United States Patent [19]

Marsan

[11] **3,713,445**

[45] **Jan. 30, 1973**

[54] **SEALING RING OR PAD FOR A POST-SURGICAL DRAINAGE POUCH**

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[21] Appl. No.: **110,234**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 795,138, Jan. 24, 1969, abandoned.

[52] **U.S. Cl.** **128/283**

[51] **Int. Cl.** **A61f 5/44**

[58] **Field of Search** 128/283, 290, 296, 268

[56] **References Cited**

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Primary Examiner—Charles F. Rosenbaum
Attorney—John F. McCanna

[57] **ABSTRACT**

The invention is characterized by the provision of a sealing ring or pad for use with a post-surgical drainage pouch such as in colostomy and ileostomy appliances, comprising a unitary structure having open cell foam filled with gelatinous sealing material whereby to provide a sealing ring or pad having effective sealing properties over a longer period of use.

2 Claims, 5 Drawing Figures

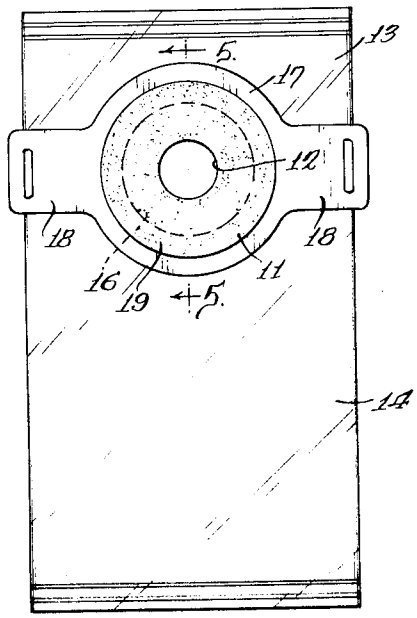


Fig. 1.

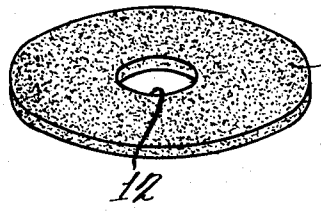


Fig. 2.

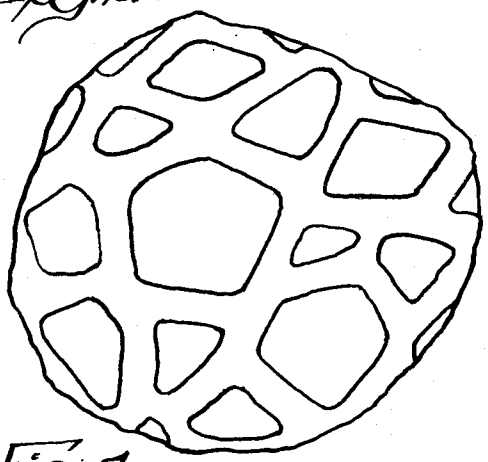


Fig. 3.

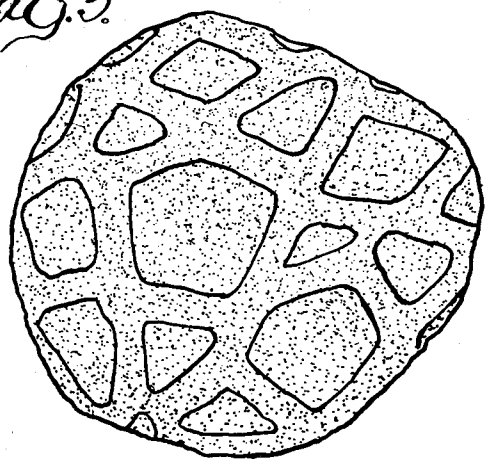


Fig. 4.

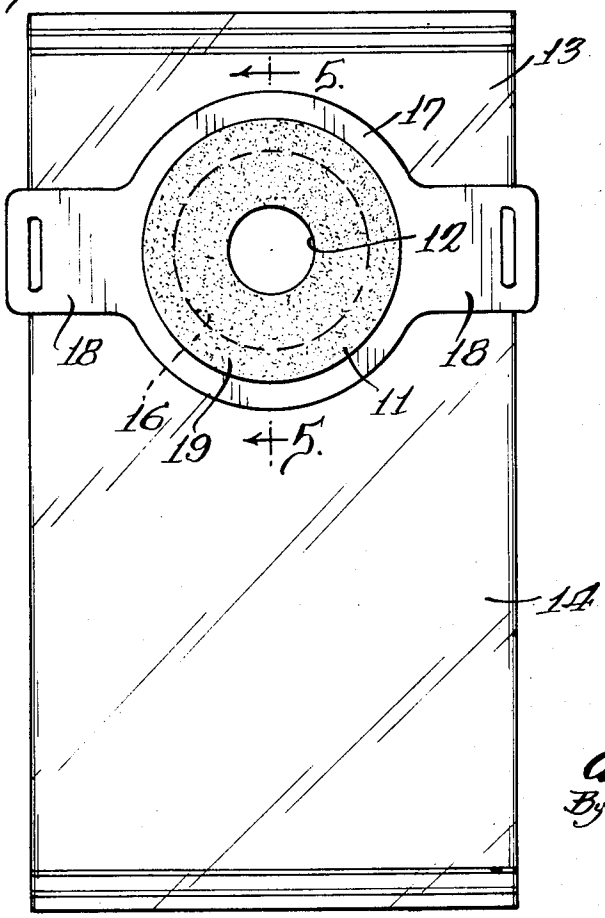
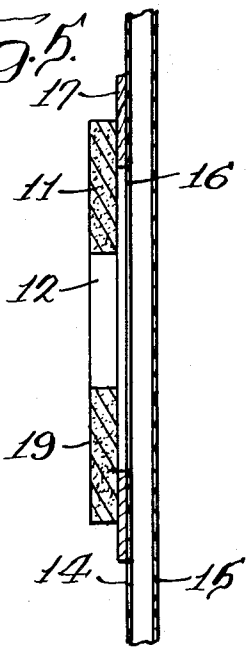


Fig. 5.



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SEALING RING OR PAD FOR A POST-SURGICAL DRAINAGE POUCH

This invention relates to surgical devices of the kind disclosed in my U.S. Pat. No. 3,302,647 issued Feb. 7, 1967; and is a continuation-in-part of my application Ser. No. 795,138 filed Jan. 24, 1969 now abandoned.

The invention deals with the problem of providing a protective covering for the patient's skin around a surgical opening. It also involves the problem of providing an effective seal between the patient's body and a pouch or other receptacle into which the stoma discharges. Protection is needed because the discharge from the stoma contains hydrochloric acid and enzymes which aid in the digestion process. When the discharge comes in contact with the skin it causes tissue breakdown resulting in open sores and a weeping excoriated condition. Under these conditions the patient suffers extreme discomfort and mental anguish. Also, repeated application of adhesives and the like to seal the drainage pouch to the skin of the stoma area are very irritating. Heretofore, karaya powder alone and in gelatinous mixes have been used as a healing means and as a sealing means in colostomy, ileostomy, and generally similar conditions, but these have not been altogether satisfactory. I have observed that after such prior sealing rings have been exposed to the action of bowel discharge there is a softening and breaking off of the karaya gel around the stoma opening due to the absorbing of bowel discharge liquids. Also, as the gel absorbs liquids it expands and loses its cohesive strength. I have termed this sloughing action. The sloughing starts at the stoma opening and gradually works its way to the outer circumference of the karaya gel ring. At this time the ring collapses and leakage occurs, soiling the patient's clothing and causing other discomfort. The sloughing action varies with each patient. It is contingent upon the nature of the discharge. The more fluid that contacts the karaya gel ring the sooner it is impaired and the karaya sloughs off. The more paste-like the fecal mass is, the longer the karaya gel ring resists the sloughing action. Another objection to such karaya gel rings is what I have termed a cold flow action. When the gel ring is not on a patient a change in the original shape of the ring occurs due to the action of gravity and the weight of the ring.

The main object of my invention is, therefore, to provide an improved surgical drainage pouch. I have aimed to provide a sealing ring structure which will overcome the objections to prior rings. More particularly, my invention provides a more effective and longer lasting surgical sealing ring. To this end my invention contemplates a number of species and methods of manufacture, described hereinafter. Each of these includes an open cell foam structure having incorporated in and filling the open cells and retained therein a material having skin healing and protective properties. As an illustration, a preferred species consists of a ring structure of so-called open cell foam and skin healing and protective material incorporated in and filling the open cells of said ring structure. I prefer to use a gelatinous material and thus obtain with the cellular structure a substantially permanently shaped ring structure which serves to increase the strength of the gel mass as liquid is absorbed. The strength of the ring structure is increased due to the fact that the surface area of the cellular structure is relatively large and

is not soluble in the liquids that are absorbed by the gelatinous material. Also, this large surface area of the open cell ring structure provides a large surface area for adhesion of the gelatinous material. Another advantage is that the relative ability of the open cell structure together with its gelatinous material to absorb or hold a liquid thereby enables it to reduce or slow down the rate of sloughing. Also, due to the structural characteristics of the sealing ring its original shape is retained throughout its use as it is insoluble in the liquids absorbed.

Another object is to provide a number of species of the invention, as described hereinafter.

Another object is to provide methods of manufacturing the surgical ring bodies of my invention, as described hereinafter.

Other objects and attendant advantages will be better understood from the descriptions herein when considered in connection with the accompanying drawings, in which

FIG. 1 is a perspective view of a surgical sealing ring embodying my invention;

FIG. 2 is a microscopic enlargement somewhat diagrammatic of any selected spot on the surface of the ring body showing the open air cells prior to incorporating into such cells the gelatinous material;

FIG. 3 is a similar view illustrating diagrammatically the air cells filled with the gelatinous material;

FIG. 4 is a side view of a conventional pouch to which a sealing ring of my invention is applied, looking at the side which seals against the skin of the patient; and

FIG. 5 is an enlarged sectional view taken on the section line 5—5 of FIG. 4.

The drawings illustrate a preferred embodiment described more in detail hereinafter. The essence of my invention is in a surgical sealing ring or pad designated generally by the reference numeral 11, shown in FIG. 1. The ring shape is preferred because it covers the entire area surrounding a stoma opening. Outside and inside diameters of the ring vary within a considerable range and are selected according to the needs of the patient. The opening 12 is for passage of discharge from the stoma into a pouch or receptacle. In FIGS. 4 and 5 I have shown the ring attached to a pouch 13. The pouch may be of any suitable kind, that shown being a conventional bag having inner and outer walls 14 and 15. The inner wall has a stoma opening 16. Except for this opening the present receptacle 13 is sealed so as to retain the discharge from the stoma. The ring 11 may be attached to the pouch by its own adhesive structure or by any suitable means. As shown, this is a belt-connecting strip 17 which has diagrammatically opposite ends 18 for connecting to a belt (not shown) which encircles the patient's waist. This strip 17 is glued or otherwise sealed to the face of the inner pouch wall 14. The ring 11 is glued or otherwise sealed to the face of the strip 17, as shown in FIG. 5. When the device is worn, the face 19 of the ring 11 is held against the skin of the patient, covering the area surrounding the stoma. It is the sealing and protecting functions of the sealing ring against the patient's skin, as embodied in the ring body 11, that concerns this invention.

My invention contemplates the use of any of various materials for the ring or pad body structure such, for

example, as synthetic open cell foam of polyurethane plastic, poly vinyls, polyethylene, and other plastics when processed to make an open air cell structure. The desired characteristics are a structure which may be cut or otherwise formed to a ring shape or pad suitable to cover the skin area to be protected, a labyrinth of open air cells in said structure to receive and retain the gelatinous or other sealing and healing material, the structure being non-soluble in water or liquids discharged from the stoma, and the structure retaining its shape and retarding the sloughing action abovementioned, and having flexibility to conform with the body of the patient and body movements. I prefer a synthetic, polyurethane plastic foam for the ring body. This has the characteristics contemplated by my invention, particularly a large volume of interconnected open air cells or cavities. This recticulated structure provides a relatively large volume of cavities and relatively large surface area of the interconnecting strands forming the boundaries of the open cells or cavities. This structure provides a relatively large contiguous surface area for adhesion of the gelatinous material and for retaining this material in the ring structure. Therefore, this structure provides resistance to sloughing action and extends the length of time the sealing structure can be used on a patient. This open cell foam structure distinguishes from prior closed cell foam rings or pads which have no openings into the interior of the cells and can not receive or retain within and throughout the foam structure a gelatinous material such as contemplated by my invention.

One method of manufacture is to mix the sealing ingredients such as karaya powder and glycerine (or other materials as noted below) to form a gel and while example, mixture is still liquid the foam ring is immersed therein and the liquid is absorbed in the open cells of the foam. The process can be aided by using compression rollers, or vacuum, or centrifugal force. Also, water, alcohol, and other solvents can be used to reduce the viscosity of the mixture and aid in absorption into the open cells of the foam ring. When compression rollers are used, the rollers would be immersed in the liquid mixture. The rollers are spaced so that the nip of the rollers is considerably less than the thickness of the foam. For example, with the sheet foam in sizes about 0.0625 to 0.250 inch thick the nip would be approximately 0.010 to 0.020 inch. The rollers would be suitably mounted and driven by power outside the liquid container. The foam rings would be fed edgewise into the nip between the rotating rollers which compress the foam, expelling the air from the cells. As the foam passes through the nip of the rollers it expands to its original size and the cells fill with the liquid mixture. The foam rings are then removed from the liquid and the excess liquid is allowed to drip back into the tank. The ring is now placed on a tray and allowed to gel at room temperature or the gelling rate can be accelerated by placing the ring in an oven at moderate heat. The resilient character of the foam body makes it particularly well adapted to compression for expelling the air and for absorbing a maximum quantity of the gelatinous mixture. When the product is completed it has substantially the same external appearance as a sealing ring composed only of a gelatinous mixture. However, as described above, the product of my invention has internally a permanent body structure, the foam.

Another species of the invention involves a method of incorporating dry karaya powder or the like into the structure. A wetting agent is applied to the open cells of the ring structure by brushing, spraying, dipping, roller action, or suitable means. While the ring structure is still wet we apply as much dry karaya powder as will adhere in the cells of the foam, the karaya forming its own adhesive in its contact with the wet ring structure. The ring structure now has a dry crust of karaya that is not tacky. This permits ease of handling. To be used on the patient, this ring may be first dipped in water or glycerine to make the surface tacky and form a gel. In this species, pores or cells of the foam retain the karaya. This ring structure so processed will absorb more than its own weight in water without disintegrating; it reduces the sloughing action; it is long lasting; and it reduces cost.

Another species is for a surgical sealing ring in which the ring structure is cut to shape from foam and dry karaya powder is incorporated into the open cells or pores of the body. This may be done by rotating or tumbling the ring in a sealed container containing dry karaya powder. The outside surface of said structure is then coated with glycerine, water, or the like. This may be done by dipping the ring into a bath of glycerine and immediately removing the ring. The ring so processed may be hung from a wire hook through the stoma opening, to drain and dry. With this process a gel will be formed on the outer surface of the ring body which is soft and tacky. The resulting product provides an effective seal having long lasting properties.

In a further species I have aimed to reduce the cost of manufacturing the product by providing lower cost materials to make a usable gel. My invention contemplates such materials as starches from corn, potato, wheat, rice, tapioca, amioca, sago, and the like. Gelatinous material may be made from these products and combined effectively in a ring structure in keeping with the teachings of my invention.

In a further species I have aimed to reduce the cost of the product by increasing the volume of the gelatinous material without increasing the weight of the karaya or the glycerine content. This is attained by whipping air or other gasses into the mixture; the entrapped air bubbles expand the volume of the gel. For example, I have used sodium bicarbonate (about 10 per cent of the weight of the karaya) which releases a carbon dioxide gas having very fine bubbles. The gas bubbles become entrapped in the viscous karaya-glycerine mixture which then turns to gel. This mixture combined with the ring structure according to my invention enables reduction of approximately one-third of the conventional karaya and glycerine gel of comparable ring size; consequently, approximately three surgical sealing rings of a given size may be produced by my invention as compared with prior practice.

It will be understood from the foregoing that my invention contemplates various species and that modifications may be made in the practice of my invention without departing from the spirit and scope of the invention expressed in the appended claims, in which

I claim:

1. A sealing ring or pad specifically for the problems incident to sealing between a drainage pouch and the skin around the stoma opening in the abdomen of a patient in ostomy cases, comprising a permanently shaped open cell foam body having the properties of flexibility, elasticity, compressibility and non-solubility in water, said body having a stoma-receiving opening, a labyrinth of interconnecting cell cavities throughout the body providing relatively large surface areas in the body, said flexibility permitting the body to conform to the shape of the abdomen around the stoma area, said elasticity permitting said stoma opening in the body to be stretched and relaxed to create a snug fit against the stoma, and said compressibility permitting a tight seal

effect between the body and the abdomen around the stoma area, a material having skin healing and protective properties incorporated in and filling said interconnecting cell cavities, said relatively large surface areas serving to effect adhesion of said material to the body and to substantially retain said material within the body, said structure providing more effective sealing action over a longer period of use in preventing passage of fecal stoma discharge through the sealing body and contacting the patient's skin.

2. A sealing ring or pad for ostomy cases as set forth in claim 1, in which the skin healing material has a starch base, whereby to lower the cost of manufacture.

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