

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 scaffolding membrane and extra cellular matrix skin substitute. 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.

HELICOLL INSTRUCTIONS FOR USE (CONTD.)

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. Further, if the provider needs, for Medically Necessity, it can be used weekly and also folded to fill deep wounds.

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.

② Do not re-sterilize the product as it cannot be reused and 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 has a minimum of 3 years shelf-life.

 **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)	



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