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U.S. PATENT APPLICATION

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Title: MASK SYSTEM

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SPECIFICATION

MASK SYSTEM

CROSS-REFERENCE TO APPLICATION

[0001] U.S. Provisional Application Nos. 61/064,406, filed March 4, 2008, and 61/071,893, filed May 23, 2008, are each incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

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

BACKGROUND OF THE INVENTION

[0003] Patient interfaces, such as a full-face or nasal mask systems, for use with blowers and flow generators in the treatment of sleep disordered breathing (SDB), typically include a soft face-contacting portion, such as a cushion, and a rigid or semi-rigid shell or frame module. In use, the interface is held in a sealing position by headgear so as to enable a supply of air at positive pressure (e.g., 2-30 cm H_2O) to be delivered to the patient's airways.

[0004] One factor in the efficacy of therapy and compliance of patients with therapy is the comfort and fit of the patient interface.

[0005] The present invention provides alternative arrangements of mask systems to enhance the efficacy of therapy and compliance of patients with therapy.

SUMMARY OF THE INVENTION

[0006] One aspect of the invention relates to a mask system including a frame module and a cushion module provided to the frame module. The cushion module includes a main body defining a breathing chamber and a cushion adapted to form a seal with the patient's face. The frame module and the cushion module are co-molded with one another. The cushion module is constructed of a first, relatively soft, elastomeric material and the frame

module is constructed of a second material that is more rigid than the cushion module. At least a portion of the cushion module includes a concertina section having a plurality of folds. Each of the folds has a side wall with the side walls of the folds becoming progressively longer away from the patient's face.

[0007] Another aspect of the invention relates to a cushion module including a main body defining a breathing chamber and a cushion adapted to form a seal with the patient's face. The main body and the cushion are co-molded with one another. The cushion is constructed of a first, relatively soft, elastomeric material and the main body is constructed of a second material that is more rigid than the cushion. At least a portion of the main body includes a concertina section.

[0008] Another aspect of the invention relates to a method for constructing a cushion module including molding a first part of the cushion module with a first, relatively soft, elastomeric material, co-molding a second part of the cushion module to the first part with a second material that is more rigid than the first material, and molding at least a portion of the second part to include a concertina section.

[0009] Another aspect of the invention relates to a frame for a mask system including an annular retaining portion having an open construction and structured to retain a cushion, a pair of upper headgear connectors provided to respective sides of the retaining portion, and a pair of lower headgear connectors provided to respective sides of the retaining portion. Each upper headgear connector includes an elongated arm and a slot at the free end of the arm adapted to receive a headgear strap. Each lower headgear connector is adapted to attach to a headgear strap. The retaining portion, the upper headgear connectors, and the lower headgear connectors are integrally formed as a one piece structure.

[0010] In an alternative embodiment, the mask system may include a headgear connector or rigidizer structured to attach to the cushion module with a snap-fit, mechanical interlock, friction fit, and/or grommet arrangement (e.g., constructed of rubber).

[0011] In an alternative embodiment, the mask system may include headgear having an arrangement of straps constructed of silicone and/or Breath-O-Prene™ material.

[0012] 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

[0013] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

[0014] Fig. 1 is a front perspective view of a mask system according to an embodiment of the present invention;

[0015] Fig. 2 is an exploded view of the mask system shown in Fig. 1;

[0016] Fig. 3 is an enlarged front perspective view of the mask system shown in Fig. 1;

[0017] Fig. 4 is a side view of the mask system shown in Fig. 1;

[0018] Figs. 5-1 is a rear view of a cushion according to an embodiment of the present invention;

[0019] Fig. 5-2 is a front view of the cushion shown in Fig. 5-1 with a partial cut-away;

[0020] Fig. 5-3 is a cross-section view through line 5-3-5-3 in Fig. 5-1;

[0021] Fig. 5-4 is a cross-section view through line 5-4-5-4 in Fig. 5-1;

[0022] Fig. 5-5 is a cross-section view through line 5-5-5-5 in Fig. 5-1;

[0023] Figs. 6-1 to 6-3 illustrate top, front, and side views respectively of a concertina section according to an embodiment of the present invention;

[0024] Fig. 7 is a side view of a mask system including a cushion module according to a variation of the present invention;

[0025] Fig. 8 illustrates a cushion including a concertina section according to an embodiment of the present invention;

[0026] Figs. 9-1 to 9-3 are front, side, and rear views of a mask system according to another embodiment of the present invention;

[0027] Fig. 10 is a perspective view of a frame module for a mask system according to an embodiment of the present invention;

[0028] Figs. 11-1 to 11-3 are perspective, front, and side views of a mask system according to another embodiment of the present invention;

[0029] Figs. 12-1 to 12-5 are perspective, front, top, side, and bottom views of a frame module of the mask system shown in Figs. 11-1 to 11-3;

[0030] Figs. 13-1 to 13-6 are perspective, front, side, bottom, and top views of a mask system according to another embodiment of the present invention;

[0031] Figs. 14-1 and 14-2 are perspective and side views of a mask system according to another embodiment of the present invention;

[0032] Fig. 14-3 is a perspective view of the main body of a cushion module of the mask system shown in Figs. 14-1 and 14-2;

[0033] Figs. 14-4 and 14-5 illustrate a retaining member of the main body shown in Fig. 14-3;

[0034] Figs. 14-6 and 14-7 illustrate a clip-on upper headgear connector of the mask system shown in Figs. 14-1 and 14-2;

[0035] Figs. 15-1 and 15-2 are rear and front perspective views of a mask system according to another embodiment of the present invention;

[0036] Figs. 15-3 and 15-4 are exploded views of the mask system shown in Figs. 15-1 and 15-2;

[0037] Figs. 15-5 to 15-12 are various views of a clip-on upper headgear connector of the mask system shown in Figs. 15-1 and 15-2;

[0038] Fig. 16-1 is a rear perspective view of a mask system according to another embodiment of the present invention;

[0039] Fig. 16-2 is an exploded view of the mask system shown in Fig. 16-1;

[0040] Figs. 16-3 to 16-7 are various views of a clip-on upper headgear connector of the mask system shown in Fig. 16-1;

[0041] Figs. 17-1 to 17-4 are perspective, side, front, and rear views of a mask system according to another embodiment of the present invention;

[0042] Fig. 18 illustrates a mask system according to another embodiment of the present invention; and

[0043] Fig. 19 illustrates a mask system according to another embodiment of the present invention.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0044] The following description is provided in relation to several embodiments which may share common characteristics and features. It is to be understood that one or more features of any one embodiment may be combinable with one or more features of the other embodiments. In addition, any single feature or combination of features in any of the embodiments may constitute additional embodiments.

[0045] While each embodiment below is described as including a full-face interface type, each embodiment may be adapted for use with other suitable interface types. That is, the interface type is merely exemplary, and each embodiment may be adapted to include other interface types, e.g., nasal interface, etc.

[0046] In this specification, the word "comprising" is to be understood in its "open" sense, that is, in the sense of "including", and thus not limited to its "closed" sense, that is the sense of "consisting only of". A corresponding meaning is to be attributed to the corresponding words "comprise", "comprised" and "comprises" where they appear.

[0047] The term "air" will be taken to include breathable gases, for example air with supplemental oxygen.

1. Mask System

[0048] Figs. 1-4 illustrate a mask system 10 according to an embodiment of the present invention. In this embodiment, the mask system 10 includes a full-face or oro-nasal interface. The mask system 10 includes a frame module 20, a cushion module 40 provided to the frame module 20 and adapted to form a seal with the patient's face, and an elbow module 70 provided to the frame module 20 and adapted to be connected to an air delivery tube that delivers breathable gas to the patient. Headgear 90 may be removably attached to the frame module 20 to maintain the mask system 10 in a desired adjusted position on the patient's face. The mask system is intended for use in positive pressure therapy for users with obstructive sleep apnea (OSA) or another respiratory disorder.

[0049] As described below, the mask system 10 provides a modular design that allows different styles and/or sizes of the frame module 20, cushion module 40, and elbow module

70 to be interchanged or mixed and matched with one another to provide a more customized mask system for the patient. In addition, such design allows selected modules to be easily replaced, e.g., treatment requirements change, worn out or damaged, etc.

1.1 Frame Module

[0050] The frame module 20 (e.g., constructed from polycarbonate, polypropylene, thermoplastic elastomer (TPE), Pocan®, etc.) is structured to maintain the cushion module 40 and the elbow module 70 in an operative position with respect to the patient's face. In addition, the frame module 20 is structured to removably attach to the headgear 90 adapted to maintain the mask system 10 in a desired position on the patient's face.

[0051] As best shown in Fig. 2, the frame module 20 (also referred to as a skeleton frame) includes an open construction that provides an annular or part annular retaining portion 22 structured to retain the cushion module 40 and the elbow module 70. The frame module 20 also includes upper and lower headgear connectors 24, 25 on each side of the retaining portion 22.

[0052] In the illustrated embodiment, each upper headgear connector 24 includes an elongated arm 26 and a slot 27 at the free end of the arm 26 adapted to receive a respective headgear strap in use. Each arm 26 may be at least semi-rigid (i.e., rigidizer) to stabilize the mask system on the patient's face. Also, each arm 26 is suitably formed, shaped, or contoured to follow the contours of the patient's face and avoid line of sight in use. A cheek pad may be provided to the inner surface of the arm 26 to support the arm 26 on the patient's cheek in use.

[0053] Each lower headgear connector 25 includes a clip receptacle 31 adapted to be removably interlocked with a headgear clip 33 associated with a respective headgear strap. As best shown in Fig. 2, each clip 33 includes two spring arms 35 adapted to interlock with the respective clip receptacle 31 with a snap-fit and a slot 37 adapted to receive a respective headgear strap in use.

[0054] In an embodiment, the arm 26 may be removably coupled to the frame module 20, e.g., arm 26 includes clip structure adapted to removably interlock with a clip receptacle provided to the frame module 20. This arrangement allows different styles of upper and lower headgear connectors to be used with the frame module, e.g., arms for both upper and

lower headgear connectors, clips for both upper and lower headgear connectors, different length arms for upper and lower headgear connectors, etc.

[0055] However, the frame module 20 may provide other suitable arrangements for attaching headgear straps of headgear. Also, the frame module 20 may include one or more additional components, e.g., forehead support.

[0056] The mask system 10 is provided without a forehead support adapted to engage the patient's forehead. This provides the mask system 10 with a less obtrusive arrangement which does not significantly affect the patient's field of view.

1.2 Cushion Module

[0057] The cushion module 40 is structured to interface with the frame module 20 and form a seal with patient's nose and mouth in use.

[0058] The cushion module 40 includes a main body 42 and a cushion 44 provided to the main body 42. In use, the main body 42 defines a breathing chamber and is adapted to interface with or otherwise attach to the frame module 20 and the cushion 44 provides a sealing portion or sealing ring adapted to form a seal with the patient's nose and/or mouth. Also, the main body 42 includes an opening 46 that is adapted to communicate with the elbow module 70.

[0059] In the illustrated embodiment, the cushion 44 is a full-face cushion adapted to engage the patient's face generally along nasal bridge, cheek, and lower lip/chin regions of the patient's face. However, other cushion interfaces are possible, e.g., nasal.

[0060] Figs. 5-1 to 5-5 illustrate various views of a cushion (e.g., constructed of silicone) according to an embodiment of the present invention. As illustrated, the cushion 44 includes a base wall 44(1) provided to the main body 42, an undercushion layer (UCL) 44(2) extending away from the base wall 44(1), and a membrane 44(3) provided to substantially cover the UCL 44(2) and provide a sealing structure. In the illustrated embodiment, the cushion 44 is structured to sit lower on the nasal bridge to reduce mask obtrusiveness and improve "line of sight" in use.

[0061] Also, as best shown in Figs. 5-3 and 5-5, the UCL 44(2) design in the nasal bridge region is structured to provide improved stability across the nasal bridge in use. As

shown in Fig. 5-1 and 5-3, the UCL is not provided in the lower lip/chin region. However, other arrangements of the UCL are possible, e.g., UCL around entire perimeter.

[0062] In an embodiment of the cushion shown in Figs. 5-1 to 5-5, D1 may be about 15-20 mm, e.g., 18.2 mm, D2 may be about 53-59 mm, e.g., 55.8 mm, D3 may be about 88-93 mm, e.g., 90 mm, D4 may be about 78-83 mm, e.g., 81.1, D5 may be about 58-63 mm, e.g., 60 mm, D6 may be about 95-100 mm, e.g., 98.1 mm, D7 may be about 57-62 mm, e.g., 59.7 mm, D8 may be about 77-82 mm, e.g., 79 mm, D9 may be about 88-93 mm, e.g., 90.7 mm, D10 may be about 30-35 mm, e.g., 33.1 mm, D11 may be about 14-19 mm, e.g., 16.4 mm, D12 may be about 8-13 mm, e.g., 9.6 mm, D13 may be about 0.3-0.5 mm, e.g., 0.35 mm, D14 may be about 0.4-0.6 mm, e.g., 0.5 mm, and D15 may be about 0.3-0.5 mm, e.g., 0.4 mm. Although specific dimensions and ranges are indicated, it is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application. For example, the exemplary dimensions may vary by 10-20% or more or less depending on application.

[0063] The mask system 10 may be provided with a number of different cushion modules 40, e.g., each having cushions of different styles and/or sizes (e.g., depending on patient preference and/or fit). For example, the main body 42 of each cushion module may include a common or universal configuration for interfacing with the frame module 20, and the cushion 44 may include different styles and/or sizes. This provides a modular arrangement that allows the frame module 20 to be selectively (e.g., and removably) coupled to one of multiple cushion modules. For example, the different cushion modules may include different size cushions (e.g., small, medium, and large) and may include a different cushion structures.

[0064] Similarly, the cushion module 40 may be provided with different frame modules 20, e.g., each frame module having a different style and/or size (e.g., frame module with forehead support, frame module with different arrangement/style of headgear connectors, etc).

1.2.1 Co-Molding Main Body and Cushion

[0065] In an embodiment, as shown in Figs. 1-4, the main body 42 and cushion 44 may be co-molded with one another to form a one-piece, integrated component. For example,

the main body 42 may be molded of a first material adapted to interface with the frame module 20 and the cushion 44 may be co-molded onto the main body 42 of a second material adapted to interface with patient's face.

[0066] In such embodiment, the cushion 44 may be constructed of a relatively soft elastomeric material (e.g., silicone) for sealing and the main body 42 may be constructed of a more rigid material than the cushion 44 (e.g., polycarbonate, polypropylene) for interfacing with the frame.

[0067] Co-molding the main body 42 to the cushion 42 provides a chemical bond without necessarily forming a mechanical interlock. As a result, the connection includes no cracks, a gas tight seal, and clean interface. Moreover, such co-molded connection relaxes tolerances as the mold materials are sufficiently flexible to fill in any gaps at the interface between the main body 42 and the cushion 44. Also, the co-molded cushion module 40 provides a reduced part count (reduced cost) and facilitates assembly/disassembly to the frame module 20.

[0068] The frame module 20 is structured to hold and secure the cushion module 40 in an operative position with respect to the patient's face. As shown in Fig. 2, the annular retaining portion 22 includes an interfacing structure 23 along an inner edge that is adapted to interface with or otherwise removably connect to an interfacing structure 48 along the outer perimeter of the main body 42 of the cushion module 40 (e.g., see Fig. 2). In the illustrated embodiment, the interfacing structure 23 is in the form of opposed flanges 23(1) that are adapted to interlock with respective locking structures 48(1) provided on opposing sides of the main body 42. However, other suitable arrangements for attaching the cushion module 40 to the frame module 20 are possible, e.g., friction fit, snap-fit, mechanical interlock, or other suitable attachment mechanism.

[0069] For example, the cushion module 40 may be coupled to the frame module 20 in a manner that allows the cushion module 40 to be locked in different angular positions with respect to the frame module 20, e.g., pivotally mounted.

1.2.2 Co-Molding Cushion Module and Frame

[0070] In the arrangement shown in Fig. 7, the main body 42 and cushion 44 may be integrally formed in one piece, e.g., of a silicone material. That is, the cushion module 40

may have the same shape and structure as described above, but be integrally molded of the same material, e.g., silicone.

[0071] In an embodiment, the integrally formed cushion module 40 may be co-molded to the frame module 20, e.g., constructed of polycarbonate or polypropylene. For example, frame module 20 may be constructed of a relatively rigid material (e.g., polycarbonate or polypropylene) and the cushion module 40 may be co-molded onto the frame module 20 of a relatively soft elastomeric material (e.g., silicone).

1.2.3 Concertina Section

[0072] As best shown in Figs. 4 and 7, a concertina section 50 is provided in a nasal bridge region of the cushion module 40. As illustrated, the concertina section 50 includes a bellows structure with one or more folds 52 that provide a higher degree of flexibility or increased movement to the main body 42. That is, the concertina section 50 provides a higher level of adaptability or flexibility to the nasal bridge region of the cushion module 40 which is a more sensitive region of the patient's face in use. Moreover, the concertina section 50 provides increased movement without compromising seal.

[0073] Figs. 6-1 to 6-3 illustrate various views of a concertina section 50 (isolated from the remainder of the cushion module) with one or more folds 52 according to an embodiment of the present invention. As best shown in Fig. 6-3, the folds may have different lengths, depths, and/or contours with respect to one another to optimize the concertina effect, e.g., provide sufficient degree of movement without compromising seal. For example, as shown in Fig. 6-3, each fold 52 includes a first side wall 52(1) and a second side wall 52(2) that interconnects adjacent side walls 52(1).

[0074] In the illustrated embodiment, the first side walls 52(1) and/or the second side walls 52(2) may become progressively longer away from the patient's face. For example, the first side wall 52(1) and/or the second side wall 52(2) adjacent patient's face, or the combination of side walls 52(1) and 52(2), may have a length that is longer than and in some cases significantly longer than the adjacent side wall 52(1) and/or 52(2) (e.g., one side wall at least 25% greater than and up to 5x as long as the other side wall, e.g., 1x, 2x, 3x, or 4x).

[0075] The folds may be constructed and arranged to provide a predetermined order of movement or folding, e.g., folds structured to fold in a sequential or progressive manner

wherein one fold collapses before an adjacent fold collapses. For example, upon application of force, the folds closest to the patient's face may fold or collapse before the folds furthest from the patient's face. Also, the folds may be constructed and arranged to provide various degrees of fold or collapse, e.g., folds may fold or collapse more than others.

[0076] In an embodiment of the concertina section shown in Figs. 6-1 to 6-3, D1 may be about 50-60 mm, e.g., 55.7 mm, D2 may be about 5-15 mm, e.g., 9.7 mm, and D3 may be about 0.3-0.5 mm, e.g., 0.4 mm. Although specific dimensions and ranges are indicated, it is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application. For example, the exemplary dimensions may vary by 10-20% or more or less depending on application.

[0077] It should be appreciated that a concertina section 50 may be provided in other regions of the cushion module 40, e.g., depending on patient comfort. For example, the concertina section 50 may be provided around the entire perimeter of the cushion module 40 or may be provided in selected regions of the cushion module 40.

[0078] Also, the flexibility of the concertina section 50 may be varied and may be varied in different regions of the cushion module 40, e.g., depending on patient comfort. For example, the cushion module 40 may include a concertina section in the nasal bridge region with a relatively high degree of flexibility and a concertina section in the lower lip/chin region with a relatively low degree of flexibility. The flexibility of the concertina section 50 may be varied by varying the number of folds 52 (e.g., 1-5 folds), the wall lengths, the wall thickness of the folds 52, the depth of the folds 52, etc.

[0079] As noted above, the cushion module may be co-molded of two parts with different materials/rigidities or may be integrally formed of the same material. In both embodiments, the concertina section may be provided in the main body and/or the cushion.

[0080] In Figs. 1-4, the cushion module 40 is co-molded of two parts (i.e., main body 42 and cushion 44) with the concertina section 50 provided in the main body 42. The main body 42 and cushion 44 include different rigidities in order to optimize the function of each part. For example, one part (i.e., cushion 44) may be constructed of a relatively soft, supple material to optimize the sealing effect and the other part (i.e., main body 42) may be constructed of a more rigid material to provide adequate support for the cushion while at the same time allowing a sufficient degree of movement to optimize the concertina effect. While

the main body is more rigid than the cushion, the main body may be constructed of a flexible material to allow the concertina effect.

[0081] In Fig. 7, the main body 42 and cushion 44 are integrally formed in one piece with the concertina section 50 provided in the main body 42. The material properties and/or dimensions may be selectively modified to optimize sealing and concertina effects.

[0082] For both embodiments of Figs. 1-4 and 7, it should be appreciated that the concertina section may be alternatively provided in the cushion 44 or in both the main body 42 and cushion 44. For example, Fig. 8 illustrates a concertina section 50 integrally formed with the cushion 44 in the nasal bridge region.

1.3 Elbow Module

[0083] The elbow module 70 includes an elbow 74, a vent arrangement 76 provided to the elbow 74 for gas washout, and an anti-asphyxia valve (AAV) 85 provided to the elbow 74.

[0084] In an embodiment, the mask system may be provided with a number of different elbow modules 70, e.g., each having a vent arrangement, AAV (in the case of an oro-nasal mask), and/or elbow of different styles and/or sizes. In the illustrated embodiment, the vent arrangement 76 and AAV 85 are structured to be removably attachable to the elbow 74. This provides a modular arrangement that allows the elbow module 70 to be selectively and removably coupled to one of multiple vent arrangements 76 and/or AAVs 85. This also allows the vent arrangement and AAV to be easily replaced, e.g., if damaged.

1.3.1 Elbow

[0085] The elbow 74 (e.g., constructed of a relatively hard material such as polycarbonate or polypropylene) includes a first end portion 74(1) and a second end portion 74(2). The first end portion 74(1) provides an interfacing structure 75 structured to interface or otherwise attach to the frame module 20. The second end portion 74(2) is provided to a swivel joint 80 adapted to be connected to an air delivery tube.

[0086] As illustrated, the first end portion 74(1) of the elbow 74 provides a relatively large diameter which allows the potential for cleaner/smoother lines thereby contributing to the overall mask aesthetic and reduced obtrusiveness. In addition, the relatively large

diameter elbow offers the potential for the patient's nose to protrude into the elbow cavity thereby permitting the mask to be brought closer to the patient's face (i.e., reduced obtrusiveness).

[0087] In the illustrated embodiment, the swivel joint 80 is provided to a short tube 82 (e.g., extendable and retractable tube) that interconnects the elbow with the air delivery tube. In an embodiment, the swivel joint 80 may be integrally formed in one piece with the short tube 82.

1.3.2 Vent Arrangement

[0088] In the illustrated embodiment, the vent arrangement 76 is in the form of a vent insert that is adapted to be removably supported within an outlet opening in the elbow 74. In an embodiment, the vent arrangement 76 includes a base adapted to be supported within the outlet opening, one or more grill components or media (e.g., filter, membrane, or other porous material) provided to the base and structured to diffuse vent flow, and a cover to maintain the grill components/media within the base. Only the cover 77 of the vent arrangement 76 is visible in Figs. 1-4.

[0089] Exemplary embodiments of such a vent arrangement are disclosed in U.S. Provisional Patent Application No. 60/957,766, filed August 24, 2007, which is incorporated herein by reference in its entirety.

[0090] However, it should be appreciated that the vent arrangement may include other suitable arrangements, e.g., vent insert with one or more vent holes.

[0091] Also, the elbow may provide an alternative venting arrangement to the vent insert. For example, as indicated in dashed lines in Fig. 4, the first end portion 74(1) of the elbow 74 (e.g., along the interfacing structure 75) may include one or more vent holes 276 for gas washout. The one or more holes 276 may be provided to a soft part (e.g., silicone seal as described below) and/or a hard part (e.g., polycarbonate, polypropylene) of the elbow. The holes 276 may extend around the entire perimeter of the first end portion 74(1) or may extend along one or more portions of the first end portion 74(1). It is noted that providing vent holes along the entire perimeter of the elbow may help to disperse the vent flow in use. However, other suitable hole arrangements, hole numbers, and/or hole shapes along the first end portion 74(1) and/or other portions of the elbow are possible.

1.3.3 AAV

[0092] The elbow 74 includes a slot to receive the AAV 85, a port 79 that is selectively closed by a flap portion 86 of the AAV 85 (depending on the presence of pressurized gas), and structure for attaching the AAV 85, e.g., with a snap-fit.

[0093] The AAV 85 includes a flap portion 86 and a clip portion 88 provided to the flap portion 86 for attaching the AAV 85 to the elbow 74. In the illustrated embodiment, the flap portion 86 and the clip portion 88 are co-molded with one another to form a one-piece, integrated component. However, the flap portion 86 and clip portion 88 may be secured to one another in other suitable manners, e.g., mechanical interlock.

[0094] In an embodiment, the flap portion 86 may be constructed of a relatively soft elastomeric material (e.g., silicone) and the clip portion 88 may be constructed of a more rigid material (e.g., rigid plastic) for interfacing with the elbow 74.

[0095] The clip portion 88 of the AAV 85 includes structure for removably interlocking with the elbow 74, e.g., with a snap-fit. For example, the clip portion 88 may include tabs structured to interlock with respective recesses/protrusions provided to the elbow 74.

[0096] Alternative embodiments of the AAV are disclosed in PCT Application No. PCT/AU2006/000031, which is incorporated herein by reference in its entirety.

1.3.4 Elbow Module Attachment to Frame Module

[0097] The frame module 20 is structured to maintain the elbow module 70 in an operative position with respect to the patient's face. That is, the frame module 20 acts as a carrier and bearing surface for the elbow module 70. The frame module 20 and elbow module 70 may connect with a friction fit, snap-fit, mechanical interlock, or other suitable attachment mechanism. However, other suitable arrangements for attaching the elbow module to the frame module are possible.

[0098] In the illustrated embodiment, the elbow module 70 may be rotatably attached to the frame module 20 so that the elbow module 70 may be rotated relative to the frame module 20 in use, e.g., 360° rotation. This arrangement allows the elbow module 70 to assume different orientations in use, e.g., depending on patient preference. For example, the

elbow module 70 may assume a first orientation so that the elbow extends generally downwardly from the mask to direct the air delivery tube under the patient's head in use. Alternatively, the elbow module 70 may be rotated and assume a second orientation so that the elbow extends upwardly from the mask to direct the air delivery tube over the patient's head in use. In an embodiment, the frame module 20 and elbow module 70 may be constructed of dissimilar materials to prevent or at least reduce squeak between the components in use.

1.4 Interface Seal

[0099] In an embodiment, a seal may be provided at the interface between the elbow module 70 and the frame module 20, at the interface between the cushion module 40 and the frame module 20, and/or at the interface between the elbow module 70 and the frame module 20. For example, a seal (e.g., elastomeric, ring-shaped seal) may be formed separately from the modules and attached at the interface (e.g., sandwiched between modules, adhesive, etc.). Alternatively, a seal may be co-molded with one or more of the modules. In an embodiment, a silicone lip seal may be provided to the cushion module to seal against the elbow module, thereby reducing leak.

[00100] In another embodiment, the interfacing structure 75 of the elbow module 70 may be constructed of a relatively soft, sealing material (e.g., silicone, which may be co-molded to the harder material of the elbow) that is structured to provide a seal at the interface between the elbow module 70 and the frame module 20. Also, the relatively soft interfacing structure 75 (e.g., silicone) provides a "soft" attachment to the relatively hard frame 20 (e.g., polycarbonate, polypropylene) which may allow an interference type fit. As noted above, one or more vent holes may be provided to the softer interfacing structure and/or the harder elbow.

1.5 Headgear

[00101] Headgear 90 may be removably attached to the headgear connectors 24, 25 of the frame module 20 to maintain the mask system in a desired position on the patient's face.

[00102] In the illustrated embodiment, the headgear 90 includes a pair of upper and lower straps 92, 94 with the upper straps 92 removably attached to respective upper headgear

connectors 24 and the lower straps 94 removably attached to respective lower headgear connectors 25. The free end of each strap may include a Velcro® tab structured to engage the remainder of the strap to secure the strap in place. Such Velcro® attachment also allows adjustment of the length of the straps. However, the upper and lower headgear straps 92, 94 may be secured to the frame module 20 in any other suitable manners, e.g., adjustable ladder-lock arrangement, etc.

[00103] The headgear 90 also includes an upper strap 96 adapted to pass over the top of the patient's head in use and a rear strap 98 adapted to pass behind the patient's head in use.

[00104] The headgear 90 is structured to be self-supporting.

2. Alternative Mask Arrangement

[00105] Figs. 9-1 to 9-3 illustrate a mask system 210 according to another embodiment of the present invention. The mask system 210 includes a similar modular design to the mask 10 described above (i.e., frame module 220, cushion module 240, elbow module 270, and headgear 290). However, as illustrated, the modular components provide alternative configurations.

2.1 Frame Module

[00106] The frame module 220 includes an annular retaining portion 222 structured to retain the cushion module 240 and upper and lower headgear connectors 224, 225 on each side of the retaining portion 222. In the illustrated embodiment, the frame module 220 is integrally formed in one piece (e.g., see Fig. 10).

[00107] In the illustrated embodiment, each upper headgear connector 224 includes an elongated arm 226 and a slot 227 at the free end of the arm 226 adapted to receive a respective rear strap 298 in use. As illustrated, the arm 226 is suitably contoured to extend along the cheeks and over the patient's ear just anterior of the patient's temple and retain the respective rear strap 298 in spaced relation over the patient's ear, e.g., to avoid the strap rubbing or irritating the patient's ear in use.

[00108] Also, each arm 226 is structured to extend along and engage an upper strap 292 of the headgear in use. As illustrated, each arm 226 is secured to the upper strap 292 to add rigidity to the strap and stabilize the mask system on the patient's face in use. In addition,

the strap 292 provides padding to the arm 226 on the patient's face in use. In an embodiment, the upper strap 292 may be fixed to the arm 226 by gluing or stitching for example. Alternatively, the arms 226 may be encapsulated by or inserted into respective straps 292 so that the arms 226 are substantially not visible.

[00109] Each lower headgear connector 225 includes an abbreviated arm 228 with a slot 229 at the free end of the arm 229 adapted to receive a respective lower strap 294 in use. As illustrated, the arm 228 is suitably oriented to retain the respective lower strap 294 in spaced relation under the patient's ear, e.g., to avoid the strap rubbing or irritating the patient's ear in use.

[00110] In an alternative embodiment, as shown in Fig. 10, each lower headgear connector 225 may include a clip receptacle 231 adapted to be removably interlocked with a headgear clip (not shown) associated with a respective lower strap 294. In an embodiment, the headgear clip receptacle and clip may be similar to that on ResMed's Mirage Liberty mask. Exemplary clip arrangements are disclosed in U.S. Patent Publication Nos. 2007/0144525 and 2006/0283461, each of which is incorporated herein by reference in its entirety.

2.2 Cushion Module

[00111] The cushion module 240 is structured to interface with the frame module 220 and form a seal with patient's nose and mouth in use. However, other cushion interfaces are possible, e.g., nasal.

[00112] The cushion module 240 includes a main body 242 and a cushion 244 provided to the main body 242. The main body 242 and cushion 244 may be integrally formed in one piece (e.g., co-molded), or the main body 242 and cushion 244 may be formed separately and attached to one another.

[00113] In the illustrated embodiment, the cushion 244 is a full-face cushion adapted to engage the patient's face generally along nasal bridge, cheek, and lower lip/chin regions of the patient's face. In this embodiment, the cushion 244 is structured such that it is positioned higher on the bridge of the nose for sealing and comfort (e.g., with respect to the cushion 44 described above). The cushion 244 may also be better for anthropometrics, i.e., the cushion will fit more people.

[00114] In an embodiment, the cushion module 244 may include a concertina section as described above (e.g., in the nasal bridge region) to enhance the flexibility of the cushion module in use.

[00115] In the illustrated embodiment, the main body 242 includes an opening to interface with the elbow module 270 and an opening to interface with the vent arrangement 276. In addition, the main body 242 includes an auxiliary port or spigot 243, e.g., for supplemental oxygen, measurement device, etc.

[00116] In an embodiment, the cushion module 240 may be removably attached to the frame module 220, e.g., friction fit, snap-fit, mechanical interlock, or other suitable attachment mechanism. Alternatively, the cushion module 240 and frame module 220 may be integrally formed in one piece, e.g., co-molded.

2.3 Elbow Module

[00117] The elbow module 270 includes an elbow 274 and an anti-asphyxia valve (AAV) 285 provided to the elbow 274. The elbow 274 may interface or otherwise attach to the frame module 220 in any suitable manner, e.g., friction fit, snap-fit, mechanical interlock, or other suitable attachment mechanism.

[00118] Similar to the above embodiment, the elbow 274 includes a port 279 that is selectively closed by a flap portion 286 of the AAV 285 (depending on the presence of pressurized gas).

2.4 Vent Arrangement

[00119] A vent arrangement 276 provided to the main body 242 of the cushion module 240 for gas washout. In the illustrated embodiment, the vent arrangement 276 is in the form of a vent insert (e.g., elastomeric vent insert) that is adapted to be removably supported within an outlet opening in the cushion module 240. The vent insert may be similar those described in U.S. Patent Nos. 6,561,190, 6,561,191, and 7,207,335, each of which is incorporated herein by reference in its entirety. However, it should be appreciated that the vent arrangement may have other suitable forms (e.g., vent holes in main body, etc.).

2.5 Headgear

[00120] The headgear 290 is attached to the headgear connectors 224, 225 of the frame module 220 to maintain the mask system in a desired position on the patient's face.

[00121] In the illustrated embodiment, the headgear 290 includes a pair of upper or top straps 292, a pair of lower or bottom straps 294, and a pair of rear straps 298. In use, the upper straps 292 are secured to respective upper connectors or arms 226, the lower straps 294 are removably attached to respective lower connectors via slots 229/clip arrangement 231, and the rear straps 298 are removably attached to respective upper connectors via slots 227. The upper straps 292 may include upper strap portions adapted to pass over the top of the patient's head and couple to one another, e.g., via a headgear buckle or adjustable ladder-lock arrangement 299. In the illustrated embodiment, the lower straps 294 and rear straps 298 are formed in one piece.

[00122] This headgear arrangement allows adjustment to occur at three positions, i.e., upper straps 292 at the headgear buckle 299, lower straps 294 at the slot 229/clip 231 connection, and rear straps 298 at the slot 227 connection.

[00123] As illustrated, the free end of each strap may include a hook and loop tab 295 (e.g., Velcro®) structured to engage the remainder of the strap to removably secure the strap in place. Such hook and loop attachment also facilitates adjustment of the length of the straps.

[00124] In the illustrated embodiment, the lower straps 294 and rear straps 298 are adapted to join and pass behind the patient's head in use (e.g., see Fig. 9-3). As illustrated, the lower straps 294 join at an angle α (e.g., similar to the bottom strap in ResMed's Mirage Liberty mask) to prevent the strap from irritating the patient's neck and/or prevent movement of the strap due to movement of the patient's neck in use.

[00125] In an embodiment, the headgear may be similar to that for ResMed's Mirage Liberty mask, however the top straps have been modified and there is an added rigidizer system. The top straps may be similar to ResMed's Swift style headgear, with the rigidizers extending along the sides.

3. Alternative Mask Arrangement

[00126] Figs. 11-1 to 11-3 illustrate a mask system 310 according to another embodiment of the present invention. As illustrated, the mask system 310 includes a frame module 320, a cushion module 340, and an elbow module 370.

[00127] As best shown in Figs. 12-1 to 12-5, the frame module 320 includes an elbow retaining portion 322 structured to retain the elbow module 370 and a headgear connector 325 on each side of the elbow retaining portion 322. In the illustrated embodiment, each headgear connector 325 includes a clip receptacle 331 adapted to be removably interlocked with a headgear clip (not shown) associated with a respective lower headgear strap.

[00128] The cushion module 340 includes a main body 342 and a cushion 344 adapted to engage the patient's face and form a seal with patient's nose and mouth in use. The main body 342 is removably attached to the frame module 320, e.g., resilient fingers 345 on elbow retaining portion 322 removably engage with an opening in the main body 342.

[00129] The main body 342 includes an upper headgear connector 324 on each upper side of the main body . Each headgear connector 324 includes a clip retainer 333 adapted to be removably interlocked with a headgear clip (not shown) associated with a respective upper headgear strap.

[00130] Also, the main body 342 includes an auxiliary port or spigot 343 on each side thereof, e.g., for supplemental oxygen, measurement device, etc. Port caps 347 are provided to seal respective ports 343.

[00131] In addition, the main body 342 includes a u-shaped slot 302 that receives a u-shaped plug-type vent 305 for gas washout. As illustrated, the plug-type vent 305 wraps around and under the opening in the main body 342 for the elbow module 370. The plug-type vent 305 includes a plurality of tracks or grooves 307 on each side thereof. In use, the grooved plug-type vent 305 forms a seal with the slot 302 so that exhausted air can exit between the slot walls and the grooves 307 on the plug-type vent 305. In an embodiment, the port caps 347 may be integrated or incorporated into the plug-type vent 305 (e.g., integrally formed in one piece). Further details of such a plug-type vent arrangement are provided in U.S. Patent Application No. 12/230,120, filed August 22, 2008, which is incorporated herein by reference in its entirety.

[00132] The elbow module 370 is structured to attach to the elbow retaining portion 322 of the frame module 320 in any suitable manner, e.g., snap-fit, mechanical interlock, or

other suitable attachment mechanism. Similar to above embodiments, the elbow module 370 includes a port 379 that is selectively closed by a flap portion of an anti-asphyxia valve (not shown). The anti-asphyxia valve may be retained within a slot 381 adjacent the port 379.

[00133] Figs. 13-1 to 13-6 illustrate an alternative version of the mask system 310, which is indicated with similar reference numerals. As illustrated, the cushion module 340 is provided without upper headgear connectors, and the each clip receptacle 331 includes an alternative configuration (e.g., holes for snap-fit tabs on the clip). Also, the frame module 320 in Figs. 13-1 to 13-6 includes support bars 329 structured to wrap around respective auxiliary ports 343, while the frame module 320 in Figs. 11-1 to 12-5 includes support bars 329 that extend in front of respective auxiliary ports 343.

[00134] In addition, Figs. 13-2 to 13-6 show the cushion module 340 with the grooved plug-type vent 305 removed so as to more clearly illustrate the u-shaped slot 302 and auxiliary ports 343 on each side thereof.

[00135] Figs. 14-1 to 14-7 illustrate the main body of a cushion module and a clip-on upper headgear connector or rigidizer according to another embodiment of the present invention.

[00136] Similar to above embodiments, the main body 442 includes an opening 449 adapted to engage a frame module and/or elbow module. Around and under the opening 449 is the u-shaped slot 402 for gas washout and auxiliary ports 443 on each side thereof.

[00137] In this embodiment, each upper side of the main body 442 includes a retaining member 433 and an upper intermediate portion of the main body 442 includes retaining grooves 435, which are structured and arranged to retain an upper headgear connector or rigidizer 424.

[00138] As best shown in Figs. 14-6 and 14-7, the upper headgear connector 424 includes a pair of elongated arms or rigidizers 426 coupled by a pair of wire members 428. Each rigidizer 426 includes a slot 427 at its free end adapted to receive a respective headgear strap in use.

[00139] In use, the upper headgear connector 424 is adapted to clip onto the main body 442 (e.g., see Figs. 14-1 and 14-2). Specifically, intermediate portions of the wire members 428 are received in respective grooves 435 of the main body 442, and end portions of the wire members 428 extend through respective retaining members 433 with the rigidizers 426

providing a shoulder to interlock with respective retaining members 433. Figs. 14-4 and 14-5 show an upper portion of a retaining member 433 to illustrate the groove 433(1) adapted to receive a respective wire. As illustrated, the end of the groove 433(1) includes tapered side walls 433(2) and drops off towards a rear side 433(3) to position the rigidizers 426 into interlocking engagement with the retaining member 433.

4. Alternative Mask Arrangement

[00140] Figs. 15-1 to 15-12 illustrate an upper portion of a main body of a cushion module and a clip-on upper headgear connector or rigidizer according to another embodiment of the present invention.

[00141] As illustrated, the upper portion of the main body 542 includes a retaining member 533 on each side thereof and a retaining groove 535 along an intermediate portion thereof, which are structured and arranged to retain an upper headgear connector or rigidizer 524.

[00142] As best shown in Figs. 15-5 and 15-12, the upper headgear connector 524 includes a pair of elongated arms or rigidizers 526 coupled by a connecting portion 528. Each rigidizer 526 includes a slot 527 at its free end adapted to receive a respective headgear strap in use. In addition, the upper headgear connector 524 includes a clip structure 525 on each side of the connecting portion 528.

[00143] In use, the upper headgear connector 524 is adapted to clip onto the main body 542 (e.g., see Figs. 15-1 and 15-2). Specifically, the connecting portion 528 is received in the groove 535 of the main body 542, and the clip structures 525 releasably interlock with respective retaining members 533. As best shown in Figs. 15-3 and 15-4, each retaining member 533 provides a cross-bar, and each clip structure 525 provides a v-shaped configuration that is adapted to resiliently deflect through the cross-bar and provide a shoulder to releasably interlock with the cross-bar.

[00144] Figs. 16-1 to 16-7 illustrate an alternative embodiment for engaging the upper headgear connector with the main body. As illustrated, each retaining member 533 provides an open-ended cross-bar, and each clip structure 525 provides an elongated arm. In this embodiment, the cross-bar is structured to resiliently deflect to allow the clip structure 525 to extend through the cross-bar and releasably engage the cross-bar, e.g., with a friction fit. In

addition, the upper headgear connector 524 of Figs. 16-1 to 16-7 includes a c-shaped clip structure 529 adapted to interlock with a tab 549 provided to the main body 542 (see Figs. 16-1 and 16-2).

5. Alternative Mask Arrangement

[00145] Figs. 17-1 to 17-4 illustrate a mask system 610 according to another embodiment of the present invention. As illustrated, the mask system 610 includes a mask 615 and headgear 690 removably attached to the mask to maintain the mask in a desired adjusted position on the patient's face.

[00146] In the illustrated embodiment, the headgear 690 includes an arrangement of straps wherein some of the straps are constructed of silicone and some of the straps are constructed of Breath-O-Prene™ material. However, the headgear may be constructed such that the straps are completely constructed of silicone or completely constructed of Breath-O-Prene™.

[00147] As illustrated, the lower strap portion 692 of the headgear is constructed of Breath-O-Prene™ and extends along the cheeks and around the back of the patient's head. The upper strap portion 694 of the headgear is constructed of silicone and includes side straps 694(1) that extend along the upper cheek and over the patient's ear, a top strap 694(2) that extends over the top of the patient's head, rear straps 694(3) that extend behind the patient's head and connects to the lower strap portion 692 (see Fig. 17-4), and connecting portions 694(4) that extend from respective side straps 694(1) in front of the patient's ear and connect to the lower strap portion 692.

[00148] The headgear straps may be connected to the mask in any suitable manner. For example, in the illustrated embodiment, the lower strap portion 692 is connected to the mask by a headgear clip arrangement and the upper strap portion 694 is connected to the mask using an elongated buckle 695 with buckle portions on each end thereof.

[00149] In an embodiment, the headgear straps are arranged such that the force vectors applied by the headgear to the mask are substantially perpendicular to the mask and substantially parallel to one another (e.g., as shown by the arrows in Fig. 17-2). This arrangement enhances the mask seal as the headgear forces the mask directly into the patient's face.

6. Alternative Mask Arrangement with Grommet Attachment

[00150] Figs. 18 and 19 illustrate an alternative mask arrangement in which the frame module is attached to the cushion module via a grommet.

[00151] For example, as shown in Fig. 18, the cushion module 740 includes a grommet 745 (e.g., constructed of a rubber) and the frame module 720 includes an opening 725 adapted to receive the grommet 745 to secure the frame module 720 to the cushion module 740. As illustrated, the frame module 720 includes elongated upper and lower arms 724, 726 each with a slot 727 at its free end adapted to receive a respective headgear strap in use.

[00152] Fig. 19 illustrates an alternative frame module 820 which includes a single arm with a slot 827 at each end adapted to receive a respective headgear strap in use. In addition, the frame module 820 provides an elongated inner slot 825 adapted to receive the grommet 745 of the cushion module 740. The elongated slot 825 allows the grommet 745 to be fixed in one of multiple positions along the length of the slot 825, in contrast to the frame module 720 which provides a single fixed position. In an embodiment, the frame module 820 may be slidable with respect to the grommet 745 to allow an infinite number of positions with respect to the cushion module 740.

[00153] In each embodiment, the grommet 745 (e.g., constructed of a rubber) fixes the frame module in position but the inherent flexibility of the grommet provides a flexible connection to decouple the frame module from the cushion module and allow a range of movement between the two components, e.g., like a ball joint or gimbal. Such arrangement helps with fitting and sealing of the mask to the patient's face. That is, the flexible connection allows the mask to selectively adjust and/or self-fit with the patient's face.

[00154] 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. Further, each independent

feature or component of any given assembly may constitute an additional embodiment. Furthermore, each individual component of any given assembly, one or more portions of an individual component of any given assembly, and various combinations of components from one or more embodiments may include one or more ornamental design features. 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, bariatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

WHAT IS CLAIMED IS:

1. A mask system, comprising:

a frame module; and

a cushion module provided to the frame module, the cushion module including a main body defining a breathing chamber and a cushion adapted to form a seal with the patient's face,

wherein the frame module and the cushion module are co-molded with one another, the cushion module being constructed of a first, relatively soft, elastomeric material and the frame module being constructed of a second material that is more rigid than the cushion module,

and at least a portion of the cushion module includes a concertina section having a plurality of folds, each of the folds having a side wall with the side walls of the folds becoming progressively longer away from the patient's face.

2. A mask system according to claim 1, wherein the cushion module is constructed of silicone.

3. A mask system according to any one of claims 1-2, wherein the frame module is constructed of polycarbonate.

4. A mask system according to any one of claims 1-3, wherein the concertina section is provided to a nasal bridge region of the cushion module.

5. A mask system according to any one of claims 1-4, wherein the cushion is a full-face cushion.

6. A mask system according to any one of claims 1-5, wherein the flexibility of the concertina section is variable.

7. A mask system according to claim 6, wherein the flexibility of the concertina section is variable by varying at least one of a number of folds, a wall thickness of each fold, and a depth of each fold.

8. A cushion module, comprising:

a main body defining a breathing chamber; and

a cushion adapted to form a seal with the patient's face,

wherein the main body and the cushion are co-molded with one another, the cushion being constructed of a first, relatively soft, elastomeric material and the main body being constructed of a second material that is more rigid than the cushion, and at least a portion of the main body includes a concertina section.

9. A cushion module according to claim 8, wherein the concertina section includes a bellows structure with one or more folds.

10. A cushion module according to claim 9, wherein the flexibility of the concertina section is variable.

11. A cushion module according to claim 10, wherein the flexibility of the concertina section is variable by varying at least one of a number of folds, a wall thickness of each fold, and a depth of each fold.

12. A cushion module according to any one of claims 8-11, wherein the concertina section is provided to a nasal bridge region of the main body.

13. A cushion module according to any one of claims 8-12, wherein the cushion is a full-face cushion.

14. A mask system, comprising:

a frame module; and

a cushion module according to any one of claims 8-13 provided to the frame module.

15. A mask system according to claim 14, wherein the frame module includes headgear connectors adapted to removably attach to respective headgear straps of headgear.

16. A mask system according to claim 15, wherein the frame module includes upper and lower headgear connectors on each side of the frame module.

17. A mask system according to claim 16, wherein each upper headgear connector includes an elongated arm and a slot at the free end of the arm adapted to receive a respective headgear strap in use.

18. A mask system according to any one of claims 16-17, wherein each lower headgear connector includes a clip receptacle adapted to be removably interlocked with a headgear clip associated with a respective headgear strap.

19. A mask system according to any one of claims 14-18, wherein the frame module includes an open construction that provides an annular cushion retaining portion structured to retain the cushion module.

20. A mask system according to any one of claims 14-19, further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient.

21. A mask system according to claim 20, wherein the elbow module is provided to the frame module.

22. A mask system according to any one of claims 20-21, wherein the elbow module includes a vent arrangement for gas washout, the vent arrangement in the form of a vent insert adapted to be removably attachable to the elbow module.

23. A mask system according to any one of claims 20-22, wherein the elbow module includes an anti-asphyxia valve, the anti-asphyxia valve in the form of an insert adapted to be removably attachable to the elbow module.

24. A mask system according to claim 23, wherein the anti-asphyxia valve includes a flap portion adapted to selectively close a port provided in the elbow module and a clip portion adapted to removably attach to the elbow module.

25. A mask system according to claim 24, wherein the flap portion and the clip portion are co-molded with one another.

26. A mask system according to any one of claims 20-25, wherein the elbow module includes at least first and second elbow modules, said at least first and second elbow modules being different from one another in at least one aspect.

27. A mask system according to any one of claims 14-26, wherein the cushion module includes at least first and second cushion modules adapted to be provided to the frame module, said at least first and second cushion modules being different from one another in at least one aspect.

28. A method for constructing a cushion module, comprising:

molding a first part of the cushion module with a first, relatively soft, elastomeric material;

co-molding a second part of the cushion module to the first part with a second material that is more rigid than the first material; and

molding at least a portion of the second part to include a concertina section.

29. A frame for a mask system, comprising:

an annular retaining portion having an open construction and structured to retain a cushion;

a pair of upper headgear connectors provided to respective sides of the retaining portion, each upper headgear connector including an elongated arm and a slot at the free end of the arm adapted to receive a headgear strap; and

a pair of lower headgear connectors provided to respective sides of the retaining portion, each lower headgear connector adapted to attach to a headgear strap,

wherein the retaining portion, the upper headgear connectors, and the lower headgear connectors are integrally formed as a one piece structure.

30. A frame according to claim 29, wherein each lower headgear connector includes an abbreviated arm and a slot at the free end of the arm adapted to receive the headgear strap.

31. A frame according to claim 29, wherein each lower headgear connector includes a clip receptacle adapted to removably interlock with a headgear clip associated with the headgear strap.

32. A frame according to claim 29, wherein the elongated arm is suitably contoured to extend over the patient's ear and retain the headgear strap in spaced relation over the patient's ear in use.

33. A frame according to claim 29, wherein the elongated arm is fixable to a headgear strap by gluing or stitching.

34. A frame according to claim 33, wherein each elongated arm is fixable to an upper headgear strap, each slot of the elongated arm is adapted to receive a rear headgear strap, and each lower headgear connector is adapted to attach to a lower headgear strap.

35. A frame according to claim 34, wherein the lower straps and rear straps are adapted to join at an angle and pass behind the patient's head in use.

ABSTRACT

A mask system includes a frame module and a cushion module provided to the frame module. The cushion module includes a main body defining a breathing chamber and a cushion adapted to form a seal with the patient's face. The frame module and the cushion module are co-molded with one another. The cushion module is constructed of a first, relatively soft, elastomeric material and the frame module is constructed of a second material that is more rigid than the cushion module. At least a portion of the cushion module includes a concertina section having a plurality of folds. Each of the folds has a side wall with the side walls of the folds becoming progressively longer away from the patient's face.

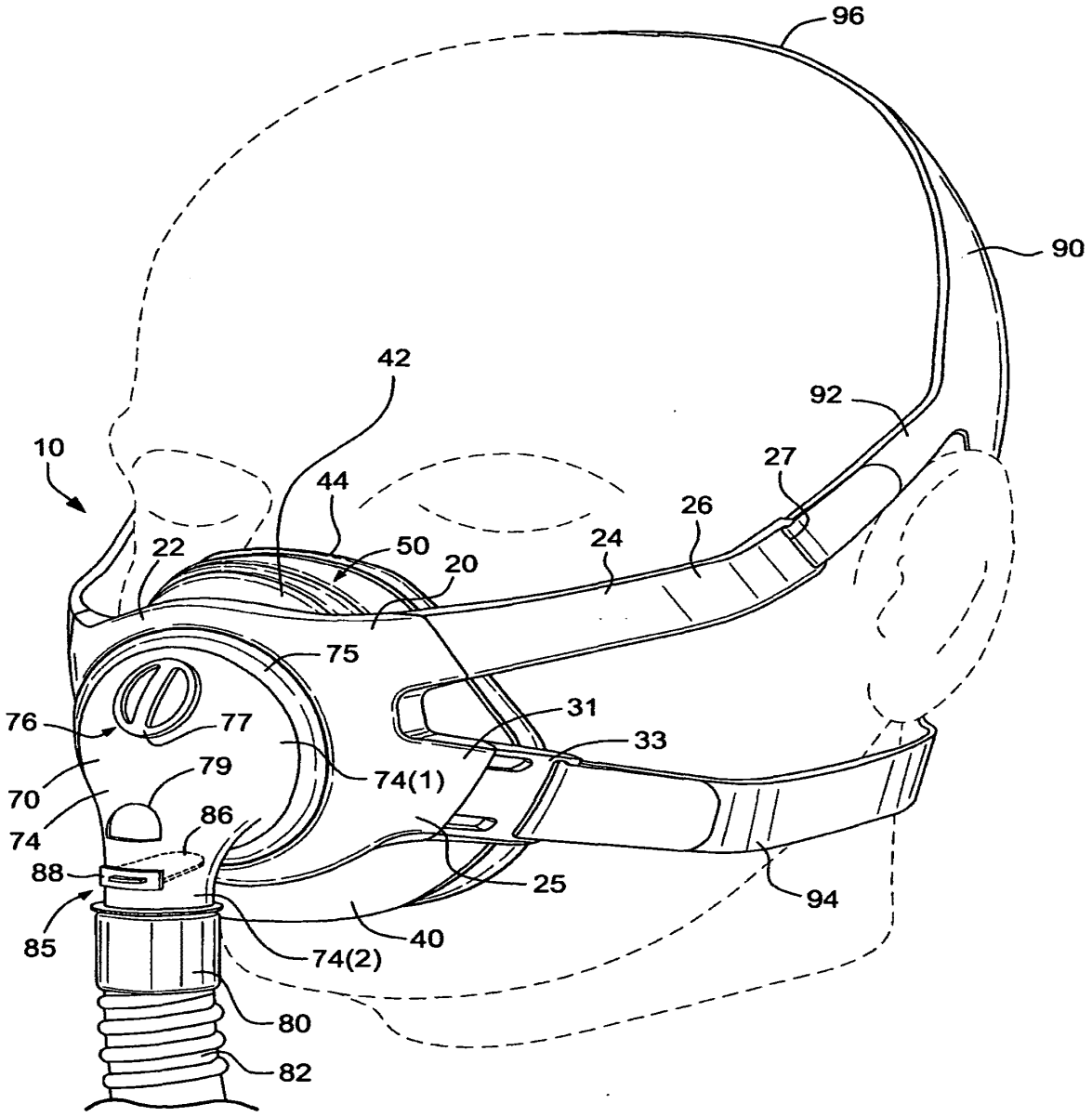

Fig. 1

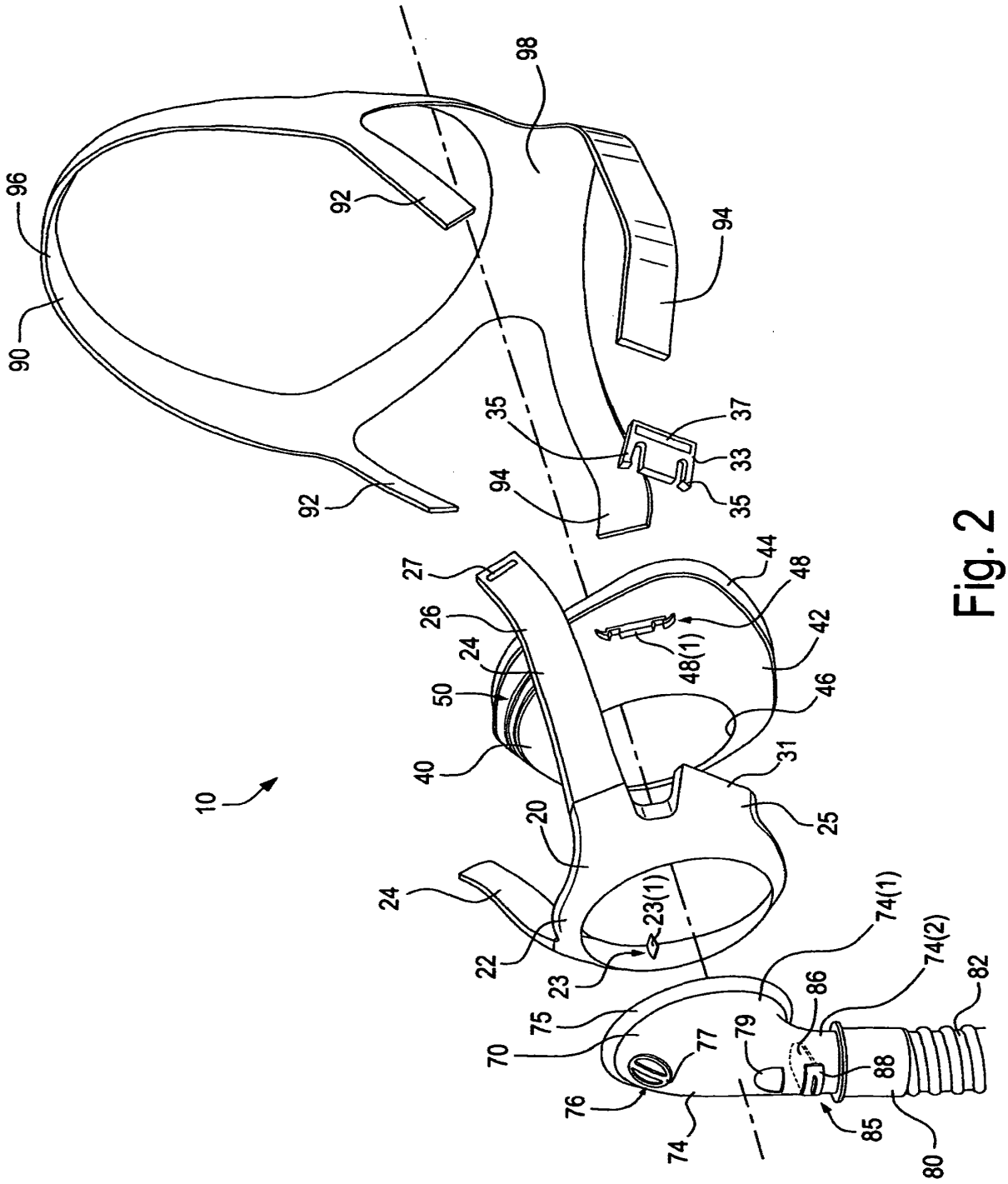

Fig. 2

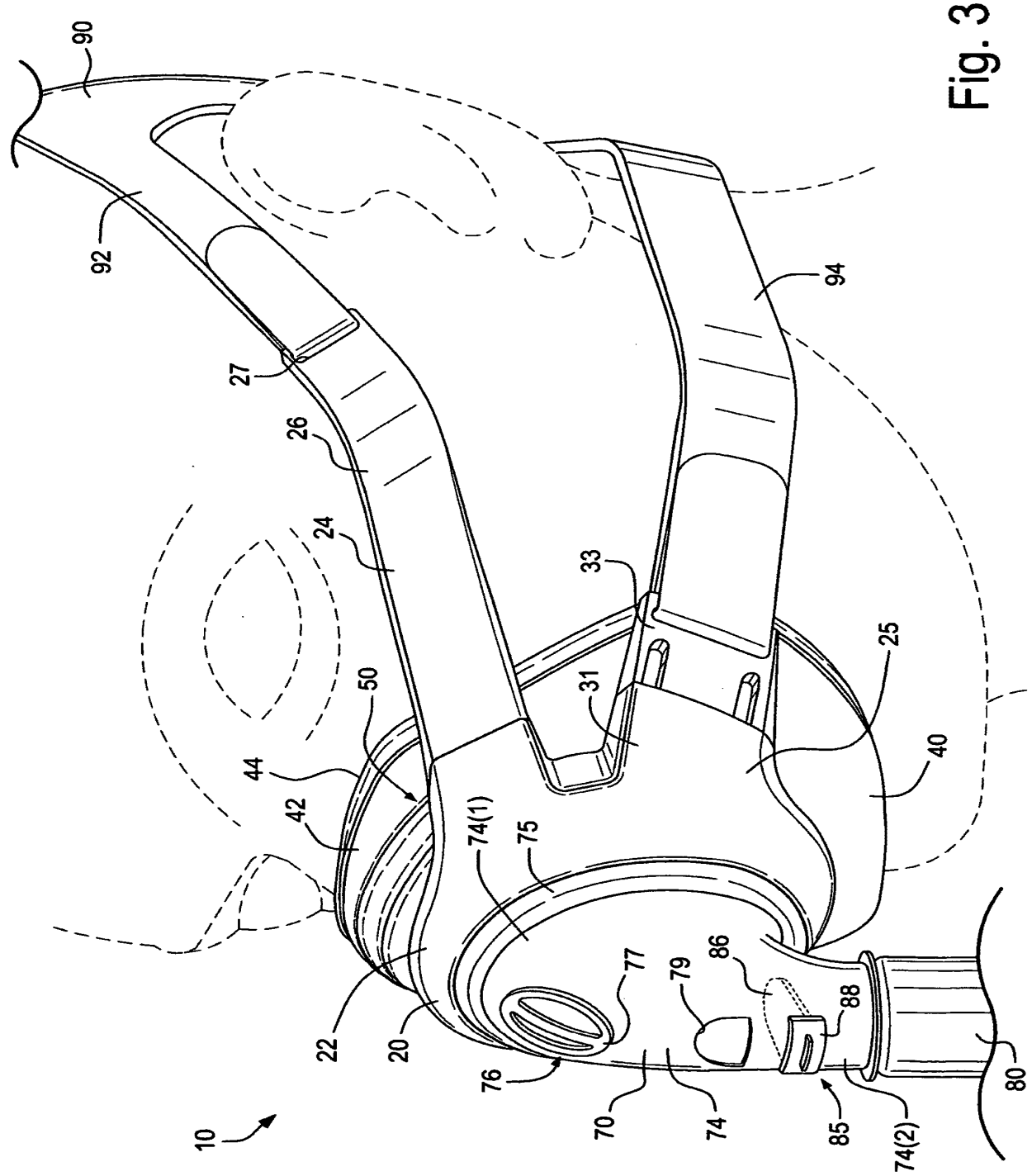

Fig. 3

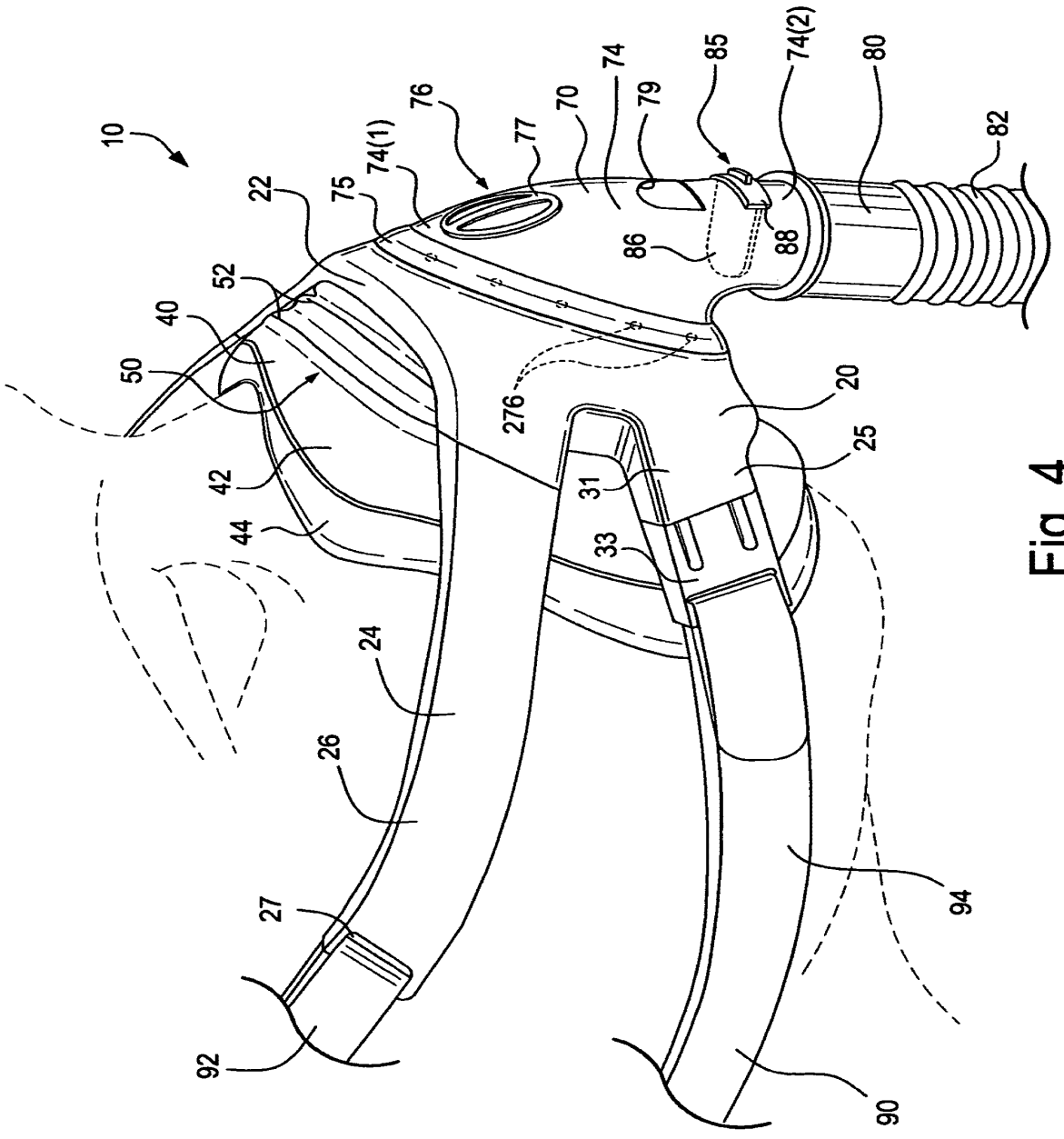

Fig. 4

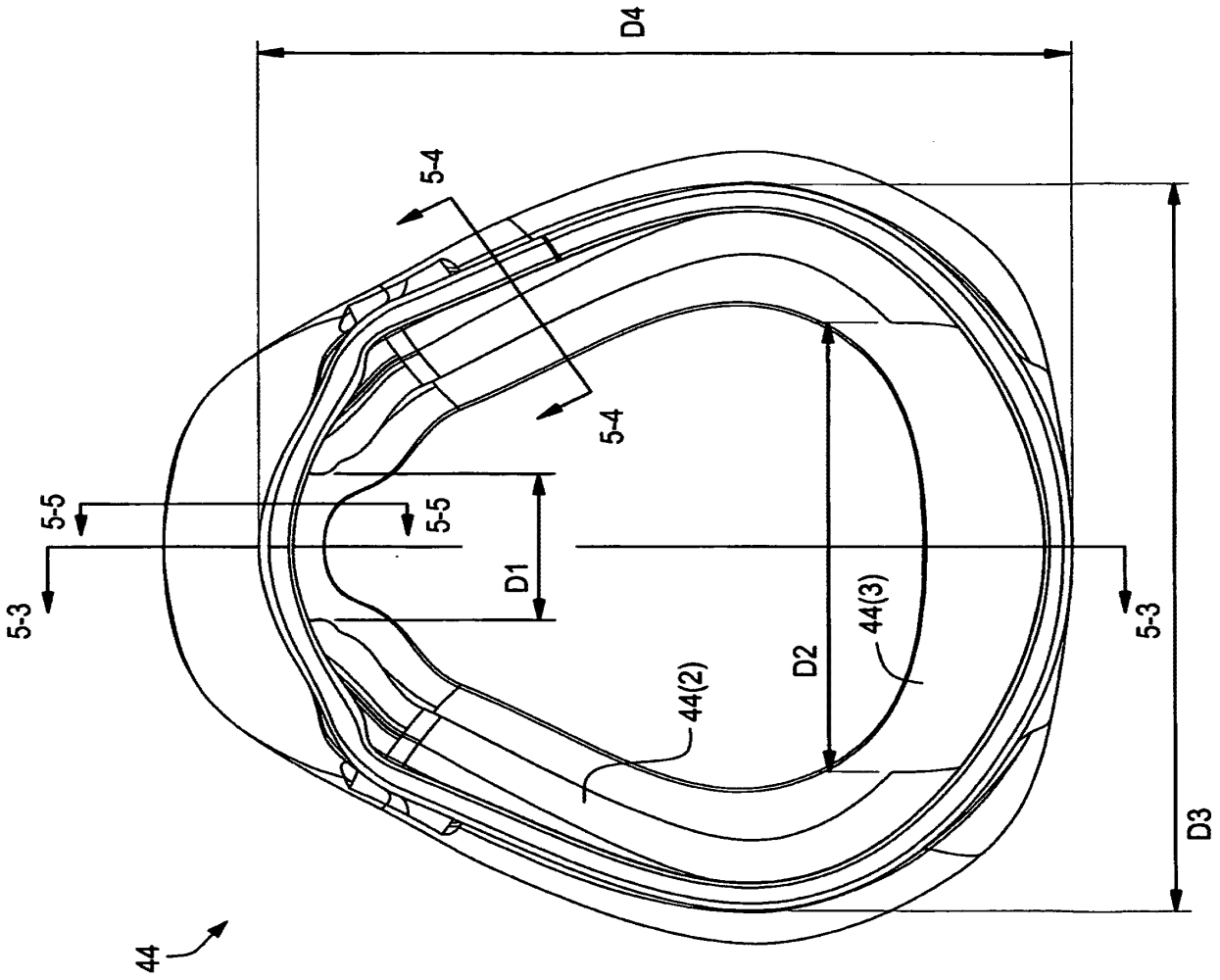

Fig. 5-1

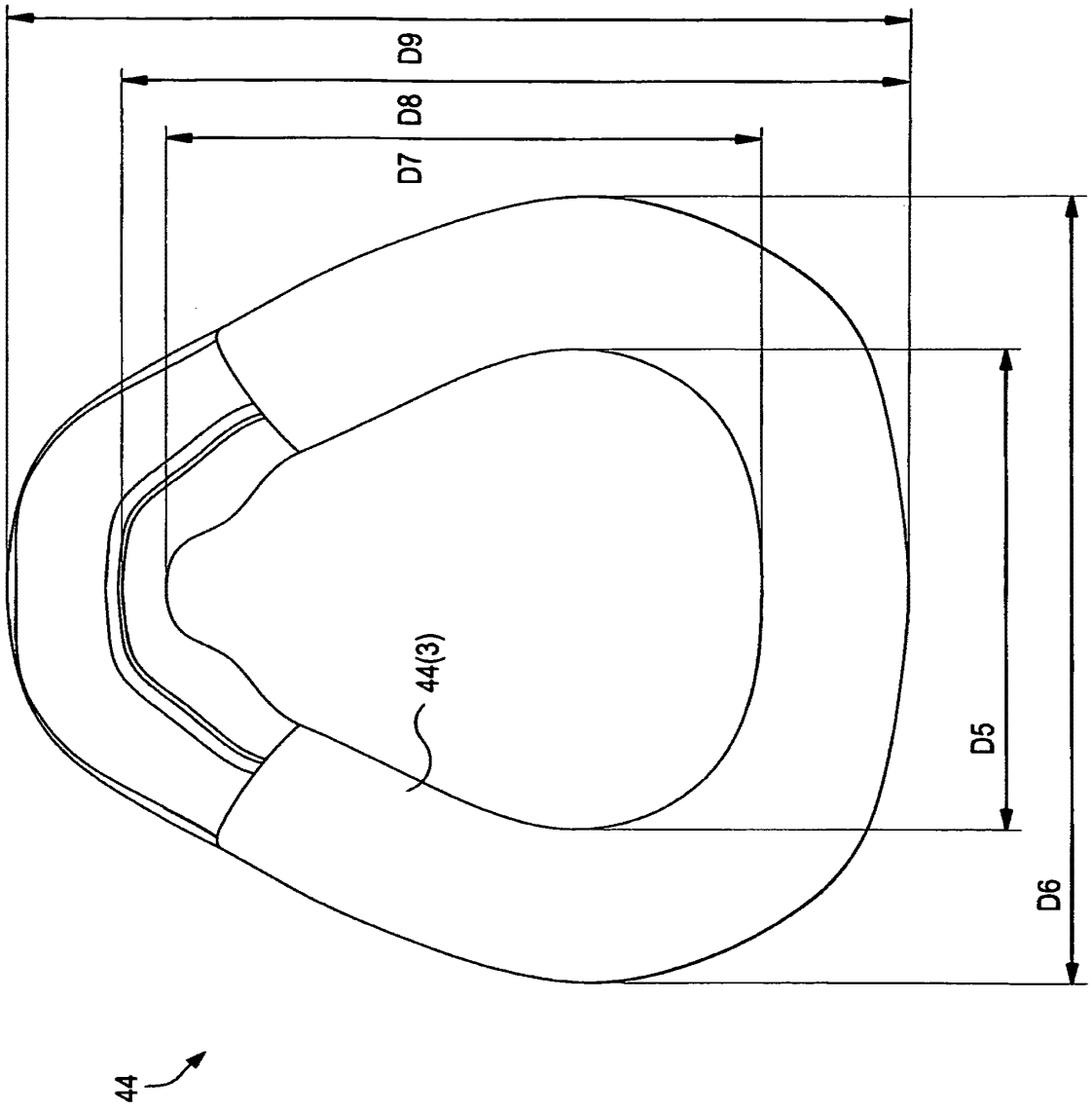

Fig. 5-2

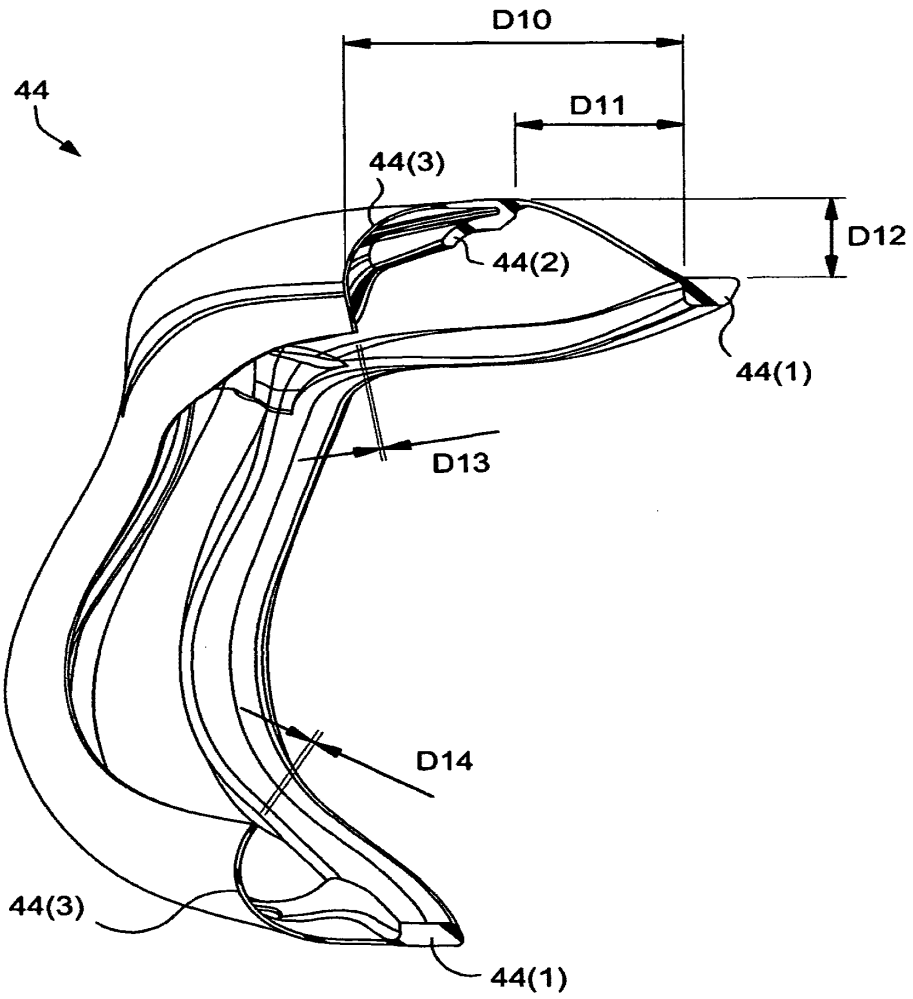

Fig. 5-3

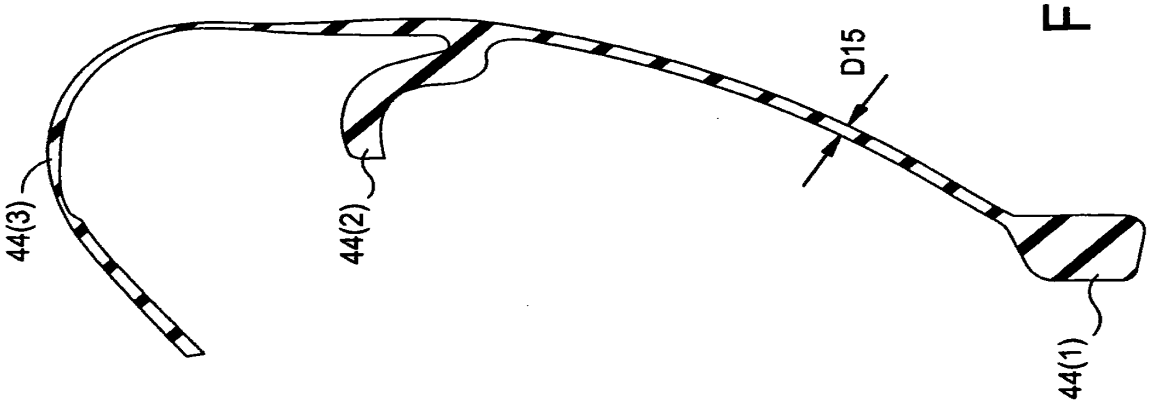

Fig. 5-5

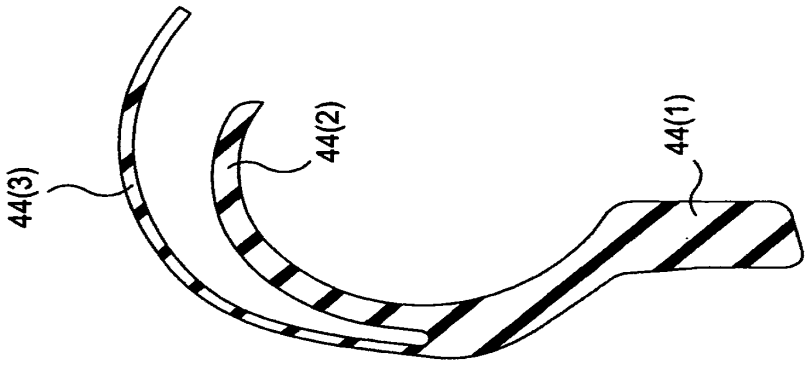

Fig. 5-4

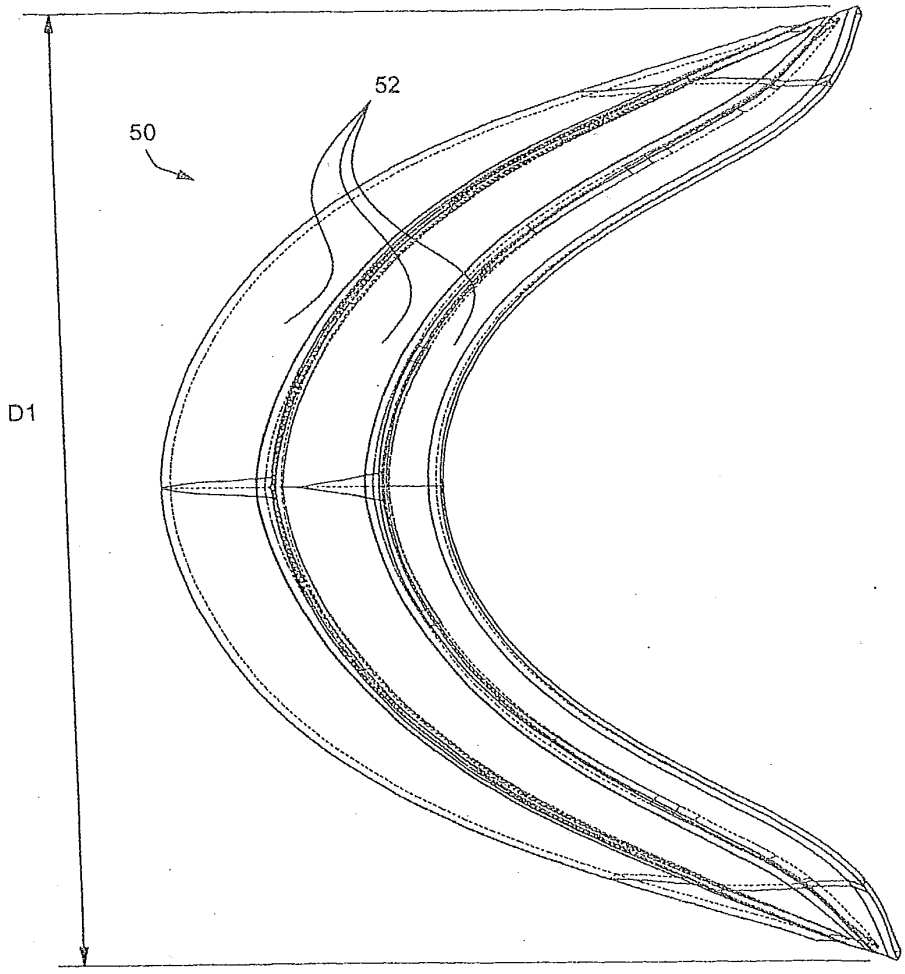

Fig. 6-1

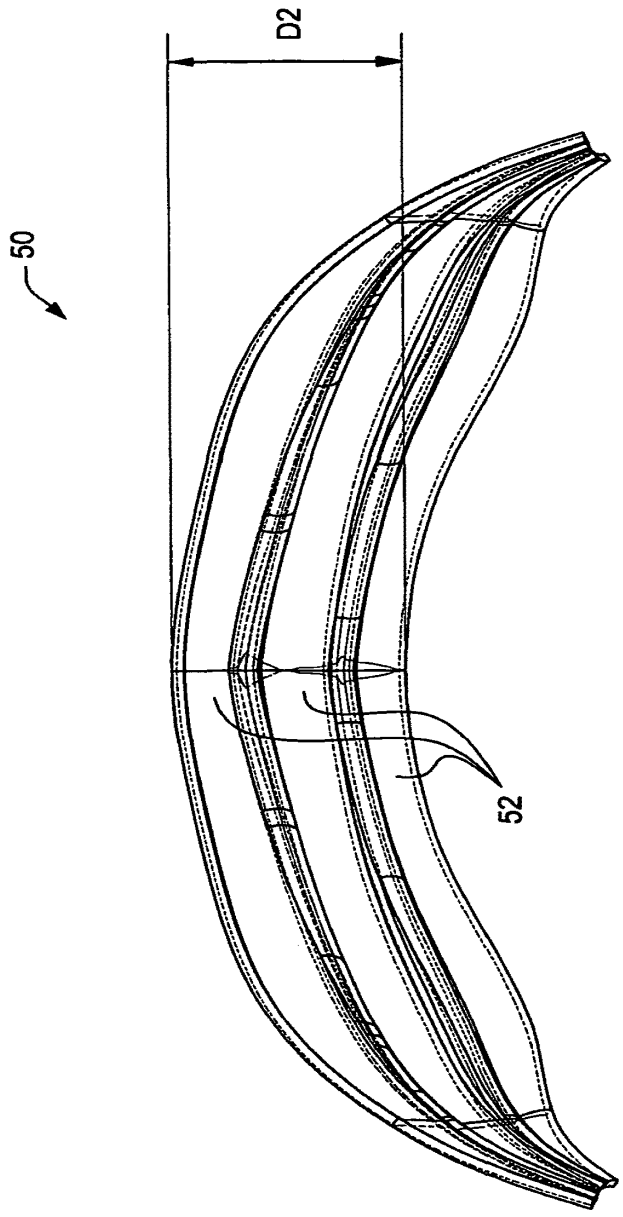

Fig. 6-2

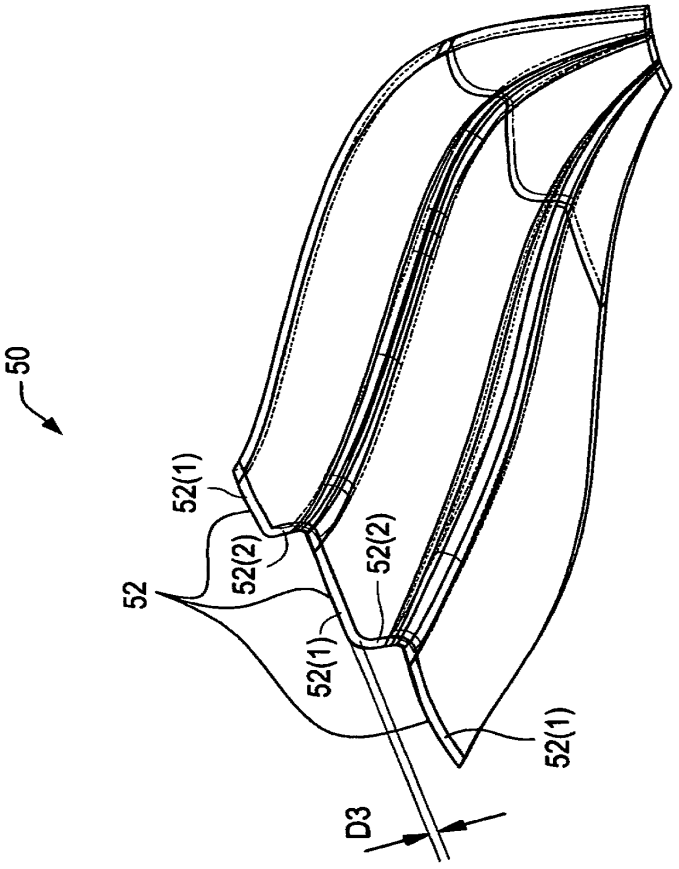

Fig. 6-3

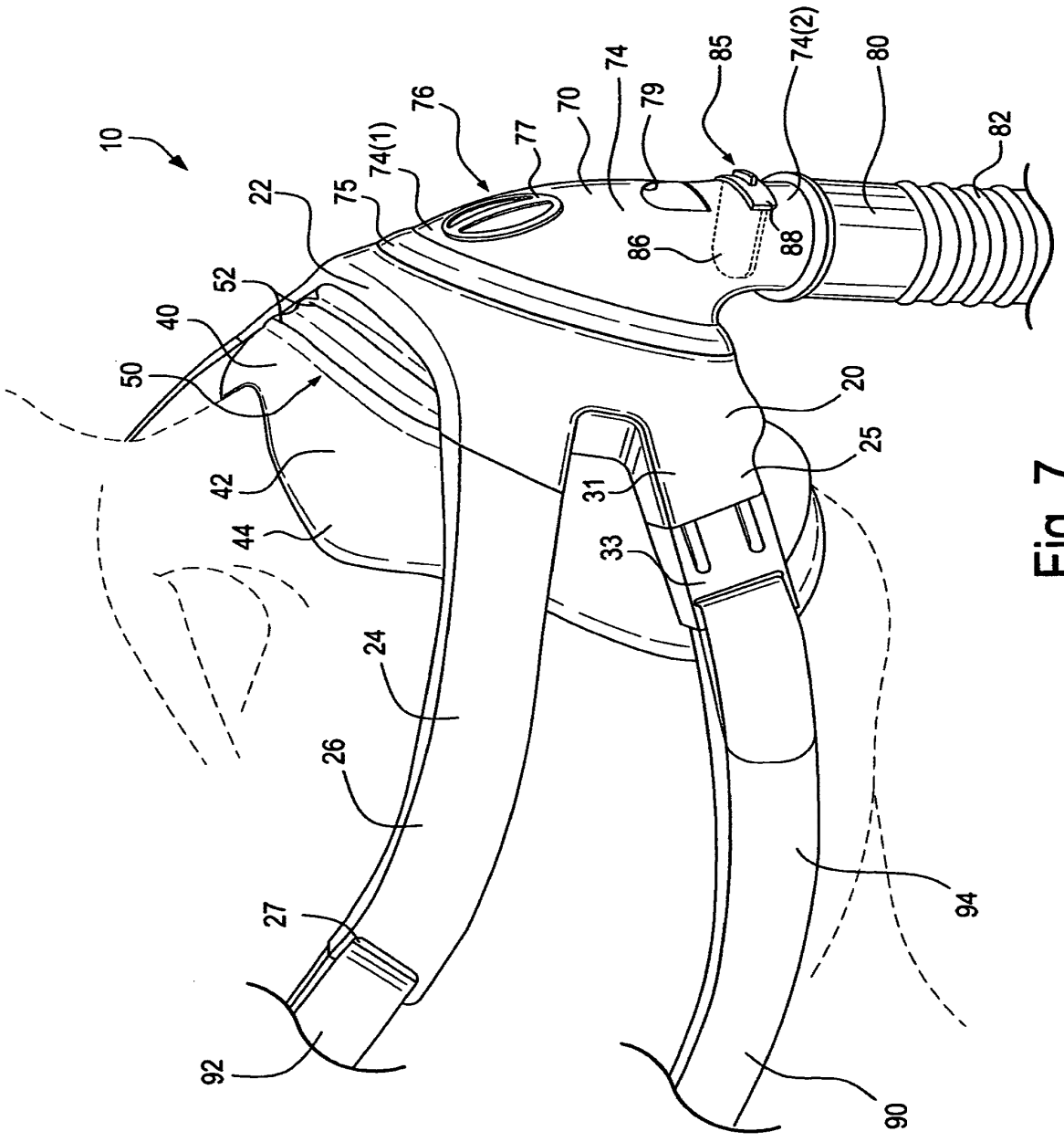

Fig. 7

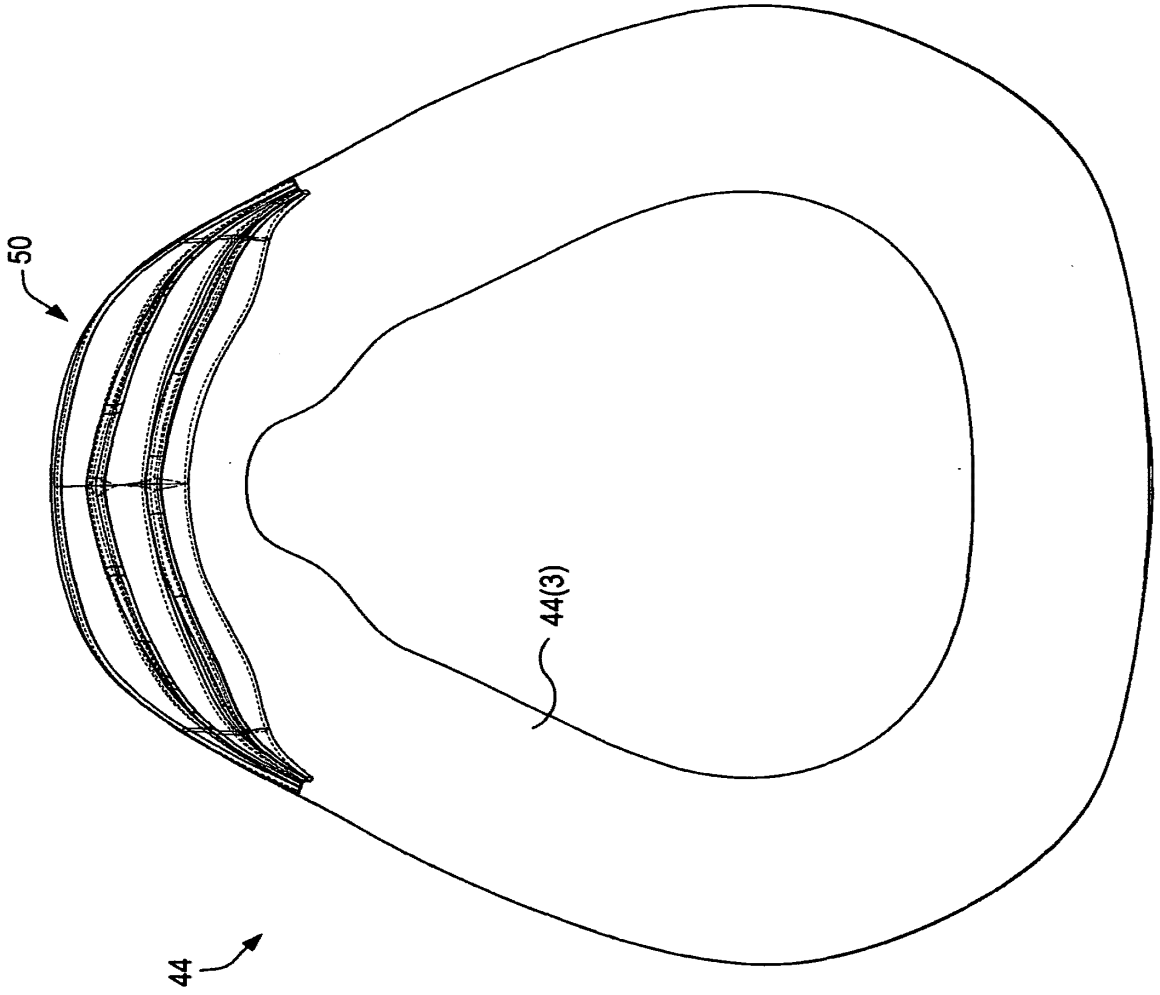

Fig. 8

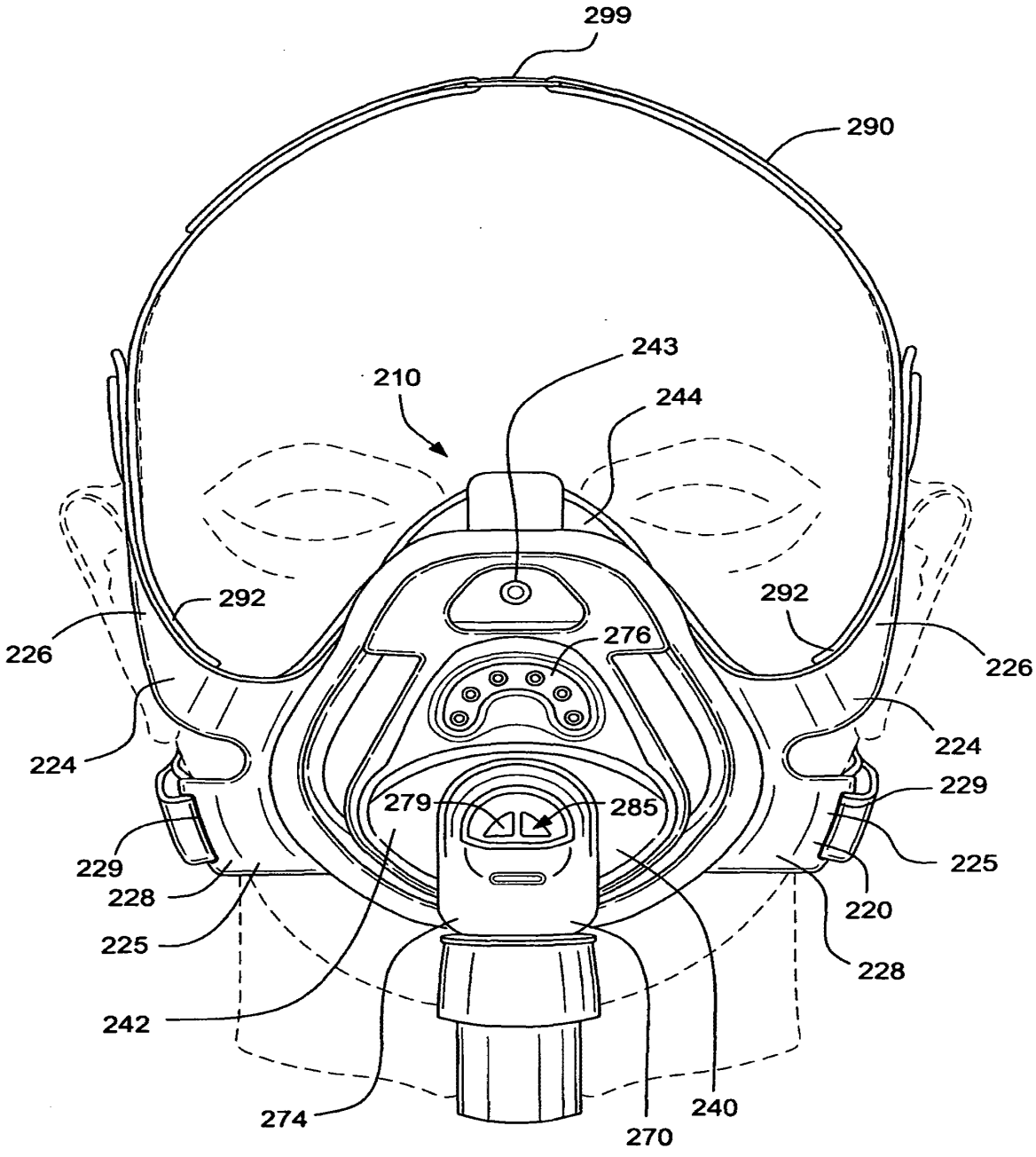

Fig. 9-1

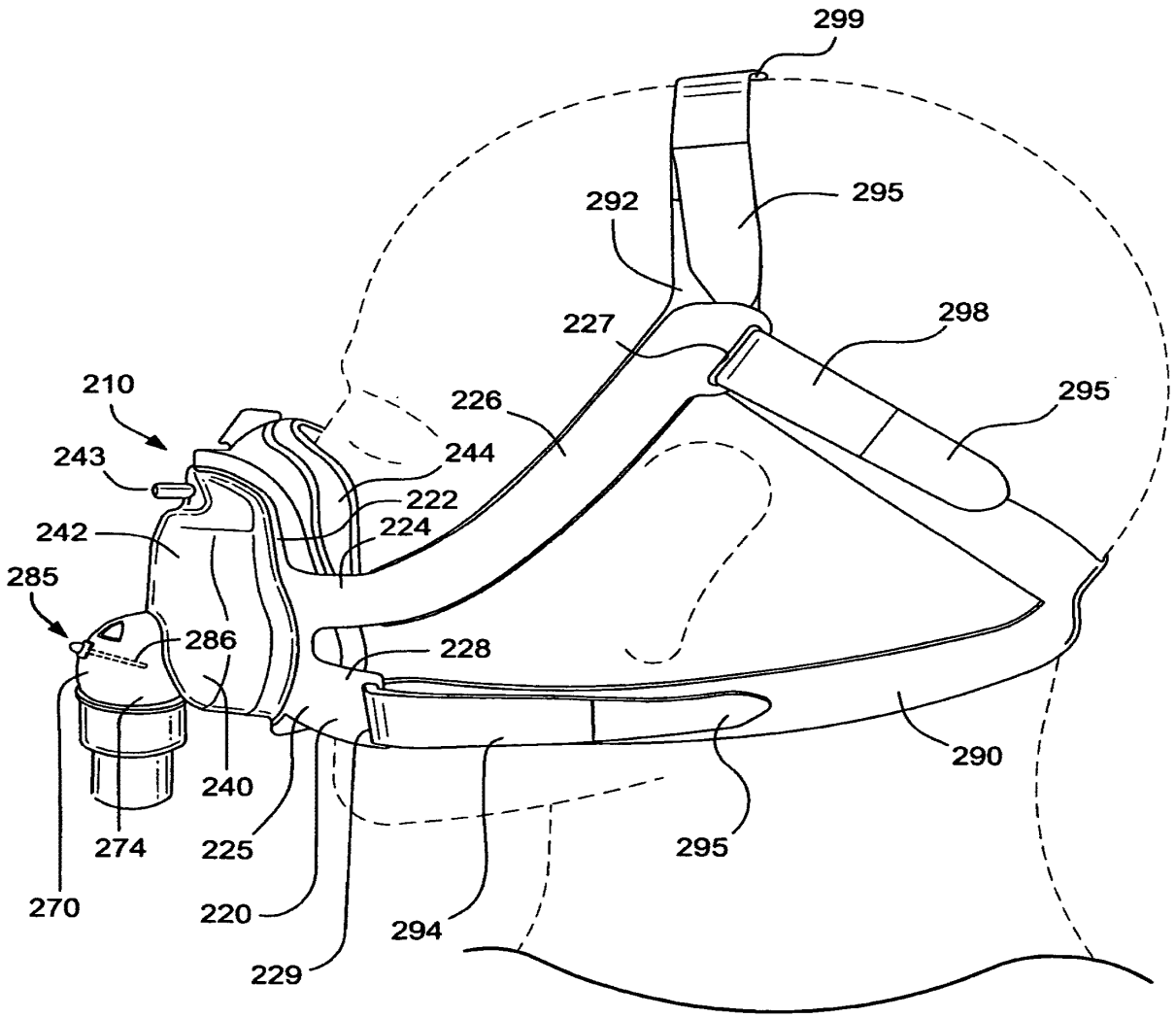

Fig. 9-2

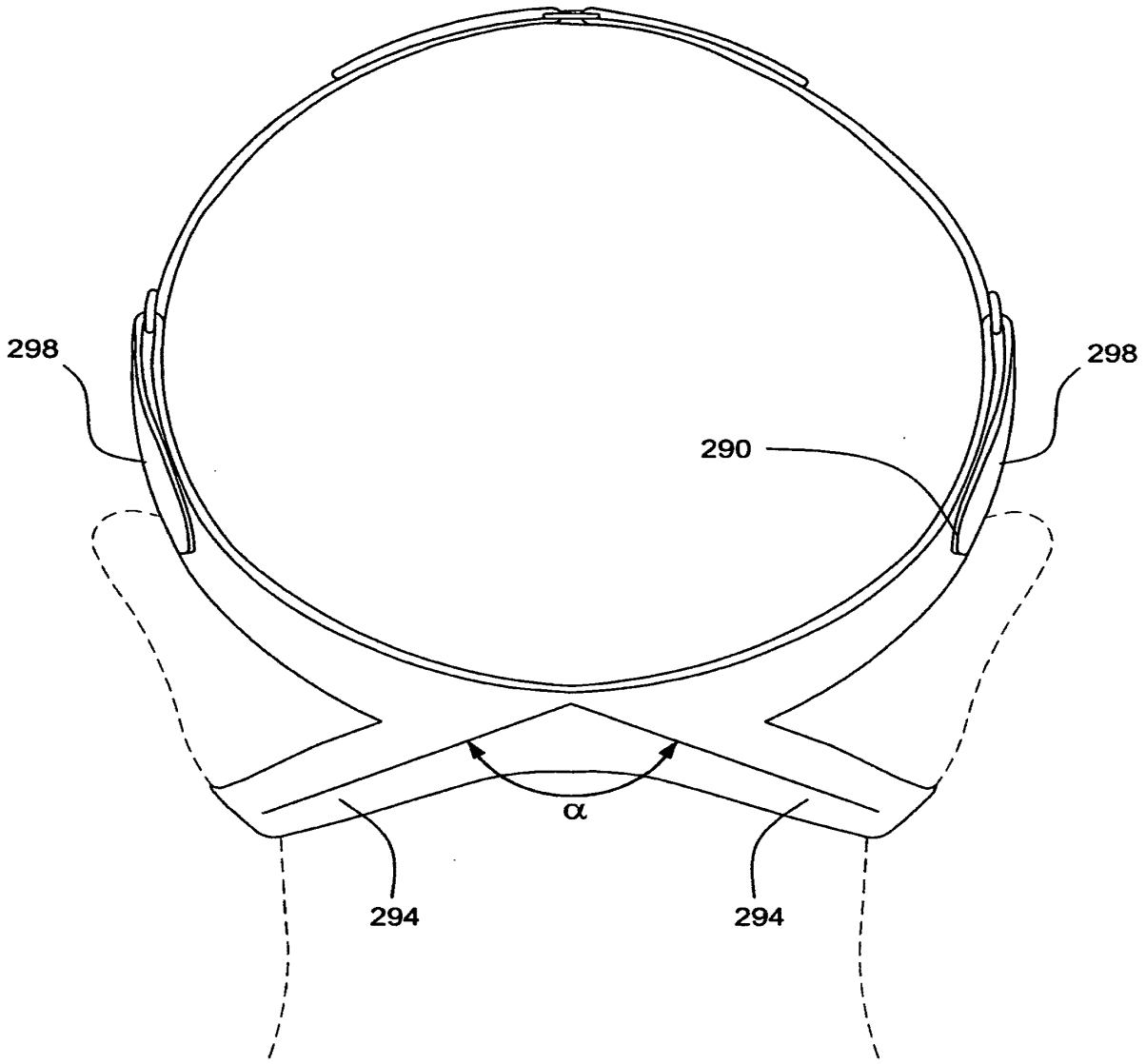

Fig. 9-3

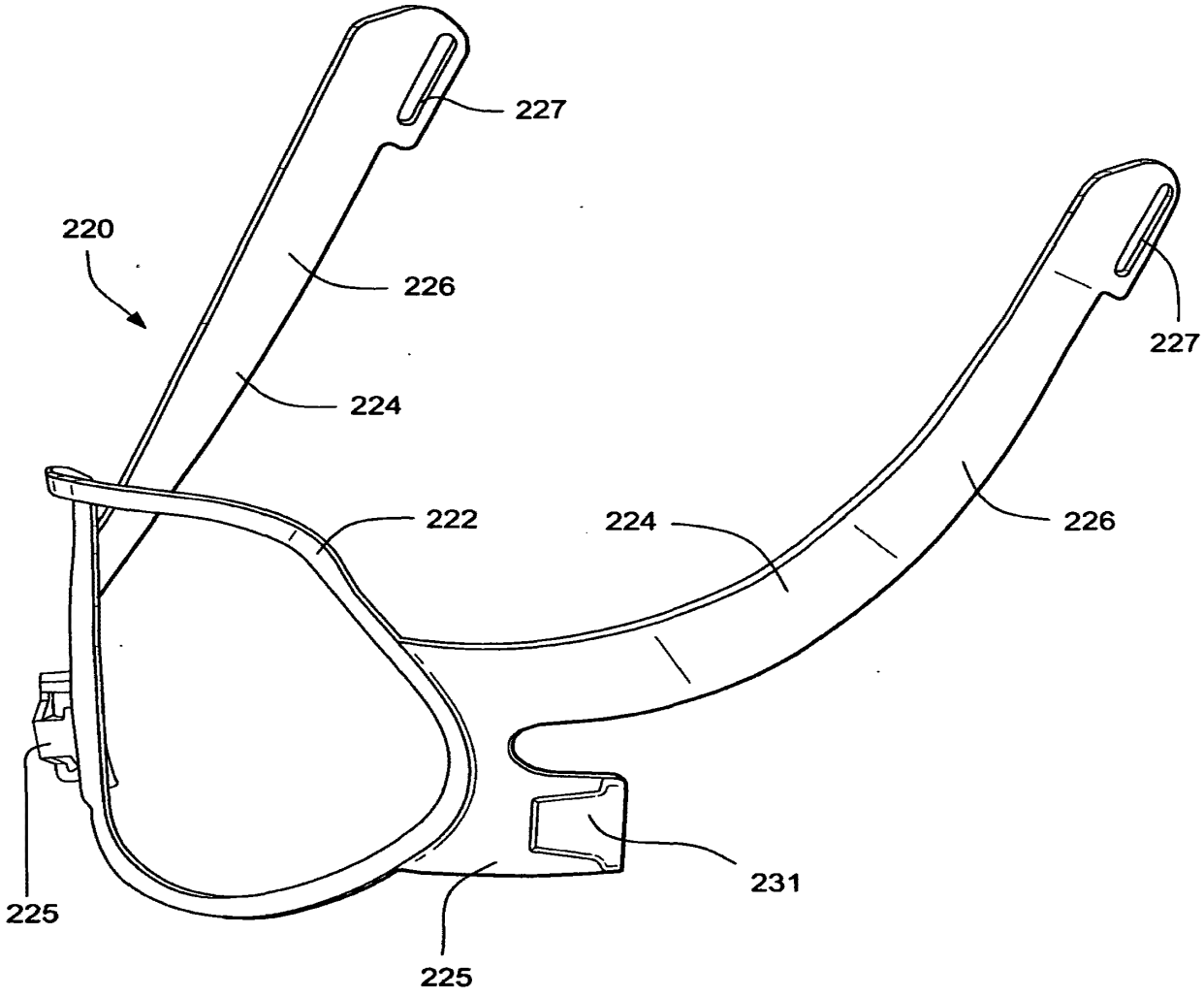

Fig. 10

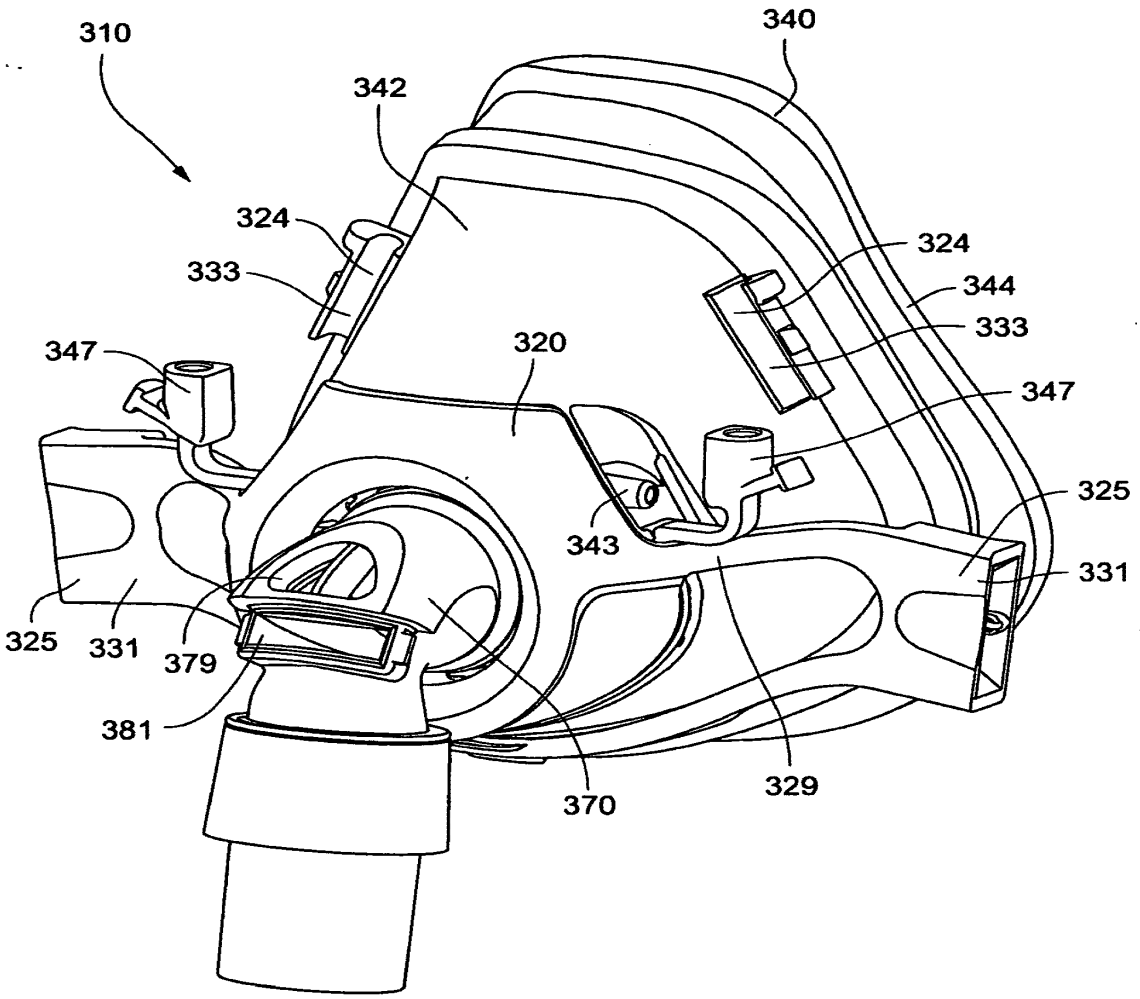

Fig. 11-1

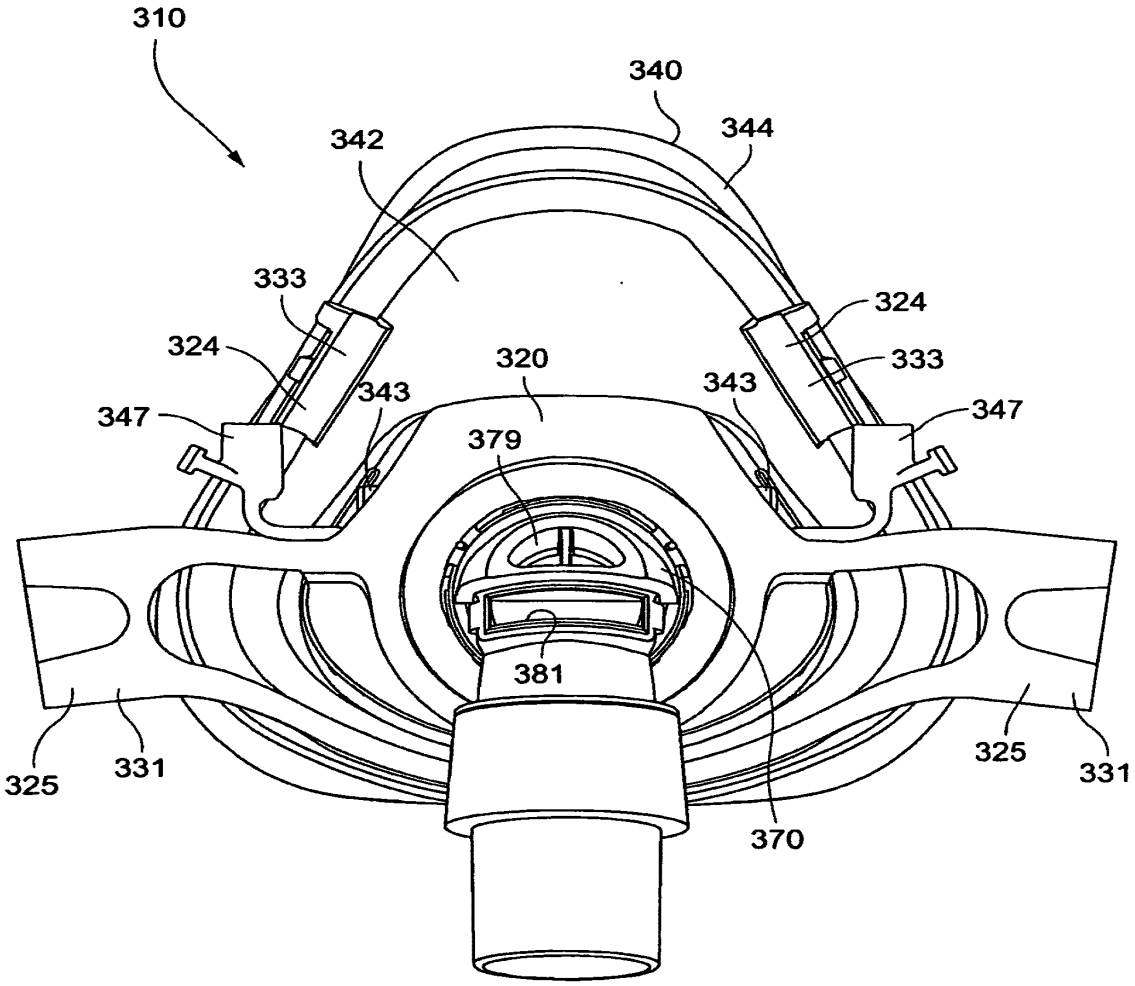

Fig. 11-2

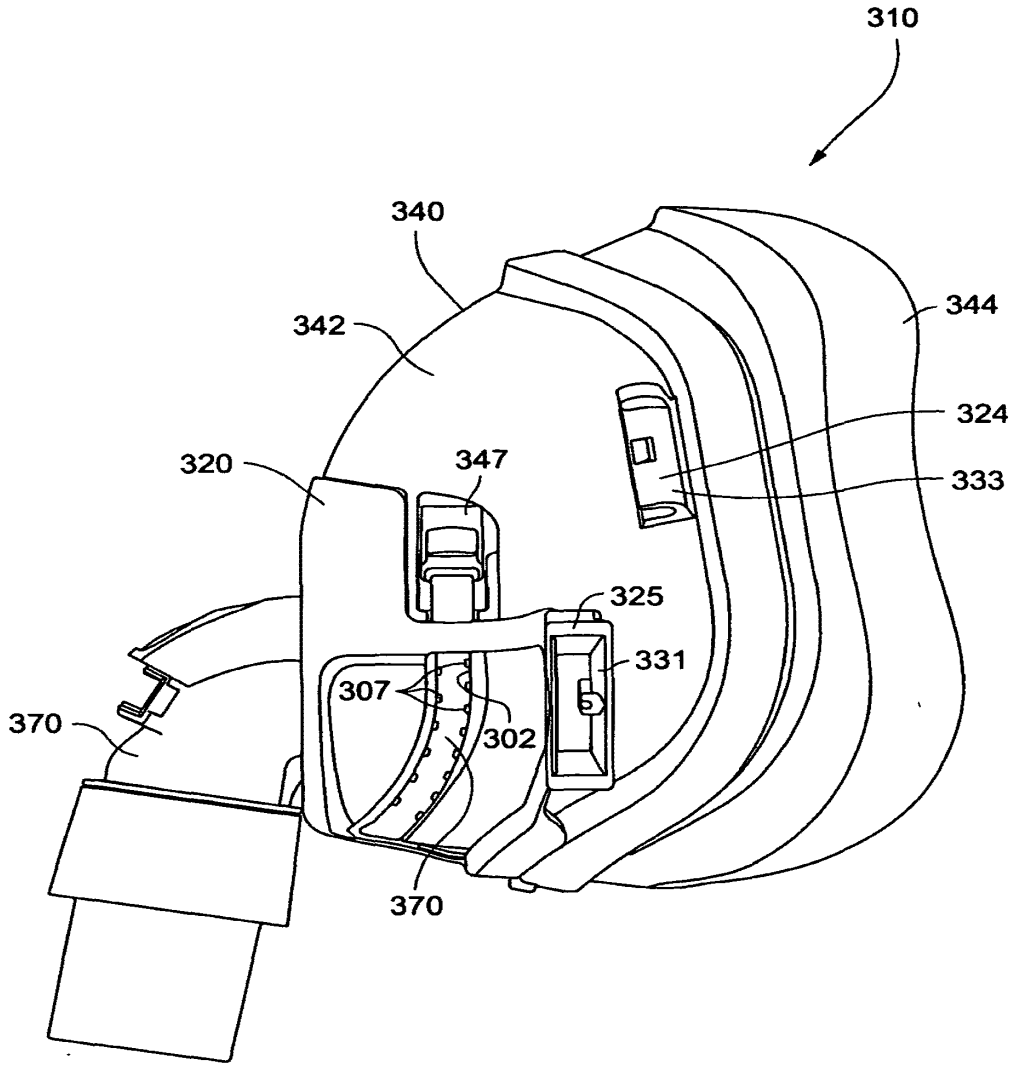

Fig. 11-3

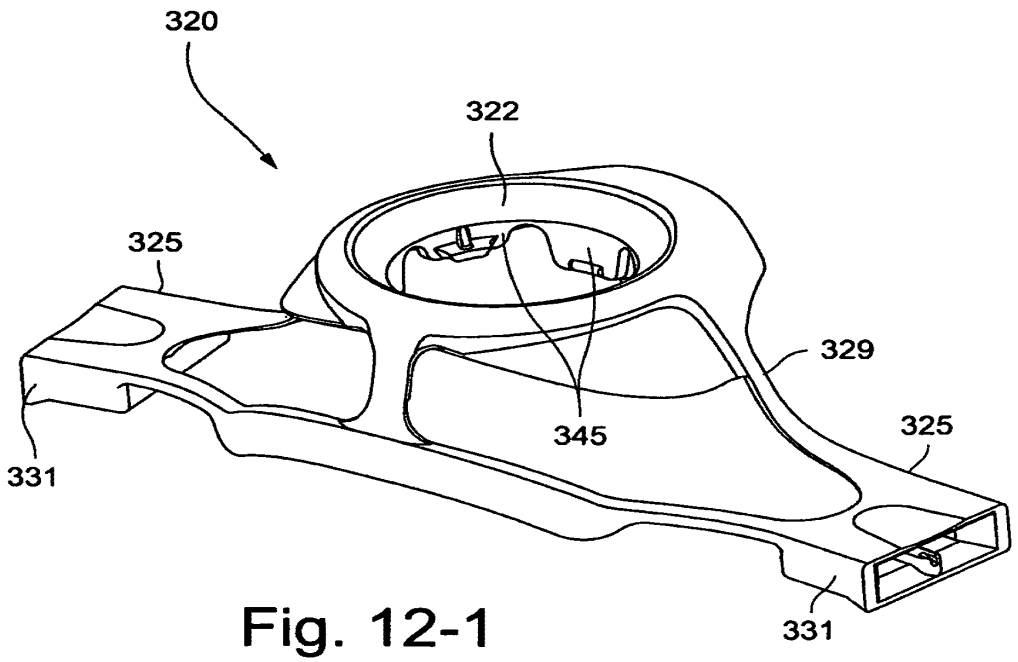

Fig. 12-1

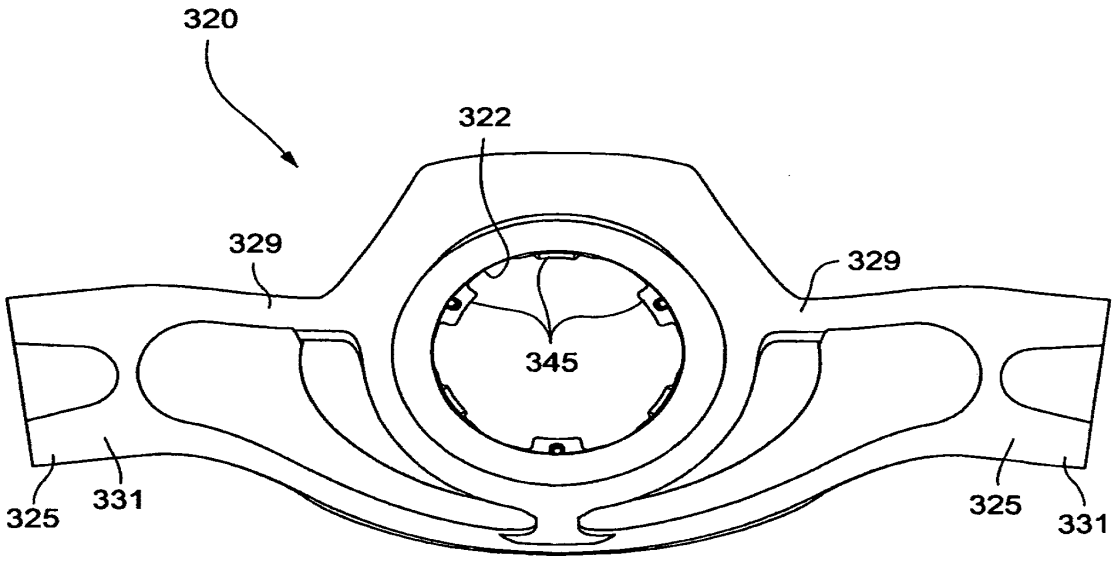

Fig. 12-2

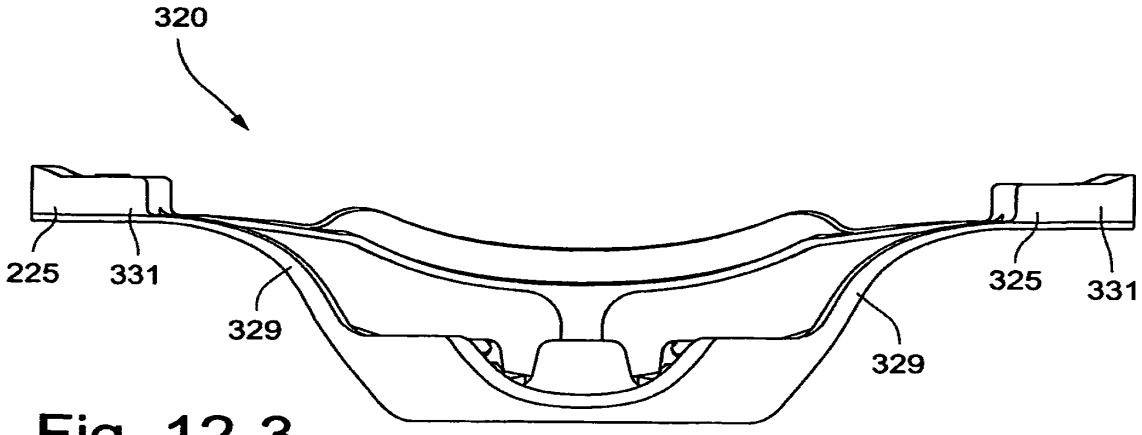

Fig. 12-3

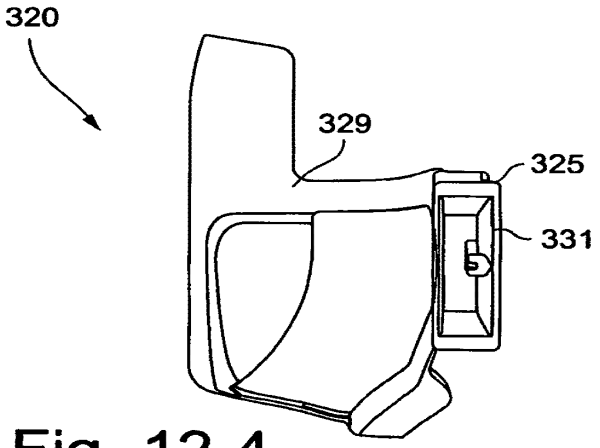

Fig. 12-4

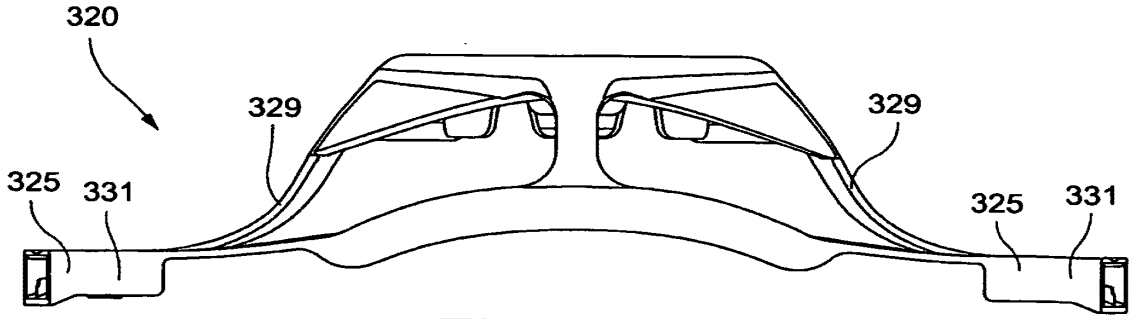

Fig. 12-5

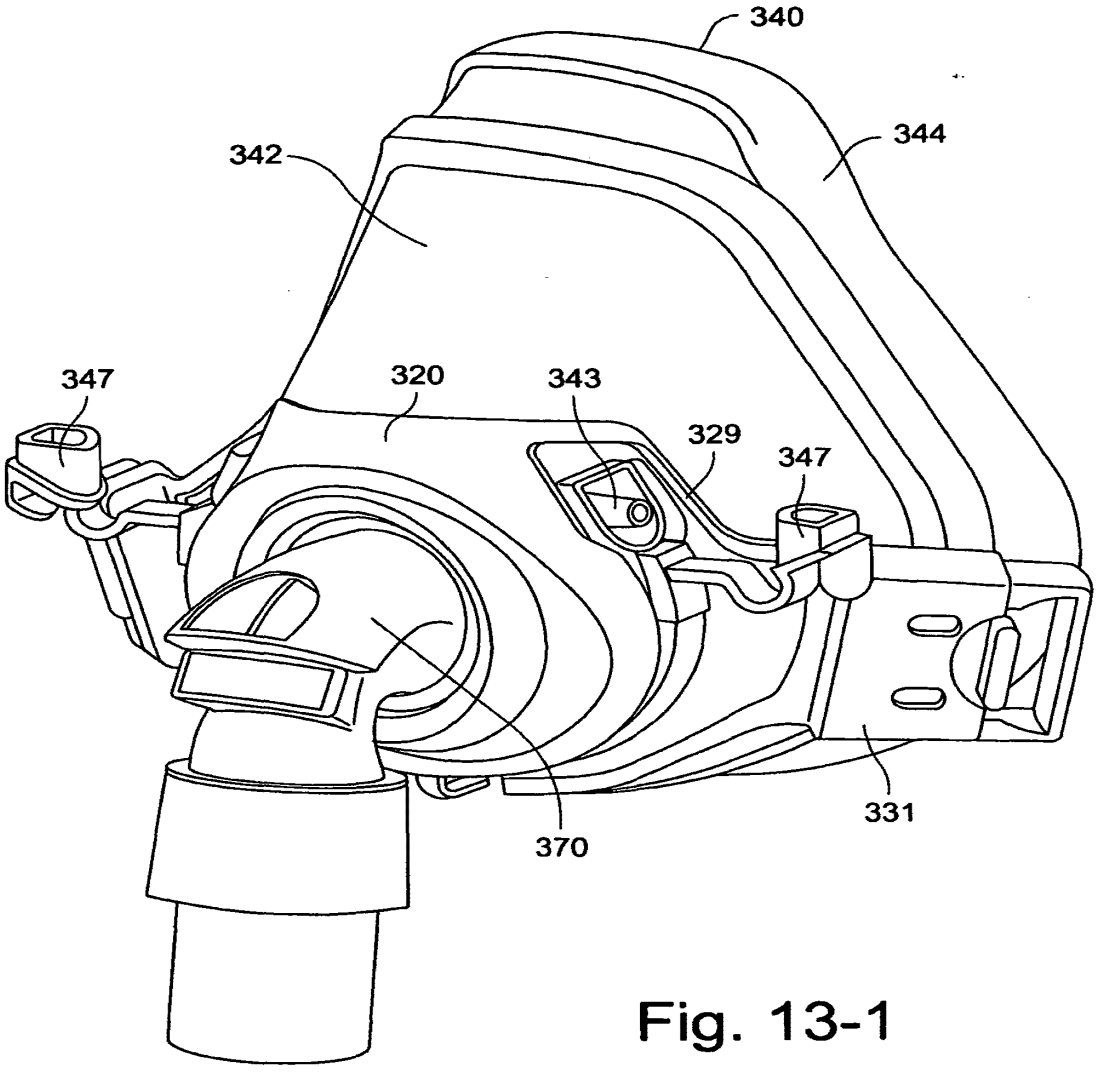

Fig. 13-1

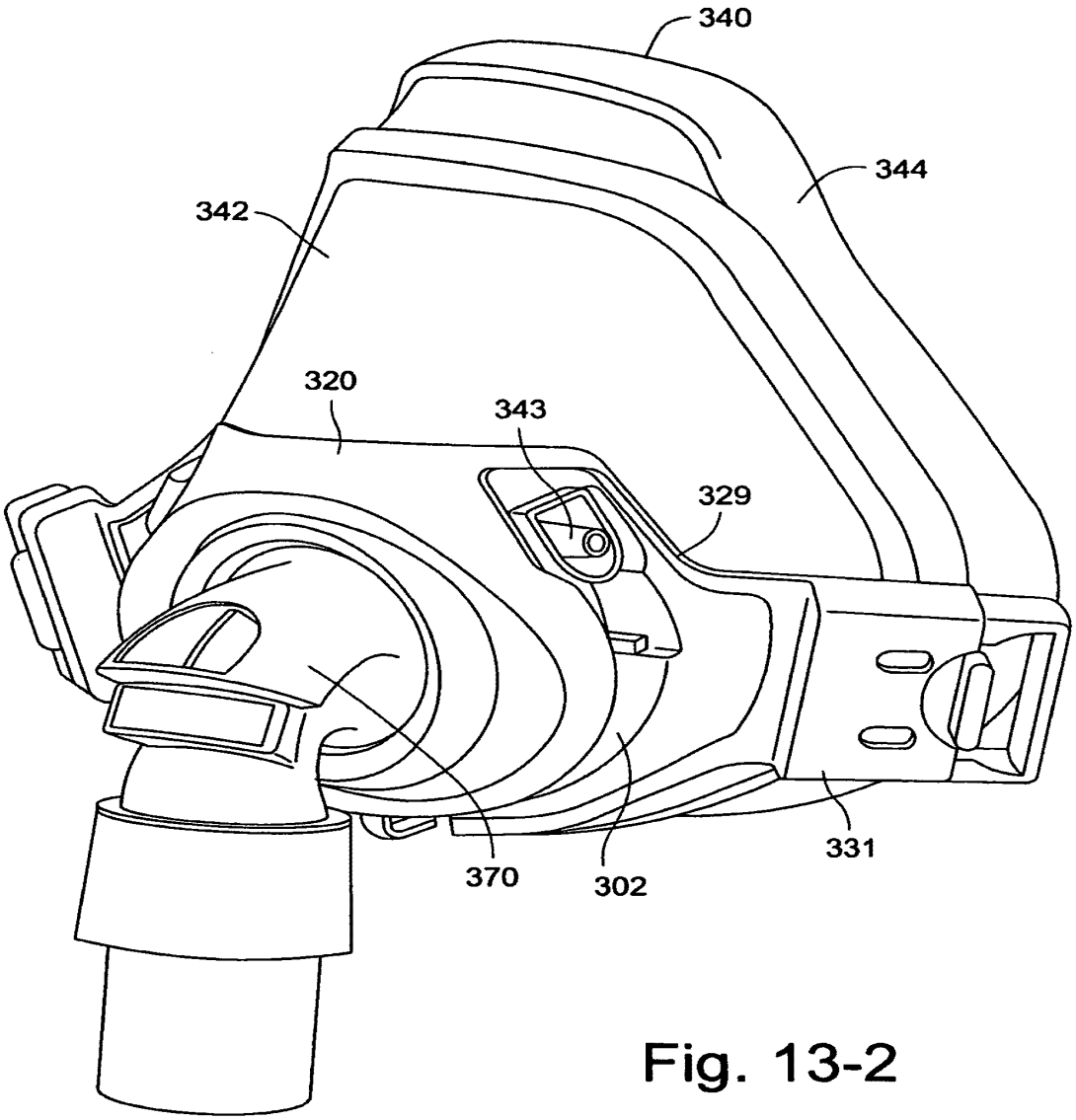

Fig. 13-2

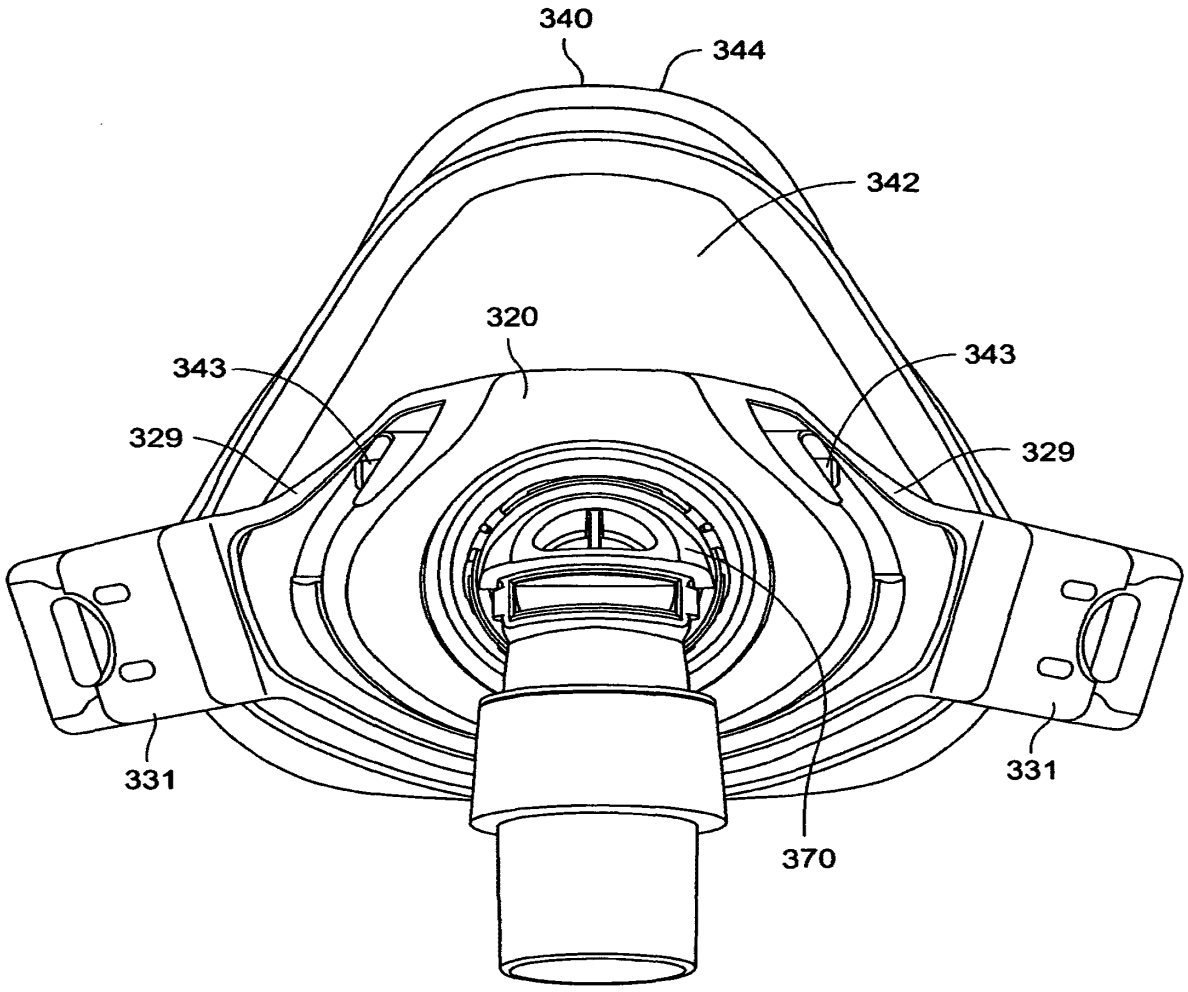

Fig. 13-3

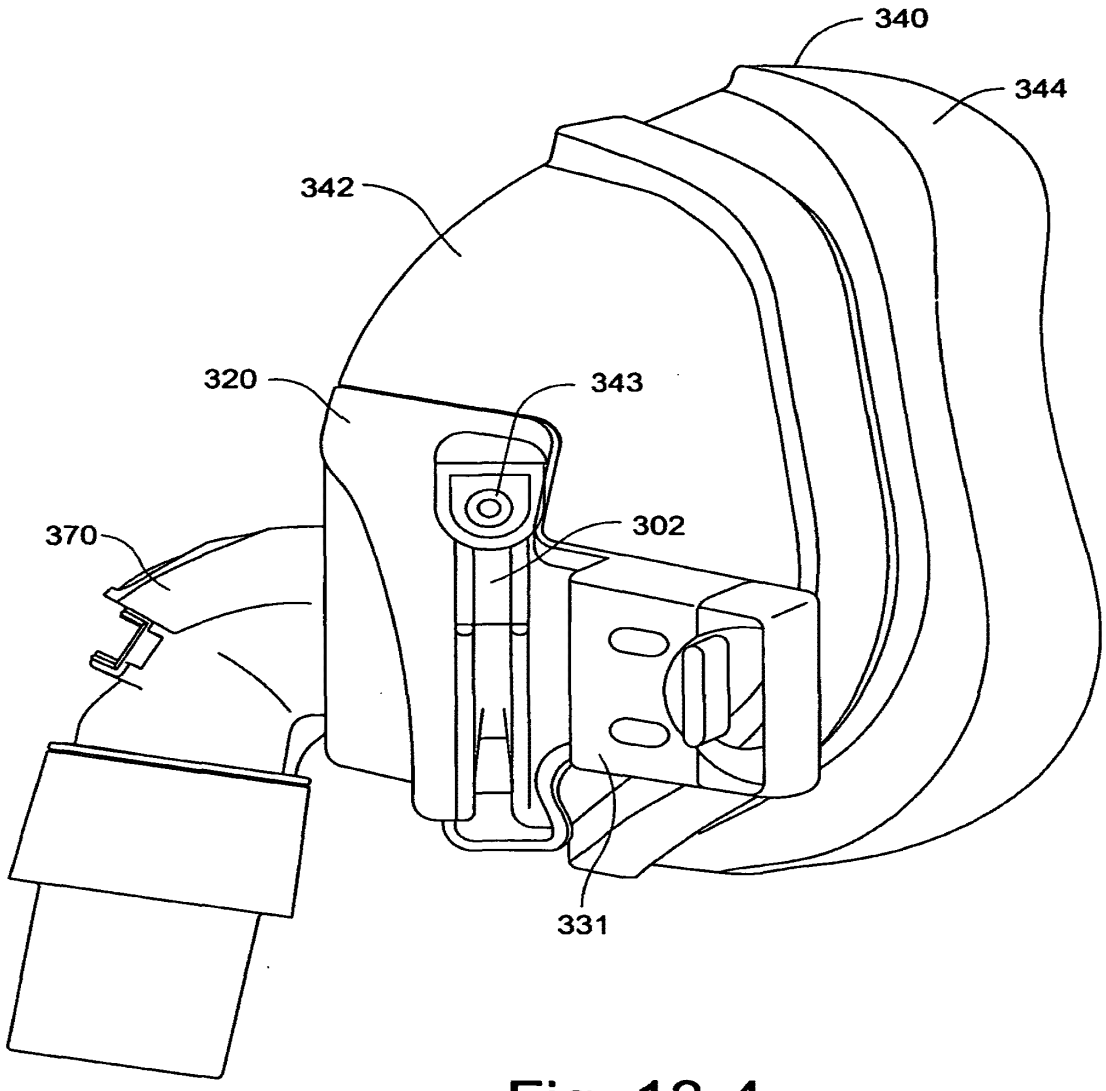

Fig. 13-4

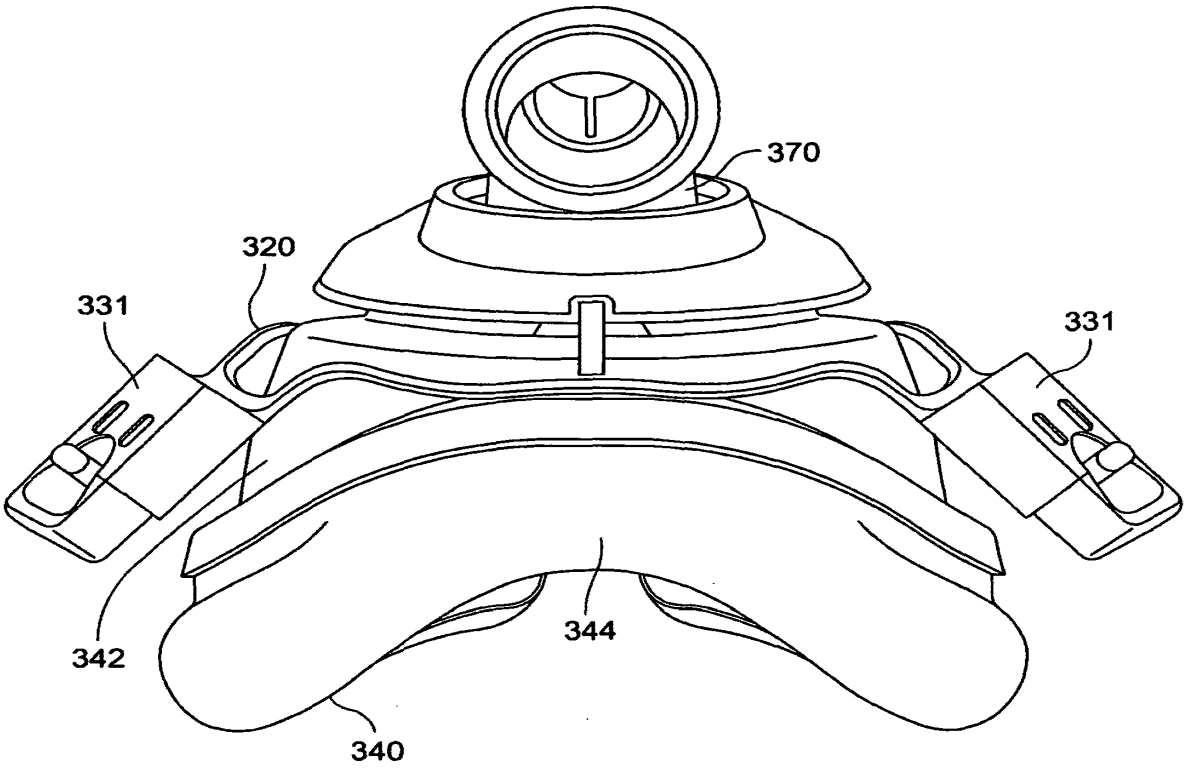

Fig. 13-5

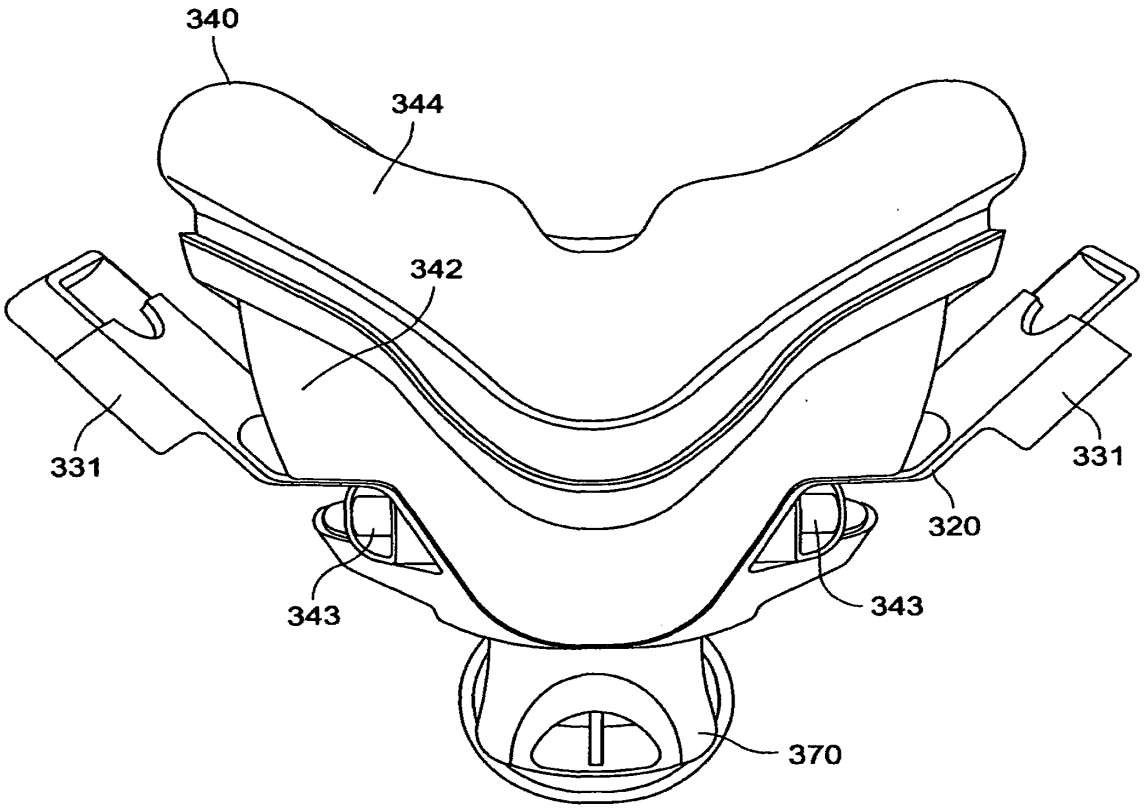

Fig. 13-6

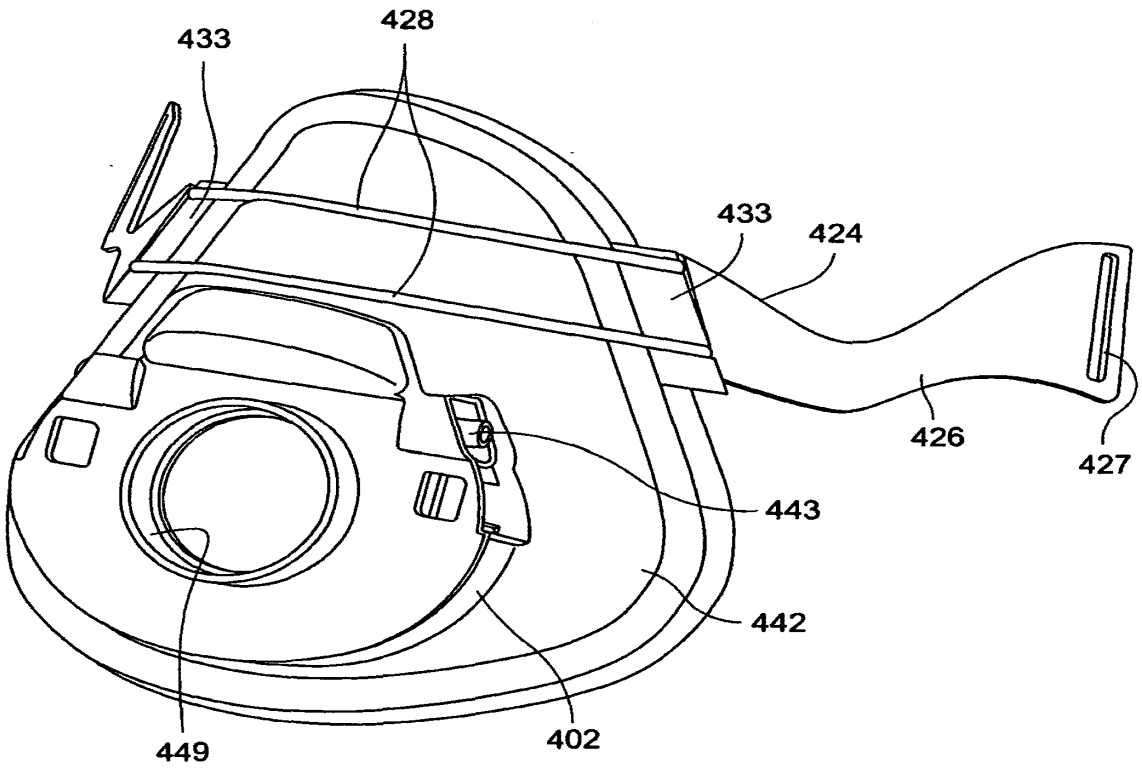

Fig. 14-1

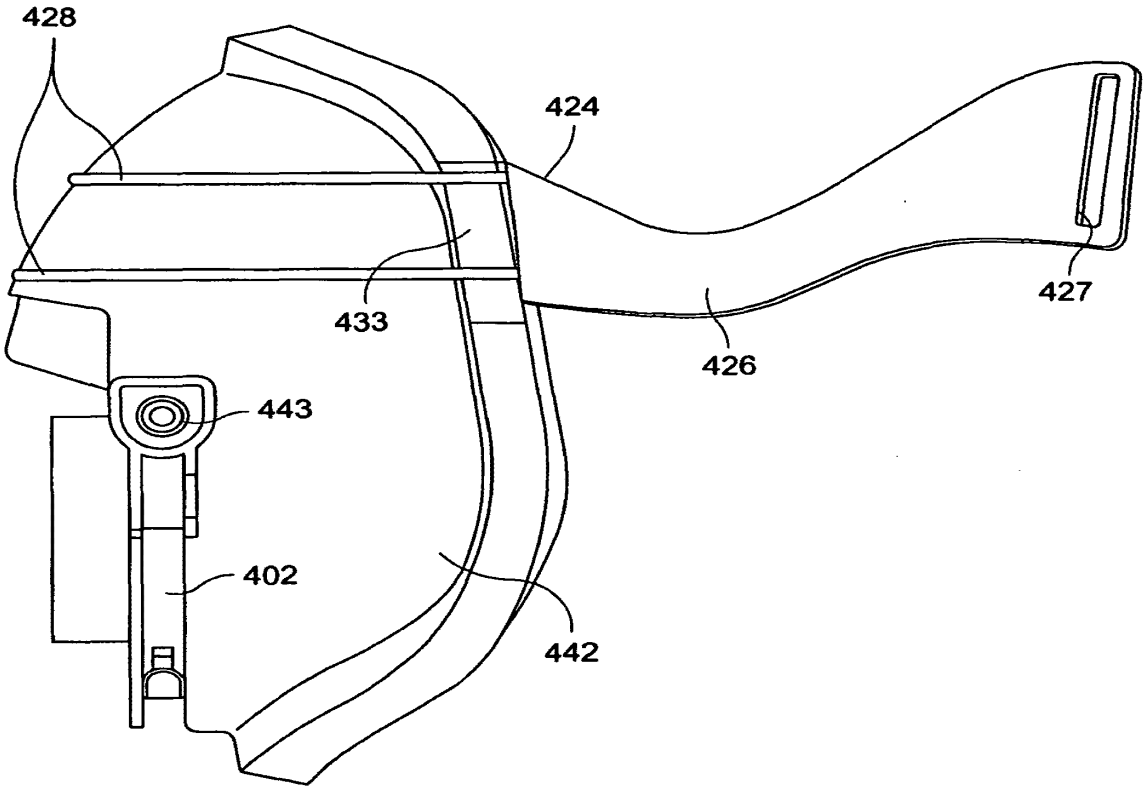

Fig. 14-2

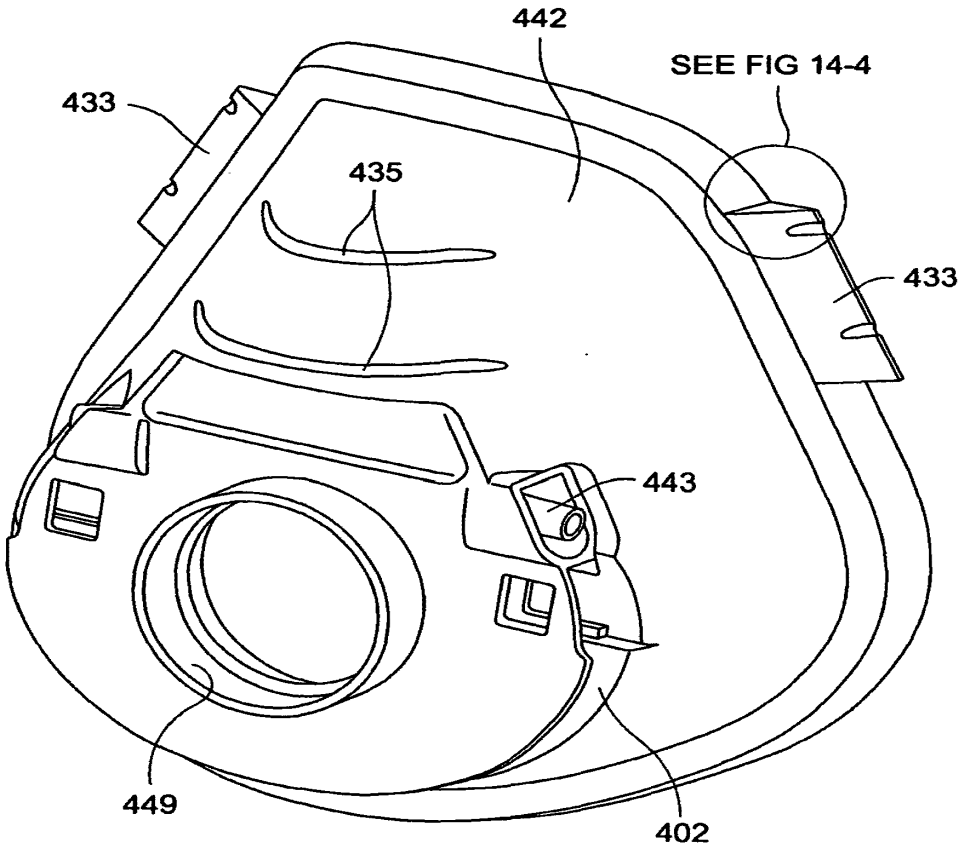

Fig. 14-3

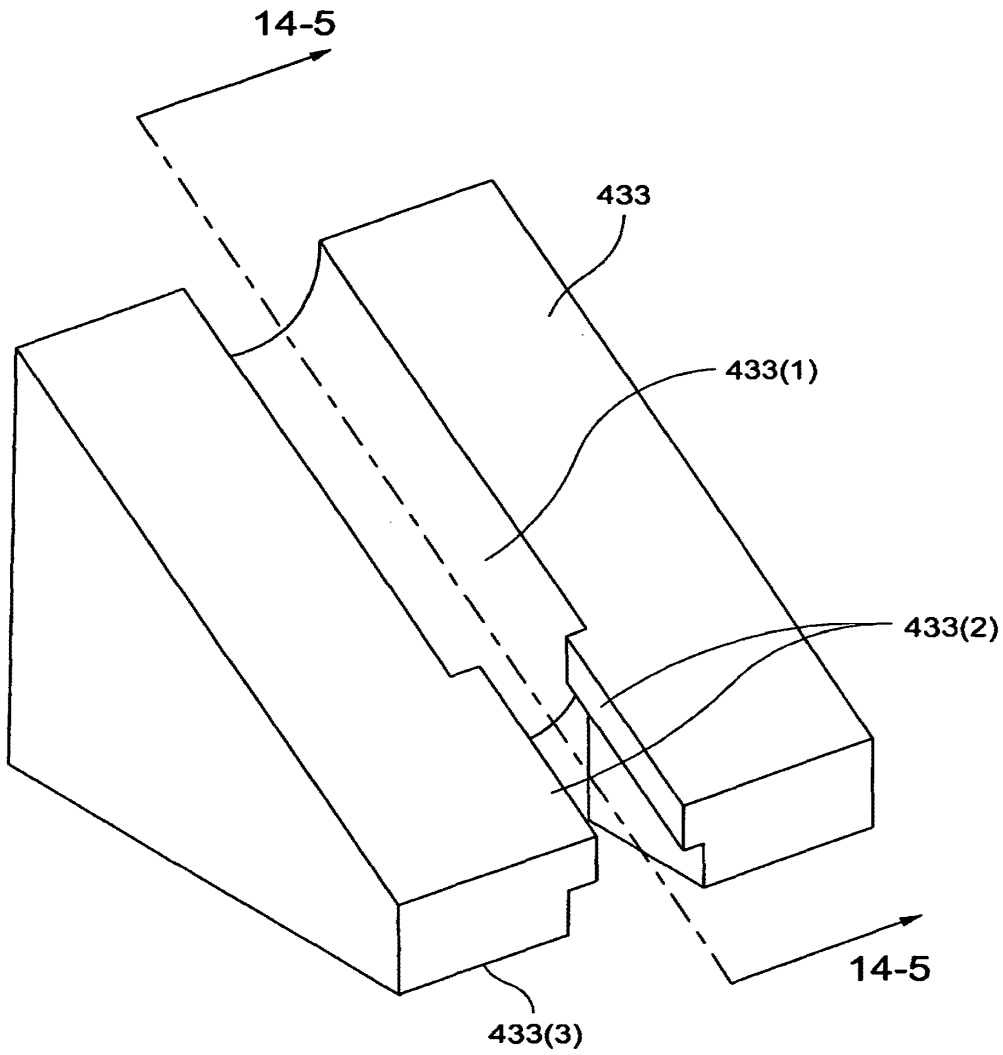

Fig. 14-4

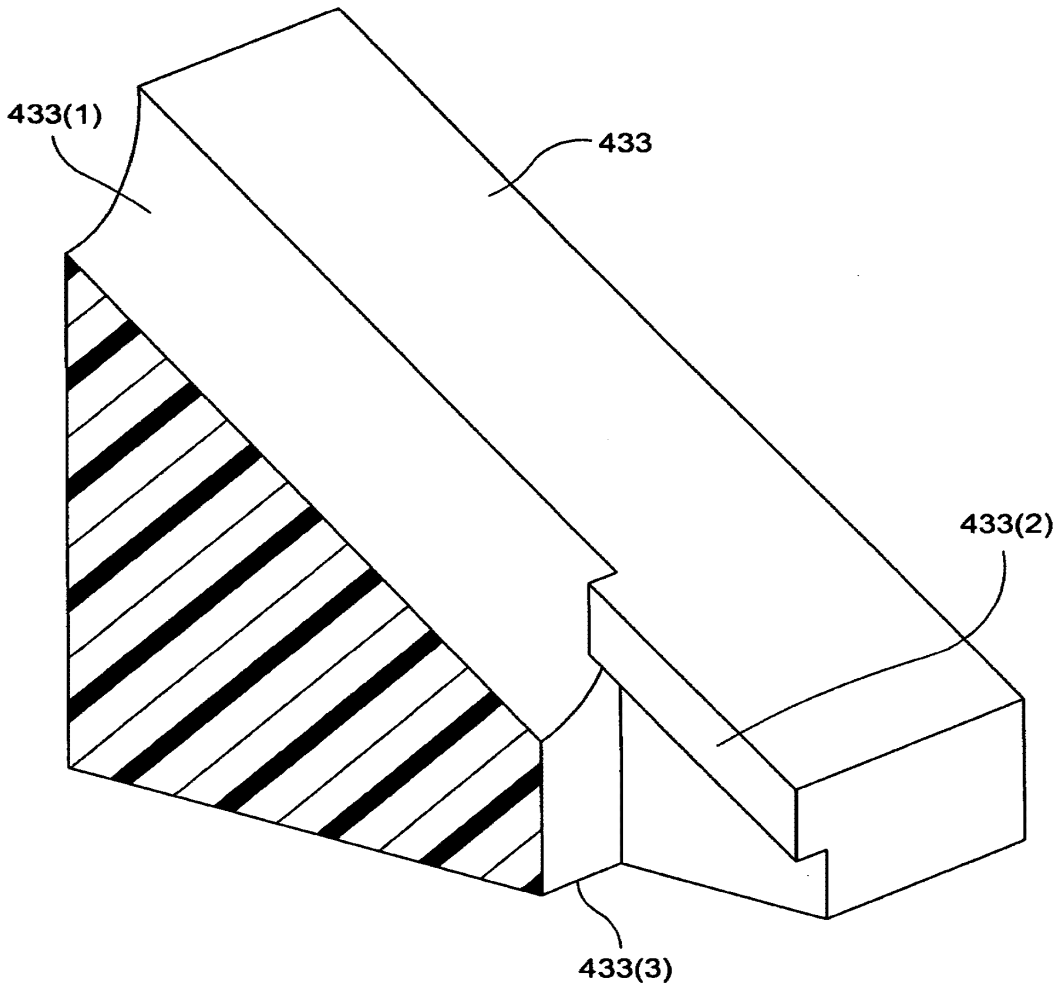

Fig. 14-5

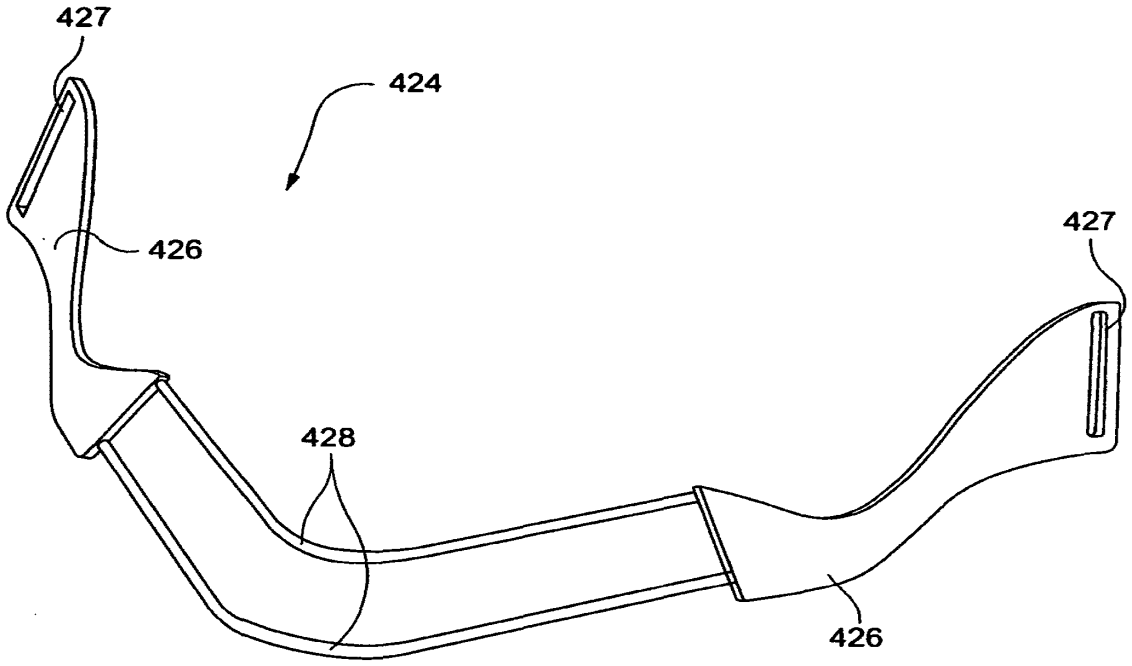

Fig. 14-6

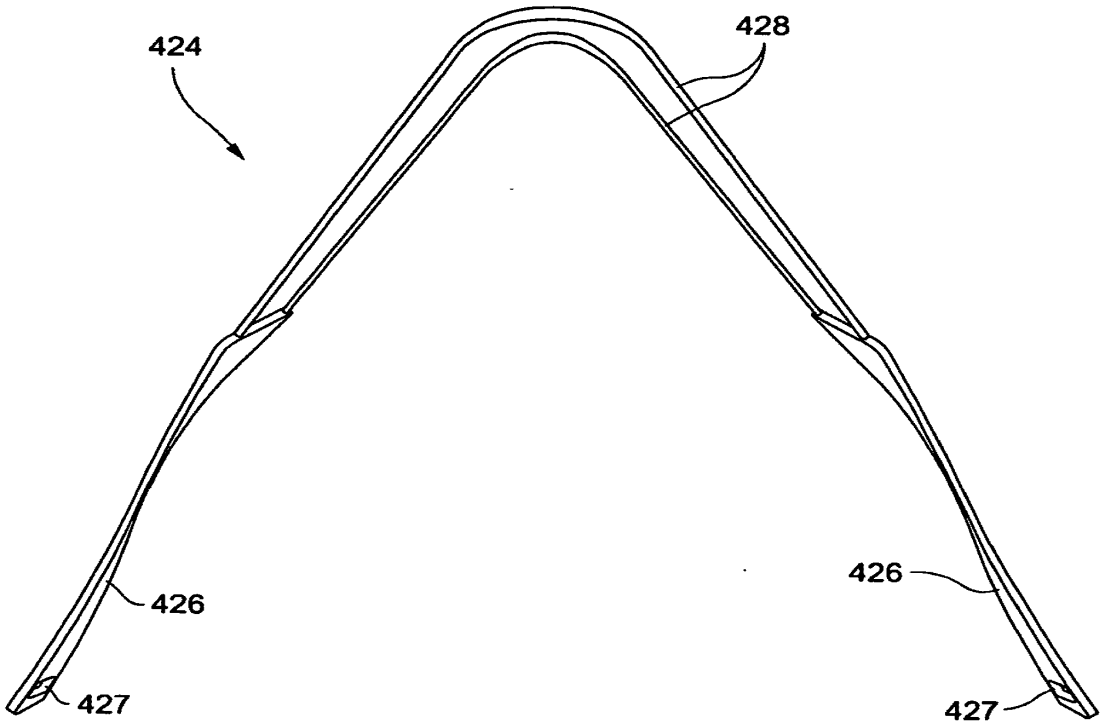

Fig. 14-7

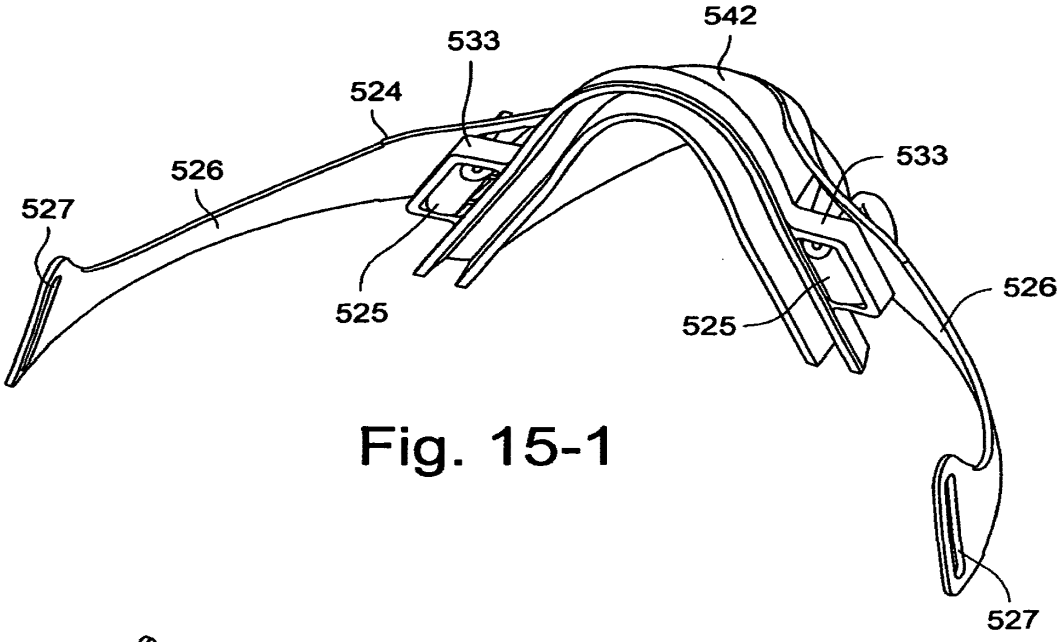

Fig. 15-1

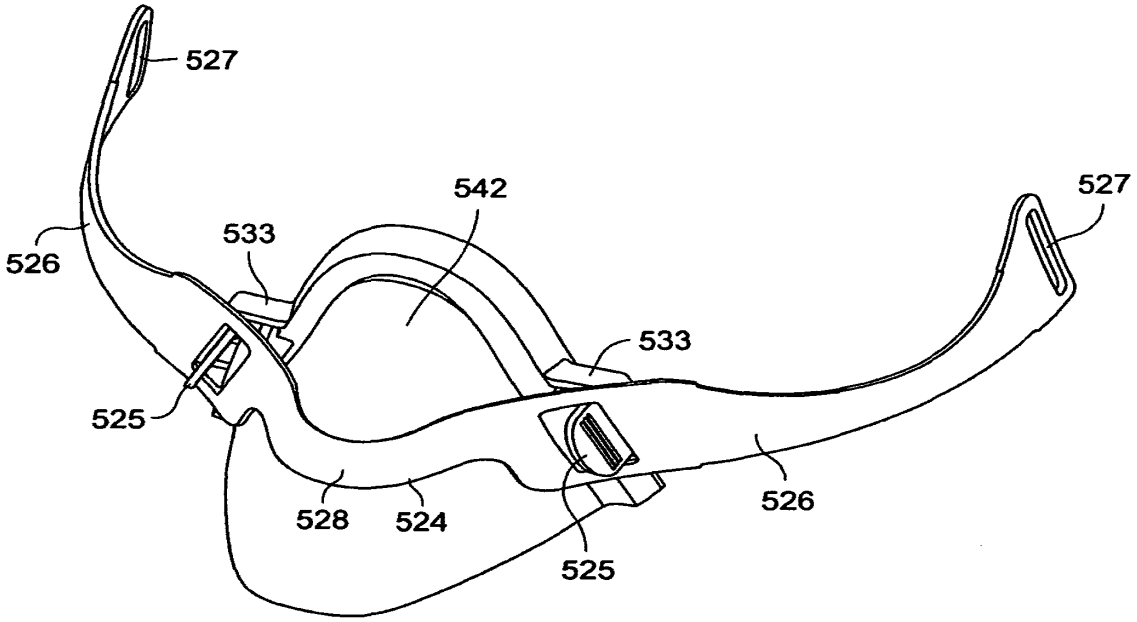

Fig. 15-2

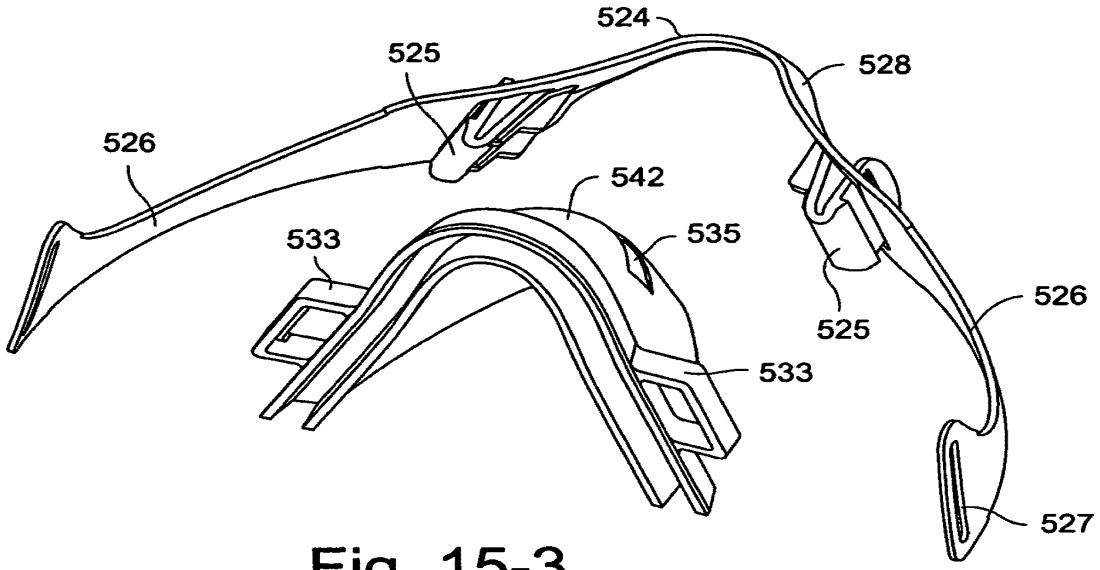

Fig. 15-3

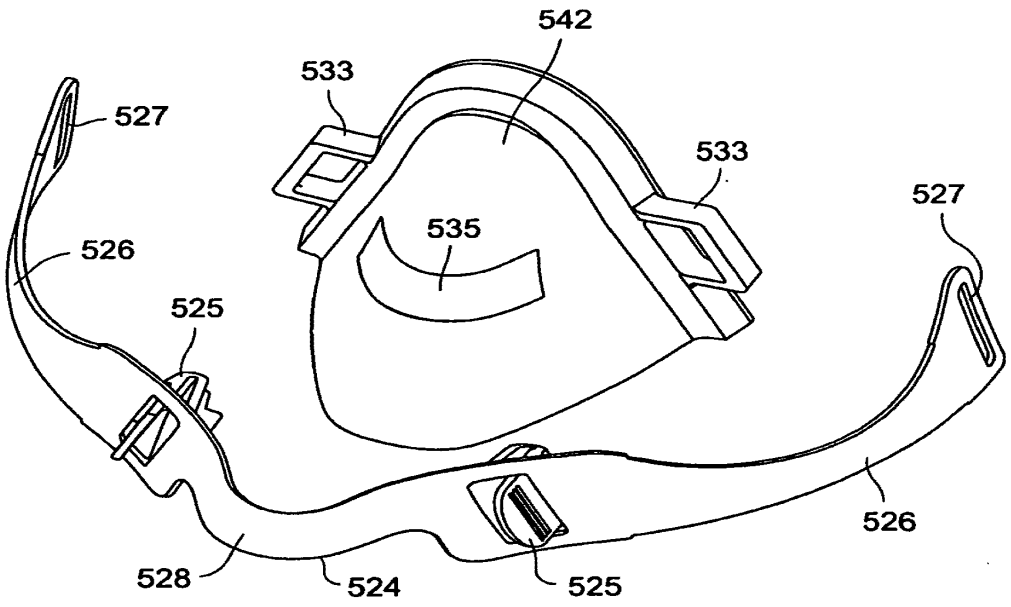

Fig. 15-4

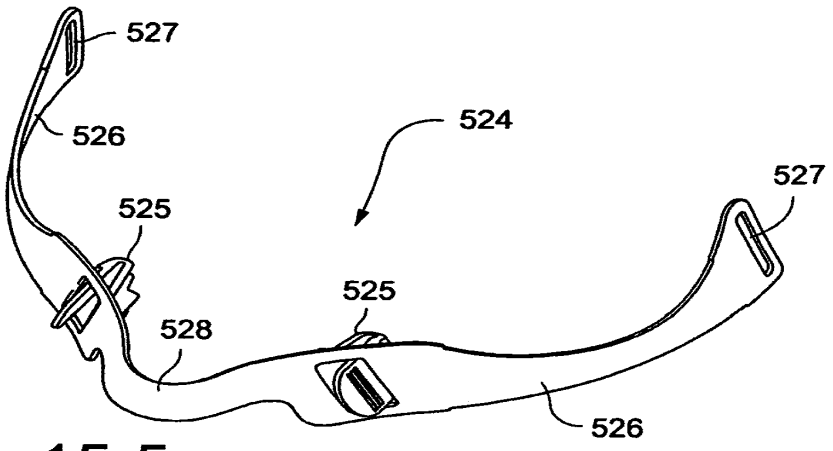

Fig. 15-5

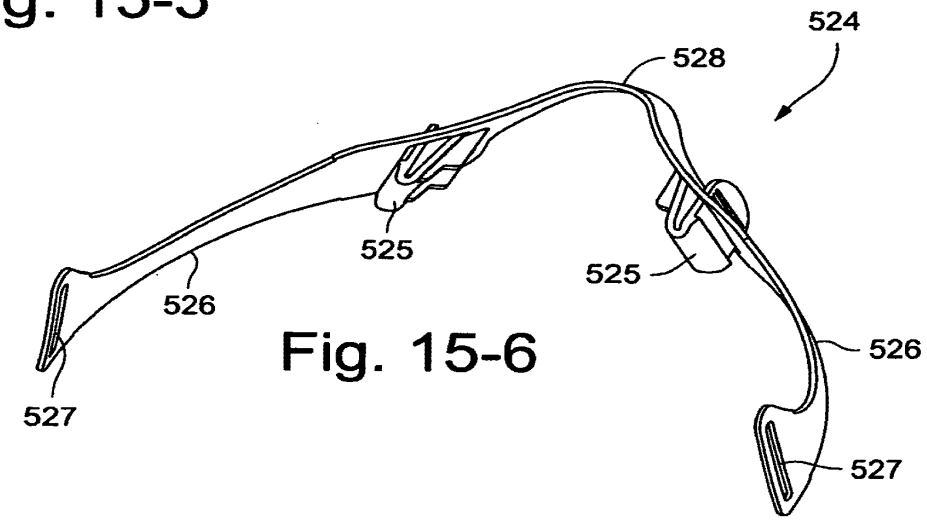

Fig. 15-6

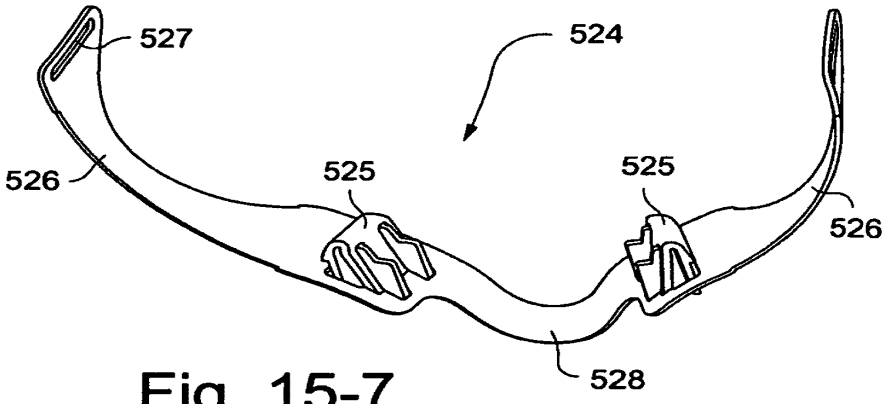

Fig. 15-7

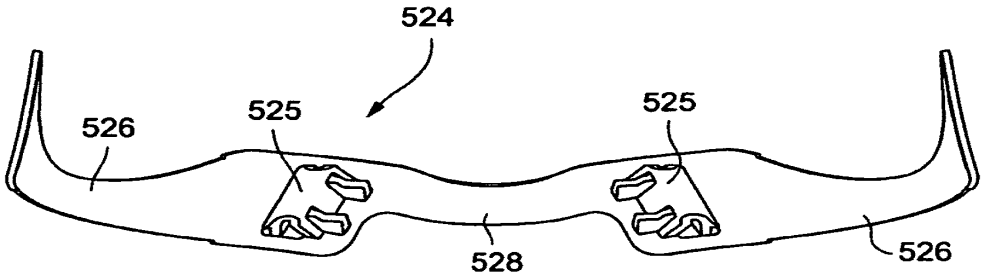

Fig. 15-8

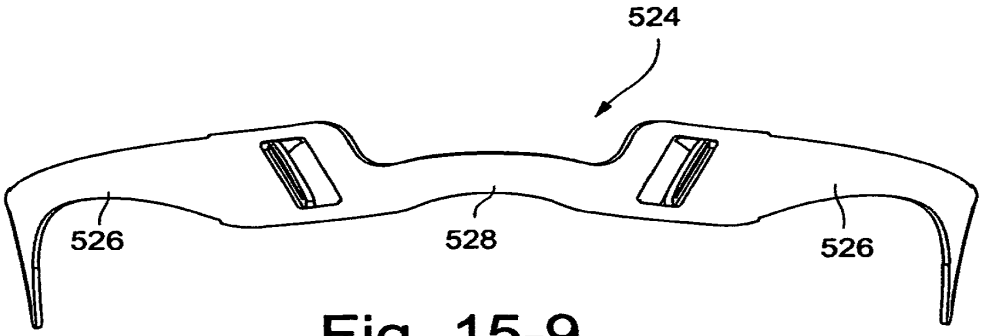

Fig. 15-9

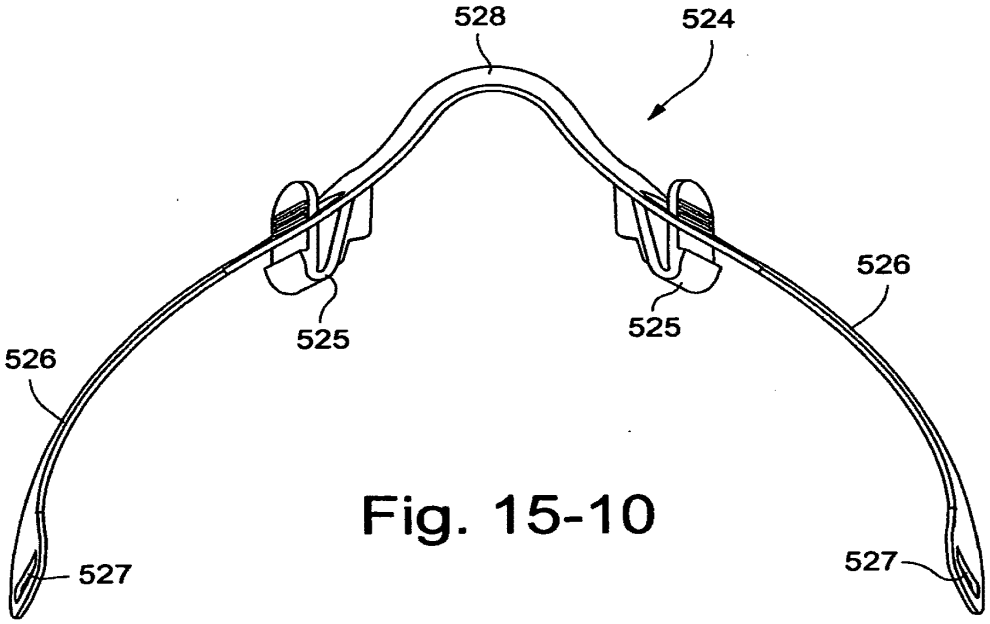

Fig. 15-10

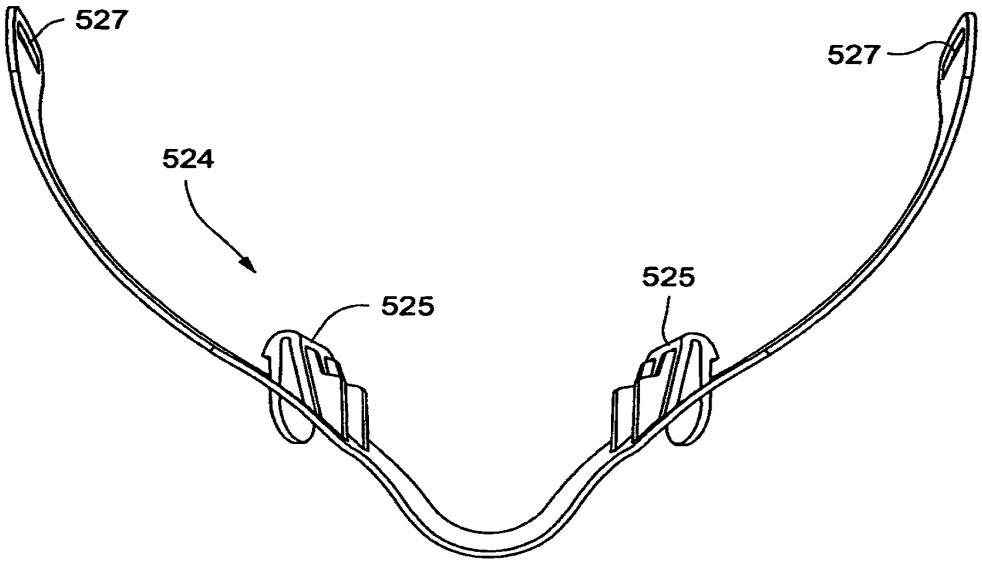

Fig. 15-11

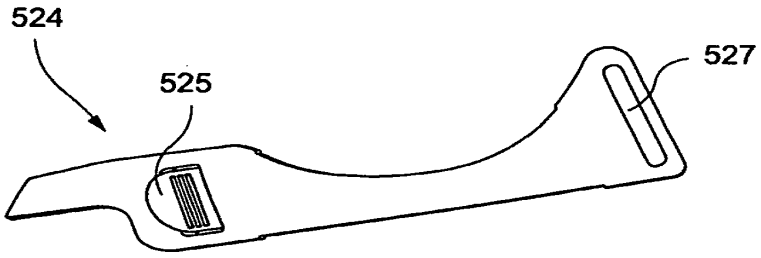

Fig. 15-12

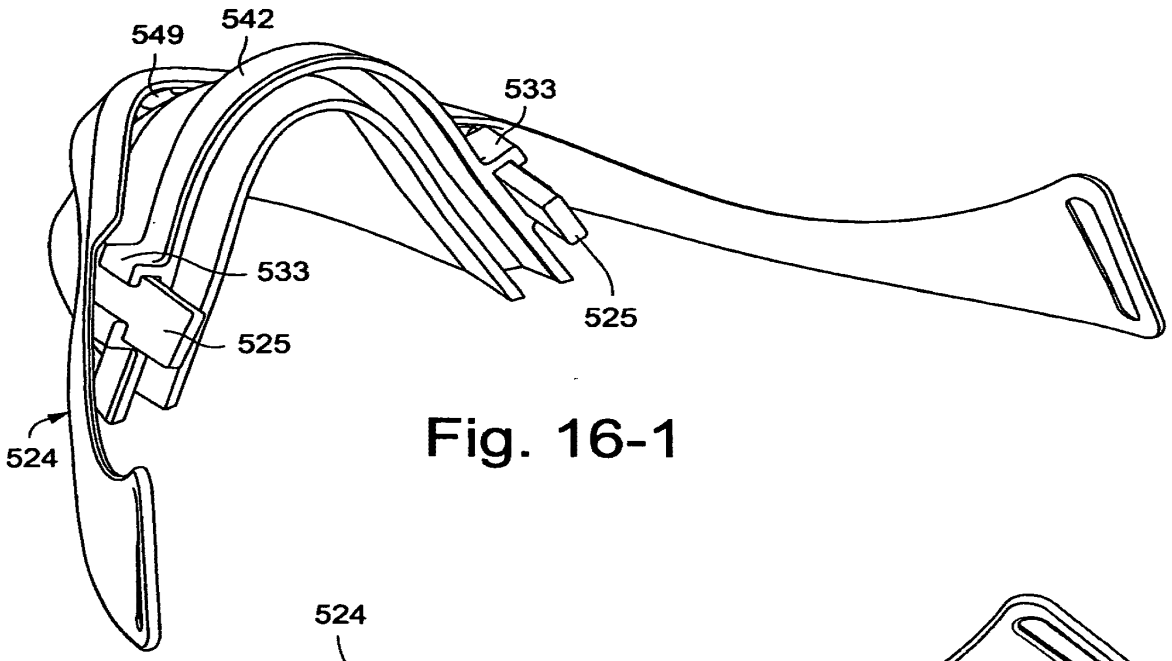

Fig. 16-1

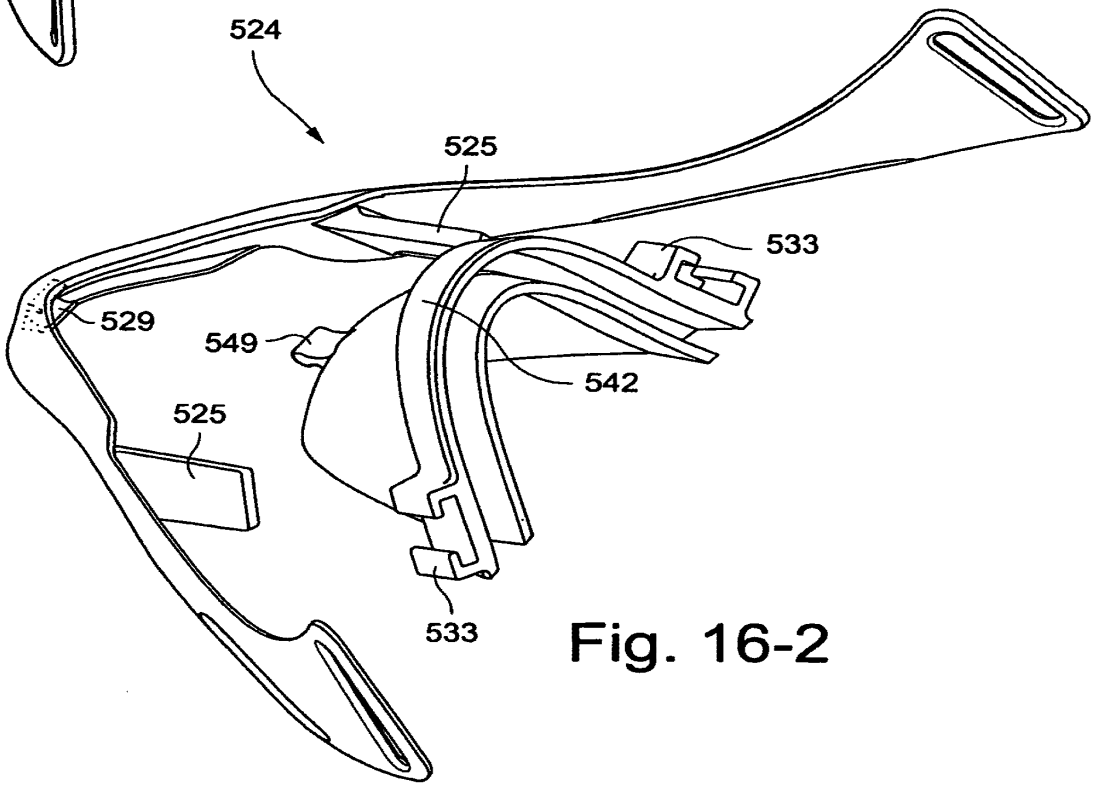

Fig. 16-2

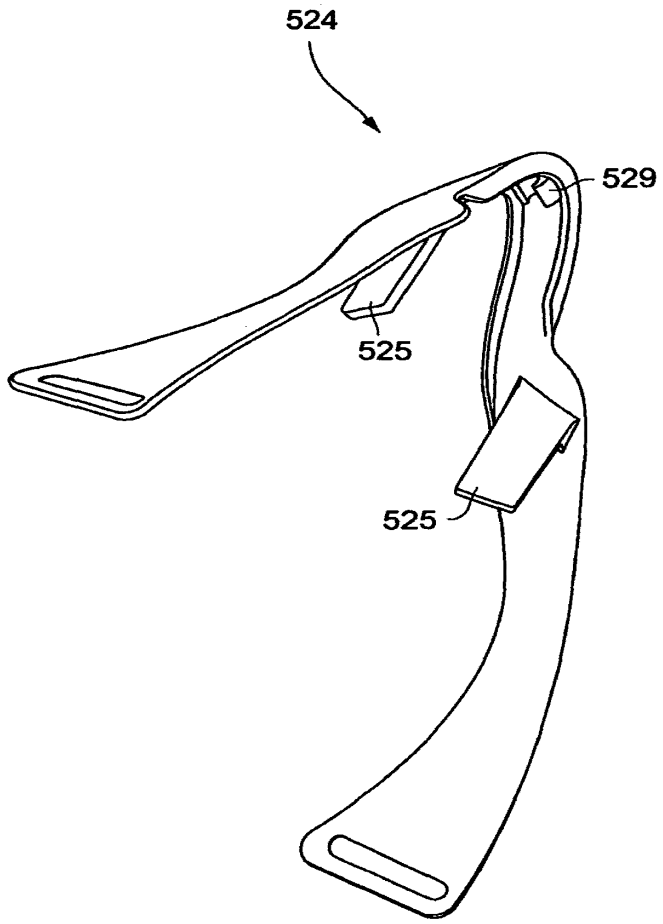

Fig. 16-3

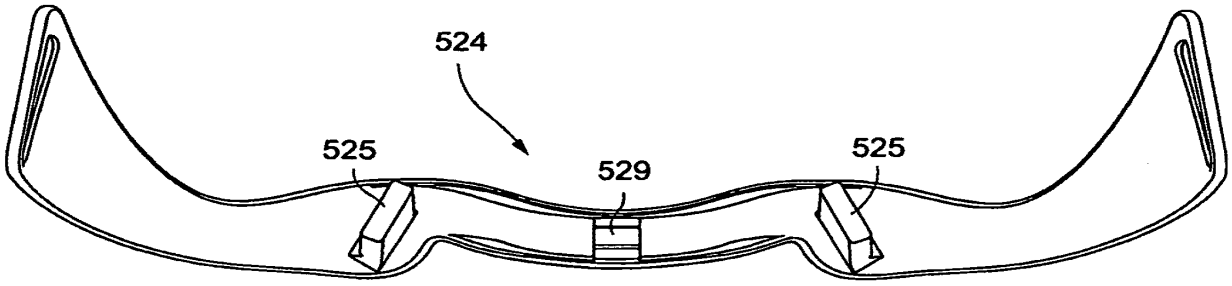

Fig. 16-4

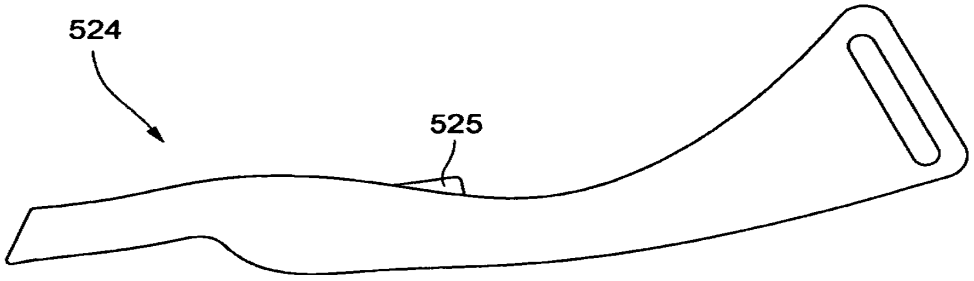

Fig. 16-5

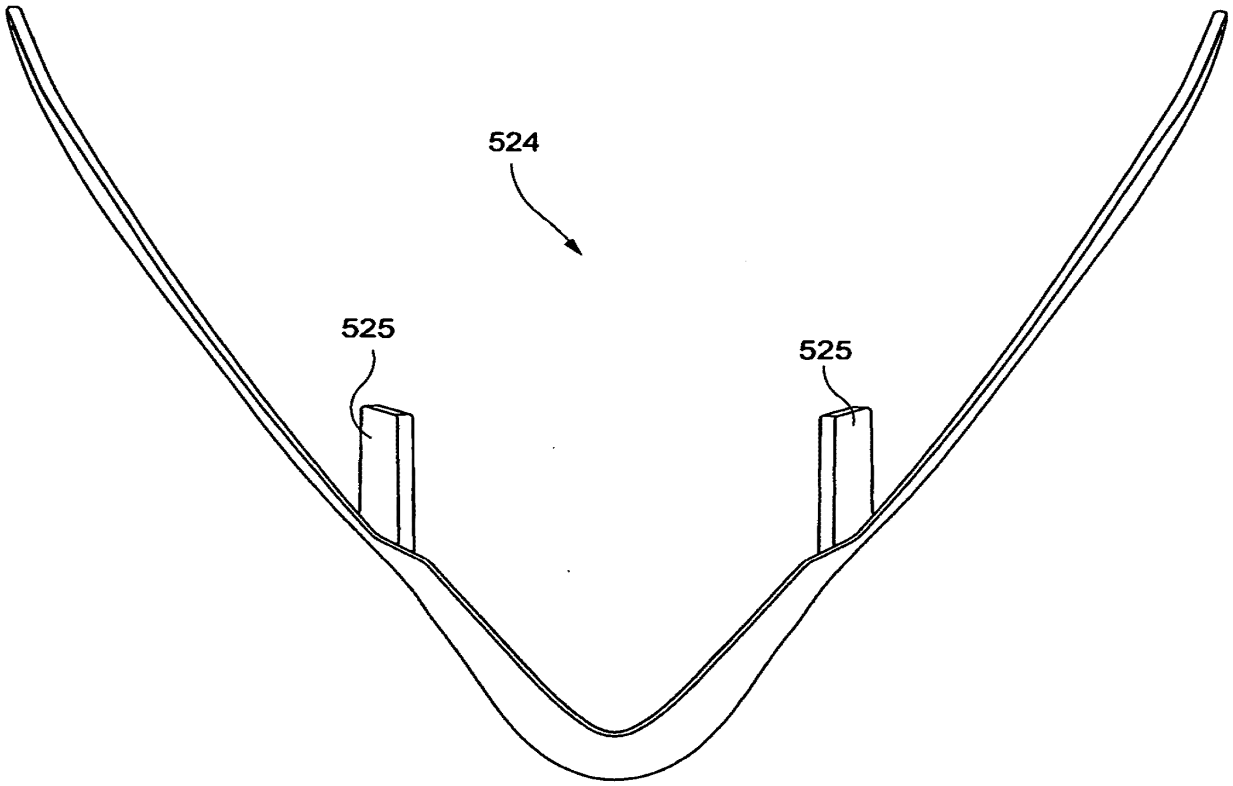

Fig. 16-6

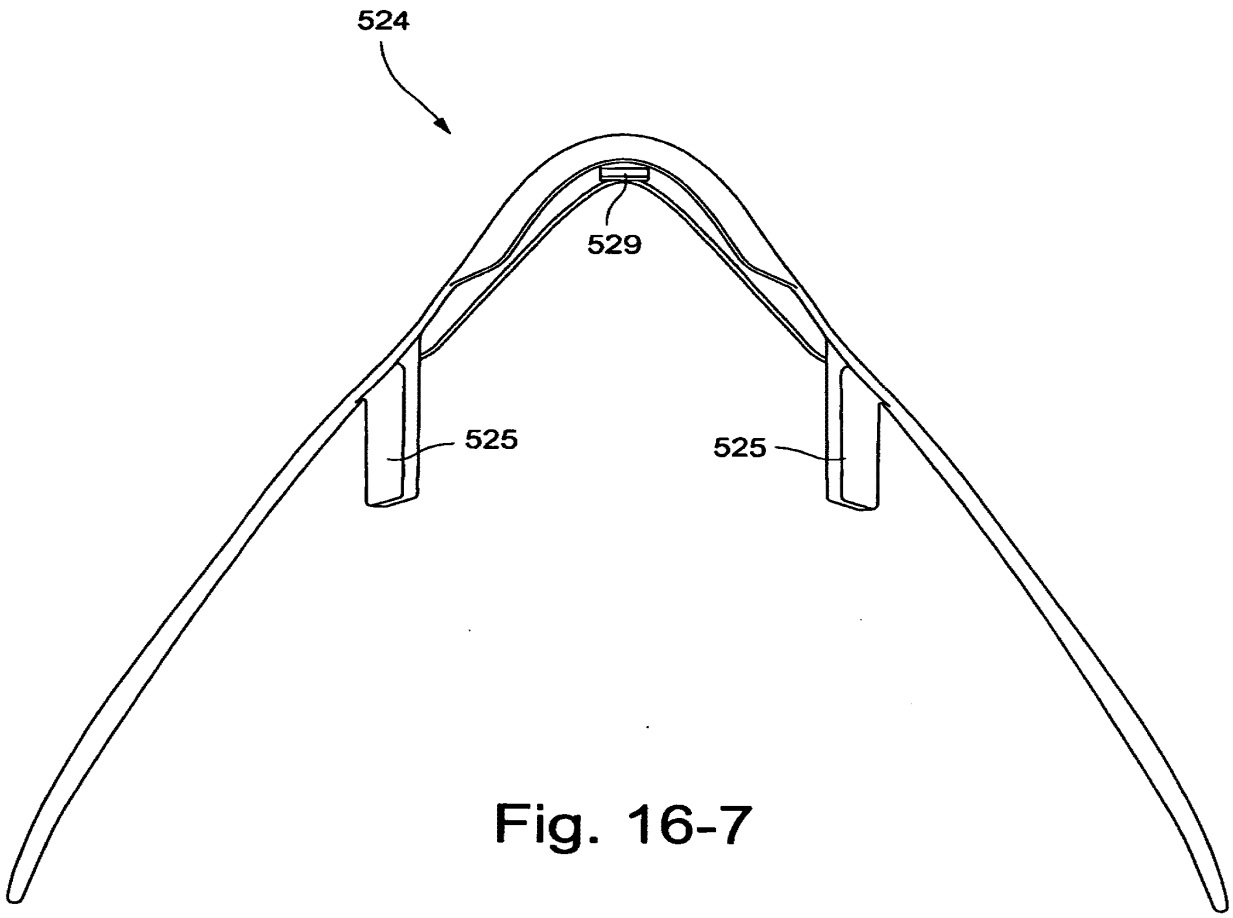

Fig. 16-7

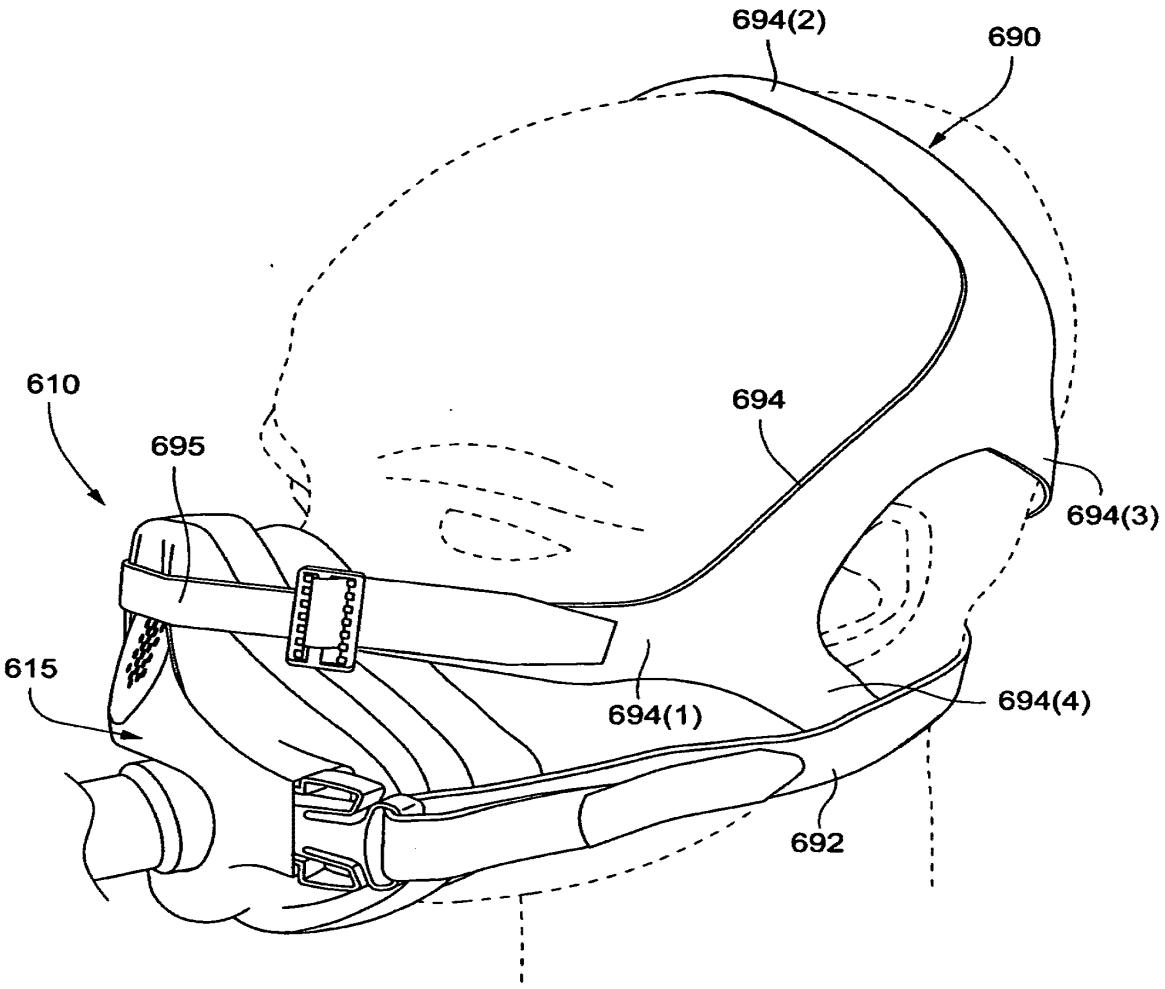

Fig. 17-1

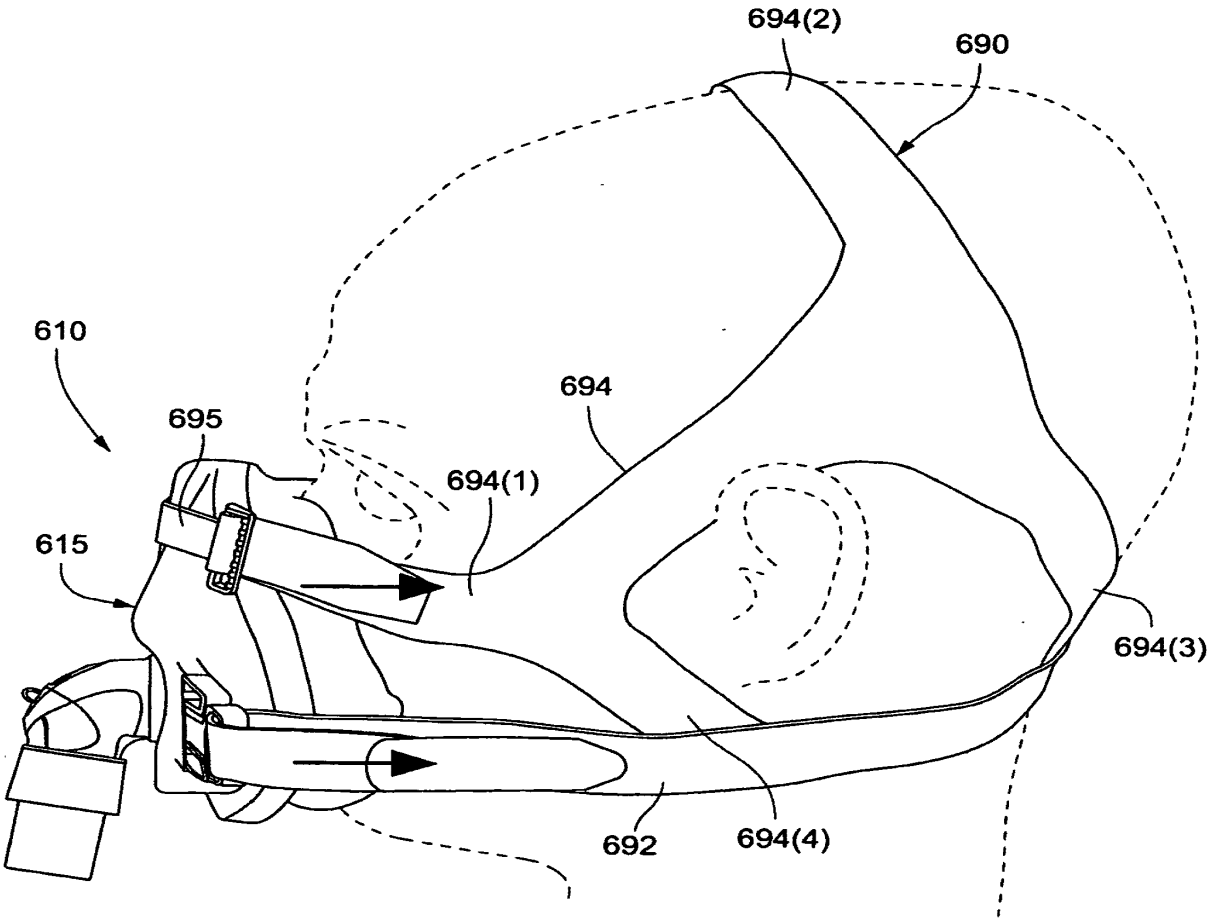

Fig. 17-2

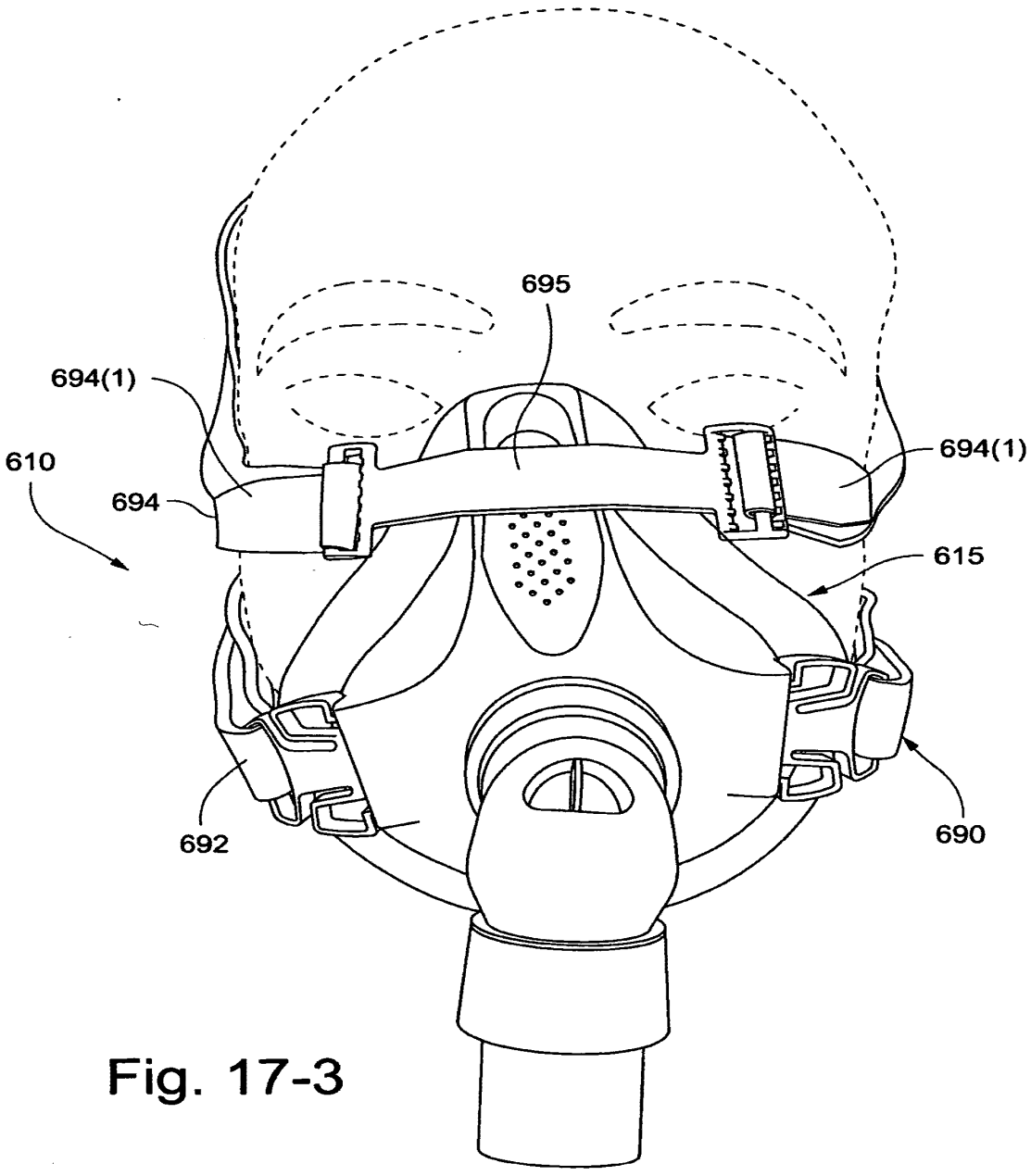

Fig. 17-3

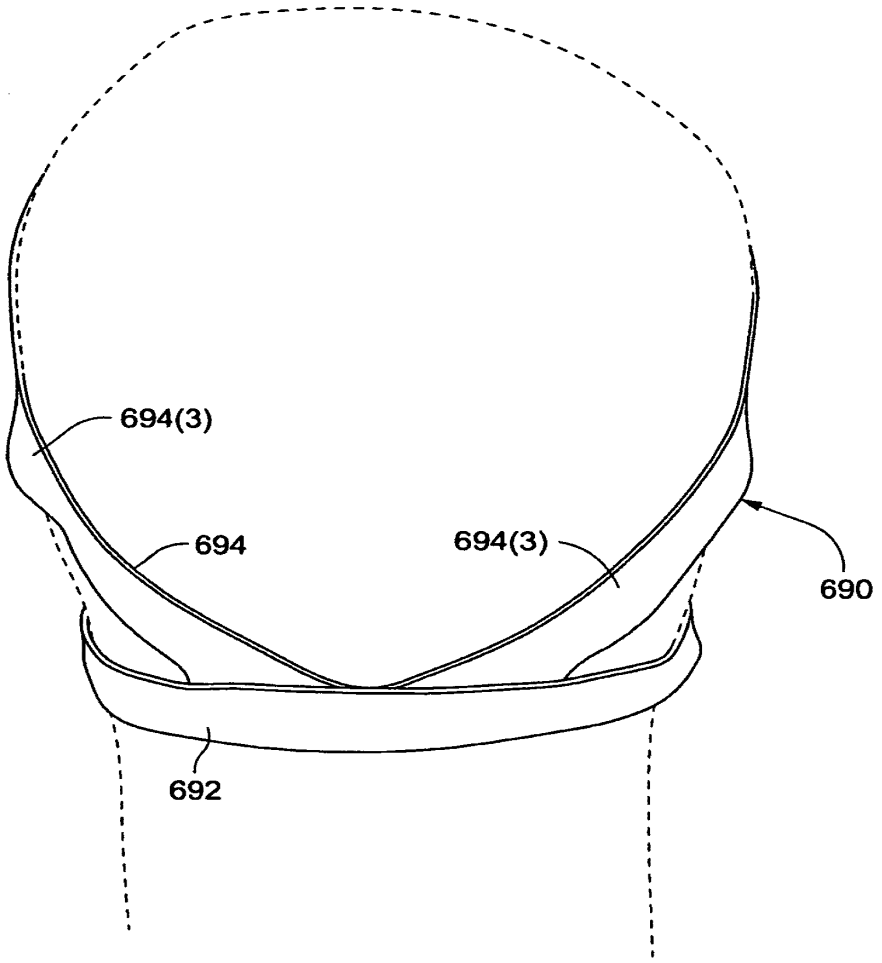

Fig. 17-4

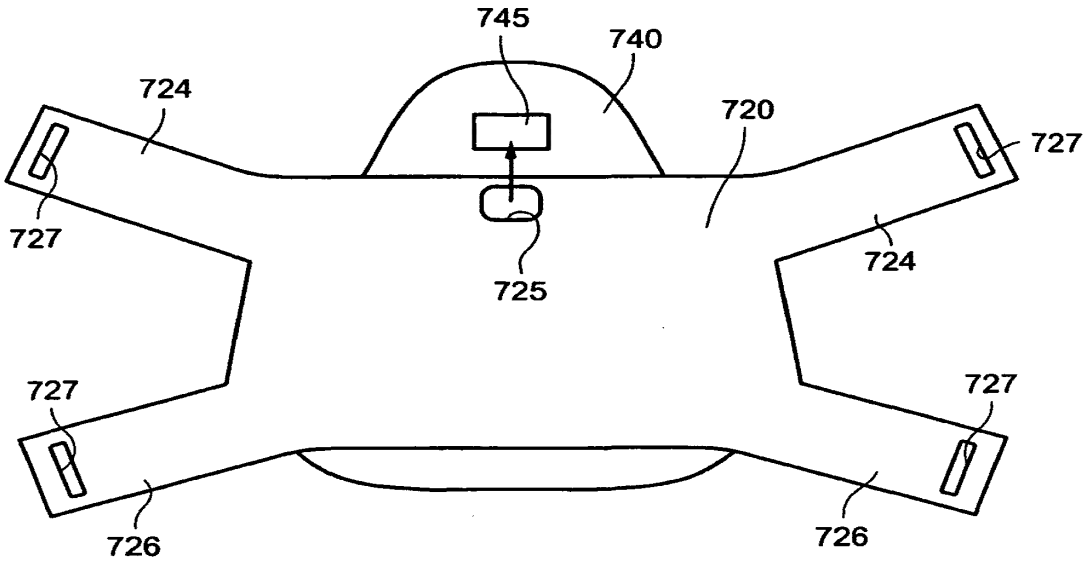

Fig. 18

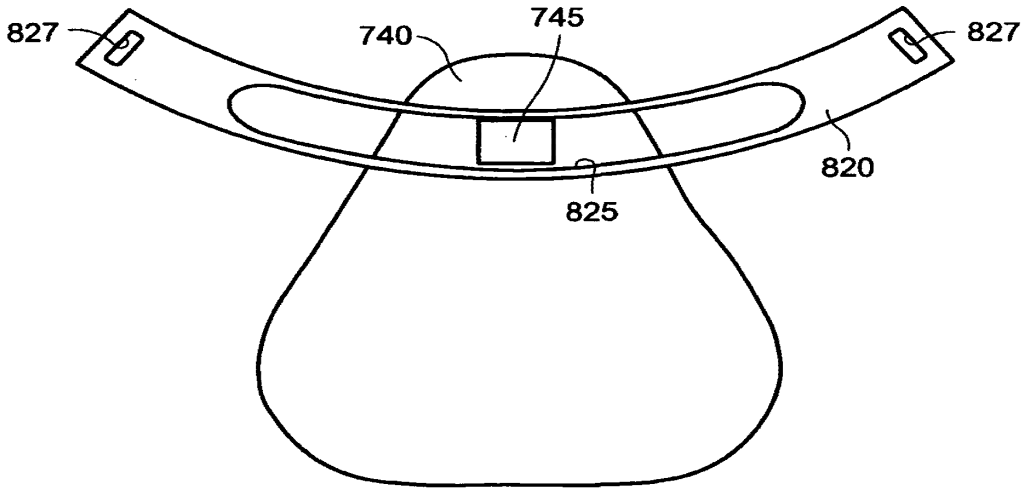

Fig. 19