United States Patent

Marsan

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[54] POST-SURGICAL DRAINAGE POUCH

[72] Inventor: **Arthur E. Marsan,** 1265 Bellaire Avenue, Denver, Colo. 80220

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[52] **U.S. Cl.** **128/283,** 264/135

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

[58] **Field of Search** 128/283, 294, 295; 264/135, 264/267, 273

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

[57] **ABSTRACT**

This invention is characterized by a drainage pouch having a bag of plastic film and a gelatinous sealing member for providing a seal between the pouch and the stoma of a patient when the pouch is in use on the patient, and novel construction whereby a single pouch and its sealing member (as an article of manufacture) serves a wide range of stoma sizes, and also whereby the film bag entirely encloses the sealing member before use and serves as the wrapper for the pouch. The invention is further characterized by a method of making the pouch wherein the sealing member is molded to shape and is in operative position within the bag and in which a wall of the film serves as a lining for the mold.

20 Claims, 32 Drawing Figures

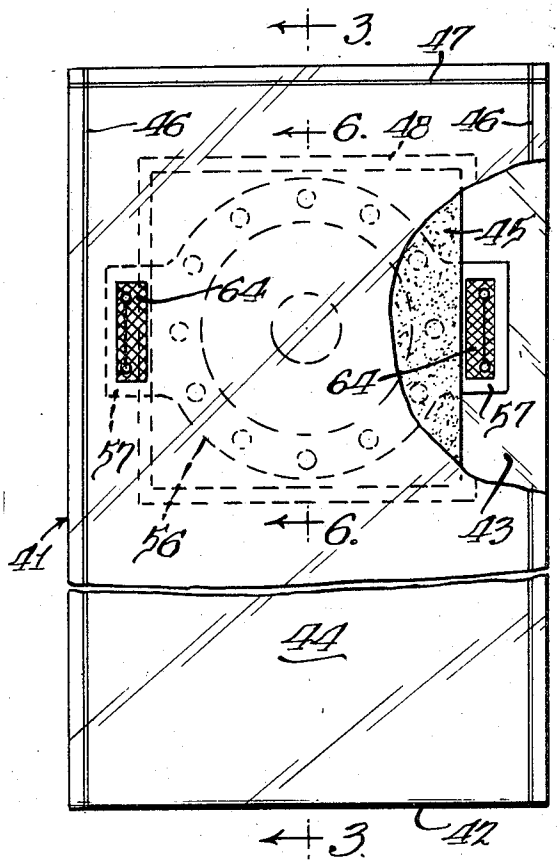


Fig. 1.

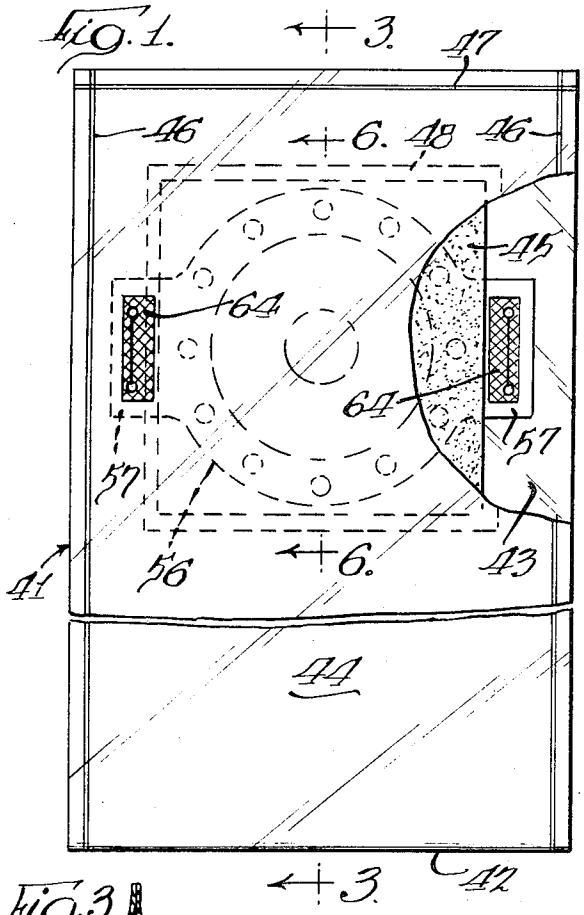


Fig. 2.

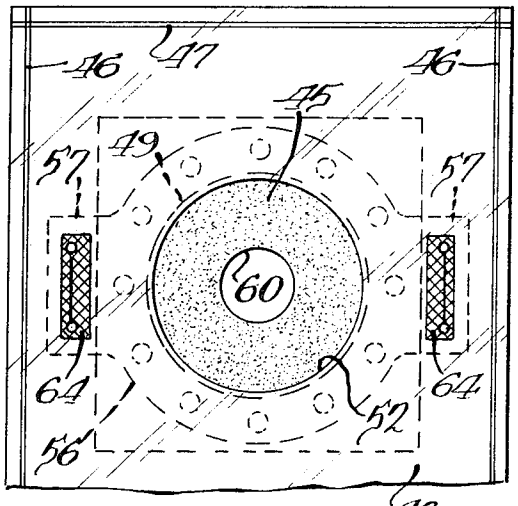


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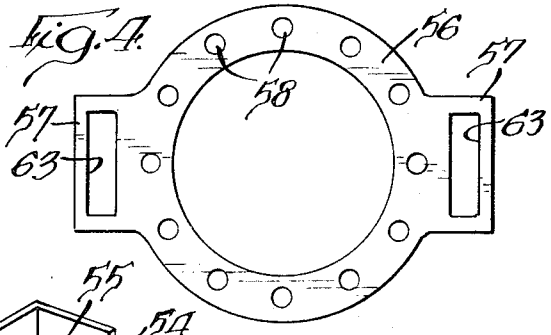


Fig. 3.

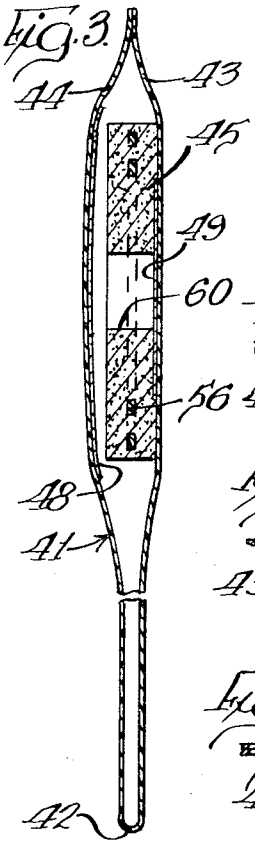


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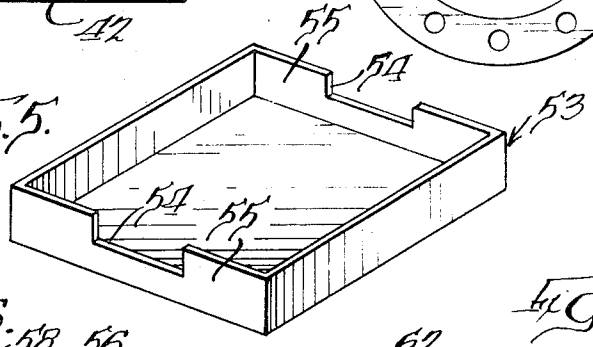


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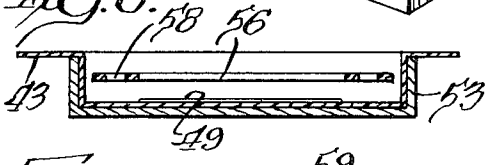


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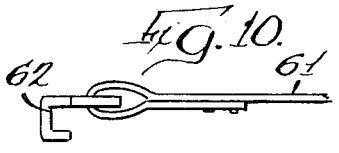


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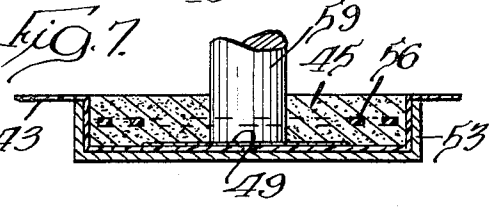


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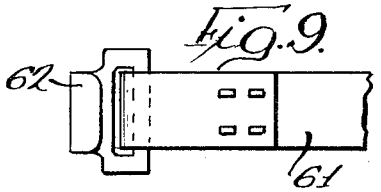
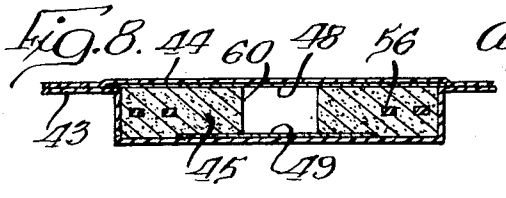


Fig. 8.



Inventor:
Arthur E. Marsan
By McCanna, Morsbach, Pillote & Muir
Attys

Fig. 11.

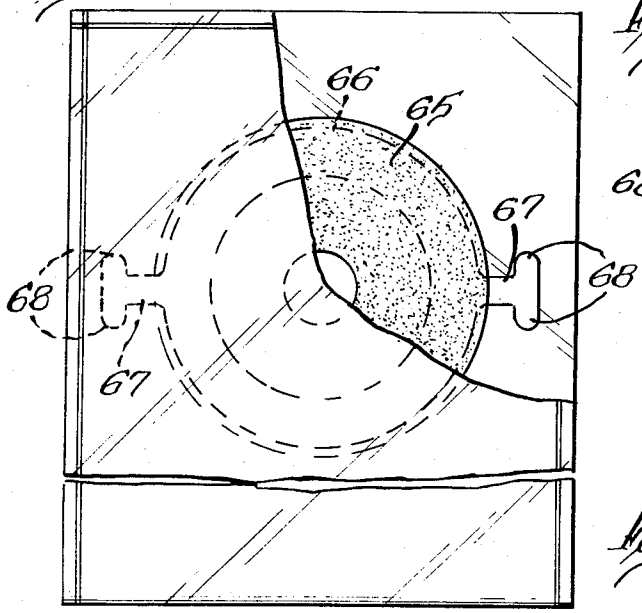


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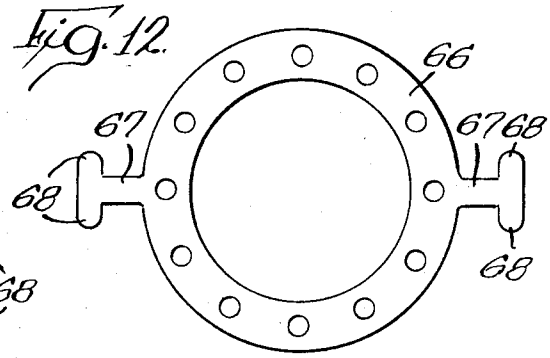


Fig. 14.



Fig. 13.

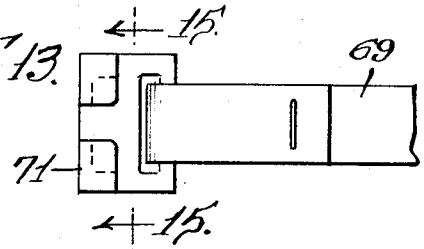


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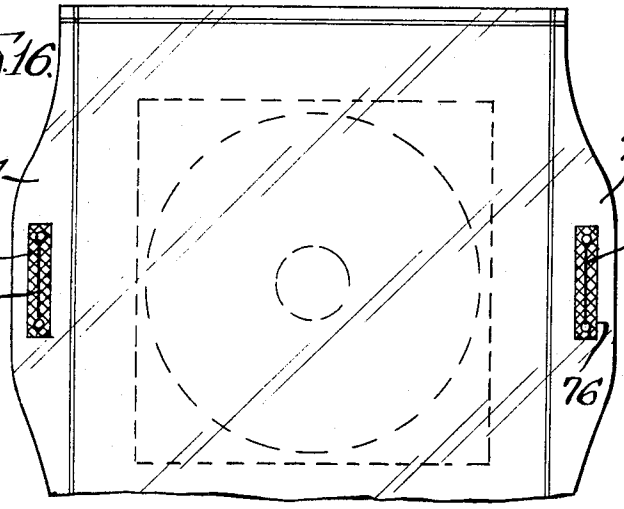


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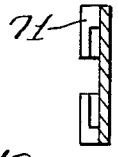
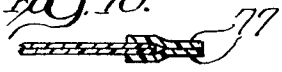


Fig. 18.



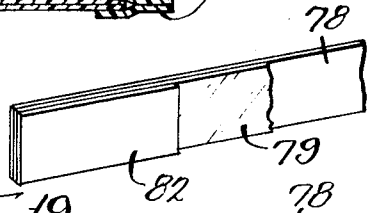


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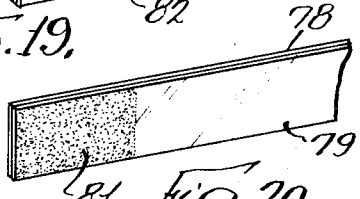
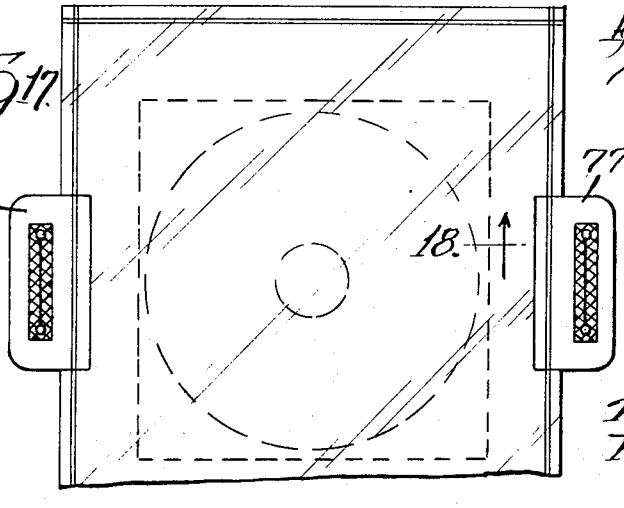


Fig. 20.

Fig. 17.



Inventor:
Arthur E. Marsan
By
McCanna, Morsbach,
Pillote & Muir
Atty's

Fig. 21.

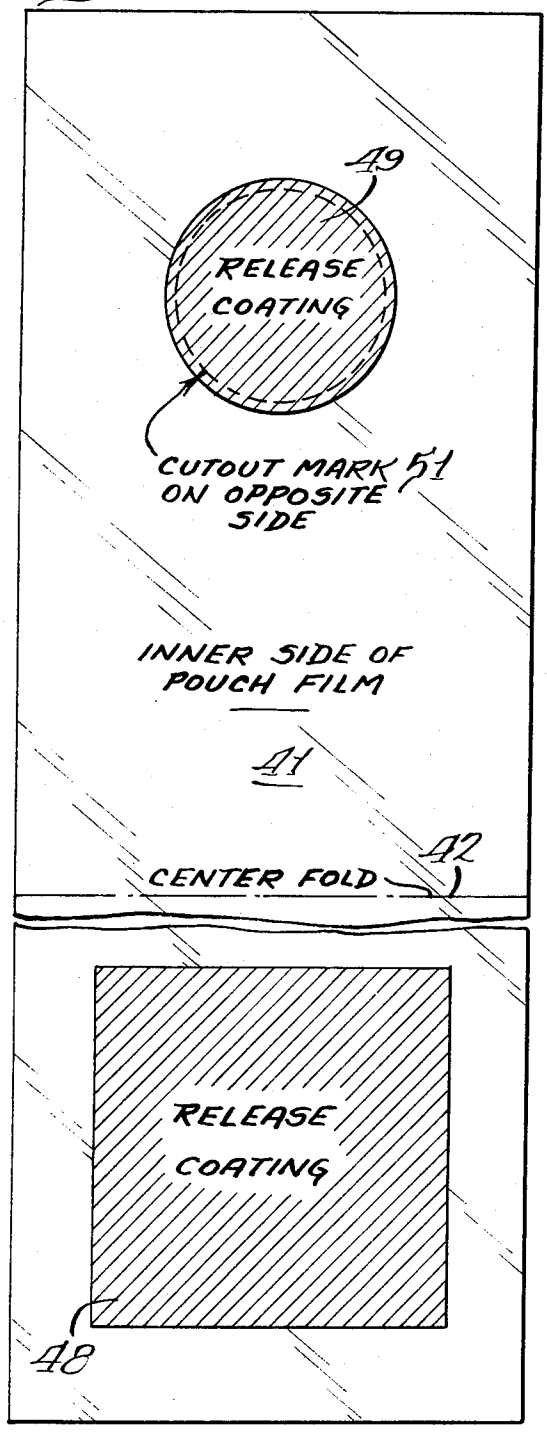


Fig. 22.

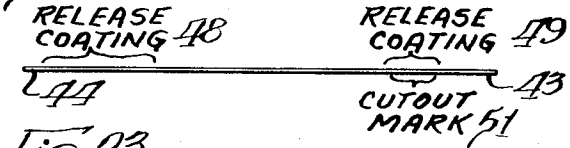


Fig. 23. POSITION MOLD UNDER FILM



Fig. 24. PRESS FILM INTO MOLD

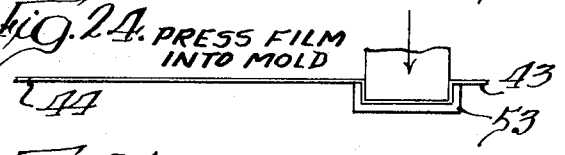


Fig. 25 INSERT GASKET 56 INTO MOLD

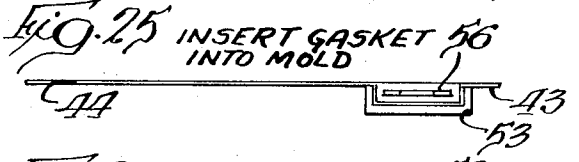


Fig. 26. INSERT CORE

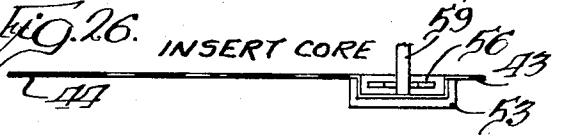


Fig. 27. FILL CAVITY WITH GEL

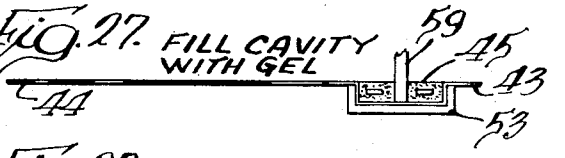
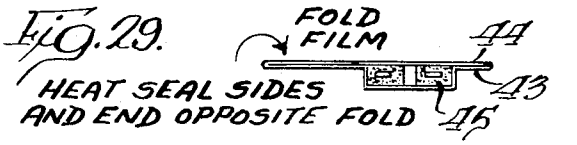


Fig. 28. GEL SETS REMOVE CORE AND MOLD



Fig. 29.



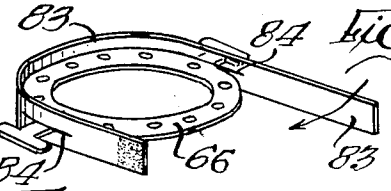
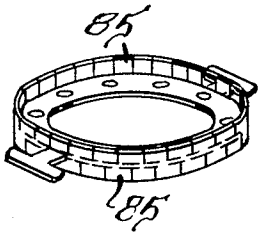


Fig. 30.

Fig. 31.



Fig. 32.



Inventor:
Arthur E. Marsan
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POST-SURGICAL DRAINAGE POUCH

This invention relates to drainage pouches for use in post-surgery in draining the discharge from the stoma of a patient. The invention is applicable generally in the medical field and particularly in colostomy, cecostomy, ileostomy, ureterostomy, ileal conduit, vesicotomy, fistula drainage, and other cases where there is discharge from a patient for collection into a pouch which is disposable after use.

Heretofore it has been the practice in this art to make drainage pouches with the bag of the pouch made of sheet film materials such as polyethylene, vinylidene chloride and laminates of the two films. In view of the different sizes of the stomas on different patients it is customary to provide as a separate article of manufacture, a separate pouch for each stoma size, sometimes as many as five to 10 different sizes. It is necessary, therefore, for the hospitals and other places where these pouches are used, to carry a large inventory of pouches to take care of the different needs of the patients. This becomes costly and troublesome in maintaining a sufficient stock of the various sizes.

One of the objects of my invention is to eliminate the need for large inventories of pouches by providing a pouch as a single article of manufacture constructed in such manner that the single pouch may be used for a wide range of stoma sizes. This makes unnecessary the manufacture of numerous sizes of pouches and also eliminates troubles incident to the selection and use of such many sizes of pouches. This object is attained particularly by a novel construction in which the sealing member through which the stoma passes into the pouch has what I have termed a universal stoma opening, as will be described hereinafter.

Another object of my invention is to provide a drainage pouch of novel construction, particularly with reference to the sealing member and its coaction with the film bag of the pouch, whereby the sealing member is completely enclosed within the bag. Thus the bag becomes the outer wrapper for the product and, in effect, a single package which does not require extraneous parts but is in itself a complete article of manufacture and can be handled and marketed as such. Furthermore, I have provided a pouch which is a water tight package in which the interior is kept clean and sterile.

Another object of my invention is to provide an improved drainage pouch with the view to economy in cost of product, considering the merits of the product. In this connection I have provided a sealing member having characteristics and functions new in this art. As will be described more in detail hereinafter, the sealing member is composed of gelatinous material having the properties of being adhesive, elastic, and resilient, and also having relatively low water solubility. In furtherence thereof, my invention contemplates a sealing member the composition of which is starch granules, together with other ingredients described hereinafter. This produces what I term a foamed gel. In the preferred embodiment of my invention and as one of its objects, I make a flowable mixture of this composition and flow it into a mold which provides the desired shape characterists of the ultimate sealing member. In this preferred embodiment the sealing member is molded directly in an operative position within the pouch bag. In this molding operation a wall of the bag film serves as a mold lining. Another feature is that because of the elasticity and resilience of the composition after it is set, the central portion of the sealing member may be expanded by finger action to admit passage of stomas of different sizes, in contrast to prior practice of providing sealing members having a large variety of stoma opening sizes. Further in this phase, my invention contemplates a universal stoma opening which provides a snug fit around the stoma of any size. This is accomplished without causing strangulation of the stoma but providing an effective seal to permit discharge from the stoma from contacting the skin of the abdomen surrounding the stoma which would cause excoriation of the skin.

Another object of my invention is to provide an improved belt means for fastening the pouch to the patient, with the view to more accurately and firmly holding the pouch in position without placing the bag under too much tension. In one phase of my invention the belt has a connector at each end which hooks into a gasket which is part of the sealing member. The construction is such that the belt connections are made without opening the pouch or admitting air to the interior thereof.

Another object is to provide a low cost disposable belt for use with the drainage pouch.

A further object is to provide a novel method of making a drainage pouch of the character described. This method includes steps or operations some of which are specific to the preferred construction, that is, the construction here shown for molding the sealing member in connection with the bag. It will be apparent, however, that some of the steps or operations are useful beyond this specific construction.

Referring to the drawings:

FIG. 1 is a face view of the outer side of a pouch, opposite from the side attached to the patient, embodying one species of my invention, with a cut-away to show a portion of the enclosed gelatinous sealing member;

FIG. 2 is a face view of the inner side of this pouch, showing a circular cut-out of the inner film sheet providing a stoma opening in the pouch;

FIG. 3 is a section lengthwise of this pouch taken on the section line 3—3 of FIG. 1;

FIG. 4 is a face view of a gasket which is to be molded in the sealing member;

FIG. 5 is a perspective view of a mold box used in making the pouch shown in FIG. 1;

FIG. 6 is a cross-section taken substantially on the section line 6—6 of FIG. 1, showing the mold box and the gasket in position for molding;

FIG. 7 is a similar section showing the gelatinous material poured into the mold with a center core in position;

FIG. 8 is a similar section showing the mold box and core removed and the outer film sheet in position closing the sealing member within the pouch;

FIG. 9 is a side view of a connector at each end of a belt for hooking into one end of the gasket shown in FIGS. 1 and 4, or in FIGS. 16 and 17 in the slits at the sides;

FIG. 10 is a top view of the belt connector shown in FIG. 9;

FIG. 11 is a face view of the outer side of a pouch embodying another species of my invention, with a portion of the outer film sheet cut away to show a portion of the gelatinous sealing member;

FIG. 12 is a face view of a modified form of gasket used in the pouch shown in FIG. 11;

FIG. 13 is a side view of the belt connector at each end of a belt for hooking into the gasket shown in FIGS. 11 and 12;

FIG. 14 is a top view of the belt connector shown in FIG. 13;

FIG. 15 is a section on the section line 5—5 of FIG. 13;

FIG. 16 is a face view of a further modified form of pouch embodying my invention;

FIG. 17 is a face view of a further modified form of a pouch embodying my invention;

FIG. 18 is a section taken on the section line 18—18 of FIG. 17;

FIG. 19 is a perspective view of one end of a belt used with pouches such as shown in FIGS. 16 and 17, or FIG. 1;

FIG. 20 is a similar view of the belt shown in FIG. 19 with a short cover sheet (release paper) removed to expose a pressure sensitive adhesive on the belt;

FIG. 21 is a face view of the outer film sheet used in the pouch shown in FIG. 1, showing the sheet before it is used in making the pouch;

FIGS. 22 to 29 inclusive show diagrammatically a series of steps in the manufacture of a pouch in accordance with my invention, with brief memoranda of the operation shown in each figure;

FIG. 30 is a perspective view of a modified form of mold used with my invention;

FIG. 31 shows the mold of FIG. 30 in pouring position on the film sheet;

FIG. 32 is a perspective view of a further modification of mold construction used with my invention.

My invention also contemplates generic and specific constructions. And, inasmuch as both article and method claims are involved, I will for purpose of clarity, start with a description of the article of manufacture shown in FIG. 1 together with the method of making it. As is customary in this art I use plastic film such as polyethylene, vinylidene chloride or laminations of the two films for the pouch bag or body, but other materials may be used suitable for the purposes of my invention. In this instance the bag is formed of a single sheet of film designated by the reference numeral 41 of uniform width (see FIG. 21) bent upon itself at 42 midway between its ends to provide an inner side wall 43 and an outer side wall 44. The inner side wall 43 will be positioned against the body, but other materials may be used suitable for the purposes of my invention. In this instance the bag is formed of a single sheet of film designated by the reference numeral 41 of uniform width (see FIG. 21) bent upon itself at 42 midway between its ends to provide an inner side wall 43 and an outer side wall 44. The inner side wall 43 will be positioned against the body of the patient when the pouch is in use. Before the outer side wall is moved to its bag-forming position shown in FIGS. 1 and 3 and is flat as shown in FIG. 22, a gelatinous sealing member designated generally by 45 is molded to the inner side of the inner wall 43 as will be presently described. Following this, the outer wall 44 will be folded over to the bag-forming position. While in this position the bag will be closed by heat sealing at 46 along the entire length of the bag at both sides and across the end 47, thus completely closing the bag to the outer atmosphere. Returning now to the molding of the sealing member, reference is made to FIGS. 1 to 8 inclusive and FIGS. 22 to 28 inclusive. However, prior to this molding operation a coating of release material is applied to one side of the film sheet at areas 48 and 49, the purpose of which will be presently apparent. Also prior to the molding, means is provided such as a marking by a circle 51 concentric with the release area 49 but on the side of the film sheet opposite from said release area for cutting out this circle portion of the film to provide a stoma opening 52 therein. Continuing with the method, a mold-box designated generally by 53 is positioned beneath the filmsheet in registration with the marking 51, as shown in FIG. 23. This mold-box defines the general depth and configuration of the sealing member to be molded. In this embodiment it is rectangular; in FIGS. 11, 16 and 17 it is circular. It may be varied. The film overlying the mold-box is then pressed or drawn by any suitable means into the cavity of the mold as shown in FIG. 24. By pressing the film sheet into the mold the film becomes a lining for the mold and the resulting sealing member will be adhered to the film and the bag. It will now be noted that a locating notch 54 is provided in each of the walls 55 of the mold. A gasket designated generally by 56 provided with extensions 57 is placed into the mold with the extensions 57 fitting into the notches 54, thereby positioning and locating the gasket within the mold. In this position it will be noted that the extensions 57 are pressed down over the film and the film is pressed into the notches. The body of the gasket is supported intermediate the top and bottom of the mold. The ring body of the gasket is perforated as by openings 58 which receive the gelatinous material when it is poured into the mold, as will be presently described. A center core 59 circular in cross-section is then positioned in the mold as shown in FIG. 26. This core forms a stoma opening 60 in the center of the sealing member. However, as described below, the sealing member may be used without this center opening. The mold and coacting parts are now in position for pouring in the gelatinous material. This material is prepared so that when heated it can flow and when cooled it will set or gel into shape. Thus, when the material is poured into the mold it will flow into all cavities including the perforations 58, with the result that the gasket 56 will be embedded in the mold as shown in FIGS. 1, 2, 3, 7, 27, 28 and 29. It will be understood that the drawings are somewhat diagrammatic in view of the difficulty of showing the exact shape of the film around the molded member. When the gelatinous material sets or gels, the core 59 will be removed, leaving the parts as shown in FIG. 28. The end half of the film sheet opposite from the molded end will now be folded over at 42 to provide the outer wall 44 of the bag, as shown in FIGS. 3 and 29. The bag will now be heat sealed along the edges 46 and 47 as described, thereby entirely closing the interior of the bag to the outer atmosphere. The pouch is now complete and ready for use. At this point it will be noted that the sealing member 45, the belt connector ends 57, and the interior of the bag are completely enclosed, thus protecting and preserving the functioning parts of the pouch. Also, this construction provides a water tight package which prevents drying out of the gelatinous sealing member and keeps the interior of the package clean and sterile. Also, the film body which forms the bag becomes a wrapper for the article of manufacture so that we now have a package which can be handled, shipped, and stored without harm to the interior parts. When the pouch is to be used, that is, applied to a patient, the circular portion of the side wall 43 noted by the circle marking 51 will be cut out, using a scalpel, razor blade, sissors, or suitable sharp implement. This cut-out 51 is facilitated because its inner surface has the release coating 49 which releases from the sealing member. This now exposes the central opening 60 in the sealing member and also the sealing surface of such member surrounding the opening 60. This opening is intended for the smallest stoma and the opening defined by the cut-out 51 the largest stoma needs. In applying the pouch to the patient the attendant will first press an object (such as the finger) through the opening 60 until it contacts the inner surface of the outer wall and upon further pressure this outer wall will be pushed outwardly, thus releasing the area 48 from adhesion to the sealing member. This opens the bag for placing the stoma in position to discharge into the bag. In practice it is suggested that the attendant insert wet fingers into the opening 60 and expand the sealing member to provide an opening slightly larger than the stoma to which the pouch is to be applied. Because of the expansible and resilient nature of the gelatinous material, this material may be easily spread to receive the stoma. The gelatinous material will contract and seal around the stoma. The attendant gently presses the central portion of the pouch, particularly the portion of the sealing member disposed within the circle cut-out 51, against the abdomen of the patient, thereby sealing the member 45 to the skin of the patient around the stoma. A belt is used to insure better attachment of the pouch to the patient. In this instance a belt 61, FIG. 9, is provided at each end with a connector 62 in the form of a hook which is adapted to be hooked into a slot opening 63 in one of the gasket extensions 57. Each such slot opening is also through the inner and outer film sheets and these sheets are heat sealed together at 64 surrounding the area through which the slots pass. This seals the interior of the bag from any air or water passage into or out of the bag in the belt connector area. Suitable means (not shown) is provided for tightening the belt, as is well known in the art.

Referring now to the composition of the sealing member 45: I refer to this as foamed gel and in my work on the invention I have used corn starch as the basic gelling ingredient and water as the vehicle. Gelatine was used as the agent to permit mechanical whipping or beating of the blended ingredients into a foam. Also, corn syrup and glycerine were used as modifying agents. As an example in making a small batch as distinguished from large batches such as would be used in production manufacture, I have used the ingredients by weight as follows: One-half ounce unflavored gelatine; 1 ounce corn starch (thin boiling type); 1 ounce glycerine; 8 ounces corn syrup; separate containers of water in quantities presently noted; and several drops of food color dye. In making this small batch I proceeded as follows: Pre soak in a first beaker the one-half ounce of gelatine in 6 ounces of cold water for one-half hour, then raise the temperature to 150° F. to insure that all the gelatine has gone into solution. In a second beaker blend the 8 ounces of corn syrup, 1 ounce of glycerine, and 4 ounces of water and bring to a slow boil. In a third beaker blend the 1

ounce of corn starch into the 4 ounces of cold water and gradually stir into the second beaker. Heat this to a boil and continue the heating and stirring until the mixture has turned from a cloudy to a clear solution. This will take from 5 to 10 minutes. Clarity is an indication that the starch particles have absorbed adequate water. Remove second beaker mixture from the heat and continue to stir until the starch solution temperature drops to 150° F. Add the contents of the first beaker into the second beaker plus a few drops of a suitable food color to provide a yellow tan-like color. If food color is not added, the foam gel will be white. Whip this mixture as with an electric kitchen egg beater, using the highest speed, usually from 3 to 5 minutes. This mixture is in condition for pouring into the mold. This foam mixture required about 4 hours to gel or set at room temperature. In production manufacture, suitable means may be used to reduce the time for the mixture to gel. Also in production, to counteract bacterial action on the starch gel, food perservatives can be added to the mixture during the blending and whipping. Some of these preservatives are sodium benzoate, ascorbic acid, lactic acid, methylparaben soda propionate, etc. This description of ingredients, volumes, times and temperatures is for purpose of illustrating a single method such as what might be termed a laboratory batch example. It should be understood, therefore, that where industrial equipment is available, foam gels for my invention may be produced on a continuous basis. Also, as to the steps in the method illustrated in FIGS. **22** to **29** inclusive, this is subject to variation according to the industrial equipment used and whether the operations should be carried out automatically in sequence or in several stages.

From the foregoing it will be apparent that my invention contemplates the provision of a gelatinous member which has the characteristics or properties of being flexible, resilient, adhesive, and of relatively low water soluability. The foam gel here described is somewhat sticky and will adhere to almost any material surface. It will adhere well to the skin around the stoma of a patient. Because of its resilient nature it may be easily expanded at its center to accommodate different stoma sizes and it will have contracting tension on the stoma without strangulation effect. Also, it has relatively long life because of its water insoluability.

It should be noted that my invention contemplates the use of ingredients and proportions other than described herein, for producing a sealing member having the characteristics described. For example, there are many starches or starch-like ingredients such as from potato, wheat, and rice starches, tapioca, and others. Also, other agents may be used for cross linking the starch molecules and the gelatin molecules which will make the molecules less soluable in water. Some such agents are glyoxal and formaldehyde.

Referring now to further pouch modifications:

FIGS. **11** and **12** show a pouch generally similar to that shown in FIG. **1** except that the gelatinous sealing member here designated by **65** is circular and the gasket **66** is provided with belt connector terminals **67** of different shape. That is, each terminal has laterally projecting ears **68** making a T-shaped connector. The belt **69**, FIGS. **13**, **14** and **15**, usually of fabric, is provided at each end with a terminal hook **71** shaped to fit over one of the T-shaped connectors **67**. These connectors **67** are enclosed within the bag as shown at the left in FIG. **11** to permit pushing the hook end **71** against film **43** and connector **67** and hooking it onto the terminal connector **71**. The T-connector and film **43** both lock into **72** or connector **67** without piercing the film.

FIG. **16** shows a pouch generally similar to that of FIG. **1** except that no gasket is used and the film sheet is shaped to provide side extensions **74** having through slots **75** and heat seals **76** around the belt slots **75**. The plastic film in this modification is heavier so that it better absorbs and carries the belt tension.

FIG. **17** is similar to FIG. **16** except that tabs **77** of heavier film are applied to the side portions of the bag, straddling the bag, and are united thereto by the heat sealing **46**.

In FIGS. **18** and **19** I have shown a disposable belt which is used with the described pouches in place of the belts **61** and **69**. It is common in prior practice to use belts of fabricated materials which when soiled are washed and reused. This is time consuming and objectionable. I have provided a disposable belt to be supplied with each disposable pouch. As shown in these figures this belt is laminated, composed of a paper or thin fabric tape **78** and a plastic tape **79** suitably adhered one to the other. The side **78** is used against the body because this side is porous to permit perspiration absorption. To each end of the belt an adhesive coating **81** is applied to the plastic side. This adhesive is of the pressure sensitive type. A short strip of release paper **82** covers and is adhered to the area **81**. The belt can be attached at one end to the pouch or to the gasket by stapling, riveting, heat sealing, or by passing one end of the belt (such as that shown in FIG. **18**) through one of the slots **75**; removing the strip **82**, and folding the adhesive end back on the plastic side of the belt and pressing it into fixed adhesive connection therewith. When the pouch has been applied to the patient as above described, the belt will be wrapped around the patient and its free end will be passed through the opposite slot in the pouch and drawn taught. This latter end can be provided with the adhesive fastening shown in FIG. **18** and fastened to the belt, as described, or the belt can be looped or tied in the holding position.

In FIGS. **30**, **31** and **32** I have shown several means for molding the sealing member **45** in the bag without using a reusable mold-box such as **53**. In FIG. **29** I show a strip of paper **83** about nine-sixteenths inch high, to be formed into a circle, square, oblong, or any desired configuration, to serve as the outer wall of a mold. In this figure the paper strip, wound around a gasket **66**, is slotted at **84** to receive the T-shaped belt connectors of the gasket. This mold will be positioned on the film sheet at the same location as the mold-box **53** in FIG. **22** except that the film sheet would be inverted because the gel would be poured into the paper mold from the top. This is shown in FIG. **31**, diagrammatically. This paper mold will remain in this position on the film sheet until the gelatinous material has jelled and could remain in the bag. In FIG. **32** I have shown a modified plastic gasket and mold which remains in the bag, similar to the paper mold in FIGS. **30** and **31**. In FIG. **32** the gasket has formed integral therewith, thin lips **85** which extend above and below the circular body of the gasket at the periphery thereof. These lips provide the side wall of the mold.

It is believed that the foregoing conveys to those skilled in this art the manner and process of making and using drainage pouches contemplated by my invention. It will be understood also that my invention contemplates various species and that modifications may be made in the construction of the drainage pouch and in the method of manufacture without departing from the spirit and scope of the invention expressed in the appended claims, in which:

I claim:

1. A post-surgical pouch for receiving discharge from the stoma of a patient, comprising a pouch bag having an inner and an outer wall with the inner wall having a stoma opening, and a sealing member within the bag composed of a gelatinous adhesive material adhered to said inner side of the inner wall covering the area surrounding said stoma opening, the sealing member providing passage of the stoma for discharge into the bag and having sealing engagement with the stoma.

2. A post-surgical pouch as set forth in claim **1**, in which the gelatinous sealing member is molded to the inner side of the inner side wall around the area of the stoma opening therein, and in which a gasket member is embedded in the sealing member and has a belt connector extending from each lateral side of the sealing member.

3. A post-surgical pouch as set forth in claim **1**, in which the sealing member has an opening at its center in alignment with the stoma opening in the inner side wall of the bag.

4. A post-surgical pouch as set forth in claim **1**, in which the outer side wall of the bag is provided at its inner side with a

release coating covering the adjacent side surface of the sealing member.

5. A post-surgical pouch as set forth in claim 1, in which the sealing member has a through opening in alignment with the stoma opening in the inner wall of the bag, and the outer wall of the bag has a release coating on its inner side covering the adjacent side surface of the sealing member.

6. A post-surgical pouch as set forth in claim 1, in which the sealing member has a central through opening of a given minimum diameter in alignment with the stoma opening in the inner wall of the bag, and in which the stoma opening in the outer wall of the bag is of a given maximum diameter.

7. A post-surgical pouch as set forth in claim 1, in which the sealing member has a through opening of a given minimum diameter in alignment with the stoma opening in the inner wall of the bag and said stoma opening in the bag is of a maximum diameter, the outer wall of the bag having at its inner side a release coating covering the adjacent side surface of the sealing member, and the inner side wall of the bag having at its inner side a release coating covering an area larger than said maximum diameter of the opening in said inner side wall.

8. A pouch for receiving discharge from a stoma or the like of a patient, comprising a pouch bag having an inner and an outer wall, the inner wall having a stoma opening, a sealing member adhered to the inner side of the inner wall covering the area around the stoma opening, said sealing member consisting of ingredients which provide a gelatinous member having adhesive, elastic, and resilient properties, a reinforcing gasket embedded in the sealing member and having extensions at opposite edges forming belt connectors, said sealing member having a central through opening in alignment with said stoma opening in the bag, the central opening in the sealing member being of a given minimum diameter for entry of a small stoma and the stoma opening in the bag being of a maximum diameter for passage therethrough of larger stomas.

9. A post-surgical pouch for receiving discharge from the stoma of a patient, comprising a pouch having spaced inner and outer walls closed on all peripheral edges and imperforate so as to form an enclosure sealed from the outer atmosphere, a ring member located inside the pouch composed of gelatinous material having resilient, adhesive properties, said member positioned against the inner side of the inner wall at a stoma entrance location and adhering to said inner side, a coating of release material at the inner side of the outer wall covering the area of the ring member, the inner wall adapted to be opened prior to use of the pouch to permit entrance of the stoma into the pouch through the ring member and to expose a portion of the ring member for sealing engagement with the skin of the patient around the stoma.

10. A post-surgical pouch as set forth in claim 9, in which the ring member has a central opening, whereby after the inner wall has been opened to provide a stoma opening, an object may be inserted through said stoma opening and through the central opening in the ring member into contact with the release coating on the inner side of the outer wall of the pouch, and whereby upon further pressure of said object outwardly the outer wall will be moved away from the ring member to provide internal enlargement of the pouch to receive drainage from the stoma.

11. A pouch for receiving discharge from a stoma or the like of a patient, comprising a pouch bag having an inner and an outer wall, the inner wall having a stoma opening, the inner side of the inner wall forming the cavity of a mold, a sealing member molded in said cavity to the inner side of the inner wall covering the area around the stoma opening therein, a reinforcing gasket embedded in the molded sealing member and having extensions at opposite edges forming belt connectors, said sealing member consisting of ingredients which when heated can flow into said mold cavity and embed said gasket therein and which when cooled will gel to provide a gelatinous member having adhesive, elastic, and resilient properties, said sealing member having a central through opening in alignment with said stoma opening in the bag, the central opening in the sealing member being of a given minimum diameter for entry of a small stoma and said stoma opening in the bag being of a given maximum diameter for passage therethrough of larger stomas, a release coating on the inner side of the outer wall in an area covering the adjacent side of the sealing member, and a belt having means for connecting to the belt connectors of the gasket.

12. A post-surgical pouch for receiving discharge from the stoma of a patient, comprising: a bag formed of an inner and an outer sheet of plastic film, a sealing member of gelatinous, adhesive material molded to the inner side of the inner sheet and having adhesive engagement therewith, a gasket embedded in the molded sealing member having belt-connector members projecting beyond its opposite sides and terminating within the bag, the outer film sheet forming the side of the bag opposite from the sealing member and having on its inner side a coating of releasing material covering and over-reaching the sealing member, the inner and outer film sheets being connected by heat sealing along their marginal edges whereby to completely close the interior of the bag from the outer atmosphere and enclose the sealing member and its gasket extensions within the bag, the inner sheet having means whereby a portion of the sheet opposite the sealing member may be removed to provide a stoma opening and to expose a portion of the sealing member so that when the pouch is applied to a patient this portion of the sealing member will be pressed into adhesive sealing engagement with the skin of the patient around the stoma, and whereby an object may be pushed through the sealing member before applying such member to the patient sufficiently to contact the coated release area and push the outer film sheet away from the sealing member to enlarge the interior capacity of the bag.

13. As an article of manufacture, a drainage pouch having a bag formed of plastic film with the interior of the bag closed to the outer atmosphere, a sealing member of gelatinous adhesive material positioned within the bag in sealing engagement against an inner side thereof, the closed bag serving as the outer wrapper of the article, and means providing a stoma opening through a wall of the bag to the sealing member and through the sealing member to the interior of the bag when the pouch is to be used on a patient.

14. As an article of manufacture, a drainage pouch of the character described having inner and outer side walls of plastic film forming a bag, the interior of the bag closed to the outer atmosphere, a sealing member of gelatinous adhesive material located entirely within the bag, the closed bag serving as the outer wrapper of the article, means providing for forming a stoma opening in said inner wall to expose an outer surface of the sealing member when the pouch is to be used on a patient and whereby a stoma can be passed through said opening and through the sealing member for discharge into the bag and whereby said exposed surface of the sealing member can be pressed into adhesive sealing engagement with the skin of a patient around the stoma.

15. As an article of manufacture, a pouch for receiving drainage from the stoma of a patient, comprising a pouch bag having inner and outer walls of plastic film, a sealing member of gelatinous adhesive material having sealing engagement with the inner side of the inner wall, the walls of the bag completely closing the interior of the bag and the sealing member from the outer atmosphere, and means for subsequently providing a stoma opening in the inner wall to expose an outer side surface of the sealing member and to permit passage of the stoma through the sealing member for discharge into the bag and whereby the exposed surface of the sealing member can be pressed into sealing engagement with the skin of the patient around the stoma.

16. As an article of manufacture, a post-surgical pouch for receiving discharge from a stoma or the like, comprising a pouch bag having a stoma opening, and a sealing member in coaction with said opening comprising for a relatively small batch, one-half ounce gelatine, 1 ounce corn starch, 1 ounce glycerine, and 8 ounces corn syrup, mixed with water heated

and whipped to form a foam gel (substantially as described) producing a sealing member product having gelatinous, adhesive, elastic, resilient, and low water solubility properties.

17. As an article of manufacture for use with a post-surgical pouch having a stoma opening through which discharge is received from a stoma or the like, a sealing member comprising a body having a stoma opening therethrough, the body composed of a mixture of starch ingredients and other ingredients producing a foamed gel having properties of adhesiveness, elasticity, resiliency, and relatively low water solubility.

18. A manufacture comprising a sealing member for use with a post-surgical pouch having a stoma-receiving opening through which discharge is received from any size stoma or the like, said sealing member comprising a body having opposed spaced wall surfaces and a stoma opening extending through the body connecting said spaced wall surfaces, the body shaped to cover an area of skin surrounding the patient's stoma for contact with said area when used on the patient, the body composed entirely of a mixture of starch ingredients and other ingredients to form a foamed gel having adhesive, elastic, resilient, and low water solubility properties.

19. A pouch for receiving discharge from a patient, and means adapted to provide a seal between the pouch and the patient around the discharge area, said means comprising a body of gelantinous material heated for flowing to a predetermined form and whipped to a foamed condition for gelling when cooled.

20. A post-surgical pouch for receiving discharge from the stoma of a patient, the pouch having an opening of given maximum diameter to receive stomas of relatively large sizes, and sealing means associated with the pouch in the area of said opening comprising a body of foamed gelatinous material having a stoma-receiving opening of given minimum diameter to receive a stoma of relatively small sizes, said gelatinous material having foamed gel properties of elasticity and resiliency whereby the body is adapted to be expanded at its stoma opening to receive larger stomas and the body will contract around said larger stomas.

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