



Silverlon® Wound Pad and Burn Pad Dressings 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® Wound Pad and Burn Pad Dressings are sterile, multi-layer, non-adherent, absorbent, antimicrobial barrier dressings.

Available as:

<u>Code</u>	<u>Pad Size</u>	<u>Code</u>	<u>Pad Size</u>	<u>Code</u>	<u>Pad Size</u>
WPD-22	2" x 2"	WPD-212	2" x 12"	BPD-44	4" x 5"
WPD-23	2" x 3"	WPD-38	3" x 8"	BPD-48	4" x 8"
WPD-26	2" x 6"	WPD-310	3" x 10"	BPD-816	8" x 16"
WPD-28	2" x 8"	WPD-316	3" x 16"		
WPD-210	2" x 10"	WPD-44	4" x 5"		

Silverlon® Wound Pad and Burn Pad 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® Wound Pad and Burn Pad 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® Wound Pad and Burn Pad 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® Wound Pad and Burn Pad 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® Wound Pad and Burn Pad 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® Wound Pad and Burn Pad Dressings may help reduce the risk of wound infection and support the body's healing process.

Silverlon® Wound Pad and Burn Pad Dressings may be used for the management of painful wounds. Silverlon® Wound Pad and Burn Pad 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® Wound Pad and Burn Pad 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® Wound Pad and Burn Pad 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® Wound Pad and Burn Pad 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® Wound Pad and Burn Pad 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 event or reports of Silverlon-resistant microbial strains have been received by Argentum.

Contraindications

- Do not use Silverlon® Wound Pad and Burn Pad Dressings on patients with known sensitivity to silver or nylon.
- Do not use Silverlon® Wound Pad and Burn Pad 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 dressing pad size that **overlaps the wound margins 1-2 cm**.
- Activate Silverlon® Wound Pad and Burn Pad Dressings by thoroughly moistening with sterile water, distilled water, or normal saline.
- Position Silverlon® Wound Pad and Burn Pad Dressings so that the pad is directly over the wound and the silver side of the dressing is in contact with the skin.
- Secure with outer dressing per local protocol.
- For exudating wounds, use an outer absorbent dressing of choice. For dry wounds, use a moisture-donating outer dressing such as hydrocolloid or pre-moistened foam or gauze.
- Periodically check the edges of the Silverlon® dressing to ensure that correct moisture levels are being maintained.



- Silverlon® Wound Pad and Burn Pad Dressings may be used for 7 days, but may require more frequent changing depending on wound condition and exudate build-up.
- To remove Silverlon® Wound Pad and Burn Pad Dressings, first remove outer dressing per local protocol, and then gently depress surrounding skin while lifting pad dressing edges.
 - If sticking of the dressing to the wound occurs, moisten the dressing with sterile water, distilled water, or normal saline as needed, until it can be easily removed by gently lifting the corners.

Storage

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