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(71) Applicant *(for all designated States except US)*: **MICROTEK MEDICAL, INC.** [US/US]; 512 Lehmberg Road, Columbus, MS 39702 (US).

(72) Inventors: **DILLON, Mark, S.**; 1702 Oswalt Road, Columbus, MS 39702 (US). **DING, Youzhen**; 9770 Talisman Drive, Alpharetta, GA 30022 (US). **ALDRIDGE, Rodney**; 1036 Co. Road 53, Ethelsville, AL 35461 (US). **ELLIS, Johnny, D.**; 378 Phillips Hill Road, Columbus, MS 37902 (US).

(74) Agent: **WITHERS, James, D.**; Withers & Keys, LLC, P.O. Box 2049, McDonough, GA 30253 (US).

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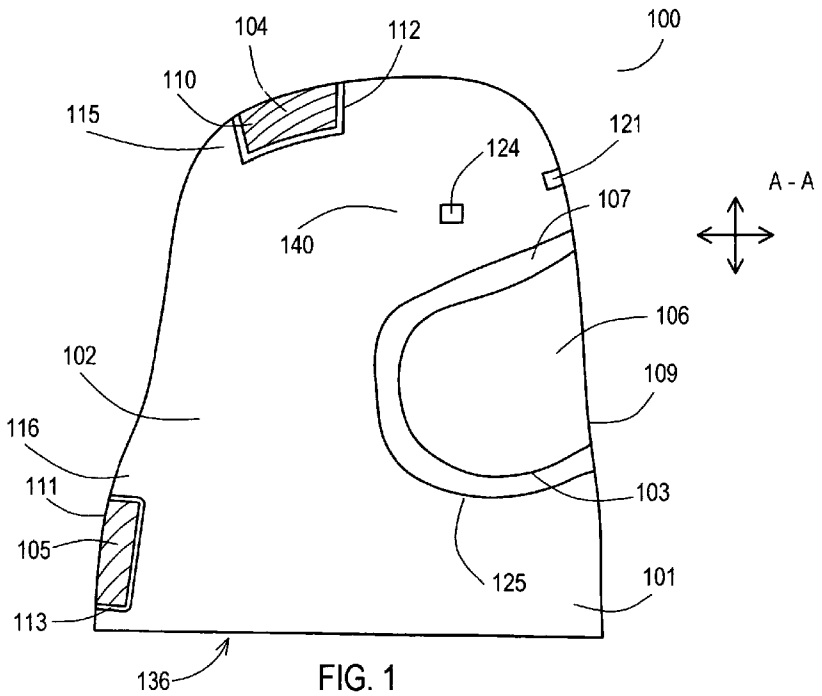

FIG. 1

(57) Abstract: Surgical helmets and helmet covers are disclosed. Methods of making and using surgical helmets and helmet covers are also disclosed.

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SURGICAL HELMET AND COVER ASSEMBLY, METHODS OF MAKING AND USING THE SAME

This application is being filed as a PCT International Patent Application in the name of Microtek Medical, Inc., a U.S. corporation, claiming priority to U.S. Patent Application Serial No. 11/710,699 filed on 26 February 2007.

FIELD OF THE INVENTION

The present invention relates generally to surgical helmets and surgical helmet components suitable for use in an operating room setting, methods of making surgical helmets and surgical helmet components, and methods of using surgical helmets and surgical helmet components, for example, in an operating room setting.

BACKGROUND OF THE INVENTION

A variety of disposable and reusable surgical helmets are used in operating rooms. Helmets are used to protect and/or cover a surgeon or other operating room personnel such as during a surgical procedure. During surgical procedures, it is important for a helmet to provide a barrier between the surgeon (or other operating room personnel) and the patient so as to protect the surgeon (or other operating room personnel) from exposure to body fluids and any other contaminants. Consequently, there is a tendency to for helmets and helmet components to be formed from barrier materials without additional considerations such as carbon dioxide build-up within the helmet during a surgical procedure.

Recent studies have shown that carbon dioxide build-up within surgical helmets is an ongoing problem with currently available surgical helmets. Carbon dioxide build-up results from poor air flow through a given surgical helmet due to one or more factors including, but not limited to, poor air flow due to the use of a fan that does not produce sufficient air flow through the helmet, poor air flow due to uncontrolled air flow through the helmet (e.g., conflicting air flow directions), and poor helmet design due to the absence of air outlets in the surgical helmet. The combination of carbon dioxide build-up and stress due to the overall weight of currently available surgical helmets continue to be important factors in the design of new surgical helmets and helmet components. Efforts continue in the design of surgical helmets and helmet components to further enhance the properties (e.g., barrier properties, as well as air flow properties) and characteristics (e.g., comfort and overall weight) of surgical helmets and helmet components.

There is a need in the art for surgical helmets and helmet components that (i) are suitable for use in an operating room setting, (ii) provide superior barrier protection to a surgeon (or

other operating room personnel) during a surgical procedure, (iii) provide a desired degree of air flow and controlled directional air flow through the surgical helmet or helmet component so as to minimize the potential for carbon dioxide buildup within the helmet, (iv) are designed to be easily operational, (v) are designed without a separate battery pack and wires for connect the separate battery pack to the fan of the helmet, (vi) are relatively lightweight to reduce stress on the wearer, or (vii) any combination of items (i) to (vi).

SUMMARY OF THE INVENTION

The present invention is directed to helmets and helmet components suitable for use in an operating room setting, an emergency room setting, a hospital setting, or a lab. The helmets and helmet components of the present invention provide one or more of the following features: (i) superior barrier protection to a surgeon (or other operating room personnel) during a surgical procedure, (ii) a desired degree of air flow and controlled directional air flow through the helmet so as to minimize the potential for carbon dioxide buildup within the helmet, (iii) a desired minimal helmet weight, and (iv) an optional integrated battery pack positioned within the helmet.

According to one exemplary embodiment of the present invention, a surgical helmet component is disclosed, wherein the helmet component comprises a surgical helmet cover assembly comprising a hood sized to extend over a surgical helmet, the hood comprising a first hood material having (i) a face shield aperture completely surrounded by the first hood material, (ii) at least one hood air inlet completely surrounded by the first hood material, (iii) at least one hood air outlet completely surrounded by the first hood material, and (iv) a hood opening completely surrounded by the first hood material, the hood opening being sized so that the hood can be positioned over and onto a surgical helmet; a transparent face shield positioned over the face shield aperture and bonded to the first hood material along an outer periphery of the face shield aperture so as to form a sterile barrier along the outer periphery between an interior volume of the hood and an exterior surface of the hood; and multiple pieces of additional hood material positioned over the at least one hood air inlet and the at least one hood air outlet, wherein the multiple pieces of additional hood material (i) are bonded to the first hood material along an outer periphery of each of the at least one hood air inlet and the at least one hood air outlet, and (ii) have an air flow permeability greater than the first hood material. The surgical helmet cover assembly is typically disposable, and may be used with disposable or reuseable surgical helmets.

According to a further exemplary embodiment of the present invention, a surgical helmet is disclosed, wherein the helmet comprises a frame operatively adapted to surround at least a

portion of a person's head; a transparent face shield attached to the frame and positioned along a front side of the helmet; an air channel having at least one air channel inlet and at least one air channel outlet, the at least one air channel outlet being positioned so as to provide air to a space bound by an inner surface of the transparent face shield; a fan in fluid communication with the air channel, the fan being operatively adapted to move air through the air channel; a hood comprising a first hood material having (i) a face shield aperture completely surrounded by the first hood material and sized so that an outer periphery of the face shield aperture surrounds the transparent face shield, (ii) at least one hood air inlet completely surrounded by the first hood material and positioned to align with the at least one air channel inlet, (iii) at least one hood air outlet completely surrounded by the first hood material and positioned on a rear portion of the hood opposite the transparent face shield, and (iv) a hood opening completely surrounded by the first hood material, the hood opening sized so that the hood can be positioned over and onto the frame, the air channel and the fan; and multiple pieces of additional hood material positioned over the at least one hood air inlet and the at least one hood air outlet, wherein the multiple pieces of additional hood material (i) are bonded to the first hood material along an outer periphery of each of the at least one hood air inlet and the at least one hood air outlet, and (ii) have an air flow permeability greater than the first hood material.

According to yet a further exemplary embodiment of the present invention, a surgical helmet is disclosed, wherein the helmet comprises a frame operatively adapted to surround at least a portion of a person's head; a foam member having an air channel therein, wherein the air channel has at least one air channel inlet and at least one air channel outlet, the at least one air channel outlet being positioned so as to provide air to a space bound by (i) the face of a wearer and (ii) an inner surface of a transparent face shield when present; and a fan supported by the foam member so as to be in fluid communication with the air channel, the fan being operatively adapted to move air through the air channel. In this exemplary embodiment, the surgical helmet may further comprise a detachable or permanently attached surgical helmet cover assembly, wherein the surgical helmet cover assembly comprises a transparent face shield attached to the frame and positioned along a front side of the helmet; a hood comprising a first hood material having (i) a face shield aperture completely surrounded by the first hood material and sized so that an outer periphery of the face shield aperture surrounds the transparent face shield, (ii) at least one hood air inlet completely surrounded by the first hood material and positioned to align with the at least one air channel inlet, (iii) at least one hood air outlet completely surrounded by the first hood material and positioned on a rear portion of the hood opposite the transparent face shield, and (iv) a hood opening completely surrounded by the first hood material, the hood

opening sized so that the hood can be positioned over and onto the frame, the air channel and the fan; and multiple pieces of additional hood material positioned over the at least one hood air inlet and the at least one hood air outlet, wherein the multiple pieces of additional hood material (i) are bonded to the first hood material along an outer periphery of each of the at least one hood air inlet and the at least one hood air outlet, and (ii) have an air flow permeability greater than the first hood material.

When the air channel of the surgical helmet is within a foam air channel containing member, the foam member may comprise an upper foam member and a lower foam member attached to one another. In one exemplary embodiment, the upper and lower foam members comprise attachment features that enable the upper and lower foam members to be attached to one another without the use of an additional fastening material (i.e., the upper and lower foam members snap together). Further, the lower foam member may be operatively adapted to surround at least a portion of a person's head. In addition, the frame may be attached to the lower foam member along with other helmet components using mechanical fasteners or adhesives.

According to yet a further exemplary embodiment of the present invention, a surgical helmet is disclosed, wherein the helmet comprises a frame operatively adapted to surround at least a portion of a person's head; a transparent face shield attached to the frame and positioned along a front side of the helmet; a foam member having an air channel therein, wherein the air channel has at least one air channel inlet and at least one air channel outlet, the at least one air channel outlet being positioned so as to provide air to a space bound by an inner surface of the transparent face shield; an upright fan in fluid communication with the air channel, the upright fan being operatively adapted to move air through the air channel; a battery pack attached to the frame and positioned above a lower edge of the transparent face shield, the battery pack being operatively adapted to supply electrical power to the upright fan; and a hood surrounding the transparent face shield and extending over and downward from the frame.

According to yet a further exemplary embodiment of the present invention, the surgical helmet comprises a frame operatively adapted to surround at least a portion of a person's head; a transparent face shield attached to the frame and positioned along a front side of the helmet; an air channel having a single air channel inlet and a single air channel outlet, the single air channel outlet being positioned so as to provide air to a space bound by an inner surface of the transparent face shield; an upright fan in fluid communication with the air channel and positioned a distance from both the single air channel inlet and the single air channel outlet, the fan being operatively adapted to move air through the air channel; a hood surrounding the

transparent face shield and extending over and downward from the frame; a single hood air inlet located within a periphery of the hood and aligned with the single air channel inlet of the air channel; and at least one hood air outlet located within a periphery of the hood, wherein the single hood air inlet and the at least one hood air outlet are operatively adapted to provide air flow through the helmet so as to decrease an amount of carbon dioxide buildup within the helmet.

The present invention is also directed to a surgical outfit comprising at least one surgical helmet. In one exemplary embodiment, the surgical outfit comprises a surgical helmet, and a surgical gown sized so as to extend from a neck region of a user to a waist region or below, wherein the hood of the helmet is sized so as to extend below the neck region of the user, and when a lower portion of the hood is tucked within an upper portion of the surgical gown, at least one air outlet of the hood, when present, is positioned above the surgical gown. In this embodiment, the helmet may comprise one or more of the following components: (1) a frame operatively adapted to surround at least a portion of a person's head; (2) an air channel (e.g., a foam member having an air channel therein) having at least one air channel inlet and at least one air channel outlet, the at least one air channel outlet being positioned so as to provide air to a space bound by (i) the face of a wearer and (ii) an inner surface of a transparent face shield when present; (3) a fan in fluid communication with the air channel, the fan being operatively adapted to move air through the air channel; and (4) a detachable or permanently attached surgical helmet cover assembly, wherein the surgical helmet cover assembly comprises (4a) a transparent face shield attached to the frame and positioned along a front side of the helmet; (4b) a hood comprising a first hood material having (i) a face shield aperture completely surrounded by the first hood material and sized so that an outer periphery of the face shield aperture surrounds the transparent face shield, (ii) at least one hood air inlet completely surrounded by the first hood material and positioned to align with the at least one air channel inlet, (iii) at least one hood air outlet completely surrounded by the first hood material and positioned on a rear portion of the hood opposite the transparent face shield, and (iv) a hood opening completely surrounded by the first hood material, the hood opening sized so that the hood can be positioned over and onto the frame, the air channel and the fan; and (4c) multiple pieces of additional hood material positioned over the at least one hood air inlet and the at least one hood air outlet, wherein the multiple pieces of additional hood material (i) are bonded to the first hood material along an outer periphery of each of the at least one hood air inlet and the at least one hood air outlet, and (ii) have an air flow permeability greater than the first hood material.

The present invention is further directed to methods of making surgical helmets and surgical helmet components. In one exemplary embodiment, the method of making a surgical helmet component comprises making a surgical helmet cover assembly, wherein the method comprises providing a hood comprising (1) a first hood material having (i) a face shield aperture along a front side of the hood and completely surrounded by the first hood material, (ii) at least one hood air inlet along an upper portion of the hood and completely surrounded by the first hood material, (iii) at least one hood air outlet along a rear side of the hood opposite the face shield aperture and completely surrounded by the first hood material, (iv) a hood opening completely surrounded by the first hood material, the hood opening sized so that the hood can be positioned over a surgical helmet; (2) a transparent face shield positioned within the face shield aperture and bonded to the first hood material along an outer periphery of the face shield aperture; and (3) multiple pieces of additional hood material positioned over the at least one hood air inlet and the at least one hood air outlet, wherein the multiple pieces of additional hood material (i) are bonded to the first hood material along an outer periphery of each of the at least one hood air inlet and the at least one hood air outlet, and (ii) have an air flow permeability greater than the first hood material. The exemplary method may further comprise a number of additional steps such as attaching the transparent face shield to the first hood material; attaching the multiple pieces of additional hood material to the first hood material; and attaching one or more attachment members to the first hood material and/or the transparent face shield. The resulting surgical helmet cover assembly may be detachable or permanently attached to a helmet frame.

In a further exemplary embodiment, the present invention is directed to a method of making a surgical helmet, wherein the method comprises providing a frame of a helmet, the frame being operatively adapted to surround at least a portion of a person's head; providing a foam member having an air channel therein, the foam member having at least one air channel inlet and at least one air channel outlet, the at least one air channel outlet being positioned so as to provide air to a space bound by (i) the face of a wearer and (ii) an inner surface of a transparent face shield when present, the foam member being attached to or integrally formed into the frame; and providing a fan in fluid communication with the air channel, the fan being operatively adapted to move air through the air channel.

The present invention is even further directed to methods of using a surgical helmet or helmet component in an operating room setting. In one exemplary embodiment of the present invention, the method comprises providing a helmet or helmet component such as one of the above-described helmets or helmet components; and cutting on the fan to provide an air flow

path from into the at least one hood air inlet, to the at least one air channel inlet, through the air channel, out of the at least one air channel outlet into a region of the helmet bound by the transparent face shield, and out of the helmet through the at least one hood air outlet. The above-described surgical helmets or helmet components provide controlled directional air flow through a given surgical helmet so as to minimize carbon dioxide build-up within the surgical helmet.

The present invention is even further directed to methods of reducing an amount of carbon dioxide within a surgical outfit during use. In one exemplary embodiment, the method comprises providing a surgical outfit of the present invention (such as the above-described surgical outfit or any surgical outfit described below), and cutting on the fan to provide an air flow path through at least one hood air inlet in a helmet, to at least one air channel inlet, through an air channel, out of at least one air channel outlet into a region of the helmet bound by a transparent face shield, and out of the helmet through at least one hood air outlet. The surgical outfit of the present invention is capable of reducing an amount of carbon dioxide within the surgical outfit, during use, to below about 2500 ppm, and even below about 1800 ppm.

These and other features and advantages of the present invention will become apparent after a review of the following detailed description of the disclosed embodiments and the appended claims.

BRIEF DESCRIPTION OF THE FIGURES

The present invention is further described with reference to the appended figures, wherein:

FIG. **1** depicts a side view of an exemplary surgical helmet cover assembly of the present invention;

FIG. **2A** depicts a frontal view of the exemplary surgical helmet cover assembly shown in FIG. **1**;

FIG. **2B** depicts a rear view of the exemplary surgical helmet cover assembly shown in FIG. **1**;

FIG. **3** depicts a cross-sectional view of the exemplary surgical helmet cover assembly of FIG. **1** as viewed perpendicularly to plane **A-A** shown in FIG. **1**;

FIG. **4** depicts a side view of an exemplary surgical helmet of the present invention;

FIG. **4A** depicts a top view of the exemplary surgical helmet shown in FIG. **4** as viewed from above the exemplary surgical helmet;

FIG. **4B** depicts a cross-sectional view of the exemplary surgical helmet shown in FIG. **4** as viewed perpendicularly to plane **B-B** shown in FIG. **4**;

FIG. **4C** depicts a close-up view of the exemplary surgical helmet shown in FIG. **4** when viewed from below the helmet;

FIG. **4D** depicts a cross-sectional view of the exemplary surgical helmet shown in FIG. **4** as viewed within plane **B-B** shown in FIG. **4**;

FIG. **5** depicts a side view of an exemplary helmet of the present invention;

FIG. **6** depicts a rear view of the exemplary helmet of FIG. **5**;

FIG. **7** depicts a close-up rear view of the exemplary helmet of FIG. **5**;

FIG. **8** depicts a view of the exemplary helmet of FIG. **5** when viewed from below the helmet;

FIG. **9** depicts a close-up view of the frame, air channel, battery pack, and fan of the exemplary helmet of FIG. **5** when viewed from below the helmet;

FIG. **10A** depicts a side view of the exemplary helmet of FIG. **5** when the hood is removed;

FIG. **10B** depicts a side view of another exemplary helmet shown without a hood component; and

FIG. **11** depicts an exemplary surgical outfit comprising the exemplary helmet of FIG. **5** in combination with a surgical gown.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to surgical helmets and surgical helmet components suitable for use in any environment in which a surgical helmet is typically used including, but not limited to, an operating room setting, an emergency room setting, a hospital setting, a lab, a clean room, etc. The present invention is further directed to methods of making surgical helmets and surgical helmet components and methods of using surgical helmets and surgical helmet components in an operating room setting or any of the above-mentioned environments. The surgical helmets and surgical helmet components of the present invention are particularly useful in providing a barrier between a surgeon and a surgical site of a patient.

I. Surgical Helmets and Surgical Helmet Components

In one exemplary embodiment of the present invention, the present invention is directed to a surgical helmet cover assembly comprising a hood sized to extend over a surgical helmet, the hood comprising a first hood material having (i) a face shield aperture completely surrounded by the first hood material, (ii) at least one hood air inlet completely surrounded by the first hood material, (iii) at least one hood air outlet completely surrounded by the first hood material, and (iv) a hood opening completely surrounded by the first hood material, the hood

opening being sized so that the hood can be positioned over and onto a surgical helmet; a transparent face shield positioned over the face shield aperture and bonded to the first hood material along an outer periphery of the face shield aperture so as to form a sterile barrier along the outer periphery between an interior volume of the hood and an exterior surface of the hood; and multiple pieces of additional hood material positioned over the at least one hood air inlet and the at least one hood air outlet, wherein the multiple pieces of additional hood material (i) are bonded to the first hood material along an outer periphery of each of the at least one hood air inlet and the at least one hood air outlet, and (ii) have an air flow permeability greater than the first hood material. An exemplary surgical helmet cover assembly is shown in FIG. **1**.

As shown in FIG. **1**, exemplary surgical helmet cover assembly **100** comprises hood **101** sized to extend over a surgical helmet (not shown), wherein hood **101** comprises first hood material **102** having (i) a face shield aperture **103** completely surrounded by first hood material **102**, (ii) at least one hood air inlet **104** completely surrounded by first hood material **102**, (iii) at least one hood air outlet **105** completely surrounded by first hood material **102**, and (iv) a hood opening **106** completely surrounded by first hood material **102**. Hood opening **136** is sized so that hood opening **136** can be positioned over and onto a surgical helmet (not shown). Exemplary surgical helmet cover assembly **100** further comprises a transparent face shield **106** positioned over face shield aperture **103** and bonded to first hood material **102** along an outer periphery **107** of face shield aperture **103** so as to form a sterile barrier along outer periphery **107** between an interior volume (e.g., interior volume **108** shown in FIG. **3**) of hood **101** and an exterior surface **109** of hood **101**. Exemplary surgical helmet cover assembly **100** further comprises multiple pieces of additional hood material **110** and **111** positioned over the at least one hood air inlet **104** and the at least one hood air outlet **105** respectively, wherein each of the multiple pieces of additional hood material **110** and **111** (i) are bonded to first hood material **102** along an outer periphery **112** and **113** of each of the at least one hood air inlet **104** and the at least one hood air outlet **105** respectively, and (ii) have an air flow permeability greater than first hood material **102**.

As shown in FIG. **1**, hood **101** of exemplary surgical helmet cover assembly **100** may further comprise a resealable fan switch knob opening **124** completely surrounded by first hood material **102**. When present, resealable fan switch knob opening **124** (i) is sized so that a fan switch knob of a surgical helmet (see, for example, fan switch knob **23** of exemplary surgical helmet **10** shown in FIG. **10B**) can fit therethrough, and (ii) is positioned along an outer surface **140** of hood **101**, desirably, above a lower edge **125** of transparent face shield **106**, and more desirably, along an outer surface of hood **101** above transparent face shield **106**.

FIG. **2A** depicts a frontal view of exemplary surgical helmet cover assembly **100** shown in FIG. **1**. As shown in FIG. **2A**, transparent face shield **106** is positioned along a front side **114** of hood **101** over face shield aperture **103**. Further, transparent face shield **106** is completely surrounded by first hood material **102**. As shown in FIG. **2A**, hood **101** may further comprises a resealable frame adjustment knob opening **121** completely surrounded by first hood material **102**, wherein resealable frame adjustment knob opening **121** (i) is sized so that a frame adjustment knob of a surgical helmet (see, for example, frame adjustment knob **14** of exemplary surgical helmet **10** shown in FIG. **9**) can fit therethrough, and (ii) is positioned along front side **114** of hood **101** and above transparent face shield **106**. When exemplary surgical helmet cover assembly **100** is used in combination with a reuseable surgical helmet, hood **101** of exemplary surgical helmet cover assembly **100** does not have to comprise resealable frame adjustment knob opening **121** given that surgical helmet/frame adjustments are typically made on the helmet prior to attachment of exemplary surgical helmet cover assembly **100** to the surgical helmet.

Hood **101** of exemplary surgical helmet cover assembly **100** typically comprises a single hood air inlet **104** positioned along an upper rear portion **115** of hood **101**, and one or more hood air outlets **105** positioned along a rear side **116** of hood **101** below single hood air inlet **104** and opposite transparent face shield **106** (e.g., in a neck region of the wearer). In one desired embodiment, hood **101** comprises two separate hood air outlets **105** positioned side-by-side along rear side **115** of hood **101** below single hood air inlet **104** and opposite transparent face shield **106** (i.e., instead of a single hood air outlet **105** as shown in FIG. **2B**, two hood air outlets **105** would be present in a neck region of the wearer similar to hood air outlets **62** shown in FIG. **7**).

As shown in FIG. **2B**, hood **101** may further comprise a pocket **117** positioned along rear side **116** of hood **101**, wherein pocket **117** is sized so as to accept a battery pack (not shown) therein. When present, pocket **117** may be positioned along any portion of an outer surface **140** of hood **101**, although pocket **117** is desirably positioned below at least one hood air inlet **104** and below at least one hood air outlet **105** as shown in FIG. **2B**. Although not shown in FIG. **2B**, hood **101** may further comprise a slot in first hood material **102**, wherein the slot is desirably positioned within pocket **117** and sized so that a battery pack connector (not shown) can extend through the slot. In some embodiments, pocket **117** may be used to store a supplemental battery, with a primary battery being positioned within a frame component or air channel containing member (e.g., foam member) of a surgical helmet as described further below.

FIG. **3** depicts a cross-sectional view of exemplary surgical helmet cover assembly **100** of FIG. **1** as viewed perpendicularly to plane **A-A** shown in FIG. **1**. As shown in FIG. **3**,

exemplary surgical helmet cover assembly **100** may further comprise one or more attachment members **118** positioned along (i) an inner surface **119** of hood **101**, (ii) an inner surface **120** of transparent face shield **106**, or (iii) both (i) and (ii). One or more attachment members **118** are operatively adapted to connect exemplary surgical helmet cover assembly **100** to a surgical helmet (for example, exemplary surgical helmet **200** shown in FIG. **4**). Attachment members **118** may comprise a variety of materials including, but not limited to, hook and/or loop material, magnets, adhesive tape, etc.

As shown in FIG. **3**, exemplary surgical helmet cover assembly **100** may further comprise one or more adjustable face shield spacers **127** positioned along an inner surface **120** of transparent face shield **106**. When present, the one or more adjustable face shield spacers **127** are operatively adapted to alter a line of curvature extending from one side of transparent face shield **106** (i.e., side **128** shown in FIG. **2A**) to an opposite side of transparent face shield **106** (i.e., side **129** shown in FIG. **2A**). Any member (e.g., a screw-like member) capable of adjusting a distance between transparent face shield **106** and a surgical helmet component, for example, as a frame or air channel containing member (described further below), may be used for each adjustable face shield spacer **127**. Alteration of the line of curvature of transparent face shield **106** may help reduce an amount of glare when viewing a surgical site through transparent face shield **106**.

First hood material **102** (and pocket **117**, when present) typically comprises a fluid/blood barrier material. The fluid/blood barrier material typically comprises a single layer of nonwoven fabric or a single layer of nonwoven fabric/film laminate having little or no air permeability. Typically, the fluid/blood barrier material has an air permeability (i.e., as measured using ASTM D737 test method) of less than about 17.1 $cm^3/min/cm^2$ of material (0.562 $ft^3/min/ft^2$ of material). In one desired embodiment, the fluid/blood barrier material comprises a breathable viral barrier (BVB) fabric commercially available from Ahlstrom Corporation (Alpharetta, GA), such as a BVB trilaminate polypropylene material having a basis weight of about 70 grams per square meter (gsm) and a thickness of about 0.35 millimeters (mm).

Multiple pieces of additional hood material **110** and **111** (also referred to herein as "air filtration material") may comprise a variety of air filtration (i.e., air permeable) materials. Typically, each of multiple pieces of additional hood material **110** and **111** comprises a nonwoven fabric, such as a spunbonded fabric, a spunlaced fabric, a needle-punched fabric, a melt-blown fabric, or any combination thereof. In one desired embodiment, each of multiple pieces of additional hood material **110** and **111** comprises a spunbonded fabric, such as a nylon spunbonded fabric commercially available under the trade designation CEREX® from Cerex

Advanced Fabrics, Inc. (Pensacola, FL).

Typically, each of multiple pieces of additional hood material **110** and **111** comprises a nonwoven fabric having a fabric basis weight of less than 100 gsm (more typically, from about 9 gsm to about 95 gsm, even more typically, from about 15 gsm to about 50 gsm) and a fabric thickness of less than about 150 microns (μm), typically, from about 75 μm to about 100 μm. In contrast, first hood material **102** typically comprises one of the above-mentioned fluid/blood barrier materials having a basis weight of greater than about 50 gsm) (more typically, from about 50 gsm to about 100 gsm, even more typically, from about 70 gsm to about 80 gsm) and a fabric thickness of greater than about 0.25 mm, typically, from about 0.35 mm to about 0.5 mm.

The above-described surgical helmet cover assemblies of the present invention are typically disposable, and may be used with disposable or reuseable surgical helmets of the present invention such as the surgical helmets described below. One exemplary surgical helmet of the present invention is shown in FIG. **4**.

As shown in FIG. **4**, exemplary surgical helmet **200** of the present invention comprises a frame **201** operatively adapted to surround at least a portion of a person's head (not shown); an air channel containing member **202** (e.g., a foam member) having an air channel therein (see, air channel **210** in FIG. **4B**), wherein the air channel has at least one air channel inlet **203** and at least one air channel outlet **204**, the at least one air channel outlet **204** being positioned so as to provide air to a space bound by (i) the face of a wearer (not shown) and (ii) an inner surface of a transparent face shield (not shown) when present; and a fan (see, fan **213** in FIG. **4A**) in fluid communication with the air channel (not shown), the fan being operatively adapted to move air through the air channel of air channel containing member **202**.

As shown in FIG. **4**, exemplary surgical helmet **200** may further comprise a frame adjustment knob **205** that can be used to adjust the dimensions of frame **201** so as to better fit onto the head of a user (not shown). Knob **205** can be used to adjust a length (i.e., a first dimension extending from front side **206** to rear side **207**) and a width of frame **201** (i.e., a dimension extending perpendicular to the first dimension, e.g., across a width of exemplary surgical helmet **200**). Exemplary surgical helmet **200** may further comprise a fan adjustment knob **205** that can be used to (i) cut "on" or "off" the fan, (ii) change a speed of the fan, or (iii) both (i) and (ii).

Exemplary surgical helmet **200** may further comprise frontal pad **209** and rear pad **211** along opposite ends of frame **201** to provide additional comfort to a user (not shown). In addition, exemplary surgical helmet **200** may further comprise one or more adjustable helmet spacers **227**, which, like adjustable face shield spacers **127** described above, are operatively

adapted to alter a line of curvature extending from one side of a transparent face shield to an opposite side of transparent face shield so as to help reduce an amount of glare when viewing a surgical site through the transparent face shield.

Exemplary surgical helmet **200** may be used in combination with a detachable or permanently attached surgical helmet cover assembly, such as exemplary surgical helmet cover assembly **100** discussed above. As shown in FIG. **4**, exemplary surgical helmet **200** may comprise one or more attachment members **218** that assist in attaching a surgical helmet cover assembly, such as exemplary surgical helmet cover assembly **100** discussed above, to exemplary surgical helmet **200**. For example, attachment members **118** of exemplary surgical helmet cover assembly **100** shown in FIG. **3** and attachment members **218** of exemplary surgical helmet **200** may comprise, for example, hook and loop material, respectively, to aid in the attachment of exemplary surgical helmet cover assembly **100** to exemplary surgical helmet **200**. In other embodiments, attachment members **118** and **218** may comprise magnets, adhesive tape, or any other type of attachment material.

FIG. **4A** depicts a top view of exemplary surgical helmet **200** shown in FIG. **4** as viewed from above exemplary surgical helmet **200**. As shown in FIG. **4A**, air channel containing member **202** has at least one air channel inlet **203** positioned along an upper rear portion **214** of air channel containing member **202**, and a fan **213** in fluid communication with the air channel (not shown). Fan **213** is positioned within slot **212** and is operatively adapted to move air through the air channel of air channel containing member **202** in a direction as shown by arrow **A** in FIG. **4A**. As shown in FIG. **4A**, air channel containing member **202** may further comprise an indention **215** sized to house a primary battery pack (not shown) for supplying electricity to fan **213**.

FIG. **4B** depicts a cross-sectional view of exemplary surgical helmet **200** shown in FIG. **4** as viewed perpendicularly to plane **B-B** shown in FIG. **4** so as to show air channel **210**. As shown in FIG. **4B**, air channel **210** of air channel containing member **202** extends from at least one air channel inlet **203** positioned along an upper rear portion **214** of air channel containing member **202** to air channel outlet **204** positioned along a front portion **216** of air channel containing member **202**. Slot **212**, which is sized so as to house fan **213** (not shown), desirably has a width slightly greater than a width of air channel **210** and a height slightly greater than a height of air channel **210**, so that fan **213** fits snugly within slot **212** and does not move out of slot **212** during operation. When air channel containing member **202** comprises a foam member as discussed further below, slot **212** of air channel containing member **202** also absorbs any

undesirable vibration of fan **213** positioned within slot **212**. In necessary, an additional piece of material (e.g., foam) (not shown) may be used to snugly position fan **213** within slot **212**.

Although not shown in FIG. **4B**, desirably fan **213** is in an upright position within slot **212**. In other words, desirably, fan **213** is positioned within slot **212** of air channel **210** so that fan blades of fan **213** move in a plane that is substantially perpendicular to a direction of air flow through air channel **210** (i.e., in a plane substantially perpendicular to a direction of air flow as shown by arrow **A**).

As discussed further below, air channel containing member **202** may further comprise one or more openings **220** within air channel containing member **202**. Openings **220** may be present to further reduce an overall weight of air channel containing member **202**. Any number of openings **220** may be present within air channel containing member **202** as long as air channel containing member **202** maintains sufficient structural integrity for supporting the various components of the disclosed surgical helmets.

As shown FIG. **4B**, air channel containing member **202** may comprise indentation **215** for housing a battery pack (not shown). Desirably, a battery pack (not shown) is positioned within indentation **215** and attached to air channel containing member **202** and/or frame **201** and positioned above a lower edge of a transparent face shield (not shown), wherein the battery pack is operatively adapted to supply electrical power to fan **213**. As discussed above, a supplemental battery pack may be positioned within a pocket (e.g., pocket **117**) along an outer surface of a hood (e.g., hood **101**) used in combination with exemplary surgical helmet **200**.

FIG. **4C** depicts a close-up view of exemplary surgical helmet **200** shown in FIG. **4** when viewed from below exemplary surgical helmet **200**. As shown in FIG. **4C**, exemplary surgical helmet **200** further comprises straps **221** extending from opposite sides of frame **201** and/or opposite sides of an inner surface **223** (or an outer surface **257**) of air channel containing member **202**. Straps **221** help support exemplary surgical helmet **200** on the head of a user (not shown). As discussed above, frame **201** along with frame adjustment knob **205** (not shown) may be used to adjust an overall length of frame loop **231** extending between points **X** and **Y** as shown in FIG. **4C**. By turning frame adjustment knob **205** (not shown), loop length adjuster **251** either (1) moves portions of frame loop **231** (e.g., loop portions at points **X** and **Y**) toward one another to decrease an overall length of frame loop **231** or (2) moves portions of frame loop **231** (e.g., loop portions at points **X** and **Y**) away from one another to increase an overall length of frame loop **231**.

In one exemplary embodiment, air channel containing member **202** comprises a foam member. In this exemplary embodiment, air channel containing member **202** may comprise an

upper foam member **240** and a lower foam member **241** attached to one another. As shown FIG. **4C**, upper foam member **240** having lower edge **224** in combination with lower foam member **241** having lower edge **222** form air channel **210** positioned between inner surface **228** of upper foam member **240** and inner surface **229** of lower foam member **241**.

As shown FIG. **4C**, lower foam member **241** is operatively adapted to surround at least a portion of a person's head (not shown). As discussed above, frame **201** (and portions thereof) may be attached to lower foam member **241** along inner surface **223**, outer surface **257**, lower edge **222**, or any combination thereof using mechanical fasteners or adhesives. Further, as discussed above, lower foam member **241** may comprise one or more openings/apertures **220** therein to reduce an overall weight of lower foam member **241**.

In one exemplary embodiment, upper foam member **240** and lower foam member **241** comprise attachment features that enable upper foam member **240** and lower foam member **241** to be attached to one another without the use of an additional fastening material. For example, upper foam member **240** and lower foam member **241** may snap together upon application of an attachment force. An example of such a configuration is shown in FIG. **4D**.

FIG. **4D** depicts a cross-sectional view of exemplary air channel containing member **202** as viewed within plane **B-B** and along line **E-E** as shown in FIG. **4**. As shown in FIG. **4D**, exemplary air channel containing member **202** comprises upper foam member **240** comprising female attachment members **244** along lower section **248**, and male attachment members **245** along upper section **247** lower foam member **241**. Female attachment members **244** and male attachment members **245** enable attachment of upper and lower foam members **240** and **241** respectively to be attached to one another without the use of an additional fastening material (e.g., an adhesive). In other embodiments, other desirable attachment members having different configurations may be used, as well as additional fastening materials (e.g., an adhesive) if so desired.

As shown in FIG. **4D**, slot **212** for fan **213** (not shown) extends across indentation section **212A** of upper foam member **240**, as well as indentation section **212B** of lower foam member **241**. As discussed above, desirably, fan **213** fits snugly within slot **212** in an upright position to reduce fan vibration, movement, noise, or any combination thereof. Although shown as only covering a portion of a cross-sectional area of air channel **210**, it should be noted that fan **213** may extend across fits air channel **210** so as to cover all of the cross-sectional area of air channel **210** or any portion thereof.

Exemplary air channel containing member **202** comprising upper foam member **240** and lower foam member **241** provides a lightweight air channel formed from foam suitable foam

material. In one exemplary embodiment, each of upper and lower foam members **240** and **241** comprise a molded closed cell polyurethane foam.

Another exemplary surgical helmet **10** is shown in FIG. **5**. As shown in FIG. **5**, exemplary surgical helmet **10** comprises a transparent face shield **11** along a front side **20** of helmet **10**, and a hood **12** surrounding an outer periphery **13** of transparent face shield **11** and extending over and downward from a frame of helmet **10** (e.g., frame **30** shown in FIG. **10** below). Exemplary surgical helmet **10** further comprises knob **14** that can be used to adjust the dimensions of the frame so as to better fit onto the head of a user. Knob **14** can be used to adjust a length (i.e., a first dimension extending from front side **20** to rear side **21**) and a width of the frame (i.e., a dimension extending perpendicular to the first dimension, e.g., across transparent face shield **11**). Exemplary surgical helmet **10** further comprises damper knob **15**, which can be used to adjust a damper positioned within a vicinity of an air outlet into the helmet. (See, for example, damper **72** in FIG. **9**, which is shown in an "up" position, but can be rotated into a "down" position away from wall **73** of frame component **33**, in the direction as indicated by the arrow "**D**", to block air flow coming out of air outlet **28**.)

Exemplary helmet **10** further comprises an air channel containing member comprising an air channel extending along upper region **17** of helmet **10** and having at least one air inlet (e.g., air inlet **22** shown in FIG. **6**) and at least one air outlet (e.g., air outlet **28** shown in FIG. **8**), wherein the at least one air outlet is positioned so as to provide air to a space **60** bound by an inner surface of transparent face shield **11**. A fan (e.g., fan **27** shown in FIG. **8** below) is in fluid communication with the air channel, and is operatively adapted to move air through the air channel.

As shown in FIG. **5**, in some desired embodiments of the present invention, exemplary hood **12** of exemplary helmet **10** comprises (i) at least one hood air inlet **16** located within a periphery of hood **12** and aligned with the at least one air inlet (e.g., air inlet **22** shown in FIG. **6**) of the air channel, and (ii) at least one hood air outlet **18** located within a periphery of hood **12**. Hood air inlet **16** and hood air outlet **18** are operatively adapted to provide air flow through helmet **10** so as to decrease an amount of carbon dioxide buildup within helmet **10**. Desirably, hood air inlet(s) **16** and hood air outlet(s) **18** are positioned along a rear side **21** of helmet **10** opposite transparent face shield **11** (see, for example, FIG. **6**); however, it should be understood that hood air inlet(s) **16** and hood air outlet(s) **18** may be positioned along any location of helmet **10** as long as hood air inlet(s) **16** and hood air outlet(s) **18** provide air flow through helmet **10** so as to decrease an amount of carbon dioxide buildup within helmet **10**.

FIG. **6** provides a rear view of exemplary helmet **10**. As shown in FIG. **6**, exemplary

hood **12** of exemplary helmet **10** comprises (i) a single hood air inlet **16** located within a periphery of hood **12**, and (ii) two substantially similar hood air outlets **18** and **19** located within a periphery of hood **12**, below hood air inlet **16**, and positioned side-by-side along a neck region of hood **12**. As shown in FIG. **6**, hood air inlet **16** is located within a periphery of the hood and aligned with air inlet **22** of air channel **25**. Hood air outlets **18** and **19** are located within a periphery of the hood, and positioned below hood air inlet **16**. In this exemplary embodiment, air enters helmet **10** at a position above a user's head, and exits helmet **10** along a neck region of the user as designated by dashed line **L-L**. Exemplary hood **12** extends below dashed line **L-L** to lower edge **24** of hood **12**.

In the exemplary embodiment of FIG. **6**, exemplary helmet **10** comprises a power switch **23** positioned along upper region **17** of helmet **10**. Power switch **23** is operatively adapted to switch from an "off" position to an "on" position so as to supply power to the fan (e.g., fan **27** shown in FIG. **8** below) and turn off power to the fan. In other exemplary embodiments, power switch **23** is provided in other locations such as a position along an upper periphery of transparent face shield **11** (see, for example, power switch **23** shown in FIG. **10**).

FIG. **7** provides a rear close-up view of exemplary helmet **10**. As shown in FIG. **7**, a first air filtration material **61** forms hood air inlet **16** of exemplary hood **12**, and a second air filtration material **62** forms hood air outlets **18** and **19** of exemplary hood **12**. First air filtration material **61** and second air filtration material **62** may comprise a variety of filtration materials such as the materials described above for the multiple pieces of additional hood material **110** and **111**. In one desired embodiment, each of first and second air filtration materials **61** and **62** comprises a spunbonded fabric, such as a nylon spunbonded fabric commercially available under the trade designation CEREX® from Cerex Advanced Fabrics, Inc. (Pensacola, FL).

The remaining portions of hood **12** (i.e., all of hood **12** other than hood air inlet **16** and hood air outlets **18** and **19**) typically comprise a fluid/blood barrier material such as the fluid/blood barrier materials described above for first hood material **102**. In one desired embodiment, hood **12** comprises any breathable viral barrier (BVB) fabric commercially available from Ahlstrom Corporation (Alpharetta, GA), such as a BVB trilaminate polypropylene material.

FIG. **8** provides a view of exemplary helmet **10** of FIG. **5** when viewed from below helmet **10** (e.g., when viewed from position **V** shown in FIG. **5**). As shown in FIG. **8**, exemplary helmet **10** comprises frame **30**, which is operatively adapted to surround at least a portion of a person's head (not shown). Frame **30** typically comprises one or more frame components. In exemplary helmet **10**, frame **30** comprises the following frame components:

adjustable frame component **31**, which extends around at least a portion of a person's head and can be adjusted in length and width dimensions using knob **14** as described above; frame component **32**, which at least partially surrounds transparent face shield **11** and attaches transparent face shield **11** to other helmet components; frame component **33**, which extends along a front side **20** of exemplary helmet **10** and connects adjustable frame component **31** to frame component **32**; knob extension member **37** extending along a portion of frame component **33** and being rotatably connected to knob **14**; and frame component **34**, which extends from a first location **65** along adjustable frame component **31** to a second location **66** along adjustable frame component **31** and is operatively adapted to conform to an outer contour of a person's head.

As shown in FIG. **8**, exemplary helmet **10** may further comprise pads **35** positioned along one or more of the above-described frame components. As shown in FIG. **8**, exemplary helmet **10** comprises multiple pads **35** positioned along adjustable frame component **31** and a single pad **35** positioned along frame component **34**.

FIG. **8** provides a view of a battery pack **26** that is present in some helmets of the present invention. As shown in FIG. **8**, exemplary battery pack **26** is positioned along opposite sides of air channel **25**. Electrical wiring (not shown) connects battery pack **26** to fan **27** and power switch **23** (shown in FIGS. **6** and **10**). Although shown on opposite sides of air channel **25**, it should be understood that battery pack **26** may be located along any portion of frame **30**. Desirably, as shown in FIGS. **8-10**, battery pack **26** is located above a lower edge of the transparent face shield, more desirably, above an upper portion of the transparent face shield and along one or both sides of air channel **25**.

FIG. **9** provides a close-up view of various helmet components within exemplary helmet **10**. As shown in FIG. **9**, exemplary helmet **10** comprises air channel **25** extending between air inlet **22** and air outlet **28**. Battery pack **26** is positioned along opposite sides of air channel **25**. Electrical wiring **39** connects battery pack **26** to fan **27** and power switch **23** (shown in FIGS. **6** and **10**). As shown in FIG. **9**, fan **27** is positioned within air channel **25** in the vicinity of air outlet **28**. However, it should be understood that fan **27** may be positioned at any location within air channel **25** or at air inlet **22**. Damper **72** is positioned adjacent wall **73** of frame component **33** in an "up" position, but can be rotated into a "down" position away from wall **73** and over air outlet **28** to block and/or redirect air flow through helmet **10**. The degree of air blockage and air flow direction can be controlled by rotating knob **15** as discussed above.

FIG. **10A** provides a side view of exemplary helmet **10** of FIG. **5** when hood **12** is removed. As shown in FIG. **10A**, exemplary helmet **10** comprises adjustable frame component

31 dimensioned so as to extend around at least a portion of a person's head; knobs **14** and **15**, which are operatively adapted to adjust dimensions of adjustable frame component **31** and air flow through the helmet respectively; frame component **32** partially surrounding transparent face shield **11**; frame component **34**, which is operatively adapted to conform to an outer contour of a person's head; battery pack **26**; fan **27**; air channel **25**; air inlet **22**; air outlet **28**; electrical wiring **40** connecting battery pack **26** to fan **27**; and power switch **23**.

FIG. **10B** provides a side view of another exemplary helmet **10** without a hood component. As shown in FIG. **10B**, exemplary helmet **100** comprises molded helmet component **78**; knob **14**, which is operatively adapted to adjust dimensions of a frame component (not shown but similar to adjustable frame component **31** shown in FIG. **10A**) extending around at least a portion of a person's head; frame component **32** partially surrounding transparent face shield **11**; frame component **34**, which is operatively adapted to conform to an outer contour of a person's head; battery pack **26**; fan **27**; air channel **25**; air inlet **22**; air outlet **28**; electrical wiring connecting battery pack **26** to fan **27** (not shown, but typically within or along an inner surface of helmet component **78**); and power switch/knob **23**, which is operatively adapted to provide electricity to the fan and adjust the fan speed (i.e., air flow through the helmet).

As shown in FIG. **6B**, fan **27** can be positioned near air inlet **22** of air channel **25**. Further, battery pack **26** can be positioned along a rear outer surface of helmet component **78**. Although power switch/knob **23** is shown as a single switch/knob on exemplary helmet **100**, it should be understood that a separate on/off switch and a separate air speed control knob could be present on exemplary helmet **100**. As discussed above, multiple air inlets **22** and/or air outlets **28** could be utilized on exemplary helmet **100** to provide air flow through exemplary helmet **100**. Further, one or more air inlets **22** and/or air outlets **28** can be positioned on exemplary helmet **100** in any desired locations so as to provide air flow through exemplary helmet **100**.

In one exemplary embodiment, any of the above-described helmets are sterilized prior to use. For example, in an operating room setting, a sterile field must be maintained around a surgical procedure site. Consequently, a surgical helmet used during such a surgical procedure must be sterilized prior to use.

Typically, the helmets of the present invention are disposable. However, in some cases, the helmets of the present invention may be reusable. When reused, the helmet may need to be subjected to a cleaning procedure and/or sterilization procedure prior to reuse.

The present invention is also directed to a surgical outfit comprising at least one helmet. An exemplary surgical outfit is shown in FIG. 7. As shown in FIG. 7, exemplary surgical outfit

70 comprises exemplary surgical helmet **10** (or exemplary surgical helmet **200** in combination with exemplary surgical helmet cover assembly **100**) in combination with surgical gown **50**. Surgical gown **50** is sized so as to extend from a neck region of a user to a waist region of the user or below. Hood **12** of surgical helmet **10** (or hood **101** of exemplary surgical helmet cover assembly **100**) is sized so as to extend below the neck region of the user. In one desired configuration shown in FIG. **7**, a lower portion **120** of hood **12** (outlined with dash line **M-M**) is tucked within an upper portion **52** of surgical gown **50**. Desirably, when at least one air outlet **18** is present in hood **12** (or hood **101** of exemplary surgical helmet cover assembly **100**), the at least one air outlet **18** is positioned above upper edge **51** of surgical gown **50**. In such a configuration, upper portion **52** of surgical gown **50** effectively blocks air flow into surgical gown **50** and out through the at least one air outlet **18**.

It should be noted that surgical helmets **10** and **200** as shown in FIGS. **1-7** are only two exemplary surgical helmets of the present invention. Various modifications could be made to exemplary surgical helmets **10** and **200** including, but not limited to, increasing the number of hood air inlet(s) **16** (or hood air inlet(s) **104**) and/or the number of hood air outlets **18** and **19** (or hood air outlet(s) **105**); increasing or decreasing the size of one or more components (e.g., transparent face shield **11** and/or hood air inlet(s) **16** and/or hood air outlets **18** and **19**) relative to other components (e.g., hood **12**); and rearranging one or more components of exemplary helmets **10** and **200** (e.g., changing the position of fan **27** to a position closer to air inlet **22** and/or changing the position of hood air outlets **18** and **19** so as to be closer to transparent face shield **11** and/or further away from hood air inlet(s) **16**).

Typically, surgical helmets of the present invention comprise from one to about five hood air inlet(s) **16** (or hood air inlet(s) **104**), from one to about five hood air outlets **18** and **19** (or hood air outlet(s) **105**), a single fan **27** (or fan **213**), and a single air channel **25** (or air channel **210**); however, surgical helmets of the present invention could comprise, for example, multiple fans and/or multiple air channels.

II. Methods of Making Surgical Helmets and Surgical Helmet Components

The present invention is further directed to methods of making surgical helmets and surgical helmet components such as the above-described surgical helmets and surgical helmet components. In one exemplary embodiment, the present invention is directed to a method of making a surgical helmet component comprising a surgical helmet cover assembly, wherein the method comprises providing a hood comprising (1) a first hood material having (i) a face shield aperture along a front side of the hood and completely surrounded by the first hood material, (ii) at least one hood air inlet along an upper portion of the hood and completely surrounded by the

first hood material, (iii) at least one hood air outlet along a rear side of the hood opposite the face shield aperture and completely surrounded by the first hood material, (iv) a hood opening completely surrounded by the first hood material, the hood opening sized so that the hood can be positioned over a surgical helmet; (2) a transparent face shield positioned within the face shield aperture and bonded to the first hood material along an outer periphery of the face shield aperture; and (3) multiple pieces of additional hood material positioned over the at least one hood air inlet and the at least one hood air outlet, wherein the multiple pieces of additional hood material (i) are bonded to the first hood material along an outer periphery of each of the at least one hood air inlet and the at least one hood air outlet, and (ii) have an air flow permeability greater than the first hood material.

The exemplary method of making a surgical helmet component may further comprise one or more of the following exemplary steps: attaching the transparent face shield to the first hood material; attaching the multiple pieces of additional hood material to the first hood material; attaching one or more attachment members onto an inner surface of the first hood material and/or the transparent face shield (e.g., attachment members **118**); attaching one or more face shield spacers onto an inner surface of the first hood material and/or the transparent face shield (e.g., spacer members **127**); cutting one or more apertures within the first hood material; attaching a pocket (e.g., pocket **117**) onto an outer surface of the first hood material; and either temporarily or permanently attaching the resulting surgical helmet component (e.g., exemplary surgical helmet cover assembly **100**) to a surgical helmet (e.g., exemplary surgical helmet **200**).

In a further exemplary embodiment, the present invention is directed to a method of making a surgical helmet, wherein the method comprises providing a frame of a helmet, the frame being operatively adapted to surround at least a portion of a person's head; providing an air channel (e.g., a foam member having an air channel therein) having at least one air channel inlet and at least one air channel outlet, the at least one air channel outlet being positioned so as to provide air to a space bound by (i) the face of a wearer and (ii) an inner surface of a transparent face shield when present, the air channel being attached to or integrally formed into the frame; and providing a fan in fluid communication with the air channel, the fan being operatively adapted to move air through the air channel.

The exemplary method of making a surgical helmet may further comprise a number of additional steps including, but not limited to, forming one or more molded components for forming an air channel containing member (e.g., air channel containing member **202**); attaching two or more components to one another (e.g., upper and lower foam members **240** and **241**) to

form an air channel containing member; providing the above-described surgical helmet cover assembly, wherein the surgical helmet cover assembly may be detachable or permanently attached to the helmet frame; attaching the above-described surgical helmet cover assembly to the surgical helmet; incorporating a battery pack into the helmet so as to be positioned above a lower edge of the transparent face shield, the battery pack being operatively adapted to supply electrical power to the fan; and positioning a fan (e.g., fan **213**) within an air channel so that the fan is a distance from the air inlet(s) and air outlet(s) of the air channel.

In a further exemplary embodiment, the method of making a helmet comprises providing a frame of a helmet, the frame being operatively adapted to surround at least a portion of a person's head; attaching a transparent face shield to the frame so as to be positioned along a front side of the helmet; providing an air channel containing member (e.g., a foam air channel containing member formed from upper and lower foam members **240** and **241**) having at least one air inlet and at least one air outlet the air channel being attached to or integrally formed into the frame; providing a fan in fluid communication with the air channel, desirably, in an upright position, the fan being operatively adapted to move air through the air channel; providing a hood such as the above-described hood (e.g., hood **101**) that surrounds the transparent face shield and extends over and downward from the frame; and optionally incorporating a battery pack into the helmet, the battery pack being operatively adapted to supply electrical power to the fan. Desirably, the at least one air outlet is positioned so as to provide air to a space bound by an inner surface of the transparent face shield. In other desired embodiments, the battery pack, when present, is positioned above a lower edge of the transparent face shield, more desirably, above an upper edge of the transparent face shield. Further, an additional battery pack may be provided in a pocket along an outer surface (e.g., a rear surface) of the hood.

In another exemplary embodiment, the method of making a helmet comprises providing a frame of a helmet, the frame being operatively adapted to surround at least a portion of a person's head; attaching a transparent face shield to the frame so as to be positioned along a front side of the helmet; providing an air channel having at least one air inlet and at least one air outlet, the air channel being attached to or integrally formed into the frame; providing a fan in fluid communication with the air channel, the fan being operatively adapted to move air through the air channel; and attaching a hood to the frame so as to surround the transparent face shield and extend over and downward from the frame, the hood comprising the above-described hood (e.g., hood 101), wherein the at least one hood air inlet and the at least one hood air outlet (in combination with the above-described fan, e.g., fan **213**) are operatively adapted to provide air flow through the helmet so as to decrease an amount of carbon dioxide buildup within the

helmet. Desirably, the at least one air outlet is positioned so as to provide air to a space bound by an inner surface of the transparent face shield.

Any of the above-described individual components used to form the helmets and helmet components of the present invention may be formed using conventional methods. For example, helmet components including, but not limited to, adjustable frame component **31**, frame component **32**, frame component **33**, frame component **34**, frame component **201**, knob extension member **37**, knobs **14** and **15**, air channel containing member **25** or **202**, and transparent face shield **11** or **206**, may be formed from any thermoformable material including, but not limited to, polymeric materials, metallic materials, or a combination thereof. The thermoformable materials can be molded or shaped using any conventional molding technique. Typically, the above-mentioned helmet components are formed from polymeric materials such as polyolefins (e.g., polyethylene, polypropylene, and olefin copolymers), polyurethanes, acrylonitrile-butadiene-styrene (ABS) copolymers, polyesters, polyethylene terephthalate glycol (PETG), polyamides, etc.

Any films or film-like components including, but not limited to, adjustable frame component **31**, frame component **34** and frame component **201** may be forming via any film-forming process including, but not limited to, a film extrusion process, a film-blowing process, etc.

Fiber-containing helmet components, such as hood **12** or hood **101**, first and second air filtration materials **61** and **62**, and multiple pieces of additional hood material **110** and **111** may be formed using conventional web-forming processes including, but not limited to, meltblowing processes, spunbonding processes, spunlacing processes, hydroentangling processes, carding processes, needlepunching processes, etc. Typically, the fiber-containing helmet components are formed from polymeric materials such as polyolefins (e.g., polyethylene, polypropylene, and olefin copolymers), nylon, acrylonitrile-butadiene-styrene (ABS) copolymers, etc.

Thermoformed parts, films and/or fabric layers may be joined to one another using any conventional bonding technique including, but not limited to, thermal bonding processes, adhesive bonding, mechanical bonding (e.g., hook and loop material), etc. In one exemplary embodiment of the present invention, the hood is formed from an Ahlstrom Corporation BVB Material (e.g., trilaminate polypropylene material) and is thermally bonded to an outer periphery of a transparent face shield formed from PETG using a conventional thermal-bonding apparatus (e.g., an ultrasound welder).

In one desired embodiment, the surgical helmets and helmet components of the present invention are formed from the following materials: a closed cell polyurethane foam molded

helmet component (e.g., helmet component **78** and upper and lower foam members **240** and **241**); frame components (e.g., frame component **201** shown in FIG. **4** and adjustable frame component **31** shown in FIG. **6A**) formed from polyethylene; a transparent face shield (e.g., transparent face shield **11** or **106**) formed from PETG; a frame component extending around the transparent face shield, when present, (e.g., frame component **32**) formed from polyvinyl chloride (PVC); head band material in the form of VELCRO® brand terry cloth; batteries - 4 AAA Alkaline batteries; and air inlet and outlet material formed from CEREX® nylon spunbonded fabric.

III. Methods of Using Surgical Helmets and Surgical Helmet Components

The present invention is further directed to methods of using the above-described helmets in an operating room setting. In one exemplary embodiment, the method comprises a method of providing a barrier between a surgeon (or other operating room personnel) and a patient in an operating room setting, wherein the method comprises the step of positioning the helmet over at least a portion of the surgeon's head (or any other operating room personnel's head) to separate the surgeon (or other operating room personnel) from a surgical procedure site. Typically, the helmet is used in combination with a surgical gown and other pieces of protective clothing (e.g., booties, gloves, etc.) to provide a barrier between the surgeon and a surgical procedure site.

In another exemplary embodiment, the present invention is directed to a method of reducing an amount of carbon dioxide within a surgical outfit during use. In this exemplary embodiment, the method comprises (A) providing a surgical outfit comprising (1) a helmet comprising (i) a frame operatively adapted to surround at least a portion of a person's head; (ii) a transparent face shield attached to the frame and positioned along a front side of the helmet; (iii) an air channel having at least one air inlet and at least one air outlet, the at least one air outlet being positioned so as to provide air to a space bound by an inner surface of the transparent face shield; and (iv) a fan in fluid communication with the air channel, the fan being operatively adapted to move air through the air channel; and (2) a hood or surgical gown surrounding the transparent face shield and extending over and downward from the frame, the hood or surgical gown comprising (i) at least one air inlet located within a periphery of the hood or surgical gown and aligned with the at least one air inlet of the air channel, and (ii) at least one air outlet located within a periphery of the hood or surgical gown; and (B) cutting on the fan to provide air flow along a path through the surgical outfit components in the following order: an air inlet in a surgical gown, at least one hood air inlet in a helmet, to at least one air inlet, through an air channel, out of at least one air outlet into a region of the helmet bound by a transparent face

shield, out of the helmet through at least one hood air outlet, and out of the surgical gown through at least one air outlet in the surgical gown.

Desirably, the method of reducing an amount of carbon dioxide within a surgical outfit comprises using the above-described exemplary surgical helmet **200** in combination with exemplary surgical helmet cover assembly **100** and a surgical gown. As discussed above, exemplary surgical helmet **200** in combination with exemplary surgical helmet cover assembly **100** provides controlled air flow, as well as controlled directional air flow through the surgical outfit. In other words, a sufficient volume of air and an essentially one-way direction of air flow (e.g., from hood air inlet **104** to at least one air channel inlet **203**, through air channel **210**, out of at least one air channel outlet **204** into a region of surgical helmet **200** bound by transparent face shield **206**, along a wearer's neck line, and out of surgical helmet **200** through at least one hood air outlet **105** in a rear portion of surgical helmet **200**) through the exemplary surgical helmet **200** and exemplary surgical helmet cover assembly **100** enables a significant reduction in carbon dioxide buildup within a surgical outfit.

In one desired embodiment, the method of reducing an amount of carbon dioxide within a surgical outfit, during use, results in a carbon dioxide level of less than about 5000 ppm, more desirably, less than about 4000 ppm, even more desirably, less than about 3500 ppm, and even more desirably, less than about 3000 ppm (or less than about 2500 ppm, or less than about 2000 ppm, or less than about 1800 ppm).

The surgical outfit of the present invention also improves air flow through the surgical outfit. For example, air flow through a surgical outfit without at least one hood air outlet may be in the range of about 0.071 to about 0.096 cubic meters per minute (cmm) (2.5 to about 3.4 cubic feet per minute (cfm)), while air flow through a surgical outfit of the present invention with at least one hood air outlet can be in the range of about 0.110 to about 0.156 cmm (3.9 to about 5.5 cfm), an increase in air flow of as much as 120%.

In some embodiments, the above-described methods may further comprise one or more of the following steps: sterilizing the helmet prior to use, removing the helmet from a packaging material, adjusting the helmet frame to fit snugly on the surgeon's head, checking the power supply to insure the fan is operational, combining the helmet with other pieces of protective clothing, tucking a portion of the hood of the helmet within a surgical gown, and turning on the power supply for the fan.

While the specification has been described in detail with respect to specific embodiments thereof, it will be appreciated that those skilled in the art, upon attaining an understanding of the foregoing, may readily conceive of alterations to, variations of, and equivalents to these

embodiments. Accordingly, the scope of the present invention should be assessed as that of the appended claims and any equivalents thereto.

WHAT IS CLAIMED IS:

1. A surgical helmet cover assembly comprising:

a hood sized to extend over a surgical helmet, said hood comprising a first hood material having (i) a face shield aperture completely surrounded by said first hood material, (ii) at least one hood air inlet completely surrounded by said first hood material, (iii) at least one hood air outlet completely surrounded by said first hood material, and (iv) a hood opening completely surrounded by said first hood material, said hood opening being sized so that said hood can be positioned over and onto a surgical helmet;

a transparent face shield positioned over said face shield aperture and bonded to said first hood material along an outer periphery of said face shield aperture so as to form a sterile barrier along said outer periphery between an interior volume of said hood and an exterior surface of said hood; and

multiple pieces of additional hood material positioned over said at least one hood air inlet and said at least one hood air outlet, wherein said multiple pieces of additional hood material (i) are bonded to said first hood material along an outer periphery of each of said at least one hood air inlet and said at least one hood air outlet, and (ii) have an air flow permeability greater than said first hood material.

2. The helmet cover assembly of claim 1, wherein said hood comprises a single hood air inlet positioned along an upper rear portion of said hood, and one or more hood air outlets positioned along a rear side of said hood below said single hood air inlet and opposite said transparent face shield.

3. The helmet cover assembly of claim 2, wherein said hood comprises two separate hood air outlets positioned along a rear side of said hood below said single hood air inlet and opposite said transparent face shield.

4. The helmet cover assembly of any one of claims 1 to 3, wherein said first hood material further comprises a resealable helmet adjustment knob opening completely surrounded by said first hood material, said resealable helmet adjustment knob opening (i) being sized so that a helmet adjustment knob of a surgical helmet can fit therethrough, and (ii) being positioned above said transparent face shield.

5. The helmet cover assembly of any one of claims 1 to 4, wherein said first hood material further comprises a resealable fan switch knob opening completely surrounded by said first hood material, said resealable fan switch knob opening (i) being sized so that a fan switch knob of a surgical helmet can fit therethrough, and (ii) being positioned above a lower edge of said transparent face shield.

6. The helmet cover assembly of any one of claims 1 to 5, wherein said first hood material comprises a single layer of nonwoven fabric material having little or no air permeability, and each of said multiple pieces of additional hood material comprises a single layer of air permeable nonwoven fabric material.

7. The helmet cover assembly of any one of claims 1 to 6, wherein said hood further comprises a pocket positioned along a rear side of said hood, said pocket being sized so as to accept a battery pack therein.

8. The helmet cover assembly of claim 7, wherein said pocket is positioned below said at least one hood air inlet and below said at least one hood air outlet.

9. The helmet cover assembly of claim 7 or 8, wherein said hood further comprises a slot in said first hood material, said slot being positioned within said pocket and sized so that a battery pack connector can extend through said slot.

10. The helmet cover assembly of any one of claims 1 to 9, wherein said helmet cover assembly further comprises one or more attachment members positioned along (i) an inner surface of said hood, (ii) an inner surface of said transparent face shield, or (iii) both (i) and (ii), said one or more attachment members being operatively adapted to connect said helmet cover assembly to a surgical helmet.

11. The helmet cover assembly of any one of claims 1 to 10, wherein said helmet cover assembly further comprises one or more face shield spacers positioned along an inner surface of said transparent face shield, said one or more face shield spacers being operatively adapted to alter a line of curvature extending from one side of said transparent face shield to an opposite side of said transparent face shield.

12. A surgical helmet comprising the helmet cover assembly of any one of claims 1 to 11.

13. A surgical helmet comprising:

a frame operatively adapted to surround at least a portion of a person's head;

a transparent face shield attached to the frame and positioned along a front side of said surgical helmet;

an air channel having at least one air channel inlet and at least one air channel outlet, said at least one air channel outlet being positioned so as to provide air to a space bound by an inner surface of the transparent face shield;

a fan in fluid communication with said air channel, said fan being operatively adapted to move air through said air channel;

a hood comprising a first hood material having (i) a face shield aperture completely surrounded by said first hood material and sized so that an outer periphery of said face shield aperture surrounds said transparent face shield, (ii) at least one hood air inlet completely surrounded by said first hood material and positioned to align with said at least one air channel inlet, (iii) at least one hood air outlet completely surrounded by said first hood material and positioned on a rear portion of said hood opposite said transparent face shield, and (iv) a hood opening completely surrounded by said first hood material, said hood opening sized so that said hood can be positioned over and onto said frame, said air channel and said fan; and

multiple pieces of additional hood material positioned over said at least one hood air inlet and said at least one hood air outlet, wherein said multiple pieces of additional hood material (i) are bonded to said first hood material along an outer periphery of each of said at least one hood air inlet and said at least one hood air outlet, and (ii) have an air flow permeability greater than said first hood material.

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14. The surgical helmet of claim 13, wherein said fan is positioned within said air channel so that fan blades of said fan move in a plane that is substantially perpendicular to a direction of air flow through said air channel.

15. The surgical helmet of claim 13 or 14, further comprising a battery pack attached to said frame and positioned above a lower edge of said transparent face shield, said battery pack being operatively adapted to supply electrical power to said fan.

16. The surgical helmet of any one of claims 13 to 15, wherein said air channel is formed within a foam member comprising an upper foam member and a lower foam member attached to one another.

17. The surgical helmet of claim 16, wherein said upper and lower foam members comprise attachment features that enable said upper and lower foam members to be attached to one another without the use of an additional fastening material.

18. The surgical helmet of claim 16 or 17, wherein said lower foam member is operatively adapted to surround at least a portion of a person's head, and said frame is attached to said lower foam member.

19. The surgical helmet of any one of claims 16 to 18, wherein said lower foam member has one or more apertures therein to reduce an overall weight of said lower foam member.

20. The surgical helmet of any one of claims 13 to 19, further comprising:

a frame adjustment knob capable of adjusting (i) a length of the frame extending in a first direction from a front side to a rear side of the helmet, (ii) a width of the frame extending in a second direction substantially perpendicular to the first direction, or (iii) both (i) and (ii), said frame adjustment knob being positioned above said transparent face shield along the front side of the helmet.

21. The surgical helmet of any one of claims 13 to 20, further comprising:

a battery pack attached to the frame and positioned above a lower edge of the transparent face shield, said battery pack being operatively adapted to supply electrical power to the fan.

22. The surgical helmet of any one of claims 13 to 21, wherein said first hood material comprises a single layer of blood barrier fabric material having little or no air permeability, and each of said multiple pieces of additional hood material comprises a single layer of air permeable nonwoven fabric material..

23. A surgical outfit comprising:

the surgical helmet of any one of claims 12 to 22; and

a surgical gown sized so as to extend from a neck region of a user to a waist region or below,

wherein the hood of the surgical helmet is sized so as to extend below the neck region of the user, and when a lower portion of the hood is tucked within an upper portion of the surgical gown, the at least one hood air outlet of the hood is positioned above the surgical gown.

24. A method of reducing an amount of carbon dioxide within a surgical outfit during use, said method comprising:

providing the surgical outfit of claim 23; and

cutting on the fan to provide an air flow path into the at least one hood air inlet, to the at least one air channel inlet, through the air channel, out of the at least one air channel outlet into a region of the helmet bound by the transparent face shield, and out of the helmet through the at least one hood air outlet.

25. The method of claim 24, wherein the amount of carbon dioxide within the surgical outfit during use ranges from about 2500 ppm to less than about 1800 ppm.

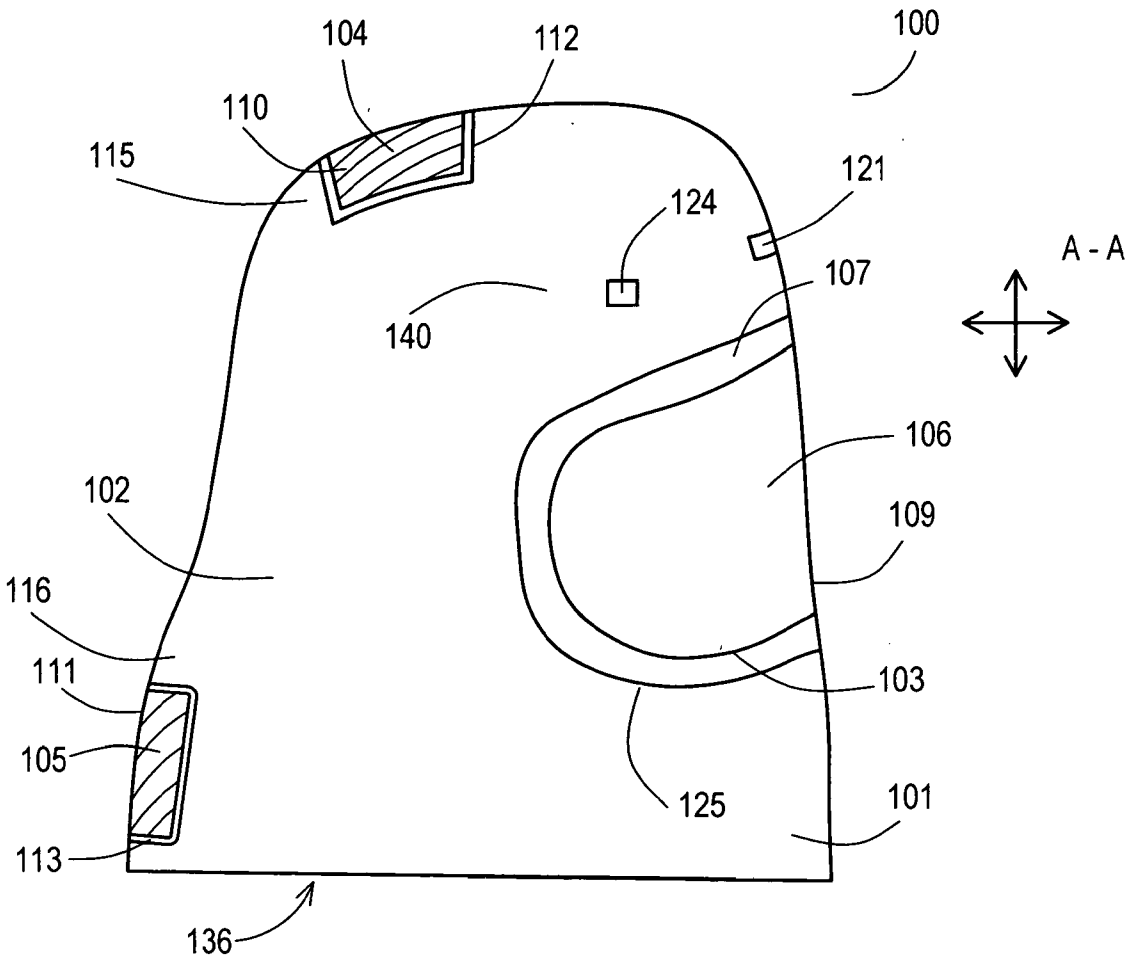
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FIG. 1

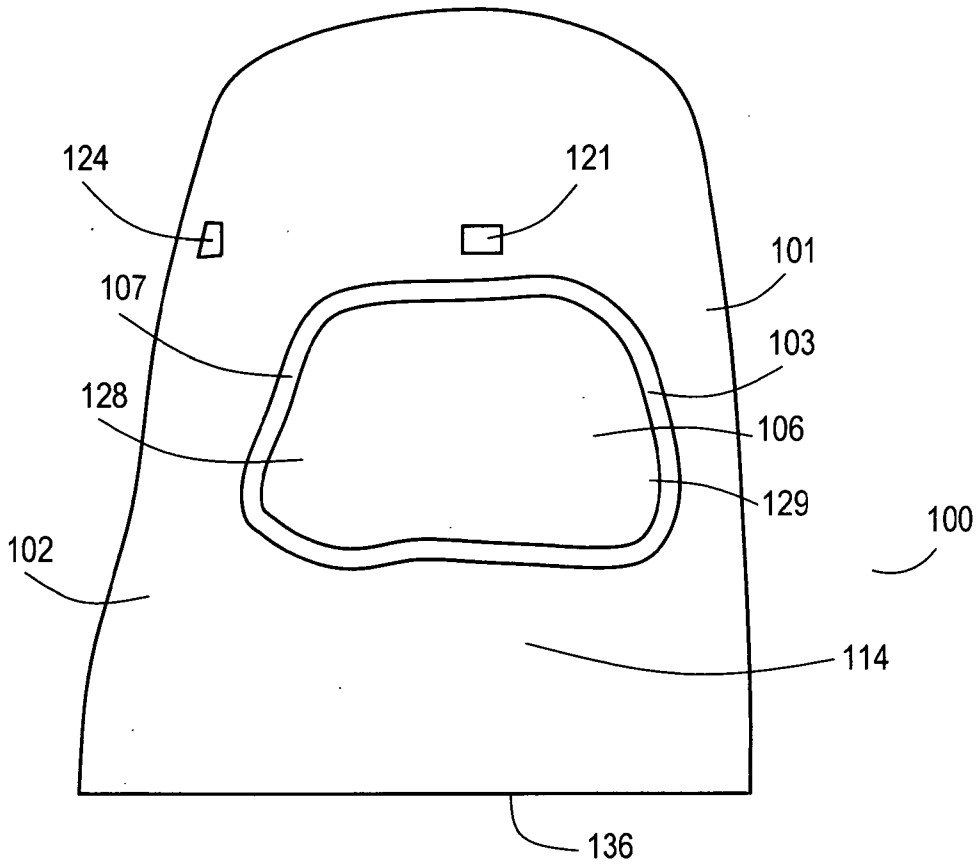

FIG. 2A

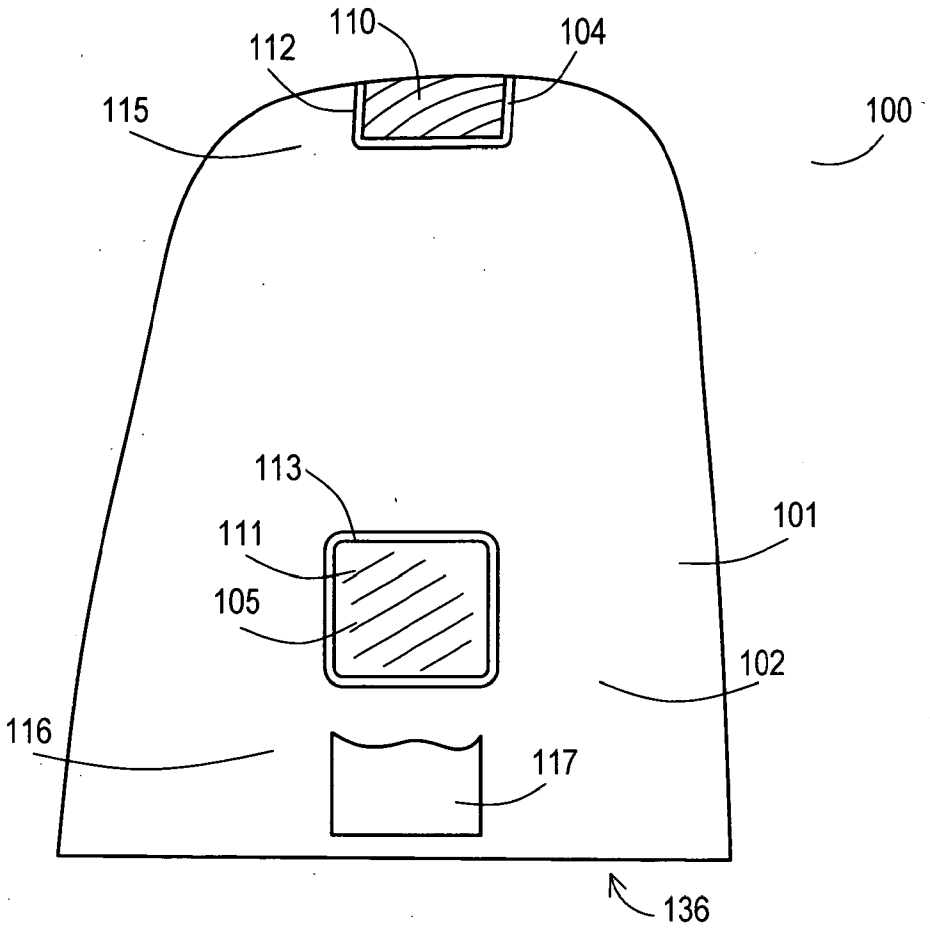

FIG. 2B

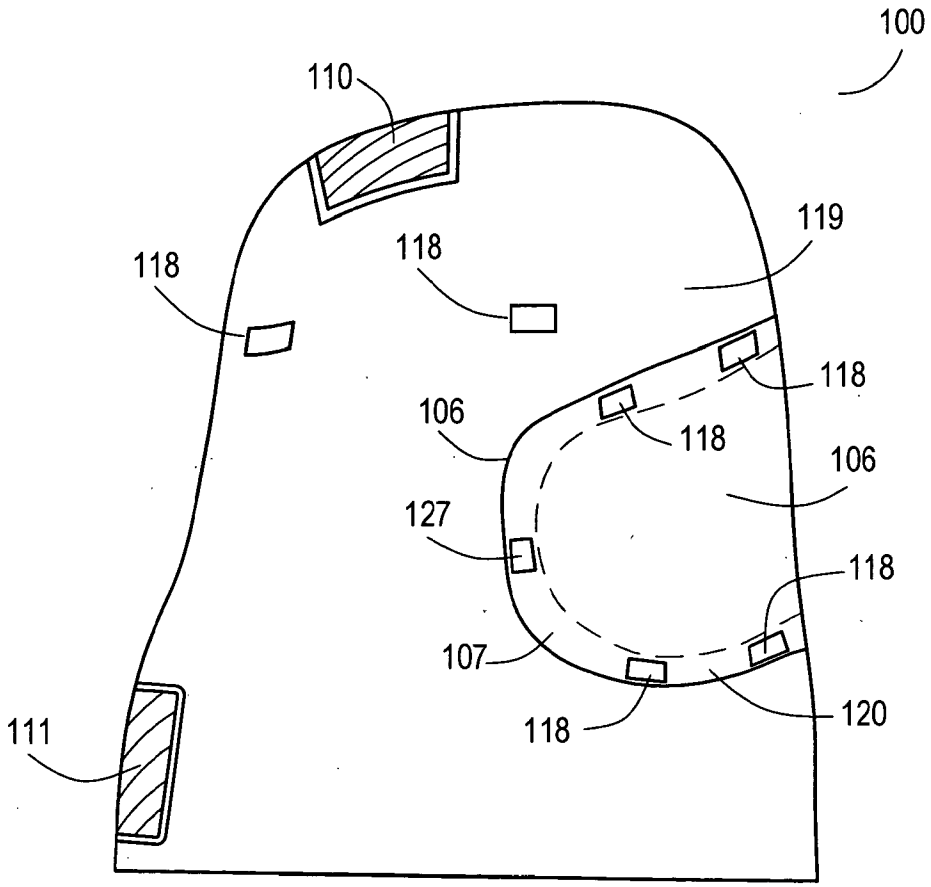

FIG. 3

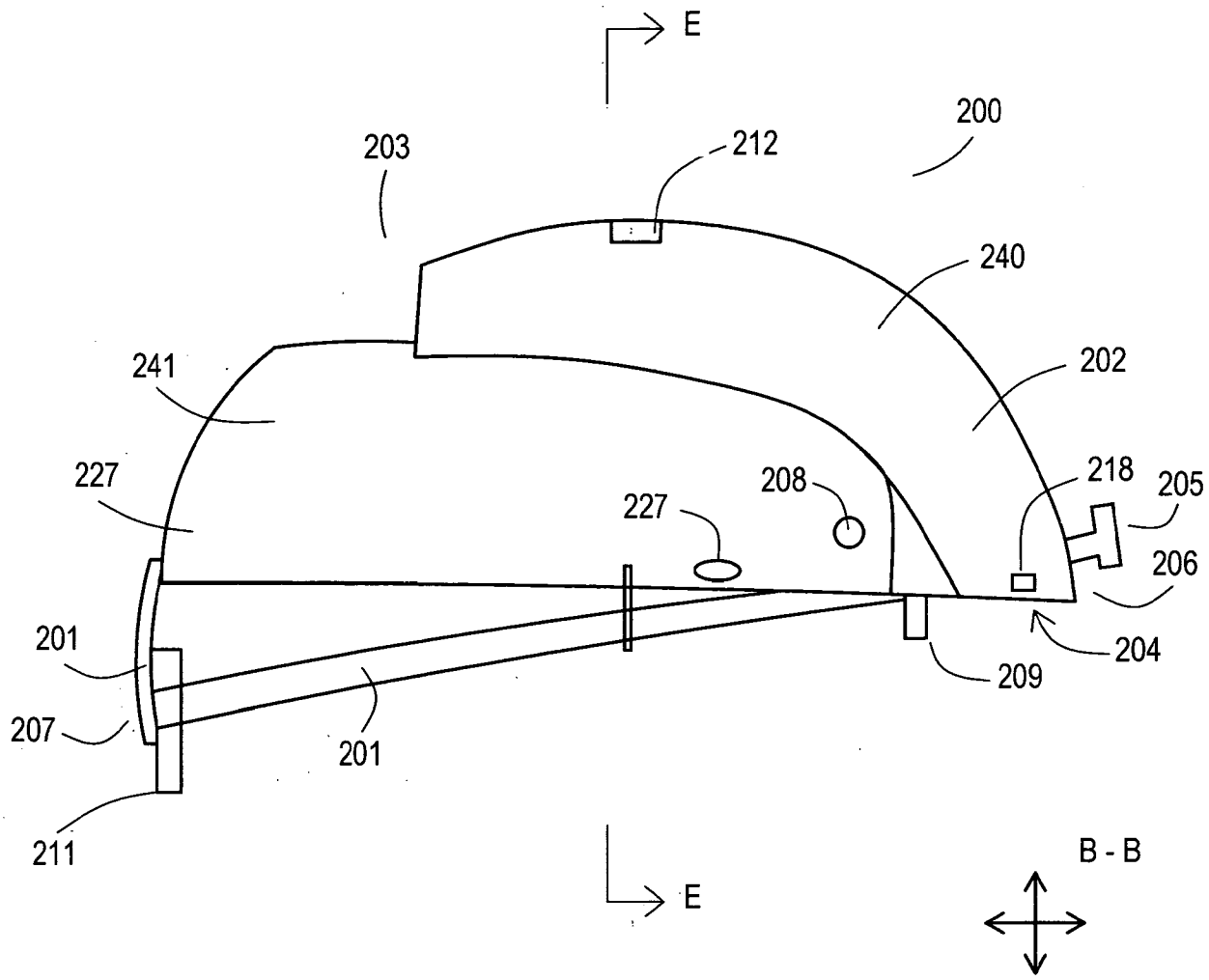
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FIG. 4

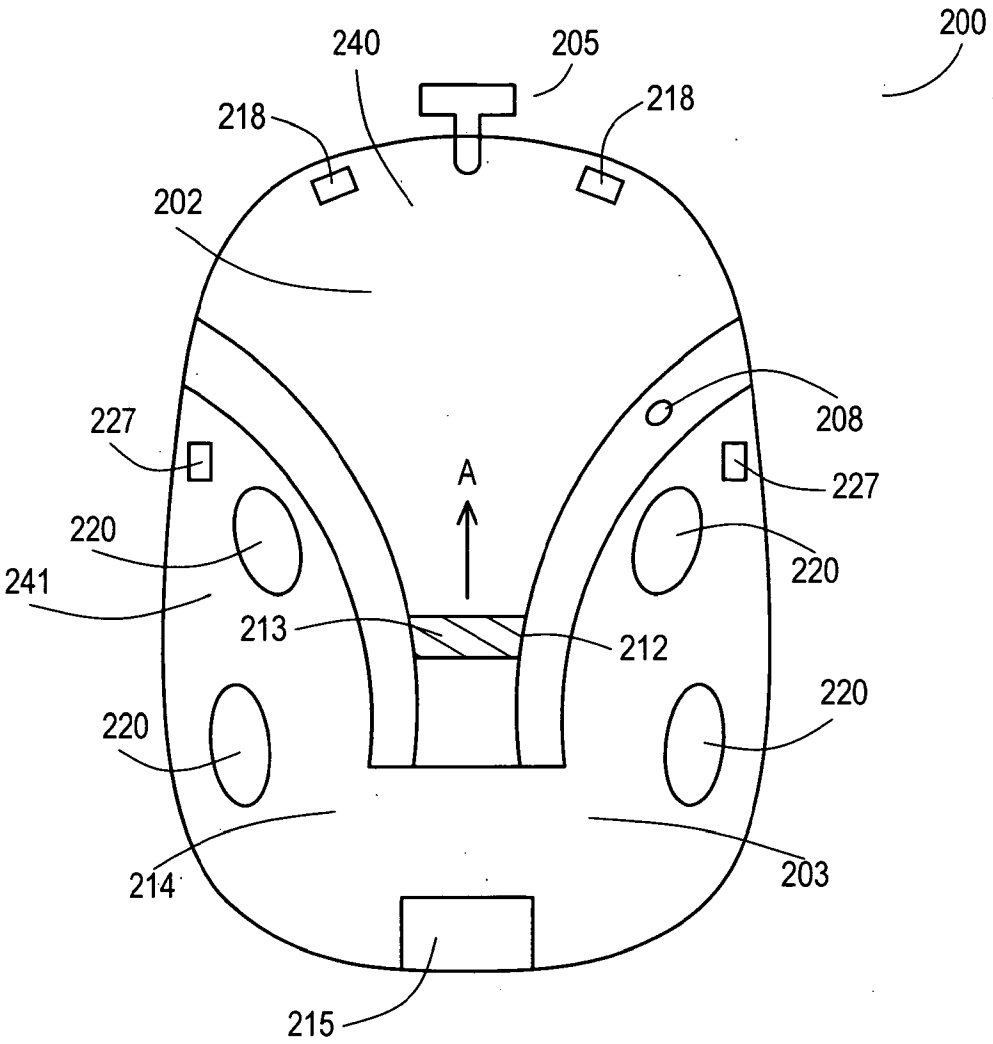
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FIG. 4A

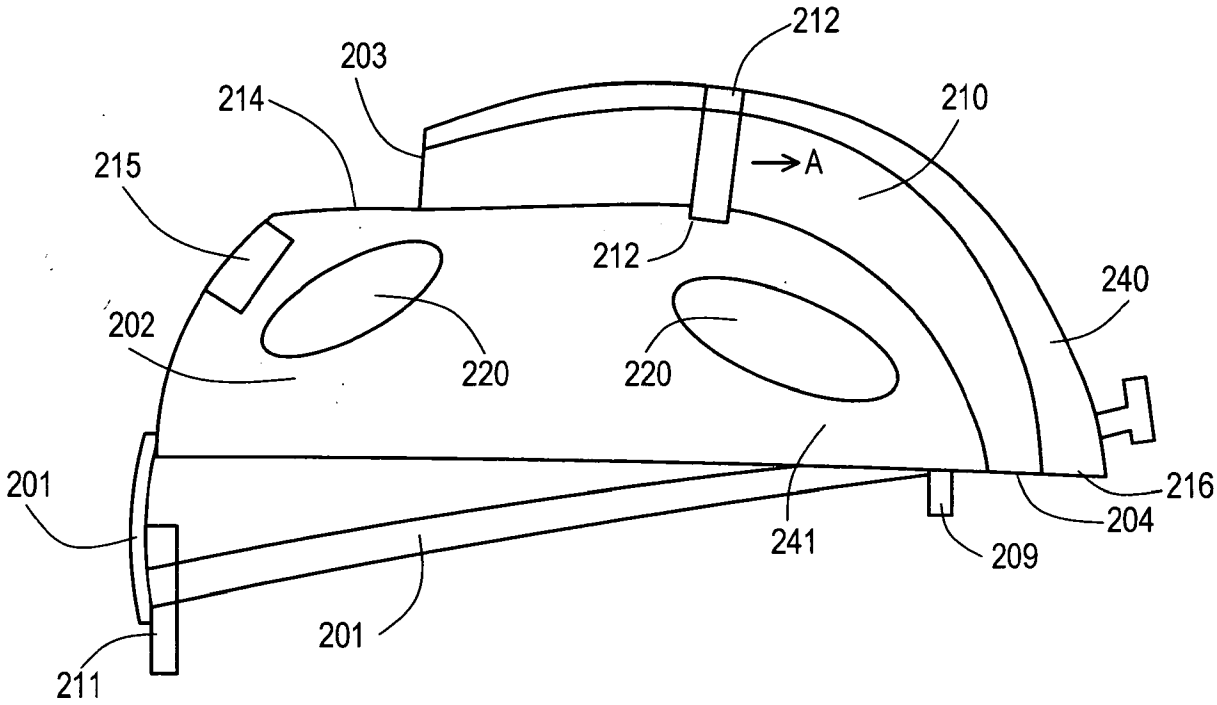
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FIG. 4B

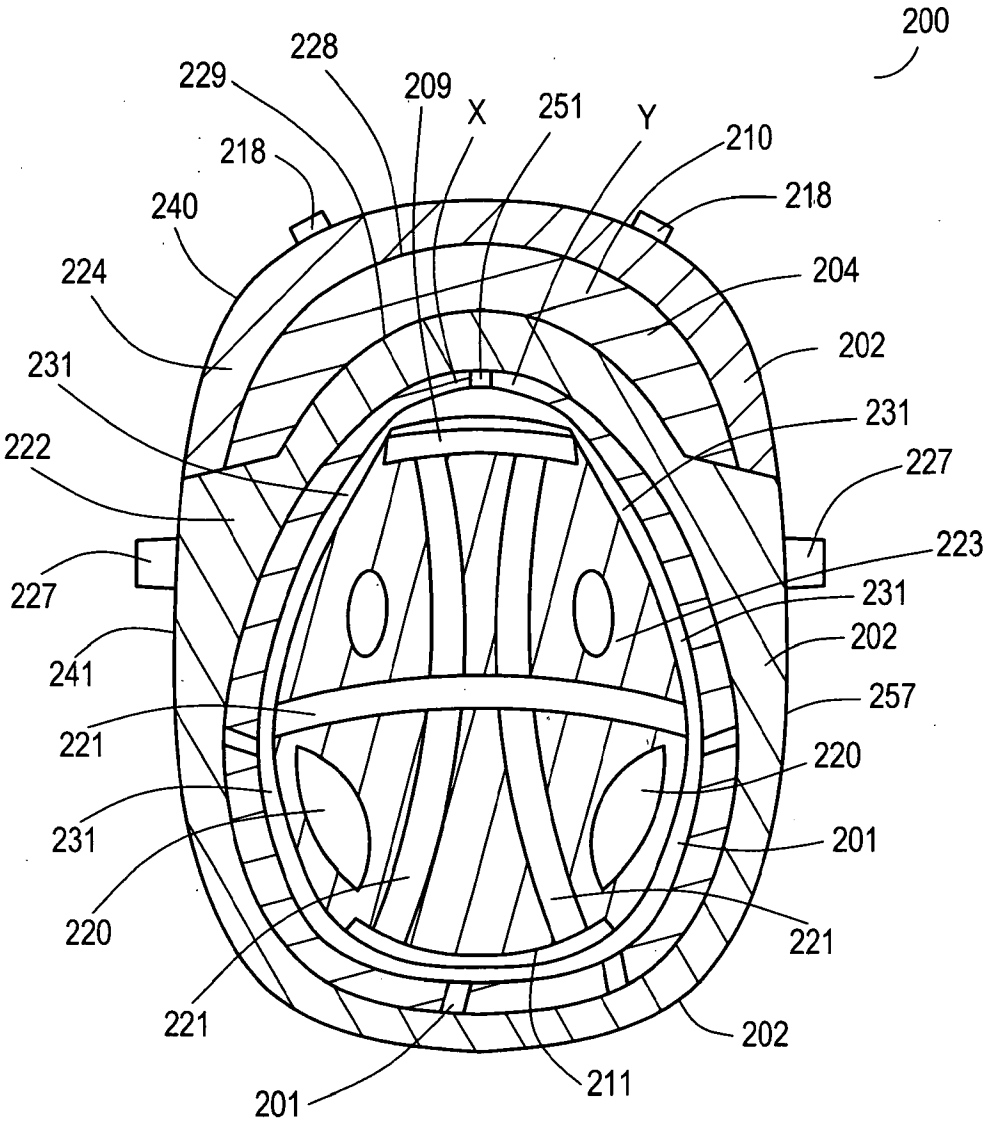
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FIG. 4C

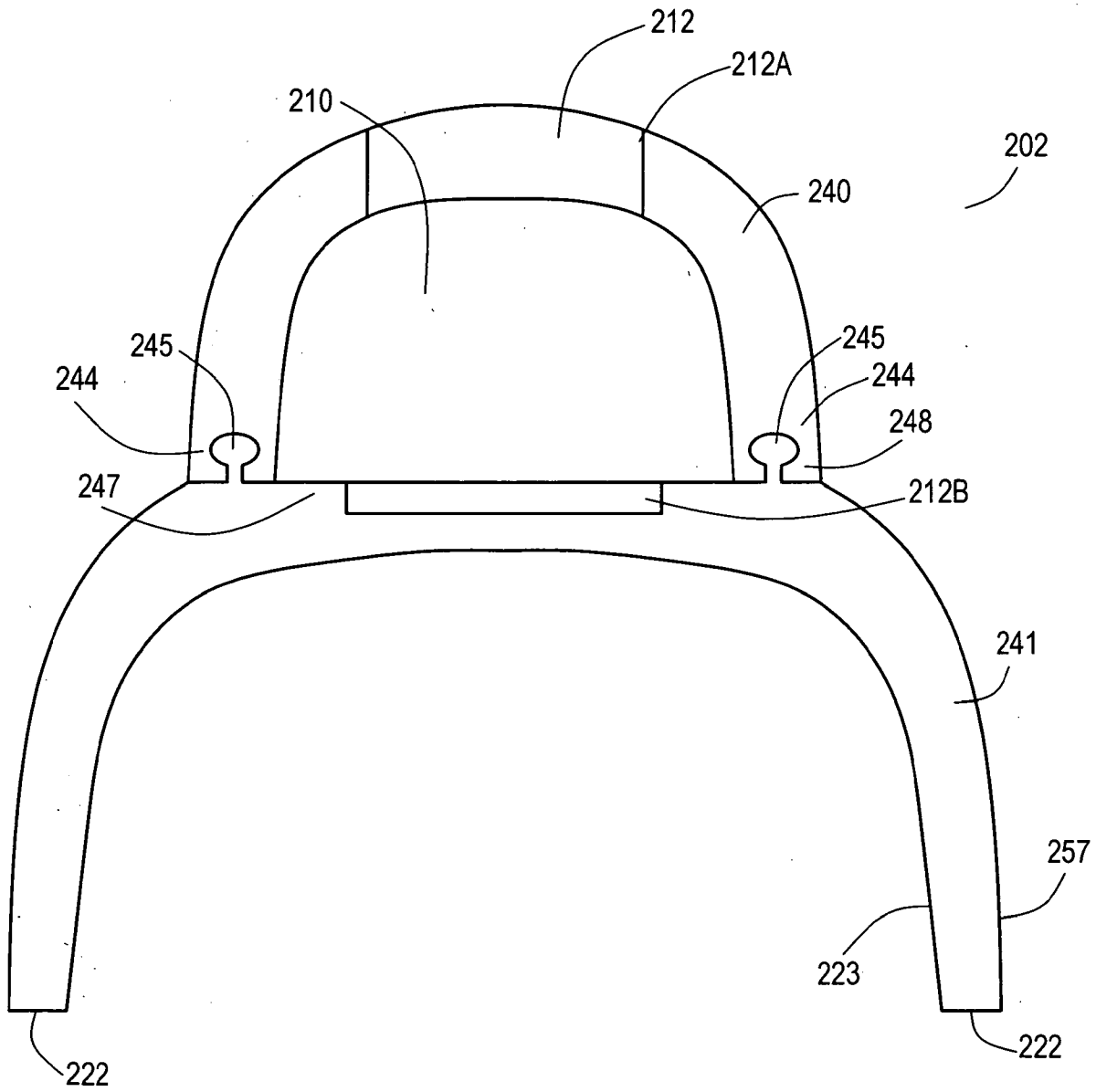
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FIG. 4D

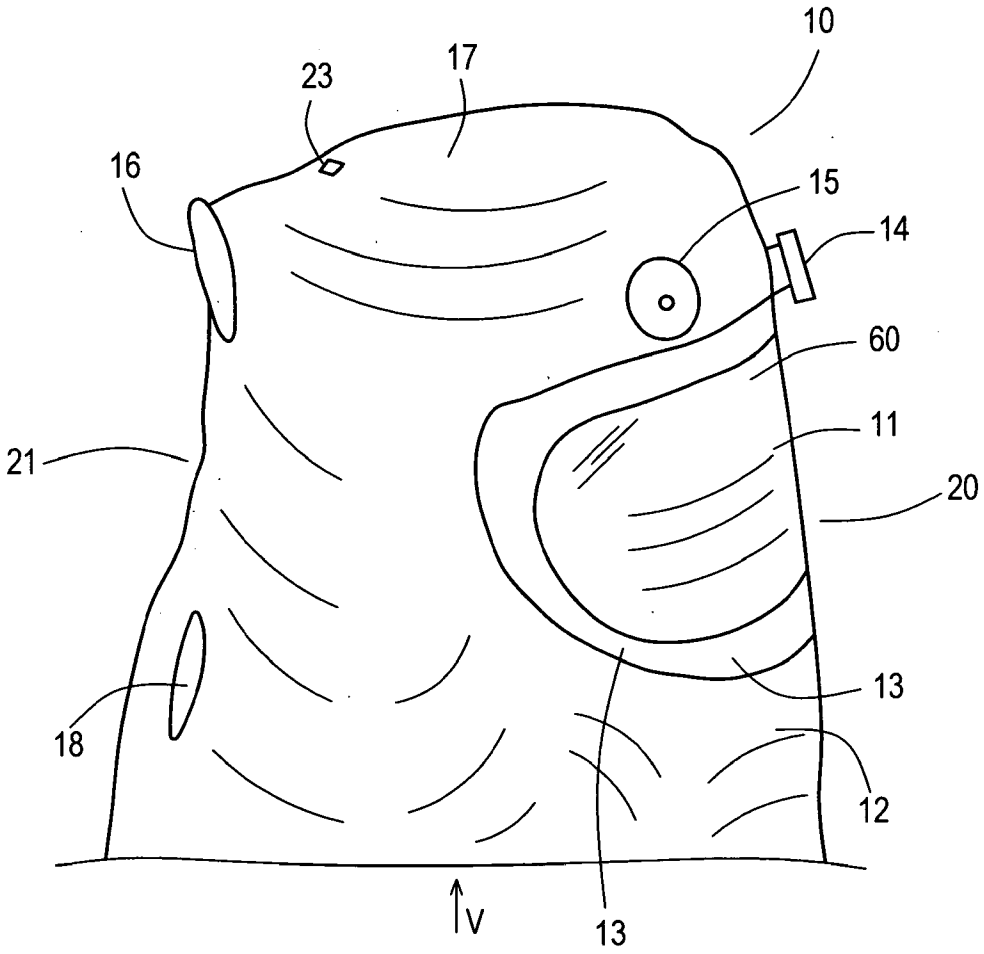


FIG. 5

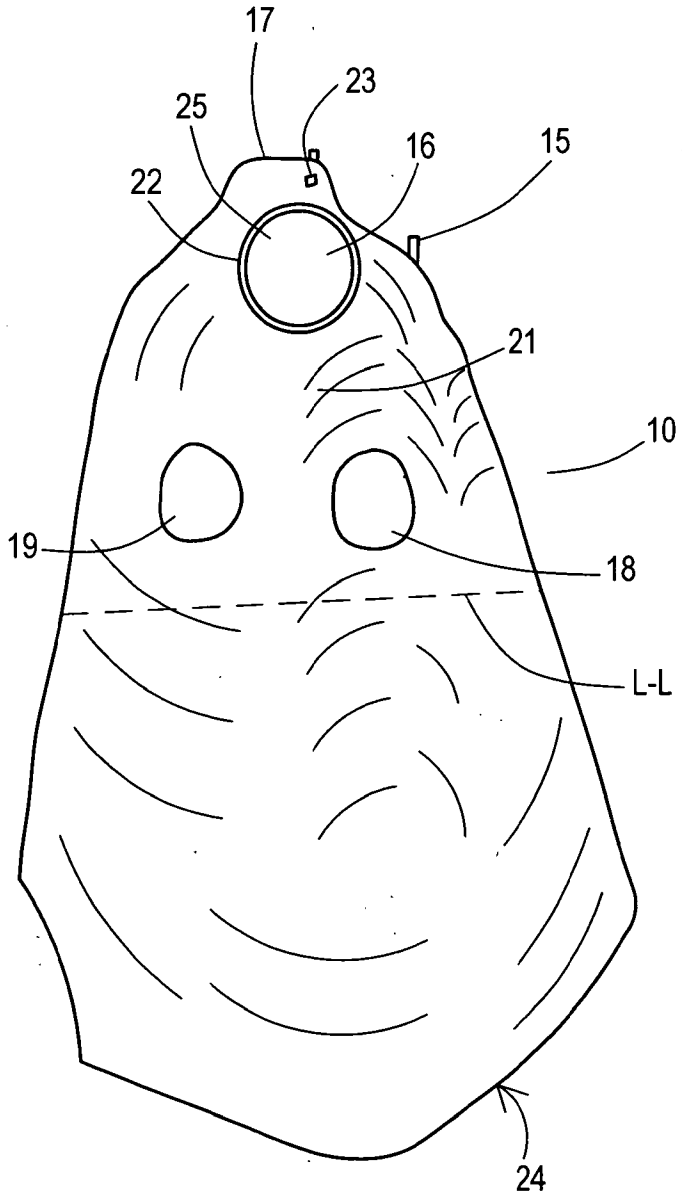
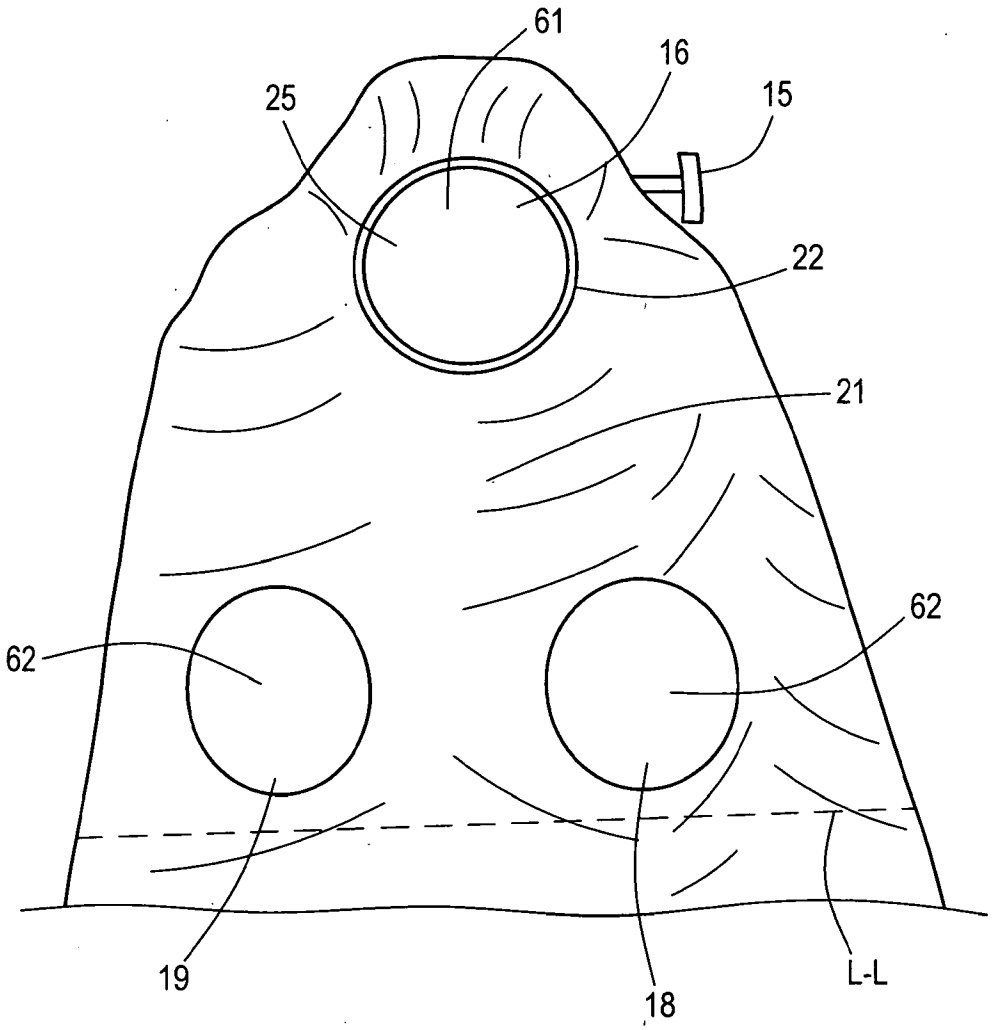


FIG. 6



G. 7

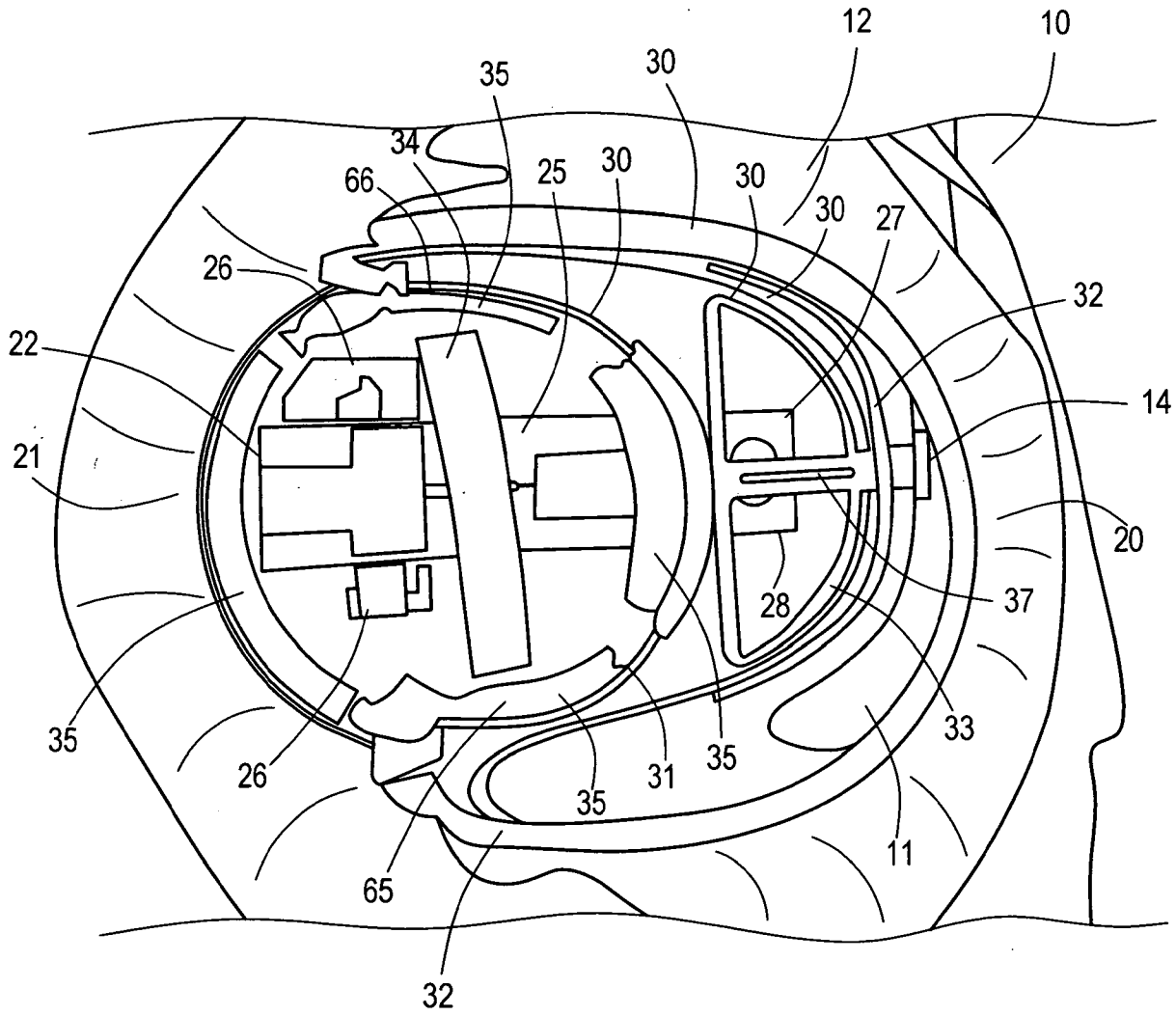

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FIG. 8

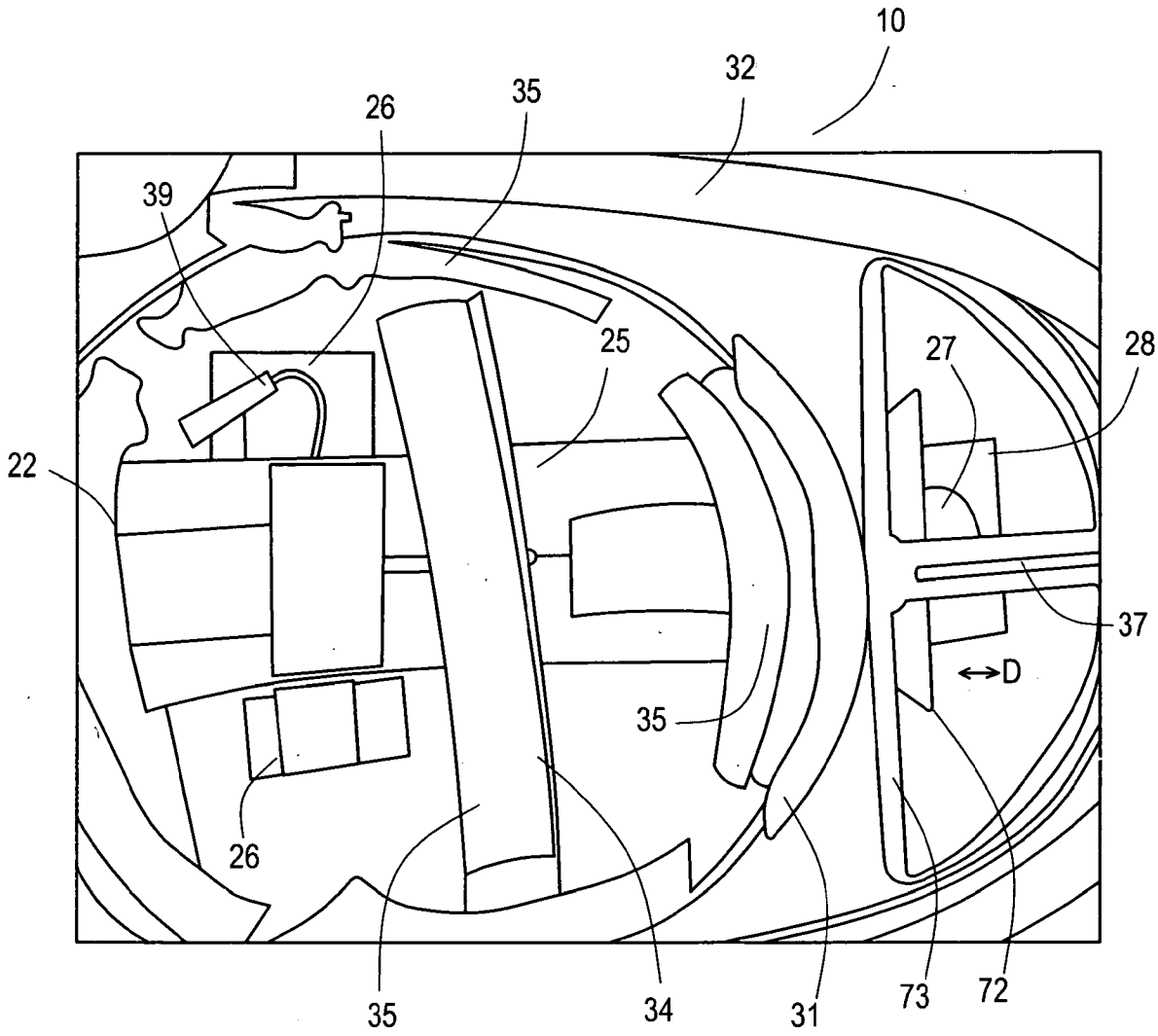

FIG. 9

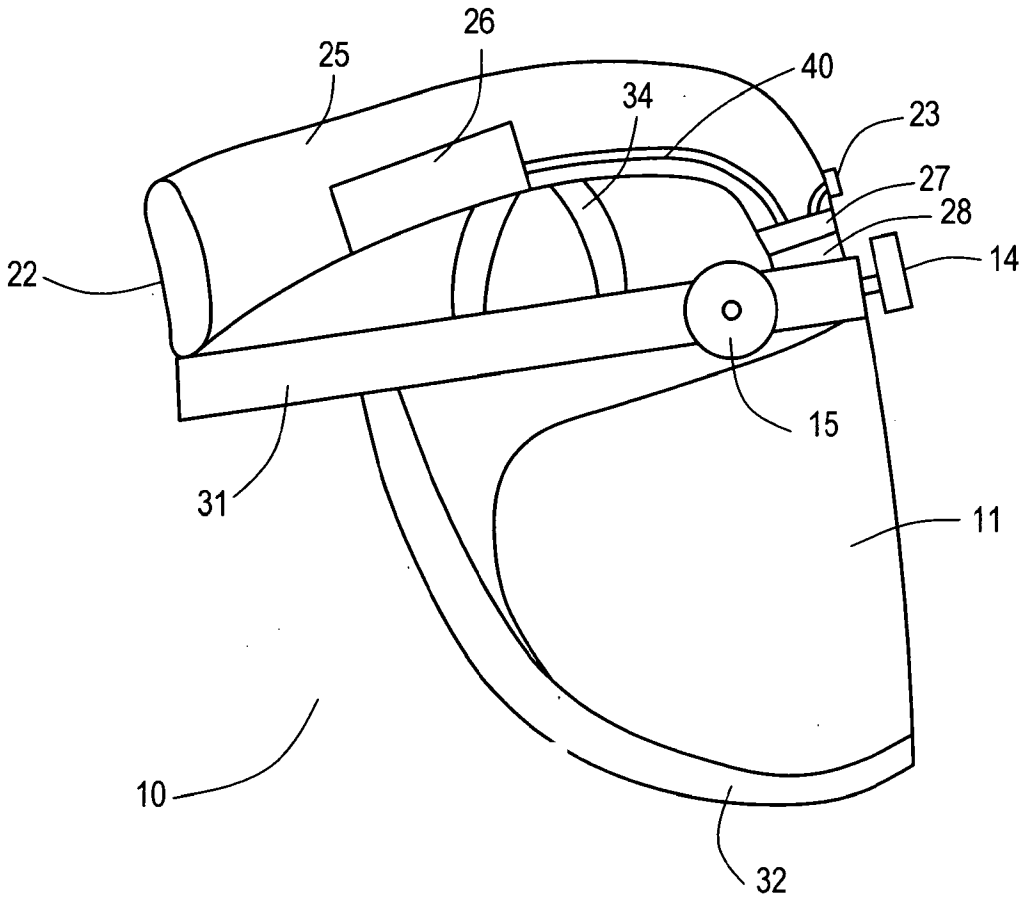

FIG. 10A

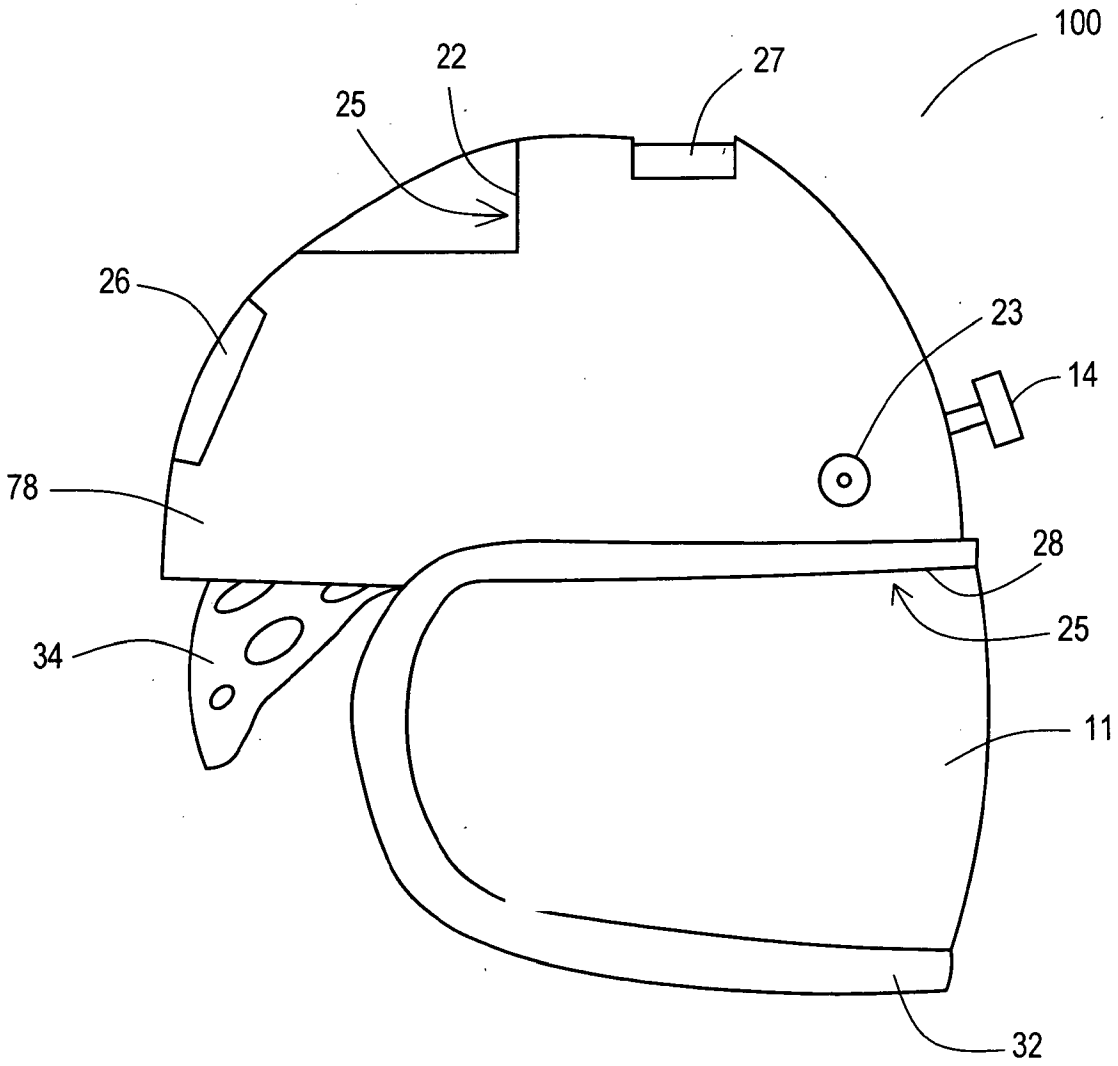

FIG. 10B

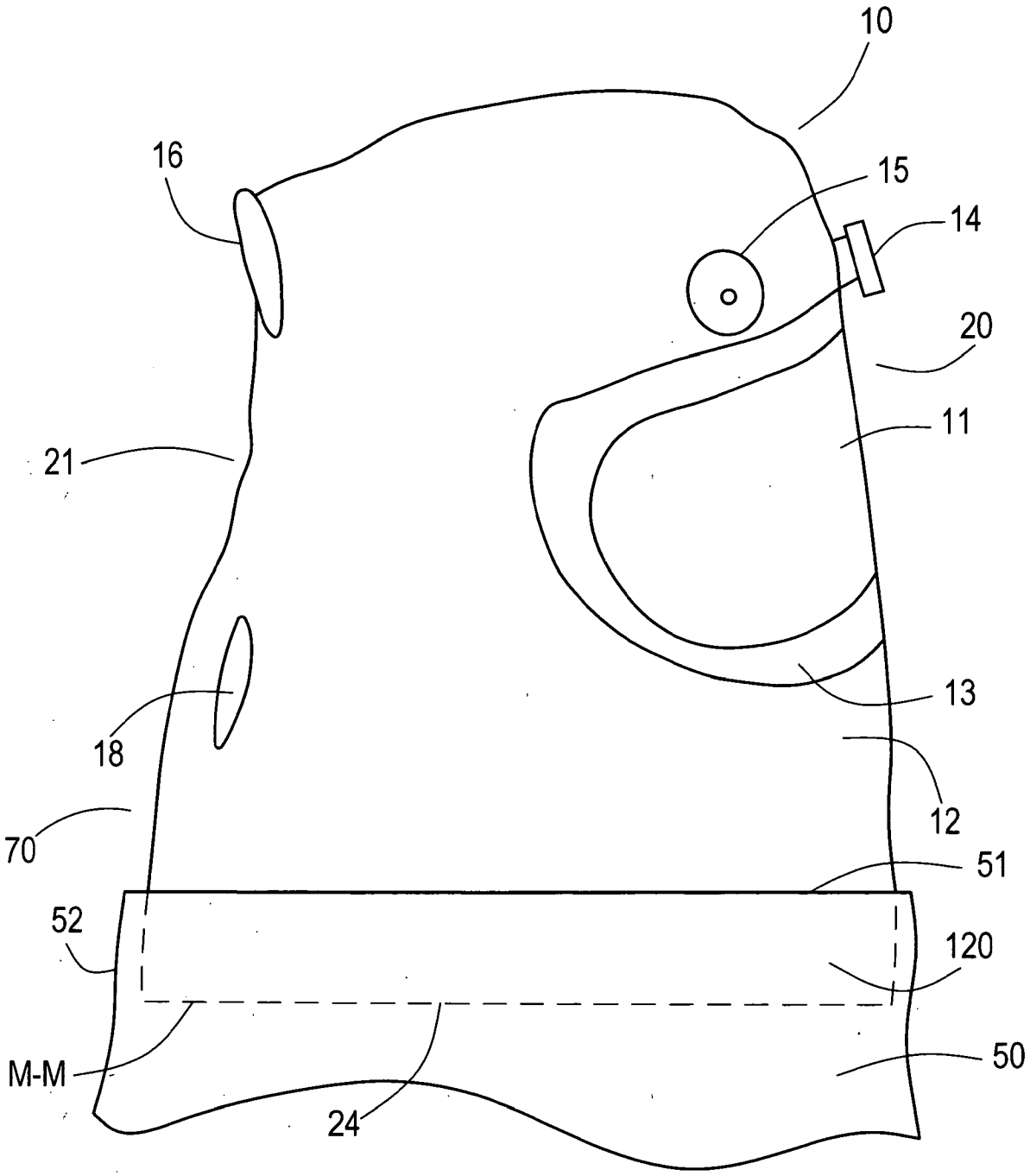

FIG. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/002535

A. CLASSIFICATION OF SUBJECT MATTER
INV. A41D13/11 A42B3/00 A62B18/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A41D A42B A62B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2003/101505 A1 (PARIS CARMEN J [US] ET AL) 5 June 2003 (2003-06-05) paragraphs [0025], [0038], [0041], [0042]; figures 1,5,7	1,4-15, 20-24
A	US 6 374 823 B1 (HAJIANPOUR MOHAMMED ALI [US]) 23 April 2002 (2002-04-23) column 3, line 63 - column 4, line 21 column 5, line 39 - line 64; claim 1; figures 1,3	1,4-15, 20-24
A	US 2003/182710 A1 (KLOTZ CONRAD LEE [US] ET AL) 2 October 2003 (2003-10-02) claims 1-9; figure 3	1,12,13, 23,24

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 June 2008	18/06/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	D'Souza, Jennifer

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/002535

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3 943 575 A (BOLKER JAMES H) 16 March 1976 (1976-03-16) column 3, line 35 - line 60; claim 1; figures 2,4	1,12,13, 23,24
A	US 2001/032348 A1 (DIAZ LUIS A [US] ET AL) 25 October 2001 (2001-10-25) paragraphs [0016] - [0018]; figure 9	1,12,13, 23,24
A	US 5 592 936 A (THOMAS JR RON [US] ET AL) 14 January 1997 (1997-01-14) claim 11; figures 1,5	1,12,13, 23,24

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/002535

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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