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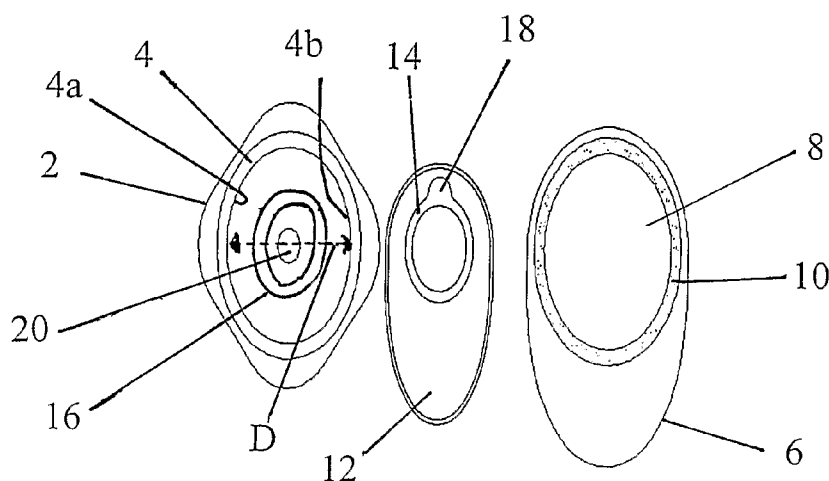
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(54) Title: OSTOMY BAG



(57) Abstract: The invention provides a drainage bag assembly for receiving bodily waste; the drainage bag assembly comprising outer (6) and inner (12) bags secured to one side of a flange (2), the flange (2) being provided with means defining an orifice to enable bodily waste to be received by the inner bag (12), and the flange (2) having connected to an opposite side thereof means for securing the drainage bag assembly to the body of a patient; the outer bag (6) being detachably secured by means of a peelable but non-repositionable adhesive to a first attachment zone (4) on the flange and the inner bag being detachably secured by means of a peelable adhesive to a second attachment zone (16) on the flange, wherein the first attachment zone (4) surrounds the second attachment zone (16) and is non-overlapping therewith; and the second attachment zone (16) surrounds the means defining the orifice; and wherein the outer bag (6) can be removed or opened to permit access to the interior thereof and removal of the inner bag (12).

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OSTOMY BAG

This invention relates to drainage bag assemblies, such as ostomy bags, for receiving bodily waste, and more particularly to an ostomy bag containing a removable inner liner.

5 Background of the Invention

Ostomy bags for receiving bodily waste from colostomy and ileostomy patients are well known. One of the problems faced by users of ostomy bags, particularly colostomy bags, is how to dispose of the contents of the bag.

Many known forms of ostomy bag are made from materials that are not
10 biodegradable and are not easily flushed down a W.C. because of, for example, the buoyancy and relative bulk of the bags. With non-flushable bags, it has been common practice to cut an edge of the bag and then deposit the contents of the bag in the W.C. for flushing away, leaving the soiled bag for separate disposal, e.g. by incineration or by wrapping and placing in a waste bin.

15 One solution to this problem has been to provide ostomy bags made from materials that are capable of being flushed down a W.C. and examples of such bags are disclosed in WO 94/12128, EP 0259184, US 2004/0059306, EP 0320895, US 5,989,235, GB 2083762, EP 388924, GB 2227668 and GB 2193925.

In many cases, the flushable ostomy bag comprises an inner bag which is formed
20 from a material that disintegrates or dissolves in water or is otherwise disposable and a protective outer bag formed from a material that is resistant to water. The outer bag can be constructed so as to be reusable several times, means being provided for opening the outer bag to permit removal and replacement of the inner bag or liner. The outer and inner bags may both be attached, directly or indirectly,
25 to an adhesive flange which comprises a layer of a bio-compatible adhesive such as a hydrocolloid adhesive to secure the ostomy bag to the body of the patient about the stomal opening.

US 2004/0059306 in particular describes several forms of construction of two piece ostomy bags in which the inner bag or liner is replaceable and a re-fastenable opening is provided in the outer bag to give access to the inner bag so that it can be replaced.

- 5 US 5,785,695 (Alcare) discloses ostomy appliances comprising inner and outer bags that are releasably attached to an adhesive flange by means of mechanical couplings comprising coupling rings having annular grooves that engage corresponding annular rims on the adhesive flange to form snap-fit connections.

- 10 US 2003/0153883 (Hansen) discloses ostomy appliances comprising an adhesive flange to which is secured a first mechanical coupling ring for the attachment of an outer bag. An inner bag or liner can also be secured to the first mechanical coupling ring by means of a second mechanical coupling ring which encircles the mouth of the inner bag and which forms a snap-fit connection against the radially inner surface of the first mechanical coupling ring.

- 15 A problem with ostomy appliances employing coupling rings to connect the inner and outer bags to an adhesive flange is that the coupling rings almost invariably make the appliance stiffer and less flexible and hence less comfortable to wear. In addition, where the coupling rings for the inner and outer bags are placed relatively close together, this can make separation and replacement of the bags difficult,
20 particularly for people with impaired or reduced manual dexterity. A further problem with using coupling rings is that they will need to be removed prior to disposal of an inner bag down a WC. Not only does this add an additional potentially awkward step to the removal and disposal process but it may also result in the user's hands coming into contact with faecal waste at the mouth of the bag.

- 25 As an alternative to using mechanical couplings, adhesive bonding has been used to secure the inner and outer bags to the adhesive flange. Examples of ostomy bags making use of adhesive bonding can be found in US 5,865,819 (Hollister) and WO 2004/082452 (Coloplast).

US 5,865,819 discloses an arrangement in which the inner and outer bags each have their own separate adhesive flange for direct connection to the body of the patient.

WO 2004/082452 discloses ostomy bags comprising an adhesive flange for attachment to the body of a patient, and inner and outer bags. The inner and outer
5 bags are each provided with adhesive rings for attachment to the adhesive flange. In the preferred ostomy bag constructions disclosed in WO 2004/082452, the outer diameter of the adhesive ring of the inner bag is larger than the inner diameter of the adhesive ring of the outer bag and hence there is overlap between the two adhesive rings.

10 **Summary of the Invention**

The present invention provides a drainage bag assembly for receiving bodily waste; the drainage bag assembly comprising outer and inner bags secured to one side of a flange, the flange being provided with means defining an orifice to enable bodily waste to be received by the inner bag, and the flange having connected to an
15 opposite side thereof means for securing the drainage bag assembly to the body of a patient; the outer bag being detachably secured by means of a peelable but non-repositionable adhesive to a first attachment zone on the flange and the inner bag being detachably secured by means of a peelable adhesive to a second attachment zone on the flange, wherein the first attachment zone surrounds the second
20 attachment zone and is non-overlapping therewith; and the second attachment zone surrounds the means defining the orifice; and wherein the outer bag can be removed or opened to permit access to the interior thereof and removal of the inner bag.

Particular and preferred embodiments of the invention are as set out in the claims appended hereto or in the paragraphs below.

25 The outer bag is secured to the adhesive flange by means of a peelable but non-repositionable adhesive to a first attachment zone on the flange. The term “non-repositionable” as used herein means that once the outer bag has been peeled away from the first attachment zone, it is not possible to reattach it to the first attachment zone by finger pressure alone. Thus, the adhesive is one which does not retain any

adhesive capability at ambient temperature after the two surfaces to which it is bonded have been peeled apart.

The peelable non-repositionable adhesive can be a hot-melt adhesive. The hot-melt adhesive can be a thermoplastic polymer that has a lower melting point than the two
5 items that it is intended to join. Thus, where the adhesive flange comprises a layer of adhesive such as a hydrocolloid adhesive carried on a backing sheet, and the backing sheet comprises a layer formed from a first polymer, the thermoplastic polymer constituting the hot-melt adhesive will be one which has a lower melting point than the said first polymer. Typically, the difference in melting points
10 between the first polymer and the hot-melt adhesive will be of the order of at least 20 °C.

Similarly, the hot-melt adhesive will have a melting point which is lower (e.g. by 20 °C or more) than the melting point of the polymer from which the outer bag is formed. Where the wall of the outer bag has a laminar structure, the hot-adhesive
15 will be formed from a thermoplastic polymer which has a lower melting point than at least one of the layers making up the laminar structure.

Examples of materials functioning as hot-melt adhesives include ethylene vinyl alcohol (EVA) and polyethylene, with EVA being preferred.

Where the outer bag and/or the backing sheet of the adhesive flange is of laminar
20 structure and one or both of the contacting surfaces of the outer bag and backing sheet are formed from a thermoplastic polymer of the appropriate melting point, this can function as the hot-melt adhesive.

For example, in one embodiment, the outer bag is formed from a laminar film material comprising layers of EVA and polyvinyl dichloride (PVDC). In this
25 embodiment, the EVA layer of the laminar film material can function as the hot-melt adhesive.

A preferred material for the backing sheet for the adhesive flange is polyurethane and it has been found that this material forms a particularly good peelable joint with

an outer bag when the outer bag is formed from a laminar film comprising EVA/PVDC layers.

An adhesive bond between the backing sheet of the adhesive flange and the outer bag is typically formed by the application of heat using an appropriately shaped
5 heat sealing tool. When EVA is used as the hot-melt adhesive, a temperature of about 120 °C to 160 °C is typically applied for a period of about 2 to 5 seconds.

The outer bag may have a sealed opening that can be opened to permit access to the interior thereof and removal and replacement of the inner bag. The sealed opening can be resealable after opening or can be non-resealable. In one embodiment, the
10 sealed opening can be resealed after opening. An advantage of this arrangement is that the inner bag can be changed one or more times before the ostomy bag is judged to be ready for complete replacement.

The sealed opening in the outer bag may be formed in a number of ways. For example, the outer bag may comprise front and rear panels bonded together around
15 their respective peripheries, but wherein a portion of the seam between the front and rear panels may be opened. Unless the context indicates otherwise, the term “front” as used herein refers to a panel or other portion of the bag which faces outwardly, i.e. away from the patient, whereas the term “rear” as used herein refers to a panel or other portion of the bag which faces inwardly, i.e. towards the patient.

20 The opening can be formed by partial opening of a seam between two panels of the outer bag, for example front and rear panels. The panels can be bonded together by Rf welding or by means of a non-peelable adhesive along a portion of the seam between the two panels and connected together by a peelable adhesive or by
25 releasable mechanical interlocking means along another portion of the seam between the two panels. The releasable mechanical interlocking means can comprise, for example, interlocking ridges and grooves that form a releasable snap-fit connection between the panels, or a “Ziploc” type fastening extending around the seam, or releasable clamping means for holding the two panels together.

In one embodiment, a reinforced hinge mechanism may be employed. The hinge mechanism may comprise a pair of arcuate limbs linked together at both ends by living hinges, one of the arcuate limbs being bonded to the front panel of the outer bag and one being bonded to the rear panel of the outer bag. The length of the arcuate limbs can, for example, approximate to the arc of a semi-circle. The limbs are typically formed from a plastics material capable of forming a living hinge and thus withstanding repeated opening and closing without breaking. Examples of such materials include polypropylene, polyethylene and polyamides such as “Nylon”.

10 In another embodiment, an opening (such as a “porthole”) is formed in a panel (e.g. a front panel) of the bag, the opening being closed by a removable cover. The cover may be releasably secured about the opening by means of a peelable adhesive or by means of a mechanical interlocking means as described above.

In the drainage bags of the invention, the attachment zones for the inner and outer bags do not overlap, and, in this respect, the bags differ from the ostomy bags disclosed in US 2004/0059306 and WO 2004/082452, where the attachment zones for the inner and outer bags are shown as overlapping.

In the bags of the present invention, the first and second attachment zones may be contiguous or they may be spaced apart.

20 Where the first and second attachment zones are spaced apart, they may be spaced apart by a distance greater than the width of either attachment zone. It will be appreciated from this that when one attachment zone is wider than the other, the first and second attachment zones are spaced apart by a distance that is greater than the width of the widest of the two attachment zones.

25 In one embodiment, the first and second attachment zones may be spaced apart by a distance greater than one and half times the width of either attachment zone, or greater than twice the width of either attachment zone.

In a preferred embodiment of the invention, the first attachment zone has opposed inner edges and the lateral distance between the opposed inner edges along a line

passing through the centre of the orifice is greater than the maximum lateral dimension of the inner bag.

The arrangement of the attachment zones for the outer and inner bags provides a number of advantages and these include greater ease of access to the interior of the
5 outer bag for replacement of the inner bag and greater ease of manufacture.

The outer bag is typically formed from a waterproof material which acts as a barrier to flatus gases. Examples of such materials include polyvinyl dichloride (PVDC), ethylene vinyl alcohol and related materials and combinations thereof.

In order to prevent the undesirable build up of flatus gases within the bag, the wall
10 of the outer bag can be provided with a flatus filter which permits gases to exit the bag but filters out malodorous and noxious gases. Such filters are well known and need not be described here.

The inner bag is detachably secured by means of adhesive to the second attachment zone on the flange. The adhesive is a peelable adhesive and may, for example, be a
15 pressure sensitive adhesive or a non-pressure-sensitive adhesive. The peelable adhesive can be located on the second attachment zone, or on a ring surrounding the mouth of the inner bag, or on both. In one embodiment, the inner bag is provided with a ring of peelable adhesive surrounding the mouth of the bag.

The inner bag may be formed from a non-disposable waterproof material of a type
20 described above for the outer bag, but preferably the inner bag is formed from a material that is biodegradable or disposable, such as polyvinyl alcohol. For example, the inner bag can be formed from a polymer, such as polyvinyl alcohol, of a type or grade that is slowly soluble in cold water but is more soluble in hot water. Examples of types of polyvinyl alcohol suitable for use in the fabrication of inner
25 bags or liners are described in our earlier application WO94/12128.

Brief Description of the Drawings

Figure 1 is an exploded schematic view showing a flange, inner bag and outer bag of an ostomy bag according to one embodiment of the invention.

Figure 2 illustrates a liner or inner bag for an ostomy bag.

Figure 3 illustrates an ostomy bag in which the outer bag has been partially peeled away to reveal the inner bag.

Figure 4 illustrates a hinge mechanism for use in an opening in an outer bag.

5 Figure 5 illustrates an outer bag with an opening along its edge seam.

Figure 6 illustrates an outer bag with a porthole to provide access to the inner bag.

Figures 7a and 7b illustrate an opening in an outer bag of an ostomy bag according to another embodiment of the invention.

Detailed Description of the Invention

10 The invention will now be described in more detail, but not limited, by reference to the specific embodiments illustrated in the drawings.

Referring now to the Figures, Figure 1 is an exploded schematic view showing the component parts of an ostomy bag according to the invention. The ostomy bag comprises an adhesive flange 2 comprising a backing layer of a polyurethane
15 material to one side of which is attached a layer of hydrocolloid adhesive. The hydrocolloid adhesive, which may be of conventional type, serves to secure the ostomy bag to the body of a patient. A silicone release layer (not shown) covers the hydrocolloid adhesive layer and protects the adhesive layer against damage and/or drying out prior to use of the bag.

20 On the side of the flange opposite to the hydrocolloid adhesive is a first attachment zone designated in Figure 1 by the numeral 4. An outer bag 6 having an opening 8 surrounded by a ring 10 of peelable but non-repositionable adhesive material is secured to the flange 2, the ring of peelable but non-repositionable adhesive 10 bonding to the flange at the first attachment zone 4. The peelable non-
25 repositionable adhesive is a hot melt adhesive such as EVA. In the embodiment shown, the EVA can be a discrete layer applied only to the area of the ring 10. Alternatively, when the wall of the outer bag 6 is formed from an EVA/PVDC

laminate or an EVA/PVDC/EVA laminate, the EVA layer of the laminate can function as the hot-melt adhesive.

The bond between the outer bag and the first attachment zone is formed by positioning the laminated film in the area of the attachment zone and applying heat
5 with an annular heat sealing tool at a temperature of 120 °C to 160 °C for a period of 2 to 5 seconds.

When (as described below) the outer bag is subsequently peeled away from the outer attachment zone, it is not possible to reattach it to the attachment zone since the EVA does not have any significant adhesive capability at room temperature and
10 pressure.

Disposed within the outer bag, is a removable inner bag or liner 12. The inner bag or liner 12 is provided with a ring of peelable adhesive 14, which bonds to the flange 2 at the second attachment zone 16. The ring of peelable adhesive 14 is provided with a tab 18 to facilitate removal of the inner bag from the flange.

15 The first attachment zone 4 and the second attachment zone 16 are spaced apart radially and the spacing between the two attachment zones is greater than the width of either of the two attachment zones. In the embodiment shown, the lateral distance D along a line running through the centre of the orifice 20 between opposed inner edges 4a and 4b of the first attachment zone is greater than the
20 maximum lateral dimension of the inner bag 12.

The outer bag 6 in this embodiment can be formed from materials well known for the construction of ostomy bags. Thus, for example, it can be formed from a tough, flexible, transparent, waterproof material such as polyvinyl dichloride (PVDC), ethylene vinyl alcohol, related materials and combinations thereof in known
25 fashion, one particular material being the EVA/PVDC/EVA film available from Sealed Air of Saddle Brook, New Jersey, US under the trade name Cryovac MF514. The outer bag may be formed from a pair of sheets of the flexible waterproof material, one sheet being cut so as to form the opening 8 and the other sheet having the same outer periphery, but no opening. The two sheets can be secured together

around their respective peripheries by welding, (for example Rf welding) or by means of adhesive.

In use, faecal material from a stomal opening passes through the opening 20 in the flange and into the interior of the inner bag or liner 12. When the inner bag or liner 12 is full, the outer bag 6 may be peeled away from the flange, giving access to the inner bag, which may also be peeled away. The adhesive flange may also then be removed. The outer bag, adhesive flange and inner bag can then be disposed of, the inner bag and its contents by flushing down a WC and the outer bag and flange through normal domestic waste channels. A new assembly of inner and outer bag and adhesive flange may then be applied to the patient.

An inner bag or liner is illustrated in more detail in Figure 2 and comprises a pair of sheets, 30 and 32 (not shown) secured together by means of a weld 34 around their peripheries. The inner bag or liner 30 has an opening 36 surrounded by a ring of a peelable adhesive 38, covered by a silicone release layer (not shown). A tab 40 assists in removal of the liner from the flange. The inner bag 30 may be formed from a non-disposable waterproof material such as polyvinyl dichloride or a PVDC/EVA laminate, or another material similar to the materials from which the outer bag is made. Alternatively, the inner bag can be formed from materials that are biodegradable or disposable. Examples of materials suitable for forming a disposable liner are described in our earlier patent application WO94/12128 and include polyvinyl alcohol of an appropriate solubility grade.

The layout of the inner and outer bags and their respective attachment zones in the assembled ostomy bag can be seen more clearly in Figure 3 which illustrates an ostomy bag in which the outer bag 6 has been partially peeled away to reveal the bag interior and the inner bag 12.

In the embodiment shown in Figure 5, the outer bag comprises front 64 and rear panels 66, the rear (i.e. body-side) surface of rear panel 66 being bonded by non-peelable adhesive or by Rf welding around its entire periphery to the adhesive flange 68. The front panel 64 is permanently bonded to the rear panel along part of its periphery but is releasably attached to the rear panel along the remainder of its

periphery by means of the line of peelable adhesive 70. Thus, in this embodiment, the seam between the front and rear panels opens up to give access to the interior of the bag for removal of the inner bag or liner 72.

5 In order to provide a firmer engagement and disengagement action between the two panels of the outer bag, a hinge mechanism may be interposed between the panels and one such mechanism is shown in Figure 4. The hinge mechanism illustrated in Figure 4 comprises a pair of generally semi-circular limbs 50 and 52, linked together by living hinges 54 and 56. Tabs 58 and 60 are provided to assist the user to pull the two limbs apart. The limb 52 of the hinge mechanism can be secured to
10 rear panel 66 of the bag shown in Figure 5, for example by Rf welding, whilst the second limb 50 of the hinge can be secured (again by Rf welding or adhesive) to the front panel 64 of the outer ostomy bag. The confronting surfaces of the two limbs may be provided with a peelable adhesive to allow them to be releasably secured together, or they may be provided with a mechanical fastening mechanism.

15 In a further form of construction, a panel or wall of the outer bag may be provided with an opening to allow access to the replaceable inner bag or liner. Figure 6 illustrates an embodiment in which a "porthole" is created in the outer bag wall, and a cover 60 is secured in place by a ring of adhesive around its periphery. A tab 62 is provided to assist in removal of the porthole cover.

20 In a further alternative, as shown in Figures 7a and 7b, an opening may be formed in the outer bag along a seam, the opening being closed by a temporary closure mechanism, such as a clip and folding mechanism using, for example, a physical interlocking system such as a closure of the "Ziploc[®]" type, or hook and loop systems of the "Velcro[®]" or Cric Crac[®] type, or interlocking "mushroom" fasteners
25 of the type manufactured by Gottlieb Binder GmbH of Holzgerlingen, Germany. Particular fasteners of interest include fasteners that provide a substantially water-tight closure.

Equivalents

It will readily be apparent that numerous modifications and alterations may be made
30 to the specific embodiments of the invention described above without departing

from the principles underlying the invention. All such modifications and alterations are intended to be embraced by this application.

CLAIMS

1. A drainage bag assembly for receiving bodily waste; the drainage bag assembly comprising outer and inner bags secured to one side of a flange, the flange being provided with means defining an orifice to enable bodily waste to be received by the inner bag, and the flange having connected to an opposite side thereof means for securing the drainage bag assembly to the body of a patient; the outer bag being detachably secured by means of a peelable but non-repositionable adhesive to a first attachment zone on the flange and the inner bag being detachably secured by means of a peelable adhesive to a second attachment zone on the flange, wherein the first attachment zone surrounds the second attachment zone and is non-overlapping therewith; and the second attachment zone surrounds the means defining the orifice; and wherein the outer bag can be removed or opened to permit access to the interior thereof and removal of the inner bag.
2. A drainage bag assembly according to claim 1 wherein the peelable but non-repositionable adhesive is a hot melt adhesive.
3. A drainage bag assembly according to claim 2 wherein the hot melt adhesive is polyethylene or ethylene vinyl alcohol.
4. A drainage bag assembly according to claim 3 wherein the hot melt adhesive is ethylene vinyl alcohol.
5. A drainage bag assembly according to any one of the preceding claims wherein the outer bag has a wall which is of laminar structure and wherein the peelable but non-repositionable adhesive is a hot melt adhesive which is constituted by a layer of the laminar structure.
6. A drainage bag assembly any one of the preceding claims wherein the first and second attachment zones are contiguous.
7. A drainage bag assembly according to any one of claims 1 to 5 wherein the first and second attachment zones are spaced apart.

8. A drainage bag according to claim 7 where the first and second attachment zones are spaced apart by a distance greater than the width of either attachment zone.
- 5 9. A drainage bag according to claim 8 wherein the first and second attachment zones are spaced apart by a distance greater than one and half times the width of either attachment zone (for example greater than twice the width of either attachment zone).
- 10 10. A drainage bag according to any one of the preceding claims wherein the first attachment zone has opposed inner edges, the lateral distance between the opposed inner edges along a line passing through the centre of the orifice being greater than the maximum lateral dimension of the inner bag.
11. A drainage bag according to any one of the preceding claims wherein the means for securing the drainage bag assembly to the body of a patient comprises a layer of adhesive such as a hydrocolloid adhesive.
- 15 12. A drainage bag according to any one of claims 1 to 11 wherein the outer bag is formed from front and rear panels secured together around their respective peripheries, a portion of a seam between the pair of panels at the peripheries thereof being openable to permit access to and replacement of the inner bag.
- 20 13. A drainage bag according to claim 12 wherein a living hinge mechanism is disposed between the panels in the openable portion of the seam, the living hinge mechanism providing a reclosable opening for the outer bag and comprising a pair of hinge limbs linked together at the two ends of each hinge limb by living hinges so as to define a reclosable opening, one of the hinge limbs being attached to a front panel of the outer bag and the other hinge limb being attached to the flange or a rear panel of the outer bag, the two hinge limbs being provided with releasable securing means on
25 confronting surfaces thereof for holding the limbs together to close the opening.

14. A drainage bag according to claim 13 wherein the hinge limbs are arcuate.
15. A drainage bag according to any one of claims 1 to 11 wherein an opening is formed in a panel (e.g. a front panel) of the outer bag, the opening being closed by a removable and replaceable cover.
- 5 16. A drainage bag according to claim 15 wherein the cover is releasably secured about the opening by means of a peelable adhesive or a mechanical interlocking means.
17. A drainage bag according to any one of the preceding claims wherein the inner bag is formed from a biodegradable material or a material that
10 disintegrates upon flushing down a W.C.
18. A drainage bag according to any one of the preceding claims wherein the flange comprises a backing layer formed from a polymeric material, to one side of which is attached the means for securing the drainage bag assembly to the body of a patient, and to the other side of which are attached the outer
15 and inner bags, and wherein the peelable but non-repositionable adhesive has a melting point at least 20 °C lower than the melting point of the said polymeric material.
19. A drainage bag according to claim 18 wherein the polymeric material is polyurethane.
- 20 20. A drainage bag according to claim 18 or claim 19 wherein the means for securing the drainage bag assembly to the body of a patient is a layer of adhesive, for example a hydrocolloid adhesive.
21. A drainage bag according to any one of the preceding claims which is an ostomy bag.
- 25 22. A drainage bag substantially as described herein with reference to the accompanying drawings.

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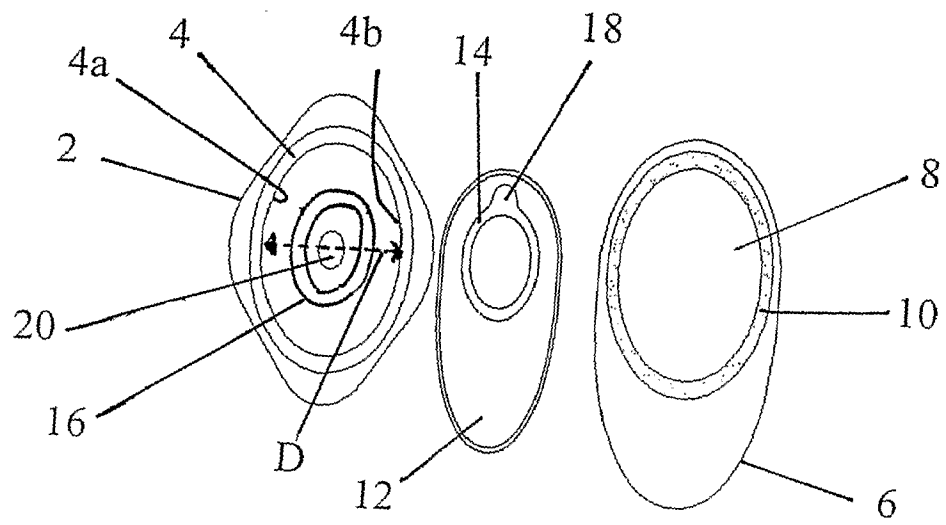


Figure 1

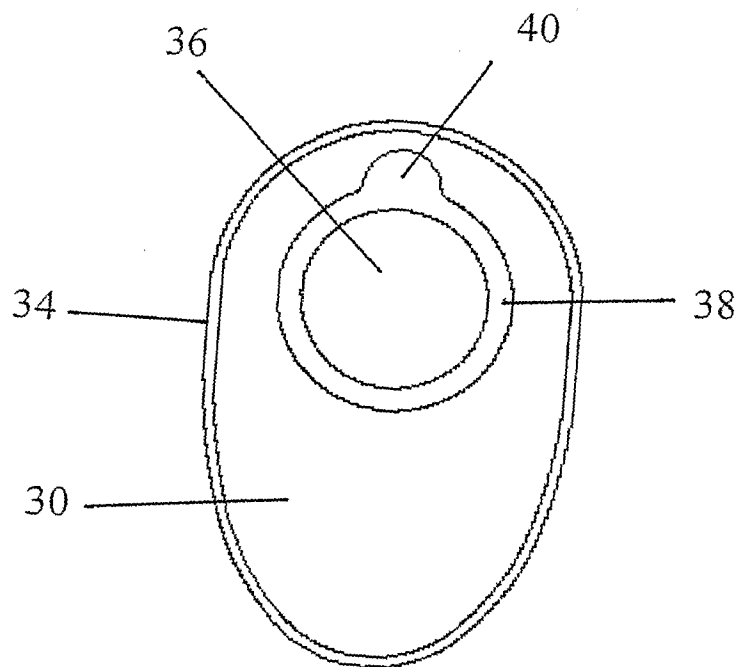


Figure 2

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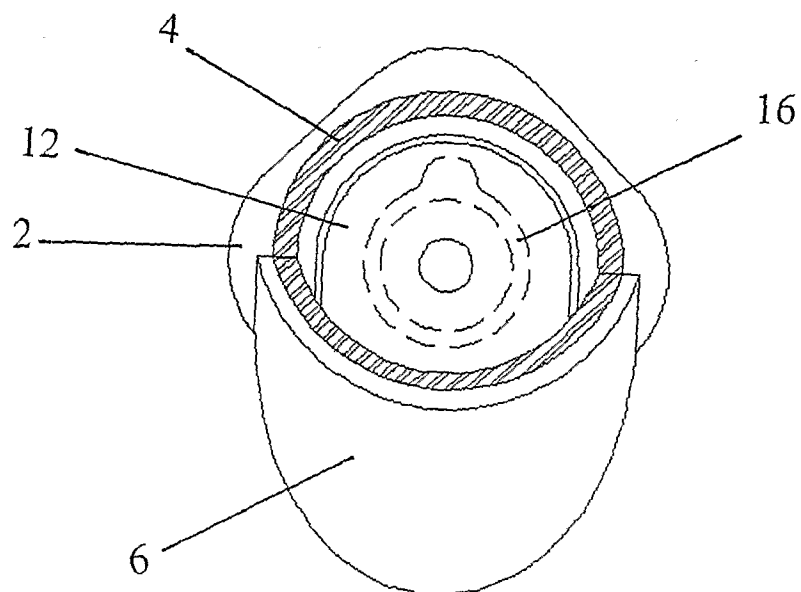


Figure 3

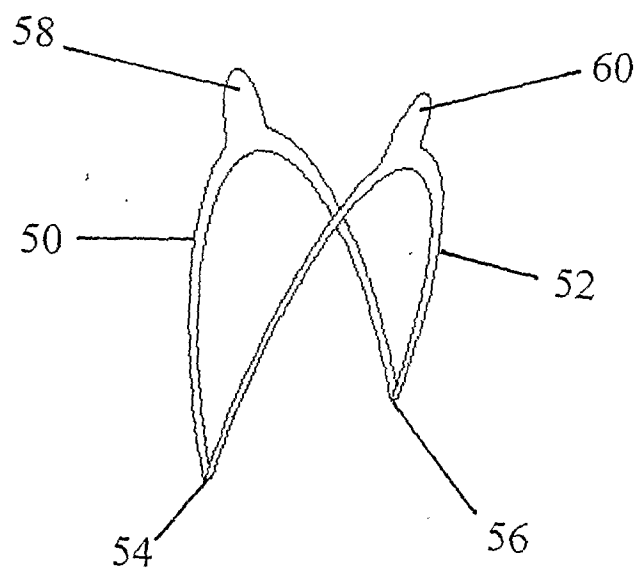


Figure 4

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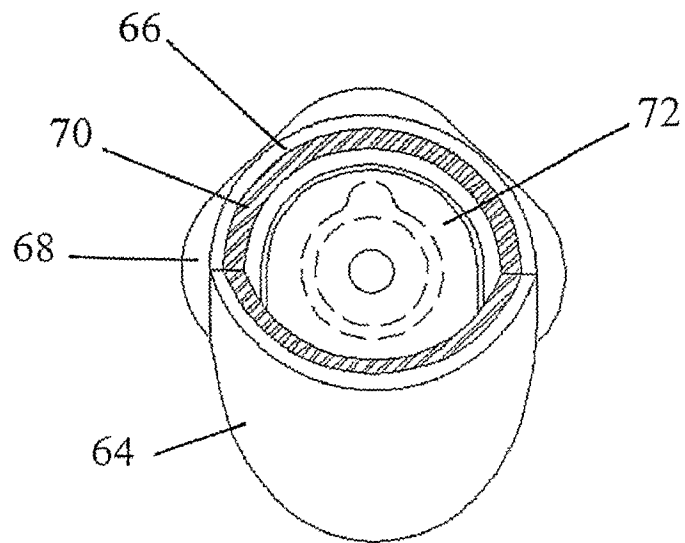


Figure 5

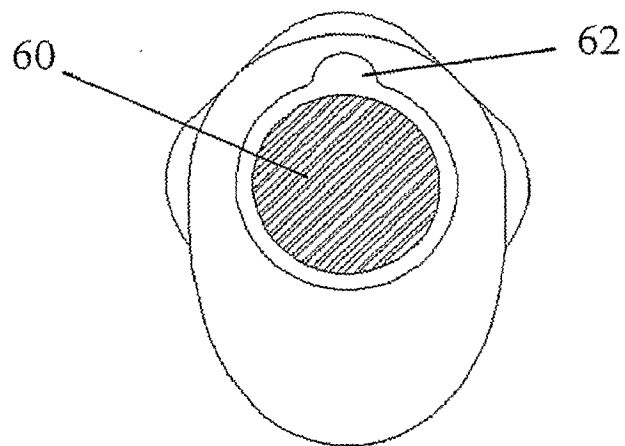


Figure 6

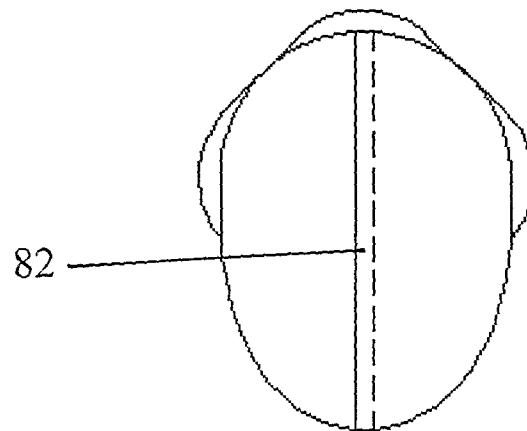


Figure 7a

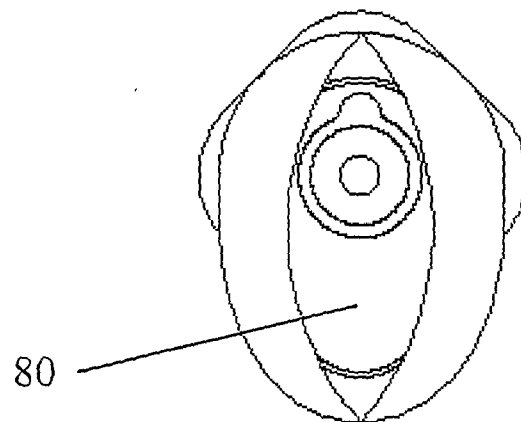


Figure 7b

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2007/000186

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F5/445

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, A	WO 2006/077438 A (WELLAND MEDICAL LTD [GB]; SMITH RORY JAMES MAXWELL [GB]; BIRD PAUL [GB] 27 July 2006 (2006-07-27) page 9, line 28 - page 10, line 18 claims 1,3-10,13-15,17-20 figures 1-7b	1,6-17, 21
A	WO 2005/082271 A (COLOPLAST AS [DK]; MUELLEJANS PETER [DK]; HANSEN MICHAEL [DK]) 9 September 2005 (2005-09-09) page 12, line 4 - page 13, line 3 page 18, line 1 - line 10 claims 25,27 figures 14,15 ----- -/--	1

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

25 May 2007

Date of mailing of the international search report

05/06/2007

Name and mailing address of the ISA/

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Storer, John

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2007/000186

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 690 622 A (SMITH RORY JAMES MAXWELL [GB] ET AL) 25 November 1997 (1997-11-25) column 2, line 38 - line 54 column 3, line 11 - line 35 figures 2,3 -----	
A	US 2004/059306 A1 (TSAL LAWRENCE M [US] ET AL) 25 March 2004 (2004-03-25) paragraph [0041] figures 1-4 -----	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2007/000186

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

The present claim 22 relates to an extremely large number of possible apparatus. Support and disclosure in the sense of Article 6 and 5 PCT is to be found in the description only for the subject-matter of claims 1-21. The non-compliance of claim 22 with the substantive provisions is to such an extent, that the present search was restricted to those apparatus defined in claims 1-21.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2007/000186

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2006077438	A	27-07-2006	GB 2422312 A	26-07-2006
WO 2005082271	A	09-09-2005	EP 1725197 A2	29-11-2006
US 5690622	A	25-11-1997	AT 195242 T	15-08-2000
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