United States Patent

Boucher et al.

[15] **3,664,335**

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[54] SURGICAL FACE MASK

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[52] **U.S. Cl.** **128/146.6**, 128/139

[51] **Int. Cl.** **A62b 23/02**

[58] **Field of Search** 128/141, 146, 146.2, 146.6, 128/139, 146.7; 2/206

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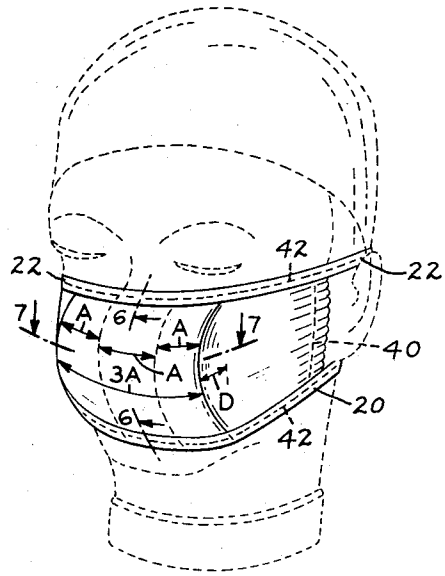
[57] **ABSTRACT**

Disposable surgical face mask comprising a flexible porous pad capable of covering the nose and the mouth of the wearer, the flexible porous pad having an inner layer of non-woven fiber material, an outer layer of non-woven fiber material, and a central layer of filter material. The three layers are stitched together along their horizontal and vertical edges. An elastic binding is secured onto each vertical edge of the flexible porous pad. The flexible porous pad has a first vertical double pleat structure and a second vertical double pleat structure. The first and second vertical double pleat structures are parallel to one another and are spaced a horizontal distance from one another. Each of the vertical double pleat structures is formed by folding the flexible porous pad back on itself a first time and then folding it back on itself a second time thereby forming a "Z" or reverse "Z." A flexible nose strip and a foam strip are situated along the upper horizontal edge of the flexible porous pad. Binding tapes are stitched into the horizontal edges of the flexible porous pad.

The vertical double pleat structures form a cavity on the inner side of the flexible porous pad. When the frontal face of the flexible porous pad is extended outwardly, the vertical double pleat structures expand and provide a semirigid box structure.

1 Claim, 7 Drawing Figures



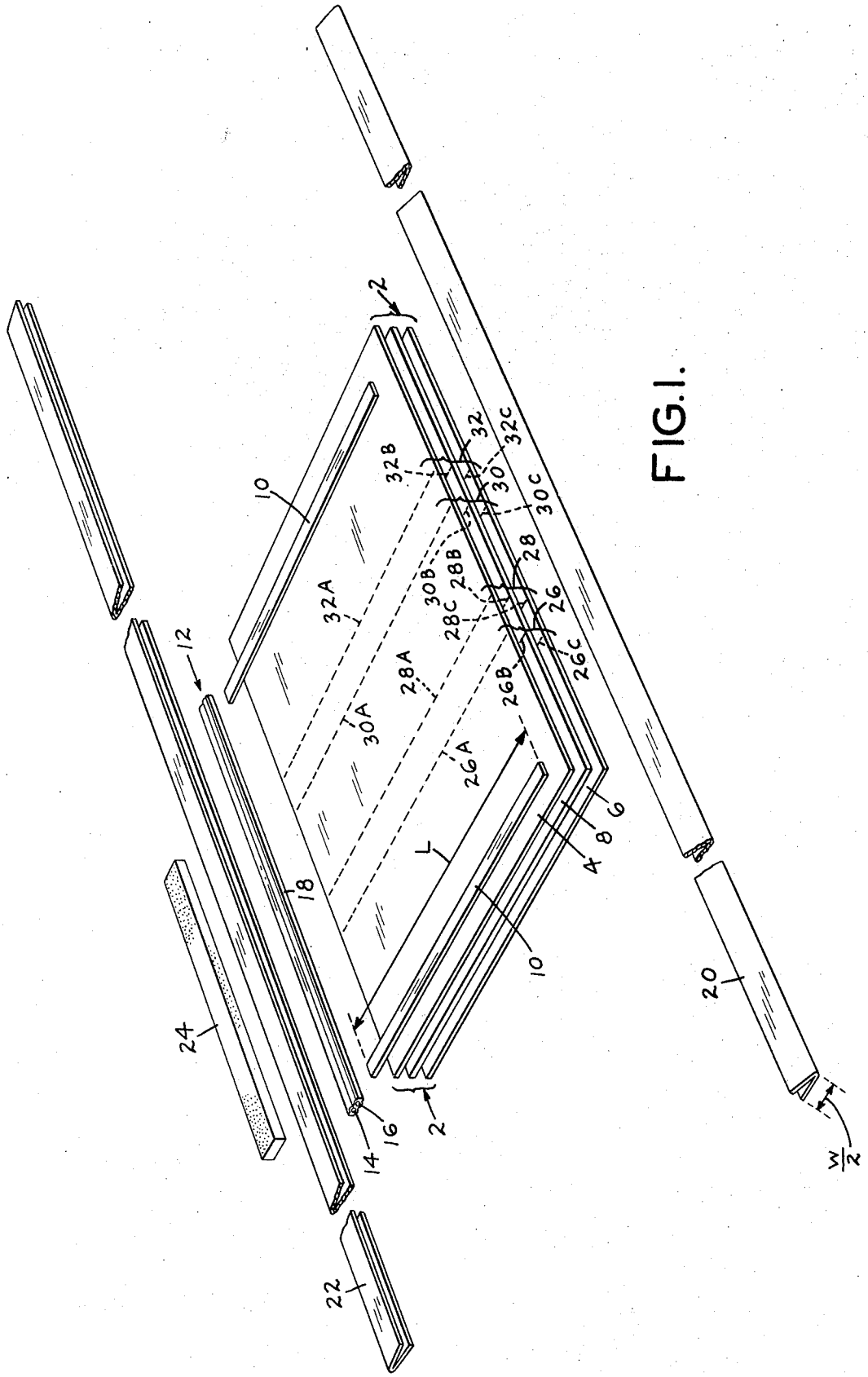

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FIG. 1.

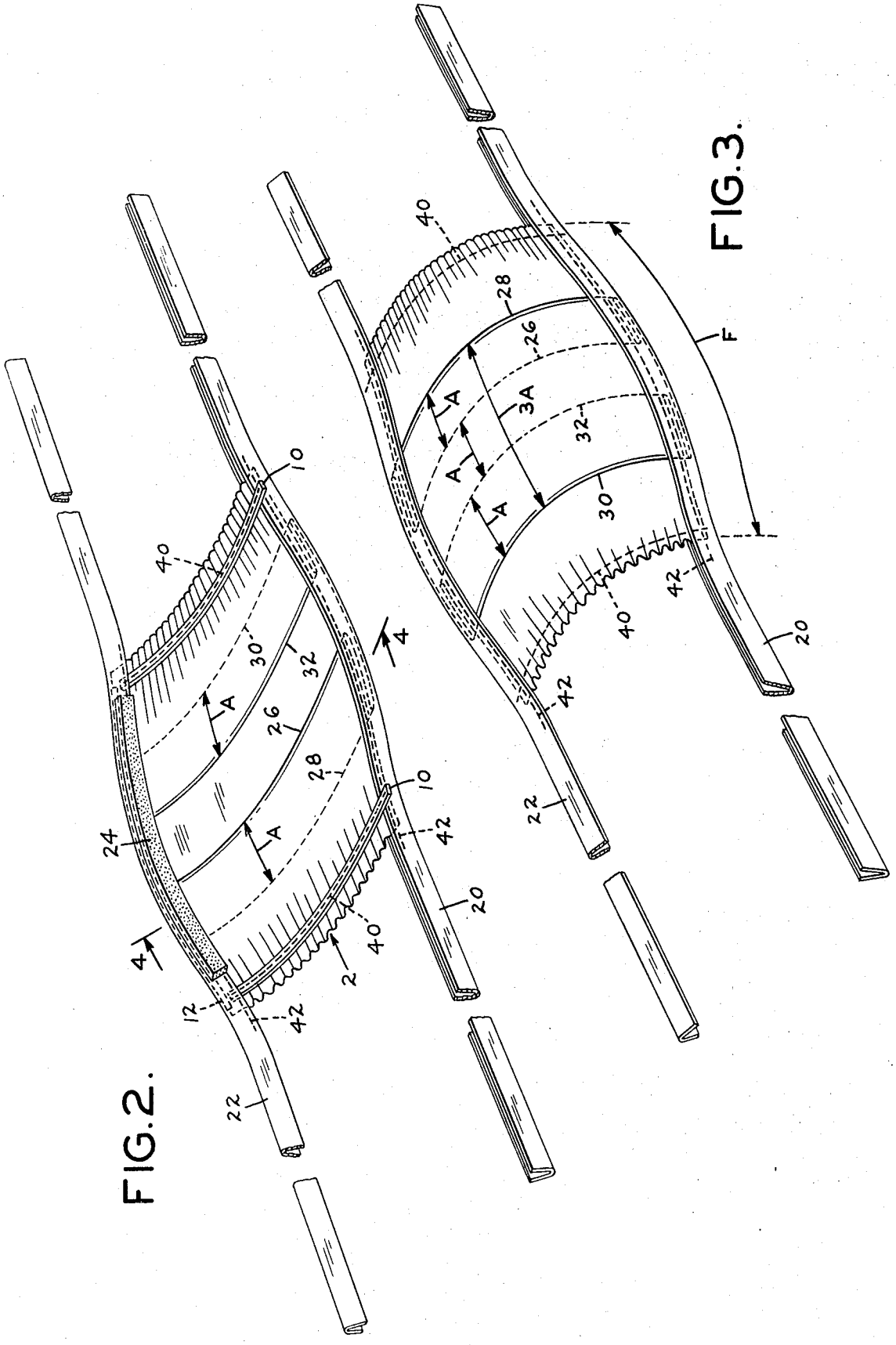


FIG.2.

FIG.3.

FIG.4.

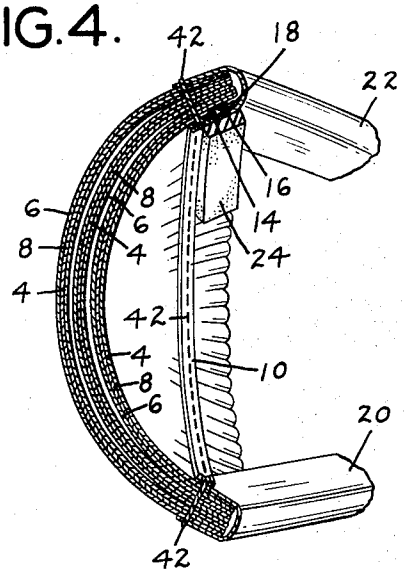


FIG.6.

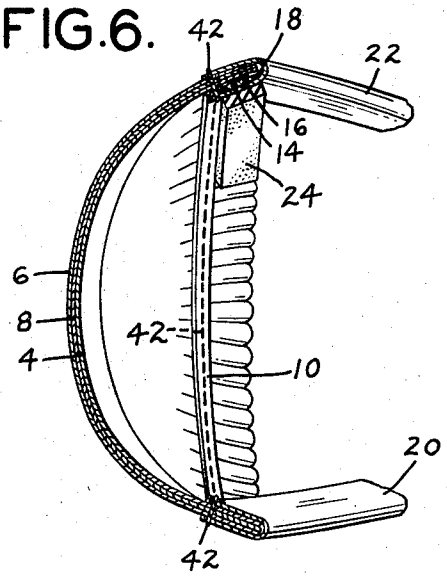


FIG.5.

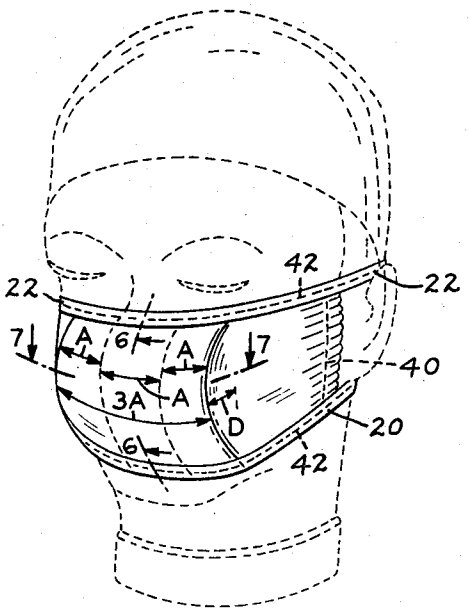
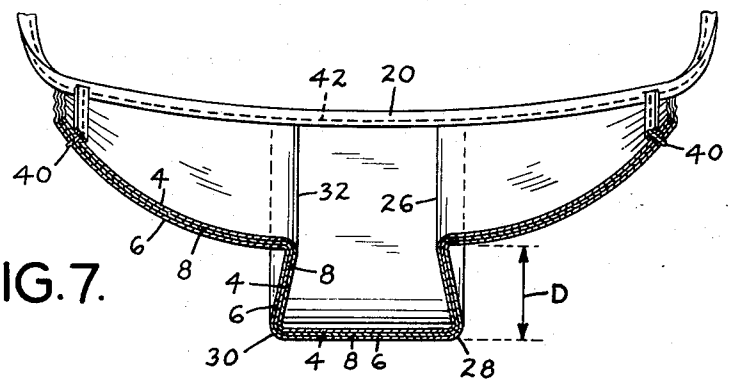


FIG.7.



SURGICAL FACE MASK

BACKGROUND OF THE INVENTION

Surgical masks should be designed to provide protection against contamination due to air-borne bacteria and the like. The requirements for an effective surgical mask are that it minimize or eliminate the number of air-borne bacteria which are exhaled by the wearer, and at the same time provide a relatively comfortable face covering which does not interfere with the actions and visibility of the wearer.

In order to clean the exhaled and inhaled air effectively, a surgical face mask should provide a tight fit around the wearer's nose and mouth. However, it is difficult to obtain an air tight seal around the periphery of the mask where the mask comes into contact with the wearer's face without the use of uncomfortable elastic bindings or rigid members affixed to the outer edges of the flexible pad. These are likely to cause excessive discomfort to the wearer.

A surgical face mask should have several characteristics. It should effectively filter the air which the wearer is inhaling and exhaling and at the same time permit moisture which the wearer is exhaling to exit from the mask. If moisture does not exit from the mask, the mask will become moist and saturated and will tend to lose its effectiveness. Attempts to provide a surgical face mask which is capable of cleaning the air passing through it effectively have resulted in indiscriminate increases in the density of the filtering material included in the porous pad. Such an increase will often result in capturing a greater amount of moisture. This will tend to cause the pad to become excessively saturated, while at the same time not permitting the carbon dioxide exhaled by the wearer to be effectively dissipated. This can result in a shortness of breath and impairment of circulation to the head as well as other objectionable symptoms.

BRIEF DESCRIPTION OF THE INVENTION

This invention relates to flexible disposable surgical face masks and particularly to disposable surgical face masks having a number of parallel vertical double pleat structures in the flexible pad portion of the mask. The flexible porous pad comprises a sandwich structure of an inner layer of non-woven fiber material and an outer layer of non-woven fiber material. Intermediate the inner layer of non-woven fiber material and the outer layer of non-woven fiber material is a filter mat or cover stock. The three layers have substantially the same peripheral configuration and are affixed to one another along their respective edges. The resultant flexible porous pad is then folded along a set of vertical pleat lines to form a first vertical double pleat structure and a second vertical double pleat structure. The first and second vertical double pleat structures are parallel to one another and are spaced a horizontal distance from one another. One of the vertical double pleat structures may be formed by folding a first portion of the flexible porous pad comprising approximately 80 percent of the horizontal dimension of the flexible porous pad over the remaining 20 percent of the flexible porous pad, and then folding the 80 percent portion back on itself to yield an overlap along approximately 10 percent of the horizontal dimension of the flexible porous pad. A similar operation is repeated in reverse at the other horizontal end of the flexible porous pad to obtain a cavity having a "Z" and reverse "Z" pleat configuration at either horizontal extremity of the cavity.

A strip of elastic binding is secured to each of the two vertical edges of the flexible porous pad. The elastic binding is secured to the vertical edges, while the elastic binding is in a stretched condition. After the binding has been secured to the vertical edges and allowed to return to its normal length, the elastic binding will crimp and foreshorten the vertical end of the flexible porous pad. A flexible nose piece is placed on the upper horizontal edge of the flexible porous pad and an upper and a lower fiber strip are stitched onto the upper and the lower horizontal ends of the flexible porous pad. The upper fiber strip covers the flexible nose piece and secures it to the flexible porous pad. A foam strip is affixed to the inner surface of the upper fiber strip. When the mask is worn, the foam strip is in contact with the bridge of the wearer's nose.

Because of the pair of vertical double pleat structures, the effective filtering area of the flexible porous pad is substantially increased. This is particularly true of the filtering surface in a substantially direct line with the wearer's nose and mouth. When the mask is to be worn, the cavity formed by the vertical double pleat structures and the portion of the flexible porous pad intermediate the vertical double pleat structures is pushed outwardly. This provides a box-like cavity for the nose, while simultaneously maintaining the flexible porous pad at a distance from the wearer's nose and mouth. Each of the vertical double pleat structures provides a semi-rigid edge structure which maintains the cavity in a popped-out condition and aids in overcoming the tendency of the flexible porous pad to assume a flat configuration. Maintaining this cavity aids in minimizing the discomfort which is present when a face mask clings to the wearer's nose and mouth and thereby impedes effective breathing.

It is an object of this invention to provide a device for protection against contamination from air-borne bacteria.

It is another object of this invention to provide a means for protection against air-borne contamination in operating theaters.

It is a further object of this invention to provide an improved surgical mask which protects the wearer from contamination from the patients and protects the patient from contamination from the wearer.

It is a still further object of this invention to provide a disposable surgical face mask having a vertical box structure to increase the effective filtration surface area of the mask.

It is yet another object of this invention to provide a disposable surgical mask which minimizes the discomfort due to the close proximity of the flexible porous pad to the nose and mouth of the wearer.

It is still another object of this invention to provide a surgical mask which has an effective edge gasket sealing system.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an exploded view partly in section of a preferred embodiment of the instant invention;

FIG. **2** is a diagrammatic view partly in section of the internal configuration of the embodiment of FIG. **1**;

FIG. **3** is an external view partly in section of the embodiment of FIG. **1**;

FIG. **4** is a vertical cross-sectional view taken along line **4—4** of FIG. **2**;

FIG. **5** is a frontal view of the embodiment of FIG. **1** showing the mask being worn;

FIG. **6** is a horizontal cross-sectional view taken along line **6—6** of FIG. **5**; and

FIG. **7** is a horizontal cross-sectional view taken along line **7—7** of FIG. **4**.

DETAILED DESCRIPTION OF ONE PREFERRED EMBODIMENT OF THE INVENTION

Referring now to FIG. **1** there is shown an exploded view of a disposable surgical mask embodying the invention. A flexible porous pad **2** is assembled comprising an inner layer **4** of non-woven fiber material, an outer layer **6** of non-woven fiber material and a center layer **8** of filter mat or cover stock. The peripheral silhouette of the inner layer **4** of non-woven fiber material and the outer layer **6** of non-woven fiber material, are substantially similar to one another. Both are substantially similar to the peripheral silhouette of the center layer **8** of filter mat or cover stock.

A strip **10** of elastic binding is situated along each one of the vertical edges of the flexible porous pad **2**. The extended length, "L," of each of the strips **10** of elastic binding is substantially equal to the dimension of the corresponding vertical

edge of the flexible porous pad 2. A flexible strip 12 is located along one horizontal edge of the flexible porous pad 2. The flexible strip 12 is comprised of a first wire 14 and a second wire 16. The first wire 14 and the second wire 16 are substantially parallel to one another over their entire length, and are covered by a coating 18 of plastic material or other material having flexible properties. The flexible strip 12 serves as a nose piece which can be shaped to form compound curves due to its dual wire structure.

A mask strip 20 of non-woven material is secured to each of the horizontal edges of the flexible porous pad 2. The mask strip 20 of non-woven fiber material has a length substantially greater than the horizontal dimension of the flexible porous pad 2 and a width "W." The mask strip 20 is folded along its longitudinal axis prior to being secured to a horizontal edge of the flexible porous pad 2. Folding the mask strip 20 results in a mask strip having an unchanged length and a width substantially equal to W/2. The resultant mask strip 20 is substantially U-shaped. The inner layer 4 of non-woven fiber material, the outer layer 6 of non-woven fiber material and the filter mat 8 are encompassed within the U formed by the mask strip when the mask strip 20 is situated in intimate contact with one of the horizontal edges of the flexible porous pad 2. A second mask strip 22, substantially similar in configuration to the mask strip 20 is situated in intimate contact with the other horizontal edge of the flexible porous pad 2. The inner layer 4, the outer layer 6 of non-woven fiber material, the filter mat 8, and the flexible strip 12 are encompassed within the second mask strip 22.

A strip of foam material 24 is mounted on the innermost surface of the mask strip 22, the innermost surface of the mask strip 22 corresponding to the inner surface of the mask. The strip of foam material 24 has a length which is substantially similar to the horizontal dimension of the flexible porous pad 2 after the pad has been appropriately folded.

A plurality of parallel, vertical fold lines are located on the inner layer 4 and the outer layer 6 of non-woven fiber material, and the center layer 8 of filter mat. A set of fold lines 26A, 28A, 30A and 32A on the inner layer 4 of non-woven fiber material, are parallel to one another and parallel to the vertical edges of the flexible porous pad 2. A second set of fold lines 26B, 28B, 30B and 32B are situated on the center layer 8 of filter mat. The fold lines are parallel to one another and parallel to the vertical edges of the flexible porous pad 2. A third set of fold lines 26C, 28C, 30C and 32C are situated on the outer layer 6 of non-woven fiber material and are parallel to one another and parallel to the vertical edges of the flexible porous pad 2. The fold lines 26A, 26B and 26C are substantially coplanar. The fold lines 28A, 28B and 28C are substantially coplanar. The fold lines 30A, 30B and 30C are similarly coplanar, and the fold lines 32A, 32B and 32C are also coplanar.

Looking now at FIG. 2, there is shown a view of the inner surface of the assembled surgical face mask embodying the invention. The strip 10 of elastic binding has been secured to the flexible porous pad 2 by means of a series of stitches 40. The stitches 40 pass through the flexible porous pad 2 and the strip 10 of elastic binding while the flexible porous pad 2 is in a flat condition and the strip 10 of elastic binding has been distended to approximately three times its normal size. Elastized thread may be employed as an edge binding rather than a strip 10 of elastic binding. The foam strip 24 is secured by means of glue or other suitable means to the inner surface of the upper mask strip 2 of non-woven material. The foam strip 24 extends over substantially the entire horizontal length of the flexible porous pad 2. The outer surface of the assembled surgical mask when the surgical mask is not in use is best shown in FIG. 3.

Referring now to FIG. 3, there is shown a view of the front surface of the surgical mask embodying the invention. The front surface of the surgical mask has a horizontal dimension "F." The horizontal dimension "F" is measured from one of the vertical edges of the mask to the other vertical edge of the mask. The distance between the outermost pleats 28 and 30 on the frontal surface of the flexible porous pad 2 is approximately F/2. Each of the outermost vertical pleats 28 and 30 is disposed approximately F/4 from the corresponding vertical edge of the flexible porous pad 2. The two innermost pleats 26 and 32 shown in phantom line in FIG. 3 are disposed at a distance "A" from one another. Each of the innermost pleats 26 and 32 is disposed a distance "A" from the next successive pleat in the flexible porous pad 2. For example, the inner pleat 32 is disposed a distance "A" from the successive outer pleat 30 which is the next pleat on the flexible porous pad 2. Therefore, the frontal surface of the flexible porous pad formed by the "Z" and reverse "Z" vertical double pleat structure has a dimension of approximately 3A in the horizontal direction.

Each of the mask strips 20 and 22 envelopes one of the horizontal edges of the flexible porous pad 2. Each of the horizontal edges of the flexible porous pad is inserted into the respective U shaped mask strip 20, 22. Each of the mask strips 20, 22 covers a distance approximately W/2 from each of the horizontal edges of the flexible porous pad 2 on both the inner surface and outer surface of the pad. Each of the mask strips 20 and 22 is secured to one of the horizontal edges of the flexible porous pad 2 by means of stitching 42. The stitching 42 passes through all three layers 4, 6, 8 of the flexible porous pad 2 and through the nine layers of the flexible porous pad where the flexible porous pad has been folded along the fold lines 26A, 28A, 30A and 32A, to achieve the "Z" and reverse "Z" structure.

Referring now to FIG. 4, there is shown a vertical cross-sectional view taken along line 4—4 of FIG. 2 of the surgical mask. FIG. 4 best illustrates the structural configuration of the surgical pad prior to "popping out" the vertical double pleat structures of the surgical pad. The vertical cross section taken is through one of the nine ply portions of the flexible porous pad 2 where the flexible porous pad 2 has been folded back on itself, as was discussed in conjunction with FIGS. 2 and 3. Each of the vertical pleat structures when viewed in cross section has a layer configuration, starting from the innermost layer in the vicinity of the wearer's face, of the layer 4 of non-woven fiber material, the center layer 8 of filter mat, the outer layer 6 of non-woven fiber material, an air space, the outer layer 6 of non-woven fiber material, the center layer 8 of filter mat, the inner layer 4 of non-woven fiber material, the inner layer 4 of non-woven fiber material, the center layer 8 of filter mat, and the outer layer 6 of non-woven fiber material. The upper and lower horizontal edges of the flexible porous pad 2 in the region of the nine ply structure of the flexible porous pad 2 are also encompassed by the mask strips 22 and 20, respectively. The stitching 42 traverses both sides of each of the mask strips 22 and 20 and also traverses the entire corresponding nine ply portion of the flexible porous pad 2.

The proper operational configuration of the surgical mask embodying the invention is best shown in FIG. 5. When the surgical face mask is to be worn, the wearer should pop the frontal surface of the flexible porous pad 2 outwardly to expand both of the vertical double pleat structures. In order to do this, the frontal surface, which has a horizontal dimension of approximately 3A, should be pushed forward and away from the plane of the surgical face mask when the surgical face mask is lying flat. This will cause the "Z" structure of each of the vertical double pleat structures to enlarge. Specifically the angles between successive layers of the flexible porous pad 2 will become less acute and will approach a 90° angle at the pleat. Preferably, the inner pleat 32 and the outer pleat 30 will lie in a plane which is transverse to the frontal surface. The inner pleat 26 and the outer pleat 28 should also lie above one another in a plane which is substantially transverse to the frontal surface. The planes formed by each of the vertical double pleat structures should approach a state of parallelism between one another. The distance between two of the successive pleats e.g., 26 and 28 measured along their coplanar surface should be approximately equal to the distance separating the pleats when the mask is in a flat condition, e.g. A.

FIG. 6 is a vertical cross-sectional view taken along line 6—6 of FIG. 5 of the surgical face mask and best exemplifies the shape of the flexible porous pad 2 after the surgical face mask has been "popped out." The upper and lower horizontal edges of the inner layer 4, the outer layer 6 of non-woven fiber material and the center layer 8 of filter mat are within the "U" formed by the two opposed sides of each of the mask strips 22 and 20, respectively. The flexible strip 12 with the inner wires 14 and 16 is situated intermediate the inner layer 4 of non-woven fiber material and the inner face of the inner portion of the upper mask strip 22. The foam strip 24 is overlayed on the outer face of the inner portion of the upper mask strip 22. The longitudinal axis of the foam strip 24 is substantially parallel to the longitudinal axis of the upper mask strip 22.

The elastic binding 10 is situated on the inner surface of the inner layer 4 of the non-woven fiber material. One strip of the elastic binding 10 is located at each one of the vertical edges of the flexible porous pad 2. Each one of the strips of elastic binding 10 is stitched into one of the vertical edges of the flexible porous pad 2. The elastic binding 10, when in a relaxed state, is approximately one-third to one-half the length of one of the vertical edges of the flexible porous pad 2. The elastic binding 10 is distended prior to being stitched into each of the vertical edges of the flexible porous pad 2. After each one of the elastic bindings 10 is stitched into one of the vertical edges of the flexible porous pad 2 the force distending each of the elastic bindings 10 is released. After the force distending each of the elastic bindings 10 is released, each of the vertical edges of the flexible porous pad 2 will become crimped due to the tension exerted on each of the vertical edges of the flexible porous pad 2 by each of the elastic bindings 10.

FIG. 7 best exemplifies the configuration of the cavity formed by the "Z" and reverse "Z" of the vertical double pleat structure. The vertical double pleat structure provides a place for the wearer's nose.

In order to effect the proper cooperation between the elements of the surgical face mask, the wearer should extend the center portion intermediate the two vertical double pleat structures so as to explode each of the vertical double pleat structures. This will expand the "Z" configuration and will generally make the angles in the "Z" less acute. A box-like structure having a depth "D" and a length in a horizontal direction approximately equal to 3A is formed. By "popping out" the frontal portion of the flexible porous pad 2, each of the folds will provide a semi-rigid support structure for the box-like configuration. The folds will be rigid enough to maintain the frontal portion of the flexible porous pad 2 away from the wearer's nose and mouth and yet the fold will not irritate or otherwise impede the wearer as might occur with rigid support members.

After the frontal portion of the mask has been "popped out" to form the box-like structure, the mask is placed over the wearer's nose and mouth. The foam strip 24 is in contact with the bridge of the wearer's nose and the lower mask strip 20 is below the lower lip of the wearer. The lower mask strip 20 is then tied behind the wearer's head and the flexible strip 12 is deformed to assume the contours of the bridge of the wearer's nose. The dual wire structure 14 and 16 in the flexible strip 12 allows the wearer to fashion the flexible strip 12 into a series of compound curves. This aids in accommodating individual variation in the bridge configuration of the wearer. One of the wires 14 may be bent into one particular configuration while the other one of the wires 16 may be bent into a substantially different configuration.

After the flexible strip 12 has been shaped to follow the contours of the bridge of the wearer's nose, the upper mask strip 22 is tied behind the wearer's head. The upper mask strip 22 is placed over the wearer's ears. The combination of the flexible strip 12 and the foam strip 24 provides an effective gasket across the bridge of the wearer's nose and aids in maintaining the flexible porous pad 2 against the wearer's cheekbones. This aids in preventing the introduction of air-borne bacteria from the patient and minimizes the possibility of infection from the patient or infection by the patient from the physician.

Different types of material may be employed for the inner layer 4 of non-woven fiber material, the outer layer 6 of non-woven fiber material, and the filter mat or cover stock 8. For example, the inner layer 4 of non-woven fiber material might be a face mask fiber which is a non-woven fiber material composed of rayon fibers bonded together with an acrylic type resin adhesive and having an average weight of approximately 300 grains per square yard. The tensile strength in the long direction typically might be in the neighborhood of 17 pounds per four ply thickness of material per 1 inch of width. The tensile strength in the cross direction for the inner layer of non-woven fiber material might typically be approximately 1.5 pounds per four ply layer thickness per 1 inch of width.

The outer layer 6 of non-woven fiber material may be of a different composition or weight than the inner layer 4 of non-woven fiber material. For example, fabric which is also primarily composed of rayon fibers bonded with an acrylic type resin adhesive may be used. However, the outer fabric may have a weight of 240 grains per square yard, a tensile strength in the long direction of approximately 35 pounds per 12 ply thickness of material per one inch of width, and a tensile strength in the cross direction of approximately 3.6 pounds per twelve ply thickness of material per 1 inch of width.

The filter mat, or cover stock can be of a variety of materials. An antiseptic solution may be placed in the cover stock prior to placing the cover stock into the flexible porous pad 2. One variety of filter material which may be employed is a web of rayon, natural fiber abaca, monocrylic fibers, glass fibers, and a binder. The basic weight of the filter typically might be in the vicinity of 37.9 ± 10 percent pounds per five hundred sheets. The thickness of the filter mat may be in the vicinity of 10 microns and the air permeability might be on the average of 300 cubic feet of air per square foot of filter material per minute, plus or minus 10 percent. Quaternary compounds may be used as antiseptics by soaking the filter mat in the compound prior to assembling the inner layer, the outer layer and the filter mat into a flexible porous pad. Amino acid sulphates such as Cytox, manufactured by American Cyanamid may also be used as antiseptics.

The terms and expressions which have been employed have been used as terms of description and not of limitation, and there is no intention in the use of such terms and expressions of excluding any equivalents of the features shown and described or portions thereof, but it is recognized that various modifications are possible within the scope of the invention claimed and particularly of the specific embodiment disclosed.

What is claimed is:

1. A surgical face mask, comprising:

a. a generally rectangular flexible porous pad having a pair of opposed parallel horizontal edges and a pair of opposed parallel vertical edges, said pad having an inner layer and an outer layer of non-woven material and a central layer of filter material, said layers being secured together along their horizontal and vertical edges to form said flexible porous pad;

b. a pair of elastic binding elements each having a relaxed length which is substantially shorter than the vertical dimension of said pad and each having a distended length substantially equal to the vertical dimension of said pad, said binding elements each being secured to a respective vertical edge of said pad while distended to said distended length thereof so that each of said vertical edges of said pad will be crimped throughout their lengths upon relaxation of said elastic binding elements;

c. a pair of spaced parallel vertical pleats in said pad extending from the top horizontal edge to the bottom horizontal edge of said pad and defining, respectively, a "Z" configuration and a reversed "Z" configuration in a plane parallel to said horizontal edges, said pleats together defining therebetween a configuration adapted to be popped out into a generally C-shaped vertical cavity ex-

tending substantially from the top horizontal edge to the bottom horizontal edge of said pad and being semirigid to maintain said pad away from the wearer's nose and mouth in service; and

d. means for retaining said flexible porous pad over the nose and mouth of a wearer.

* * * * *