COLLAGEN BASED
STERILE WOUND DRESSING

For Trauma, Second-degree Burn,
Chronic Skin Ulcers and Skin Donor Sites

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

EnColl
Helicoll™

Helicoll is a semi-occlusive, self-adhesive collagen membrane with unique advantages of the highest biocompatibility, flexibility with moderate tackiness. Helicoll is a reconstituted type-I collagen sheet free of contaminants like lipids, elastin and other immunogenic proteins. Collagen used in Helicoll collagen dressing is based on a patented technology to obtain high purity, high quality type-I collagen. It is processed under GMP conditions and with stringent USP quality tests as per WHO and other international standards.

Applications

Partial and full-thickness wounds.

Pressure ulcers.

Venous ulcers.

Chronic vascular ulcers.

Diabetic ulcers.

Trauma wounds: abrasions, lacerations, skin tears, second-degree burns.

Advantages of Helicoll Dressing

Helicoll can be applied immediately upon soaking in sterile water or normal saline solution for 2 to 3 minutes. It does not require any pretreatments or extensive washing to remove preservatives, etc as in other collagen products.

Helicoll reduces the wound pain significantly compared to other dressings and while accelerating tissue remodeling without causing irritation, Helicoll reduces post-treatment care requirements.

Helicoll, like any biocompatible collagen, is intended to accelerate the healing rate and reduces 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 repeated dressings, hospital stay and has been shown to reduce the overall wound treatment cost by over 40%.
Directions for Use

Note: Helicoll comes in a sterile double packing as a transparent pliable sheet with 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 soaked in sterile water/normal saline solution for 2 to 3 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.
* If there is a need to retain the dressing in place, the perimetry can be taped or sutured if preferred by the doctor. IF a secondary dressing is required, the backing sheet of polymer can be placed first prior to making a bandage around to prevent any unwanted adherence of the bandage to our collagen sheet.
* Repeated dressing is not required, unless the wound is infected or found accumulate excessive exudate underneath that can not be drained by making slit openings in the dressing.
* Helicoll peels off as the wound heals. However, in some circumstances it may need to be moistened with saline before removal.
* For donor site application, after surgical removal of donor tissue, arrest bleeding by conventional methods, clean the site and apply Helicoll.
* Concurrent systemic therapy may be given as prescribed in infected cases and non-infected cases 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 a 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. Alternatively, Helicoll may form a caramel-colored gel, which can be rinsed away with gentle irrigation.
Contra-indications: Helicoll is derived from a bovine source and should not be used in patients with known sensitivity to bovine 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 and Unused portions of Helicoll.

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

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
(Each individually sterile packaged)

Manufactured & Marketed by:

EnColl

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US FDA K #040314, issued Aug. 2004
(U.S. Patents 5,814,328; 6,127,143 & 6,548,077)
ENCOLL’S HELICOLL TECHNOLOGY

Collagen Wound Dressing

HeliColl™ is the reconstituted Type-I collagen sheet free of contaminants like lipids, elastin and other immunogenic proteins. HeliColl™ is derived from selected animal tissues, using US patented process to obtain high quality collagen Type I. HeliColl™ is processed under GMP conditions and stringent USP quality tests as per international standards. Helicoll™ is transparent and dry membrane with unique advantage of flexibility and moderate tackiness. HeliColl™ is presented with a backing sheet, individually packaged in synthetic micro porous pouch and is gas sterilized.

MEDICAL APPLICATIONS:

As Single Application
First or second degree burns Non-infected or pre-cleansed 2nd degree Burns Trauma with skin loss Chronic skin ulcers Skin donor sites

As Repeated Application
Amputation site. Covering material for bedsore. Diabetic and other type of Ulcers.

COMPARISONS:

<table>
<thead>
<tr>
<th>Type</th>
<th>Drawbacks / Advantages</th>
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<tbody>
<tr>
<td>Synthetic Dressing (ex.: Paraffin gauzes, Polyurethane dressings)</td>
<td>Non-biological, Non-bioactive, Needs repeated dressing.</td>
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<tr>
<td>Natural Dressing Plant (ex.: Alginate dressings)</td>
<td>Non-bioactive, Non-resorbable, Limited application.</td>
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<td>Other Collagen Dressings</td>
<td>May contain other non-collagenous components or denatured/cross-linked collagen and may be chemically treated to reduce the natural bioactivity of collagen and further they may also contain immunogenic and allergic factors to retard and damage the healing process.</td>
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<tr>
<td>HELICOLL Collagen Dressing</td>
<td>Provides Hemostasis, high patient comfort and very cost effective. Proven to reduce the pain significantly. The dry nature of collagen sheet provides longer shelf life and unwanted hydrolysis of collagen can be avoided in dry sheet preparations. Unlike Gamma radiation, the ETO sterilization better preserves the surface chemistry of collagen for ideal healing.</td>
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