

Silverlon® Wound Pad and Burn Pad Dressings Instructions 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>	Pad Size	<u>Code</u>	Pad Size	<u>Code</u>	Pad Size
WPD22	2" x 2"	WPD212	2" x 12"	BPD44	4" x 5"
WPD23	2" x 3"	WPD38	3" x 8"	BPD48	4" x 8"
WPD26	2" x 6"	WPD310	3" x 10"	BPD816	8" x 16"
WPD28	2" x 8"	WPD316	3" x 16"		
WPD210	2" x 10"	WPD44	4" x 5"		

Silverlon® Wound Pad and Burn Pad Dressing 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 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 Wound Pad and Burn Pad Dressing 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 Dressing 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® Wound 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 fill thickness dermal ulcers (stage I-IV pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers).

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

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



Warnings and Precautions

Silverlon® Wound Pad and Burn Pad Dressing 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 Dressing 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 April, 2014 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 Dressing by thoroughly moistening with sterile water, distilled water, or normal saline.
- Position Silverlon® Wound Pad and Burn Pad Dressing 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 Dressings and Burn Pad Dressings in normal warehouse conditions. Keep dry. Avoid excessive heat or humidity.