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AUSTRALIA
PATENTS ACT 1990
NOTICE OF ENTITLEMENT

We, **Coloplast A/S**, the applicant/Nominated Person in respect of Application No. 25521/92 state the following:-

The Nominated Person is entitled to the grant of the patent because the Nominated Person derives title to the invention from the inventor by assignment.

The Nominated Person is entitled to claim priority from the application listed in the declaration under Article 8 of the PCT because the Nominated Person made the application listed in the declaration under Article 8 of the PCT, and because that application was the first application made in a Convention country in respect of the invention.

DATED this TWENTY FIFTH day of FEBRUARY 1994



.....
a member of the firm of
DAVIES COLLISON
CAVE for and on behalf
of the applicant(s)

(DCC ref: 1645742)



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AN ADAPTER FOR USE IN CONNECTION WITH OSTOMY EQUIPMENT
- International Patent Classification(s)
(51)⁵ A61F 005/448
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- (87) PCT Publication Number : WO93/04646
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- (56) Prior Art Documents
US 4710182
US 4834731
US 4973323
- (57) Claim

1. An adapter for use with ostomy equipment and comprising a ring-shaped member with a radial extent between an inner periphery and an outer periphery and having a proximal surface and a distal surface, said proximal surface having a convex face and on its proximal side a layer of adhesive by means of which the adapter can be adhered to a user's skin, the ring-shaped member comprising a central, relatively rigid ring with the convex face and a peripheral part which is an integrated part of the relatively rigid ring, characterized in that the peripheral part is relatively flexible and extends radially considerably further than the relatively rigid ring, the peripheral part having a proximal side and a distal side, the proximal side being in contact with the layer of adhesive, and at least as far as the layer of adhesive, the distal side being flat and non-adhesive and being adapted for direct connection with the ostomy equipment.

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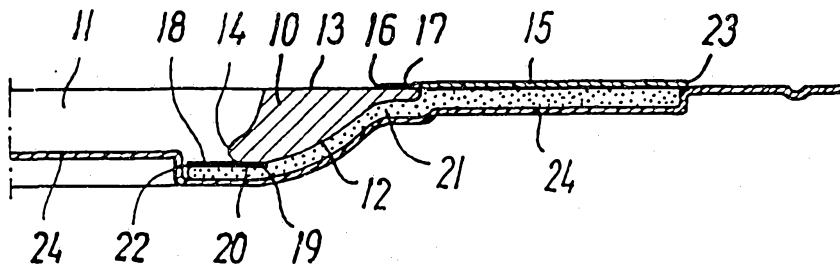


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..... UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/DK92/00258 (22) International Filing Date: 31 August 1992 (31.08.92) (30) Priority data: 1529/91 30 August 1991 (30.08.91) DK (71) Applicant (for all designated States except US): COLOPLAST A/S [DK/DK]; Bronzevej 2-8, DK-3060 Espergærde (DK). (72) Inventor; and (75) Inventor/Applicant (for US only) : OLSEN, Hans [DK/DK]; Usserød Kongevej 85 B, DK-2970 Hørsholm (DK). (74) Agent: HOFMAN-BANG & BCUTARD A/S; Adelgade 15, DK-1304 Copenhagen K (DK).</p>		<p>(81) Designated States: AT, AU, BB, BG, BR, CA, CH, CS, DE, DK, ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MN, MW, NL, NO, PL, RO, RU, SD, SE, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG).</p> <p>Published With international search report. In English translation (filed in Danish).</p> <p>659213</p>

(54) Title: AN ADAPTER FOR USE IN CONNECTION WITH OSTOMY EQUIPMENT



(57) Abstract

A convex adapter for use in connection with ostomy equipment comprises a ring-shaped member (10, 15, 18). The ring-shaped member (10, 15, 18) comprises a central, relatively rigid ring (10) with a convex face (12) as well as a peripheral, relatively flexible part (15) extending considerably longer and radially than the relatively rigid ring (10).

An adapter for use in connection with ostomy equipment

The invention concerns a ring-shaped adapter for use in connection with ostomy equipment.

Below an ostomy patient or an ostomist denotes a person having a colostomy, an ileostomy or a urostomy. In such persons the colon, the ileum or the ureter has been exposed surgically such that the waste products of the body, which are conveyed through these organs, are discharged through an artificial opening and are collected in a collection bag, which is ordinarily adhered to the skin by means of an adhesive plate with an opening surrounding the stoma.

It is frequently seen in ostomy patients that the closest surroundings of the stoma, at a distance of 1-2 cm, are recessed or are positioned in a crater or a cavity with respect to the rest of the skin surface that surrounds the stoma. For such patients it is expedient to use an ostomy appliance where the adhesive surface around its opening for receiving the stoma has a part which protrudes toward the user with a view to enabling the adhesive face of the ostomy equipment to engage and adhere to the skin everywhere in the crater or the cavity. In particular, it is important that the ostomy equipment adheres to the skin as closely to the stoma as possible, and this location is most frequently the one lying deepest. The shape of the forwardly protruding part of the adhesive face may e.g. be domed or conical, and such appliances are known under the



designation convex appliances. Throughout the specification the term convex has this broad meaning irrespective of the actual embodiment.

5 The invention concerns a convex adapter where the proximal side (the side facing toward the patient) has a convex face, and where an ordinary ostomy bag is adhered to the distal side of the adapter (the side facing away from the patient).

10

EP 416 397 discloses an adapter of the present type which is provided with a layer of adhesive protruding beyond the outer periphery of the ring-shaped, convex member, the adhesive being exposed on the distal side of the adapter so that when coupled with the adhesive plate of the ostomy equipment it will be in direct contact with the adhesive of this plate. The adhesive of the adapter and the adhesive of the ostomy equipment must be compatible here, which puts a limit to the selection of adhesives. Furthermore, an adapter adhered to ostomy equipment cannot be separated later, which makes it impossible to use the adapter for several collection bags.

15

20

EP 317 326 describes a convex adapter where a rigid ring on its entire convex side carries an intermediate ring of soft thermoplastic foam adhered to the rigid ring. The intermediate ring carries a layer of adhesive for mounting the adapter on the skin of a user. The foam ring is a cost-increasing component, and attachment by adhesion to the rigid ring makes the manufacturing process more expensive. Such an adapter requires the use of collection bags having a skin-friendly adhesive which is expensive.

25

30

A preferred
The object of the invention is to provide a universally useful convex adapter which is not vitiated by the above-mentioned drawbacks, but which can be used together with

35



any known type of ostomy equipment, and which preferably enables use of collection bags with industrial adhesives which are frequently more inexpensive than special medical grade skin adhesives.

5

According to the present invention there is provided an adapter for use with ostomy equipment and comprising a ring-shaped member with a radial extent between an inner periphery and an outer periphery and having a proximal surface and a
10 distal surface, said proximal surface having a convex face and on its proximal side a layer of adhesive by means of which the adapter can be adhered to a user's skin, the ring-shaped member comprising a central, relatively rigid ring with the convex face and a peripheral part which is an
15 integrated part of the relatively rigid ring, characterized in that the peripheral part is relatively flexible and extends radially considerably further than the relatively rigid ring, the peripheral part having a proximal side and a distal side, the proximal side being in contact with the
20 layer of adhesive, and at least as far as the layer of adhesive, the distal side being flat and non-adhesive and being adapted for direct connection with the ostomy equipment.

25 Handling of the product is facilitated considerably when the user is to use the product. The user can decide to mount the adapter on the ostomy equipment before this is placed on the user's skin around the stoma. Alternatively, the adapter can first be placed on the skin around the stoma, and then the
30 ostomy bag is fitted on this. Furthermore, the adapter of an embodiment of the invention has just one adhesive face, which, in contrast to two opposed adhesive faces, gives an easier and safer handling.

35 The structure of embodiments of the adapter are such that its adhesive will not get in contact with the adhesive of the ostomy equipment. Plasticizers, if any, in the adhesive are



thereby prevented from migrating or diffusing from one adhesive to the other. This makes it possible to use even widely different adhesives on the adapter and on the ostomy equipment. The adhesive on the adapter and ostomy equipment
5 which gets in contact with the user's skin should be of a special skin-friendly type, but the adapter of the invention makes it possible to use ostomy equipment with any suitable adhesives without special requirements on skin friendliness, because skin contact can be avoided.

10

Because the adapter of an embodiment of the invention has just one adhesive face, it cannot be mounted wrongly. In adapters having two opposed, adhesive faces, each of which is covered by a protective layer, it is theoretically possible
15 that the



user uses the product wrongly.

5 Since the adhesive of the adapter is always carried by the ring-shaped member and the sheet integrated with it, the adhesive is never completely exposed. The ring-shaped member and the sheets integrated with it always support and carry the adhesive, thus ensuring that the user will not unintentionally tear the adhesive.

10 Furthermore, a special embodiment of the invention is possible in which controlled release properties are imparted to the distal side of the adapter, so that an adhered ostomy bag can be removed without the convex adapter, placed around a user's stoma, being removed too. When the
15 bag is to be exchanged, the adapter therefore remains on the user's skin, thereby permitting the same adapter to be used for several bags successively.

20 An embodiment of the invention will now be described by way of example only with reference to the drawings, in which:

Fig. 1 shows a preferred embodiment of the adapter of the invention, and

25 Fig. 2 shows a section through the adapter in Fig. 1 along the line II-II.

30 The shown adapter has a ring 10 with a central opening 11 and a convex, curved face 12. The convex face 12 is intended to face toward the user, and this side of the adapter is therefore called the proximal side. The opposite side 13 of the ring 10 is flat. The central opening 11 of the ring 10 has a rounded edge 14 near the proximal side of the ring, and distally from the edge 14 the central opening 11 expands toward the flat, distal side 13 of
35 the ring.

5 A ring-shaped sheet 15 is placed so as to protrude, with its inner periphery 16, inwardly over the flat, distal side 13 of the ring 10, to which it is attached by means of a weld 17 so that the ring 10 and the sheet 15 are contiguous.

10 A ring-shaped sheet 18 is placed so as to protrude, with its outer periphery 19, inwardly over the convex face 12 of the ring 10, to which it is attached by a weld 20 so that the sheet 18 and the ring 10 are contiguous.

15 In the preferred embodiment the ring 10, the sheet 15 and the sheet 18 consist of the same material, viz. EVA. The ring 10 has dimensions so that it is relatively rigid with the selected material, i.e. it substantially maintains its shape and dimensions when subjected to normally occurring forces. The sheets 15 and 18 have a thickness so that they are flexible with the selected material, i.e. they are substantially dimensionally stable and are capable of
20 adapting to the contours of the skin and the stoma.

25 The ring 10 and the sheets 15 and 18 serve as an integrated, ring-shaped member and can optionally be produced by moulding in one process. A layer 21 of a skin-friendly adhesive, which is usually employed for products of this type, is applied on the proximal side of this member 10, 15, 18. A preferred adhesive is described in the DK Patent 157899. Such adhesives usually have a thickness of about 1
30 mm, while other industrial adhesives typically have a thickness of 0.02-0.03 mm. During the ordinarily long contact with the user's skin the adhesive must be capable of adsorbing the moisture which is constantly released from the skin, and the adhesive must therefore have the mentioned relatively great thickness.

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The adhesive 21 extends as an unbroken layer substantially from the inner periphery 22 of the sheet 18 and to the outer periphery 23 of the sheet 15. Adhesives of the type used here may tend to flow or creep, and it may therefore
5 be expedient that the adhesive 21 does not extend right into the inner periphery 22, nor right out to the outer periphery 23, thereby providing an additional margin for compensation for the flow of the adhesive.

10 The adapter is moreover provided with a removable protective layer 24, which is formed e.g. by vacuum forming so that ideally the protective layer has the same shape as the convex side of the adhesive 21. The protective layer is to offer protection against drying of the adhesive, but
15 also to support the adhesive so that cold flow is limited to the greatest extent possible, and the ideal shape of the adhesive is maintained. The protective layer 24 therefore also covers the inner and outer peripheries of the adhesive. On the side facing toward the adhesive 21 the
20 protective layer is provided with a release coating so that it can easily be removed before the adapter is put to use.

The adhesive plate of the ostomy equipment, with which the
25 adapter of the invention is to be used, may typically have a diameter of 10 cm, which corresponds to the outer diameter of the sheet 15 in a preferred embodiment of the invention. The adhesive plate of the ostomy equipment is then attached by adhesion to the flat, distal side of the
30 adapter, which consists of the flat, distal side 13 of the ring 10 as well as the distal side of the sheet 15. The sheet 15, which is thus positioned between the adhesive 21 of the adapter and the adhesive of the ostomy equipment (not shown), here provides mechanical stabilization of the
35 adhesive layers and protects against migration of plasticizers between the two optionally different adhesives.

5 It is noted that in the embodiment shown here the adhesives of the ostomy equipment at no time come into direct contact with the user's skin, but only adhere the ostomy equipment to the distal side of the adapter. Here, any adhesive technically suitable for the purpose may be used for the ostomy equipment, without such an adhesive having to possess special medical properties, e.g. in the form of skin-friendliness.

10 The ostomy equipment (not shown) with which the adapter of the invention is to be used, may be a collection bag with an integrated adhesive plate, or ostomy equipment consisting of two parts which are coupled together in use, one of which carrying an adhesive plate with a coupling part for
15 coupling with the other part of the ostomy equipment which consists of a collection bag with the other part of the coupling. A preferred coupling is described in the International Patent Application PCT/DK90/00192. The part of such an ostomy coupling which is integrated with the adhesive plate may advantageously be integrated with the
20 adapter of the invention, since this coupling part may advantageously be contiguous with the ring 10 and be attached to it by welding.

25 In use the central opening 11 of the adapter surrounds the user's stoma, which often protrudes somewhat from the surrounding skin and into the central opening 11. The sheet 18 is flexible so that it can yield and conform to the stoma. However, the user often needs to adapt the ostomy
30 equipment to the shape of the stoma, and the user can here cut the sheet 18 and the part of the adhesive 21 positioned across the sheet 18, thereby providing an opening which fits the stoma in the best way possible.

35 Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.



THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. An adapter for use with ostomy equipment and comprising a ring-shaped member with a radial extent between an inner periphery and an outer periphery and having a proximal surface and a distal surface, said proximal surface having a convex face and on its proximal side a layer of adhesive by means of which the adapter can be adhered to a user's skin, the ring-shaped member comprising a central, relatively rigid ring with the convex face and a peripheral part which is an integrated part of the relatively rigid ring, characterized in that the peripheral part is relatively flexible and extends radially considerably further than the relatively rigid ring, the peripheral part having a proximal side and a distal side, the proximal side being in contact with the layer of adhesive, and at least as far as the layer of adhesive, the distal side being flat and non-adhesive and being adapted for direct connection with the ostomy equipment.

2. An adapter according to claim 1, characterized in that the peripheral part is an outer flexible sheet which is welded to the central ring.

3. An adapter according to claim 1 or claim 2, characterized in that the ring-shaped member comprises an inner relatively flexible sheet which is an integrated part of the relatively rigid ring and extends inwards of the inner periphery of said ring.

4. An adapter according to claim 3, characterized in that the inner relatively flexible sheet is welded to the relatively rigid ring.

5. An adapter according to any one of claims 1 to 4, characterized in that the adhesive layer is covered by a removable protective sheet.



6. An adapter according to claim 5, characterized in that the protective sheet has a shape which is adapted to the proximal side of the adapter.

7. An adapter according to claim 1, characterized in that the peripheral part is made of a material impermeable to substances harmful to the skin to thereby provide a barrier between such substances and the layer of the adhesive.

8. An adapter substantially as hereinbefore described with reference to the accompanying drawings.

DATED this 23rd day of February, 1995.

COLOPLAST A/S

By its Patent Attorneys:

DAVIES COLLISON CAVE



25521/92

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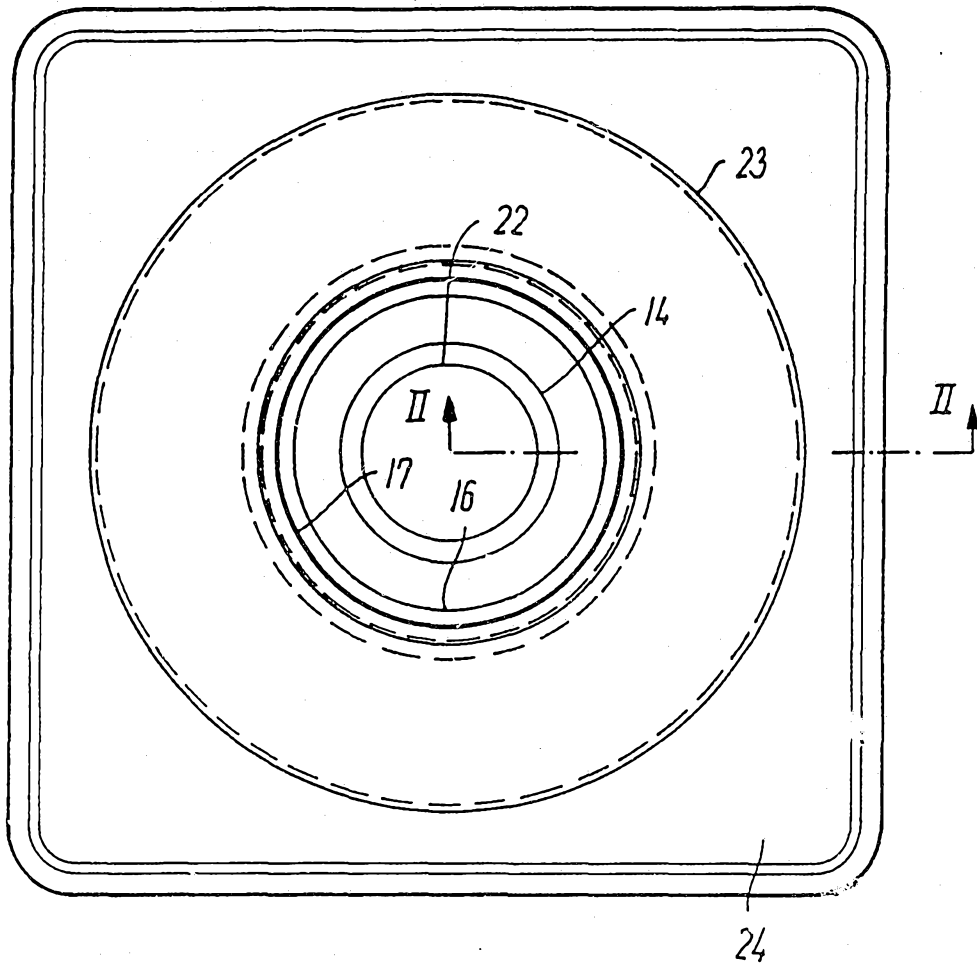


FIG. 1

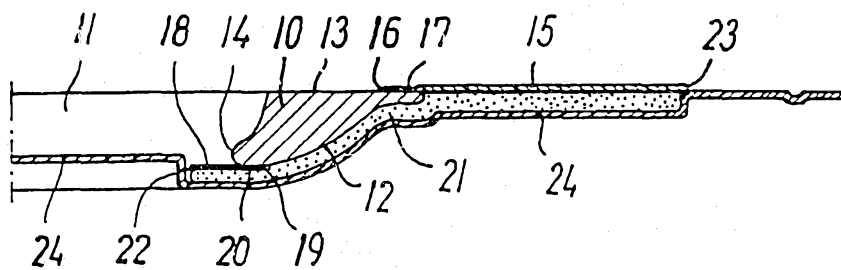


FIG. 2

INTERNATIONAL SEARCH REPORT

International Application No PCT/DK 92/00258

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC5: A 61 F 5/448		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC5	A 61 F	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in Fields Searched ⁸		
SE,DK,FI,NO classes as above		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	US, A, 4710182 (BRYSON) 1 December 1987, see column 4, line 6 - line 35; figures 4-5 --	1,5-6
X	US, A, 4834731 (NOWAK ET AL) 30 May 1989, see column 3, line 33 - column 6, line 52; figures 1,8 --	1-6
X	US, A, 4973323 (KACZMAREK ET AL) 27 November 1990, see column 3, line 11 - column 6, line 8; figure 3 --	1-4
A	US, A, 4219023 (GALINDO) 26 August 1980, see figure 2 -- -----	1
<p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"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</p> <p>"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search		Date of Mailing of this International Search Report
3rd December 1992		07-12-1992
International Searching Authority		Signature of Authorized Officer
SWEDISH PATENT OFFICE		Leif Brander

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.PCT/DK 92/00258**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the Swedish Patent Office EDP file on **30/10/92**. The Swedish Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4710182	87-12-01	AU-B- 598068	90-06-14
		AU-D- 8204387	88-06-09
		CA-A- 1269293	90-05-22
		DE-A- 3740713	88-07-07
		FR-A- 2607697	88-06-10
		GB-A-B- 2199250	88-07-06
		JP-A- 63150067	88-06-22
US-A- 4834731	89-05-30	AU-D- 2479588	89-05-25
		EP-A- 0317326	89-05-24
		GB-A-B- 2212400	89-07-26
		JP-A- 1164374	89-06-28
US-A- 4973323	90-11-27	AU-B- 622041	92-03-26
		AU-D- 6084190	91-03-07
		CA-A- 2023254	91-03-02
		EP-A- 0415592	91-03-06
		JP-A- 3099660	91-04-24
US-A- 4219023	80-08-26	CA-A- 1129290	82-08-10