



**ZeniFiber Ag**

Calcium Alginate with Silver

STERILE

Single Patient Use Only, Disposable

Part #'s: 60022-AG, 60045-AG,  
600660-AG, 60012-AG

**Description**

Mainly sodium alginate, calcium alginate and silver particles

**ZeniFiber Ag** Calcium Alginate with Silver is made of natural fibers derived from seaweed through a series of special process. It is designed to be highly, fast absorbent. The dressing absorbs exudates and forms a gellike covering over the wound, maintains a moist environment for wound healing. The gel-like surface also keeps the dressing from adhering to the wound so it is painless removal. Also, **ZeniFiber Ag** Calcium Alginate with Silver can restrain the bacteria growing, and reduce infection. **ZeniFiber Ag** Calcium Alginate with Silver has been tested in vitro and found to be effective against bacteria such as: Staphylococcus aureus, Enterococcus faecalis, Streptococcus pyogenes, Escherichia coli, Pseudomonas aeruginosa, Klebsiella pneumoniae.

**Indications**

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

- 1.Trauma wounds
- 2.Pressure ulcers
- 3.Diabetic ulcers
- 4.Leg ulcers
- 5.Graft and donor sites
- 6.Post-operative surgical wounds

**Contraindications**

- 1.Do not use **ZeniFiber Ag** Calcium Alginate with Silver on patients with known sensitivity to silver.
- 2.**ZeniFiber Ag** Calcium Alginate with Silver 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:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 50ug/100cm <sup>2</sup> silver particles

**In Vitro Study Results:**

The device is non-irritating, non-sensitising, non-cytotoxic and biocompatible in a wound environment.

The device is tested for antibacterial activity till day-1. The device has board spectrum antibacterial effect for Gram positive and Gram negative bacteria.

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

Bacterial	Escherichia coli ATCC 8739	Klesiella pneumonlae ATCC 4352	Pseudomonas aeruginosa 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 of dressing to cover the wound according to wound area.
- 3.Cover and secure the **ZeniFiber Ag** Calcium Alginate with Silver 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 be slowdown.
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 single use. Do not use if pouch is damaged or open.
- 2.Do not suggest using this product on dry wound.
- 3.To have 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**

**ZeniFiber Ag** Calcium Alginate with Silver has been subjected to independent standard 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 **ZeniFiber Ag** Calcium Alginate with Silver is safe for its intended use.

**Specifications**

Code	Size
60022-AG	2"x2"
60045-AG	4"x5"
600660-AG	6"x6"
60012-AG	12" Rope

**Storage:** Please store the product in sealed, cool and dry place avoiding light.

**Shelf life:** 3 years from date of manufacture

**Manufactured for:**

ZeniMedical  
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