COLOSTOMY APPLIANCE ADHESIVE PATCH FOR FASTENING SAME TO THE BODY

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This invention relates to a double-faced adhesive patch of non-woven fibrous material particularly well suited for use as a means for temporarily fastening medical appliances and the like to the skin. The patch is characterized by a coating of a non-drying pressure sensitive adhesive on both sides of the fabric that remains covered and thus protected until ready for use by a conventional silicon-impregnated paper rip-strip that forms a laminate therewith. The invention also encompasses the method of making the laminate which consists of coating the releasable surfaces of the silicone-coated rip-strips with the pressure-sensitive non-drying adhesive preparatory to sandwiching the base uncoated fabric therebetween. The invention additionally includes a colostomy appliance consisting of a slightly modified form of the patch permanently glued to the rear face of a side-pleated expandable polyethylene bag having a foldable flap at the bottom and permanently folded flap at the top, the outer layer of which can be turned inside out.

4 Claims. 5 Drawing Figures
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Surgical procedures such as, for example, circumostomies, colostomies, cutaneous ureterostomies, ileostomies and the like result in the patient being provided with a new waste material outlet or stoma in the body as a result of having had to by-pass the natural openings either temporarily or permanently. In order to handle the body waste discharge through said stoma, it becomes necessary to temporarily attach a bag or other suitable receptacle in position to receive same as the patient is left without any natural ability to control such emissions. Accordingly, the patient is provided with what is known as a colostomy appliance that consists of a disposable plastic bag openable and reclosable at its lower end and some means for temporarily fastening same to the body so that the inlet thereto registers with the surgically-produced stoma and is sealed therearound. Ordinarily, these appliances remain affixed to the body only a relatively short time before they come off and have to be replaced with a fresh one. Some people, in fact, experience considerable difficulty in getting the appliances to adhere at all to their skin while others are subject to considerable irritation of the skin area bordering the opening due to the presence of the appliance. Even so, generally speaking, a patient tries to keep the appliance on as long as possible because of the difficulty and inconvenience occasioned by having to change same.

The prior art colostomy appliances leave much to be desired in the way of convenience, comfort, reliability, lack of irritation, sanitation and ability to stay in place for prolonged periods of use. Several methods are currently employed to fasten the bags in place over the stoma opening into the colon, one of the most widely used being that of strapping, gluing or otherwise fastening a flexible yet essentially non-elastic and fluid-impervious carrier to the skin with an opening therein registering with the surgically-created stoma and then hanging a disposable plastic bag from such carrier. Proper sealing of the carrier to the skin is most difficult to achieve, especially when the non-elastic nature of the carrier will not accommodate the stretching of the skin therebeneath that takes place even with ordinary body motion such as that occasioned by breathing, walking, bending and other activities that are anything but hyperactive. Also, the impervious nature of the carrier is such that many persons experience severe skin irritation due to lack of air circulation, perspiration, the presence of the sealant or adhesive and the reaction to the body wastes which are difficult, if not impossible, to effectively isolate.

Conversely, the use of a carrier has the advantage over the practice of fastening the appliance directly to the body in that the carrier need not be removed every time the bag is changed and, therefore, it becomes in a sense, semi-permanent; whereas, the directly-attached bag is, at best, highly temporary and must, by its very nature, be changed at frequent intervals. Nevertheless, the bag adapted for direct attachment to the body has certain distinct advantages of its own. To begin with, it is far better able to accommodate flexion of the skin therebeneath although it still leaves much to be desired in this connection and still suffers from the disadvantage of not being able to “breath”, i.e. allow air to circulate between the bag and the body. Accordingly, skin irritation remains very much a problem and, in fact, it may well be heightened in severity due to the necessity for changing same more frequently.

The bags themselves are, likewise, something less than ideal in that they rarely, if ever, provide a resealable opening in the top which some users find most convenient for purposes of periodic irrigation and inspection as well as the occasional introduction of deodorants and other additives. The bags should lay flat against the body, yet, expand as needed to accept the waste products. Most important, however, is the fact that the appliance including the bag should be able to withstand considerable handling while remaining capable of being resealed and all without becoming unfastened from the body.

It has now been found in accordance with the teaching of the instant invention that these and other shortcomings of the prior art colostomy appliances, both those using a carrier and those without, can, in large measure, be overcome through the use of a novel and improved double-faced adhesive-coated non-woven fabric patch that can either be used to attach the carrier to the body or alternatively, the bag itself. The non-woven fabric, while extremely thin, allows air to reach the skin due to the random arrangement of the fibers. Even more significant, however, is the ability of the fabric to bend, stretch and otherwise conform and deform to whatever extent required to accommodate the contours of the body as well as the movement of the skin therebeneath even under active conditions. Both of these factors contribute to the comfort of the appliance, greatly increase its retention properties, reduce skin irritation and otherwise lessen the burdens and inconvenience associated with having to wear same, all without detracting in any way with the function performed thereby.

Furthermore, an improved appliance has been discovered which, in addition to the aforementioned patch for fastening same directly to the body, has a novel side-pleated expandable bag provided with a permanently-folded flap along the opening in the top that includes an outer layer which can be turned inside out to define a marginal cuff bordering said opening that can be reclosed.

Finally, a unique method of making the patch has been discovered wherein, instead of coating both sides of the non-woven fabric with the pressure-sensitive non-drying adhesive preparatory to overlaying same with the silicone-coated rip-strips that form the protective cover therefor as would be expected, instead the releasable faces of the protective covers are first coated with the adhesive and the bare untreated fabric is subsequently sandwiched therebetween.

Accordingly, it is the principal object of the present invention to provide a novel and improved colostomy appliance.

A second objective of the invention herein disclosed and claimed is the provision of a special double-faced non-woven adhesive patch for detachably fastening the appliance to the skin, either directly or through the medium of a suitable carrier forming a part thereof.

Another object is to provide a unique method for making the patch which eliminates the problems associated with having to directly coat both sides of the non-woven fabric with adhesive.

Still another objective of the within described invention is the provision of an adhesively-attached colost-
tomy appliance wherein the bag is provided with side pleats and a reclosable and resealable opening in the top thereof.

Some additional objects of the invention forming the subject matter hereof are to provide a colostomy appliance that is comfortable, versatile, reliable, compact, safe to use, sanitary, completely disposable, easy to clean, simple to operate and quite inexpensive.

Further objects are to provide a double-faced patch of non-woven material coated on both sides with a non-drying pressure sensitive adhesive that can be fastened to the skin, yet which is non-irritating, secure, easy to affix and remove, porous, flexible as well as stretchable to the degree required to accommodate movement of the skin therebeneath, simple to manufacture, lightweight, soft, breathable and readily adapted for use with various types, styles and designs of medical appliances that must be detachably fastened to the patient.

Other objects will be in part apparent and in part pointed out specifically hereinafter in connection with the description of the drawings that follows, and in which:

FIG. 1 is a perspective view looking down and to the right upon the rear of the colostomy appliance prior to complete removal of the protective release paper in the back of the double-faced adhesive patch;

FIG. 2 is a front elevation showing the flaps at both ends, the one at the bottom being partially unfolded while the one at the top is broken away to better reveal the construction thereof;

FIG. 3 is a perspective view showing the back of the appliance as it would be seen from a point above and to the right of its upper righthand corner, the outer layer of the flap at the upper end having been shown, turned inside out to open the top of the bag while cooperating with the inner layer to define a marginal cuff encircling the latter;

FIG. 4 is an exploded view of the carrier and a modified form of patch for use therewith; and

FIG. 5 is a schematic view illustrating the method of forming the patch.

Referring next to the drawings for a detailed description of the present invention and, initially, to FIGS. 1, 2 and 3 for this purpose, reference numeral 10 has been chosen to broadly designate the colostomy appliance in its entirety while numeral 12 similarly designates a laminated subassembly affixed to the bag 14. This bag, in the particular form shown, comprises a polyethylene tube open at both its upper and lower ends that has been flattened and folded inwardly along both side margins in a manner to produce expansion pleats 16. Following formation of the pleats, the lower corners 18 are folded over on a 45° fold so as to bring the bottom margins 20 thereof into side-by-side parallel relation. Then, the isosceles triangle 22 (FIG. 1) thus formed is folded up along horizontal fold 24 and secured with a suitable fastener 26 to produce the necessary sealed, but reopentable, fluid-tight closure at the bottom.

The side pleats 16 do not extend all the way to the top of the bag, but instead, are opened up as shown in FIG. 1 preparatory to folding over flap 28 along the top of the bag. Next, the side margins 30 of the flap 28 are permanently heat-sealed to the corresponding margins 32 along the sides of the main body of the bag so as to define a common seam 34. With the flap 28 folded over and seamed as shown in FIGS. 1 and 2, the top opening 36 in the bag is essentially sealed. To open same, the user grasps the outer layer 38 of the flap and turns it inside out as shown in FIG. 3 thus producing a marginal cuff 40 around the open top of the bag. Removal of the fastener at the bottom allows the folded corners and bottom flap to be unfolded in the usual manner.

Directly underneath cuff 40 is permanently glued a laminated subassembly 42 that includes a non-woven fibrous patch 44 with an opening 46 in the center thereof registering with a corresponding opening in the rear wall 48 of the bag that is, in turn, placed over the stoma in the user's body (not shown). The exposed face 50 of the patch is coated with a pressure-sensitive non-drying adhesive protected until used by a rip-stripe 52 of silicone-coated paper or the like. If desired, a corner of the exposed face of the patch can be left uncoated to facilitate removal of the rip-strip or, alternatively, a permanent tab 54 can be fastened thereto in the well-known manner exemplified in FIG. 4. While the patch is "double-faced" in the sense that both sides are adhesive-coated, it is conceivable that the so-called "hidden" face 54 that lies against the bag could be coated with a permanent rather than a non-drying pressure-sensitive adhesive like the exposed face provided, of course, this could be done in such a way as to not interfere with the stripping action of the rip-stripe and the novel manufacturing process to be described presently. Accordingly, while this remains a possibility, the advantages attendant to using different types of adhesives on the hidden and exposed faces of the patch are so minimal when compared with using the same non-drying pressure-sensitive adhesive on both that the latter is much to be preferred.

While various formulations of non-drying pressure-sensitive adhesives well known in the art can be used with comparable results, a pressure-sensitive resin solution of low-molecular weight acrylic polymer has proven quite satisfactory. Care must be taken, of course, in the selection of a suitable adhesive to insure that it is free of skin irritants and, especially, that it is non-toxic for the reason that it will ultimately lie closely adjacent a stoma opening directly in to the user's colon. Such adhesives are, of course, widely used in bandaging materials and the like already.

Undoubtedly, the most important single feature of the invention is the non-woven fibrous material used as a base for the patch 42. Excellent results have been obtained by using as the base fabric the 0.3 ounce per square yard spunbonded "Nylon" sold by Monsanto Chemical Company under the trademark "Cerex." This fabric and others like it comprises an open porous network of randomly-laid fibers bonded together at their points of intersection to define sheets that can be obtained in varying thicknesses and porosities. For purposes of the present invention, the desired characteristics of the fabric are, first of all, the tensile strength it supplies to the pressure-sensitive patch. In other words, a pressure-sensitive non-drying adhesive applied directly to the rear face of either the bag or carrier for purposes of fastening the latter to the human body in the manner of ordinary adhesive tape or the like, is unsatisfactory because the adhesive has far too little tensile strength. When laminated with the non-woven fibrous material on the other hand, the patch thus produced provides the missing tensile strength necessary for good retention.
Secondly, the patch is thin and provides excellent conformity with the irregular surface of the user's body to which it is attached. This, together with its ability to flex and stretch in all directions to whatever degree necessary to accommodate the movements of the skin thereon, is also one of the most important criteria.

Third, due to the random lay of the fibers from which the fabric is constructed, it has the ability to "breathe" through the edges thereof and thus considerably reduce, if not eliminate altogether, skin irritation beneath the patch that is ordinarily encountered. This occurs even though the inside (exposed) face 48 of the patch is tightly sealed against the wearer's body and the outside (hidden) face 54 is similarly sealed against the non-porous bag or carrier therefor.

Finally, the base fabric must be soft, pliable and non-toxic so as to not contribute to any irritation of the skin over which it is laid nor to introduce any impurities into the body through the stoma it borders. While other fabrics commonly employed as bandaging materials such as, for example, gauze and like, possess some of these same properties, they are woven and, therefore, do not possess the same ability to conform, breathe and stretch in all directions as the non-woven fabric preferred herein. Furthermore, woven fabrics are characteristically many times thicker.

The rip-strip 50 is of conventional design and preferably comprises silicone-coated paper having a release factor as determined by a Keil tester of somewhere around 30 to 80 grams per inch of strip width. While other types of rip-strips can be substituted for the silicone-coated paper type with comparable results, the latter type has proven quite satisfactory.

In order to use the appliance, the user needs only remove the rip-strip from the exposed face 48 of the patch 42, cut a hole in the rear wall of the bag of the same size as the body opening and fasten the unit in place. If desired, the patch could, perhaps, be pre-punched in which event the opening thus formed could be employed as a template to assist the user in cutting a registering hole in the bag.

Next, with reference to FIG. 4, reference numeral 56 shows a representative bag carrier of the type that is strapped or adhesively attached to the wearer's body over the opening therein preparatory to hanging the disposable bags therefrom. The rear face 58 shown is the one that lies next to the wearer's skin and is, therefore, the only one that concerns us here. The front face (not shown) customarily has some kind of marginal flange or lip bordering the opening 60 therethrough to which the open neck of a suitably-shaped disposable bag is detachably connected and held in place by an elastic band, clip or some similar fastening means.

For present purposes, all that concerns us here is the rear face 58 to which is adhesively attached the double-faced patch 42.

The patch 42m is supplied to the user in the form of a laminated subsystem which differs slightly from the laminate 12 of FIGS. 1, 2 and 3 that fastens the bag directly to the wearer's body in that it has a shape adapted to mate with the carrier 56 to be used therewith and, secondly, its hidden face is also left covered by a rip-strip 50h until just before use. In order to attach the carrier to the body, the user simply removes the rip-strip 50h from the hidden face of the patch 42m and sticks the latter on the rear face 58 of the carrier.

Then, the second rip-strip 50e is removed from the exposed face 48 of the patch 42m preparatory to fastening the assembly thus formed to the body. A corner of the patch 42m is preferably covered permanently by a small tab 52 so as to facilitate removal of the rip-strips therefrom as well as the patch itself from both the body and carrier following use.

Finally, with reference to FIG. 5, the novel method of making the laminate has been shown schematically. The extremely thin character of the non-woven fabric 62 from which the patch 42 is fabricated renders it unsuitable for applying adhesive-coatings thereto by the usual methods. While the fabric can be dipped in adhesive, the resulting patch is rendered essentially non-porous due to the interstices between the fibers being filled with the latter. Furthermore, the resulting patch is stiff, less elastic, somewhat more abrasive and generally less suitable all around. Accordingly, it has been discovered that the best way of preserving the desirable characteristics inherent in the non-woven fabric that render it ideally suited for use in the instant application is to not coat the adhesive 64 on the fabric directly but, instead, indirectly by coating the releasable surfaces 66 of the rip-strips 50h and 50e therewith preparatory to sandwiching the uncoated fabric 62 therebetween. This unique method of forming the laminate is represented in FIG. 5 by the pinch rollers 68 which are shown squeezing a layer of the uncoated non-woven fabric 62 between two sheets of silicone-impregnated rip-strip 50h and 50e to the opposed releasable surfaces 66 of which has been applied a coating of the non-drying pressure-sensitive adhesive 64. The procedure of sandwiching the uncoated fabric between the adhesive-coated sheets of rip-strip transfers the adhesive to the fabric thus forming the patch 42. When the rip-strips are removed, the adhesive stays with the fabric due to its substantially greater retention ability or affinity for the latter.

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