

## PIVOT Silver Alginate Dressing (Rx only)

## PIVOT Silver Alginate Rope Dressing (Rx only)

### Device Description

PIVOT Silver Alginate Dressing is a sterile non-woven pad, composed of a high G (Guluronic acid) calcium alginate fibers and metallic silver particles. It is highly absorbent and absorbs up to 20 times its weight. In contact with wound exudate, the calcium ion in the alginate fibers exchanges with the sodium ion in the exudate, which causes the alginate to swell and become a gelatinous covering over the wound, which assists in maintaining a moist environment for optimal wound healing. The gel-like surface also keeps the dressing from adhering to the wound, which makes dressing removal painless.

Metallic silver particles (50ug/100cm<sup>2</sup>) are added to each dressing to inhibit the growth of bacteria within the dressing material. AATCC 100-2004 was used to evaluate the antibacterial activity of the product. Although this method only specifies the use of one gram positive and one gram negative bacteria, the manufacturer evaluated a total of six (3 Gram positive and 3 Gram negative) bacteria (Staphylococcus aureus, Enterococcus faecalis, Streptococcus pyogenes, Escherichia coli, Pseudomonas aeruginosa, and Klebsiella pneumonia) in vitro to identify the broad spectrum effectiveness of the Silver Alginate Dressing. The bacteria reduction effect in the dressing reduces odor.

PIVOT Silver Alginate Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. Its performance meets the requirements of its predefined acceptance criteria and intended uses. PIVOT Silver Alginate Dressings are sterilized by irradiation using conditions validated following ISO 11137-2:2006. PIVOT Silver Alginate Dressings are available in various sizes, including a rope dressing for wound/ulcer cavities.

### FDA Listing

D188509; 510(k) K120181; Product Code: FRO. Listed under brand name Luofucon.

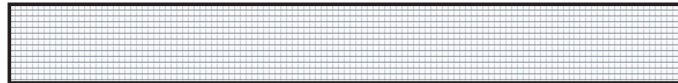
### Structure

Calcium alginate fibers and metallic silver particles.

Silver Alginate Dressing



Silver Alginate Rope Dressing



## Composition

ITEM DESCRIPTION	ITEM NUMBER	SIZE: INCH (cm)	WEIGHT	COMPOSITION	% WEIGHT
Silver Alginate Dressing	SA2X2	2"x2" (5cmx5cm)	0.36	Calcium Alginate Sodium Alginate Silver Particle	97 2.997 0.003
Silver Alginate Dressing	SA4X4	4"x4" (10cmx10cm)	1.45	Calcium Alginate Sodium Alginate Silver Particle	97 2.997 0.003
Silver Alginate Dressing	SA4X5	4"x5" (10cmx12.5cm)	1.81	Calcium Alginate Sodium Alginate Silver Particle	97 2.997 0.003
Silver Alginate Dressing	SA6X6	6"x6" (15cmx15cm)	3.25	Calcium Alginate Sodium Alginate Silver Particle	97 2.997 0.003
Silver Alginate Rope Dressing	SA1X12	1"x12" (2.5cmx30cm)	1.08	Calcium Alginate Sodium Alginate Silver Particle	97 2.997 0.003

## Indications

Indicated for the management of moderate to heavily exuding partial to full thickness wounds, including post-operative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites.

## Contraindications

This product is for single use. Do not use on third-degree burns. Do not use on dry wounds. Do not use on patients with known sensitivity to silver.

## Change Frequency

Usual dressing change is once daily. A dressing should not be used on the wound for more than seven (7) days.

## Product Information

- Antibacterial Agent: Metallic Silver Particles
- Antibacterial Activity of the silver particles: Gram positive and Gram negative bacteria
- Spectrum of Activity: Broad spectrum antibacterial effect for Gram positive and Gram negative bacteria
- Concentration on the device: Each dressing contains 50ug/100cm metallic silver particles

## Brand Names

PIVOT Silver Alginate Dressing

PIVOT Silver Alginate Rope Dressing

## Manufactured for:

Links Medical Products, Inc.

15979 North 76th Street, Unit D, Scottsdale, AZ 85260 USA

**FDA Registered Establishment Number:** 2031987

[www.linksmedwoundcare.com](http://www.linksmedwoundcare.com)

## Manufactured by:

Huizhou Foryou Medical Devices Co., Ltd.

**FDA Registered Establishment Number:** 3007735241

[www.foryoumedical.com](http://www.foryoumedical.com)

**Reference**

Luofucon Silver Alginate Dressing Technical Data Sheet dated 05/25/2018. MSDS Luofucon Silver Alginate Dressing 2011930. Huizhou Foryou Medical Devices Co., Ltd.