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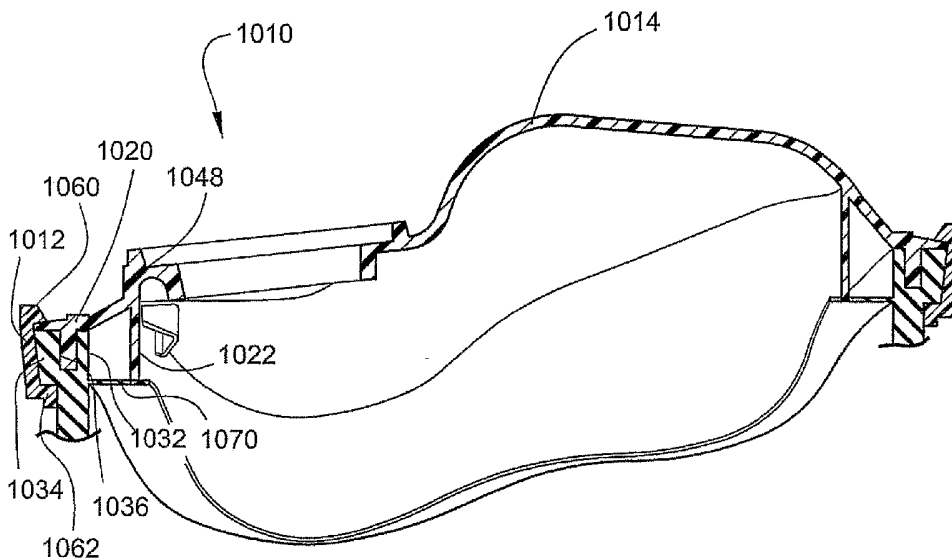
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(54) Title: CUSHION TO FRAME ASSEMBLY MECHANISM



(57) Abstract: A full-face mask assembly (710, 1010, 1210, 1510, 2010, 2110) includes a frame (714, 1014, 1114, 1214, 1514, 2014, 2114) and a cushion (716, 1016, 1116, 1216, 1516, 2016, 2116) provided to the frame (714, 1014, 1114, 1214, 1514, 2014, 2114). The cushion (716, 1016, 1116, 1216, 1516, 2016, 2116) is adapted to form a seal around the patient's nose and mouth. A flexible lip (770, 1070, 1170, 1270, 1570, 2070, 2170) is provided to an interior wall of the cushion (716, 1016, 1116, 1216, 1516, 2016, 2116). The flexible lip (770, 1070, 1170, 1270, 1570, 2070, 2170) is adapted to engage the frame (714, 1014, 1114, 1214, 1514, 2014, 2114) to provide a seal in use.

## **CUSHION TO FRAME ASSEMBLY MECHANISM**

### **CROSS-REFERENCE TO APPLICATIONS**

**[0001]** This application claims the benefit of U.S. Provisional Application Nos. 60/726,265, filed October 14, 2005, and 60/734,746, filed November 9, 2005, each of which is incorporated herein by reference in its entirety.

### **FIELD OF THE INVENTION**

**[0002]** The present invention relates to a method and apparatus for assembling a patient interface for use in treatment of sleep disordered breathing (SDB) such as obstructive sleep apnea (OSA). In particular, the present invention relates to a method and apparatus for securing a face-contacting portion of a patient interface, such as a cushion, to a frame or shell of the patient interface.

### **BACKGROUND OF THE INVENTION**

**[0003]** Patient interfaces, such as a mask assembly, for use with blowers and flow generators in the treatment of sleep disordered breathing (SDB) typically include a soft-patient contacting portion, such as a cushion, and a rigid shell or frame. In use, the patient interface is held in a sealing position by headgear so as to enable a supply of air at positive pressure to be delivered to the patient's airways. When the cushion and frame are manufactured from different materials, they need to be held together in some way. It is also generally desirable that the patient interface be cleanable, for example, allowing a person to wash a mask between uses. While some semi-permanent assembly methods are available, they generally leave small gaps and crevices that can accumulate dirt and be difficult to clean. Hence, it is generally desirable that the frame and cushion include a mechanism that enables both assembly and disassembly. It is also desirable that there be a seal between the frame and cushion to reduce or eliminate leaks from the assembly in use. Since many patients lack dexterity, a good design is simple and easy to use for patients.

[0004] A number of cushion to frame assembly mechanisms are known. For example, see U.S. Patent Nos. 6,412,487 to Gunaratnam, et al. and 6,823,869 to Raje et al. Also see ResMed's MIRAGE®, ULTRA MIRAGE®, ACTIVA®, and VISTA® masks.

[0005] A problem with existing assembly mechanisms includes difficulty with alignment and assembly, e.g., both putting the cushion onto the frame and putting the cushion clip into the sub-assembly. Another problem with existing assembly mechanisms includes difficulty with adhesive, e.g., gluing, that does not allow disassembly for cleaning. Yet another problem with existing assembly mechanisms includes overmolded parts that can still have points of ingress that cannot be easily cleaned, e.g., see Respiration's ComfortCurve mask. Still another problem with existing assembly mechanisms includes interference methods that can be difficult to use on large frames, e.g. full-face mask, and can have misalignment issues.

[0006] Thus, there is a need for an improved assembly mechanism that does not suffer from at least one of the above-mentioned drawbacks.

## SUMMARY OF THE INVENTION

[0007] One aspect of the invention relates to a cushion to frame assembly mechanism structured to facilitate assembly and provide a compliant seal between the cushion and the frame.

[0008] Another aspect of the invention relates to a cushion to frame assembly mechanism that includes an angled lip or flap provided to the cushion interior wall that forms a seal against the frame.

[0009] Another aspect of the invention relates to a cushion to frame assembly mechanism that is integrated with the frame mating geometry.

[0010] Another aspect of the invention relates to a cushion to frame assembly mechanism that includes an overall wedge, taper, or angle in the slot of the frame that receives the cushion.

[0011] Another aspect of the invention relates to a cushion to frame assembly mechanism that includes a cushion clip.

[0012] Another aspect of the invention relates to a full-face mask assembly including a frame and a cushion provided to the frame. The cushion is adapted to form a seal around

the patient's nose and mouth. A flexible lip is provided to an interior wall of the cushion. The flexible lip is adapted to engage the frame to provide a seal in use.

[0013] Another aspect of the invention relates to a full-face mask assembly including a frame and a cushion provided to the frame. The cushion is adapted to form a seal around the patient's nose and mouth. The frame includes a retaining recess that is adapted to receive a retaining portion provided to the cushion. The retaining recess has an angled configuration with respect to the frame.

[0014] Another aspect of the invention relates to a full-face mask assembly including a frame, a cushion provided to the frame, and a clip to maintain the cushion to the frame. The cushion is adapted to form a seal around the patient's nose and mouth.

[0015] Another aspect of the invention relates to a full-face mask assembly including a frame, a cushion provided to the frame, and a skeleton frame to maintain the cushion to the frame. The cushion is adapted to form a seal around the patient's nose and mouth. The skeleton frame includes at least one of an upper support member adapted to support a forehead support, lower headgear clip receptacles adapted to be engaged with clips provided to straps of a headgear assembly, and an annular elbow connection seal adapted to engage an inlet conduit.

[0016] Yet another aspect of the invention relates to a full-face mask assembly including a frame and a cushion provided to the frame. The cushion is adapted to form a seal around the patient's nose and mouth. The cushion includes hooks or tabs integrally formed therewith that are adapted to interlock with locking features integrally formed with the frame.

[0017] Yet another aspect of the invention relates to a full-face mask assembly including a frame and a cushion provided to the frame. The cushion is adapted to form a seal around the patient's nose and mouth. The frame includes outer and inner walls that define a retaining recess adapted to receive therein a retaining portion provided to the cushion. The retaining portion includes a flexible lip to engage the inner wall and provide a seal in use. The retaining portion includes a space behind the flexible lip to provide the flexible lip with a range of movement.

[0018] Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying

drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

- [0019] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:
- [0020] Fig. 1 is a top perspective view of a mask assembly including a cushion to frame assembly mechanism according to an embodiment of the present invention, the mask assembly in a pre-assembled condition;
- [0021] Fig. 2 is a top perspective view of the mask assembly shown in Fig. 1, the mask assembly in an assembled condition;
- [0022] Fig. 2B is a cross-sectional view through line 2B-2B in Fig. 2;
- [0023] Fig. 3 is a top perspective view of a mask assembly including a cushion to frame assembly mechanism according to another embodiment of the present invention, the mask assembly in a pre-assembled condition;
- [0024] Fig. 4 is a top perspective view of the mask assembly shown in Fig. 3, the mask assembly in an assembled condition;
- [0025] Fig. 5 is a top perspective view of a mask assembly including a cushion to frame assembly mechanism according to another embodiment of the present invention, the mask assembly in a pre-assembled condition;
- [0026] Fig. 6 is a top perspective view of a mask assembly including a cushion to frame assembly mechanism according to another embodiment of the present invention, the mask assembly in a pre-assembled condition;
- [0027] Fig. 7 is a top perspective view of the mask assembly shown in Fig. 6, the mask assembly in a partial assembled condition;
- [0028] Fig. 8 is a top perspective view of the mask assembly shown in Fig. 6, the mask assembly in an assembled condition;
- [0029] Fig. 9 is a side perspective view of a mask assembly including a cushion to frame assembly mechanism according to another embodiment of the present invention, the mask assembly in an assembled condition;

- [0030] Fig. 10 is a top perspective view of a mask assembly including a cushion to frame assembly mechanism according to another embodiment of the present invention, the mask assembly in a pre-assembled condition;
- [0031] Fig. 11 is a top perspective view of the mask assembly shown in Fig. 10, the mask assembly in an assembled condition;
- [0032] Fig. 12 is a side perspective view of a mask assembly including a cushion to frame assembly mechanism according to another embodiment of the present invention, the mask assembly in a pre-assembled condition;
- [0033] Fig. 13 is a side perspective view of the mask assembly shown in Fig. 12, the mask assembly in an assembled condition;
- [0034] Fig. 14 is a top perspective view of a mask assembly including a cushion to frame assembly mechanism according to another embodiment of the present invention, the mask assembly in a pre-assembled condition;
- [0035] Fig. 15 is a top perspective view of the mask assembly shown in Fig. 14, the mask assembly in a first partial assembled condition;
- [0036] Fig. 16 is a top perspective view of the mask assembly shown in Fig. 14, the mask assembly in a second partial assembled condition;
- [0037] Fig. 17 is a top perspective view of the mask assembly shown in Fig. 14, the mask assembly in an assembled condition;
- [0038] Fig. 18 is a top perspective view of a mask assembly including a cushion to frame assembly mechanism according to another embodiment of the present invention, the mask assembly in a pre-assembled condition;
- [0039] Fig. 19 is a top perspective view of the mask assembly shown in Fig. 18, the mask assembly in a partial assembled condition;
- [0040] Fig. 20 is a top perspective view of the mask assembly shown in Fig. 18, the mask assembly in an assembled condition;
- [0041] Fig. 21 is a top perspective view of a cushion according to another embodiment of the present invention;
- [0042] Fig. 22 is a top perspective view of a cushion including a cushion to frame assembly mechanism according to another embodiment of the present invention;
- [0043] Fig. 23 is a cross-sectional view of the cushion shown in Fig. 22;

- [0044] Fig. 24 is a cross-sectional view of the cushion shown in Fig. 22 engaged with a mask frame according to an embodiment of the present invention;
- [0045] Figs. 25-26 are cross-sectional views illustrating a cushion clip to maintain the engagement between the frame and the cushion shown in Fig. 24;
- [0046] Fig. 27 is a perspective view of a mask frame according to another embodiment of the present invention;
- [0047] Fig. 28 is a cross-sectional view of the frame shown in Fig. 27 engaged with a mask cushion according to an embodiment of the present invention;
- [0048] Figs. 29-32 are cross-sectional views illustrating a cushion to frame assembly mechanism according to another embodiment of the present invention;
- [0049] Figs. 33-34 are cross-sectional views illustrating a bottom assembling frame clip to maintain the engagement between the frame and the cushion shown in Figs. 29-32;
- [0050] Figs. 35-39 illustrate a top assembling frame clip to maintain the engagement between the frame and the cushion shown in Figs. 29-32;
- [0051] Fig. 40 illustrates a mask frame according to another embodiment of the present invention, the mask frame adapted for use with the cushion shown in Figs. 29-32;
- [0052] Figs. 41-44 illustrate a cushion to frame assembly mechanism according to yet another embodiment of the present invention;
- [0053] Figs. 45-46 illustrate a cushion to frame assembly mechanism according to another embodiment of the present invention;
- [0054] Figs. 47-49 illustrate a cushion to frame assembly mechanism according to another embodiment of the present invention;
- [0055] Figs. 50-51 illustrate alternative frame clip designs;
- [0056] Fig. 52 is a top perspective view of a mask assembly including a cushion to frame assembly mechanism according to another embodiment of the present invention, the mask assembly in a pre-assembled condition;
- [0057] Fig. 53 is a top perspective view of the mask assembly shown in Fig. 52, the mask assembly in a partial assembled condition;
- [0058] Fig. 54 is a top perspective view of the mask assembly shown in Fig. 52, the mask assembly in an assembled condition;
- [0059] Fig. 55 is a cross-sectional view of the mask assembly shown in Fig. 52;

- [0060] Fig. 56 is a top view of the mask assembly shown in Fig. 52;
- [0061] Figs. 57-61 are various views of the frame of the mask assembly shown in Fig. 52 and showing exemplary dimensions of an embodiment;
- [0062] Figs. 62-66 are various views of the cushion of the mask assembly shown in Fig. 52 and showing exemplary dimensions of an embodiment;
- [0063] Figs. 67-71 are various views of the cushion clip of the mask assembly shown in Fig. 52 and showing exemplary dimensions of an embodiment;
- [0064] Fig. 72 is a top perspective view of a mask assembly including a cushion to frame assembly mechanism according to another embodiment of the present invention, the mask assembly in a pre-assembled condition;
- [0065] Fig. 73 is a top perspective view of the mask assembly shown in Fig. 72, the mask assembly in a partial assembled condition;
- [0066] Fig. 74 is a top perspective view of the mask assembly shown in Fig. 72, the mask assembly in an assembled condition;
- [0067] Fig. 75 is a cross-sectional view of the mask assembly shown in Fig. 72;
- [0068] Fig. 76 is a top view of the mask assembly shown in Fig. 72;
- [0069] Figs. 77-81 are various views of the frame of the mask assembly shown in Fig. 72 and showing exemplary dimensions of an embodiment;
- [0070] Figs. 82-86 are various views of the cushion of the mask assembly shown in Fig. 72 and showing exemplary dimensions of an embodiment;
- [0071] Figs. 87-91 are various views of the frame clip of the mask assembly shown in Fig. 72 and showing exemplary dimensions of an embodiment;
- [0072] Fig. 92 is an exploded top perspective view of a mask assembly including a cushion to frame assembly mechanism according to another embodiment of the present invention, the mask assembly being in a pre-assembled condition;
- [0073] Fig. 93 is a top perspective view of the mask assembly shown in Fig. 92, the mask assembly being in a partial assembled condition;
- [0074] Fig. 94 is a top perspective view of the mask assembly shown in Fig. 92, the mask assembly being in an assembled condition;
- [0075] Fig. 95 are cross-sectional views of the assembled mask assembly shown in Fig. 94;



[0076] Fig. 96 is a cross-sectional view of the cushion of the mask assembly shown in Fig. 92;

[0077] Figs. 97-105 are various views of the cushion clip of the mask assembly shown in Fig. 92 and showing exemplary dimensions of an embodiment; and

[0078] Figs. 106-107 are cross-sectional views at top and bottom portions of a mask assembly according to another embodiment of the present invention.

#### DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0079] The following includes descriptions of mask assemblies including cushion to frame assembly mechanisms according to several illustrated embodiments of the present invention. In each of the illustrated embodiments, the mask assembly includes a cushion that is adapted to be removably connected to a frame via a cushion to frame assembly mechanism.

[0080] The cushion to frame assembly mechanism provides an interface between the cushion and frame to facilitate assembly and disassembly. In addition, the cushion to frame assembly mechanism may be structured to provide a compliant seal between the cushion and frame and reduce or eliminate the risk of leakage.

[0081] In the illustrated embodiment, the cushion and frame form a part of a full-face mask. Specifically, the cushion provides a seal around the patient's nose and mouth to enable the delivery of breathable gas to the patient's nose and mouth. However, aspects of the present invention may be applicable to other breathing arrangements, e.g., a nasal mask, a mouth mask, etc. Also, each illustrated embodiment includes features that may be used with and/or in the other illustrated embodiments, as would be apparent to those of ordinary skill in the art.

##### 1. First Embodiment of Cushion to Frame Assembly Mechanism

[0082] Figs. 1 2, and 2B illustrate a mask assembly 10 including a cushion to frame assembly mechanism according to an embodiment of the present invention. In the illustrated embodiment, the cushion to frame assembly mechanism includes a slide-on frame clip 12 that is adapted to removably connect the frame 14 to the cushion 16.

[0083] Specifically, the frame 14 includes a main body that provides an opening 18 for communicating with an inlet conduit. At least a portion of the frame perimeter includes

spaced apart upper and lower retaining wall portions 20, 22. The cushion 16 (only half being shown) includes a cushion wall 24 and a face-contacting portion 26, e.g., membrane. The cushion wall 24 includes a central opening with upper and lower walls 21, 23 that define an inner edge 28 (see Fig. 2B). As shown in Fig. 1, the frame 14 is received within the central opening of the cushion 16 so that the inner edge 28 of the cushion 16 is received between the upper and lower retaining wall portions 20, 22 of the frame 14. This partially secures the cushion 16 to the frame 14 to provide a cushion/frame sub-assembly 30. A slide-on frame clip 12 is engaged with the sub-assembly 30 to maintain engagement between the frame 14 and cushion 16.

**[0084]** As illustrated, the frame clip 12 has a U-shaped configuration that provides upper and lower retaining wall portions 32, 34. The frame clip 12 is slid onto the sub-assembly 30 such that the upper and lower retaining wall portions 32, 34 straddle the upper wall portion 20 of the frame 14. In addition, the lower wall portion 34 of the frame clip 12 sandwiches the U-shaped recess formed by the upper and lower walls 21, 23 of the inner edge 28 of the cushion 16 against the corresponding U-shaped configuration formed by the upper wall portion 20 and lower wall portion 22 of the frame 14 (see Fig. 2B). This arrangement provides a compressive force into the cushion 16 (in the direction of the arrow shown in Fig. 2B). Further, as shown in Fig. 2, the frame clip 12 provides support wings 36 that support the cushion wall 24 in use.

**[0085]** In an embodiment, the frame 14 and frame clip 12 may be constructed of polycarbonate and the cushion 16 may be constructed of liquid silicone rubber (LSR). However, other suitable materials may be used.

**[0086]** In an embodiment, the frame 14 could potentially be over-molded with cushion 16, thereby negating the need for frame clip 12.

## 2. Second Embodiment of Cushion to Frame Assembly Mechanism

**[0087]** Figs. 3 and 4 illustrate a mask assembly 210 including a cushion to frame assembly mechanism according to another embodiment of the present invention. In the illustrated embodiment, the cushion to frame assembly mechanism includes a skeleton frame 212 that is adapted to removably interlock with a cushion/frame sub-assembly 230.

[0088] Specifically, a frame and a cushion are integrally molded in one-piece to provide a cushion/frame sub-assembly 230. In an embodiment, the cushion/frame sub-assembly 230 may be constructed of liquid silicone rubber (LSR). However, other suitable materials may be used.

[0089] The cushion/frame sub-assembly 230 includes an upper wall 220 that provides an opening 218 for communicating with an inlet conduit. An annular wall 240 surrounds the opening 218. A side wall 224 extends from the upper wall 220 and leads to a face contacting portion 226. In an embodiment, the face contacting portion 226 has a double wall construction, e.g., membrane and underlying support cushion. The side wall 224 includes elongated protrusions 242 that extend around the perimeter of the cushion/frame sub-assembly 230. In the illustrated embodiment, the side wall 224 includes three spaced apart elongated protrusions 242 (only two being visible). However, the side wall 224 may include one continuous protrusion, or any suitable number of spaced apart protrusions.

[0090] The skeleton frame 212 includes an upper support member 244 adapted to support a forehead support, lower headgear clip receptacles 246 adapted to be engaged with clips provided to straps of a headgear assembly (not shown), and an annular elbow connection seal 248 adapted to engage an inlet conduit, e.g., elbow. The upper support member 244 and clip receptacles 246 are interconnected via elongated frame members 250. In the illustrated embodiment, the skeleton frame 212 is formed of plastic and has an integral one-piece construction.

[0091] As shown in Fig. 4, the skeleton frame 212 is engaged with the cushion/frame sub-assembly 230 such that the annular elbow connection seal 248 interlocks with the annular wall 240 of the cushion/frame sub-assembly 230, the upper support member 244 interlocks or is frictionally engaged with a top portion 231 of the cushion/frame sub-assembly 230, and the elongated frame members 250 interlock with respective protrusions 242 provided around the perimeter of the cushion/frame sub-assembly 230. The skeleton frame 212 adds rigidity to the cushion/frame sub-assembly 230 and provides attachment points for a forehead support, a headgear assembly, and an inlet conduit.

[0092] Fig. 5 illustrates a mask assembly 310 including a cushion to frame assembly mechanism according to another embodiment of the present invention. Similar to the above embodiment, the cushion to frame assembly mechanism includes a skeleton frame 312 that is

adapted to removably interlock with a one-piece integrally molded cushion/frame sub-assembly 330.

[0093] As illustrated, each side wall 324 of the cushion/frame sub-assembly 330 includes a protrusion 341 and an elongated extension 342 that provides a slot 343. The skeleton frame 312 includes elongated frame members 350 that each include a tab 351. The skeleton frame 312 is engaged with the cushion/frame sub-assembly 330 such that the tabs 351 are received within respective slots 343 of the cushion/frame sub-assembly 330, and the elongated frame members 350 interlock with respective protrusions 341 provided on the perimeter of the cushion/frame sub-assembly 330. When interlocked, the tabs 351 provide support to the face contacting portion 326, e.g., membrane and underlying support cushion, of the cushion 316.

[0094] Also, the skeleton frame 312 and/or cushion/frame sub-assembly 330 is designed such that the tool core is along a single line of draw (indicated by the arrow).

[0095] In an embodiment, the cushion/frame sub-assembly 230, 330 could potentially be over-molded with the skeleton frame 212, 312.

### 3. Third Embodiment of Cushion to Frame Assembly Mechanism

[0096] Figs. 6-8 illustrate a mask assembly 410 including a cushion to frame assembly mechanism according to another embodiment of the present invention. In the illustrated embodiment, the cushion to frame assembly mechanism includes a skeleton frame 412 that is adapted to removably interlock with a cushion/frame sub-assembly 430.

[0097] Specifically, a frame 414 and a cushion 416 are formed separately from one another and then interlocked to provide a cushion/frame sub-assembly 430. As shown in Fig. 6, the cushion 416 includes a side wall 424 and a face contacting portion 426 extending from the side wall 424. In an embodiment, the face contacting portion 426 has a double wall construction, e.g., membrane and underlying support cushion. Also, in an embodiment, the cushion 416 is constructed of liquid silicone rubber (LSR). However, other suitable materials may be used.

[0098] The frame 414 includes an upper wall that provides an opening 418 for communicating with an inlet conduit. An annular wall 440 surrounds the opening 418. A side wall 420 extends from the upper wall and includes elongated protrusions 442 that extend

around the perimeter thereof. In the illustrated embodiment, the side wall 420 includes three spaced apart elongated protrusions 442 (only two being visible). However, the side wall 420 may include one continuous protrusion, or any suitable number of spaced apart protrusions. In an embodiment, the frame 414 is constructed of polycarbonate.

[0099] As shown in Fig. 7, the cushion 416 is interlocked with the frame 414 to provide the cushion/frame sub-assembly 430. The cushion 416 may be interlocked with the frame 414 in any suitable manner, e.g., mechanical interlock, etc.

[00100] As best shown in Figs. 6 and 7, the skeleton frame 412 includes an upper support member 444 adapted to support a forehead support, lower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of a headgear assembly (not shown), and an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow. The upper support member 444 and clip receptacles 446 are interconnected via elongated frame members 450. In the illustrated embodiment, the skeleton frame 412 is formed of plastic and has an integral one-piece construction.

[00101] As shown in Fig. 8, the skeleton frame 412 is engaged with the cushion/frame sub-assembly 430 such that the annular elbow connection seal 448 interlocks with the annular wall 440 of the cushion/frame sub-assembly 430, the upper support member 444 interlocks with a top portion 431 of the cushion/frame sub-assembly 430, and the elongated frame members 450 interlock with respective protrusions 442 provided around the perimeter of the cushion/frame sub-assembly 430. The skeleton frame 412 adds rigidity to the cushion/frame sub-assembly 430 and provides attachment points for a forehead support, a headgear assembly, and an inlet conduit.

[00102] Fig. 9 illustrates a mask assembly 510 including a cushion to frame assembly mechanism according to another embodiment of the present invention. Similar to the above embodiment, the cushion to frame assembly mechanism includes a skeleton frame 512 that is adapted to removably interlock with a separately formed and interlocked cushion/frame sub-assembly 530.

[00103] The skeleton frame 512 is interlocked with the cushion/frame sub-assembly 530 via snap-fit clips 552. As illustrated, when the skeleton frame 512 is interlocked with the cushion/frame sub-assembly 530, the elongated frame members 550 of the skeleton frame

512 trap the cushion 516 to the frame 514. That is, the skeleton frame 512 and the frame side wall 520 sandwich the cushion side wall 524 to secure the cushion 516 to the frame 514.

[00104] In an embodiment, the frame 414 could potentially be over-molded with the cushion 416. Also, the cushion/frame sub-assembly 430, 530 could potentially be over-molded with the skeleton frame 412, 512.

#### 4. Fourth Embodiment of Cushion to Frame Assembly Mechanism

[00105] Figs. 10-11 illustrate a mask assembly 610 including a cushion to frame assembly mechanism according to another embodiment of the present invention. In the illustrated embodiment, the cushion to frame assembly mechanism includes a cushion 616 with integrally molded hooks 652 that are adapted to removably interlock and/or engage with features molded onto the frame 614.

[00106] As shown in Fig. 10, the cushion 616 includes a side wall 624 and a face contacting portion 626 extending from the side wall 624. In an embodiment, the face contacting portion 626 has a double wall construction, e.g., membrane and underlying support cushion. Also, in an embodiment, the cushion 626 is constructed of liquid silicone rubber (LSR). However, other suitable materials may be used. As illustrated, interlocking members in the form of hooks 652 protrude from the side walls 624. In the illustrated embodiment, four hooks 652 are provided. However, the cushion 616 may include any suitable number of hooks 652.

[00107] The frame 614 includes an upper support member 644 adapted to support a forehead support, lower headgear clip receptacles 646 adapted to be engaged with clips provided to straps of a headgear assembly (not shown), and an annular elbow connection seal 648 adapted to engage an inlet conduit, e.g., elbow. Also, the frame side wall 620 includes a series of recesses 621 around the perimeter thereof. In the illustrated embodiment, the side wall 620 includes the same number of recesses 621 as hooks 652 on the cushion 616, e.g., four. In an embodiment, the frame 614 is molded in one-piece with polycarbonate and the recesses 651 are integrally molded into the frame 614.

[00108] As shown in Fig. 11, the cushion 616 is engaged with the frame 614 such that the hooks 652 interlock with respective recesses 621 provided around the perimeter of the frame 614, e.g., with a friction fit. In an embodiment, each recess 621 may provide a

projection adapted to extend through a respective hook 652 to facilitate attachment of the cushion 616. Further, the cushion 616 includes an additional projection 656 that engages with an additional recess 657 provided on the frame 614. The additional projection 656/recess 657 may facilitate alignment and/or interlocking engagement between the cushion 616 and the frame 614.

**[00109]** Figs. 12 and 13 illustrate a mask assembly 710 including a cushion to frame assembly mechanism according to another embodiment of the present invention. Similar to the above embodiment, the cushion to frame assembly mechanism includes a cushion 716 with integrally molded tabs 752 that are adapted to removably interlock with locking features molded onto the frame 714.

**[00110]** As illustrated, each side wall 724 of the cushion 716 includes a protruding tab 752 that defines an opening 753. In addition, each side wall 724 includes a first locking member 760 that extends along the length thereof. The frame 714 includes a protrusion 754 on opposite side walls 720 thereof. In addition, the side walls 720 each include a second locking member 762 that extends along the length thereof.

**[00111]** As shown in Fig. 13, the cushion 716 is engaged with the frame 714 such that the tabs 752 interlock with respective protrusions 754 provided on the frame 714. Specifically, the tabs 752 are pulled over respective protrusions 754 until the protrusions 754 protrude through respective openings 753 in the tabs 752. In addition, the first locking member 760 interlocks with the second locking member 762 to further secure the cushion 716 to the frame 714 and provide a seal. As illustrated, the first locking member 760 includes an elongated resiliently flexible lip 770 is adapted to engage the lower edge of the frame 714. The lip 770 is resiliently flexible so that it provides a pressure assisted seal in use.

**[00112]** In an embodiment, the frame 614 could potentially be over-molded with the cushion 616, thereby negating the need for frame recesses 621 and respective cushion hooks 652. Also, the frame 714 could potentially be over-molded with the cushion 716, thereby negating the need for frame protrusions 754 and respective cushion protruding tabs 752.

##### 5. Fifth Embodiment of Cushion to Frame Assembly Mechanism

**[00113]** Figs. 14-17 illustrate a mask assembly 810 including a cushion to frame assembly mechanism according to another embodiment of the present invention. In the

illustrated embodiment, the cushion to frame assembly mechanism includes a frame clip 812 and fold-over clips 852 that are adapted to removably connect the frame 814 to the cushion 816.

[00114] As shown in Fig. 14, the cushion 816 includes a side wall 824 and a face contacting portion 826 extending from the side wall 824. In an embodiment, the face contacting portion 826 has a double wall construction, e.g., membrane and underlying support cushion. Also, in an embodiment, the cushion 816 is constructed of liquid silicone rubber (LSR). However, other suitable materials may be used. As illustrated, a flange 828 protrudes outwardly from the side wall 824 around the perimeter thereof. A recess 829 is provided in a portion of the flange 828.

[00115] The frame 814 includes an upper support member 844 adapted to support a forehead support, lower headgear clip receptacles 846 (Fig. 16) adapted to be engaged with clips provided to straps of a headgear assembly (not shown), and an annular elbow connection seal 848 adapted to engage an inlet conduit, e.g., elbow. Also, the frame side wall 820 includes a flange 840 around a portion of the perimeter thereof. A recess 842 is provided in a portion of the flange 840. Further, latching features 843, e.g., two recessed portions, are provided on the flange 840. In an embodiment, the frame 814 is molded in one-piece with polycarbonate and the latching features 843 are integrally molded into the frame 814.

[00116] The frame clip 812, e.g., molded of plastic, has a hoop-like configuration that generally corresponds in shape to the cushion 816 and frame 814, e.g., generally triangular. A projection 856 is provided in a portion of the frame clip 812.

[00117] Fold-over clips 852, e.g., molded of plastic, are provided to interconnect the frame clip 812, cushion 816, and frame 814. The fold-over clips 852 may be molded separately from the frame clip 812 and then assembled thereto. Alternatively, the fold-over clips 852 may be integrally molded onto the frame clip 812. As illustrated, two fold-over clips 852 are provided. However, other suitable numbers of fold-over clips may be used, e.g., more than two, to interconnect the frame clip 812, cushion 816, and frame 814.

[00118] As shown in Fig. 15, the frame clip 812 is engaged with the cushion 816 so that it extends around the cushion perimeter and abuts the flange 828. In addition, the projection 856 of the frame clip 812 extends through the recess 829 to facilitate alignment. Further, the fold-over clips 852 (if formed separately from the frame clip 812) each include a



first latching end 853 (see Fig. 14) that is adapted to engage the frame clip 812 at a position that will align with a respective latching feature 843 of the frame 814.

[00119] As shown in Fig. 16, the frame 814 is engaged with the cushion 816/frame clip 812/fold-over clip 852 sub-assembly such that the projection 856 of the frame clip 812 extends through the recess 842 in the frame 814. Then, the fold-over clips 852 are folded over so that they engage or latch onto respective latching features 843 provided on the frame 814. Fig. 17 illustrates the assembled mask assembly 810.

[00120] In the illustrated embodiment, the frame clip 812 is assembled from the bottom, e.g., cushion side, and the fold-over clips 852 latch onto latching features 843 molded onto the frame 814. In another embodiment, the frame clip 812 may be assembled from the top, e.g., frame side, and the fold-over clips 852 may latch onto latching features molded onto the cushion 816.

[00121] As described above, the cushion 816 may include a resiliently flexible lip that is adapted to engage the frame 814 to provide a pressure assisted seal in use.

[00122] In an embodiment, the frame clip 812 may be over-molded with the cushion 816. In another embodiment, the fold-over clips 852 may be integrally molded with the frame 814 (inverse configuration from that shown, i.e., the fold-over clips 852 would latch onto the cushion 816).

## 6. Sixth Embodiment of Cushion to Frame Assembly Mechanism

[00123] Figs. 18-20 illustrate a mask assembly 910 including a cushion to frame assembly mechanism according to another embodiment of the present invention. In the illustrated embodiment, the cushion to frame assembly mechanism includes a cushion clip 912 that is adapted to removably connect the cushion 916 to the frame 914.

[00124] As shown in Fig. 18, the cushion 916 includes a side wall 924 and a face contacting portion 926 extending from the side wall 924. In an embodiment, the face contacting portion 926 has a double wall construction, e.g., membrane and underlying support cushion. Also, in an embodiment, the cushion 916 is constructed of liquid silicone rubber (LSR). However, other suitable materials may be used. As illustrated, a flange 928 protrudes inwardly from the side wall 924 around the perimeter thereof.

[00125] The frame 914 includes an upper support member 944 adapted to support a forehead support, lower headgear clip receptacles 946 adapted to be engaged with clips provided to straps of a headgear assembly (not shown), and an annular elbow connection seal 948 adapted to engage an inlet conduit, e.g., elbow. Also, the top wall of the frame 914 includes a plurality of slots 942 therethrough, e.g., three slots. In an embodiment, the frame 914 is molded in one-piece with polycarbonate, e.g., clear polycarbonate.

[00126] The cushion clip 912, e.g., molded of plastic, has a hoop-like configuration that generally corresponds in shape to the cushion 916 and frame 914, e.g., generally triangular. One or more flange portions 950 are provided around the perimeter of the cushion clip 912. Also, the cushion clip 912 includes a plurality of clip portions 952. As illustrated, the cushion clip 912 includes the same number of clip portions 952 as slots 942 on the frame 914, e.g., three clip portions.

[00127] As shown in Fig. 19, the cushion clip 912 is first assembled or interlocked with the cushion 916 to provide a cushion clip/cushion sub-assembly 980. Specifically, the cushion 916 is assembled around the cushion clip 912 by engaging the flange portions 950 of the cushion clip 912 with the flange 928 of the cushion 916. The cushion clip/cushion sub-assembly 980 is engaged with the frame 914 by inserting the clip portions 952 of the cushion clip 912 into respective slots 942 of the frame 914. The clip portions 952 are adapted to engage respective slots 942 with a snap-fit. Fig. 20 illustrates the assembled mask assembly 910 with the cushion clip/cushion sub-assembly 980 retained at three perimeter points on the frame 914.

[00128] As described above, the cushion 916 may include a resiliently flexible lip that is adapted to engage the frame 914 to provide a pressure assisted seal in use.

[00129] Also, as shown in Fig. 21, the cushion 916 may have tab features 966 on a cushion lip thereof to facilitate easier assembly of the cushion clip 912.

[00130] In an embodiment, the cushion clip 912 may be over-molded with the cushion 916.

## 7. Seventh Embodiment of Cushion to Frame Assembly Mechanism

[00131] Figs. 22-26 illustrate a mask assembly 1010 including a cushion to frame assembly mechanism according to another embodiment of the present invention. In the

illustrated embodiment, the cushion to frame assembly mechanism includes a pressure assisted lip seal design.

[00132] As best shown in Figs. 22-23, the cushion 1016 includes a side wall 1024, a face-contacting portion 1026, and a non-face-contacting portion 1027. In the illustrated embodiment, the face-contacting portion 1026 has a double wall construction, e.g., membrane and underlying support cushion. The non-face-contacting portion 1027 provides a frame connection. Specifically, the non-face-contacting portion 1027 includes inner and outer 1032, 1034 that define a retaining recess 1036 around the perimeter of the cushion 1016. In addition, the non-face-contacting portion 1027 provides an elongated resiliently flexible lip 1070 that is adapted to engage the frame 1014 to provide a pressure assisted seal in use. As shown in Fig. 22, the lip 1070 has a non-planar trajectory or configuration. In an embodiment, the lip 1070 has a length of 4-12 mm, preferably 8 mm, and a width of 0.25-1.25, preferably 0.75 mm. However, other dimensions are possible depending on application. Also, in an embodiment, the cushion 1016 is constructed of liquid silicone rubber (LSR). However, other suitable materials may be used.

[00133] As shown in Figs. 24-26, the frame 1014 includes an annular elbow connection seal 1048 adapted to engage an inlet conduit, e.g., elbow. Also, the frame 1014 provides a cushion connection including an outer wall 1020 and an inner wall 1022 that extend around the perimeter of the frame 1014. In an embodiment, the frame 1014 is molded in one-piece with polycarbonate.

[00134] As shown in Fig. 24, the cushion 1016 is engaged with the frame 1014 to provide a cushion/frame sub-assembly 1030. Specifically, the outer wall 1020 of the frame 1014 is inserted into the retaining recess 1036 of the cushion 1016, e.g., with a friction fit. In addition, the lip 1070 of the cushion 1016 resiliently engages the inner wall 1022 of the frame 1014 to provide a seal in use.

[00135] As shown in Figs. 25 and 26, a cushion clip 1012, e.g., molded of plastic, is provided to maintain engagement between the frame 1014 and the cushion 1016. As illustrated, the cushion clip 1012 includes a first retaining portion 1060 that provides a shoulder for engaging the frame 1014 and a second retaining portion 1062 that provides a shoulder for engaging the cushion 1016. Thus, the cushion clip 1012 sandwiches the frame 1014 and the cushion 1016 to maintain their engagement.

[00136] In an embodiment, the frame clip 1012 may be over-molded with the cushion 1016. In another embodiment, the frame 1014 may be over-molded with the cushion 1016, thereby negating the need for the frame clip 1012.

[00137] Figs. 27 and 28 illustrate a cushion to frame assembly mechanism according to another embodiment of the present invention. As illustrated, the frame 1114 provides a cushion connection including a side wall 1120 and an upper wall 1132 and a lower wall 1134 that extend around the perimeter of the side wall 1120. In the illustrated embodiment, the upper and lower walls 1132, 1134 are inclined such that the walls 1120, 1132, 1134 define a generally k-shaped cross-sectional configuration.

[00138] As shown in Fig. 28, the non-face-contacting portion 1127 of the cushion 1116 includes a retaining wall 1124 that is inclined towards the cushion interior. As illustrated, the end 1125 of the retaining wall 1124 has an angled or pointed configuration. In addition, the non-face-contacting portion 1127 provides an elongated resiliently flexible lip 1170.

[00139] The cushion 1116 is engaged with the frame 1114 by stretching the cushion 1116 over the frame perimeter such that the retaining wall 1124 engages within the retaining recess 1136 defined between the upper and lower walls 1132, 1134. As illustrated, the angled or pointed end 1125 of the retaining wall 1124 conforms to the incline defined by the upper and lower walls 1132, 1134. In addition, the lip 1170 of the cushion 1116 resiliently engages the inner end of the frame side wall 1120 to provide a seal in use. A cushion clip (not shown) may be provided, e.g., around the cushion perimeter, to maintain engagement between the frame 1114 and the cushion 1116.

[00140] In an embodiment, the frame 1114 could potentially be over-molded with the cushion 1116, thereby negating need for a cushion clip.

#### 8. Eighth Embodiment of Cushion to Frame Assembly Mechanism

[00141] Figs. 29-32 illustrate a mask assembly 1210 including a cushion to frame assembly mechanism according to another embodiment of the present invention. In the illustrated embodiment, the cushion to frame assembly mechanism includes an integrated lip seal design.

[00142] As illustrated, the frame 1214 includes an annular elbow connection seal 1248 adapted to engage an inlet conduit, e.g., elbow. Also, the frame 1214 provides a cushion

connection including an outer wall 1220 and an inner wall 1222 that extend around the perimeter of the frame 1214. The outer and inner walls 1220, 1222 define a retaining recess 1236 therebetween. In an embodiment, the frame 1214 is molded in one-piece with polycarbonate.

**[00143]** The non-face-contacting portion 1227 of the cushion 1216 includes a retaining portion 1260. As illustrated, the end 1261 of the retaining portion 1260 has an angled or pointed configuration. In addition, the non-face-contacting portion 1227 provides a resiliently flexible lip 1270. A space 1271 is provided behind the lip 1270 to provide the lip 1270 with a range of movement in use.

**[00144]** As shown in Figs. 30 and 32, the frame 1214 is engaged with the cushion 1216 such that the retaining portion 1260 of the cushion 1216 engages within the retaining recess 1236 defined between the outer and inner walls 1220, 1222. As illustrated, the angled or pointed end 1261 of the retaining portion 1260 conforms to the incline defined by the outer and inner walls 1220, 1222. In addition, the lip 1270 of the cushion 1216 resiliently engages the inner wall 1222 of the frame 1214 to provide a seal in use. The lip 1270 may deflect inwardly into the space 1271, against resiliency thereof, to provide the seal. Also, as shown in Fig. 30, a pressure line 1276 may be incorporated into the flange perimeter of the frame 1214 and cushion 1216.

**[00145]** A frame clip may be provided to maintain engagement between the frame 1214 and the cushion 1216. The frame clip may be assembled from the bottom, e.g., cushion side, or the frame clip may be assembled from the top, e.g., frame side.

**[00146]** Figs. 33-34 illustrate a bottom assembling frame clip 1312. As illustrated, the frame clip 1312, e.g., molded of plastic, is assembled over the cushion 1216 and includes a first retaining portion 1375 that provides a shoulder for engaging the cushion flange 1254 and a plurality of second retaining portions 1377 that provide a shoulder for engaging the frame 1214. Thus, the frame clip 1312 sandwiches the frame 1214 and the cushion 1216 to maintain their engagement.

**[00147]** In an embodiment, the frame clip 1312 may be over-molded with the cushion 1216. In another embodiment, the frame 1214 may be over-molded with the cushion 1216, thereby negating the need for the frame clip 1312.

[00148] Figs. 35-39 illustrate a top assembling frame clip 1412. Similar to the above, the frame 1214 is engaged with the cushion 1216 such that the retaining portion 1260 of the cushion 1216 engages within the retaining recess 1236 defined between the outer and inner walls 1220, 1222 (see Figs. 35-36). Fig. 38 illustrates a portion of the cushion 1216 to show the retaining portion 1260, the lip 1270, and the face-contacting portion 1226 thereof. Fig. 38 also illustrates an undercut region 1266 in the cushion 1216 that defines the cushion flange 1254.

[00149] The frame clip 1412, e.g., molded of plastic, is assembled over the frame 1214 and includes a first retaining portion 1475 that provides a shoulder for engaging the frame 1214 and a plurality of second retaining portions 1477, e.g., three retaining portions, that provide a shoulder for engaging the cushion flange 1254, as shown in Figs. 36, 37, and 39. Thus, the frame clip 1412 sandwiches the frame 1214 and the cushion 1216 to maintain their engagement as best shown in Fig. 39.

[00150] In an embodiment, the frame 1214 could potentially be over-molded with the cushion 1216, thereby negating the need for the frame clip 1412.

[00151] In an alternative embodiment, as shown in Fig. 40, the inner wall 1222 of the frame 1214 may include a protrusion 1223 along the perimeter thereof. The protrusion 1223 provides interference with the cushion 1216 in use, thereby preventing inadvertent removal of the cushion 1216 from the frame 1214. Moreover, the protrusion 1223 may provide sufficient interference to avoid the need for a frame clip.

[00152] Figs. 41-44 illustrate another cushion to frame assembly mechanism including a cushion clip 1512 for use with a cushion 1516 having an integrated lip seal. As illustrated, the non-face-contacting portion 1527 of the cushion 1516 includes a retaining recess 1536 around the perimeter thereof that is adapted to engage the cushion clip 1512. Specifically, the cushion clip 1512, e.g., molded of plastic, includes one or more flange portions 1550 around the perimeter thereof that are engaged within the retaining recess 1536 of the cushion 1516 to provide a cushion clip/cushion sub-assembly 1580.

[00153] The cushion clip/cushion sub-assembly 1580 is then engaged with the frame 1514 by inserting the clip portions 1552, e.g., three clip portions, of the cushion clip 1512 into respective slots 1542 of the frame 1514. The clip portions 1552 are adapted to engage respective slots 1542 with a snap-fit. Fig. 44 illustrates the assembled mask assembly 1510

with the cushion clip/cushion sub-assembly 1580 retained on the frame 1514. As illustrated, the lip 1570 of the cushion 1516 resiliently engages the inner wall 1520 of the frame 1514 to provide a seal in use.

[00154] In an embodiment, the cushion clip 1512 could potentially be over-molded with the cushion 1516.

#### 9. Ninth Embodiment of Cushion to Frame Assembly Mechanism

[00155] Figs. 45 and 46 illustrate a mask assembly 1610 including a cushion to frame assembly mechanism according to another embodiment of the present invention. In the illustrated embodiment, the cushion to frame assembly mechanism includes a slide-on two-part frame clip 1612 that is adapted to removably connect the cushion 1616 to the frame 1614.

[00156] As shown in Fig. 45, the cushion 1616 includes a side wall 1624 and a face contacting portion 1626 extending from the side wall 1624. In an embodiment, the face contacting portion 1626 may have a double wall construction, e.g., membrane and underlying support cushion. Also, in an embodiment, the cushion 1616 is constructed of liquid silicone rubber (LSR). However, other suitable materials may be used. As illustrated, a flange 1628 protrudes inwardly from the side wall 1624 around the perimeter thereof.

[00157] The frame 1614 includes an opening 1648 that is communicated with an inlet conduit. Also, the frame 1614 provides a flange 1620 that extends around the perimeter of the frame 1614. In an embodiment, the frame 1614 is molded in one-piece with polycarbonate.

[00158] The slide-on two-part frame clip 1612 includes a first part 1632 and a second part 1634 attachable to the first part 1632, e.g., with a snap-fit. The first part 1632 includes an upper support member 1644 adapted to support a forehead support and an annular elbow connection seal 1649 adapted to engage an inlet conduit, e.g., elbow. Also, the perimeter of the first part 1632 includes spaced apart upper and lower wall portions 1636, 1638. The second part 1634 includes lower headgear clip receptacles 1646 adapted to be engaged with clips provided to straps of a headgear assembly (not shown) and retaining members 1647 adapted to interlock with the first part 1632. Also, the perimeter of the second part 1634

includes spaced apart upper and lower wall portions (not shown). In an embodiment, the first and second parts 1632, 1634 of the frame clip 1612 are molded with polycarbonate.

**[00159]** The cushion 1616 is first engaged with the frame 1614 to provide a cushion/frame sub-assembly. Specifically, the side wall 1624 of the cushion 1616 is engaged with the side wall of the frame 1614, e.g., with a friction fit, such that the cushion flange 1628 engages against the frame flange 1620 (see Fig. 46).

**[00160]** Then, the first part 1632 of the frame clip 1612 is slid onto one side of the cushion/frame sub-assembly and the second part 1634 is slid onto the opposite side of the cushion/frame sub-assembly such that the upper and lower wall portions 1636, 1638 of the first and second parts 1632, 1634 sandwich the cushion flange 1628 and the frame flange 1620 therebetween (see Fig. 46). The first and second parts 1632, 1634 are slid towards one another until the retaining members 1647 of the second part 1634 interlock with the first part 1632, e.g., with a snap-fit. Thus, the first and second parts 1632, 1634 sandwich the frame 1614 and the cushion 1616 to maintain their engagement. The upper and lower wall portions 1636, 1638 of the first and second parts 1632, 1634 provide a compression seal in use.

**[00161]** Figs. 47-49 illustrate a mask assembly substantially similar to the mask assembly 1610 described above. Therefore, similar components are indicated with similar reference numerals. In contrast, the second part 1634 includes lower headgear cross-bars 1746 adapted to be engaged with straps of a headgear assembly (not shown). Also, an inner frame member provided between the cushion 1616 and frame clip 1612 is not shown.

**[00162]** In each embodiment, the cushion to frame assembly mechanism provides a flat or radial slide path.

**[00163]** In an embodiment, the frame 1614 and cushion 1616 may be integrally molded in one-piece, e.g., with LSR, to provide a one-piece cushion/frame sub-assembly.

**[00164]** Figs. 50-51 illustrate alternative frame clip designs. Fig. 50 illustrates an over-center clip 1812 having a plurality of hinged links 1813, e.g., three links, that can be pivoted to secure the clip 1812 in place. Fig. 51 illustrates a ratchet clip 1912 having arms 1913, 1915 that are pivotable about hinge point P. The arms 1913, 1915 have toothed end portions 1917, 1919 that interlock to secure the clip 1912 in place.



#### 10. Tenth Embodiment of Cushion to Frame Assembly Mechanism

**[00165]** Figs. 52-71 illustrate a mask assembly 2010 including a cushion to frame assembly mechanism according to another embodiment of the present invention. In the illustrated embodiment, the cushion to frame assembly mechanism includes a cushion clip 2012 that is adapted to removably connect the cushion 2016 to the frame 2014.

**[00166]** As shown in Figs. 52-55 and 62-66, the cushion 2016 includes a face-contacting portion 2026 and a non-face-contacting portion 2027. In an embodiment, the face contacting portion 2026 has a double wall construction, e.g., membrane and underlying support cushion. Also, in an embodiment, the cushion 2016 is constructed of liquid silicone rubber (LSR). However, other suitable materials may be used. As illustrated, the non-face-contacting portion 2027 of the cushion 2016 includes a retaining recess 2036 around the perimeter thereof that is adapted to engage the cushion clip 2012.

**[00167]** As shown in Figs. 52-61, the frame 2014 includes an upper support member 2044 adapted to support a forehead support, lower headgear clip receptacles 2046 adapted to be engaged with clips provided to straps of a headgear assembly (not shown), and an annular elbow connection seal 2048 adapted to engage an inlet conduit, e.g., elbow. Also, the top wall of the frame 2014 includes a plurality of slots 2042 therethrough, e.g., three slots. In an embodiment, the frame 2014 is molded in one-piece with polycarbonate.

**[00168]** As shown in Figs. 52-56 and 67-71, the cushion clip 2012, e.g., molded of plastic, has a hoop-like configuration that generally corresponds in shape to the cushion 2016 and frame 2014, e.g., generally triangular. In addition, the cushion clip 2012 is contoured to match the contour of the frame 2014 and cushion 2016. One or more flange portions 2050 are provided around the perimeter of the cushion clip 2012. Also, the cushion clip 2012 includes a plurality of clip portions 2052. As illustrated, the cushion clip 2012 includes the same number of clip portions 2052 as slots 2042 on the frame 2014, e.g., three clip portions.

**[00169]** As shown in Fig. 53, the cushion clip 2012 is first assembled or interlocked with the cushion 2016 to provide a cushion clip/cushion sub-assembly 2080. Specifically, the cushion 2016 is assembled around the cushion clip 2012 by engaging the flange portions 2050 of the cushion clip 2012 within the retaining recess 2036 of the cushion 2016. The cushion clip/cushion sub-assembly 2080 is then engaged with the frame 2014 by inserting the clip portions 2052 of the cushion clip 2012 into respective slots 2042 of the frame 2014. The clip

portions 2052 are adapted to engage respective slots 2042 with a snap-fit. Fig. 54-56 illustrate the assembled mask assembly 2010 with the cushion clip/cushion sub-assembly 2080 retained at three perimeter points on the frame 2014.

[00170] As best shown in Figs. 52, 63B, 64, and 70, the cushion clip 2012 includes slots 2013 on opposing sides thereof, i.e., created by breaks in the flange portions 2050, that interlock or engage with respective solid sections 2037 provided in the retaining recess 2036 on opposing sides of the cushion 2016. The two solid sections 2037 assist with the correct orientation or alignment of the cushion clip 2012 onto the cushion 2016.

[00171] As best shown in Figs. 55 and 66, the cushion 2016 includes a resiliently flexible lip 2070 that resiliently engages the inner wall 2020 of the frame 2014 to provide a seal in use. Also, the cushion 2016 includes finger grips 2092 on a flange portion thereof to facilitate assembly (e.g., see Figs. 62, 65, and 66).

[00172] The clip portions 2052 of the cushion clip 2012 include contoured finger grips 2094 to facilitate assembly. As illustrated, the finger grips 2094 are relatively thick for ease of finding and use.

[00173] Figs. 92-105 illustrate a mask assembly substantially similar to the mask assembly 2010 described above. Therefore, similar components are indicated with similar reference numerals. In contrast, the cushion clip 2012 of Figs. 92-105 includes a continuous flange 2050 that extends or runs around the entire perimeter of the cushion clip 2012. Thus, the cushion clip 2012 of Figs. 92-105 does not include any slots along the flange 2050, and the two solid sections in the cushion retaining recess of the cushion shown in Figs. 52-71 may be removed. Removal of the interlocking feature, i.e., slot of clip interlocked with solid section of cushion, provides more support to the cushion 2016 to prevent leak between the cushion and the frame. The continuous flange 2050 of Figs. 92-105 also makes the cushion clip 2012 stiffer.

[00174] Figs. 55 and 95 illustrate the assembled cushion 2016, cushion clip 2012, and frame 2014 at top and bottom portions of the mask assembly. Figs. 106 and 107 illustrate an alternative embodiment at top and bottom portions of the mask assembly. For example, the top wall 2001 of the frame 2014 at top and bottom portions thereof may have a steeper angle or incline for styling or aesthetics purposes. Also, the exterior or outer surface 2017 of the cushion 2016 may be angled or inclined. The inclined outer surface 2017 varies the gap or

distance between the outer surface 2017 and the inner surface of the frame side wall 2003. This may facilitate reduction of the possible movement range between the cushion 2016 and the frame wall 2003, which in turn reduces system leakage under side loading.

[00175] In each of the embodiments, the cushion clip 2012 could potentially be over-molded with the cushion 2016.

#### 11. Eleventh Embodiment of Cushion to Frame Assembly Mechanism

[00176] Figs. 72-91 illustrate a mask assembly 2110 including a cushion to frame assembly mechanism according to another embodiment of the present invention. In the illustrated embodiment, the cushion to frame assembly mechanism includes an integrated lip seal design and a frame clip 2112 that is adapted to removably connect the cushion 2116 to the frame 2114.

[00177] As shown in Figs. 72-81, the frame 2114 includes an upper support member 2144 adapted to support a forehead support, lower headgear clip receptacles 2146 adapted to be engaged with clips provided to straps of a headgear assembly (not shown), and an annular elbow connection seal 2148 adapted to engage an inlet conduit, e.g., elbow. Also, the frame 2114 provides a cushion connection including an outer wall 2120 and an inner wall 2122 that extend around the perimeter of the frame 2114. The outer and inner walls 2120, 2122 define a retaining recess 2136 therebetween. In an embodiment, the frame 2114 is molded in one-piece with polycarbonate.

[00178] As shown in Figs. 72-75 and 82-86, the cushion 2116 includes a face-contacting portion 2126 and a non-face-contacting portion 2127. In an embodiment, the face contacting portion 2126 has a double wall construction, e.g., membrane and underlying support cushion. Also, in an embodiment, the cushion 2116 is constructed of liquid silicone rubber (LSR). However, other suitable materials may be used. The non-face-contacting portion 2127 of the cushion 2116 includes a retaining portion 2160. As illustrated, the end 2161 of the retaining portion 2160 has an angled or pointed configuration. In addition, the non-face-contacting portion 2127 provides a resiliently flexible lip 2170. A space 2171 is provided behind the lip 2170 to provide the lip 2170 with a range of movement in use.

[00179] As shown in Figs. 73 and 75, the frame 2114 is engaged with the cushion 2116 such that the retaining portion 2160 of the cushion 2116 engages within the retaining recess

2136 defined between the outer and inner walls 2120, 2122. As illustrated, the angled or pointed end 2161 of the retaining portion 2160 conforms to the incline defined by the outer and inner walls 2120, 2122. In addition, the lip 2170 of the cushion 2116 resiliently engages the inner wall 2122 of the frame 2114 to provide a seal in use. The lip 2170 may deflect inwardly into the space 2171, against resiliency thereof, to provide the seal.

**[00180]** As shown in Figs. 72-76 and 87-91, a bottom assembling frame clip 2112 is provided to maintain engagement between the frame 2114 and the cushion 2116. The frame clip 2112 is contoured to match the contour of the frame 2114 and cushion 2116. As illustrated, the frame clip 2112, e.g., molded of polycarbonate, is assembled over the cushion 2116 and includes a first retaining portion 2175 that provides a shoulder for engaging the cushion flange 2154 and a plurality of second retaining portions 2177, e.g., three retaining portions 2177, that provide a shoulder for engaging the frame 2114. Thus, the frame clip 2112 sandwiches the frame 2114 and the cushion 2116 to maintain their engagement as shown in Figs. 74-76.

**[00181]** The retaining portions 2177 of the frame clip 2112 include contoured finger grips 2194 to facilitate assembly. As illustrated, the finger grips 2194 are relatively thick for ease of finding and use.

**[00182]** In the illustrated embodiment, the cushion to frame assembly mechanism includes three retention points, e.g., three retaining portions 2177. Three retention points makes assembly time quicker and reduces the perceived (aesthetic) and actual (physical) assembly task complexity. Also, because the cushion 2116 includes the lip seal 2170, a high compression force between the frame 2114, cushion 2116, and frame clip 2112 is not required and three retaining portions 2177 are sufficient for sealing/retaining purposes.

**[00183]** Also, the frame 2114 includes top hat sections 2196 that engage respective retaining portions 2177 of the frame clip 2112 in use (e.g., see Figs. 72, 73, and 77-79). The top hat sections 2196 provide a visual cue or indication as to where the frame clip 2112 clips onto the frame 2114, aid with alignment of the 2116 cushion onto the frame 2114 (e.g., cushion 2116 may have integrally molded protruding sections that align with the top hat sections 2196 of the frame 2114), provide guide or alignment points for possible automated assembly, and provide aesthetic interest or feature to the frame 2114.

**[00184]** In an embodiment, the frame clip 2112 may be over-molded with the cushion 2116. In another embodiment, the frame 2114 may be over-molded with the cushion 2116, thereby negating the need for the frame clip 2112.

**[00185]** While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, barriatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

## WHAT IS CLAIMED IS:

1. A full-face mask assembly, comprising:  
a frame;  
a cushion provided to the frame, the cushion adapted to form a seal around the patient's nose and mouth; and  
a flexible lip provided to an interior wall of the cushion, the flexible lip adapted to engage the frame to provide a seal in use.
2. The full-face mask assembly according to claim 1, wherein the flexible lip is integrally formed in one piece with the cushion.
3. The full-face mask assembly according to any one of claims 1-2, wherein the frame includes an outer wall adapted to engage a frame connector provided to the cushion and an inner wall adapted to engage the flexible lip.
4. The full-face mask assembly according to any one of claims 1-3, wherein the lip has a non-planar trajectory around the perimeter of the cushion.
5. The full-face mask assembly according to any one of claims 1-4, wherein the frame includes outer and inner walls that define a retaining recess adapted to receive therein a retaining portion provided to the cushion, the flexible lip provided to the retaining portion to engage the inner wall.
6. The full-face mask assembly according to claim 5, wherein the retaining portion includes a space behind the lip to provide the lip with a range of movement in use.
7. The full-face mask assembly according to any one of claims 1-6, further comprising a clip to maintain the cushion to the frame.

8. A full-face mask assembly, comprising:  
a frame; and  
a cushion provided to the frame, the cushion adapted to form a seal around the patient's nose and mouth,  
the frame including a retaining recess that is adapted to receive a retaining portion provided to the cushion, the retaining recess having an angled configuration with respect to the frame.

9. The full-face mask assembly according to claim 8, wherein the frame includes a side wall and an upper wall and a lower wall that extend around the perimeter of the side wall, the upper wall and lower wall defining the retaining recess and being inclined such that the side wall, upper wall, and lower wall define a generally k-shaped cross-sectional configuration.

10. A full-face mask assembly, comprising:  
a frame;  
a cushion provided to the frame, the cushion adapted to form a seal around the patient's nose and mouth; and  
a clip to maintain the cushion to the frame.

11. The full-face mask assembly according to claim 10; wherein the cushion includes a cushion wall and a face-contacting portion extending from the cushion wall, and the clip provides support wings that support the cushion wall in use.

12. The full-face mask assembly according to any one of claims 10-11, wherein the clip is slid onto the frame and the cushion so that the clip and the frame sandwich the cushion therebetween.

13. The full-face mask assembly according to claim 10, further comprising fold-over clips that sandwich the clip, cushion, and frame therebetween.

14. The full-face mask assembly according to claim 13, wherein the fold-over clips are integrally molded in one-piece with the clip.
15. The full-face mask assembly according to claim 13, wherein the fold-over clips are formed separately from the clip and attached thereto.
16. The full-face mask assembly according to any one of claims 13-15, wherein the fold-over clips latch onto latching features provided to the frame.
17. The full-face mask assembly according to claim 10, wherein the clip includes flange portions adapted to engage the cushion and clip portions adapted to engage respective slots provided to the frame.
18. The full-face mask assembly according to claim 10, wherein the clip includes a first part and a second part attachable to the first part.
19. The full-face mask assembly according to claim 18, wherein the first part includes an upper support member adapted to support a forehead support and an annular elbow connection seal adapted to engage an inlet conduit, and the second part includes lower headgear clip receptacles adapted to be engaged with clips provided to straps of a headgear assembly.
20. The full-face mask assembly according to any one of claims 18-19, wherein the first and second parts are slid onto the frame and the cushion so that the first and second parts cooperate to sandwich the frame and the cushion therebetween.
21. The full-face mask assembly according to any one of claims 18-20, wherein the first and second parts are interlockable with a snap-fit.
22. The full-face mask assembly according to claim 10, wherein the clip includes a plurality of hinged links that can be pivoted to secure the clip in place.



23. The full-face mask assembly according to claim 10, wherein the clip includes a pair of arms that are pivotable about a hinge point, the arms having toothed end portions that interlock to secure the clip in place.

24. The full-face mask assembly according to claim 10, wherein the clip includes a flange that extends around at least a portion of the perimeter of the clip, the flange engaged within a retaining recess provided to the cushion.

25. The full-face mask assembly according to claim 24, wherein the flange is continuous and extends around the entire perimeter of the clip.

26. The full-face mask assembly according to claim 24, wherein the flange defines at least one slot that interlocks with a respective solid section provided within the retaining recess of the cushion.

27. The full-face mask assembly according to claim 26, wherein the flange defines two slots that interlock with respective solid sections provided within the retaining recess of the cushion.

28. The full-face mask assembly according to claim 10, wherein the cushion includes an inclined exterior surface that varies a gap between the inclined exterior surface and an inner surface of the frame.

29. The full-face mask assembly according to claim 10, wherein the frame includes a top wall that defines a portion of a channel for receiving the cushion, the top wall having an incline.

30. A full-face mask assembly, comprising:  
a frame;  
a cushion provided to the frame, the cushion adapted to form a seal around the patient's nose and mouth; and

a skeleton frame to maintain the cushion to the frame, the skeleton frame including at least one of an upper support member adapted to support a forehead support, lower headgear clip receptacles adapted to be engaged with clips provided to straps of a headgear assembly, and an annular elbow connection seal adapted to engage an inlet conduit.

31. The full-face mask assembly according to claim 30, wherein frame and cushion are integrally molded in one-piece to provide a cushion/frame sub-assembly.

32. The full-face mask assembly according to claim 30, wherein the frame and cushion are formed separately from one another and then interlocked to provide a cushion/frame sub-assembly.

33. The full-face mask assembly according to any one of claims 30-32, wherein the skeleton frame includes elongated frame members that interlock with respective protrusions provided to the cushion/frame sub-assembly.

34. The full-face mask assembly according to any one of claims 30-33, wherein the skeleton frame includes tabs that are received within respective slots provided to the cushion/frame sub-assembly.

35. A full-face mask assembly, comprising:  
a frame; and  
a cushion provided to the frame, the cushion adapted to form a seal around the patient's nose and mouth,  
the cushion including hooks or tabs integrally formed therewith that are adapted to interlock with locking features integrally formed with the frame.

36. The full-face mask assembly according to claim 35, wherein the cushion includes hooks that interlock with respective recesses provided to the frame.

37. The full-face mask assembly according to claim 35, wherein the cushion includes tabs that are pulled over respective protrusions provided to the frame until the protrusions protrude through respective openings in the tabs.

38. A full-face mask assembly, comprising:  
a frame; and  
a cushion provided to the frame, the cushion adapted to form a seal around the patient's nose and mouth,  
the frame including outer and inner walls that define a retaining recess adapted to receive therein a retaining portion provided to the cushion, the retaining portion including a flexible lip to engage the inner wall and provide a seal in use, and the retaining portion including a space behind the flexible lip to provide the flexible lip with a range of movement.

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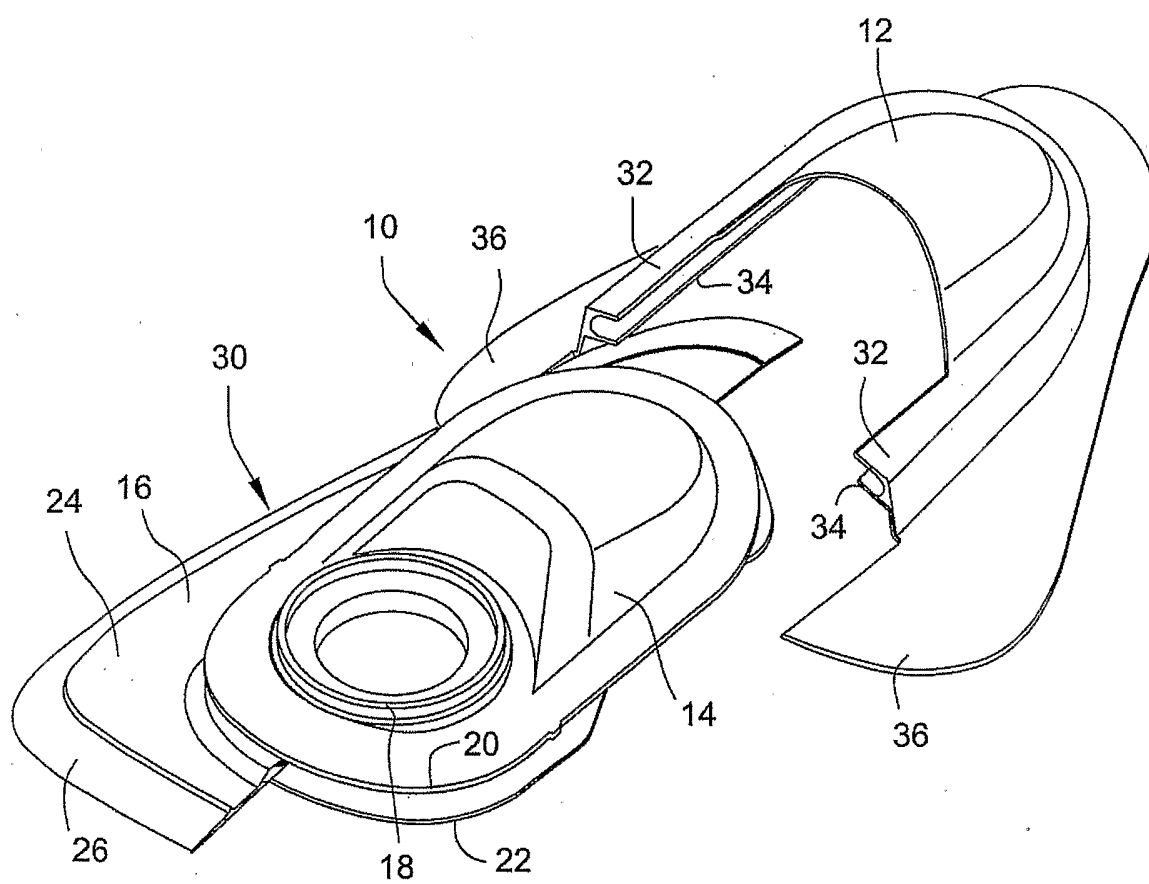


Fig. 1

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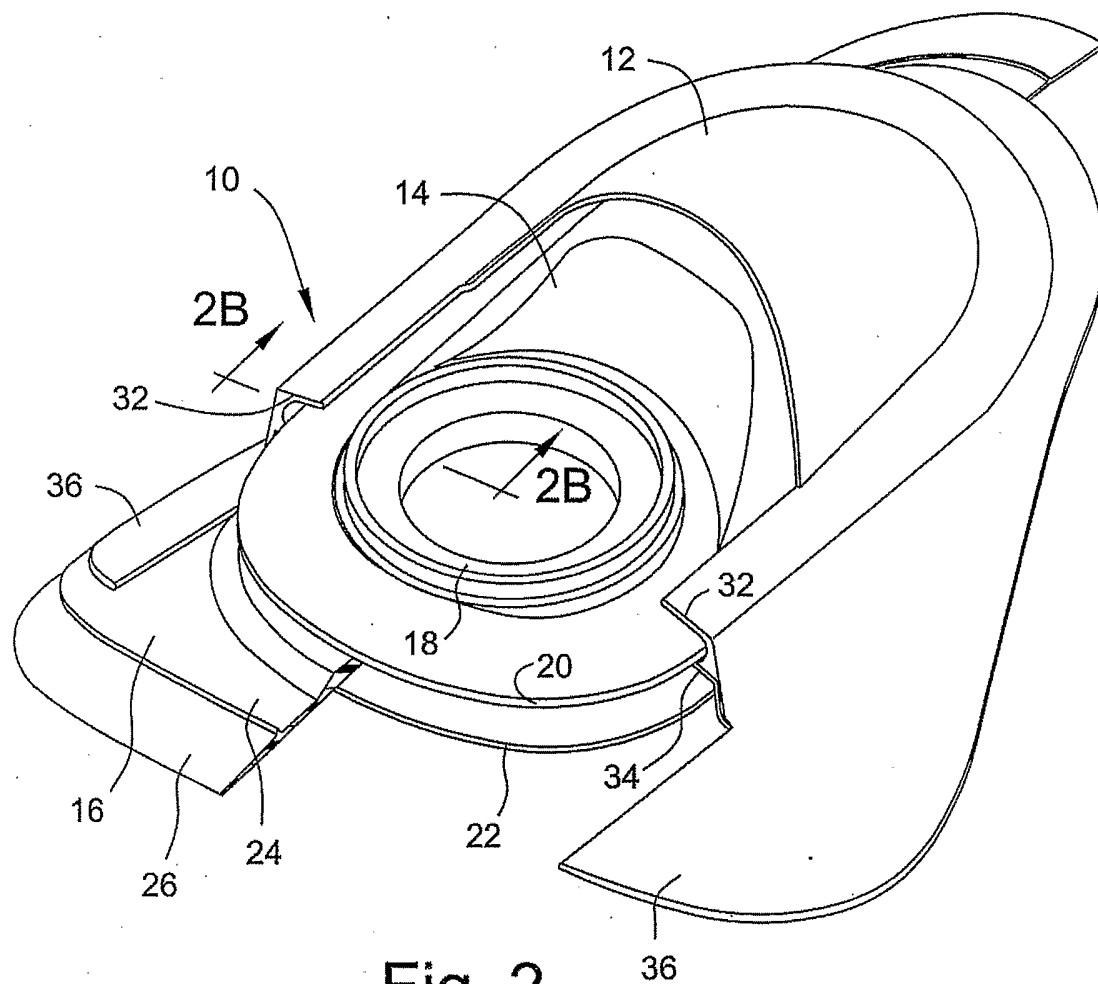


Fig. 2

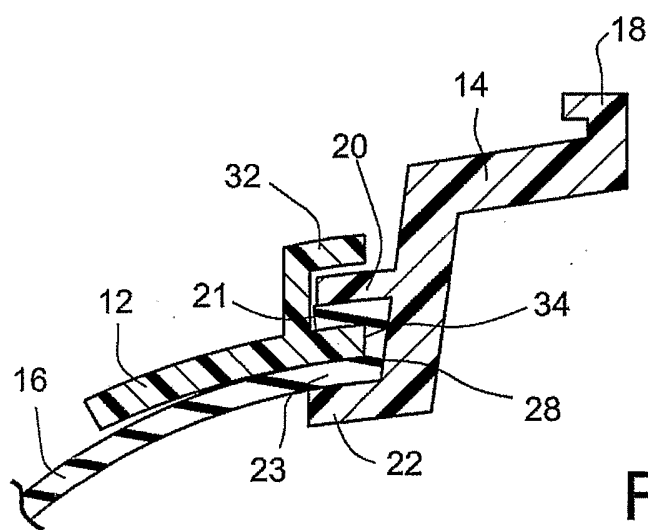
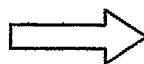
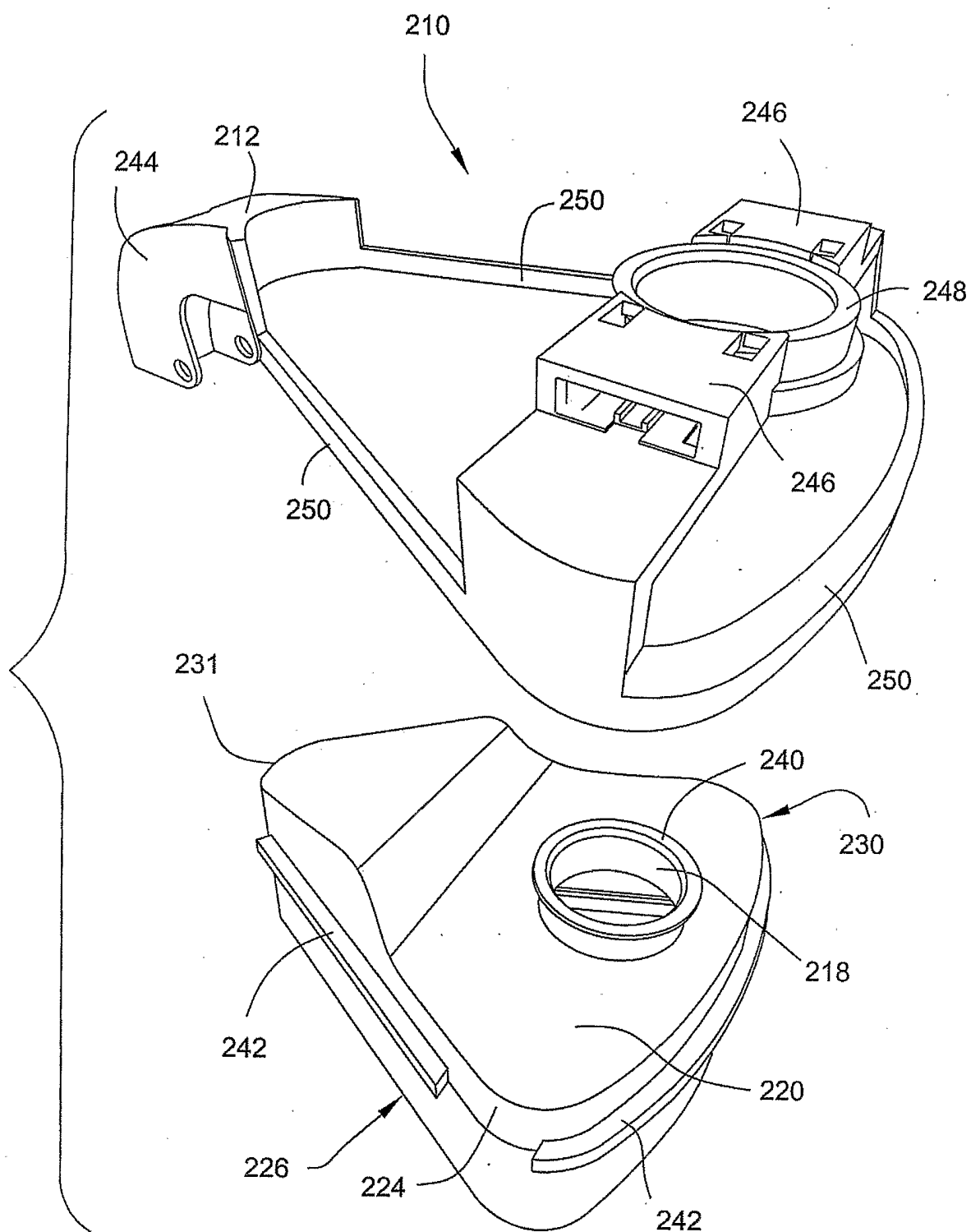


Fig. 2B



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**Fig. 3**

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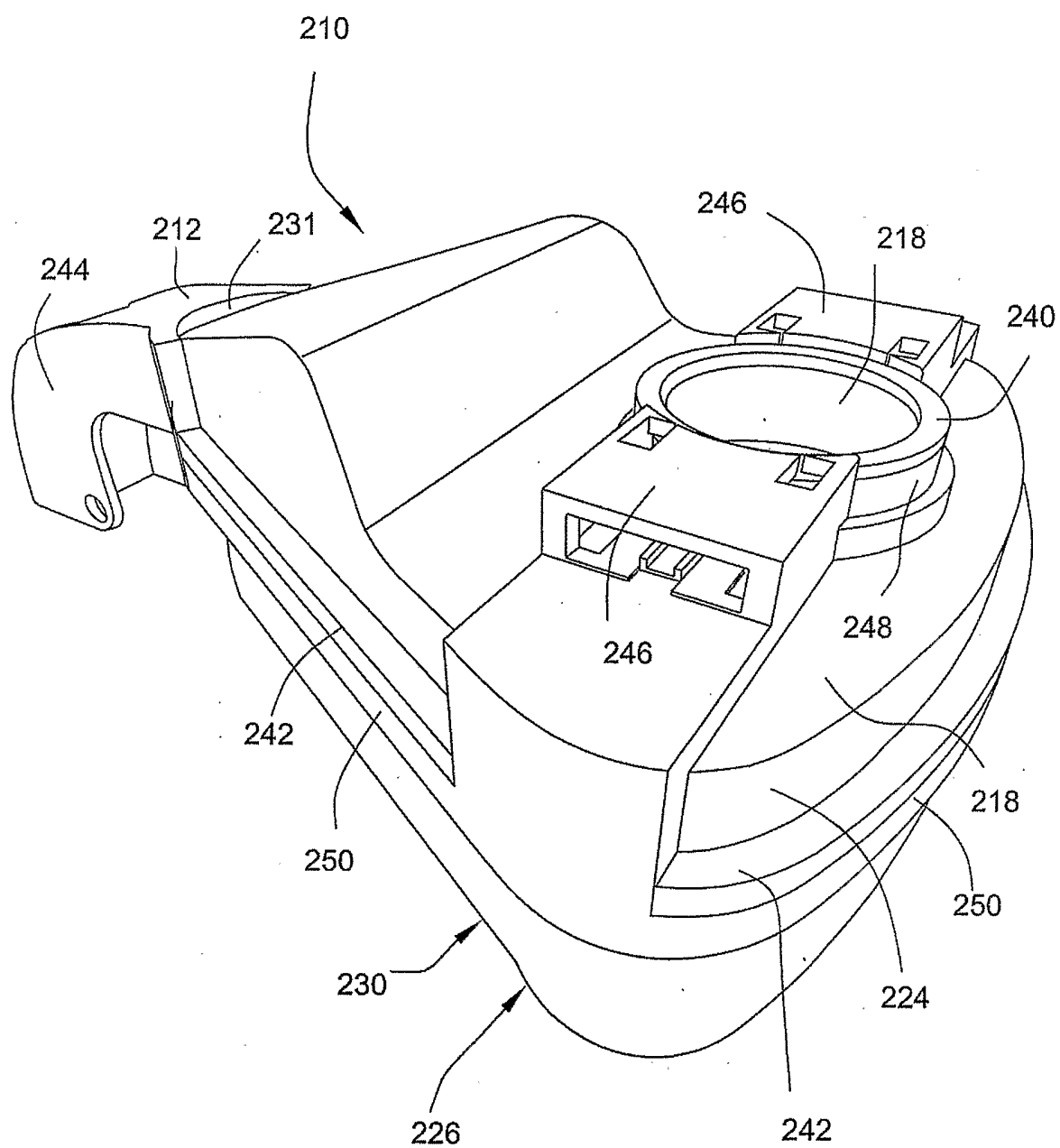
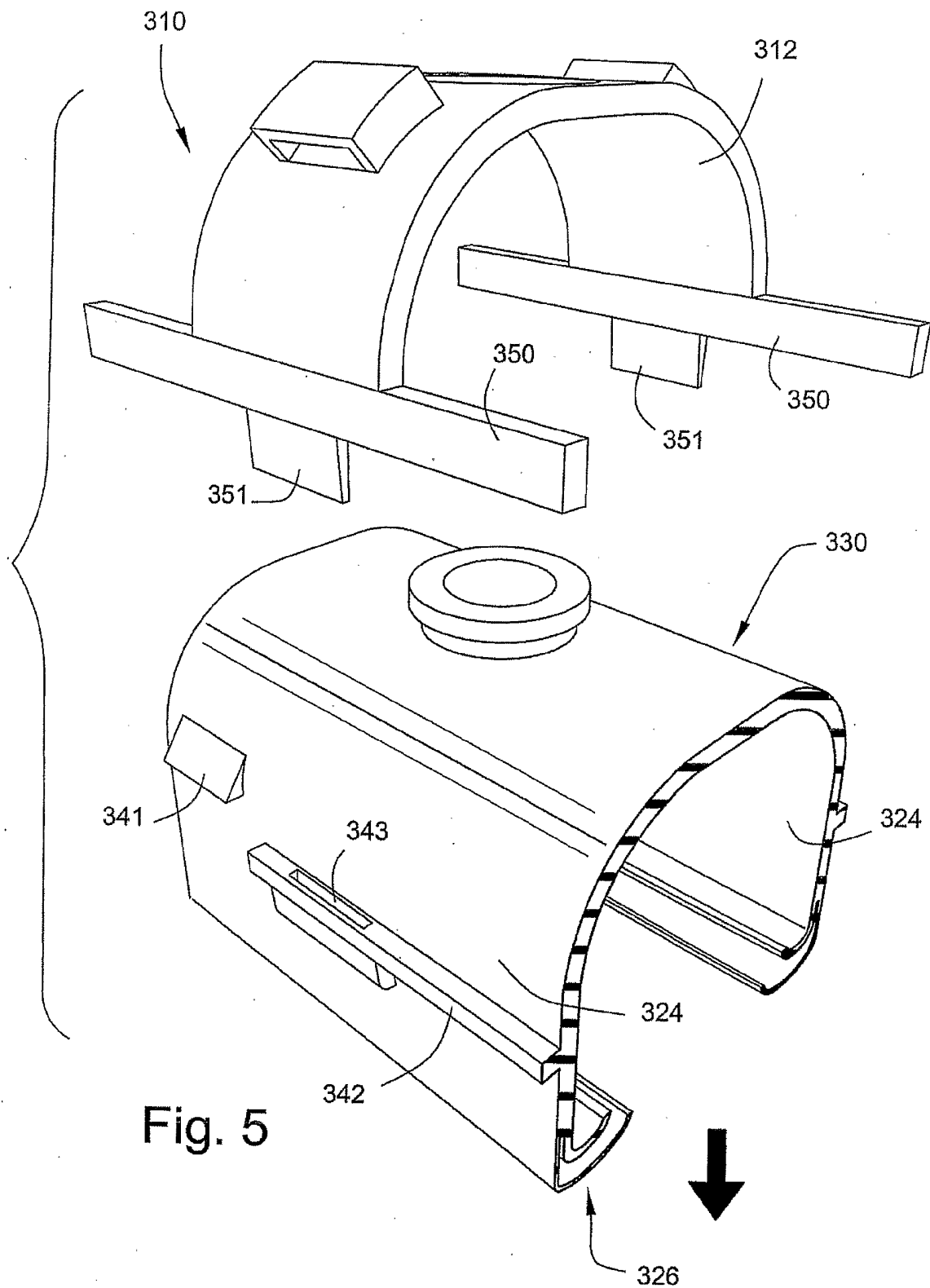


Fig. 4

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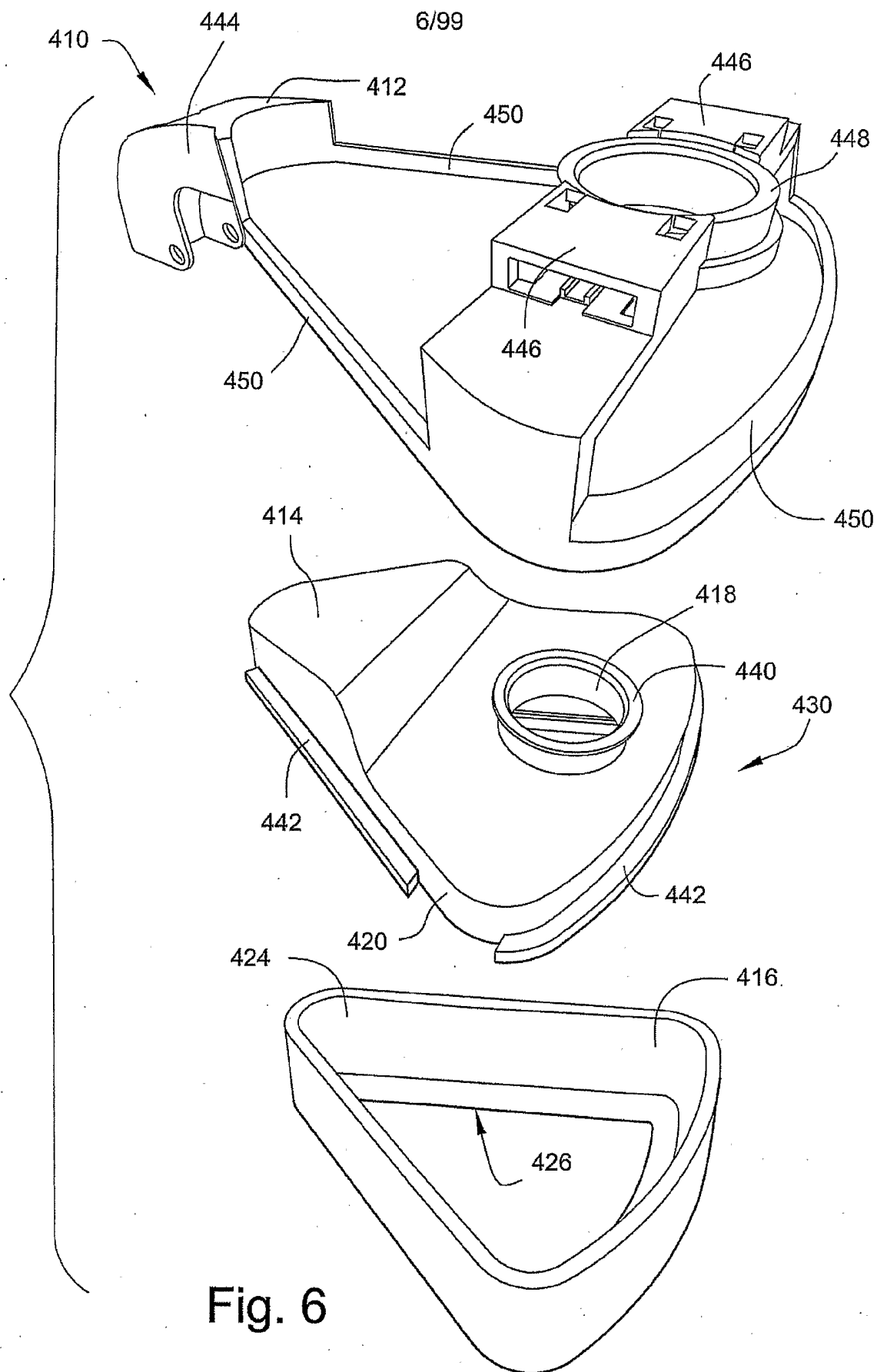


Fig. 6

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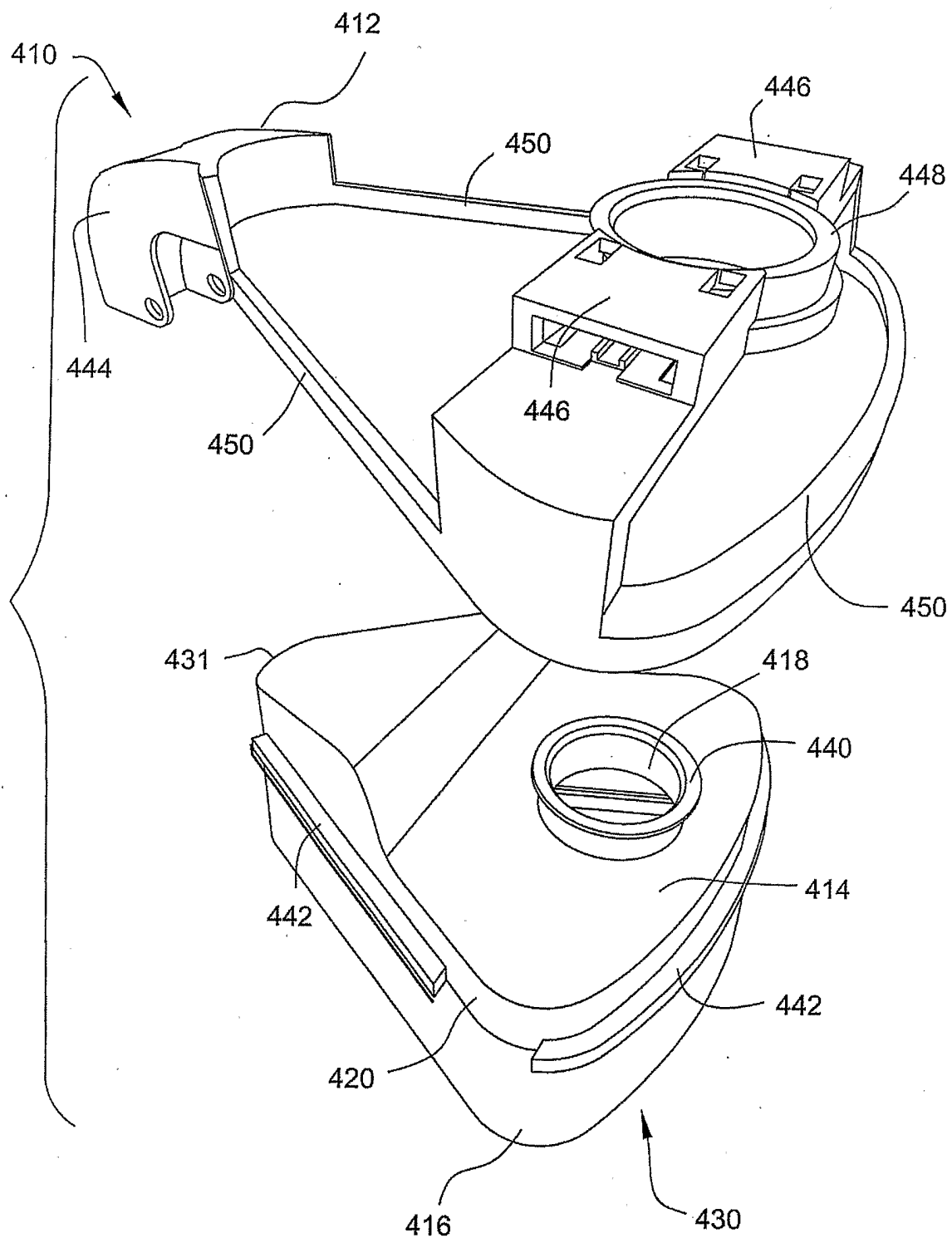


Fig. 7

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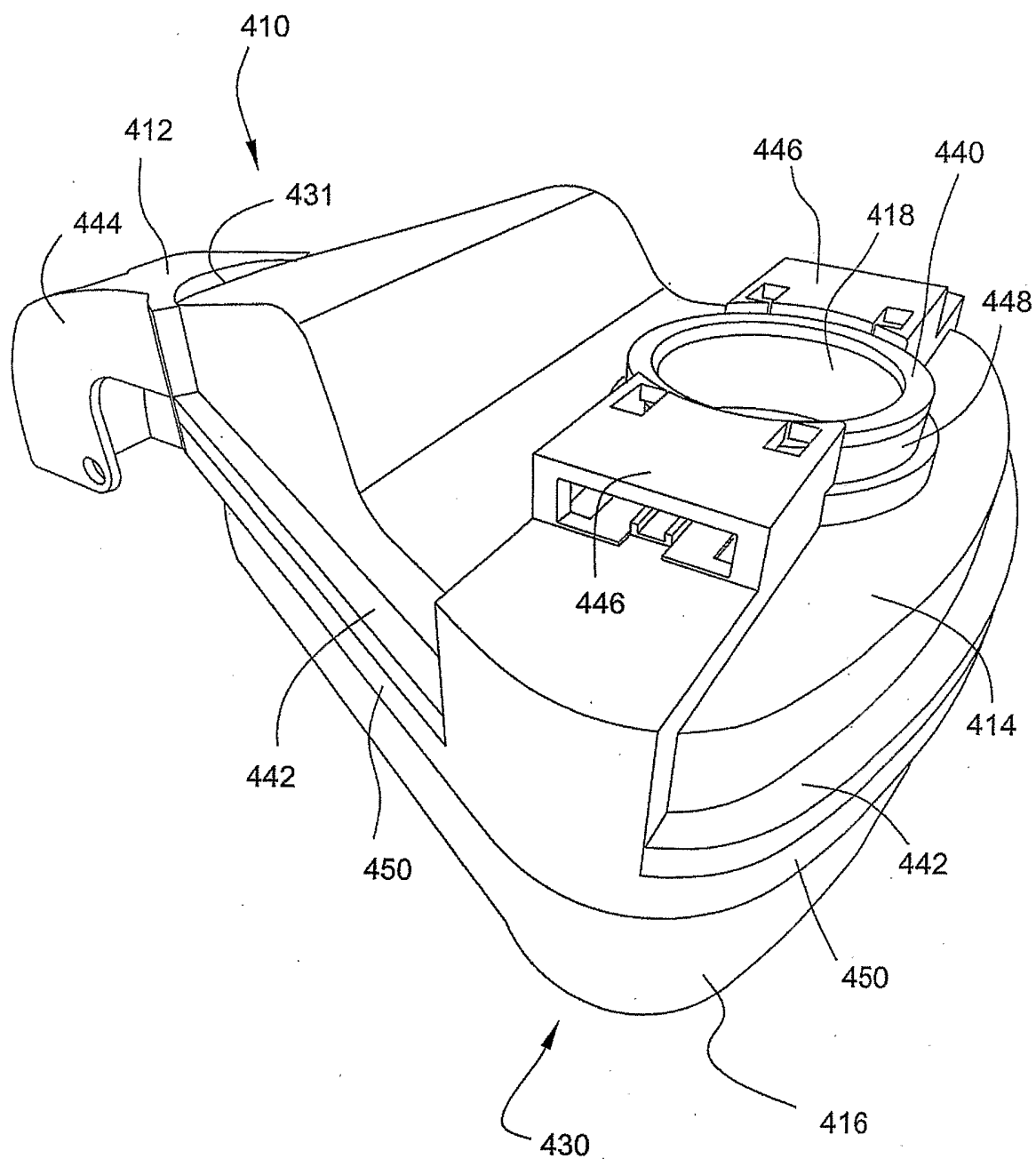


Fig. 8

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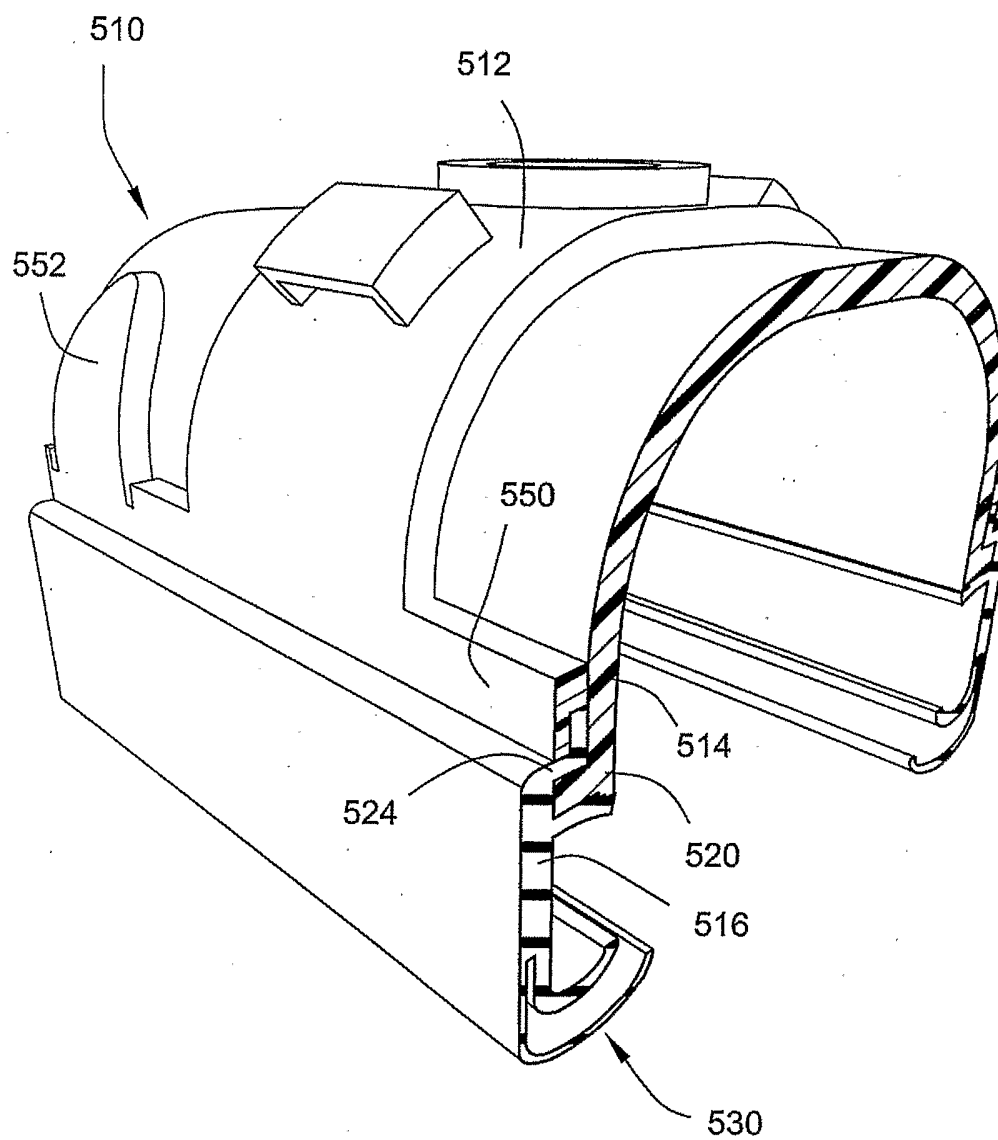


Fig. 9

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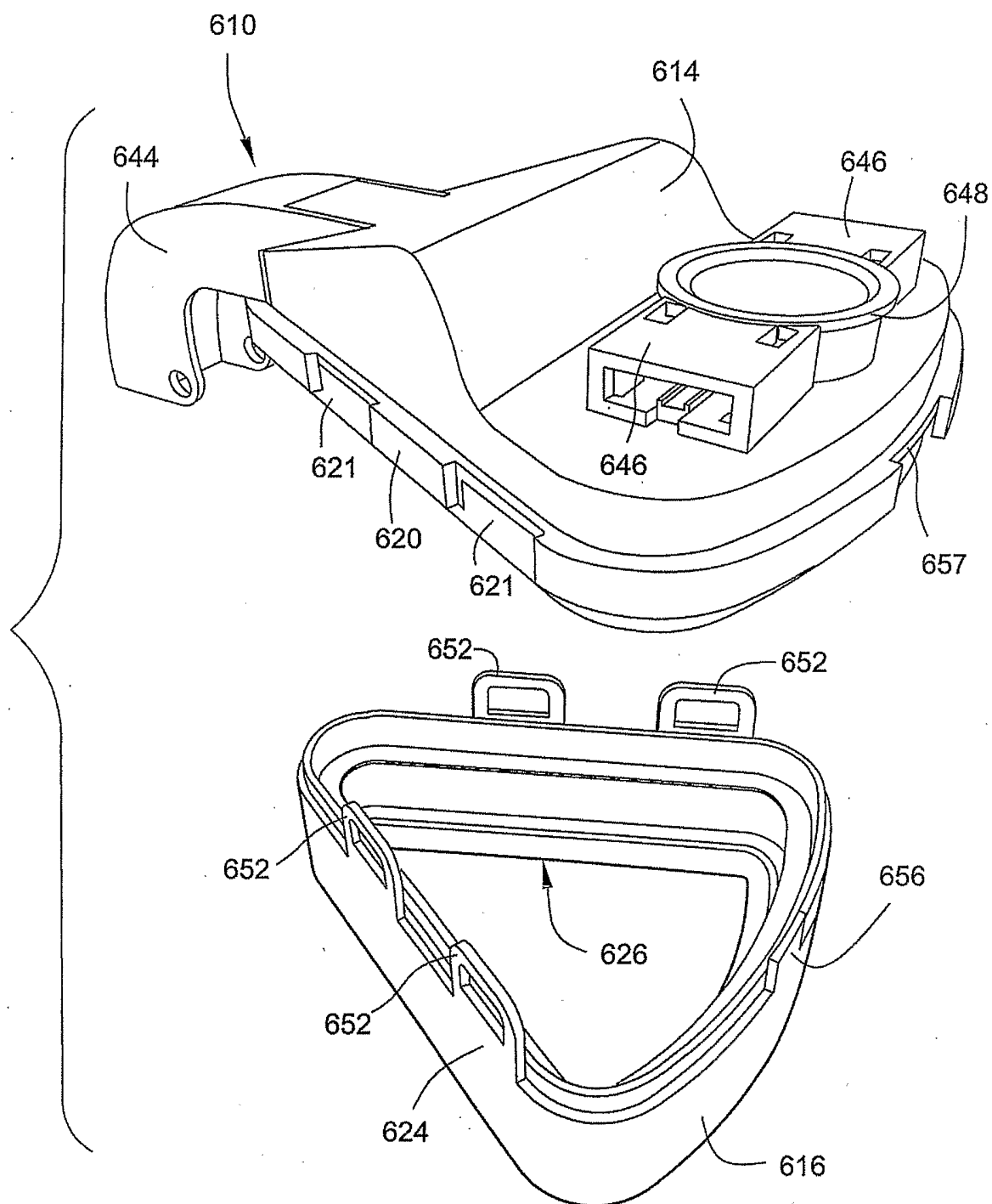


Fig. 10

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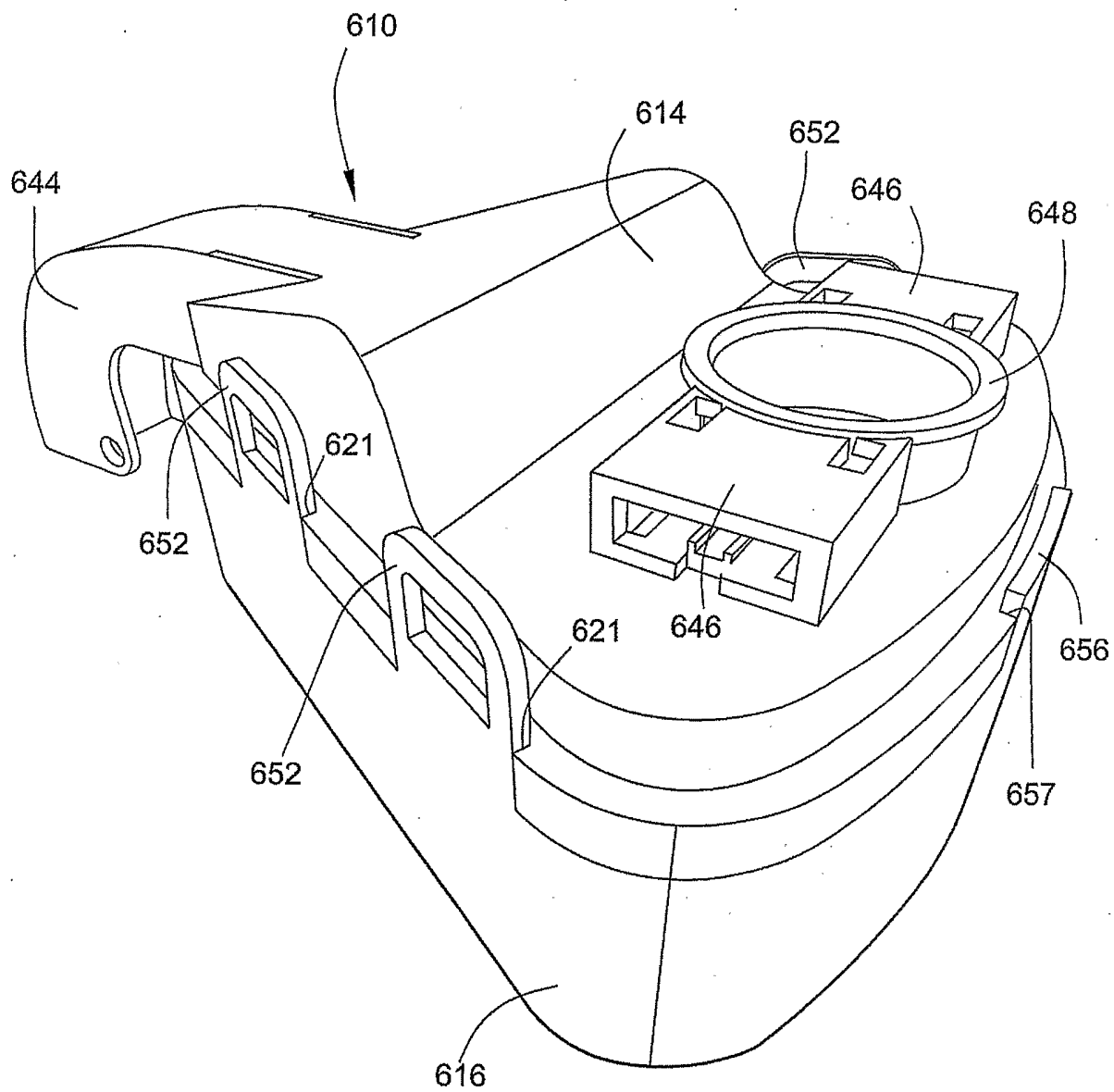
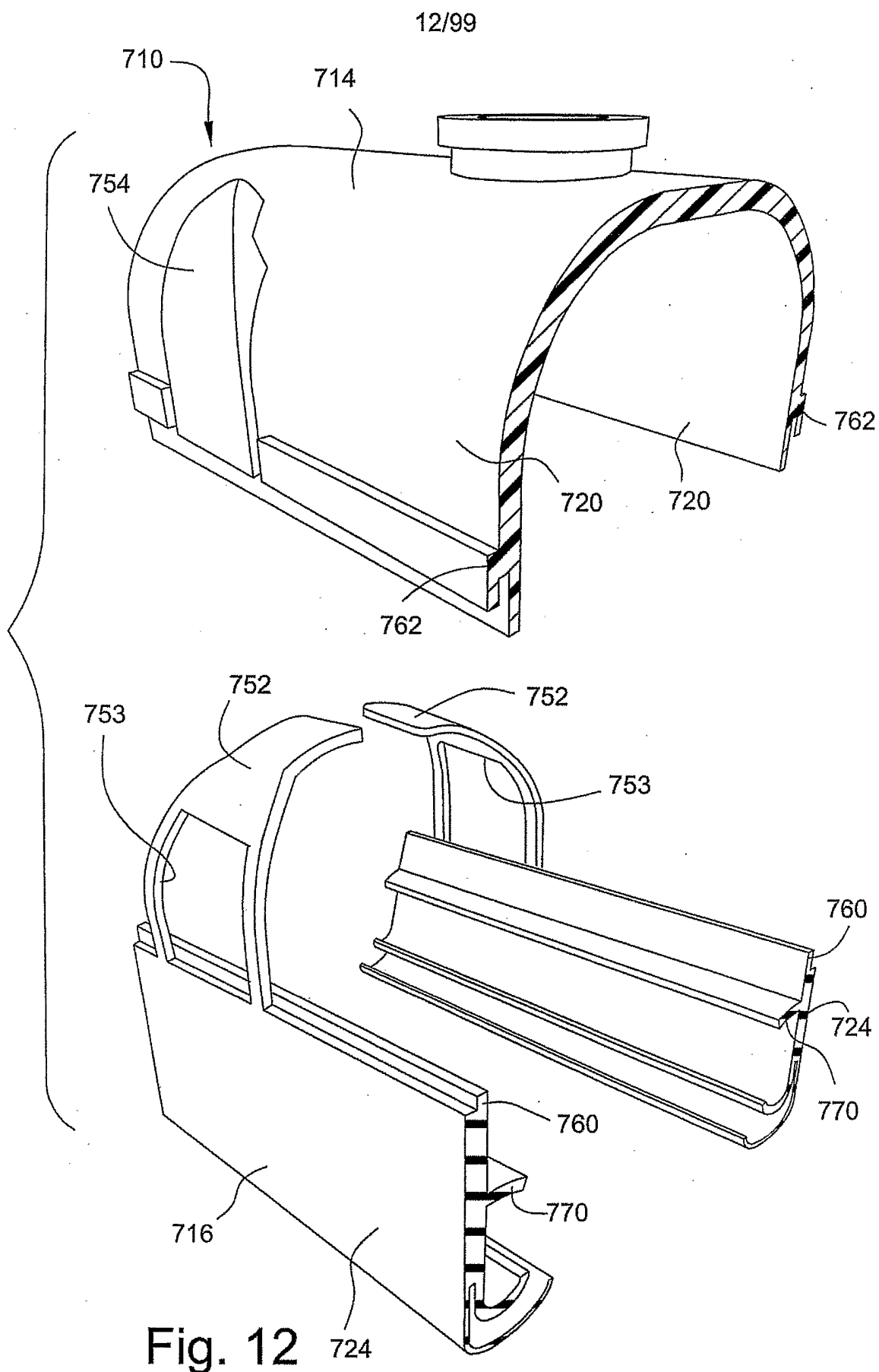


Fig. 11



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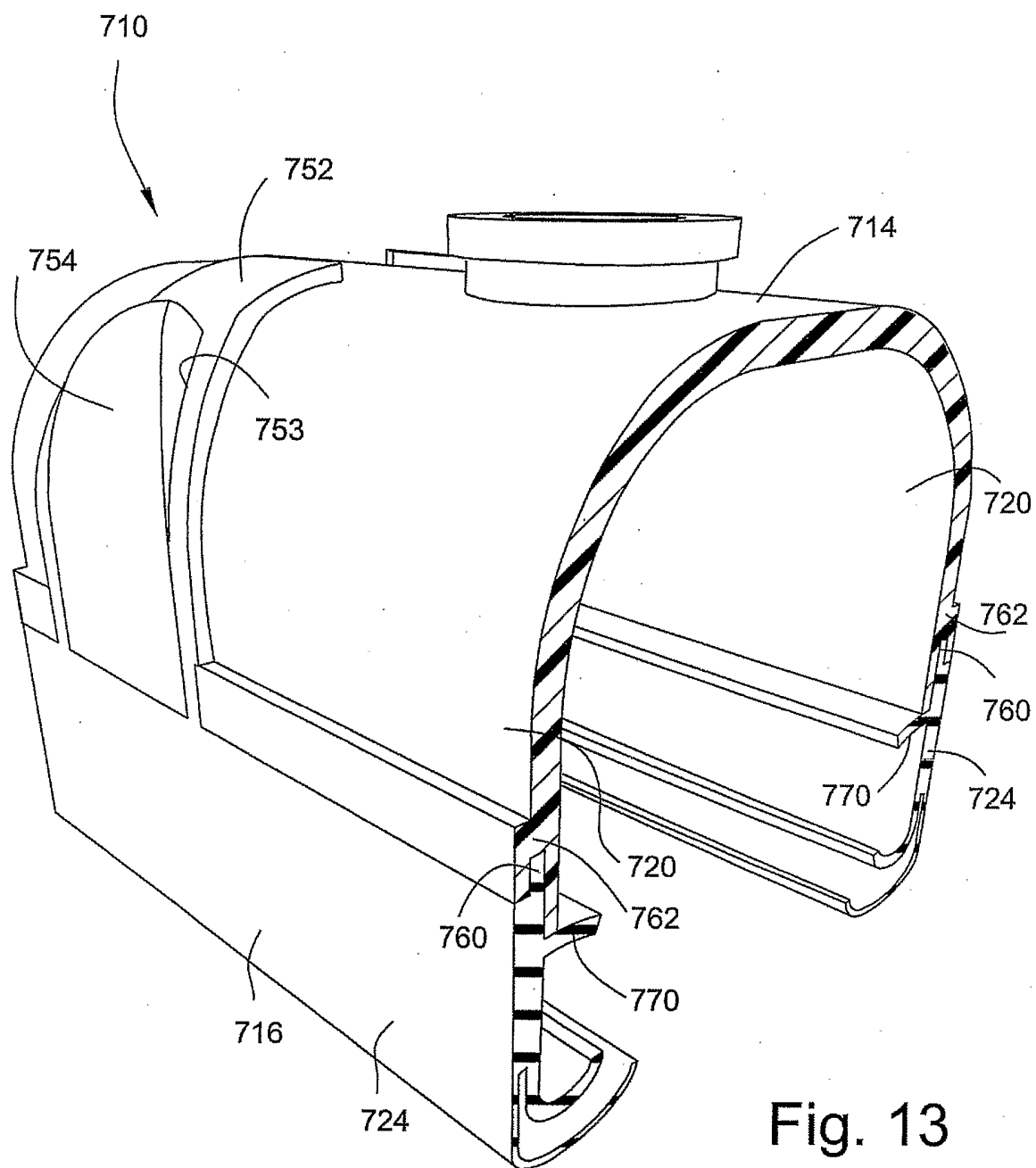


Fig. 13



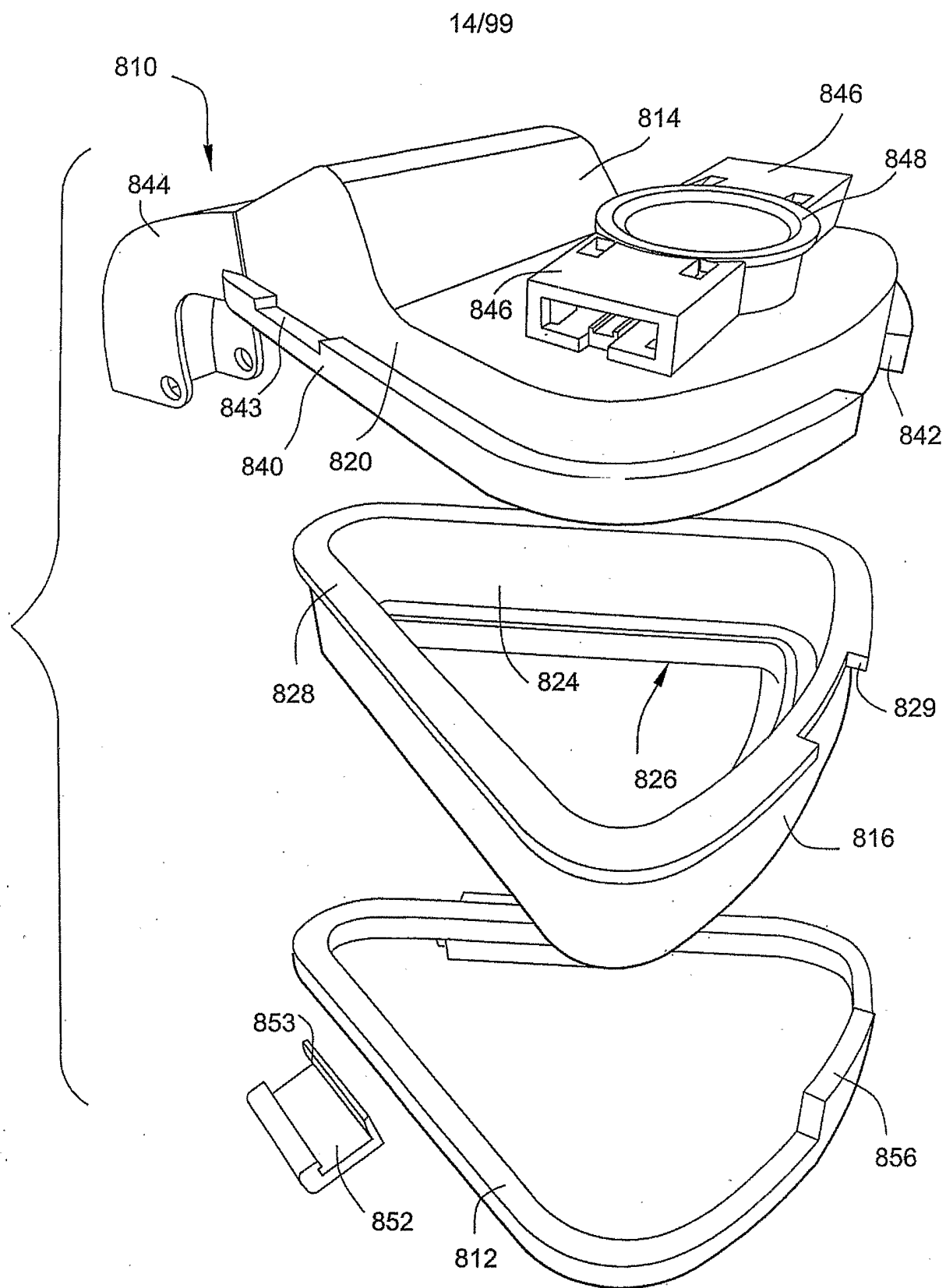


Fig. 14

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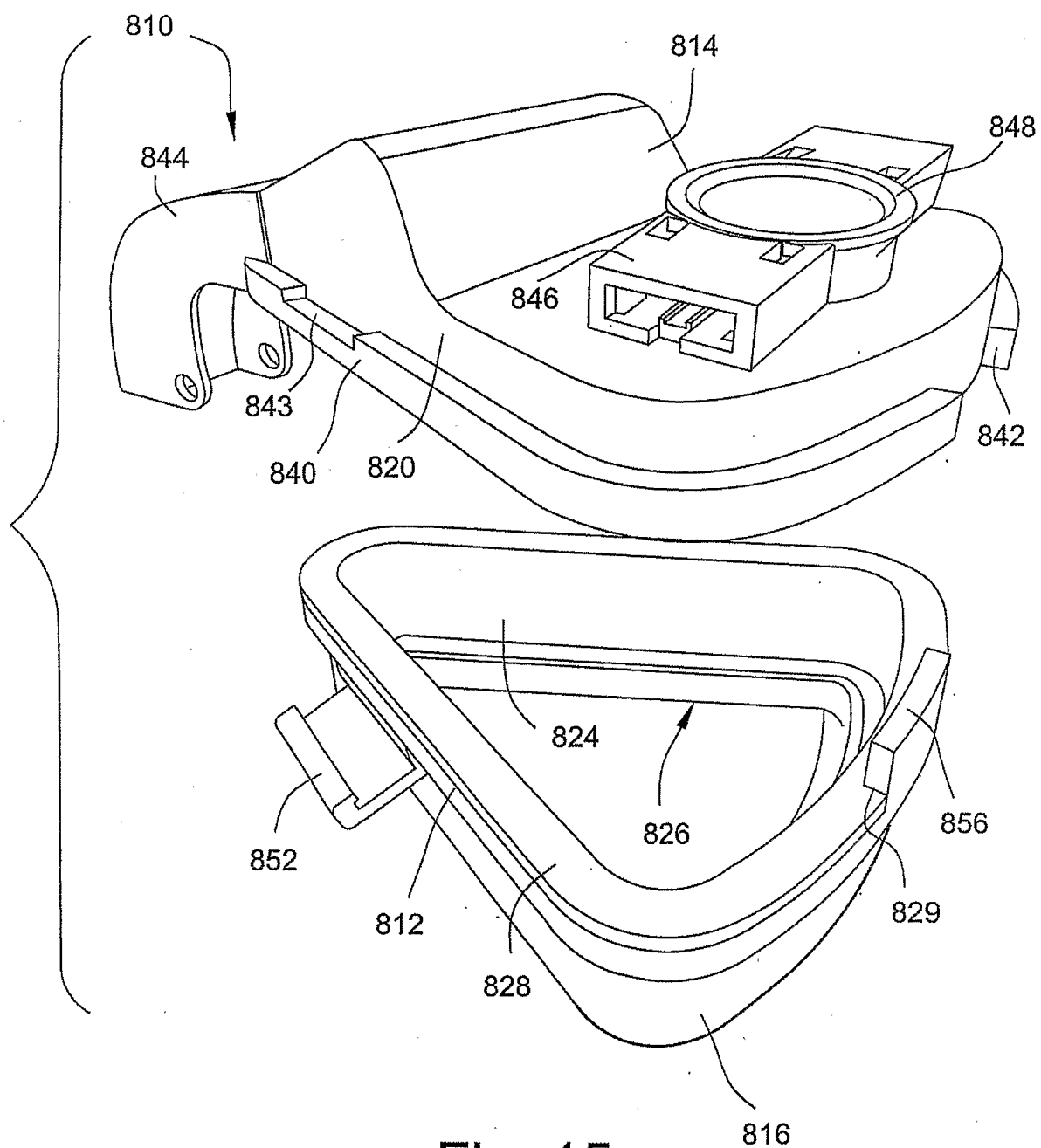
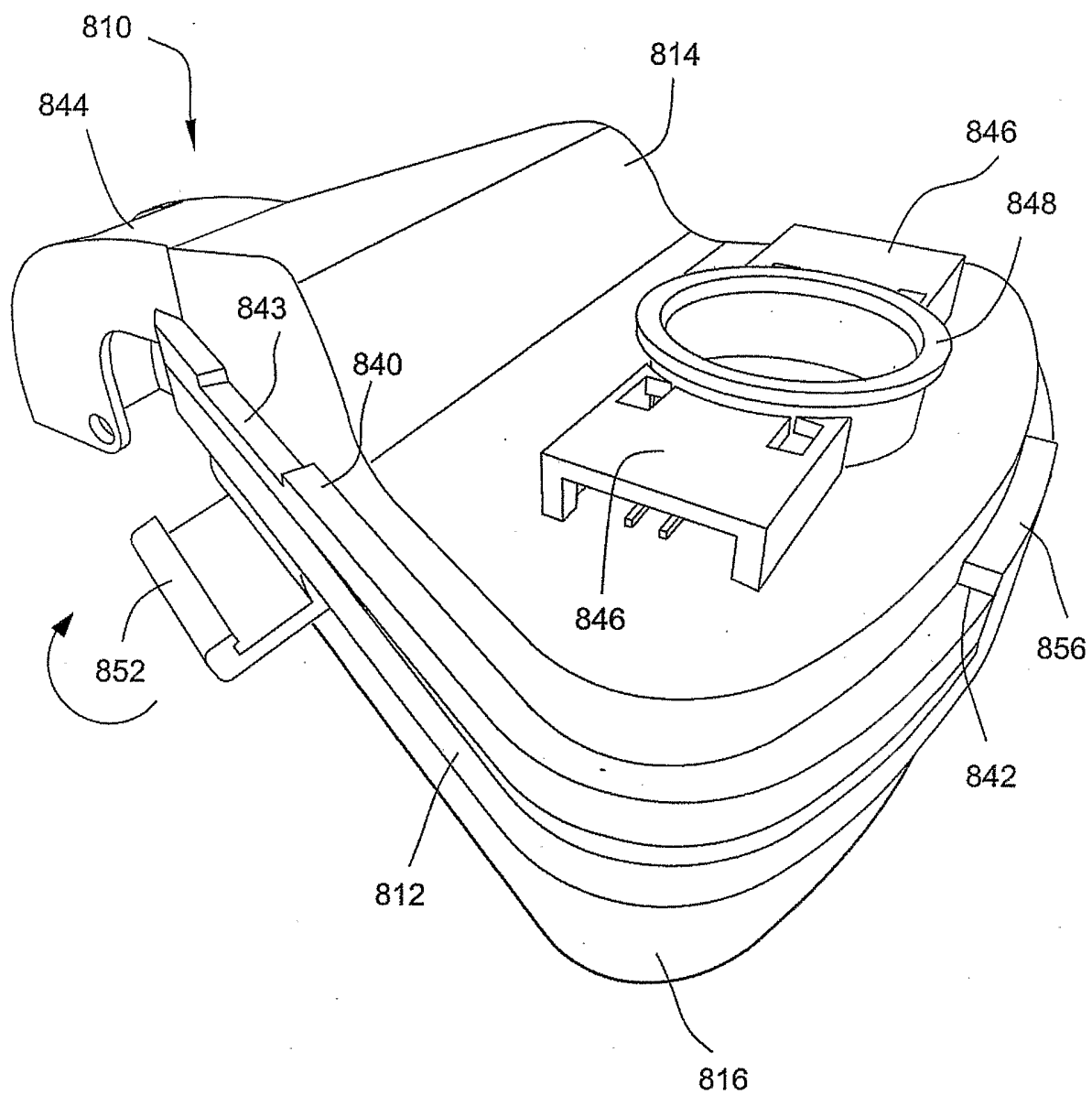


Fig. 15

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**Fig. 16**

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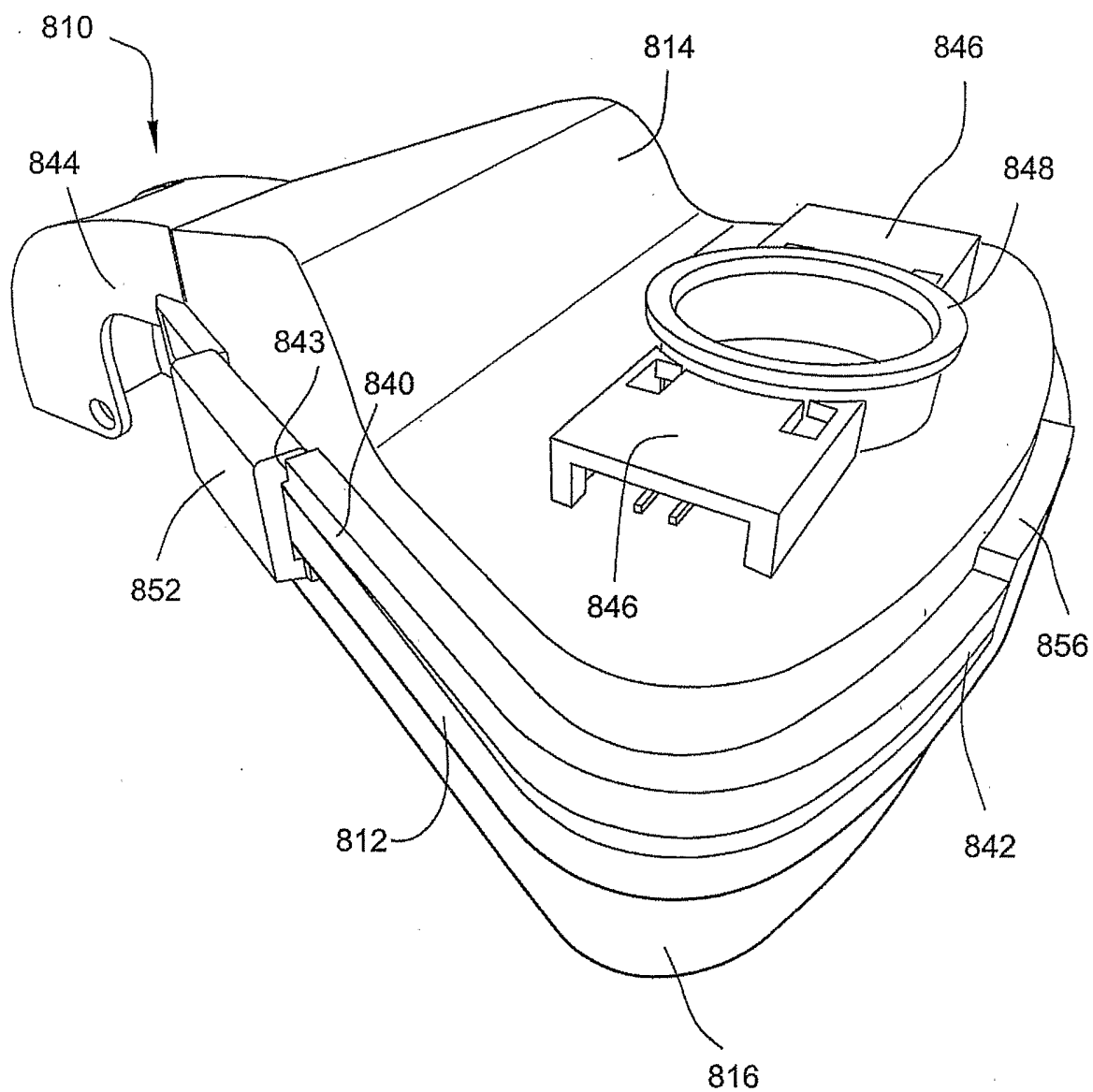


Fig. 17

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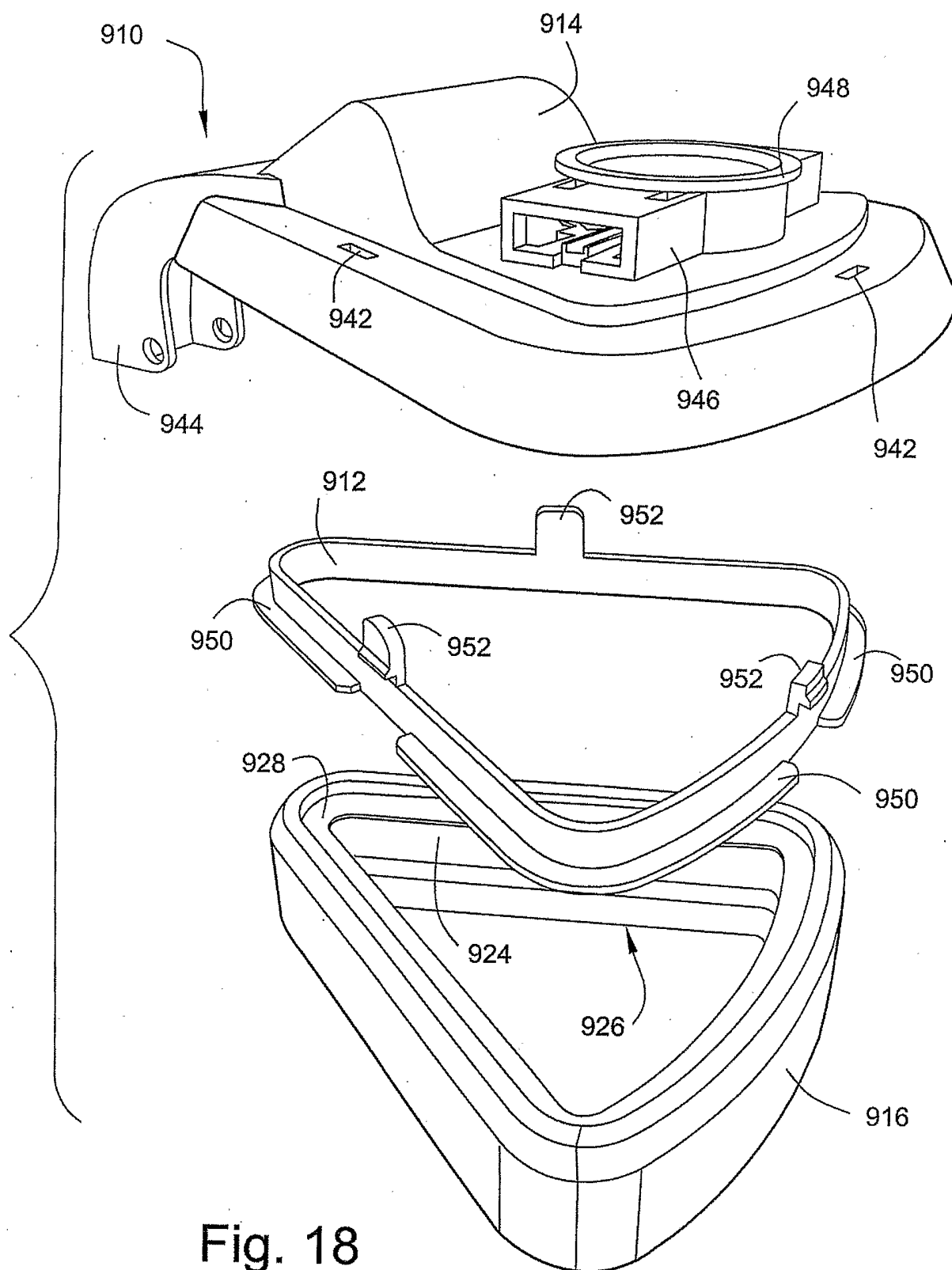


Fig. 18

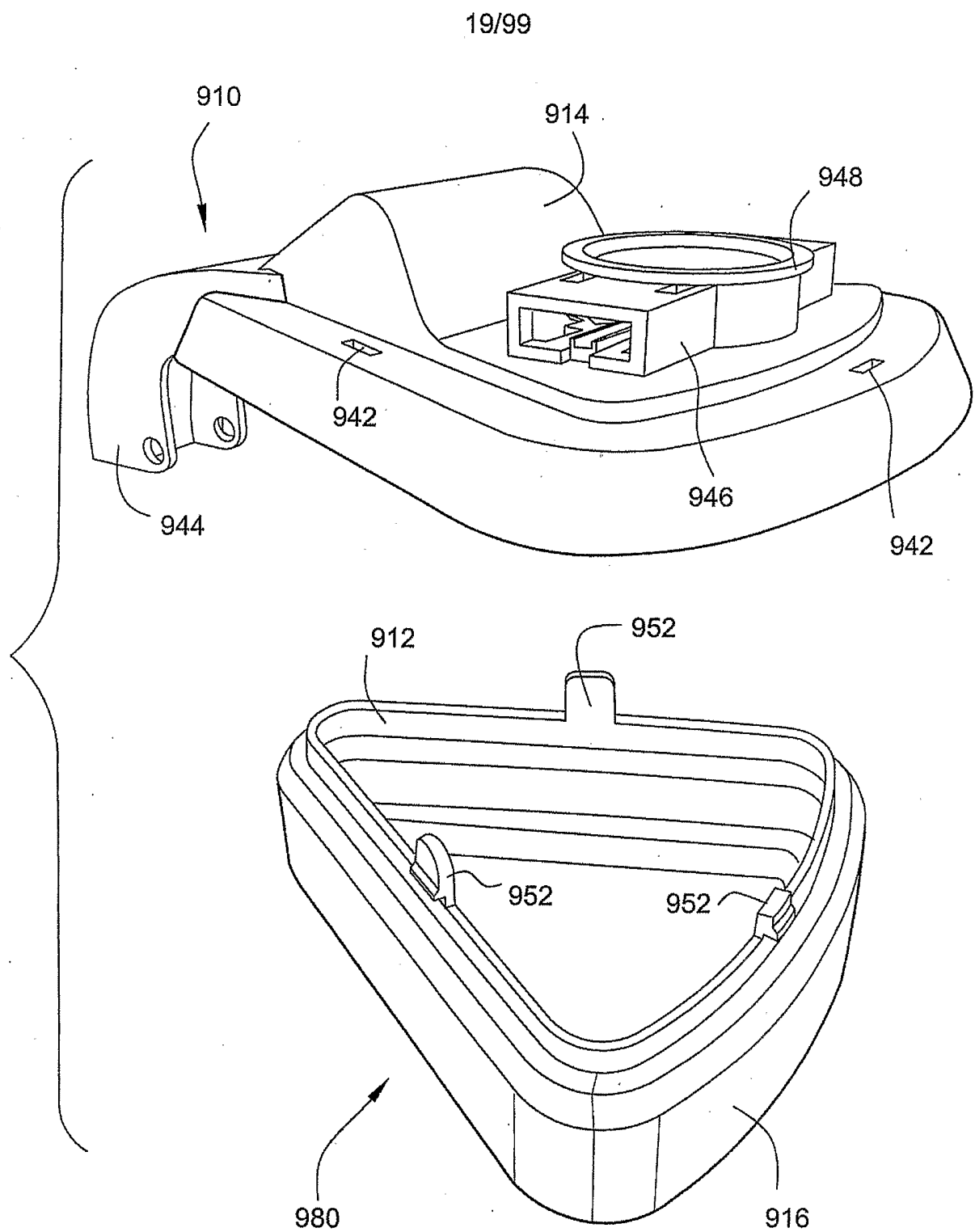


Fig. 19

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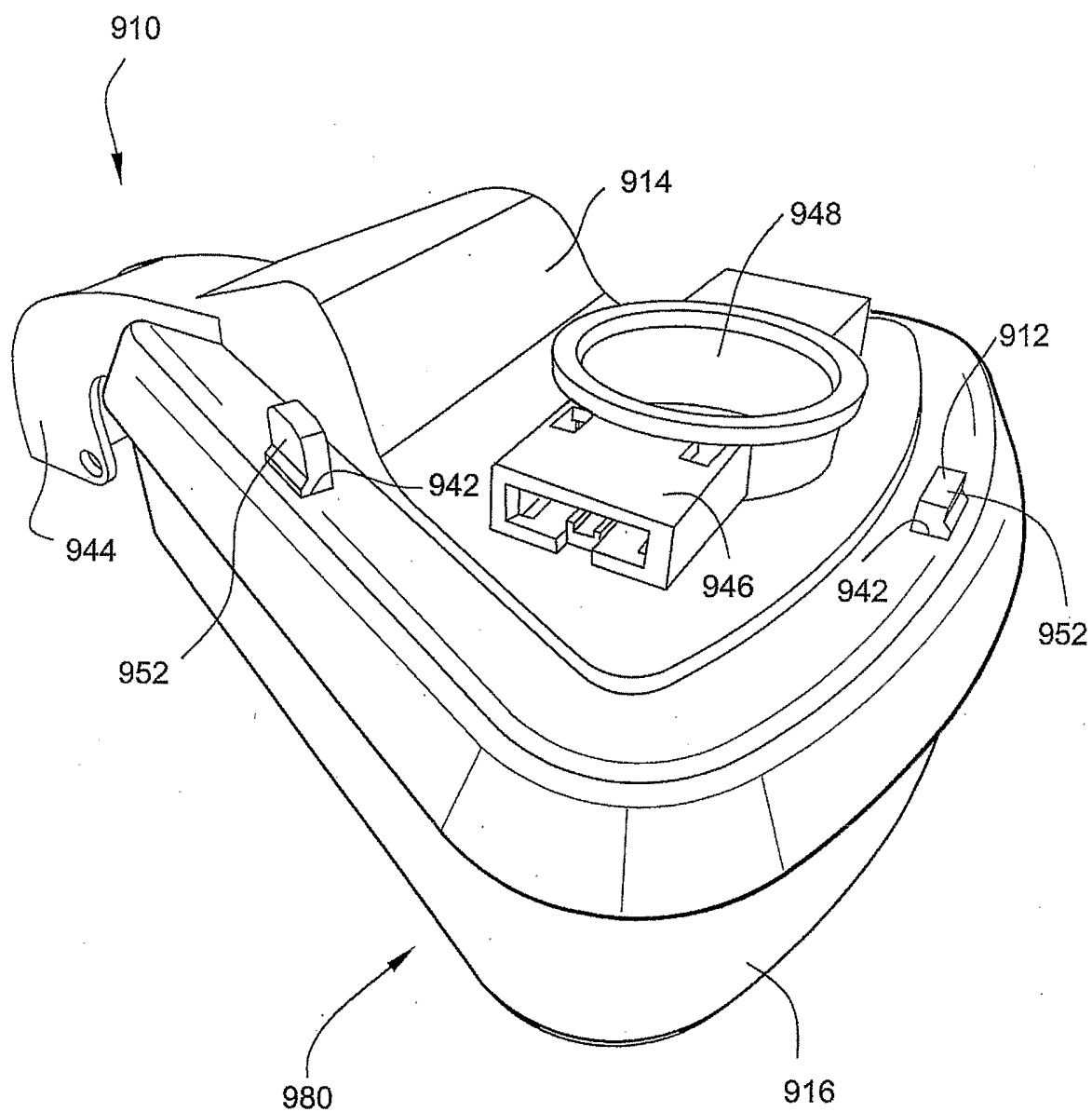


Fig. 20

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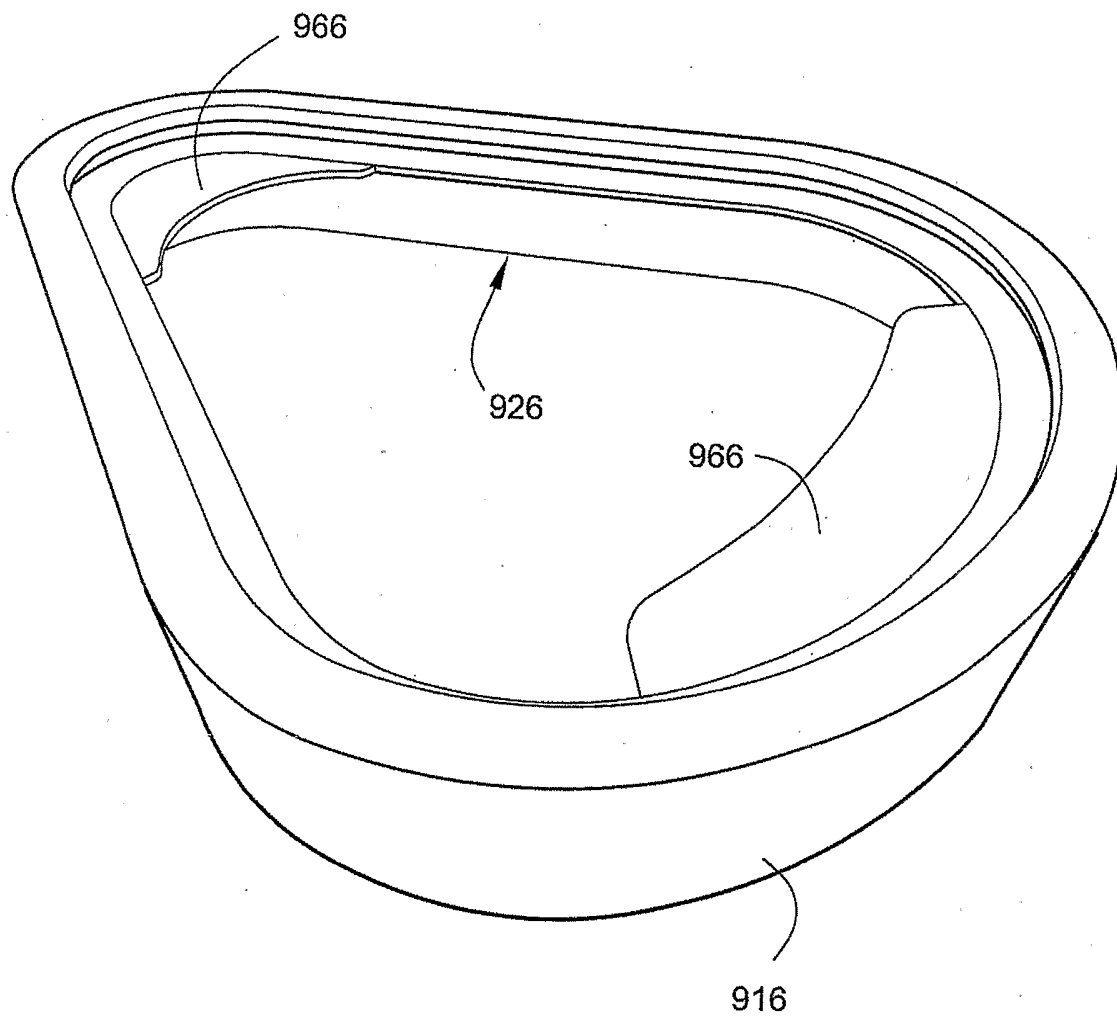


Fig. 21



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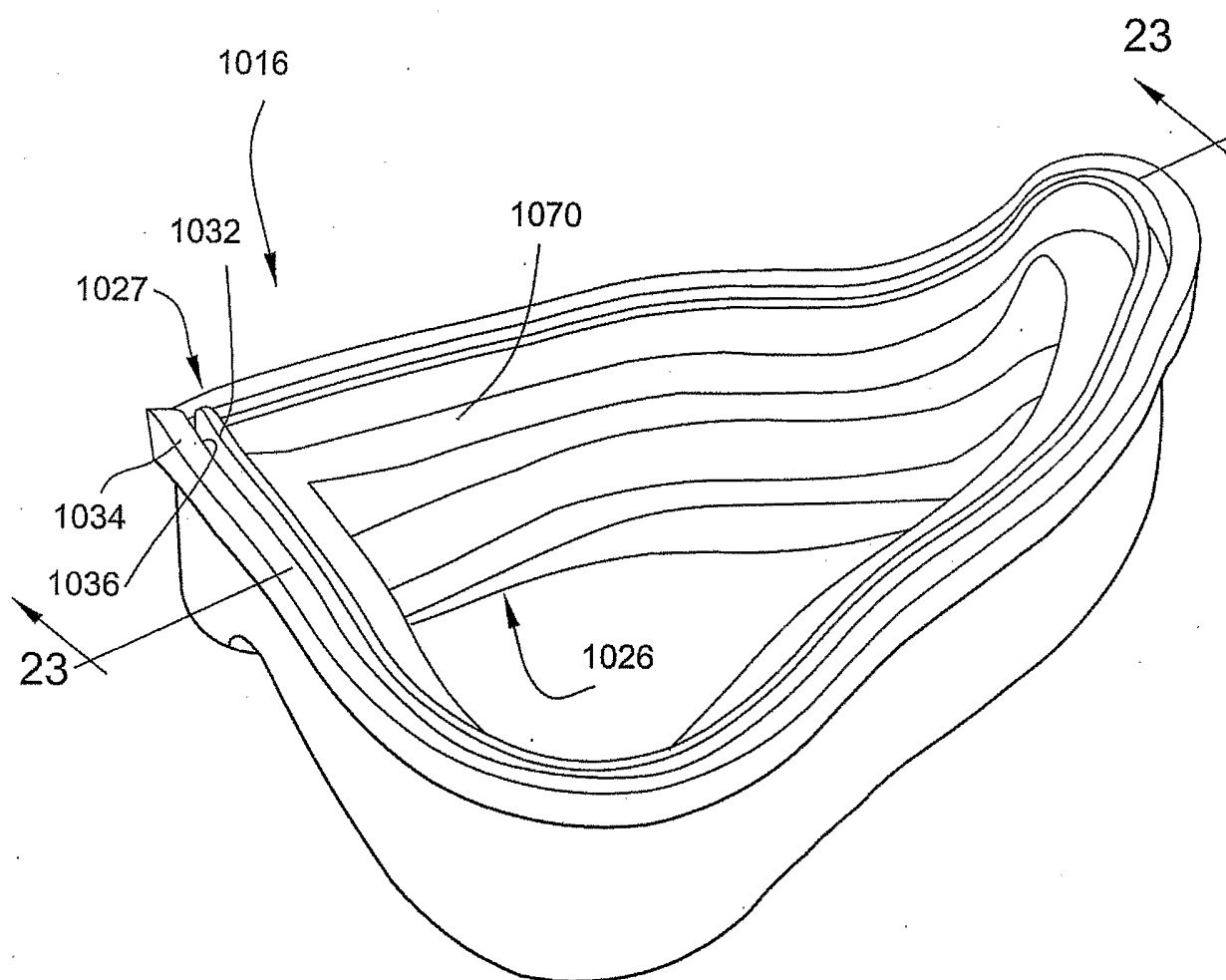


Fig. 22

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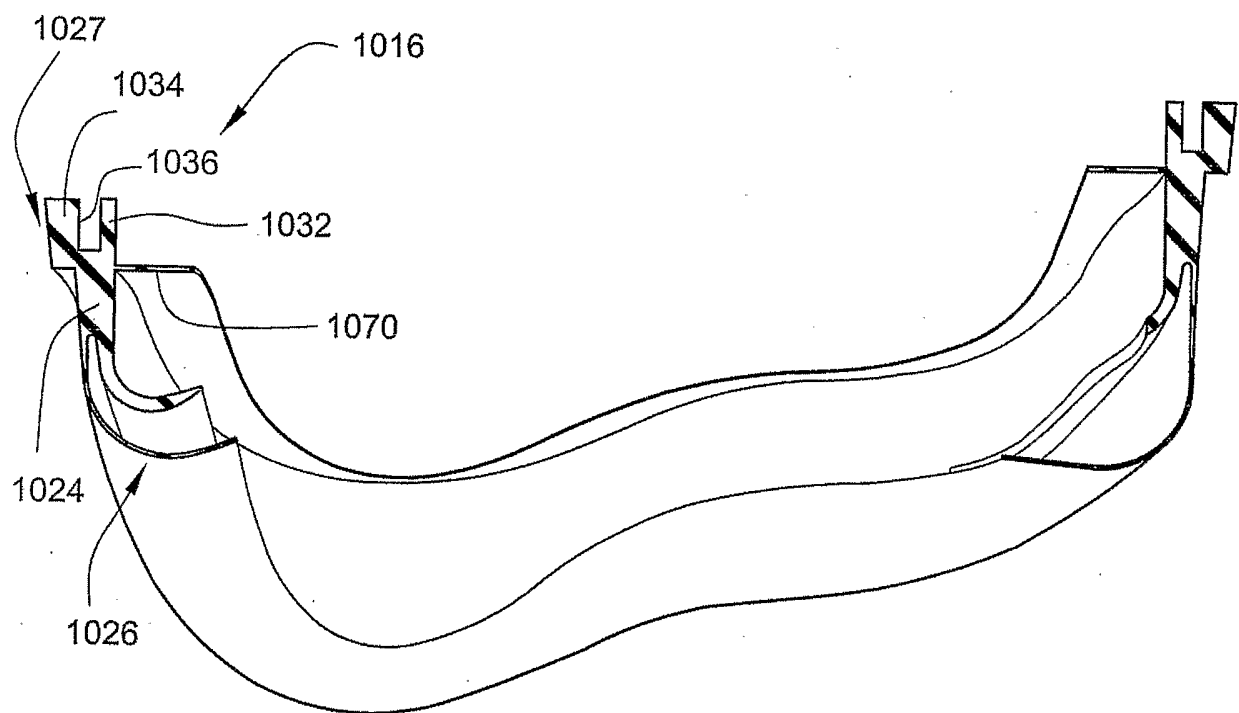


Fig. 23

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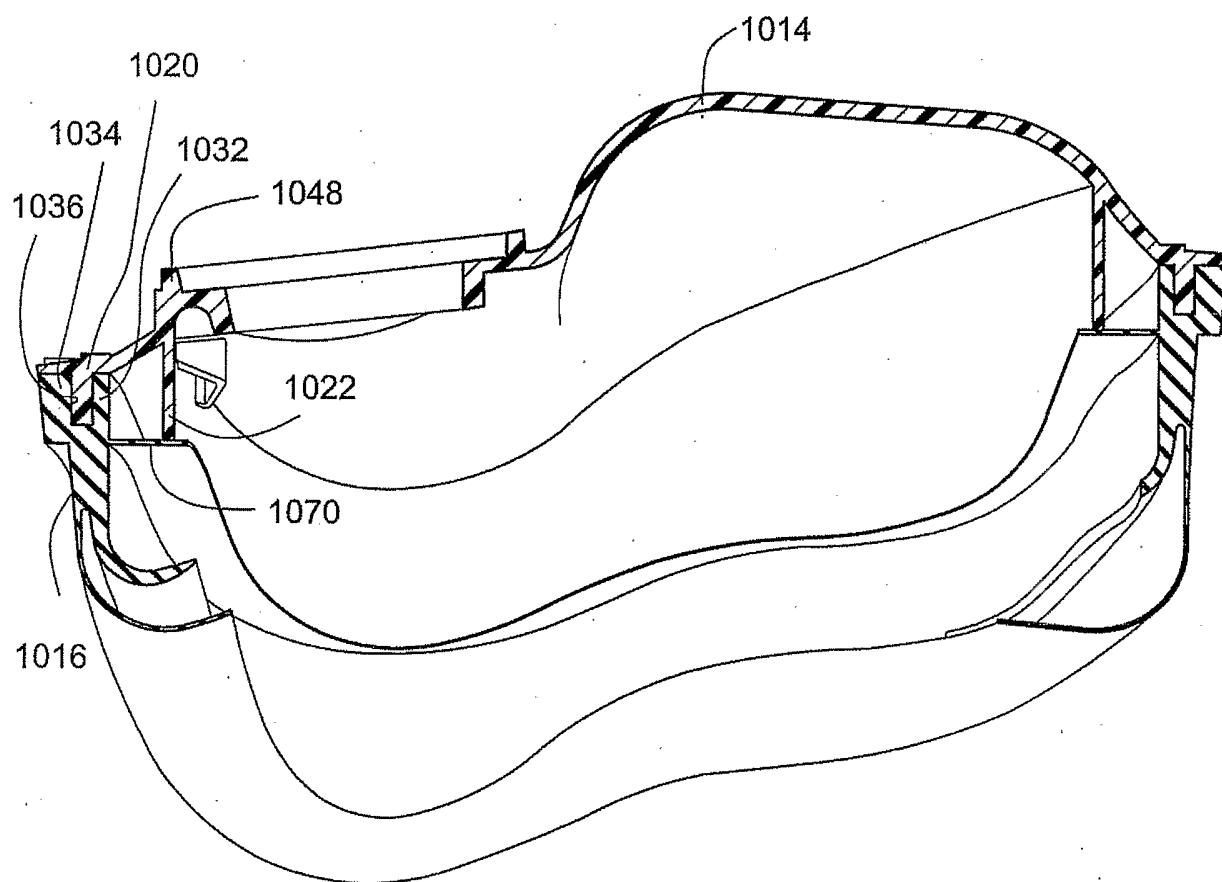


Fig. 24

25/99

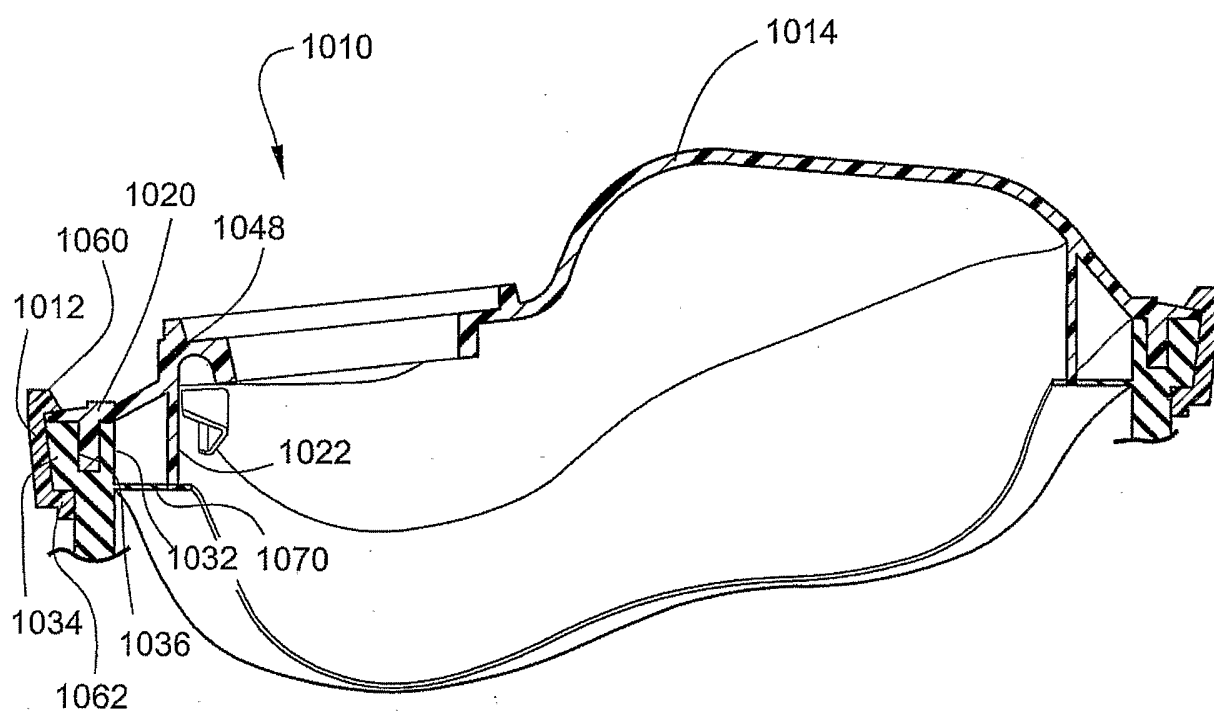


Fig. 25

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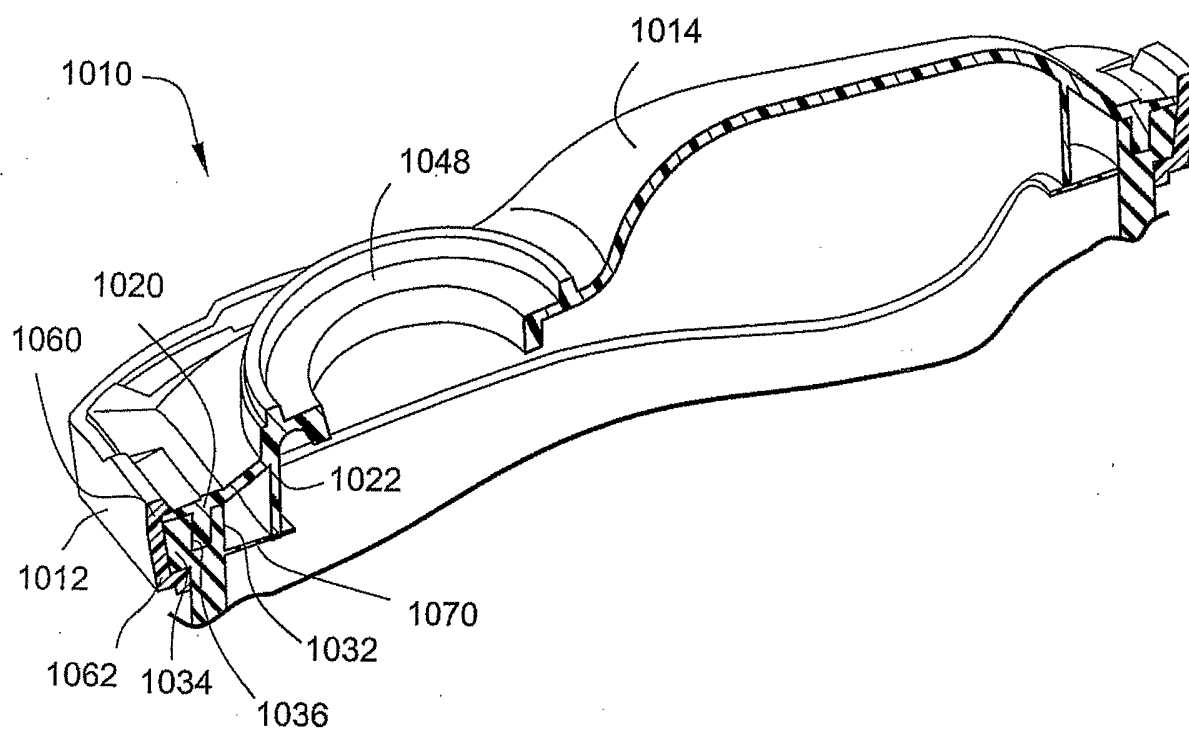


Fig. 26

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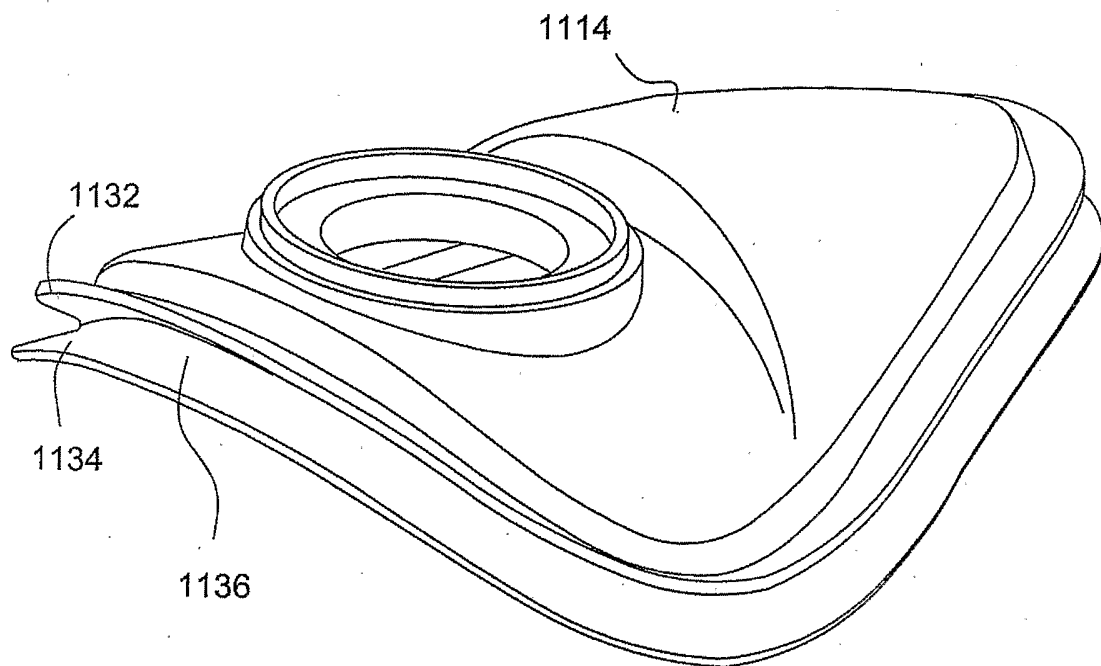


Fig. 27

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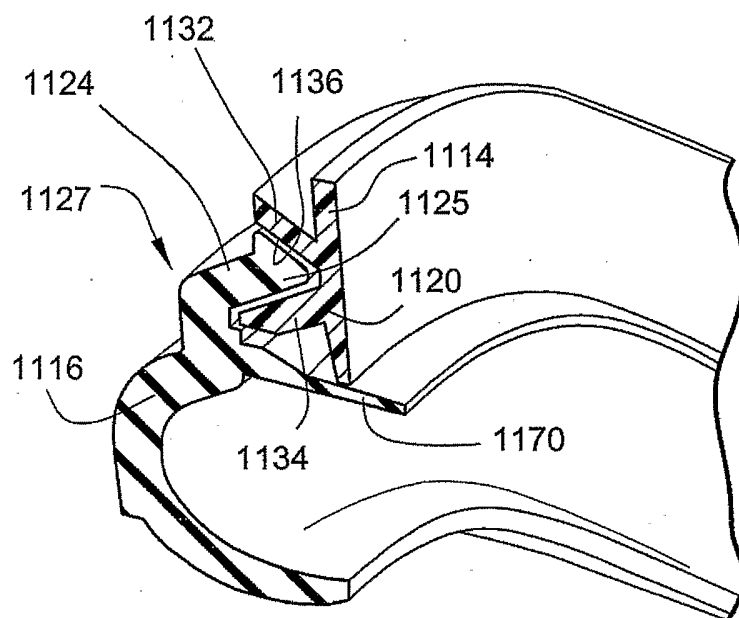


Fig. 28

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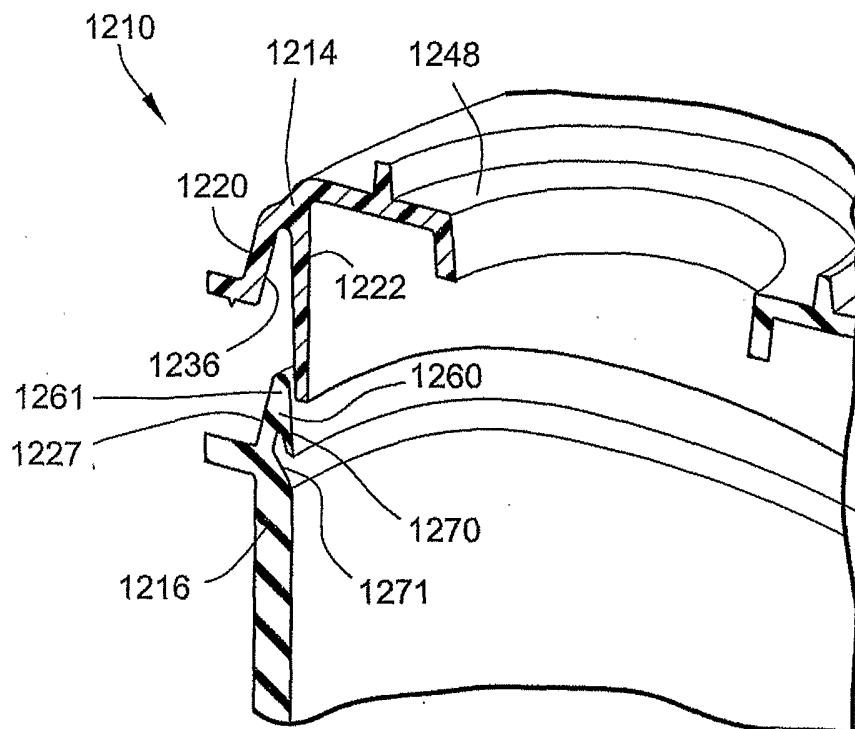


Fig. 29

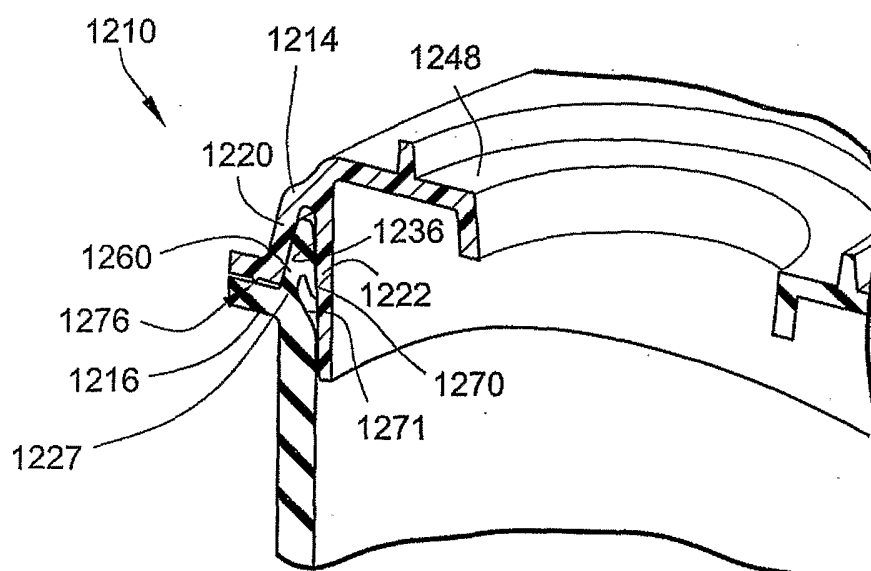


Fig. 30



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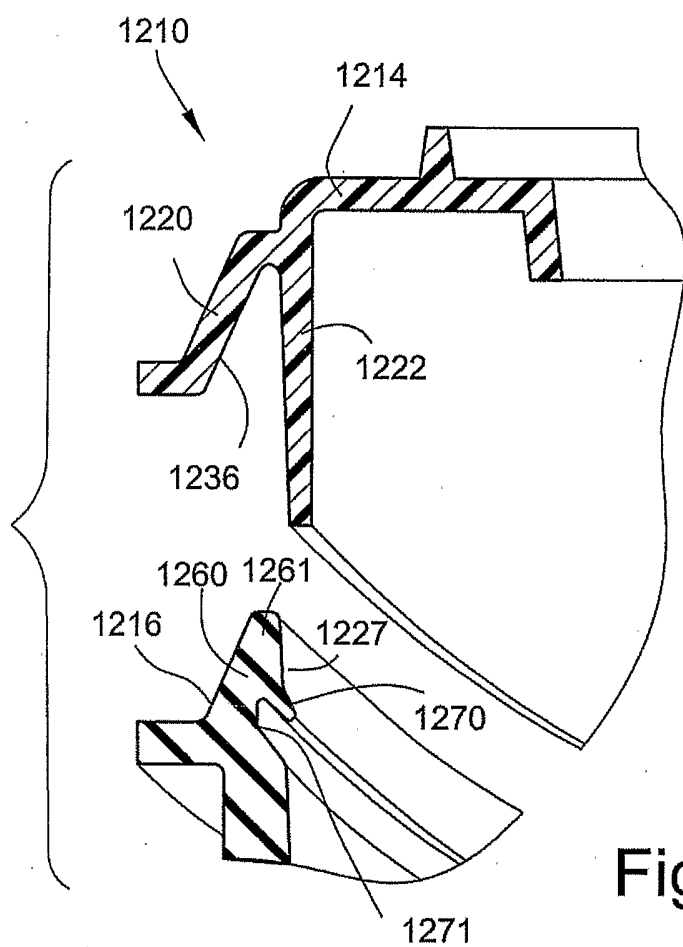


Fig. 31

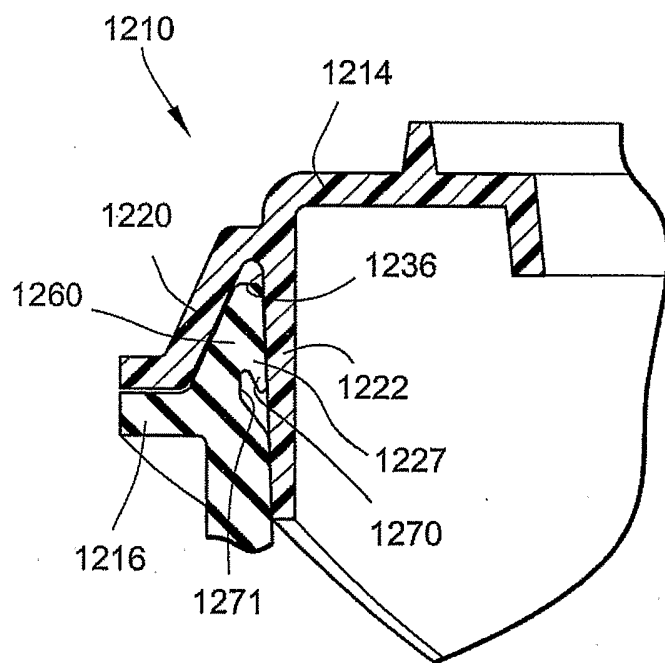


Fig. 32

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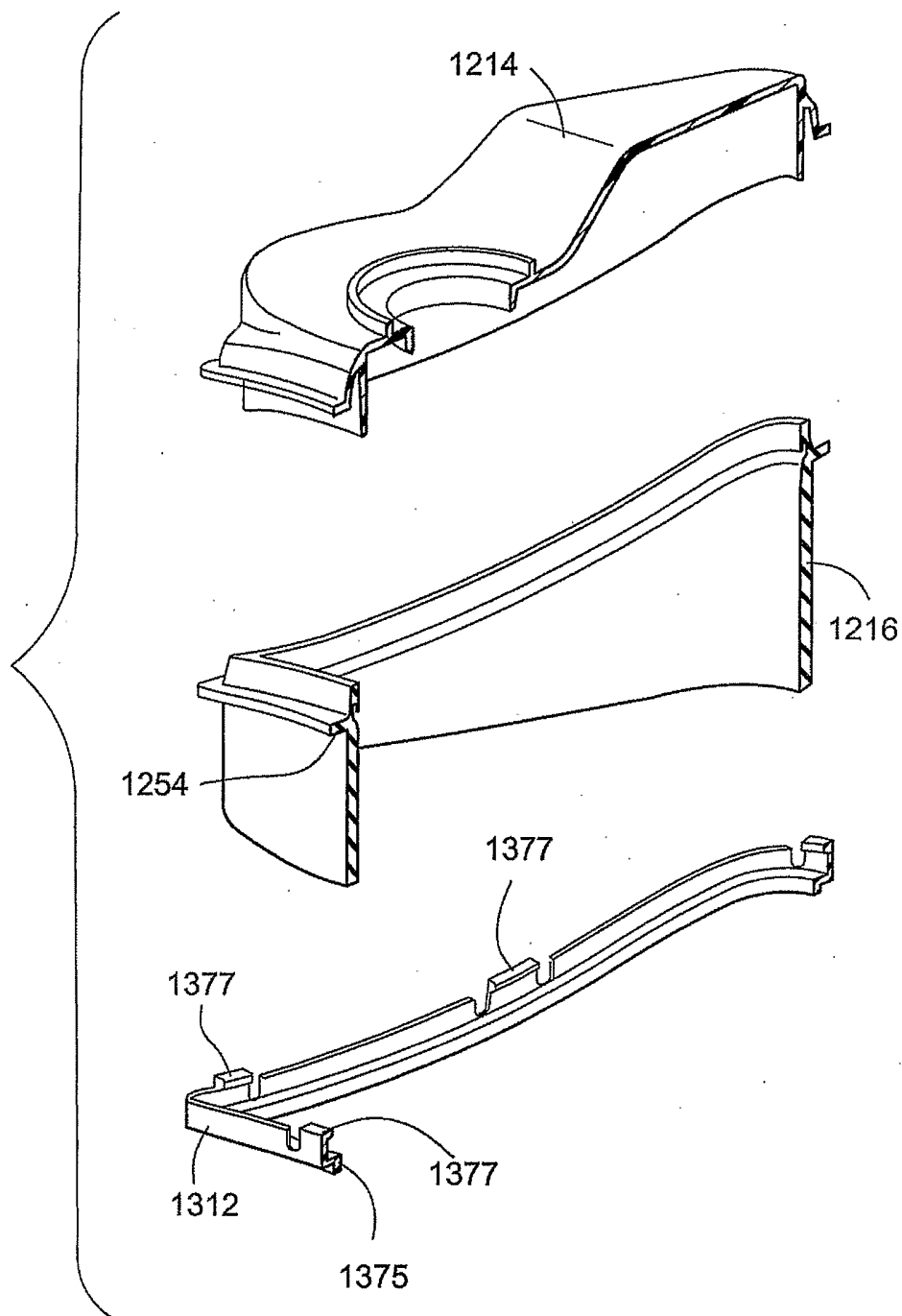


Fig. 33



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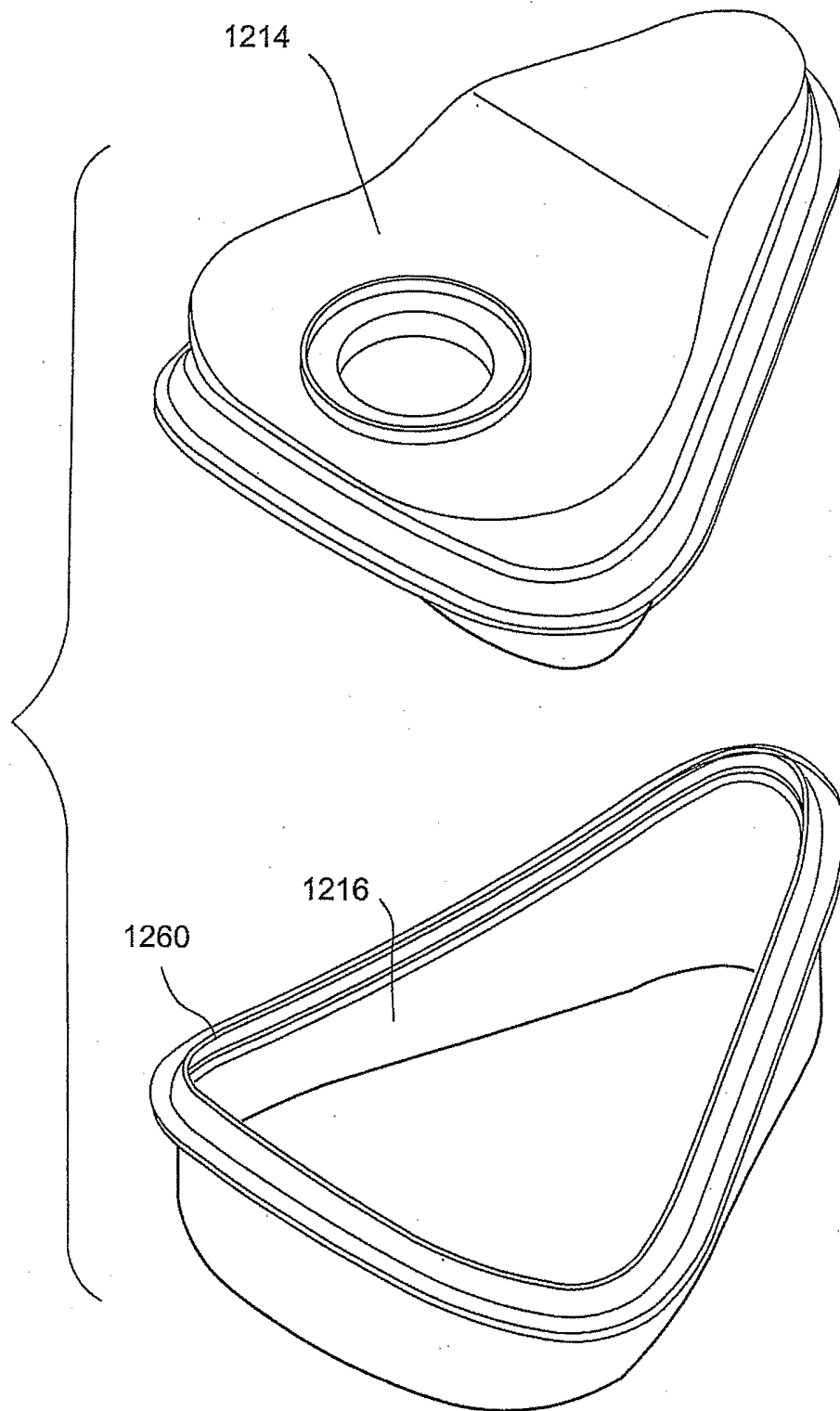


Fig. 35

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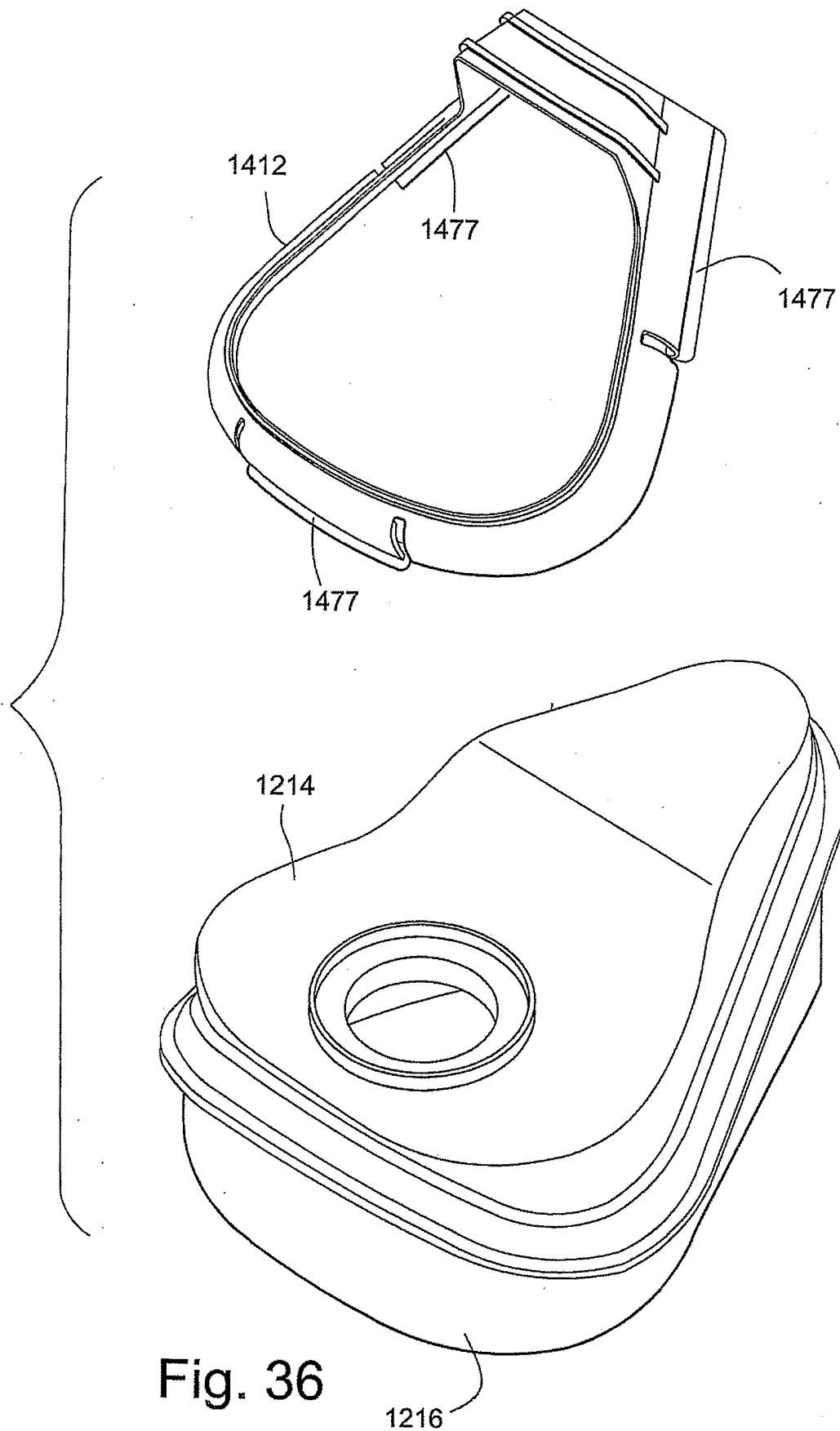


Fig. 36

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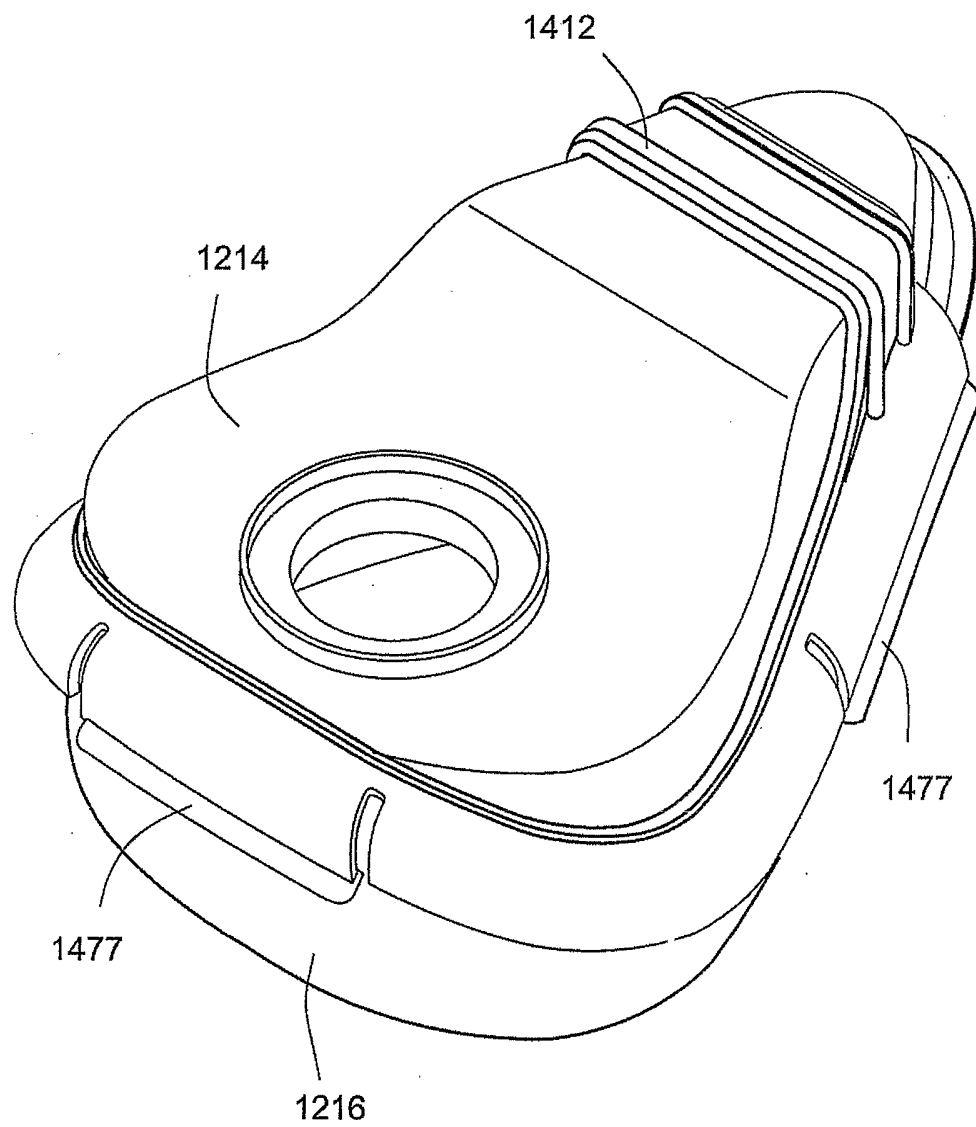
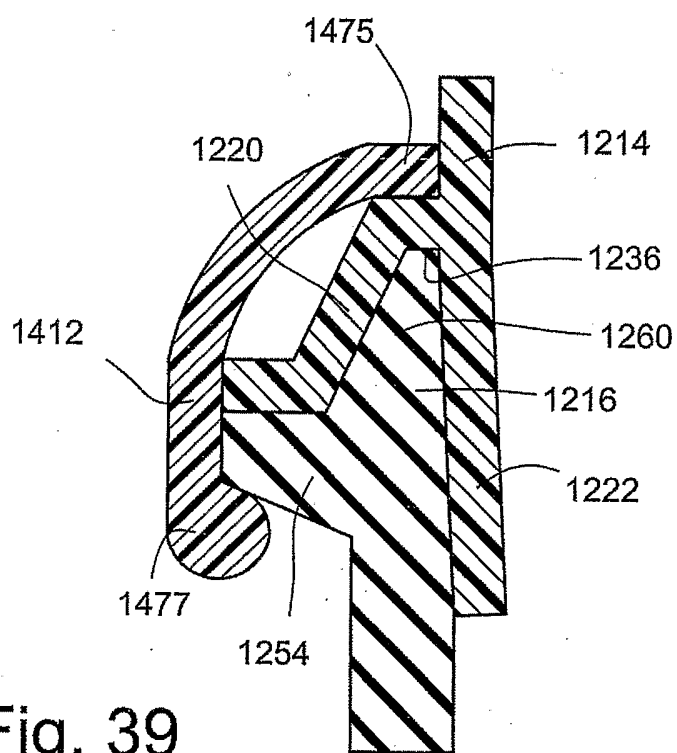
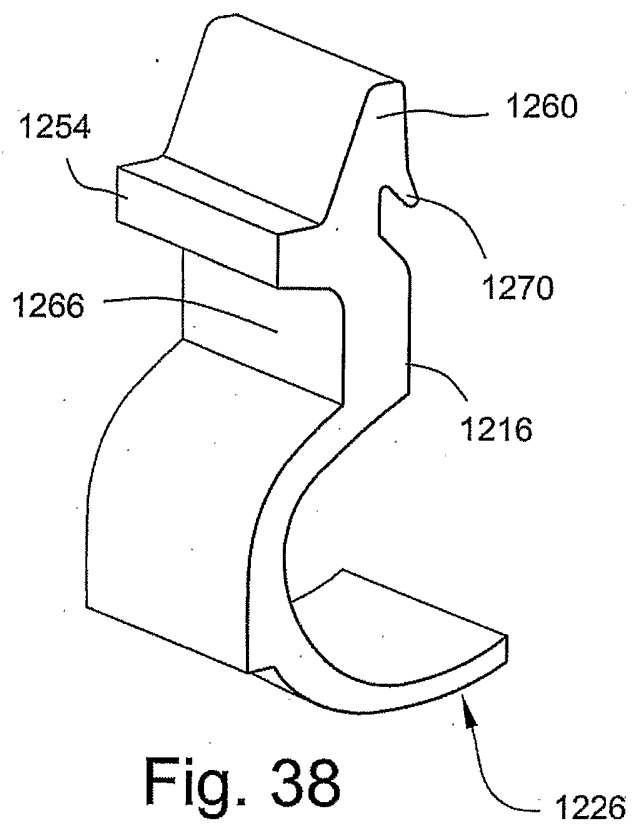


Fig. 37

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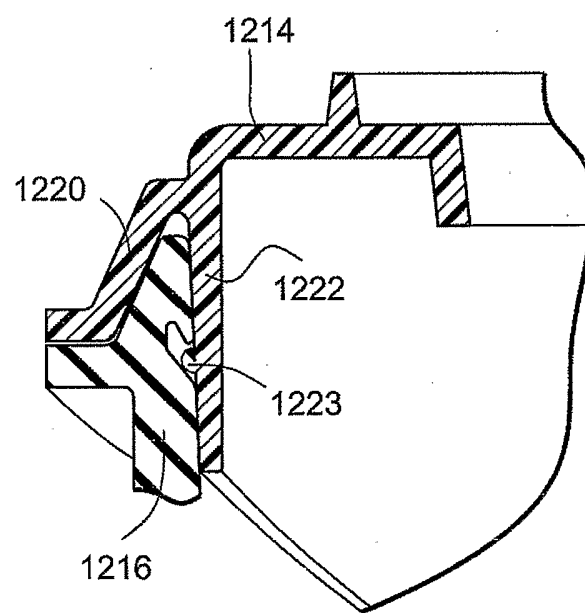


Fig. 40



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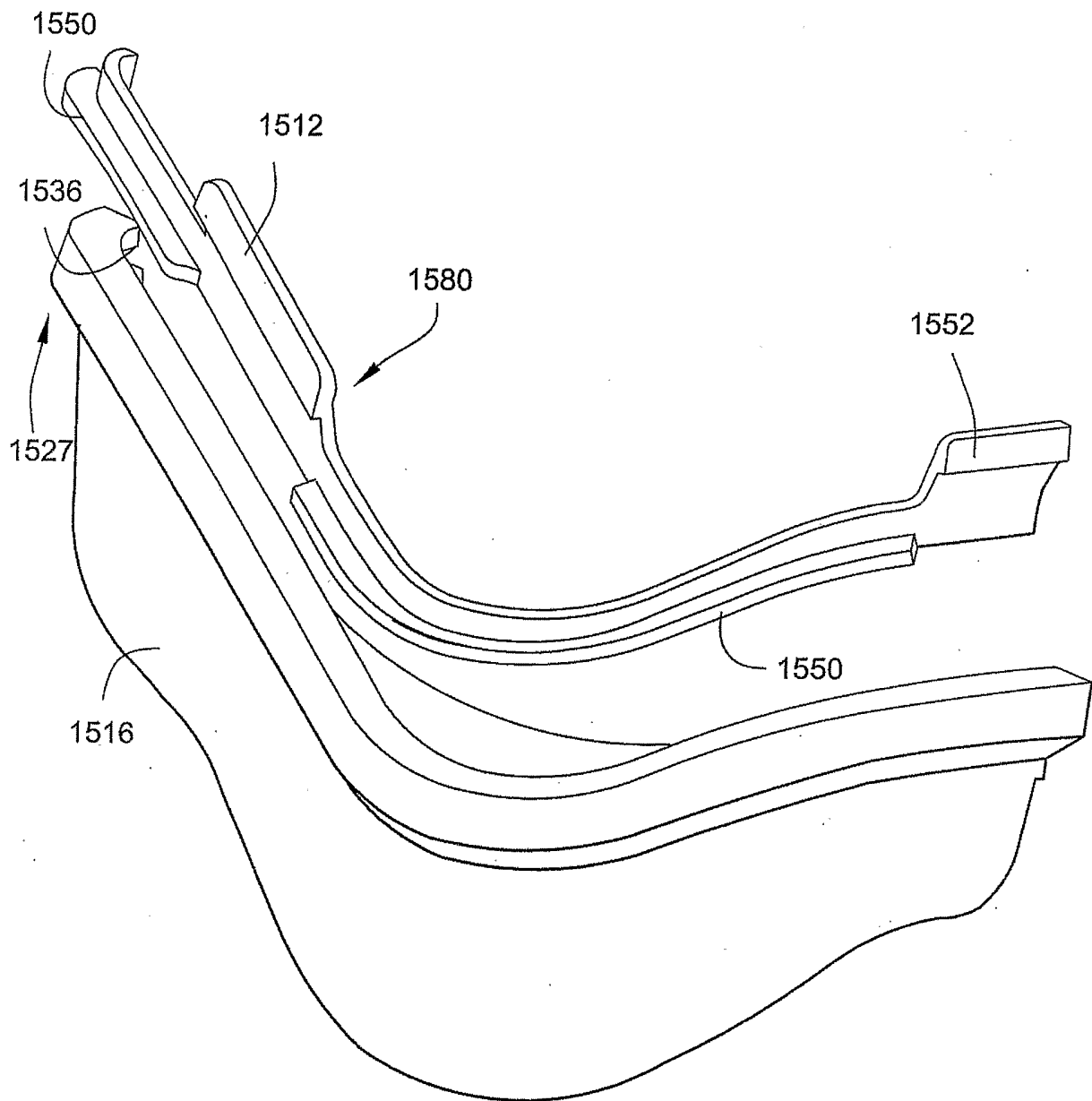


Fig. 41

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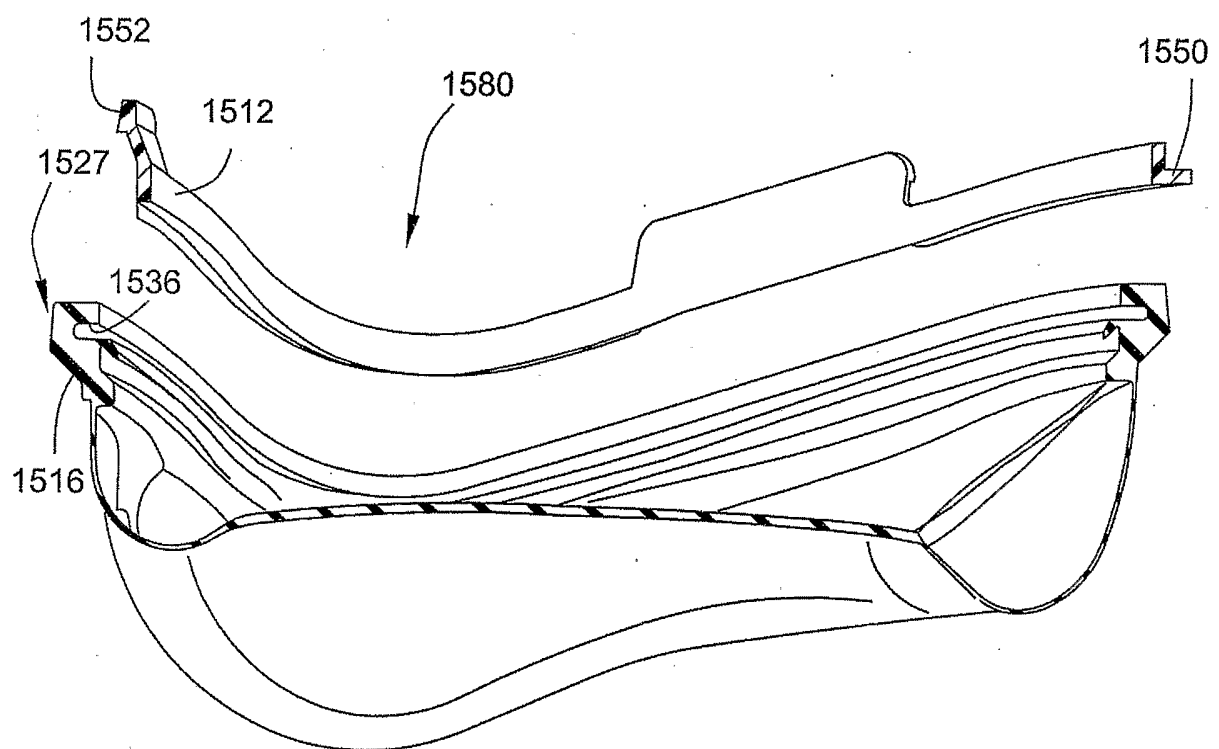


Fig. 42

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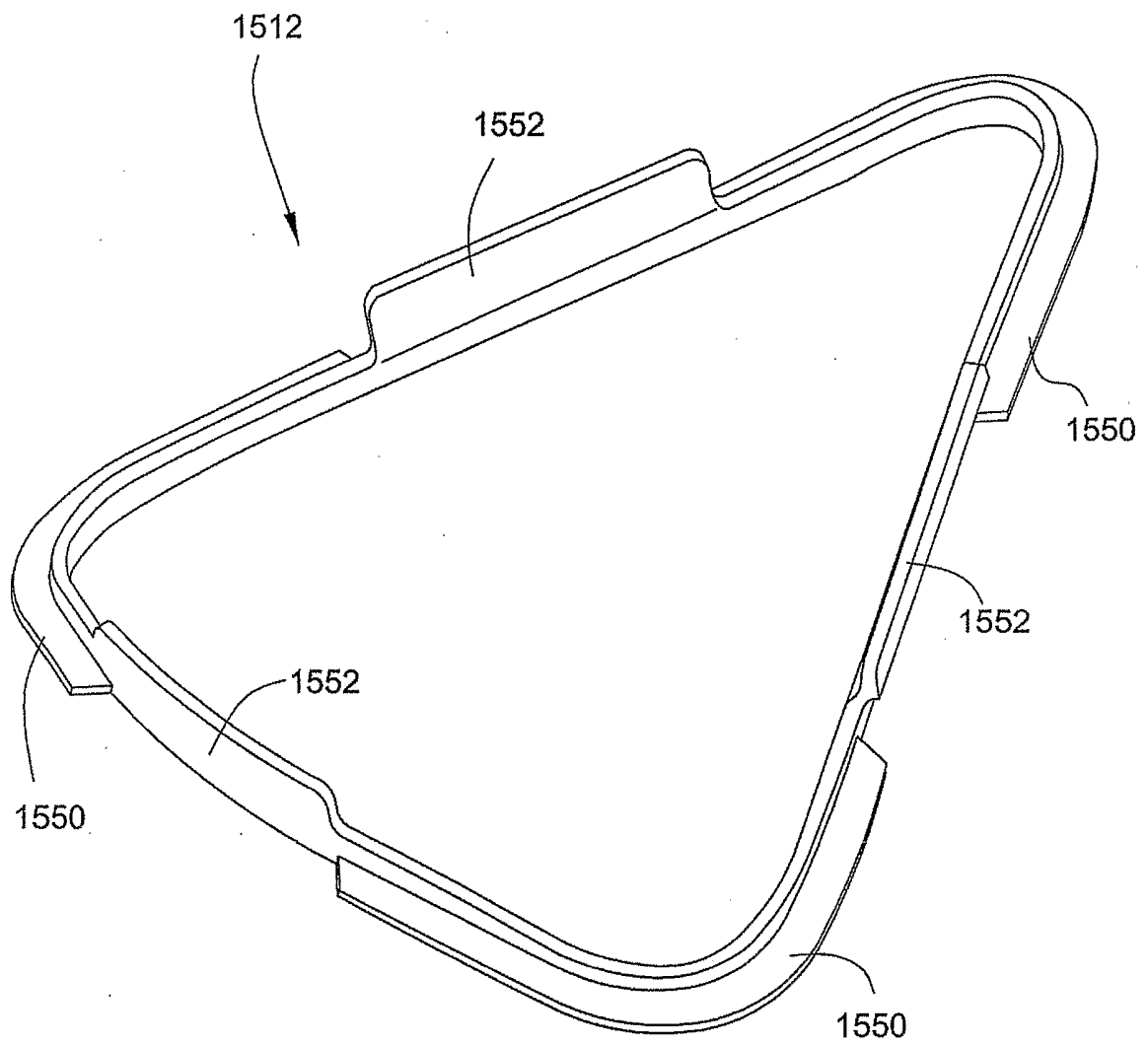


Fig. 43

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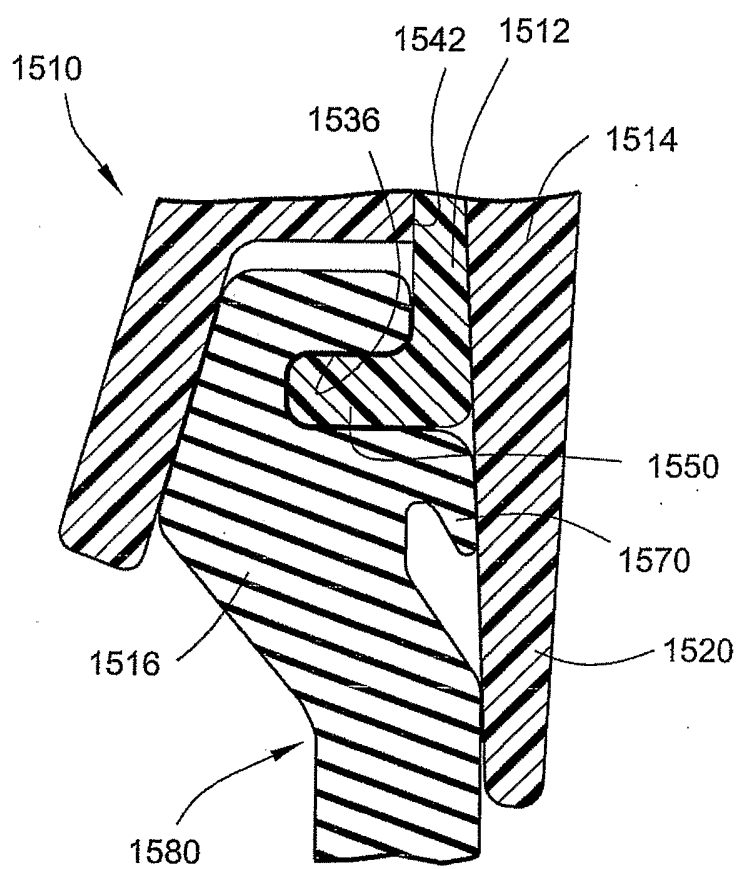


Fig. 44

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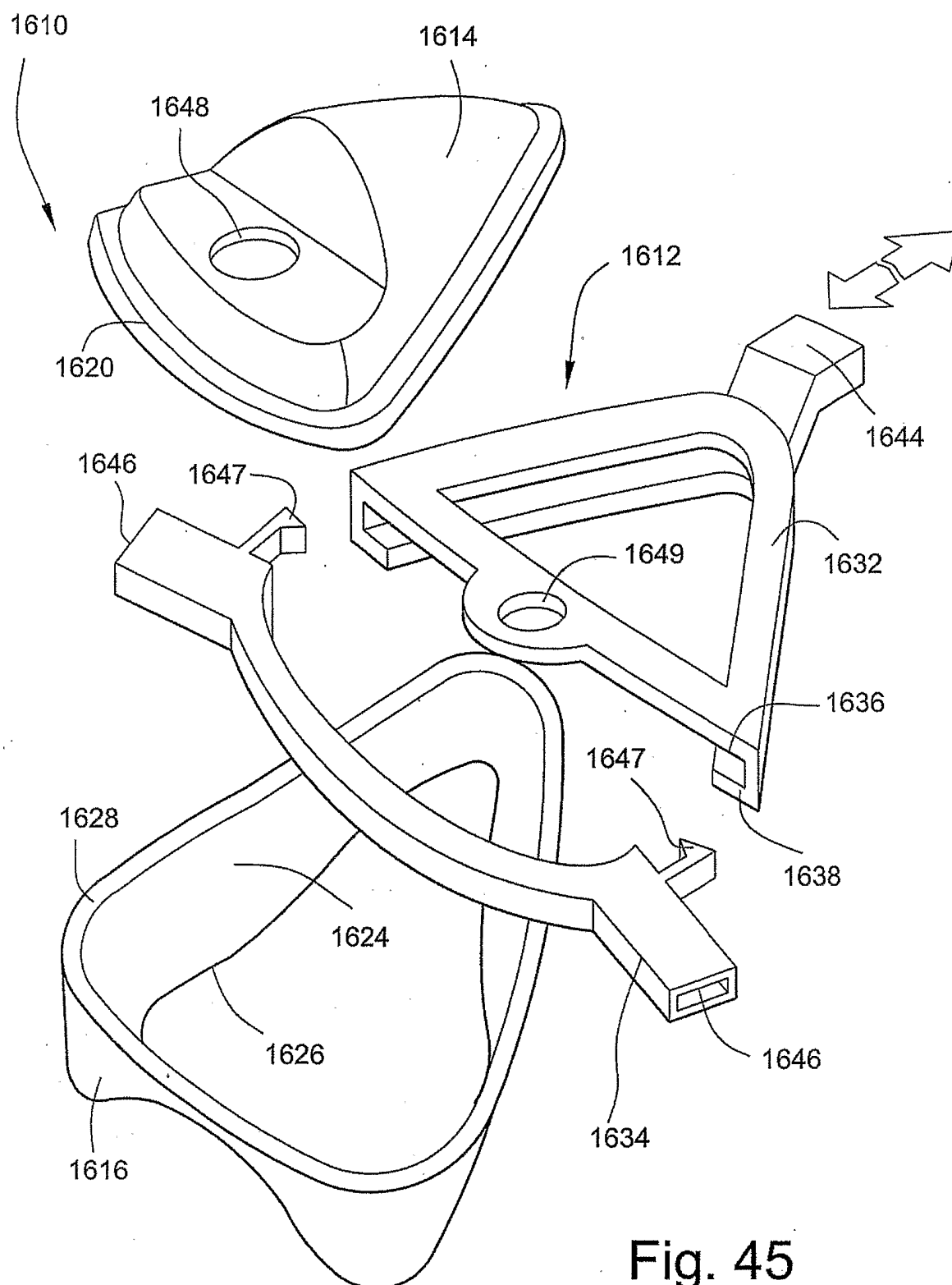


Fig. 45

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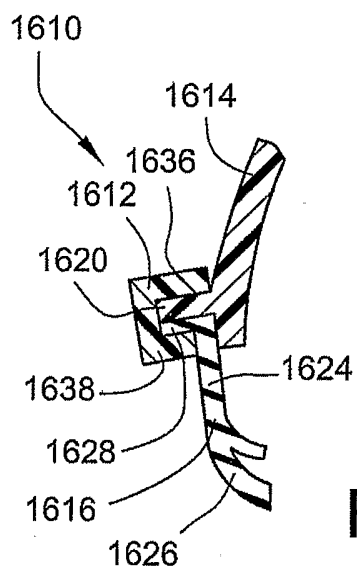


Fig. 46

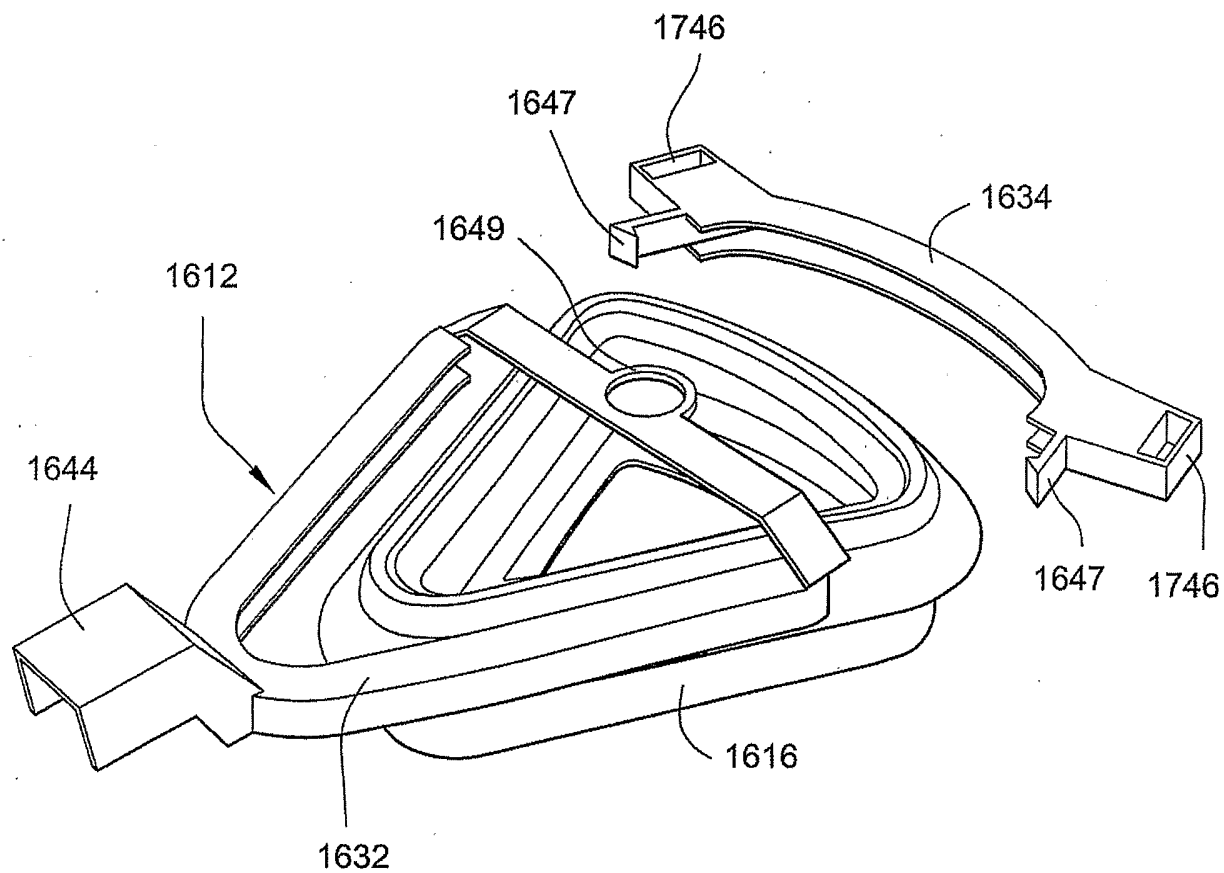


Fig. 47

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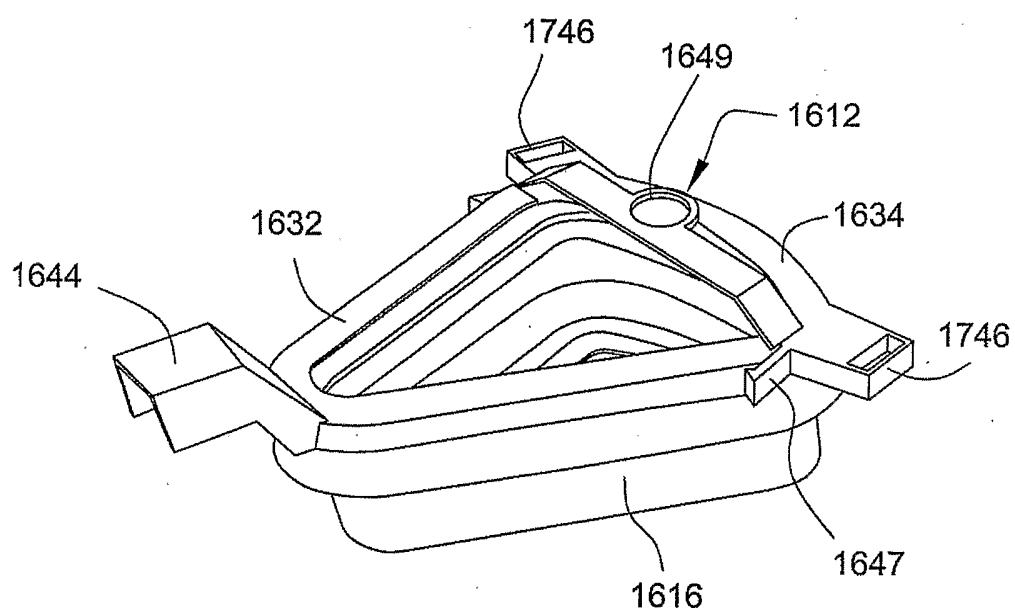


Fig. 48

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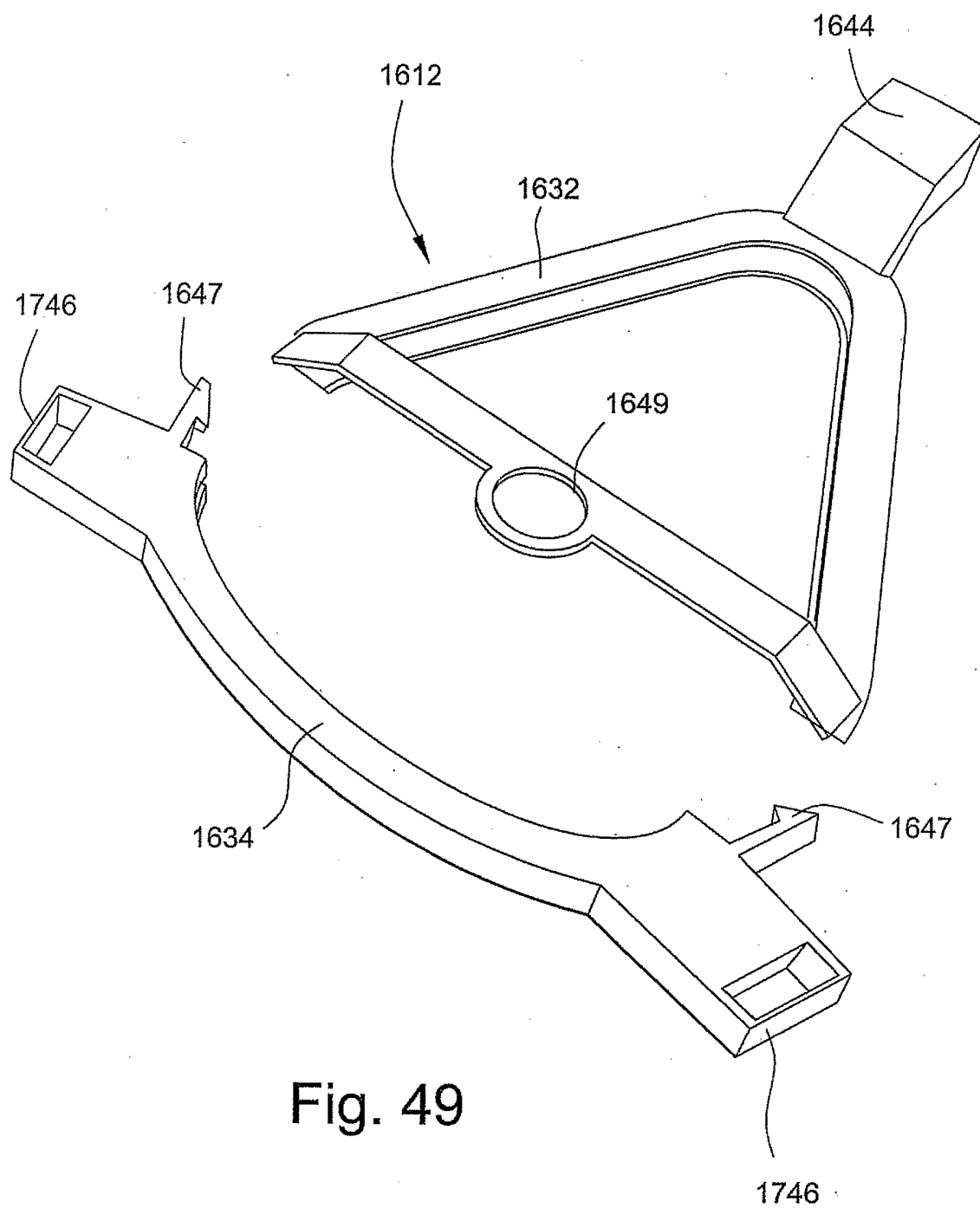


Fig. 49



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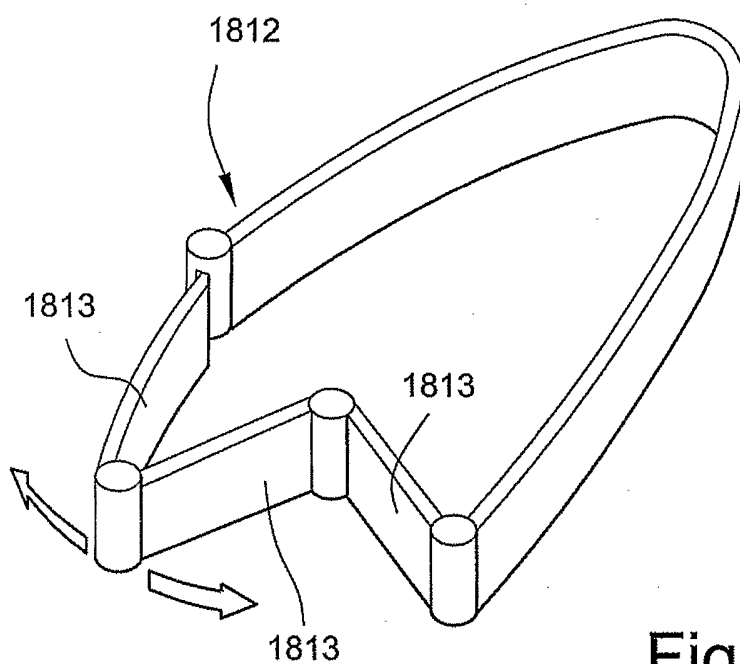


Fig. 50

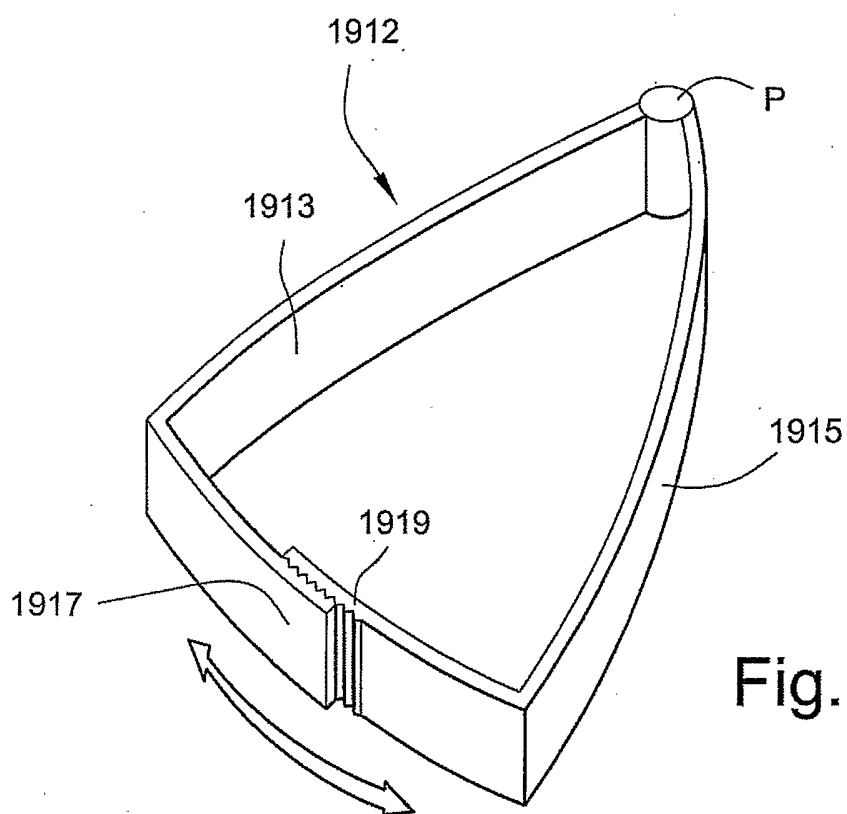


Fig. 51

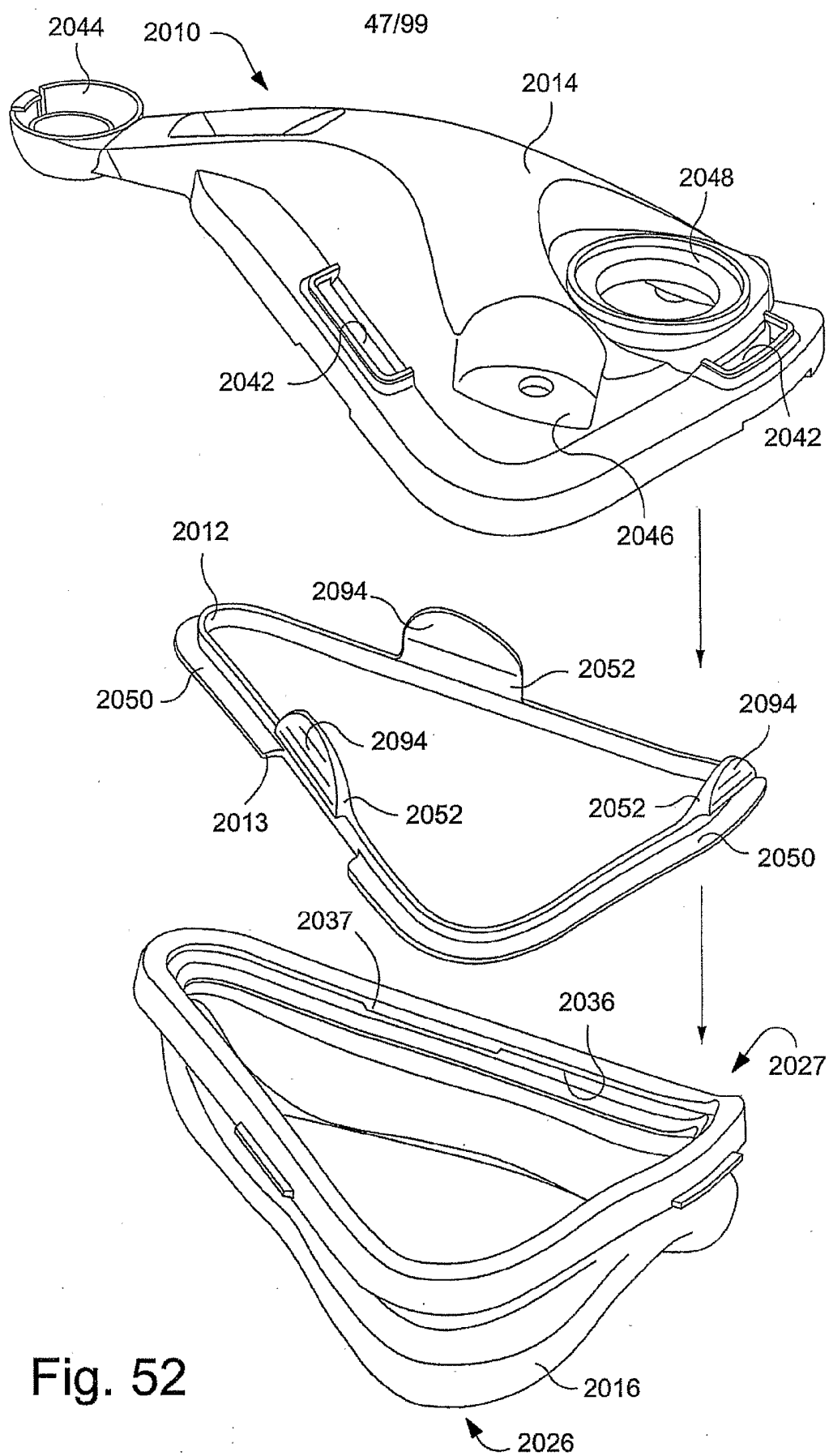


Fig. 52

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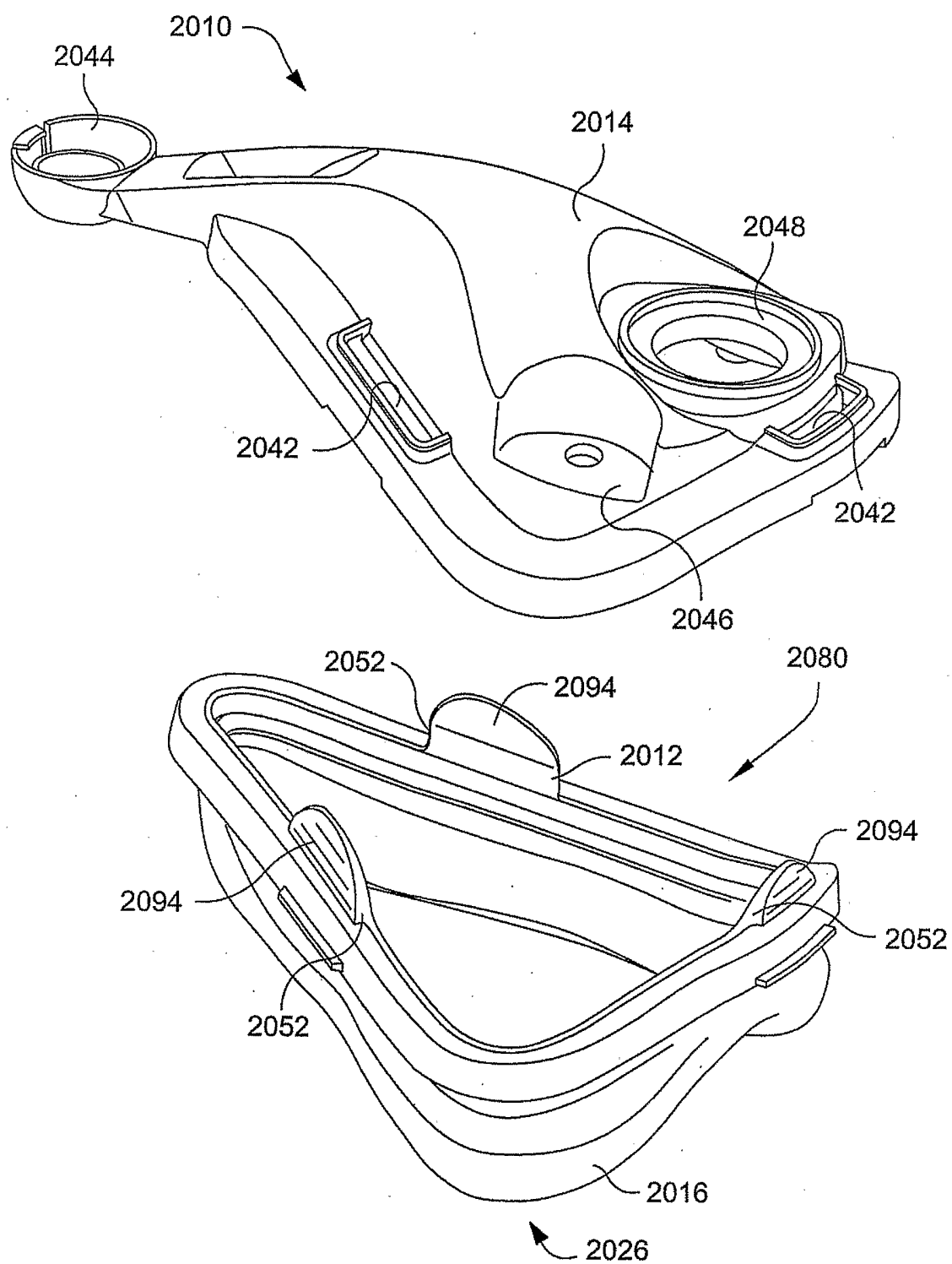


Fig. 53

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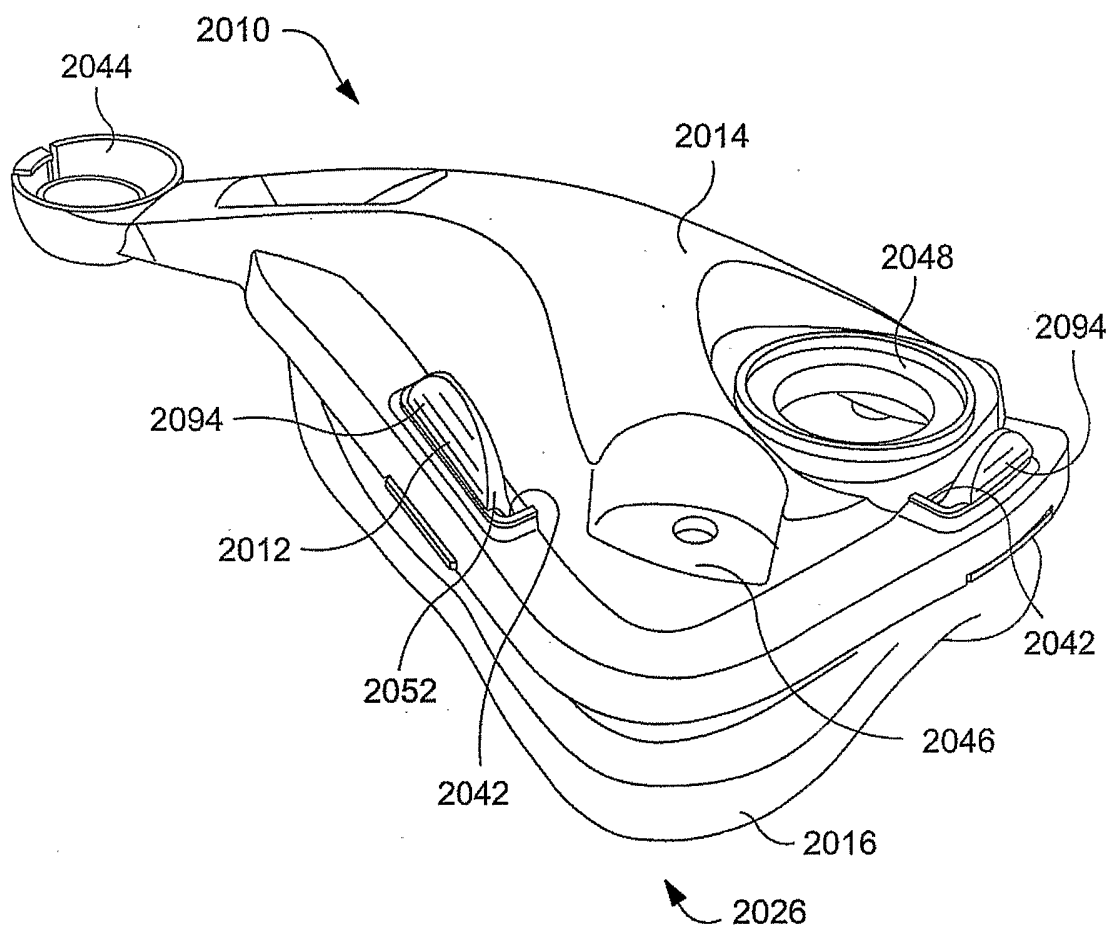


Fig. 54

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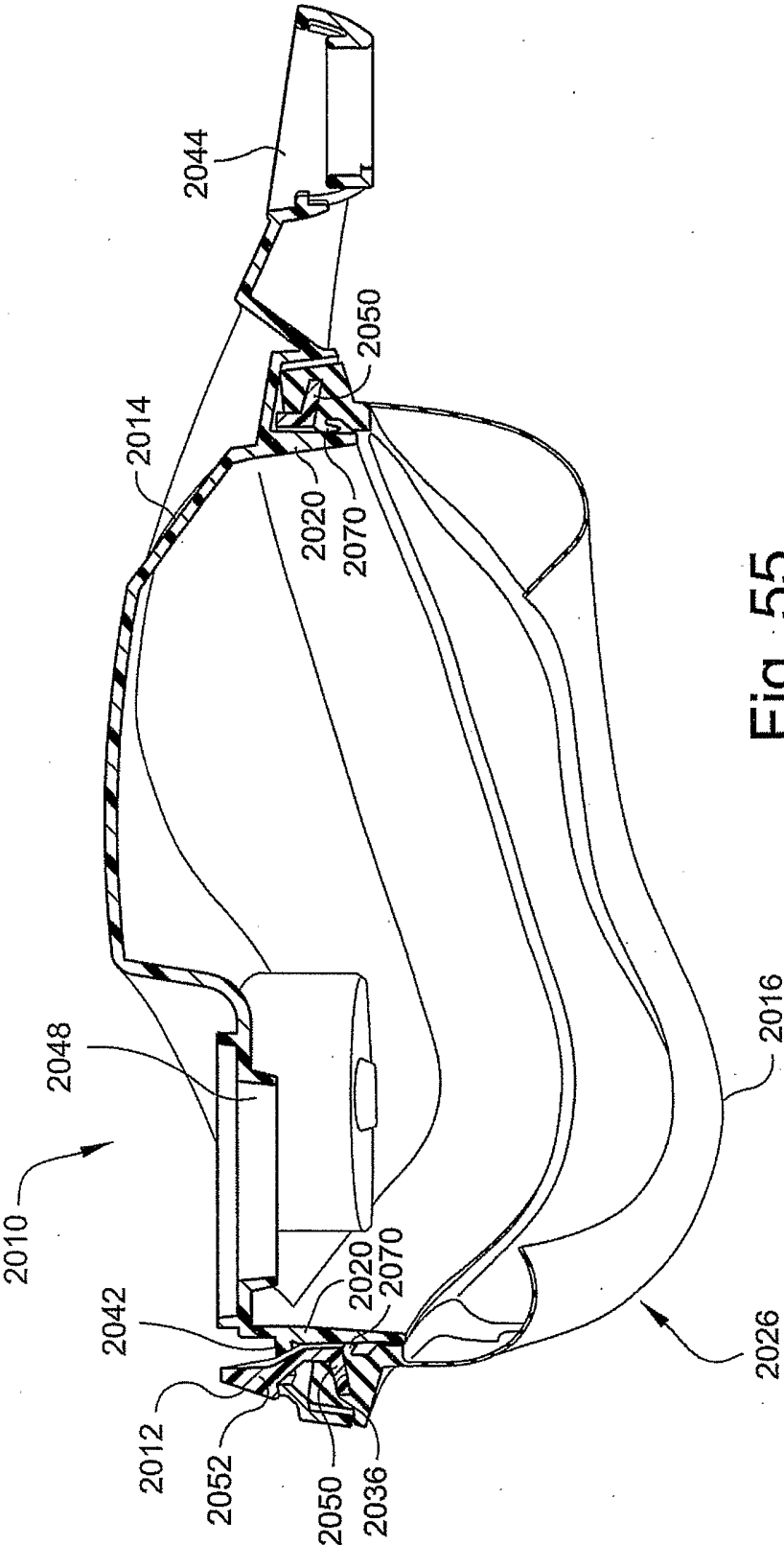


Fig. 55

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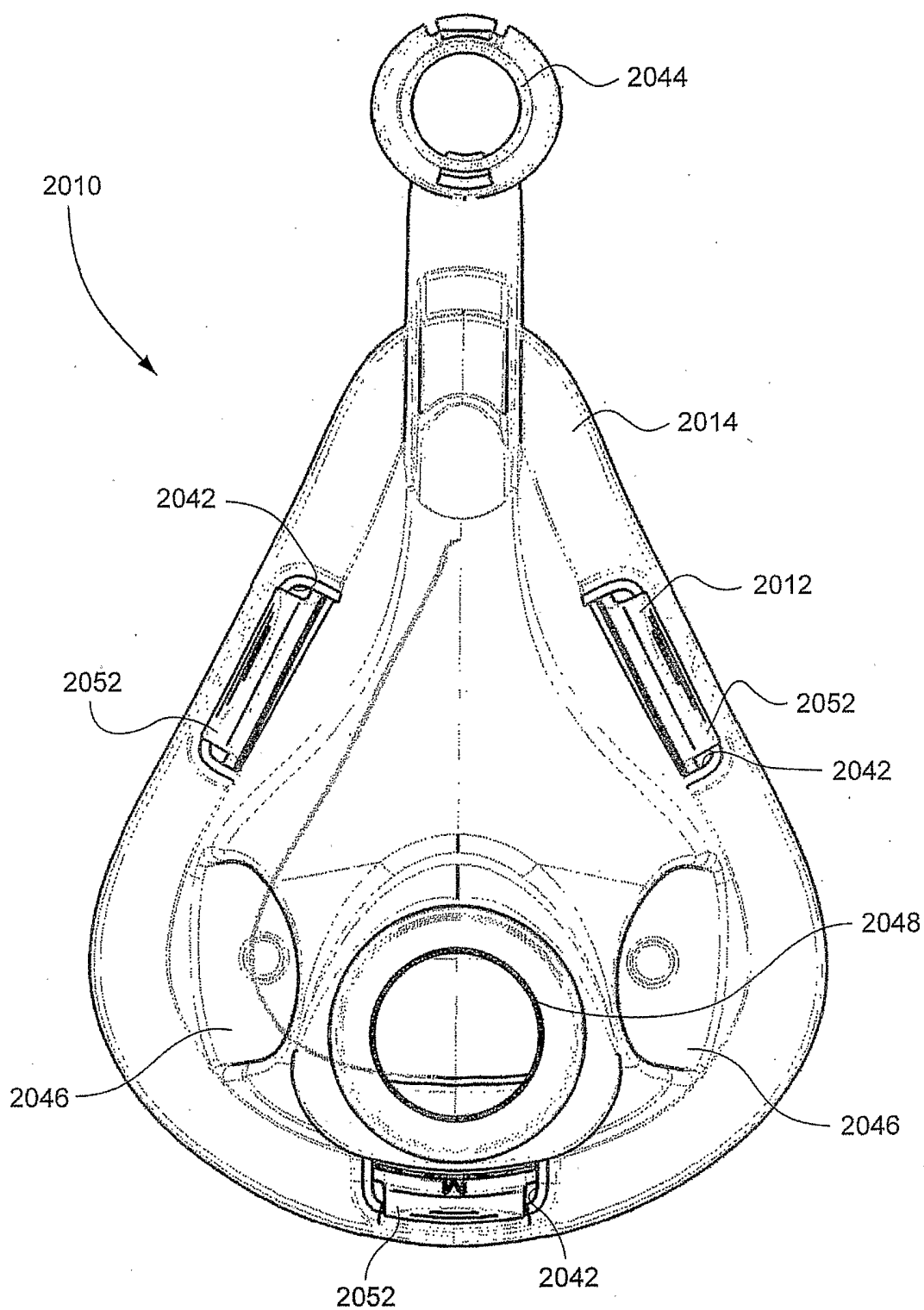


Fig. 56

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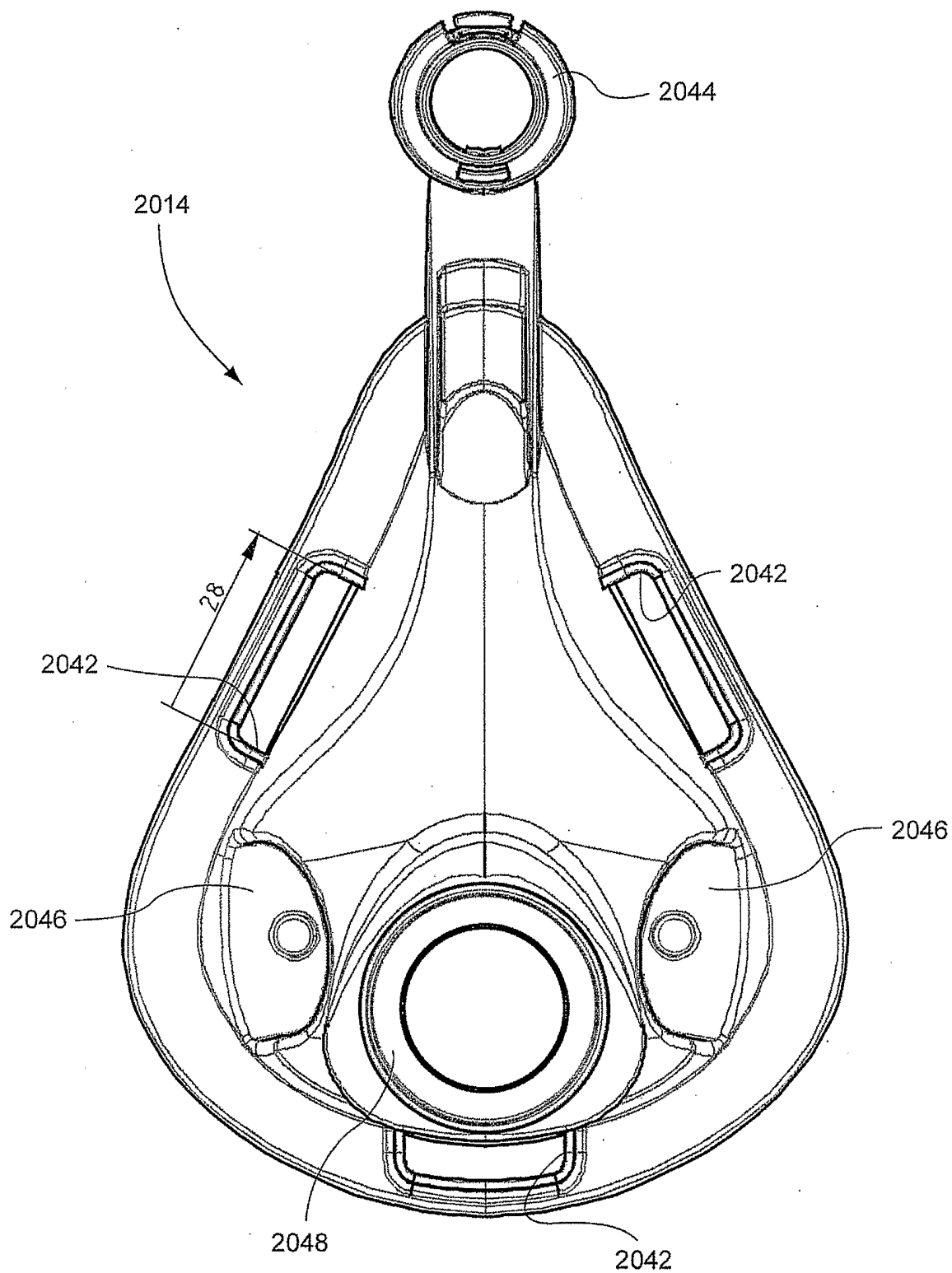


Fig. 57

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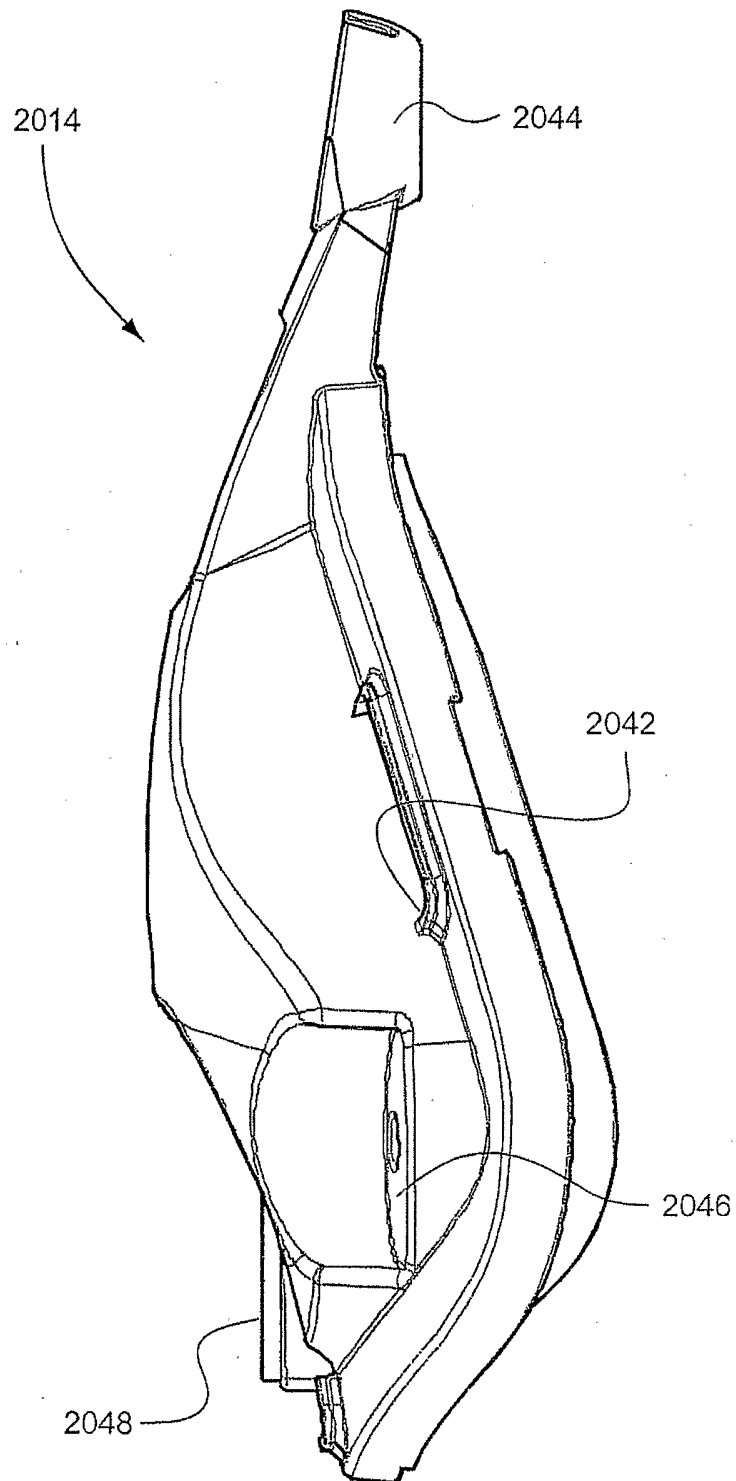


Fig. 58



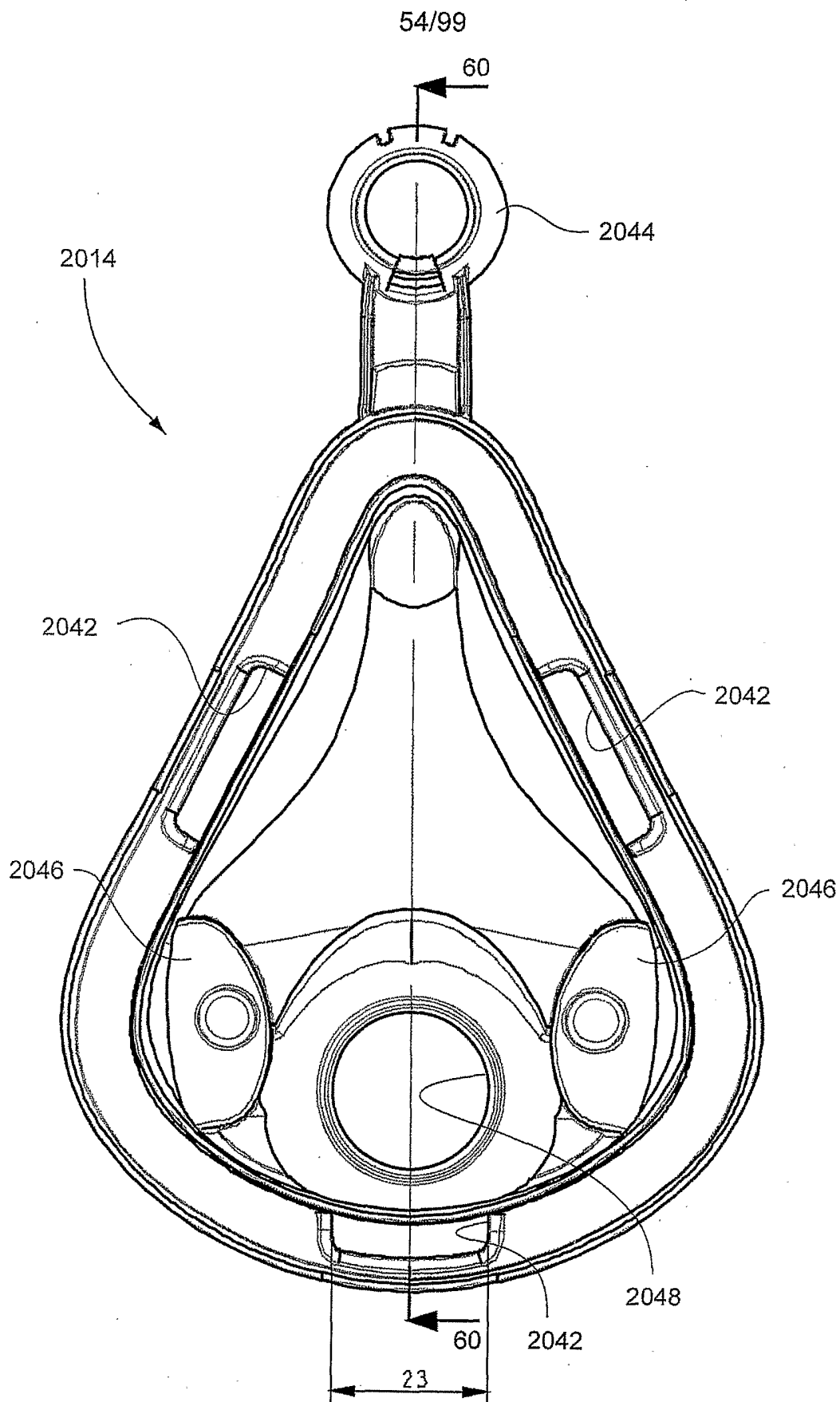


Fig. 59

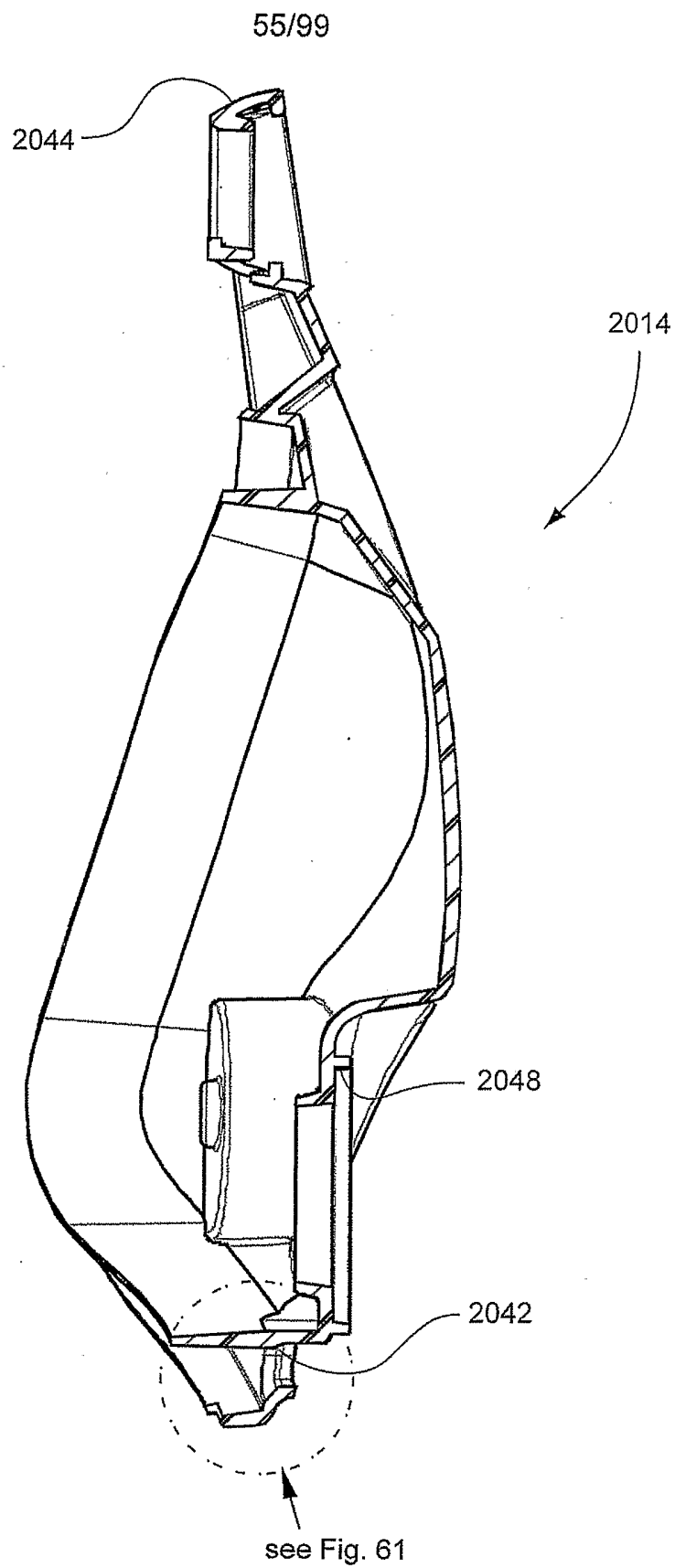


Fig. 60

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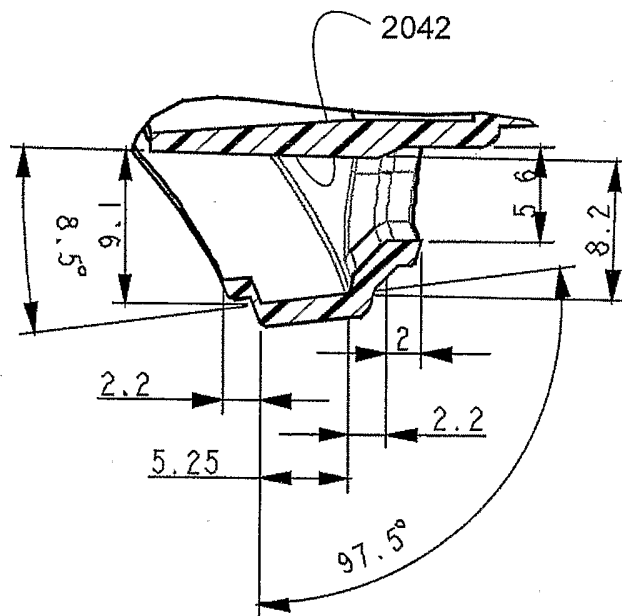


Fig. 61

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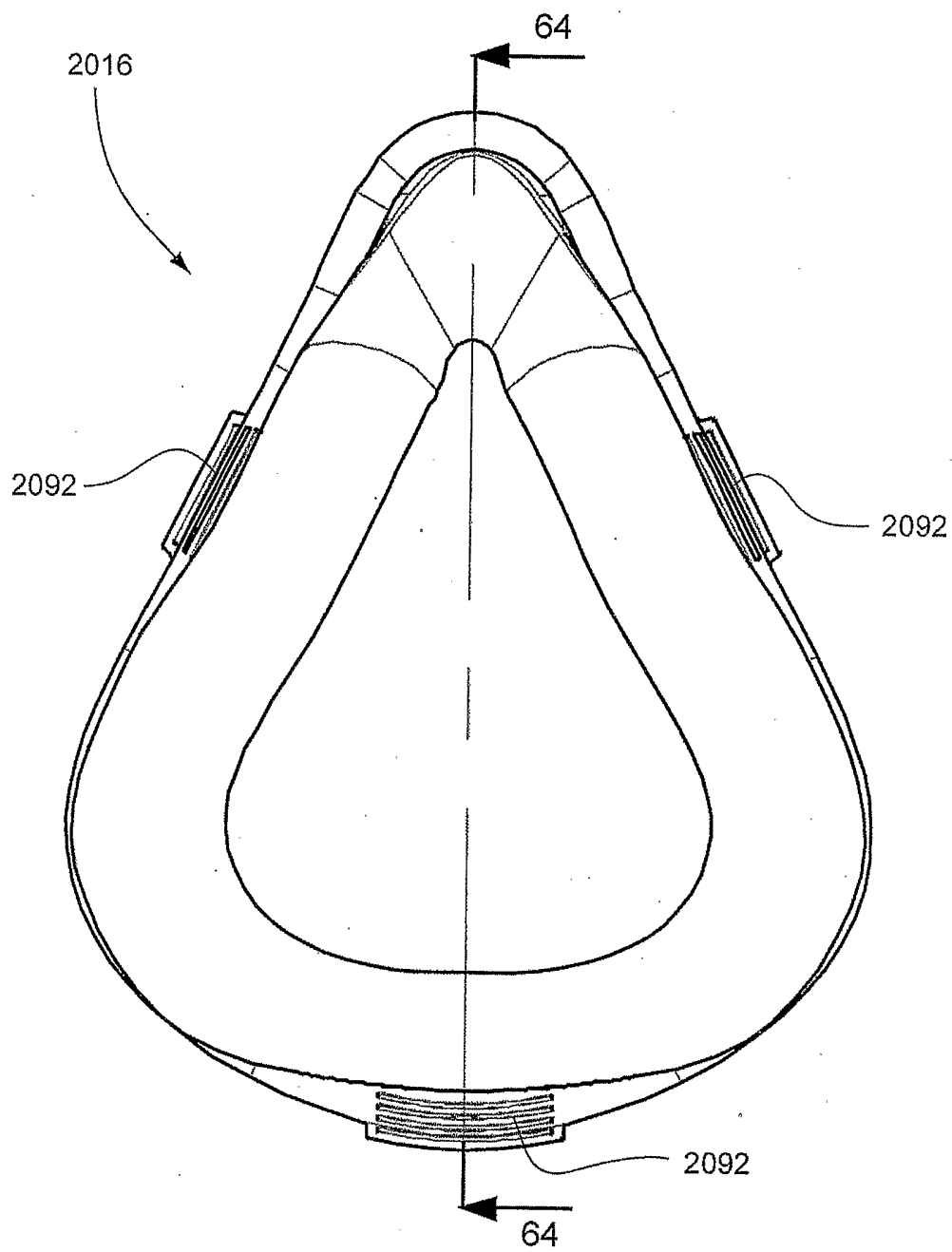


Fig. 62

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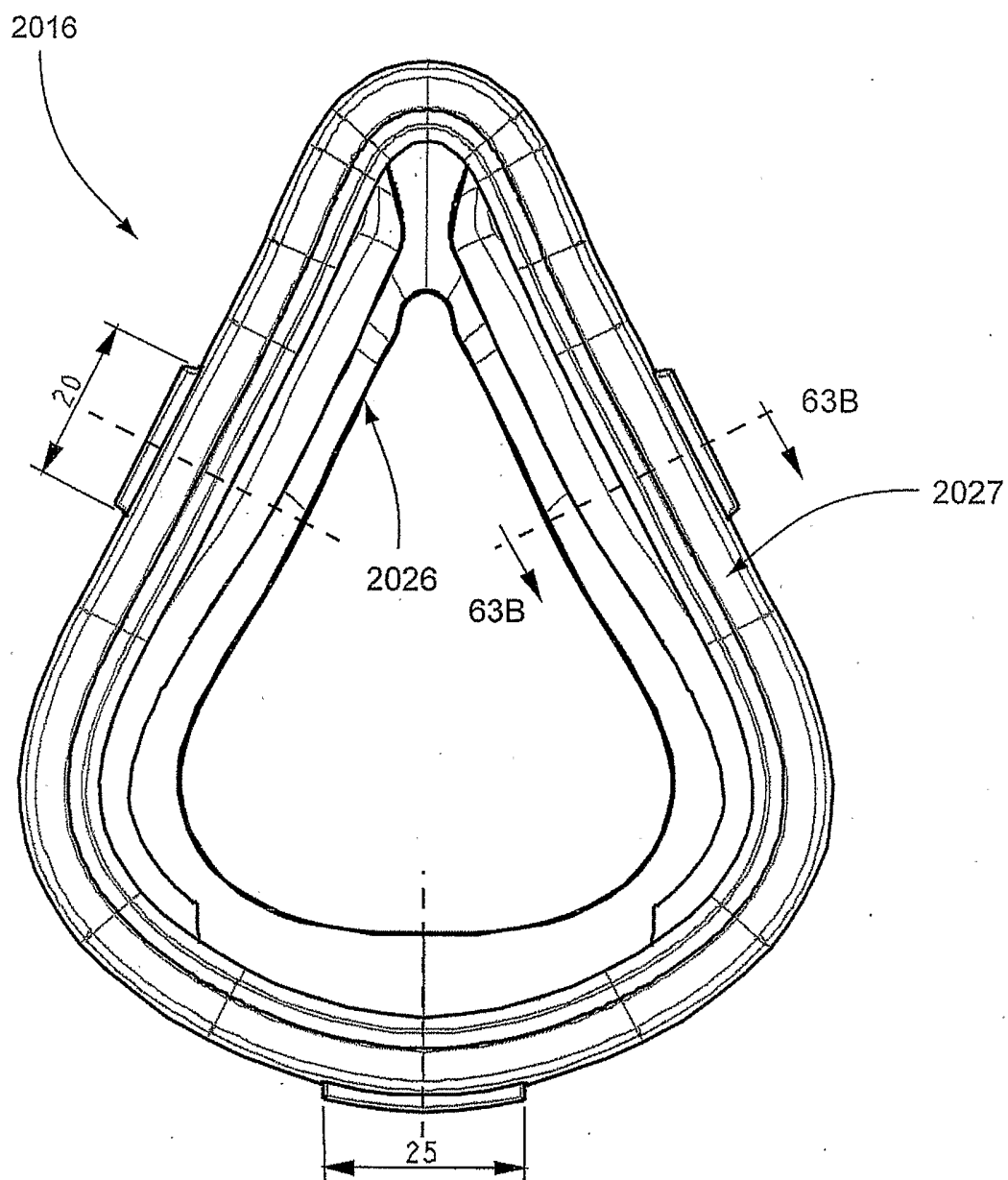


Fig. 63

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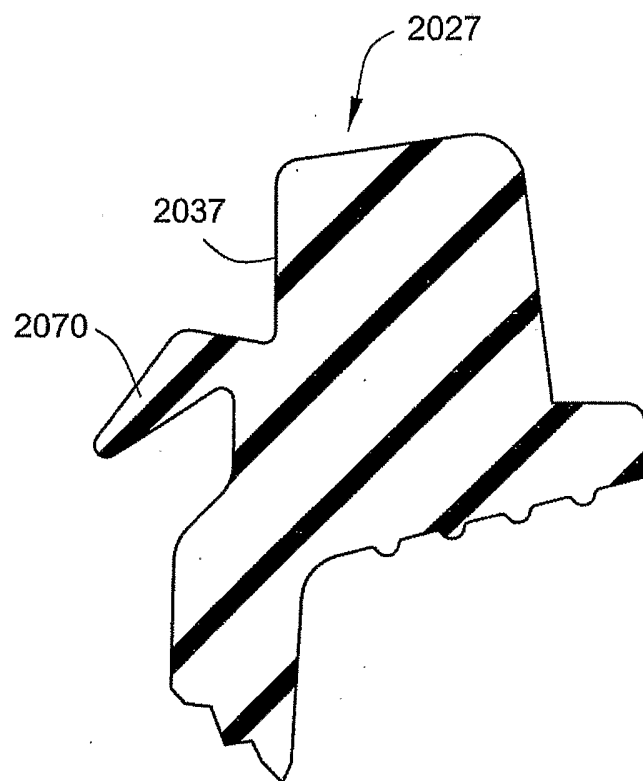
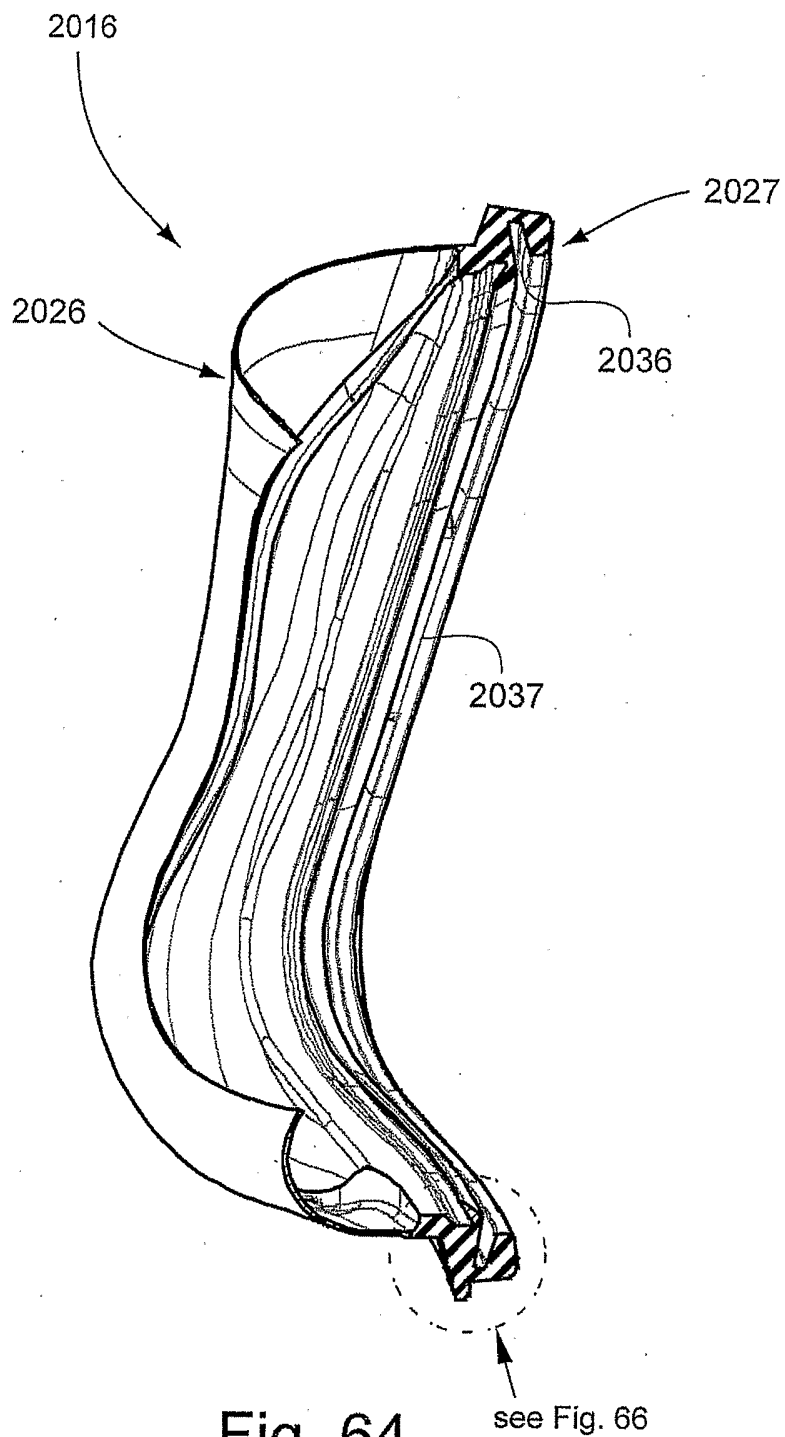


Fig. 63B

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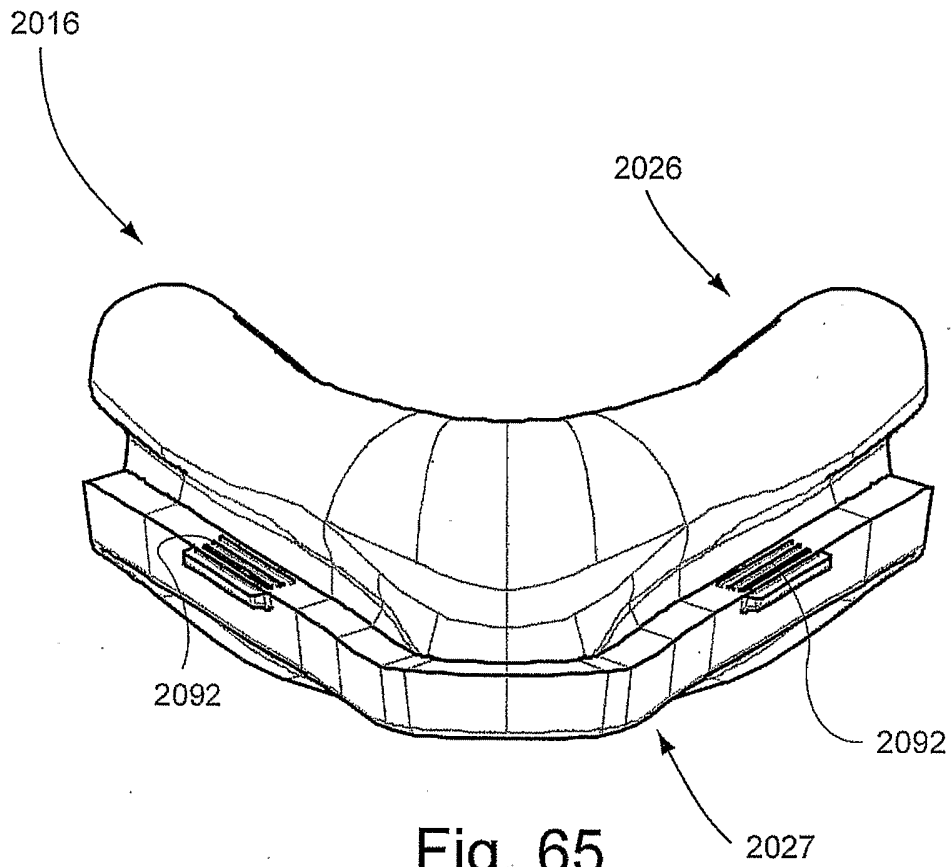


Fig. 65



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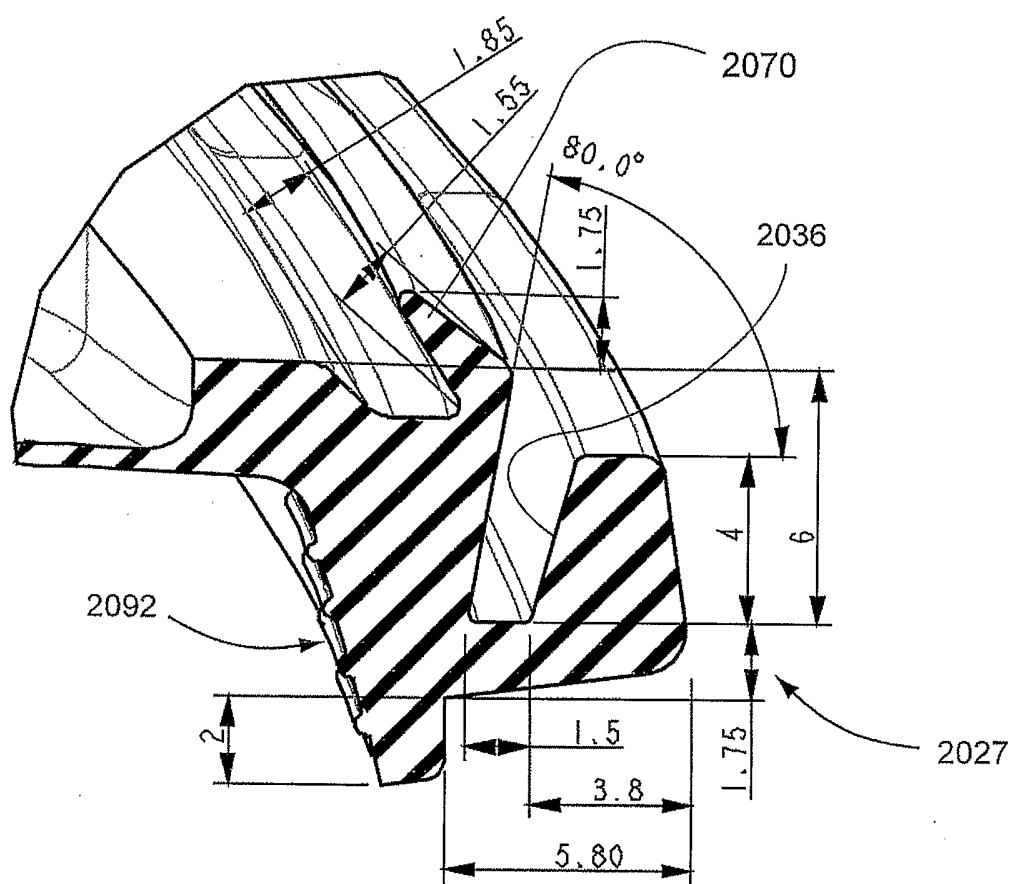


Fig. 66

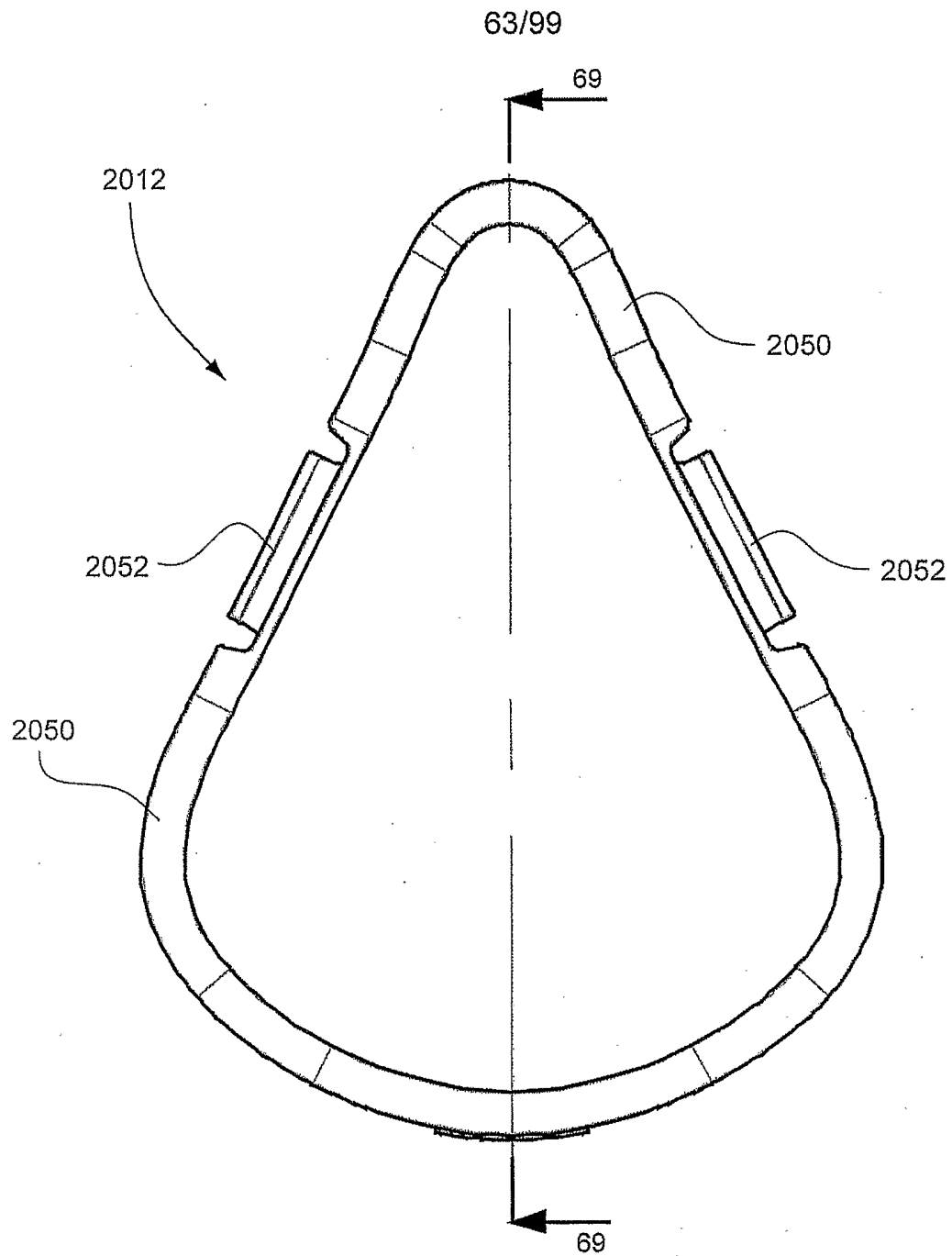
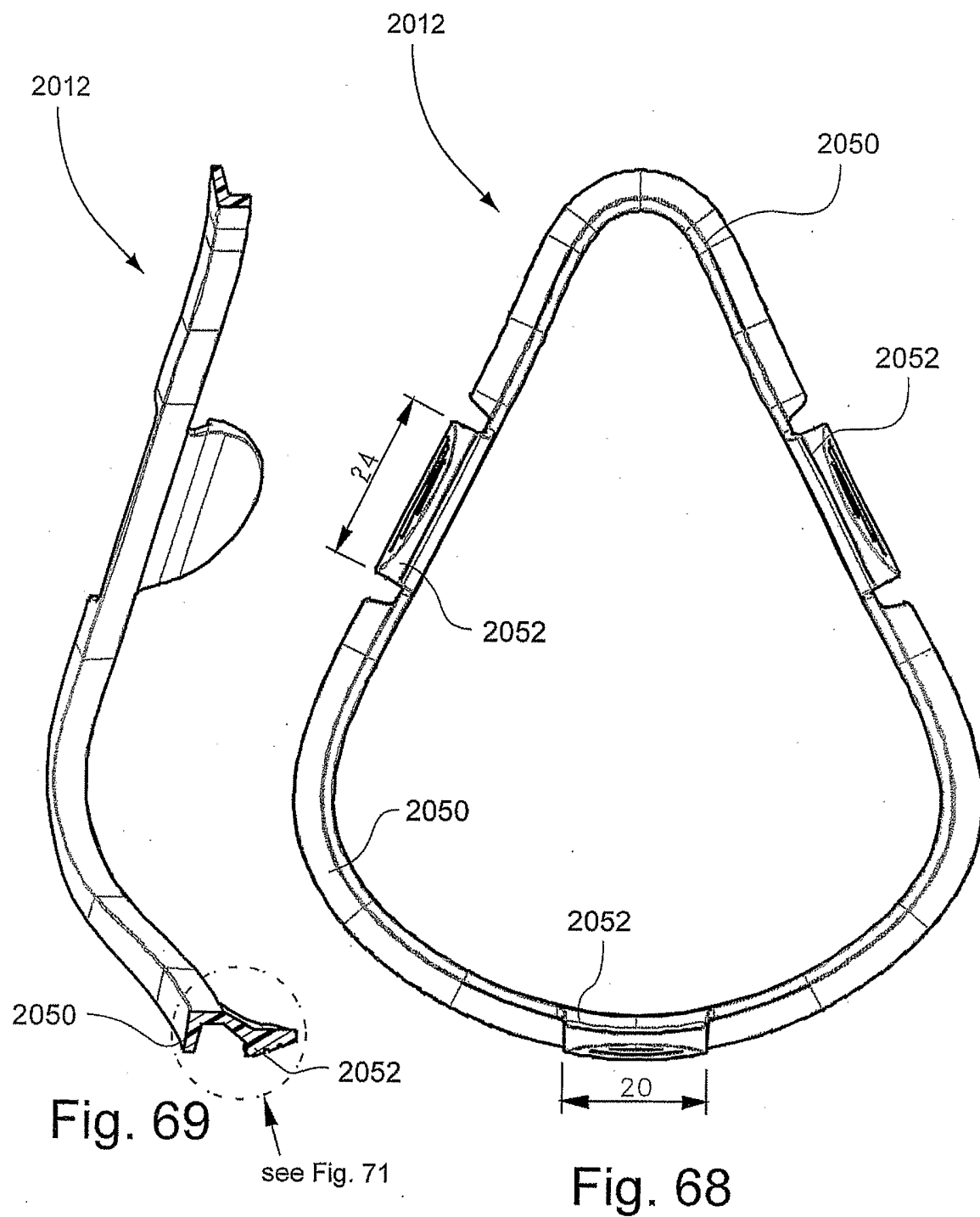


Fig. 67

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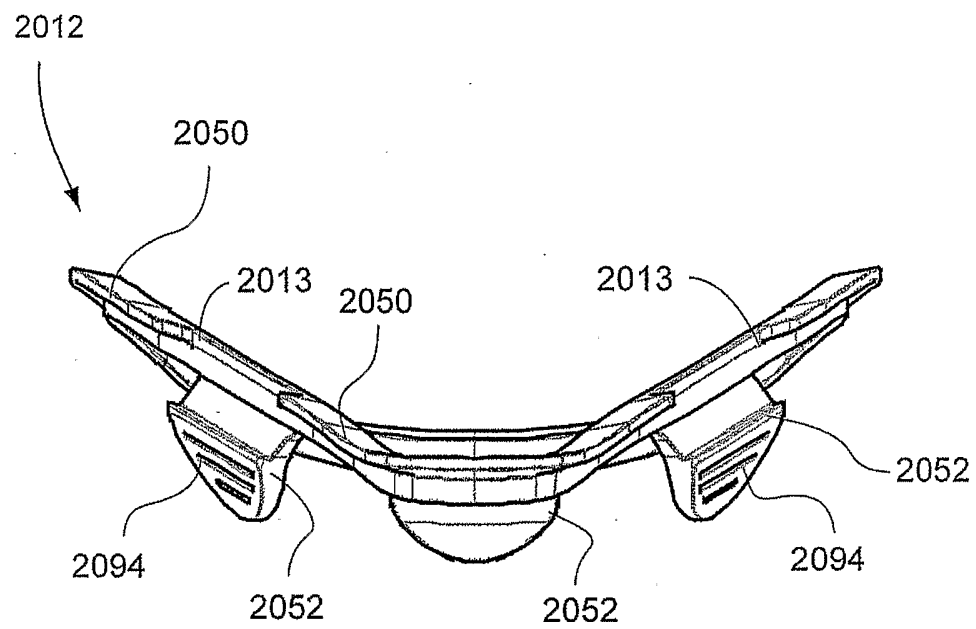


Fig. 70

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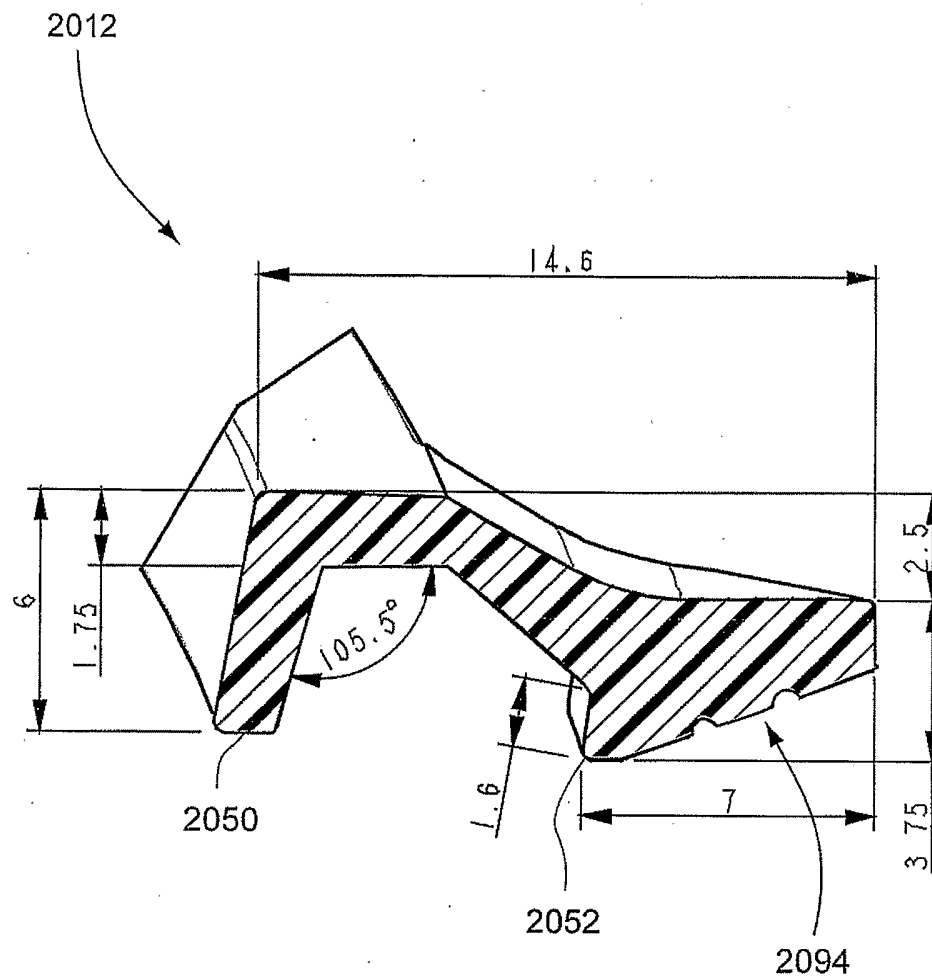


Fig. 71

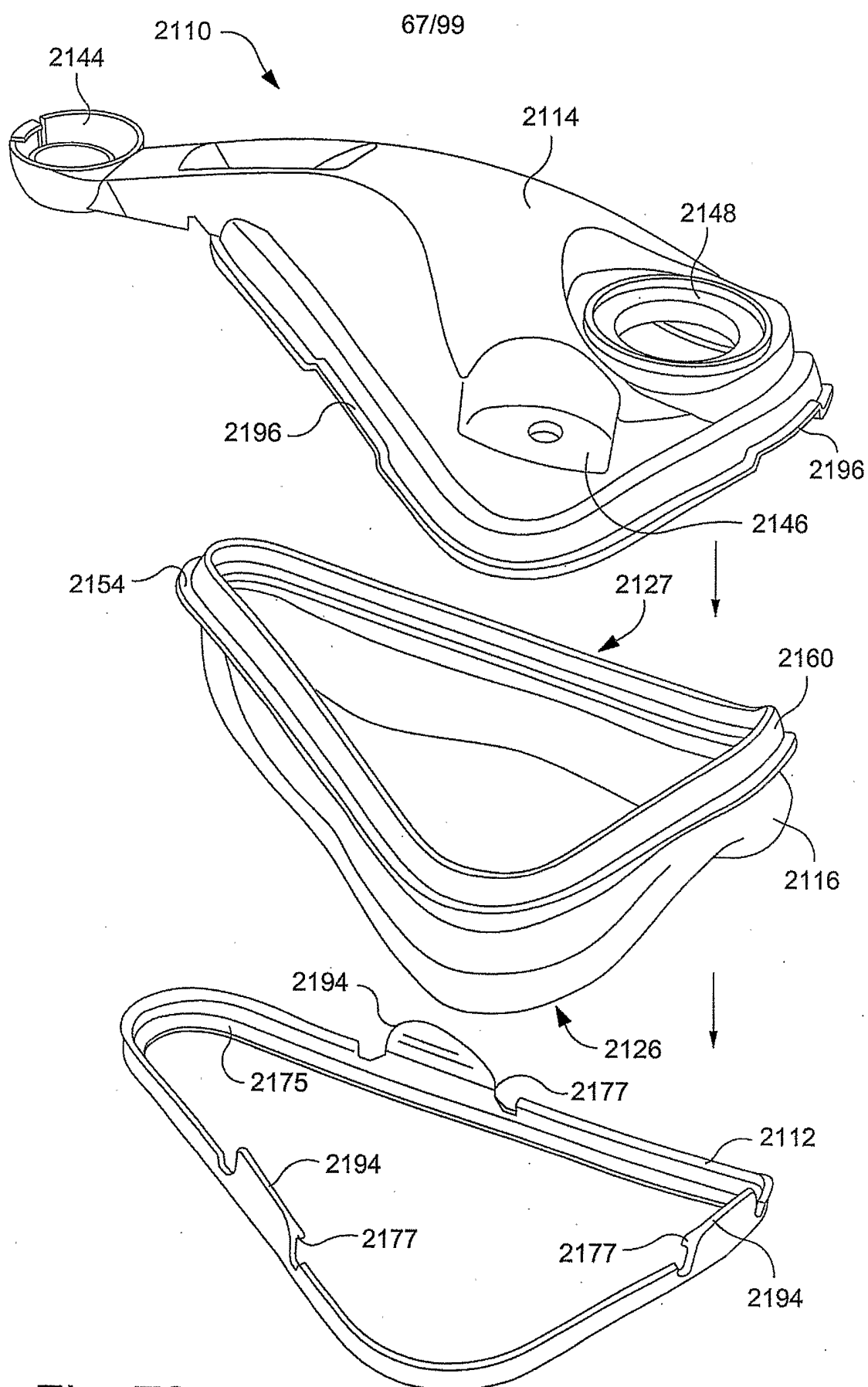


Fig. 72

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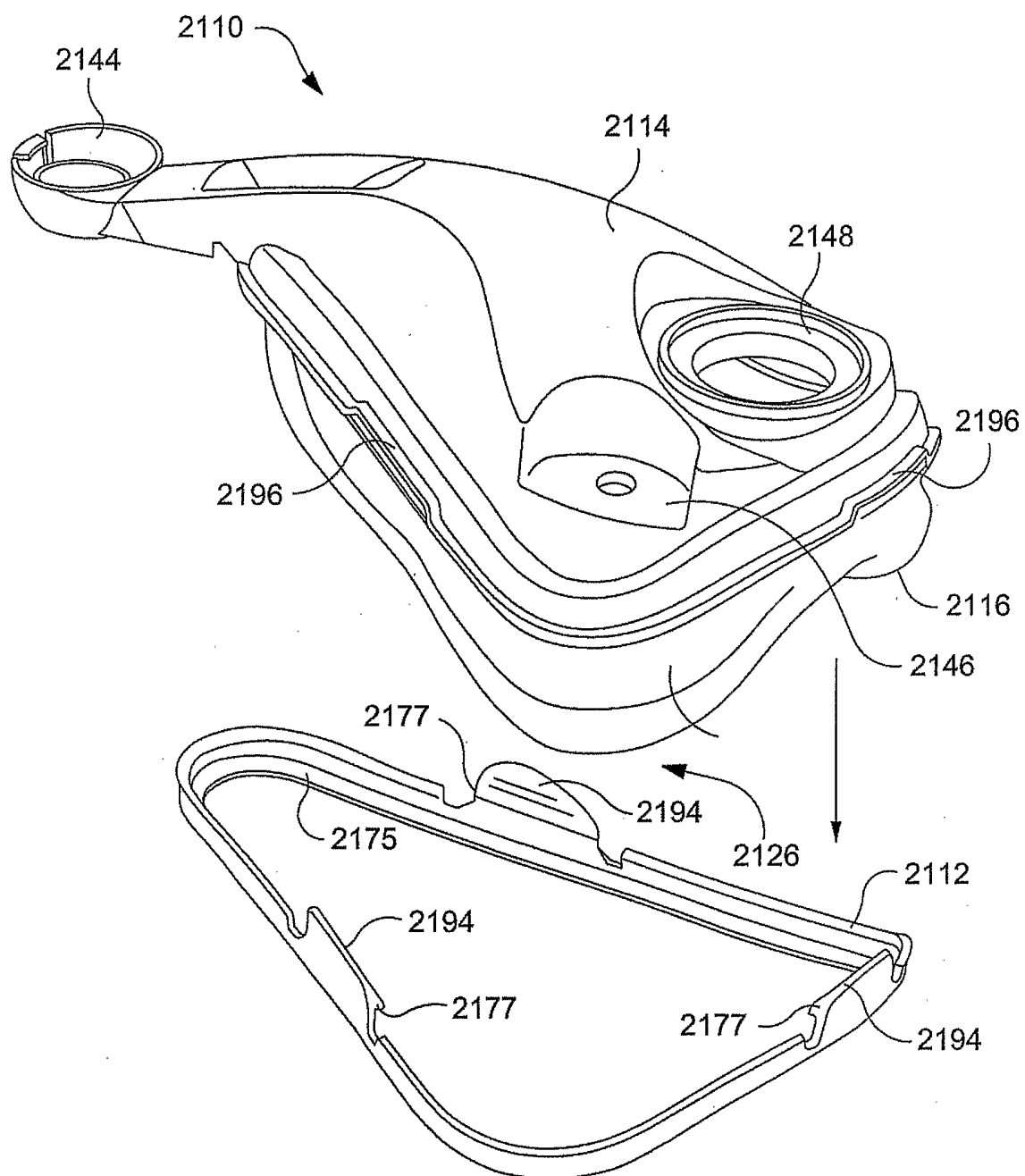


Fig. 73

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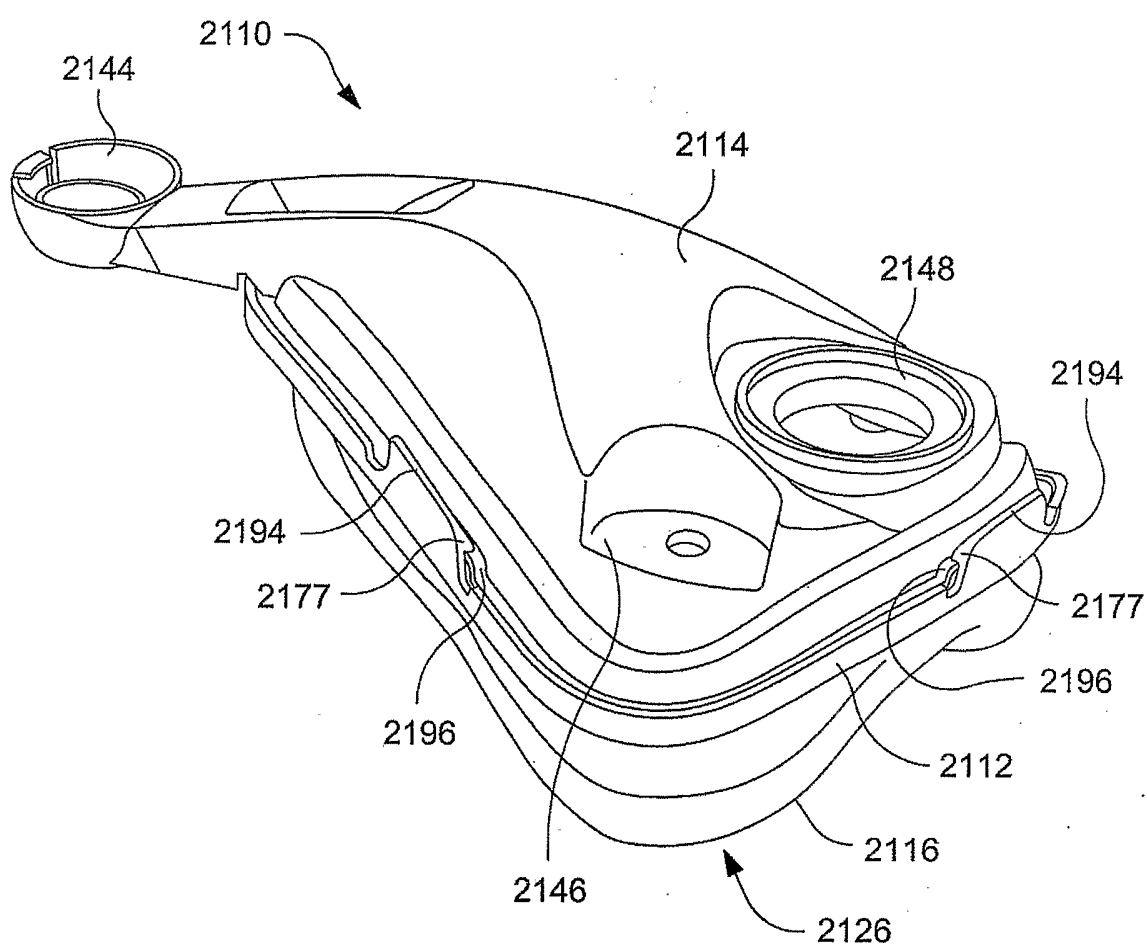


Fig. 74



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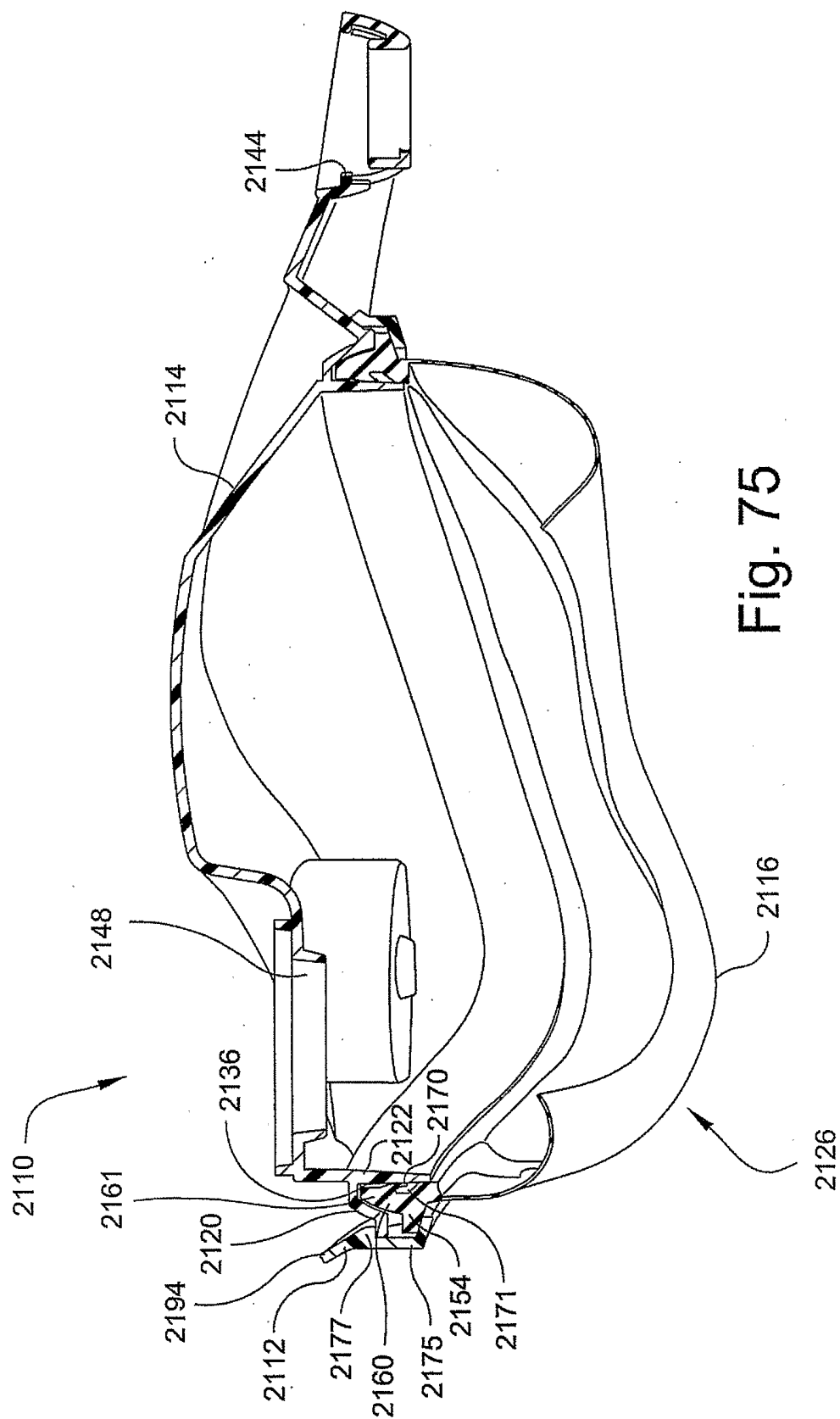


Fig. 75

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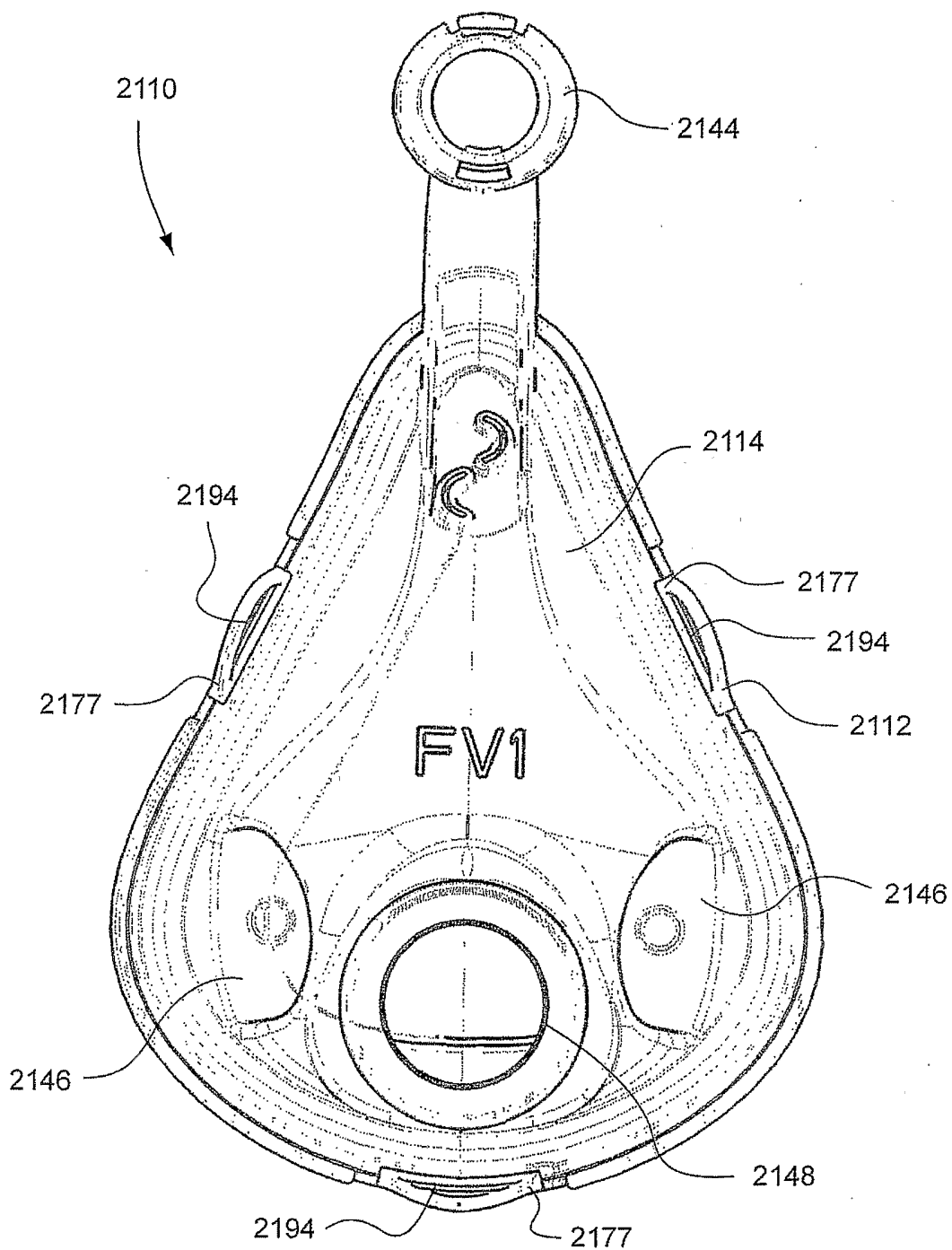


Fig. 76

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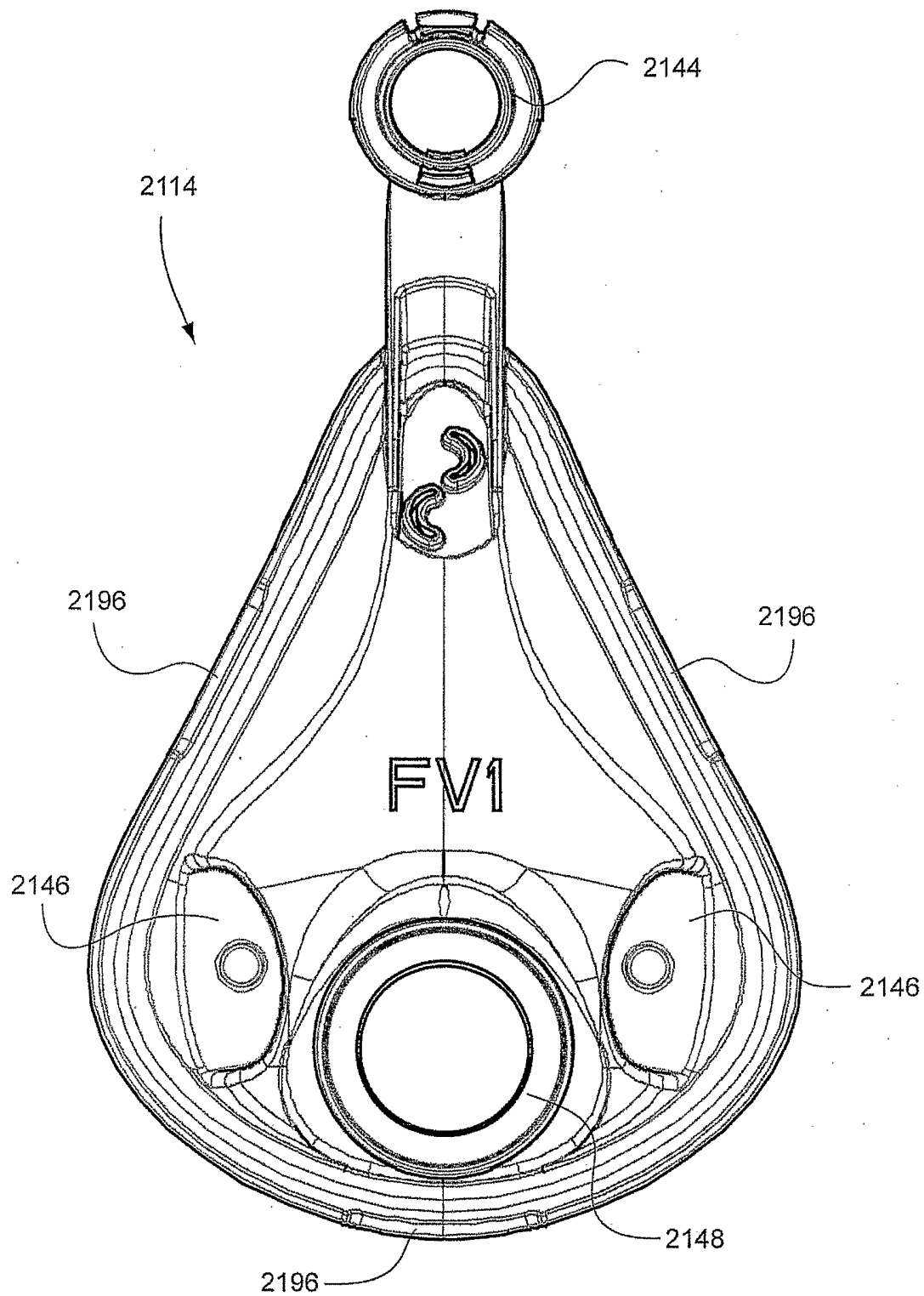


Fig. 77

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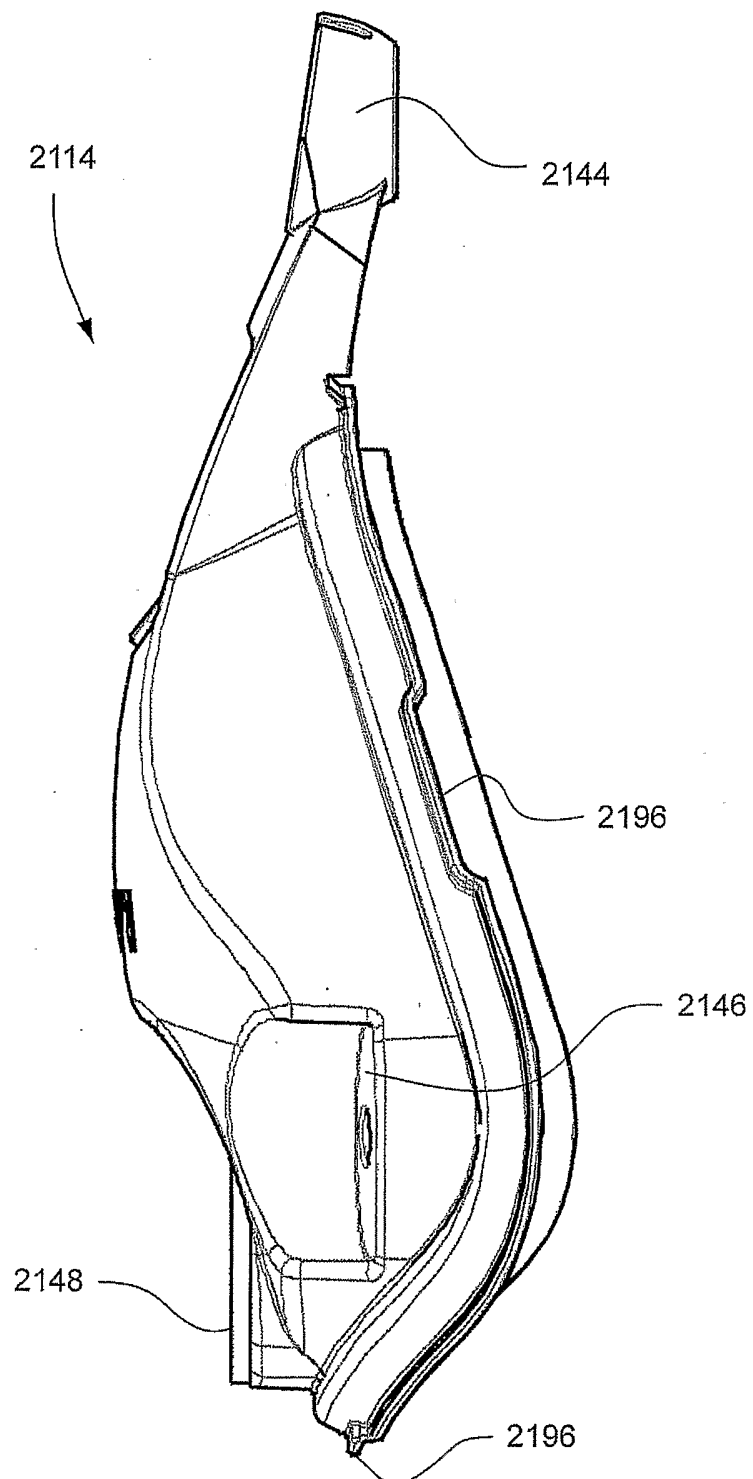
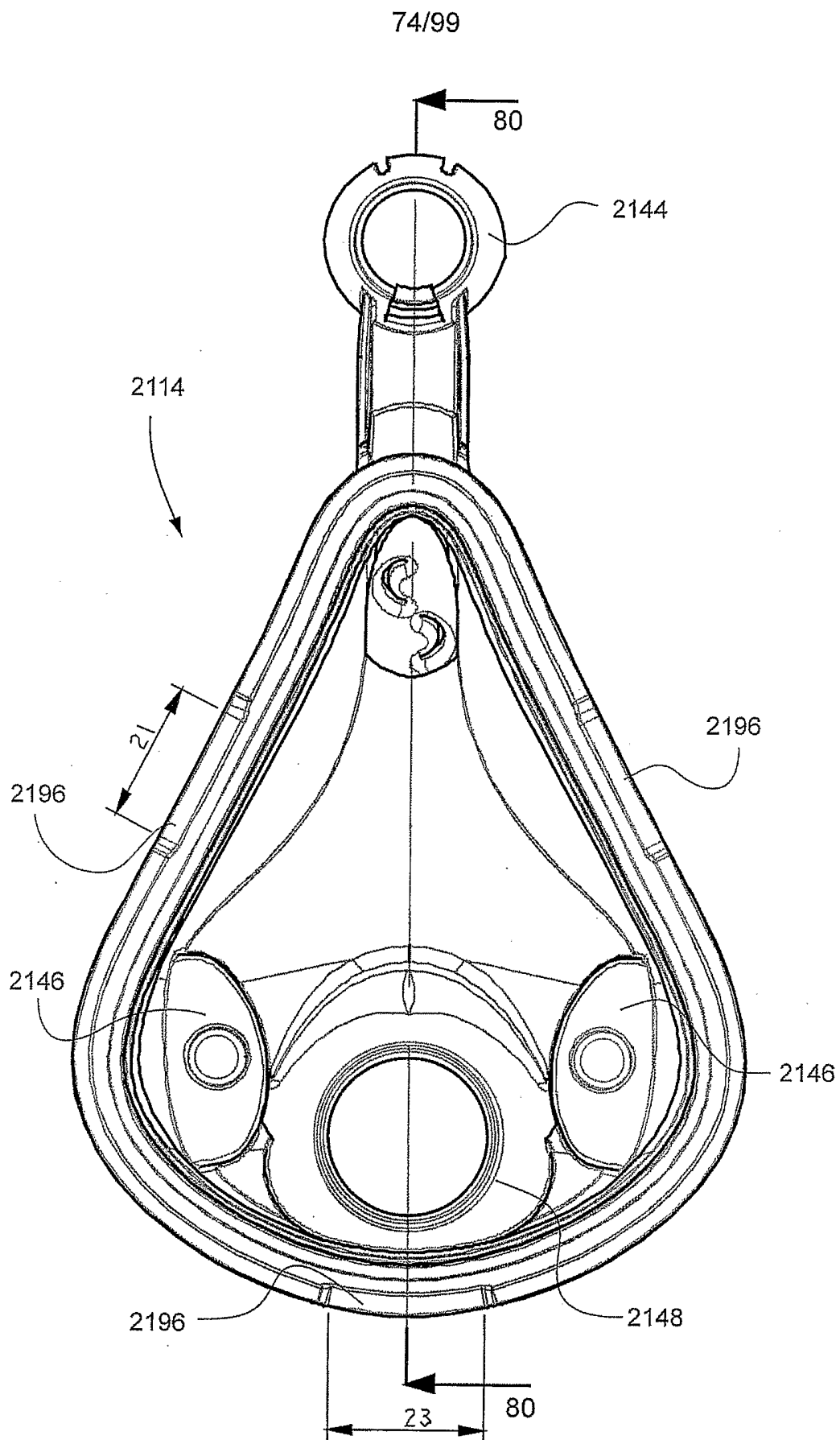


Fig. 78



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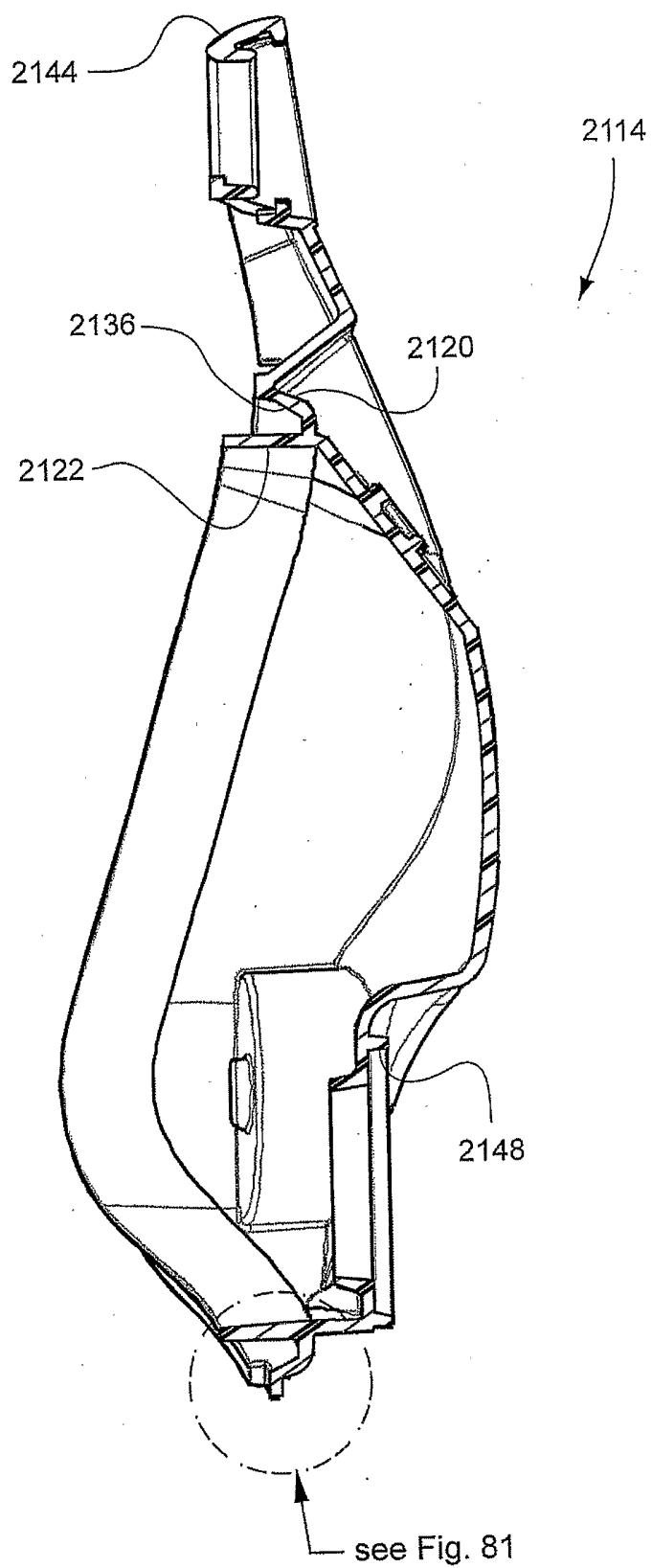


Fig. 80

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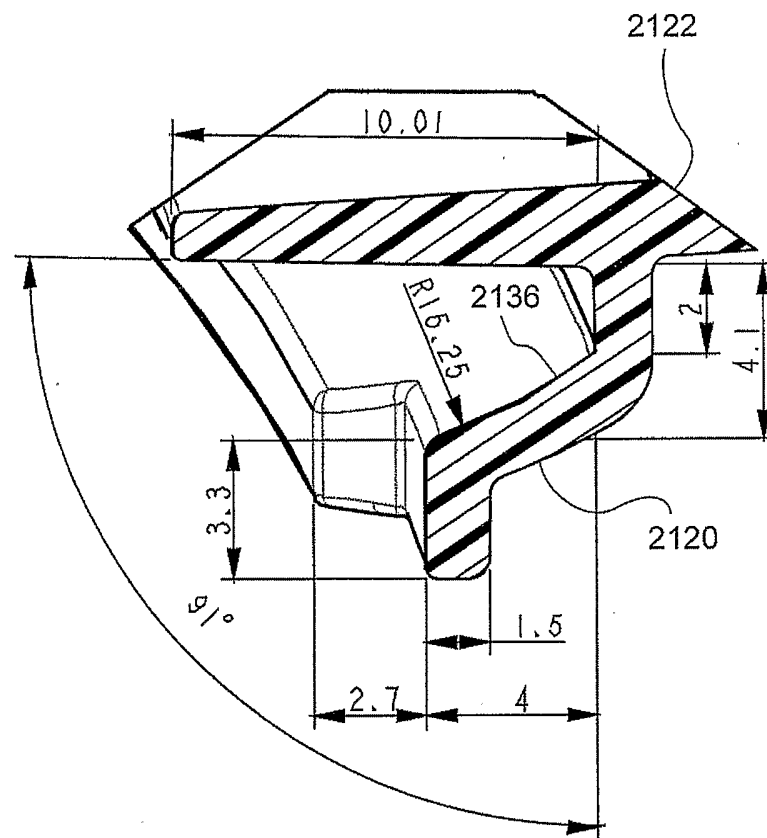


Fig. 81

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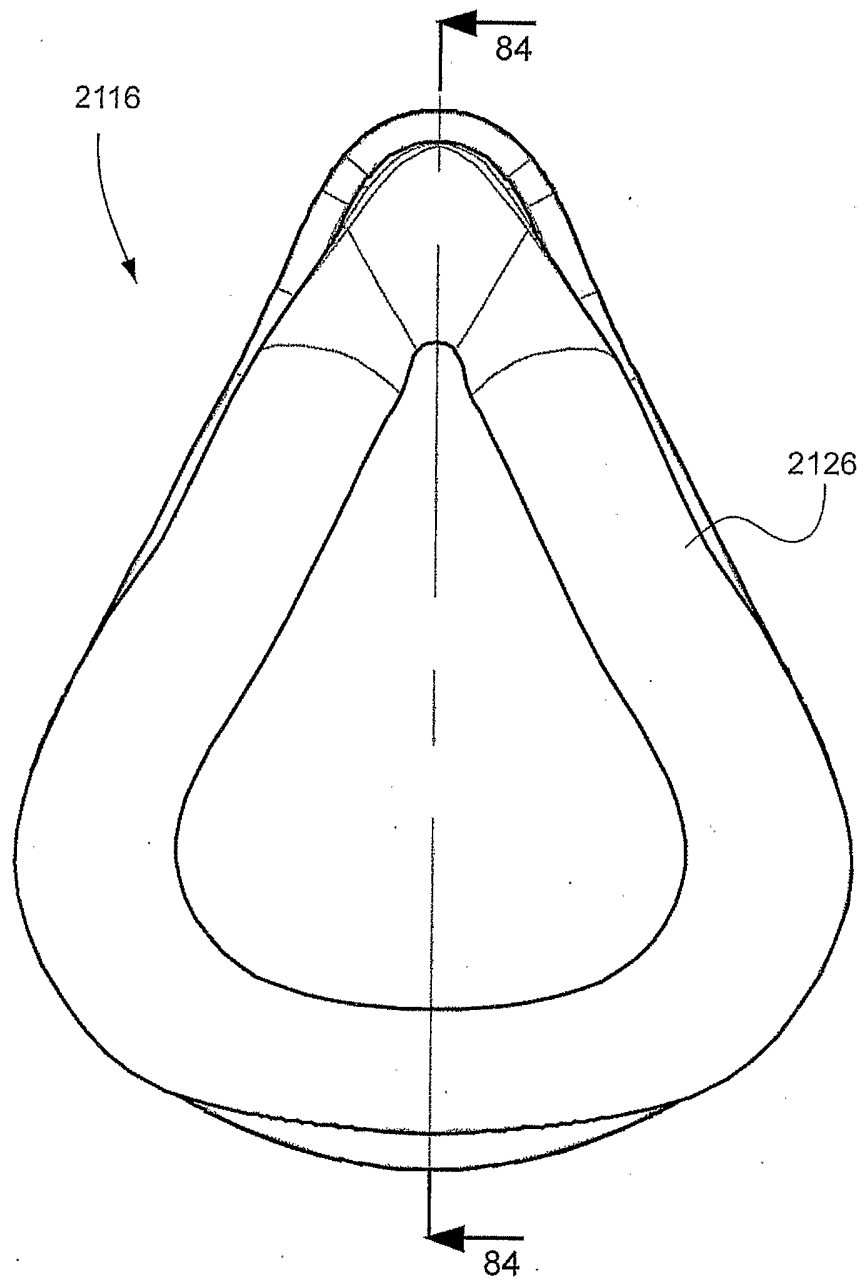


Fig. 82



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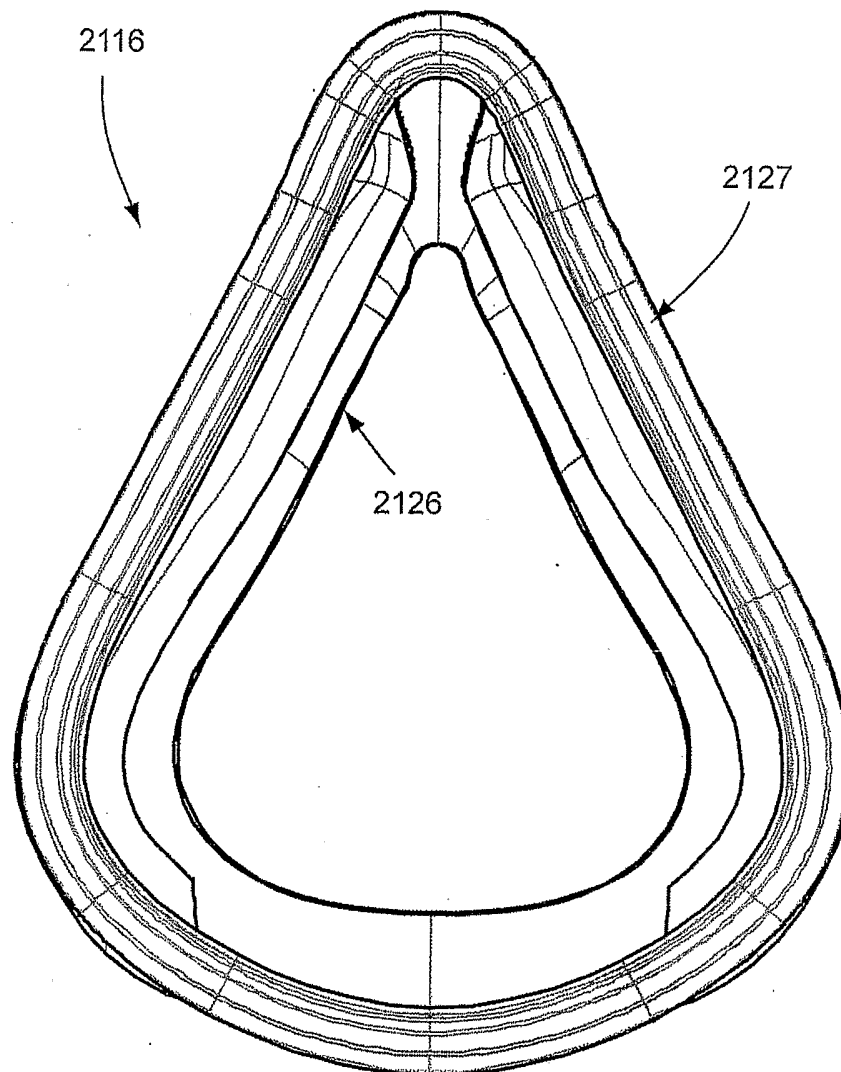


Fig. 83

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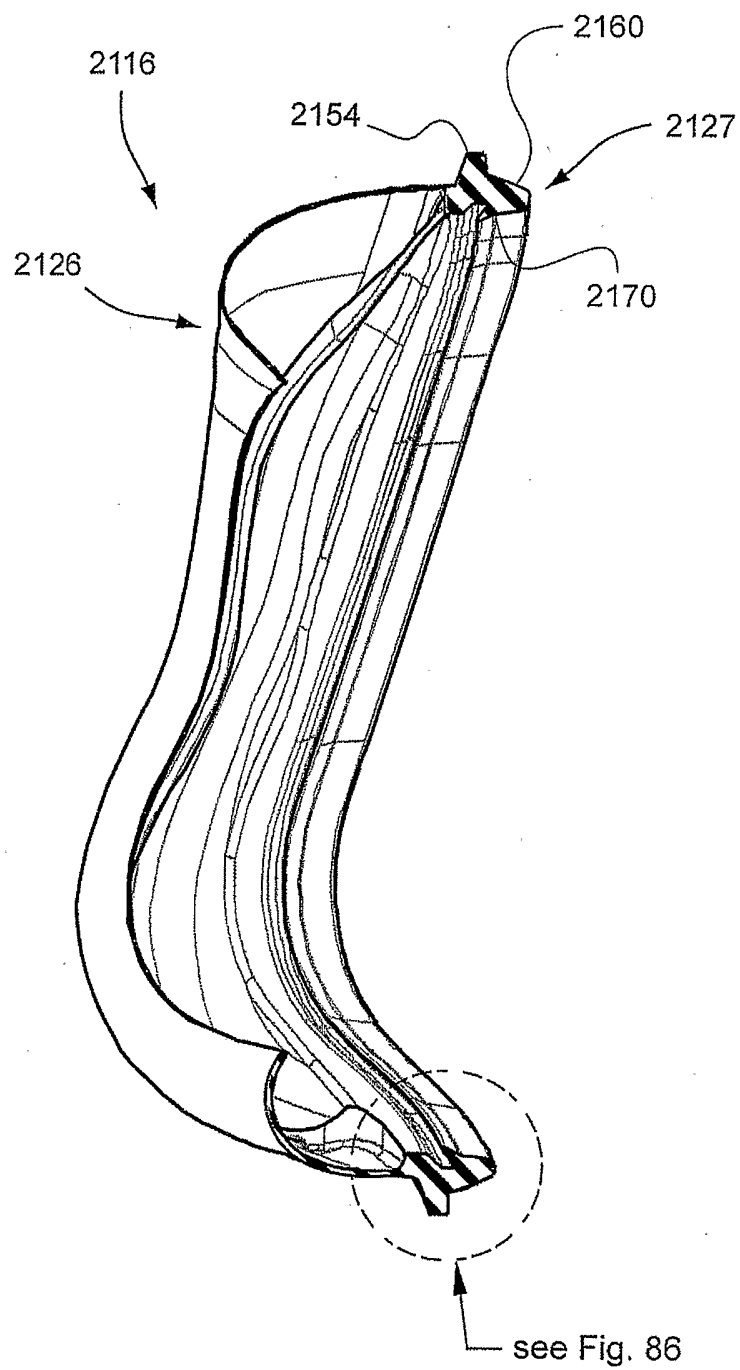


Fig. 84

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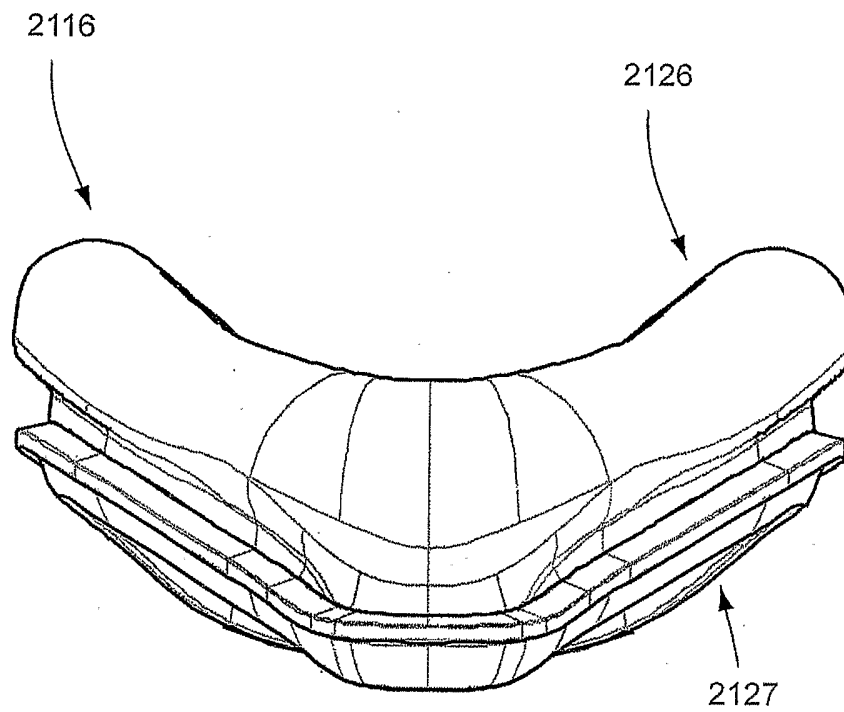


Fig. 85

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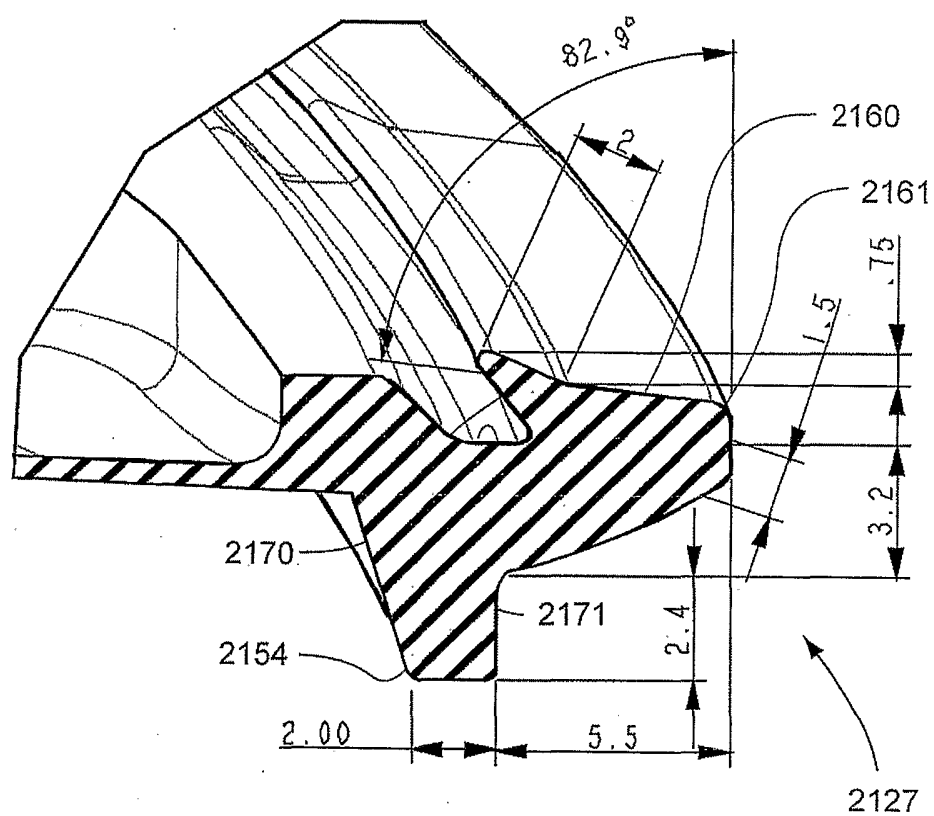


Fig. 86

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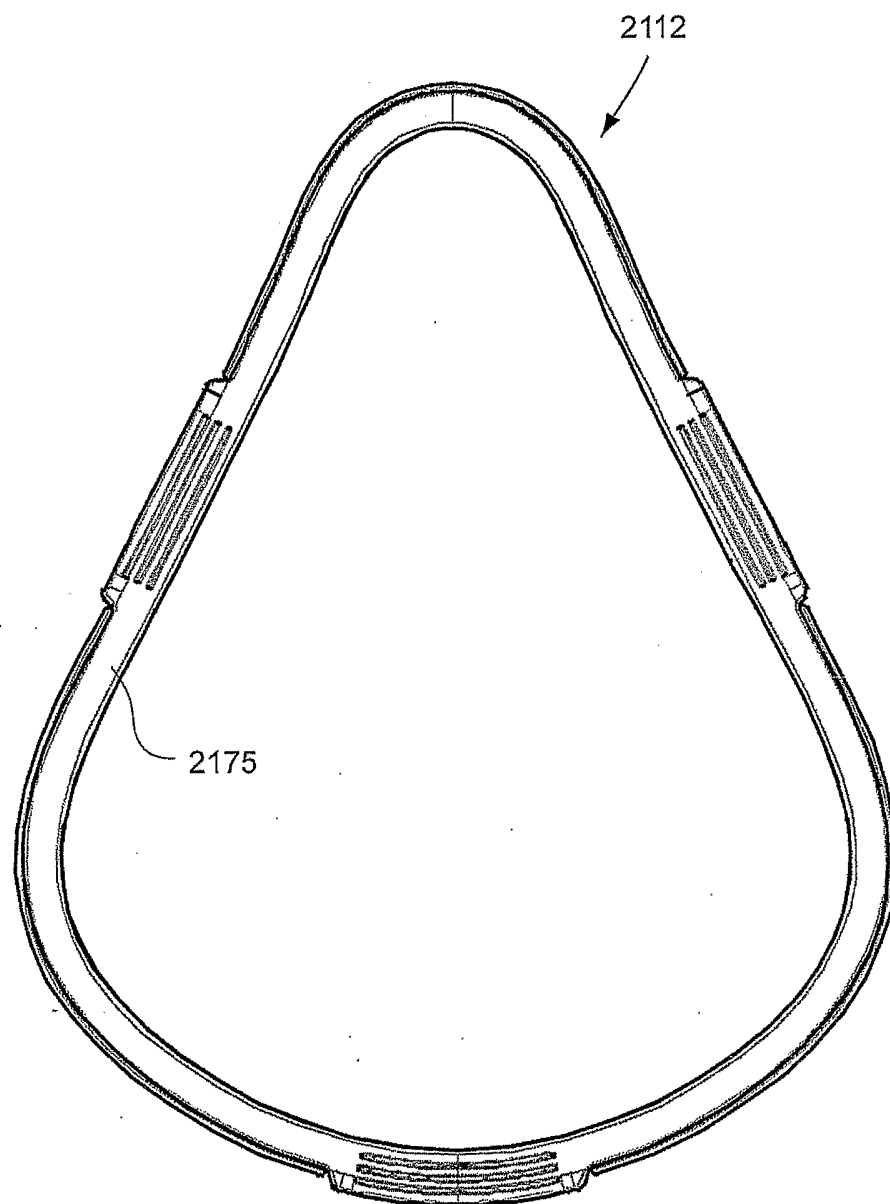


Fig. 87

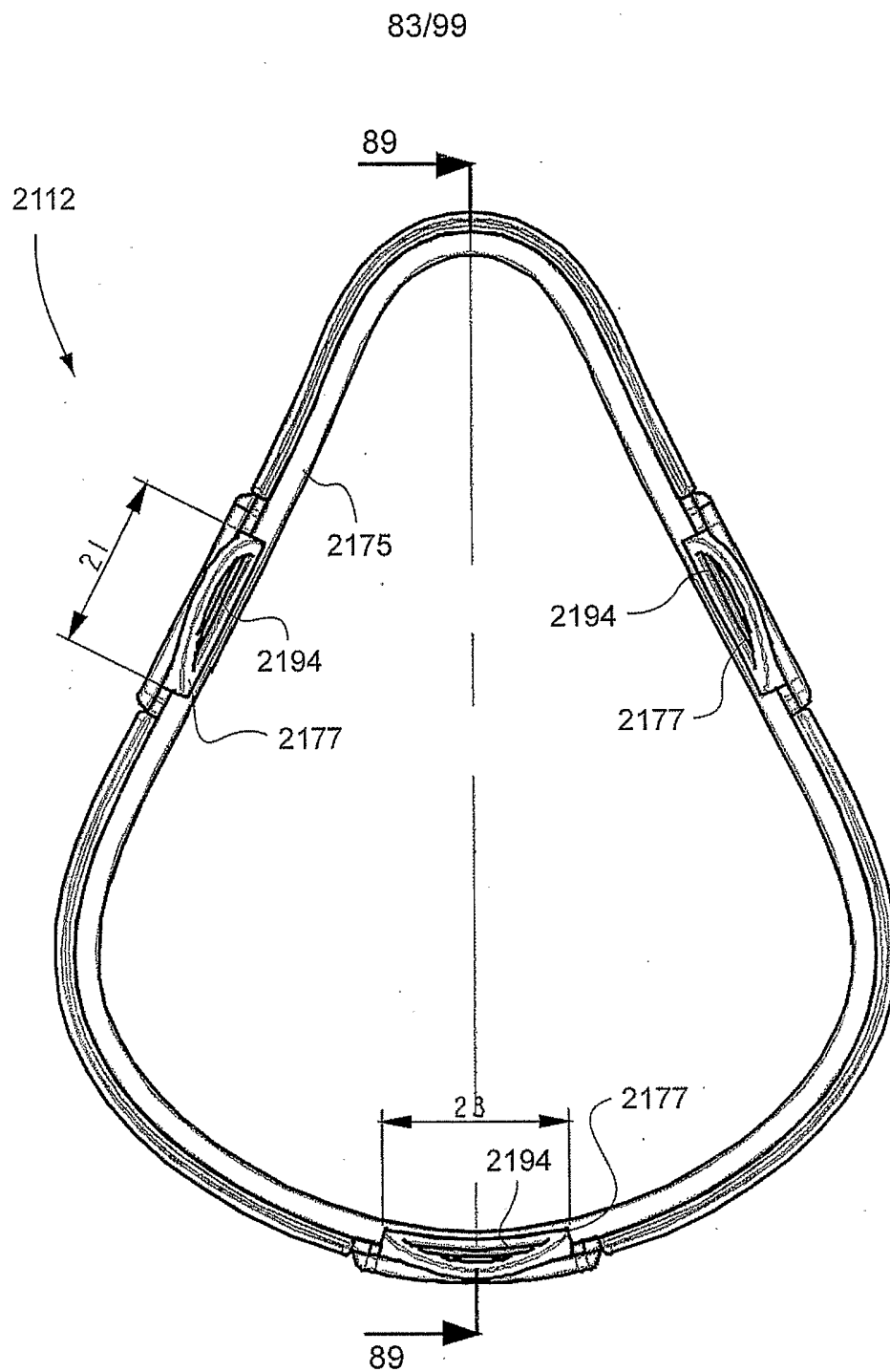


Fig. 88

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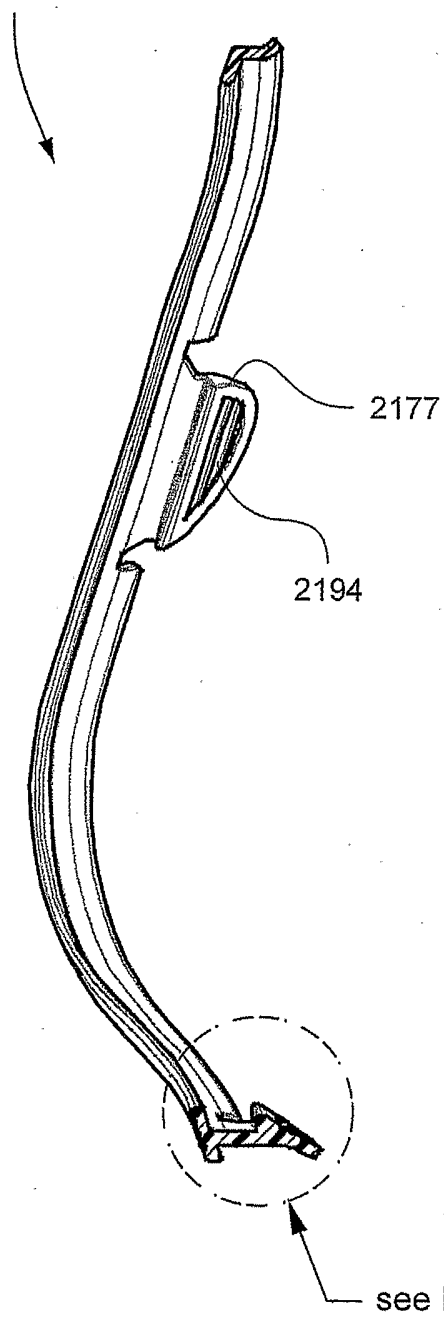


Fig. 89

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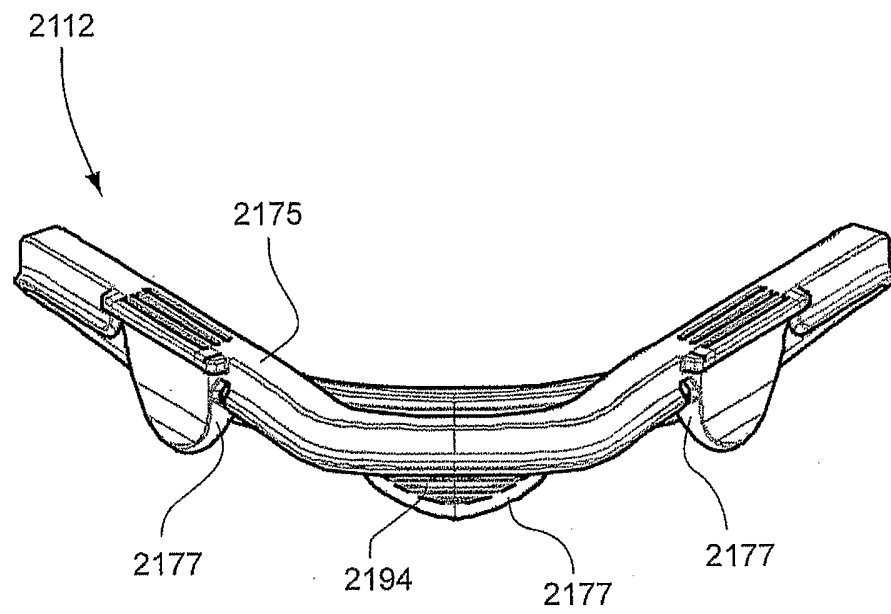


Fig. 90



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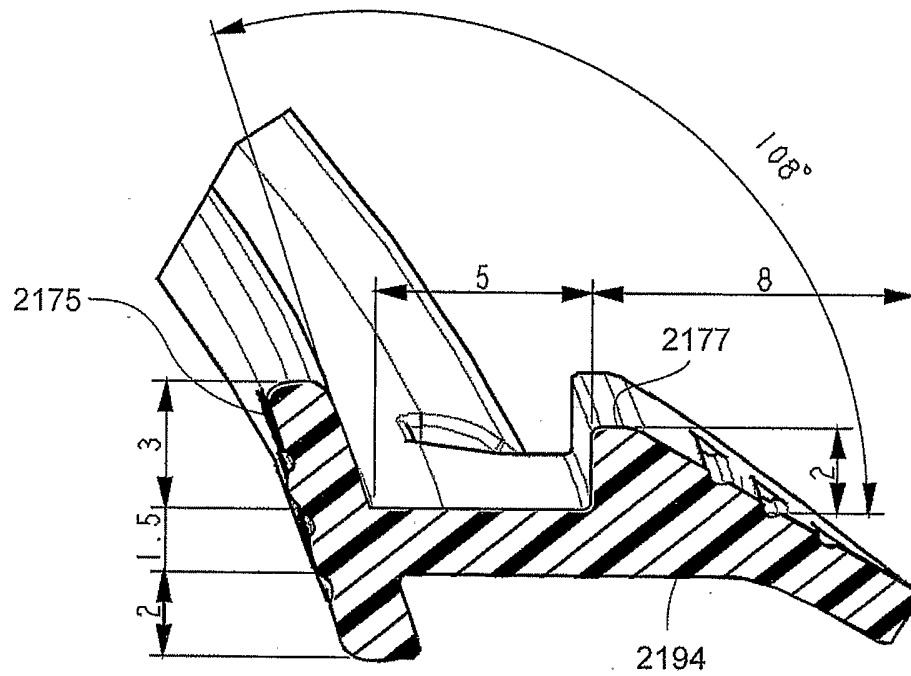


Fig. 91

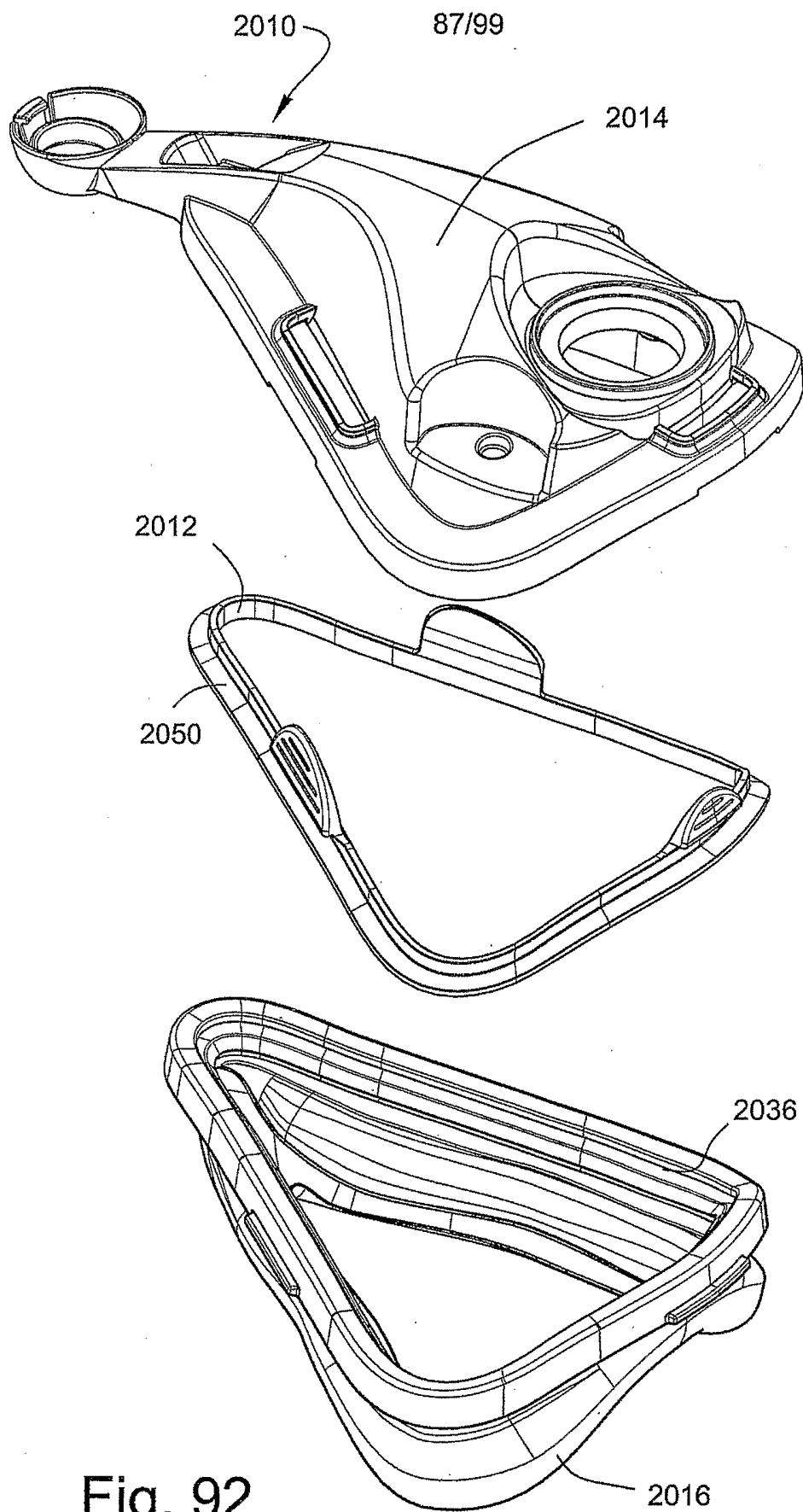


Fig. 92

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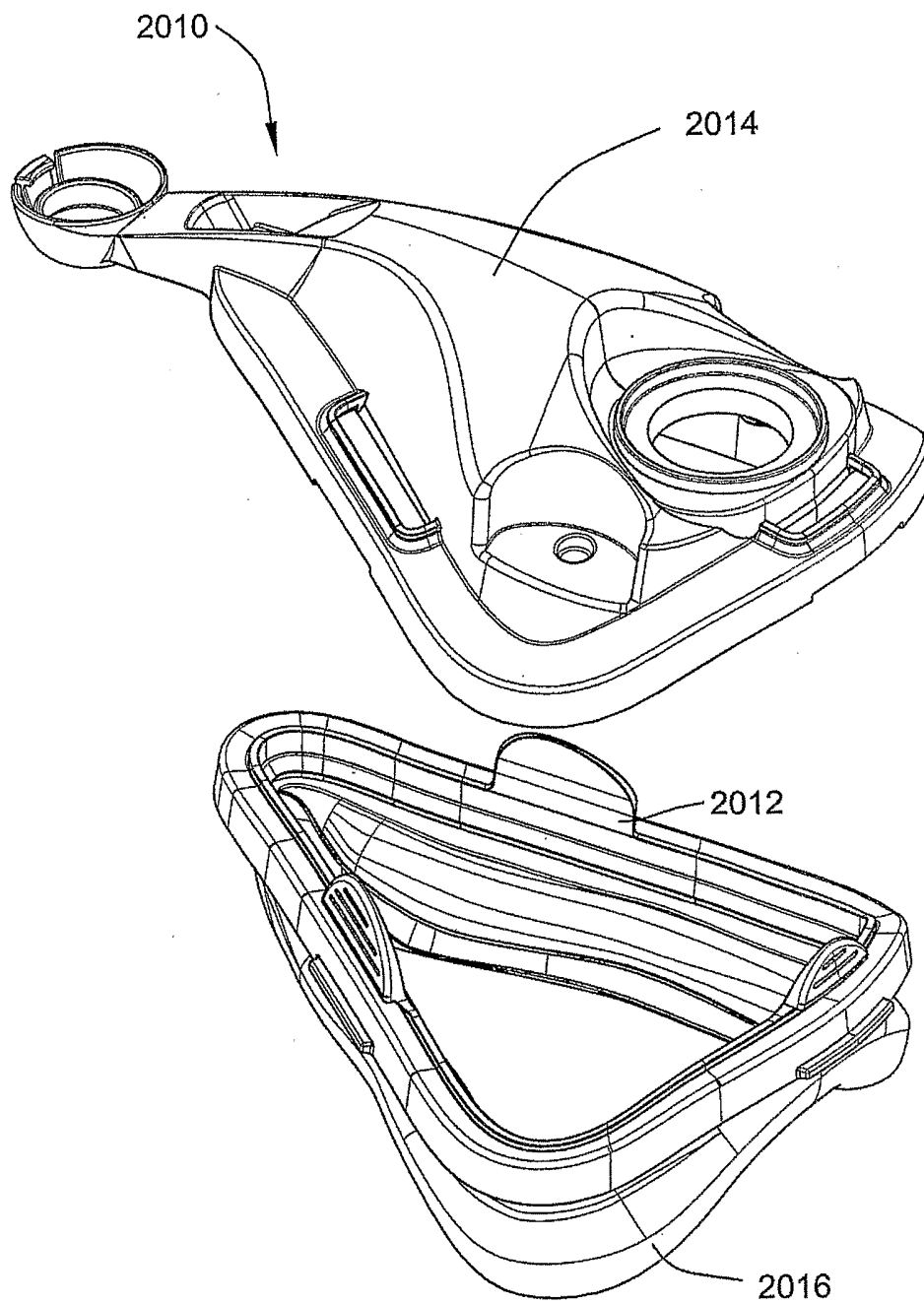


Fig. 93

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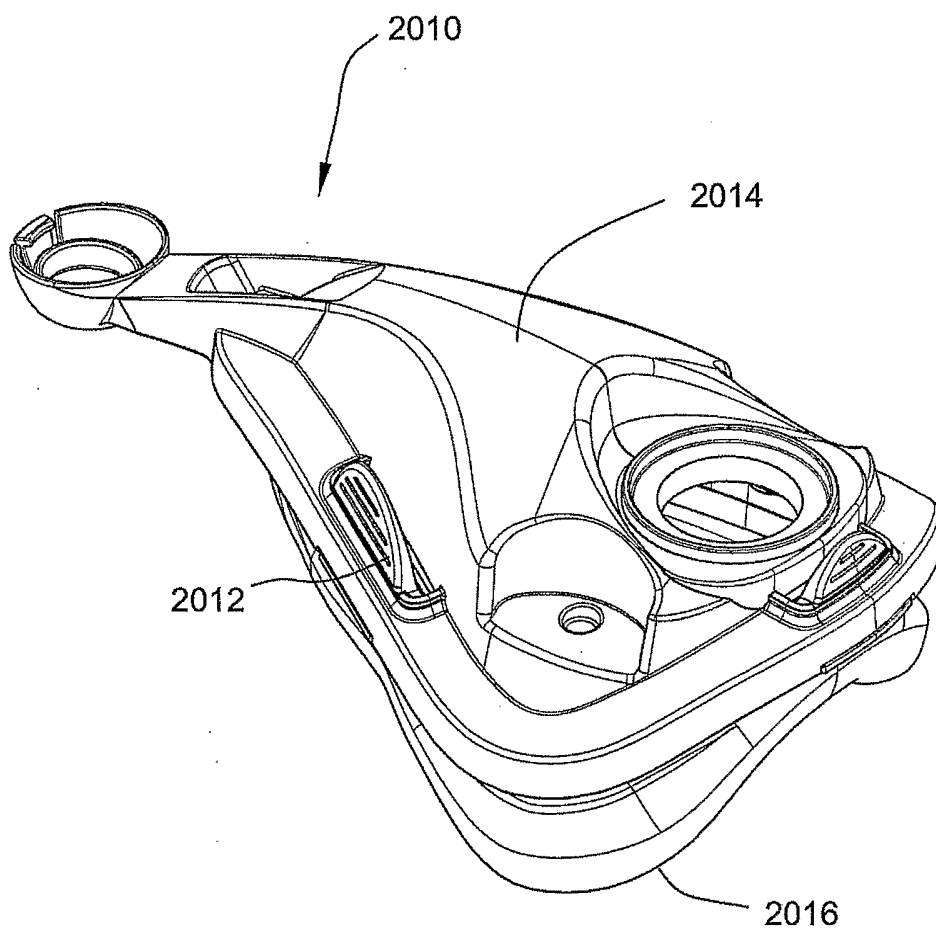


Fig. 94

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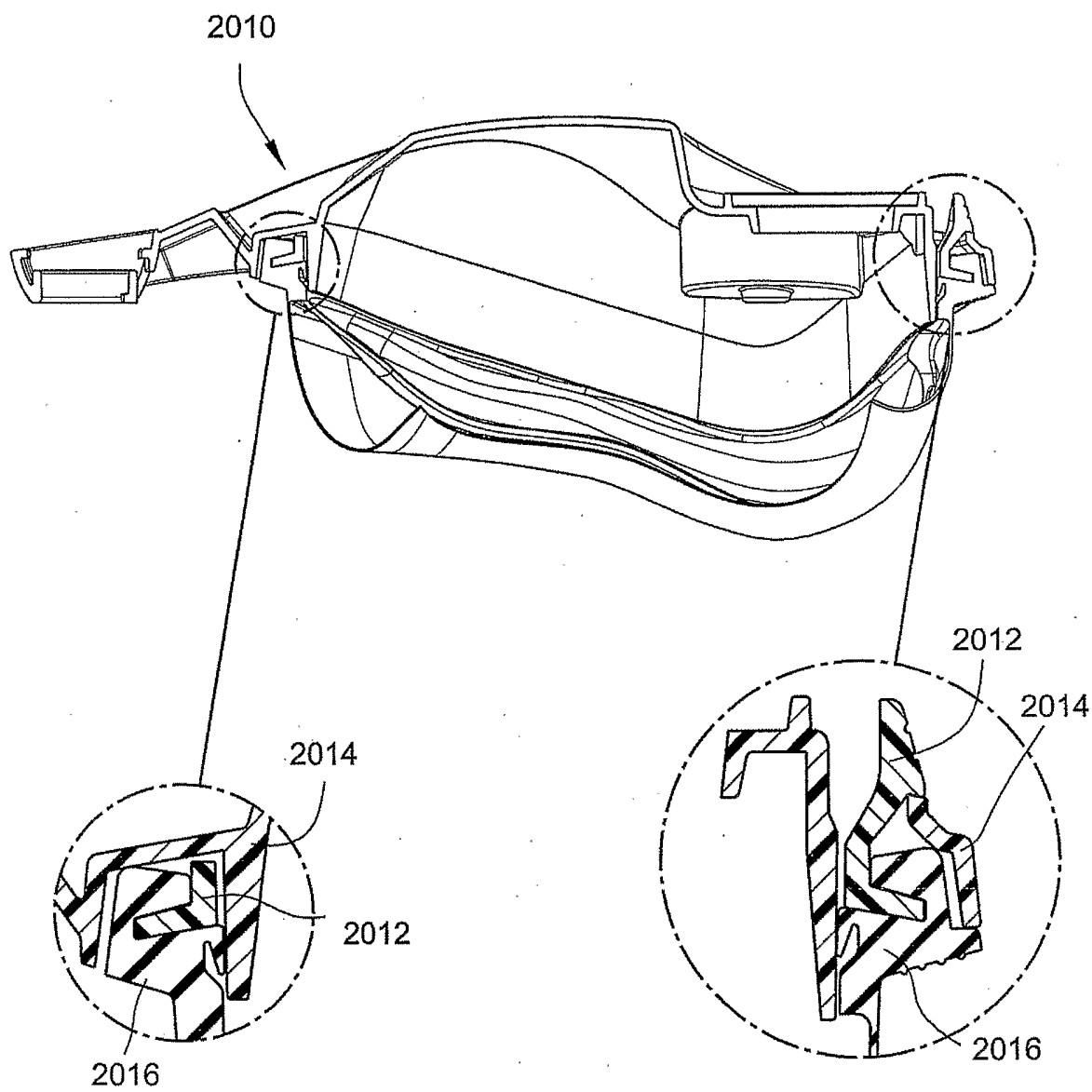


Fig. 95

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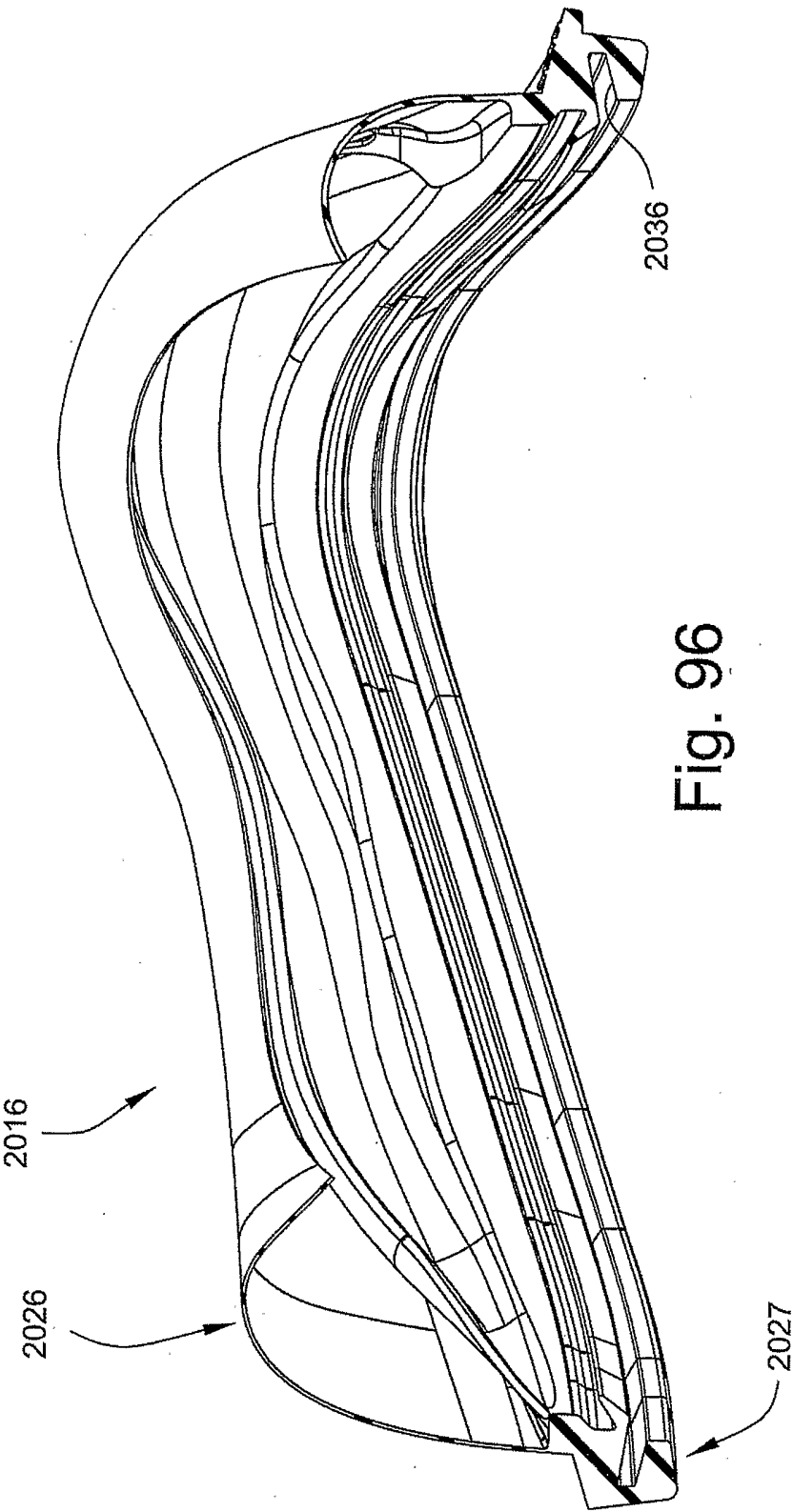


Fig. 96

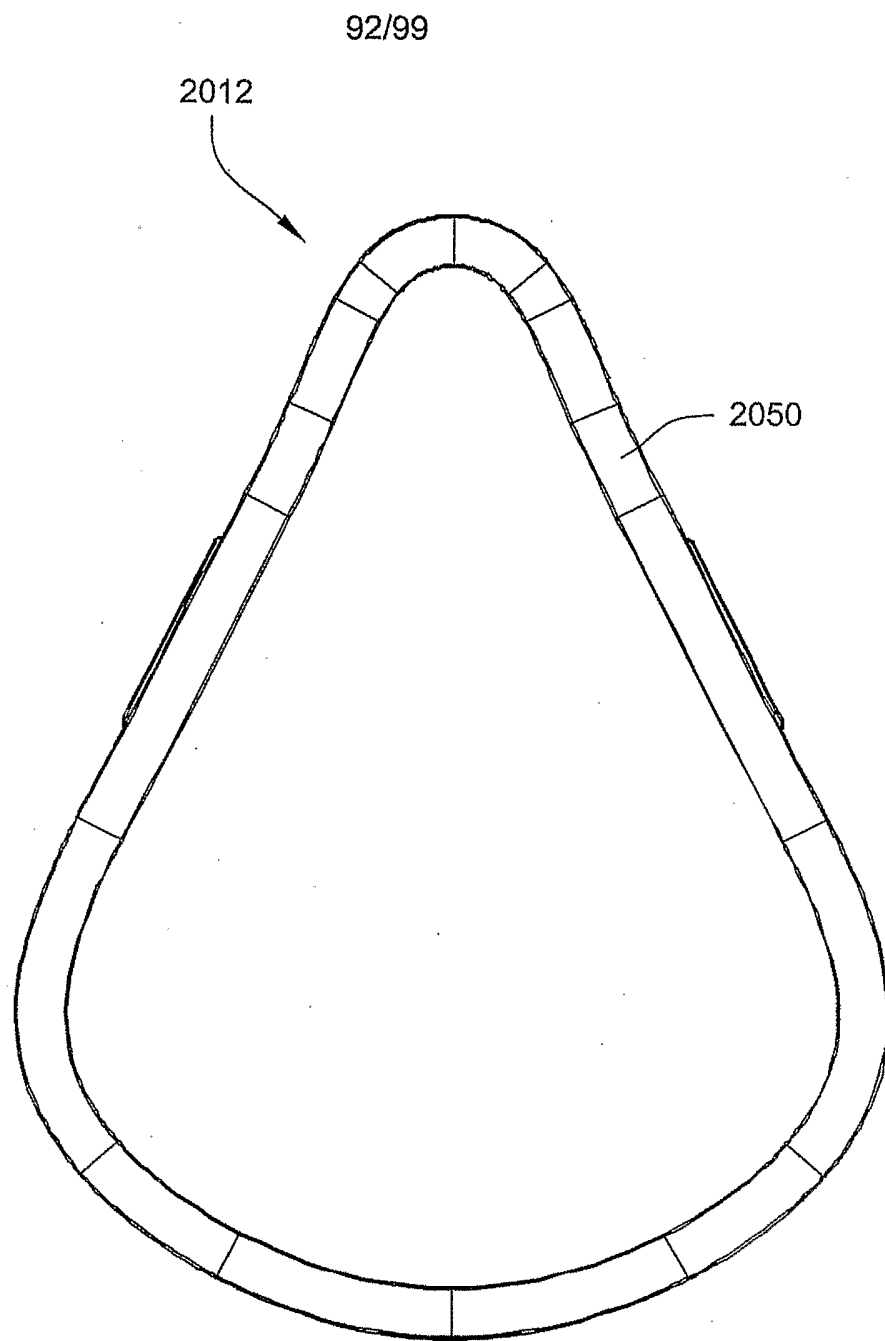


Fig. 97

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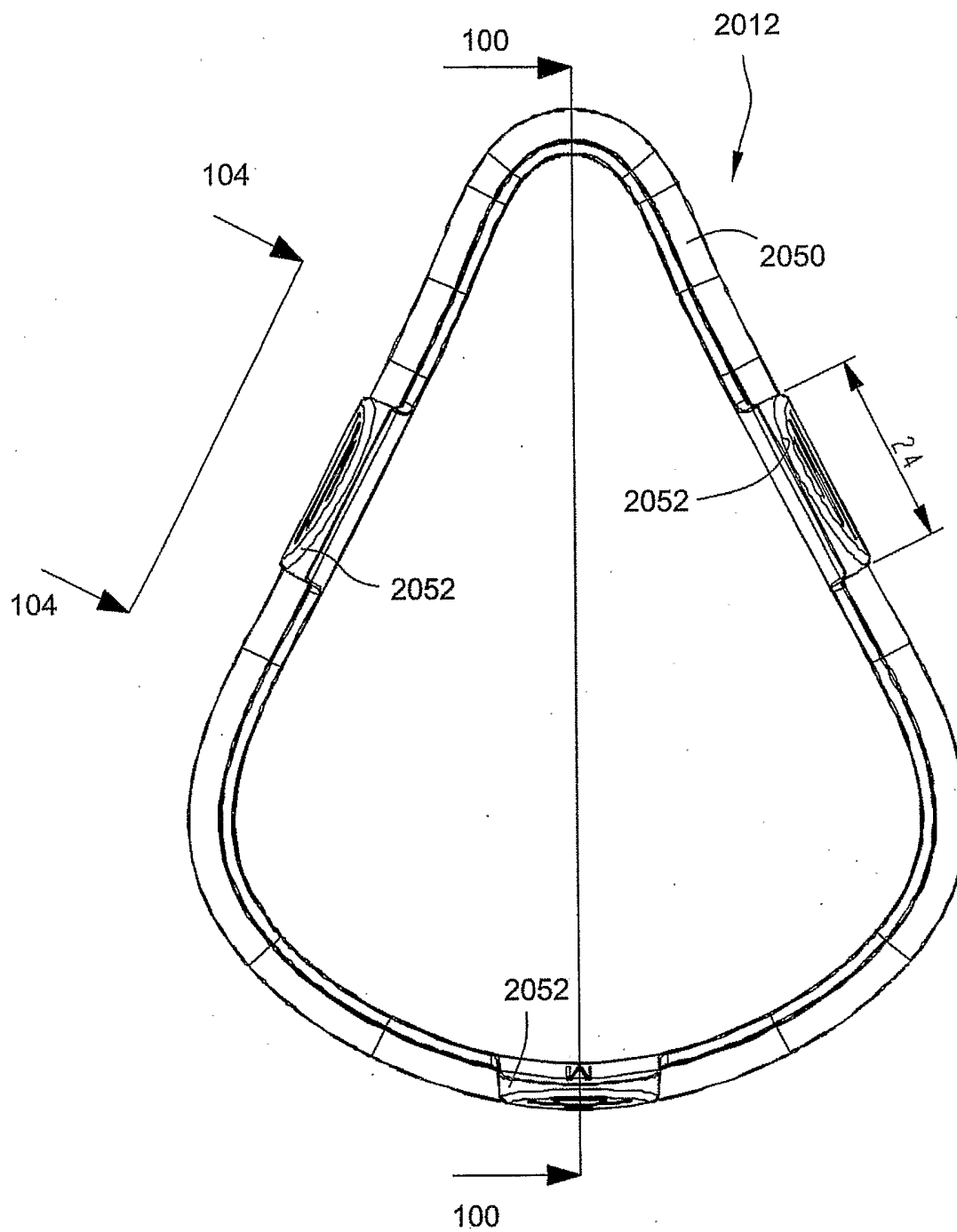


Fig. 98



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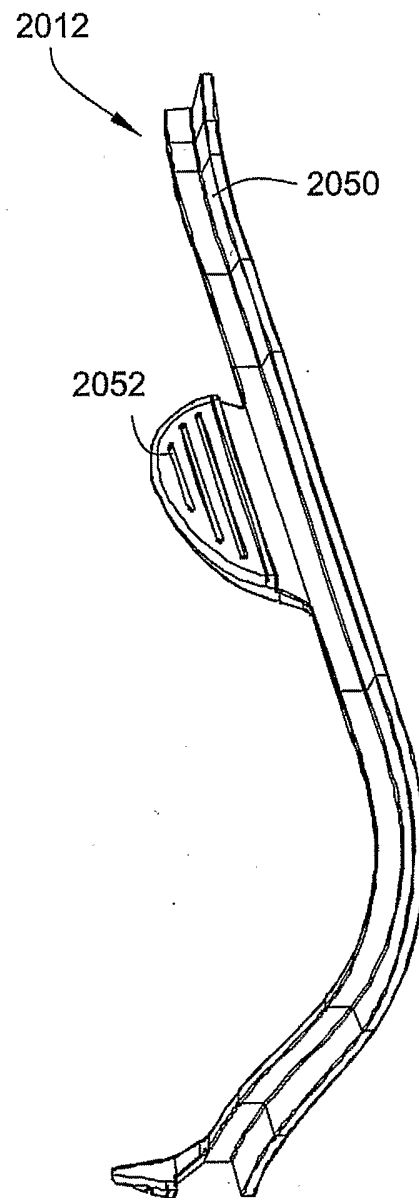


Fig. 99

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2012

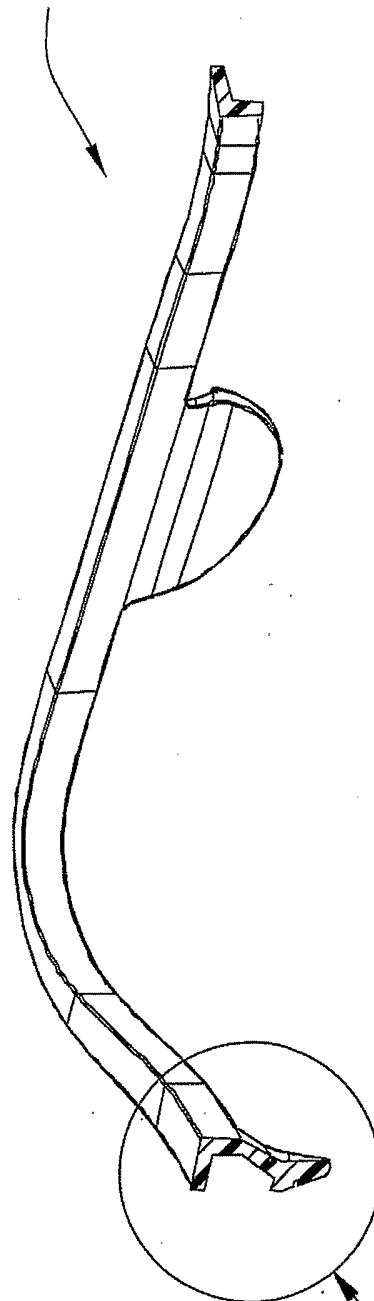


Fig. 103

Fig. 100

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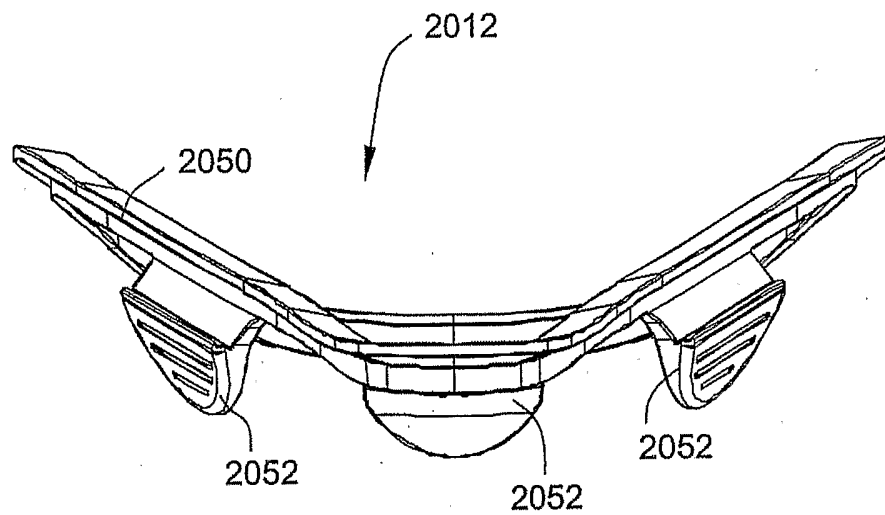


Fig. 101

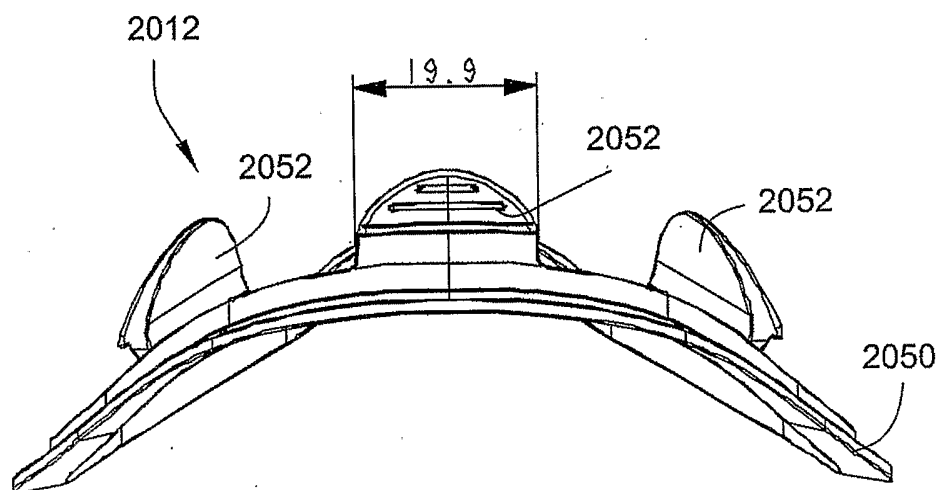


Fig. 102

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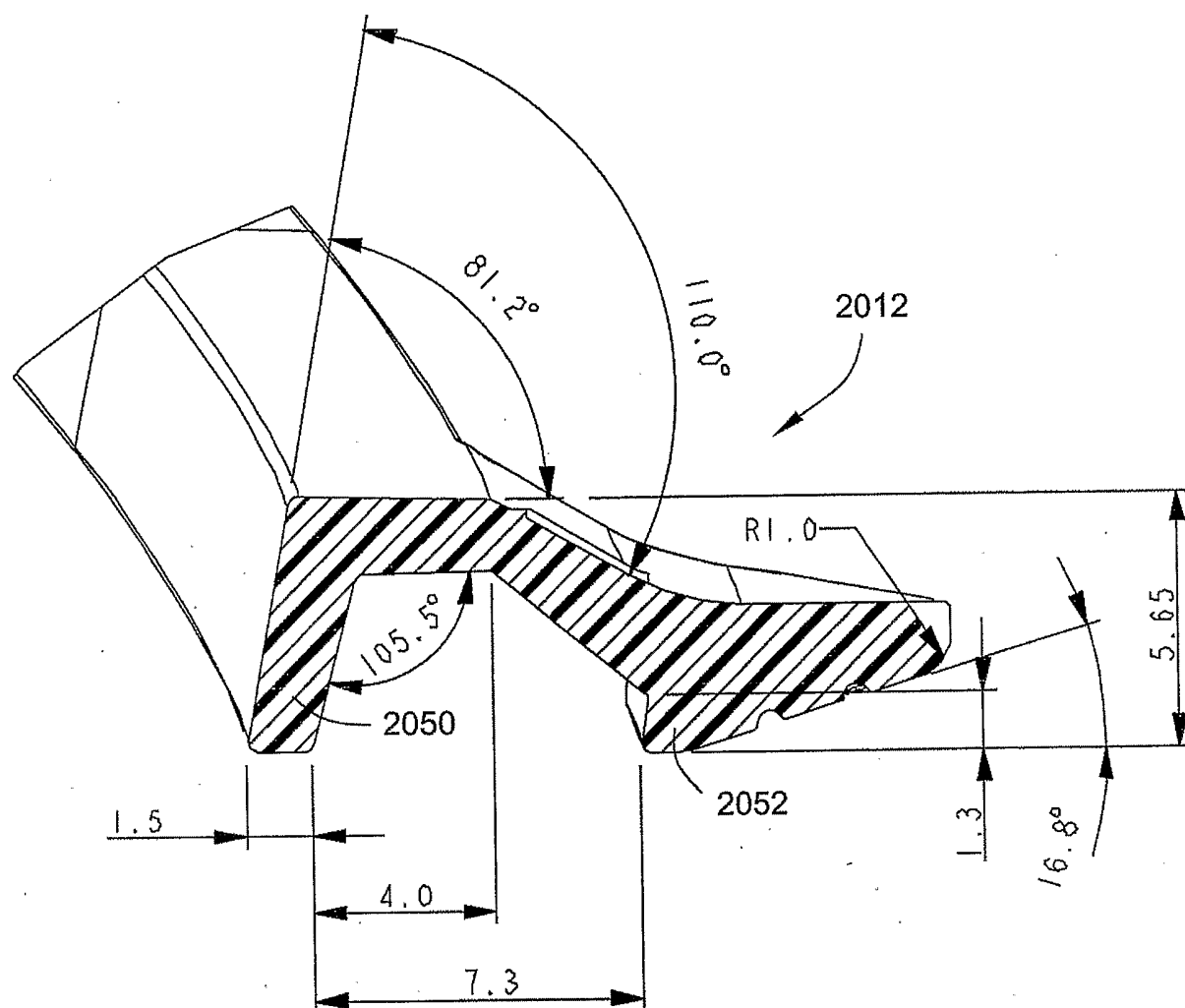


Fig. 103

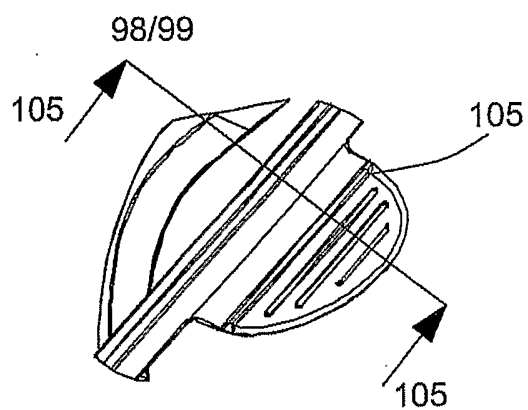


Fig. 104

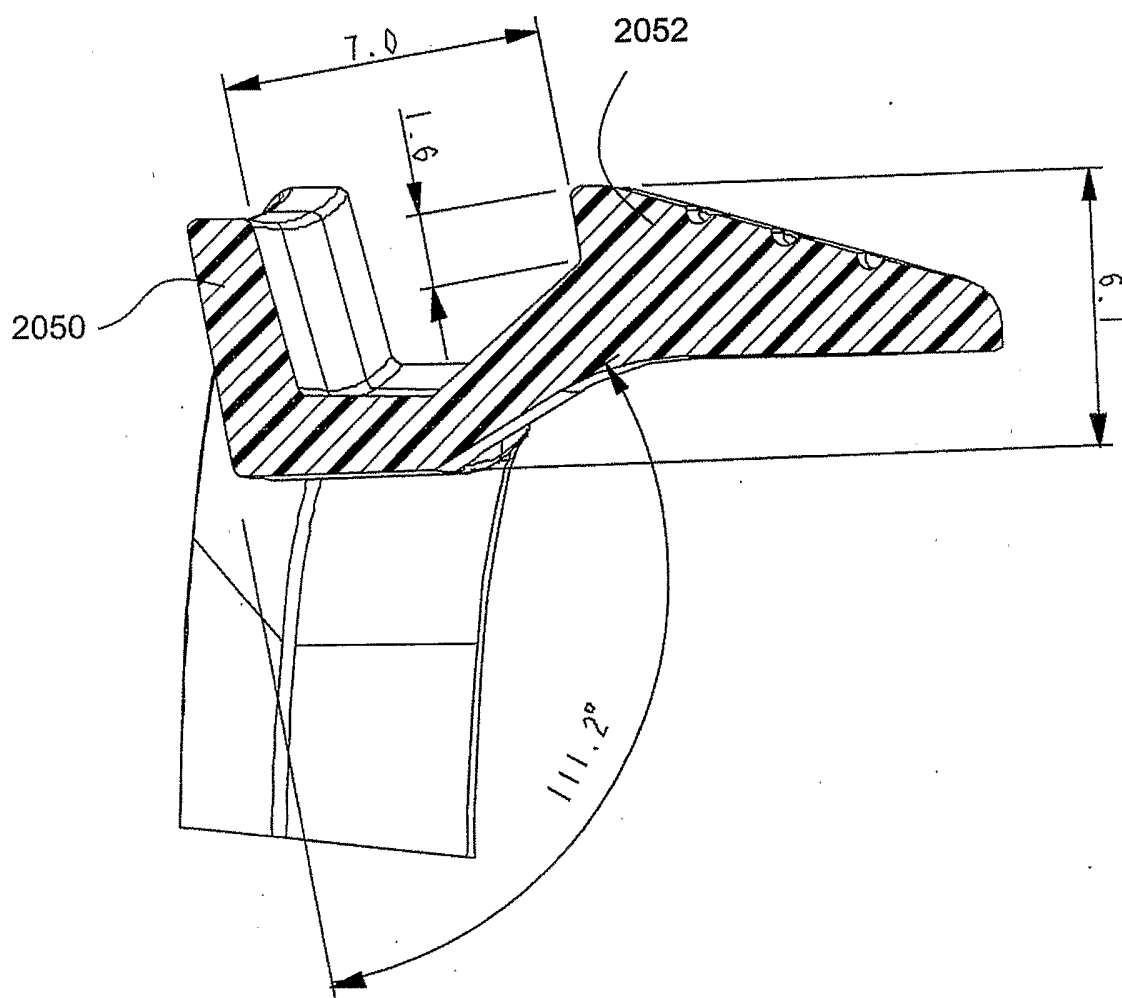


Fig. 105

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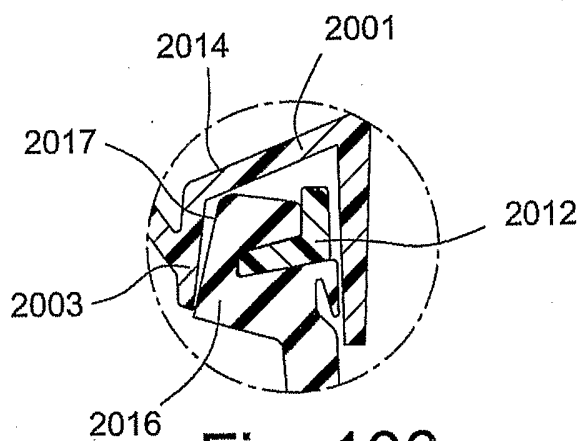


Fig. 106

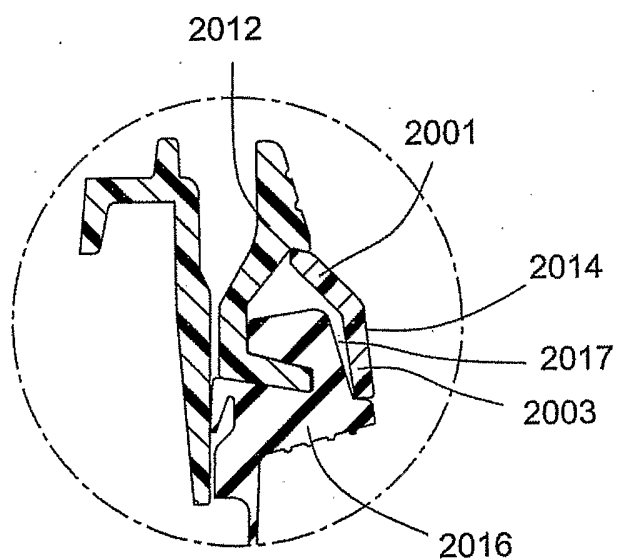


Fig. 107

# INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/AU2006/000035**

## A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

**A61M 16/06** (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
DWPI and IPC A61M 16/06, A62B 18/02 and Keywords (mask, cushion, frame, connect, assemble, clean, lip, flexible) and like terms

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/0075180 A1 (RAJE et al) 24 April 2003 See in particular paragraph [0256], Figs. F82, F90	1-7, 38
A	US 2002/0108613 A1 (GUNARATNAM et al) 15 August 2002 Whole document	
A	US 2001/0020474 A1 (HECKER et al) 13 September 2001 paragraph [0034], Fig. 1	

☐

Further documents are listed in the continuation of Box C

☒

See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search  
**20 February 2006**

Date of mailing of the international search report  
**- 6 MAR 2006**

Name and mailing address of the ISA/AU  
AUSTRALIAN PATENT OFFICE  
PO BOX 200, WODEN ACT 2606, AUSTRALIA  
E-mail address: pct@ipaustralia.gov.au  
Facsimile No. (02) 6285 3929

Authorized officer

**SUE THOMAS**

Telephone No : (02) 6283 2454

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/AU2006/000035

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-7, 38

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.



**Supplemental Box**

(To be used when the space in any of Boxes I to VIII is not sufficient)

**Continuation of Box No: III**

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-7 are directed to a full-face mask assembly comprising a flexible lip provided to an interior wall of a cushion and adapted to engage a frame to provide a seal in use. It is considered that the flexible lip comprises a first distinguishing feature.
- Claims 8 and 9 are directed to a full-face mask assembly comprising a retaining recess provided to a frame adapted to receive a retaining portion provided to a cushion having an angled configuration with respect to the frame. It is considered that the retaining recess comprises a second distinguishing feature.
- Claims 10-29 are directed to a full-face mask assembly comprising a clip to maintain a cushion to a frame. It is considered that the clip comprises a third distinguishing feature.
- Claims 30-34 are directed to a full-face mask assembly comprising a skeleton frame to maintain a cushion to a frame. It is considered that the skeleton frame comprises a fourth distinguishing feature.
- Claims 35-37 are directed to a full-face mask assembly comprising a cushion including hooks or tabs to interlock with locking features of a frame. It is considered that the hooks or tabs comprise a fifth distinguishing feature.

Since Claim 38 includes the first and second distinguishing feature it may be included with either the first or second group of inventions.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

Each of the abovementioned groups of claims has a different distinguishing feature and they do not share any feature which could satisfy the requirement for being a special technical feature. Because there is no common special technical feature it follows that there is no technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a priori*.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2006/000035

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
US	2003/0075180	AU	2003257270	AU	2003257271	AU	2003257273
		AU	2003257274	CN	1681551	CN	1681552
		CN	1681553	CN	1688358	EP	1334742
		EP	1539288	EP	1545673	EP	1545674
		EP	1545675	JP	2003175106	US	6812762
		US	6823869	US	6927613	US	2003080799
		US	2003090308	US	2004112384	US	2004112385
		US	2004112387	US	2004118406	US	2005081858
		US	2005151572	WO	03023962	WO	03023963
		WO	2004022144	WO	2004022145	WO	2004022146
		WO	2004022147				
US	2002/0108613	AU	12454/97	AU	14892/00	AU	16355/00
		AU	16811/02	AU	26505/00	AU	34293/97
		AU	42476/99	AU	49012/00	AU	52005/00
		AU	52007/00	AU	52691/00	AU	61522/01
		AU	2004205283	CA	2261790	CA	2298129
		CA	2470671	CA	2519452	EP	0956069
		EP	1027905	EP	1187647	EP	1187648
		EP	1187649	EP	1187650	EP	1479406
		EP	1525895	EP	1621225	EP	1625868
		JP	2000279520	JP	2004041779	JP	2005111287
		NZ	513052	NZ	526165	NZ	526168
		US	6112746	US	6357441	US	6374826
		US	6412487	US	6428231	US	6439230
		US	6491034	US	6513526	US	6532961
		US	6561710	US	6581602	US	6585441
		Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.					
CONTINUED NEXT SHEET							

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2006/000035

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report			Patent Family Member			
	US	6634358	US	6691707	US	6701927
	US	6796308	US	6860269	US	6871649
	US	2002005198	US	2002005200	US	2002023649
	US	2002023650	US	2002029781	US	2002074001
	US	2002083948	US	2002096176	US	2002104540
	US	2002153012	US	2002157672	US	2002174867
	US	2002174868	US	2003034034	US	2004025881
	US	2004086319	US	2004094159	US	2004099272
	US	2004134497	US	2005022818	WO	0078381
	WO	0078382	WO	0078383	WO	0078384
	WO	0134406	WO	0184979	WO	9804310
US	2001/0020474	DE	10002571	EP	1118346	
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.						
END OF ANNEX						