

## PACKAGE INSERT

### SILVERSEAL® Hydrogel Wound Dressing Made with X-Static® (Package Insert)

Product Description: SILVERSEAL® Hydrogel Wound Dressings made with X-Static® are flexible, sterile, non-adherent hydrogel dressings that are 0.1 cm thick and consist of 1.5% nylon fiber suspension with a metallic silver surface containing 99.9% pure elemental silver, 92.7% de-ionized water, and polyethylene oxide. The dressings are available in the following sizes: 2" x 3" and 4" x 5".

The silver in the dressing provides an effective barrier to microbial contamination in contact with the dressing. The hydrogel component of the dressing promotes healing by maintaining a moist wound environment and aids in the removal of non-viable tissue from the wound (autolytic debridement). Silverseal® provides a soothing wound interface that allows for non-traumatic removal of the dressing. Silverseal® provides easy to use antimicrobial protection with no need to pre-wet even on dry wounds.

Topical application of SILVERSEAL® Hydrogel Wound Dressing made with X-Static® protects the wound area, has the ability to donate or absorb moisture and permits the passage of wound fluid through the product to be taken up by an overlying absorbent material. The silver provides effective protection of the wound against microbial contamination in contact with the dressing. All antimicrobial testing claims are the result of relevant *In vitro* studies. *In vitro* studies have shown that the silver-nylon suspension in SILVERSEAL® Hydrogel Wound Dressing made with X-Static® is effective in resisting the growth of bacteria. The antimicrobial effect has not been studied in a clinical setting.

Indications: *SILVERSEAL® Hydrogel Wound Dressing made with X-Static® is intended for the management of wounds and to provide an antimicrobial barrier.*

The dressing is indicated for use on:

- Partial and full thickness dermal ulcers
- Leg ulcers
- First and second degree burns
- Donor sites
- Over debrided and/or grafted partial thickness wounds
- Superficial wounds, abrasions

#### Directions for Use:

- Before applying the dressing, cleanse the wound area with an appropriate wound cleanser
- The dressing should completely cover the wound bed and can be cut if necessary
- Remove and discard the blue release liners from the dressing
- Apply SILVERSEAL® Hydrogel Wound Dressing directly to the wound with the gel side down.
- Then cover SILVERSEAL® Hydrogel Wound Dressing with a secondary dressing such as a foam dressing, gauze, or other appropriate dressing that will maintain a moist wound environment
- In case of more highly exuding wounds the clear backing layer of the dressing can be removed and an absorbent secondary dressing is appropriate
- SILVERSEAL® Hydrogel Wound Dressing is designed to be left in contact with the wound for not longer than 7 days. The frequency of dressing change depends on the amount of exudate present and the condition of the wound
- This product is for single use only and is supplied sterile
- Discard all opened but unused dressings
- SILVERSEAL® Hydrogel Wound Dressing is designed for non-traumatic removal from the wound. When removing SILVERSEAL® Hydrogel Wound Dressing, if the dressing has dried, moisten with water or saline to assist removal and avoid disruption of the wound bed

- Where the product is used on infected wounds, the infection should be inspected and treated per local clinical protocol
- Dressing should be removed prior to cardiac defibrillation and MRI Scans
- Do not attempt to re-sterilize

Warnings: Do not use if package is damaged. If condition worsens, consult your physician immediately. Keep this product out of reach of children.

Ingredients: SILVERSEAL® Hydrogel Wound Dressings made with X-Static® are flexible, sterile, non-adherent hydrogel dressings that are 0.1 cm thick and consist of 1.5% of nylon fiber suspension with a metallic silver surface containing 99.9% of pure elemental silver and 92.7% de-ionized water and 5.50% polyethylene oxide. SILVERSEAL® Hydrogel Wound Dressing made with X-Static® contains methylparaben and propylparaben.

Contraindications: Ascertained individual hypersensitivity to nylon or silver; cardiac defibrillators

Interactions: There are no known interactions.

Precautions:

- SILVERSEAL® Hydrogel Wound Dressing made with X-Static® is intended for external use only
- Do not use on patients during MRI (Magnetic Resonance Imaging) examination
- Prior to administering radiation therapy, remove SILVERSEAL® Hydrogel Wound Dressing. A new dressing can be applied following treatment
- SILVERSEAL® Hydrogel Wound Dressing is not compatible with oil based products such as petrolatum

Adverse Reactions: There are no known or reasonably suspected adverse reactions associated with either the use of nylon for topical application to wounds, or associated with the presence of silver in the amounts present in SILVERSEAL® Hydrogel Wound Dressing.

Storage: Store SILVERSEAL® Hydrogel Wound Dressing in sealed package at room temperature. Avoid excess heat and humidity.

How Supplied: SILVERSEAL® Hydrogel Wound Dressing is supplied in the following sizes:

Product No.	Size	How Supplied
AB-200300-103	2" x 3"	Box of 10 Pouches
AB-400500-105	4" x 5"	Box of 10 Pouches