| [54] DRAINAGE POUCH AND METHOD OF MAKING | | |
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| [52] U.S. Cl. 128/283 [51] Int. Cl. A61f 5/44 [58] Field of Search 128/275, 283, 294–295 | | |
| [56] | | References Cited |
| UNITED STATES PATENTS | | |
| 3,292 | ,368 9/19 ,626 12/19 ,145 1/19 | 66 Schneider128/295 |

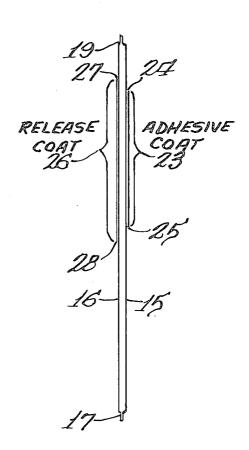
FOREIGN PATENTS OR APPLICATIONS

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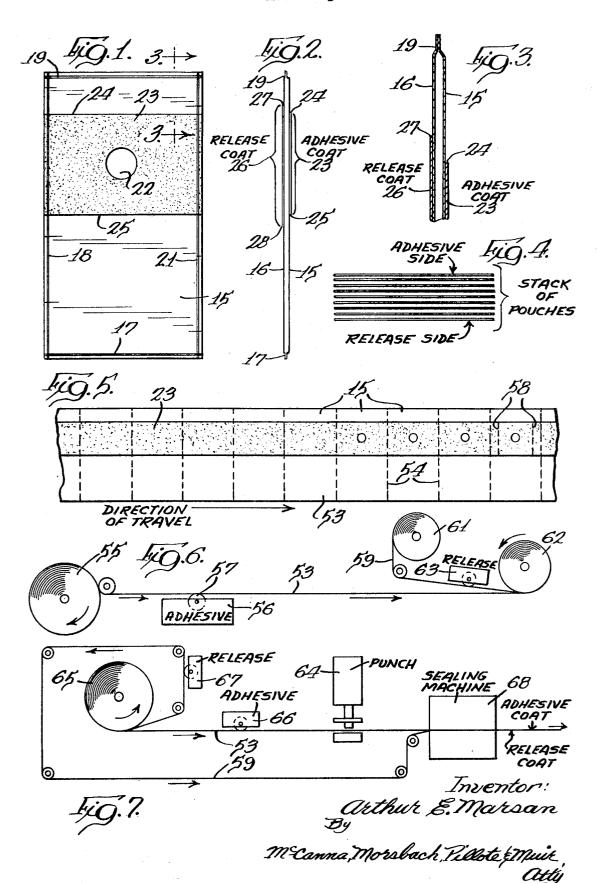
[57] ABSTRACT

The invention is characterized by a drainage pouch having on one side an adhesive adapted to cover an area which surrounds the drainage opening in the patient's skin for sealing the pouch to the skin when applied for use, and a release material on the pouch in an area in coactive relation with the adhesive area, whereby in such coaction the adhesive area of one pouch will be covered by the release area. The invention is further characterized by the method of making the drainage pouch.

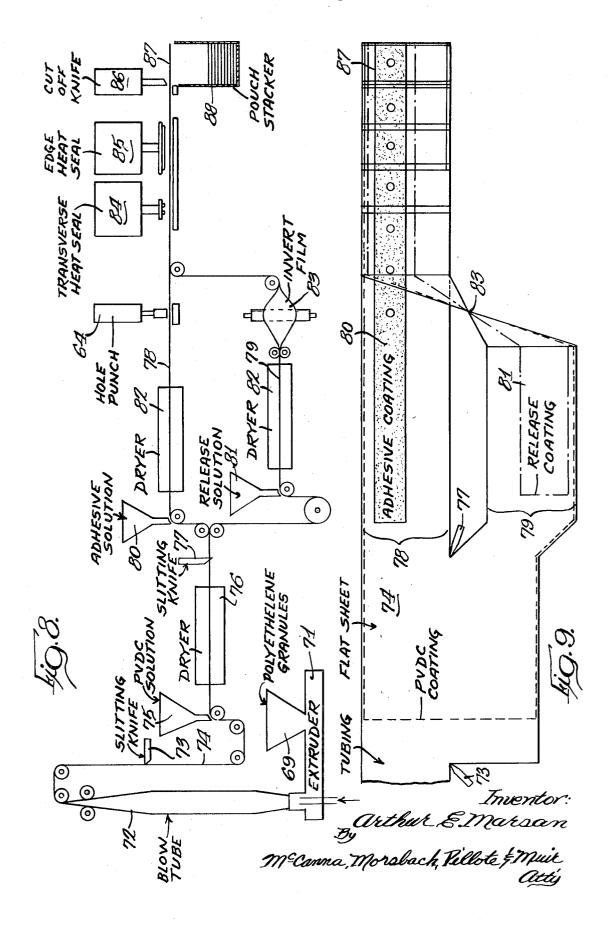
10 Claims, 15 Drawing Figures



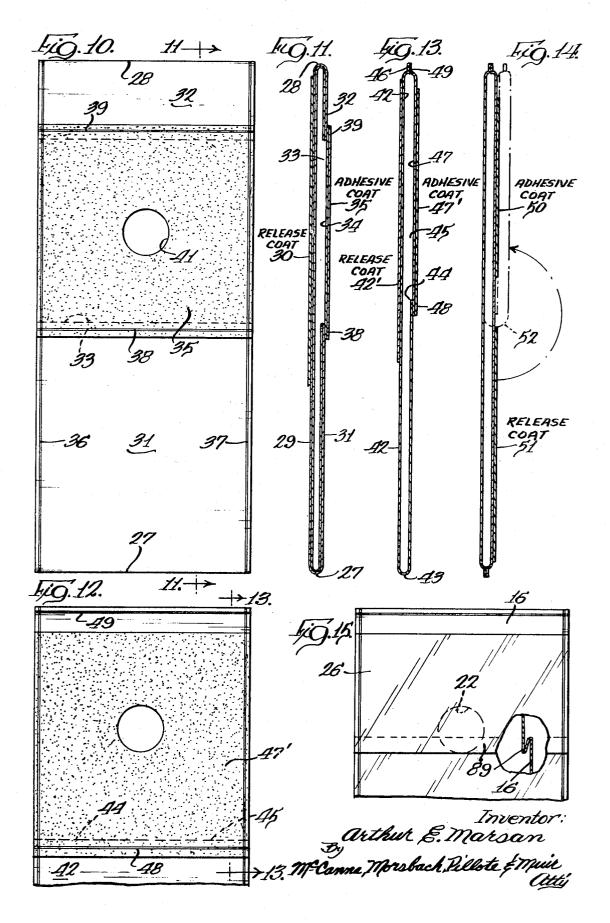
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SHEET 2 OF 3



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DRAINAGE POUCH AND METHOD OF MAKING

This invention relates to what is known as a stickon pouch for use in the medical field, particularly in colostomy, doublebarrel colostomy, wet colostomy, cecostomy, transverse colostomy, ileostomy, ureterostomy, ileal conduit, vesicotomy, fistuaa drainage, and related cases where a pouch having an adhesive sealing means is applied to the skin of the patient to provide a seal around the opening through which the drainage occurs.

Heretofore it has been the practice in this art to make 10 drainage pouches of film such as polyethylene consisting of two separate units of manufacture. One unit is a pouch of polyethylene film or other material. The second is a sealing unit which is permanently applied to one side of the pouch. Such sealing units vary in size, shape, and construction, but es- 15 8; sentially they comprise a sheet of material double coated with pressure-sensitive adhesive, that is, with the adhesive applied to each side of the sheet. This sheet is pressed to the opening side of the pouch to make permanent adhesive connection therewith. To the opposite adhesive side of this sheet is 20 pressed a nonadhesive sheet of material for the purpose of covering the outer adhesive side of the double coated adhesive sheet. This second sheet covers the outer adhesive which would be otherwise exposed before using the pouch. This outer sheet must be pulled off to expose the outer adhesive 25 side of the double coated sheet so that the pouch may be applied to the patient with this outer exposed adhesive of the pouch pressed against the skin. This attaches the pouch to the patient and seals the area between the pouch and the skin surrounding the drainage or stoma opening. This prior practice 30 inherently involves difficulties both in the manufacture of the pouch unit and the sealing unit. Also difficulties occur in removing the outer sheet of the sealing unit before the pouch may be used.

One object of my invention is to provide an improved 35 drainage pouch designed for greater convenience and ease of application to the patient. In this connection my invention contemplates the provision of a number of different forms or species of drainage pouches embodying features of my invention.

In furtherence of my invention I eliminate the so-called double-coated adhesive sealing unit above described. Also I eliminate the technical difficulties in the manufacture, assembly, and use of such prior pouches. To this end my invention contemplates a pouch of simple construction which may 45 be embodied in different forms or species. In a preferred form the pouch has at one side a pressure-sensitive adhesive in an area around the drainage opening, and on its opposite side a release agent or material in an area in predetermined and coacting relation to the adhesive area around the drainage opening, whereby the pouches may be stacked one upon another with the adhesive area of one pouch against and covering the release area of an adjoining pouch. Thus the pouches may be stacked for storage or for packaging in boxes for sale. The user simply removes one pouch at a time, as from 55 the top of the stack. This pouch is ready for immediate use because the sealing adhesive is inherent in and a part of the pouch side which is to be pressed against the skin of the patient around the drainage or stoma opening.

Another object of my invention is to provide improved 60 methods of manufacture with the view to producing these drainage pouches at low cost. In this connection my invention aims to simplify the manufacturing process, using mainly standard machinery and equipment.

In the drawings I have shown several modifications of 65 drainage pouches made in accordance with my invention. Also the drawings illustrate variations in the manufacture contemplated by my invention.

Referring to the drawings:

FIG. 1 is a face view of the side of a drainage pouch em- 70 bodying my invention, showing the adhesive side which is applied to the patient;

FIG. 2 is an edge view of the pouch shown in FIG. 1;

FIG. 3 is an enlarged section taken on the section line 3-3 of FIG. 1;

FIG. 4 is a schematic view to illustrate stacking a plurality of the pouches:

FIG. 5 shows a web of film to which adhesive is applied to one side thereof continuously over the full width of individual pouches which are to be subsequently severed from the film web:

FIG. 6 shows diagrammatically one way of applying adhesive and release materials under the method phase of my invention;

FIG. 7 shows diagrammatically a modified method of making pouches in accordance with my invention;

FIG. 8 shows diagrammatically a more comprehensive method of making pouches in accordance with my invention;

FIG. 9 is a plan view of a portion of the method steps of FIG.

FIG. 10 is a view similar to FIG. 1 showing a modified form of drainage pouch embodying my invention;

FIG. 11 is a section taken on the section line 11-11 of FIG.

FIG. 12 shows another modification of drainage pouch embodying my invention;

FIG. 13 is a section lengthwise of the pouch taken on the section line 13-13 of FIG. 12;

FIG. 14 is a section lengthwise of the pouch showing another modification; and

FIG. 15 is a face view of a modified form of pouch having a fold in the release area side.

In FIGS. 1 to 3 I have shown a preferred form of the invention. Here the pouch is formed from two sheets of film web, one designated 15, the side to be attached to the patient, and the other 16 which faces outwardly when applied to the patient. These may be polyethylene film, but other materials may be used suitable for the purposes of my invention. In this instance the edges of the film are closed, that is, united by heat sealing at 17, 18, 19, and 21 to make a closed pouch. The pouch may be formed in other ways as will be described hereinafter. The sheet 15 is provided with a drainage opening 22. The outer side of this sheet has incorporated therein as a part thereof an adhesive 23 preferably of the pressure-sensitive kind. This adhesive may be embodied in the sheet as a step in the manufacture or it may be applied externally as by coating over a given area such as shown in FIG. 1. This area is designed to surround the drainage or stoma opening in the patent. In this form the area extends continuously between the edges 18 and 21 and across a limited area lengthwise of the pouch, such as between the upper and lower edges 24 and 25, respectively. The other sheet 16 has a release agent or material 26 applied continuously from side to side of the pouch cor-50 responding with the adhesive but in a larger area lengthwise, as from 27 to 28 to overlap the adhesive area, as shown in FIG. 3. This release area 26 is in coacting relation with respect to the adhesive area 23 so as to completely cover the latter area across the width of the pouch and overlap the area at its upper and lower edges when the finished pouches are stacked as shown in FIG. 4.

In FIGS. 10 and 11 I have shown a modified form of the drainage pouch in which the pouch is formed from a single sheet of film folded back upon itself at 27 and at the opposite end at 28. This provides a side 29 corresponding with the release side 16 in FIGS. 1 to 3 and a side comprising turnedover portions 31 and 32 which leave an intermediate opening 33. A separate film sheet 34 closes the opening 33 from side to side of the pouch and is covered on its outer side with an adhesive coating 35. The side edges 36 and 37 of the pouch are closed by heat sealing which also seals the side edges of the adhesive coated sheet 34. This sheet is heat sealed at 38 and 39 along the open edges of sheet portions 31 and 32 throughout the full width of the opening 33, completely closing the pouch except for a drainage opening 41 through the sheet 34. Release coating 30 is applied to the outer side of the pouch similar to the coating 26 in FIG. 1. In FIG. 11 the sheet forming the pouch proper as well as the adhesive sheet is shown diagrammatically as double thickness. This is to indicate treatment on the outer sides of the pouch by a Saran film or coating

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as described below in connection with the method of manufacturing the pouches.

In FIGS. 12 and 13 another form of the pouch is shown in which a single sheet of film 42 is folded back upon itself at 43 and terminates at 44 leaving an opening 45 extending to the end 46 of the sheet opposite from the fold 43. A separate sheet of film 47 similar to the sheet 34 in FIGS. 10 and 11 covers the opening 45 and is heat-sealed at 48 and 49 to the edges 44 and 46, respectively, and also along its side edges lengthwise of the pouch similar to the edges 36 and 37 in FIGS. 10 and 11. This sheet 47 has adhesive 47' on its outer face and a centrally located drain opening as in FIGS. 10 and 11. The sheet 42 has a release agent 42' covering a limited area of its side opposite from the adhesive side, as in previously described forms.

In FIG. 14 I have shown a form similar to FIG. 1 except that the release agent is applied at 51 to the same side as the adhesive. In this form the release portion of the pouch is to be folded upwardly at 52 so that this portion covers the adhesive portion of the pouch. This modification wherein the release portion covers the adhesive portion of the same pouch, may be useful where it is desired to carry or handle a pouch without stacking.

Referring now to the method of making the drainage pouches, it will be understood that my invention contemplates various steps depending on what different embodiment of the pouches is to be manufactured and also on the manufacturer's selection of equipment, materials, and treatments desired. For example, equipment is available on the market for performing the various operations and one skilled in this art may arrange 30 or assemble such equipment under the teachings of my invention. My object mainly is to provide for what may be termed automatic production wherein the several steps may be performed in succession from station to station using machines known in this art. It will be apparent, however, that some 35 variations may be desired in view of the novelty in the construction of the pouches. Also, various kinds of film may be used in making the pouches. Film may be selected having thickness ranging from 0.001 to 0.010 of an inch, but pouches made under my invention may be of thinner or thicker materi- 40 als. I prefer a heavier film for the side or portion of the pouch having the adhesive coating. Also, there may be preferences in the density of the selected film. One approach is to use a lowor medium-density film for the outside wall of the pouch (above referred as the release side) and a high-density film for the side or poration having the adhesive. Another is to apply a Saran treatment to the film or portions thereof at a preparatory stage. In what I would term a finer technique of manufacture, the polyethylene film may be treated or coated with Saran or similar materials to improve various properties and enhance the quality of the pouches. For example, to reduce the transmission of odors through the polyethylene it is advisable to either laminate the polyethylene with Saran film or coat one side with a polyvinylidene chloride solution or emulsion. Such treatment of the polyethylene may be on the inside or the outside of the pouch film. I prefer such treatment on the outside because it also improves adhesion of the pressure-sensitive adhesive to the pouch of my invention. Also, the heatsealing operations are more effective with the Saran treatment 60 on the outside of the polyethylene because this film fuses at a lower melting point. The Saran treatment is optional to the manufacturer and its use is aside from my invention.

Referring more specifically to the method phase of my invention, it is contemplated that the adhesive and the release sides of the pouch be produced in what may be described as continuous production manufacture. As shown in FIG. 5, individual pouch sides such as 15 are formed from a film web 53. This web is severed at 54 after the adhesive is applied to the web and after the drainage openings are cut, also after this web is assembled with the release web and heat-sealed as described above. The web 53 is fed from a supply roll such as 55, FIG. 6, and the adhesive may be applied by suitable means as by a coating machine 56 having a roller 57 for applying the adhesive. The adhesive may be applied by other known 755

methods such as spraying, silk screen, gravure, hot melts, curtain coating, extrusion, calendaring, etc. Some of these methods require oven drying to remove solvents. As described above, the adhesive area surrounds the drainage opening 22 a suitable distance lengthwise of the pouch and extends the full width of the pouch. This is in effect a continuous adhesive applying operation. However, as described below it may be desirable to interrupt the adhesive coating in an area adjacent to each separation line 54' so as to leave nonadhesive areas at each side of the area 23, as indicated at 58 at the right-hand end of the web in FIG. 5. A pouch made in this manner may be more suitable to a patient whose condition requires less adhesive sealing area. Also, this construction would permit the pouch to expand outwardly from all four sides. This nonsealing area entirely around the adhesive sealing area may also be attained by taking a pouch such as shown in FIG. 1 and applying along each side area such as 58, talcum powder or the like, or strips of toilet paper, or Kleenex, or other material. A further modification of the pouch is shown in FIG. 15 in which the pouch proper is similar to that in FIG. 1. To allow greater outward expansion of the release area side 16 of the pouch I provide this side with a fold 89 extending entirely across the pouch and opposite the drainage opening 22. This folded portion will expand outwardly to accommodate the projecting stoma. Referring again to the method shown in FIG. 6, the second sheet 16 (corresponding with the form FIG. 1) is made from a film web 59 taken from a supply roll 61 and wound onto a roll 62 at the inner side of the web 53. After leaving the roll 61 the web 59 is treated at one side to a release agent or material applied by a coating machine 63. This release coating is applied continuously similar to the adhesive 23 in FIG. 5 except that the release coating covers a wider area as shown in FIGS. 2 and 3. The film webs 53 and 59 having been brought into coacting relation with the adhesive and the release areas on opposite sides may now be unwound to a fabricating machine or equipment for heat-sealing and severing the pouches individually from the assembled webs. It will be understood that openings 22 will be cut in the adhesive sides prior to the final sealing. This step is shown in FIG. 7, performed by a suitable punch 64. In FIG. 7 both film webs 53 and 59 are originally wound on a supply roll 65. Adhesive is applied to one side of the film 53 at a station 66 and release material is applied to the opposite side of the film 59 at a station 67. After the punching operation the film webs are brought together in the described relationship before entering a sealing machine 68 which heat seals the pouches as described above. The pouches may be individually cut from the assembly at any desired station after the sealing.

In FIGS. 8 and 9 I have illustrated diagrammatically an example of a more comprehensive and complete production line for the manufacture of drainage pouches of my invention. This starts with production of the film web from polyethylene granules in a supply hopper 69. The granules flow into an extruder 71 from which they emerge in a tubular form 72. In this form, compressed air or other gas is introduced as indicated by the arrow to expand the tube. However, the extruder die may be of a type to produce a flat web instead of tubing. When a tube is formed it is slit by a knife 73 to form a flat web 74, FIG. 9. In actual practice there may be a large variety of auxiliary steps in treating the film depending on the ultimate specifications desired by the manufacturer. In FIG. 8 I have illustrated merely some conventional steps such as PVDC (vinylidine/chloride) solution treatment at 75 and a dryer treatment at 76 to remove solvents. At this point I have shown slitting the film by knife 77 into sheets 78 and 79 which are similar to the above-described web sheets 15 and 16, respectively. To these webs are applied the adhesive and the release solutions at 80 and 81. These webs may be passed through dryers 82 to remove solvents. A punch 64 similar to that in FIG. 7 cuts drainage openings in the adhesive area. Web 79 is inverted at 83 to position the release side on the bottom of the assembled webs opposite from the adhesive side. The assem-

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machines 84 and 85. At 86 the pouches are cut off individually from the combined adhesive and release webs. The finished pouch 87 is then dropped or fed into a stacker 88 or any suitable container for storage, shipping, or sale of the pouches to the user. In practice it may be desired to combine the transverse heat seal machine 84 and the edge heat seal machine 85 in a single machine to make one continuous heat seal around the outer periphery of the pouch or to make all heat sealing in the one machine. In addition, the cutoff may also be included in this same operation.

It will be understood from the foregoing 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.

I claim:

- 1. A manufacture comprising a stack of individual drainage pouches, each pouch having a face to which an adhesive is applied in an area surrounding a drainage opening in said face whereby the adhesive area serves for attachment of the pouch 20 to a patient, and each pouch having on its opposite face a release coating covering an area larger than said adhesive area and in coactive relation to said adhesive area whereby to cover said adhesive area when its pouch is placed face to face over an adjoining pouch when the pouches are stacked one upon another in an assembly for packaging and shipping, and whereby the pouches are individually removable from one end of the stack for usage on the patient.
- 2. A drainage pouch for use with colostomy and the like, comprising an elongated pouch body having spaced sidewalls, one such wall having a drainage opening adjacent to the upper end of the pouch and an adhesive applied to the outer side of said wall in an area surrounding said opening, a release agent applied to said outer sidewall in an area located beyond a medial portion of the pouch at the lower end portion of the 35 pouch, the lower end portion of the pouch being folded at said medial portion to release agent area over and in contact with the adhesive area when the pouch is in nonuse condition before application to a patient, the release agent area being of whereby said folded release area portion can be pulled back to uncover the adhesive area and to position said release area portion at the lower end of the pouch whereby the pouch is in condition for application to a patient with the adhesive area sealing against the skin of the patient.
- 3. A stack of individual drainage pouches, each pouch having spaced sheets of film with one sheet having a drainage opening and an adhesive covering an area around said opening at the outer face of the pouch for direct application to the skin of the patient for sealing engagement therewith, and the other 50 edges of each of the opposed strips. sheet having a release agent on its outer face opposite from

said adhesive face and covering an area in cooperative relation with said adhesive area, the pouches being placed in faceto-face relationship in the stack with the release area of one pouch covering the adhesive area of an adjoining pouch.

- 4. The method of making a drainage pouch consisting in applying to the face of a film web a coating of adhesive over an area sufficient for providing a seal around the drainage opening of a patient when the pouch is applied to the patient, applying to the face of a second film web a coating of release material over an area sufficient to cover said adhesive area, assembling said webs back to back with said adhesive and release areas on opposite sides of the combined webs, and severing the webs at spaced intervals to form individual pouches.
- 15 5. The method of making drainage pouches as set forth in claim 4, in which the adhesive and releasing coatings are applied continuously to the respective webs.
 - 6. The method of making drainage pouches including the steps of applying adhesive to one side of a first film web continuously over an area sufficient for sealing around a drainage opening in a patient, applying a release material to one side of a second film web continuously over a given area sufficient for covering said adhesive area, and causing said film webs to be brought together in a coacting relationship wherein said webs form opposite sides of a pouch and wherein the adhesive area and the release area are in coacting relation one with respect to the other on the outer opposite sides of the pouch.
- 7. The method of making drainage pouches set forth in claim 6, in which the webs are wound onto a roll with the ad-30 hesive are side of the first web positioned on the opposite side of the release area side of the second web.
 - 8. The method of making drainage pouches set forth in claim 6, wherein a drainage opening is formed at spaced intervals through the adhesive area, the webs are brought into coacting relation one with respect to the other with the adhesive area on the side opposite from the release area, and severing the webs intermediate adjoining drainage openings to form
- 9. The method of making drainage pouches set forth in scope sufficient to cover the adhesive area when so folded, 40 claim 6, wherein the peripheral edges of the webs are heat sealed to close the pouch except for the drainage opening.
 - 10. The method of making drainage pouches including the steps of applying adhesive continuously across one face of a film strip in a given area thereof, cutting a drainage opening 45 through the adhesive area of the film strip at spaced intervals, respectively, positioning a second film strip in cooperative relation with the first mentioned film strip, severing both film strips at points intermediate said openings to provide opposed strips for forming individual pouches, and sealing the severed

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