

HealicolTM

Contra-indications: **Healicol** 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. **Healicol** 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 **Healicol** and any unused portions. **Healicol** is available by medical prescription only.

Storage: **Healicol** should be stored in a clean, dry location at room temperature. Do not store above 32°C (90°F).

Sterilization: **Healicol** has been sterilized with ethylene oxide.

Shelf Life: **Healicol** shelf life is 3 years.

Available Sizes (in cms):

5x5	5x10	2x25	10x10	10x15	10x20	10x25	15x15	15x20	15x30
15x45	15x65	20x20	20x25	25x25	20x30	20x40	30x30	40x40	60x60
20x35									

(Each individually sterile packaged)
US FDA K # 040314, issued Aug. 2004

Mfg. Lic. Number : 675

Manufactured & Marketed by:



Advanced Biotech Products (P) Ltd.

77, First Cross Street,
Ragavan Colony, Chennai - 600083, India.

Under the Technology from :

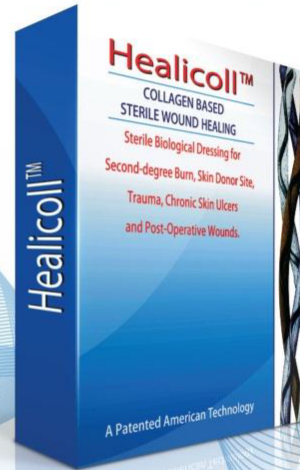
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COLLAGEN BASED STERILE MEMBRANE BIO - ENGINEERED SKIN SUBSTITUTE

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 Wound Care Professional



Advanced Biotech Products (P) Ltd

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Healicol™

Healicol 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. Healicol 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 Healicol. 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 Healicol Biological Skin Substitute

Healicol 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). Healicol does not require any pretreatment or extensive washing to remove preservatives, etc. Healicol reduces the wound pain significantly compared to other advanced products. It accelerates tissue remodeling without causing irritation and basically reduces post-treatment care requirements.

Healicol 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.

Healicol provides a faster healing process while reducing patient pain and discomfort. Healicol reduces the need for repeated dressings and hospital stay thereby reducing the overall wound treatment cost by over 40%.

Directions for Use

Note: Healicol 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 Healicol 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 Healicol membrane. Healicol 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 Healicol.
- Do not try to over stretch the Healicol membrane.
- Place carefully over the wound, press out any air pockets underneath, making sure Healicol membrane contacts well to the surface of the wound. Any excess Healicol can be cut and placed as a second layer. Excessive exudate underneath Healicol can be drained by making slits through the membrane.
- If there is a need to secure Healicol 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 Healicol membrane to the secondary dressing. Change secondary dressing as required.
- Additional application of Healicol membrane is not generally required unless patient is hyperglycemic.
- 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 Healicol application.
- Removal of a Healicol membrane is not required except when wound is infected; or, if excessive exudate is under the Healicol membrane, or, for slowly healing chronic ulcers 5 to 7 days after an application of Healicol membrane. Moisten the Healicol membrane with saline and gently remove.
- Depending on the treatment modality, sometimes Healicol 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, Healicol may get incorporated into the wound bed in about 4 to 5 days resulting in complete absorption of Healicol.
- For donor site application, after surgical removal of donor tissue, arrest bleeding by conventional methods, clean the site and apply Healicol.
- 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 Healicol using aseptic techniques. Healicol should not be applied until excessive exudate, bleeding, acute swelling, and infection is controlled. If air pockets appear beneath the applied Healicol, it can be gently pressed and removed using sterile methods. In case of localized bulging due to fluid accumulation beneath Healicol, a small incision can be made to exude fluid. This incision can be patched with a small piece of Healicol adhering to the original applied Healicol 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 Healicol that may adhere to the wound. Healicol may form a caramel-colored gel, which can be rinsed away with gentle irrigation.