Contra-Indications: 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.

Precautions: Do not resterilize. Helicoll is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken. The device must be used prior to the expiration date. Discard all open Helicoll and any unused portions. Helicoll is available by medical prescription only.

Storage: Helicoll should be stored in a clean, dry location at room temperature.

Sterilization: Helicoll has been sterilized with ethylene oxide.

Shelf Life: Helicoll shelf life is 3 years.

Available Sizes (in inches & in cm):

0.5 in dia disc (1.27 cm dia disc) **1 sq cm**	**1.0 in dia disc** (2.54 cm dia disc) **5 sq cm**	**0.8 in x 1.6 in** (2 cm x 4 cm) **8 sq cm**
1.2 in x 1.6 in (3 cm x 4 cm) **12 sq cm**	**1.6 in x 1.6 in** (4 cm x 4 cm) **16 sq cm**	**2 in x 2 in** (5 cm x 5 cm) **25 sq cm**
2 in x 4 in (5 cm x 10 cm) **50 sq cm**	and other custom sizes. (Each individually sterile packaged)	

(U.S. Patents 5,814,328; 6,127,143 & 6,548,077)

Manufactured & Marketed by:

ENCOLL
Enhancing life through collagen

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

CP0005.F

Helicoll®

Collagen Based Sterile Bioengineered Skin Substitute

For Partial and Full Thickness Wounds, Second-degree Burns, Trauma, Skin Ulcers, and Skin Donor Sites.

ENCOLL
Enhancing life through collagen

Advanced Patented High Purity Type-I Collagen Technology for Wound Care Professional

Helicoll®

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.

Applications

- **Partial and full-thickness wounds**
- **Pressure ulcers**
- **Venous ulcers**
- **Chronic vascular ulcers**
- **Diabetic ulcers**
- **Trauma wounds: Abrasions, Lacerations, Skin tears, Second-degree burns**
- **Surgical wounds: Donor sites/grafts, Post- Mohs' surgery, Post Laser surgery, Podiatric, Wound dehiscence.**

Advantages of Helicoll Biological Skin Substitute:

High purity Type-I Collagen: Helicoll is a patented reconstituted bioactive collagen sheet, free of immunogenic proteins, lipids, and elastin. The native structure of 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.

Innovative Technology: Better than intact tissue-based membranes like an amnion, intestinal wall, urinary bladder etc. which contain >15% elastin that is recently discovered to be carcinogenic.

Pain Control: Effectively reduces pain.

Easy Application: No washing needed prior to use. The overall clinical usage of Helicoll is simple and easy as it can be cut, sutured or stapled.

Cost-Effective: Accelerated wound healing and tissue remodeling with minimal applications reduce the treatment cost by over 40%.

Directions for Use:

Note: Helicoll comes in a sterile double packaging as a transparent pliable sheet with a back and a top protection cover sheet of medical grade synthetic polymer.

- Upon opening the sterile package, carefully remove the top sheet of polymer and soak the Helicoll membrane in sterile saline solution for 5 to 10 minutes to easily remove the other backing sheet, (soaking time is not critical for the efficacy of the product).
- Prepare wound area using standard methods to ensure wound is free of debris and necrotic tissue. An initial surgical debridement of the wound may be necessary to ensure the wound edges contain viable tissue.
- Do not apply ointment or any greasy cream on site prior to Helicoll membrane.
- Helicoll membrane can be applied on either surface and it adheres to the wound. In case of dry wounds, sprinkle with sterile saline solution before applying Helicoll.
- Do not try to over-stretch the Helicoll membrane.
- Place carefully over the wound, press out any air pockets under to make sure Helicoll membrane contacts well to the surface of the wound. Any excess Helicoll can be cut and placed as a second layer. Excessive exudate underneath Helicoll can be drained by making slits through the skin substitute.
- If there is a need to secure Helicoll membrane in place, the edges can be taped, sutured or stapled if preferred by the doctor. If a secondary dressing is required, use any non-adherent dressing to prevent unnecessary adherence of Helicoll membrane to the secondary dressing. Change secondary dressing as required.
- Additional application of Helicoll membrane is not generally required unless patient is hyperglycemic.
- Repeated application on every 2nd or 3rd day like a typical wound dressing is not required, unless the wound is infected or accumulates excessive exudate underneath which can be drained by making slit openings in the Helicoll dressing.
- Removal of a Helicoll membrane is not required except when wound is infected; or, if excessive exudate is under the Helicoll membrane; or, for slowly healing chronic ulcers 5 to 7 days after an application of Helicoll membrane. Moisten the Helicoll membrane with saline and gently remove.
- Depending on the treatment modality, sometimes Helicoll may remain intact and gets peeled off as the wound heals which may carefully be removed by moistening with saline soaked gauze for a few minutes. However in some cases, Helicoll may get incorporated into the wound bed in about 4 to 5 days resulting in complete absorption of Helicoll.
- For donor site application, after surgical removal of donor tissue, arrest bleeding by conventional methods, clean the site and apply Helicoll.
- Oral or systemic antibiotics may be given as prescribed in infected cases and in non-infected cases as a preventive measure for better and faster results.

Caution:

Always handle Helicoll using aseptic techniques. Helicoll should not be applied until excessive exudate, bleeding, acute swelling, and infection is controlled. If air pockets appear beneath the applied Helicoll, it can be gently pressed and removed using sterile methods. In case of localized bulging due to fluid accumulation beneath Helicoll, a small incision can be made to exude fluid. This incision can be patched with a small piece of Helicoll adhering to the original applied Helicoll sheet. After application, use an appropriate, non-adherent, secondary dressing to maintain a moist wound environment. Frequency of secondary dressing change will depend on the volume of exudate produced and the type of dressing used. Do not forcibly remove sections of Helicoll that may adhere to the wound. Helicoll may form a caramel-colored gel, which can be rinsed away with gentle irrigation.

HELICOLL®
INSTRUCTIONS FOR USE

HELICOLL®
Semi-Occlusive, Self Adhering and Sterilized Type-I Collagen Sheet for Wound Treatments, Second Degree Burns, and Chronic Ulcers.

DESCRIPTION OF THE DEVICE
HELICOLL is a translucent, off-white, semi-occlusive, self-adhering and pre-sterilized Type-I Collagen Sheet for uses as a bioactive membrane. HELICOLL is flexible with moderate tackiness. HELICOLL is a reconstituted collagen sheet free of contaminants like lipids, elastin and other immunogenic proteins (US Patented). HELICOLL maintains a physiologically moist microenvironment at the wound surface.

INTENDED USES

HELICOLL is intended for the topical wound management that includes:

- Partial and full-thickness wounds.
- Pressure ulcers.
- Venous ulcers.
- Chronic vascular ulcers.
- Diabetic ulcers.
- Trauma wounds (abrasions, lacerations, second-degree burns, skin tears).
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence).

ADVANTAGES OF HELICOLL MEMBRANE

High purity type-I Collagen: Helicoll is a patented reconstituted bioactive collagen sheet, free of immunogenic proteins, lipids, and elastin.

Faster Healing: Collagen phosphorylation attracts cells, regenerates tissue, and stimulates blood capillaries/granulation within 4 to 5 days.

Innovative Technology: Better than intact tissue-based membranes like amnion, intestinal wall, urinary bladder, etc. which contain 15% elastin.

Easy Application: No washing needed prior to use.

Pain Control: Effectively reduces pain.

Various Sizes: Choose from standard or customized dimensions.

Cost-Effective: Accelerated wound healing and tissue remodeling with minimal applications.

Long Shelf Life: Remains clinically usable for 3 years when stored in room temperature conditions.

DIRECTION FOR USE
Helicoll comes in a sterile double packaging as a transparent pliable sheet. It has a back and a top protection cover sheet of medical grade synthetic polymer.

Upon opening the sterile package, the top sheet of polymer can be removed carefully and the remaining can be soaked in sterile water or normal saline solution for 5 to 10 minutes to easily remove the backing sheet.

Prepare wound area using standard methods to ensure wound is free of debris and necrotic tissue. An initial surgical debridement of the wound may be necessary to ensure the wound edges contain viable tissue.

Do not apply ointment or any greasy cream on the site prior to Helicoll. Do not try to over stretch the membrane.

Helicoll can be applied on either of its surfaces and it adheres to the wound instantly. In case of dry wounds, sprinkle sterile saline solution on the surface and apply.

If there is a need to retain the skin-substitute in place, the perimetry can be taped, sutured or stapled as preferred by the doctor. If a secondary dressing is required, a non-adherent gauze with or without antibiotic can be placed to prevent unwanted adherence of the bandage to Helicoll.

Repeated application on every 2nd or 3rd day like a typical wound dressing is not required, unless the wound is infected or accumulates excessive exudate underneath, which can be drained by making slit openings in the Helicoll product.

Depending on the treatment modality, sometimes Helicoll may remain intact and gets peeled off as the wound heals, which may carefully be removed by moistening with saline soaked gauze for a few minutes. However, in some cases, Helicoll may get incorporated into the wound bed in about 4 to 5 days resulting in complete absorption of Helicoll.

For donor site application, after surgical removal of donor tissue, arrest bleeding by conventional methods, clean the site and apply Helicoll.

Oral or systemic antibiotics may be given as prescribed in infected cases and in non-infected cases as a preventive measure for better and faster results.

CAUTION: Always handle Helicoll using aseptic techniques. Helicoll should not be applied until excessive exudate, bleeding, acute swelling, and infection is controlled. If air pockets appear beneath the applied Helicoll, it can be gently pressed and removed using sterile methods. In case of localized bulging due to fluid accumulation beneath Helicoll, a small incision can be made to exude fluid. This incision can be patched with a small piece of Helicoll adhering to the original applied Helicoll sheet. After application, use an appropriate, non-adherent, secondary dressing to maintain a moist wound environment. Frequency of secondary dressing change will depend on the volume of exudate produced and the type of dressing used. Do not forcibly remove sections of Helicoll that may adhere to the wound. Helicoll may form a caramel-colored gel, which can be rinsed away with gentle irrigation.

CONTRA-INDICATIONS: 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 use in third degree burns.

PRECAUTIONS: Helicoll is sterile if the package is dry, unopened, and undamaged. Do not use if the package seal is broken. The device must be used prior to the expiration date. Discard all open and unused portions of Helicoll.

Do not re-sterilize the products and this device is intended for one time use only.

℞ only HELICOLL is available by medical prescription only.

STORAGE: HELICOLL should be stored in a clean, dry location at room temperature under normal storage conditions, Do Not Store Above 32°C (90°F). Helicoll has a minimum of 3 years shelf-life.

STERILE EO **STERILIZATION:** HELICOLL has been sterilized with ethylene oxide.

AVAILABLE SIZES (inches & centimeters):

0.5 in dia disc (1.27 cm dia disc) **1 sq cm**	1.0 in dia disc (2.54 cm dia disc) **5 sq cm**	0.8 in x 1.6 in (2 cm x 4 cm) **8 sq cm**
1.2 in x 1.6 in (3 cm x 4 cm) **12 sq cm**	1.6 in x 1.6 in (4 cm x 4 cm) **16 sq cm**	2 in x 2 in (5 cm x 5 cm) **25 sq cm**
2 in x 4 in (5 cm x 10 cm) **50 sq cm**	other custom sizes available. (Each individually sterile packaged)	

Manufactured and Marketed by:

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