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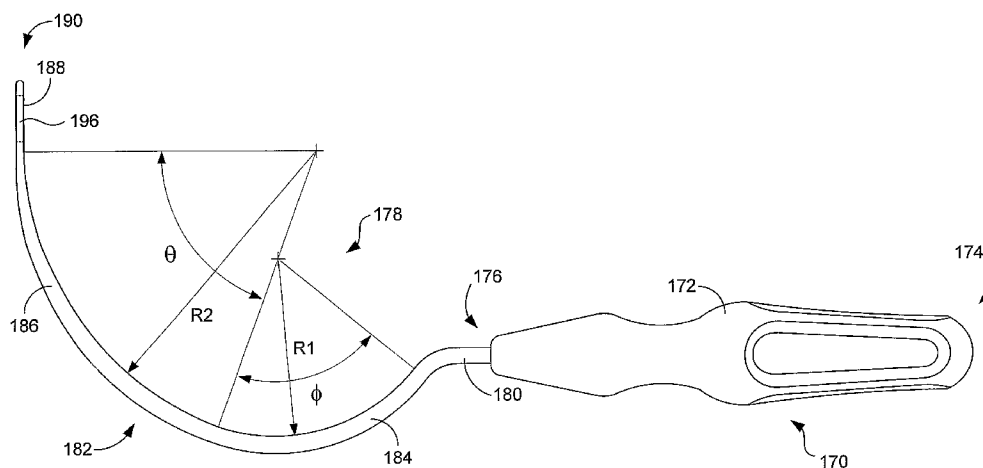
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(54) Title: PELVIC IMPLANT SYSTEMS AND METHODS



(57) Abstract: Systems and methods for implanting pelvic implants. In one embodiment, an anterior implant has multiple arms that extend outwardly from a body portion of the implant in opposite directions. In one embodiment, a posterior implant has multiple arms that generally extend in a same direction. In one embodiment, an anterior introducer includes a needle having a curved section that is sized and configured for implanting an anterior prolapse implant, hi one embodiment, a posterior introducer includes a needle having a curved section that has a first curved portion and a second curved portion, the two curved portions having radii of curvature that are different from each other.

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PELVIC IMPLANT SYSTEMS AND METHODS
CROSS-REFERENCE TO RELATED APPLICATION

This application is related to copending U.S. provisional patent applications entitled
5 “Soft Tissue Anchoring Systems”, filed on August 4, 2006, and accorded serial number
60/705,569, “Apparatus And Methods For Vaginal Prolapse Repair”, filed on August 4, 2006,
and accorded serial number 60/705,624, and “Systems and Methods for Pelvic Floor Repair”,
filed June 1, 2006, and accorded serial number 60/810,065, each of which is entirely
incorporated herein by reference.

BACKGROUND

Pelvic implants are used to treat various ailments. For example, pelvic implants are
used to perform prolapse repair and to treat urinary incontinence. Such implants are often
composed of a knitted mesh that, once implanted, enables the ingrowth of soft tissue to fix
the implant in place. Although various implants have been proposed, many do not adequately
15 conform to the anatomy of the patient.

Positioning an implant within the human body, such as within the pelvis, can be
challenging due to the anatomy of the body and the placement of the implant that may be
required to treat a given ailment. For instance, the treatment of rectocele may require
accessing the vaginal vault from a position deep within the pelvis so as to form a passage in
20 which a portion, such as an anchoring arm, of the implant can be placed. Given the
configuration and dimensions of the human pelvis and its organs, it can be difficult to
navigate a needle through such a tortuous path without causing damage to or otherwise
disrupting the tissues of the pelvis, such as the pelvic floor muscles.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosed systems and methods can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale.

FIG. 1 is a top view of an embodiment of an anterior implant suitable for use in treating
5 cystocele.

FIG. 2 is a perspective view of the anterior implant of FIG. 1.

FIG. 3 is a top view of an embodiment of a posterior implant suitable for use in treating
rectocele.

FIG. 4 is a perspective view of the posterior implant of FIG. 3.

10 FIG. 5 is a top view of an embodiment of an anterior introducer suitable for use in
implanting the anterior implant of FIGs. 1 and 2.

FIG. 6 is a side view of the anterior introducer of FIG. 5.

FIG. 7 is a cross-sectional view of a needle of the anterior introducer of FIG. 6 taken
along lines 7-7.

15 FIG. 8 is a top view of an embodiment of a posterior introducer suitable for use in
implanting the posterior implant of FIGs. 3 and 4.

FIG. 9 is a side view of the posterior introducer of FIG. 8.

FIG. 10 is a detail view of a portion of the anterior introducer needle of FIGs. 8 and 9.

20 FIGs. 11A-11F illustrate steps performed in an embodiment of a method for implanting
the anterior implant of FIGs. 1 and 2.

FIGs. 12A-12L illustrate steps performed in an embodiment of a method for implanting
the posterior implant of FIGs. 3 and 4.

FIG. 13 is a top view of a second embodiment of an anterior implant.

FIG. 14 is a top view of a second embodiment of a posterior implant.

25 FIG. 15 is a side view of a second embodiment of a posterior introducer.

FIG. 16 is a further side view of the posterior introducer of FIG. 15 illustrating extension of a tip member of the introducer.

FIG. 17A is a side view of a first embodiment of a tip member that can be provided on the posterior introducer of FIGs. 15 and 16.

FIG. 17B is a side view of a second embodiment of a tip member that can be provided on the posterior introducer of FIGs. 15 and 16.

FIG. 18 is a top view of a pelvic implant that comprises soft tissue anchors.

DETAILED DESCRIPTION

Disclosed herein are pelvic implant systems and methods for the treatment of pelvic ailments. More particularly, described are prolapse repair implants, introducers for implanting the implants, and methods for implanting the implants. Although prolapse repair is described with specificity in the following, it will be understood that the systems and/or methods of the present disclosure may be relevant to the treatment of other pelvic ailments, such as urinary incontinence. Moreover, although specific embodiments are presented in the following, it is to be appreciated that those embodiments are mere example implementations of the disclosed systems and methods and other embodiments are possible. All such embodiments are intended to fall within the scope of this disclosure.

FIGs. 1-4 illustrate embodiments of implants suitable for use in treating prolapse. The implants each have a body portion and arms that extend from the body portion. The body portion can be positioned adjacent an organ to be supported, such as the bladder, rectum, uterus, or urethra. Generally speaking, the implants are formed from a flexible material. The implant material can be a synthetic material, a natural material, or a combination of both synthetic and natural materials. The natural material can comprise, for example, a porcine dermal collagen material. The synthetic material can comprise a polymeric mesh, for

example, polypropylene mesh. In some embodiments, the synthetic material comprises knitted monofilament, polypropylene mesh having multidirectional elasticity that provides long-term reinforcement of pelvic support structures. Irrespective of the material used to construct the implants, the implants are highly flexible yet have the strength needed for tension-free fixation of the implant.

FIGs. 1 and 2 illustrate an embodiment of an anterior implant 10, which may be used to treat cystocele. As indicated in FIG. 1, the implant 10 generally comprises a body portion 12, two front arms 14 and 16, and two rear arms 18 and 20. The body portion 12 defines a central axis 21 about which the implant 10 is substantially symmetric and generally comprises a front side 22 defined by front edge 24 and a rear side 26 defined by a rear edge 28. In the illustrated embodiment, the front edge 24 is substantially straight while the rear edge 28 is rounded so as to form a rear projection 30 that extends rearwardly from the rear arms 18, 20. The body portion 12 further comprises lateral edges 32 and 34. As is apparent from FIG. 1, the lateral edges 32, 34 extend from the front side 22 to the rear side 26 of the body portion 12 (i.e., from the front arms 14, 16 to the rear arms 18, 20) at an angle relative to the central axis 21 such that the body portion 12 widens from front to back. With the above-described configuration, the body portion 12 is shaped and configured to support the bladder with the front edge 24 positioned adjacent the bladder neck and the rear edge 28 positioned relatively deep within the pelvis. In such a position, the rounded rear edge 28 is adapted to accommodate the contours of the pelvis interior. By way of example, the body portion 12 has a length (along the central axis 21) of approximately 70 (millimeters) mm.

The front arms 14, 16 extend laterally from the front side 22 of the body portion 12 substantially perpendicular to the central axis 21. In the illustrated embodiment, the front arms 14, 16 are substantially parallel to each other and comprise front edges 36 and 38 that are contiguous with the front edge 24 of the body portion 12. In addition, the front arms 14,

16 comprise rear edges 40 and 42 that are, in some embodiments, substantially parallel to the front edges 36, 38 and to each other. The rear edges 40, 42 join the body portion 12 at rounded inner corners 44 and 46. As is further depicted in FIG. 1, the front arms 14, 16 terminate in rounded ends 48 and 50. By way of example, the front arms 14, 16 span a length of approximately 350 mm.

With continued reference to FIG. 1, the rear arms 18, 20 also extend laterally from the body portion 12 substantially perpendicular to the central axis 21. In the embodiment of FIG. 1, the rear arms 18, 20 are substantially parallel to the front arms 14, 16 and to each other. The rear arms 18, 20 comprise front edges 52 and 54 and rear edges 56 and 58. In some embodiments, the front edges 52, 54 and the rear edges 56, 58 are substantially parallel. Like the front arms 14, 16, the rear arms 18, 20 terminate in ends 60 and 62. Unlike the ends 48 and 50, however, the ends 60 and 62 of the rear arms 18, 20 are pointed due to the provision of angled edges 64 and 66 that extend from the front edges 52, 54 of the arms 18, 20 to the rear edges 56, 58 of the arms. In the illustrated embodiment, the angled edges 64, 66 are angled outwardly from the front of the arms 18, 20 to the rear. As described below, the pointed ends 60, 62 both facilitate threading of the rear arms 18, 20 through an introducer needle as well as aid the surgeon in distinguishing the rear arms from the front arms 14, 16. By way of example, the rear arms span a distance of approximately 395 mm so as to be slightly longer than the front arms 14, 16.

In some embodiments all or at least a portion of the body portion 12 is formed of a relatively soft material as compared to the relatively coarse material of the arms 14, 16, 18, and 20 such that the portion of the implant 10 that supports the bladder is relatively soft and compliant while the arms are less compliant to ensure secure fixation and avoid implant migration. In the embodiment of FIG. 1, a central portion defined by the area bounded by dashed lines 68 and 70 (which extend from the front side 22 to the rear side 26 of the body

portion 12) and having a width of approximately 43 mm comprises the relatively soft material. In addition, substantially the entire body portion 12, on both sides, can be provided with a coating of an absorbable, hydrophilic film of porcine collagen. In the embodiment of FIG. 1, the coating covers the area bounded by the hidden lines 72 and 74 (which extend from the front side 22 to the rear side 26 of the body portion 12).

FIG. 2 shows the anterior implant 10 in a perspective view in free space. The flexibility of the implant 10 is apparent from the illustrated orientation of the implant.

FIGs. 3 and 4 illustrate an embodiment of a posterior implant 78, which may be used to treat rectocele. As indicated in FIG. 3, the implant 78 generally comprises an elongated body portion 80, two front arms 82 and 84, and two rear arms 86 and 88. The posterior implant 78 is substantially symmetric about a longitudinal axis 89 that extends along the body portion 80. The body portion 80 is shaped and configured to be positioned between the vagina and the rectum and comprises a substantially rectangular shape defined by front side 90, a rear side 92, and opposed lateral sides 93 and 95. The front side 90 comprises a rounded edge 94 that extends inwardly towards the center of the body portion 80. The rear side 90 comprises a substantially straight edge 96. In addition, the body portion 80 comprises substantially straight lateral edges 98 and 100 that, in some embodiments, are substantially parallel to each other. By way of example, the body portion 80 has a width dimension of approximately 40 mm and length dimension of approximately 100 mm.

The front arms 82, 84 each comprise two sections, first sections 102 and 104 that extend directly from the body portion 80, and second sections 106 and 108 that extend from the first sections 102 and 104. The first sections 102, 104 extend from the body portion 80 at divergent angles relative to the longitudinal axis 89. By way of example, each first section 102, 104 forms an angle, α , of approximately 20 degrees with the longitudinal axis 89. The second sections 106, 108 extend from the first sections 102, 104 in a direction that is

substantially parallel to the longitudinal axis 89 and to each other. The second sections 106, 108, and the front arms 82, 84 generally, terminate in rounded ends 110 and 112. By way of example, the front arms 106, 108 extend from the body portion 80 a distance of approximately 100 mm.

5 The rear arms 86, 88 extend from the rear side 92 of the body portion 80 past the front side 90 of the body portion to terminate adjacent the termination point of the front arms 106, 108. In the embodiment of FIG. 3, the rear arms 86, 88 initially extend laterally from the body portion 80 (substantially perpendicular to the longitudinal axis 89) along lateral sections 114 and 116. The lateral sections 114, 116 are defined by substantially straight rear edges 118 and 120, which are contiguous with the rear edge 96 of the body portion, and rounded edges 122 and 124. Extending from the lateral sections 114, 116 are longitudinal sections 126 and 128 that are substantially parallel to the longitudinal axis 89 and to each other. The longitudinal sections 126, 128 terminate in pointed ends 130 and 132 that are defined by angled edges 134 and 136. In the embodiment of FIG. 3, the angled edges 134, 136 diverge
10 outwardly relative to the longitudinal axis 89. As with the pointed ends 60, 62 of the anterior implant 10 (FIG. 1), the pointed ends 130, 132 facilitate threading of the rear arms 86, 88 through a needle and aid the surgeon in distinguishing the rear arms from the front arms 82, 84. By way of example, the rear arms 86, 88 span a distance (from the rear edge 96 of the body portion 80) of approximately 200 mm and are therefore approximately twice as long as
15 the front arms 82, 84.
20

 In some embodiments, all or a portion of the body portion 80 is formed of a relatively soft material as compared to the material of the arms 82, 84, 86, and 88 such that the portion of the implant 78 that is positioned between the vagina and the rectum is relatively soft and compliant while the arms are less compliant to ensure secure fixation and avoid implant
25 migration. In the embodiment of FIG. 3, a central area bounded by dashed lines 136 and 138

(which extend from the rear side 92 past the front side 90 of the body portion 12 and along the front arms 82, 84) and having a width of approximately 43 mm comprises the relatively soft material. In addition, substantially the entire body portion 12, part of the rear arms 86, 88, and part of the front arms 82, 84 are provided with a coating of an absorbable, hydrophilic film of porcine collagen. In the embodiment of FIG. 3, the extent of the coating is identified by the hidden lines 140, 142, 144, and 146, with the lines 140, 142 being substantially parallel to the longitudinal axis 89 and the lines 144, 146 being angled relative to the longitudinal axis.

FIG. 4 shows the posterior implant 78 in a perspective view in free space. The flexibility of the implant 78 is apparent in FIG. 4 from the illustrated orientation of the implant.

FIGs. 5 and 6 illustrate an embodiment of an anterior introducer 148, which can be used to implant the anterior implant 10. As indicated in those figures, the introducer 148 comprises a handle 150 that includes a proximal end 152 and a distal end 154. The handle 148 is generally sized and shaped to fit within a surgeon's hand and, as depicted in FIGs. 5 and 6, can be contoured to facilitate firm gripping.

A needle 156 extends from the distal end 154 of the handle 150. As shown in FIG. 5, the needle 156 exists substantially within a single plane. As is most clearly shown in FIG. 6, the needle 156 comprises a first substantially straight section 158 that directly extends from the handle 150 substantially parallel to a longitudinal axis of the handle (not identified). Extending from the straight section 158 is a curved section 160. By way of example, the curved section 160 extends along an arc having a radius of curvature of approximately 36.5 mm. The curved section 160 leads to a second substantially straight section 161 that terminates in a blunt tip 162. As is apparent from FIGs. 5 and 7, the straight section 161 is narrowed relative to the remainder of the needle 156 and is defined by two opposed lateral

flat surfaces 164 and 166. Returning to FIG. 6, an elongated opening 168 is formed through the straight section 161 adjacent the tip 162. The opening 168 generally extends along the length direction of the needle 156 and serves as an attachment mechanism for releasably attaching an arm of an implant (e.g., anterior implant 10) to the needle. As shown in the cross-sectional view of FIG. 7, the opening 168 extends from one flat surface 164 to the other flat surface 166 of the needle 162. Notably, although an opening has been identified, the needle 156 can be provided with other attachment mechanisms that can secure the implant to the needle.

In terms of materials, the handle 150 can be constructed of any suitable rigid material, such as a metal or a polymeric material. The needle 156 can be constructed of a biocompatible, strong material, such as stainless steel. In some embodiments, the handle 150 and needle 156 can be composed of the same material and may even be unitarily formed together so as to have a monolithic configuration.

FIGs. 8 and 9 illustrate an embodiment of a posterior introducer 170, which can be used to implant the posterior implant 78. As indicated in the figures, the introducer 170 comprises a handle 172 that includes a proximal end 174 and a distal end 176. The handle 172 is generally sized and shaped to fit within a surgeon's hand and, as depicted in FIGs. 8 and 9, can be contoured to facilitate firm gripping.

A needle 178 extends from the distal end 176 of the handle 172. As shown in FIG. 8, the needle 178 exists substantially within a single plane. As is most clearly shown in FIG. 9, the needle 178 comprises a first substantially straight section 180 that directly extends from the handle 172 substantially parallel to a longitudinal axis of the handle (not identified). Extending from the straight section 180 is a curved section 182. In the illustrated embodiment, the curved section 182 comprises first curved portion 184 adjacent the straight portion 180 that has a relatively small radius of curvature, and a second curved portion 186

distant from the straight portion that has a relatively large radius of curvature. The two distinct portions 184, 186 of the curved section 182 facilitate manipulation of the needle 178 within the body such that the needle can be passed through an external incision, passed deep into the pelvic cavity adjacent the ischial spine, introduced into the vaginal vault, passed down through the vagina, and exteriorized from the vaginal introitus. More particularly, as is apparent from FIGs. 12A-12E described below, the second curved portion 186 having the greater radius of curvature is used to form a relatively straight passage deep into the pelvic cavity and to traverse the distance from the vaginal vault to the vaginal introitus, while the first curved portion 184 having the smaller radius of curvature is used to rotate or pivot the second curved portion to enable its traversal through the pelvis. By way of example, the first curved portion 184 has a radius of curvature $R1$ of approximately 48 mm through an angle Φ of approximately 72 degrees, while the second curved portion 186 has a radius of curvature $R2$ of approximately 78 mm through an angle Θ of approximately 70 degrees, such that the second curved portion has a radius of curvature that is nearly twice that of the radius of curvature of the first curved portion.

Extending from the second curved portion 186 is a second substantially straight section 188 that is substantially perpendicular to the first substantially straight section 180 and that terminates in a blunt tip 190. As is most clearly shown in the detail view of FIG. 10, the straight section 188 comprises substantially flat opposed edges 192 and 194. Between those edges is an elongated opening 196 that serves as an attachment mechanism for releasably attaching an arm of an implant (e.g., posterior implant 78) to the needle 178. Notably, while the opening 168 of the anterior introducer 148 may be said to extend laterally through the needle 156, the opening 196 of the posterior introducer 170 extends proximally to distally through the needle 178. Although an opening has been identified, the needle 178 can be provided with other attachment mechanisms that can secure the implant to the needle.

In terms of materials, the handle 172 can be constructed of any suitable rigid material, such as a metal or a polymeric material. The needle 178 can be constructed of a biocompatible, strong material, such as stainless steel. In some embodiments, the handle 172 and needle 178 can be composed of the same material and may even be unitarily formed together so as to have a monolithic configuration.

FIGs. 11A-5F illustrate an embodiment of a method for implanting a pelvic implant. More particularly, FIGs. 11A-11F illustrate a procedure for implanting the anterior implant 10 between the vagina and the bladder using the anterior introducer 148. Beginning with FIG. 11A, superior and inferior incisions 198 and 200 are made in the paravaginal region 202 in alignment with the obturator foramina 204 of the pubic bone (not shown). Those incisions 198, 200 can be made with a sharp device, such as a scalpel 206. In addition, a midline incision 208 can be made in the anterior vaginal wall 210 to provide access to the space between the vagina and the bladder. That space can then be separated by blunt and/or sharp dissection.

Turning to FIG. 11B, the needle 156 of the anterior introducer 148 is passed through one of the inferior incisions 200 and through the soft tissue of the pelvis until the tip 162 emerges from the vaginal incision 208 to become visible to the surgeon. Referring to FIG. 11C, the anterior implant 10 can then be associated with the needle 156. More particularly, one of the arms of the implant (e.g., rear arm 18) is passed through the opening 168 formed in the needle 156 adjacent the needle tip 162. Notably, the surgeon can easily distinguish between the rear arms and the front arms of the implant 10 due to the pointed tips of the rear arms.

Once the implant arm 18 is associated with the needle 156, the needle may be drawn back through the passage it formed pulling in the implant arm in tow until the needle exits the

body and the implant arm occupies the passage and extends out from the inferior incision 200, as indicated in FIG. 11D.

At that point, one of the front arms (e.g., arm 14) can be implanted. This is accomplished by passing the needle 156 through one the superior incisions 198, for example the incision adjacent the inferior incision 200 through which the rear arm 18 was passed, until the needle tip 162 emerges from the vaginal incision 208, as indicated in FIG. 11E. The arm 14 can be associated with the needle 156 in similar manner to that described above by passing the arm through the needle opening 168. The arm 14 can then be drawn through the passage formed by the needle 156 in similar manner to that used to draw the rear arm 18 through its passage (not shown).

The front and rear arms (e.g., arms 16 and 20) on the opposite side of the implant 10 can then be positioned in similar manner to the methods described above. One or more of the arms can then be tensioned as required to pull the body portion 12 into position between the vagina and the bladder, as indicated in FIG. 11F. At that point, the portions of the arms that extend beyond their respective incisions can be trimmed, the vaginal incision 208 can be closed, and the various external incisions can be closed.

FIGs. 12A-12L illustrate a further embodiment of a method for implanting a pelvic implant. More particularly, FIGs. 12A-12L illustrate a procedure for implanting the posterior implant 78 between the vagina and the rectum using the posterior introducer 170. Beginning with FIG. 12A, small pararectal incisions 210 are made on either side of the anus 212 with a sharp device, such as a scalpel 214. By way of example, the incisions 210 are made 2-3 centimeters (cm) posterior and lateral to the anus 212. In addition, a midline incision is made in the posterior vaginal wall 216 to form an opening 218 that extends from the vaginal introitus to the vaginal apex to provide access to the space between the vagina and the rectum.

The vaginal mucosa may then be dissected away from the rectum using blunt and/or sharp dissection.

Turning to FIG. 12B, the tip 190 of the posterior introducer needle 178 is positioned at one of the incisions 210 with the introducer 170 oriented so that the handle 172 is generally vertical. Referring next to FIG. 12C, the introducer needle 178 is passed through the incision 210 and through the soft tissue of the pelvis toward the ischial spine (not identified). As the needle 178 passes through the soft tissue, the introducer 170 is rotated so that the handle 172 approximates a generally horizontal orientation, as indicated in FIG. 12D. As is further shown in FIG. 12D, the needle tip 190 is advanced through the posterior vaginal wall and into the vaginal vault 220 such that the tip is positioned within the vagina 222. That process can be aided by placing a finger (not shown) within the vagina 222 to guide the needle tip 190 into position.

With reference next to FIG. 12E, the introducer handle 172 is pivoted downwardly and rotated laterally relative to the patient to bring the tip 190 of the needle 178 to the vaginal introitus 224 such that the needle tip and the opening 196 adjacent the tip are visible and accessible to the surgeon.

Referring next to FIG. 12F, one of the longitudinal arms (e.g., arm 88) of the posterior implant 78 is associated with the needle 178. In particular, the arm 88 is passed through the opening 196 of the needle 178. Again, the surgeon can distinguish the rear arms from the front arms due to the pointed tips of the rear arms.

Turning to FIG. 12G, the needle tip 190 can be retracted along the vagina 222 to the vaginal vault 220 to draw the implant arm 88 back toward the vaginal vault. Referring to FIG. 12H, the implant arm 88 can further be drawn through the passage formed by the needle 178 until the arm extends through the pelvis and out through the pararectal incision 210. At that point, the implant arm 88 can be disassociated from the needle 178.

Next, as indicated in FIG. 12I, the needle 178 can be reintroduced through the same
pararectal incision 210 from which the implant arm 88 extends in order to position the front
arm (e.g., arm 84) on the same side of the implant 78 as the implanted rear arm. As indicated
in FIG. 12J, the needle tip 190 is passed along a relatively shallow path through the soft tissue
of the pelvis until it emerges from the vaginal introitus 224. At that point, the front arm 84
can be associated with the needle 178 by passing the arm through the opening 196 of the
needle, and the arm can be drawn through the pelvis and out through the incision 210 in
similar manner to the rear arm 88. Similar procedures may then be performed to implant the
arms (e.g., arms 82, 86) on the opposite side of the implant 78 on the opposite side of the
vagina.

FIG. 12K illustrates the result after each arm has been implanted. As can be
appreciated from that figure, the rear arms (only arm 88 visible) are positioned relatively
deeply and the front arms (only arm 84 visible) are positioned relatively shallowly within the
pelvis, and the body portion 80 of the implant 78 is positioned between the vagina 222 and
the rectum 226. At that point, the excess portions of the arms can then be trimmed, the
vaginal incision can be closed, and the external incisions 210 can be closed.

FIGs. 13 and 14 illustrate alternative pelvic implants that comprise both natural and
synthetic material. Beginning with FIG. 13, an anterior implant 230 having a shape and
dimensions similar to the implant 10 of FIG. 1 is illustrated. Like the implant 10, the implant
230 comprises a body portion 232 from which multiple arms 234, 236, 238, and 240 extend.
However, with the implant 230, the body portion 232 is composed substantially exclusively
of a natural material while each of the arms 234, 236, 238, and 240 at least comprises a
synthetic material. By way of example, the natural material comprises a cross-linked porcine
dermal collagen material, such as Pelvicol[®] surgical implant from Tissue Science
Laboratories plc, or Pelvisoft[®] acellular collagen biomesh produced by Sofradim. In a further

alternative, the body portion 232 comprises a layer of natural material that is affixed to a layer of synthetic material. In such a case, the natural material may be positioned so as to face the organ to be supported. In yet another alternative, the body portion 232 comprises two layers of natural material, one provided on either side of a layer of synthetic material. In cases in which natural material is connected to the synthetic material, various connection means may be used such as suturing, stapling, riveting, adhesive, bonding, heat laminating, and the like.

Turning to FIG. 14, a posterior implant 242 having a shape and dimensions similar to the implant 78 of FIG. 3 is illustrated. Like the implant 78, the implant 242 comprises a body portion 244 from which multiple arms 246, 248, 250, and 252 extend. However, with the implant 242, the body portion 244 is composed substantially exclusively of a natural material while each of the arms 246, 248, 250, and 252 at least comprises a synthetic material. By way of example, the natural material comprises a cross-linked porcine dermal collagen material, such as Pelvicol[®] surgical implant or Pelvisoft[®] acellular collagen biomesh. In a further alternative, the body portion 244 comprises a layer of natural material that is affixed to a layer of synthetic material. In such a case, the natural material may be positioned so as to face the organ to be supported. In yet another alternative, the body portion 244 comprises two layers of natural material, one provided on either side of a layer of synthetic material. In cases in which natural material is connected to the synthetic material, various connection means may be used such as suturing, stapling, riveting, adhesive, bonding, heat laminating, and the like.

FIG. 15 illustrates an alternative embodiment of an introducer 260. By way of example, shown is a posterior introducer that can be used to implant a posterior implant, such as implant 78 (FIG. 3). As indicated in FIG. 15, the introducer 260 is similar in construction to the introducer 170 of FIG. 9. Therefore, the introducer 260 comprises a handle 262 that includes a proximal end 264 and a distal end 266. The handle 262 is generally sized and shaped to fit within a surgeon's hand and can be contoured to facilitate firm gripping.

~~FIG. 1A: A needle 268 extends from~~ the distal end 266 of the handle 262. The needle 268 comprises a needle body 269 that includes a substantially straight section 270 that directly extends from the handle 262 substantially parallel to a longitudinal axis of the handle (not identified). Extending from the straight section 270 is a curved section that comprises first
5 curved portion 272 adjacent the straight portion 270 that has a relatively small radius of curvature, and a second curved portion 272 distant from the straight portion that has a relatively large radius of curvature.

Positioned at a distal end of the needle body 269 is an extendible tip member 276 that terminates in a blunt tip 278. The tip member 276 is configured for releasable attachment to
10 the needle body 269 and for detachment therefrom such that the tip member can be extended away from the needle body to facilitate association of the needle 268 with an implant. Enabling extension of the tip member 276 is an actuator 278 that is provided on the handle 262. In the embodiment of FIG. 15, the actuator comprises a slide member that can, for example, be operated by the surgeon's thumb.

15 FIG. 16 illustrates extension of the tip member 276 from the needle body 269. As indicated in FIG. 16, the tip member 276 has been extended away from the needle body 269 in a direction indicated by arrow 280 through manipulation of the actuator 278 in the direction of arrow 282. More particularly, displacement of the actuator 278 has caused similar displacement of a connector member 284 that extends through the needle body 269
20 (which is hollow) to connect the actuator to the tip member 274. The connector member 284 is flexible so as to conform to the contours of the needle body 269 yet has sufficient column strength to dislodge the tip member 274 from the needle body and extend the tip member from the needle body. By way of example, the connector member 284 comprises a single or multiple metal and/or polymeric wires. In cases in which the connector member is metal,
25 suitable metal materials include nitinol and stainless steel.

FIGS. 17A and 17B illustrate two alternative embodiments for the tip member 274.

Both tip members 274' (FIG. 17A) and 274" (FIG. 17B) comprise a tang 286 that seats within the needle body 269 when the tip member is fully retracted. The tang 286 aids in securing the tip member 274', 274" to the needle body 269 as the needle 268 is passed through the soft tissue of the pelvis. Tip member 274' comprises an opening 288 that is provided through an exterior portion of the tip member adjacent the tip 276. In contrast, tip member 274" comprises an opening 290 that is provided through the tang 286.

The introducer 260 can be used to access the vagina in similar manner to that described above in relation to the other introducers. Once the tip member 274 has penetrated the vagina, however, the tip member can be dislodged from the needle body 269 and extended down along the vagina to exteriorize the opening (e.g., opening 288 or 290) to enable attachment of an implant to the tip member. The tip member 274 can then be retracted through the vagina and reconnected to the needle body 269. In embodiments in which an opening is provided through the tip member tang 286, the implant can be at least partially drawn into the needle body 269 to secure the implant.

FIG. 18 illustrates a further alternative pelvic implant. More particularly, illustrated is an anterior implant 300 having a shape and dimensions similar to the implant 10 of FIG. 1. Like the implant 10, the implant 300 comprises a body portion 302 from which multiple arms 304, 306, 308, and 310 extend. Attached to each of those arms is an anchor 312 that can be used to secure the ends of the arms within a desired area of soft tissue within the pelvis. In the embodiment of FIG. 18, each anchor 312 comprises an opening 314 through which an arm of an implant can be passed and a sharp tip 316 that can penetrate and be securely lodged within soft tissue. In some embodiments, the opening 314 is sized and configured to limit free passage of the implant arm through the opening. With such a configuration, the surgeon

can adjust the length of the arm without having the length later change due to the anchor slipping along the arm.

As described above, procedures other than prolapse repair can be performed using the apparatus described above or similar apparatus. For example, the introducers disclosed
5 herein can be used in some embodiments to introduce an implant intended to treat urinary incontinence. In such a procedure, similar steps can be performed except that the implant can comprise a urethral sling that is positioned below the urethra to provide support to the urethra. In some cases, the anterior implant may also serve to alleviate urinary incontinence.

CLAIMS

1. A pelvic implant comprising:
a body portion configured to support an organ, the body portion defining a central axis about which the implant is substantially symmetric; and
multiple arms that extend from the body portion, at least one arm being substantially perpendicular to the central axis.
2. The implant of claim 1, wherein the body portion comprises a substantially straight front edge, a rounded rear edge, and opposed lateral edges.
3. The implant of claim 2, wherein the rounded rear edge forms a rear projection that extends rearwardly from the body portion.
4. The implant of claim 2, wherein the lateral edges are angled relative to the central axis such that the body portion widens from front to back.
5. The implant of claim 1, wherein each of the arms is substantially perpendicular to the central axis.
6. The implant of claim 1, wherein the arms comprise two front arms and two rear arms.
7. The implant of claim 6, wherein the front arms comprise front edges that are contiguous with a front edge of the body portion.

8. The implant of claim 6, wherein the front arms have rounded ends and the rear arms have pointed ends.

9. The implant of claim 6, wherein the front arms are approximately as long as the rear arms.

10. The implant of claim 1, wherein the implant is formed from mesh material.

11. The implant of claim 10, wherein the body portion comprises an area of relatively soft mesh material and the arms comprise areas of relatively coarse mesh material.

12. The implant of claim 10, wherein at least the body portion is coated with a film of collagen.

13. The implant of claim 1, wherein the implant is an anterior prolapse implant and is shaped and configured to support the bladder.

14. An anterior prolapse implant comprising:
a body portion configured to support a bladder, the body portion defining a central axis about which the implant is substantially symmetric;
two front arms that extend from the body portion in substantially opposite directions, each of the front arms being substantially perpendicular to the central axis;
two rear arms that extend from the body portion in substantially opposite directions, each of the rear arms being substantially perpendicular to the central axis and parallel to the front arms; and

~~a rear projection contiguous~~ with the body portion that extends rearwardly from the rear arms;

wherein the implant is formed from synthetic mesh material, the body portion comprising a relatively soft mesh material and the arms comprising relatively coarse mesh material.

15. The implant of claim 14, wherein the body portion comprises a substantially straight front edge, a rounded rear edge, and opposed lateral edges.

16. The implant of claim 15, wherein the lateral edges are angled relative to the central axis such that the body portion widens from front to back.

17. The implant of claim 14, wherein the front arms comprise front edges that are contiguous with a front edge of the body portion.

18. The implant of claim 14, wherein the front arms have rounded ends and the rear arms have pointed ends.

19. The implant of claim 14, wherein the front arms are approximately as long as the rear arms.

20. The implant of claim 14, wherein at least the body portion is coated with a film of collagen.

~~PCT/US2006/030370~~
21. A pelvic implant comprising:

a body portion configured to support an organ, the body portion defining a longitudinal axis about which the implant is substantially symmetric; and

multiple arms that extend from the body portion, at least one arm being substantially parallel to the longitudinal axis.

22. The implant of claim 21, wherein the body portion is substantially rectangular.

23. The implant of claim 22, wherein the body portion comprises a substantially straight front edge, an inwardly extending rounded rear edge, and opposed lateral edges.

24. The implant of claim 23, wherein the lateral edges are substantially parallel to the longitudinal axis.

25. The implant of claim 21, wherein the arms comprise two front arms and two rear arms.

26. The implant of claim 25, wherein each front arm comprises a first section that extends from the body portion at a divergent angle and a second section that extends from the first section in a direction substantially parallel to the longitudinal axis.

27. The implant of claim 25, wherein each rear arm comprises a lateral section that extends from the body portion substantially perpendicular to the longitudinal axis and a longitudinal section that extends from the lateral section substantially parallel to the longitudinal axis.

28. The implant of claim 25, wherein the front arms have rounded ends and the rear arms have pointed ends.

29. The implant of claim 25, wherein the rear arms are approximately twice as long as the front arms.

30. The implant of claim 21, wherein the implant is formed from mesh material.

31. The implant of claim 30, wherein the body portion comprises an area of relatively soft mesh material and the arms comprise areas of relatively coarse mesh material.

32. The implant of claim 30, wherein at least the body portion is coated with a film of collagen.

33. The implant of claim 31, wherein the implant is a posterior prolapse implant and is shaped and configured to support the rectum.

34. A posterior prolapse implant comprising:
an elongated body portion configured to support a rectum, the body portion defining a longitudinal axis about which the implant is substantially symmetric;
two front arms that generally extend from the body portion in a first direction, each front arm including a first section that extends from the body portion at a divergent angle and a second section that extends from the first section in a direction substantially parallel to the longitudinal axis; and

~~two rear arms that generally~~ extend from the body portion in the first direction, each of the rear arms including a lateral portion that extends from the body portion in a direction substantially perpendicular to the longitudinal axis and a longitudinal section that extends from the lateral section in a direction substantially parallel to the longitudinal axis;

wherein the implant is formed from synthetic mesh material, the body portion comprising a relatively soft mesh material and the arms comprising relatively coarse mesh material.

35. The implant of claim 34, wherein the body portion is substantially rectangular.

36. The implant of claim 35, wherein the body portion comprises a substantially straight front edge, an inwardly extending rounded rear edge, and opposed lateral edges.

37. The implant of claim 34, wherein the front arms have rounded ends and the rear arms have pointed ends.

38. The implant of claim 34, wherein the rear arms are approximately twice as long as the front arms.

39. The implant of claim 34, wherein at least the body portion is coated with a film of collagen.

40. ~~An anterior prolapse implant introducer comprising:~~

a handle having a proximal end and a distal end; and

a needle that extends from the distal end of the handle, the needle comprising a first straight section connected to the handle, a curved section extending from the first straight section, and a second straight section extending from the curved section and forming a tip of the needle, the needle further comprising an opening formed in the straight section adjacent the tip;

wherein the needle is sized and configured to pass through an external paravaginal incision soft tissue of the pelvis to the vagina until the tip emerges from the vaginal introitus to enable association of an anterior prolapse implant with the needle opening.

41. The introducer of claim 40, wherein the curved section of the needle has a radius of curvature no less than 36.5 millimeters.

42. The introducer of claim 40, wherein the second straight section is narrowed relative to the remainder of the needle and is defined by two opposed lateral flat surfaces.

43. The introducer of claim 42, wherein the opening extends from one flat surface to the other flat surface of the second straight section.

44. An introducer comprising:

a handle having a proximal end and a distal end; and

a needle that extends from the distal end of the handle, the needle comprising a first straight section connected to the handle, a curved section extending from the first straight section, and a second straight section extending from the curved section and forming a tip of

the needle, the needle further comprising an opening formed in the second straight section adjacent the tip;

wherein the curved section comprises a first curved portion adjacent the handle having a first radius of curvature and a second curved portion distant from the handle having a second radius of curvature that is different from the first radius of curvature.

45. The introducer of claim 44, wherein the first radius of curvature is smaller than the second radius of curvature.

46. The introducer of claim 44, wherein the second radius of curvature is nearly twice as large as the first radius of curvature.

47. The introducer of claim 44, wherein the first radius of curvature is approximately 50 millimeters and the second radius of curvature is approximately 80 millimeters.

48. The introducer of claim 44, wherein the second straight section is substantially perpendicular to the first straight section.

49. The introducer of claim 44, wherein the second straight section comprises substantially flat opposed edges through which the opening passes.

50. A method for implanting an implant, the method comprising:

- forming a midline incision in the anterior vaginal wall;
- forming external paravaginal incisions aligned with the obturator foramina;
- passing a needle through one of the paravaginal incisions and out through the incision in the anterior vaginal wall;
- attaching an arm of an anterior prolapse implant to the needle;
- drawing the needle back through a passage formed by the needle until the needle is withdrawn from its paravaginal incision such that the implant arm extends through an obturator foramen and out from the paravaginal incision.

51. The method of claim 50, further comprising repeating the drawing step for each paravaginal incision and each arm of the implant until each arm has been extended through an obturator foramen and out from a paravaginal incision.

52. The method of claim 51, further comprising trimming portions of the arms that extend from the paravaginal incisions.

53. A method for implanting an implant, the method comprising:

- forming a midline incision in the posterior vaginal wall;
- forming external pararectal incisions;
- passing a needle through one of the paravaginal incisions;
- passing the needle deep within the pelvis until a tip of the needle is positioned adjacent the ischial spine;
- passing the needle tip into the vaginal vault;

~~passing the needle down~~ through the vagina until the needle tip emerges from the vaginal introitus so as to be exposed;

attaching a rear arm of a posterior prolapse implant to the exposed needle;

drawing the needle back through the deep passage formed by the needle until the needle is withdrawn from its pararectal incision such that the rear arm extends out from the pararectal incision.

54. The method of claim 53, further comprising:

passing the needle back through the pararectal incision from which the implant arm extends, passing the needle shallow within the pelvis until a tip of the needle enters the vagina and emerges from the vaginal introitus so as to be exposed;

attaching a front arm of a posterior prolapse implant to the exposed needle;

drawing the needle back through the shallow passage formed by the needle until the needle is withdrawn from its pararectal incision such that the front arm also extends out from the pararectal incision.

55. The method of claim 54, further comprising implanting a front and a rear arm provided on an opposite side of the implant on an opposite side of the vagina such that one front arm and one rear arm extend from a first pararectal incision and another front arm and another rear arm extend from a second pararectal incision.

56. The method of claim 55, further comprising trimming portions of the arms that extend from the pararectal incisions.

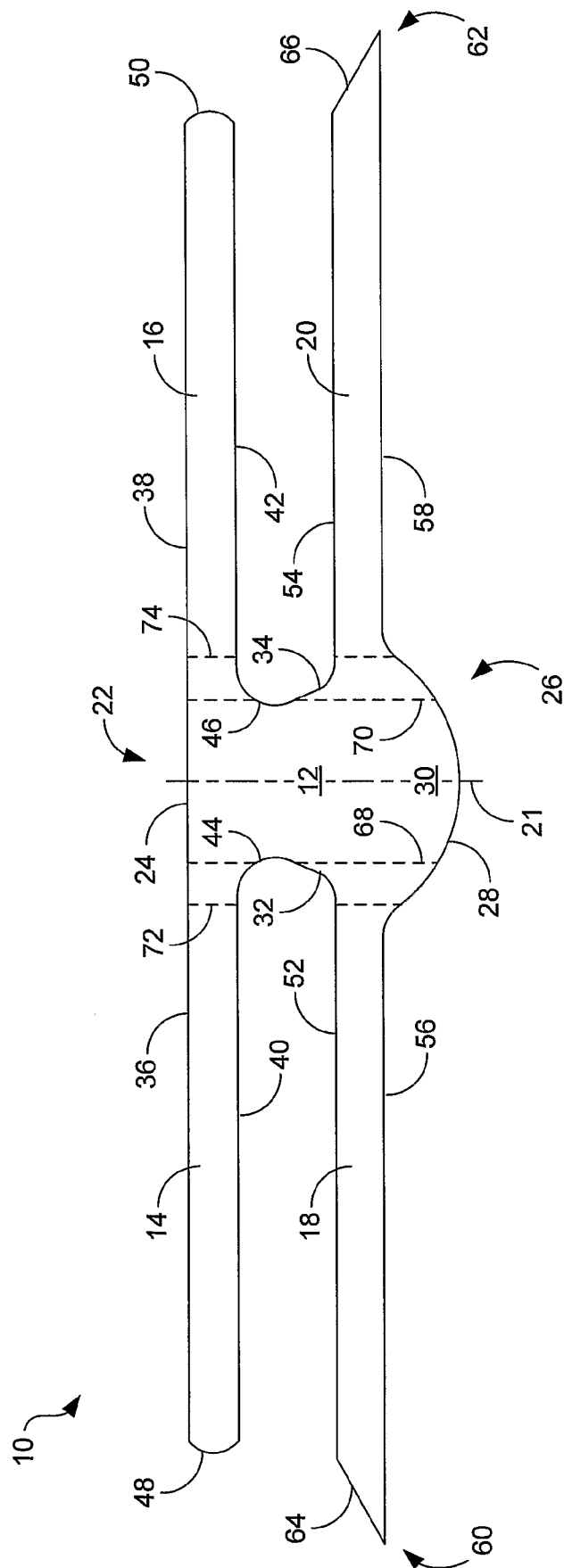


FIG. 1

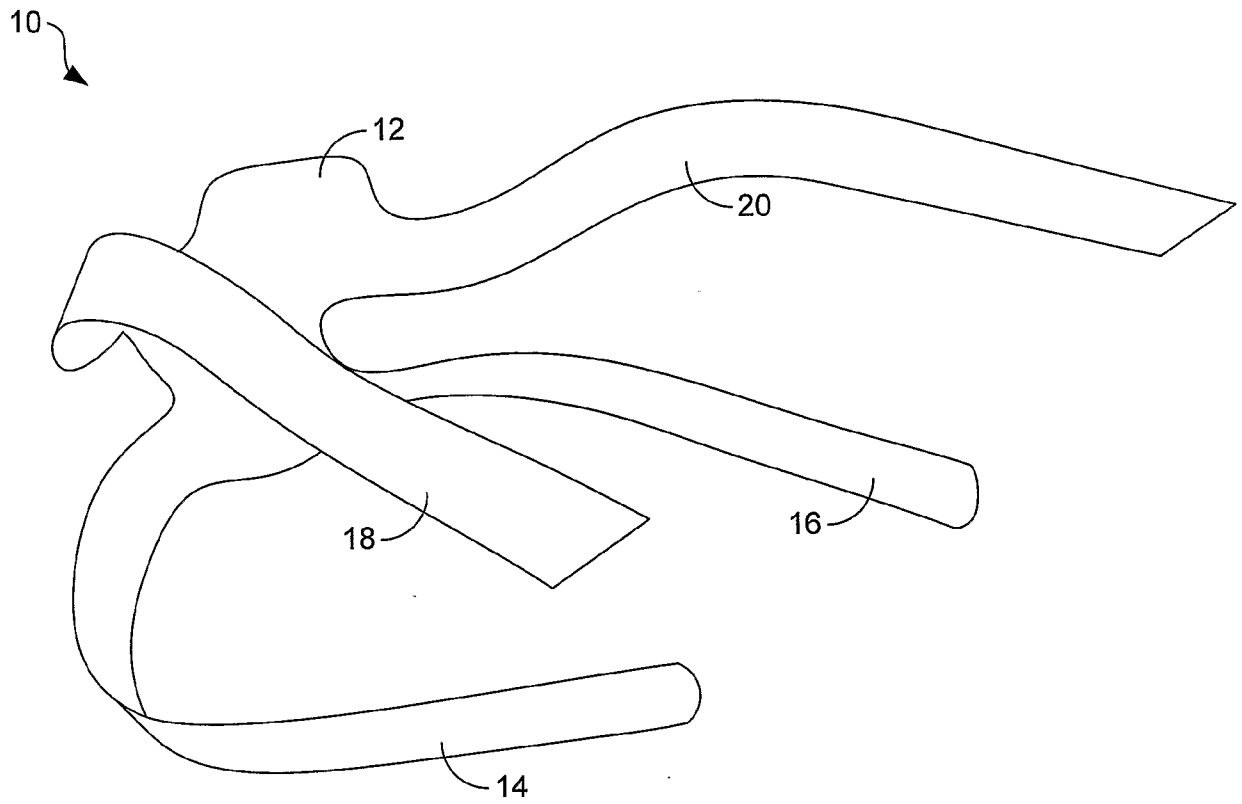


FIG. 2

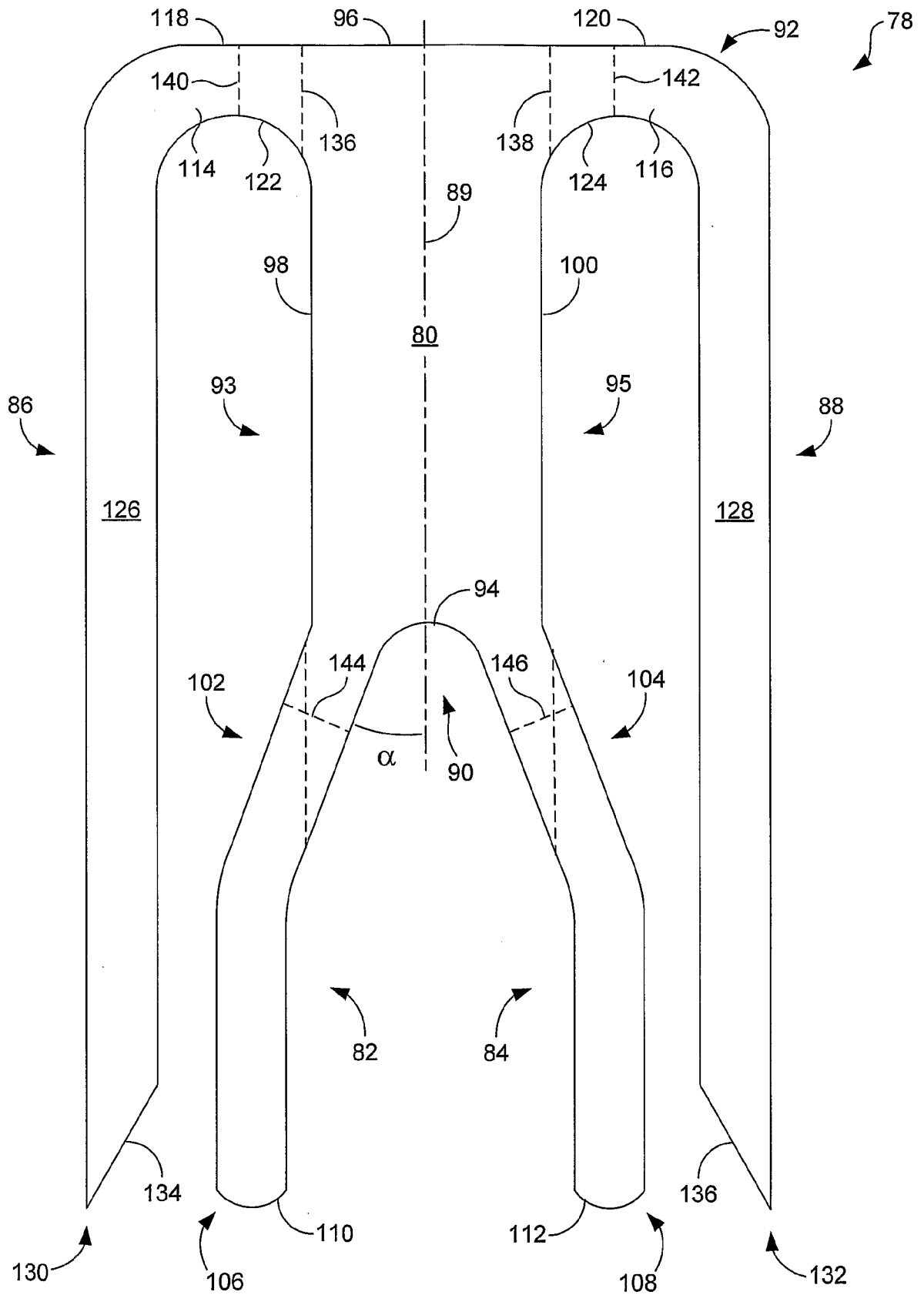


FIG. 3

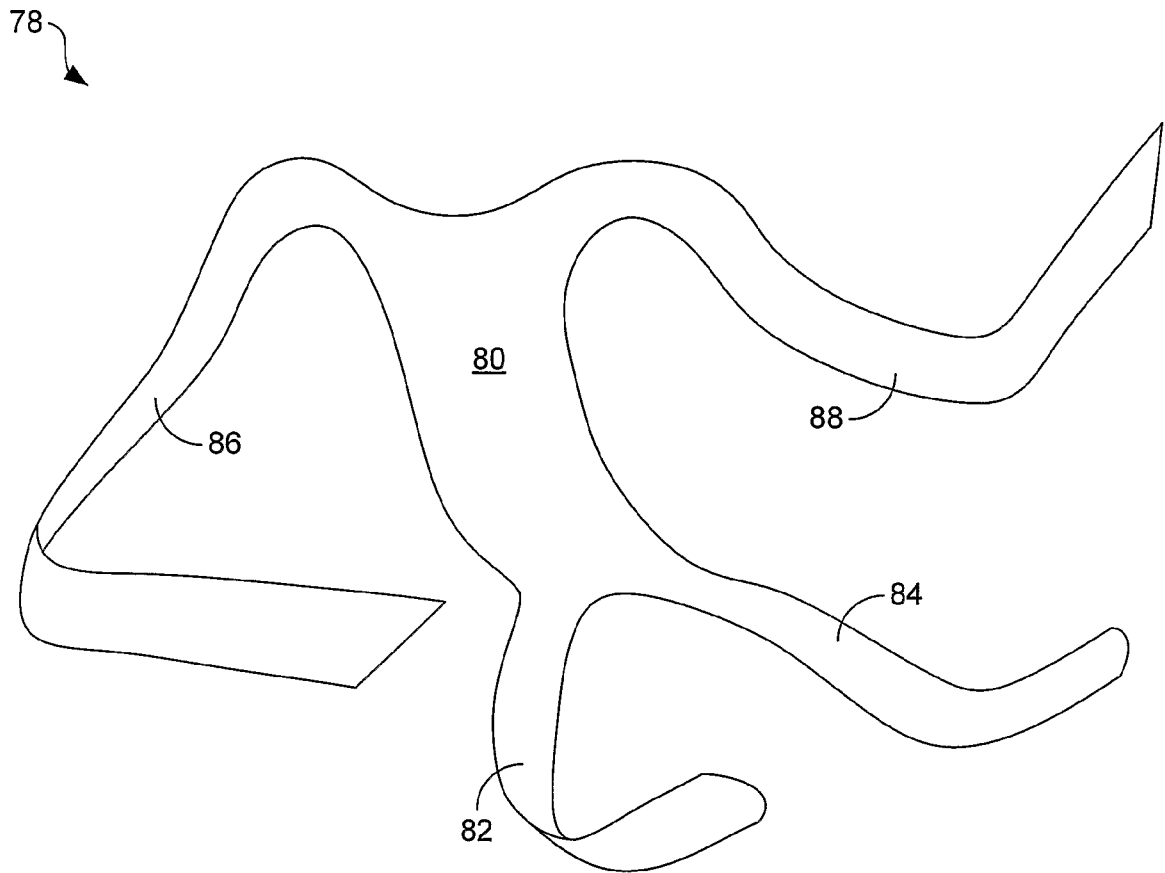
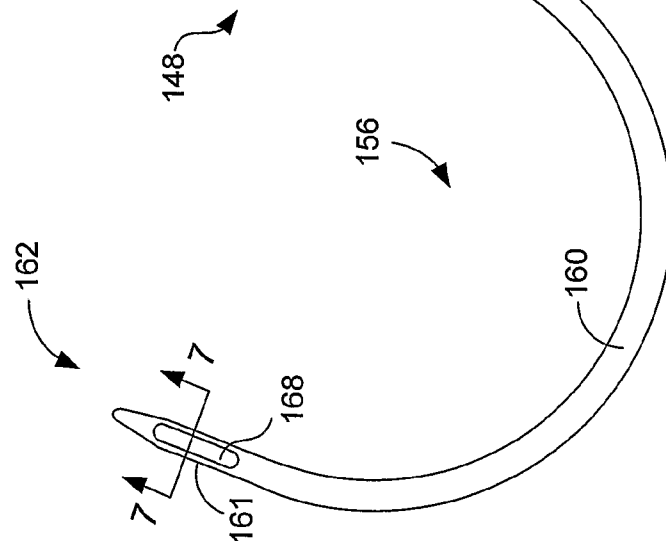
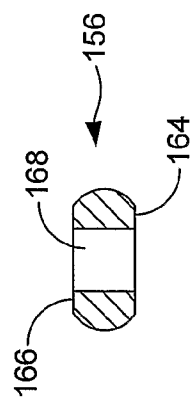
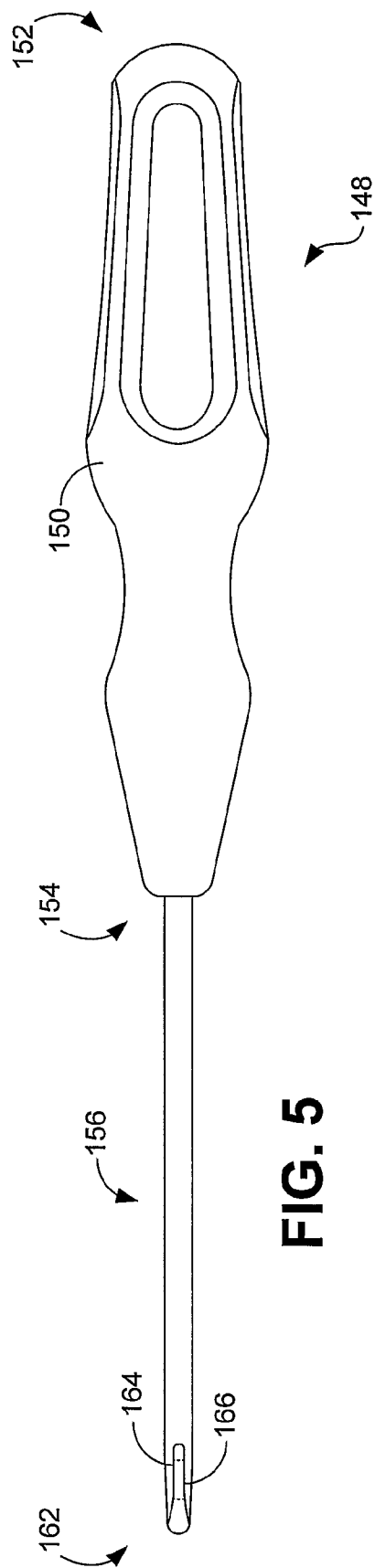


FIG. 4



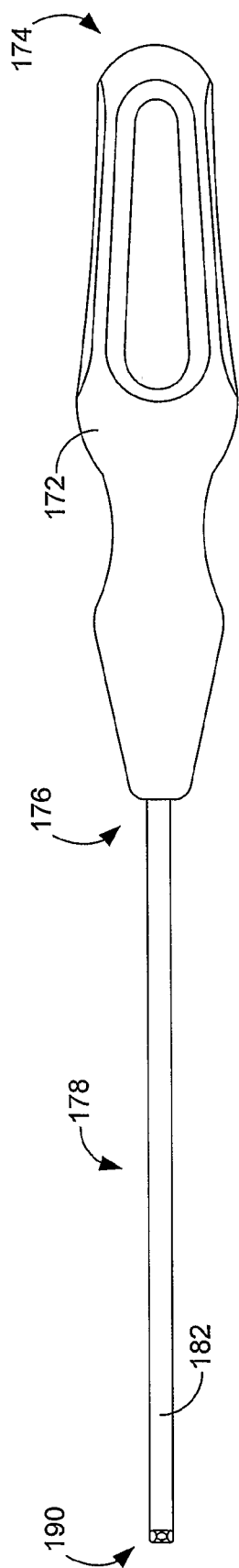


FIG. 8

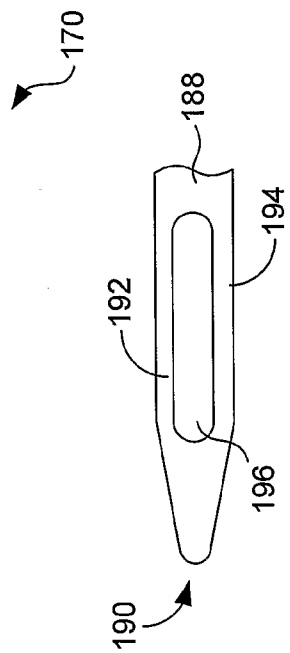


FIG. 10

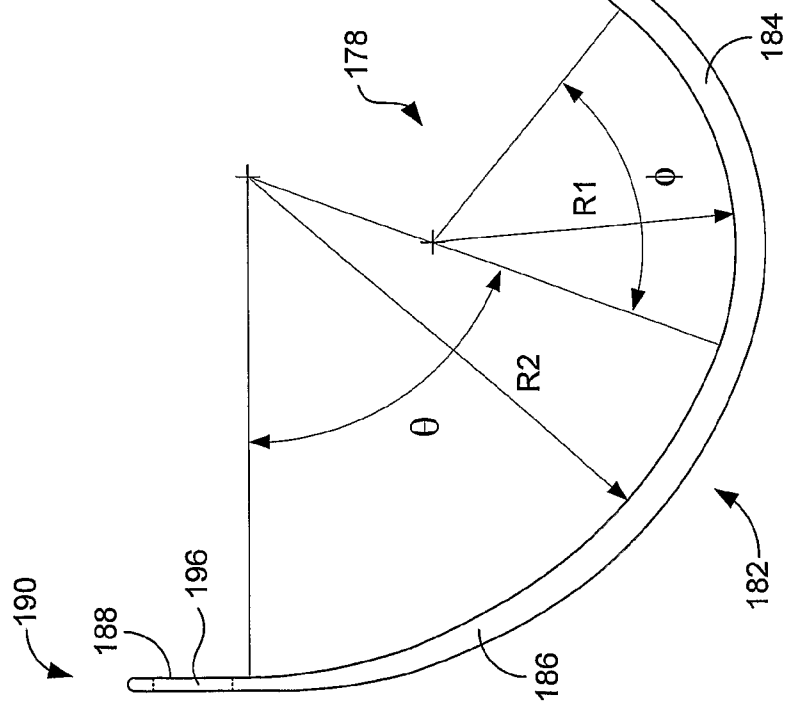


FIG. 9

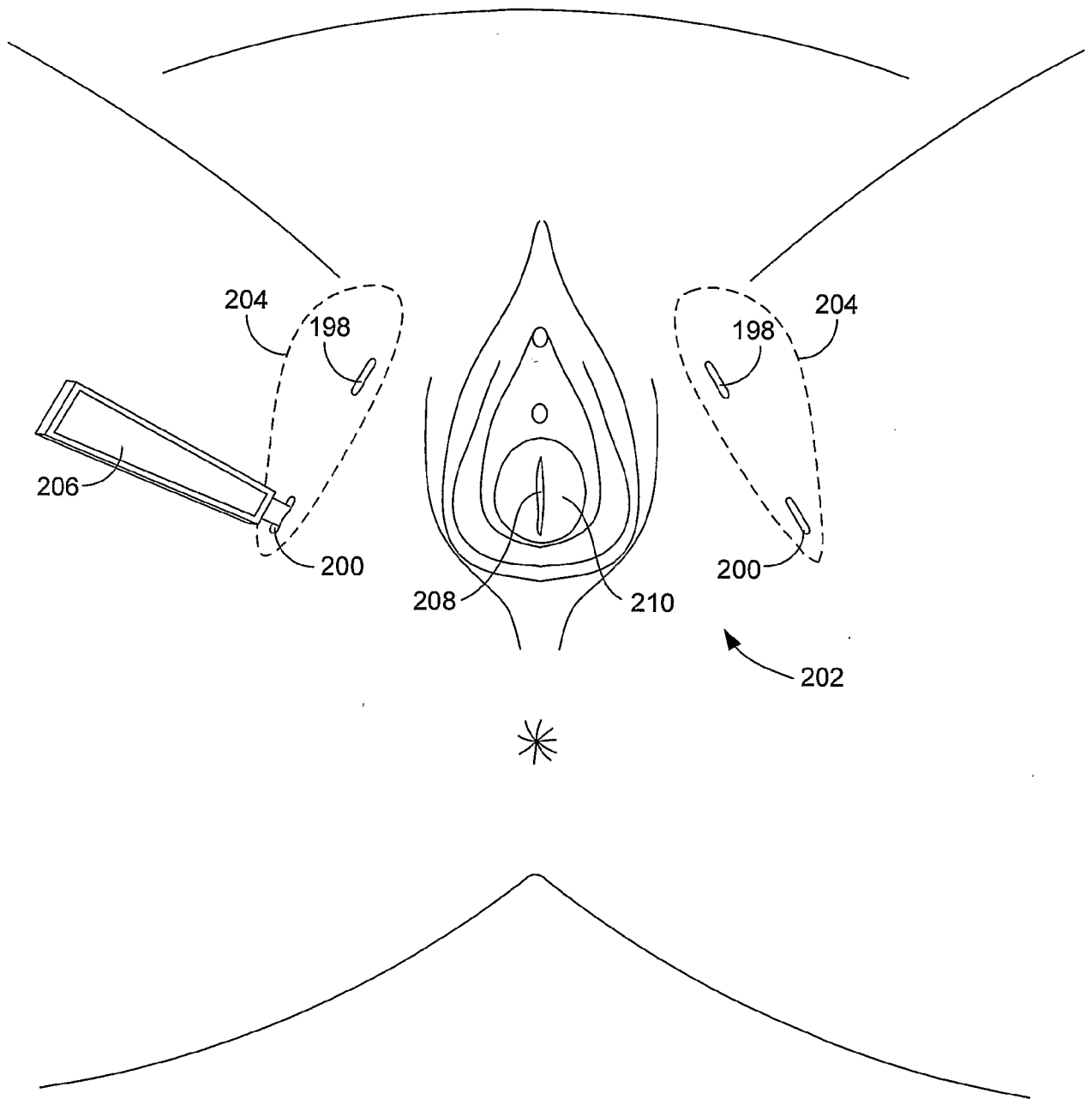


FIG. 11A

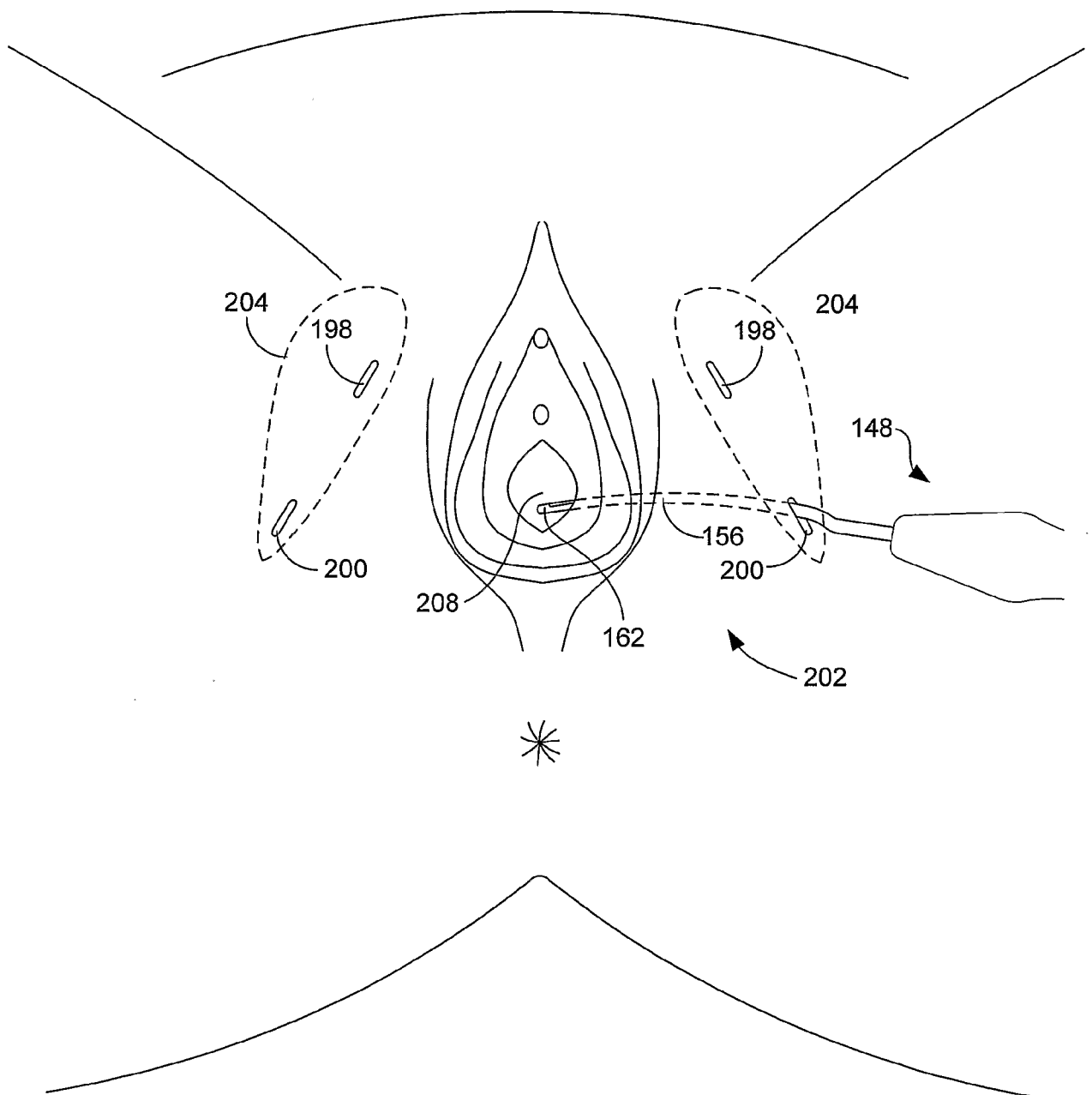


FIG. 11B

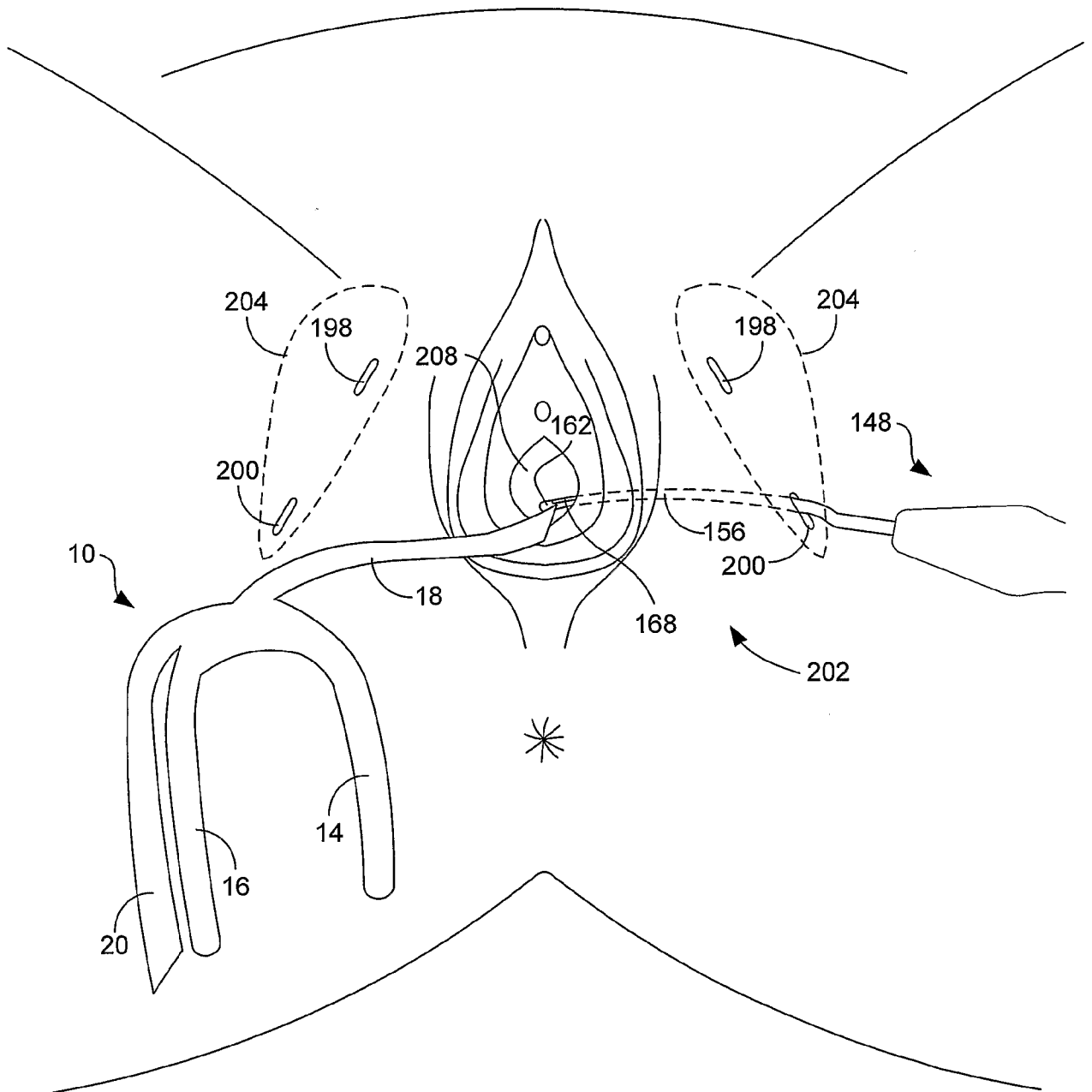


FIG. 11C

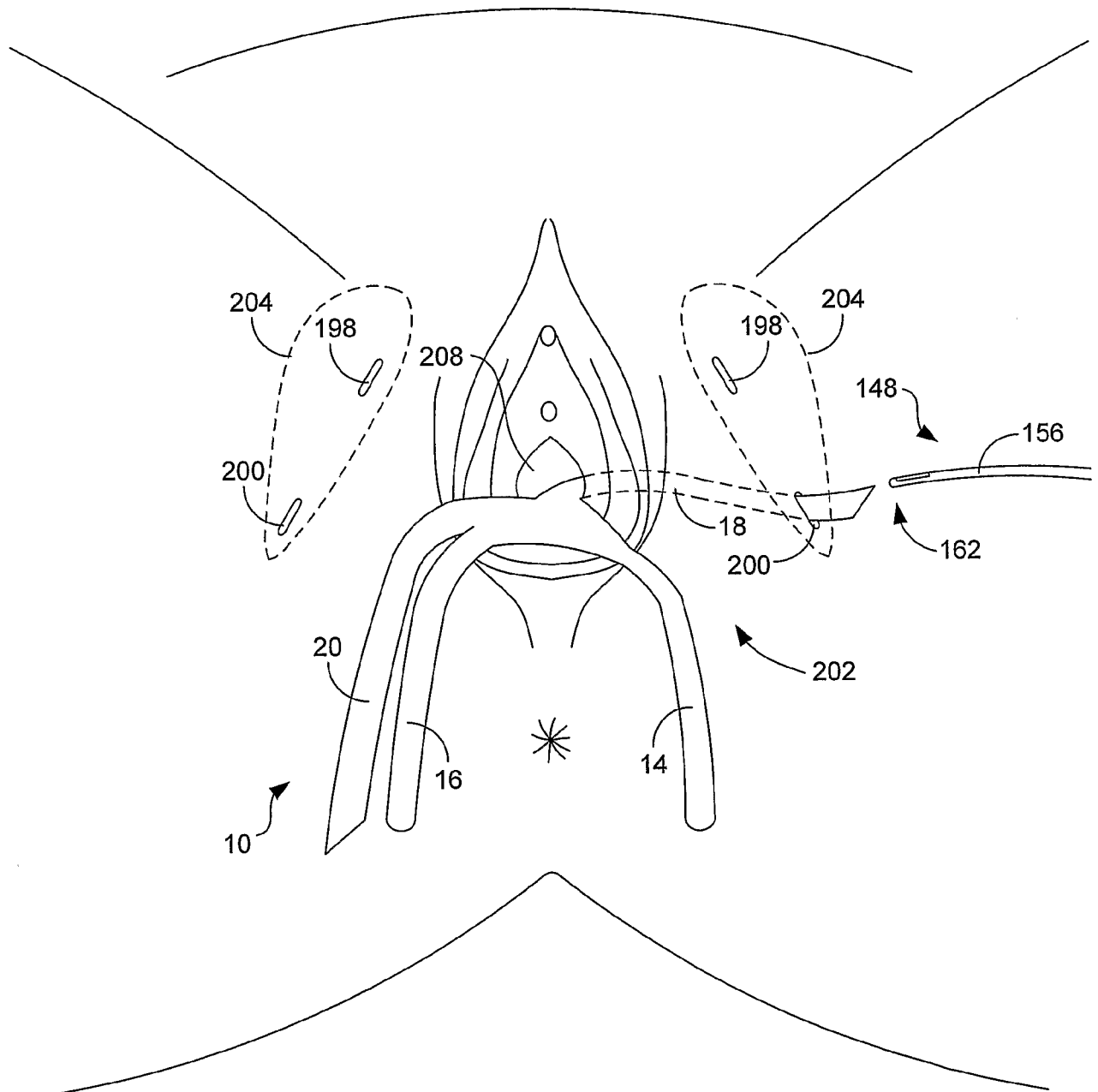
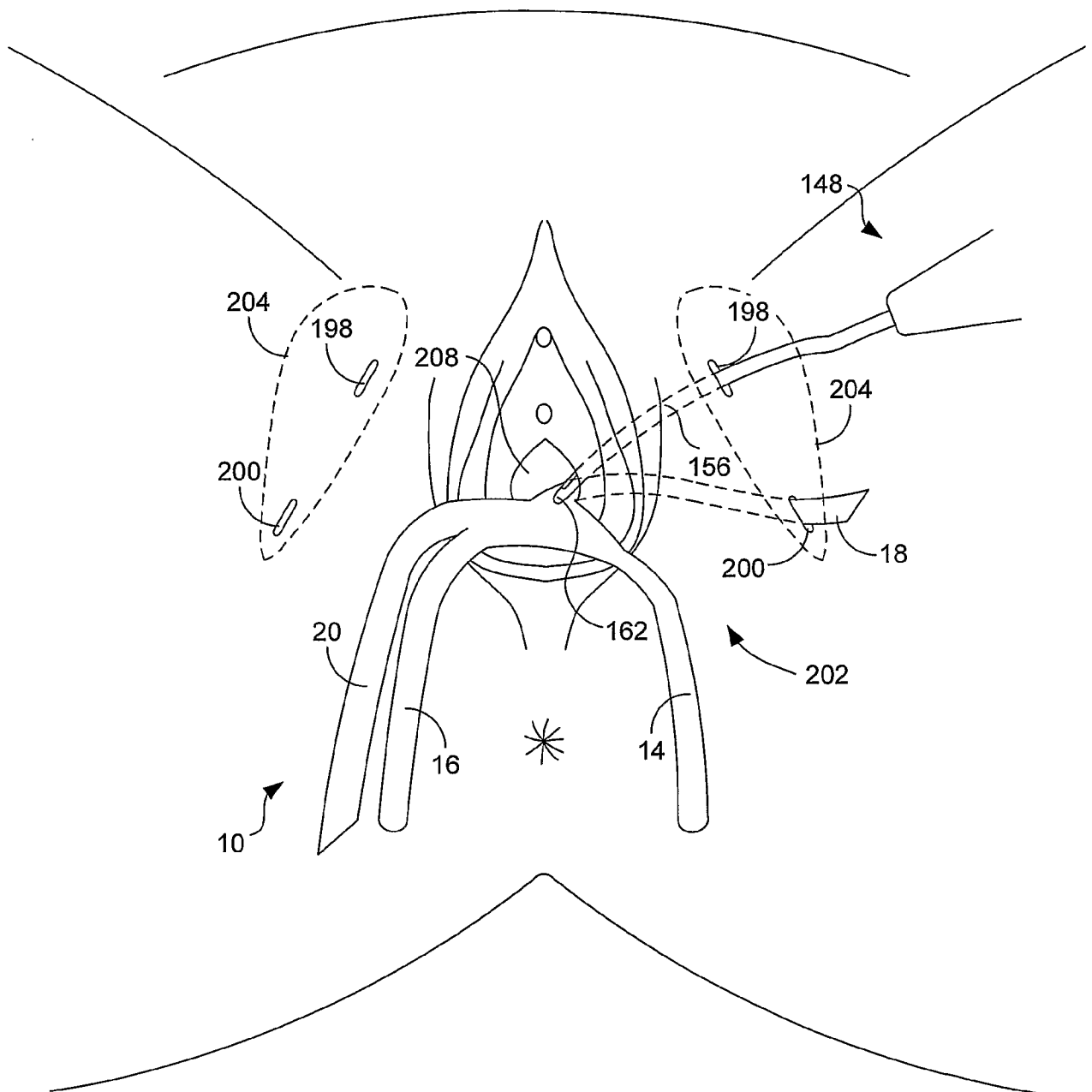
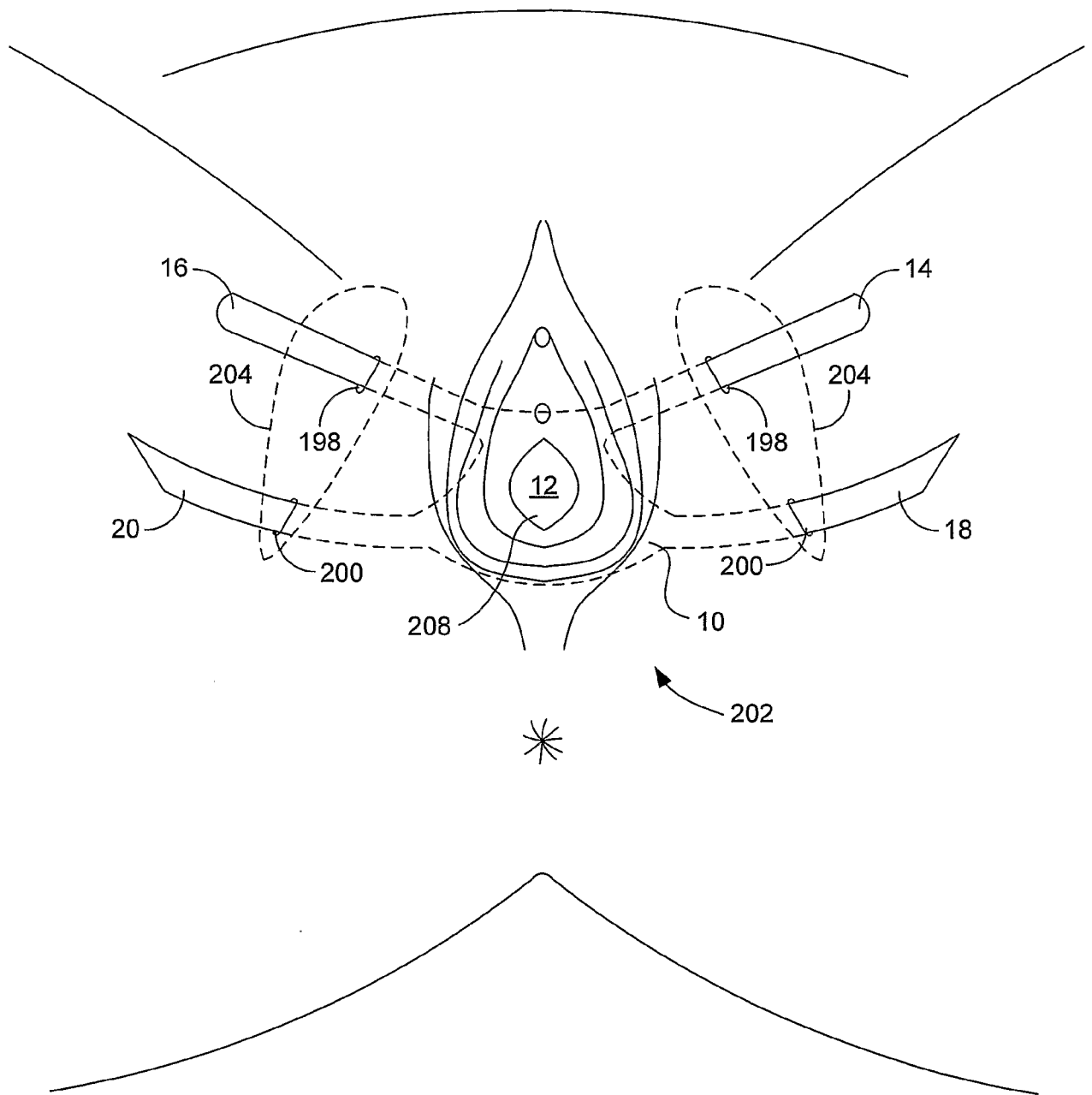
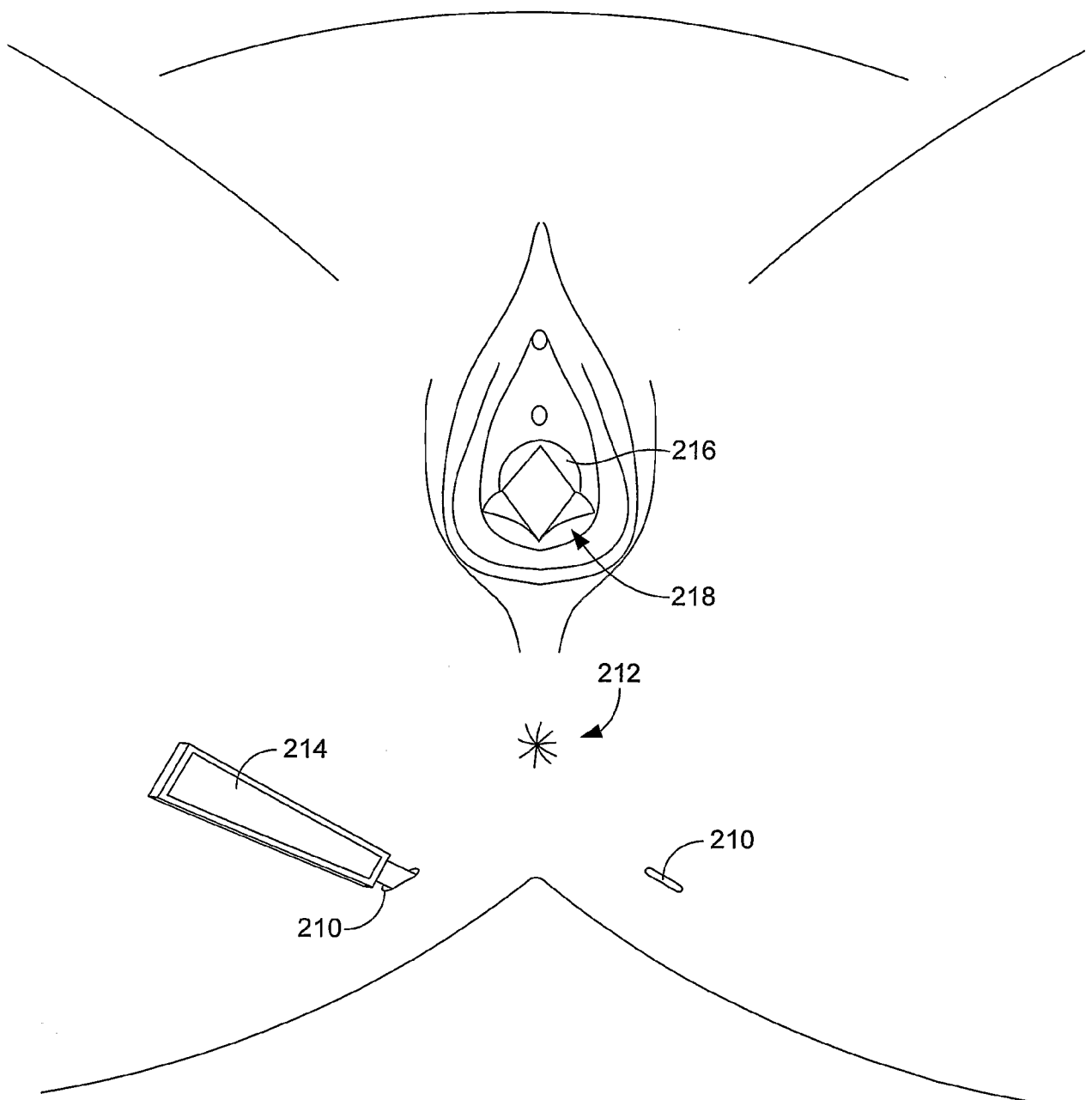


FIG. 11D

**FIG. 11E**

**FIG. 11F**

**FIG. 12A**

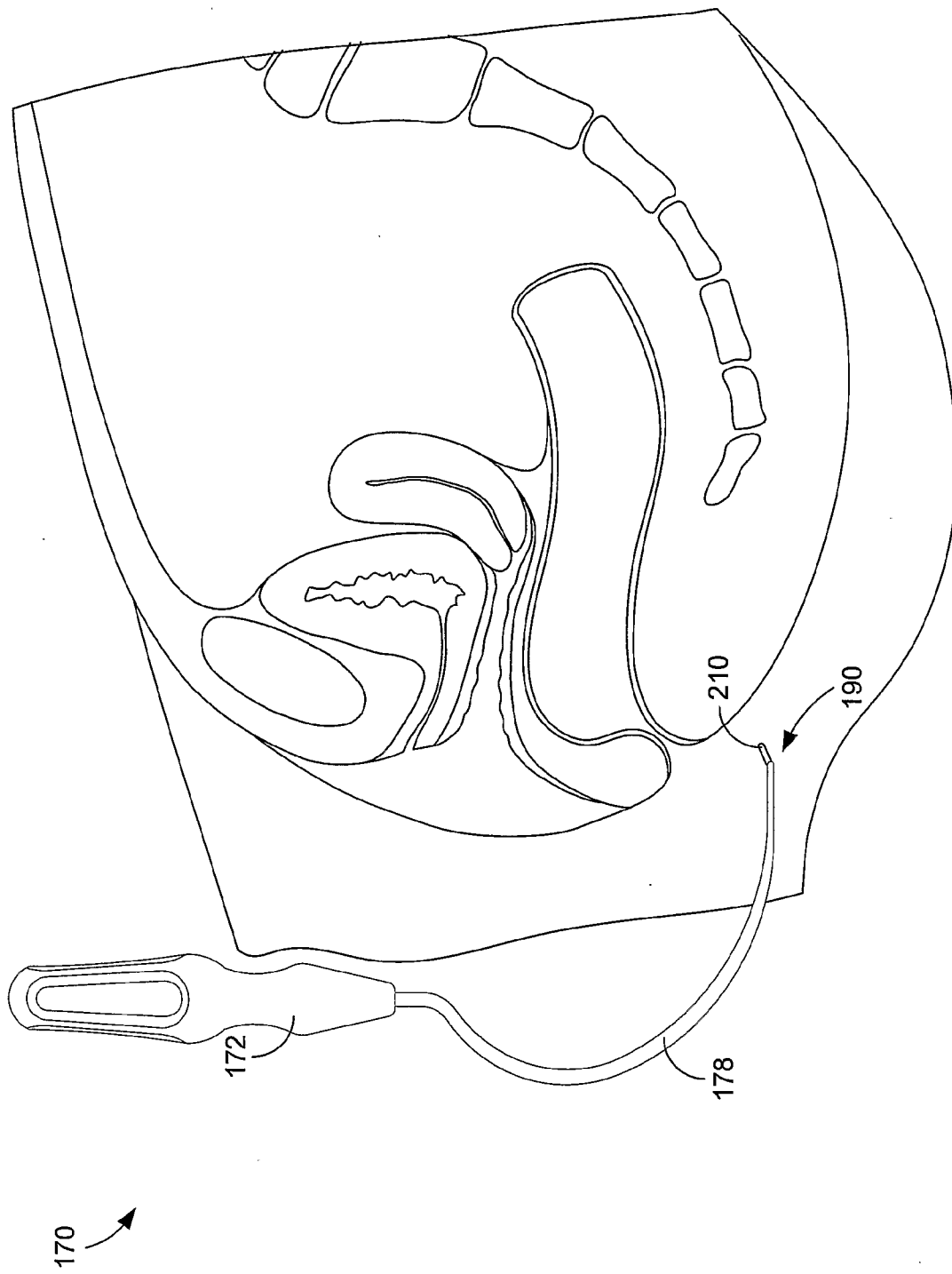


FIG. 12B

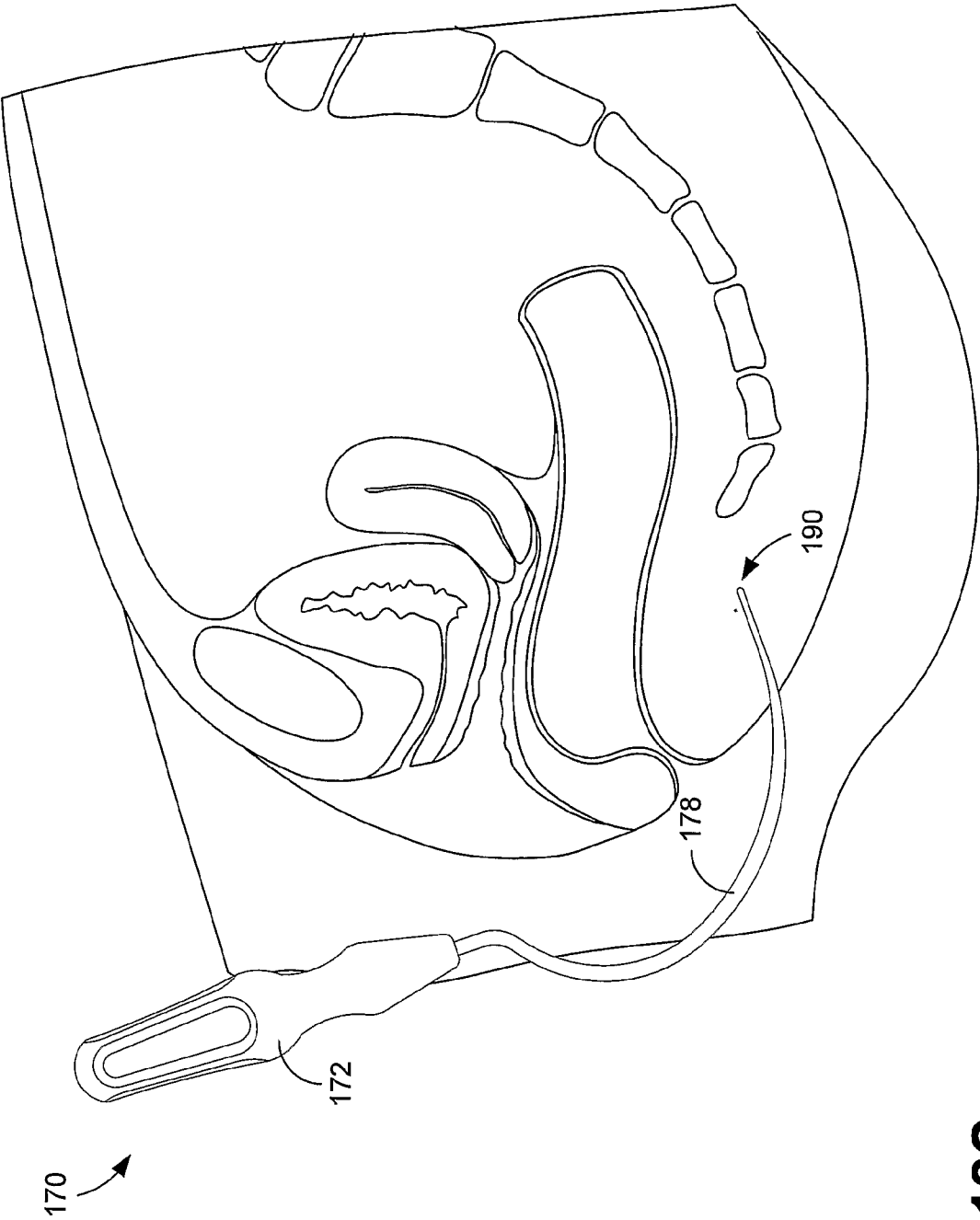
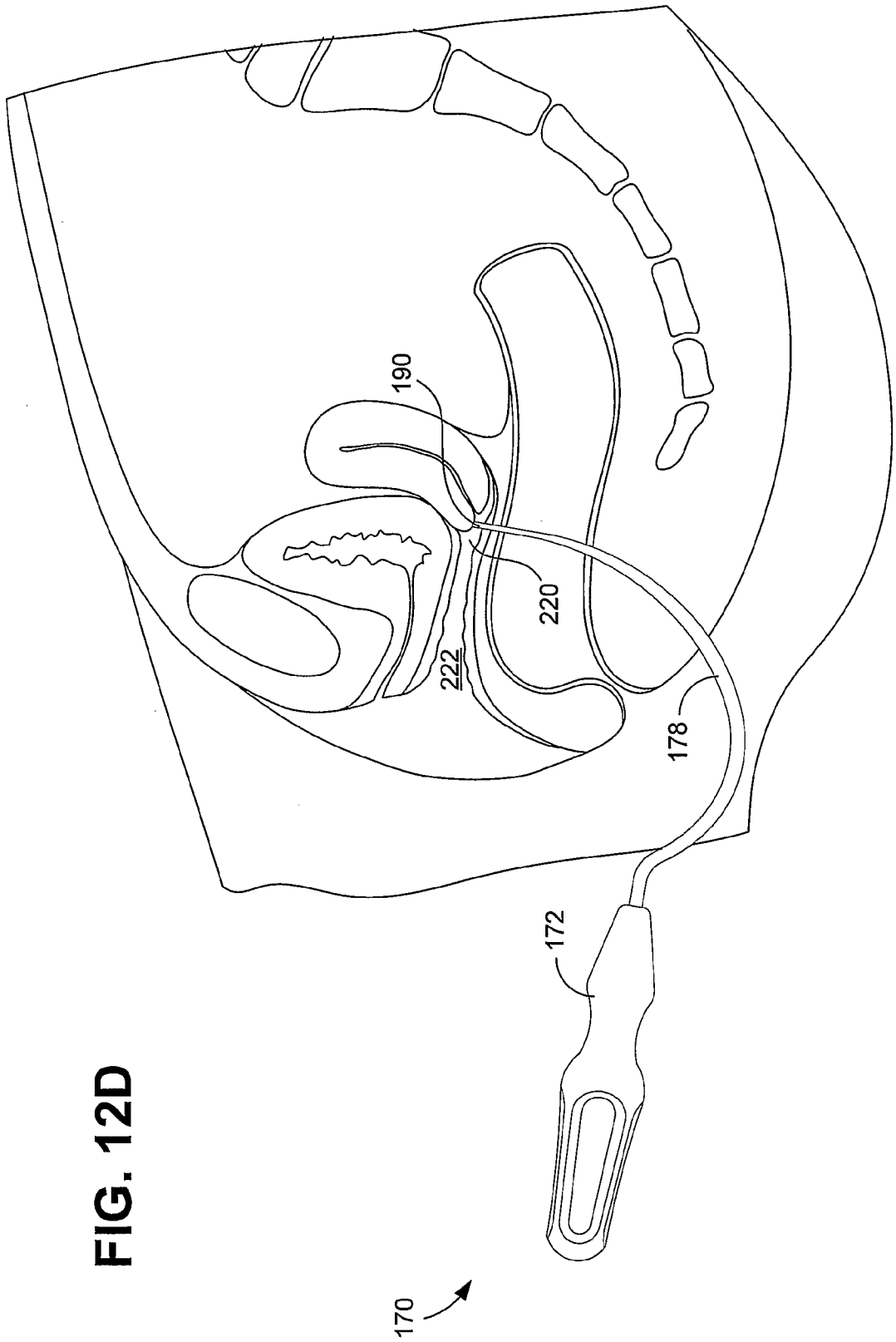


FIG. 12C



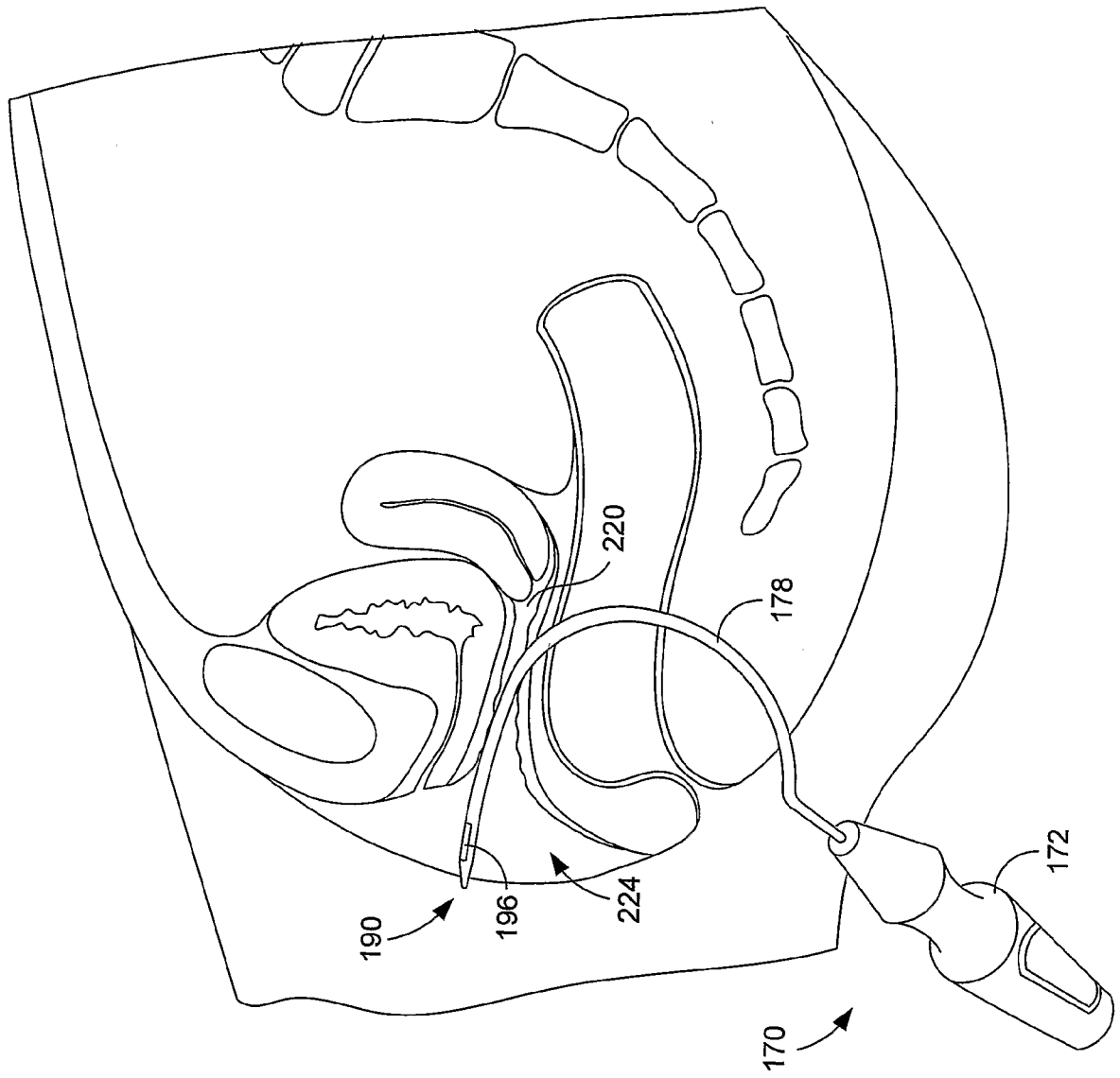


FIG. 12E

FIG. 12F

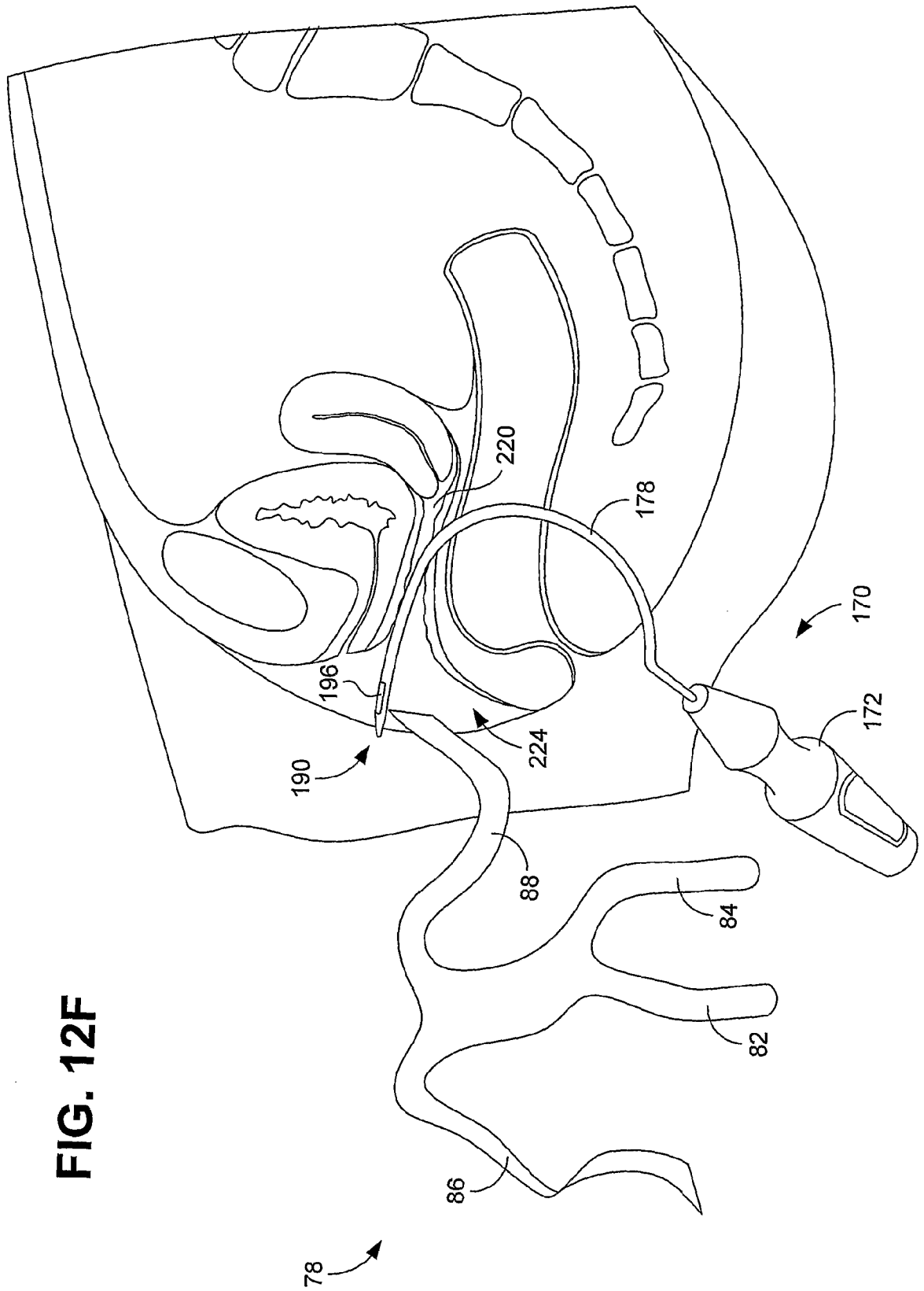
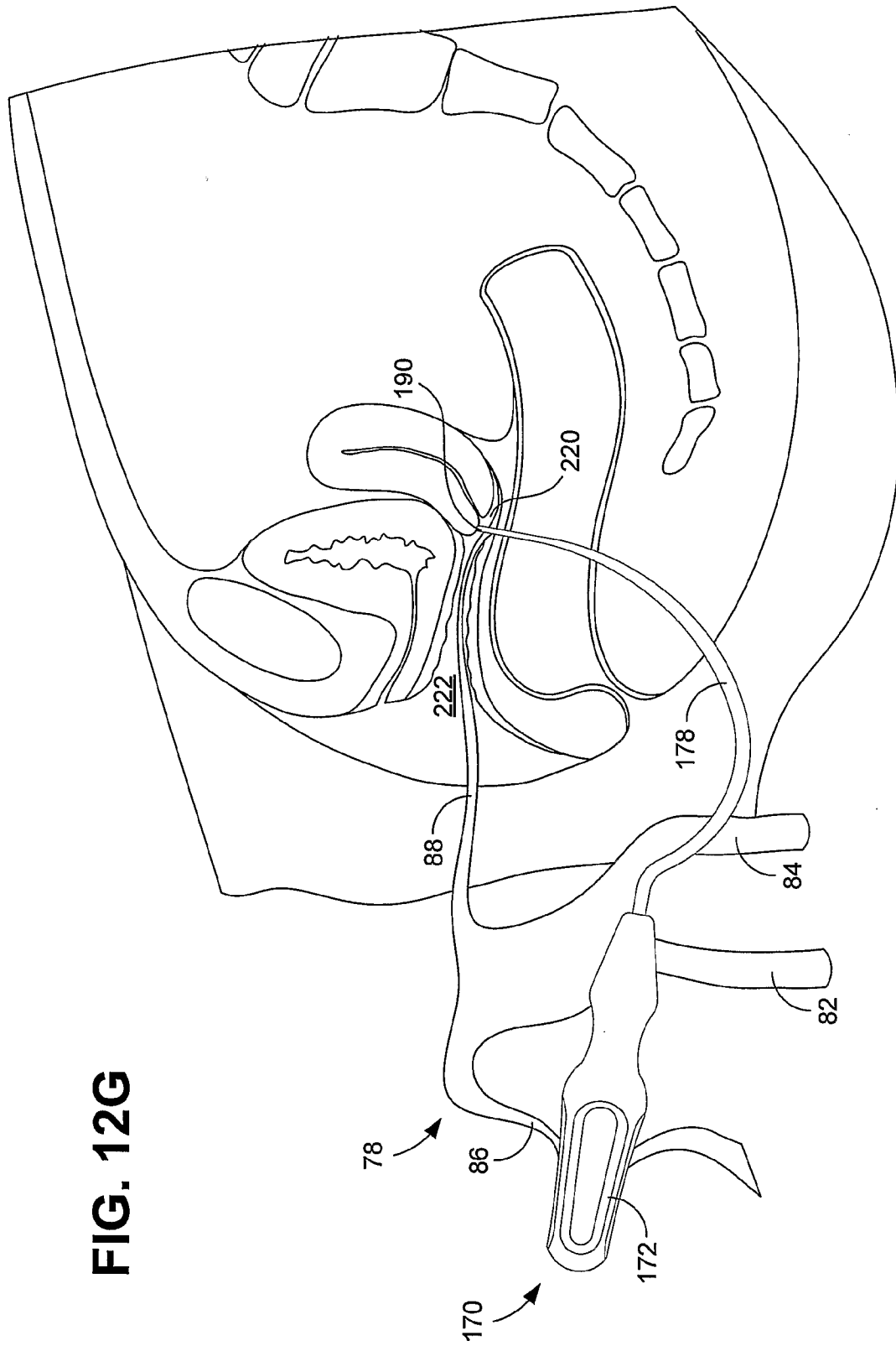


FIG. 12G



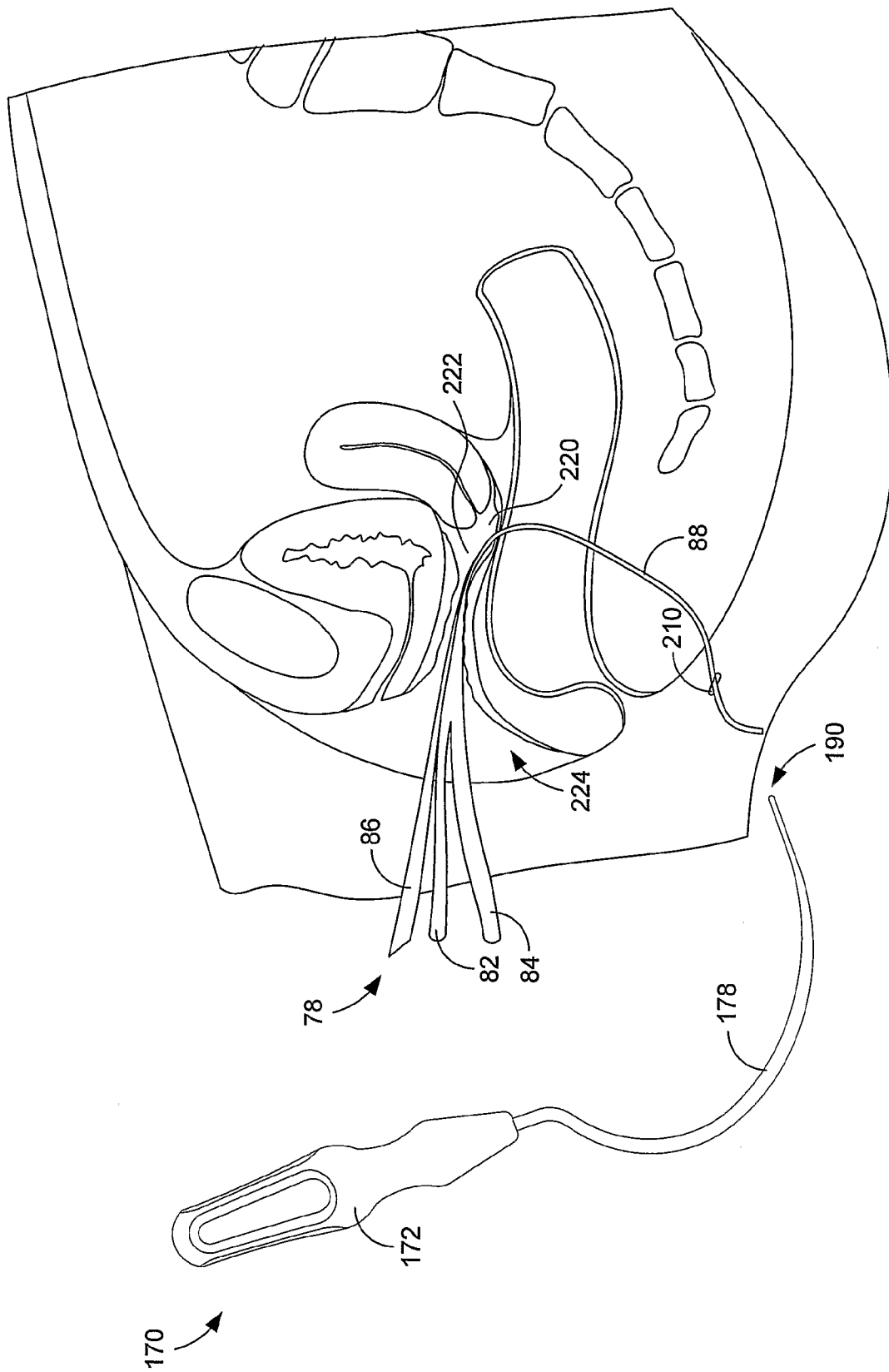


FIG. 12H

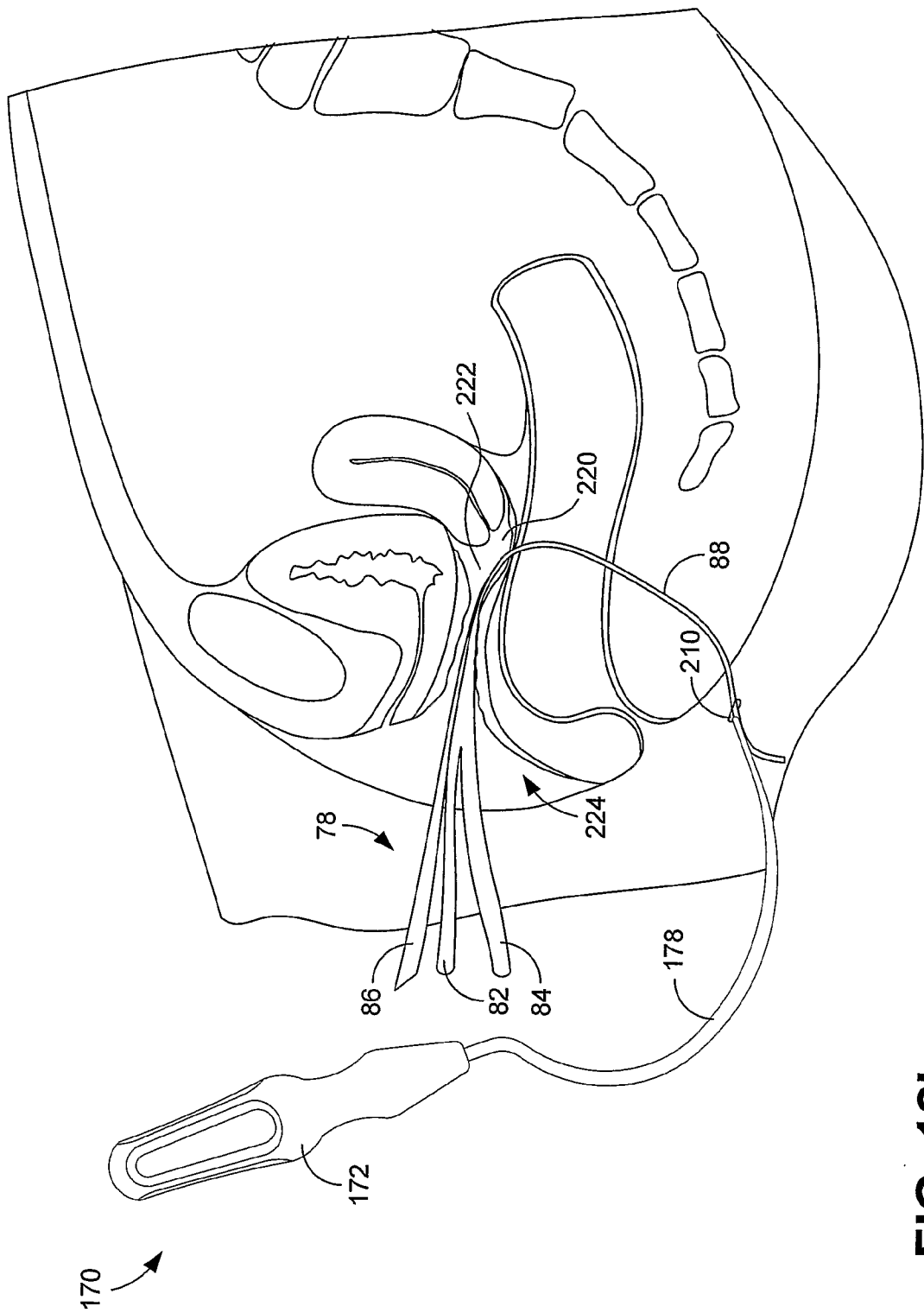


FIG. 12I

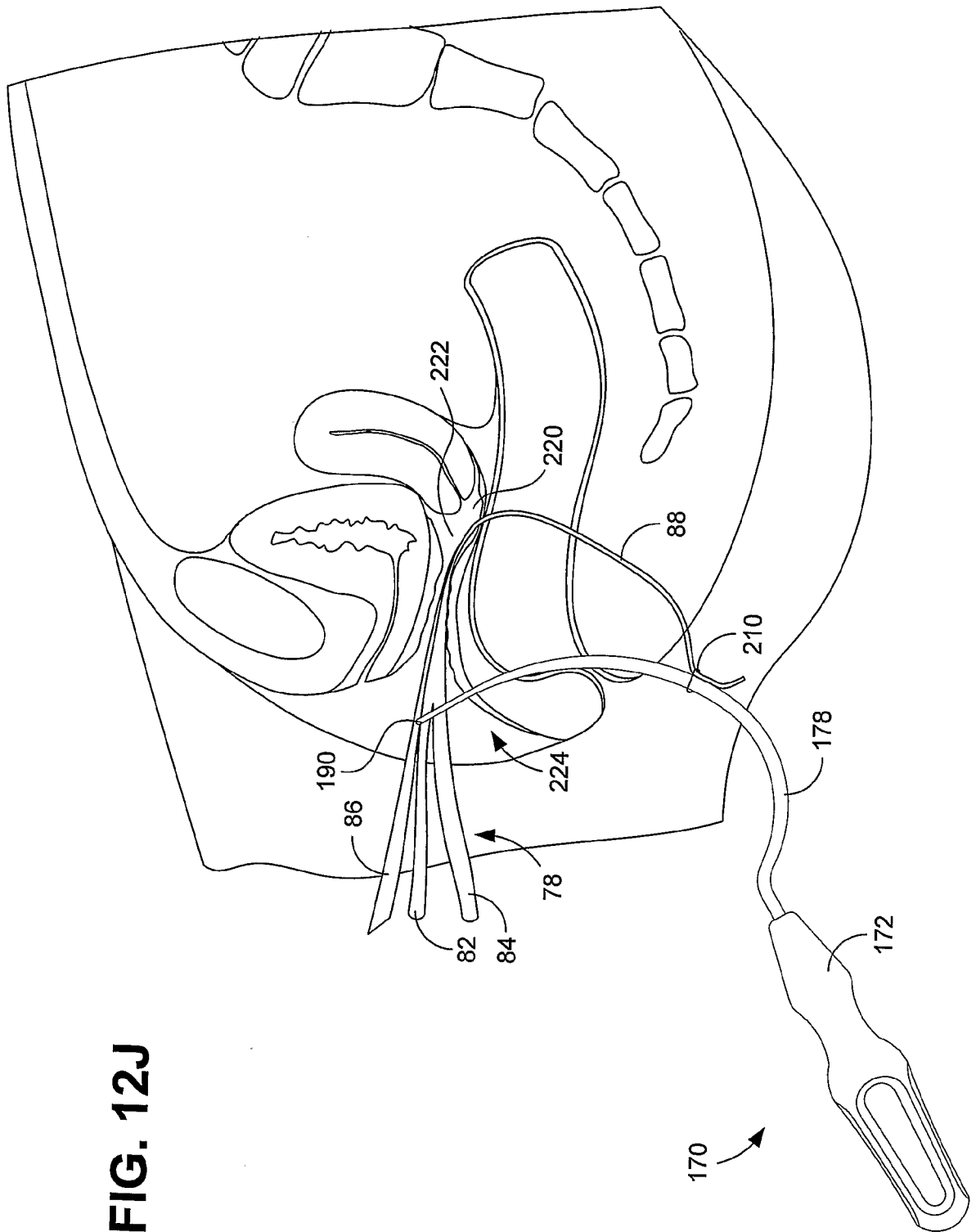


FIG. 12J

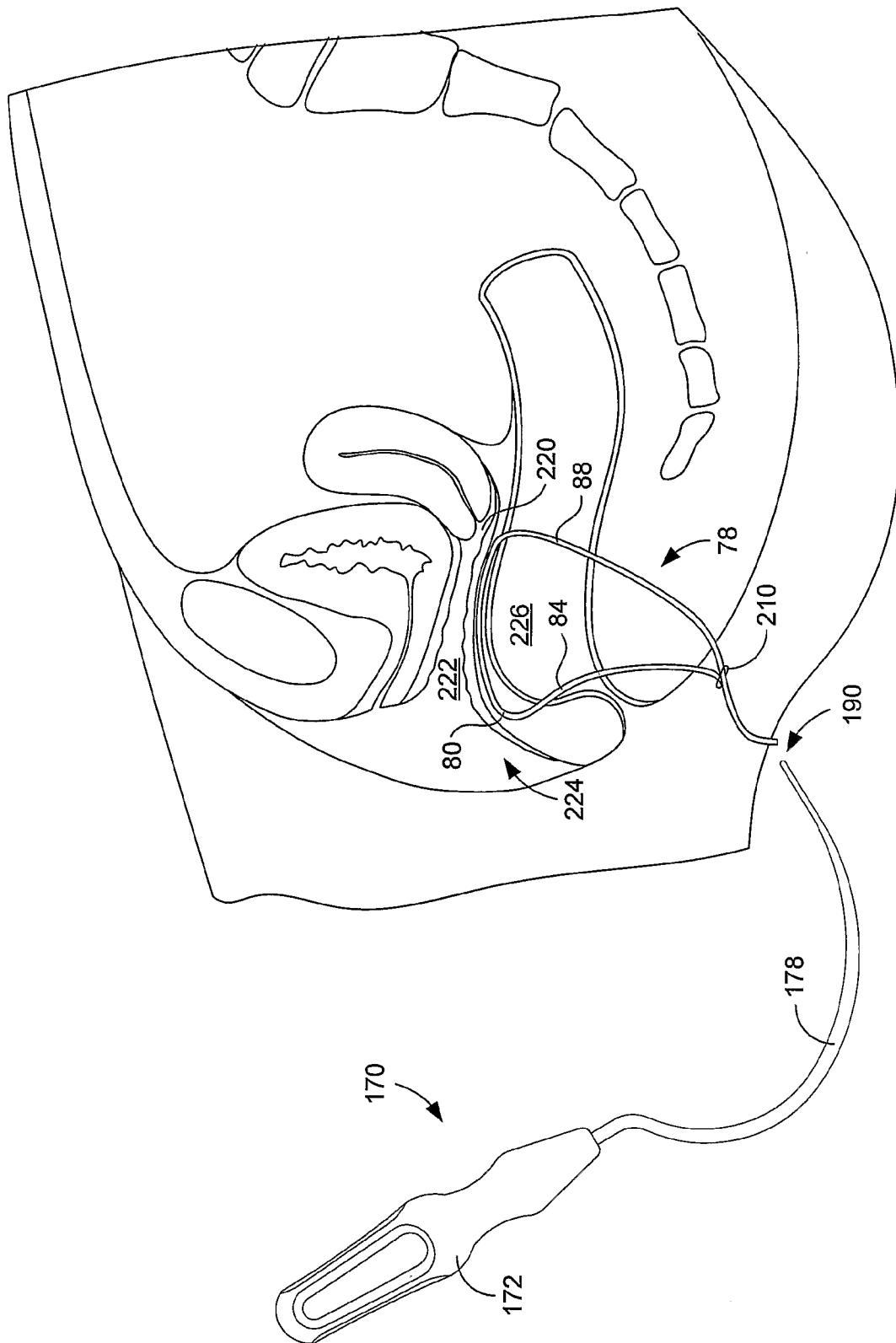


FIG. 12K

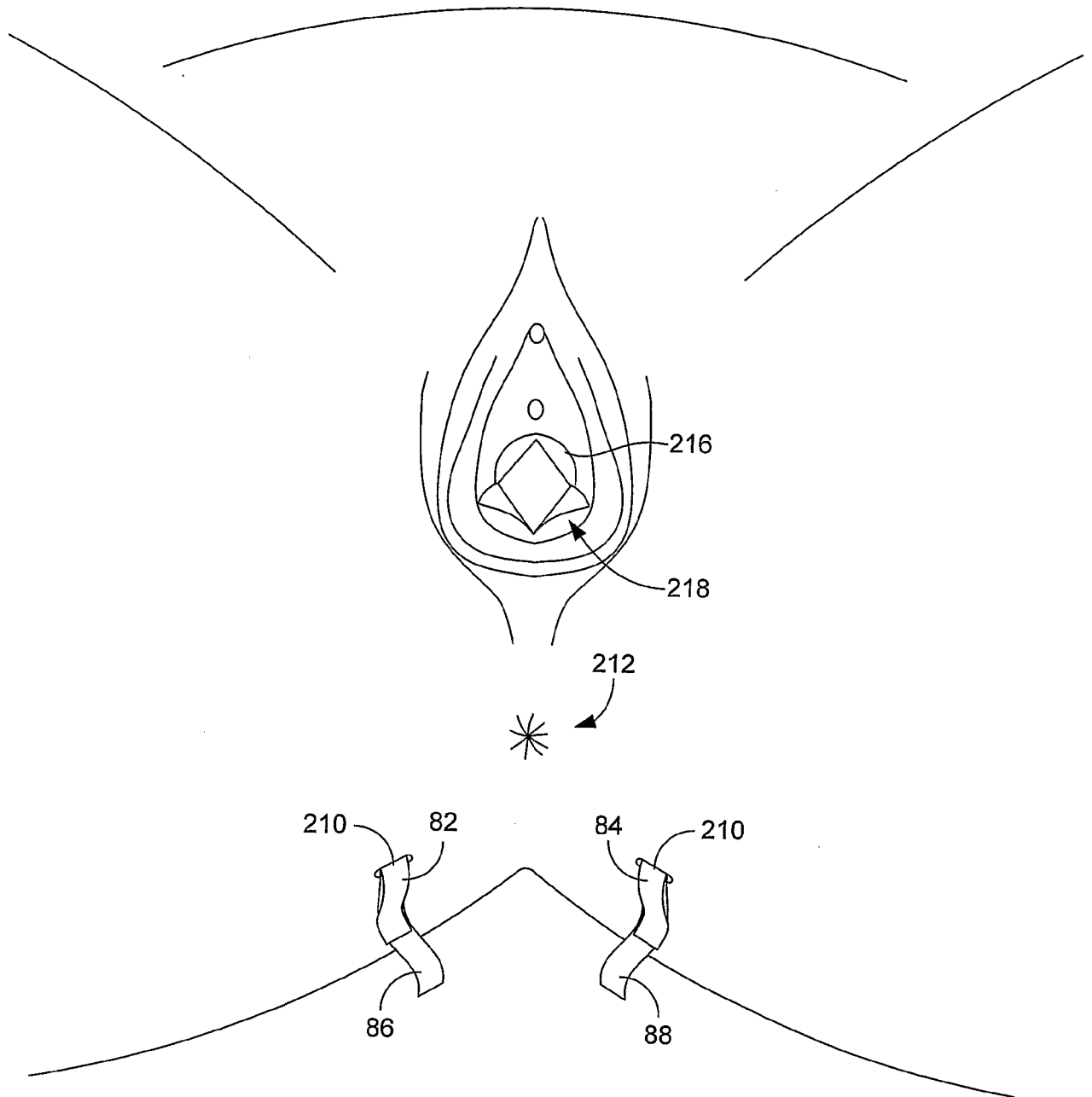


FIG. 12L

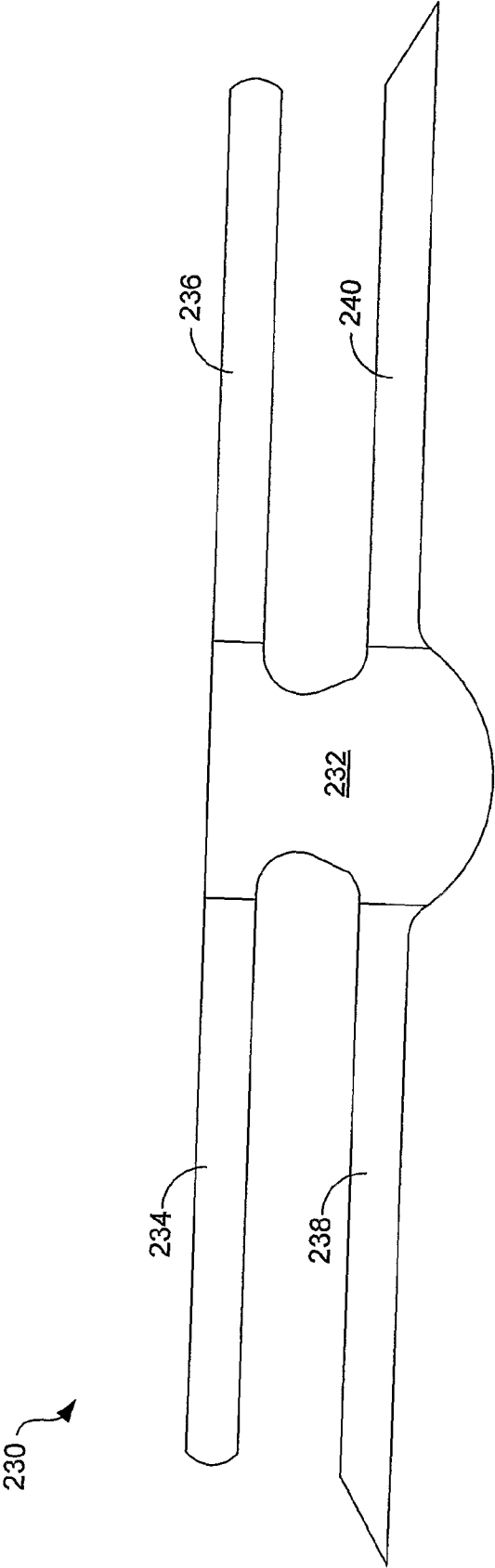


FIG. 13

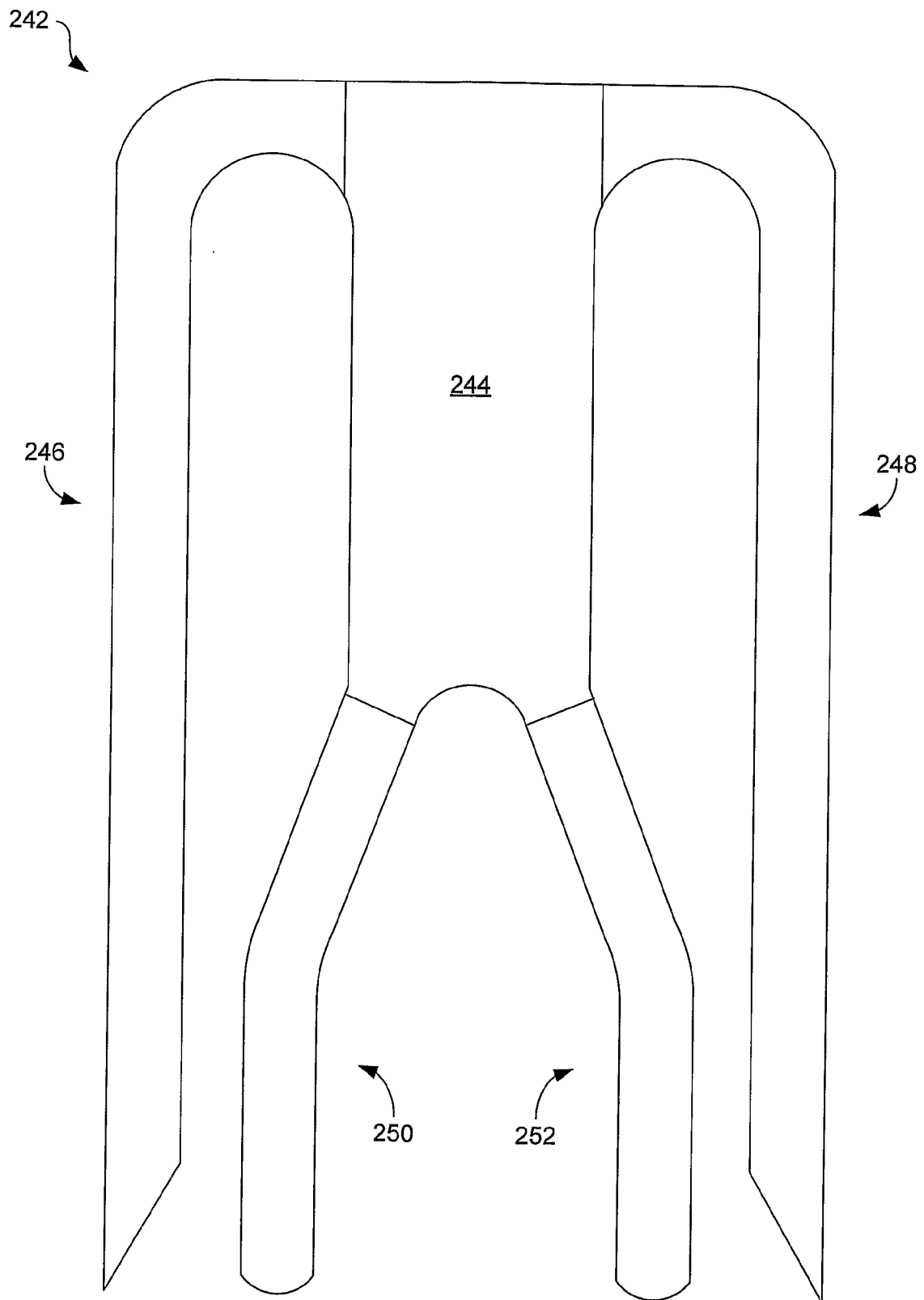


FIG. 14

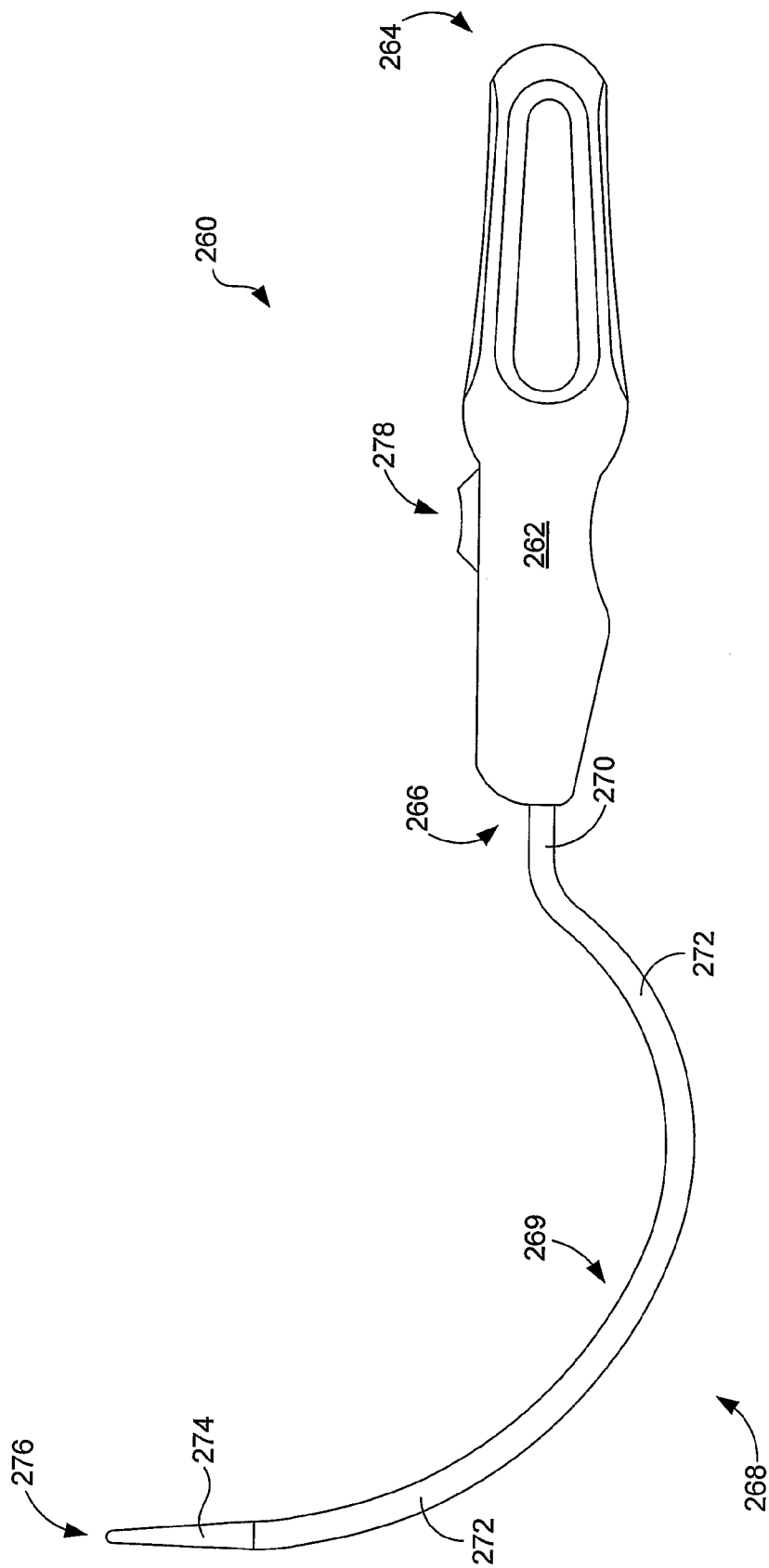


FIG. 15

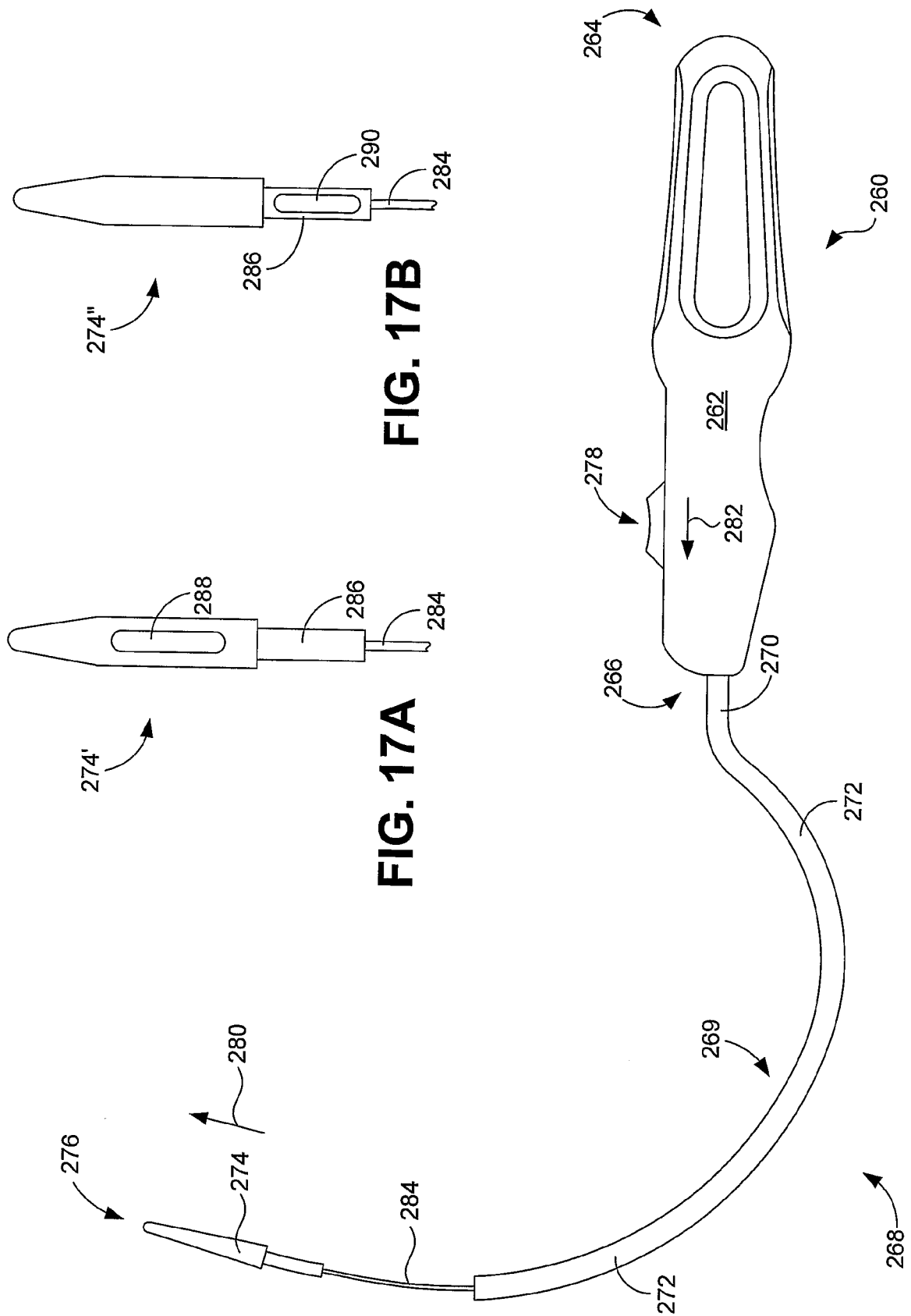


FIG. 17B

FIG. 17A

FIG. 16

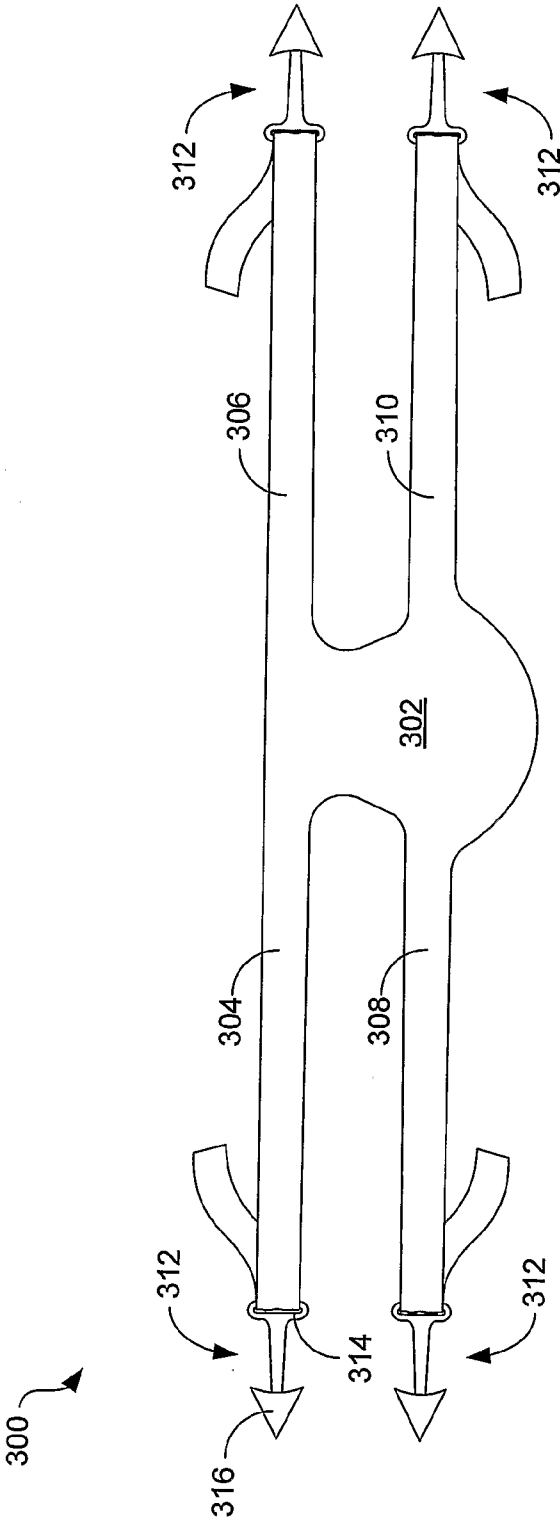


FIG. 18