

## Hydrotul<sup>®</sup>



Spec-No: D 4.0145

Department: SM-PDW

Date: 2011-09-29

### 1. General Product Description

Hydrotul<sup>®</sup> is a hydroactive, non occlusive tulle dressing for atraumatic wound treatment.

Hydrotul<sup>®</sup> 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<sup>®</sup> and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

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

### 2. Application / Indication

Hydrotul<sup>®</sup> is suitable for treatment of superficial acut and chronical 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

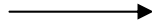
15 x 20

### 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/m<sup>2</sup>

### Impregnation:

- Drop point: > 43 °C

### Finished Product:

- Coating Weight: min. 180 g/m<sup>2</sup>

## 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<sup>®</sup> 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: 29<sup>th</sup> September 2011

PAUL HARTMANN AG  
Product Development SM-PDW

p.p.

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

Maier