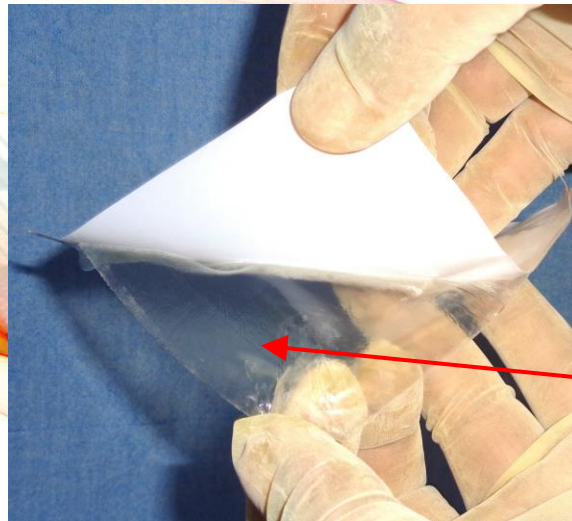


Helicoll[®]

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	HC0.5dia, HC1.0dia, HC0.8X1.6, HC1.2X1.6, HC1.6X1.6, HC2X2, HC2X4
Manufacturer	EnColl Corporation
Website links	www.Helicoll.com

PRODUCT DETAILS

Item Name, Size &	Cat/Item #	HCPCS Code	NDC/UDI code for Billing	Pkg Type	No. of sheets
Helicoll 0.5 in dia disc/1.27 cm dia disc (1 sq cm)		Q4164	74745-0051-01	Single Sheet	1
Helicoll 0.5 in dia disc/1.27 cm dia disc (1 sq cm)	HC0.5dia	Q4164	74745-0052-02	2 sheets per box	2
Helicoll 1.0 in dia disc/2.54 cm dia disc (5 sq cm)		Q4164	74745-0101-01	Single Sheet	1
Helicoll 1.0 in dia disc/2.54 cm dia disc (5 sq cm)	HC1.0dia	Q4164	74745-0102-02	2 sheets per box	2
Helicoll 0.8 in x 1.6 in/2 cm x 4 cm (8 sq cm)		Q4164	74745-0081-01	Single Sheet	1
Helicoll 0.8 in x 1.6 in/2 cm x 4 cm (8 sq cm)	HC0.8x1.6	Q4164	74745-0082-02	2 sheets per box	2
Helicoll 1.2 in x 1.6 in/3 cm x 4 cm (12 sq cm)		Q4164	74745-0121-01	Single Sheet	1
Helicoll 1.2 in x 1.6 in/3 cm x 4 cm (12 sq cm)	HC1.2x1.6	Q4164	74745-0122-02	2 sheets per box	2
Helicoll 1.6 in x 1.6 in/4 cm x 4 cm (16 sq cm)		Q4164	74745-0161-01	Single Sheet	1
Helicoll 1.6 in x 1.6 in/4 cm x 4 cm (16 sq cm)	HC1.6x1.6	Q4164	74745-0162-02	2 sheets per box	2
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	5 sheets per box	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	5 sheets per box	5

CONTACT INFO

Representative Company	Murugan – VP Sales & Marketing
Phone Number	EnColl Corporation
Email Address	(510) 709-8663
	murugan@encoll.com

PRODUCT INFO

Product Description



Helicoll is a bioengineered high purity Type-I collagen (>97% pure) forming an acellular skin substitute construct that is highly bioactive, cell conducive, 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 cell migration due to the resorbable properties of Helicoll. Treatment course typically involves 1 to 4 applications.

How is Helicoll better than the alternative?

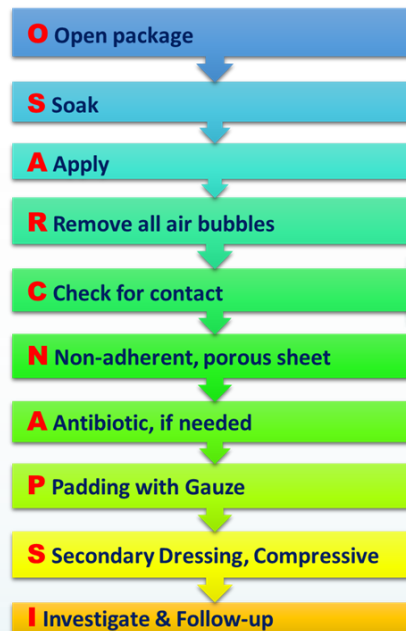
Advantages of Helicoll over Alternative Products:

- **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, 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



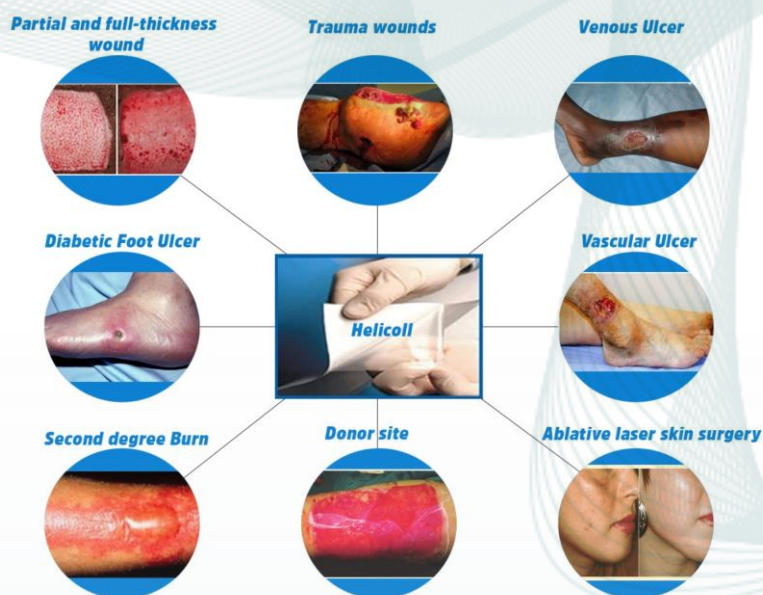
Helicoll Product Brochure & IFU:
(Scan the QR code to view in Mobile)

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

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510k Market Clearance



FDA Manufacturing License



REIMBURSEMENT INFO

CPT

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

HCPCS

Q4164

Reimbursement Guide

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Medicare Billing Guide



Sample Medical Necessity



Payment Allowance Limits for Medicare Part B Drugs Effective October 1, 2024 through December 31, 2024

Note 1: Payment allowance limits subject to the ASP methodology are based on 2Q24 ASP data.

Note 2: The absence or presence of a HCPCS code and the payment allowance limits in this table does not indicate whether Medicare covers a drug. These determinations shall be made by the local Medicare contractor processing the claim.

HCPCS Code	Short Description	HCPCS Code Dosage	Payment Limit	Co-insurance Percentage
Q4303	Complete aa, per sq cm	1 SQ CM	3460.882	20.000
Q4280	Xcell amnio matrix per sq cm	1 SQ CM	3180.000	20.000
Q4204	Xwrap 1 sq cm	1 SQ CM	2989.200	20.000
Q4299	Amnicore pro+, per sq cm	1 SQ CM	2491.000	20.000
Q4239	Amnio-maxx or lite per sq cm	1 SQ CM	2464.699	20.000
Q4279	Vendaje ac, per sq cm	1 SQ CM	2385.000	20.000
Q4301	Activate matrix, per sq cm	1 SQ CM	2385.000	20.000
Q4294	Amnio quad-core, per sq cm	1 SQ CM	2279.000	20.000
Q4296	Rebound matrix, per sq cm	1 SQ CM	2279.000	20.000
Q4297	Emerge matrix, per sq cm	1 SQ CM	2279.000	20.000
Q4265	Neostim tl per sq cm	1 SQ CM	2114.700	20.000
Q4300	Acesso tl, per sq cm	1 SQ CM	2114.700	20.000
Q4193	Coll-e-derm 1 sq cm	1 SQ CM	2067.000	20.000
Q4295	Amnio tri-core, per sq cm	1 SQ CM	2067.000	20.000
Q4221	Amniowrap2 per sq cm	1 SQ CM	2014.000	20.000
Q4302	Complete aca, per sq cm	1 SQ CM	2008.700	20.000
Q4290	Membrane wrap hydr per sq cm	1 SQ CM	1961.000	20.000
Q4161	Bio-connekt per square cm	1 SQ CM	1855.896	20.000
Q4332	Axolotl dualgraft, per sq cm	1 SQ CM	1722.500	20.000
Q4164	Helicoll, per square cm	1 SQ CM	1635.069	20.000
Q4271	Complete ft per sq cm	1 SQ CM	1591.400	20.000
Q4293	Acesso dl, per sq cm	1 SQ CM	1584.700	20.000
Q4266	Neostim per sq cm	1 SQ CM	1542.651	20.000
Q4225	Amnio or derma tl, per sq cm	1 SQ CM	1537.000	20.000
Q4205	Membrane graft or wrap sq cm	1 SQ CM	1310.446	20.000

SAFETY INFO

Safety Documents

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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:



Enhancing life through collagen

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