United States Patent

[11] **3,618,606**

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[54] **STOMA BAG**
6 Claims, 12 Drawing Figs.

[52] **U.S. Cl.** **128/283**
[51] **Int. Cl.** **A61f 5/44**
[50] **Field of Search** 128/275, 283, 294, 295

[56] **References Cited**

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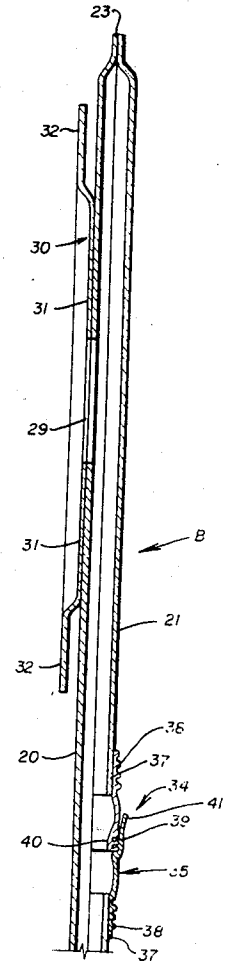
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ABSTRACT: A stoma bag formed of flat sheets of polyethylene or like material, characterized by a mounting pad at the intake thereof which is adapted to be cemented to the body of a patient. The mounting pad is affixed to the bag at a connecting face about the stoma orifice and this pad includes a peripheral flap about the connecting face. At the outer side of the bag, an access means is provided, either as a slit normally closed by enmeshing closure strips, or a flap valve. A further embodiment, adapted for a ureterostomy bag includes a check valve within the bag.



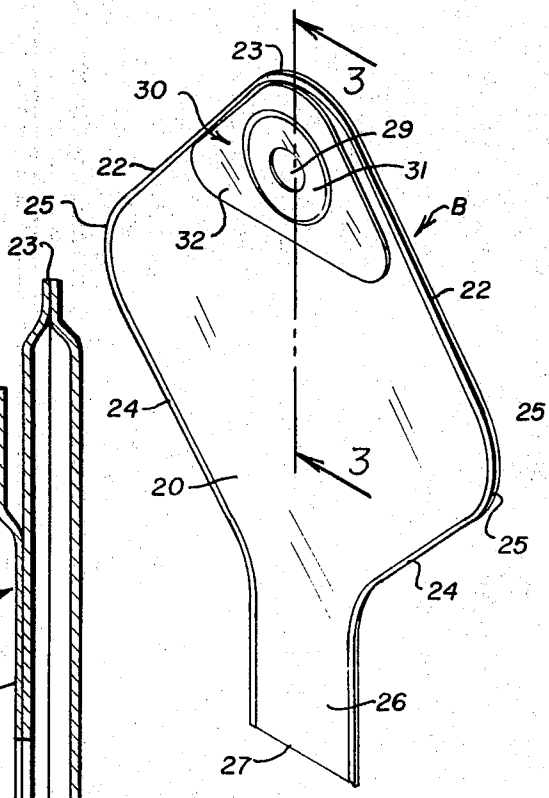


FIG. 1

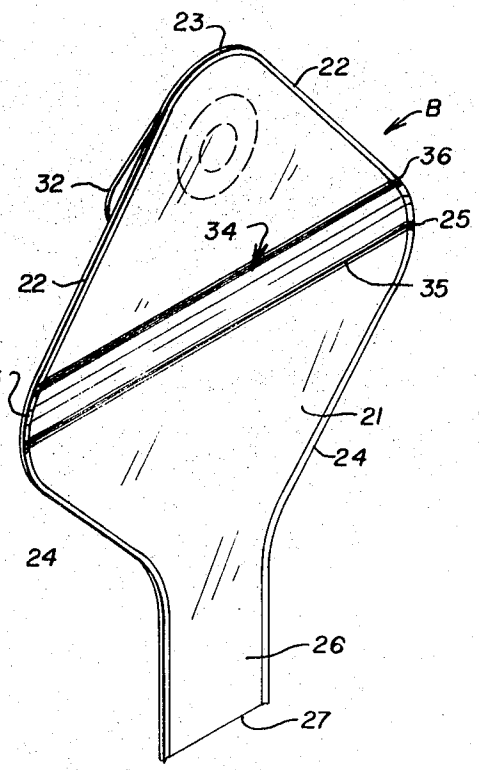


FIG. 2

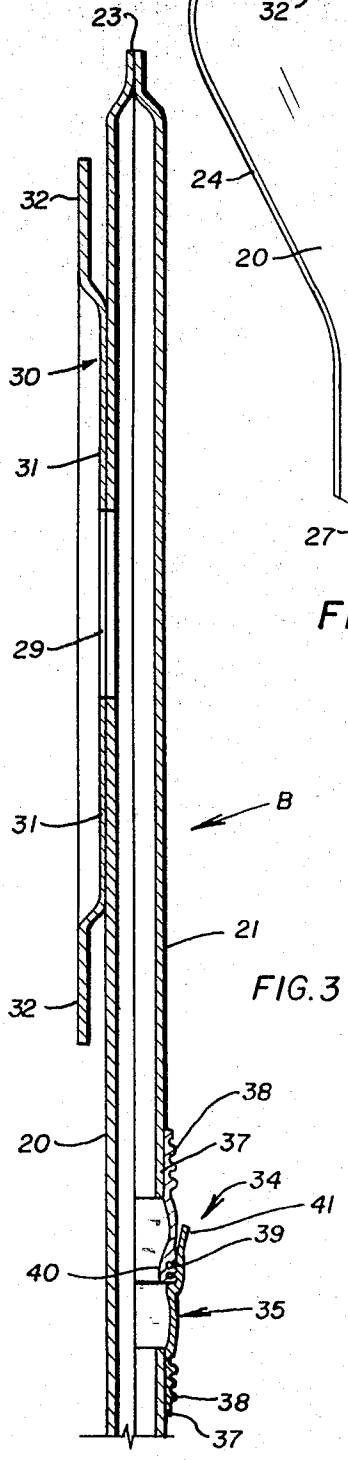


FIG. 3

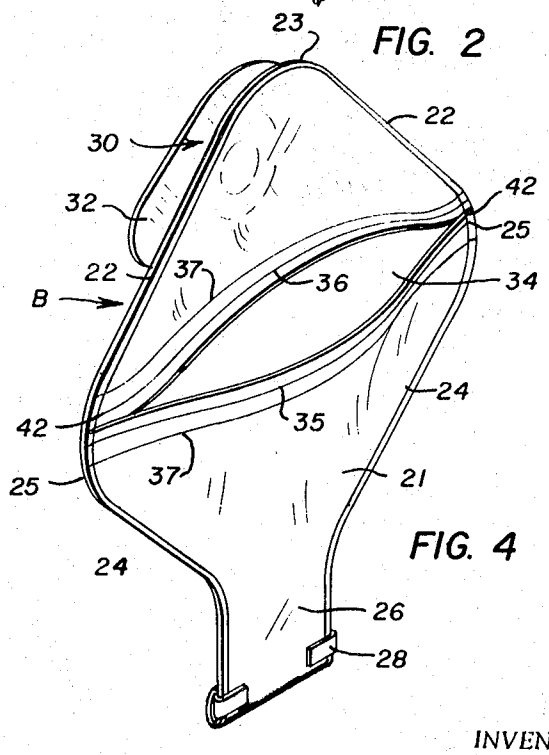


FIG. 4

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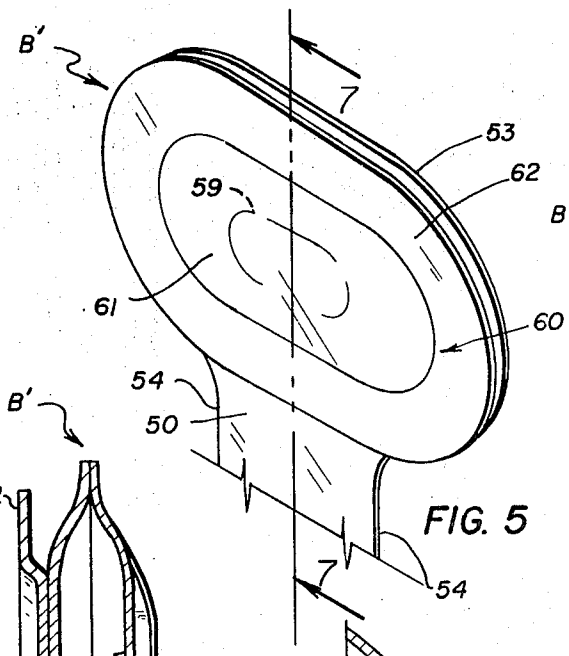


FIG. 5

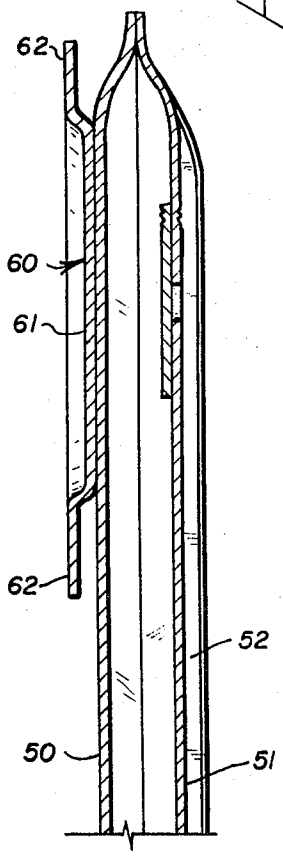


FIG. 7

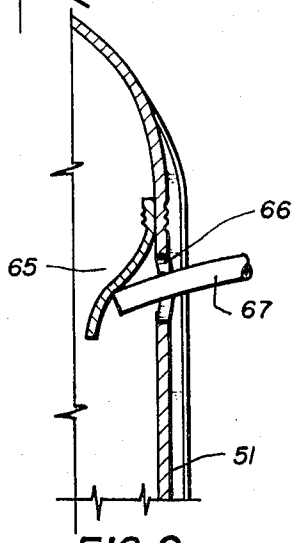


FIG. 9

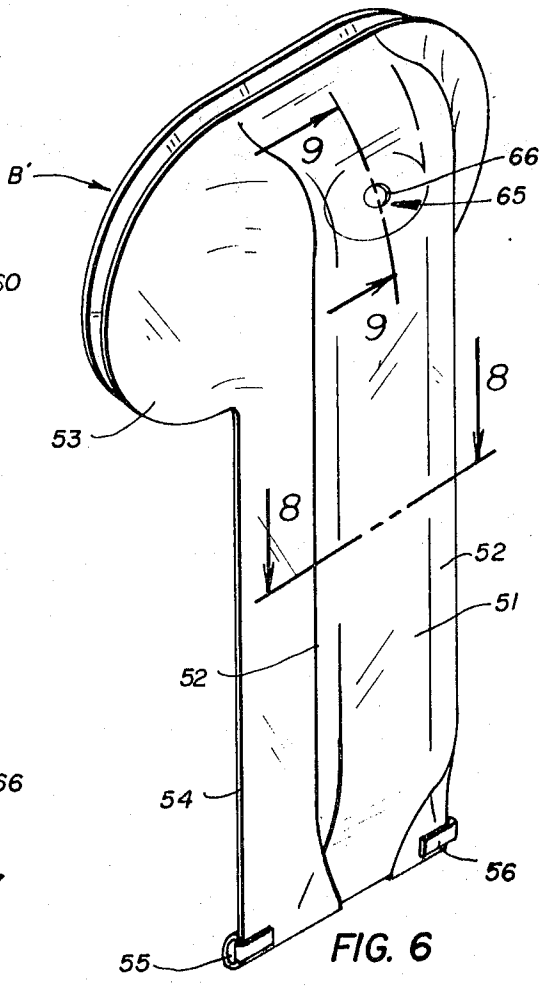


FIG. 6

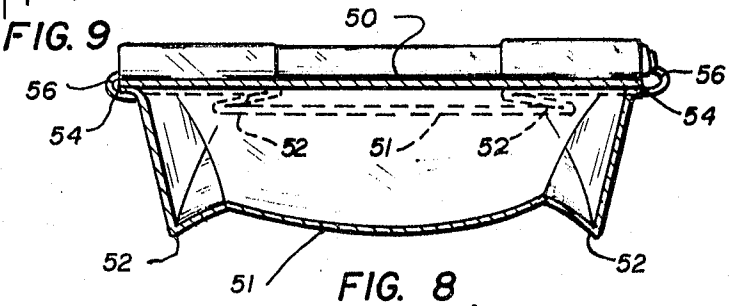


FIG. 8

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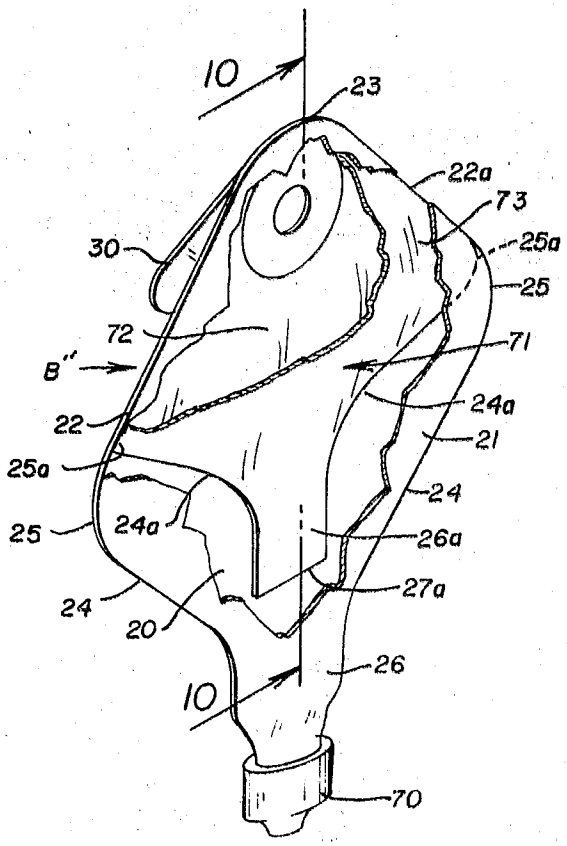


FIG. 10

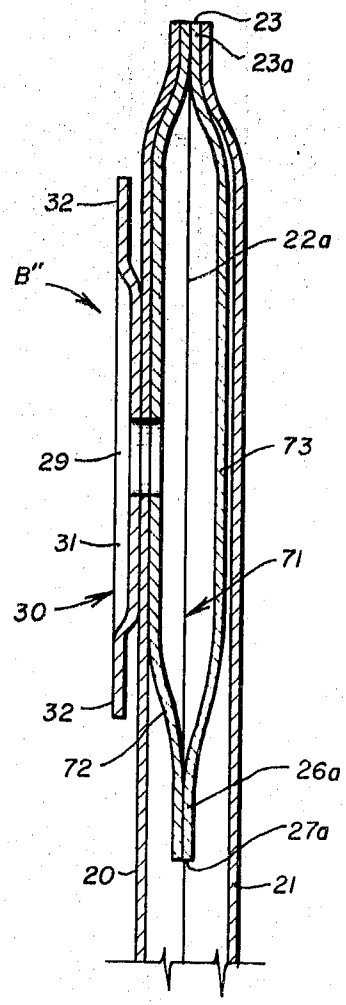


FIG. 11

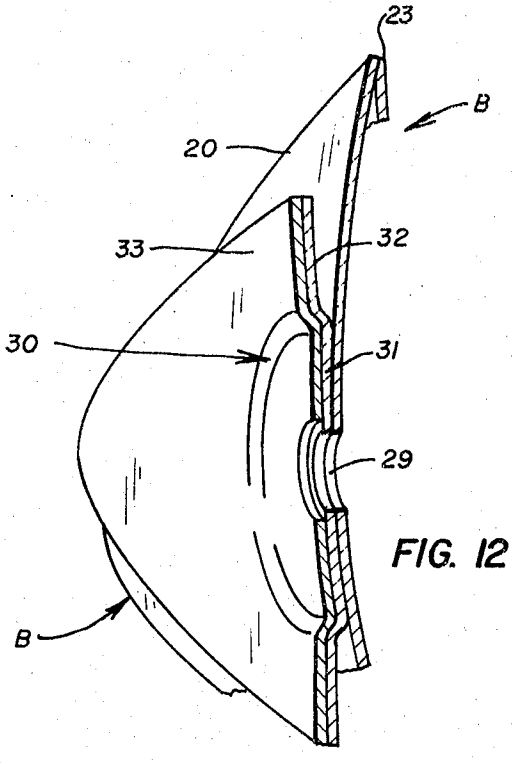


FIG. 12

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STOMA BAG

This invention relates to postsurgical appliances and more particularly to stoma bags, the general objects of the invention being to provide a novel and improved construction of a stoma bag to enhance the comfort of the patient using it, and to render the use of the bag more versatile and better adapted to the needs of the patient.

A stoma bag is necessary for patients who have undergone abdominal surgery involving a colostomy, ileostomy, ureterostomy or the like. Such surgical procedures will necessitate the diversion of a bowel or uretal duct through the patient's abdominal wall to there form a stoma wherethrough excretory substances and fluids will be discharged. This discharge is usually in a manner which cannot be controlled by the patient and it is necessary to provide a bag which is attached to the body over the stoma to receive such discharge. The bag must be removable or at least capable of being opened so that it may be emptied and otherwise attended to at convenient times.

The earlier types of stoma bags were secured to the body of the patient by straps. Such a bag was usually formed with a comparatively heavy flange at its inlet which was forcibly held over the stoma. For example, such a bag is disclosed in the U.S. Pat. No. 1,922,763 by Gricks. Subsequently, improvements in body adhesives of various sorts permitted these bags to be cemented directly upon the patient's body. A bag using this mode of attachment is disclosed in the U.S. Pat. No. 3,366,116 To Huck, where a pliable, thin-sheet polyethylene bag is used and a sheet of double faced adhesive material is affixed at the upper portion of the bag about the opening and to the body of the patient. That bag, as disclosed in the Huck patent, is more specifically a urine bag, and a more popular mode for the attachment of stoma bags has been to provide a comparatively heavy and substantially rigid, oval mounting plate of a plastic material such as polyethylene. This plate is formed with a central orifice through it wherethrough the stoma will protrude and a flanged mounting ring encircles the orifice. In use, the plate is cemented to the patient'body over the stoma and thereafter, a bag having an elastic opening is fitted upon this ring. The advantage of such an arrangement is that the bag can be removed for treatment of the stoma or for therapeutic irrigation or the like.

Certain disadvantages are inherent in the use of either type of the bags which are cemented to the body. The use of a rigid mounting plate can produce considerable discomfort, and movements such as bending and stooping, are often accompanied by a painful pulling of the skin about the plate. Also, the same result occurs whenever a pliable bag is cemented directly onto the patient and becomes partially full. Moreover, whenever a bag is cemented directly to the patient's body, there is the further disadvantage of limiting the access to the stoma unless the bag is removed.

In using either bag, the type with a rigid plate cemented to the patient's body, or the type which is cemented directly upon the patient's body, it was found necessary to connect the plate or bag to a substantial area of surface skin, and substantially more than a narrow ring of skin about the stoma, to prevent the overstressing of and pulling of the patient's skin. The dilemma arises because whenever the area of skin to which the bag is cemented is sufficiently large as to comfortably resist the pull of a filled bag, the area is so large as to impose a restraint upon the patient's normal body movements.

The present invention was conceived and developed to provide a stoma bag which overcomes the above-mentioned objections to the existing types of bags and comprises, in essence, a stoma bag formed with a pliable mounting flap at the opening. This flap has an adequate surface area to be cemented to the skin of the patient's body, but is secured to only a limited portion of the bag about its opening, The invention comprises further, in combination with the mounting flap, a simplified means to permit easy and quick access to the pouch interior for controlling and restraining fluids flowing into the bag.

Accordingly, an object of the invention is to provide a novel and improved stoma bag which is cemented to the body of a patient in a manner which insures a maximum degree of comfort to the patient.

Another object of the invention is to provide a novel and improved stoma bag which is adapted to be cemented to the body of a patient, and also be easily opened for access to the stoma for cleansing and treatment of the same.

Another object of the invention is to provide a novel and improved colostomy bag which is adapted to be cemented to the body of a patient and also includes a simple, effective access into the upper portion of the bag for irrigation, treatment and pressure relief.

A further object of the invention is to provide a novel and improved ureterostomy bag adapted to be cemented to the body of a patient and which also includes a simple, effective valving arrangement at the intake which prevents backflow of fluids into the stoma duct.

Other objects of the invention are to provide in a novel and improved stoma bag, a simple, versatile, low-cost and reliable unit.

With the foregoing and other object in view, all of which more fully hereinafter appear, our invention comprises certain constructions, combinations and arrangements of parts and elements, as hereinafter described, defined in the appended claims and illustrated in the accompanying drawing in which:

FIG. 1 is an isometric body-side view of a stoma bag constructed according to the invention and formed to be especially useful as an ileostomy bag or a ureterostomy bag.

FIG. 2 is an isometric front view of a bag such as an ileostomy bag, and as such, having an access slit therein which is shown as being closed.

FIG. 3 is a fragmentary sectional elevation view, as taken from the indicated line 3—3 at FIG. 1, but on an enlarged scale and with the thickness of the components forming the bag being somewhat exaggerated to better illustrate their construction.

FIG. 4 is an isometric front view of the bag illustrated at Fig. 2, but with the bag being distorted as when in use, and with the access slit being opened and the discharge end of the bag being closed.

FIG. 5 is an isometric body-side view of the upper portion of a stoma bag constructed according to the invention, which is especially useful as a colostomy bag.

FIG. 6 is an isometric front view of the colostomy bag illustrated at Fig. 5, but showing the entire bag, with the bottom thereof closed and with the bag being partially distended as when in use.

FIG. 7 is a fragmentary sectional elevation view as taken from the indicated line 7—7 at Fig. 5, but on an enlarged scale and with the thickness of the components being somewhat exaggerated to better illustrate their construction.

FIG. 8 is a transverse sectional detail as taken from the indicated line 8—8 at Fig. 6, but on an enlarged scale and with broken lines indicating the form of the bag when it is collapsed.

FIG. 9 is a fragmentary sectional detail as taken from the indicated line 9—9 at Fig. 6, but on an enlarged scale and with a device being inserted into the interior of the bag through the valve structure depicted therein.

FIG. 10 is an isometric front elevational view of a bag constructed in the general form of the unit illustrated at Figs. 1 and 2, but being especially adapted as a ureterostomy bag and with portions being removed to show a flap valve construction within the unit.

FIG. 11 is a fragmentary sectional elevation view as taken from the indicated line 11–11 at Fig. 10, but on an enlarged scale and with the thickness of the components being somewhat exaggerated to better illustrate their construction.

FIG. 12 is a fragmentary isometric sectional view of a portion of the body-side of a bag constructed according to the invention, showing the structure as being modified to include a layer of body cement on the mounting pad portion thereof.

The improved stoma bags, hereinafter described, are conveniently formed of sheets of a thin, impermeable, pliable, but tough synthetic resin plastic such as polyethylene. Polyethylene is ideally suited for this purpose for the edges and surfaces are easily welded or heat sealed together. The stoma bags which may be in the order of 4 to 8 inches wide and 9 to 18 inches long, may be formed of polyethylene sheets having a thickness of only 4 mills and still be adequately strong for the purpose at hand. Accordingly, the bags will be hereinafter described as being made of polyethylene, but it is to be understood that they may be made of other, similar materials.

Referring more particularly to the drawing, the bag B illustrated at Figs. **1** to **4**, is suitable for use as an ileostomy bag or as a ureterostomy bag under circumstances where access to the interior of the bag is desirable. This bag is formed of two flat sheets of polyethylene welded together at their edges with one sheet constituting the body-side sheet **20** and the other, a similar sheet, the outer-side sheet **21**. Accordingly, when the bag is empty, it is in a generally flat form, that of the sheets **20** and **21**, and is preferably diamond shaped with upward sloping edges **22** converging to a rounded apex **23**. Downward sloping edges **24** below rounded equator points **25** converge but turn downwardly at the base to form a flaplike discharge passage **26** and a comparatively narrow opening **27** at the bottom edge of the unit. In use, it is to be noted that this discharge flap **26** will be closed in any suitable manner as by a clamp **28**, illustrated at Fig. **4**.

The inlet of this bag, near the top of the bag, is formed as an orifice **29** in the body sheet **20**, a short distance below the apex **23**. This orifice also extends through the sheet **20** and a mounting pad **30** is affixed to the body sheet **20** about the orifice. This pad is also formed of a thin sheet of polyethylene, or like material, and is preferably somewhat thicker than the sheet material forming the pad, but not thick enough to modify the basic characteristics of the material. For example, with a 4-mil thickness of the sheet **20**, an 8-mil thickness of the pad is adequate.

The mounting pad **30** is formed as two portions: a circular, central connective face **31** which is heat sealed to the body pad **30** and a flap **32** circumscribing the connective face **31**. The flap may be in any suitable form such as the triangular form illustrated. The total area of this pad **30** is large enough to cover a sufficient surface area of the patient's skin to reduce the unit stress or pull thereon to a comfortable minimum. At the same time, the area of the connective face **31** is not only large enough to merely secure the bag to the pad, but is substantially larger to better hold the bag to the patient's skin and also providing an allowance for increasing the size of the orifice **29** therein whenever such becomes necessary. As clearly shown at Figs. **1** and **3**, this welded area **31** has a diameter substantially greater than twice the diameter of the orifice **29**.

With this arrangement, the mounting pads **30** may be cemented onto the body of the patient, but only that portion of the bag which is at the connective face **31** will be held against the patient's skin about the stoma and the remainder of the bag may pull away from lying against the body of the patient. Nevertheless, the entire skin area covered by the peripheral flap will facilitate holding the bag B in place, all without unduly pulling the patient's skin.

As heretofore stated, a number of commercial cements are available to cement the polyethylene pad to the body surface of the patient. Two such cements are: 3-M Seal-Body Cement and Tincture of Benzoine. The manner in which these cements are used is well known. For example, a layer of cement may be applied to the pad **30** and another layer applied to the body of the patient about the stoma. When the cement has dried to a proper stage of tackiness, the pad may be pressed into position with the stoma extending through the orifice **29**. Yet, a further expedient is to provide a layer of doubly faced adhesive material, such as Micrapor tape **33**, upon the face of the pad, as illustrated at Fig. **10**. The tape **33** will adhere to the pad **30** and the exposed face will adhere to the body skin when the unit is pressed into position against the patient's body over the stoma.

In the construction illustrated at Figs. **2**, **3** and **4**, the outer side **21** of the bag is provided with a transverse, slitlike opening **34** across its center, that is, from each equator point **25**. This opening is provided with a closure which consists of two intermeshing lengths of zipperlike closure strips **35** and **36**, of a type which effects a complete closure when closed, but which may be opened to provide access to the interior of the bag. These zipperlike closure strips may be of a type furnished by the Flex-Grip Company or Orangeburg, N.Y., generally sold under the trademark FLEXTITE GRIP and are provided as polyvinyl and polyethylene extrusions which may be welded to the outer side of the bag by the same heat seal methods used in forming other portions of the bag.

The manner in which the closure strips function is illustrated at Figs. **3** and **4**. Each extruded or molded polyethylene strip **35** and **36** has a ribbonlike base **37** which is welded to the polyethylene sheet **20** and small ridges **38** are formed in this base to enhance its rigidity. The sealing of each with the other is accomplished by a pair of convoluted ridges **39** on the strip **35** which meshes with mating, opposing, convoluted ridges **40** of the opposite strip **36**. The lower, outer strip **35** of these two is also provided with a small gripper ribbon **41** which facilitates pulling the intermeshing ridges **39** and **40** apart when it is desired to open the unit.

In the manufacture of this bag B, the components are formed by conventional heat seal procedures as heretofore mentioned. The first step is to weld the mounting pad **30** upon the body sheet **20** and to weld the closure strips **35** and **36** upon the outer sheet **21**. Next, the sheets are placed together in registration and are simultaneously cut to form and welded together about their peripheral edges. A special welding step may be necessary at the equator points **25** where the ends of the closure strips join to prevent leaking at the end of the strips and a small pad weld **42** may be required to effect a good seal action.

In use, this bag is first prepared by opening the orifice **29** to a size suitable to fit about the stoma of the patient. Next, the stoma may be temporarily plugged by an absorbent pad to prevent the flow of body fluids while the bag is being attached thereto as with a body cement, as heretofore described. After the bag is properly cemented to the body of the patient, the plug is removed from the stoma to permit normal function and operation thereof. As a final step, the discharge flap at the bottom of the bag is closed by the clamp **28** and the bag is ready for use. As the bag fills, it may be periodically discharged by releasing the clamp **28** and less frequently, the stoma may be treated by separating the closure strips **35** and **36**. Once the stoma is treated, the bag is again closed for reuse and for a period of several weeks or until it becomes detached from the skin through a natural sluffing of the patient's skin.

The colostomy bag B', illustrated at Figs. **5** through **8**, is formed as a similar, but comparatively elongated structure of polyethylene sheets including a body sheet **50** and an outer sheet **51**, which are heat welded together about their peripheral edges. The body sheet is a flat sheet adapted to lie flatly against a patient's body while the outer sheet **51** is also formed flatly, but with a pair of opposing, longitudinal pleats **52** in its central portion. These sheets **50** and **51**, when lying together, form an oval head **53** from which extends the elongated, downwardly directed bag portion with parallel sides **54** and with an open, bottom edge **55** which may normally be closed by a wrap-up clamp **56**.

A mounting pad **60**, of the same form as the head **53**, includes an oval central connecting face **61** which is welded to the body sheet **50** and a flap **62** circumscribes this central portion. In the construction illustrated, an orifice within the central face **61** is not shown; however, it is to be understood that it may be easily cut therein as with scissors, to the form shown in broken lines **59** or to any other desired form to fit about a stoma.

As an additional feature, the outer sheet **51** includes a flap valve **65** near the upper end and at a location which will oppose the orifice **59** through which the stoma will protrude. This flap valve is formed as an orifice **66** on the wall of the outer sheet **51** and the flap **65** is a small tab of polyethylene sheet which is welded to the upper edge of the inner side of the sheet **51**. The flap will normally cover the orifice, but is adapted to flex inwardly away from the orifice so that access to the interior of the bag is possible, by inserting an irrigation tube **67** or the like into the orifice.

The construction illustrated at Figs. **9** and **10** shows a bag B'' constructed similar to that of Fig. **1**, but adapted especially as a ureterstoma bag. The general form of the bag is substantially the same as that heretofore described, a two-piece unit having a body side sheet **20** and an outer side sheet **21** in the general form of a diamond-shaped unit with upper, sloping edges **22**, a rounded apex point **23**, downward sloping edges **24** from the opposite equator points **25**, which turn into a discharge passage **26** as heretofore described. For the purpose at hand, the discharge may terminate as a slit-opening **27** which may be closed by a clamp **28**, as previously described, or as a manual valve **70** as illustrated at Fig. **9**. The unit is also provided with a mounting pad **30** at the upper end of the body-side sheet as heretofore described.

The upper, triangular portion of the bag, defined by the sloping edges **22** extending from the equator points **25** to the apex **23**, contains a check valve **71**, a supplemental bag, which lies between the polyethylene sheets **20** and **21**. This check valve bag **71** is also formed of two flat polyethylene sheets, a body-side sheet **72** and an outer-side sheet **73** and is similar in shape to the bag B'', although approximately half as large. The check valve bag **71** will include top edges **22***a* which merge to an apex **23***a* to be congruent with and heat sealed to the upper portions of the bag **22** and apex **23**. The lower edges **24***a* of this check valve bag **71** converge downwardly from equator points **25***a* to a narrowed discharge passage **26***a* which has an opening at its bottom edge **27***a*, at the center of the bag B''. In mounting the check valve bag **71** within the bag B'', the body-side sheet **72** is welded to the body-side sheet **20** in the area above the central connecting surface **31** of the pad **30** as illustrated at Fig. **10**. However, it is contemplated that the outer side sheet **73** will be free from connection with the outer side sheet **21** except along the common edges **22** and **22***a* and common apex points **23** and **23***a*.

This bag is affixed to a body of a patient in precisely the same manner as that heretofore described and as fluid is discharged from the ureterostoma, it will pass through the flap valve and be directed into the bag therebelow and ultimately, periodically disposed of by opening the valve **70**. It is apparent that fluids discharged through the flap valve **71** and into the bag B' cannot reverse in flow and into the check valve for any bag pressure will tightly close the discharge passage **26***a*. This is especially desirable where a patient wearing the bag happens to be sleeping and unknowingly rolls over and onto a partially filled bag creating a substantial pressure in the bag. Naturally, when the bag is made of good quality polyethylene, it will not rupture because of the pressure of the weight of the patient upon it, but at the same time, there will be no tendency for a reversal of flow to either cause a leak at the connection between the pad and the patients's body or to even initiate a reverse flow into the uterine tube terminating at the stoma.

We have now described our invention in considerable detail. However, it is obvious that others skilled in the art can build and devise alternate and equivalent constructions which are nevertheless within the spirit and scope of our invention. Hence, we desire that our protection be limited, not by the constructions illustrated and described, but only by the proper scope of the appended claims.

We claim:

1. In a stoma bag of the type adapted to be attached to the body of a patient and formed of two thin sheets of tough but pliable material, having the general characteristics of polyethylene, welded together at the peripheral edges thereof with one sheet constituting the body-side of the bag and the other sheet the outer-side of the bag and having further, a small intake orifice near the top of the body-side sheet and a discharge outlet at the base of the bag, the improvement comprising:

a mounting pad connected to the stoma bag about said intake orifice for attachment of the stoma bag to the body of the patient, formed as a thin flat sheet of a lightweight, tough, but pliable material having a thickness not substantially greater than the thickness of the bar, having the general characteristics of polyethylene and being weldable to the body-side sheet of the stoma bag;

the width and length of said pad being comparable to each other with the proportions of the width and length being substantially greater than the intake orifice in the stoma bag;

a substantial central portion of said pad being flatly welded to the surface of the body-side sheet of the stoma bag, about the orifice,

and having a diameter at least twice the diameter of the orifice with the remainder of the pad forming a flat, peripheral flap completely about the central welded portion adapted to lie flatly in the plane of the central welded portion;

and said pad including a body cement means at its entire outer face for attachment of the same flatly against the patient's body.

2. In the organization defined in claim **1** wherein

the aforesaid central portion of said pad and the portion of the body-side sheet to which this central portion is welded covers an area substantially greater than the orifice to permit the same to be cut about the orifice to enlarge the orifice to fit about a patient's stoma.

3. In the organization defined in claim **1** wherein said bag is formed as a diamond-shaped unit, with said intake and pad being near the top apex point thereof;

an access opening at the outer side sheet of the bag across the equator thereof, from near one side point of the diamond to the opposite side point of the diamond;

intermeshing closure strips affixed to the surface of the opening, at each side thereof, to be normally engaged to maintain the bag in a closed condition, but adapted to be separated to open the bag; and

a downward extension of said bag at the base point of the diamond forming said discharge outlet.

4. In the organization defined in claim **1**, wherein the bag is an elongated construction having an enlarged transverse head near the top thereof, at the intake; and

wherein the aforesaid outer side sheet is pleated at the outer side of the bag, the full length of the bag, to permit the same to expand as the bag is filled.

5. In the organization defined in claim **1**, wherein the sheets forming the stoma bag are approximately 4 mils thick and the sheet forming the mounting pad is in the same range of thickness and not greatly exceeding, as a maximum thickness, 8 mils whereby to provide a flexibility and pliability comparable to the sheets forming the stoma bag.

6. In the organization set forth in claim **1**, including a means for access into the bag from the outer-side sheet thereof which is located generally at the center of the portion of the bag near the intake thereof.

* * * * *