

PIVOT Calcium Alginate Dressing

Device Description

PIVOT Calcium Alginate Dressing is a sterile non-woven pad, composed of a high G (Guluronic acid) calcium alginate fibers derived from seaweed. 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.

PIVOT Calcium 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. All dressings are sterilized by irradiation validated following ISO 11137-2:2006. PIVOT Calcium Alginate Dressings are available in various sizes.

FDA Listing

D090438; Classification: I; Product Code: NAC

Structure

Calcium alginate fibers.

Calcium Alginate Dressing



Composition

ITEM DESCRIPTION	ITEM NUMBER	SIZE: INCH (cm)	WEIGHT	COMPOSITION	% WEIGHT
Calcium Alginate Dressing	CA2X2	2"x2" (5cmx5cm)	0.36	Calcium Alginate Sodium Alginate	97 3
Calcium Alginate Dressing	CA4X4	4"x4" (10cmx10cm)	1.45	Calcium Alginate Sodium Alginate	97 3
Calcium Alginate Dressing	CA4X5	4"x5" (10cmx12.5cm)	1.81	Calcium Alginate Sodium Alginate	97 3
Calcium Alginate Dressing	CA6X6	6"x6" (15cmx15cm)	3.25	Calcium Alginate Sodium Alginate	97 3

Indications

Absorbent dressing for the management of moderately to highly exudating full thickness wounds, including trauma wounds, pressure ulcers, diabetic ulcers, leg ulcers, graft and donor sites, and post-operative wounds.

Contraindications

This product is for single use. Do not use on dry wounds. Do not use on third-degree burns.

Change Frequency

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

Brand Name

PIVOT Calcium Alginate 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

Manufactured by:

Huizhou Foryou Medical Devices Co., Ltd.

FDA Registered Establishment Number: 3007735241

www.foryoumedical.com

Reference Source

Luofucon Alginate Dressing Technical Data Sheet dated 05/25/2018, Huizhou Foryou Medical Devices Co., Ltd. MSDS 2020421 Luofucon Alginate Dressing dated April 21, 2020.