


Specification.- **D 7.1603**  
No.:  
Department: **TME**  
Date: 26.05.2003

### CHANGE CONTROL REPORT

Page /Edition	replaces Page/Edition	Reason for Change
1-2 from 26.05.2003	-----	New Technical Data Sheet

Department	Date	Signature
Technical Medical Development (TME)	26.05.2003	

## PermaFoam

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### 1. General Product Description

PermaFoam is a two-layer laminate of an absorptive foam and a skin tanned backing foam. The wound contacting foam is based on hydrophilic poly-urethane polymers - the backing material consists of polyurethane foam which is extremely flexible, gas- and vapour permeable but liquid- and germ proof.

PermaFoam Comfort is a two-layer laminate which is based on the same chemistry principle as PermaFoam, but the absorptive foam layer is formed as a wound pad and the backing foam creates an adhesive border which is coated with a low irritating acrylic adhesive.

Classification for sterile medical devices class IIb, acc. EEC-Directive 93/42

### 2. Application / Indication

PermaFoam and PermaFoam Comfort take up wound exudate at high speed from heavily or moderately exuding wounds and create a moist wound environment that stimulates wound healing. Change of the dressings is atraumatic as the products are designed to prevent adhesion to the wound bed. The products do not leave any residue on the wound.

The intense swelling of the foam matrix in vertical direction helps to conform to wounds which are rugged.

### 3. Presentations

Type	Dimensions (cm)	Dimensions of wound pad (cm)	Content pieces per box
PermaFoam	10x10	10x10	16, 10, 3
	15x15	15x15	5, 3
	10x20	10x20	5
	20x20	20x20	3
PermaFoam Comfort	11x11	6x6	16, 10, 3
	15x15	10x10	3, 5
	10x20	5x14	5
	20x20	14x14	3

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### 4. Product Characteristics

Permafoam is a hydro-active foam dressing with a high absorption capacity for wound fluids. The capacity exceeds the product weight manifold.

On top of that both variants have a high water vapour permeability so that the fluid handling capacity is typically about 80 g/100 cm<sup>2</sup> in 24 hours (base; isotonic saline solution).

This is, besides the high absorption rate, based on a water vapour transmission rate of about 2400 g/m<sup>2</sup> for the Island Dressing and more than 10 000 g/m<sup>2</sup> in 24 h for the non bordered product.

The dressings are water- and bacteria-tight. The adhesive of Permafoam Comfort is a skin friendly acrylic composition without aggressive tack. The elasticity of the backing is high so that the product offers high wear comfort and helps preventing mechanical irritation at the points of fixation.

Permafoam non bordered because of its high absorption capacity under pressure is suitable especially for compression therapy.

### 5. Labelling

Lot-No. with 8-digit code:

e.g.:

3  
year

12  
week of production

XXXXX  
for internal purposes only

Corresponds to production week 12 of 2003

### 6. Packaging

Boxes in transportation carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

26 May 2003

A handwritten signature in blue ink, appearing to read "Culle".

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- Technical Medical Development -