



Office de la Propriété  
Intellectuelle  
du Canada

Un organisme  
d'Industrie Canada

Canadian  
Intellectual Property  
Office

An agency of  
Industry Canada

CA 2817613 A1 2013/12/05

(21) **2 817 613**

(12) **DEMANDE DE BREVET CANADIEN**  
**CANADIAN PATENT APPLICATION**

(13) **A1**

(22) Date de dépôt/Filing Date: 2013/06/04

(41) Mise à la disp. pub./Open to Public Insp.: 2013/12/05

(30) Priorités/Priorities: 2012/06/05 (US61/655,623);  
2013/03/14 (US13/831,239)

(51) Cl.Int./Int.Cl. *A62B 18/02* (2006.01),  
*A62B 18/08* (2006.01)

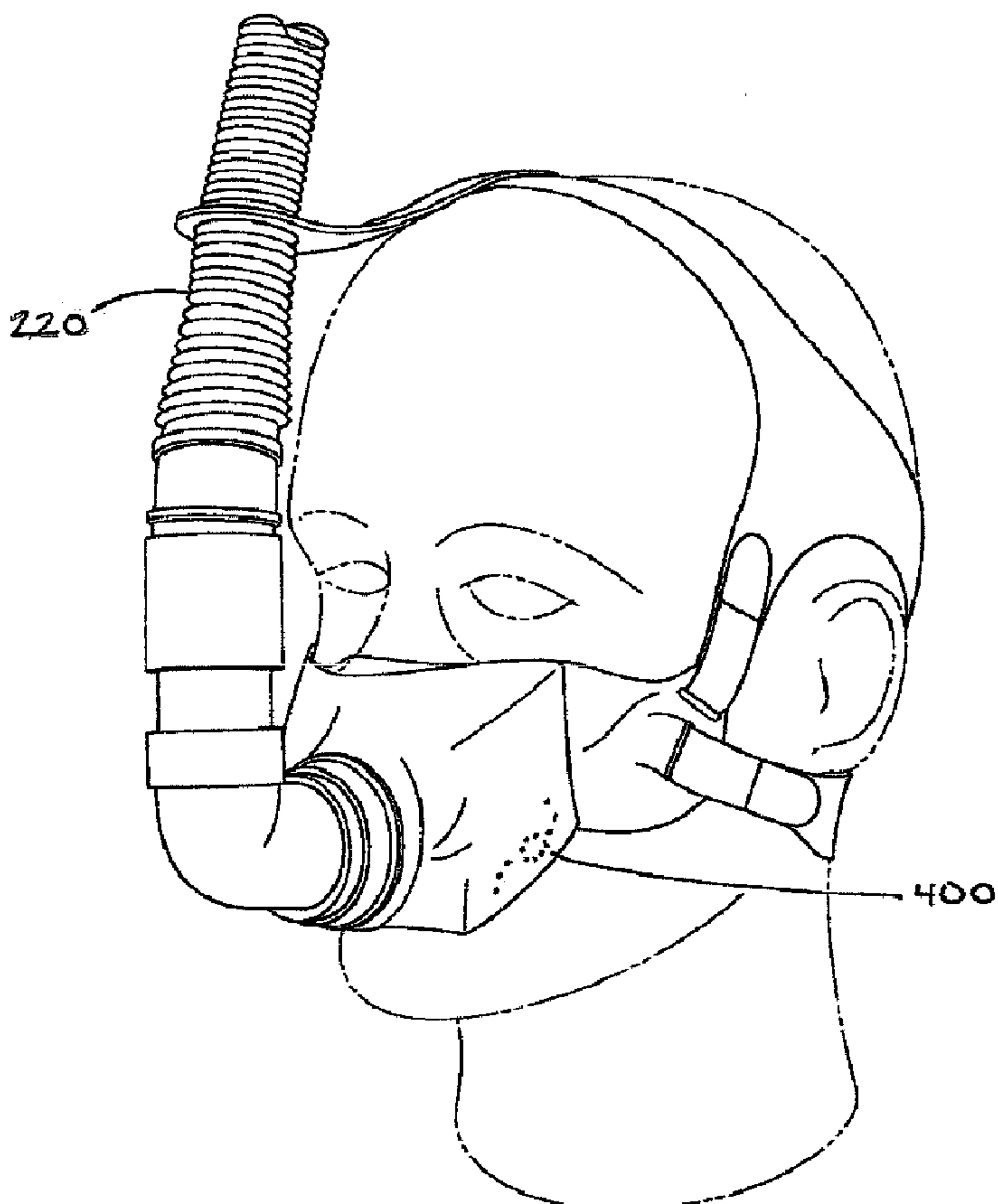
(71) Demandeur/Applicant:  
CIRCADIANCE, LLC, US

(72) Inventeurs/Inventors:  
GROLL, DAVID, US;  
MAHOFSKI, RONNIE E., US;  
SCANDINARO, NADINE, US

(74) Agent: MARKS & CLERK

(54) Titre : MASQUE RESPIRATOIRE AMELIORE AVEC CORPS EN TOILE JETABLE

(54) Title: IMPROVED RESPIRATORY MASK WITH DISPOSABLE CLOTH BODY



(57) Abrégé/Abstract:

The invention is a frameless, disposable cloth body for use with a respiratory mask, such as for continuous positive airway pressure therapy for those having sleep apnea. The cloth body is inflatable and moisture-vapor breathable and has an inner side having a

## (57) Abrégé(suite)/Abstract(continued):

nasal interface portion disposed on it and an outer side, and also has a circular aperture formed in a central location on the body, sized to sealingly receive an air delivery arrangement. The cloth body also has a pair of wings on opposite sides with slits arranged at optimal angles for receiving headgear straps.

**Abstract**

The invention is a frameless, disposable cloth body for use with a respiratory mask, such as for continuous positive airway pressure therapy for those having sleep apnea. The cloth body is inflatable and moisture-vapor breathable and has an inner side having a nasal interface portion disposed on it and an outer side, and also has a circular aperture formed in a central location on the body, sized to sealingly receive an air delivery arrangement. The cloth body also has a pair of wings on opposite sides with slits arranged at optimal angles for receiving headgear straps.

## **IMPROVED RESPIRATORY MASK WITH DISPOSABLE CLOTH BODY**

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

**[0001]** This patent application is a continuation-in-part and claims priority from pending U.S. Application Serial No. 12/070,463, filed February 19, 2008 and pending U.S. Patent Application Serial No. 12/905,404, filed October 15, 2010. This application also claims priority to Provisional Patent Application 61/655,623, filed June 5, 2012. The entire specifications of all three applications are incorporated by reference herein.

### **FIELD OF THE INVENTION**

**[0002]** The present invention relates, in general, to equipment used in the treatment of sleep apnea and other respiratory ailments and, more particularly, the instant invention relates to an improved nasal cloth body for an apparatus to deliver a fluid pressure to a patient in order to maintain the patient's airway open while sleeping and deliver oxygen to such patient.

### **BACKGROUND OF THE INVENTION**

**[0003]** As is well known in the medical field, sleep apnea is a disorder that affects more than 12 million people in the United States alone. It takes its name from the Greek word apnea, which means "without breath." People with sleep apnea literally stop breathing repeatedly during their sleep, often for a minute or longer, and as many as hundreds of times during a single night.

**[0004]** Sleep apnea is known to be caused by either complete obstruction of the airway (obstructive apnea) or partial obstruction (obstructive hypopnea), both of which can cause the person suffering from such sleep apnea to wake up, temporarily, in order to breathe.

There are three types of sleep apnea--obstructive, central, and mixed. Of these, obstructive sleep apnea (OSA) is the most common. OSA occurs in approximately 2 percent of women and 4 percent of men over the age of 35.

**[0005]** The exact cause of OSA remains unclear. The site of obstruction in most patients is the soft palate, extending to the region at the base of the tongue. There are no rigid structures, such as cartilage or bone, in this area to hold the airway open. During the day, muscles in the region keep the passage wide open. But as a person with OSA falls asleep, these muscles relax to a point where the airway collapses and breathing becomes impossible. When breathing stops, the sleeper partially awakens, involuntarily tenses the muscles in the region to open the airway in order to breathe, and falls back asleep. The arousal from sleep usually lasts only a few seconds, but these brief arousals disrupt continuous sleep and prevent the person from reaching the deep stages of slumber, such as rapid eye movement (REM) sleep, which the body needs in order to rest and replenish its strength. Even though normal breathing is restored when the person awakens briefly, the cycle is repeated throughout the night. Typically, the frequency of waking episodes is somewhere between 10 and 60, although a person with severe OSA may have more than 100 waking episodes in a single night.

**[0006]** Positive airway pressure has been demonstrated to be a very effective treatment for obstructive sleep apnea. It has three forms: continuous positive airway pressure (CPAP), autotitration, and bi-level positive airway pressure (BIPAP). While positive airway pressure is usually easier to tolerate at lower pressures, every patient requires a different pressure. In order to determine each individual patient's optimum airway pressure, it is necessary to titrate the pressure to each individual patient during a

polysomnogram. A polysomnogram will show not only when the respiratory events have ceased, but also when the arousals from the respiratory events occur.

**[0007]** CPAP, the most common of the three therapy modes, is usually administered at bedtime through a facial mask held in place by straps around the patient's head. The mask is connected by a tube to a small air compressor about the size of a shoe box. The CPAP machine sends air under pressure through the tube into the mask, where, assuming a good seal with the patient's face, it applies a positive air pressure to the upper airways. This positive air pressure essentially "splints" the upper airway open and keeps it from collapsing.

**[0008]** Approximately 55 percent of patients who use CPAP do so on a nightly basis for more than four hours. The advantages of CPAP are that it is very safe and completely reversible. Generally, the treatment is well tolerated; however, it suffers from the disadvantage that it requires active participation every night; that is, the patient must put it on for it to work. If the mask is ill-fitting or causes unwanted side effects, compliance will not be maintained.

**[0009]** Nasal CPAP Masks on the market today fall into one of three design categories. They are either nasal masks, full face masks (i.e., those which cover the mouth and nose) or nasal pillows. The vast majority of CPAP masks that are currently on the market are comprised of a rigid plastic frame buffered by an elastomeric, rubbery "cushion" that makes the actual contact with the patient's face. These masks are sealed to the patient's face by tightening straps that hold the mask to the patient's head to increase mechanical pressure against and into the skin of the face. The skin and tissue of the patient's face is compressed by the mask, which forms a "gasket" that creates a seal and keeps the air

pressure inside the mask elevated. Unfortunately, aside from being uncomfortable, a disadvantage to this approach is that the mechanical pressure applied to the patient's skin often exceeds the perfusion pressure in the tissue under the skin. Consequently blood flow to the tissue is diminished or cut off entirely. This leads to pain and can ultimately cause pressure sores on the patient's face. Additionally, it has been discovered that some of the masks, which use a silicone or a polyurethane gel to touch the face, have caused allergic reactions in some users.

**[0010]** These problems were largely overcome by the soft cloth mask disclosed in U.S. Patent Application Serial No. 12/070,463 (the “‘463 application”). The ‘463 application disclosed a nasal CPAP mask that was entirely comprised of a non-rigid, compliant material that had no fixed shape unless breathable gas at positive pressure was flowing into it. While the nasal mask of the ‘463 application remedied many of the drawbacks with then-existing masks , it still occasionally suffered from air leakage at the interface between the patient's nose and the mask, due largely to the manner in which the nasal interface was constructed. The air leakage was a problem for many reasons, including, reduction of positive pressure applied to the patient's airway, dry eyes from air blowing into them, disruption of sleep of bed partner caused by both blowing jets of air and noise associated therewith.

**[0011]** The problems with air leakage in masks constructed in accordance with the ‘463 application were largely remedied by the introduction of the nasal interface disclosed in U.S. Patent Application Serial No. 12/905,404 (the “‘404 application”); however, there remained a small population of mask users who still experienced some difficulty in getting the mask to fit properly. When the previously disclosed mask was tightened on a

user's face using the straps, the compliant material was occasionally stretched in a way that provided a less than optimal fit. Additionally, the mask of the '463 and '404 applications had a swivel connector that was affixed to the mask with tape, which made repeated cleaning of the mask challenging as re-taping the swivel to the inside of the mask required dexterity not possessed by all. Still further, the mask of the '463 and '404 applications included a headgear that connected to the mask from the top of the head, down across the forehead and between the eyes and to the bridge of the nose, which sometimes got in the way while the user was watching TV or reading a book. The mask of the '463 and '404 applications also included a swivel connector that allowed the air hose to rotate 360-degrees axially, but did not provide any angular freedom in that it only permitted the air hose to be directed downward away from the mask instead of providing the option to be directed sideways or upward toward the hairline of the user, for example. The present invention resolves the aforementioned problems.

#### **SUMMARY OF THE INVENTION**

**[0012]** It is, therefore, one of the primary objects of the present invention to provide a replaceable body portion, an improved nasal interface and headgear arrangement, an improved mechanism for detaching and attaching the swivel connector, a CPAP tube connector that allows 360° rotation of the tube to any placement preference of the user and a quieter exhalation system for an apparatus for communicating a positive fluid pressure to a patient's nasal and/or air passageways which has improved air sealing capability while still being more comfortable for the patient.

**[0013]** A further object of the present invention is to provide an apparatus for communicating a positive fluid pressure to a patient's nasal air passageways wherein

substantially all portions of the apparatus that touch a patient's face are made of a stretchy, composite, moisture-vapor breathable material that is substantially capable of conforming to the patient's facial features and in which there are no rigid parts to press against the patient's skin

**[0014]** In addition to the various objects and advantages of the present invention which have been described above, various other objects and advantages of the invention will become more readily apparent to those persons skilled in the relevant art from the following more detailed description of the invention, particularly, when such description is taken in conjunction with the attached drawing figures and with the appended claims.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

**[0015]** Fig. 1 is a perspective view of a CPAP mask of the present invention.

**[0016]** Fig. 2 is an exploded perspective view of the cloth body and air delivery arrangement of the present invention.

**[0017]** Fig. 3 is an illustration of the inner side of the cloth body illustrating the nasal interface portion of the present invention.

**[0018]** Fig. 4 is a cut-away portion of a headgear for use with the cloth body of the present invention.

**[0019]** Fig. 5 is a perspective view of the CPAP mask and headgear of the present invention on the head of a patient.

**[0020]** Fig. 6 is a perspective view of the CPAP mask and headgear of the present invention on the head of a patient.

## DETAILED DESCRIPTION OF THE DRAWINGS

[0021] Prior to proceeding to the more detailed description of the instant invention it should be noted that identical components having identical functions have been designated with identical reference numerals throughout the several views illustrated in the drawings for the sake of clarity.

[0022] As used in the present specification and claims, the term “cloth body” means that portion of the mask that inflates as a result of the delivery of air from a pump through a tube with a swivel connector, including that portion that actually makes contact with the patient’s nose and face when the CPAP mask is being used as intended.

[0023] As used in the present specification and claims, the term “compliant” means a material having very little rigidity such that it is easily bendable.

[0024] The term “inflatable” as used herein, means a material or a structure having two configurations: an uninflated configuration and an inflated configuration that is different from the uninflated configuration.

[0025] As used herein, the term “cloth” is meant to include natural and synthetic fiber cloth, treated cloth, laminates having a cloth base and cloth which is permeable or impermeable to air.

### The Cloth Body

[0026] Referring now to Figs. 1 and 2, a mask **10** of the present invention is illustrated fully assembled in Fig. 1 and in disassembled fashion in Fig. 2. Both figures illustrate a cloth body **30** and an air delivery arrangement **15**. More specifically, Fig. 2 shows a swivel connector base portion **20**, cloth body **30**, washer **40**, swivel connector clamping portion **50**, and elbow **60** that combine to form the mask in an embodiment. While the

swivel connector base portion **20** in the disclosed embodiment has a cylindrical projection **22** that is threaded to enable a tight connection with the connector clamping portion **50**, which is matingly threaded on an interior portion **52**, the washer **40** being insertable between the swivel connector base portion **20** and the clamping portion **50** to protect the cloth body material when the connector clamping portion is screwed onto the swivel connector base portion, and to form a more perfect airtight seal. As will be apparent to those of skill in the art, other means of connecting the clamping portion **50** and the base portion **20**, such as a snap fit arrangement, can be used.

**[0027]** Generally, the cloth body **30** has an inner side **32**, an outer side **34**, and a pair of wings **80**. Further, the inner side **32** includes a nasal interface portion **90** centrally disposed thereon. For assembly purposes, the cylindrical projection **22** is inserted through a circular aperture **70** formed in the cloth body **30**, from the inner side **32**, the aperture **70** having generally the same diameter as the cylindrical projection **22**. A flange **24** keeps the base portion **20** from passing all the way through the aperture **70**. As the flange **24** has generally the same outside diameter as the washer **40**, connecting the swivel connector base portion **20** with the clamping portion **50** in the manner described, yields an airtight seal for air delivery into the cloth body from an air hose **220** that, when in operation, is connected to the outermost portion **62** of the elbow **60**. Preferably, the elbow **60** comprises a three hundred sixty (360) degree swivel within the clamping portion **50** to permit an air hose **220** to be routed in multiple directions away from the cloth body **30**. The outermost portion **62** also rotates axially within the elbow **60** to prevent the air hose **220** from kinking.

[0028] The cloth body **30** is frameless and does not have any rigid parts or aspects, nor does it need to be inserted into a rigid frame in order to work properly. Instead, it is comprised of soft, flexible, compliant materials that are light and flimsy, which is naturally more comfortable for the user than rubbery, rigid or molded masks. This design allows the cloth body **30** to have two distinct configurations: uninflated when not in use, and inflated when pressurized air is flowing through the mask, such was when therapy is being provided. Of course, the inflated configuration is different than the uninflated configuration. This composition also results in a mask that is much lighter than prior art masks. The following table illustrates the differences in weight between the present invention and other “lightweight” masks currently on the market:

#### Weight Comparison

	Present Invention	Resmed – Mirage FX™	Respironics – Easy Life™ (Medium)
Mask & Headgear	1.505 oz	2.480 oz	3.685 oz
Mask Only	.735 oz	1.385 oz	2.520 oz
Patient Interface	.140 oz	.795 oz	1.505 oz

The “patient interface” row in the above table provides a comparison between the weight of the cloth body as presently disclosed and the weights of those portions of the Mirage FX™ and Easy Life™ masks that touch the user’s face, are replaceable, and which are generally described in the industry as “cushions”. Thus, it is clear that the fully assembled mask and headgear of the present invention is nearly 40% lighter than the Mirage FX and less than half the weight of the Easy Life. The comparison of the masks and patient interfaces is even more striking. This reduction in weight means a more comfortable

mask for the user, who has to wear it on their face a significant amount of time each night.

**[0029]** In a preferred embodiment, the majority of the cloth body **30**, excluding the nasal interface portion **90**, is comprised of an inelastic yet flexible composite material that is relatively impermeable to gas and is soft to touch. Preferably, this composite material is moisture-vapor breathable and comprised of a polyester cloth having a flexible coating such as a polyester or polyurethane film on the inner side **32**.

**[0030]** The construction of the present invention, therefore, enables easy replacement of the used cloth body portion, while permitting re-use of the more durable hard plastic swivel connector base portion **20**, washer **40**, swivel connector clamping portion **50**, and elbow **60**, which reduces waste and shipping costs.

**[0031]** Referring more specifically now to Fig. 3, the inner side **32** of the cloth body **30** is illustrated. In a preferred embodiment, a nasal interface portion **90** of the cloth body is designed to comfortably make contact with the nose and face of a user and is manufactured using an elastic moisture-vapor breathable material that is sewn or otherwise disposed onto the cloth body **30** from the inner side **32**.

**[0032]** As used herein, the term “moisture-vapor breathable” refers to a fabric or other material that allows water vapor to pass through it from one side to the other. Moisture-vapor breathable materials are used because it has been shown that very small amounts of moisture within or under a mask can create the sensation of discomfort in a patient. Often, a mere 3% to 5% of increase in humidity is enough to create discomfort. If liquid water from sweating or exhalation cannot be dissipated quickly, as is the case with prior art nasal masks that use a silicone or polyurethane gel that contacts the skin, the humidity

of the air in the space in between the skin and the cloth body rises. This increased humidity prevents rapid evaporation of liquid water on the skin and creates an increased sensation of heat, which, ironically, is what triggered the sweating in the first place. Consequently, the body responds with increased sweating to dissipate the excess thermal energy, which feeds into an unfortunate cycle of increased humidity and discomfort for the patient. The advantage of using a moisture-vapor breathable material, then, is that moisture and heat are wicked away from the skin as the cloth body is worn, which increases comfort, improves compliance, reduces heat, and reduces the moisture build-up at the cloth body contact area for the patient.

**[0033]** In a preferred embodiment, the elastic moisture-vapor breathable material used for the nasal interface portion **90** of the cloth body **30** of the present invention is a nylon and elastane (also referred to as Lycra<sup>®</sup>) combination with a polyurethane backing, which all together, is comprised of preferably seventy-two (72%) percent nylon (where the term nylon includes both the stretchy elastane and the nylon) and twenty-eight (28%) percent polyurethane. Further describing this preferred material, it weighs 138 grams per square meter, has waterproofness of 10,000 millimeters of water, and has tear strength of 18.4 Newtons x 11.6 Newtons. Additionally, the moisture-vapor breathable material of the preferred embodiment has a moisture permeability of a range of approximately fifteen thousand to thirty-eight thousand (38,000) grams per meter squared per 24 hours using the Inverted Cup test JIS-L 1099 B-1.

**[0034]** In an alternative embodiment, the material used for the nasal interface portion **90** comprises fifty-six (56%) percent nylon, twenty-two (22%) percent elastane and twenty-two (22%) percent polyurethane. Further describing this material, it weighs 90

grams per square meter, has a moisture-vapor breathability transmission rate of 8,000 grams per meter squared per 24 hours using the ISO 15496 measurement method, a water proofness of greater than 10,000 millimeters of water using ISO 811 and has a breaking strength of 200 Newtons measured using the ISO 13934/1 test method. Other combinations of materials that accomplish the same task, however, will be apparent to those of skill in the art.

**[0035]** With continued reference to Fig. 3, the nasal interface portion **90** comprises at least a nose cradling portion **94** and an upper lip portion **96**, each such portion having a first vertical edge **91** and a second vertical edge **93**. The linear amount of material, measured laterally, from the first vertical edge **91** to the second vertical edge **93** is greater for the nose cradling portion **94** than for the upper lip portion **96** in order to comfortably and fittingly accommodate the patient's nose when the cloth body **30** is worn. The shape that is created by the combination of the nose cradling portion **94** and the upper lip portion **96**, in conjunction with the elastic and stretchy quality of the material will cause it to naturally conform to the patient's nose as opposed to being stretched over the nose in an overly taut and uncomfortable manner. Additionally, the upper lip portion **96** has at least one wrapped section **98** that provides a soft contact point with the user's upper lip and is loosely and slidingly sleeved around an inner section **99**, which provides a mechanism for increased width of the cloth body without sacrificing comfort. When the upper lip portion is stretched, such as with users with wider faces, the inner section becomes firmer than other portions of the mask and the wrapped section protects the user's upper lip against this firmness for additional comfort.

[0036] When the CPAP machine is turned on and the mask is in place on a user, the air pressure will build in the mask and inflate the cloth body **30** and, in conjunction with the headgear **140**, cause the nasal interface portion **90** to gently and evenly push against the patient's skin to create the necessary seal. In this manner, it can be seen that the addition or removal of air pressure causes the cloth body to move between two different configurations: an uninflated configuration and an inflated configuration.

**The Exhalation System**

[0037] A CPAP mask must have an exhalation system in order to facilitate the removal of carbon dioxide exhaled by the user. The cloth body **30** of the present invention has seams **200** where pieces of fabric have been stitched together with thread and these seams **200** function as part of the exhalation system in order to obtain an appropriate leak rate while still maintaining a minimal noise level so that the user's bed partner is not disturbed. Since each stitch is created by making a tiny hole in the fabric for the stitch and pulling the two separate pieces of fabric tightly together, the leak rate of a cloth body **30** can be modified by adjusting the length of fabric sewn together along with the number of stitches per inch to create the cloth body **30**. In a preferred embodiment, then, it has been determined that the optimal leak rate is achieved through the use of between 6 and 30 stitches per inch over a seam length of between 16 and 22 inches in the cloth body **30**, plus the use of a plurality of exhalation apertures **400**. It has been discovered that the larger the cloth body, the longer the seams are and the fewer exhalation apertures are needed. So, in an embodiment for a large mask, a number of apertures in the range of 30 are necessary to provide the optimal exhalation rate for a given therapeutic pressure whereas a smaller mask requires more, such as a number in the range of 110 apertures,

for the same therapeutic pressure and exhalation rate. In embodiments, the number of exhalation apertures can range from ten (10) to one hundred fifty (150) with each individual aperture being in a range of 0.004 and 0.006 inches in diameter. Further, while the exhalation apertures **400** illustrated in Fig. 5 are on the side of the cloth body, it is preferable that they be placed on the bottom to minimize the chance of any air being blown on a sleeping partner.

*The Wings and Headgear*

[0038] Referring now to Figs. 3 through 6, wings **80** are laterally disposed on the body on both sides of the nasal interface portion **90** in order to connect the cloth body **30**, and correspondingly the mask **10**, to the headgear **140** to achieve the best fit possible. The wings each have a distal edge **85** and, in a preferred embodiment, an outer slit **100** disposed generally parallel to the distal edge **85** and an inner slit **110** tilted at an angle of approximately seventy (70) degrees from parallel with an upper terminus of the inner slit **110** being closer to the outer slit **100** than a lower terminus of the inner slit **110**. The purpose of the slits **100, 110** is to slidingly receive a first headgear strap **120** and a second headgear strap **130** on a headgear **140** in order to provide the best possible fit without compromising the seal. In a preferred embodiment both headgear straps have hook and loop fastening systems **150** disposed thereon for ease of adjustment as is well-known in the art.

[0039] The wings **80** are made of a heavier material than the rest of the cloth body and can be manufactured with polyurethane foam coated with a nylon, by way of example, or in an alternative embodiment, can be reinforced by doubling up the material used for the body. In one embodiment, two pieces of composite material used for the body are heated

at four hundred twenty-five (425) degrees for 7 seconds with a pressure setting of 7 on a George Knight DK-76 Heat Press so that they are heat welded together and the resulting heat welded material is use for the wings. As will be apparent to those of skill in the art, other means of bonding and/or other process settings can be used to bond two pieces of fabric. With this stronger material, the wings do not collapse or fold when the headgear straps are tightened by the user. The stronger material also has the effect of decentralizing pressure points and optimizing fit.

**[0040]** When worn, the first headgear strap **120** is slid by the user through the outer slit **100** and the second headgear strap **130** is slid through the inner slit **110** and both headgear straps are then adjusted until the user is comfortable. The angles of the slits have been intentionally chosen so that the first headgear strap **120** that is slid through the outer slit **100** substantially controls the vertical height of the mask on the user's face; whereas the second headgear strap **130** that is fed through the inner slit **110** substantially controls the tightness of the mask on the user's face. The hook and loop fastening system is color coded to ensure both headgear straps are placed in the appropriate slits. In embodiments, different headgear strap sizes may also be used to ensure they are inserted through the appropriate slits. The headgear is designed so the headgear straps curve above and below the ear in order to maintain maximum comfort and provide optimum nasal mask support. Additionally, the wings **80** are curved to ensure the wearer's eyes are not covered or interfered with.

**[0041]** Surprisingly, this headgear **140** eliminates the need for a strap that travels from the top of the mask, up the bridge of the nose and between the eyes to the top of the head, thus increasing the types of activities a wearer can comfortably participate in while

undergoing treatment, but before falling asleep. Once the wearer decides to go to sleep, however, a tether strap **300** can be attached to the air hose **220** at a first end **310** and removably disposed on the headgear **140** at a second end **320** in order to allow the patient to have the tube placed directly over their head while sleeping, if desired. In a preferred embodiment, the tether strap **300** has sufficient rigidity to keep the air hose **220** from touching the user's face while he or she is sleeping on their back and also has a hole formed therein that is slightly smaller than the air hose **220** at the first end **310** so that the air hose **220** can be frictionally held stationary in relation to the tether strap **300**. In an embodiment, the tether strap is comprised of polyurethane foam coated with a nylon and lycra combination and is attached to the headgear via a hook and loop fastening system.

**[0042]** If not otherwise stated herein, it is to be assumed that all patents, patent applications, patent publications and other publications (including web-based publications) mentioned and cited herein are hereby fully incorporated by reference herein as if set forth in their entirety herein.

**[0043]** While in accordance with the patent statutes the presently preferred and various alternative embodiments of the instant invention have been described in detail above, it should be understood that various other modifications and alternatives can be envisioned by those persons skilled in the art without departing from either the spirit of the invention or the scope of the appended claims.

What is claimed is:

1. A frameless inflatable respiratory mask comprising:  
a cloth body having a circular aperture, an inner side and an outer side, the body further having a pair of wings disposed on opposite sides laterally; an air delivery arrangement adapted to sealingly deliver air through the circular aperture; an exhalation system disposed on the mask; and a headgear for securing and adjusting the mask on a user's head adjustably disposed on the wings; whereby air that is delivered to the mask via the air delivery arrangement inflates the cloth body to enable air to be delivered at a therapeutic pressure.
2. The frameless inflatable respiratory mask of claim 1, wherein the cloth body is manufactured with an inelastic yet flexible material.
3. The frameless inflatable respiratory mask of claim 2, wherein the wings are comprised of two layers of the material.
4. The frameless inflatable respiratory mask of claim 1, wherein the wings are comprised of a heavier material that is thicker than the inelastic yet flexible material.
5. The frameless inflatable respiratory mask of claim 2, wherein the material is a polyester cloth.
6. The frameless inflatable respiratory mask of claim 2, wherein the material has an impermeable to air coating.
7. The frameless inflatable respiratory mask of claim 6, wherein the coating is either a polyester film or a polyurethane film.
8. The frameless inflatable respiratory mask of claim 1, wherein the cloth body shape is created by sewing the body together with thread, the sewing creating seams in the body.

9. The frameless inflatable respiratory mask of claim 1, wherein the cloth body has a first uninflated configuration and a second inflated configuration different than the first uninflated configuration.
10. The frameless inflatable respiratory mask of claim 1, wherein the cloth body further has a nasal interface portion disposed on the inner side.
11. The frameless inflatable respiratory mask of claim 10, wherein the nasal interface portion is manufactured with an elastic moisture-vapor breathable material.
12. The frameless inflatable respiratory mask of claim 11, wherein the elastic moisture-vapor breathable material is a combination of nylon, elastane and polyurethane.
13. The frameless inflatable respiratory mask of claim 10, wherein the nasal interface portion comprises a nose-cradling portion and an upper lip portion wherein the amount of material measured laterally for the nose-cradling portion is greater than the amount of material used for the upper lip portion.
14. The frameless inflatable respiratory mask of claim 13, wherein the upper lip portion comprises at least one wrapped inelastic section loosely sleeved around the upper lip portion.
15. The frameless inflatable respiratory mask of claim 1, wherein the air delivery arrangement is removably sealed to the cloth body.
16. The frameless inflatable respiratory mask of claim 1, wherein the air delivery arrangement is sealed to the cloth body with a threaded projection that passes from the inner side through the aperture and connects to a clamping portion on the outer side.
17. The frameless inflatable respiratory mask of claim 1, wherein the exhalation system comprises a plurality of apertures in the cloth body.

18. The frameless inflatable respiratory mask of claim 17, wherein the exhalation system further comprises the seams.
19. The frameless inflatable respiratory mask of claim 1, wherein the headgear further comprises a tether strap with a first end disposed on the headgear and a second end forming an aperture to frictionally receive an air hose therethrough, the strap being of sufficient rigidity to keep the air hose at least a predetermined distance away from the user's face.
20. The frameless inflatable respiratory mask of claim 1, wherein the wings each have a distal edge, each distal edge having a plurality of slits formed therein for receiving headgear straps.
21. The frameless inflatable respiratory mask of claim 20, wherein an outer slit is oriented parallel to the distal edge for receiving an upper strap and an inner slit adjacent to the outer slit, oriented at an angle to the outer slit to receive a lower strap.
22. The frameless inflatable respiratory mask of claim 21, wherein the angle is substantially seventy degrees.
23. The frameless inflatable respiratory mask of claim 20, wherein the headgear straps curve around the ear and the wings curve under the eyes to be more comfortable for the user.
24. The frameless inflatable respiratory mask of claim 1, wherein the headgear further comprises a tether strap having sufficient stiffness to keep an air hose substantially away from the user's face during CPAP therapy.
25. A disposable body for a respiratory mask comprising a cloth body having an inner side, an outer side, the cloth body forming a circular aperture sized to sealingly receive an

air delivery arrangement; a pair of wings disposed on opposite lateral sides of the body for receiving headgear straps; and a nasal interface portion disposed on the inner side of the cloth body for securely cradling a nose of a user.

26. A kit comprising:

one or more disposable cloth bodies having an inner side, an outer side, an aperture formed in the bodies, a pair of wings disposed on opposite lateral sides of the bodies for receiving headgear straps; and a nasal interface portion disposed on the inner side of the cloth bodies for securely cradling a nose of a user, and packaging capable of housing one or more cloth bodies.

27. A method of delivering air at a therapeutic pressure to a patient comprising:

providing a respiratory mask having cloth body forming a circular aperture, an inner side, and an outer side, the body further having a pair of wings disposed on opposite sides laterally, an air delivery arrangement adapted to sealingly deliver air through the circular aperture; an exhalation system disposed on the mask, and a headgear for securing and adjusting the mask on a user adjustably disposed on the wings; whereby air that is delivered to the mask via the air delivery arrangement inflates the cloth body to enable air to be delivered at a therapeutic pressure;

securing the respiratory mask to the user such that the respiratory mask covers a nose of the patient; and

delivering air to the patient via the mask.

(1/6)

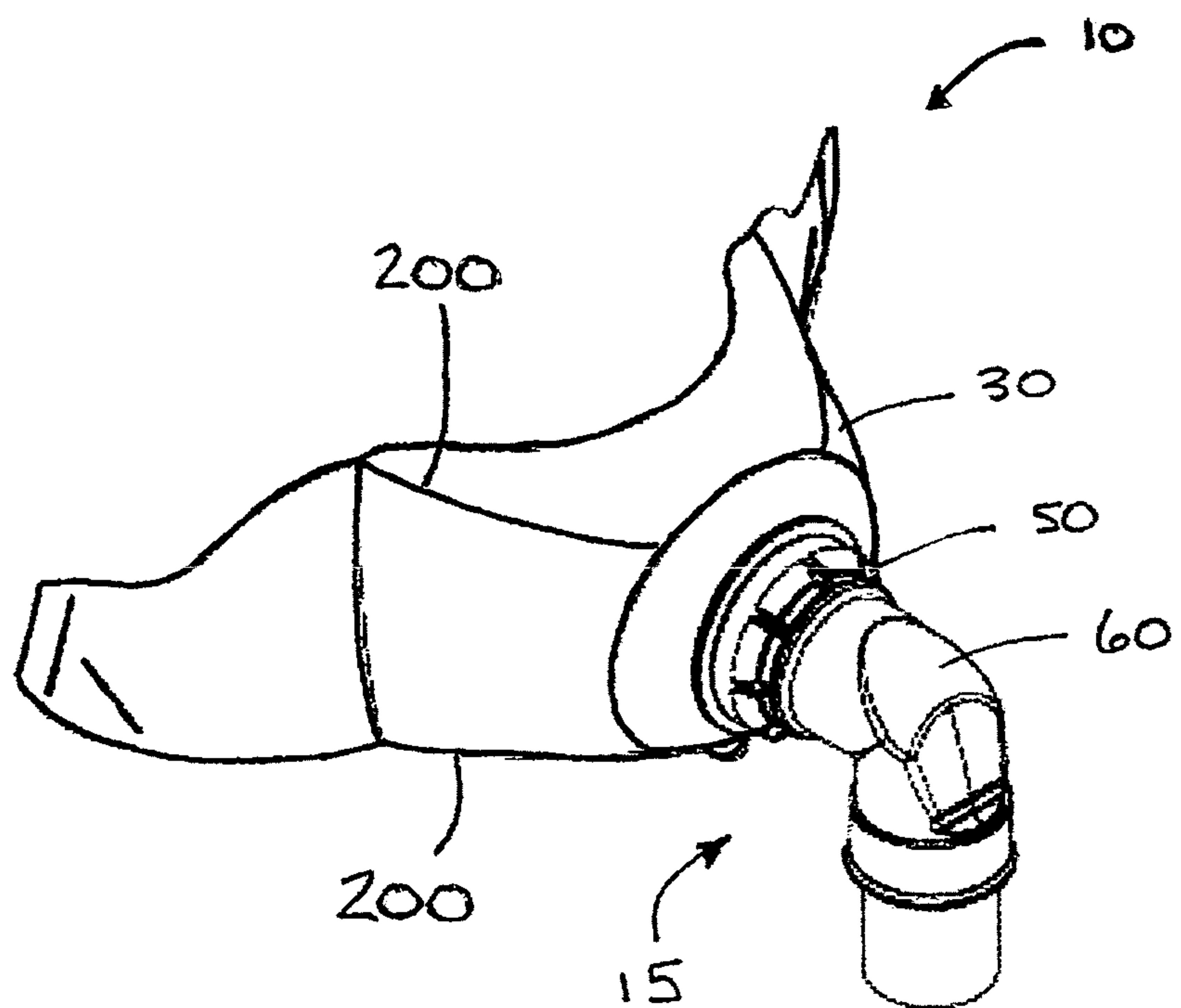


FIG. 1

(2/6)

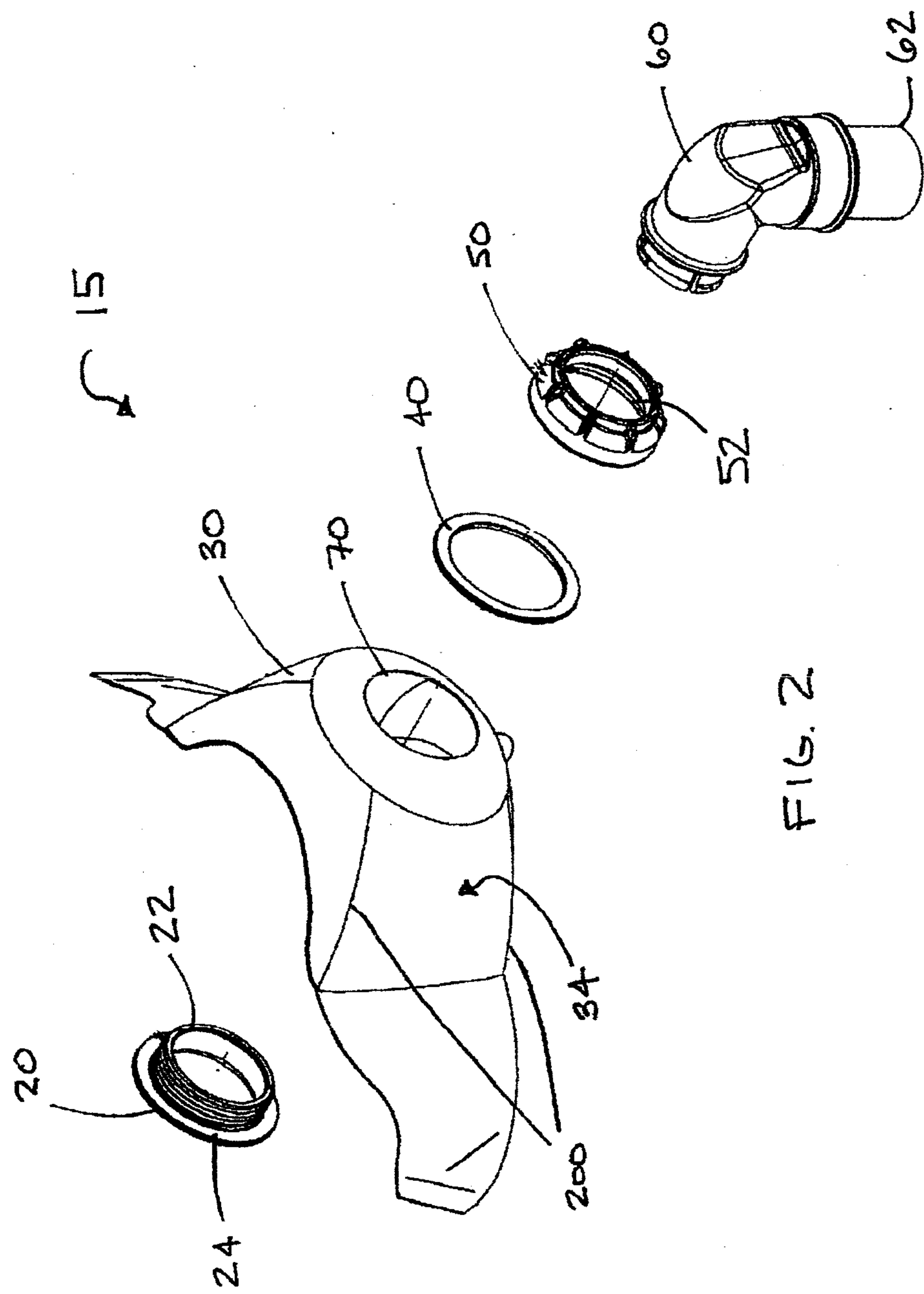


FIG. 2

(3/6)

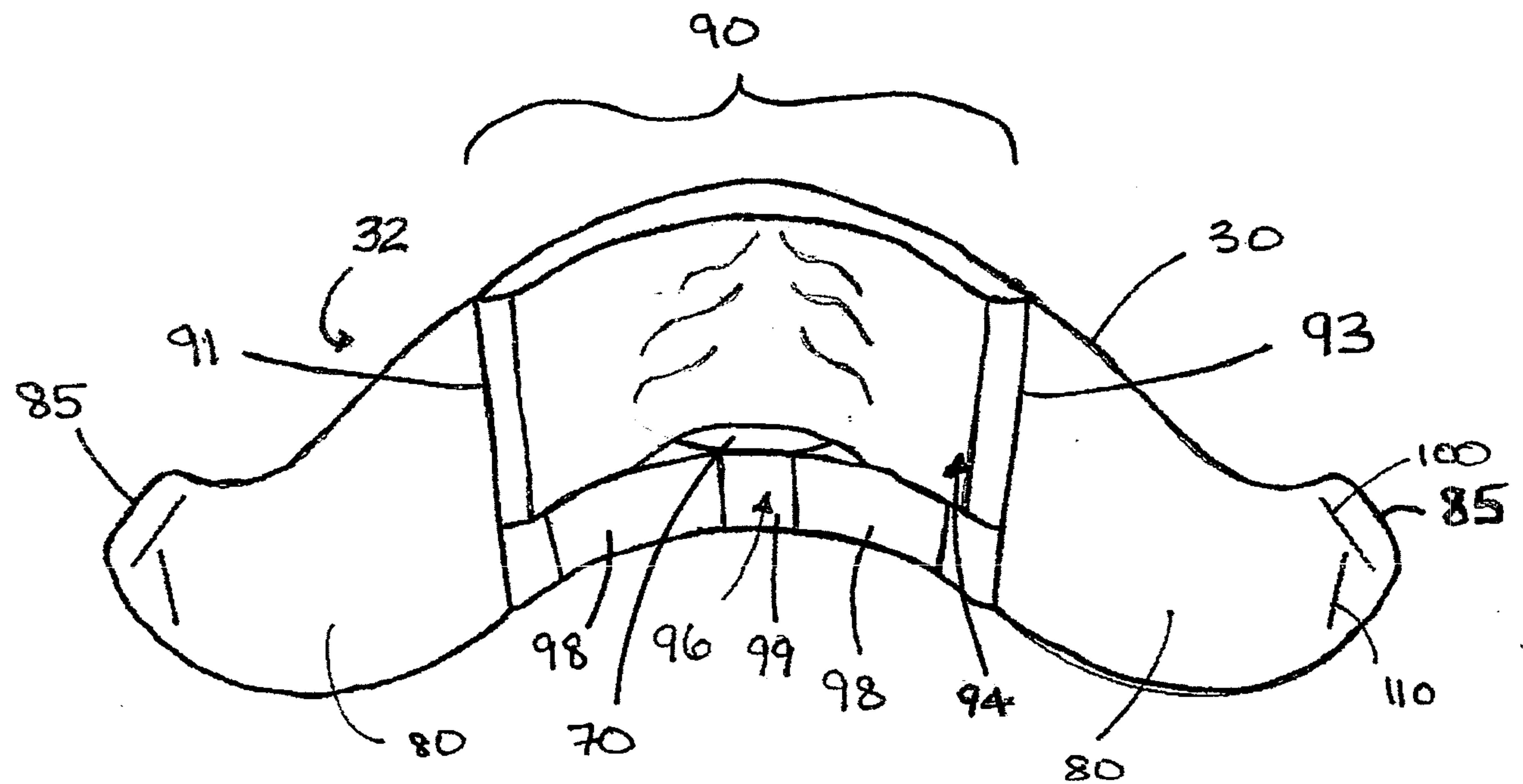


FIG. 3

(4/6)

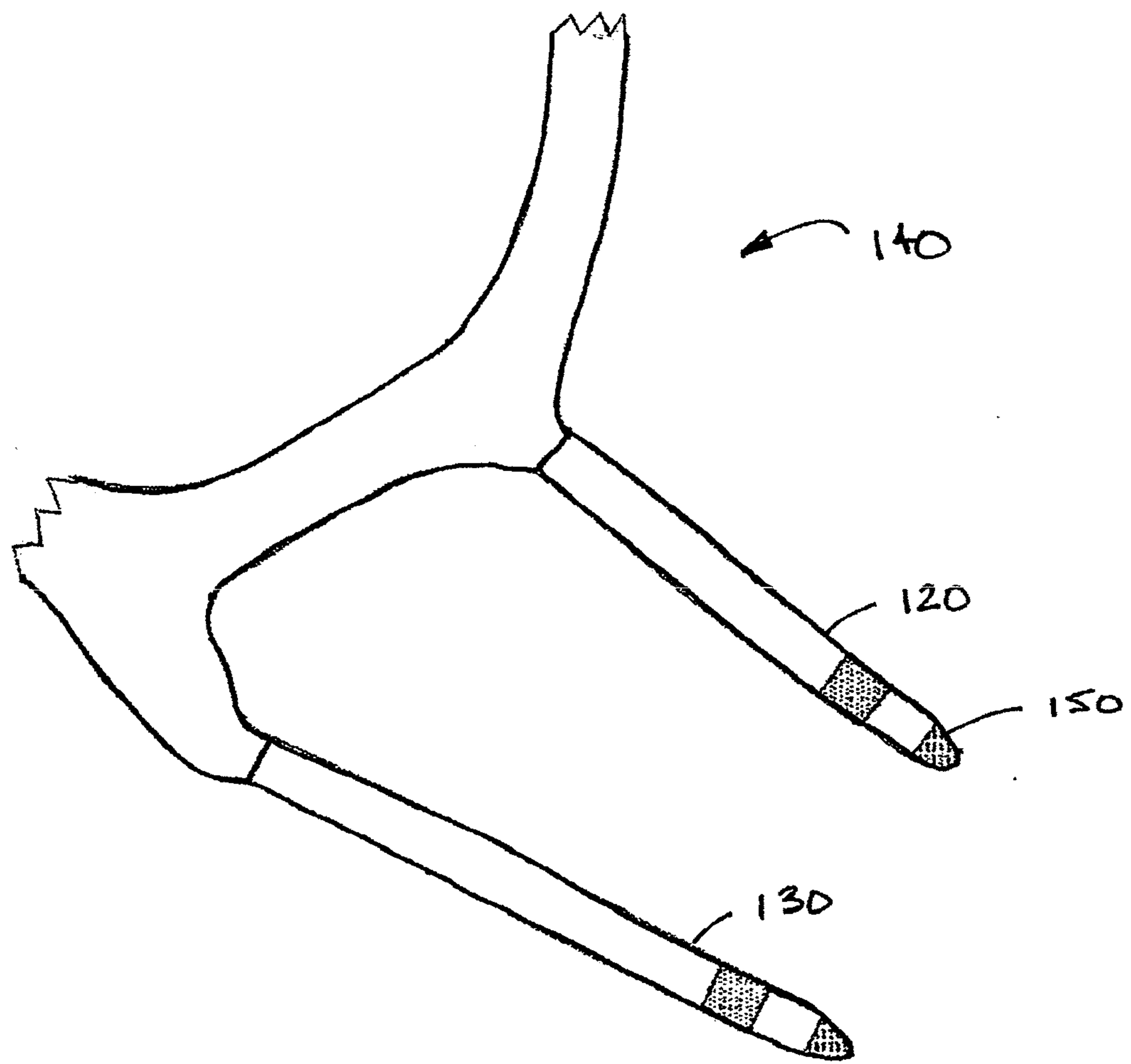


FIG. 4

(5/6)

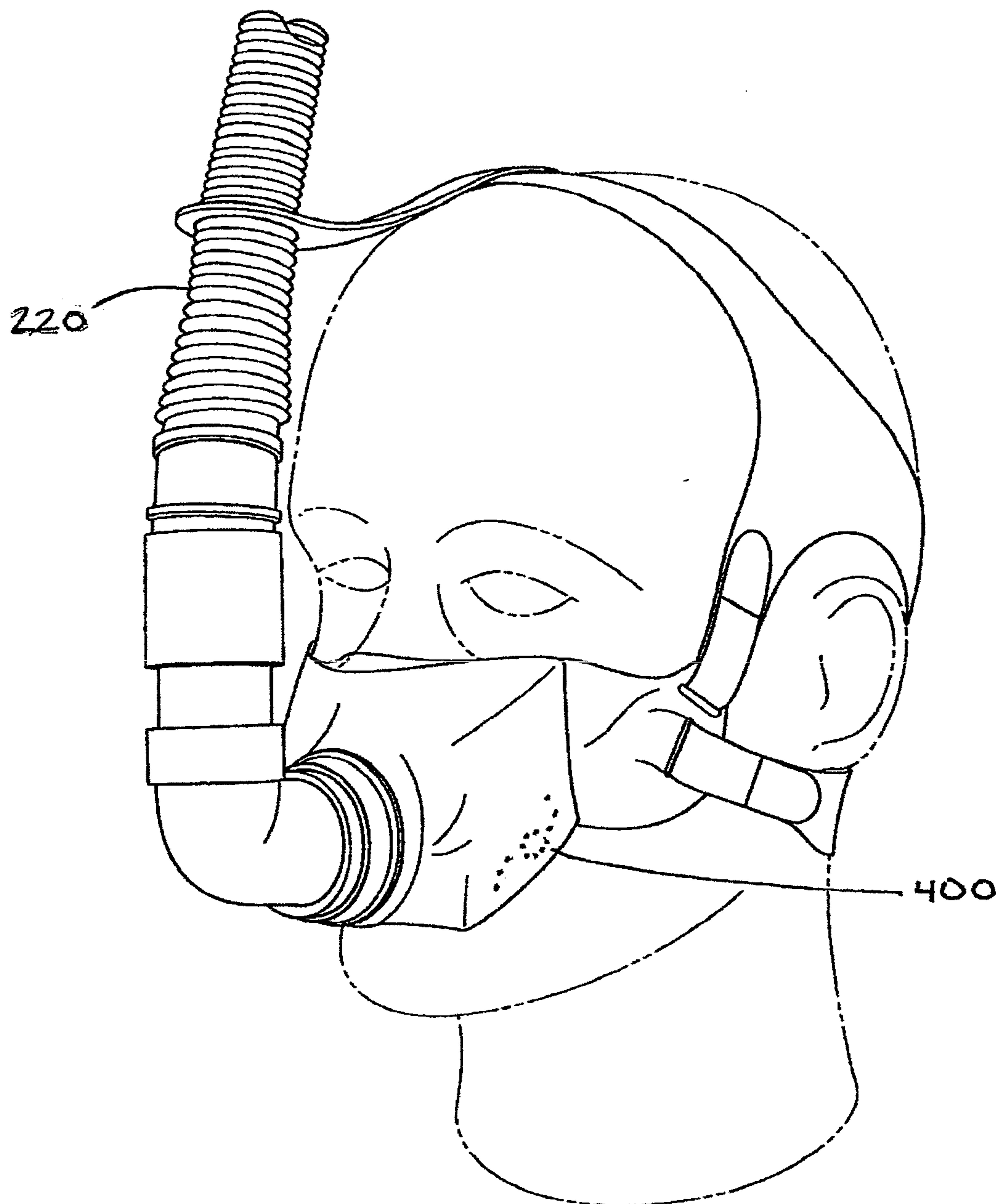


FIG. 5

(6/6)

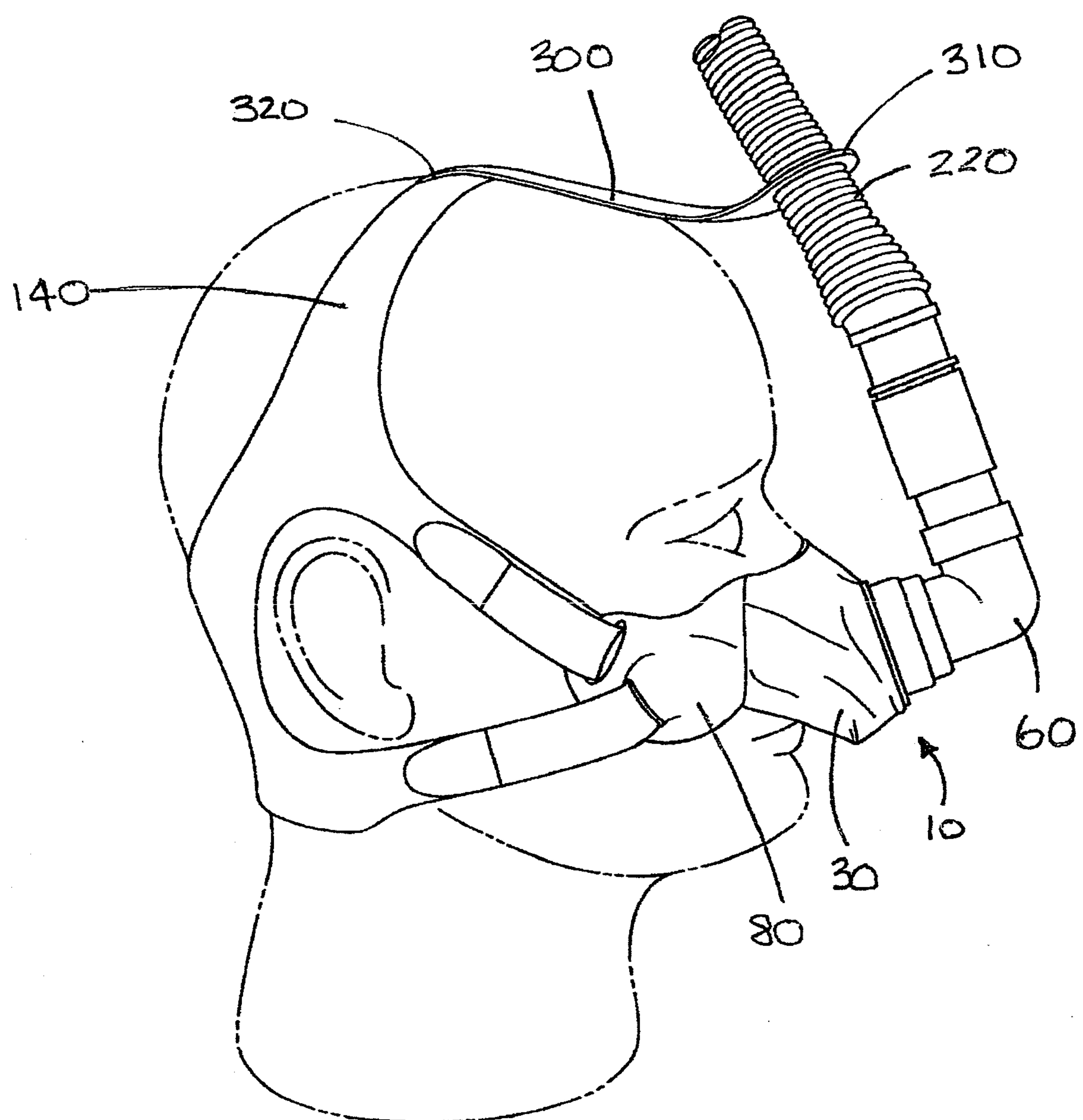


FIG. 6

