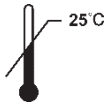




# Silverlon® Wound Pad Dressings

# Silverlon® Burn Pad Dressings

Publication Date: 04/2025



STERILE EO



[www.silverlon.com/ifu](http://www.silverlon.com/ifu)



Emergo Consulting (UK) Limited,  
c/o Cr 360 – UL International,  
Compass House, Vision Park  
Histon, Cambridge CB24 9BZ,  
United Kingdom  
Tel: +44 (0)1256 312 118



Argentum Medical LLC dba Bravida Medical  
2571 Kaneville Ct  
Geneva, IL 60134 USA  
Tel. (+1) 888.551.0188  
Fax. (+1) 888.558.9923  
[www.bravidamedical.com](http://www.bravidamedical.com)

LC-CEUK-IFU-WPD-BPD; Rev C

## Silverlon® Wound Pad Dressings Silverlon® Burn Pad Dressings

### 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>
WPD-22	5 x 5 cm	WPD-212	5 x 30 cm	BPD-44	10 x 12 cm
WPD-23	5 x 8 cm	WPD-38	8 x 20 cm	BPD-48	10 x 20 cm
WPD-26	5 x 15 cm	WPD-310	8 x 25 cm	BPD-816	20 x 40 cm
WPD-28	5 x 20 cm	WPD-316	8 x 40 cm		
WPD-210	5 x 25 cm	WPD-44	10 x 12 cm		

Silverlon® Wound Pad and Burn Pad Dressings 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 microorganisms such as: *Enterococcus faecalis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Acinetobacter Baumannii*, *Enterobacter cloacae*, *Staphylococcus epidermidis* and *Klebsiella pneumoniae*.

In vitro testing has shown Silverlon® Wound Pad and Burn Pad Dressings to be MRI compatible.

Silverlon® Wound Pad and Burn Pad Dressings are recommended for use by professional healthcare providers and clinical practitioners.

### Intended Purpose

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.

### Indications

Silverlon® Wound Pad Dressing and Burn Pad Dressings are professional use wound dressings intended for use on acute and chronic wounds for local management of:

- 1st and 2nd degree burns
- Donor and graft site wounds
- Diabetic, pressure and venous ulcers
- Trauma and surgical wounds
- Infected wounds\*

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

Silverlon® Wound Pad and Burn Pad 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.
- Do not use petroleum-based ointments or creams under Silverlon® Wound Pad and Burn Pad Dressing.
- Avoid contact with electrodes or conductive gels during electronic measurements e.g. EEG and ECG.
- Do not moisten Silverlon® Wound Pad and Burn Pad Dressings with hydrogen peroxide, or povidone iodine.
- If patients experience any allergic reactions such as blistering, itching, irritation, redness, skin rashes or discoloration, discontinue use and/or contact healthcare providers.
- In the event of clinical infection, topical silver does not replace the need for systemic therapy or other adequate infection treatment.
- Silverlon® Wound Pad and Burn Pad Dressings should not be used for children, babies, premature infants, neonates, pregnant and lactating women due to limited clinical data.
- 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

- Do not use 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.

BASIC UDI- DI - 08402473MLAWDFR

Please refer to the following Eudamed link (URL) for summary of safety and clinical performance (SSCP) under Argentum Medical Silverlon Antimicrobial Wound Dressings utilizing Basic UDI-DI.

<https://ec.europa.eu/tools/eudamed>

## 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.

Any serious incident or complaint in relation to the device report to Manufacturer Argentum Medical LLC, 2571 Kaneville court, Geneva, IL 60134 Phone no. +1 888.551.0188 and To UK Rep Emergo Consulting (UK) Limited, c/o Cr 360 – UL International, Compass House, Vision Park Histon, Cambridge CB24 9BZ, United Kingdom Tel: +44 (0)1256 312 118 and report to local competent authority.

## 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 exuding 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.

Post application, all Silverlon® wound care products are disposed of as biomedical waste per local protocol.