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(54) **MASK, MASK SHELL AND SEAL WITH IMPROVED MOUNTING, MASK SEAL, METHOD OF MASK MANUFACTURE AND MASK WITH REDUCED EXHALATION NOISE**

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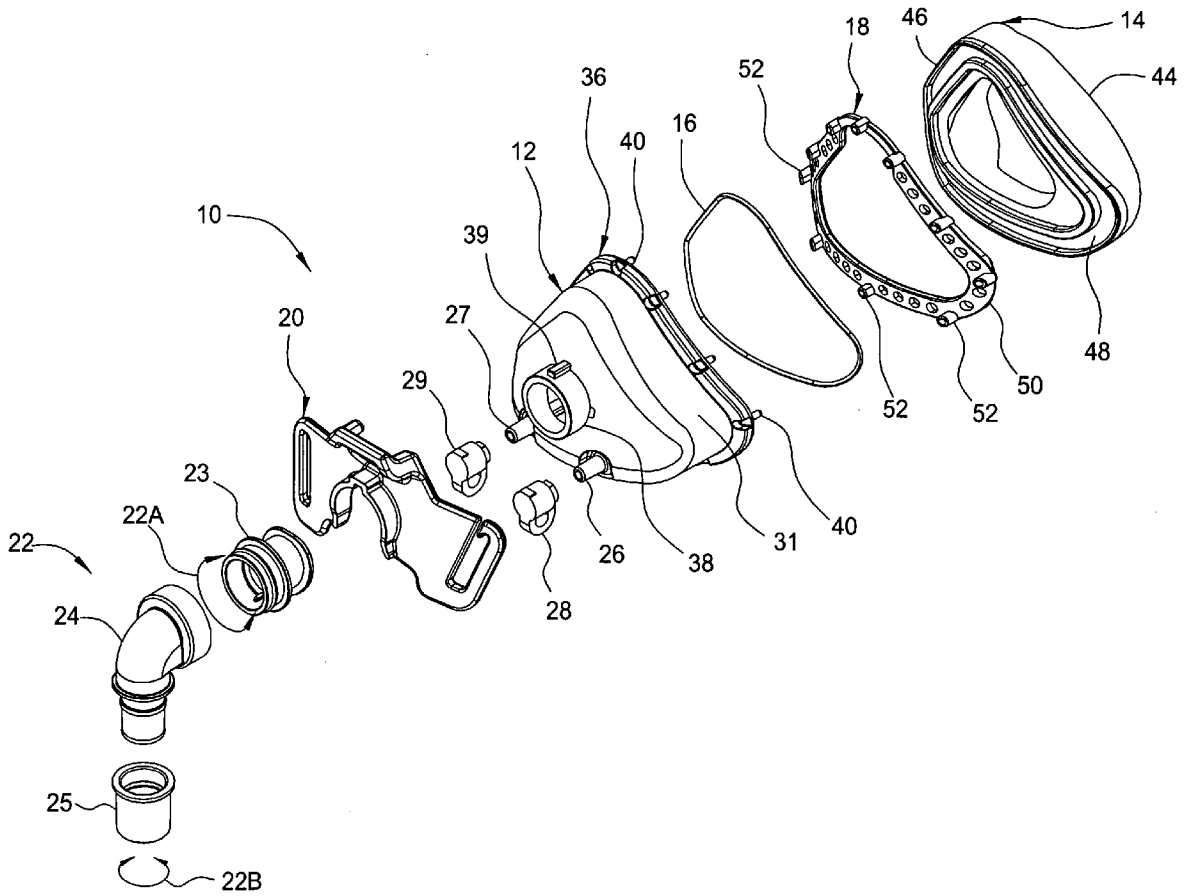
(57) **ABSTRACT**

A mask, a mask shell and seal provided with cooperative mounting members for mounting the seal to the shell, method of manufacturing such mask, mask shell and seal, a mask including a plurality of headstraps and a headstrap retention bracket for mounting the headstraps removably to the mask, a mask seal including an embedded seal mounting member for mounting the seal to a mask shell, a mask shell including a malleable member in its peripheral portion which may be deformed to customize the mask seal to a person's face, and a mask with a plurality of angular vent holes for reducing the noise of a mask wearer's exhaled breath and for directing the exhaled breath away substantially parallel to the mask wearer's body.



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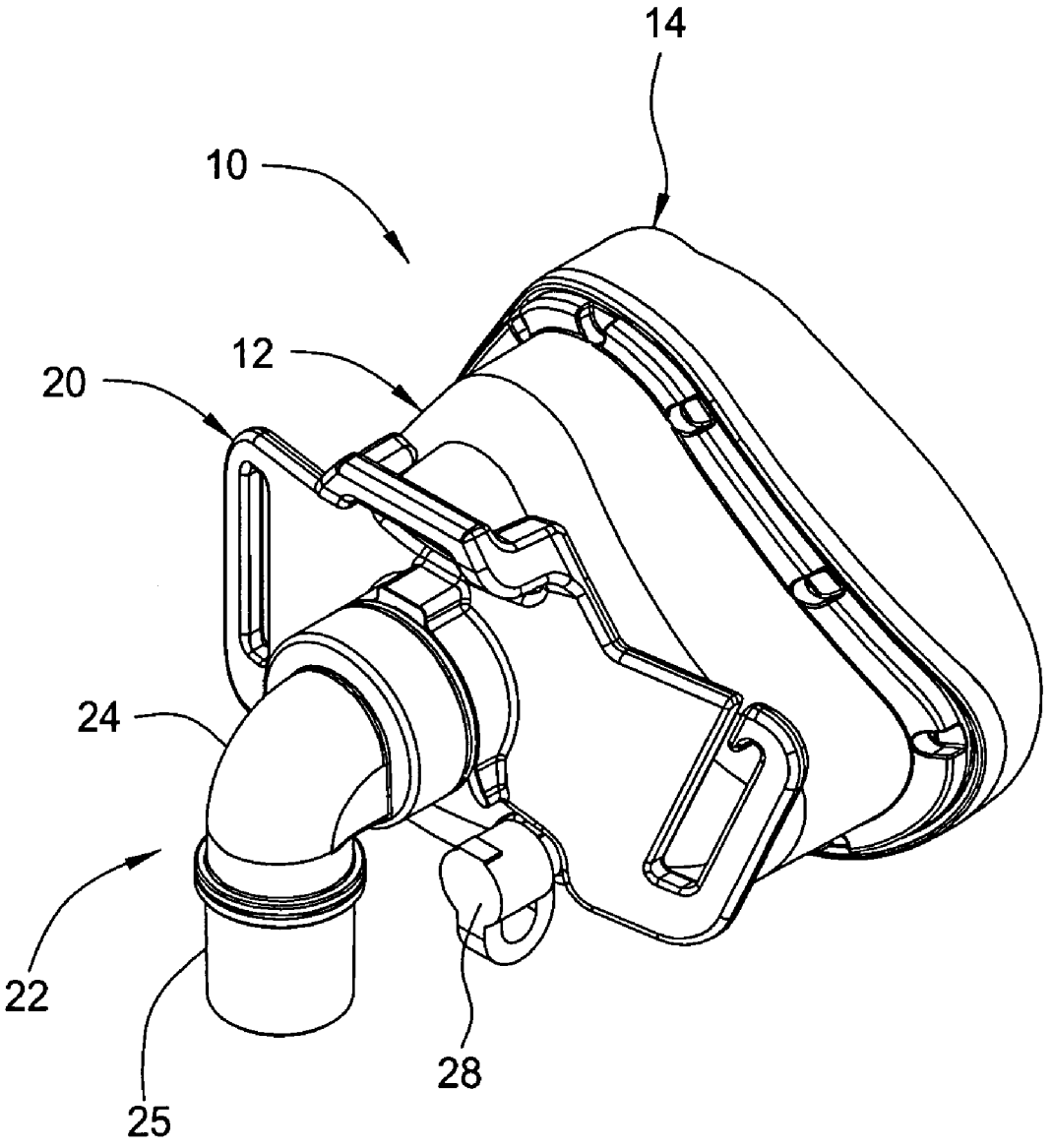

FIG. 1

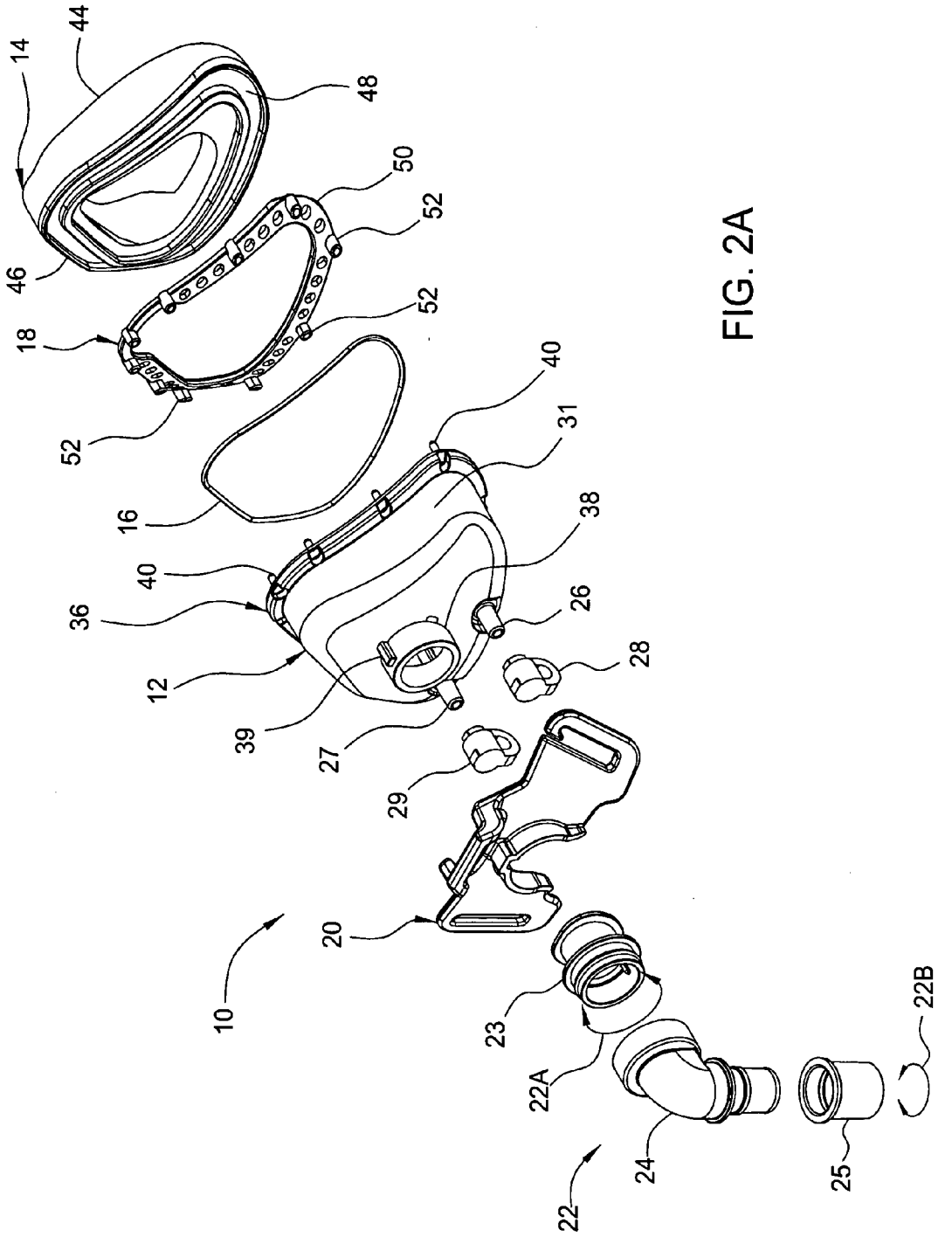
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FIG. 2A

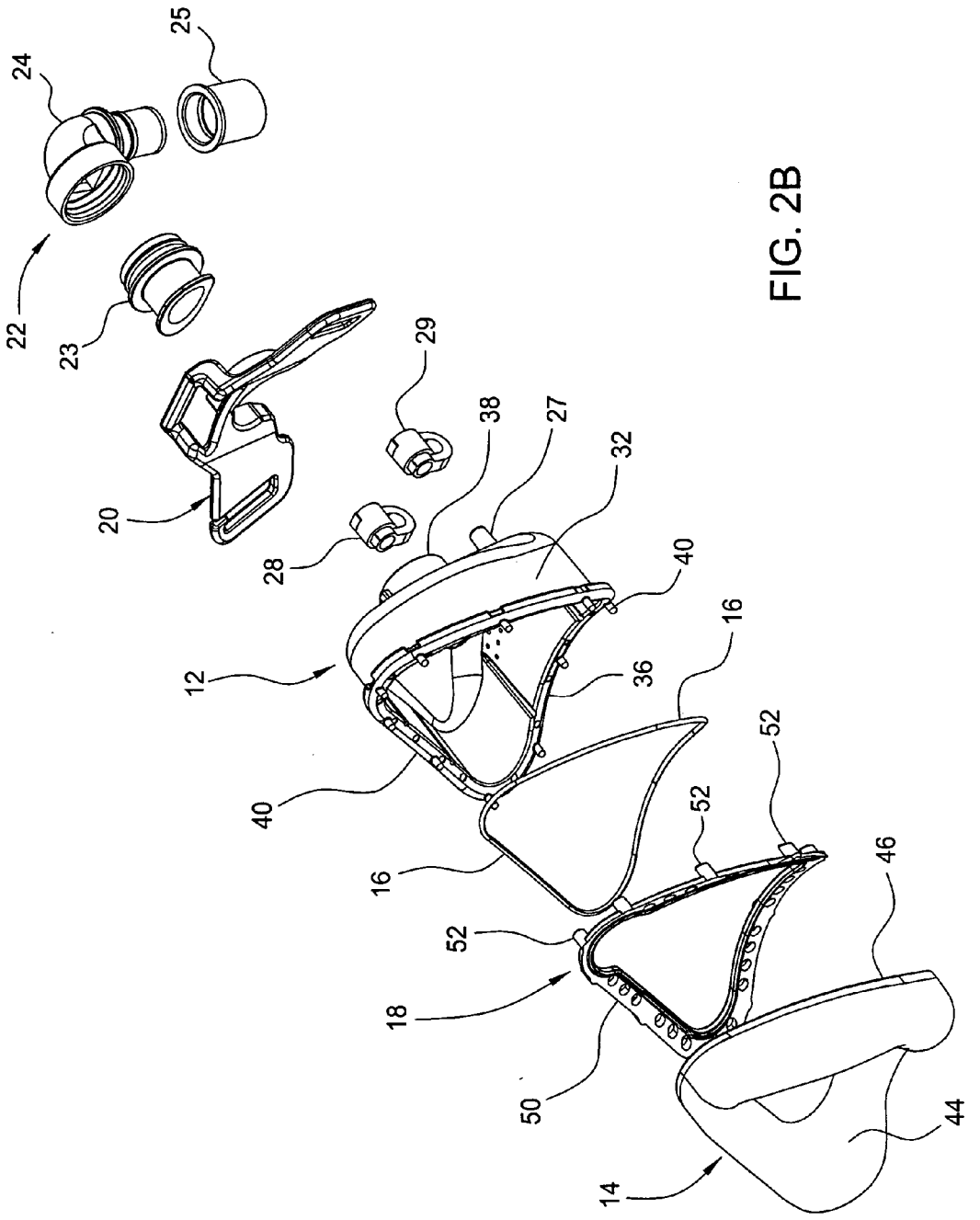

FIG. 2B

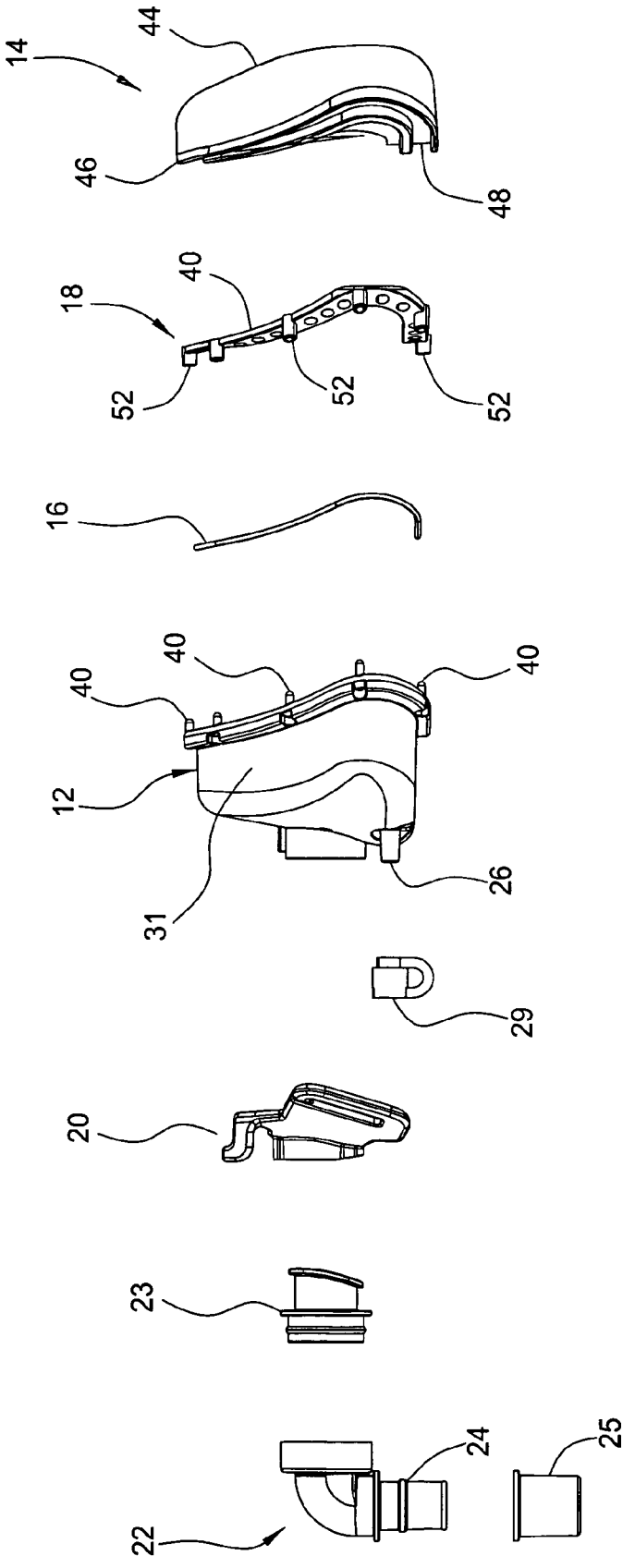

FIG. 2C

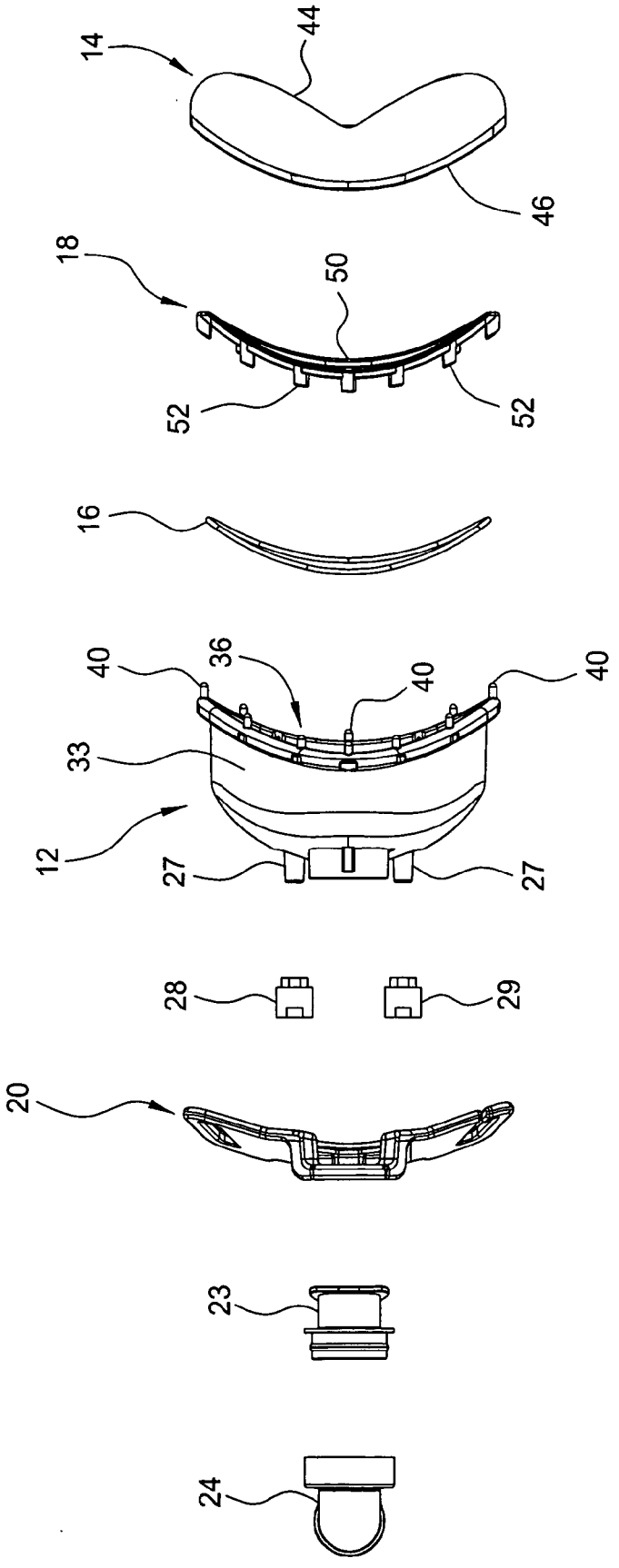

FIG. 2D

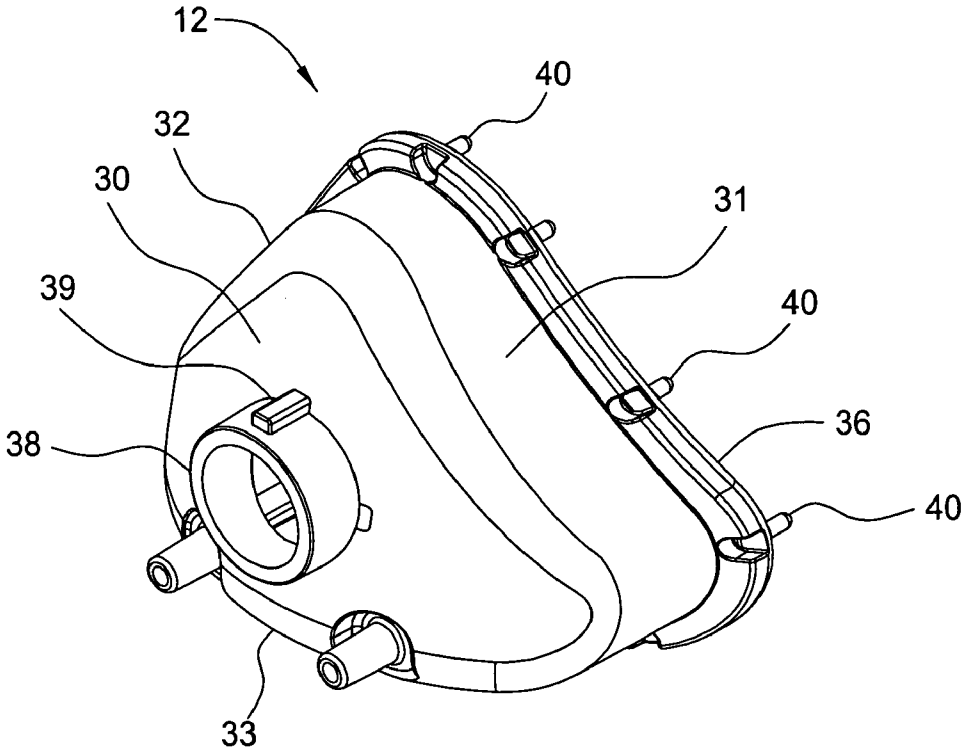

FIG. 3

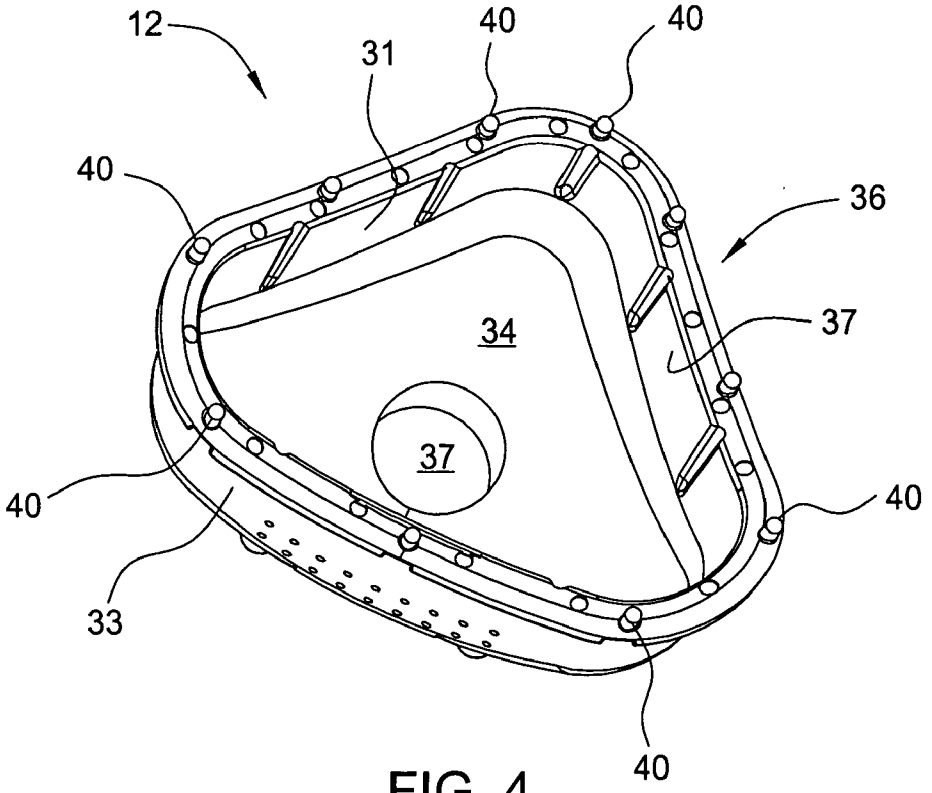

FIG. 4

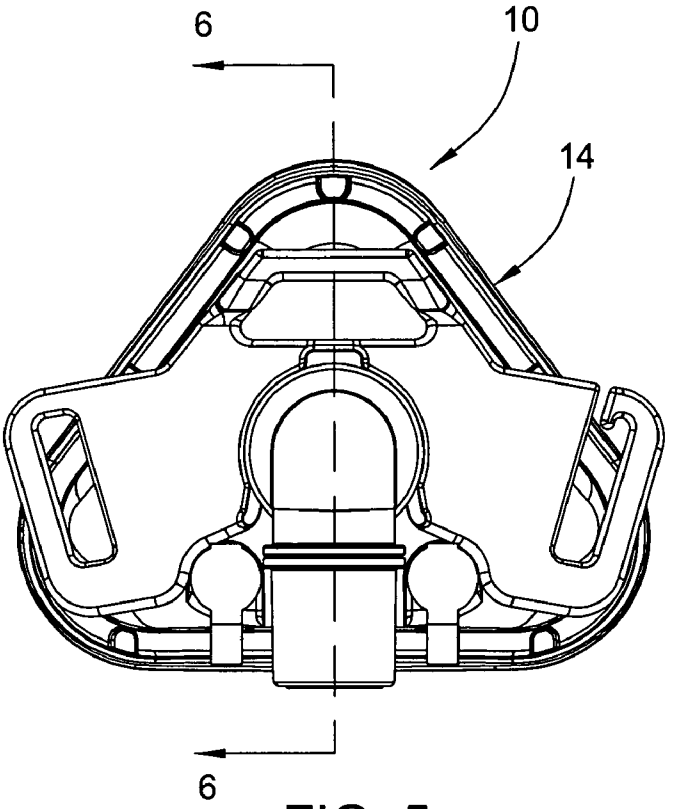

FIG. 5

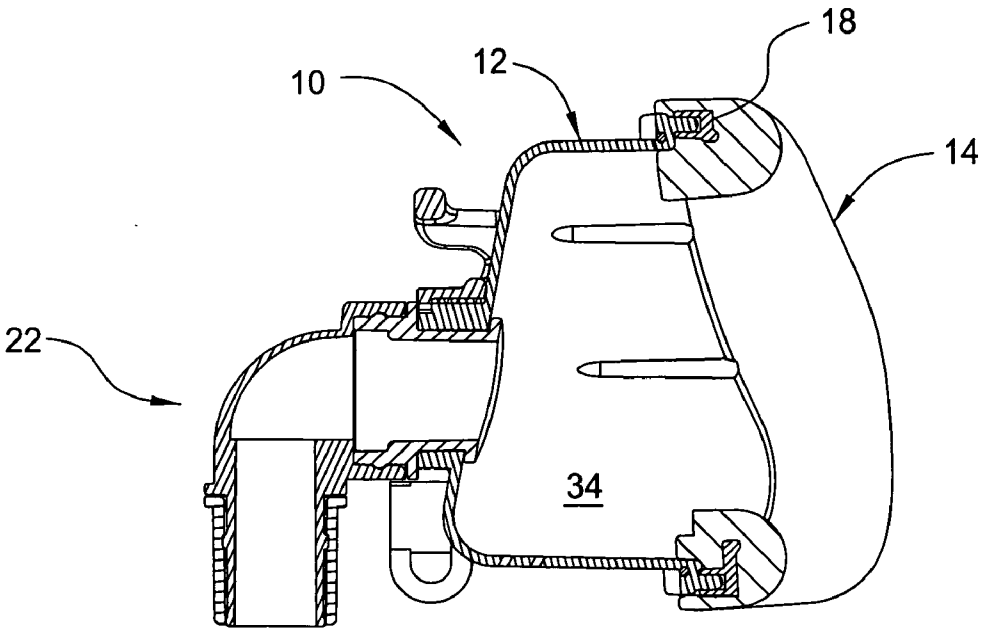

FIG. 6

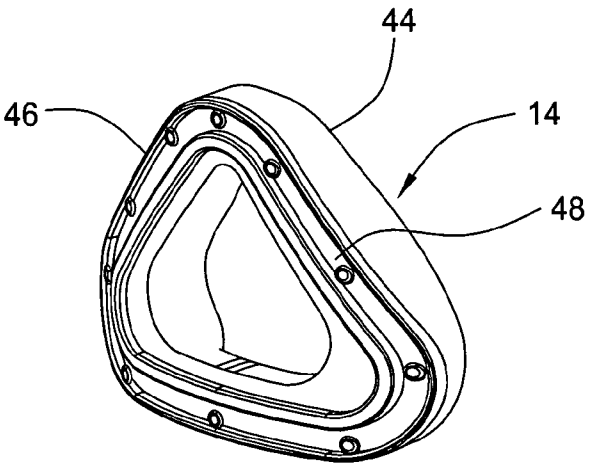

FIG. 7

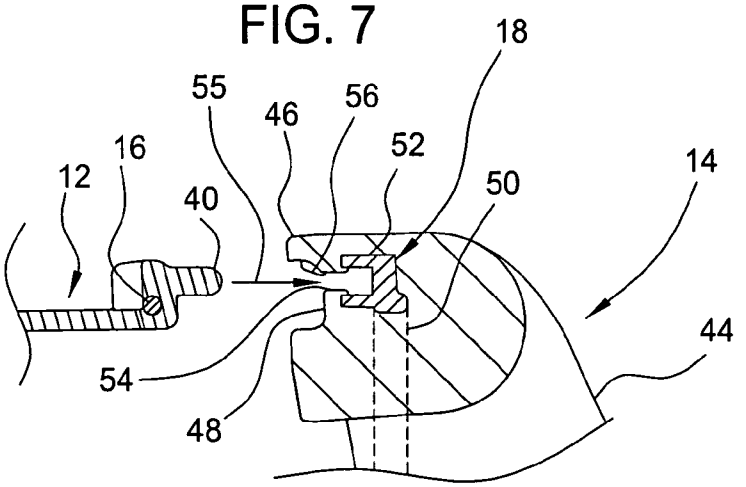

FIG. 8

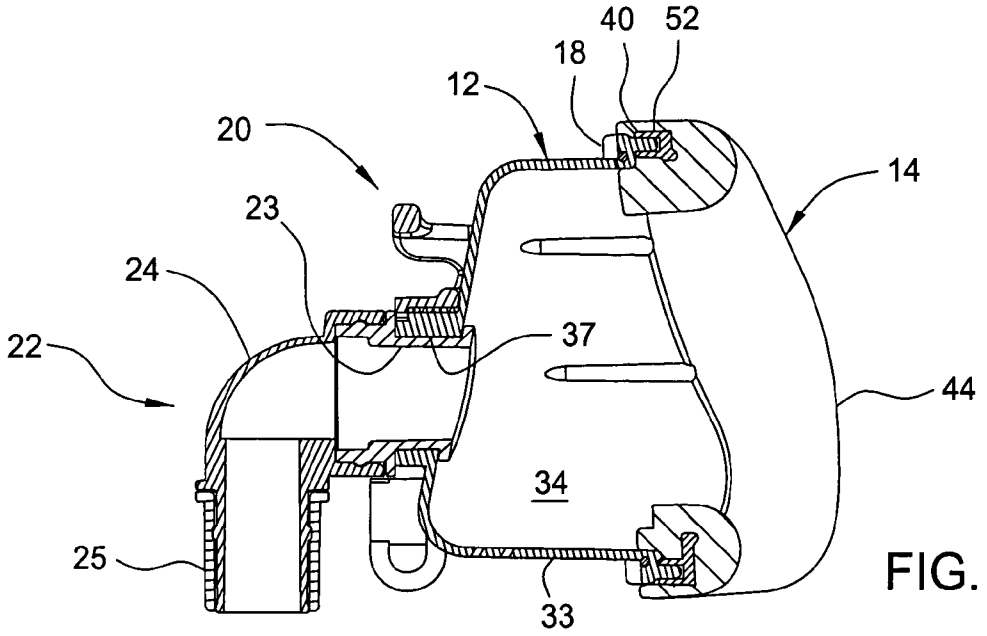

FIG. 9

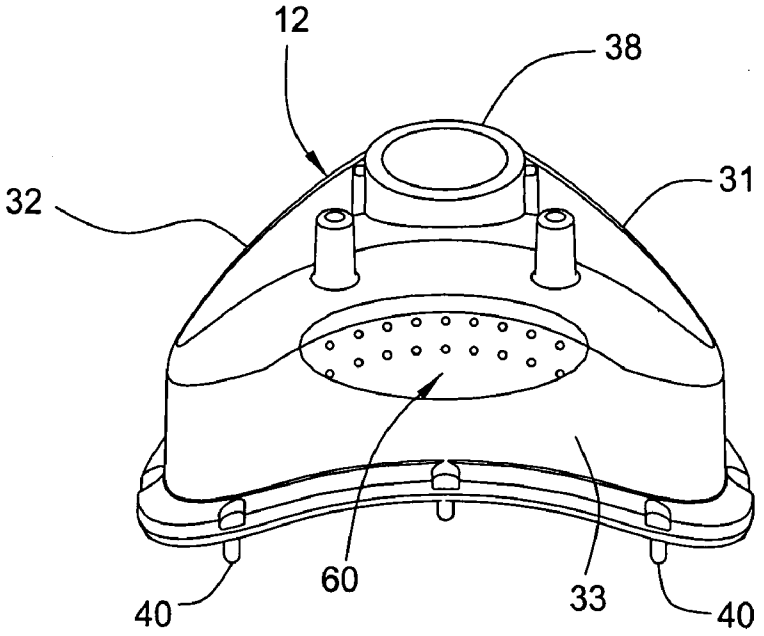

FIG. 10

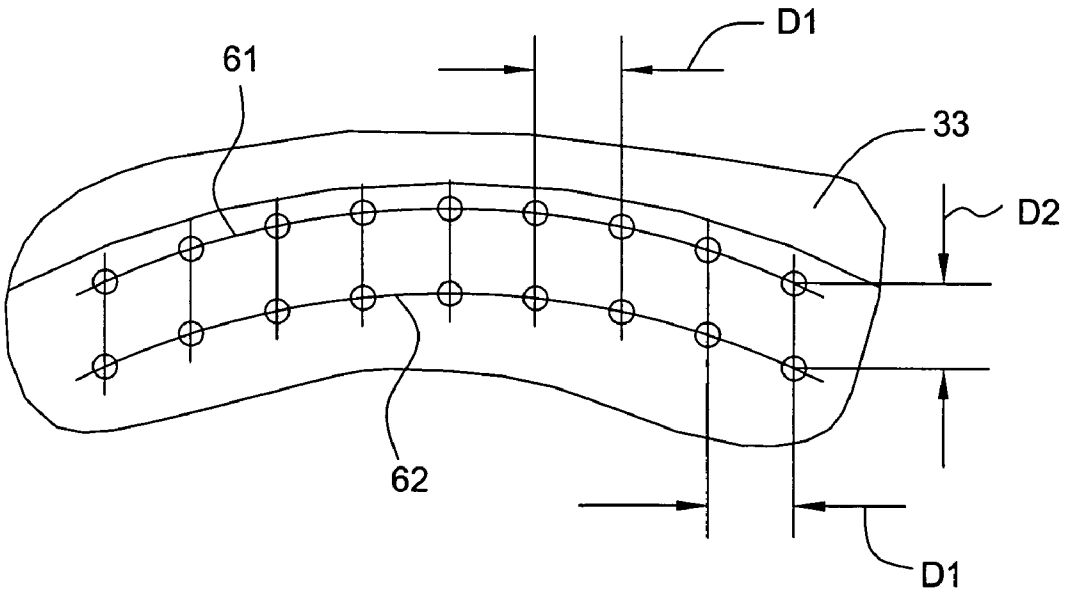

FIG. 11

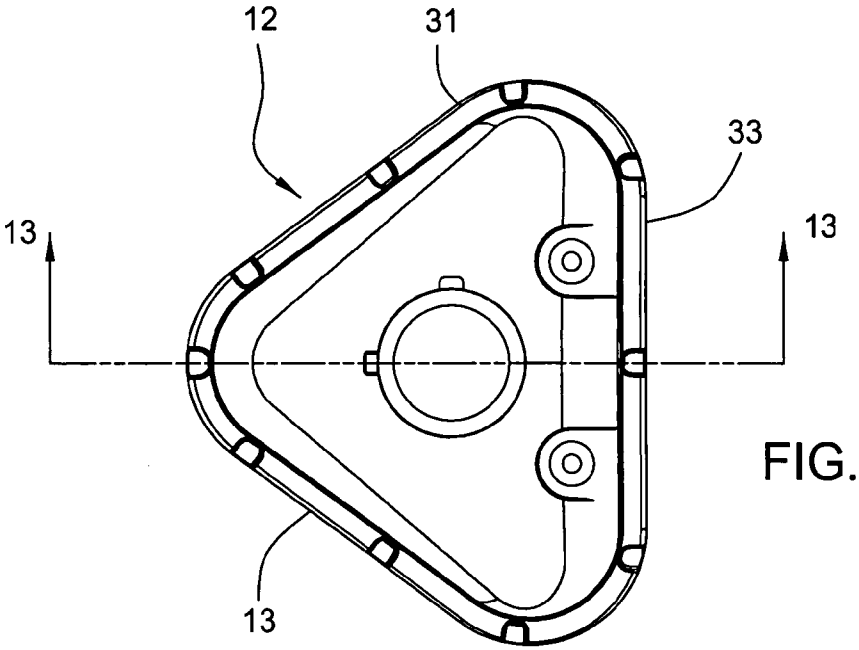

FIG. 12

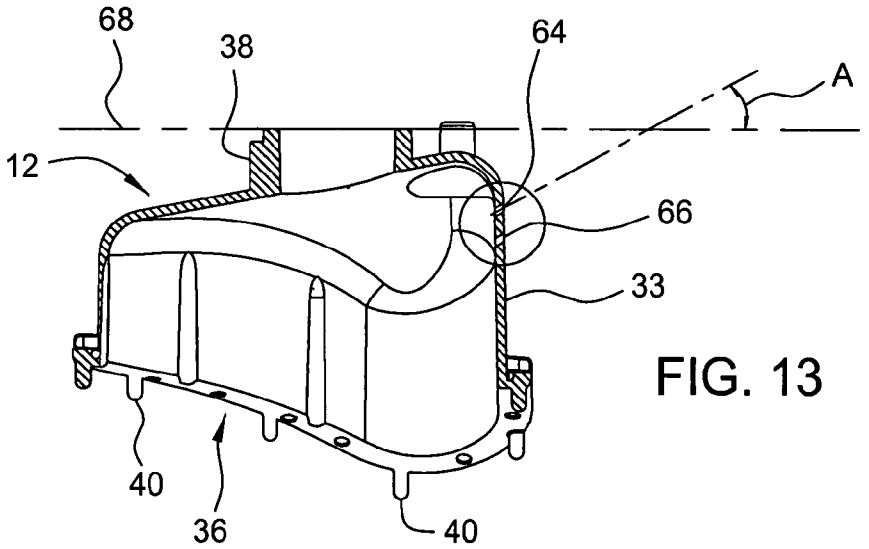

FIG. 13

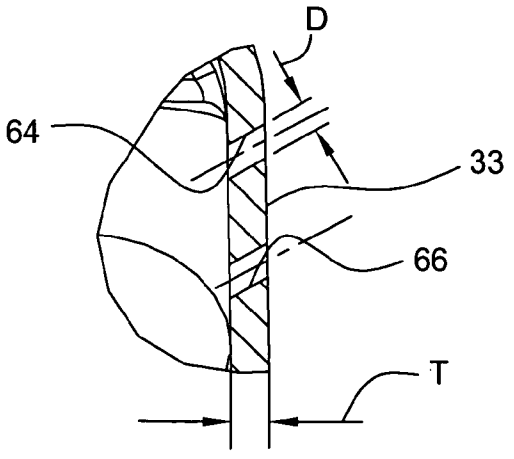

FIG. 13A

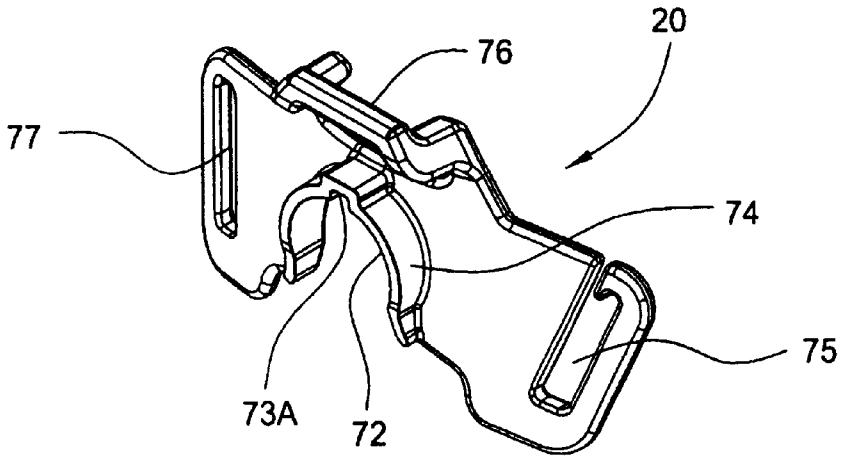

FIG. 14

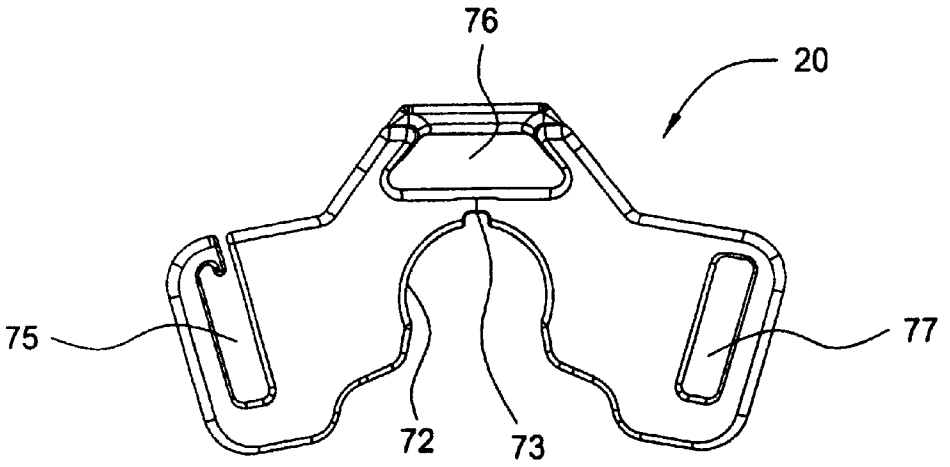

FIG. 15

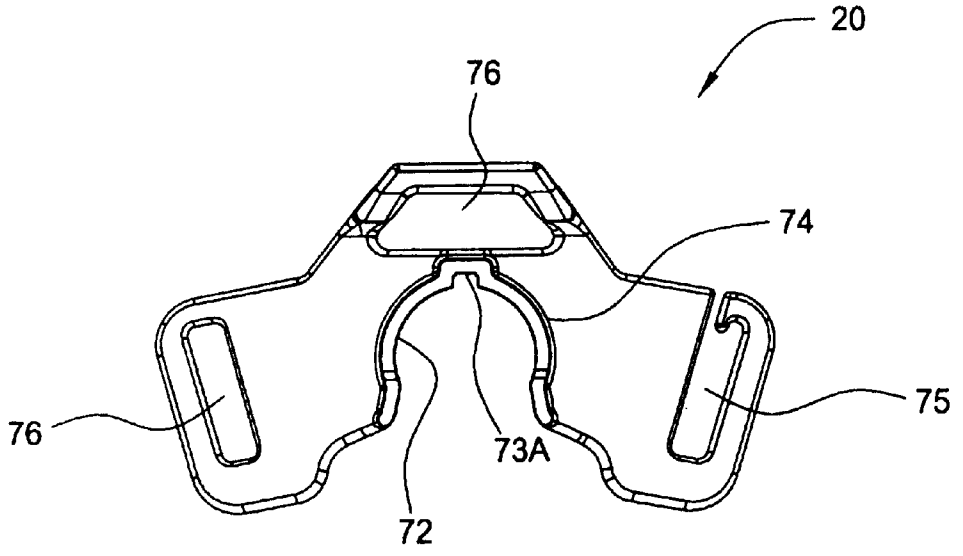

FIG. 16

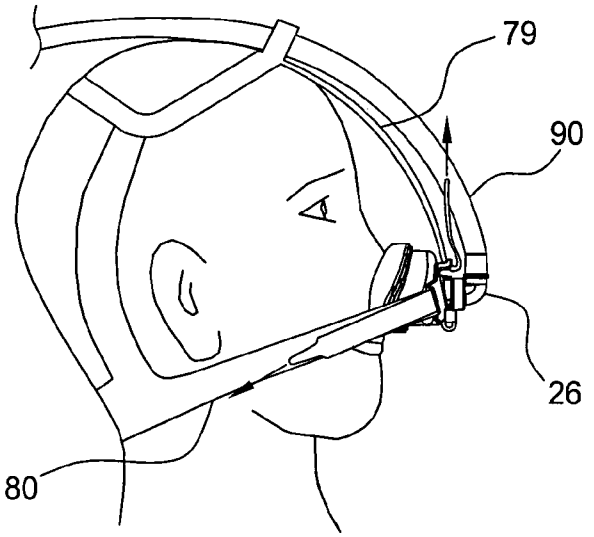

FIG. 17

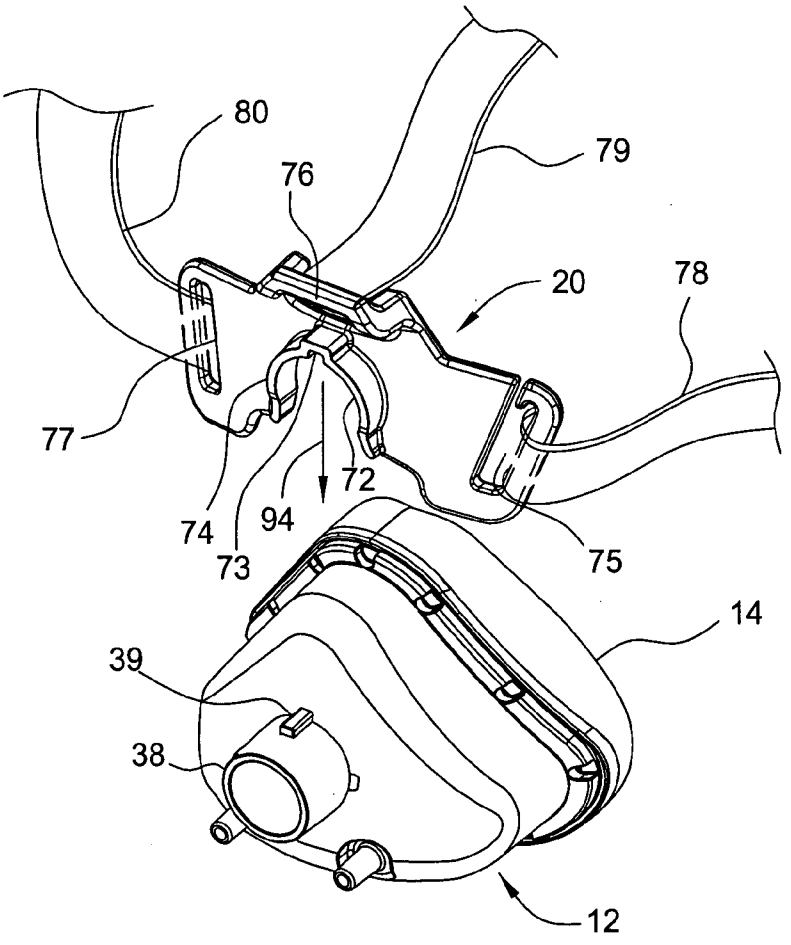

FIG. 18

MASK, MASK SHELL AND SEAL WITH IMPROVED MOUNTING, MASK SEAL, METHOD OF MASK MANUFACTURE AND MASK WITH REDUCED EXHALATION NOISE

BACKGROUND OF THE INVENTION

[0001] This invention relates generally to masks for supplying breathable gas to a person, and more particularly, relates to a nasal CPAP (Continuous Positive Airway Pressure) mask particularly useful for supplying pressurized breathing gas, such as oxygen, to a person in the treatment of obstructive sleep apnea.

[0002] The prior art is replete with masks which are of many different sizes, structures and for use in many different applications. Many different full face masks covering both the nose and the mouth are known to the art, and many different nasal masks covering only the nose are known to the art. A typical mask may include a shell of relatively hard or stiff material and a seal mounted to the shell and for conforming to the contours of a person's face, surrounding the nose and/or mouth, and for engaging such contours in an air-tight or sealing engagement. Such shell and seal may be made of numerous materials known to the art and also known to the art are numerous methods and structures for mounting the seal to the shell.

[0003] As is further known to the art, such masks typically include head gear comprising a plurality of headstraps which encircle the person's head and/or neck and which are adjustable to individualize the tension applied to the mask thereby individualizing the amount of force applied to the seal so that the seal will sealingly engage different contours of the faces of different people.

[0004] As is further known, the shells of such prior art masks are provided with venting means, such as a hole or plurality of holes, for preventing the accumulation of carbon dioxide in the shell and for providing for the exiting of the person's exhaled breath. Such prior art venting can produce a noisy or turbulent air flow or jet of air which can impinge annoyingly on the mask wearer or onto nearby persons such as a sleep partner.

[0005] Accordingly, it is believed that there is a need in the art for a mask having improved venting which reduces the noise level of the vented air and which directs the vented air away from the mask wearer thereby reducing discomfort to the mask wearer and annoyance to adjacent people such as a sleep partner.

[0006] Referring more particularly to the above-noted obstructive sleep apnea treatment, typically, in the night time treatment of obstructive sleep apnea, a nasal mask is placed over a person's nose and forced into sealing engagement with the contours of the patient's face surrounding the nose by adjusting and tightening the above-noted headstraps. The mask is connected to a ventilator which supplies breathing gas to the patient for the night time obstructive sleep apnea treatment. Typically, the adjustable headstraps are mounted fixedly to the mask which requires the headstraps to be loosened or removed to free the person from the mask for movement during the night time such as going to the bathroom. Upon return and recommencement of the obstructive sleep apnea treatment, the mask must again be placed into sealing engagement with the face and the headstraps again readjusted or retightened. This loosening and retightening of the headstraps is known to be quite annoying.

[0007] Further, the mask, particularly the seal, must be cleaned and since, as noted, the mask is typically mounted fixedly to the headstraps, this makes cleaning more difficult than is desirable. Further, the cleaning of a mask or seal mounted fixedly to the headstraps can cause the headstraps to become wet and possibly suffer shrinkage or at least some structural or functional impairment.

[0008] Accordingly, it is believed there is a need in the art for a new and improved mask mounted removably to the adjustable headstraps which permits the mask to be removed from the headstraps during the night time, freeing the person from the mask and ventilator and permitting the person to move about while the headstraps remain on the person's head, tightened and still individually adjusted to the patient's head. It is also believed there is a need in the art for such removable mask and headstrap combination which permits the mask and seal to be cleaned separately and apart from the headstraps.

[0009] Referring again to the prior art mask seals, some prior art mask seals are comprised of thermoset silicone, closed-cell foams, molded silicone and some include a soft material interposed between two thin plastic films and which are mounted to the mask shell by different mounting techniques. These prior art seal structures are generally known to be costly to manufacture.

[0010] Accordingly, it is further believed that there is a need in the art for a new and improved mask seal which may be manufactured cost effectively and for a new and improved structure for mounting the seal to the shell.

SUMMARY OF THE INVENTION

[0011] A mask including a shell provided with shell mounting members and a seal provided with seal mounting members for engaging the shell mounting members to mount the seal to the shell, method of manufacturing a mask including such mask shell and seal, a mask including a plurality of headstraps and a headstrap retention bracket mounted to the headstrap for mounting the headstraps removably to a mask, a mask seal of generally hollow triangular soft resilient material including a peripheral portion and a generally hollow triangular seal mounting member embedded in the seal peripheral portion and for mounting the seal to a mask shell, a mask shell having a deformable malleable member in its peripheral portion which may be deformed to customize the mask seal to a person's face and a mask with a plurality of angular vent holes for reducing the noise of a mask wearer's exhaled breath and for directing the exhaled breath away substantially parallel to the mask wearer's body.

DESCRIPTION OF THE DRAWINGS

[0012] **FIG. 1** is a perspective view of a mask embodying the present invention;

[0013] **FIG. 2A** is an exploded view taken generally from the left to the right showing the elements comprising the mask shell and seal of the present invention;

[0014] **FIG. 2B** is an exploded view substantially the reverse of **FIG. 2A**;

[0015] **FIG. 2C** is a side view of the mask elements shown in **FIG. 2A**;

[0016] **FIG. 2D** is a top view of the mask element shown in **FIG. 2A**;

[0017] **FIG. 3** is a front perspective view of the mask shell of the present invention;

[0018] **FIG. 4** is generally the reverse of **FIG. 3** showing the interior of the mask shell;

[0019] **FIG. 5** is a front elevational view of the mask of the present invention;

[0020] **FIG. 6** is a cross-sectional view taken generally along the line **6-6** in **FIG. 5** and in the direction of the arrows;

[0021] **FIG. 7** is a perspective view of the mask seal of the present invention;

[0022] **FIG. 8** is a diagrammatical illustration of the mounting of the mask seal to the mask shell of the present invention;

[0023] **FIG. 9** is the same as **FIG. 6** but showing in detail the mounting of the mask seal to the mask shell of the present invention and further illustrating in detail the mounting of the dual swivel members to the mask shell of the present invention;

[0024] **FIG. 10** is a perspective view taken generally from the bottom of the mask shell of the present invention and illustrating the vent holes of the present invention;

[0025] **FIG. 11** is an enlarged view of the encircled portion of **FIG. 10**;

[0026] **FIG. 12** is a front view of the mask shell of the present invention;

[0027] **FIG. 13** is a cross-sectional view taken generally along the line **13-13** in **FIG. 12** and in the direction of the arrows;

[0028] **FIG. 13A** is an enlarged view of the encircled portion of **FIG. 13**;

[0029] **FIG. 14** is a separate perspective view of the headstrap retention bracket of the present invention;

[0030] **FIG. 15** is a rear elevational view of the headstrap retention bracket of the present invention;

[0031] **FIG. 16** is a front elevational view of the headstrap retention bracket of the present invention;

[0032] **FIG. 17** is an illustration of the mask of the present invention attached by headstraps to the portions of a person's face surrounding the nose; and

[0033] **FIG. 18** is an illustration of the removable mounting of the mask shell and seal of the present invention to a headstrap retention bracket of the present invention and thereby to the headstraps of the mask of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0034] An embodiment of the mask of the present invention is shown in the drawings and indicated by general numerical designation **10**. It will be understood that the mask **10** is dimensioned to be a nasal mask particularly useful as a nasal CPAP mask, but it will be still further understood that the mask of the present invention also may be embodied as other masks such as, for example and not by way of limitation, a full face mask.

[0035] The mask **10**, referring particularly to **FIGS. 1 and 2A-2D**, includes a mask shell indicated by general numerical designation **12**, a mask seal indicated by general numerical designation **14**, a hollow generally triangular malleable member **16**, a hollow generally triangular seal mounting member indicated by general numerical designation **18**, a head strap retention bracket indicated by general numerical designation **20**, and a dual swivel indicated by general numerical designation **22** and of the type known to the art for providing swiveling in two directions as indicated by the double headed arrows **22A** and **22B** in **FIG. 2A**. The dual swivel **22** includes hollow conduit swivel members **23**, **24** and **25** for being connected by a suitable gas supply hose to a suitable gas supply such as a ventilator or other positive airway pressure device (not shown) for supplying pressurized breathing gas to a wearer of the mask **10** during obstructive sleep apnea treatment. The mask shell **12**, **FIG. 2A**, may be provided with two hollow cylindrical port members **26** and **27** in fluid communication with the interior of the shell and the mask may further include two removable port cap members **28** and **29** for opening and closing the port members **26** and **27**. The port member **26** may be used, for example, to measure the pressure inside the mask and the port member **27** may be used to provide supplemental breathing gas, such as supplemental oxygen, to the mask and thereby to a wearer of the mask.

[0036] The mask shell **12**, referring particularly to **FIGS. 3 and 4**, includes a top or an apex portion **30** and triangular walls **31**, **32** and **33**. The apex portion **30** and the triangular walls **31**, **32** and **33** cooperatively provide the shell **12** with a generally triangular hollow interior **34** and the triangular walls **31**, **32** and **33** terminate in, or provide the shell with, an outer shell periphery or peripheral portion indicated by general numerical designation **36**. As may be best seen in **FIG. 3**, the shell apex portion **30** is provided with a circular opening **37** circumscribed by, as may be best seen in **FIG. 3**, an outwardly extending hollow cylindrical wall **38** provided with an outwardly extending rectangular radial ridge **39**. The shell outer peripheral portion **36** is provided, as shown in **FIGS. 3 and 4**, with a plurality of outwardly extending solid generally cylindrical pins or connecting pins **40**.

[0037] The mask shell **12** may be made from a suitable plastic, such as for example polyurethane, and made by suitable injection molding. It will be further understood that the hollow generally triangular malleable member **16** may be injection molded into the shell outer peripheral portion **36** by suitable injection molding techniques known to the art. The malleable member **16** in the preferred embodiment was a 0.304 stainless steel wire fully annealed at finish and having a diameter of about 0.052 inch.

[0038] The seal **14**, **FIGS. 2A-2D**, and **7-9**, may be made of a suitable soft resilient material sufficiently soft to conform to the contours of a person's face surrounding the mask wearer's nose and sufficiently resilient to return to its original, or at least substantially its original, shape upon removal from the person's face. In the preferred embodi-

ment, the seal **12** was made of a body of material comprising styrene-ethylene butylene-styrene copolymer modified with a mineral oil. Such material may also contain antioxidants and Vitamin E. Such material is available from California Medical Innovations, 873 E. Arrow Highway, Pamona, California 91767 and available under the name Dermasol. California Medical Innovations states that such material is a thermoplastic elastomer which has a durometer of 15-20 on the Shore 00 scale. It has been found that when such material is injection molded it has a durometer of about 63.6 on the Shore 000 scale. As shown in **FIGS. 2A-2D**, the seal **14** includes peripheral portions **44** and **46** with the peripheral portion **44** being provided with a contour to enhance sealing engagement with portions or contours of a person's face surrounding the nose and the peripheral portion **46**, note particularly **FIGS. 2A and 2C**, and **FIG. 7**, is provided with a generally triangular indentation **48** complementary in shape to and for receiving the generally triangular shell peripheral portion **36** (**FIGS. 3 and 4**). The seal mounting member **18**, note particularly **FIGS. 2A and 2B**, includes a hollow generally triangular frame **50** provided with a plurality of outwardly extending bosses **52**. The seal mounting member **18** is molded into the seal periphery or peripheral portion **46** using injection molding techniques known to the art and is thereby embedded in the seal peripheral portion **46** as may be best understood from **FIGS. 8 and 9**. As will be further understood from **FIG. 8**, the mask seal **14** is mounted to the mask shell **12** by inserting, or forcing, the mask shell connecting pins **40** into the mask seal bosses **52** as indicated by the arrow **55** in **FIG. 8**. It will be understood that the shell connecting pins **40** and the seal bosses **52** are suitably dimensioned for an interference fit so as to mount the seal **14** fixedly to the shell **12**. Such mounting is illustrated in detail in **FIG. 9**. Referring again to **FIG. 8**, it will be understood that the representative embedded seal boss **52** is slightly recessed behind the seal indentation **48** whereby the seal peripheral portions **56** and **57** will compress upon the pins **40** being inserted into the bosses **52** and act or function as a gasket to assure an air tight seal between the seal **14** and shell **12**.

[**0039**] As will be understood from **FIG. 9**, the dual swivel member **23** is mounted into the circular opening **37** (**FIG. 4**) formed in the apex shell portion **30** and the swivel members **24** and **25** are thereafter suitably mounted to each other, in the manner known to the art, to provide the above-described dual swiveling indicated by the double headed arrows **22**A and **22**B in **FIG. 2A**.

[**0040**] The mask and mask vent holes of the present invention are illustrated in **FIGS. 10-13**. The vent holes are exit vent holes and are for venting the exhaled breath of a wearer of the mask **10**. As shown in **FIGS. 10 and 11**, the vent holes comprise a plurality of vent holes which are disposed in a curved array of vent holes including, in the preferred embodiment, two curved rows of vent holes; the plurality or curved array of vent holes are indicated by general numerical designation **60** in **FIGS. 10 and 11**, and the two rows of curved vent holes are indicated by numerical designations **61** and **62** in **FIG. 11**. It will be understood from **FIG. 11** that the distance D1 between the vent holes in each row is equal to, or at least substantially equal to, the distance D2 between opposed vent holes or the vent holes in each curved row that are opposed to each other. The vent holes have a diameter, and it will be further understood from **FIG. 11** that the distances D1 and D2 are equal to at least three times the diameter of the vent holes. In the preferred embodiment, the vent holes had a diameter of 0.040 inch and the distances D1 and D2 were 0.140 inch. It has been found that such vent hole diameter and vent hole spacings create a pattern of discrete laminar flow jets such that the flow exiting one vent hole does not generate turbulence in the flow from adjacent vent holes. This reduces the noise level generally associated with a person's exhaled breath exiting mask vent holes and such noise reduction reduces the annoyance to the wearer of the mask, and to a sleep partner, which generally arises from a patient's exhaled breath exiting mask vent holes known to the prior art.

[**0041**] The angular disposition of the cylindrical vent holes of the present invention is illustrated in **FIGS. 12-13A**. Representative vent holes **64** and **66** are shown in **FIGS. 13 and 13**A. As will be understood from **FIG. 13**, the outwardly extending hollow cylindrical wall **38** of the mask shell **12** terminates in a plane **68**, and as will be further understood from **FIG. 13** the vent holes, note representative vent hole **64**, are disposed at an acute exit angle A with respect to the plane **68**; in the preferred embodiment the angle A was 30°. As will be further understood from **FIG. 13A**, the wall **33** in which the vent holes are formed has a thickness T and the vent holes have a diameter D which is less than the thickness T. In the preferred embodiment, the mask wall **33** had a thickness of 0.050 inch and the vent holes had a diameter D of 0.040 inch. It has been found that such angular disposition of the vent holes in the mask shell wall **33** causes the patient's exhaled breath to exit in a flow stream which is substantially parallel to the body of the wearer of the mask **10**. This permits the person's exhaled breath to escape the mask without causing discomfort to the wearer of the mask or to a sleep partner onto which the escaped exhaled breath may be flowing or escaping.

[**0042**] The removable mounting of the mask seal **14** and shell **12** of the mask **10** of the present invention to the headstraps for fastening the mask to a wearer's face is provided, in part, by the headstrap retention bracket **20** shown in separate detail in **FIGS. 14-16**. The headstrap retention bracket **20** is provided with a generally semi-circular indentation **72**, **FIG. 15**, which is provided generally centrally with an outwardly extending rectangular indentation **73**. The indentations **72** and **73**, **FIGS. 14 and 16**, are circumscribed by an outwardly extending generally semi-circular wall or member **74** including a radially outwardly extending portion providing a radially inwardly extending recess **73**A. The wall **74** is complementary in shape to and for receiving portions of the shell hollow cylindrical wall **38** in a wedged or friction engagement with the radial ridge being received in the radial recess **73**A. The headstrap retention member **20**, **FIGS. 14-16**, is provided with three openings **75**, **76** and **77** for respectively receiving headstraps **78**, **79** and **80** as shown in **FIGS. 17 and 18**.

[**0043**] The mask **10** of the present invention may include such headstraps and is illustrated as being attached to a person's face in **FIG. 17** as a nasal CPAP mask for the treatment of obstructive sleep apnea treatment. A corrugated gas supply hose **90** is attached to the dual swivel hollow conduit member **26** (**FIG. 1**) and is inserted through a headstrap member **92**, **FIG. 17**, and is further connected to a ventilator (not shown), in the manner known to the art, for supplying pressurized breathing gas to a person for the above-noted night time sleep apnea treatment.

[0044] The removable mounting of the mask shell **12** and seal **14** to the headstraps **78-80** is illustrated diagrammatically in **FIG. 18**. The headstraps are inserted through the loops or holes formed in the headstrap retention bracket **20**, as illustrated diagrammatically in **FIG. 18**, and the headstrap retention bracket **20**, as indicated by the downwardly extending arrow **94** in **FIG. 18** is forced downwardly, with manual force applied by the person to wear the mask, to force the generally semi-circular wall **74** of the headstrap retention bracket **20** into wedged or interference friction engagement with the portions of hollow cylindrical wall **38** provided on the mask shell **12** and with the mask shell outwardly extending rectangular radial ridge **39** being received within the inwardly extending rectangular recess **73** formed in the wall **74** of the head retention bracket **20**. The receipt of the ridge **39** in the recess **73**A orients the head retention bracket **20** to the shell **12** and seal **14** and thereby orients the headstraps to the mask shell and seal. Also, this mounts the mask shell **12** and seal **14** removably to the headstrap retention bracket **20**, and thereby removably to the headstraps **78-80**, which permits the mask shell **12** and seal to be removed from the headstrap retention bracket, and thereby from the headstraps, with the use of manual force from the mask wearer.

[0045] Upon the mask shell **12** and seal **14** being mounted to the headstrap retention bracket **20** and the headstraps **78-80**, the headstraps may be placed over and around portions of the person's head as shown in **FIG. 17** and manual force from the mask wearer is used to apply tension to the adjustable headstrap members, as indicated by the arrows in **FIG. 17**, to adjust the tension supplied to the mask and to adjust the amount of force with which the mask seal **14** is forced into air tight sealing engagement with the portions of the mask wearer's face surrounding the nose. The malleable member **16**, embedded in the outer peripheral portion of the mask shell **12**, particularly **FIGS. 8 and 9**, may be deformed to further individualize or customize the fitting of the mask seal **14** to the portions or contours of the mask wearer's face surrounding the nose.

[0046] Should, for example, the mask wearer undergoing the noted obstructive sleep apnea treatment need to get up and move about, such as to go to the bathroom, the previously adjusted headstraps need not be removed from the person's face but instead, the previously adjusted headstraps may remain adjusted and fastened to the person's head, and the mask shell **12** and seal **14** may be removed from the headstrap retention bracket while the headstraps remain attached to the person's head. Such removal is accomplished by the use of manual force from the mask wearer with the mask shell **12** and seal **14** being pulled downwardly, opposite the direction of the arrow **94** in **FIG. 18**, to disengage or unwedge the mask shell cylindrical wall **38** from the semi-cylindrical wall **74** of the headstrap retention bracket **20**. The gas supply hose **90**, **FIG. 19**, is then removed from the headstrap member **92** and the person is now free from the mask shell **12**, seal **14** and the gas supply hose **90**. The person may move about freely while the headstraps remain previously individualized and attached to the person's head. Upon the person returning to resume the sleep apnea treatment, the mask shell **12** and seal **14** are again mounted to the headstrap retention bracket **20** as described above and illustrated in **FIG. 18**.

[0047] It will be understood by those skilled in the art that many variations and modifications may be made in the present invention without departing from the spirit and the scope thereof.

What is claimed is:

1. Mask, comprising:

a generally triangular shell including an apex portion and triangular walls providing an interior and including a shell outer peripheral portion, said apex portion provided with a circular opening circumscribed by an outwardly extending hollow cylindrical member terminating in a plane and for supplying gas to said mask, said shell outer peripheral portion provided with first mounting means;

a seal including a seal outer peripheral portion provided with second mounting means for engaging said first mounting means to mount said seal to said shell;

one of said walls for being disposed beneath a person's nose and wherein said one wall is provided with a plurality of vent holes extending upwardly from said interior and angularly outwardly through said one wall;

a malleable member mounted in said shell outer peripheral portion and for being deformed to deform said shell and thereby said seal to fit said seal to portions of a person's face;

a plurality of adjustable headstraps for surrounding and being attached to a person's head; and

a headstrap retention bracket mounted to said plurality of headstraps and provided with a generally inwardly extending indentation generally complementary in shape to said cylindrical member and for permitting said headstrap retention bracket to wedgedly engage said cylindrical member to mount said shell and said seal removably to said plurality of headstraps.

2. The mask according to claim 1 wherein said first mounting means comprise a plurality of pins extending outwardly from said shell outer peripheral portion and wherein said second mounting means comprise a plurality of bosses extending outwardly to said seal outer peripheral portion and for wedgedly receiving said pins.

3. The mask according to claim 1 wherein said seal comprises a generally hollow triangular body comprising a styrene-ethylene butylene-styrene copolymer modified with a mineral oil.

4. The mask according to claim 1 wherein said seal comprises a generally hollow triangular body comprising a styrene-ethylene butylene-styrene copolymer modified with a mineral oil having a durometer of about 63.6 on the Shore 000 scale.

5. The mask according to claim 1 wherein said seal comprises a body of moldable material and wherein said second mounting means is molded into said moldable material.

6. The mask according to claim 5 wherein said moldable material comprises a styrene-ethylene butylene-styrene copolymer modified with a mineral oil.

7. The mask according to claim 1 wherein said shell comprises a body of first moldable material, wherein said first mounting means comprise a plurality of pins extending outwardly from said shell outer peripheral portion, and wherein said seal comprises a body of second moldable

material and wherein said second mounting means comprise a plurality of outwardly extending bosses for wedgedly receiving said pins.

8. The mask according to claim 7 wherein said second mounting means comprise a hollow generally triangular frame molded into said seal outer peripheral portion and provided with said plurality of bosses.

9. The mask according to claim 1 wherein said mask comprises a body of moldable material and wherein said malleable member is molded into said shell outer peripheral portion.

10. The mask according to claim 1 wherein said plurality of vent holes are disposed at an exit angle of approximately 30° with respect to said plane.

11. The mask according to claim 1 wherein said one wall has a thickness and wherein said vent holes are cylindrical and have a diameter less than said thickness of said one wall.

12. The mask according to claim 1 wherein said hollow cylindrical member is provided with an outwardly extending radial ridge, wherein said indentation is a generally semi-circular indentation provided with a generally central inwardly extending radial indentation, wherein said indentations are circumscribed by an outwardly extending generally semi-cylindrical member including an inwardly extending portion providing a radial recess and wherein said generally semi-cylindrical member is for wedgedly engaging said cylindrical member with said radial recess receiving said radial ridge to orient said retention bracket with respect to said shell and to mount said shell and said seal removably to said plurality of headstraps.

13. The mask according to claim 1 wherein said seal outer peripheral portion is provided with a seal indentation complementary to and for receiving said shell outer peripheral portion to facilitate mounting of said seal to said shell.

14. The method of manufacturing a mask, comprising the steps of:

molding a seal having first mounting means molded therein; and

providing a shell having second mounting means, and mounting said seal to said shell by engaging said first mounting means with said second mounting means.

15. The method of manufacturing a mask, comprising the steps of:

molding a seal including a seal outer peripheral portion having first mounting means molded therein;

molding a shell including a shell outer peripheral portion having a malleable member molded therein and provided with second mounting means; and

mounting said seal to said shell by engaging said first mounting means with said second mounting means.

16. The method of manufacturing a mask, comprising the steps of:

providing a body comprising a styrene-ethylene butylene-styrene copolymer modified with a mineral oil;

providing a generally hollow triangular seal mounting member provided with a plurality of outwardly extending bosses;

injection molding said body to have a seal outer peripheral portion and molding said seal mounting member into said seal outer peripheral portion with said plurality of bosses extending outwardly to said seal outer peripheral portion;

providing a hollow generally triangular malleable member;

molding a generally hollow triangular mask shell having a shell outer peripheral portion provided with a plurality of outwardly extending pins and molding said malleable member into said shell outer peripheral portion; and

wedgedly inserting said pins into said plurality of bosses to mount said seal and mask together.

17. The method according to claim 16 including the further step of molding said mask shell to include triangular walls providing an interior and to include an apex portion provided with a circular opening circumscribed by an outwardly extending wall terminating in a plane; and

forming a plurality of vent holes extending upwardly from said interior and angularly outwardly through one of said walls at an acute angle with respect to said plane.

18. The method according to claim 17 wherein said vent holes are formed at an exit angle of about 30° with respect to said plane.

19. The method according to claim 17 wherein said mask shell molding step includes the further step of forming said one wall to have a thickness and wherein said vent holes forming step includes the step of forming said vent holes to be cylindrical and to have a diameter less than said one wall thickness.

20. The method according to claim 16 wherein said step of providing said body comprises the steps of providing a body comprising a styrene-ethylene butylene-styrene copolymer modified with a mineral oil and having a durometer of about 15-20 on the Shore 00 scale and injection molding said body to have a durometer of about 63.6 on the Shore 000 scale.

21. A mask, comprising:

a shell and a seal mounted to said shell, said shell provided with an outwardly extending hollow cylinder for supplying gas and in fluid communication with said shell;

a plurality of headstraps; and

a headstrap retention bracket mounted to said headstraps and provided with an inwardly extending indentation permitting said bracket to wedgedly engage said cylinder and mount said shell and said seal removably to said plurality of headstraps.

22. The mask according to claim 21 wherein said cylindrical member is provided with a radially outwardly extending ridge, wherein said indentation is provided with a generally central radial indentation, wherein said indentations are circumscribed by an outwardly extending generally semi-cylindrical member including a portion providing a radially outwardly extending recess and wherein said generally semi-cylindrical member is for wedgedly engaging portions of said cylindrical member with said radial recess for receiving said radial ridge to orient said headstraps with respect to said shell and said seal and to mount said shell and said seal removably to said plurality of headstraps.

23. A mask, comprising:

a shell provided with first mounting means;

a seal; and

second mounting means embedded in said seal and for engaging said first mounting means to mount said seal to said shell.

24. The mask according to claim 23 wherein said shell includes a shell peripheral portion provided with a plurality of outwardly extending pins and wherein said seal includes a seal peripheral portion and wherein said second mounting means comprise a generally triangular frame embedded in said seal peripheral portion and provided with a plurality of outwardly extending bosses for wedgedly receiving said pins to mount said seal to said shell.

25. The mask according to claim 23 wherein said seal comprises a generally hollow triangular body comprising a styrene-ethylene butylene-styrene copolymer modified with a mineral oil.

26. The mask according to claim 25 wherein said copolymer modified with a mineral oil has a durometer of about 63.6 on the Shore 000 scale.

27. The mask according to claim 23 wherein said seal comprises a body of moldable material and wherein said second mounting means is molded into said moldable material.

28. The mask according to claim 27 wherein said moldable material comprises a styrene-ethylene butylene-styrene copolymer modified with a mineral oil.

29. The mask according to claim 23 wherein said shell includes an outwardly extending hollow cylinder terminating in a plane and includes a wall provided with a plurality of vent holes extending upwardly through said wall and disposed angularly with respect to said plane.

30. The mask according to claim 29 wherein said plurality of vent holes is disposed at an exit angle of about 30° with respect to said plane.

31. The mask according to claim 23 wherein said shell comprises an apex provided with a circular opening circumscribed by an outwardly extending cylindrical wall terminating in a plane, wherein said shell further comprises generally triangular walls providing an interior, wherein one of said walls is for being disposed beneath a person's nose and wherein said one wall is provided with a plurality of vent holes extending upwardly from said interior and angularly outwardly through said one wall and disposed at an acute angle with respect to said plane.

32. The mask according to claim 31 wherein said plurality of vent holes are disposed at an acute exit angle of about 30° with respect to said plane.

33. The mask according to claim 31 wherein said one wall has a thickness and wherein said vent holes are cylindrical and have a diameter less than said thickness of said one wall.

34. A mask seal comprising a generally hollow triangular body of styrene-ethylene butylene-styrene copolymer modified with a mineral oil.

35. The mask seal according to claim 34 wherein said copolymer is further modified with anti-oxidants and vitamin E.

36. The mask seal according to claim 34 wherein said body has a durometer of about 63.6 on the Shore 000 scale.

37. The mask seal according to claim 34 wherein said mask seal is for being mounted to a mask shell and wherein said body includes a peripheral portion provided with an indentation complementary in shape to and for receiving the outer peripheral portion of a mask shell.

38. The mask seal according to claim 34 wherein said body includes a peripheral portion and wherein said mask seal further comprises a generally hollow triangular seal mounting member embedded in said peripheral portion, said seal mounting member including a plurality of bosses extending outwardly through said peripheral portion and for mounting said mask seal to a mask shell.

39. The mask seal according to claim 34 wherein said body includes a seal peripheral portion provided with an indentation complementary in shape to and for receiving the outer peripheral portion of a mask shell, and wherein said mask seal further comprises a generally hollow triangular seal mounting member embedded in said seal outer peripheral portion and including a plurality of bosses extending outwardly and accessible through said indentation and for mounting said mask seal to a mask shell.

40. The mask according to claim 1 wherein said plurality of vent holes comprise an array of vent holes including at least two opposed curved rows of vent holes.

41. The mask according to claim 40 wherein the distance between the vent holes in each row is substantially the same as the distance between opposed vent holes.

42. The mask according to claim 41 wherein said vent holes have a diameter and wherein said distances between vent holes are at least three times said diameter.

43. A mask seal comprising a generally hollow triangular body of soft resilient material including a peripheral portion and a generally hollow triangular mask seal mounting member embedded in said peripheral portion.

44. The mask seal according to claim 43 wherein said peripheral portion is provided with a generally triangular indentation and wherein said mask seal mounting member includes a generally hollow triangular frame embedded in said peripheral portion and provided with a plurality of bosses extending outwardly and accessible through said indentation.

45. The mask seal according to claim 43 wherein said body of soft resilient material comprises a body of styrene-ethylene butylene-styrene copolymer modified with a mineral oil.

46. The mask seal according to claim 45 wherein said body has a durometer of about 63.6 on the Shore 000 scale.

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