

COLOSTOMY APPLIANCE AND COLOSTOMY OR
ILEOSTOMY BAG

This invention relates to a colostomy appliance, and to a colostomy or ileostomy bag.

One of the perennial problems faced by colostomists is the distension of their stoma bags by flatus. A fully
5 inflated stoma bag is cumbersome and uncomfortable, and for many years the only solution to this problem has been to pierce the inflated bag with a pin, vent the gas, and then re-seal the bag with a piece of adhesive tape. This
10 procedure is both inconvenient and unnecessarily awkward, especially for the older arthritic patient.

Over the last two or three years this situation has been improved somewhat by the introduction of the flatus filter. This device takes the form of a small vent in the
15 stoma bag which is covered by a material with deodourizing properties, e.g. activated charcoal. Flatus passes freely through this vent, without causing odour problems, and thus does not inflate the bag to any large degree. The main
20 problem with this device is that the permanently open vent allows a completely uncontrolled passage of flatus and therefore the bag becomes completely deflated. When this
happens the front wall of the bag may stick to the stoma, and any faecal matter which passes cannot fall to the bottom of the bag and clogs the bag around the stoma. This can lead
to faecal leakage between the body and the adhesive.

25 As a result of this problem, many patients immobilize the filter by sticking a piece of impermeable adhesive tape over it. They then achieve a degree of continence of flatus in that they choose when to remove the tape and allow flatus to vent. However, in order to carry out this
30 operation, it is necessary for the patient to be in private because he has first to loosen or remove clothing. This is a severe disadvantage because it is when the patient is in company that the distension of the bag is a particular problem.

British Patent Specification No. 1,379,464 discloses a collection pouch such as a stoma bag provided with a releasably sealable vent aperture for exhausting gases from the bag.

5 British Patent Specification No. 1,416,594 discloses a colostomy or ileostomy bag provided with a venting valve covered by an adhesive-covered disc.

British Patent Application No. 2,036,564 discloses a collection appliance such as a colostomy pouch provided
10 with gas outlet aperture means in the form of a slit which performs a valving function.

U.S. Patent Specification No. 3,865,109 discloses a colostomy attachment employing a faecal pouch with self venting means for trapped gases.

15 U.S. Patent Specification No. 3,216,420 discloses a colostomy attachment comprising a colostomy bag provided with normally closed manually openable valve means for release of trapped gases.

U.S. Patent Specification No. 4,120,715 discloses
20 a method of making a filter for use in venting a colostomy or ileostomy bag.

U.S. Patent Specification No. 4,268,286 discloses an attachable and detachable filter for use with an ostomy bag, said filter comprising a plastics housing
25 member having two sections hinged together by an integral hinge.

The present invention provides a colostomy appliance comprising a stoma bag having a vent outlet sealed with a pressure relief valve forming a fluid-tight seal when closed, said valve being adapted to open when a predetermined gas pressure, specified below,

is reached in said bag, said vent outlet being associated with a deodourizing filter through which gas is vented from said bag.

The maximum pressure at which the pressure relief valve opens must be less than the bursting pressure of the stoma bag, and the minimum pressure should be sufficient to ensure sufficient inflation of the bag to prevent collapse of the bag onto the stoma. Therefore the pressure relief valve is adapted to open at relatively low pressures, viz. 0.15 to 0.8 p.s.i.g. (0.0105 to 0.0562 Kg/cm² gauge), preferably 0.3 to 0.65 p.s.i.g. (0.0211 to 0.0457 Kg/cm² gauge).

The pressure relief valve preferably comprises a diaphragm valve member normally sealingly seated against a valve seat and arranged to lift therefrom when the above-mentioned gas pressure is reached in the stoma bag.

Although pressure relief valves comprising a diaphragm valve member have been referred to above, pressure relief valves of alternative construction may be employed if desired.

5 Preferably the pressure relief valve is so profiled and positioned relative to the stoma bag as to avoid being snagged and rendered inoperative by clothing.

10 The deodourizing filter preferably comprises carbon cloth as described, for example, in British Patent Specification No. 1,301,101. Alternatively it may, for example, comprise activated carbon granules. The deodourizing filter may, for example, be secured to the pressure relief valve. Alternatively it may be secured to the bag, e.g. across the vent outlet.

15 A preferred colostomy appliance in accordance with the present invention, and some preferred pressure relief valves therefor, will now be described, by way of example, with reference to the accompanying diagrammatic Drawings, in which:

20 Figure 1 is a cross-section through the colostomy appliance;

Figure 2 is a cross-section through one pressure relief valve, separated into its two parts, for use in the appliance of Figure 1;

Figure 3 is a plan view of the valve of Figure 2;

25 Figure 4 is a cross-section through an alternative pressure relief valve for use in the appliance of Figure 1;

Figure 5 is a cross-section through a second alternative pressure relief valve for use in the appliance of Figure 1;

30 Figure 6 is a cross-section through a third alternative pressure relief valve for use in the appliance of Figure 1; and

Figure 7 is a plan view of the valve of Figure 6.

In the Drawings, like reference numerals indicate the same or similar parts.

Referring to Figure 1 of the Drawings, the colostomy appliance comprises a stoma bag indicated generally at 1 having a vent outlet 2 provided with a pressure relief valve 3 adapted to open when a predetermined gas pressure is reached in the bag 1, as more fully described hereinafter, the vent outlet 2 being associated with a deodourizing filter 4 through which gas is vented from the bag 1.

The bag 1 is disposable, and comprises two plies of odour-resistant plastics film, e.g. a polyvinyl chloride (pvc) film sold under the Trade Mark VELBEX EA 265, forming front and back walls 5, 6 respectively, welded together at their edges 7 as by radio-frequency welding. The wall 6 has a circular opening 8 surrounded by a circular flange 9 of pvc film welded to the ply 6, the flange 9 being provided with a layer 10 of contact adhesive for securing the stoma bag to the stoma opening of the patient. The layer 10 of adhesive is protected, prior to use, by a peelable cover sheet 11.

e.g.

A sheet 12 of soft nonwoven fabric is secured to the lower part of wall 6, which rests against the patient's body in use, to minimise discomfort.

The pressure relief valve 3 is shown in Figures 2 and 3. The valve 3 comprises a cylindrical valve housing 13 formed of two parts 14, 15 (shown separate in Figure 2) injection-moulded from plastics material. These parts are fitted together, and at the same time secured to bag wall 6, to provide a fluid-tight seal of the vent outlet 2.

The marginal portion 16 of the wall 6 surrounding the vent outlet 2 is clamped in fluid-tight manner between clamping jaws constituted by circular flanges 17, 18 provided at the base of circular walls 19, 20 respectively of parts 14, 15. The wall 20 is inserted through the vent outlet 2 from within the bag 1 and received within the circular wall 19. A peripheral bead 21 on wall 20 snap-fits within a corresponding recess 22 in wall 19. Likewise a peripheral bead 23 on flange 18 snap-fits within a corresponding recess

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24 in flange 17, the portion 16 being deformed in the region of the snap-fit. The use of such a valve obviates the necessity of welding the valve to the stoma bag and thereby simplifies manufacture of the bag, which is a significant
5 advantage.

The valve 3 further comprises a bowed circular flexible diaphragm valve member 25. The diaphragm 25 may be of rubber for example. Diaphragm 25 is supported by a valve support constituted by a frusto-conical member 26
10 integral with wall 20 and apertured to provide inlet ports 27 into the valve housing 13. When the outer marginal portion 28 of diaphragm 25 is lifted from a valve seat constituted by a circular knife edge 29, integral with support 26, on which said portion 28 is normally sealingly
15 seated, entry of gas into housing 13 is afforded. The diaphragm 25 is apertured at its centre and is fitted over a peg 30 upstanding from the support 26.

The peg 20 is push-fitted into a corresponding socket 31 depending from end-wall 32 of part 14 when parts 14 and
20 15 are fitted together, thereby clamping diaphragm 25 to support 26. End-wall 32 is apertured to provide outlet ports 33 from the valve housing 13. The valve housing is less than 1" (2.54 cm) in diameter and about 0.15" (0.381 cm) in depth.

The valve housing may be a single piece rather than
25 formed of two parts, and may be secured to bag wall 6 by welding, or an adhesive, for example.

Secured within the housing 14 is a circular layer of e.g. carbon cloth or nonwoven cloth impregnated with activated charcoal, constituting the deodourizing filter 4
30 through which gas is vented from the stoma bag 1. If desired, the deodourizing filter 4 may be secured over outlet ports 33 or inlet ports 27, as by double-sided porous adhesive tape.

It will be appreciated that gas entering the bag 1
35 through the opening 8 can be vented from the bag through vent outlet 2 only when the gas pressure in the bag 1 is sufficient to lift the diaphragm 25 from its valve seat 29. Because of its bowed shape, the diaphragm 25 is tensioned and

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(43)

urged into fluid-tight contact with valve seat 29.

The pressure relief valve 3 must open before the stoma bag 1 is unduly distended which causes discomfort and may lead to rupture. However sufficient inflation of the stoma bag 1 should be permitted to prevent collapse of the bag 1 onto the stoma. We specify relatively low pressures, viz. 0.15 to 0.8 p.s.i.g. (0.0105 to 0.0562 Kg/cm² gauge), preferably 0.3 to 0.65 p.s.i.g. (0.0211 to 0.0457 Kg/cm² gauge).

If the patient so desires, he may cause the bag 1 to vent at any time by exerting manual pressure on it. Accordingly, the release pressure may be such that normally the bag would not reach it, so that slight external pressure on the bag would always be required to cause it to open. This external pressure could be applied by the colostomist at any time to provide a more convenient form of control than that currently available, the deodourizing filter preventing the omission of disagreeable odours at all times so that the operation can be carried out even in company.

The pressure relief valve 3 is so small and so positioned as not to be interfered with by the clothing of the patient and rendered inoperative. A suitable location is as shown in Figure 1, namely in an upper part of rear wall 6.

Other pressure relief valves may be used in the stoma bag 1 as shown in Figures 4 to 7. The pressure relief valve shown in Figure 4 comprises a cylindrical one-piece valve housing 34 open at one end and having a peripheral flange 35 at that end for securing it, by welding or by an adhesive for example, to the inner wall 6 of the stoma bag 1. A rigid diaphragm valve member 36 is urged by a coiled spring 37 against a valve seat constituted by an internal flange 38 integral with the housing 34, the top end of the spring 37 bearing against an end wall 39 of the valve housing 34. The end wall 39 is apertured to provide outlet ports 40. In this embodiment the charcoal cloth filter 4 is secured over the vent outlet 2 to the marginal portion 16 of the bag wall 6.

The pressure relief valve of Figure 5 is adjustable, that is to say the valve can be adjusted to open at

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different pressures. An Allen screw 41 is used to urge a flexible diaphragm valve member 42, e.g. of plastics material, against a valve seat 43. By screwing the Allen screw 41 into the valve housing 44, the desired degree of bow is imparted to the diaphragm valve member 42, and the desired pressure required in the stoma bag 1 to open the valve is achieved. A similar pressure relief valve may be employed in which a fixed stud is used instead of the Allen screw. Such a valve is not adjustable.

10 The valve of Figures 6 and 7 comprises a rigid diaphragm valve member 45. The valve housing 46 is provided with four downwardly pointing fingers 47 which flex under pressure to allow the diaphragm valve member 45 to lift from a valve seat 48. Alternatively, a flexible diaphragm valve member and stiff fingers could be used.

The invention includes a colostomy bag or ileostomy bag having a vent outlet sealed with a pressure relief valve, and further comprising a deodourizing filter associated with the vent outlet, said pressure relief valve comprising a valve housing, at least one inlet port to said housing, at least one outlet port from said housing, a diaphragm valve member sealing said inlet port(s), and a valve seat against which said valve member is urged in fluid-tight contact, said valve member being adapted to lift from said valve seat to open said valve when said valve is subjected to a predetermined fluid pressure as specified earlier herein.

25 Optionally said valve housing is formed in two parts which, when fitted together, provide clamping means for securing the valve in an aperture. For example, said parts of said housing comprise inner and outer cylindrical walls received one within the other, each of said walls having a peripheral flange at its base to constitute said clamping means.

In one embodiment, the diaphragm valve member is flexible. Means may be provided for urging said diaphragm valve member into fluid-tight contact with the valve seat, the means being adjustable to set the pressure at which the valve is opened. The valve seat may be constituted by a knife edge. Means may be provided for clamping the diaphragm valve member to a valve support.

The valve housing may be cylindrical and the valve support is, e.g. a frusto-conical member secured within the valve housing and apertured to define the inlet port(s).

- 5 In a colostomy bag or ileostomy bag as described in the last four preceding paragraphs, it is to be understood that the pressure relief valve mentioned may more specifically be as shown in Figures 2 to 7.



Claims:-

1. A colostomy appliance comprising a stoma bag having a vent outlet sealed with a pressure relief valve forming a fluid-tight seal when closed, said valve being

adapted to open when a predetermined gas pressure is reached in said bag, said vent outlet being associated with a deodourizing filter through which gas is vented from said bag, and the predetermined gas pressure at which the pressure relief valve is adapted to open being a

pressure of 0.15 to 0.8 p.s.i.g. (0.0105 to 0.0562 Kg/cm² gauge).

2. A colostomy appliance according to claim 1 wherein the pressure relief valve is adapted to open at a pressure of 0.3 to 0.65 p.s.i.g. (0.0211 to 0.0457 Kg/cm² gauge).

3. A colostomy appliance according to claims 1 or 2 wherein the pressure relief valve comprises a diaphragm valve member normally sealingly seated against a valve seat and arranged to lift therefrom when the predetermined gas pressure is reached in the stoma bag.



4. A colostomy appliance according to any one of Claims 1 to 3 wherein the deodourizing filter comprises carbon cloth.

5 5. A colostomy bag or ileostomy bag having a vent outlet sealed with a pressure relief valve, and further comprising a deodourizing filter associated with the vent outlet, said pressure relief valve comprising a valve housing, at least one inlet port to said housing, at least one outlet port from said housing, a diaphragm valve member sealing said inlet port(s), and a valve seat against which said valve member is urged in fluid-tight contact, said valve member being adapted to lift from said valve seat to open said valve at a fluid pressure of
10 0.15 to 0.8 p.s.i.g. (0.0105 to 0.0562 Kg/cm² gauge).
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6. A bag according to Claim 5 wherein the diaphragm valve member is flexible.

7. A bag according to Claim 5 or Claim 6 including means for urging said diaphragm valve member into fluid-tight contact with the valve seat, said means being adjustable to set the pressure at which the valve is opened.
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8. A bag according to any one of Claims 5 to 7 wherein the valve housing is formed in two parts which provide clamping means for securing the valve in an aperture.
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9. A bag according to Claim 8 wherein said parts of said housing comprise inner and outer cylindrical walls received one within the other, each of said walls having a peripheral flange at its base to constitute said clamping means.
