



## Silverlon® Antimicrobial Wound Contact Negative Pressure Dressing Instructions for Use

### Device Description

Silverlon® Antimicrobial Wound Contact Negative Pressure Dressings are sterile, single use, single layer dressings of knitted nylon fiber substrate coated with metallic silver. This Silverlon® Antimicrobial Wound Contact Negative Pressure Dressings model is knitted to a specified knit pattern designed to allow optimal flow rate of wound exudates when used as the primary wound contact layer in a NPWT dressing set. It is circumferentially coated with metallic silver 5.05 mg / cm<sup>2</sup> (50.5 g/m<sup>2</sup>).

### Available as:

| <u>Code</u> | <u>Size</u> | <u>Code</u> | <u>Size</u> |
|-------------|-------------|-------------|-------------|
| NPD-22      | 2" x 2"     | NPD-212     | 1.5" x 12"  |
| NPD-45      | 4" x 5"     | NPD-512     | 5" x 12"    |
| NPD-58      | 5" x 8"     | NPD-1212    | 12" x 12"   |
|             |             | NPG-L       | Glove       |

Silverlon® Antimicrobial Wound Contact Negative Pressure Dressings delivers antimicrobial silver ions in the dressing when activated by moisture. The silver ions in the dressing kill wound bacteria held in the dressing and provides an antimicrobial barrier for bacterial penetration of the dressing which may help reduce infection. Silverlon® Negative Pressure Dressing have tested *in vitro* and found effective against microorganisms: Gram Positive Bacteria - Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin Resistant Enterococcus (VRE), Staphylococcus epidermidis Gram Negative Bacteria - *Escherichia coli* (EColi), *Pseudomonas aeruginosa*, *Enterobacter cloacae*, Yeast/ Mold - *Candida albicans*, and *Aspergillus brasiliensis*

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

Silverlon® Antimicrobial Wound Contact Negative Pressure Dressing has been subjected to independent standard in vitro and in vivo biocompatibility tests; 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.

Silverlon® Antimicrobial Wound Contact Negative Pressure Dressing is not made with natural rubber latex.

### Indications

Silverlon® Fenestrated Wound Contact Dressings (Silverlon® Antimicrobial Wound Contact Negative Pressure Dressing and Silverlon® Easy Ag™ Antimicrobial Wound Contact Negative Pressure Dressings) are intended to provide moist wound environment and are used for the management of chronic, acute, surgical, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts; when used in conjunction with an NPWT pump that is intended to be used for negative pressure wound therapy (NPWT), the NPWT system is indicated for patients who benefit from wound management therapy via the application of negative pressure wound therapy for removal of fluids and excess exudates, infectious material, and tissue debris which may promote wound healing. It provides a non-adherent, conformable, antimicrobial barrier and may help reduce infection when placed under reticulated foam, gauze, or other wound fillers. Silverlon® Fenestrated Wound Contact Dressings may be cut or overlapped to fit any wound size.

### Warnings and Precautions

Silverlon® Fenestrated Wound Contact Dressings (Silverlon® Antimicrobial Wound Contact Negative Pressure Dressing and Silverlon® Easy Ag™ Antimicrobial Wound Contact Negative Pressure Dressings) are intended for external use only. Contact a health care professional if any of the following signs or symptoms are noted:



- Increased pain, increased bleeding, increased swelling, increased wound drainage or increased redness in and around the wound site;
- There is a change in wound color and/or wound odor;
- The wound does not begin to show signs of healing; and any other unexpected symptoms occur. Consult a health care professional when Silverlon® Fenestrated Wound Contact Dressings are used with other wound care products.
- When using Silverlon® Fenestrated Wound Contact 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® Fenestrated Wound Contact Dressing 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.
- 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® Dressings.
- Do not moisten Silverlon® Dressings with hydrogen peroxide or povidone iodine.

Some clinical studies have reported finding silver-resistant microbial strains when using silver based antimicrobial products. As of April 2014, no adverse event or reports of Silverlon-resistant microbial strains have been received by Argentum.

#### **Contraindications**

- Do not use Silverlon® Fenestrated Wound Contact Dressings on patients with known sensitivity to silver or nylon.
- Do not use Silverlon® Fenestrated Wound Contact Dressings on 3rd degree burns.

#### **Adverse Reactions - N/A**

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

#### **Storage**

Store Silverlon® Dressings in normal warehouse conditions. Keep dry. Avoid excessive heat or humidity.