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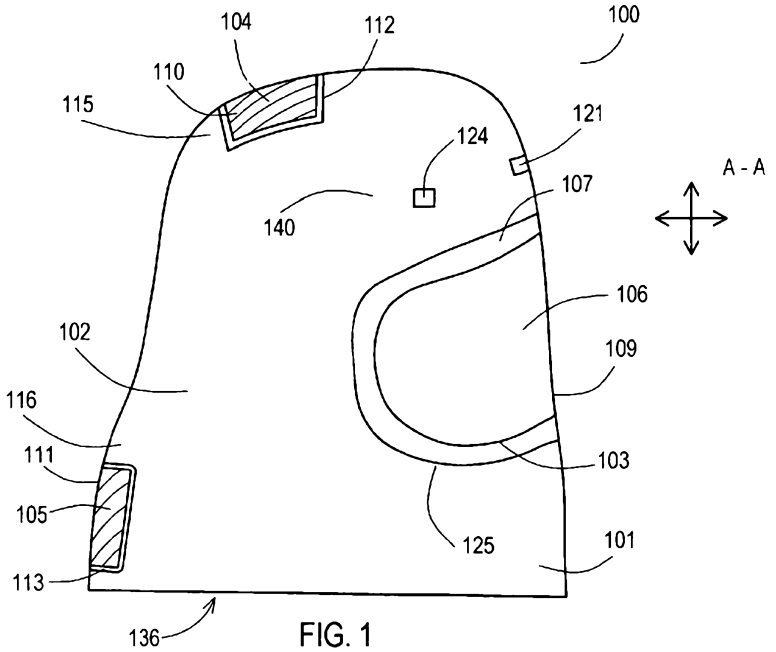

FIG. 1

(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

Technical Field

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 Art

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 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.

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Object of Invention

It is the object of the present invention to substantially overcome or ameliorate one or more of the above disadvantages, or at least provide a useful alternative.

Summary of Invention

According to a first aspect of the present invention there is disclosed herein a 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 helmet; an air channel having at least one air inlet and an air outlet consisting of a single air outlet, said single air 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, said fan being operatively adapted to move air through said air channel; a battery pack attached to the frame and positioned above a lower edge of the transparent face shield and along opposite sides of the air channel, said battery pack being operatively adapted to supply electrical power to the fan; and a hood surrounding the transparent face shield and extending over and downward from the frame.

Preferably the helmet comprises at least one hood air inlet located within a periphery of the hood and aligned with the at least one air inlet of the air channel.

Preferably the at least one hood air inlet is positioned along an outer surface of the helmet opposite the transparent face shield.

Preferably the helmet comprises: at least one hood air inlet located within a periphery of the hood and aligned with the at least one air inlet of the air channel; and at least one hood air outlet located within a periphery of the hood, wherein the at least one hood air inlet is positioned along an outer surface of the helmet, and the at least one hood air outlet is positioned below the at least one hood air inlet.

Preferably the helmet further comprises: a power switch operatively adapted to (1) switch from an "off' position to an "on" position so as to supply power to the fan and turn off power to the fan, and optionally (2) provide variable speed settings for the fan.

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Preferably the power switch is positioned along an upper periphery of the transparent face shield.

Preferably the battery pack is positioned along an outer surface of the helmet opposite the transparent face shield.

According to a second aspect of the present invention there is disclosed herein a 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 helmet; an air channel having at least one air inlet and an air outlet consisting of a single air outlet, said single air 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, said fan being operatively adapted to move air through said air channel; a battery pack attached to the frame and positioned above a lower edge of the transparent face shield and along opposite sides of the air channel, said battery pack being operatively adapted to supply electrical power to the fan; a hood surrounding the transparent face shield and extending over and downward from the frame; at least one hood air inlet located within a periphery of the hood and aligned with the at least one air inlet of the air channel; and at least one hood air outlet located within a periphery of the hood, wherein the at least one 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.

Preferably the at least one hood air inlet is positioned along a rear side of the helmet opposite the transparent face shield, and the at least one hood air outlet is positioned below the at least one hood air inlet.

Preferably the at least one hood air inlet comprises a single hood air inlet, and the at least one hood air outlet comprises one or more air outlets positioned along a neck region of the hood.

Preferably each of the hood, the at least one hood air inlet, and the at least one hood air outlet comprises nonwoven fabric materials.

Preferably the helmet is sterilized.

Preferably the helmet is disposable.

According to a third aspect of the present invention there is disclosed herein a surgical outfit comprising: a helmet according to either the first or second aspects; 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, the at least one air outlet of the hood is positioned above the surgical gown.

According to a fourth aspect of the present invention there is disclosed herein a method of making a helmet suitable for use in an operating room setting, said method comprising: 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 one air outlet, the one air outlet being positioned so as to provide air to a space bound by an inner surface of the transparent face shield, 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; incorporating a battery pack into the helmet so as to be positioned above a lower edge of the transparent face shield and along opposite sides of the air channel, the battery pack being operatively adapted to supply electrical power to the fan; and providing a hood that surrounds the transparent face shield and extends over and downward from the frame.

Preferably the hood comprises: at least one hood air inlet located within a periphery of the hood and aligned with the at least one air inlet of the air channel; and one hood air outlet located within a periphery of the hood, wherein the at least one hood air inlet and the 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.

According to a fifth aspect of the present invention there is disclosed herein a method of reducing an amount of carbon dioxide within a surgical outfit during use, said method comprising: providing a surgical outfit comprising: a 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 helmet; an air channel having at least one air inlet and one air outlet, said one air 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, said fan being operatively adapted to move air through said air channel; a battery pack attached to the frame and positioned above a lower edge of the transparent face shield and along opposite sides of the air channel, said battery pack being operatively adapted to supply electrical power to the fan; and a hood surrounding the transparent face shield and extending over and downward from the frame; 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, the at least one air outlet of the hood is positioned above the surgical gown; 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 inlet, through the air channel, out of the at least one air 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.

Preferably the amount of carbon dioxide within the surgical outfit during use is below 2500 parts per million.

Brief Description of Drawings

Preferred embodiments of the present invention will now be described, by way of an examples only, with reference to the accompanying drawings 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;

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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.

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Description of Embodiments

Preferred embodiments of the invention are 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. Preferred embodiments of the present invention are 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 embodiments 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 embodiment 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 75μm 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 embodiments 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

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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. 1OB, 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 embodiments of the present invention are disposable. However, in some cases, the helmets of embodiments 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.

Embodiments of the present invention are 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, embodiment 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, embodiment 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

Preferred embodiments of 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 embodiments 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

Preferred embodiments of 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 preferred embodiments 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 a preferred embodiment 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.

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The claims defining the invention are as follows:

1. A 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 helmet;

an air channel having at least one air inlet and an air outlet consisting of a single air outlet, said single air 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, said fan being operatively adapted to move air through said air channel;

a battery pack attached to the frame and positioned above a lower edge of the transparent face shield and along opposite sides of the air channel, said battery pack being operatively adapted to supply electrical power to the fan; and

a hood surrounding the transparent face shield and extending over and downward from the frame.

2. The helmet of claim 1, further comprising:

at least one hood air inlet located within a periphery of the hood and aligned with the at least one air inlet of the air channel.

3. The helmet of claim 2, wherein the at least one hood air inlet is positioned along an outer surface of the helmet opposite the transparent face shield.

4. The helmet of claim 1, further comprising:

at least one hood air inlet located within a periphery of the hood and aligned with the at least one air inlet of the air channel; and

at least one hood air outlet located within a periphery of the hood, wherein the at least one hood air inlet is positioned along an outer surface of the helmet, and the at least one hood air outlet is positioned below the at least one hood air inlet.

5. The helmet according to any one of the preceding claims, further comprising:

a power switch operatively adapted to (1) switch from an "off' position to an "on" position so as to supply power to the fan and tum off power to the fan, and optionally (2) provide variable speed settings for the fan.

6. The helmet of claim 6, wherein the power switch is positioned along an upper periphery of the transparent face shield.

7. The helmet according to any one of the preceding claims, wherein the battery pack is positioned along an outer surface of the helmet opposite the transparent face shield.

8. A 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 helmet;

an air channel having at least one air inlet and an air outlet consisting of a single air outlet, said single air 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, said fan being operatively adapted to move air through said air channel;

a battery pack attached to the frame and positioned above a lower edge of the transparent face shield and along opposite sides of the air channel, said battery pack being operatively adapted to supply electrical power to the fan;

a hood surrounding the transparent face shield and extending over and downward from the frame;

at least one hood air inlet located within a periphery of the hood and aligned with the at least one air inlet of the air channel; and

at least one hood air outlet located within a periphery of the hood, wherein the at least one 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.

9. The helmet of claim 9, wherein the at least one hood air inlet is positioned along a rear side of the helmet opposite the transparent face shield, and the at least one hood air outlet is positioned below the at least one hood air inlet.

10. The helmet according to claim 9, wherein the at least one hood air inlet comprises a single hood air inlet, and the at least one hood air outlet comprises one or more air outlets positioned along a neck region of the hood.

11. The helmet according to any one of claims 8 to 10, wherein each of the hood, the at least one hood air inlet, and the at least one hood air outlet comprises nonwoven fabric materials.

12. The helmet according to any one of claims 8 to 11, wherein the helmet is sterilized.

13. The helmet according to any one of claims 8 to 12, wherein the helmet is disposable.

14. A surgical outfit comprising:

a helmet according to any one of claims 1 to 13; 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, the at least one air outlet of the hood is positioned above the surgical gown.

15. A method of making a helmet suitable for use in an operating room setting, said method comprising:

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 one air outlet, the one air outlet being positioned so as to provide air to a space bound by an inner

surface of the transparent face shield, 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;

incorporating a battery pack into the helmet so as to be positioned above a lower edge of the transparent face shield and along opposite sides of the air channel, the battery pack being operatively adapted to supply electrical power to the fan; and

providing a hood that surrounds the transparent face shield and extends over and downward from the frame.

16. The method of claim 15, wherein the hood comprises:

at least one hood air inlet located within a periphery of the hood and aligned with the at least one air inlet of the air channel; and

one hood air outlet located within a periphery of the hood,

wherein the at least one hood air inlet and the 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.

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

providing a surgical outfit comprising:

a 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 helmet;

an air channel having at least one air inlet and one air outlet, said one air 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, said fan being operatively adapted to move air through said air channel;

a battery pack attached to the frame and positioned above a lower edge of the transparent face shield and along opposite sides of the air channel, said battery pack being operatively adapted to supply electrical power to the fan; and

a hood surrounding the transparent face shield and extending over and downward from the frame; 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, the at least one air outlet of the hood is positioned above the surgical gown; 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 inlet, through the air channel, out of the at least one air 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.

18. The method of claim 17, wherein the amount of carbon dioxide within the surgical outfit during use is below 2500 parts per million.

19. A helmet substantially as hereinbefore described with reference to Figures 1 to 3, Figures 4 to 4D, Figures 5 to 10A, Figure 10B or Figure 11 of the accompanying drawings.

20. A method of making a helmet suitable for use in an operating room setting, the method being substantially as hereinbefore described with reference to Figures 1 to 3, Figures 4 to 4D, Figures 5 to 10A, Figure 10B or Figure 11 of the accompanying drawings.

Dated 30 June, 2011
Microtek Medical, Inc.
Patent Attorneys for the Applicant/Nominated Person
SPRUSON & FERGUSON

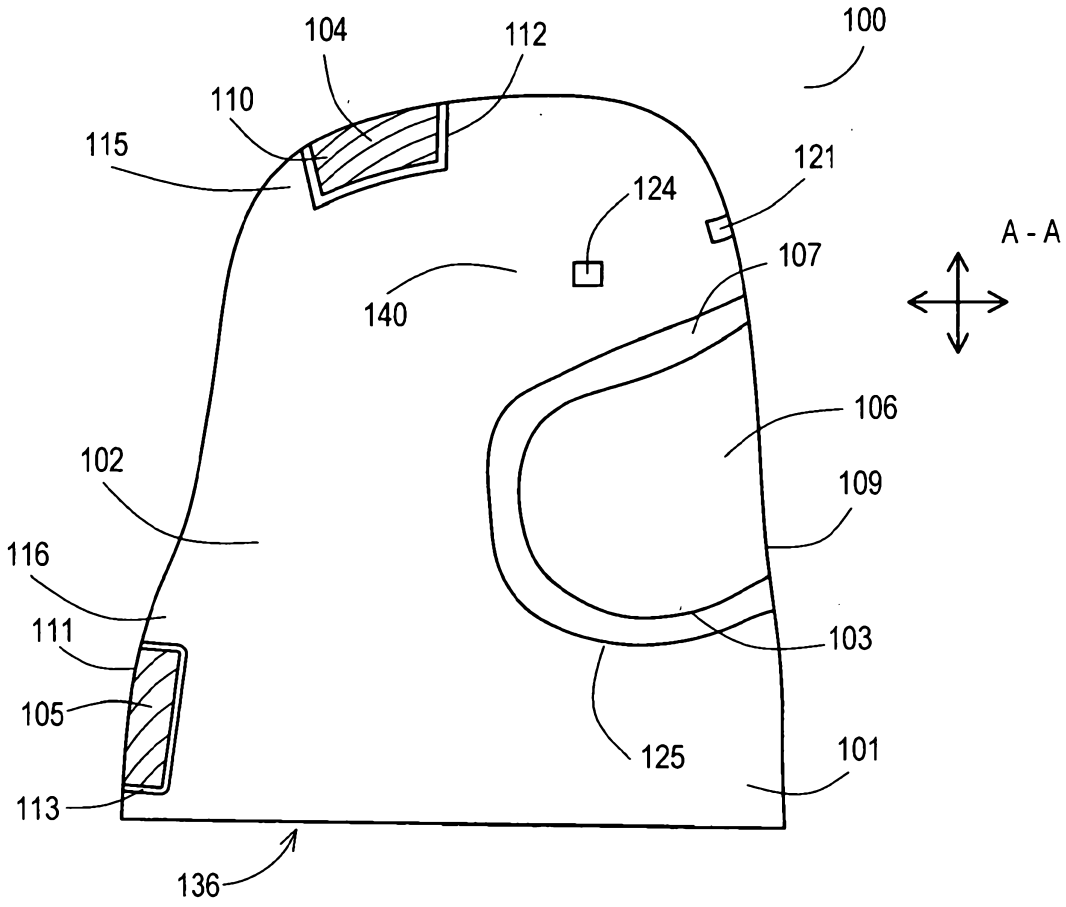
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FIG. 1

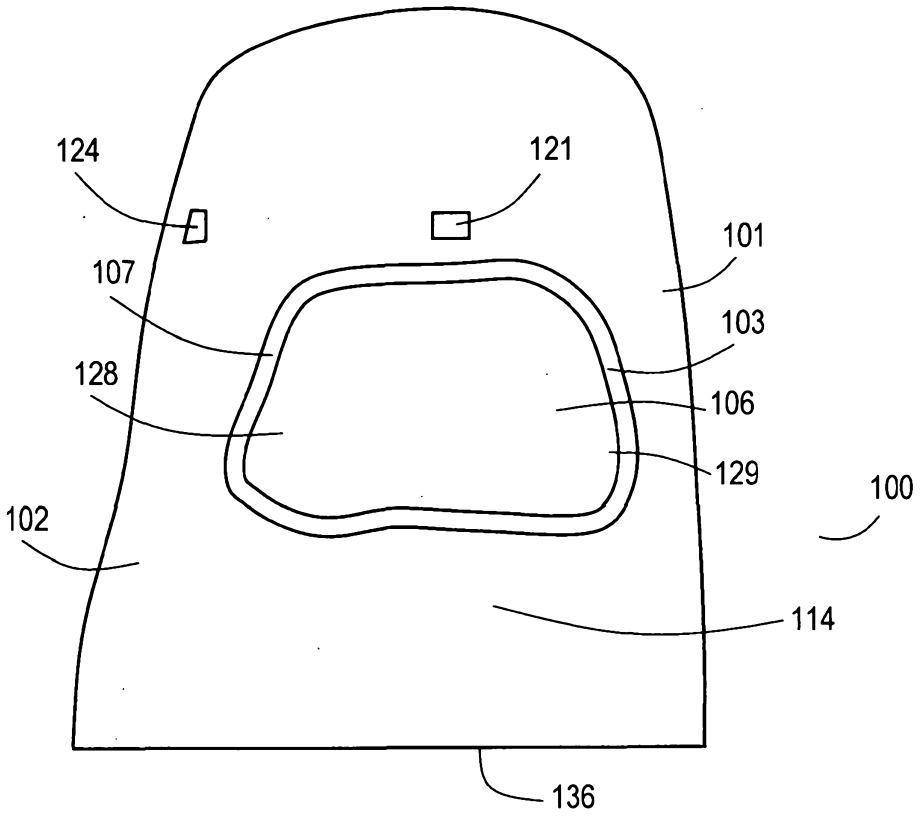

FIG. 2A

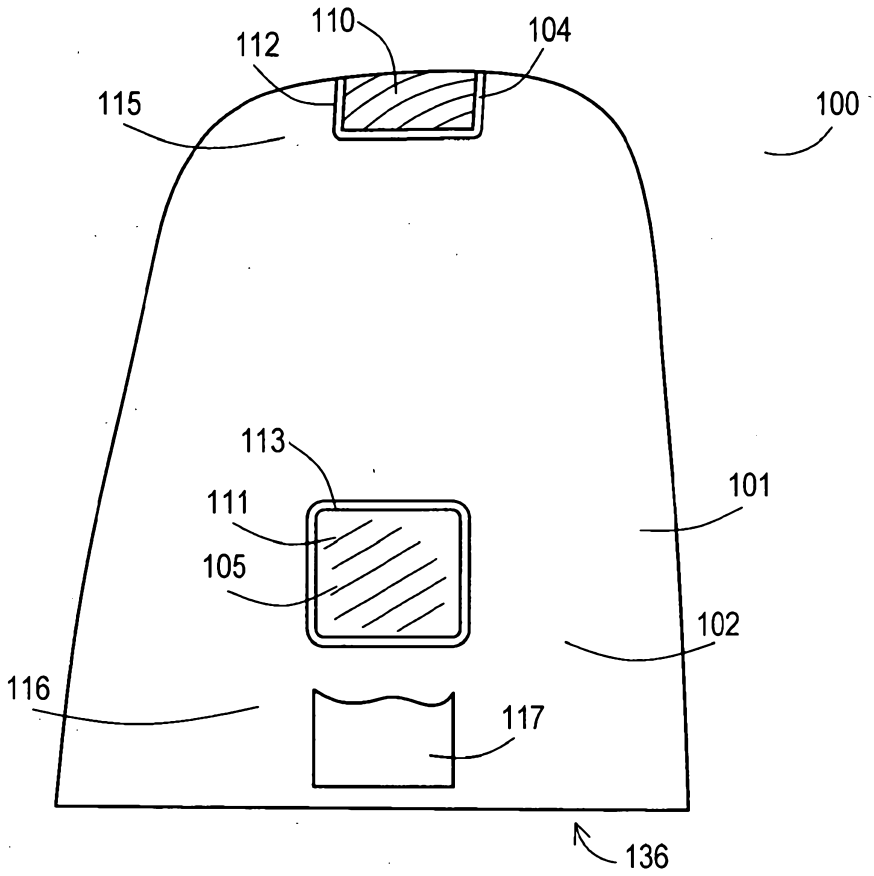

FIG. 2B

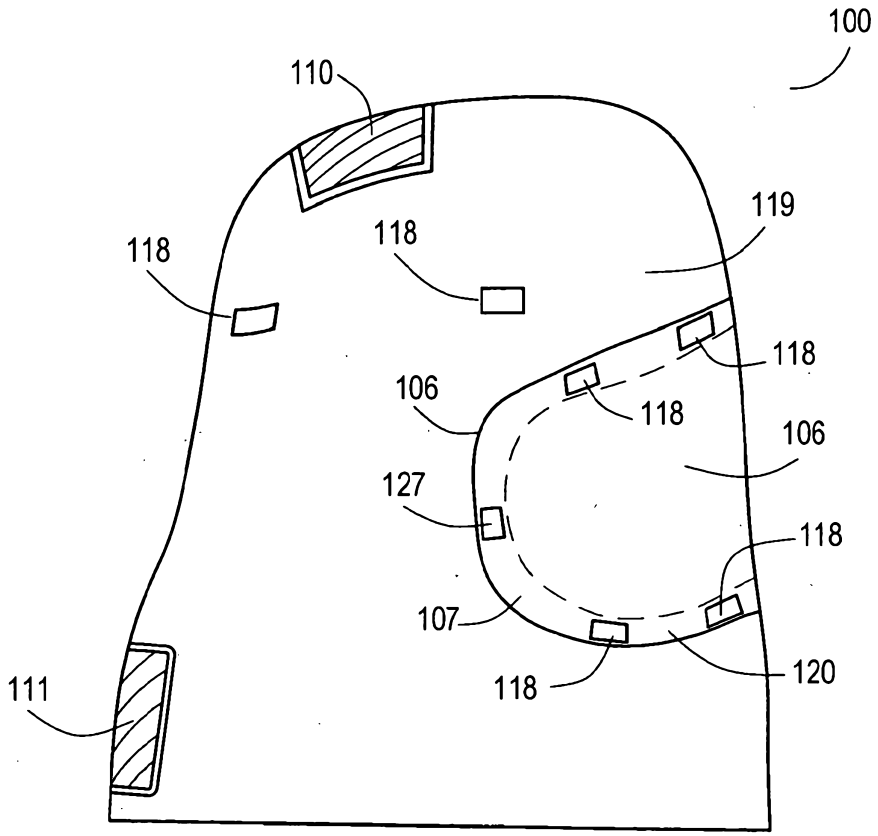

FIG. 3

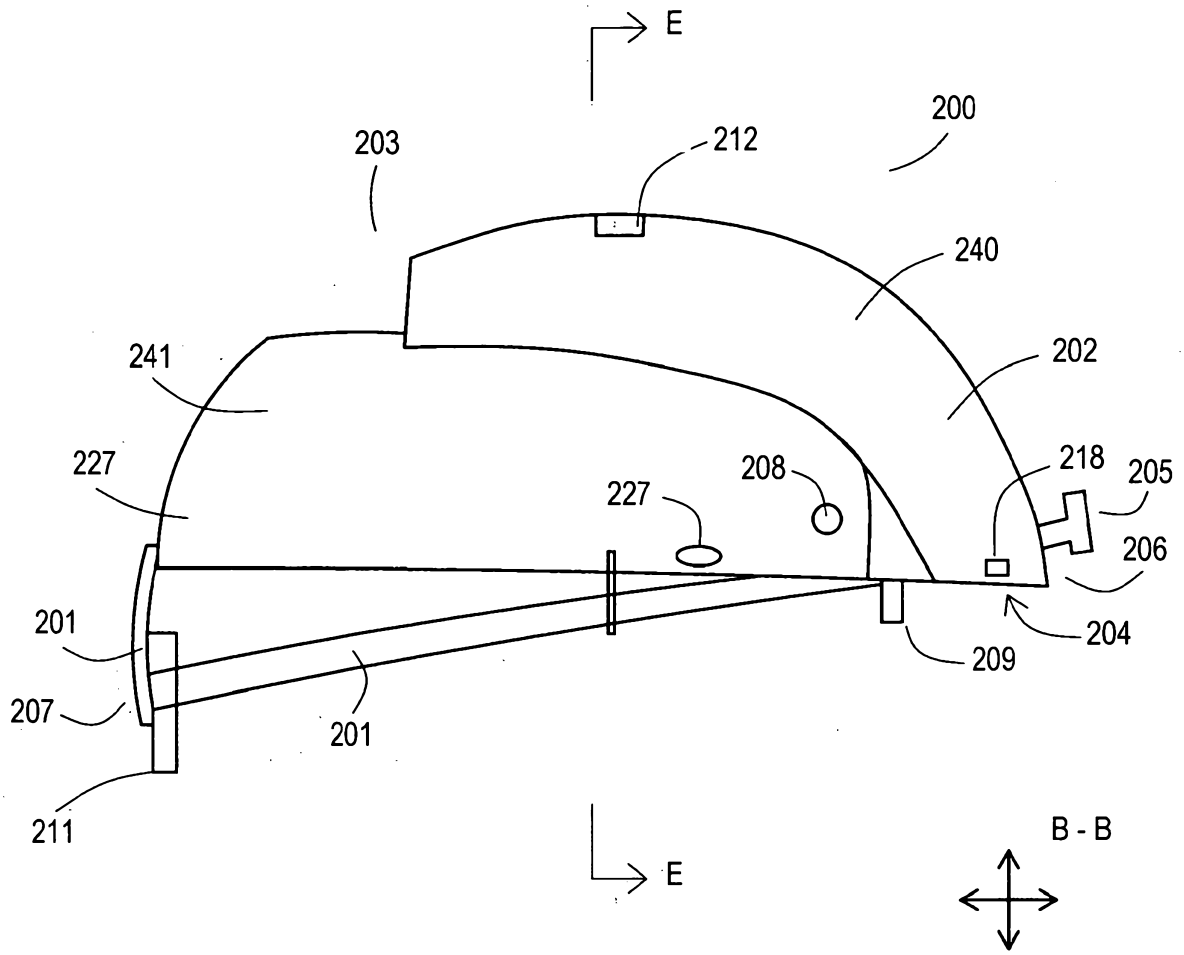
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FIG. 4

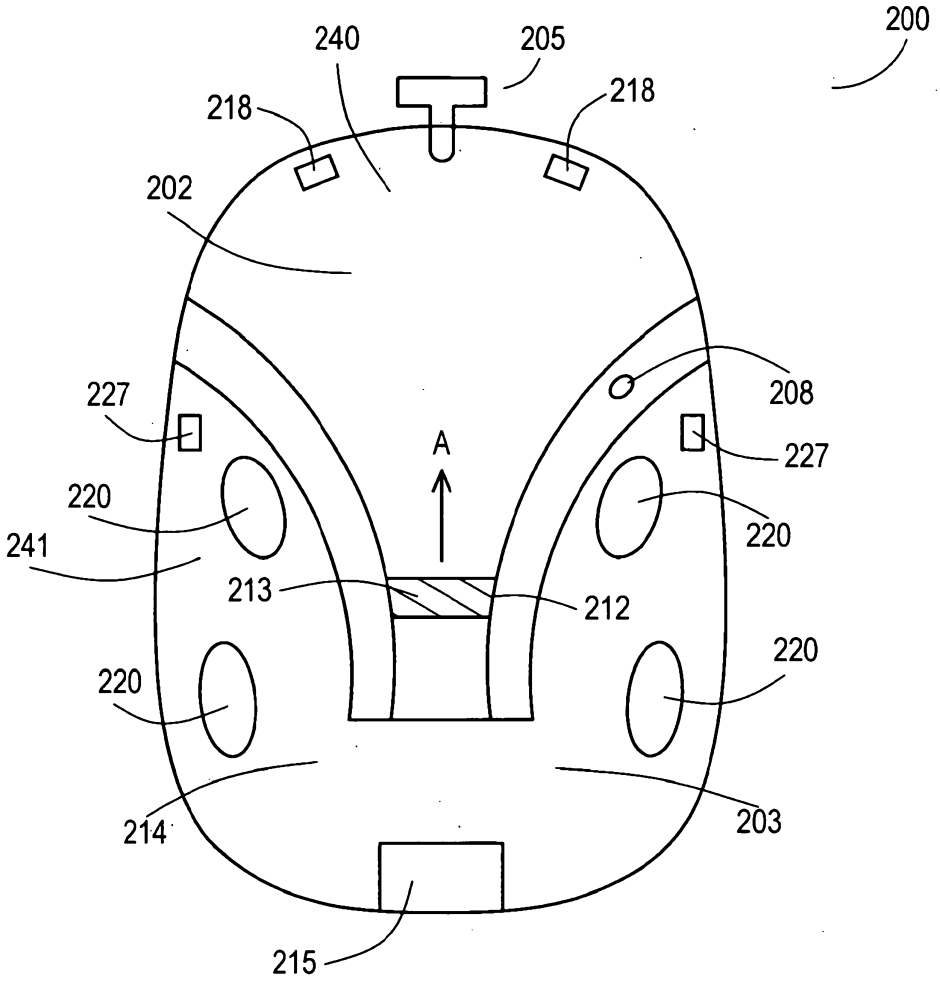
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FIG. 4A

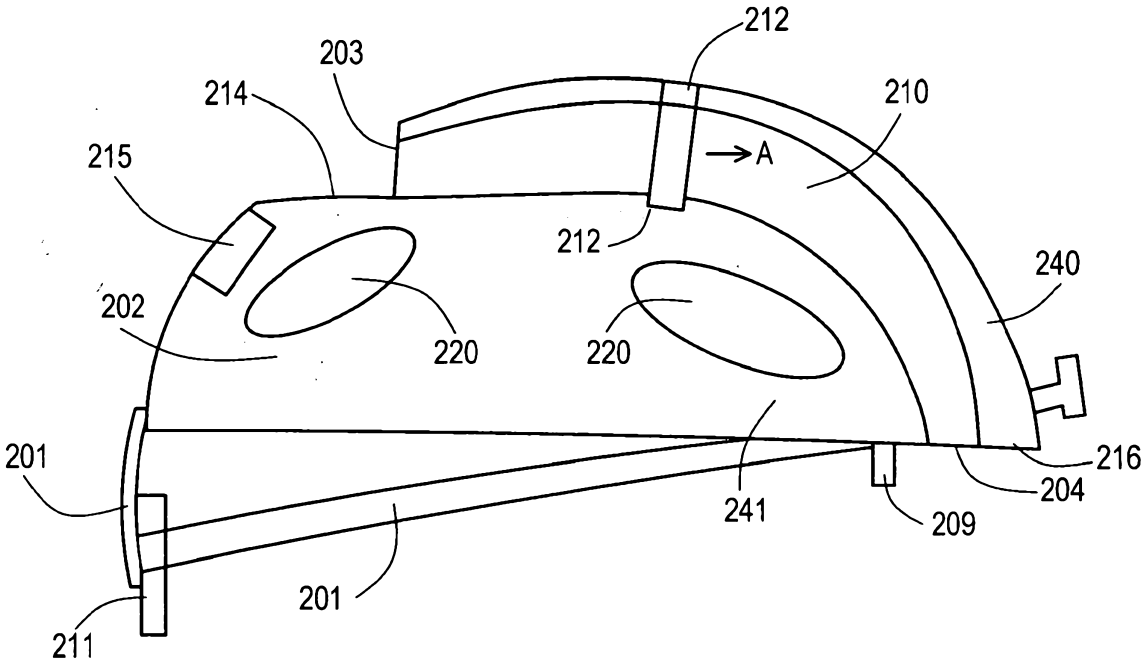
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FIG. 4B

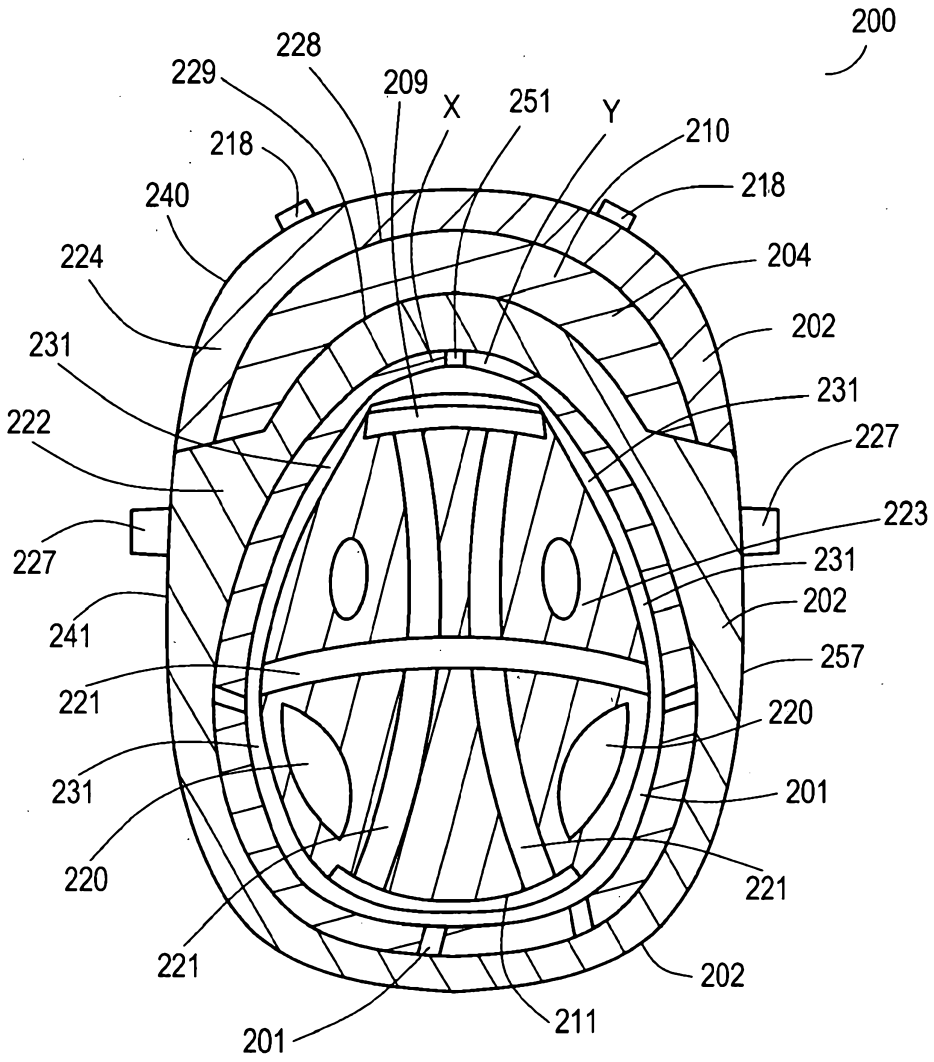
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FIG. 4C

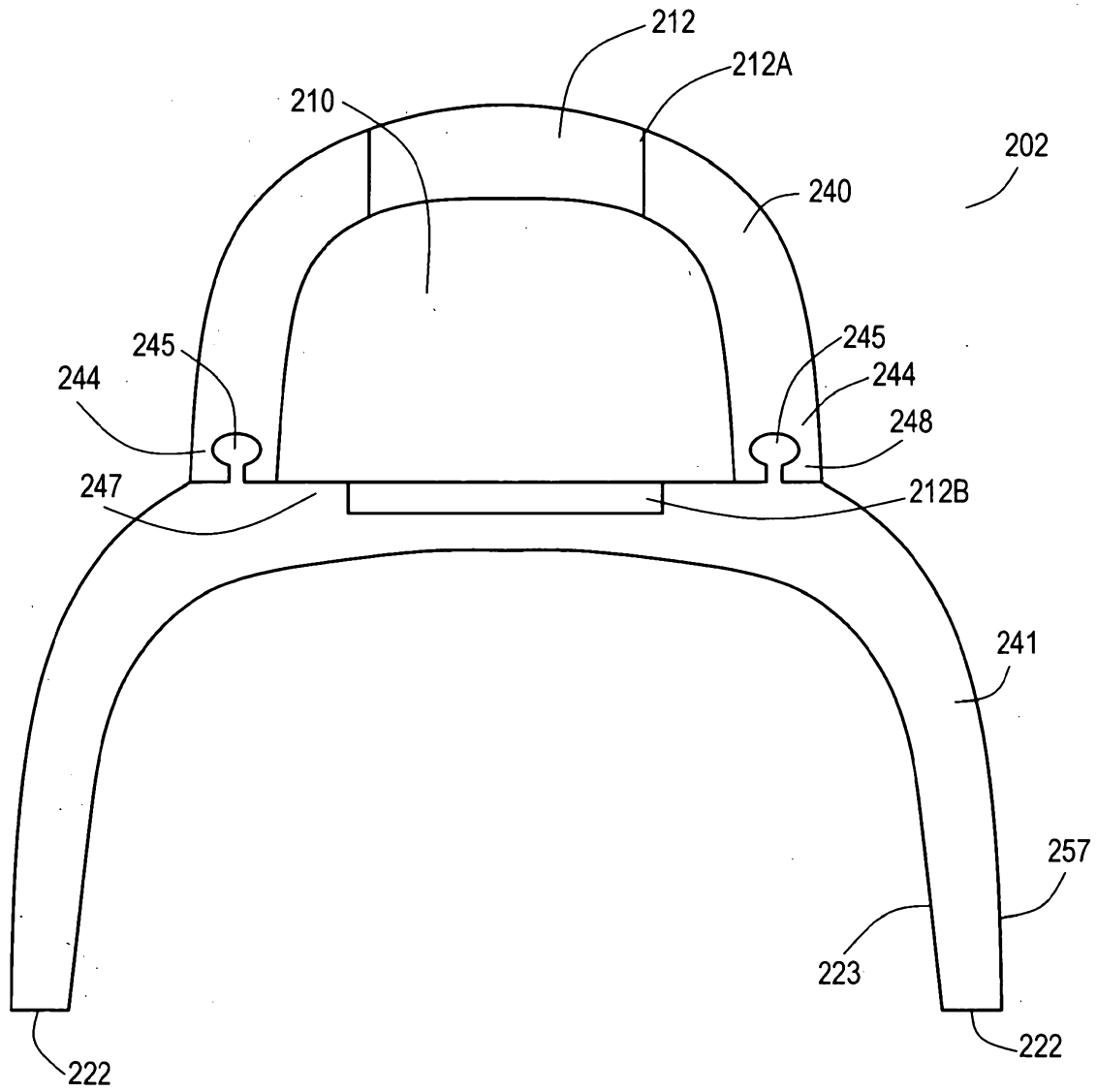
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FIG. 4D

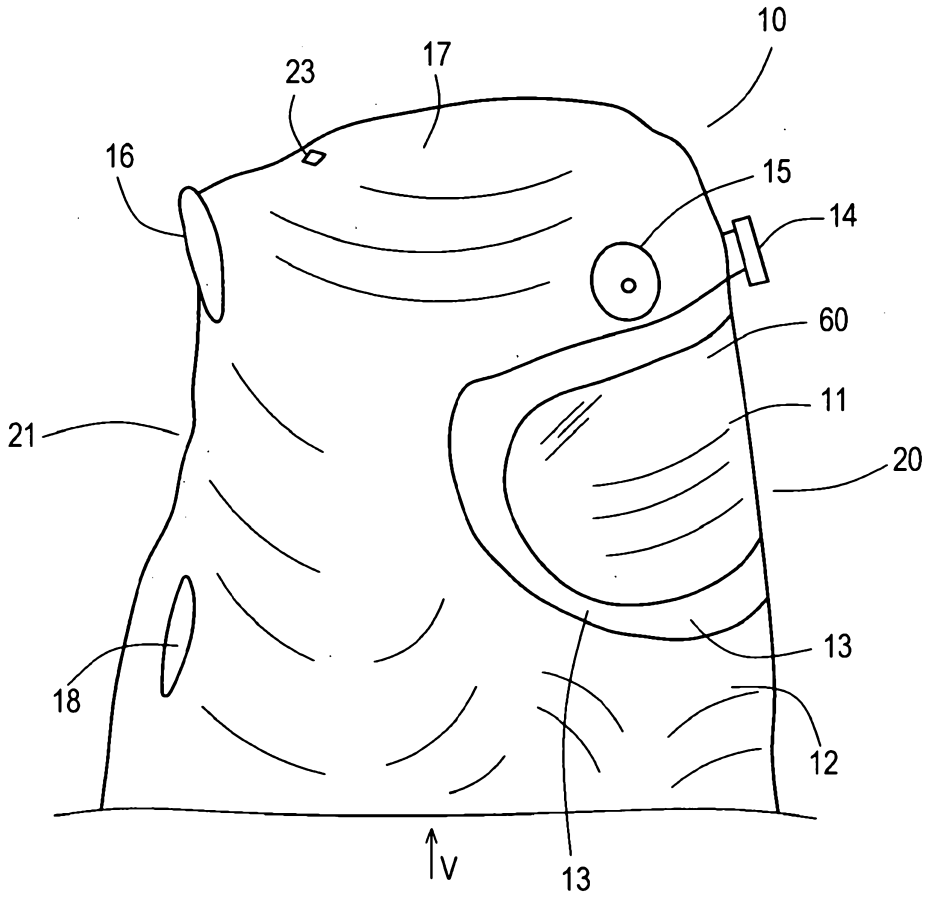


FIG. 5

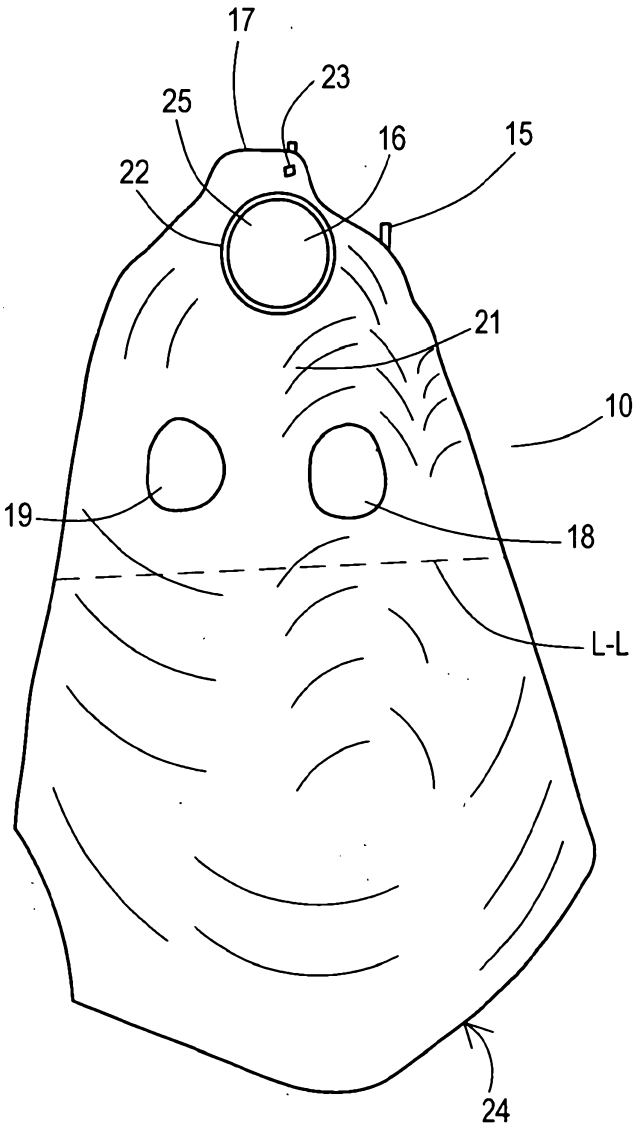
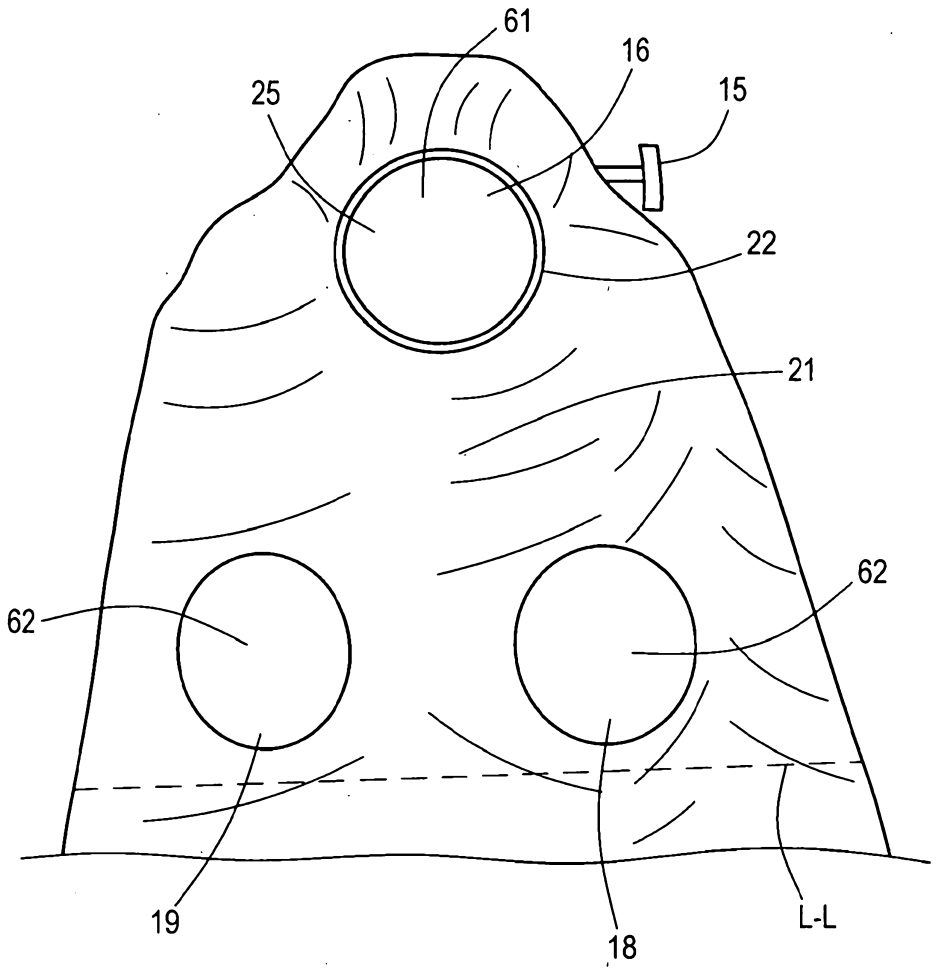


FIG. 6



G. 7

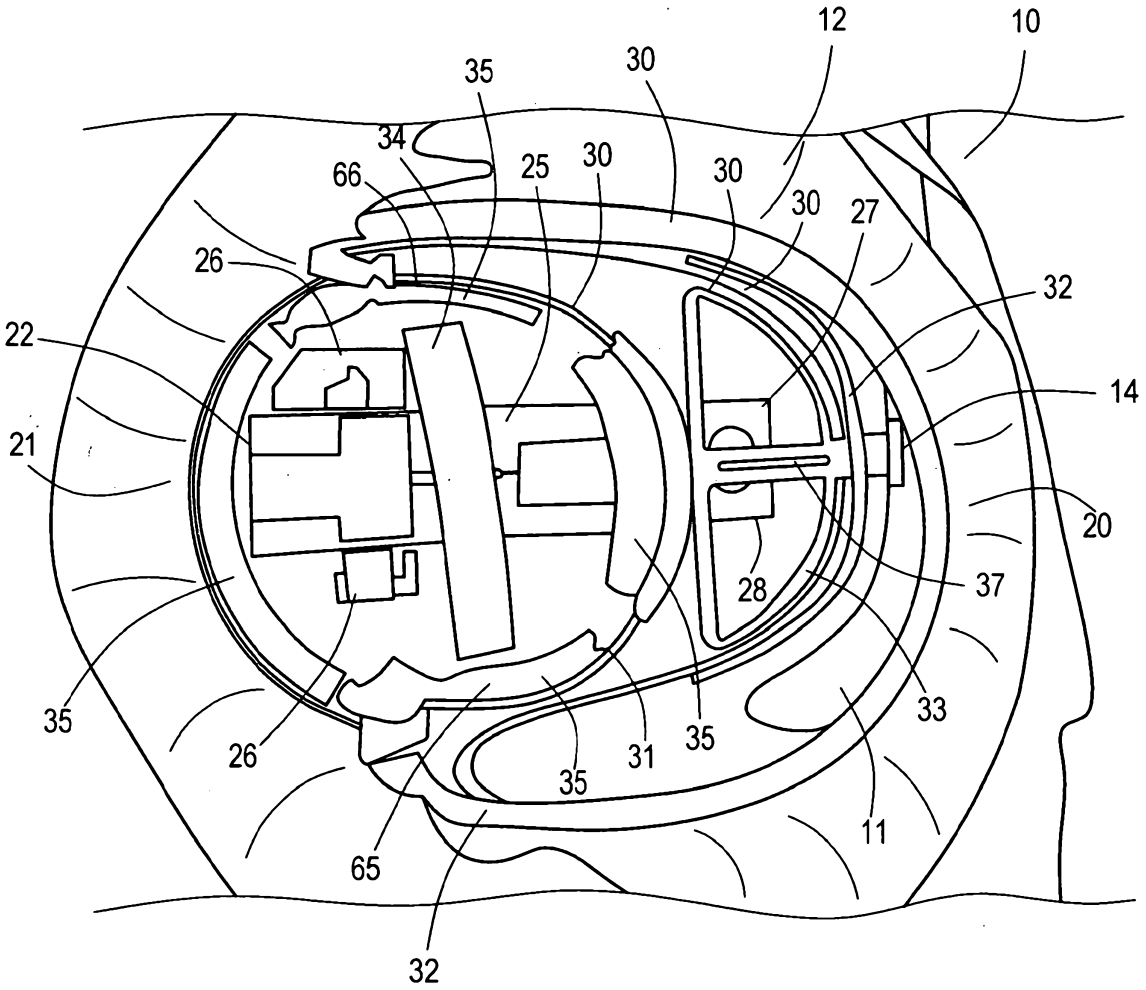

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FIG. 8

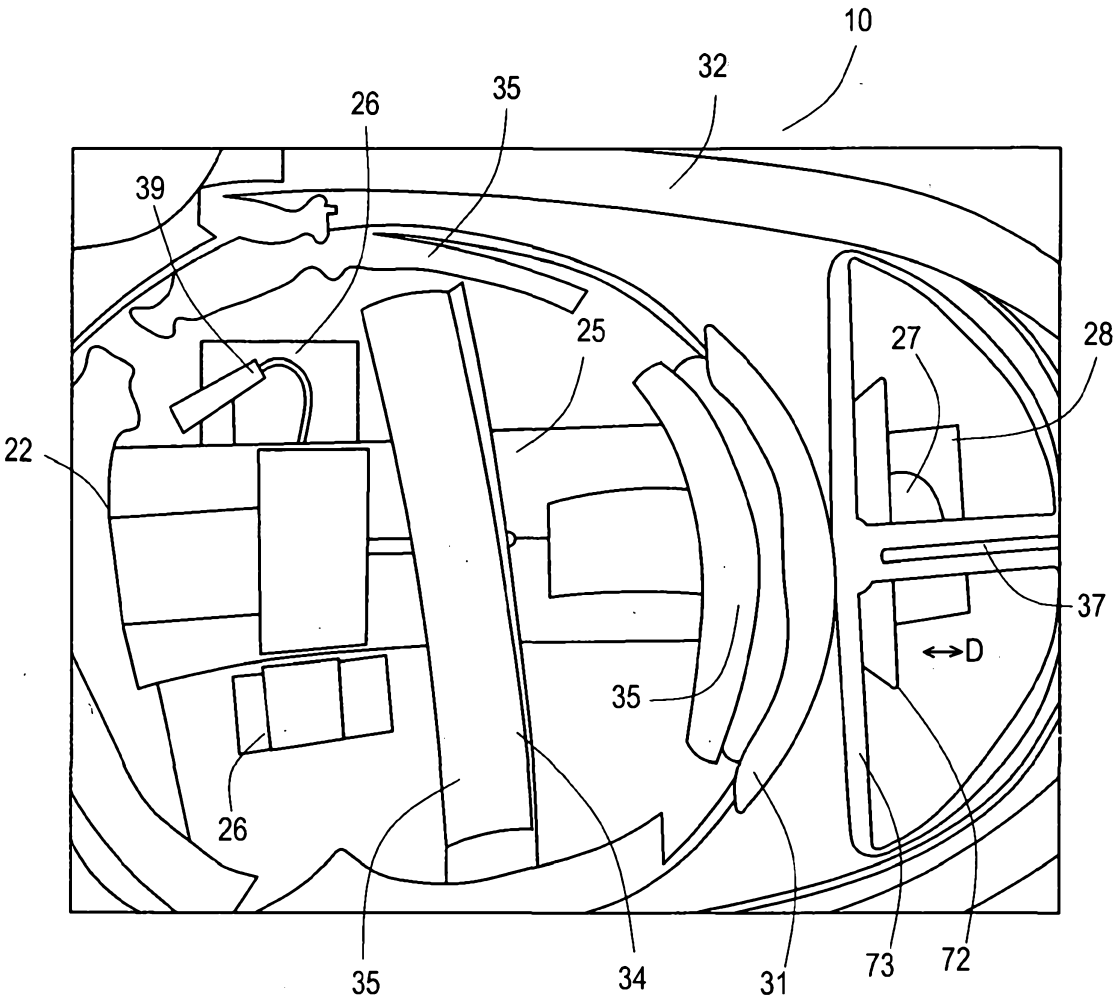

FIG. 9

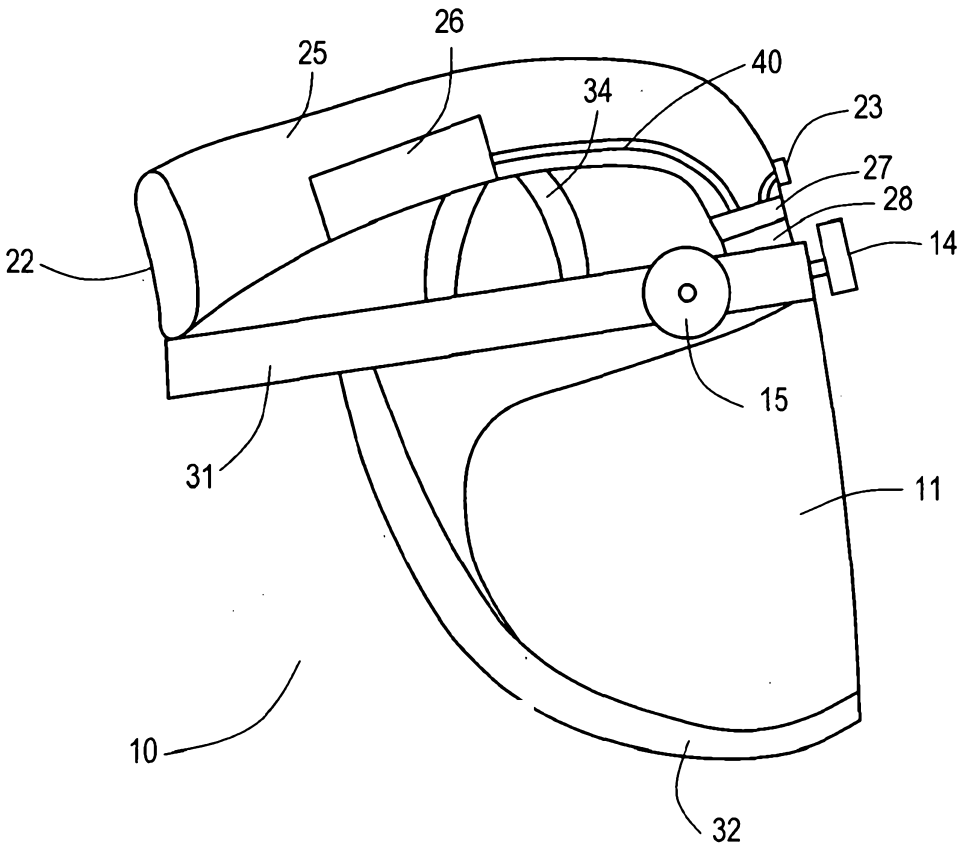

FIG. 10A

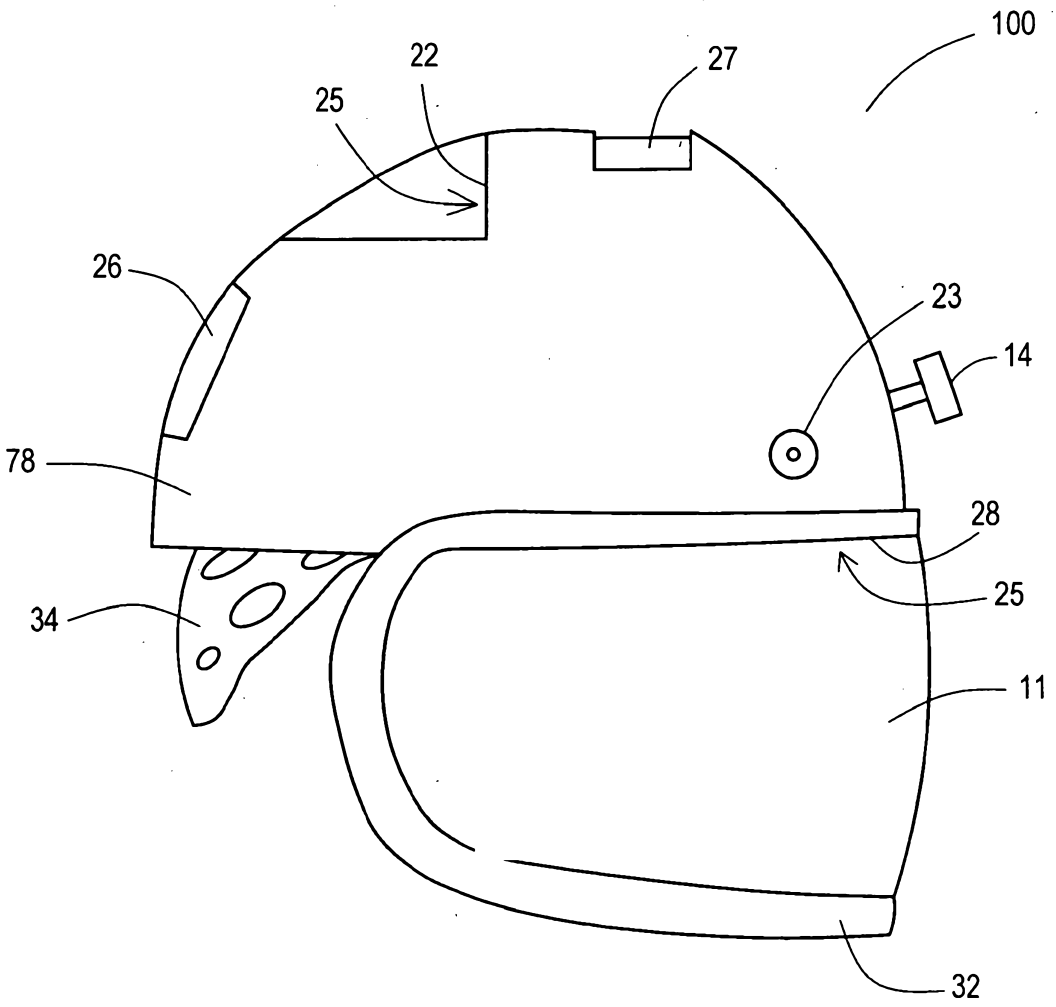

FIG. 10B

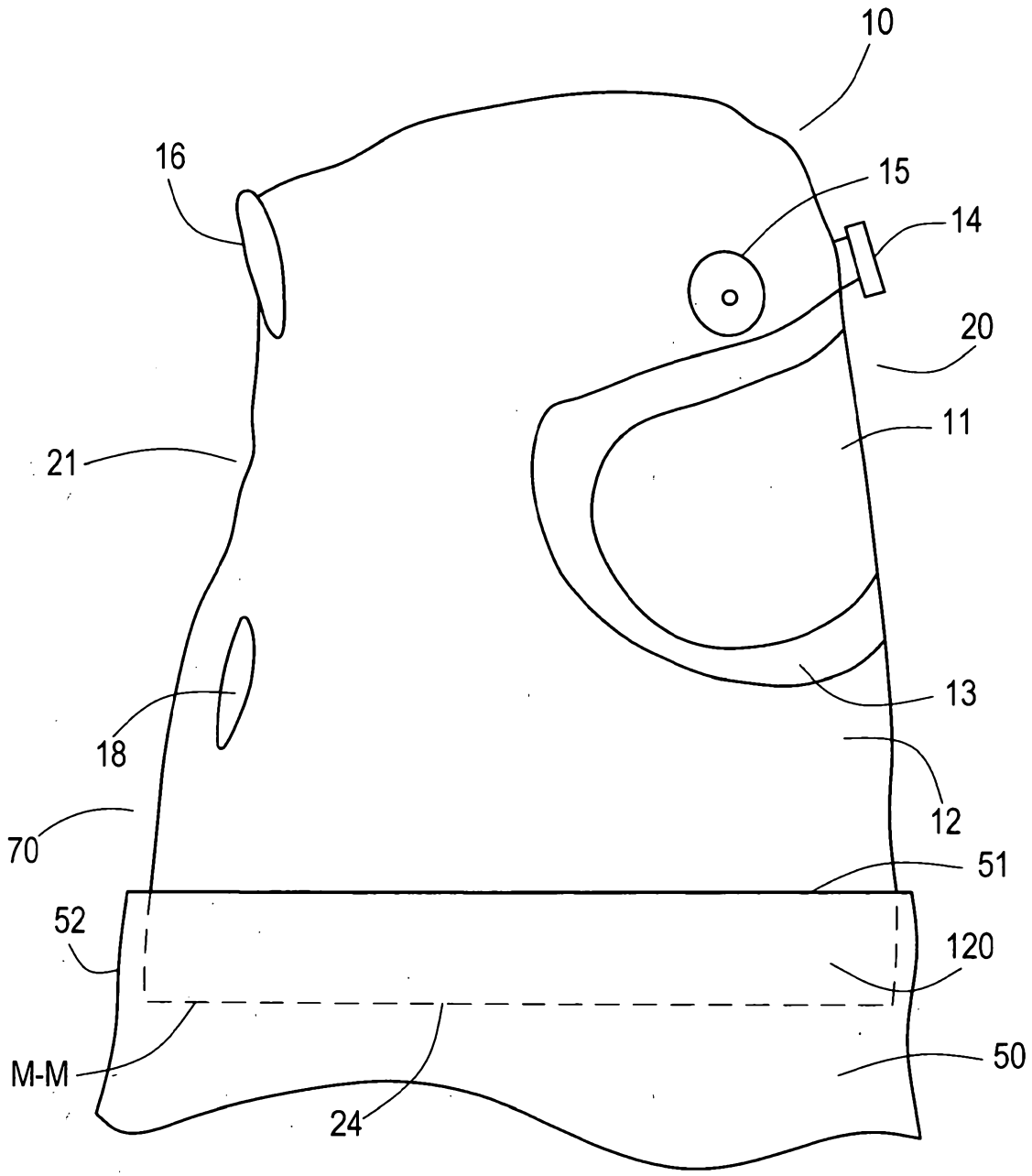

FIG. 11