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- (71) Applicant(s)
3M Innovative Properties Company
- (72) Inventor(s)
Gebrewold, Yonas;Martin, Philip G.;Ponzio, Claudio;Lovo, Francesco;Mattano, Dan;Skulley, Thomas G.;Johnson, Erik J.;Henderson, Christopher P.
- (74) Agent / Attorney
Freehills Patent & Trade Mark Attorneys, Level 38 MLC Centre Martin Place, Sydney, NSW, 2000
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(71) Applicant (for all designated States except US): **3M INNOVATIVE PROPERTIES COMPANY** [US/US]; 3M Center, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **GEBREWOLD, Yonas** [US/US]; 3M Center, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US). **SKULLEY, Thomas**

G. [US/US]; 686 East Third Street, Saint Paul, Minnesota 55105 (US). **JOHNSON, Erik J.** [US/US]; 3M Center, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US). **MARTIN, Philip G.** [US/US]; 3M Center, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US). **HENDERSON, Christopher P.** [GB/GB]; Cain Road, Bracknell Berkshire RG12 8HT (GB). **LOVO, Francesco** [IT/IT]; PININFARINA EXTRA S.r.l., Via Nazionale 30, I-10020 Cambiano (IT). **MATTANO, Dan** [IT/IT]; PININFARINA Extra S.r.l., Via Nazionale 30, I-10020 Cambiano (IT). **PONZIO, Claudio** [IT/IT]; PININFARINA Extra S.r.l., Via Nazionale 30, I-10020 Cambiano (IT).

(74) Agents: **HANSON, Karl G.**, et al.; 3M Center, Office of Intellectual Property Counsel, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US).

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(54) Title: RESPIRATOR HAVING DYNAMIC SUPPORT STRUCTURE AND PLEATED FILTERING STRUCTURE

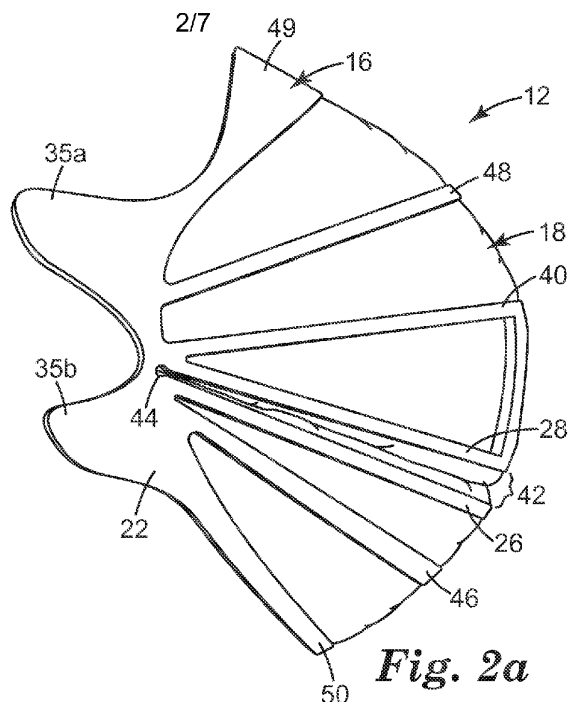


Fig. 2a

(57) Abstract: A filtering face-piece respirator 10 that has a support structure 16 and a filtering structure 18. The support structure 16 includes first and second transversely extending members 26, 28 that can move toward and apart from each other in the longitudinal direction. The filtering structure 18 has a filtration layer 52 and a pleat 58. The pleat 58 allows the filtering structure 18 to contract and expand when the first and second transversely extending members 26, 28 move toward and apart from each other, respectively. This ability to expand and contract in an accordion-like manner enables the mask body to better accommodate wearer jaw movement.



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RESPIRATOR HAVING DYNAMIC SUPPORT STRUCTURE AND PLEATED FILTERING STRUCTURE

[0001] The present invention pertains to a filtering face-piece respirator that is capable of expanding and contracting in the longitudinal direction to accommodate wearer jaw movement. The respirator expansion is achieved by providing the mask body with a moveable support structure in conjunction with a pleated filtering structure.

BACKGROUND

[0002] Respirators are commonly worn over the breathing passages of a person for at least one of two common purposes: (1) to prevent impurities or contaminants from entering the wearer's breathing track; and (2) to protect other persons or things from being exposed to pathogens and other contaminants exhaled by the wearer. In the first situation, the respirator is worn in an environment where the air contains particles that are harmful to the wearer, for example, in an auto body shop. In the second situation, the respirator is worn in an environment where there is risk of contamination to other persons or things, for example, in an operating room or clean room.

[0003] Some respirators are categorized as being "filtering face-pieces" because the mask body itself functions as the filtering mechanism. Unlike respirators that use rubber or elastomeric mask bodies in conjunction with attachable filter cartridges (see, e.g., U.S. Patent RE39,493 to Yuschak et al.) or insert-molded filter elements (see, e.g., U.S. Patent 4,790,306 to Braun), filtering face-piece respirators have the filter media comprise much of the whole mask body so that there is no need for installing or replacing a filter cartridge. As such, filtering face-piece respirators are relatively light in weight and easy to use.

[0004] Filtering face-piece respirators generally fall into one of two categories, namely, shaped respirators and fold-flat respirators.

[0005] Shaped respirators are more-or-less permanently formed into a desired face-fitting configuration and generally retain that configuration during storage and use. Shaped filtering face-piece respirators regularly include a molded supporting shell structure, generally referred to as a "shaping layer", which is commonly made from thermally bonding fibers or an open-work plastic mesh. The shaping layer is primarily

designed to provide support for a filtration layer. Relative to the filtration layer, the shaping layer may reside on an inner portion of the mask (adjacent to the face of the wearer), or it may reside on an outer portion of the mask, or on both inner and outer portions. Examples of patents that disclose shaping layers to support filtration layers include U.S. Patents 4,536,440 to Berg, 4,807,619 to Dyrud et al., 4,850,347 to Skov., and Des 285,374 to Huber et al.

[0006] In known shaped filtering face-piece respirators, the filtration layer typically is attached to the shaping layer by entanglement of the fibers at the interface between the layers or by binding of the fibers to the shaping layer. Alternatively, the filtration layer may be bonded to the shaping layer shell across its entire inner surface through use of an appropriate adhesive — see U.S. Patents 6,923,182 and 6,041,782 to Angadjivand et al. Known filtering face-piece respirators also may be welded at the periphery of the mask body to join the assembled layers together.

[0007] Unlike shaped respirators, fold-flat respirators are stored flat but include seams, pleats, and/or folds that allow the mask body to be opened into a cup-shaped configuration for use. Examples of flat-fold filtering face-piece respirators are shown in U.S. Patents 6,568,392 and 6,484,722 to Bostock et al. and 6,394,090 to Chen. Some commercially-available pleated respirators have been designed with pleated structures that unfold or expand when the respirator is being placed on the wearer's face. These known pleated products typically do not use a support structure to define the shape of the respirator mask body. Known commercially-available pleated respirators also are generally not worn in spaced relation to a wearer's face and do not fit tight to the wearer's face around the perimeter. These pleated respirators are primarily used in environments where there is a risk of contamination to another person or thing. In these working environments, the impurities or contaminants that the wearer may be exposed to tend to be transitory in nature, for example, splash fluids. As such, the respirators are not constructed with a support structure that provides a tight fit against a wearer's face at the perimeter and that provides a spaced cup-shaped air chamber away from the wearer's face. Examples of pleated filtering face masks are shown in the following U.S. Patent documents: 7,036,507 to Jensen, 6,474,336 to Wolfe, 4,248,220 to White, 4,300,549 to Parker, 2006/0130841 to Spence et al., and 2005/0096524 to Chang.

SUMMARY OF THE INVENTION

[0008] As discussed above, persons skilled in the art of designing filtering face-piece respirators have developed a variety of methods for supporting a filtration layer in a pre-shaped mask body. The mask bodies that have been designed, however, have generally been non-dynamic structures that do not accommodate the motion of the wearer's jaw. Respirator wearers often need to talk to their colleagues when working. The jaw movement that occurs when talking can cause the mask body to shift in location on the wearer's face. When the respirator shifts from its desired position on the wearer's face, opportunities may be created for contaminated air to enter the mask interior unfiltered. In addition, the opening of the jaw tends to pull the mask body downward, causing a clamping action on the nose. The non-dynamic structure of conventional respirators thus may create uncomfortable conditions for the wearer.

[0009] The present invention addresses a need for a shaped filtering face-piece respirator that can dynamically accommodate wearer jaw movement so that the respirator suitably and comfortably resides fitted to the wearer's face during use. In so doing, the present invention provides a filtering face-piece respirator that includes a mask body that comprises: (a) a support structure that includes first and second transversely extending members that can move toward and apart from each other in the longitudinal dimension; and (b) a filtering structure that comprises: (i) a filtration layer; and (ii) a pleat; wherein the pleat allows the filtering structure to contract and expand when the first and second transversely-extending members move toward and apart from each other, respectively.

[0010] As indicated above, mask bodies for conventional shaped filtering face-piece respirators have regularly used a support structure that comprised a nonwoven web of thermally-bonded fibers or an open-work plastic mesh to support the filtration layer. These conventional support structures were lacking in an ability to dynamically respond to wearer jaw movement. The provision of a support structure that includes first and second transversely-extending members and a filtering structure that includes a pleat that is capable of expanding when first and second transversely-extending members of the support structure move away from each other allows the mask body to expand longitudinally to better accommodate the opening motion of a person's jaw. The mask body also may contract when the jaw closes. The ability to accommodate wearer jaw movement in accordance with the present invention can enable the mask body to better

remain in its desired position on a wearer's face during use. The expandable nature of the mask body also can allow a single respirator to fit a greater range of face sizes and may alleviate the clamping action on the nose.

Glossary

- [0011] The terms set forth below will have the meanings as defined:
- [0012] "bisect(s)" means to divide into two generally equal parts;
- [0013] "center line" means a line that bisects the mask vertically when viewed from the front (FIG. 7);
- [0014] "centrally spaced" means separated significantly from one another along a line or plane that bisects the mask body vertically when viewed from the front;
- [0015] "comprises (or comprising)" means its definition as is standard in patent terminology, being an open-ended term that is generally synonymous with "includes", "having", or "containing". Although "comprises", "includes", "having", and "containing" and variations thereof are commonly-used, open-ended terms, this invention also may be suitably described using narrower terms such as "consists essentially of", which is semi open-ended term in that it excludes only those things or elements that would have a deleterious effect on the performance of the inventive respirator in serving its intended function;
- [0016] "clean air" means a volume of atmospheric ambient air that has been filtered to remove contaminants;
- [0017] "contaminants" means particles (including dusts, mists, and fumes) and/or other substances that generally may not be considered to be particles (e.g., organic vapors, et cetera) but which may be suspended in air, including air in an exhale flow stream;
- [0018] "crosswise dimension" is the dimension that extends laterally across the respirator from side-to-side when the respirator is viewed from the front;
- [0019] "exterior gas space" means the ambient atmospheric gas space into which exhaled gas enters after passing through and beyond the mask body and/or exhalation valve;
- [0020] "filtering face-piece" means that the mask body itself is designed to filter air that passes through it; there are no separately identifiable filter cartridges or inserted-molded filter elements attached to or molded into the mask body to achieve this purpose;

[0021] "filter" or "filtration layer" means one or more layers of air-permeable material, which layer(s) is adapted for the primary purpose of removing contaminants (such as particles) from an air stream that passes through it;

[0022] "filtering structure" means a construction that is designed primarily for filtering air;

[0023] "first side" means an area of the mask body that is laterally distanced from a plane that bisects the respirator vertically and that would reside in the region of a wearer's cheek and/or jaw when the respirator is being donned;

[0024] "harness" means a structure or combination of parts that assists in supporting the mask body on a wearer's face;

[0025] "hinder movement" means impede, restrict, or deprive of movement when exposed to forces that exist under normal use conditions;

[0026] "integral" means that the parts in question were made at the same time a single part and not two separate parts subsequently joined together;

[0027] "interior gas space" means the space between a mask body and a person's face;

[0028] "line of demarcation" means a fold, seam, weld line, bond line, stitch line, hinge line, and/or any combination thereof;

[0029] "living hinge" means a mechanism that allows members that integrally extend therefrom to generally pivot thereabout in a rotational-type manner with such ease that damage is not caused to the members or to the hinge joint under normal use;

[0030] "longitudinally-movable" means capable of being moved in the longitudinal direction in response to mere finger pressure;

[0031] "mask body" means an air-permeable structure that is designed to fit over the nose and mouth of a person and that helps define an interior gas space separated from an exterior gas space;

[0032] "member", in relation to the support structure, means an individually and readily identifiable solid part that is sized to contribute significantly to the overall construction and configuration of the support structure;

[0033] "perimeter" means the outer edge of the mask body, which outer edge would be disposed generally proximate to a wearer's face when the respirator is being donned by a person;

[0034] "pleat" means a portion that is designed to be folded back upon itself;

- [0035] "pleated" means being folded back upon itself;
- [0036] "polymeric" and "plastic" each mean a material that mainly includes one or more polymers and may contain other ingredients as well;
- [0037] "plurality" means two or more;
- [0038] "respirator" means an air filtration device that is worn by a person to provide the wearer with clean air to breathe;
- [0039] "second side" means an area of the mask body that is distanced from a plane line that bisects the mask vertically (the second side being opposite the first side) and that would reside in the region of a wearer's cheek and/or jaw when the respirator is being donned;
- [0040] "support structure" means a construction that is designed to have sufficient structural integrity to retain its desired shape, and to help retain the intended shape of the filtering structure that is supported by it, under normal handling;
- [0041] "spaced" means physically separated or having measurable distance therebetween; and
- [0042] "transversely extending" means extending generally in the crosswise dimension.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0043] FIG. 1 shows a front perspective view of a filtering face-piece respirator **10**, in accordance with the present invention, being worn on a person's face;
- [0044] FIG. 2a illustrates a side view of a mask body **12**, in accordance with the present invention, where the longitudinally-movable, transversely-extending member **26** is located near member **28** in a non-expanded condition;
- [0045] FIG. 2b illustrates the mask body **12** where the longitudinally-movable, transversely-extending member **26** is separated from member **28** to place the mask body in an open expanded configuration;
- [0046] FIG. 3 is a cross-sectional view of the filtering structure **18** taken along lines 3-3 of FIG. 2b;
- [0047] FIG. 4 is a perspective view of a filtering structure **18** that may be used in connection with the present invention;

[0048] FIG. 5 is a side view of an alternative embodiment of living hinges **64a**, **64b** that may be used in a support structure **16'** to allow rotational movement of members **26**, **28**, **40**, **46**, **48**, **49**, and **50**;

[0049] FIG. 5E is an enlarged view of the area within broken-line circle **5E** of FIG. 5;

[0050] FIGs. 6a and 6b are side views of a another embodiment of a respirator **10"** having a different support structure **16"** and including a nose clip **72** and exhalation valve **74**;

[0051] FIG. 7 is a front view of the mask body **12**, illustrating a film strip **76** that may be secured to it at opposing top and bottom locations to assist in expanding the mask body **12** in the longitudinal dimension during testing;

[0052] FIG. 8 is a plan view of a blank that is used to form a multi-layered filtering structure **18** (FIG. 4) in accordance with the present invention;

[0053] FIG. 9 is a graph that plots Load v. Tensile Strain for filtering face-piece respirators of the present invention and Moldex 2200 filtering face-piece respirators; and

[0054] FIG. 10 is a graph that plots the force needed to separate two adjacent transversely-extending members over a longitudinal distance.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0055] In practicing the present invention, a filtering face-piece respirator is provided that has the ability to function like an accordion in one or more locations so that the mask body can expand and retract in coordination with the motion of a person's jaw. Workers regularly need to communicate with one another on the job. Conventional shaped filtering face-piece respirators, however, have not used a mask body that enabled significant dynamic movement in coordination with the motion of a wearer's jaw. Accordingly, conventional respirators exhibited an opportunity to shift in location on a wearer's face when the respirator wearer was talking. The nose portion of the respirator also became pulled down against the wearer's nose when the jaw moved in a downward direction. The present invention addresses these drawbacks by providing one or more longitudinally-movable, transversely-extending members that can move apart or move toward another member, as the case may be, in conjunction with the opening and closing of a pleat in a filtering structure, when a wearer opens and closes their mouth while wearing the shaped respiratory mask.

[0056] FIG. 1 shows a shaped filtering face-piece respirator **10** that is being worn over the nose and mouth of a person. The respirator **10** includes a mask body **12** and a harness **14**. The mask body **12** has a support structure **16** and a filtering structure **18**. The support structure **16** includes a perimeter **20**, a first side **22**, and an opposing second side **24**. The perimeter member **20** of the support structure **16** may, but not necessarily, contact the wearer's face when the respirator **10** is being donned. The perimeter member **20** may comprise a member, or combination of members, that extend 360° continuously about, and adjacent to, the periphery of the mask body **12**. The perimeter member also can be segmented. Typically, the wearer's face will contact only the inner surface or periphery of the filtering structure **18** (or an additional face seal material) so that a comfortable fit is achieved. Thus, the peripheral edge of the filtering structure **18** may extend slightly beyond the perimeter **20** of the support structure **16**. The support structure **16** also includes a longitudinally-movable, transversely-extending member **26**. This longitudinally-movable, transversely-extending member **26** extends from a first side **22** of the mask body **12** to a second side **24**, preferably without being joined together between sides **22** and **24** by any longitudinally-extending member(s) that could hinder movement of the transversely-extending members **26** in a longitudinal direction. That is, there preferably is no structural member that joins member **26** to member **28** so as to restrict member **26** from moving away from member **28** when the wearer expands their jaw or opens their mouth. The longitudinal movement that is beneficially achieved according to the illustrated embodiment is particularly pronounced along the center line **29**. When viewing the respirator as projected onto a plane from the front, the transverse direction is the direction that extends across the respirator in the general "x" direction, and the longitudinal direction is the dimension that extends between the bottom and top of the respirator **10** in the general "y" direction. When viewed through such a planar projection, the transversely-extending member **26** can move towards and away from member **28** in the general "y" direction. In so doing, the member **26** moves towards and away from member **28** a greater distance along the center line **29** than at the first and second sides **22** and **24** where the transversely-extending members merge together. The harness **14** includes first and second straps **30** and **32** that may be adjusted in length by one or more buckles **34**. The harness **14** may be secured to the mask body **12** at the first and second sides **22**, **24** at

harness-securement flange members **35a**, **35b**. The buckles **34** may be secured to the mask body **12** at flange members **35a**, **35b** by a variety of methods, including stapling, adhesive bonding, welding, and the like. The buckles also may be integrally molded into the support structure **16**; see, U.S. Patent Application U.S. Serial No. 60/974,031 (attorney docket number 63355US002) entitled *Filtering Face-Piece Respirator Having Buckles Integral To The Mask Body Support Structure*, filed on the same day as this patent application. The mask body **12** also includes an optional frame **36** that has an opening **38** located therein. The frame **36** provides a location or foundation for securing an exhalation valve (not shown) to the mask body **12**. Although the transversely-extending members **28** and **40** are joined together by longitudinally extending members **37** on the frame **36**, the mask body **12** nonetheless may be expanded by relatively free movement between members **26** and **28** and other members that are not so joined relative to one another. Thus, although the invention contemplates having one or more members (2, 3, 4, 5, et cetera) that exhibit the capacity to move at least longitudinally toward or away from each other, not all transversely extending members need to demonstrate such behavior with respect to each adjacent member to accomplish objectives in accordance with the present invention.

[0057] Exhalation valves that may be secured to the support structure **16** at frame **36** may have a construction similar to the unidirectional valves described in U.S. Patents 7,188,622, 7,028,689, and 7,013,895 to Martin et al.; 7,117,868, 6,854,463, 6,843,248, and 5,325,892 to Japuntich et al.; 6,883,518 to Mittelstadt et al.; and RE37,974 to Bowers. The exhalation valve may be secured to the frame **36** by a variety of means, including sonic welds, adhesive bonding, mechanical clamping, and the like. The valve seat may be fashioned to include a cylinder that passes through the opening **38** and that is folded back upon itself in a clamping relationship with the frame **36** — see, for example, U.S. Patents 7,069,931, 7,007,695, 6,959,709, and 6,604,524 to Curran et al and EP1,030,721 to Williams et al. A valve cover also can be placed over the valve seat to create an internal chamber that protects the valve diaphragm. Examples of valve cover designs are shown in U.S. Patents Des. 347,298 to Japuntich et al. and DES. 347,299 to Bryant et al.

[0058] FIG. 2a illustrates a side view of the mask body **12** where transversely-extending members **26** and **28** are positioned adjacent to one another such that the filtering structure **18** becomes pleated therebetween in pleatable region **42**. The support structure

16 of mask body **12** may further include a living hinge **44** located in the region where movable transversely extending member **26** meets member **28**. The living hinge **44** is beneficial in that it allows transversely-extending members **26** and **28** to more easily move towards one another or to move apart from one another. As shown, the living hinge **44** may have a cul-de-sac shape. The living hinge **44** preferably also is disposed between upper and lower harness attachment flanges **35a** and **35b** in the "y" dimension when the mask **12** is viewed from the side and oriented in an upright configuration as shown in FIGs. 2a and 2b. Preferably, there are one, two, three, or more living hinges disposed between the point where the harness **14** (FIG. 1) exerts its force on the mask body (in this instance at flanges **35a** and **35b**). As shown in FIG. 2a, there are other transversely-extending members **46**, **48**, **49**, and **50** that do not have longitudinally-extending members located therebetween away from each side **22** or **24**. Thus, while transversely-extending members **46** and **48**, for example, may be able to move in a longitudinal dimension to allow the mask body **12** to expand or contract, these members may not be as freely movable as member **26** because the former lacks a cul-de-sac-shaped living hinge where they come together at the first and second side portions **22** and **24**. Therefore, although only one such living hinge **44** is illustrated at each end of the transversely-extending members **26**, **28**, **46**, **48**, **49** and **50**, the present invention does indeed contemplate using such additional living hinges between additional transversely-extending members. The living hinges may be used where the transversely-extending members meet. There should not, however, be any longitudinally-extending members located between members that are intended to move longitudinally toward or away from one another.

[0059] FIG. 2b shows the mask body **12** in a configuration where the pleatable region **42** is expanded. In this configuration, the transversely-extending members **26** and **28** are centrally spaced apart from one another at a near maximum distance. In comparing the mask body configuration of FIG. 2a with the configuration of FIG. 2b, it is apparent that the mask body **12** of the present invention has the ability to function in an accordion-like manner at pleatable region **42**. This ability is particularly beneficial, as indicated above, to accommodate jaw movement of various sized faces. The filtering structure **18** may be attached to the supporting structure **16** of the mask body **12** at multiple contact points. This connection may be made along the perimeter **20** of the support structure and/or at

various locations where the transversely-extending members **26, 28, 40, 46, 48, 49** and **50** meet the filtering structure **18**. The support structure **16** and filtering structure **18** may be secured together by a variety of means including adhesive bonding, welding, over molding, and the like. A temporary joining mechanism also may be used to allow the support structure **16** to be reused when the filtering structure **18** has met the end of its service life. In such a situation, the wearer could replace the filtering structure **18** and retain the support structure **16** so that only the filtering structure **18** needs to be discarded when the filter has met the end of its service life. One or more of the transversely-extending members preferably has the ability to move longitudinally in response to mere pressure from a person's finger(s). That is, by simply pushing on the transversely-extending member in the longitudinal direction, the transversely-extending member can be readily deflected. The ability of the transversely-extending member to be so easily deflected is further manifested by the *Transversely-Extending Member Movement Test* (TEMMT) set forth below. Under this test, one or more of the transversely-extending members can move more than 5 mm when subjected to a force of only 0.2N. More preferably, one or more transversely extending members can move at least 10 mm when subjected to a force of only 0.3 N when subjected to the TEMMT. The longitudinally-movable, transversely-extending members will move a greater distance along the center line **29** (FIG. 1) than at the sides **22** and **24** of the mask body. Typically, at least one of the centrally-spaced transversely-extending members can move longitudinally at the center line **29** over a distance of about 5, 10, 15, 20, or even 35 mm without causing significant structural injury to the transversely-extending member and/or to the living hinge when subjected to the *Transversely Extending Member Movement Test* at a force of only about 0.7 N or less. Typically, the whole mask body may be expanded up to about 20 to 35 mm without causing damage thereto when testing the respirator under the *Respirator Expansion Test* set forth below.

[0060] The support structure may be made by known techniques such as injection molding. Known plastics such as olefins including, polyethylene, polypropylene, polybutylene, and polymethyl(pentene); plastomers; thermoplastics; thermoplastic elastomers; and blends thereof may be used to make the support structure. Additives such as pigments, UV stabilizers, anti-block agents, nucleating agents, fungicides, and bactericides also may be added to the composition that forms the support structure. The

plastic used preferably is able to exhibit resilience, shape memory, and resistance to flexural fatigue so that the supporting structure can be deformed many times (i.e. greater than 100), particularly at any hinge points, and return to its original position. The plastic selected should be able to withstand an indefinite number of deformations so that the support structure exhibits a greater service life than the filter structure. The material selected for the support structure preferably is a plastic that exhibits a Stiffness in Flexure of about 75 to 300 Mega Pascals (MPa), more typically about 100 to 250 MPa, and still typically about 175 to 225 MPa. It also may be possible to use a metal or ceramic material in lieu of plastic to construct the support structure, although a plastic may be preferred for disposal/cost reasons. The support structure is a part or assembly that is not integral to (or made from) the filtering structure. The support structure members are sized to be larger than mere fibers or filaments used in the filtering structure. The members may be rectangular, circular, triangular, elliptical, trapezoidal, etc., when viewed in cross-section.

[0061] FIG. 3 shows a cross-section of the filtering structure **18**. As illustrated, the filtering structure **18** may include one or more cover webs **51a** and **51b** and a filtration layer **52**. The cover webs **51a** and **51b** may be located on opposing sides of the filtration layer **52** to capture any fibers that could come loose therefrom. Typically, the cover webs **51a** and **51b** are made from a selection of fibers that provide a comfortable feel, particularly on the side of the filtering structure **18** that makes contact with the wearer's face. The construction of various filter layers and cover webs that may be used in conjunction with the support structure of the present invention are described below in more detail.

[0062] FIG. 4 shows a perspective view of the filtering structure **18**. The filtering structure **18** may include a first and second transversely-extending lines of demarcation **53a** and **53b**. These lines of demarcation **53a**, **53b** may be substantially spaced from one another in the central portion of the filtering structure **18** but may converge towards each other, moving laterally in the direction of the sides **54** and **56**. The lines of demarcation **53a**, **53b** may comprise a fold, weld line, stitch line, bond line, hinge line, or combination thereof. Generally, the first and second lines of demarcation **53a** and **53b** correspond to the location of certain transversely-extending members on the support structure. When the first and second lines of demarcation **53a**, **53b** define a pleat **58** that may be formed therebetween, the first and second lines of demarcation **53a**, **53b** preferably are secured to

longitudinally-movable, transversely-extending members **26** and **28**, thereby allowing the filtering structure to open and close in an accordion-like manner about the pleat **58** that is located therebetween. The filtering structure **18** also includes a generally vertical line of demarcation **60** that may be provided in the nose region of the filtering structure. This vertically-oriented line of demarcation **60** results from the method of making the filtering structure **18**. Generally such a line of demarcation is employed to eliminate excess material that would otherwise accumulate in the nose region during the manufacturing process. A similar generally vertical line of demarcation also may be included at the chin portion **62** of the filtering structure **18**. Although the filtering structure **18** has been illustrated with only two transversely-extending lines of demarcation **53a**, **53b** that would define a single pleat **58**, the filtering structure **18** may include two or more of such pleats in the cross-wise dimension. Thus, there can be multiple pleats (3, 4, 5, et cetera) where the filtering structure can expand to accommodate a concomitant expansion of the support structure **16** (FIGs. 2a and 2b). Under such circumstances, it is preferable to provide a support structure that has multiple living hinges. To improve fit and wearer comfort, an elastomeric face seal can be secured to the perimeter **61** of the filtering structure **18**. Such a face seal may extend radially inward to contact the wearer's face when the respirator is being donned. The face seal may be made from a thermoplastic elastomer. Examples of face seals are described in U.S. Patents 6,568,392 to Bostock et al., 5,617,849 to Springett et al., and 4,600,002 to Maryyanek et al., and in Canadian Patent 1,296,487 to Yard.

[0063] The filtering structure may take on a variety of different shapes and configurations. Preferably the filtering structure is adapted so that it properly fits against or within the support structure. Generally the shape and configuration of the filtering structure corresponds to the general shape of the support structure. The filtering structure may be disposed radially inward from the support structure, it may be disposed radially outward from the support structure, or it may be disposed between various members that comprise the support structure. Although the present filtering structure **18** has been illustrated with multiple layers that include a filtration layer **52** and cover webs **51a**, **51b**, the filtering structure may simply comprise a filtration layer or a combination of filtration layers. For example, a pre-filter may be disposed upstream to a more refined and selective downstream filtration layer. Additionally, sorptive materials such as activated carbon may be disposed between the fibers and/or various layers that comprise the filtering structure.

Further, separate particulate filtration layers may be used in conjunction with sorptive layers to provide filtration for both particulates and vapors. Further details regarding filtration layer(s) that may be used in the filtering structure are provided below.

[0064] FIG. 5 shows an embodiment of a support structure **16'** that has multiple living hinges **64a** and **64b**. Living hinges **64a** have similar constructions and would provide relative ease of rotation about the center point of the hinge. As shown, living hinges **64a** have minimal width and have the transversely-extending members **26**, **28**, **46**, and **50** spaced not far from one another at the point where they meet each hinge **64a**.

Transversely-extending members **26**, **28**, **46**, and **50** therefore are able to move towards or apart from one another using minimal force. Living hinges that are used in conjunction with the present invention, preferably allow the respirator mask body to exhibit a Maximum Load of less than about 8 Newtons (N), 7N, and even less than 6N at a 30% tensile expansion when tested according to the *Respirator Expansion Test* set forth below. Respirators of the invention also exhibit an average Hysteresis of less than 8%, 7%, and even less than 6% when tested under the same test. Living hinges **64b** as shown, tend to be wider than hinges **64a** and have greater space in between the transversely-extending members **28**, **40**, and **48**. As such, these hinges — while being able to provide rotational movement of the transversely-extending members — require relatively greater force to enable the transversely-extending members **28**, **40**, and **48** to move apart from one another. Because the motion from a wearer's jaw generally impacts the lower half of the respirator greater than the upper half, the living hinge(s) preferably are located such that the transversely-extending members are disposed on the lower half of the mask to provide greater ease of movement. The thickness of the transversely-extending members of the support structure may be about 0.25 to 5 mm, more typically about 1 to 3 mm and may have a cross-sectional area of about 2 to 12 mm², typically about 4 to 8 mm². The thickness of the harness flanges **35a**, **35b** typically may be about 2 to 4 mm.

[0065] FIG. 5E is an expanded view of the circled area **5E** of FIG. 5. As shown in FIG. 5E, the living hinge may be u-shaped and may include an apex **63** and a base **65**. The closest distance between the hinge apex **63** and the hinge base **65** is noted as width **W**. The apex **63** typically is defined by a curvature having a radius that ranges from about 0.5 to 10 mm, more typically 1 to 4 mm. The width **W** of the living hinge typically is about 0.3 to 5 mm, more typically about 0.5 to 2.5 mm. The living hinge also may be s-

shaped or w-shaped or may comprise other shapes as shown in U.S. Patent Application Serial No. 60/974,017, entitled *Filtering Face-Piece Respirator Support Structure That Has Living Hinges* filed on the same day as this patent application (attorney docket number 63167US002).

[0066] FIGs. 6a and 6b show another embodiment of a respiratory mask **10"**. As shown in this embodiment, the nose portion **66** may be provided with a more open configuration to make the mask cooler to wear in that area of the wearer's face. As such, the support structure **16"** is not entirely solid in this area but has an opening **67** defined by transversely-extending members **68** and **70**. Opening **67** makes nose clip **72** visible to the user and readily accessible for adjustment. The nose clip **72** allows the filtering structure **18** to be adapted to the size and shape of the wearer's nose. The nose clip **72** may be made from a malleable strip of metal such as aluminum as described in U.S. Patents 5,558,089 and Des. 412,573 to Castiglione. The nose clip also could take the form of a spring-loaded clip as described in U.S. Patent Publication 2007-0044803A1 to Xue et al. or may be a malleable plastic as described in U.S. Patent Publication 2007-0068529A1 to Kalatoor et al. The embodiment shown in FIG. 6a and 6b also illustrates an exhalation valve **74** that is disposed on the mask body **16"** between members **28** and **40**.

[0067] The support structure used in a mask body of the invention also may be constructed using a lesser number of transversely extending members and may exclude the use of a frame (**36**, FIG. 1) if no exhalation valve is desired. Preferably, there is at least one transversely-extending member that is capable of moving longitudinally relative to another transversely-extending member, including a transversely-extending member that defines the periphery of the support structure. Although the present invention, in its various embodiments, has been illustrated with a support structure that includes multiple transversely-extending members, it may be possible to fashion the mask such that the support structure only includes the peripheral transversely-extending members **49** or **70** and **50**. In such an embodiment, it may be desirable to fashion the filtering structure such that it is capable of maintaining its cup-shaped configuration without the need for support from further transversely-extending members. In such an embodiment, the filtering structure may include one or more stiffening layers that allow such a cup-shaped configuration to be maintained. Alternatively, the filtering structure could have one or

more horizontal and/or vertical lines of demarcation that contribute to its structural integrity to help maintain the cup-shaped configuration.

[0068] The filtering structure that is used in a mask body of the invention can be of a particle capture or gas and vapor type filter. The filtering structure also may be a barrier layer that prevents the transfer of liquid from one side of the filter layer to another to prevent, for instance, liquid aerosols or liquid splashes from penetrating the filter layer. Multiple layers of similar or dissimilar filter media may be used to construct the filtering structure of the invention as the application requires. Filters that may be beneficially employed in a layered mask body of the invention are generally low in pressure drop (for example, less than about 195 to 295 Pascals at a face velocity of 13.8 centimeters per second) to minimize the breathing work of the mask wearer. Filtration layers additionally are flexible and have sufficient shear strength so that they generally retain their structure under expected use conditions. Examples of particle capture filters include one or more webs of fine inorganic fibers (such as fiberglass) or polymeric synthetic fibers. Synthetic fiber webs may include electret charged polymeric microfibers that are produced from processes such as meltblowing. Polyolefin microfibers formed from polypropylene that has been electrically charged provide particular utility for particulate capture applications. An alternate filter layer may comprise a sorbent component for removing hazardous or odorous gases from the breathing air. Sorbents may include powders or granules that are bound in a filter layer by adhesives, binders, or fibrous structures — see U.S. Patent 3,971,373 to Braun. A sorbent layer can be formed by coating a substrate, such as fibrous or reticulated foam, to form a thin coherent layer. Sorbent materials may include activated carbons that are chemically treated or not, porous alumina-silica catalyst substrates, and alumina particles. An example of a sorptive filtration structure that may be conformed into various configurations is described in U.S. Patent 6,391,429 to Senkus et al.

[0069] The filtration layer is typically chosen to achieve a desired filtering effect and, generally, removes a high percentage of particles and/or other contaminants from the gaseous stream that passes through it. For fibrous filter layers, the fibers selected depend upon the kind of substance to be filtered and, typically, are chosen so that they do not become bonded together during the molding operation. As indicated, the filtration layer may come in a variety of shapes and forms and typically has a thickness of about 0.2 millimeters (mm) to 1 centimeter (cm), more typically about 0.3 mm to 0.5 cm, and it

could be a generally planar web or it could be corrugated to provide an expanded surface area — see, for example, U.S. Patents 5,804,295 and 5,656,368 to Braun et al. The filtration layer also may include multiple filtration layers joined together by an adhesive or any other means. Essentially any suitable material that is known (or later developed) for forming a filtering layer may be used for the filtering material. Webs of melt-blown fibers, such as those taught in Wentz, Van A., *Superfine Thermoplastic Fibers*, 48 Indus. Engn. Chem., 1342 et seq. (1956), especially when in a persistent electrically charged (electret) form are especially useful (see, for example, U.S. Pat. No. 4,215,682 to Kubik et al.). These melt-blown fibers may be microfibers that have an effective fiber diameter less than about 20 micrometers (μm) (referred to as BMF for "blown microfiber"), typically about 1 to 12 μm . Effective fiber diameter may be determined according to Davies, C. N., *The Separation Of Airborne Dust Particles*, Institution Of Mechanical Engineers, London, Proceedings 1B, 1952. Particularly preferred are BMF webs that contain fibers formed from polypropylene, poly(4-methyl-1-pentene), and combinations thereof. Electrically charged fibrillated-film fibers as taught in van Turnhout, U.S. Patent Re. 31,285, may also be suitable, as well as rosin-wool fibrous webs and webs of glass fibers or solution-blown, or electrostatically sprayed fibers, especially in microfilm form. Electric charge can be imparted to the fibers by contacting the fibers with water as disclosed in U.S. Patents 6,824,718 to Eitzman et al., 6,783,574 to Angadjivand et al., 6,743,464 to Insley et al., 6,454,986 and 6,406,657 to Eitzman et al., and 6,375,886 and 5,496,507 to Angadjivand et al. Electric charge also may be imparted to the fibers by corona charging as disclosed in U.S. Patent 4,588,537 to Klasse et al. or by tribocharging as disclosed in U.S. Patent 4,798,850 to Brown. Also, additives can be included in the fibers to enhance the filtration performance of webs produced through the hydro-charging process (see U.S. Patent 5,908,598 to Rousseau et al.). Fluorine atoms, in particular, can be disposed at the surface of the fibers in the filter layer to improve filtration performance in an oily mist environment — see U.S. Patents 6,398,847 B1, 6,397,458 B1, and 6,409,806 B1 to Jones et al. Typical basis weights for electret BMF filtration layers are about 10 to 100 grams per square meter. When electrically charged according to techniques described in, for example, the '507 patent, and when including fluorine atoms as mentioned in the Jones et

al. patents, the basis weight may be about 20 to 40 g/m² and about 10 to 30 g/m², respectively.

[0070] An inner cover web can be used to provide a smooth surface for contacting the wearer's face, and an outer cover web can be used to entrap loose fibers in the mask body or for aesthetic reasons. The cover web typically does not provide any substantial filtering benefits to the filtering structure, although it can act as a pre-filter when disposed on the exterior (or upstream to) the filtration layer. To obtain a suitable degree of comfort, an inner cover web preferably has a comparatively low basis weight and is formed from comparatively fine fibers. More particularly, the cover web may be fashioned to have a basis weight of about 5 to 50g/m² (typically 10 to 30g/m²), and the fibers are less than 3.5 denier (typically less than 2 denier, and more typically less than 1 denier but greater than 0.1). Fibers used in the cover web often have an average fiber diameter of about 5 to 24 micrometers, typically of about 7 to 18 micrometers, and more typically of about 8 to 12 micrometers. The cover web material may have a degree of elasticity (typically, but not necessarily, 100 to 200% at break) and may be plastically deformable.

[0071] Suitable materials for the cover web are blown microfiber (BMF) materials, particularly polyolefin BMF materials, for example polypropylene BMF materials (including polypropylene blends and also blends of polypropylene and polyethylene). A suitable process for producing BMF materials for a cover web is described in U.S. Patent 4,013,816 to Sabee et al. The web may be formed by collecting the fibers on a smooth surface, typically a smooth-surfaced drum. Spun-bond fibers also may be used.

[0072] A typical cover web may be made from polypropylene or a polypropylene/polyolefin blend that contains 50 weight percent or more polypropylene. These materials have been found to offer high degrees of softness and comfort to the wearer and also, when the filter material is a polypropylene BMF material, to remain secured to the filter material without requiring an adhesive between the layers. Polyolefin materials that are suitable for use in a cover web may include, for example, a single polypropylene, blends of two polypropylenes, and blends of polypropylene and polyethylene, blends of polypropylene and poly(4-methyl-1-pentene), and/or blends of polypropylene and polybutylene. One example of a fiber for the cover web is a polypropylene BMF made from the polypropylene resin "Escorene 3505G" from Exxon

Corporation, providing a basis weight of about 25 g/m² and having a fiber denier in the range 0.2 to 3.1 (with an average, measured over 100 fibers of about 0.8). Another suitable fiber is a polypropylene/polyethylene BMF (produced from a mixture comprising 85 percent of the resin "Escorene 3505G" and 15 percent of the ethylene/alpha-olefin copolymer "Exact 4023" also from Exxon Corporation) providing a basis weight of about 25 g/m² and having an average fiber denier of about 0.8. Suitable spunbond materials are available, under the trade designations "Corosoft Plus 20", "Corosoft Classic 20" and "Corovin PP-S-14", from Corovin GmbH of Peine, Germany, and a carded polypropylene/viscose material available, under the trade designation "370/15", from J.W. Suominen OY of Nakila, Finland.

[0073] Cover webs that are used in the invention preferably have very few fibers protruding from the web surface after processing and therefore have a smooth outer surface. Examples of cover webs that may be used in the present invention are disclosed, for example, in U.S. Patent 6,041,782 to Angadjivand, U.S. Patent 6,123,077 to Bostock et al., and WO 96/28216A to Bostock et al.

EXAMPLES

Test Methods

1. Stiffness in Flexure Test (SFT)

[0074] The stiffness in flexure of material used to make the support structure was measured according to ASTM D 5342-97 section 12.1 to 12.7. In so doing, six test specimens were cut from a blank film into rectangular pieces that were about 25.4 mm wide by about 70 mm long. The specimens were prepared as described below. Taber V-5 Stiffener tester Model 150-E (from Taber Corporation, 455 Bryant Street, North Tonawanda, New York, 14120) was used in 10 - 100 Taber stiffness unit configurations to measure the test specimens. The Taber Stiffness readings were recorded from the equipment display at the end of the test, and the stiffness in flexure was calculated using the following equation:

$$\text{Stiffness in Flexure (Pa)} = 7,492 \frac{\text{Ncm}^4}{\text{M}^2} \left(\frac{\text{Taber Stiffness}}{\text{Width} * \text{thickness}^3} \right)$$

Taber Stiffness = recorded material resistance to bending measured according to ASTM D5342-97 section 12.1 to 12.7.

Width = width of test film specimen in cm, which was 2.54 cm.

Thickness = average thickness of test specimen in cm measured using standard digital caliper at five equally-spaced locations along the length, of the material.

[0075] The stiffness in flexure from the six samples were averaged to give the Stiffness in Flexure.

2. *Respirator Expansion Test (RET)*

[0076] The respirator's Maximum Load at a 30% Tensile Expansion and the Hysteresis were measured under this test. These parameters are indicative of the dynamic performance of the respirator support structure. The Maximum Load at a 30% Tensile Expansion measures the flexibility (or resistance to expansion) of the support structure in the longitudinal dimension under dynamic expansion. Lower Maximum Load values are indicative of greater ease of respirator expansion. The Hysteresis measures the support structure's inability to return to its original shape or condition when the force that causes the change in shape or condition has been removed. Thus, for purposes of the invention, a lower Hysteresis is desired. The Maximum Load at a 30% Tensile Expansional Hysteresis were measured using an Instron, 4302 Universal material testing instrument (from Instron Corporation, 100 Royall Street, Canton, Massachusetts, 02021). During the test, data was collected every 1 second using an Instron Merlin Data acquisition software, also available from the Instron Corporation. The "gauge length" was set in the Instron test equipment such that it was equal to the longitudinal length of the mask body in its relaxed or unstressed condition (**D**, FIG. 7). For the inventive respirator, the gauge length was set at 114 mm. For a commercially available Moldex 2200 N 95 respirator, the gauge length and was set at 127 mm. A three cycle test for each specimen was set at a 30% expansion at a cross head speed of 254 mm per minute. For each cycle, the data acquisition software generated Maximum Load and Hysteresis data, as well as % Tensile Strain vs. Load.

[0077] Before testing, a 0.76 mm thick High Density Polyethylene (HDPE) film strip **76** that was 51 mm long and 25.4 mm wide (from Loose Plastic Inc, 3132 West Dale Road, Beaverton, MI, 48612), was stapled centrally to the top and bottom of the mask body **12** as shown in FIG. 7. The HDPE film **76** was attached to the mask body **12** such that the mask body shape was preserved. Two pieces of the HDPE film **76** were attached

to the top and bottom of the respirator centrally along bisecting line **29** by placing one piece of the film on the inside and one piece on the outside so that the applied force is more evenly distributed through the mask body **12** (rather than just being applied to the inside or outside). Heavy Duty STANLEY stapler wire **78** (12.7 mm) from Stanley Bostitch, East Greenwich, RI 02818 was used to staple the HDPE film **76** to the finished respirators. The tensile expansion was achieved by pulling on the respirator in the "y" direction at tabs **76**. To achieve a 30% expansion, the tensile strain was increased from the respirator rest condition at a distance **D** to a distance of 1.3**D**.

3. *Transversely-Extending Member Movement Test (TEMMT)*

[0078] Maximum force required to move the transversely-extending members was measured by imposing tensile strain on the transversally-extending members. The test was done using an Instron 4302 Universal material testing instrument described in the Modulus Test Method above. Gauge length between the two pneumatic grips of Instron test equipment was set at 114 mm. The two transversely-extending members were first set at their relaxed spaced-apart distance, which in this case was 5 mm. The two transversely-extending members were then pulled apart to impose tensile strain thereon. The tensile strain was exerted on the members until they were spaced up to about 3.5 cm beyond the baseline starting point. The distance extended was measured along the center line. The tensile strain was imposed at a cross head speed of 254 mm per minute. The tensile strain was imposed at a cross head speed of 254 mm per minute. The initial rest state 5 mm gap was set as a zero reference point for this test. Each specimen was then tested three times by opening and closing the gap between the two members. Then force versus distance data for each cycle was collected.

Sample Preparation

1. *Stiffness in Flexure Test Specimen*

[0079] Test specimens for the *Stiffness in Flexure Test* were prepared from the same compounded polymer ingredients that were blended together to make the respirator support structure. See Table 2 for the polymeric composition of the support structure. Forty (40) grams of the compound were used to make a circular film that was 114 mm in radius and 0.51 to 0.64 mm thick. The first 40 grams of the compounded material was

poured into a twin screw roller blade Type Six BRABENDER mixer (from C.W. Brabender instruments Inc., 50 East Wesley Street, P.O. Box 2127, South Hackensack, NJ, 07606). The mixer was operating at 75 revolutions per minute (RPM) and at a temperature of 185°C. After blending the molten compound for about 10 minutes, the mixture was pressed under 44.5 kilonewtons (KN) of force to make the 0.51 to 0.64 mm thick flat circular film that was 114 mm in diameter. The compression was conducted using a hot platen set at 149 °C. The hot platen was a Genesis 30 ton Compression molding press from WABASH Equipments 1569 Morris Street, P.O. Box 298, Wabash, IN 46992. Before testing for stiffness in flexure, the films were cut to the required test specimen sizes of 25.4 mm wide by 70 mm long.

2. *Respirator Support Structure Manufacture*

[0080] Samples of the respirator support structure were made using a standard injection molding process. Single cavity male and female molds, matching the geometry of the frame shown in FIGs. 1-2 were manufactured at a tool manufacturer. At a relaxed state, or while the support structure was still on the mold, the support structure measured 114 mm, top to bottom, and 120 mm from side to side. The measurement was made along a direct line between the highest and lowest points on the perimeter and two living hinge points, respectively while the respirator was in an unstressed state. The targeted thickness of the members that comprised the support structure was 2.5 millimeters. The transversely-extending members were given a trapezoidal cross-section to allow the support structure to be more easily removed from the mold. The cross-sectional area of the transversely-extending members ranged from about 4 to 12 mm².

[0081] A 110 Ton Toshiba VIS-6 molding press was used during the injection molding process to make the support structure under the conditions and set points shown in Table 1:

Table 1
Respirator Support Structure Injection Molding Conditions

Process Condition	Set Point	Unit
Cycle time	40	Sec
Injection time	3	Sec
Fill Time	0.86	Sec
Charge Time	1-2	Sec
Cooling Time	12	Sec
Injection Pressure	276	MPa
Barrel temperature (nozzle, front, center and rear)	204	Degree C

[0082] A compounding of polymers listed in Table 2 below at the specified weight percentages were mixed to obtain the desired physical properties of the support structure.

Table 2
Support Structure Composition

Weight %	Tradename	Material Type	Supplier
39.72%	Engage 8490	Polyolefin Elastomer: ethylene-octene copolymer	Dupont Dow Elastomers L.L.C., Bellvue Park Corporate Center, 300 Bellevue Parkway, Wilmington, DE 19809
39.72%	Hypel PELLD 20	Linear Low Density Polyethylene	Entec Polymers L.L.C., 2301 Maitland Center Parkway, Suite 240, Maitland, FL 32751
14.02%	Kraton G1657	Thermoplastic Elastomer: styrene-ethylene-butylene-styrene block copolymer	Kraton Polymers LLC, 700 Milma, North Tower, 13 th Floor, Houston, TX 77002
0.93%	Atmer 1753	Erucamide	Unichema North America, 4650 South Racine Avenue, Chicago, IL 60609-3321
5.61%	Silver Pigment	Pigment	Clariant Masterbatches, 9101 International Parkway, Minneapolis, MN 55428
	UN 5001 Omnicolor Blue Dye*	Pigment	Clariant Masterbatches, 17 Holden Industrial park Holden, MA 01520

*Comprised less than 1 wt. % of the total composition.

3. *Respirator Filtering Structure Manufacture*

[0083] Respirator filtering structures were formed from two layers of nonwoven fibrous electret filter material that was 254 mm wide, laminated between one 50 grams per square meter (gsm) outer layer of white nonwoven fibrous spunbond material and one 22 gsm inner layer of white nonwoven fibrous spunbond material having the same width. Both layers of the nonwoven fibrous spunbond materials were made of polypropylene. The electret filter material was the standard filter material that is used in a 3M 8511 N95 respirator. The laminated web blank was cut into the 254 mm long pieces to form a square before being formed into a cup formation that had a three-dimension (3D) pleat extending transversely across the filtering structure.

[0084] As shown in FIG. 8, where the dotted lines represent fold lines and the solid lines represent weld (or the lines of demarcation **53a** and **53b** in FIG. 4), the complex 3D pleat (**42**, FIGs. 2a and 2b) was formed by ultrasonically welding two curves **53a**, **53b** of same radius of curvature (258.5 mm radius). The distance between the highest points on each curve was 40 mm, and the two ends of the curves met at left and right end points, which were about 202 mm apart. The first curve **53b** was created by folding the laminated filter media along the first fold line **80** at least 76 mm away from one edge of laminated web. The second curve **53a** was formed by welding along the secondary curve line by folding the laminated web at a secondary fold line **82**, which is located 62 mm from the first fold line **80**. Once the two curves that make the 3D pleat are formed, excess material outside of the curve lines was removed. The layered material was then folded along the vertical center line **84** and a line of demarcation **60** (FIG. 4) was welded, starting 51 mm away from the center of the second curve line as shown in FIG. 8. This step removes any excess material and forms a cup that properly fits in the respirator support structure. An ultrasonic welding process was used to make the welds. Branson 2000ae Ultrasonic welding equipment and power supply was used at a peak power mode, 100% amplitude and air pressure of 483 MPa.

4. *Other Respirator Components*

[0085] *Face seal*: Standard 3M 4000 Series respirator face seal.

[0086] *Nose clip*: Standard 3M 8210 Plus N 95 Respirator nose clip.

[0087] *Headband*: Standard 3M 8210 Plus N 95 Respirator headband material but white in color. The Yellow pigment for 3M 8210 *Plus* respirator headband was removed.

[0088] *Buckle*: A buckle similar to a back-pack buckle with flexible hinge to allow comfortable adjustment of headband material was used.

5. *Respirator Assembly*

[0089] The face seal material was cut to pieces that were about 140 mm by 180 mm. A die cut tool was then used to create an oval opening that was 125 mm by 70 mm and was located in the center of the face seal. The face seal with the central cut out opening was attached to respirator filtering structure made as described above. The same equipment that was used to ultrasonically weld the filtering element structure was used to secure the face seal to the filtering structure under similar process conditions. The welding anvil had an oval shape of about 168 mm wide and 114 mm long. After the face seal was joined to the filtering structure, excess material outside of the weld line was removed. The nose clip was adhered to the outside of the assembled filtering structure crosswise over the nose area. Then the pre-assembled filtering element was inserted into the support structure in its desired orientation. The complex 3D pleat was strategically located between transversely extending members **26** and **28** shown in FIGs. 2a and 2b. A handheld Branson E-150 Ultrasonic welding equipment, at 100% output and 1.0 second weld time, was used to create attachment points between the support structure and the filtering structure at an interval of 20 to 25 mm along each transversely extending member. Four headband buckles were stapled to the harness flanges **35** using 12.7 mm Heavy Duty STANLEY staple wire on both sides of the support structure above and below living hinge **44**. A 450 mm long braided headband material was threaded through the buckles to complete the respirator assembly process.

[0090] For comparison purposes, five samples of commercially available Moldex 2200 N 95 respirators from Moldex Metric Inc., 10111 W. Jefferson Boulevard, Culver City, CA 90232 were also tested according to the Respirator Expansion Text described above. The Moldex 2200 series respirator has a Dura-Mesh™ shell that is designed to resist collapse in heat and humidity. A Moldex face mask that uses an open-work flexible plastic layer as a shell is described in Moldex's U.S. Patent 4,850,347 (Skov).

Test Results

1. Stiffness in Flexure

[0091] The compounded ingredients listed in Table 2 were selected to match desired structural and flexibility properties needed for the support structure. The calculated stiffness in flexure for the support structure material is listed in Table 3 below:

Table 3
Respirator Support Structure Material Stiffness in Flexure

Specimen	Thickness (cm)	Taber Stiffness (g·cm)	Stiffness in Flexure (MPa)
1	0.0627	14.5	173
2	0.0594	16.9	230
3	0.0561	11.9	199
4	0.0508	9.3	209
5	0.0546	11.3	205
6	0.0541	10.7	196
Average	0.0563	12.4	202
Std Deviation	0.042	2.8	18.7

[0092] The data set forth in Table 3 show that the Stiffness in Flexure of the support structure materials is about 200 MPa.

2. Physical Performance of Finished Products

[0093] The maximum force required to cause a 30% longitudinal expansion of the mask body and the hysteresis of the support structure were measured on finished respiratory masks using the *Respirator Expansion Test* described above.

i. Maximum Load For Each Cycle

[0094] The Maximum Load required to expand the respirator was measured by recording the maximum force used for each cycle.

Table 4
Max Force Data

Product	Example	Max Load First Cycle (N)	Max Load Second Cycle (N)	Max Load Third Cycle (N)
Invention prototypes	1	4.4	4.3	4.3
	2	7.9	7.7	7.7
	3	6.7	6.5	6.4
	4	4.7	4.5	4.5
	5	5.8	5.7	5.6
Average		5.9	5.8	5.7
Standard Deviation		1.5	1.4	1.4
Moldex 2200	C1	32.8	31.3	30.5
	C2	23.6	23.0	22.5
	C3	25.2	23.9	23.3
	C4	25.4	24.4	24.0
	C5	25.5	24.4	23.9
Average		26.5	25.4	24.9
Standard Deviation		3.6	3.4	3.2

[0095] The data shown in Table 4 demonstrate that extraordinarily less force is needed to achieve a 30% tensile expansion of the mask body when compared to a Moldex 2200 respirator.

ii. Hysteresis after 30% Vertical Expansion

Table 5
Hysteresis Data

Product	Example #	Hysteresis First Cycle (%)	Hysteresis Second Cycle (%)	Hysteresis Third Cycle (%)
Invention prototypes	1	5.04	4.38	4.25
	2	8.85	7.4	7.13
	3	7.66	6.45	6.18
	4	5.92	5.14	4.96
	5	7.13	5.99	5.79
Average		6.9	5.9	5.7
Standard Deviation		1.5	1.2	1.1
Moldex 2200	C1	21.3	13.9	13.11
	C2	16.1	11.1	10.5
	C3	16.6	12.6	11.9
	C4	15.4	10.6	9.9
	C5	18.3	13.2	12.4
Average		17.5	12.3	11.6
Standard Deviation		2.4	1.4	1.3

[0096] The data in Table 5 show that the inventive respirators exhibit substantially less Hysteresis when compared to commercially available Moldex 2200 respirators. That is, the respirators that have support structures made from longitudinally-movable, transversely-extending members and have pleated filtering structures exhibit substantially less inability to return to their original condition when the expansion force has ceased.

iii. Percent Tensile Strain v. Load

[0097] The "% Tensile Strain vs. Load" data was plotted on a graph. The plotted data is shown in FIG. 9. As is apparent from the plotted data, the inventive respirator requires substantially less load to strain the respirator 30%.

iv. Transversely-Extending Member Movement Measurements

[0098] Five respirator support structures were made as described in sample preparation section above. To eliminate the interference from the rest of the support structure, the 24.5 mm wide and 76 mm long HDPE films described above were attached

to the transversely extending members (**26** and **28**, FIGS. 1, 2a, 2b) using 12.7 mm Heavy Duty STANLEY stapler wire from STANLEY BOSTITCH.

[0099] The force required to longitudinally move the transversely-extending members **26** and **28** of the support structure at the vertical center were measured using test method described above. The forces set forth below in Table 6 represent forces required to extend the transversely-extending members in the longitudinal direction.

Table 6
TEMMT Data

Distance of Longitudinal Extension (mm) From Neutral Rest Position	First Cycle Force (N)	Second Cycle Force (N)	Third Cycle Force(N)
5	0.3	0.2	0.2
10	0.3	0.3	0.3
15	0.4	0.4	0.3
20	0.5	0.4	0.4
25	0.5	0.5	0.5
30	0.6	0.6	0.6
35	0.7	0.7	0.6

[00100] The data set forth in Table 6 show that very little force is needed to separate adjacent transversely-extending members in the longitudinal direction. A graph of this data is set forth in FIG. 10.

[00101] This invention may take on various modifications and alterations without departing from its spirit and scope. Accordingly, this invention is not limited to the above-described but is to be controlled by the limitations set forth in the following claims and any equivalents thereof.

[00102] This invention also may be suitably practiced in the absence of any element not specifically disclosed herein.

[00103] All patents and patent applications cited above, including those in the Background section, are incorporated by reference into this document in total. To the extent that there is a conflict or discrepancy between the disclosure in the incorporated document and the above specification, the above specification will control.

What is claimed is:

1. A filtering face-piece respirator that includes a mask body that comprises:
 - (a) a support structure that includes first and second transversely extending members that can move towards and apart from each other in the longitudinal dimension; and
 - (b) a filtering structure that comprises:
 - (i) a filtration layer; and
 - (ii) a pleat;wherein the pleat allows the filtering structure to contract and to expand when the first and second transversely-extending members move toward and apart from each other, respectively.
2. The filtering face-piece of claim 1, wherein the pleat is defined by first and second lines of demarcation that each extend from a first side of the filtering structure to a second side.
3. The filtering face-piece respirator of claim 2, wherein the first and second lines of demarcation converge towards each other as the lines approach the first and second sides of the filtering structure.
4. The filtering face-piece respirator of claim 2, wherein the first and second lines of demarcation are located adjacent to the first and second transversely-extending members, respectively.
5. The filtering face-piece respirator of claim 4, further comprising third and fourth lines of demarcation on the filtering structure and third and fourth transversely-extending members on the support structure, wherein the third and fourth lines of demarcation are located adjacent to the third and fourth transversely-extending members, respectively.
6. The filtering face-piece respirator of claim 4, wherein the support structure further includes first and second flanges on each side of the mask body, there being a

harness that is attached to the support structure at each of the flanges, and wherein the first and second transversely-extending members and the first and second lines of demarcation are located between the first and second flanges when viewing the mask body from the side.

5 7. The filtering face-piece respirator of claim 6, wherein the mask body may be expanded up to about 20 to 35 millimeters without causing damage thereto when subjecting the respirator to the *Respirator Expansion Test*.

10 8. The filtering face-piece respirator of claim 4, wherein the first and second transversely-extending members can move over a distance of at least 15 millimeters without causing significant structural injury to either the first or second transversely-extending members or to the pleat.

15 9. The filtering face-piece respirator of claim 1, wherein the filtering structure further comprises first and second cover webs that are disposed on first and second major surfaces of the filtration layer, the pleat causing the first and second cover webs and the filtration layer to be folded such that when fully pleated the outer cover web surface is folded back upon itself in a contacting relationship.

 10. The filtering face-piece respirator of claim 1, wherein the first and second transversely-extending members can move more than 5 millimeters when subjected to a force of only 0.2 Newtons under the *Transversely-Extending Member Movement Test*.

20 11. The filtering face-piece respirator of claim 1, wherein the first and second transversely-extending members can move more than 10 millimeters when subjected to a force of only 0.3 Newtons under the *Transversely-Extending Member Movement Test*.

12. A method of making a filtering face-piece respirator, which method comprises:

- 5 (a) providing a support structure that includes first and second transversely extending members that can move towards and apart from each other in the longitudinal dimension;
- (b) providing a filtering structure that comprises a filtration layer and a pleat; and
- 10 (c) joining the filtering structure to the support structure to form a mask body that can contract and to expand at the pleat when the first and second transversely-extending members move toward and part from each other, respectively.

13. The method of claim 12, further comprising (d) securing a harness to the mask body at first, second, third, and fourth securement points, wherein the first and second transversely-extending members converge toward each other at first and second convergence locations disposed at first and second sides of the mask body, the

15 convergence locations being disposed between the first and second securement points and the third and fourth securement points, on the first and second sides of the mask body, respectively, when viewing the mask body from the side in an upright orientation.

14. The method of claim 12, wherein the support structure comprises plastic that has a Stiffness in Flexure of about 75 to 300 MPa.

20 15. The method of claim 12, wherein the support structure comprises plastic that has a Stiffness in Flexure of about 100 to 250 MPa.

16. The method of claim 12, wherein the support structure comprises plastic that has a Stiffness in Flexure of about 175 to 225 MPa.

17. A filtering face-piece respirator substantially as hereinbefore described with reference to the accompanying drawings.

18. A method of making a filtering face-piece respirator as hereinbefore described with reference to the accompanying drawings.

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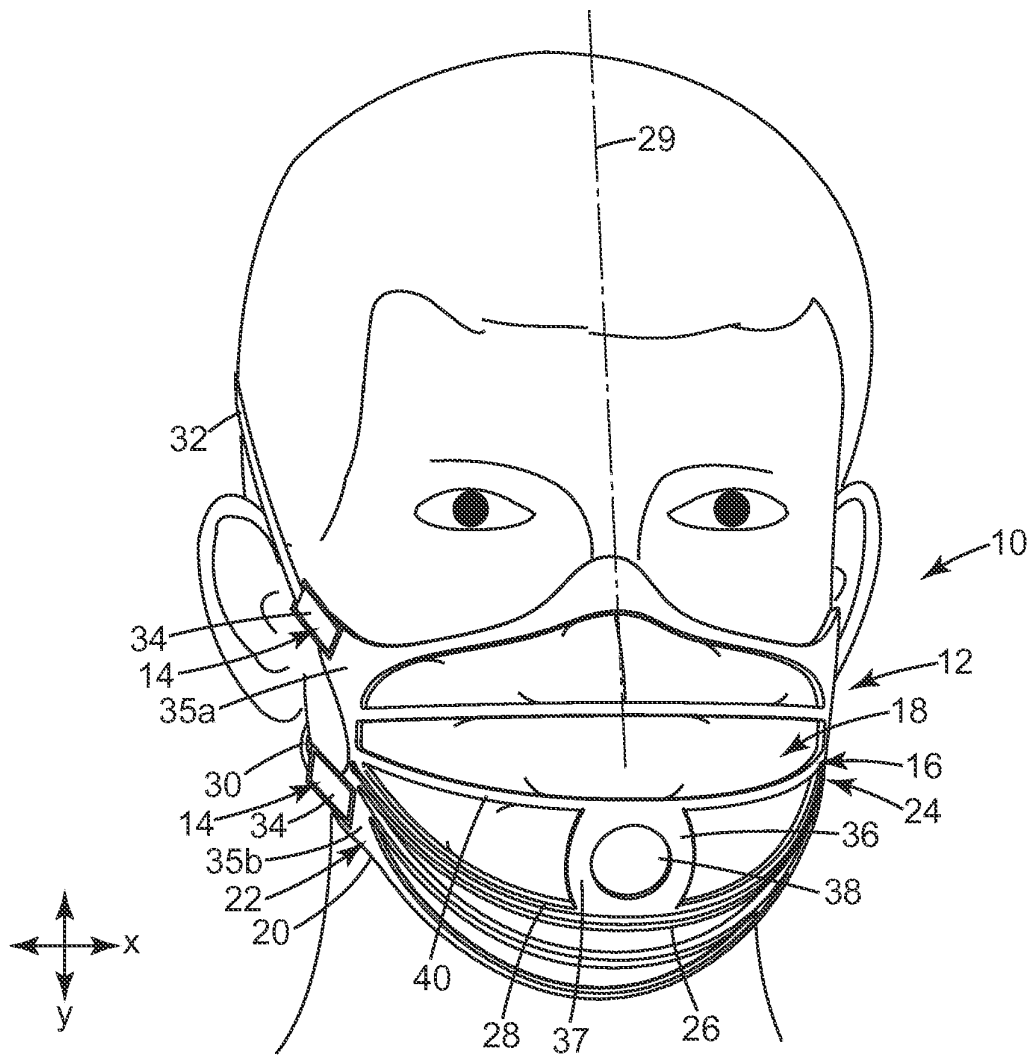


Fig. 1

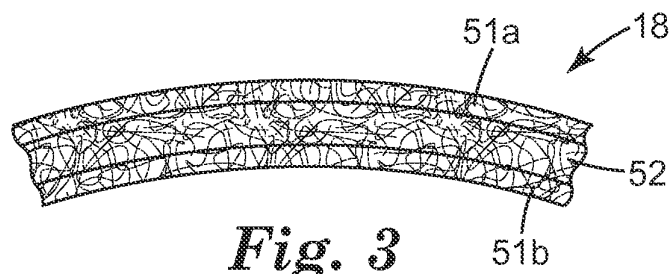
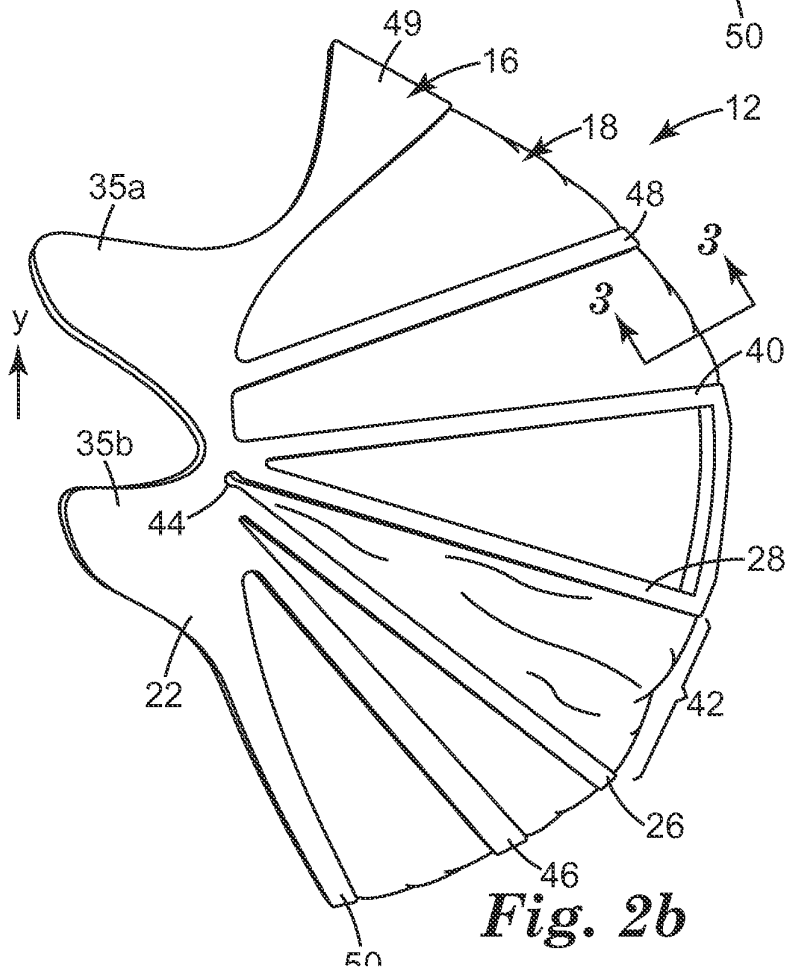
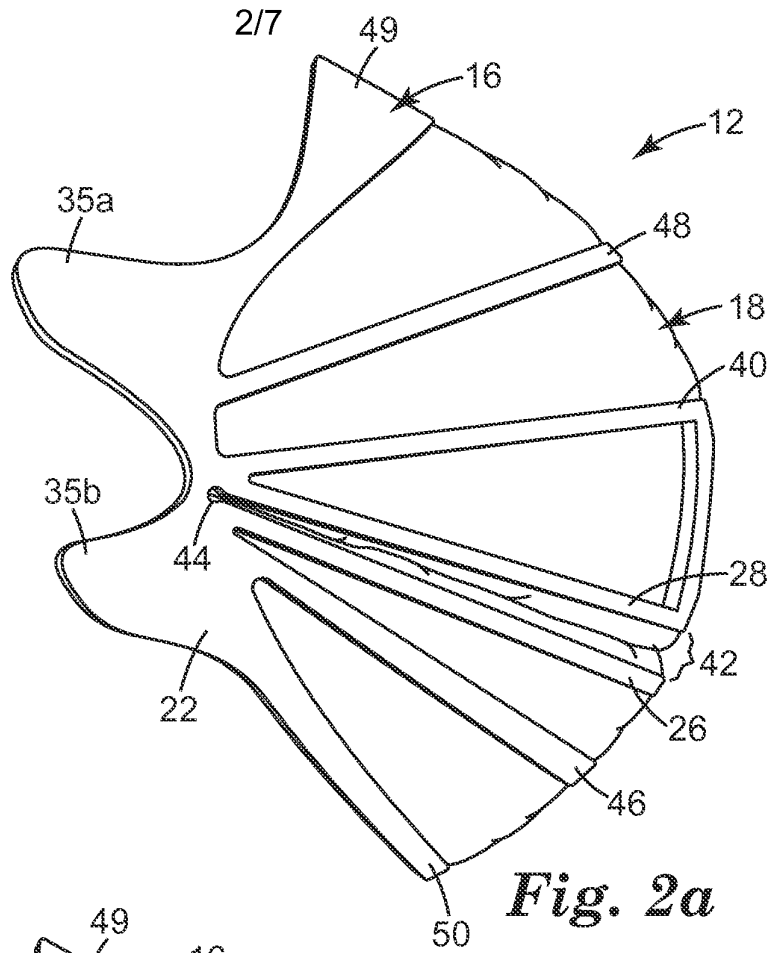


Fig. 3



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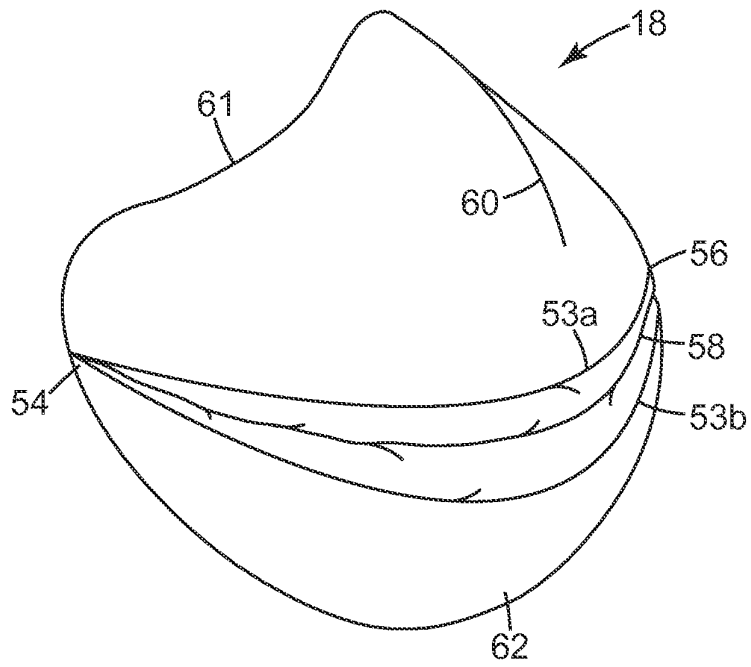


Fig. 4

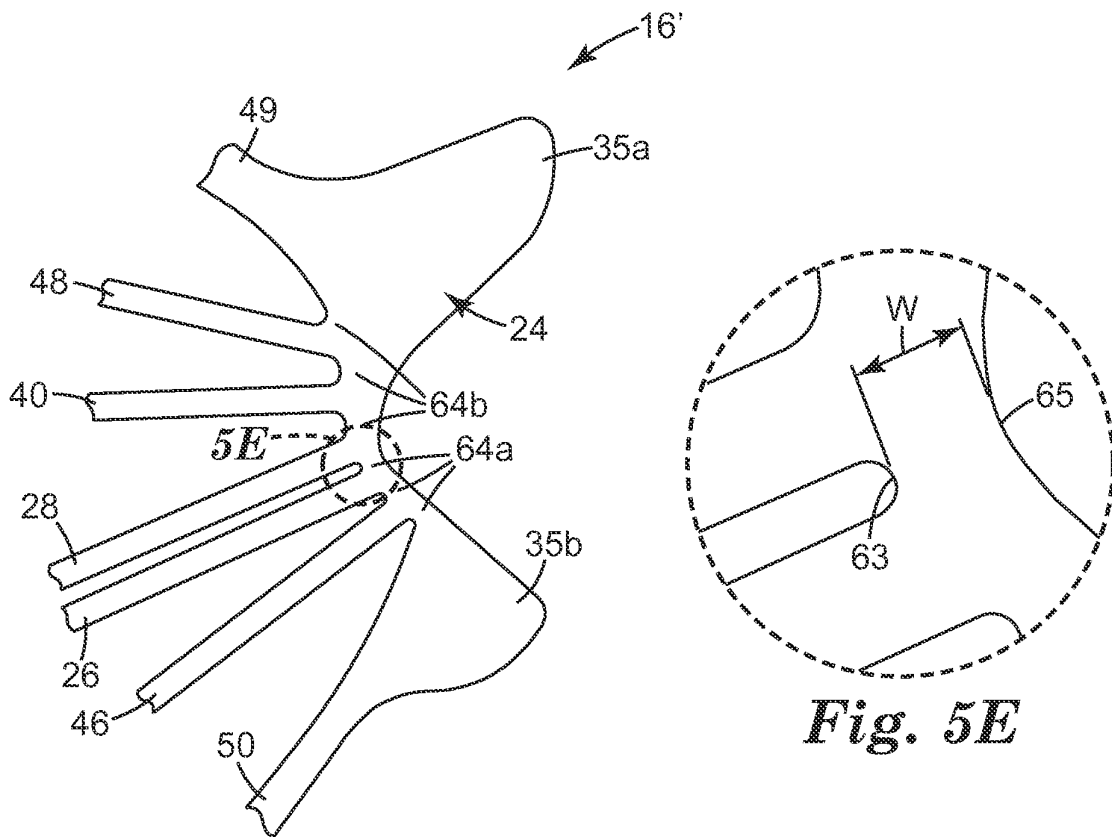


Fig. 5

Fig. 5E

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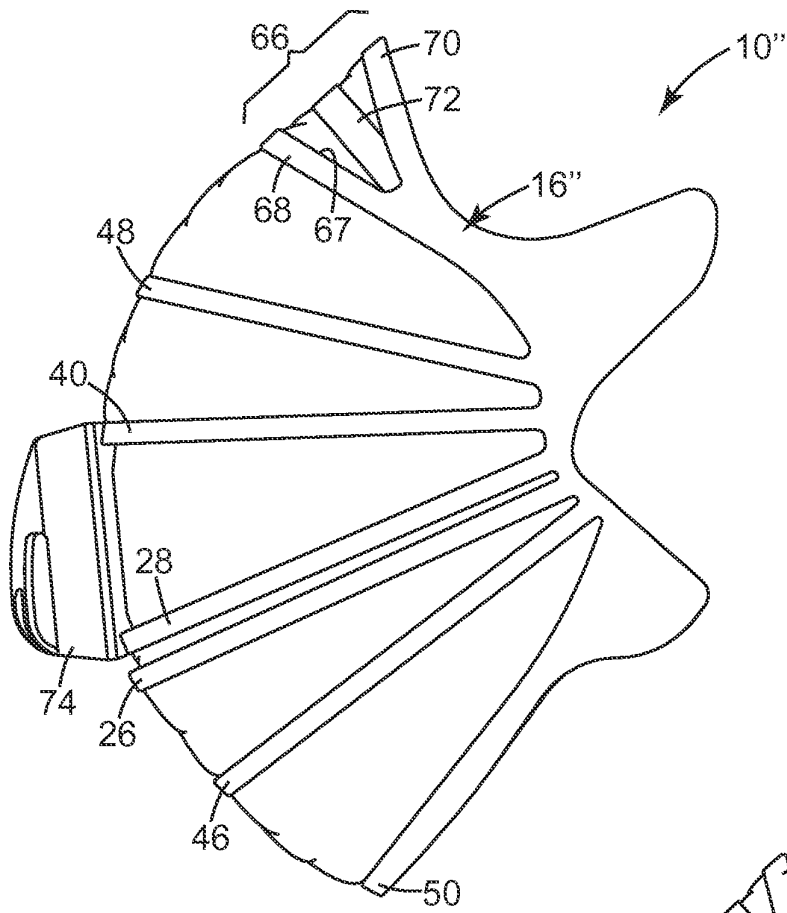


Fig. 6a

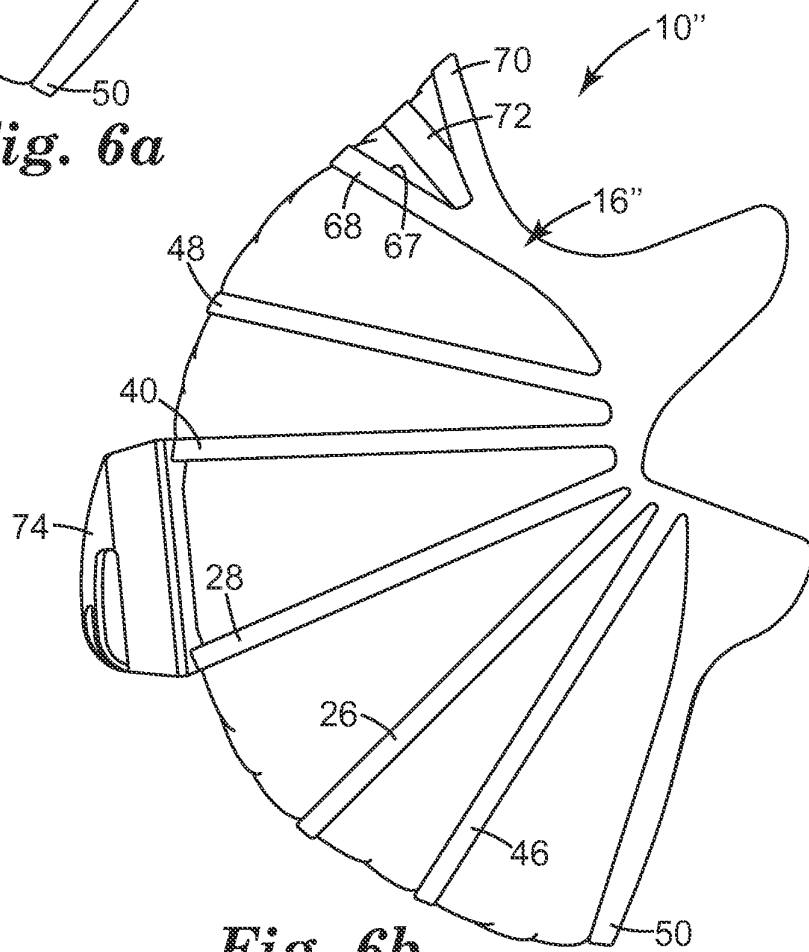
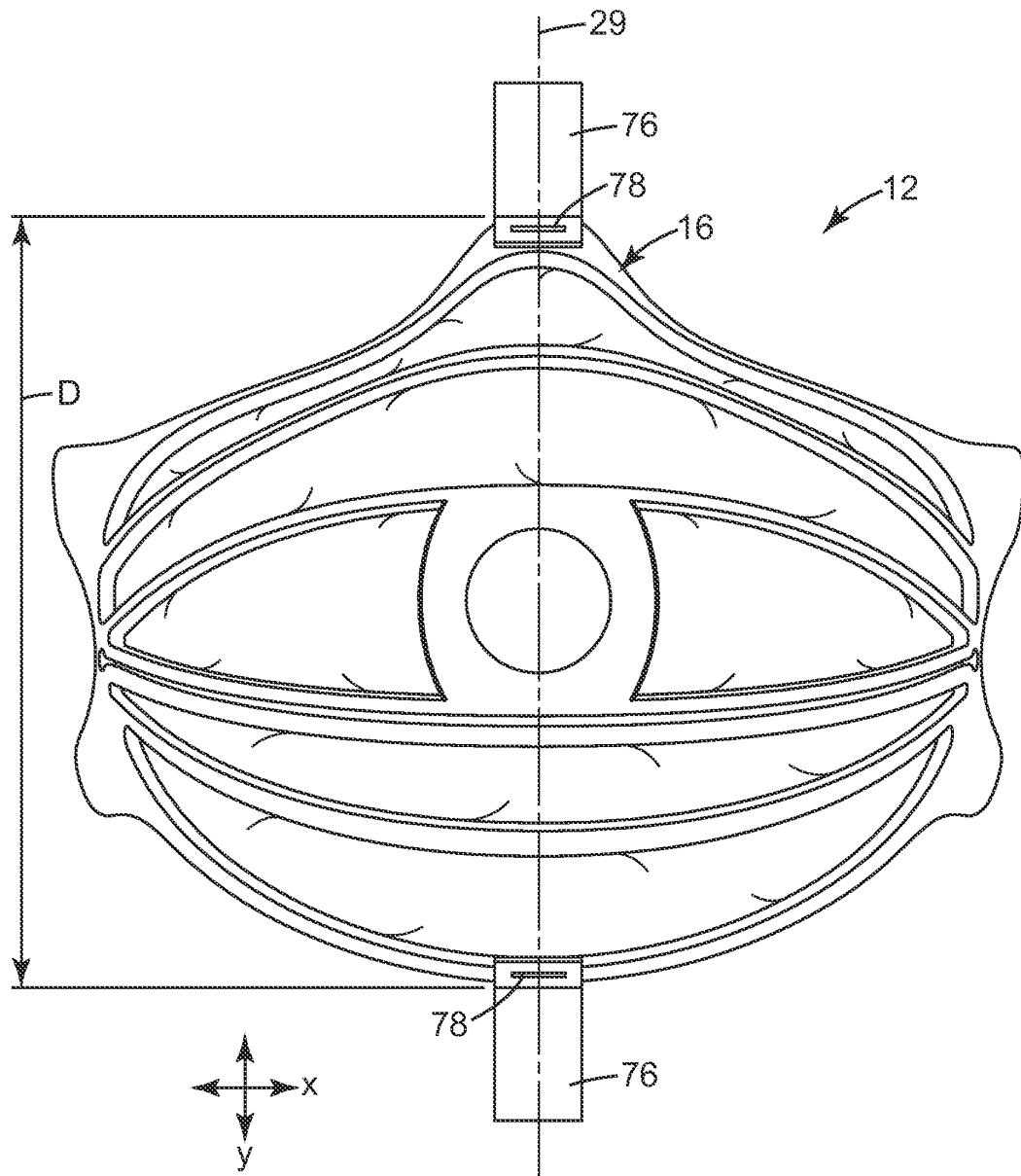
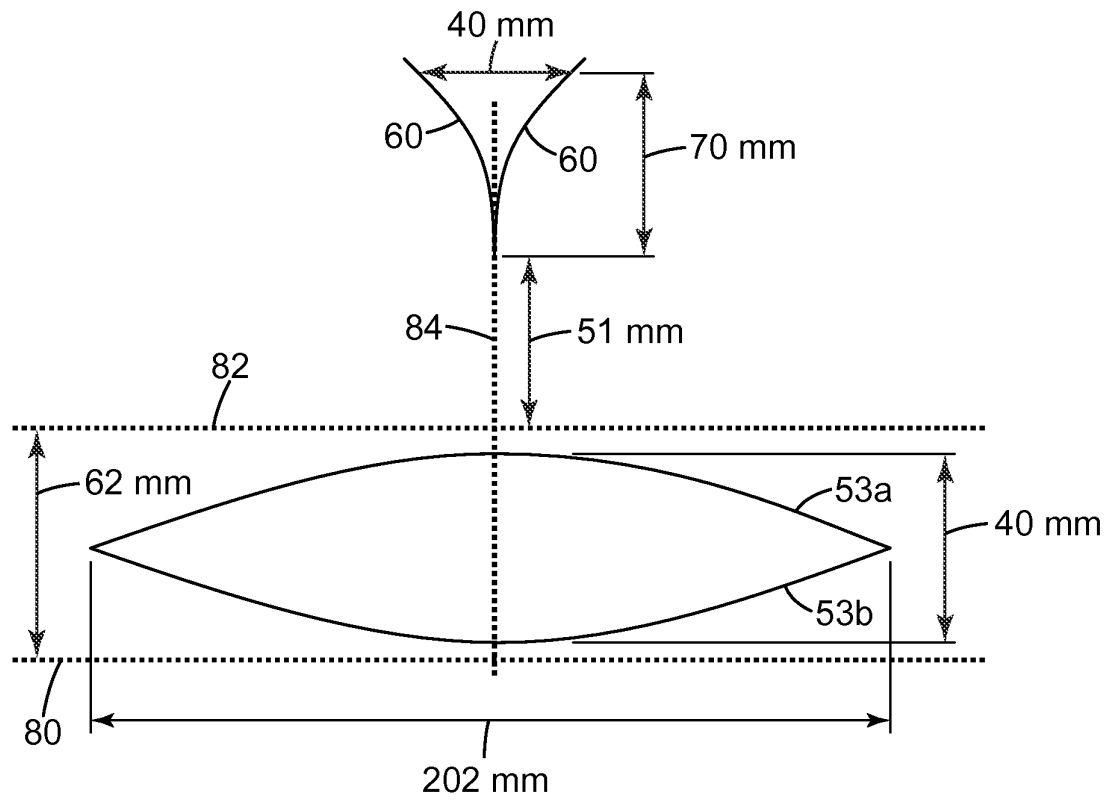


Fig. 6b

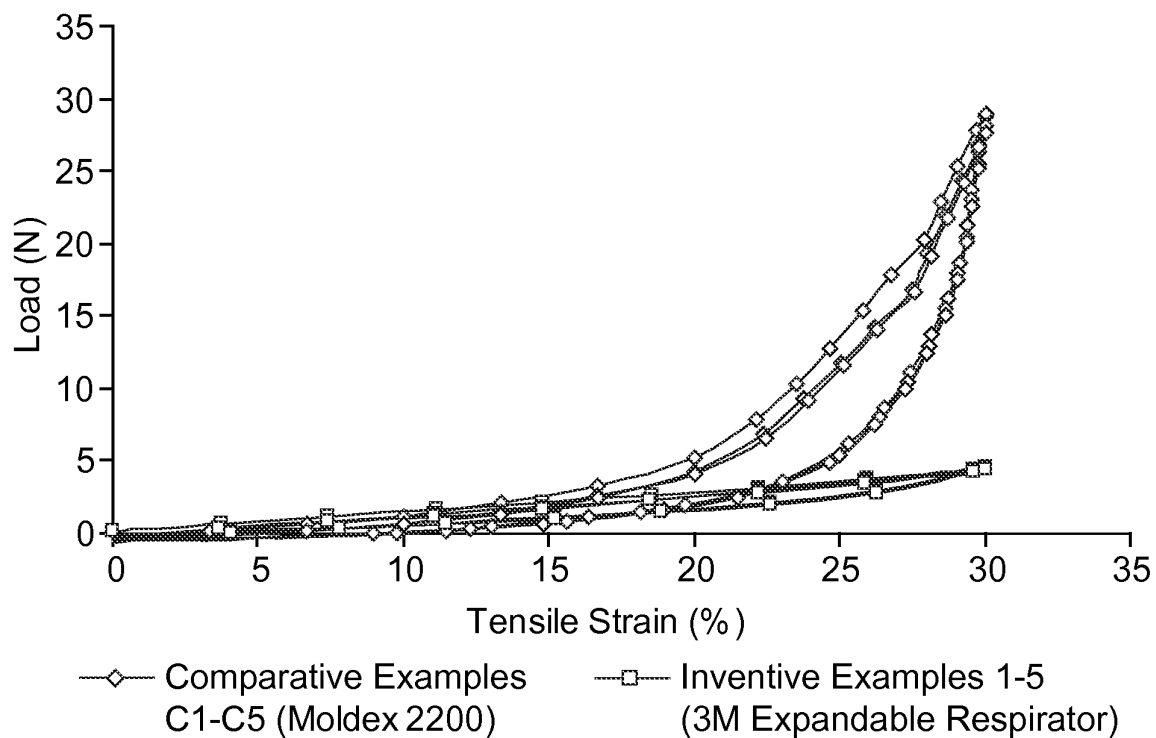
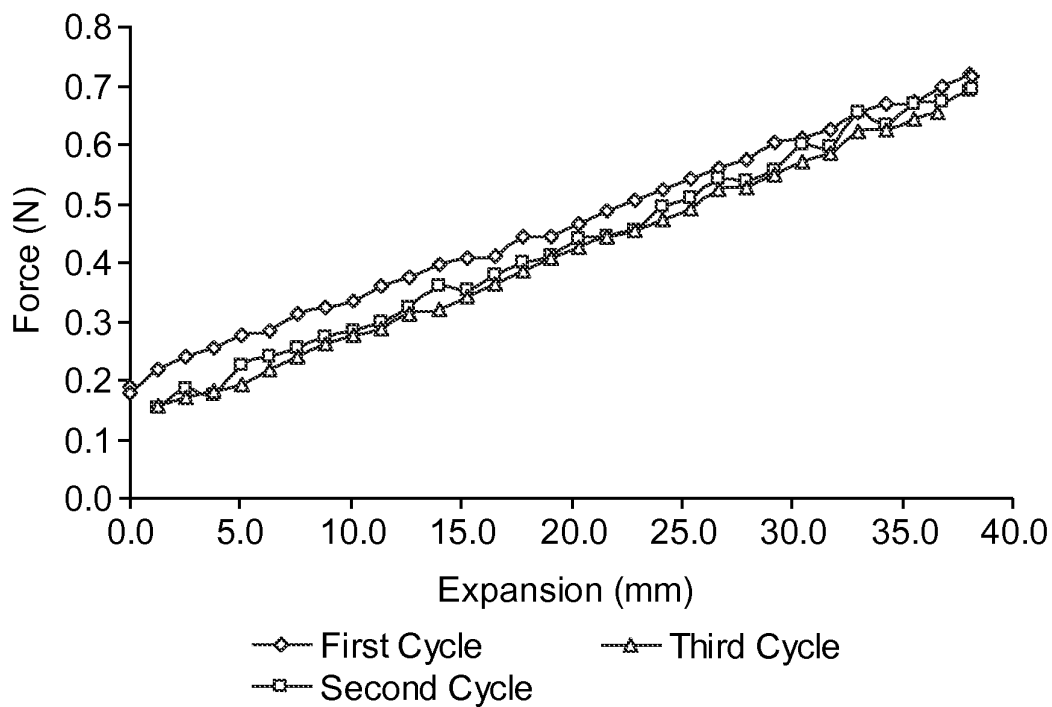
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*Fig. 7*

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*Fig. 8*

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*Fig. 9**Fig. 10*