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(54) **RESPIRATORY MASK**

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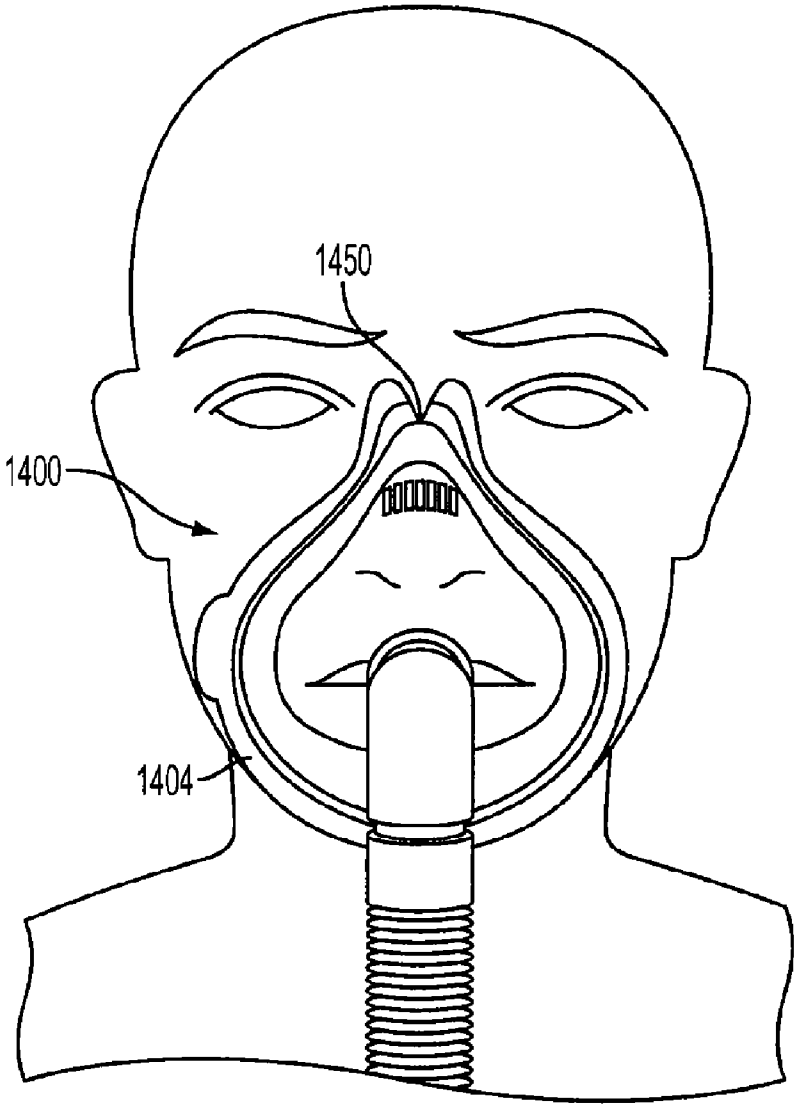
(57) **ABSTRACT**

A respiratory mask having a shell and a cushion that is adhered to a user's face is sufficiently rigid to provide dimensional stability and a constant volume between the respiratory mask and the user's face, while also being comfortable and conformable to a user's individual facial features. The respiratory mask may cover the nose, the mouth, or both of the user and is useful for respiratory therapies including sleep apnea. The respiratory mask may have a quick release mechanism such as a pull tab that tears a portion of the mask when pulled to allow access to the user's breathing passage or a pull string embedded in the adhesive that breaks the seal between the adhesive and the user's face when pulled.



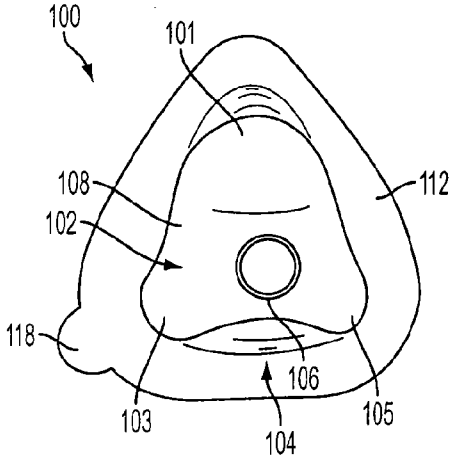


FIG. 1

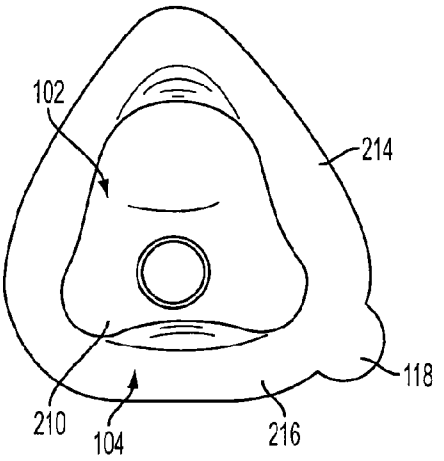


FIG. 2

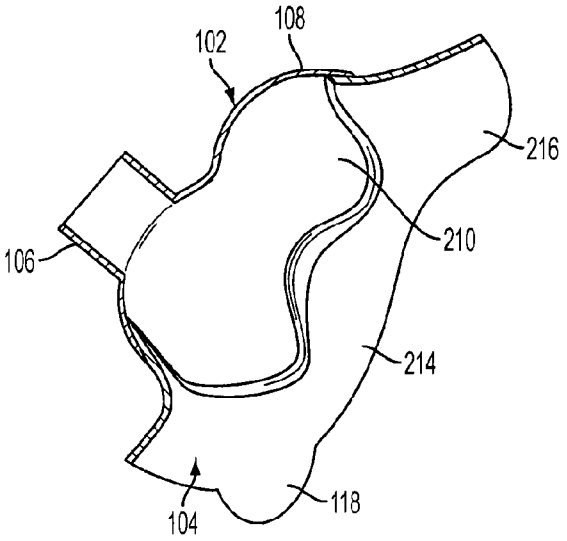


FIG. 3

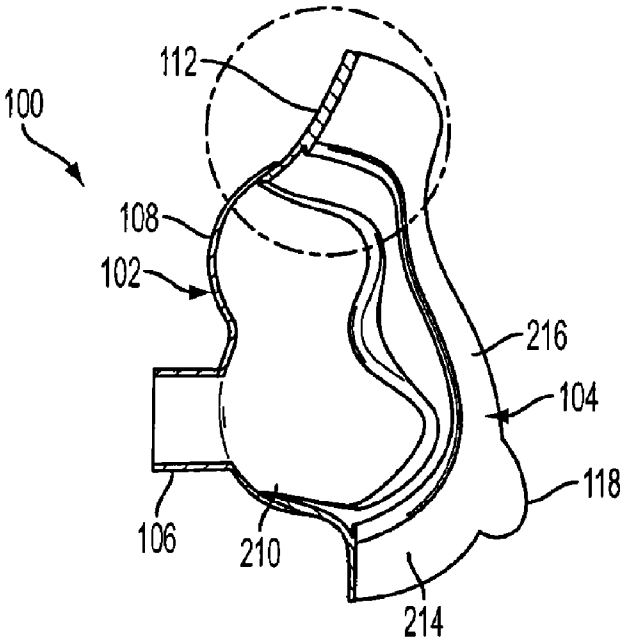

112
100
108
102
216
104
118
106
210
214

FIG. 4

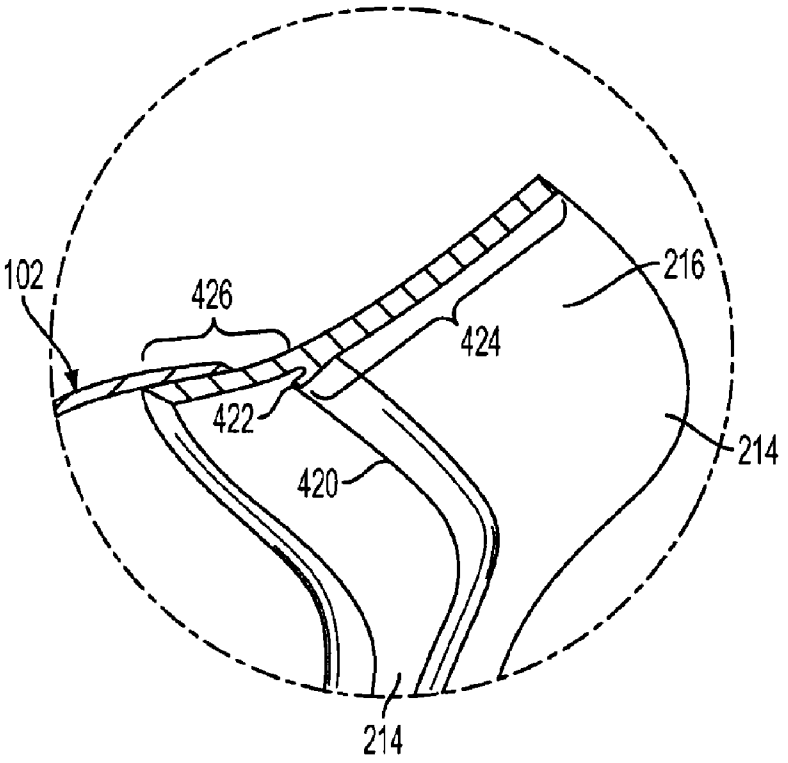

102
426
216
424
422
214
420
214

FIG. 4A

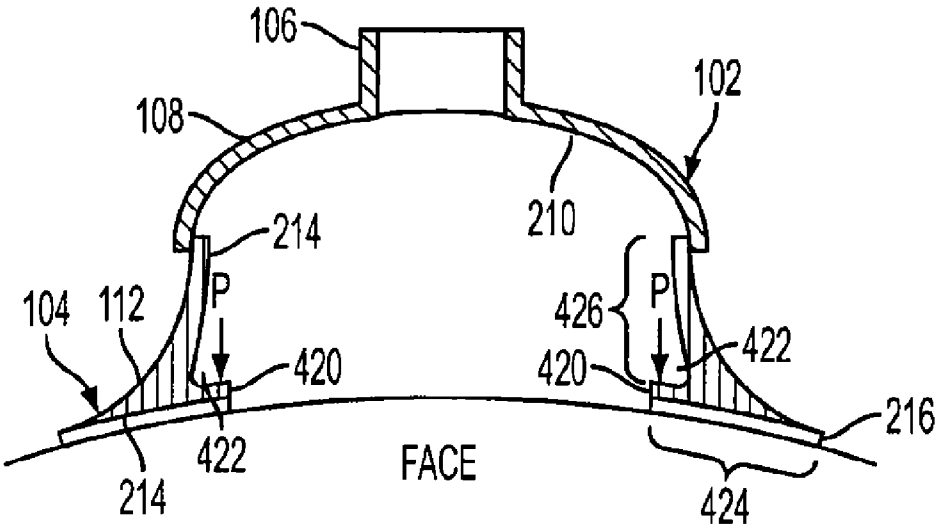

106
108
102
210
214
104
112
P
420
422
214
FACE
426
P
420
422
216
424

FIG. 4B

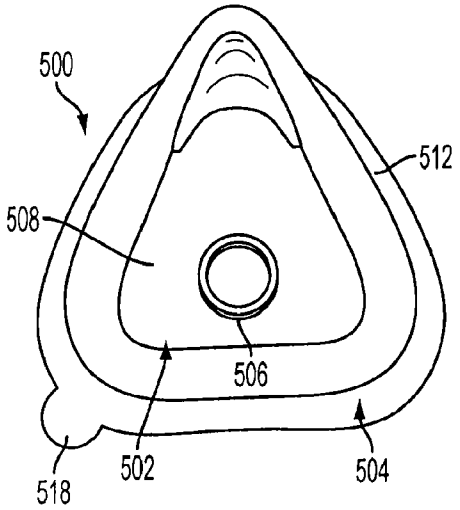


FIG. 5

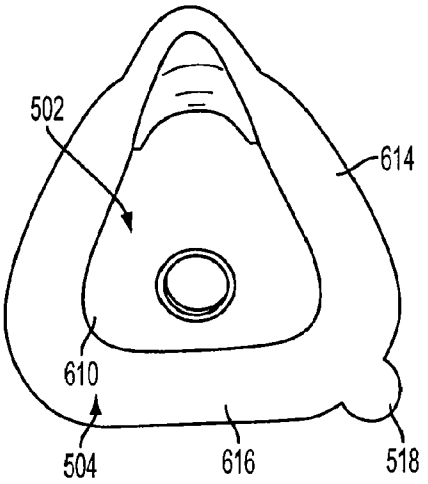


FIG. 6

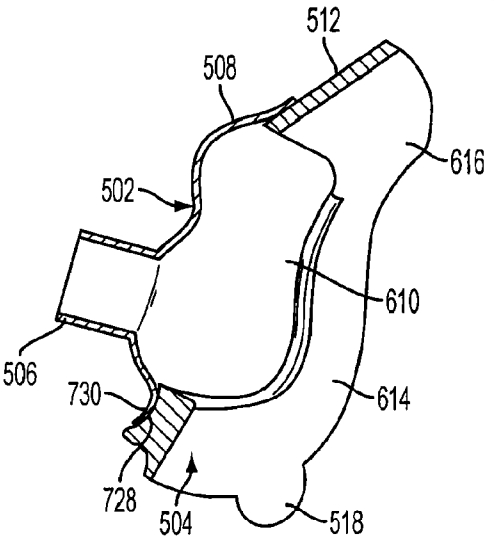


FIG. 7

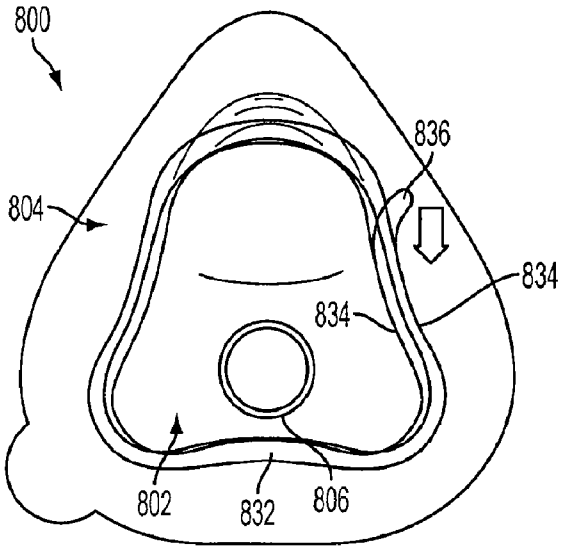


FIG. 8

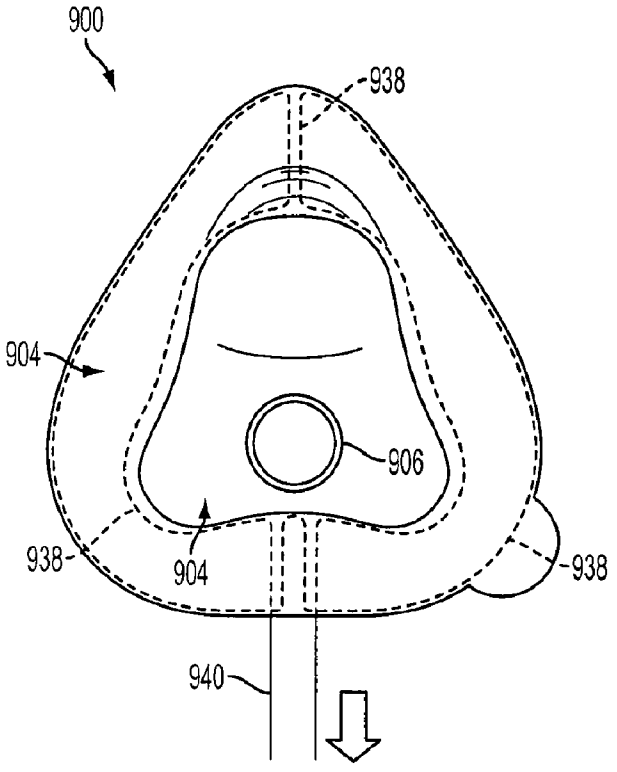


FIG. 9

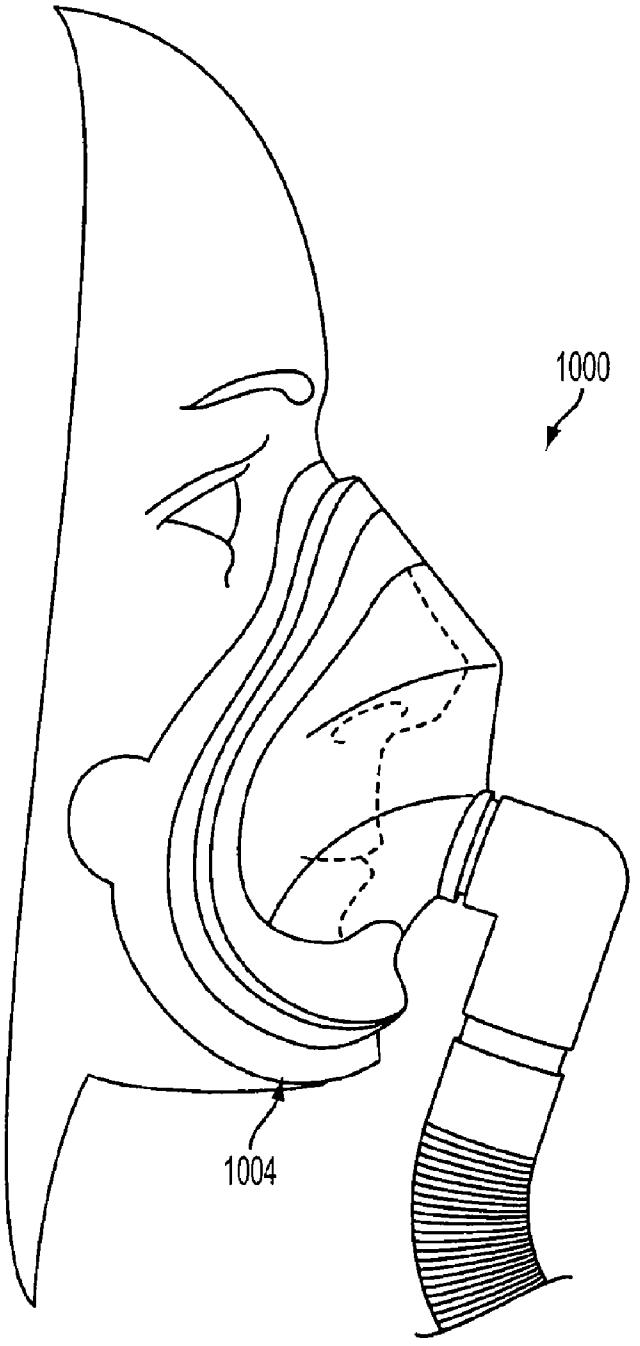


FIG. 10

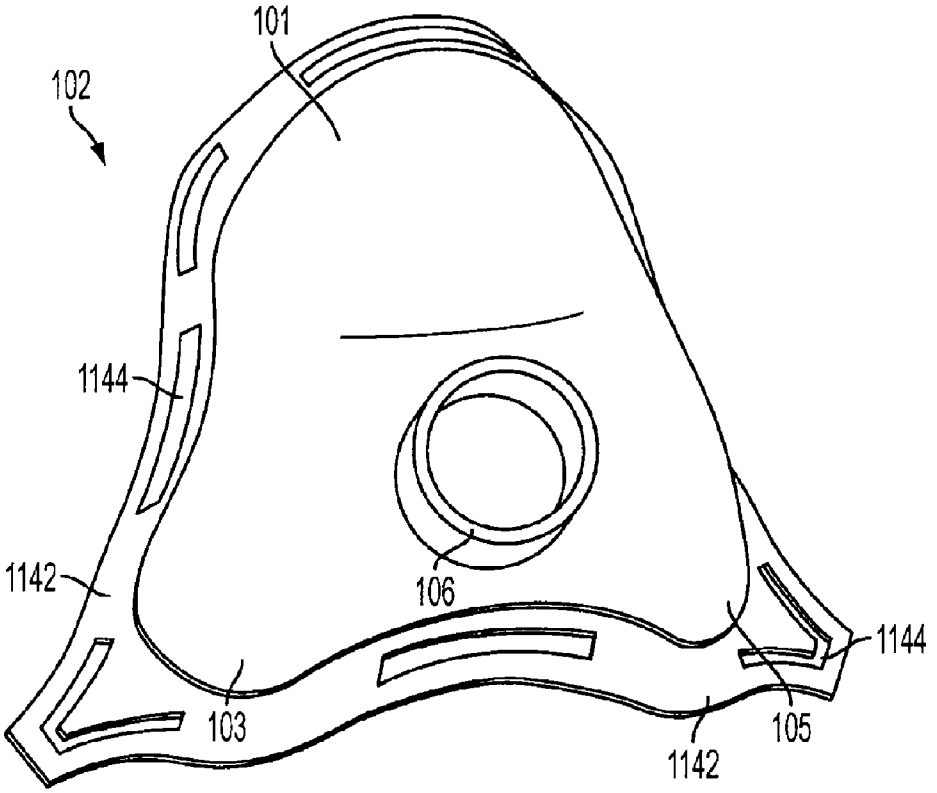


FIG. 11

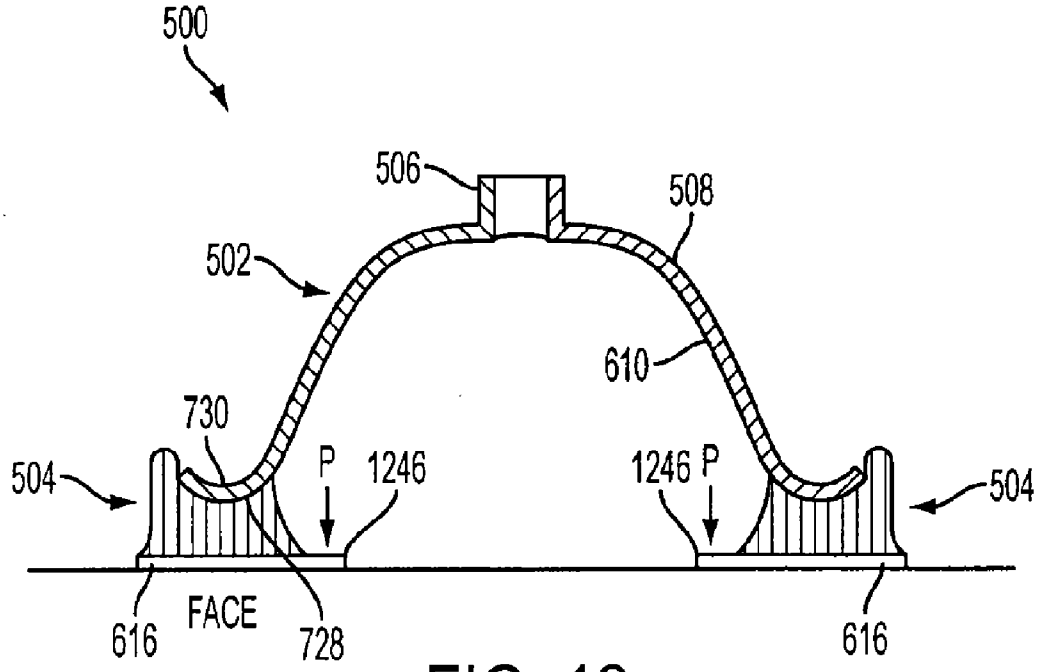


FIG. 12

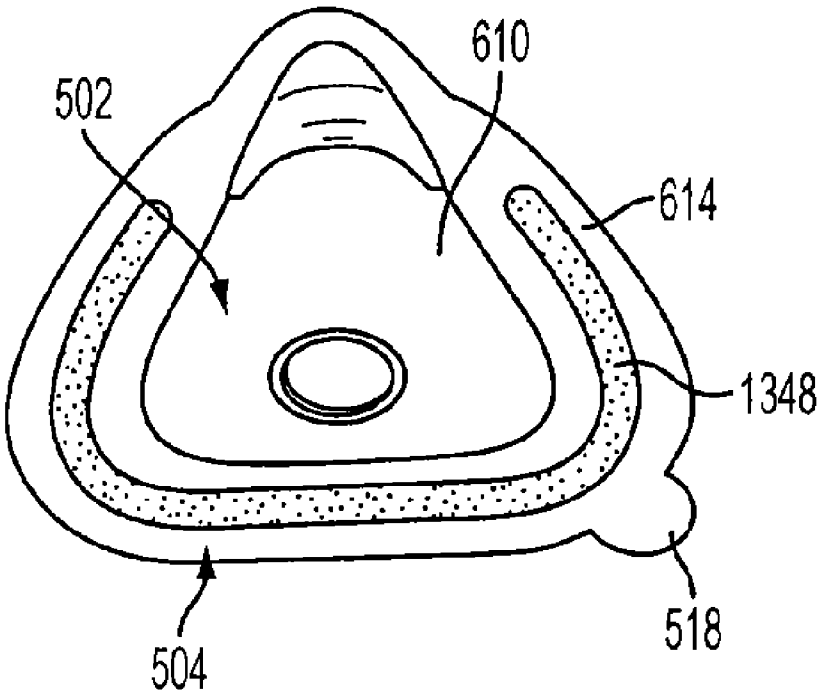


FIG. 13

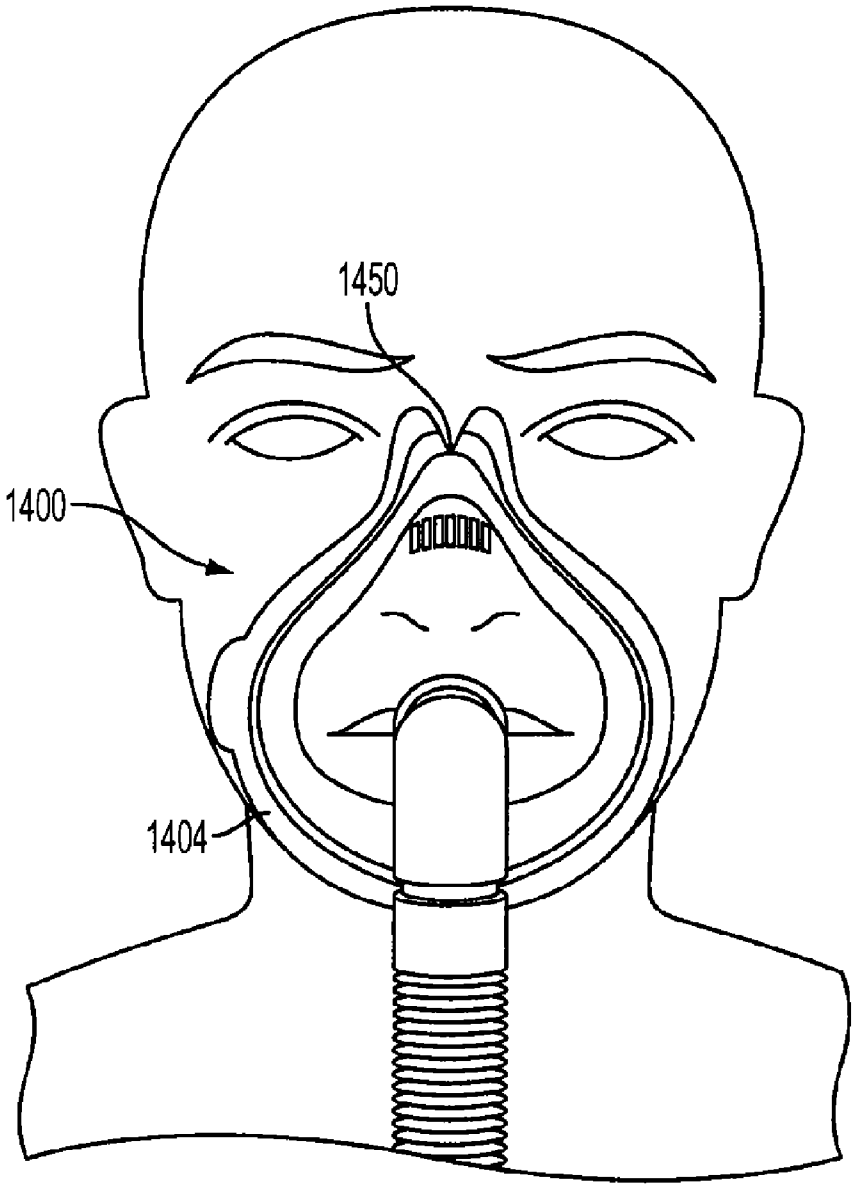


FIG. 14

RESPIRATORY MASK

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application contains subject matter which is related to co-pending U.S. patent application Ser. No. 11/405,948, titled "Method and System for Controlling Breathing," filed on Apr. 17, 2006 and U.S. application Ser. No. 11/787,854, titled "Method and System for Controlling Breathing," filed on Apr. 17, 2007, both of which are incorporated in their entirety by reference thereto.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention is directed to a respiratory mask.

[0004] 2. Background Art

[0005] Respiratory masks provide a gas or gases to a user in a variety of applications, including treatment of sleep apnea, anesthesiology, and to assist in breathing.

[0006] It is critical to many respiratory therapies to manage precisely the inhaled, mixed, and exhaled gases of a user, which may be achieved through a tight seal between the mask and the facial contours of the user. Leaks in the mask present a potential threat to anyone near the user as a result of leaked gases, and to the user himself for which specific amounts of gases and gas concentrations may be delivered based on the composition of gases assuming a tight seal. For example, when a respiratory mask is utilized in treating complex sleep apnea, a closed system is required to control the amount of carbon dioxide inhaled by the user.

[0007] In the past, a tight seal has been achieved through the use of straps and harnesses to pull the mask tightly against the user's face. Since facial geometries vary, the amount of force such straps and harnesses apply to generate an effective seal varies from person to person. In some instances, the force is so great it causes serious skin breakdown and damage to the face of the user as a result of reduced blood flow to the skin resulting from the pressing of the mask against the user's face. Therefore, it may be desirable to have a mask that conforms to a user's face and puts no pressure on the user's face while remaining safe and providing a sufficient seal.

[0008] Many respiratory therapies also have hoses and tubing connected to the mask to provide the gases. It may be desirable for the mask to be sufficiently rigid or stiff to provide a stable physical position and user perception of stability of the mask when in use, as the attached hoses and tubing may pull the mask in various directions. Stiffness and rigidity of the mask may also be important in maintaining a constant volume between the mask and the face of the user. For example, when a respiratory mask is utilized in treating complex sleep apnea, the mask is connected to a continuous positive airway pressure (CPAP) machine that provides positive air from the CPAP machine to the mask to help the wearer breathe consistently while sleeping. An important part of such a therapy is a closed system with a constant volume that controls the amount of carbon dioxide inhaled by the user.

[0009] A competing concern to the rigidity of a mask is its ability to conform to a user's individual facial features while providing comfort to the user. Compliance with continuous positive airway pressure therapy is reported to be less than 50% after one year, primarily as a result of mask discomfort. The ability of a mask to conform to a user's face comfortably is generally provided by a cushion. However, the cushion also serves to distribute forces applied to the mask such as pulling caused by the attached hoses and tubing, thereby limiting the degree of conformability and the degree of comfort. Therefore, it may be desirable to have a mask that is sufficiently rigid to provide stability and a constant volume, while also being comfortable and conformable to a user's individual facial features.

BRIEF SUMMARY OF THE INVENTION

[0010] Disclosed herein is a respiratory mask having a cushion shaped to surround a breathing passage of a user having a first surface and a second surface, an adhesive disposed on the first surface of the cushion to adhere the cushion to the face of the user, a shell disposed on the second surface of the cushion, a port formed in the shell, and a pull tab disposed on the respiratory mask. When the pull tab is pulled, at least a portion of the respiratory mask is torn to at least partially remove the portion to allow access to the breathing passage of the user.

[0011] Also disclosed herein is a respiratory mask having a cushion shaped to surround a breathing passage of a user having a first surface and a second surface, an adhesive disposed on the first surface of the cushion to adhere the cushion to the face of the user, a shell disposed on the second surface of the cushion, a port formed in the shell, and a string embedded in the adhesive. At least one end of the string is accessible to the user when in use such that when the user pulls the string, a seal between the adhesive and the user's face is broken and the respiratory mask may be easily removed.

[0012] Also disclosed herein is a respiratory mask having a cushion shaped to surround a breathing passage of a user having a first surface, a second surface, and a flange extending from the first surface of the cushion dividing the surface into a first section and a second section, an adhesive for adhering the cushion to the face of a user disposed on the first section of the first surface, a groove formed between the flange and the second section of the surface such that sheer forces are minimized when positive pressure is applied to the respiratory mask, a shell disposed the second surface of the cushion, and a port formed in the shell.

[0013] Also disclosed herein is a respiratory mask having a cushion shaped to surround a breathing passage of a user having a first surface and a second surface, an adhesive disposed on the first surface of the cushion to adhere the cushion to the face of the user, a shell disposed on the second surface of the cushion, and a port formed in the shell. The shell is sufficiently rigid to provide dimensional stability and a constant seal between said respiratory mask and a face of a user.

[0014] Also disclosed herein is a respiratory mask having a cushion shaped to surround at least the mouth of a user having a first surface and a second surface, an adhesive disposed on the first surface of the cushion to adhere the cushion to a user's face including the chin of a user to prevent a user's mouth from opening, a shell disposed on the second surface of the cushion, and a port formed in the shell.

BRIEF DESCRIPTION OF THE DRAWINGS/FIGURES

[0015] FIG. **1** is a front view of an exemplary respiratory mask.

[0016] FIG. **2** is a rear view of the exemplary respiratory mask of FIG. **1**.

[0017] FIG. **3** is a cross-sectional side view of one embodiment of the exemplary respiratory mask of FIG. **1**.

[0018] FIG. **4** is a cross-sectional side view of an alternative embodiment of the exemplary respiratory mask of FIG. **1**.

[0019] FIG. **4***a* is an enlarged view of the circled section of FIG. **4**.

[0020] FIG. **4***b* is a cross-section view of the exemplary respiratory mask of FIG. **4** when attached to the face of a user.

[0021] FIG. **5** is a front view of an alternative exemplary respiratory mask.

[0022] FIG. **6** is a rear view of the exemplary respiratory mask of FIG. **5**.

[0023] FIG. **7** is a cross-sectional side view of one embodiment of exemplary respiratory mask of FIG. **5**.

[0024] FIG. **8** is front view of an exemplary respiratory mask with a quick removal mechanism.

[0025] FIG. **9** is front view of an exemplary respiratory mask with an alternative quick removal mechanism.

[0026] FIG. **10** is a side view of an exemplary respiratory mask attached to the face of a user.

[0027] FIG. **11** is a perspective view of an exemplary shell.

[0028] FIG. **12** is a cross-sectional view of an alternative embodiment of exemplary respiratory mask of FIG. **5** when attached to the face of a user.

[0029] FIG. **13** is a rear view of an exemplary respiratory mask having an exemplary stiffening insert.

[0030] FIG. **14** is a front view of an exemplary respiratory mask having a notch in the cushion.

DETAILED DESCRIPTION OF THE INVENTION

[0031] Disclosed herein is a respiratory mask shaped to surround a breathing passage of a user, including the nose, the mouth, or both, that is tightly sealed to the user's face, preferably utilizing an adhesive.

[0032] As shown in FIGS. **1-3**, in one embodiment of the present invention a respiratory mask **100** includes a shell **102** disposed on a cushion **104**. Shell **102** may have a first surface **108** facing an exterior of mask **100** and a second surface **210** facing an interior of mask **100**. A port **106** may extend from first surface **108** of mask **100** to provide a connection for a hose or tubing connected to a CPAP machine, breathing machine, an anti-asphyxiation valve or other respiratory aid or therapy device. Shell **102** may be made of a rigid and transparent material including, but not limited to, polypropylene, polystyrene, and/or polycarbonate.

[0033] In certain embodiments of the present invention, it may be advantageous for the material of shell **102** to be sufficiently rigid to maintain a consistent interior volume of space in the interior of the mask **100** between mask **100** and the face of the user. Maintaining a consistent volume is critical to many respiratory therapies that require a constant volume in calculating the amount of drugs or gases delivered thereto. The constant volume may be, but is not limited to, less than about 100 ml. Shell **102** maintains its geometry despite externally applied forces to shell **102** such as when a user sleeps on his side or from shell **102** being pulled by hoses or tubes connected to port **106**. Shell **102** may have lobes **101**, **103**, and **105**, which when connected generally form the shape of a triangle, that provide structural stability to mask **100**.

[0034] In an embodiment of the present invention, the material of shell **102** may be transparent such that others may determine if the user (e.g. an elderly patient) is breathing or if the user has vomited into mask **100**.

[0035] Cushion **104** may have a first surface **112**, at least a portion of which contacts second surface **210** of shell **102** and/or first surface **108** of shell **102**, and a second surface **214**, at least a portion of which directly or indirectly contacts the skin of a user. A portion of second surface **214** of cushion **104**, which contacts the skin of a user may have an adhesive **216**. Adhesive **216** may be a medical adhesive including, but not limited to a pressure sensitive adhesive, such as, for example, 3M-1509 double sided medical tape available from 3M Co. St. Paul, Minn., that allows mask **100** to be sealed to a user's face without the use of straps that when tightened may exert high forces on the user's skin and cause discomfort and/or skin trauma. The strength of adhesive **216** may increase over time and may be able to adhere to a user's face for at least 8 hours. Cushion **104** may also have one or more tabs **118** that a user may grip to aid in peeling off or otherwise removing mask **100**. When adhesive **216** is a double sided tape, it may be adhered to cushion **104** first and then to the face of the user, or alternatively it may be applied to the face of the user first and then cushion **104** of mask **100** may be adhered to adhesive **216**.

[0036] The material for cushion **104** may be a soft and compliant material including, but not limited to, a thermoplastic elastomer or thermoplastic urethane, such that cushion **104** conforms to the user's facial contours. In this manner, cushion **104** may provide comfort to the user and maintain a proper seal while fitting a variety of facial contours without customization. Adhesive **216** and the compliant nature of cushion **104** may provide mask **100** with a substantially leak proof seal.

[0037] Shell **102** and cushion **104** may both be molded and may be co-molded utilizing standard techniques including, but not limited to, overmolding and two shot injection molding. When cushion **104** is overmolded onto shell **102**, shell **102** may have an outer flange **1142** extending from its periphery with a plurality of openings **1144**, as shown in FIG. **11**, such that cushion **104** may be molded around shell **102**. During the molding process, the material for cushion **104** would flow through openings **1144** in flange **1142** of shell **102** and engulf flange **1142**, thereby connecting shell **102** to cushion **104**.

[0038] Mask **100**, as shown in FIGS. **4** and **4***a*, may have a feature to prevent mask **100** from peeling off the face of the user as a result of sheer forces applied to the interior of mask **100**. Cushion **104** may have a flange **420** extending outward from second surface **214** of cushion **104**. Flange **420** may divide second surface **214** of cushion **104** into a first section **424** and a second section **426**. First section of **424** of second surface **214** of cushion **104** has adhesive **216** applied thereto and contacts the skin of the user. A groove **422** may be formed between flange **420** and second section **426** of second surface **214** of cushion **104**.

[0039] As shown in FIG. **4***b*, when mask **100** with flange **420** is applied to face of a user, an angle of groove **422** between flange **420** and second section **426** of second surface **214** of cushion **104** increases. When positive pressure is applied to an interior of mask **100**, the pressure may create a sheer force parallel to a line of tangency between the user's skin and cushion **104** that causes adhesive **216** on cushion **104** to shift and peel mask **100** from the user's face. However, when flange **420** is present, positive pressure P present in the area of groove **422** exerts a force on flange **420** normal to the skin of the user, forcing flange **420** and adhesive **216** thereon against the skin of the user, thereby reinforcing the seal of

mask **100** to the user's face. Flange **420** may have a tapered thickness such that it is thickest where connected to cushion **104** and thinnest at its edge. A tapered flange **420** allows flange **420** to flex against the skin of the user independent of a remainder of cushion **104**, which permits a force P to act normal to the face of the user thereby minimizing peeling forces that would separate the mask from the face. The pressure exerted on flange **420** normal to the face allows for an adhesive that may have lower adhesion properties and thus reduce any user discomfort that may occur if a more aggressive adhesive were necessary.

[0040] An alternative respiratory mask **500**, as shown in FIGS. **5-7**, may have a shell **502** disposed on a cushion **504**. Shell **502** may have a first surface **508** facing an exterior of mask **500** and a second surface **610** facing an interior of mask **500**. A port **506** may extend from first surface **508** of mask **500** to provide a connection for a hose or tubing connected to a CPAP machine, breathing machine, an anti-asphyxiation valve or other respiratory aid or therapy device. Shell **502** may be made of a rigid and transparent material including, but not limited to, polypropylene, polystyrene, and/or polycarbonate in order to have the same advantages as discussed above with reference to shell **102**. Shell **502** may have lobes (not shown) similar to lobes **101**, **103**, and **105** in shell **102**, which when connected generally form the shape of a triangle, that provide structural stability to mask **500**.

[0041] Cushion **504** may have a first surface **512**, a portion of which contacts second surface **610** of shell **502**, and a second surface **614**, a portion of which contacts the skin of a user. A portion of second surface **614** of cushion **504**, which contacts the skin of a user may have an adhesive **616**. Adhesive **616** may be a medical adhesive including, but not limited to a pressure sensitive adhesive, such as, for example, 3M-1509 double sided medical tape available from 3M Co. St. Paul, Minn., that allows mask **500** to be sealed to a user's face without the use of straps that when tightened may exert high forces on the user's skin and cause skin trauma. The strength of adhesive **616** may increase over time and may be able to adhere to a user's face for at least 8 hours. Cushion **504** may also have one or more tabs **518** that a user may grip to aid in peeling off or otherwise removing mask **500**. In one embodiment, adhesive **616** may comprise double sided tape. When adhesive **616** is a double sided tape, it may be adhered to cushion **504** first and then to the face of the user, or alternatively it may be applied to the face of the user first and then cushion **504** of mask **500** may be adhered to adhesive **616**.

[0042] The material for cushion **504** may be soft and compliant including, but not limited to, a foam, a thermoplastic elastomer, or thermoplastic urethane, such that cushion **504** conforms to the user's facial contours. When cushion **504** is a foam, the foam may be a substantially impermeable elastomer foam, for example a closed-cell, cross-linked polyester foam or may be a permeable elastomer foam, for example an open-cell foam. If an open-cell foam is utilized as the cushion, the exterior of the cushion may be sealed with a membrane of impermeable material including, but not limited to thermoplastic urethane or thermoplastic elastomer. Alternatively, a coating may be sprayed into a mold when forming an open-cell foam cushion to form a "skin" thereon. When cushion **504** is a thermoplastic elastomer or thermoplastic urethane, cushion **504** may be a solid molded material or may be a bladder made of thermoplastic elastomer or thermoplastic urethane filled with a fluid. In this manner, cushion **504** may provide comfort to the user and maintain a proper seal while fitting a variety of facial contours without customization. Adhesive **616** and the compliant nature of cushion **504** provides mask **500** with a substantially leak proof seal.

[0043] First surface **512** of cushion **504** may have a concave channel **728** formed thereon for receiving a flange **730** extending from a perimeter of shell **502**. An adhesive may be applied to channel **728** of cushion **504** or flange **730** of shell **502** to adhere shell **502** to cushion **504**. The adhesive used to bond shell **502** to cushion **504** may be weaker in strength than adhesive **616** used to bond mask **500** to the user's face such that shell **502** may be pulled apart from cushion **504** and cushion **504** remains sealed to the user's face, yet strong enough to maintain a tight seal between shell **502** and cushion **504** during operation. In an embodiment of the present invention, a portion of flange **730** of shell **502** may extend past cushion **504** to provide a grip for pulling shell **502** off of cushion **504**. The adhesives may be the same or different depending upon the materials of shell **502** and cushion **504**. In this manner, mask **500** may provide immediate access to a user's breathing passages if needed. Cushion **504** may then be removed at a later time. In such an instance, shell **502** may be utilized multiple times in conjunction with a plurality of single use cushions **504**. This feature may also be realized by having other mechanical interlocks between shell **502** and cushion **504** including, but not limited to, a zipper or hook and loop fasteners.

[0044] Flange **730** of shell **502** allows for shell **502** to be utilized in load distribution. Flange **730** may be substantially parallel to the user's skin such that any load or forces applied to shell **502**, such as pulling caused by hoses and tubing attached to port **506**, are distributed by flange **730**. This minimizes the amount of forces cushion **504** needs to distribute, thereby allowing cushion **504** to have greater conformability and to be more comfortable. Utilizing shell **502** with flange **728** also has an added benefit of minimizing the dead space (interior volume) of mask **500** giving mask **500** a lower profile, which may be more aesthetically pleasing to a user. Flange **730** may be shaped to apply to a flat surface of cushion **504** or to a curved channel **728** in cushion **504**. Curved channel **728** allows for increased rigidity of shell **502** around its perimeter by preventing bending of shell **502**. In addition, the increased rigidity of the perimeter of shell **502** gained through the combination of curved channel **728** and flange **730** allows shell **502** to act as a sling for the jaw of the user to keep the user's mouth in a closed or semi-closed position, as discussed in more detail below.

[0045] In an embodiment of the invention, flange **730** of shell **502** may also have a plurality of holes or perforations as discussed above with reference to FIG. **11** such that cushion **504** may be molded around shell **502**. During the molding process, the material for cushion **504** would flow through the holes in flange **730** of shell **502** and engulf flange **730** and thereby connect shell **502** to cushion **504**. In case immediate access is needed to a user's breathing passages, this arrangement may allow shell **502** to be ripped from cushion **504**, leaving cushion **504** connected to the user's skin. It is contemplated that the plurality of holes may be provided either with or without adhesives to provide the required connection between shell **502** and cushion **504**.

[0046] Mask **500**, as shown in FIG. **12**, may have a feature to prevent mask **500** from peeling off the face of the user as a result of sheer forces applied to the interior of mask **500**. Adhesive **616** may be in the form of a tape and extend inward past cushion **504** to form an adhesive flange **1246**. When

positive pressure is applied to an interior of mask **500**, the pressure may create a sheer force parallel to a line of tangency between the user's skin and cushion **504** that causes adhesive **616** on cushion **504** to shift and peel mask **500** from the user's face. However, when adhesive flange **1246** is present, positive pressure present in mask **500** exerts a force P on adhesive flange **1246** normal to the skin of the user, forcing adhesive flange **1246** against the skin of the user, thereby reinforcing the seal of mask **500** to the user's face.

[0047] As discussed above, it is sometimes necessary to quickly remove a respiratory mask in case of a medical emergency or panic attack, and slowly peeling an adhesive from the skin of a user is less desirable. FIG. **8** shows one mechanism for providing an emergency removal that may be incorporated into either mask **100** or mask **500**. Mask **800** may have a shell **802**, having a port **806**, disposed on a cushion **804**. Mask **800** may have a pull tab **832** disposed on mask **800**. Pull tab **832** may comprise a thin strip of material having two edges of perforation or weakness **834** thereon and an end **836**. When end **836** is grasped and pulled, lines of perforations or weakness **834** are torn, thereby removing pull tab **832** from mask **800**. Pull tab **832** may extend around a periphery of a portion of mask **800** to allow an entire piece of mask **800** to be removed providing access to the user's breathing passage(s) and leaving a remainder of mask **800** still adhered to the user's skin. Alternatively, pull tab **832** may extend about a portion of a mask **800** to allow a portion of mask **800** to be removed creating a flap which may be folded over to provide access to the user's breathing passage(s) and mask **800** remains adhered to the skin of the user.

[0048] Pull tab **832** may be formed in shell **802** or at an interface between shell **802** and cushion **804**. In such an instance, pull tab **832** may be the same material as shell **802**. Pull tab **832** may also be formed in cushion **804** when cushion **804** is a thermoplastic elastomer or thermoplastic urethane such as in cushion **104**. In such an instance, pull tab **832** may be the same material as cushion **104**.

[0049] FIG. **9** shows an alternative mechanism for providing an emergency removal that may be incorporated into either mask **100** or mask **500**. Mask **900** may have a shell **902**, having a port **906**, disposed on a cushion **904**. Mask **900** may have a string **938** embedded in at least a portion of adhesive **216** or **616**. String **938** may include a free end **940** which may be accessed while mask **900** is in use. When required, free end **940** of string **938** may be pulled, thereby causing string **938** to break the seal between adhesive **216** or **616** and the user's face such that mask **900** may be removed in its entirety. String **938** may extend around substantially an entire inner and outer border of adhesive **216** or **616**. The material for string **938** may be a lubricous material including, but not limited to, polytetrafluoroethylene, polyester, and nylon. Alternatively, string **938** may be coated in a medically safe and lubricous material, such as, for example, wax.

[0050] It is noted that while respiratory masks **100**, **500**, **800**, and **900** are shaped to surround a user's mouth and nose, respiratory masks that are shaped to surround only the mouth or only the nose are also within the scope of the present invention.

[0051] Embodiments of the present invention in which the mask surrounds a user's mouth may be shaped such that the mask may be adhered below the user's lower lip on his chin. This positioning of the respiratory mask keeps the mouth and jaw of the user in a more forward and natural position and in a closed or semi-closed position. As shown in FIG. **10**, respiratory mask **1000** is shaped to surround a user's mouth and nose and a lower portion of cushion **1004** rests on the chin of the user. There are many situations when keeping a patient's mouth closed in advantageous in the delivery of gases and in aiding ventilation. Many ventilation and gas therapies are more effective when delivered through the nose and keeping a patient's mouth closed reduces the pressure required for a CPAP machine when treating sleep apnea and reduces the amount of gases delivered. Keeping the mouth and jaw forward and in a closed or semi-closed position may improve the therapeutic value of breathing therapies for sleep apnea patients, as it increases airway caliber and decreases airway resistance in comparison to current appliances that use chin, head, or jaw straps and harnesses to keep the mouth closed through pulling the jaw backward, thereby restricting the airway. The use of adhesive to seal the mask to the user's face, the stiffness and geometry of the mask, and/or the use of the user's facial features keeps the mouth and jaw in this position without the use of cumbersome straps, harnesses, or chin supports.

[0052] Embodiments of the present invention, as shown in FIG. **13**, may have an insert **1348** for providing additional dimensional stability to mask positioned within a recess (not shown) on second surface **614** of cushion **504**. Insert **1348** may be flush with second surface **614** of cushion **1304** and an adhesive (not shown), such as a double sided tape similar to adhesive **616**, may be applied to second surface **614** of cushion **504** and insert **1348**. Alternatively, insert **1348** may be embedded within cushion **504**. Insert **1348** may comprise, for example, a strip of polyester. Insert **1348** may be stiff enough not to deform easily in the plane of the user's face while being sufficiently flexible in the plane normal to the face to lay comfortably on a variety of facial topologies. Insert **1348** may be horseshoe shaped to go under the mouth and up either side of the mouth and nose of the user, thereby providing a sling for the jaw to keep the user's mouth in the closed or semi-closed position as discussed above.

[0053] Embodiments of the present invention in which the mask surrounds the nose may be shaped such that when the mask is placed over the nose and adhered to the nose, the mask spreads the exterior nasal skin to open and keep open the nasal cavity to improve breathing.

[0054] Embodiments of the present invention, as shown in FIG. **14**, may include a mask **1400** having a cushion **1404** with a notch **1450** located in a region of cushion **1404** corresponding to the bridge of the nose of a user. Notch **1450** may be v-shaped and may be cut or molded into cushion **1404**. Material for cushion **1404** includes, but is not limited to, a foam, a thermoplastic elastomer, or a thermoplastic urethane. Notch **1450** provides a better fit around the nose of the user, lowers the profile of the mask, and when applied to the nose, creates a compound surface to increase the sealing surface area.

[0055] Embodiments of the present invention may increase compliance of a patient with his respiratory therapies because they are more comfortable than previous masks. Embodiments of the present invention may be lightweight to increase the user's mobility and to decrease the uncomfortable feeling of a heavy mask on the face, both of which increase compliance.

[0056] Respiratory masks of the present invention may be utilized in pressured, non-pressured, negative pressured environments as well as during alternating pulsing of positive and negative pressures.

[0057] Respiratory masks of the present invention may be discarded after each use to avoid the need to clean the mask after each use and may be manufactured in a cost effective manner so they are competitive and affordable in relation to reusable masks.

[0058] The foregoing description of the specific embodiments will so fully reveal the general nature of the invention that others can, by applying knowledge within the skill of the art, readily modify and/or adapt for various applications such specific embodiments, without undue experimentation, without departing from the general concept of the present invention. Therefore, such adaptations and modifications are intended to be within the meaning and range of equivalents of the disclosed embodiments, based on the teaching and guidance presented herein. It is to be understood that the phraseology or terminology herein is for the purpose of description and not of limitation, such that the terminology or phraseology of the present specification is to be interpreted by the skilled artisan in light of the teachings and guidance.

[0059] The breadth and scope of the present invention should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the following claims and their equivalents.

What is claimed is:

1. A respiratory mask, comprising:
- a cushion shaped to surround a breathing passage of a user, said cushion having a first surface and a second surface;
- an adhesive disposed on said first surface of said cushion to adhere said cushion to the face of the user;
- a shell disposed on said second surface of said cushion;
- a port formed in said shell; and
- a pull tab disposed on said respiratory mask wherein when said pull tab is pulled, at least a portion of said respiratory mask is torn to at least partially remove said portion to allow access to the breathing passage of the user.

2. The respiratory mask of claim **1**, wherein said pull tab is disposed on said shell.

3. The respiratory mask of claim **1**, wherein said pull tab is disposed on said cushion.

4. The respiratory mask of claim **1**, wherein said pull tab is disposed at an interface between said shell and said cushion.

5. The respiratory mask of claim **1**, wherein said shell is transparent.

6. The respiratory mask of claim **1**, wherein said adhesive is a double sided tape.

7. A respiratory mask, comprising:
- a cushion shaped to surround a breathing passage of a user, said cushion having a first surface and a second surface;
- an adhesive disposed on said first surface of said cushion to adhere said cushion to the face of a user;
- a shell disposed on said second surface of said cushion;
- a port formed in said shell; and
- a string embedded in said adhesive wherein at least one end of said string is accessible to the user when in use such that when the user pulls said string, a seal between said adhesive and the user's face is broken and said respiratory mask may be removed.

8. The respiratory mask of claim **7**, wherein said string is selected from the group consisting of polytetrafluoroethylene, polyester, and nylon.

9. The respiratory mask of claim **7**, wherein said shell is transparent.

10. The respiratory mask of claim **7**, wherein said adhesive is a double sided tape.

11. A respiratory mask, comprising:
- a cushion shaped to surround a breathing passage of a user, said cushion having a first surface, a second surface and a flange extending from said first surface such that positive pressure present in an interior of said respiratory mask exerts a force on said flange normal to the skin of a user, forcing said flange against the skin of a user, thereby reinforcing a seal of said respiratory mask to the face of a user;
- an adhesive for adhering said cushion to the face of a user disposed on said first surface;
- a shell disposed on said second surface of said cushion; and
- a port formed in said shell.

12. The respiratory mask of claim **11**, wherein:
- said flange is part of said cushion and divides said first surface of said cushion into a first section and a second section forming a groove between said flange and said second section of said first surface; and
- said adhesive is disposed on said first section of said first surface of said cushion.

13. The respiratory mask of claim **12**, wherein said flange is movable to change an angle of said groove between said flange and said second section of said first surface.

14. The respiratory mask of claim **11**, wherein said adhesive is a double sided tape and said flange is part of said adhesive that extends inward past said first surface of said cushion.

15. The respiratory mask of claim **11**, wherein said shell provides dimensional stability to maintain a constant volume between said respiratory mask and a face of a user.

16. The respiratory mask of claim **11**, further comprising an emergency removal mechanism.

17. The respiratory mask of claim **16**, wherein said emergency removal mechanism is a pull tab disposed on said respiratory mask wherein when said pull tab is pulled, at least a portion of said respiratory mask is torn to at least partially remove said portion to allow access to said breathing passage of the user.

18. The respiratory mask of claim **16**, wherein said emergency removal mechanism is a string embedded in said adhesive wherein at least one end of said string is accessible to the user when in use such that when the user pulls said string, a seal between said adhesive and the user's face is broken and said respiratory mask may be easily removed.

19. The respiratory mask of claim **11**, wherein said adhesive is a double sided tape.

20. A respiratory mask, comprising:
- a cushion shaped to surround a breathing passage of a user, said cushion having a first surface and a second surface;
- an adhesive disposed on said first surface of said cushion to seal said cushion to a user's face; and
- a shell disposed on a second surface of said cushion, wherein said shell is sufficiently rigid to provide dimensional stability and a constant volume between said respiratory mask and a face of a user; and
- a port formed in said shell.

21. The respiratory mask of claim **20**, wherein said constant volume is less than 100 ml.

22. The respiratory mask of claim **20**, wherein said shell comprises a flange extending around a perimeter of said shell such that said flange contacts said second surface of said cushion.

23. The respiratory mask of claim **22**, wherein said flange is substantially parallel to the skin of a user when said respiratory mask is sealed to the face of a user.

24. The respiratory mask of claim **22**, wherein said second surface of said cushion comprises a concave channel that receives said flange of said shell.

25. The respiratory mask of claim **24**, wherein said flange is substantially parallel to the skin of a user when said respiratory mask is sealed to the face of a user.

26. The respiratory mask of claim **20**, wherein said respiratory mask surrounds the nose of a user and said cushion has a notch corresponding to a region of said cushion that covers the bridge of the nose of a user.

27. The respiratory mask of claim **20**, wherein said respiratory mask surrounds the nose of a user and said cushion is shaped such that when said respiratory mask is placed over the nose and adhered to the nose, the mask spreads the exterior nasal skin to open and keep open the nasal cavity.

28. The respiratory mask of claim **20**, further comprising an emergency removal mechanism.

29. The respiratory mask of claim **28**, wherein said emergency removal mechanism is a pull tab disposed on said respiratory mask wherein when said pull tab is pulled, at least a portion of said respiratory mask is torn to at least partially remove said portion to allow access to said breathing passage of the user.

30. The respiratory mask of claim **28**, wherein said emergency removal mechanism is a string embedded in said adhesive wherein at least one end of said string is accessible to the user when in use such that when the user pulls said string, a seal between said adhesive and the user's face is broken and said respiratory mask may be easily removed.

31. The respiratory mask of claim **20**, wherein said adhesive is a double sided tape.

32. A respiratory mask, comprising:

a cushion shaped to surround at least the mouth of a user, said cushion having a first surface and a second surface;

an adhesive disposed on a first surface of said cushion to seal said cushion to a user's face including the chin of a user to prevent a user's mouth from opening;

a shell disposed on a second surface of said cushion; and

a port formed in said shell.

33. The respiratory mask of claim **32**, wherein said shell comprises a flange extending around a perimeter of said shell such that said flange contacts said second surface of said cushion.

34. The respiratory mask of claim **33**, wherein said flange is substantially parallel to the skin of a user when said respiratory mask is sealed to the face of a user.

35. The respiratory mask of claim **33**, wherein said second surface of said cushion comprises a concave channel that receives said flange of said shell.

36. The respiratory mask of claim **35**, wherein said flange is substantially parallel to the skin of a user when said respiratory mask is sealed to the face of a user.

37. The respiratory mask of claim **33**, wherein said cushion has a stiffening insert that acts as a sling for the jaw of the user.

38. The respiratory mask of claim **32**, wherein said respiratory mask surrounds the nose of a user and said cushion has a notch corresponding to a region of said cushion that covers the bridge of the nose of a user.

39. The respiratory mask of claim **32**, wherein said respiratory mask surrounds the nose of a user and said cushion is shaped such that when said respiratory mask is placed over the nose and adhered to the nose, the mask spreads the exterior nasal skin to open and keep open the nasal cavity.

40. The respiratory mask of claim **32**, wherein said shell provides dimensional stability to maintain a constant volume between said respiratory mask and a face of a user.

41. The respiratory mask of claim **32**, further comprising an emergency removal mechanism.

42. The respiratory mask of claim **41**, wherein said emergency removal mechanism is a pull tab disposed on said respiratory mask wherein when said pull tab is pulled, at least a portion of said respiratory mask is torn to at least partially remove said portion to allow access to said breathing passage of the user.

43. The respiratory mask of claim **41**, wherein said emergency removal mechanism is a string embedded in said adhesive wherein at least one end of said string is accessible to the user when in use such that when the user pulls said string, a seal between said adhesive and the user's face is broken and said respiratory mask may be easily removed.

44. The respiratory mask of claim **32**, wherein said cushion also surrounds the nose of a user.

45. The respiratory mask of claim **32**, wherein said adhesive is a double sided tape.

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