

Hydrotul®



Spec-No: **D 4.0145**

Department: **SM-PDW**

Date: **2011-09-29**

1. General Product Description

Hydrotul® is a hydroactive, non occlusive tulle dressing for atraumatic wound treatment.

Hydrotul® carries the CE mark according to EU-directive 93/42/EWG for medical devices. The product is classified as a class IIb medical device.

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

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

2. Application / Indication

Hydrotul® is suitable for treatment of superficial acut and chonical wounds.

In combination with ichor the non active impregnation forms a gel, that conditions the wound in a optimal way, stimulating the healing of the wound.

3. Presentations

Sterile, both sides covered and individually sealed

Size (cm)

5 x 5

10 x 12

15 x 20

4. Product Characteristics

Material composition:

Fabric:	Polyamide tulle (honeycomb style)
Impregnation:	Soft, non adhering impregnation; The impregnation contains (INCI) Petrolatum, Caprylic/Capric/Myristic/Stearic Triglyceride, Cellulose Gum (Sodium carboxy-methylcellulose), Bis-diglyceryl Polyacyladipate-2, Isostearyl Diglyceryl Succinate, Glyceryl Stearate, Hydrogenated Coco Glycerydes
Liner:	Glassine paper on both sides

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5. Product Requirements

Fabric:

- Weight: ca. 88 g/m²

Impregnation:

- Drop point: > 43 °C

Finished Product:

- Coating Weight: min. 180 g/m²

6. Labelling

The Lot code is defined as follows:

1	XXX	XX	11	X
Year	Internal Code	Internal Code	Plant	Control digit

The Expiry date is defined as follows:

⌚ 2014-09 → Expiry date September 2014

Shelf life: 3 years

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7. Packaging

Hydrotul[®] is individually sealed into a peel pouch. Peel pouches are packed in a folding box; boxes are packed in a transport box acc. DIN, sealed with adhesive tapes and packed onto euro palette.

Date: 29th September 2011

PAUL HARTMANN AG
Product Development SM-PDW

p.p.

A handwritten signature in black ink, appearing to read "R. Maier".

Maier