

**(12) STANDARD PATENT**  
**(19) AUSTRALIAN PATENT OFFICE**

(11) Application No. **AU 2019276067 B2**

(54) Title  
**Multifunctional release liner for dressings**

(51) International Patent Classification(s)  
**A61F 13/02** (2006.01)                      **A61F 13/00** (2006.01)

(21) Application No: **2019276067**                      (22) Date of Filing: **2019.05.28**

(87) WIPO No: **WO19/229090**

(30) Priority Data

(31) Number	(32) Date	(33) Country
<b>18175192.6</b>	<b>2018.05.30</b>	<b>EP</b>

(43) Publication Date: **2019.12.05**

(44) Accepted Journal Date: **2024.11.14**

(71) Applicant(s)  
**Mölnlycke Health Care AB**

(72) Inventor(s)  
**JOELSSON, Hans;HALLERSTIG, Linn Liu;EIBPOOSH, Shiva;BLOMQVIST, Annelie**

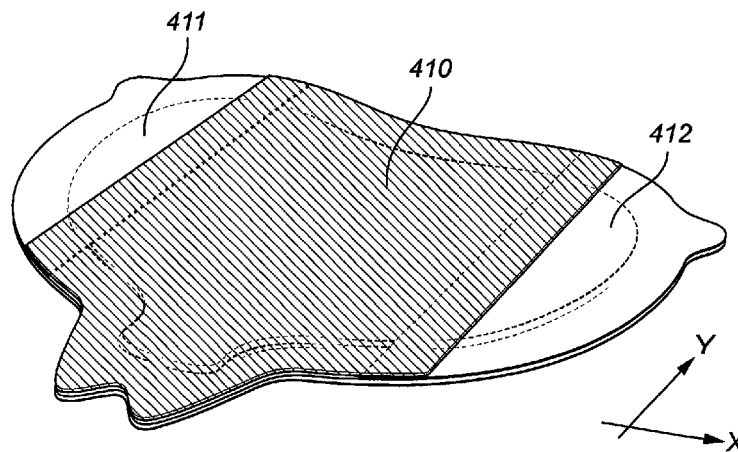
(74) Agent / Attorney  
**FB Rice Pty Ltd, L 23 44 Market St, Sydney, NSW, 2000, AU**

(56) Related Art  
**US 2010/0106120 A1**  
**US 2004/0049146 A1**



- (51) **International Patent Classification:**  
*A61F 13/02* (2006.01)      *A61F 13/00* (2006.01)
- (21) **International Application Number:**  
PCT/EP2019/063880
- (22) **International Filing Date:**  
28 May 2019 (28.05.2019)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**  
18175192.6      30 May 2018 (30.05.2018)      EP
- (71) **Applicant:** **MÖLNLYCKE HEALTH CARE AB** [SE/SE]; Gamlestadsvägen 3C, 40252 Göteborg (SE).
- (72) **Inventors:** **JOELSSON, Hans**; Doktor Bex gata 7a, 41324 Göteborg (SE). **HALLERSTIG, Linn Liu**; Bratteråsbacken 39, 41762 Göteborg (SE). **EIBPOOSH, Shiva**; Rustmästaregatan 27, 41528 Göteborg (SE). **BLOMQVIST, Annelie**; Haglingevägen 7, 44447 Stenungsund (SE).
- (74) **Agent:** **TOSTMANN, Holger**; Wallinger Ricker Schlotter Tostmann, Patent- und Rechtsanwälte mbB, Zweibrückenstr. 5-7, 80331 München (DE).
- (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, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, 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, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, 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, RS, SE, SI, SK, SM,

(54) **Title:** MULTIFUNCTIONAL RELEASE LINER FOR DRESSINGS



**Fig. 4**

(57) **Abstract:** The present invention generally relates to a dressing comprising a backing layer, an (absorbent) pad, an adhesive coating and a release liner. The release liner is releasably attached to the adhesive coating. The release liner is configured to stiffen up and protect protrusions and/or border portions of the dressing that may otherwise be wrinkled, folded, kinked or otherwise damaged or impaired prior to (transportation or storage) or during application at the point-of-use. The dressing of the present invention is suitable for wound treatment. The dressing is, in particular, suitable for preventing shear and/or friction from causing (deep tissue) skin damage, in particular for the prevention of pressure ulcers.



TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,  
KM, ML, MR, NE, SN, TD, TG).

**Published:**

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

## MULTIFUNCTIONAL RELEASE LINER FOR DRESSINGS

### 5 Technical field

The present invention relates to a dressing comprising a backing layer, a pad, an adhesive coating and a release liner. Said release liner is releasably attached to an adhesive coating. The release liner is configured to stiffen up and protect protrusions  
10 and/or border portions of the dressing, which may otherwise be wrinkled, folded, kinked or in any way damaged or impaired, for example during transportation or storage, or during application at the point-of-use.

The dressing of the present invention is suitable for wound treatment and wound  
15 prevention, in particular for wound prevention, further particular for application onto contoured body parts.

### Background

20 Dressings of various sizes and shapes that have more sophisticated release liners are known from the art, in principle, for example from WO 2017/081012, WO 2017/220401 or WO 2017/220402 (all assigned to *Mölnlycke Health Care*). The release liners protect the dressing from contamination prior to use, and may also facilitate application of the dressing, thus increasing functionality and durability of the dressing in use.

25 WO 2017/220401 and WO 2017/220402 disclose dressings adapted to be applied to contoured body parts, i.e. particularly the sacrum and the heel, respectively. These dressings are suitable for preventing pressure ulcers. These types of dressings may be comparatively large and may have protrusions, i.e. areas that extend beyond the

characteristic extensions of the overall dressing, for example border regions at the edges of such dressings

5 Issues of stability that may arise in for such dressings having one or more protrusion is perhaps best exemplified in **Figure 1**, which shows two commercially available dressings for application onto contoured body parts, in particular the heel (figure 1a) and the sacrum (fig 1b). For example, protrusions (103a, 103a') and (103b, 104b') of a thinner border region (102, 102') extend beyond the thicker pad (101, 101'), by a distance  $d1'$ .

10 Typically, each dressing is packed into a single pack, and then a number of single packed dressings are packed into a larger packaging, such as a carton box. During storage and transport, the protrusions may fold or wrinkle when pressed against an inner surface of the single pack. Besides impairing the visual appearance of the dressing when removed from the package, such folding or wrinkling may have an effect on the dressing's stay-on  
15 ability. There is a risk that wrinkles formed turn into compartments for body fluids, eventually leading to fluid accumulation and reduced stay-on ability. These potential problems may be exacerbated for larger dressings and/or for dressings that have comparatively limited intrinsic stiffness, for example because the dressings have to be thin or comparatively flexible.

20 Even if such "flexible" dressings or dressings with portions that are susceptible to bending are temporarily protected and supported by a stiff or otherwise particularly designed *packaging*, dressings must eventually be taken out of the packaging, handled by a patient or caregiver and must ultimately be applied, which again, may cause the dressing to get  
25 wrinkled, wrapped, kinked or otherwise impaired during the application process (i.e. before all release liners are removed and the dressing is securely placed on the patient).

The present application may provide a dressing that has protrusions, wherein the problems associated with such dressings, as outlined above, are avoided or mitigated.

### Summary of the Invention

These and other problems are at least partially solved by a dressing having a maximum lateral (X2) (i.e. "sideways") and a maximum longitudinal (Y2) (i.e. perpendicular to the "sideways" extension and preferably along a line of symmetry) extension; wherein said dressing has at least one protrusion, wherein said protrusion has a lateral (X1) or a longitudinal (Y1) extension, or both, that is less than 50% of the maximum lateral (X2) or the maximum longitudinal (Y2) extension, or both, of the overall dressing; wherein said dressing has a first side and a second opposing side, the first side comprising an adhesive coating having a skin-facing surface adapted to detachably adhere the dressing to a dermal surface, wherein the dressing comprises a release liner that is releasably attached to the adhesive coating; wherein said release liner has an area of increased thickness or of increased stiffness, or both, in at least part of the area of said at least one protrusion, *and* in a part of the area outside of said at least one protrusion (but not in the entire area outside of said at least one protrusion); wherein said increased thickness or increased stiffness, or both, is or are measured vis-à-vis the thickness or stiffness, or both, of the release liner in the remaining area, i.e. the area in which the release liner is not reinforced in regard to thickness and/or stiffness (which is the "*remaining area*").

In embodiments, the dressing comprises

- a backing layer;
  - a pad contoured by a pair of lateral edges, wherein said lateral edges preferably extend essentially in parallel to each other in the longitudinal direction, and contoured by a pair of longitudinal edges, wherein said longitudinal edges preferably extend essentially in parallel to each other in the lateral direction;
- wherein said pad is arranged between said backing layer and said adhesive layer.

In accordance with the present invention, a “**protrusion**” is a segment of the dressing that extends beyond the central area of the dressing and is characterized by (maximum) lateral and longitudinal extensions that are 50% or less than the respective (maximum) lateral and longitudinal extensions of the overall dressing. An example of a protrusion is  
5 segment (103a /103a’) in Figure 1a/1b, segment 203 in Figure 2 or segment (303) in Figure 3.

While a part of the outline of the protrusion is defined by and coincides with the outer contour of the overall dressing, the remainder of the protrusion is defined by an imaginary  
10 line that separates the remaining area of the dressing from the protrusion. Such a separating line for protrusions (203) and (303) is shown as a dotted line in Figures 2 and 3, respectively. The exact position of this (imaginary) line is of no relevance for the present invention as the “reinforced” (increased thickness and/or stiffness) release liner of the present invention extends past this imaginary line and covers not only at least a part of  
15 the protrusion, but also at least a part of the remaining area of the dressing. This ensures that the protrusion “benefits” from the stability and stiffness of the overall dressing, in particular of the remaining area.

In embodiments of the present invention, the release liner has an area of increased  
20 thickness and/or increased stiffness in the entire area of the protrusion, and in a part of the area outside of said at least one protrusion.

In embodiments of the present invention, said area of said at least one protrusion is from  
25  $100 \text{ mm}^2$  to  $5000 \text{ mm}^2$ , preferably from  $100 \text{ mm}^2$  to  $2000 \text{ mm}^2$ , wherein said remaining area is from  $500 \text{ mm}^2$  to  $50000 \text{ mm}^2$ , preferably from  $1000 \text{ mm}^2$  to  $40000 \text{ mm}^2$ .

In embodiments of the invention, the dressing comprises a pad, preferably an absorbent pad and the backing layer extends beyond the periphery of said pad to define a **border portion** along at least a part of the contour of said pad, preferably along the entire contour  
30 of said pad.

The presence and relevance of such a border portion is perhaps best illustrated in **Figures 1a and 1b**, which show dressings (100, 100’) having a border portion (102, 102’)

running around the entire periphery of the pad (101, 101'), but being particularly pronounced - and defining protrusions (103a, 103a') and (103b, 103b') – in the bottom part of the dressings.

- 5 This border portion of a dressing is generally significantly more flexible and less rigid than the inside (central) part of the dressing (“remaining area”) that is reinforced by a pad. Therefore, this border portion, or parts thereof, may generally be more susceptible to wrinkling, folding, kinking etc.
- 10 Therefore in embodiments of the invention, at least parts of the border portion are encompassed by the area of the release liner that is of increased thickness or of increased stiffness, or both.

In embodiments of the present invention, at least a part of the border portion defines at  
15 least a part of a protrusion. In preferred embodiments at least a part of the border portion is a protrusion.

In embodiments of the present invention, the dressing comprises a central segment and a border portion, wherein the thickness of the central segment is from 1 mm to 20 mm,  
20 preferably from 2 mm to 10 mm, while the thickness of the border portion is from 10  $\mu\text{m}$  to 200  $\mu\text{m}$ , preferably from 20  $\mu\text{m}$  to 100  $\mu\text{m}$ .

In embodiments of the invention, the maximum distance  $d_1$  between a lateral or a longitudinal (i.e. the outermost) edge of at least one protrusion (in particular a border  
25 portion) to the closest edge of said pad, in particular measured from the outer edge of the protrusion (border portion) to the outer edge of said pad is from 10mm to 80mm, e.g. from 25 mm to 60 mm.

In embodiments of the present invention, at least two lateral and/or at least two  
30 longitudinal edges of the border run essentially in parallel.

In accordance with the present invention, lateral (longitudinal) edges of the border run “*essentially in parallel*” if a secant or a tangent for a given lateral (longitudinal) edge can

be defined that encompasses said lateral (longitudinal) edge, and a second lateral (longitudinal) edge is present, for which also such an "encompassing" secant or tangent can be defined, wherein the angle between these two secants or tangents of these two lateral (longitudinal) edges have an angle with respect to each other that is 0 degrees +/-  
5 45 degrees, preferably 0 degrees +/- 20 degrees. For (fully) parallel edges, the two secants tangents have an angle of 0 degrees.

In general, the **release liner** acts as a barrier that can protect the sterility of dressing including all of its layers before the dressing is used.

10

As used herein, the term "*releasably attached*" means that the release layer may be peeled away from the rest of the dressing by hand.

In embodiments of the present invention, removable portions of the release liner are  
15 releasably connected to each other, meaning that they are connected such that the portions remain connected absent a separation force applied to one or all of the portions, and where the portions are capable of being separated upon the application of a separation force.

20 Specifically in the regard to the realization of the release liner as being divided into at least two different portions, the respective content of WO 2017/081012 is relevant and is incorporated by reference.

The realization of the release liner as two or more separate portions that can be removed  
25 separately, respectively, preferably divided along dividing lines, is preferred.

A realization of the release liner as one integral unit, having an area of increased thickness or stiffness, or both, is also within the scope of the present invention.

30 In embodiments of the invention, if two or more separate portions of the release liner are present, these two or more separate portions may be of the same material or may be of different materials.

In accordance with the present invention, the primary function of the **adhesive coating** is to adhere the release liner to the remainder of the dressing. As will be outlined in more detail below, the adhesive coating may also be realized as an adhesive layer and may also, preferably, function as or be part of a wound (body) contact layer.

5

In embodiments of the present invention, the adhesive coating is applied directly onto the pad or onto the release liner or onto both.

In embodiments, the adhesive coating is realized as a layer that has a skin-facing surface and a non-skin-facing surface and that preferably has a thickness of from 5  $\mu\text{m}$  to 100  $\mu\text{m}$ , further preferably of from 10  $\mu\text{m}$  to 60  $\mu\text{m}$ .

10

In embodiments of the present invention, the adhesive coating or layer fully or partly covers the pad.

15

In embodiments of the present invention, the adhesive coating is configured to also function as a wound contact layer, preferably wherein the adhesive coating is a coating comprising silicone gel.

In accordance with the present invention, the release liner of the dressing has an area of **increased thickness** or of increased stiffness, or both, in at least part of the area of said at least one protrusion and in a part of the area outside of said at least one protrusion ("*thicker/stiffer area*"), but not in the entire area outside of side protrusion.

The increased thickness or increased stiffness, or both, is or are measured vis-à-vis the thickness or stiffness, or both, of the release liner in the remaining area, i.e. the area that is not reinforced in regard to thickness and/or stiffness ("*remaining area*").

In embodiments of the invention, the increased thickness of the release liner in said part of an area of said at least one protrusion and in said part of the area outside of said at least one protrusion is in the range of from 50  $\mu\text{m}$  to 1000  $\mu\text{m}$ , optionally from 100  $\mu\text{m}$  to 500  $\mu\text{m}$ , optionally thereto from 150  $\mu\text{m}$  to 400  $\mu\text{m}$ , optionally thereto from 180  $\mu\text{m}$  to 300  $\mu\text{m}$ , and wherein the thickness of the release liner in said remaining area is lower

30

than in said part of an area of said at least one protrusion and in said part of the area outside of said at least one protrusion, and is in the range of from 10  $\mu\text{m}$  to 500  $\mu\text{m}$ , optionally from 20  $\mu\text{m}$  to 200  $\mu\text{m}$ , optionally thereto from 20  $\mu\text{m}$  to 180  $\mu\text{m}$ , optionally thereto from 50  $\mu\text{m}$  to 150  $\mu\text{m}$ .

5

In embodiments of the invention, the increased thickness of the release liner in said at least part of an area of said at least one protrusion and in said part of the area outside of said at least one protrusion is greater by at least 25%, preferably by at least 40% than the thickness of the release liner in said remaining area.

10

In embodiments of the invention, the increased stiffness of the release liner, as defined by the load at material deformation in said at least part of an area of said at least one protrusion and in said part of the area outside of said at least one protrusion is from 25 N to 150 N, preferably from 40 to 80 N, wherein the stiffness of the release liner in said remaining area is from 10 N to 60 N, preferably from 20 to 40 N, as measured according to the method described below.

15

Without wishing to be bound by theory, it is believed that if the stiffness of the dressing is too low; i.e. below the range given above for the stiffness of the remaining area, there is not sufficient protection against wrinkle formation when packed in a single-pack. On the other hand, if the dressing is "too stiff"; i.e. above the range specified, the dressing may actually damage the single pack by "cutting/sticking through the paper or plastic single pack of the dressing.

20

In embodiments of the invention, the stiffness of the release liner, defined by the load at material deformation in said area of said at least one protrusion and in said part of said area outside of said at least one protrusion, is greater by at least 25%, preferably by at least 40% than the stiffness of the release liner in said remaining area, wherein said stiffness is measured according to the method described in the specification.

25

30

In embodiments of the present invention the "stiffer" part of the release liner may be reinforced vis-à-vis the remaining part of the release liner by way of including one or more

additional material layer(s), for example a nonwoven or a plastic film, and/or by way of embossing this part of the release liner, thereby rendering the release liner stiffer.

5 In principle, no limitations exist in regard to the **material** used for the release liner, as long as different degrees of thickness and/or stiffness can be adjusted and the liner material is otherwise flexible enough to conform to the contour of a body.

10 In embodiments of the present invention, the release liner is or comprises polyurethane, polyethylene or polypropylene, or any combination thereof, in particular low density polyurethane.

15 In embodiments of the present invention, the release liner comprises polyethylene, polyester, polypropylene or silicone coated paper. For example, the release liner may be a polyethylene film having a thickness in the range of from 30 to 300  $\mu\text{m}$ , e.g. from 50 to 150  $\mu\text{m}$ .

20 In embodiments the thicker and/or stiffer part of the release liner encompasses at least 15%, preferably at least 20%, further preferably at least 25% of the overall area of the release liner, while, at the same time, encompassing less than 75%, preferably less than 50%, further preferably less than 40% of the of the overall area of the release liner.

In embodiments of the present invention, the dressing has only one **axis of symmetry** or has no axis of symmetry.

25 In preferred embodiments of the present invention, the dressing has one axis of symmetry, wherein said symmetry axis also encompasses said at least one protrusion, wherein said symmetry axis also encompasses said part of the area outside of said at least one protrusion that is also of said increased thickness or said increased stiffness, or both.

30 In embodiments of the present invention, said (exactly) one axis of symmetry coincides with the maximum longitudinal extension Y2.

In embodiments of the present invention the dressing is divided into **three separate zones** along the longitudinal (y) extension of the dressing: one central zone and two lateral zones, wherein the release liner is of increased thickness and/or stiffness in the central zone.

5

In embodiments of the present invention, the dressing is configured for use so that the portion of the release liner that is of increased thickness and/or increased stiffness is removed first. This embodiment preferably applies to a dressing that is primarily intended to be used for the sacrum.

10

In other embodiments, the sequence can also be reversed, i.e. the portion of the release liner that is not of increased thickness and/or increased stiffness is removed first. This embodiment may apply to a dressing that is primarily intended to be used for the heel.

15 In exemplary embodiments, instructions and/or visual indicators may be associated with the release liner(s) to facilitate the removal of the release liner as well as application of the dressing onto the skin of a human body.

In embodiments of the present invention, the dressing comprises at least one gripping tab; preferably wherein the **gripping tab** is coplanar with and projecting outwardly from the periphery of the dressing. For example, the gripping tab projects outwardly from the border portion of the dressing.

20 In embodiments of the present invention, said dressing is a dressing for **application** to a contoured body part, in particular the sacrum, heel, elbow, knee and the like.

25 In embodiments of the present invention the dressing as described herein is used in prevention and/or in treatment or wound care, preferably in prevention.

Brief description of the drawings

- Figure 1** shows two commercially available dressings for application on a contoured body part, in particular the heel (Fig. 1a) and the sacrum (Fig. 1b).
- 5 **Figure 2** illustrates the dressing of figure 1a, wherein the central release liner is peeled off.
- Figure 3** shows a dressing suitable for the sacrum that has one axis of symmetry and a “w”-shaped protrusion at the bottom end.
- Figure 4** shows an embodiment in accordance with the present invention: the central area of a three-part release liner is of increased thickness and/or of increased stiffness and covers and stiffens up the bottom protrusion.
- 10
- Figure 5** shows a dressing according to one exemplary embodiment of the invention.

Detailed description

15 The present invention will now be described more fully hereinafter with reference to the accompanying drawings, in which currently preferred embodiments of the present invention are shown. The present invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided for thoroughness and completeness, and to more fully convey the scope of the present invention to the skilled person.

20

The **adhesive** used in the adhesive coating is preferably skin-friendly and sufficiently adherent to skin such that the dressing stays in place, and maintains its adherence with repeated removal and re-application. The adhesive should be easy to remove without causing trauma.

25

In embodiments of the invention the adhesive comprises a silicone gel, preferably a soft silicone gel. Examples of suitable silicone gels include the two component RTV systems, such as Q72218 (Dow Corning), and SilGel 612 (Wacker Chemie AG), as well as NuSil silicone elastomers.

30

In embodiments of the present invention, the adhesive layer of the dressing covers at least 50% of the surface of the pad, preferably at least 60%, further preferably at least 70% of the pad. This ensures or at least facilitates the overall dressing to sufficiently adhere to the skin of a patient during use.

5

The adhesive layer may be perforated or non-perforated.

In embodiments of the present invention, the adhesive layer may be configured to be a body contact layer. As used herein, the term "body contact layer" means the layer that is in contact with the skin of a wearer.

10

In the field of medical dressings, in particular, wound dressings, a film provided with an adhesive layer for adhering to the patient is often referred to as a wound contact layer. The dressing of the invention may be used on a human body area which has no wound, and therefore the combined film and adhesive layer will be referred to as a body contact layer.

15

The film onto which the adhesive layer is applied in such a body/wound contact layer may be comprised of a thin plastic film, or a laminate comprising a thin plastic film. Suitable materials for the film include, but are not limited to breathable polyolefin based films (such as polyethylene), polyamide, polyester polyurethane, and silicone. A suitable material for use as the film is a thin polyurethane film. For example, the film of the body contact layer may be a polyurethane film having a thickness of from 15 and 100  $\mu\text{m}$ , e.g. from 40 to 80  $\mu\text{m}$ , preferably from 45 to 60  $\mu\text{m}$ .

25

As already discussed above, in embodiments of the present invention, the dressing comprises a **border portion** [see, e.g. (102 and 102') in Figure 1a/1b or (302) in Figure 3]. In embodiments, at least the backing layer extends beyond the periphery of the (absorbent) pad to define a border portion around the contour of the pad, or also only parts of the pad. In Figure 1, the backing layer and the adhesive layer extend beyond the periphery of the pad to define a border portion around the contour of the pad.

30

The adhesive layer is preferably co-extensive with the backing layer, and has the same outer dimensions (lateral and longitudinal extension, including all protrusions).

5 In embodiments of the invention, and in particular in order to achieve sufficient adhesion properties, the border portion has a width of 5 to 60 mm and extends along at least parts of the contour of the pad, preferably along the entire pad.

A smaller sized dressing may have a smaller border portion than a larger sized dressing.

10 In embodiments of the invention, the dressing as such and hence if present, the corresponding border portion, may be **substantially heart shaped** such that a first and a second lobed portion form part of the lobed upper sides of a heart shape (see Figure 3). The dressing has an axis of symmetry (304), a maximum lateral extension X2 and a maximum longitudinal extension Y2.

15 In this illustrative embodiment, the dressing is symmetric about a longitudinal center line (304) and comprises a first lobed portion (305) one side of the longitudinal center line (304), and a second lobed portion (306) on the other side of the longitudinal center line. The first and second lobed portions (305 and 306) are separated by a forked portion ("w"-  
20 portion) (307) which replaces the pointed lower part of a heart shape. The forked portion (307) as such is a protrusion or may be seen as comprising a protrusion on either side of an interstice located coaxially with the longitudinal center line. Either way, this protrusion or these two protrusions are advantageously protected from wrinkling or kinking by incorporating a reinforced (increased thickness or stiffness or both) part of the release  
25 liner, in accordance with the present invention.

As used herein, the term "lobed portion" means a curved or rounded portion of the dressing. In embodiments, the tab projects "outwardly" from the border portion. In this connection it should be understood that inwardly means a direction towards the inner  
30 perimeter of the border area, i.e. a direction towards the pad, while outwardly is an opposite direction.

The dressing has a border region (302) and a pad (301), as well as gripping tabs (308) and (309). The shape of this preferred dressing is adapted to fit to the sacral region of a human body. The forked portion allows for improved stay-on ability in the gluteal cleft region. It is important that this kind of dressing remains adhered in this region since otherwise body fluids (for example as a result of incontinence) may enter into the dressing and impair the adhesion to the skin.

The maximum extension of the protrusion in the lateral (x) direction, X1, is from 10% to 40% of the maximum extension X2, of the overall dressing in the lateral (x) direction.

The maximum extension X2 of such a preferred sacrum dressing is typically in the range of from 12 to 30 cm, preferably from 15 to 20 cm. The maximum extension X1 of the protrusion is preferably in the range of from 2 to 10 cm, e.g. from 4 to 7 cm, depending on the size of the dressing.

In embodiments of the present invention, the pad is arranged to taper downwards, towards the lower region and has a more narrow width in the lower region of the dressing. This shape of the pad allows for proper protection of the coccyx, which is a bony prominence at risk for the development of pressure ulcers. Such a pad also conforms well to the body in the gluteal cleft region. As illustrated in figure 3, this part of the pad (301) may also be part of the protrusion (303) and therefore also aid in increasing the stability/stiffness of said protrusion, preferably together with a reinforced release liner.

In embodiments of the present invention, the pad is absorbent. The pad may be comprised of one layer or of a plurality of layers.

In embodiments of the present invention, the **backing layer** of the overall dressing is a thin film, sheet or membrane that is vapor permeable and waterproof. Examples of suitable materials for the backing layer include, but are not limited to polyurethane, polyethylene or polyamide films, silicone films, polyester based nonwoven materials, and laminates of polyester-based nonwoven materials and polyurethane films.

In embodiments of the invention, the backing layer is a polyurethane film and preferably has a thickness of from 5 to 40  $\mu\text{m}$ , e.g. from 15 to 25  $\mu\text{m}$ .

The backing layer may be partly or fully bonded to the pad, for example, via an adhesive such as a pressure sensitive adhesive (e.g. an acrylic adhesive).

- 5 In embodiments, the dressing comprises at least one **gripping tab**; the gripping tab preferably being coplanar with and projecting outwardly from the periphery of the dressing [see (308) and (309) in Figure 3].

10 The gripping tab guides the caregiver to lift the dressing, inspect the skin underneath the dressing, and to thereafter re-apply the dressing onto the skin (in case the skin looks ok). Inspection of skin may still be required, albeit on a less frequent basis when the dressing is transparent.

15 In embodiments, the gripping tab is made in one piece with and projecting outwardly from the border. The gripping tab may be made of the same materials as the border portion, e.g. it may be made from the backing layer and the body contact layer. Hence, the border portion may extend uninterrupted from the border to the gripping tab. This may be beneficial from a manufacturing perspective. However, in at least some exemplary  
20 embodiments the gripping tab may be made from a different (or same) material and attached to the border portion.

25 Since the inspection of the skin typically takes place where the patient is lying on the side in the bed, in preferred embodiments that apply for a sacrum dressing in particular, the dressing comprises at least two gripping tabs such that the caregiver can lift the dressing regardless of which side the patient lies. Hence, in embodiments, the gripping tab is a first gripping tab, and the dressing further comprises a second gripping tab that is coplanar with and projects outwardly from the second lobed portion.

30 As best illustrated in figure 4, the dressing may be divided into **three separate zones** along the longitudinal (y) extension of the dressing: one central zone (410) and two lateral zones (411 and 412), preferably wherein the central part of the release liner is the reinforced part of the release liner, i.e. is of increased thickness or stiffness, or both (see hatched area). As mentioned hereinbefore, the release liner covering the central zone

(410) of the dressing is preferably removed first. The release liners (411 and 412) are preferably thinner and/or less stiff than the central part. In order to facilitate smooth application of the dressing onto the skin of a patient.

- 5 Referring back to figure 2, illustrating a heel dressing, the central release liner (212a) is preferably removed first. Subsequently, the remaining release liner portions (212b-212e) are removed and the dressing is gently applied to the body of a patient. In the embodiment illustrated in figure 2, the central part of the release liner (212a) may be the stiff and/or thick release liner portion (as long as it provides sufficient coverage and protection of the protrusions). Alternatively, the release liner portions 212b-212e are stiffer and/or thicker than the central portion (212a).
- 10

The characteristic dimensions of an exemplary dressing are further exemplified in Figure 5, showing the bottom view of a sacrum dressing having a pad (501) and a border portion (502). Protrusion (P) comprising the “w”-shaped extension (506) is separated by an (imaginary) dotted line from the remaining area (RA). As can be seen from this exemplary embodiment, the protrusion comprises the “w”-shaped part of the border portion, but also the narrow part of the pad. In this embodiment, the reinforced release liner (509, hatched area) not only covers the entire protrusion, but also a significant part of the remaining area, thus stabilizing the protrusion.

15

20

#### Measurement of the release liner stiffness (Standard: ASTM D882-12)

Test specimens for a release liner having a width of 25 mm and a length of 150 mm were punched out from two different polyethylene films: one having a thickness of 100  $\mu\text{m}$  and a basis weight of 92g/m<sup>2</sup> (sample A) and one having a thickness of 200  $\mu\text{m}$  and a basis weight of 184 g/m<sup>2</sup> (sample B). A tensile tester (Insight MTS) was used to determine the elastic modulus and the **peak load at deformation** of the materials. The tensile tester was calibrated according to the apparatus (tensile tester: Insight, supplier: MTS, year: 2008) instructions and set to zero. The samples were mounted in the clamps and the test speed was set to 50 mm/min. The gauge length was 80 mm.

25

30

The tensile tester was started and the samples were elongated until break or until reaching 100% elongation. Measurements resulting from premature failures (i.e. the sample breaking at the clamp, or becoming damaged during preparation) were ignored.

- 5 The tensile force and elongation were measured during the entire test, and the following results were obtained from the measurements:

Peak load (N) – the maximal load recorded during the test

Strain at peak load (%)

Young's modulus at 10% strain was obtained by the following formula:

- 10  $E_{10\%} = \text{Stress at 10\% strain} / 0.1$  (the calculations were based on data points before deformation of the material had begun; i.e. before data plot becomes linear)

The results are summarized in table 1 below.

Sample	Peak load at deformation (N)	Young's Modulus at 10% strain (kPa)
Sample A	23.0	85.1
Sample B	50.2	93.8

CLAIMS

1. A dressing having a maximum lateral (X2) and a maximum longitudinal (Y2)  
5 extension;

wherein said dressing has at least one protrusion, wherein said protrusion has a lateral (X1) or a longitudinal (Y1) extension, or both, that is less than 50% of the maximum lateral (X2) or the maximum longitudinal (Y2) extension, or both, of the overall dressing;

10 wherein said dressing has a first side and a second opposing side, the first side comprising an adhesive coating having a skin-facing surface adapted to detachably adhere the dressing to a dermal surface,

wherein the dressing comprises a release liner that is releasably attached to the adhesive coating;

15 wherein the at least one protrusion has an area;

wherein said release liner has an area of increased thickness or an area of increased stiffness, or both, in at least a part of the area of said at least one protrusion, and in a part of an area outside of said at least one protrusion;

20 wherein said increased thickness or increased stiffness, or both, is or are measured vis-à-vis the thickness or stiffness, or both, of the release liner in a remaining area, the remaining area being an area of the release liner in which the release liner is not reinforced in regard to thickness and/or stiffness.

2. The dressing according to claim 1, wherein said dressing comprises

- 25
- a backing layer;
  - a pad contoured by a pair of lateral edges, wherein said lateral edges optionally extend essentially in parallel to each other in the longitudinal direction, and contoured by a pair of longitudinal edges, wherein said longitudinal edges optionally extend essentially in parallel to each other in the  
30 lateral direction;

wherein said pad is arranged between said backing layer and said adhesive layer.

- 5
3. The dressing according to claim 2, wherein said backing layer extends beyond the periphery of said pad to define a border portion along at least a part of the contour of said pad, optionally along the entire contour of said pad.
- 10
4. The dressing according to any one of claims 1 to 3, wherein at least a part of the border portion defines at least a part of a protrusion.
- 15
5. The dressing according to claim 3, wherein the maximum distance  $d_1$  between a lateral or a longitudinal edge of at least one protrusion to a closest edge of said pad, optionally from the outer edge of said protrusion to the outer edge of said pad, is from 10 mm to 80 mm, optionally from 20 mm to 60 mm.
- 20
6. The dressing according to any one of the preceding claims, wherein the increased thickness of the release liner in said area of said at least one protrusion and in said part of the area outside of said at least one protrusion is in the range of from 50  $\mu\text{m}$  to 1000  $\mu\text{m}$ , optionally from 100  $\mu\text{m}$  to 500  $\mu\text{m}$ , optionally thereto from 150  $\mu\text{m}$  to 400  $\mu\text{m}$ , optionally thereto from 180  $\mu\text{m}$  to 300  $\mu\text{m}$ , and wherein the thickness of the release liner in said remaining area is lower than in said part of an area of said at least one protrusion and in said part of the area outside of said at least one protrusion, and is in the range of from 10  $\mu\text{m}$  to 500  $\mu\text{m}$ , optionally from 20  $\mu\text{m}$  to 200  $\mu\text{m}$ , optionally thereto from 20  $\mu\text{m}$  to 180  $\mu\text{m}$ , optionally thereto from 50  $\mu\text{m}$  to 25
7. The dressing according to any one of the preceding claims, wherein the increased thickness of the release liner in said area of said at least one protrusion and in said part of the area outside of said at least one protrusion is greater by at least 25%, optionally by at least 40% than the thickness of the release liner in said remaining area.
- 30

- 5
8. The dressing according to any one of the preceding claims, wherein the increased stiffness of the release liner, as defined by the load at material deformation in said area of said at least one protrusion and in said part of the area outside of said at least one protrusion is from 25 N to 150 N, optionally from 40 to 80 N, wherein the stiffness of the release liner in said remaining area is from 10 N to 60 N, optionally from 20 to 40 N, as measured according to the method described in the specification.
- 10
9. The dressing according to any one of the preceding claims, wherein the stiffness of the release liner, defined by the load at material deformation in said area of said at least one protrusion and in said part of said area outside of said at least one protrusion, is greater by at least 25%, optionally by at least 40% than the stiffness of the release liner in said remaining area, wherein said stiffness is measured according to the method described in the specification.
- 15
10. The dressing according to any one of the preceding claims, wherein the dressing has only one axis of symmetry or has no axis of symmetry.
- 20
11. The dressing according to claim 10, wherein the dressing has one axis of symmetry, wherein said symmetry axis also encompasses said at least one protrusion, wherein said symmetry axis also encompasses said part of the area outside of said at least one protrusion that is also of said increased thickness or said increased stiffness, or both.
- 25
12. The dressing according to any one of the preceding claims, wherein at least one protrusion has a lateral (X1) extension or a longitudinal (Y1) extension of 30% or less, optionally 20% or less, of the maximum lateral (X2) or of the maximum longitudinal (Y2) extension, or of both, of the overall dressing.
- 30
13. The dressing according to any one of the preceding claims, wherein the dressing is divided into three separate zones along the longitudinal (y) extension of the dressing: one central zone and two lateral zones, optionally wherein the release liner is of increased thickness and/or stiffness in the central zone.

2019276067 03 Oct 2024

14. The dressing according to any one of the preceding claims, wherein said dressing is a dressing for application to a contoured body part, optionally the sacrum, heel, elbow, knee and the like.
- 5
15. The dressing according to any one of the preceding claims, wherein the dressing comprises at least one gripping tab; optionally wherein the gripping tab is coplanar with and projecting outwardly from the periphery of the dressing.
- 10
16. Use of the dressing according to any one of the preceding claims in the prevention or treatment of wounds.

1/4

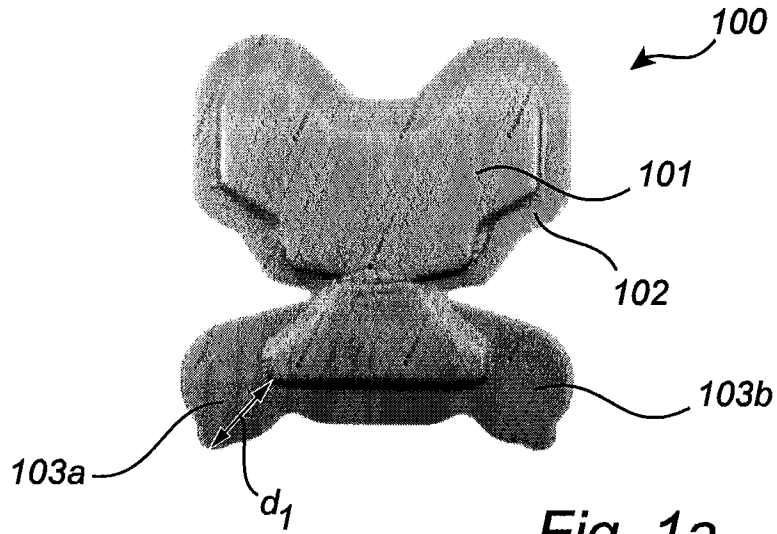


Fig. 1a

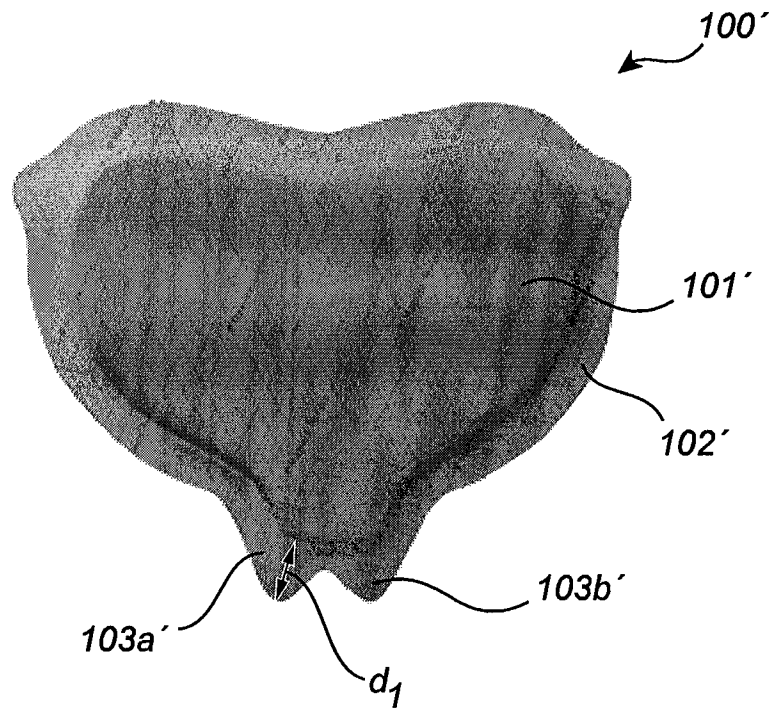


Fig. 1b

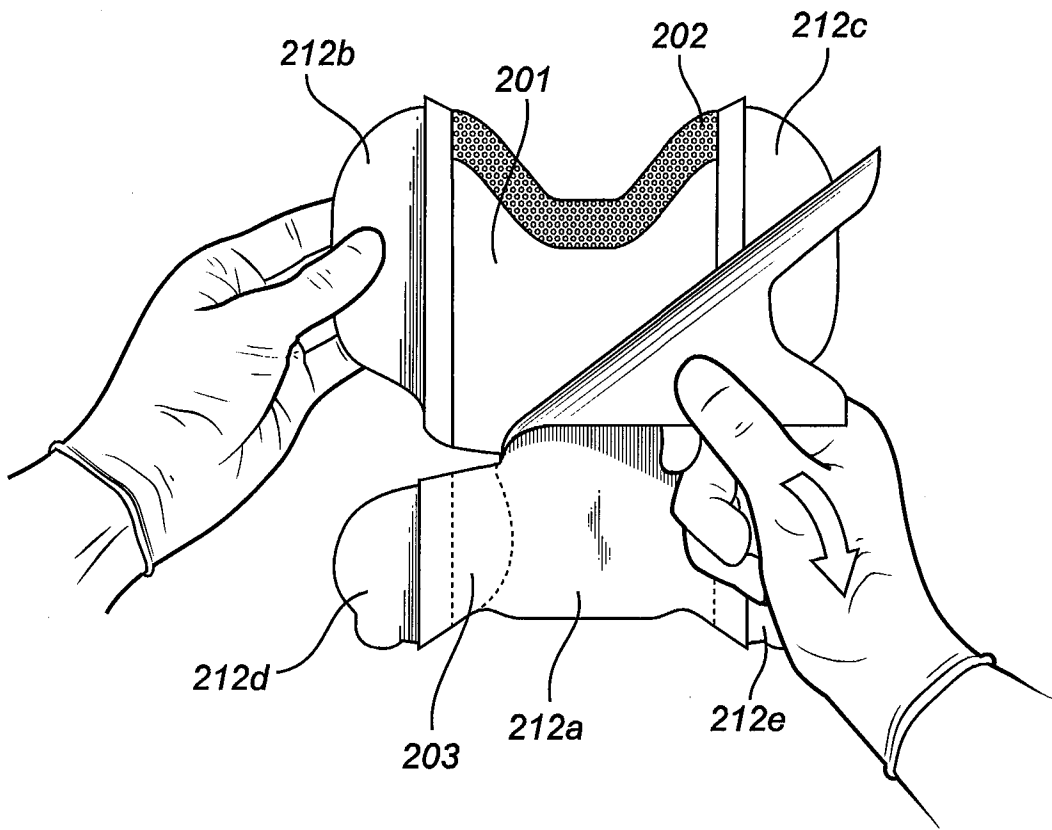


Fig. 2

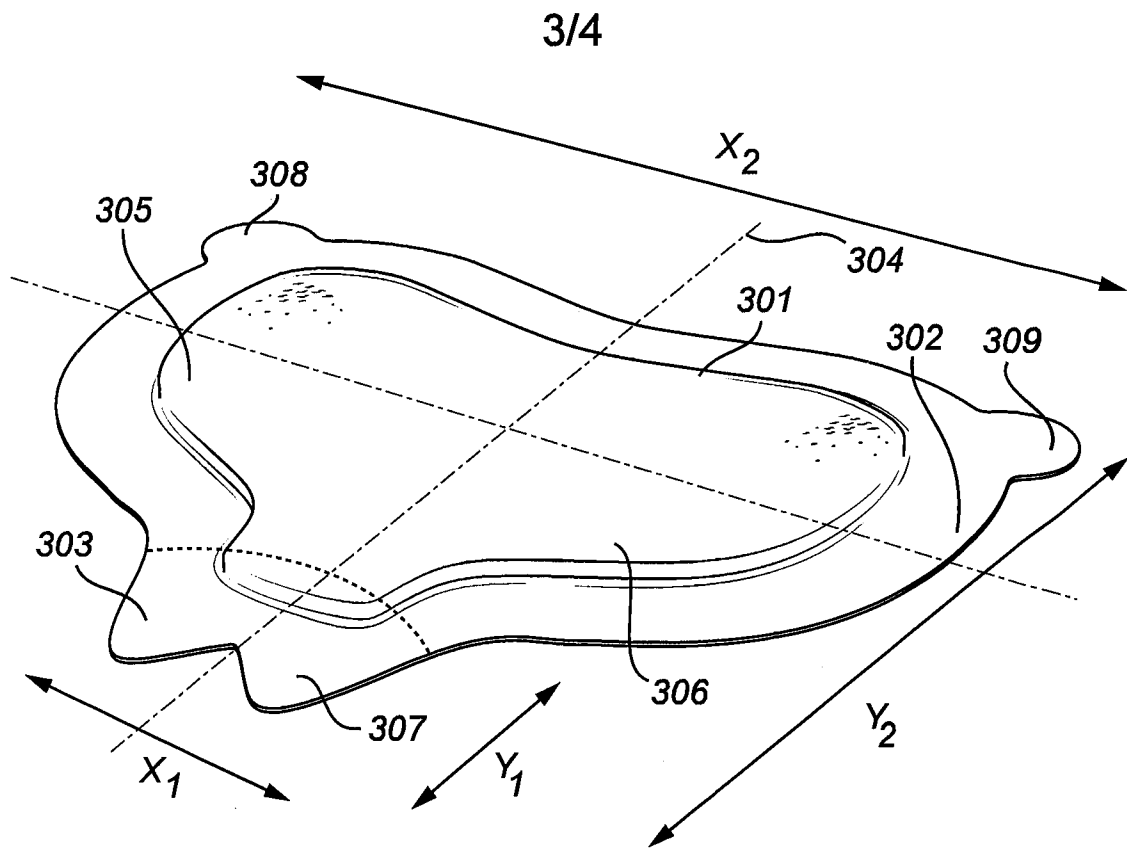


Fig. 3

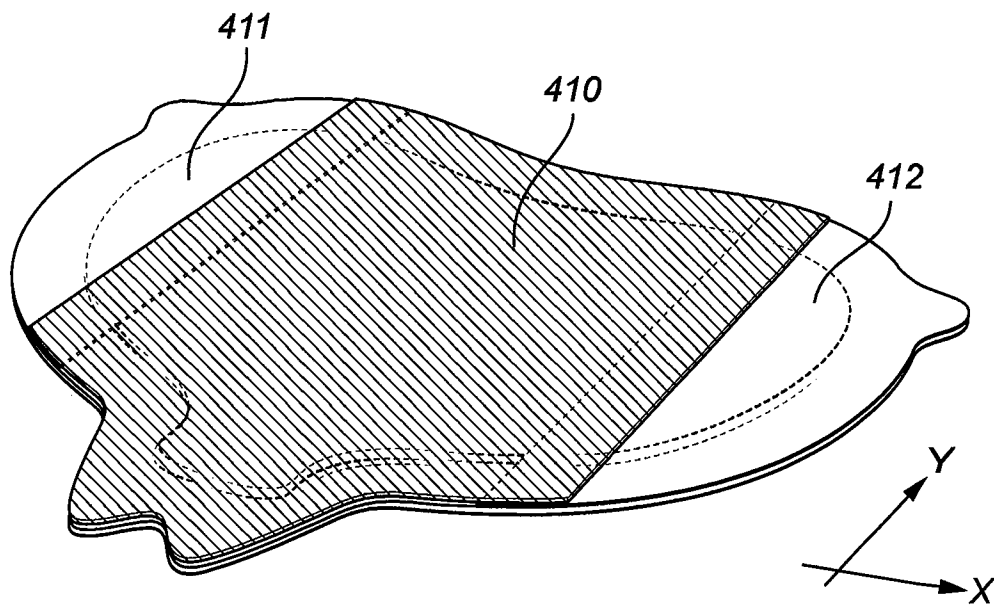


Fig. 4

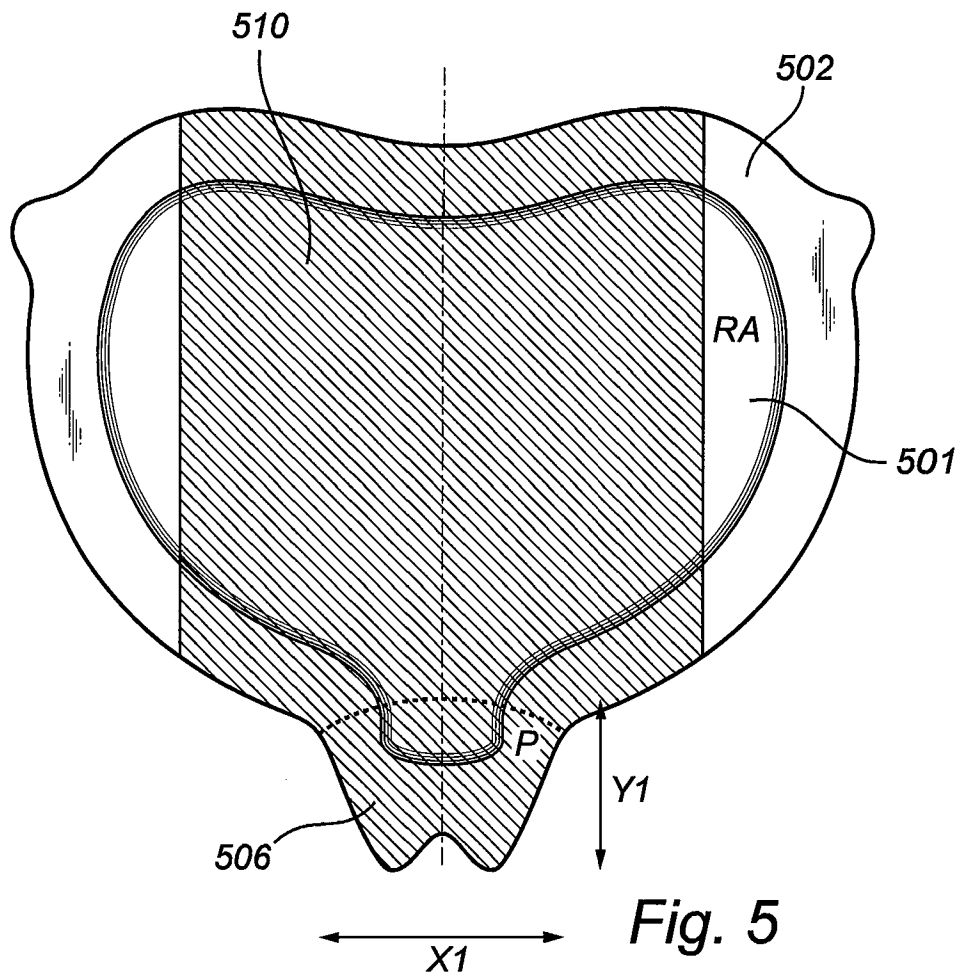


Fig. 5