

surface portion can comprise at least one pair of grip surface portions substantially opposite one another.

5 **[0012]** In some such configurations, the support defines a mount for mounting the nasal seal to the frame. The mount can comprise a first member that is connectable to a second member, wherein the first member and the second member capture a portion of the seal body between them. The first member can be positioned within a cavity of the seal body and can comprise a sleeve portion that extends outwardly from the cavity. The second member can surround the sleeve portion of the first member.

10 **[0013]** In some such configurations, the stiffened regions are disposed in rearmost and lowermost sections of the side portions. The rearmost and lowermost sections of the side portions can flare outwardly relative to adjacent portions of the seal body.

15 **[0014]** In some such configurations, the one or more delivery openings comprise a first delivery opening and a second delivery opening. The nasal seal can further comprise a nostril locator associated with and forming a portion of each delivery opening, wherein a deflection region is defined within an annular transition portion between each of the nostril locators and a surrounding portion of the interior side. The deflection region has a lower stiffness relative to another region of the annular transition portion not within the deflection region.

20 **[0015]** In some such configurations, the lower stiffness is achieved by the deflection regions having a smaller thickness than the other regions of the annular transition portion. The deflection regions can be located on the outer sides of the nostril locators. The deflection regions can be limited to less than or equal to one-half of the annular transition portion.

25 **[0016]** In some such configurations, the central portion of the seal body defines a thinned region that permits forward movement of an upper portion of the interior side of the central portion as a result of rolling movement of the seal body.

30 **[0017]** In some configurations, a nasal seal configured to be removably coupled to a frame of a patient interface or a patient interface incorporating a seal includes a seal body formed of a soft flexible material and defining an inner cavity and one or more delivery openings for supply of breathing gases from the inner cavity to the patient. The seal body

[0082] Figure 30 is a more fully exploded perspective view of the interface assembly of Figure 29.

[0083] Figure 31 is a perspective view of the interface assembly of Figure 29.

[0084] Figure 32 is a sectioned view taken along the line 32-32 in Figure 31.

5 [0085] Figure 33 is a sectioned view taken along the line 33-33 in Figure 31.

[0086] Figure 34 is an enlarged view of a portion of Figure 33.

[0087] Figures 35-37 are views of a seal member of the interface assembly of Figure 29 illustrating material thicknesses of the proximal wall.

10 [0088] Figures 38-40 are views of the seal member illustrating material thicknesses of the distal wall.

[0089] Figure 41 is an enlarged view of a portion of the section of the seal member shown in Figure 33.

[0090] Figure 42 is a rear view of the seal member of the interface assembly of Figure 29.

15 [0091] Figure 43 is a sectioned view of another interface assembly that is arranged and configured in accordance with certain features, aspects and advantages of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

20 [0092] Figure 1 illustrates a patient interface 100 that is arranged and configured in accordance with certain features, aspects and advantages of the present invention. The interface 100 can be used to supply pressurized breathing gases to a recipient. The interface 100 is well suited for providing breathing gases to the recipient in situations where significant pressure changes are likely to be encountered. For example but without limitation, the
25 interface 100 can be used for delivering continuous positive airway pressure (CPAP).

[0093] With continued reference to Figure 1, the interface 100 is shown separate from a patient who would wear the interface 100. Some aspects of the patient interface 100, and variations on each aspect, have been described in U.S. Patent Application No. 12/945,141, filed November 12, 2010, which is hereby incorporated by reference in its
30 entirety. The interface 100 broadly comprises a mask 102. In some configurations, a strap

104 can attach to the mask 102 and can be used to secure the mask 102 to the patient. In some configurations, the interface 100 also comprises a flexible supply conduit 106 that can connect to the mask 102.

5 **[0094]** With continued reference to Figure 1 and with additional reference to Figure 2, the mask 102 is configured to fit over or overlies both nostrils of the patient. In some configurations, the mask 102 can include lateral portions 110 (see Figure 2) that are configured to curve around toward each lateral side of a nose of the patient. These lateral portions 110 can form a perimeter seal on outwardly facing surfaces of flanks of the nose. The strap 104 can pass around the user's head in a simple loop above the user's ears.

10 **[0095]** The flexible conduit 106 can depend from a central connection 112. In some configurations, the central connection 112 can be positioned at a frontal portion of the mask 102. The central connection 112 preferably comprises a swiveling elbow. The elbow can enable the flexible conduit 106 to pivot relative to the mask 102. By enabling pivoting, the elbow can help the interface 100 to better adapt to the sleeping position of the patient. In
15 some configurations, the central connection 112 may comprise a ball joint so that the elbow can pivot about axes parallel to and perpendicular to its connection with the mask 102.

[0096] The illustrated mask 102 generally comprises a seal 114 and a body or frame 116. The seal 114 and the frame 116 can be connected in any suitable manner.

[0097] The seal 114 preferably defines a supply pocket or envelope that can
20 contain a recess region. In some configurations, the seal 114 can comprise a low wall thickness and can be formed of any suitable material. For example but without limitation, the seal 114 can be formed of latex, vinyl, silicone or polyurethane. In some configurations, the wall thickness can be below about 0.5 mm and could be lower than about 0.2 mm in some regions and in some configurations. In some configurations, the seal 114 can be formed of a
25 material having sufficient elasticity and yield strength so that the combination renders the seal 114 supple. The seal 114 preferably is capable of withstanding repeated drastic deformations without failure.

[0098] With reference to Figure 3, the seal 114 preferably comprises one or two nostril locators 120. The nostril locators 120 can protrude from the seal 114. In some
30 configurations, the nostril locators extend generally upwardly and rearwardly from a proximal

wall 124 of the seal 114. In some configurations, the nostril locators 120 extend generally rearwardly from the proximal wall 124 of the seal 114.

[0099] In the configuration illustrated in Figures 1-3, the nostril locators 120 are formed integrally (i.e., in one monolithic piece) with the seal 114. Each nostril locator 120 can comprise an outlet aperture 118 through which gas can be supplied from the flexible conduit 106. In some configurations, the gas can be supplied from within the pocket or envelope defined by the seal 114. In other configurations, the gas that is supplied can be separate from the gas supplied to the pocket or envelope defined by the seal 114.

[0100] The seal 114 generally comprises a distal wall 122 and the proximal wall 124. An outer surface of the distal wall 122 preferably faces away from the user while an outer surface of the proximal wall 124 preferably faces the user. A rim 126 (see Figures 1 and 2) can connect an outer perimeter of the distal wall 122 and an outer perimeter of the proximal wall 124. The envelope or pocket described above can be defined within at least the distal wall 122 and the proximal wall 124.

[0101] The seal 114 preferably is designed to wrap around the tip or lower portion (e.g., locations below the bridge) of the user's nose. As such, the illustrated seal 114 comprises a central portion 128 (see Figure 1) positioned between side portions or wings 130. The central portion 128 can underlie the user's nose and preferably incorporates the nostril locators 120. In some configurations, the central portion 128 can extend upward over a tip of the user's nose. In other configurations, the central portion 128 does not extend upward over the tip of the user's nose. The wings 130 can form at least a portion of the lateral portions 110 discussed above. The wings 130 can be configured to extend completely or substantially completely over the sides of the user's nose and may extend at least partially over the user's cheeks.

[0102] As described above, at least a substantial portion of the seal 114 can be supple. For example, a region surrounding the nostril locators 120 can be more supple than at least a portion of the wings 130. At least the proximal wall 124 and the rim 126 of each side portion can be very supple so that they can expand to conform to the contours of the user's face, and in particular, to the contours of the outside flanks of the user's nose. Preferably, the supple portions of the seal 114 are of sufficient dimension and shape that,

to wear glasses while wearing the interface 100. Preferably, the frame 116 is formed from an elastomeric material, which will allow the frame 116 to flex to conform slightly to the face of the user. The frame 116, however, provides support for the seal 114. By providing support for the seal 114, the seal can be more effectively pressed into contact with the face and around the nose of the user. The frame 116 can be formed by injection molding, preferably from an elastomeric material, such as silicone or polyurethane, for example but without limitation. In some configurations, the frame 116 can be formed of more rigid materials, such as polycarbonate, polyester, polystyrene, or nylon, for example but without limitation.

[0107] In use, the portions of the supple proximal wall 124 that are above, below and to each side of the nostril locators 120 can be inflated by pressure inside the seal 114 (e.g., inflated from the flow of gases supplied to the patient interface 100) to press against the skin of the user and conform to contours of the outside surfaces of the nose of the user, to surfaces of the lower portion of the nose of the user and to surfaces of the upper lip of the user immediately below the nose. Movement of the mask 102 is not likely to significantly break this seal with the face because the supple perimeter or periphery of the seal 114 allows the mask 102 to move in all directions (other than directly away from the face) to at least a small extent. The supple portions of the seal 114 somewhat decouple the position of the nostril locators 120 from the position of the mask 102, which decoupling allows the mask 102 to displace somewhat in at least one or both of the lateral and vertical directions (i.e., lateral and vertical relative to axes of the patient's face). The wings 130 engage the sides of the user's nose and form an additional seal. The wings 130 also support the location of the mask.

[0108] With reference to Figure 4, when donning the interface 100, the mask 102 can be opened by spreading the wings 130 apart, which increases the angle between the wings 130. With the wings 130 having been pulled open, the nostril locators 120 (see Figure 3) that are positioned on the proximal wall 124 better present toward the user and guide the location of the mask 102 onto the face of the user. With the nostril locators 120 properly positioned, the mask 102 can be secured in position with the strap 104, which forms a loop around the head of the user at a location vertically higher than the ears. Other techniques for donning the interface also can be used.

some configurations, the material of the seal 114a, the frame 116a or the seal 114a and the frame 116a combined may be stiff enough to allow separation or spreading of the ends 146 of the seal 114a through manipulation of the pads 142 without including the cross member 152. By holding the arms 150 apart at a location between the pads 142 and the ends 146, depressing the pads 142 toward each other will result in the ends 146 moving apart from each other. In some configurations, the arms 150 can be joined together by a living hinge, by a rigid connection to a flexible cross member that elastically deforms or by a pin joint or the like.

[0113] By manipulating the shape of the uninflated seal 114a (e.g., by separating the ends 146 to alter how the seal 114a initially presents itself to the user), the seal 114a is opened for placement onto the face of the user. Once in place, the seal 114a can be inflated, which causes the seal 114a to swell around the nares of the user.

[0114] With reference now to Figure 7, another seal 114b is illustrated. The seal 114b has been provided with another seal manipulation configuration 140b. In the illustrated seal 114b, the seal manipulation configuration 140b can be attached to or integrally formed with a portion of the distal wall 122b. Preferably, the seal manipulation configuration 140b is positioned along the distal wall 122b along the lateral portions 110b or wings 130b.

[0115] The seal manipulation configuration 140b can take any suitable configuration. In some configurations, for example but without limitation, the seal manipulation configuration 140b comprises walls 154 that can define loops of material into which fingers can be inserted. In the illustrated configuration, the seal manipulation configuration 140b comprises pockets 156. Each of the pockets 156 can have a rim 160 at the distal end. The rim 160 can define an opening sufficiently large to receive a finger tip. The proximal end of each of the pockets 156 can be enclosed or open. In the illustrated configuration, the proximal end of each of the pockets 156 is enclosed.

[0116] In some configurations, a surface feature 158 can be provided adjacent to the opening defined by the rim 160. The surface feature 158 can be a recess or a surface texture. The surface feature 158 can be positioned just forward of the opening to guide fingers into a desired location. The surface feature 158 can provide additional clearance to facilitate insertion of the fingers.

formed from more than one component, the seal 114e otherwise can be configured generally in the same manner as the seal 114 shown in Figures 1-4 and described above. For example, the seal 114e can be configured with more supple and less supple regions similar to the seals disclosed above.

5 **[0126]** The nasal insert 190 comprises at least one nostril locator 194. The nostril locators 194 can sit atop a main body 196. In the illustrated configuration, two nostril locators 194 are integrally formed with the main body 196. In some configurations, the two nostril locators 194 can be separable from the main body 196.

10 **[0127]** The main body 196 comprises a plug portion 200 and the seal member 192 comprises a socket portion 202. The plug portion 200 can be received within the socket portion 202 as indicated by the arrow in Figure 10. In some configurations, the plug portion 200 locks into position within the socket portion 202. In some configurations, the plug portion 200 is secured by a friction fit within the socket portion 202. Other suitable techniques for securing the plug portion 200 and the socket portion 202 can be used.

15 **[0128]** A distal end 204 of the main body 196 comprises an inlet opening and, proximally of the inlet opening, the main body 196 comprises one or more openings 206. The inlet opening can be connected to the flexible supply conduit 106. The seal member 192 comprises one or more internal voids or openings 208 and, when the plug portion 200 is positioned within the socket portion 202, the one or more internal voids or openings 208 can be in fluid communication with the one or more openings 206. Thus, in the configuration of Figure 10, the gases flow from the flexible conduit, into the nasal insert 190 and a portion of the gases flow from the nasal insert 190 into the seal member 192 while a portion of the gases flow from the nasal insert 190 through the nostril locators 194 to the user.

20 **[0129]** With reference to Figure 11, a nasal insert 190a and a seal member 192a can combine to define a mask. The nasal insert 190a can have an inlet at a plug portion 200a, which is located at a distal end of the nasal insert 190a. The inlet can be formed by the plug portion 200a. The seal member 192a, however, can have a distal inlet (not shown) that connects directly to a supply conduit (i.e., connects to the supply conduit rather than receiving flow from the nasal insert 190a) and an outlet that connects to the nasal insert 190a.

25 The nasal insert 190a may include but does not require the openings used in the configuration

30

of Figure 10. Thus, in the configuration shown in Figure 11, gases are supplied to the seal member 192a first and the seal member 192a passes the gases on to the nasal insert 190a through the inlet at the distal end of the nasal insert 190a prior to the nasal insert 190a passing the gases from the nasal insert 190a to the nostril locators 194a.

5 **[0130]** With reference now to Figure 12, a further multi-piece seal construction will be described. The multi-piece construction enables customization of the seal to the user. For example, different size nostril locators can be used with a universal seal member or different size seal members. In addition, nostril locators having differing stiffness or rigidity can be used and/or seal members with different levels of stiffness can be used. In some
10 configurations, the seal member and the nostril locators can be formed of the same material. In some configurations, the seal member and the nostril locators can be formed of differing grades of the same material.

[0131] The seal member 192b shown in Figure 12 comprises one or more outlet openings 208 formed on a proximal surface. In the illustrated configuration, the seal member
15 192b comprises two openings 208 that receive individual nostril locators 210. The openings 208 can define sockets while distal ends 212 of the nostril locators 210 can define plugs. As illustrated in Figure 12, the distal ends 212 fit into the openings 208. The nostril locators 210 can be connected to the seal member 192b in any suitable manner. In some configurations, the nostril locators 210 can be friction fit into the openings 208. In some configurations, the
20 distal ends 212 and the openings 208 can be configured to connect in only one rotational orientation. In some configurations, the rotational orientation can be varied to customize the fit of the nostril locators 210. In some configurations, the relative rotational orientation between the openings 208 and the nostril locators 210 can be indexable such that the two can be rotationally adjusted and secured in a desired rotational position.

25 **[0132]** With reference now to Figure 13, a seal 214 is illustrated that features a separable nasal insert 216 and seal member 218. The seal 214 can be similar to the construction of any of the configurations described above. In some configurations, however, the nasal insert 216 comprises an auxiliary component 220. As illustrated in Figure 13, the auxiliary component 220 can be positioned between the one or more nostril locators 222 and
30 a base 224 of the nasal insert 216. In some configurations, a rim 230 can encircle the one or

more nostril locators 222 and the auxiliary component 220 can be positioned between the rim 230 and the base 224. In some configurations, the rim 230 can be positioned between the one or more nostril locators 222 and the auxiliary component 220. In the illustrated configuration, the base 224 of the nasal insert 216 can comprises one or more opening 226 but need not.

[0133] The seal member 218 can be supplied, as described above. In the illustrated configuration, the seal member 218 comprises an opening 228 that receives at least a portion of the nasal insert 216. The opening 228 and the auxiliary component 220 are supplied enough to enable the auxiliary component 220 of the nasal insert 216 to be inserted into the pocket defined within the walls of the seal member 218. In some configurations, the opening 228 seals about a portion of the nasal insert 216 between the auxiliary component 220 and the rim 230.

[0134] The rim 230 and the auxiliary component 220 can be separated by a gap, a recess, a channel, or a groove, for example but without limitation. The seal member 218 can include a lip that is received within the gap, recess, channel or groove that can be defined between the rim 230 and at least a portion of the auxiliary component 220. In other words, the auxiliary component 220 can overlie, and can be separated from, at least a portion of the rim 230. The gap between the auxiliary component 220 and the rim 230 can be sized and configured to receive at least a portion of the seal 214. In this manner, the seal member 218 and the nasal insert 216 can be secured together, for example but without limitation. Moreover, in the illustrated configuration, the seal member 218 and the nasal insert 216 can be sealed together.

[0135] With reference now to Figures 14A-14D, a sampling of different constructions of auxiliary components will be described. A nasal insert 216a is shown in Figure 14A in which the auxiliary component 220a comprises a slightly curved blade member 232. The blade member 232 extends laterally outward beyond the nostril locators 222a and laterally outward beyond an outermost extent of the rim 230a that generally encircles the nostril locators 222a. The blade member 232 can be formed integrally with the nasal insert 216a or can be formed separate of the nasal insert 216a and secured thereto in any suitable manner. In some configurations, the blade member 232 is formed of silicone. The blade

The auxiliary component 220d can comprise a dish member 238 that is stable in the first position P1 and in the second position P2. In some configurations, the dish member 238 can flip between the first position P1 and the second position P2 but will return to the first position P1 with the application of minimal force. As shown in Figure 14D, the dish member 238 can be flexed into the second position P2 for donning of the mask. With the dish member 238 in the second position P2, the seal member 218d can be held in the open position. Once positioned as desired on the user, a slight urging of the dish member 238 toward the face of the user causes the dish member 238 to pop back into the first position P1, which allows the seal member 218d to move to a more closed position.

[0142] Accordingly, to don the mask with the assembly illustrated in Figure 14D, the dish member 238 can be flexed from the first position P1 to the second position P2. The dish member 238 temporarily is stabilized in the second position as the mask is being positioned such that the nostril locators 222d can be positioned within the nostrils of the user. As the mask is brought into engagement with the face of the user, the forces applied through the seal member 218d transfer to the dish member 238, which pops back or otherwise returns to the first position P1. With the dish member 238 in the first position, the seal member 218d can close around the tip of the nose of the user, which allows the mask with the assembly illustrated in Figure 17 to seal around the tip of the nose of the user.

[0143] With reference now to Figure 15A, a portion of a seal member 250 is shown. The seal member 250 can be configured in accordance with any combination of features of any of the constructions described within this specification, for example but without limitation. The seal member 250 can comprise a distal wall 252 and a proximal wall 254. An opening 256 can be defined within the distal wall 252. A supply of gases can pass into the seal member 250 through the opening 256.

[0144] As shown in Figure 15A, the distal wall 252 can have a thicker cross-section, for example, relative to the proximal wall 254. The thicker cross-section provides increased rigidity to the distal wall 252 relative to the proximal wall 254. In some configurations, the thickness of the walls can be the same while the material used has an increased rigidity. In some configurations, both the thickness and the rigidity of the material can be used to provide differing degrees of rigidity.

[0145] In the illustrated configuration of Figure 15A, a nostril locator 260 can be positioned along the proximal wall 254. The illustrated nostril locator 260 can generally taper such that it narrows toward a proximal opening 262. As such, the proximal opening 262 may have a smaller diameter than a distal opening into the nostril locator 260. Generally speaking, the nostril locator 260 can taper in a proximal direction.

[0146] To improve lateral stability of the mask assembly, outriggers or other support structures can be used. In the configurations illustrated in Figures 15A-15D, however, the support structures are shown integrated into the structure of the seal member 250 itself. With reference to Figures 15A-15C, a support structure 270 is shown that is integrated into the seal member 250. With the integrated support structure 270, the mask is more comfortable than other masks that might use separate support structures that are more rigid than the seal member. Moreover, because the support structure 270 can be directly adjacent to the user's face, the integrated design provides for better support to the sealing member 250.

[0147] The illustrated support structure 270 can be one or more thickened regions. For example, where the seal member 250 is formed of silicone, the support structure 270 can be a thickened region of silicone. In some such configurations, the support structure 270 can be molded into the seal member 250. In some configurations, foam could be injected or inserted into the support structure 270. For example, in some such configurations, the support structure 270 can be formed with a hollow region (or material could be removed) and the region can be filled with any desired gel or foam substance. In some configurations, the support structure 270 can be formed of silicone and the hollow region can be filled with a different grade of silicone. Such composite support structures can reduce the weight of the seal and mask assembly.

[0148] By molding the support structure 270 into the seal member 250, the support structure can flex with the seal member 250. Flexing of the seal member 250 allows the seal member 250 to better fit different face shapes. Additionally, the support structure 270 can move with the seal member 250 and the seal member 250 can sit closer to the face. Furthermore, integration of the support structure 270 into the seal member 250 simplifies manufacture of the mask because, by integrating the support structure 270 into the seal

locators away from the nares on flatter user face profiles. To help provide improved flexibility, the seal member 280 can be reinforced in regions closer to the nose compared to the cheeks.

[0152] With reference to Figure 16, the seal member 280 can comprise a marginal surface 292 that connects the proximal wall 284 to the distal wall 282. The marginal surface 292 in the illustrated configuration is wider at the bottom than at the top. As illustrated, the marginal surface can provide a wider portion on the bottom of the illustrated seal member 280. The seal member 280 can have a thicker wall in the bottom corners while the proximal wall 284 can have a reduced thickness in the region surrounding or at least partially surrounding the nostril locators 286. The thicker region of the bottom corners can extend upward and follow the generally vertical line illustrated in Figure 17.

[0153] While a majority of the entire seal member 280 can be configured to balloon, the thicker regions can be configured to balloon less than the regions with a reduced thickness. The thicker regions can help control ballooning such that the proximal surface experiences a majority of the ballooning compared to the marginal surface 292 and the distal surface 282. Thus, the region surrounding the nostril locators 286 can balloon more while the lower corners balloon less, which increases comfort and improves sealing of the mask.

[0154] With reference again to Figure 3, the nostril locators 120 typically are configured to be positioned within the nares. In order to fit within the nares of the user, the nostril locators 120 can be stiff enough to resist crushing during fitting and use. As such, the proximal ends of the nostril locators 120 have been discovered to slightly pinch the septum or otherwise reduce the comfort of the user. Accordingly, removing some of the rigidity of the nostril locators 120, and especially of the proximal ends of the nostril locators 120 and/or in a transition location between the nostril locators 120 and surrounding structure (described below with reference to Figures 29-42), can be desirable.

[0155] With reference now to Figure 19, a sealing member 300 is shown in cross-section. A nostril locator 302 is shown extending from a proximal surface 304. The nostril locator 302 can include an opening 306. In the illustrated configuration, the opening 306 can be defined by a rim 308. The rim 308 preferably includes at least one interruption 310. With reference to Figure 19, the illustrated interruptions 310 comprise a larger opening 312 that is

connected to a slot 314 that intersects with the rim 308. In the illustrated configuration, the rim 308 includes two interruptions 310. The interruptions 310 are positioned to be at the top and the bottom of the opening 306 in the illustrated configuration. In other words, when positioned in the nares of the user, the interruptions 310 facilitate flexure in a lateral direction in the configuration illustrated in Figure 19.

[0156] In some configurations, the rim 308 that defines the opening 306 is generally elliptical and includes a longer axis L1 and a shorter axis L2, as shown in Figure 19. In such configurations, the interruptions 310 can be intersected by the longer axis L1. In some configurations, one or more interruption 310 can be positioned along the portion of the rim 308 that is above the shorter axis L2. For example, a single interruption 310 can be positioned on the upper side of the shorter axis L2. In some such configurations, the single interruption 310 can be positioned closer to the apex of that portion of the elliptical opening 306. In some such configurations, the single interruption 310 can be intersected by the longer axis L1. In some such configurations, the single interruption 310 can be centered upon the longer axis L1.

[0157] With continued reference to Figure 19, the interruptions 310 define recesses into the nostril locators 302 that extend from the rim 308 into the material of the nostril locators 302. The interruptions 310 can extend any suitable distance along the length of the nostril locator 302. The length preferably is not so long as to create a leak path but long enough to allow some radial relief to the rim 308. As the length of the interruptions 310 increases, the stiffness of the nostril locator 302 decreases.

[0158] With reference to Figures 20A-20E, other configurations of interruptions 310 are illustrated. As illustrated, the interruptions 310 can have many different shapes and can be moved away from a region of the nostril locators 302 that will contact the septum. As illustrated, the interruptions 310 can be as few as one or as many as desired. In some configurations, the interruptions 310 result in a serrated end to the nostril locator 302. Other configurations also are possible.

[0159] With reference now to Figures 21 and 22, a sealing member 330 is illustrated. The sealing member 330 can have features, aspects and characteristics in common with any other configuration described herein. In the illustrated configuration, the

sealing member 330 comprises at least one flexible prong 332. In some configurations, the sealing member 330 can comprise two flexible prongs 332. The flexible prongs 332 comprise a distal end that is connected to a proximal surface 334. The flexible prongs 332 can extend generally proximally from the proximal surface 334. The flexible prongs 332 can have one or more opening 336 that are positioned generally at a proximal end of the prongs 332. In the illustrated configuration, the opening 336 can form a slit that extends generally vertically through the proximal most end.

[0160] The prongs 332 preferably comprise a stalk 340 that extends generally between the proximal surface 334 and the opening 336. The stalk 340 can be configured to roll or otherwise deflect with ease. For example, a cross-sectional thickness of the material used to form the sealing member 330 and/or the flexible prongs 332 can be reduced that connects at least a portion of the prongs 332 to the sealing member 330. In some configurations, a different material or a different grade of material can be used to provide increased mobility to the prongs 332.

[0161] In the illustrated configuration, as shown by comparing Figure 21 and Figure 22, the prongs 332 can be configured to telescope or extend/retract. By configuring the prongs 332 to extend, the prongs 332 can have increased flexibility. As illustrated, the prongs 332 can compress along the axial direction. By compressing, the prongs 332 can improve comfort when sealing against the nares of the user.

[0162] In some configurations, the prongs can be configured with a bellows-type shape. The bellows-type shape can provide axial compressibility. The pleated appearance of the bellows-type shape can be formed along all of the stalk 340 or just a portion of the stalk 340. By providing the bellows-type shape, the stalk 340 also can allow the proximal end of the prongs 332 to wobble about the distal end of the prongs 332. In other words, the proximal end of the prongs 332 can bend in all directions without rotation of the prongs 332.

[0163] With reference now to Figures 23A-23C, a portion of a sealing member 350 is shown. In some configurations, the sealing member 350 includes nostril locators 352 similar to those described above. At least a proximal portion of the nostril locators 352 can be partially or fully covered with an end member 354, as shown in each of Figures 23A-23C. The end members 354 can be formed of a material that is as soft as, or softer than, the

material of the nostril locator 352. In some configurations, the end members 354 can be partially or fully formed of a softer silicone material. In other words, the end members 354 can be used to provide increased comfort by being positioned over the proximal end of the nostril locators 352.

5 **[0164]** The end member 354 can define openings 356 through which airflow from the nostril locator 352 can pass. In the illustrated configurations, the end members 354 have a rounded appearance. The softer material and the rounded shape facilitate rolling around the axis of the nostril locator 352. The underlying nostril locator 352 can be sufficiently rigid to provide the structure while the cap formed by the end member 354 can improve the comfort. 10 In some configurations, the proximal end of the nostril locator 352 can be enclosed with perforations or laterally extending openings to allow air to flow out of the nostril locator while the soft end member creates a seal with the nares of the user. In addition, in some such configurations, the end member 354 can have a larger outer diameter than the nostril locator 352 such that the nostril locator 352 can have improved flexibility while the end member 15 provides an effective sealing component.

[0165] With reference now to Figure 24, a further seal member 360 is illustrated. The seal member 360 includes a multiple wall nostril locator 362. In the illustrated configuration, the nostril locator 362 comprises a thin outer wall 364 and a thicker inner wall 366. In some configurations, the outer wall 364 is spaced from the inner wall 366 such that 20 the two walls are capable of relative movement. In some configurations, the inner wall 366 can terminate within the outer wall 364. In other words, the outer wall 364 may extend further proximally relative to the inner wall 366.

[0166] The inner wall 366 can comprise a foam or gel insert, for example but without limitation. The inner wall 366 underlies and supports the outer wall 364. Thus, with 25 the support of the separately formed inner wall 366, the outer wall 364 could be formed of a very thin layer. In some configurations, the outer wall 364 can be a very thin silicone wall that is intermittently or substantially completely supported by the inner wall 366, which can be a much softer material than the outer wall 364.

[0167] With reference now to Figures 25A and 25B, a seal member 380 is 30 illustrated therein. The seal member 380 can include one or more nostril locators 382. In

some configurations, the seal member 380 can be configured such that the nostril locators 382 direct the airflow in a more upward direction. With reference to Figure 25A, the nostril locators 382 are shown directing the airflow more rearwardly when compared to the nostril locators 382 shown in Figure 25B. By raising the rearmost wall of the nostril locators (see 5 384), for example, the trajectory of the airflow can be altered to a more upwardly directed flow. In some configurations, the nostril locators are configured such that the resultant airflow is more upwardly and forward. By redirecting the airflow in this manner, the airflow is not blown straight into the nose, which improves the comfort to the user. In some configurations, the nostril locators 382 can be positioned on a ball joint, for example but 10 without limitation, such that the air flow can be tuned by the user as desired.

[0168] With reference now to Figure 26, the illustrated seal member 400 can be structured in any configuration described above. The configuration illustrated, however, features a proximal surface 402 that omits one or both nostril locators. In the illustrated configuration, one or more of the nostril locators is replaced by an opening 404 that is formed 15 in the proximal surface 402. Thus, the nostrils of the user can simply overlie an opening 404 that is formed in the proximal surface. The configuration of Figure 27 shows a single opening 404 that can underlie one or both nostrils of the user while the configuration of Figure 28 also shows a single protrusion 406 that can help indicate to the user when the mask is properly located under the nose. With reference to Figure 28, in some configurations, the 20 tip of the nose can sit at the crossing 408 of the two facet lines. The protrusion 406 can be a short nostril locator, a complete nostril locator or any other suitable structure to help the user confirm a desired placement of the mask sealing member relative to the nostrils. In some configurations, the nose fits into or around the opening and the seal member can balloon around the nose of the user. For example, the tip of the nose can go into the opening or the 25 opening can sit under the tip of the nose to provide seal. The ballooning improves sealing of the seal member, especially where nothing extends into the nares of the user.

[0169] With reference now to Figures 29-42, a further interface assembly 420 is illustrated that is arranged and configured in accordance with certain features, aspects and advantages of the present invention. The interface assembly 420 generally comprises a frame 30 or body 422 and a seal 424. The seal 424 can be removably secured to the frame 422 for use.

orientations of the current Pilairo® nasal mask. Relative to a central, vertical plane passing through the seal member 428, the major axes 494 are oriented at an angle of about 20-25 degrees with the lower ends of the major axes 494 being further outward (further from the central plane) than the upper ends of the major axes 494. The surface defining the tips of the nostril locators 456 have been rotated outwardly by about 4 degrees relative to the current Pilairo® nasal mask such that the surfaces define an angle of about 20-25 degrees with the central plane with the outer portions of the tips of the nostril locators 456 being further rearward than the inner portions. The length of the nostril locators 456 has been reduced by about 1 mm to about 11 mm. The outlet aperture 492 defines a more round shape. For example, the dimension along the major axis 494 can be about 10 mm and the dimension along the minor axis can be about 5.5 mm. The nostril locators 456 are also spaced slightly wider apart. For example, the spacing of the major axes 494 at the bases and the tips of the nostril locators 456 can be about 18.5 mm and about 11 mm, respectively.

[0196] With reference to Figure 43, a further interface assembly 500 is illustrated that is arranged and configured in accordance with certain features, aspects and advantages of the present invention. The interface assembly 500 generally comprises a frame or body 502 and a seal 504. The seal 504 can be removably secured to the frame 502 for use. In the illustrated configuration, the frame 502 provides attachment points for headgear or the like. The illustrated seal 504 incorporates a connecting or mounting assembly 506 that can be joined to the flexible seal member 508. The seal member 508 comprises a proximal surface 530 (i.e., the surface that is closest to the face of the user in use) and a distal surface 532 (i.e., the surface further away from the face of the user in use). The interface assembly 500 is described in the context of the differences relative to other interface assemblies described herein. Thus, features that are not described can be assumed to be the same as or similar to corresponding features of the other interface assemblies disclosed herein, or can be of another suitable arrangement.

[0197] The seal member 508 of Figure 43 preferably includes features that facilitate or promote deflection of an upper, central portion of the seal member 508 that is aligned with the user's nose to inhibit or prevent excess pressure from being applied to the nose. In some configurations, portions of the seal member 508 defining both the proximal

surface 530 and the distal surface 532 in the central portion deflect forwardly to accommodate a user's nose. That is, in some configurations, the entire upper, central portion of the seal member 508 can deflect in a forward direction rather than the proximal surface 530 simply moving closer to the, often substantially stationary, distal surface 532, which can cause stretching of the proximal surface 530 and, thus, discomfort. Deflection of the seal member 508 may not occur in all situations. For example, certain facial geometries may result in little to no deflection, while other facial geometries may result in significant deflection.

[0198] The illustrated seal member 508 includes a rib or protrusion 536 that provides for connection to the connecting or mounting assembly 506. A joining region 554 can connect the rib or protrusion 536 to the balance of the seal member 508. In some configurations, portions of the joining region 554 can have a thickness of about 1.0 mm with some variation being possible slightly higher and lower keeping in mind a desire to reduce or eliminate the likelihood of tearing during normal use. However, the upper, central portion 560 of the seal member 508, which may include portions of the joining region 554, preferably has a lower wall thickness to facilitate or promote deflection (illustrated in broken line). The wall thickness of the upper, central portion 560 can be the same as or similar to the surround region 458 of the seal member 428 of Figures 29-42, such as about 0.25 mm, for example. In some configurations, the upper, central portion 560 can be connected to or integrated with a surround region 558, which surrounds nostril locators 556 of the seal member 508. In the illustrated arrangement, the reduced wall thickness of the upper, central portion 560 begins substantially immediately outward of the connecting or mounting assembly 506. Other suitable arrangements to permit deflection and/or rolling movement of the upper, central portion 560 of the seal member 508 can also be used, such as the concepts and arrangements disclosed in WO 2014/062070, the entirety of which is incorporated by reference herein.

[0199] Unless the context clearly requires otherwise, throughout the description and the claims, the words "comprise", "comprising", and the like, are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense, that is to say, in the sense of "including, but not limited to".

WHAT IS CLAIMED IS:

1. A nasal seal configured to be removably coupled to a frame of a patient interface, the nasal seal comprising:

a seal body formed of a soft flexible material and defining an inner cavity and one or more delivery openings for supply of breathing gases from the inner cavity to a patient;

wherein the seal body comprises a central portion and a side portion extending from each end of the central portion, the seal body further comprising an interior side and an exterior side, wherein the interior side of the central portion is configured to extend across a base of a user's nose and the interior side of each of the side portions is configured to extend across a side of the nose, wherein the interior side of the seal is supple and configured to conform under internal pressure to surfaces of the user's nose, including, at the side portions of the seal, to outside surfaces of the side of the nose; and

a support supporting a portion of the seal body;

wherein the support defines a mount for mounting the nasal seal to the frame, the mount comprising a first member that is connectable to a second member, wherein the first member and the second member capture a portion of the seal body between them, and the mount is more rigid than the seal member.

2. The nasal seal of Claim 1, wherein the support defines at least one grip surface portion extending along the exterior side of the seal body.

3. The nasal seal of Claim 2, wherein the at least one grip surface portion comprises at least one pair of grip surface portions substantially opposite one another.

4. The nasal seal of any one of Claims 1-3, wherein the first member is positioned within the inner cavity of the seal body and comprises a sleeve portion that extends outwardly from the inner cavity.

5. The nasal seal of Claim 5, wherein the second member surrounds the sleeve portion of the first member.

6. The nasal seal of any one of Claims 1-5, wherein the exterior side of the seal body defines an inlet opening configured to admit breathing gases into the inner cavity of the

seal body, and the portion of the seal body captured between the first member and the second member comprises a rib or protrusion that circumscribes the inlet opening.

7. The nasal seal of Claim 6, wherein the rib or protrusion is offset inwardly by a portion of the exterior side that extends generally normal or perpendicular to an axis of the inlet opening.

8. The nasal seal of any one of Claims 5-7, wherein the second member comprises at least one grip comprising a portion or tab that extends rearwardly over the exterior side of the seal.

9. The nasal seal of Claim 8, wherein the seal comprises a recess that accepts the grip.

10. The nasal seal of Claim 8 or 9, wherein the first member comprises a portion that extends rearwardly in general alignment with the grip and within the inner cavity of the seal.

11. The nasal seal of any one of Claims 8-10, wherein the at least one grip is located on the top of the seal.

12. The nasal seal of any one of Claims 8-10, wherein the at least one grip is located on the bottom of the seal.

13. The nasal seal of any one of Claims 8-10, wherein the at least one grip is located on the side of the seal.

14. The nasal seal of any one of Claims 8-13, wherein the at least one grip comprises at least one opposed pair of grips.

15. The nasal seal of any one of Claims 1-14, wherein the frame and mount comprise orientation features to confirm correct alignment and orientation of the seal to the frame.

16. The nasal seal of Claim 15, wherein the mount comprises a tongue, protrusion or boss feature and the frame comprises a groove, recess or relief feature.

17. The nasal seal of any one of Claims 1-16, wherein the one or more delivery openings comprises a first delivery opening and a second delivery opening, further comprising a nostril locator associated with and forming a portion of each delivery opening, wherein a deflection region is defined within an annular transition portion between each of

the nostril locators and a surrounding portion of the interior side, wherein the deflection region has a lower stiffness relative to another region of the annular transition portion not within the deflection region.

5 18. The nasal seal of Claim 17, wherein the lower stiffness is achieved by the deflection regions having a smaller thickness than the other regions of the annular transition portion.

 19. The nasal seal of Claim 17 or 18, wherein the deflection regions are located on the outer sides of the nostril locators.

10 20. The nasal seal of Claim 19, wherein the deflection regions provide less resistance to outward tilting of the nostril locators relative to tilting in one or more other directions.

 21. The nasal seal of any one of Claims 17-20, wherein the deflection regions are limited to less than or equal to one-half of the annular transition portion.

15 22. The nasal seal of any one of Claims 17-21, wherein the deflection regions are greater than or equal to one-third of the annular transition portion.