

DynaFoam™ AG

Silver Foam Dressings

Bordered



INSTRUCTIONS FOR USE

Description

DynaFoam™ AG Silver Foam Dressing mainly includes polyurethane foam, polyvinyl alcohol, silver sulfate and silver chloride. It is a highly absorbent foam dressing with ionic silver as the active component. The dressing provides an optimal moist wound healing environment, combining an effective antibacterial activity in the dressing with exudates management. The dressing has broad spectrum antibacterial effect for Gram positive and Gram negative bacteria. It has been shown to have 4 log bacterial reductions up to 7 days in vitro against the following bacteria: Staphylococcus aureus, Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Klebsiella pneumoniae, and Pseudomonas aeruginosa. DynaFoam™ AG Silver Foam Dressing is available in various sizes and shapes. The dressings are packaged in individual bags.

Indications

DynaFoam™ AG Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds, including leg ulcers, pressure ulcers, diabetic ulcers, first and second-degree burns, donor sites, post-operative wounds and skin abrasions.

Contraindications

1. Do not use DynaFoam™ AG Silver Foam Dressing on patients with known sensitivity to silver.

Product Information:

Antibacterial Agent:	Silver sulfate and silver chloride
Spectrum of Activity:	Broad spectrum antibacterial effect for Gram positive & Gram negative bacteria
Concentration on the Device:	Each dressing contains 0.35~0.40mg/cm ² silver

In Vitro Study Results:

The device is non-irritating, non-cytotoxic and biocompatible in a wound environment. The device is tested for antibacterial activity for up to 168 hours. The device has broad spectrum antibacterial effect for Gram positive and Gram negative bacteria.

Bacterial	Staphylococcus aureus	Streptococcus pyogenes	Enterococcus faecalis
	ATCC 6538	ATCC 19615	ATCC 29212
168 Hour % Reduction	>99.99%	>99.99%	>99.99%

Bacterial	Escherichia coli	Klebsiella pneumoniae	Pseudomonas aeruginosa
	ATCC 8739	ATCC 4352	ATCC 9027
168 Hour % Reduction	>99.99%	>99.99%	>99.99%

Instructions for Use

1. Clean the wound with sterile saline water and dry the surrounding skin gently.
2. Choose the right size of dressing to cover the wound according to wound area.
3. Dressing change frequency will depend on patient condition and the level of exudates. Initially, it may be necessary to change the dressing every 24 hours. When exudates reduce, the frequency may decrease.
4. If the wound appears dry, saturate the dressing with sterile saline water prior to removal.

Warnings

1. This product is for single use. Do not use if pouch is damaged or open.
2. Do not use this product on a dry wound.
3. Frequent or prolonged use of this product may result in permanent discoloration of the skin.
4. The silver is only present as a preservative within the dressing.
5. DynaFoam™ AG Silver Foam Dressing is intended for short-term use and should not be used for more than 28 days over multiple dressing changes.
6. Reduction in colonization or microbial growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed.

Specifications: 4" × 4" (10 cm × 10 cm), Bordered

Sterilization: The products are sterilized by irradiation, single use only.

Shelf life: 3 years from date of manufacture.

