Hydrocoll

Spec.-No.: D 7.4000
Department: SM-PDW
Date: 2009-04-20

1. General Product Description

Hydrocoll is a sterile self adhesive absorbent hydrocolloid wound dressing consisting of a wound contact layer of caboxymethylcellulose hydrocolloid particles contained within an adhesive polymer matrix and an outer gas permeable polyurethane film which is impermeable to liquids and bacteria. On contact with a wound the hydrocolloid takes up the wound exudate whereby a gel is formed that ensures a moist wound environment. The gel layer prevents Hydrocoll from sticking to the wound. The dressing does not irritate granulation tissue or epithelial tissue and causes minimal discomfort for the patient. Hydrocoll is self adhesive.

Hydrocoll carries the CE mark according to EU directive 93/42/ EEC for medical devices.
The product is classified as a class IIb medical device.
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 of Hydrocoll therefore, is ensured if the product is used in line with the intended purpose.

Hydroregulation Class: Hydroactive™

Regulatory Status: Medical Device with a CE Mark

2. Application / Indication

Hydrocoll is suitable for the treatment of wounds with light to moderate exudates.
Hydrocoll is indicated for the management of chronic exuding wounds such as leg ulcers and pressure ulcers and acute exuding wounds including minor burns, skin donor sites, and other surgical and traumatic wounds.
Hydrocoll sacral is indicated for the specific treatment of pressure sores within the sacral region; Hydrocoll thin, having a lower absorption capacity, should preferably be used for light exudating wounds and during the epitheliasation phase.

Contraindications: Do not use Hydrocoll on wounds extending into muscle, tendon or bone, on clinically infected wounds or full thickness burns.

Precautions/Warnings: Hydrocoll can only be effective when a holistic assessment of the patient and the wound has taken place. Treatment with Hydrocoll cannot replace treatment of the cause of the impaired healing. Daily dressing changes are not necessary.
Inappropriate use or too frequent dressing changes may result in skin irritation or stripping.

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Application: Select the correct size and shape of Hydrocoll. The dressing should extend at least 1 centimetre beyond the edge of the wound on all sides to ensure that it stays firmly in place.

Hydrocoll/Hydrocoll thin: remove the protective paper liner, place Hydrocoll on the wound, adjust the edges to fit and press on.

Hydrocoll sacral: remove the protective paper liner and press the center of the dressing into the natal cleft. The tip of the dressing can point up- or downwards depending on the position and depth of the ulcer. Press the edges on firmly.

Removal: Frequency of dressing changes will depend on the state of the wound. Hydrocoll should be changed when there is a visible discoloration of the dressing and blister formation is about the size of the wound. To change the dressing, lift Hydrocoll at the edges and remove the whole dressing carefully. A layer of Hydrocolloid gel remains on the wound which should not be confused with pus. It will not impair the healing of the wound and can be rinsed off if necessary.

In uncomplicated wounds, Hydrocoll can be left in place for intervals of up to 7 days.

3. Presentations

Sizes:	**Standard**	**Thin**	**Special dressings**
	5cm x 5cm	5cm x 5cm	13,5 cm x 13,5cm (Concave f. Heel & Elbow)
	7,5 cm x 7,5 cm	7,5 cm x 7,5 cm	18 cm x 18 cm (Sacral)
	10 cm x 10 cm	10 cm x 10 cm	20 cm x 20 cm (Sacral)
	15 cm x 15 cm	15 cm x 15 cm	25 cm x 5 cm (Post-OP)
	20 cm x 20 cm		

4. Product Characteristics

Carrier:	Transparent, breathable polyurethane film
Adhesive:	Hydrocolloid absorbent adhesive
Liner:	White easy release paper, 2-piece folded for easy application
Hydrocolloid matrix:	The hydrocolloid system is composed of a synthetic rubber based adhesive (free of tackifiers and mineral oil) and Sodium Carbomethylcellulose. The material does not contain components of animal origin, and no components known or suspected to be irritants or to cause allergic reactions, such as colophonium and its derivatives.

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5. Labelling

Each sales unit contains an instruction leaflet which describes the properties, the indications, Contra-indications, the application etc. of Hydrocoll.

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

9	XXX	12	XXX
year	for internal purposes	week of production	for internal purposes

Expiry date:

e.g.: ⌛ 2014 year 04 month

Shelf life: 5 years

6. Packaging

Storage Precautions: Single use only.
Beta-sterilised. Sterile unless open or damaged.
Store at room temperature, avoid refrigeration and exposure to high humidity

Date: 2009-04-20

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

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