

Silverlon® Adhesive Strip Dressing Instructions for Use

Device Description

Silverlon® Adhesive Strip Dressings are designed to intimately contact the wound as a primary dressing.

Available as:

<u>Code</u>	Tape Size	Pad Size
AS-6001/ AS-6003	1" x 3"	1" x 1"

Silverlon® Adhesive Strip Dressings delivers antimicrobial silver ions in the dressing when activated by moisture. The silver ions in the dressing kill wound bacteria held in the dressing and provides an antimicrobial barrier for bacterial penetration of the dressing which may help reduce infection. Silverlon® dressings have been tested in vitro and found effective against microorganisms such as: Staphylococcus aureus (MRSA), Vancomycin Resistant Enterococcus (VRE), Staphylococcus epidermidis, Escherichia Coli (E. coli), Shigella sonnei, Pseudomonas aeruginosa, Pseudomonas cepacia, Pseudomonas maltophiliaa, Acinetobacter calcoaceticus, Enterobacter cloacae, Salmonella typhimurium, Salmonella typhi, Enterococcus sp., Serratia marcescens, Listeria monocytogenes, Enterobacter cloacae, Staphylococcus, Streptococcus, Group B Streptococcus, Candida albicans, and Aspergillus niger.

Silverlon® Adhesive Strip Dressings have been subjected to independent standard in vitro and in vivo biocompatibility tests, including cytotoxicity, sensitization and intracutaneous reactivity. All tests were performed in accordance with the International Standard Organization (ISO) 10993 Standard Series for Biological Evaluation of Medical Devices.

Silverlon® Adhesive Strip Dressings are not made with natural rubber latex.

Indications

Silverlon® Adhesive Strip Dressings are professional use wound dressings intended for local management of vascular access or peripheral IV sites, orthopedic external pin sites, wound drain sites, stage I-IV dermal ulcers (vascular, venous, pressure, and diabetic), superficial wounds, surgical incisions, partial thickness burns, donor and graft sites, and abrasions and lacerations.

LC-IFU-AS; Version A



Warnings and Precautions

Silverlon® Adhesive Strip Dressings are intended for external use only. Contact a health care professional if any of the following signs or symptoms are noted:

- Increased pain, increased bleeding, increased swelling, increased wound drainage or increased redness in and around the wound site;
- There is a change in wound color and/or wound odor;
- The wound does not begin to show signs of healing; and
- Any other unexpected symptoms occur.
- Do not use past expiration date on the product packaging.
- Do not use if pouch is damaged or open.
- Do not use petroleum-based ointments or creams under Silverlon® Adhesive Strips.
- Do not moisten Silverlon® Adhesive Strips with hydrogen peroxide or povidone iodine.

Contraindications

Do not use Silverlon® Adhesive Strip Dressings on patients with known sensitivity to silver or nylon.

Do not use Adhesive Strip Dressings on 3rd degree burns.

Adverse Reactions

N/A

Instructions for Use

- Cleanse wound with sterile water, distilled water, or normal saline, removing necrotic debris or eschar as needed per normal protocol.
- Use the Silverlon® Adhesive Strip Dressing with a pad size that overlaps the wound margins.
- Activate Silverlon® Adhesive Strip Dressing by carefully moistening the pad with sterile water, distilled water, or normal saline; do not moisten the adhesive tape.
- Remove the adhesive tape release liner from one side of the Silverlon® Adhesive Strip Dressing; position the dressing with the pad directly over wound, so that the silver side of the dressing contacts the skin.
- Apply the dressing to the wound and smooth the adhesive tape into place on the intact skin surrounding the wound.
- Remove the release liner from the remaining side of the dressing and smooth the adhesive tape into place on the intact skin surrounding the wound.
- Silverlon® Adhesive Strip Dressings may be used for seven days; frequency of dressing change will depend on patient condition and the level of wound exudates.
- To remove Silverlon® Adhesive Strip Dressings, gently depress the surrounding skin while lifting the adhesive tape edges.
 - If the dressing pad adheres to the wound, moisten the dressing as needed with sterile water, distilled water, or normal saline, until the dressing can be easily removed.

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