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(72) Inventeurs/Inventors:
SALMON, ANDREW PAUL MAXWELL, NZ;
SIEW, SILAS SAO JIN, NZ;
HUANG, WEN DONG, NZ;
ALLAN, OLIVIA MARIE, NZ;
MCLAREN, MARK, NZ;
PRENTICE, CRAIG ROBERT, NZ;
GARDIOLA, ARVIN SAN JOSE, NZ;
MCAULEY, ALASTAIR EDWIN, MZ

(73) Propriétaire/Owner:
FISHER & PAYKEL HEALTHCARE LIMITED, NZ

(74) Agent: RICHES, MCKENZIE & HERBERT LLP

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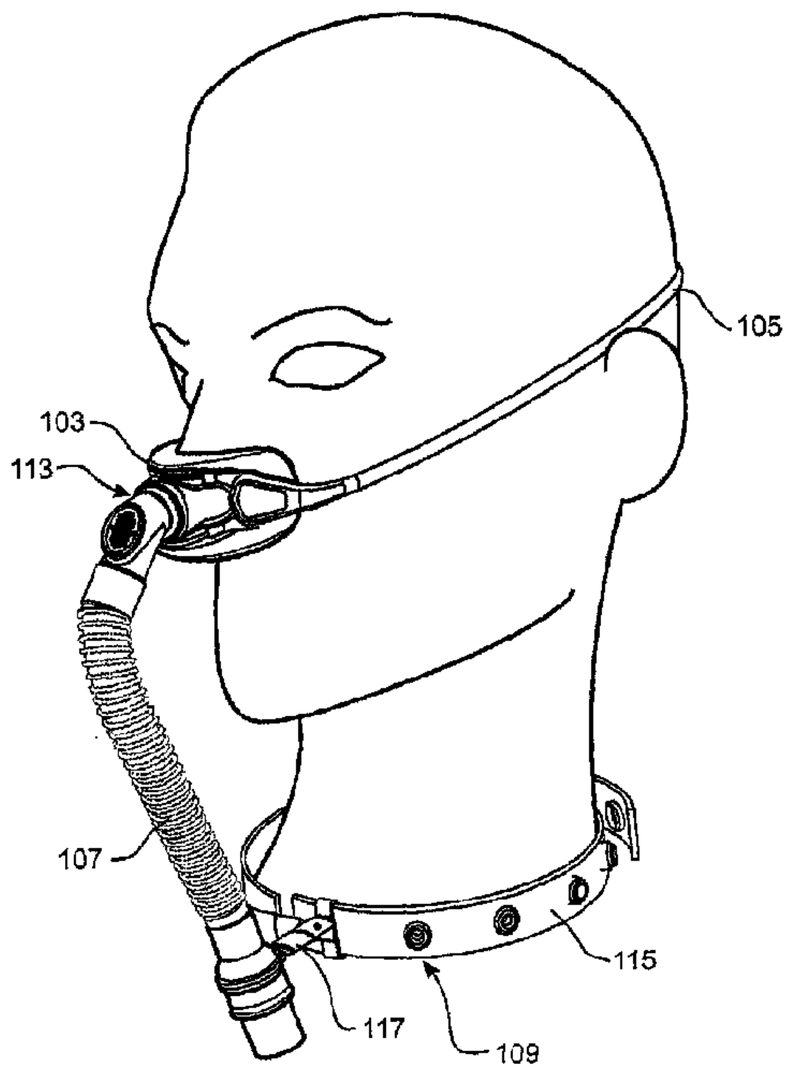

(57) Abrégé/Abstract:
A patient interface including a nasal seal including a face contacting side. The nasal seal is formed of a soft flexible material, and includes a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion. Each side portion extends across the a side of the nose. A face contacting side of the seal is supple to conform under internal pressure to the surfaces of the nose of a wearer, including, at the side portions of the seal, to outside surfaces of the sides of the nose. An exterior side includes regions much stiffer than the supple interior side, the regions extending into the side portions of the seal.

ABSTRACT

A patient interface including a nasal seal including a face contacting side. The nasal seal is formed of a soft flexible material, and includes a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion. Each side portion extends across the a side of the nose. A face contacting side of the seal is supple to conform under internal pressure to the surfaces of the nose of a wearer, including, at the side portions of the seal, to outside surfaces of the sides of the nose. An exterior side includes regions much stiffer than the supple interior side, the regions extending into the side portions of the seal.

"PATIENT INTERFACE AND ASPECTS THEREOF"

RELATED APPLICATIONS

This application is a divisional of Canadian Application Serial No. 2,761,741 filed May 10, 2010 and which has been submitted as the Canadian national phase application corresponding to International Patent Application No. PCT/IB2010/052061 filed May 10, 2010.

FIELD OF THE INVENTION

The present invention relates to patient interfaces for delivering breathing gases to a patient and aspects of patient interfaces.

SUMMARY OF THE PRIOR ART

The present invention relates to patient interfaces for delivering breathing gases to a patient. The invention will be particularly described with reference to patient interfaces for delivering PAP therapy to a patient, for example, to a patient suffering from obstructive sleep apnea (OSA). However, the patient interface could be used for other treatments. Furthermore, aspects of the patient interface could be combined with aspects of other patient interfaces for use in PAP therapy or for use in other therapy.

Desirable traits for patient interfaces used in PAP therapy include lightweight, comfortable, intuitive to use, good seal and stable and secure during use.

In this specification where reference has been made to patent specifications, other external documents, or other sources of information, this is generally for the purpose of providing a context for discussing the features of the invention. Unless specifically stated otherwise, reference to such external documents is not to be construed as an admission that such documents, or such sources of information, in any jurisdiction, are prior art, or form part of the common general knowledge in the art.

SUMMARY OF THE INVENTION

An object of the present invention is to provide a patient interface, or aspects of a patient interface which will at least provide the public with a useful choice.

In one aspect, the present invention may broadly be said to consist in a patient interface comprising a nasal seal including a face contacting side, the nasal seal being formed of a soft flexible material, and including a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each side portion extending across the a side of the nose, a face contacting side of the seal being supple to conform under internal pressure to the surfaces of the nose of a wearer, including, at the side portions of the seal, to outside surfaces of the sides of the nose, an exterior side including regions much stiffer than the supple interior side, the regions extending into the side portions of the seal. According to a further aspect the side portions of the seal are substantially parallel to each other and substantially normal to the central portion of the seal.

According to a further aspect the side portions of the seal are substantially parallel to each other and substantially normal to the central portion of the seal.

According to a further aspect the outer walls of the side portions of the seal are aligned to have an angle between their orientations between 0 degrees and 30 degrees.

According to a further aspect the seal includes a pair of nasal locators on the face contacting side, and the seal is stiffer in the region immediately adjacent and including the nasal locators than in a region surrounding this region, on the face contacting side of the seal.

According to a further aspect a peripheral portion of the seal, joining the face contacting side to the exterior side is supple and allows the interior side of the seal to displace relative to the exterior side.

According to a further aspect the exterior side of the central portion of the seal includes an aperture for passing gases to and from the interior of the seal.

According to a further aspect the supple portions of the seal comprise a silicone material with a thickness between 0.05mm and 0.5mm.

According to a further aspect the le portions of the seal comprise an elastomer with a thickness between 0.1mm and 0.2mm.

According to a further aspect the stiff portions of the seal comprise a silicone material with a thickness between 2mm and 5mm.

According to a further aspect the supple portions of the seal comprise an elastomer with a thickness between 2mm and 3mm.

According to a further aspect the region immediately adjacent and including the nasal locators comprises a silicone material with a thickness between 0.5mm and 2mm.

According to a further aspect the seal has an overall width from outside surface of one side portion to outside surface of the other side portion of between 30mm and 60mm.

According to a further aspect the seal has an overall depth, from the outer surface of the central portion to a line joining the extreme ends of each side portion, between 40mm and 65mm.

According to a further aspect a body assembled to the nasal seal, the body being formed of a material more rigid than the nasal seal, and together with the nasal seal forming an enclosure having an inlet opening and a patient outlet opening, with a swivelling elbow connected to the inlet opening.

According to a further aspect the connection of the swivel elbow to the body provides for rotation of the swivel elbow relative to the body and pivoting of the swivel elbow relative to the body about at least a transverse axis.

According to a further aspect the connection comprises a ball joint.

According to a further aspect the elbow includes a first end and a second end and a flow path between the first end and the second end, the flow path aligned in the first direction at the first end and the second direction at the second end, and the first direction and the second direction including an angle of between 120° and 180°,

According to a further aspect the angle is between 120° and 150°.

According to a further aspect the angle is between 130° and 140°.

According to a further aspect the elbow includes a gas washout vent.

According to a further aspect the gas washout vent is aligned with a gas flow path into the elbow from the nasal seal and body assembly.

According to a further aspect the gas washout vent comprises a plurality of holes through a wall of the elbow.

According to a further aspect the patient interface includes a body assembled to the seal, and a strap extending from the assembled body and nasal seal in a loop, the strap departing a first portion of the assembled body and nasal seal at one end and a second portion of the assembled body and nasal seal at its other end.

According to a further aspect the strap comprises a single undivided band along the length of the strap that engages the head of the wearer.

According to a further aspect the strap engages the body at either end.

According to a further aspect the strap engages the body with a releasable connector at either end.

According to a further aspect the band is narrow, preferably less than 10mm wide.

According to a further aspect the band is less than 6mm wide.

According to a further aspect the band has a stiffness less than 2N per 100mm extension from a relaxed condition.

According to a further aspect the band is formed from a knitted or braided yarn incorporating filaments of a material with high elasticity and filaments of material of much higher stiffness.

According to a further aspect the patient interface includes a tube depending from the seal and body, and a tube support, connected to the tube and connectable to the neck or clothing of a patient.

According to a further aspect the tube support includes a collar fastenable about the neck of a wearer.

According to a further aspect the collar has a first end portion and a second end portion, the first end portion and the second end portion include a fastening arrangement allowing the end portions to be fastened with a selected amount of overlap.

According to a further aspect the collar includes a third end portion and a fourth end portion and a connector connecting the third end portion to the fourth end portion.

According to a further aspect the connector is configured to release the third end portion from the fourth end portion upon application of tension across the connector greater than a release tension, wherein the release tension is less than 10N.

According to a further aspect the collar is between 30mm and 60mm wide.

According to a further aspect the collar has a core material and a cover material surrounding the core material.

According to a further aspect the core material is a dimensionally stable, breathable mesh.

According to a further aspect the cover material is a braided or knitted natural fibre.

According to a further aspect the tube support includes a tether extending from the collar, with a connector at one end secured or securable to the tube.

According to a further aspect the tether includes a connector at the outer end, with the collar passing through the second connector.

According to a further aspect the tether includes a first end and a second end and a connector connecting the first end and the second end, the connector being configured to release upon application of a tension above a release tension, wherein the release tension is less than 10N.

According to a further aspect the connector of the strap includes a first portion and a second portion, and in the engaged condition, the first portion can swivel relative to the second portion.

According to a further aspect the connector to engage with the tube comprises a ring.

According to a further aspect the patient interface includes a body connected to the seal, and wherein the body includes a nasal seal engaging portion that engages an outward side of the seal, an inlet opening and at least one strap engaging portion from which extends a loop strap to secure the interface to the patient.

According to a further aspect the body includes two strap engaging portions, each strap engaging portion extending laterally away from the inlet opening, from opposite sides of the inlet opening.

According to a further aspect each strap engaging portion extends away from the inlet opening in a region where the strap engaging portion overlaps with the outer wall of the seal.

According to a further aspect a central portion of the body defines a convex shape generally matching a convex shape of the outer wall of the body, with strap engaging portions extending from lateral extremes of the central portion, the strap engaging portions extending away from the central portion at an angle outwardly aligned relative to the general convex shape.

According to a further aspect the strap engaging portions extend away from the outer wall of the seal with an included angle between them greater than 30degrees.

According to a further aspect the strap engaging portion from the point where it diverges from the outer wall of the seal is between 50% and 150% of the length of the equivalent length of the outer wall of the seal.

According to a further aspect the patient interface includes a body engaged with the nasal seal, the body being more rigid than the nasal seal, wherein a lip support depends from the body, and extends beyond an edge of the seal.

According to a further aspect the lip support includes one or more pads for engaging against an upper lip portion of the wearer.

According to a further aspect the lip support includes two depending legs, spaced apart at either lateral region of the seal, each leg extending beyond a lateral portion of the lower edge of the seal.

According to a further aspect each leg carries a pad portion oriented to present a face against the upper lip.

According to a further aspect the legs are moulded to have lower stiffness about an axis parallel to the lip portion of the wearer which they will contact, than about an axis normal to the plane of the lips.

In a further aspect, the present invention may broadly be said to consist in headgear for a patient interface, the headgear comprising resilient band having a width between 3mm and 6mm, a stiffness providing an extension of 150mm with a force less than 2N, a first end connected or connectable to a first lateral portion of a mask, and a second end connected or connectable to a second lateral portion of a mask.

According to a further aspect the strap is between 350mm and 450mm long in its relaxed length.

According to a further aspect the strap is between 60mm and 110mm longer upon application of an extension force of 1N.

According to a further aspect the strap is constructed from a knitted or braided yarn, where the yarn includes filaments of a first material and filaments of a second material of high elasticity but much lower stiffness than the first material.

According to a further aspect the strap includes a first connector at the first end and a second connector at the second end.

In a further aspect, the present invention consists in a patient interface including a strap as described in any one of the above paragraphs.

In a further aspect, the present invention may broadly be said to consist in a patient interface comprising a nasal seal including a face contacting side, the nasal seal being formed of a soft flexible material, a body assembled to the nasal seal, the body being formed of a material more rigid than the nasal seal, and together with the nasal seal forming an enclosure having an inlet opening and a patient outlet opening, and a lip support depends from the body, and extends beyond an edge of the seal.

According to a further aspect the lip support includes one or more pads for engaging against an upper lip portion of the wearer.

According to a further aspect the lip support includes two depending legs, spaced apart at either lateral region of the seal, each leg extending beyond a lateral portion of the lower edge of the seal.

According to a further aspect each leg carries a pad portion oriented to present a face against the upper lip.

According to a further aspect the legs are moulded to have lower stiffness about an axis parallel to the lip portion of the wearer which they will contact, than about an axis normal to the plane of the lips.

According to a further aspect the interface includes a gases supply tube depending from the body and a strap extending from the assembled frame and nasal seal in a loop, the strap departing a first portion of the assembled body and nasal seal at one end and a second portion of the assembled body and nasal seal at its other end.

In a further aspect, the present invention may broadly be said to consist in a patient interface comprising a mask, a tube depending from the mask, and a tube support, connected to the tube and including a collar fastenable about the neck of a wearer.

According to a further aspect the collar has a first end portion and a second end portion, the first end portion and the second end portion including a fastening arrangement allowing the end portions to be fastened with a selected amount of overlap.

According to a further aspect the collar includes a third end portion and a fourth end portion and a connector connecting the third end portion to the fourth end portion.

According to a further aspect the connector is configured to release the third end portion from the fourth end portion upon application of tension across the connector greater than a release tension, wherein the release tension is less than 10N.

According to a further aspect the collar is between 30mm and 60mm wide.

According to a further aspect the collar has a core material and a cover material surrounding the core material.

According to a further aspect the core material is a dimensionally stable, breathable mesh.

According to a further aspect the cover material is a braided or knitted natural fibre.

According to a further aspect the tube support includes a tether extending from the collar, with a connector at one end secured or securable to the tube.

According to a further aspect the tether includes a connector at the outer end, with the collar passing through the second connector.

According to a further aspect the tether includes a first end and a second end and a connector connecting the first end and the second end, the connector being configured to release upon application of a tension above a release tension, wherein the release tension is less than 10N.

According to a further aspect the connector of the tether includes a first portion and a second portion, and in the engaged condition, the first portion can swivel relative to the second portion.

In a further aspect, the present invention may broadly be said to consist in a patient interface comprising a nasal seal including a face contacting side, the nasal seal being formed of a soft flexible material, and including a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each side portion extending across the a side of the nose, a body connected to the seal, including a nasal seal engaging portion that engages an outward side of the seal, an inlet opening and at least two strap engaging portions, each strap engaging portion extending laterally away from the inlet opening, from opposite sides of the inlet opening, and a strap extending between the strap engaging portions.

According to a further aspect each strap engaging portion extends away from the inlet opening in a region where the strap engaging portion overlaps with the outer wall of the seal.

According to a further aspect a central portion of the body defines a convex shape generally matching a convex shape of the outer wall of the body, with strap engaging portions extending from lateral extremes of the central portion, the strap engaging portions extending away from the central portion at an angle outwardly aligned relative to the general convex shape.

According to a further aspect the strap engaging portions extend away from the outer wall of the seal with an included angle between them greater than 30 degrees.

According to a further aspect the strap engaging portion from the point where it diverges from the outer wall of the seal is between 50% and 150% of the length of the equivalent length of the outer wall of the seal.

The term "comprising" is used in the specification and claims, means "consisting at least in part of". When interpreting a statement in this specification and claims that includes "comprising", features other than that or those prefaced by the term may also be present. Related terms such as "comprise" and "comprises" are to be interpreted in the same manner.

In this specification where reference has been made to patent specifications, other external documents, or other sources of information, this is generally for the purpose of providing a context for discussing the features of the invention. Unless specifically stated otherwise, reference to such external documents is not to be construed as an admission that such documents, or such sources of information, in any jurisdiction, are prior art, or form part of the common general knowledge in the art.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred forms of the present invention will be described with reference to the accompanying drawings.

Figure 1 is a perspective view of a person wearing a patient interface.

Figure 2 is a perspective view of the patient interface of Figure 1 without the patient.

Figure 3 is an exploded view illustrating the components making up the interface of Figure 2.

Figures 4A to 4C illustrate, from different angles, a seal component of the patient interface of Figure 2. Figure 4A shows the seal component from an outward facing side, Figure 4B shows the seal from a patient-facing side and Figure 4C shows a side view of the seal.

Figure 5A is an exploded view of the seal and mask frame showing how they can be brought together to be assembled.

Figure 5B is a side view of the interface of Figure 2, partially disassembled to show the connection of an elbow to the mask frame.

Figure 5C is a front perspective view of the interface of Figure 2 illustrating assembly of the elbow with the mask frame, with a gas washout vent present in the elbow.

Figure 6 is a front view of the assembled seal and mask frame.

Figure 7A is a top view of the assembled seal and mask frame.

Figure 7B is a side view of the seal and frame of Figure 7A, unsectioned.

Figure 7C is a view of the patient side of the seal of Figures 4A and 4C.

Figure 7D is a side elevation of the seal of Figure 7C, sectioned through line EE.

Figure 8 is a side view of the seal and mask frame of Figure 7A taken through line DD.

Figure 9A is a top view of the seal of Figure 7C, sectioned through line FF of Figure 7D.

Figure 9B is a top view of the seal of Figure 7C, sectioned through line GG of Figure 7D.

Figures 10 and 11 show views of a further embodiment of an interface with an inflatable nasal seal and frame. The seal is shaped to wrap around the user's nose.

Figure 12 shows the seal of Figures 10 and 11 with the frame removed.

Figure 13 shows a further embodiment of an interface with an inflatable seal. The interface includes a seal body, frame, tubing and head strap.

Figure 14 shows the seal body of the interface of Figure 13.

Figure 15 is a perspective view of the frame and seal body of the interface of Figure 13.

Figure 16 is a front view of the frame and seal body of the interface of Figure 13.

Figure 17 is a side view of the frame and seal body of the interface of Figure 13.

Figure 18 is a cross-section of the frame and seal body through BB in Figure 17.

Figure 19 is an alternative cross-sectional view of the seal body.

Figure 20 is a cross-section of the seal body through AA of Figure 16.

Figure 21 is an alternative embodiment of a seal body of the interface of the present invention.

Figure 22 is yet a further embodiment of a seal body of an interface of the present invention.

Figure 23 is another embodiment of a seal body of an interface of the present invention.

Figure 24 shows a first embodiment of a head strap that may be used with an interface of the present invention.

Figures 24a and 24b show two alternative cross-sections of the head strap of Figure 24.

Figure 25 shows a second embodiment of a head strap that may be used with an interface of the present invention.

Figures 25a and 25b show two alternative cross-sections of the head strap of Figure 25.

Figure 26 shows a third embodiment of a head strap that may be used with an interface of the present invention.

Figure 27 shows a fourth embodiment of a head strap that may be used with an interface of the present invention.

Figure 27a shows the extendible portion of the head strap of Figure 27 in extended and contracted conditions.

Figure 28 shows a fifth embodiment of a head strap that may be used with an interface of the present invention.

Figure 29 shows a sixth embodiment of a head strap that may be used with an interface of the present invention.

Figure 30 shows a first embodiment of the connection between a seal body and frame of the interface of the present invention.

Figure 31 shows a second embodiment of the connection between a seal body and frame of the interface of the present invention.

Figure 32 shows a third embodiment of the connection between a seal body and frame of the interface of the present invention.

Figure 33 shows a forth embodiment of the connection between a seal body and frame of the interface of the present invention.

Figure 34 shows a first embodiment of a brace that may be used with the interface of the present invention to fix tubing connected to the interface to the user.

Figure 35 shows a second embodiment of a brace that may be used with the interface of the present invention to fix tubing connected to the interface to the user.

Figure 36 shows a third embodiment of a brace that may be used with the interface of the present invention to fix tubing connected to the interface to the user.

Figure 37 shows a fourth embodiment of a brace that may be used with the interface of the present invention to fix tubing connected to the interface to the user.

Figure 38 shows a fifth embodiment of a brace that may be used with the interface of the present invention to fix tubing connected to the interface to the user.

Figure 39 shows a sixth embodiment of a brace that may be used with the interface of the present invention to fix tubing connected to the interface to the user.

Figure 40 shows a seventh embodiment of a brace that may be used with the interface of the present invention to fix tubing connected to the interface to the user.

Figure 41 is a perspective view of a supporting collar.

Figure 42 is a perspective view of a patient wearing the supporting collar of Figure 41.

Figure 43 is a perspective view of the collar of Figure 41 from a different angle.

Figure 44 is a front view of a patient wearing the collar of Figure 41.

Figure 45 is a top view of the collar of Figure 41.

Figure 46 is a top view of a portion of the collar of Figure 41 illustrating a dome fastener connector.

Figure 47 is a top view of a portion of the collar including an alternative fastener.

Figure 48 is a top view of a portion of the collar including an alternative fastener.

Figure 49 is a top view of a portion of the collar including a further alternative fastener.

Figure 50A is a side view of a portion of the collar including a securing clip in an engaged configuration.

Figure 50B is a side view of the portion of the collar from Figure 50A in a disengaged condition.

Figure 51A is a side view of a portion of the collar including a securing clip according to an alternative embodiment in a disengaged condition.

Figure 51B is a side view of the portion of the collar of Figure 51A in an engaged condition.

Figure 52 is a perspective view of a tether depending from a portion of the collar, with the tether including a quick disconnect connector.

Figure 53 is a perspective view illustrating a tether depending from the collar, the tether including a quick disconnect connector which can also swivel.

Figure 54A is a top view of a tether similar to the tether of Figure 51B, but of minimal length.

Figure 54B is a top view of the tether of Figure 54A with the quick release connector disengaged.

Figure 54C is a side view of the tether of Figure 54A.

Figure 55 is an exploded view illustrating connection of a ring of the tether from the supporting collar to a conduit.

Figure 56 is a perspective view of an interface including an alternative arrangement for supporting the conduit from the patient.

Figure 57 is a perspective view of a patient wearing an interface including a further alternative arrangement for supporting the conduit on the patient.

Figure 58 is a side elevation of a frame and seal, the frame incorporating depending lip stabilisers in accordance with a further invention herein.

Figure 59 is a top view of the frame and seal of Figure 58.

Figure 60 is a front view of the frame and seal of Figure 58.

Figure 61 is a perspective view of an interface incorporating the frame and seal of Figure 58.

Figure 62 is a graph of tested extension forces against extension of sample strap materials.

DETAILED DESCRIPTION

One invention herein provides an interface that includes an inflatable nasal seal having a supple wall structure. The inflatable seal has a pair of locating protrusions that engage in the nostrils of the user. The locating protrusions supply gases flow to the user from inside the seal. The patient side of the seal is so supple, and of sufficient dimension and shape, that when the

inflated seal is pressed against the face of a user, with the locating protrusions engaged in the nostrils of the user, the seal conforms to the surfaces of the user's face (particularly the sides of the nose and the upper lip) and provides a seal. An outwardly facing wall of the seal is more rigid, and supports the inner wall of the seal in a position wrapped around the wearer's nose.

The seal is formed from a material having sufficient elasticity and yield strength that the combination renders the envelope supple. The supple portion is capable of repeated drastic deformations without failure. Possible materials include latex, vinyl, silicone and polyurethane. Typically wall thickness of the supple portions of the seal would be below 0.5mm and could be lower than 0.2mm.

The seal body includes a pair of nasal locators protruding from the patient facing wall. Preferably the nasal locators are formed integral with the seal. Each nasal locator includes an outlet aperture for supplying gas from inside the envelope to a user wearing the interface.

The seal body includes an inlet opening, approximately opposite the nasal locators.

A substantial extent of the seal body or envelope is supple. A region adjacent and including the nasal locators and a region adjacent and including the inlet opening are much stiffer. These areas hold the overall shape of the seal and can be of any suitable stiffness. As such they may be formed of a stiffer material, or formed thicker in the same material as the rest of the envelope.

The seal is supported by a mask body or frame. The inlet opening of the seal is fitted to the frame, or directly to a conduit extending through the frame.

The frame is preferably a minimal design to provide little visual obstruction, allowing a clear field of view and allowing the user to wear glasses while wearing the interface.

The frame may be formed by injection moulding, for example from an elastomeric material such as silicone or polyurethane. Alternatively, more rigid materials such as polycarbonate, or polyester, polystyrene or nylon may be used.

The preferred frame includes connection points for connecting straps to the frame. The strap attachment points provide for anchoring the straps. The strap attachment points may provide for adjusting the strap lengths.

In other forms the nasal seal body may include integral strap attachment points. These attachments may be connection elements on the surface of the envelope. However, they could be integral straps or wings formed in the envelope that extend out either side of the envelope.

The interface is intended to be supported by a single strap passing around the back of the head. The strap may be formed from an elastic or elastomeric material. For example suitable strap materials may include a woven elastic strip or a narrow strip of foam and fabric, such as

Breathoprene™. The strap extending around the back of the head provides pressure on the mask and helps keep the seal against the user's face.

A flexible tube extends from the frame. The flexible tube delivers breathable gas. The distal end of the flexible tube connects to the main CPAP delivery tube.

A connector may connect the tube and the frame. The connection mechanism may be any suitable connection. This could include a snap fit, hooks into the silicone, keyhole inserts, over moulding, insert moulding, screw attachments or gluing, or any combination.

The connector may include a limited flow outlet (or bias flow outlet) for providing gas washout from the interface. The outlet may be in the form of a collection of small apertures in the connector. Internally the connector may include a funnel or extension leading from the vent into the mouth of the envelope.

Figures 1 and 2 illustrate an example patient interface incorporating inventions disclosed in this application. For clarity, the patient interface is shown separate from the patient in Figure 2 and as worn by a patient in Figure 1.

The patient interface 101 broadly includes a mask 103, a strap 105 for securing the mask to the patient, a flexible supply conduit 107 connecting to the mask 103 and a conduit support structure 109 which attaches to a patient and supports the weight of conduit portion 107 and of any connected conduit supplying gases to the inlet end 111 of conduit portion 107.

Particular aspects of this patient interface, and variations on each aspect, will be discussed with reference to other Figures. An interface may incorporate some aspects but not other aspects. For example, an interface might incorporate aspects of the mask while using a different arrangement for securing the mask to the user. An interface might include a different mask while using inventive aspects of the strap to secure that mask to the user. An interface may incorporate aspects of the mask but not make use of a similar, or any, structure for supporting the weight of the conduit from the body of the patient. All of these variations are considered within the scope of this application.

Referring to Figure 1, the mask 103 fits over the nostrils of the patient and includes lateral portions which curve around either side of the nose. These lateral portions provide for forming a perimeter seal on the outwardly facing surfaces of the flanks of the nose. The strap 105 passes around the user's head in a simple loop above the user's ears.

The conduit portion 107 depends from a central connection 113 at the front of mask 103. The central connection 113 is preferably a swivelling elbow so that the path of the conduit relative to the positioning of the mask on the face of the patient can adapt to the sleeping

position of the patient. The swivelling elbow may be in the form of a ball joint so that the elbow can pivot about axes parallel to and perpendicular to its connection with the mask.

The illustrated conduit support 109 comprises a collar 115 connected around the neck of the user. A tether 117 connects between the collar and the conduit 107.

The component parts of this exemplary interface are illustrated in Figure 3. The mask 103 includes a seal 301 and a body or frame 303. The seal and body are illustrated in more detail in Figure 5A. Their engagement will be described in more detail with reference to Figure 5A and Figure 8.

The body 303 includes a socket 305 and connector portions 307. Socket 305 receives an engagement portion 311 of elbow 333. Elbow 333 is connected to the end of a length of flexible tubing 315. The other end of flexible tubing 315 is terminated with a cuff 317. Connector portions 307 of mask body 303 are for engagement with connector portions 321 of the head strap 105. The head strap 105 includes a single length 323 of stretchable material. Connector portions 321 are provided at either end of the length 323.

The collar 115 includes a band 325 of a material intended to be comfortable when worn during periods of sleep. The band includes a first adjustable connection 327 and a second non-adjustable connection 329. At the adjustable connection 327, free ends of the band overlap, and the degree of this overlap may be varied to a desired amount and fixed at this desired amount. At the non-adjustable connection 329, free ends of the band may simply be secured or released. Once the adjustable connection 327 has been adjusted, the collar may be opened for fitting to the patient or removal from the client and secured after fitting to the client, by disconnecting or connecting the non-adjustable connection 329. The non-adjustable connection 329 may be a quick release connector that disconnects with applied tension within predetermined range. This ensures that the collar will release without injuring the patient if any adverse situation arises.

The tether 109 includes a first portion 331 attached to the collar and a second portion 333 which attaches to the conduit. These portions are preferably releasably engaged by another quick release connector, which preferably disconnects on application of a tension within a predetermined range.

The tether portion 333 connects to conduit 315. The tether portion 333 includes a portion of the quick release connector and a fitting 337 that engages the conduit. The fitting 337 may be an open clip to engage a corrugation of the conduit, or a recess of the cuff 317, or to engage around the general cylindrical shape of the conduit, or to a cylindrical portion of the cuff. Alternatively, and as illustrated, the portion 337 may comprise a ring that fits around a portion of the conduit, or a portion of the cuff. In the illustrated embodiment, the ring 337 is captive

between the cuff 317 and a connector portion of a swivel 335. The ring fits over a portion 339 of cuff 317 and is held captive by an end portion 341 of the swivel 335, which has a larger diameter than the internal diameter of the ring.

The external form of a preferred seal is illustrated in Figures 4A to 4C. The seal 301 includes a patient-facing side, broadly illustrated in Figure 4B, and an outward-facing side, broadly illustrated in Figure 4A. A pair of nasal locators 401 protrude from the patient-facing side. Broadly speaking, the wall of the seal forming the patient-facing side is very supple with the exception of the nasal locators, the area immediately adjacent the nasal locators, or both. Variations in the suppleness will be described in more detail with reference to the cross sections illustrated in Figure 7D, Figure 8 and Figure 9A and 9B.

In overall form, the seal has a central portion including nasal locators on the patient-facing side and an opening 403 on the outward-facing side. The extent of this central portion 407 is broadly indicated by broken line 409 in Figures 4C and 4A. For clarity, broken line 409 is also included in Figure 7A which comprises a top view of the mask portion of the interface.

Lateral or side portions 411 extend from the central portion 407. Each side portion includes an outward face 413 and an inward face 415 and a peripheral edge portion 417 that joins the inward face portion and the outward face portion. The peripheral edge portion 417 extends around a top edge 419, an end edge 423 and a lower edge 420. Accordingly, considered from inside the seal, the side portions 411 resemble a pocket.

Each side portion is quite extensive. Preferably, the side portion extends greater than 10mm (most preferably greater than 20mm) or at least a distance 70% of the distance separating the centres of the nostril locators 401 beyond the base of each nostril locator.

At least the inside wall 415 and the perimeter wall 417 of each side portion are very supple, so that they can conform to contours of the user's face, and in particular, to contours of the outside of the sides of the user's nose. At least portions of the outside facing wall 413 of the side portion are also supple, but may be progressively less supple moving toward the central portion 407.

The central portion 407 of the seal includes opening 403 to pass a gases flow to and from the mask body 303. The opening 403 may include features such as lips and/or channels to engage with features such as channels and/or lips on the body 303. The opening 403 may be formed with clip portions, or clip portions may be attached to or over-moulded to the perimeter of the opening 403 to facilitate engagement with the frame 303. Typically, the opening 403 will be substantially thicker and more rigid than the supple sealing portions of the seal 301. The opening 403 should be at least the size of the interior cross section of the supply conduit 315.

Preferably, and as illustrated, the opening 403 is commensurate with the extent of the body 303 of the mask, this extent being commensurate with the general width of the interface and approximately with the width of the nose of the intended wearer.

In the preferred form, the interface is intended to be of small size and the body portion 303 of the mask curves to follow approximately the contour of the upper lip of the wearer, and the seal is formed such that the opening 403 follows this approximate curve, in plan.

The central portion 407 of the seal extends above and below the opening 403. Above the opening 403, and the nostril locators 401, the central portion includes an outer-facing wall 431, and inward-facing wall 433 and a perimeter portion 435. At least the inwardly-facing wall portion 433 and the outwardly-facing portion 435 are preferably thin and supple.

Below the opening 403, the central portion 407 includes an outer wall portion 441, an inner wall portion 443 and a peripheral portion 445. At least the inner portion 443 and the peripheral portion 445 are preferably thin and supple.

In use, the supple interior wall portions above, below and to each side of the nasal locators are inflated by pressure inside the seal (from the flow of gases supplied to the patient interface) to press against the skin of the wearer and conform to the contours of the outside surfaces of the nose of the wearer and to the surfaces of the lower face of the nose of the wearer and to the surfaces of the upper lip of the wearer immediately below the nose. Movement of the mask body does not break this seal, as the supple perimeter or periphery of the seal allows the mask body to move in the direction of movement to at least a small extent. The supple perimeter de-couples the position of the nostril locators from the position of the mask body, allowing the mask body to displace both laterally and vertically (relative to axes of the patient's face). The side portions 411 engage the sides of the patient's nose, and form some additional seal against them and support the location of the mask.

The mask body and seal are illustrated in larger format in Figure 5A and in Figures 5B and 5C. As previously described, the seal includes opening 403, with arrangements to secure the seal to the mask body. The mask body includes a socket 502 for connecting with the supply conduit, and a seal opening 501 for engaging with the opening 403 of the seal. The seal opening 501 and the opening 403 of the seal are provided with complementary features to engage them together. In the illustrated form, the seal opening 403 includes arrangement 507 of lip and channels, and the periphery of the seal opening 501 of the mask body includes a complementary arrangement of 505 of channels and lips. The arrangement of channels and lips is devised to ensure that when the seal is properly fitted to the mask body, and supplied with gases under

pressure, there are no leaks at this join. Many other ways can be devised for connecting the seal and the mask body and this arrangement is only illustrative.

In the mask body, the outlet opening 501 to the seal is directly opposite the opening of socket 502, so that the opening 502 is centrally located. Either side of socket 502 extends a central side portion 509. The central side portion 509 may be a plain covering wall, enclosing a portion of the opening 403 of the seal. The central side portions 509 may include small apertures as part of a gas washout vent.

In the preferred embodiment illustrated, side arms 511 extend beyond the extent of the seal opening 501, best illustrated in Figure 7A, the side arms 511 preferably extend beyond the extreme width of the seal. Each side arm 511 includes a connector portion 513 for connecting to connector portion 321 of the strap. In the illustrated embodiment, the connector portions comprise a securing post with a perimeter undercut. The strap has a small loop formed at each end which stretches over the securing post and engages in the undercut. This connector form is simple and intuitive, but other connector forms may be provided, for example, each side arm 511 could be provided with a portion (for example a male or female part) of a clip.

As best illustrated in Figure 7A, the side arms 511 diverge from the outside wall of the seal, for example at an angle 713 of between 30° and 80°. A strap secured to post 513 leaves the side arm in a manner as illustrated by line 715 in Figure 7A, at a location spaced apart from the seal, and spaced apart from the face of the wearer. This is illustrated by the relative locations of the tip 717 of the side arm 511 compared with the centre line 719 of the interface. The distance 721 from the centre line to the tip of the side arm is preferably between 25mm and 50mm, and most preferably about 45mm. This compares with the distance 723 between the centre line 719 and the central axis of the nasal locator, which is preferably between 5mm and 10mm, and most preferably about 7mm. It also compares with the approximate location of the inner wall surface of the side portion of the seal, where it leaves the central portion of the seal. This location is illustrated by broken line 725 in Figure 7A. Preferably this separation 727 is between 10mm and 20mm, and most preferably about 15mm. For further comparison, the outer most extent of the side portion is illustrated by broken line 729. The displacement 731 of broken line 729 from centre line 719 is preferably between 15mm and 30mm, and most preferably about 25mm.

In the front to back direction, the tips 717 are preferably rearward of the base of the nasal locators, so that bases of the nasal locators are between the central portion of the mask body and a line connecting the tips 717.

With further reference to Figure 7A, overall, the mask seal may have a broadest exterior extent 741 of between 30mm and 60mm and most preferably about 50mm. The seal and mask

frame may have an overall depth 743, preferably between 40mm and 65mm and most preferably about 55mm. Within this depth, the interior space defined by the seal, which wraps around the nose of the user in use, may have a depth 745 that is preferably between 20mm and 40mm and most preferably about 30mm.

As can be seen from Figure 7A, in overall form, the seal curves through a significant arc such that the side portions are generally parallel with each other and opposed across the space that will accommodate the nose. The orientation planes of the side portions may form together an angle of between 0° and 45° and preferably between 0° and 25°. Preferably this applies to both the inner wall, and the outer wall, as illustrated in Figures 9A and 9B. Preferably this is also true for substantially all of the vertically displaced levels within the seal, as illustrated by the different levels shown in Figures 9A and 9B.

The overall plan form of the seal, as illustrated in Figure 7A, could be considered parabolic, half elliptical, half oval or U-shaped. Viewed generally, the central portion of the seal defines the width of the seal, with the side portions of the seal extending away from the lateral ends of the central portion in a direction substantially parallel with each other and substantially perpendicular to this width dimension.

Figures 5B and 5C also show the connection of the swivel elbow 313 to the mask body 303. The swivel elbow 313 includes a ball portion 515 and opening 517. The outer surface of ball portion 515 is preferably a frustospherical surface, but could be formed with variation and still achieve a substantial seal with socket 502. Similarly, the socket 502 is preferably a frustospherical surface with a slight intruding lip. This is best illustrated in Figure 8, where lip 802 intrudes slightly relative to the remainder frustopherical surface 804.

The swivel elbow 313 preferably defines an angle between flow in the conduit, and flow through the connection to the mask of between 0° and 90°, preferably between 30° and 60°, and most preferably about 45°. The elbow may incorporate apertures 519 forming part or all of a gas washout vent for the patient interface. The apertures are preferably located on the outside of the bend of the elbow, substantially in the line of the flow path of gases leaving the mask.

Figures 5B and 5C also illustrate the connector portions 321 of the strap, engaged over posts 513 of the mask body.

Figures 7A to 7D give context for cross sections illustrated in Figures 8, 7D, 9A and 9B.

Figure 7D is a cross section through line EE of the seal of Figure 7C. Figure 7D illustrates the thicknesses of portions of the seal in the vertical centre plane of the seal. This shows a thickening of the seal in the region 731 immediately adjacent and between the nostril locators. The cross section also illustrates a thickening of the seal in the outer wall portion 431 of

the central portion of the seal above the outlet 403 and thickening of the outer wall portion 441of the central portion below the opening 403. These thickened sections are preferably gradually thickening from the thin supple perimeter portions 435 and 445 respectively to a thickness of approximately 2mm to 4mm. The supple wall portions, being the peripheral portions 435 and 445 and the lower inside wall portion 443 and upper inside wall portion 433 preferably have a wall thickness between 0.05mm and 0.5mm and most preferably between 0.1mm and 0.2mm.

The portion 731 between the nasal locators preferably has a thickness between 2mm and 0.5mm and preferably between 0.8mm and 1mm.

These dimensions are given relevant to a silicone material having a Shore A hardness of about 40. If the seal is formed of other materials commensurate alterations of dimension may be possible while retaining suppleness of the envelope in the regions preferred supple and retaining sufficient stiffness to provide form to the envelope in regions intended to provide shape.

Figure 8 is a section through DD of the mask seal and body of Figure 7A. This illustrates the cross section of the central portion of the seal at the outward side as illustrated and described already in reference to Figure 7D, but illustrates the connection of the seal opening to the opening of the mask body. However, the section of Figure 8 also illustrates a preferred cross-sectional form of a nasal locator. In particular, the thickness of the material of the wall 806 of the nasal locator is preferably between 0.5mm and 2mm and most preferably between 0.8mm and 1mm.

The nasal locator includes a base portion 808 and a nozzle portion 810 with a central opening 812. The portion including opening 812 fits inside the nostril of the user. The base portion 808 provides primary location at the entrance to the nostril.

Figure 9A is a section through line GG of Figure 7D of the seal. This is a cross section of the seal approximately on the horizontal centre plane passing through the nostril locators. This section shows that the wall portions 806 of the nostril locators, the immediately adjacent region 902 outside the perimeter of the nostril locators, and the centre portion 731 between the nostril locators all having a thickened wall relative to the supple wall portions 415 and 423 of the side portions of the seal. In particular, the regions immediately adjacent and including the nasal locators preferably have a thickness between 0.5mm and 2mm and most preferably between 0.8mm and 1mm.

The outer wall portions 413 of the side portions of the seal are substantially thicker again than the portions adjacent the nostril locators. These portions preferably have a thickness

between 2mm and 5mm and most preferably between 3mm and 5mm. These portions gradually taper in thickness to reach the supple thickness where they become the peripheral portion 423.

The thickened portion of the outer side wall 413 of the side portions preferably extends to within 10mm of the outer most tip of the side portion.

The thickening and stiffness of these outer side portions 413 provides substantial form to the seal and stability with the seal in place. The side wall resists outward flexing of the side portions of the seal when the seal is inflated under pressure from the supply while the wall portions 413 will flex outwardly under pressure and have sufficient reaction force to retain the seal wrapped around the nose of the wearer.

The stiffening produced by thicker regions of the seal could be provided by a composite material, or combination of parts. For example, the stiffness could be provided by reinforcement in the silicone, or by a flexible insert of stiff material. The insert of stiff material could be integrated to the mask body. Preferably, the construction is such that the side portions of the seal provide resistance to flexing with an effective stiffness of at least 1N force at the end of the stiffened region to flex the side portion through an angle of about 60°.

Figure 9B illustrates a further, substantially horizontal plane, above the cross section of Figure 9A. This cross section is taken through line FF of Figure 7D. This again illustrates the thickness of the outer side wall portions 413 of the side portions of the seal relative to the inner side wall portions 415 and perimeter portions 423 and relative to the thickness of the upper internal wall portion 433.

Again, the side portions 413 preferably have a thickness between 2mm and 5mm, most preferably between 5mm and 3mm. The supple portions 415, 423 and 433 have thickness between 0.05mm and 0.5mm, and most preferably between 0.1mm and 0.2mm.

Figures 10 to 12 show a further example of an interface with a seal of this type. The interface includes a seal body 1000. The seal body 1000 includes a seal envelope 1001. The seal body 1000 has a curved shape to match the contours of a human face. The seal body 1000 has an inner surface 1002 and an outer surface 1003. The inner surface 1002 includes nasal locators 1004, 1005. The nasal locators 1004, 1005 each have outlets to allow gases to pass to the user. In use, the inner surface 1002 presses against the user's face and the nasal locators 1004, 1005 extend into or sit about the user's nostrils.

The seal body 1000 is shaped to wrap around the user's nose. The seal body 1000 has side portions or wings 1006, 1007 that extend completely over the sides of the user's nose and may also extend at least partially over the user's cheeks. The seal body 1000 curves about and does not extend over the region of the user's nasal bridge. So effectively, there is a cut out region

1008 in the seal body. The cut out region 1008 means that in use the seal body does not put pressure on the user's nasal bridge region, a common area where pressure sores can occur on users of interfaces that extend over a user's nasal bridge.

The seal body 1000 includes an inlet opening or gases supply aperture 1009. The inlet opening 1009 is opposite the nasal locators and receives a frame 1010. The frame 1010 is curved to match the seal body and provides support to the seal body. The frame 1010 includes a connector 1011 that attaches in use to tubing (for example tubing 114 as shown in Figures 1 and 2) that receives pressurised gases for supply the user.

The frame 1010 is made from a plastics material. The plastics material may be a flexible material or maybe a more rigid type material. For example, the frame may be made from a polycarbonate. Alternatively the frame may be made from a more flexible material such as silicone.

In use, the seal of Figures 10 to 12 is supplied with pressurised gases via tubing and through the connector 1011 on the frame 1010. The gases inflate the seal body 1000 and cause it to press against and about the user's nose. The nasal locators 1004, 1005 are caused to seal in or about the user's nostrils and the pressurised gases pass through the locator outlets 1012, 1013 into the user's nostrils.

The frame or seal body includes at least two strap connectors (not shown) similar to those described above. The connectors allow a head strap to be attached to the interface 1000. The head strap will extend about the back of the user's head and provide additional tension on the interface to help with the sealing of the interface on the user's face.

The seal body is made from a flexible material. Examples of possible materials include latex, vinyl, silicone and polyurethane. In a preferred form the seal body's outer wall 1003 is formed to be thicker in cross section material than the inner surface 1002. The thicker outer wall of the seal body holds its predetermined shape while the inner wall is able to flex to conform with the surfaces of the wearer's face.

Figures 13 to 20 show a further embodiment of an interface with a wrap around inflating seal. The interface 1100 includes a seal body 1101 and frame 1102 similar to the embodiment of Figures 10 to 12. The frame 1102 fits in the same way to the seal body 1101 as described above with reference to Figures 10 to 12.

Attached to the frame 1102 is tubing 1112 that is attached to a gases supply apparatus. The tubing supplies gases to the mask frame and seal. The tubing 1112 may be tethered to the user (wearing the interface 1100) by a lanyard 1113. In use the lanyard 1113 extends about the

user's neck. The lanyard 1113 is affixed to the tube by known methods, however, shown is a c-shaped clip 1114 attached to the lanyard 1113 that clips about the tubing.

The interface 1100 is held in place over the user's nose by way of a head strap 1114. The strap is preferably made of a flexible type material, such as silicone or a laminated material well known in the art of head gear straps. Each end of the strap 1114 is preferably fitted to a clip 1116 that attaches to a corresponding eyelet 1117 formed in or attached to the seal body 1101. The strap may be a flat moulded silicone strap, a small hollow silicone tube, or appropriate configurations as are known in the art.

The frame 1102 may have formed in it a plurality of bias flow holes 1115 to allow for exhausting of the user's exhalated gases from the interface. Alternatively, bias flow holes may be formed in the seal body 1101 to allow for exhausting of gases.

The seal body 1101 is again a supple or inflatable type seal. The seal body 1101 is curved in shape to match the contours of a human face and extends about the user's nose, wrapping the user's nose. The seal body 1101 preferably extends completely over the side of the user's nose and may also extend partially over the user's cheeks. The seal 1101 comprises an inner wall with an inner 1103 and an exterior wall with an outer surface 1104. Projecting from the inner surface 1103 are nasal locators 1105, 1106, each with outlets 1107, 1108.

As with the embodiment of Figures 10 to 12 the seal body 1101 includes an inlet opening 1109 that is opposite the nasal locators 1105, 1106 and receives the frame 1102.

The seal 1101 has a variable wall thickness such that there is rigidity around the portions of the seal that project out, and flexibility between the nasal locators 1105, 1106 and a periphery 1110 of the inlet opening 1109 of the seal. This means there is a decoupling effect between the nasal locators 1105, 1106 and the inlet periphery 1110, and subsequently to the mask frame 1102. This will mean that some movement of the mask frame will be possible without disrupting the sealing of the nasal locators 1105, 1106 on or in the user's nostrils.

As can be seen in Figure 18 the inlet periphery 1110, which defines the gases inlet 1105 to the seal, has a substantially thick cross-section. This provides rigidity to the inlet periphery 1110. Similarly, the nasal locators 1105, 1106 have a substantially thick cross-section. However, the thickness of the nasal locators may not necessarily be as thick as or thicker than the inlet periphery 1110. In the preferred form the thickness of the nasal locators is less than that of the inlet periphery.

The areas between the inlet periphery 1110 and the nasal locators 1105, 1106 is preferably thinner in cross-section than both nasal locations and the inlet periphery. For example, in Figure 18 the length of the seal 1101 between X and Y is formed to be substantially thinner in cross-

section than either the inlet periphery or the nasal locators. This means this length is more flexible, effectively allowing more movement of the nasal locators 1105, 1106. Furthermore, as the length between X and Y, including an outer periphery 1111, is thinner in cross section the seal will easily inflate to assist in the sealing of the seal about the user's nose.

As shown in Figure 18, preferably a region 1118 of the envelope adjacent to the base or root of each nasal locator has a thickened cross section. As shown, preferable the length or region 1119 of the seal between region 1118 and the thickened inlet periphery 1110 is formed to be substantially thinner in cross-section than either the inlet periphery 1110, the nasal locators 1105, 1106 or region 1118.

In an alternative embodiment, the envelope includes a thickened region 1118 adjacent the root of the nasal locators and the thickness of the cross section of the nasal locators is not thickened. For example, the thickness of the cross section of the nasal locators may be similar to the thickness of the envelope region 1119 extending between the region 1118 adjacent the nasal locators and the inlet periphery 1110. The thickened region 1118 adjacent the root of the nasal locators prevents the base of the nasal locators from deforming or ballooning excessively under typical CPAP pressure. However, the thinner wall of the nasal locators 1105, 1106 in this embodiment may balloon under CPAP pressure.

Preferably the seal 1101 is formed from silicone with a Shore A hardness of about 40. Alternatively other materials with similar properties may be used. For silicone with a Shore A hardness of 40, or other material with similar properties, the thickness of the envelop region 1119 extending between the nasal locators and the inlet periphery is less than approximately 0.5mm. Preferably this region 1119 has a thickness of 0.1mm to 0.2mm. Alternatively this region 1119 of the envelope may have a thickness of less than 0.1mm, for example 0.05mm.

The thickness of the region 1118 adjacent the base of the nasal locators preferably has a thickness of less than 2mm. Preferably the thickness of the region 1118 adjacent the base of the nasal locators is approximately 0.8mm to 1.0mm. Alternatively the thickness of the region 1118 adjacent the base of the nasal locators may be less than 0.8mm, for example 0.5mm.

The thickness of the region adjacent the inlet periphery is approximately 3mm to 5mm, but could be thinner, for example 2mm.

The nasal locators have a thickness of less than 2mm. In the preferred embodiment, the nasal locators have a thickness of approximately 0.8mm to 1.0mm. Alternatively the thickness of the nasal locators may be less than 0.8mm, for example 0.5mm.

In the alternative embodiment described above, the thickness of the nasal locators is similar to the thickness of the envelope region 1119 extending between the nasal locators and the

inlet periphery. In this embodiment, the nasal locators have a preferred thickness of approximately 0.1mm to 0.2mm. Alternatively the thickness of the nasal locators may be less than 0.2mm, for example 0.05mm.

Preferably the change in thickness from one region of the seal to another occurs gradually. For example, the thickness of the seal changes gradually from thickened portion 1118 to thinner portion 1119. Similarly, the thickness of the seal changes gradually from thickened portion 1110 to thinner portion 1119.

Referring now to Figure 20, which shows the seal 1101 in cross-section through AA of Figure 16. This figure shows an alternative view of the seal 1101 showing the varying thicknesses of parts of the seal. In particular, the inlet periphery 1110 and nasal locators 1106, 1108 are thick in cross-section compared to the outer periphery 1111. At least in the lateral direction, the thickened region 1110 adjacent the inlet extends for at least half of the distance from the inlet to the outer peripheral edge 1121. In the upward direction the thickened region extends at least half the distance from the inlet to the top peripheral edge 1123. In the downward direction the thickened region extends at least half the distance to a lower face portion 1125. The areas of the seal between the nasal locators 1106, 1107, generally indicated as 1112, are also thicker in cross-section to provide additional stability in these areas for the nasal locators.

In Figure 21 an alternative embodiment of the seal is shown. In this alternative embodiment the areas between the nasal locators, indicated as 1113, are substantially thinner in cross-section than that of the inlet periphery 1110 and nasal locators 1106, 1108. This configuration would provide additional flexibility between the nasal locators 1106, 1108.

A yet further embodiment of a seal of the present invention is shown in Figure 22. Here the seal is an inflatable type, but the seal extends down to occlude the user's mouth in use. This seal 1200 has nasal locators 1201, 1202 and is received in a frame similar to that described in any of the embodiments detailed above. The seal 1200 has an extension 1203 that goes over the user's mouth creating a seal and reducing mouth leaks.

Another embodiment of a seal of the present invention is shown in Figure 23. This seal 1300 is of the same form as that in Figure 22, with nasal locators 1301, 1302 and a mouth covering extension 1203, but includes an outlet 1304 directed to the user's mouth, allowing for gases to be delivered simultaneously to the user's mouth as well as the user's nasal passages through the nasal locators 1301, 1302.

Figures 24 to 29 show various head straps that might be used with any of the embodiments of the interfaces described herein.

Figure 24 shows a single head strap 1402 attached to the interface 1400, particularly to the flexible and inflatable seal 1401 by any appropriate means as known in the art of interfaces and head straps. The strap 1402 may be a hollow tube 1402 as shown in Figure 24a or a solid tube 1402' as shown in Figure 24b. The hollow tube could, for example, be an extended silicone tube, with a diameter between 3mm and 6mm and a wall thickness of 0.2mm to 1mm.

Figure 25 shows a single head strap 1410 attached to the interface 1400, particularly to the flexible and inflatable seal 1401 by any appropriate means as known in the art of interfaces and head straps. The strap 1410 may be a hollow elongated tube 1410 as shown in Figure 25a or a solid elongated tube 1410' as shown in Figure 25b. The strap is preferably thinner in width at its ends 1411, 1412 that attach to the seal 1401 and thicker in width at its midpoint that sits at the back of the user's head in use.

Figure 26 shows a double head strap 1420 attached to the interface 1400. The strap 1420 extends about the user's ears and has two attachment points on each side of the seal 1401 where the strap attaches to the seal 1401.

Figures 27 and 27a show an extendible head strap 1430 attached to the interface 1400. The strap 1430 has an area 1431 that can be extended and contracted to better fit the strap to the user's head.

Figure 28 shows an alternative head strap 1440 attached to the interface 1400, particularly to the seal 1401. The head strap 1440 preferably includes side straps 1441 having areas of rigidity 1442, 1443, to provide additional stability to the side straps 1441. The head strap 1440 also preferably includes a top strap 1444 and a back strap 1445 that each extends over the head or behind the head respectively. This head strap is detailed further in US Patent Application No. 12/307993 of Fisher and Paykel Healthcare,

Figures 29 and 29a shows yet a further alternative head strap 1450 attached to the interface 1400, particularly to the seal 1401. The head strap 1450 is curved and has partitions 1451 that provide additional support or rigidity to the strap.

The head straps detailed above may be formed of any appropriate material, such as, flexible plastics, silicone, laminated fabrics, or other appropriate materials.

Figures 30 to 33 show various ways in which an interface frame may be attached to an inflatable seal body. In Figure 30 the seal body 1500 includes overmoulded or bonded rigid plastic barbs 1502. The barbs 1502 clip into correspondingly shaped recesses 1503 formed in the frame 1501 and hold the seal body 1500 in sealing engagement with the frame 1501.

Similarly, in Figure 31the seal body 1500 has a periphery 1502 that is formed with a overmoulded or bonded rigid plastic looped clip 1503 that clips to the frame 1501. Further details of such a clipping mechanism are described in US Patent Application Number 12/502528 of Fisher and Paykel Healthcare.

Alternatively, as shown in Figure 32 the seal body 1500 may have an inlet 1502 that has a stretch interference fit about the frame 1501. The frame preferably has a groove 1503 and raised edge 1504 that allows the inlet 1502 to engage with the frame.

In a further alternative form as shown in Figure 33, a seal body 1500 may be permanently attached to the frame 1501 by overmoulding or bonding.

Figures 34 to 40 illustrate various ways in which the tubing (1112, see Figure 13) extending from the interface 1100 may be secured to a user. The advantage of securing the tubing to the user is to take the weight of the tubing off the interface, reducing the possibility of the interface being pulled from the user's face. Each of the braces described below is preferably made from fabric straps. It is preferred that the fabric is a breathable type material, but other appropriate fabrics may be used. In all forms detailed herein the tubing is fixed to the brace by way of a clip or pin.

In Figure 34 a brace 1600 is shown that is made from a looped strap of fabric that in use is placed about the user's head and one shoulder.

In Figure 35 an alternative brace 1610 is shown. This brace is also preferably made from fabric that is formed in a central cross across the user's chest and is braced around each of the user's arms.

In Figure 36 a further alternative brace 1620 is shown. Here the brace 1620 has a central cross of straps across the user's chest, but it is braced across the user's neck and back.

Alternatively, as shown in Figure 37, a brace 1630 could be used to secure tubing to the user where a brace is formed from the looped strap that is extended about the user's chest and under their arms.

As shown in Figures 38 or 39, a brace 1640 may additionally include two shoulder straps 1641, 1642 or simply one shoulder strap 1643.

Alternatively, as shown in Figure 40, a simple brace 1650 may be used with the interface of the present invention that simply fits in use about the user's shoulder or upper arm.

Additional tube support arrangements will be described with reference to Figures 41 to 57. Figures 41 to 51 describe a supporting collar intended to be worn around the neck of the user, and to which the tube may be supported by a tether. Figures 52 to 55 describe aspects of a tether that might be used with such a collar, or might be used with other arrangements for

securing one end of the tether to the patient. Figures 56 and 57 illustrate two such arrangements for securing a tether to the patient. Figures 34 to 40 illustrate other arrangements for securing such a tether to the patient.

Figures 41 to 45 illustrate in further detail the collar previously described in broad terms in relation to Figures 1 to 3. The collar includes an adjustable connection 327 and a secondary connection 329. The adjustable connection operates between a first end of the collar 4100 and a second end 4102. The adjustable connection 327 allows the user to set the amount of overlap of the ends 4100 and 4102 to be set. Figures 41 to 45 illustrate an adjustable connection 327 in the form of a dome fastener system. One fastener portion 4104 is fixed to the first strap end 4100. A number of complementary fastener portions 4106 are provided spaced along the second strap end 4102. Engaging the fastener 4104 with one of the series of fastener portions 4106 sets the overlap of end 4100 relative to end 4102. The fastener portions 4106 may be spaced at intervals between 2cm and 5cm, preferably between 3cm to 4cm. This provides a degree of variation in the circumference of the collar in increments of between 3cm 4cm.

Preferably the outer overlapping end 4100 includes a single connector portion and the inner strap end includes a series of outwardly-facing second connector portions. According to this arrangement, no connector portion faces toward the patient neck. Accordingly, the internal surface of the collar is free of distracting projections.

The connector portions may be portions of, for example, a dome fastener of known type.

The extreme end of inner end 4102 may include an outwardly projecting loop engaging over the overlapping portion of the collar strap. This loop 4302, shown only in Figure 43, would align the free end of underlapping end 4102 with the overlapping portion of the collar when the collar is set on tighter sizes.

Alternative connectors for the adjustable connection are illustrated in Figures 46 to 49. The dome fastener connection is illustrated in more detail in Figure 46.

An alternative fastener using engaging magnets is illustrated in Figure 47. The outer strap end 4702 includes an inwardly-facing magnet portion 4704. The inner strap end 4706 includes an outwardly-facing magnet portion 4708. The inwardly-facing magnet portion 4704 preferably is magnetized to a first polarity facing inwards. The outwardly-facing magnet portion 4708 is preferably magnetized with a complementary polarity facing outwards. A series of outwardly-facing magnets 4708 would be spaced along the outer surface of the inner strap portion 4706.

The magnet portions may be fixed to a base portion 4710 which in turn may be fixed to the strap. For example, the magnets may be glued to a substrate material that can be stitched to

the strap. Alternatively, magnets might be moulded to include holes to allow the magnets to be directly stitched to the strap.

The magnet 4704 could be replaced by a magnetic material which would be attracted by magnets 4708 but not be a magnet itself. Alternatively, magnets 4708 could be replaced by portions of a material that is magnetic but not itself a magnet. By way of example, the magnets may be ferrite or rare earth, while magnetic materials might be small sections of steel. Ferrite powder bonded with a flexible polymer may allow the magnets to be flexible while maintaining sufficient strength to secure the collar.

Figure 48 illustrates the adjustable connection being made by a hook and loop fastener system. For example, the outer end portion 4802 may include a short section 4804 of a material with projecting hooks. The inner strap end 4806 may include an outwardly-facing section 4808 covered with loops, to which the hooks may engage and disengage. Suitable hooks and loop fastener material is sold under the Velcro brand.

The outwardly facing loop material may be stitched to the collar strap, or the collar strap may be formed from a material that integrally includes the loops. The length of the loop portion 4808 is much greater than the length of the hook portion 4804 and preferably extends a length equivalent to the adjustment required to be available to the collar. For example, the loop fastener material would have a length of about 15cm along the collar strap.

Figure 49 illustrates an alternative mechanical fastener similar to the dome fastener. This type of dome fastener includes a smaller receiving aperture 4902 on the female portion and smaller projecting pins 4904 on the male portion.

Referring back to Figures 43 to 45, the collar preferably includes a second releasable connection 329 between a third end 4302 and a fourth end 4304. Thus, the overall ring of the collar is divided into two separate strap sections. Each strap section includes at one end part of the adjustable connections 327 and at the other end part of the second connection 329.

Preferably this second connection is not adjustable. This second connection 329 is intended to be engaged and disengaged at each use of the collar. The adjustable connection can be adjusted to the correct length and set, and the second connection 329 can be used to secure and release the collar.

This second connection 329 may be formed by any suitable means, including the examples illustrated in Figures 46 to 49, or including a plain releasable fastening clip such as illustrated in Figures 50A and 50B (50A in the connected condition and 50B in the open condition), or a breakaway connector which releases upon application of tension in a predetermined range.

The connection 329 illustrated in Figure 45 includes a breakaway connector having a first body portion 4502 secured to strap end 4302 and a second body portion 4504 secured to fourth strap end 4304. The first and second body portions each include a projecting tang and a socket. The projecting tang of one body is complementary with the socket of the other body. The projecting tang and socket preferably have an interference fit. The amount of interference and the force required to pull the tang from the socket defines the release force for the breakaway clip.

This preferred breakaway clip is illustrated in more detail in Figures 51A and 51B. In Figure 51A, the clip is illustrated in the open configuration where a tang 5102 projects from each clip body portion and each tang 5102 includes a small lateral projection 5104. The socket in each body portion of the clip includes a lateral aperture 5106. When the tang 5102 is pushed into the socket, the projection 5104 extends into the aperture 5106. The interference fit is provided by engagement of the projection 5104 in the aperture 5106. This connector is shown in its engaged condition in Figure 51B.

Referring again to Figures 41 to 45, a tether extends from the collar. The tether 4112 is connected with the collar at one end and to an engaging clip 4114 at its free end. The engaging clip 4114 is for connection with the supply conduit for the patient interface. The engaging clip 4114 is illustrated in greater detail in Figure 55, where an enlarged view of its fitting with the cuff of the conduit is illustrated. The preferred connector includes an open ring which fits over a sleeve portion of the cuff and is held in place between a flange 5502 of the cuff and a flange 5504 of a swivel conduit connected to the cuff.

The preferred tether includes a breakaway clip at some position along its length between the connection to the collar and the conduit connector. The breakaway connector may be of the form described already with reference to Figures 51A and 51B. That form of breakaway connector is illustrated in Figures 52, 54A and 54B.

Alternatively, the breakaway connector may also include a swivel, such that the collar does not need to be correctly oriented relative to the conduit before donning the patient interface. In this case, the breakaway connector may include a socket portion 5302 and a male portion 5304, with the male portion 5304 being rotationally symmetric. For example, the male portion 5304 may include a projecting knob 5306 with an enlarged end 5308. The socket 5302 would include projecting portions or an annular projecting portion around the internal circumference adjacent the open end. The socket 5302 may be required to be made in two pieces subsequently secured together to produce this projecting lip or lips. The socket portion 5302

may be open at its other end 5310 so that the connector portion 5302 can be formed in one piece. This end may accommodate an end of a strap portion 5312 of the tether.

Alternatively, a swivel may be included at another location along the tether.

Preferably the tether is formed with a sliding connector 5202 at one end for connection over the collar. The sliding connector 5202 preferably comprises a moulded loop including straight sections either side of the web of the collar and joined by transverse sections above and below the collar edge. The loop preferably has a moderately tight fit on the collar so that once moved into a position, it tends to stay in that position but can be moved along the collar upon application of sufficient force. The loop 5202 essentially mirrors the profile of the web of the collar. A tether portion may extend from the loop 5202, preferably being integrally formed with the loop 5202. Preferably the tether portion and loop are formed from a flexible resilient material such as silicone.

Another tether portion extends from the quick release connector to the conduit in engagement clip. Again, this may be formed of any suitable material, preferably flexible and preferably a silicone material.

The tether may be of fixed or adjustable length. Preferably, the tether may be provided in multiple lengths, for selection by a patient. The tether may be of a length between 3cm and 15cm. A tether at approximately 3cm is illustrated in Figures 54A to 54B, the tether including limited, if any, strap portions. This tether is mostly made by its loop connector to the collar, by the quick release connector and by its connection to the conduit connector.

A longer tether is illustrated in Figure 52 and in Figure 53, including a substantial strap portion between the connecting loop 5202 and the quick release connector and another substantial strap portion between the quick release connector and the conduit connector. These portions of the tether could be interchanged, so that for example, the strap portion of the tether could be provided entirely to one side or other of the breakaway connector.

Figure 56 illustrates an alternative support arrangement to the use of a collar. The tether 5602 terminates in a clip 5604 instead of terminating at a connector for the collar. The clip 5604, preferably in the form of a type of peg, alligator clip or other arrangement having gripping jaws, is intended for attachment to the neckline or other convenient portion of clothing worn by the patient. Alternative, the tether may be terminated at a connector for connecting to brace structures to be worn by the patient as described earlier.

The tether may or may not include a breakaway connector.

Figure 57 illustrates another alternative for connection to clothing 5702 on the patient. This illustrates the push clip 5704 connected to the collar line of the clothing and including a breakaway connector 5706.

The preferred collar is constructed from materials comfortable to the wearer. In the simplest form, the collar might be, for example, a strap of a soft, flexible material having sufficient stiffness to hold the general collar form, sufficient strength to resist any substantial extension or stretching and comfortable inside surface facing the patient. One suitable material might be, for example, a laminated foam material such as Breathoprene, which has a foam web, faced on either side with a knitted fabric.

However, the preferred collar is more resistant to stretch than the Breathoprene material, and more breathable than the Breathoprene material. For comfort against the skin, the collar is preferably faced with a woven, knitted or braided natural fibre fabric. For example, a braided or knitted tube of cotton or bamboo yarn. To provide form to the collar, the braided or knitted tube surrounds a flexible skeleton. The flexible skeleton might comprise a series of hingedly connected frames, or a moulded flexible strap formed with an open framework. Preferably it comprises a narrow strap of plastic mesh. An example of a suitable mesh is 3MESH, manufacture by Mullter Texti Group of Germany. The open framework or mesh form allows moisture and heat to pass readily through the collar, reducing discomfort of the patient wearing the collar for long periods.

The collar strap is preferably 3cm to 6cm wide and between 3mm and 8mm thick.

The preferred simple head strap is illustrated in Figures 1 to 3. It includes a single, non-bifurcated strap terminated with a connector at either end. The strap could be permanently connected to either end of the frame, but preferably the connectors are configured to be removable from the body of the mask.

The single non-bifurcated strap preferably accommodates a substantial variation in head size without adjustment. The preferred strap has a very low stiffness, with extension of a 400mm king strap from a fully laid out but unstretched condition to a condition 1.3 times its original length requires a force not exceeding 4N, and preferably not exceeding 2N. Figure 62 is a graph illustrating the force versus extension characteristics of four sample strap materials. The preferred material comprises a knitted tube nylon yarn incorporating strands of Lycra. The nylon yarn is sufficiently loosely formed that is capable of extension beyond the range required without becoming tight. The amount of Lycra strands in the yarn may be varied to vary the stiffness of the strap. An overall diameter of the strap is preferably less than 10mm and most preferably less than 6mm.

The end connectors of the strap may be fixed to the strap in any suitable manner. Preferably the end connectors are overmoulded to ends of the straps. Test results for a range of alternative strap materials are illustrated in Figure 62. All test results are for extensions of a length of the tested material from an "at rest" length of about 400mm.

Line 6202 shows extension test results for a knitted yarn of nylon incorporating Lycra filaments, the knitted tube having a nominal diameter of 5mm. This also is stiffer than desirable.

Line 6206 illustrates a hypothetical most desirable response determined by the inventors.

Line 6209 illustrates the response for an extended silicone hollow tube with a wall thickness of 0.25mm and an outside diameter of 3mm.

Line 6207 illustrates the response for an extended silicone hollow tube with a wall thickness of 0.25mm and an outside diameter of 6mm.

Both these silicone extensions show satisfactory characteristics.

Line 6205 illustrates the response of the preferred knitted nylon yarn incorporating Lycra filaments. This knitted tube had a nominal diameter of 4mm.

Line 6208 illustrates the response of a length of 3mm woven elastic webbing. This product exhibited similar characteristics to the preferred knitted yarn, however the elastic webbing has a tendency to catch hair and to lose elasticity.

Figures 58 to 61 illustrate another patient interface incorporating a seal substantially as described earlier, but which includes features that may eliminate or reduce the need for additional support to the conduit. According to this embodiment, the body of the mask includes depending stabilizers 6102. A depending stabilizer is provided at each side of the mask body. Each depending stabilizer extends beyond the perimeter of the mask seal and includes a foot 6104 to engage against the upper lip of the wearer. Preferably, the stabilizer does not extend beyond the inside surface of the seal, but is spaced forwards from the inside surface of the seal, with the feet 6104 located in a position such that with the mask donned and in use symmetrically on the patient, the feet 6104 of the depending stabilizers do not contact the wearer. Each foot 6104 may include a pad 6106 of soft material such as a soft polymer or elastomer foam or a section of hollow silicone extrusion. The stabilizers be integrated with the seal rather than the frame, for example, being integrally formed as a moulded silicone body extending from adjacent the central opening to protrude beyond the lower edge of the seal. In this case, features on the mask body could secure the position of the in board ends of the stabilisers.

Each stabilizer extends in a downward direction to a region below the seal, and is intended to engage in the area of the upper lip of the patient in the area bounded by the mouth, the nose and the nasolabial folds and, preferably, not against the cheeks of the patient.

Accordingly, the feet are profiled and positioned to fit within this area. Each stabilizer 6102 and arm 6108 extending from the lateral central portion 6110 of the mask body. The form of this arm, and the material of this arm may be such that the arm is rigid, or that the arm has a desired degree of flexibility. Generally, this arm should be rigid.

The purpose of the stabilizers is to reside closely spaced from the upper lip portion of the user when the interface is correctly placed and to contact the upper lip region of the user when the interface is rocked to one side or the other relative to the user's nose, for example, under the influence of the supply conduit. Gentle pressure on the foot 6104 of the stabilizer, which is laterally spaced from the centre line of the mask, preferably toward the extreme edges of the mask, supports the mask against these side forces from the conduit, stopping the mask rocking too far across the face and breaking the seal.

Furthermore, the stabilizers depend below the mask and support the mask if the weight of the conduit tends to rotate mask forward. In that case, the feet 6104 of both stabilizers will contact the user's upper lip and support the position of the mask.

The stabilizers are illustrated in preferred form as having a substantially rigid construction, but with flexible or soft pads 6106. However, to account for variations in patient geometry, these stabilizers could be a selectable appendage, with a connection arrangement to the mask allowing replacement with stabilizers of a different form. Alternatively the stabilizers could be made to be adjusted, such as by providing hinge portions capable of multiple fixed positions along the length of the stabiliser, or at the junction of the arms and feet or both. Alternatively, the arms could be formed of a malleable material which is capable of substantial yield. According to this, the arms could be flexed into a desired position by yielding of the material and stay in that position.

In the embodiment with hinging of the arms or feet, a linkage arrangement could be provided to link the movement of each of the stabilizers, or the stabilizers may be individually or collectively supported in position by a spring or springs or other resilient member.

With the addition of the stabilizers, the mask may be sufficiently secure and placed on the patient without any desire for additional support of the conduit. This in turn may allow a shorter length of flexible coupling tube 6120. Accordingly, the flexible coupling tube 6210 (which would typically be much more flexible than the main supply conduit) can be reduced in length to between 5cm and 15cm, and preferably about 10cm. In systems that include a humidified gases supply and a heated main supply conduit, this short flexible coupling tube is usually unheated. Where the coupling tube needs to be supported by a lanyard or collar, there is a minimum length generally exceeding 15cm. If the requirement for the lanyard in collar is eliminated, the shorter

coupling tube is only provided for flexibility, to de-couple the relatively rigid supply conduit from the mask and facilitate freedom of movement of the wearer's head. As the coupling tube is typically unheated, the humidity of the gases carried in the tube can rainout on the cooler wall surface creating collections of water which can ultimately be blown into the user's nostrils creating discomfort. Providing a shorter tube, as allowed by the lip stabilisers, reduces the likely rainout in the conduit.

We Claim:

1. A patient interface comprising:

a nasal seal with a pair of nasal locators on a face contacting side and an opening on an outward facing side, the nasal seal being formed of a soft flexible material, and a periphery of the opening comprising a rigid clip,

a body assembled to the nasal seal to form an enclosure, the body formed of a material more rigid than the material of the nasal seal and including a nasal seal engaging portion that engages the clip of the seal,

an inlet opening provided at a central location of the body,

side arms extending from each side of the body, beyond the width of the seal, and a strap engaging portion on each said side arm,

a strap extending between the strap engaging portions, and

bias flow vents in the body on each side of the inlet opening.

2. A patient interface as claimed in claim 1, wherein the nasal seal includes a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each side portion extending across a side of the nose.

3. A patient interface as claimed in claim 1 or 2 wherein the strap is formed of a material comprising a tube.

4. A patient interface as claimed in claim 3 wherein the strap is formed of a material comprising a knitted elastic tube.

5. A patient interface as claimed in claim 4 wherein the knitted elastic tube is hollow and elongated.

6. A patient interface as claimed in claim 5 wherein the knitted elastic tube comprises first and second flattened elongated side walls with a hollow area disposed between the first and second side walls, the first side wall having an outer surface facing toward a user in use and the second side wall having an outer surface facing away from a user in use.

7. A patient interface as claimed in any one of claims 1 to 6 wherein the strap is formed of a material constructed from a knitted or braided yarn.

8. A patient interface as claimed in claim 7 wherein the yarn incorporates filaments of a material with high elasticity and filaments of material of much higher stiffness.

9. A patient interface as claimed in claim 8 wherein the yarn comprises nylon and Lycra.

10. A patient interface as claimed in any one of Claims 1 to 9 wherein the strap has an area that can be extended and contracted to better fit the strap to the user's head.

11. A patient interface as claimed in any one of claims 1 to 10 wherein the strap attaches to the strap engaging portions at a location spaced apart from the seal and spaced apart from the face of a user.

12. A patient interface as claimed in any one of claims 1 to 11 wherein the strap is removably connectable with the strap engaging portions.

13. A patient interface as claimed in any one of claims 1 to 12 wherein tips of the arms are rearward of a base of the nasal locators.

14. A patient interface as claimed in any one of claims 1 to 13 wherein the body curves to follow approximately the contour of the upper lip of a wearer, and the opening of the seal follows the curve of the body.

15. A patient interface as claimed in any one of claims 1 to 14 wherein the inlet opening angles downwards.

16. A patient interface as claimed in claim 15 further comprising flexible tubing extending from the inlet opening of the body.

17. A patient interface as claimed in any one of claims 1 to 16 wherein the strap is non-bifurcated along the length of the strap.

18. A patient interface as claimed in any one of claims 1 to 17 wherein the strap is a single strap.

19. A patient interface as claimed in any one of claims 1 to 18 wherein the rigid clip is overmoulded or bonded to the periphery of the opening of the nasal seal.

20. A patient interface comprising:

a nasal seal with a pair of nasal locators on a face contacting side and an opening on an outward facing side, the nasal seal being formed of a soft flexible material, and a periphery of the opening comprising a rigid clip, wherein the rigid clip is overmoulded or bonded to the periphery of the opening of the nasal seal,

a body assembled to the nasal seal to form an enclosure, the body formed of a material more rigid than material of the nasal seal and including a nasal seal engaging portion that engages the clip of the seal, wherein the body curves to follow approximately the contour of the upper lip of a wearer, and the opening of the seal follows the curve of the body,

an inlet opening provided at a central location of the body, wherein the inlet opening angles downwards,

flexible tubing extending from the inlet opening of the body,

side arms extending from each side of the body, beyond the width of the seal, and a strap engaging portion on each said side arm, wherein tips of the arms are rearward of a base of the nasal locators,

a single strap extending between the strap engaging portions, the strap being formed of a material comprising a knitted elastic tube constructed from a knitted or braided yarn, and

bias flow vents in the body on each side of the inlet opening.

21. A patient interface as claimed in claim 20, wherein the nasal seal includes a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each side portion extending across a side of the nose.

22. A patient interface as claimed in claim 20 or 21 wherein the strap attaches to the strap engaging portions at a location spaced apart from the nasal seal and spaced apart from the face of a user.

23. A patient interface as claimed in any one of claims 20 to 22 wherein the strap is non-bifurcated along the length of the strap.

24. A patient interface comprising:

a nasal seal with a pair of nasal locators on a face contacting side and an opening on an outward facing side, the nasal seal being formed of a soft flexible material, and a periphery of the opening comprising a rigid clip, wherein the rigid clip is overmoulded or bonded to the periphery of the opening of the nasal seal,

a body assembled to the nasal seal to form an enclosure, the body formed of a material more rigid than material of the nasal seal and including a nasal seal engaging portion that engages the clip of the seal, wherein the body curves to follow approximately the contour of the upper lip of a wearer, and the opening of the seal follows the curve of the body,

an inlet opening provided at a central location of the body, wherein the inlet opening angles downwards,

flexible tubing extending from the inlet opening of the body,

side arms extending from each side of the body, beyond the width of the seal, and a strap engaging portion on each said side arm, wherein tips of the arms are rearward of a base of the nasal locators,

a strap extending between the strap engaging portions, the strap being formed of a material comprising a knitted elastic tube constructed from a knitted or braided yarn, and

bias flow vents in the body on each side of the inlet opening.

25. A patient interface as claimed in claim 24, wherein the nasal seal includes a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each side portion extending across a side of the nose.

26. A patient interface as claimed in claim 24 or 25 wherein the strap attaches to the strap engaging portions at a location spaced apart from the nasal seal and spaced apart from the face of a user.

27. A patient interface as claimed in any one of claims 24 to 26 wherein the strap is non-bifurcated along the length of the strap.

28. A patient interface as claimed in any one of claims 24 to 27, wherein the strap is a single strap.

29. A patient interface comprising:

a nasal seal with a pair of nasal locators on a face contacting side and an opening on an outward facing side, the nasal seal being formed of a soft flexible material, and a periphery of the

opening comprising a rigid clip, wherein the rigid clip is overmoulded or bonded to the periphery of the opening of the nasal seal,

a body assembled to the nasal seal to form an enclosure, the body formed of a material more rigid than material of the nasal seal and including a nasal seal engaging portion that engages the clip of the seal,

an inlet opening provided at a central location of the body, wherein the inlet opening angles downwards,

flexible tubing extending from the inlet opening of the body,

side arms extending from each side of the body, beyond the width of the seal, and a strap engaging portion on each said side arm, wherein tips of the arms are rearward of a base of the nasal locators,

a strap extending between the strap engaging portions, the strap being formed of a material comprising a knitted elastic tube constructed from a knitted or braided yarn, and

bias flow vents in the body on each side of the inlet opening.

30. A patient interface as claimed in claim 29, wherein the nasal seal includes a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each side portion extending across a side of the nose.

31. A patient interface as claimed in claim 29 or 30 wherein the strap attaches to the strap engaging portions at a location spaced apart from the nasal seal and spaced apart from the face of a user.

32. A patient interface as claimed in any one of claims 29 to 31 wherein the body curves to follow approximately the contour of the upper lip of a wearer, and the opening of the nasal seal follows the curve of the body.

33. A patient interface as claimed in any one of claims 29 to 32 wherein the strap is non-bifurcated along the length of the strap.

34. A patient interface as claimed in any one of claims 29 to 33, wherein the strap is a single strap.

35. A patient interface comprising:

a nasal seal with a pair of nasal locators on a face contacting side and an opening on an outward facing side, the nasal seal being formed of a soft flexible material, and a periphery of the opening comprising a rigid clip, wherein the rigid clip is overmoulded or bonded to the periphery of the opening of the nasal seal,

a body assembled to the nasal seal to form an enclosure, the body formed of a material more rigid than material of the nasal seal and including a nasal seal engaging portion that engages the clip of the seal,

an inlet opening provided at a central location of the body, wherein the inlet opening angles downwards,

flexible tubing extending from the inlet opening of the body,

side arms extending from each side of the body, beyond the width of the seal, and a strap engaging portion on each said side arm,

a strap extending between the strap engaging portions, the strap being formed of a material comprising a knitted elastic tube constructed from a knitted or braided yarn, and

bias flow vents in the body on each side of the inlet opening.

36. A patient interface as claimed in claim 35, wherein the nasal seal includes a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each side portion extending across a side of the nose.

37. A patient interface as claimed in claim 35 or 36 wherein the strap attaches to the strap engaging portions at a location spaced apart from the nasal seal and spaced apart from the face of a user.

38. A patient interface as claimed in any one of claims 35 to 37 wherein tips of the arms are rearward of a base of the nasal locators.

39. A patient interface as claimed in any one of claims 35 to 38 wherein the body curves to follow approximately the contour of the upper lip of a wearer, and the opening of the nasal seal follows the curve of the body.

40. A patient interface as claimed in any one of claims 35 to 39 wherein the strap is non-bifurcated along the length of the strap.

41. A patient interface as claimed in any one of claims 35 to 40, wherein the strap is a single strap.

42. A patient interface comprising:

a nasal seal with a pair of nasal locators on a face contacting side and an opening on an outward facing side, the nasal seal being formed of a soft flexible material, and a periphery of the opening comprising first and second rigid barbs projecting at locations adjacent to the opening,

a body assembled to the nasal seal to form an enclosure, the body formed of a material more rigid than the material of the nasal seal and including first and second recesses engaging the first and second rigid barbs of the seal, holding the seal in sealing engagement with the body,

an inlet opening provided on the body,

side arms extending from each side of the body, beyond the width of the seal, and a strap engaging portion on each said side arm, each strap engaging portion comprising a post,

a strap extending between the strap engaging portions, the strap being formed of a material comprising a knitted elastic tube.

43. A patient interface as claimed in Claim 42, wherein the nasal seal includes a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each side portion extending across a side of the nose.

44. A patient interface as claimed in Claim 42 or 43 wherein the first and second rigid barbs are on opposite sides of the opening.

45. A patient interface as claimed in any one of Claims 42 to 44 wherein the knitted elastic tube is hollow and elongated.

46. A patient interface as claimed in any one of Claims 42 to 45 wherein the knitted elastic tube comprises first and second flattened elongated side walls with a hollow area disposed between the first and second side walls, the first side wall having an outer surface facing toward a user in use and the second side wall having an outer surface facing away from a user in use.

47. A patient interface as claimed in any one of Claims 42 to 46 wherein the strap is formed of a material constructed from a knitted yarn incorporating filaments of a material with high elasticity and filaments of material of much higher stiffness.

48. A patient interface as claimed in Claim 47 wherein the knitted yarn comprises nylon and Lycra.

49. A patient interface as claimed in any one of Claims 42 to 48 wherein the strap has an area that can be extended and contracted to better fit the strap to the user's head.

50. A patient interface as claimed in any one of Claims 42 to 49 wherein the strap attaches to the strap engaging portions at a location spaced apart from the seal and spaced apart from the face of a user.

51. A patient interface as claimed in any one of Claims 42 to 50, wherein the strap is removably connectable with the strap engaging portions.

52. A patient interface as claimed in any one of Claims 42 to 51 wherein tips of the arms are rearward of a base of the nasal locators.

53. A patient interface as claimed in any one of Claims 42 to 52 wherein the body curves to follow approximately the contour of the upper lip of a wearer, and the opening of the seal follows the curve of the body.

54. A patient interface as claimed in any one of Claims 42 to 53 wherein the inlet opening is provided at a central location of the body.

55. A patient interface as claimed in any one of Claims 42 to 54 wherein the inlet opening angles downwards.

56. A patient interface as claimed in Claim 55 further comprising flexible tubing extending from the inlet opening of the body.

57. A patient interface as claimed in any one of Claims 42 to 56 comprising bias flow vents in the body on each side of the inlet opening.

58. A patient interface as claimed in any one of Claims 42 to 57 wherein the strap is non-bifurcated along the length of the strap.

59. A patient interface as claimed in any one of Claims 42 to 58, wherein the strap is a single strap.

60. A patient interface as claimed in any one of Claims 42 to 59 wherein the first and second rigid barbs are overmoulded or bonded to the periphery of the opening of the nasal seal.

61. A mask assembly for delivering breathing gases to a patient, comprising:
a nasal seal, a mask frame, and a head strap;
the nasal seal comprising:
a seal opening on an outward-facing side of the nasal seal, the seal opening including lips and/or channels located on a perimeter of the seal opening; and
a pair of nasal locators protruding from a patient-facing side of the nasal seal, each of the nasal locators having a base portion;
the mask frame being made from a rigid plastics material, and comprising:
a socket for connecting with a supply conduit;
an outlet opening directly opposite an opening of the socket, so that the opening of the socket is centrally located on the mask frame, and including channels and/or lips for engagement with the lips and/or channels of the seal opening;
a pair of side arms extending from the mask frame, beyond an extreme width of the nasal seal, the side arms having tips rearward of the base portions of the nasal locators, wherein the base portions of the nasal locators are between a central portion of the mask frame and a line connecting the tips of the side arms, each of the side arms including a connector portion for engagement with the head strap; and
a pair of central side portions, each extending between a left and a right side of the socket and the respective side arm, each of the central side portions including small apertures as part of a gas washout vent; and
the head strap comprising:
connector portions for engagement with the connector portions of the side arms.

62. The mask assembly according to claim 61, wherein the mask frame is curved to follow approximately the contour of the upper lip of the patient.

63. The mask assembly according to claim 62, wherein the seal opening follows the approximate curve of the mask frame.

64. The mask assembly according to any of claims 61 to 63, wherein the seal opening comprises clip portions to facilitate engagement of the nasal seal with the mask frame.

65. The mask assembly of claim 64, wherein the clip portions are attached to or over-moulded to the perimeter of the seal opening.

66. The mask assembly according to any of claims 61 to 65, wherein the seal opening is commensurate with the extent of the mask frame, this extent being commensurate with the general width of the nasal seal and approximately with the width of the nose of the patient.

67. The mask assembly accordingly to any of claims 61 to 66, wherein the connector portions of the side arms comprise a securing post with a perimeter undercut.

68. The mask assembly according to claim 67, wherein the connector portions of the head strap each comprise a small loop formed at each end of the head strap.

69. The mask assembly according to claim 68, wherein the small loop stretches over the securing post and engages the perimeter undercut.

70. The mask assembly according to any of claims 61 to 69, wherein the overall plan form of the nasal seal is parabolic, half elliptical, half oval or U-shaped.

71. The mask assembly according to any of claims 61 to 70, wherein the head strap extends about the back of the patient's head and provides additional tension on the interface to help with the sealing of the interface on the patient's face.

72. The mask assembly according to any of claims 61 to 71, wherein the head strap is a hollow tube.

73. The mask assembly according to any of claims 61 to 72, wherein the head strap is a hollow elongated tube.

74. The mask assembly according to any of claims 61 to 73, wherein the head strap is extendible.

75. The mask assembly according to claim 74, wherein the head strap includes an area that can be extended and contracted to better fit the strap to the patient's head.

76. The mask assembly according to any of claims 61 to 75, wherein the head strap comprises a knitted tube of yarns.

77. The mask assembly according to claim 76, wherein the knitted tube of yarns incorporates filaments of a material with high elasticity and filaments of material of much higher stiffness.

78. The mask assembly according to claim 61, wherein the head strap includes a single length of stretchable material.

79. The mask assembly according to claim 61, wherein the head strap includes side straps having areas of rigidity to provide additional stability to the side straps.

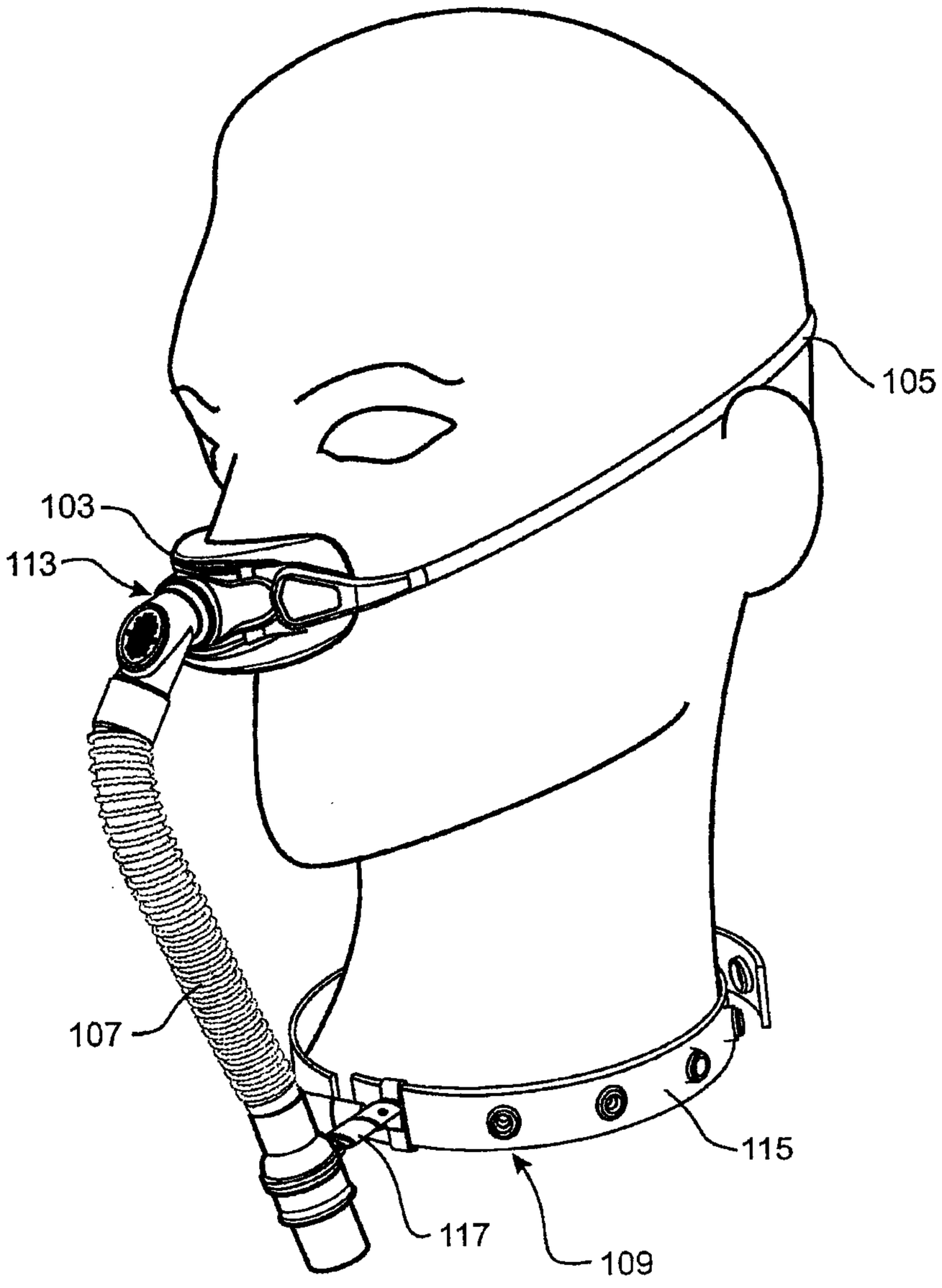

FIG. 1

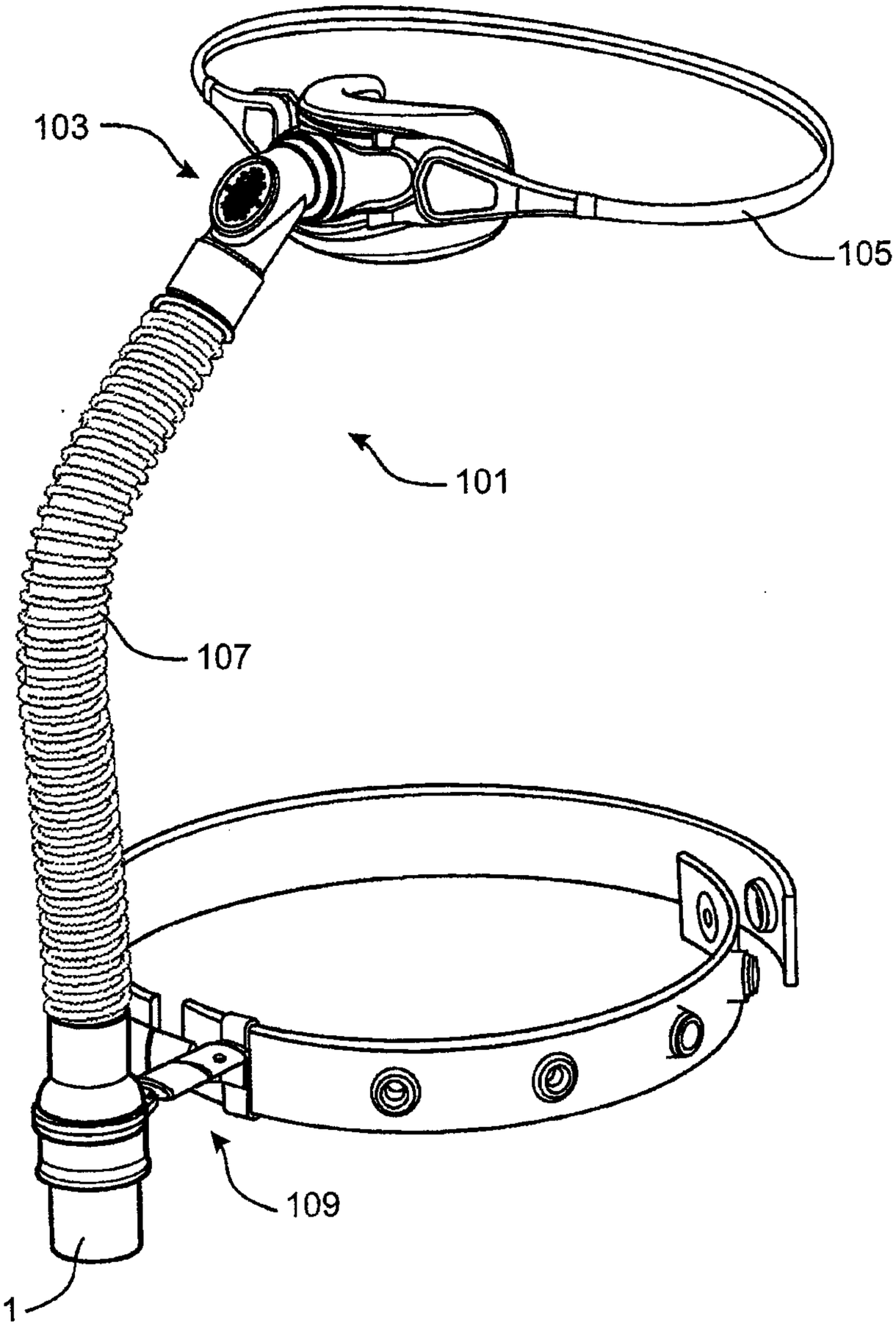

FIG. 2

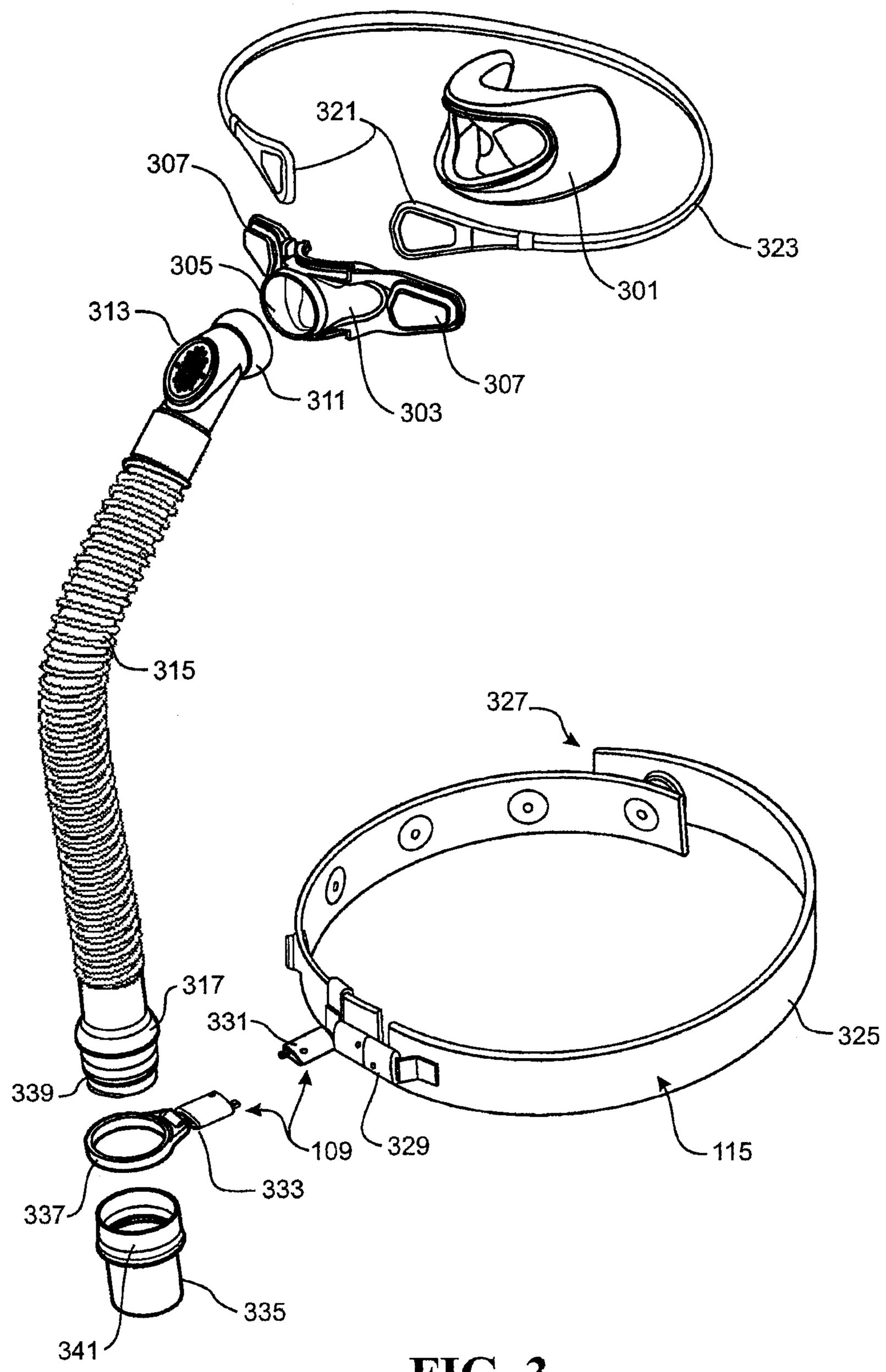
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FIG. 3

FIG. 4A

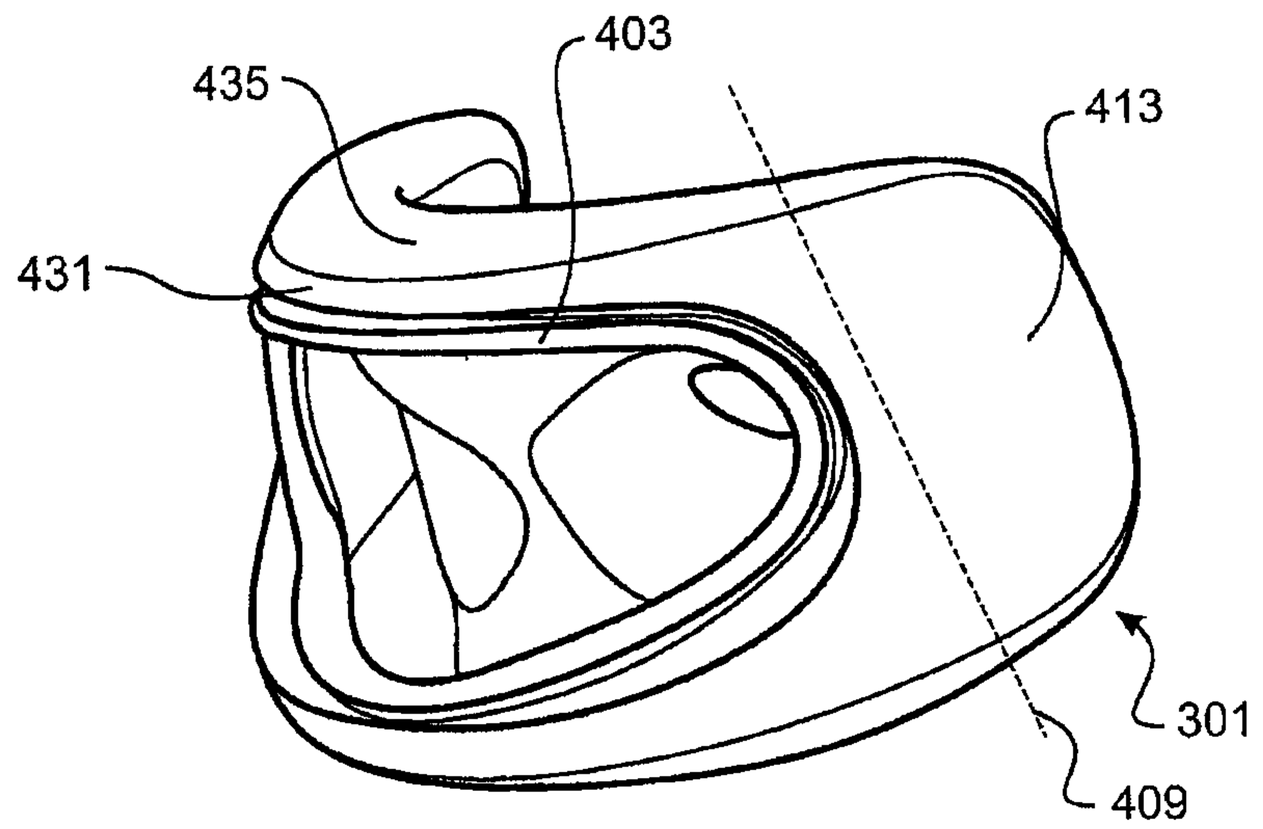


FIG. 4B

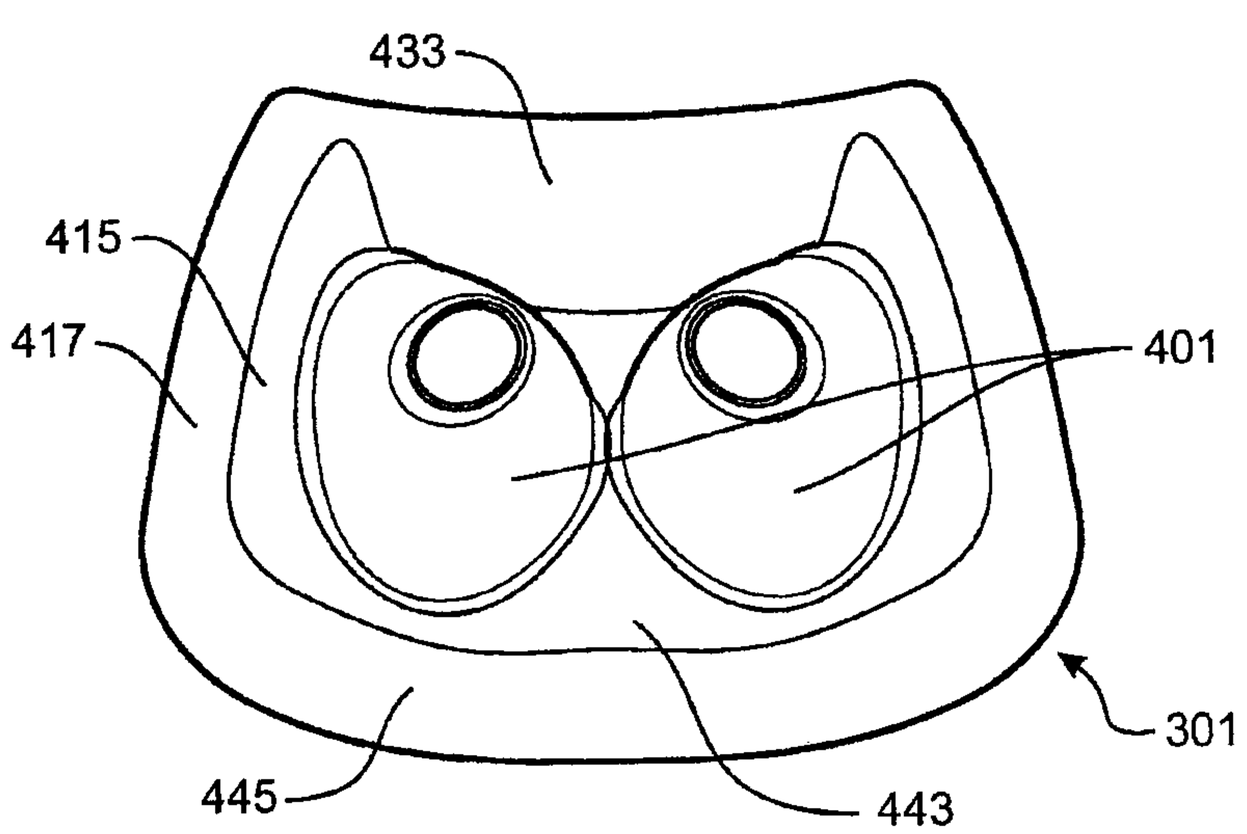
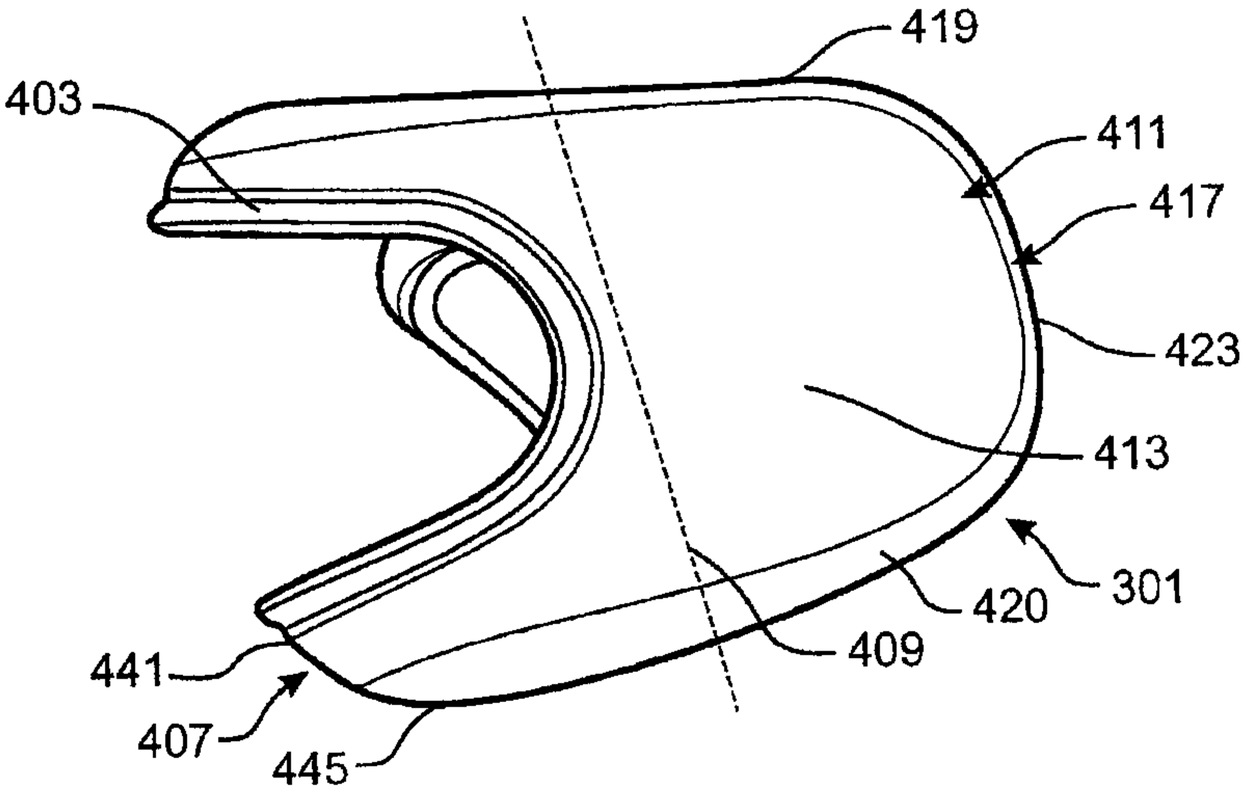


FIG. 4C



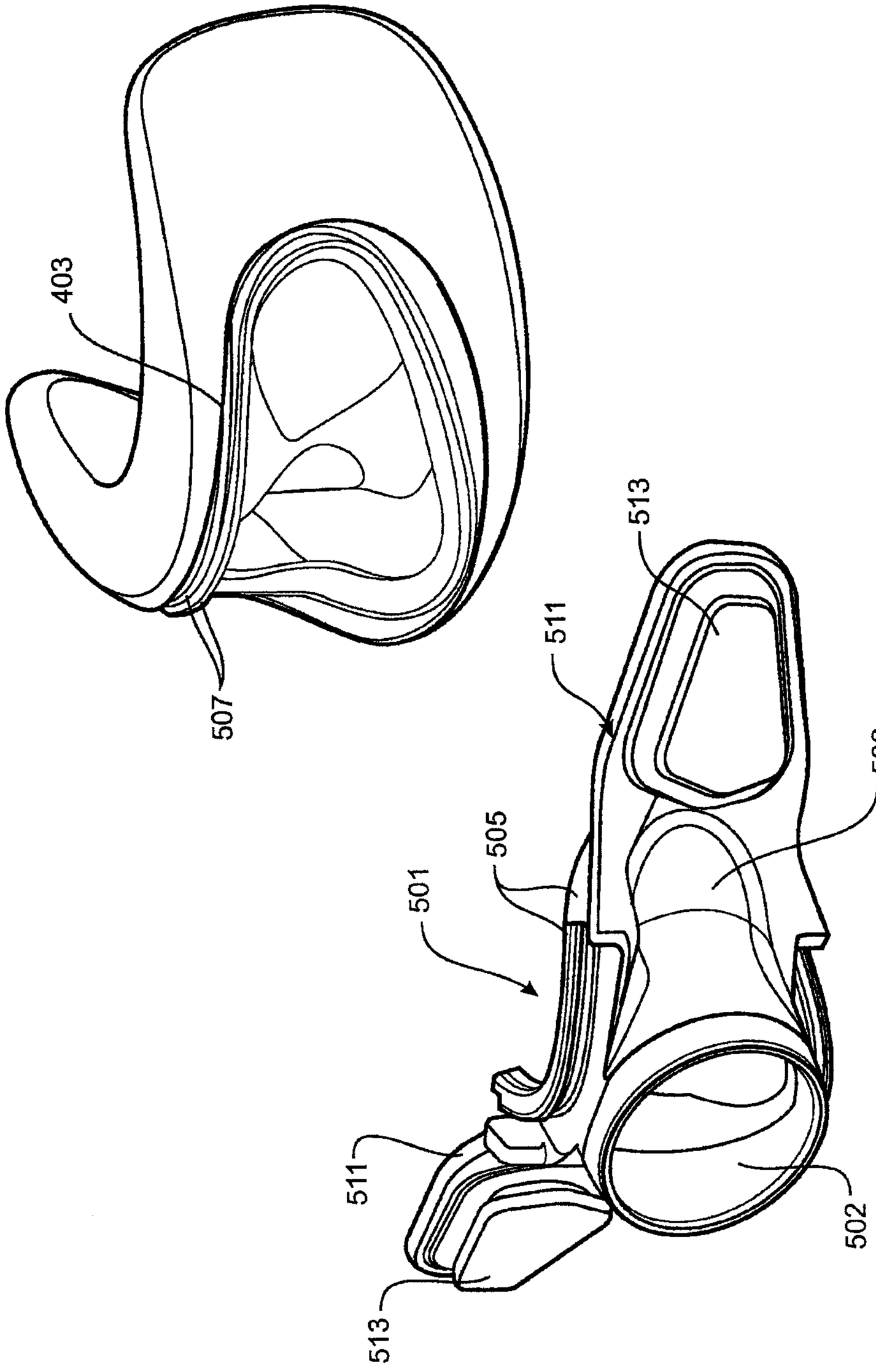


FIG. 5A

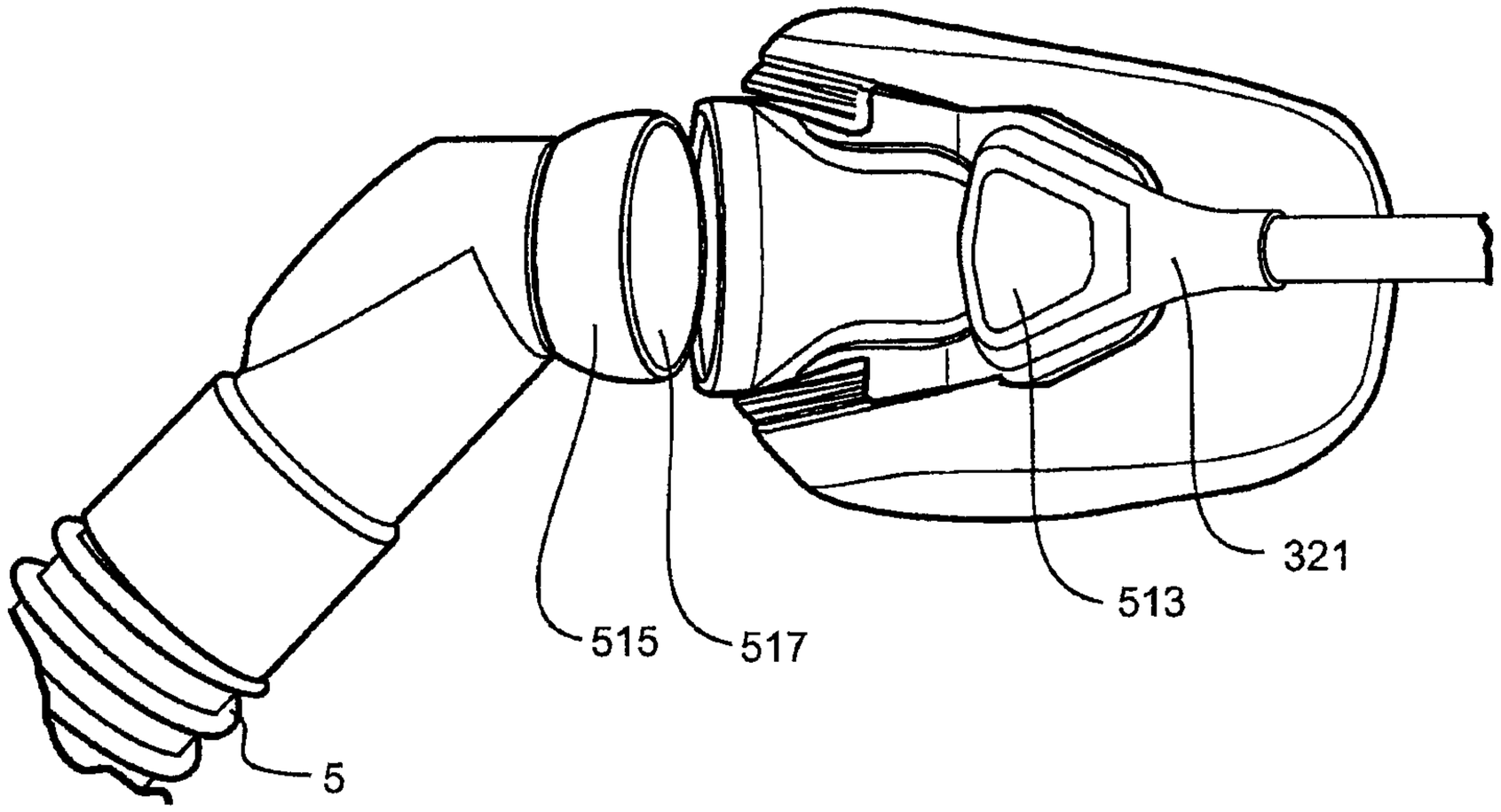


FIG. 5B

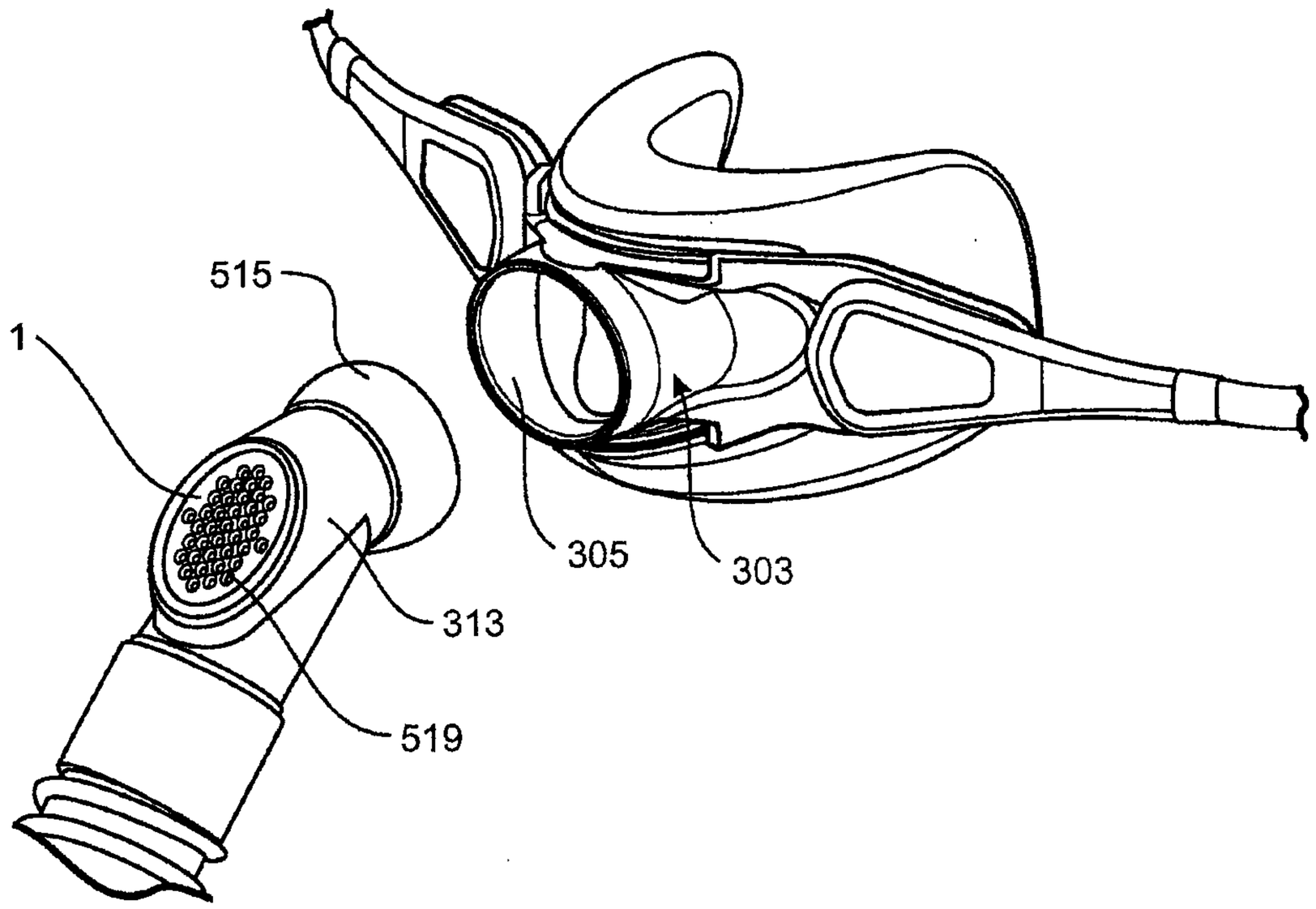


FIG. 5C

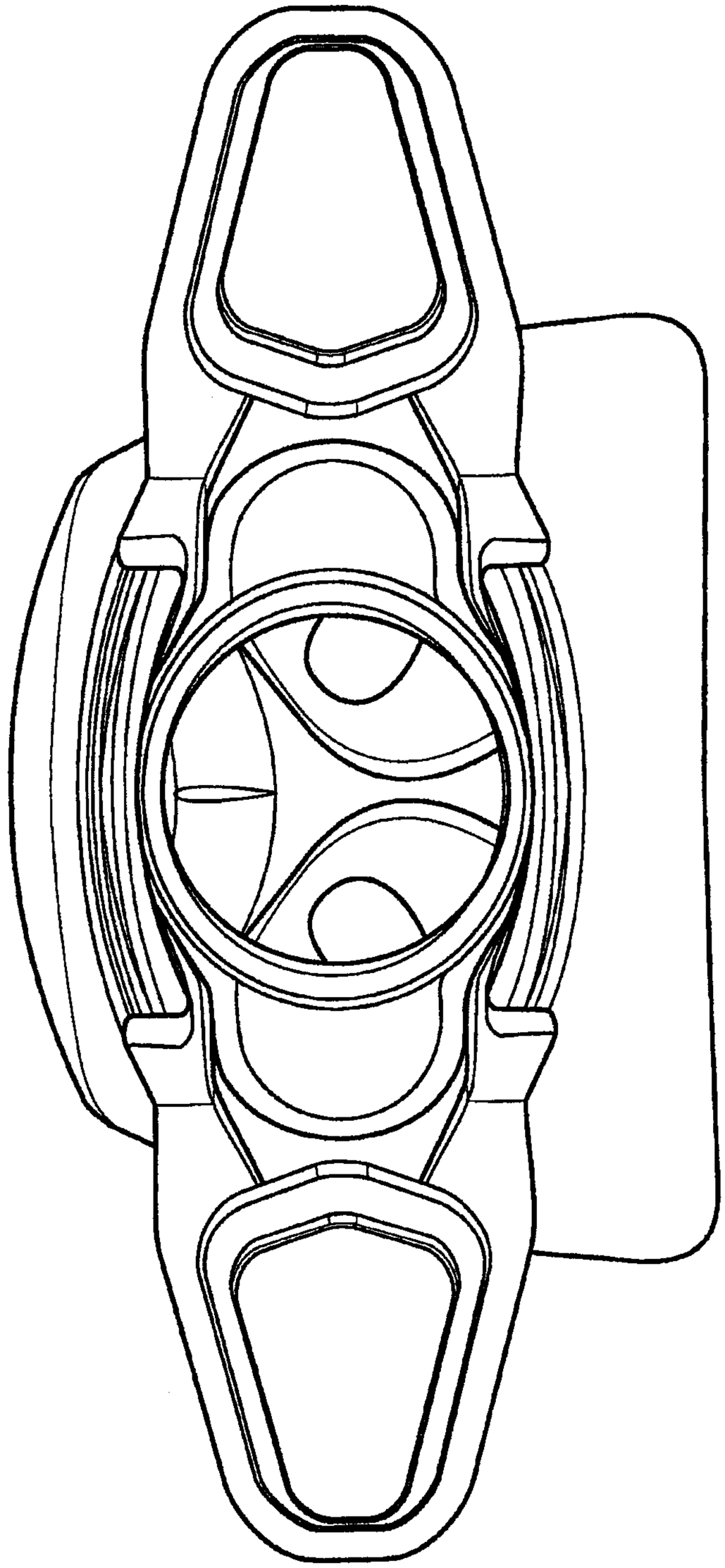


FIG. 6

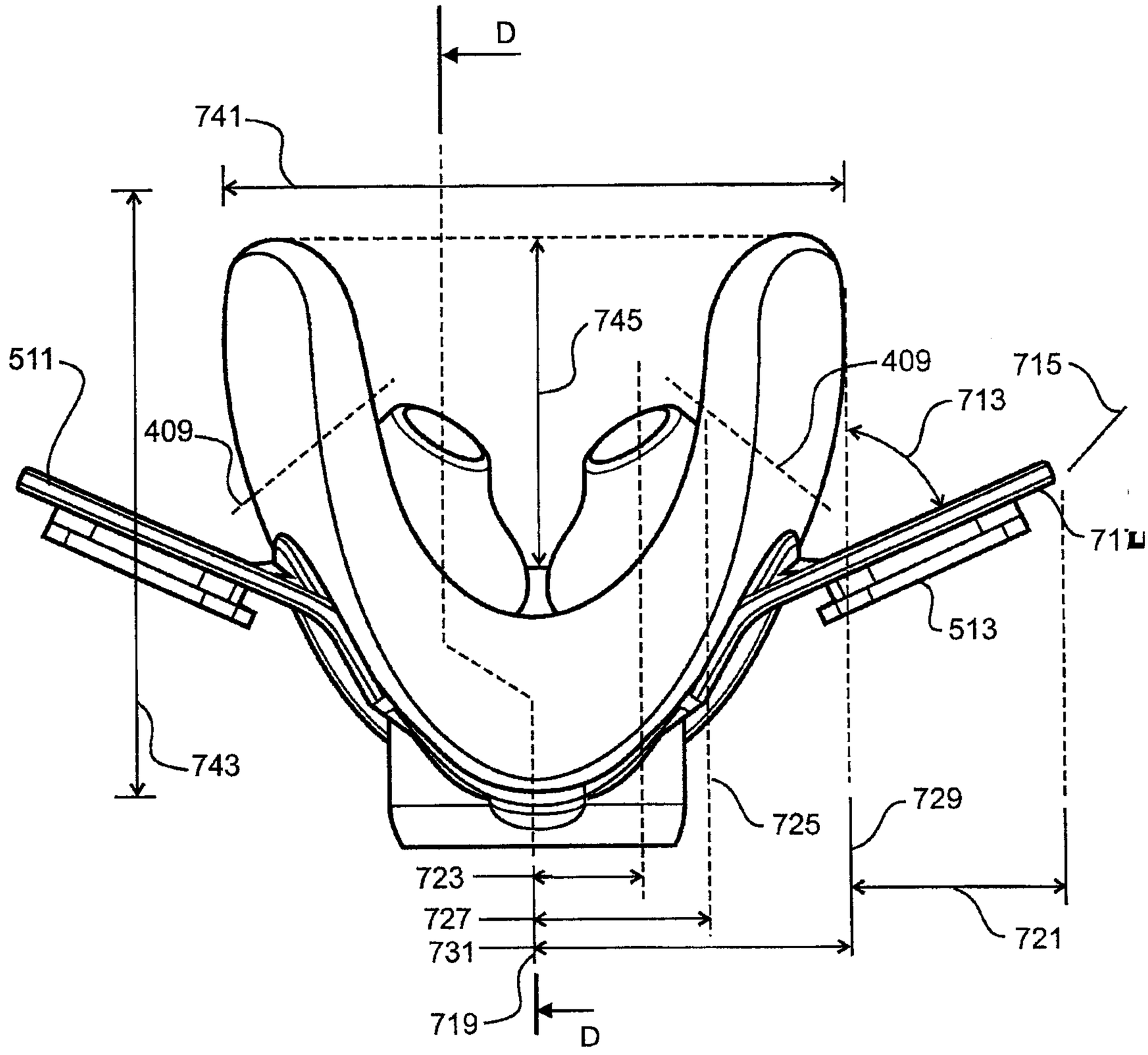

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FIG. 7A

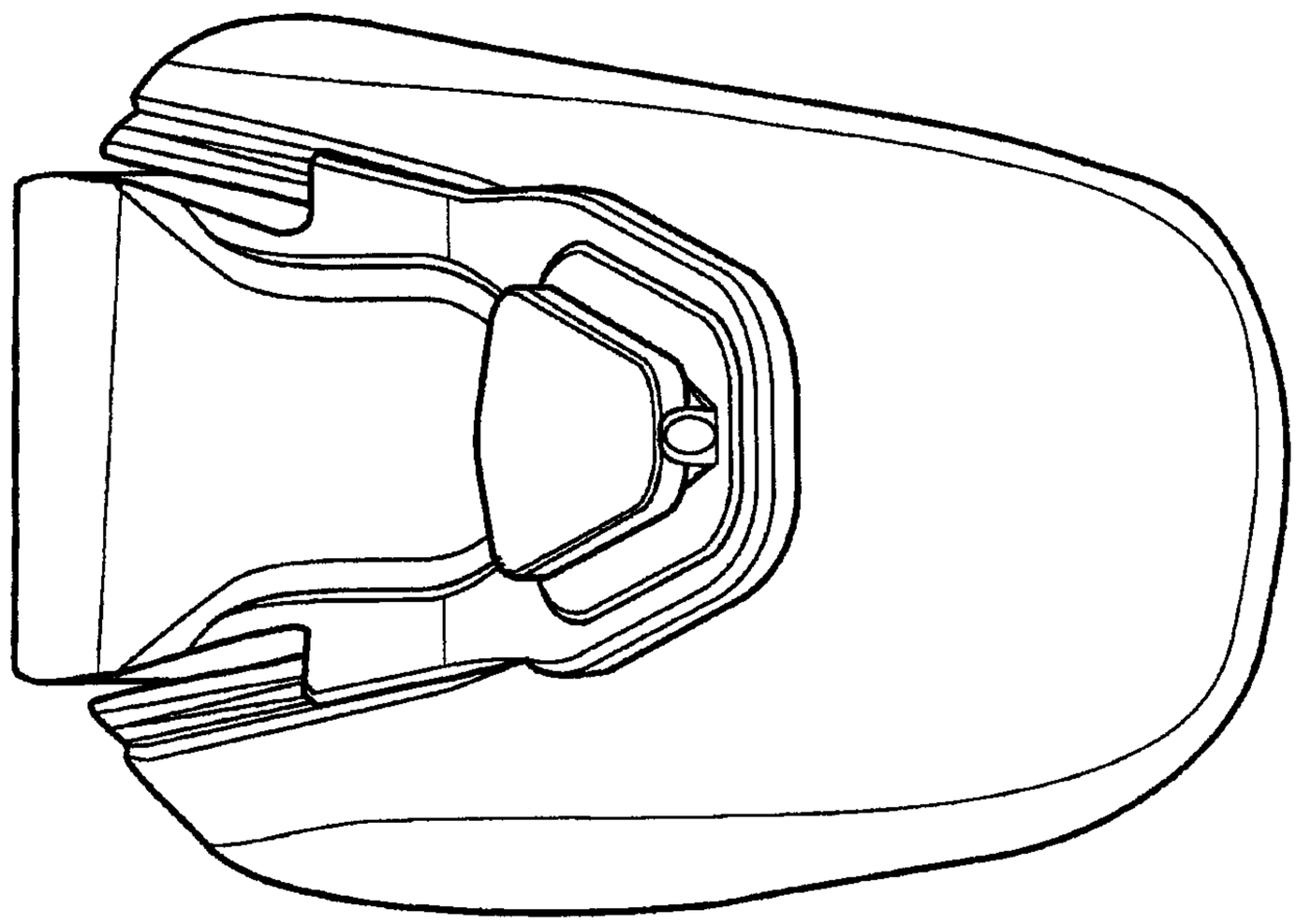


FIG. 7B

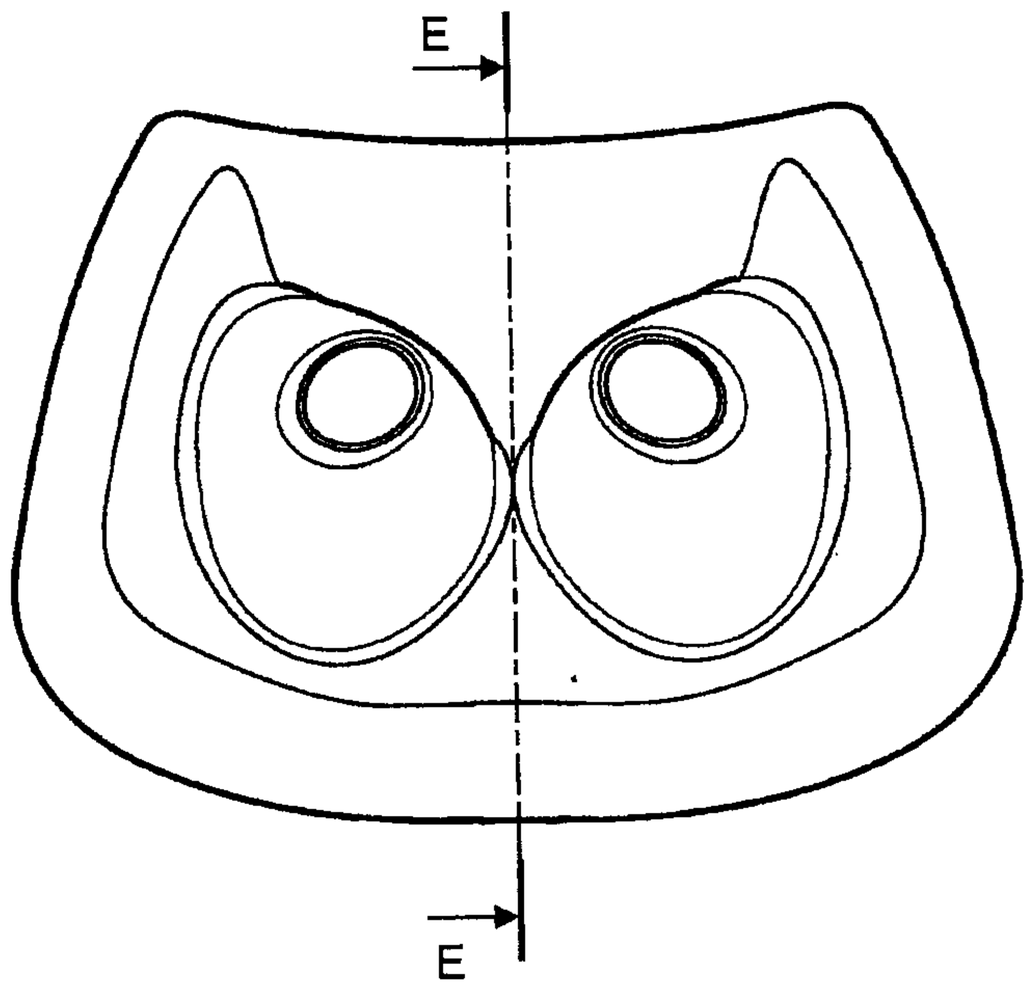


FIG. 7C

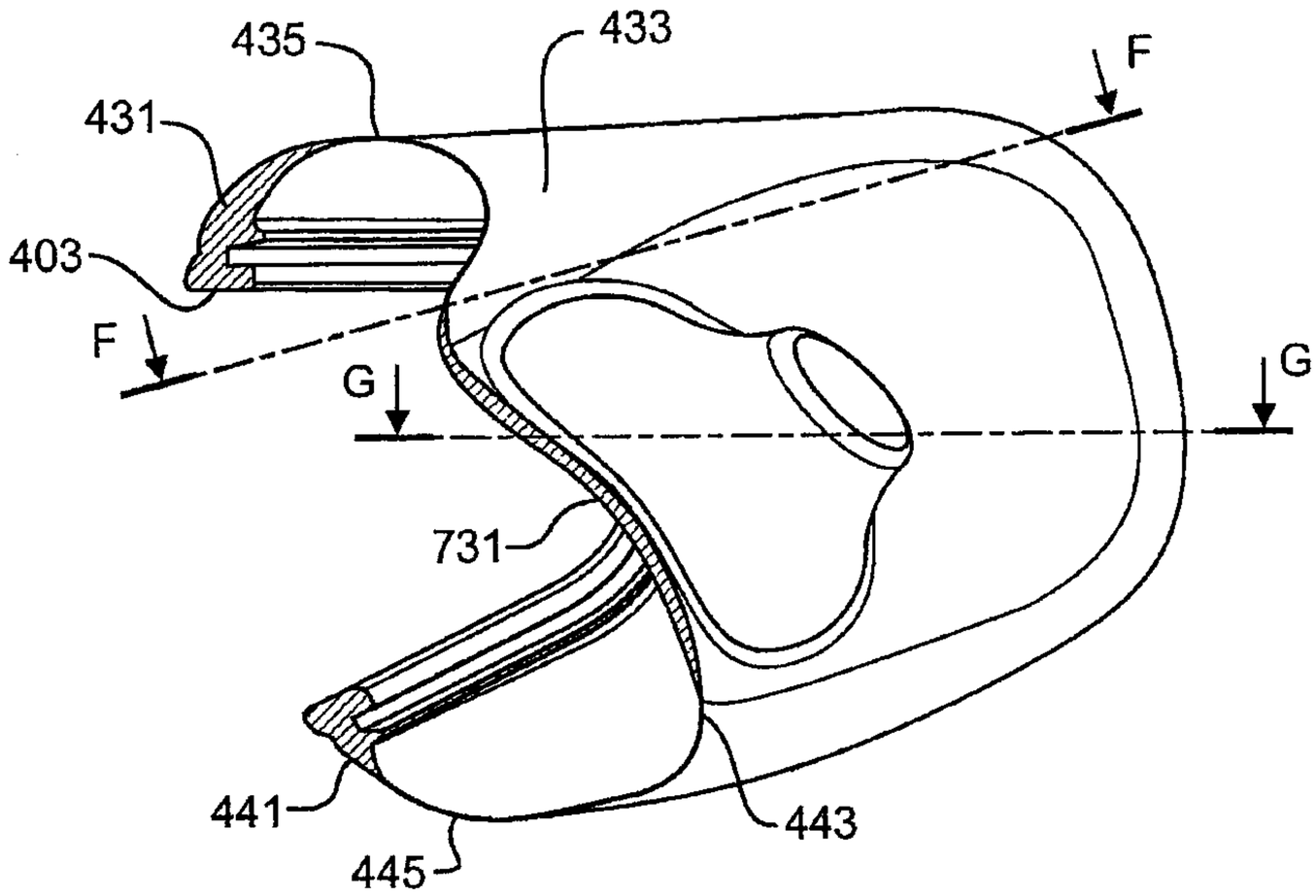


FIG. 7D

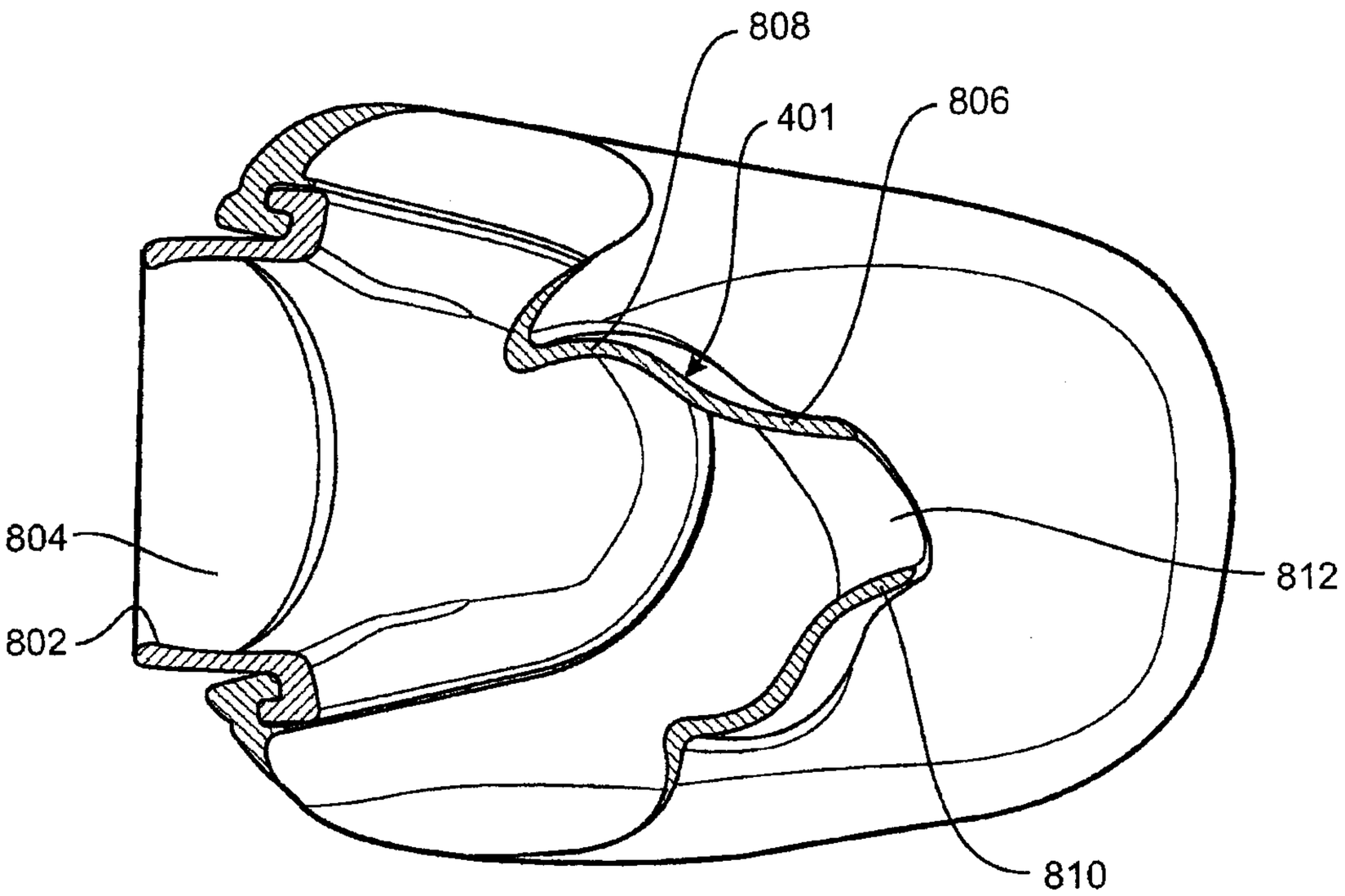


FIG. 8

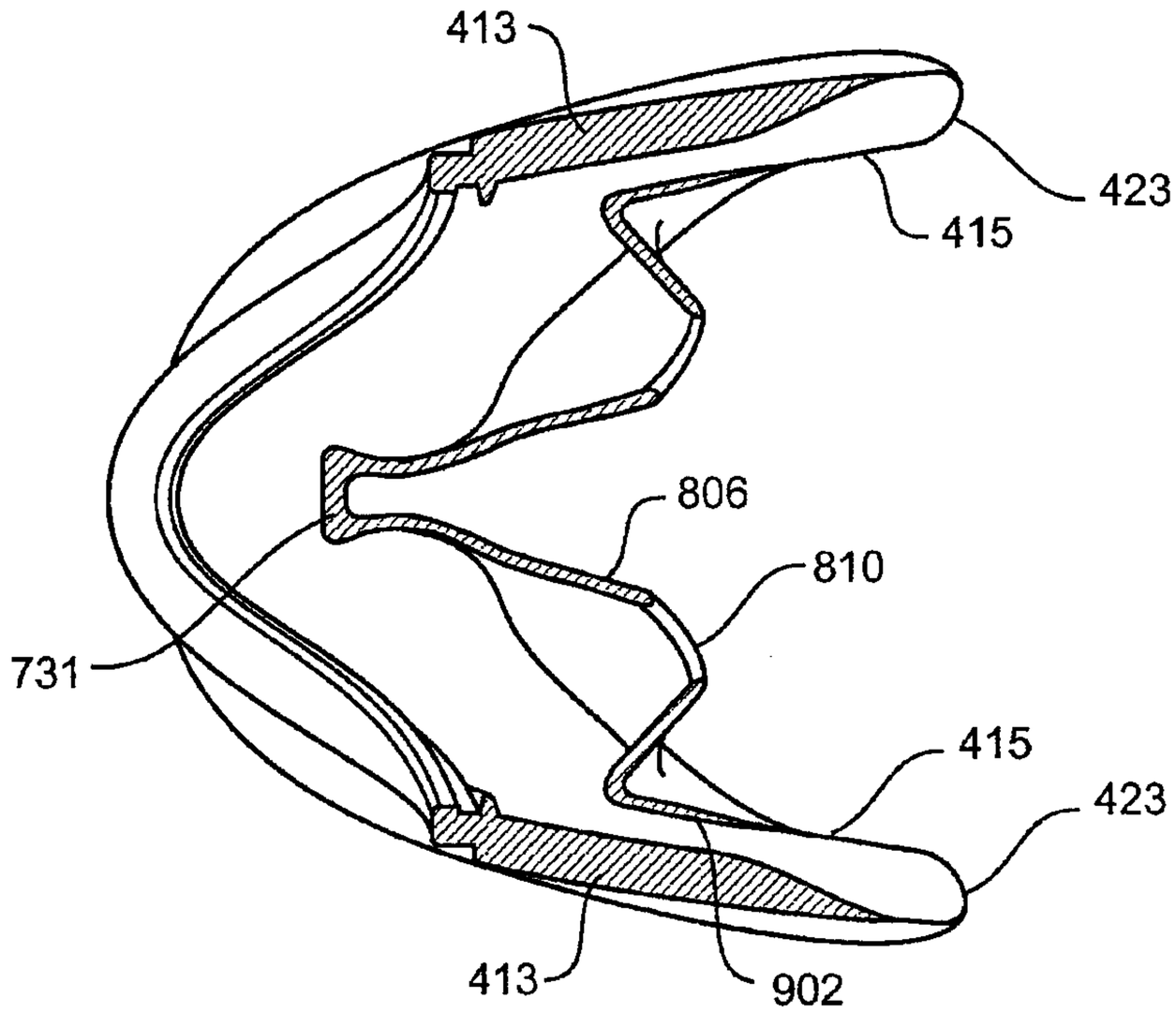


FIG. 9A

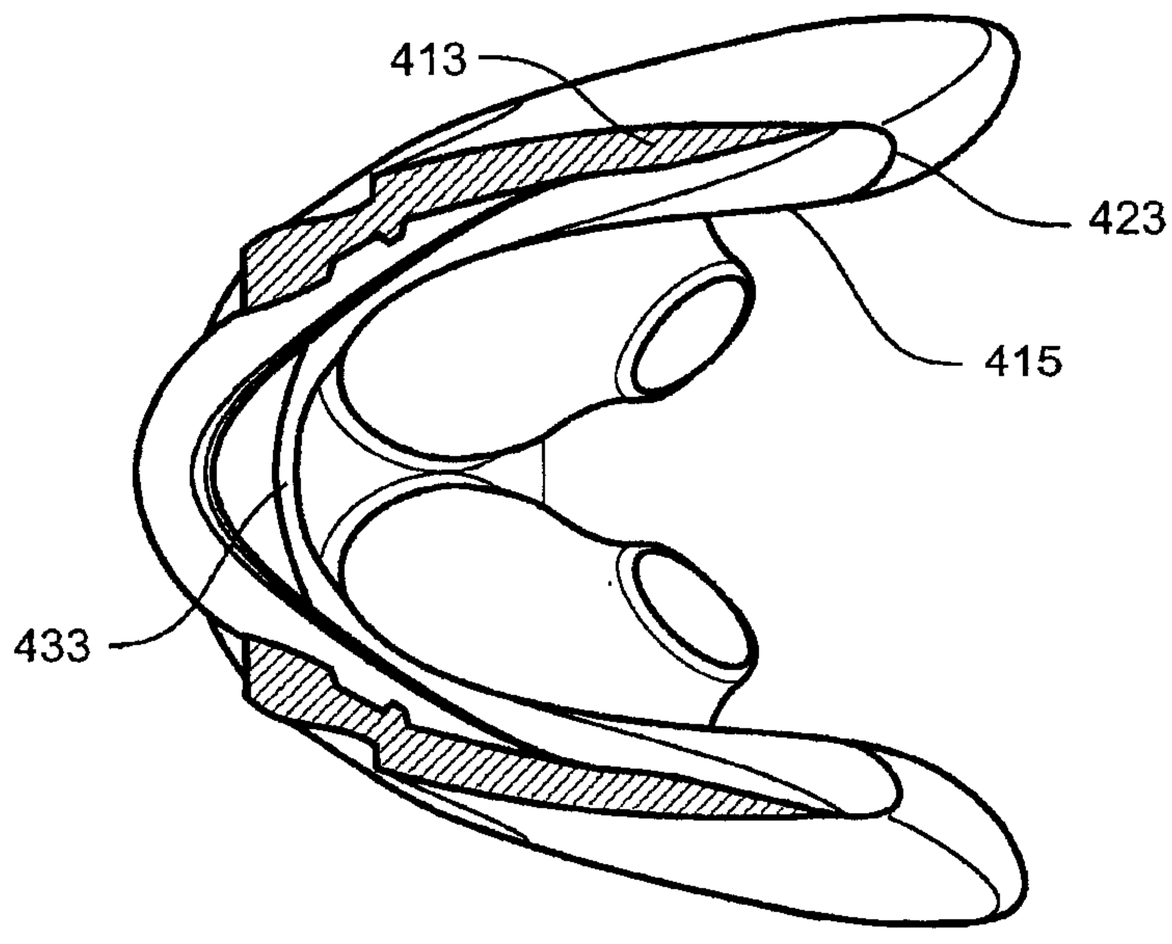


FIG. 9B

FIG. 10

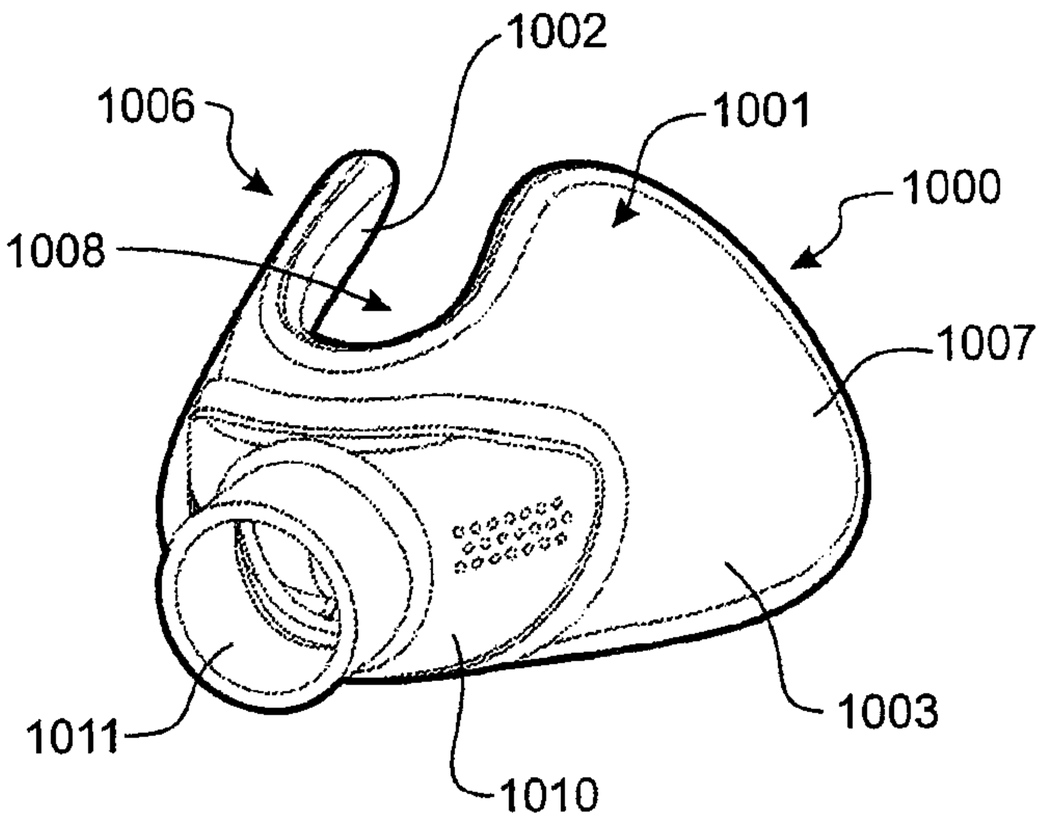


FIG. 11

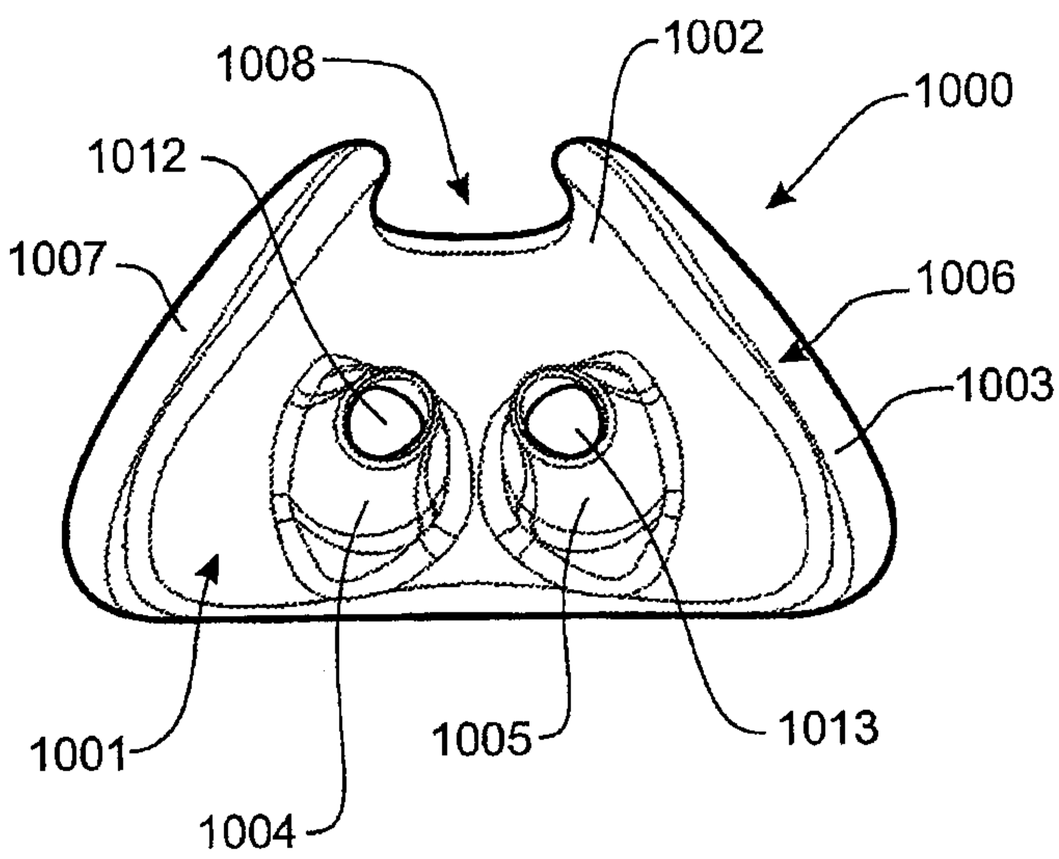
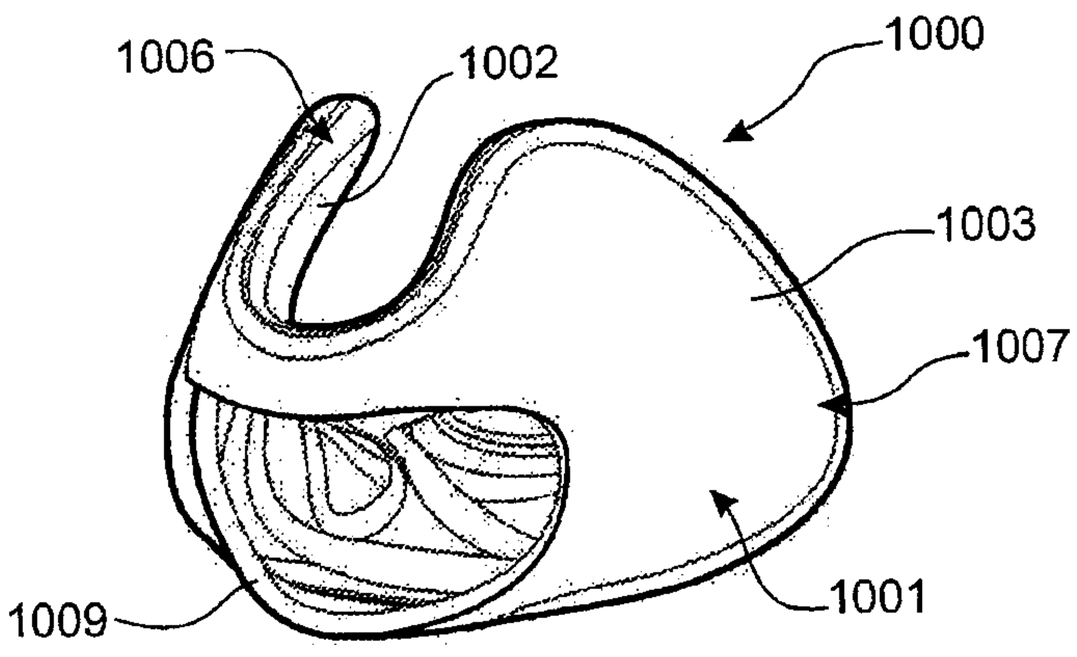


FIG. 12



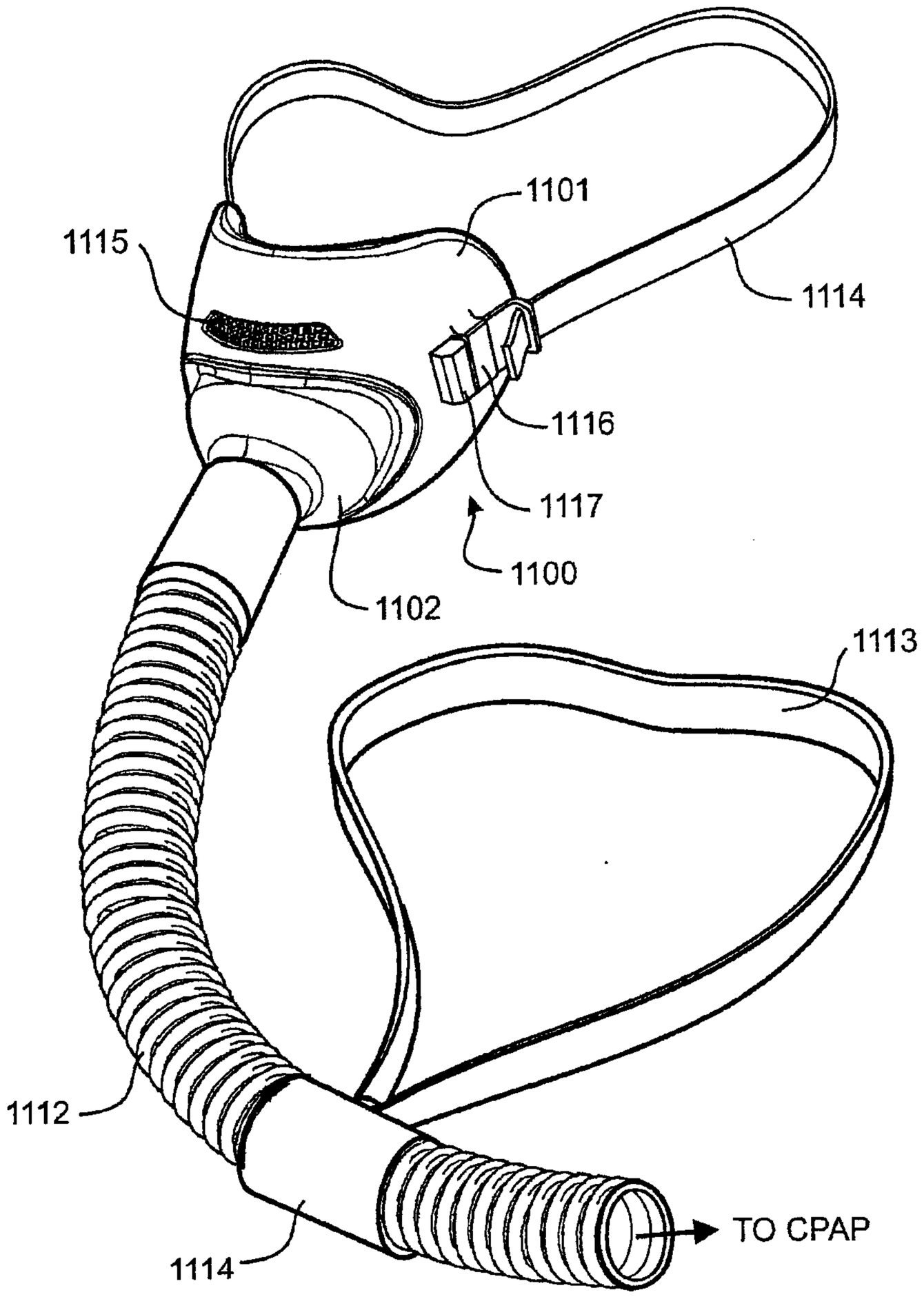


FIG. 13

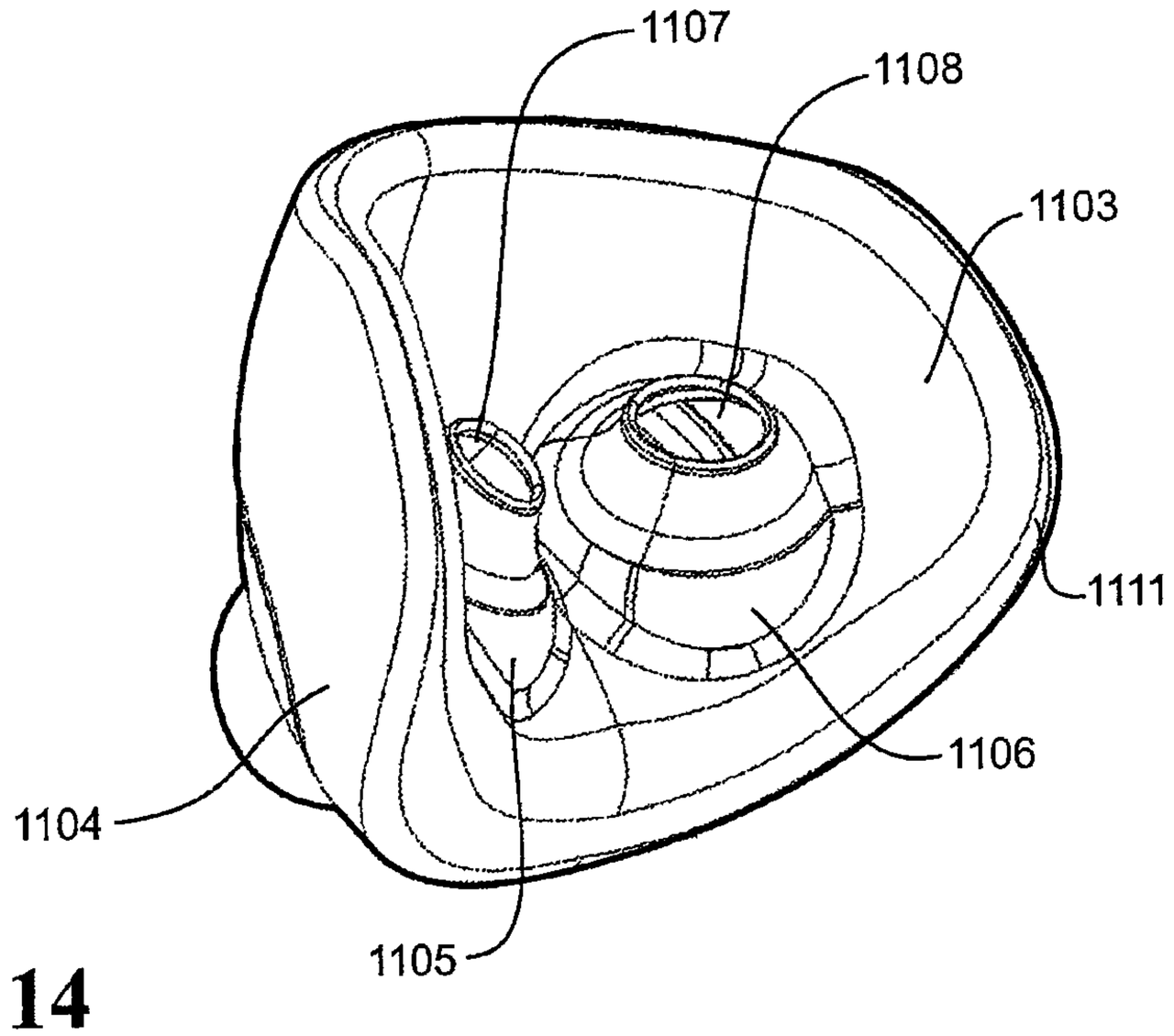


FIG. 14

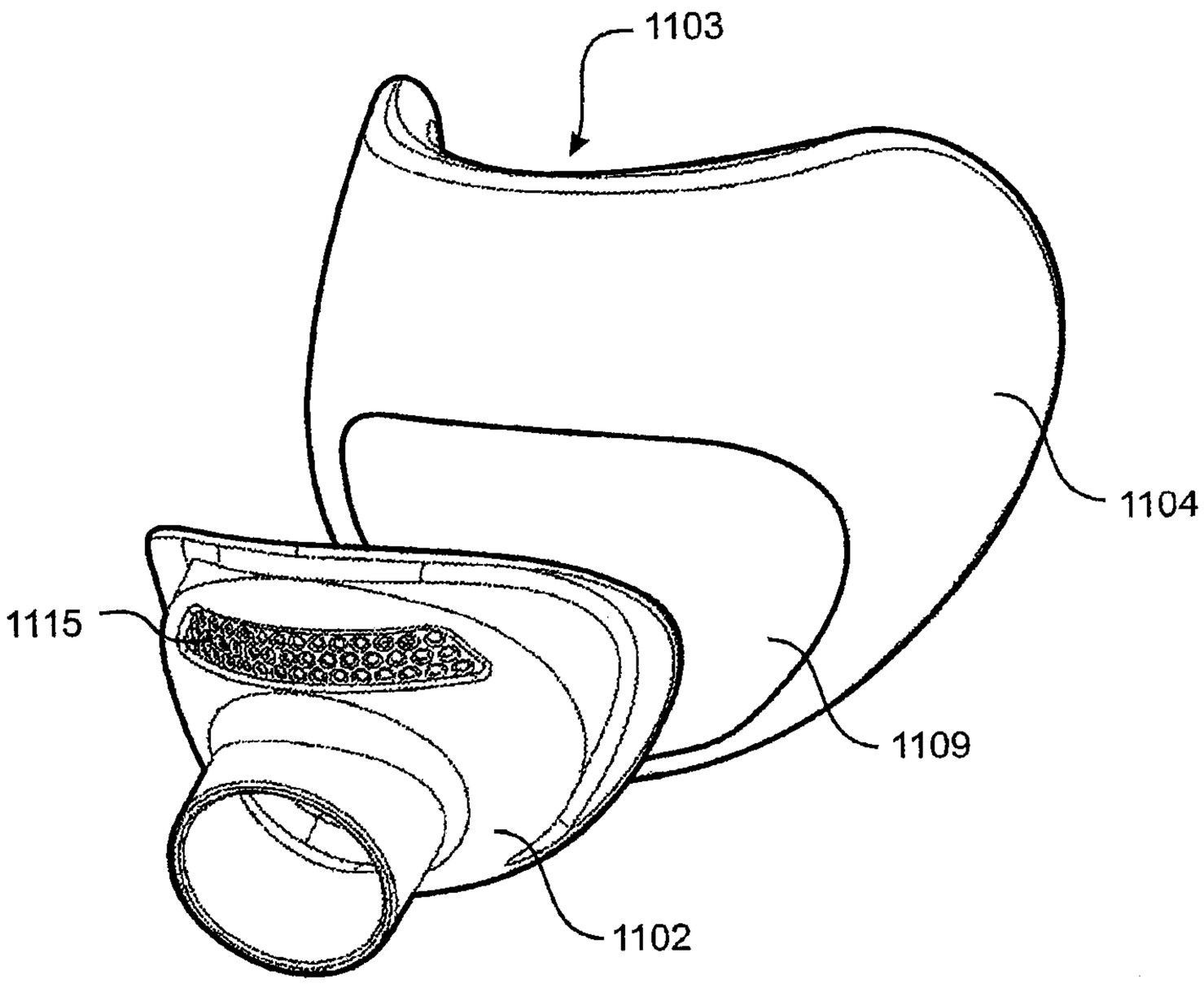


FIG. 15

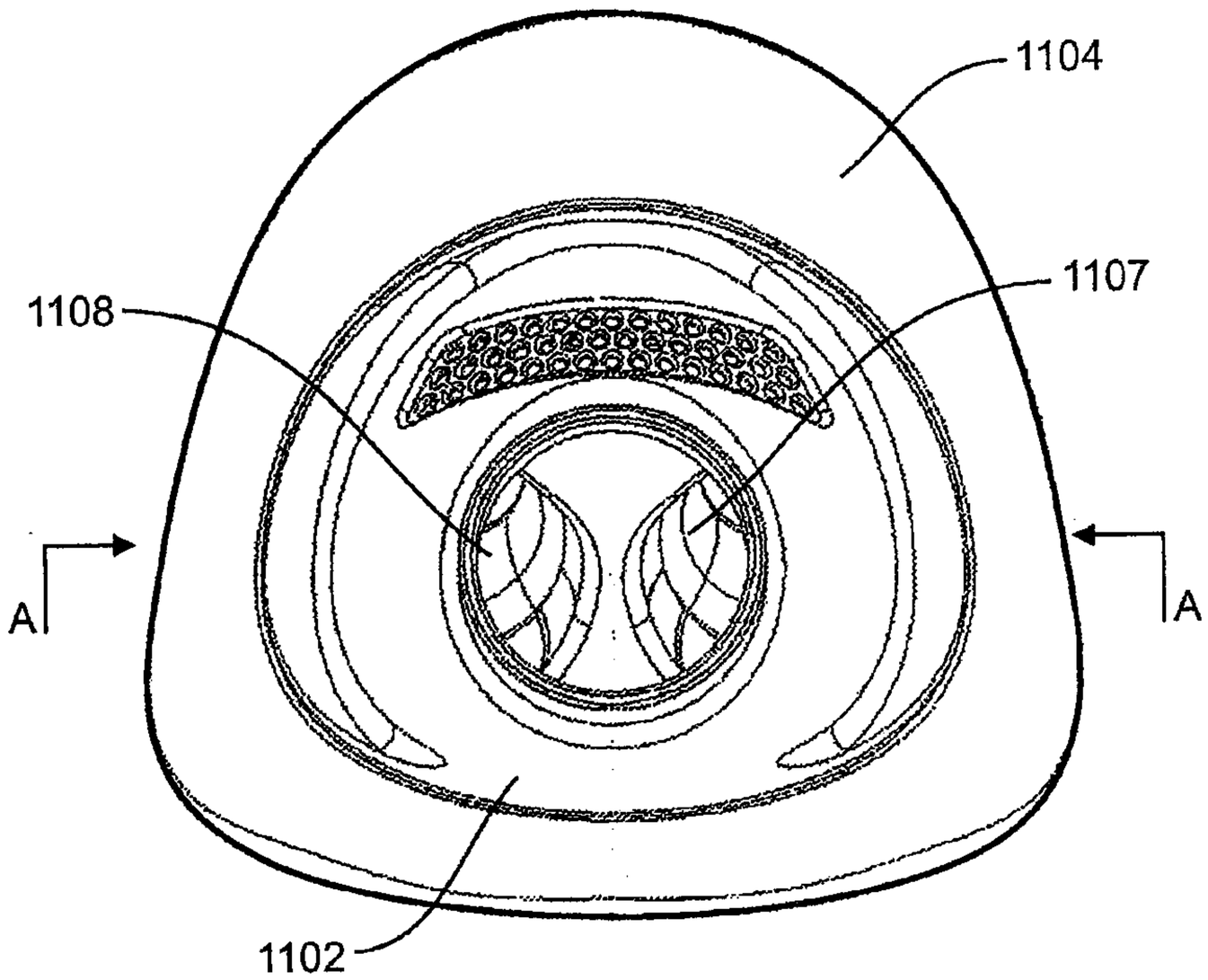


FIG. 16

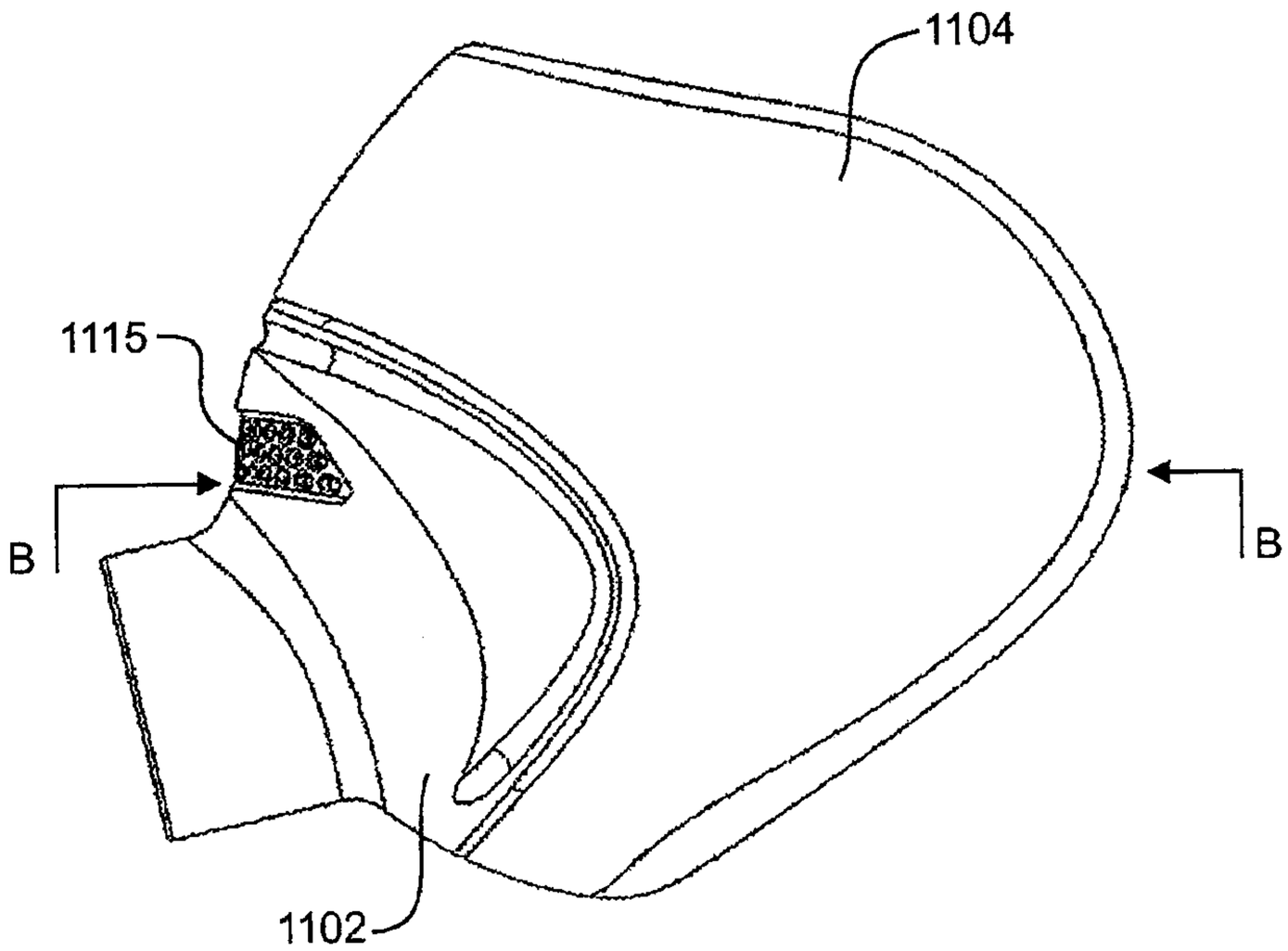


FIG. 17

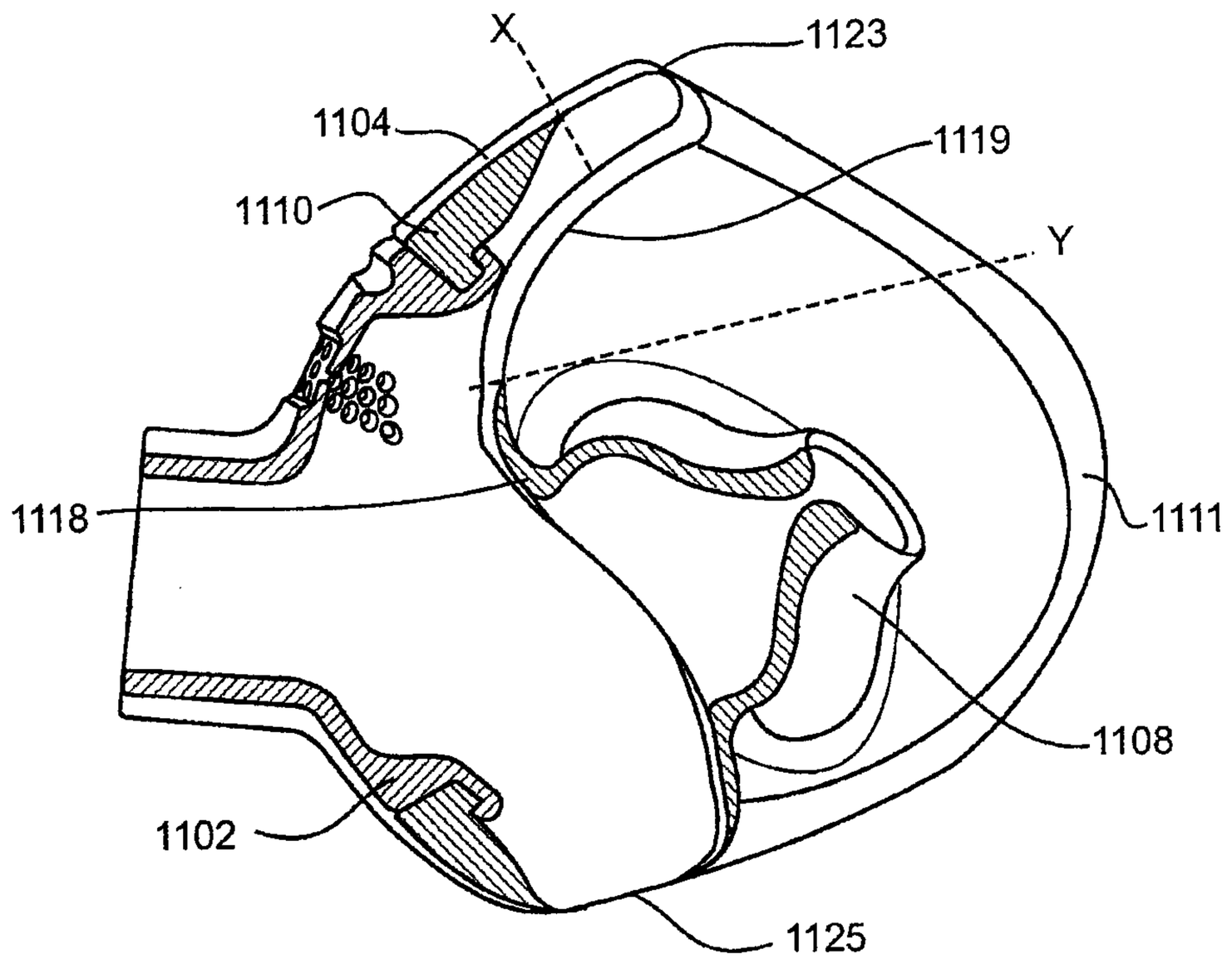

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FIG. 18

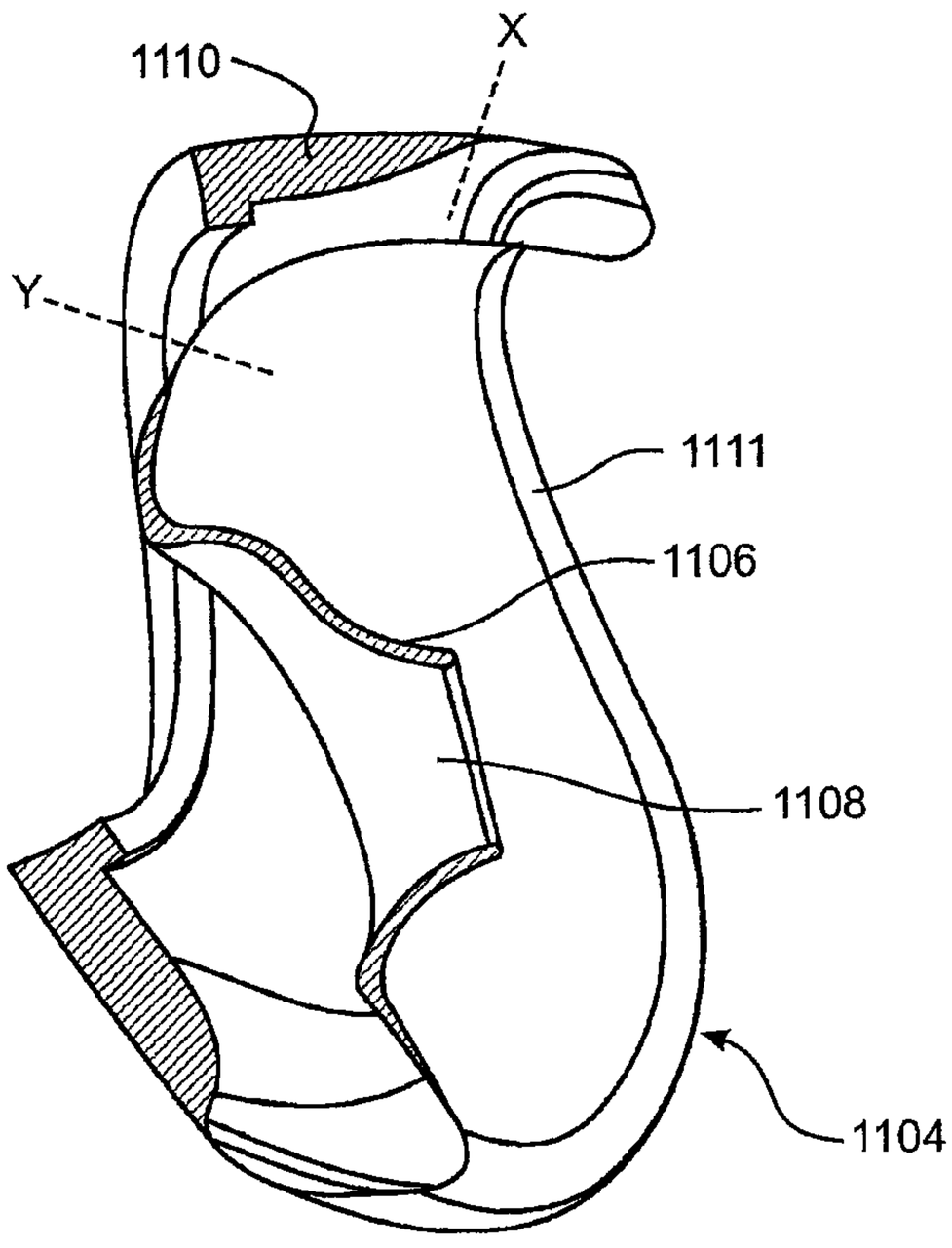
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FIG. 19

FIG. 20

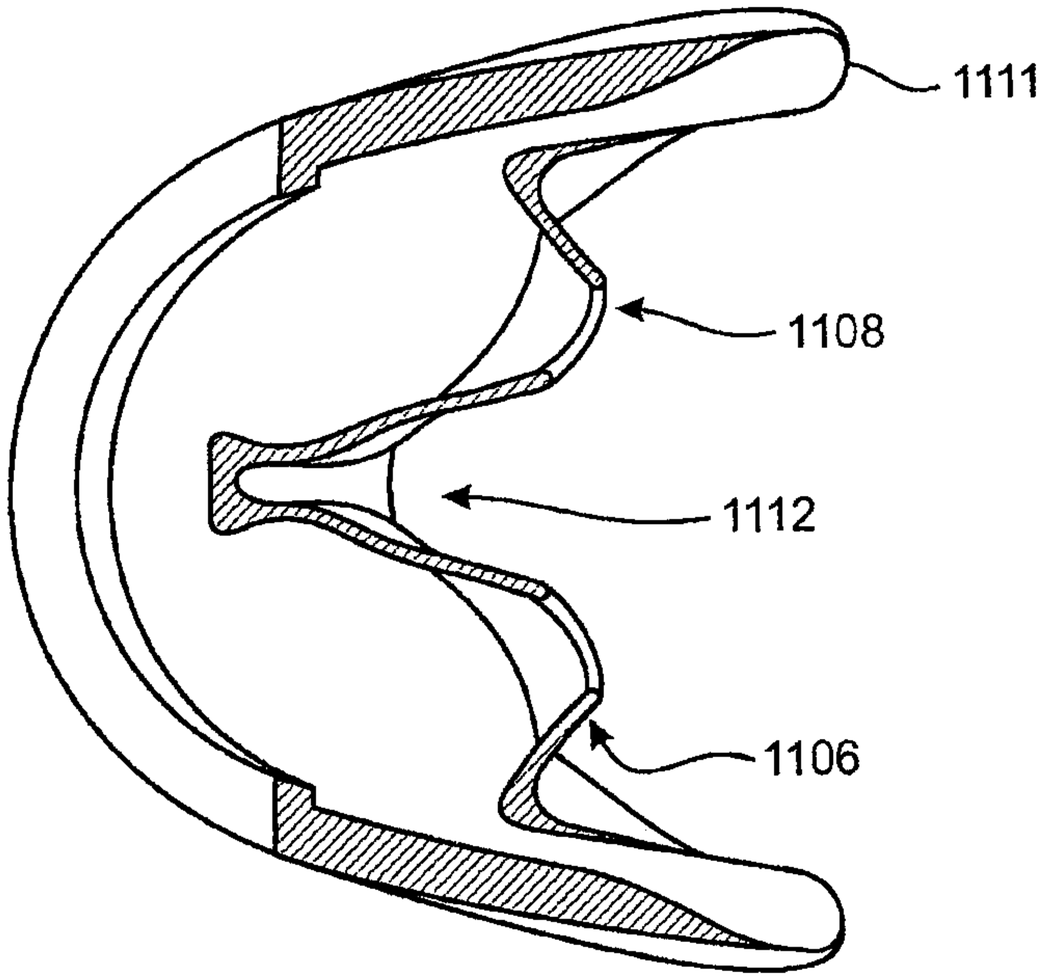
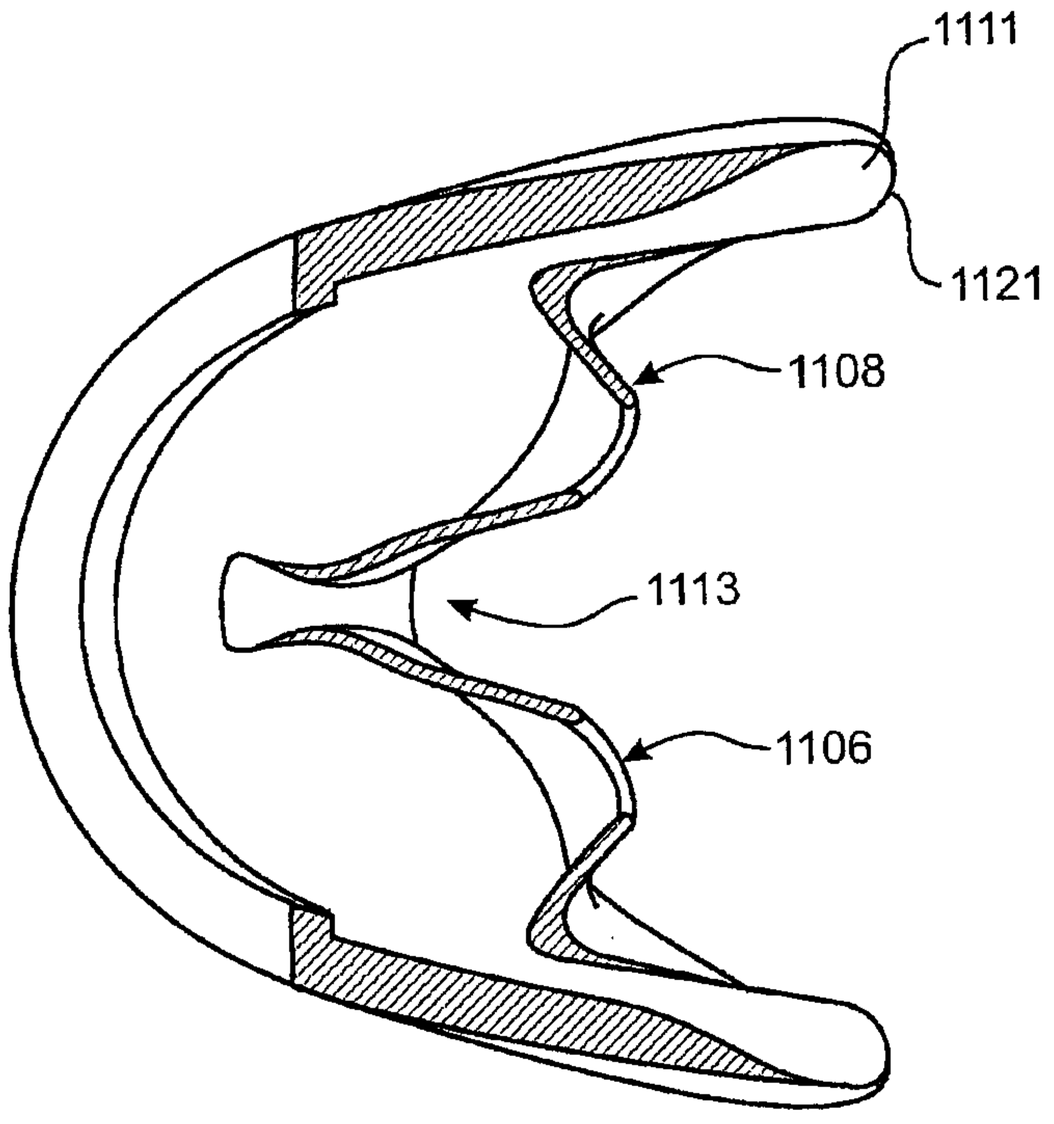


FIG. 21



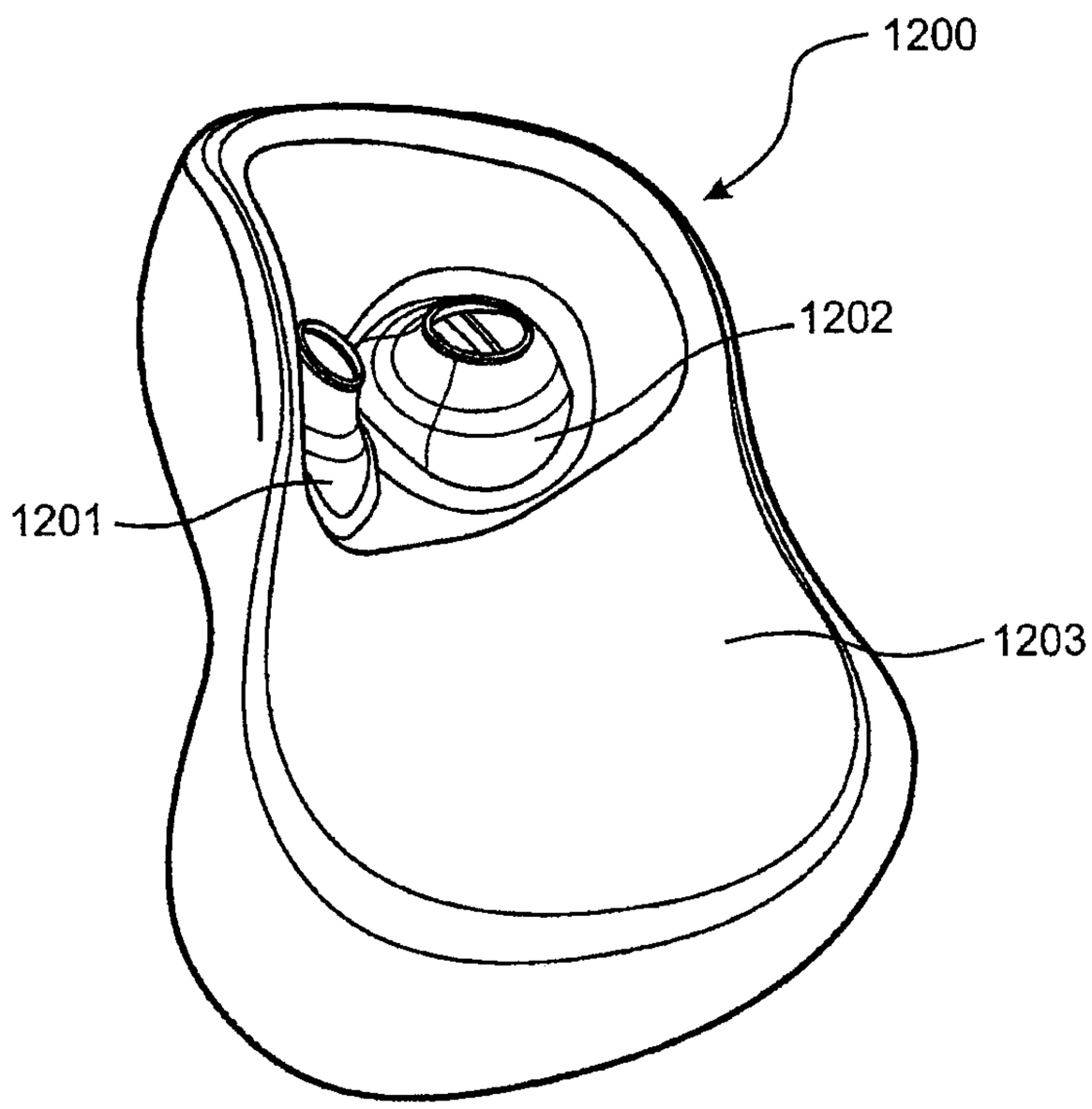


FIG. 22

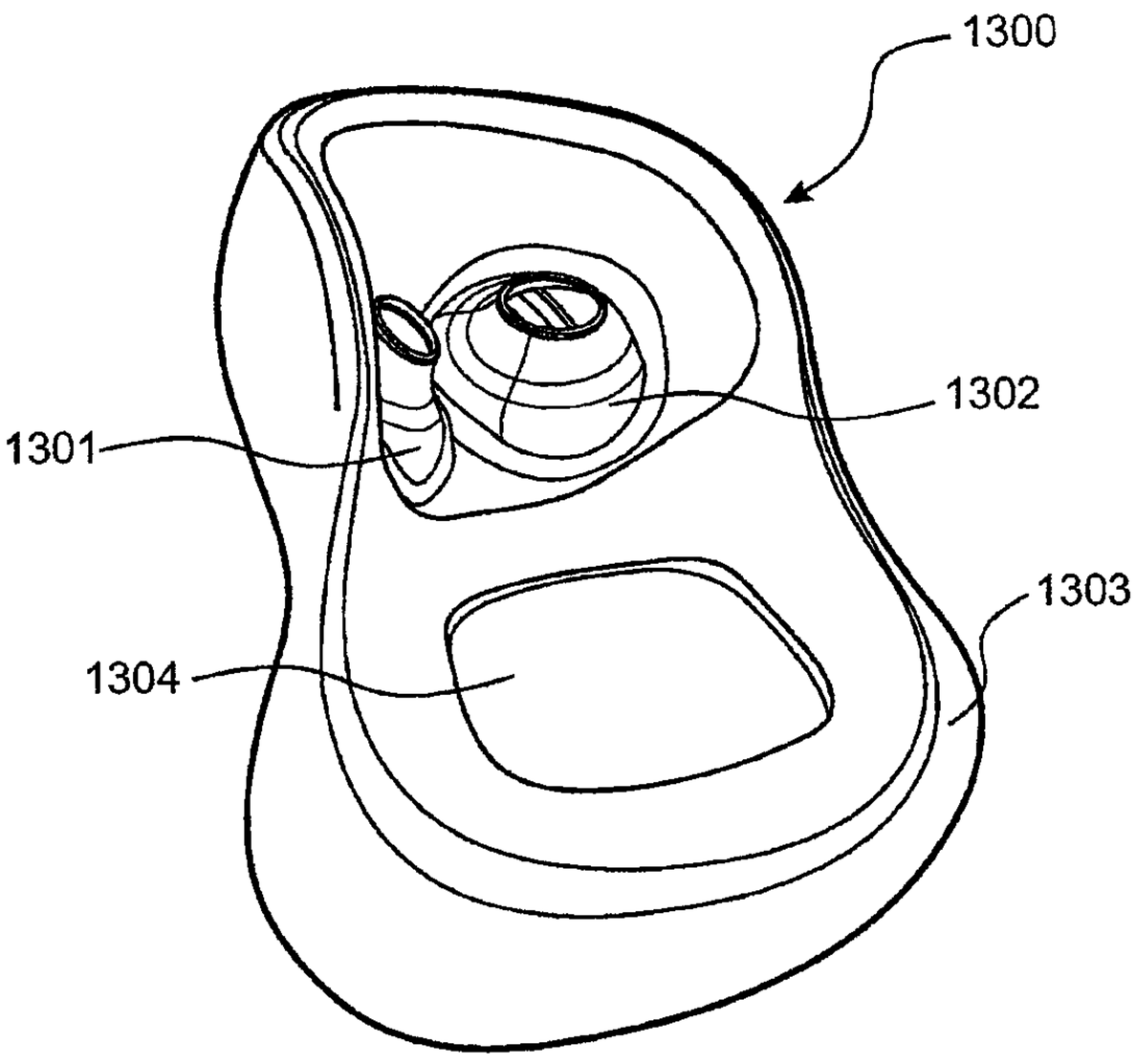


FIG. 23

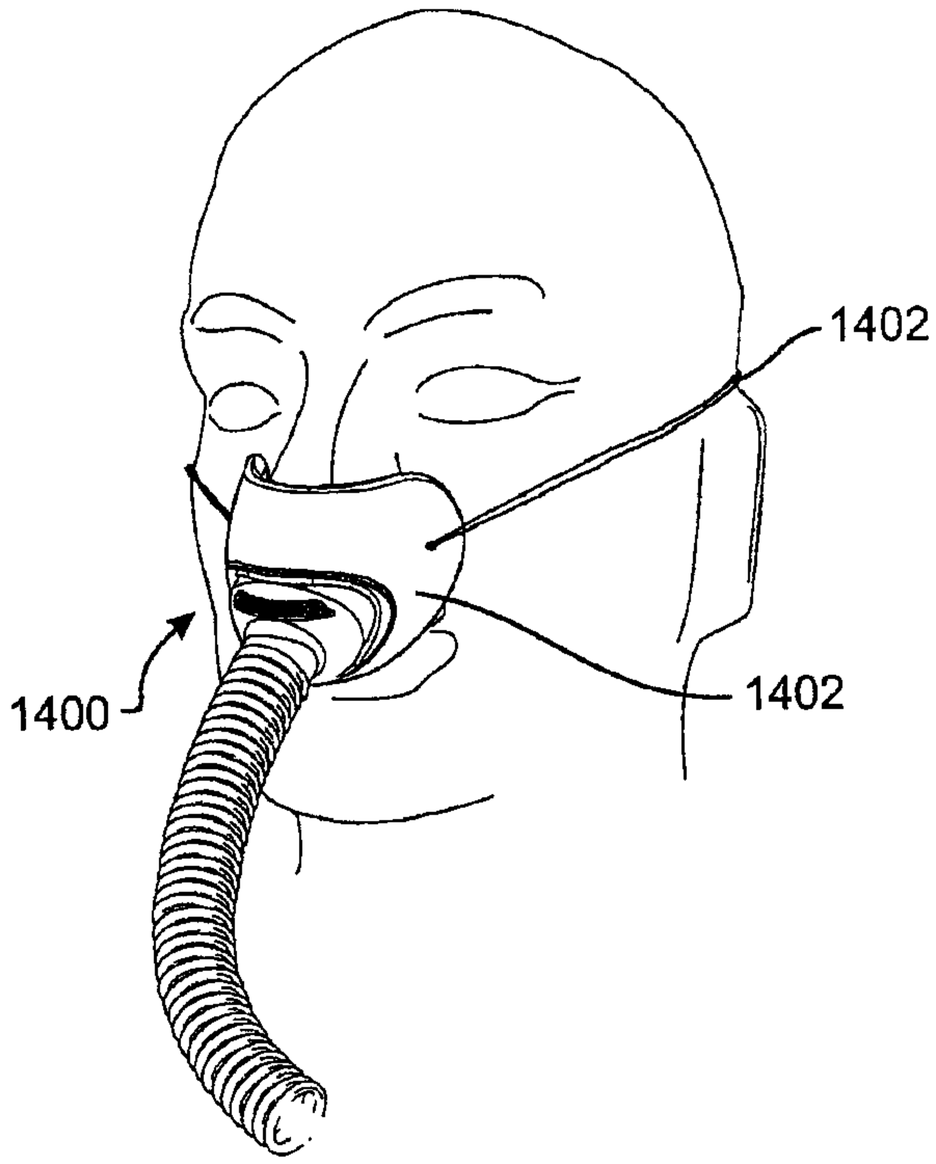


FIG. 24

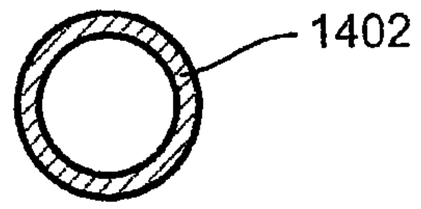


FIG. 24a

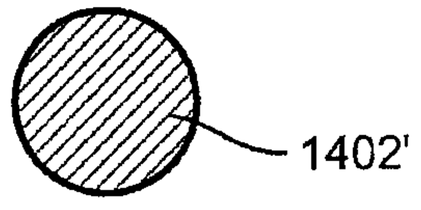


FIG. 24b

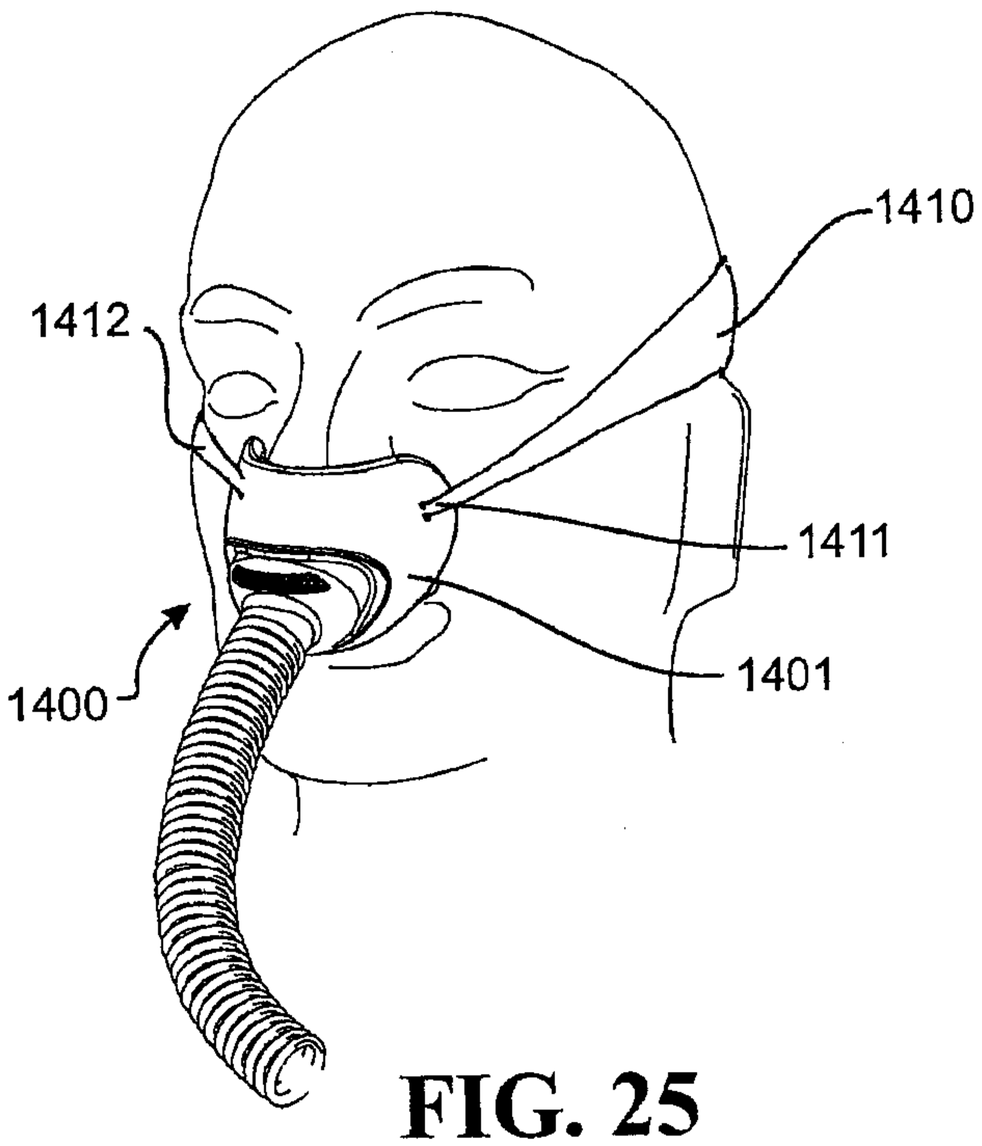


FIG. 25

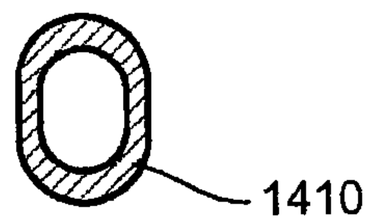


FIG. 25a

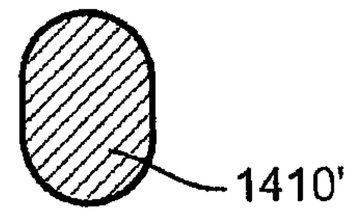


FIG. 25b

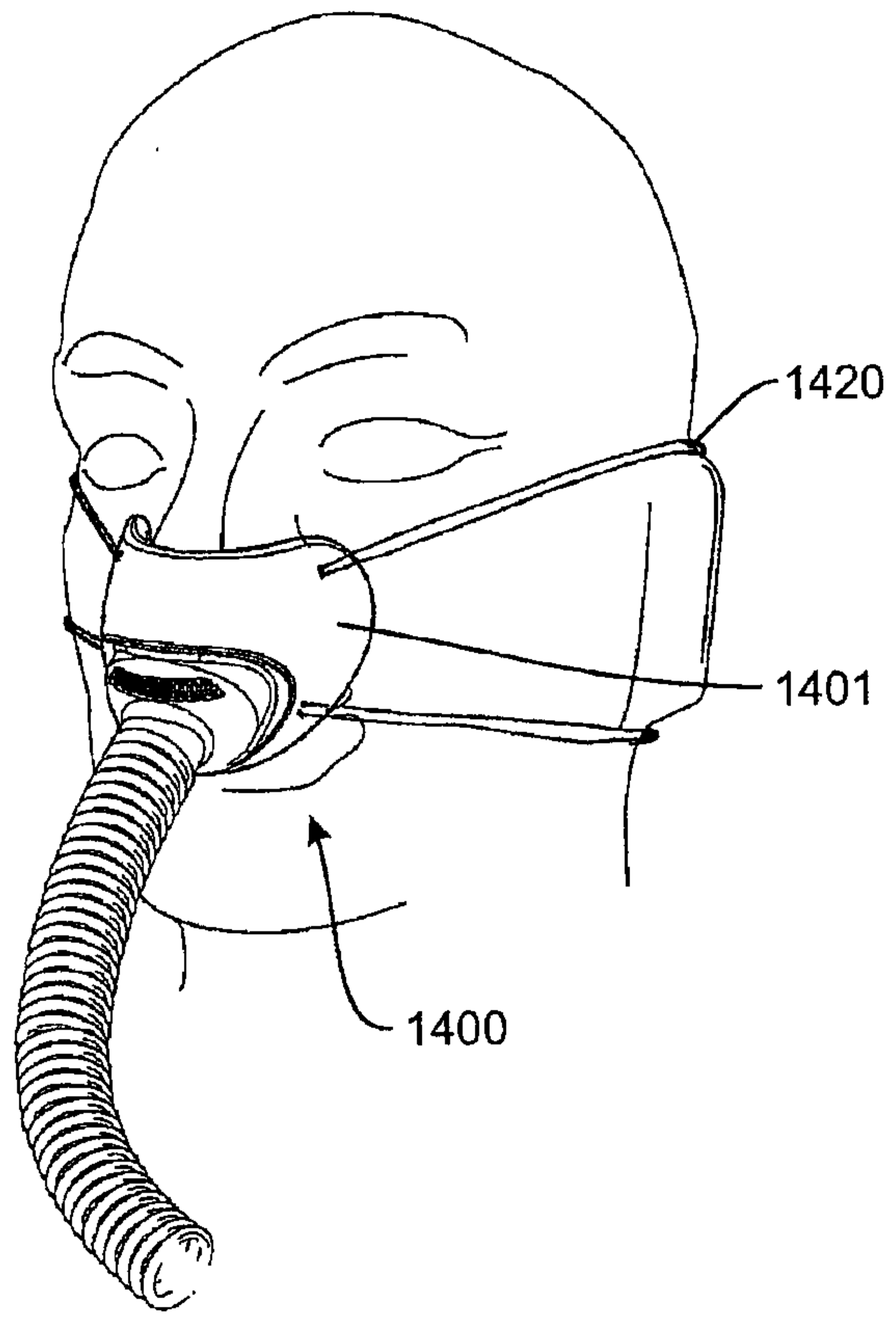


FIG. 26

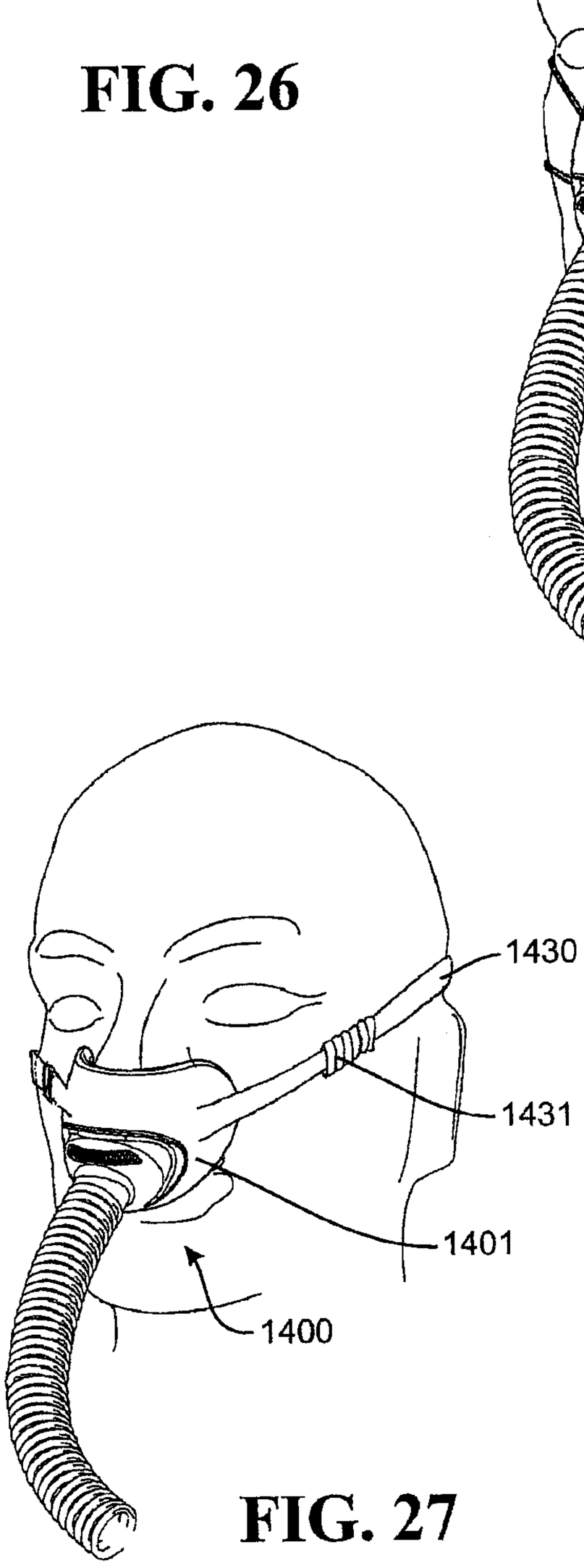


FIG. 27

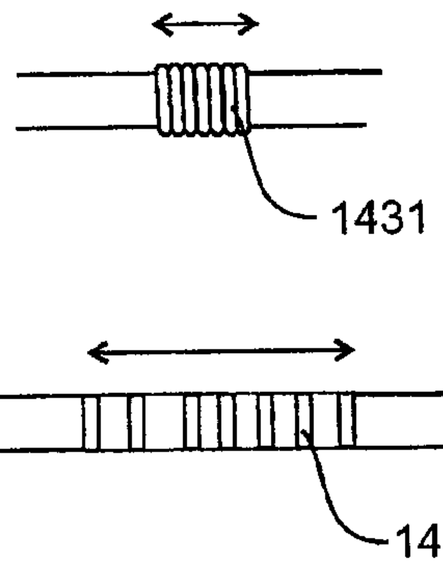


FIG. 27a

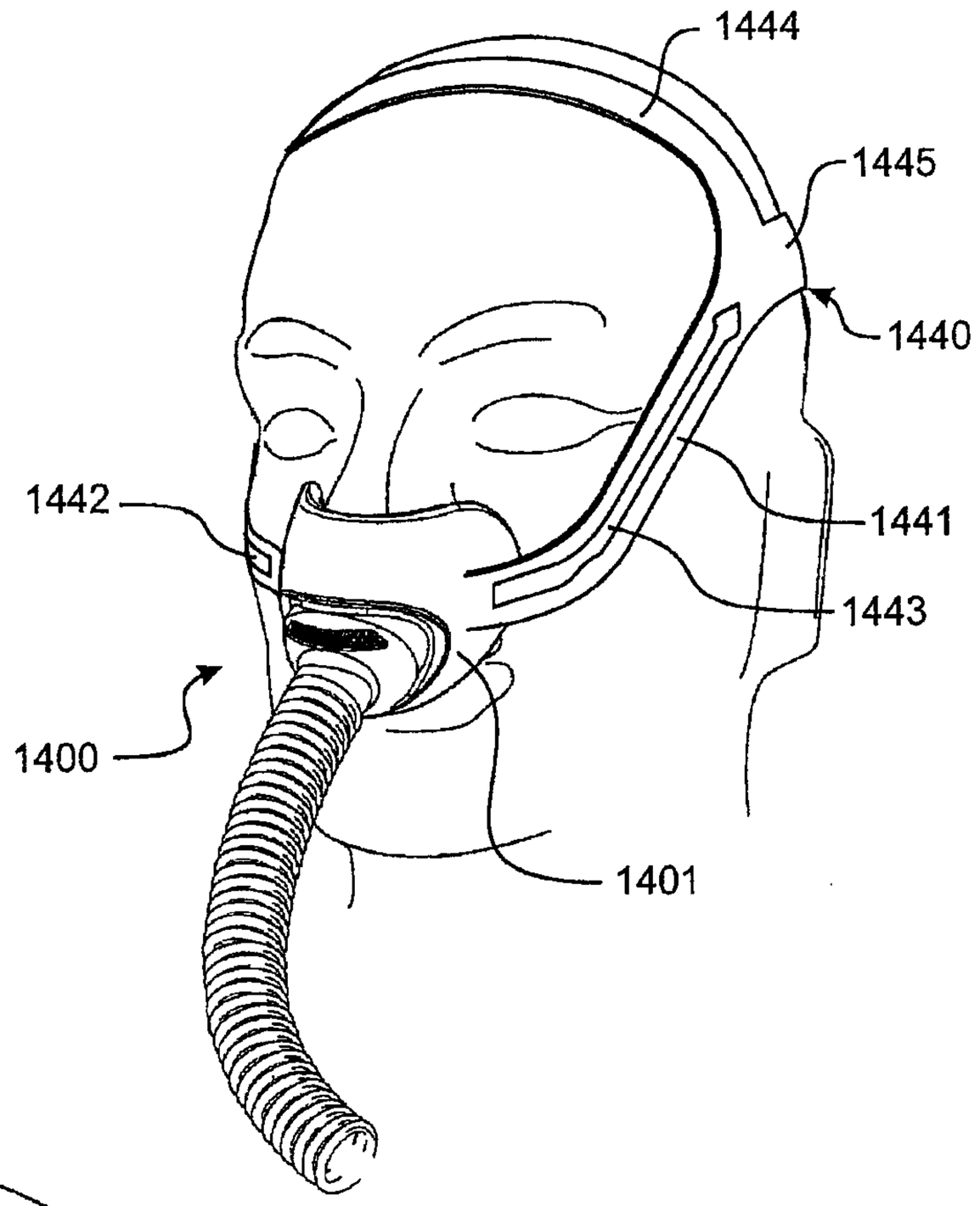
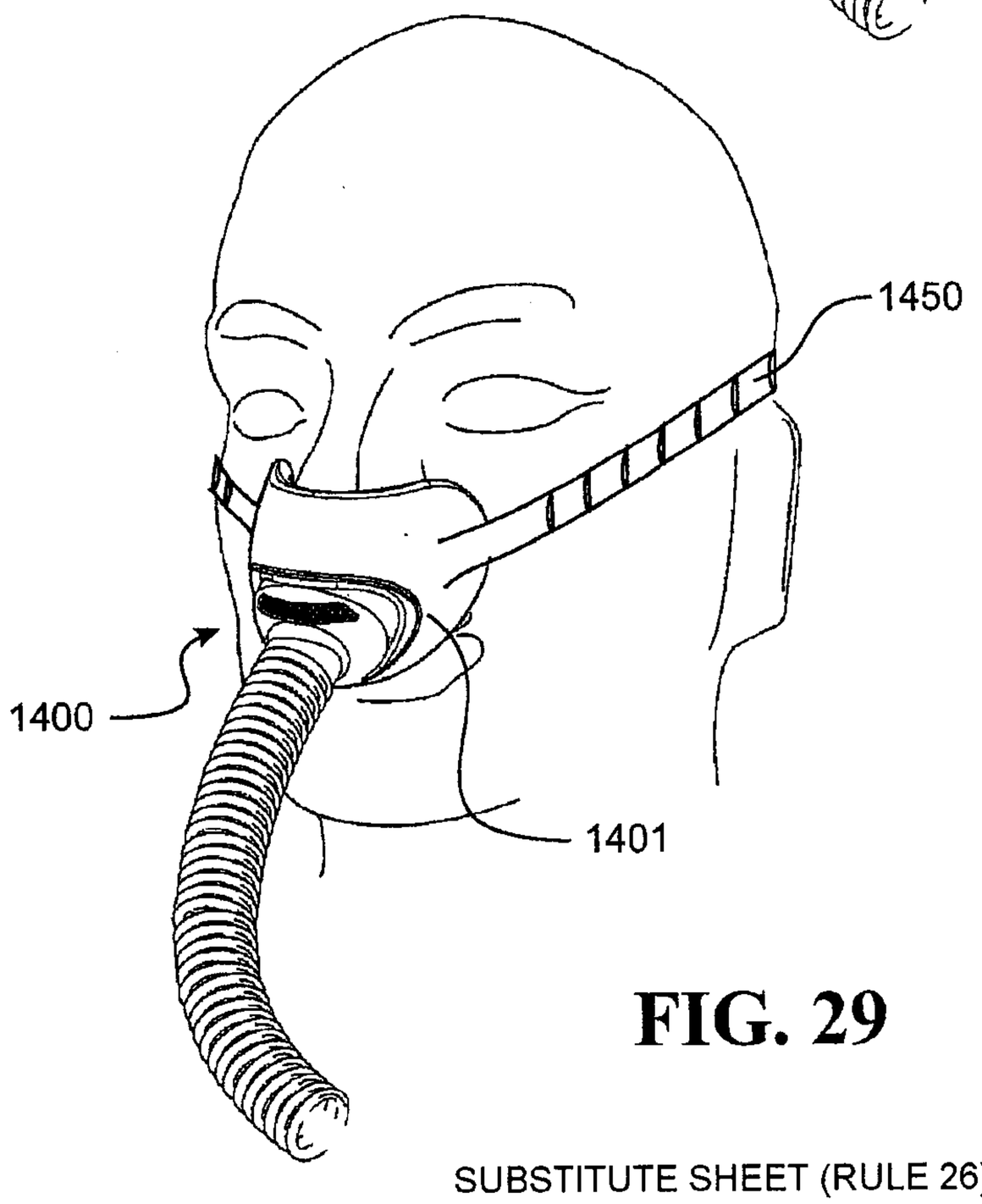


FIG. 28



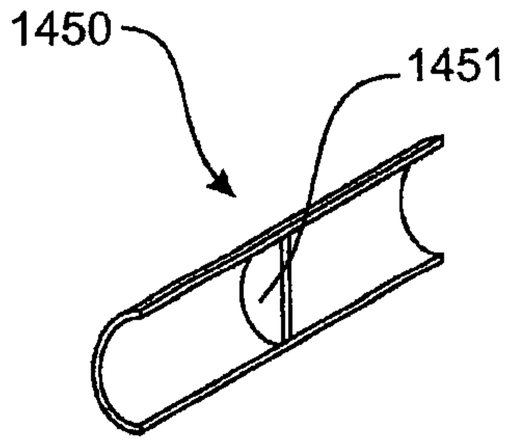


FIG. 29a

FIG. 29

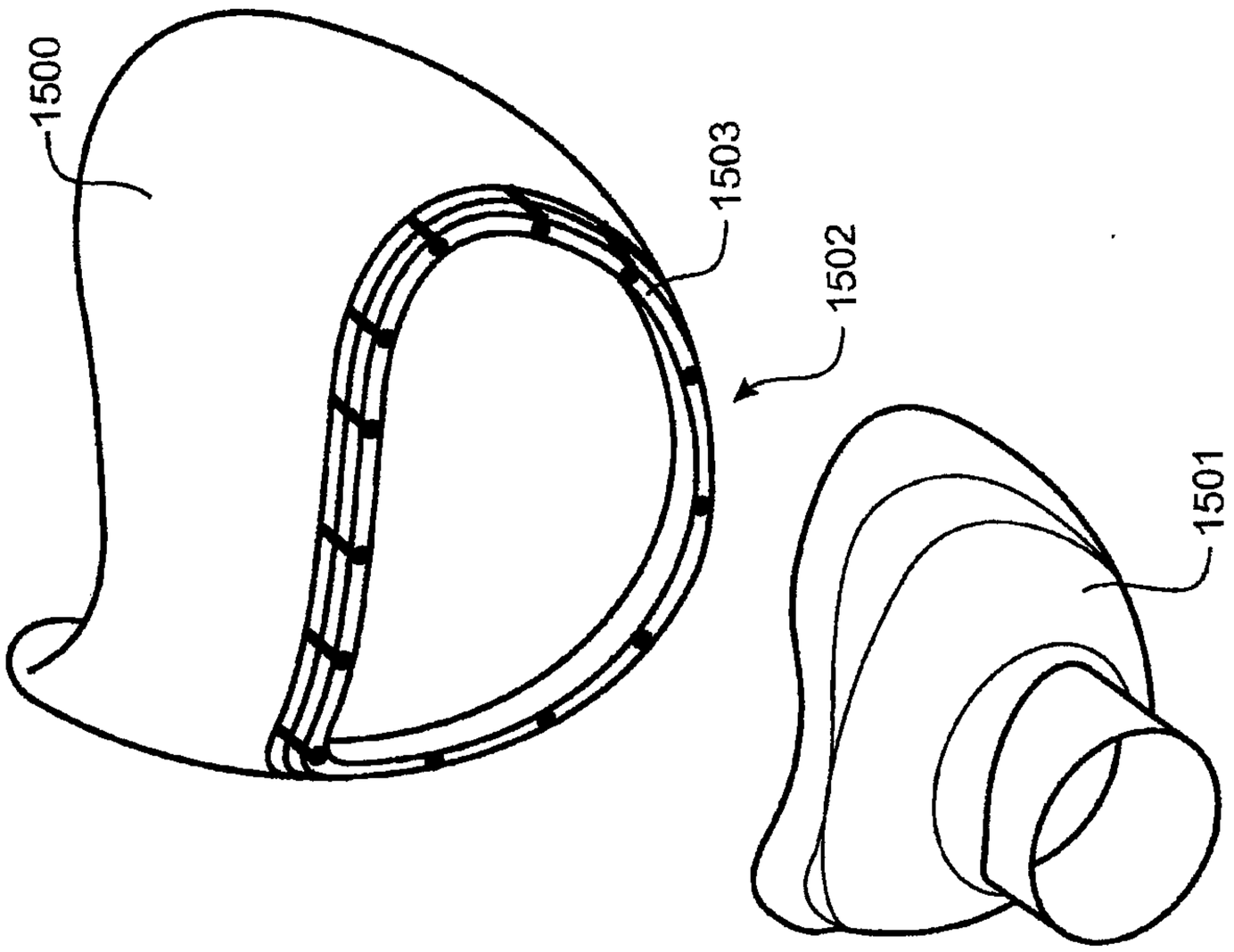


FIG. 31

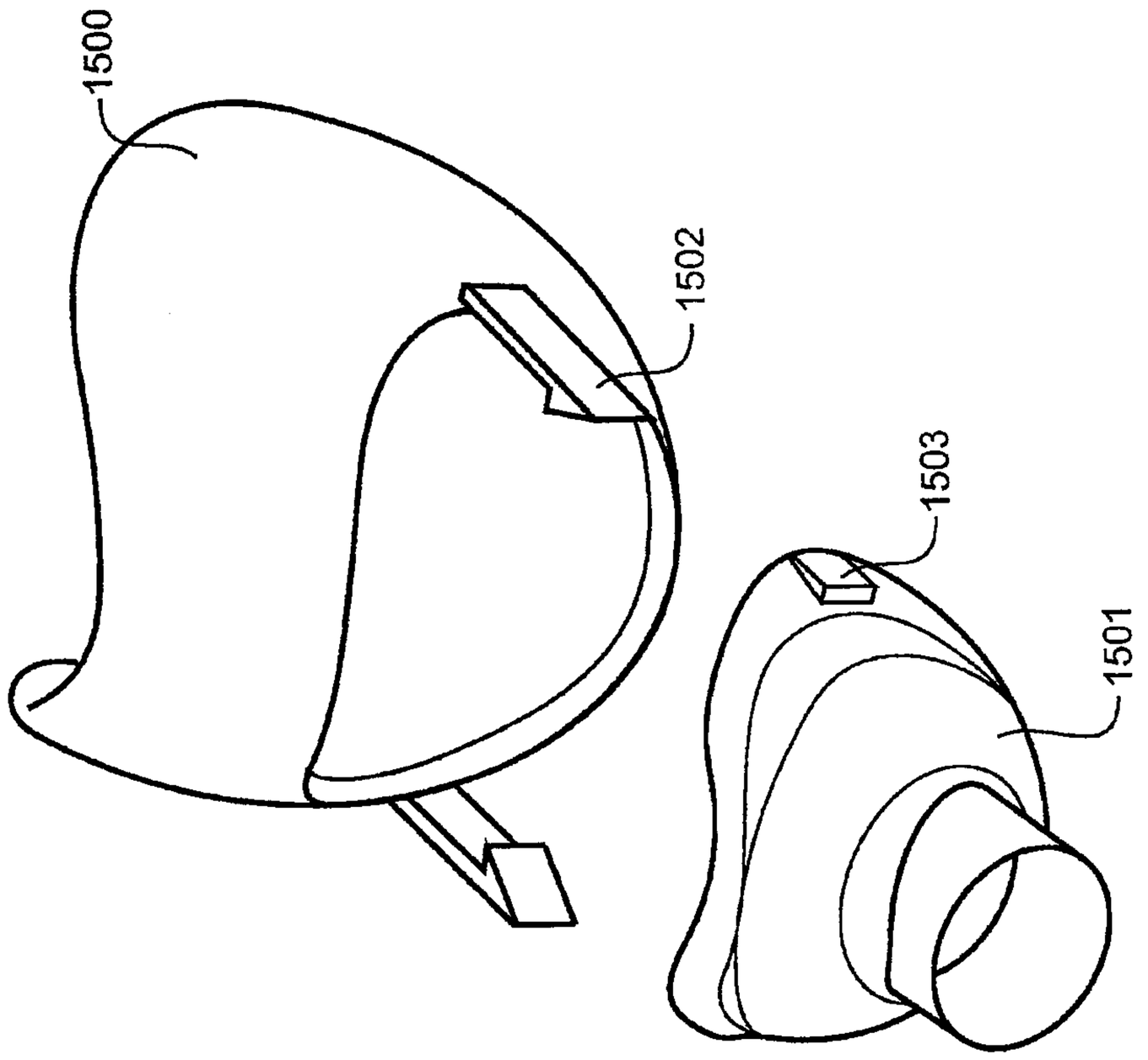


FIG. 30

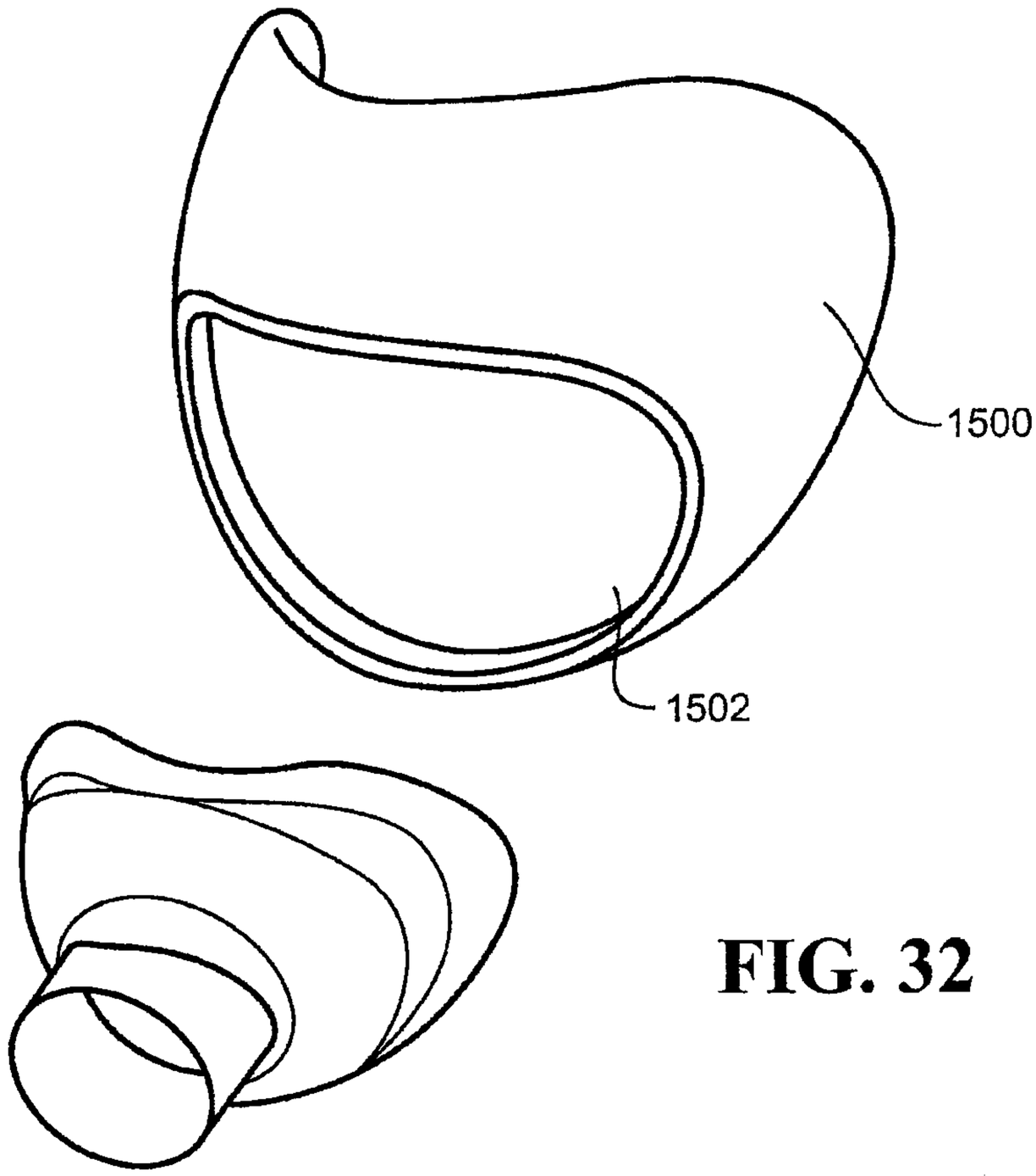


FIG. 32

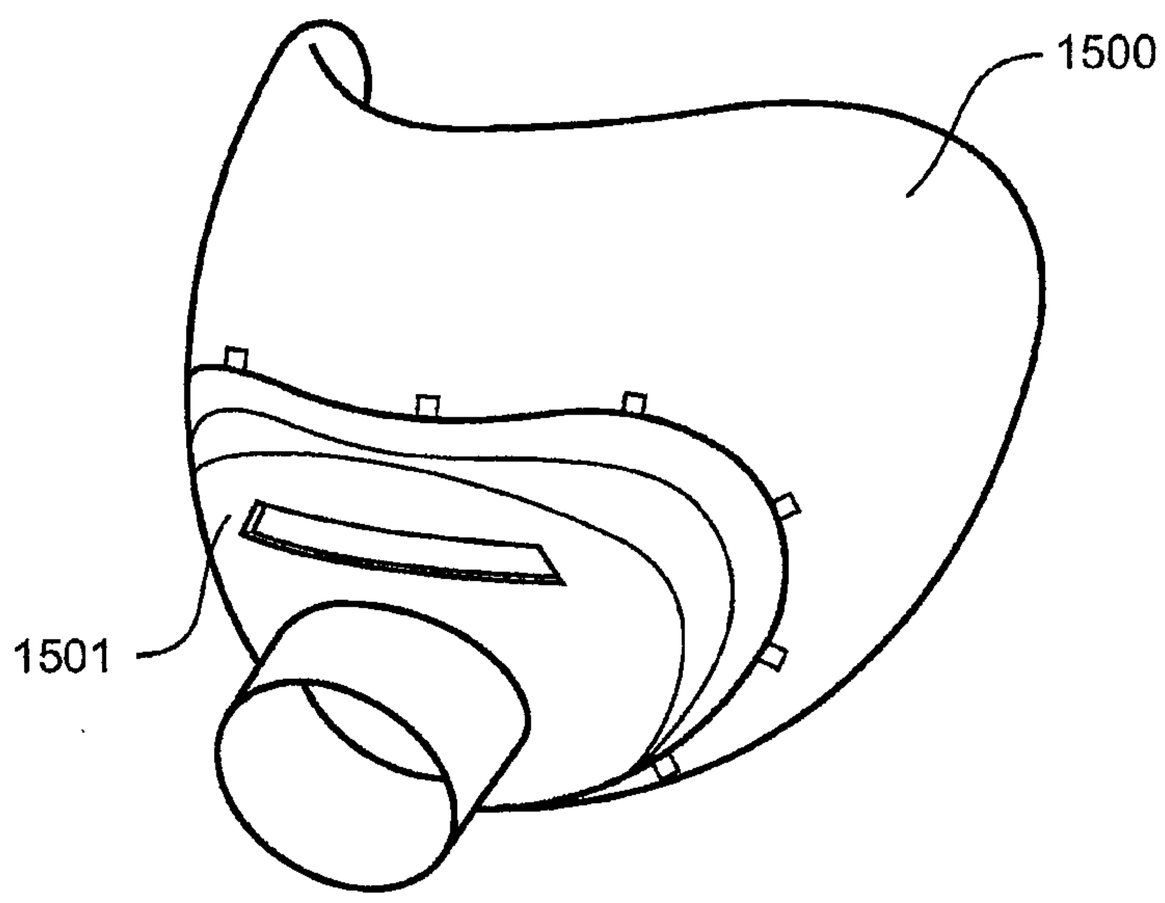


FIG. 33

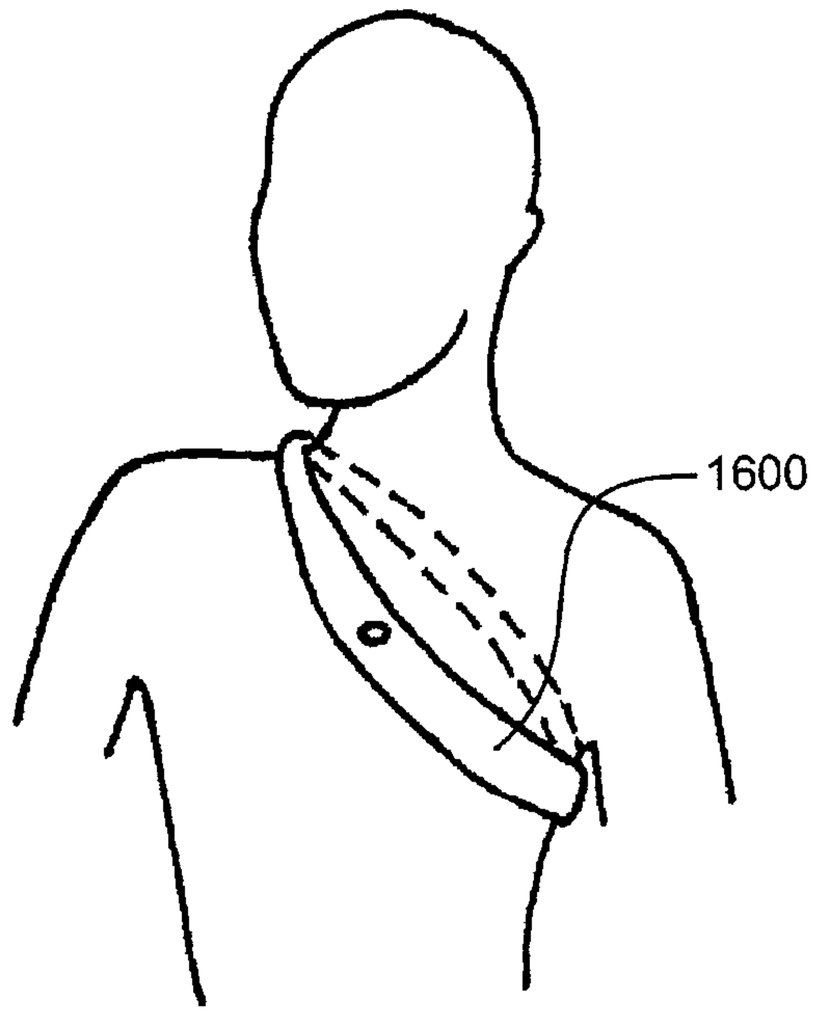


FIGURE 34

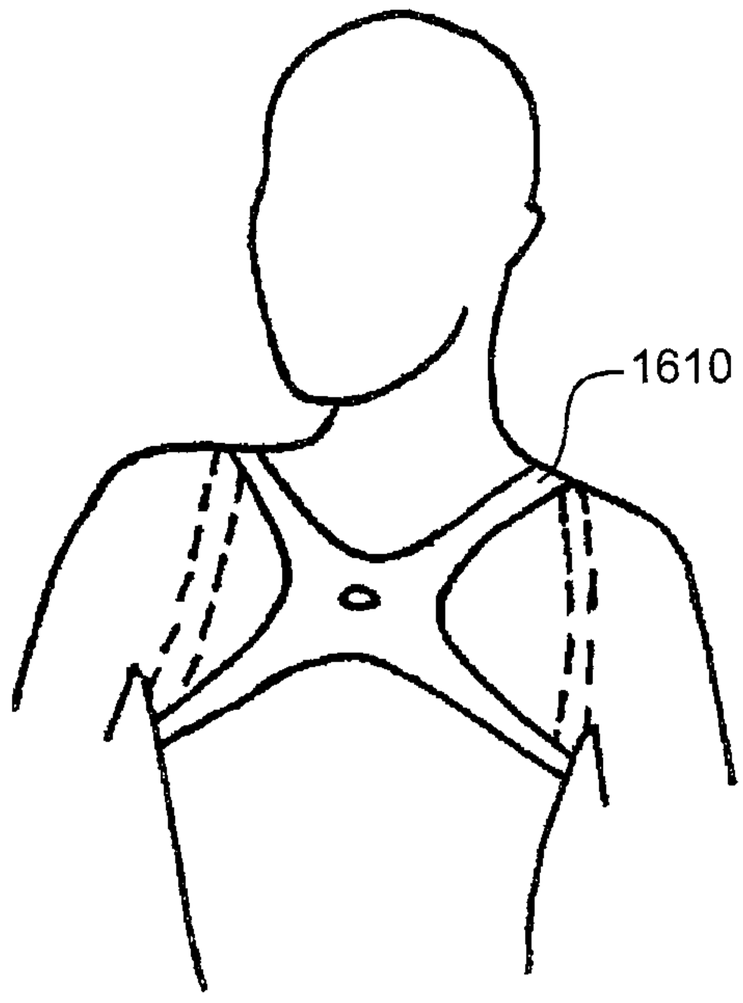


FIGURE 35

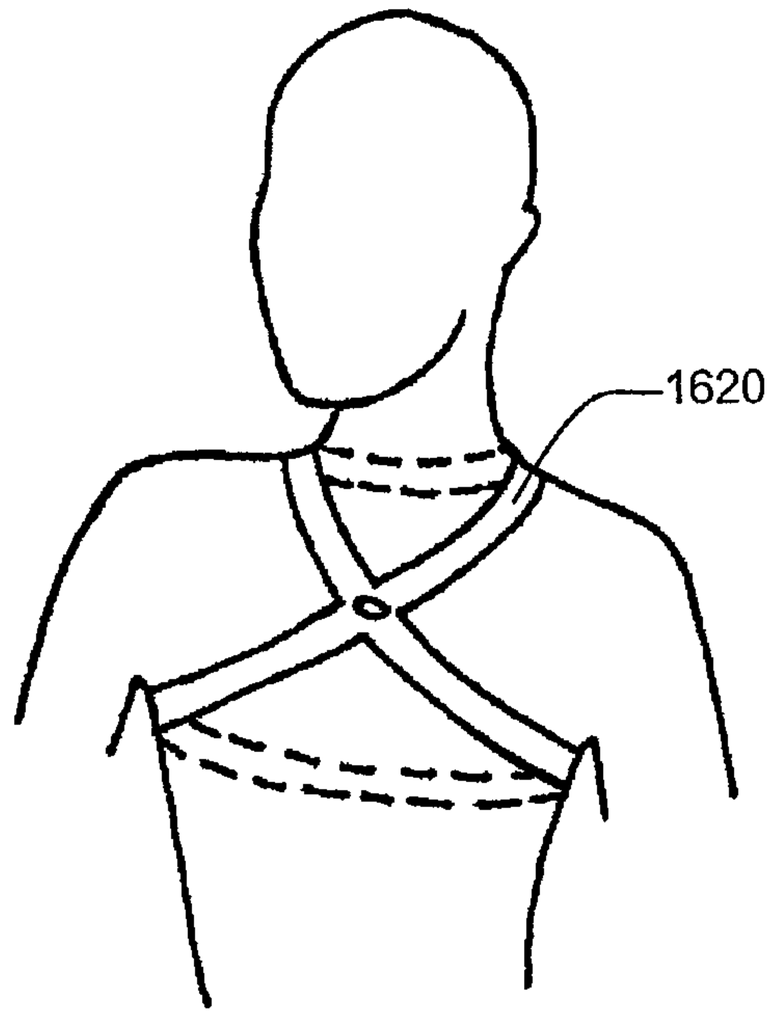


FIGURE 36

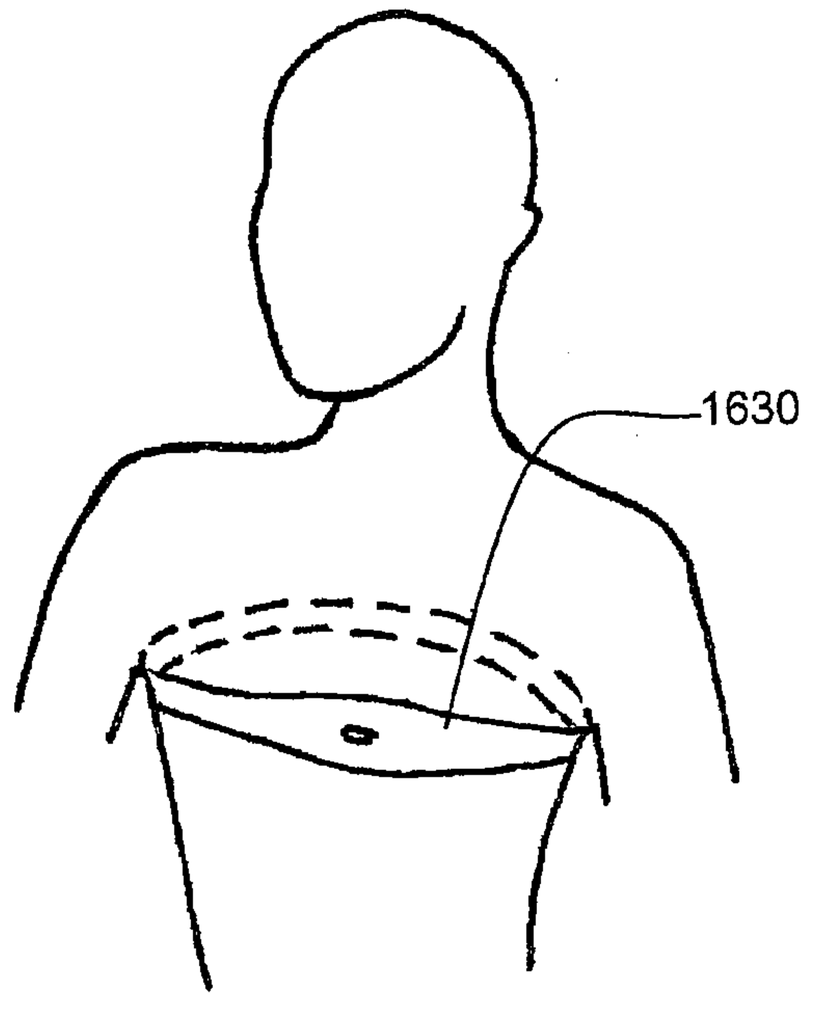


FIGURE 37

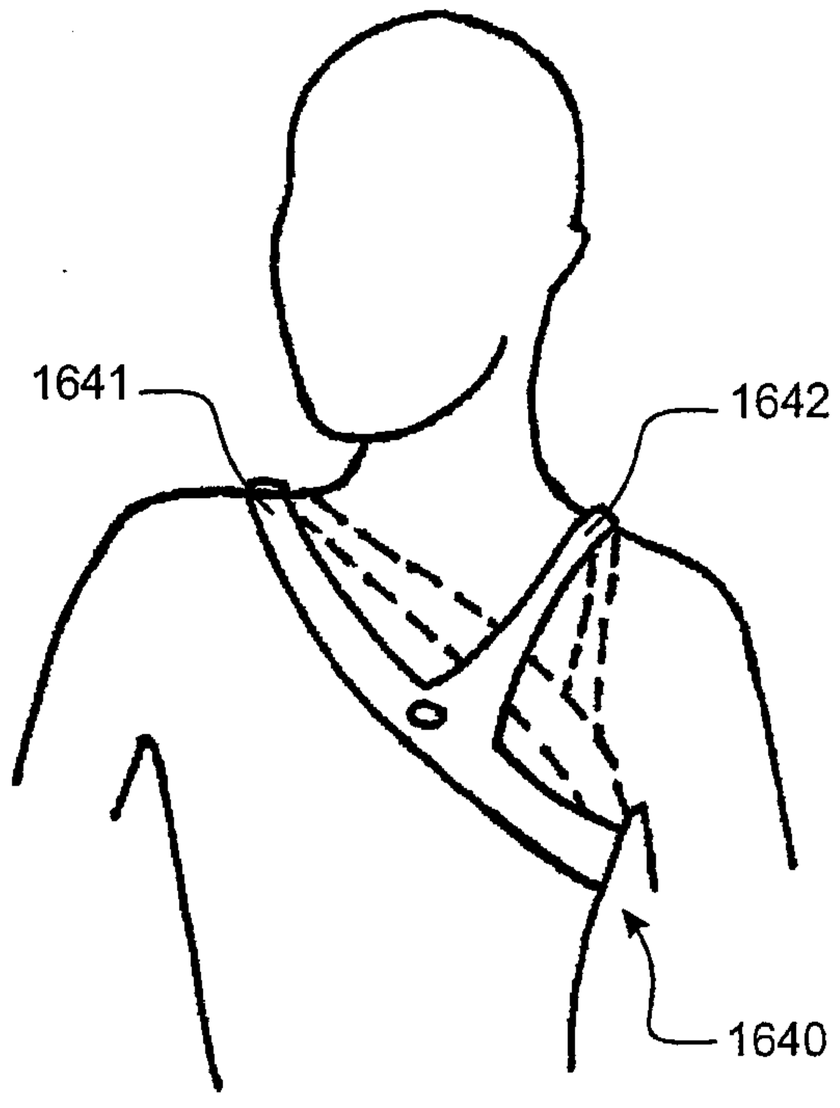


FIGURE 38

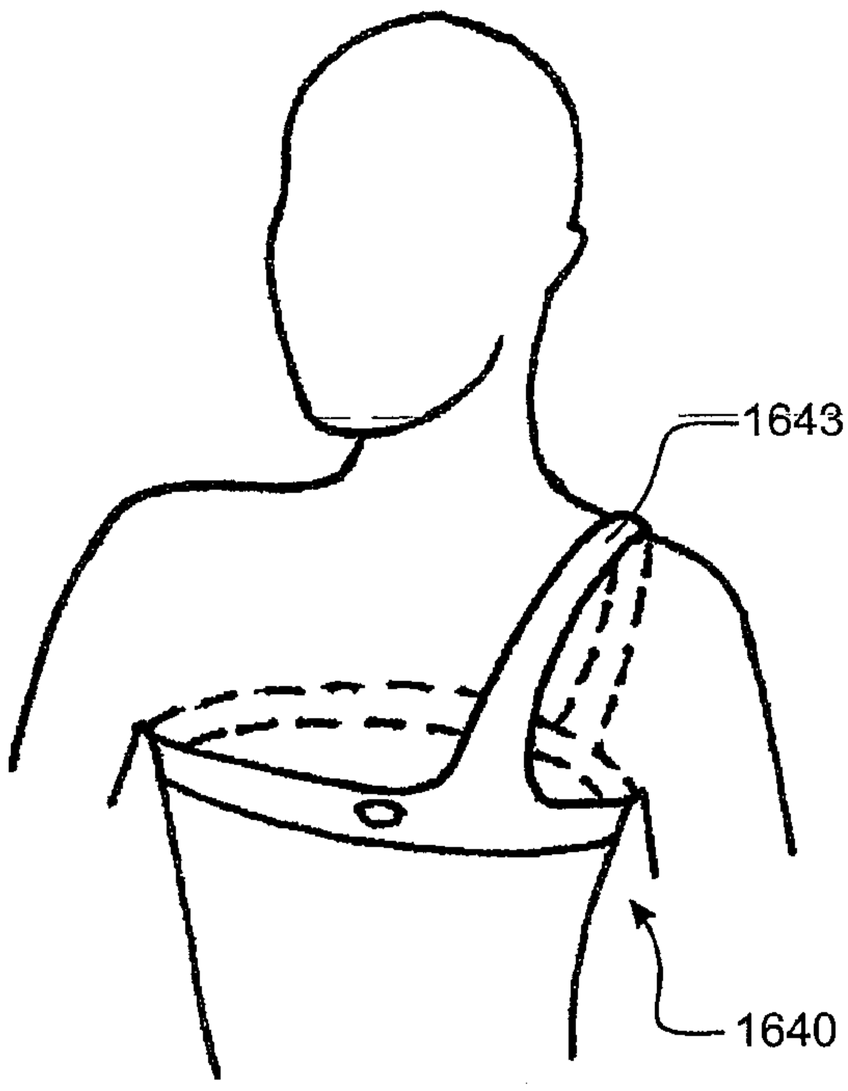


FIGURE 39

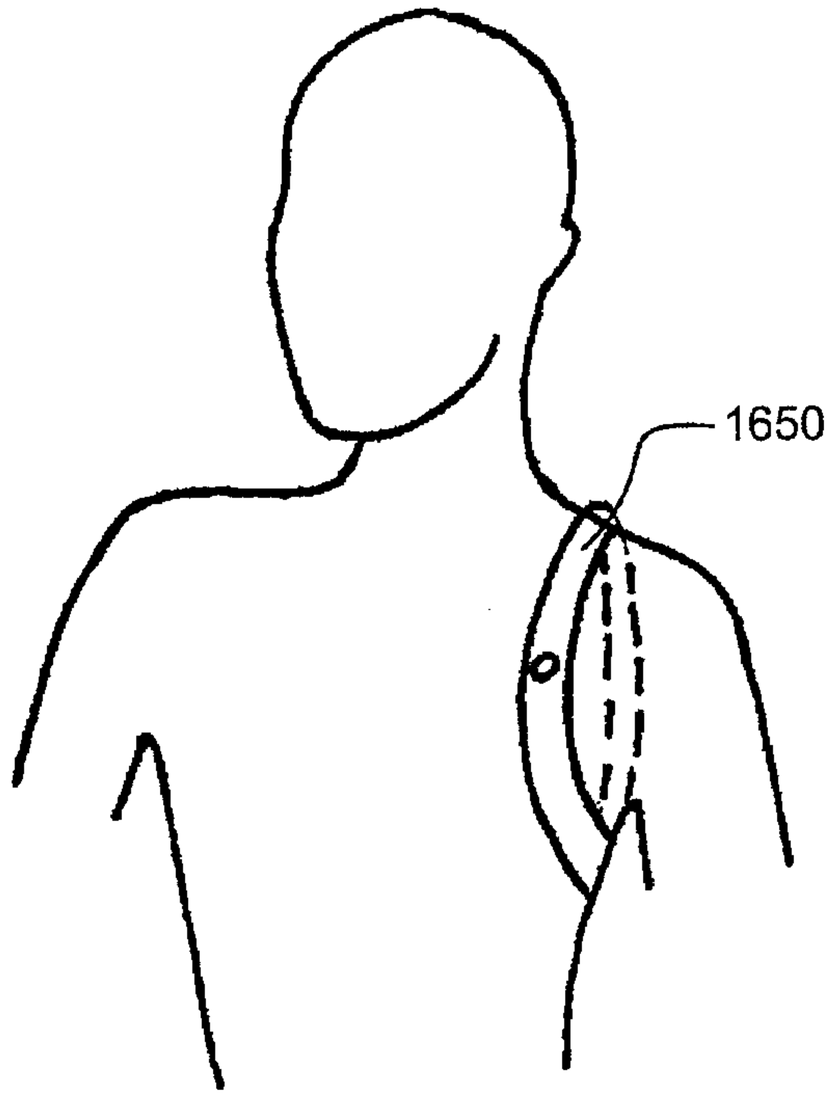


FIG. 40

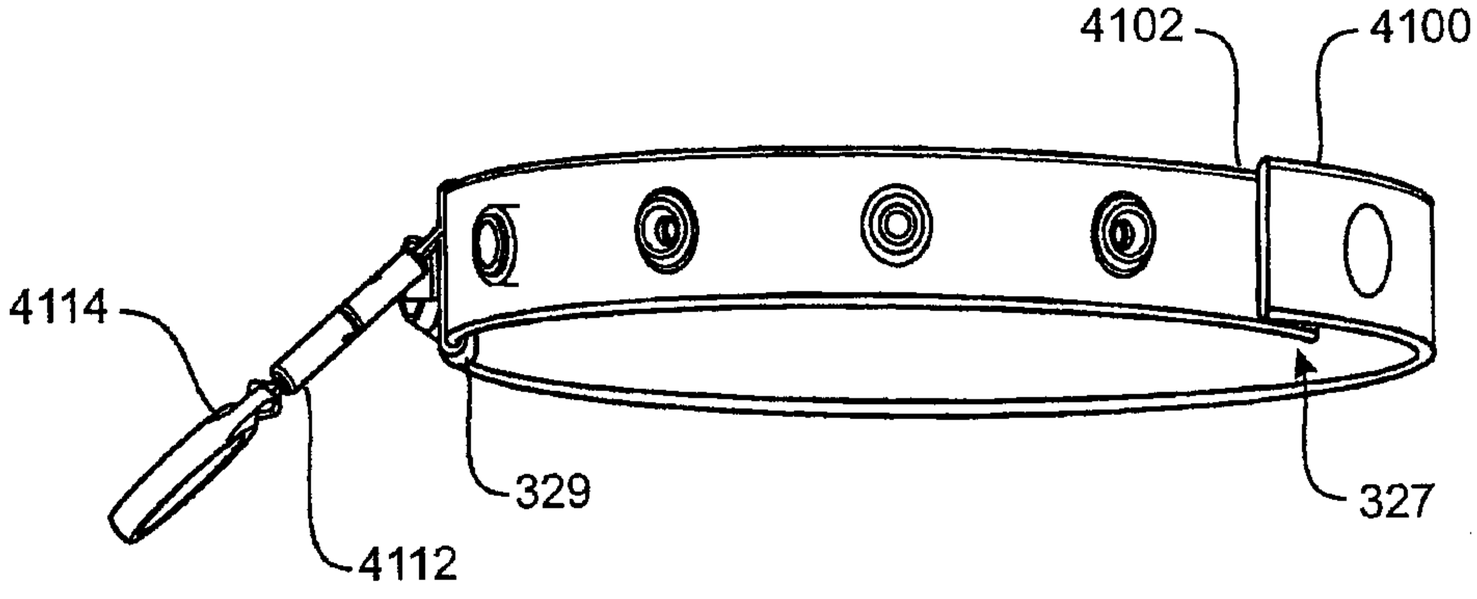


FIG. 41

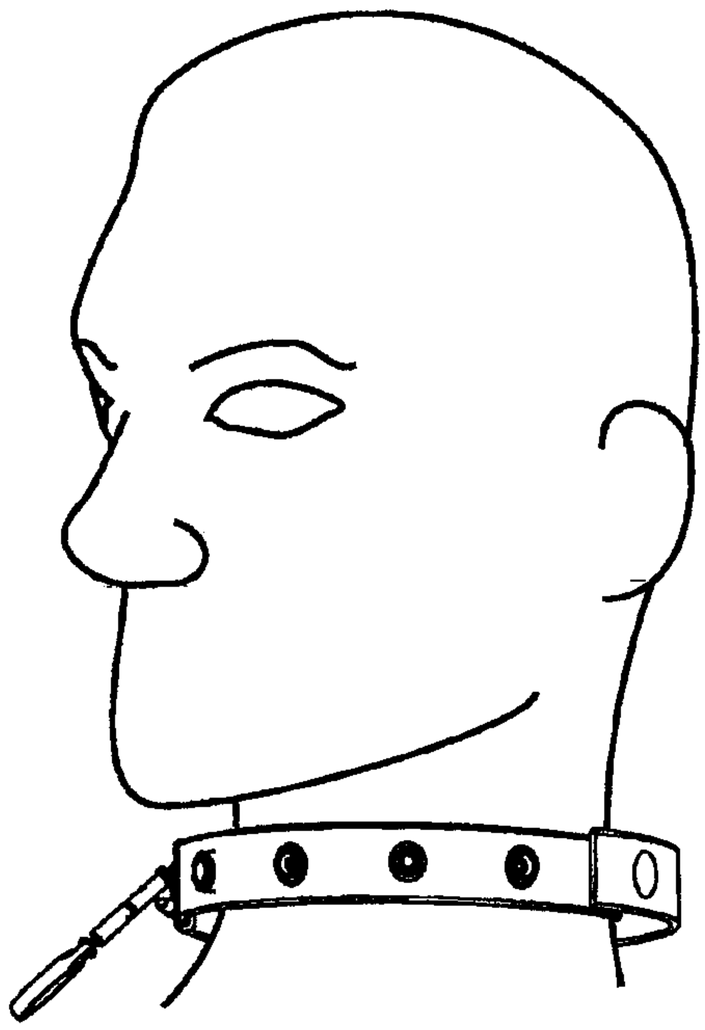


FIG. 42

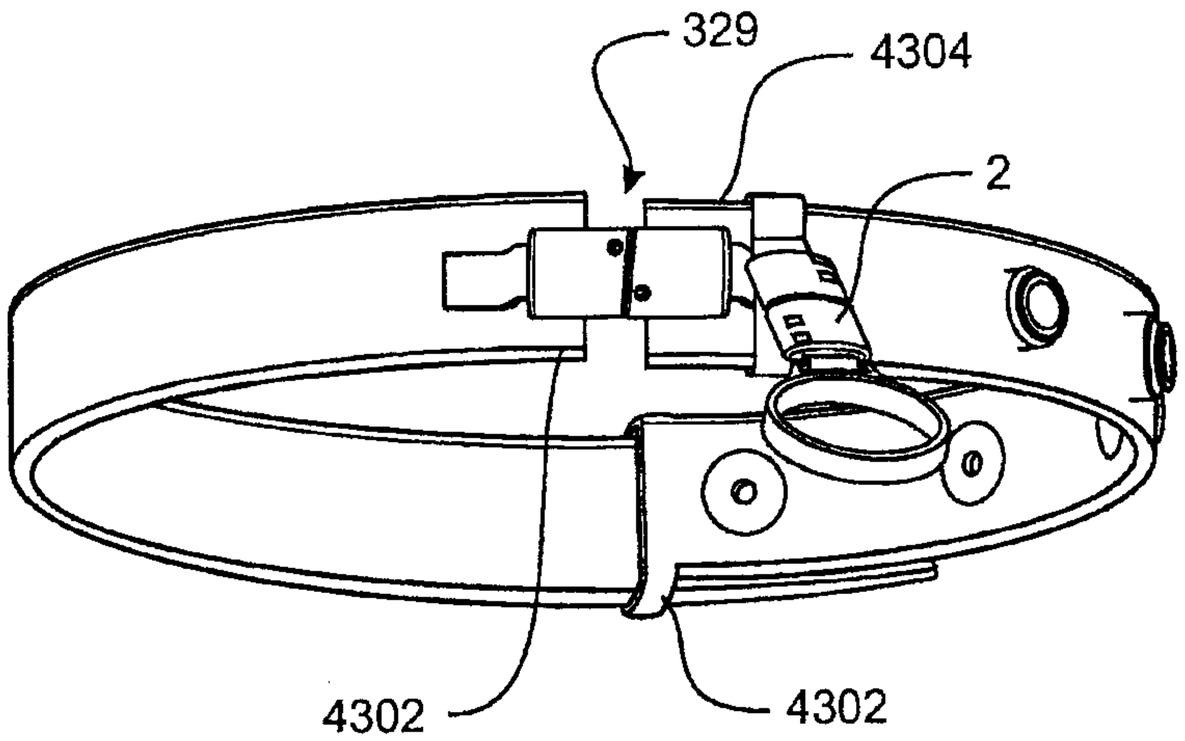


FIG. 43

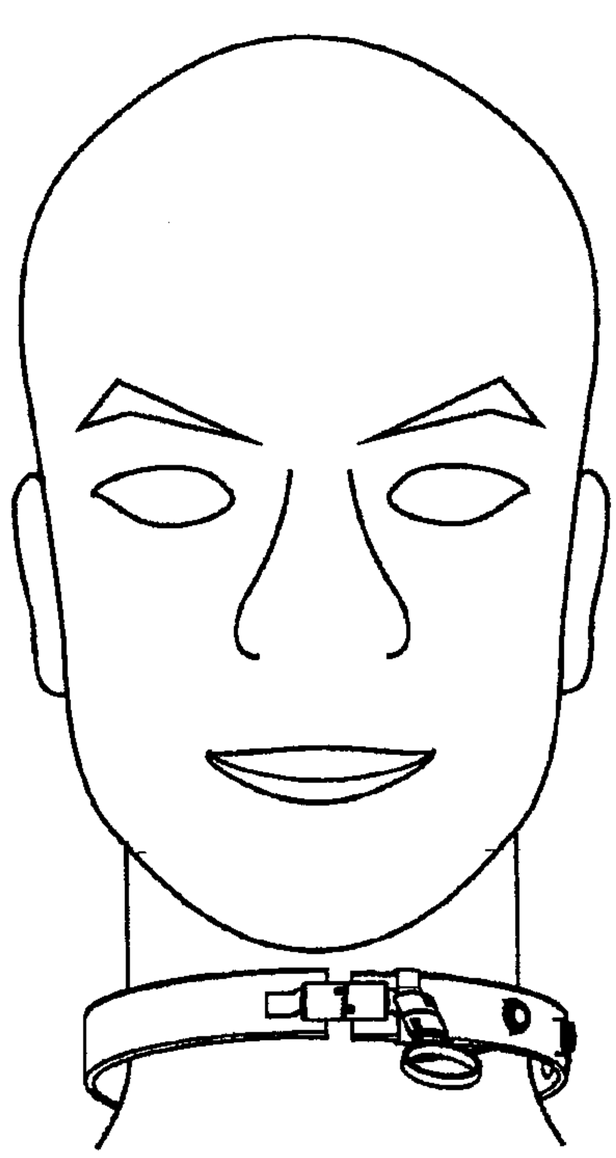


FIG. 44

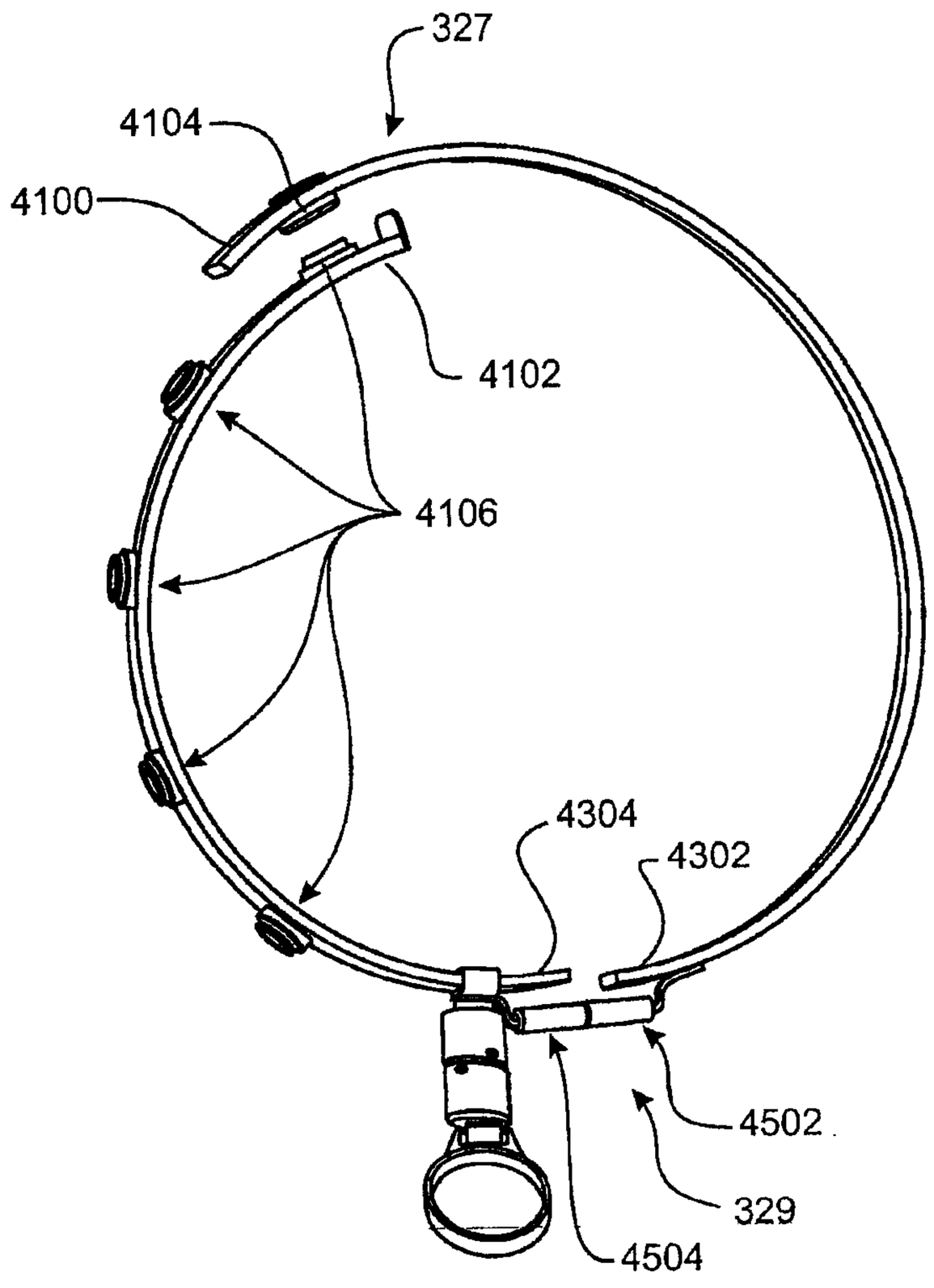


FIG. 45

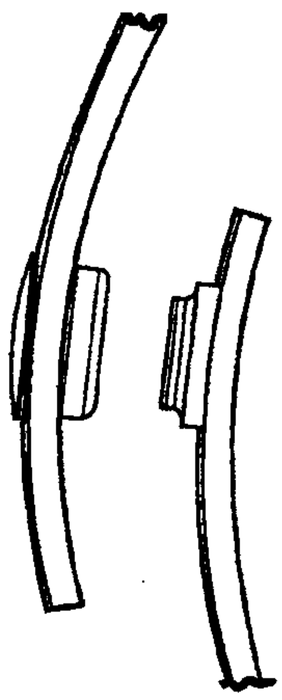


FIG. 46

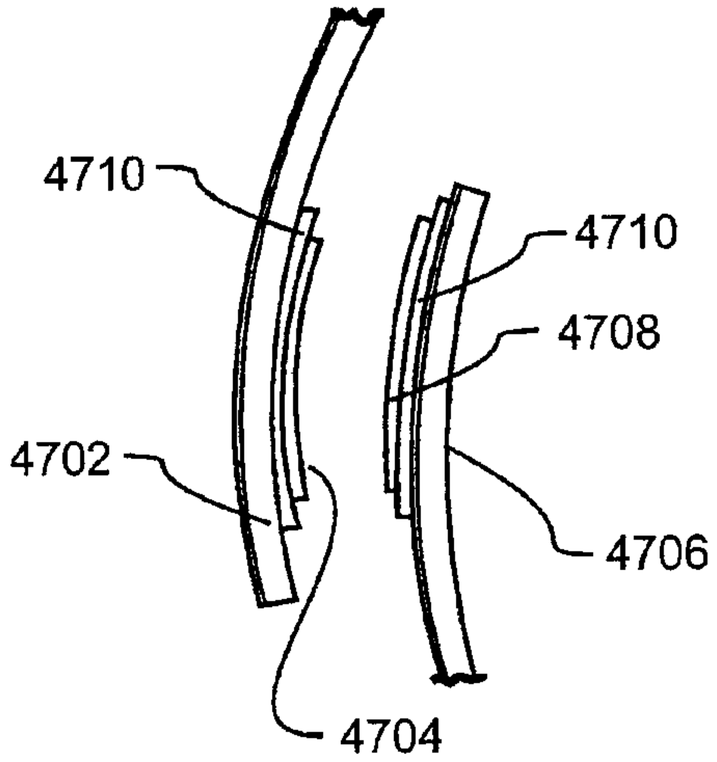


FIG. 47

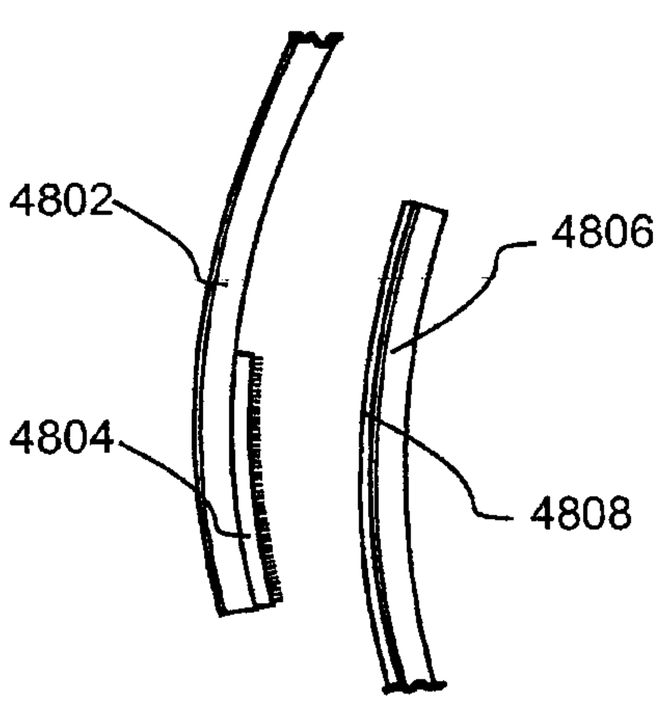


FIG. 48

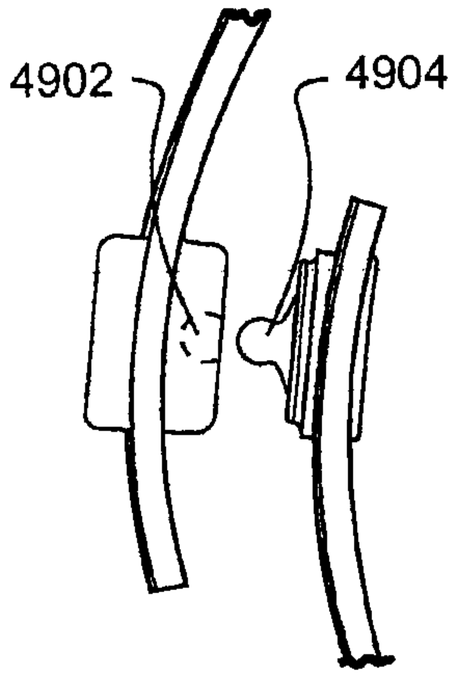


FIG. 49

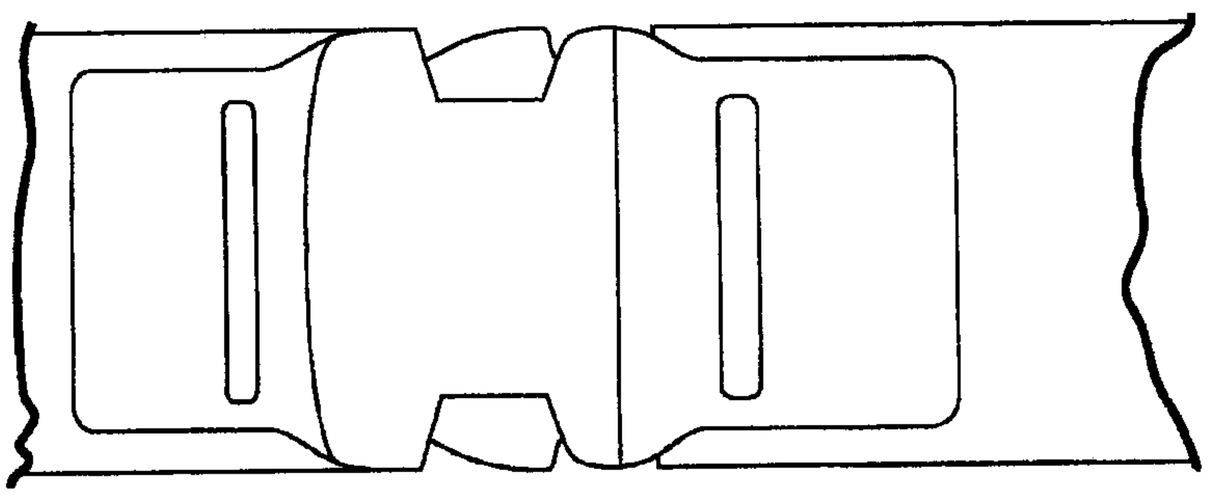


FIGURE 50A

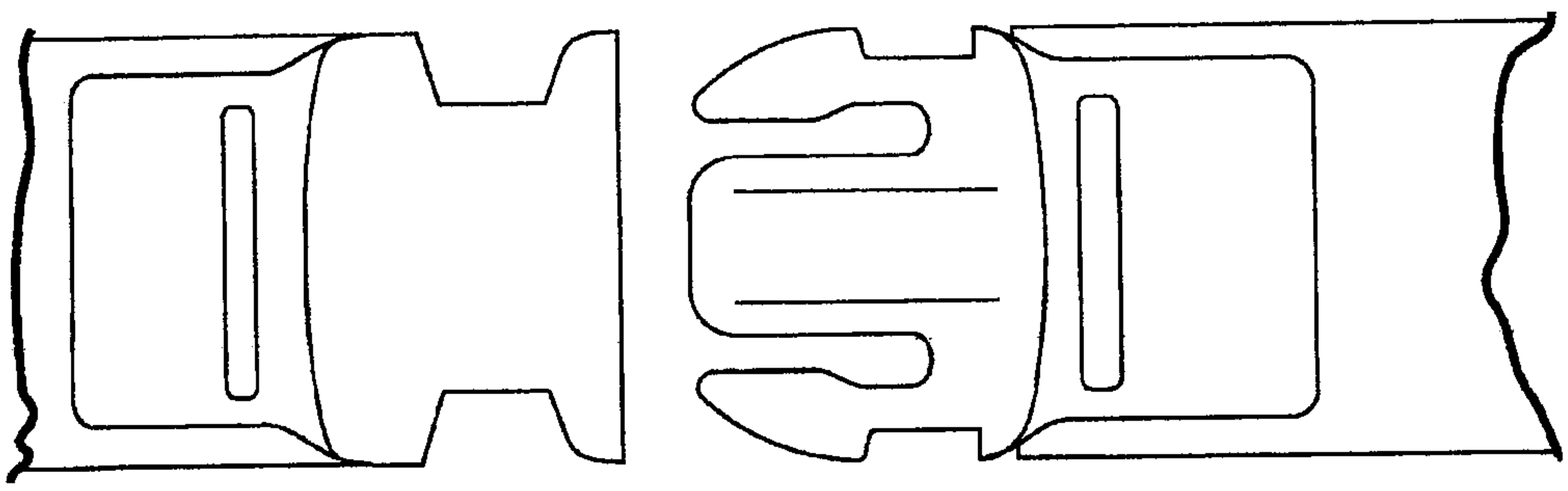


FIGURE 50B

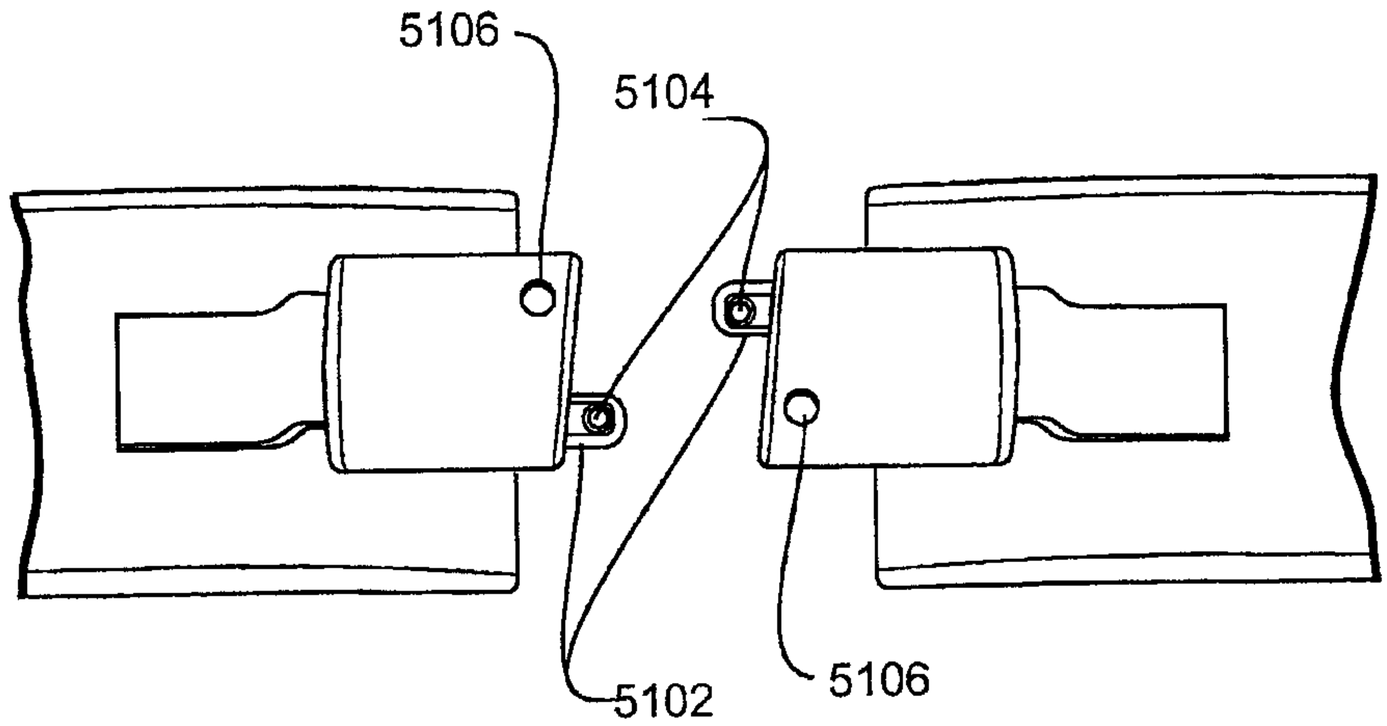


FIGURE 51A

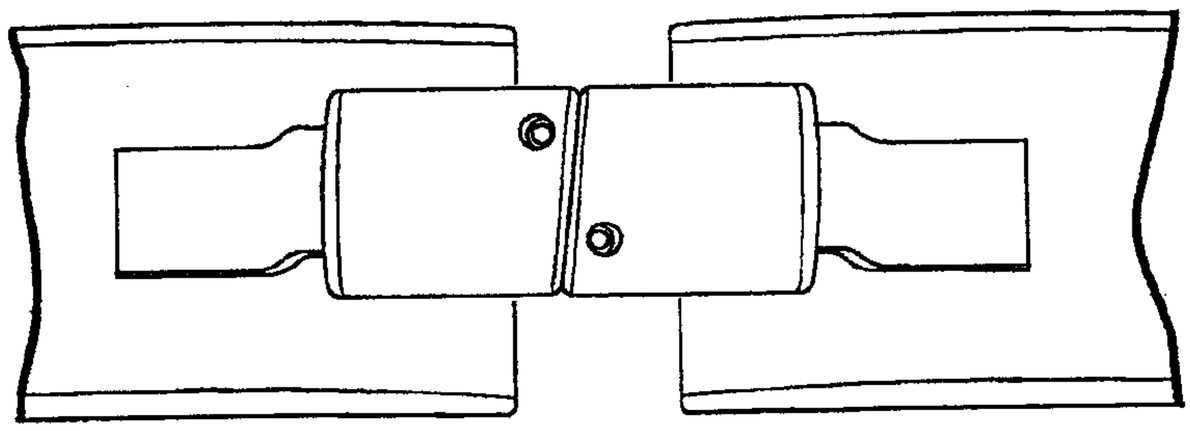


FIGURE 51B

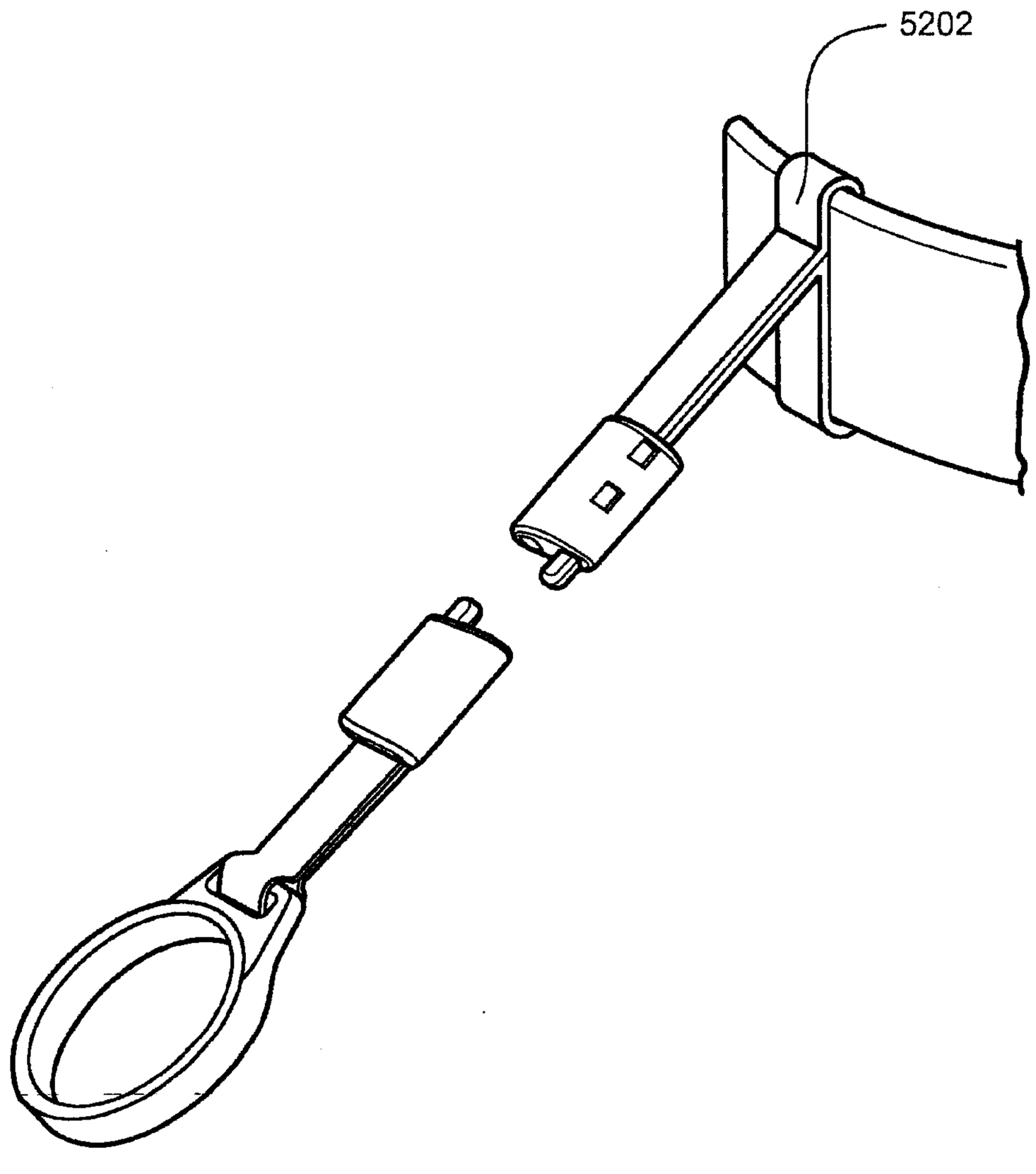


FIGURE 52

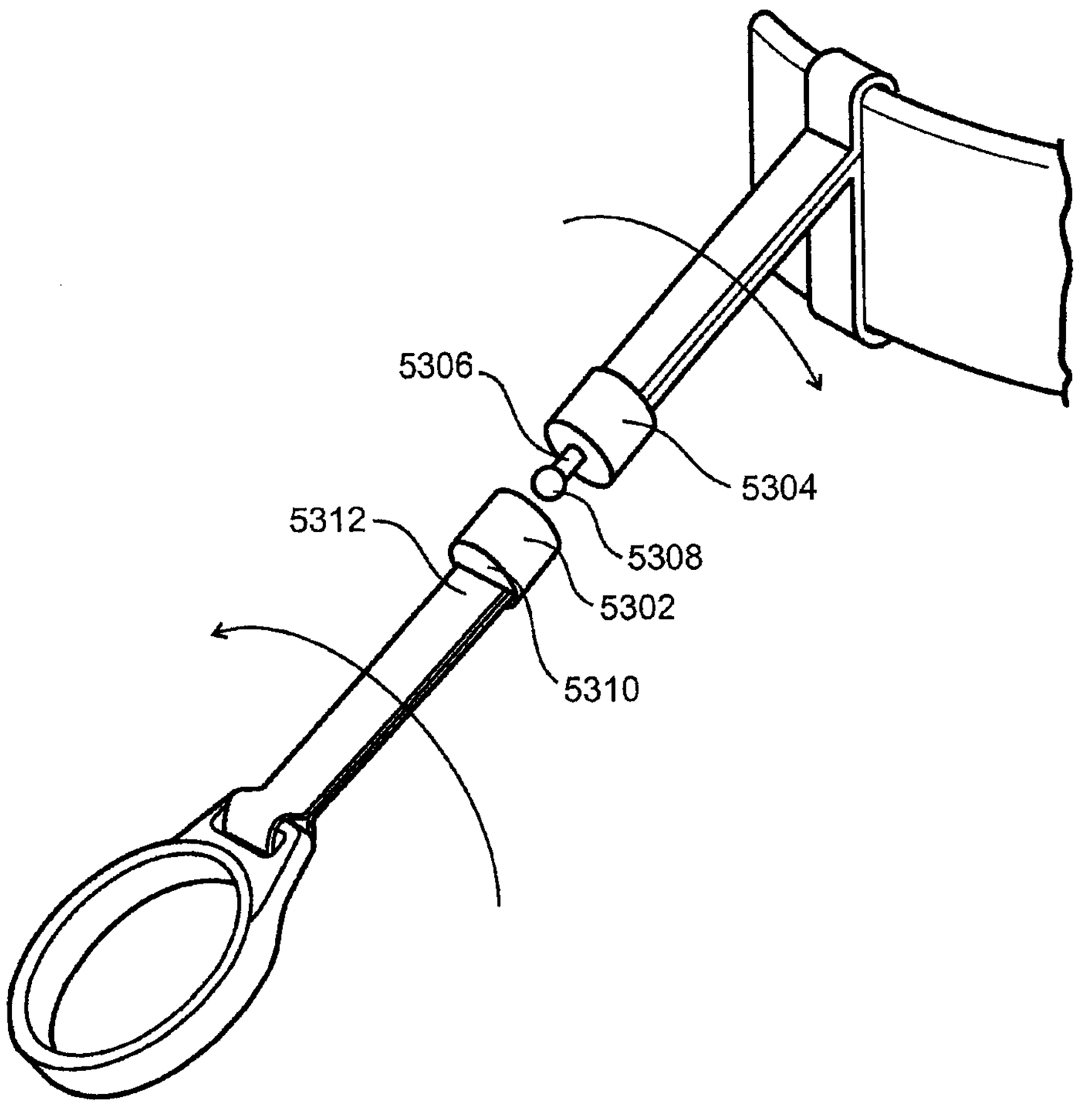


FIGURE 53

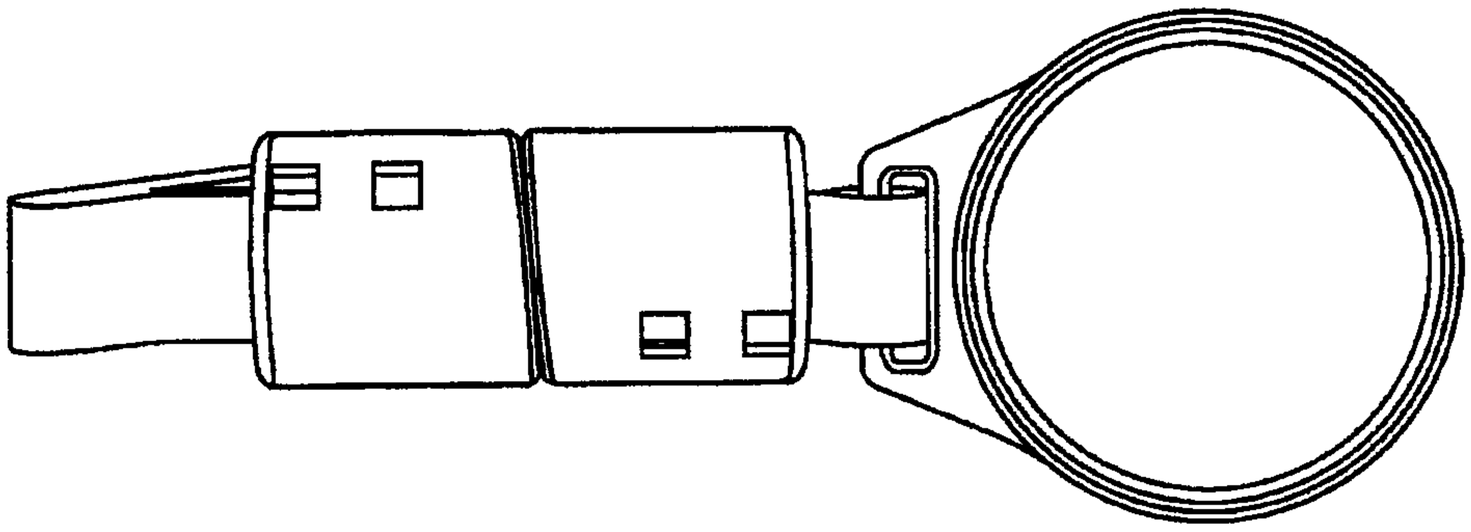


FIGURE 54A

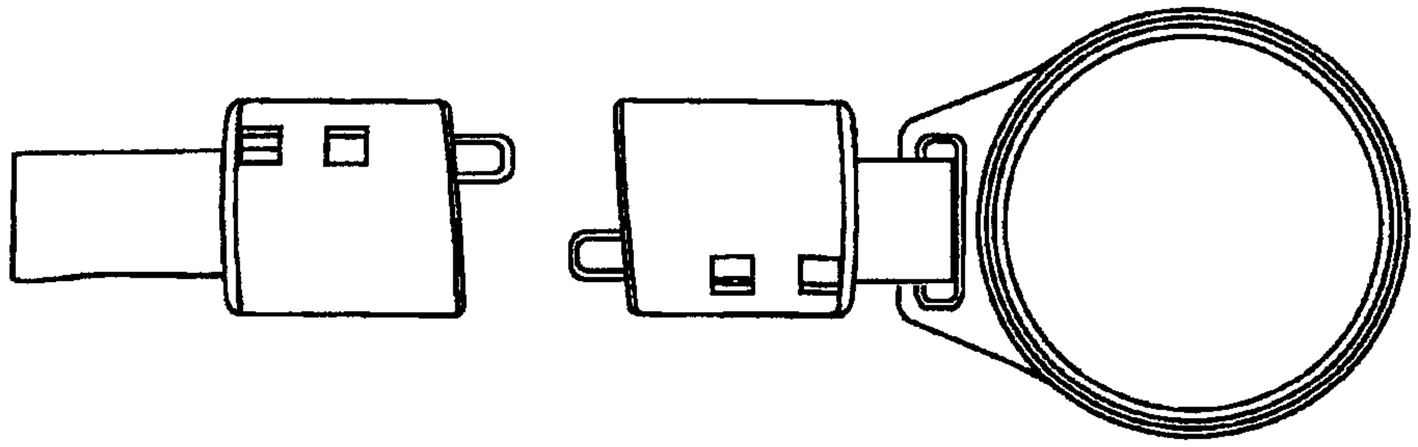


FIGURE 54B

FIGURE 54C

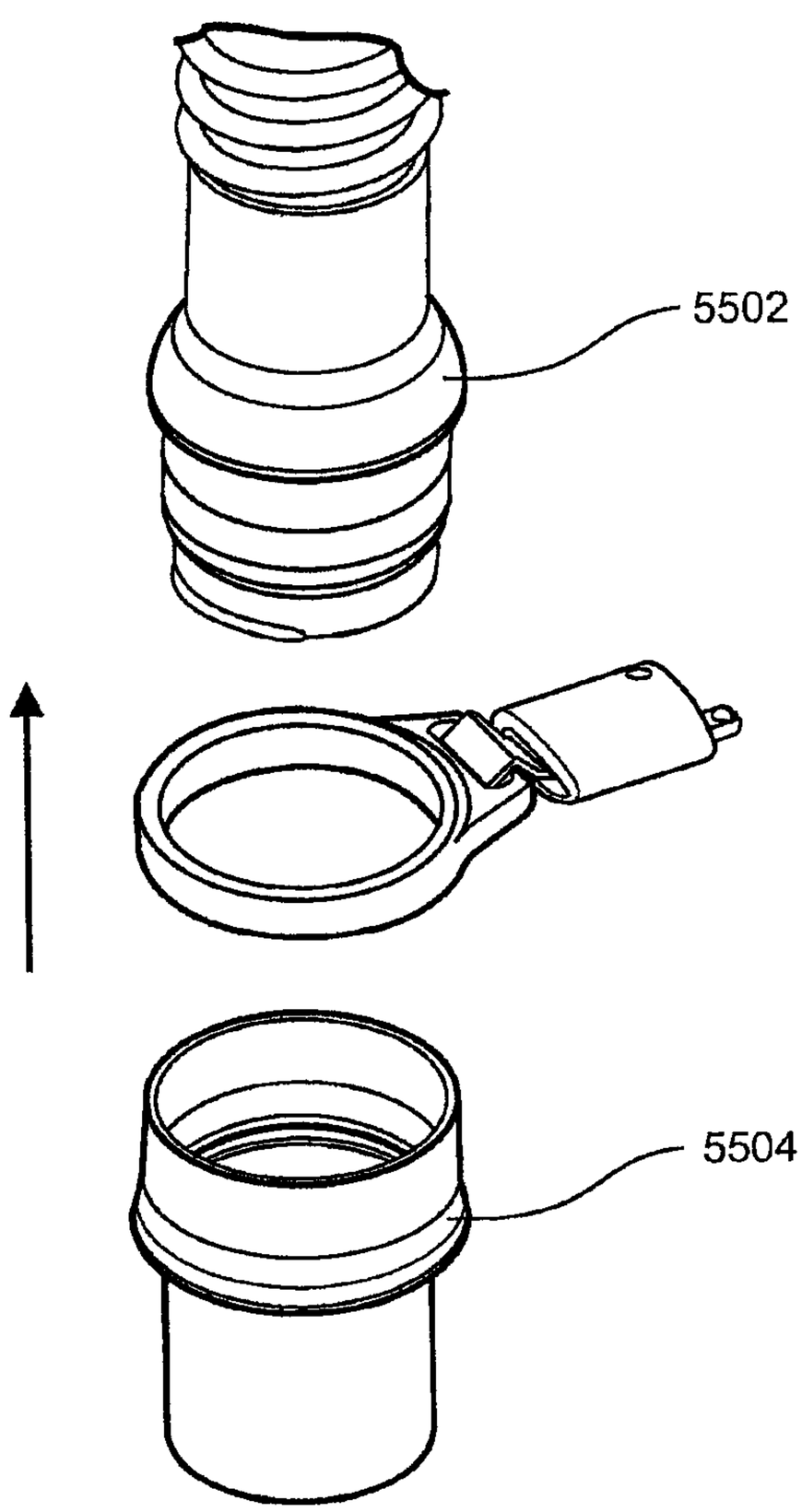


FIGURE 55

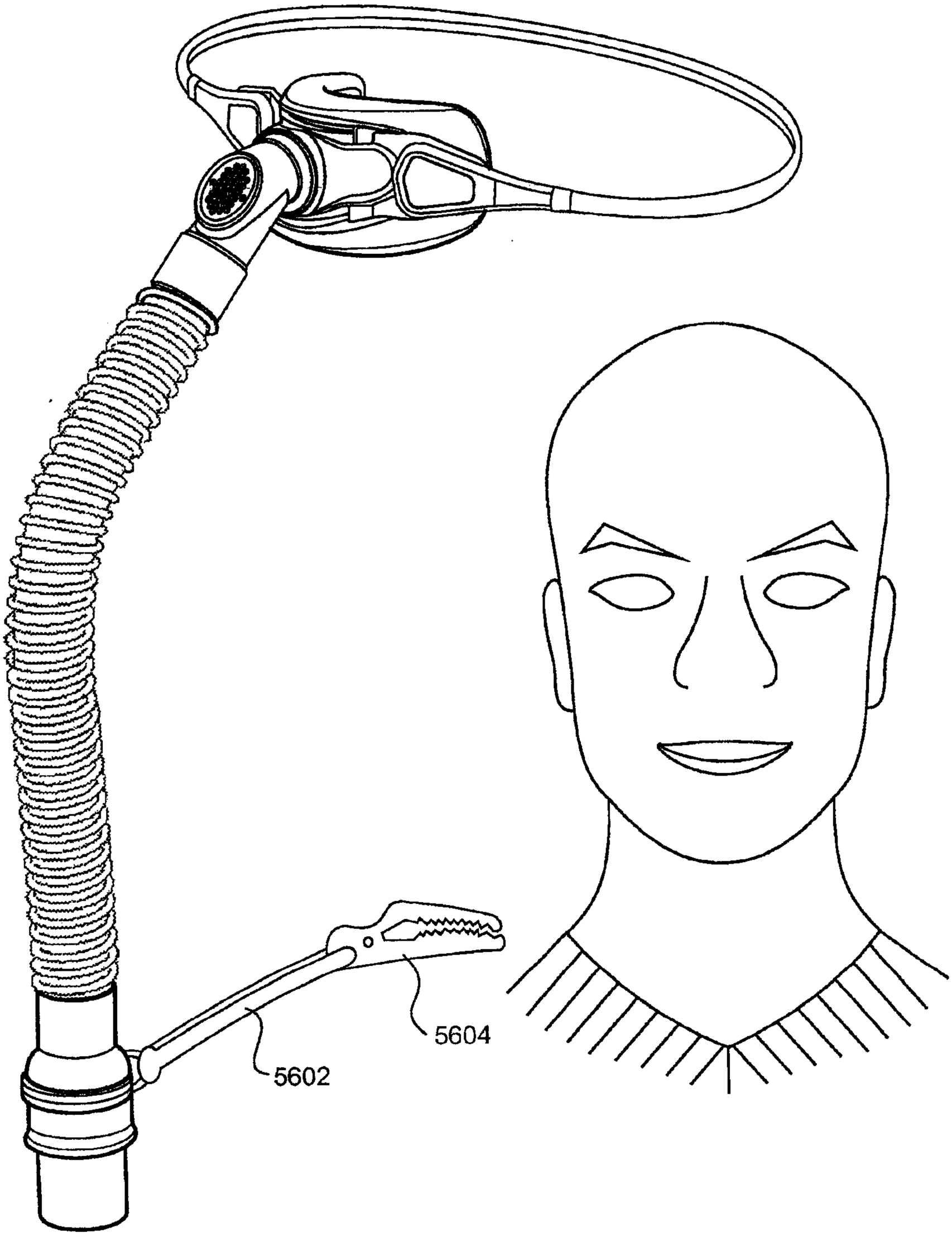


FIGURE 56

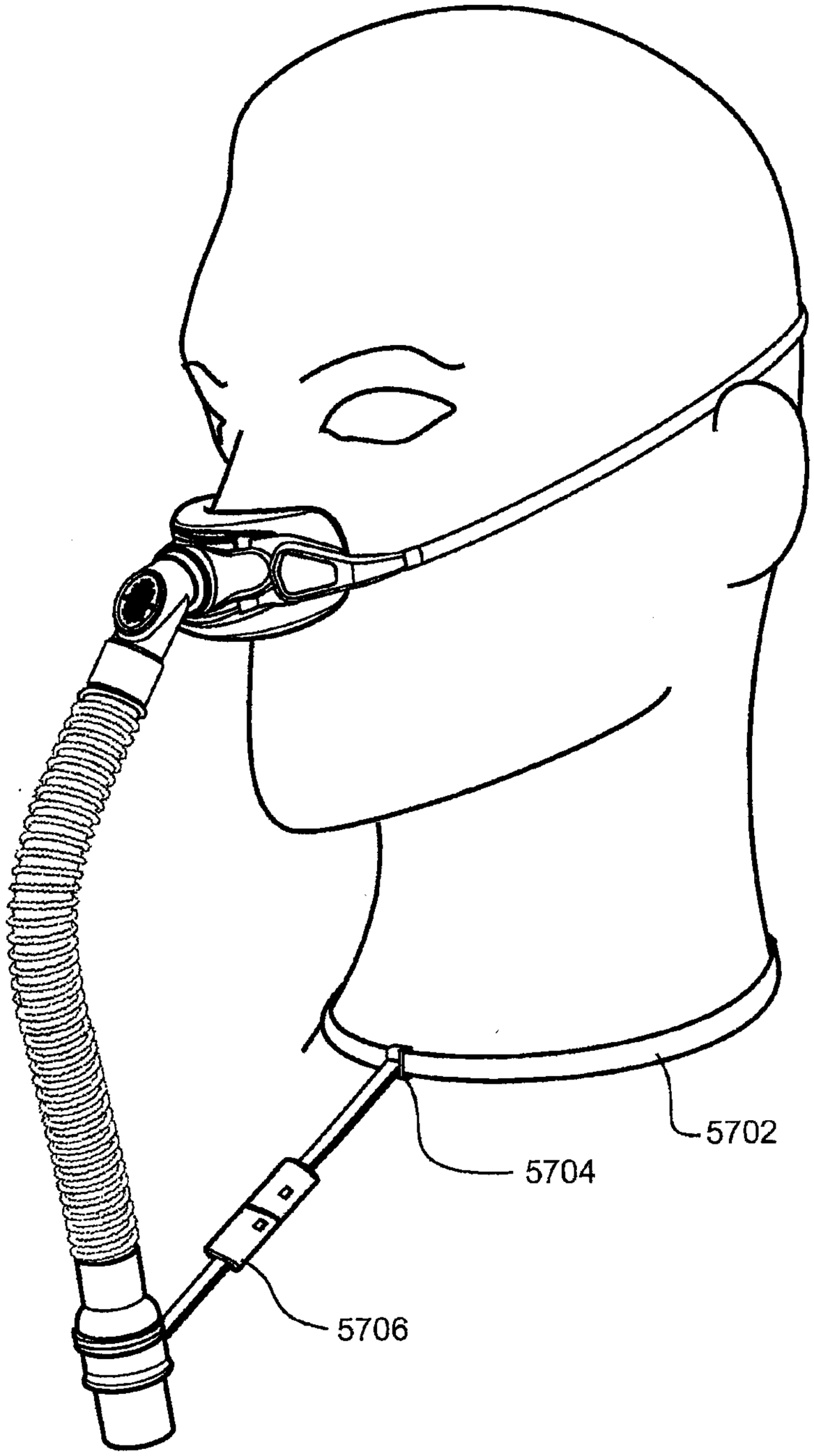


FIGURE 57

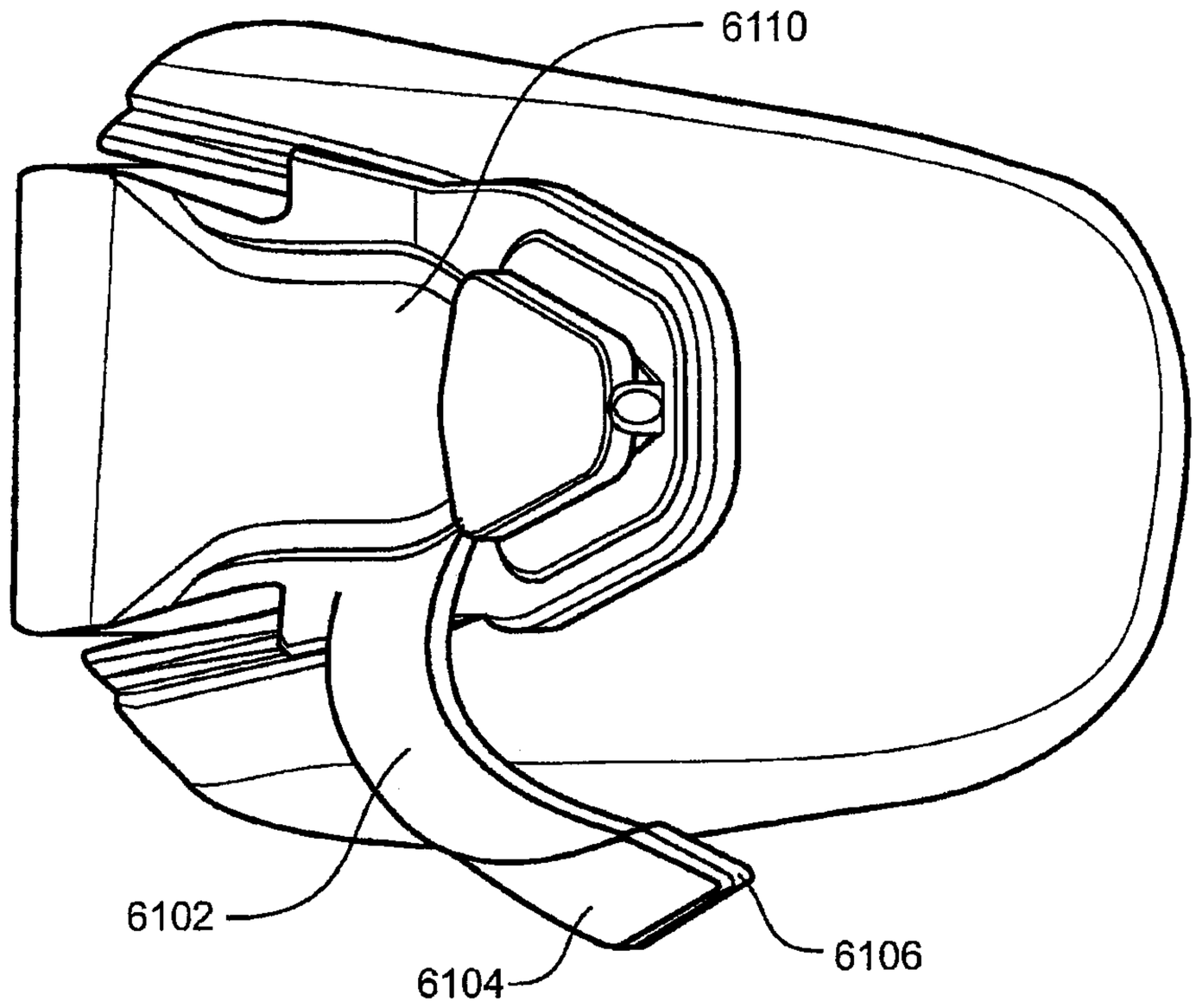


FIGURE 58

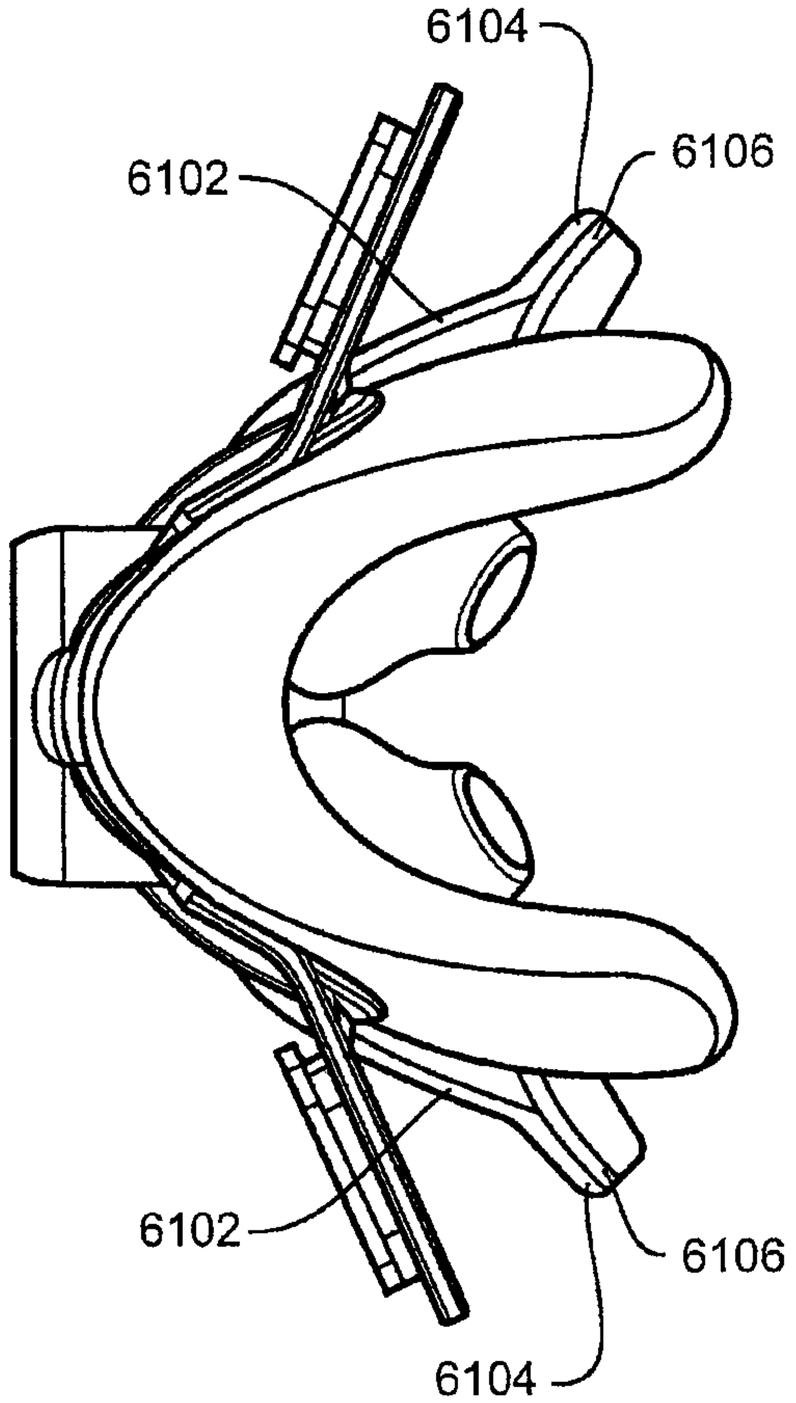


FIGURE 59

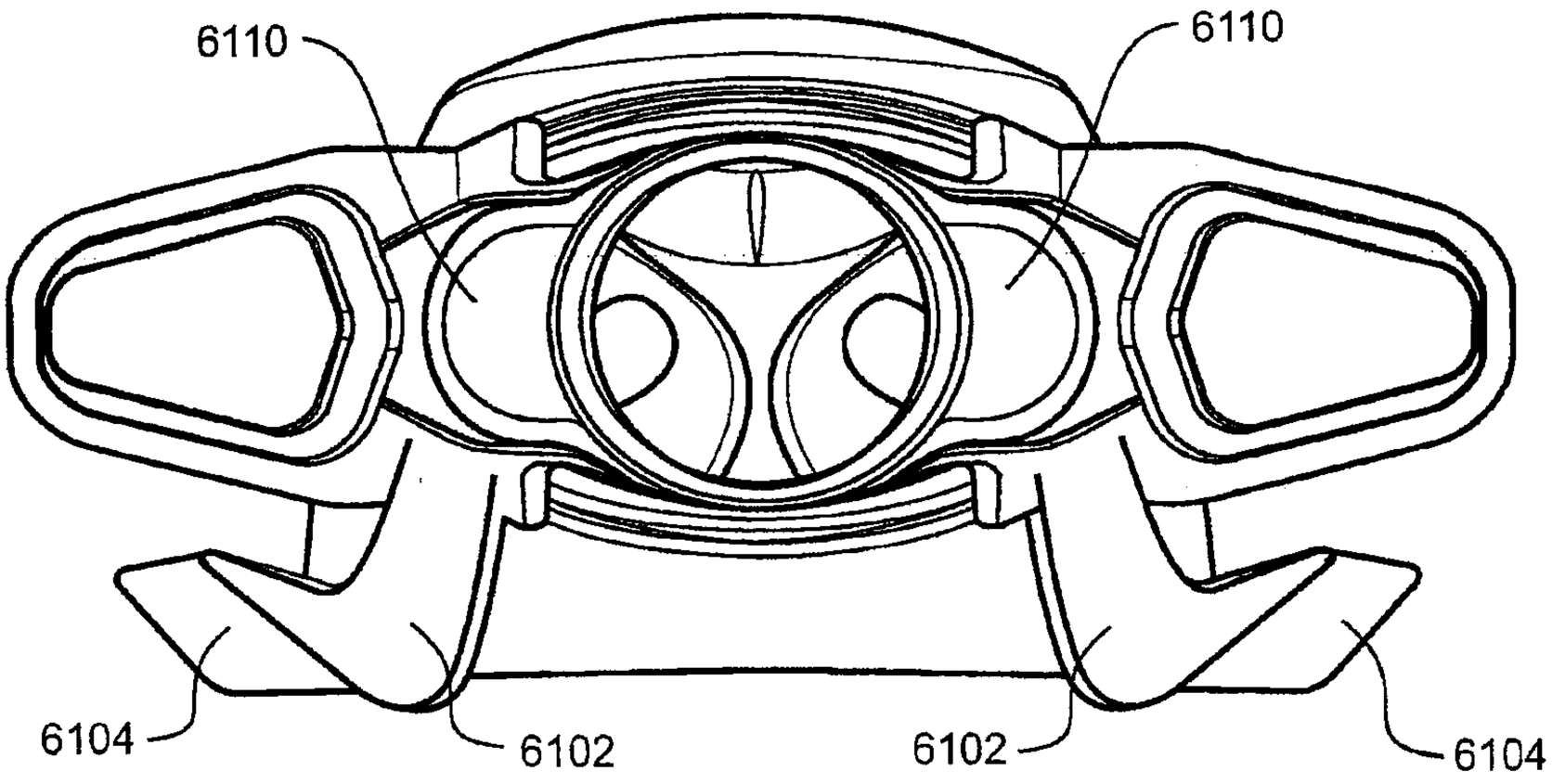


FIGURE 60

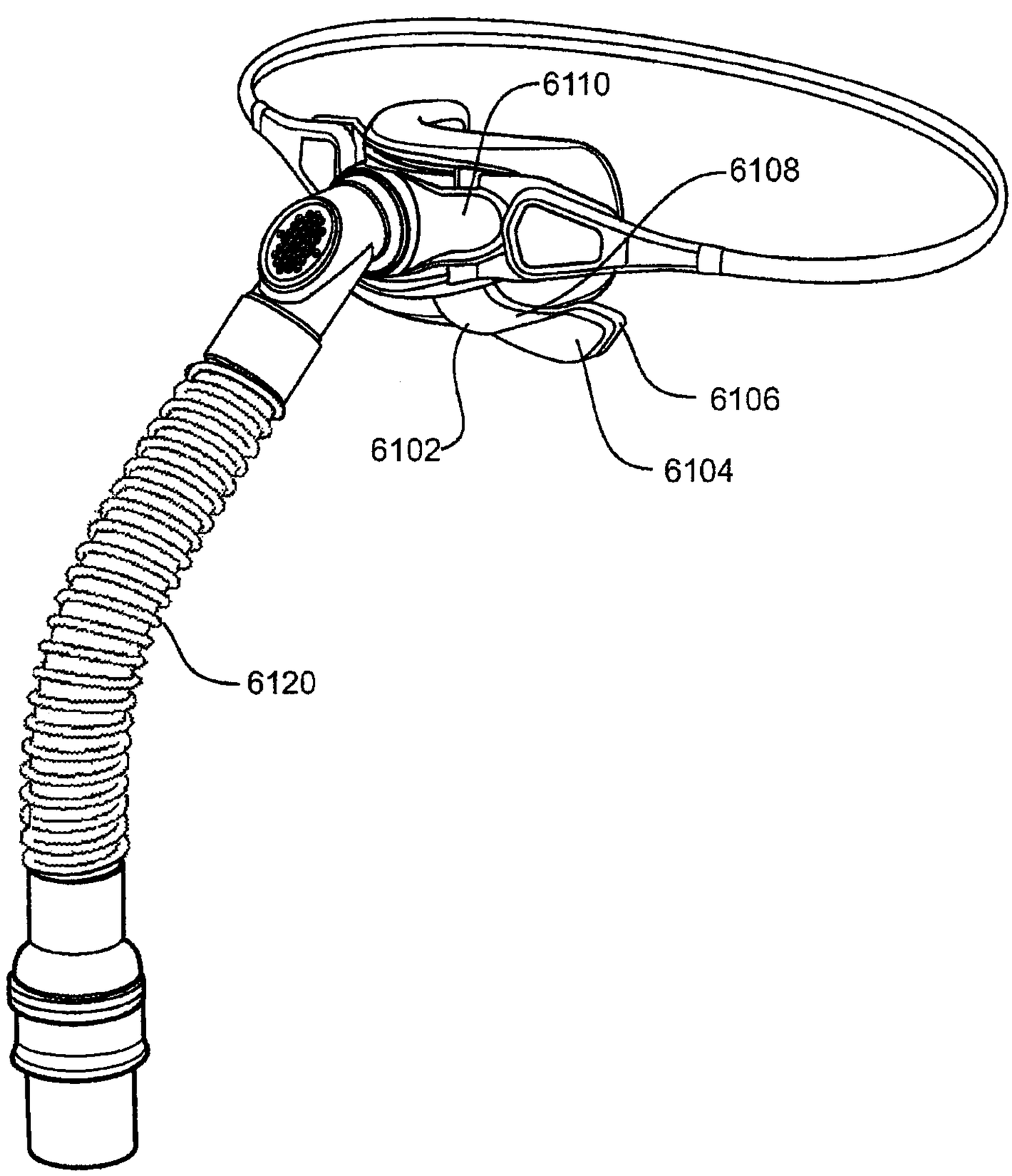
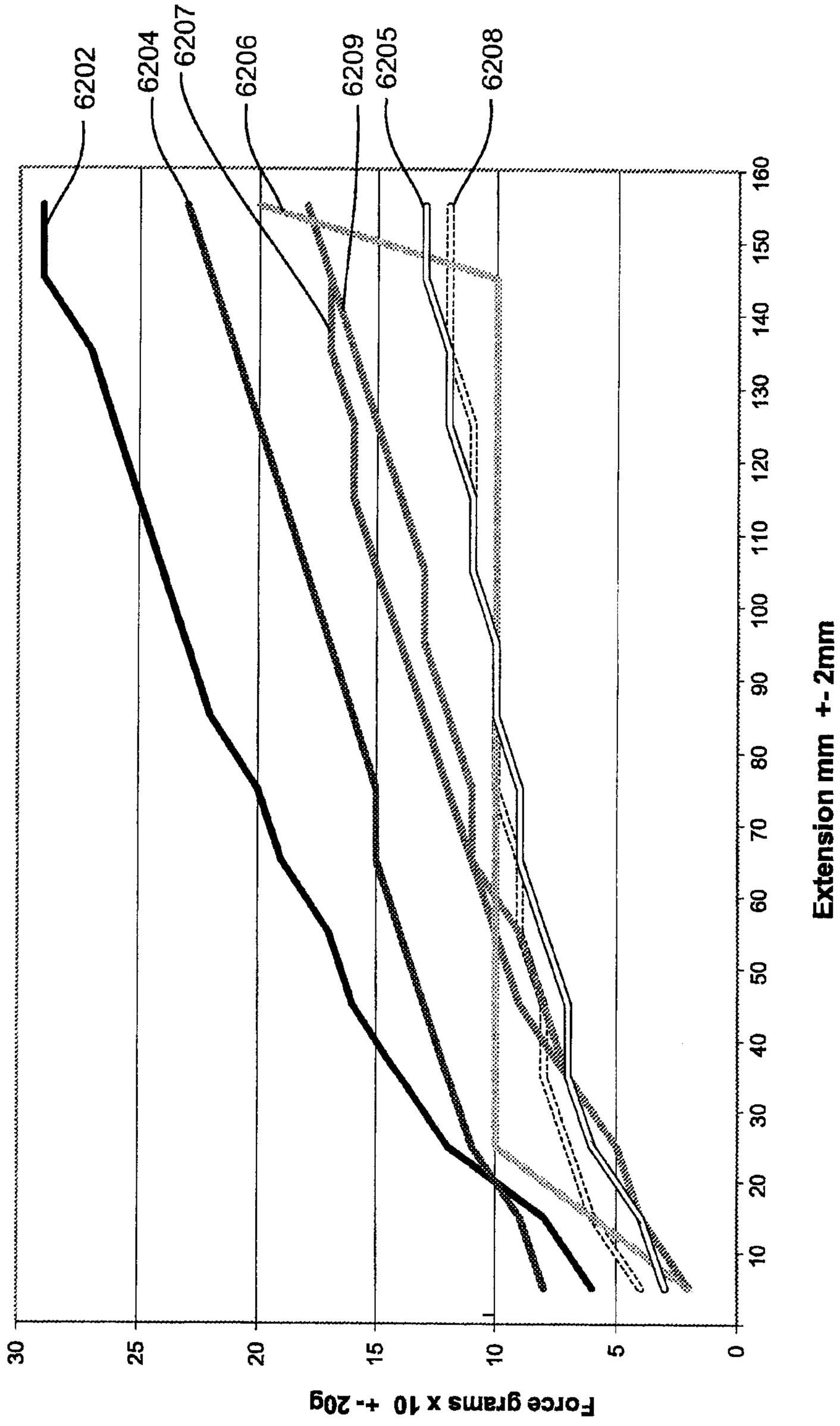


FIGURE 61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25
20
15
10
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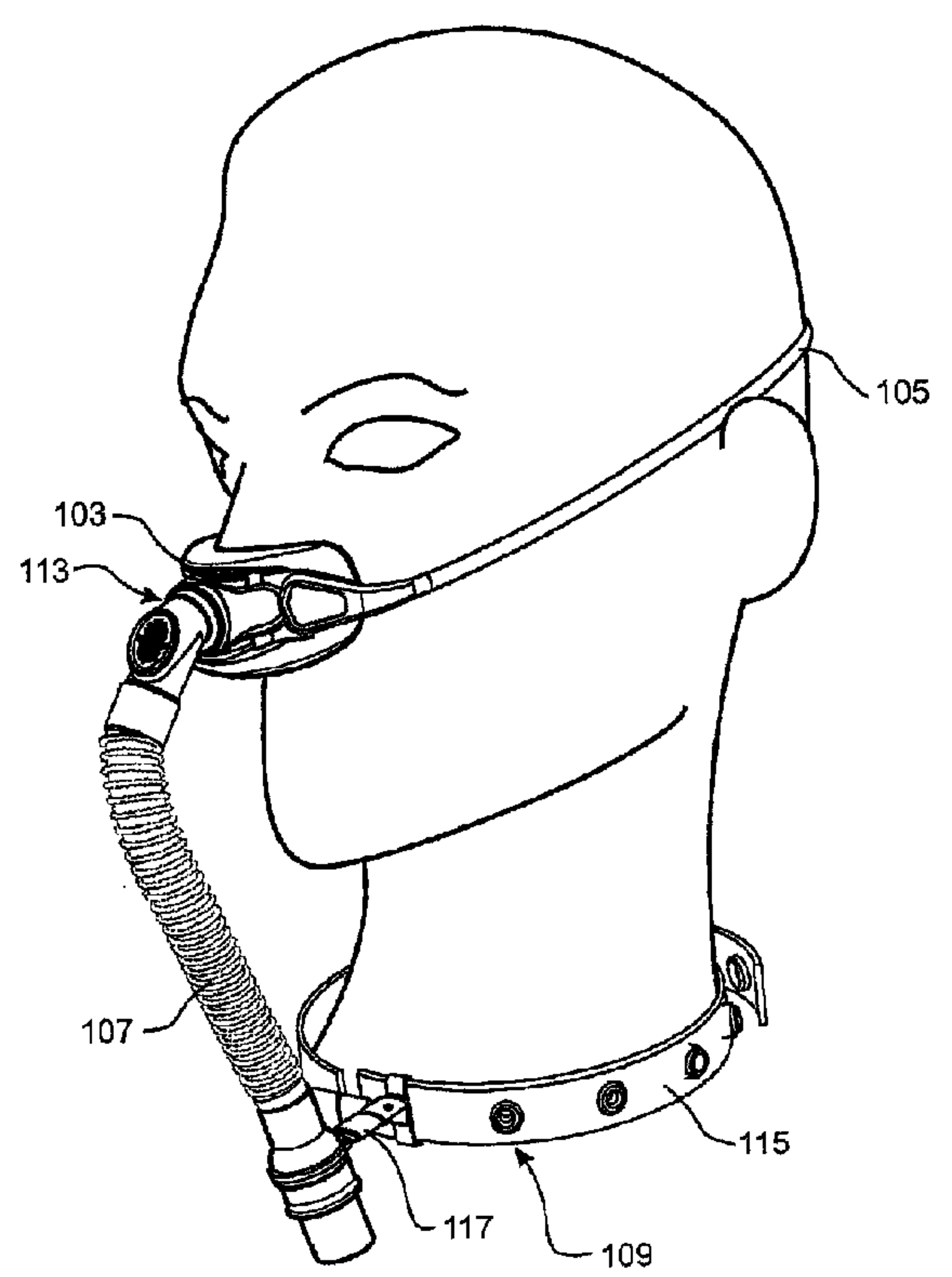
0
Force grams x 10 +- 20g

FIGURE 62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