Silverlon® Acute Burn Glove Dressings Instructions for Use

OTC Use: This device may be used over-the-counter (OTC). The OTC uses are specified in this Instruction for Use.
Rx Use: Caution: Federal law restricts this device to sale by or on the order of a physician for the Rx uses specified in this Instruction 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 fingers, which is designed to fit comfortably over the hand, covering the entire skin surface of the hand.

Available as:

Code	Size
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 maltophiliaa, 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

Over-the-Counter Use:
Local management of superficial wounds, minor burns, abrasions and lacerations.

Rx Use:
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), first- and second-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 use up to 7 days for decontaminated stable unroofed first- and second-degree mustard-induced vesicant injuries not requiring skin grafting.

Silverlon® Acute Burn Glove Dressings are indicated for use up to 7 days for radiation dermatitis.

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Silverlon® Acute Burn Glove Dressings are indicated for use up to 7 days for acute cutaneous radiation injury including moist desquamation without full thickness skin ulceration and/or necrosis.

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.

MRI Safety Information

MR Conditional

The Silverlon® Acute Burn Glove Dressings are MR Conditional. A patient with the Silverlon® Acute Burn Glove Dressings may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Parameter	***Condition***
Nominal Values of Static Magnetic Field (T)	1.5-T or 3.0-T
Maximum Spatial Field Gradient z (T/m and gauss/cm)	40-T/m (4,000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature-driven)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks)
MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.

Warnings and Precautions

Do not use Silverlon® Acute Burn Glove Dressings on non-excised 3rd degree burns. Excise dead tissue before applying Silverlon® dressing.

Silverlon® Acute Burn Glove 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.

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Consult a health care professional when Silverlon® Acute Burn Glove 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.

Additional Guidance for Cutaneous Radiation Injuries

Silverlon® Acute Burn Glove Dressings are indicated for cutaneous radiation injuries with the following guidance:

- Patients with cutaneous radiation injuries should seek immediate consultation with an appropriate healthcare specialist familiar with cutaneous radiation injuries.
- Experts have developed the following standardized criteria to describe the severity of cutaneous radiation injuries, the Common Terminology Criteria for Adverse Events (CTCAE) grading scale. *Silverlon® Acute Burn Glove Dressings are indicated for CTCAE-defined grades 1, 2, and 3. Do not use Silverlon® Dressings for grade 4 injuries.*

CTCAE[1] grading scale for cutaneous inflammatory reaction occurring as a result of exposure to biologically effective levels of ionizing radiation		Use *Silverlon® Acute Burn Glove Dressings (YES/NO)*
CTCAE Grade	**CTCAE Grade Description**	
1	Faint erythema or dry desquamation	YES
2	Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema	YES
3	Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion	YES
4	Life-threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated	NO

[1]Common Terminology Criteria for Adverse Events, version 5.0, published November 27, 2017, by the U.S. Department of Health and Human Services.

- Cutaneous radiation injuries can worsen over time even after significant healing is observed. If cutaneous radiation injuries worsen to grade 4, seek immediate consultation with an appropriate healthcare specialist familiar with cutaneous radiation injuries and discontinue use of *Silverlon® Dressings.*

Additional Guidance for Mustard-Induced Vesicant Injuries

For mustard-induced vesicant injuries, Silverlon® Acute Burn Glove Dressing are indicated for up to 7 days for decontaminated stable unroofed first- and second-degree mustard-induced vesicant injuries not requiring skin grafting, defined as:

- *Decontaminated:* a mustard vapor injury that has received sufficient debridement to remove all traces of the mustard agent.
- *Stable:* a mustard vapor injury that has not become deeper or larger during the preceding 2-4 days.
- *Unroofed:* a mustard vapor injury in which debridement of all appropriate blisters has been performed.

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.
- Silverlon dressings may be used with topical care treatments.
- 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.

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