

## Hydrofilm®



Spec.-No.: D 7.4021a  
 Department: SM-SPE  
 Date: 2007-10-08

### 1. General Product Description

Hydrofilm® is a self-adhesive film dressings made of semi-permeable, waterproof polyurethane film, transparent; protect against bacterial penetration; with hypoallergenic adhesive, can be removed painlessly without leaving any residues.

Hydrofilm® carries the CE mark according to EU directive 93/42/ EEC for medical devices. The product is classified as a class IIa medical device.

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

The safe use of Hydrofilm® therefore, is ensured if the product is used in line with the intended purpose.

The semi permeable polyurethane film allows the free passage of water vapour and gases. The hypoallergenic adhesive layer ensures good adhesion, even on conical areas of the body.

### 2. Application / Indication

Hydrofilm® as a protective layer over the wound to reduce the risk of secondary infection and protect against physical damage on dry, primary healing wounds and nearly healed epithelial wounds; to secure catheters or cannulae; ideal as a secondary dressing, e.g. to cover gel-forming calcium alginate dressings.

### 3. Contraindication

Hydrofilm® should not be used on clinically infected, bleeding or highly exudative wounds.

### 4. Presentations

Hydrofilm® sterile, individually sealed

| Ref. No. | Dimensions      | Number peel pouch per folding box |
|----------|-----------------|-----------------------------------|
| 685 755  | 6 cm x 7 cm     | P10                               |
| 685 756  | 6 cm x 7 cm     | P100                              |
| 685 757  | 10 cm x 12,5 cm | P10                               |
| 685 758  | 10 cm x 12,5 cm | P100                              |
| 685 759  | 10 cm x 15 cm   | P10                               |
| 685 760  | 10 cm x 15 cm   | P50                               |
| 685 761  | 15 cm x 20 cm   | P10                               |
| 685 762  | 15 cm x 20 cm   | P50                               |
| 685 763  | 10 cm x 25 cm   | P25                               |
| 685 764  | 12 cm x 25 cm   | P25                               |
| 685 765  | 20 cm x 30 cm   | P10                               |

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### 5. Product Characteristics

Composition:

- backing: semi-permeable, transparent polyurethane film
- adhesive: acrylic adhesive, hypoallergenic, colophonium-free
- handling aid two-piece supporting film (based on polyester)
- Moisture vapour transition rate (MVTR) according to DIN EN 13726-2: > 1.100 g/m<sup>2</sup> / 24h (typical value around 1.300 g/m<sup>2</sup> / 24h)
- Adaptiveness according to DIN EN 13726-4: 1,2 N/cm
- persistent deformation: 1 %

### 6. Product Requirements

- sterilization ethylenoxide, using a validated procedure (e.g.: ISO 11135)
- adhesive power > 4 N / in

### 7. Labelling

Lot-No. with 9-digit code:

e.g.:

|      |                       |                    |                            |
|------|-----------------------|--------------------|----------------------------|
| 7    | XXX                   | 12                 | XXX                        |
| year | for internal purposes | week of production | for internal purposes only |

Expiry date:

e.g.:  2012 year 09 month

Shelf life: 5 years

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## 8. Packaging

Separate sealed into peelpack out of sterile paper, in folding box; Transport carton acc. DIN, sealed with adhesive tapes; packed onto europallet.

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*A. B. S.*

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