OTC Use: This device may be used Over-the-Counter (OTC) for the OTC uses specified in this Instructions 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 Instructions For Use.

Silverlon® Wound (WCD) or Burn (BCD) Contact Dressings Instructions for Use

Device Description - Silverlon® Wound Contact, Burn Contact Dressings are sterile, porous, non-adherent, knitted nylon plated with approximately 99% elemental silver and 1% silver oxide.

Available as:

Code	*Size*	*Code*	*Size*	*Code*	*Size*
WCD-22	2” x 2”	BCD-44	4” x 5”	BCD-CDM	26” x 25”
WCD-44	4” x 5”	BCD-48	4” x 8”	BCD-CDL	30” x 25.5”
WCD-412	4” x 12”	BCD-816	8” x 16”	BCD-FM	14” x 9”
WCD-1012	10” x 12”	BCD-1616	16” x 16”	BWD-466	4” x 66”
WCD-466	4” x 66”	BCD-2424	24” x 24”	BWD-6108	6” x 108”
WCD-FM	14” x 24”			DS-112	1” x 12”

Silverlon® Wound Contact Dressing and Burn Contact Dressings 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® 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® Wound Contact, Burn Contact Dressings are not made with natural rubber latex.

Indications

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

Prescription Indications:

Silverlon® Wound Contact, Burn Contact 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 thermal 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® Wound Contact, Burn Contact 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® Wound Contact, Burn Contact Dressings are indicated for use up to 7 days for radiation dermatitis.

Silverlon® Wound Contact, Burn Contact 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.

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Silverlon® Wound Contact, Burn Contact 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® Wound Contact, Burn Contact Dressings may help reduce the risk of wound infection and support the body's healing process.

Silverlon® Wound Contact, Burn Contact Dressings may be used for the management of painful wounds. Silverlon® Wound Contact, Wound Burn Dressings are a non-adherent wound contact layer that reduces pain during dressing changes and evaporation of moisture in the dressing may soothe the wound.

MRI Safety Information

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

MR Conditional

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® Wound Contact Dressing and Burn Contact Dressings on non-excised 3rd degree burns. Excise dead tissue before applying Silverlon® dressing.

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.

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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.

Additional guidance for cutaneous radiation injuries:
Silverlon® Wound Contact Dressing and Burn Contact 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® Wound Contact Dressing and Burn Contact 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® Wound Contact Dressing and Burn Contact 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® Wound Contact, Burn Contact Dressings 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.

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Contraindications
Do not use Silverlon® Wound Contact Dressing and Burn Contact Dressings on patients with known sensitivity to silver or nylon.

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 dressing size that overlaps the wound margins by 1-2 cm.
- Activate Silverlon® Wound Contact Dressing and Burn Contact Dressing by thoroughly moistening with sterile water, distilled water or normal saline.
- Position the Silverlon® 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® dressing to ensure that it is maintained in a moist condition.
- Silverlon® Wound Contact Dressing and Burn Contact Dressing may be used for 7 days, but may require more frequent changing depending on wound condition and exudate build-up.
- Silverlon dressings may be used with topical care treatments.
- To remove Silverlon® Wound Contact Dressing and Burn Contact Dressing, first remove the outer secondary dressing per local protocol, and then gently depress surrounding skin while lifting the dressing edges.
    - 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® Wound Contact Dressing and Burn Contact Dressings in normal warehouse conditions. Keep dry. Avoid excessive heat or humidity.

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