

PIVOT Silicone Foam Border Dressing

Device Description

PIVOT Silicone Foam Border Dressing is an island dressing constructed of three layers to facilitate dynamic fluid management, which provides a moist environment for optimal wound healing and reduces the risk of skin maceration.

The first (bottom) layer of the dressing is the perforated gentle silicone wound contact and self-adherent border. This self-adherent silicone layer 1) provides secure but gentle adhesion around the border of the dressing while facilitating the flow of exudate to the absorbent polyurethane foam pad, and 2) permits repositioning without loss of adhesion and removal without pain.

The second (middle layer) of the dressing is a super absorbent polyurethane foam pad, which absorbs and locks away exudates to prevent skin maceration and wound breakdown.

The third (top) layer of the dressing is a polyethylene moisture vapor transmission (MVTR) protective film that permits vapor transmission from the absorbent pad and protects the dressing from external contamination.

PIVOT Silicone Foam Border Dressing is sterilized by the ethylene oxide method.

PIVOT Silicone Foam Border Dressing meets the biocompatibility requirements per ISO I0883-5, ISO I0883-10, and ISO I0993-11. The dressing's performance meets the requirements of its predefined acceptance criteria and intended uses. The product is safe and effective for its intended use. PIVOT Silicone Foam Border Dressings are available in various sizes.

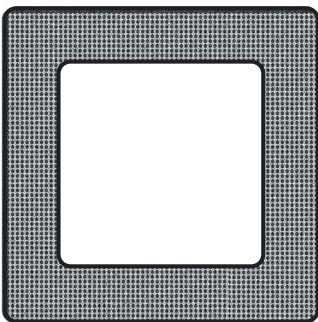
FDA Listing

D090427; Classification: I; Product Code: NAD

Structure

Silicone wound contact and self-adherent border, a polyurethane foam pad, and a polyethylene protective film.

Silicone Foam Border Dressing



Composition

ITEM DESCRIPTION	ITEM NUMBER	SIZE: INCH (cm)	PAD SIZE	WEIGHT	COMPOSITION	% WEIGHT
Silicone Foam Border Dressing	SF2X2B	2"x2" (5cmx5cm)	1"x1" (2.5cmx2.5cm)	1.35g	Silicone contact layer	46
					Polyurethane foam pad layer	48
					Polyethylene protective film layer	6
Silicone Foam Border Dressing	SF3X3B	3"x3" (7.5cmx7.5cm)	1.5"x1.5" (3.8cmx3.8cm)	3.26g	Silicone contact layer	43
					Polyurethane foam pad layer	52
					Polyethylene protective film layer	5
Silicone Foam Border Dressing	SF4X4B	4"x4" (10cmx10cm)	2.5"x2.5" (6.2cmx6.2cm)	7g	Silicone contact layer	43
					Polyurethane foam pad layer	45
					Polyethylene protective film layer	12
Silicone Foam Border Dressing	SF6X6B	6"x6" (15cm x15cm)	4.2"x4.2" (10.5cmx10.5cm)	16g	Silicone contact layer	43
					Polyurethane foam pad layer	45
					Polyethylene protective film layer	12
Silicone Foam Border Dressing	SF8X4B	8"x4" (20cm x10cm)	6"x2" (15cmx5cm)	11.92g	Silicone contact layer	42
					Polyurethane foam pad layer	53
					Polyethylene protective film layer	5

Indications

Absorbent dressing for the management of moderately to highly exudating full thickness wounds, including pressure ulcers, leg and foot ulcers, trauma wounds, surgical wounds, donor sites, skin tears, and burns (1st and 2nd degree).

Contraindications

This product is for single use. Do not use on dry wounds. Do not use on third-degree burns. Do not use with oxidizing agents such as hypochlorite solutions or hydrogen peroxide.

Change Frequency

Usual dressing change is three (3) times per week, or as needed, depending on level of exudate.

Brand Name

PIVOT Silicone Foam Border 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

Luofucon Silicone Border Dressing Technical Data Sheet dated 01/26/2019.MSDS GP2019003.
Huizhou Foryou Medical Devices Co., Ltd.

PIVOT Silicone Foam Border Sacral Dressing

Device Description

PIVOT Silicone Foam Border Sacral Dressing is designed and constructed as a heart-shaped island dressing fit for the sacrum. The dressing is constructed of three layers to facilitate dynamic fluid management which provides a moist wound environment optimal for wound healing and reduces the risk of skin maceration.

The first (bottom) layer of the dressing is the perforated gentle silicone wound contact and self-adherent border. This self-adherent silicone layer 1) provides secure but gentle adhesion around the border of the dressing while facilitating the flow of exudate to the absorbent polyurethane foam pad, and 2) permits repositioning without loss of adhesion and removal without pain.

The second (middle layer) of the dressing is a super absorbent polyurethane foam pad, which absorbs and locks away exudates to prevent skin maceration and wound breakdown.

The third (top) layer of the dressing is a polyethylene moisture vapor transmission (MVTR) protective film that permits vapor transmission from the absorbent pad and protects the dressing from external contamination.

PIVOT Silicone Foam Border Sacral Dressing is sterilized by the ethylene oxide method.

PIVOT Silicone Foam Border Sacral Dressing meets the biocompatibility requirements per ISO I0883-5, ISO I0883-10, and ISO I0993-11. The dressing's performance meets the requirements of its predefined acceptance criteria and intended uses. The product is safe and effective for its intended use.

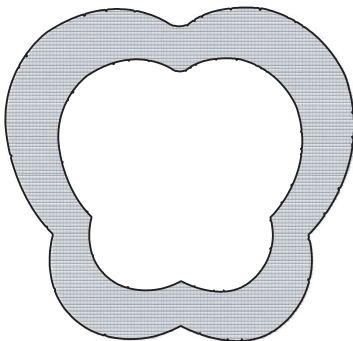
FDA Listing

D090427; Classification: I; Product Code: NAD

Structure

Silicone wound contact and self-adherent border, a polyurethane foam pad, and a polyethylene protective film.

Silicone Foam Border Sacral Dressing



Composition

ITEM DESCRIPTION	ITEM NUMBER	SIZE: INCH (cm)	PAD SIZE	WEIGHT	COMPOSITION	% WEIGHT
Silicone Foam Border Sacral Dressing	SF7X7B	7"x6.8" (17.5cmx17cm)	5"x4.8" (12.5cmx12cm)	15g	Silicone contact layer	43
					Polyurethane foam pad layer	47
					Polyethylene protective film layer	10
Silicone Foam Border Sacral Dressing	SF8X8B	8.4"x8.4" (21cmx21cm)	6.6"x6.2" (16.5cmx15.5cm)	22.57g	Silicone contact layer	40
					Polyurethane foam pad layer	56
					Polyethylene protective film layer	4
Silicone Foam Border Sacral Dressing	SF9X9B	9.2"x9.2" (23cmx23cm)	6.8"x6.6" (17cmx16.5cm)	27.10g	Silicone contact layer	40
					Polyurethane foam pad layer	55
					Polyethylene protective film layer	5

Indications

Absorbent dressing for the management of moderately to highly exudating full thickness wounds, including pressure ulcers, leg and foot ulcers, trauma wounds, surgical wounds, donor sites, skin tears, and burns (1st and 2nd degree).

Contraindications

This product is for single use. Do not use on dry wounds. Do not use on third-degree burns. Do not use with oxidizing agents such as hypochlorite solutions or hydrogen peroxide.

Change Frequency

Usual dressing change is three (3) times per week, or as needed, depending on level of exudate.

Brand Name

PIVOT Silicone Foam Border Sacral Dressing

Manufactured for:

Links Medical Products, Inc.
9247 Research Drive
Irvine, CA 92618

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 Silicone Sacrum Dressing (Border) Technical Data Sheet dated 01/26/2019, MSDS GP2019003.
Huizhou Foryou Medical Devices Co., Ltd.