Derma-Gide®

stimlabs®

Instructions for Use for Derma-Gide

Read Before Use

Caution: Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

Description

Derma-Gide is an acellular advanced wound care matrix device. Derma-Gide is derived from porcine tissue and is processed using proprietary technologies to remove bacteria and inactivate viruses. Derma-Gide is sterilized by gamma-irradiation and features a bilayer structure. The upper dense compact collagen layer protects the wound. This structure has a smooth texture with appropriate pull-out strength properties to allow suturing. The second lower layer consists of a thick, porous spongeous collagen scaffold.

Properties

The biocompatibility and low antigenicity of Derma-Gide supports use in the management of wounds. The long-fibered microstructure of Derma-Gide readily absorbs fluid. Due to the inherent structure of the material, small variations in device thickness may be noted.

Accessories

None.

Intended Use & Indications For Use

Derma-Gide is intended for the management of wounds including:

- partial and full thickness wounds
- pressure ulcers
- venous ulcers
- diabetic ulcers
- chronic vascular ulcers
- surgical wounds (donor sites/grafts, post Mohs surgery, post laser surgery, podiatric, wound dehiscence)
- trauma skin wounds (abrasions, lacerations, partial thickness second-degree burns and skin tears)

Instructions For Use

The product should only be used by licensed health care practitioners trained in wound and surgical procedures.

The general principles of sterile working and standard procedures in wound management have to be followed when using Derma-Gide. These suggested instructions are designed to serve only as a general guideline.

They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

Preparation of Wound Bed

- Prior to applying Derma-Gide, the wound site must be carefully cleaned (free of debris and devitalized tissue) and disinfected. An initial debridement of the wound may be necessary to ensure the wound edges contain viable tissue.
- The wound should be treated by following recognized treatment guidelines. Remove excess exudate and control bleeding prior to application according to standard practices.

Application of Derma-Gide

- Tear open the aluminum pouch and remove the sterile inner blister containing Derma-Gide. NOTE: The barcode for the product is located on the outer box. Do not discard until scanning has been completed (if applicable).
- Aseptically deliver the inner, sterile package to the sterile field. Prior to discarding the package, remove the patient chart stickers that are affixed and transfer to applicable documentation.
- Peel open the lid to remove Derma-Gide from the inner blister and prepare it on a sterile surface.
- Trim Derma-Gide to match the size of the wound bed using standard instruments (scissors or scalpel).
- **When applying the product, the lower porous layer should face down and in close contact with the wound bed.**
- Place Derma-Gide directly onto the wound in a **dry state** (no soaking or rinsing is required) and attach with physician's preferred fixation method. Once applied and fixed, ensure that Derma-Gide is completely hydrated, preferably with blood. If adequate blood supply is not available, hydrate Derma-Gide using a sterile saline solution.
- To maintain the functional benefit of the bilayer composition, excessive compression of the dry Derma-Gide during application should be avoided.
- Cover the site with standard wound dressing for excision wounds (e.g., hydrocolloid dressing) to prevent desiccation.
- Additional further dressings can be applied according to the physician preference if appropriate.
- Local use of Derma-Gide with medicinal products, alcohol, or antibiotics has not been studied.

Wound Care Follow Up

- Any non-adhesive (secondary) dressing change should be performed in a manner such that the newly formed tissue underneath is not damaged.
- Should the non-adhesive (secondary) dressing adhere to Derma-Gide, use sterile saline to gently lift off the secondary dressing.
- In the case of chronic wounds, the standard wound dressing covering Derma-Gide (secondary dressing) should be renewed 2–4 days after application to enable a humidified wound for appropriate healing. Further dressing changes might be indicated.
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- The wound exudate (if present) should be managed according to the standard protocol used by the physician with special care not to remove Derma-Gide.
- The wound hematoma (if present) should be managed according to the standard protocol used by the physician followed by a new application of Derma-Gide.
- **Frequency of the secondary dressing change will be dependent upon volume of exudate produced, type of dressing used, and the clinician's need to inspect the wound bed for signs of infection or healing.**
- Monitor tissue surrounding the edges of wound. As wound healing occurs, redness and swelling decreases and wound drainage lessens. These are signs of wound healing and often seen before new epithelium is obvious.

Restrictions on Use

Contraindications

- Derma-Gide must not be used if there is an acute infection in the area of the skin lesion. The health care practitioner must make sure that any active or prior infections have been properly treated before using Derma-Gide.
- Derma-Gide is derived from a porcine source and should not be used in patients with known sensitivity to porcine material or collagen allergies.
- Derma-Gide is not indicated for use in third degree burns.

Precautions

- Exercise particular care in using Derma-Gide in patients:
  - *with chronic infections in the surgical area*
  - *with uncontrolled metabolic disorders such as diabetes or thyroid malfunction*
  - *with autoimmune diseases*
  - *undergoing long-term corticosteroid therapy*
  - *undergoing radiation therapy*
  - *receiving an anti-coagulation therapy, chemotherapy or drug treatment which might disrupt wound healing*
  - *consuming tobacco, alcohol or drugs, which might disrupt wound healing*
- Derma-Gide has not been tested on pregnant or breastfeeding women or on children. For safety reasons, Derma-Gide should not be used on breastfeeding or pregnant women.
- Derma-Gide should not be used until excessive exudate, bleeding, and acute swelling are controlled and infections have been cleared.
- As it may negatively affect product properties, skin preparations containing tea-tree oil should not be used for pre- or post-wound treatment.
- Safety of using more than two 5x6 Derma-Gide units (60cm^2) in a single application has not been evaluated.

Potential Complications

- Infection caused by a surgical procedure
- Chronic inflammation (the procedure may be associated with transient, mild, localized inflammation)
- Allergic reaction
- Excessive redness, pain, swelling, or blistering
- Reduced tissue healing
- Discomfort
- Bleeding and
- Local necrosis

Warnings

- Do not use after the expiration date.
- The content of the double packaging is designed for **single use only**.
- Do not reuse or resterilize Derma-Gide.
- The matrix must be handled using sterile gloves and sterile instruments.
- The matrix is sterile unless the packaging has been opened, damaged or otherwise contaminated.
- Store in a dry place at room temperature (15–25°C/59–77°F).
- Keep away from sunlight.

Packaging

Derma-Gide is packed in sterile double packaging. Each double packaging contains one Derma-Gide.

Re-Order Number	Sizes
500480	Derma-Gide 18 mm Disk
500474	Derma-Gide 2 cm x 2 cm
500427	Derma-Gide 3 cm x 4 cm
502010	Derma-Gide 5 cm x 6 cm

ISO 15223-1 Medical Devices Symbols Legend		
Symbol	ISO 15223 Reference Number and Definition	
	5.1.1	Manufacturer
	5.1.4	Use-by-date
	5.2.4	Sterilization by radiation
	5.2.8	Do not use if package is damaged
	5.3.4	Keep dry
	5.4.2	Do not reuse
	5.4.3	Consult instructions for use
	5.4.4	Warnings
		Prescription only
	5.2.6	Do not re-sterilize
	5.3.7	Temperature limitation (15-25°C)
	5.3.2	Keep away from sunlight

Complaints must be immediately reported to StimLabs at *complaints@stimlabs.com*.

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