

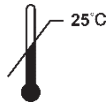


# Silverlon®

## LifeSaver IV/Catheter

### Dressings

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



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LC-CEUK-IFU-IVCD; Rev C

## Silverlon® Lifesaver® IV/Catheter Dressings

### Device Description

Silverlon® Lifesaver® IV/ Catheter Dressings are sterile, multilayer, 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>
IVCD-15	2.5 cm circle with 1.5 mm center hole
IVCD-40	2.5 cm circle with 4.0 mm center hole
IVCD-70	2.5 cm circle with 7.0 mm center hole
IVCD-MINI	1.5 cm circle with 1.5 mm hole
IVCD-15-85	4 cm x 4 cm dressing with 8.5 mm hole
DPD-20-12	5 cm x 5 cm dressing with 12 mm hole

Silverlon® Lifesaver® IV/ Catheter 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® 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® Lifesaver® IV/ Catheter Dressings to be MRI compatible.

Silverlon® IV / Catheter Dressings are recommended for use by professional healthcare providers and clinical practitioners.

### Intended Purpose

Silverlon® Lifesaver® IV/ Catheter 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® Lifesaver® IV/ Catheter Dressings are professional use wound dressings indicated for local management of:

- Vascular access sites (including around IV catheters, central venous lines, arterial catheters, dialysis catheters);
- Drainage tube access sites;
- Epidural catheter access sites;

Silverlon® Lifesaver® IV/ Catheter 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® Lifesaver® IV/ Catheter Dressing.
- Avoid contact with electrodes or conductive gels during electronic measurements e.g. EEG and ECG.

- Do not moisten Silverlon® Lifesaver® IV/Catheter Dressing in 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® Lifesaver® IV/Catheter Dressings should not be used for children, babies, premature infants, neonates, pregnant and lactating women due to limited clinical data.
- Silverlon® Lifesaver® IV/Catheter 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.

### **Contraindications**

- Do not use Silverlon® Lifesaver® IV/Catheter Dressings on patients with known sensitivity to silver or nylon.
- Silverlon® Lifesaver® IV/Catheter Dressings are not intended for use on 3<sup>rd</sup> degree burns.

BASIC UDI- DI - 08402473IVCDJT

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® Lifesaver® IV/ Catheter 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 these studies indicated that Silverlon® Lifesaver® IV/ Catheter 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**

- Prepare the skin around wound site according to hospital protocol.
- Select the Silverlon® Lifesaver® IV/ Catheter Dressing with a hole size that is slightly larger in diameter than the catheter (or other device) protruding from the wound.
- Activate Silverlon® Lifesaver® IV/ Catheter Dressing by wetting it with sterile water, distilled water, or normal saline.
- Place the Silverlon Lifesaver® IV/ Catheter Dressing around the device protruding from the wound, so that the silver side of the dressing is in direct contact with the skin.
- Secure Silverlon® Lifesaver® IV/ Catheter Dressing in position with a transparent film dressing.
- Silverlon® Lifesaver® IV/ Catheter Dressing may be used for up to 7 days, but may require more frequent changing depending on wound condition and exudate buildup.
- To remove Silverlon® Lifesaver® IV/ Catheter Dressing, first remove the outer dressing per local protocol, then gently lift the edges of the Silverlon® Lifesaver® IV/ Catheter Dressing.
  - If the dressing sticks to the skin, 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.