PERFORMANCE. POWER. SPEED.

# Silverlon® CA (Calcium Alginate) Dressings Instructions for Use

## Device Description

Silverlon® CA Advanced Antimicrobial Alginate dressing is a sterile, non-woven pad composed of a High M (mannuronic acid) alginate and a silver nylon contact layer. The release of silver ions provides an antimicrobial barrier, which protects the dressing from bacterial contamination. The dressing absorbs exudates, maintains a moist wound environment and allows for intact removal.

## Available as:

| Product Code | Pad Size | Product Code | Pad Size | Product Code | Pad Size |
|---|---|---|---|---|---|
| CA22 | 2" x 2" | CA48 | 4" x 8" | CA7512 | ¾" x 12 " |
| CA475 | 4" x 4¾" | CA812 | 8" x 12" | | |

Silverlon® CA dressing contains silver to provide an effective barrier to microbial penetration for moderate to heavy exudating partial and full thickness wounds, including pressure ulcers, venous ulcers, diabetic ulcers, donor and graft sites, traumatic and surgical wounds and 1st and 2nd degree burns. Silverlon® dressings have been tested in vitro and found effective against microorganisms such as: Staphylococcus aureus (MRSA), Vancomycin Resistant Enterococcus (VRE), Staphylococcus epidermidis, Escherichia Coli (E. coli), Shigella sonnei, Pseudomonas aeruginosa, Pseudomonas cepacia, Pseudomonas maltophilia, Acinetobacter calcoaceticus, Enterobacter cloacae, Salmonella typhimurium, Salmonella typhi, Enterococcus sp., Serratia marcescens, Listeria monocytogenes, Enterobacter cloacae, Staphylococcus, Streptococcus, Group B Streptococcus, Candida albicans, and Aspergillus niger.

Silverlon® CA 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.

Silverlon® CA dressings are not made with natural rubber latex.

## Indications

Silverlon® CA dressing is a professional use wound dressing indicated for the management of moderately – to heavily-exudating, partial and full thickness wounds, including 1st and 2nd degree burns, skin graft and donor sites, chronic wounds such as pressure ulcers, dermal ulcers, vascular ulcers, diabetic ulcers, traumatic and surgical wounds.

## Warnings and Precautions

Silverlon® CA 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.

Argentum Medical LLC
2571 Kaneville Court, Geneva, Illinois 60134, USA
Tel. (+1) 630.232.2507 Fax. (+1) 630.232.8005

SILVERLON®

PERFORMANCE. POWER. SPEED.

Consult a health care professional when Silverlon® CA dressings are used with other wound care products.

- 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® CA dressings on patients with known sensitivity to silver or nylon.
- Do not use Silverlon® CA 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 size of dressing that covers the wound but does not overlap the wound margins.
- Apply pad to wound with the gray (silver) side of pad toward the wound.
- For heavily exudating wounds, apply the dressing directly to the wound bed; loosely pack deep wounds, ensuring that the dressing does not overlap the wound margins.
- For lightly exudating wounds, moisten the wound bed with sterile water, distilled water or normal saline before applying the dressing.
- Cover and secure with non-occlusive secondary dressing per local protocol.
- Remove Silverlon® CA dressing when saturated or when local wound care practice dictates.
- Silverlon® CA dressings may be used for 7 days; frequency of dressing change will depend on patient condition and the level of wound exudates.
    - Initially, it might be necessary to change the dressing every 24 hours.
- To remove Silverlon® CA dressing, first remove the outer secondary dressing per local protocol. Then gently lift the edges of the Silverlon® CA dressing.
    - If the wound appears dry, or sticking of the dressing occurs, moisten Silverlon® CA dressing with sterile water, distilled water, or normal saline until the dressing can be easily removed by gently lifting the corners.
- Irrigate the wound per local protocol after dressing removal.

**Storage**

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