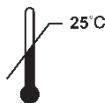




Silverlon®

Flex Wound Contact Negative Pressure Dressings

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www.silverlon.com/ifu



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LC-CEUK-IFU-NPS-FLX; Rev C

Silverlon® Flex Wound Contact Negative Pressure Dressings

Device Description

Silverlon® Flex Wound Contact Negative Pressure Dressings are sterile, single layer, non-adherent, antimicrobial barrier dressings, intended for topical use in wound management and in negative pressure wound therapy (NPWT), to reduce risk of wound infection.

Available as:

<u>Code</u>	<u>Size</u>	<u>Code</u>	<u>Size</u>
WCD22-NPS(-FLX)	5 x 5 cm	WCD48-NPS(-FLX)	10 x 20 cm
WCD44-NPS(-FLX)	10 x 10 cm	WCD88-NPS(-FLX)	20 x 20 cm

Silverlon® Flex Wound Contact Negative Pressure 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*. Silverlon® Flex Wound Contact Negative Pressure Dressings may be used with all types of negative pressure wound therapy porous foam/gauze dressings and equipment.

In vitro testing has shown Silverlon® Flex Wound Contact Negative Pressure Dressings to be MRI-compatible.

Silverlon® Flex Wound Contact Negative Pressure Dressings are recommended for use by professional healthcare providers and clinical practitioners.

Intended Purpose

Silverlon® Flex Wound Contact Negative Pressure Dressings are sterile, single layer, non-adherent, antimicrobial barrier dressings, intended for topical use in wound management and in negative pressure wound therapy (NPWT), to reduce risk of wound infection.

Indications

Silverlon® Flex Wound Contact Negative Pressure Dressings are professional use wound dressings indicated for use on acute and chronic wounds and in conjunction with negative pressure wound therapy (NPWT), for local management of:

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

* Silverlon® Flex Wound Contact Negative Pressure Dressings may be used on those infected wounds listed above. Where used on infected wounds, the infection should be treated as per local clinical protocol.

Silverlon® Flex Wound Contact Negative Pressure 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® Flex Wound Contact Negative Pressure Dressings.
- Avoid contact with electrodes or conductive gels during electronic measurements e.g. EEG and ECG.
- Do not moisten Silverlon® Flex Wound Contact Negative Pressure Dressings with hydrogen peroxide or povidone iodine.
- Silverlon® Flex Wound Contact Negative Pressure Dressings dressings should not be used for children, babies, premature infants, neonates, pregnant and lactating women due to limited clinical data.
- 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® Flex Wound Contact Negative Pressure 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® Flex Wound Contact Negative Pressure Dressings (i.e. where treatment involves consecutive application of individual dressings) should not exceed 30 days.
- Silverlon® Flex Wound Contact Negative Pressure Dressings are not intended for direct application to exposed underlying structures (i.e. blood vessels, bone, tendons, nerves).
- When using Silverlon® Flex Wound Contact Negative Pressure Dressings in conjunction with commercially available negative pressure wound therapy systems, users should follow the directions for use supplied by the negative pressure wound therapy system manufacturer concerning the protection of exposed underlying structures.
- When using Silverlon® Flex Wound Contact Negative Pressure Dressings in conjunction with commercially available negative pressure wound therapy systems, users should follow the directions for use supplied by the negative pressure wound therapy system manufacturer concerning specific wound conditions not suitable for negative pressure wound therapy and precautions to take in the event of the occurrence of bleeding during negative pressure wound therapy.

Contraindications

- Do not use Silverlon® Flex Wound Contact Negative Pressure Dressings on patients with known sensitivity to silver or nylon.
- Silverlon® Flex Wound Contact Negative Pressure Dressings are not intended for use on 3rd degree burns.

BASIC UDI- DI -08402473ANPWDEE

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® Flex Wound Contact Negative Pressure 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® Flex Wound Contact Negative Pressure 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 Silverlon® Flex Wound Contact Negative Pressure Dressing size that fully covers the wound up to the wound margins; trim the dressing edges as necessary.
- Activate the Silverlon® Flex dressing by thoroughly moistening with sterile water, distilled water, or normal saline.
- Position the Silverlon® Flex 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® Flex dressing to ensure that it is maintained in a moist condition.
- For NPWT Use - Position the Silverlon® Flex Dressing directly over the wound, in contact with the skin; place foam or gauze fill media of choice on top of the Silverlon® Flex dressing and secure in place according to the instructions supplied by the manufacture of the negative pressure wound therapy equipment.
- Silverlon® Flex Wound Contact Negative Pressure Dressings may be used for up to 7 days, but may require more frequent changing depending on wound condition and exudate build-up.
 - In conjunction with negative pressure replace the Silverlon® Flex dressing whenever the foam / gauze fill media are replaced.
- To remove Silverlon® Flex Wound Contact Negative Pressure Dressings, first remove the foam / gauze fill media per local protocol, and then gently depress surrounding skin while lifting the edges of the Silverlon® Flex dressing.
 - 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.