



CALCIUM ALGINATE DRESSING WITH ANTIMICROBIAL SILVER


ALGICELL® Ag

INSTRUCTIONS FOR USE (USA)

Latex-Free

 - For single use

 - See Insert for Instructions For Use

 - Store at Room Temperature

STERILE  - Gamma Sterilized

PRODUCT DESCRIPTION

ALGICELL® Ag is a primary wound dressing made of Calcium Alginate containing 1.4% silver. In the presence of wound exudate, the sodium ions from the exudate take the place of the silver ions, releasing the silver ions. As wound exudate is absorbed, the alginate forms a gel, which assists in maintaining a moist environment for optimal wound healing, and allows intact removal. The silver ions released in the presence of wound fluid protect the dressing from bacterial colonization, and provide an effective barrier to bacterial penetration. Antibacterial effectiveness of the dressing was demonstrated for *Staphylococcus aureus* and *Pseudomonas aeruginosa* by the Kirby-Bauer antimicrobial susceptibility test and ASTM E2149-01 (determining antimicrobial activity of immobilized antimicrobial agents).

INDICATIONS

Under the supervision of a healthcare professional, ALGICELL® Ag dressing is an effective barrier to bacterial penetration in moderate to heavily exuding wounds such as:

- Diabetic foot ulcers
- Leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology)
- Pressure ulcers / sores (partial and full thickness)
- Donor sites, and traumatic and surgical wounds

CONTRAINDICATIONS

- ALGICELL® Ag dressing is not indicated for:
- 3rd degree burns
 - Patients with a known sensitivity to alginates or silver
 - Controlling of heavy bleeding

PRECAUTIONS

If the dressing is not easily removed, soak with sterile saline or water until it is removed without difficulty. Excess use of petrolatum-based ointments could impair the performance of this dressing.

DIRECTIONS FOR USE

- Prior to application of ALGICELL® Ag dressing, debride and cleanse the wound area as necessary.
- Use an appropriately sized ALGICELL® Ag dressing, slightly overlapping the wound area by about ½ inch (1 cm). For deeper wounds, loosely pack and ensure that the dressing does not overlap the wound margins.
- Apply directly to the wound bed for heavily exuding wounds. Apply to a saline moistened wound bed for wounds with minimal exudate.
- Use an appropriate secondary dressing (such as hydrocolloid, foam, thin film, or island/composite) to cover the ALGICELL® Ag dressing. See package inserts of secondary cover dressings for complete instructions for use.

DRESSING CHANGE AND REMOVAL

- ALGICELL® Ag dressing provides an antimicrobial effect lasting up to seven days. However, the dressing change frequency will depend on the condition of the patient as well as the level of wound exudate.
- Reapply when the secondary dressing has reached its absorbent capacity or as directed by a wound care professional.
- Moisten with sterile saline if the wound bed appears dry before removal of the dressing.
- Remove the dressing from the wound bed gently.
- Cleanse the wound bed prior to application of new dressing.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed healthcare professional).

Do not use product if the immediate product packaging is damaged.

Store at room temperature: 10 – 25°C (50 – 77°F). Keep dry.



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+603 7713 5611