



## **INDICATIONS FOR USE**

**HEALADEX® Wound Dressing** provides a moist environment that is supportive of wound healing. HEALADEX is indicated for dry, light and moderately exudating partial and full thickness wounds such as:

- First and second degree burns
- Severe sunburns
- Superficial injuries, superficial lacerations, cuts, abrasions, incisions/surgical wounds, and skin tears

HEALADEX® should be used under a health care professional's direction for the following indications:

- Pressure ulcers, Stage I-IV
- Lower extremity ulcers
- Venous ulcers
- Arterial ulcers
- Ulcers of mixed etiology
- Diabetic ulcers
- Donor sites and skin grafts
- Burns caused by radiation oncology procedures

## **WARNINGS**

Do not use on third degree burns.

Individuals with a known sensitivity to porcine products should not use HEALADEX.

## **DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION**

HEALADEX is a sterile wound-dressing comprised of a lyophilized matrix containing sodium carboxymethylcellulose and porcine serum. This dressing aids the healing process by maintaining a moist environment at the wound site.

## **INSTRUCTIONS FOR USE**

1. Wash hands and apply gloves. If needed, put on appropriate personal protective equipment.
2. Carefully remove and discard soiled dressings.
3. Carefully remove gloves and discard. Wash hands thoroughly and apply new gloves.
4. Cleanse the wound with normal saline.
5. Gently pat dry the skin peripheral to the wound.
6. Apply a liquid skin barrier to the treatment area as needed.
7. Remove the dressing from the foil pouch.
8. Apply HEALADEX® at the center of the wound base. Use aseptic technique during application.
  - Note: You may pre-wet HEALADEX with sterile saline for application to a dry wound.
9. Apply a secondary dressing to secure HEALADEX to the wound site. Choose a secondary dressing to manage exudate.
10. Ensure that wound assessment and dressing change are appropriately documented.
11. Post-application: keep the site dry and free from debris.
12. HEALADEX absorbs wound exudate forming a gel like material and can remain in place for up to 72 hours.
13. When the gel material approaches or exceeds the border of the secondary dressing, the dressing should be changed.
14. In the event of dressing leakage or non-adherence, the dressing should be changed immediately.
15. In the event of uncharacteristic odor at the wound site, contact your health care professional.

## **PRODUCT HANDLING AND STORAGE**

- Product should be stored at room temperature.
- The product is **sterile** unless opened or the pouch is damaged. Do not use the package if the peel pouch is damaged or open.
- Do not attempt to re-sterilize this product.
- This product is for single use only.

## **PRODUCT REPORTING**

In the event of an adverse reaction, please contact HEALAGENICS immediately for information on device components. Use in a manner other than that which is in conformity with the current recommendations may lead to injury. Please follow instructions included with the product.

Please report incidents immediately to HEALAGENICS at 1-781-376-4114 or 1-866-213-8976.



## **HEALAGENICS, INC.**

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