

<b>PermaFoam® / PermaFoam® comfort</b>			Spec.-No.:	D 7.1603
			Department:	CMO-DMW
			Date:	2013-07-16

### 1. General Product Description

PermaFoam® and PermaFoam® comfort are hydroactive foam dressings with a water-vapour permeable polyurethane cover; the special hydrophilic foam structure enhances absorption by capillary action to ensure rapid drainage of wound exudates and thus creates a moisture-balanced wound environment; germs and cell debris are securely locked in and remain retained even under compression.

PermaFoam® and PermaFoam® comfort carry the CE-mark according to EU directive 93/42/ EEC for medical devices.

The product is classified as a class II b medical device.

A conformity assessment has been performed for PermaFoam® and PermaFoam® comfort and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use and effectiveness of PermaFoam® and PermaFoam® comfort, therefore, is ensured if the product is used in line with the intended purpose.

### 2. Application / Indication

To clean non-infected, heavy or medium exuding wounds and build up granulation tissue, particularly with chronic problem wounds e.g. varicose ulcer or decubitus; especially suited to the treatment of venous ulcers in combination with compression treatment; for the care of up to second degree burns.

### 3. Presentations

sterile, individually sealed

Type	Dimensions (cm)	Dimensions of wound pad (cm)
PermaFoam®	10 x 10	10 x 10
PermaFoam®	15 x 15	15 x 15
PermaFoam®	10 x 20	10 x 20
PermaFoam®	20 x 20	20 x 20
PermaFoam® cavity	10 x 10	10 x 10
PermaFoam® Tracheostomy	8 x 8	8 x 8
PermaFoam®	6 (round)	6 (round)
PermaFoam® Comfort	11 x 11	6 x 6
PermaFoam® Comfort	15 x 15	10 x 10
PermaFoam® Comfort	10 x 20	5 x 14
PermaFoam® Comfort	20 x 20	14 x 14
PermaFoam® Comfort	8 x 8	3,5 x 3,5
PermaFoam® sacral small	18 x 18	11 x 9,5
PermaFoam® sacral large	22 x 22	14,5 x 12,5
PermaFoam® concave	16,5 x 18	10,5 x 12

PermaFoam® /  
PermaFoam® comfort



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#### 4. Product Characteristics

Material composition:

##### **PermaFoam®**

Carrier material	Elastic, water-vapour permeable top-layer made of polyurethane
Absorbing foam	Soft, absorbent yellowish foam made of polyurethane

##### **PermaFoam® Comfort**

Carrier material	Elastic, water-vapour permeable top-layer made of polyurethane
Absorbing foam	Soft, absorbent yellowish foam made of polyurethane
Adhesive	acrylic adhesive
Cover sheet	Silicon paper

#### 5. Product requirements

##### **PermaFoam®**

Absorbtioncapacity measured acc. to DIN EN 13726-1, 3min	> 10 g/g
Water vapour transmission rate upright: measured acc. to DIN EN 13726-2	> 1600 g/m <sup>2</sup> during 24 h
Water vapour transmission rate inverted: measured acc. to DIN EN 13726-2	> 5000 g/m <sup>2</sup> during 24 h

##### **PermaFoam® Comfort**

Absorbtioncapacity measured acc. to DIN EN 13726-1, 3min	> 11 g/g
Water vapour transmission rate upright: measured acc. to DIN EN 13726-2	> 800 g/m <sup>2</sup> during 24 h
Water vapour transmission rate inverted: measured acc. to DIN EN 13726-2	> 1800 g/m <sup>2</sup> during 24 h
Adhesion on polished stainless steel plate	≥ 2 N/25 mm

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6. Labelling

Lot-No. with 9-digit code:

e.g.:        1 XXX XX XXX

<b>LOT</b>	1	XXX	XX	XXX
	year	for internal purposes only	week of production	for internal pur- poses only

Expiry date: 6-digit code:

e.g.:        ⌚        2016        06  
                 year        month

Shelf life:        5 years

7. Packaging

PermaFoam® and PermaFoam® comfort is sealed individually in peel pouches. Peel pouches are packed in folding boxes. Boxes are packed in transport carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

Date: 2013-07-16

PAUL HARTMANN AG  
- CMO-DMW Development MWC

i. A.



Sybille Hörmann