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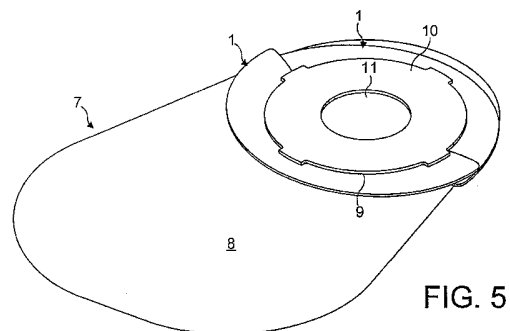
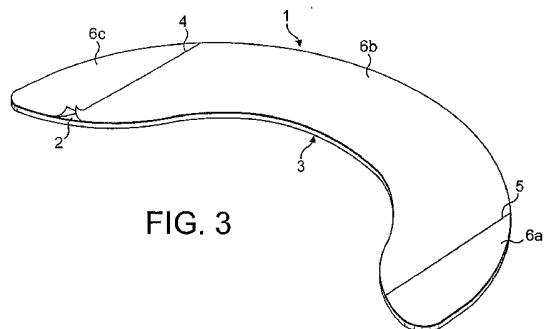
(56) Documents Cited:
GB 2397230 A **GB 2094809 A**
EP 0955347 A2 **EP 0081907 A1**
US 6846508 B1 **US 6746765 B1**
US 4327727 A

(58) Field of Search:
UK CL (Edition X) **A5R**
INT CL **A61F, A61L**
Other: **EPODOC, WPI.**

(54) Abstract Title: **A support for an ostomy device with silicone adhesive**

(57) The invention provides a support 1 for an ostomy bag, the support 1 being shaped to fit around and extend a portion of a flange 9 of an ostomy bag 7, characterised in that the support 1 comprises a backing layer 3, a layer of silicone adhesive 2, and a releasable cover layer 6a, 6b, 6c on the silicone adhesive 2.

The support 1 may be semi-circular so that they can be arranged around the flange 10 of an ostomy bag 8, and extend beyond the diameter of the flange 10.



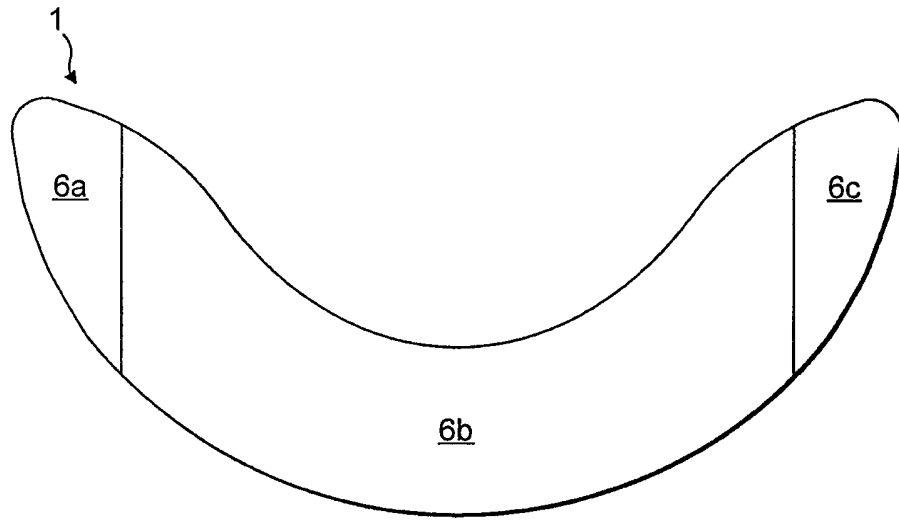


FIG. 1A

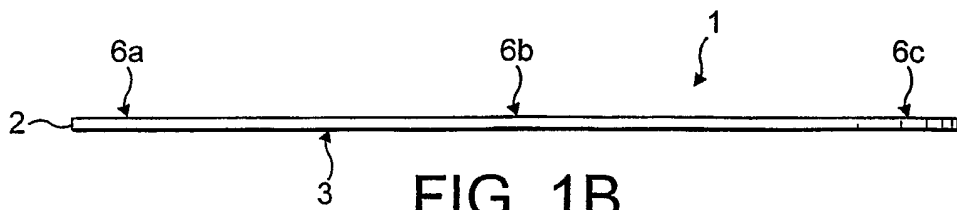


FIG. 1B

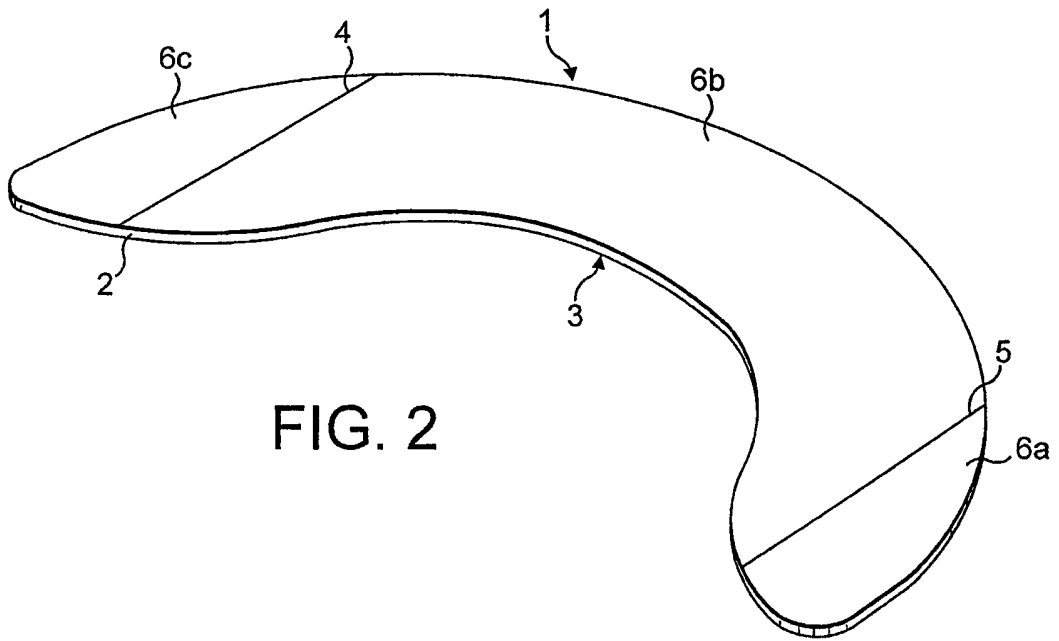


FIG. 2

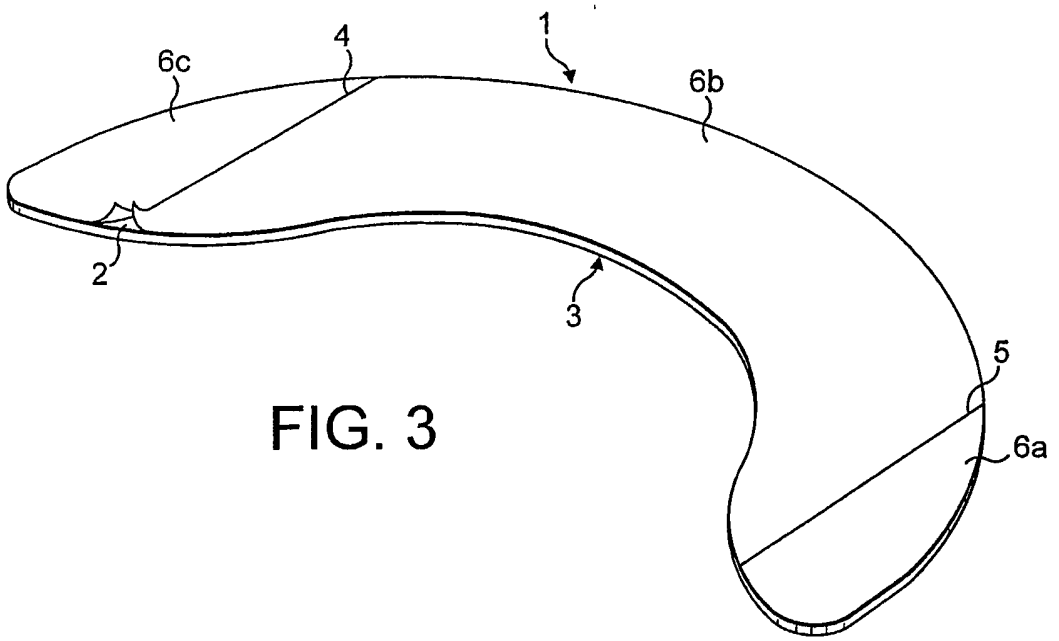


FIG. 3

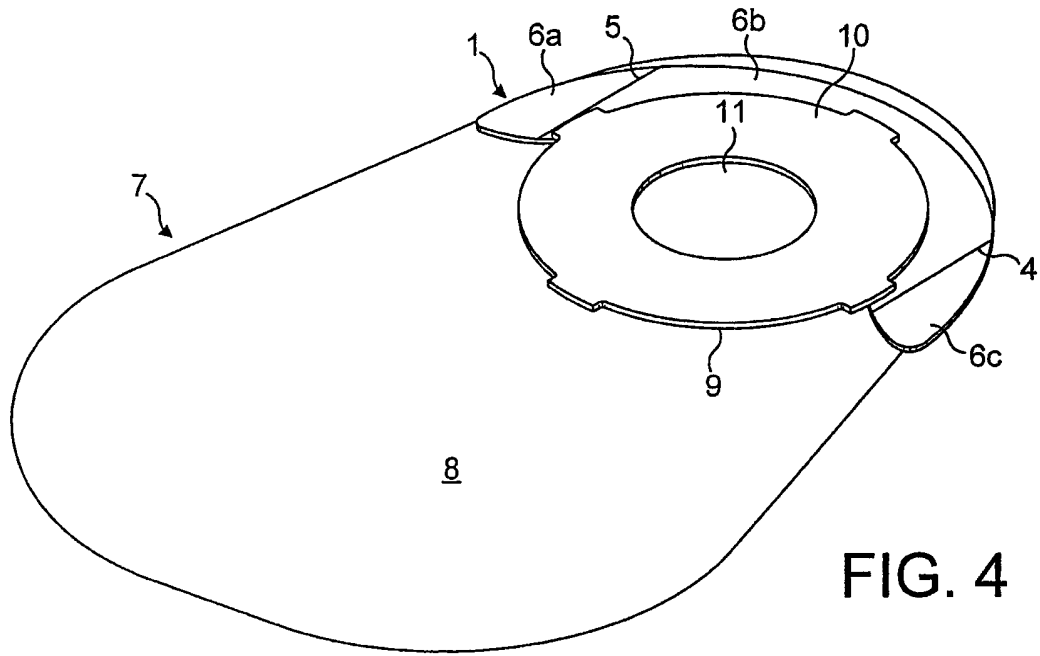


FIG. 4

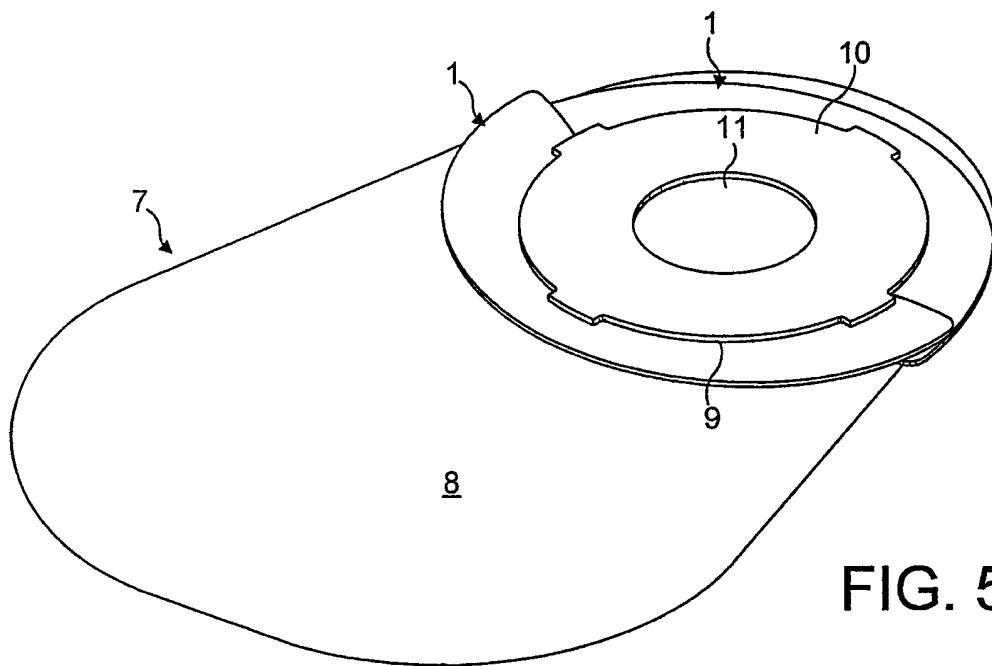


FIG. 5

A SUPPORT FOR AN OSTOMY BAG

The present invention relates to a support for an ostomy bag, but is also applicable to wound drainage bags. For the purposes of the present specification, including the claims, all references to ostomy bags are to be interpreted to include wound-
5 drainage bags and wound managers.

Background of the Invention

The main types of ostomy bags are colostomy bags, ileostomy bags and urostomy bags. These together with wound drainage or wound manager bags have in common that they form a seal around the stoma, or wound, through which waste
10 material is drained from the body.

Ostomy bags comprise a receptacle for the waste having an aperture for receiving the waste. This aperture is normally surrounded by a flange of hydrocolloid adhesive. Hydrocolloid adhesive is particularly "skin friendly" and typically comprises approximately 20% gelatine, 20% pectin and 20% carboxymethyl
15 cellulose in an organic matrix of polyisobutylene, the polyisobutylene constituting the remaining 40% of the hydrocolloid adhesive.

The proportions of the components of the hydrocolloid adhesive may vary, but an important property of the material is that it is breathable. This is important because a particular problem with ostomy bags arises from the extended periods for which
20 they have to be worn by a patient, normally 24 hours a day. This commonly results in maceration where the skin cannot breath and becomes saturated.

The wear time of an ostomy bag is often limited by the seal about the flange failing, whereby waste fluids from the body may leak past the seal, requiring the wearer to replace the ostomy bag, thus replacing the seal formed with the bag. This leakage
25 is not only unpleasant and potentially embarrassing for the wearer, but the waste is also corrosive to the skin when the skin is exposed to the waste for any significant period of time. This, together with any maceration that may occur, reduces the likelihood of any subsequent ostomy bag correctly sealing.

Increasing the flange size on an ostomy bag might be thought to improve the sealing ability of the flange. However, a problem with using an excessively large flange is that this will expose a larger area of skin to the possible risk of maceration and also cause problems due to the flexing of the body under the area of the flange.

- 5 Ostomy bags normally have a standard size of flange that is considered appropriate for the “average” wearer. However, all wearers are different and some find that the standard flange of an ostomy bag does not seal, or fails before the ostomy bag is full. This often happens where there are bony protuberances close to the stoma or where stomal hernias arise, often as a side effect of the skin being cut to form the
10 stoma.

There are currently several products available to a wearer who suffers problems with leaking ostomy bags. One product comprises a hydrocolloid strip, formed by extruding and rolling hydrocolloid material. The strip is cut to length by a wearer and applied in the area where the flange seal normally fails.

- 15 An alternative product used by some ostomy bag wearers is sold under the trade mark “SECUPLAST” and comprises an annular disk of tape covered with an acrylic adhesive which is placed behind and around the flange of an ostomy bag thereby extending the flange. However, a problem with the “SECUPLAST” product is that the acrylic adhesive is not as “skin friendly” as the hydrocolloid
20 material and tends to increase skin trauma, which in turn causes problems with the subsequent fitting of further ostomy bags.

A further approach to solving the problem of ostomy bag leakage is described in WO2004/062537. WO2004/062537 discloses an ancillary pad of hydrocolloid adhesive that can fit around and extend a portion of the flange of an ostomy bag.

- 25 The present invention is primarily but not exclusively directed to improvements in the adhesive pads disclosed in WO2004/062537.

Summary of the Invention

The present invention provides a support for an ostomy bag, the support being shaped to fit around and extend a portion of a flange of the ostomy bag, characterised in that the support comprises a backing layer, a layer of silicone adhesive, and a releasable cover layer on the silicone adhesive.

5 The present invention enables a wearer to fit a support to that portion of the flange of an ostomy bag that is most prone to fail, when fitted to that particular wearer. The shaping of the support to fit around and extend the flange, ensures a large section of the circumference of the flange is extended whilst minimising the additional area of skin covered.

10 The invention is particularly advantageous in that it permits a support of a standard size and shape or range of supports to be used with one or more standard ostomy bags.

A further advantage of the supports of the invention is that, when in place, they seal the edges of the hydrocolloid flange and prevent or inhibit the ingress of water.

15 This means that when the wearer is in a situation where contact with water is involved, for example when bathing, showering or swimming, the likelihood of water coming into contact with the hydrocolloid adhesive of the flange and eroding the flange is substantially reduced.

The silicone adhesive is covered by a release layer arranged to be removed prior to
20 use. This permits the support to be correctly positioned partially behind the flange and the release paper removed, such that the support can be adhered to the flange in the correct position and, where the flange is provided with a similar releasable cover, the cover of the flange then removed prior to mounting the ostomy bag upon the wearer.

25 Preferably, the support is arcuate in shape, thus corresponding closely to the shape of the flange of the ostomy bag. In one embodiment, the support is substantially semi-circular in shape. A plurality of supports may be used around the circumference of the flange. For example, two supports may be arranged in opposed positions about the flange, so that they extend around the complete

circumference of the flange, thereby enabling the whole flange to be extended, where this is desired by a particular wearer.

In another aspect, the invention provides a combination of an ostomy bag and one or more supports as defined herein.

- 5 In a further aspect, the invention provides an ostomy bag having secured thereto one or more supports as defined herein.

Brief Description of the Drawings

The present invention will now be described, by way of example only, with reference to the accompanying drawings.

- 10 Figure 1A is a plan view of a support in accordance with the present invention.

Figure 1B is a side elevation of the support of Figure 1A.

Figure 2 is a perspective view of the support of Figures 1A and 1B.

Figure 3 is a perspective view of the support of Figure 2, showing the release paper partially peeled back.

- 15 Figure 4 illustrates an ostomy bag fitted with a support in accordance with the present invention.

Figure 5 illustrates an ostomy bag fitted with two supports in accordance with the present invention.

Detailed Description of the Invention

- 20 Referring to Figures 1A, 1B and 2, a support for an ostomy bag in accordance with the present invention, indicated generally as 1, comprises a layer of 0.6 mm thick cured RTV silicone gel 2, an EU40 25 μ m thick polyurethane film backing 3 and a release paper divided by two cuts 4 and 5 into three sections 6a, 6b and 6c, the release paper being standard sterling coated paper.

Figure 3 illustrates how the support 1 can be slightly flexed in the region of the slit 4 permitting the release paper to be held and peeled back. The release paper can similarly be removed starting at the slit 5.

Referring to Figure 4, there is illustrated a standard ostomy bag, referred to generally as 7, comprising a receptacle portion 8, for receiving waste, and a flange 9. The flange 9 is formed of hydrocolloid material and has a release paper on its upper surface 10. In use the release paper is removed and the flange 9 centred on a stoma or wound of the wearer, such that fluid drains from the stoma or wound into the receptacle 8, via aperture 11 in the flange 9.

10 The support 1 of the present invention is placed in any desired position about the flange 9, and then slid partly behind the flange with the release paper 6a, 6b, 6c uppermost, as shown. In this position, starting at one of the slits 4 or 5, the release papers are peeled from the support 1 and the support adhered to the flange 9. Then the release paper (not shown) of the flange 9 is removed from the uppermost
15 surface 10 and the flange 9 and support 1 simultaneously adhered to the wearer.

As shown in Figure 5, a number of supports in accordance with the invention may be used on an ostomy bag, either to completely surround the flange as shown in Figure 5, to further extend the flange in a particular direction, that is to say further than it could be extended by use of a single support, or a number of supports may
20 be built up in depth so as to account for any depression in the surface of the wearer adjacent a stoma. Although not illustrated, it is possible that supports of different sizes may also be provided.

The present invention has been illustrated by way of example only and further embodiments may be apparent within the scope of the appended claims.

CLAIMS

1. A support for an ostomy bag, the support being shaped to fit around and extend a portion of a flange of an ostomy bag, characterised in that the support comprises a backing layer, a layer of silicone adhesive, and a
5 releasable cover layer on the silicone adhesive.
2. A support according to claim 1 which is arcuate in shape.
3. A support according to Claim 2 which is substantially semicircular.
4. A support according to Claim 2 or Claim 3 which is arranged to co-operate
10 with one or more similar supports to form a collar extending around the complete circumference of the flange.
5. A support for an ostomy bag substantially as hereinbefore described with reference to, and/or as illustrated in, one or more of the accompanying figures.
6. A combination of an ostomy bag and one or more supports as defined in any
15 one of the preceding claims.
7. An ostomy bag having secured thereto one or more supports as defined in any one of claims 1 to 5.



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Examiner: Mr Alex Robinson

Claims searched: 1 to 4, 6 and 7

Date of search: 3 April 2006

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
Y	1 to 7	GB 2397230 A (Clinimed) Whole document.
Y	1 to 7	EP 0081907 A1 (E.R. Squib) Whole document.
Y	1 to 7	US 4327727 A (Prah) Whole document
Y	1 to 7	EP 0955347 A2 (Dow Corning) Whole document.
Y	1 to 7	US 6846508 B1 (Colas) Whole document.
Y	1 to 7	GB 2094809 A (Johnson and Johnson) Whole document.
Y	1 to 7	US 6746765 B1 (Fattman) Whole document.

Categories:

X Document indicating lack of novelty or inventive step	A Document indicating technological background and/or state of the art.
Y Document indicating lack of inventive step if combined with one or more other documents of same category.	P Document published on or after the declared priority date but before the filing date of this invention.
& Member of the same patent family	E Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^X :

A5R

Worldwide search of patent documents classified in the following areas of the IPC

A61F; A61L



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The following online and other databases have been used in the preparation of this search report

EPODOC, WPI.