

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: Do not re-sterilize. **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):

2x2 2x4 4x4 4x6 4x8 6x6 4x10 6x8 8x8
6x12 8x10 8x12 8x16 12x12 6x26 10x18 16x16 6x18

and other custom sizes.

(Each individually sterile packaged)

US FDA K # 040314, issued Aug. 2004

Manufactured & Marketed by:



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

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HelicollTM

COLLAGEN BASED STERILE MEMBRANE BIOENGINEERED SKIN SUBSTITUTE

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



Advanced Patented High Purity Type-I Collagen
Technology for WoundCare Professional



Helicoll™

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 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

Helicoll can be applied immediately after soaking in sterile water or normal saline solution for approximately 5 to 10 minutes (soaking time is not critical for the efficacy of the product). **Helicoll** does not require any pretreatment or extensive washing to remove preservatives, etc.

Helicoll reduces the wound pain significantly compared to other dressings. It accelerates tissue remodeling without causing irritation and basically reduces post-treatment care requirements.

Helicoll is intended to accelerate the healing rate and to reduce scar formation by depositing oriented and organized collagen fibers, and by regulating the amount of collagenase expressed by keratinocytes.

Helicoll provides a faster healing process while reducing patient pain and discomfort. **Helicoll** reduces the need for repeated dressings and hospital stay thereby reducing the overall wound 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 dressing, making 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 dressing.
- ❖ 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 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 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/grfts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence).

ADVANTAGES OF HELICOLL MEMBRANE:

HELICOLL can be applied immediately upon soaking in sterile water or normal saline solution for 5 to 10 minutes. It does not require any pretreatments or extensive washing to remove preservatives etc. like some other collagen products.

HELICOLL reduces the wound pain significantly over other such products and does not irritate, therefore application of Helicoll does not require post-treatment care that much.

HELICOLL, like any biocompatible collagen, intends to accelerate the healing rate and accordingly reduces the repeated application.

HELICOLL reduces scarring by depositing oriented and organized fibers and by regulating the amount of collagenase expressed by keratinocytes.

HELICOLL provides faster healing process while reducing patient pain and discomfort. HELICOLL reduces the repeated dressings, hospital stay and pain thereby; overall wound treatment cost would be reduced over 40% compared to most other products.

DIRECTIONS FOR USE:

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

Upon opening the sterile package, the top sheet of polymer can be removed carefully and 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 surface and it adheres to the wound instantly. In case of dry wounds, sprinkle sterile saline solution on the surface and apply.

HELICOLL INSTRUCTIONS FOR USE (CONTD.)

If there is a need to retain the dressing 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 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 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.

℞ 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 would have a minimum of 3 years shelf-life.

☞ **STERILIZATION:** HELICOLL has been sterilized with ethylene oxide.

AVAILABLE SIZES (in inches):

2x2	2x4	4x4	4x6	4x8
6x6	4x10	6x8	8x8	6x12
8x10	8x12	8x16	12x12	6x26
10x18	16x16	6x18	Other Custom Size	



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