

## PIVOT CollagenDressing

### Device Description

PIVOT Collagen Wound Dressing is comprised of 100% native non-denatured bovine Type-1 collagen, provides as a sterile, single-use, white or off-white, pliable, absorbent, and biodegradable wound dressing.

When the wound dressing absorbs wound exudates or sterile water, the dressing transforms into a soft, conformable gel sheet, maintains a moist wound environment, to protect the wound and support natural healing.

PIVOT Collagen Wound Dressing can be used as a primary wound dressing in direct contact with the wound or be used in combination with other suitable secondary dressings. The dressing can be cut to the exact size of the wound and can be used in multiple layers.

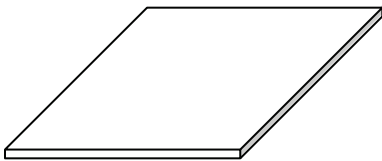
### FDA Listing

K213598; Unclassified

### Structure

PIVOT Collagen Wound Dressing is a sheet structure with single layer.

Collagen Dressing



### Composition

ITEM DESCRIPTION	ITEM NUMBER	SIZE: INCH (cm)	COMPOSITION	% WEIGHT
Collagen Dressing	CO2X2	2"x2" (5cmx5cm)	Collagen	100
Collagen Dressing	CO4X4	4"x4" (10cmx10cm)	Collagen	100

## **Indications**

PIVOT Collagen Wound Dressing is intended for the management of wounds including:

Full thickness and partial thickness wounds

Pressure ulcers

Venous ulcers

Ulcers caused by mixed vascular etiologies

Diabetic ulcers

Partial thickness burns

Donor sites and other bleeding surface wounds

Abrasions

Traumatic wounds healing by secondary intention

Dehiscenced surgical incisions

## **Contraindications**

PIVOT Collagen Wound Dressing should not be used on patients sensitive to bovine collagen, third-degree burns or wounds with active infection.

## **Change Frequency**

Dressing can be changed daily (per HCPCS), but should be determined by physician based on condition of wound.

## **Brand Name**

PIVOT Collagen 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 Source**

Luofucon Collagen Wound Dressing Technical Data Sheet dated 11/23/23, Huizhou Foryou Medical Devices Co., Ltd.

MSDS Luofucon Collagen Wound Dressing issue date, 9/9/22.