

Hydrocoll



Spec.-No.: D 9.2004

Department: SM-PDW

Date: 2011-09-29

1. General Product Description

Hydrocoll is a self-adhesive, absorbent hydrocolloid dressings covered with a semi-permeable layer to prevent bacterial penetration, the hydrocolloids transform into a gel and form a moist wound environment which has a stimulating effect on granulation and epithelialization; flexible and conformable, can be moulded easily onto the body's contours; can be removed painlessly.

Hydrocoll carries the CE mark according to EU directive 93/42/ EEC for medical devices.

The product is classified as a class medical device.IIb.

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

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

2. Application / Indication

Hydrocoll is suitable for the treatment of wounds with light to moderate exudate.

For moist wound treatment, e.g. for treatment of chronic, slow healing wounds which are not clinically infected, e.g. ulcers of the leg, pressure sores, second-degree burns.

Hydrocoll sacral is designed for the specific treatment of pressure sores within the sacral region;

Hydrocoll concave is designed for treatment of wounds on the heel and elbow;

Hydrocoll thin, having a lower absorption capacity, should preferably be used during the epithelialization phase.

3. Presentations

Sterile, individually sealed dressings

Typ	Dimension (cm x cm)
Hydrocoll	5 x 5
	7,5 x 7,5
	10 x 10
	15 x 15
	20 x 20
Hydrocoll sacral	12 x 18
Hydrocoll concave	8 x 12
Hydrocoll thin	7,5x7,5
	10 x 10
	15 x 15
	5 x 25

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4. Product Characteristics

Material composition

Carrier:

Transparent, breathable polyurethane film

Liner:

White easy release paper

Hydrocolloid matrix:

The hydrocolloid system is composed of a synthetic Elastomer, Mineral Oil, a tackifier, Sodium Carboxymethylcellulose.
The material does not contain components of animal origin.

5. Product Requirements

Moisture Vapor Transmission Rate (24 hrs): min. 140 g/m²

Water absorption capacity (24 hrs):

Hydrocoll/-sacral/-concave

min. 1,4 g / 10 cm²

Hydrocoll thin

min. 0,5 g / 10 cm²

pH-value:

4 - 8

6. Labelling

Lot-No. with 9-digit code:

expiry date:

e.g.:



2016 – 06

year – month

Shelf life:

The shelf life is 5 years.

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7. Packaging

Hydrocoll is individually sealed in peel-pouches, packaged into folding box; transport carton, sealed with adhesive tapes, packaged onto europallet.

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

i. A.



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