



(51) International Patent Classification:
A61F 5/44 (2006.01)

(21) International Application Number:
PCT/GB2009/000657

(22) International Filing Date:
11 March 2009 (11.03.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0805483.5 26 March 2008 (26.03.2008) GB

(71) Applicant (for all designated States except US): **SALTS HEALTHCARE LIMITED** [GB/GB]; Richard Street, Aston, Birmingham B7 4AA (GB).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **WILTSHIRE, Neil** [GB/GB]; Salts Healthcare Limited, Richard Street, Aston, Birmingham, West Midlands B7 4AA (GB). **DAVISON, Eric** [GB/—]; Salts Healthcare Limited, Richard Street, Aston, Birmingham, West Midlands B7 4AA (GB).

(74) Agent: **FORRESTER KETLEY & CO**; Chamberlain House, Paradise Place, Birmingham B3 3HP (GB).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: OSTOMY APPLIANCE

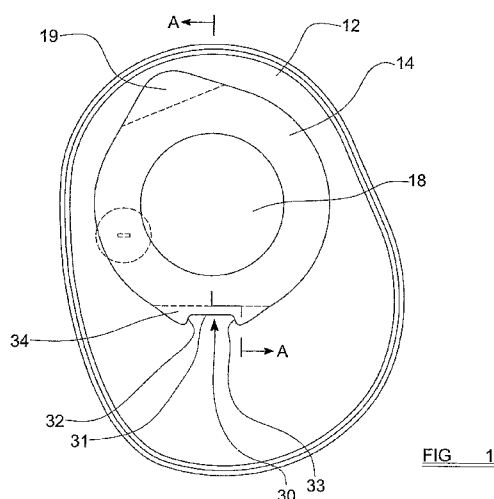


FIG. 1

(57) Abstract: A two piece ostomy appliance is described having: a pouch (12) for receipt of waste; a pouch flange (14) connected to the pouch, the pouch flange having an opening (18) communicating with an interior of the pouch; and a bodyside flange (20) with an opening (24) and a hydrocolloid layer (22) for securing the bodyside flange to a body of a user around their stoma, the bodyside flange including a location projection (40) which is receivable in a recess in a part of the pouch flange to align the opening of the pouch flange relative to the opening of the bodyside flange; wherein a surface of the pouch flange which in use faces the bodyside flange includes an adhesive for adhering the pouch flange to the bodyside flange, characterised in that the recess is positioned at a periphery of the pouch flange and extends outwardly away from the opening communicating with an interior of the pouch.

Ostomy Appliance

Description of Invention

- 5 The invention relates to an ostomy appliance and in particular to a coupling system incorporated into an ostomy appliance which comprises a first part (a "bodyside" part) for securing to the body of the user and a pouch releasably securable to the bodyside part for receipt of waste.
- 10 Such ostomy appliances are known and are referred to as two piece appliances. The manner of securing the pouch to the bodyside part be adhesive or by means of some form of engagement system with co-operating formations on the bodyside part and on the pouch. Many prior art products suffer from the problem that users, who are often elderly and thus have
- 15 relatively poor eyesight and/or are not very dextrous, have difficulty aligning the pouch with the bodyside part to ensure good connection, and thus an unobstructed fluid passage between the body side part and the pouch. This can lead to leaks and poor customer satisfaction.
- 20 It is an aim of the present invention to provide an alternative two piece ostomy appliance which seeks to mitigate the above described problem.

According to a first aspect of the present invention there is provided an ostomy appliance having:

- 25 a pouch for receipt of waste;
a pouch flange connected to the pouch, the pouch flange having an opening communicating with an interior of the pouch; and
a bodyside flange with an opening and a hydrocolloid layer for securing the bodyside flange to a body of a user around their stoma, the bodyside
- 30 flange including a location projection which is receivable in a recess in a part of the pouch flange to align the opening of the pouch flange relative to the opening of the bodyside flange;

wherein a surface of the pouch flange which in use faces the bodyside flange includes an adhesive for adhering the pouch flange to the bodyside flange,

characterised in that the recess is positioned at a periphery of the
5 pouch flange and extends outwardly away from the opening communicating with an interior of the pouch.

The invention provides the advantage that the locating projection on the bodyside flange assists the user in locating the pouch flange accurately with
10 respect to the bodyside flange by feel rather than sight, so that the opening in the bodyside flange is aligned relative to the opening in the pouch flange.

Further features of the invention are set out in claims 2 to 13 appended hereto.

15

Examples of the invention will now be described by way of example only with reference to the accompanying drawings, of which:-

Figure 1 is a front view of a pouch and pouch flange in accordance with the
20 present invention;

Figure 2 is a cross-sectional view of the pouch and pouch flange of figure 1 through the plane A-A;

25 Figure 3 is a front view of bodyside flange in accordance with the present invention;

Figure 4 is a cross-sectional view of the bodyside flange of figure 3 through the plane B-B; and

30

Figure 5 is a side view of the pouch flange and bodyside flange connected to each other.

Referring to figures, these show an ostomy appliance which has two main parts: a) pouch-side part including a pouch 12 for receipt of waste and a pouch flange 14 connected thereto; and b) a bodyside part including a bodyside flange 20.

The pouch flange 14 is substantially annular and is connected to the pouch 12 by a suitable adhesive, by heat welding or any other suitable joining method. The pouch flange 14 has an opening 18, substantially centrally therethrough which communicates with an interior 20 of the pouch 12. The components parts of the pouch 12 are well known in the art and will therefore not be discussed in any further detail herein. A surface of the pouch flange 14 which in use faces a user includes an adhesive layer 15 for adhering the pouch flange 14 to a bodyside flange 20 (discussed below). The adhesive layer 15 is strong enough to hold the pouch flange 14, and hence the pouch 12, relative to the bodyside flange 20, but permits the two flanges to be separated when it is required to remove the pouch 12 for emptying and/or to replace the pouch 12 with a fresh one. Whilst the pouch flange 14 is not in use, the adhesive layer 15 is covered by a removable cover 17, to maintain the integrity of the adhering properties of the layer 15.

The pouch flange 14 has a tab portion 19 at its uppermost end (in normal use), the surface of which is non-adhesive, either as a result of no adhesive being present at that portion of the flange 14 or as a result of a cover which is adhered to the tab portion 19. The non-adhesive characteristics of the tab portion 19 permit a user to grasp an adjacent portion of the cover 17, so that the cover 17 can be removed (discussed in detail later). The tab portion 19 also acts as a means for removing the pouch flange 14 from the bodyside flange 20.

The pouch flange 14 includes a recess 30 which in the present example is positioned at a periphery of the pouch flange 14. The recess 30 extends, substantially radially outwardly away from the opening 18. The recess 30 has a pair of side walls 32, 33 which are connected by a substantially flattened
5 base wall 31. The side walls 32, 33 extend away from each other as they extend away from the opening 18.

A region of the surface of the pouch flange 14 which surrounds the recess 30 is non-adhesive. In the present example, this is achieved by adhering a cover
10 34 to the surface surrounding the recess 30. The outermost surface of the cover 34 is non-adhesive, thus ensuring that the cover 17 does not adhere to that region of the pouch flange 14.

As discussed above, the appliance also includes a bodyside flange 20 which
15 is also annular. The bodyside flange 20 has a hydrocolloid layer 22 for securing the bodyside flange 20 to a body of a user around their stoma, and an opening 24 therethrough to provide for fluid communication between the user's stoma and the opening 18 in the pouch flange 14. The opening 24 can be increased in size by cutting the hydrocolloid layer 22, as is well known in
20 the art. The hydrocolloid layer 22 is covered by a removable cover 25 which has a tab portion 26 for assisting in removal of the cover 25.

The bodyside flange 20 also includes a location projection 40 which is positioned at a periphery of the flange 20. The location projection 40 is an
25 elongate substantially straight ledge, which extends substantially perpendicularly away from a general plane of the flange 20. A surface 41 of the location projection 40 which faces the opening 24 is flattened.

In use, the location projection 40 is received in the recess 30 so that the
30 opening 18 of the pouch flange 14 is aligned relative to the opening 24 of the bodyside flange 20. This is achieved as follows.

The bodyside flange 20 is adhered to a user's skin such that the opening 24 is aligned with, and, if possible, receives the user's stoma. The hydrocolloid layer 22 (having had the cover 25 removed therefrom) adheres to the user's skin so as to provide a comfortable, strong and water-tight seal. Ideally, the
5 bodyside flange 20 should be positioned on the user such that, when the user is standing upright, the flattened surface 41 of the location projection 40 is vertically beneath a centre of the opening and such that the flattened surface 41 is substantially horizontal.

10 The user then positions the pouch flange 14 by moving it downwardly until the flattened base wall 31 engages the flattened surface 41 of the location projection 40. Once the location projection 40 is received in the recess 30, the pouch flange 14 is aligned relative to the bodyside flange 20 such that opening 18 is also aligned relative to the opening 24. The user then removes
15 the cover 17, by grasping the tab portion 19 and pulling the tab portion outwardly and downwardly, until the cover 17 is completely removed. The user then pivots the pouch flange 14 towards the bodyside flange 20, using the flattened surface 41 of the location projection 40 as a fulcrum, until the pouch flange 14 is adhered completely to the bodyside flange 20.
20 Alternatively, the user may remove the cover 17 partially or completely before engaging the flattened surface 41 of the location projection 40 with the flattened base wall 31 of the recess 30.

The present invention is advantageous over known designs because, when
25 the location projection 40 is fully received in the recess 30, rotational movement of the pouch flange 14 and bodyside flange 20 relative to each other, about an axis which extends substantially perpendicularly through the flanges 14, 20 (more particularly about an axis which extends substantially through the flanges in a vicinity of the recess 30), is inhibited. This helps the
30 user ensure that the flanges 14, 24 are aligned before they are adhered to each other. In addition, the pair of opposing side walls 32, 33 inhibit lateral

movement of the pouch flange 14 relative to the bodyside flange 20, thus providing further assurance for the user that the flanges 14, 20 are correctly aligned.

- 5 The provision of the non-adhesive region, in the present example the cover 34, surrounding the recess 30 allows for a user to make slight adjustments of the position of the pouch flange 14 relative to the bodyside flange 20 when engaging the location projection 40 in the recess 30, because the region surrounding the recess will not adhere to the bodyside flange 20. The cover
- 10 34 also ensures that the user can easily remove the cover 17 without having to disengage the projection 40 from the recess.

It should be appreciated that the adhesive layer 15 and its cover 17 could, alternatively, be provided on the bodyside flange 20, rather than on the pouch

15 flange 14. In that case, it would be desirable for a region surrounding the location projection 40 (at least the region adjacent the flattened surface 41) to be non-adhesive, for the same reasons as mentioned above regarding the cover 34.

- 20 The materials from which the embodiments of the invention may be constructed are not limited in any way except by the properties of the materials themselves. However, examples of suitable materials are:
- for the pouches themselves one or more layers of ethylene vinyl acetate (EVA) and a barrier layer such as polyvinylidene chloride (PVDC);
- 25 for foam elements, polyethylene foam;
- for the injection moulded plastic flanges, ethylene vinyl acetate (EVA) or polyethylene.

When used in this specification and claims, the terms "comprises" and

30 "comprising" and variations thereof mean that the specified features, steps or

integers are included. The terms are not to be interpreted to exclude the presence of other features, steps or components.

- 5 The features disclosed in the foregoing description, or the following claims, or the accompanying drawings, expressed in their specific forms or in terms of a means for performing the disclosed function, or a method or process for attaining the disclosed result, as appropriate, may, separately, or in any combination of such features, be utilised for realising the invention in diverse forms thereof.

Claims

1. An ostomy appliance having:
 - a pouch for receipt of waste;
 - 5 a pouch flange connected to the pouch, the pouch flange having an opening communicating with an interior of the pouch; and
 - a bodyside flange with an opening and a hydrocolloid layer for securing the bodyside flange to a body of a user around their stoma, the bodyside flange including a location projection which is receivable in a recess in a part
 - 10 of the pouch flange to align the opening of the pouch flange relative to the opening of the bodyside flange;
 - wherein a surface of the pouch flange which in use faces the bodyside flange includes an adhesive for adhering the pouch flange to the bodyside flange,
 - 15 characterised in that the recess is positioned at a periphery of the pouch flange and extends outwardly away from the opening communicating with an interior of the pouch.
2. An ostomy appliance according to claim 1 wherein when the location
- 20 projection is received in the recess, rotational movement of the pouch flange and bodyside flange relative to each other, about an axis which extends substantially perpendicularly through the flanges, is inhibited.
3. An ostomy appliance according to claim 1 or 2 wherein when the
- 25 location projection is received in the recess, angular movement of the pouch flange and bodyside flange relative to each other, about an axis which extends substantially perpendicularly through the flanges in a vicinity of the recess, is inhibited.

4. An ostomy appliance according to any preceding claim wherein the projection has a flattened portion which engages a correspondingly flattened portion of the recess.

5 5. An ostomy appliance according to any preceding claim wherein the recess includes a pair of opposing side walls which inhibit lateral movement of the pouch flange relative to the bodyside flange.

10 6. An ostomy appliance according to claim 5 wherein the side walls of the recess extend away from each other as they extend away from the opening communicating with an interior of the pouch.

15 7. An ostomy appliance according to claim 6 wherein the side walls extend away from the opening communicating with an interior of the pouch in a general plan of the pouch flange.

8. An ostomy appliance according to any preceding claim wherein the location projection is an elongate.

20 9. An ostomy appliance according to any preceding claim wherein the location projection is substantially straight.

10. An ostomy appliance according to any preceding claim wherein the location projection is ledge-shaped.

25

11. An ostomy appliance according to any preceding claim including a removable cover member which covers the adhesive surface of the pouch flange prior to use.

12. An ostomy appliance according to any preceding claim wherein a region of the surface of the pouch flange which surrounds the recess is non-adhesive.

- 5 13. An ostomy appliance according to any preceding claim wherein a region of the surface of the pouch flange which surrounds the recess is adhesive and is covered by a cover the outermost surface of which is non-adhesive, the cover intended to remain in situ when the flanges are adhered to each other.

10

14. An ostomy appliance substantially as hereinbefore described with reference to and as shown in the accompanying drawings.

15

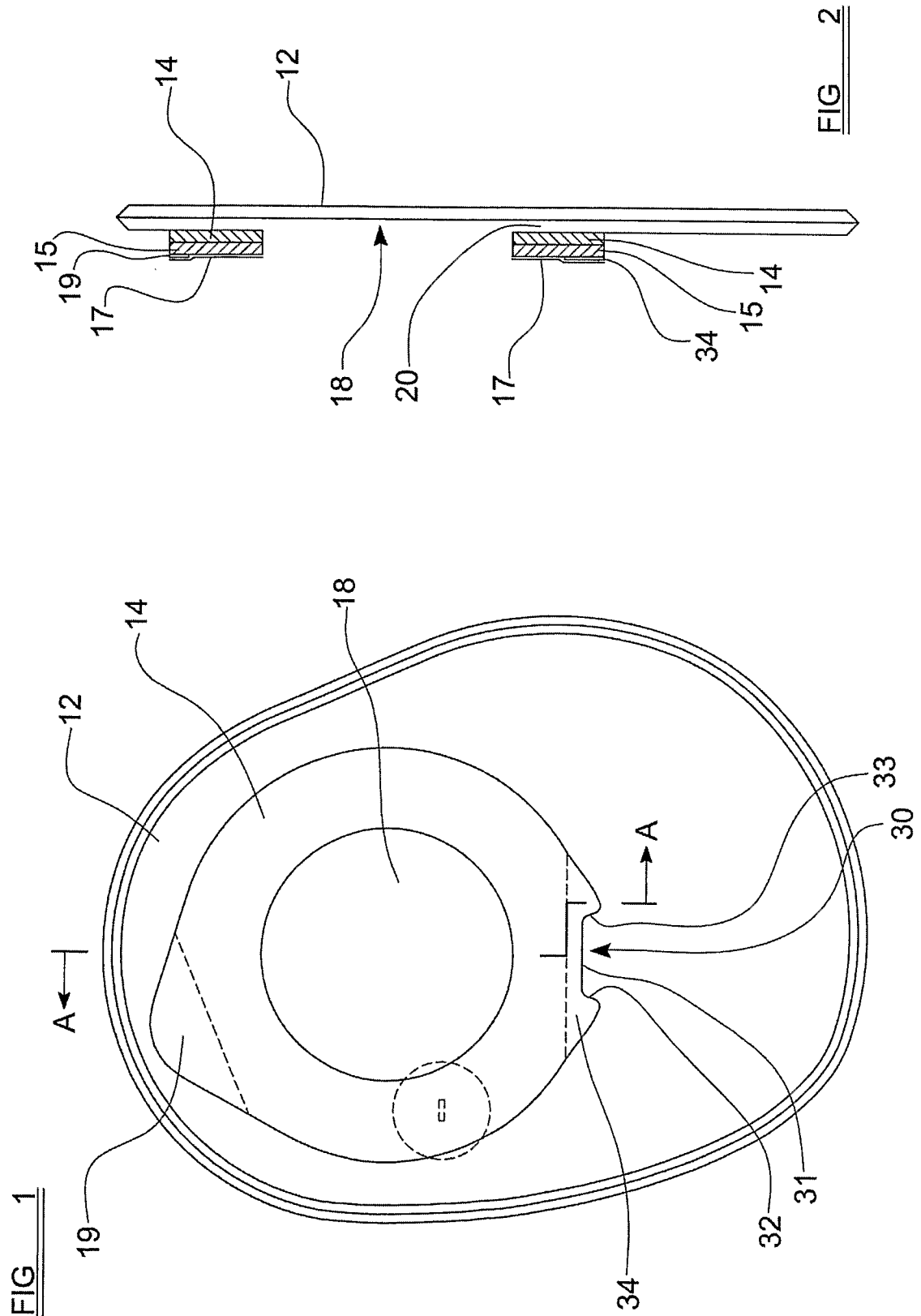


FIG 2

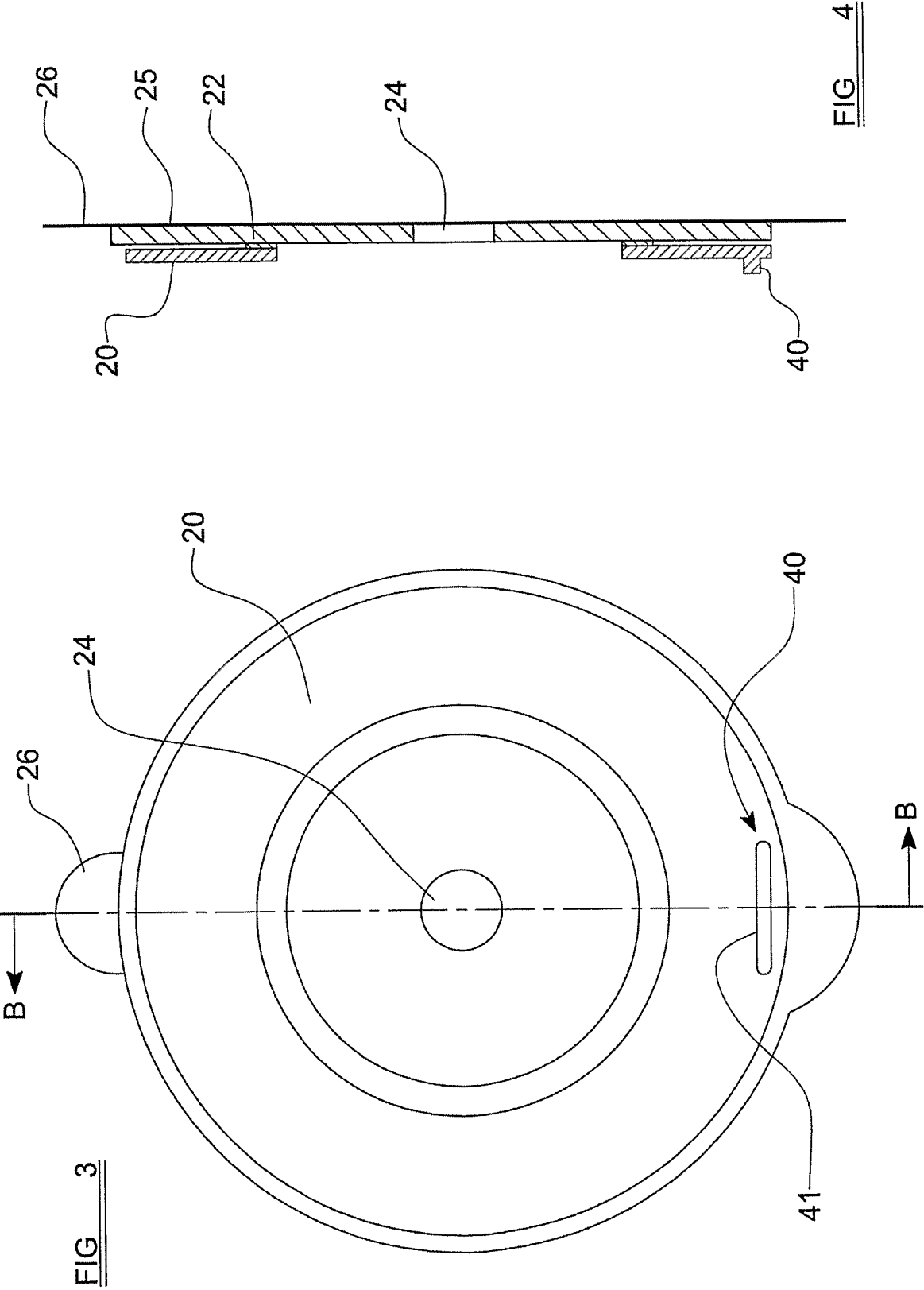
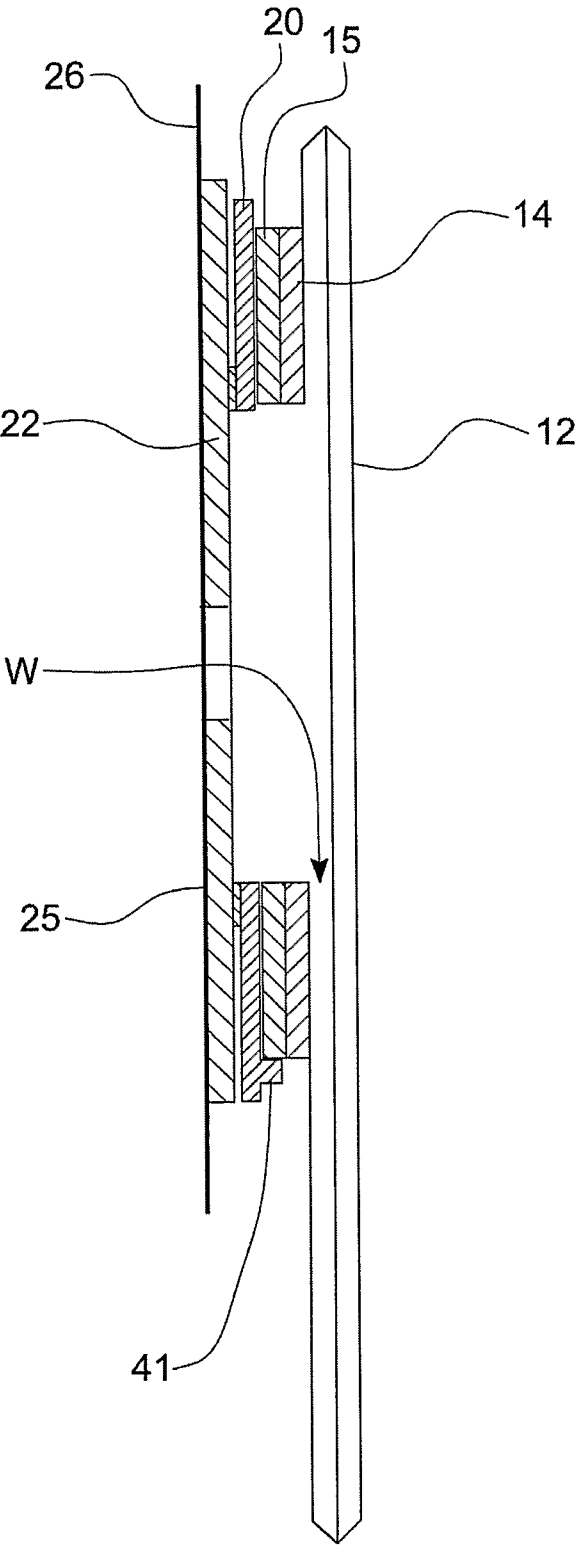


FIG 5



INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2009/000657

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F5/44

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.
X	US 2007/005032 A1 (SHAN NICOLAS [FR] ET AL) 4 January 2007 (2007-01-04)	1-3,8-13
A	abstract; figures paragraphs [0016] - [0018] paragraphs [0049] - [0056] paragraphs [0070] - [0072]	4-7
A	US 5 356 399 A (TAKAHASHI TETSUYA [JP]) 18 October 1994 (1994-10-18) abstract; figures column 2, lines 35-68 column 3, line 53 - column 4, line 48 column 5, line 30 - column 6, line 12 ----- -/--	1-13

☒ 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

7 May 2009

Date of mailing of the international search report

18/05/2009

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Lager, Johan

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2009/000657

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2005/082271 A (COLOPLAST AS [DK]; MUELLEJANS PETER [DK]; HANSEN MICHAEL [DK]) 9 September 2005 (2005-09-09) abstract; figure 12 page 1, lines 4-7 page 4, lines 2-28 page 17, lines 13-22 -----	
A	EP 0 463 359 A (SQUIBB & SONS INC [US]) 2 January 1992 (1992-01-02) abstract; figures -----	
A	DE 12 66 929 B (CAROLI FA HEINRICH) 25 April 1968 (1968-04-25) figures -----	

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 14

The claim makes references to the description and drawings contrary to Rule 6.2(a) PCT.

Continuation of Box II.2

Claims Nos.: 14

The claim makes refereces to the description and drawings contrary to Rule 6.2(a) PCT.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2009/000657

Box No. 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.: 14
because they relate to subject matter not required to be searched by this Authority, namely:
The claim makes references to the description and drawings.
The claim makes references to the description and drawings contrary to Rule 6.2(a) PCT.
2. ☒ Claims Nos.: 14
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 No. 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 allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International search reportcovers 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 and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2009/000657

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2007005032	A1	04-01-2007	AT 424793 T EP 1663084 A2 WO 2005025466 A2 JP 2007505664 T	15-03-2009 07-06-2006 24-03-2005 15-03-2007
US 5356399	A	18-10-1994	CA 2061229 A1 DE 4203950 A1 GB 2253146 A	16-08-1992 20-08-1992 02-09-1992
WO 2005082271	A	09-09-2005	EP 1725197 A2 US 2007260206 A1	29-11-2006 08-11-2007
EP 0463359	A	02-01-1992	AT 144122 T CA 2042651 A1 DE 9116605 U1 DE 69122669 D1 DE 69122669 T2 DK 0463359 T3 ES 2093045 T3 GR 3022270 T3 IE 911665 A1 JP 4231045 A NO 912068 A NZ 238170 A US 5088992 A ZA 9103607 A	15-11-1996 01-12-1991 19-05-1993 21-11-1996 20-03-1997 18-11-1996 16-12-1996 30-04-1997 04-12-1991 19-08-1992 02-12-1991 26-05-1994 18-02-1992 25-03-1992
DE 1266929	B	25-04-1968	NONE	