

# Hydrocoll

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

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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.

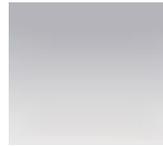
### 3. Presentations

| Sizes: | Standard      | Thin          | Special dressings |
|--------|---------------|---------------|-------------------|
|        | 10 cm x 10 cm | 10 cm x 10 cm | a)                |

### 4. \_\_\_\_\_

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components known or suspected  
reactions, such as colophonium



## 5. Labelling

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Store at room temperature, avoid refrigeration and exposure to high humidity

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- Product Development Wound Management

i. A.

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

Dr. Axel Eckstein