

Hydrofilm® Plus



Spec.-No.: D 7.4021b

Department: SM-SPE

Date: 2008-02-21

1. General Product Description

Hydrofilm® plus is a transparent adhesive wound dressing with an absorbent pad that does not stick to the wound. Thanks to the transparent, extremely thin film, the area surrounding the wound and the secretion absorbed by the wound pad can be inspected at any time.

Unnecessary changes of dressing are thus avoided and the wound is not disturbed.

Since Hydrofilm® plus is germproof and waterproof, the risk of secondary infection is minimised and the patient can have a bath or a shower.

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.

Hydrofilm® plus 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® plus and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

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

2. Application / Indication

Hydrofilm® plus is suitable for the sterile post-operative care of slightly secreting wounds and as a wound covering after surgical procedures and injuries.

3. Contraindication

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

4. Presentations

Hydrofilm® plus sterile, individually sealed

Ref. No.	Dimensions	Absorbent wound pad	Number peel pouch per folding box
685 770	5 cm x 7,2 cm	2,5 cm x 4 cm	P5
685 771	5 cm x 7,2 cm	2,5 cm x 4 cm	P50
685 772	9 cm x 10 cm	4 cm x 6 cm	P5
685 773	9 cm x 10 cm	4 cm x 6 cm	P50
685 774	9 cm x 15 cm	4 cm x 11 cm	P5
685 775	9 cm x 15 cm	4 cm x 11 cm	P25
685 776	10 cm x 12 cm	5 cm x 8 cm	P25
685 777	10 cm x 20 cm	5 cm x 16 cm	P5
685 778	10 cm x 20 cm	5 cm x 16 cm	P25
685 779	10 cm x 25 cm	5 cm x 20 cm	P25
685 780	10 cm x 30 cm	5 cm x 25 cm	P25

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5. Product Characteristics

peel adhesion:	> 4 N/25 mm
moisture vapour transition rate (MVTR) according to DIN EN 13726-2:	> 1.100 g/m ² / 24h (typical value 1.300 g/m ² / 24h)
adaptiveness according to DIN EN 13726-4:	1.2 N/cm
persistent deformation	1 %
absorbent capacity of wound pad according to DIN EN 13726-1:	> 11 g/100 cm ²
sterilization	ethylenoxide, using a validated procedure (e.g.: ISO 11135)

6. Product Requirements

material:	
- backing:	polyurethane film
- adhesive:	acrylic adhesive, hypoallergenic, colophony-free
- wound pad:	viscose fibres; anti-adherent polyethylene net
- liner:	siliconized paper
- handling system:	two-piece supporting film (made of polyester film)

7. Labelling

Lot-No. with 9-digit code:
e.g.:

7
year

XXX
for internal
purposes only

12
week of production

XXX
for internal
purposes only

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Expiry date:

e.g.: ⌚ 2012 09
 year month

Shelf life: 5 years

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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