

1. Break open the backing paper by folding the dressing back over itself along the cut in the backing.
2. Hold the dressing by the side with the smaller release backing. With the other hand, separate the backing paper from the hydrocolloid. Remove the larger backing paper first, pulling it back over the dressing and being careful not to touch the wound contact surface of the dressing.
3. With the smaller release backing still on the dressing, center the dressing over the wound site and apply. Be careful not to touch the wound contact surface of the dressing.
4. Remove the remaining backing paper by peeling the backing paper back under itself.
5. Smoothing out all wrinkles, place hand over the dressing and apply slight pressure for 30 to 40 seconds to warm the dressing and enhance adherence.



Dressing Removal

To remove Hydrocol[®] II dressings:

1. Starting at one corner of the dressing, press down on the skin and carefully peel back the dressing. Continue this process around the dressing until all edges are free of the skin.
2. Carefully wash or irrigate the wound to remove any residue. Apply a new dressing as described above.



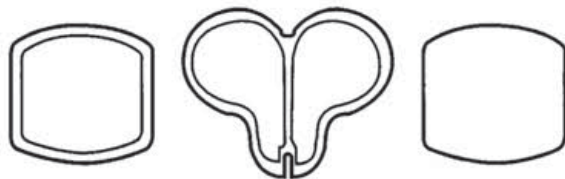
Dressing Changes

Hydrocol[®] II dressings should be changed after they have been in place for a maximum of seven days. However, they should be changed immediately when they reach full absorbency or when there is leakage. Used dressings should be disposed of per local regulation.

Hydrocol[®] II

HYDROCOLLOID DRESSING

Hydrocol[®] II
Hydrocol[®] II Sacral
Hydrocol[®] II Thin



Hydrocol[®] II

HYDROCOLLOID DRESSING

	Product No.	Size	Dressings/Box
Hydrocol [®] II	8818	4" x 4"	10
Hydrocol [®] II Sacral	8875	6" x 7" (approx.)	5
Hydrocol [®] II Thin	8918	4" x 4"	10

Manufactured by: EuroMed Inc. Orangeburg, NY 10962
for Mylan Bertek Pharmaceuticals Inc.
under one or more of the following US patents:
6,309,500; 6,143,798; 5,998,694; 5,704,905;
5,827,213; 5,591,447; 5,133,821



Distributed by:
MYLAN III BERTEK
PHARMACEUTICALS INC.
Morgantown, WV 26505
(877-446-3679)

064.5

PRODUCT DESCRIPTION

Hydrocol[®] II is a family of sterile hydrocolloid wound dressings formulated to provide a moist environment conducive to wound healing. The Hydrocol[®] II line includes Hydrocol[®] II, Hydrocol[®] II Sacral, and Hydrocol[®] II Thin. The indications for each are provided in the next section.

The wound contact surface of Hydrocol[®] II dressings consists of a layer of hydrocolloid and other polymers. The outer layer is a semi-permeable, low-friction polyurethane film.

The hydrocolloid dressing material interacts with the wound exudate to form a soft gel that helps create and maintain an optimal moist wound-healing environment. Hydrocol[®] II absorbs excess exudate to help prevent the over-accumulation of fluid. The dressing also protects the wound from exogenous bacteria, urine and feces, and other contamination.

Hydrocol[®] II's unique formulation allows most of the gel – including the absorbed exudate and debris – to come out of the wound with the removal of the dressing. Hydrocol[®] II leaves minimal residue in the wound and may be removed without damaging newly-formed tissue.

Hydrocol[®] II dressings are waterproof and will remain in place during showering.

SPECIAL FEATURES of Hydrocol[®] II

Studies reveal that Hydrocol[®] II's unique formulation provides absorption and moisture vapor transfer capabilities superior to those of leading hydrocolloid dressings currently available.

The borders on Hydrocol[®] II and Hydrocol[®] II Sacral are tapered to improve conformability and reduce shear, thus helping to keep the dressings from rolling back at the edges. Hydrocol[®] II Sacral is specially shaped to conform with the contours of the sacral area and features a unique flexible "hinge" to ensure secure application.

INDICATIONS

General

Hydrocol[®] II dressings are indicated for the following types of wounds:

- Dermal wounds, including full-thickness wounds
- Pressure ulcers, Stages I through IV
- Leg ulcers
- Superficial wounds and abrasions
- Trauma wounds
- Surgical wounds

Product Selection

Indication:	Recommendation:
Light to moderately heavy exuding wounds	Hydrocol [®] II
Sacral ulcers and breakdowns	Hydrocol [®] II Sacral
Superficial wounds and abrasions where maximum dressing wear time is desired	Hydrocol [®] II Thin

CONTRAINDICATIONS

Hydrocol[®] II is not indicated for use on third-degree burns or on individuals with known sensitivity to the dressing or its components.

PRECAUTIONS AND OBSERVATIONS

Color of Gel: The gel formed under the Hydrocol[®] II dressing appears yellow in color.

Odor: Wounds, particularly those that are large or necrotic, are often accompanied by a disagreeable odor. This is not necessarily indicative of an infection. The odor should disappear when the wound is cleansed. (See "Infection" in the right text column under "Precautions and Observations (Continued)")

PRECAUTIONS AND OBSERVATIONS (Continued)

Increased Wound Size: The wound may increase in size during debridement. This may be a normal part of the healing process as necrotic debris is cleaned away. Do not stop the treatment, since the wound should gradually reduce in size.

Infection: If signs of clinical infection should develop, a bacterial culture of the wound site should be taken. Such signs would include an uncharacteristic odor, a change in exudate color, a fever, or cellulitis (tenderness and erythema in the wound area).

If infection is present, appropriate medical treatment should be initiated. Hydrocol[®] II dressings may be continued during the course of treatment at the discretion of the clinician.

Storage: Hydrocol[®] II dressings should be stored in a cool, dry area. Sterility is guaranteed unless the product package has been opened or damaged.

INSTRUCTION FOR USE

Preparing the Wound Area

Before applying a Hydrocol[®] II dressing:

1. Thoroughly rinse or irrigate the wound area with saline or an appropriate cleansing solution. The periwound area should be clean and dry to ensure optimal adherence.
2. A skin prep may be used on the periwound area to increase the adherence and wear time of the dressing.
3. While Hydrocol[®] II facilitates autolytic debridement, eschar that is particularly thick or attached to the wound margins should be removed prior to application of the dressing.

Dressing the Wound

Select a dressing size that allows the dressing to extend beyond the wound margin by at least one inch on all sides. Dressings may be overlapped or trimmed with scissors to accommodate the wound.

Hydrocol[®] II dressings are sterile and should be handled appropriately.

Applying Hydrocol[®] II Sacral

1. Fold the dressing down the center crease and back onto itself (backing paper should be facing out). Separate the backing paper from only one side of the dressing and peel off. Be careful not to touch the wound contact surface of the dressing.
2. With the dressing still folded, center and place the hinge in the coccygeal fold. Apply slight pressure to the side without the backing paper to obtain adherence.
3. Remove the backing paper for the other half of the dressing and secure in place.
4. Smoothing out all wrinkles, place hand over the dressing and apply slight pressure for 30 to 40 seconds to warm the dressing and enhance adherence.

