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Silverlon® Acute Burn Glove Dressings Instructions for Use

Device Description

Silverlon® Acute Burn Glove Dressing are sterile, porous, non-adherent, knitted nylon plated with approximately 99% elemental silver and 1% silver oxide, in the form of a glove with open finger, which is designed to fit comfortably over the hand, covering the entire skin surface of the hand.

Available as:

| <u>Code</u> | <u>Size</u> |
|------------------|-------------------------|
| ABG-01XS | Adult Extra Small |
| ABG-01S | Adult Small |
| ABG-01M | Adult Medium |
| ABG-01L | Adult Large |
| ABG-01XL | Adult Extra Large |
| ABG-01XXL | Adult Extra Extra Large |

Silverlon® Acute Burn Glove Dressing deliver 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® 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® Acute Burn Glove 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® Acute Burn Glove Dressings are not made with natural rubber latex.

Indications

OTC Use

Local management of superficial wounds, minor burns, abrasions and lacerations.

Prescription Indications:

Silverlon® Acute Burn Glove Dressings are indicated for use up to 7 days for partial and full thickness wounds including traumatic wounds, surgical wounds (donor and graft sites, incisions), 1st and 2nd degree burns, as well as dermal ulcers (stage I-IV pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers), vascular access or peripheral IV sites, orthopedic external pin sites and wound drain sites.

Silverlon® Acute Burn Glove Dressings are indicated for the management of infected wounds, as the silver in the dressing provides an antimicrobial barrier that may be helpful in managing these wounds. In addition, the moist wound healing environment and control of wound bacteria within the Silverlon® Dressings may help reduce the risk of wound infection and support the body's healing process.

Silverlon® Acute Burn Glove Dressings may be used for the management of painful wounds. Silverlon® Acute Burn Glove Dressing is a non-adherent wound contact layer that reduces pain during dressing changes and evaporation of moisture in the dressing may sooth the wound.

Warnings and Precautions

Do not use Silverlon® Wound Contact Dressing and Burn Contact Dressings on non-excised 3rd degree burns. Excise dead tissue before applying Silverlon® dressing.



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Silverlon® Wound Contact Dressing and Burn Contact Dressings are intended for external use only. Contact a health care professional if any of the following signs or symptoms is 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® Wound Contact Dressing and Burn Contact 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® Acute Burn Glove Dressings on patients with known sensitivity to silver or nylon.

Adverse Reactions

N/A

Instructions for Use

- Cleanse the wound with sterile water, distilled water, or normal saline removing necrotic debris or eschar as needed per local protocol.
- Select the Silverlon® Acute Burn Glove Dressing size that best covers the hand and makes light contact with the skin.
- The glove fingers may be trimmed to fit (or folded over and the end secured) per local protocols.
- Activate Silverlon® Acute Burn Glove Dressing by thoroughly moistening it with sterile water, distilled water or normal saline.
- Gently slide the hand into the glove and secure the glove in position with an outer secondary dressing (i.e. gauze wrap, tubular stretch knit bandage or other compressive wrap dressing) per local protocol.
 - It is recommended to use a moisture-donating outer dressing such as hydrocolloid or pre-moistened foam or gauze.
 - Wrap and secure the outer secondary dressing as per local protocol.
- Silverlon® Acute Burn Glove Dressing may be worn while bathing / showering, although the outer secondary dressing should be removed first.
- Silverlon® Acute Burn Glove Dressing may be used for 7 days, but may require more frequent changing depending on wound condition.
- To remove Silverlon® Acute Burn Glove Dressing to enable wound inspection and clinical attention, first remove and discard the outer secondary dressing, then soak the hand encased in Silverlon® Acute Burn Dressing in room temperature sterile water, distilled water, or normal saline for 5 - 15 minutes.
 - Next, gently remove Silverlon® Acute Burn Dressing.
 - If the dressing sticks to the skin or wound during removal, repeat soaking until it can be easily removed.

Storage

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