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(54) **BREATHING ASSISTANCE APPARATUS**

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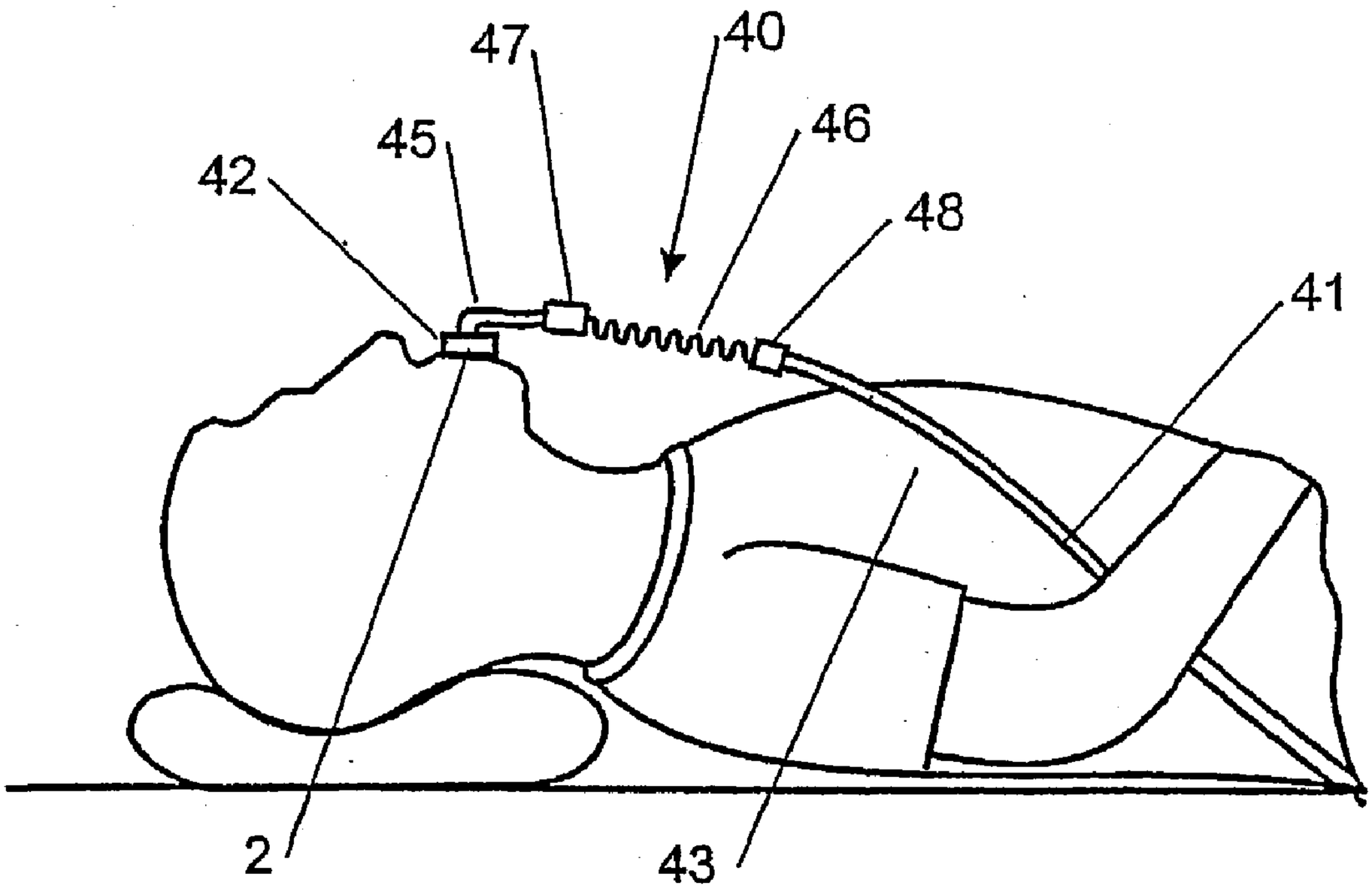
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(57) **ABSTRACT**

A CPAP system for supplying humidified gases to a user. Various interfaces are described for delivering the gases. A mask cushion including a deformable cushion and a thin sheath is described. A forehead rest with a horizontal pivot is attached to the mask. An outlet vent to reduce the noise from exhausted carbon dioxide is described. A mouthpiece is also described with an outlet diffuser including Heat Moisture Exchanger Material.



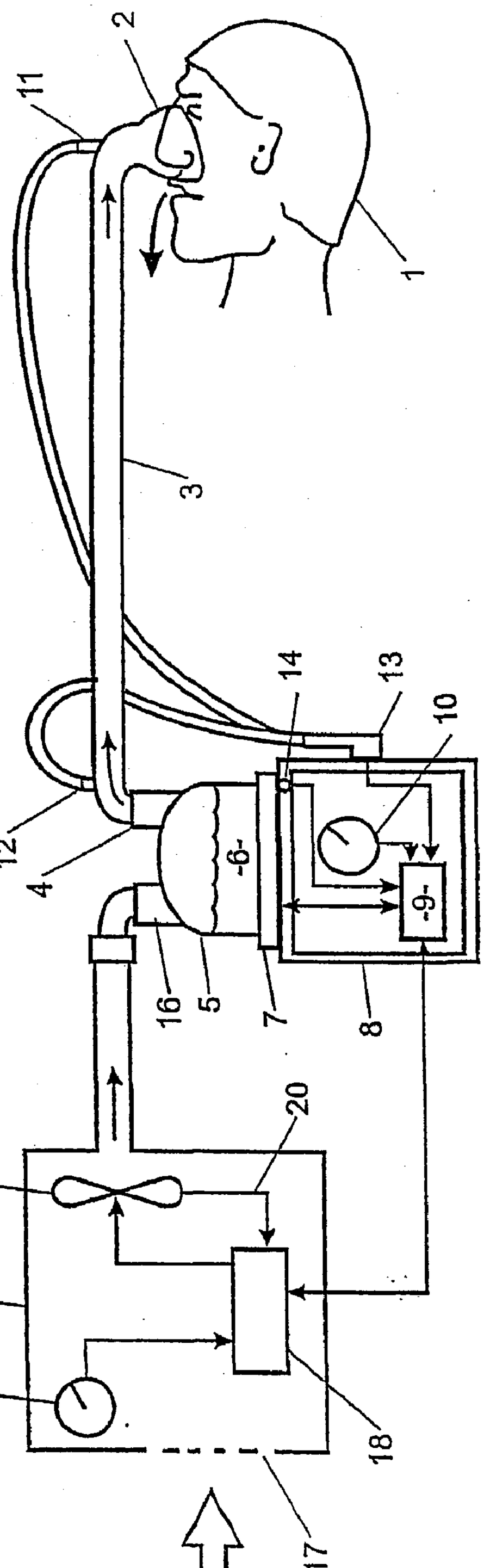


FIGURE 1

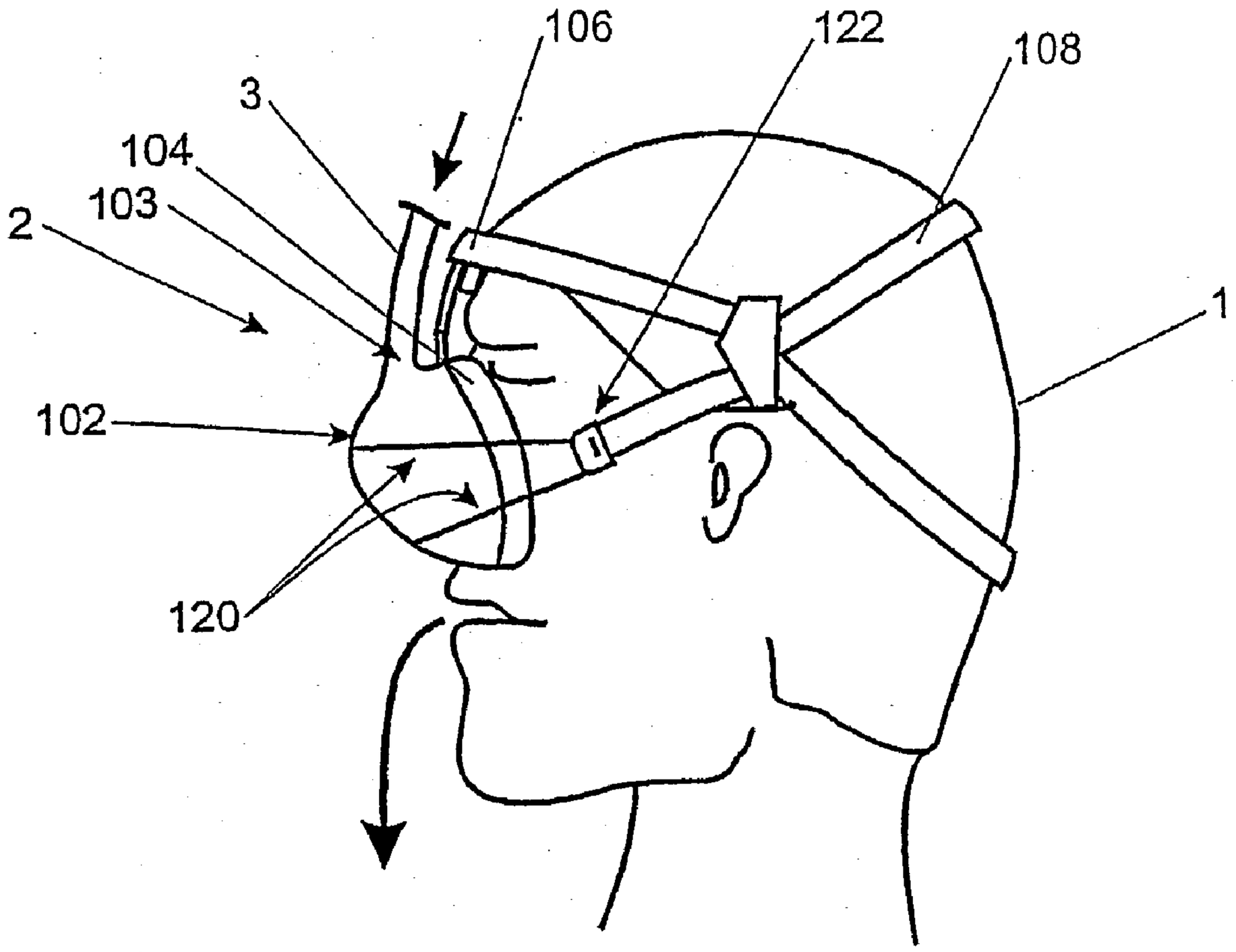


FIGURE 2

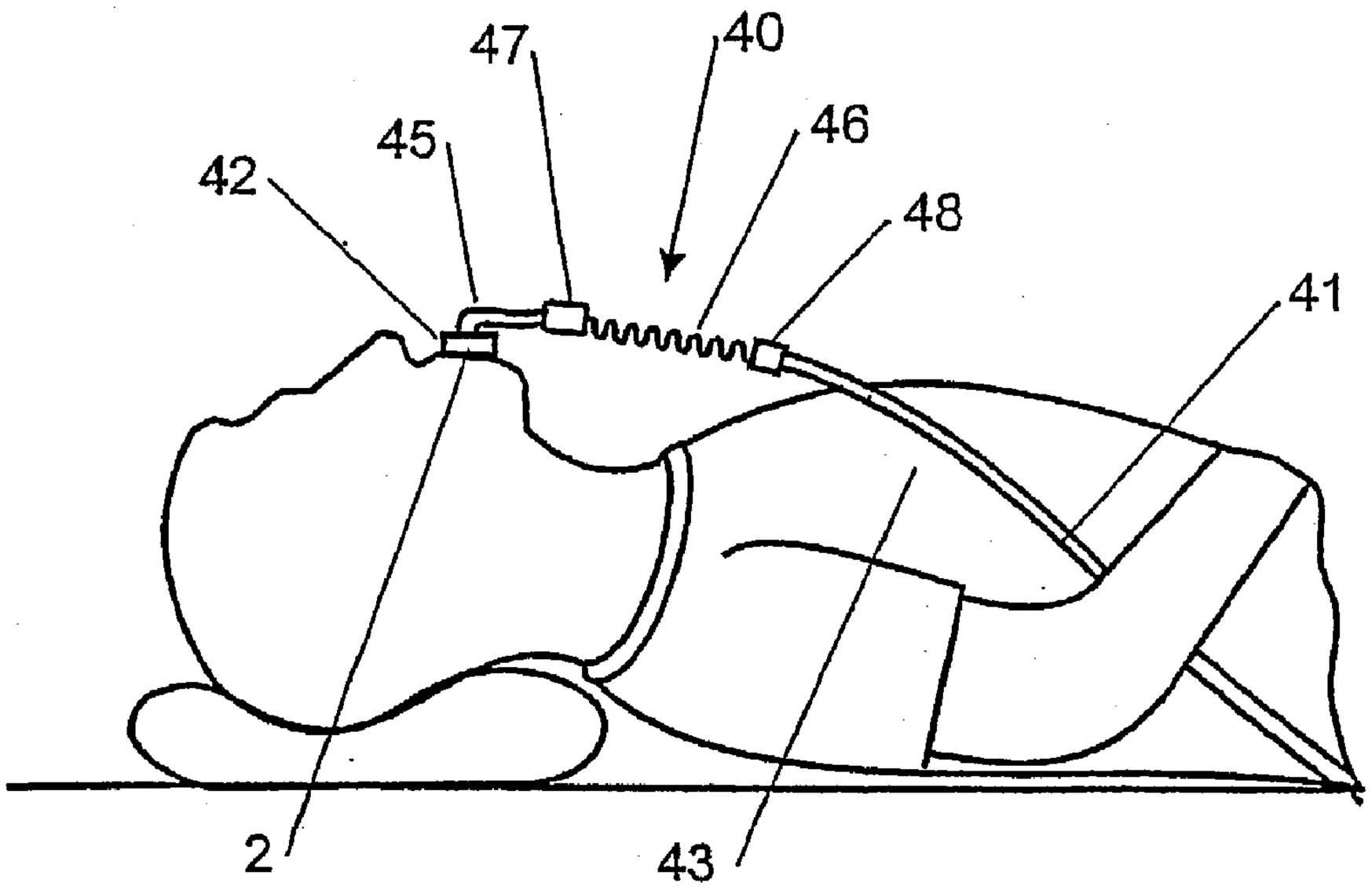


FIGURE 3

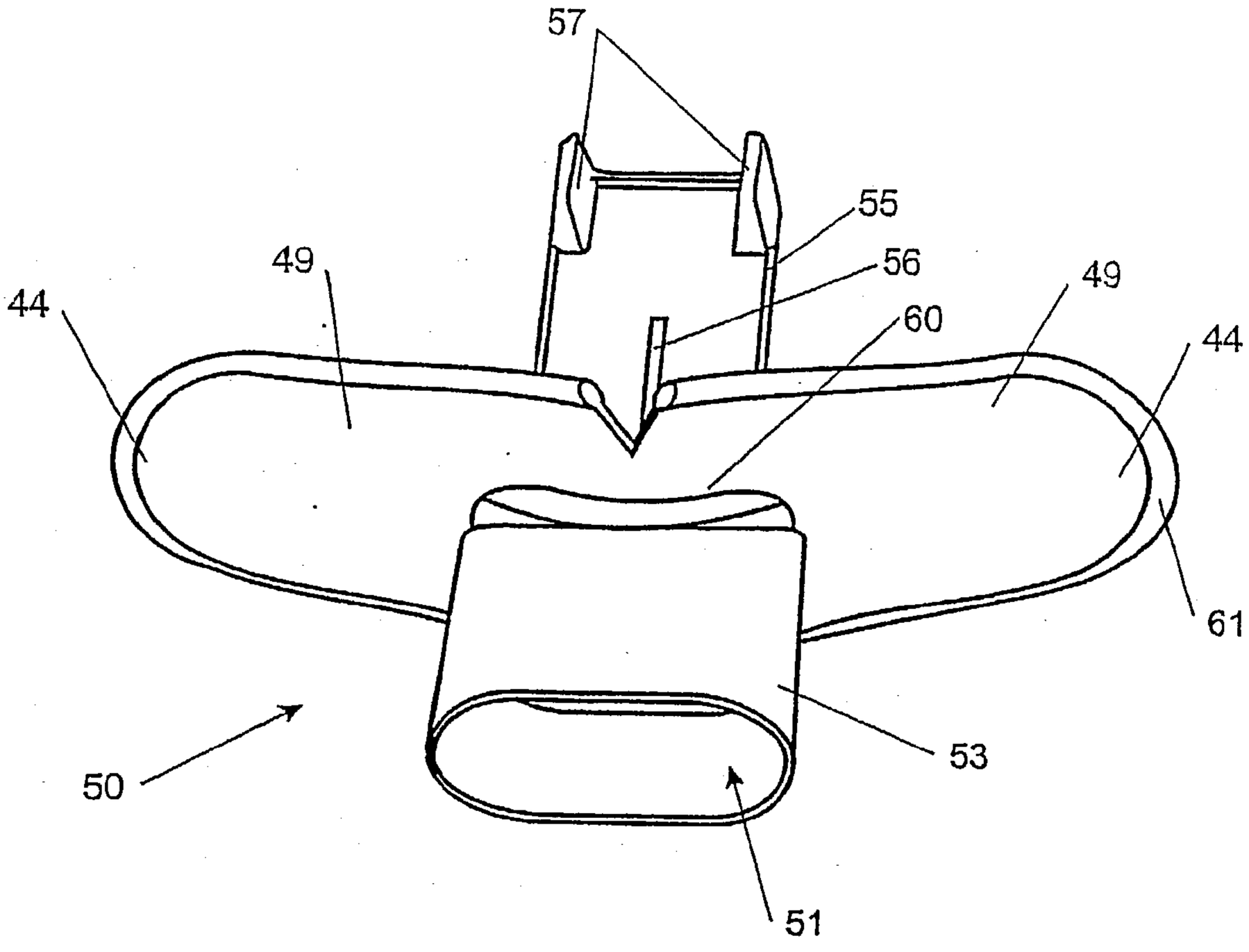


FIGURE 4

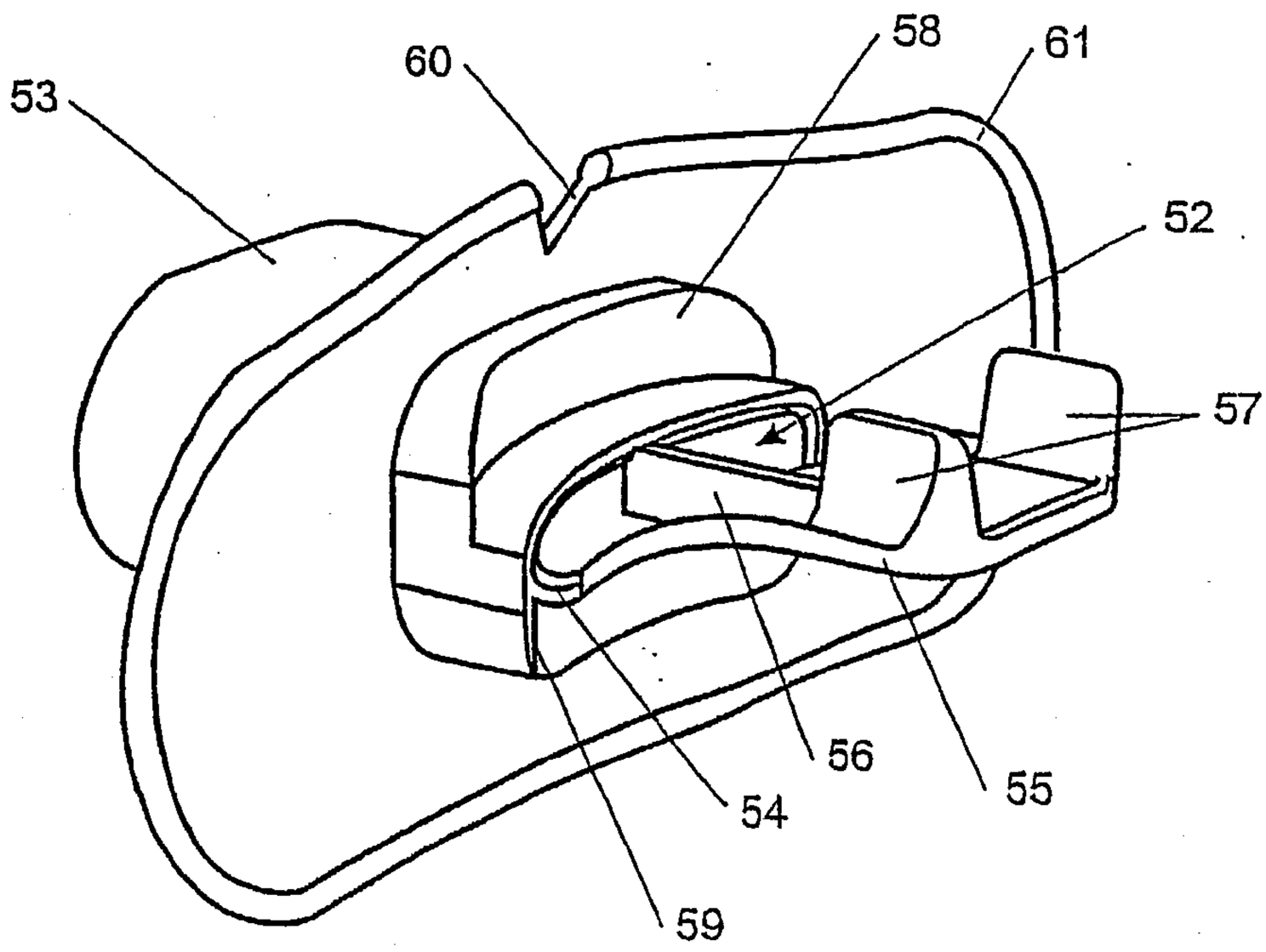


FIGURE 5

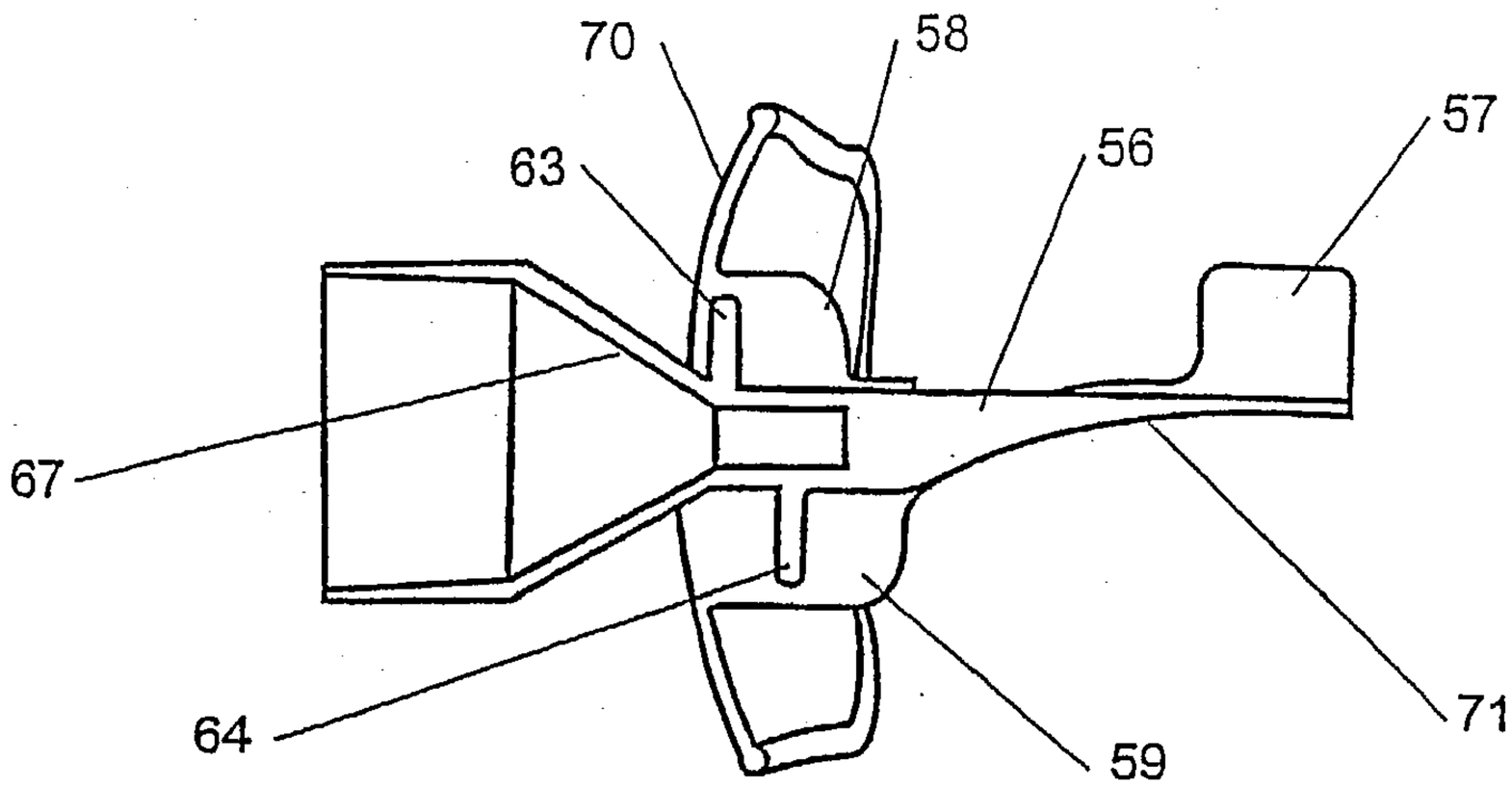


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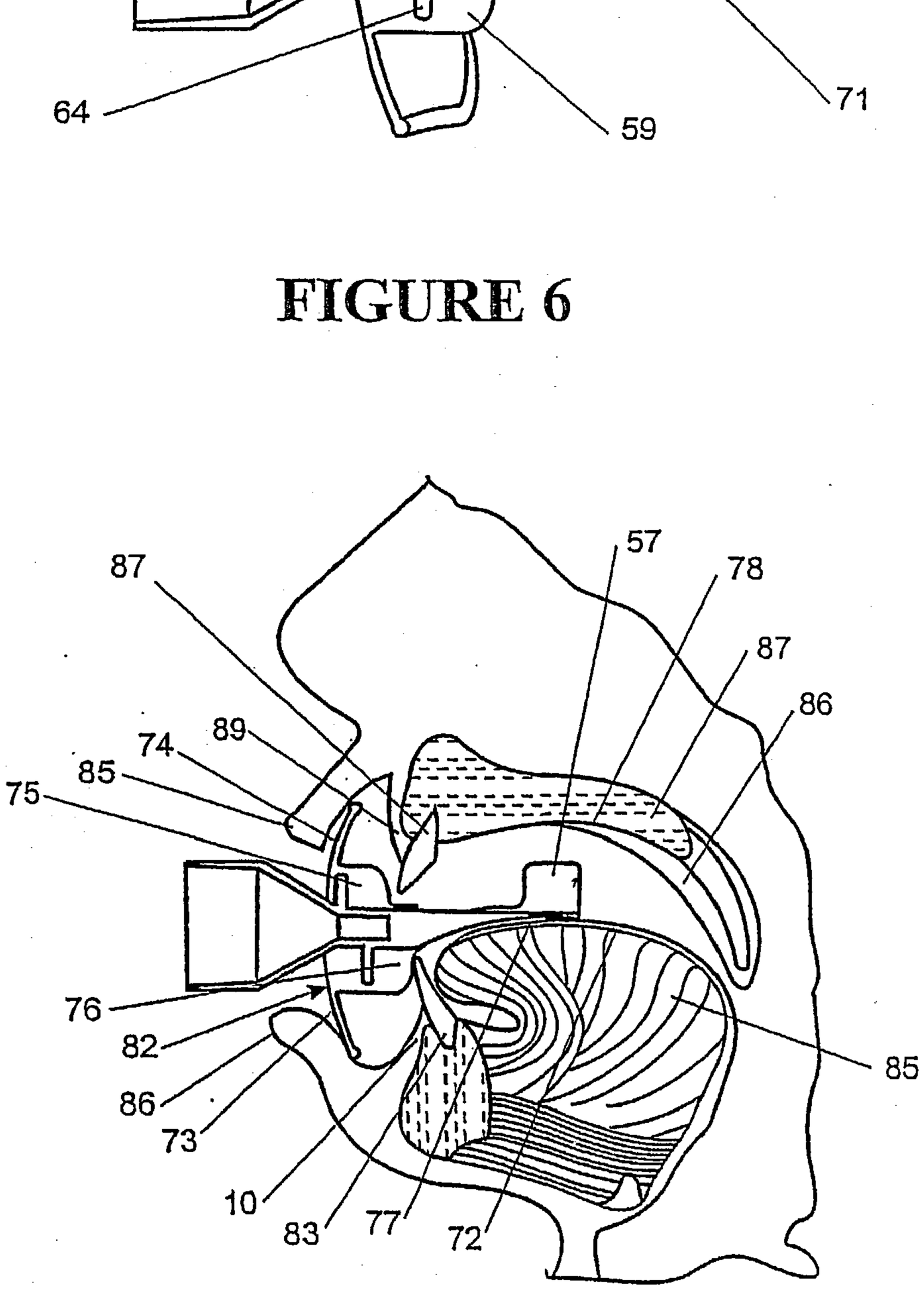


FIGURE 7

FIGURE 8

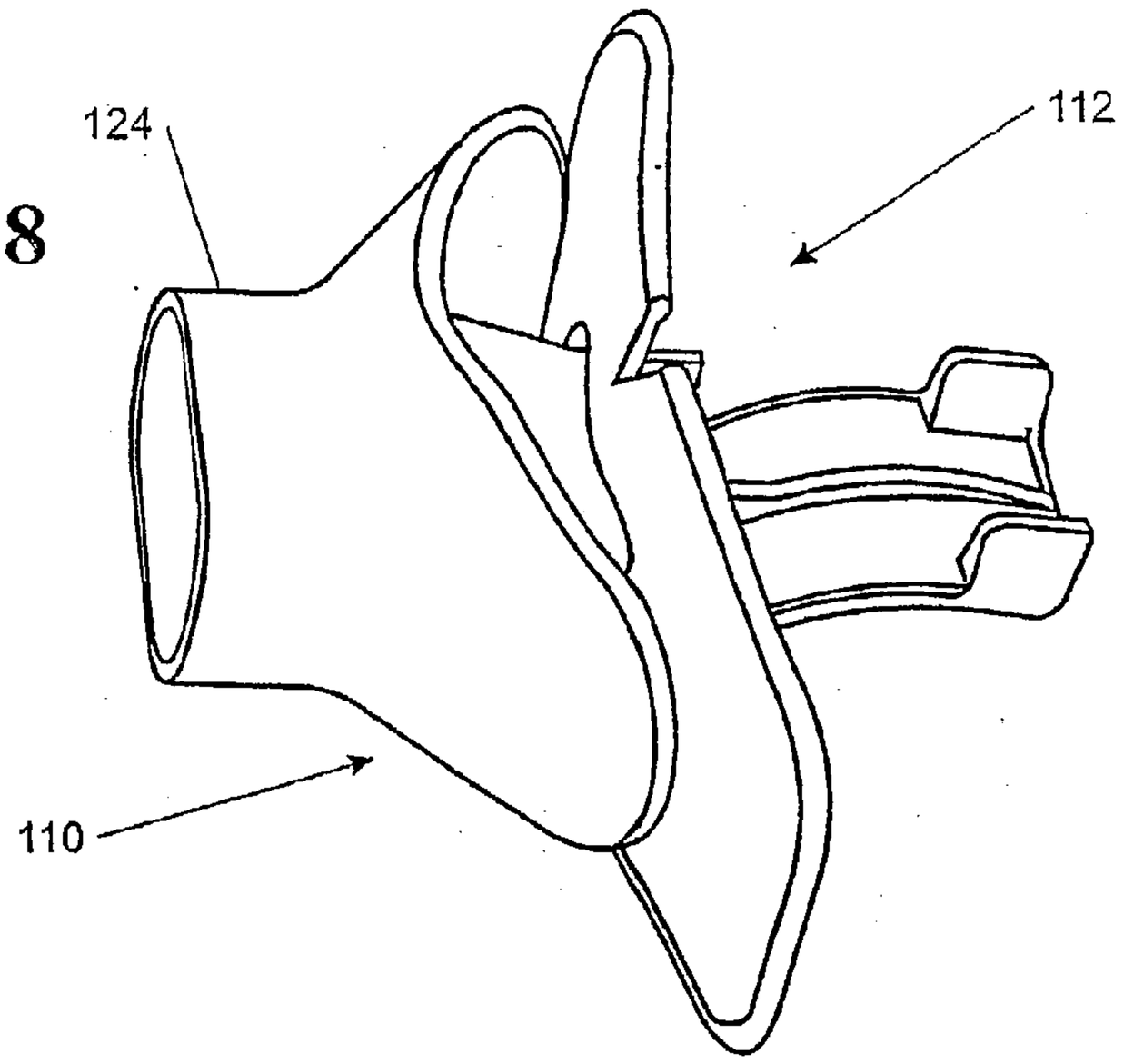
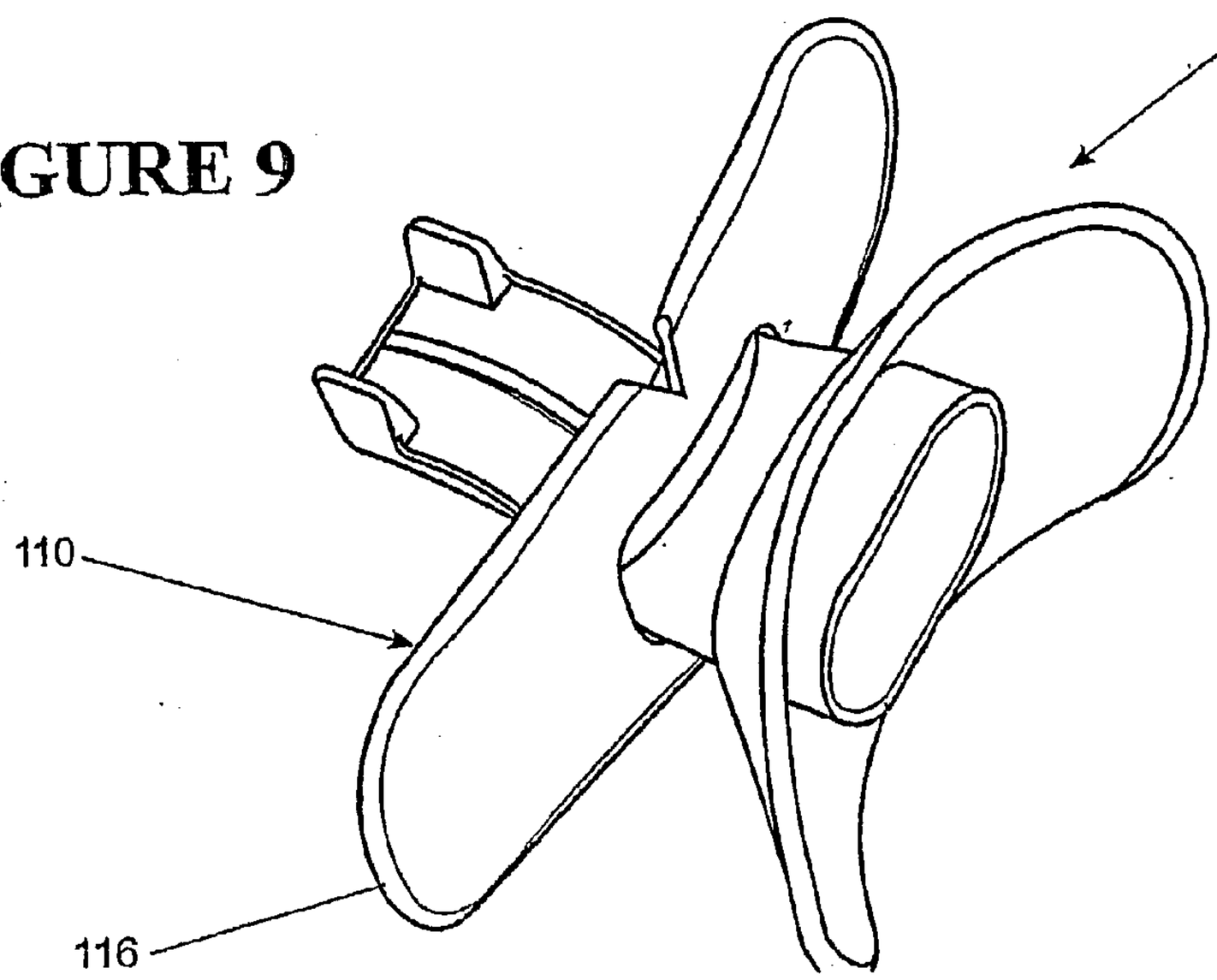


FIGURE 9



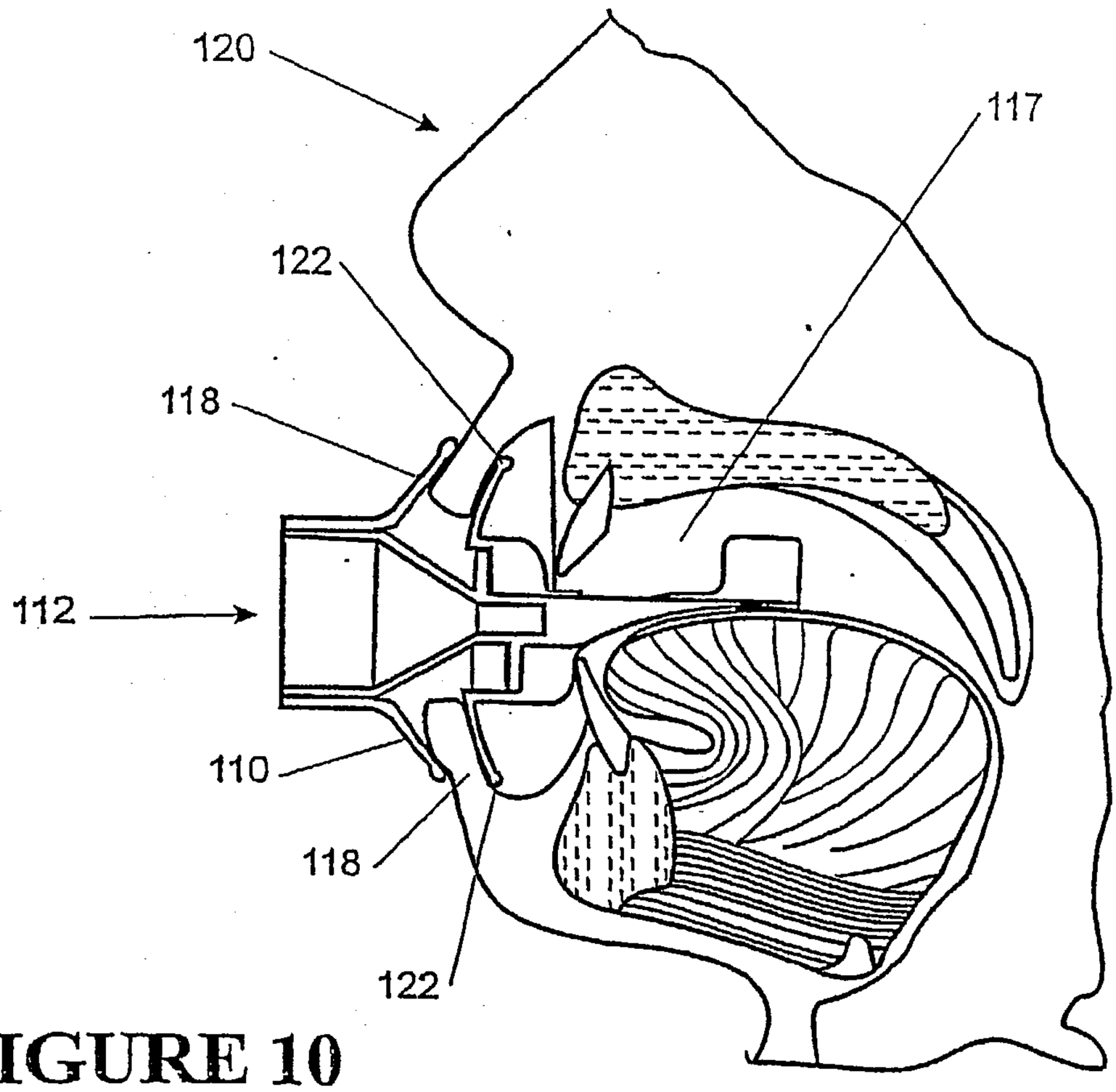
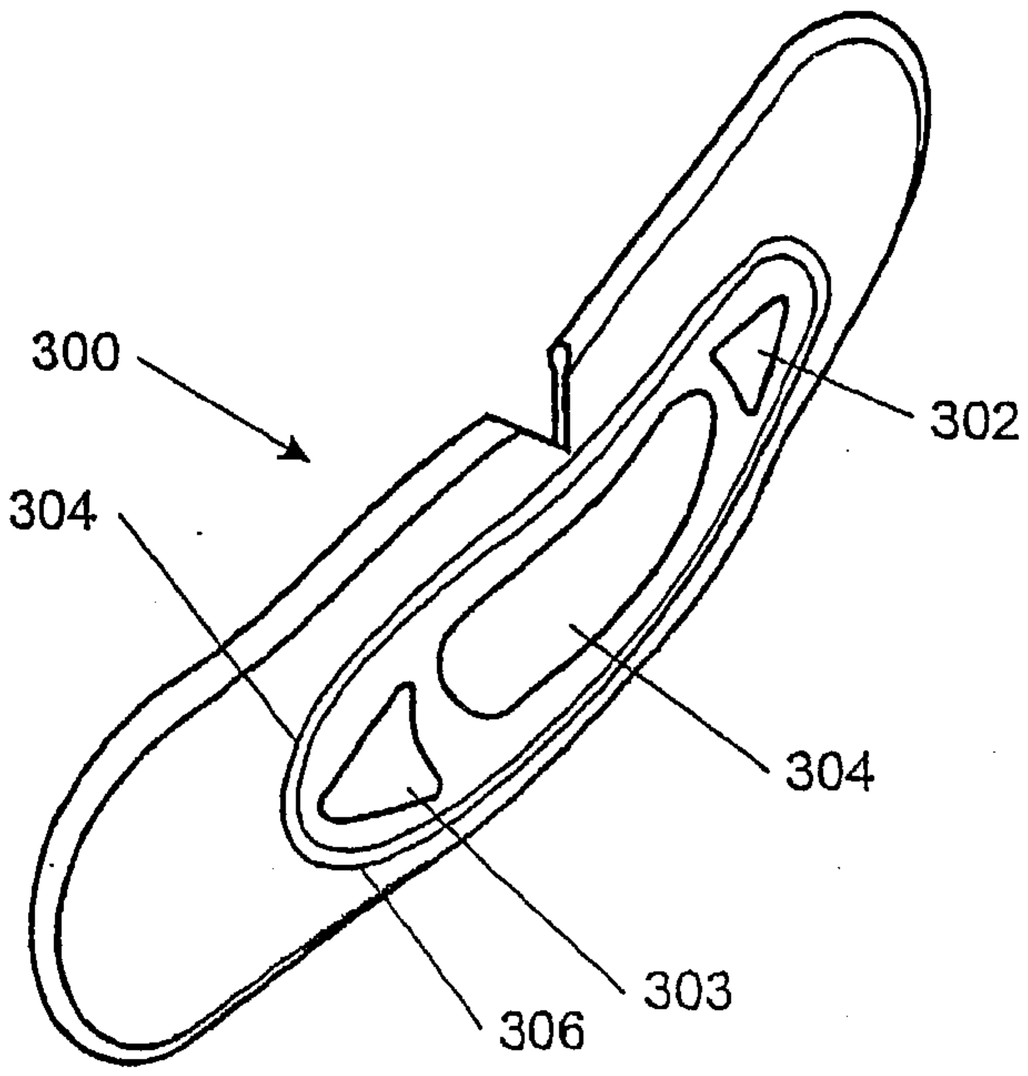


FIGURE 10

FIGURE 11



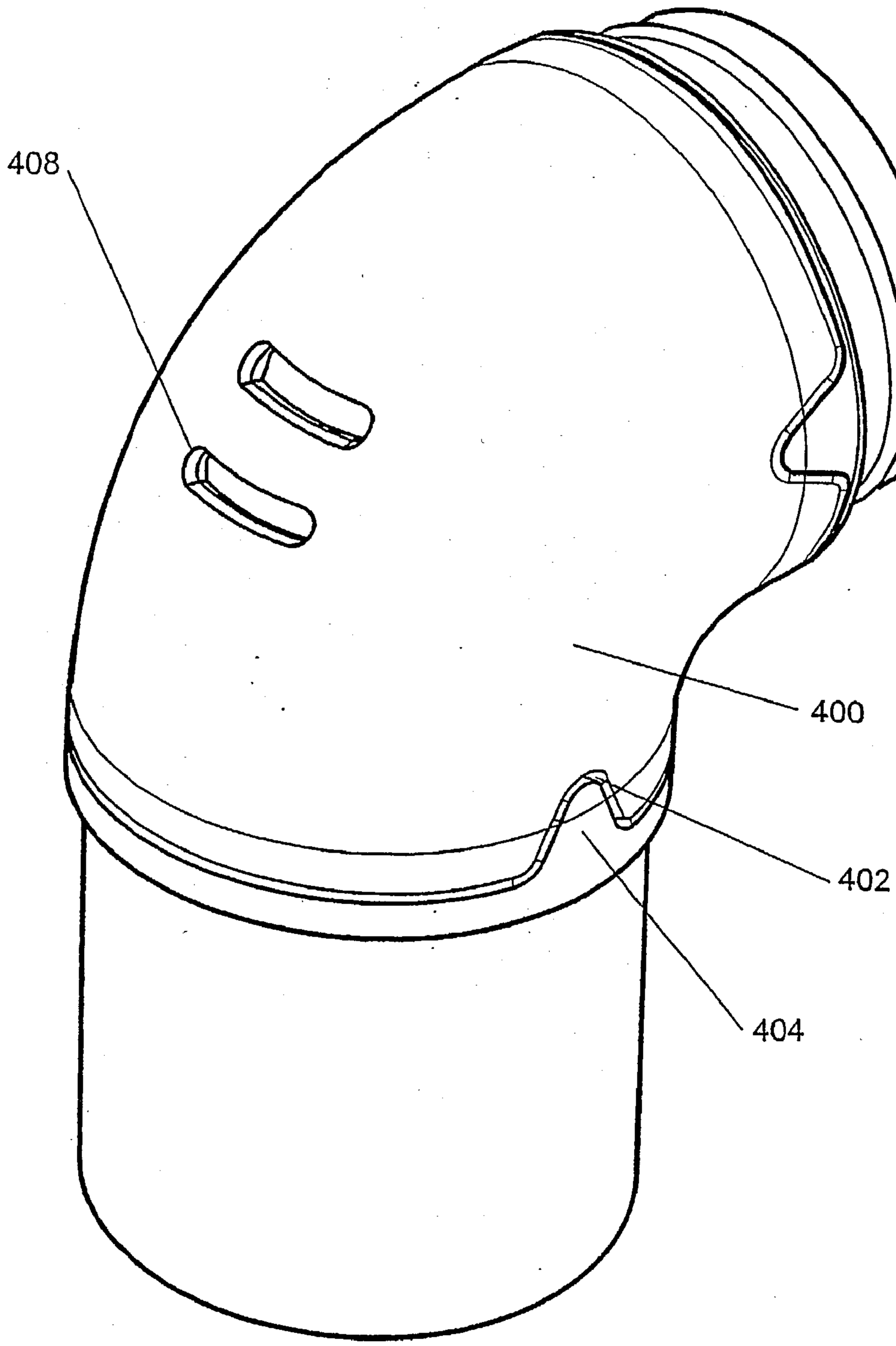


FIGURE 12

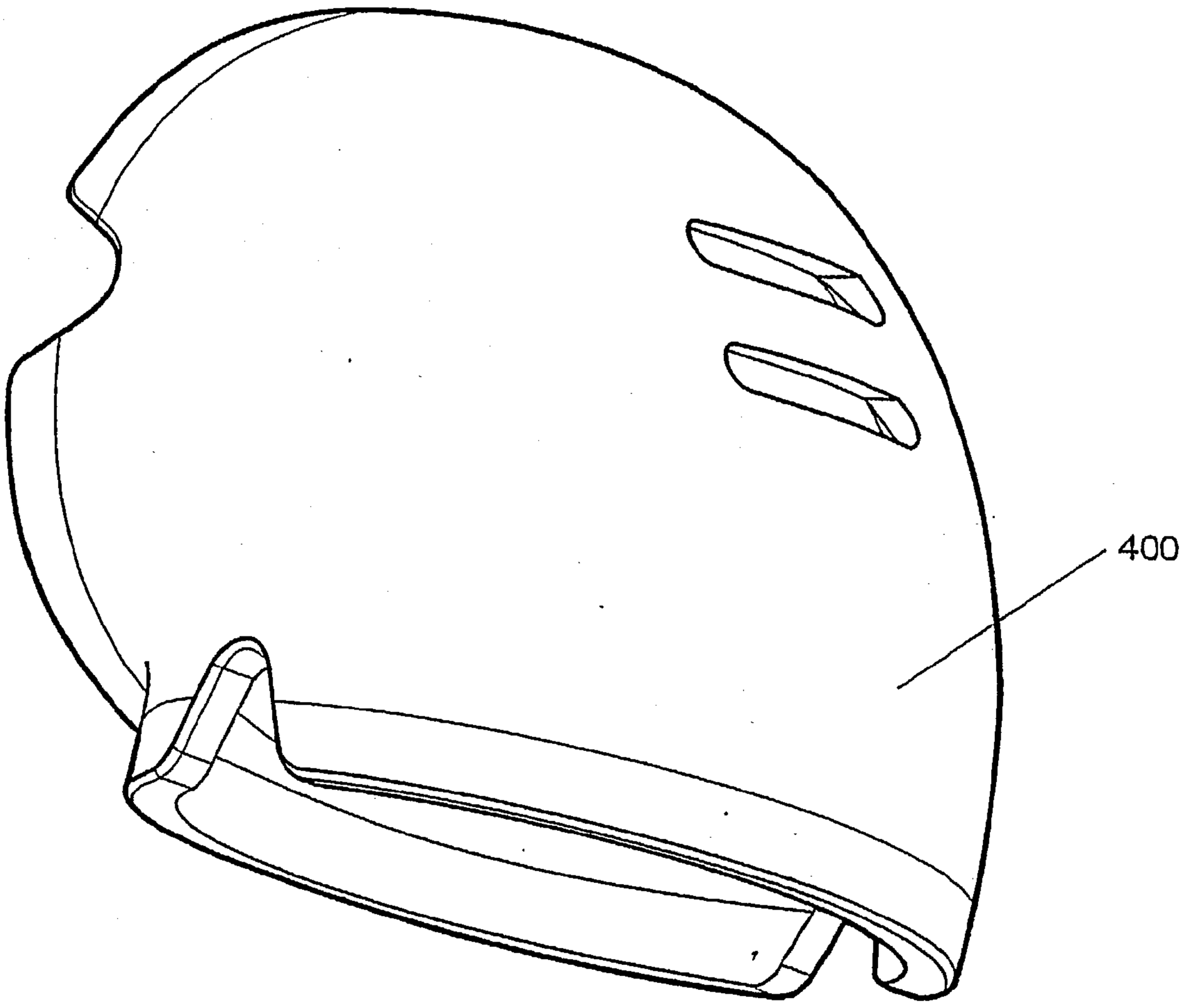


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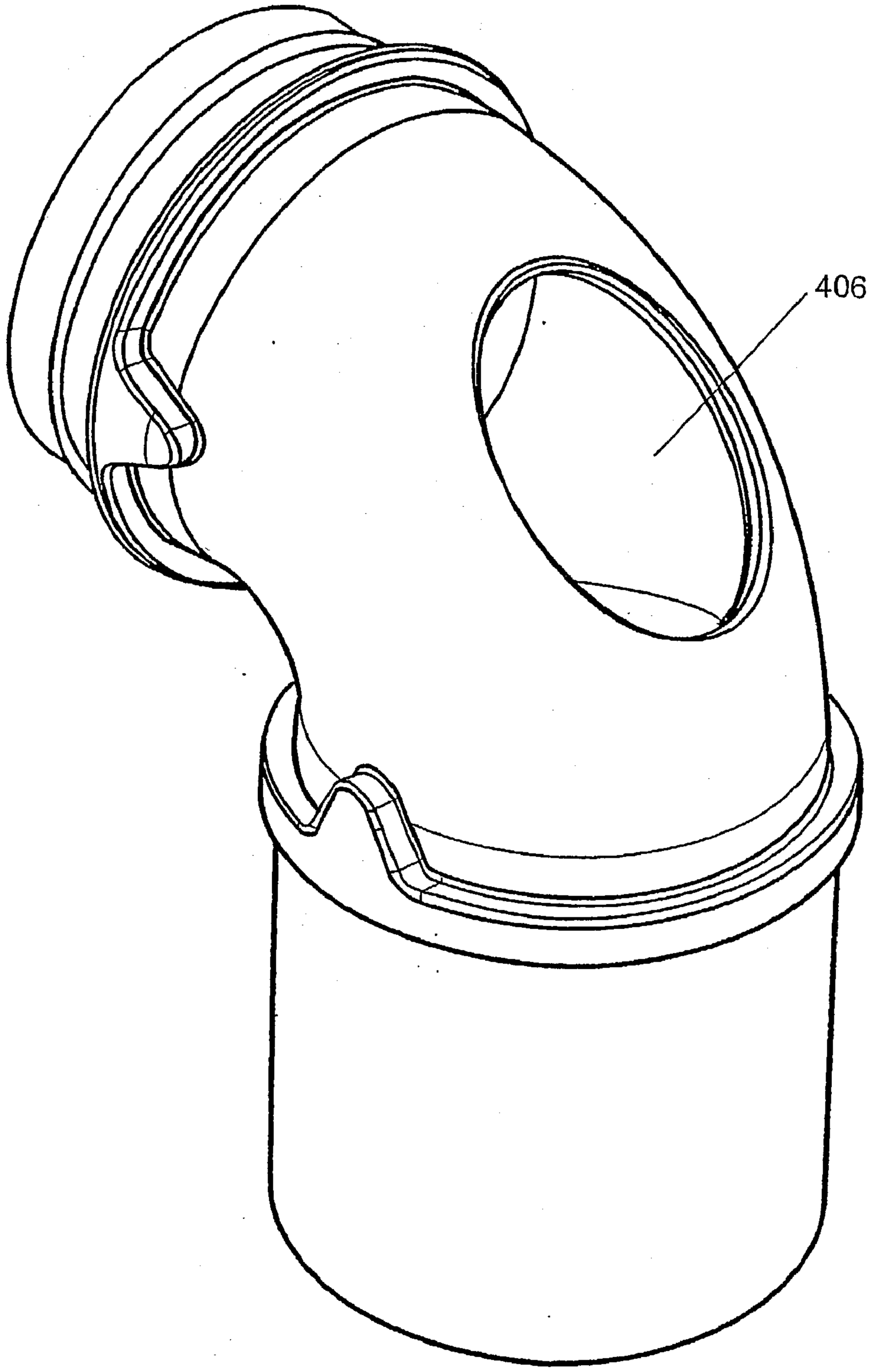


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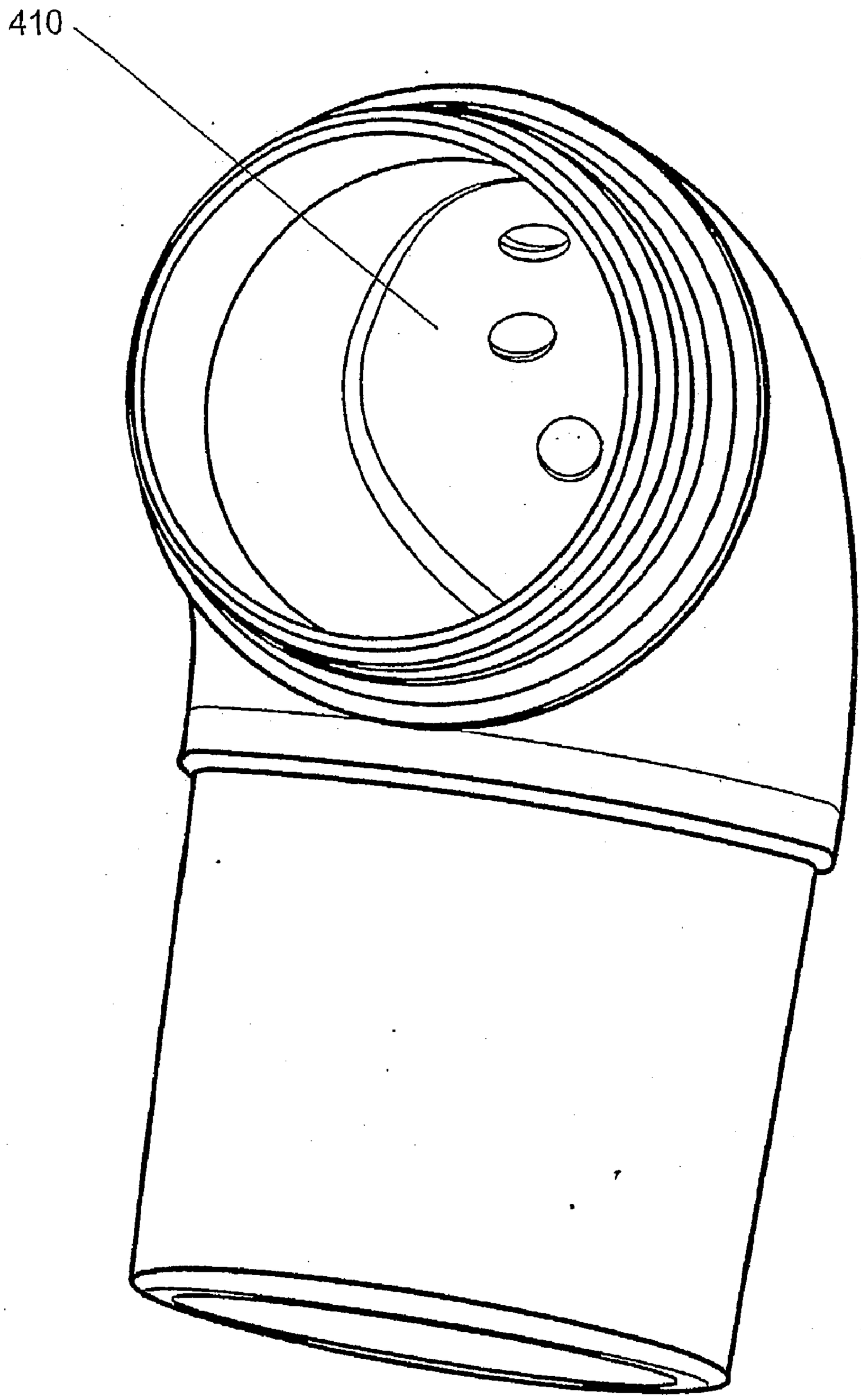


FIGURE 15

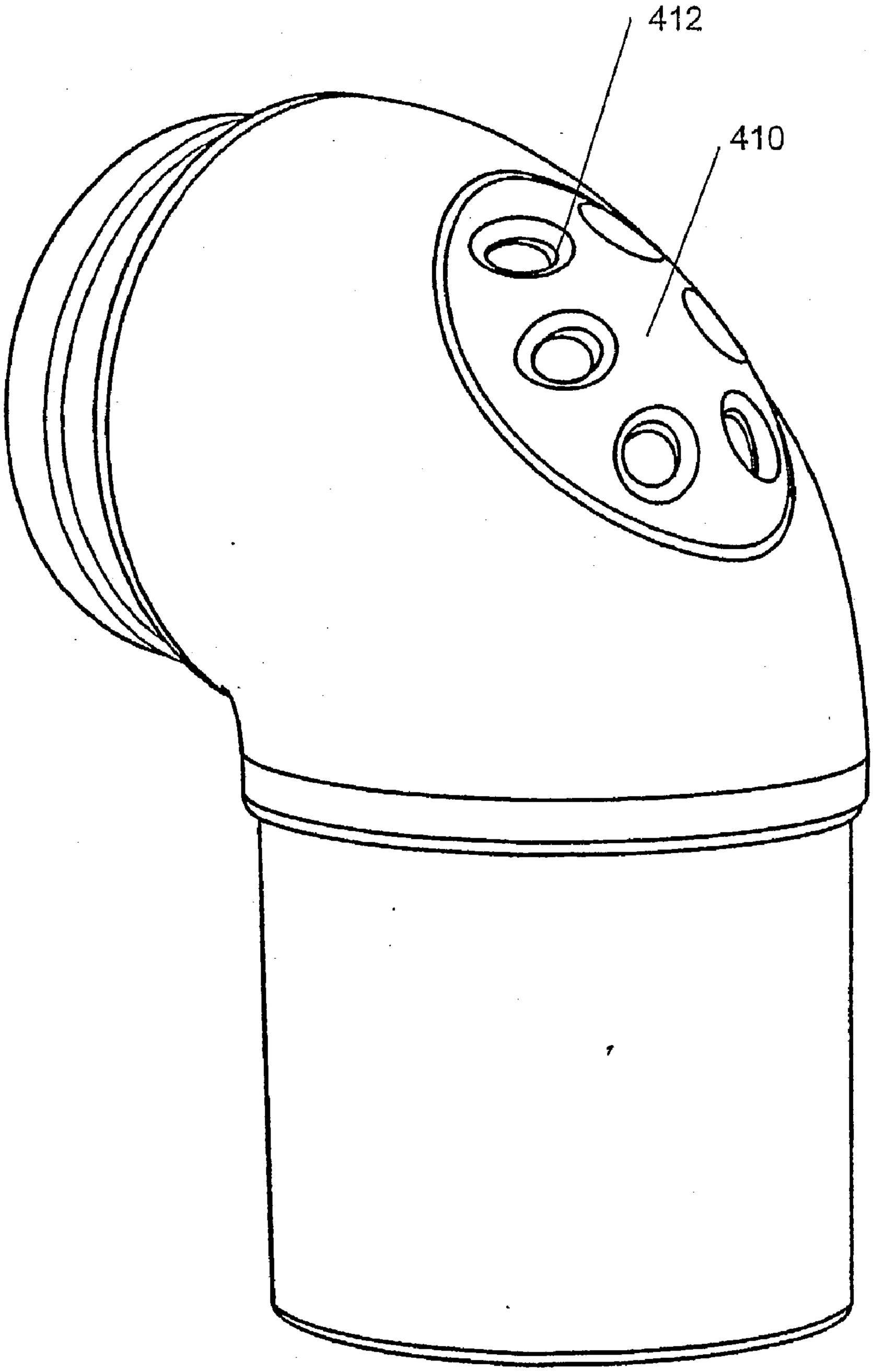


FIGURE 16

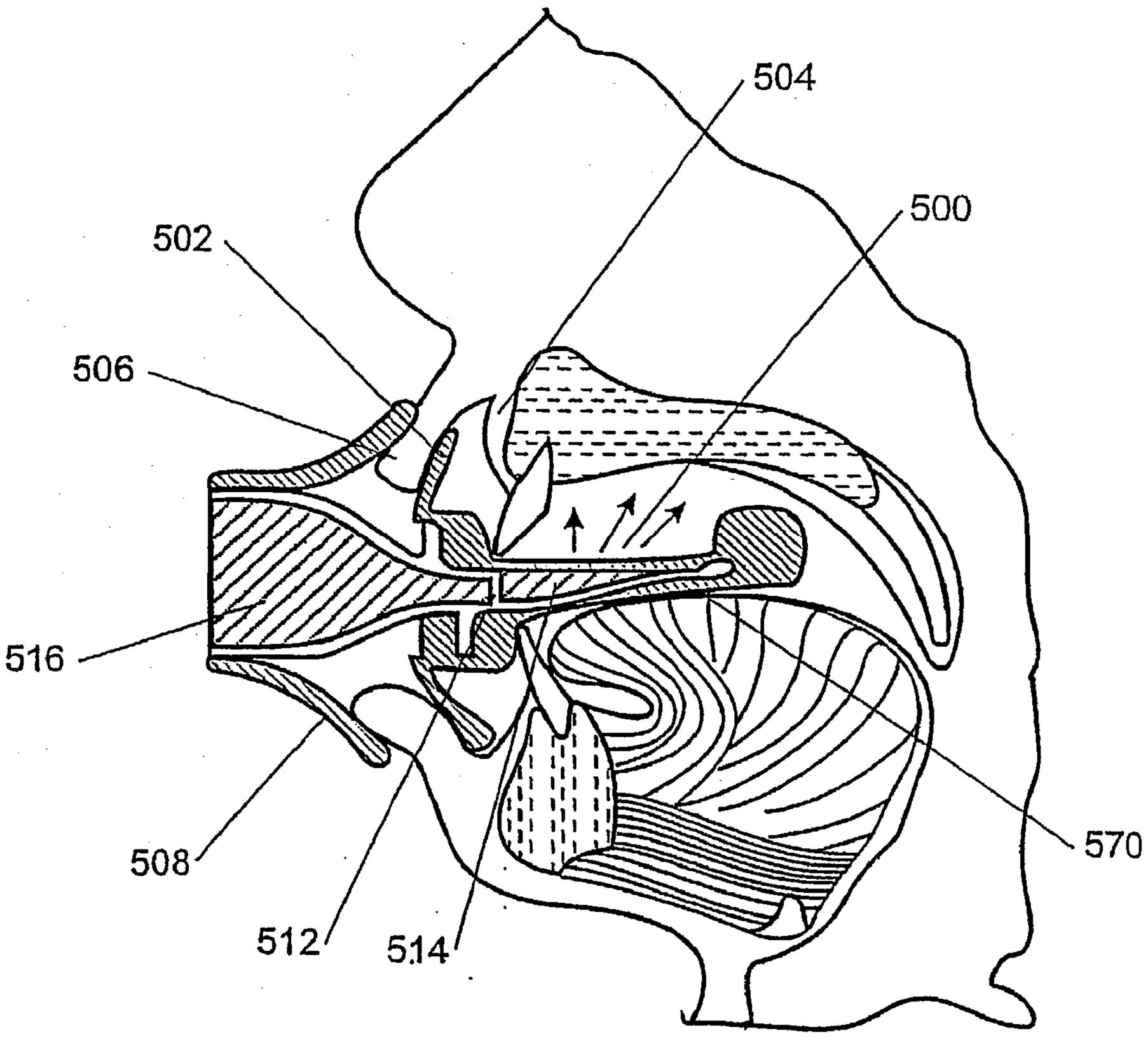


FIGURE 17

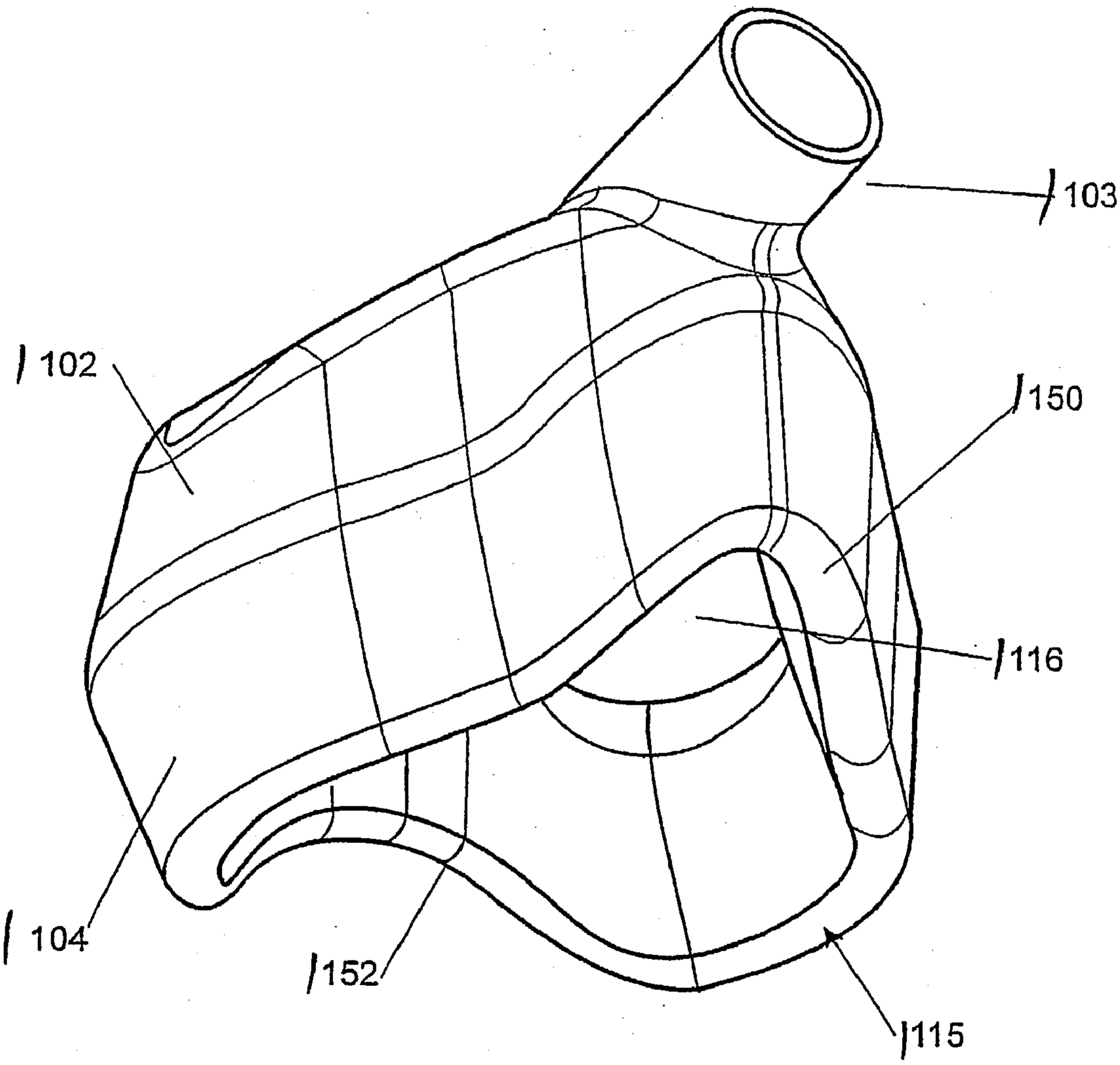


FIGURE 18

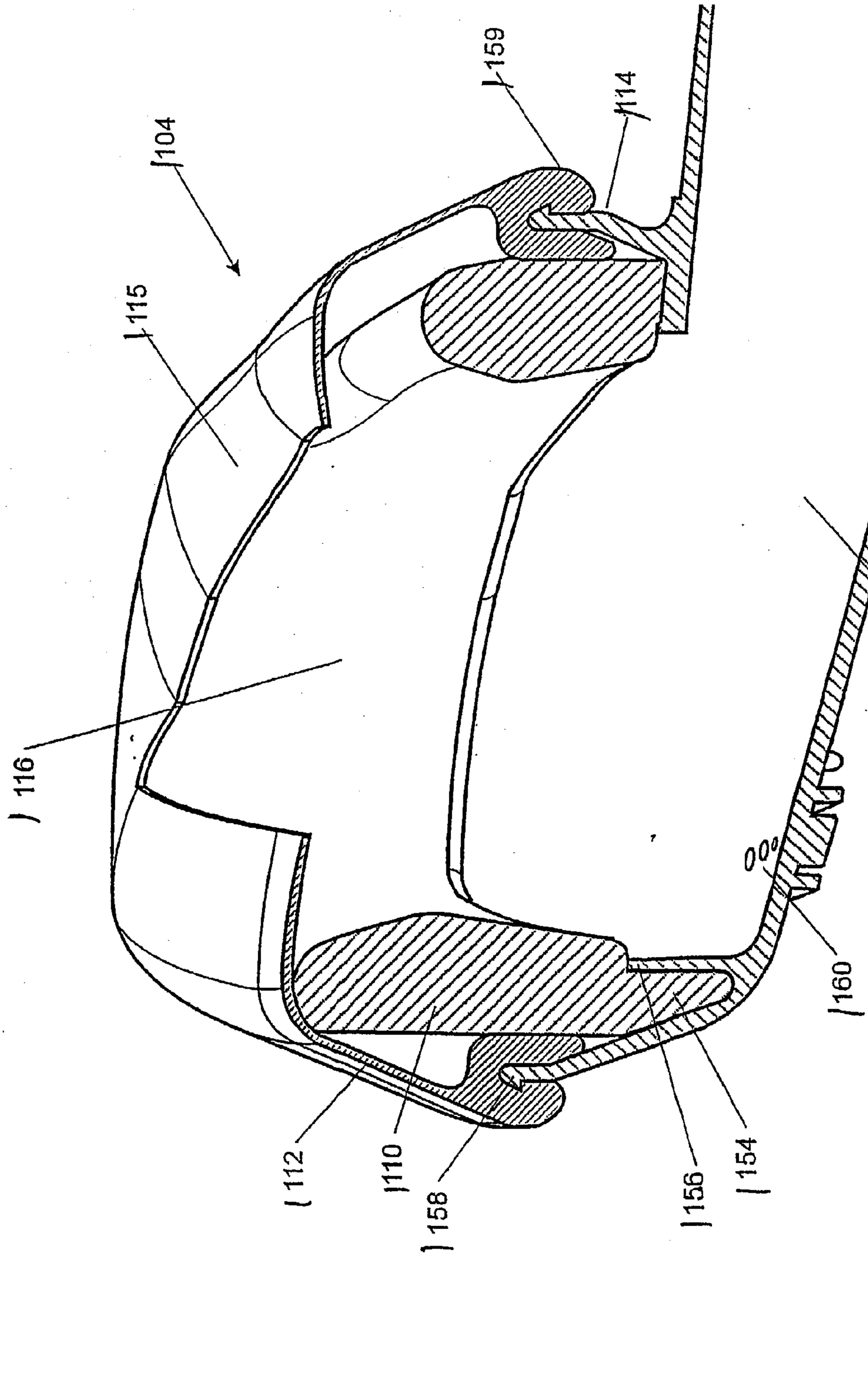


FIGURE 19

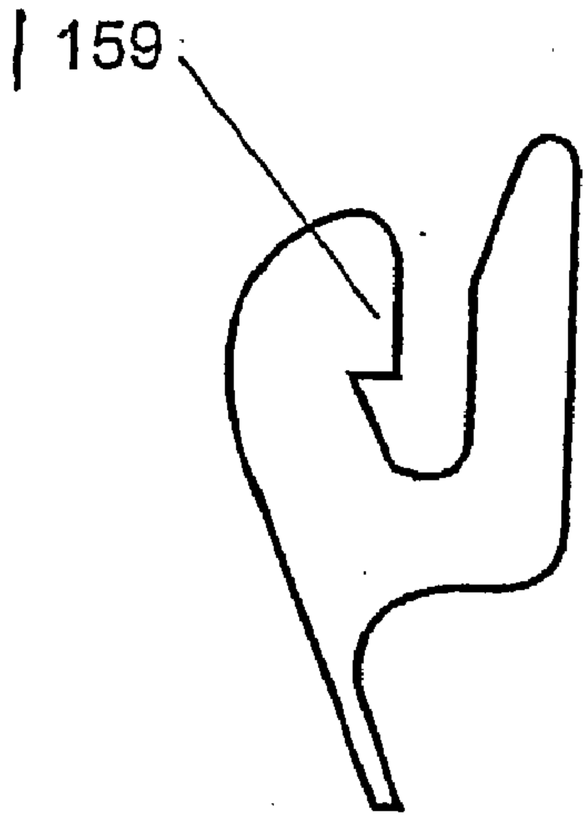


FIGURE 20

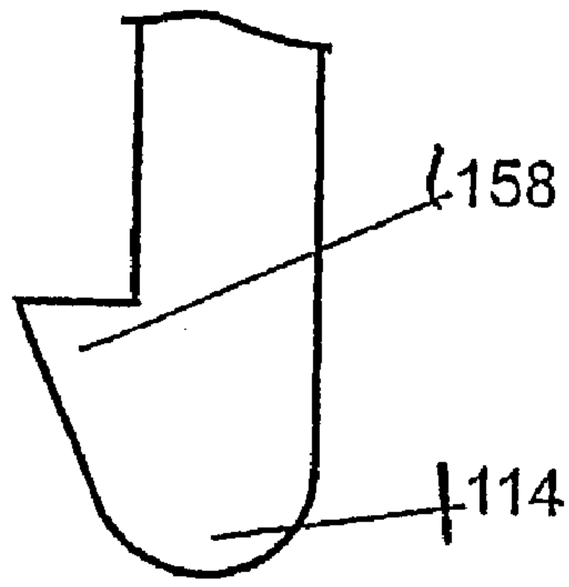


FIGURE 21

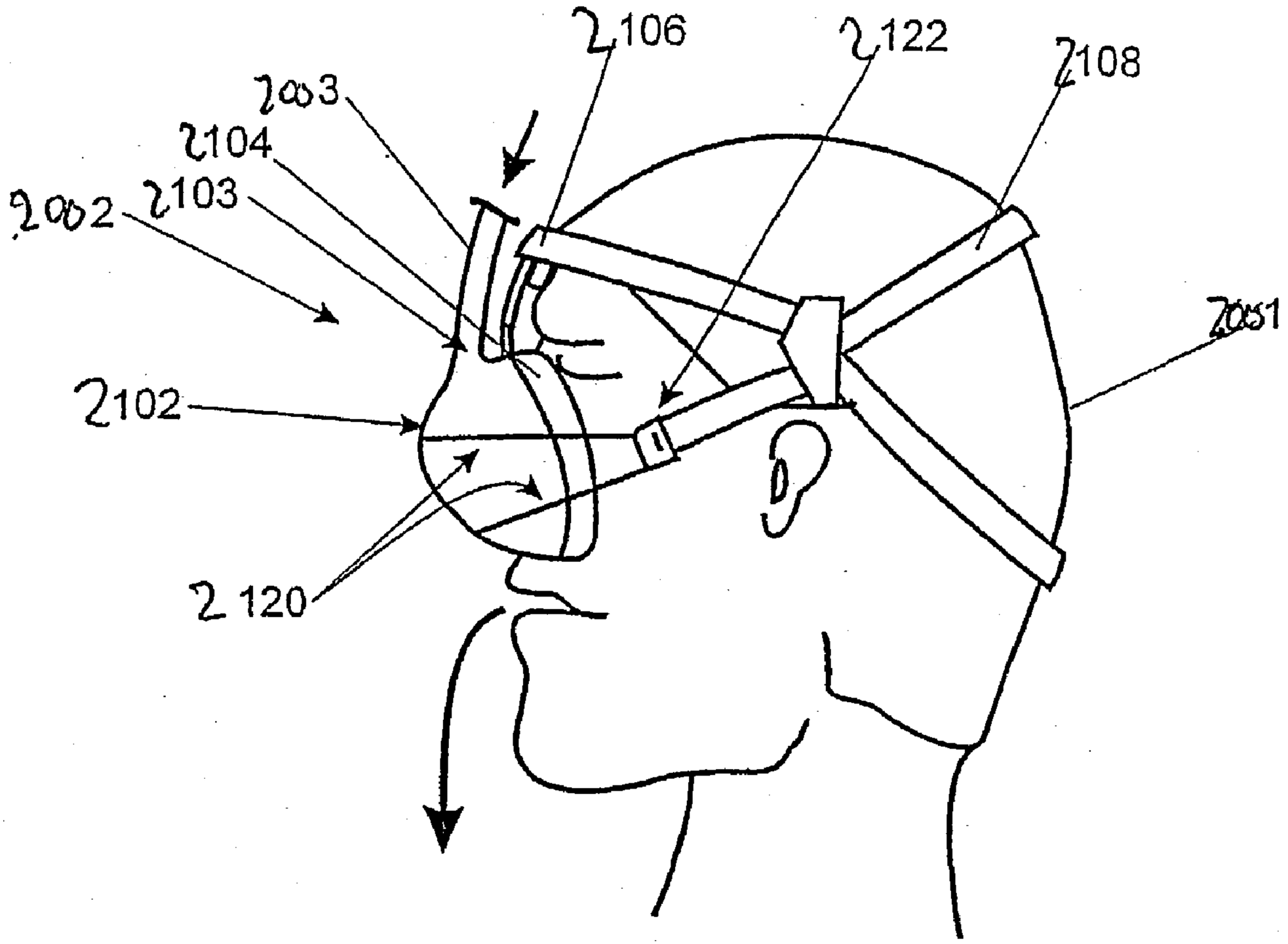


FIGURE 22

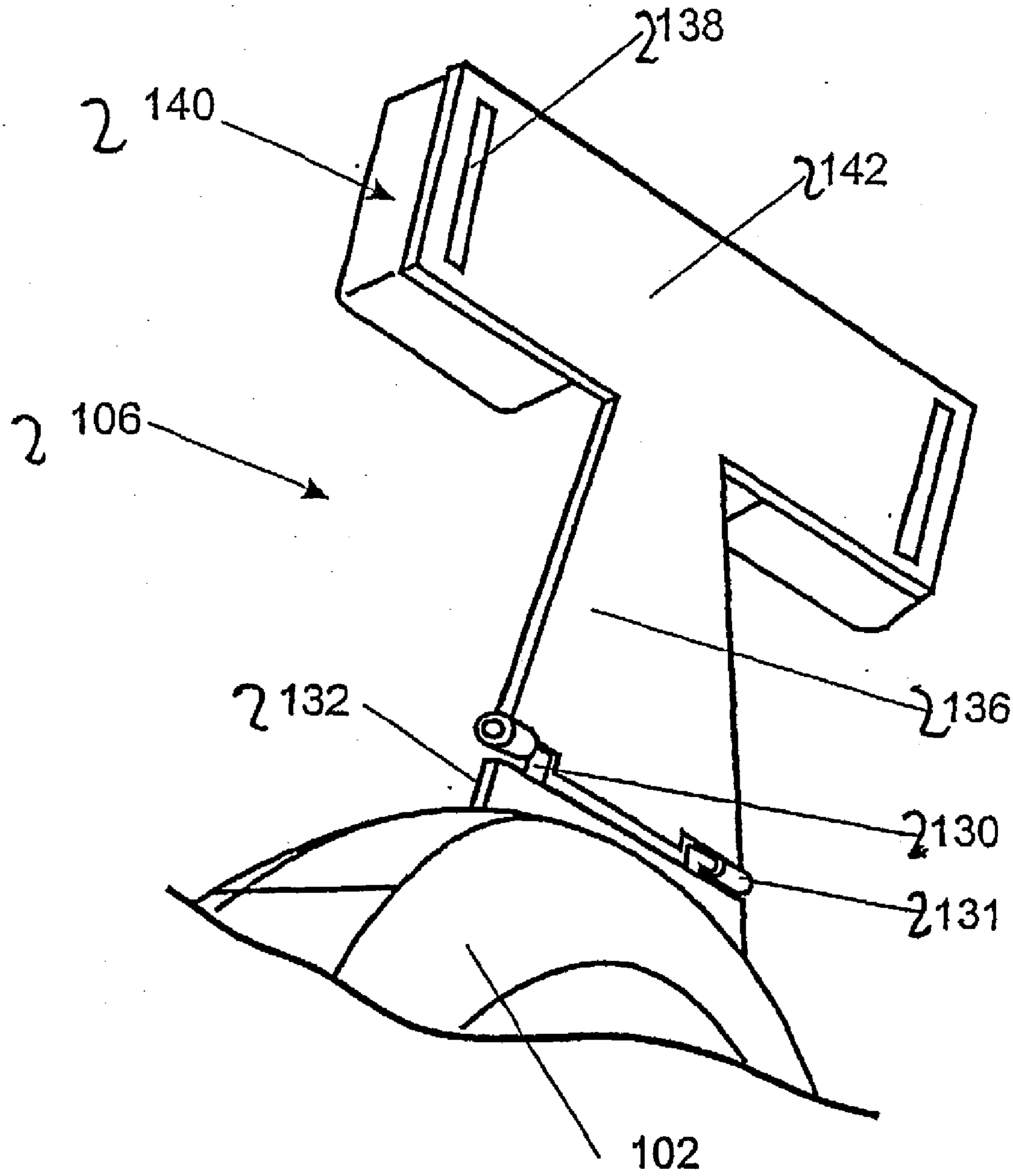


FIGURE 3

BREATHING ASSISTANCE APPARATUS

FIELD OF INVENTION

[0001] This invention relates to patient interfaces particularly though not solely for use in delivering CPAP therapy to patients suffering from obstructive sleep apnoea (OSA).

BACKGROUND OF THE INVENTION

[0002] In the art of respiration devices, there are well known variety of respiratory masks which cover the nose and/or mouth of a human user in order to provide a continuous seal around the nasal and/or oral areas of the face such that gas may be provided at positive pressure within the mask for consumption by the user. The uses for such masks range from high altitude breathing (i.e., aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

[0003] One requisite of such respiratory masks has been that they provide an effective seal against the user's face to prevent leakage of the gas being supplied. Commonly, in prior mask configurations, a good mask-to-face seal has been attained in many instances only with considerable discomfort for the user. This problem is most crucial in those applications, especially medical applications, which require the user to wear such a mask continuously for hours or perhaps even days. In such situations, the user will not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable user discomfort.

[0004] U.S. Pat. No. 5,243,971 and U.S. Pat. No. 6,112,746 are examples of prior art attempts to improve the mask system U.S. Pat. No. 5,570,689 and PCT publication No. WO 00/78384 are examples of attempts to improve the forehead rest.

[0005] Where such masks are used in respiratory therapy, in particular treatment of obstructive sleep apnea (OSA) using continuance positive airway pressure (CPAP) therapy, there is generally provided in the art a vent for washout of the bias flow or expired gases to the atmosphere. Such a vent may be provided for example, as part of the mask, or in the case of some respirators where a further conduit carries the expiratory gases, at the respirator. A further requisite of such masks is the washout of gas from the mask to ensure that carbon dioxide build up does not occur over the range of flow rates. In the typical flow rates in CPAP treatment, usually between 4 cm H_2O to 20 cm H_2O, prior art attempts at such vents have resulted in excessive noise causing irritation to the user and any bed partners.

[0006] Various approaches have been developed in the prior art to attempt to reduce the noise when CPAP therapy is provided. For example, in PCT Patent Application No. WO98/34665 it has been proposed that the vent include a resilient plug with rounded edge apertures to reproduce noise. However, this is not entirely effective in eliminating the extra noise created by a vent at the mask.

[0007] In common with all attempts to improve the fit, sealing and user comfort is the need to avoid a concentrated flow of air at any portion of the respiratory tracts. In particular with oral masks or mouthpieces it is a disadvantage of prior art devices that the oral cavity may become overly dehydrated by use of the device, causing irritation and possible later complications.

SUMMARY OF THE INVENTION

[0008] It is an object of the present invention to attempt to provide a patient interface which goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

[0009] Accordingly in one aspect the invention may broadly be said to consist in a device for delivering a supply of gases to a user comprising:

[0010] a patient interface, in use in fluid communication with said supply of gases, engaging with said user and thereby supplying said gases to said user.

[0011] outlet means associated with said patient interface including a plurality of outlet vents formed in a flexible portion of said outlet means, said outlet means in use passing a substantial portion of the expired gases of said user.

[0012] Preferably said patient interface is a mouthpiece.

[0013] Alternatively said patient interface is a nasal mask.

[0014] Preferably said mouthpiece comprises:

[0015] a vestibular shield having an inner surface and an outer surface, said vestibular shield having a predetermined height which will overlap said user's teeth and gums when positioned in the mouth vestibule of said user;

[0016] gases passageway means extending from said outer surface of said vestibular shield to said inner surface of said vestibular shield for allowing the passage of said gases through said mouthpiece; and

[0017] extra-oral sealing means associated with said gases passageway which may be adjusted into one of two configurations, a first condition when said mouthpiece is inserted into said user's mouth being substantially unengaged with said user's face, and a second condition when correctly positioned in said user's mouth being substantially engaged with said user's face and under compression thereupon.

[0018] Preferably said nasal mask comprises restraining means attached to or around the head of said user, a hard body portion having an inlet receiving said supply of gases and an open section, sealing means attached to said body portion substantially contoured to the facial contours of said user and a receiving means attached to said hard body which in use engages with said restraining means.

[0019] Preferably said flexible portion of said outlet means comprises a sleeve having a plurality of outlet vents, said sleeve attaching over said outlet means, said sleeve composed of a substantially flexible material, said outlet means having a outlet aperture and in use said sleeve located on said outlet means such that said outlet aperture matches up with said plurality of outlet vents thereby in use passing a substantial portion of the expired gases of said user.

[0020] Alternatively, said outlet means is either integral or in fluid communication with said patient interface, said outlet means being composed substantially of a single material, and said flexible portion comprising a portion of

said outlet means in which the thickness of said material is substantially less than, and therefore substantially more flexible than, the remainder of said outlet means.

[0021] To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

[0022] The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] One preferred form of the present invention will now be described with reference to the accompanying drawings in which;

[0024] **FIG. 1** is a block diagram of a humidified continuous positive airway pressure (system) as might be used in conjunction with the present invention,

[0025] **FIG. 2** is an illustration of the nasal mask in use according to the preferred embodiment of the present invention,

[0026] **FIG. 3** is a side elevational view of the mouthpiece as being used by a patient,

[0027] **FIG. 4** is a perspective view from above of the mouthpiece,

[0028] **FIG. 5** is a perspective view from one side and from an inward direction of the mouthpiece of **FIG. 4**,

[0029] **FIG. 6** is a cross-section of the mouthpiece of **FIG. 4**,

[0030] **FIG. 7** is a cross-sectional view of the mouthpiece of **FIG. 4** and a user with the mouthpiece in place to demonstrate the location and positioning thereof in relation to the main features of the user's anatomy,

[0031] **FIG. 8** is a perspective view of the mouthpiece with the outer flap in place,

[0032] **FIG. 9** is a perspective view of the outer flap bent back,

[0033] **FIG. 10** is a cutaway view of the mouthpiece with the outer flap in use,

[0034] **FIG. 11** is a perspective view of the outer flap including the ventilation apertures and moisture barrier,

[0035] **FIG. 12** shows the outlet vent sleeve installed on the elbow,

[0036] **FIG. 13** shows the outlet vent sleeve in isolation,

[0037] **FIG. 14** shows the elbow in isolation,

[0038] **FIG. 15** shows the one piece elbow outlet vent interior,

[0039] **FIG. 16** shows the one piece elbow outlet vent exterior,

[0040] **FIG. 17** shows a cross section of the mouthpiece with a dispersing filter,

[0041] **FIG. 18** shows a perspective view of the mask with cushion,

[0042] **FIG. 19** is a cuttaway view of the mask showing the cushion,

[0043] **FIG. 20** is a cuttaway view of the periphery of the outer membrane,

[0044] **FIG. 21** is a cuttaway view of the periphery of the mask body portion,

[0045] **FIG. 22** shows a make with the forehead rest on a user, and

[0046] **FIG. 23** shows the forehead rest in isolation.

[0047] The present invention provides improvements in the delivery of CPAP therapy. In particular a patient interface is described which is quieter for the user to wear and reduces the side leakage as compared with the prior art. It will be appreciated that the patient interface as described in the preferred embodiment of the present invention can be used in respiratory care generally or with a ventilator but will now be described below with reference to use in a humidified CPAP system. It will also be appreciated that the present invention can be applied to any form of patient interface including, but not limited to, nasal masks, oral masks and mouthpieces.

[0048] With reference to **FIG. 1 a** humidified Continuous Positive Airway Pressure (CPAP) system is shown in which a patient **1** is receiving humidified and pressurised gases through a patient interface **2** connected to a humidified gases transportation pathway or inspiratory conduit **3**. It should be understood that delivery systems could also be VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. Inspiratory conduit **3** is connected to the outlet **4** of a humidification chamber **5** which contains a volume of water **6**. Inspiratory conduit **3** may contain heating means or heater wires (not shown) which heat the walls of the conduit to reduce condensation of humidified gases within the conduit. Humidification chamber **6** is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) which is in direct contact with a heater plate **7** of humidifier **8**. Humidifier **8** is provided with control means or electronic controller **9** which may comprise a microprocessor based controller executing computer software commands stored in associated memory.

[0049] Controller **9** receives input from sources such as user input means or dial **10** through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient **1**. The controller may also receive input from other sources, for example temperature and/or flow velocity sensors **11** and **12** through connector **13** and heater plate temperature sensor **14**. In response to the user set humidity or temperature value input via dial **10** and the other inputs, controller **9** determines when (or to what level) to energise heater plate **7** to heat the water **6** within humidification chamber **5**. As the volume of water **6** within humidification chamber **5** is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber **5** outlet **4** with the flow of gases (for example air) provided from a gases supply

means or blower **15** which enters the chamber through inlet **16**. Exhaled gases from the patient's mouth are passed directly to ambient surroundings in **FIG. 1**.

[**0050**] Blower **15** is provided with variable pressure regulating means or variable speed fan **21** which draws air or other gases through blower inlet **17**. The speed of variable speed fan **21** is controlled by electronic controller **18** (or alternatively the function of controller **18** could carried out by controller **9**) in response to inputs from controller **9** and a user set predetermined required value (preset value) of pressure or fan speed via dial **19**.

[**0051**] Nasal Mask

[**0052**] According to a first embodiment of the present invention the patient interface is shown in **FIG. 2** as a nasal mask. The mask includes a hollow body **102** with an inlet **103** connected to the inspiratory conduit **3**. The mask **2** is positioned around the nose of the user **1** with the headgear **108** secured around the back of the head of the patient **1**. The restraining force from the headgear **108** on the hollow body **102** and the forehead rest **106** ensures enough compressive force on the mask cushion **104**, to provide an effective seal against the patient's face.

[**0053**] The hollow body **102** is constructed of a relatively inflexible material for example, polycarbonate plastic. Such a material would provide the requisite rigidity as well as being transparent and a relatively good insulator. The expiratory gases can be expelled through a valve (not shown) in the mask, a further expiratory conduit (not shown), or any other such method as is known in the art.

[**0054**] Mask Cushion

[**0055**] Referring now to **FIGS. 18 and 19** in particular, the mask cushion **1104** is provided around the periphery of the nasal mask **1102** to provide an effective seal onto the face of the user to prevent leakage. The mask cushion **1104** is shaped to approximately follow the contours of a patient's face. The mask cushion **104** will deform when pressure is applied by the headgear **1108** to adapt to the individual contours of any particular user. In particular, there is an indented section **1150** intended to fit over the bridge of the user's nose as well as a less indented section **1152** to seal around the section beneath the nose and above the upper lip.

[**0056**] In **FIG. 19** we see that the mask cushion **1104** is composed of a inner foam cushion **1110** covered by an outer sealing sheath **1112**. The inner cushion **1110** is constructed of a resilient material for example polyurethane foam, to distribute the pressure evenly along the seal around the user's face. The inner cushion **1110** is located around the outer periphery **1114** of the open face **1116** of the hollow body **1102**. Similarly the outer sheath **1112** may be commonly attached at its base **1113** to the periphery **1114** and loosely covers over the top of the inner cushion **1110**.

[**0057**] In the preferred embodiment shown in FIGS. **19-21** the bottom of the inner cushion **1110** fits into a generally triangular cavity **1154** in the hollow body **1102**. The cavity **1154** is formed from a flange **1156** running mid-way around the interior of the hollow body.

[**0058**] The outer sheath **1112** fits in place over the cushion **1110**, holding it in place. The sheath **1112** is secured by a snap-fit to the periphery **1114** of the hollow body. In FIGS. **20-21** the periphery **1114** is shown including an outer bead **1158**. The sheath **1112** includes a matching bead **1159**, whereby once stretched around the periphery, the two beads engage to hold the sheath in place.

[**0059**] Forehead Rest

[**0060**] In the preferred embodiment of the present invention the nasal mask **2102** includes a hinged forehead rest **2106** (seen in **FIGS. 22 and 23**). The attachment of the forehead rest **2106** to the hollow body **2102** effectively allows the forehead rest **2106** to move freely in proximity to the user but with no lateral movement.

[**0061**] In one form shown in **FIG. 23**, pins **2130** are provided mounted on a base **2132** attached to the hollow body **2102**. These pins **2130** are co-axial within cylinders **21-31** mounted on a bridge member **2136**.

[**0062**] At the top end **2142** (around the user's forehead) of the bridge member **2136** harnessing slots **2138** are provided which allow straps from the headgear to be inserted to secure the mask to the headgear. For the user's comfort one or more resilient cushions **2140** are provided underneath the top end **2142** of the bridge member **2136**, which rest on the forehead of the user. The cushion **2140** might be constructed of silicon or any foam materials as is known in the art for providing cushioning.

[**0063**] For example the forehead rest **2106** described previously may include a weakened section **2130** at its base **2132** which allows the joining member **2136** to pivot from the hollow body **2102**. The bridge member extends up to the forehead of the user. In a further alternative the mask may include a vertical upwardly extending inlet. In this case the member **2136** is hinged at its base **2132** to either side of the inlet passage. Again the member would then extend to the forehead.

[**0064**] Alternatively any well-known form of hinge can be used to provide the pivoting action.

[**0065**] Mouthpiece

[**0066**] Now with reference to a further inlet embodiment of the present invention the patient interface **2** is shown in FIGS. **3** to **10** as a mouthpiece. In this embodiment, the mouthpiece **50** includes a vestibular shield **49** being a generally flat and generally rectangularly-shaped member in front elevation having a curved profile that reflects the curvature of a user's jaw and in turn the curvature of the labial vestibule region. A gases passageway extends through the vestibular shield from an inlet **51** to an outlet **52** in much the same way as with the earlier embodiments. In the preferred embodiment the inlet **51** is provided by a flattened oval-shaped connector **53**. The outlet **52** has an even more laterally extended flattened oval shape **54**. The major differences between the mouthpiece **50** and the embodiments described above are provided on the inner face of the vestibular shield. Most prominently, the mouthpiece **50** includes a tongue depressor **55** extending from the inner face of the vestibular shield **49**. The operation of the tongue depressor will be described further on with reference to **FIG. 5** The tongue depressor includes a vertical stiffening flange **56** centrally located on its upper surface and extending from the gases outlet **52**. In use gases flow easily around the stiffening flange **56** effectively bifurcating the gases outlet **52**. The tongue depressor **55** further includes a pair of vertically extending spacers **57** which in use may abut

against the roof of the wearer's mouth and ensure that the tongue cannot completely block the air passageway. In the mouthpiece **50** the sealing effect of the vestibular shield **49** against the lips of the user is enhanced by providing teeth abutments of significantly increased thickness than the raised area **20** of the earlier embodiments. In particular, an upper teeth abutment **58** and a lower teeth abutment **59** are provided, with the lower teeth abutment **59** protruding further from the inner face of the vestibular shield **49** than the upper teeth abutment **58**. This difference serves to match the typical over-bite of most users. The abutments **58** and **59** are not required to be wider than the gases outlet **52**.

[**0067**] A notch **60** is provided centrally in the upper edge of the vestibular shield **49** to accommodate the upper frenal attachment. A slight bead **61** is provided around the edge of the vestibular shield **49** for user comfort, with the vestibular shield **49** otherwise being very thin for additional suppleness.

[**0068**] Referring particularly to **FIG. 6**, in its preferred form the mouthpiece **50** is preferably formed by over-moulding a soft and supple material part **70** over a stiffer material part **67**. These can generally be termed the shield part and the passageway-forming insert. The passageway-forming insert preferably includes a pair of upper and lower vertical flanges **63** and **64** to fully engage within the supple material. The passageway-forming insert **67** includes the vertically extending stiffening flange **56** of the tongue depressor **55**, together with a curved planar portion **71** forming the backbone of the tongue depressor **55**. The vertically extending spacers **57** are of the soft and supple material and are part of the over-moulding **70**, a§are the upper and lower teeth abutments **58** and **59**.

[**0069**] Referring now to **FIG. 7**, use of the mouthpiece according to FIGS. **4** to **6** is depicted. With the present mouthpiece **50**, the upper and lower lips **85**, **86** are further distended by the abutment action of the abutments **75**, **76** against the upper and lower teeth **87**, **88** respectively, thus forming a seal of greater pressure between the lips **85**, **86** and the upper and lower portions respectively of the vestibular shield **49**. A lower face **77** of the tongue depressor **55** impinges if necessary on the upper surface **72** of the tongue **85** and retains the tongue in the lower portion of the mouth. This ensures a clear gases outlet **52** from the gases passageway through the vestibular shield. The vertically extending spacers **57**, if forced by pressure from the tongue, will engage against the roof of the user's mouth and maintain a clear air passageway. This stops the sleeping patient unconsciously blocking the oral passageway and reverting to nasal breathing.

[**0070**] Referring now to **FIG. 8** of the present invention is illustrated including an extra-oral sealing flap **110**. The flap **110** in its natural bias is tapered, the wide open end of which is shaped to conform to the facial contours around the outside of the mouth of a user. The narrow end joins to a cylindrical section, which is designed to slide over the inlet port **114** of the mouthpiece **112**. While this is one method of attachment the flap **100** might also be constructed as an integral part of the mouthpiece **112**. The flap **110** needs to be constructed of flexible material, therefore materials such as silicone rubber can be employed to fashion the flap.

[**0071**] The outer flap **110** is seen in **FIG. 9**, in a bent back position. It will be appreciated that when the mouthpiece **112** is being inserted into the mouth of a user, the outer flap **110** is intended to be in this bent back position to aid insertion. Prior to insertion, the outer flap is bent back by simply pressing on its outer periphery **116**, until it snaps into the bent back position, in which it will stay unaided.

[**0072**] In **FIG. 10** we see the outer flap **110** in use with the mouthpiece **112** in the mouth **117** of a user **120**. Once correctly positioned in the mouth **116**, the outer flap **110** may be adjusted into its operational position by pressing on its outer periphery **116** until it snaps back to press against the outside of the mouth **118**. Due to the relative position of the vestibular shield **122** and the outer flap **110**, the outer flap **110** is unable to fully reach its natural bias and thereby inflicts a compressive force on the outside of the mouth **118**.

[**0073**] It will be appreciated that as well as providing a substantially airtight seal the addition of the outer flap provides enough compressive force on the mouth to keep the mouthpiece and conduit in place without the need for straps. This allows the administering of CPAP therapy to be considerably less obtrusive than traditional methods.

[**0074**] In a further additional improvement shown in **FIG. 11**, the outer flap **300** is shown in perspective. Included are ventilation apertures **302**, **303** either side of the gases port **304**, which are surrounded by a ridge **306** acting as a moisture barrier. The apertures **302**,**303** are provided such that any excess moisture leaking from the mouth will migrate to the apertures where they may evaporate. Small vents in the conduit may be used to direct small amounts of pressurised gas at the apertures to aid evaporation. The ridge **306** is included to ensure that no moisture migrates further into the sealing region **308**, as this would be detrimental to the sealing properties of the flap.

[**0075**] Interface Connection

[**0076**] Attention is now directed to **FIG. 3**. It has been found that an additional factor in the effectiveness of any patient interface **2**, is the manner in which the interface is connected to the breathing circuit **41**. The weight of the breathing circuit **41**, and any attempted movement of one other of the breathing circuit **41** and the interface **2** relative to the other, is one of the largest influences tending to dislodge the interface **2**. It must be noted that the interface **2** must remain in position and maintain a seal during all sleep, when the user has no muscle tone.

[**0077**] The connection **40** as provided in the present invention between the breathing circuit **41** and the interface **2** decouples the interface **2** from the breathing circuit **41**. As a result, the connection **40** is effective in reducing the forces placed on the interface **2** by the breathing circuit **41** when the user moves around during sleep. In the preferred sleeping position, the breathing circuit **41** is laid across the chest **43** of the user, and may be secured to the user's bed clothes or sleeping garments. The breathing circuit **41** is preferably laid on the chest of the user to take the weight of the breathing circuit **41** off of the interface **2**.

[**0078**] To connect between the gases outlet **14** which is vertical when the user is laying on his or her back and the breathing circuit **41** which is generally horizontal, an L-shaped elbow **45** is incorporated in the connection **40**. The elbow **45** may be incorporated in the interface **2**. The elbow **45** is formed at a right angle and provides a positive pressure on the interface **2**. The elbow **45** may include a swivel joint

and may be disconnected from gaseous outlet **42**. The connection **40** further includes an extremely flexible connecting tube **46** provided between the elbow **45** and the breathing circuit **41**. The connecting tube **46** is preferably connected to the breathing circuit **41** by a swivel joint **48** for reasons described herein. The breathing circuit **41**, while flexible, will necessarily be stiff enough to maintain its integrity over comparatively long tuns, while the connecting tube **46**, being only a short length, for example **10** centimetres, merely has to span between the user's mouth and chest, and can thereby be made in a manner that would not be suitable for long runs. Furthermore, as a result of the short length of the connecting tube **46**, the connecting tube **46** does not need to incorporate significant insulation or heating capability. The connecting tube **46** may be formed from a thin plastic membrane supported over a helical or double helical or corrugated supporting ribs. In such a case, the support makes the connection tube **46** laterally flexible and resistant to torsion. The elbow swivel joint **45** allows for movement of the connection tube **46** relative to the interface **2**. The swivel joint **48** allows for movement of the connection tube **46** relative to the breathing circuit **41**. It is to be understood that one or both of the swivel joints **45**, **48** could be eliminated, but the preferred embodiment includes swivel joint **48**.

[**0079**] Outlet Vent

[**0080**] The present invention will now be described with reference to the various different embodiments previously described. In order to reduce the noise caused by expiratory gases being expelled from the patient interface **2**, the present invention is illustrated in FIGS. **12** to **17** with the elbow connector (previously designated as **45**) including an outlet vent. It would be appreciated by one skilled in the art that the elbow connector as described herein will be equally applicable to all proceeding embodiments and all other forms of patient interface for delivering CPAP therapy.

[**0081**] Referring particularly now to FIGS. **12** to **14**, the elbow connector is illustrated including a flexible sleeve **400** which fits overtop of the elbow connector. The sleeve **400** is preferably constructed of silicon) but it will be appreciated by one skilled in the art that a number of other flexible materials will be equally applicable. The sleeve **400** includes locating indents **402** which once installed on the elbow connector match up with and lock into locating notches **404** on the elbow connector. The location is necessary so that the outlet aperture **406** in the elbow connector always matches up with the outlet vents **408** in the outlet sleeve **400**. This then prevents the undesirable situation where the sleeve could slip and the outlet vents **408** not match up with the outlet aperture **406** with resulting consequences to the patient.

[**0082**] Referring now to **FIGS. 15 and 16**, the present invention is shown with a one-piece elbow. In this case the elbow is preferably constructed of either "Hytrel" plastic or polycarbonate. In this fashion the elbow connector is manufactured to have a thin portion **410** surrounding the outlet vents **412** in comparison to the remainder of the elbow connector which is considerably thicker. The properties of the material chosen for the elbow connector are such that its flexibility is dependent on its thickness. Therefore in the thin section **410** the elbow connector is relatively flexible and in the remainder is relatively rigid. Accordingly the outlet vents **412**, which are also rounded on their periphery are formed in a flexible portion, and therefore achieve the desirable low noise properties when expiratory gases are vented therethrough.

[**0083**] Flow Diffuser

[**0084**] Referring now particularly to the use of mouthpieces, a further improvement is shown in **FIG. 17**. It is documented that when CPAP therapy is delivered to patients they often complain of drying of the airways and resulting irritation and discomfort. In particular when a concentrated airflow of under humidified gases flows past the oral or nasal cavities, or the airway of the user then drying and irritation may occur. Accordingly the present invention as illustrated in **FIG. 17** includes a mouthpiece with a flow diffuser **500**.

[**0085**] As described in the preceding embodiments, the mouthpiece sits with a vestibular shield **502** between the gums **504** and the lips **506** of a user. An outer flap **508** provides compressor force on the lips **506** to keep the mouthpiece in place in the user's mouth. Again the mouthpiece includes a tough depressor **510** extending into the user's oral cavity.

[**0086**] In the preceding embodiments the delivered gases would flow through passageway **512** in the mouthpiece, causing a relatively concentrated flow of gases to flow through the oral cavity and down the airway. With the flow diffuser **500** fitted overtop of the passageway **512** the flow is defused over the much larger area of the diffuser **500**, and therefore both the speed and side effects are reduced.

[**0087**] Alternatively the space between the passageway **512** and the diffuser **500** could be filled with a Humidity Moisture Exchange (HME) material. This would allow moisture through on the inspiratory flow put prevent it passing out an expiration. This would further prevent against the patient's passageways drying out. Further, if the HME material was in the form of foam, then it might also act as the diffuser **500**. It will also be appreciated that the HME material could be used in the space **516** all the way out to the elbow connector (not shown) to maximise its effect.

[**0088**] It will be appreciated that by providing such a system the present invention effectively minimises the noise generated by the outward flow of expiratory gases from the mask. The present invention requires little or no maintenance. The present invention also provides a flow diffuser for use with the mouthpiece, which reduces any side effects of orally delivered CPAP therapy and improves user comfort.

The invention claimed is:

1. A mouthpiece for delivering a supply of gases to a user from a breathing assistance apparatus comprising:

engagement means adapted to in use juxtapose said mouthpiece in or about the oral cavity of a user and substantially seal thereabouts,

a conduit adapted to fluidically communicate a breathing assistance apparatus with the oral cavity of a user, and

diffusing means adapted to be in fluid communication with said conduit and located substantially within, and delivering said supply of gases in a substantially diffused manner to, the oral cavity of a user.

2. A mouthpiece for delivering a supply of gases to a user as claimed in claim 1 wherein said conduit includes an inlet, in use fluid communication with said supply of gases, and an outlet in fluid communication with said inlet, said diffusing means including a diffusing material engaged over said outlet in use through which said gases pass and are thereby discharged in a diffused manner.

3. A mouthpiece for delivering a supply of gases to a user as claimed in claim 2 wherein said diffusing material comprises a portion of porous material in use through which said gases pass.

4. A mouthpiece for delivering a supply of gases to a user as claimed in claim 3 wherein said porous material is material chosen from those known to have heat and moisture exchanging properties.

5. A mouthpiece for delivering a supply of gases to a user as claimed in claim 4 wherein said material substantially allows moisture to pass inwardly from said conduit to, but prevents egress outwardly from, the oral cavity of a user.

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