Surgical Face Mask

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ABSTRACT

There is disclosed a surgical face mask comprising two layers of a porous, nonwoven facing fabric and a nonwoven fabric filtration medium between the layer of facing fabric. The nonwoven fabric filtration medium is a spunbonded fabric made for continuous length filaments having a diameter of from 14–20 microns. The major proportion of the length of the filaments lie in planes which are substantially parallel to the major surfaces of the fabric and, therefore, perpendicular to the direction of air flow through the mask.

6 Claims, 6 Drawing Figures
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SURGICAL FACE MASK

BACKGROUND OF THE INVENTION

This invention relates to an improved surgical face mask. Surgical face masks have been employed in surgery for some time. The purpose of these masks is to prevent the bacteria exhaled by the surgeon, or other operating room personnel, from contaminating the patient undergoing surgery, and also to protect the surgeon and other operating room personnel from bacteria originating from the patient. The original face masks that were used in surgery were multiple plies of gauze fabric which were positioned over the nose and mouth of the surgeon. Multiple plies of linen fabric were also used. These materials are not particularly good bacterial filters and have efficiencies, in terms of filtering bacteria, of less than 50 percent. These fabric face masks, although not efficient bacterial filters, were extremely comfortable to wear, that is, they were comfortable to the face of the surgeon and also had low air resistance. Air resistance, as used herein, is a measure of the resistance to air flow through the mask. It is determined by measuring the pressure drop across the mask when the mask is placed in an air stream. Air could readily flow through the woven fabric masks because of the openness of the fabrics. That is, the interstices formed by the weave of the fabrics were large enough in number and individual size to provide a significant proportion of open or fiber free area in the mask. The low air resistance made these fabric masks quite easy to breathe through. The relatively open arrangement of the fibers in the fabric mask which allow the ready passage of air through the mask also allowed bacteria to penetrate through the mask.

Because of the poor bacteria filtration efficiency of the fabric masks, efforts were directed to the production of a single use disposable mask which would have greater bacterial filtration efficiency than the fabric masks previously used. The single use masks have substantially increased bacterial efficacy as compared to the fabric masks, attaining efficiencies in the range of 90 percent or greater, but have created another problem. The new problem of the single use mask is that with the high bacterial efficiency, air resistance has substantially increased. These single use masks have air resistances so great that the mask will literally move away from the mouth of the wearer when the wearer exhales. This indicates that air is not flowing through the mask but building up pressure between the inner surface of the mask and the mouth and nose of the wearer. This pressure not only makes these masks uncomfortable to wear but also forces the mask away from the face when exhaling and allows the bacteria to escape out of the edges of the mask thus defeating the purpose of wearing the mask. Additionally, a number of these single use masks have been made with very short fiberglass, asbestos or other fibers which tend to become detached from the filter medium of the mask and are inhaled by the wearer. These small particles have a tendency to irritate the wearer of the mask. The high air resistance of these masks also makes the masks uncomfortably warm when worn. This is especially true when the masks are being worn for any length of time. The passages within the mask that allow air to flow through tend to eventually clog from dust or bacteria or other extraneous small particles found in the atmosphere of the operating room and eventually, over a period of two or three hours, it becomes extremely difficult to breathe through the mask. This condition creates considerable discomfort to the wearer of the mask.

SUMMARY OF THE PRESENT INVENTION

The present invention provides a surgical face mask that has high bacteria filtration efficiency and yet has very low air resistance. It would normally be expected that as the bacteria filtration efficiency is increased, the air resistance would increase or at least remain at a relatively constant level. The air resistance can be considered to be related to the number of openings in the effective filtration medium of the face mask or the total open area in the mask. As the total open area of the mask increases, the air resistance would decrease but so would the bacteria filtration efficiency. In the present mask, I have obtained a low air resistance but have maintained the level of bacteria filtration efficiency that is equivalent to the previously used single use surgical masks. This seemingly contradictory result has been obtained by employing as the filtration medium a continuous length synthetic thermoplastic filament rather than short fibers. The term, continuous length filament, as used herein is in length than two and one half inches and preferably, of an indeterminate length. These filaments are arranged in the form of a nonwoven fabric by bonding the filaments immediately after extrusion into a self-supporting web by the application of minimal amounts of pressure to the web but using no binder. The particular nonwoven fabric that has been found to be useful is made from polyethylene terephthalate filaments which are deposited to form a fabric immediately after extrusion in the manner taught by Canadian Pat. No. 775,807. Generally this process consists of spinning the filaments, applying an electrostatic charge to the filaments, permitting the filaments to separate due to the applied electrostatic charge, orienting the filaments, and laying the filaments down in a random nonwoven web which is essentially free of filament aggregates. The process may be operated to give a high level of crimp to the filaments. The filaments in the fabric are arranged in a substantially parallel relationship in planes perpendicular to the direction which air will move through the fabric in the mask. The reason why this arrangement of the filaments results in a high bacterial filtration efficiency mask with a low air resistance is not clear. It would appear that the arrangement of the filaments of a particular diameter in this manner provides for a maximum number of open areas and yet maintains a relatively small diameter of these open areas so as to effectively trap bacteria and prevent them from moving through the filter medium while at the same time providing a high volume of air to move through the mask. It is also possible that the high bacterial filtration efficiency of the mask is related to the electrostatic charge that is placed on the filaments in the processing of forming the web. The electrostatic charge could either attract and hold the bacteria in the mask or even exert a lethal electrostatic charge to bacteria passing through the mask.

The elimination of the binder in the fabric substantially contributes to the conformability of the finished face mask. The binder content in nonwoven fabrics has a tendency to stiffen the fabrics. In the present face
mask, the filtration medium is substantially free of binder and is readily conformable to the contours of the face of the wearer. The presence of the binder does not aid in increasing the filtration efficiency of the filtration medium in the mask.

DETAILED DESCRIPTION OF THE INVENTION

The present invention may best be understood with reference to the following drawings in which:

FIG. 1 is an isometric view of the mask of the present invention folded in the form it would appear on the wearer's face.

FIG. 2 is a plan view of the fabric of the present mask showing the folds in the mask and a magnified exploded section of the mask.

FIG. 3 is a schematic cross sectional view taken along the lines 3—3 in FIG. 2 showing the folds in the fabric of FIG. 3.

FIG. 4 is an enlarged cross sectional view of the mask along the lines 4—4 of FIG. 2.

FIG. 5 is a photomicrograph of the filtration medium of the present mask at a magnification of 100 X.

FIG. 6 is another photomicrograph of the filtration medium of the present mask at a magnification of 150 X.

As shown in FIG. 1, the face mask, as it appears in use, consists of a main body 10 to which is attached at the upper edge, a metal nose clip 11. The metal nose clip is made from a metal which can be easily bent to conform to the nose of the wearer, such as aluminum. The mask has attached to the main body, by sewing or heat sealing or other suitable means, a seam binding 12 on the upper and low edges of the mask. There is also attached to the main body of the mask on the side edges of the mask, an additional seam binding 12 which is of sufficient length to extend beyond the top and bottom edges of the mask and is employed as the tie string to affix the mask to the head of the wearer. There also appears in FIG. 1, bonding points 14 whose function will be later explained.

FIG. 2 shows the configuration of the folds of the mask. The laminate which constitutes the main body of the mask is folded on itself in an accordion shape from the edge of the mask 15 to the bottom edge of the mask 16. The mask of FIG. 2 is shown to be folded in three places at 17, 18 and 19, but the particular folding arrangement or number of folds is not part of the present invention. This particular configuration of the mask has previously been found to provide excellent conformability to the face of the user.

The magnified break away portion 20 of FIG. 2 shows the various layers of the mask. The outside surface of the mask is a highly porous nonwoven facing fabric 21. The center portion containing the spun bonded filtration medium 22 of the present invention lies between the facing fabric 21 and another layer of facing fabric 23. Both layers of facing fabric may be constructed of the same highly porous nonwoven fabric. The purpose of the facing fabric portions of the mask is to contain and retain the filtration medium. The outside layers are a highly porous nonwoven fabric of relatively light weight and contribute very little if any filtration properties to the mask construction. Being highly porous, these materials also offer very little resistance to the flow of air through the mask. The weight of the facing layer of the mask may be between about 200 and 400 grams per square yard. It is advantageous to use extremely light weight facing webs so as not to increase the stiffness and thereby reduce the conformability of the face mask. The facing material can be a carded nonwoven fabric bonded with a thermoplastic binder. A suitable thermoplastic binder is an emulsion polymerized self-curing acrylic binder.

It has been found to be advantageous to spot bond, by heat sealing or other bonding procedures, the three layers of the face mask together. As each of the individual layers of the laminate are relatively light weight, the layers are bonded together so they may be pleated and the seam binding applied with the minimum possibility of tearing or otherwise disintegrating the webs during the fabrication of the mask. Additionally, the bonding of the inner layer of the face mask to the fabric filtration medium at certain points prevents the inner layer of the mask from moving over the nose or mouth of the wearer as the wearer inhales. If the inner layer is not bonded, it is possible that it could move against the nose or mouth of the wearer when the wearer inhales. Although this does not reduce the efficiency of the mask, it has been found to cause some wearer discomfort. The bonding may be carried out by heat sealing the laminate together with sufficient force to effectuate the bond through all layers of the mask. It has been found that a heat sealer heated to a temperature of approximately 400°F and using 80 psi and a 1 second dwell time is sufficient pressure to bond the three layers of the mask together. As shown in 14 in FIG. 4, the bonded spot may extend through the total depth of the mask. As the filtration medium fabric filaments are thermoplastic, the application of heat and pressure causes the filaments to melt upon cooling and harden and form a permanent bond between the three layers of the mask.

It is also possible to employ hot melt adhesives, or other adhesive materials to effectuate the spot bonding of the layers of the mask together. It is desirable to make the total bond areas as small as possible. It has been found that six to nine bonded areas located beneath the folds of the mask, each area approximately one-eighth inch square, are sufficient to bond the three layers of the mask into a unitary laminate. The total area of the bond points is not critical although it should be recognized that the bond area must be large enough to accomplish the desired result but not so large that it could materially reduce the filtration efficiency or increase the air resistance of the mask. The bond points tend to be imperious areas which prevent passage of air through the mask. A total bonded area covering less than 1 percent of the total surface area of the mask has been found to be adequate to provide the desired bonded properties. A total bonded area of this order will not measurably reduce the bacterial filtration efficiency or increase the air resistance of the mask.

Although the particular placement of the bond areas on the mask is not critical to the functioning of the mask, I prefer to place the bond area beneath the folds of the mask as shown schematically in FIG. 3.

As previously stated, the filtration medium itself is a spunbonded fabric. A spunbonded fabric of a weight of between about 1.4 to about 1.6 ounces per square yard has been found to offer the desirable combinations of high bacterial efficiency and low air resistance. The filaments in the spunbonded fabric are from about 14 to about 20 microns in diameter. The filaments are not perfectly circular in diameter as can readily be seen.
from the photomicrographs FIG. 5 and FIG. 6. In a spunbonded fabric of the type used in the present invention, the greater majority if not all of the filaments in the fabric are of indeterminate length. When the spunbonded fabric is made, these filaments are extruded as a continuous filament and are laid down on a moving belt in a random fashion, but the major portion of the length of the filaments lies in planes that are substantially parallel to the conveying direction of the moving belt. This can be seen in FIG. 4. The facing fabrics 21 and 23 contain short fibers some of which are oriented perpendicular to the major faces 24 and 25 of the mask. The filaments in the filtration medium fabric 22 are oriented so that the major portion of the filament length lies in planes that are parallel to the major faces of the mask or perpendicular to the direction of air flow through the mask. These filaments are shown as 26 and 27 in FIG. 4. The fabric is utilized in the face mask in such a manner that the air flow through the mask is in the direction perpendicular to the parallel planes in which the fibers are arranged. This results in a maximum utilization of the filaments in the fabric to form fiber free openings in the web and these openings are of a sufficiently small size to prevent passage of bacteria through the web.

In order to maintain a high degree of conformability that is desirable in the surgical face mask, I employ a spunbonded fabric which has relatively low tensile strength. Tensile strengths of less than 1 pound per square inch width are suitable for the spunbonded fabric filtration medium. These relatively low tensile strengths are present in the spunbonded fabrics which contain no binder and relatively few self-bonded areas. The addition of binder has a tendency to increase the tensile strength of the spunbonded fabric filtration medium, thereby reducing the conformability but adding no particular advantage in filtration efficiency. I have found that the filtration medium fabric should be one which contains no significant amounts of added binder. The number of self-bonded areas should be only those that are required to process the fabric filtration medium web through the remaining process equipment. Additional bond points add no particular advantage in bacterial filtration efficiency and can reduce the conformability of the web and thus the conformability of the face mask.

EXAMPLE I

Table I shows the result of a comparison of the average filtration efficiency and air resistance of six surgical face masks with a construction containing polyethylene terephthalate (reported as A) filtration medium of the present invention with six masks containing a glass fiber filtration medium of the prior art (reported as B).

<table>
<thead>
<tr>
<th>TABLE I</th>
</tr>
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<tbody>
<tr>
<td><strong>Air Resistance</strong></td>
</tr>
<tr>
<td>A</td>
</tr>
<tr>
<td>0.620''</td>
</tr>
</tbody>
</table>

The bacterial filtration efficiency was determined in the following manner: Staphylococcus aureus bacteria was nebulized into a spray mist and forced through an aperture in a closed conduit. The bacteria passing through the aperture were trapped on a Millipore filter, and then inoculated on agar plates. After a period of 24 hours, the bacteria colonies were counted. The same procedure was repeated with a face mask blocking the aperture of the conduit. The efficiency of the face mask is determined by comparing the colony count of the plates with and without the face mask in the aperture.

The air resistance, reported in Tables I and II in inches of water differential, was determined by passing air at a predetermined flow rate (85 liters per minute in Table I) through 17.8 square inches of a face mask of the indicated construction. The pressure drop between the upstream and downstream sides of the mask is a measure of the air resistance of the mask. Table II shows the effect of air resistance at different flow rates of masks of the construction of A and B above and on both facing layers of the masks which were identical in both the A and the B masks.

<table>
<thead>
<tr>
<th>TABLE II</th>
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<tbody>
<tr>
<td><strong>Flow Rate</strong></td>
</tr>
<tr>
<td>85 L/min</td>
</tr>
<tr>
<td>0.0183''</td>
</tr>
<tr>
<td>0.0089''</td>
</tr>
<tr>
<td>100 L/min</td>
</tr>
<tr>
<td>0.0066''</td>
</tr>
<tr>
<td>125 L/min</td>
</tr>
<tr>
<td>0.0035''</td>
</tr>
</tbody>
</table>

Tables I and II clearly show the low air resistance of the face masks of the present invention. The air resistance of the mask of the present invention is less than the air resistance of the prior art mask by a factor of about 10.

The spunbonded fabric filtration medium when formed by extruding the polymeric filaments onto a moving conveyor and subsequently subjecting the web to light pressure to self-bond the filaments tends to keep the filaments in planes which are parallel to the surface of the conveyor on which the web is formed. FIG. 5 and FIG. 6 are photomicrographs of the spunbonded fabric employed in the face mask. It can readily be seen from these photomicrographs that the majority or substantially all of the fibers lie in planes which are parallel to the surface of the sheet of the drawing. As previously stated, this parallel arrangement of fibers in which the fiber diameter is from 14 to 20 microns results in a filtration medium containing a large number of open areas but with a relatively small size of any individual open area. There is thus provided a relatively large total cross sectional area in the mask for air to pass through, but each individual opening is small enough to prevent the passage of bacteria. The filtration fabric is formed in relatively thin webs of from about 0.01 to about 0.02 inches in thickness and preferably between 0.014 and 0.018 inches. This thickness is sufficient to prevent the passage of more than 90 percent of the bacteria that could pass through the mask as determined by invitro tests. The void volume, that is, the total volume which contains no filaments is greater than 85 percent. The high void volume and the low air resistance would indicate that most of the filaments lie in planes which are parallel to the major surfaces of the filtration medium, and that there is a relatively small percentage of filaments which extend from one of the major surfaces of the filtration medium to the other. Both FIG. 5 and FIG. 6 which show a relatively small number of filament ends also would tend to support this conclusion.

Having thus described my invention, what I claim is:

1. A face mask having a body portion adapted to cover the nose and mouth and having means to secure said body portion over the nose and mouth, said body
portion comprising a filtration medium comprising a nonwoven fabric formed of continuous thermoplastic filaments having a length of at least 2.5 inches and a diameter of from 14 to 20 microns, substantially all of said filaments lying generally in planes perpendicular to the direction of the flow of air through the mask, said filtration fabric having a weight of from 1.4 to 1.8 ounces per square yard and having a thickness of from 0.01 to 0.02 inches and a void volume of about 85 percent and being substantially free of binder, and a lightweight porous nonwoven facing fabric on each major side of said filtration medium.

2. The face mask of claim 1 in which the facing fabric has a weight of from 200 to 400 grains per square yard.

3. The face mask of claim 1 in which the facing fabric is bonded together with a thermoplastic binder.

4. The face mask of claim 3 in which the facing fabric and the filtration medium are bonded together at intermittent points in both directions over the surface of said mask.

5. The face mask of claim 4 in which the bond points constitute less than 1 percent of the total filtration surface of the mask.

6. The face mask of claim 1 in which the filtration medium comprises filaments of poly(ethylene terephthalate).