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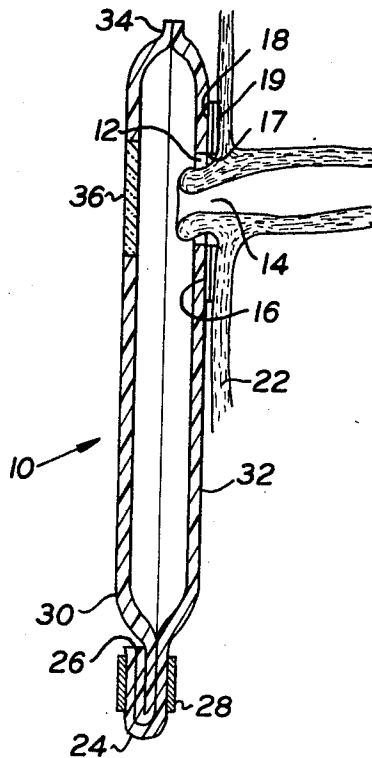
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Primary Examiner—Charles F. Rosenbaum  
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[54] **ENTEROSTOMY POUCH**  
 9 Claims, 4 Drawing Figs.

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

**ABSTRACT:** An opaque enterostomy pouch having a transparent window which permits visual access to the stoma-receiving opening in the pouch thereby permitting visual verification of its fit and alignment on the user.



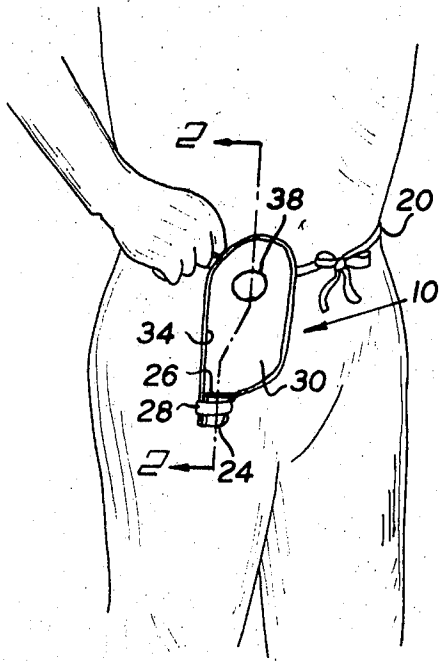


Fig. 1

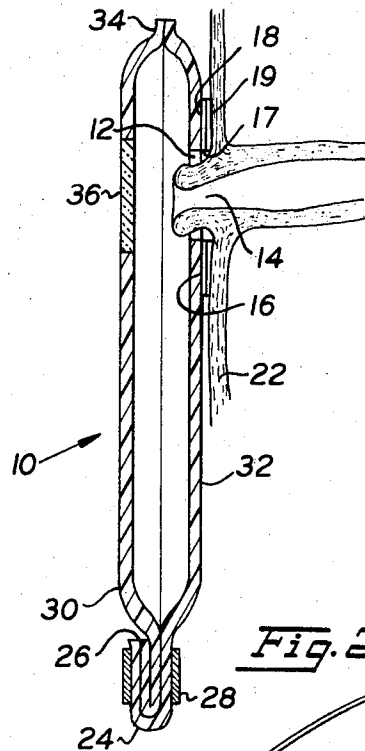


Fig. 2

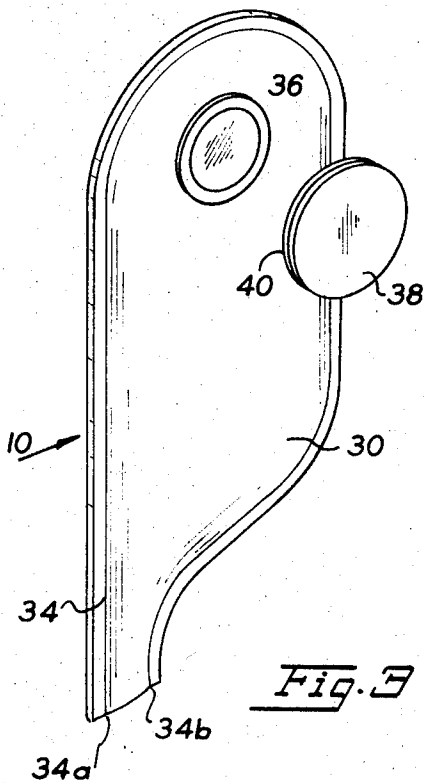


Fig. 3

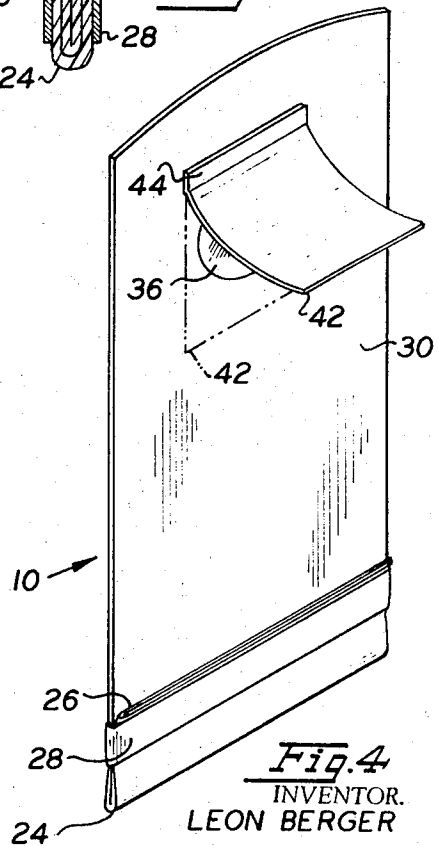


Fig. 4

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# 1

## ENTEROSTOMY POUCH

### BACKGROUND OF THE INVENTION

While the invention is subject to a wide range of applications, it is especially suited for use with enterostomy pouches or receptacles used to collect fecal matter from surgically made fistulas discharging through the surface of the body, and will be particularly described in this connection.

The present invention is intended to be placed over the opening formed by a colostomy, ileostomy, ureterostomy and similar types of surgical procedures which form artificial openings through which a discharge of organic body matter occurs. An artificial opening of this nature is referred to as the "mucosa" or "stoma."

Heretofore, it has been the practice to utilize pouches formed solely of either an opaque or a transparent material to collect the organic or fecal matter discharged from the stoma. At present, these pouches are usually formed from thin sheets of a pliable material, such as, natural or synthetic rubber, polyethylene, polyvinylidene chloride, polyvinylchloride or some other organic polymer. It is, of course, understood that these materials may be opaque or transparent.

The proper positioning of the pouch having a stoma-receiving opening, on the user or patient, is of paramount importance. An improperly positioned pouch permits friction and pressure to the mucosa which can produce and create fistulas in the stoma. A properly positioned pouch protects and prevents damage to the mucosa and stoma. These fistulas are undesirable in that the fecal discharge will thereafter emanate from the fistulas rather than from the end of the stoma thereby creating difficulties in assuring a leakproof union of the pouch to the body, a condition which often requires correction by additional surgical procedures.

Therefore, it has been the practice in the past to utilize a transparent pouch to provide visual access to the stoma opening and facilitate the proper alignment and fit of the stoma-receiving opening of the pouch with the patient's stoma. It is to be noted that the size and shape of the stoma will vary from patient to patient requiring the stoma-receiving opening in the pouch to be cut out to each individual's requirements. An opening too large for the stoma permits an excoriating discharge to irritate the skin causing discomfort and inability to wear the pouch properly. It is, of course, obvious that this would be greatly simplified if a visual verification of the actual fit is possible. However, despite their utility, the transparent pouches have the disadvantage of creating a distracting appearance in that the stoma and the fecal discharge therefrom are visible through the walls of the pouch. In fact, the color of the stoma and fecal discharge can sometimes be seen through the garment worn by the user.

To overcome this nonaesthetic and unsightly appearance, others have resorted to fabricating the pouch from opaque material. This solved the problem of obscuring the distracting and unsightly appearance of the contents of the pouch. It was no longer distracting to intimate participants in normal social activities. However, the opaque pouch still did not solve the important problem, it still deprived the patient of visual access to the stoma-receiving opening thereby preventing visual verification of the fit and location of the pouch on and about the stoma.

It is an object of the present invention, therefore, to provide a new and useful enterostomy pouch of the type hereinafter described, which obviates the limitations and disadvantages of prior pouches of this type.

It is another object of the present invention to provide a new and improved enterostomy pouch of the type hereinafter described, which may be visually and accurately positioned on the user and which does not present an unsightly appearance.

### SUMMARY OF THE INVENTION

In accordance with the invention, there is provided an enterostomy pouch comprising at least front and backwalls

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defining a chamber. At least the front wall is substantially opaque and the backwall has a stoma-receiving opening so that the opening is viewable therethrough. To enhance to appearance of the invention there is also provided means for obscuring the transparent window.

For a better understanding of the present invention together with further objects and features thereof, reference is had to the following description, to be read in conjunction with the accompanying drawings, wherein like components in the several views are identified by the same reference numeral, while its scope will be pointed out in the appended claims.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an enterostomy pouch embodying the present invention as it is disposed on a patient; FIG. 2 is a longitudinal section through the pouch taken along line 2-2 of FIG. 1; and

FIG. 3 and 4 are perspective views of different embodiments of enterostomy pouches illustrating the different means for obscuring the transparent window.

### DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawings, FIG. 1, shows an enterostomy pouch generally identified by the numeral 10 as it may be worn by a patient. Pouch 10, as it is illustrated in FIG. 2, has a stoma-receiving opening 12 which is located over the stoma 14 of the patient to properly direct the fecal discharge from the stoma 14 into the pouch 10. The stoma 14, as was previously explained, is the opening, formed in the body of a patient by a colostomy or ileostomy or similar surgical procedure, and through which a discharge of organic matter is afforded.

A supporting device, such as disc 16, having an opening 17 may be used to secure pouch 10 to the body of the user. Disc 16 may be bonded integral with the pouch 10 at 18 at their adjacent surfaces or it can be attached thereto by any conventional means, for example, by cement or an adhesive. When so secured together the disc 16 has its opening 17 aligned with the opening 12 so that the disc forms an integral part of the pouch 10. The disc 16 provides a soft support by which the pouch 10 is affixed to the body of the patient. To enable this to be accomplished, its surface facing the patient's body may be provided with one of the adhesives, cements or vegetable gums 19 conventionally used for this purpose. In practice, the pouch is often retained in position on the patient's body mechanically, for instance, by a belt 20 as shown in FIG. 1.

Alternatively, the disc 16 may be omitted and the pouch 10 may be provided with the adhesive surface 19 surrounding stoma-receiving opening 12, to enable the pouch 10 to be affixed directly in place to the skin 22 of the patient. Inasmuch as the adhesives 19 and the use of a disc 16 are known, such details form no part of the invention. Hence, the details of construction of the pouch 10, define the invention regardless of the means used to attach the pouch 10 to the patient.

The lower end of pouch 10, designated by the numeral 24, may include an outlet opening 26 through which waste accumulated therein can be removed. The opening 26 is closed in any convenient manner when in use as by folding the lower end 24 of pouch 10 back on itself and securing the fold by any suitable means, such as clasp 28. The pouch 10 is emptied by removing clasp 28 and thereafter may be flushed clean.

The front and backwalls 30 and 32, respectively, of the pouch 10 are preferably formed of a sheetlike elastomeric material of a type which is resistant to attack by body chemicals or fecal matter. In the embodiment of FIGS. 1 and 2, the walls 30 and 32 have been fabricated from opaque vinyl plastic material. However, in the practice of the invention, it has been found that the front wall 30 may be of opaque material and backwall 32 of a transparent material since it is not visible through the front wall, yet it does enable the user to see the contents of the pouch 10 when necessary.

The marginal edges of front wall 30 and backwall 32 are fluid tightly sealed together at peripheral seal 34 from point 34a to point 34b thereby forming the pouch 10. Seal 34 is preferably formed in a single operation. Any suitable means of sealing may be employed, for example, sealing by means of heat.

As shown in FIG. 2 and noted above, the stoma-receiving opening 12 should be precisely located and retained in position over the stoma 14. If the pouch 10 is improperly located about the stoma 14, the stoma will be damaged and its function impaired by the creation and formation of fistulas therein. The proper positioning of the opening 12, conforming in shape and configuration and in precise alignment with the stoma 14, protects the skin against the excoriating organic body discharge that causes discomfort and skin breakdown. Not infrequently this undesirable condition may result in infection and may require medical treatment or other corrective procedures. Therefore, it is quite obvious that the importance of properly shaping or configuring, fitting and aligning the stoma-receiving opening 12 with stoma 14 cannot be overstated.

It is also readily understood that a surgical procedure, such as a colostomy or ileostomy, which requires a pouch 10 to be utilized, may have a severe adverse psychological effect on the patient. For this reason, among others, it has often been the practice to utilize an all opaque pouch to obscure from view the stoma and the fecal discharge. Although this improves the appearance of the pouch, it also presents visual verification of the contour, fit and alignment of opening 12 with stoma 14. A decision whether to use a transparent or opaque pouch would then be based on the advantages and disadvantages of each type. The user would have to sacrifice appearance for safety and vice versa.

To this end, the present invention recognizes the benefits of both the transparent and opaque pouches. Referring to FIGS. 1, 2 and 3, there is shown a view of front wall 30 in which a transparent window 36 is provided that is substantially larger than and in alignment with the stoma-receiving opening 12 defined in the backwall 32. The alignment of window 36 in front wall 30 with stoma-receiving opening 12 in backwall 32 need not be exact but should be such as to permit a clear view of the opening 12. Hence, to enable it to perform its function all that is necessary is that the location of window 36 relative to stoma-receiving opening 12 be such that opening 12 is viewable through window 36. It is to be noted that the size and shape of window 36 need not be the same as the size and shape of stoma-receiving opening 12. However, window 36 should be large enough to provide visual access to opening 12 to permit visual verification of the congruent contour and alignment of the opening 12 and the stoma 14.

In practice, it has been found that the window 36 may be fabricated in any conventional manner. For example, the front wall 30, may be formed from a clear plastic material. The front wall 30, and if desired, the backwall 32 also may then be painted or colored throughout its outer surface with an opaque material except for the area comprising window 36. In this way, the front wall 30, except for the window 36 is opaque.

Alternatively, the front wall 30 may be formed of an opaque material having an aperture defined therethrough in the area intended to form the window 36. A patch of transparent material is then placed over the aperture and bonded about its periphery to the defines of the apertures in a fluid tight seal thereby forming the window 36.

As was previously noted, the present invention is intended to adopt the benefits afforded by both the opaque and transparent pouches. In this regard, the present invention utilizes an opaque front wall 30 and preferably an opaque backwall 32. Use of opaque material obscures the color of the organic discharge as well as the sight of the stoma and presents a more appealing appearance.

To further augment this improved appearance, it may be that certain users of pouch 10 do not wish the window 36 to

remain exposed when the pouch 10 is in use. In these instances, means for obscuring window 36 may be provided. For instance, referring to FIG. 3, it has been found that an opaque patch covering 38, having an adhesive backing 40, may be utilized. Patch 38 can be secured to the front wall 30 over the window 36 to render the entire front wall opaque.

Alternatively, referring to FIG. 4, a covering opaque flap or shade 42 may be permanently affixed by any conventional means, such as adhesive or heat. Flap 42 would then be disposed to obscure the window 36 by hanging loosely in front thereof or it may have an adhesive backing as does the patch cover 38 of FIG. 3.

It is well to mention at this point that, as the size and the shape of window 36 forms no part of this invention, neither does the size and shape of patch 38, flap 42, front wall 30 nor backwall 32. This statement is, of course, obvious when one views FIGS. 3 and 4. Those skilled in the art will readily recognize that the coverings 38 and 42 may be of a color that matches that of the front wall 30 so as not to distract from its uniform appearance.

In some embodiments of pouch 10, front and backwalls 30 and 32, respectively, may each be multi-ply or multilayer. In such cases, it will be obvious to those skilled in the art that either a window 36 would have to be incorporated in each layer comprising front wall 30 or each inside layer would have to be fabricated from transparent material.

The size and shape of the stoma 14 varies in different patients. In the application of a pouch to a patient, the stoma-receiving opening 12 should be sized and shaped to the approximate dimensions and configuration of the stoma so it can be precisely located over and in alignment with the stoma to insure that all the organic discharge will be directed into the pouch without damage to the stoma or skin. Before the present invention, it has been found that the initial contouring and configuration of the size and shape of the stoma-receiving opening 12 is often inaccurate. However, the present invention now assures that the stoma-receiving opening 12 will be contoured and sized precisely to the shape and dimensions of the stoma 14.

Although trial and error applications of the opening 12 to the stoma 14 is required, the user quickly becomes adept at initially cutting to size and shaping the opening 12 to the approximate size and shape of the stoma 14. Thereafter, by placing the opening 12 over the stoma 14 and viewing it through the window 36, the user can now accurately see how to reshape and resize the opening 12 to fit exactly to the contour and size of the stoma 14 and to verify its placement precisely in positive alignment with the stoma. Without this ability to actually see and verify the congruent relationship of the stoma-receiving opening 12 with the stoma 14, all prior applications of the pouch 10 to the stoma 14 were blindly performed on a hit and miss basis and were highly susceptible of error and miscalculation. The present invention eliminates all the guess work of the prior art. It now provides a simple and effective structure by which the stoma mucous membrane can be protected by the application of the pouch to the stoma and obviates the unattractive and distractive appearance presented by prior art pouches.

While what has been shown and described is believed to be the best mode and preferred embodiment of the invention, modifications and variations can be made therein, as will be clear to those skilled in the art, without departing from the spirit of the invention and, consequently, the scope of the invention is intended to be limited solely by the appended claims;

I claim:

1. An enterostomic pouch having at least front and backwalls defining a fecal chamber there between, the improvement comprising:

said front wall being substantially opaque, and said backwall having a stoma-receiving opening defined therein:  
a transparent window located in the front wall, said window being substantially opposite said stoma-receiving opening

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so that said opening is viewable directly therethrough; and

wherein at least the front wall is formed of a transparent vinyl material, said material being coated throughout its outer surface with an opaque material, and an area of said outer surface being free of the coating to result in said transparent window.

2. An enterostomic pouch as in claim 1, and opaque covering means on said front wall to removably cover said transparent window to obscure from view said window and stoma-receiving opening and to uncover the same for viewing.

3. An enterostomic pouch having at least front and backwalls defining a fecal chamber therebetween, the improvement comprising:

said front wall being substantially opaque, and said backwall having a stoma-receiving opening defined therein:

a transparent window located in the front wall, said window being substantially opposite said stoma-receiving opening so that said opening is viewable directly therethrough; and

wherein the substantially opaque front wall is formed of a substantially opaque vinyl material having an aperture defined therethrough, and a piece of transparent vinyl material bonded to said front wall covering said aperture to form a fluid tight transparent window in said front wall.

4. An enterostomic pouch as in claim 3, and opaque covering means on said front wall to removably cover said transparent window to obscure the view from said window and

stoma-receiving opening and to uncover the same for viewing.

5. An enterostomic pouch comprising:

a chamber having at least front and backwalls, at least the front wall being opaque and the backwall having a stoma-receiving opening therethrough wherein the improvement comprises;

said front wall having a transparent window, said stoma-receiving opening being located in said backwall such that the same is viewable through said window; and

means on said front wall for obscuring said transparent window and said stoma-receiving opening from view.

6. An enterostomic pouch as in claim 5, wherein the means for obscuring said transparent window comprises an opaque member having an adhesive backing whereby said patch may be positioned to cover and uncover said window, and to be secured in place when covering said window.

7. An enterostomic pouch as in claim 5, wherein the means for obscuring said transparent window comprises an opaque covering flap, at least one end of which is secured to the front wall and positioned on said front wall to hang in front said window.

8. An enterostomic pouch as in claim 6, said means for obscuring said transparent window being of the same color as said front wall.

9. An enterostomic pouch as in claim 7, said means for obscuring said transparent window being of the same color as said front wall.

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UNITED STATES PATENT OFFICE  
CERTIFICATE OF CORRECTION

Patent No. 3,570,490 Dated March 16, 1971

Inventor(s) LEON BERGER

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

IN THE CLAIMS:

- Claim 1, Line 2, change "backwalls" to -- back walls --  
Claim 1, Line 2, change "there between" to -- therebetween  
Claim 1, Line 3, after "comprising" delete the colon  
Claim 1, Line 4, change "backwall" to -- back wall --  
Claim 1, Line 5, after "therein" change the colon to a -- ,  
Claim 1, Line 8, after "therethrough" change the semicolon  
a -- , --  
Claim 1, Line 9, delete "and"  
Claim 3, Line 2, change "backwalls" to -- back walls --  
Claim 3, Line 3, after "comprising" delete the colon  
Claim 3, Line 4, change "backwall" to -- back wall --  
Claim 3, Line 5, after "therein" change the colon to a -- ,  
Claim 3, Line 8, after "therethrough" change the semicolon  
to a -- , --  
Claim 3, Line 9, delete "and"  
Claim 4, Line 3, after "obscure" delete "the" and substitut  
-- from -- and after "view" delete "from"  
Claim 5, Line 1, after "comprising" delete the colon  
Claim 5, Line 2, change "backwalls" to -- back walls --  
Claim 5, Line 3, change "backwall" to -- back wall --  
Claim 5, Line 5, after "comprises" delete the semicolon  
Claim 5, Line 7, change "backwall" to -- back wall --  
Claim 5, Line 8, at the end thereof, delete "and" and inser  
the same in front of Line 9  
Claim 7, Line 4, after "hang in front", delete "said" and  
substitute -- of --

Signed and sealed this 10th day of August 1971.

(SEAL)

Attest:

EDWARD M. FLETCHER, JR.

Attesting Officer

WILLIAM E. SCHUYLER, JR.

Commissioner of Patents