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 [21] Appl. No. **835,657**
 [22] Filed **June 23, 1969**
 [45] Patented **Oct. 12, 1971**
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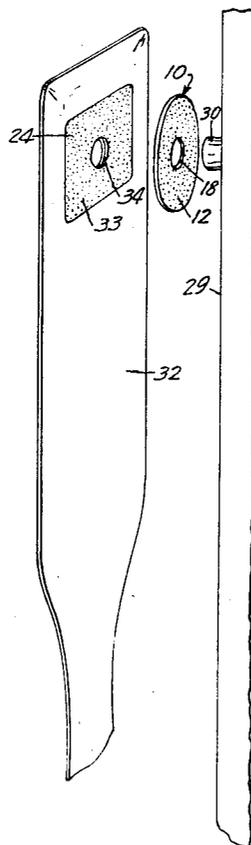
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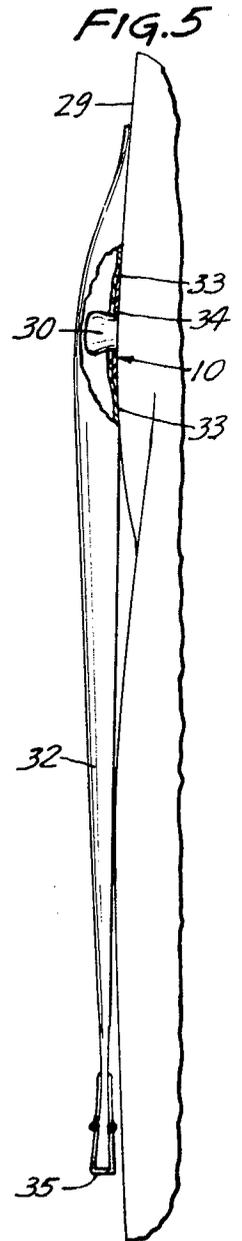
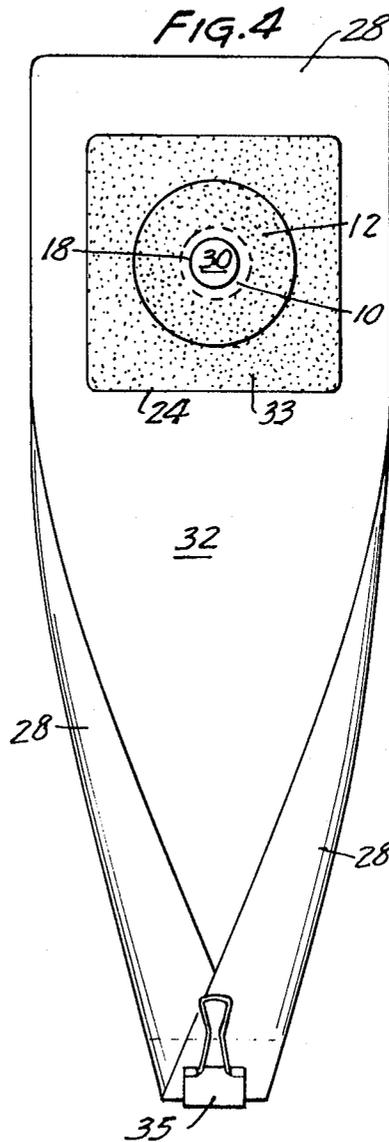
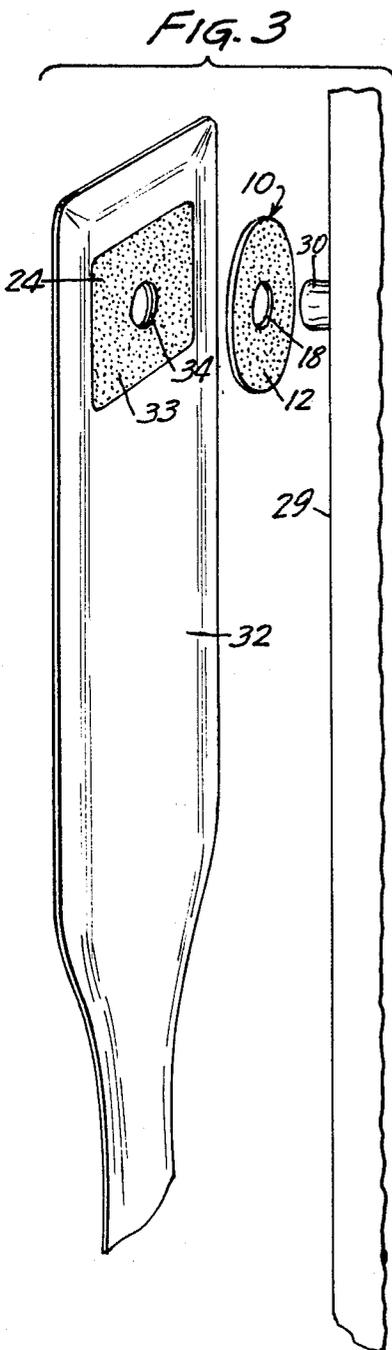
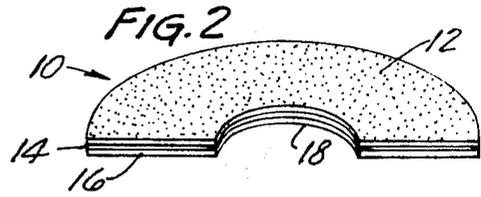
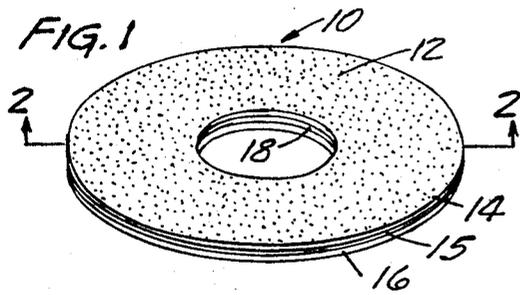
[54] **OSTOMY SEALING WASHER**
11 Claims, 5 Drawing Figs.

[52] U.S. Cl..... **128/283**
 [51] Int. Cl..... **A61f 5/44**
 [50] Field of Search..... **128/283**

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ABSTRACT: An ostomy-sealing washer is provided which is adapted to fit over an intestinal stoma for use with a postsurgical drainage pouch; it comprises a pliable, resiliently flexible elastoplastic sheet material body having a water-activatable adhesive on one surface which, after activation, becomes water insoluble. The ostomy-sealing washer has an aperture therethrough sufficient to receive the stoma and is adapted to be adhered to the human skin on that side having the adhesive and to an adherent drainage pouch on the other side forming a seal therebetween preventing leakage between the stoma and the pouch.





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OSTOMY SEALING WASHER

BACKGROUND OF THE INVENTION

This invention relates to an improved sealing device for use with surgical drainage pouches. More particularly, this invention relates to an ostomy-sealing washer which may be used with a postsurgical drainage pouch, adhering the pouch to the patient after an ileostomy or colostomy-preventing leakage onto the skin.

Certain abdominal surgery, such as an ileostomy, where the large intestine is entirely removed and part of the small intestine is brought through the abdominal wall; or a colostomy, where the large intestine is brought through the abdominal wall, requires an opening to be made in the abdominal wall to permit drainage from the internal organs of the patient. In those cases where the anal opening is relocated, the intestine protrudes through the opening in the wall. This protruding portion of the intestine is usually referred to as the stoma. Postsurgical drainage pouches are available which are attached to the body adjacent the stoma to receive the discharge from the intestine since the patient cannot control drainage from the organs.

One difficulty that has arisen using drainage pouches is that some leakage from the intestine occurs between the drainage pouch and the patient's skin causing irritation thereto. The constant flow of the digestive juices on the skin causes the "digestion" of some of the skin (excoriation). Thus, there have been attempts to prevent the leakage between the pouch and the skin by providing an impermeable seal between the patient's skin and the pouch.

Various sealing devices have been made comprising mechanical structures fabricated from cardboard and the like. See, for example, U.S. Pat. No. 2,524,750, and 3,444,788. These structures are, however, quite cumbersome and uncomfortable and, in many cases, extremely irritating to the protruding stoma. As exemplified in U.S. Pat. No. 3,302,647 sealing pads have been formed of a mixture of a nonevaporative oleaginous liquid carrier in a healing powder miscible with the carrier, forming a gel when mixed in sufficient quantities with the carrier. Preferably karaya powder, a well-known natural gum, is mixed with glycerol to form a sealing ring which is used to bond the pouch to the skin. It has been found, however, that the material used to fabricate this type of sealing pad is soluble in water, which may be present in the form of perspiration from the body or in the discharge from the body, and thus the seal disintegrates somewhat during use allowing leakage of the drainage onto the patient's skin.

SUMMARY OF THE INVENTION

According to the present invention, an ostomy-sealing washer is provided which may be used with a postsurgical drainage pouch to provide an impermeable seal between the protruding stoma of the intestine and the pouch. The washer is a flat body, usually disc shaped, having a central aperture adapted to receive the stoma and is composed of a pliable, resiliently flexible elastoplastic sheet material which has a water activatable adhesive on one side. The washer is very soft and flexible, being quite limp, which aids in preventing irritation when in contact with the stoma, and which readily conforms to the stoma and forms an impermeable seal therearound preventing leakage of the drainage from the intestine onto the patient's skin. When the washer is to be used, the adhesive side is placed against the patient's skin and moisture exuded by the body activates the adhesive forming an impermeable seal between the sealing washer and the skin. Additional moisture may be applied to induce adhesion. An adhesive is used, which after activation, becomes water insoluble so that no disintegration of the adhesive material occurs and bonds the washer firmly to the skin. A drainage pouch, having an adhesive on that surface which is to receive the stoma, is adapted to be placed over the stoma and onto a portion of the sealing washer and the skin forming a seal between the washer and the pouch which results in a complete seal

from the patient's skin to the pouch. The adhesive on the pouch aids in holding the pouch on the skin but, due to the weight of the discharge in the pouch, a belt or strap is usually necessary to hold the pouch in place.

The objects, features, and advantages of the present invention will be more fully understandable with reference to the following drawings wherein:

FIG. 1 is a prospective view of the sealing washer of the invention,

FIG. 2 is a cross-sectional view of the sealing washer,

FIG. 3 is a telescopic view showing the relationship of the stoma, the sealing washer, and the drainage pouch,

FIG. 4 is a fragmentary section view of the drainage pouch in place over the sealing washer and stoma, and

FIG. 5 is a sectional view of the drainage pouch and sealing washer as shown in FIG. 4.

There are many variations of which the present invention is susceptible, other than as illustrated in the drawings. Description of the drawings in the present disclosure is to be considered as an exemplification of the principle of the invention and is not intended to be limiting.

Referring to the drawings, FIG. 1 shows the sealing washer of the present invention in the preferred embodiment. The sealing washer 10 is in the form of a circular disc primarily because of the circular nature of the stoma and has a centrally located aperture 18 therethrough which is placed over the stoma. The washer comprises a laminate of oil-extended block copolymer 14 covering a second thinner layer 15 also comprising an oil-extended block copolymer. It is not necessary that two distinct layers of the elastoplastic material be used, but is generally preferred because the two layers may have different ratios of oil to copolymer, thereby giving different consistencies to the layers. Preferably the thicker layer 14 has a less firm consistency allowing the seal to have very flexible elastoplastic properties while the thinner layer 15 is of somewhat firmer consistency giving structural stability to the seal. More importantly, the more elastoplastic material enhances the resiliency and pliability of the washer and also provides a tacky surface to hold an adhesive powder. Because of the large amount of oil in this layer, however, there may be some leaking of the oil out of the washer. Thus a firmer layer of elastoplastic material is laminated to the surface of the more elastoplastic material minimizing oil leakage therefrom. It has been found that the seal should be thick enough so that upon contracting around the stoma there will be no space between the stoma and the periphery of the aperture to allow drainage therethrough. The sealing washer should preferably have a total thickness of from about 2.5 to 3 mm. The thinner layer is about 0.1 to 0.3 mm. thick and the thicker layer accounts for the balance.

The sealing washer is supported by a release liner 16 to permit easier handling of the washer and also to protect it during packaging and storage. The surface of the washer has a water-activatable adhesive 12 thereon which is used to form a seal between the patient's skin and the washer. The adhesive is activated by moisture, which may be produced by the body, and thereafter becomes water insoluble. Thus, moisture present in excess of the amount necessary for activation will not disintegrate the adhesive after activation.

Due to the elastoplastic nature of the sealing washer, the aperture 18, which is slightly smaller than the stoma, is capable of being enlarged sufficiently to fit over the stoma. The washer is merely stretched manually and placed over the stoma and upon its recovery, the washer fits snugly around the stoma forming an impermeable seal therebetween.

The elastoplastic material which comprises the bulk of the sealing washer preferably has a modulus of elasticity of from about 1,000 to 30,000 dynes per square centimeter to insure a snug fit around the stoma upon recovery of the washer after stretching. The modulus of elasticity may be below 1,000 dynes per square centimeter as long as the washer retains its shape. The advantage is using materials with a low modulus of elasticity is that the aperture can be made smaller than the

stoma allowing a snug but not highly constrictive fit therearound upon recovery and thus minimizing leakage. When higher elastic modulus materials are employed, the aperture size must be varied to compensate the elastic properties of the washer, and if the modulus of elasticity is too high, the washer is too constrictive for any extended use.

Materials which have proven quite satisfactory for preparing the washer are oil-extended block copolymers. Examples of such materials are styrene-isoprene and styrene butadiene block copolymers having a molecular weight of from about 100,000 to 220,000. The copolymers are extended with an oil, such as mineral oil, to increase their elasticity. The ratio of oil to copolymer may be from about 3 parts oil to 7 parts block copolymer to 12 parts oil to 1 block copolymer. Both the oil and block copolymer are nontoxic and nonirritable to the skin which is an essential requirement of any material which is to be placed on the skin. Further, the material is flexible and insoluble in water and body fluids. Materials having similar elastoplastic properties may be used.

The adhesive material 12 which is used to adhere the sealing washer to the skin is a water-activatable adhesive and must also be nontoxic and nonirritating to the skin. Further, the adhesive must be capable of being rendered insoluble in water and in any drainage from the intestine so that no leakage will occur between the washer and the skin. It is preferred that the adhesive be activated only after it is placed over the stoma and onto the skin so that there is no premature adhesion before the washer is properly situated. Adhesives which are well suited for this purpose are dry powdered adhesives, such as those prepared by combining a powdered polyacid with a powdered metal oxide. Preferably, the polyacid component of the adhesive has at least 10 percent available acid groups. The metal oxide may be any polyvalent nonrefractory metal oxide which is nontoxic. The preferred metal oxides are calcium, magnesium, zinc and barium oxides or any combinations thereof. The preferred ratio of polyacid powder to metal oxide powder is about 5 parts polyacid to 1 part metal oxide although from about one to eight parts polyacid to 1 part metal oxide may be used satisfactorily. One such adhesive is prepared from a mixture of powdered ethylene maleic acid and powdered zinc oxide. The adhesive becomes tacky upon contact with sufficient moisture such as that given off by the skin and thus adheres to the skin around the stoma. At the same time, the two components of the water-sensitive adhesive cross-link and become water insoluble so that additional moisture does not weaken the bond between the seal and the skin. Other polyacid, metal oxide water-activatable adhesives which may be used are methyl vinyl ether-maleic acid copolymer (available from General Aniline Corp. under the trade name C Gantrez HY) with zinc oxide powder; polyacrylic acid powder (available from Rohm and Hass under the trade name "Aerysol") with zinc oxide powder, and polymaleic acid with zinc oxide powder. Polymers and copolymers derived from itaconic and citraconic acids may also be used. The powdered adhesive is applied to the block copolymer film and is held thereon due to the inherent tackiness of the film. The excess is removed by brushing it off or by other suitable means.

The sealing washer of the present invention is used in conjunction with a drainage pouch as illustrated in FIG. 3. When a new drainage pouch is to be applied, the sealing washer 10 is removed from its protective liner 16 and is expanded so that the aperture 18 can pass over the stoma 30. The ring is placed around the stoma adjacent thereto so that the adhesive 12 on the washer is in contact with the skin. Immediately after the ring is placed around the stoma, a drainage bag having an aperture 34 to receive the stoma and an adhesive portion 33 around the aperture is placed over the stoma 30 so that the stoma is received by the aperture 34 in the pouch. The adhesive on the pouch causes it to adhere very tightly to the surface of the seal 10 and also on the skin.

After about one-half to two minutes, moisture from the body activates the adhesive surface 12 which is in contact with the skin allowing the washer to tightly bond to the skin. This bond is not so strong, however, that the seal may not be easily removed from the skin when a new disposable pouch is to be

applied.

As illustrated in FIGS. 4 and 5, the aperture in the sealing washer 10 is in contact with the stoma at its periphery. The aperture 34 in the drainage pouch, however, need not form a tight fit around the stoma but may be larger than the stoma as the impermeability between the stoma and the skin is the result of the tightly fitting sealing washer on the skin which in turn is adhered to the pouch forming a kind of telescopic seal therebetween. The adhesive on the pouch serves two purposes. First, it adheres the pouch to the washer creating impermeability therebetween and secondly, it is adhered to the washer and the skin around the washer thus helping to hold the washer tightly against the skin. The adhesive 33 on the back of the pouch 32 should be nontoxic and nonirritating to the skin and preferably a hypoallergenic adhesive such as the acrylate copolymer adhesives of Uhlich, U.S. Pat. No. 2,884,126, is used. Other adhesives fulfilling these requirements and which may be used on the drainage pouch are medical grade pressure-sensitive and silicone adhesives. Further, the adhesive need not be incorporated as a component of the pouch during manufacture but can also be an independent piece of pressure-sensitive tape, having two tacky surfaces, which may be interposed between the seal and the pouch immediately prior to use. Thus, many of the drainage pouches used presently which do not have an adhesive incorporated thereon may be used to take advantage of the novel sealing washer of this invention.

A sealing washer is thus provided which virtually eliminates the flow of intestinal drainage onto the skin. The moisture resistant adhesive allows the sealing washer to remain firmly in place on the patient's skin adjacent to the stoma and the elastoplastic nature of the washer allows it to fit snugly around the base of the stoma providing a leakproof seal between the stoma and pouch which will not diminish with time. When the pouch is filled, it may be removed from the skin and sealing washer and discarded. Similarly, the sealing washer may be easily removed from the stoma without causing irritation thereto. In many instances, the sealing washer remains adhered to the pouch when the pouch is removed from the patient. A further advantage of the sealing washer of this invention is that no noticeable residue is left on the skin or stoma after removal of the washer. Any slight residue that does remain may be removed by normal cleansing procedures.

The sealing washer is generally prepared by extruding the elastoplastic material as a film on a silicone paper release liner. The film is then electrically discharge treated on one side to prime the surface so that its capability of adhesion is enhanced. One extruded film which is about 12 mils has a somewhat firmer consistency than the other which is about 100-mils thick. Although the two layer construction is preferred, a single layer having suitable elastoplastic properties may be used for the entire washer. The film is run through a hot melt coater at about 200° to 400° F. and then cooled. An excess of adhesive, in powdered form, is then applied to the tacky surface of the film, the excess removed, and the sealing washer is subsequently die cut from the film.

The invention will be further understood by reference to the following illustrative, but nonlimiting, example in which all parts are by weight unless otherwise noted.

EXAMPLE

The following formulation was used in preparing the thin layer of the sealing washer of the present invention:

Compound	Parts
styrene-butadiene-styrene block copolymer, (average molecular weight 120,000 to 160,000) available from Shell Chemical Co. as "Kraton 1101"	120
White mineral oil	80
Antioxidant available from Geigy Chemical Co. as "Irganox 1010"	0.6
Pigment available from Konstamm Dye Co. under the trade name "Konstamm Raw Umber No. 1983"	0.25
Pigment available from Konstamm Dye Co. under the trade name "Konstamm Burnt Sienna No. 2673"	0.05

The materials were placed in a drum tumbler and mixed for about 15 hours to combine the oil with the block copolymer. The materials, which were small pieces, were then placed in a conventional horizontal cast film extruder having a screw with a three to one compression ratio and having a constant cross-sectional area die. The mixture was heated to 400° F. in the extruder and extruded to a thickness of 12 mils and a width of about 26 inches wide onto a silicone coated release paper liner. The hot film is then run through cold rolls to allow solidification.

The film was then treated by conventional electrical discharge methods on the side not in contact with the silicone liner to increase the adhesive affinity of that surface. The film and liner were then rolled into a jumbo roll. While in the roll form, the treated surface of the film has a greater tendency to adhere to the liner than does the untreated surface, preferably sticks to the silicone liner. Thus, upon unwinding from the roll the untreated surface is exposed and the treated surface is covered by the liner so that this surface is protected from subsequent contaminants.

The thicker layer is prepared from the following:

Compound	Parts
Kraton 1108	1
White mineral oil	8

The materials were heated under vacuum in a closed insulated kettle at a temperature of about 350° F. until the mixture was entirely liquid. The liquid was then cast onto the untreated side of the previously formed thin film layer to a thickness of 2.5 mm. by means of a flat bed coater, which is only one of several types of coaters that could be used. The inherent tackiness of this materials allows it to bond to the thinner layer at the interface therebetween. The film is then pulled through a dry ice bath to allow cooling.

After cooling, which takes about 1 to 10 minutes, a water-activatable adhesive powder was sprinkled on the tacky surface of the thicker layer of film. The adhesive used was a mixture of 5 parts powdered ethylene maleic acid (commercially available from Monsanto Company under the trade name "EMA-22") and 1 part zinc oxide powder. The excess powdered adhesive was then removed by brushing leaving only enough powder to cover the surface of the film.

The film carrying the adhesive was then slit into rolls having a width of 2 (3/4) inches. From these rolls the ostomy-sealing washer comprising a circular sealing ring with a central aperture, was die cut, the aperture having a diameter of about 1/2 inch and the washer diameter being 2 (1/2) inch. When the washer was applied, the silicone liner was removed and the washer was placed on the skin. A drainage pouch, having a pressure-sensitive adhesive on one side was placed over the outer surface of the washer and extended onto the skin helping to hold the washer in place. Upon activation of the adhesive on the washer by moisture from the body, a strong bond was formed between the sealing washer and the skin which did not diminish upon the release of more moisture by the body.

What is claimed is:

1. An ostomy-sealing washer adapted to fit over an intestinal stoma for use with a postsurgical drainage pouch comprising a pliable, resiliently flexible, elastoplastic flat body

having an aperture therethrough, said body having a modulus of elasticity from about 1,000 to 30,000 dynes per square centimeter, said body having a water-activatable adhesive on one surface, said adhesive becoming water insoluble upon activation and being hypoallergenic to the human skin, said washer aperture being smaller than the stoma the washer is to fit, said washer being capable of tenacious adherence to the human skin by its adhesive surface and to a drainage pouch by its other surface, thereby preventing intestinal drainage onto the human skin.

2. An ostomy-sealing washer adapted to fit over an intestinal stoma for use with a postsurgical drainage pouch comprising an elastoplastic, oil-extended block copolymer flat body having an aperture therethrough, said body having a water-activatable adhesive on one side which becomes water insoluble upon activation and being hypoallergenic to the human skin, said washer aperture being slightly smaller than said stoma the washer is to fit, said washer being capable of tenacious adherence to the human skin by its adhesive surface and to a drainage pouch by its other surface, thereby preventing intestinal drainage onto the human skin.

3. The ostomy-sealing washer of claim 2 wherein said block copolymer is a styrene-butadiene block copolymer and said oil is mineral oil.

4. The ostomy-sealing washer of claim 2 wherein said block copolymer is a styrene-isoprene block copolymer and said oil is mineral oil.

5. The ostomy-sealing washer of claim 2 wherein said water activatable adhesive comprises a mixture of a polyacid powder and metal acid powder.

6. The ostomy-sealing washer of claim 2 wherein said oil-extended block copolymer comprises about one part copolymer extended with from about 4 to 12 parts oil.

7. An ostomy-sealing washer adapted to fit over an intestinal stoma for use with a postsurgical drainage pouch and comprising a first flat layer of an elastoplastic oil-extended block copolymer consisting essentially of 6 parts styrene-butadiene block copolymer extended with 4 parts mineral oil and a second flat layer of elastoplastic oil-extended block copolymer comprising 1 part of styrene-isoprene block copolymer extended with 8 parts mineral oil, said first and second layers being bonded at their interface, said second layer having a water-activatable adhesive of powdered ethylene maleic acid and powdered zinc oxide thereon, said washer having an aperture therethrough sufficient to be expanded over said stoma and, upon recovery after expansion, sufficiently elastic to fit snugly around said stoma, said washer being capable of tenacious adherence to the human skin by its adhesive surface and to a drainage pouch by its other surface, thereby preventing intestinal drainage onto the human skin.

8. The washer of claim 7 wherein said first and second layers comprise a styrene-isoprene-styrene block copolymer.

9. The washer of claim 7 wherein said first and second layers comprise a styrene-butadiene-styrene block copolymer.

10. The ostomy seal of claim 7 wherein said adhesive comprises a mixture of 5 parts powdered ethylene maleic acid to 1 part powdered zinc oxide.

11. The ostomy seal of claim 7 wherein said styrene-isoprene block copolymer has a molecular weight of about 120,000 to 160,000 and a modulus of elasticity of about 4,000 dynes per square centimeter.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,612,053 Dated October 12, 1971

Inventor(s) Ronnie L. Pratt and Robert W. H. Chang

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 4, line 49, "miles" should be changed to read "mils".

In the drawing beneath the inventor's name "Ronnie L. Pratt", insert the inventor's name --Robert W. H. Chang--.

On the title page after the word "inventor" the inventors should be --Ronnie L. Pratt and Robert W. H. Chang--.

Signed and sealed this 6th day of June 1972.

(SEAL)

Attest:

EDWARD M. FLETCHER, JR.
Attesting Officer

ROBERT GOTTSCHALK
Commissioner of Patents