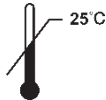




# Silverlon® Island Dressings

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STERILE EO



[www.silverlon.com/ifu](http://www.silverlon.com/ifu)



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LC-CEUK-IFU-ID; Rev C

## Silverlon® Island Dressing Instructions for Use

### Device Description

Silverlon® Island Dressings are sterile, multi-layer, absorbent, antimicrobial barrier dressings with attached adhesive tape.

### Available as:

<u>Code</u>	<u>Tape Size</u>	<u>Pad Size</u>
ID-23	5 x 8 cm	2.5 x 5 cm
ID-34	8 x 10 cm	5 x 6.5 cm
ID-44	10 x 10 cm	5 x 5 cm
ID-46	10 x 15 cm	5 x 10 cm
ID-410	10 x 25 cm	5 x 20 cm
ID-412	10 x 30 cm	5 x 25 cm
ID-414	10 x 36 cm	5 x 30 cm
ID-66	15 x 15 cm	10 x 10 cm

Silverlon® Island Dressings contain silver to provide an ancillary, local antimicrobial effect to reduce the risk of wound infection by organisms sensitive to silver. Ionic silver is a broad spectrum antimicrobial, which has been shown effective against a range of pathogens associated with wound infection.

Silverlon® dressings have been tested in vitro and found effective against microorganisms such as: *Enterococcus faecalis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Acinetobacter Baumannii*, *Enterobacter cloacae*, *Staphylococcus epidermidis*, and *Klebsiella pneumoniae*.

In vitro testing has shown Silverlon® Island Dressings to be MRI-compatible.

Silverlon® Island Dressings are latex free.

Silverlon® Island Dressings are recommended for use by professional healthcare providers and clinical practitioners.

### Intended Purpose

Silverlon® Island Dressings are professional wound dressings intended for the management of acute and chronic wounds.

### Indications

Silverlon® Island Dressings are professional use wound dressings indicated for use on acute and chronic wounds, for local management of:

- Donor and graft site wounds
- Diabetic, pressure and vascular ulcers
- Traumatic and surgical wounds
- Infected wounds\*

\*Silverlon® Island Dressings may be used on those infected wound types listed above. Where used on infected wounds, the infection should be treated as per local clinical protocol.

Silverlon® Island Dressings are indicated for a total duration of contact (i.e. where treatment involves consecutive application of individual dressings) not to exceed 30 days.

### Warnings

- 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® Island Dressing.

- Avoid contact with electrodes or conductive gels during electronic measurements e.g. EEG and ECG.
- Do not moisten Silverlon® Island Dressing with hydrogen peroxide or povidone iodine.
- If patients experience any allergic reactions such as blistering, itching, irritation, redness, skin rashes or discoloration, discontinue use and/or contact healthcare providers.
- In the event of clinical infection, topical silver does not replace the need for systemic therapy or other adequate infection treatment.
- Silverlon® Island Dressings should not be used for children, babies, premature infants, neonates, pregnant and lactating women due to limited clinical data.
- Silverlon® Island Dressings are intended for single use only and should not be re-used. Re-use may adversely affect the dressing's performance characteristics and also presents a risk of infection to the patient.

### **Contraindications**

- Do not use Silverlon® Island Dressings on patients with known sensitivity to silver or nylon.
- Silverlon® Island Dressings are not intended for use on 3rd degree burn.

BASIC UDI- DI - 08402473AIAWDAAY

Please refer to the following Eudamed link (URL) for summary of safety and clinical performance (SSCP) under Argentum Medical Silverlon Antimicrobial Wound Dressings utilizing Basic UDI-DI.

<https://ec.europa.eu/tools/eudamed>

### **Adverse Reactions**

Silverlon® Island 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. The results of these studies indicated that Silverlon® Island Dressings are safe for their intended use.

Any serious incident or complaint in relation to the device report to Manufacturer Argentum Medical LLC, 2571 Kaneville court, Geneva, IL 60134 Phone no. + 1 888.551.0188 and To UK Rep Emergo Consulting (UK) Limited, c/o Cr 360 – UL International, Compass House, Vision Park Histon, Cambridge CB24 9BZ, United Kingdom Tel: +44 (0)1256 312 118 and report to local competent authority.

### **Instructions for Use**

- Cleanse wound with sterile water, distilled water, or normal saline, removing necrotic debris or eschar as needed per local protocol.
- Select the Silverlon® Island Dressing with a pad size that overlaps the wound margins by 1-2 cm.
- Activate Silverlon® Island Dressing by thoroughly moistening 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® Island 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 each remaining side of the dressing and smooth the adhesive tape into place on the intact skin surrounding the wound.
- Silverlon® Island Dressings may be used for up to 7 days, but may require more frequent changing depending on wound condition and exudate buildup.
- To remove Silverlon® Island 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.

Post application, all Silverlon® wound care products are disposed of as biomedical waste per local protocol.