

Manufactured for:
 Dynarex Corporation
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Made in China

DynaGinate™ AG

Silver Calcium Alginate Dressing




INSTRUCTIONS FOR USE

Rx Only **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician



Description

DynaGinate™ AG Silver Calcium Alginate Dressing is made of natural fibers (mainly sodium alginate, calcium alginate and silver particles) derived from seaweed through a series of special processes. It is designed to be fast and highly absorbent. The dressing absorbs exudates and forms a gel-like covering over the wound, maintaining a moist environment for wound healing. The gel-like surface also keeps the dressing from adhering to the wound for painless removal. Also, DynaGinate™ AG Silver Calcium Alginate Dressing restricts bacteria growth, thereby reducing infection. DynaGinate™ AG Silver Calcium Alginate Dressing has been tested in vitro and found to be effective against bacteria such as: Staphylococcus aureus, Enterococcus faecalis, Streptococcus pyogenes, Escherichia coli, Pseudomonas aeruginosa and Klebsiella pneumoniae.

Indications

Moderately to heavily exuding partial to full thickness wounds, including:

- Trauma wounds
- Leg ulcers
- Pressure ulcers
- Graft and donor sites
- Diabetic ulcers
- Post-operative surgical wounds

Contraindications

1. Do not use DynaGinate™ AG Silver Calcium Alginate Dressing on patients with known sensitivity to silver.
2. DynaGinate™ AG Silver Calcium Alginate Dressing is not intended for use on third-degree burns.

Product Information:

Antibacterial Agent:	Silver particles
Active Against Pathogens:	Gram-positive and gram-negative bacteria
Spectrum of Activity:	Broad spectrum antibacterial effect for gram-positive & gram-negative bacteria
Concentration on the Device:	Each dressing contains 50 ug/100 cm ² silver particles

In Vitro Study Results:

The device is non-irritating, non-sensitizing, non-cytotoxic and biocompatible in a wound environment. The device is tested for antibacterial activity for up to 24 hours. The device has broad spectrum antibacterial effect for gram positive and gram negative bacteria.

Bacterial	Staphylococcus aureus	Streptococcus pyogenes	Enterococcus Eaealis
	ATCC 6538	ATCC 19615	ATCC 29212
24 Hour % Reduction	>99.99%	>99.99%	>99.99%

Bacterial	Escherichia coli	Klebsiella pneumoniae	Pseudomonas aeruginosa
	ATCC 8739	ATCC 4352	ATCC 9027
24 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 dressing to cover the wound area.
3. Cover and secure the DynaGinate™ AG Silver Calcium Alginate Dressing with a secondary dressing.
4. 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 the exudates reduce, the frequency may decrease.
5. Gently remove the secondary dressing. 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. For effective antibacterial effect, the dressing should be changed daily.
4. Frequent or prolonged use of this product may result in permanent discoloration of skin.

Adverse Reactions

DynaGinate™ AG Silver Calcium Alginate Dressing has been subjected to independent standards for in vitro biocompatibility tests, including cytotoxicity, sensitization, skin irritation and systemic toxicity. All tests were performed in accordance with the ISO 10993 Standard Series for Biological Evaluation of Medical Devices. The results of the studies indicated that DynaGinate™ AG Silver Calcium Alginate Dressing is safe for its intended use.

Specifications

Reorder No.	Size
3030	5 cm × 5 cm
3031	10 cm × 12.5 cm
3032	10 cm × 20 cm
3033	30 cm

Shelf life:

3 years from date of manufacture.

R220802



SYMBOL GLOSSARY
 For an explanation of symbols used in Dynarex packaging, visit dynarex.com/symbols.php