

HelicollTM

BIO-ENGINEERED SKIN SUBSTITUTE



Product Profile Overview

Contact Information:

Subra Guna
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Manufactured & Marketed by:

Encoll Corp.

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Website: www.helicoll.com

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

CONTACT INFORMATION

Representative	Subra Guna, PhD - President
Company	EnColl Corporation
Phone Number	(510) 396-8581
Email Address	guna@encoll.com

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 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.

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?

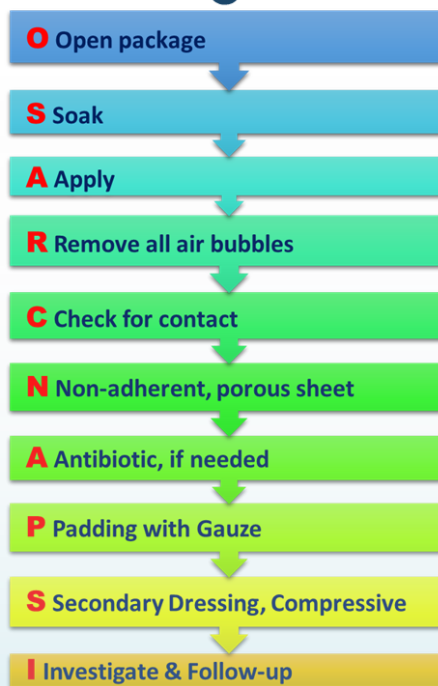
Advantages of Helicoll over Alternative Products:

- **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, 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. 20μ 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



Is Helicoll price competitive?	Yes
Is Helicoll disposable?	Yes
Does Helicoll contain latex?	No

Does Helicoll require sterilization? **No**

Comparative Information:

https://helicoll.com/pdf/Helicoll_comparison_with_other_FDA_approved_prime_products_table.pdf

Helicoll Product Brochure:

https://helicoll.com/images/Helicoll_Brochure.pdf

Helicoll's product cross-reference sheet that compares all similar product(s)

https://helicoll.com/pdf/Helicoll_Cross-Reference_Sheet_Greenlight_Med.pdf

Will a clinical evaluation / trial be conducted with Helicoll? If yes, provide details of the evaluation (data, methods, dates, etc.) and upload any necessary documents.

No. If the Doctor wants to see the comparison, we can provide the clinical data and if they prefer, we can also encourage a clinical trial.

REGULATORY

Class
FDA Product Code
FDA Registration Number
510(k) Number
Helicoll FDA Approved 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
- Helicoll is bioresorbable and can be used for the treatment of tunneling and undermine wounds
- 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.

Instructions for Use

https://helicoll.com/images/HELICOLL_IFU_Leaflet_CP0004_D.pdf

FDA Approval

https://helicoll.com/pdf/Helicoll_FDA_Approval_510K_k040314_Etc.pdf
https://helicoll.com/pdf/Encoll_FDA_Mfg_License_Facility_Regn.pdf

SAFETY

Safety Documents

https://helicoll.com/pdf/HELICOLL_16POINTS_MSDS.pdf
https://helicoll.com/pdf/Helicoll_Safety_Information.pdf

CLINICAL

Reduces patient mortality?

Yes

How does Helicoll improve patient outcomes?

Helicoll Bioengineered Skin Substitute has been designed with the Institute for Healthcare Improvement (IHI) for the Triple Aim in mind, that is "Better Health, Better Care at a Lower Cost". By that we mean that patients heal faster because of our proprietary, pure Type I collagen which reduces immunogenicity, promotes cell migration with increased neovascularity due to added phosphorylation of Type-I collagen.

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. There are fewer applications per patient which leads to a reduction in inpatient bed days and outpatient visits lowering the cost to both the hospital and the patient. Because of our 3-year shelf-life at room temperature, there is no need for special storage or handling which also reduces inventory management costs.

Helicoll Clinical Studies

www.helicoll.com/pdf/Helicoll_published_Stanford_Article.pdf
www.helicoll.com/pdf/Comparison_of_type-I_collagen_with_Integra_skin_substitute.pdf
http://www.helicoll.com/pdf/Shriners_Hospital_Burn_Ctr_Galveston_TX.pdf
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REIMBURSEMENT

CPT
HCPCS

15271, +15272, 15273, +15274, 15275, +15276, 15277, +15278
Q4164

Additional Notes on Reimbursement

Helicoll has already been approved by a few of the GPOs and Health Systems as follows:

1. Vizient Inc. (Contract # MS7561)
2. Premier Health
3. Huntsville Hospital Health System

Reimbursement Guide

https://helicoll.com/pdf/Helicoll_Billing_Guide_MEDICARE.pdf
https://helicoll.com/pdf/Helicoll_Billing_Guide_MEDI_CAL.pdf
https://helicoll.com/pdf/Letter_of_Medical_Necessity_and_Review.pdf

What are the ICD-10 codes for Helicoll?

Please refer to the billing guide for the ICD-10 codes

FINANCIAL ANALYSIS

Is Helicoll available for consignment?

Yes

We may be able to deliver the products with an Invoice on a Consignment basis for the payment after the consumption.

Additional Notes on Pricing

Tier Pricing may be added upon seeing the end users' preference.

CONTRACT MANAGEMENT

Is the Helicoll included in an active GPO?

Yes

Vizient inc. GPO Approval number MS7561

ADDITIONAL INFORMATION

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

Yes

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

Additional Notes

Helicoll Skin substitute product has been declared with Vizient's "Innovative Technology Award" in 2019. Upon approval of Helicoll, we intend to provide the same competitive pricing as contracted by Vizient Inc. The Advantages of our product have been already provided above along with the comparative superiority chart against other equivalent products. Please be aware of the alarming fact about the safety concerns of using an intact tissue membrane-based regenerative matrix. They all contain 15 to 51% elastin in them which happens to be the culprit.

(See the whitepaper on Carcinogenicity of Elastin by clicking here https://helicoll.com/pdf/whitepaper_on_elastin_causing_cancer.pdf)

Examples of elastin containing products made from intact tissue membranes are given below:

Amniofix, Epifix, Amnioexcel, Xwrap: derived from amnion (42% elastin, Ref 1)

Grafix: derived from placenta (49% elastin, Ref 2)

Cellesta Cord: derived from umbilical cord (25% elastin, Ref 3)

Architect: derived from equine pericardium (at least 10% elastin)

Cytal: derived from porcine urinary bladder (9% elastin, Ref 4)

Oasis: derived from porcine SIS intestinal wall (10% elastin, Ref 5)

Kerecis: derived from fish skin (10% elastin, Ref 6)

EZ Derm: derived from porcine dermis (10% elastin, Ref 6)

Apligraf: derived from bovine skin (10% elastin, Ref 6)

The biological degradation of Elastin resulting in Elastomer/Elastokine fragments is proven to be carcinogenic

[ref. www.nature.com/articles/s41467-020-18794-x.pdf] and could cause various pathological conditions including emphysema, chronic obstructive pulmonary disease, atherosclerosis, metabolic syndrome, etc. [ref. www.tandfonline.com/doi/full/10.1080/10409238.2020.1768208].

References:

1. <https://pubmed.ncbi.nlm.nih.gov/16968153/>
2. www.liebertpub.com/doi/10.1089/ten.tea.2011.0738
3. <https://pubmed.ncbi.nlm.nih.gov/9852359/>
4. <http://www.scielo.br/j/ibju/a/pp3bVw7XTtLdVVMzGNFJGK/?lang=en>
5. <https://link.springer.com/article/10.1007/s10029-020-02238-y>
6. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC6940999/>

Additional Files

https://helicoll.com/pdf/helicoll_unique_features.pdf
<https://www.helicoll.com/case-reports.php>
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https://www.helicoll.com/images/Helicoll_in_NPWT.pdf
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https://helicoll.com/pdf/Encoll_CA_Small_Business_Supplier_Cert.pdf

HelicollTM

BIO-ENGINEERED SKIN SUBSTITUTE

Manufactured & Marketed by:



ENCOLL

Enhancing life through collagen

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