

## Aquaclear® Aquaclear® Adhesive

Spec.-No.: D 6.1801c  
D 6.1802c  
Department: SM-PDW  
Date: 2010-11-30

### 1. General Product Description

#### **Aquaclear®**

Aquaclear® is an absorbent hydrocellular gel dressings covered with a semi-permeable layer to prevent bacterial penetration; transparent; because of the high water content of approx. 60% they provide a moist wound environment; detach necrotic tissue rapidly, stimulate granulation and epithelialization; can be removed painlessly without leaving any residues.

#### **Aquaclear® Adhesive**

**Aquaclear® Adhesive** is an absorbent hydrocellular gel dressings with properties of Aquaclear®; with additional hypoallergenic adhesive film border.

Aquaclear® and Aquaclear® Adhesive carries the CE mark according to EU directive 93/42/ EEC for medical devices.

The product is classified as a class IIb medical device.

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

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

### 2. Application / Indication

Aquaclear® and Aquaclear® Adhesive for moist wound treatment, especially suitable for the treatment of chronic, slow-healing wounds which are not clinically infected, e.g. ulcers of the leg, pressure sores, second-degree burns, for covering donor sites after split skin grafts, abrasions.

### 3. Presentations

#### **Aquaclear®**

sterile, individually sealed

Dimension: 5,0 x 7,5 cm  
10 x 10 cm

#### **Aquaclear® Adhesive**

sterile, individually sealed

external  
dimension: 7,5 x 10 cm  
12,5 x 12,5 cm

internal  
dimension: 4,0 x 6,8 cm  
80,0 x 8,0 cm

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### 4. Product Characteristics

#### **Aquaclear®**

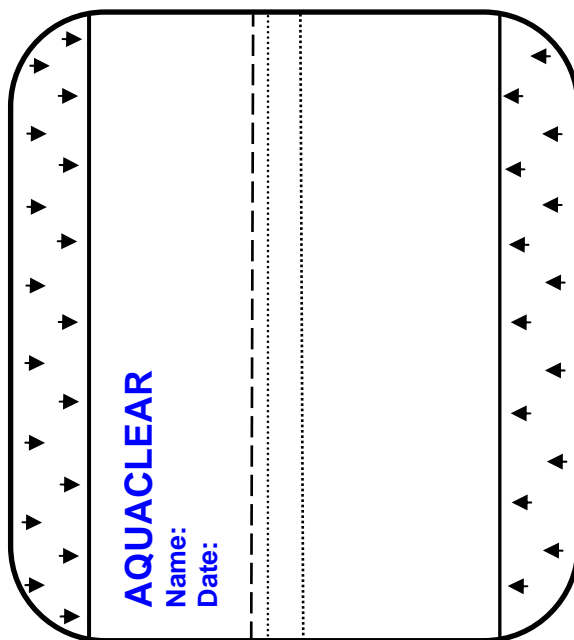
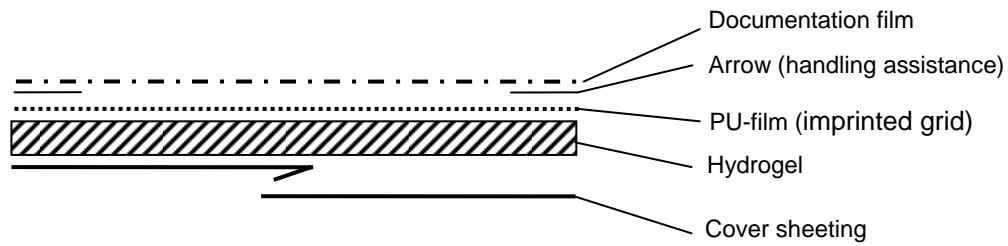
material composition:

- documentation film: Polyethylene foil with application help
- PU-film: semipermeable, transparent polyurethane film, with imprinted grid.
- hydrogel: Polymer-matrix based on polyurea / polyurethane hybrid with a water content of approx. 60 %.
- backing film: one-sided siliconized HDPE-film; blue

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**Product drawing:**



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### **Aquaclear® Adhesive**

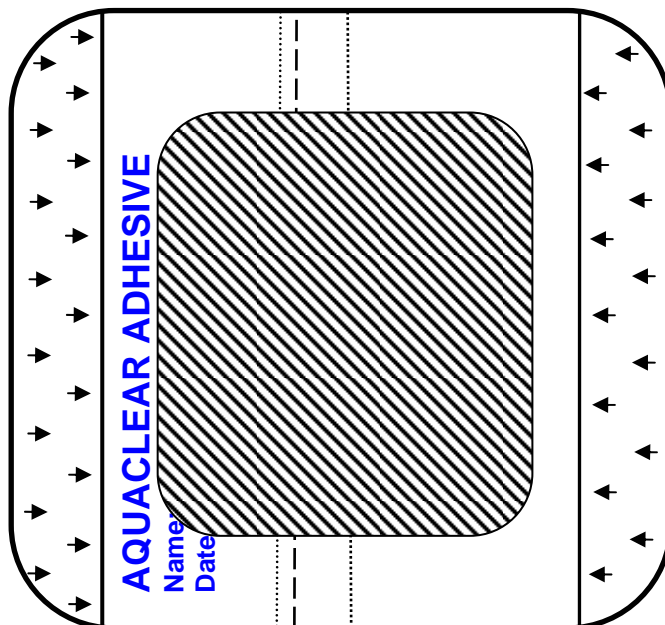
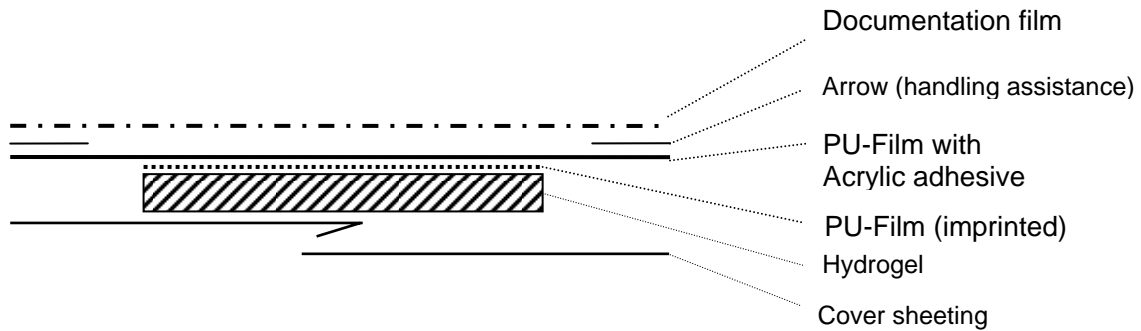
material composition:

- documentation film: Polyethylene film with application help
- PU-film: semipermeable, transparent polyurethane film, coated with an acrylic adhesive, and with imprinted grid respectively.
- hydrogel: Polymer-matrix based on polyurea / polyurethane hybrid with a water content of approx. 60 %.
- backing film: one-sided siliconized HDPE-film; blue

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### 5. Product Requirements

#### **Aquaclear® / Aquaclear® Adhesive**

mass [kg/m²]: 2.16 kg ± 0.2  
water absorption capacity: after 1h: min 0.3 g/g  
after 48h: min 1.0 g/g


### 6. Labelling

Lot-No. with 9-digit code:

e.g.: x xxx xx xxx

LOT	x	xxx	xx	xxx
	year	for internal purposes only	week of production	for internal purposes only

expiry date: 6-digit code:

e.g.:  2003 – 06  
year – month

shelf life: 3 years

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## 7. Packaging

Aquaclear® and Aquaclear® Adhesive is individually sealed into a peelpouch, peelpouches are packaged in a folding box; boxes are packaged in a transport carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

Date: 2010-11-30

PAUL HARTMANN AG  
- SM-PDW- Solution Management  
- Product Development Wound Management

i. A.

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

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Martin Junginger