



PRODUCT INFORMATION

This device is intended for single use only.

All open and unused packets must be discarded.

Sterility guaranteed in unopened, undamaged package only.

Store at temperatures between 50-80° F.

Helix3-CM™ - dressings consist of a fibrous collagen matrix similar to the dermis which provides the scaffolding necessary to stimulate the healing process.

Properties and Mode of Action:

Helix3-CM™ is topically applied and designed to come into contact with wound exudate. It maintains a moist wound environment at the wound surface which aids in the formation of granulation tissue and epithelization.

Indications for Use:

Helix3-CM™ is intended for use in the management of burns, sores, blisters, ulcers and other wounds.

DIRECTIONS FOR USE:

A. Preparation of Wound Bed:

1) Debride and cleanse the wound. Gently irrigate wound with a sterile wound cleanser or saline until it is free of debris (necrotic tissue, slough, etc.). Use enough irrigation pressure to enhance wound cleansing without causing trauma to the wound bed. Safe and effective irrigation pressures range from 4 to 15 pounds per square inch (psi). An irrigation pressure of 8 psi effectively cleanses the wound and reduces the risk of trauma and wound infection. Certain concentrations of povidone iodine, hydrogen peroxide, sodium hypochlorite, etc. are cytotoxic and should not be used to cleanse the wound.

2) Gently blot wound edges dry.

3) An ointment or cream may be applied to the wound margin if desired to protect the area.

4) If a topical medication is ordered, apply to the wound bed.

B. Application of Helix3-CM™:

1) Apply Helix3-CM™ to cover the wound surface. Apply Helix3-CM™ to the wound. If the wound margin is at risk for maceration, cut the Helix3-CM™ to fit the size of the wound. (Avoid overlapping Helix3-CM™ on the skin surrounding the wound).

a) Minimally Draining Wounds - Helix3-CM™ should be hydrated with sterile saline prior to application.

b) Moderately Draining Wounds - Helix3-CM™ may be used dry on moderately draining wounds. If dressing has to be changed more than daily due to excessive drainage, discontinue Helix3-CM™ and switch to Helix3-CP™ (follow instructions for application of Helix3 CP™).

2) Apply secondary dressings. The secondary dressings should be selected to maintain a moist wound environment. **IT IS VERY IMPORTANT TO KEEP THE WOUND BED MOIST!** When necessary, GENTLY secure wound cover dressings with surgical netting or a tape.

a) Minimally Draining or Dry Wounds - Secondary dressings may include: non-adherent dressings, hydrocolloid, hydrogel sheet, semi-permeable film or foam, etc.

b) Moderately Draining Wounds - Secondary dressings may include: conventional gauze, abdominal pads, specialty absorptive, etc.

C. Removal of Helix3-CM™:

1) Gently remove secondary dressing and any remaining Helix3-CM™.

2) If the Helix3-CM™ has become adhered to the wound, irrigate with sterile saline solution. Lift gently.

3) If the Helix3-CM™ is still adherent after irrigation, DO NOT attempt to remove. (This can cause damage to granulating wound bed). Rehydrate with sterile saline solution and dress with a secondary dressing that will promote and maintain moisture. (See Application of Helix3-CM™ for minimally draining/dry wounds).

D. Precautions and Comments:

Normal reactions: Wounds may appear larger during the first several days of treatment due to the reduction of

edema and the removal of necrotic tissue and/or slough. An increase in drainage (which may or may not have an odor) may be seen in the first several days of treatment.

Allergic reaction: Helix3-CM™ is of bovine origin. Signs and symptoms of local allergic reaction are pain (to the wound site) and localized redness that may extend beyond the perimeters of the wound. Irrigate the wound with sterile saline to remove the product and the symptoms should disappear. **Do not use Helix3-CM™ (if patient) is sensitive to materials of bovine origin.**

Wound debridement: Wet to dry gauze dressings should **NOT** be used in conjunction with Helix3-CM™. Although this procedure will remove necrotic tissue and slough, it can also damage new granulation tissue.

A collagenase enzymatic debriding agent should **NOT** be used in conjunction with Helix3-CM™. Other enzymatic debriding agents may be used in conjunction with or prior to utilization of Helix3-CM™.

WARNING: Discontinue the use of Helix3-CM™ and notify your doctor if excessive redness, pain, swelling or blistering occurs.

WARNING: Potential risk of loss of sterility and infection if opened and reused.

Secondary wound dressings that may be used with Helix3-CM™:

1. Gauze roll dressings
2. Gauze (impregnated and non-impregnated)
3. Non-adherent
4. Specialty absorptive
5. Hydrocolloids
6. Hydrogels
7. Semi-permeable film
8. Semi-permeable foam



Manufactured For:
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