated with a hysterectomy followed by a vaginal vault suspension. Various devices and procedures are used to deliver and secure pelvic implants within a variety of different anatomical structures within a pelvic region. Implants can be

delivered to a pelvic region through one or more vaginal incisions, and/or through exterior incisions in the patient.

[0006] Known methods of delivering or implanting implants, such as slings, within the body include the use sleeves. In such known methods, a sleeve is disposed about the implant during insertion such that the sleeve and the implant are inserted within a bodily tissue. The sleeve, with the implant inside, is inserted through a bodily tissue. Once the implant is, for example, in a desired positioned within the bodily tissue, the sleeve can be removed from the body leaving the implant disposed within the bodily tissue. The sleeve protects the tissue from abrasion by the implant during delivery and adjustment, and protects the implant from over-stretching during delivery. The use of such known sleeves during implantation, however, can result in trauma to the bodily tissue through which the sleeve and implant have been inserted. More specifically, the sleeve adds bulk to the implant, and is typically stiffer than the implant, requiring larger incisions needed and/or holes created within the bodily tissue (for example, double the size). Undesirably large forces may also be required to pull the sleeved implant through a bodily tissue.

[0007] Thus, a need exists for a medical device that reduces trauma to the bodily tissue during insertion of an implant, i.e. by reducing the required size of the incision and/or the hole through the tissue. Also, a need exists for a medical device that reduces the force required to move the device through the bodily tissue.

Summary

[0008] In some embodiments, a method includes extending a dilator into a body of a patient in a first direction such that a distal end portion of the dilator extends from the body. The dilator defines a lumen therethrough. At least a portion of the dilator is disposed within the body when the distal end portion extends from the body. At least a portion of an implant is passed through the lumen defined by the dilator. The dilator is removed from the body by moving the dilator in the first direction.

Brief Description of the Drawings

[0008] FIG. 1 is a schematic illustration of a dilator according to an embodiment.

[0009] FIG. 2 is a schematic illustration of a delivery needle coupled to the dilator in FIG. 1 according to an embodiment.

[0010] FIG. 3 is a schematic illustration of a delivery needle coupled to the dilator in FIG. 1 according to another embodiment.

[0011] FIG. 4 is a flow chart of a method of inserting an implant into a body using the dilator in FIG. 1 according to an embodiment.

[0012] FIGS. 5-8 are schematic illustrations showing a method of inserting the implant into the body using the dilator in FIG. 1.

[0013] FIG. 9 is a schematic illustration of a dilator assembly according to an embodiment.

[0014] FIG. 10 is a flow chart of a method of inserting an implant into a body using the dilator assembly in FIG. 9 according to another embodiment.

[0015] FIGS. 11-15 are schematic illustrations showing a method of inserting the implant into the body using the dilator assembly in FIG. 9.

Detailed Description

[0016] The devices and methods described herein are generally directed to implants (e.g., slings for treatment of incontinence, such as by bladder neck suspension, posterior support implants, anterior support implants, and total pelvic floor repair implants) and the delivery and placement of such implants within a pelvic region of a patient using one or more dilators. An implant can be placed into the pelvic space of a patient and secured at one or more locations within the pelvic space to treat many different female pelvic floor dysfunctions.

[0017] The insertion device (i.e., the one or more dilators) is configured to place, deposit, or otherwise insert an implant (e.g., a sling) into one or more bodily tissues of a patient. The implant is configured to suspend or support a bodily tissue or organ when the implant is retained within the patient through tissue ingrowth and/or temporary suturing. For example, in one embodiment, the insertion device can place the implant under the bladder neck through the both obturator externus muscles and further through corresponding skin incisions for incontinence treatment.

[0018] As used in this specification, unless otherwise apparent from the context, the words "proximal" and "distal" refer to the direction closer to and further away from, respectively, an operator (e.g., surgeon, physician, nurse, technician, etc.) who would use an insertion device during a procedure. For example, the end of an insertion device first to contact the patient's body would be the distal end, while the opposite end of the insertion device (e.g., the end of the insertion device being operated by the operator) would be the proximal end of the insertion device. Similarly, the end of a insertion device implanted the furthest within the patient's body would be the distal end, while the opposite end of the insertion device (e.g., the end of the insertion device that is inserted the least amount within the body or the end of the insertion device that is disposed outside of the body) would be the proximal end.

[0019] FIG. 1 is a schematic illustration of a dilator 100 configured to be inserted within a body of a patient and to deliver an implant within the body. The dilator 100, which can be, for example, a tube, includes a proximal end portion 103 and a distal end portion 102. Additionally, the dilator 100 defines a distal opening 107, a proximal opening 108 and a lumen (not identified) extending therethrough. The distal opening 107 is in fluid communication with the proximal opening 108 via the lumen. The lumen is configured to receive at least a portion of an implant (not illustrated) via the distal opening 107 and/or the proximal opening 108, as described herein. The lumen is also configured to receive at least a portion of a delivery needle (not illustrated) via the distal opening 107 and/or the proximal opening 108, as described herein.

[0020] The distal end portion 102 of the dilator 100 is configured to be inserted into a bodily tissue through an incision. Such a bodily tissue can be, for example, a vaginal tissue, an obturator membrane, a supra-pubic tissue, a retro-pubic tissue and/or the like. The distal end portion 102 of the dilator 100 may include a tapered tip 105. The tapered tip 105 is configured to allow the dilator 100 to advance through the bodily tissue more easily. Said another way, the tapered tip 105 facilitates a smooth insertion of the dilator 100 into the bodily tissue. The tapered tip 105 can be tapered at any suitable angle (or rate) to reduce tissue resistance during insertion.

[0021] The proximal end portion 103 of the dilator 100 includes an enlarged portion 106. The enlarged portion 106, which may have, for example, a cone shape, is configured to operate as a funnel for the dilator 100. For example, the enlarged portion 106 can receive, via

the proximal opening 108, a portion of an implant having a lateral dimension larger than a diameter of the lumen. The enlarged portion 106 can facilitate advancing the implant through the lumen by enabling the implant to gradually contract to a dimension sufficient to fit through the lumen without the exertion of undue force on the dilator 100 and/or the implant. In some instances, when the proximal end portion 103 of the dilator 100 is extended through a bodily tissue, the enlarged portion 106 provides a surgeon (or other doctor) a larger area with which to perform a procedure. The enlarged portion 106 can increase at any suitable angle (or rate). Although the enlarged portion 106 is illustrated and described above as having a cone shape (i.e., a circular funnel shape), in other embodiments, the enlarged portion 106 can have any suitable shape and/or size. For example, in some embodiments, the enlarged portion 106 can have a flat funnel shape. In some embodiments, however, the dilator 106 does not include an enlarged portion 106.

[0022] In use, the dilator 100 is configured to engage a delivery needle (e.g., delivery needle 230 or 330 shown in FIGS. 2 and 3, respectively) prior to insertion into the body. The delivery needle is configured to either push or pull the dilator 100 through an incision and into the body, as described in more detail herein. In one example, the delivery needle can push the dilator 100 through a vaginal incision. The delivery needle can further push the distal end portion 102 of the dilator 100 through the pelvic region of the body (including, for example, the retropubic space or the obturator foramens) and out of a skin incision, e.g. suprapubic or perineal. In such an example, the dilator 100 is positioned within the body such that the proximal end portion 103 is disposed flush with the first layer of tissue in which the implant is to be anchored and the distal end portion 102 is disposed through the skin incision, extending from the body.

[0023] Once the dilator 100 is positioned within the body, the delivery needle is disengaged from the dilator 100 and a portion of an implant can be advanced through the lumen of the dilator 100. The implant can be, for example, a mesh sling or a mesh tape having a flat configuration or a rolled configuration. In some embodiments, a portion of the implant can be pushed through the dilator 100 in a distal direction via a pusher. In some embodiments, a portion of the implant can be coupled to a suture such that the suture is passed distally through the lumen and out of the distal opening 107 of the dilator 100. The surgeon, for example, can then pull the suture and guide the implant into the lumen of the dilator 100 via the suture.

[0024] Once a suitable portion of the implant is disposed within the dilator 100, the implant can be adjusted and/or tensioned. Since the length of the dilator 100 is sufficient to extend through body tissue from an entrance incision (e.g., in tissue in the pelvic region, accessed via a vaginal incision) to an exit incision (e.g. the supra-pubic incision), the implant can be inserted and positioned within the body within the dilator 100 without contacting any portion of the body other than the desired tissue or organ the implant is configured to support, as described in more detail herein. It should be understood that, although the procedure described above refers to only one dilator 100, insertion of an implant, such as a sling, often involves the use of two dilators (see, for example, FIG. 9). For example, the dilator 100 can be used to implant a right portion of a sling and another dilator can be used to implant a left portion of the sling such that a body portion of the sling is disposed beneath and supports a bladder neck. In such an example, the dilator 100 extends through tissue in the retropubic region and a right supra-pubic incision, while the other dilator extends through tissue in the retropubic region and a left supra-pubic incision. Thus, an adjustment or tensioning of the sling can include adjusting the right portion of the sling relative to the left portion of the sling such that the body portion of the sling is properly tensioned to support the bladder neck.

[0025] The dilator 100 can be removed from the body after the implant is positioned within the body (albeit within the dilator 100, which is within the body). The implant remains within the body and now contacts the bodily tissue between the supra-pubic incision site and the internal tissue incision. The vaginal incision can then be closed via suturing and/or the like. The portion of the implant extending from the external (e.g. supra-pubic) incision can be trimmed off, and the external incision can also be closed (with the portion of the implant disposed therein) via suturing and/or the like. In some embodiments, the dilator 100 can be removed from the body by moving the dilator 100 in the distal direction (i.e., the same direction as the insertion). In this manner, the proximal end portion 103 of the dilator 100 exits the body via the skin incision.

[0026] The dilator 100 can have any suitable shape and/or size. The dilator 100 can be constructed of any suitable, biocompatible material configured to be disposed within the body. For example, the dilator 100 can be constructed of a substantially rigid material, such as a stainless steel. In some embodiments, the dilator 100 can be constructed of a polymer. The dilator 100 can be formed, for example, by molding, extruding, casting, sintering, forging, machining, or other known methods of manufacturing such medical devices.

[0027] The dilator 100 can have a substantially smooth and/or continuous outer surface to prevent or reduce friction produced between the dilator 100 and the bodily tissue when the dilator 100 contacts the bodily tissue during insertion. As friction between the dilator 100 and the bodily tissue decreases, the amount of force required to insert or move the dilator 100 through the bodily tissue decreases. Thus, the likelihood of damaging the bodily tissue during insertion also decreases.

[0028] In some embodiments, the distal end portion 102 of the dilator 100 can include an aperture (not illustrated in the embodiment of FIG. 1, but illustrated, for example in the embodiment of FIG. 9) through which a suture can extend. For example, as described above, the implant can be coupled to a suture such that the suture is passed through the dilator 100 and used to pull or guide the implant through the dilator 100. In this embodiment, an end of the suture can be laced through the aperture and, for example, tied to the distal end portion 102 of the dilator 100 such that the suture is releasably coupled to the dilator 100 before insertion. In this manner, the dilator 100 is inserted within the body along with the suture. When the surgeon, for example, is ready to move the implant into the dilator 100, the suture can be decoupled (e.g., untied), removed from the aperture and pulled in the same manner described above. In some embodiments, however, the suture can be fixedly coupled within the aperture and/or a distal end potion 102 of the dilator 100.

[0029] FIG. 2 is schematic illustration of the dilator 100 coupled to a delivery needle 230 prior to insertion into a body. The delivery needle 230 is configured to push the dilator 100 through the body. The method of inserting the dilator 100 via the delivery needle 230, as disclosed below, is herein referred to as the "push" method. The delivery needle 230 includes a handle 231 and a needle 232 with a tip 233. The needle 232, which has a slight curvature along its length, is coupled to the handle 231.

[0030] When the delivery needle 230 is coupled to the dilator 100, the needle 232 is disposed within the lumen defined by the dilator 100 such that the tip 233 of the needle 232 extends from the distal opening 107 of the dilator 100. In some embodiments, the tip 233 and/or another portion of the needle 232 can form an interference fit with the dilator 100 when the needle 232 is disposed within the distal opening 107. In this manner, the dilator 100 can be restricted from moving or uncoupling from the delivery needle 230 during insertion. On other embodiments, however, the needle 232 can be coupled to the dilator 100 in any other suitable manner.

[0031] In use, the delivery needle 230 is coupled to the dilator 100 in the manner described above, and inserted into the body, for example, via a vaginal incision. The delivery needle 230 can be operated, for example, by a surgeon. The delivery needle 230 is pushed through the body toward, for example, a supra-pubic incision, such that the dilator 100 is pushed through body tissue toward the supra-pubic incision. In some embodiments, the delivery needle 230 can be pushed through the body toward, for example, a retro-pubic incision, a perineum incision and/or the like. Additionally, in some embodiments, pushing the delivery needle 230 through the body includes pushing the delivery needle 230 and a portion of the dilator 100 through an obturator membrane.

[0032] The advancement of the delivery needle 230 through the body is halted after the tip 233 of the delivery needle 230 reaches the supra-pubic incision (or other desired incision) and the distal end portion 102 of the dilator 100 extends from the body through the supra-pubic incision (or other desired incision), once the proximal opening 108 of the dilator is approximately flush with the body tissue into which the dilator 100 has been inserted. The delivery needle 230 can then be uncoupled from the dilator 100 and removed from the body. The delivery needle 230 is removed by moving (or pulling) the needle 232 in the opposite direction from which it was pushed through the body. In this manner, the delivery needle 230 is removed from the vaginal incision (i.e., the same incision through which it was inserted). The dilator 100 remains within the body.

[0033] FIG. 3 is a schematic illustration of the dilator 100 coupled to a delivery needle 330 during insertion into a body. The delivery needle 330 is configured to pull the dilator 100 through the body tissue. Thus, as will be described in more detail herein, the delivery needle 330 is configured to be inserted within the body before the dilator 100. The method of inserting the dilator 100 via the delivery needle 330, as disclosed below, is herein referred to as the "pull" method. The delivery needle 330 includes a handle 331 and a needle 332 with a tip 333. The needle 332, which has a C-shaped curvature, is coupled to the handle 331. The needle 332 can have any suitable shape and/or size. For example, in some embodiments, the needle 332 can have the same shape and/or size as the needle 232 of the delivery needle 230 shown in FIG. 2.

[0034] When the delivery needle 330 is coupled to the dilator 100, the tip 333 of the needle 332 is disposed within, or adjacent to, the distal opening 107 defined by the dilator 100. More specifically, as shown in FIG. 3, the tip 333 of the needle 332 extends within the

lumen of the dilator 100. In some embodiments, the tip 333 and/or another portion of the needle 332 can form an interference fit with the dilator 100 when the needle 332 is disposed within the distal opening 107. In this manner, the dilator 100 can be restricted from moving or uncoupling from the delivery needle 330 during insertion. In some embodiments, the tip 333 and/or another portion of the needle 332 can define a groove or recess configured to receive and/or couple to the distal end portion 102 of the dilator 100.

[0035] In use, the delivery needle 330 is inserted into the body via an exit incision, such as, for example, a supra-pubic incision. The exit incision is the incision from which the distal end portion 102 of the dilator 100 will extend once placed, as discussed in more detail herein. In some embodiments, the exit incision can be, for example, a retro-pubic incision, a perineum incision and/or the like. The delivery needle 330, which can be operated, for example, by a surgeon, is pushed through the body tissue toward an entry point adjacent the tissue or organ to be engaged by the implant. Once the tip 333 of the needle 332 passes through the entry point and enters a region of the pelvic area where it can be accessed (e.g. via a vaginal incision), the delivery needle 330 is coupled to the dilator 100 in the manner described above. The delivery needle 330, with the dilator 100, is then retracted or pulled back into the body in the opposite direction from which it was inserted.

[0036] The delivery needle 330 continues to retract through the body, pulling the dilator 100, until the distal end portion 102 of the dilator 100 extends from the body through the supra-pubic incision. In some embodiments, pulling the delivery needle 330 through the body includes pulling the delivery needle 330 and a portion of the dilator 100 through an obturator membrane and out through a perineal incision. The delivery needle 330 can then be uncoupled from the dilator 100 and removed from the body. In some embodiments, however, the delivery needle 330 is removed from or disposed outside of the body when the delivery needle 330 is uncoupled from the dilator 100. In embodiments where a portion of the delivery needle 330 (e.g., the tip 333) is disposed within the body when the delivery needle 330 is uncoupled from the dilator 100, the delivery needle 330 can be removed by moving (or pulling) the remainder of the needle 332 from the body in the same direction along which it pulled the dilator 100 through the body. In this manner, the delivery needle 330 is removed from the supra-pubic incision (i.e., the same incision through which it was inserted). The dilator 100 remains within the body.

[0037] The needles 232 and/or 332 can be constructed from any suitable material and can have any suitable shape and/or size, as discussed briefly above. Similarly, the handles 231 and/or 331 can be any suitable handle. The needles 232 and/or 332 can be constructed of any suitable material and can have any suitable shape and/or size.

[0038] In some embodiments, the needle (e.g., needle 232 and/or needle 233) can include a coupling member (not illustrated) configured to couple the needle to the dilator 100. The coupling member, which can be disposed on the distal end of the needle, is configured to be disposed within the lumen of the dilator 100 when the needle is coupled to the dilator 100. In some embodiments, the coupling member can be portion of the needle having an increased diameter such that the needle is coupled to the dilator 100 via friction. Said another way, the dilator 100 and the needle can form an interference fit via the coupling member, when the coupling member is disposed within the lumen of the dilator 100. In some such embodiments, the coupling member can be remotely controlled such that the diameter of that portion of the needle can increase and/or decrease on command. The coupling member can be actuated, for example, by pulling a wire on a handle (e.g., handle 231 and/or 331) of the needle, by pushing a button disposed on the handle, by squeezing a portion of the handle, and/or the like.

[0039] In some embodiments, the coupling member can include female threads configured to receive male threads disposed on the distal end portion 102 of the dilator 100. In this manner, the needle (e.g., needle 232 and/or needle 233) and the dilator 100 are releasably and threadedly coupled together.

[0040] FIG. 4 is a flow chart of a method 450 of inserting an implant 510 into a body B of a patient. The method illustrated in FIG. 4 is discussed with references FIGS. 5-8, which are schematic illustrations of the implant 510 being inserted into the body B via dilators 100 and 500. The term "implant" will be referred to herein as a "sling," unless otherwise specified. It should be understood, however, that the implant 510 can be any suitable implant including, but not limited to, a sling. For example, the implant 510 can be a mesh tape having a flat configuration or a rolled configuration. The method 450 includes extending a dilator through a body tissue of a patient in a first direction such that a distal end portion of the dilator extends from the body tissue, 451. Referring to FIGS. 5 and 6, the dilator 100 extends through the body B of the patient in a distal direction AA such that the distal end portion 102 of the dilator 100 extends from the body B. Similarly, the dilator 500 extends

through the body B of the patient in a distal direction BB such that a distal end portion 502 of the dilator 500 extends from the body B. The dilator 500 has substantially the same structure and operation as dilator 100 and thus, will not be described in detail herein. Also, it should be understood that, during the procedures described herein, the dilator 500 performs the same steps or operations that dilator 100 performs. Therefore, when the dilator 100 is described as or referred to in performing a particular step or operation, it should be understood that dilator 500 is also involved in or performing that particular step or operation, unless otherwise specified.

[0041] The dilator 100 is inserted into the body B of the patient via a vaginal incision, Iy (shown in FIG. 6). The dilator 500 is also inserted into the body B of the patient via the vaginal incision Iy. In this manner, there is only a single incision in the vaginal wall V through which both dilators 100 and 500 are inserted to access the tissue through which they will extend to the exterior of the body B, i.e. through incisions in the skin of body B. The incision Iy can be made at any suitable location along the vaginal wall V depending on the intended implantation site of the sling 510 within the pelvic region. For example, the vaginal incision I_v is shown in FIG. 6 as being located in the anterior vaginal wall V proximate the mid-urethra (i.e., the intended implantation location/site).

[0042] The distal end portion 102 of the dilator 100 extends from the body B of the patient via a first supra-pubic incision Isi- Similarly, the distal end portion 502 of the dilator 500 extends from the body B of the patient via a second supra-pubic incision I_{S2}. The first supra-pubic incision I_Si is located toward the right side of the body B and the second supra-pubic incision I_{S2} is located toward the left side of the body B relative to the perspective of the patient. In some embodiments, however, the supra-pubic incisions Isi and I_{S2} can be made at any location in the supra-pubic region of the body B. In some embodiments, the location of the supra-pubic incisions ¾i and/or I_{S2} can depend, for example, on the intended implantation site of the sling 510 within the pelvic region.

[0043] The dilator 100 can be inserted into the body B using one of the methods described above with reference to FIGS. 2 and 3. More particularly, the dilator 100 can be pushed into the body B (through body tissue) using, for example, the delivery needle 230 (i.e., the "push" method). Or, the dilator 100 can be pulled into the body B using, for example, the delivery needle 330 (i.e., the "pull" method). In most instances, however, the "push" method is regularly used for procedures involving supra-pubic incisions. As such, the

dilator 100 is inserted into the body B by being pushed through the vaginal incision I_V and further through the pelvic region (including, the tissue in the supra-pubic space), in distal direction AA, until the distal end portion 102 of the dilator 100 extends from the first supra-pubic incision I_{S1}. In some embodiments, the dilator 100 can be inserted into the body B in a manner different from the dilator 500. For example, the dilator 100 can be inserted into the body B via the "push" method, and the dilator 500 can be inserted into the body B via the "pull" method. Regardless of the method used to insert the dilators 100 or 500, the dilator 100 is moved through the body B in direction AA during insertion and dilator 500 is moved through the body B in direction BB during insertion.

[0044] When the dilator 100 is extended through the body B, as shown in FIGS. 5 and 6, the proximal end portion 103 of the dilator 100 is disposed within at least the first layer of tissue Ti (via a first tissue layer incision I_T) in which the sling 510 is to be anchored and a proximal-most end (not identified) of the dilator 100 is flush with that first layer of tissue T_1. In some embodiments, however, the proximal-most end of the dilator 100 can be flush with the vaginal wall V (i.e., the vaginal tissue). The placement of the proximal-most end of the dilator 100 can facilitate a more accurate placement of the sling 510 at the desired implantation site within the body B. For example, the ability to tension and/or adjust the sling 510 with respect to the urethra (or another desired implantation site) may be restricted in instances where the proximal-most end(s) of the dilators 100 and/or 500 extend beyond the first layer of tissue TV In instances where the proximal-most end(s) of the dilators 100 and/or 500 are recessed within that first layer of tissue TV the tissue surrounding the first tissue layer incision I_T can close up around the dilator 100. In some embodiments, however, the proximal-most end of the dilator 100 can be recessed within the first layer of tissue Ti or can extend into the vagina through the vaginal incision Iy.

[0045] As shown in FIG. 5, a first suture 522 is disposed within the lumen defined by the dilator 100. The first suture 522 has a first portion (not identified), which extends from the distal opening 107 of the dilator 100, and a second portion (not identified), which is coupled to a first arm 512 of the sling 510. Similarly, a second suture 523 is disposed within the lumen defined by the dilator 500. The second suture 523 has a first portion (not identified), which extends through the distal opening 507 of the dilator 500, and a second portion (not identified), which is coupled to a second arm 513 of the sling 510. As discussed in more detail herein, the sutures 522 and 523 are configured to facilitate the placement of the sling

510 within the body B. During this phase of the implantation procedure, however, the sling 510 may remain outside of the body B.

[0046] Returning to the flow chart shown in FIG. 4, at least a portion of an implant can be passed through the lumen defined by the dilator, 452. As shown in FIG. 7, the first arm 512 of the sling 510 is passed or moved in distal direction AA through the lumen defined by the dilator 100. More specifically, the first portion of the first suture 522 is moved in distal direction AA (i.e., away from the body B and/or the dilator 100) such that the first arm 512 of the sling 510 is moved in the distal direction AA. The first suture 522 can continue to be moved or pulled in the distal direction AA until the first arm 512 of the sling 510 is in the desired position within the lumen defined by the dilator 100. The desired position of the first arm 512 of the sling 510 within the lumen can, for example, correspond to the desired location of the sling 510 within the body B after implantation. Such a desired position can be achieved by, for example, adjusting and/or tensioning the first arm 512 of the sling 510 within the lumen relative to the second arm 513. The first suture 522 is, therefore, configured to guide the first arm 512 of the sling 510 into the lumen defined by the dilator 100 and to facilitate its placement within the lumen.

[0047] As shown in FIG. 7, the dilator 100 is configured to act a barrier between the first arm 512 of the sling 510 and the body B (including the body tissue through which the dilator is passed) when the first arm 512 is disposed within the lumen of the dilator 100. Said another way, the dilator 100 substantially prevents the first arm 512 of the sling 510 from contacting body tissue (other than the organ it is intended to support) when the first arm 512 is disposed within the lumen of the dilator 100. The first arm 512 of the sling 510 has a length sufficient to extend through body tissue from the vaginal incision I_v or the desired implantation site, to the first supra-pubic incision Isi- The length of the first arm 512 of the sling 510, however, is shorter than the length of the dilator 100. As a result, the first arm 512 of the sling 510 remains within the lumen of the dilator 100 while at least the first portion of the suture 522 extends through the distal opening 107 of the dilator 100 and outside of the body B. In some embodiments, however, the first arm 512 of the sling 510 can have any suitable length. For example, in some embodiments, the length of the first arm 512 of the sling 510 can be greater than the length of the dilator 100 such that a portion of the first arm 512 can extend through the distal opening 107 of dilator and/or outside of the body B.

[0048] Returning to the flow chart shown in FIG. 4, the dilator is removed from the body tissue by moving the dilator in the first direction, 453. As shown in FIG. 8, the dilator 100 is removed from the body B by moving the dilator 100 in the distal direction AA. In this manner, the dilator 100 is inserted into the body B and removed from the body B in the same direction. Thus, the dilator 100 enters the body B via the vaginal incision Iy and exits the body B via the first supra-pubic incision ¾ı.

[0049] As shown in FIG. 8, the sling 510 remains within the body B after the dilator 100 is removed from the body B. Thus, the sling 510 is in contact with the body tissue between the first supra-pubic incision ¾i and the first layer tissue incision I_T after the dilator 100 is removed from the body B. In some embodiments, the sling 510 can be configured to promote tissue ingrowth in the surrounding bodily tissue (e.g., the tissue between the first supra-pubic incision ¾i and the first layer tissue incision I_T and/or the tissue of the organ) after the dilator 100 is removed and the sling 510 is placed in contact with the tissue of body B.

[0050] The sling 510 maintains a substantially constant position within the body B when the dilator 100 is removed.

[0051] Once the dilator 100 is removed from the body B, the sutures 522 and/or 523 can be trimmed off or otherwise removed from the respective arms 512 and/or 513 of the sling 510. The sling 510 itself can also be trimmed after the dilator 100 is removed form the body B. Additionally, the vaginal incision Iy, the first tissue layer incision I_T (or any other internal incisions), and/or each of the supra-pubic incisions Isi and I_{S2} can be closed via any suitable manner.

[0052] Although the sling 510 is illustrated and described above as being coupled to sutures 522 and 523, in other embodiments, the sling 510 is not coupled to sutures. In such embodiments, the first arm 512 of the sling 510 can be passed through the lumen defined by the dilator 100 via a pusher or like device. Similarly, the second arm 513 of the sling 510 can be passed through the lumen defined by the dilator 500 via a pusher or like device. In some embodiments, the sling 510 is attached to only one of the sutures 522 or 523.

[0053] FIG. 9 is a schematic illustration of a dilator assembly, which includes dilators 600 and 700 coupled to an implant 610. The dilators 600 and 700 are configured to be inserted within a body of a patient and to deliver the implant 610 within the body. The term "implant" will be referred to herein as a "sling" in the same manner discussed above with

reference to implant 510 (i.e., sling 510). The dilator 600 includes a proximal end portion 603 having an enlarged portion 606, and a distal end portion 602 having a tapered tip 605. Additionally, the dilator 600 defines a distal opening 607, a proximal opening 608, an aperture 609 and a lumen (not identified) extending therethrough. The dilator 600 has substantially the same structure and operation as dilator 100, but includes an aperture 609 in the distal end portion 602 of the dilator 600. Thus, the proximal end portion 603, the distal end portion 602, the enlarged portion 606, and the tapered tip 605 have substantially the same structure and operation as the proximal end portion 103, the distal end portion 102, the enlarged portion 106, and the tapered tip 105 of the dilator 100, and are, therefore, not described in detail herein unless otherwise specified. Additionally, the distal opening 607, the proximal opening 608, and the lumen have substantially the same structure and operation as the distal opening 107, the proximal opening 108, and the lumen defined by the dilator 100, and are, therefore, not described in detail herein unless otherwise specified. Furthermore, the dilator 700 has substantially the same structure and operation as dilator 600 and thus, will not be described in detail herein unless otherwise specified.

[0054] The aperture 609 is located in the distal end portion 602 of the dilator 600. The aperture 609 is configured to receive a portion of a first suture 622, as described in more detail herein. The aperture 609 can have any suitable shape and/or size. For example, although the aperture 609 is illustrated in FIG. 9 as having a substantially circular shape, in other embodiments, the aperture 609 can have, for example, an oval shape, a square shape, a star shape and/or the like. Additionally, the aperture 609 can be formed by any suitable process, such as, for example, molding, drilling, casting, or the like.

[0055] The sling 610 is operatively coupled to the dilators 600 and 700 via sutures 622 and 623, respectively. The sling 610 is configured to be implanted within the body to support a desired tissue or organ within the body. The sling 610, which is illustrated in FIG. 9 as a flat mesh tape, includes a first arm 612 and a second arm 613. The first arm 612 is coupled to a second portion (not identified) of the first suture 622, and the second arm 613 is coupled to a second portion (not identified) of the second suture 623. As will be described in more detail herein, the first arm 612 is configured to be implanted within the body via the dilator 600 and the second arm 613 is configured to be implanted within the body via the dilator 700. The arms 612 and 613 are configured to be received within the lumens of the dilators 600 and 700, respectively.

[0056] As shown in FIG. 9, the first suture 622 is disposed within at least a portion of the lumen defined by the dilator 600 when the second portion of the first suture 622 is coupled to the first arm 612 of the sling 610. The first suture 622 includes a first portion (not identified) that extends through the aperture 609 (i.e., from the inside-out) and is coupled to the distal end portion 602 of the dilator 600 via the aperture 609. In some embodiments, the first portion of the first suture 622 can include a knot to prevent the first portion from receding back through the aperture 609, which thereby couples the first suture 622 to the dilator 600. The first portion of the first suture 622, however, can include any suitable anchor to prevent the first portion from receding back through the aperture 609. For example, in some embodiments, the first portion of the first suture 622 can be fixedly coupled within the aperture 609 via an adhesive.

[0057] The first portion of the first suture 622 can be coupled to the distal end portion 602 of the dilator 600 via the aperture 609 in any suitable manner. For example, in some embodiments, the first portion of the first suture 622 can be pulled through the distal opening 607 of the dilator 600 and then laced through the aperture 609 from the outside-in. A knot can be formed at the first portion of the first suture 622 to prevent the first suture 622 from receding back through the aperture 609. In some embodiments, a portion of the exposed first suture 622 can further be formed into a loop (shown, for example, in FIGS. 11 and 12). The surgeon, for example, can exert a force on the first suture 622 via the loop such that the knot (or other anchor) is forced through the aperture 609, thereby uncoupling the first suture 622 from the dilator 600. The loop can then be used to pull or move the first arm 612 of the sling 610 into the lumen of the dilator 600, as described herein.

[0058] In some embodiments, a kit can include the dilators 600 and 700 and the implant 610. In some such embodiments, the kit can be pre-assembled such that the implant 610 is coupled to the dilators 600 and 700 via sutures 622 and 623, respectively. The implant 610 can be coupled to the dilators 600 and/or 700 in any manner described herein. In some embodiments, the sling 610 can be pre-formed into a roll and included in the kit. In this manner, the sling 610 can be inserted into the body in its pre-formed configuration and can, for example, unroll into its original configuration at some time during or after the implantation procedure.

[0059] FIG. 10 is a flow chart of a method 860 of inserting an implant 610 into a body B of a patient. The method illustrated in FIG. 10 is discussed with references FIGS. 11-15,

which are schematic illustrations of the implant 610 being inserted into the body B via the dilator assembly shown in FIG. 9. The term "implant" will be referred to herein as a "sling," as discussed above. The method 860 includes extending a dilator through a body tissue of a patient such that a distal end portion of the dilator extends from the body tissue, 861. Referring to FIGS. 11 and 12, the dilator 600 extends through the body B (including internal body tissue) of the patient such that the distal end portion 602 of the dilator 600 extends from the body B. Similarly, the dilator 700 extends through the body B of the patient such that a distal end portion 702 of the dilator 700 extends from the body B. It should be understood that, during the procedures described herein, the dilator 700 performs the same steps or operations that dilator 600 performs. Therefore, when the dilator 600 is described as or referred to in performing a particular step or operation, it should be understood that dilator 700 is also involved in or performing that particular step or operation, unless otherwise specified.

[0060] The dilator 600 is inserted into the body B via a vaginal incision, Iy (shown in FIG. 12). The dilator 700 is also inserted into the body B via the vaginal incision Iy. In this manner, there is only a single incision in the vaginal wall V through which both dilators 600 and 700 extend. In some embodiments, however, the dilators 600 and/or 700 are inserted into the body B via separate vaginal incisions. The incision Iy can be made at any location along the vaginal wall V depending on the intended implantation site of the sling 610 within the pelvic region, as described above. When the dilator 600 is extended through the body B, as shown in FIG. 12, the proximal end portion 603 of the dilator 600 is disposed within at least the first layer of tissue Ti (via a first tissue layer incision I_T) in which the sling 510 is to be anchored and a proximal-most end (not identified) of the dilator 600 is flush with that first layer of tissue T_1, as described above.

[0061] As shown in FIG. 12, the dilator 600 extends through an obturator membrane $\mathbf{O_B}$ within the body B when the distal end portion 602 of the dilator 600 extends through the body B. More particularly, the dilator 600 extends through a first obturator incision $\mathbf{IO_{BI}}$ when the distal end portion 602 of the dilator 600 extends from a first perineum incision Ipi. Similarly, the dilator 700 extends through the opposing obturator membrane (not illustrated) via a second obturator incision (not illustrated) when the distal end portion 702 of the dilator 700 extends from the body B via a second perineum incision Ip_2. The first perineum incision Ipi and the obturator membrane $\mathbf{O_B}$ are located toward the right side of the body B, and the

second perineum incision I_{P_2} and opposing obturator membrane are located toward the left side of the body B relative to the perspective of the patient. In some embodiments, however, the perineum incisions Ipi and I_{P_2} can be made at any location in the perineum region of the body B. Similarly, the obturator incisions (e.g., the first obturator incision I_{0BI}) can be made at any location along the obturator membranes (e.g., the obturator membrane O_B) The location of the perineum incisions Ipi and/or I_{P_2} can depend, for example, on the intended implantation site of the sling 610 within the pelvic region.

[0062] The dilator 600 can be inserted into the body B using one of the methods described above with reference to FIGS. 2 and 3. More particularly, the dilator 600 can be pushed through the body B using, for example, the delivery needle 230 (i.e., the "push" method). Or, the dilator 600 can be pulled through the body B using, for example, the delivery needle 330 (i.e., the "pull" method). In most instances, however, the "pull" method is regularly used for procedures involving perineum and/or obturator incisions. As such, the delivery needle (e.g., delivery needle 330) is inserted and moved within the body B along a path that includes the first perineum incision Ipi, the first obturator incision IO_{BI}, the first tissue layer incision I_T (and any other internal body tissue incisions) and the vaginal incision Iy. Once the delivery needle reaches the vaginal incision Iy, the distal end portion 602 of the dilator 600 can be coupled to the delivery needle, in the manner described above, and inserted into the body B. The dilator 600 is inserted into the body B by being pulled in distal direction CC through the vaginal incision Iy, through the first tissue layer incision I_T, through the obturator incision IO_{BI}, and further through the first perineum incision I_Pi until the distal end portion 602 of the dilator 600 extends through the first perineum incision Ipi. In some embodiments, the dilator 700 can be inserted into the body B in a manner different from the dilator 600, as discussed above.

[0063] The dilators 600 and 700 are inserted into the body B in a similar configuration to that shown in FIG. 9. Similar to the configuration shown in FIG. 9, the sling 610 is operatively coupled to the dilators 600 and 700 via sutures 622 and 623 when the dilators 600 and 700 are inserted within the body B. The sutures 622 and 623 shown in FIGS. 11 and 12, however, are in a looped configuration. More specifically, with respect to dilator 600, the first portion of the first suture 622 extends through the lumen and out from the distal opening 607, then loops around the outside of the dilator 600 and through the aperture 609. The first portion of the first suture 622 disposed through the aperture 609 is then securely fastened to

the dilator 600, for example, via a knot, as described above. A loop (not identified) is then formed with the portion of the first suture 622 disposed outside of the dilator 600. During this phase of the implantation procedure, the sling 610 remains outside of the body **B**.

[0064] Returning to the flow chart shown in FIG. 10, the first portion of the suture is uncoupled from the distal end portion of the dilator, 862. As shown in FIG. 13, the first portion of the first suture 622 is uncoupled from the distal end portion 602 of the dilator 600 when the first suture 622 is moved in direction CC. A surgeon, for example, can pull the first suture 622 (e.g., via the loop) such that the force exerted on the first suture 622 in the distal direction CC forces the knot through the aperture 609 and, thereby uncouples the first suture 622 from the distal end portion 602 of the dilator 600. In some embodiments, however, the first portion of the first suture 622 is uncoupled from distal end portion 602 of the dilator 600 in any suitable manner, such as, for example, via severing.

[0065] Returning to the flow chart shown in FIG. 10, at least a portion of an implant is passed through the lumen defined by the dilator by pulling on the first portion of the suture, 863. As shown in FIG. 14, the first arm 612 of the sling 610 is passed or moved through the lumen defined by the dilator 600 by pulling the first portion of the first suture 622 in distal direction CC. For example, once the first suture 622 is uncoupled from the distal end portion 602 of the dilator 600, the surgeon, for example, can continue to pull the first suture 622 (e.g., via the loop) in the distal direction CC until the first arm 612 of the sling 610 is pulled into the lumen of the dilator 600. In some embodiments, the acts of pulling the first portion of the first suture 622 to uncouple it from the dilator 600 and to pull the sling 610 into the dilator 600 is performed in a continuous motion. In some embodiments, the first suture 622 can continue to be pulled until the first arm 612 of the sling 610 is in the desired position within the lumen defined by the dilator 600. As described above, the desired position of the first arm 612 of the sling 610 within the lumen can, for example, correspond to the desired location of the sling 610 within the body **B** after implantation. Such a desired position can be achieved by, for example, adjusting and/or tensioning the first arm 612 of the sling 610 within the lumen relative to the second arm 613.

[0066] As shown in FIG. 14 and described above, when the first arm 612 is disposed within the lumen of the dilator 600, the dilator 600 is configured to act a barrier between the first arm 612 of the sling 610, the obturator membrane $\mathbf{O_B}$ and the body **B** (including any bodily tissue other that the tissue or organ it is intended to support). The first arm 612 of the

sling 610 has a length sufficient to extend through body tissue from the vaginal incision ly or the desired implantation site, to the first perineum incision Ipi. The length of the first arm 612 of the sling 610, however, is shorter than the length of the dilator 600. As a result, the first arm 612 of the sling 610 remains within the lumen of the dilator 600 while at least the first portion of the first suture 622 extends through the distal opening 607 of the dilator 600 and outside of the body B, as described above. In some embodiments, however, the first arm 612 of the sling 610 can have any suitable length, as described above. For example, in some embodiments, the length of the first arm 612 is only sufficient to extend from the vaginal incision ly or the desired implantation site, to the first obturator incision IO_{BI}.

[0067] Returning to the flow chart shown in FIG. 10, the dilator is removed from the body tissue through a skin incision, 864. As shown in FIG. 15, the dilator 600 is removed from the body B through the first perineum incision I_{P1}. In this manner, the dilator 600 is inserted into the body B and removed from the body B in the same direction (i.e., distal direction CC). Thus, the dilator 600 enters the body B via the vaginal incision ly and exits the body B via the first perineum incision Ipi. In some embodiments, however, the dilator 600 can be removed from the body B through the vaginal incision I_V. In this manner, the dilator 600 is inserted and removed from the same incision.

[0068] As shown in FIG. 15, the sling 610 remains within the body B after the dilator 600 is removed from the body B, as described above. Thus, the sling 610 is in contact with the body tissue between the first layer tissue incision I_T and the first perineum incision I_{P1} (including the obturator membrane $\mathbf{O_B}$) after the dilator 600 is removed from the body B. In some embodiments, the sling 610 can be configured to promote tissue ingrowth in the surrounding bodily tissue, including the obturator membrane $\mathbf{O_B}$, after the dilator 600 is removed and the sling 610 is placed in contact with the body B.

[0069] Once the dilators 600 and 700 are removed from the body B, the sutures 622 and/or 623 can be trimmed off or otherwise removed from the respective arms 612 and/or 613 of the sling 610. The sling 610 itself can also be trimmed off after the dilators 600 and 700 are removed form the body B. Additionally, the vaginal incision ly, the first layer tissue incision I_T, the obturator incision IO_{BI} and/or each of the perineum incisions I_{P1} and I_{P2} can be closed via any suitable manner.

[0070] Although the sling 610 is illustrated and described above as being coupled to sutures 622 and 623, in other embodiments, the sling 610 is not coupled to sutures. In such embodiments, the first arm 612 of the sling 610 can be passed through the lumen defined by the dilator 600 via a pusher or like device. Similarly, the second arm 613 of the sling 610 can be passed through the lumen defined by the dilator 600 via a pusher or like device. In some embodiments, the sling 610 is attached to only one of the sutures 622 or 623.

[0071] While various embodiments of the invention have been described above, it should be understood that they have been presented by way of example only, and not limitation. Thus, the breadth and scope of the invention should not be limited by any of the above-described embodiments, but should be defined only in accordance with the following claims and their equivalents. While the invention has been particularly shown and described with reference to specific embodiments thereof, it will be understood that various changes in form and details may be made.

[0072] Although the dilators illustrated and described above were used to delivery or implant an implant into a pelvic region via a specific approach, in other embodiments, the dilator(s) can be used to deliver or implant an implant into a pelvic region using a variety of different approaches, including for example, a transvaginal approach, a retropubic approach, a supra pubic approach, or a transobturator approach.

[0073] Although the dilators are illustrated and described above as being positioned within the body such that the proximal end portion of the dilators are disposed within the vaginal area and the distal end portion of the dilators are disposed adjacent the outer surface of the body, in other embodiments, a dilator is positioned within the body in the opposite configuration. For example, the dilator can be positioned within the body such that the distal end portion of the dilator is disposed within the vaginal area and the proximal end portion of the dilator is disposed adjacent the outer surface of the body. In some such embodiments, a suture coupled to an implant, or the implant itself, is pulled into the lumen of the dilator via the distal opening. In this manner, the suture and/or the implant moves or passes through the lumen of the dilator in the opposite direction to that described above (i.e., from the distal end portion of the lumen to the proximal end portion of the lumen). The suture and/or the implant can be moved through the lumen by any of the means described above. For example, in some embodiments, the suture and/or the implant is coupled to a delivery needle (e.g., delivery needle 230 or 330) and pulled through the lumen.

[0074] Although the dilators and procedures are illustrated and described above with reference to a female pelvic region, it should be understood that the same dilators and/or procedures can be used in the male pelvic region without substantial modification. For example, where the female pelvic region is accessed via a vaginal incision in the aforementioned procedures, the male pelvic region can be accessed via right and left perineum incisions. In some embodiments, the female pelvic region can be accessed via perineum incisions rather than a vaginal incision in the aforementioned procedures.

[0075] The implant(s) described herein can be formed with a variety of different materials, such as biocompatible plastics and/or metals. In some embodiments, the implant is formed at least in part with a mesh material to promote tissue in-growth. An implant can also be formed fully or in part with biological or natural materials or combinations of biological and synthetic materials. An implant can be formed at least in part with, for example, the Advantage® Mesh by Boston Scientific Corporation. Alternatively, the implant can be formed with Polyform® Synthetic Mesh material by Boston Scientific Corporation.

[0076] The implant(s) can have a variety of different configurations and/or different sizes (e.g. lengths, widths), depending on the intended use for the particular implant and the intended implantation site for the implant within the pelvic region.

[0077] The previous description of the embodiments is provided to enable any person skilled in the art to make or use the invention. While the invention has been particularly shown and described with reference to embodiments thereof, it will be understood by those skilled in art that various changes in form and details may be made. For example, a dilator can include various combinations and sub-combinations of the various embodiments described herein.

[0078] In some embodiments, a method includes extending a dilator into a body tissue of a patient in a first direction such that a distal end portion of the dilator extends from the body of the patient. The dilator defines a lumen therethrough. At least a portion of the dilator is disposed within the body tissue when the distal end portion extends from the body. At least a portion of an implant is passed through the lumen defined by the dilator. The dilator is removed from the body tissue by moving the dilator in the first direction.

[0079] In some embodiments, the dilator can be extended by pushing the distal end portion of the dilator through the body tissue.

[0080] In some embodiments, the dilator can be extended by pulling the distal end portion of the dilator through the body tissue.

[0081] In some embodiments, the dilator can be extended into a portion of the body tissue in a pelvic region of the patient.

[0082] In some embodiments, the dilator can be extended such that a proximal end of the dilator is aligned with a surface of the body tissue. In this manner, the proximal end is flush with the surface.

[0083] In some embodiments, the distal end portion of the dilator can be configured to contact a portion of a delivery needle when the dilator is being extended into the body tissue.

[0084] In some embodiments, the dilator can be extended into the body tissue via a first incision, and is removed from the body via a second incision.

[0085] In some embodiments, the portion of the implant can be passed through the lumen by pushing the portion of the implant through the lumen in the first direction.

[0086] In some embodiments, the portion of the implant can be passed through the lumen by pulling the portion of the implant through the lumen in the first direction.

[0087] In some embodiments, the portion of the implant can be passed through the lumen in a second direction opposite the first direction.

[0088] In some embodiments, the first direction can be a distal direction.

[0089] In some embodiments, a proximal end portion of the dilator can include an enlarged portion, which is in fluid communication with the lumen. In some such embodiments, the enlarged portion can be configured to facilitate the passing of the portion of the implant through the lumen.

[0090] In some embodiments, the implant can be configured to be used to treat male incontinence.

[0091] In some embodiments, a method includes extending a dilator into body tissue of a patient such that a distal end portion of the dilator extends from the body of the patient. The distal end portion of the dilator is coupled to a first portion of a suture such that the first

portion of the suture is disposed outside of the body when the distal end portion of the dilator extends from the body. The suture has a second portion coupled to an implant. The dilator defines a lumen therethrough. The first portion of the suture is uncoupled from the distal end portion of the dilator and at least a portion of the implant is passed through the lumen defined by the dilator by pulling on the first portion of the suture. The dilator is removed from the body tissue through a skin incision.

[0092] In some embodiments, the method can also include coupling the first portion of the suture to the distal end portion of the dilator. In some such embodiments, the distal end portion of the dilator can define an aperture through which the first portion of the suture is disposed.

[0093] In some embodiments, after the dilator is removed from the body tissue, the method can also include, trimming the portion of the implant that extends from the bodily tissue such that the suture is detached from the implant.

[0094] In some embodiments, the dilator can be extended into a body tissue in a pelvic region of the patient.

[0095] In some embodiments, the dilator can be extended into the body tissue in a first direction, and can be removed from the body tissue in a direction substantially the same as the first direction.

[0096] In some embodiments, the dilator can be extended into the body tissue in a first direction, and can be removed from the body tissue in a second direction substantially opposite the first direction.

[0097] In some embodiments, the dilator can be extended into the body tissue and through a portion of an obturator.

[0098] In some embodiments, the distal end portion of the dilator can be configured to contact a portion of a delivery needle when the dilator is being extended into the body tissue.

[0099] In some embodiments, the suture can be uncoupled by pulling on a loop formed by the first portion of the suture such that the first portion of the suture uncouples from the distal end portion of the dilator.

[00100] In some embodiments, the incision can be one of a supra-pelvic incision, a retro-pubic incision, or a perineum incision.

[00101] In some embodiments, the implant can be configured to be used to treat male incontinence.

[00102] In some embodiments, the implant can be a mesh implant.

WHAT IS CLAIMED IS:

1. A method, comprising:

extending a dilator into a body of a patient in a first direction such that a distal end portion of the dilator extends from the body, the dilator defining a lumen therethrough, at least a portion of the dilator being disposed within the body when the distal end portion extends from the body;

passing at least a portion of an implant through the lumen defined by the dilator; and

removing the dilator from the body by moving the dilator in the first direction.

2. The method of claim 1, wherein the extending includes pushing the distal end portion of the dilator through the body.

3. The method of claim 1, wherein the extending includes pulling the distal end portion of the dilator through the body.

4. The method of claim 1, wherein the extending includes extending the dilator into a portion of the body in a pelvic region of the patient.

5. The method of claim 1, wherein the extending includes aligning a proximal end of the dilator with a surface of the body such that the proximal end is flush with the surface.

6. The method of claim 1, wherein, during the extending, the distal end portion of the dilator is configured to contact a portion of a delivery needle.

7. The method of claim 1, wherein the extending includes extending the dilator into the body via a first skin incision, and the removing includes removing the dilator from the body via a second skin incision.

8. The method of claim 1, wherein the passing includes pushing the portion of the implant through the lumen in the first direction.

9. The method of claim 1, wherein the passing includes pulling the portion of the implant through the lumen in the first direction.

10. The method of claim 1, wherein the passing includes passing the portion of the implant through the lumen in a second direction opposite the first direction.

11. The method of claim 1, wherein the first direction is a distal direction.

12. The method of claim 1, wherein a proximal end portion of the dilator includes an enlarged portion in fluid communication with the lumen, the enlarged portion configured to facilitate the passing.

13. The method of claim 1, wherein the implant is configured to be used to treat male incontinence.

14. A method, comprising:

extending a dilator into a body of a patient such that a distal end portion of the dilator extends from the body, the distal end portion of the dilator being coupled to a first portion of a suture such that the first portion of the suture is disposed within the body when the distal end portion of the dilator extends from the body, the suture having a second portion coupled to an implant, the dilator defining a lumen therethrough,;

uncoupling the first portion of the suture from the distal end portion of the dilator;

passing at least a portion of the implant through the lumen defined by the dilator by pulling on the first portion of the suture;

removing the dilator from the body through a skin incision.

15. The method of claim 14, further comprising:

coupling the first portion of the suture to the distal end portion of the dilator, the distal end portion of the dilator defining an aperture through which the first portion of the suture is disposed.

16. The method of claim 14, further comprising:

after the removing, trimming the portion of the implant extending through the bodily tissue such that the suture is detached from the implant.

17. The method of claim 14, wherein the extending includes extending the dilator into a portion of the body in a pelvic region of the patient.

18. The method of claim 14, wherein the extending includes extending the dilator into the body in a first direction, and the removing includes removing the dilator from the body in a direction substantially the same as the first direction.

19. The method of claim 14, wherein the extending includes extending the dilator into the body in a first direction, and the removing includes removing the dilator from the body in a second direction substantially opposite the first direction.

20. The method of claim 14, wherein the extending includes extending the dilator into the body and through a portion of an obturator.

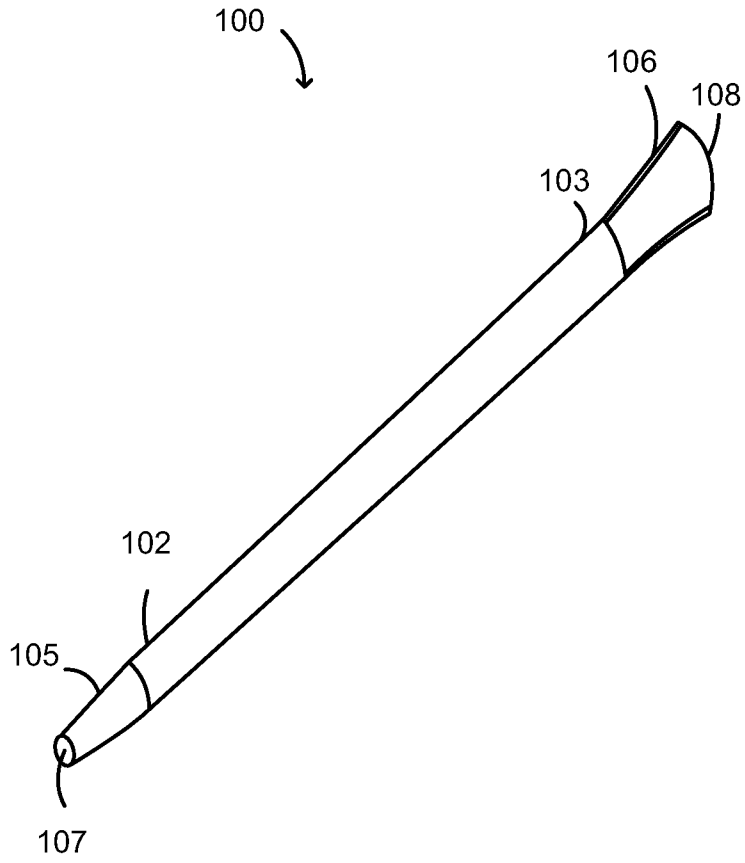

FIG. 1

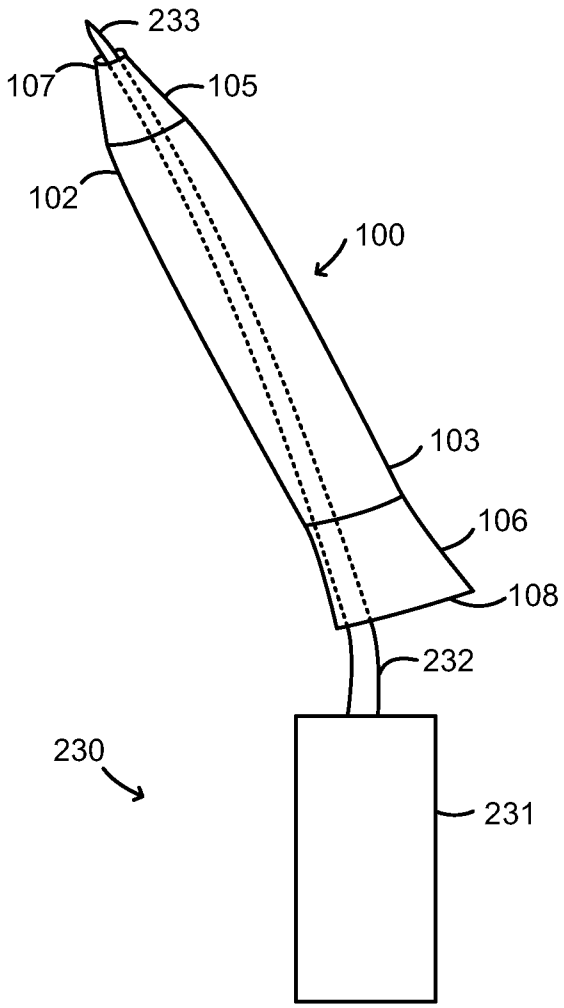

FIG. 2

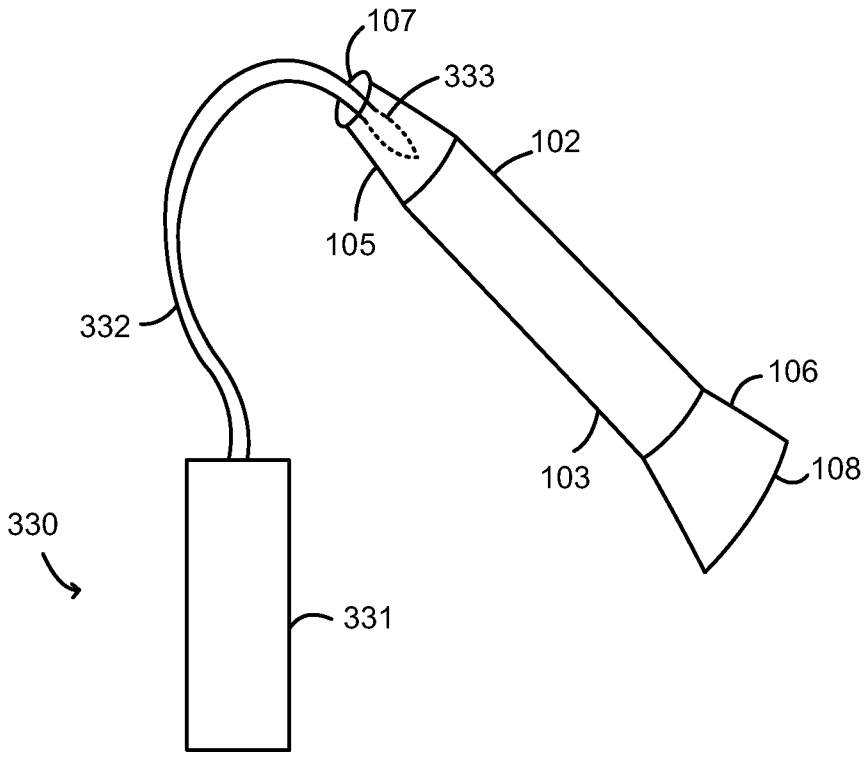

FIG. 3

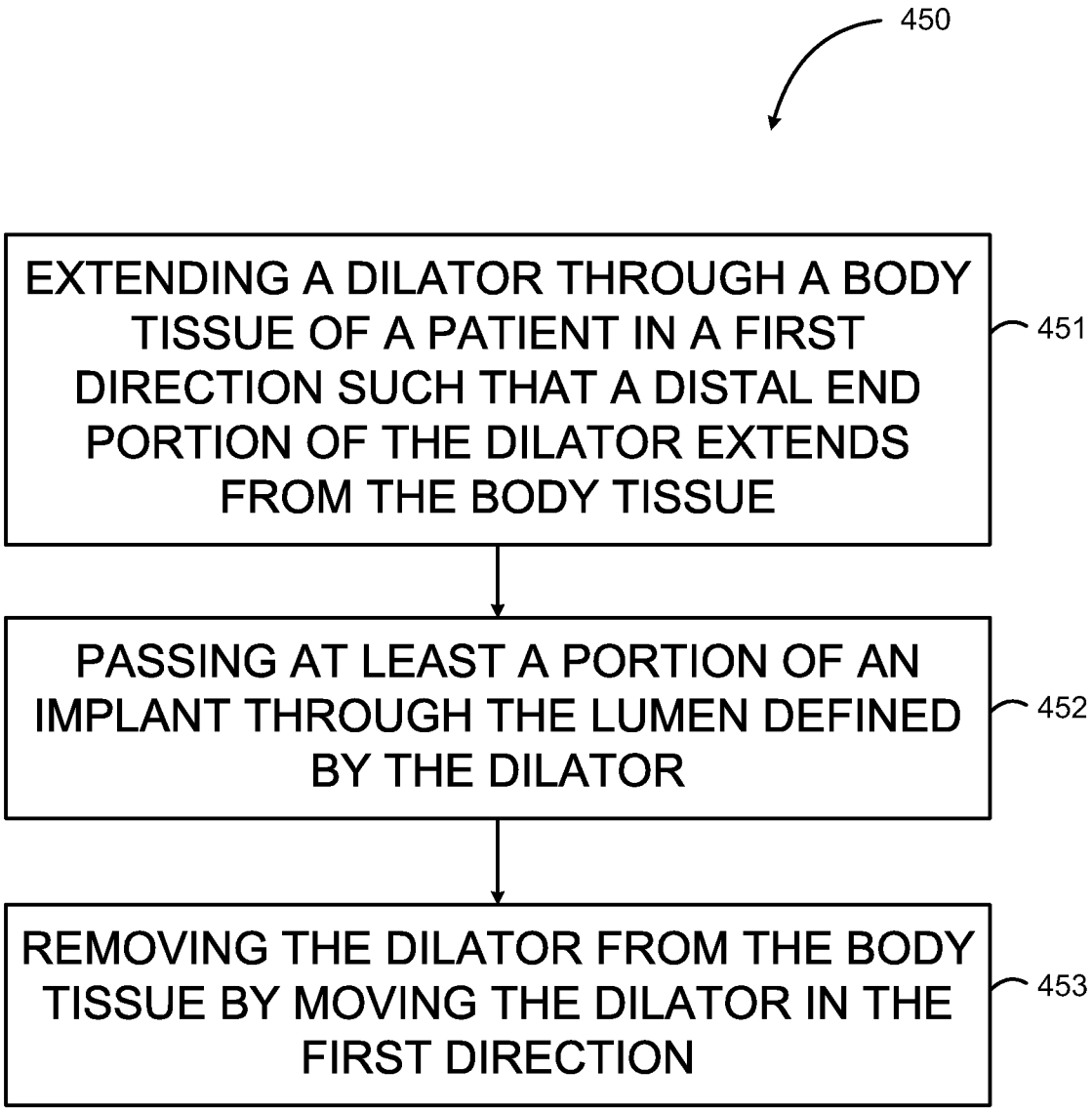
450
EXTENDING A DILATOR THROUGH A BODY TISSUE OF A PATIENT IN A FIRST DIRECTION SUCH THAT A DISTAL END PORTION OF THE DILATOR EXTENDS FROM THE BODY TISSUE
451
PASSING AT LEAST A PORTION OF AN IMPLANT THROUGH THE LUMEN DEFINED BY THE DILATOR
452
REMOVING THE DILATOR FROM THE BODY TISSUE BY MOVING THE DILATOR IN THE FIRST DIRECTION
453

FIG. 4

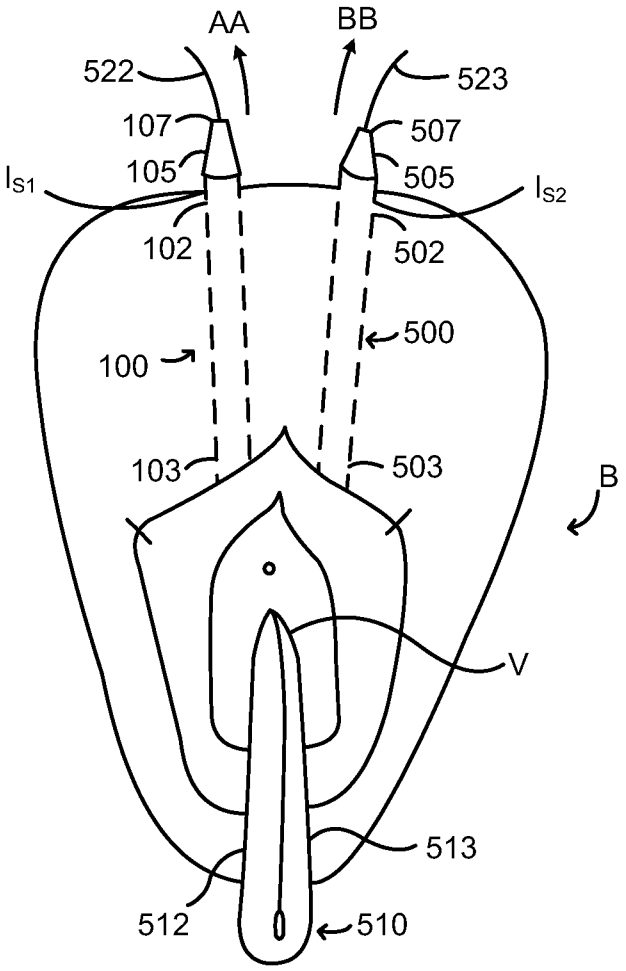
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FIG. 5

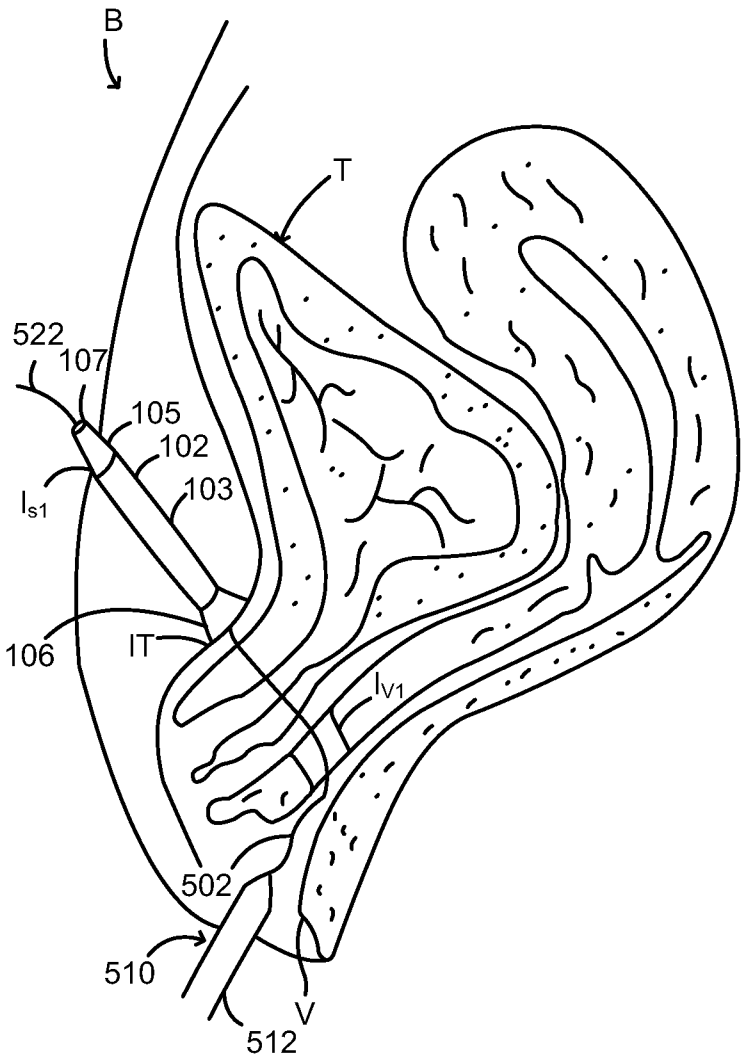

FIG. 6

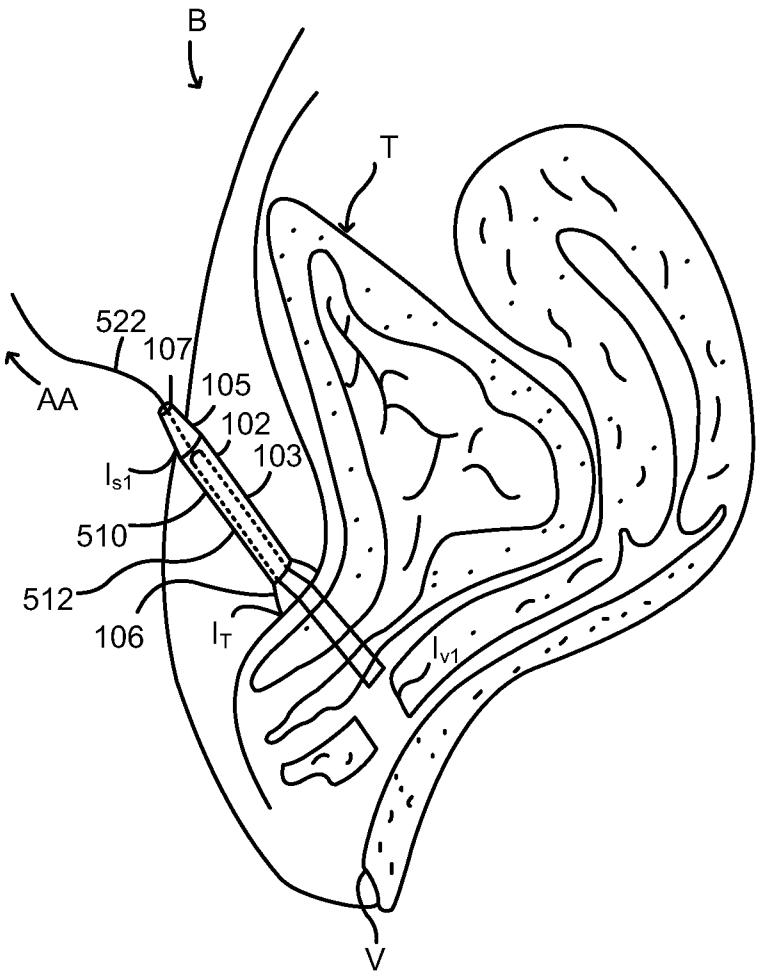

FIG. 7

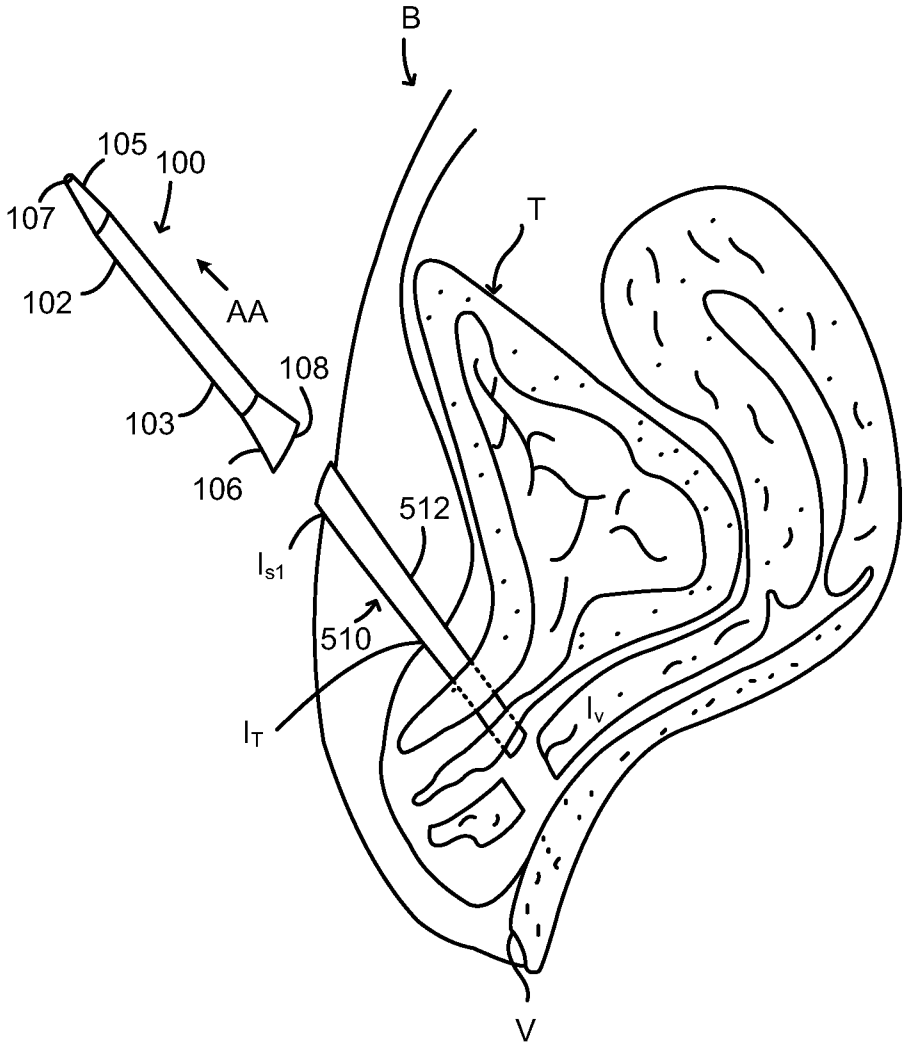

FIG. 8

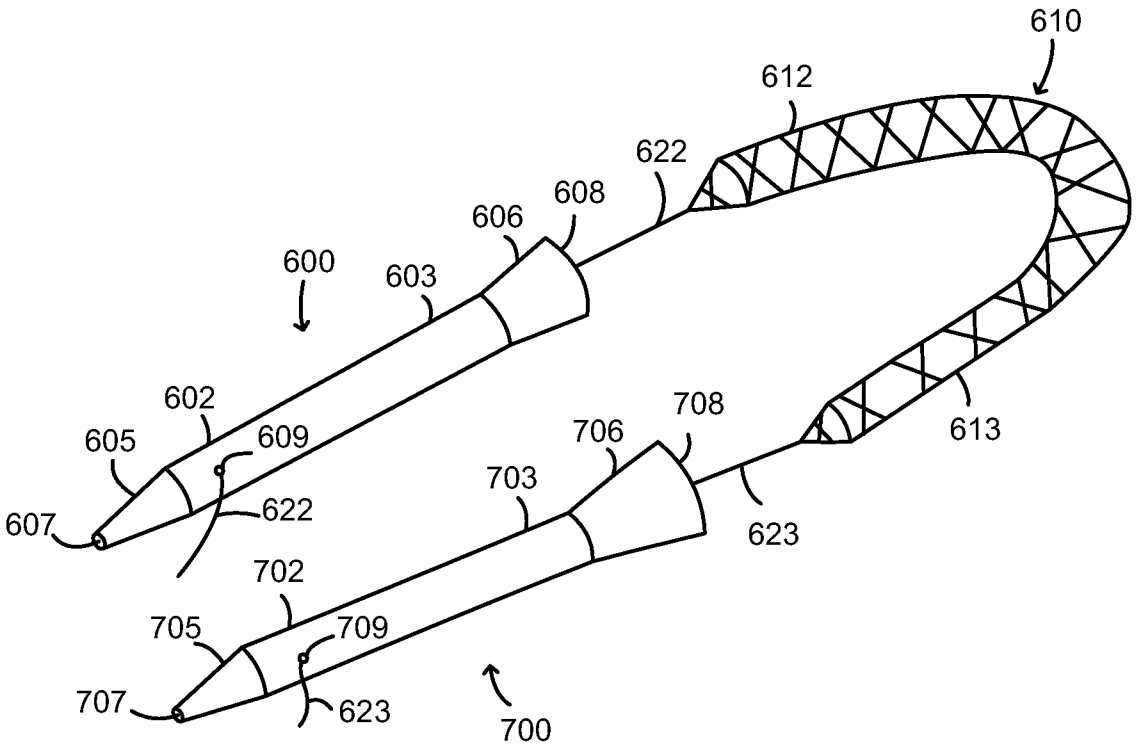
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FIG. 9

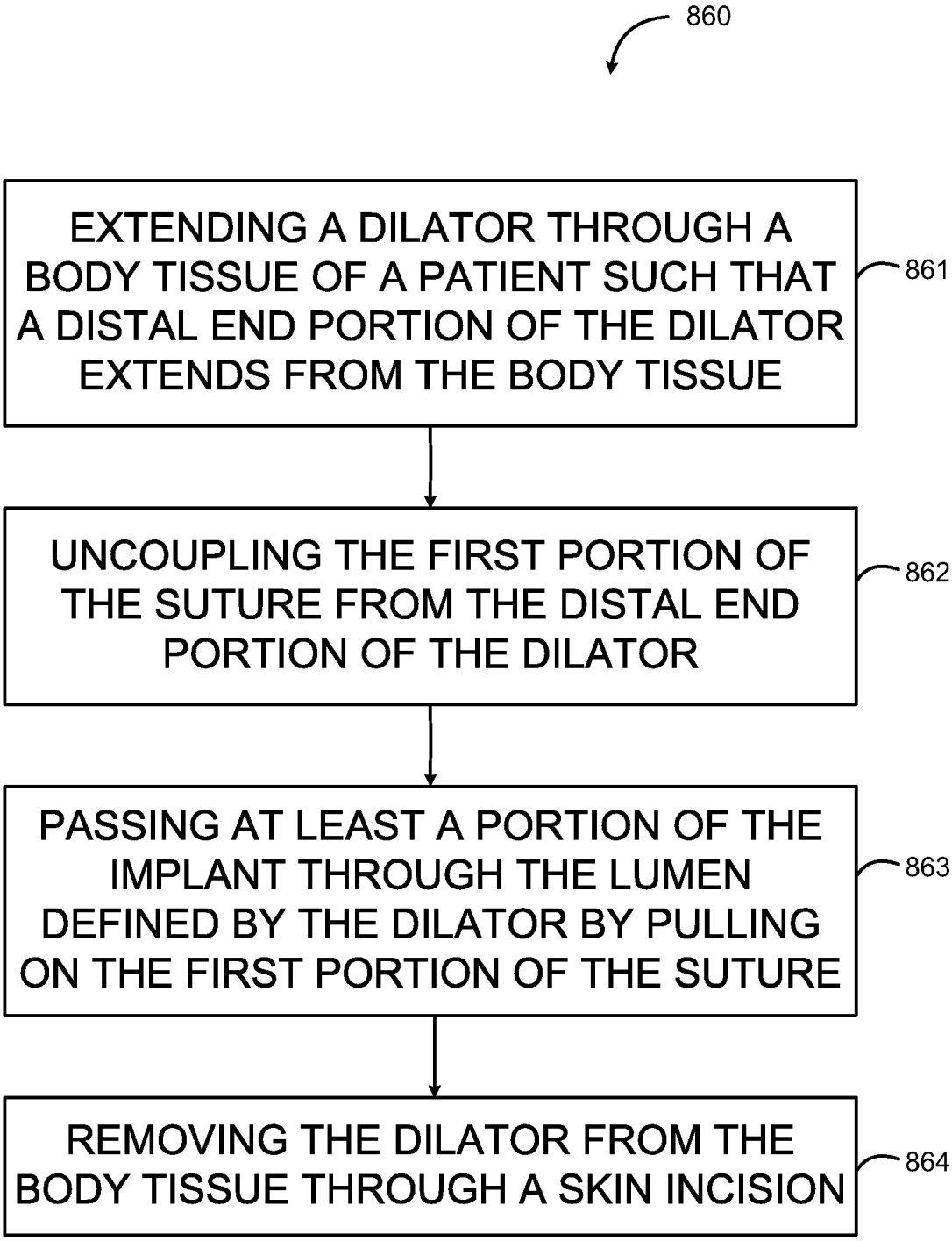
860
EXTENDING A DILATOR THROUGH A BODY TISSUE OF A PATIENT SUCH THAT A DISTAL END PORTION OF THE DILATOR EXTENDS FROM THE BODY TISSUE
861
UNCOUPLING THE FIRST PORTION OF THE SUTURE FROM THE DISTAL END PORTION OF THE DILATOR
862
PASSING AT LEAST A PORTION OF THE IMPLANT THROUGH THE LUMEN DEFINED BY THE DILATOR BY PULLING ON THE FIRST PORTION OF THE SUTURE
863
REMOVING THE DILATOR FROM THE BODY TISSUE THROUGH A SKIN INCISION
864

FIG. 10

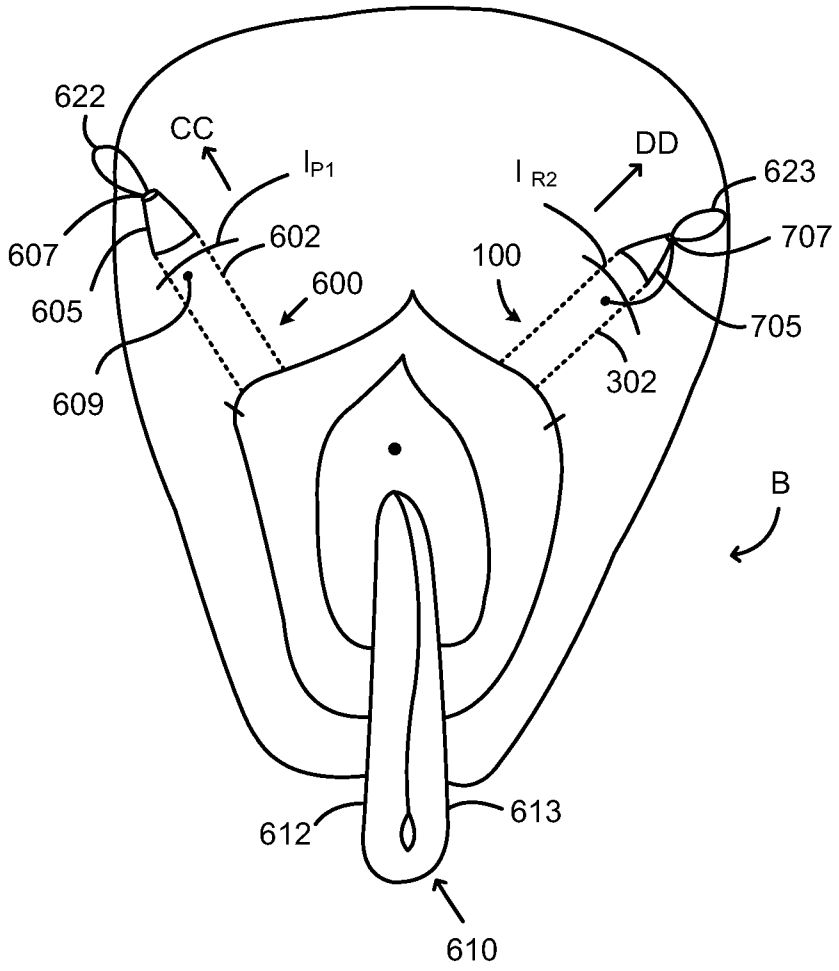
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FIG. 11

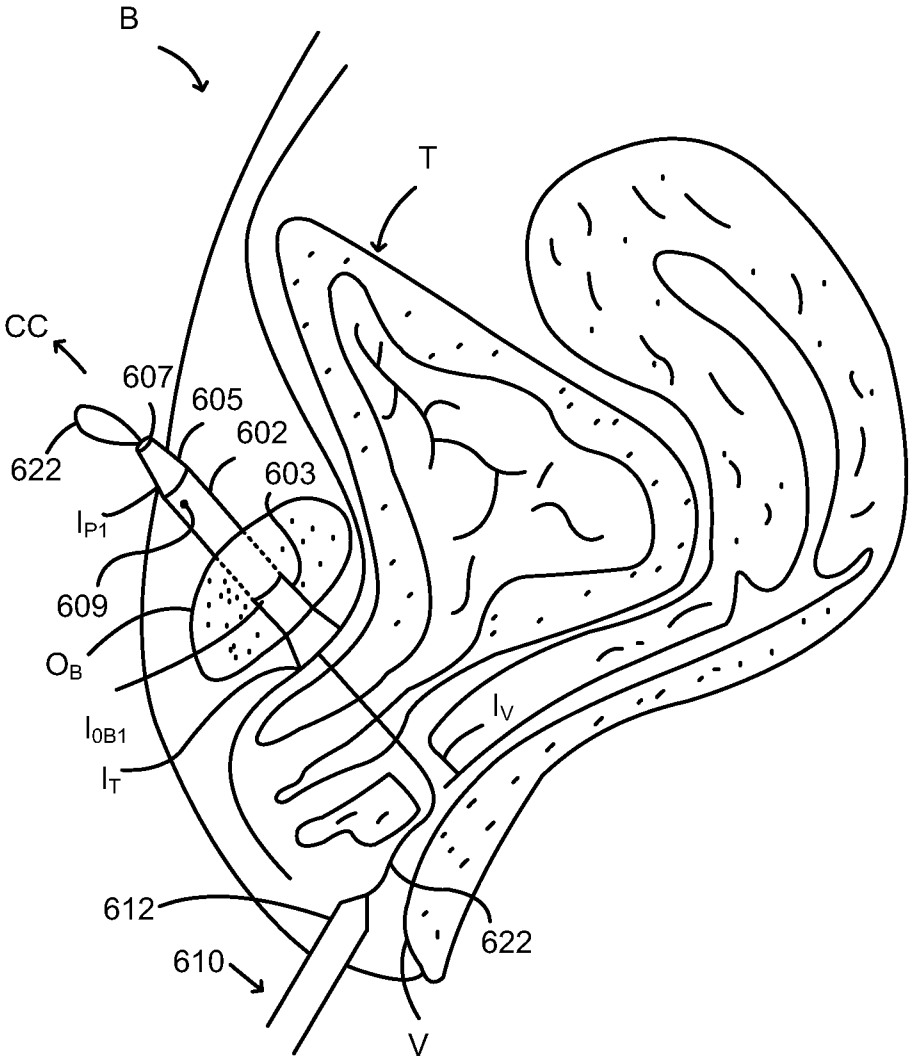

FIG. 12

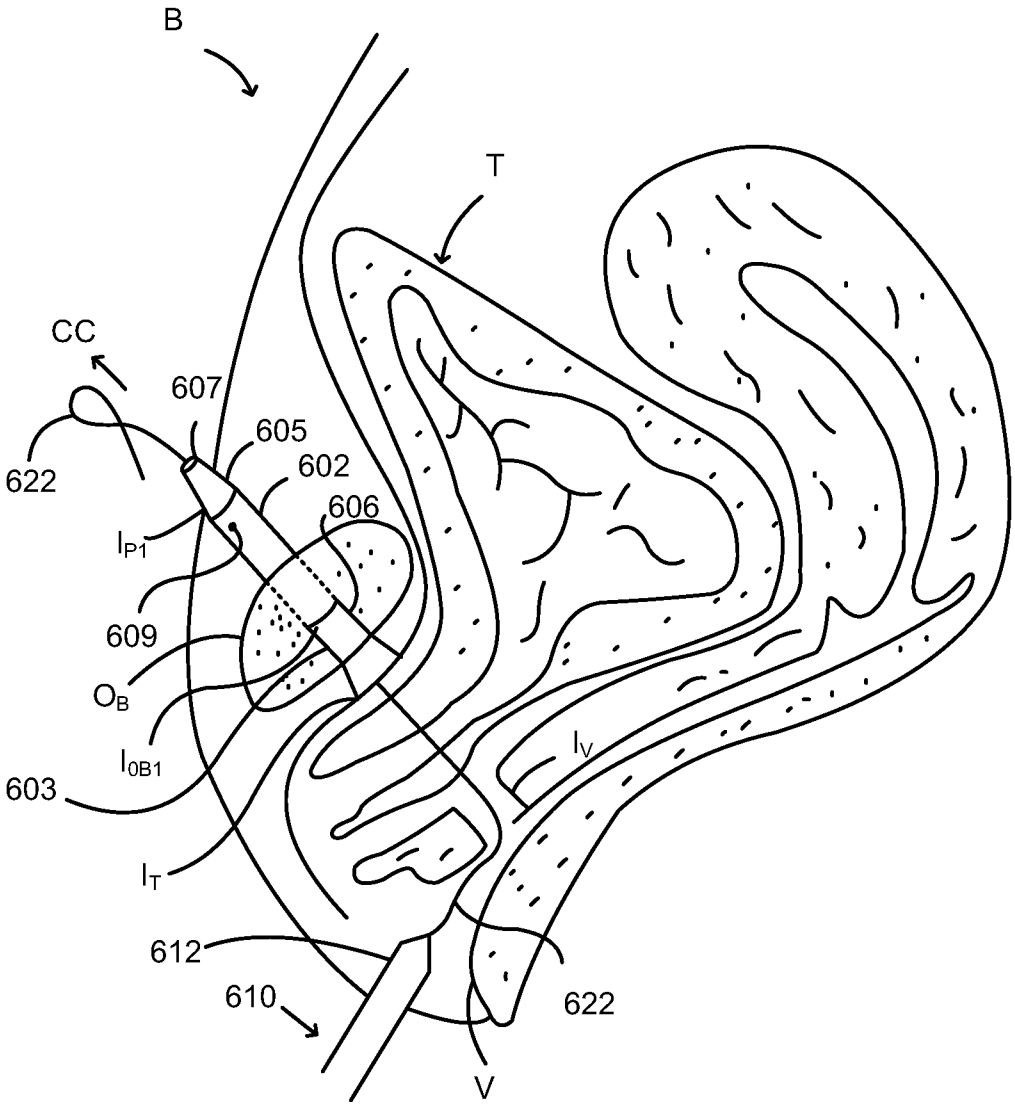

FIG. 13

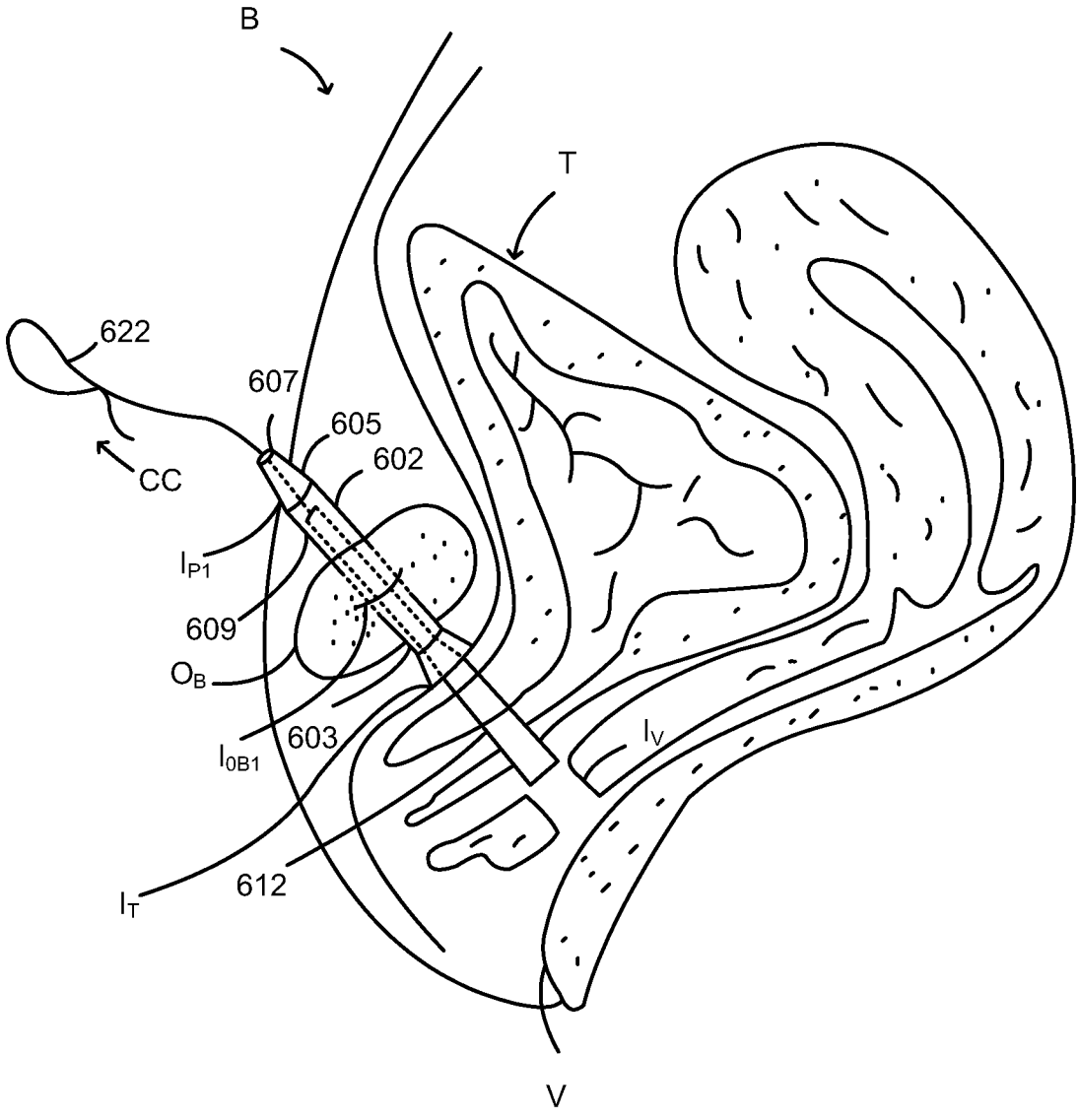

FIG. 14

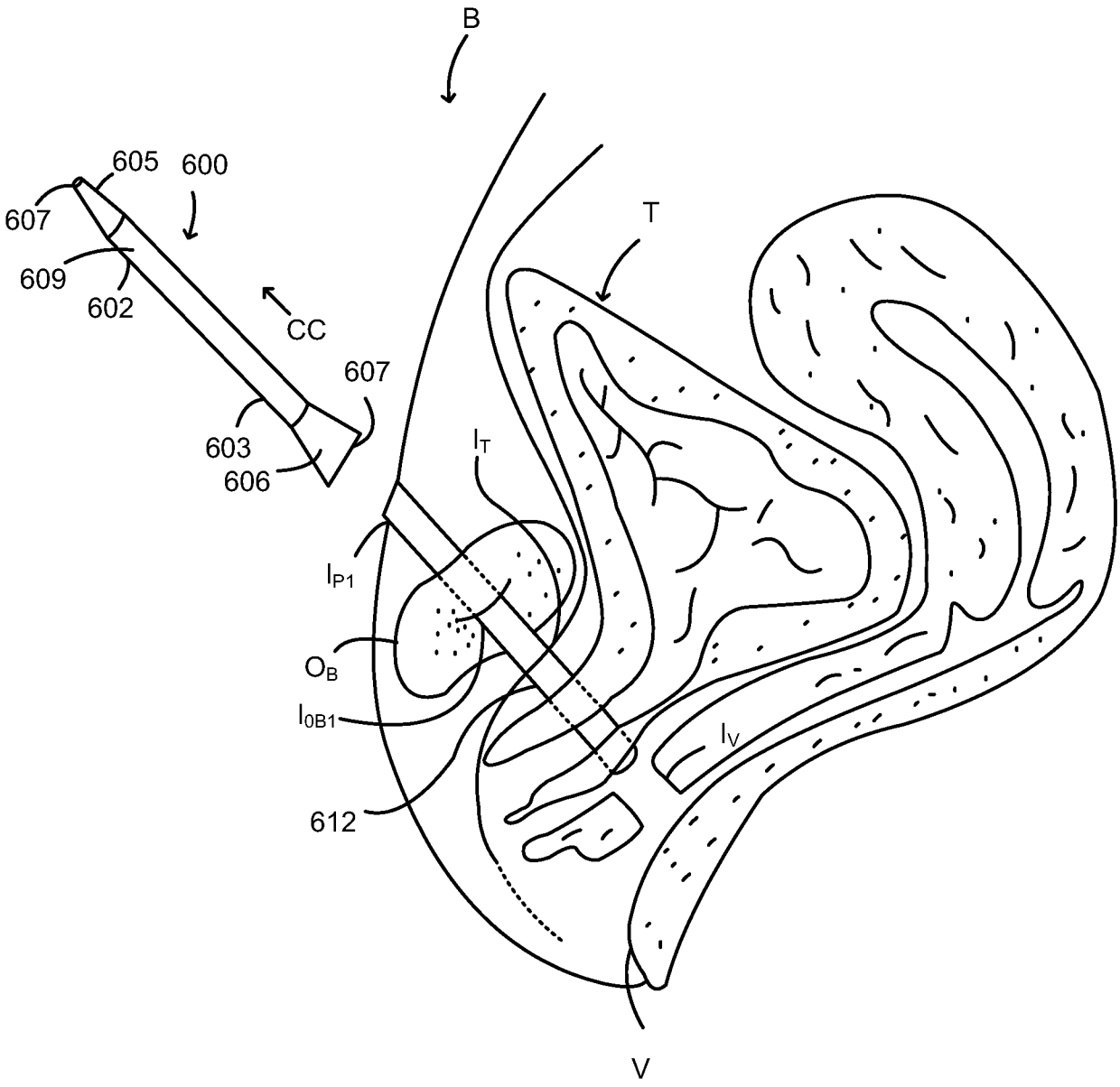

FIG. 15

PATENT COOPERATION TREATY

PCT

DECLARATION OF NON-ESTABLISHMENT OF INTERNATIONAL SEARCH REPORT

(PCT Article 17(2)(a), Rules 13fer.1 (c) and Rule 39)

Applicant's or agent's file reference	IMPORTANT DECLARATION	Date of mailing *(day/month/year)*
0073-075WO1		21 March 2011 (21-03-2011)
International application No.	International filing date *(day/month/year)*	(Earliest) Priority date *(day/month/year)*
PCT/US2010/061879	22 December 2010 (22-12-2010)	23 December 2009 (23-12-2009)
International Patent Classification (IPC) or both national classification and IPC		
A61F2/00, A61B17/06		
Applicant		
BOSTON SCIENTIFIC SCIMED, INC.		

This International Searching Authority hereby declares, according to Article 17(2)(a), that **no international search report will be established** on the international application for the reasons indicated below

1. [X] The subject matter of the international application relates to:
   - a. [ ] scientific theories
   - b. [ ] mathematical theories
   - c. [ ] plant varieties
   - d. [ ] animal varieties
   - e. [ ] essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes
   - f. [ ] schemes, rules or methods of doing business
   - g. [ ] schemes, rules or methods of performing purely mental acts
   - h. [ ] schemes, rules or methods of playing games
   - i. [X] methods for treatment of the human body by surgery or therapy
   - j. [X] methods for treatment of the animal body by surgery or therapy
   - k. [ ] diagnostic methods practised on the human or animal body
   - l. [ ] mere presentations of information
   - mm. [ ] computer programs for which this International Searching Authority is not equipped to search prior art

2. [X] The failure of the following parts of the international application to comply with prescribed requirements prevents a meaningful search from being carried out:
   [ ] the description [X] the claims [ ] the drawings

3. [ ] A meaningful search could not be carried out without the sequence listing; the applicant did not, within the prescribed time limit:
   - [ ] furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
   - [ ] furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
   - [ ] pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13fer.1 (a) or (b).

4. Further comments:

Name and mailing address of the International Searching Authority	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax: (+31-70) 340-3016	SCHERTL, Vera Tel: +49 (0)89 2399-5658

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 203

All claims 1-20 relate to:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery; and
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.