

INSTRUCTIONS FOR USE FOR GEISTLICH DERMA-GIDE™

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

DESCRIPTION

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

PROPERTIES

The biocompatibility and low antigenicity of Geistlich Derma-Gide™ supports use in the management of wounds. The long-fibered microstructure of Geistlich 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 AND INDICATIONS FOR USE

Geistlich Derma-Gide™ is intended to be used for the management of wounds including:

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

INSTRUCTIONS FOR USE

The product should only be used by licensed health care practitioners trained in skin and wound care surgical procedures. The general principles of sterile working and state of the art procedures in wound management have to be followed when using Geistlich 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 the Geistlich Derma-Gide™ the affected skin 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 skin wound is treated surgically following recognized treatment guidelines. Remove excess exudate and control bleeding prior to application according to state of the art practices.
- As it may negatively affect the management success, alcohol or iodine-containing disinfectant must not be used for pre- or post-surgical wound treatment.

Application of Geistlich Derma-Gide™

- Remove the sterile inner blister containing the Geistlich Derma-Gide™ from the outer aluminum pouch by peeling off the lid. 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.
- Remove Geistlich Derma-Gide™ from the inner blister, and prepare it on a sterile surface.
- Trim Geistlich Derma-Gide™ to match the size of the wound bed using standard instruments (scissors or scalpel).
- **When applying the product, the porous lower layer should face down and adjacent to the wound bed.**
- Place the Geistlich 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 Geistlich Derma-Gide™ is completely hydrated, preferably with blood. If adequate blood supply is not available, hydrate Geistlich Derma-Gide™ using a sterile saline solution.
- To maintain the functional benefit of the bilayer composition, excessive compression of the dry Geistlich 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.

Wound Care Follow-Up

- Any non-adhesive (secondary) dressing change should be performed in a manner such that the newly formed epithelium underneath is not damaged.
- Should the non-adhesive (secondary) dressing adhere to the Geistlich Derma-Gide™, use sterile saline to gently lift off the secondary dressing.
- In the case of chronic wounds, the standard wound dressing covering Geistlich Derma-Gide™ (secondary dressing) should be renewed 2–4 days after surgery to enable a humidified wound for appropriate healing. Further dressing changes might be indicated.
- The standard wound dressing covering Geistlich Derma-Gide™ should be renewed 2–4 days after surgery to enable a humidified wound for appropriate healing. Further dressing changes might be indicated.
- The wound exudate (if present), should be managed according to the standard protocol used by the physician with special care not to remove the Geistlich 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 the Geistlich 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*

- Geistlich 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 Geistlich Derma-Gide™.
- Geistlich Derma-Gide™ is derived from a porcine source and should not be used in patients with known sensitivity to porcine material or collagen allergies.
- Geistlich Derma-Gide™ is not indicated for use in third degree burns.

Precautions

- Exercise particular care in using Geistlich 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.
- Geistlich Derma-Gide™ has not been tested on pregnant or breastfeeding women or on children. For safety reasons, the Geistlich Derma-Gide™ should not be used on breastfeeding or pregnant women.
- Geistlich Derma-Gide™ should not be used until excessive exudate, bleeding, and acute swelling are controlled and infections have been cleared.
- Alcohol or iodine containing disinfectant must not be used for pre- or post-surgical wound treatment when using the Geistlich Derma-Gide™.

POTENTIAL COMPLICATIONS

- Infection caused by the surgical procedure
 - Chronic inflammation (the procedure may be associated with transient, mild, localized inflammation)
- Allergic reaction
 - Excessive redness, pain, swelling, or blistering

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 Geistlich 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).

PACKAGING

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

Re-Order No.	Sizes
500477	Geistlich Derma-Gide™ 12mm Disk
500478	Geistlich Derma-Gide™ 14mm Disk
500479	Geistlich Derma-Gide™ 16mm Disk
500480	Geistlich Derma-Gide™ 18mm Disk
500425	Geistlich Derma-Gide™ 1.5cm x 2cm
500474	Geistlich Derma-Gide™ 2cm x 2cm
500426	Geistlich Derma-Gide™ 2cm x 3cm
500475	Geistlich Derma-Gide™ 2cm x 4cm
500427	Geistlich Derma-Gide™ 3cm x 4cm

Distributed by:

Geistlich Pharma North America Inc.
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www.geistlich-na.com

Manufacturer:

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Switzerland

May be covered by US Patent No. 6,713,085

Made in Switzerland

Package insert: www.derma-gide.com

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