Silverlon® Hydrocolloid Island Dressing Instructions for Use

DEVICE DESCRIPTION

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

Available as:

Product Code	Tape Size	Antimicrobial Contact Size	Antimicrobial Contact Area
IDHC48	4" x 8"	1¼" x 5"	6.13 in^2
IDHC410	4" x 10"	1¼" x 7"	8.63 in^2
IDHC412	4" x 12"	1¼" x 9"	11.13 in^2

Silverlon® Hydrocolloid Island 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 provide 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*, *Aspergillus niger, Candida auris, mycobacterium and Propionibacterium acnes*.

Silverlon® Hydrocolloid Island Dressings have been subjected to independent standards 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® Hydrocolloid Island Dressings are not made with natural rubber latex.

INDICATIONS

Over-The-Counter Indications:

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

RX Use

Under the supervision of a healthcare professional Silverlon® Hydrocolloid Island 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 fill thickness dermal ulcers (stage I-IV pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers).

Silverlon® Hydrocolloid Island Dressings are 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® Hydrocolloid Island Dressing may help reduce the risk of wound infection and support the body's healing process.

Silverlon® Hydrocolloid Island Dressings may be used for the management of painful wounds. Silverlon® Hydrocolloid Island 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® Hydrocolloid Island 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® Hydrocolloid Island Dressings are expected to produce a maximum temperature rise of less than 6° C after 15 minutes of continuous scanning.

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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® Hydrocolloid Island 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® Hydrocolloid Island 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 June 2021, no adverse events or reports of Silverlon-resistant microbial strains have been received by Argentum.

CONTRAINDICATIONS

- Do not use Silverlon® Hydrocolloid Island Dressings on patients with known sensitivity to silver or nylon.
- Do not use Silverlon® Hydrocolloid Island 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. Dry thoroughly before application.
- Select the Silverlon® Hydrocolloid Island Dressing with a pad size that ***overlaps the wound margins by 1-2 cm***.
- Activate Silverlon® Hydrocolloid 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® Hydrocolloid Island Dressing.
- Position the dressing with the pad directly over wound and the silver side of the dressing contacting 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® Hydrocolloid Island 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® Hydrocolloid 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.

Storage
Store Silverlon® Hydrocolloid Island Dressings in normal warehouse conditions, not to exceed 25 °C. Keep dry. Avoid excessive heat or humidity.

Other Information
Independent, peer-reviewed and published clinical studies suggests Silverlon® Hydrocolloid Island Dressings can be an important element in wound care and control of wound bacteria within the dressing and may help reduce the risk of wound infection.[1][2][3]

[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)