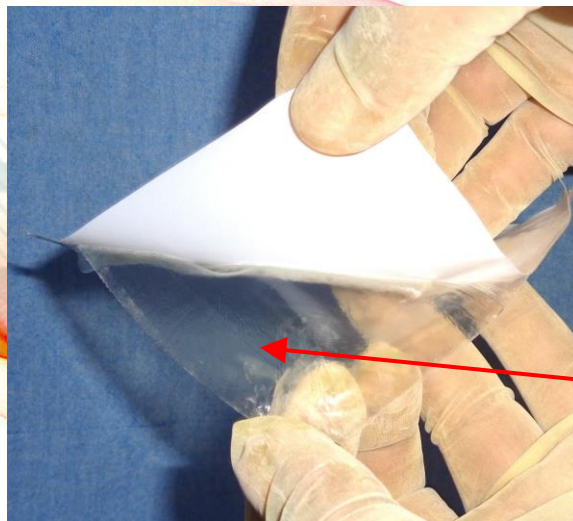


Helicoll®

COLLAGEN BASED STERILE
BIO-ENGINEERED SKIN SUBSTITUTE



Helicoll Sheet

Product Profile Overview

Manufactured & Marketed by:

Encoll Corp.

4576 Enterprise Street, Fremont, CA – 94538

Website: www.Helicoll.com

Contact Information:

S. Gunasekaran, PhD (for Technology)
guna@encoll.com, +1 (510) 396-8581

Murugan G. (for Business & Sales)
murugan@encoll.com, +1 (510) 709-8663

HELICOLL PRODUCT TECHNICAL & CLINICAL FEATURES

PRODUCT OVERVIEW

Product Name	Helicoll, Biological Skin Substitute
Model/Catalog	HC2X2, HC2X4, HC4X4, HC8X8
Manufacturer	EnColl Corporation
Website links	www.helicoll.com
Product video	https://helicoll.com/images/Helicoll_AV.mp4

PRODUCT DETAILS

Item Name, Size &	Cat/Item #	HCPCS Code	NDC/UDI code for Billing	Pkg Type	No. of sheets
Helicoll 2in x 2in (5cm x 5cm=25 sq cm)		Q4164	74745-0221-01	Single Sheet	1
Helicoll 2in x 2in (5cm x 5cm=25 sq cm)	HC2x2	Q4164	74745-0225-05	Box of 5 sheets	5
Helicoll 2in x 4in (5cm x 10cm=50 sq cm)		Q4164	74745-0241-01	Single Sheet	1
Helicoll 2in x 4in (5cm x 10cm=50 sq cm)	HC2x4	Q4164	74745-0245-05	Box of 5 sheets	5
Helicoll 4in x 4in (10cm x 10cm=100 sq cm)		Q4164	74745-0441-01	Single Sheet	1
Helicoll 4in x 4in (10cm x 10cm=100 sq cm)	HC4x4	Q4164	74745-0445-05	Box of 5 sheets	5
Helicoll 8in x 8in (20cm x 20cm=400 sq cm)		Q4164	74745-0881-01	Single Sheet	1
Helicoll 8in x 8in (20cm x 20cm=400 sq cm)	HC8x8	Q4164	74745-0885-05	Box of 5 sheets	5

PRODUCT INFORMATION

Product Description



Helicoll is a bioengineered high purity Type-I collagen (>97% pure) forming an acellular skin substitute construct that is highly bioactive, cell conductive, and supportive towards enhancing tissue generation for wound management. Helicoll is an acellular dermal replacement product and is within the definition of a bioengineered skin substitute. It provides a framework that promotes the regeneration of blood vessels and supports biologic migration due to the resorbable properties of Helicoll. Treatment typically involves 1 to 4 applications.

What products are comparable to Helicoll?

Gammagraft	Oasis wound matrix	Woundex, bioskin
Apligraf	Dermagraft	Primatrix
Theraskin	Amnioexcel biodexcel	Puraply & Puraply am
Nushield	Biovance	Amnioband, guardian
Grafix stravax prime pl	Epifix	Palingen or palingen xplus
Epicord	Affinity	Phoenix Wound Matrix

How is Helicoll better than the alternative?

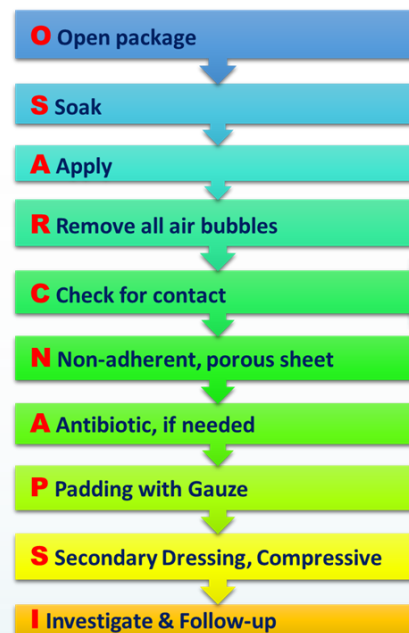
Advantages of Helicoll over Alternative Products:

- **High purity type-I Collagen:** Helicoll is a patented reconstituted bioactive collagen sheet, free of immunogenic proteins, lipids, and elastin. The native structure of the collagen is not altered or cross-linked which maintains its high bioactivity.
- **Faster Healing:** Collagen phosphorylation attracts cells, regenerates tissue, and stimulates blood capillaries/granulation within 4 to 5 days through cell signal transduction.
- **Innovative Technology:** Helicoll's phosphorylated type-I collagen is unique with high biocompatibility and bioactivity compared to other collagen products. Can be used with negative pressure wound therapy (NPWT) with slit openings for exudate release. Better than intact tissue-based membranes like an amnion, intestinal wall,

tissue, and stimulates blood capillaries/granulation within 4 to 5 days through cell signal transduction.

- **Innovative Technology:** Helicoll's phosphorylated Type-I collagen is unique with high biocompatibility and bioactivity compared to other collagen products. Can be used with negative pressure wound therapy (NPWT) with slit openings for exudate release. Better than intact tissue-based membranes like an amnion, intestinal wall, urinary bladder, etc. which contain >15% elastin that is recently
- **Easy Application:** No washing is needed prior to use. The overall clinical usage of Helicoll is simple and easy as it can be cut, sutured, or stapled.
- **Pain Control:** Effectively reduces pain, as proven by clinical studies.
- **Structural advantage:** Unlike random fibrillar configuration in other collagen products, Helicoll collagen fibrils are organized in a parallel pattern similar to that of native tissue fibrillar structure. The porosity is approx. 20 μ to attract more cells/regenerative factors.
- **Various Sizes:** Choose from standard or customized dimensions.
- **Cost-Effective:** Accelerated wound healing and tissue remodeling with minimal applications reduce the treatment cost by over 40%.
- **Long Shelf Life:** Remains clinically usable for 3 years when stored in room temperature conditions.

Helicoll Usage Procedure



Product Brochure



Product IFU



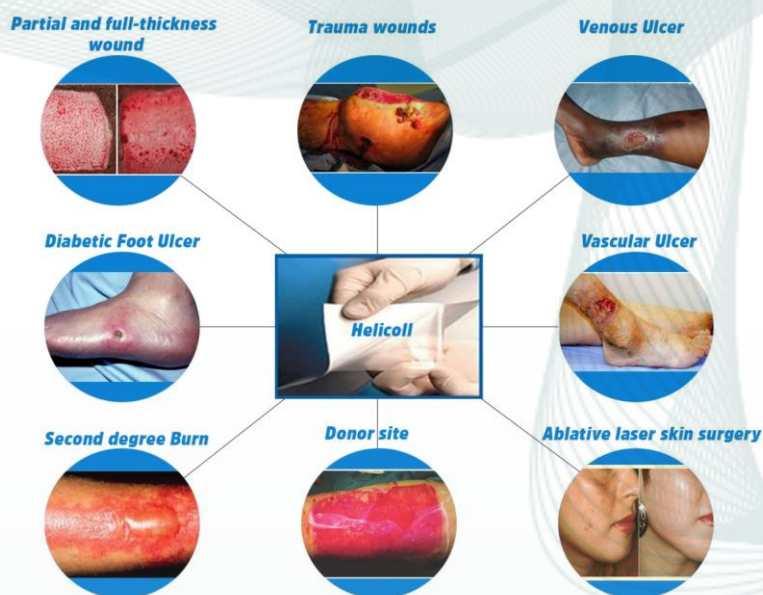
Helicoll Product Brochure & IFU:
(Scan the QR code to view in Mobile)

REGULATORY INFO

Class
FDA Product Code
FDA Registration Number
510(k) Number
Helicoll FDA Cleared Indications

Unclassified
KGN - Dressing, Wound, Collagen
3004117927
K040314

- Partial and full-thickness wounds
- Pressure, Venous, Chronic vascular and Diabetic ulcers
- Trauma wounds: Abrasions, Lacerations, Skin tears, Second-degree burns Surgical wounds: Donor sites/grfts, Post Mohs' surgery, Post laser surgery, Podiatric, Wound dehiscence
- Excessive exudate underneath Helicoll can be drained through slit openings that also is applicable when using Negative Pressure Wound Therapy (NPWT)
- The product also can be secured in place using sutures and/or staples



FDA Contraindications

Helicoll is derived from a bovine or ovine source and should not be used in patients with known sensitivity to such material. This device is not indicated for third-degree burns.

FDA Clearance

(Scan the QR code to view in Mobile)

510k Market Clearance



FDA Manufacturing License



REIMBURSEMENT INFO

CPT

15271, +15272, 15273, +15274, 15275, +15276, 15277, +15278

HCPCS

Q4164

Reimbursement Guide

(Scan the QR code to view in Mobile)

Medicare Billing Guide



Sample Medical Necessity



SAFETY INFO

Safety Documents

(Scan the QR code to view in Mobile)

Material Safety Data Sheet for Helicoll Finished Product



CLINICAL INFO

Reduces patient mortality?

Yes

Our proprietary, pure Type I collagen reduces immunogenicity, promotes cell migration with increased neovascularity due to added phosphorylation of Type-I collagen.

How does Helicoll improve patient outcomes?

Helicoll has unique clinical evidence for the formation of granulation and neo-vascularization within 4 to 5 days upon application. This results in faster wound healing and tissue regeneration compared to other alternate products.

Helicoll Clinical Studies

(Scan the QR code to view in Mobile)

Stanford Study



Shriners Burn Study



Exposed Bone & Tendons



Surgical Mucosal Defects



ADDITIONAL INFO

Does Helicoll require user certification, staff training or in-service?

Yes

We perform in-service training and web conferencing whichever is your preference.

Helicoll, an Ideal Tissue Regeneration Scaffold



Additional Files

(Scan the QR code to view in Mobile)

Scientific Review Article on Etiology of Diabetic Ulcers



Helicoll[®]

COLLAGEN BASED STERILE BIO-ENGINEERED SKIN SUBSTITUTE

Manufactured & Marketed by:



Address: 4576 Enterprise St. Fremont, CA 94538 USA
Tel: (510) 659-1466, Email: info@helicoll.com