

– Instructions for Use –

Product Description: Silver Calcium Alginate Dressings and Ropes are composed of calcium alginate, sodium alginate, and silver particles. Vitale[®] STRONG[™] Calcium Alginate Dressings are made of absorbent fibers produced by a special process. The dressing absorbs exudate and forms a gel-like covering over the wound. This maintains a moist wound healing environment and keeps the dressing from adhering to the wound. Vitale STRONG Silver Calcium Alginate Dressings have been tested in vitro and found to be effective against bacteria such as: Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli, Pseudomonas aeruginosa, Klebsiella pneumoniae, and Staphylococcus epidermidis.

Indications:

Rx: May be used as a primary wound dressing for moderate to heavily exuding partial to full thickness wounds, including: postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, and graft and donor sites.

Contraindications: Silver Calcium Alginate Dressing with STRONG Fiber Blend should not be used on patients with a known sensitivity to silver. Not intended for use on third degree burns.

Product Information:

Preservative Agent:	Silver particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	In vitro test results show antibacterial preservative effect for 24 hours against Gram positive and Gram negative bacteria such as Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Streptococcus pyogenes.
Concentration on the device:	Each 4" x 4" (100 mm x 100 mm) dressing contains 16.0 mg (1.4% w/w) silver particles

Warnings:

- This product is single use. Do not use if pouch is damaged or open.
- Not suggested for use on dry wounds.
- The dressing should be changed daily to avoid colonization of the dressing.
- Frequent or prolonged use of this product may result in permanent discoloration of skin.

In Vitro Study Results: The device is non-irritating, non-sensitizing, non-cytotoxic when tested in vitro. The device has shown antibacterial preservative effect for 24 hours against both Gram positive and Gram negative bacteria.

Gram negative bacteria

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

Gram positive bacteria

Bacterial	Staphylococcus aureus	Staphylococcus epidermidis	Streptococcus pyogenes
	ATCC 6538	ATCC 12228	ATCC 19615
24 Hour Reduction (%)	>99.99%	>99.99%	>99.99%

Instructions for Use:

- Clean the wound with sterile physiological saline using existing clinical protocol. Dry the surrounding skin gently.
- Choose the right size dressing to cover the wound area.
- Cover and secure the Vitale Silver Calcium Alginate Dressing with a secondary dressing.
- 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.
- Gently remove the secondary dressing. If the wound appears dry, saturate the dressing with sterile saline prior to removal.

Adverse Reactions:

Silver Calcium Alginate Dressing with STRONG Fiber Blend has been tested for in-vitro biocompatibility, 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 these studies indicate that Silver Calcium Alginate Dressing is safe for its intended use.

Sterilization: Vitale Calcium Alginate Dressings with Antibacterial Silver are sterilized by exposure to Gamma Radiation, and must not be re-sterilized.

– Product Line –

Catalog Number:	Description:	Size:	Dressings/Box:
20550	Vitale STRONG Silver Calcium Alginate Ropes	12" long	5
20552	Vitale STRONG Silver Calcium Alginate Dressings	2"x 2" (5cm x 5cm)	10
20554	Vitale STRONG Silver Calcium Alginate Dressings	4"x 4" (10cm x 10cm)	10
20555	Vitale STRONG Silver Calcium Alginate Dressings	4"x 5" (10cm x 12cm)	10
20556	Vitale STRONG Silver Calcium Alginate Dressings	6" x 6" (15cm x 15cm)	5
20558	Vitale STRONG Silver Calcium Alginate Dressings	4"x 8" (10cm x 20cm)	5



CellEra, LLC Cincinnati, OH
www.celleralc.com



Do not use if package is damaged



Single-Use



Keep Dry



Storage Temperature



Sterilized using Gamma Radiation



Not made with natural rubber latex

Rx Only