OSTOMY SEAL AND METHOD OF MAKING THE SAME

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A nonirritating seal to be used in conjunction with an ostomy bag for patients who have undergone operations such as colostomies and ileostomies, wherein the seal is provided with a flexible backing material such as a polyethylene film to enable the seal to retain its shape and also permitting the seal to have an interference fit with a plastic retaining ring carrying the ostomy bag. The seal is made by a novel method which includes placing in a rigid mold an upper and lower sheet of thin flexible plastic material and injecting the seal material into the mold between the sheets so that upon removal one flexible sheet becomes a backing for supporting the seal while the other forms a "peel-off" type of cover for the face of the seal which can be removed immediately before applying the same against the skin of a patient.

2 Claims, 9 Drawing Figures

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OSTOMY SEAL AND METHOD OF MAKING THE SAME

BACKGROUND OF THE INVENTION

Major operations of the “ostomy” type, namely, colostomies and ileostomies, are becoming more commonly performed principally to remove malignant or diseased tissue, thereby prolonging the life of the patient and in many cases effecting a complete cure of the malignant or diseased condition. In such operations, a section of the intestine is removed and an opening is made in the abdominal wall of the patient so that waste material accumulating in the intestine may be discharged through a discharge opening called a stoma. The waste material is directed into a container, usually in the form of a flexible plastic bag, from which it may be emptied periodically. It is necessary that a liquid-proof seal be maintained between the patient’s skin and a relatively stiff plastic retaining member which supports the bag, and which in turn is supported by a belt or other means on the patient, thereby to prevent leakage of the waste material onto the skin of the patient surrounding the stoma or even thereafter. In addition to the odor which would result from such leakage, irritation of the skin of the patient surrounding the stoma is extremely likely under circumstances of leakage, and in ileostomy cases where the discharge is from the small intestine digestive liquids are still very active and can actually digest the skin of the patient if they come in contact therewith. Accordingly, there has been developed a soft, oleaginous seal containing karaya which, when used in combination with a retainer on an ostomy bag, not only effects a liquid-tight seal between the interior of the bag and the stoma, but also appears to assist greatly in the prevention and even healing of irritated skin arising out of the use of other forms of seals. Karaya seals of the type referred to are disclosed in U.S. Pat. No. 3,302,647. Karaya seals of the type disclosed in said patent, when used in combination with an ostomy bag, sometimes under the pressure exerted in holding the bag in position, have exhibited tendencies to lose their shape by flattening out with a consequent impairment in their sealing capabilities and also with a reduction in the useful life of the seal. Furthermore, when karaya seals are stored for any period of time, the seals near the bottom of a stack of seals will occasionally become deformed due to the weight of the overlying material. In such cases the deformed seals may be unusable, or at least unsuitable.

BRIEF SUMMARY OF THE INVENTION

According to the present invention, a karaya seal which may be made in accordance with the teachings of said U.S. Pat. No. 3,302,647 is provided with a substantially nonstretched backing. In its simple version, the backing may take the form of a sheet of flexible plastic material such as polyethylene. The backing, although made of flexible material, aids the karaya ring in holding its shape and thus inhibits the spreading or other deformation of the seal during actual use and also during transit and storage. In its preferred form, the back of the karaya ring is formed with a groove or other engaging portion, again covered by the film of flexible plastic material, with the groove forming an interference fit with a complementary receiving portion on the retainer forming a part of an ostomy bag. In accordance with the invention, the karaya ring may be formed by providing a mold having a contoured surface (to form the above-mentioned groove in the ring). A sheet of polyethylene is laid in the mold and heated somewhat so as to conform to the shape thereof, a second sheet of polyethylene is laid over the first, and a backing plate provided to close the upper face of the mold. Karaya ring forming material is then injected into the mold between the two sheets of plastic material. Before removal from the mold, and in some cases before filling the form, the two sheets are heat sealed together around the inner and outer peripheries of the karaya ring, with the face sheet forming the aforementioned backing material and with the second sheet forming a removable covering for the front face of the seal, that is the face that is pressed against the skin of the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view showing an ostomy bag in place on the body of a patient; FIG. 2 is an enlarged view of the upper portion of FIG. 1; FIG. 3 is a sectional view taken along line 3—3 of FIG. 2; FIG. 4 is a vertical sectional through a circular mold in which the karaya ring is formed; FIG. 5 is a view like FIG. 4 but including the upper portion of the mold; FIG. 6 is a sectional view showing a portion of the karaya ring encased between two sheets of flexible plastic material and illustrating a step in the process of forming the same; FIG. 7 is an elevational view of the karaya ring and flexible sheets after the same have been withdrawn from the mold; FIG. 8 is a view like FIG. 7 showing the peel off feature of the invention; and FIG. 9 is a sectional view through a portion of an ostomy bag including the karaya ring of the present invention, showing the same in place on the body of a patient.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings, there is shown in FIGS. 1 and 2 an ostomy bag including a retainer 10 provided with a pair of integral projections 11 to which a belt 12 may be secured for holding the ostomy appliance in place on the body of a patient. The retainer 10 is provided with an annular seal-receiving portion 13 for receiving and retaining an annular seal of oleaginous material, preferably including karaya, said seal being indicated as 14. The seal is backed by a flexible plastic sheet 15 of substantially non-stretchable material, such as polyethylene, and covers the back portion of the seal including an engaging portion 16 formed in the seal, which engaging portion is complementary to the seal-receiving portion 13 to provide therebetween an interference fit for holding the sealing ring in place on the retaining member. An ostomy bag 17 of flexible soft plastic material is secured to the retainer 10 and is provided with a suitable opening surrounding the circular opening formed in the retainer.

From the foregoing it can be seen that the ostomy appliance, including the bag 17 and attached retainer 10, can be supplied with karaya seals simply by pressing the
seal into position on the retainer so that the engaging portion 16 of the seal engages the seal-receiving portion 13 on the retainer. This "interference fit" helps hold the karaya seal in position while the patient is wearing the appliance. When so positioned, and even though the backing sheet 15 is of soft plastic film material, the seal is capable of maintaining its shape and hence its sealing ability under conditions of stress arising from use and heat. If desired, adhesive may be used to hold the karaya seal even more firmly to the retainer.

The preferred method of forming the seal of the present invention comprises an annular mold 20 having an annular cavity 21 formed therein. The mold is made of stiff material, for example metal, and into the mold there is laid a sheet of flexible plastic material 15 which has a portion 15a bridging the center of the mold. For this purpose the mold or the sheet may be heated to enable the latter more closely to conform to the shape of the mold. A covering sheet 22 of similar plastic material is then laid over the mold 20 and a backing plate 23 placed thereon to complete the mold. A plastic tab 30 is heat-sealed to covering sheet 22. Sheet 15 and covering sheet 22 are heat-sealed together at 28 and 29 as shown in FIG. 6 after sheet 15 has been formed to conform to the annular cavity 21 in the mold 20. Oleaginous material to form the sealing ring is then injected by perforating the covering sheet 22 or through opening 24 formed therein, by means of an injector nozzle 25. As clearly seen from the drawings, the karaya seal material when injected conforms to the shape of the mold and is completely enclosed between the covering sheet 22 and the sheet 15, where it sets and becomes firm. The effect of heat sealing is akin to die cutting the material as the excess portion can readily be removed, including the bridging portion 15a and the portion 27 which extends beyond the outer extremity of the karaya ring. Since the heat sealing operation acts something like die cutting, the annular remaining portion of the covering sheet 22 may be stripped off as illustrated in FIG. 8 simply by pulling on the free end 31 of the tab 30. This latter operation, of course, occurs after the seal has been pressed or glued into position on the retainer, as illustrated in FIG. 3, and before applying the same to the skin of the patient as illustrated in FIG. 9.

I claim:

1. A seal adapted to be used in combination with an ostomy bag secured to a retainer with said retainer having an opening therein to surround the stoma of an ostomy patient, there being an annular contoured locating element formed around the periphery of said opening, said seal comprising a ring of gelatinous material, said ring having an annular portion on one face thereof shaped complementary to said annular contoured locating element, a sheet of flexible substantially non-stretchable material covering said face of said ring, a second sheet of flexible substantially non-stretchable material covering the other face of said ring, said sheets being heat sealed together around the inner and outer peripheries of said ring, and a pull tab having one end free and having its other end heat sealed to said second sheet whereby said second sheet may be removed from the ring by pulling on said tab.

2. A seal adapted to be used in combination with an ostomy bag secured to a retainer with said retainer having an opening therein to surround the stoma of an ostomy patient, there being an annular rib formed around the periphery of said opening, said seal comprising a ring of gelatinous material containing karaya, said ring having an annular groove on one face thereof complementary to said annular rib, a sheet of flexible substantially non-stretchable material covering said face of said ring, a second sheet of flexible substantially non-stretchable material covering the other face of said ring, said sheets being heat sealed together around the inner and outer peripheries of said ring, and a pull tab having one end free and having its other end heat sealed to said second sheet whereby said second sheet may be removed from the ring by pulling on said tab.

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