

Silverlon® Wound Pad Dressings Silverlon® Burn Pad Dressings

SILVERLON

safe, strong, simple.™

EC REP

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Device Description

Silverlon® Wound Pad and Burn Pad Dressings are sterile, multi-layer, non-adherent, absorbent, antimicrobial barrier dressings, intended for topical use in wound management, to reduce risk of wound infection.

Available as:

<u>Code</u>	<u>Pad Size</u>	<u>Code</u>	<u>Pad Size</u>	<u>Code</u>	<u>Pad Size</u>
WPD22	2" x 2"	WPD212	2" x 12"	BPD44	4" x 4"
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 4"		

Silverlon® Wound Pad and Burn Pad Dressing 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 to be effective against a range of pathogens associated with wound infection. Silverlon® Wound Pad and Burn Pad Dressings have been tested in vitro and found effective against micro organisms such as: Enterococcus faecalis, Staphylococcus aureus, Pseudomonas aeruginosa, Acinetobacter Baumannii, Enterobacter cloacae, Staphylococcus epidermidis and Klebsiella pneumoniae.

In vitro testing has shown Silverlon® dressings to be MRI compatible.

Indications

Silverlon® Negative Pressure Dressing and Silverlon® Easy Ag™ Negative Pressure Dressing are professional use wound dressings intended for use in conjunction with negative pressure wound therapy, for local management of:

- trauma wounds
- surgical wounds
- donor and graft site wounds
- lacerations and abrasions
- 1st and 2nd degree burns
- chronic wounds (diabetic, pressure and venous ulcers)

Silverlon® Wound Pad and Burn Pad Dressings may be used on infected wounds. Where used on infected wounds, the infection should be treated as per local clinical protocol.

Silverlon® Wound Pad and Burn Pad Dressings Dressings are indicated for a total duration of contact (i.e. where treatment involves consecutive application of individual dressings) of up to 30 days.

Warnings

- Do not use past expiration date on the product packaging.
- Do not use if pouch is damaged or open.
- Clinicians / Healthcare Professionals should be aware that there are very limited data on prolonged and repeated use of silver-containing dressings, particularly in children and neonates.
- Silverlon® dressings should not be used during pregnancy or lactation because of the lack of data concerning the effects of silver on reproduction.
- Do not use petroleum-based ointments or creams under Silverlon® Wound Pad and Burn Pad Dressing.
- Do not moisten Silverlon® Wound Pad and Burn Pad Dressings with hydrogen peroxide, or povidone iodine.
- Silverlon® Wound Pad and Burn Pad 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.
- Total duration of use of Silverlon® Wound Pad and Burn Pad Dressings (i.e. where treatment involves consecutive application of individual dressings) should not exceed 30 days.

Contraindications

- Avoid using Silverlon® Wound Pad and Burn Pad Dressings on patients with known sensitivity to silver or nylon.
- Silverlon® Wound Pad and Burn Pad Dressings are not intended for use on 3rd degree burns.

Adverse Reactions

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. The results of the studies indicated that Silverlon® Wound Pad and Burn Pad Dressings are safe for their intended use.

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 Dressing and Burn Pad Dressing may be used for up to 7 days, but may require more frequent changing depending on wound condition and exudate build-up.

- To remove Silverlon® Wound Pad and Burn Pad Dressing first remove outer dressing per local protocol, 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.