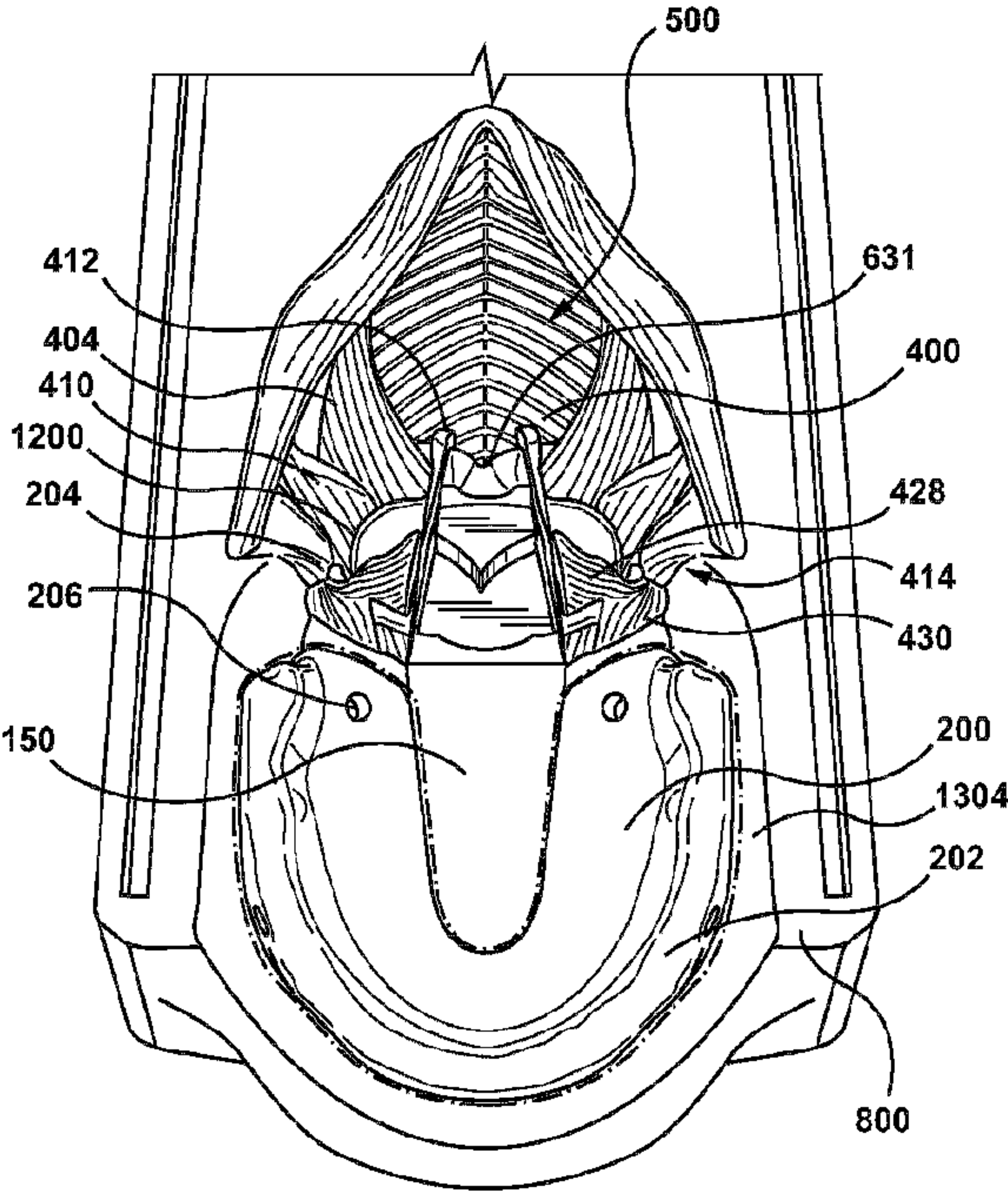




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(54) Titre : SIMULATEUR POUR L'ENTRAINEMENT A LA CHIRURGIE TRANS-ORALE ET SON PROCEDE D'UTILISATION

(54) Title: SIMULATOR FOR PRACTICING TRANS-ORAL SURGERY AND METHOD OF USE THEREOF



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Simulators for practicing trans-oral surgery and methods of use thereof, are described. The simulator may include a simulated soft palate musculature adjacent to the simulated hard palate, and a simulated mucosal layer covering at least a portion of the simulated hard palate and at least a portion of the simulated soft palate musculature, wherein the simulated mucosal layer is configured to conform to and follow the contours of surface features of the covered portions of the simulated hard palate and simulated soft palate musculature.

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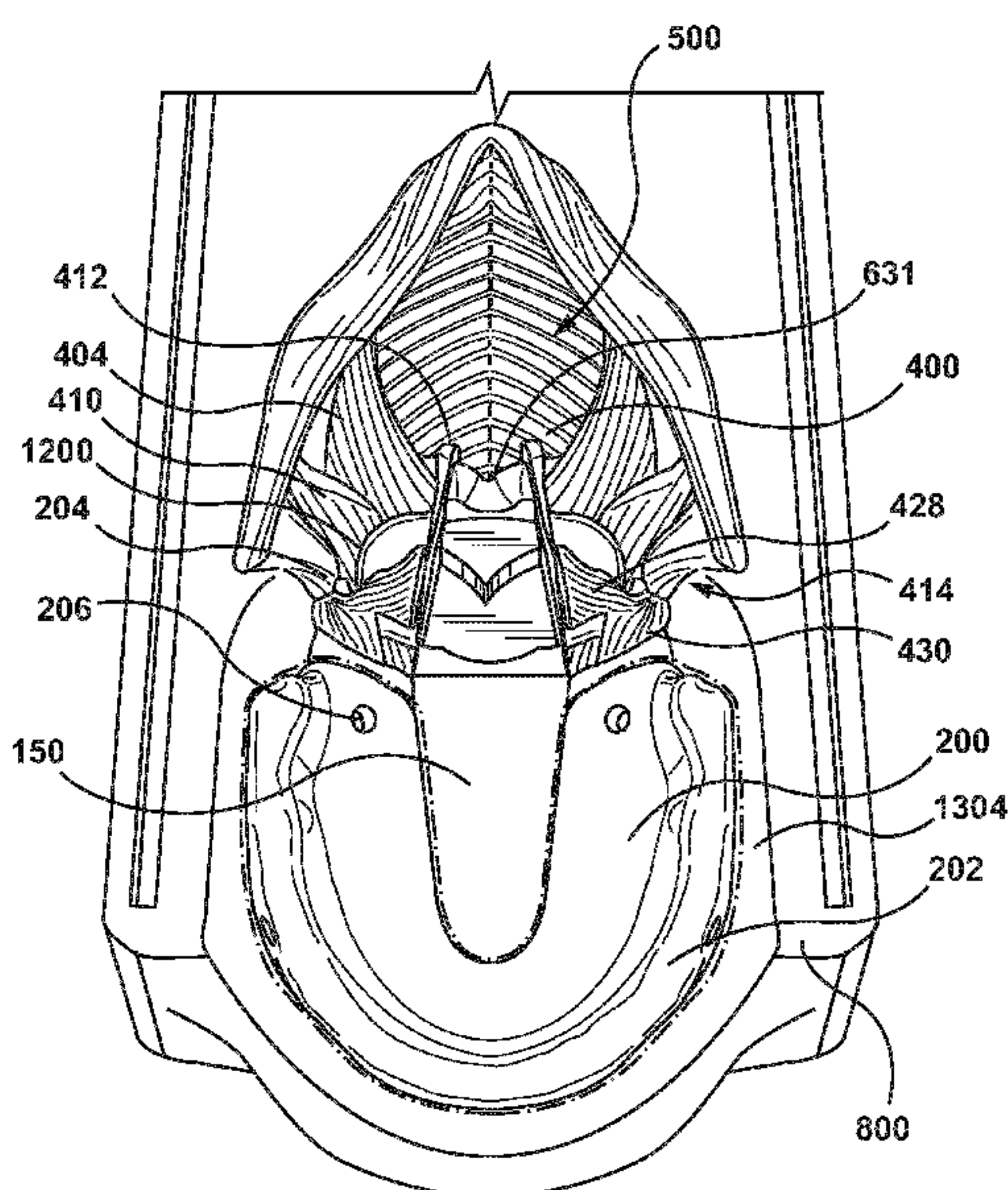


FIG. 2

(57) Abstract: Simulators for practicing trans-oral surgery and methods of use thereof, are described. The simulator may include a simulated soft palate musculature adjacent to the simulated hard palate, and a simulated mucosal layer covering at least a portion of the simulated hard palate and at least a portion of the simulated soft palate musculature, wherein the simulated mucosal layer is configured to conform to and follow the contours of surface features of the covered portions of the simulated hard palate and simulated soft palate musculature.

SIMULATOR FOR PRACTICING TRANS-ORAL SURGERY
AND METHOD OF USE THEREOF

5 [0001]

BACKGROUND

[0002] The use of surgical simulation has increased over the past two decades (Stefanidis D, Sevdalis N, Paige J, Zevin B, Aggarwal R, Grantcharov T, et al. Simulation in surgery: what's needed next? *Annals of surgery*. 2015;261(5):846-53) likely due to an increased demand for patient safety (Gerben E. Breimer VB, Thomas Looi, James Drake. Design and evaluation of a new synthetic brain simulator for endoscopic third ventriculostomy. *Journal of neurosurgery Pediatrics*. 2015;15:82-8) and declining trainee operative case-loads (Breimer GE, Bodani V, Looi T, Drake JM. Design and evaluation of a new synthetic brain simulator for endoscopic third ventriculostomy. *Journal of neurosurgery Pediatrics*. 2015;15(1):82-8; Sheckter CC, Kane JT, Minneti M, Garner W, Sullivan M, Talving P, et al. Incorporation of fresh tissue surgical simulation into plastic surgery education: maximizing extraclinical surgical experience. *J Surg Educ*. 2013;70(4):466-74). In addition, there has tended to be a shift of the apprenticeship model of learning to include more objective competency based metrics (Stefanidis D, Sevdalis N, Paige J, Zevin B, Aggarwal R, Grantcharov T, et al. Simulation in surgery: what's needed next? *Annals of surgery*. 2015;261(5):846-53; Rosen JM, Long SA, McGrath DM, Greer SE. Simulation in plastic surgery training and education: the path forward. *Plastic and reconstructive surgery*. 2009;123(2):729-38; discussion 39-40). This has been complemented by studies indicating that surgical simulation tends to translate into improved operating room performance (Palter VN, Grantcharov TP. Individualized deliberate practice on a virtual reality simulator improves technical performance of surgical novices in the operating room: a randomized controlled trial. *Annals of surgery*. 2014;259(3):443-8; Palter VN, Grantcharov TP. Development and validation of a comprehensive curriculum to teach an advanced

controlled trial. *Annals of surgery*. 2014;259(3):443-8; Palter VN, Grantcharov TP. Development and validation of a comprehensive curriculum to teach an advanced minimally invasive procedure: a randomized controlled trial. *Annals of surgery*. 2012;256(1):25-32; Crochet P, Aggarwal R, Dubb SS, Ziprin P, Rajaretnam N, Grantcharov T, et al. Deliberate practice on a virtual reality laparoscopic simulator enhances the quality of surgical technical skills. *Annals of surgery*. 2011;253(6):1216-22; Barsuk JH, McGaghie WC, Cohen ER, O'Leary KJ, Wayne DB. Simulation-based mastery learning reduces complications during central venous catheter insertion in a medical intensive care unit. *Critical care medicine*. 2009;37(10):2697-701; Barsuk JH, McGaghie WC, Cohen ER, Balachandran JS, Wayne DB. Use of simulation-based mastery learning to improve the quality of central venous catheter placement in a medical intensive care unit. *Journal of hospital medicine*. 2009;4(7):397-403).

[0003] Simulation in plastic surgery has included both physical and computer models (Matthes AG, Perin LF, Rancati A, da Fonseca L, Lyra M. Mastotrainer: new training project for breast aesthetic and reconstructive surgery. *Plastic and reconstructive surgery*. 2012;130(3):502e-4e; Long SA, Stern, Carrie Scharf, Napier, Zachary. Educational Efficacy of a Procedural Surgical Simulator in Plastic Surgery: A Phase I Multicenter Study. *Plastic & Reconstructive Surgery*. 2013;132(4S-1):13; Juma AMV, Gunasekar; Martin, John A see-through in vitro tendon repair model. *Plastic & Reconstructive Surgery*. 2004;113(3):1097-8; Wanzel KR, Matsumoto ED, Hamstra SJ, Anastakis DJ. Teaching technical skills: training on a simple, inexpensive, and portable model. *Plastic and reconstructive surgery*. 2002;109(1):258-63; Zabaneh G, Lederer R, Grosvenor A, Wilkes G. Rhinoplasty: a hands-on training module. *Plastic and reconstructive surgery*. 2009;124(3):952-4). Physical models often tend to be basic, lacking complexity (Sheckter CC, Kane JT, Minneti M, Garner W, Sullivan M, Talving P, et al. Incorporation of fresh tissue surgical simulation into plastic surgery education: maximizing extraclinical surgical experience. *J Surg Educ*. 2013;70(4):466-74). Computer models may aid in understanding anatomy and provide decision making drills, however, they tend not to provide the technical skill gained from practicing within a physical workspace. As such, cadaver or animal models are usually used to learn plastic surgery procedures outside of the operating room (Sheckter CC, Kane JT,

Minneti M, Garner W, Sullivan M, Talving P, et al. Incorporation of fresh tissue surgical simulation into plastic surgery education: maximizing extraclinical surgical experience. J Surg Educ. 2013;70(4):466-74). However, with respect to cleft palate and cleft lip repair surgery, cadaver models tend to be virtually non-existent and animal models tend to be
5 inaccessible.

[0004] Trans-oral surgeries, such as cleft palate repair, tend to be technically demanding procedures that require delicate tissue handling and dissection within a confined space with reduced access and visualization (Vadodaria S, Watkin N, Thiessen F, Ponniah A. The first cleft palate simulator. Plastic and reconstructive surgery. 2007;120(1):259-61). As a result, surgeries such as cleft palate repair tend to
10 be challenging procedures to learn with limited teaching opportunities.

[0005] Cleft palate simulators have been developed to augment operating room experience (Vadodaria S, Watkin N, Thiessen F, Ponniah A. The first cleft palate simulator. Plastic and reconstructive surgery. 2007;120(1):259-61; Senturk S. The simplest cleft palate simulator. The Journal of craniofacial surgery. 2013;24(3):1056; Nagy K, Mommaerts MY. Advanced s(t)imulator for cleft palate repair techniques. The Cleft palate-craniofacial journal : official publication of the American Cleft Palate-Craniofacial Association. 2009;46(1):1-5; Matthews MS. A teaching device for Furlow palatoplasty. The Cleft palate-craniofacial journal : official publication of the American
15 Cleft Palate-Craniofacial Association. 1999;36(1):64-6). However, they tend to be highly simplified and are of limited value as teaching tools.
20

SUMMARY

[0006] In various aspects, embodiments of the invention relate to surgical simulators, and more particularly to simulators for practicing trans-oral surgery and
25 methods of use thereof.

[0007] According to one aspect there is provided a simulator for practicing trans-oral surgery, comprising a simulated hard palate; a simulated soft palate musculature adjacent to the simulated hard palate; and a simulated mucosal layer covering at least a portion of the simulated hard palate and at least a portion of the simulated soft palate musculature, wherein the simulated mucosal layer is configured to conform to and
30

follow the contours of surface features of the covered portions of the simulated hard palate and simulated soft palate musculature.

[0008] The simulated mucosal layer may be thicker over the simulated hard palate than over the simulated soft palate musculature.

5 **[0009]** The simulated mucosal layer may be attached to the simulated soft palate musculature and the simulated hard palate, and a first strength of attachment between the simulated mucosal layer and the simulated soft palate musculature may differ from a second strength of attachment between the simulated mucosal layer and the simulated hard palate. The first strength of attachment may be less than the second strength of attachment. Alternatively, the first strength of attachment may be greater than the
10 second strength of attachment.

[0010] The simulated mucosal layer may be attached to the simulated soft palate musculature and the simulated hard palate, and the simulated hard palate may comprise a simulated hamulus, the simulator further comprising a simulated cranial
15 base extending from the simulated hard palate, the cranial base comprising a simulated medial pterygoid plate, and the simulator further comprising a simulated superior constrictor muscle attached to the simulated hamulus and simulated medial pterygoid plate, wherein the simulated mucosal layer may be less strongly attached to the simulated superior constrictor muscle than to the simulated hard palate.

20 **[0011]** The simulated soft palate musculature may comprise a simulated palatopharyngeus muscle and a simulated tensor veli palatini muscle, the simulated tensor veli palatini muscle comprising a tensor veli palatini aponeurosis, the simulator further comprising a simulated soft tissue fatty layer located between and attached to the simulated palatopharyngeus muscle and the simulated tensor veli palatini
25 aponeurosis, wherein the simulated soft tissue fatty layer may be less strongly attached to the simulated palatopharyngeus muscle than to the tensor veli palatini aponeurosis.

[0012] The simulated soft palate musculature may comprise one or both of a simulated palatopharyngeus muscle and a simulated levator veli palatini muscle; and at least one of a simulated tensor veli palatini muscle, a simulated palatoglossus muscle,
30 and a simulated musculus uvula, wherein one or both of the simulated

palatopharyngeus muscle and the simulated levator veli palatini muscle are made of a harder material than the at least one of a simulated tensor veli palatini muscle, a simulated palatoglossus muscle, and a simulated musculus uvula.

[0013] The simulated mucosal layer may be attached to the simulated soft palate musculature and the simulated hard palate, the simulated soft palate musculature may comprise a simulated palatopharyngeus muscle and a simulated palatoglossus muscle, and the simulated hard palate may comprise a simulated hamulus, the simulator may further comprise a simulated cranial base extending from the simulated hard palate, the simulated cranial base comprising a simulated medial pterygoid plate, and the simulator further comprising a simulated superior constrictor muscle attached to the simulated hamulus and simulated medial pterygoid plate, and wherein the simulated palatopharyngeus muscle, the simulated palatoglossus muscle and simulated superior constrictor muscle are formed as a complex.

[0014] The simulated soft palate musculature may comprise a simulated levator palatini muscle and a simulated palatopharyngeus muscle, and wherein the simulated levator palatini muscle may be attached to the simulated palatopharyngeus muscle.

[0015] The simulated soft palate musculature may comprise a simulated palatopharyngeus muscle, the simulator further comprising a simulated cranial base extending from the simulated hard palate, the simulated cranial base comprising a simulated palatopharyngeus insertion, wherein the simulated palatopharyngeus muscle may be attached to the simulated palatopharyngeus insertion.

[0016] The simulated soft palate musculature may comprise a simulated tensor veli palatini muscle which may comprise one or more simulated anterior fibers, and the simulated hard palate may comprise at least a simulated tensor veli palatini anterior fiber insertion, and wherein the one or more simulated anterior fibers may be attached to the simulated tensor veli palatini anterior fiber insertion.

[0017] The simulated soft palate musculature may comprise a simulated tensor veli palatini muscle and a simulated palatopharyngeus muscle, wherein the simulated tensor veli palatini muscle may comprise one or more simulated anterior fibers, the one

or more simulated anterior fibers being attached to the simulated palatopharyngeus muscle.]

[0018] The simulated soft palate musculature may comprise a simulated palatopharyngeus muscle and a simulated tensor veli palatini muscle, the simulated
5 tensor veli palatini muscle comprising a tensor veli palatini aponeurosis, the simulator further comprising a simulated soft tissue fatty layer located between the simulated palatopharyngeus muscle and the simulated tensor veli palatini aponeurosis, the tensor veli palatini aponeurosis being embedded in the simulated soft tissue fatty layer and the simulated mucosal layer.

10 **[0019]** The simulator may further comprise a simulated pedicle attached to or embedded in the simulated hard palate.

[0020] The simulator may further comprise a simulated cranial base extending from the simulated hard palate, and wherein the simulated soft palate musculature may comprise at least a simulated levator veli palatini muscle, and the simulator further
15 comprising a simulated eustachian tube attached to the simulated levator veli palatini muscle and to the simulated cranial base. The eustachian tube may be made of a material harder than that used for the simulated soft palate musculature or the simulated superior constrictor muscle.

[0021] The simulator may further comprise a simulated cleft in at least one of the
20 simulated hard palate and the simulated soft palate musculature.

[0022] The simulator may further comprise a simulated oral aperture; a simulated oral cavity extending from the simulated oral aperture; two opposed simulated lateral oral cavity walls extending from the simulated oral aperture; and a simulated tongue spanning the opposed simulated lateral oral cavity walls at a first end of said walls,
25 wherein the simulated hard palate, and the simulated mucosal layer are attached to opposed simulated lateral oral cavity walls at a second end of said walls.

[0023] The simulator may form a cartridge that replaceably fits within a complete or partial simulated face.

[0024] A 3D printer may be used to create the simulator or any component thereof.

[0025] According to another aspect there is provided a method of practicing or learning trans-oral surgery, the method comprising one or more steps of providing a simulator having a simulated hard palate, a simulated soft palate musculature adjacent to the simulated hard palate; and a simulated mucosal layer covering at least a portion of the simulated hard palate and at least a portion of the simulated soft palate musculature, wherein the simulated mucosal layer is configured to conform to and follow the contours of surface features of the covered portions of the simulated hard palate and simulated soft palate musculature; incising the simulated mucosal layer; dissecting the simulated mucosal layer away from one or both of the simulated hard palate or the simulated soft palate musculature; moving, mobilizing, or reorienting the simulated mucosal layer; moving, mobilizing, or reorienting the simulated soft palate musculature; incising the simulated soft palate musculature; suturing the simulated soft palate musculature; and suturing the simulated mucosal layer. The steps of incising, dissecting, moving, mobilizing, reorienting or suturing may be performed through the use of manual instruments, powered instruments or a surgical robot.

BRIEF DESCRIPTION OF THE FIGURES

[0026] The invention is illustrated in the figures of the accompanying drawings which are meant to be exemplary and not limiting, in which like reference numbers indicate like features.

[0027] Figure 1A is a side view diagram of a simulator for practicing trans-oral surgery in accordance with one embodiment of the present invention.

[0028] Figure 1B is a side view diagram of a simulator for practicing trans-oral surgery in accordance with another embodiment of the present invention.

[0029] Figure 1C is a perspective view diagram of a simulator for practicing trans-oral surgery in accordance with yet another embodiment of the present invention.

[0030] Figure 1D is a perspective view diagram of a simulator for practicing trans-oral surgery in accordance with a further embodiment of the present invention.

[0031] Figure 2 is a perspective view of a simulated soft palate musculature and a simulated hard palate, showing a portion of the simulated hard palate enclosed by a dot-dash line to be coated with an attachment agent in accordance with one embodiment of the present invention.

5 **[0032]** Figure 3 is a perspective view of the simulated soft palate musculature and the simulated hard palate of Figure 2, showing a portion of the simulated soft palate musculature enclosed by a dot-dash line to be coated with an attachment agent in accordance with one embodiment of the present invention.

10 **[0033]** Figure 4 is a perspective view of a mucosal layer attached to the simulated soft palate musculature and the simulated hard palate of Figures 2 and 3.

[0034] Figure 5 is a top view of a simulated hard palate and a simulated cranial base in accordance with one embodiment of the present invention.

[0035] Figure 6 is a perspective view of a simulated hard palate and simulated cranial base in accordance with another embodiment of the present invention.

15 **[0036]** Figure 7 is an enlarged fragmentary top view of the hard bony palate and simulated cranial base of Figure 5.

[0037] Figure 8 is a perspective view of a simulated soft palate musculature attached to the simulated cranial base of Figure 5 in accordance with one embodiment of the present invention.

20 **[0038]** Figure 9 is an enlarged fragmentary perspective view of the simulated soft palate musculature of Figure 8 attached to the simulated cranial base of Figure 5, showing a simulated oral head of a simulated palatopharyngeus muscle located to one side of a simulated levator veli palatini muscle in accordance with one embodiment of the present invention.

25 **[0039]** Figure 10 is an enlarged fragmentary perspective view of a simulated oral head of a simulated palatopharyngeus muscle and simulated nasal head of a simulated palatopharyngeus muscle wrapped around a simulated levator veli palatini muscle in accordance with another embodiment of the present invention.

[0040] Figure 11 is a perspective view of a simulated soft palate musculature and simulated superior constrictor muscle attached to the simulated hard palate and cranial base of Figure 2 in accordance with one embodiment of the present invention.

5 **[0041]** Figure 12 is an enlarged fragmentary perspective view of the simulated soft palate musculature and simulated superior constrictor muscle of Figure 12 with underlying structures in dotted lines to show transparency in accordance with one embodiment of the present invention.

10 **[0042]** Figures 13A-C are, respectively, inferior, medial, and lateral views of a simulated palatopharyngeus muscle in accordance with one embodiment of the present invention.

[0043] Figures 14A-C are, respectively, inferior, medial and lateral views of a simulated levator veli palatini muscle in accordance with one embodiment of the present invention.

15 **[0044]** Figure 15 is a perspective view of the simulated levator veli palatini muscle of Figures 14A-C attached to the simulated cranial base of Figure 5.

[0045] Figures 16A-C are, respectively, inferior, medial and lateral views of a simulated tensor veli palatini muscle in accordance with one embodiment of the present invention.

20 **[0046]** Figure 17 is a perspective view of the simulated tensor veli palatini muscle of Figures 16A-C attached to the simulated cranial base of Figure 5.

[0047] Figures 18A-C are, respectively, inferior, medial and lateral views of a simulated palatoglossus muscle in accordance with one embodiment of the present invention.

25 **[0048]** Figures 19A-C are, respectively, anterior, inferior and perspective views of a simulated superior constrictor muscle in accordance with one embodiment of the present invention.

[0049] Figure 20 is a perspective view of the simulated superior constrictor muscle of Figures 19A-C inset within a simulated oral cavity in accordance with one embodiment of the present invention.

[0050] Figure 21 is a perspective view showing a simulated eustachian tube and a simulated soft palate musculature attached to the simulated hard palate and simulated cranial base of Figure 5 in accordance with one embodiment of the present invention.

5 **[0051]** Figure 22 is a perspective view showing a simulated eustachian tube and a simulated soft palate musculature attached to the simulated hard palate and simulated cranial base of Figure 5 in accordance with one embodiment of the present invention.

[0052] Figure 23 is a perspective view showing a simulated eustachian tube and a simulated soft palate musculature attached to the simulated hard palate and simulated cranial base of Figure 5 in accordance with one embodiment of the present invention.

10 **[0053]** Figure 24 is a perspective view showing a simulated eustachian tube and a simulated soft palate musculature in accordance with one embodiment of the present invention.

[0054] Figure 25 is a perspective view showing a simulated pedicle in accordance with one embodiment of the present invention.

15 **[0055]** Figure 26 is a perspective view of a base in accordance with one embodiment of the present invention.

[0056] Figures 27A is a perspective view of a base in accordance with another embodiment of the present invention.

20 **[0057]** Figures 27B is a perspective view of the base of Figure 27A after rotation about a rotation point.

[0058] Figure 28 is a top view of the simulated bony palate and cranial base of Figure 5 inserted into the base of Figure 26.

[0059] Figure 29 is a side view of the simulated bony palate and cranial base of Figure 5 inserted into the base of Figure 26.

25 **[0060]** Figure 30 is a perspective view of a simulator forming a cartridge in accordance with one embodiment of the present invention.

[0061] Figures 31A-B are perspective views showing formation of a cartridge in accordance with one embodiment of the present invention.

[0062] Figures 32A-B are perspective views showing formation of a cartridge in accordance with another embodiment of the present invention.

[0063] Figures 32C-D are cross-sectional and plan views of the cartridge of Figures 32A-B.

5 **[0064]** Figure 33 is a perspective view of a cartridge in accordance with one embodiment of the present invention.

[0065] Figure 34 is a perspective view of the base of Figure 26 with a partial simulated face attached thereto in accordance with one embodiment of the present invention.

10 **[0066]** Figures 35A-C are perspective views of a cartridge being inserted into the base and partial simulated face attached thereto of Figure 34.

[0067] Figure 36 is a perspective view of the cartridge of Figures 35A-C inserted into the base and partial simulated face attached thereto of Figure 35.

15 **[0068]** Figures 37A-D are perspective views showing a locking mechanism in accordance with one embodiment of the present invention.

[0069] Figure 38 is a bottom view of a simulator showing a simulated mucosal layer covering a portion of the simulated hard palate coated with an attachment agent enclosed by a dot-dash line in accordance with one embodiment of the present invention

20 **[0070]** Figure 39 is a bottom view showing a locking mechanism in accordance with another embodiment of the present invention.

[0071] Figures 40A-B are enlarged fragmentary views of the locking mechanism of Figure 39.

25 **[0072]** Figure 41 is an exploded view diagram of a simulator for practicing trans-oral surgery in accordance with an embodiment of the present invention.

[0073] Figures 42-46 are perspective views showing use a simulator for trans-oral surgery in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENTS

[0074] The description which follows, and the embodiments described therein, are provided by way of illustration of an example, or examples, of particular embodiments of the principles of the present invention. These examples are provided
5 for the purposes of explanation, and not limitation, of those principles and of the invention.

[0075] Figures 1A-D show exemplary simulators 100 for practicing trans-oral surgery. Simulator 100 may include a simulated hard palate 200, a simulated soft palate musculature 400 adjacent to simulated hard palate 200, and a simulated mucosal
10 layer 300 covering at least a portion of simulated hard palate 200 and at least a portion of simulated soft palate musculature 400. Simulated mucosal layer 300 may be configured to conform to and follow the contours of surface features of the covered portions of simulated hard palate 200 and simulated soft palate musculature 400. Simulated mucosal layer 300 may include a simulated oral mucosa and a simulated
15 nasal mucosa, which in some embodiments may form a continuous layer.

[0076] In certain embodiments, simulated mucosal layer 300 may be created by pouring the material used to create simulated mucosal layer 300 over simulated hard palate 200 and simulated soft palate musculature 400 while they are turned by use of a rotational system rotating about at least one axis. This method tends to provide an
20 even coat. Multiple layers of the material used to create simulated mucosal layer 300 may be poured to promote the appropriate or desired mucosal thickness. To provide a thicker simulated mucosal layer 300 over simulated hard palate 200 as compared to over simulated soft palate musculature 400, the two may be placed on a rotational system with a slight downward tilt towards the simulated hard palate 200 while the
25 material used to create the simulated mucosal layer 300 is poured. In some embodiments, the thickness of simulated mucosal layer 300 over simulated hard palate 200 may be between 2-4 mm, whereas the thickness of simulated mucosal layer 300 over simulated soft palate musculature 400 may be 0.5-2 mm. In some embodiments, the portion of simulated mucosal layer 300 covering at least a portion of simulated hard
30 palate 200 may be of the same firmness or of a different firmness as compared to the

portion of simulated mucosal layer 300 covering simulated soft palate musculature 400. In some embodiments, simulator 100 may comprise simulated dimple area 302 in simulated mucosal layer 300 (see for example Figure 4).

[0077] The strength of attachment between simulated mucosal layer 300 and simulated soft palate musculature 400 may differ from the strength of attachment between simulated mucosal layer 300 and simulated hard palate 200. In certain embodiments, simulated mucosal layer 300 may be less strongly attached to simulated soft palate musculature 400 than to simulated hard palate 200. For example, the amount of force required to dissect simulated mucosal layer 300 from the simulated soft palate musculature 400 may be less than the amount of force required to dissect simulated mucosal layer 300 from simulated hard palate 200. In other embodiments, simulated mucosal layer 300 may be more strongly attached to simulated soft palate musculature 400 than to simulated hard palate 200.

[0078] In some embodiments, an attachment agent may be used to attach simulated mucosal layer 300 to simulated soft palate musculature 400. The same attachment agent or a different attachment agent, can be used to attach simulated mucosal layer 300 to simulated hard palate 200. As used herein, an attachment agent may refer to one or more of an adhesive, release agent, soft material (such as silicone or a polymer), hard material (such as an adhesive, release agent or polymer that cures as a hard substance) or any combination thereof. For example, an attachment agent may comprise an adhesive such as a glue mixed with a release agent. An attachment agent may be applied using any means, such as manually or by use of a 3D printer.

[0079] In embodiments where simulated mucosal layer 300 is less strongly attached to simulated soft palate musculature 400 than to simulated hard palate 200, simulated hard palate 200 may be made of a hard material with properties simulating a biological hard palate (such as polylactic acid or acrylonitrile butadiene styrene plastic) and a portion of it (such as the area enclosed by the dot-dash line in Figure 2 or the area enclosed by the dot-dash line of Figure 38) may be coated with shellac (such as Zinsser Bulls Eye Shellac). Simulated soft palate musculature 400 may be made of a soft material with properties simulating biological soft palate musculature (such as

silicone, which can be Smooth-on® FX-Pro®, Ecoflex ® 20 or Ecoflex ® 30), and a portion of it (such as the area enclosed by the dot-dash line in Figure 3) may be coated with a release agent (such as a mold release, which can be Ease Release 200). The simulated mucosal layer 300 may be made of a soft material with properties simulating biological mucosa (such as silicone, which can be Ecoflex® 20 or Ecoflex® 30). In some embodiments, to match the high Young's Modulus of the oral mucosa, a flexible high transparency wire mesh sheet may be added to the simulated mucosal layer 300 during mucosal development.

[0080] In some embodiments, the portion of simulated mucosal layer 300 covering simulated hard palate 200 may be of a different firmness than the portion of simulated mucosal layer 300 covering simulated soft palate musculature 400. For example, the portion of simulated mucosal layer 300 covering simulated hard palate 200 may be firmer than the portion of simulated mucosal layer 300 covering simulated soft palate musculature 400. In alternate embodiments, the portion of simulated mucosal layer 300 covering simulated hard palate 200 may be less firm than the portion of simulated mucosal layer 300 covering simulated soft palate musculature 400.

[0081] In certain embodiments, simulator 100 may comprise a simulated cleft 150 in at least one of simulated hard palate 200 and simulated soft palate musculature 400 (see for example Figures 2-4). Simulated cleft 150 may come in a variety of shapes and types, such as incomplete lip only, lip and alveolus, lip and primary palate, lip and palate, incomplete secondary palate behind hard-soft junction, incomplete secondary palate into the hard palate, complete secondary palate, complete primary palate and incomplete secondary palate, unilateral cleft lip and palate, bilateral cleft lip and primary palate only, bilateral cleft lip and palate and cleft palate only, or other combinations of the foregoing. For example, simulated cleft 150 may at the greatest extent be approximately 8 mm. Other sizes of simulated clefts may be provided in other embodiments, such as below 8 mm or over 8 mm.

[0082] As seen in Figure 5, the simulated hard palate 200 may comprise one or more of a simulated alveolus 202, a simulated hamulus 204, a simulated greater palatine foramen 206, a simulated tensor veli palatini anterior fiber insertion 612, a

simulated bony spike 208 beside the greater palatine foramen, or a combination thereof. Simulated greater palatine foramen 206 can be anterior to simulated hamulus 204.

[0083] Simulated hard palate 200 may be made of a hard material that is resistant to deformation with properties simulating a biological hard palate (such as polylactic acid, acrylonitrile butadiene styrene plastic hard plastic, ceramic, metal). In some embodiments, simulated hard palate 200 can be made using a 3D printer, such as an extrusion, light polymerized, powder bed, laminated or wire type 3D printer.

[0084] Simulator 100 may also include a simulated cranial base 600 extending from simulated hard palate 200, as seen in Figures 5 and 6. As seen in Figures 5-7, simulated cranial base 600 may comprise one or more of a simulated carotid canal 602, a simulated medial pterygoid plate 604, a simulated lateral pterygoid plate 606, a simulated levator veli palatini insertion 608, a simulated levator veli palatini origin 610, a simulated tensor veli palatini origin 614, a simulated foramen lacerum 616, a simulated foramen ovale 618, a simulated foramen spinosum 620, a simulated foramen magnum 622, a simulated bony origin of the eustachian tube 624, a simulated palatopharyngeus insertion 626, a simulated palatopharyngeus origin 627, a simulated pharyngeal tubercle 630, or a combination thereof. In some embodiments, simulated cranial base 600 may extend to the level of simulated carotid canal 602, which is a landmark just posterior to the simulated levator veli palatini origin 610. Thus, part of the petrous component of a simulated temporal bone 638 may be included in simulator 100.

[0085] Simulated cranial base 600 may be made of a hard material that is resistant to deformation with properties simulating a biological cranial base (such as polylactic acid, acrylonitrile butadiene styrene plastic, hard plastic, ceramic, metal). In some embodiments, simulated cranial base 600 can be made using a 3D printer, such as an extrusion, light polymerized, powder bed, laminated or wire type 3D printer.

[0086] As seen in Figures 8-12, simulated soft palate musculature 400 can comprise one or more of a simulated palatopharyngeus muscle 404, a simulated levator veli palatini muscle 406, a simulated tensor veli palatini muscle 408, a simulated palatoglossus muscle 410, a simulated musculus uvula 412, or a combination thereof.

[0087] In some embodiments, the above described components of the simulated soft palate musculature 400 can be formed separately and adhered together as described below. For example, a distinct simulated palatopharyngeus muscle 404, a distinct simulated levator veli palatini muscle 406, a distinct simulated tensor veli palatini muscle 408, a distinct simulated palatoglossus muscle 410, a distinct simulated musculus uvula 412, and a distinct simulated superior constrictor muscle 500 (further described below) may be attached to each other so as to emulate dissection planes. As another example, a distinct simulated palatopharyngeus muscle 404 and a distinct simulated palatoglossus muscle 410 may be attached so as to emulate dissection planes to a distinct simulated superior constrictor muscle 500.

[0088] In other embodiments, any combination of the above components of the simulated soft palate musculature 400 may be formed as a complex, which tends to simulate the integration of muscles as occurs in nature. For example, simulated palatopharyngeus muscle 404, simulated palatoglossus muscle 410 and simulated superior constrictor muscle 500 may be formed as a complex which tends to simulate the integration of the three muscles as occurs in nature. In another embodiment, simulated palatoglossus muscle 410 may be distinct, while simulated palatopharyngeus muscle 404, simulated levator veli palatini muscle 406, simulated tensor veli palatini muscle 408 and simulated musculus uvula 412 are formed as a single unit. In yet another embodiment, simulated palatoglossus muscle 410 and simulated palatopharyngeus muscle 404 may each be distinct and glued to a complex that consists of simulated levator veli palatini muscle 406, simulated tensor veli palatini muscle 408 and simulated musculus uvula 412. In still further embodiments, the whole of simulated soft palate musculature 400 may be formed as a single complex.

[0089] In certain embodiments, the components of simulated soft palate musculature 400 are made of a soft material with properties simulating a biological soft palate musculature. In certain embodiments, the components of simulated soft palate musculature 400 may be made of a material that is less firm, equally firm, or firmer than that used for simulated mucosal layer 300. For example, the components of simulated soft palate musculature 400 may be made of a natural polymeric material or a synthetic polymeric material. Natural polymeric materials can include shellac, amber, wool, silk,

and simulated levator veli palatini muscle 406 may be made of a harder material than the other components of simulated soft palate musculature 400. For example, simulated palatopharyngeus muscle 404 or simulated levator veli palatini muscle 406 may be made of Smooth-on® Ecoflex® 30 or Smooth-on® Ecoflex® 50 or Smooth-on® Dragon Skin 10-30 or FX-Pro. In further embodiments, the individual components of simulated soft palate musculature 400 may be made of materials of different colours to allow one to visually distinguish the components from one another. In some embodiments, simulated soft palate musculature 400 can be made using a 3D printer, such as an extrusion, light polymerized, powder bed, laminated or wire type 3D printer.

10 **[0090]** As seen in Figures 8-13, simulated palatopharyngeus muscle 404 may be attached to the simulated superior constrictor muscle 500 at a simulated palatopharyngeus origin inset 627 that attaches to simulated superior constrictor muscle 500. Simulated palatopharyngeus muscle 404 may have a simulated nasal head 419. Simulated palatopharyngeus muscle 404 may also have a simulated oral head 418 that
15 is thicker and more developed than simulated nasal head 419, as seen for example in Figures 10 and 21. In certain embodiments, as seen for example in Figure 9, simulated palatopharyngeus muscle 404 may only have simulated oral head 418 located on the oral side of simulated levator veli palatini muscle 406. In alternative embodiments, as seen for example in Figure 10 and Figure 21, palatopharyngeus muscle 404 may have
20 simulated oral head 418 and simulated nasal head 419 clasp simulated levator veli palatini muscle 406 before inserting into the simulated hard palate 200. Lateral and anterior to simulated levator veli palatini muscle 406, simulated oral head 418 and simulated nasal head 419 come together and traverse into a broad sheet of muscle in the lateral and anterior direction to intermingle with a simulated superior constrictor
25 muscle 500 and simulated palatopharyngeus insertion 626. Palatopharyngeus muscle 404 may be attached to simulated palatopharyngeus insertion 626. Simulated palatopharyngeus muscle 404 may also be adhered to the simulated superior constrictor muscle 500 at a simulated palatopharyngeus origin inset 627. Adhesion can be sufficiently strong such that when one dissects simulated mucosa layer 300 away
30 from simulated palatopharyngeus muscle 404, simulated palatopharyngeus muscle 404 remains attached to simulated palatopharyngeus insertion 626. This can be done, for

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palatopharyngeus muscle 404 may also be adhered to the simulated superior constrictor muscle 500 at a simulated palatopharyngeus origin inset 627. Adhesion can be sufficiently strong such that when one dissects simulated mucosa layer 300 away from simulated palatopharyngeus muscle 404, simulated palatopharyngeus muscle 404 remains attached to simulated palatopharyngeus insertion 626. This can be done, for example, by using mechanical fasters (such as screws or nails or pins), a polymer, or glue (such as Loctite® 4851 cyanoacrylate glue).

[0091] As shown in Figures 8-12 and 14-15, simulated levator veli palatini muscle 406 may traverse from simulated cranial base 600 towards simulated soft palate musculature 400. The muscle bundle outside of the simulated soft palate musculature 400 can descend anteriorly and medially from the simulated cranial base 600 towards the simulated soft palate musculature 400 as a cylindrical muscle. Simulated levator veli palatini origin 610 may run from the apical portion of the petrous component of simulated temporal bone 638 and from the edge of simulated carotid canal 602 and a simulated eustachian tube 900. Simulated levator veli palatini muscle 406 may gently spiral as it approaches the midline. Simulated levator veli palatini muscle 406 may occupy the gap between simulated superior constrictor muscle 500 and simulated cranial base 600. As simulated levator veli palatini muscle 406 enters the simulated soft palate musculature 400, it can fan out between simulated oral head 418 and simulated nasal head 419 of simulated palatopharyngeus muscle 404. Within simulated soft palate musculature area 400, simulated levator veli palatini muscle 406 may occupy approximately 50% of the length. The simulated levator veli palatini origin 610 may be anteromedial to simulated carotid canal 602. Simulated anterolateral fibers 420 of simulated levator veli palatini muscle 406 may run from the inferior third of simulated levator veli palatini muscle 406 towards simulated hamulus 204 and simulated tensor veli palatini aponeurosis 428. Simulated levator veli palatini origin 610 may be adhered to simulated cranial base 600. Simulated levator veli palatini insertion 608 may be adhered to one or both of simulated oral head 418 and simulator nasal head 419 of simulated palatopharyngeus muscle 404. Adhesion of simulated levator veli palatini origin 610 to simulated cranial base 600 can be sufficiently strong such that they remain attached during dissection. Adhesion of levator veli palatini insertion 608 to simulated

palatopharyngeus muscle 404 may be strong enough to prevent detachment during dissection in some embodiments, or weak enough in other embodiments to allow for dissection of simulated levator veli palatini muscle 406 from simulated palatopharyngeus muscle 404. This can be done, for example, by using mechanical fasters (such as screws or nails or pins), a polymer, or glue (such as Loctite® 4851 cyanoacrylate glue).

[0092] As shown in Figures 8-12 and 16-17, simulated tensor veli palatini muscle 408 may split into a simulated tensor veli palatini aponeurosis 428 and one or more simulated anterior fibers 430 as it passes by simulated hamulus 204. Simulated tensor veli palatini aponeurosis 428 may be a thin fascial layer that traverses medially towards simulated medial cleft margin 450 of the simulated soft palate musculature 400. Simulated anterior fibers 430 may spiral off simulated tensor veli palatini muscle 408 anteriorly and medially after simulated tensor veli palatini muscle 408 passes by simulated hamulus 204 and may insert into simulated tensor veli palatini anterior fiber insertion 612 and simulated palatopharyngeus insertion 626. Simulated tensor veli palatini muscle 408 may originate in the simulated scaphoid fossa 432 near the superior end of simulated medial pterygoid plate 604. Simulated tensor veli palatini muscle 408 can descend vertically like an inverted triangle and then curve around simulated hamulus 204 where the one or more simulated anterior fibers 430 traverse anteriorly towards the simulated tensor veli palatini anterior fiber insertion 612 and then the simulated tensor veli palatini aponeurosis 428, which fans out towards simulated medial cleft margin 450. Simulated tensor veli palatini origin 614 may be adhered to simulated cranial base 600, simulated scaphoid fossa 432, or simulated hamulus 204. Simulated anterior fibers 430 may be adhered to the simulated tensor veli palatini anterior fiber insertion 612 and to the lateral side of simulated palatopharyngeus muscle 404. Simulated tensor veli palatini aponeurosis 428 may be embedded with simulated mucosal layer 300, and may also be adhered to a simulated soft tissue fatty layer 1200 (described below). Adhesion can be sufficiently strong such that during dissection, simulated tensor veli palatini aponeurosis 428 remains attached to simulated soft tissue fatty layer 1200. This can be done, for example, by using mechanical fasters (such as screws nails or pins), a polymer, or glue (such as Loctite® 4851 cyanoacrylate glue).

[0093] In some embodiments, simulated levator veli palatini muscle 406 and simulated tensor veli palatini muscle 408 are attached respectively to the simulated levator veli palatini origin 610 and simulated tensor veli palatini origin 614.

[0094] As seen in Figures 8-12 and 18, simulated palatoglossus muscle 410 represents the anterior tonsillar pillar. Simulated palatoglossus muscle 410 may be connected to the simulated soft palate musculature 400 and simulated hamulus 204 superiorly and traverse inferiorly and anteriorly towards a base of a simulated tongue 1306 (described below) attaching to simulated superior constrictor muscle 500. Simulated palatoglossus muscle 410 may be assembled after simulated superior constrictor muscle 500 is added. Simulated palatoglossus origin 640 may be adhered to simulated superior constrictor muscle 500. Adhesion can be sufficiently strong such that during dissection, simulated palatoglossus origin 640 remains attached to simulated superior constrictor muscle 500. This can be done, for example, by using mechanical fasters (such as screws or nails or pins), a polymer, or glue (such as Loctite® 4851 cyanoacrylate glue).

[0095] Simulated musculus uvula 412, seen in Figures 8-12, may, in some embodiments, be attached to simulated palatopharyngeus muscle 404. This can be done, for example, by using mechanical fasters (such as screws or nails or pins), a polymer, or glue (such as Loctite® 4851 cyanoacrylate glue). In other embodiments, simulated musculus uvula 412 may be formed as a complex with simulated palatopharyngeus muscle 404.

[0096] In some embodiments, simulator 100 may comprise a simulated superior constrictor muscle 500. As seen in Figures 8-12 and 19-20, simulated superior constrictor muscle 500 represents a flat sheet of muscle that originates at simulated hamulus 204 and the inferior third of simulated medial pterygoid plate 604. This origin extends inferior along a simulated pterygomandibular ligament 414. From the simulated pterygomandibular ligament 414, simulated superior constrictor muscle 500 may circle posteriorly to envelope the simulated pharynx 416 at the level of the mouth. Simulated superior constrictor muscle 500 may insert into the simulated pharyngeal tubercle 630 of the simulated occipital bone 631 in the midline raphe of the simulated pharynx 416. In

certain embodiments, simulated superior constrictor muscle 500 is made of a soft material with properties simulating a biological superior constrictor muscle. In certain embodiments, simulated superior constrictor muscle 500 may be made of a material that is less firm or more firm than that used for simulated mucosal layer 300. For example, simulated superior constrictor muscle 500 may be made of a natural polymeric material or a synthetic polymeric material. Natural polymeric materials can include shellac, amber, wool, silk, natural rubber, and cellulose. Synthetic polymers can include synthetic rubber, phenol formaldehyde resin, neoprene, nylon, polyvinyl chloride, polystyrene, polyethylene, polypropylene, polyacrylonitrile, polyvinyl butyral, or silicone. In embodiments where silicone is used, the silicone may be Smooth-on® Ecoflex® 20 or Smooth-on® Ecoflex® 30. In further embodiments, superior constrictor muscle 500 and the individual components of simulated soft palate musculature 400 may be made of materials of different colours to allow one to visually distinguish the components from one another. In some embodiments, simulated superior constrictor muscle 500 can be made using a 3D printer, such as an extrusion, light polymerized, powder bed, laminated or wire type 3D printer. Simulated superior constrictor muscle 500 may be adhered to an oral cavity template 800. Oral cavity template 800 may in turn be adhered to simulated hard palate 200 and attached cranial base 600. Simulated superior constrictor muscle 500 may additionally be adhered to simulated hamulus 204 and medial pterygoid plate 604. Adhesion can be sufficiently strong such that during dissection, simulated superior constrictor muscle 500 remains attached to simulated hard palate 200. This can be done, for example, by using mechanical fasters (such as screws or nails or pins), a polymer, or glue (such as Loctite® 4851 cyanoacrylate glue). Simulated superior constrictor muscle 500 may be provided with insets 502 that tend to assist the simulated superior constrictor 500 in fitting into superior component 1312 through matching insets 1313.

[0097] As seen in Figure 9, in some embodiments of simulator 100, there is a simulated soft tissue fatty layer 1200 between the simulated soft palate musculature 400 and the simulated mucosal layer 300. In certain embodiments, simulated soft tissue fatty layer 1200 is made of a soft material with properties simulating a biological soft tissue fatty layer, such as Smooth-on® Ecoflex® 20. Simulated soft tissue fatty

layer 1200 may be loosely attached to simulated palatopharyngeus muscle 404 such that simulated soft tissue fatty layer 1200 tends to easily elevate off simulated palatopharyngeus muscle 404 in a single plane during dissection. This loose attachment may be accomplished, for example, by painting a layer of mold release, such as Ease® Release 200 or 205, on the oral side of simulated palatopharyngeus muscle 404 followed by painting on simulated soft tissue fatty layer 1200 over the mold release surface. Simulated tensor veli palatini aponeurosis 428 may be adhered to the oral side of the simulated soft tissue fatty layer 1200, after which simulated mucosal layer 300 may be applied, adhering to the exposed simulated tensor veli palatini aponeurosis 428 and soft tissue fatty layer 1200.

[0098] In some embodiments, simulator 100 may comprise one or two simulated eustachian tubes 900, as seen in Figures 22-25. Simulated eustachian tube 900 may have a cartilaginous section and a membranous section. Eustachian tube 900 may be made of a material harder than that used for simulated soft palate musculature 400 or simulated superior constrictor muscle 500. For example, simulated eustachian tube 900 may be made of silicone, such as Smooth-on Dragon Skin® 30 or FX-Pro. In some embodiments, simulated eustachian tube 900 is attached to simulated levator veli palatini muscle 406 and to simulated cranial base 600. Adhesion can be sufficiently strong such that during dissection, eustachian tube 900 remains attached to simulated levator veli palatini muscle 406 and to simulated cranial base 600. This can be done, for example, by using mechanical fasters (such as screws or nails or pins), a polymer, or glue (such as Loctite® 4851 cyanoacrylate glue). In some embodiments, simulated levator veli palatini origin 610 may be at the posteromedial aspect of simulated eustachian tube 900 at the junction of its cartilaginous section and bony section. Simulated levator veli palatini muscle 406 may descend anteriorly and medially toward simulated soft palate musculature 400, lying in the space between the simulated superior constrictor muscle 500 and the simulated cranial base 600. In the path of simulated levator veli palatini muscle 406 toward the simulated soft palate musculature 400, simulated levator veli palatini muscle 406 may be related inferiorly and lie almost parallel to simulated eustachian tube 900. Simulated levator veli palatini muscle 406 may lie inferior and medial to simulated eustachian tube 900 throughout its length

except at each end. At the cranial end, simulated levator veli palatini muscle 406 may be curved superiorly and posteriorly around simulated eustachian tube 900 to attach to its posteromedial aspect. At the pharyngeal end, simulated levator veli palatini muscle 406 may curve slightly anteriorly so that it lies inferior to the membranous part and anterolateral to the cartilaginous part of simulated eustachian tube 900. Simulated levator veli palatini muscle 406 may spiral around simulated eustachian tube 900 with the cranial end posteromedial to simulated eustachian tube 900 and the pharyngeal end slightly anterolateral to simulated eustachian tube 900. In certain embodiments, simulated tensor veli palatini muscle 408 may originate from simulated scaphoid fossa 432 near the superior end of the simulated medial pterygoid plate 604, and adjacent the superolateral aspect of the cartilaginous and membranous parts of the length of simulated eustachian tube 900. The axis of simulated tensor veli palatini muscle 408 may be oblique to simulated eustachian tube 900; for example, the angle between the two may be 30 to 45 degrees. In some embodiments, simulated tensor veli palatini muscle 408 descends vertically as a single flat and wide sheet of muscle.

[0099] As shown in Figure 25, some embodiments of the simulator 100 may comprise one or two simulated pedicles 1400 attached to or embedded in simulated hard palate 200. Simulated pedicle 1400 may be created by infusing the material used to create it within simulated greater palatine foramen 206 so that the material cures with an anchor embedded within simulated hard palate 200. This anchor may be confluent with the overlying simulated mucosal layer 300 so that simulated mucosal layer 300 is adherent to simulated pedicle 1400 in this area and dissection around simulated pedicle 1400 gives the visual appearance and tactile feel that occurs during an actual palate repair. Simulated pedicle 1400 may be created using a soft material with properties simulating a biological pedicle. In some embodiments, simulated pedicle 1400 is made of a material that may tear when simulator 100 is used to practice surgery, as is sometimes seen in practice if a surgeon is not careful when performing trans-oral surgery. Simulated pedicle 1400 may be made with a silicone, such as Ecoflex® 20 or Ecoflex® 30.

[00100] Optionally, simulated hard palate 200 with attached cranial base 600 can be supported by a base, such as base 700 as shown in Figure 26 or base 702 as shown

in Figure 27. As shown, simulated base 702 has a rotation point 704 to simulate head flexion and/or extension from, for example, neutral (0 degrees) to full extension (90 degrees). In some embodiments, simulated hard palate 200 with attached cranial base 600 can slide in and out of either base 700 or 702. Figure 28, for example, shows
5 simulated hard palate 200 with attached cranial base 600 supported by base 700. In some embodiments, simulated hard palate 200 and cranial base 600 may have inset slides 1316 that allow it to slide in and out of either base 700 or 702. The angle simulated hard palate 200 takes upon being support by a base can represent the angle of the palate and the perspective seen by a surgeon during trans-oral surgery, such as
10 shown in Figure 29.

[00101] As shown in Figures 30-32, in some embodiments, simulator 100 may further comprise a simulated oral aperture 1300 with a simulated oral cavity 1302 extending therethrough. Extending from simulated oral aperture 1300 can be opposed simulated lateral oral cavity walls 1304 and a simulated tongue 1306 spanning the
15 opposed simulated lateral oral cavity walls 1304 at a first end of said walls 1304. Simulated oral cavity 1302 may be made with a material with properties simulating a biological oral cavity, such as silicon, (which can be Ecoflex® 20 or Ecoflex® 30). Simulated hard palate 200 and simulated soft palate musculature 400 can be attached to opposed simulated lateral oral cavity walls 1304 at a second end of said walls 1304.
20 The structures accessible from within simulated oral cavity 1302, except for simulated tongue 1306, may then be coated with simulated mucosal layer 300. In certain embodiments, simulator 100 may further comprise a complete or partial simulated face 1308, which in some embodiments is made of silicone, such as Smooth-On Dragon Skin 30 with 1:1 ratio with Smooth-on Slacker, extending from the simulated oral
25 aperture 1300. Complete or partial simulated face 1308 may be attached to base 700 or 702, in certain embodiments. This can be done, for example, by using Loctite® 4851 cyanoacrylate glue.

[00102] As seen in Figures 30-36, in some embodiments, simulator 100 forms a replaceable cartridge 1310 that replaceably fits within a complete or partial simulated
30 face 1308 attached to base 700 or 702. The cartridge may comprise simulated hard palate 200, simulated soft palate musculature 400, simulated mucosal layer 300,

simulated superior constrictor muscle 500, simulated cranial base 600, simulated Eustachian tube 900, simulated soft tissue fatty layer 1200, simulated pedicle 1400, simulated oral aperture 1300, simulated oral cavity 1302, simulated lateral oral cavity walls 1304, simulated tongue 1306, or any combination thereof. Use of cartridge 1310
5 allows one to replace cartridge 1310 alone, and not the complete or partial simulated face 1308 and attached base 700 or 702, after practicing trans-oral surgery with cartridge 1310.

[00103] Replaceable cartridge 1310 may be made of a superior component 1312 and an inferior component 1314, which may be made of silicone, such as Ecoflex® 20
10 or Ecoflex® 30. Superior component 1312 may have insets 1313 to receive simulated superior constrictor muscle 500. Superior component 1312 and an inferior component 1314 can fit together by use of lock and key insets. In some embodiments, superior component 1312 and an inferior component 1314 may be attached to one another using, for example, mechanical fasters (such as screws or nails or pins) or glue (such
15 as Loctite® 4851 cyanoacrylate glue). Simulated oral aperture 1300 can be made of both superior component 1312 and inferior component 1314 (see for example Figures 31A-B). Alternatively, simulated oral aperture 1300 may be made as one piece, such as out of superior component 1312 only (see for example Figures 32A-B). Making simulated oral aperture 1300 of one piece may tend to prevent tearing of simulated oral
20 aperture 1300 during retraction. As seen in Figure 33, in some embodiments, a hard material, such as steel plate 1315, may be embedded within inferior component 1314, which may tend to prevent deformation during retraction. This can be done, for example, by applying a thin layer, such as 2 mm, of silicone, such as Ecoflex® 20 or Ecoflex® 30, in a cartridge mold and allowing it to cure. The steel plate may then be
25 laid over top this layer of cured silicone and the remainder of the cartridge casted embedding the piece of steel within the silicone.

[00104] Replaceable cartridge 1310 may further comprise a locking mechanism. As seen in Figure 37 and 38, the locking mechanism may comprise horizontal slides 1318 that insert across the base 700 or 702 passing anterior to cranial base 600
30 preventing anterior movement of replaceable cartridge 1310 when retracted.

Alternatively, as seen in Figures 39 and 40, the locking mechanism may be of a lock and key type.

[00105] Figure 41 is an exploded view diagram of simulator 100 in accordance with an embodiment of the present invention.

5 **[00106]** In the embodiment shown in Figure 23, simulator 100 is asymmetrical in that only a portion of the simulated soft palate musculature 400 and one eustachian tube 900 of a palate are present. Such embodiments excluding certain simulated biological features can tend to be useful to provide better access (including visual sight lines) to simulated features of interest. It will be appreciated that in other embodiments,
10 different portions of a palate may be simulated, which may in different embodiments exclude certain simulated elements.

[00107] The components of simulator 100 may be made using any known process. For example, many of the above-described components may be cast using molds, where a plug component can be created using a 3D printer, such as a FormLabs
15 Form1+ 3D printer. For components made of silicone, the molds may be casted using platinum cured silicone. This can be done by mixing a first and second component of the silicone, degassing the silicone and then injecting it using a syringe into the molds through an injection port. The molds may then be clamped. The silicone tends to cure over time. Following the curing process, the silicone casts may be removed.
20 Alternatively, many of the above components may be made using a 3D printer, such as an extrusion, light polymerized, powder bed, laminated or wire type 3D printer.

[00108] The exemplary simulators described above can be developed from patient imaging using CT scans. The simulators can be modified to represent a patient of any age or oral cavity size by imaging a patient of the age or oral cavity size in question and,
25 for example, can be modified to develop patient specific simulators prior to operating on that specific patient.

[00109] Simulator 100 described above can be used for a variety of purposes, such as for teaching, training, or research. For example, simulator 100 may be used for practicing trans-oral surgery or as an anatomical model. Simulator 100 can also be
30 used to develop new surgical instruments or robotic instruments.

[00110] Methods of practicing or learning trans-oral surgery using simulator 100 may comprise one or more of providing a simulator having simulated hard palate 200, a simulated mucosal layer 300, a first portion thereof covering and attached to at least a portion of the simulated hard palate 200, and a simulated soft palate musculature 400
5 configured wherein a second portion of the simulated mucosal layer 300 is covering and attached to at least a portion of the simulated soft palate musculature 400, and wherein the strength of attachment between simulated mucosal layer 300 and the simulated soft palate musculature 400 differs from the strength of attachment between simulated mucosal layer 300 and the simulated hard palate 200; dissecting the simulated mucosal
10 layer 300 away from one or both of the simulated hard palate 200 or the simulated soft palate musculature 400; moving, mobilizing, removing or reorienting simulated mucosal layer 300; moving, mobilizing, or reorienting the simulated soft palate musculature 400; incising the simulated soft palate musculature 400; suturing the simulated soft palate musculature 400; and suturing the simulated mucosal layer 300. The steps of incising,
15 dissecting and suturing may be performed through the use of manual instruments, powered instruments or a surgical robot.

[00111] More particularly, the method may comprise one or more of opening simulated oral cavity 1302, which may be done using one or more of a retractor, such as Dingman retractor 1500 (see for example Figure 42); retracting the simulated
20 musculus uvula 412 with a skin hook while incising along simulated medial cleft 150 margin of simulated soft palate musculature 400 (see Figure 43); creating lateral relaxing incisions at simulated dimple area 302; incising along simulated medial cleft 150 margin of the simulated hard palate 200 and simulated soft palate musculature 400; elevating a mucosal flap from simulated hard palate 200; dissecting simulated mucosal
25 layer 300 just posterior to simulated soft palate musculature 400 encountering simulated soft tissue fatty layer 1200; elevating the mucosal flap from simulated soft palate musculature 400 under simulated soft tissue fatty layer 1200; elevating simulated mucosal layer 300 at the hard-soft palate junction with visible simulated pedicle 1400, simulated palatopharyngeus muscle 404 and simulated anterior fibers 430 of simulated
30 tensor veli palatini muscle 408 attached to posterior simulated hard palate 200; releasing simulated palatopharyngeus muscle 404 from simulated posterior cleft 150

margin; releasing simulated palatopharyngeus muscle 404 from simulated anterior fibers 430 of simulated tensor veli palatini muscle 408; mobilizing the simulated palatopharyngeus muscle 404 with attached simulated levator veli palatini muscle 406 (see for example Figure 44); dissecting simulated soft palate musculature 400 towards
5 simulated levator tunnel 470 (see for example Figure 44) ; suturing the simulated mucosal layer 300 together; suturing simulated soft palate musculature 400 together (see for example Figure 45); exposing simulated right hamulus 204 with attached simulated superior constrictor muscle 500 and simulated tensor veli palatini aponeurosis 428 traversing towards simulated medial 150 cleft margin with simulated anterior fibers
10 430 of simulated tensor veli palatini muscle 408 visible; and closing simulated mucosal layer 300 with bilateral simulated pedicles 1400 visible through lateral relaxing incisions (see for example Figure 46).

[00112] The above methods may be performed either directly by a medical student, resident, fellow, surgeon, or medical practitioner using manual instruments or
15 through use of a surgical robot.

EXAMPLES

[00113] Porcine lingual gingival closest to palate mucosa is known to have the following tensile properties: a failure load of 10.89 N, a tensile strength of 2.83 MPa (410 PSI), and a Young's Modulus of 18.83 MPa (2731 PSI); and the following stress
20 relaxation data: initial stress of 1.88 and equilibrium stress of 0.97 (Goktas S, Dmytryk JJ, McFetridge PS. Biomechanical behavior of oral soft tissues. Journal of periodontology. 2011;82(8):1178-86).

[00114] Matching of properties of simulated components to biological tissue properties can be done by material testing porcine tissue. Tensile testing was
25 performed to determine the tear strength of the porcine masticatory mucosa as well as the tear strength of the soft palate using ASTM D624 standard. The range of tear strengths obtained on testing four samples of porcine masticatory mucosa was 11.3-23.81 pli. The tear strength obtained on testing one sample of porcine soft palate was 2.48 pli. The tear strength obtained is on the same order of magnitude to Smooth-On
30 ® Ecoflex® 10-30 platinum cured silicone.

[00115] Three expert cleft palate surgeons incised through Ecoflex® 10, Ecoflex® 20 and Ecoflex® 30. Testing revealed that incising through Ecoflex® 20 (which has a tear strength of 30 pli) or Ecoflex® 30 (which has a tear strength of 38 pli) tends to simulate the feel of incising through actual oral mucosa.

- 5 **[00116]** While the foregoing invention has been described in some detail for purposes of clarity and understanding, it will be appreciated by those skilled in the relevant arts, once they have been made familiar with this disclosure, that various changes in form and detail can be made without departing from the true scope of the invention in the appended claims. The invention is therefore not to be limited to the
- 10 exact components or details of construction or methodology set forth above. Except to the extent necessary or inherent, no particular order to steps or stages of methods or processes described in this disclosure, including the Figures, is intended or implied. In many cases, the order of method steps may be varied without changing the purpose, effect or import of the methods described.

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What is claimed is:

1. A simulator for practicing trans-oral surgery, comprising:
 - a simulated hard palate;
 - 5 a simulated soft palate musculature adjacent to the simulated hard palate; and
 - a simulated mucosal layer covering at least a portion of the simulated hard palate and at least a portion of the simulated soft palate musculature,
 - wherein the simulated mucosal layer is configured to conform to and follow the contours of surface features of the covered portions of the simulated hard
 - 10 palate and simulated soft palate musculature,
 - wherein the simulated mucosal layer is thicker over the simulated hard palate than over the simulated soft palate musculature.
2. The simulator of claim 1, wherein the simulated mucosal layer is attached to the
- 15 simulated soft palate musculature and the simulated hard palate, and a first strength of attachment between the simulated mucosal layer and the simulated soft palate musculature differs from a second strength of attachment between the simulated mucosal layer and the simulated hard palate, wherein the first strength of attachment is less than the second strength of attachment.
- 20
3. The simulator of claim 1, wherein the simulated mucosal layer is attached to the simulated soft palate musculature and the simulated hard palate, and a first strength of attachment between the simulated mucosal layer and the simulated soft palate musculature differs from a second strength of attachment between the simulated
- 25 mucosal layer and the simulated hard palate, wherein the first strength of attachment is greater than the second strength of attachment.

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4. The simulator of claim 1, wherein the simulated mucosal layer is attached to the simulated soft palate musculature and the simulated hard palate, and the simulated hard palate comprises a simulated hamulus, the simulator further comprising a simulated cranial base extending from the simulated hard palate, the cranial base comprising a simulated medial pterygoid plate, and the simulator further comprising a simulated superior constrictor muscle attached to the simulated hamulus and simulated medial pterygoid plate, wherein the simulated mucosal layer is less strongly attached to the simulated superior constrictor muscle than to the simulated hard palate.

10

5. The simulator of any one of claims 1-4, wherein the simulated soft palate musculature comprises a simulated palatopharyngeus muscle and a simulated tensor veli palatini muscle, the simulated tensor veli palatini muscle comprising a simulated tensor veli palatini aponeurosis, the simulator further comprising a simulated soft tissue fatty layer located between and attached to the simulated palatopharyngeus muscle and the simulated tensor veli palatini aponeurosis, wherein the simulated soft tissue fatty layer is less strongly attached to the simulated palatopharyngeus muscle than to the simulated tensor veli palatini aponeurosis.

20 6. The simulator of any one of claims 1-4, wherein the simulated soft palate musculature comprises:

one or both of a simulated palatopharyngeus muscle and a simulated levator veli palatini muscle; and

25 at least one of a simulated tensor veli palatini muscle, a simulated palatoglossus muscle, and a simulated musculus uvula,

wherein one or both of the simulated palatopharyngeus muscle and the simulated levator veli palatini muscle are made of a harder material than

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the at least one of the simulated tensor veli palatini muscle, the simulated palatoglossus muscle, and the simulated musculus uvula.

7. The simulator of claim 1, wherein the simulated mucosal layer is attached to the
5 simulated soft palate musculature and the simulated hard palate, the simulated soft
palate musculature comprises a simulated palatopharyngeus muscle and a simulated
palatoglossus muscle, and the simulated hard palate comprises a simulated hamulus,
the simulator further comprising a simulated cranial base extending from the simulated
hard palate, the simulated cranial base comprising a simulated medial pterygoid plate,
10 and the simulator further comprising a simulated superior constrictor muscle attached to
the simulated hamulus and simulated medial pterygoid plate, and wherein the simulated
palatopharyngeus muscle, the simulated palatoglossus muscle and the simulated
superior constrictor muscle are formed as a complex.

15 8. The simulator of any one of claims 1-4, wherein the simulated soft palate
musculature comprises a simulated levator veli palatini muscle and a simulated
palatopharyngeus muscle, and wherein the simulated levator veli palatini muscle is
attached to the simulated palatopharyngeus muscle.

20 9. The simulator of any one of claims 1-8, further comprising a simulated pedicle
attached to or embedded in the simulated hard palate.

10. The simulator of any one of claims 1 to 3, further comprising a simulated cranial
base extending from the simulated hard palate, and wherein the simulated soft palate
25 musculature comprises at least a simulated levator veli palatini muscle, and the
simulator further comprising a simulated eustachian tube attached to the simulated
levator veli palatini muscle and to the simulated cranial base.

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11. The simulator of claim 10, wherein the simulated hard palate comprises a simulated hamulus and the simulated cranial base comprises a simulated medial pterygoid plate, the simulator further comprising a simulated superior constrictor muscle attached to the
5 simulated hamulus and the simulated medial pterygoid plate, and wherein the simulated eustachian tube is made of a material harder than that used for the simulated soft palate musculature or the simulated superior constrictor muscle.

12. The simulator of any one of claims 1-11, further comprising a simulated cleft in at
10 least one of the simulated hard palate and the simulated soft palate musculature.

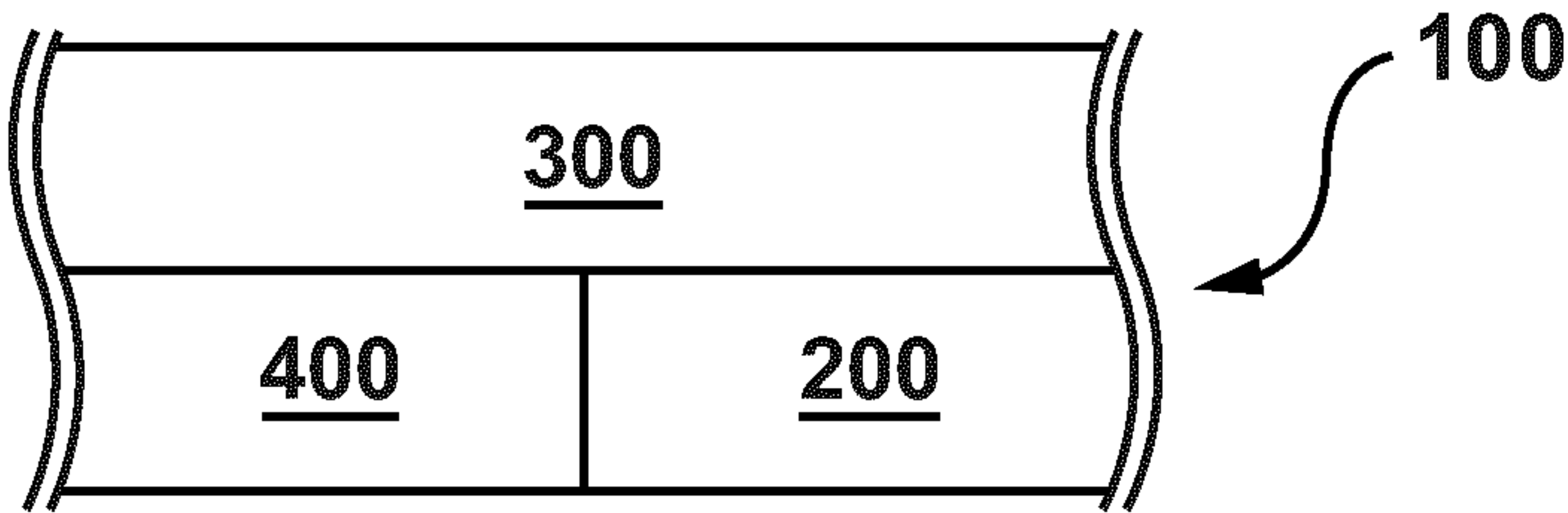


FIG. 1A

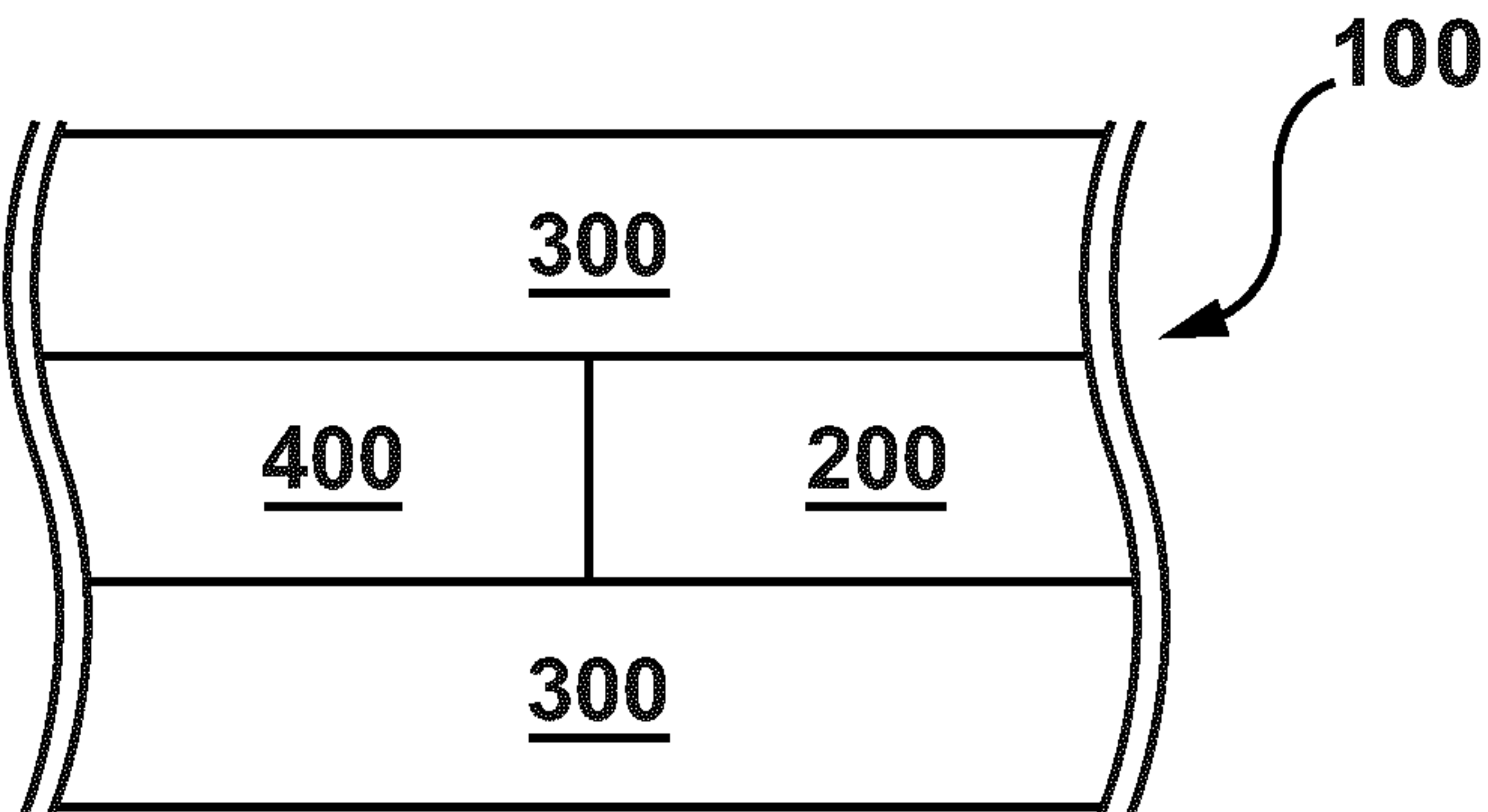


FIG. 1B

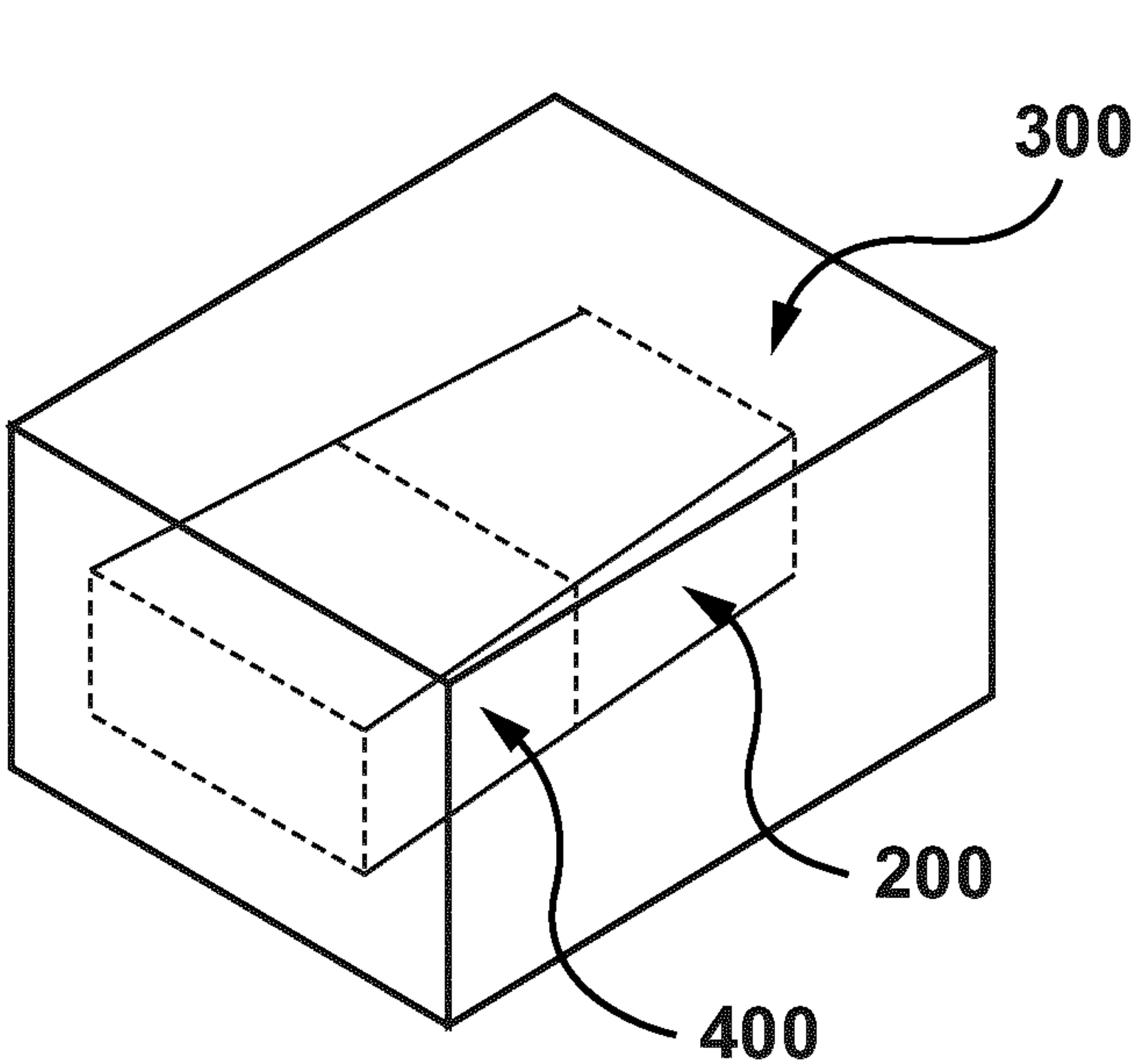


FIG. 1C

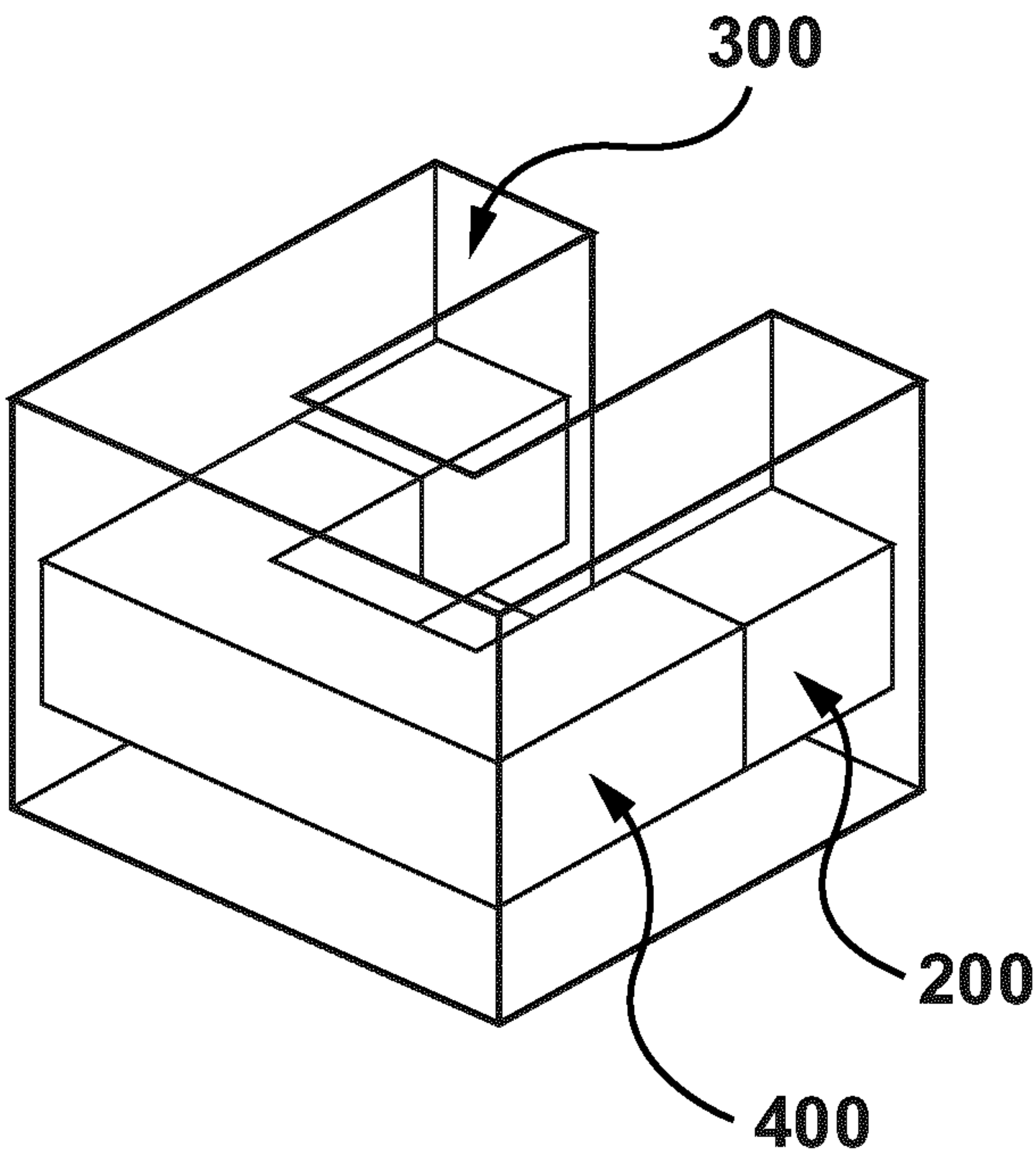


FIG. 1D

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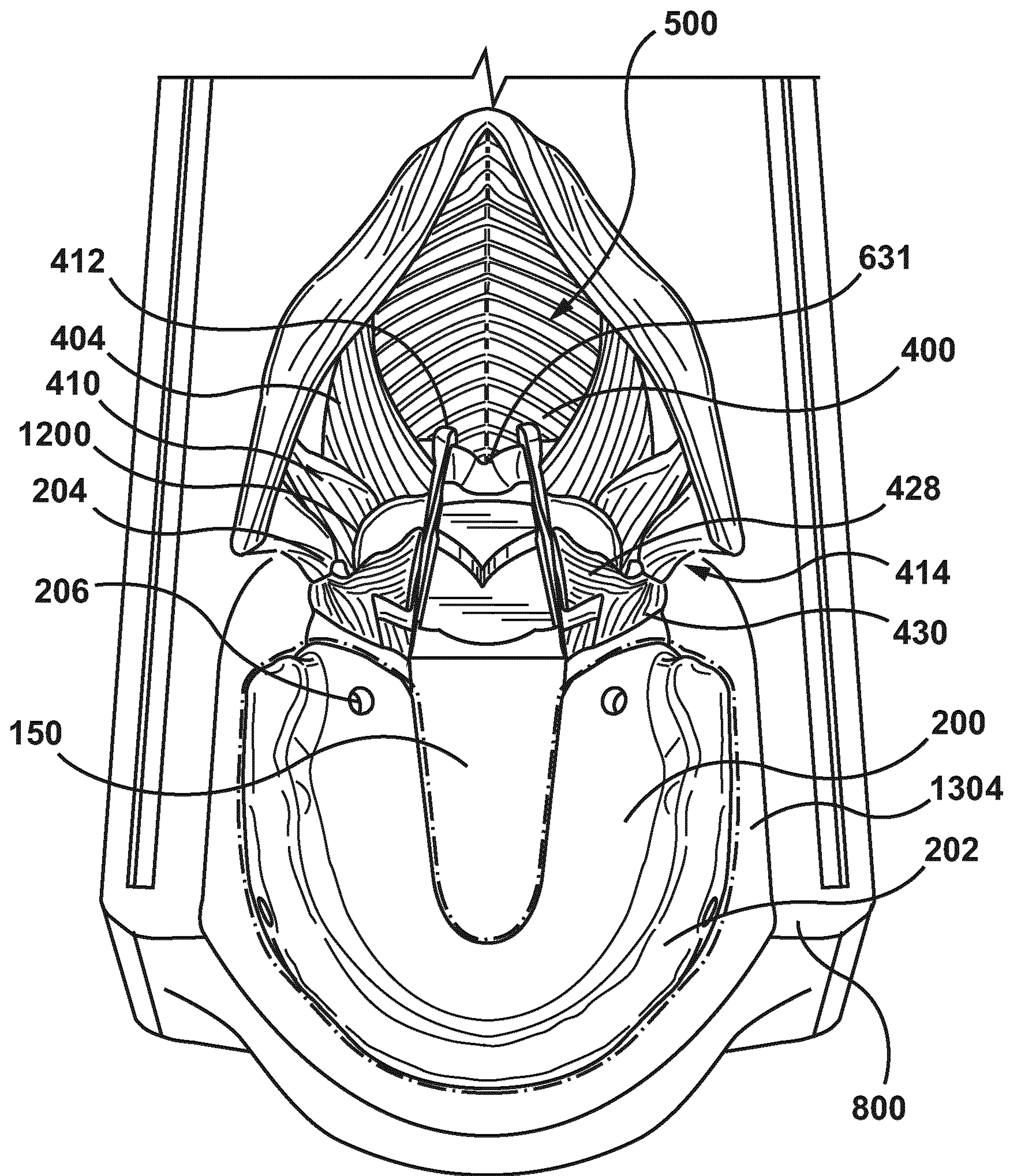
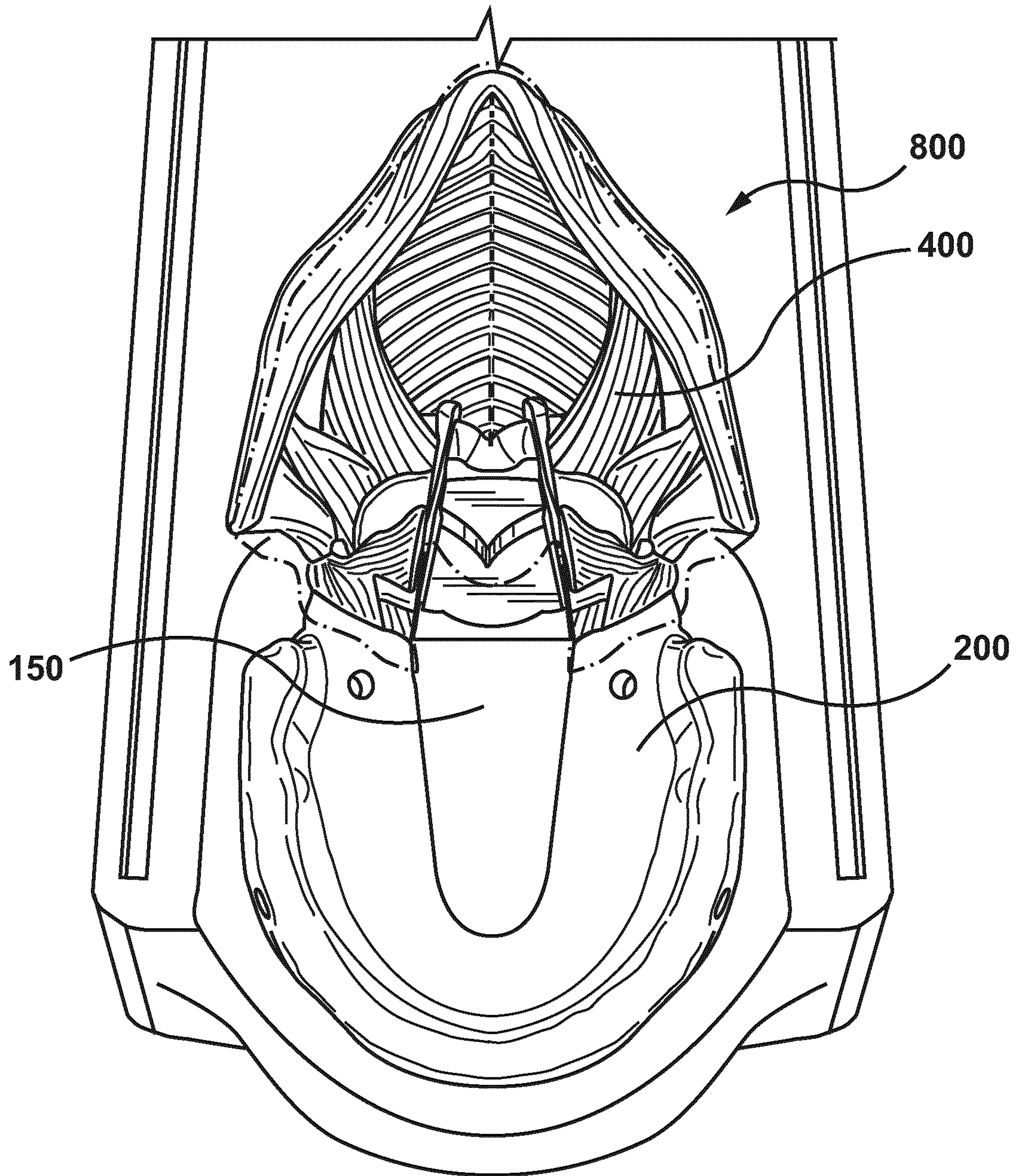
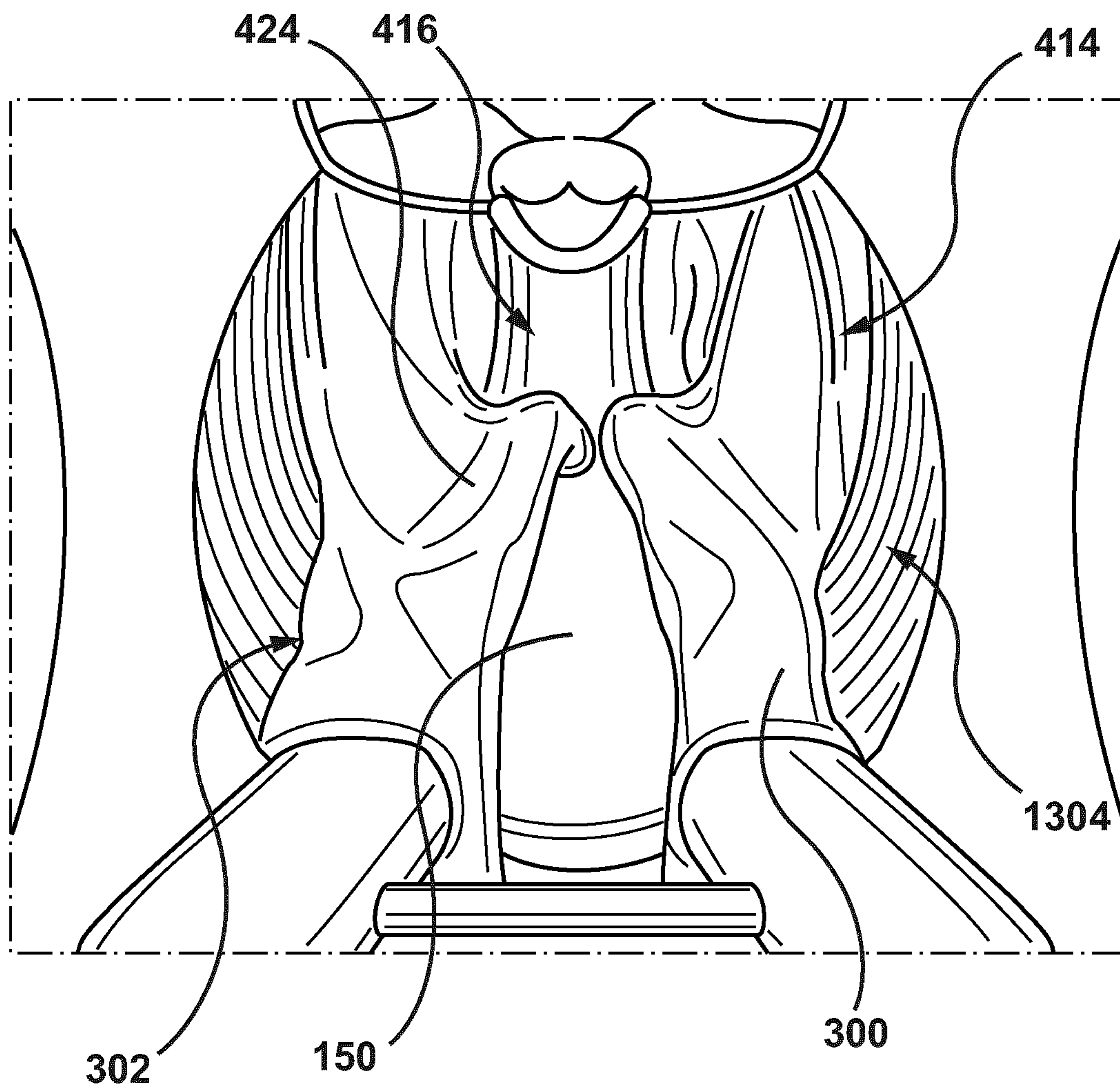


FIG. 2

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**FIG. 3**

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**FIG. 4**

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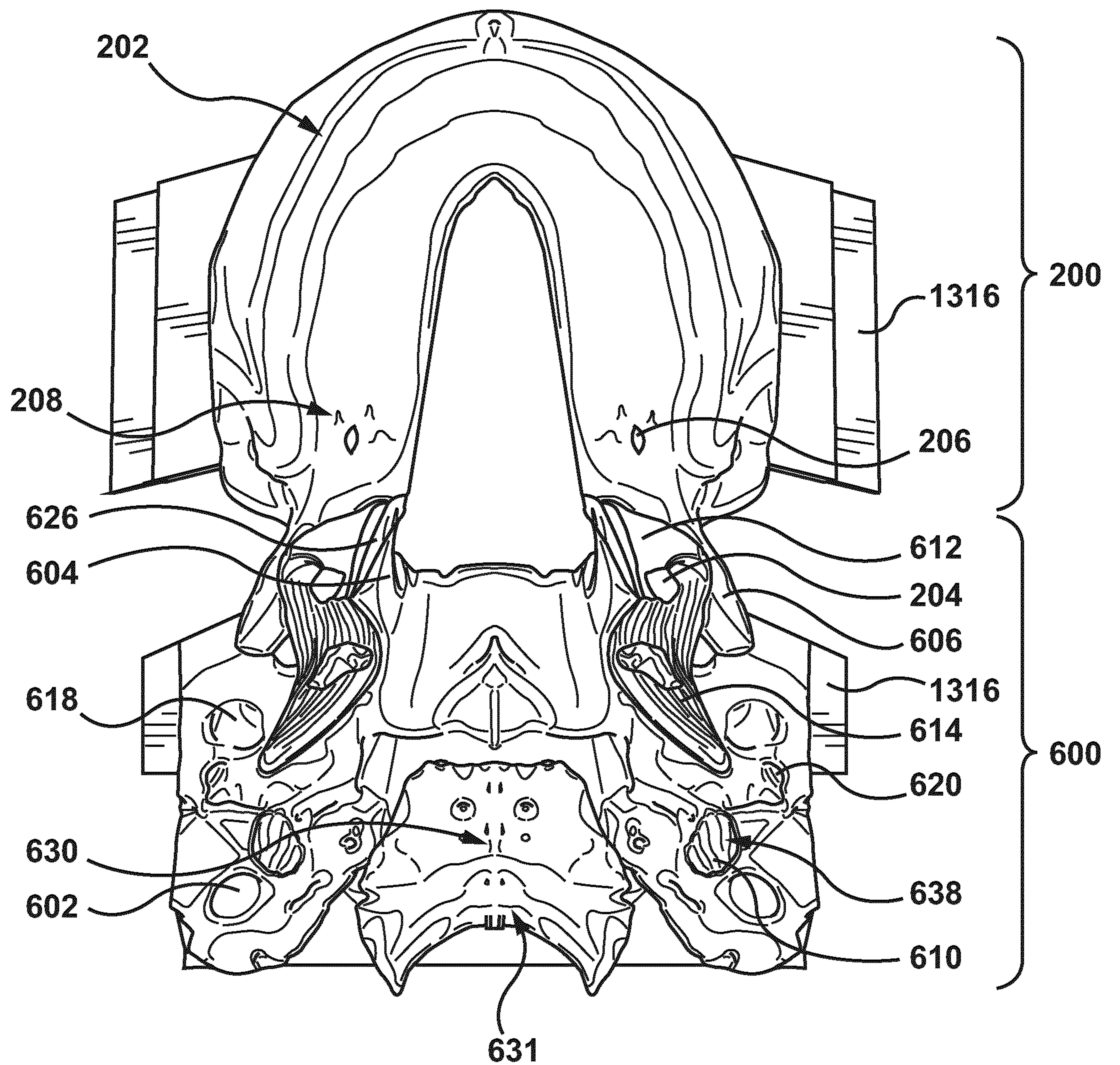
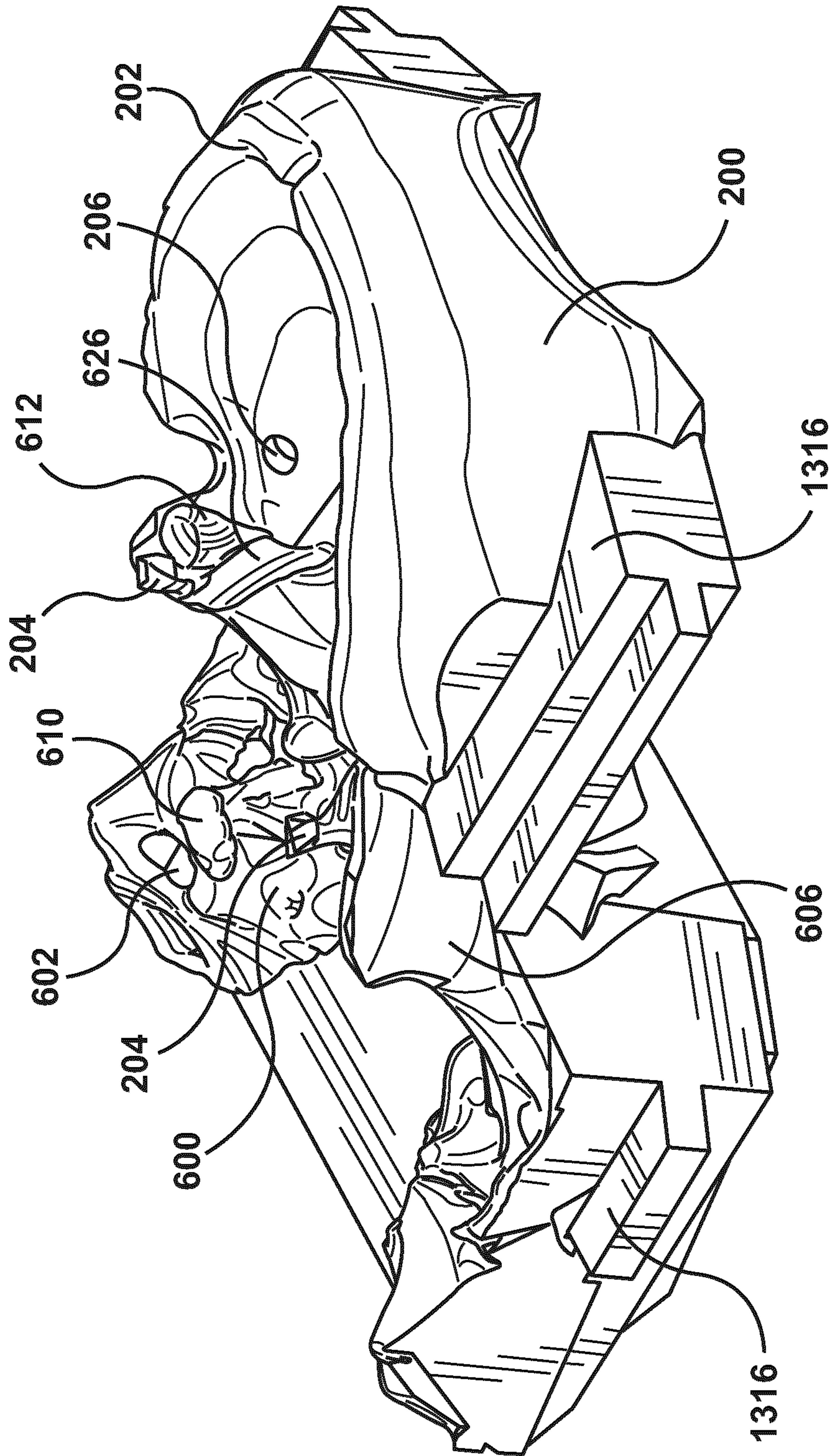


FIG. 5

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**FIG. 6**

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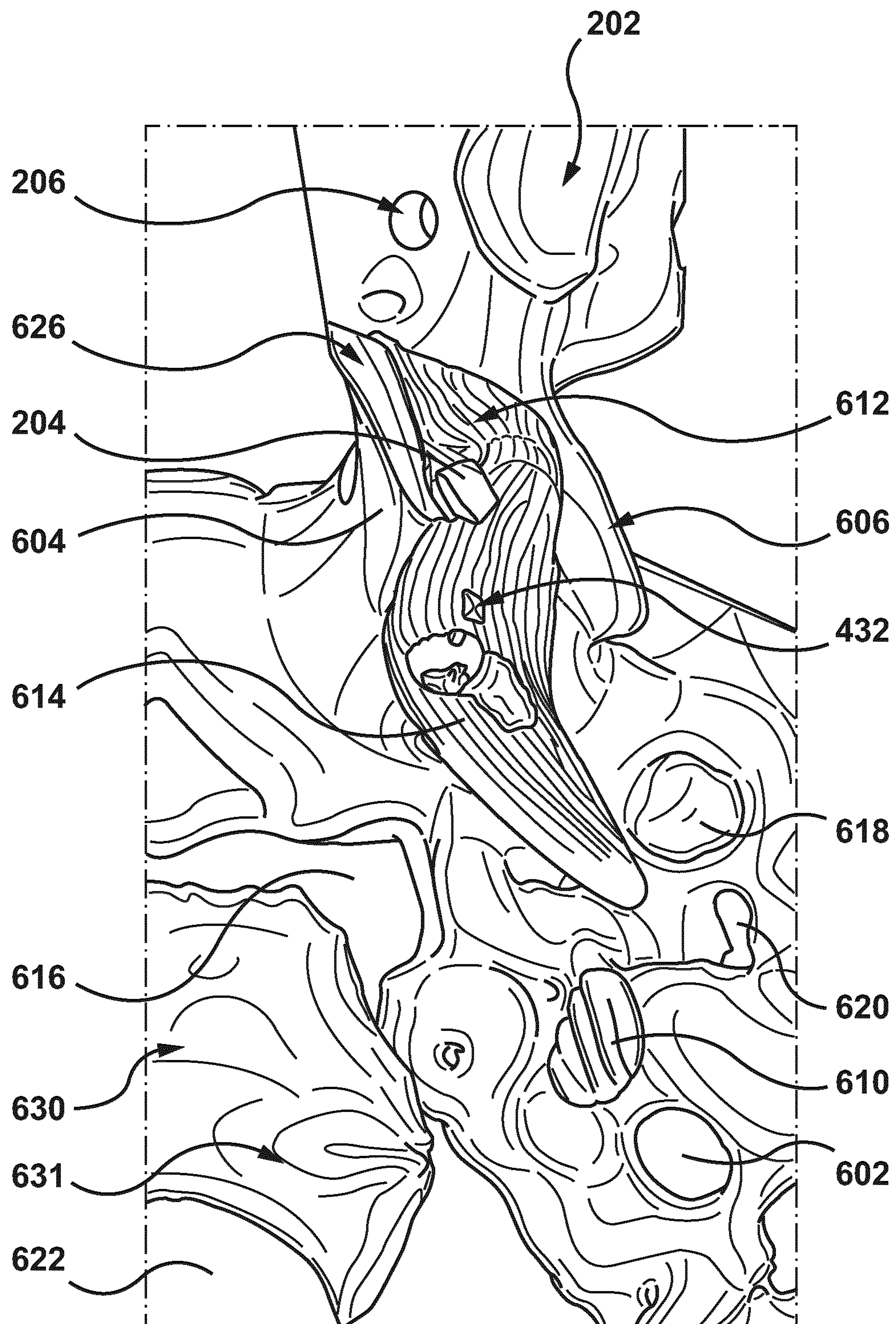
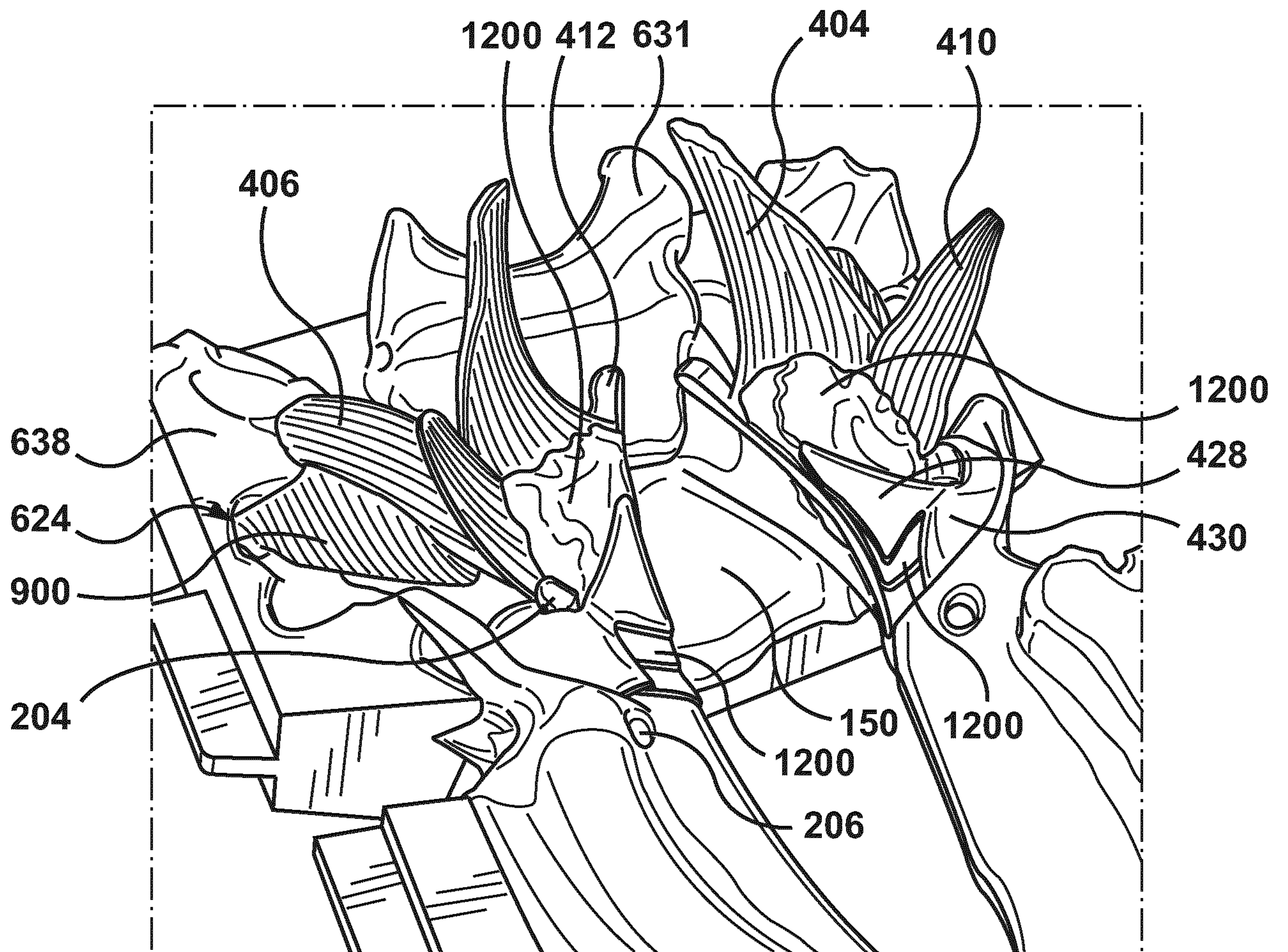


FIG. 7

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**FIG. 8**

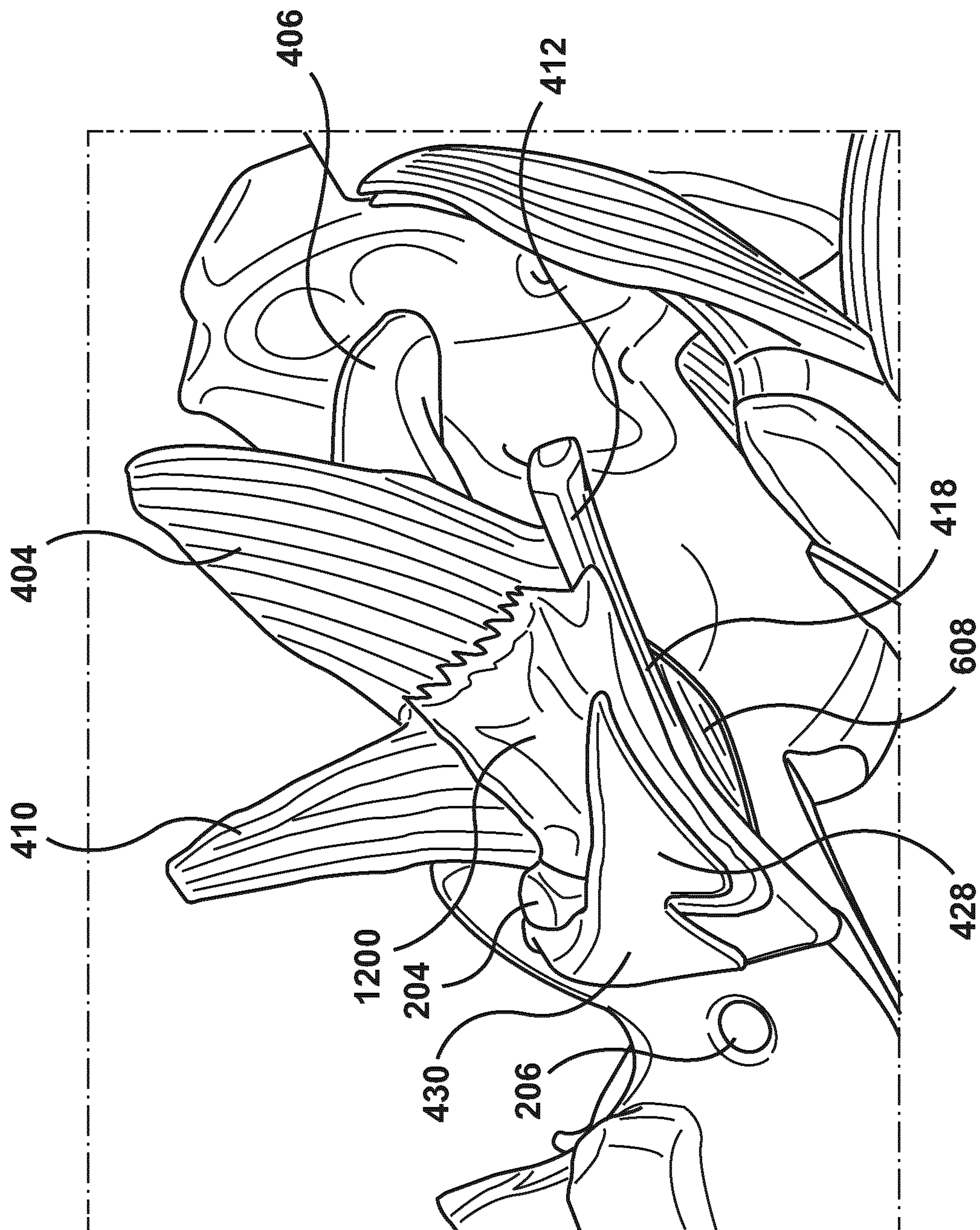


Fig. 9.

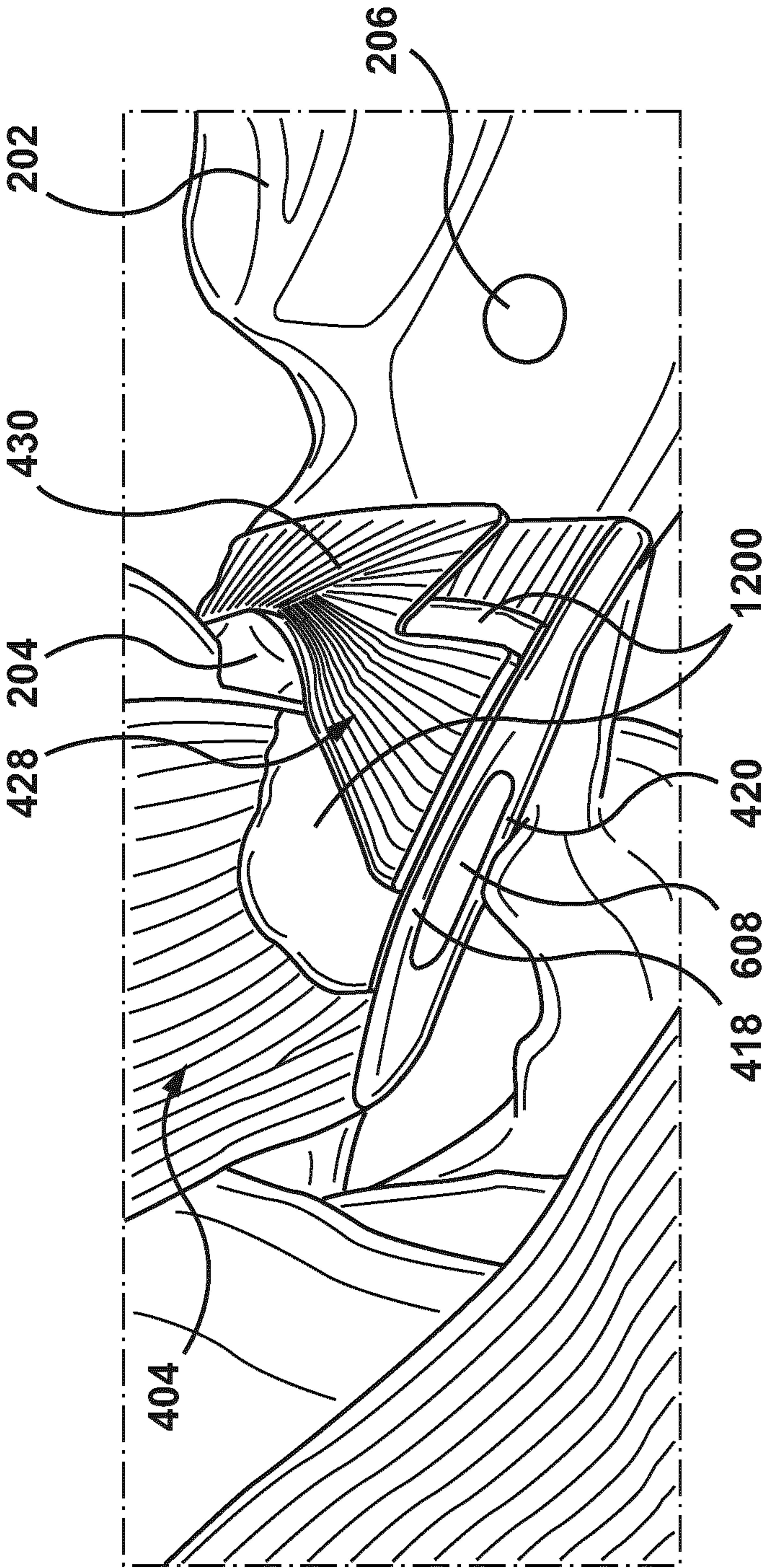
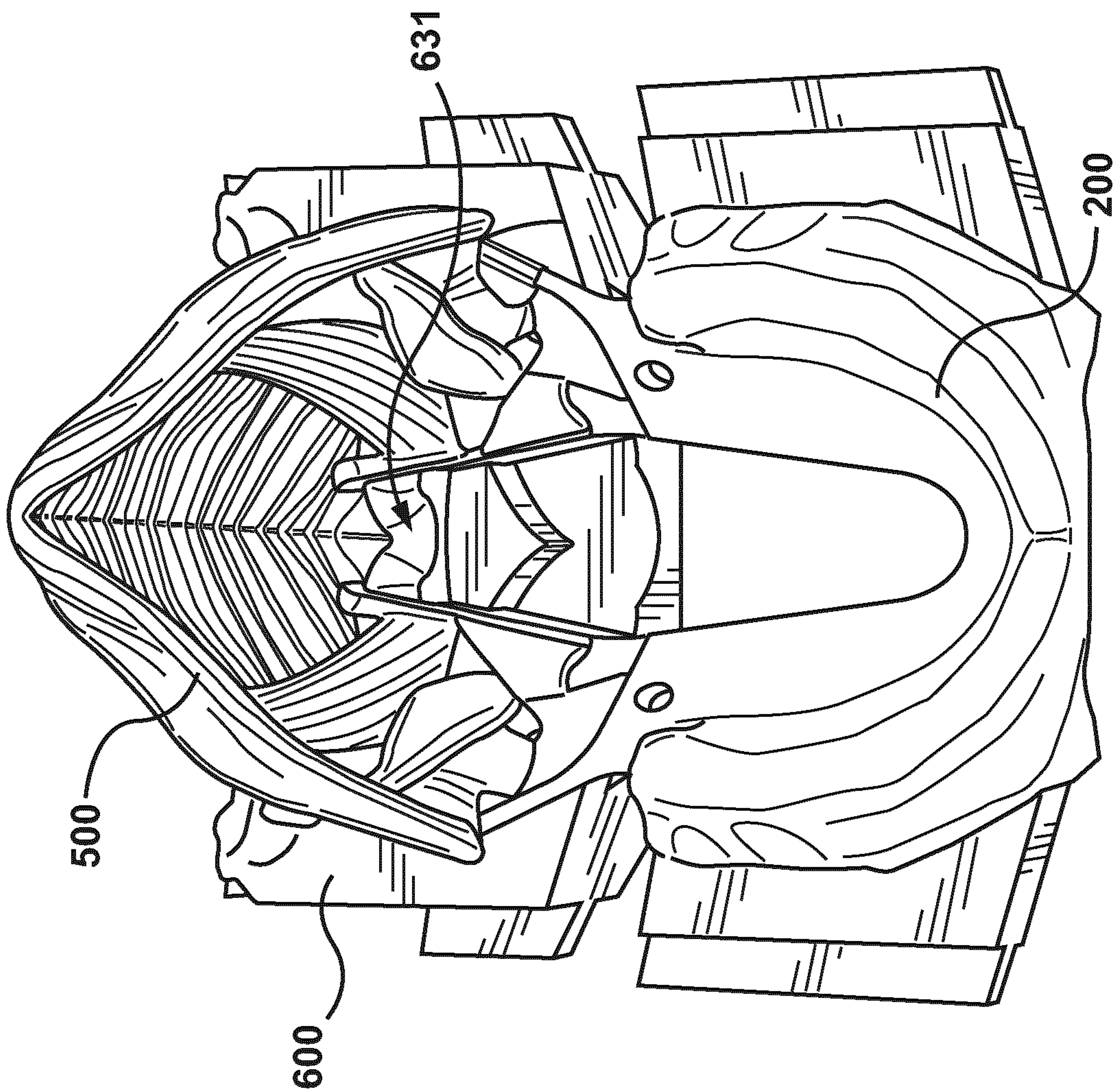
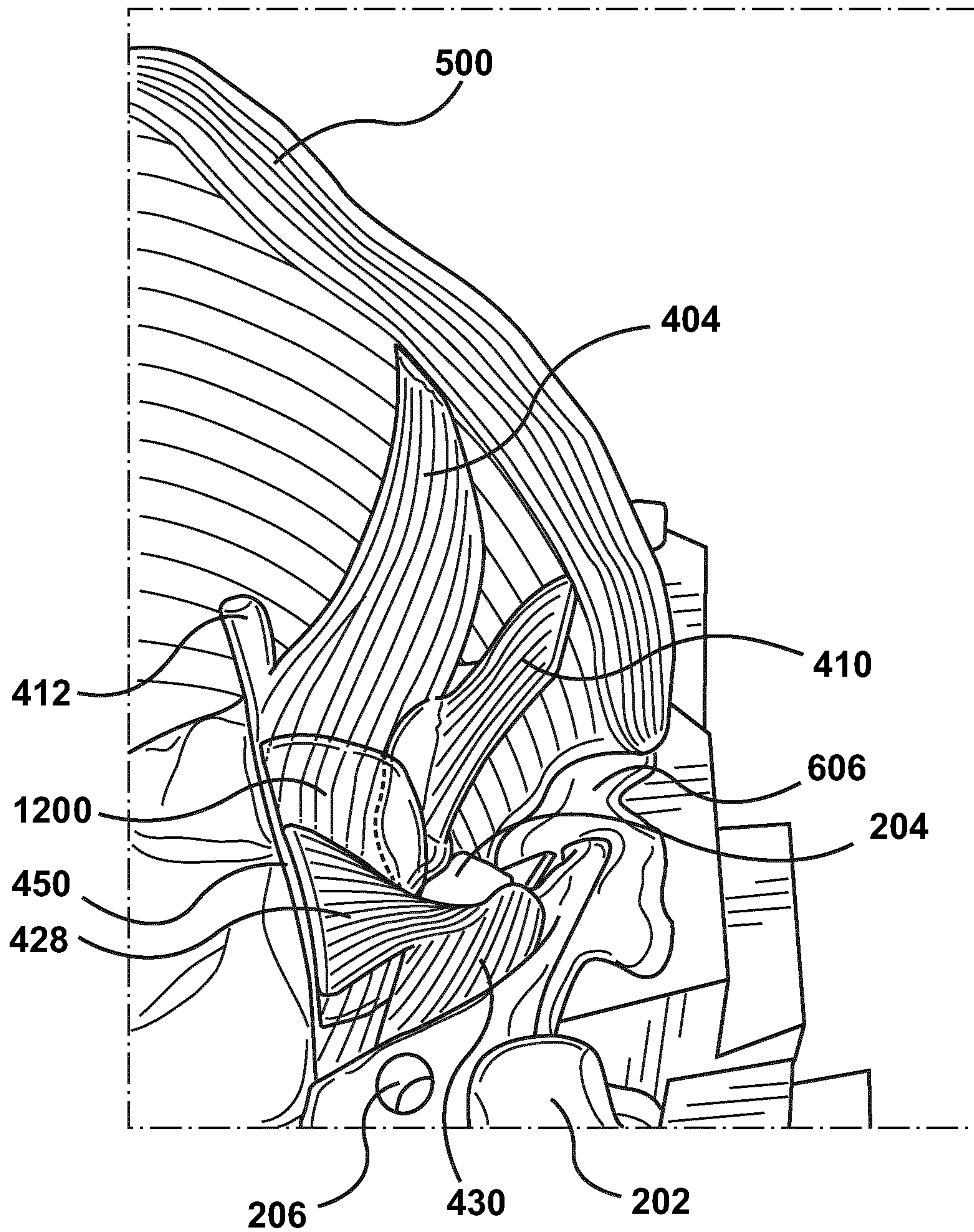


FIG. 10

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**FIG. 11**

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**FIG. 12**

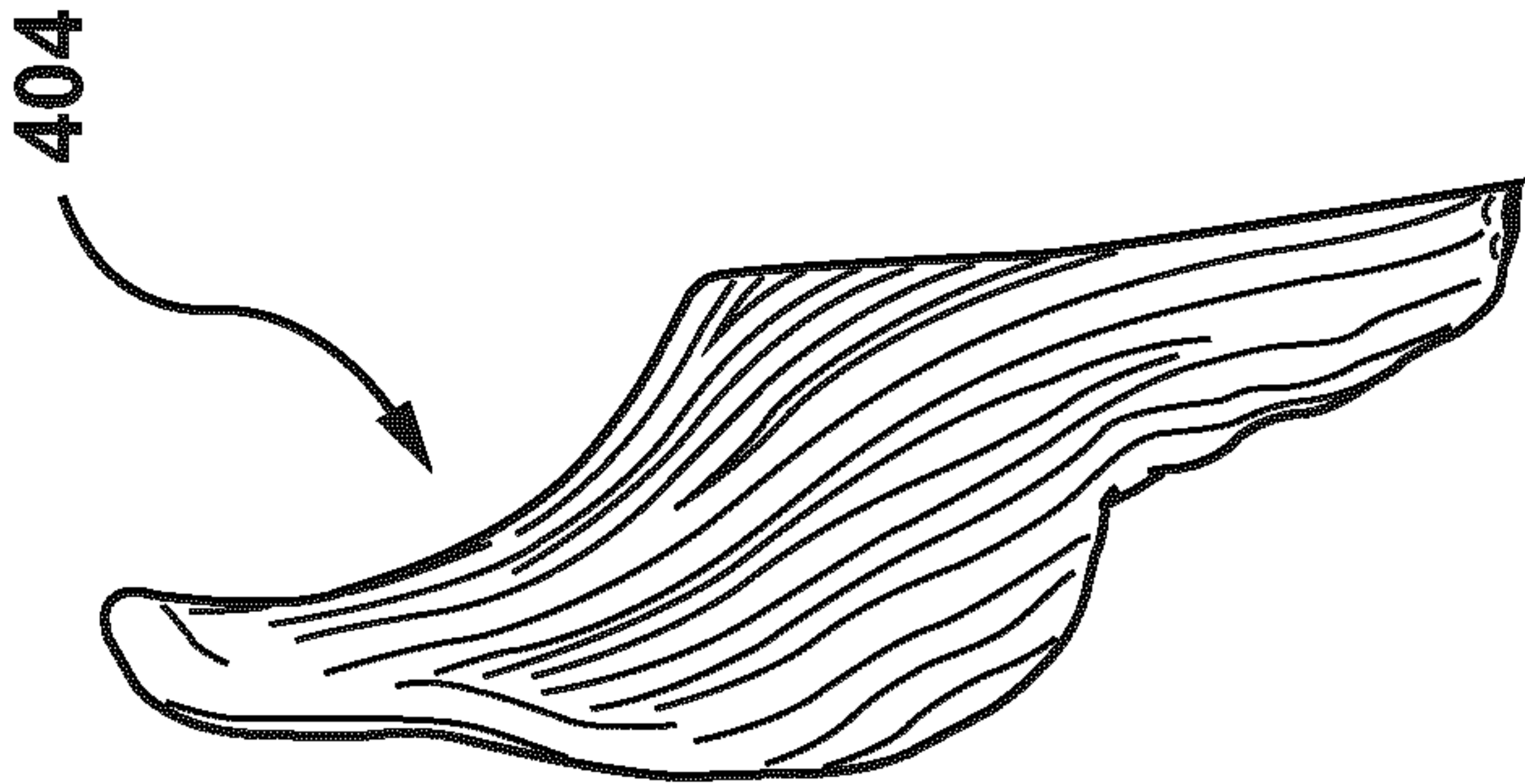


FIG. 13A

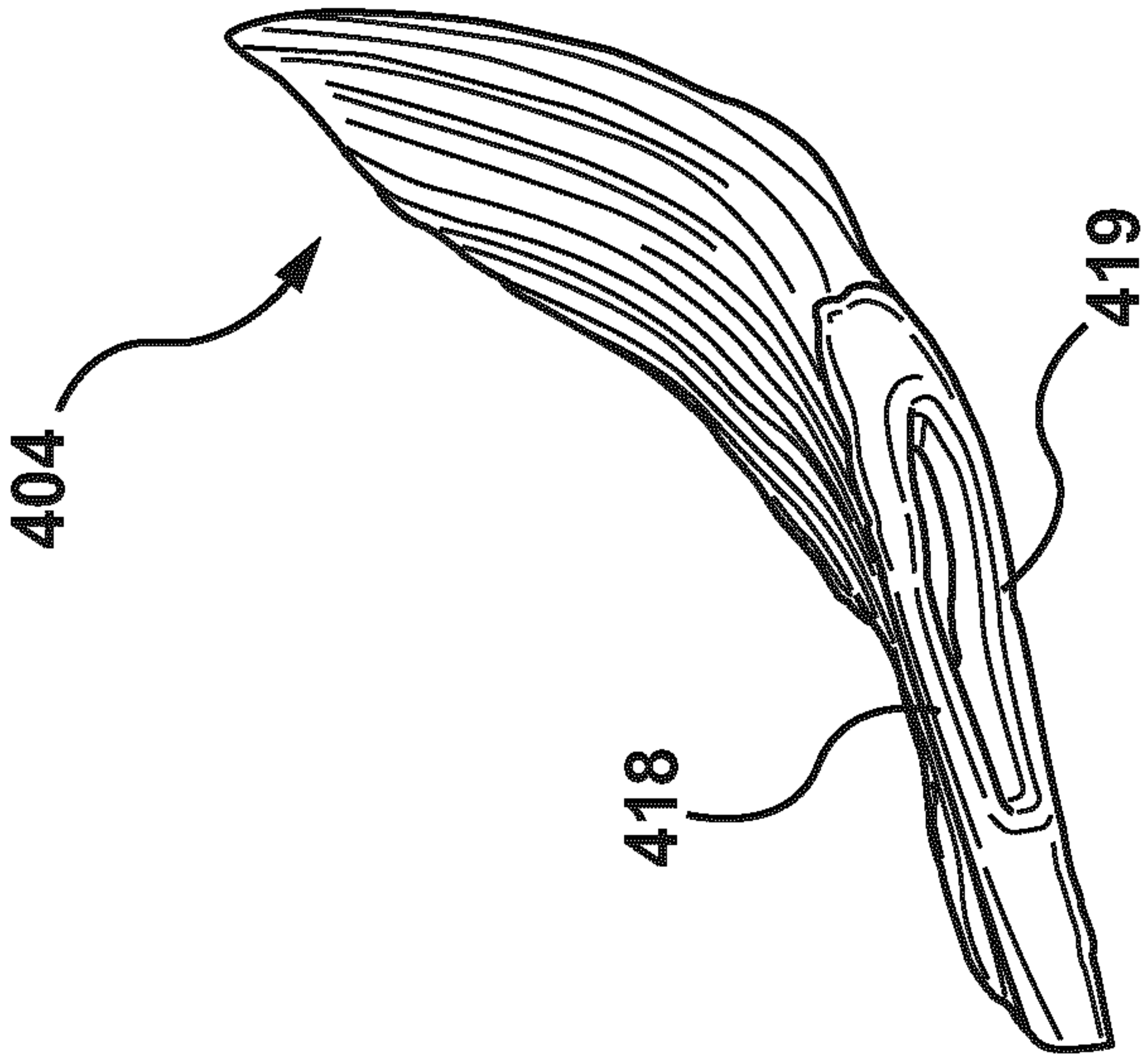


FIG. 13B

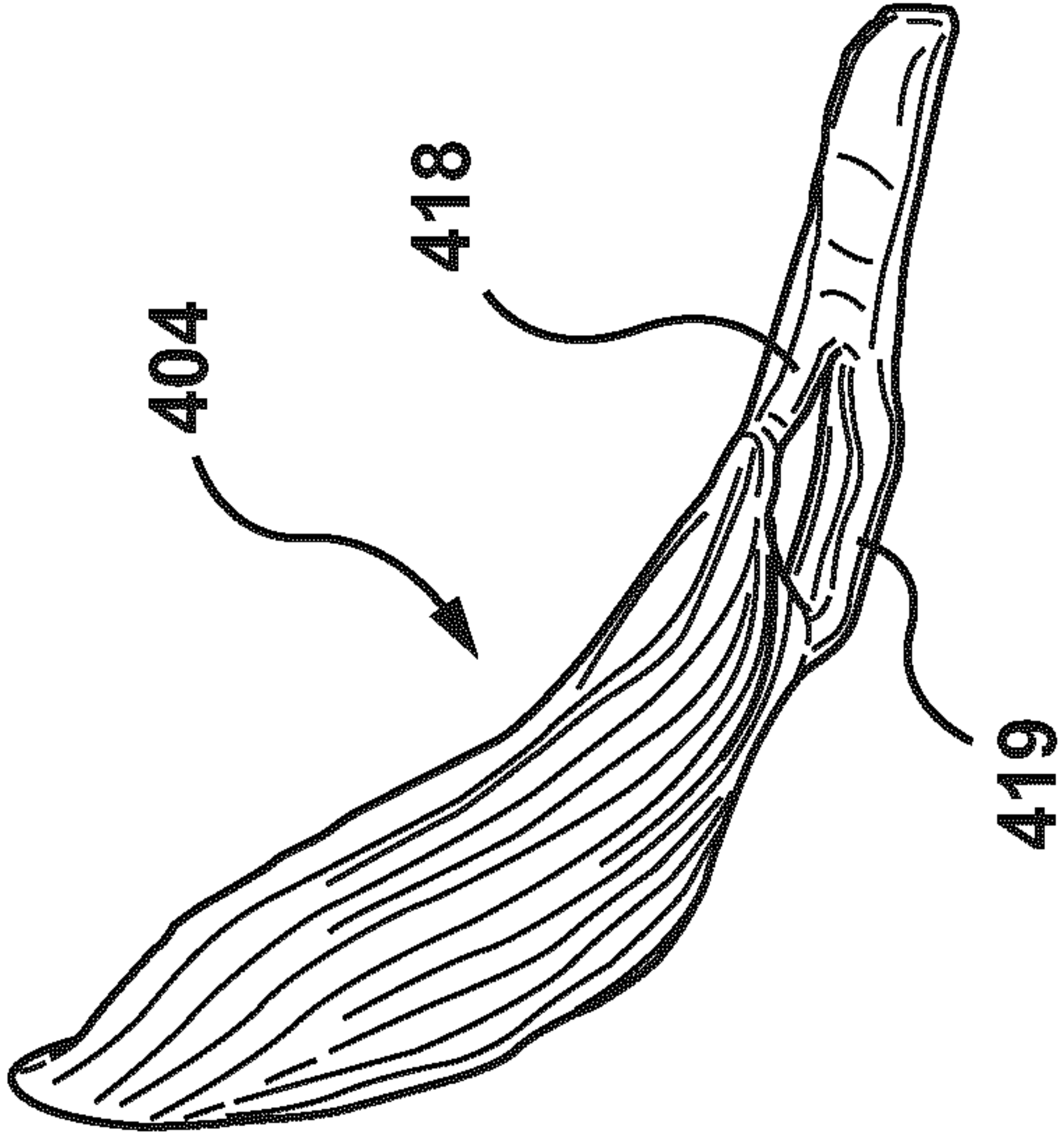


FIG. 13C

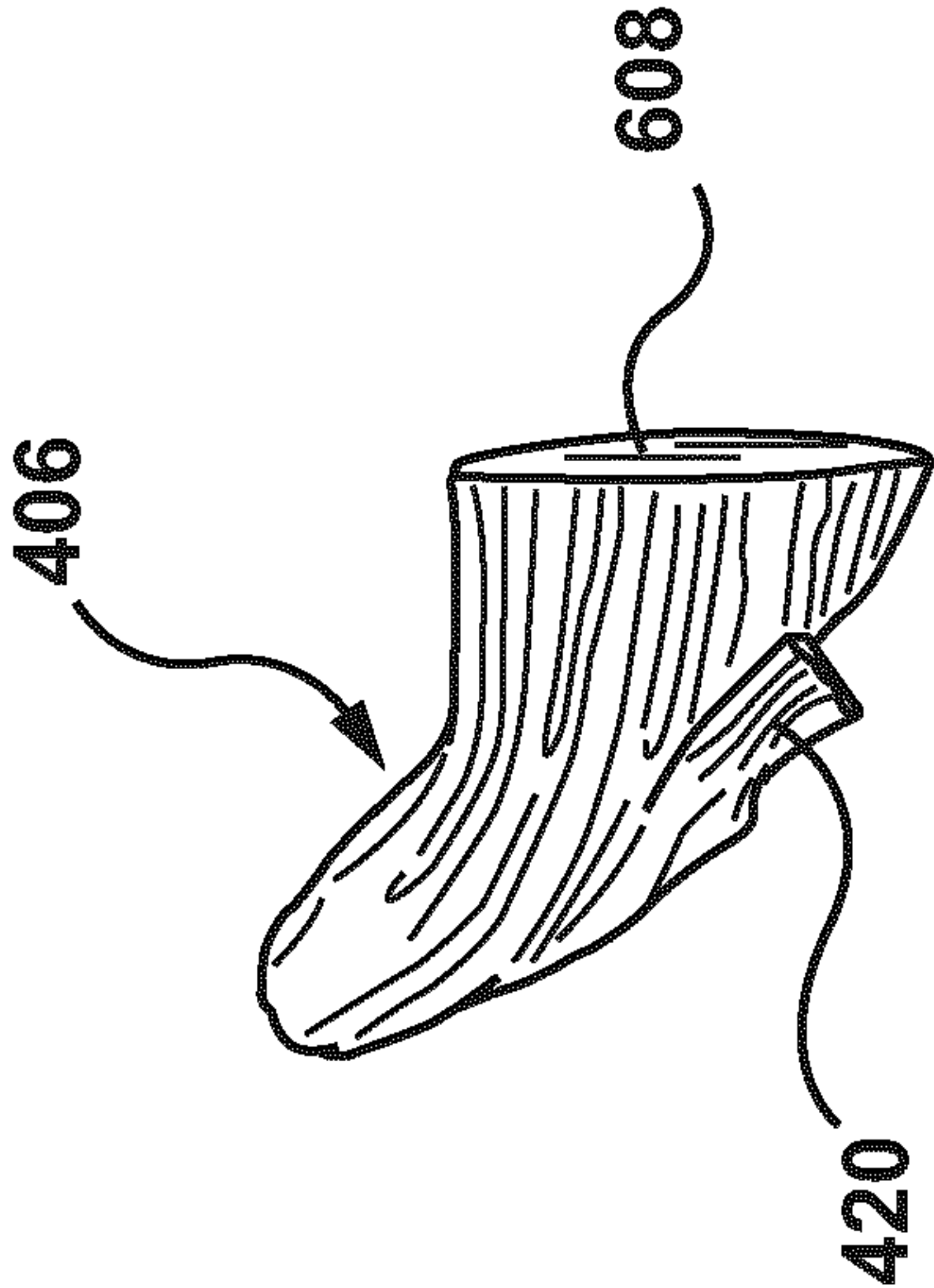


FIG. 14A

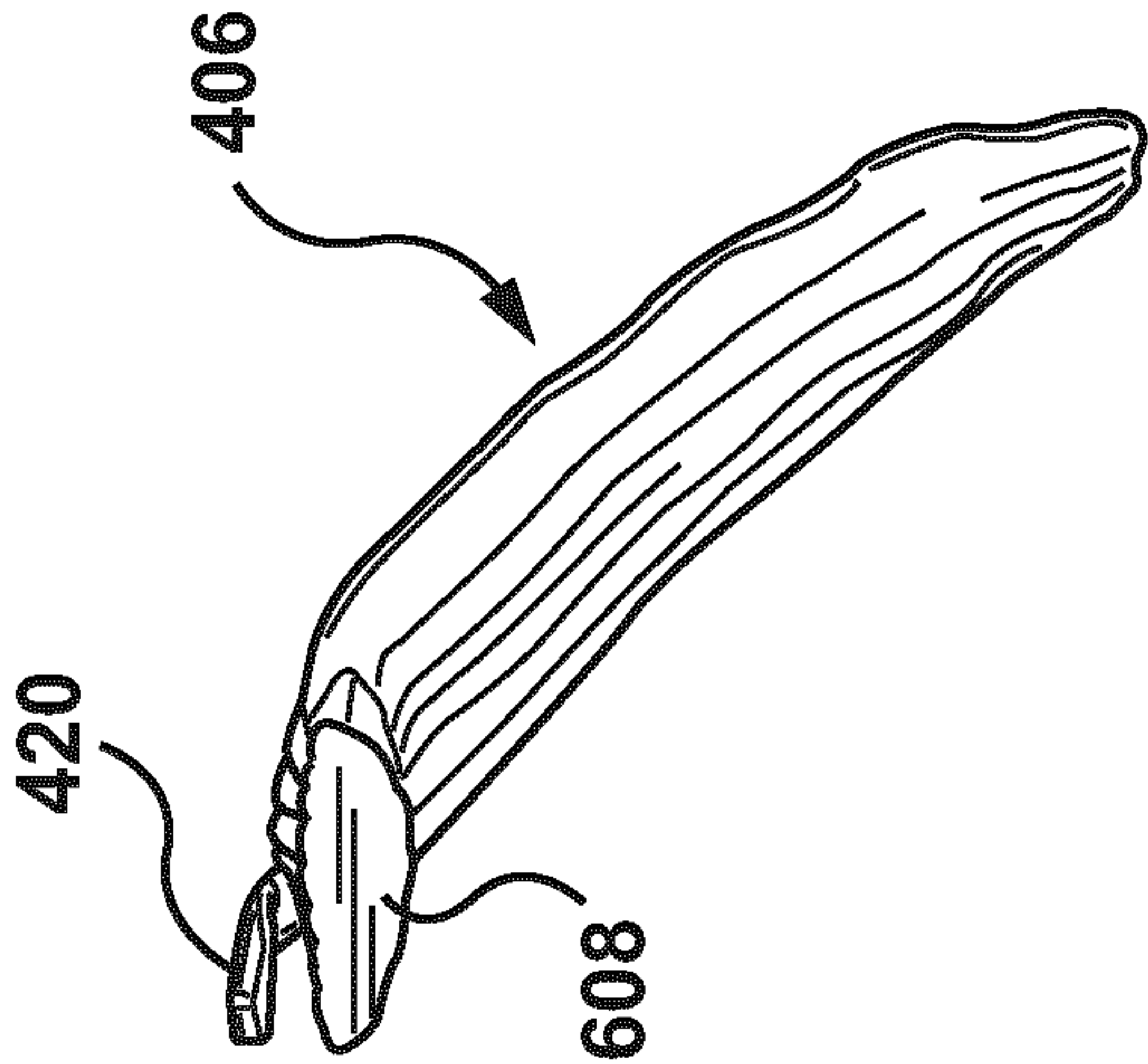


FIG. 14B

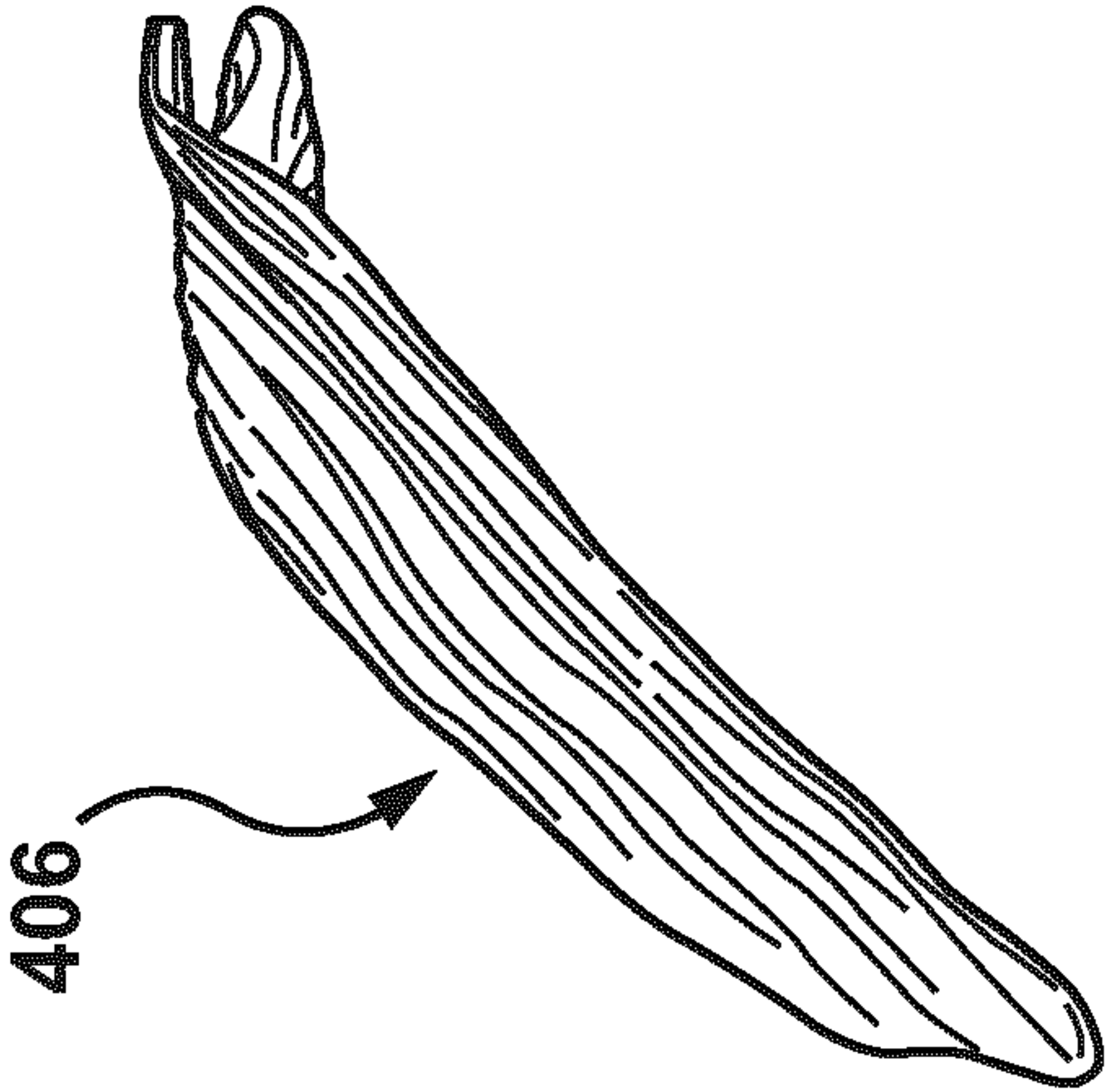
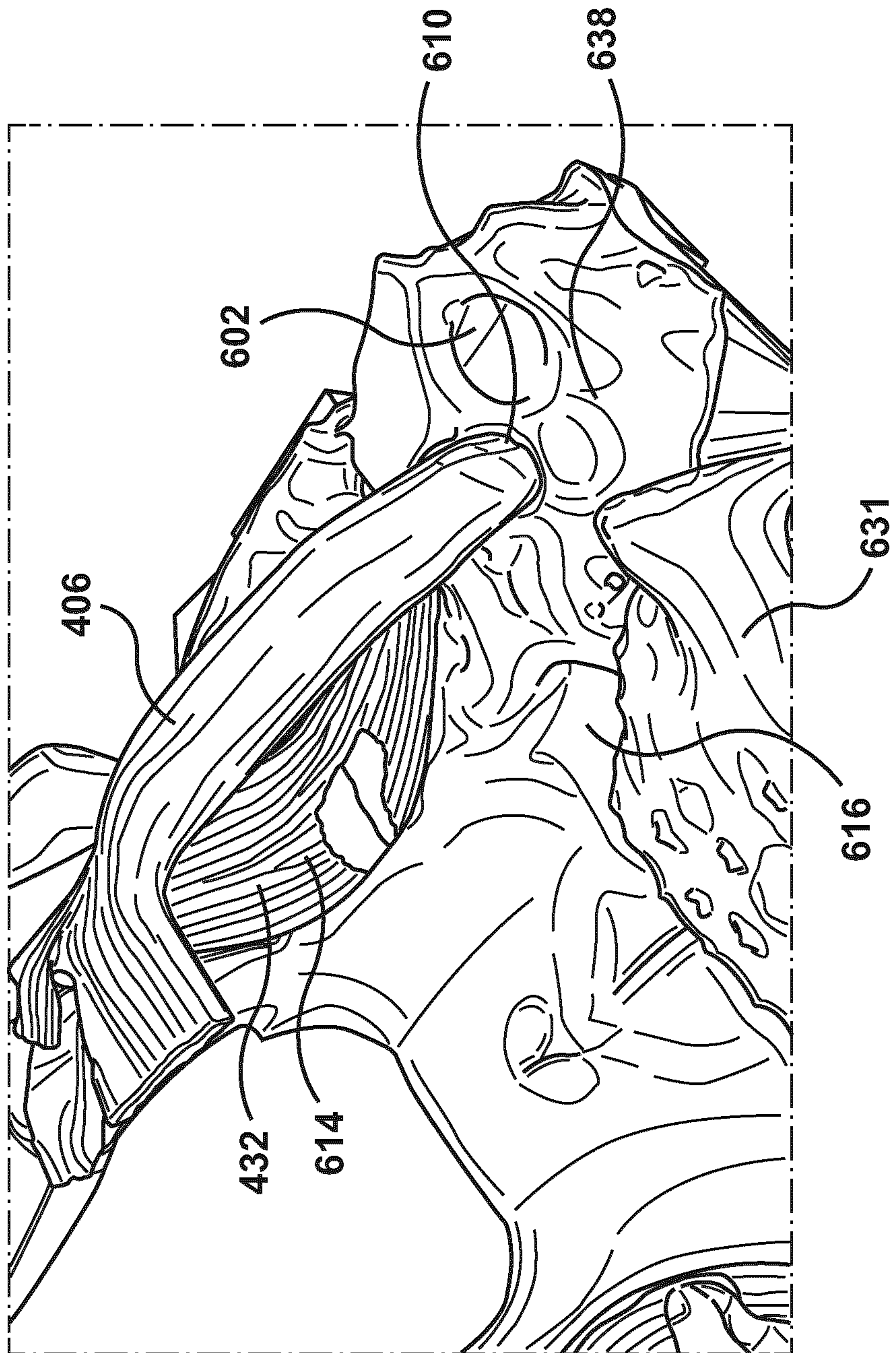
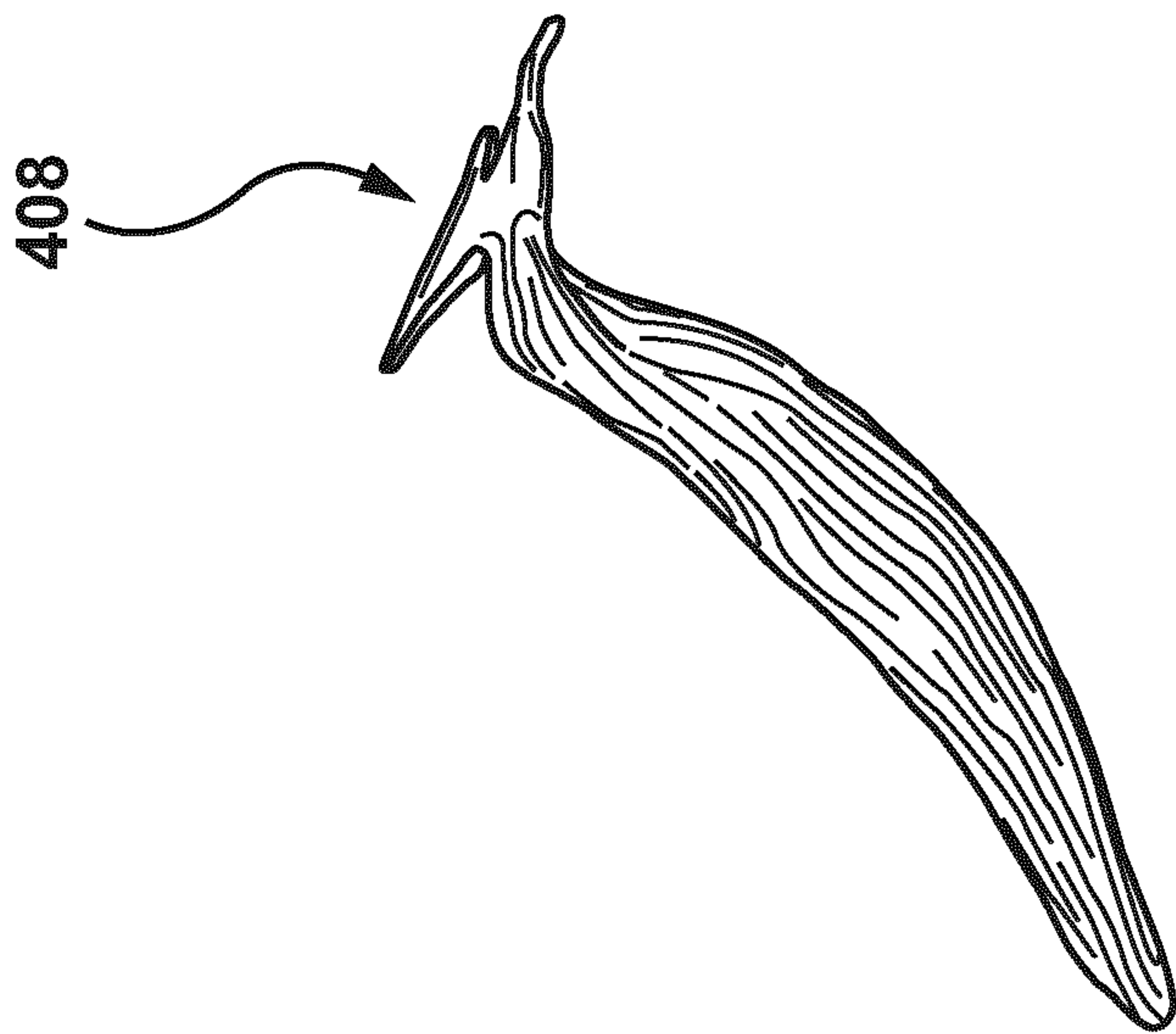
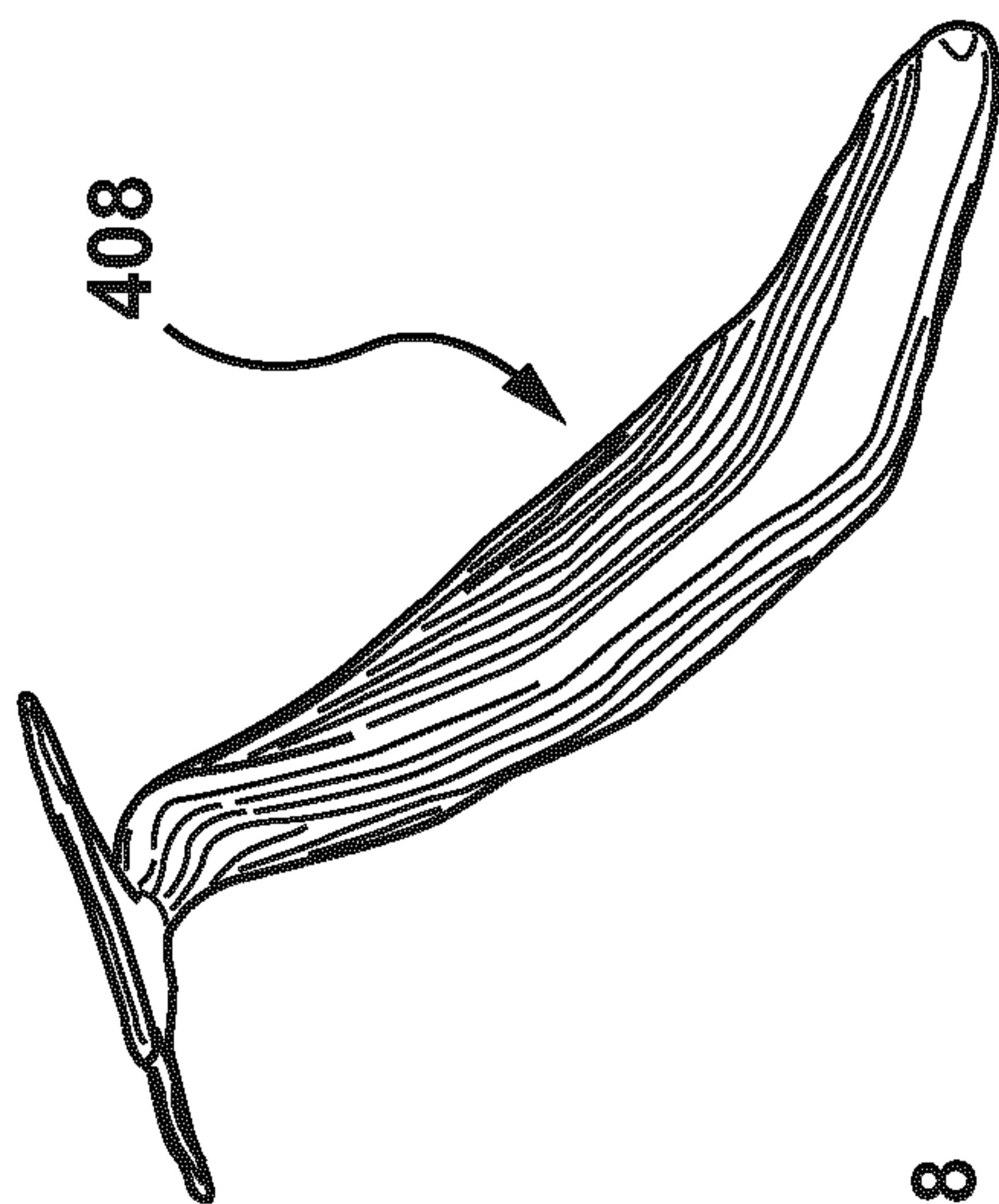
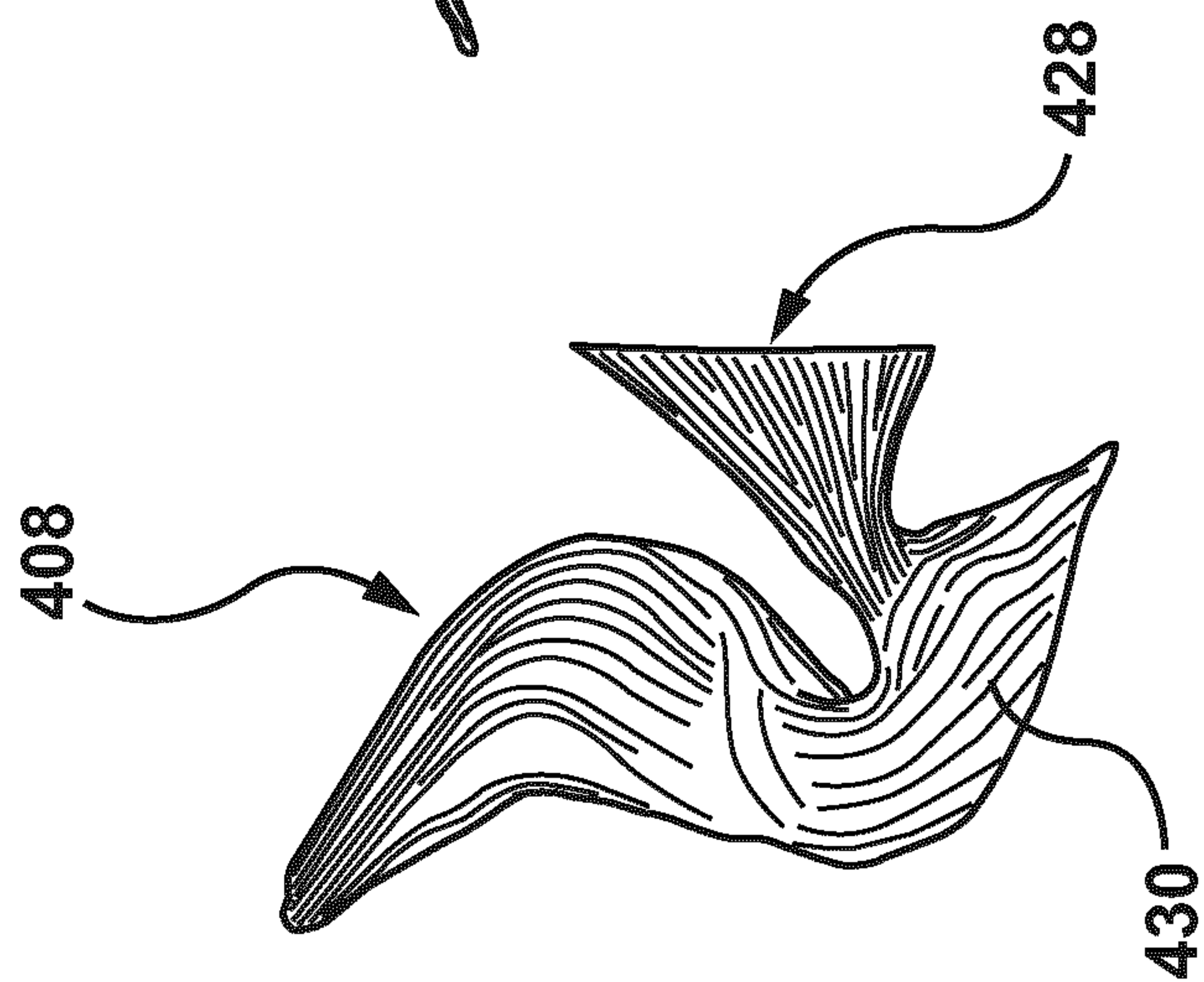


FIG. 14C

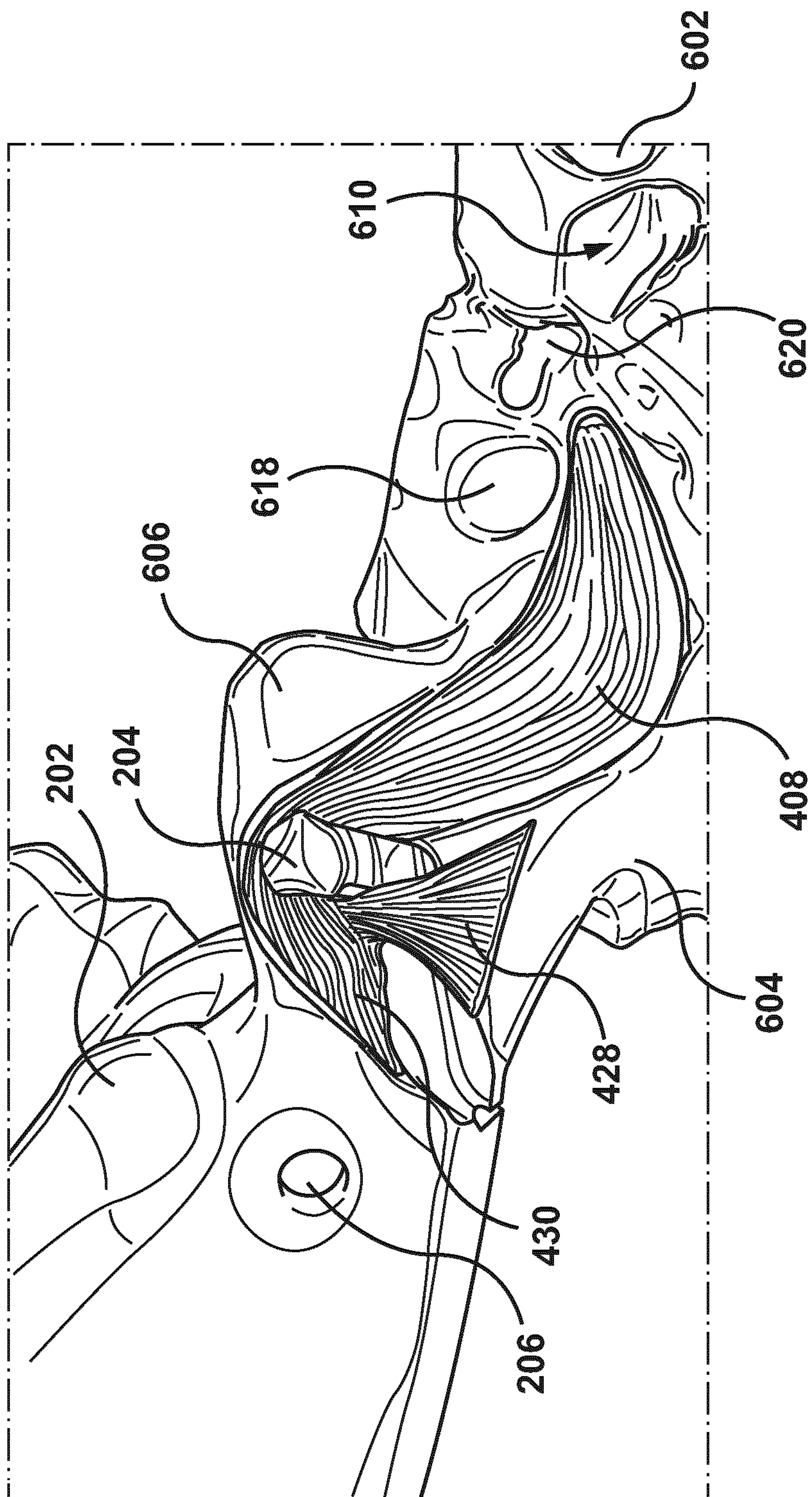
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**FIG. 15**

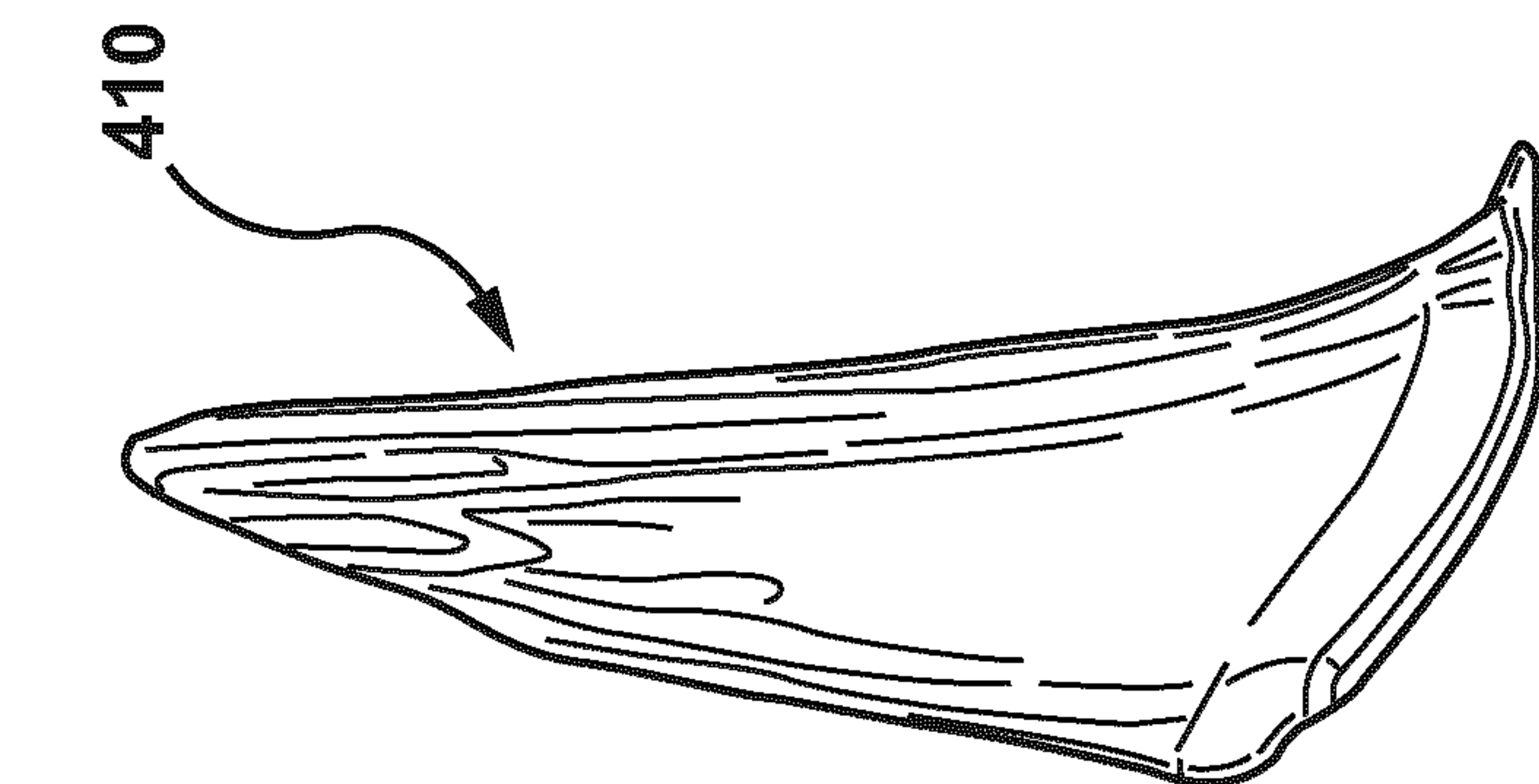
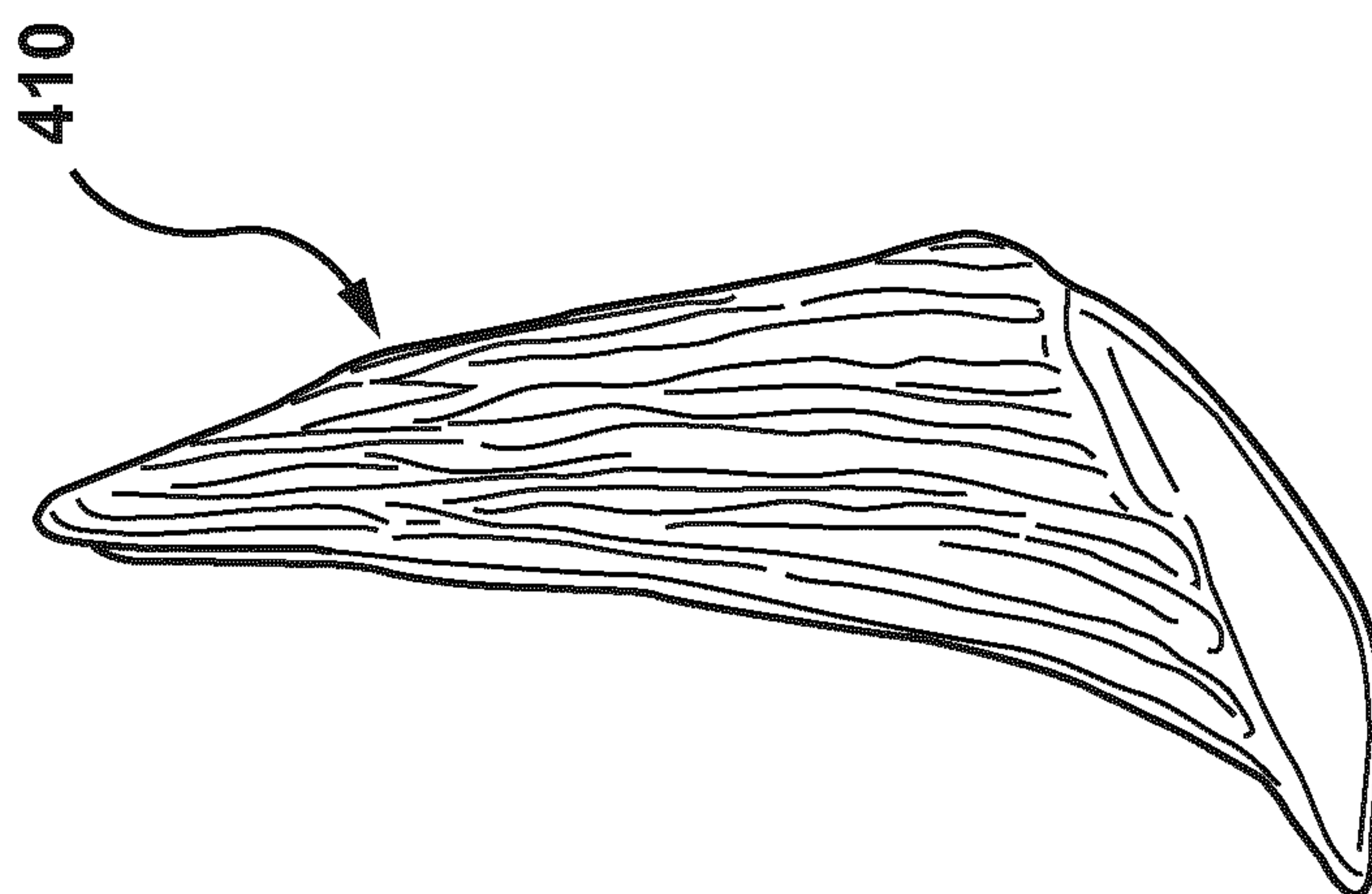
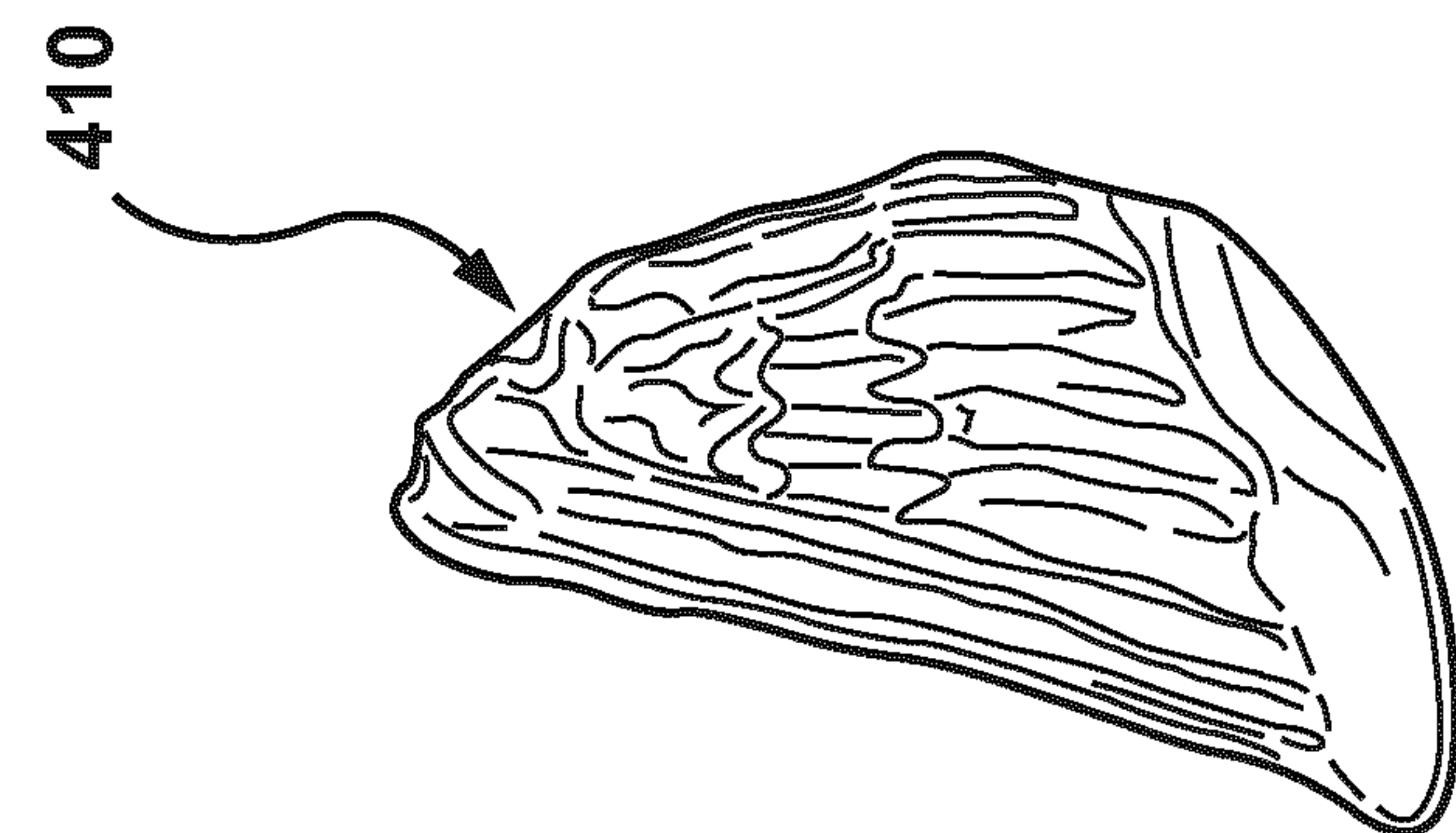
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FIG. 16CFIG. 16BFIG. 16A

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**FIG. 17**

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FIG. 18AFIG. 18BFIG. 18C

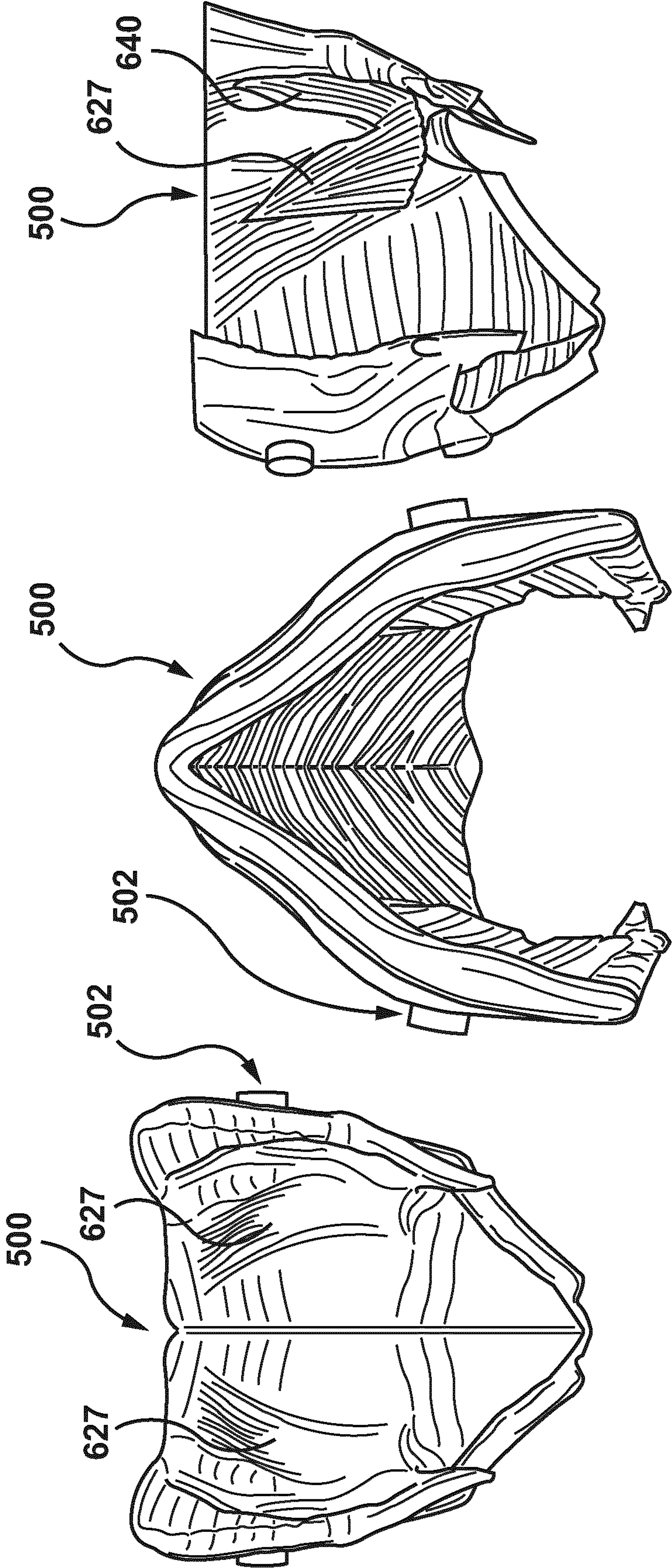
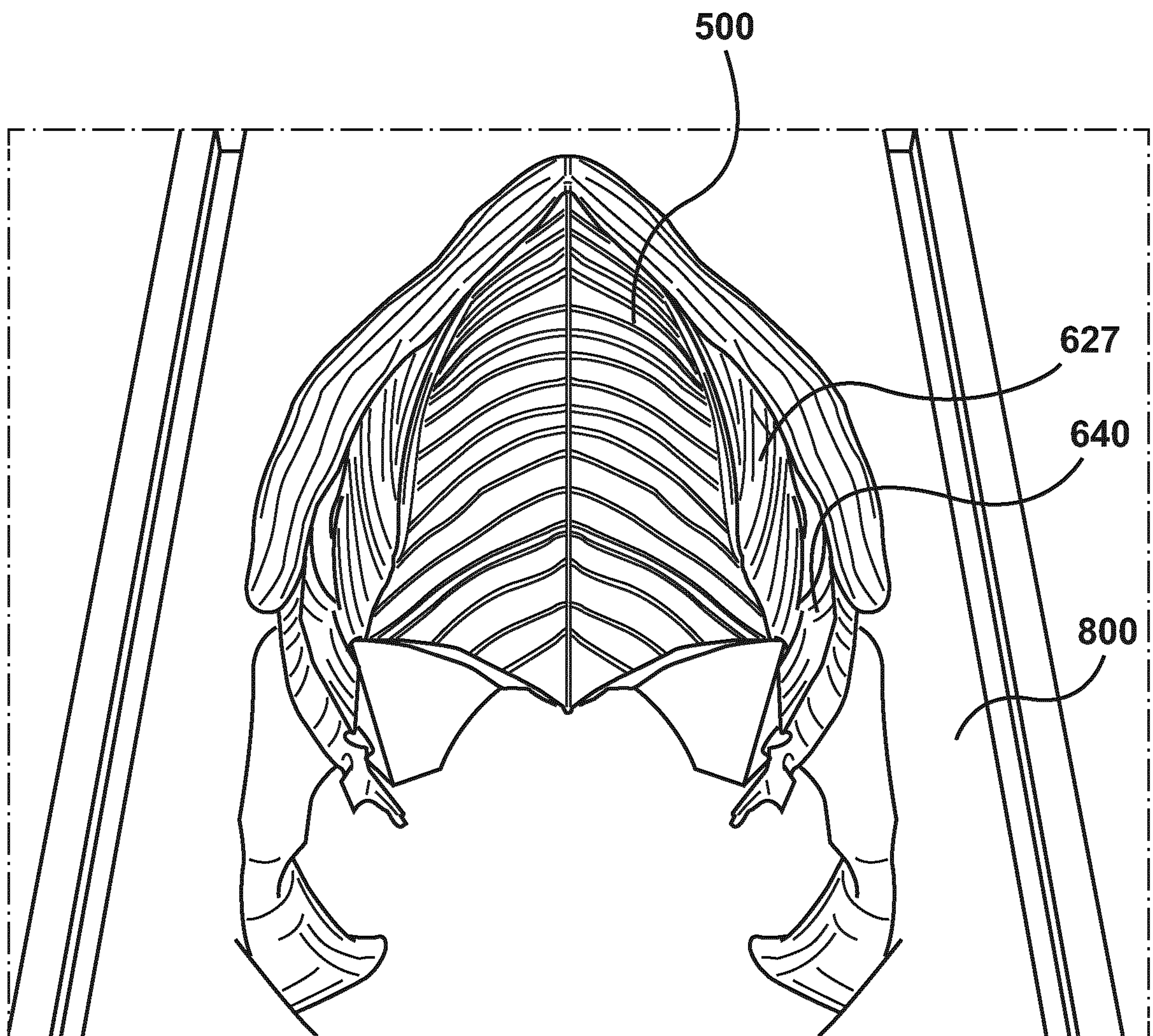


FIG. 19C

FIG. 19B

FIG. 19A

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**FIG. 20**

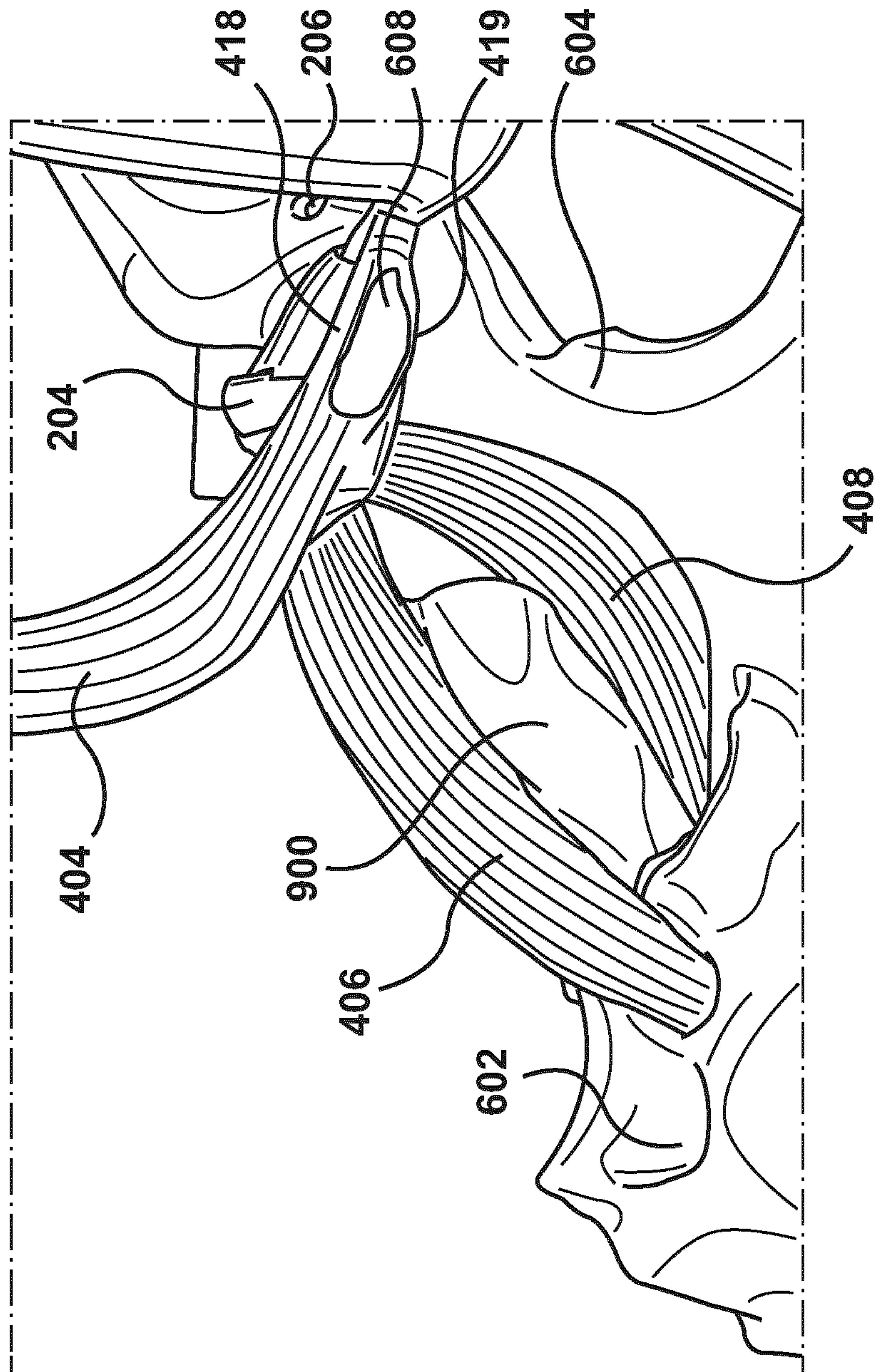
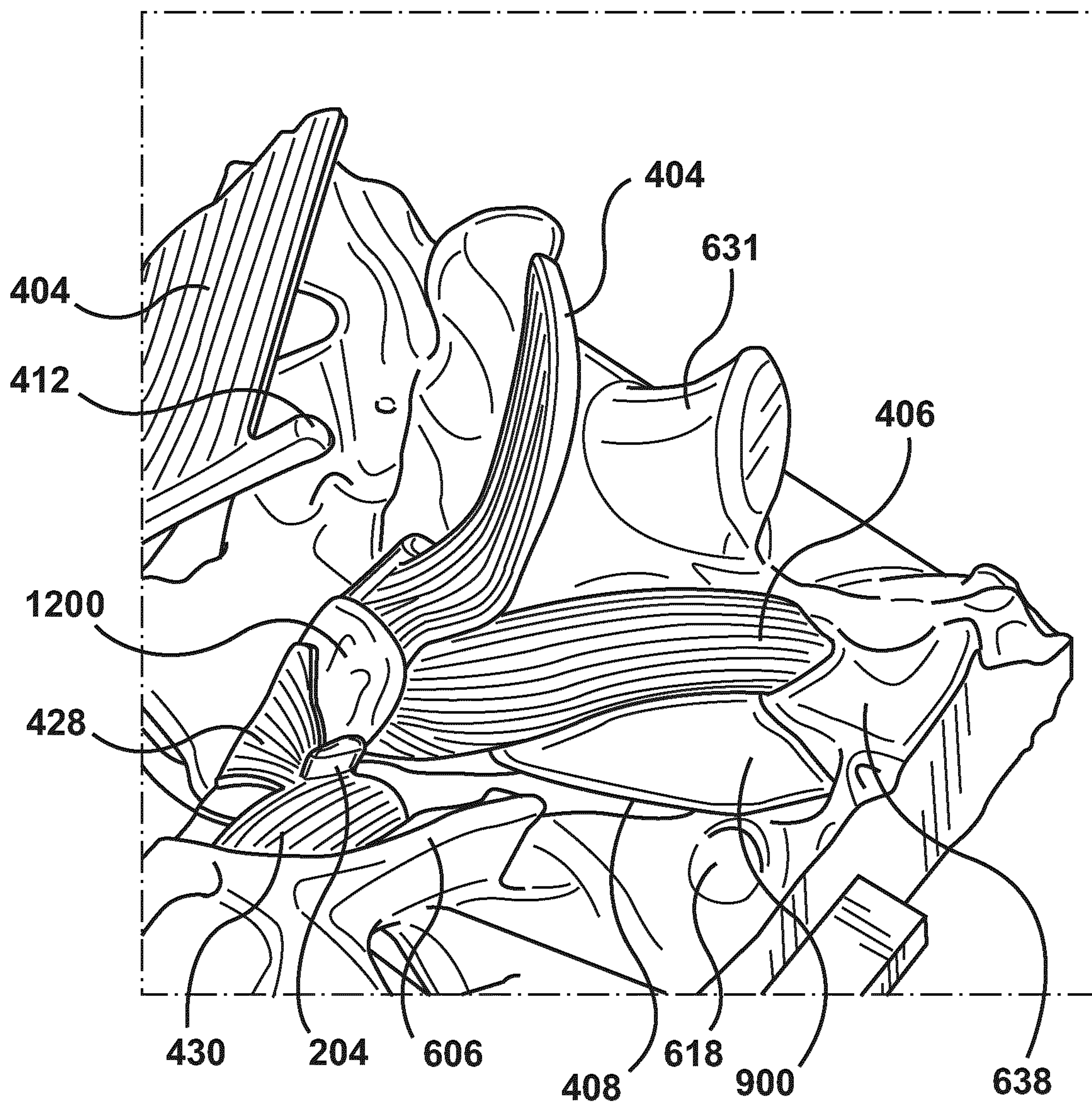
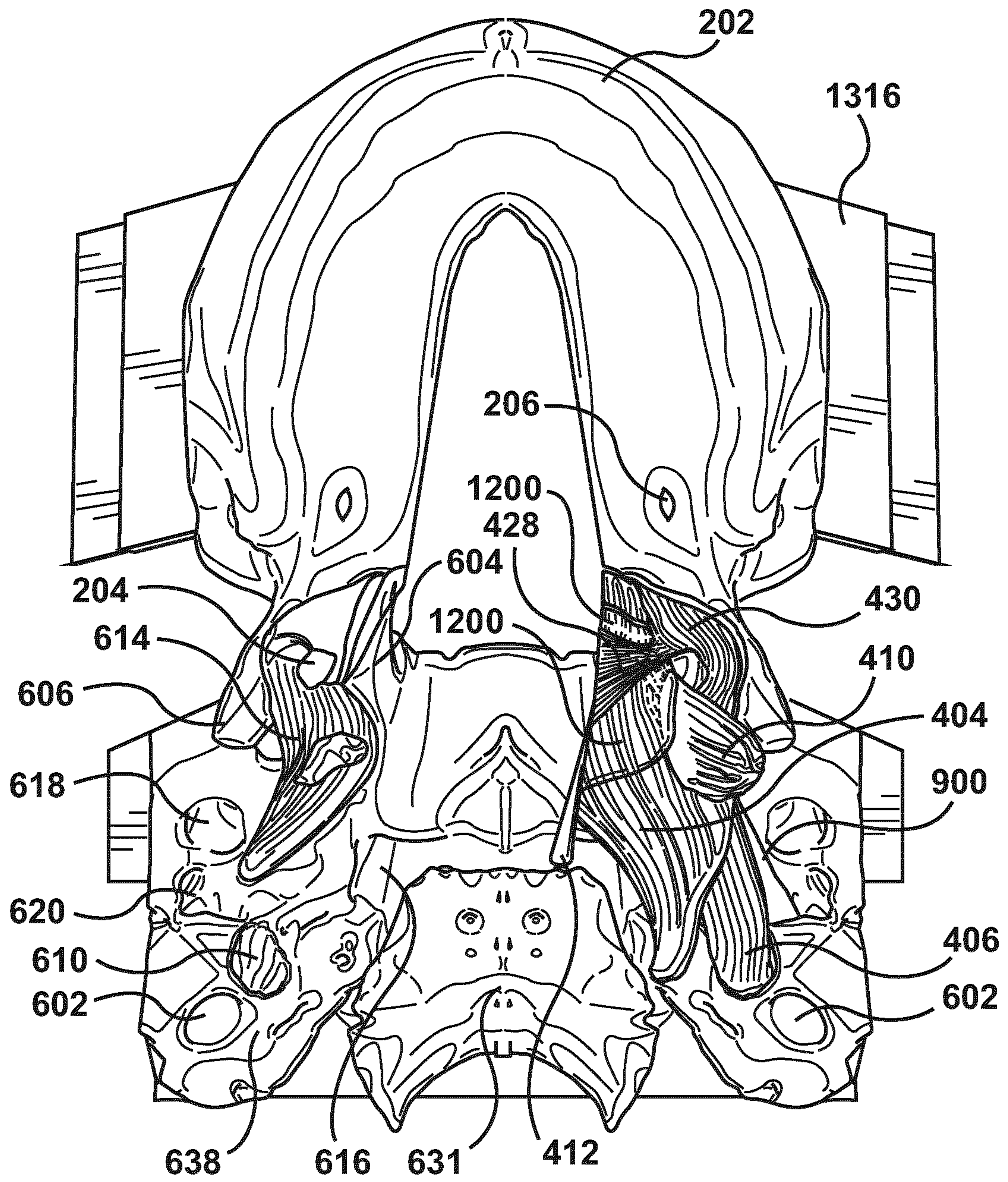


FIG. 21

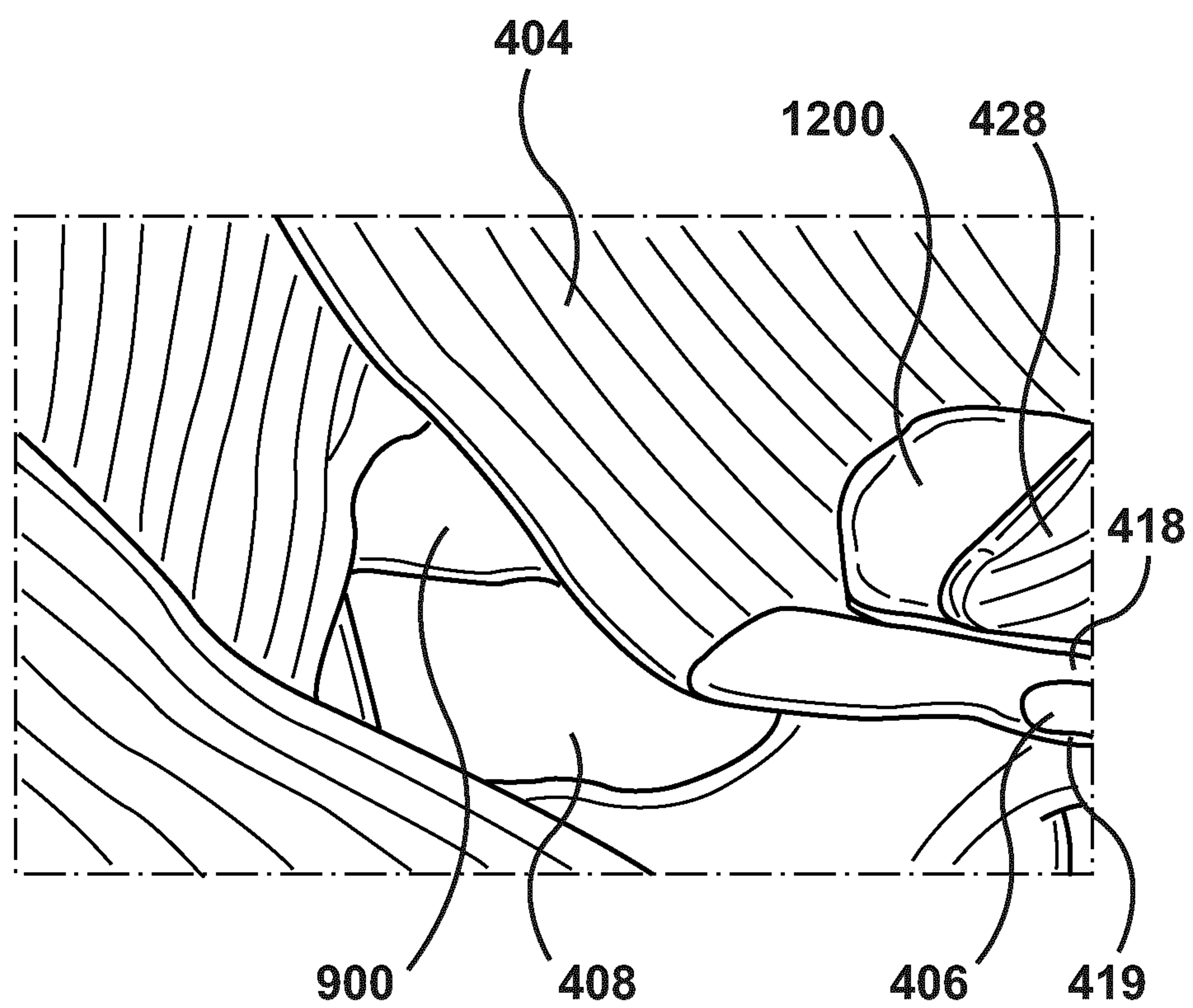
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**FIG. 22**

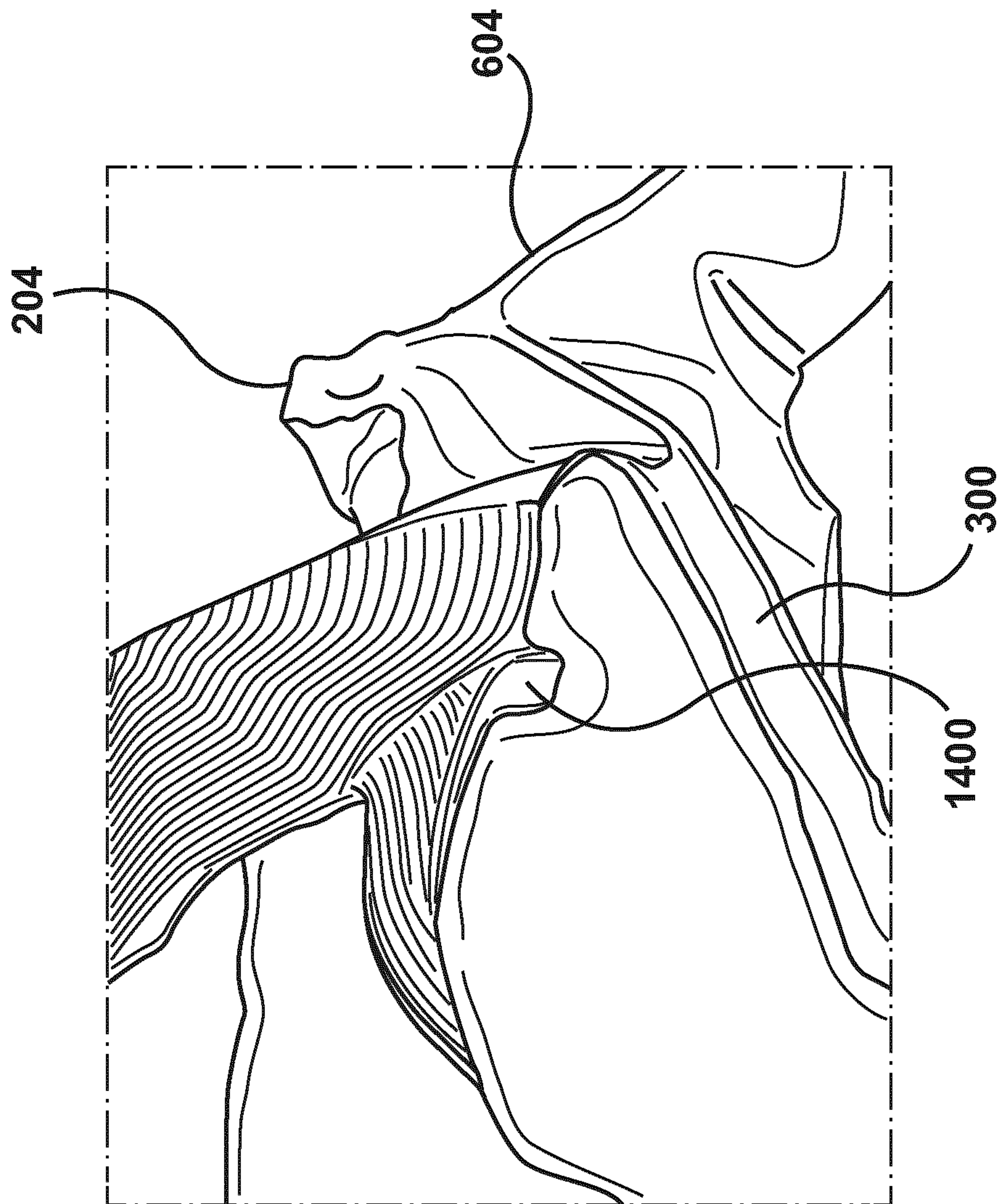
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**FIG. 23**

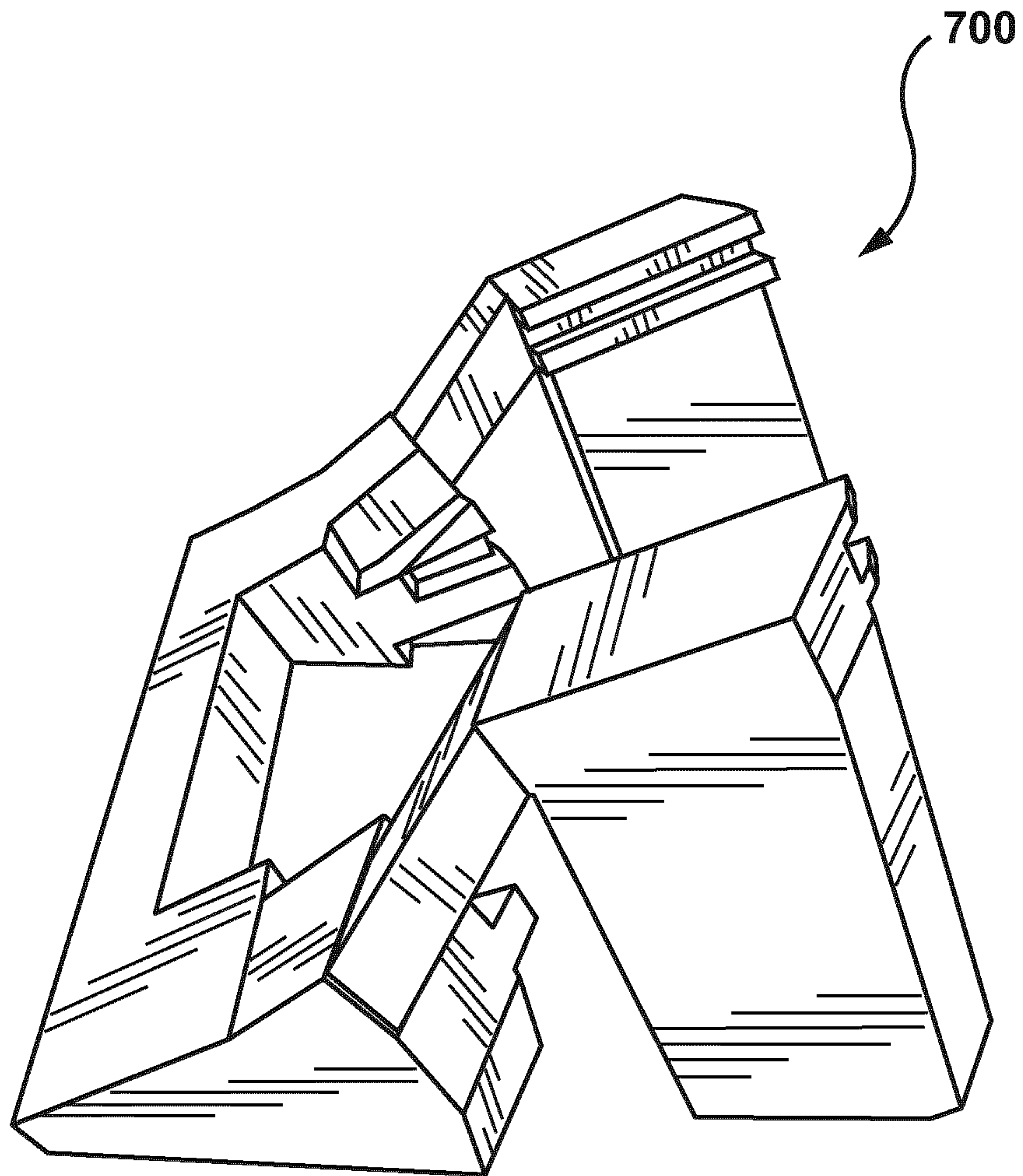
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**FIG. 24**

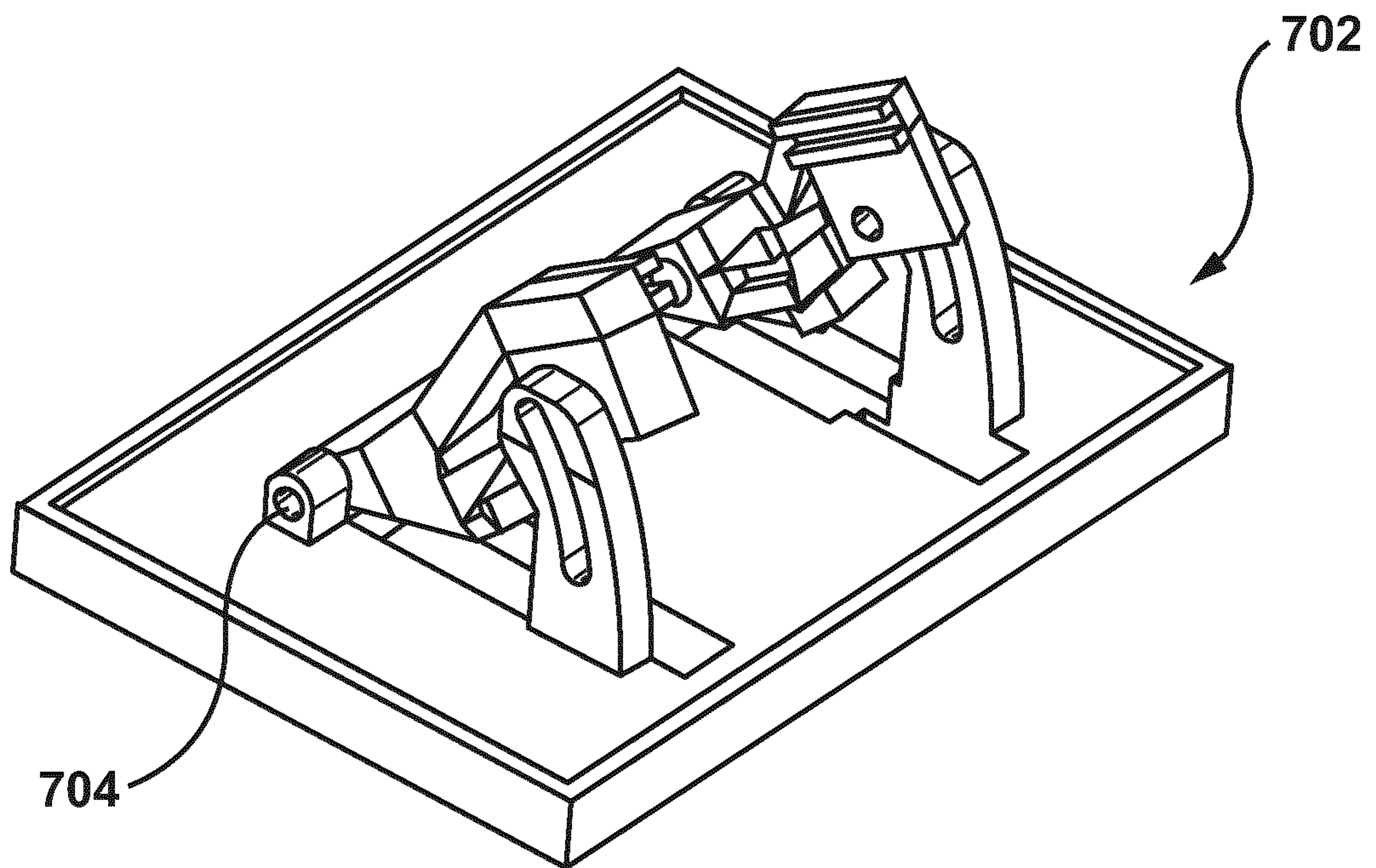
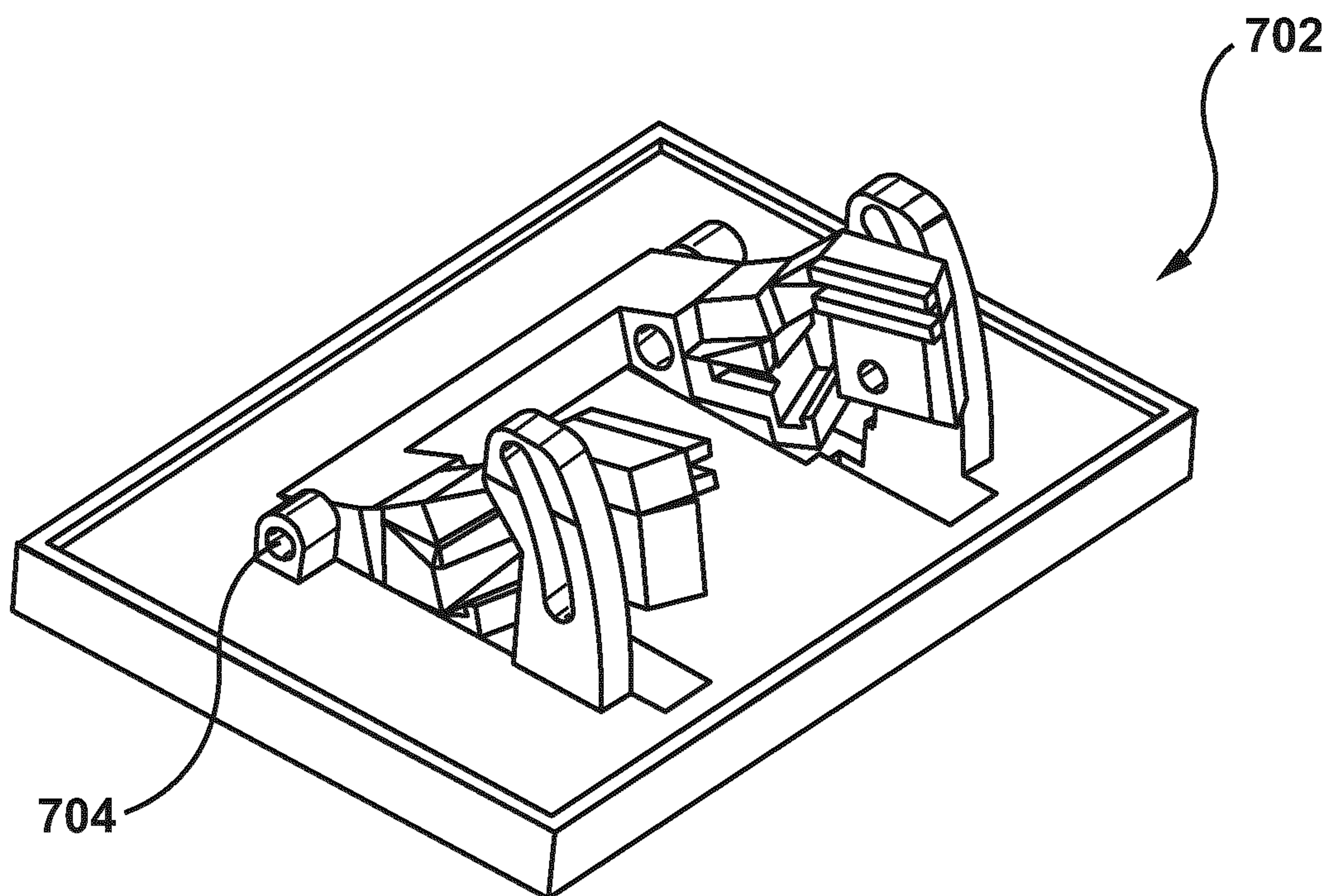
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**FIG. 25**

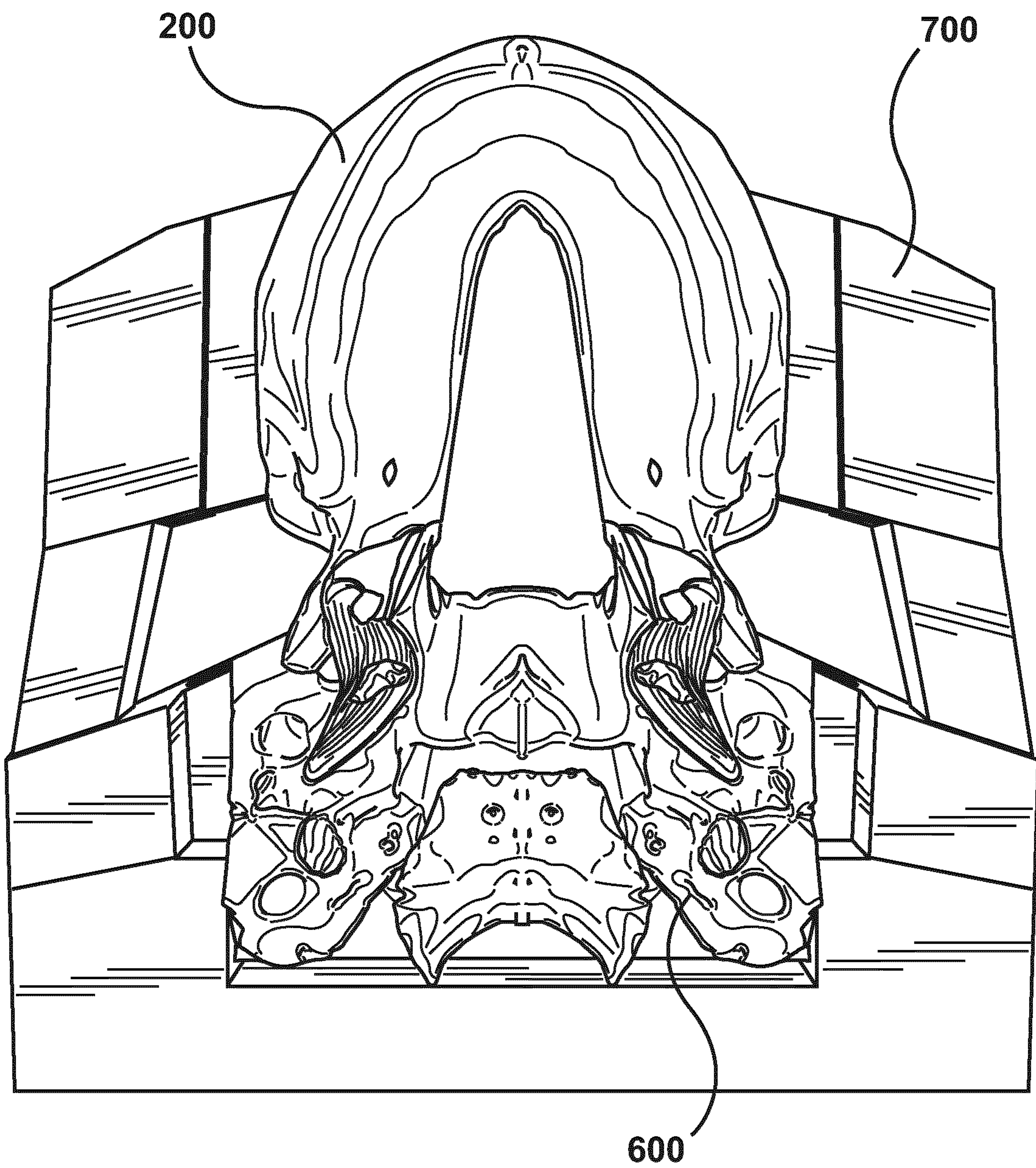
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**FIG. 26**

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**FIG. 27A****FIG. 27B**

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**FIG. 28**

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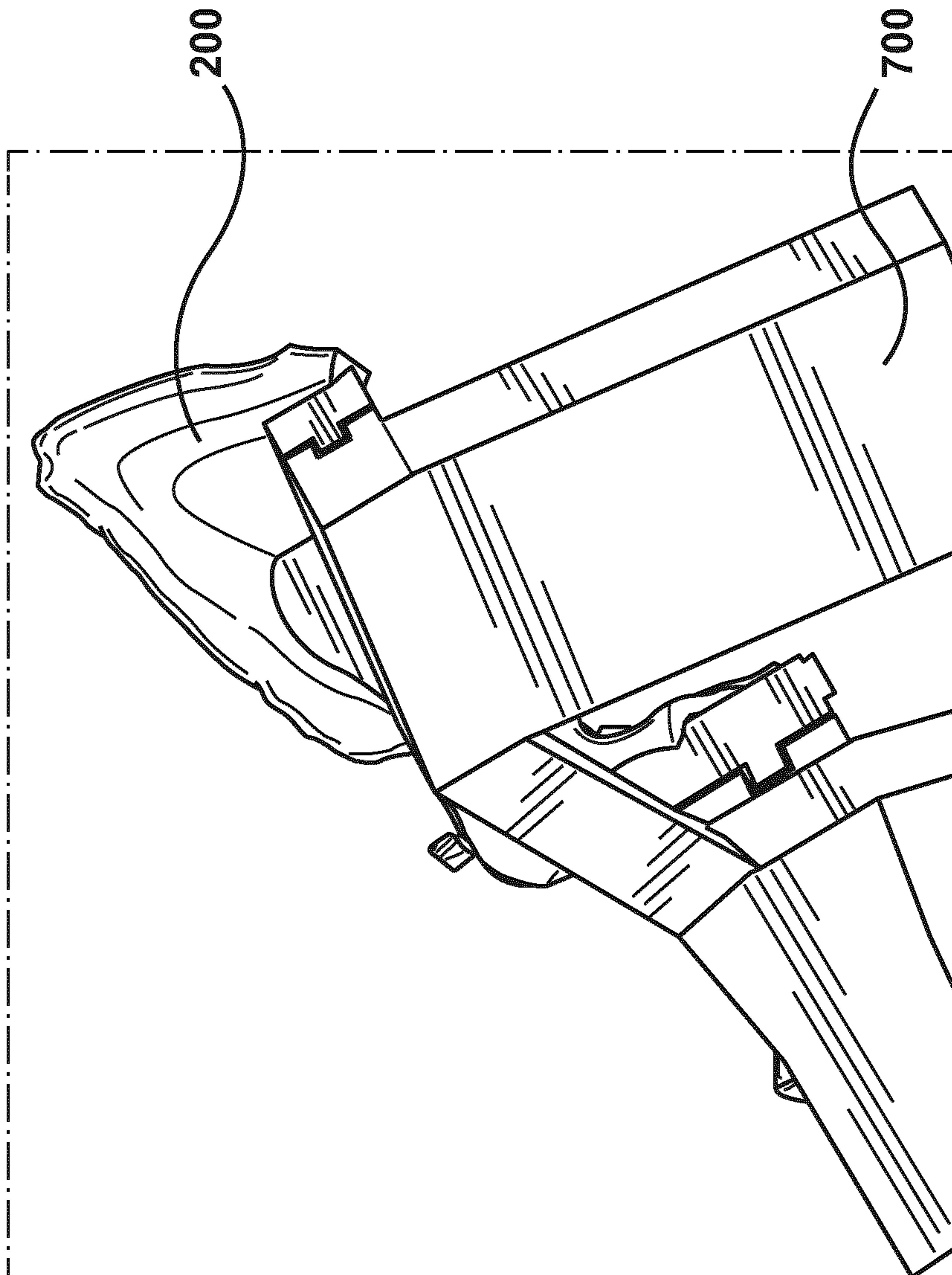
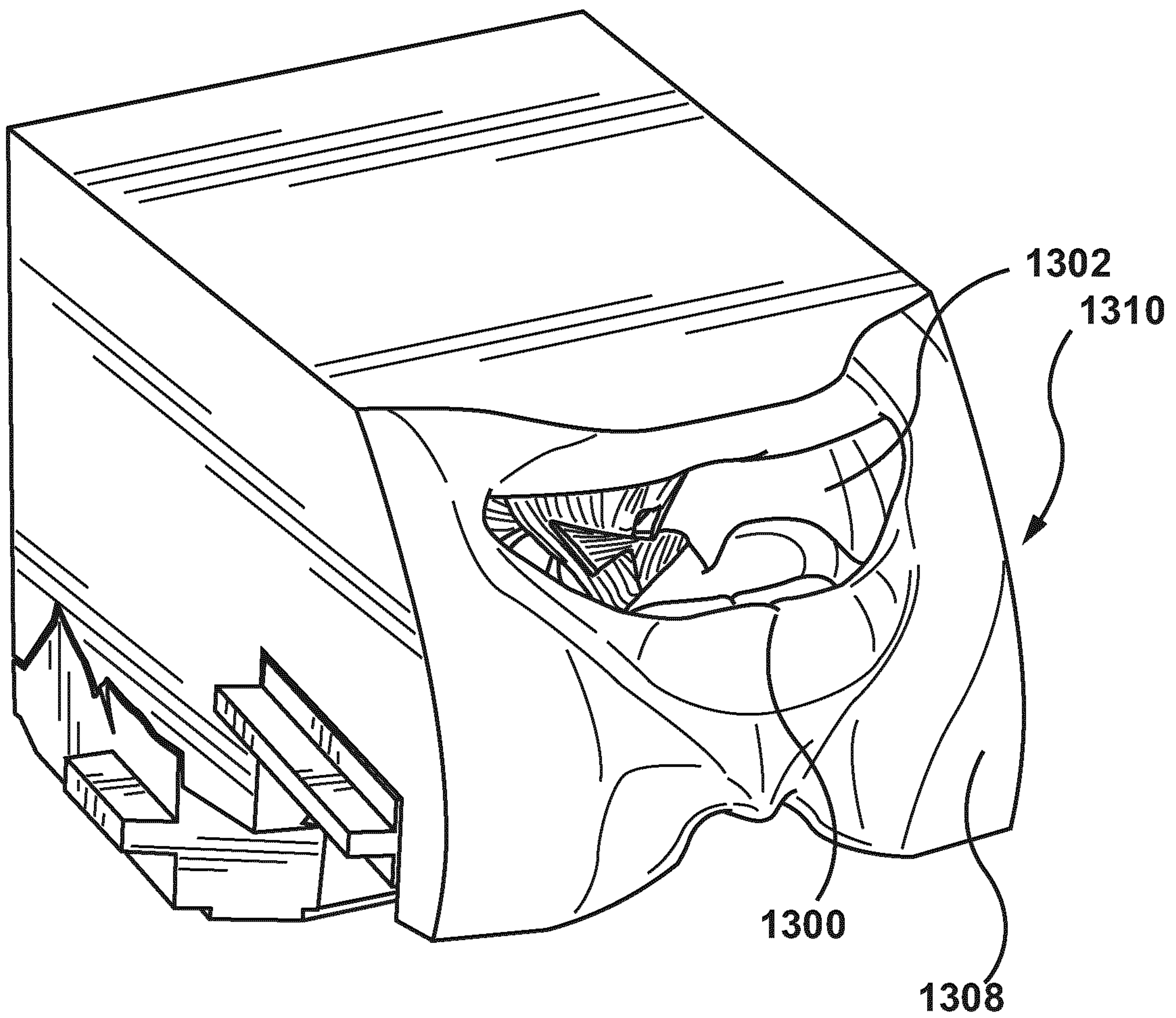
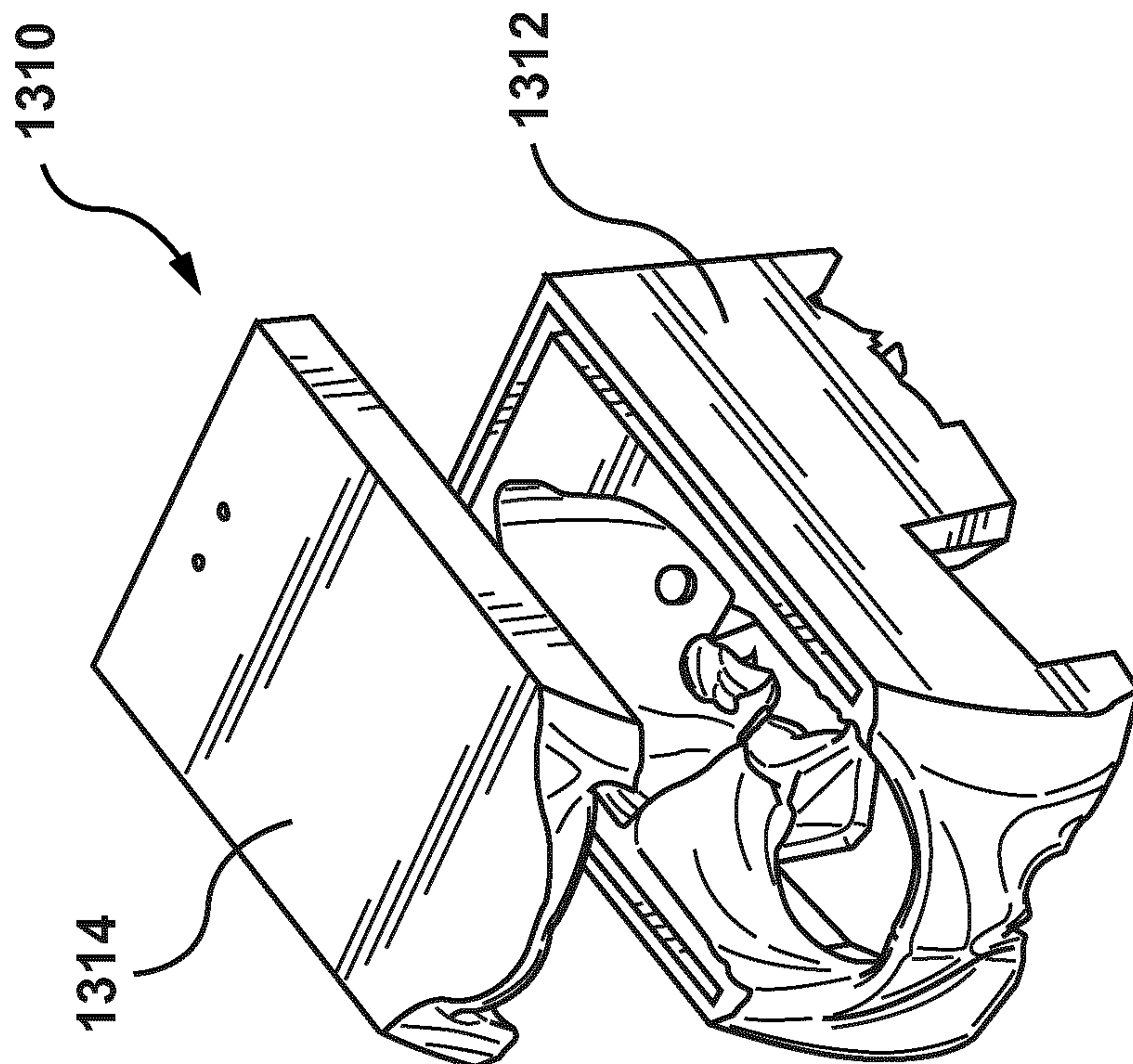
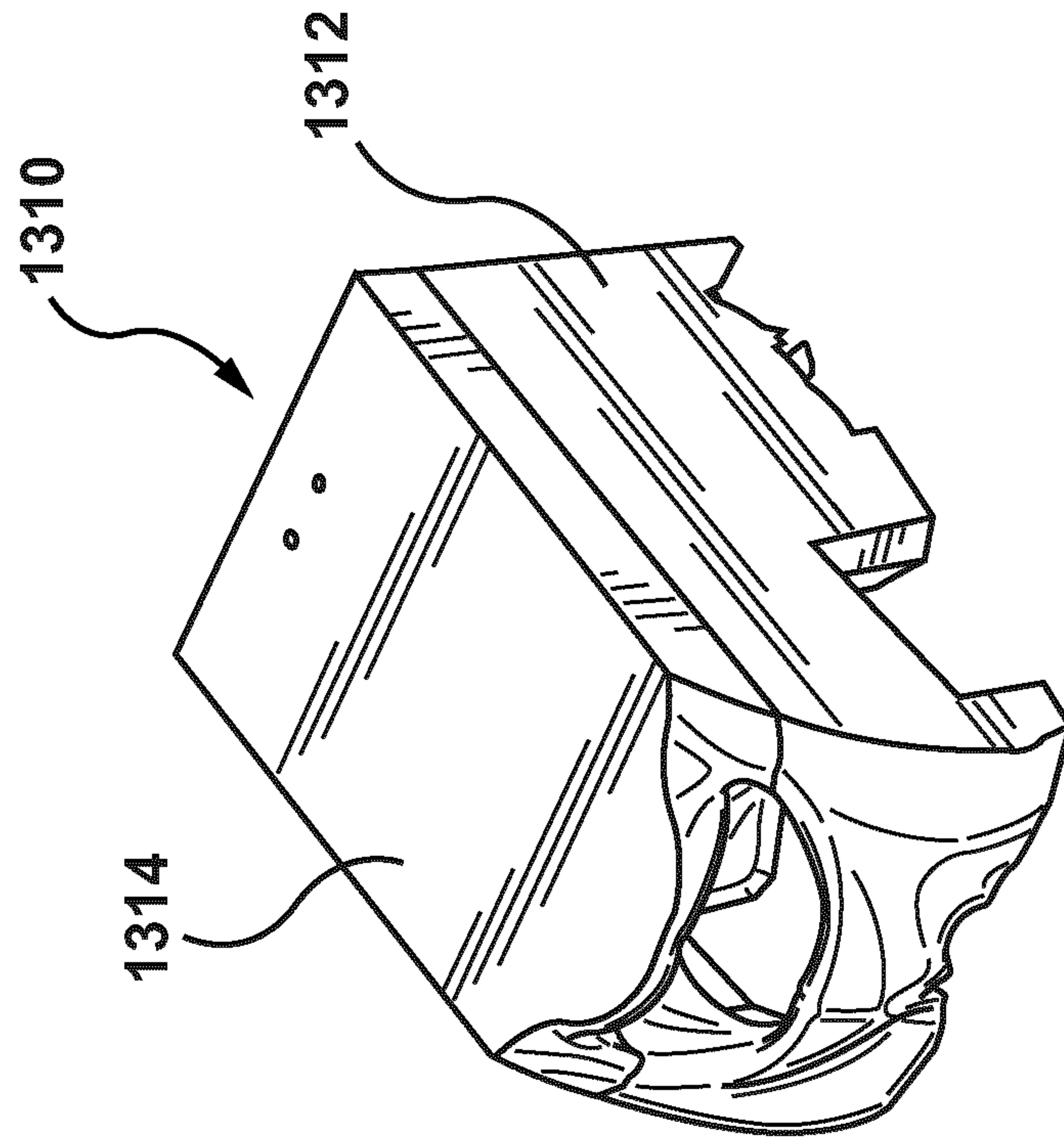


FIG. 29

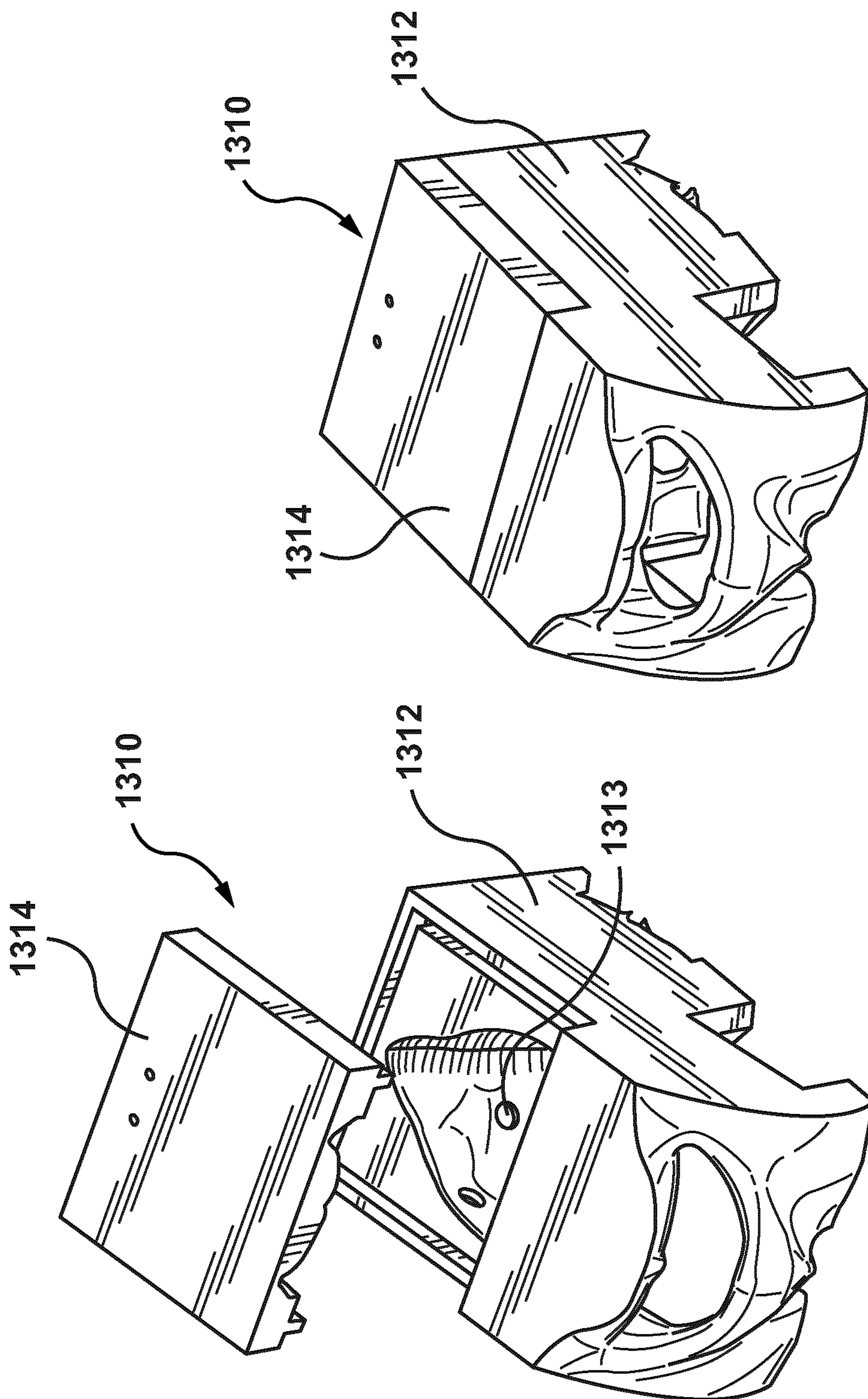
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**FIG. 30**

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FIG. 32BFIG. 32A

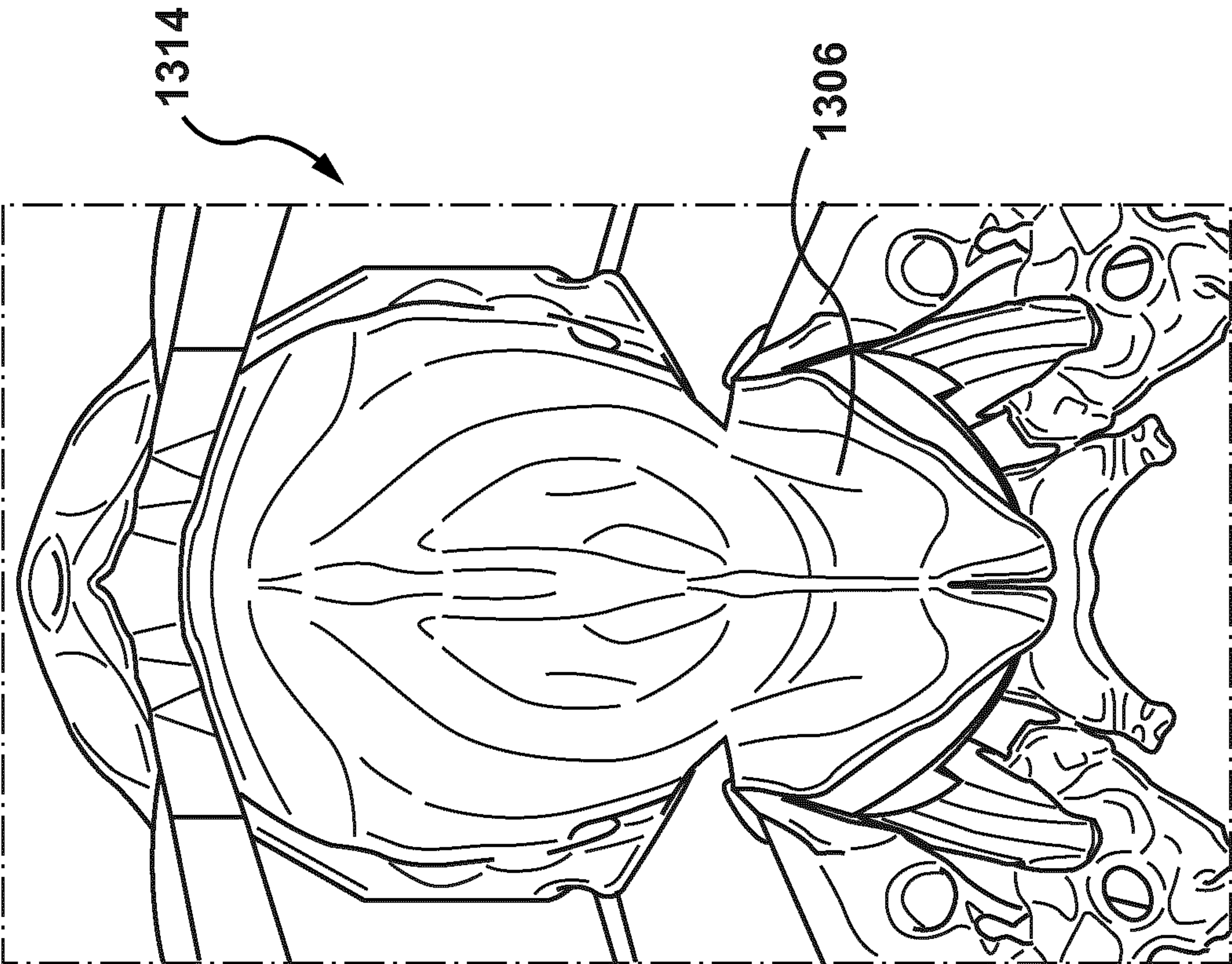


FIG. 32D

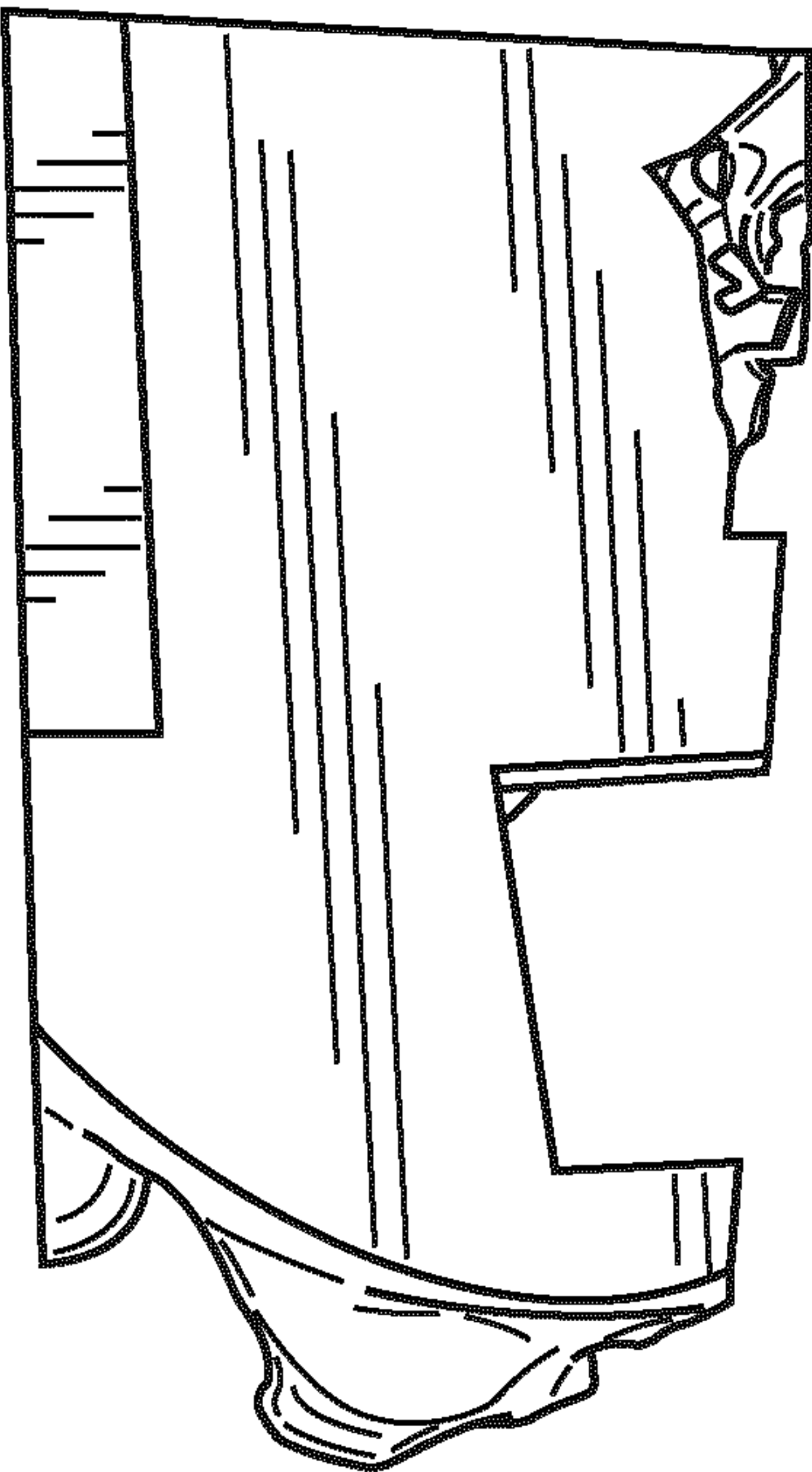


FIG. 32C

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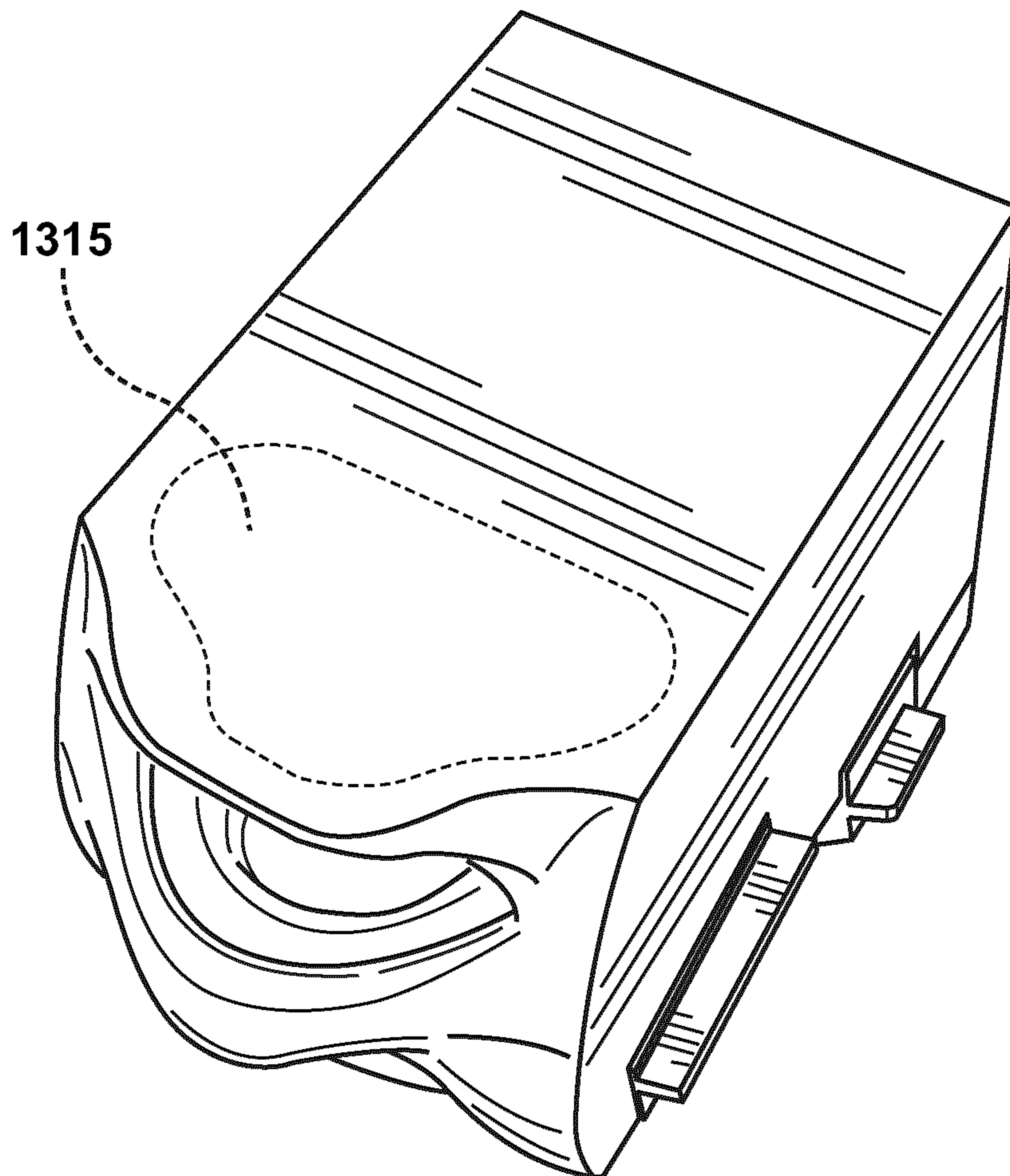
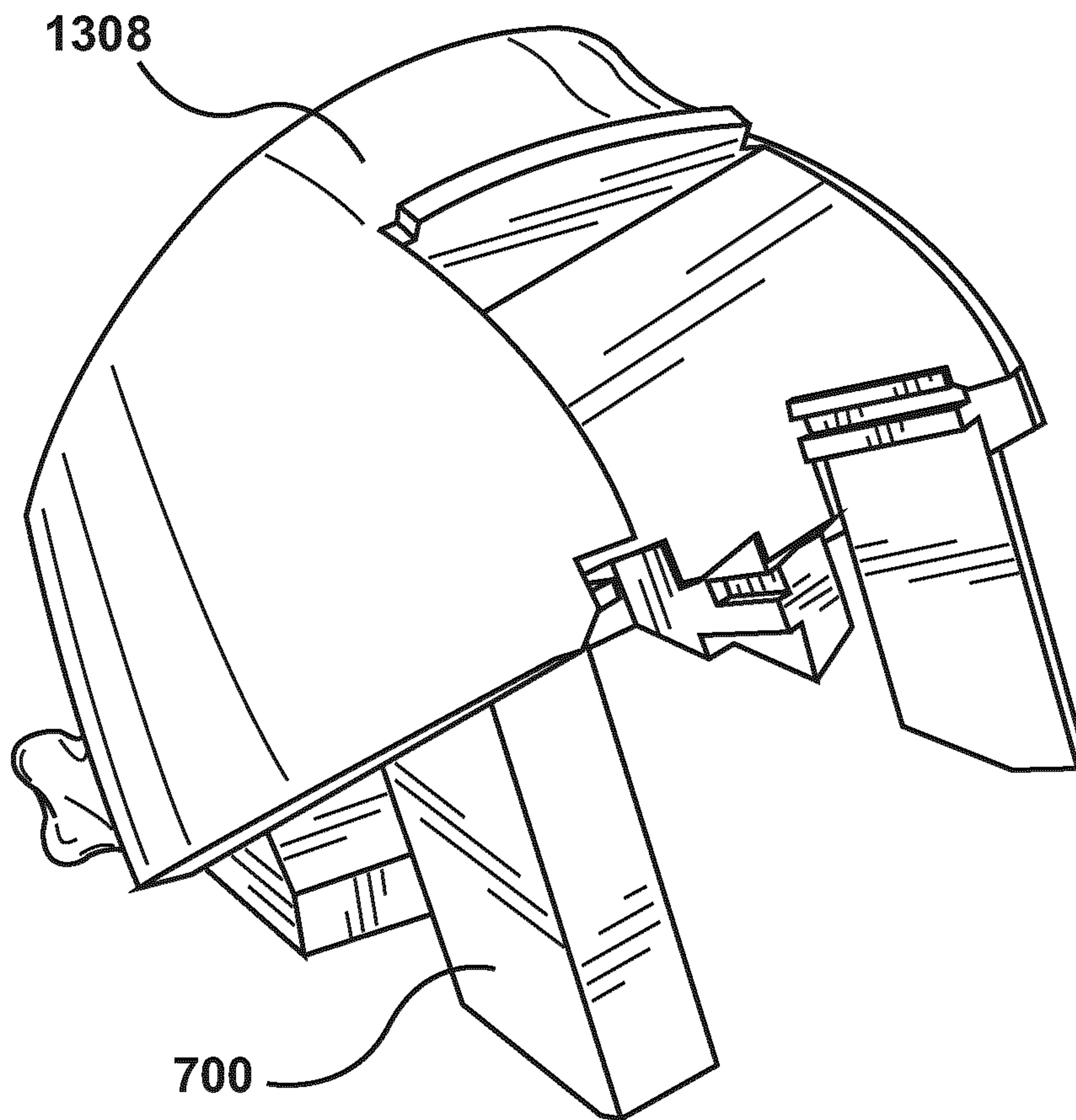
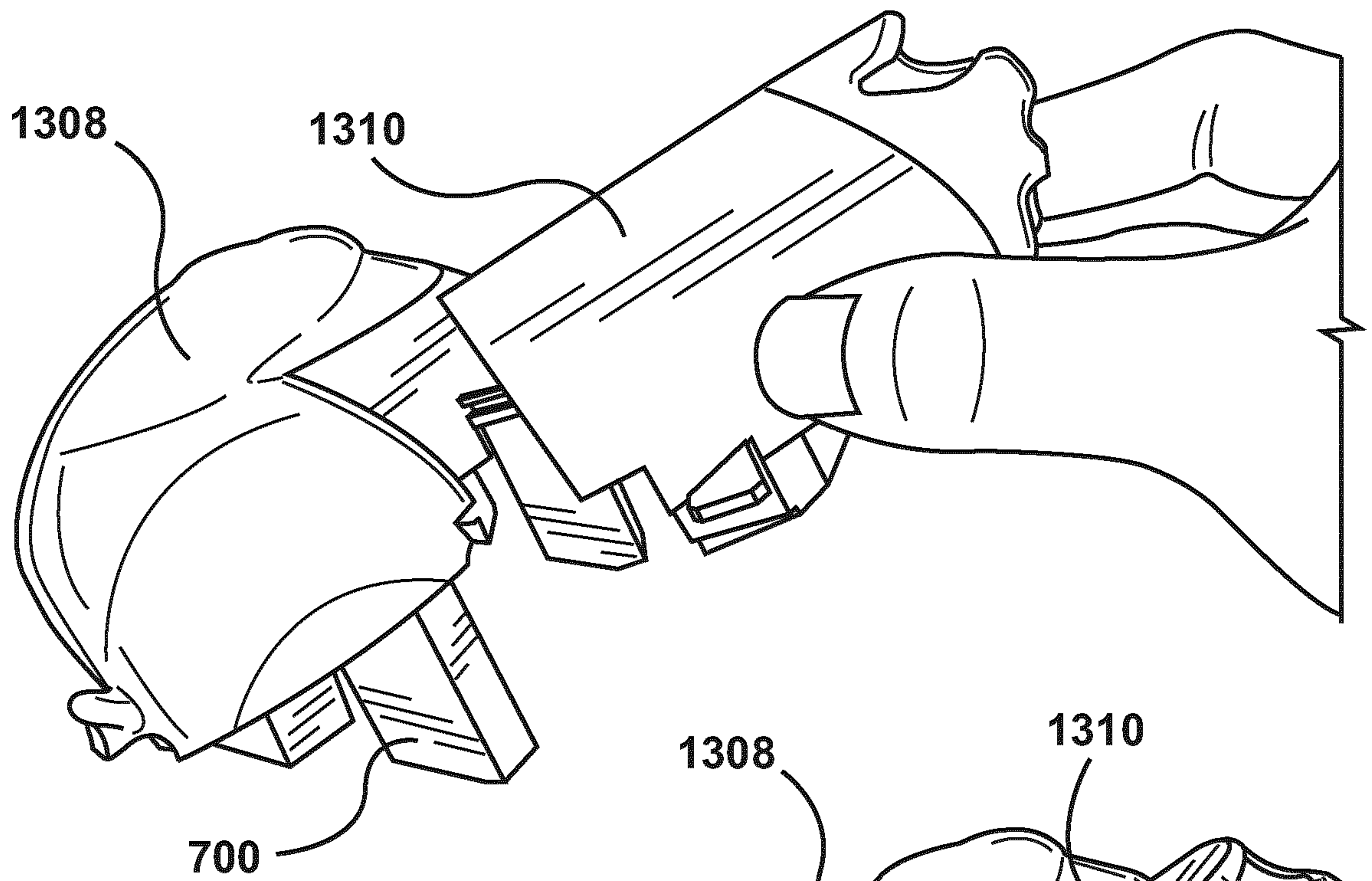
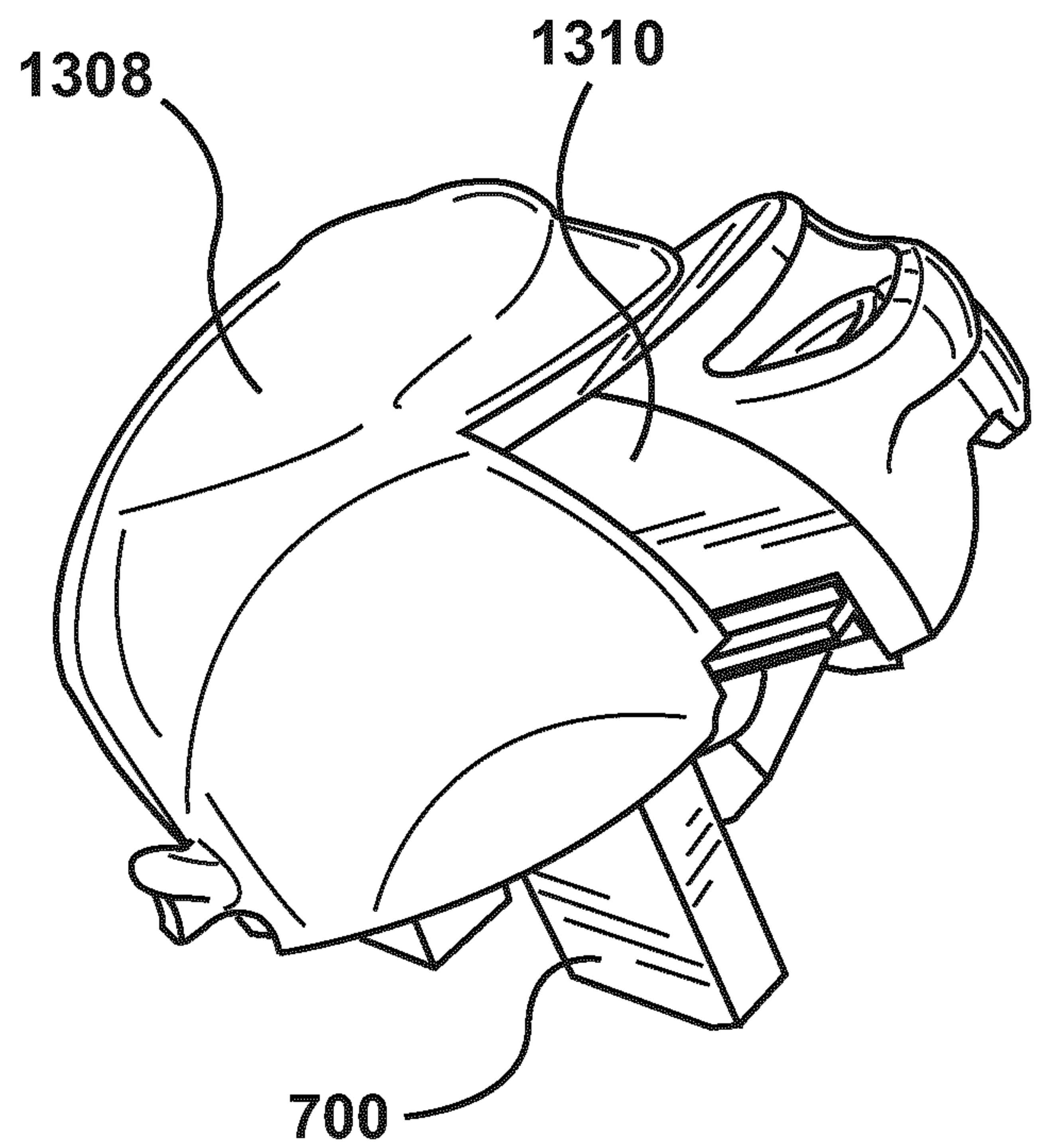
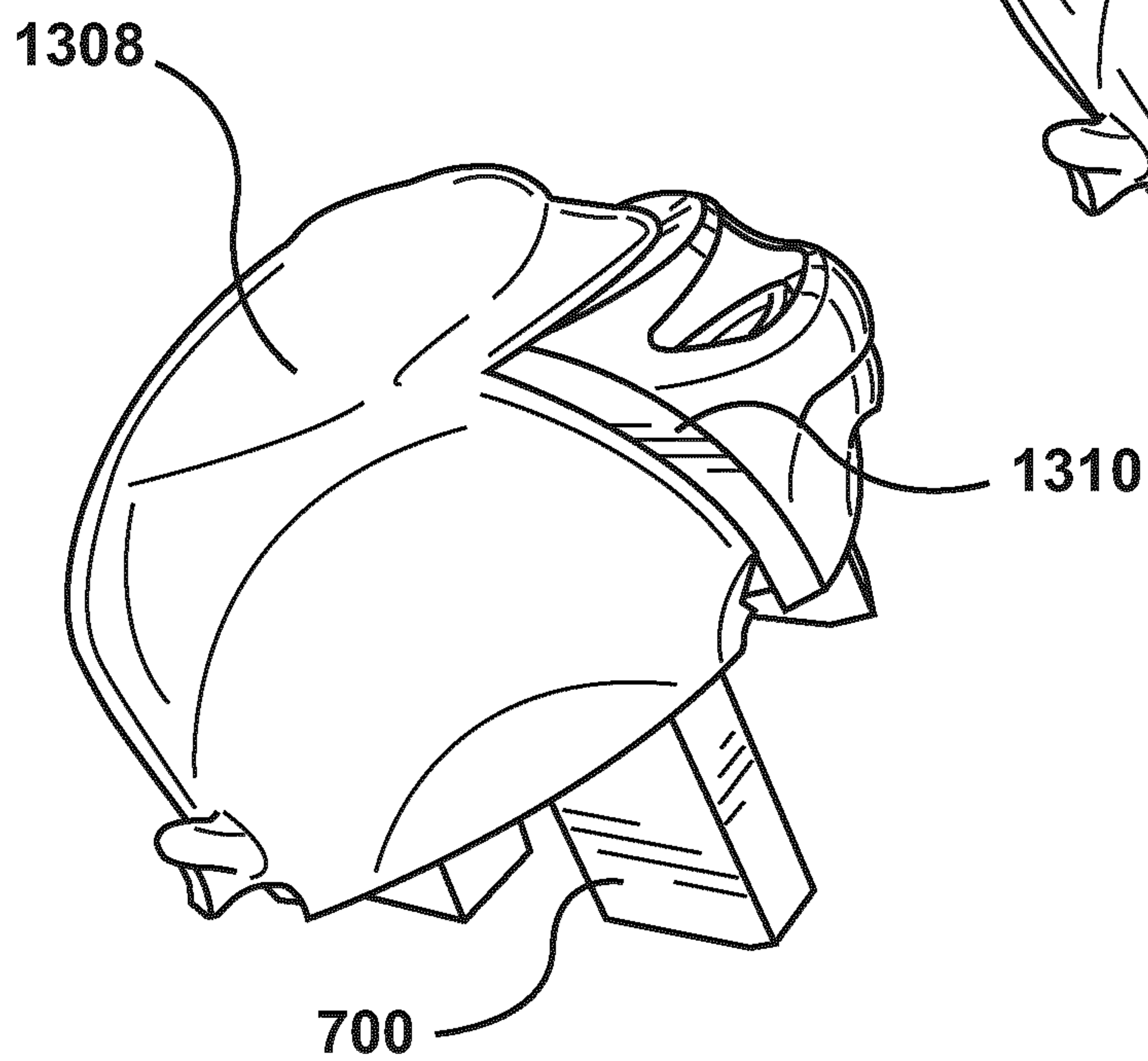


FIG. 33

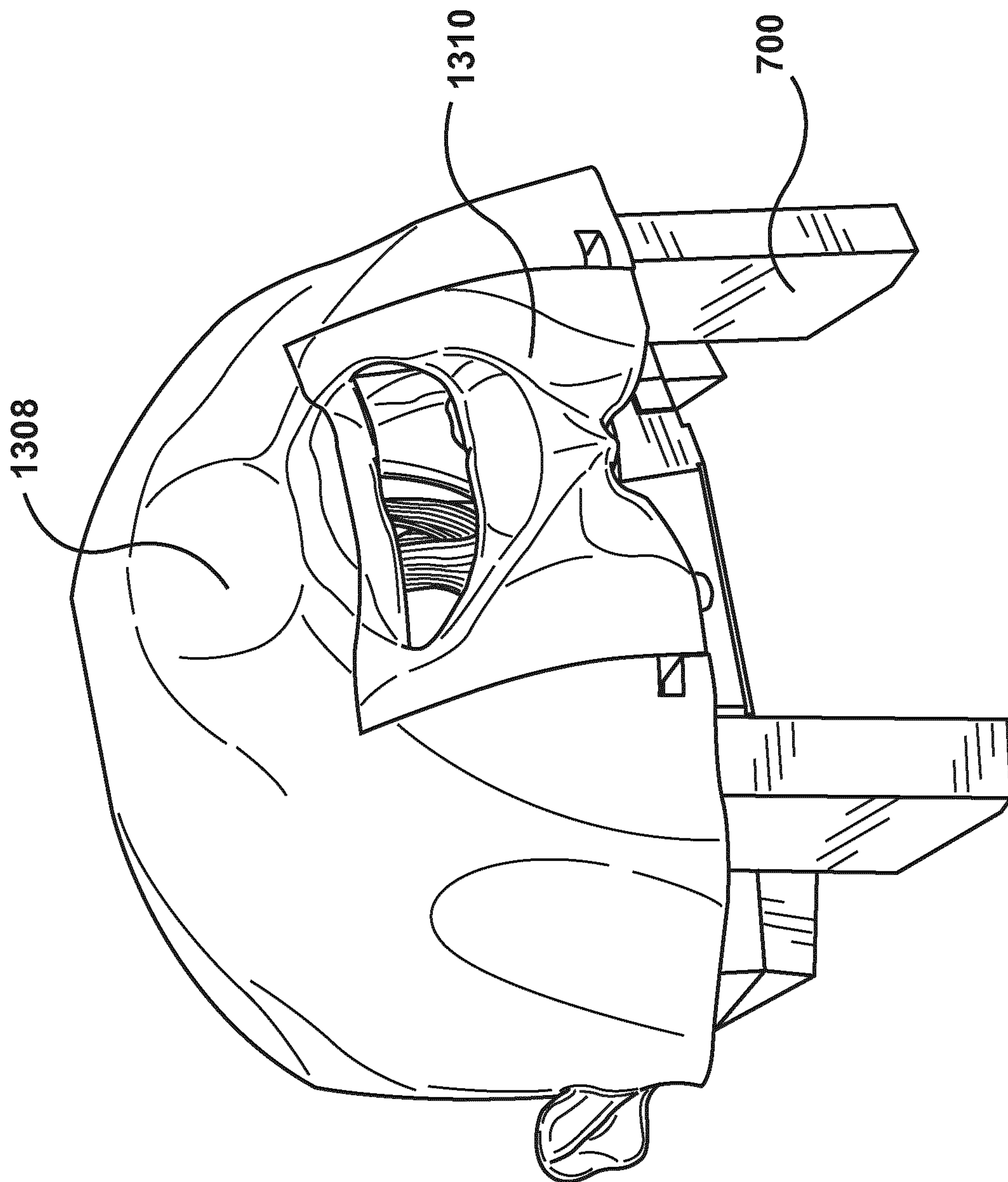
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**FIG. 34**

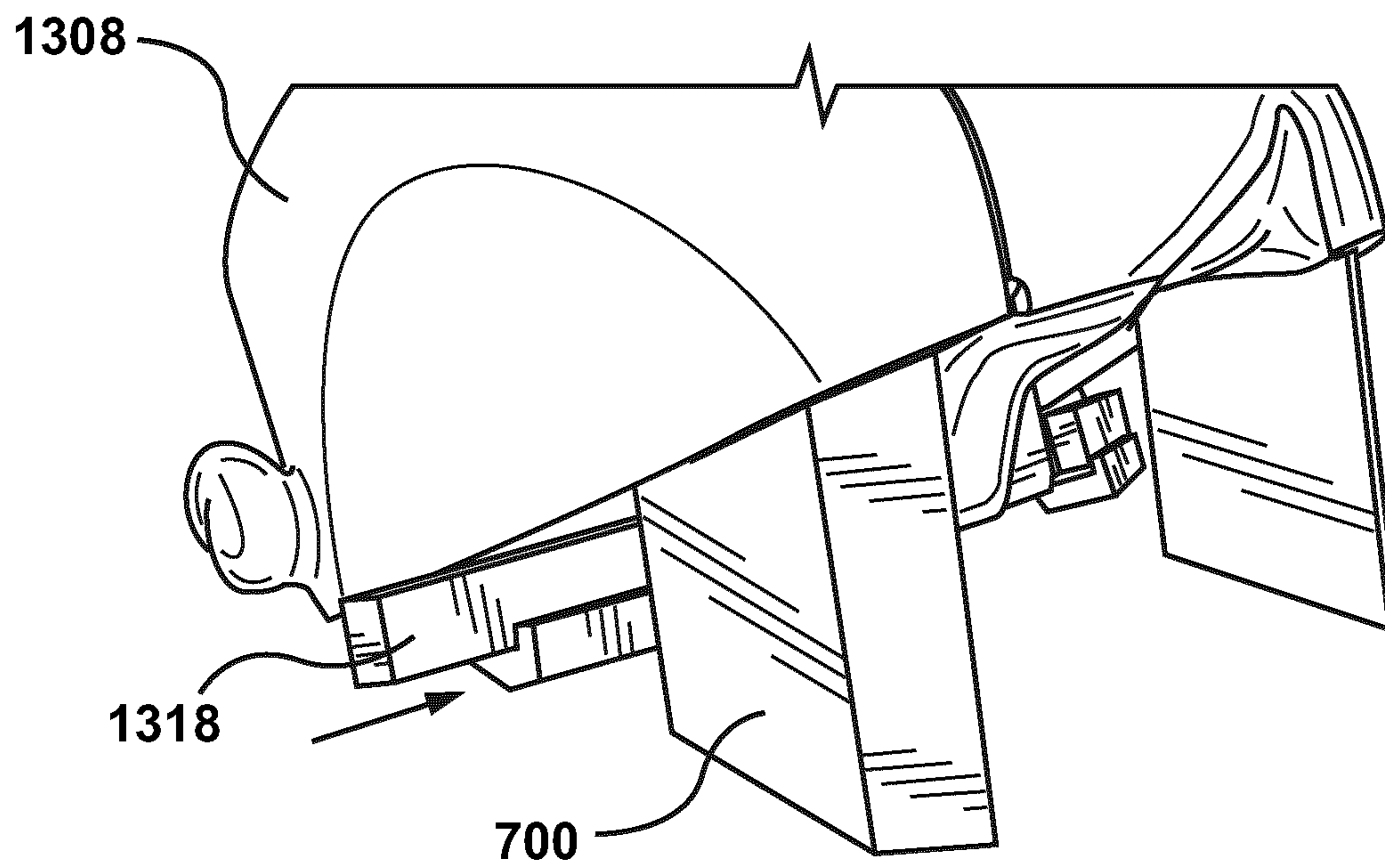
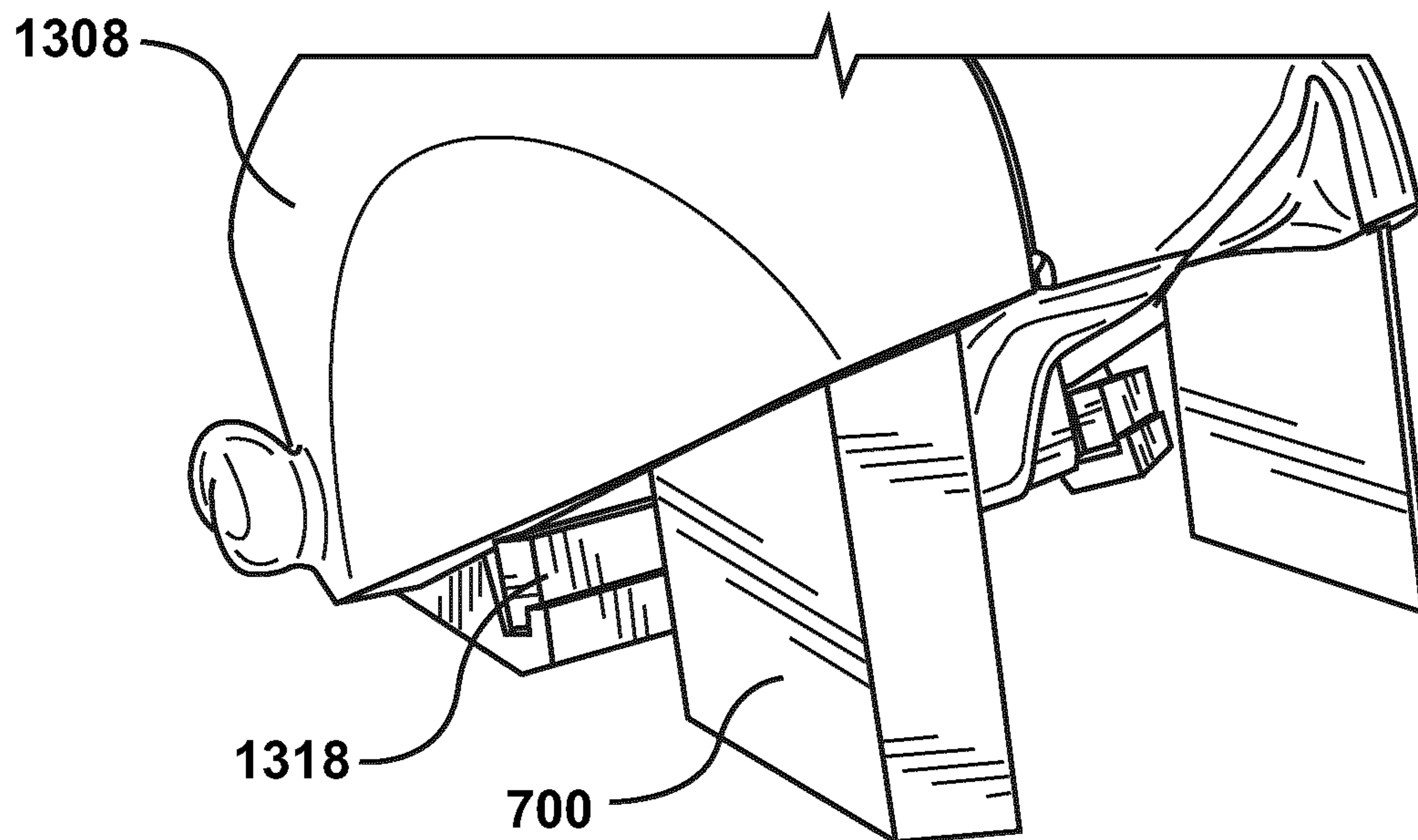
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**FIG. 35A****FIG. 35B****FIG. 35C**

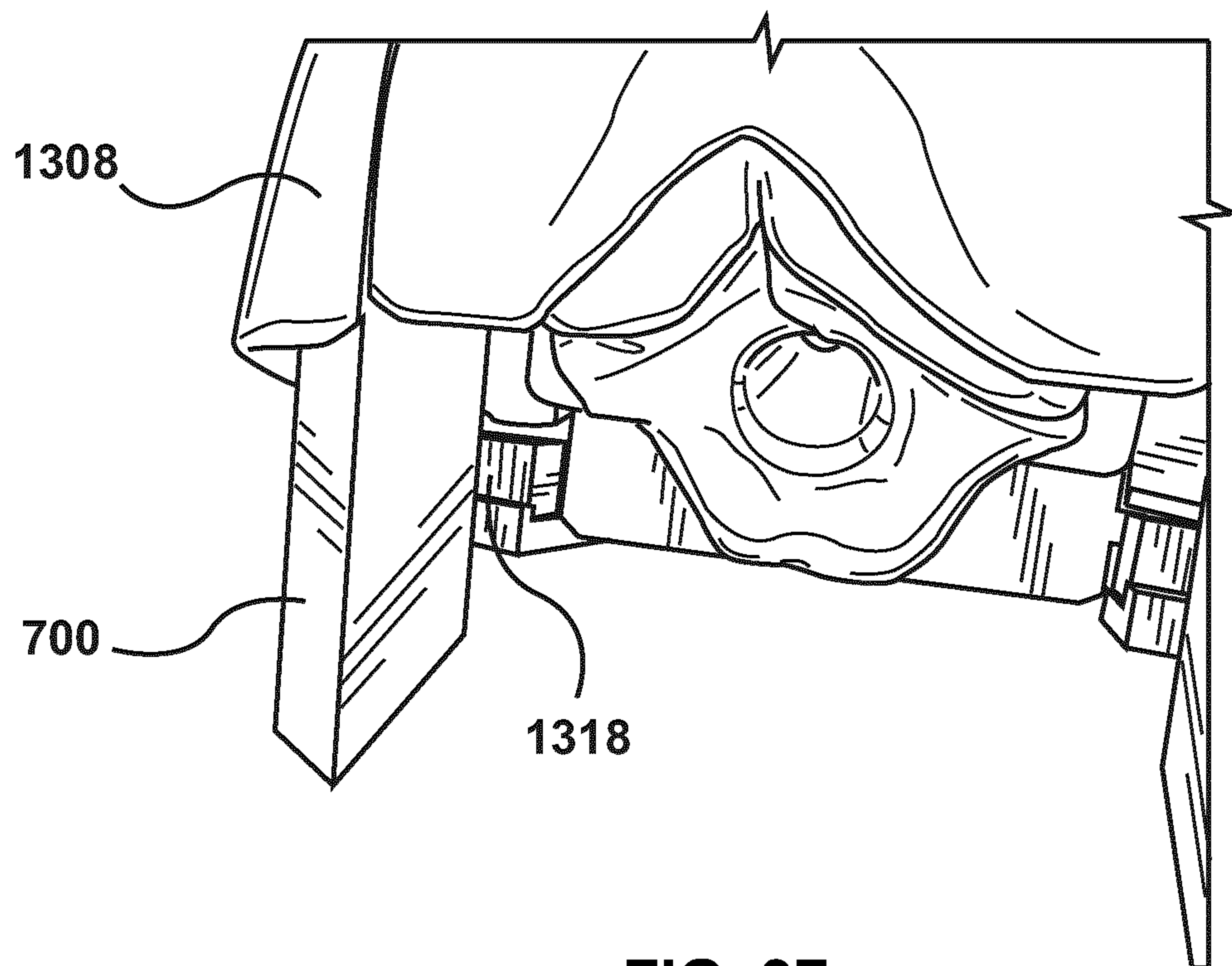
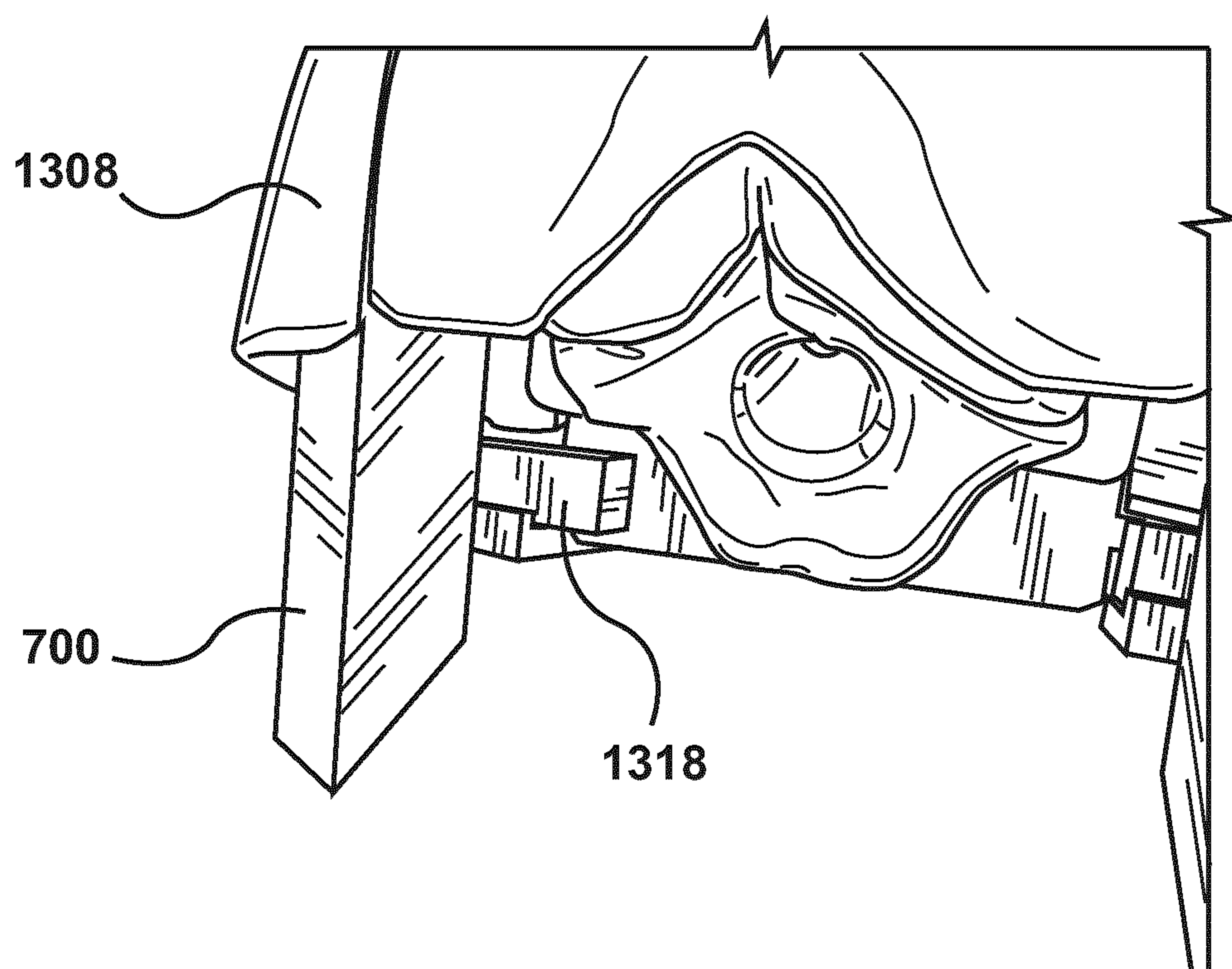
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**FIG. 36**

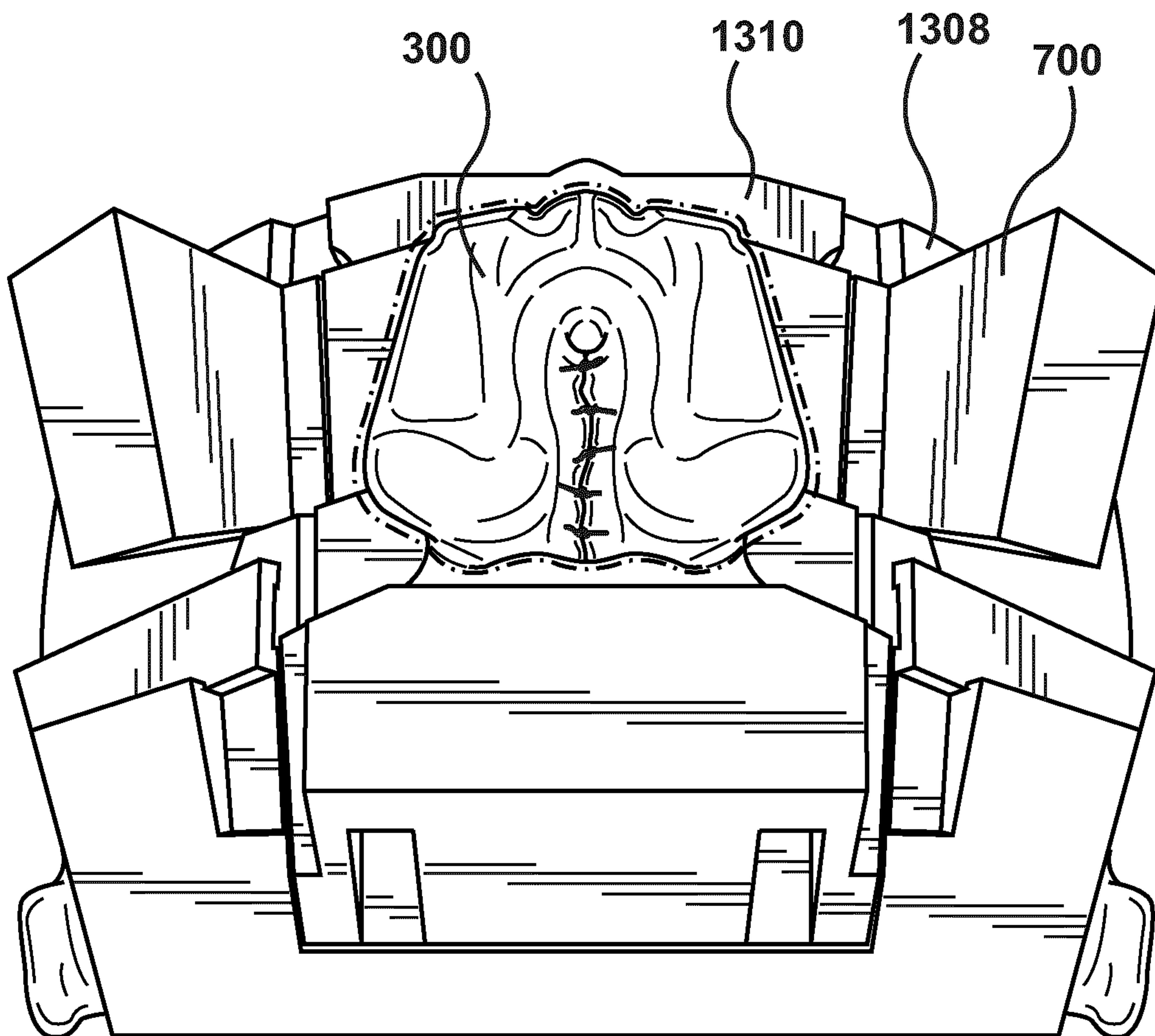
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**FIG. 37a****FIG. 37b**

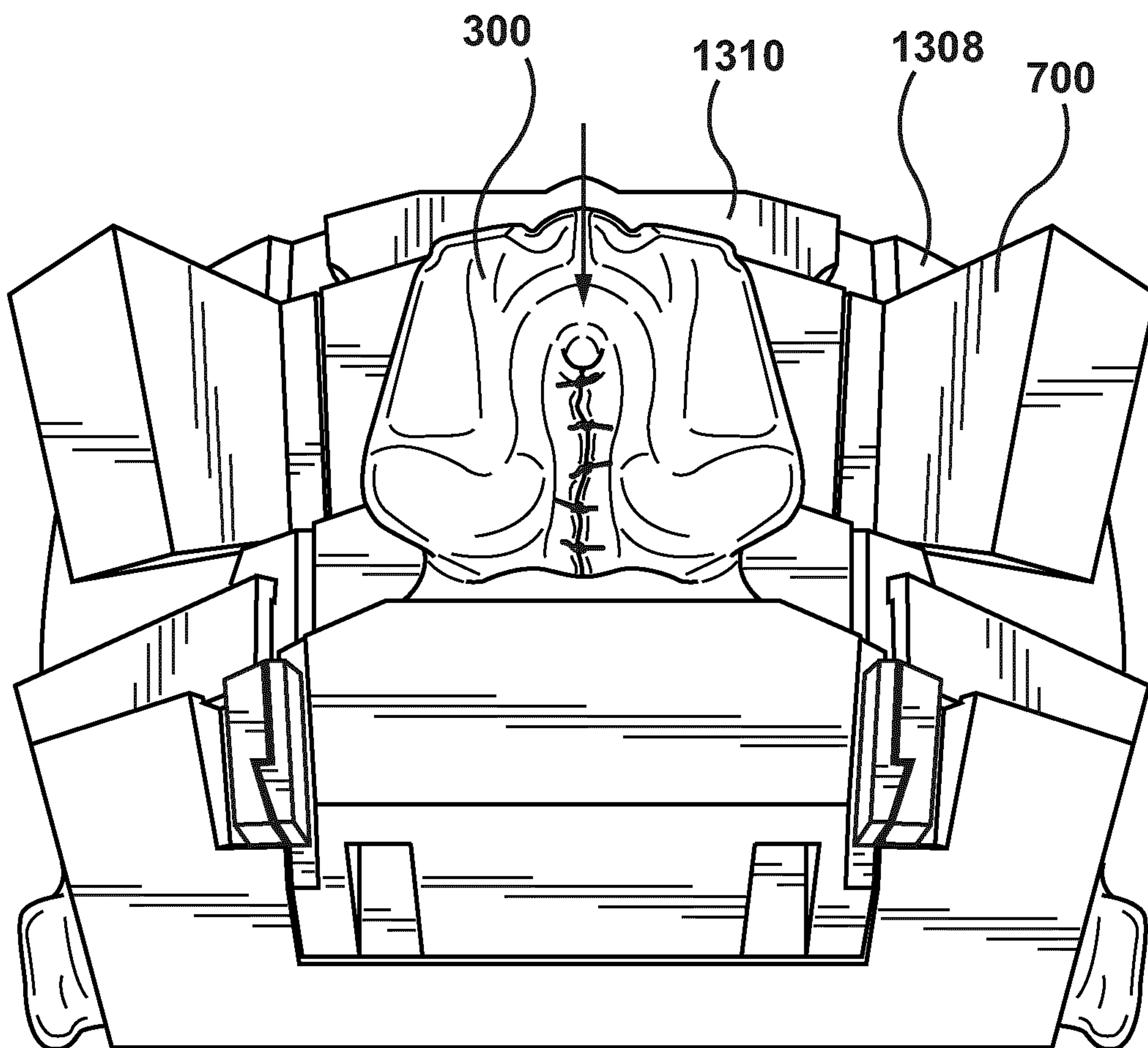
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**FIG. 37c****FIG. 37d**

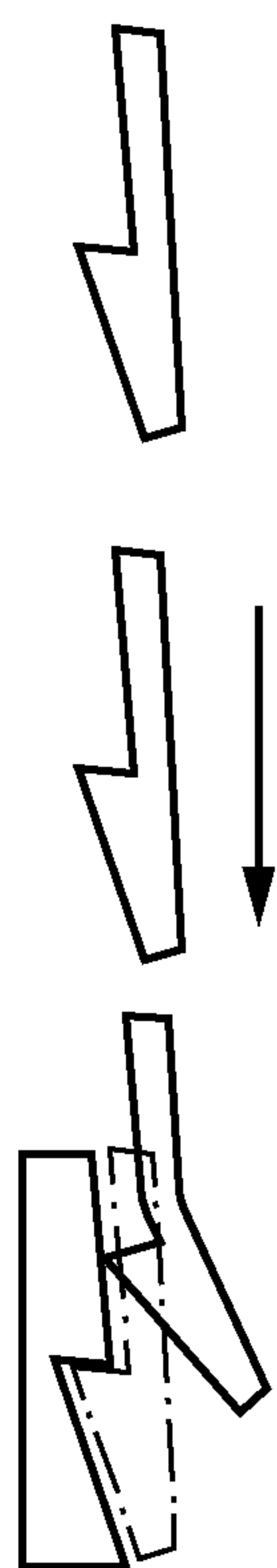
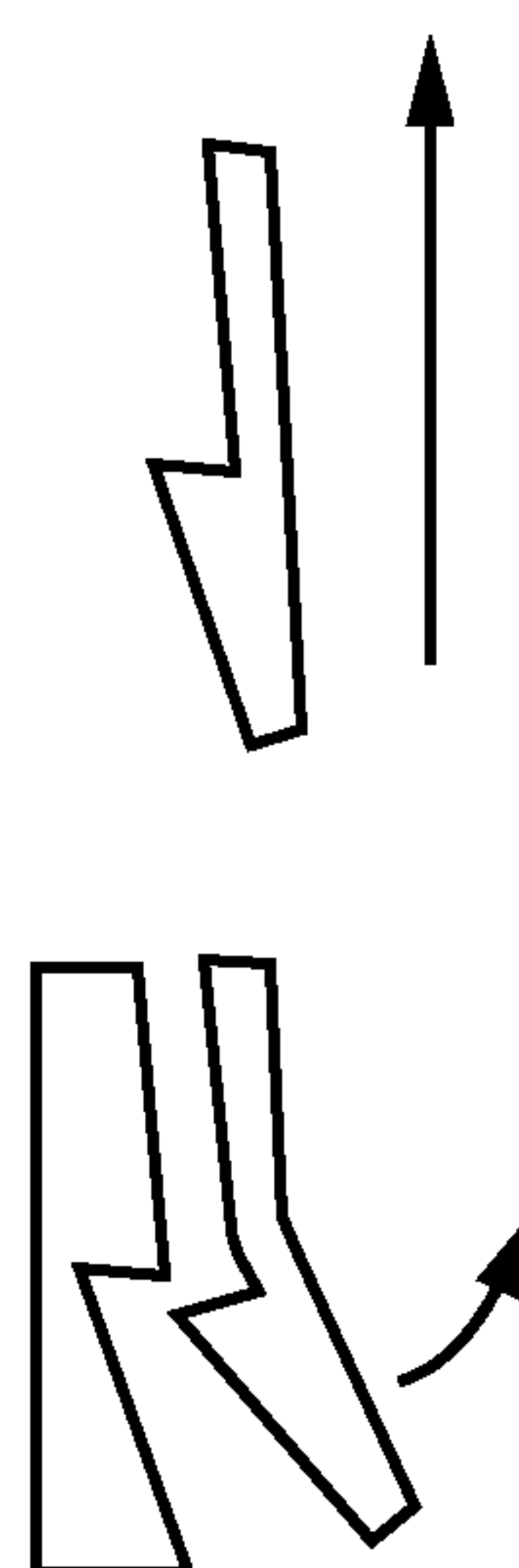
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**FIG. 38**

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**FIG. 39**

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FIG. 40AFIG. 40B

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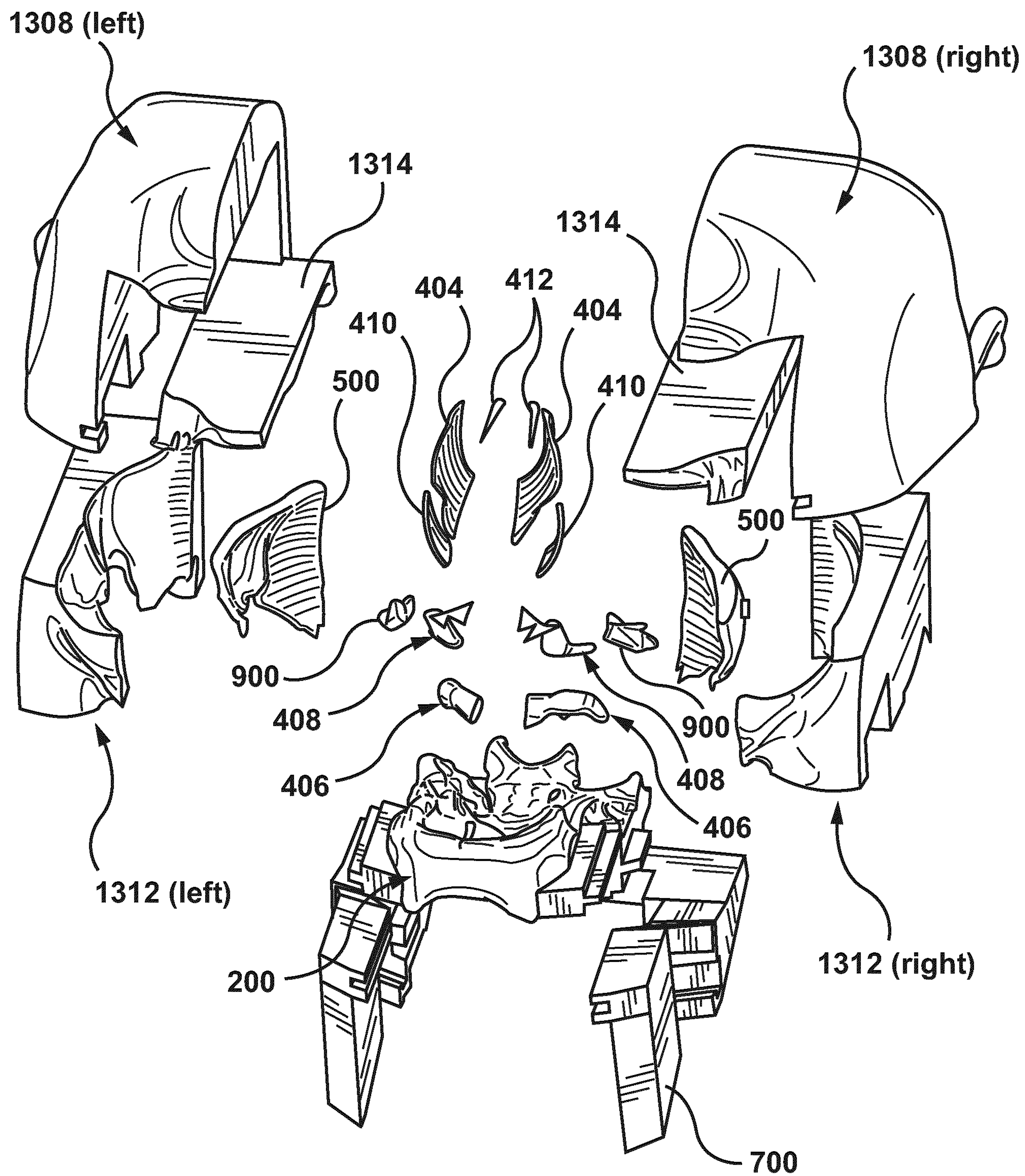
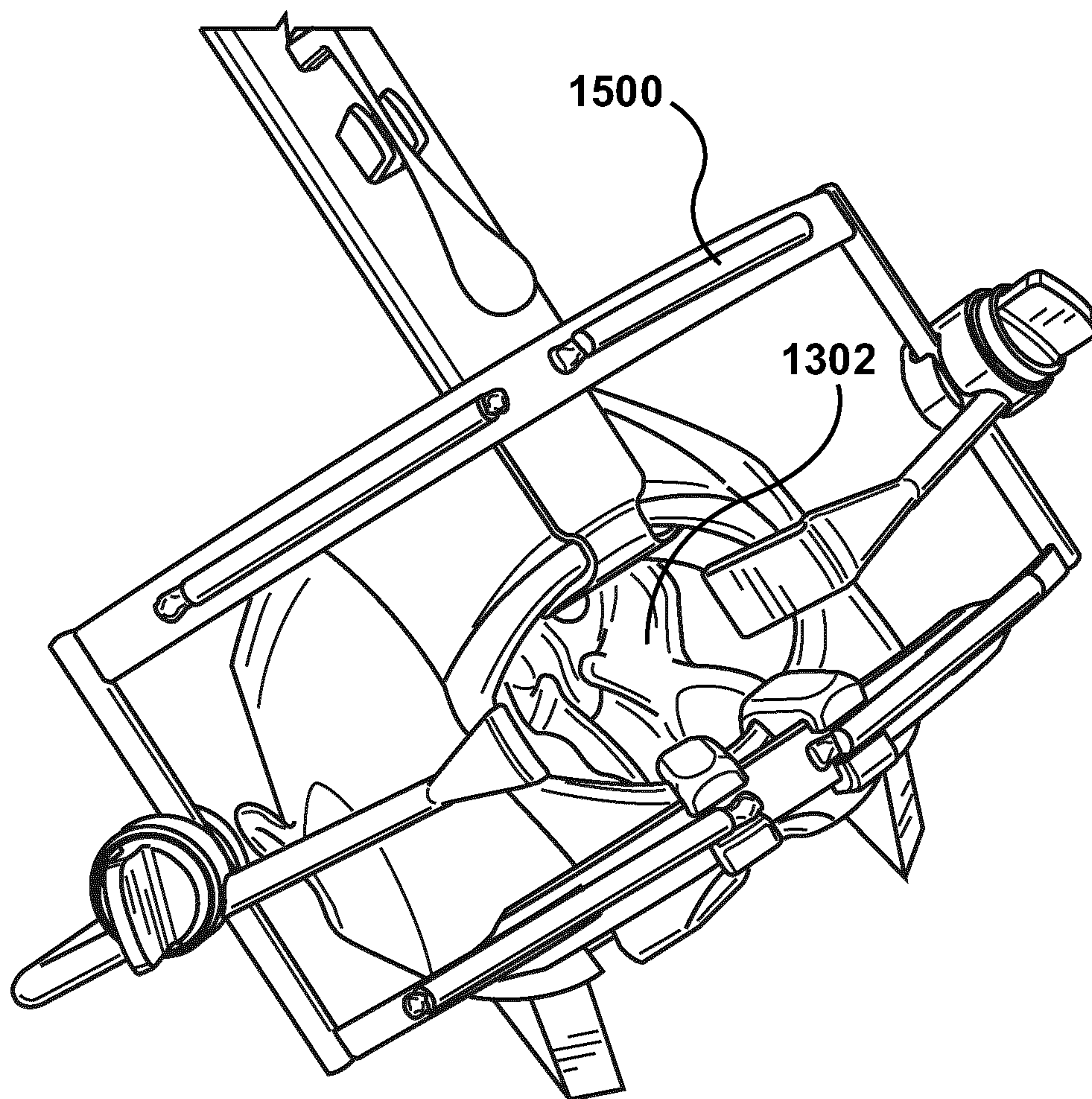
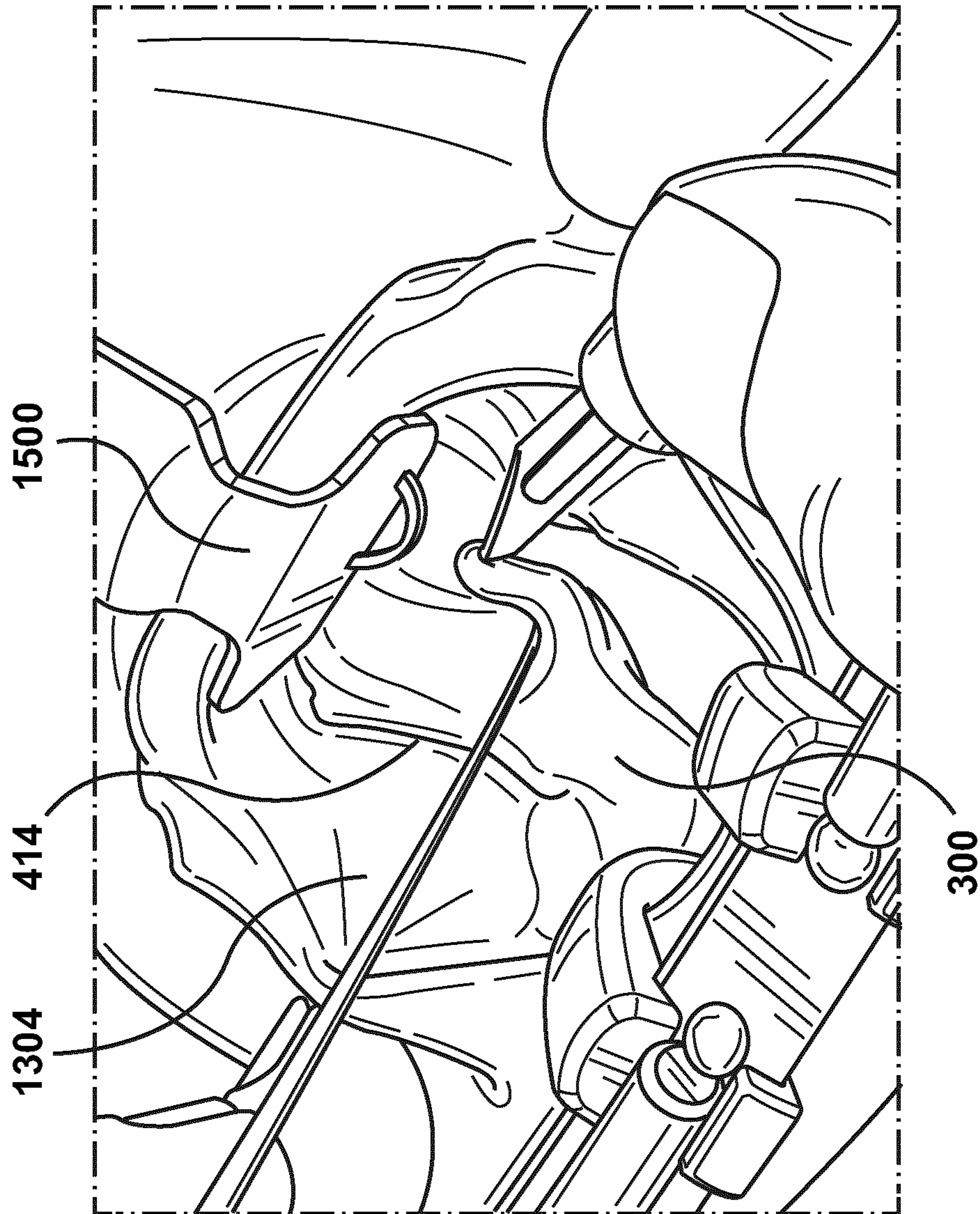


FIG. 41

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**FIG. 42**

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**FIG. 43**

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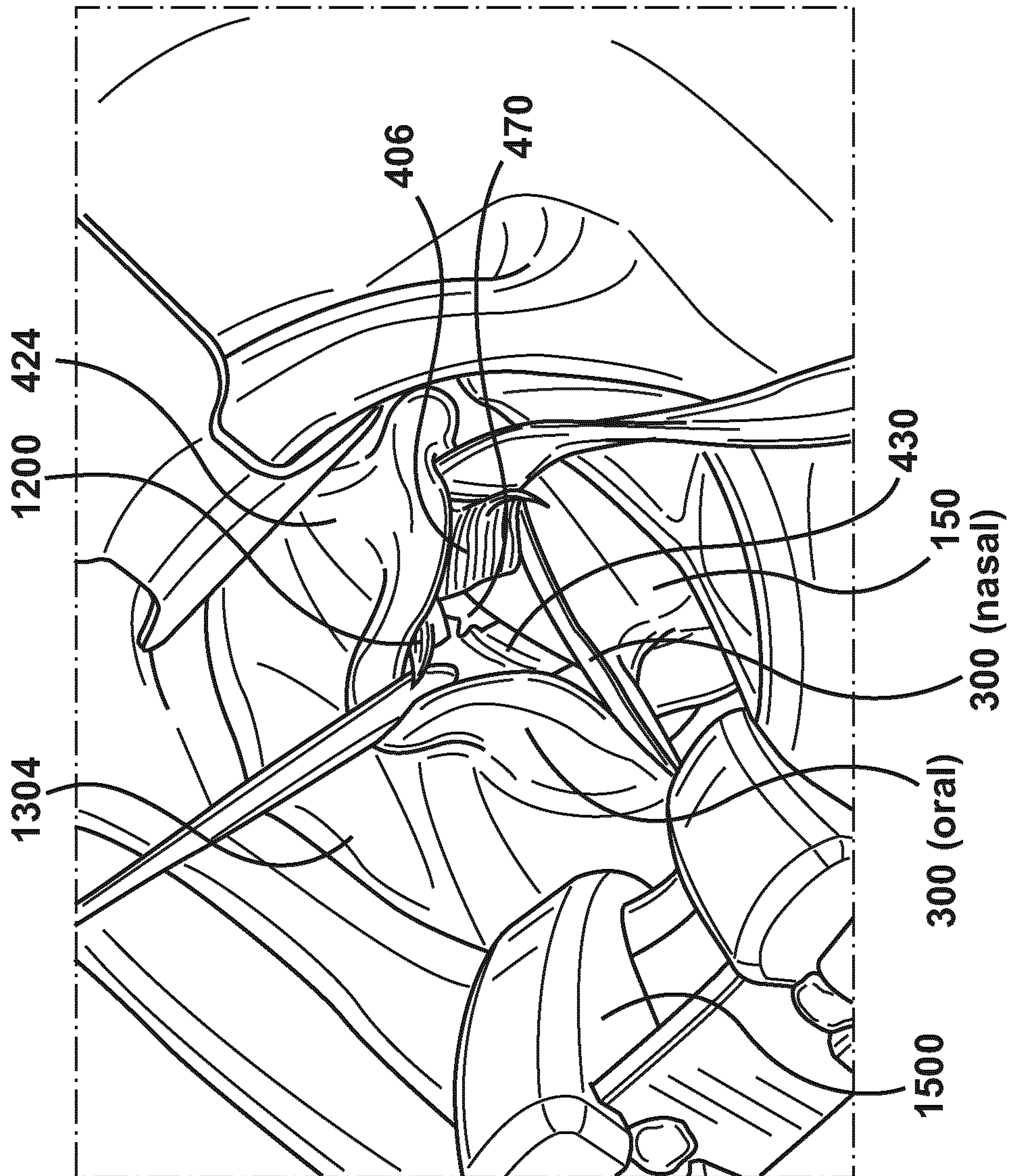


FIG. 44

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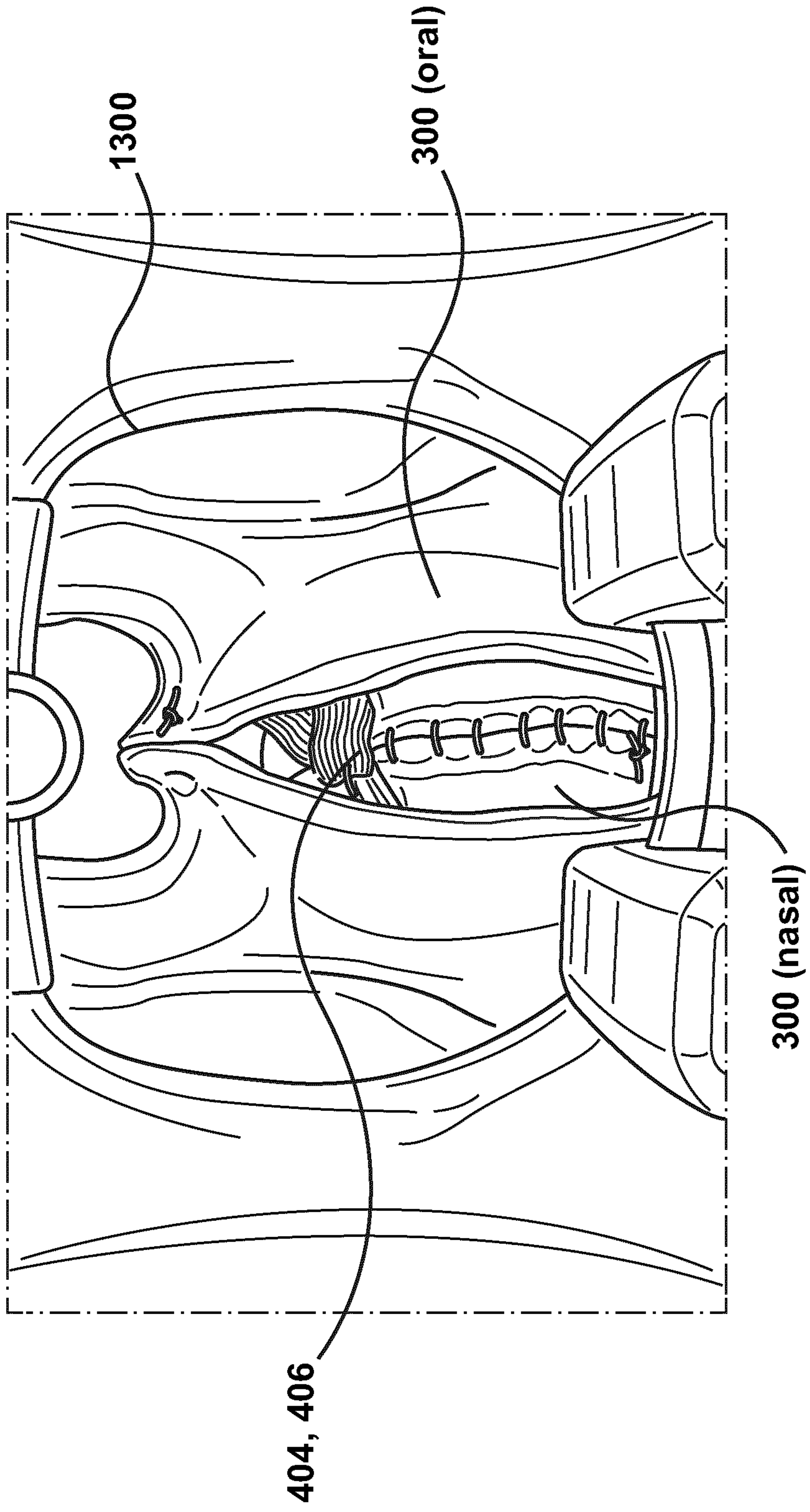
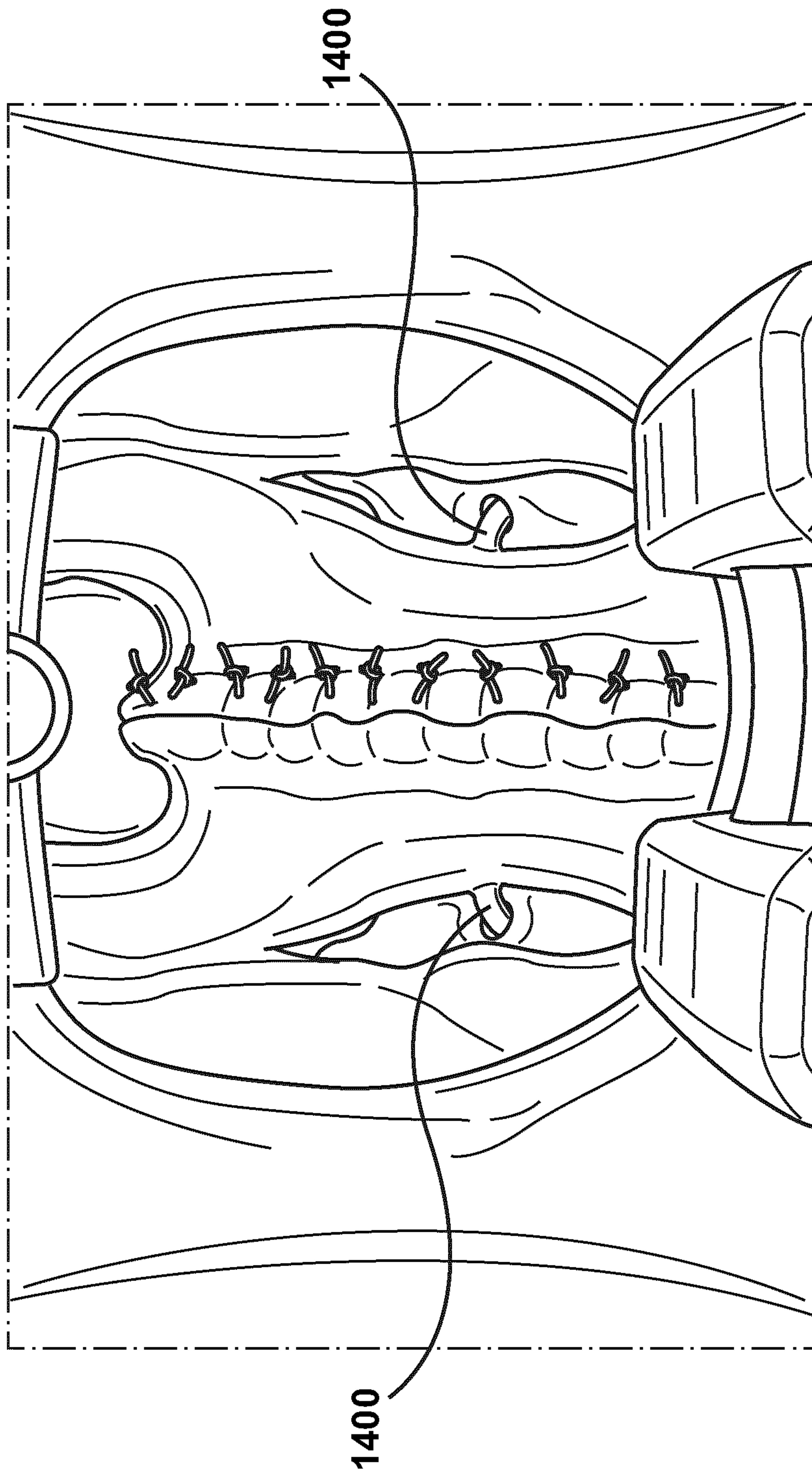


FIG. 45

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**FIG. 46**

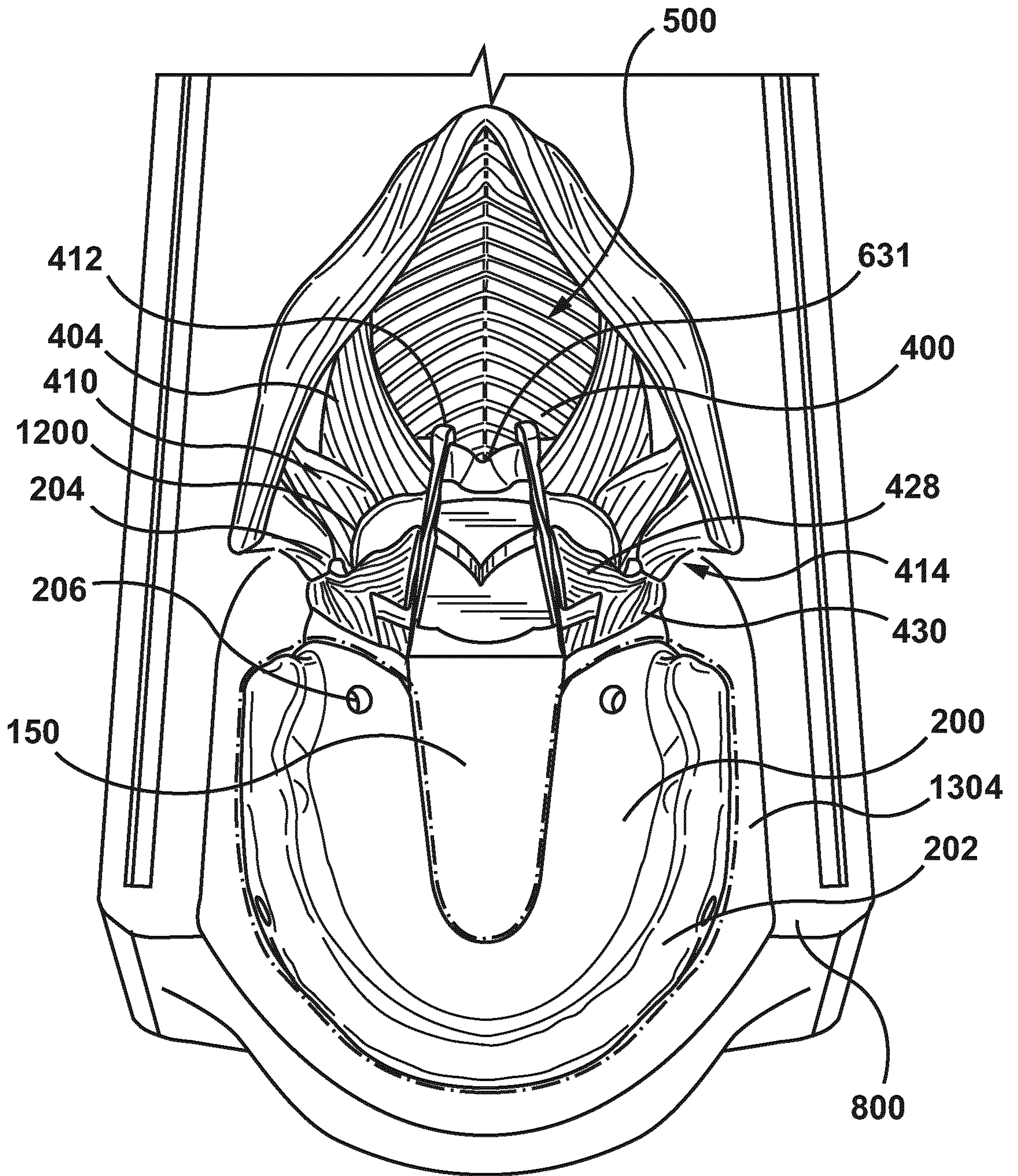


FIG. 2