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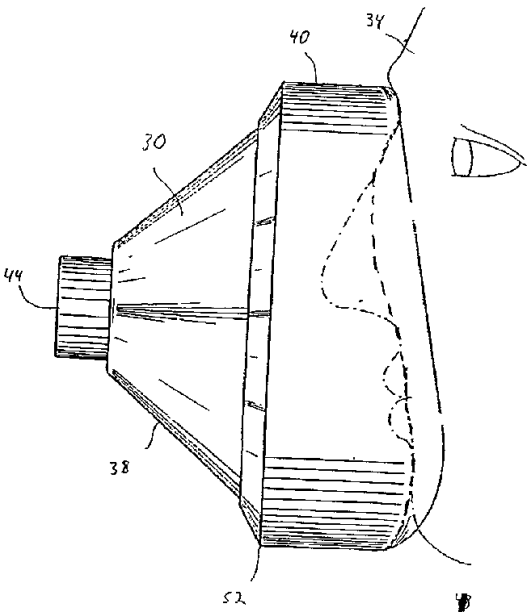
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(54)【発明の名称】二段射出成形された鼻／口マスク

(57)【要約】
使用者の気道に呼吸気体流を連絡するマスクは、二段射出成形法により形成される。マスクは、マスク本体とマスク密封材とを備え、マスク密封材の少なくとも一部は二段射出成形法によりマスク本体にモールド成形される。二段射出成形法の結果、マスク密封材又はその一部は、マスク本体を冷却する未硬化間にマスク本体に分子的に接着される。



【特許請求の範囲】
【請求項１】
呼吸気体の供給源に連結される第１の開口部（４４）と、第２の開口部（４６）とを有するマスク本体（３８，８２）と、
マスク本体を使用者に装着する使用者当接部を形成して、呼吸気体流を使用者の気道に供給するマスク密封材（４０，７６）とを備え、
マスク本体を冷却する未硬化間に、第２の開口部付近でマスク本体にマスク密封材の少なくとも一部を二段射出成形法によりモールド成形し、二段射出成型法の結果、マスク密封材の一部をマスク本体に分子的に接着したことを特徴とする呼吸気体流を使用者の気道に連絡するマスク。
【請求項２】
マスク密封材は、第１の舌片（７８）と、組立られた形態のマスクに対して、第１の舌片付近上に重ねて配置される第２の舌片（８０）とを備え、第１の舌片は、マスク本体にモールド成形されるマスク密封材の一部である請求項１に記載のマスク。
【請求項３】
第２の舌片は、着脱自在にマスク本体に取り付けられる請求項２に記載のマスク。
【請求項４】
マスク本体を冷却する未硬化間に、第１の開口部付近でマスク本体に対して二段射出成形法によりモールド成形される連結部材（９６）を備え、二段射出成形法の結果、連結部材の一部をマスク本体に分子的に接着した請求項１に記載のマスク。
【請求項５】
マスク本体は、樹脂により形成される請求項１に記載のマスク。
【請求項６】
マスク密封材は、シリコーン材料の単一片である請求項１に記載のマスク。
【請求項７】
マスク本体は、マスク本体の内部に形成される空洞部と、第２の開口部に形成される外周端部とを備え、第２の開口部は、着用者の鼻の少なくとも一部に空洞部を連絡して、第１の開口部は空洞部に連絡して、呼吸気体流を空洞部に搬送する導管に連結する継手となる請求項１に記載のマスク。
【請求項８】
マスク密封材は、マスク本体の外周端部に配置される請求項７に記載のマスク。
【請求項９】
呼吸気体流を供給する圧力発生装置（３２）と、
呼吸気体流を使用者に供給する圧力発生装置に作動連結される導管（３６）と、
使用者の気道に呼吸気体流を連絡する導管に連結されるマスク（３０，７４）とを備え、
マスクは、
導管に作動連結されるマスク本体（３８，８２）と、
マスク本体を冷却する未硬化間に、マスク本体に対して二段射出成型法によりモールド成形される少なくとも一部を有するマスク密封材（４０，７６）とを備え、二段射出成型法の結果、マスク密封材の一部をマスク本体に分子的に接着したことを特徴とする圧力支援装置。
【請求項１０】
マスク密封材は、第１の舌片（７８）と、組立られた形態のマスクに対して、第１の舌片付近上に重ねて配置される第２の舌片（８０）とを備え、第１の舌片は、マスク本体にモールド成形されるマスク密封材の一部である請求項９に記載の圧力支援装置。
【請求項１１】
第２の舌片は、着脱自在にマスク本体に取り付けられる請求項１０に記載の圧力支援装置。
【請求項１２】
マスク本体を冷却する未硬化間に、導管をマスクに連結する位置付近でマスク本体に対し

て二段射出成形法によりモールド成形される連結部材（９６）を備え、二段射出成形法の結果、連結部材の一部をマスク本体に分子的に接着した請求項９に記載の圧力支援装置。
【請求項１３】
マスク本体は、樹脂により形成される請求項９に記載の圧力支援装置。
【請求項１４】
マスク密封材は、シリコーン材料の単一片により形成される請求項９に記載の圧力支援装置。
【請求項１５】
マスク本体は、
マスク本体内部に形成される鼻収容空洞部と、
外周端部を有する第１の端部と、
第１の端部とほぼ反対側に形成される第２の端部と、
着用者の鼻孔をマスク本体の鼻収容空洞部に連結させて、着用者の鼻の少なくとも一部を収容する第１の端部に形成される第１の開口部と、
第２の端部に形成される第２の開口部とを備え、第２の開口部は、鼻収容空洞部に連絡しかつ導管への継手となる請求項９に記載の圧力支援装置。
【請求項１６】
マスク密封材は、マスク本体の第１の端部を構成する外周端部に配置される請求項１５に記載の圧力支援装置。
【請求項１７】
マスク成形型（６０，６２）を準備する工程と、
マスクのマスク本体（３８，８２）を形成するマスク成形型に第１の材料を注入する工程と、
マスク本体を冷却する未硬化間にマスク成形型に第２の材料を注入して、マスクのマスク密封材（４０，７６）の少なくとも一部を形成し、この方法において、マスク成形型に第２の材料を注入する結果、マスク密封材をマスク本体に分子的に接着する工程とを含むことを特徴とする使用者の気道に呼吸気体流を連絡するマスクを形成する二段射出成形法。
【請求項１８】
第２の材料をマスク成形型に注入する工程により、マスク密封材の第１の舌片（７８）を形成し、組立られた形態のマスクに対して、第１の舌片付近上に重ねて配置される第２の舌片（８０）を備える請求項１７に記載の射出成形法。
【請求項１９】
マスク本体に着脱自在に第２の舌片を取り付けて、マスク組立体を形成する請求項１８に記載の射出成形法。
【請求項２０】
マスク成形型に第２の材料を注入する工程により、マスク本体にモールド成形される連結部材（９６）を形成する請求項１７に記載の射出成形法。
【請求項２１】
マスク成形型（６０，６２）を準備する工程と、
マスクのマスク本体（３８，８２）を形成するマスク成形型に第１の材料を注入する工程と、
マスク本体を冷却する未硬化間にマスク成形型に第２の材料を注入して、マスクのマスク密封材（４０，７６）を形成し、この方法において、マスク成形型に第２の材料を注入する結果、マスク密封材をマスク本体に分子的に接着する工程とを含むことを特徴とする二段射出成形法により製造される使用者の気道に呼吸気体流を連絡するマスク。
【請求項２２】
第２の材料をマスク成形型に注入する工程により、マスク密封材の第１の舌片（７８）を形成し、組立られた形態のマスクに対して、第１の舌片付近上に重ねて配置される第２の舌片（８０）を備える請求項２１に記載のマスク。
【請求項２３】

マスク本体に第２の舌片を着脱自在に取り付けてマスク組立体を形成する請求項２１に記載のマスク。
【請求項２４】
マスク成形型に第２の材料を注入する工程により、マスク本体に対してモールド成形される連結部材（９６）を形成する請求項２１に記載のマスク。
【発明の詳細な説明】
【０００１】
発明の背景
１．発明の技術分野
本発明は、圧力支援装置により呼吸気体流を使用者の気道に供給する鼻／口マスク、特に、二段射出成形法を使用して、マスク本体と、マスク密封材の少なくとも一部との両方を形成しかつ接合するマスクに属する。
【０００２】
２．関連技術の説明
２部品モールド成形された鼻マスク及び鼻／口マスクは、圧力支援装置により、被験者循環路から被験者の気道に呼吸気体流を供給できる。このマスクは、被験者に当接するマスク部分となるマスク密封材（マスク緩衝部材としても公知）と、マスク密封材を取り付けるマスク本体とを備える。マスク本体は、被験者循環路に接続して、被験者に呼吸気体流を供給する。従来のマスクでは、機械的に又は接着剤によりマスク密封材がマスク本体に接続される。
【０００３】
従来の２部品マスクではいくつかの不具合がある。例えば、マスク密封材とマスク本体とを機械的に接続するには、マスク密封材、マスク本体又はその両方に、２部品間を機械的に接続する構造を必要とする。これは、マスク本体、密封材又はその両方に対して追加材料を一般に使用しなければならないため、マスクの設計及び製造がより複雑となる欠点がある。マスク本体とマスク密封材とを接着結合するには、マスク密封材、マスク本体及びその両方に対して接着剤を塗布しなければならないため、マスク製造に必要な材料が増加する欠点もある。また、接着剤の塗布に限らず、機械的接続又は接着結合の両方とも、一般にマスクの２部品を手作業により組立て又は取扱うことを要し、製造コスト及び製造時間が増す。
【０００４】
発明の開示
従って、本発明の目的は、従来の２部品マスクの欠点を解消できかつ被験者の気道に呼吸気体流に連絡するマスクを提供することにある。この目的は、マスク本体及びマスク密封材（マスク緩衝部材）を備えるマスクを提供する本発明の一実施の形態により実行され、二段（２ショット）射出成形法により、冷却されるマスク本体が完全に硬化しない間に、マスク密封材の少なくとも一部をマスク本体にモールド成形する。二段射出成形法の結果、マスク密封材又はその一部はマスク本体に分子的に接着される。
【０００５】
更に、本発明は、前記マスクを使用する圧力支援装置を提供することを目的とする。
【０００６】
更に、本発明の他の目的は、従来のマスク製造法に付随する欠点のないマスク形成法を提供することである。本目的は、（１）マスク成形型を準備する工程と、（２）マスク成形型に第１の材料を注入してマスク本体を形成する工程と、（３）マスク本体を冷却するが不完全に硬化する間に、マスク成形型に第２の材料を注入して、マスクのマスク密封材の少なくとも一部を形成する工程とを含むマスクを形成する二段射出形成法により実行される。この方法では、マスク密封材又はその一部は、マスク成形型に注入される第２の材料によってマスク本体に分子的に接着される。
【０００７】
本発明の他の目的は、直近の前記段落に記載される方法により製造されるマスクを提供す

ることである。

【０００８】

参照符号が各図の対応する部分を示す添付図面に関する以下の説明、請求の範囲及び本明細書の全構成部分により、本発明の前記目的及び他の目的、特徴及び特性、構造の関連要素の操作法及び機能、部品の組み合わせ並びに製造経済性が明らかとなろう。しかしながら、図面は図解及び説明の目的に過ぎず、発明の範囲を制限するものではない。

【０００９】

本発明の好適な実施の形態の詳細な説明

図１及び図２は、本発明の原理を使用して二段射出成形法により製造されたマスク３０の例示的な第１の実施の形態を示す。マスク３０は、人工呼吸器、圧力支援装置（例えば、持続陽圧呼吸（ＣＰＡＰ）装置、２レベル装置若しくは自動滴定装置）、酸素若しくは酸素混合気体の加圧タンク又は酸素濃縮装置等の気体供給源３２から被験者３４の気道に気体流を供給する医療環境で使用される。一般に被験者循環路として図２の点線で示す可撓性導管３６は、気体供給源３２を圧力支援装置のマスクに連結して、気体供給源３２から被験者に呼吸気体流を供給する。

【００１０】

マスク３０は、マスク本体３８とマスク密封材４０とを備える。マスク密封材４０は、被験者に接触するマスク３０の当接部となるため、マスク３０を使用者に装着して、呼吸気体流を使用者の気道に供給できる。このように、マスク密封材４０は、被験者に比較的緊密な密着性を与え、装置からの気体漏洩量を最小化しなければならない。加圧気体流が被験者に供給される間の長時間、被験者はほぼマスク３０を着用し続ける。例えば、睡眠時無呼吸症に苦しむ被験者は、ほぼ一晩中マスクを着用して、この症状を治療するため周囲大気圧より高い圧力で呼吸気体流が気道に供給される。従って、快適に装着できかつ比較的緊密な密着性を被験者に与えるシリコーン等の熱可塑性エラストマー等の軽量で、可撓性及び柔軟性を備える材料でマスク密封材４０を形成することが好ましい。

【００１１】

通常、密封材４０を支持するマスク本体３８は、密封材４０より剛性のある硬質合成樹脂又は半硬質合成樹脂等の材料から形成される。また、マスク本体３８は、マスク３０を被験者に固定するヘッドギアへの接続部（図示せず）を有する。

【００１２】

マスク本体３８及び密封材４０は、図１に示す使用者の鼻等の部位を収容するのに適する空洞部４２を個々に及び一体に形成する。第１の開口部４４は、マスク本体３８の一端に形成され、外周端部４８を有する第２の開口部４６は、マスク本体３８の他端に形成される。第１の開口部４４は、可撓性導管３６の継手となって、呼吸気体流が気体供給源３２から空洞部４２に供給される。マスク密封材４０の第１の端部５０は、二段射出成形法を使用して外周端部４８でマスク本体３８に固定され、気密接合部５２は、マスク本体３８とマスク密封材４０とを確実に連結する。被験者の鼻等の部位を収容するマスク密封材４０の第２の端部５６に形成される開口部５４は、空洞部４２を被験者の気道に連絡する。マスク密封材４０の第２の端部５６は、被験者の顔面上に配置されて、マスクと被験者との間に密封状態を形成し、圧力支援装置の動作間に、気体漏洩量を最小化し又は漏洩を防止することが好ましい。

【００１３】

射出成形装置５８の複数の型片を略示する図３と、射出成形装置の部分断面図を略示する図４Ａ－図４Ｂとについて、マスク３０を形成する二段射出成形法を説明する。射出成形装置５８は、第１の型片６０と第２の型片６２とを備え、矢印Ａに示す方向に型締めされて、マスク成形型を形成する。第１の型片６０と第２の型片６２とは、矢印Ｂに示すように離型可能であり、射出成形装置５８から成形されたマスクを排出して、後述の型部分を再整合させる。第１の型片６０は、第２の型片６２に形成された第２の本体型部６６と密封材型部６８とに協同する第１の本体型部６４を備え、マスク本体３８とマスク密封材４０とを形成する完成型を形成する。

【００１４】
本発明の好適な実施の形態では、１又は２以上の第２の本体型部６６は、第１の型片６０に設けられた複数の第１の本体型部６４の第１組に整合して、第２の型片６２の一方側に形成され、第２の本体型部６６と同数の密封材型部６８は、第１の型片６０に設けられた第１の本体型部６４の他の組に整合して、第２の型片６２の他方側に形成される。図４Ａに示すように、第１の本体型部６４と第２の本体型部分６６とが協同して、マスク本体３８が形成される。同様に、図４Ｂに示すように第１の本体型部６４と密封材型部６８とが協同して、マスク本体３８に接着されるマスク密封材４０を形成する。図３に示すように、射出成形装置の各部は、例えば矢印Ｃに示すように軸７０上で互いに対して回転可能であり、第１の本体型部６４をまず第２の本体型部６６に整合させ、その後、密封材型部６８に整合させる。

【００１５】
即ち、第１の本体型部６４はマスク本体３８の露出面又は外面の表面輪郭を形成し、第２の本体型部６６は、マスク本体３８の内面の表面輪郭を形成する。第１の本体型部６０と第２の本体型部６２とを共に互いに押圧して型締めすると、第１の本体型部６４と第２の本体型部６６との間に形成される間隙７２にマスク本体３８を形成する完全なキャビティ（空洞）が形成される。第１の型片６０と第２の型片６２との間、即ち第１の本体型部６４と第２の本体型部６６との間に形成される間隙７２内への溶融樹脂等の材料注入を制御する図示しない制御装置が第１の型片６０及び第２の型片６２の一方又は両方に設けられる。間隙７２内に供給される材料は、硬質の構造用樹脂材料に硬化して、マスク本体３８を形成する。

【００１６】
マスク本体３８が完全に硬化する前に、マスク本体３８を第１の本体型部６４内に残存させて、第１の型片６０と第２の型片６２とを離型することが好ましい。例えば、第１の型片６０に対して第２の型片６２を角度１８０°回転させて、又は第２の型片６２に対して第１の型片６０を角度１８０°回転させて、第１の型片６０と第２の型片６２とを再び心合わせすることにより、図４Ｂに示すように、硬化中のマスク本体を含む第１の本体型部６４を第２の型片６２の密封材型部６８に整合させて位置決めする。容易に図示しかつ型部の詳細を明確に視覚化するために、第１の型片６０と第２の型片６２とを互いに離間させて図４Ｂを図示することに留意すべきである。実際の使用では、第１の型片６０と第２の型片６２とを互いに押圧して型締めし、マスク本体３８に接着されるマスク密封材４０を成形する第２の型を形成する。図４Ｂに図示するように、マスク密封材４０の第１の端部５０は、第２の開口部４６の外周端部４８に接合される。

【００１７】
溶融樹脂の注入後に、マスク本体３８の硬質樹脂は直ちに冷却及び硬化を開始する。マスク本体３８が硬化しかつ冷却している間に、マスク本体３８に対するマスク密封材４０のモールド成形を実行し、シリコーン等のマスク密封材４０を形成する材料をマスク本体３８の未硬化材料に分子的に接着させて、マスク本体３８とマスク密封材４０との間を接合部５２で確実かつ気密に接合することが好ましい。従って、第２の本体型部６６を第１の本体型部６４から離型するとき、新しく形成されたマスク本体３８が自立する程度に十分に冷却した直後に、第１の型片６０と第２の型片６２との離型、回転及び再型締めが実行される。

【００１８】
最終的に、第１の型片６０と第２の型片６２とを離型して、完成したマスク３０を射出成形装置から取り外す。この方法では、射出成形装置の構造により射出成形装置の一方の型片上にマスク本体３８を形成し、同時に、マスク本体３８に接着されるマスク密封材４０を射出成形装置の他方の型片上に形成できればよい。特に、第１の型片６０と第２の型片６２とを互いに押圧して型締めするとき、第１の本体型部６４と第２の本体型部６６とを使用して、２つのマスク本体３８を射出成形装置の第１の側で形成しながら、同時に、第１の本体型成形部６４と密封材型部６８とを使用して、予め形成された２つのマスク本体

３８を射出成形装置の第２の側でマスク密封材４０にモールド成形できる。第１の型片６０と第２の型片６２とをその後離型すると、射出成形装置の第２の側に２つの完成したマスクを形成できる。

【００１９】

図１及び図２に示すマスク本体３８とマスク密封材４０との間の接合部５２は、図４Ａ及び図４Ｂに示すマスク本体３８とマスク密封材４０との間の接合部に比べて僅かに異なることに留意する必要がある。これは、本発明がマスク本体３８とマスク密封材４０との間の接合部に、多種多様な組合せの接合面構造を付与できることを企図するものである。例えば、マスク本体とマスク密封材との各組合せ端に嵌合構造を設けて、マスクの２部品間で接着される領域の表面積を増加させることにより、接合部５２の密封強度を向上できる。また、マスク本体とマスク密封材との両端部を当接させることを要しないが、マスクの２部品間に十分な接着強度が得られる限り、図示のように、介在部品なしに部分的に接合し又は隣接部品と組み合わせて両端部を形成してもよい。

【００２０】

マスク３０は、着用者の鼻孔と口との両方に被せて密封する全面型面体である。しかしながら、本発明は、この射出成形法を使用して形成されるマスクが、着用者の鼻孔全体だけを密封して口を開放する鼻マスクの大きさ及び形状に形成できることも企図する。また、マスク本体、密封材（マスク緩衝部材としても公知）又はその両方は、図示するものに加え、様々な構造、形態及び大きさを備え、他の特徴を含んでもよい。前記部品の多種多様の構造、形態及び大きさに対する唯一の制約は、射出成形装置の物理的限界である。更に、例示的な実施の形態には図示しないが、マスク本体及び／又はマスク密封材は、ヘッドギア接続部、圧力口及び排気口等の追加構造を含んでもよい。

【００２１】

更に、図１～図４Ｂに示す単一構造体からマスク本体、マスク密封材又はその両方を形成する必要はない。単一構造体ではなく、例えば、本発明は、図５～図７に示すように、第１の舌片７８（別称第１の緩衝部材）と第２の舌片８０（別称第２の緩衝部材）との組合せにより形成されるマスク密封材７６を備えるマスク７４を提供することを企図する。本実施の形態では、第２の舌片８０を機械的にマスク本体８２に接合して、第１の舌片７８付近上に重ねると、第２の舌片８０は、マスク密封材７６の被験者との当接部として機能する。少なくとも第２の舌片８０の外周端部８１を比較的可撓性のある柔軟な材料により形成して、被験者の顔面に良好な密着性を与えると共に、被験者に接触する快適な当接面を形成することが好ましい。

【００２２】

図６に単品で示す第１の舌片７８は、第２の舌片８０より剛性が高いため、比較的可撓性のある第２の舌片８０単独に比べて、第１の舌片７８は、マスク密封材７６に対するより強固な支持構造体となる。被験者に対してマスクをより緊密に装着するため、これは特に重要である。本実施の形態では、第１の舌片７８は、二段射出成形法を使用してマスク本体８２にモールド成形されるマスク密封材７６の一部である。詳細に後述するように、第２の舌片８０をマスクに永久的に取り付けずに、機械的にマスクに固定することが好ましい。第１の舌片７８と第２の舌片８０とを同一の材料又は異なる材料から形成できる。

【００２３】

図７に示すように、マスク７４の周囲に沿ってフランジ８８を形成して、第１の舌片７８の端部８４とマスク本体８２の端部８６とを接合する。マスク本体８２の材料が未硬化の間に、各端部８４及び８６を互いに接着するため、端部８４と端部８６とは、接合部９０で有効に融合し合い、これにより、マスク本体８２と第１の舌片７８との間に気密かつ強固な相互接着構造が形成される。

【００２４】

フランジ８８は、マスク７４に対して第２の舌片８０を着脱自在に固定する接続構造体となる。特に、第２の舌片８０は、フランジ８８を収容する溝９２を備え、マスク７４を完全に組立ると、第１の舌片７８付近上に第２の舌片８０を重ねて配置できる。第２の舌片

８０は、交換又は手入れが容易な構造を備え、異なる大きさ及び形状を有する第２の舌片８０を共通のマスク本体／第１の舌片の組立体と共に使用することにより、幅広い範囲で被験者に有効に適合するマスク形成を単純化すると共に、必要な部品数を減少させる。

【００２５】

前記マスクの実施の形態では、二段射出成形法によりマスク本体８２とマスク密封材７６とを形成し接着することにより、マスクの２部品を機械的に接合する別個の接着剤の必要性を回避する。しかしながら、本発明は、前記二段射出成形法を使用して、マスクの他の追加部品の形成も企図すると理解すべきである。例えば図８は、マスク９４の断面図を示し、マスク本体８２に対して第１の開口部９８付近にモールド成形される連結部材９６をマスク９４が含む以外、多くの点でマスク７４に類似する。第１の舌片７８と同様に、マスク本体８２を冷却する未硬化間に、二段射出成型法により連結部材９６をマスク本体８２に接合させるため、連結部材９６の一部がマスク本体８２に分子的に接着される。マスク本体８２の材料と比較してより変形可能な材料により連結部材９６を形成して、容易かつ緊密に被験者循環路の端部にマスクを密着することが好ましい。

【００２６】

好適な実施の形態では、被験者にマスク９４を固定するヘッドギア接続部を含む環部（図示せず）に連結部材９６を装着する。また、連結部材９６は、その内側に溝部１００を形成して、被験者循環路の端部にマスク９４を正確に整合して接続できる。

【００２７】

本発明は、第１の舌片７８の形成と同時に連結部材９６を形成することを企図する。これは、例えば射出成形装置の密封材型部６８を配置し、マスク空洞部１０２を通じて、マスク本体８２の第１の開口部９８付近領域に連結部材９６を形成する材料を供給することにより実行される。別法として又はこれに加えて、マスク本体部材８２の内面及び／若しくは外面又は内面及び外面の何れかを形成する成形型の表面に形成した溝を通じて、マスク本体８２の第１の開口部９８の付近の領域に密封材を形成する材料を流動させて、連結部材９６を形成できる。また、本発明は、連結部材を形成する第３の射出成形工程を企図する。マスク密封材を形成する前後何れかに、第３の射出成形工程を実行することが好ましく、マスク本体８２を冷却する未硬化間に、連結部材９６の一部をマスク本体８２に分子的に接着できる。

【００２８】

現在最も実用的で好適と思われる実施の形態を図示し詳述したが、前記記載は単に説明の便宜に過ぎず、本発明は、本発明を開示する実施の形態に限定されず、特許請求の範囲及びその趣旨に該当する変更及び均等の装置を包含する。

【図面の簡単な説明】

【図１】本発明の二段射出成形法により製造されるマスクの側面図

【図２】代表的な圧力支援装置に設けられた図１のマスクの略示断面図

【図３】本発明の原理により二段射出成形されるマスクを形成する成形装置の斜視図

【図４Ａ及び図４Ｂ】二段射出成形法を使用してマスクを成形する工程に含まれる２つの工程を略示する図３の成形装置の部分断面図

【図５】本発明の二段射出成形法により製造されるマスクの第２の実施の形態を示す部分断面斜視図

【図６】外部舌片密封材、即ち第２の舌片密封材を除去した図５のマスクを示す斜視図

【図７】図５に示すマスクのマスク本体と第２の舌片密封材の接合面を示す部分断面斜視図

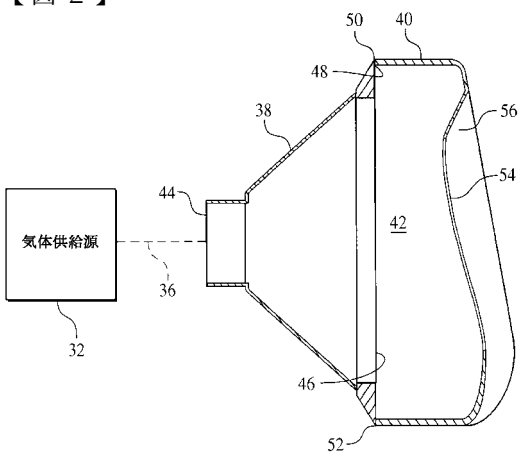
【図８】本発明による二段射出成形法によるマスク本体にモールド成形された連結部材を備える図５のマスクの断面図

【符号の説明】

（３０，７４）・・マスク、　（３２）・・圧力発生装置（気体供給源）、　（３６）・・導管、　（３８，８２）・・マスク本体、　（４０，７６）・・マスク密封材、　（４４）・・第１の開口部、　（４６）・・第２の開口部、　（６０，６２）・・マスク成形

型、　（７８）・・第１の舌片、　（８０）・・第２の舌片、　（９６）・・連結部材、

【図２】



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(54) Title: TWO-SHOT INJECTION MOLDED NASAL/ORAL MASK

(57) Abstract: A mask that communicates a flow of breathing gas with an airway of a user is formed by a two-shot injection molding process. The mask includes a mask body and a mask seal member, at least a portion of which is molded to the mask body by a two-shot injection molding process, while the mask body is cooling and incompletely cured. The mask seal member, or a portion thereof, is molecularly bonded to the mask body as a consequence of the two-shot injection molding process.

TWO-SHOT INJECTION MOLDED NASAL/ORAL MASK

BACKGROUND OF THE INVENTION

1. Field of the Invention

[01] The present invention pertains to a nasal/oral mask for use in communicating a flow of breathing gas to an airway of user in a pressure support system, and, in particular, to a mask in which both the mask body and at least a portion of a mask seal are formed and joined using a two-shot injection molding process.

2. Description of the Related Art

[02] Two-part molded nasal and nasal/oral masks are available for communicating a flow of breathing gas from a patient circuit to an airway of a patient in a pressure support system. Such masks consist of mask seal, also known as a mask cushion, which is the portion of the mask that contacts the patient, and a mask body to which the mask seal is attached. The mask body couples to the patient circuit for communicating the flow of breathing gas to the patient. In conventional masks, the mask seal is bonded to the mask body either mechanically or with an adhesive.

[03] There are several disadvantages associated with conventional two-part masks. For example, mechanically bonding the mask seal with the mask body requires providing structures in the mask seal, the mask body, or both, that allow for the mechanical linkage between the two components. This typically requires using additional material to form the mask body, seal, or both, and increases the complexity of the design and manufacture of the mask. Adhesively bonding the mask seal to the mask body requires that an adhesive be applied to the mask seal, mask body, or both, thereby increasing the materials needed to produce the mask. In addition, both mechanical or adhesive bonding typically require hand assembly or hand manipulation of the two parts of the mask, as well as application of the adhesive, which is expensive and time-consuming.

SUMMARY OF THE INVENTION

[04] Accordingly, it is an object of the present invention to provide a mask for communicating a flow of breathing gas to an airway of a patient that overcomes the

shortcomings of conventional two-part masks. This object is achieved according to one embodiment of the present invention by providing a mask that includes a mask body and a mask seal member (mask cushion), where at least a portion of the mask seal member is molded to the mask body using a two-shot injection molding process while the mask body is cooling and incompletely cured. The mask seal member or a portion thereof is molecularly bonded to the mask body as a consequence of the two-shot injection molding process.

[05] It is yet another object of the present invention to provide a pressure support system using such a mask.

[06] It is a still further object of the present invention to provide a method of forming such a mask that does not suffer from the disadvantages associated with conventional mask manufacturing techniques. This object is achieved by providing a two-shot injection molding method of forming a mask that includes (1) providing a mask mold, (2) injecting a first material into the mask mold to define a mask body, (3) injecting a second material into the mask mold while the mask body is cooling and incompletely cured to define at least a portion of a mask seal member for the mask. The mask seal member or a portion thereof is molecularly bonded to the mask body as a consequence of the second material being injected into the mask mold in this manner.

[07] It is a further object of the present invention to provide a mask manufactured according to the process set forth in the immediately preceding paragraph.

[08] These and other objects, features and characteristics of the present invention, as well as the methods of operation and functions of the related elements of structure and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[09] Fig. 1 is a side view of a mask manufactured in accordance with the two-shot injection molding technique of the present invention;

[10] Fig. 2 is a cross-sectional view of the mask of Fig. 1 schematically shown in a typical pressure support system;

[11] Fig. 3 is a perspective view of a molding apparatus for forming a two-shot injection molded mask in accordance with the principles of the present invention;

[12] Figs. 4A and 4B are cross sectional views of portions of the molding apparatus of Fig. 3 schematically illustrating two steps involved in forming masks using the two-shot injection molding technique;

[13] Fig. 5 is a perspective view, partially in section, of second embodiment of a mask manufactured in accordance with the two-shot injection molding technique of the present invention;

[14] Fig. 6 is a perspective view of the mask of Fig. 5 with the exterior or second flap seal member removed;

[15] Fig. 7 is a detailed view of the mask body and second flap seal member interface in the mask of Fig. 5; and

[16] Fig. 8 is a cross-sectional view of the mask of Fig. 5 further including a coupling member molded to the mask body in accordance with the two-shot injection molding technique of the present invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS OF THE INVENTION

[17] Figs. 1 and 2 illustrate a first exemplary embodiment of a mask 30 manufactured by means of a two-shot injection molding technique in accordance with the principles of the present invention. Mask 30 is used in a medical environment to deliver a flow of gas from a gas source 32, such as, a ventilator, pressure support device (e.g., CPAP, bi-level, or auto-titration device), pressurized tank of oxygen or an oxygen mixture, or oxygen concentrator, to an airway of a patient 34. Typically a flexible conduit 36, referred to as a patient circuit and which is shown schematically as a dashed line in Fig. 2,

couples the gas source to the mask in a pressure support system for delivering a flow of breathing gas from the gas source to the patient.

[18] Mask 30 includes a mask body 38 and a mask seal member 40. The mask seal member is the portion of the mask that contacts the patient, thereby coupling the mask to the user to enable the flow of breathing gas to be delivered to the airway of the user. As such, the mask seal member must provide a relatively tight seal with the patient to minimize leakage of gas from the system. Mask 30 is typically worn by a patient for a prolonged period of time while a pressurized flow of gas is delivered to the patient. For example, patients suffering from sleep apnea typically wear a mask throughout the night in order for a flow of breathing gas to be delivered to their airway at a pressure elevated above the ambient atmospheric pressure as a treatment for this condition. Therefore, mask seal member 40 is preferably made from a lightweight, flexible, and soft material, preferably a thermoplastic elastomer, such as silicone, so that it is comfortable yet offers a relatively tight seal with the patient.

[19] Mask body 38 supports seal member 40 and is typically formed from a material that is more rigid than the seal member, such as a rigid or semi-rigid plastic. Mask body 38 can also provide attachment points for headgear (not shown) for securing the mask to the patient.

[20] Mask body 38 and mask seal member 40, individually and collectively, define a cavity 42 that is adapted to receive a portion of the user, such as the user's nose as shown in Fig. 1. A first opening 44 is defined in one end of mask body 38 and a second opening 46 having a peripheral edge 48 is defined at the other end of the mask body. The first opening serves as coupling for the flexible conduit so that the flow of breathing gas from the gas source is communicated to cavity 42. A first end 50 of mask seal member 40 is secured to mask body 38 at peripheral edge 48 using a two-shot injection molding technique so that an airtight joint 52 securely couples the mask body and the mask seal member. An opening 54 is provided in a second end 56 of mask seal member 40 for receiving a portion of the patient, such as the patient's nose, so that an airway of the patient communicates with cavity 42. Second end 56 of mask seal member 40 overlies the patient and forms a seal between the mask and the patient that minimizes or preferably has no gas leaks during operation of the pressure support system.

[21] The two-shot injection molding process for forming mask 30 is described below with reference to Fig. 3, which is a schematic diagram of the die sections of an injection molding apparatus 58, and with reference to Figs. 4A-4B, which are cross-sectional schematic views of a portion of the injection molding apparatus. Injection molding apparatus 58 includes a first section 60 and a second section 62 that press together, as indicated by arrow A, to define a mold for forming a mask. First and second sections 60 and 62 are separable, as indicated by arrow B, to eject molded masks from the molding apparatus and to realign mold portions, as described below. First section 60 includes first mask body mold portions 64 that cooperate with second body mold portions 66 and mask seal mold portions 68 provided in second section 62 to form a complete mold for forming the mask body and mask seal member.

[22] In a preferred embodiment of the present invention, one or more second body mold portions 66 are provided on one side of second section 62 in alignment with a first set of first body mold portions 64 on first section 60, and an equal number of mask seal mold portions 68 are provided on the other side of second section 62, also in alignment with another set of first body mold portions 64 in first section 60. The cooperation of first body mold portions 64 and second body mold portions 66, as shown in Fig. 4A, forms mask body 38. Similarly, the cooperation of first body mold portions 64 and seal mold portions 68, as shown in Fig. 4B, forms mask seal member 40 bonded to mask body 38. As shown in Fig. 3, the sections of the injection molding apparatus are rotatable relative to one another, for example on a shaft 70 as indicated by arrow C, to provide separate alignments of first mask body mold portions 64 with second body mold portions 66 and then with mask seal mold portions 68.

[23] More specifically, first body mold portions 64 provide the surface outline of the exposed or outer surface of mask body 38, and second body mold portions 66 provide the surface outline of the interior surface of the mask body. When first and second body mold portions 60 and 62 are pressed together, first body mold portions 64 and second first body mold portions 66 mate to form complete molds for forming mask body 38 in a gap 72 therebetween. Although not illustrated, one or both of first section 60 and second section 62 includes structures for controlling the injection of material, such as molten plastic, into gap 72 defined between the first and second sections, i.e., between first body

mold portions 64 and second body mold portion 66. This material supplied to gap 72 cures to a hard, structural plastic material, that forms mask body 38.

[24] Preferably before curing of mask body 38 is complete, first section 60 and second section 62 are separated in such a manner that mask body 38 remains within first body mold portion 64. First section 60 and second section 62 are then realigned, for example, by rotating the second section 180° relative to the first section or by rotating the first section 180° relative to the second section, so that the first body mold portions containing the curing mask body are brought into registration with seal mold portions 68 of second section 62, as shown in Fig. 4B. It should be noted that first section 60 and second section 62 are illustrated in Fig. 4B as being separated from one another for ease of illustration purposes and so that the details of the mold portions can be clearly visualized. In actual use, first and second sections 60 and 62 are pressed together to form a second mold for forming mask seal member 40 bonded to mask body 38. As schematically shown in Fig 4B, first end 50 of mask seal member 40 is joined to peripheral edge 48 of second opening 46.

[25] The hard plastic of mask body 38 begins cooling and curing immediately after injection of molten plastic ceases. Preferably, the molding of mask seal member 40 to mask body 38 is performed while the mask body is still curing and cooling so that the material defining mask seal member 40, such as silicone, molecularly bonds with the as-yet uncured material of mask body 38, thereby forming a secure, airtight bond between the mask body and the mask seal member at joint 52. Accordingly, the separation, rotation, and re-engagement of first and second sections 60 and 62 takes place as soon as the newly formed mask body has cooled to a sufficient extent to be self-supporting when second body mold portions 66 are removed from first body mold portions 64.

[26] Finally, first and second sections 60 and 62 are separated and the completed mask 30 is removed from the injection molding apparatus. It can be appreciated that the construction of the molding apparatus in this manner makes it possible to form the mask body on one half of the apparatus and simultaneously form the mask seal member in bonded relation with the mask body on the other half of the injection molding apparatus. In particular, when first and second sections 60 and 62 are pressed together, two mask

bodies are formed on a first side of the apparatus using first and second body mold portions 64 and 66, while simultaneously two previously-formed mask bodies are molded to the mask seal member on a second side of the apparatus using first body mold portion 64 and seal mold portions 68. When first and second sections 60 and 62 are subsequently separated, two completed masks are formed in the second side of the apparatus.

[27] It should be noted that the joint between the mask body and mask seal member in Figs. 1-2 is slightly different than the joint between the mask body and mask seal member shown in Figs. 4A-4B. This is done to illustrate the fact that the present invention contemplates that a wide variety of different surface mating interface configurations can be provided for the joint between the mask body and the mask seal member. For example, interlocking contours can be provided at the mating ends of the mask body and the mask seal member for increasing the surface area of the bonded region between these two components of the mask, thereby increasing the sealing strength of joint 52. Also, the ends of the mask body and the mask seal member need not be abutting, as shown in the figures, but may be provided in an overlapping fashion, alone or in combination with an abutting relation, so long as a sufficient bond is provided between these portions of the mask.

[28] Mask 30 is a full face mask that it seals over both the user's nares and mouth. It is to be understood, however, that the present invention contemplates that the mask formed using this molding technique can be sized and configured as a nasal mask, which only seals over the user's nares, leaving the mouth uncovered. In addition, the mask body, mask seal member (also known as mask cushion), or both can have a variety of configurations, shapes, and sizes in addition to those illustrated in the figures and can include other features. The only constraints on the variety of different configurations, shapes, and sizes for these components are the physical limitations of the molding apparatus. In addition, the mask body and/or mask seal member can include additional items, such as headgear attachment points, pressure ports, and exhaust ports, not shown in the illustrated exemplary embodiments.

[29] Furthermore, the mask body, mask seal member, or both need not be formed from unitary structures as shown in Figs. 1-4B. On the contrary, the present invention contemplates, for example, providing a mask 74 having a mask seal member 76

that is defined by a combination of a first flap member 78 (a.k.a. first cushion) and a second flap member 80 (a.k.a. second cushion), as shown in Figs. 5-7. In this embodiment, second flap member 80 is mechanically coupled to the mask body 82 such that it generally overlies first flap member 78 and serves as the patient contacting portion of the mask seal member 76. Preferably, at least a distal end 81 of second flap member 80 is formed from a relatively flexible and soft material to provide a comfortable surface for contacting the patient while providing a good seal with the surface of the patient.

[30] First flap member 78, which is illustrated by itself in Fig. 6, is generally more rigid than second flap member so that the first flap member provides a greater degree of structural support for the mask seal member than is possible by the relatively flexible second flap member alone. This is especially important as the mask is strapped more tightly on the patient. In this embodiment, first flap member 78 is the portion of the mask seal member that is molded to a mask body 82 using the above described two-shot injection molding technique. As described in greater detail below, second flap member 80 is preferably not permanently attached to the mask, but is mechanically fastened to the mask. First and second flap members can be formed from the same or different substances.

[31] As shown in Fig. 7, an end 84 of first flap member 78 and an end 86 of mask body 82 are joined in such a manner that a flange 88 is provided along the circumference of mask 74. Because ends 84 and 86 are bonded together while the material of mask body 82 is incompletely cured, ends 84 and 86 effectively fuse together at joint 90, thereby providing an airtight and strong interconnection between the mask body and the first flap member.

[32] Flange 88 serves as an attachment mechanism for removeably securing second flap member 80 to mask 74. More specifically, second flap member 80 includes a channel 92 adapted to receive flange 88 so that the second flap member generally overlies the first flap member when the mask is fully assembled. This configuration for the second flap member allows the second flap member to be easily replaced or cleaned and also allows differently sized or configured second flap members to be used in combination with a common mask body/first flap member assembly, thereby simplifying and reducing the number of parts required to provide a mask that effectively fits a wide range of patients.

[33] In the embodiments of the mask described above, the mask body and mask seal member are formed and joined by a two-shot injection molding technique, thereby avoiding the need for a separate adhesive for mechanical joining of these two mask components. It is to be understood, however, that the present invention contemplates forming other components of the mask using the above-described two-shot injection molding technique. Fig. 8, for example, is a cross-sectional view of a mask 94 that is similar in many respects to mask 74, except that mask 94 includes a coupling member 96 molded to mask body 82 generally at a first opening 98. Coupling member 96, like first flap member 78, is bonded to mask body 82 by means of the two-shot injection molding process while the mask body is cooling and incompletely cured so that a portion of the coupling member is molecularly bonded to the mask body. Coupling member 96 is preferably formed from a material that is relatively more deformable than the material of mask body 82 so that the mask can be easily, yet snuggly fitted to the end of a patient circuit.

[34] In a preferred embodiment, coupling member 96 attaches to a collar portion (not shown) that includes headgear attachment points for securing mask 94 to a patient. Coupling member 96 can also include channels 100 defined therein for assisting in correctly aligning mask 94 on the end of a patient circuit.

[35] The present invention contemplates forming coupling member 96 at the same time first flap member 78 is formed. This can be accomplished, for example, by configuring the seal mold portions of the injection molding apparatus to provide the material that forms the coupling member through mask cavity 102 to an area proximate to first opening 98 of mask body 82. Alternatively, or in addition, channels can be defined in the interior and/or exterior surface of body member 82 or in the surface of the mold that forms either of these surfaces, so that the material that forms the seal can flow to the area proximate to first opening 98 of mask body 82 to form the coupling member. The present invention also contemplates providing a third injection molding step for forming the coupling member. This third molding preferably is performed either before or after the mask seal member is formed and while the mask body is cooling and incompletely cured, so that a portion of the coupling member is molecularly bonded to the mask body.

[36] Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims.

What is Claimed is:

1. A mask adapted to communicate a flow of breathing gas with an airway of a user, the mask comprising:

a mask body (38, 82) having a first opening (44) adapted to be coupled to a source of breathing gas and a second opening(46) ; and

a mask seal member (40, 76) defining a user contacting portion that couples the mask body to a user so as to enable the flow of breathing gas to be delivered to an airway of such a user, and wherein at least a portion of the mask seal member is molded to the mask body generally at the second opening by a two-shot injection molding process while the mask body is cooling and incompletely cured so that a portion of the mask seal member is molecularly bonded to the mask body as a consequence of the two-shot injection molding process.

2. The mask of claim 1, wherein the mask seal includes a first flap member (78) and a second flap member (80) that generally overlies the first flap member responsive to the mask being in an assembled configuration, wherein the first flap member is the portion of the mask seal member that is molded to the mask body.

3. The mask of claim 2, wherein the second flap member is removeably attachable to the mask body.

4. The mask of claim 1, further comprising a coupling member (96) molded to the mask body generally at the first opening by a two-shot injection molding process while the mask body is cooling and incompletely cured so that a portion of the coupling member is molecularly bonded to the mask body as a consequence of the two-shot injection molding process.

5. The mask of claim 1, wherein the mask body is defined by a plastic.

6. The mask of claim 1, wherein the mask seal member is unitary piece of silicone material.

7. The mask of claim 1, wherein the mask body includes a cavity defined therein and a peripheral edge defined at the second opening, wherein the second opening is adapted to communicate the cavity with at least a portion of a nose of a user, and wherein the first opening communicates with the cavity and provides a coupling adapted to couple to a conduit that carries the flow of breathing gas to the cavity.

8. The mask of claim 7, wherein the mask seal member is disposed on the peripheral edge of the mask body.

9. A pressure support system comprising:

a pressure generator (32) adapted to provide a flow of breathing gas;

a conduit (36) operatively coupled to the pressure generator to deliver the flow of breathing gas to a user; and

a mask (30, 74) coupled to the conduit to communicate the flow of breathing gas to an airway of a user, the mask comprising:

a mask body (38, 82) coupled to the conduit; and

a mask seal member (40, 76) having at least one portion that is molded to the mask body by a two-shot injection molding process while the mask body is cooling and incompletely cured, wherein the portion of the mask seal member is molecularly bonded to the mask body as a consequence of the two-shot injection molding process.

10. The system of claim 9, wherein the mask seal includes a first flap member (78) and a second flap member (80) that generally overlies the first flap member responsive to the mask being in an assembled configuration, wherein the first flap member is the portion of the mask seal member that is molded to the mask body.

11. The system of claim 10, wherein the second flap member is removeably attachable to the mask body.

12. The system claim 9, further comprising a coupling member (96) molded to the mask body generally at a location where the conduit coupled to the mask by a two-shot injection molding process while the mask body is cooling and incompletely cured so that a portion of the coupling member is molecularly bonded to the mask body as a consequence of the two-shot injection molding process.

13. The system of claim 9, wherein the mask body is defined by a plastic.

14. The system of claim 9, wherein the mask seal member is defined by a unitary piece of silicone material.

15. The system of claim 9, wherein the mask body includes:

a nose receiving cavity defined therein;

a first end portion having a peripheral edge;

a second end portion generally opposite the first end portion;

a first opening defined in the first end portion adapted to receive at least a portion of a nose of a user such that nares of a user communicate with the nose receiving cavity in the mask body; and

a second opening defined in the second end portion, the second opening communicating with the nose receiving cavity and providing a coupling for the conduit.

16. The system of claim 15, wherein the mask seal member is disposed on the peripheral edge of the first end portion of the mask body.

17. A two-shot injection molding method of forming a mask that is adapted to communicate a flow of breathing gas with an airway of a user, the method comprising:

providing a mask mold (60, 62);

injecting a first material into the mask mold to define a mask body (38, 82) of the mask;

injecting a second material into the mask mold while the mask body is cooling and incompletely cured to define at least a portion of a mask seal member (40, 76) of the mask, wherein the mask seal member is molecularly bonded to the mask body as a consequence of the second material being injected into the mask mold in this manner.

18. The method of claim 17, wherein injecting a second material into the mask mold defines a first flap member (78) of the mask seal member and further comprising a second flap member (80) that generally overlies the first flap member responsive to the mask being in an assembled configuration.

19. The method of claim 18, wherein the second flap member is removeably attached to the mask body to define an assembled mask.

20. The method of claim 17, wherein injecting the second material into the mask mold also defines a coupling member (96) molded to the mask body.

21. A mask adapted to communicate a flow of breathing gas with an airway of a user manufactured according to a two-shot injection molding process comprising the steps of:

providing a mask mold (60, 62);

injecting a first material into the mask mold to define a mask body (38, 82) of the mask;

injecting a second material into the mask mold while the mask body is cooling and incompletely cured to define a mask seal member (40, 76) of the mask, wherein the mask seal member is molecularly bonded to the mask body as a consequence of the second material being injected into the mask mold in this manner.

22. The mask of claim 21, wherein injecting a second material into the mask mold defines a first flap member (78) of the mask seal member and further comprising a second flap member (80) that generally overlies the first flap member responsive to the mask being in an assembled configuration.

23. The mask of claim 21, wherein the second flap member is removeably attached to the mask body to define an assembled mask.

24. The mask of claim 21, wherein injecting the second material into the mask mold also defines a coupling member (96) molded to the mask body.

Fig. 1

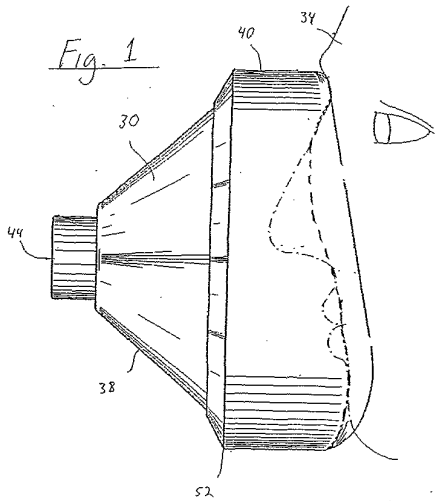
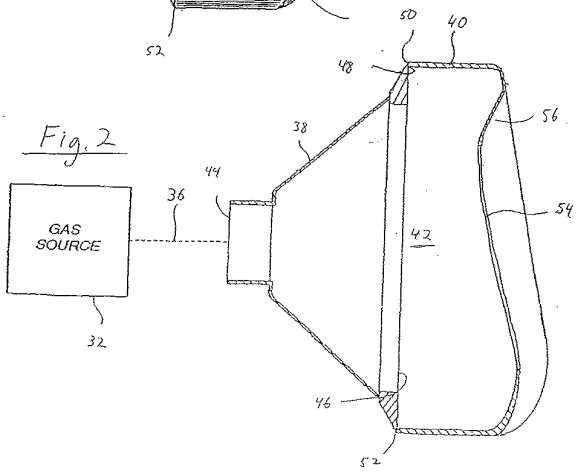


Fig. 2



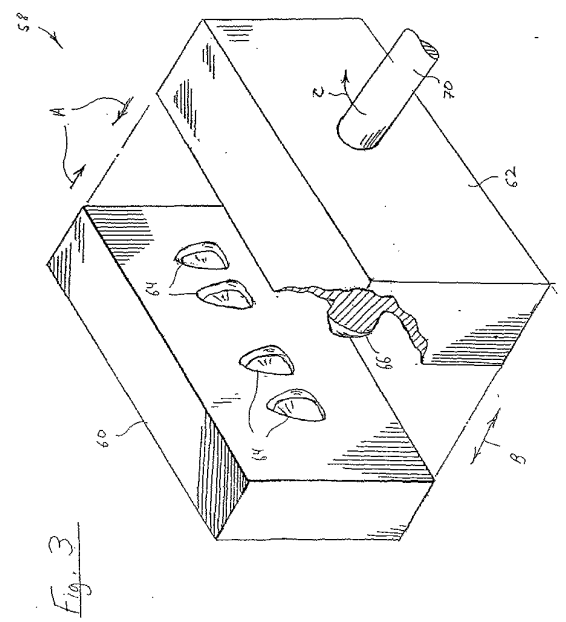


Fig. 3

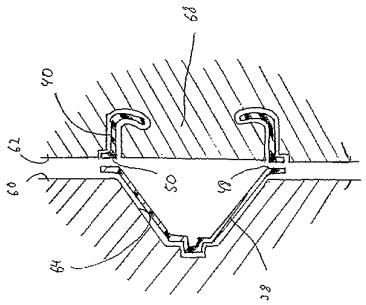


Fig. 4B

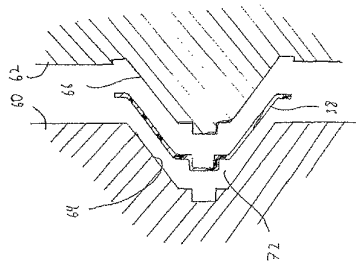


Fig. 4A

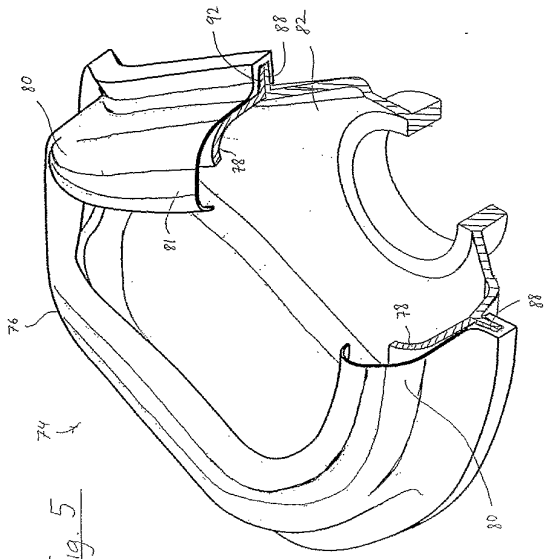


Fig. 5

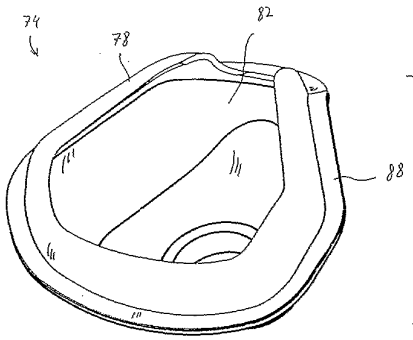


Fig. 6

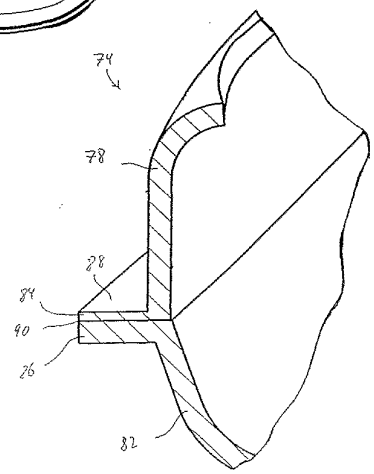
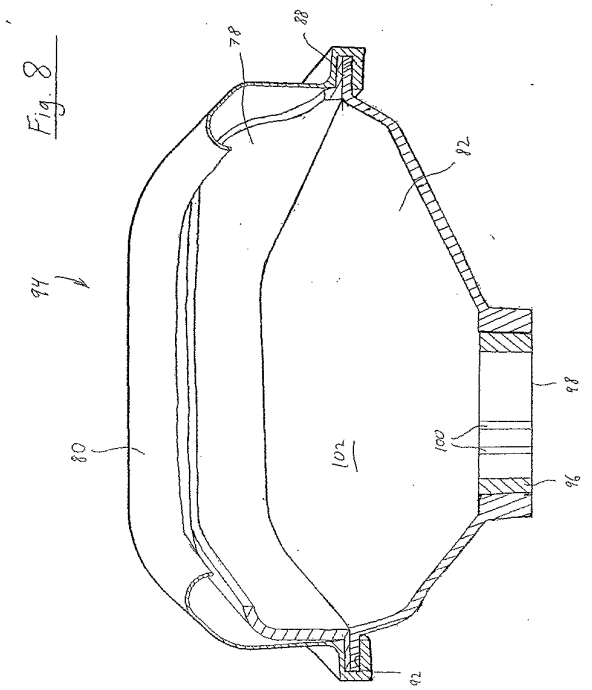


Fig. 7

Fig. 8



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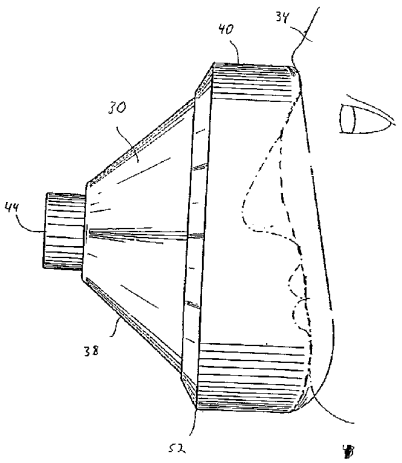
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(54) Title: TWO-SHOT INJECTION MOLDED NASAL/ORAL MASK



(57) Abstract: A mask that communicates a flow of breathing gas with an airway of a user is formed by a two-shot injection molding process. The mask includes a mask body (38) and a mask seal member (40), at least a portion of which is molded to the mask body by a two-shot injection molding process, while the mask body is cooling and incompletely cured. The mask seal member, or a portion thereof, is molecularly bonded to the mask body as a consequence of the two-shot injection molding process.

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【国際調査報告】

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
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US CL : 128/206.12, 206.16, 206.21, 206.24, 206.26
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 128/206.12, 206.16, 206.21, 206.24, 206.26

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,724,965 A (Handke et al) 10 March 1998, see entire document.	1
A	US 5,676,133 A (Hickle et al) 14 October 1997, see entire document.	1
A	US 5,657,752 A (Landis et al) 19 August 1997, see entire document.	1
A	US 5,538,014 A (Wilson et al.) 23 July 1996, see entire document.	1
A	US 5,094,236 A (Tayebi) 10 March 1992, see entire document.	1
A	US 5,080,094 A (Tayebi) 14 January 1992, see entire document.	1
A	US 5,062,421 A (Burns et al) 05 November 1991, see entire document.	1
A	US 4,941,467 A (Takata) 17 July 1990, see entire document.	1
A	US 4,848,334 A (Bellm) 18 July 1989, see entire document.	1

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
29 December 2001 (29.12.2001)	08 JUL 2002
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer John Weiss Telephone No. 703-308-0858

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/25097

C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,764,990 A (Markert) 23 August 1988, see entire document.	1
Y	US 4,454,881 A (Huber et al) 19 June 1984, see entire document.	1, 4, 5, 6, 7, 8

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/25097

Continuation of B. FIELDS SEARCHED Item 3:
EAST
injection molding, mask

フロントページの続き

Ｆターム(参考) 4F206 AA33 AH70 JA07 JB28 JC01 JQ81