

[54] **MEMBRANE STOMA SEAL FOR OSTOMY PATIENTS**

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[58] **Field of Search** **128/283, 294, 295, 275**

[56] **References Cited**

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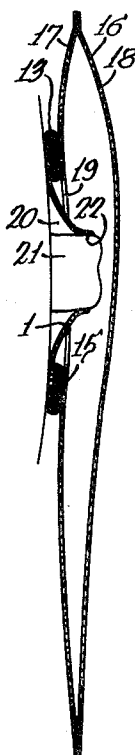
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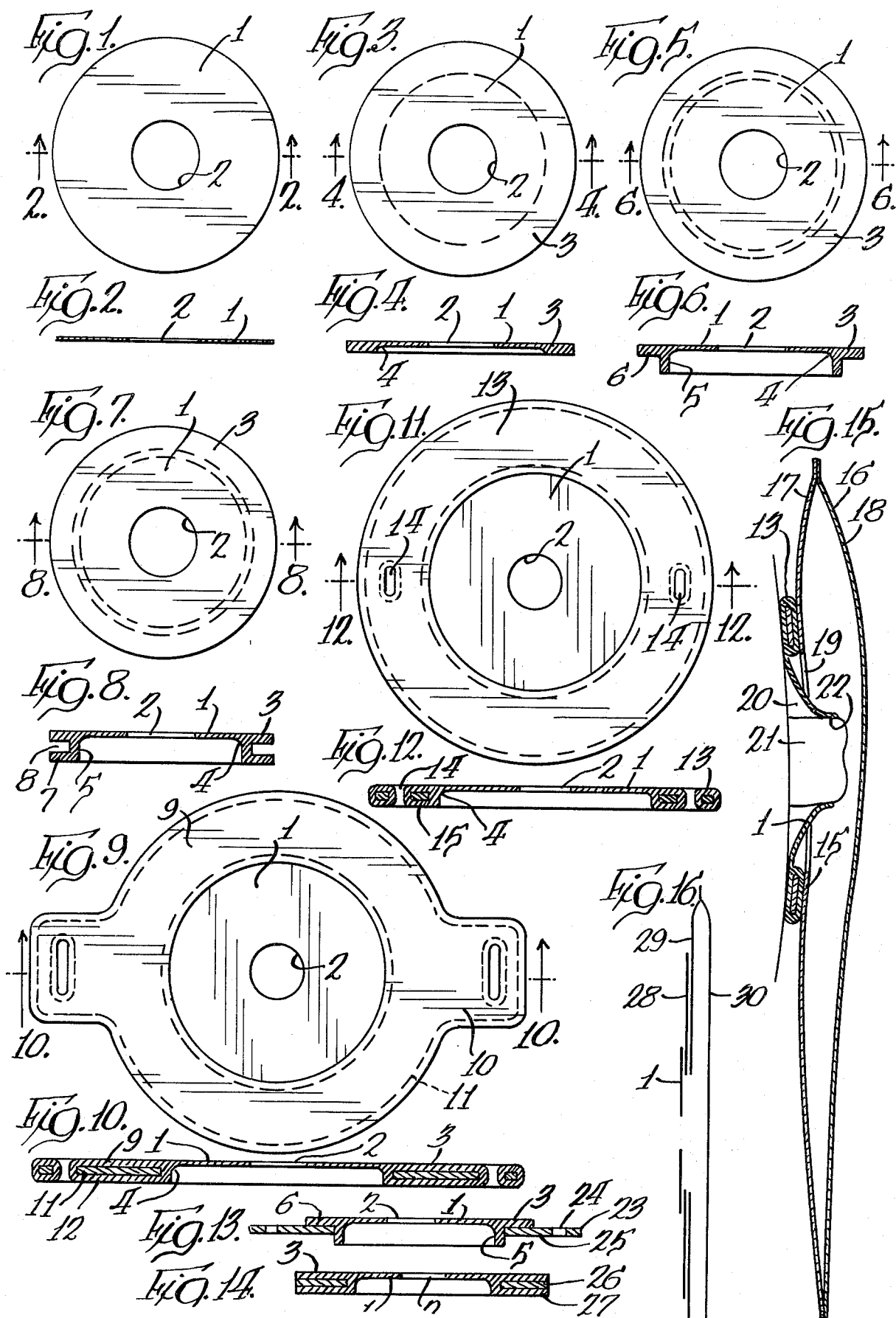
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[57] **ABSTRACT**

The invention provides a natural or synthetic membrane for use as a stoma seal in ostomy conditions. The membrane is very thin, very flexible, and very elastic. It is provided with a centrally located opening smaller than the stoma, whereby the membrane will easily stretch over the stoma and assume the shape of the stoma at the area of contact around the stoma, thereby forming a leakproof seal without strangulating or injuring the stoma. The invention also provides means for supporting the thin membrane at its circumference in a manner to isolate the membrane seal from excessive external stresses and whereby the membrane is supported so as to only be subjected to the stress applied by inserting the stoma through the membrane opening. The advantages of this membrane stoma seal are described in the specification.

11 Claims, 16 Drawing Figures





MEMBRANE STOMA SEAL FOR OSTOMY PATIENTS

HISTORY

The term "Ostomy" has come into use to define, in a broad sense, the surgical procedures known as colostomy, ileostomy, cecostomy, ureterostomy, ileal conduit, ileal bladder, wet colostomy, etc. This surgery usually results in an artificial opening through the abdominal wall for the terminal end of the intestine or a duct, called a stoma to discharge the body wastes of feces or urine.

Many devices have been developed through the years to aid the ostomy patient. There is not a single device that is suitable for all patients. This is due mainly to the differences in surgical techniques and the physiological condition of the patient.

THE PROBLEM AND THE CURRENT SOLUTION

In a broad sense, the problem facing most patients is to collect the discharge from the stoma in some type of container without restricting the patients general activities. A specific problem encountered by many patients is to prevent the discharge from contacting the skin surrounding the stoma as it can cause excoriation of the skin which can be very painful. Face plates of appliances have been cemented to the skin to prevent excoriation but are only successful for a limited time. The use of the karaya gel seals (U.S. Pat. No. 3,302,647) did much to help eliminate the problem of excoriation; however, it is not the complete answer for every patient. Some of the objections are the high cost of the karaya seals (up to 45 cents each) and the relatively short useable life due to its water solubility. Another objection is that some patients have developed a skin sensitivity to the karaya seals. Another objection is that the karaya gel seals do dry out and become hard and brittle while on the dealer's shelves waiting to be sold. When gel seals absorb moisture from the discharge they swell and can cause strangulation of the stoma and restricting the discharge flow. These conditions are very undesirable.

Furthermore, the time required to remove a gel seal and clean the area with repeated washing with soap and water and dry thoroughly before re-application of skin preparations can be most objectionable. And face plates that have been cemented on the skin with waterproof adhesives must be removed periodically and usually organic solvents must be applied to remove residual adhesive that remains on the skin. Organic solvents are not beneficial to the skin as they do remove natural oils; also, they are costly, have a bad odor, are usually inflammable, and are very time consuming.

THE INVENTION

This invention was developed to overcome the above described objections to the high cost of karaya gels, water solubility, strangulation of the stoma, excoriated skin, loss of time, and the use of adhesives and organic solvents.

My invention provides a stoma seal of a very thin water-proof membrane designated by the reference number 1 in the drawings. The membrane is composed of a material having soft, flexible, and highly elastic qualities, and preferably of a thinness approximating 0.001 of an inch to 0.010 of an inch. However, in some modifications noted hereinafter, thinness of the membrane

may be varied while still performing the desired functions. The membrane has a small opening 2 generally in its center. The opening is smaller in diameter than the stoma to which the membrane is to be applied, so that the membrane will easily stretch over the stoma and assume a flange or band-like contact means 22 on the wall shape of the stoma at a substantial area of contact completely around the stoma as shown in FIG. 15, thereby forming a leak-proof seal between the membrane and the stoma without strangulating or injuring the stoma. By the term "strangulating" I mean any engagement of the ostomy appliance with the stoma which would be tight or hard enough to restrict normal or adequate blood circulation in the stoma. This snug fit of the membrane around the stoma prevents the discharge from the stoma from contacting the skin of the abdomen, as will be apparent from the further description.

My invention also provides for attaching the membrane to the appliance in a manner to insure discharge from the stoma into the pouch or receptacle and for normal shifting of the pouch without disturbing the mechanical bond between the membrane and the stoma. To this end the outer periphery of the membrane is attached to the pouch in fixed relation thereto. This attachment may be made in various ways as, for example, through a circumferential rim 3 on the membrane integral therewith. Also, the membrane may be connected at its circumference to a gasket.

The invention eliminates the sealing of the appliance to the skin of the patient by the fact that an effective seal is provided directly between the membrane and the stoma, thus overcoming many disadvantages in prior ostomy appliances. However, my invention may be applied to the generally manufactured pouches, including the so-called stick-on type.

My invention also permits air to circulate in the skin area around the stoma by reason of the membrane function and its application, whereby such circulation of air aids the perspiration function of the skin.

Another advantage of my invention is due to the flexibility and elasticity of the membrane and the manner in which it is applied, in that the pouch can be shifted radially and also in a direction parallel with respect to the stoma without breaking the mechanical bond of the membrane to the stoma. This ability of the membrane will permit examination of the skin surrounding the stoma and the application of medication without removing the pouch. This ability of the membrane is very helpful to the person with a stoma that is discharging urine, because the flow of urine is practically continuous and interferes with cleaning and treating the skin surrounding the stoma.

Another advantage is that the cost of the membrane is very low, permitting it to be used only once and disposed as a component of a disposable pouch. The membrane could retail for 5 cents or less.

Referring to the drawings, it will be understood that they are diagrammatic and, together with the specification, illustrate the principles of my invention.

FIG. 1 is a face view of the simplest construction of a membrane for sealing a stoma in accordance with my invention;

FIG. 2 is a cross section through the membrane taken on the section line 2—2 of FIG. 1, illustrating the thinness of the membrane;

FIG. 3 is a face view of a membrane having an outer circumference or rim which adds strength to the membrane and aids in applying it to a pouch;

FIG. 4 is a cross section taken on the section line 4—4 of FIG. 3, illustrating a modification having greater thickness and a circumferential strengthening rim;

FIG. 5 is a face view of another modification of the membrane and rim;

FIG. 6 is a cross section taken on the section line 6—6 of FIG. 5;

FIG. 7 is a face view of another embodiment in which the membrane rim has a peripheral groove to receive a gasket;

FIG. 8 is a cross section taken on the section line 8—8 of FIG. 7;

FIG. 9 is a face view of a gasket adapted to be applied to a pouch, the gasket having a rigid center core and an outer skin providing a thin membrane in keeping with this invention;

FIG. 10 is a cross section taken on the section line 10—10 of FIG. 9;

FIG. 11 is a face view of another form of gasket having a rigid core and an outer skin providing a membrane;

FIG. 12 is a cross section taken on the section line 12—12 of FIG. 11;

FIG. 13 is a cross section through a membrane of the type shown in FIGS. 5—6, applied to a gasket;

FIG. 14 is a cross section through a membrane of the type shown in FIGS. 7—8, applied to a gasket;

FIG. 15 is a vertical section of an ostomy appliance having a pouch, a gasket, and a membrane stretched over the stoma and forming a band-like seal around the stoma, as applied to a patient; and

FIG. 16 is a diagrammatic vertical section of an ostomy appliance having a membrane such as shown in FIG. 1 together with a pressure sensitive adhesive patch which is secured to the inner wall of a pouch. This is a so-called "stick-on" type of appliance.

Referring further to the drawings, FIGS. 3—4 illustrate the above mentioned rim 3 integral with the membrane 1. In this form the membrane has a thinness of 0.005 of an inch and the rim about 0.060 of an inch. A radius 4 reinforces the junction of the membrane and rim. This reinforcing rim facilitates handling of the very thin membrane of FIG. 1 which can easily fold or distort when attempting to assemble it to a pouch. The rim serves to retain the membrane in its flat circular form which is helpful when applying the membrane to a pouch assembly.

The modification in FIGS. 5—6 has an annular component 5 integral with the rim 3 and of the same material as the membrane and rim. This form can be applied loosely in an assembly or the rim can be cemented or heat-sealed at its face 6 to a gasket as described below with reference to FIGS. 13 and 15. Since most gasket members are rigid the component 5 forms a cushion between the rigid or hard gasket and the easily injured stoma which is soft, thin-skinned, and contains many blood capillaries.

The modification shown in FIGS. 7—8 has an additional component 7 which forms a groove in the rim, this component being of the same material as the membrane. When this membrane is used on a gasket as shown in FIG. 14, it does not require glue to hold it in position, because it covers the rigid gasket on its inner

circumference and the two adjacent sides. This soft membrane provides further protection against the rigid gasket injuring the stoma.

In FIGS. 9—10 a gasket 9 of typical outward shape having extensions 10 for attachment of a belt, is made up of a rigid center core 11 and an outer skin 12 of the same material as the membrane. The rigid core serves to withstand forces that could distort the membrane and impair its function when it is held on a patient by the belt tension.

FIGS. 11—12 show a gasket 13 similar in principle to FIGS. 9—10 but eliminating the extensions 10 and having openings 14 for attachment of a belt. This gasket and membrane may be attached to a pouch by an adhesive or heat-sealing between the face 15 of the gasket and a pouch 16 having inner and outer walls 17 and 18, respectively, as shown in FIG. 15. The inner wall 17 has an opening 19 of a diameter substantially the same as the inner diameter of the gasket. In this assembly the belt (not shown) embraces the patient's waist and holds the membrane in sealing position and also holds the pouch in position. An air space 20 is formed when the stoma 21 is forced through the small opening in the membrane. This Figure shows the membrane stretched to form the band-like seal of some length in the area 22 lengthwise of and completely around the stoma as described above.

FIG. 13 shows a membrane of the form shown in FIGS. 5—6 applied to a gasket 23 having openings 24 for attachment of a belt. As abovementioned, the rim 3 can be cemented or heat-sealed at its face 6 to a gasket or it may be loose and removable. The membrane and gasket of FIG. 13 can be applied to a pouch in the relationship of the membrane and gasket shown in FIG. 15. That is, the gasket 23 would be applied to a pouch by cementing or otherwise sealing its face 25 to the face of the inner wall 17. To show the application of FIG. 13 to FIG. 15, move FIG. 13 in a counterclockwise direction to a vertical position in which the gasket 23 will be in the same position as the gasket 13 and its membrane will function the same as the membrane in FIG. 15.

In FIG. 14 the membrane of FIGS. 7—8 is applied to a gasket 26 which fits into a peripheral groove similar in principle to the groove 8. This membrane and gasket can be applied to a pouch in the same manner as the membrane and gasket of FIG. 13.

FIG. 16 illustrates diametrically a stick-on type of assembly in which a double coated pressure sensitive patch (adhesive on both faces) is secured to the face of the inner wall 29 of a pouch 30. The membrane 1 is applied to the patch 28 with a peripheral portion of the membrane overlapping the inner circumference of the patch and secured in position by adhesive engagement therewith. Generally the exposed surface of the pressure sensitive patch is covered with a release coated paper which serves to protect the adhesive surface until the pouch is to be applied to a patient, at which time the release paper is removed. This illustrates one embodiment of a membrane shown in FIG. 1 applied to a stick-on pouch. The assembly is held in position on a patient by the adhesion of the face of the patch against the patient's skin in an area surrounding the outer circumference of the membrane.

The size and shape of the membrane 1 can be varied to suit any size pouch of any manufacturer of ostomy appliances. The membrane will be made with stoma

openings 2 of various sizes to fit the sizes of stomas of various patients; and the opening in the membrane must always be smaller in diameter than the stoma so that the membrane will function in the manner described above. The shape of the circumference of the membrane referred to as the rim 3 can be adapted to any manufacturer's pouch. Also, the membrane can be manufactured to become an integral part of an ostomy appliance, either as a loose element or by mechanical attachment, gluing, heat-sealing, or by molding the membrane as a part of a gasket component.

What is common to all of the above is that the membrane in the area that contacts the stoma is very thin, very soft, very flexible, very elastic, that the opening in the membrane is smaller than the outer circumference of the stoma, and that the membrane stretches when applied to the stoma allowing the membrane to form a band-like fitting and seal in a substantial area completely around the circumference of the stoma that can prevent leakage at that point without strangulating or injuring the stoma.

Regarding the materials and methods of making a membrane in accordance with the invention:

The degree of thinness is determined by the materials to be used and the methods of manufacture. As above stated, I prefer to make the membrane within a range of approximately 0.001 of an inch to 0.010 of an inch. Inasmuch as this is a very thin film, the methods used to make thin films are extrusion, casting, molding, calendering, dip coating, powder coating, electro phoresis, spreading, and curtain coating.

Since the thin membrane film may be used without thick rims, the membrane may be cut from sheet material using low cost steel rule dies. The membrane having circumferential rims may be made in open faced, one piece aluminium molds.

The material to be used in making the thin membrane may be a vinyl plastisol. I have made suitable membranes using a plastisol which was blended in a mechanical mixer at low speed and composed of the following ingredients:

100 grams vinyl chloride QYKV-2	) Union Carbide Corp.
	) 270 Park Avenue
100 grams dioctyl phthalate	) New York, N.Y.
10 grams Drapex 6.8	) Argus Chemical Corp.
	) 633 Court Street
3 grams Marks 152	) Brooklyn, N.Y. 11231

This plastisol was spread on polished aluminum sheet to a thickness of about 0.005 of an inch and heat cured at 350°F. for up to 15 minutes. Also, membrane films were made curing at 450°F. for 1 minute. The material was cooled to room temperature and then stripped from the base. The material was then die cut to shape. This plastisol was also cast into a mold having a cross section shape similar to FIGS. 3 and 4, cured for 20 minutes at 350°F., cooled and then stripped from the mold. Also, by raising the temperature to 450°F. the time to cure was reduced to 2 minutes. The stoma opening was then die cut in the membrane and it was ready to be applied to a pouch for use on a patient.

Additional formulas used to make membrane films for my invention are as follows:

In one method "Plastisol A" supplied by Plasticrafts, 2800 North Speer Blvd., Denver, Colorado, was poured into an aluminum mold and cured for 2 minutes at 400°F.. It produced an acceptable seal but it can be

improved if it was more elastic. Therefore, additional plasticizer was added. In this case dioctyl phthalate was added, producing a softer and more elastic membrane. The formula and method are as follows: 5 grams Plastisol A and 2 grams dioctyl phthalate. These materials were mixed and poured into an aluminum mold and cured for 2 minutes at 400°F..

Another example is using commercially available silicone rubber compounds supplied by Dow Corning Corporation, Midland, Michigan, as follows: 10 grams of Silastic E RTV, 1 gram of Silastic RTV thinner, and 1 gram of Silastic E RTV catalyst. These ingredients were mixed, de-aerated to remove entrapped air bubbles, and the mixture was then poured into an aluminum mold and cured for 2 minutes at 300°F.. The mold was allowed to cool and then the membrane was removed. This mold produced a finished membrane such as shown in FIGS. 5-6. Also, the same mixture was poured onto an aluminum sheet and spread to a thinness of 0.010 of an inch and then heated for 2 minutes at 300°F. to cure. After the aluminum sheet was cooled to room temperature the cured silicone rubber membrane was stripped from the aluminum sheet and it was ready to be die-cut to the desired shape.

Another example is the use of latex rubber sheeting 0.005 of an inch thin, supplied by the Hygienic Dental Manufacturing Company, 1245 Home Avenue, Akron, Ohio.

There are many suitable elastomeric materials suitable for making a thin membrane for use of my invention, for example, vinyl chloride, latex rubber (natural or synthetic), vinyl copolymers, nitrile rubber, neoprene, buna S, polyurethane, silicone rubber, and a multitude of synthesized organic elastic materials. In the practice of my invention these elastomers would usually be modified with plasticizers, stabilizers, extenders, fillers, antioxidants, coloring agents, and foaming agents.

It should be understood that the above description of materials to make a thin elastic membrane of my invention are not to be construed as being a limitation, since other materials may be used to make a thin elastic membrane which will serve the intended functions of my invention.

I claim:

1. A membrane for use as a stoma seal for a pouch in ostomy conditions, the membrane comprising a sheet of extremely thin material having a high degree of elasticity and a thinness functioning as of approximately about one thousandth of an inch to ten thousandths of an inch throughout its area, a means for embracing and sealing the stoma comprising an opening in its center for receiving the stoma, said opening being smaller in diameter than the diameter of the stoma to which the membrane is to be applied and defining a band-like means around the stoma when applied thereto so that the membrane maintains a seal with the outer circumference of the stoma wall completely around the stoma.

2. For use in colostomy conditions, the subject matter set forth in claim 1, in which the membrane includes the ingredients vinyl chloride QYKV-2 and dioctyl phthalate.

3. For use in colostomy conditions, the subject matter set forth in claim 1, in which the membrane includes the ingredients silastic E RTV a silicone rubber compound supplied by Dow Corning Corporation, Mid-

land, Michigan, one gram of silastic E RTV catalyst, and one gram silastic RTV thinner.

4. For use with a body fluid receiving means in colostomy conditions, a membrane for application to the patient's the stoma, the throughout its area being of a thinness approximating one thousandth of an inch to ten thousandths of an inch, the membrane being of waterproof material that is soft, flexible, and very elastic, the membrane having in its center an opening smaller in diameter than the diameter of the stoma so that the central area of the membrane will stretch to provide a band-like contact seal means around the stoma when applied thereto and maintain sealing engagement with the circumference of the stoma in a substantial area completely around the wall of the stoma.

5. For use in colostomy conditions, a membrane as set forth in claim 4, and means for applying the membrane to a patient in a manner to provide a membrane area peripherally around said central area serving by its extreme thinness and elasticity to allow relative movements between said applying means and the stoma seal at the central area of the stoma, thereby providing a leak-proof stoma seal without strangulating or injuring the stoma and its seal under the varying conditions incident to use.

6. A membrane stoma seal as set forth in claim 1, in combination with means providing for leak-proof attachment of the membrane circumferentially thereof to

a pouch.

7. A membrane stoma seal as set forth in claim 1, in combination with means providing a substantially rigid support for the membrane circumferentially thereof, and means for attaching said support to a pouch with the stoma extending into the pouch, whereby normal strains on the pouch when it is worn on a patient will not be transferred beyond said support in a manner to disturb the seal of the membrane with the stoma.

8. A membrane stoma seal as set forth in claim 1, in combination with means to isolate the membrane seal from external stresses when it is worn on a patient.

9. A membrane stoma seal as set forth in claim 1, in combination with a pouch and means for supporting the membrane in co-active relation with the pouch and with the membrane positioned so that the seal will only be subjected to the stress applied by inserting the stoma into the membrane opening.

10. For use in ostomy conditions, a membrane as set forth in claim 1, the membrane having a circumferential strengthening rim of the same material as the membrane and integral therewith.

11. For use in ostomy conditions, a membrane as set forth in claim 1, in which the rim has incorporated therewith an annular strengthening component at the periphery of the membrane.

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