



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-CP® Collagen Powder—Type 1 fibrillar collagen powder that lays down a collagen matrix in the wound bed attracting the cellular components necessary to stimulate the healing process.

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-CP:

- 1) **Apply HELIX3-CP to cover the wound surface. DO NOT PACK THE WOUND TIGHTLY.**
 - a) **Minimally Draining Wounds**—Lightly sprinkle just enough powder to completely cover the surface of the wound bed.
 - b) **Moderately Draining Wounds**—Cover wound surface in a layer approximately ¼ inch thick.
 - c) **Heavily Draining Wounds**—Cover wound surface in a layer approximately ¼ inch thick.

Properties and Mode of Action:

HELIX3-CP is topically applied and designed to come into contact with wound exudate. It maintains a moist wound environment at the wound surface that aids in the formation of granulation tissue and epithelization.

Indications for Use:

HELIX3-CP is intended for use in the management of burns, sores, blisters, ulcers and other wounds.

NOTE: DO NOT PACK THE WOUND TIGHTLY WITH HELIX3-CP. HELIX3-CP is highly absorbent and needs room for expansion. If packed tightly into a wound, there may be increased pressure on surrounding tissue as the powder expands which may affect healing. If there is a “dead space,” gently fill the wound with dressing of choice to prevent premature closure of wound. Do not pack tightly. Always maintain a moist wound environment.

2) Apply secondary dressings.

- a) Cover with a non-adherent, absorbent dressing (conventional gauze/abdominal pads, specialty absorptive, etc.). Dressings should be changed when saturated (or as recommended by dressing manufacturer) until excessive drainage is resolved.
- b) Always maintain a moist (not wet) wound environment.
- c) When necessary, gently secure wound cover dressing with surgical netting or tape.

C. Other Considerations:

1) If the wound is infected:

- a) If a topical medication is ordered, apply the topical agent to the wound first and sprinkle the HELIX3-CP to completely cover the topical agent.
- b) Change HELIX3-CP daily until infection is resolved (or more often, depending on the amount of drainage).

2) If the wound is contaminated:

- a) Change HELIX3-CP after each occurrence of contamination.
- b) May use a semi-permeable film over secondary dressing to protect wound from contamination.



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3) If the wound is undermined and/or tunneled:

- a) HELIX3-CP can be mixed with sterile saline to make a thick solution. Combine HELIX3-CP with sterile saline and mix (in a sterile receptacle) to a thick liquid consistency.
- b) Draw mixture into syringe (DO NOT USE A NEEDLE) and apply to tunneled or undermined areas.
- c) Gently pack the wound with gauze or dressing of choice to eliminate dead space and prevent premature closure of the wound. HELIX3-CP paste may be applied to packing material before application to the wound.

D. Removal of HELIX3-CP:

- 1) **Change the secondary (cover) dressing daily** or as indicated by the amount of drainage.
- 2) **Remove the secondary (cover) dressing.** If secondary dressing is adhered to the wound, irrigate with sterile saline until dressing loosens. Lift gently.
- 3) **Irrigate wound with saline solution to cleanse** the area thoroughly to remove all traces of foreign bodies present in the wound bed. If after irrigating the wound with sterile saline, HELIX3-CP adheres to wound, DO NOT attempt to remove. This can cause trauma to the new granulation bed.
- 4) **Frequency of dressing changes** is determined by wound characteristics and amount of drainage.
 - a) **Minimally Draining Wounds**—Dressings may be changed every 2-3 days until wound is healed. It is very important to keep the wound bed moist.
 - b) **Moderately or Heavily Draining Wounds**—Dressings should be changed when saturated or until excessive drainage is resolved. Once drainage subsides, dressing changes may be reduced to every 2-3 days until wound is healed.
 - c) **Undermined or Tunneling Wounds**—Wounds should be flushed daily with sterile normal saline and HELIX3-CP reapplied.

E. 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-CP 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 normal saline to remove the product and the symptoms should disappear. **DO NOT use HELIX3-CP if sensitive to materials of bovine origin.**

Wound debridement: Wet to dry gauze dressings should **NOT** be used in conjunction with HELIX3-CP. 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-CP. Other enzymatic debriding agents may be used in conjunction with or prior to utilization of HELIX3-CP.

WARNINGS: Discontinue the use of HELIX3-CP and notify your doctor if excessive redness, pain, swelling or blistering occurs. Potential risk of loss of sterility and infection if opened and reused.

Secondary wound dressings that may be used with HELIX3-CP:

- 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



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