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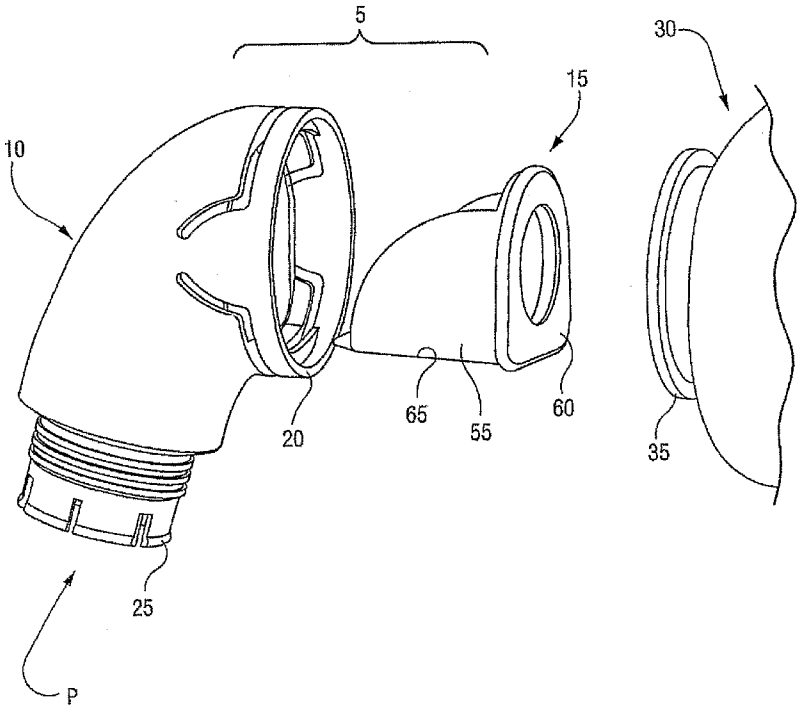

(57) Abstract: An elbow assembly (5) for a mask assembly includes an anti-asphyxia valve (AAV) assembly (15) that may take the form of a box-like frame work, a drop-in arrangement, or a slot-in arrangement. In each case, the AAV assembly (15) may include a flap element (45) which is movable so as to either direct ambient gas/air to the elbow assembly (5) and thus the patient using the mask assembly, or to allow the passage of pressurized gas to the patient.

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ANTI-ASPHYXIA VALVE ASSEMBLY FOR RESPIRATORY MASK

CROSS-REFERENCE TO APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/726,699, filed October 17, 2005, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to an elbow for use with a mask assembly used for treatment, e.g., of Sleep Disordered Breathing (SDB) with Continuous Positive Airway Pressure (CPAP) or Non-Invasive Positive Pressure Ventilation (NPPV).

BACKGROUND OF THE INVENTION

[0003] A mask assembly typically includes a relatively rigid shell, e.g., a frame, and a patient interface, e.g., a pair of nozzles (which may be in the form of nasal pillows, nasal prongs, cannulae, or nasal puffs) or a cushion (nasal or full-face), that is supported by the rigid shell and structured to deliver pressurized gas to the patient or user in a comfortable, sealed manner. The mask assembly is usually held in place using a headgear assembly.

[0004] In some applications, there may be a clinical requirement to provide the mask assembly with one or more safety devices, such as means for CO_2 washout, vents, anti-asphyxia valves and the like. In some cases, these additional components are assembled between the gas delivery conduit and the mask assembly. Problems with prior art assemblies may include:

[0005] (a) inadvertent assembly without one or more of the safety devices;

[0006] (b) incorrect assembly/alignment; and/or

[0007] (c) incorrect re-assembly following inadvertent dis-assembly during the course of treatment.

[0008] Flow generators typically deliver pressurized breathable gas (air) to a patient wearing the mask assembly. In CPAP treatment, gas is delivered to the patient's airways at about 2-30 cm H_20 above atmospheric pressure. The flow generator is generally connected to flexible tubing (air delivery tube) that is secured to the mask assembly worn by the patient. If the flow generator's operation is interrupted as a result of power outage or other mechanical/electrical failure, there may be a significant build up of carbon dioxide in the mask as the patient's exhaled air is not washed out of outlet vents that are usually provided to the mask assembly. This may present a health risk to the patient.

[0009] Several patents have addressed this risk, e.g., by use of a safely valve for gas or air delivery mask assemblies. See, e.g., U.S. Patent nos. 3,796,216 to Schwarz, and 5,438,981 to Starr et al., as well as PCT international application no. PCT/AU97/00849.

BRIEF SUMMARY OF THE INVENTION

[0010] According to one aspect of the invention, there is provided an elbow assembly comprising an elbow; an anti-asphyxia valve (AAV) assembly provided to the elbow; and a clip member or portion to secure the AAV assembly to the elbow

[0011] According to yet another aspect of the invention, there is provided an elbow assembly for a mask, comprising: an elbow having a first portion structured to engage with a mask frame and a second portion structured to receive pressurized gas; a first gas path defined between the first and the second portions; a port in communication with atmosphere and in selective communication with the first portion of the elbow; a second gas path defined between the first portion and the port; and an anti-asphyxia valve (AAV) assembly, said AAV assembly including a flap portion and a frame assembly integrally supporting the flap portion, the flap portion being movable to selectively open and close the port, wherein said flap portion assumes a closed position when pressurized gas less than or equal to a predetermined threshold is delivered to the second portion of the elbow, in which case the port can communicate with the first portion via the second gas path, and said flap assumes an open position when pressurized gas above the predetermined threshold is delivered to

the second portion, in which case the flap portion seals the port and the first portion is in communication with the second portion via the first gas path.

[0012] According to still another aspect of the present invention, there is provided a mask assembly comprising a frame; an elbow provided to the frame; and an anti-asphyxia valve (AAV) assembly secured within the elbow upon assembly of the elbow to the frame.

[0013] According to yet another embodiment of the present invention, there is provided an elbow assembly comprising an elbow, the elbow having a first portion adapted to be secured to a mask and a second portion adapted to receive pressurized gas, the first and the second portions having connection structure allowing selective connection and disconnection between the first and second portions, the connection structure including a pair of resilient arms provided on one of the first and second portions and a flange provided on the other of the first and second portions, each of the arms including a claw to lock with the flange; and an anti-asphyxia valve (AAV) assembly provided within the elbow and sandwiched between the first and second portions.

[0014] Another aspect of the present invention relates to a mask assembly including a frame, an elbow provided to the frame, and an elbow to frame assembly mechanism to releasably assemble the elbow to the frame. The elbow to frame assembly mechanism includes an elbow to frame adaptor that attaches to the frame and provides a flanged collar member onto which the elbow can be releasably assembled.

[0015] Another aspect of the present invention relates to a mask assembly including a frame, an elbow having one end provided to the frame and an opposite end provided to a swivel, and an elbow-to-swivel adaptor to connect the elbow to the swivel. The elbow-to-swivel adaptor includes a snap-fit tab to connect the elbow-to-swivel adaptor to the elbow with a snap-fit.

[0016] Another aspect of the present invention relates to a mask assembly including a frame, an elbow provided to the frame, and an integrated elbow seal and port cap assembly provided between the elbow and the frame. The elbow seal and port cap assembly includes an elbow seal to provide a seal between the elbow and the frame and a port cap to releasably connect to a port provided to the frame.

[0017] 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

[0018] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

[0019] FIG. 1 is an exploded, perspective view of an elbow assembly according to one embodiment of the present invention;

[0020] FIG. 2 is a cross-sectional view of the elbow assembly of FIG. 1 in the assembled condition;

[0021] FIG. 3 is a rear view of the elbow assembly of FIG 1;

[0022] FIG. 4 is a front perspective view of the AAV assembly of FIG 1;

[0023] FIG. 5 is a reverse perspective view thereof;

[0024] FIG. 6 is a side elevation view thereof;

[0025] FIG. 7 is a front view thereof;

[0026] FIG. 8 is a rear view thereof;

[0027] FIG. 9 is a cross-sectional view thereof;

[0028] FIG. 10 is a perspective view of an elbow assembly according to another embodiment of the present invention;

[0029] FIG. 11 is a reverse perspective view thereof;

[0030] FIG. 12 is a cross-sectional view thereof;

[0031] FIGS. 13 and 14 are exploded, perspective views thereof;

[0032] FIG. 15 is a perspective view of a mask assembly according to yet another embodiment of the present invention;

[0033] FIG. 16 is a side view thereof;

[0034] FIG. 17 is a cross-sectional view thereof;

[0035] FIG. 18 is a cross-sectional view of an elbow assembly according to still another embodiment of the present invention;

[0036] FIG. 19 is a perspective view of the elbow without the AAV assembly;

[0037] FIG. 20 is a perspective view of the AAV assembly shown in Fig. 18;

[0038] FIG. 21 is another perspective view of the AAV assembly shown in Fig. 18;

[0039] FIG. 22 is a bottom view thereof;

[0040] FIG. 23 is a perspective view of an elbow assembly according to another embodiment of the present invention;

[0041] FIG. 24 is a reverse perspective view thereof;

[0042] FIG. 25 is a cross-sectional view thereof;

[0043] FIG. 26 is a cross-sectional view of an elbow according to another embodiment of the present invention;

[0044] FIG. 27 is a perspective view thereof;

[0045] FIG. 28 is a cross-sectional view of an AAV assembly for use with the elbow shown in FIGS. 27 and 28;

[0046] FIG. 29 is a perspective view thereof;

[0047] FIG. 30 is a perspective view of the elbow assembly;

[0048] FIG. 31 is a reverse perspective view thereof;

[0049] FIG. 32 is a side elevation view thereof;

[0050] FIG. 33 is a cross-sectional view thereof;

[0051] FIG. 34 is an exploded perspective view of an elbow assembly according to another embodiment of the present invention;

[0052] FIG. 35 is an assembled view thereof, from a different perspective;

[0053] FIG. 36 is a cross-sectional view thereof;

[0054] FIG. 37 is a perspective view of the elbow without the AAV assembly;

[0055] FIG. 38 is a perspective view of the clip member shown in FIGS. 34-36;

[0056] FIG. 39 is a plan view of the AAV assembly in isolation;

[0057] FIG. 40 is a perspective view of a clip/AAV assembly;

[0058] FIG. 41 is an exploded perspective view thereof;

[0059] FIG. 42 is a perspective view of an over-molded clip/AAV assembly according to an embodiment of the present invention;

[0060] FIG. 43 is a cross-sectional view of the AAV assembly shown in Fig. 41;

[0061] FIGS. 44-47 illustrate several different embodiments of AAV assemblies having different hinge arrangements;

[0062] FIG. 48 is a perspective view of an elbow assembly according to another embodiment of the present invention;

[0063] FIG. 49 is cross-sectional view thereof;

[0064] FIG. 50 is a perspective view of an elbow assembly according to another embodiment of the present invention;

[0065] FIG. 51 is a side view thereof;

[0066] FIG. 52 is a reverse perspective view thereof;

[0067] FIG. 53 is a cross-sectional view of an elbow assembly according to another embodiment of the present invention;

[0068] FIG. 54 is a cross-sectional view thereof from a different perspective;

[0069] FIG. 55 is rear perspective view thereof;

[0070] FIG. 56 is an exploded perspective view of an elbow assembly according to yet another embodiment of the present invention;

[0071] FIG. 57 is a perspective view thereof in an assembled condition;

[0072] FIG. 58 is cross-sectional view thereof;

[0073] FIG. 59 is perspective view of a portion of an elbow assembly on a conduit having an AAV assembly according to an embodiment of the present invention;

[0074] FIG. 60 is a top view thereof;

[0075] FIG. 61 is cross-sectional view thereof;

[0076] FIGS. 62-67 illustrate alternative embodiments of an AAV assembly and clip member;

[0077] FIGS. 68-89 show various views of an elbow assembly according to another embodiment of the present invention;

[0078] FIGS. 90-111 show various views of an elbow assembly according to another embodiment of the present invention;

[0079] FIGS. 112-133 show various views of an elbow assembly according to another embodiment of the present invention;

[0080] FIGS. 134-154 show various views of an elbow assembly according to another embodiment of the present invention;

[0081] FIGS. 155-156 are exploded views illustrating the elbow of Figs. 134-154 being assembled between a mask frame and a swivel joint;

[0082] FIGS. 157-161 show various views of the elbow of Figs. 134-154 connected between the mask frame and the swivel joint of Figs. 155-156;

[0083] FIG. 162 is an exploded perspective view of an elbow assembly according to an embodiment of the present invention;

[0084] FIG. 163 is an assembled view thereof;

[0085] FIG. 164 is as side elevation view thereof;

[0086] FIG. 165 is an exploded view of a mask assembly according to an embodiment of the present invention;

[0087] FIG. 166 is cross-sectional depiction thereof;

[0088] FIG. 167 is an exploded view of the elbow assembly thereof;

[0089] FIG. 168 is a cross-sectional view thereof;

[0090] FIG. 169 is a cross-sectional view of an elbow assembly according to an embodiment of the present invention;

[0091] FIG. 170 is a top view of an AAV assembly for use in the assembly of FIG. 169;

[0092] FIG. 171 is a perspective view thereof with the AAV assembly with the flap portion in an upright position;

[0093] FIGS. 172-173 illustrate an elbow assembly with a drop-in AAV assembly according to another embodiment of the present invention;

[0094] FIGS. 174-185 illustrate an elbow to frame assembly mechanism according to an embodiment of the present invention;

[0095] FIGS. 186-203 illustrate an elbow to frame assembly mechanism according to another embodiment of the present invention;

[0096] FIGS. 204-221 illustrate an elbow to frame assembly mechanism according to another embodiment of the present invention;

[0097] FIGS. 222-233 illustrate an elbow to frame assembly mechanism according to another embodiment of the present invention;

[0098] FIGS. 234-251 illustrate an elbow to frame assembly mechanism according to another embodiment of the present invention;

[0099] FIGS. 252-269 illustrate an elbow to frame assembly mechanism according to another embodiment of the present invention;

[00100] FIGS. 270-281 illustrate an elbow to frame assembly mechanism according to another embodiment of the present invention; and

[00101] FIGS. 282-299 illustrate an elbow to frame assembly mechanism according to still another embodiment of the present invention.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[00102] The following description is provided in relation to several embodiments which may share common characteristics and features. It is understood that one or more features of any one embodiment may be combinable with one or more features of the other embodiments.

1.0 "Letter Box" AAV Assembly

1.1 First Embodiment

[00103] Figures 1-9 illustrate an elbow assembly 5 according to a first embodiment of the invention. As shown in Figure 1, the elbow assembly 5 generally comprises an elbow 10 and an anti-asphyxia valve 15 (AAV) assembly.

[00104] The elbow has a first portion 20 and a second portion 25. The first portion 20 is connected or otherwise provided to a mask frame 30 of a mask assembly (not shown in Fig. 1), e.g., in a snap-fit manner, as is known from U.S. patent application publication no. 2003/0196656 incorporated herein by reference. Only a portion of the frame of the mask assembly is shown in Fig. 1. The frame includes a flanged collar member 35 onto which the first portion 20 of the elbow 10 can be releasably connected.

[00105] The second portion 25 is intended to receive pressurized gas from a source of pressurized gas (e.g., air from a CPAP machine or other ventilation device). The second portion 25 typically will be provided with a swivel joint which in turn is connected to an air delivery tube in communication with a flow generator. However, the second portion 25 may have other connections, e.g., tapered joint to allow

attachment to a short tube. The elbow 10 can be made from a relatively rigid material, such as polycarbonate or other plastic.

[00106] The cross-section of Fig. 2 shows the assembled condition of the AAV assembly 15 and the elbow 10. The elbow 10 includes a port 40 that may be selectively closed by a flap portion 45 of the AAV assembly. If the pressurized gas provided to the second portion 25 of the elbow 10 is of sufficient magnitude, the flap portion 45 will raise to the block off the port 40. In this case, pressurized gas will be guided from the second portion 25 toward the first portion 20, for delivery to the mask and the patient's airways. If pressurized gas is not delivered due to a power outage and/or mechanical/electrical failure, the flap portion 45 will remain in the "rest" position shown in Fig. 2, so that the patient can breathe in ambient air and exhale through the port 40. Fig. 3 shows that the port includes a cross member 50 provided as part of the elbow.

[00107] The AAV assembly can be inserted from the direction of the frame 30 to elbow 10 (right to left in Fig. 1). Accordingly, the AAV assembly is sandwiched in place when the elbow assembly (elbow and AAV assembly) are connected to the frame. This helps avoid inadvertent disassembly.

[00108] The elbow 10 includes internal structure to hold the AAV assembly 15 in position. More specifically, the AAV assembly 15 includes a frame assembly 55 which in this embodiment generally resembles a "letter box" or "mail box", including an main wall member 60, side wall members 65 and a base portion 70 that supports the flap portion 45. The side wall members 65 are tapered so as to generally match the interior contour of the elbow 10.

[00109] The main wall member 60 includes an outer rim 75 including a protruding bead that is intended to be received in a corresponding groove 80 in the elbow 10. The AAV assembly is easily disassembled once the elbow is removed from the frame. The AAV assembly is a relatively large, three dimensional component, which reduces the chance that it will become lost. Its size and shape also facilitates finding, holding and assembling the AAV assembly. Moreover, the AAV assembly can only be assembled in one manner. The cross member 50 is provided on the elbow to prevent the flap portion from being over-pressurized. The cross member

50 also prevents inadvertent AAV assembly, e.g., pushing through the atmospheric hole, and blocking the atmospheric hole which could cause inadvertent deactivation.

[00110] The main wall member 60 also includes an aperture 85 defined by a circumferential seal lip 90 that is intended to sealingly engage a portion of the mask frame upon assembly (see Fig. 17, discussed more below). The AAV assembly therefore combines the typical function of an AAV assembly with that of sealing the elbow to frame connection. Sealing in this manner may provide one or more of the following advantages: prevent/reduce elbow/frame rattling; provide high quality feel; prevent/reduce overly free rotation; dampen vibration; prevent/reduce squeak; reduce inadvertent (and often variable) leak; and/or reduce tolerance requirements for the "hard" components (e.g., frame, elbow, etc.).

[00111] The elbow also includes an internal shoulder 95 that supports the AAV assembly. In this embodiment, the shoulder supports the base portion 70 of the AAV assembly. The flap portion 45 is movably provided, e.g., hingedly connected, to the base portion in an orientation such that the flap portion pivots at a point just below the port 40. This pivoting occurs at a position which is opposite to the main wall member 60. The free end 100 of the flap portion is also supported by the shoulder of the elbow, as shown in Fig. 2.

[00112] Figs. 4-9 are enlarged views of the AAV assembly and show further details of the frame assembly, flap portion, base portion, main wall member and side wall members. As seen in Figs. 4-6, the AAV assembly includes a slightly curved portion which is intended to match the shape of the cylindrical portion of the elbow where the AAV assembly is supported. Further, Fig. 6 shows the tapered side view which is intended to match the shape of the upper portion of the elbow. Fig. 9 shows in more detail the seal lip 90 as well as the connection 105 (e.g., an integral or living hinge) between the flap portion and the base portion. In the illustrated embodiment, the connection 105 is thinner than the flap portion 45, e.g., approximately 0.5 mm. Generally, the AAV assembly forms part of the internal geometry of the elbow. Furthermore, the AAV assembly can perform the functions of an anti-asphyxia valve, elbow-to-frame seal and oxygen diverter valve.

[00113] All components of the AAV assembly are formed of a single piece of material in this embodiment. The AAV assembly is preferably formed from a silicone

based material, such as molded liquid silicone rubber (LSR). This design suits an open and shut tool with one single core, form which the AAV assembly can be de-molded. However, the AAV assembly may be formed by more than one part of silicone and/or rigid material, e.g., over-molding, mechanical interlock.

1.2 Second Embodiment

[00114] Figs. 10-14 illustrate an elbow assembly 5 according to another embodiment of the invention. This embodiment is similar to the first embodiment, but includes a few changes. The following will provide a description of the main differences between the embodiments, although other differences may be apparent to the skilled artisan. For example, the port 40 shown in Fig. 10 has a slightly different configuration.

[00115] The AAV assembly has a very similar manner of operation and structure. However, the AAV assembly is secured in the elbow in a slightly different manner. In particular, while the AAV assembly in the first embodiment is secured (in part) using a bead that protrudes from an outer circumference 75 of the AAV assembly into a groove 80 in the elbow, the AAV assembly in Fig. 12 includes a shoulder 110 that engages with an edge 115 of the elbow 10. The lower end 120 of the main wall member 60 is supported by a surface 125 of the elbow.

1.3 Third Embodiment

[00116] Figs. 15 -17 illustrate an mask assembly according to yet another embodiment of the present invention. In this embodiment, elbow assembly 5 is similar to those described above, but Figs. 15-17 show the elbow assembly connected to a sample mask frame 130. Fig. 17 is a cross-sectional view showing the interconnection between the frame and the elbow. The flanged collar 35 of the frame 130 is shown in its locked orientation relative to the elbow assembly. Further, the frame 130 includes a baffle portion 135 having an exterior surface that is sealingly engaged by the seal member 90, upon assembly. The baffle portion 135 may extend into the breathing chamber 140 of the mask assembly.

1.4 Fourth Embodiment

[00117] Figs. 18-22 illustrate an elbow assembly 5 according to yet another embodiment of the present invention. The elbow as shown in Fig. 19 includes a port 40 that is generally rectangular in shape. Accordingly, the AAV assembly 15 also has a frame assembly having a generally rectangular box-like shape. The frame assembly includes, in addition to an main wall portion 60, side wall portions 65, a flap portion 45 and a base portion 70, a top wall portion 145. The top wall portion 145 includes a stop member 150 limiting the upward maximum amount of movement of the flap portion 45. Main wall portion 60 includes one or more cross members 50.

[00118] AAV assembly in this embodiment can be assembled from either the port side or the first portion of the elbow closest to the frame. AAV assembly can be held in place relative to the elbow using friction, and the assembly may also include additional mechanical locking structure and/or glue. The main wall portion 60 is positioned within the port and is generally flush with the exterior surface 155 of the elbow.

[00119] Figs. 20-22 show the AAV assembly in isolation where additional detail can be seen.

1.5 Fifth Embodiment

[00120] Figs. 23-25 illustrate an elbow assembly 5 according to another embodiment of the present invention. The AAV assembly 15 and the elbow 10 are connected using a tongue and groove arrangement. In this example, the elbow 10 includes a tongue 160 and the AAV assembly includes a groove 165. Once engaged, a portion 170 of the AAV assembly extends beyond the rear end of the elbow 10. The portion 170 is generally cylindrical and matches the shape of the cylindrical portion of the elbow.

[00121] The AAV assembly 15 is assembled from the port side toward the first portion of the frame. The AAV assembly includes a top portion that is generally contoured to match the tapered top portion if the interior of the elbow. The top portion includes a stop portion 175 to limit the maximum travel of the flap portion 45. The AAV assembly has a forward portion 180 oriented towards the frame that may sealingly engage a portion of the frame upon connection.

1.6 Sixth Embodiment

[00122] Figs. 26-33 illustrate an elbow assembly according to a further embodiment of the invention. This embodiment may not technically fall under the heading of " 'Letter Box' AAV assembly", but is being grouped herewith since there are similarities with the previous embodiment.

[00123] Figs. 26-27 show the elbow 10, Figs. 28-29 show the AAV assembly 15, and Figs. 30-33 show the elbow/AAV assembly 5. The AAV assembly 15 and elbow 10 are connected using a tongue and groove 185 arrangement, where the AAV assembly includes a groove that receives a tongue or flange 190 of the elbow. As shown in Fig. 28, the AAV assembly includes a flap portion 45 and defines the port 40. The flap portion 45 rests on interior features of the elbow, as shown in Fig. 33.

2.0 Slot-In AAV Assembly

2.1 First Embodiment

[00124] Figs. 34-47 are directed towards an elbow assembly 5 according to another embodiment of the present invention. Elbow assembly includes an elbow 10, an AAV assembly 15 and a clip member or portion 200 to secure the AAV assembly 15 to the elbow 10.

[00125] Elbow 10 includes a first portion 20 and a second portion 25, as described above. Elbow also includes a slot 205, just below the port 40, that is structured to receive the AAV assembly 15.

[00126] As best shown in Fig. 36, the slot 205 is formed by a ledge. The ledge supports the AAV assembly 15 during use, guides assembly and disassembly, and prevents misassembly (i.e., back to front). That is, the upper ridge and lower surface in the elbow form a housing which acts as a lead-in for the AAV assembly 15 and supports the outer edge of the AAV assembly 15 in use.

[00127] AAV assembly 15 is preferably molded LSR. AAV assembly includes an main wall member 60 and a base portion 70 that extends away from the main wall member 60. A flap portion 45 is hingedly connected to the main wall member (Fig. 36). AAV assembly is generally D-shaped in profile (Fig. 39), and generally

trapezoidal from the side (Fig. 36). This helps to prevent assembly in the wrong way and ensures assembly in the correct manner.

[00128] The clip member 200 has a generally U-shape. Clip member 200 has a central wall 210 and two arms 215. Each arm 215 includes a protrusion 220 to lockingly engage with a corresponding recess 225 formed in the sides of the elbow 10. The assembled condition of the elbow/AAV assembly is shown in Figs. 35 and 36. In Fig. 36, it can be seen that the flap portion 45 can move to selectively cover the port 40, depending on the presence of pressurized gas p.

[00129] Both the clip member 200 and AAV assembly 15 have symmetrical shapes which allows both of them to be properly assembled in either vertical orientation, i.e., the clip member can be turned upside down without affecting operation. If the flap portion 45 gets caught upon assembly, the clip member will not slot-in, which provides for fail safe assembly. When the clip member 200 is fully located with in slot 205 with the arms 215 locked in place, an audible and/or tactile 'click' is observed, confirming full assembly – to act as feedback for the user.

[00130] The outer part (or base portion 70) of the flap portion 45 may be solid (e.g., part of overmold). The gap 218 between the outer part 70 and the moving flap portion 45 should be relatively small, e.g., about 0.5-1mm or about 0.75mm, to prevent oxygen or other gases from being delivered to the patient from the flow generator, and/or to prevent rebreathed CO_2 accumulating in the tube, when the flap portion 45 is not activated.

[00131] The interior surface 225 of the elbow 10 that engages the flap portion 45 is preferably flat to provide an improved sealing mechanism by preventing inadvertent disassembly through pressure on the reverse side. The flat surface also assists in reducing inadvertent deactivation or flutter, and helps the flap portion to activate at a lower pressure. The flap portion moves through an angle of about 20-90 degrees, 50-70 degrees, or about 60 degrees, by engaging the flat surface at that angle. This angle helps entry impedance of the air to the mask and also improves the compactness of the design. The flat surface also promotes smooth flow entering the mask and reduces noise and turbulence.

[00132] In the example shown in Fig. 36, the elbow assembly is dimensioned as follows:

Surface area of the flap portion: about 250 mm^2 –area promotes activation at lower pressures

Area of port (or atmospheric hole): about 100mm^2 – maximize size of hole to accommodate the flap portion and allow area for sealing (may also be suitably sized to activate at lower pressures)

Angle of port: greater than 45 degrees; about 60 degrees

Overlap of flap portion over port: about 1.4-2.9 mm (varies with position)

Height of flap portion: about 1mm

Hinge height: 0.1-0.9mm, preferably about 0.4-0.6 or about 0.5mm

Hinge length: about 5-20mm, preferably about 15-17mm

[00133] It should again be noted that these dimensions are examples only, and the dimensions could be modified depending on application. For example, the dimensions could vary up to ± 20% of the values provided.

[00134] Fig. 37 shows the elbow in isolation, in which the slot 205 is clearly visible. As illustrated, a bead feature 206 is provided outside the slot 205. The bead feature 206 provides a sealing feature between the elbow and the wall member 60 of the AAV assembly 15. Fig. 38 shows the clip member 200 in isolation, while Fig. 39 shows the AAV assembly 15 in isolation.

[00135] The AAV assembly 15 and the clip member 200 may be made separately and assembled as described above or the clip member and AAV assembly may be initially combined into a sub-assembly and then inserted into the slot of the elbow. Combining of the AAV assembly and the clip member can be achieved using various expedients, such as over-molding, gluing, mechanical lock, etc. The clip member may be an overclip member or a push fit clip, e.g., one that clips to internal structure of the elbow.

[00136] One example of a mechanical lock method is shown in Figs. 40-41. In this embodiment, the main wall member 60 of the AAV assembly includes a locking leg 230 integrally molded with the AAV assembly. The AAV assembly, including the locking leg, is preferably made from LSR. The locking leg includes an enlarged head portion that protrudes through a hole 235 in the central wall of the clip. The

head portion expands once through the hole to lock the AAV assembly to the clip. Fig. 43 shows a cross section of the clip member with the locking leg.

[00137] Fig. 42 shows an example of an over-molded clip/AAV assembly. This is a relatively permanent connection method, unlike the mechanical connection described in relation to Figs. 40-41.

[00138] Figs. 44-47 show various embodiments in which there is a variation on the hinge 240. The length of the hinge 240 modifies the activation/deactivation pressure. The hinge could be straight across, with gaps at the ends, or a gap in the middle. While none of these embodiments use a locking leg, it is to be understood that each could be formed with such. Fig. 44 is the case where the hinge between the flap portion and the main wall member extends over substantially the entire length of the flap portion. Fig. 45 includes a small gap near the central portion of the flap portion. Fig. 46 includes a large central hinged portion, while the end portions include gaps. Fig. 47 is the opposite arrangement where the hinges are only formed along the end portions. It is to be understood that "hingedly connected" also encompasses the situation where the flap portion merely bends relative to its support. Moreover, the flap portion could be arranged to move in a more linear fashion, and is thus not limited to bending or pivoting movement.

2.2 Second Embodiment

[00139] Figs. 48-49 show an elbow assembly 5 according to an alternative embodiment of the present invention. In particular, cross-sectional Fig. 49 illustrates how the AAV assembly 15 is seated relative to the elbow 10. The elbow 10 includes a shoulder 245 that supports the flanged portion 250 of main wall member 60 such that the flanged portion is flush with the outer surface of the elbow. The clip member 200 is positioned over the AAV assembly to hold it in place relative to the elbow. The clip member and AAV assembly may be connected via a tongue and groove arrangement or a snapping arrangement. The clip member may "snap" in place to provide confirmation of correct assembly to the user.

2.3 Third Embodiment

[00140] Figs. 50-52 show an elbow assembly according to yet another embodiment of the present invention. This embodiment is similar to the above embodiment but includes a shroud-like clip 200.

2.4 Fourth Embodiment

[00141] Figs. 53-55 illustrate an elbow assembly according to still another embodiment of the present invention. In this embodiment, the clip member or portion 200 is formed as part of the AAV assembly 15, thus eliminating a part. The main wall member 60 includes a clip portion 200 that is directly connected to the elbow 10 by inserting a rim 252 of the elbow surrounding the slot 205 into a correspondingly shaped groove 255 formed in the edge of the main wall member. The AAV assembly is made of LSR which allows it to be compressed into the slot formed in the elbow. The resiliency of the AAV assembly returns it to its original shape whereby it will flex into locking relationship with the slot. The outer surface 260 of the main wall member is substantially flush with the outer surface 265 of the elbow, as seen in Figs. 53-55.

2.5 Fifth Embodiment

[00142] Figs. 56-58 show an elbow assembly 5 according to another embodiment of the present invention. The elbow assembly 5 includes an elbow and an AAV assembly. The elbow includes a port 40 that includes a cylindrical conduit 266 leading to the interior of the elbow. The conduit forms an end portion intended to form a generally flat engagement portion with flap portion 45, when activated. The elbow includes molded extension members 270, just below the port, that form an attachment interface 275 for engagement with the AAV assembly. The attachment interface 275 includes a flanged portion 280 that extends about the periphery of the slot. The flanged portion engages with a groove 290 formed in the main wall member 60.

[00143] The AAV assembly is generally wedge shaped and slides in drawer-like fashion into the slot 205 of the elbow. The surrounding portion 295 of the AAV assembly is generally hoop shaped and may include an internal ledge 300 to support

the flap portion in the rest position. The inside surface of the elbow may include a shoulder 305 or ledge to support the lower portion of the hoop shaped portion.

2.6 Sixth Embodiment

[00144] Figs. 59-61 show a portion of an elbow assembly 5 according to another embodiment of the present invention. This embodiment is similar to the prior embodiment, but the cylindrical portion 310 of the elbow does not include extension members that present a generally flat attachment portion for the AAV assembly 15. Instead, the main wall member has a curved profile so that it can be locked with the flanged portion 315 formed on the cylindrical portion 310 of the elbow. The main wall member 60 can be preformed in a curved manner, or it can simply bend upon engagement with the elbow.

2.7 Seventh Embodiment

[00145] Figs. 62-67 illustrate three alternative embodiments of an AAV assembly 15 and clip member 200 for insertion into the slot of an elbow. In each of the embodiments, the AAV assembly 15 and clip member 200 may be independent parts, permanently joined (e.g., glued, overmolded), or semi-permanently joined (e.g., mechanical interlock). Also, the shape of the AAV assembly 15 and clip member 200 may be modified in other suitable manners. In addition, some combination of features of the three alternative embodiments may be used.

[00146] Figs. 62 and 63 illustrate an embodiment that provides a clip member 200 that is relatively rigid. This arrangement provides additional protection of the AAV assembly 15 and limits incorrect assembly modes. Also, the relatively rigid support provides a more robust appearance.

[00147] Figs. 64 and 65 illustrate an embodiment that provides a clip member 200 with a relatively flexible base member 70. This arrangement is relatively easier to assemble into clip than the rigid support, and is relatively larger to provide a perception of robustness. In addition, there is less chance of damaging the hinge supporting the flat portion 45 (compared to the rigid support).

[00148] Figs. 66 and 67 illustrate an embodiment that provides an AAV assembly 15 with an open flap portion 45. This arrangement is relatively easier to

assemble than rigid and flexible supports, and limits incorrect assembly modes. Also, this arrangement allows a more streamlined elbow design.

2.8 Eighth Embodiment

[00149] Figs. 68-89 illustrate an elbow assembly 5 according to another embodiment of the present invention. As illustrated, the elbow assembly 5 includes an elbow 10, an AAV assembly 15, and a clip member 200 to secure the AAV assembly 15 to the elbow 10.

[00150] The elbow 10 includes a first portion 404 provided to the mask frame and a second portion 406 provided to a swivel joint connected to an air delivery tube. The first portion 404 includes snap-fit tabs 408, e.g., six tabs, to connect the first portion 404 to the mask frame with a snap-fit. However, more or less snap-fit tabs may be used, e.g., 2-10 tabs. A unique mold/tool configuration may be used to produce the snap-fit tabs 408 which are less prone to molding stress build-up and therefore less likely to break off the elbow. Localized stress during the molding process may be reduced by the incorporation of radii on internal edges. Two of the snap-fit tabs 408, e.g., upper and lower tabs, are more elongated and extend into the mask frame when connected. These elongated tabs 408 may be squeezed to release the elbow 10 from the mask frame.

[00151] The second portion 406 includes snap-fit tabs 410, e.g., six tabs, to connect the second portion 406 to the swivel joint. A unique mold/tool configuration may be used to produce the snap-fit tabs 410 which are less prone to molding stress build-up and therefore less likely to break off the elbow. Localized stress during the molding process may be reduced by the incorporation of radii on internal edges. The snap-fit diameter at the second portion 406 is smaller than the snap-fit diameter at the first portion 404 to prevent incorrect assembly. Also, the retention force of the snap-fit at the second portion 406 is smaller than the retention force of the snap-fit at the first portion 404. This arrangement provides a quick-release safety and convenience feature.

[00152] Annular rings 412, e.g., three rings, are provided on the second portion 406 for improved seal with the swivel joint and improved manufacturability.

[00153] The elbow 10 also includes a slot 414 to receive the AAV assembly 15, a port 416 that is selectively closed by the flap portion 45 of the AAV assembly 15, and two recesses 418 for attaching the clip member 200 with a snap-fit. The slot 414 has a thin bead around its opening which forms a line contact sealing region to prevent air leak.

[00154] The AAV assembly 15 interlocks with the clip member 200 to provide a sub-assembly that is removably attached to the elbow 10 with a snap-fit. Specifically, the AAV assembly 15, e.g., constructed of flexible silicone, includes a protrusion 420 that removably interlocks with a slot 422 provided on the clip member 200, e.g., constructed of rigid plastic. The clip member 200 includes two tabs 424 that interlock with respective recesses 418 provided to the elbow 10.

[00155] Fig. 68 is an exploded view of the elbow assembly 5, Figs. 69-75 are assembled views of the elbow assembly 5, Figs. 76-82 are isolated views of the elbow 10, and Figs. 83-89 are isolated views of the clip member 200.

2.9 Ninth Embodiment

[00156] Figs. 90-111 illustrate an elbow assembly 5 according to another embodiment of the present invention. As illustrated, the elbow assembly 5 includes an elbow 10, an AAV assembly 15, and a clip member 200 to secure the AAV assembly 15 to the elbow 10.

[00157] This embodiment is similar to the elbow assembly 5 shown in Figs. 68-89. In contrast, the elbow assembly 5 of Figs. 90-111 includes two rigid tabs 430 integrally molded with the elbow 10 to prevent over-extension of the elongated snap-fit tabs 408 during disassembly and thereby prevent their breakage. Also, the clip member 200 has a shroud-like configuration with a hole 432 that aligns with the port 416.

[00158] Fig. 90 is an exploded view of the elbow assembly 5, Figs. 91-97 are assembled views of the elbow assembly 5, Figs. 98-104 are isolated views of the elbow 10, and Figs. 105-111 are isolated views of the clip member 200.

2.10 Tenth Embodiment

[00159] Figs. 112-133 illustrate an elbow assembly 5 according to another embodiment of the present invention. As illustrated, the elbow assembly 5 includes an elbow 10, an AAV assembly 15, and a clip member 200 to secure the AAV assembly 15 to the elbow 10.

[00160] This embodiment is similar to the elbow assembly 5 shown in Figs. 90-111. Annular rings 413 and 412 are provided on first and second end portions 404, 406, respectively, for an improved seal with the frame and swivel joint, respectively, and improved manufacturability. In contrast, the clip member 200 of Figs. 112-133 includes a more elongated shroud-like configuration. Also, the first portion 404 does not include elongated tabs 408 aligned with rigid tabs 430. In addition, the elbow of Figs. 112-133 includes protrusions 415 rather than a recess which interact with protrusions on the clip member 200. The elongated shroud-like configuration of the clip member 200 provides a visual indicator to aid correct assembly of the clip member to the elbow 10.

[00161] Fig. 112 is an exploded view of the elbow assembly 5, Figs. 113-119 are assembled views of the elbow assembly 5, Figs. 120-126 are isolated views of the elbow 10, and Figs. 127-133 are isolated views of the clip member 200. The clip member 200 is relatively large and is easier for patients with low dexterity to manipulate. Further, if dropped, it is easier to locate, particularly in the dark.

2.11 Eleventh Embodiment

[00162] Figs. 134-154 illustrate an elbow assembly 5 according to another embodiment of the present invention. As illustrated, the elbow assembly 5 includes an elbow 10, an AAV assembly 15, and a clip member 200 to secure the AAV assembly 15 to the elbow 10.

[00163] This embodiment is similar to the elbow assembly 5 shown in Figs. 68-89. In contrast, the elbow assembly 5 of Figs. 134-154 is structured such that the clip member 200 is substantially flush with a surface 435 surrounding the port 416. Also, the first portion 404 does not include elongated tabs 408. The port 416 also has a central rib 436 to prevent small objects from falling in or being placed in the port 416 and thereby affecting AAV function.

[00164] Fig. 134 is an exploded view of the elbow assembly 5, Figs. 135-140 are assembled views of the elbow assembly 5, Figs. 141-147 are isolated views of the elbow 10, and Figs. 148-154 are isolated views of the clip member 200.

[00165] Figs. 155-156 are exploded views illustrating the elbow 10 of Figs. 134-154 being assembled between a mask frame 440 (via throughhole 442) and a swivel joint 445. Figs. 157-161 are various views illustrating the elbow 10 of Figs. 134-154 connected between the mask frame 440 and the swivel joint 445. As illustrated, the first portion 404 of the elbow 10 snap-fits to the mask frame 440, and the elbow 10 may be removed from the mask frame 440 by pulling outwards. The swivel joint 445 snap-fits to the second portion 406 of the elbow 10, and the swivel joint 445 may be removed from the elbow 10 by pulling downwards or levering off. The clip member of Figs. 134-154 no longer has lugs to connect it to the elbow, rather the clip member has a recess. The clip member also has an overhang portion 437 to make disassembly easier, i.e., the overhang portion 437 provides an edge or finger grip/catch.

3.0 Drop-In AAV Assembly

3.1 First Embodiment

[00166] Figs. 162-164 illustrate an elbow assembly 5 according to yet another embodiment of the present invention. The elbow assembly includes a first elbow portion 320, a second elbow portion 325 and an AAV assembly 15. The AAV assembly may be similar to the AAV assembly described above.

[00167] First elbow portion 320 and second elbow portion 325 are connected by a locking assembly. The locking assembly may include a one or more arms 330 having a locking claw 335 that engage with a flange 340. The position of the arms and flange may be interchanged, although Fig. 162 shows the arms/claws on the first (or upper) elbow portion, and the flange on the second (or lower) elbow portion.

[00168] The AAV assembly 15 is supported on the second elbow portion 325. The second elbow portion includes a ledge 345 to support the bottom of the AAV assembly and a wall 350 to laterally support the AAV assembly. The wall and the AAV assembly have a generally D-shaped profile to facilitate alignment. The upper

elbow portion includes a D-shaped recess 355 so that the lower elbow portion can only be inserted in one orientation. While the AAV assembly is shown to have a D-shape, it need not have a wedge shape as in the prior embodiments.

3.2 Second Embodiment

[00169] Figs. 165-168 show a mask assembly 360 according to another embodiment of the present invention. The mask assembly 360 includes a full face mask frame 365, an elbow assembly 5, and a swivel joint 370. A portion of an air delivery conduit 375 which is in communication with a flow generator is also shown.

[00170] The elbow assembly 5 as shown in Figs. 167-168 includes a first elbow portion 380, a second elbow portion 385 and an AAV assembly 15 positioned therebetween. The first elbow portion 380 includes a shoulder 390 to support the AAV assembly, while the second elbow portion includes a channel 395 to receive the AAV assembly. The AAV assembly and the interfacing portions of the first and second elbow portions have a unique shape that allows for the correct orientation of the hinge portion of the flap portion relative to the port in the elbow. In one example, these portions are generally D-shaped. The D-shape of the AAV assembly allows it to be assembled in one of two correct positions (right side up or upside down), as described above. The side walls of the AAV assembly may be generally curved as well, as shown in Fig. 168.

[00171] As seen in Fig. 167, the first elbow portion 380 includes a port 40 that can be selectively opened when the flap portion of the AAV assembly has been closed. The port 40 in this example is oriented towards the mask frame, or on the inside curve of the elbow. The AAV assembly is oriented to accommodate for the changed location of the port as well.

3.3 Third Embodiment

[00172] Figs. 169-171 illustrate an elbow assembly 5 according to yet another embodiment of the present invention. Elbow assembly 5 includes a first elbow portion 396, a second elbow portion 398 and an AAV assembly 15 sandwiched between the first and second portions of the elbow. The AAV assembly in this

example has a generally cylindrical base member 70 and a flap portion 45 hinged to an inside surface of the base member.

[00173] The first elbow portion 396 includes a port 40 that can be engaged by the flap portion 45 of the AAV assembly. The first and second portions of the elbow are connected via a tongue and groove arrangement.

3.4 Fourth Embodiment

[00174] Figs. 172 and 173 illustrate another embodiment of an elbow assembly 5 including an AAV assembly 15 sandwiched between first and second portions 400, 402 of the elbow. In the illustrated embodiment, the port 40 protrudes into the elbow. However, the port 40 may have a flat face as illustrated in above described embodiments.

[00175] This embodiment has the additional advantage that the AAV assembly 15 forms an oxygen diverter valve with the lower portion of the elbow.

4.0 Elbow-to-Frame Interface

[00176] The following includes descriptions of mask assemblies including elbow to frame interfaces or assembly mechanisms according to several illustrated embodiments of the present invention. In each of the illustrated embodiments, the mask assembly includes an elbow that is adapted to be removably connected to a frame via an elbow to frame assembly mechanism.

[00177] The elbow to frame assembly mechanism provides an interface between the elbow and frame to facilitate assembly and disassembly. In addition, the elbow to frame assembly mechanism may be structured to facilitate molding of the elbow and/or frame.

[00178] In the illustrated embodiment, the elbow and frame form a part of a full-face mask. 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.

4.1 First Embodiment

[00179] Figs. 174-185 illustrate an elbow to frame assembly mechanism according to an embodiment of the present invention. As illustrated, the elbow 10 includes two snap-fit tabs 450 to connect the elbow 10 to the mask frame 455 with a snap-fit. Specifically, each snap-fit tab 450 includes a hook portion 452 that interlocks with an elbow retaining feature, e.g., annular ring 456, provided to the mask frame 455. Each snap-fit tab 450 includes external finger grips 454 to facilitate release of the elbow 10 from the mask frame 455 by pressing inwards on the external finger grips 454. The elbow retaining feature may be molded in a line of draw, i.e., easy to mold.

[00180] Figs. 174-179 are exploded views illustrating the elbow 10 being assembled to the mask frame 455, and Figs. 180-185 are various views illustrating the elbow 10 connected to the mask frame 455. This type of mechanism may be used in conjunction with embodiments 2.8, 2.9, 2.10, and 2.11, for example.

4.2 Second Embodiment

[00181] Figs. 186-203 illustrate an elbow to frame assembly mechanism according to another embodiment of the present invention. As illustrated, the mask frame 460 includes an elbow-to-frame adaptor 462 to connect the elbow 10 to the mask frame 460 with a snap-fit. Specifically, the elbow-to-frame adaptor 462, e.g., constructed of rigid plastic, is attached to the mask frame 460 with a snap-fit. The elbow-to-frame adaptor 462 may be removable or permanently assembled, e.g., ultrasonic welding. The elbow-to-frame adaptor 462 is formed separately from the mask frame 460, e.g., molded as a separate part, to simplify molding of the mask frame 460. The elbow-to-frame adaptor 462 may be formed or molded in a different material from the mask frame 460 for aesthetic purposes and/or in a different material from the elbow to reduce the chance of squeak between like materials.

[00182] The elbow-to-frame adaptor 462 includes a flanged collar member 464 onto which the elbow 10 can be releasably connected. The elbow 10 is connected to the elbow-to-frame adaptor 462 in a snap-fit manner as is known from U.S. patent application publication no. 2003/0196656 incorporated herein by reference. The

elbow 10 may be release from the elbow-to-frame adaptor 462 by pressing inwards on two external finger grips 468 provided to the elbow 10.

[00183] The elbow-to-frame adaptor 462 also includes a opening 466 that accommodates a port cap 470, e.g., formed of flexible silicone, releasably connected to a port provided to the mask frame 460. The port cap 470 may be permanently attached to the adaptor 462 via co-molding, etc., or remain separate.

[00184] Figs. 186-191 are exploded views illustrating the elbow 10, mask frame 460, elbow-to-frame adaptor 462, and port cap 470, Figs. 192-197 are partial assembled views illustrating the elbow-to-frame adaptor 462 connected to the mask frame 460, and Figs. 198-203 are various assembled views illustrating the elbow 10 and port cap 470 connected to the mask frame 460.

4.3 Third Embodiment

[00185] Figs. 204-221 illustrate an elbow to frame assembly mechanism according to another embodiment of the present invention. As illustrated, an elbow seal 472 is provided to the mask frame 474 to provide a seal between the elbow 10 and the mask frame 474. Specifically, the elbow seal 472, e.g., constructed of flexible silicone, is attached to the collar member of the mask frame 474. The elbow seal 472 covers air gaps and/or incorporates protrusions to interlock with gaps 480 in the mask frame 474 and also acts to reduce any sloppy fit between the mask frame 474 and the elbow 10, thereby reducing noise or squeak. A port cap 476, e.g., formed of flexible silicone, is integrated with the elbow seal 472. The port cap 476 is releasably connected to a port provided to the mask frame 474. The elbow seal 472 may be co-molded to the elbow or molded and vibration welded to the elbow if a TPE plastic, for example.

[00186] The collar member of the mask frame 474 includes a castellated rim that provides flange segments 478 that engage or interface with the elbow 10. The elbow 10 is connected to the flange segments 478 in a snap-fit manner as is known from U.S. patent application publication no. 2003/0196656 incorporated herein by reference.

[00187] As best shown in Figs. 209, 215, and 221, localized gaps 480 are formed in the mask frame 474 as a result of the molding process. The localized gaps

480 enable the castellated feature on the collar member of the mask frame 474 to be molded more easily.

[00188] Figs. 204-209 are exploded views illustrating the elbow 10, mask frame 474, and elbow seal and integrated port cap 472, 476, Figs. 210-215 are partial assembled views illustrating the elbow seal and integrated port cap 472, 476 connected to the mask frame 474, and Figs. 216-221 are various assembled views illustrating the elbow 10 connected to the mask frame 474.

[00189] In the illustrated embodiment, the elbow seal is provided between the elbow and the frame. In an alternative embodiment, an over seal may be provided that seals with an exterior surface of the elbow and an exterior rib provided to the frame. Thus, the over seal seals over the elbow and frame. The seal may be integrated, co-molded, or over-molded to the elbow, for example.

4.4 Fourth Embodiment

[00190] Figs. 222-233 illustrate an elbow to frame assembly mechanism according to another embodiment of the present invention. As illustrated, the elbow 10 includes a snap-fit tab 482 on a top portion thereof to connect the elbow 10 to the mask frame 484 with a snap-fit. Specifically, the snap-fit tab 482 includes a hook portion 486 that interlocks with a collar 488 provided to the mask frame 484. The elbow 10 is pulled outwardly while depressing tab 482 to release the elbow 10 from the mask frame 484. The elbow-to-frame interface detail or collar 488 may be molded in a line of draw and with side cores, i.e., relatively easy to mold. The tab 482 may be used in conjunction with snap-fit tabs described previously (e.g., see Figs. 68-89 and 234-251), of which there may be any suitable number of previously described snap-fit tabs, e.g., 2-10 tabs.

[00191] Figs. 222-227 are exploded views illustrating the elbow 10 being assembled to the mask frame 484, and Figs. 228-233 are various views illustrating the elbow 10 connected to the mask frame 484.

4.5 Fifth Embodiment

[00192] Figs. 234-251 illustrate an elbow to frame assembly mechanism according to another embodiment of the present invention. As illustrated, the mask

frame elbow 10 includes an elbow-to-swivel adaptor 490 to connect the elbow 10 to a swivel (not shown) with a snap-fit. Specifically, the elbow-to-swivel adaptor 490, e.g., constructed of rigid plastic, includes a snap-fit tab 492 to connect the adaptor 490 to the elbow 10 with a snap-fit. Specifically, the snap-fit tab 492 includes a hook portion 494 that interlocks with an opening 496 provided to the elbow 10. The snap-fit tab 494 is pushed inwardly to release the adaptor 490 from the elbow 10. The end of the adaptor includes multiple snap-fit tabs 498 to connect the adaptor 490 to a swivel. The elbow 10 also includes multiple snap-fit tabs 500 to connect the elbow 10 to the mask frame 502 with a snap-fit. In this embodiment, the snap-fit tabs 500 are a semi-permanent connection and the quick release connection is via tab 492.

[00193] Figs. 234-239 are exploded views illustrating the elbow 10, mask frame 502, and elbow-to-swivel adaptor 490, Figs. 240-245 are partial assembled views illustrating the elbow 10 connected to the mask frame 502, and Figs. 246-251 are various assembled views illustrating the elbow 10 connected to the mask frame 502 and elbow-to-swivel adaptor 490.

4.6 Sixth Embodiment

[00194] Figs. 252-269 illustrate an elbow to frame assembly mechanism according to another embodiment of the present invention. As illustrated, the mask frame 505 includes an elbow-to-frame adaptor 506 to connect the elbow 10 to the mask frame 505 with a snap-fit. Specifically, the elbow-to-frame adaptor 506, e.g., constructed of rigid plastic, is attached to the mask frame 505. The elbow-to-frame adaptor 506 may be removably attached (e.g., snap-fit assembly, bayonet connection), glued, or ultrasonically welded in place to the mask frame 505. The elbow-to-frame adaptor 506 is formed separately from the mask frame 505, e.g., molded as a separate part, to simplify molding of the mask frame 505.

[00195] The elbow-to-frame adaptor 506 includes a flanged collar member 508 onto which the elbow 10 can be releasably connected. The elbow 10 is connected to the elbow-to-frame adaptor 506 in a snap-fit manner as is known from U.S. patent application publication no. 2003/0196656 incorporated herein by reference.

[00196] Figs. 252-257 are exploded views illustrating the elbow 10, mask frame 505, and elbow-to-frame adaptor 506, Figs. 258-263 are partial assembled

views illustrating the elbow-to-frame adaptor 506 connected to the mask frame 505, and Figs. 264-269 are various assembled views illustrating the elbow 10 connected to the mask frame 505.

4.7 Seventh Embodiment

[00197] Figs. 270-281 illustrate an elbow to frame assembly mechanism according to another embodiment of the present invention. As illustrated, the mask frame 510 includes a flanged collar member 512 onto which the elbow 10 can be releasably connected. The elbow 10 is connected to the flanged collar member 512 in a snap-fit manner as is known from U.S. patent application publication no. 10/390,682 incorporated herein by reference. In an embodiment, the flanged collar member 512 or interface rim is integrally molded with the mask frame 510 using a 3-part split collar in the mold.

[00198] Figs. 270-275 are exploded views illustrating the elbow 10 being assembled to the mask frame 510, and Figs. 276-281 are various views illustrating the elbow 10 connected to the mask frame 510.

4.8 Eighth Embodiment

[00199] Figs. 282-299 illustrate an elbow to frame assembly mechanism according to another embodiment of the present invention. As illustrated, the mask frame 515 includes an elbow-to-frame adaptor 516 to connect the elbow 10 to the mask frame 515 with a snap-fit. Specifically, the elbow-to-frame adaptor 516, e.g., constructed of rigid plastic, is attached to the mask frame 515. In the illustrated embodiment, the elbow-to-frame adaptor 516 is removably attached to the mask frame 515 via a bayonet-style fitting. That is, the adaptor 516 includes tabs 518 that interlock with respective recesses 520 provided to the mask frame 515. The elbow-to-frame adaptor 516 is formed separately from the mask frame 515, e.g., molded as a separate part, to simplify molding of the mask frame 515.

[00200] The elbow-to-frame adaptor 516 includes a flanged collar member 522 onto which the elbow 10 can be releasably connected. The elbow 10 is connected to the elbow-to-frame adaptor 516 in a snap-fit manner as is known from U.S. patent application publication no. 2003/0196656 incorporated herein by reference.

[00201] Figs. 282-287 are exploded views illustrating the elbow 10, mask frame 515, and elbow-to-frame adaptor 516, Figs. 288-293 are partial assembled views illustrating the elbow-to-frame adaptor 516 connected to the mask frame 515, and Figs. 294-299 are various assembled views illustrating the elbow 10 connected to the mask frame 515.

[00202] An advantage of the above-described embodiments is that they may be suitable for multi-patient multi-use (MPMU). That is, the entire elbow assembly may be sterilized or disinfected as appropriate for use between different patients. The above-described embodiments have the advantage of MPMU due to their increased size over known AAV assemblies and the fact that the elbow, AAV assembly, and clip member may be pulled apart for cleaning. This is different to other known designs that are permanently assembly, e.g., Respironics Comfort Full.

[00203] The AAV assemblies 15 are not limited to the shapes and/or sizes described above. For example, the AAV assemblies 15 may have oval, rectangular, or other suitable shapes. Also, the elbow slot for receiving the AAV assembly may have an angle in the range of 20-40° with respect to horizontal, e.g., 30°. Further, the AAV assemblies may be constructed of LSR as well as other suitable materials, e.g., TPU, TPE.

[00204] It will be understood that, in each of the above-described embodiments, reference to an AAV assembly 15 may include an integral one-piece structure, or multiple parts that are formed separately from one another and then interconnected.

[00205] 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. An elbow assembly comprising:
an elbow;
an anti-asphyxia valve (AAV) assembly provided to the elbow; and
a clip member or portion to secure the AAV assembly to the elbow.

2. The elbow assembly of claim 1, wherein the elbow includes a slot to receive at least a portion of the AAV assembly.

3. The elbow assembly of claim 2, wherein the slot is structured to receive the AAV assembly and the clip member is secured to an exterior surface of the elbow.

4 . The elbow assembly of claim 2, wherein the clip member is formed as part of a main wall member of the AAV assembly.

5. The elbow assembly of claim 4, wherein the main wall member and elbow are secured via a tongue and groove arrangement.

6. The elbow assembly of any one of claims 4-6, wherein the main wall member includes a circumferential groove that receives a tongue of the elbow.

7 . The elbow assembly of claim 1, wherein the AAV assembly includes a main wall member secured to a cylindrical portion of the elbow.

8. The elbow assembly of claim 7, wherein the main wall member is generally planar.

9. The elbow assembly of any one of claims 7-8, wherein the cylindrical portion of the elbow includes an extension presenting a substantially planar surface for securing of the AAV assembly.

10. The elbow assembly of claim 7 , wherein the cylindrical portion of the elbow includes an opening provided with a tongue provided along the perimeter of the opening, and the AAV assembly has a curved shape conforming to the shape of the cylindrical portion of the elbow.

11. The elbow assembly of any one of claims 1-10, wherein the AAV assembly is positioned adjacent to an atmospheric port formed in the elbow.

12. The elbow assembly of claim 11, wherein the port includes a cylindrical wall member that can be selectively engaged by a portion of the AAV assembly.

13. The elbow assembly of any one of claims 4-12, wherein the main wall member is substantially flush with an outer surface of the elbow.

14. The elbow assembly of any one of claims 1-13, wherein the clip member comprises an overclip member.

15. The elbow assembly of any one of claims 1-13, wherein the clip member comprises a push-fit clip member.

16. The elbow assembly of any one of claims 1-13, wherein the clip member comprises a shroud-type clip member.

17. The elbow assembly of any one of claims 1-16, wherein the clip member and the AAV assembly are formed as an integral unit.

18. The elbow assembly of any one of claims 1-17, wherein the clip member and the AAV assembly are secured by over-molding, gluing and/or a mechanical lock.

19. The elbow assembly of any one of claims 1-18, wherein the clip member includes an aperture and the AAV assembly includes a lug which is received within the aperture.

20. The elbow assembly of any one of claims 1-19, wherein the AAV assembly is generally D-shaped in plan view.

21. The elbow assembly of any one of claims 1-20, wherein the AAV assembly is generally trapezoidal in profile.

22. The elbow assembly of any one of claims 1-21, wherein the AAV assembly includes a base portion and a flap portion hingedly provided to the base portion.

23. The elbow assembly of claim 22, wherein the hinge is in the form of a living hinge.

24. The elbow assembly of any one of claims 22-23, wherein the hinge is formed along only a portion between the base portion and the flap portion.

25. The elbow assembly of any one of claims 22-24, wherein the AAV assembly includes a rim surrounding the base portion.

26. The elbow assembly of claim 1, wherein the AAV assembly includes a main wall member having at least one dimension that is larger than an AAV insertion slot provided in the elbow, the main wall member being substantially perpendicular to the AAV assembly insertion direction.

27. The elbow assembly of any one of claims 1-26, wherein the clip member is generally U-shaped and includes a central wall and side arms, each of the side arms including a retaining mechanism secured to the elbow.

28. The elbow assembly of claims 27, wherein the retaining mechanism includes a lug provided to each arm that is received within a slot provided on each side of the elbow.

29. The elbow assembly of claim 1, wherein the elbow includes a first portion adapted to be secured to a frame of a mask assembly and a second portion structured to receive pressurized gas, and a first gas path is defined between the first and second portions.

30. The elbow assembly of claims 29, wherein an atmospheric slot is provided between the first and second portions.

31. The elbow assembly of claim 30, further comprising a second gas path defined between the first portion and the slot.

32. The elbow assembly of any one of claims 29-31, wherein the AAV assembly includes a flap portion to selectively allow either pressurized gas or ambient air to be directed to the first portion of the elbow.

33. The elbow assembly of claim 32, wherein the flap portion is made of silicone or TPE.

34. The elbow assembly of any one of claims 32-33, wherein the flap portion comprises liquid silicone rubber.

35. An elbow assembly for a mask, comprising:

an elbow having a first portion structured to engage with a mask frame and a second portion structured to receive pressurized gas;

a first gas path defined between the first and the second portions;

a port in communication with atmosphere and in selective communication with the first portion of the elbow;

a second gas path defined between the first portion and the port; and

an anti-asphyxia valve (AAV) assembly, said AAV assembly including a flap portion and a frame assembly integrally supporting the flap portion, the flap portion being movable to selectively open and close the port, wherein:

said flap portion assumes a closed position when pressurized gas less than or equal to a predetermined threshold is delivered to the second portion of the elbow, in which case the port can communicate with the first portion via the second gas path, and

said flap assumes an open position when pressurized gas above the predetermined threshold is delivered to the second portion, in which case the flap portion seals the port and the first portion is in communication with the second portion via the first gas path.

36. The elbow assembly of claim 35, wherein the frame assembly has a letter box-like configuration.

37. The elbow assembly of any one of claims 35-36, wherein the frame assembly is supported adjacent the first portion of the elbow and/or the port of the elbow.

38. The elbow assembly of any one of claims 35-37, wherein the frame assembly includes a main wall member including an outer perimeter engaged with a groove provided adjacent the first portion.

39. The elbow assembly of any one of claims 35-38, wherein the main wall member is oriented within the port and includes an aperture defining a part of the second gas path.

40. The elbow assembly of claim 39, wherein the flap portion is movably mounted near the aperture of the main wall member.

41. The elbow assembly of any one of claims 39-40, wherein the main wall member includes one or more cross ribs.

42. The elbow assembly of claim 38, wherein the main wall member is oriented toward the first portion and includes an aperture having a seal portion structure adapted to seal against the mask frame upon assembly therewith.

43. The elbow assembly of any one of claims 35-42, wherein the flap portion is hinged at a location remote from the main wall member.

44. The elbow assembly of any one of claims 35-43, wherein the AAV assembly includes a base portion to support the flap portion.

45. The elbow assembly of claim 44, wherein the base portion includes a shoulder portion to support the flap portion.

46. The elbow assembly of any one of claims 44-45, wherein the base portion is seated on a shoulder portion formed on the elbow.

47. The elbow assembly of claim 46, wherein at least a part of the flap portion, when in the closed position, rests against the shoulder portion.

48. The elbow assembly of any one of claims 44-47, wherein at least the base portion and the flap portion are formed of one piece.

49. The elbow assembly of any one of claims 44-48, wherein the AAV assembly includes side wall portions extending from the base portion.

50. The elbow assembly of claim 49, wherein the side wall portions have a geometry and/or shape that substantially matches that of an inside portion of the elbow.

51. The elbow assembly of any one of claims 49-50, wherein the side walls are generally tapered down from the first portion towards the port.

52. The elbow assembly of any one of claims 49-50, wherein the side walls are generally tapered down from the port toward the first portion.

53. The elbow assembly of any one of claims 35-53, wherein the port has a generally rectangular shape and an outer perimeter of the AAV assembly substantially matches the rectangular shape.

54. The elbow assembly of claim 53, wherein the AAV assembly includes a top wall portion positioned opposite the base portion.

55. The elbow assembly of claim 54, wherein the top wall portion includes a stop on which the flap portion rests when the flap portion is in the open position, to sealingly close off the port.

56. The elbow assembly of claim 55, wherein the flap portion is configured to move in the range of about 20-90 degrees to seal the port.

57. The elbow assembly of any one of claims 35-56, wherein at least a portion of the AAV assembly is substantially flush with an outer surface of the elbow.

58. The elbow assembly of any one of claims 53-57, wherein the AAV assembly is positioned within the elbow via the port.

59. The elbow assembly of any one of claims 35-58, wherein the AAV is positioned within the elbow via an aperture in the first portion.

60. The elbow assembly of any one of claims 35-59, wherein the AAV assembly and the elbow engage via a tongue and groove arrangement.

61. The elbow assembly of claim 60, wherein the AAV assembly includes a groove and the elbow includes a tongue.

62. The elbow assembly of claim 35, wherein the AAV assembly is in the form of a cap that includes the flap portion and the port.

63. The elbow assembly of claim 35, wherein an outer perimeter of the AAV assembly is generally cylindrical and is substantially flush with an outer surface of the elbow.

64. The elbow assembly of any one of claim 63, wherein at least a portion of the AAV assembly forms a portion of the port.

65. The elbow assembly of claim 64, wherein the portion of the AAV assembly tapers down in cross section from an inlet side of the port.

66. The elbow assembly of any one of claims 35-65, wherein the flap portion is generally planar.

67. The elbow assembly of any one of claims 35-65, wherein the flap portion is pivotable along an arc within a predetermined range.

68. The elbow assembly of claim 67, wherein the range is between about 20-90 degrees.

69 . The elbow assembly of any one of claims 67-68, wherein the range is between about 50-70 degrees.

70. The elbow assembly of any one of claims 67-69, wherein the angle is about 60 degrees.

71. The elbow assembly of any one of claims 35-70, wherein the AAV assembly comprises molded liquid silicone rubber (LSR) or TPE.

72. A mask assembly comprising:

a frame;

an elbow provided to the frame; and

an anti-asphyxia valve (AAV) assembly secured within the elbow upon assembly of the elbow to the frame.

73. The mask assembly of claim 72, wherein the AAV assembly comprises a three-dimensional structure including a flap portion and a main wall.

74. The mask assembly of claim 72, wherein the AAV assembly comprises a unitary piece.

75. The mask assembly of claim 72, wherein the AAV comprises silicone.

76. The mask assembly of claim 72, wherein the AAV comprises LSR or TPE.

77. An elbow assembly comprising:

an elbow, the elbow having a first portion adapted to be secured to a mask and a second portion adapted to receive pressurized gas, the first and the second portions having connection structure allowing selective connection and disconnection between the first and second portions, the connection structure including a pair of resilient arms provided on one of the first and second portions and a flange provided on the other of the first and second portions, each of the arms including a claw to lock with the flange; and

an anti-asphyxia valve (AAV) assembly provided within the elbow and sandwiched between the first and second portions.

78. The elbow assembly of claim 77, wherein the AAV assembly has a unique shape.

79. The elbow assembly of any one of claims 77-78, wherein the AAV assembly has a generally D-shaped profile.

80. The elbow assembly of claim 79, wherein the first and second portions of the elbow have a shape substantially matching the shape of the AAV assembly.

81. The elbow assembly of any one of claims 77-80, wherein the first portion includes a port that is selectively closed by the AAV assembly in dependence of the magnitude of pressurized gas provided to the elbow.

82. A mask assembly comprising:
a frame; and
an elbow assembly according to any one of claims 1-81.

83. The mask assembly of claim 82, wherein the frame includes a baffle portion that engages with a seal lip of the AAV assembly upon assembly of the elbow assembly with the mask frame.

84. A mask assembly comprising:
a frame;
an elbow provided to the frame; and
an elbow to frame assembly mechanism to releasably assemble the elbow to the frame, the elbow to frame assembly mechanism including an elbow to frame adaptor that attaches to the frame and provides a flanged collar member onto which the elbow can be releasably assembled.

85. The mask assembly of claim 84, wherein the elbow to frame adaptor is removably attached to the frame.

86. The mask assembly of claim 85, wherein the elbow to frame adaptor attaches to the frame with a snap-fit.

87. The mask assembly of claim 85, wherein the elbow to frame adaptor attaches to the frame with a bayonet-style fitting.

88. The mask assembly of claim 84, wherein the elbow to frame adaptor is permanently fixed to the frame via co-molding, over-molding, vibration welding, or ultrasonic welding.

89. A mask assembly comprising:

a frame;

an elbow having one end provided to the frame and an opposite end provided to a swivel; and

an elbow-to-swivel adaptor to connect the elbow to the swivel, the elbow-to-swivel adaptor including a snap-fit tab to connect the elbow-to-swivel adaptor to the elbow with a snap-fit.

90. A mask assembly comprising:

a frame;

an elbow provided to the frame; and

an integrated elbow seal and port cap assembly provided between the elbow and the frame, the elbow seal and port cap assembly including an elbow seal to provide a seal between the elbow and the frame and a port cap to releasably connect to a port provided to the frame.

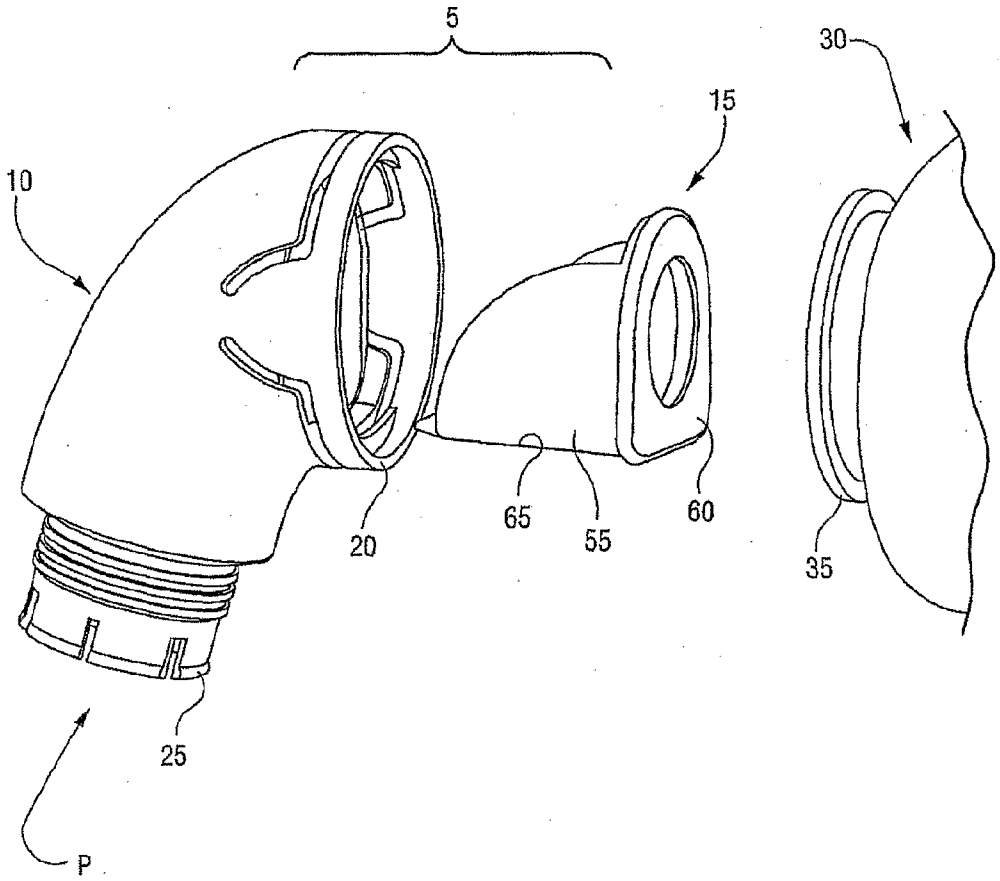


Fig. 1

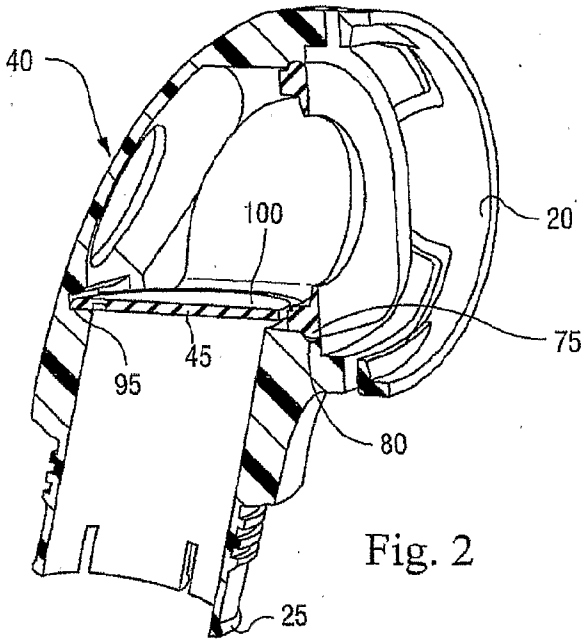


Fig. 2

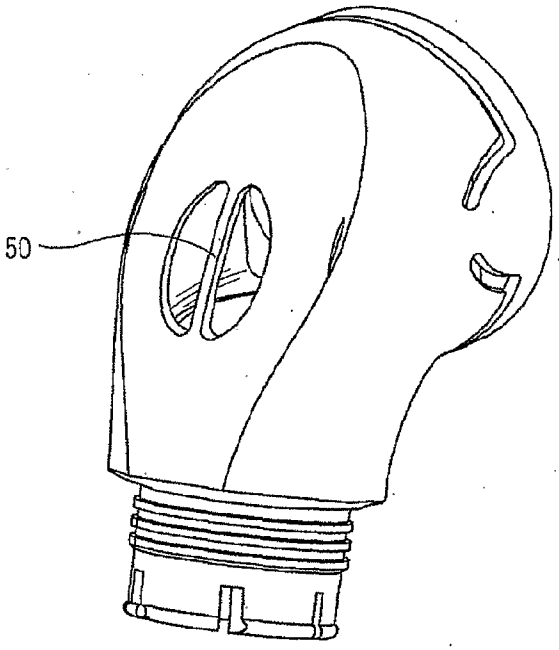


Fig. 3

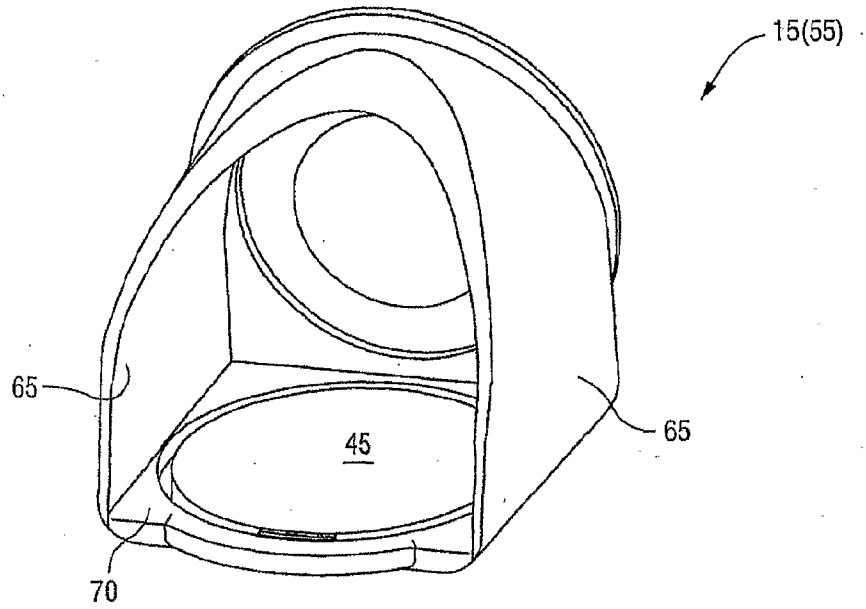


Fig. 4

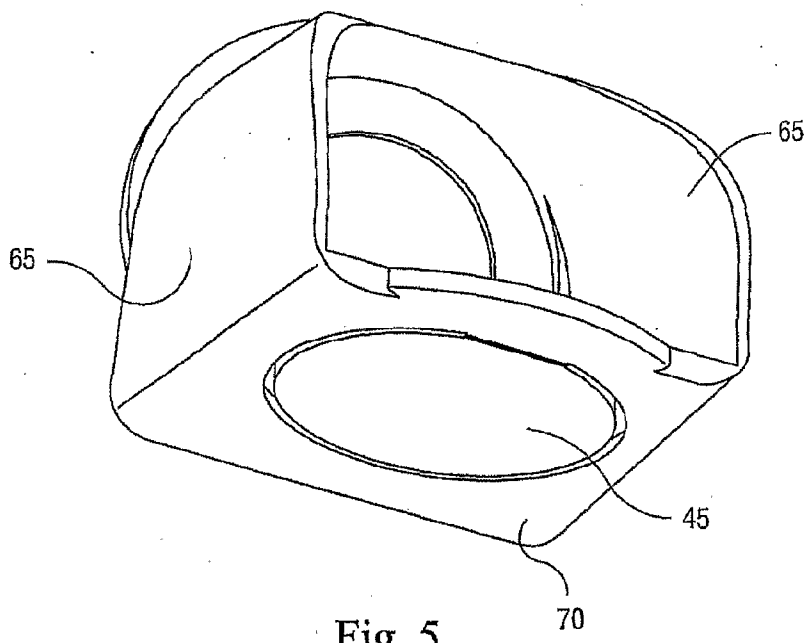


Fig. 5

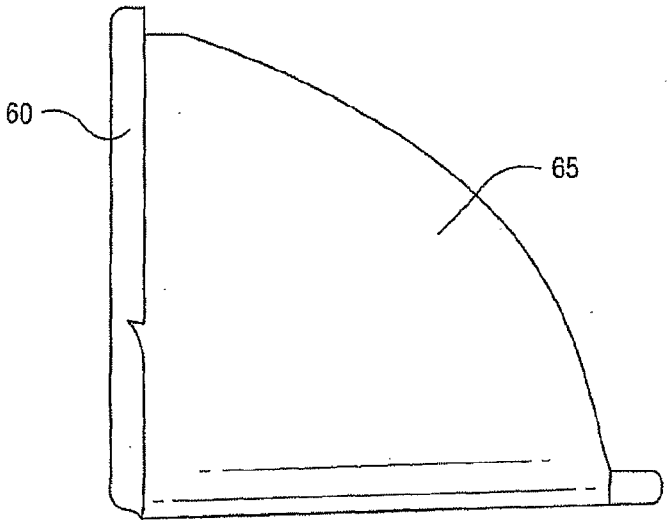


Fig. 6

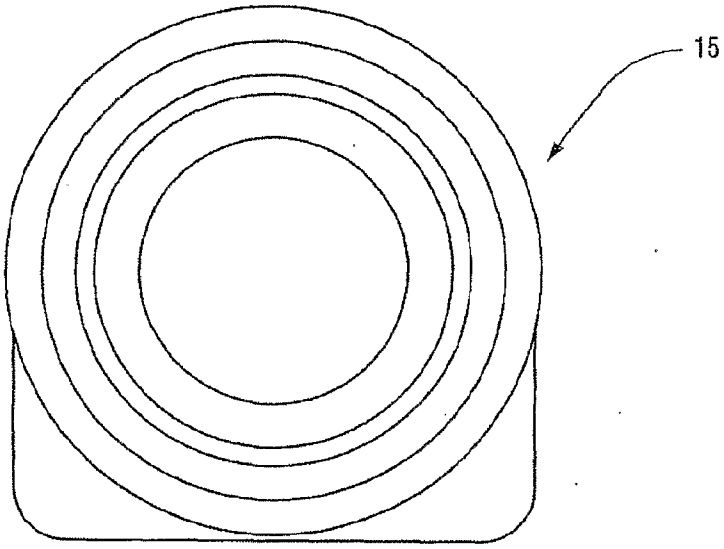


Fig. 7

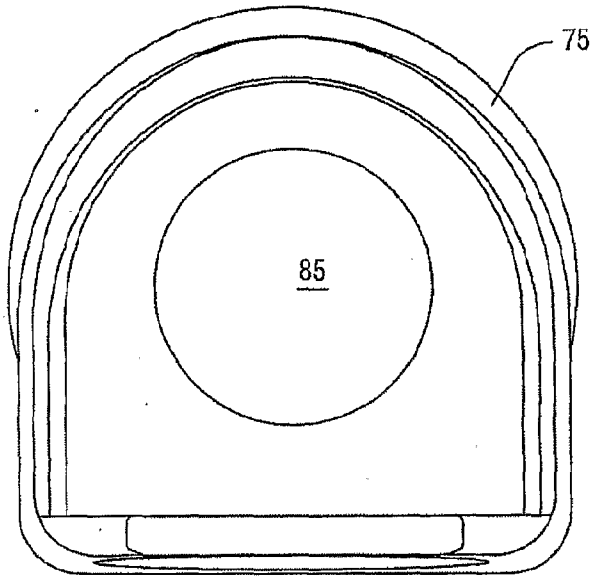


Fig. 8

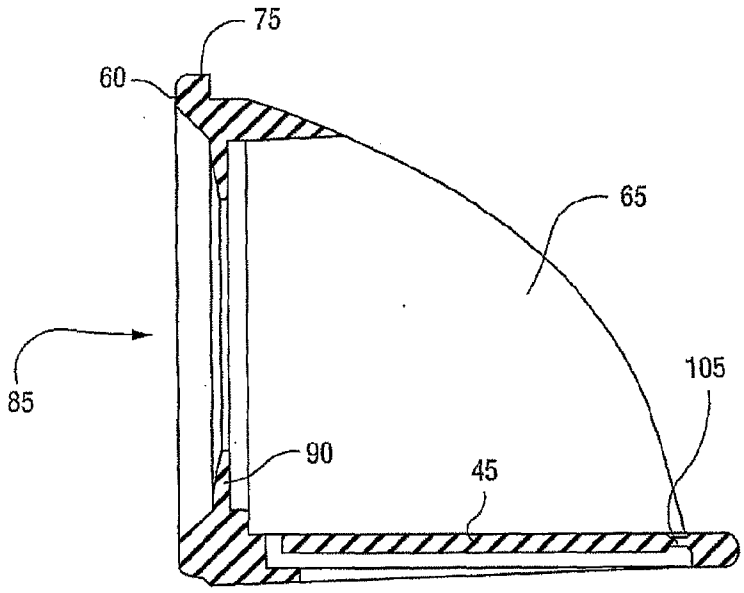


Fig. 9

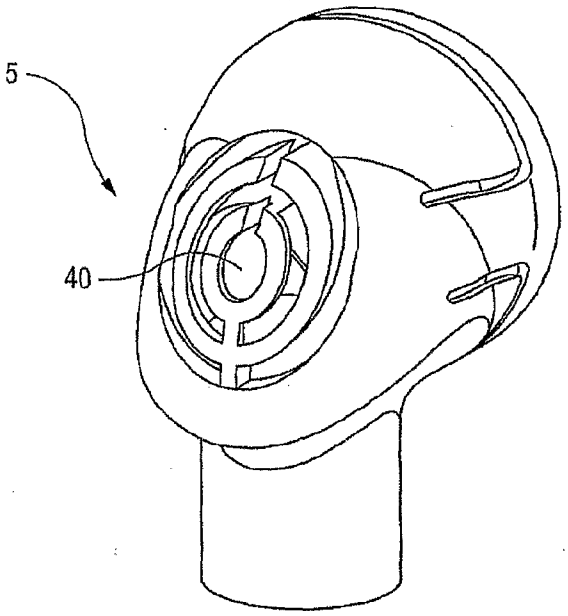


Fig. 10

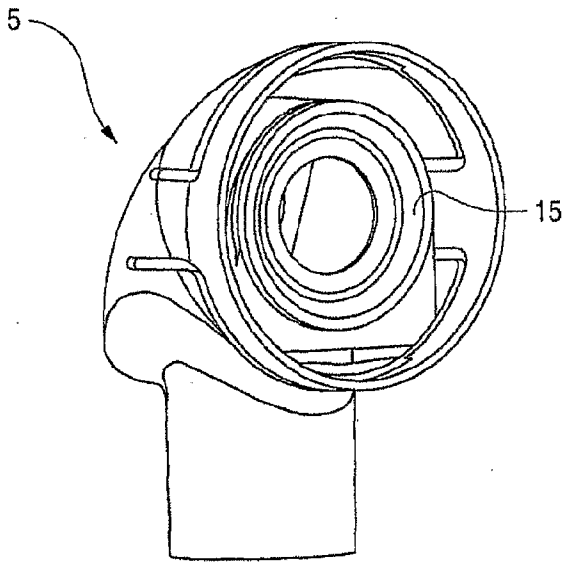


Fig. 11

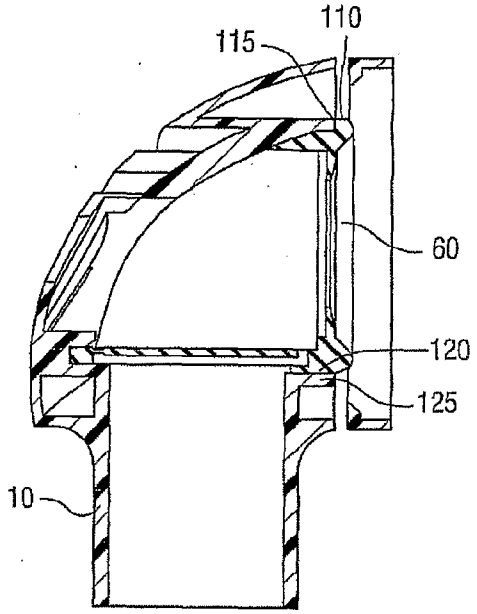


Fig. 12

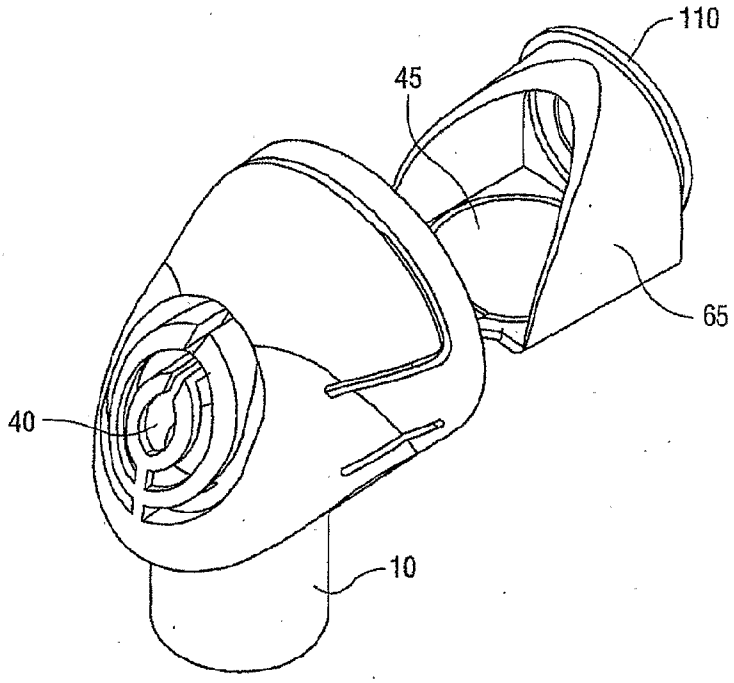


Fig. 13

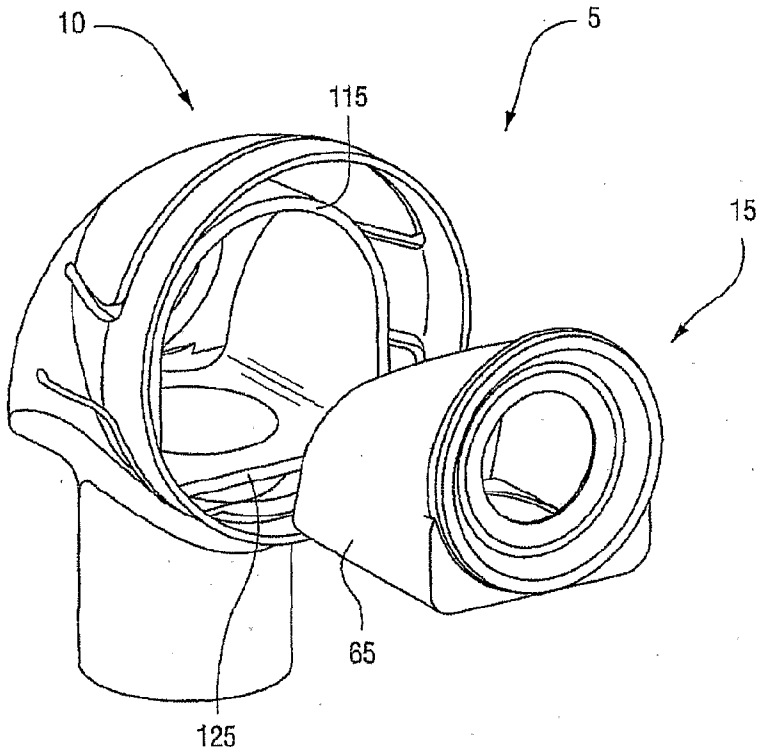


Fig. 14

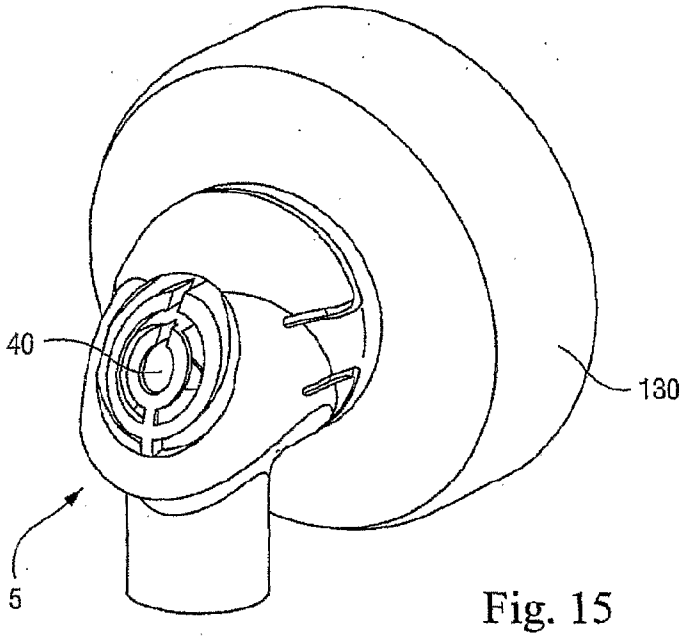


Fig. 15

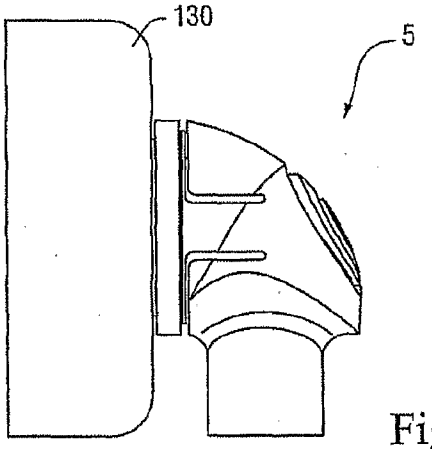


Fig. 16

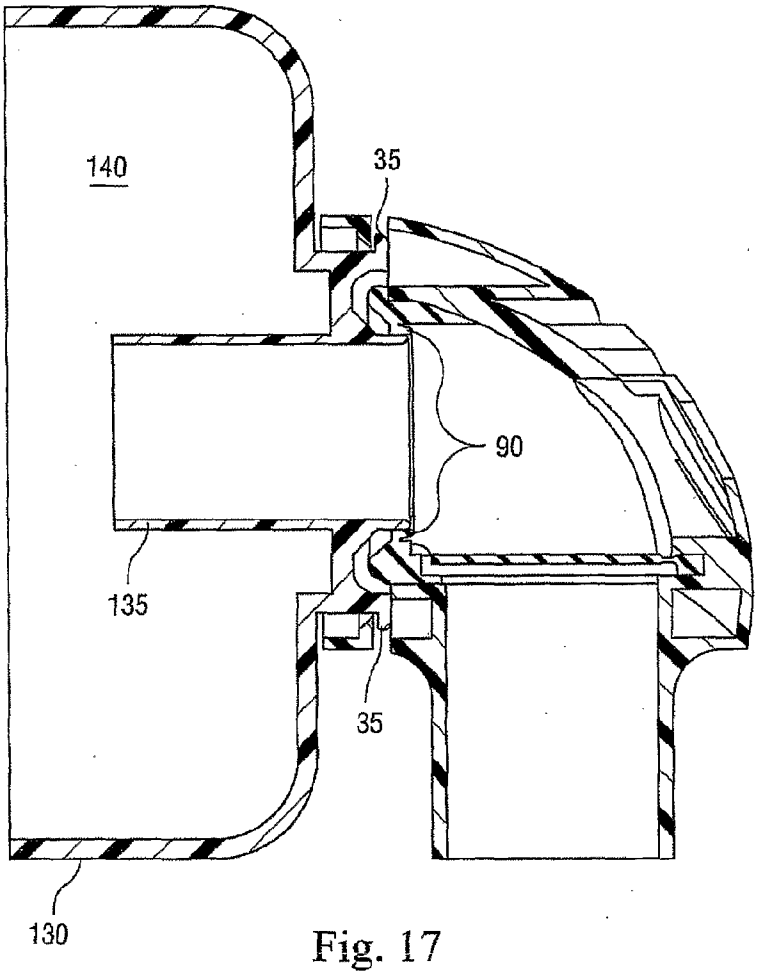


Fig. 17

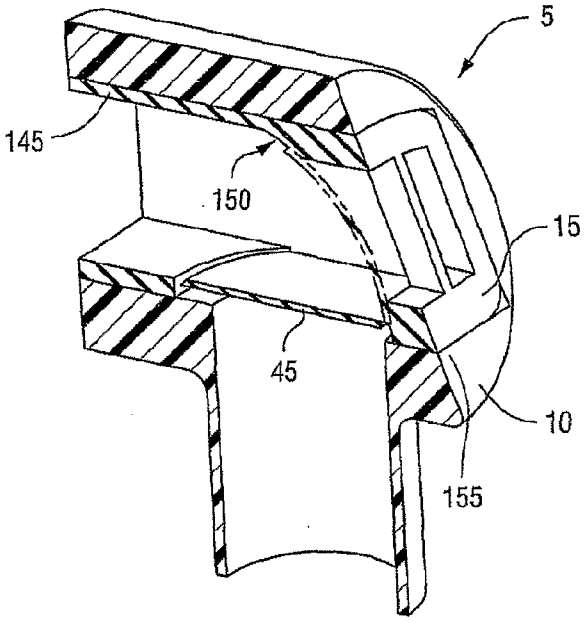


Fig. 18

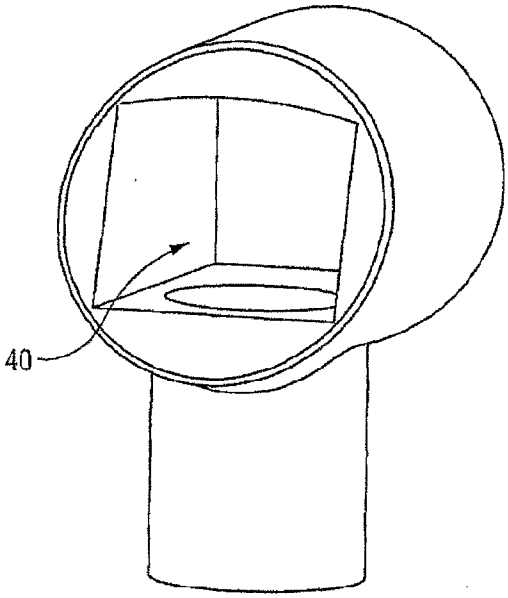


Fig. 19

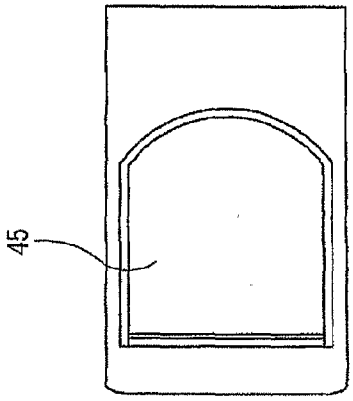


Fig. 22

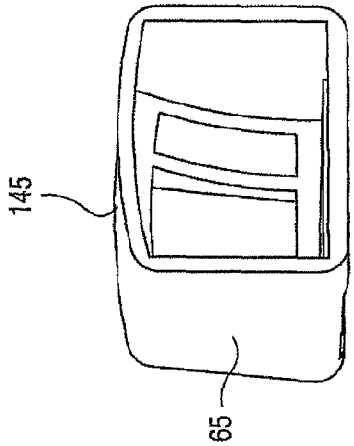


Fig. 21

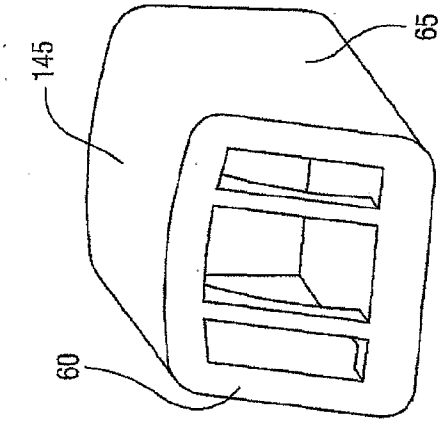


Fig. 20

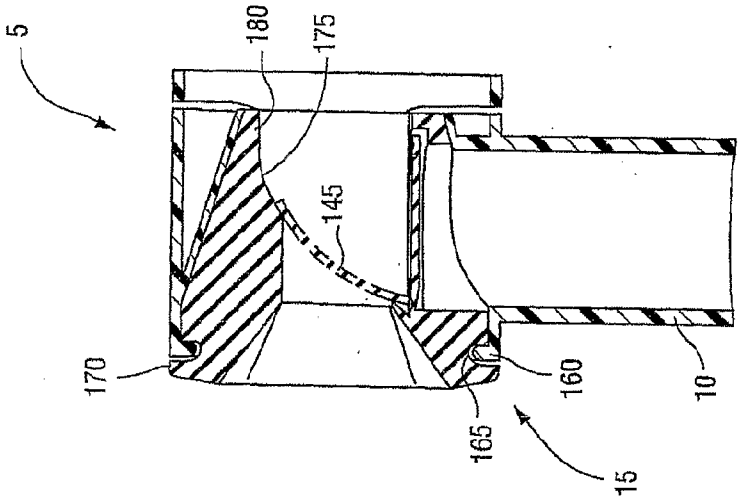


Fig. 25

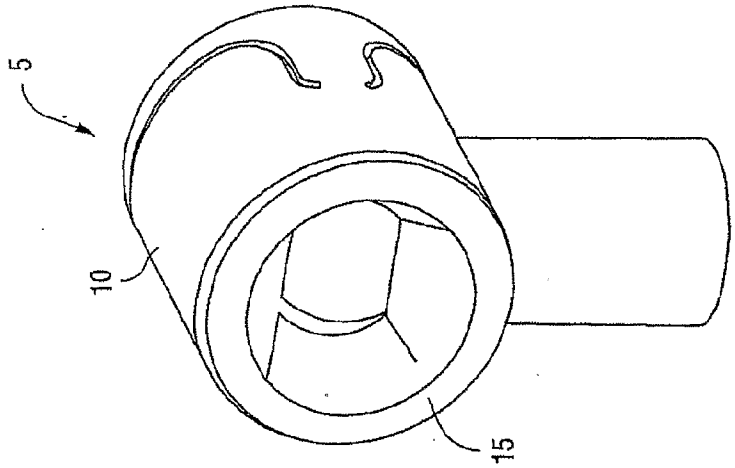


Fig. 24

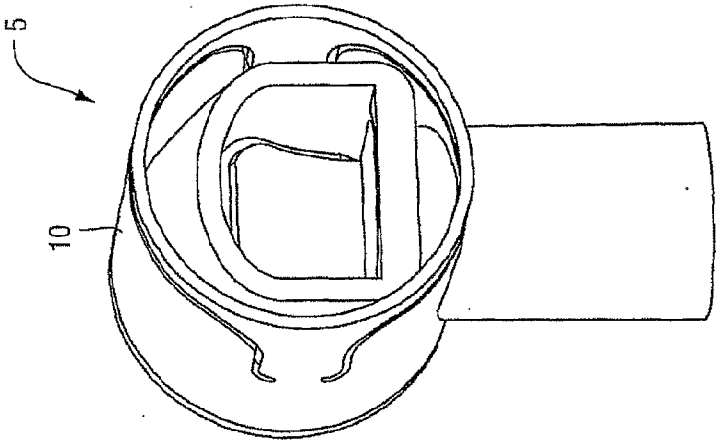


Fig. 23

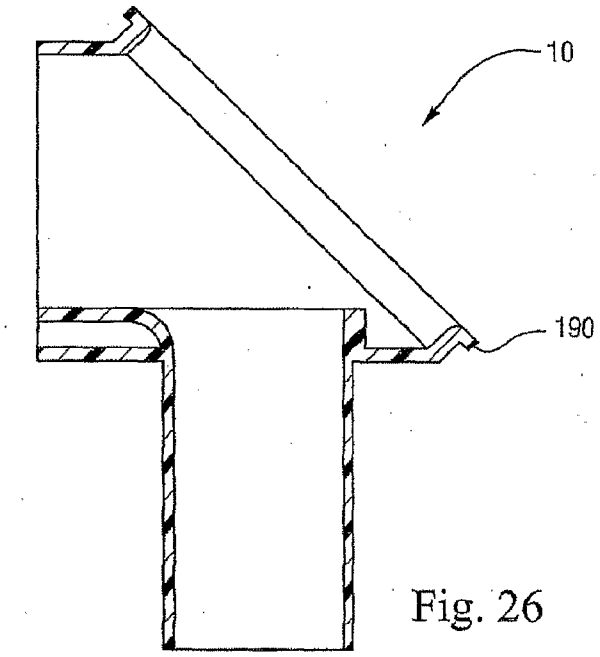


Fig. 26

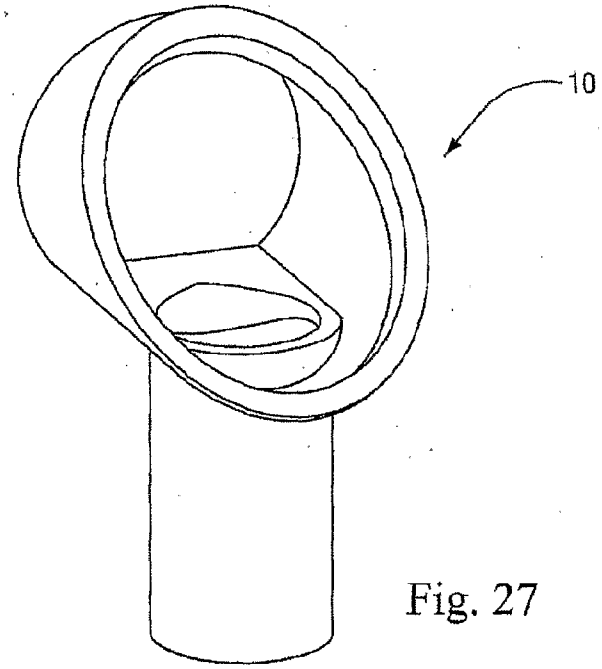


Fig. 27

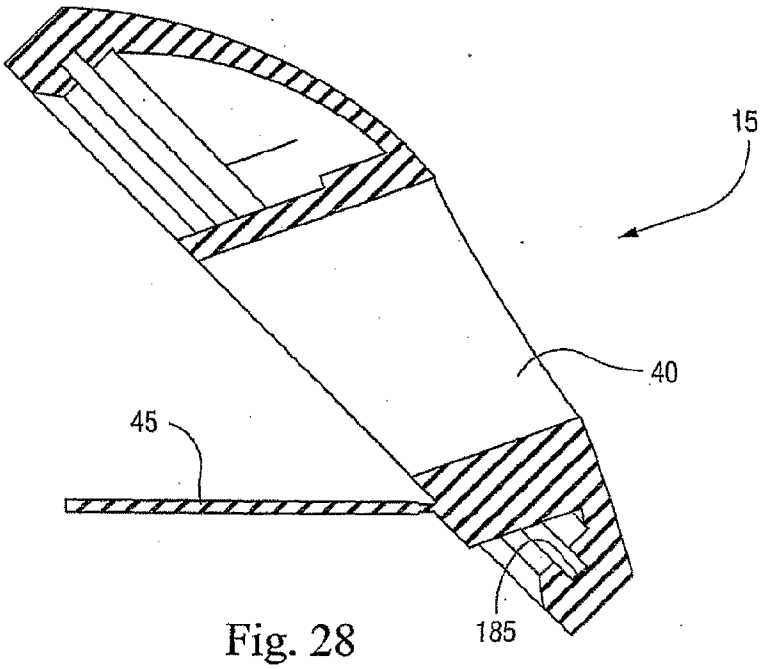


Fig. 28

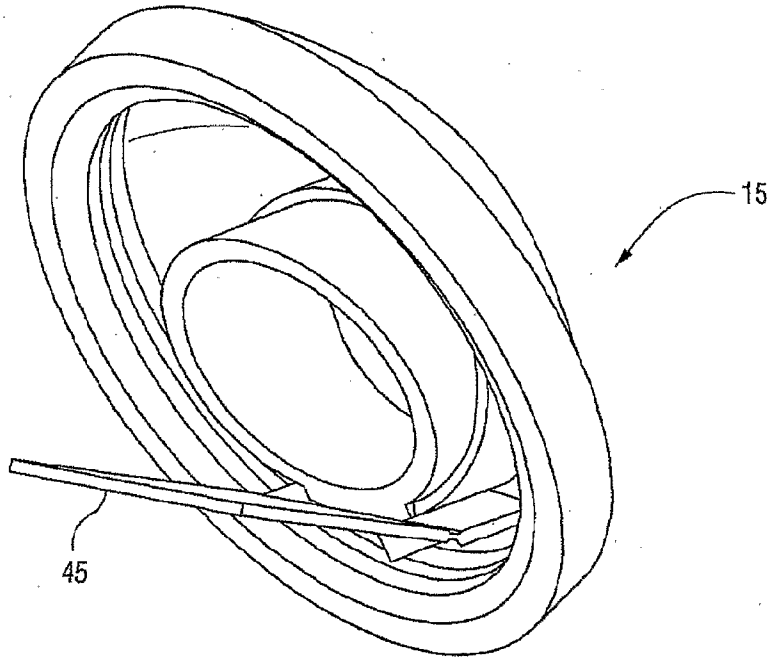


Fig. 29

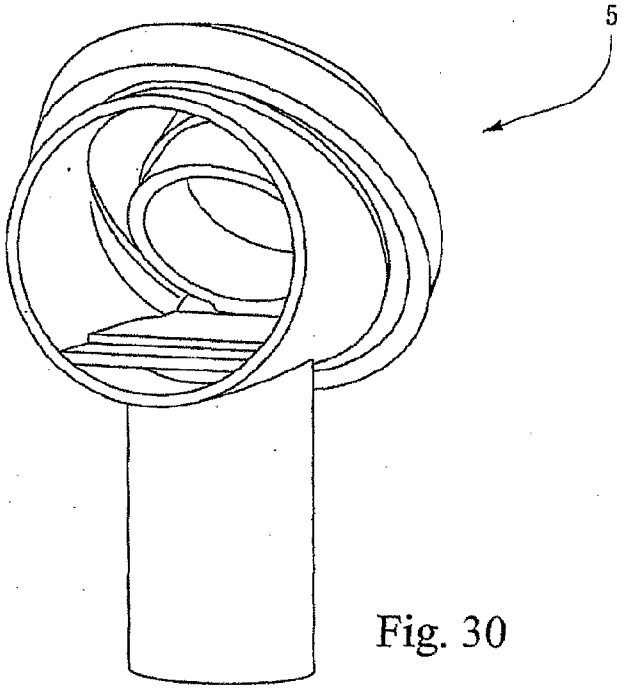


Fig. 30

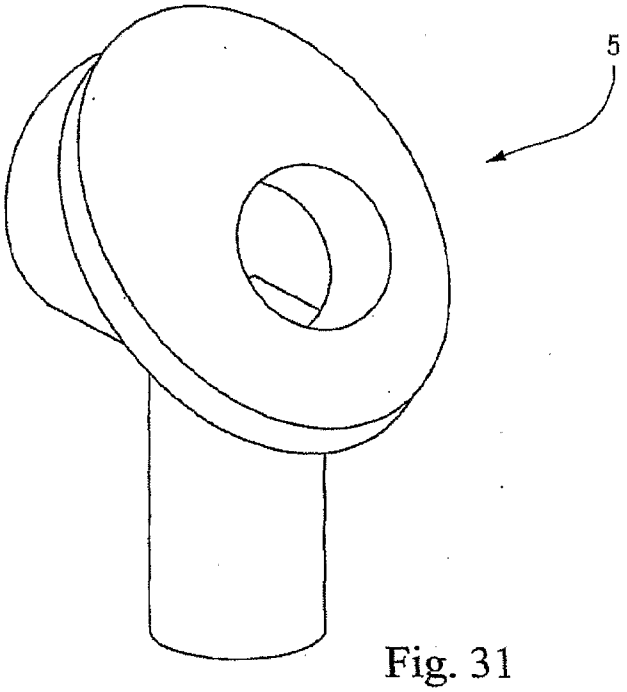


Fig. 31

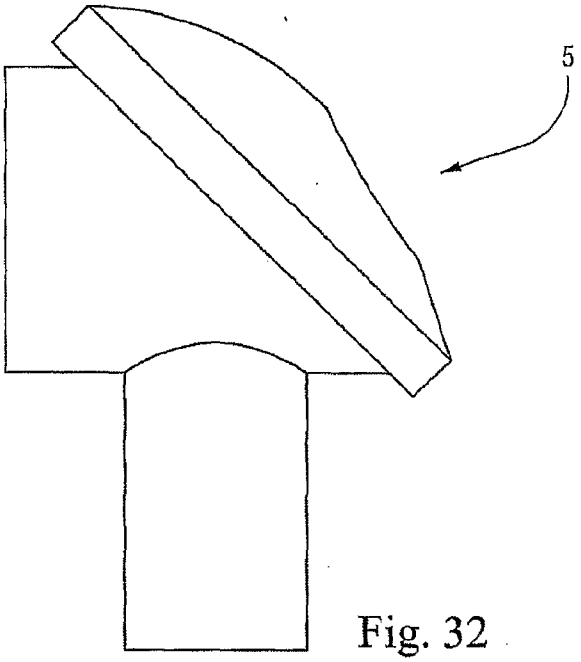


Fig. 32

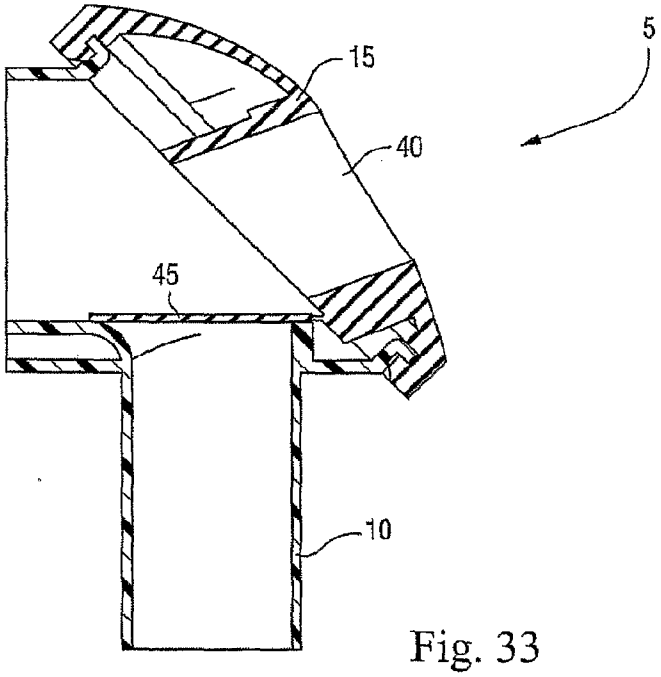


Fig. 33

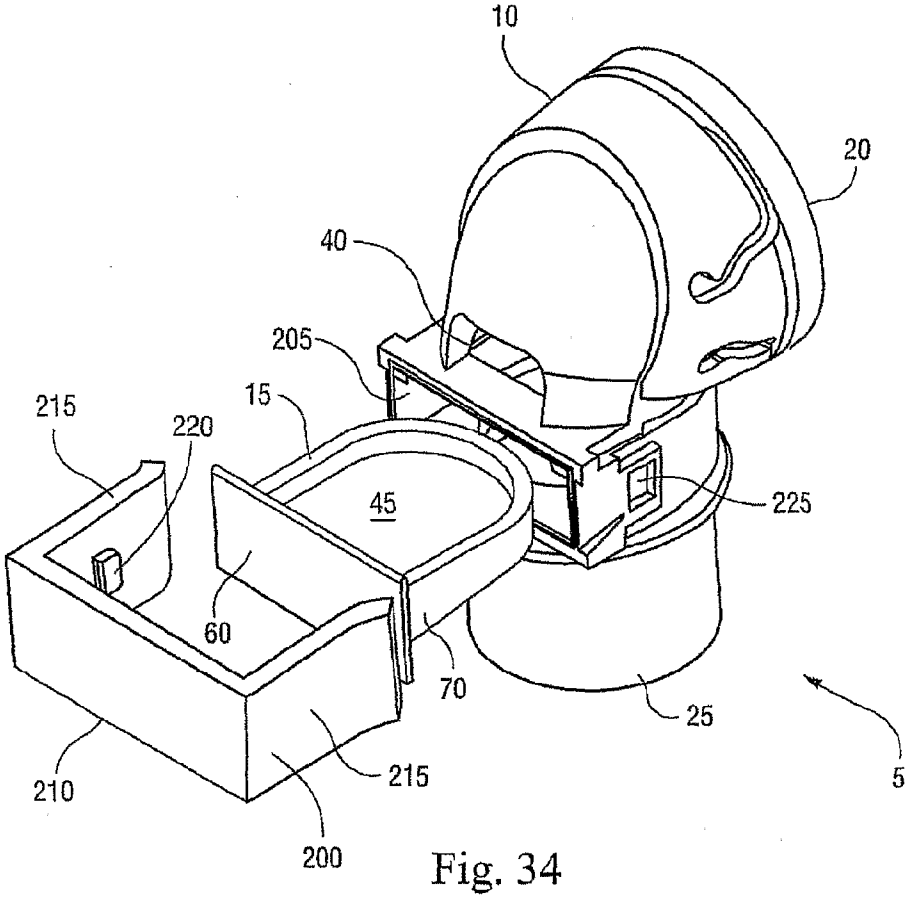


Fig. 34

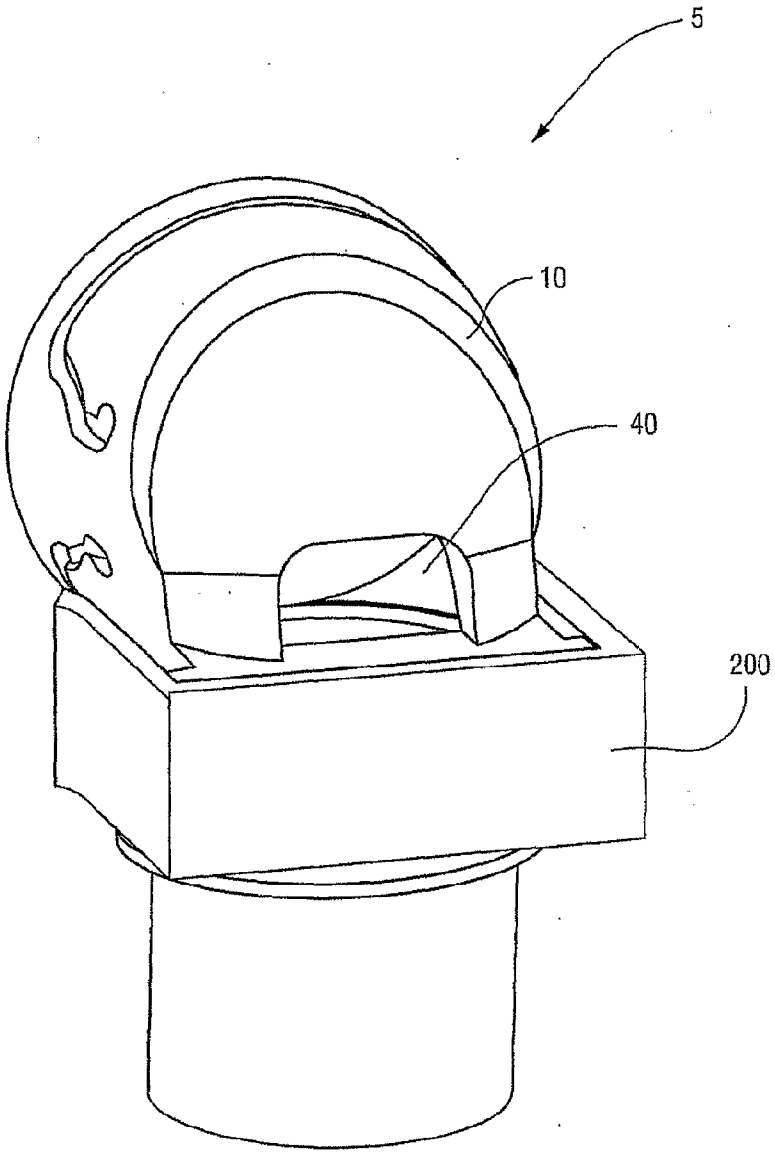


Fig. 35

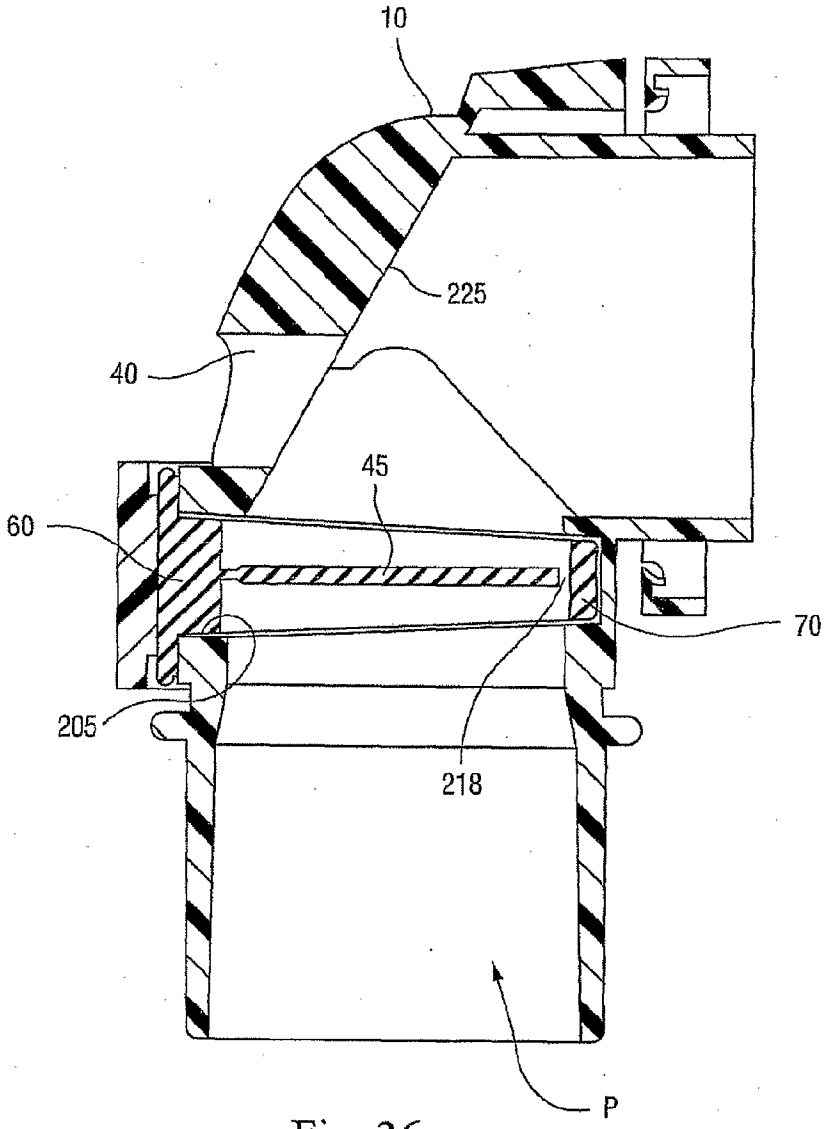


Fig. 36

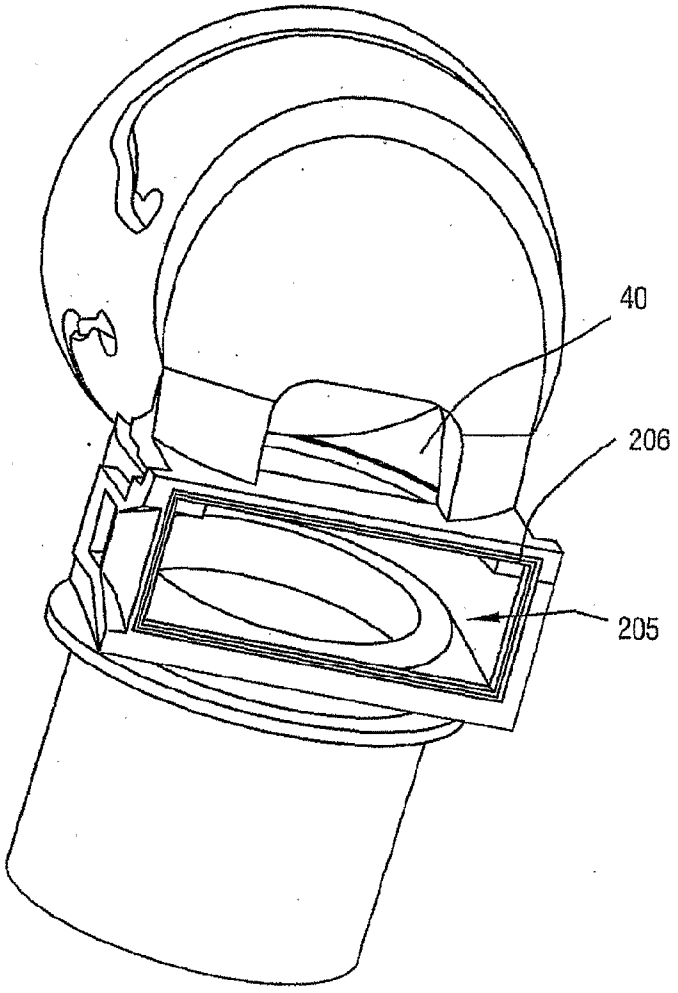
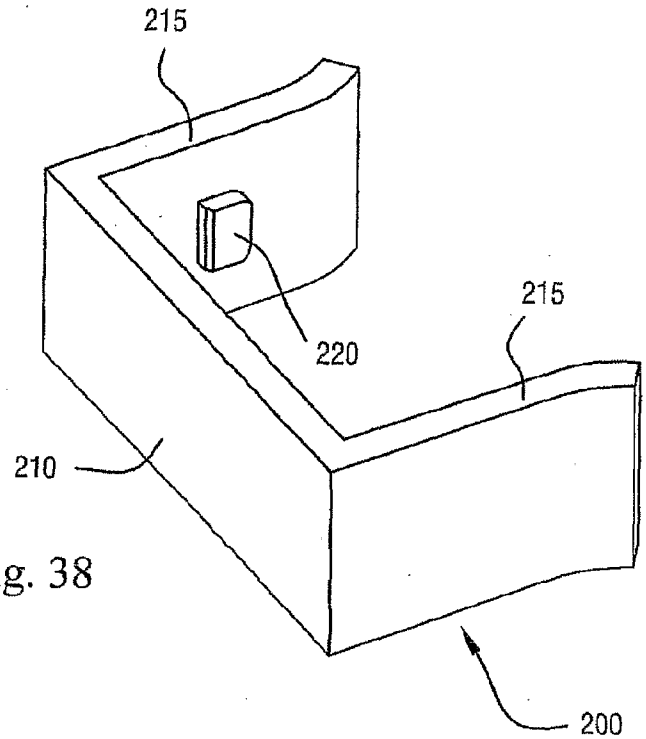


Fig. 37



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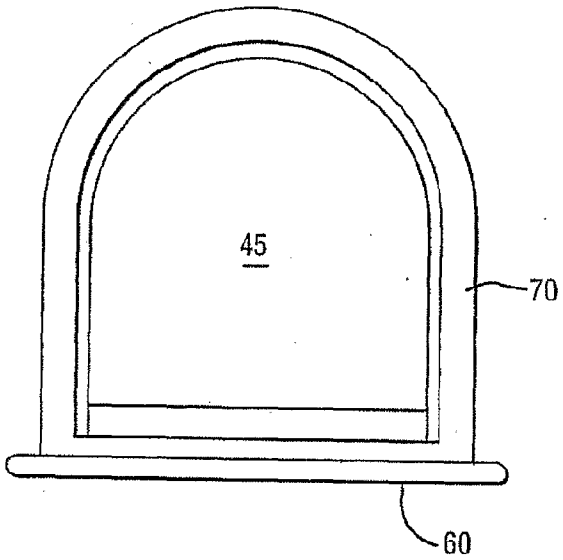

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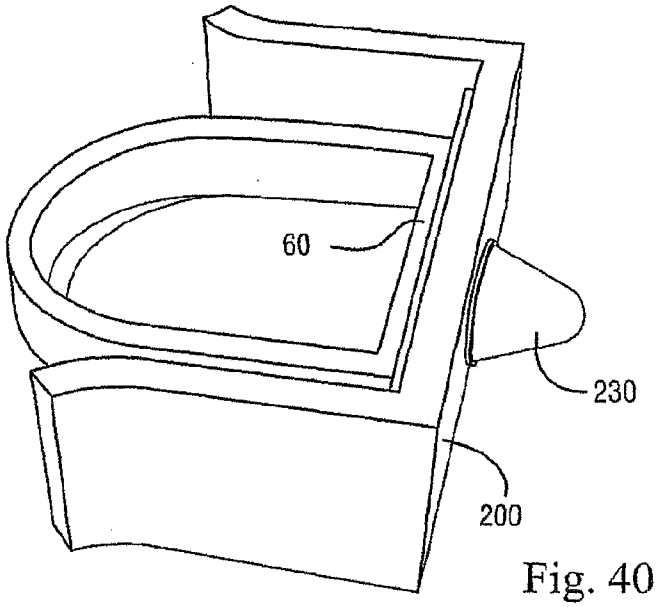

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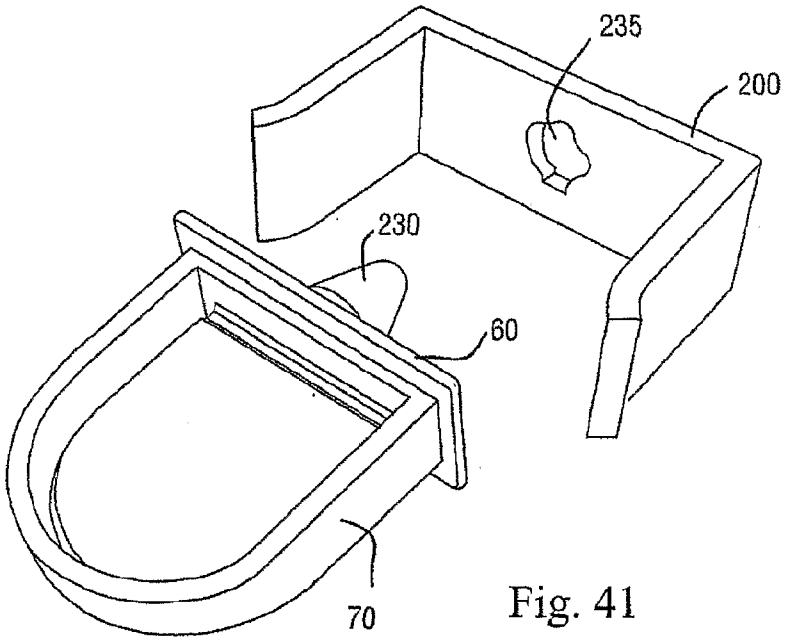

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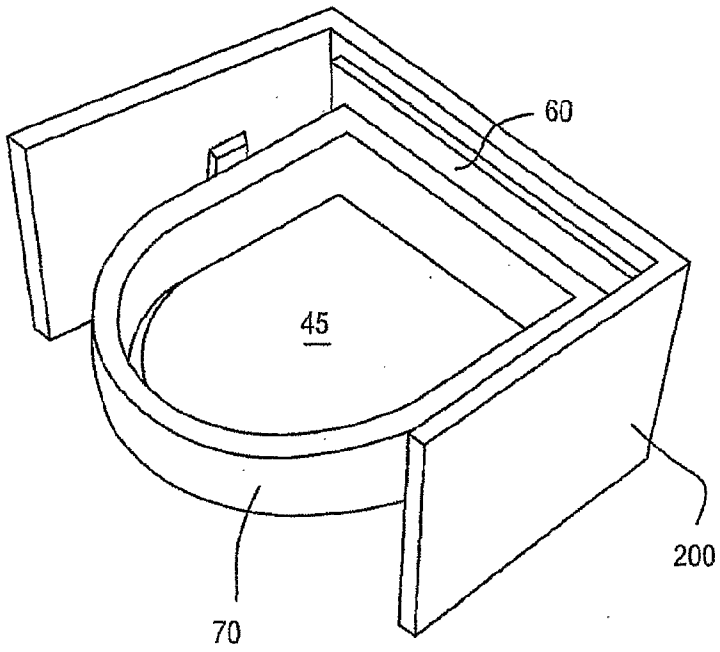

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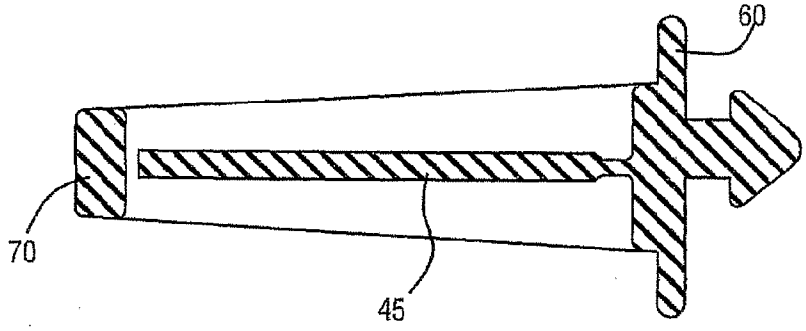

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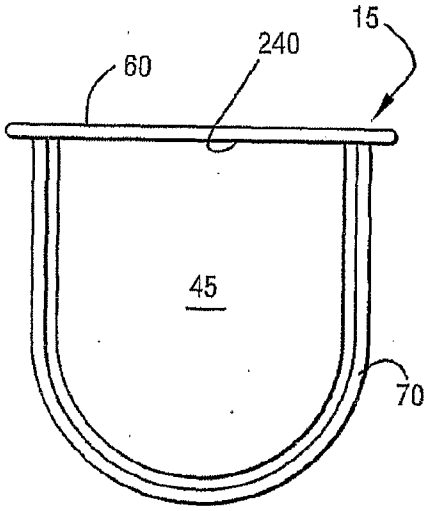

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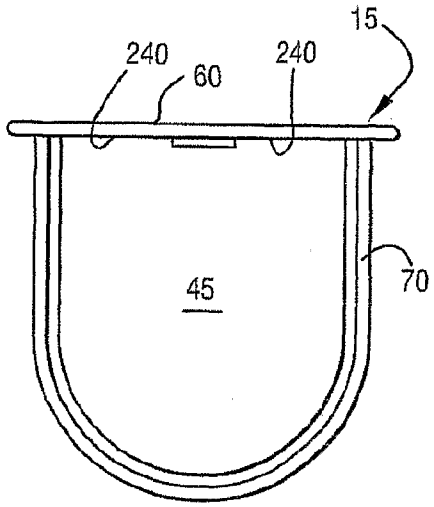

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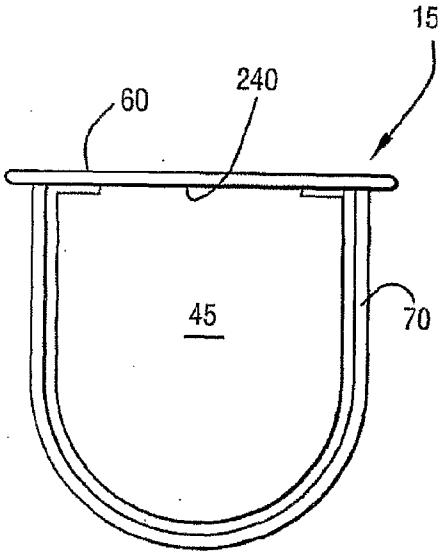

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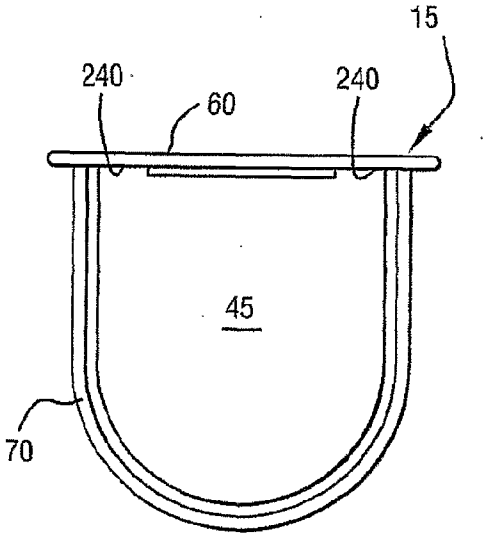

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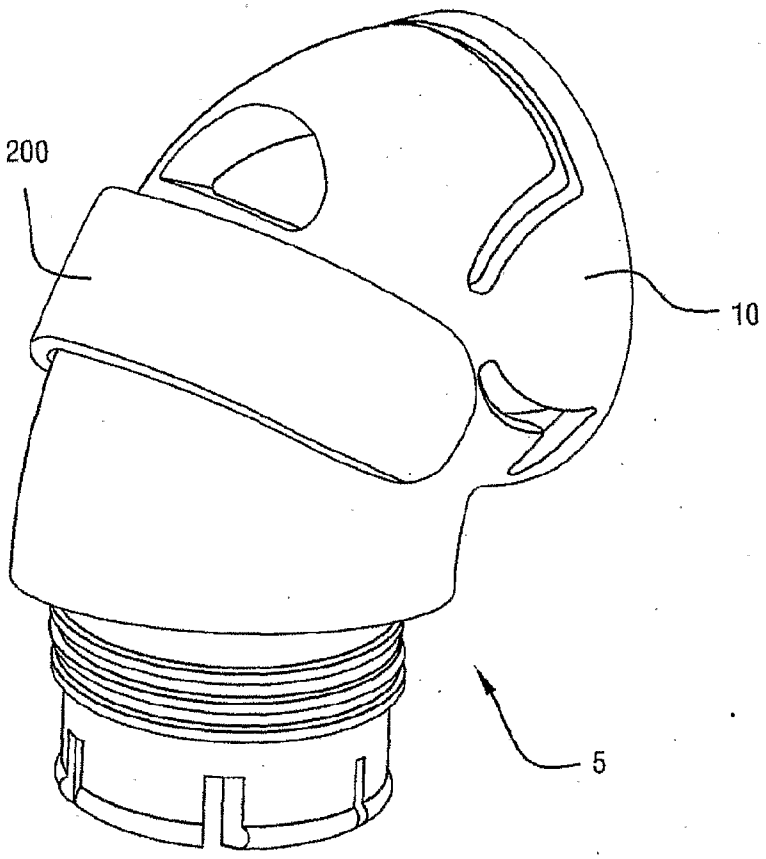

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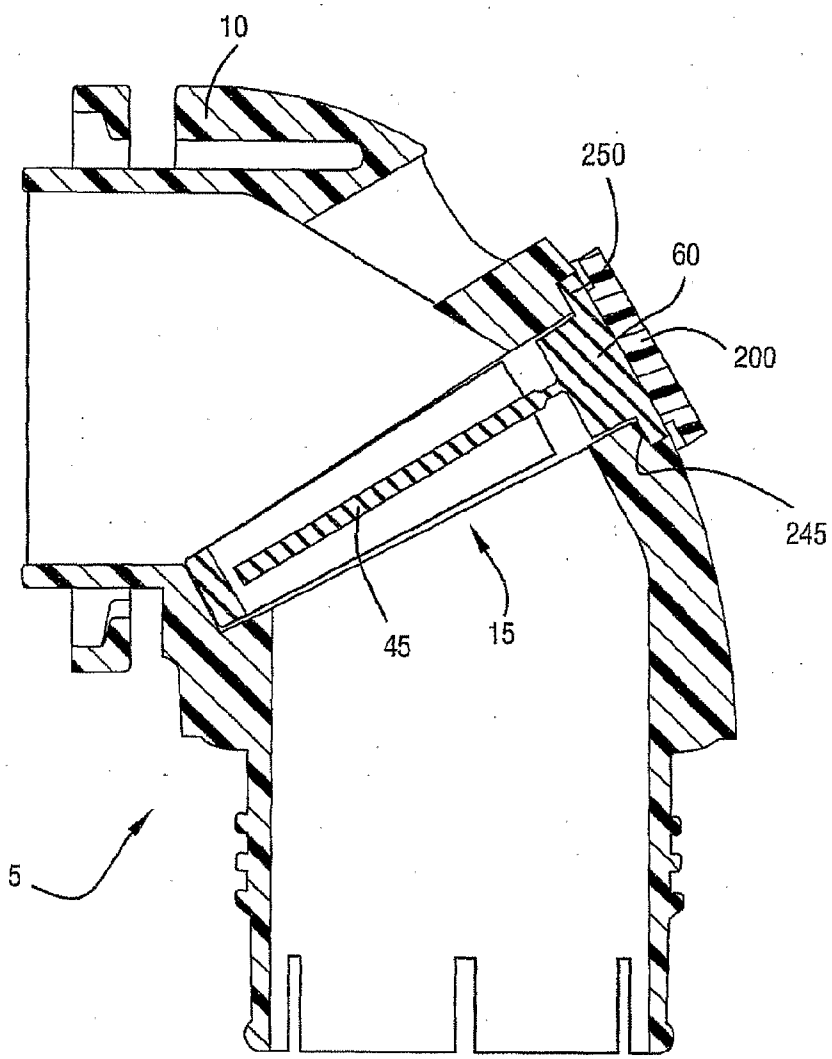

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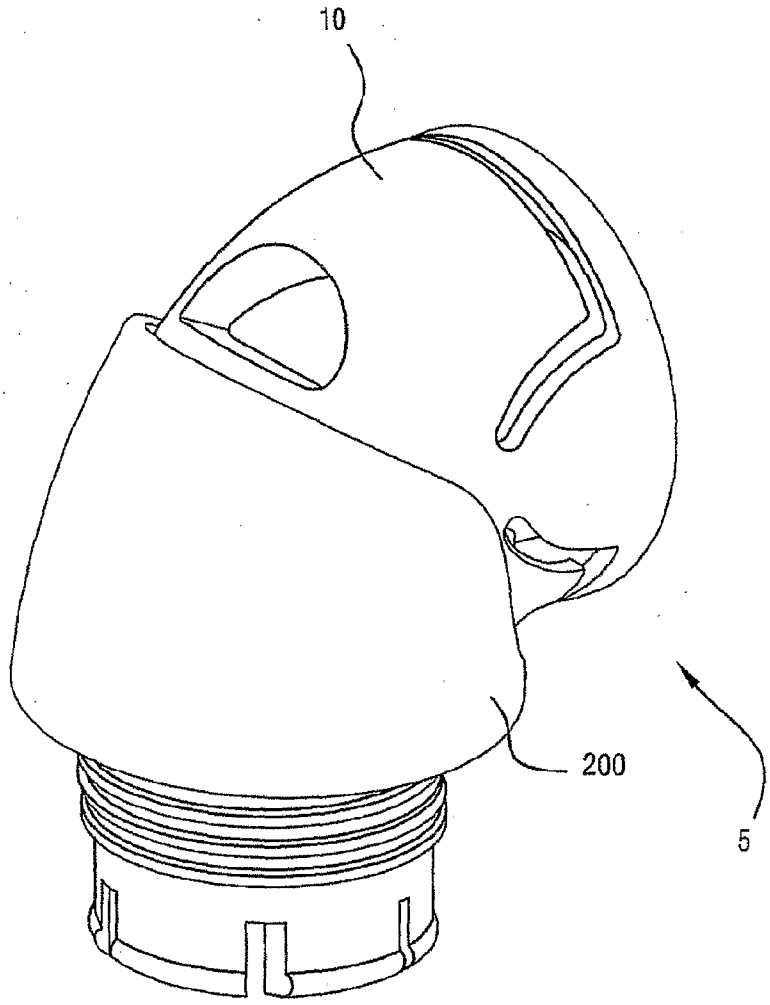

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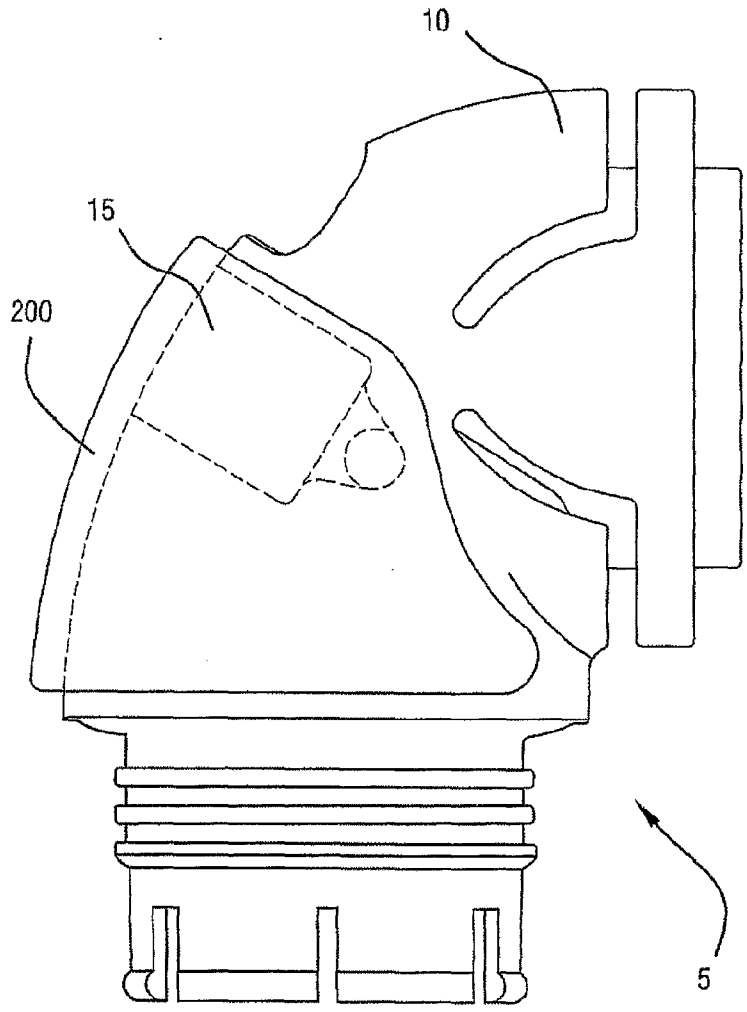

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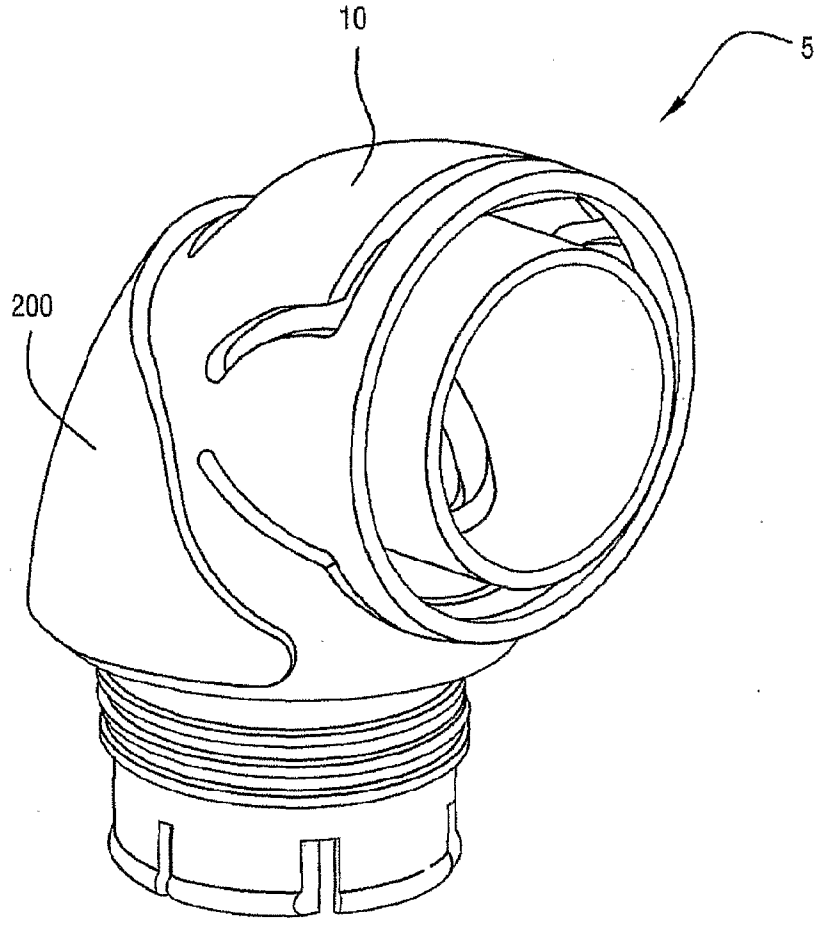

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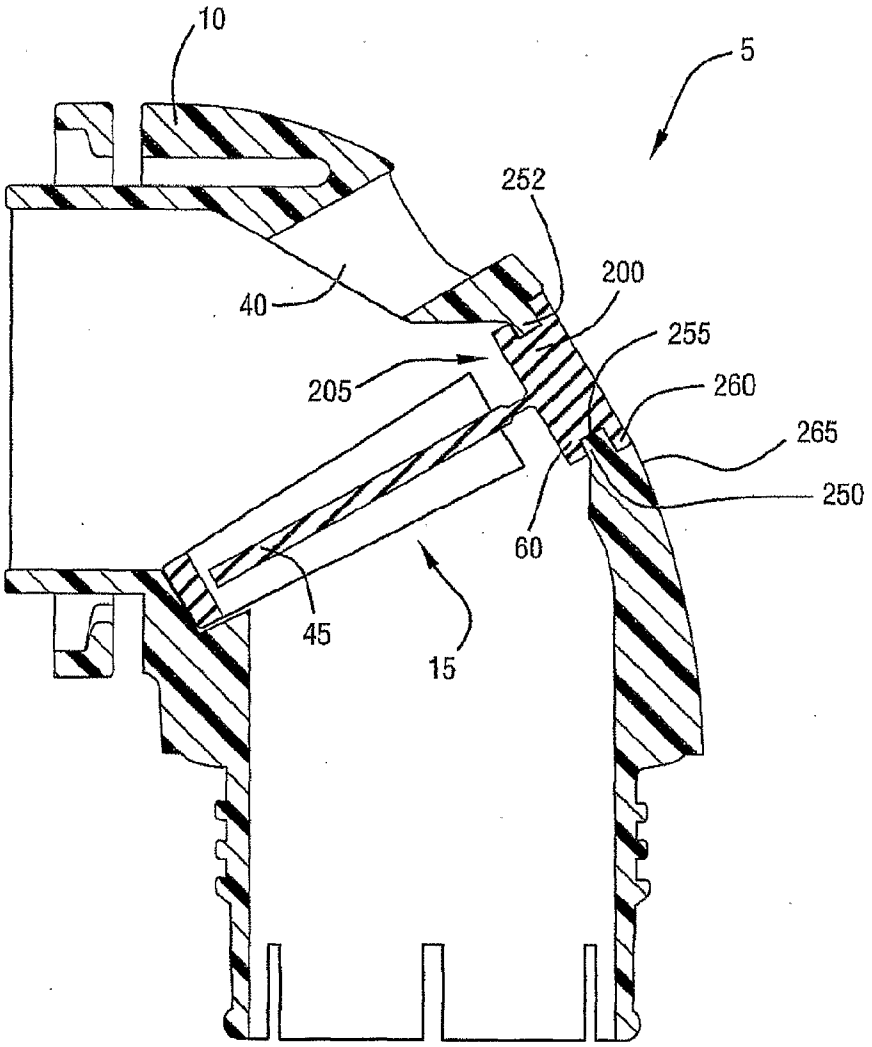

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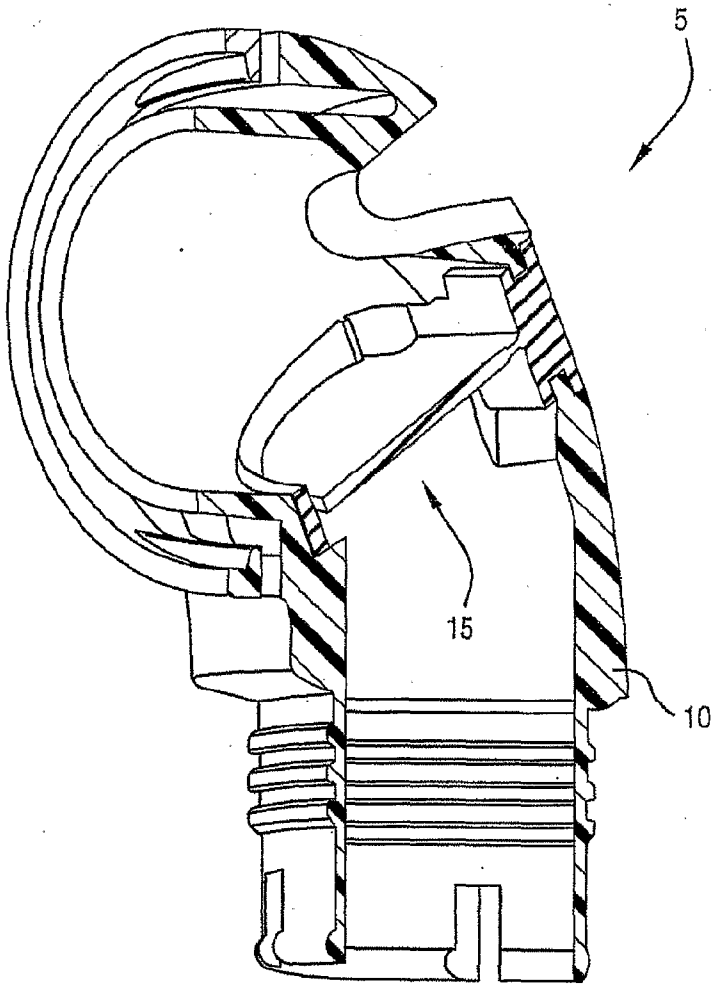

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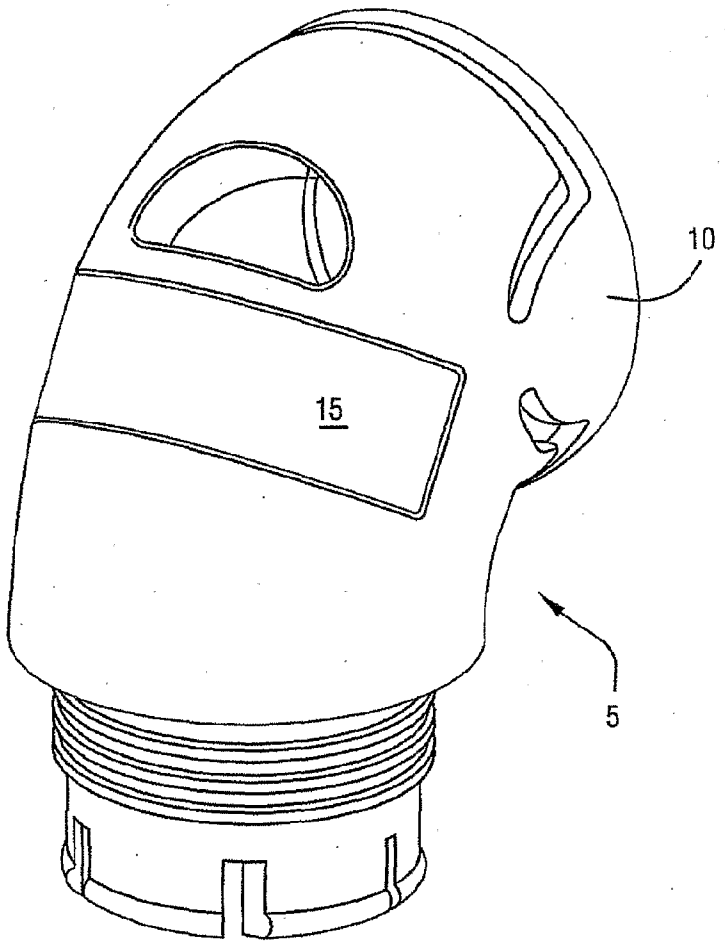

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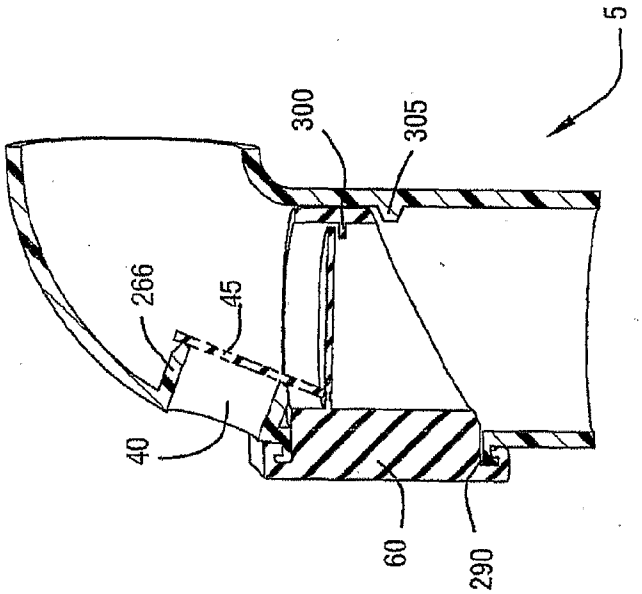

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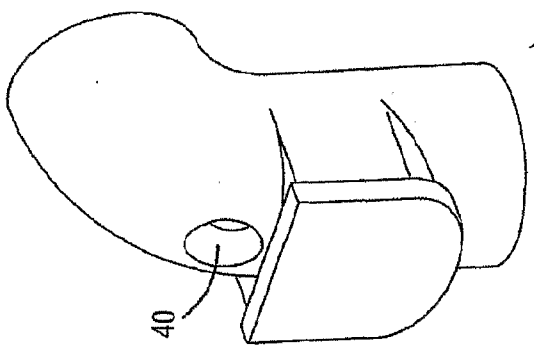

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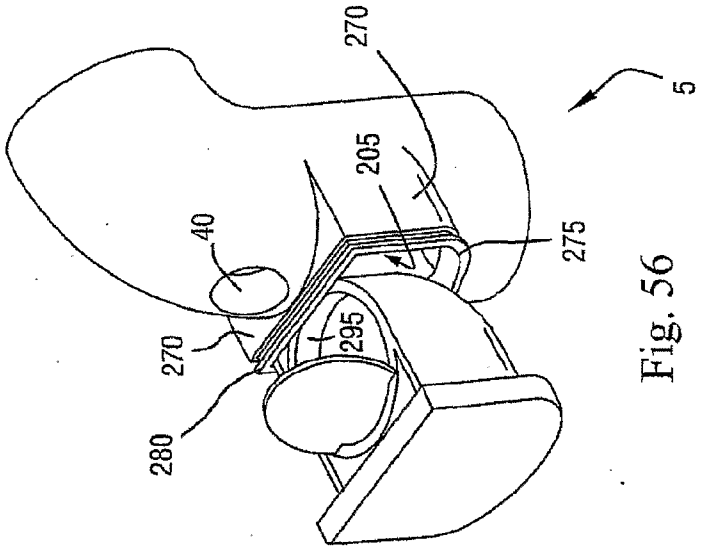

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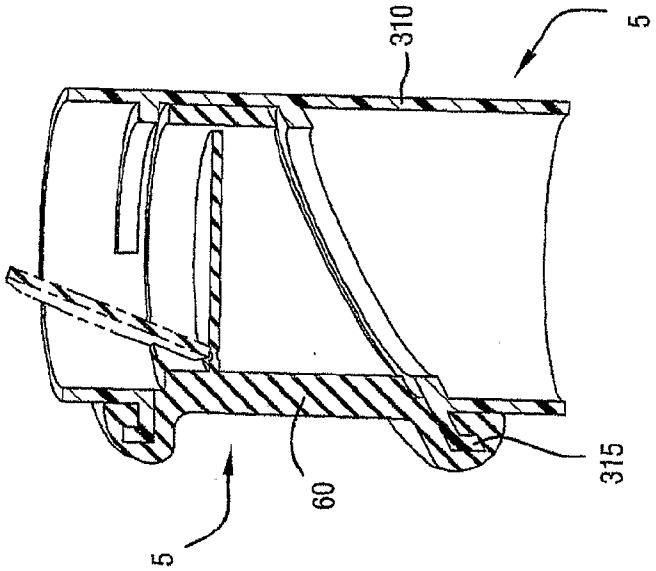

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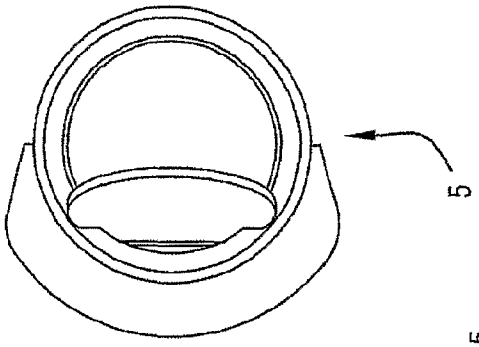

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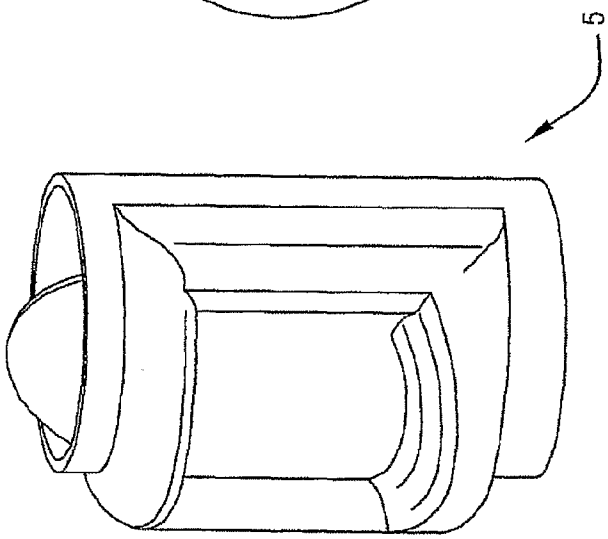

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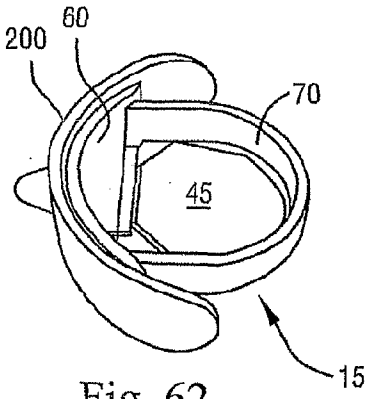

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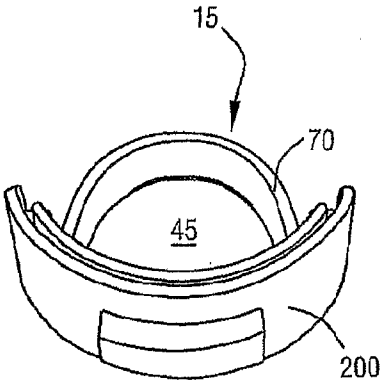

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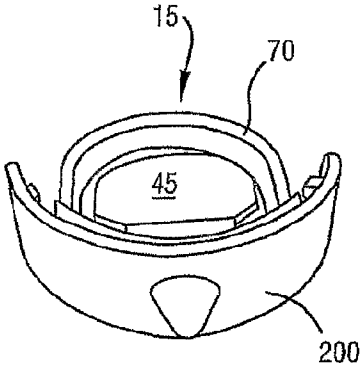

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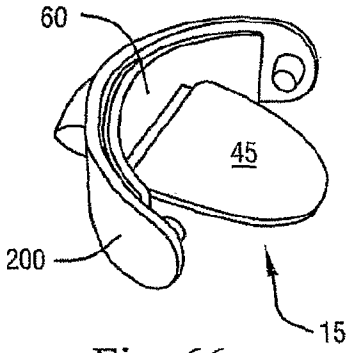

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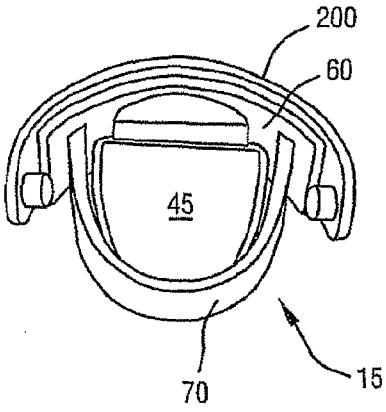

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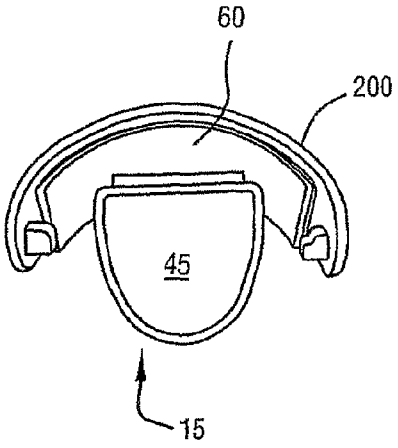

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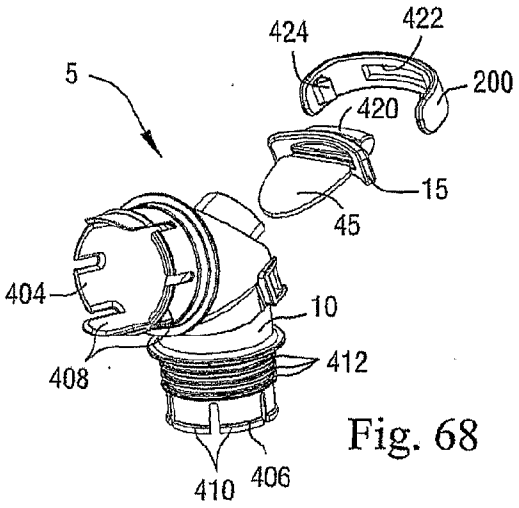

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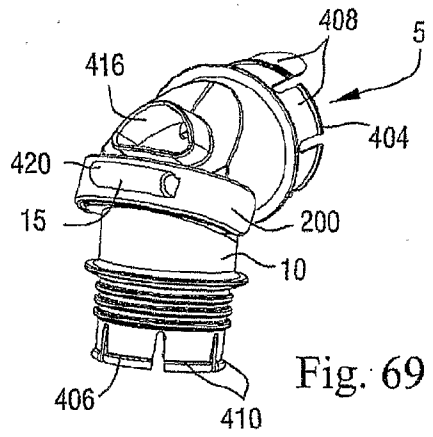

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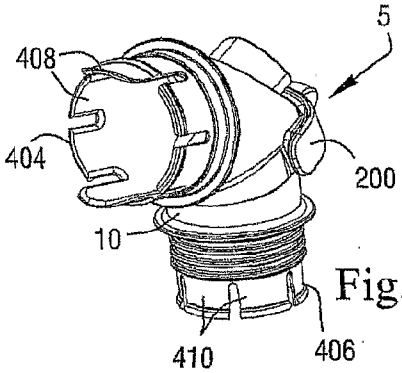

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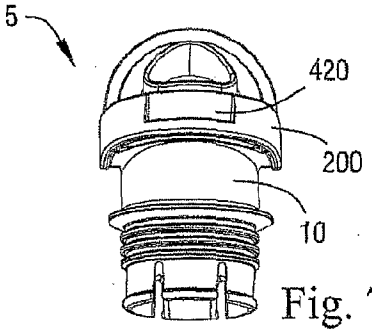

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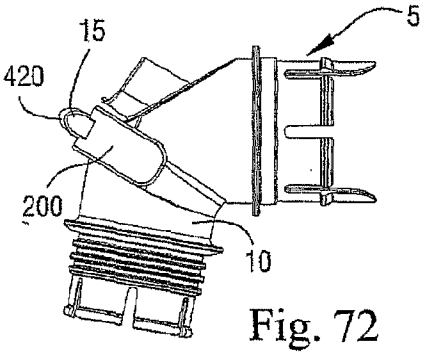

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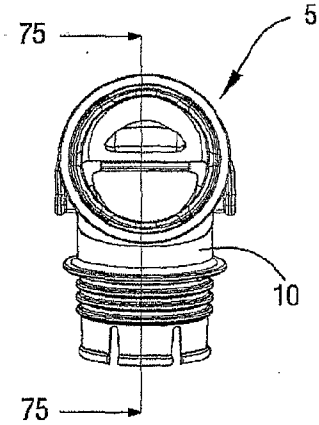

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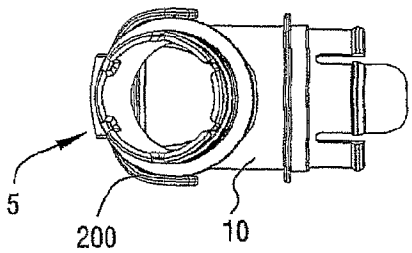
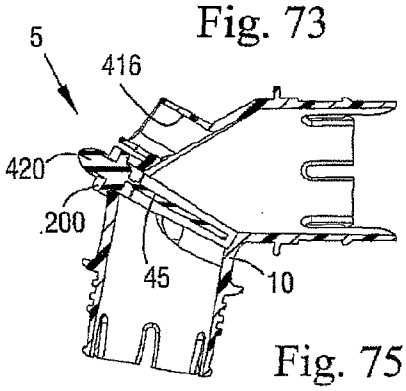


Fig.74



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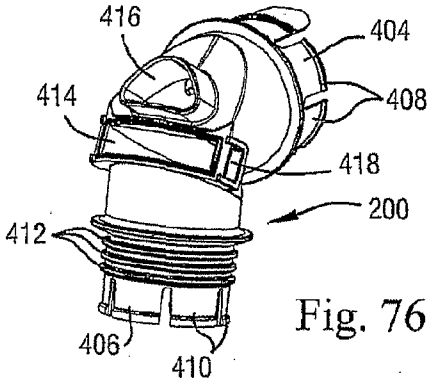

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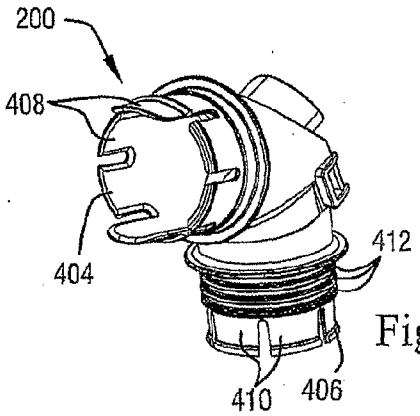

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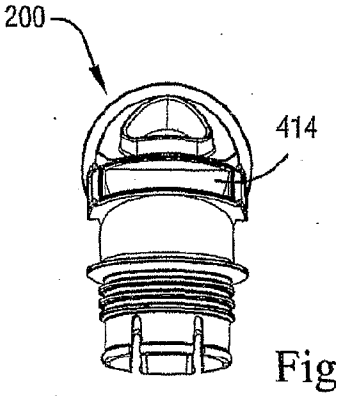

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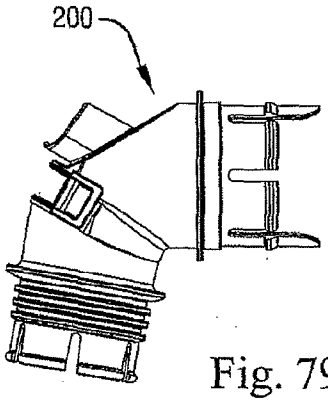


Fig. 79

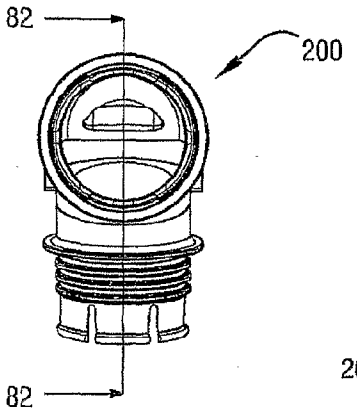


Fig. 80

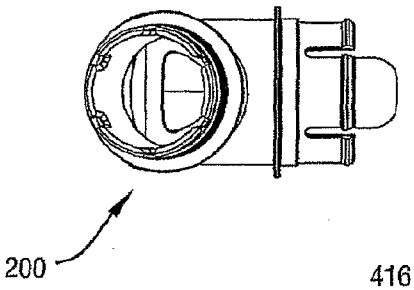
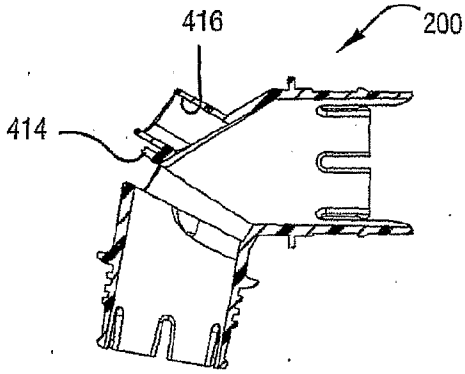


Fig. 81



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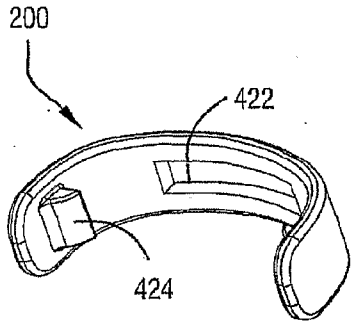


Fig. 83

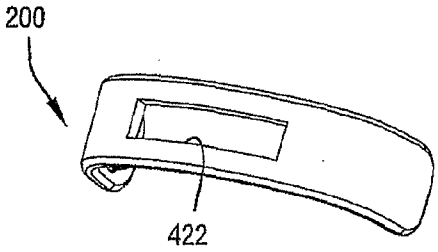


Fig. 84

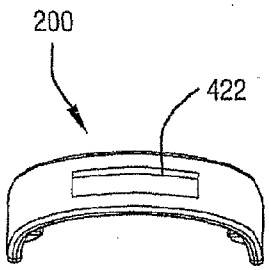
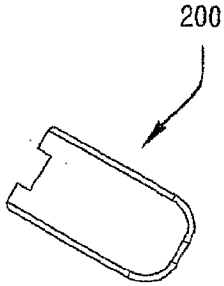


Fig. 85



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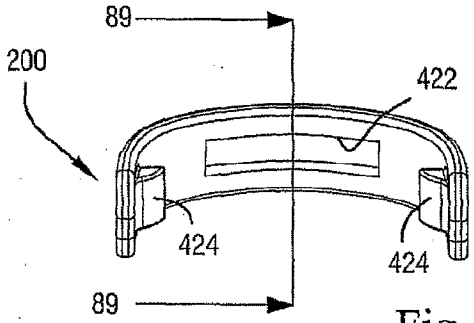
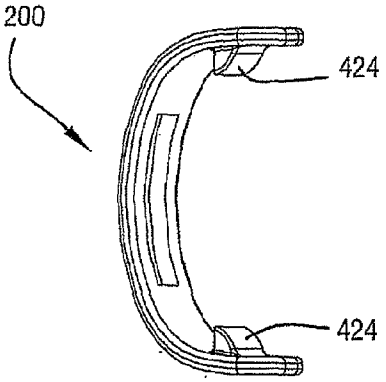


Fig. 87



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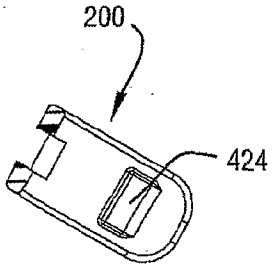

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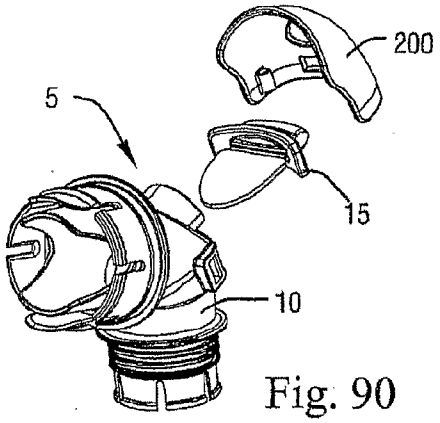

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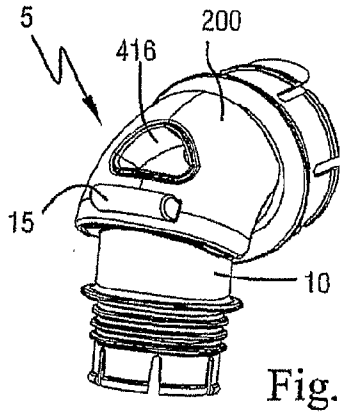


Fig. 91

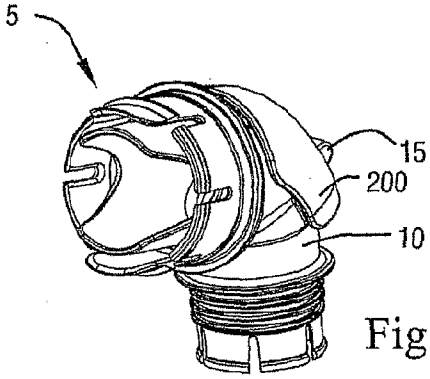


Fig. 92

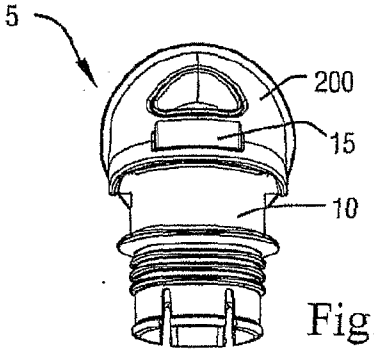


Fig. 93

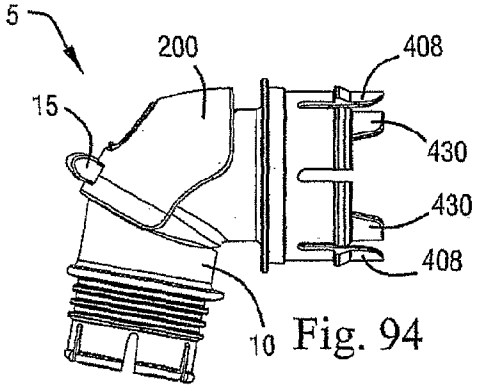


Fig. 94

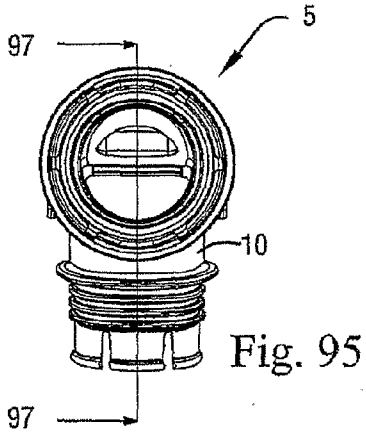


Fig. 95

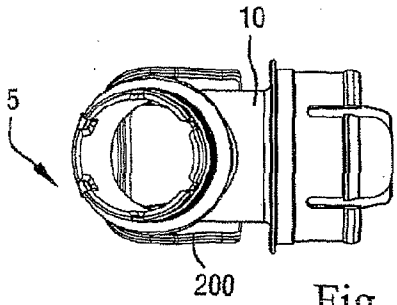


Fig. 96

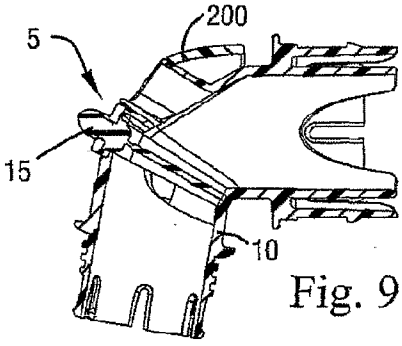


Fig. 97

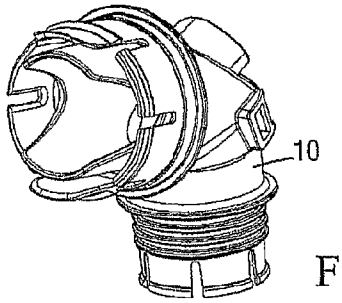
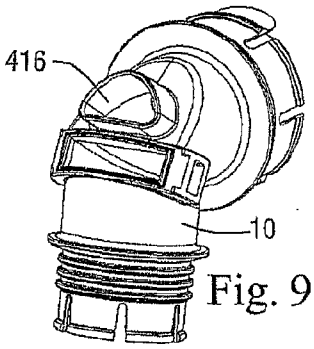


Fig. 98



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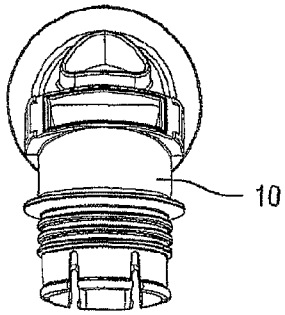


Fig. 100

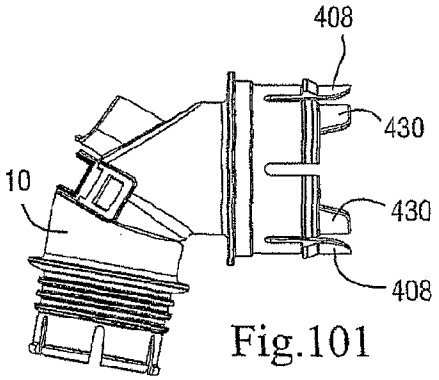
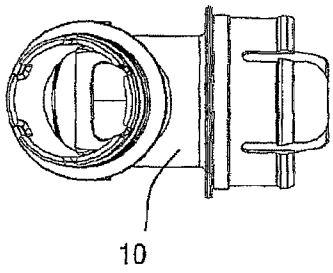


Fig.101



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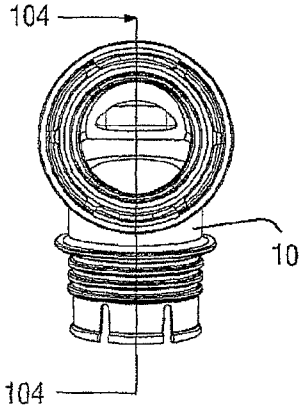

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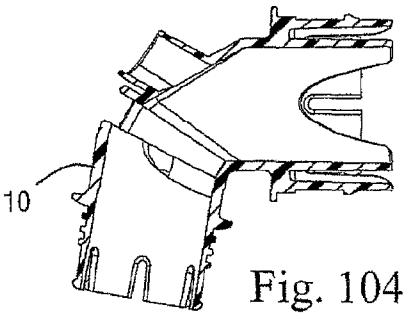

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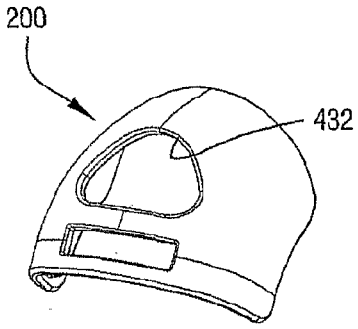

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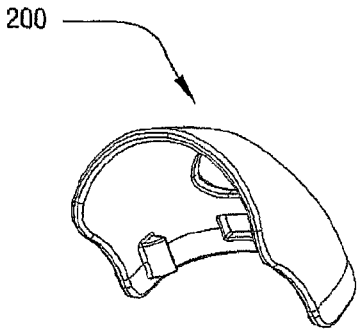

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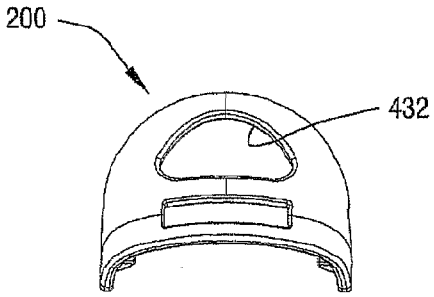

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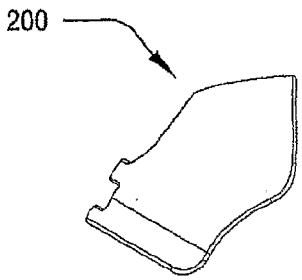

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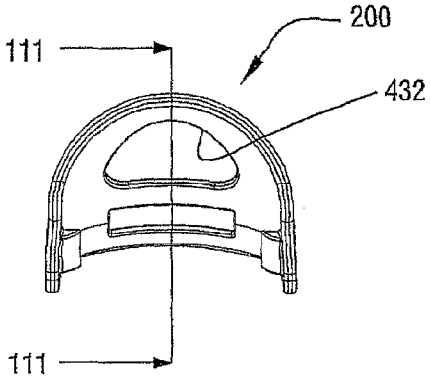

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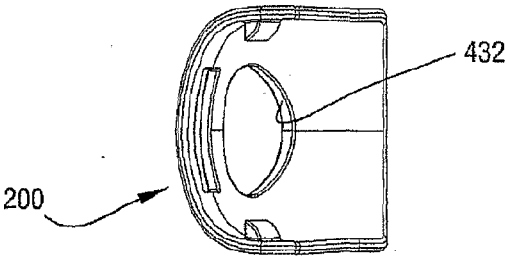

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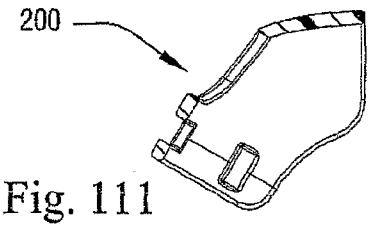

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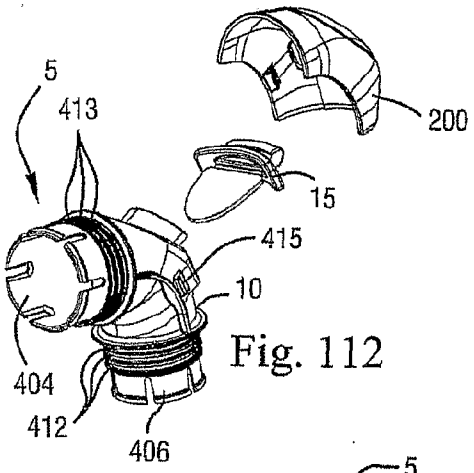

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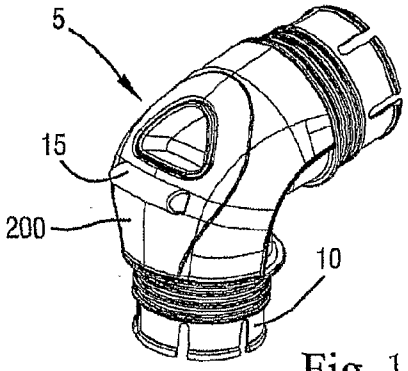
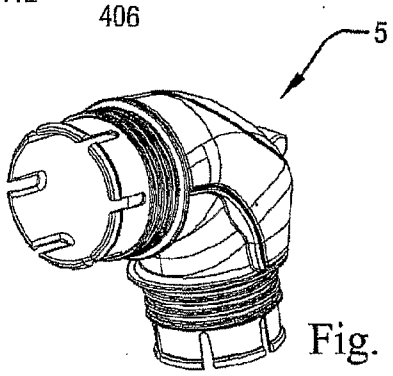


Fig. 113



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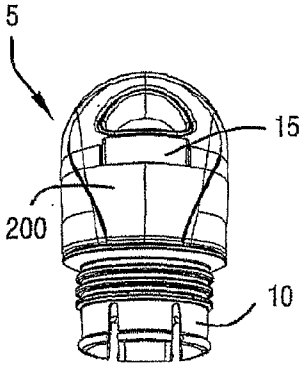

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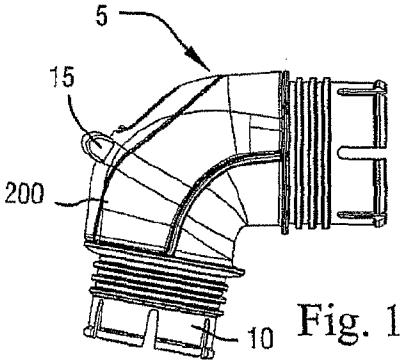

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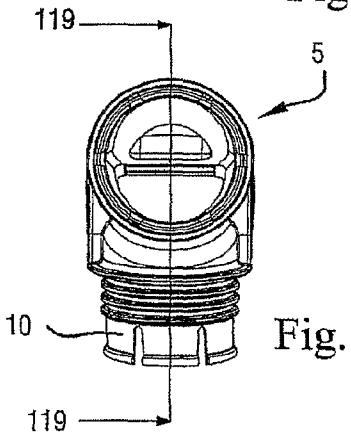

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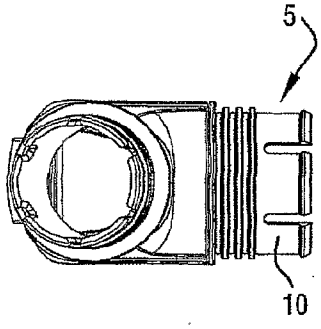

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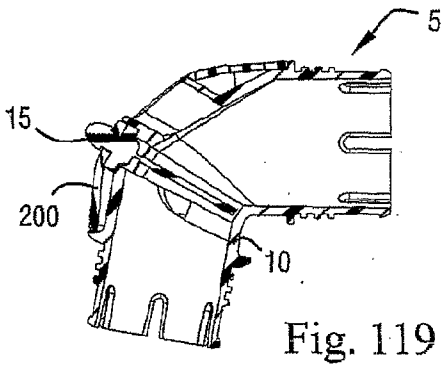

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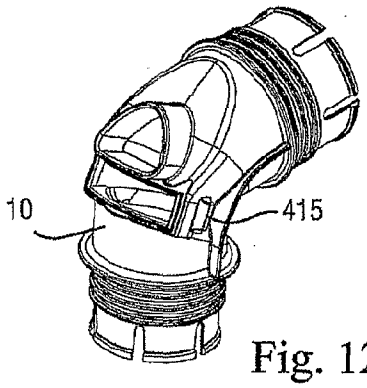

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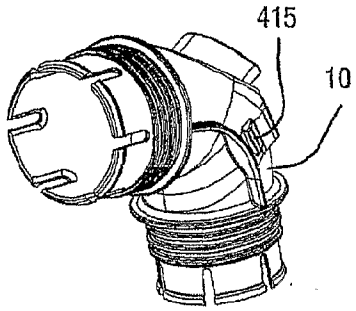

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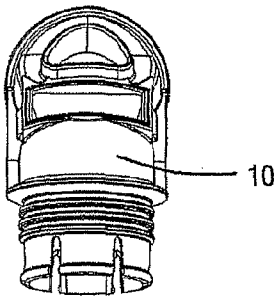

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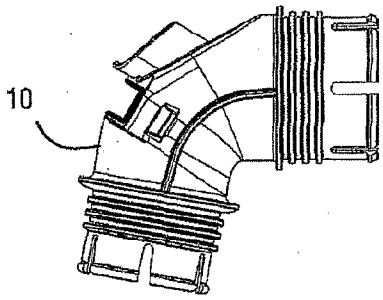

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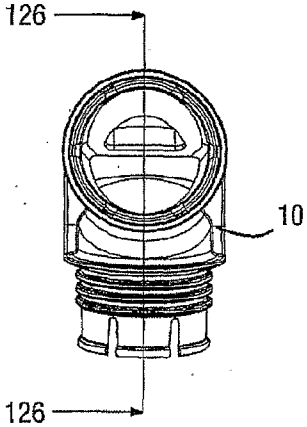

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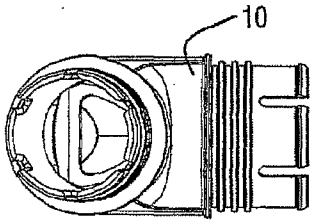

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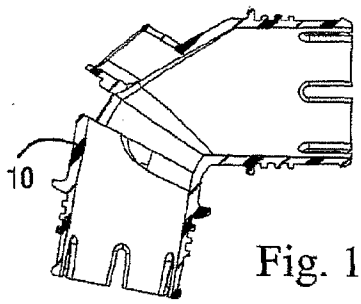

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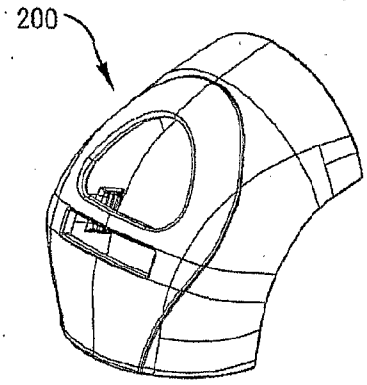

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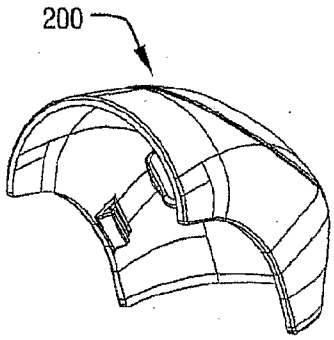

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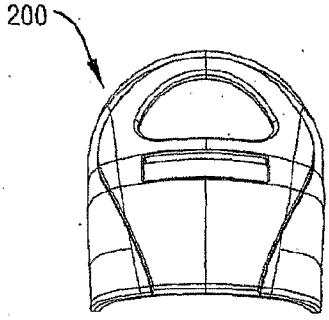

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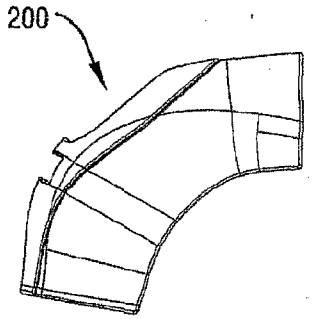

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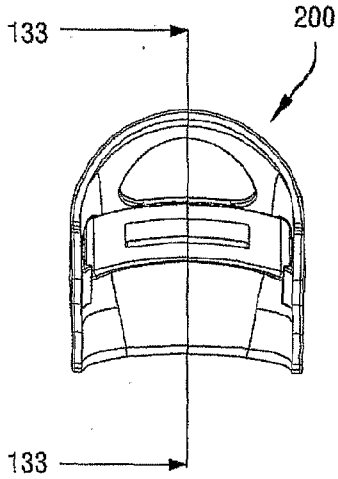

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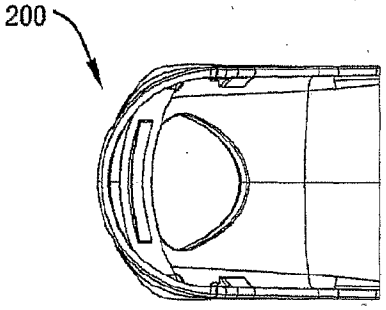

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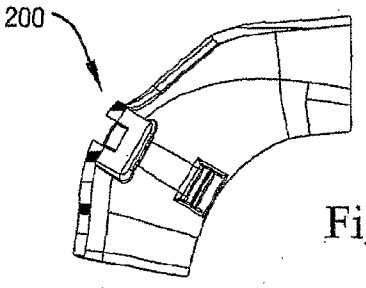

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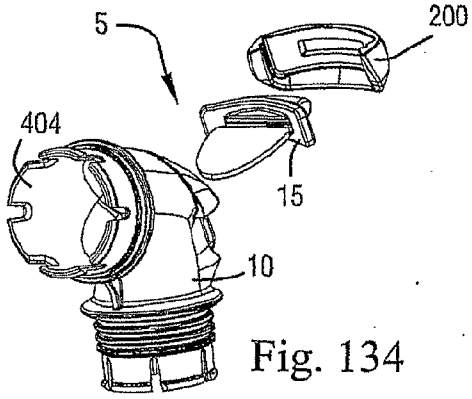

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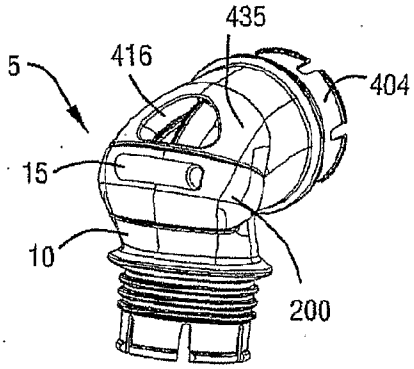

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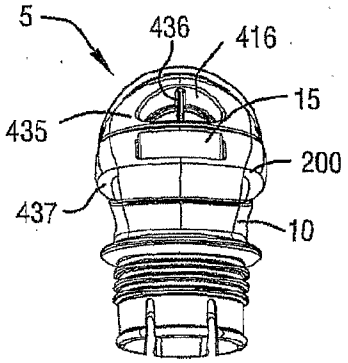
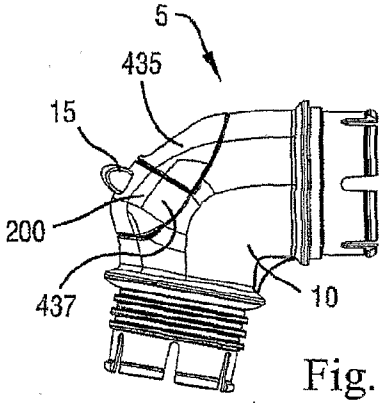


Fig. 136



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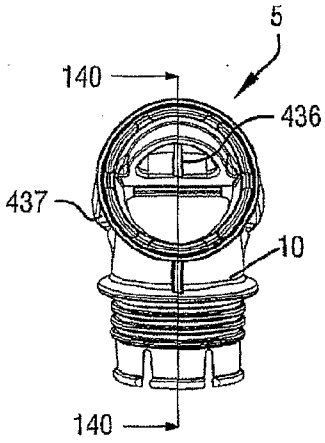


Fig. 138

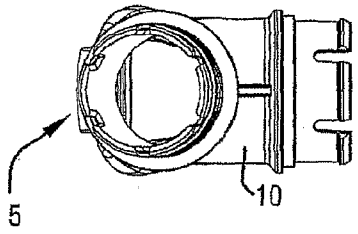


Fig. 139

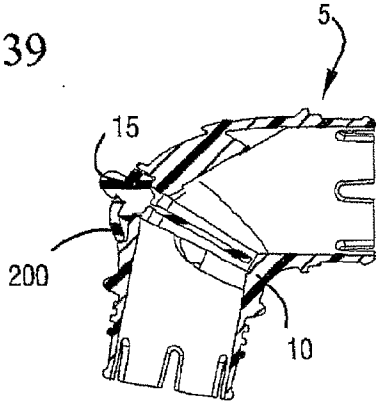


Fig. 140

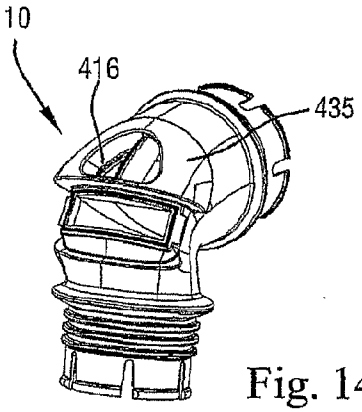


Fig. 141

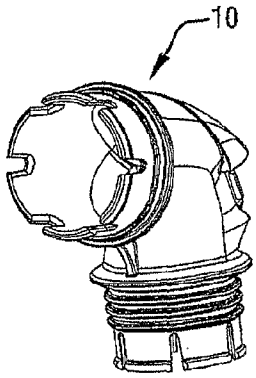


Fig. 142

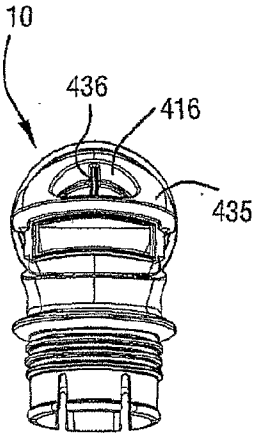


Fig. 143

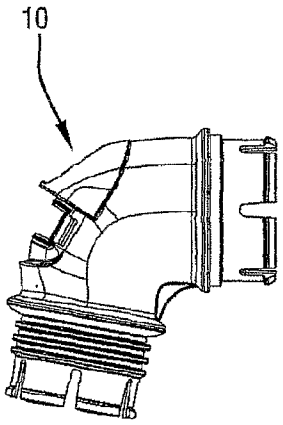


Fig. 144

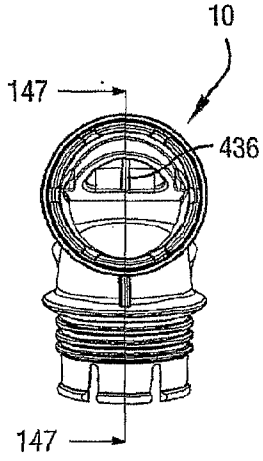
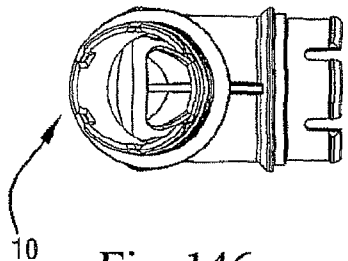


Fig. 145



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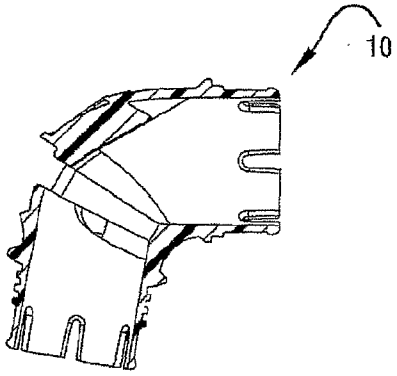


Fig. 147

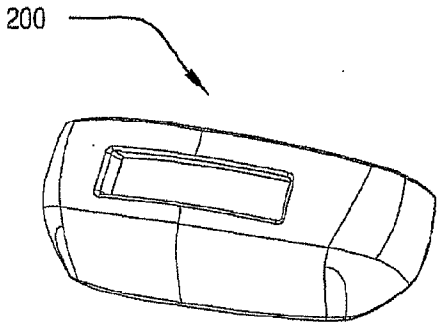


Fig. 148

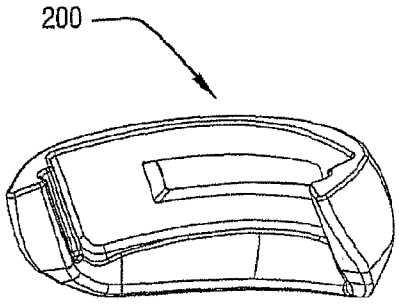


Fig. 149

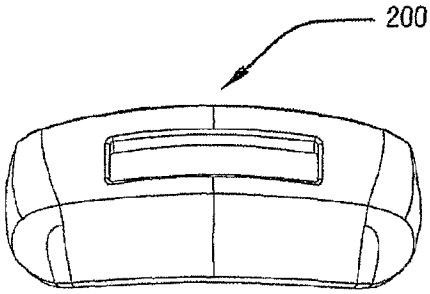


Fig. 150

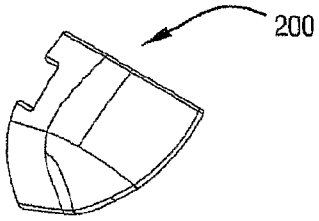
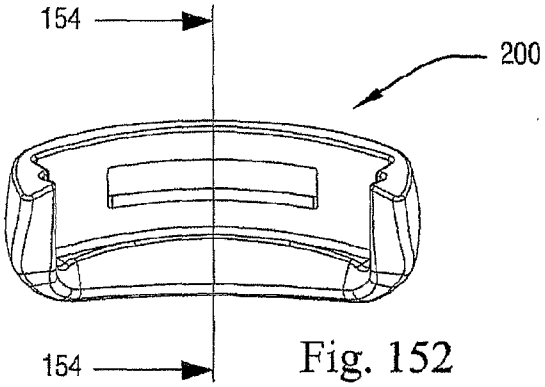


Fig. 151



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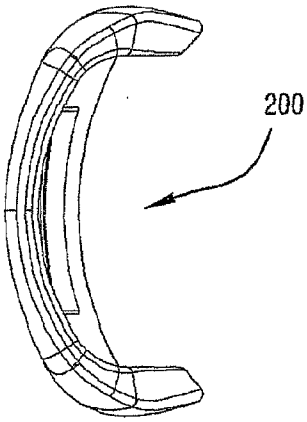


Fig. 153

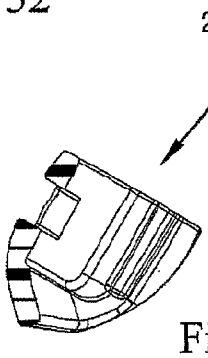


Fig. 154

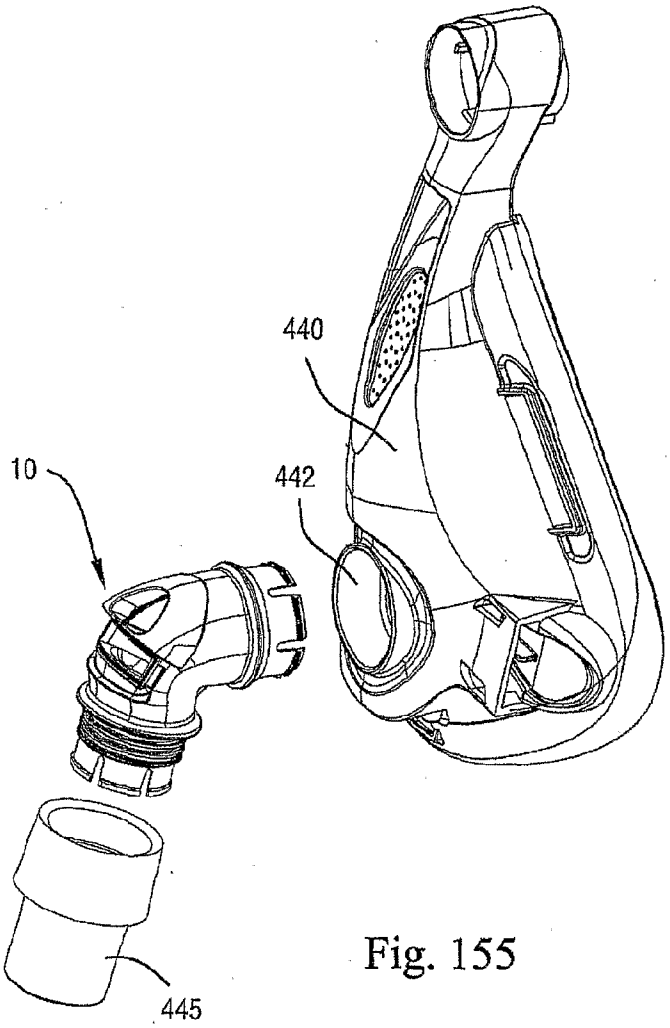


Fig. 155

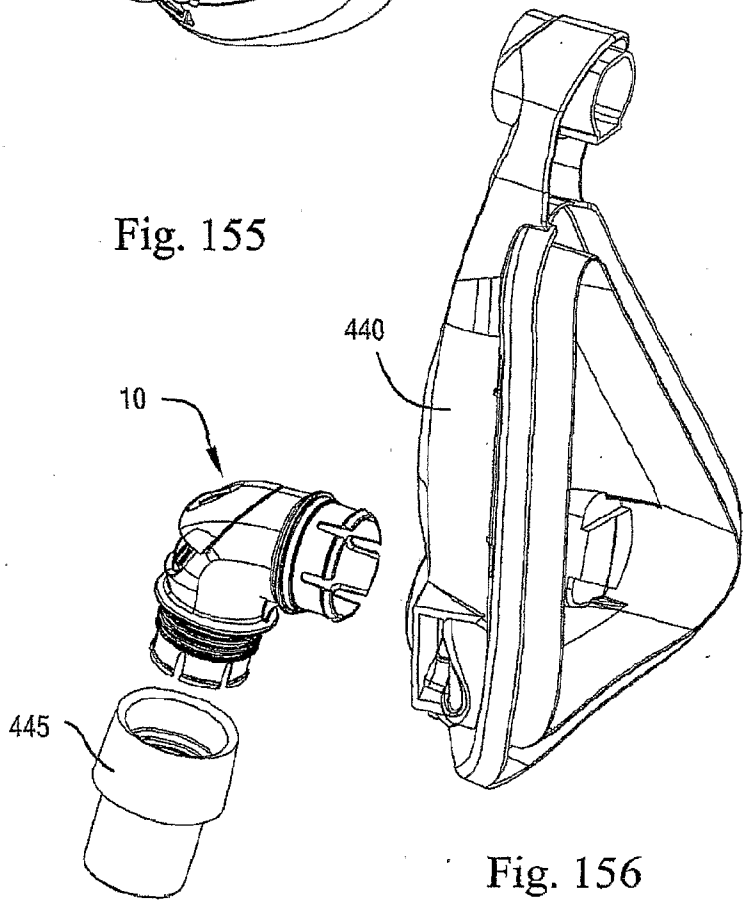


Fig. 156

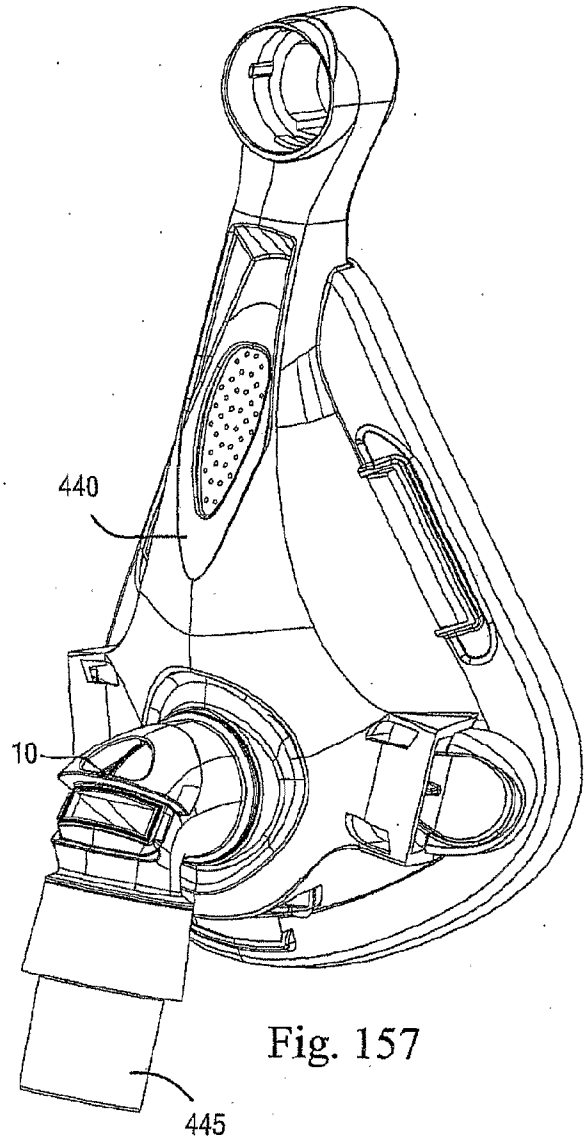
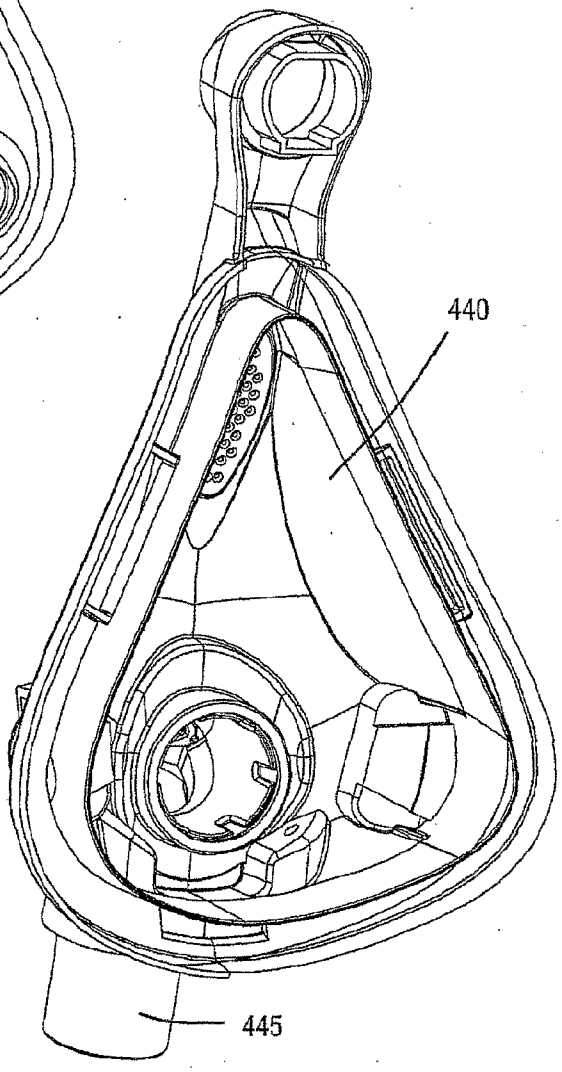


Fig. 157



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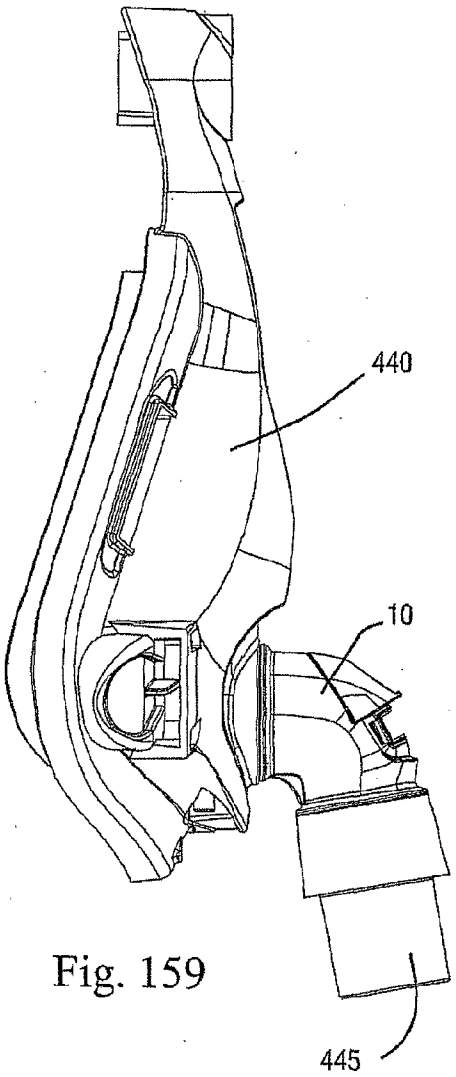

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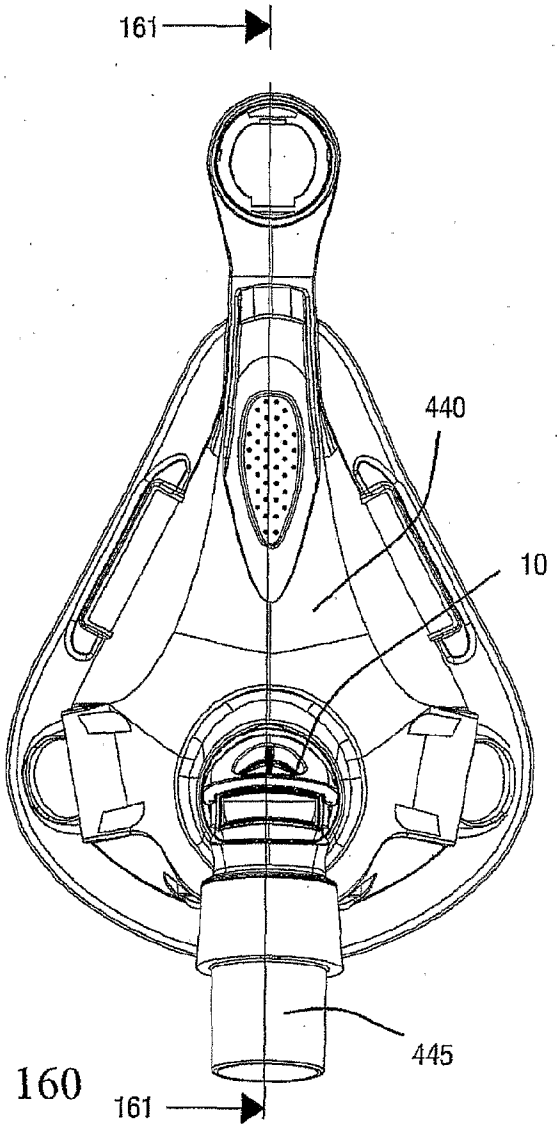

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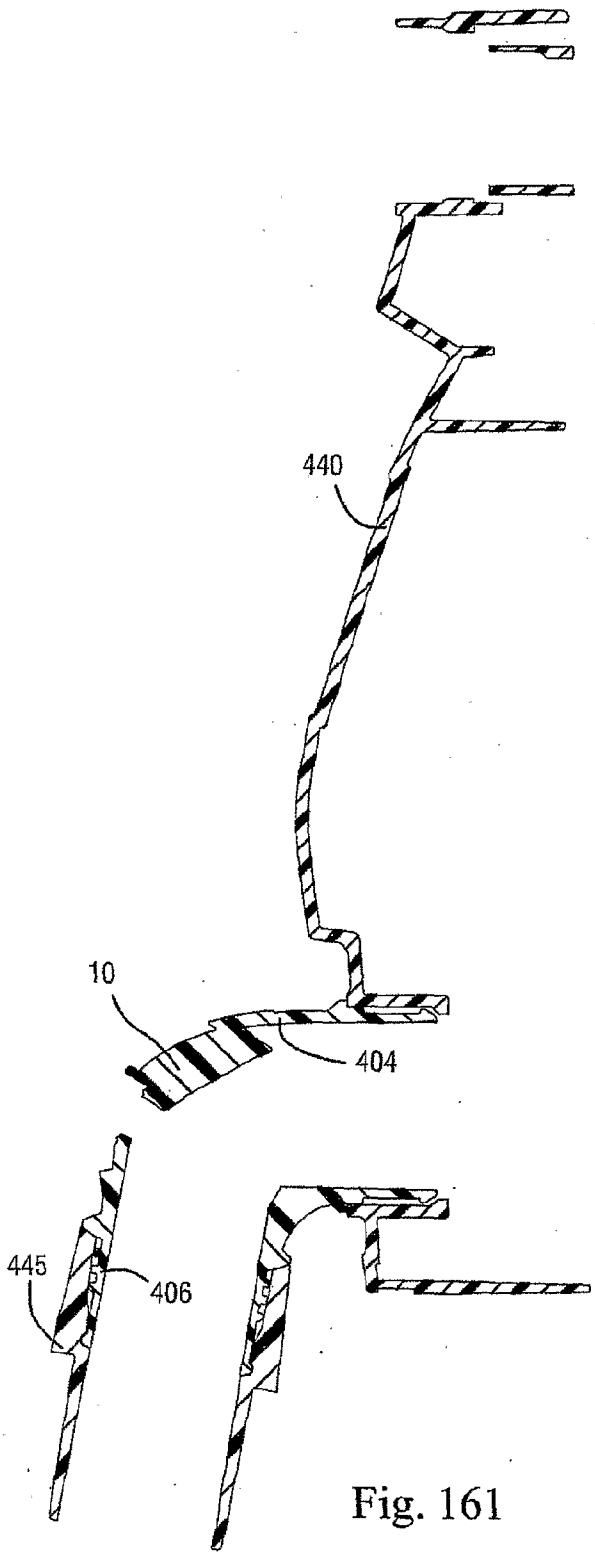

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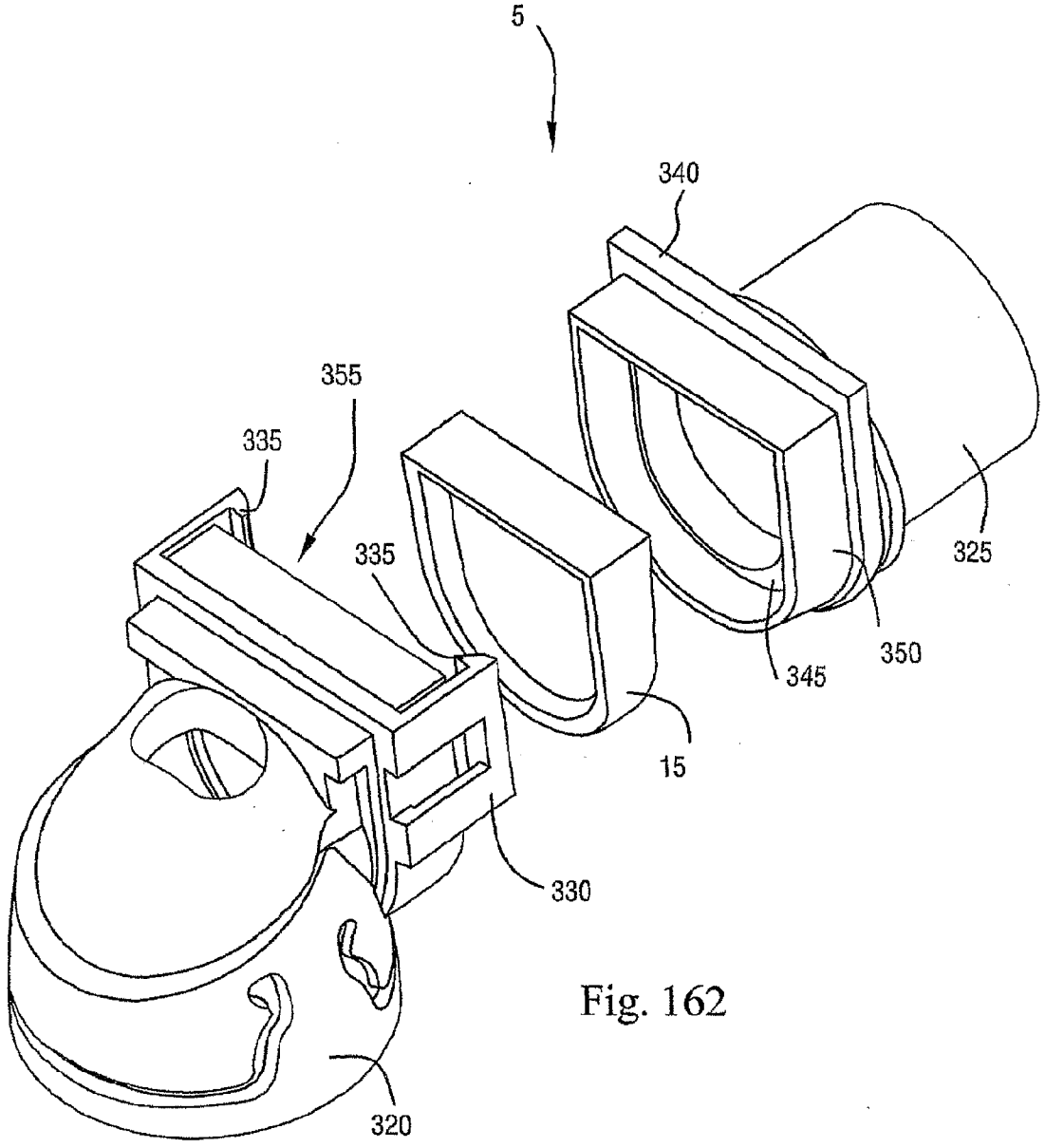

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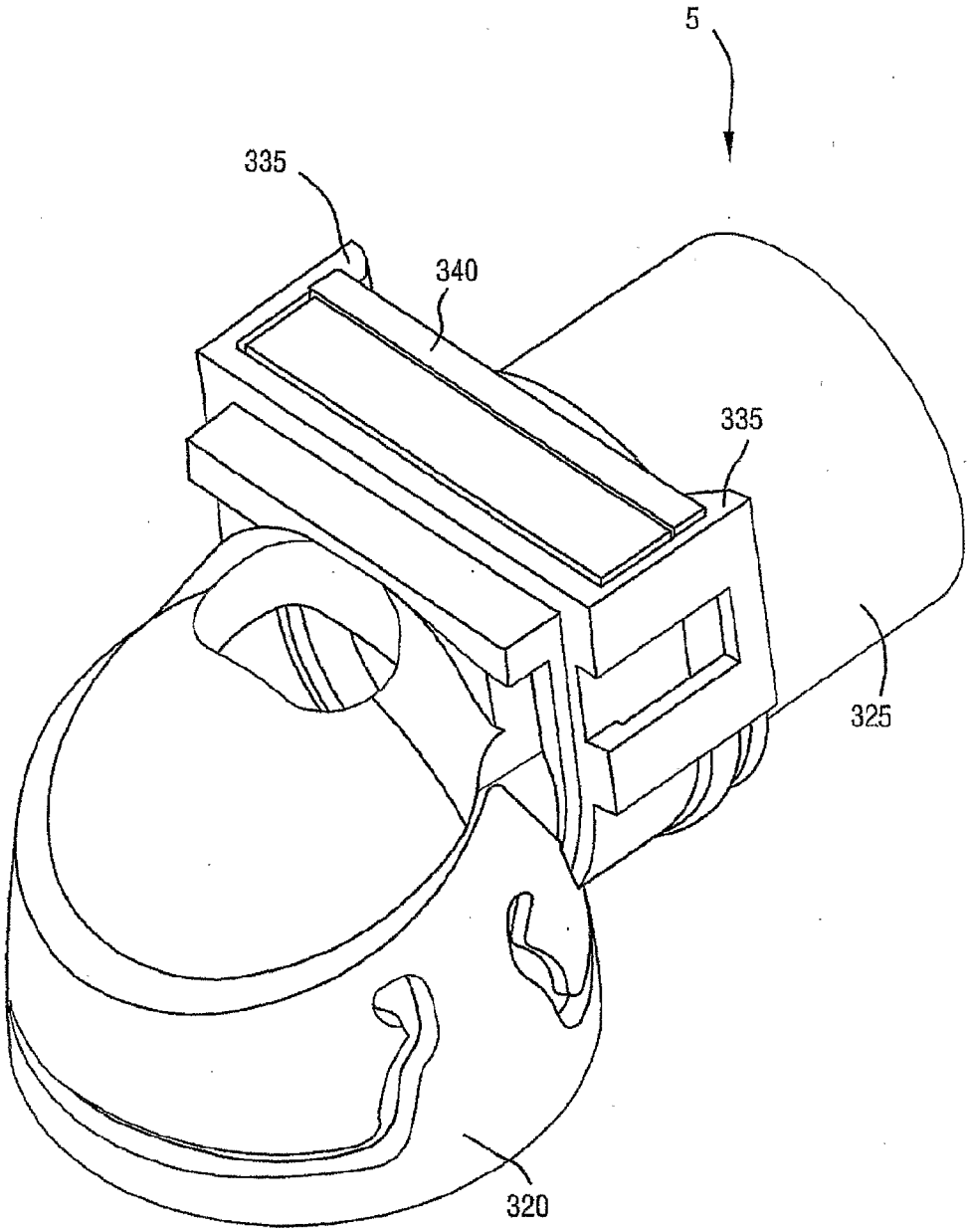

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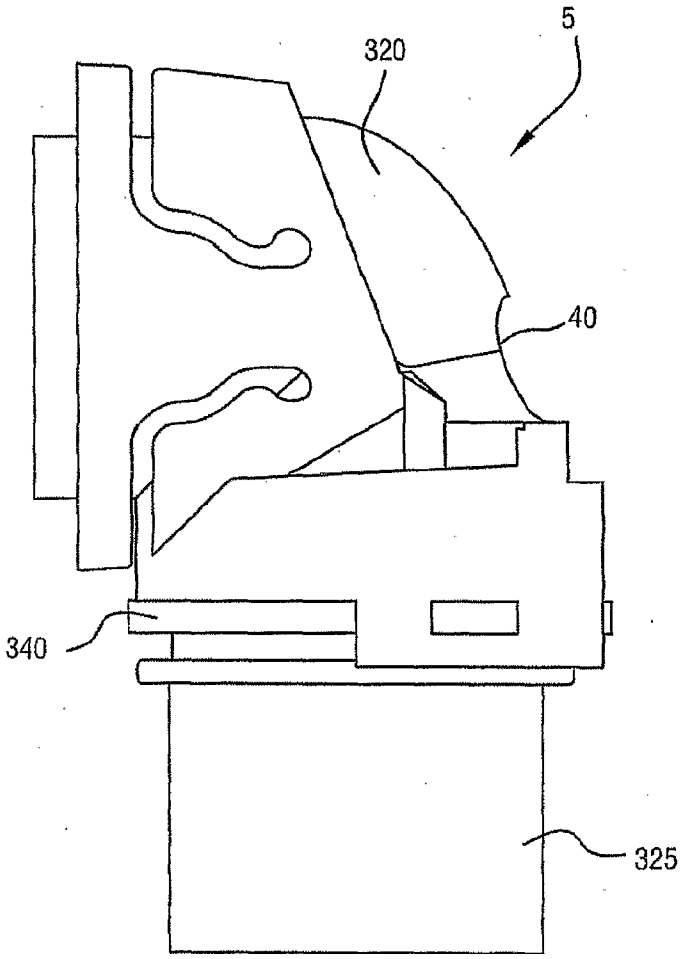

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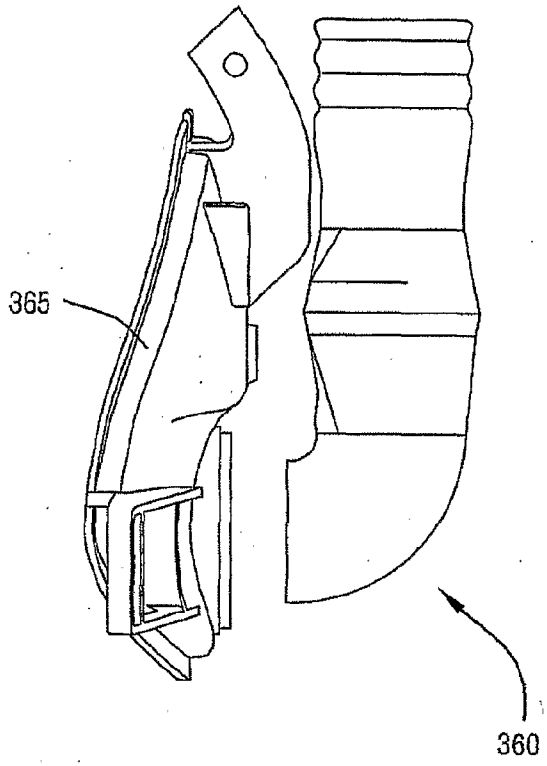

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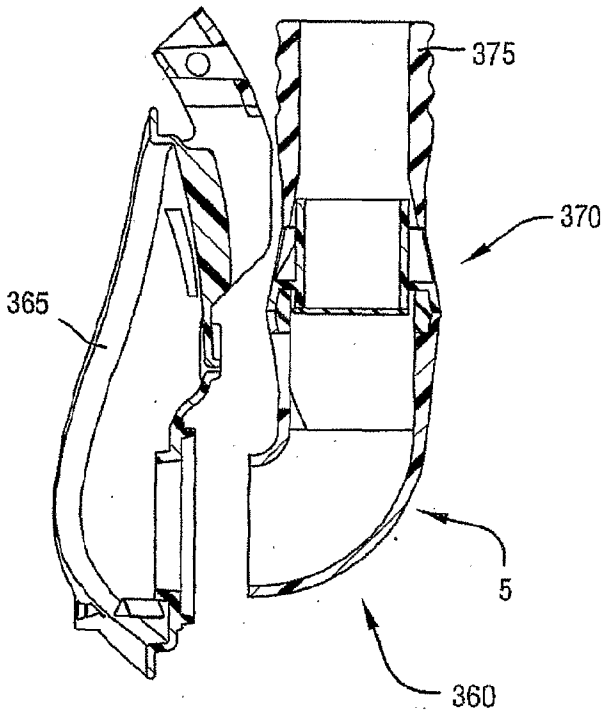

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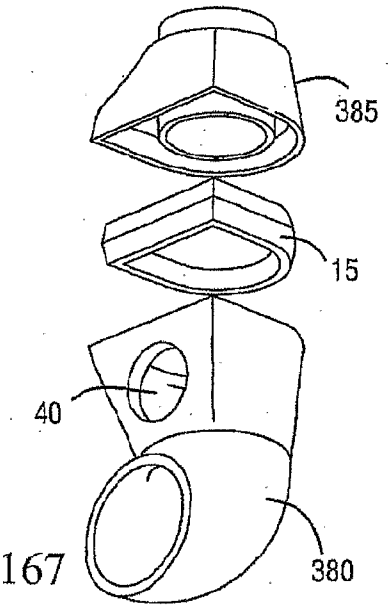

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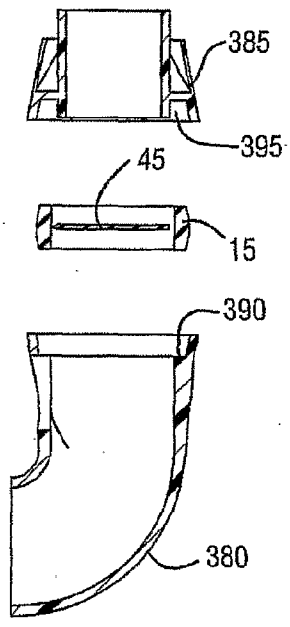

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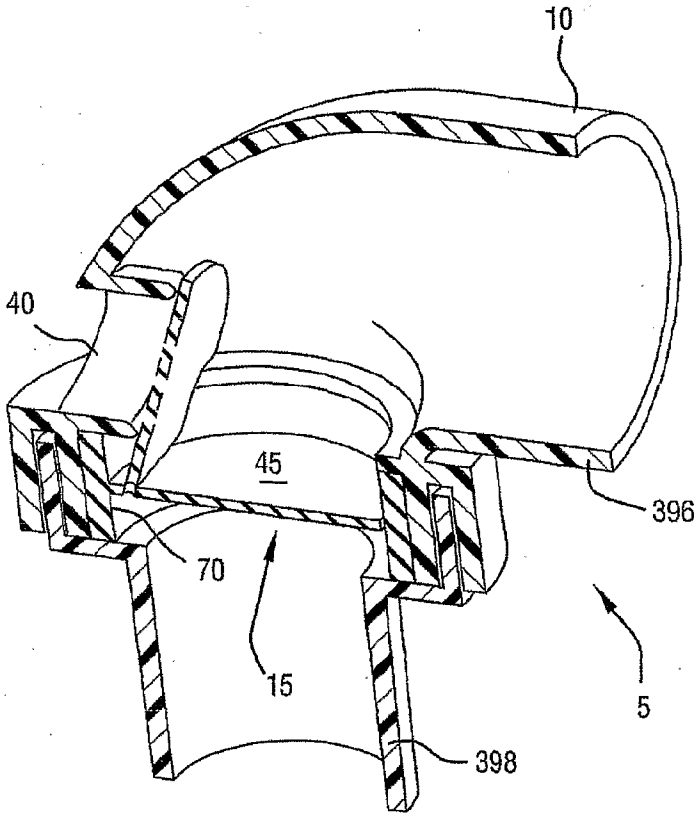

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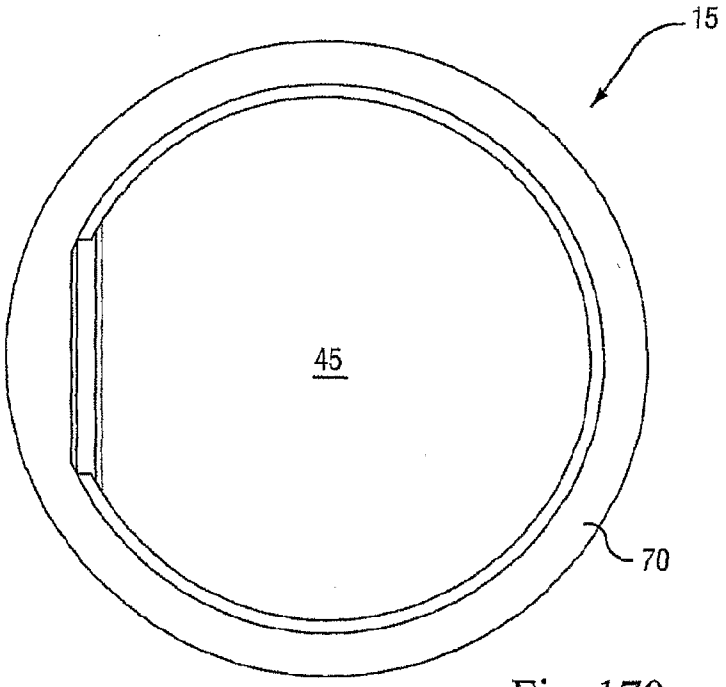

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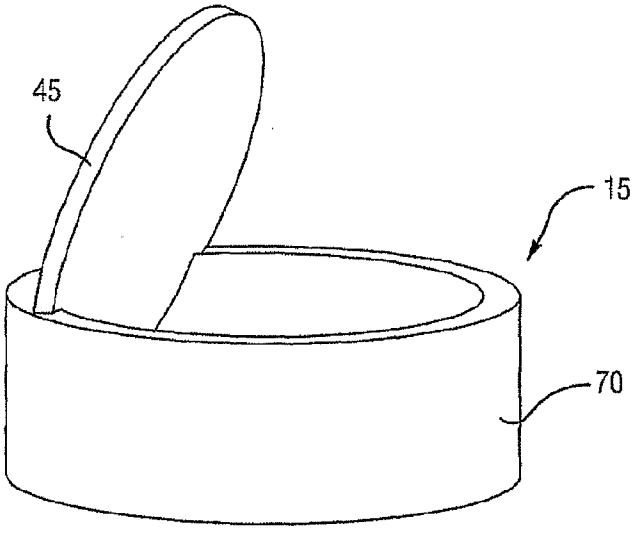

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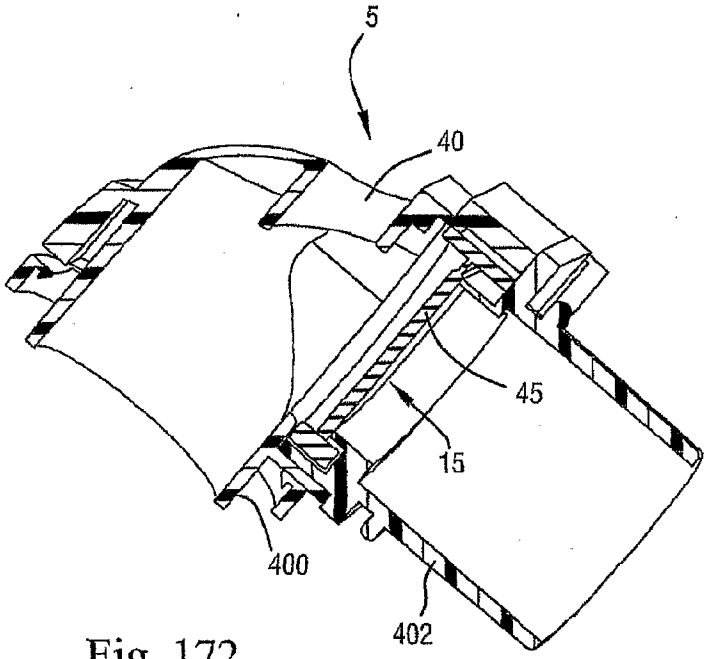

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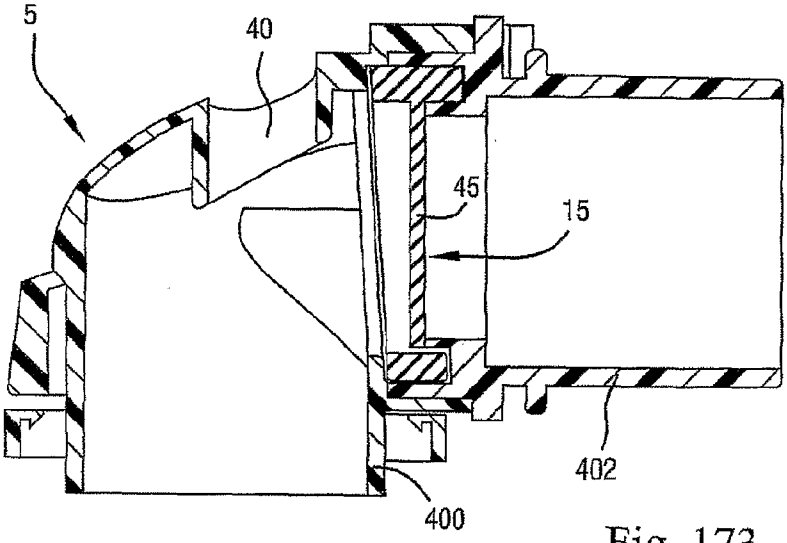
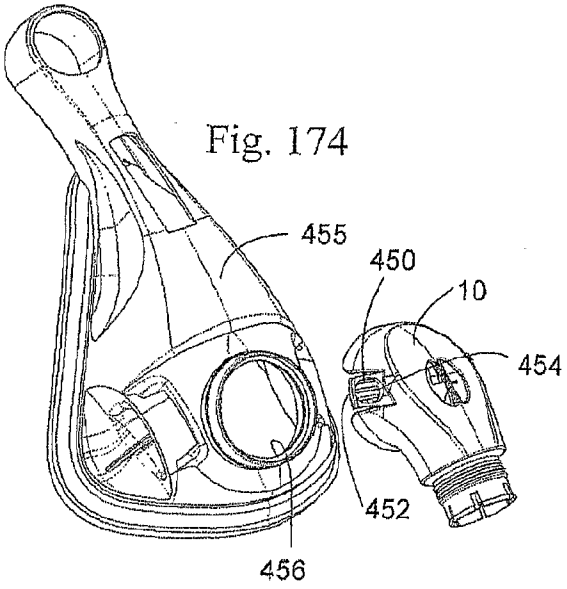


Fig. 173



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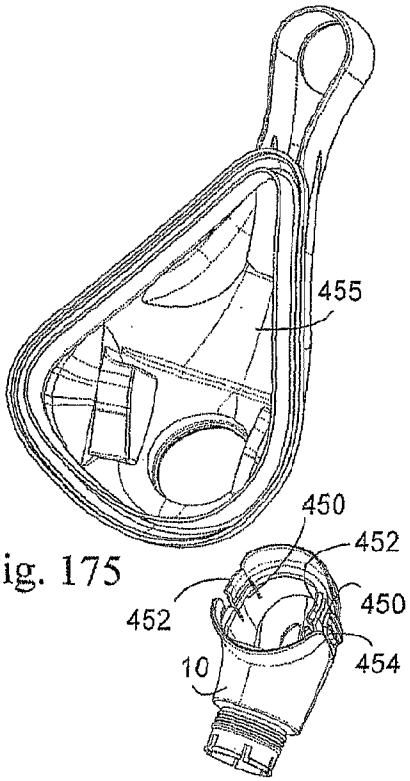

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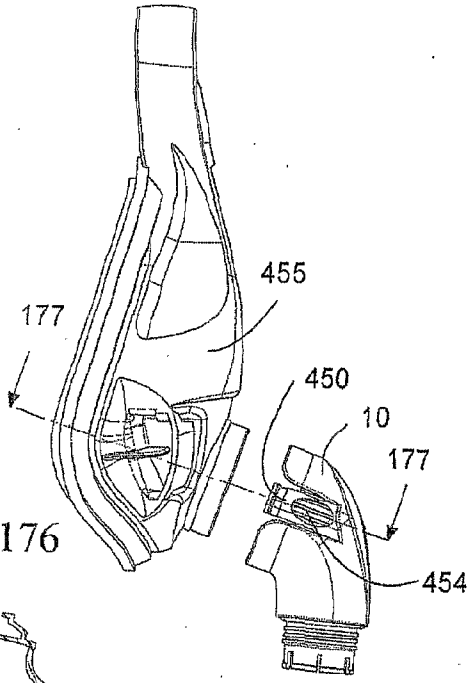

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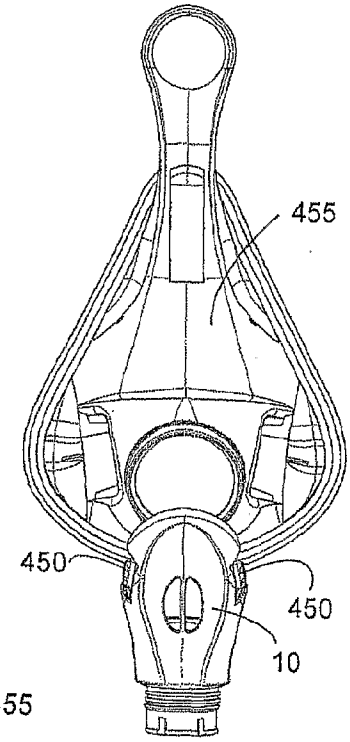

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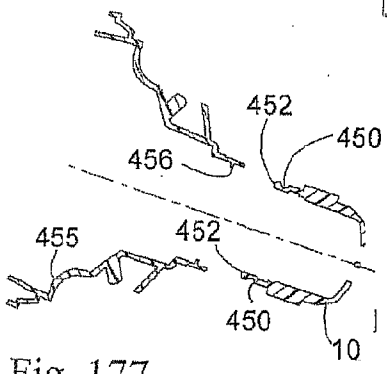

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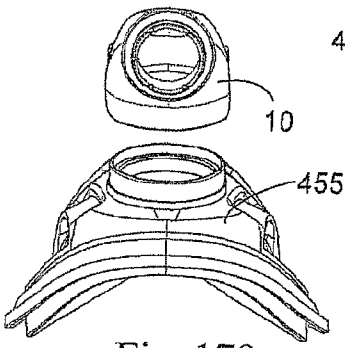

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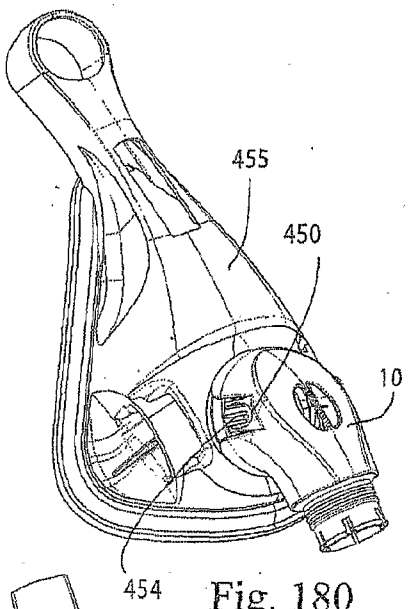

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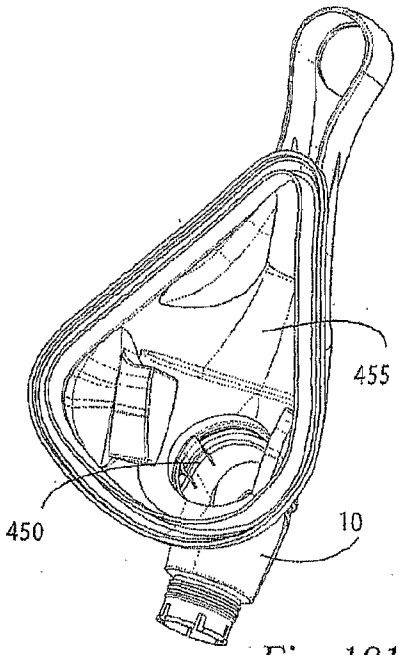

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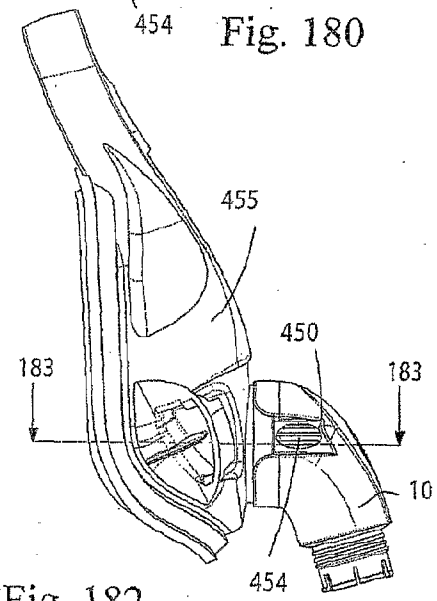

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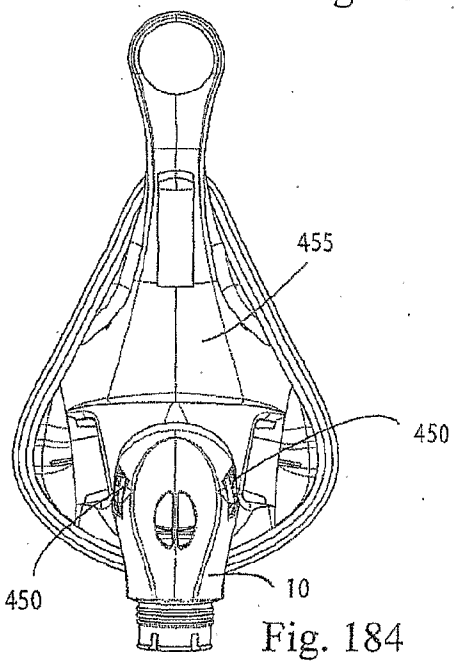

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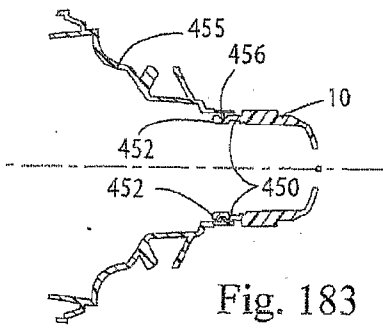

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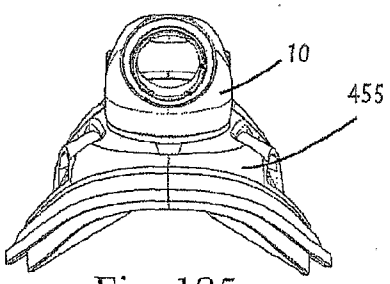

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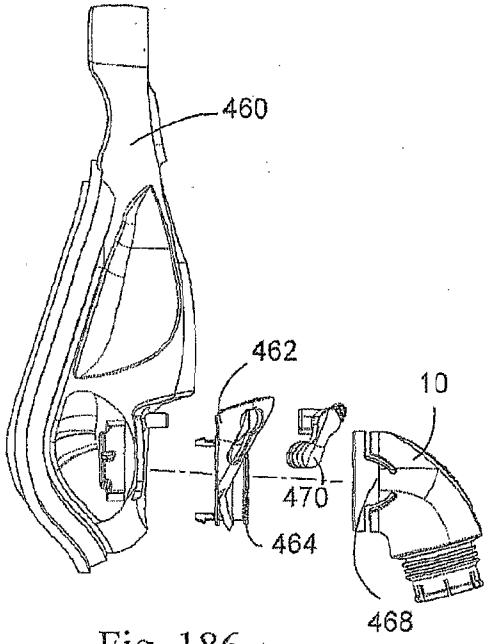

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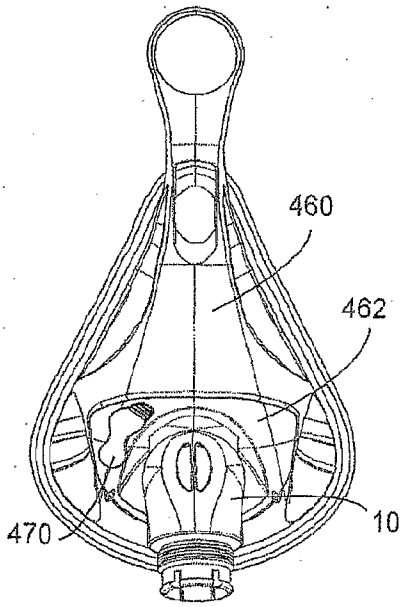

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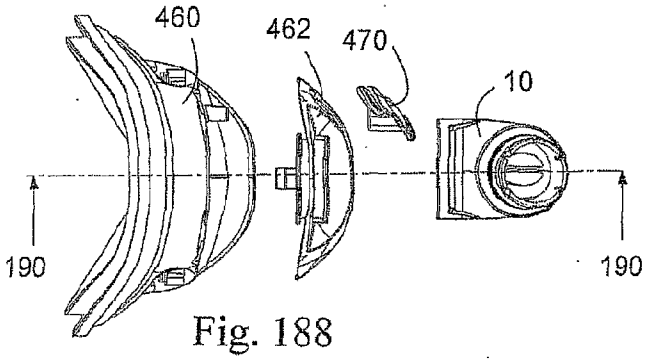

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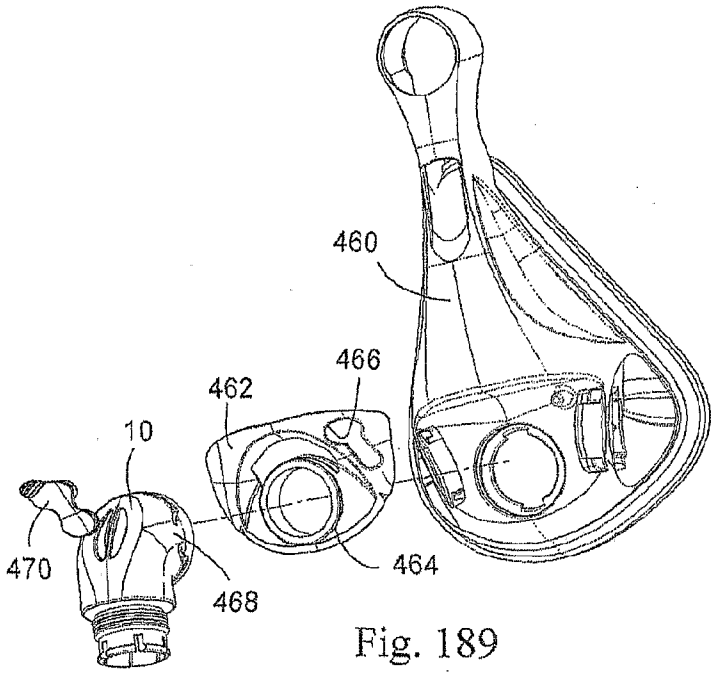

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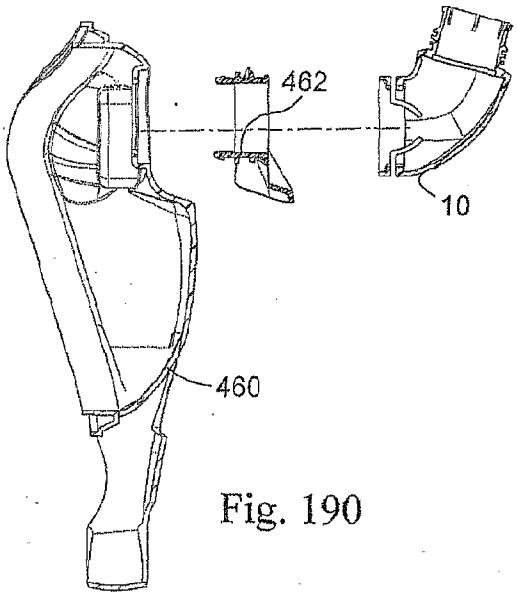

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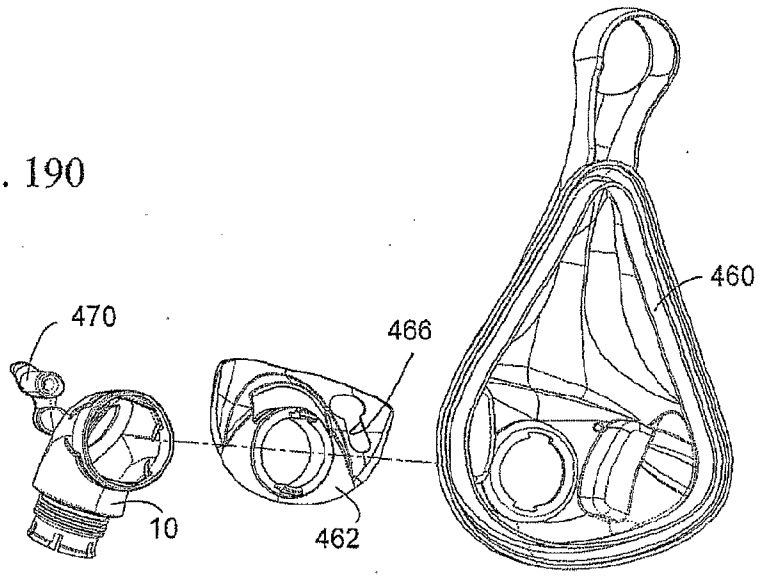

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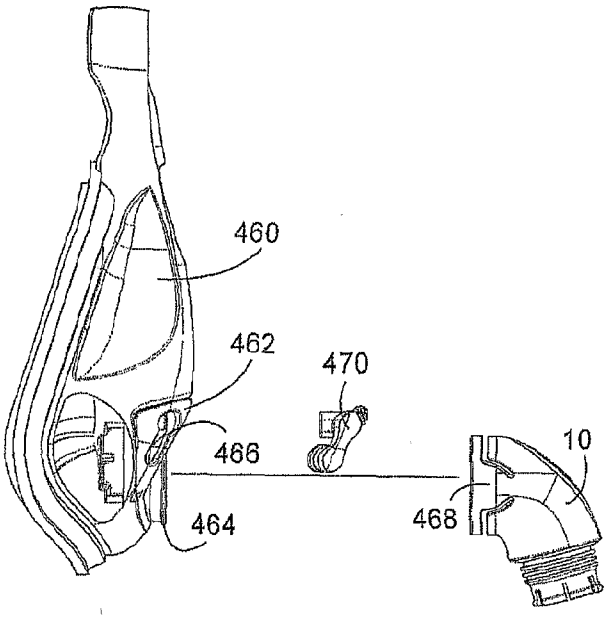

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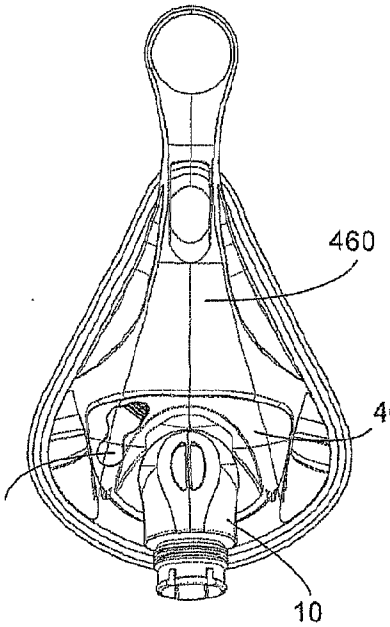

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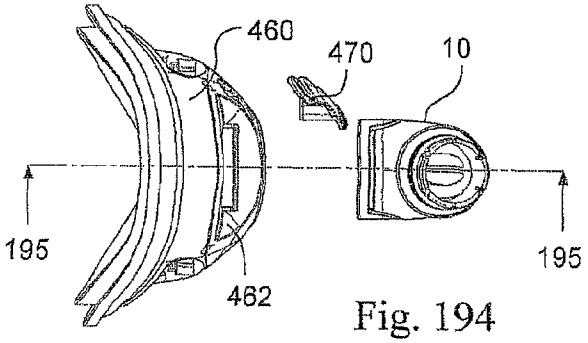

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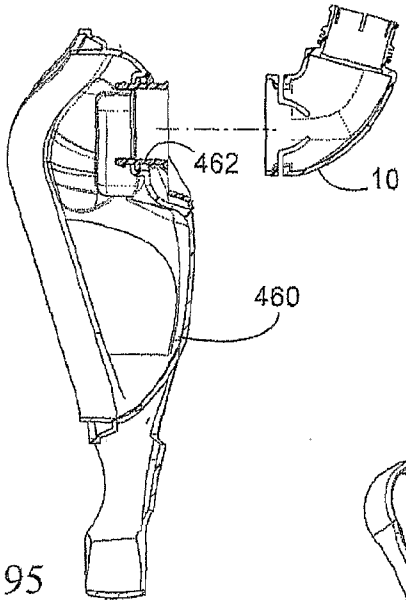

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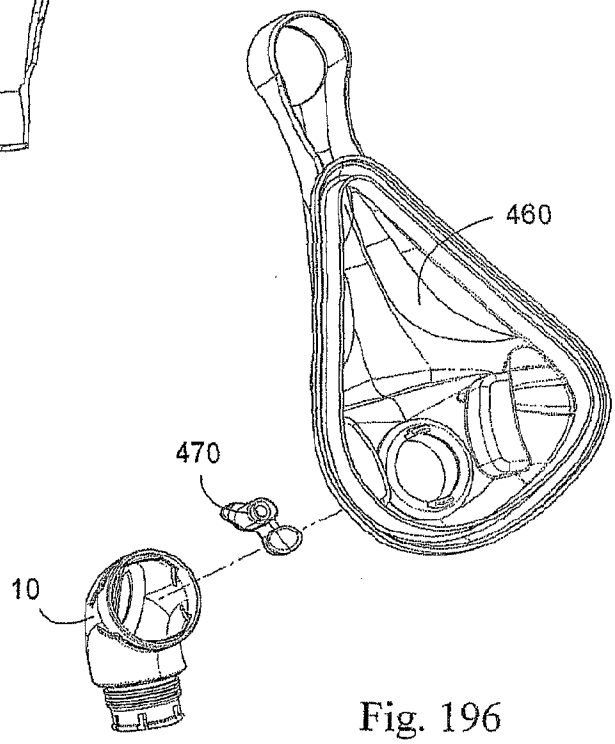

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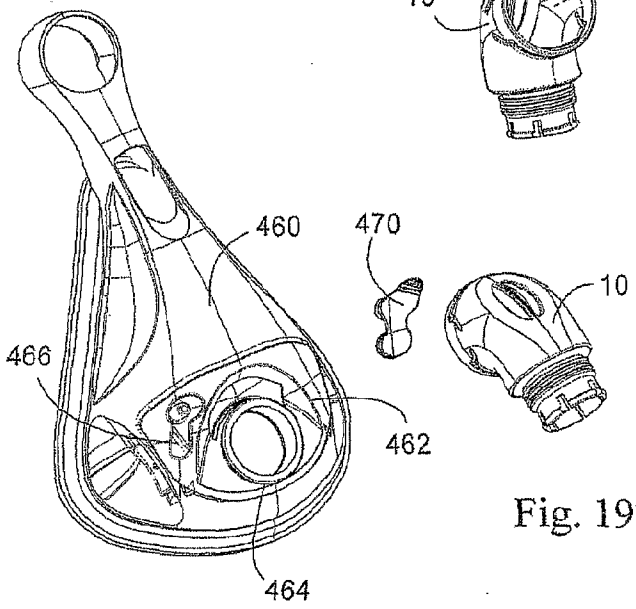

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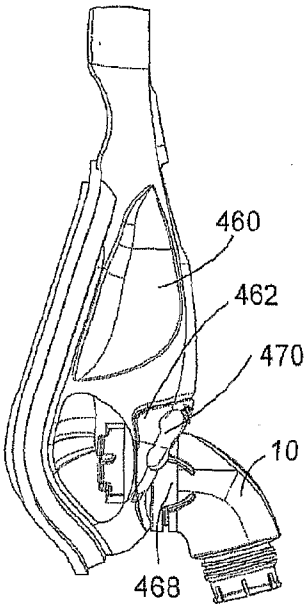


Fig. 198

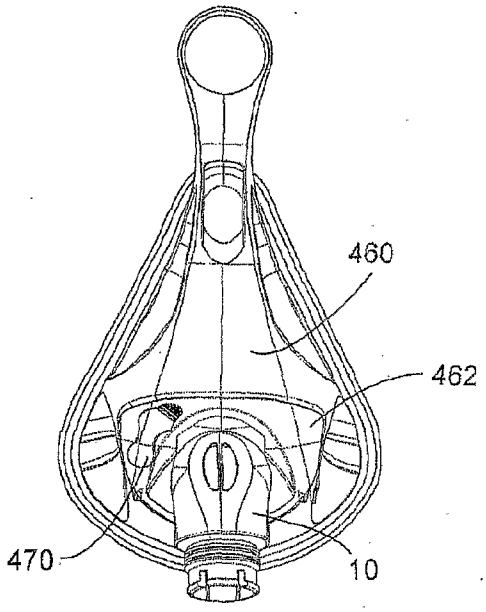
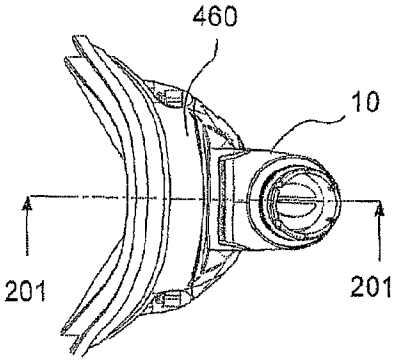


Fig. 199



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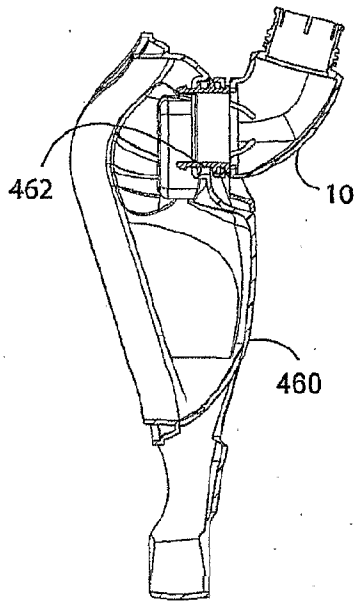

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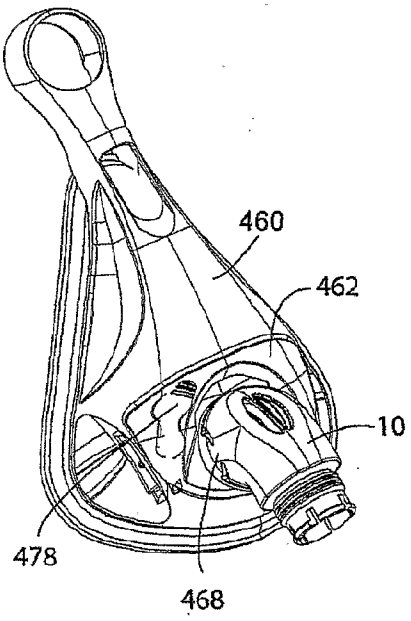

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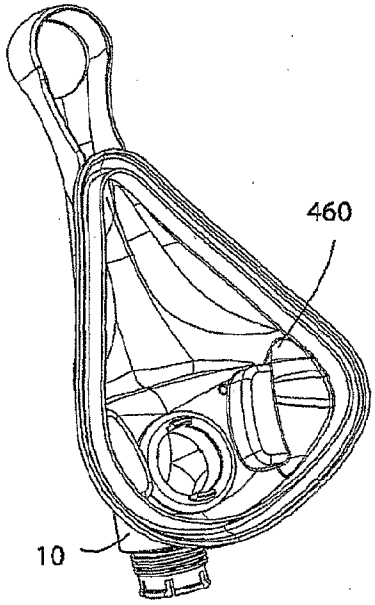

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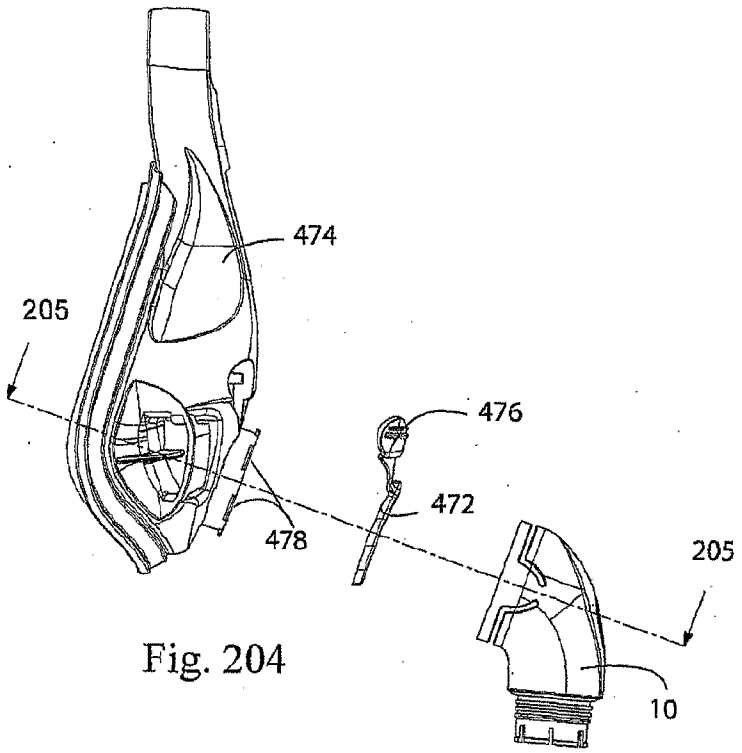

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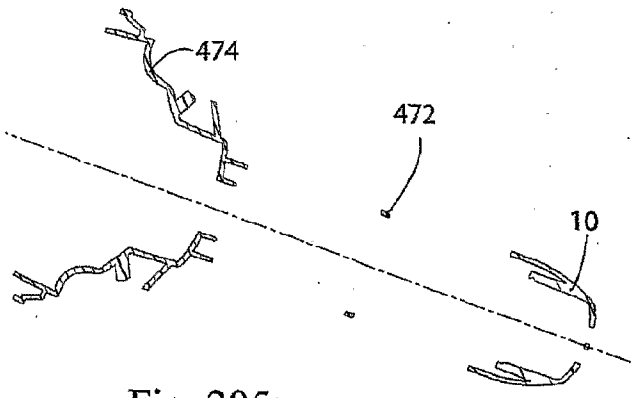

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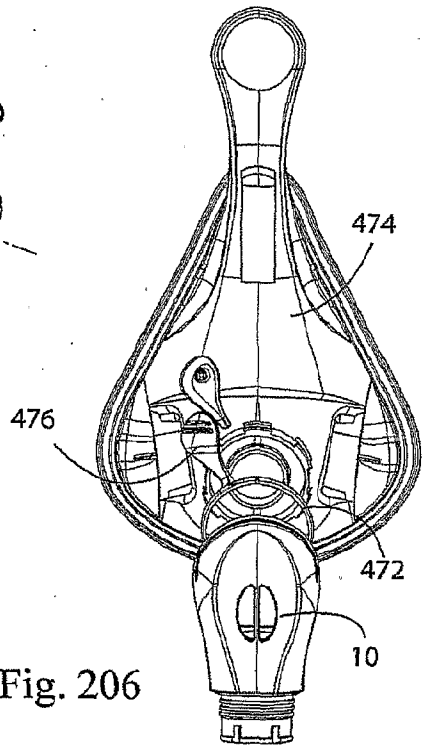

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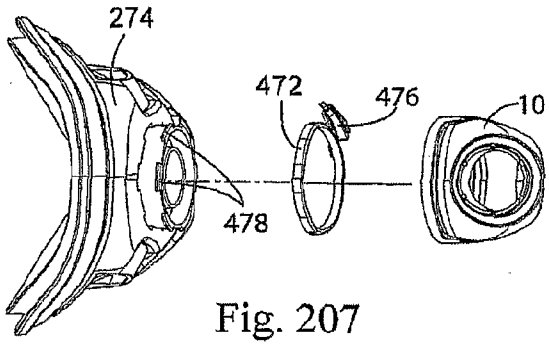

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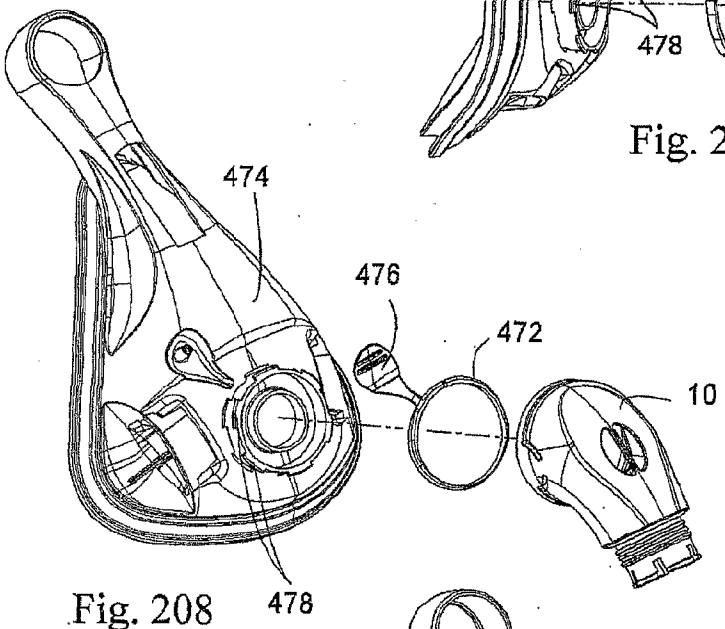

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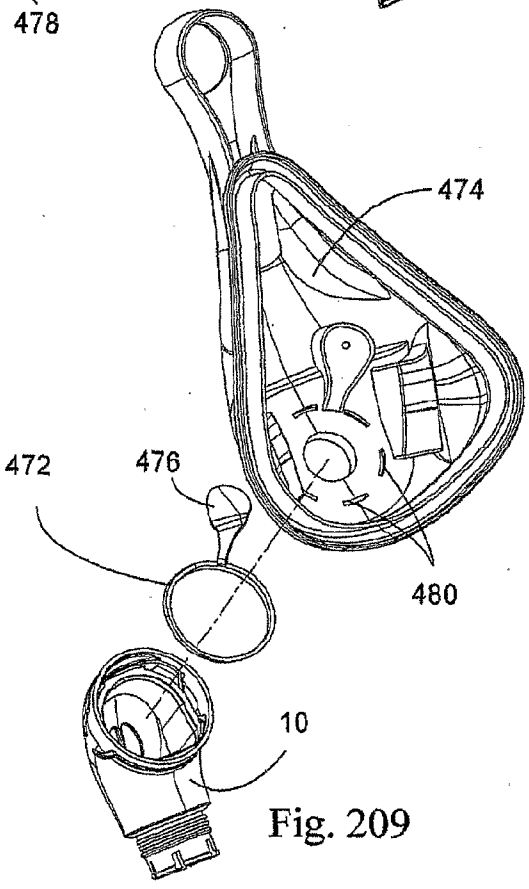

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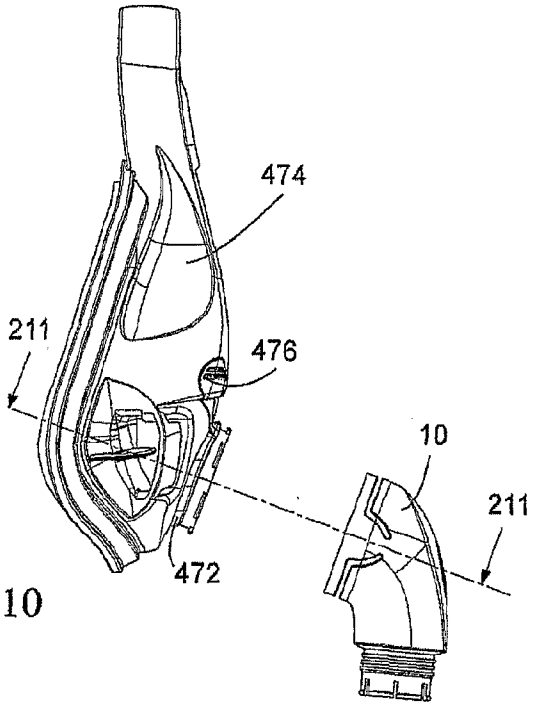
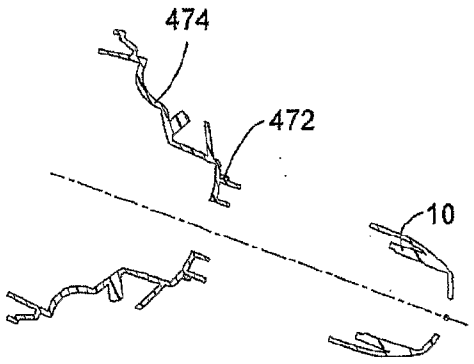


Fig. 210



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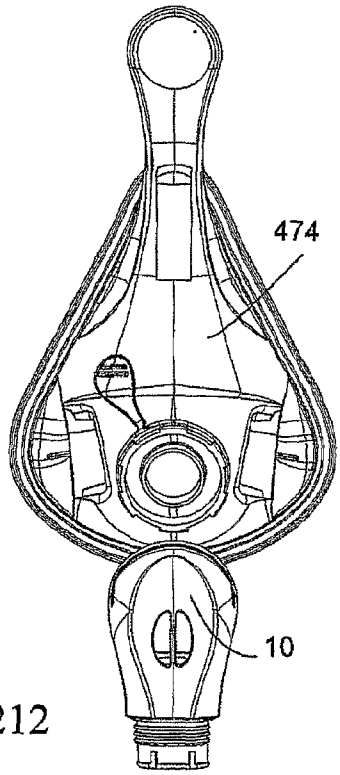

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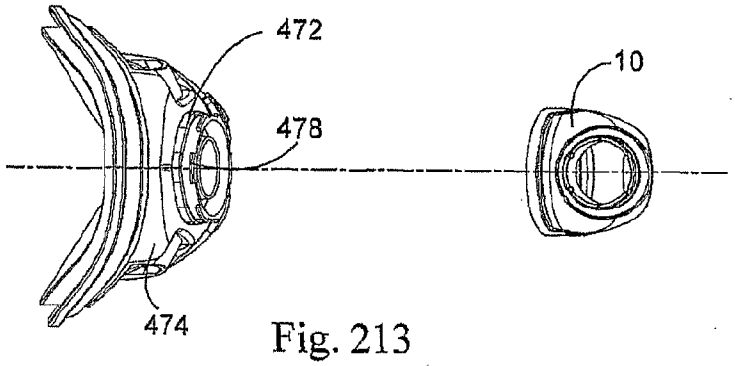
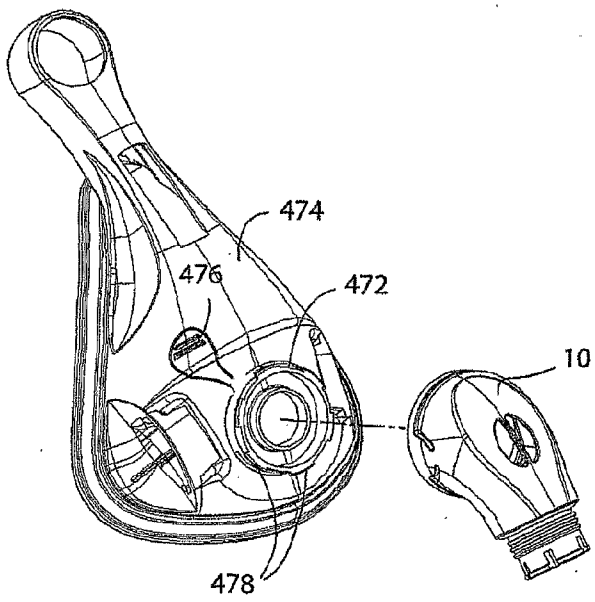


Fig. 213



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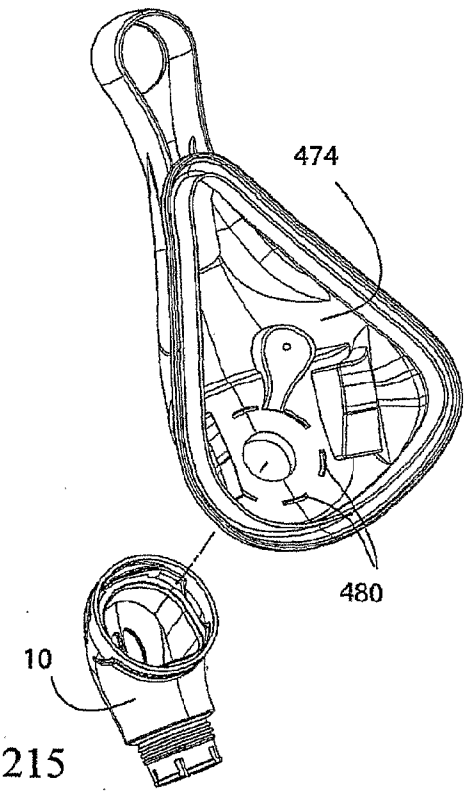


Fig. 215

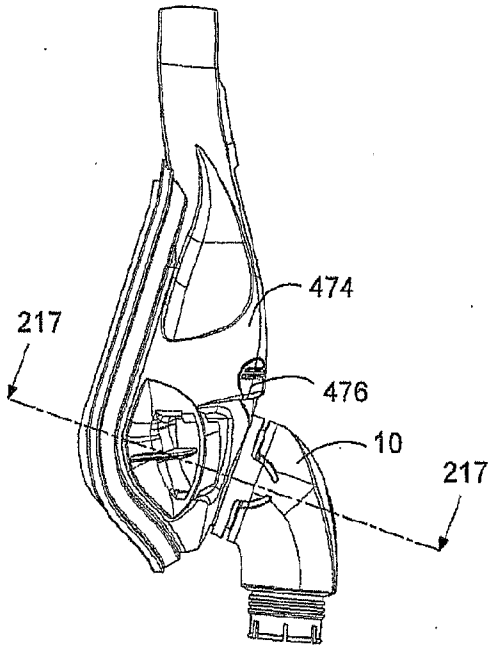


Fig. 216

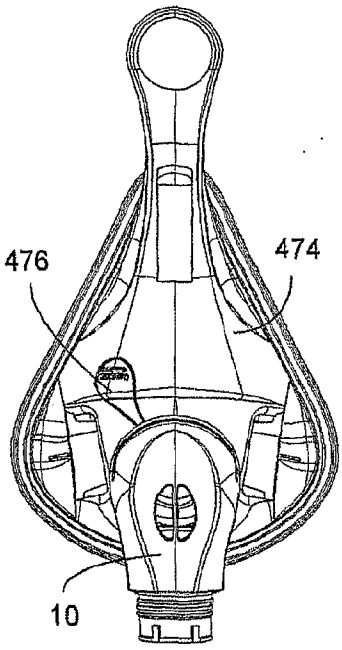


Fig. 218

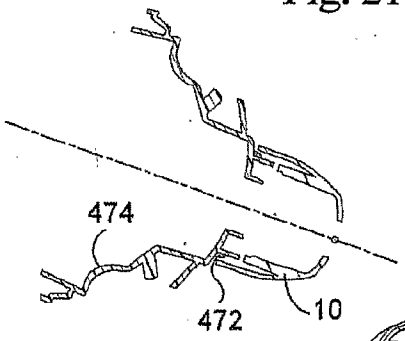
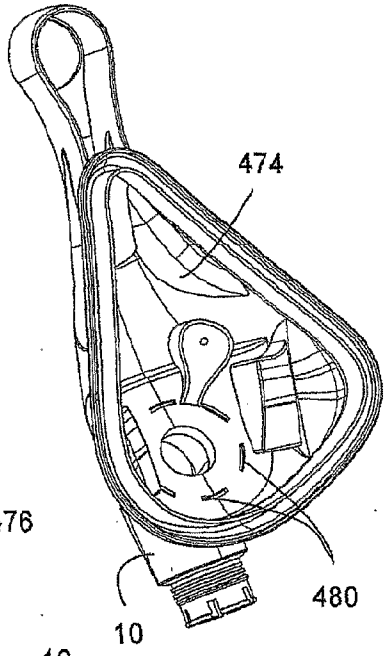


Fig. 217



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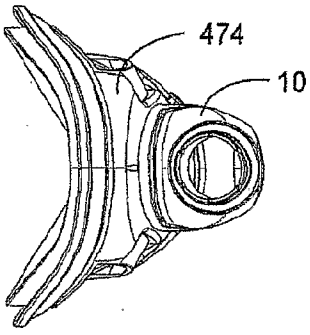

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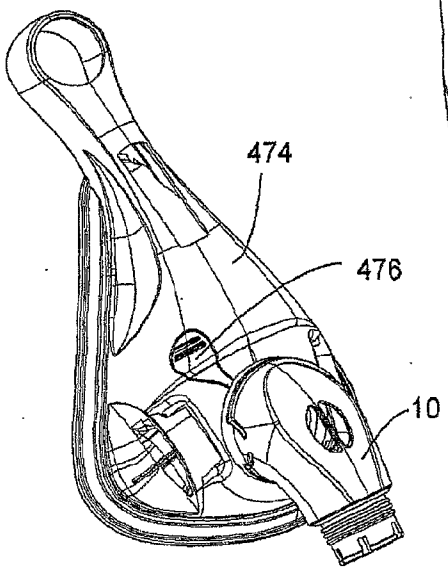

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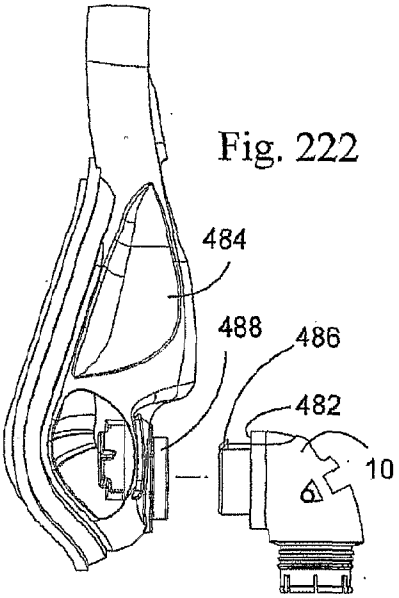

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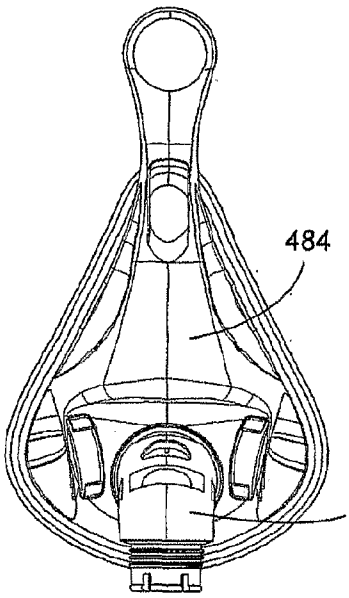

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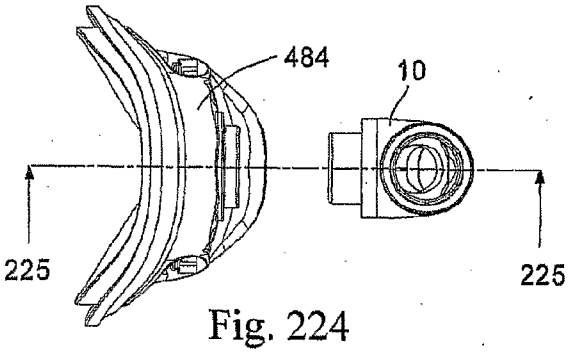

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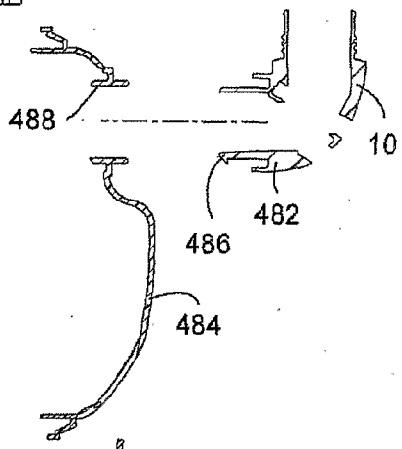

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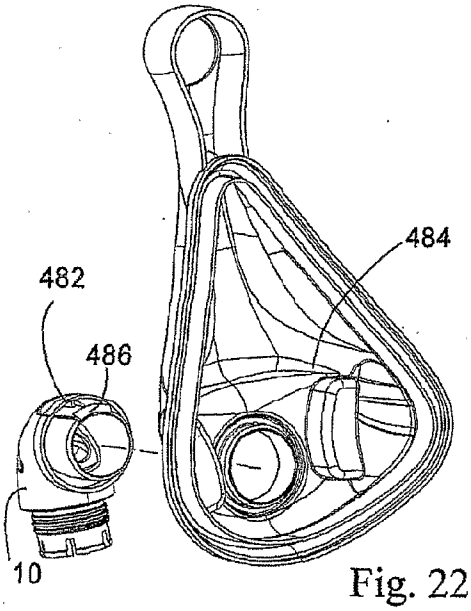

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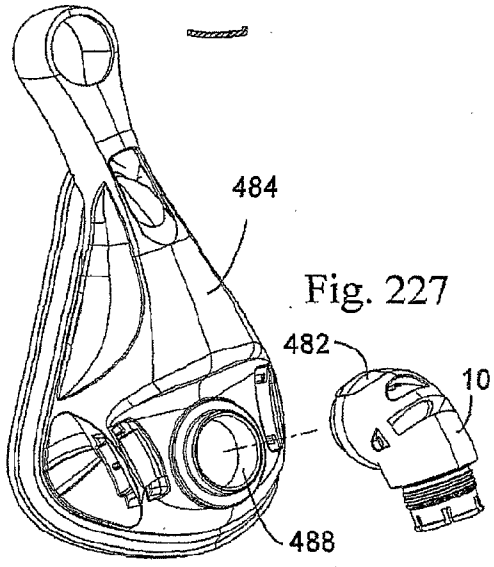

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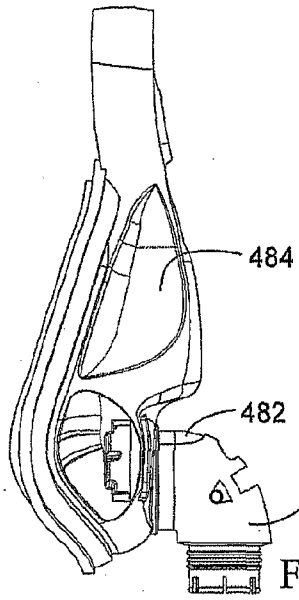

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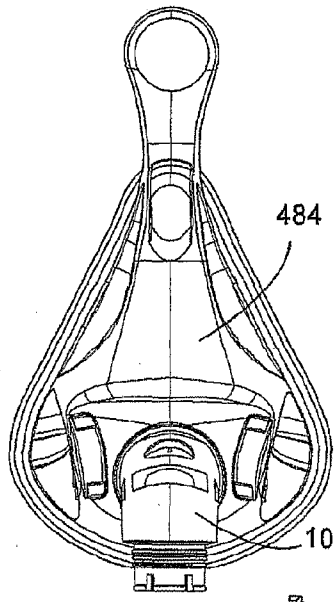

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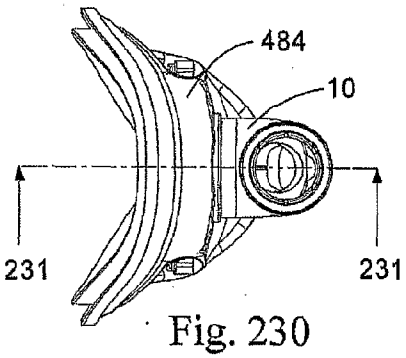

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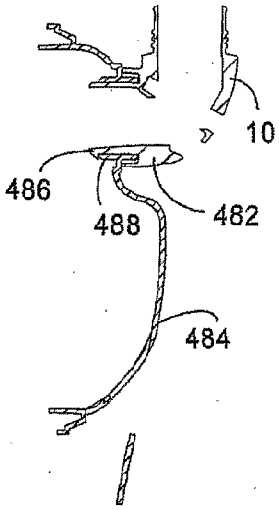

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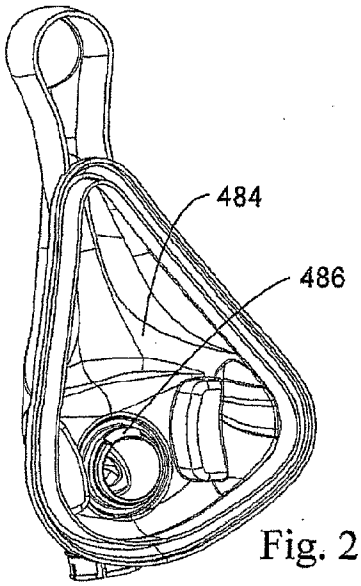

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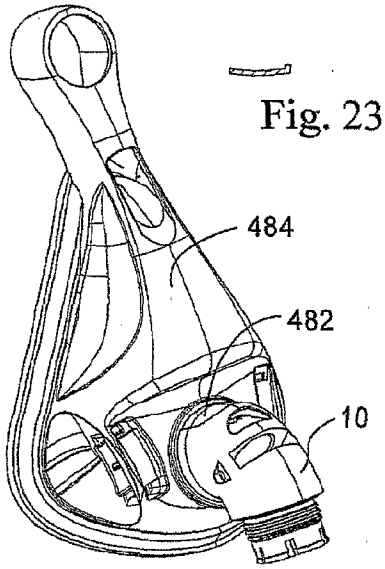

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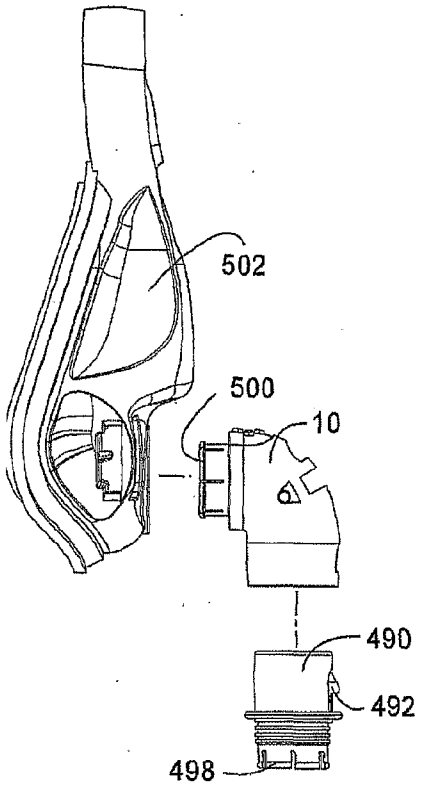

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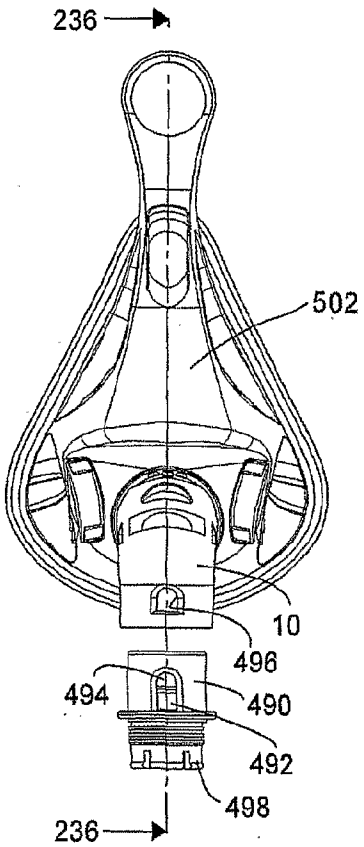

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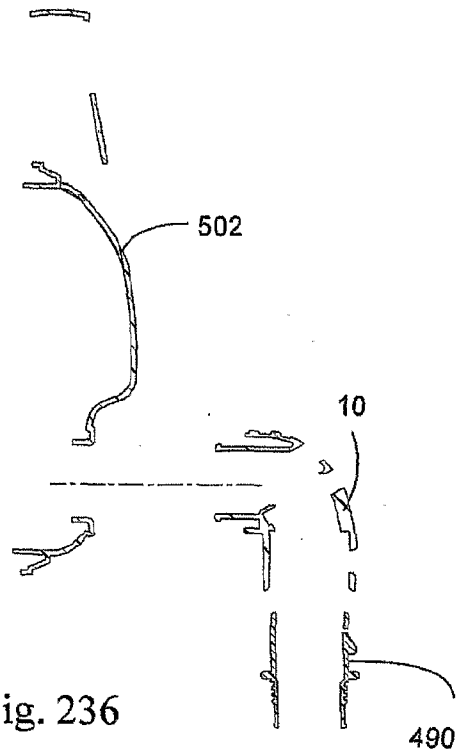

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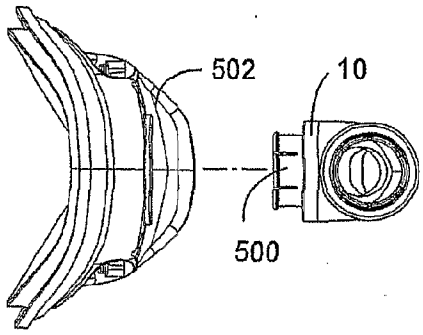

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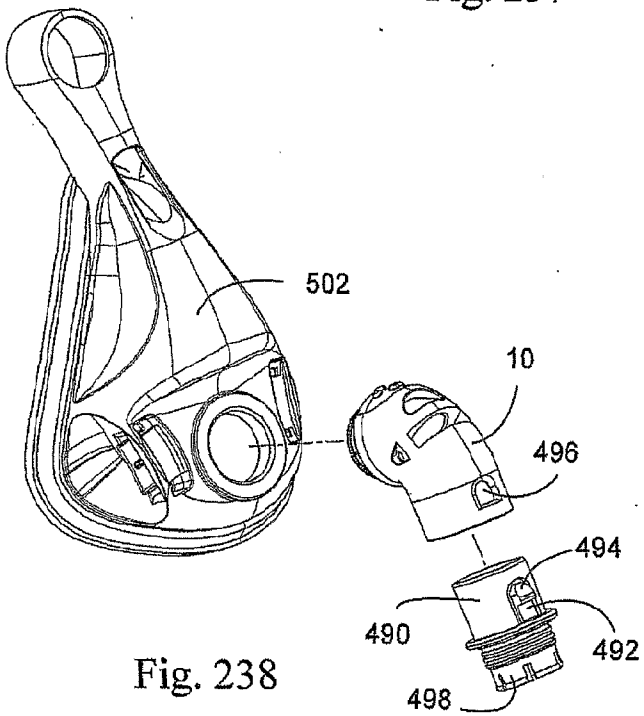

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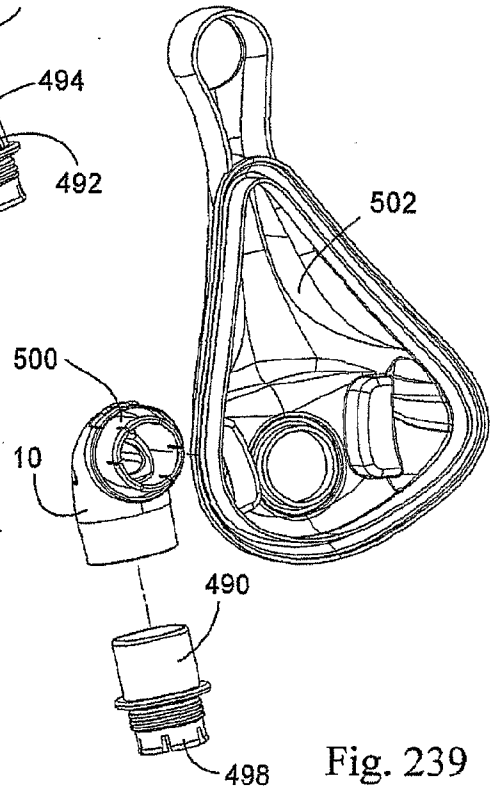

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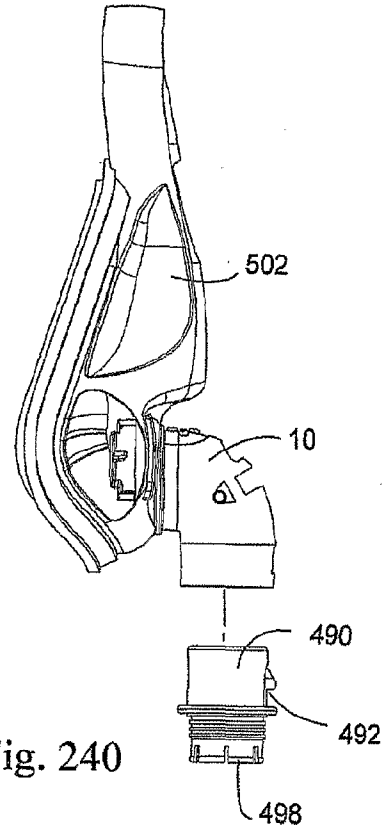

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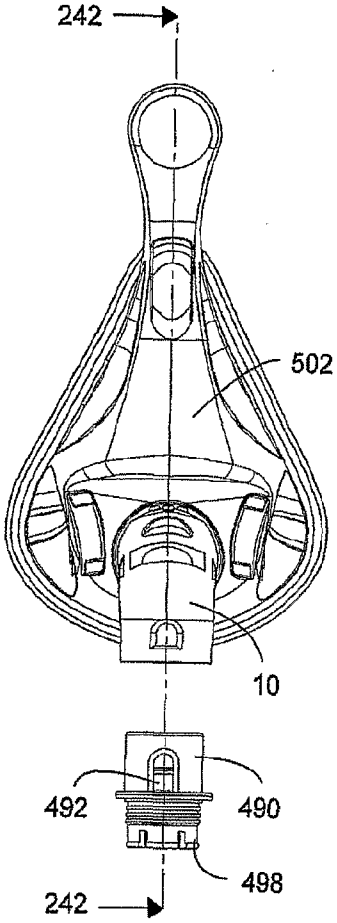

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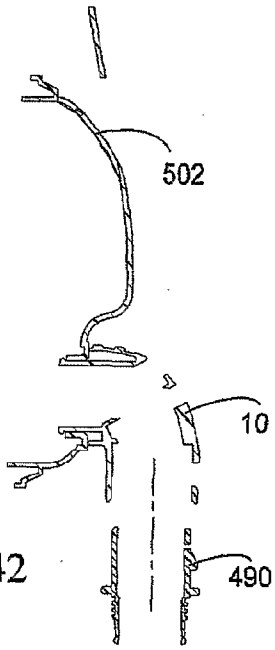

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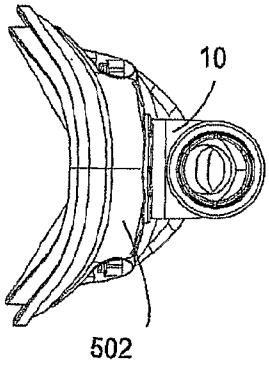

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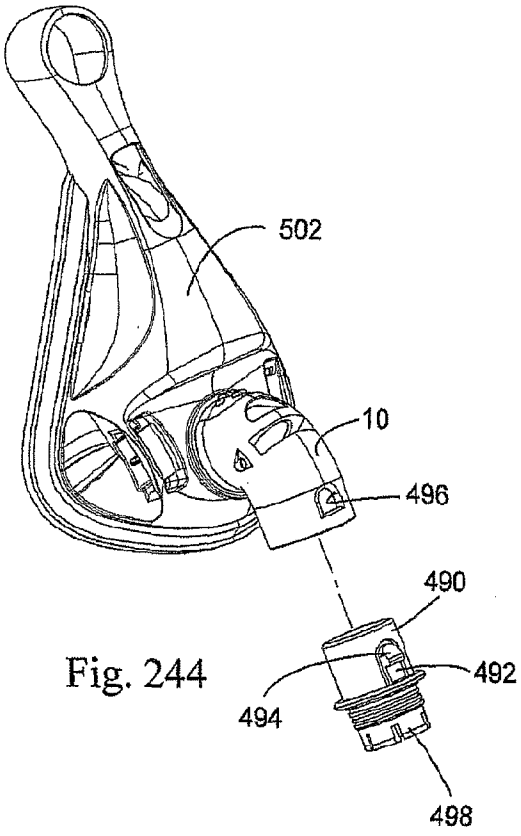

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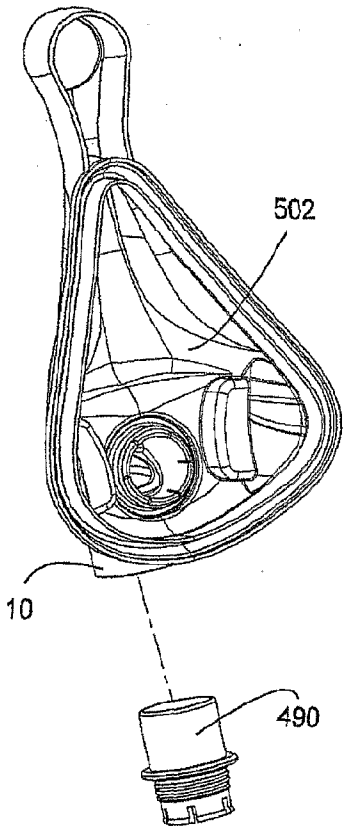

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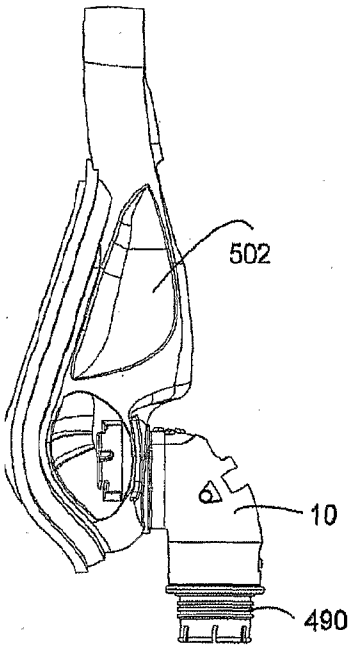

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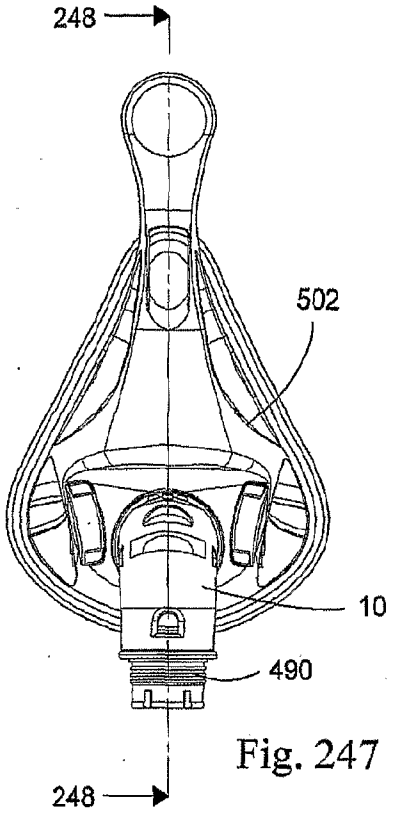

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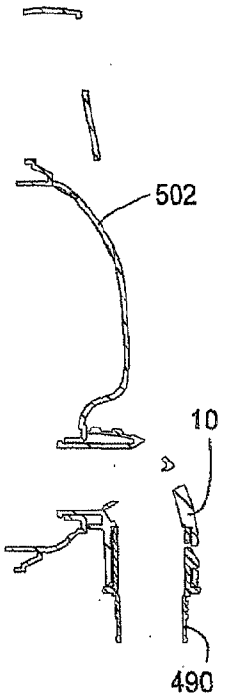

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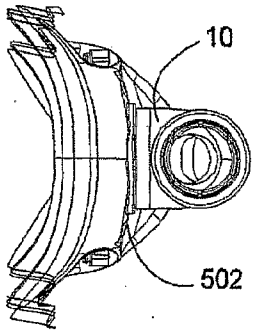

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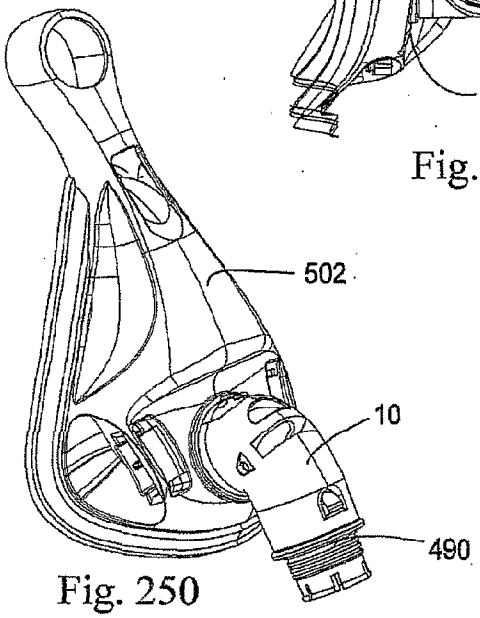

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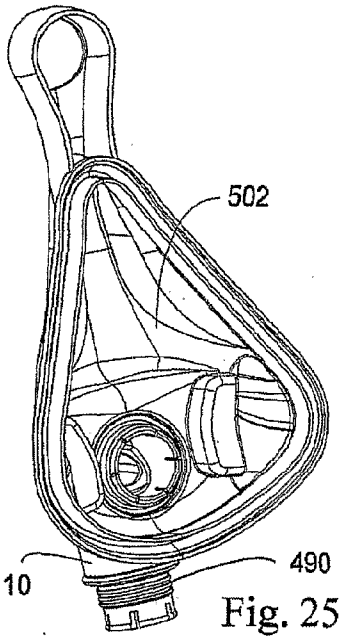

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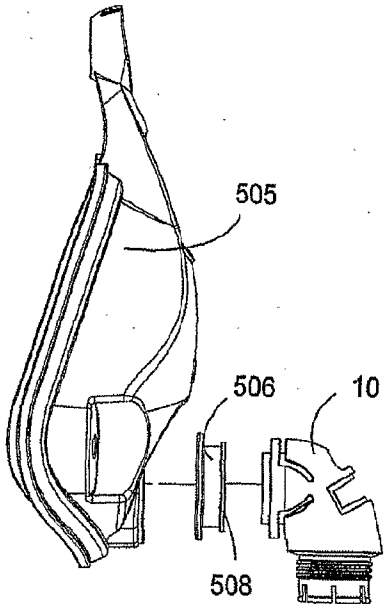

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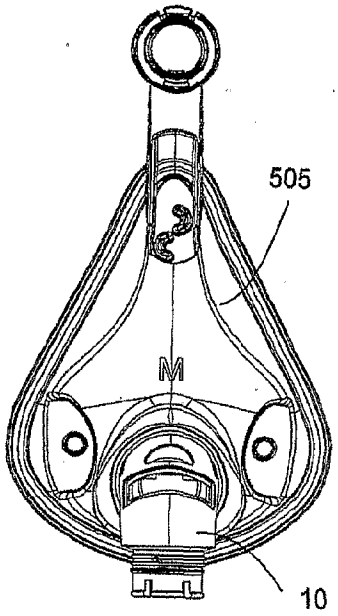

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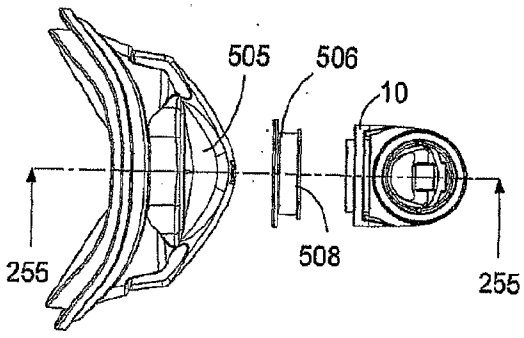

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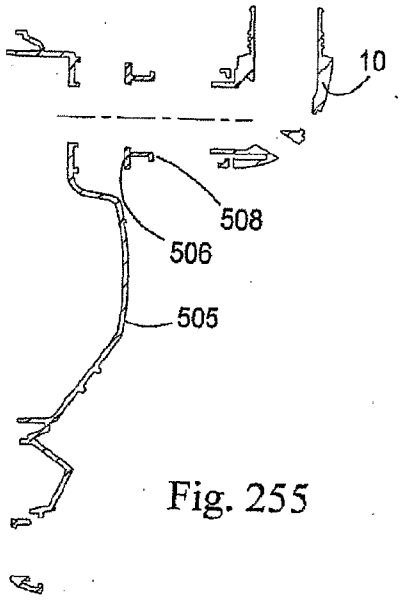

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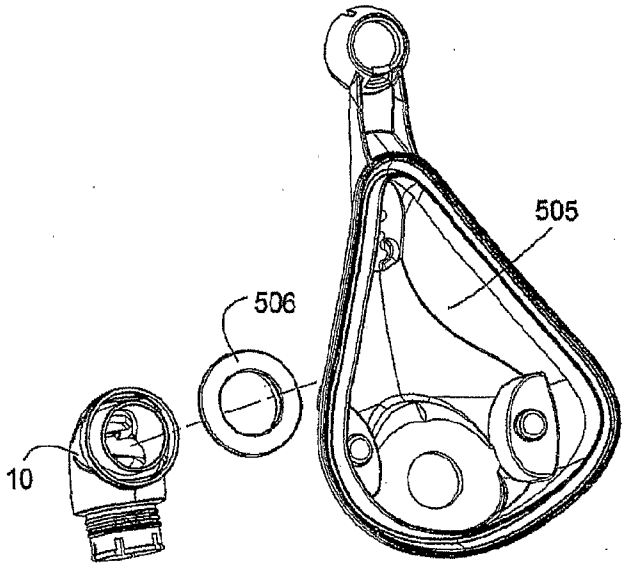

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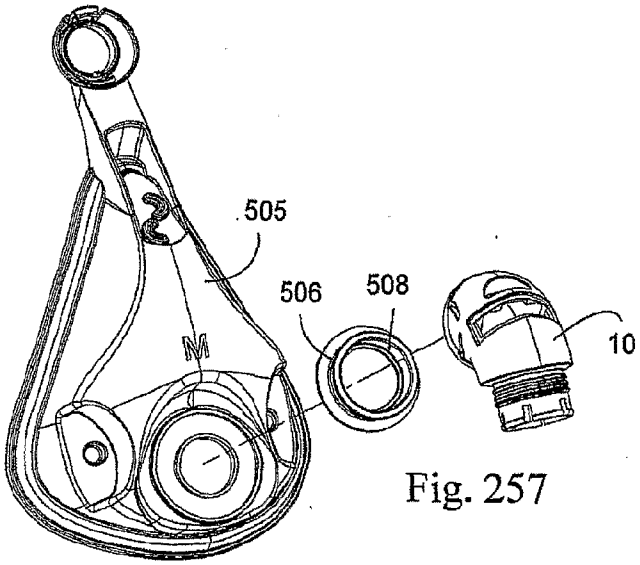

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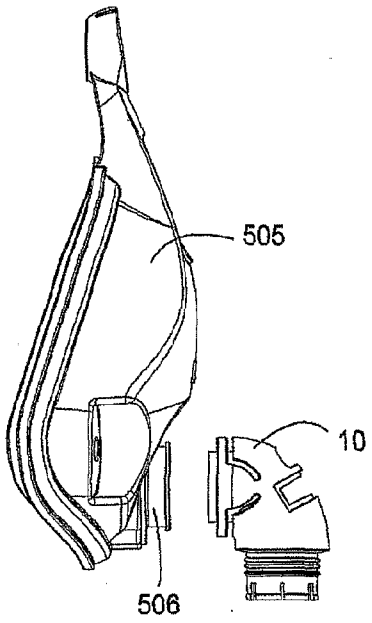

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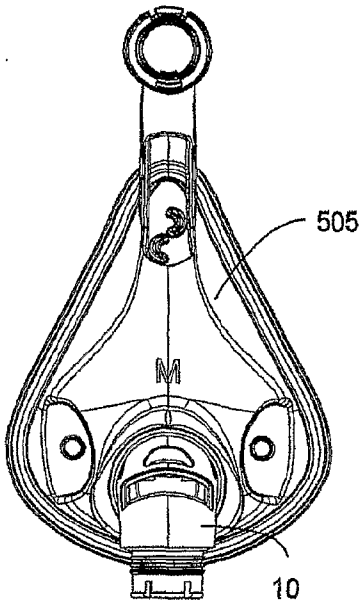

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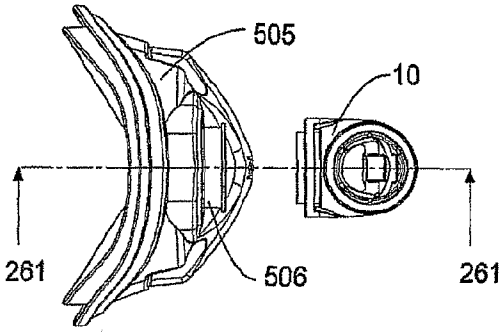

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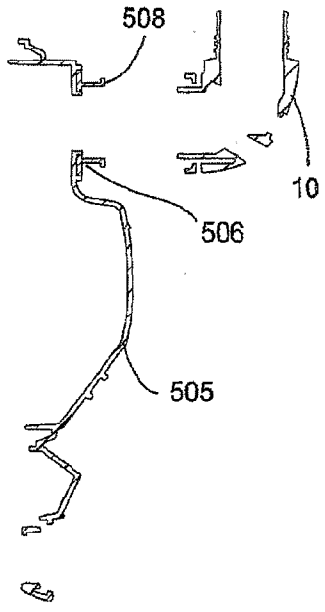

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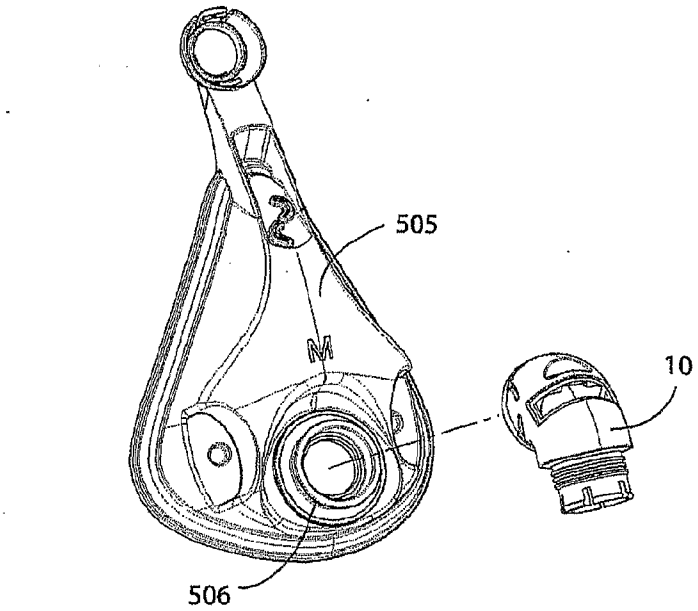

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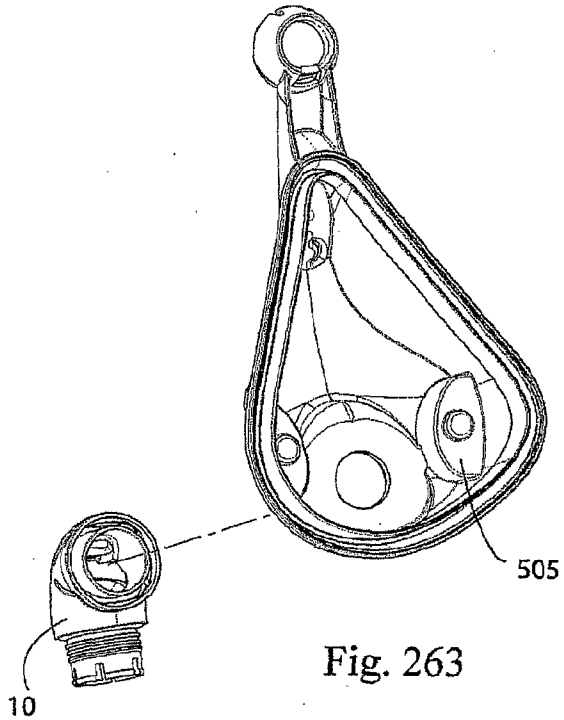

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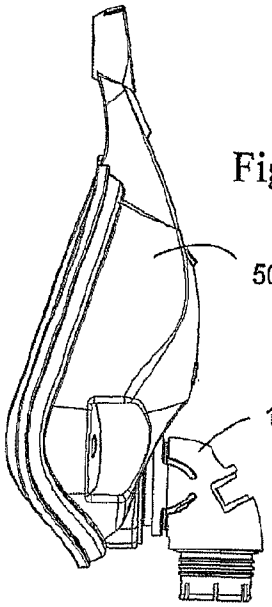

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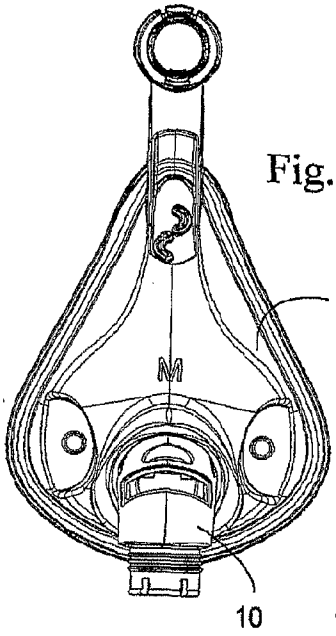

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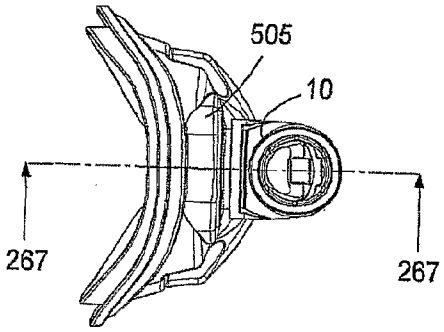

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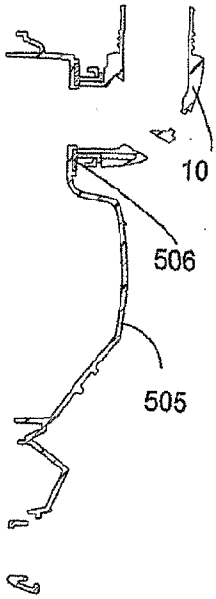

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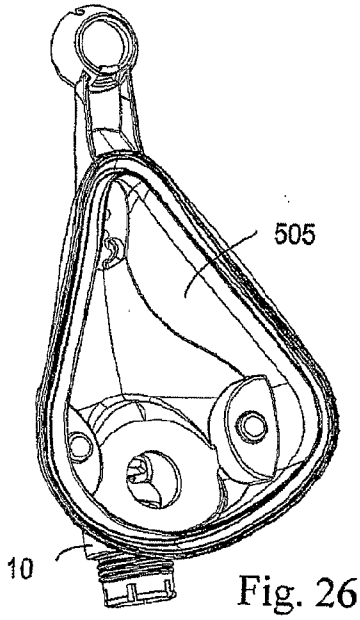

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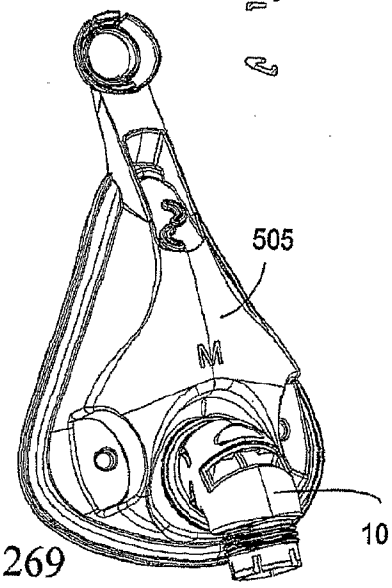

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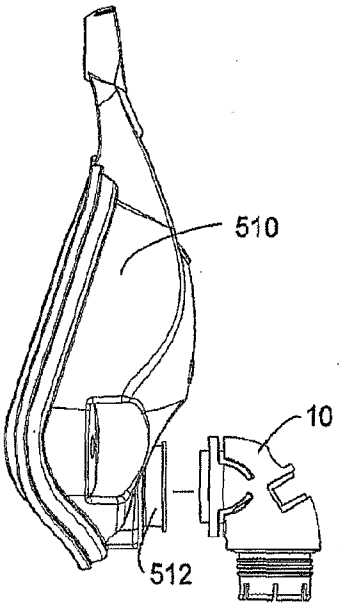
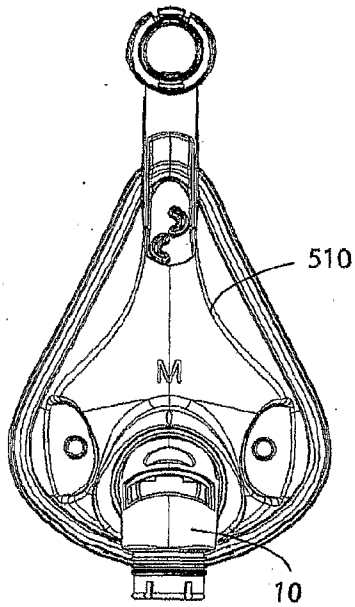


Fig. 270



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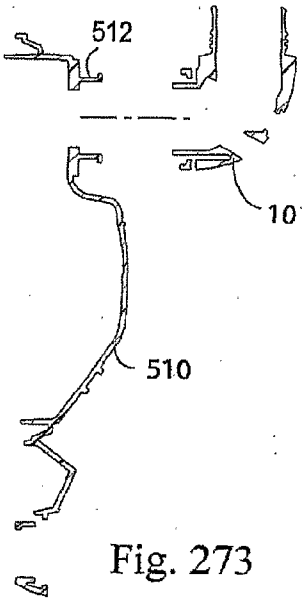

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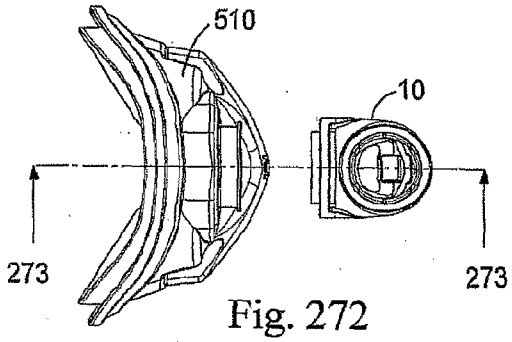

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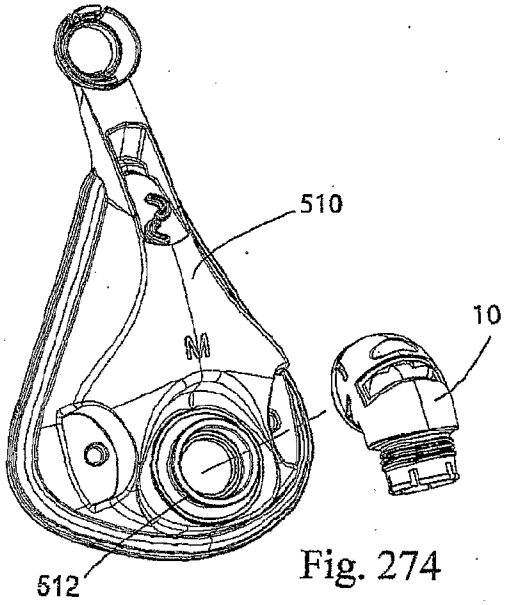

Fig. 274

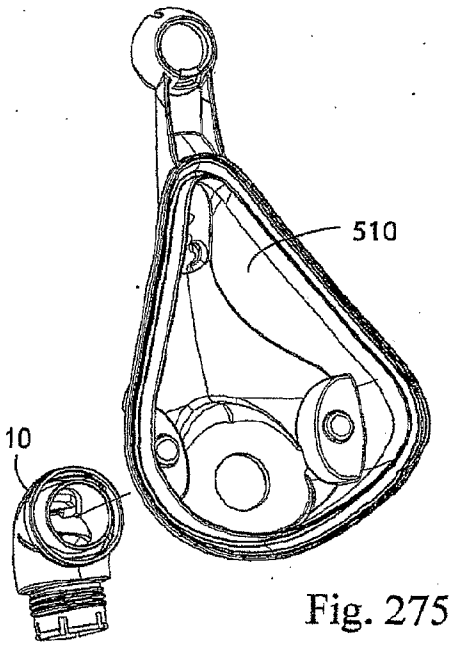

Fig. 275

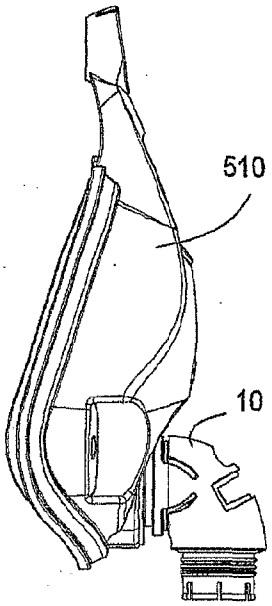

Fig. 276

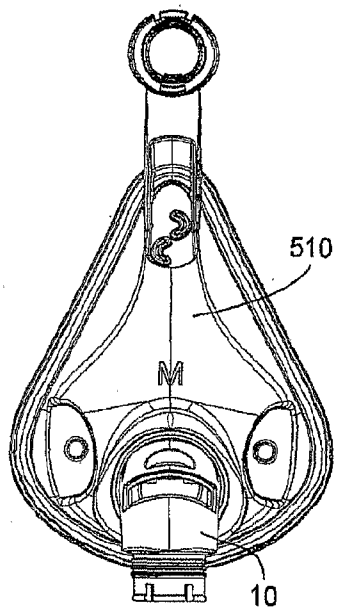

Fig. 277

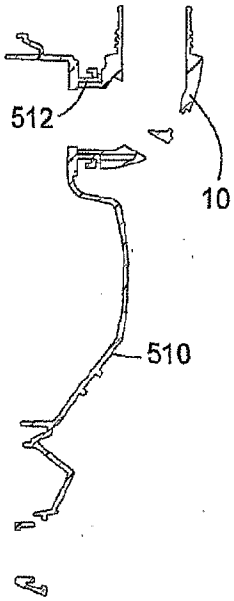

Fig. 279

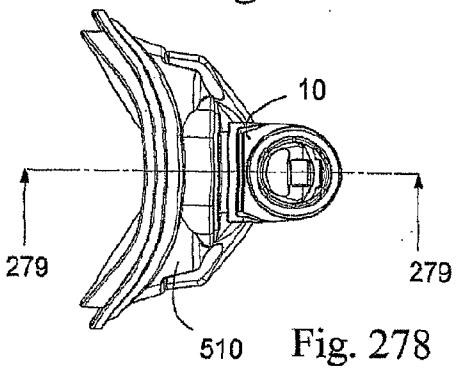

Fig. 278

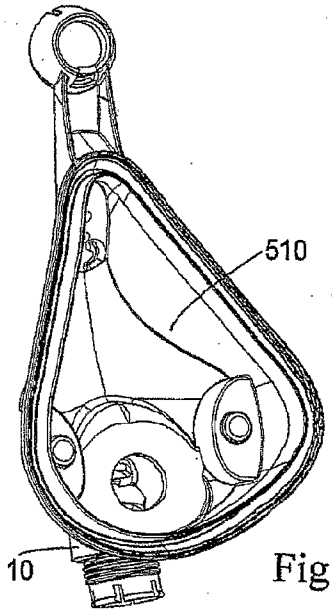

Fig. 280

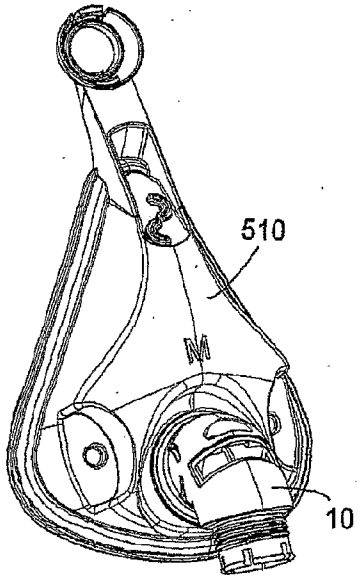

Fig. 281

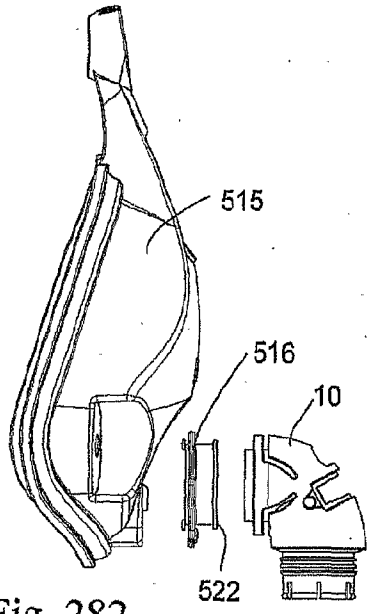

Fig. 282

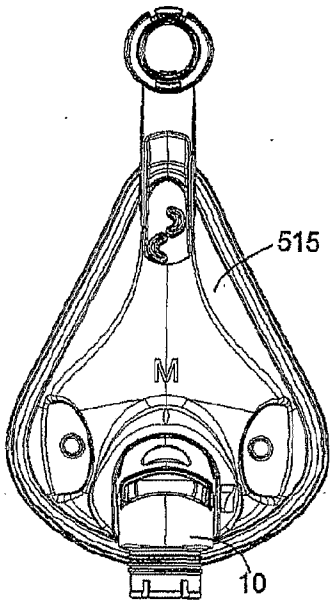

Fig. 283

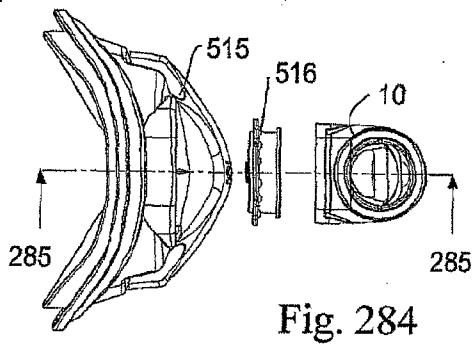

Fig. 284

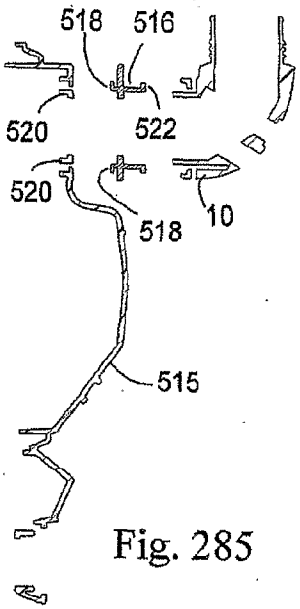

Fig. 285

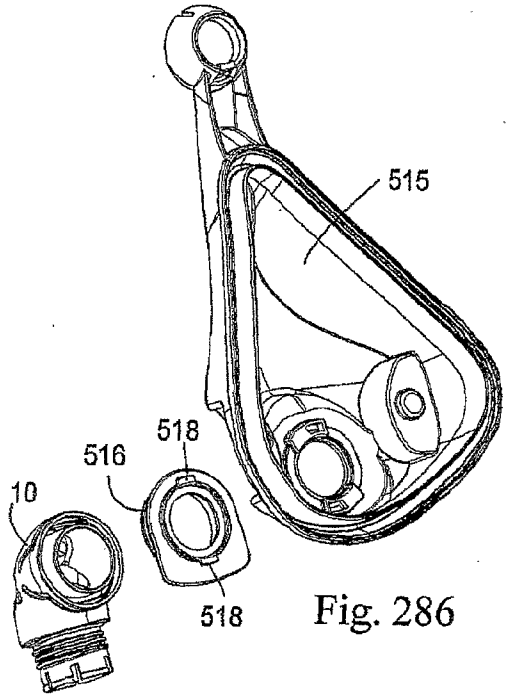

Fig. 286

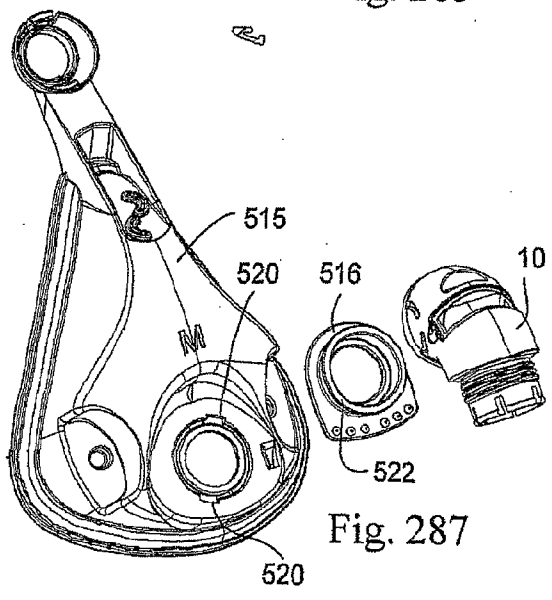

Fig. 287

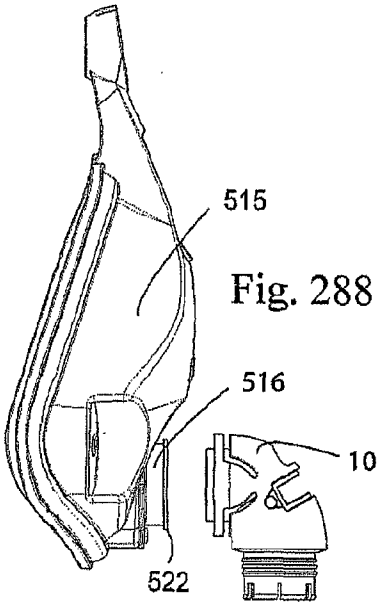

Fig. 288

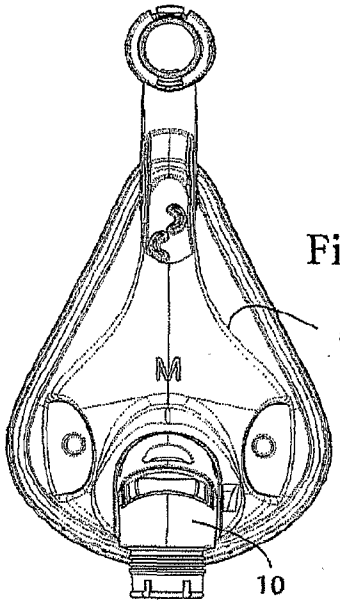

Fig. 289

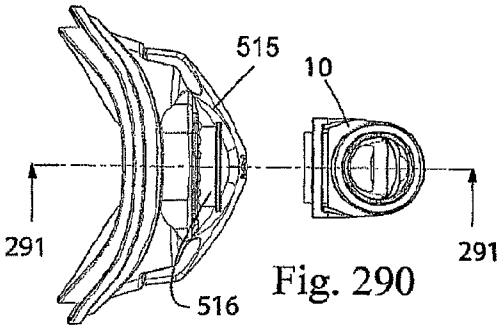

Fig. 290

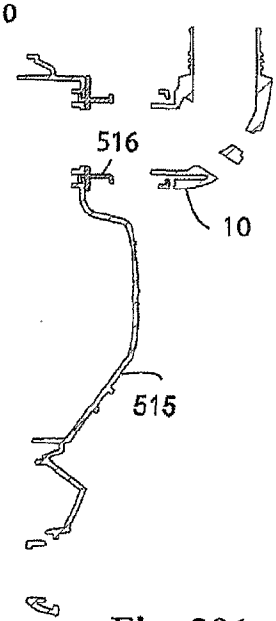

Fig. 291

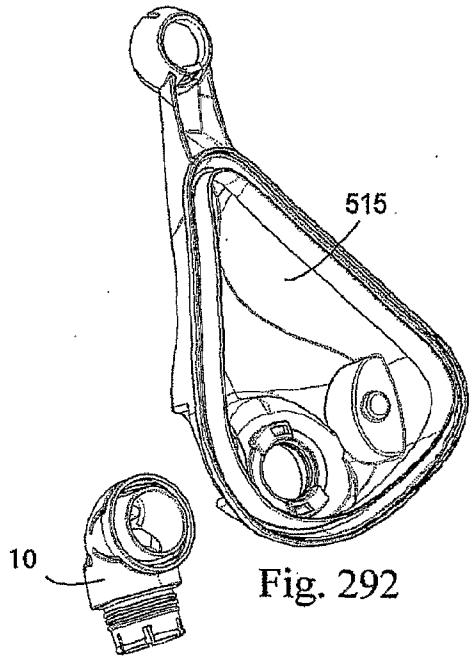

Fig. 292

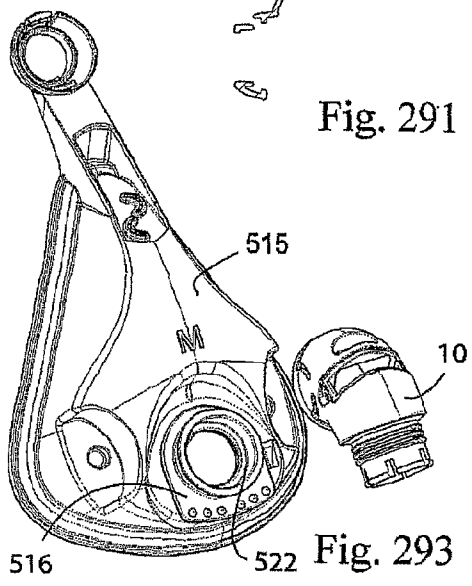

Fig. 293

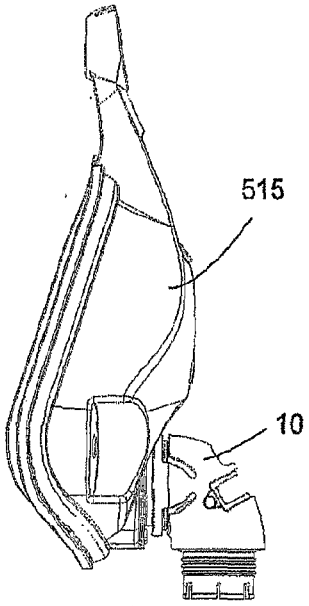

Fig. 294

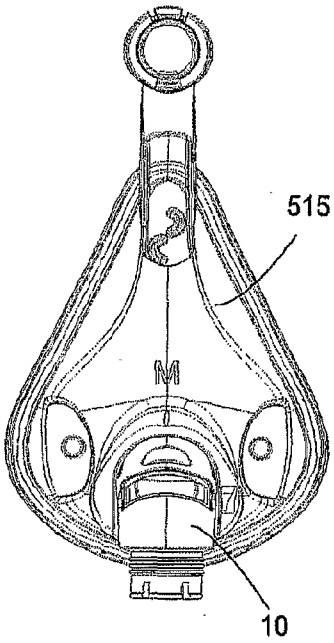

Fig. 295

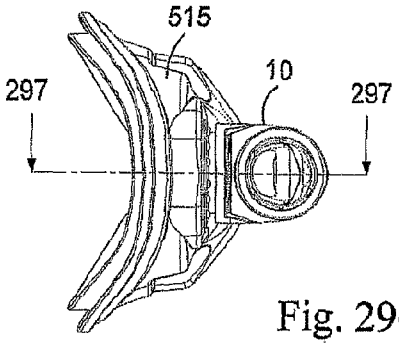

Fig. 296

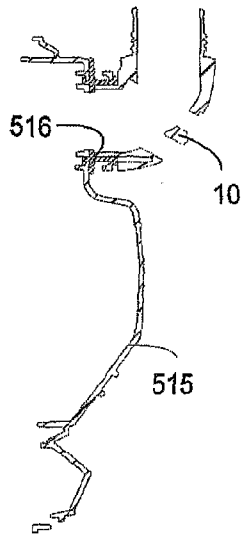

Fig. 297

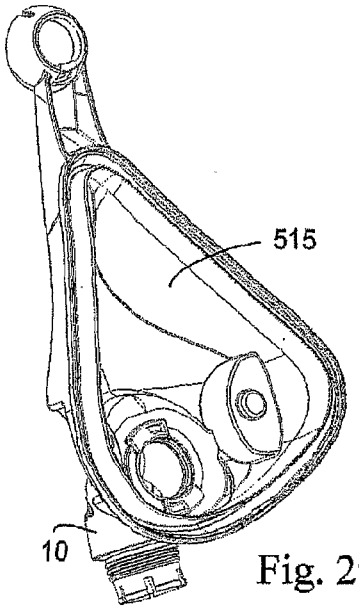

Fig. 298

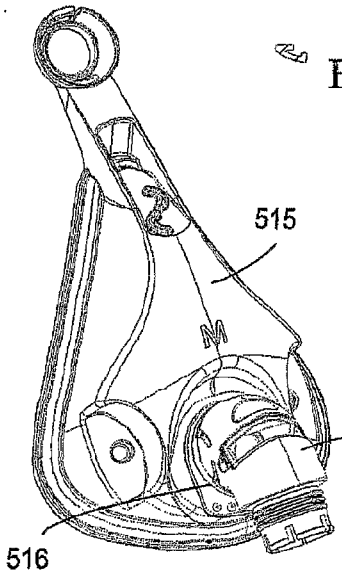

Fig. 299

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/000031

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 16/20 (2006.01) *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 keywords: A61M and valve and safety and asphyxia and similar terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1525895 A2 (RESMED LIMITED) 27 April 2005 Paragraphs 14 to 18	1-34,77-83
X	WO 2000/038772 A1 (RESMED LIMITED) 6 July 2000 Page 4 line 33 to page 7 line 5	1-9,13-24, 29-34,82
X	US 5647355 A (STARR et al.) 15 July 1997 Column 3 line 54 to column 4 line 21	35,37,82,83
X	WO 2005/063326 A1 (RESMED LIMITED) 14 July 2005 Paragraph 82	1,2,7-9,11-25, 29-35,37,38, 43-50,53-76, 82,83

[X] Further documents are listed in the continuation of Box C [X] 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

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 March 2006	28 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 D. Melhuish **DAVID MELHUISH** Telephone No : (02) 6283 2426

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/000031

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2004/0255948 A1 (SMITH et al.) 23 December 2004 Whole document	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/000031

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 supplementary 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 – 83**

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 Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

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

- Claims 1 to 83 directed to an elbow assembly for a respiratory mask wherein the elbow is provided with an anti-asphyxia valve. It is considered that the valve being in the elbow comprises a first distinguishing feature.
- Claims 84 to 88 directed to a mask assembly comprising a frame and an elbow, wherein the elbow is releasably connected to the frame. It is considered that the releasable connection comprises a second distinguishing feature.
- Claim 89 directed to a mask assembly comprising an elbow, a swivel and an elbow-to-swivel adaptor. It is considered that the adaptor comprises a third distinguishing feature.
- Claim 90 directed to a mask assembly comprising a frame and an elbow, wherein the seal between the frame and the elbow includes an integrated port cap assembly. It is considered that the integrated seal and port cap assembly comprises a fourth distinguishing feature.

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/AU2006/000031

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					
EP	1525895	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	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	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	2002108613
		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
WO	0038772	AU	27821/00	AU	65527/99	EP	1152787
US	5647355	US	5438981				
WO	2005063326	US	2005172969	WO	2005063327		
US	2004255948	NONE					

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX