



Silverlon® Island Wound Dressing Instructions for Use

OTC Use: This device may be used over-the-counter (OTC). The OTC uses are specified in this Instruction for Use.

Rx Use: Caution: Federal law restricts this device to sale by or on the order of a physician for the Rx uses specified in this Instruction for Use.

Device Description

Silverlon® Island Wound Dressings is a multi-layer, sterile, non-adherent, absorbent, antimicrobial barrier wound dressing with an attached adhesive tape.

Available as:

<u>Code</u>	<u>Tape Size</u>	<u>Pad Size</u>	<u>Code</u>	<u>Tape Size</u>	<u>Pad Size</u>	<u>Code</u>	<u>Tape Size</u>	<u>Pad Size</u>
ID-23	2" x 3"	1" x 1.5"	ID-49	4" x 9"	2" x 6"	ID-413	4" x 13"	2" x 10"
ID-34	3" x 4"	2" x 2.5"	ID-66	6" x 6"	4" x 4"	ID-414	4" x 14"	2" x 12"
ID-44	4" x 4"	2" x 2"	ID-410	4" x 10"	2" x 8"	ID-512	4.5" x 12"	2.5" x 9"
ID-46	4" x 6"	2" x 4"	ID-411	4" x 11"	2" x 8"	ID-515	4.5" x 15"	2.5" x 12"
ID-48	4" x 8"	2" x 6"	ID-412	4" x 12"	2" x 10"			

Silverlon® Island Wound Dressings deliver 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 maltophilia*, *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® Island Wound 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® Island Wound Dressings are not made with natural rubber latex.

Indications

Over-the-Counter Use:

Local management of superficial wounds, minor burns, abrasions and lacerations.

RX Use:

Under the supervision of a healthcare professional Silverlon® Island Wound Dressings are intended for up to 7-day use for wounds such as vascular access or peripheral IV sites, orthopedic external pin sites, wound drain sites, surgical wounds (donor and graft sites, incisions), and partial to full thickness dermal ulcers (stage I-IV pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers).

Silverlon® Island Wound Dressing is indicated for the management of infected wounds, as the silver in the dressing provides an antimicrobial barrier that may be helpful in managing these wounds. In addition, the moist wound healing environment and control of wound bacteria within the Silverlon® Island Wound Dressing may help reduce the risk of wound infection and support the body's healing process.

Silverlon® Island Wound Dressing may be used for the management of painful wounds. Silverlon® Island Wound Dressing's non-adherent wound contact layer reduces pain during dressing changes and evaporation of moisture in the dressing may soothe the wound.



MRI Safety Information

Non-clinical testing and in-vivo electromagnetic simulations have demonstrated that the Silverlon® Island Wound Dressings are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following requirements:

- Static magnetic field of 1.5 or 3.0 T
- Maximum spatial field gradient of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg in 1.5T (Normal Level Controlled Operating Mode) and 4 W/kg in 3T (First Level Controlled Operating Mode).

Under the scan conditions defined above, the Silverlon® Island Wound Dressings are expected to produce a maximum temperature rise of less than 6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 1 mm from the device when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

Warnings and Precautions

Silverlon® Island Wound 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.

Consult a health care professional when Silverlon® Island Wound Dressings are used with other wound care products.

- 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® Dressings.
- Do not moisten Silverlon® Dressings with hydrogen peroxide or povidone iodine.

Some clinical studies have reported finding silver-resistant microbial strains when using silver based antimicrobial products. As of November 2017, no adverse events or reports of Silverlon-resistant microbial strains have been received by Argentum.

Contraindications

- Do not use Silverlon® Island Wound Dressing on patients with known sensitivity to silver or nylon.
- Do not use Silverlon® Island Wound 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 local protocol.
- Select the Silverlon® Island Wound Dressing with a pad size that **overlaps the wound margins by 1-2 cm.**
- Activate Silverlon® Island Wound 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 Wound Dressing.
- Position the dressing with the pad directly over wound and the silver side of the dressing contacts the skin.
- 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 Wound Dressings may be used for 7 days; frequency of dressing change will depend on patient condition and the level of wound exudates.
- To remove Silverlon® Island Wound 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.

Storage

Store Silverlon® Island Wound Dressings in normal warehouse conditions, not to exceed 50 °C. Keep dry. Avoid excessive heat or humidity.

Other Information

Independent, peer-reviewed and published clinical studies suggests Silverlon® Island Wound Dressings can be an important element in wound care and control of wound bacteria within the dressing may help reduce the risk of wound infection.¹²³

¹ The Use of Silver Nylon in Preventing Surgical Site Infections Following Colon and Rectal Surgery; Krieger, Beth R. et al, (2011)

² Do silver-impregnated dressings limit infections after lumbar laminectomy with instrumented fusion? Epstein NE. Surg Neurol. 2007;68:483-5

³ A Clinical Trial to Investigate the Effect of Silver Nylon Dressings on Mediastinitis Rates in Postoperative Cardiac Sternotomy Incisions; Huckfeldt, Roger et al, (2008)