

[54] **STARCH SEAL AND APPLIANCE FOR OSTOMY**[76] Inventor: **Arthur E. Marsan**, 640 Washington Boulevard, Oak Park, Ill. 60302[22] Filed: **Nov. 17, 1970**[21] Appl. No.: **90,368****Related U.S. Application Data**

[63] Continuation-in-part of Ser. No. 795,138, Jan. 24, 1969, abandoned, and a continuation-in-part of Ser. No. 110,234, Jan. 27, 1971.

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

[58] Field of Search 128/283

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[57]

ABSTRACT

This invention provides an improved sealing means for application to patients who have had surgery for colostomy or ileostomy, and the like, for effecting a seal between the patient's skin around the stoma and a pouch or container which receives the fecal discharge from the stoma. The sealing means is characterized by its starch content, which has qualities providing new and beneficial functions and advantages distinguishing from the prior art. The sealing means is made by methods which I have termed the liquid pouring type and the dough type.

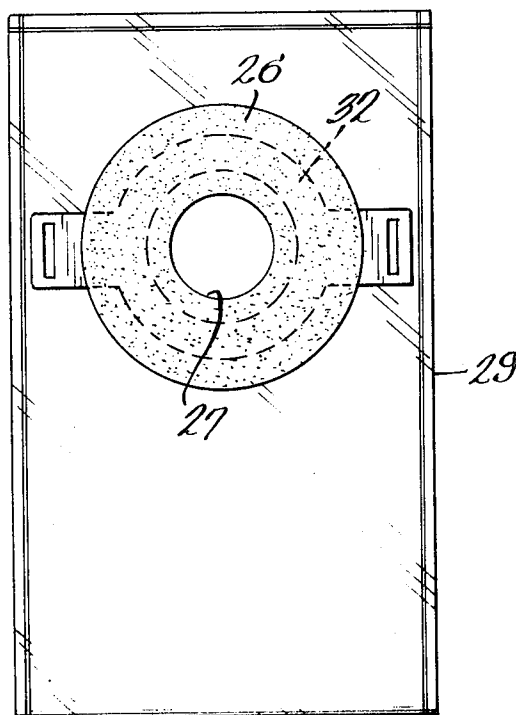
3 Claims, 22 Drawing Figures

Fig. 1.

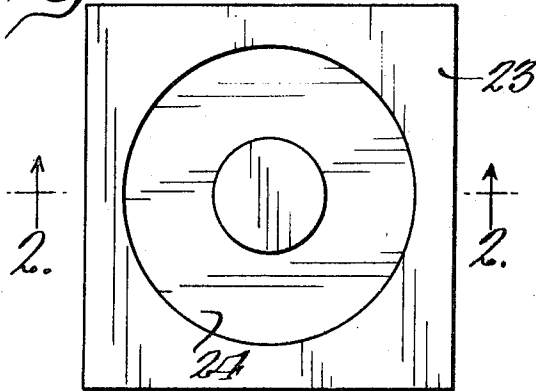


Fig. 2.

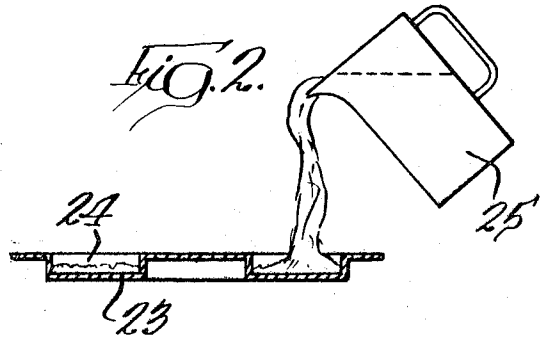


Fig. 3.

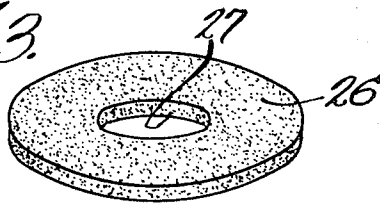


Fig. 4.

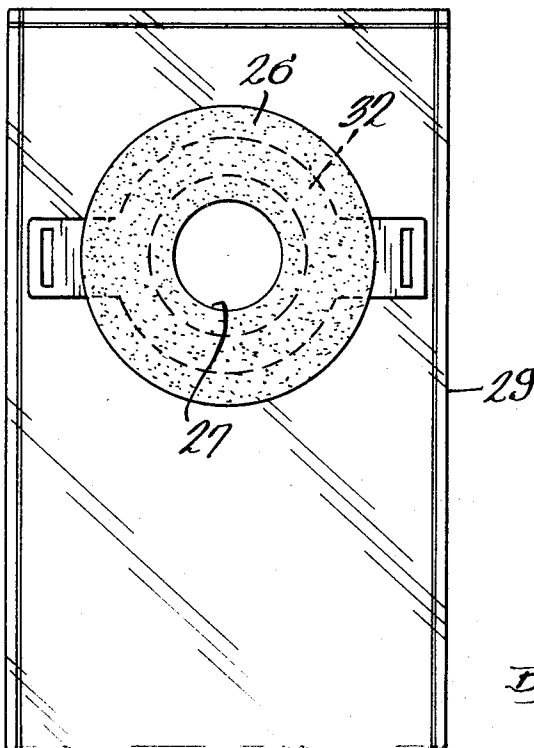
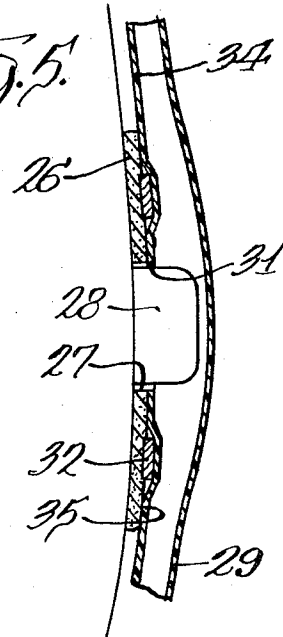


Fig. 5.



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FIG. 6.

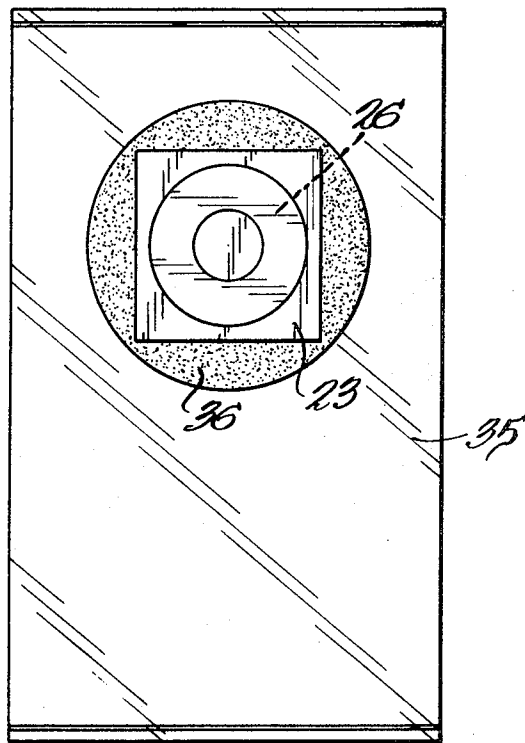


FIG. 8. 9 →

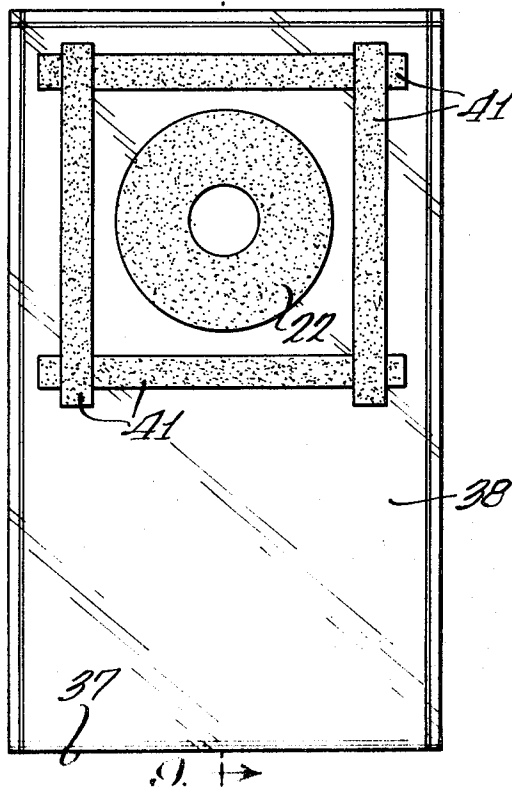


FIG. 7.

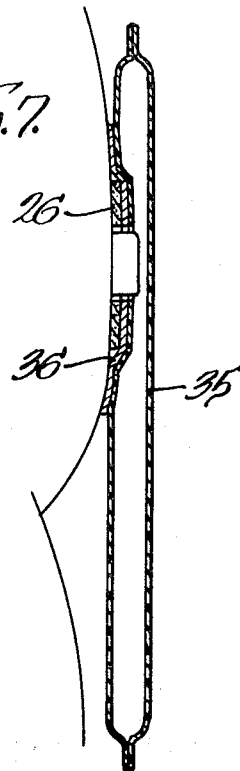
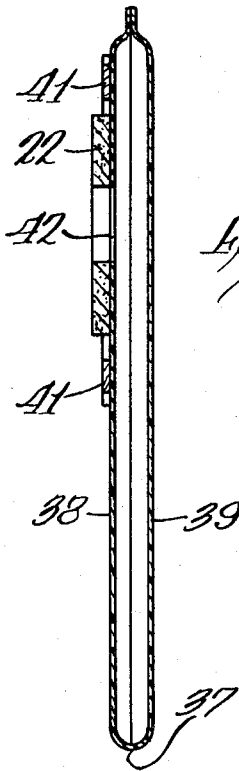
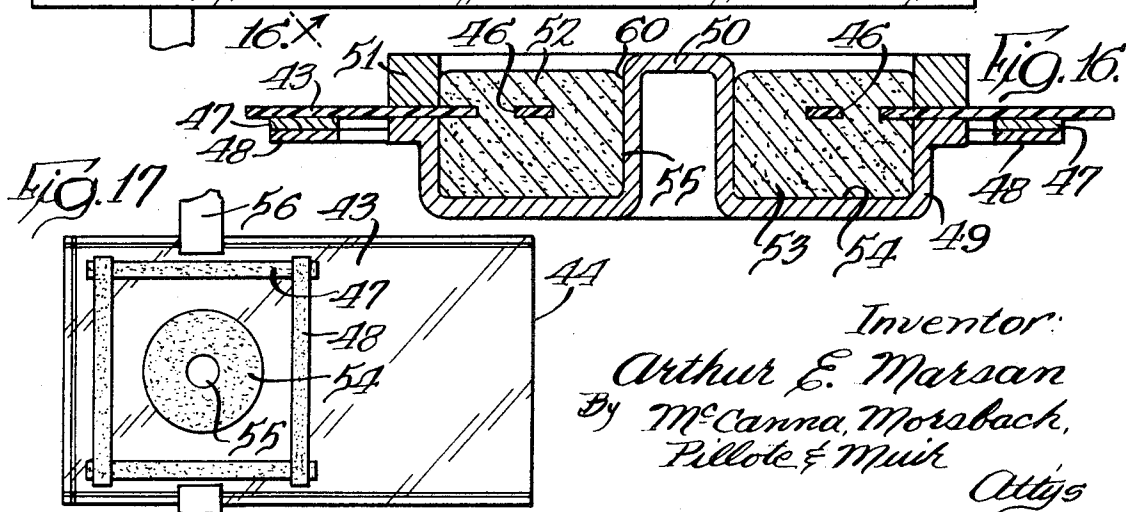
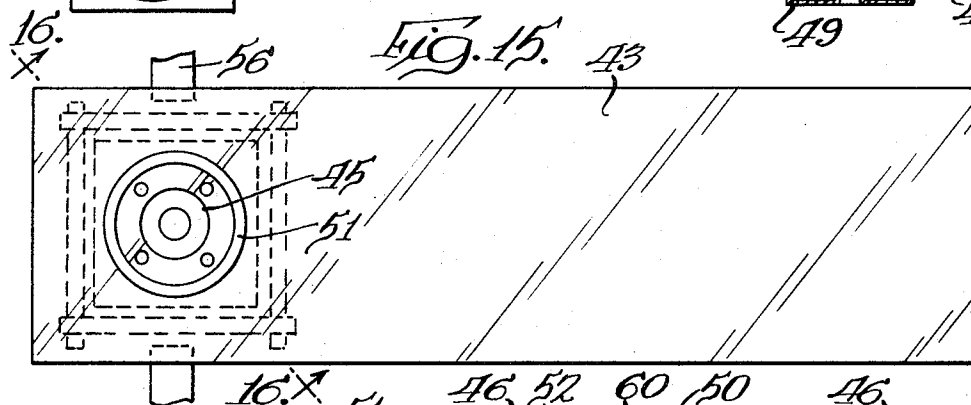
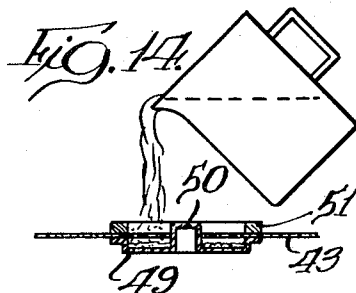
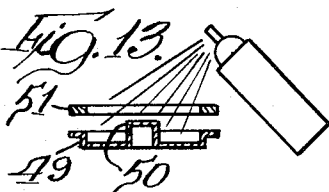
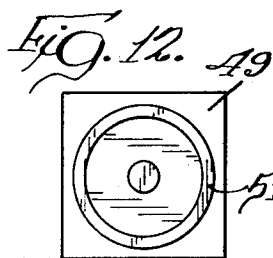
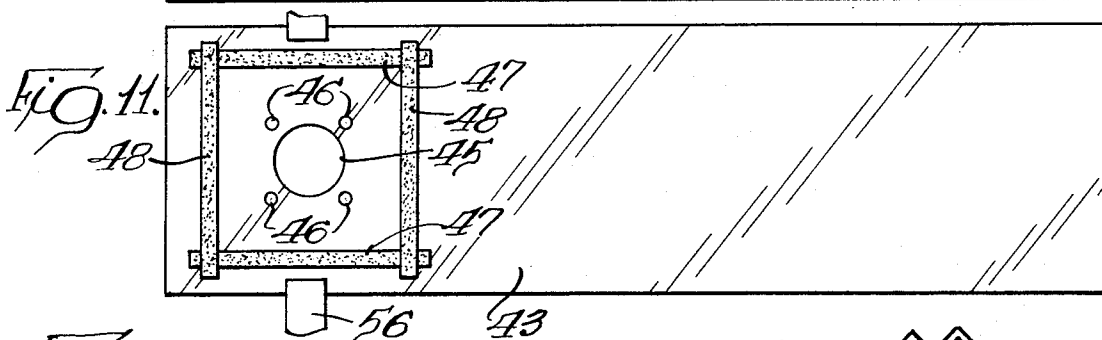
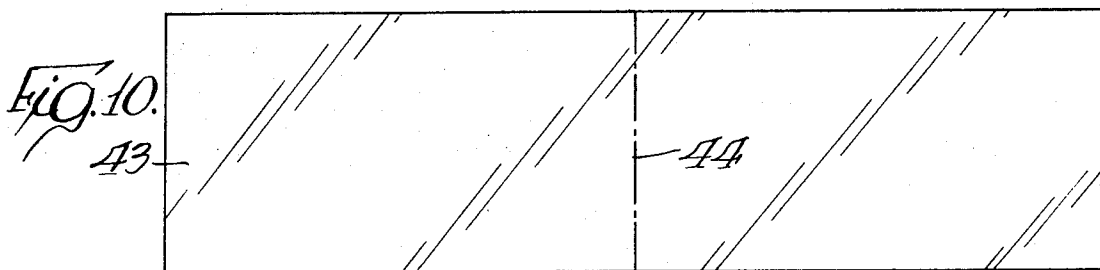


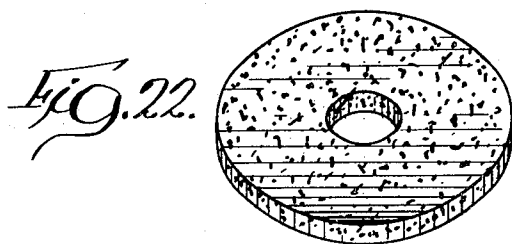
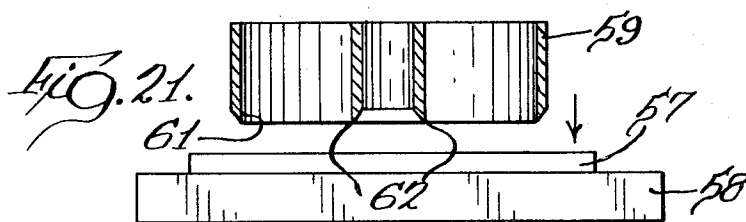
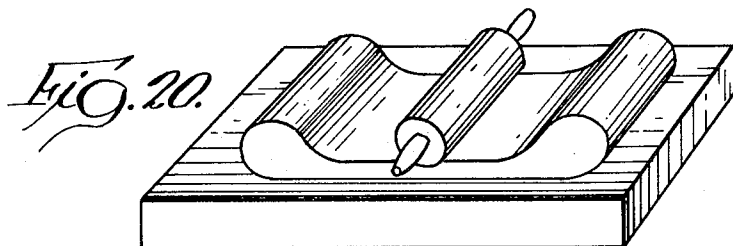
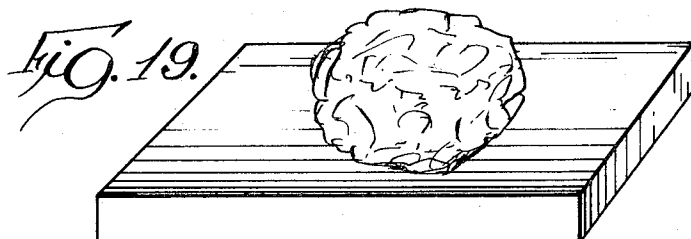
FIG. 9.



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STARCH SEAL AND APPLIANCE FOR OSTOMY

This application is a continuation-in-part of my application for patent Ser. No. 795,138, filed Jan. 24, 1969 now abandoned and continuation-in-part of Ser. No. 110,234, filed Jan. 27, 1971.

This invention relates to the so-called "ostomy" field, to the post-operative care of patients having had colostomy or ileostomy surgery, and the like. It relates to appliances used in the care of the patient after the surgical operation, particularly to providing a seal between the patient's skin surrounding the stoma and an appliance such as a pouch or bag for receiving the discharge from the stoma. In recent years the practice in this field has been toward making these appliances disposable after each use. This involves many problems, such as the cost of producing the disposable appliances and components, the sanitary conditions incident to use of such appliances, the effectiveness of sealing the area surrounding the stoma, and the ability to satisfactorily meet the requirements of the many different conditions and variations in individual patients. My invention deals primarily with the sealing functions of such appliances.

The primary object of my invention is to provide an ostomy seal superior to prior seals. By this I mean sealing means of novel composition which in comparison is more satisfactory than the seals of the prior art. The advantages and new results inherent in this invention involve a considerable saving in cost of manufacture, together with novel functioning which surpasses the prior seals and makes for greater satisfaction to the ultimate user. In explanation, may I point out that many of the seals on the market have been characterized by the use of karaya gum or powder. Regardless of the individual formulas of such seals, the cost of production is relatively high because of the high cost of karaya. Also, such prior seals have inherent disadvantages which are overcome with the present invention.

My invention aims, therefore, to provide a new seal and a new technique in the making of ostomy seals, whereby to better serve the needs of patients. To this end my invention provides a seal structure which is essentially composed of starch ingredients. The composition of such starch seals may vary considerably under the contemplation of my invention, as will be described hereinafter.

Broadly, my invention contemplates the provision of a starch seal generally of ring form which seats against the body of the patient around the stoma and provides a seal between the patient's skin and a pouch or bag which receives the discharge from the stoma. The starch seal is distinctive and has many desirable qualities, among which are:

1. It will possess the necessary surface tact to adhere to the skin and to the pouch on its opposite side without the necessity of applying any other adhesive to either surface;
2. It has the internal strength to permit handling and manipulating without excessive distortion that goes beyond the elastic limit;
3. It has the internal strength to withstand compression applied to it by the pouch gasket and belt (if such are used) when in use on the patient;
4. It has a relatively high rate of absorbency;
5. The ingredients are non-toxic and do not cause skin irritation. It can be removed from the skin using

water as the solvent instead of painful skin-irritating organic solvents;

6. The starch seals can be made to be clear to make for better observation of the skin and the bond between the seal and the skin;

7. The white characteristics of the starch permits ready visual detection of fecal leakage between the seal and the skin;

8. It has no inherent objectionable odors;

9. It is readily available in large quantities worldwide; and

10. The cost of starches at the present time has been stable and is from \$0.07 to \$0.25 a pound as against the continually rising cost of karaya which is about \$0.80 to \$0.90 a pound. This can result in a considerable saving.

More particularly, the starch seal of my invention overcomes the many objections to the karaya gel seals commonly used in the present practice. For example, karaya gum is the dried exudation from trees of the *Sterculia nurens* genus, a native tree of India, affecting its availability and cost; karaya being a natural product of exuded resin from a tree, it acts as a food for bacterial growth and may become contaminated; the properties of karaya are not always uniform; karaya gum being a natural product subject to exposure to the atmosphere is apt to contain impurities such as sand, dirt, and bark, and is available in many grades of purity; karaya gel seals have caused skin irritation or allergy; karaya has an objectionable odor of acetic acid; karaya gels have a tendency to soften and flow due to body heat, thereby reducing the effective life of the seal; such seals have a tendency to exhibit so-called "cold flow" while the seal is in storage and prior to its use on a patient, and distortions from such cold flow prevent effective sealing around the stoma; karaya gel seals are opaque, brown, tan or amber in color, and do not permit visual examination of the patient's skin when on the patient, thus making it impossible for the nurse or patient to determine visually whether there is leakage of the discharge or any skin excoriation; and karaya is a polysaccharide and cannot be used by body tissue unless it is first reduced to a monosaccharide by enzyme action; the cost of karaya is relatively high; the cost of commercially producing karaya gel seals is relatively high.

Another object of my invention is to provide a wide range of ostomy seals using starch ingredients and characterized by what I term gel type and dough type seals.

Another object of my invention is the provision of starch formulas for ostomy seals eliminating the use of water and the necessity for boiling.

Another object is to incorporate a starch type seal as a component of an ostomy appliance.

Another object is a modification in which a starch sealing ring serves as the support for the pouch, thus eliminating gaskets and the like.

Another object is a modification in which the starch sealing ring is molded to both sides of the pouch film.

My invention is not limited to the formulas herein described, but contemplates broadly the use of starch in the production of ostomy seals. The starch or the starch ingredients supplant the more expensive gums and other materials used in the current practice and

have qualities serving desirable advantages, as described herein.

Other objects and attendant advantages will be better understood by reference to the following description when considered in connection with the accompanying drawings, in which:

FIG. 1 is a face view of a mold for making a starch gel seal according to my invention;

FIG. 2 is a cross-section through the mold taken on the section line 2—2 of FIG. 1 and showing the step of pouring a liquid starch mixture into the mold;

FIG. 3 is a perspective view of a starch gel seal ring after it has gelled, removed from the mold;

FIG. 4 is a face view of a pouch to which a starch gel seal ring is applied, illustrating one example of use;

FIG. 5 is a diagrammatic vertical sectional view illustrating the application to a human body, of a pouch and seal ring shown in FIG. 4;

FIG. 6 is a face view of a pouch, illustrating another form of use;

FIG. 7 is a diagrammatic vertical section view illustrating the application to a human body, of the pouch and seal ring shown in FIG. 6;

FIG. 8 is a face view of a pouch, illustrating another modification in the use of my invention;

FIG. 9 is a section lengthwise of the pouch taken on the section line 9—9 of FIG. 8;

FIGS. 10 to 17 inclusive illustrate steps in the manufacture of another embodiment of starch gel seal and pouch according to my invention, individually described as follows;

FIG. 10 shows a sheet of film a first step in making this form of my invention;

FIG. 11 shows several steps applied to the pouch of FIG. 10;

FIG. 12 is a face view of a two-part mold for making this embodiment of the starch seal ring;

FIG. 13 shows the application of a release coating to the mold of FIG. 12;

FIG. 14 illustrates pouring the gel mixture into the lower part of the mold of FIG. 13;

FIG. 15 shows the film sheet of FIG. 10 inverted and placed on the lower mold with the upper ring part of the mold on top of the film in co-relation with the lower mold part;

FIG. 16 is an enlarged section taken on the section line 16—16 of FIG. 15;

FIG. 17 shows the completed appliance with the film of FIG. 10 folded over and heat sealed at the side and top edges to complete the pouch;

FIGS. 18 to 22 inclusive illustrate steps in making a starch sealing ring of the dough type above mentioned, individually described as follows:

FIG. 18 illustrates mixing the ingredients to make a dough;

FIG. 19 illustrates kneading the dough;

FIG. 20 illustrates calendering the dough to a thin sheet;

FIG. 21 illustrates die-cutting the sheet of dough to the form of a sealing member; and

FIG. 22 is a perspective view of the resulting sealing member.

First, I will describe the gel type of starch seal illustrated in FIGS. 1 to 17 inclusive. Referring now to FIGS. 1 to 5:

One of my early formulas, this invention brings to this art a sealing ring body of starch having the qualities and advantages, among others, such as listed above. The starch may be of different varieties and sources suitable for producing a seal for the purposes of the invention. To this end the formulas and the steps for making the starch seal may be varied, as illustrated hereinafter. Also, the seal may be applied commercially in different ways, for example, as a single unit to be used directly by the patient or sold to manufacturers of ostomy appliances, or incorporated as a component in an appliance which is a complete article of manufacture. As stated above, the starch seal is of such relatively low cost to manufacture that it is particularly suitable and economical for disposal after each use.

One of my early formulas for the gel type seal is as follows:

1 ounce corn starch, 8 ounces water, 4 ounces corn syrup, and 2 ounces glycerine. These ingredients are all boiled together and then poured into molds to cool and gel. In FIGS. 1 and 2 I have shown an individual mold designated generally by 23 of suitable plastic material having an open top ring-shaped cavity 24. The liquid mixture is poured into the mold cavity from a suitable container 25 under suitable control. The mold is pre-coated with a release agent such as a lecithin solution. Without the release agent the gel adheres to the inside of the mold and cannot be removed without tearing or distorting the gel ring. The resultant seal ring 26 is shown in FIG. 3. This is preferably flat, clear, gel body having a central opening 27 adapted to receive the stoma 28 when positioned on a patient as shown in FIG. 5. This sealing ring surrounds the stoma opening and on one side seals against the skin of the patient. The peripheral shape of the ring body may vary. Also, the size of the central opening 27 may vary according to the size of the stoma. As shown in FIGS. 4 and 5 the sealing ring is used with a pouch or bag 29 which is closed except for an opening 31 to receive the stoma. The pouch may be one of this type made by several different manufacturers, generally, the material of pouch is preferably a water proof plastic film. A gasket 32 of suitable material and form is sealed by contact adhesion against the outer side of the ring body 26. The gasket has diametrically opposite slotted extensions 33 for attachment of a suitable belt (not shown in these figures). The inner wall 34 of the pouch seals against the outer side 35 of the sealing ring body. The belt aids in holding the pouch and the sealing ring in position on the patient. Generally, the seal of my invention is first removed from the mold and applied to the patient. Next, the pouch is applied to the outer exposed surface of the seal and encompasses the stoma. The gasket is part of the pouch assembly. A belt attached to the slotted ends of the gasket is then wrapped around the patient, securing the assembly on the patient as shown in FIG. 5.

Another formula I have used in making the gel type seal:

1 ounce corn starch, 4 ounces water, 4 ounces corn syrup, 2 ounces glycerine, and 4 ounces water. The ingredients are blended as follows: The 4 ounces of water, glycerine and corn syrup are blended together to form a clear liquid. This mixture is then heated in an open pan to reach a vigorous boil, a temperature of

about 190° F. The starch and 4 ounces of water are then mixed cold and form a milky slurry. This milky starch slurry is then poured gradually into the boiling syrup solution while stirring rapidly. Boiling is continued for four minutes or until the solution is clear and thick but still pourable. The solution is removed from the heat and poured into molds such as shown in FIG. 2 that have been pre-coated with a release agent as described. The filled molds are then placed in a drying oven at 125°F. for about 12 hours. This accelerates the removal of excess water from the gel and increases the strength of the gel so that it can be easily removed from the molds without tearing. In the boiling process, heat can be reduced to a simmer, about 180°F. but it requires approximately 10 minutes to obtain the same viscosity as with the vigorous boil. Boiling of the mixture beyond the time it takes to provide a clear solution helps to remove excess water from the gel. Starch gels can also be made using high production continuous starch steam cookers. The corn syrup provides flexibility to the starch gel and is an aid to surface tack. The corn syrup contains dextrose which is a monosaccharide and requires no additional enzyme to make it usable by human tissue as a food. Badly excoriated skin tissue could absorb and utilize this dextrose as a food to help rebuild the skin tissue.

The gel of my invention does not exhibit cold flow which is a major problem where ostomy appliances of the prior art were held over long periods of storage on dealer's shelves. The word "tack" used as a quality of the starch gel seal refers to the sticking or holding power of the gel to the skin of the patient. The degree of tack must be such that the gel ring body will hold to the skin of the patient without any other means than its own even when the patient pursues activities.

Another formula of the starch gel type: one-half ounce Q.E.D. 5069 thin boiling starch, 4 ounces water, 4 ounces corn syrup 1033, 2 ounces glycerine, and 100,000 units Mystatin (antibiotic). The Mystatin combats bacterial action.

Another formula of this type: one-half ounce Q.E.D. 5069 thin boiling starch, 4 ounces water, 4 ounces corn syrup 1033, 1 ounce glycerine, 0.1 gram sodium hydroxide, and 0.3 grams Hexachlorophene. This results in a clear gel ranging in color from yellow to dark amber. Corn syrup contains dextrose and when dextrose and hydroxide such as sodium react with it, a characteristic yellow color is observed. Eliminating the sodium hydroxide would result in a white opaque gel. Hexachlorophene acts as an anti-fungus agent.

Another formula is similar to the preceding formula but substitutes one ounce of sucrose for the 4 ounces of corn syrup. This will result in a clear colorless gel.

Another formula is based on the preceding formula but adds one-half ounce of B919 SNOW FLAKE pregelatinized instant stabilizer starch (which ingredient will be referred to in the next described formula). The addition of the B919 starch produces a seal with greater water absorption ability.

Further with reference to the gel type seal, I have found that a desired starch gel may be produced by the elimination of water from the formulation, and also the necessity for boiling the mixture. To this end I use a starch known as B919 SNOW FLAKE instant stabilizer starch. It is a pregelatinized, cross-linked, waxy starch.

This starch has the capability of hydrating to a high viscosity consistency with minimum solids. It has better capabilities of absorbing water. This formula is as follows: 5 grams B919 starch, 15 grams glycerol. Mix and then pour into a mold as in FIG. 2 and place in an oven for an hour at about 125°F. I have also used this formula with 15 grams of ethylene glycol instead of glycerol. In another formula with 5 grams of B919 starch I have used 15 grams of propylene glycol. This mixture was heated in an oven for about 1 hour at 290°F. Another formula using 5 grams of 5069 Q.E.D. starch and 15 grams of glycerol was mixed, poured into a mold and heated for 1 hour at 290°F. All these formulas produced a satisfactory gel.

FIGS. 6 to 9 illustrate the embodiment of a starch gel seal in several forms used with appliance units which are complete articles of manufacture. In each form the mold such as shown in FIGS. 1 and 2 remains on the seal when the seal becomes a part of the appliance. Preferably, the mold is not removed from the seal until just before use on the patient. Thus the gel seal is protected from contamination. Referring to FIGS. 6 and 7, an adhesive patch 36 having pressure sensitive adhesive on both sides is first applied to the inner face of the pouch. The sealing ring 26 is then applied at one side to the face of the adhesive patch 36 as shown in FIG. 7. At this stage the mold 23 is still on the sealing ring as shown in FIG. 6 and serves as a protective covering for the ring. This mold is removed just prior to application of the appliance to the patient as shown in FIG. 7. The outside diameter of the ring 26 is smaller than the outside diameter or shape of the patch 36 so that the latter provides for additional adhesive surface and increased bonding or sealing between the pouch and the skin of the patient. The patch aids in the effectiveness of sealing the assembled appliance to the skin of the patient because the patch is an effective water insoluble adhesive. In this case no belt is used because of the larger sealing surface provided by the seal 26 and the patch 36. FIGS. 6 and 7 illustrate pouches of a type currently manufactured by several different concerns. They generally consist of a pouch of plastic film and a pressure sensitive adhesive patch which is used to secure the pouch to the patient. The adhesive patch is usually coated on both sides with the adhesive. The adhesive is usually of a water proof type. The side of this patch that contacts the patient's skin is generally protected with a release paper until application to the patient.

FIGS. 8 and 9 illustrate another embodiment of my invention in which the starch sealing ring is applied as a component to a factory assembly including a pouch, generally similar to FIGS. 6 and 7. In this form I prefer to combine the sealing ring with the pouch in the course of making and assembling the appliance as an article of manufacture. Since the starch gel is extremely tacky when hot and adheres very aggressively to most surfaces, I apply the pouch film to the starch gel before the gel cools in the mold. The sheet of film will be large enough to be folded at the middle 37, providing inner and outer side walls 38 and 39, respectively. The inner wall 38 is placed on top of the hot starch gel in the mold and is bonded to the molded gel ring when it cools. The cooled and gelled sealing ring together with its mold and the pouch film which is bonded thereto, are a unit of assembly. The mold remains on the seal and acts as a

protective cover until application to the patient. The film sheet will then be folded at 37 as above mentioned and heat sealed at the side and top edges, completing the pouch. Additional adhesive means can be applied to the inner face of the film wall 38 surrounding the starch gel ring, such as strips of tape 41 having pressure sensitive adhesive on both sides. These strips of adhesive are less expensive than a die-cut patch such as 36 shown in FIGS. 6 and 7. The outer side of these strips 41 is normally covered with a release paper. When the patient is ready to use this appliance this release paper is removed from the adhesive strips. Then the mold is removed from the gel ring. At this point a stoma opening 42 is formed in the inner wall 38 of the pouch with a blade or scissors. This pouch is now ready to be applied to the patient. The gel ring 22 and the tapes 41 will be pressed against the skin around the stoma making sealing engagement with the skin.

In FIGS. 10 to 17 I have shown another embodiment of my invention as a completely assembled factory production appliance. These figures as well as the others above described, are somewhat diagrammatic and intended merely to illustrate. FIG. 10 shows a sheet of water-proof plastic film 43 large enough for both sides of a pouch when it is folded in half at 44. A stoma opening 45 and a plurality of small openings 46 are provided in the film adjacent to one end, as shown in FIG. 11. This figure also shows the application of adhesive means around the stoma opening and the starch gel sealing ring, presently to be described. This means may be in the form of tapes 47 and 48 having pressure sensitive adhesive on both sides. FIG. 12 is an open face view of a disposable mold 49 and a re-usable ring 51 used in molding the starch gel ring body to the pouch film, as will presently be described. The mold part 49 is similar to 23 above described except that the mold part 49 has a central extension 50 to mold an extended stoma opening in the starch body. FIG. 13 illustrates application of a release agent to both the mold parts 49 and 51 by spraying, dipping or any suitable method. Next, the mold part 49 is filled with liquid starch gel, similar to the description referring to FIG. 2. The film 43 is then inverted and placed on top of the mold part 49 with the stoma opening 45 concentric with this mold part, as shown in FIG. 15. This figure also shows the ring-shaped mold part 51 in position on top of the film sheet concentric with the mold part 49. In this relationship additional liquid starch gel is poured into the ring mold, filling the two-part mold, as shown in FIG. 16. It will be here noted that the resulting starch gel seal body is molded to both sides of the film sheet with a portion 52 at one side of said sheet and a portion 53 at the opposite side. The film is now encased by starch liquid gel on both sides and through openings 46. The liquid gel will now be allowed to cool and solidify. The mold ring 51 will now be removed. This mold member is reusable for additional moldings. The film sheet will now be folded at the middle 44 and the sides and end will be heat sealed, completing the appliance. To use the appliance on a patient it is necessary to first remove the disposable mold part 49 to expose the tacky gel surface 54 which is to be sealed against the skin of the patient. In this form a release paper may be applied to cover the tape strips 47-48. In use the appliance will be positioned on the patient with the stoma extending through

the opening 55 (FIG. 16) formed by the molding operation, and the pouch will be pressed in toward the patient's abdomen to adhere the starch gel seal body against the patient's skin around the stoma opening in the abdomen. Also, the additional sealing means 47-48 will be pressed in to effect further adhesion, if needed. A belt 56 heat sealed to the pouch can be wrapped around the patient as additional securing means. The adhesive strips and the belt are additional means of securing the pouch to the patient and are used in an optional manner if needed. If the belt is not desired it can be cut off at the edges of the pouch. If the adhesive strips are not to be used, then the release paper is not removed to expose the adhesive surface of the tapes. It will be noted that the construction of the modification is unique in that it places the pouch film within the mass of the seal body by reason of the fact that the seal body is molded or cast to both sides of the pouch film. In use on the patient, the water content of the fecal discharge that contacts the starch seal is absorbed at a relatively high rate. This occurs to a greater or lesser degree depending on the composition of the starch seal member and the water in the feces. The plastic pouch film is a water insoluble member and retards the solvent action on the starch seal, thereby increasing the effective time that the pouch can be used on the patient. This reduces patient care cost. As the fecal discharge leaves the stoma it contacts the exposed surface of the seal that is within the pouch. The liquid content of the discharge tends to gradually wear away the seal. This water wearing action is retarded by the water-insoluble film encased in the seal. For example, referring to FIG. 16, surface 54 is the direct seal between the patient's skin and the pouch and the object of this seal is to protect the skin surrounding the stoma. The fecal discharge first contacts the starch seal surface at location 60 surrounding the stoma. As the fecal discharge drops into the pouch it tends to dissolve the starch seal body. By encasing the film within the mass of the starch seal body, the rate of dissolving action is retarded. The unique construction of this pouch assembly provides effective protection of the patient's skin for a longer period of time. Also, this construction provides sufficient rigidity to eliminate the need for a rigid gasket member such as used in FIG. 4.

Another phase of my invention involves the making of a seal by using a starch mixture worked into a dough as distinguished from a liquid mixture to be poured into a mold as described above. One of the advantages in using a starch dough is that I am able to use a larger percentage of starch. This is beneficial both to the manufacturer and the patient, as will presently be noted. For example, in one formula I use the proportions of about 60 percent starch and 40 percent glycerine mixed together by any suitable means. In FIG. 18 this mixing is by hand, using a mortar and pestle. In commercial quantity production suitable mixing equipment would be used. After mixing the mixture will be kneaded or compounded to produce uniformity of texture and consistency. These qualities of the dough are desirable, since otherwise the dough might contain relatively hard lumps which in the finished seal could do damage to the stoma. The kneading may be done by hand for small batches as illustrated in FIG. 19, or by production equipment known as a rubber compound

mill using a plurality of rollers. The next step is to roll the dough to sheet form of the desired thickness. This may be done by hand using a roller such as the well known rolling pin as illustrated in FIG. 20, or by machine for quantity production using a calendering machine. Calendering to about one-eighth inch thickness will serve the purpose. Next, the sheet of dough will be die-cut into sealing members having a stoma-receiving opening of the desired size and a surrounding body, usually of ring shape. This step illustrated in FIG. 21, the numeral 57 indicating a sheet of dough, 58 a flat table or support for the dough sheet, and 59 a die for cutting the dough. In this case the peripheral edge 61 cuts the peripheral shape and the interior edge 62 cuts the stoma-receiving opening. After the sheet has been cut into seals, the excess dough or trimmings may be added to the next batch to be processed. The ring seals can then be placed in an oven for about 1 hour at 125°-150°F. to complete the fusion of the mixture. This temperature range may be varied upward to shorten the baking time. After removal of the ring seals from the oven they are allowed to cool to room temperature. The seals are then ready for use on a patient. A finished seal is shown in FIG. 22. Inasmuch as in this embodiment of my invention a larger percentage of starch ingredients is used in the seal, it has the advantage of being able to absorb larger quantities of liquid discharge. This serves to promote longer use on the patient before the need to replace. Also, the material cost of such a sealing unit is reduced. This dough mixture may be varied by changing the percentages of the ingredients, and incorporating extenders, modifiers, release agents, fillers, preservative, medication agents, and healing agents. As an illustration of the use of modifying agents, a satisfactory seal can be obtained in the following manner: Use 8 grams of Mor-Rex, a hydrolyzed cereal solid, and 12 grams of glycerol. These are mixed to a clear solution. Add to this mixture 0.1 gram vegetable type coloring. Then add 0.1 gram Hexachlorophene, an anti-bacterial chemical. The above ingredients are in a liquid state. Next add and mix in 10 grams of B919 SNOW FLAKE instant stabilizer starch. This mixture will become dough-like and will require kneading to make it uniform. From here on the processing will be similar to the above description regarding the dough seal. In further reference to the variations in the dough mixture, the Mor-Rex is a powder cereal solid and acts in several ways, namely, it increases the solids and is soluble in both glycerine and water and acts as a filler and extender, and it reduces cost of materials as it is about one-half the cost of B919 starch. Also, it slows down the rate of curing, which is an advantage in the manufacturing process in that it permits larger batches to be weighed, mixed, and processed at one time, and it per-

mits reuse of die-cut trimmings or scrap dough because this can be blended back into a new batch. As to Hexachlorophene in this formula, this is an anti-fungus chemical agent. The reason for coloring would be for identification and aesthetic value. The B919 starch is advantageous in that it provides cohesiveness in the dough mixture, it acts as the absorbant when in use on the patient, it provides the adhesive quality in use on the patient, and it provides the elasticity and sealability in use on the patient. In the dough seal the glycerol is the solvent agent and plasticizer.

The starch dough mixtures also are suitable for molding into sealing ring shapes utilizing high production plastic compression, injection or extrusion machines.

In general, referring to all embodiments of my invention, starches are used to have the quality of liquid absorption from the discharge from the patient at a relatively high rate so as to prevent such discharge from making contact with the skin. Such contact would impair the effectiveness of the seal and result in skin irritation and tissue breakdown causing skin sores and discomfort to the patient. Prior seals with a slower rate of absorbency will permit stoma discharge to contact the skin by capillary action between the seal and the skin.

The terms "ring" and "ring shape" are used in the specification and claims as meaning any seal body that surrounds the stoma without limitation as to the peripheral shape of the seal body. The terms "dough" and "dough-like" are used as meaning any starch mixture that would require pressure to form it as compared with a liquid starch mixture which can be poured.

It is believed that the foregoing conveys a clear description of my invention and it will be understood that in practice many changes and variations may be made in the ingredients and in the methods without departing from the spirit and scope of the invention as expressed in the following claims, in which:

I claim:

1. In an appliance for ostomy conditions and the like, a pouch for receiving the fecal discharge, the pouch having a stoma-receiving opening through which the stoma discharges into the pouch, and sealing means for effecting a seal between the pouch and the patient's skin in an area around the stoma-receiving opening, the sealing means comprising a gel body, the mass of said body composed essentially of a low cost gelling agent, namely, a starch gel having properties of surface tact, cohesive internal strength throughout providing elasticity, flexibility and compressibility, and relatively high rate of fluid absorbency of the fecal discharge.

2. In an appliance as set forth in claim 1, the sealing means having the quality of transparency.

3. In an appliance as set forth in claim 1, the sealing means having the quality of translucency.

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