



Silverlon®

Wound Packing Strips

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LC-CEUK-IFU-WPS; Rev C

Silverlon® Wound Packing Strips

Device Description

Silverlon® Wound Packing Strips are sterile, single layer, non-adherent, absorbent, antimicrobial dressings, intended for use in wound management, to reduce risk of wound infection.

Available as:

<u>Code</u>	<u>Size</u>
WPS-112	3 cm x 30 cm
WPS-124	3 cm x 61 cm

Silverlon® Wound Packing Strips 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® 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*.

Silverlon® Wound Packing Strips 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 Packing Strips are professional use wound dressings indicated for the management of acute and chronic wounds with tunneling and undermining within cavity wounds including:

- Traumatic and surgical wounds
- Diabetic, pressure and vascular ulcers
- Infected wounds*

*Silverlon® Wound Packing Strips 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 Packing Strips 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 Packing Strips.
- Avoid contact with electrodes or conductive gels during electronic measurements e.g. EEG and ECG.
- Do not moisten Silverlon® Wound Packing Strips with hydrogen peroxide or povidone iodine.
- If patients experience any allergic reaction such as blistering, itching, irritation, redness, skin rashes or significant discoloration, discontinue use or/and contact healthcare practitioners.
- In the event of clinical infection, topical silver does not replace the need for systemic therapy or other adequate infection treatment.
- Silverlon® Wound Packing Strips 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.

- Silverlon® Wound Packing strip dressings should not be used for children, babies, premature infants, neonates, pregnant and lactating women due to limited clinical data.

Contraindications

- Do not use Silverlon® Wound Packing Strips on patients with known sensitivity to silver or nylon.
- Silverlon® Wound Packing Strips 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 Packing Strips. 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 Packing Strips 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 these studies indicated that Silverlon® Wound Packing Strips 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.
- To allow for easy removal select the dressing size that will leave at least 1 to 2 cm (½") of Silverlon® Wound Packing Strip protruding from the wound.
- Trim dressing length as necessary.
- Activate Silverlon® Wound Packing Strip by thoroughly moistening the dressing with sterile water, distilled water, or normal saline.
- Gently pack wound per local protocol ensuring maximum direct contact between Silverlon® Wound Packing Strip and the wound bed.
- Cover and secure Silverlon® Wound Packing Strip with conventional absorbent and non-occlusive dressings per local protocol.
- To remove Silverlon® Wound Packing Strip, first remove the outer dressing per local protocol, then gently grasp and pull the protruding section of Silverlon® Wound Packing Strip.
 - 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 pulling the Silverlon® Wound Packing Strip.
- Silverlon® Wound Packing Strips are intended for use for up to 7 days, but dressing change frequency will depend on wound condition and the amount of exudates.
 - Remove and replace Silverlon® Wound Packing Strip whenever it becomes heavily coated with wound exudates or wound debris.
 - If applicable, remove Silverlon® Wound Packing Strip intact after 7 days from a cavity wound

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