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Silverlon® Wound Packing Strips (WPS) Instructions for Use

Device Description

Silverlon® Wound Packing Strips are sterile, single layer, non-adherent, absorbent, antimicrobial dressings.

Available as:

<u>Code</u>	<u>Size</u>
WPS112	1" x 12"
WPS124	1" x 24"

Silverlon® Wound Packing Strips contain silver to provide an ancillary local antimicrobial to the barrier functions of the dressing. 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® Wound Packing Strips 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 Packing Strips are not made with natural rubber latex.

Indications

Silverlon® Wound Packing Strips are professional use wound dressings intended for:

- Control of local wound bleeding, including nasal hemorrhage;
- Encouraging absorption and drainage of wound exudates from a body cavity, infected wound, or abscess by wicking fluids;
- Helping to remove necrotic tissue from ulcers or other infected wounds when used as a “wet-to-dry” packing.

Silverlon® Wound Packing Strips may be used as an interface between the wound and a conventional secondary absorbent dressing, permitting passage of wound fluid through the product to the overlying absorbent dressing.

Silverlon® Wound Packing Strips may be used on infected wounds, under medical supervision, when used as a “wet to dry packing”.

Warnings and Precautions

Silverlon® Wound Packing Strips 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;

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- 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 Packing Strips 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® Wound Packing Strips on patients with known sensitivity to silver or nylon.
- Do not use Silverlon® Wound Packing Strips 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.
- To allow for easy removal select the dressing size that will leave at least ½” of Silverlon® Wound Packing Strip protruding from the wound. Trim dressing length as necessary.
- Activate Silverlon® Wound Packing Strip by thoroughly moistening the dressing with sterile water, distilled water, or normal saline.
- Gently pack wound per local protocol ensuring maximum direct contact between Silverlon® Wound Packing Strip and the wound bed.
- Cover and secure Silverlon® Wound Packing Strip with conventional absorbent and non- occlusive dressings per local protocol.
- To remove Silverlon® Wound Packing Strip, first remove the outer dressing per local protocol, then gently grasp and pull the protruding section of Silverlon® Wound Packing Strip. 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 pulling the Silverlon® Wound Packing Strip.
- Silverlon® Wound Packing Strips are intended for use for 7 days, dressing change frequency will depend on wound condition and the amount of exudates.
- Remove and replace Silverlon® Wound Packing Strip whenever it becomes heavily coated with wound exudates or wound debris.

Storage

Store Silverlon® Wound Packing Strips in normal warehouse conditions. Keep dry. Avoid excessive heat or humidity.