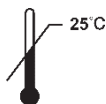




Silverlon®
Wound Contact Dressings
Silverlon®
Burn Contact Dressings
Silverlon®
Elastic Burn Wrap Dressings

Publication Date: 04/2025



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

LC-CEUK-IFU-WCD-BCD-BWD; Rev C

**Silverlon® Wound Contact Dressing
Silverlon® Burn Contact Dressing
Silverlon® Elastic Burn Wrap Dressing**

Device Description

Silverlon® Wound Contact Dressing, Burn Contact Dressing and Elastic Burn Wrap Dressings are sterile, single layer, non-adherent, antimicrobial barrier dressings, intended for topical use in wound management, to reduce risk of wound infection.

Available as:

<u>Code</u>	<u>Size</u>	<u>Code</u>	<u>Size</u>	<u>Code</u>	<u>Size</u>
WCD-22	5 x 5 cm	BCD-44	10 x 12 cm	BCD-CDM	66 x 64 cm
WCD-44	10 x 12 cm	BCD-48	10 x 20 cm	BCD-CDL	76 x 65 cm
WCD-412	10 x 30 cm	BCD-816	20 x 40 cm	BWD-466	10 x 168 cm
WCD-1012	25 x 30 cm	BCD-1616	40 x 40 cm	BWD-6108	15 x 274 cm
WCD-466	10 x 168cm	BCD-2424	61 x 61 cm		

Silverlon® Wound Contact Dressing, Burn Contact Dressing and Elastic Burn Wrap 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 Contact Dressing and Burn Contact Dressing have been tested in vitro and found to be effective against microorganisms such as: Enterococcus faecalis, Staphylococcus aureus, Pseudomonas aeruginosa, Acinetobacter Baumannii, Enterobacter cloacae, Staphylococcus epidermidis, and Klebsiella pneumoniae.

Silverlon® Wound Contact Dressing, Burn Contact Dressing and Elastic Burn Wrap Dressing are recommended for use by professional healthcare providers and clinical practitioners.

Intended Purpose

Silverlon® dressings are designed to be used for the management of wounds by minimizing or eliminating the presence of pathogen and wound debris.

Indications

Silverlon® Wound Contact Dressing, Burn Contact Dressing and Elastic Burn Wrap Dressing are professional use wound dressings indicated for use on acute and chronic wounds, for local management of:

- 1st and 2nd degree burns
- Donor and graft site wounds
- Traumatic and surgical wounds
- Diabetic, pressure and vascular ulcers
- Infected wounds*

*Silverlon® Wound Contact Dressing, Burn Contact Dressing and Elastic Burn Wrap Dressing may be used on those infected wound types listed above. Where used on infected wounds, the infection should be treated as per local clinical protocol.

Silverlon® Wound Contact Dressing, Burn Contact Dressing and Elastic Burn Wrap Dressing 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 Contact Dressing, Burn Contact Dressing and Elastic Burn Wrap Dressing.
- Avoid contact with electrodes or conductive gels during electronic measurements e.g. EEG and ECG.
- Do not moisten Silverlon® Wound Contact Dressing, Burn Contact Dressing and Elastic Burn Wrap Dressing 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 Contact, Burn Contact and Elastic Burn Wrap dressings should not be used for children, babies, premature infants, neonates, pregnant and lactating women due to limited clinical data.
- Silverlon® Wound Contact Dressing, Burn Contact Dressing, Elastic Burn Wrap Dressing are intended for single use only and should not be reused. Re-use may adversely affect the dressing's performance characteristics and also presents a risk of infection to the patient.

Contraindications

- Do not use Silverlon® Wound Contact Dressing, Burn Contact Dressing and Elastic Burn Wrap Dressing on patients with known sensitivity to silver or nylon.
- Silverlon® Wound Contact Dressing, Burn Contact Dressing and Elastic Burn Wrap Dressing are not intended for use on 3rd degree burns.
- Do not use on patients during MRI (Magnetic Resonance Imaging) examination.
- Prior to administering radiation therapy, remove Silverlon® Wound Contact Dressing, Burn Contact Dressing, and Elastic Burn Wrap dressing. A new dressing can be applied following treatment.

Basic UDI- DI - 08402473SLAWDHT

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 Contact Dressing, Burn Contact Dressing, Elastic Burn Wrap 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. The results of the studies indicated that Silverlon® Wound Contact Dressing, Burn Contact Dressing, Elastic Burn Wrap 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 or 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 size that overlaps the wound margins by 1-2 cm.
- The dressings may be cut to shape as necessary.

- Activate the Silverlon® dressing by thoroughly moistening with sterile water, distilled water or normal saline.
- Position the Silverlon® dressing directly over wound, with either silver side in contact with the skin; secure the dressing in place using a secondary dressing per local protocol.
 - For exudating wounds, use an absorbent secondary dressing of choice.
 - For dry wounds, use a moisture donating secondary dressing such as hydrocolloid or pre-moistened foam or gauze.
- Periodically check the edges of the Silverlon® dressing to ensure that it is maintained in a moist condition.
- Silverlon® Wound Contact Dressing, Burn Contact Dressing, Elastic Burn Wrap may be used for up to 7 days, but may require more frequent changing depending on wound condition and exudate buildup.
- To remove Silverlon® Wound Contact Dressing, Burn Contact Dressing, Elastic Burn Wrap first remove the outer secondary dressing per local protocol, and then gently depress surrounding skin while lifting the dressing edges.
 - If sticking of the dressing to the wound occurs, moisten the dressing as needed with sterile water, distilled water or normal saline 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.