Instuctions for Use PATENTED

**HYPROTEC**®

 Hydrolyzed Collagen with 10% Polysulfated Glycosaminoglycan (PSGAG)

 *Topical Wound Gel*

A combination device for wound care applications containing hydrolyzed collagen and polysulfated glycosaminoglycan (PSGAG). The hyCURE® hydrolyzed collagen when combined with chondroprotective agents such as Hymed’s PSGAG become highly synergistic. This synergism allows each product’s attributes to become more powerful and interactive. Hydrolyzed collagen with 10% PSGAG gel is made from natural materials that contain the proteins and amino acids that constitute the major building blocks of normal skin and connective tissue. The collagen forms a biological platform for new cell growth1; supplies nutritive protein directly to the cell/wound site(s)2; promotes and accelerates cellular regeneration3; and provides mechanical protection against physical and bacterial insult4. Hydrolyzed collagen has been experimentally tested as a hemostatic agent and as a tissue adhesive5. PSGAGs support and enhance the connective tissue and soft tissue while rehydrating dry wounds, protect from tissue trauma and maintain a moist healing environment.6,7,8

Hymed’s PSGAG has been shown to prepare the granulation tissue for migration by maintaining a uniform, low density granulation tissue more easily modified by the migrating epithelium, improving the rate of epithelialization (healing) of a full thickness wound and reducing scarring.9

**Description:** HYPROTEC® is a gel composed of hydrolyzed collagen and 10% PSGAG; a preservative may or may not be added at client’s request and post-sterilization can be added for “sterile” product status.

**Indications:** \*Pressure Ulcers (Stages I-IV) \*Venous Stasis Ulcers \*Diabetic Ulcers \*First and Second Degree Burns \*Surgical Wounds \*Traumatic Wounds \*Superficial Wounds \*Ulcers resulting from Arterial Insufficiency \*Grafted Wounds and Donor Sites

**OTC Indications:**

\*Minor Abrasions

\*Lacerations

\*Minor Cuts

\*Minor Scalds and Burns

**Characteristics and Attributes:**

\*Provides a physiologically favorable environment that encourages wound healing

\*Protects the wound bed and newly formed granulation tissue by the formation of an occlusive gelatinous barrier

\*Reduces pain

\*Conforms to any wound site

\*Biocompatible and biodegradable

\*Controls the evaporation of fluid

\*Soothes and deodorizes

\*Naturally highly absorbent

\*Easy to handle and deliver

\*Promotes natural autolysis by rehydrating and softening necrotic tissue and eschar thereby encouraging autolytic debridement

**Precautions and Contraindications:**

\* No known side effects.

\* Contraindications for individuals with a known sensitivity to bovine or collagen.

**Product Administration:**

1. The wound site should be debrided and cleansed with sterile water or normal saline solution.
2. The skin surrounding the wound site should be dried, leaving the wound site moist.
3. Open the package and apply HYPROTEC® directly onto the wound site (approximately ¼” thickness).
4. Apply a non-adherent dressing such as polyurethane film or gauze to the wound site.
5. Change dressing as needed. With subsequent dressing changes, any remaining HYPROTEC® does not need to be removed.

**Storage:**

\*Store at controlled room temperature (150-300 C)

\*Protect from freezing

**How Supplied:**

\*HYPROTEC® is supplied as a gel in 6gm, 28gm, and 42gm tubes.

**References:** 1. Jain MK, Berg, RA. Material properties of hard tissue substitutes, Man. In Prep. 2. Stotts N, Tevis D. “Co-factors in impaired wound healing.” Ostomy/Wound Management, 42:48, 1996. 3. Silver FH. Biological Materials, Structure, properties, and Modeling of Soft Tissues, NYU press 1987. 4. Chvapil M, Van Winkle Jr W. “Medical and surgical applications of collagen.” International Review of Connective Tissue Research 6:36, 1973. 5. Cooper CW, Falb RD. Ann. N.Y. Acad. Sci. 146:214. 6. Lassus, A. Jeskahen, L., et al: Imdeen for the treatment of degenerated skin in females. Journal of Int’l Research. 19(2): 147-52. 7. Cooper, ML, Hansbrough, JF. Use of a composite skin graft composed of fibroblasts and a collagen-GAG matrix to cover full-thickness wounds. Surgery. Feb. 1991; 109(2):198-207. 8. Breborowitz, A., et al: Glycosaminoglycan chondroitin sulfate prevent loss of ultra filtration during peritoneal dialysis in rats. Nephron. 1994; 67(3): 346-50. 9. Data on file and available upon request from the company.

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