DermaForm™

stimlabs®

Instructions for Use for DermaForm

Read Before Use

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

Description

DermaForm is an acellular advanced wound care device derived from porcine tissue. The device is supplied in a particle form in units of 500 mg and packed in sterile double layer packaging. The device consists of a collagen scaffold that protects the wound and the open healing process. DermaForm is terminally sterilized by gamma- irradiation.

Properties

The biocompatibility and low immunogenicity of DermaForm supports use in the management of wounds. The fibrous microstructure of DermaForm readily absorbs fluid.

Accessories

None.

Intended Use & Indications For Use

DermaForm 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
- tunnel/undermined wounds
- surgical wounds (donor sites/grafts, post Mohs surgery, post laser surgery, podiatric, wound dehiscence)
- trauma wounds (abrasions, lacerations, second-degree burns and skin tears)
- draining wounds

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 should be followed when using DermaForm. 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.

Device Application

The following procedures only serve as a suggested guideline for the management of wounds with DermaForm. The provided suggestions are not intended to supersede internal institutional protocols and sound clinical judgment.

1. Clean wound bed and irrigate to remove exudate and debris.
2. Perform standard debridement procedures in-line with internal institutional protocols.
3. Using standard aseptic/sterile technique, open blister and remove glass vial. Carefully open the glass vial.
4. DermaForm may be applied dry or in a rehydrated state. Apply device directly to the wound bed, lightly covering the entire wound. Product can be poured in its dry state directly from the container.
5. Alternatively, DermaForm can be hydrated with sterile saline to form a paste prior to application. To make a paste, dispense DermaForm into a separate sterile container. Slowly add sterile saline until the desired consistency is obtained and then apply to the wound in an aseptic manner.
6. Apply secondary dressing(s) according to standard of care.
7. Discard any unused portion of the device.

Wound Care Follow-Up (as determined by the health care provider):

- Inspect primary dressing at least every 7 days. Remove exudate and apply new device to any non-covered wound areas as necessary. During new device application, cover device with a new and appropriate secondary dressing, as described below.
- 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 DermaForm, use sterile saline to gently lift off the secondary dressing.
- The standard wound dressing covering DermaForm should be renewed 2–4 days after surgery to enable a moist 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 DermaForm.
- Frequency of the secondary dressing change will be dependent upon volume of exudate produced, type of dressing(s) 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

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

Precautions

- Exercise particular care in using DermaForm 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*
  - *having a clinical condition or receiving treatment which might disrupt wound healing (e.g., an anti-coagulation therapy, chemotherapy or drug treatment)*
  - *consuming tobacco, alcohol or drugs, which might disrupt wound healing*
- DermaForm has not been tested on pregnant or breastfeeding women or on children. For safety reasons, DermaForm should not be used on breastfeeding or pregnant women.
- DermaForm should not be used until excessive exudate, bleeding, and acute swelling are controlled and infections have been cleared.
- Disinfectants containing tea tree oil should not be used for pre- or post-surgical wound treatment when using DermaForm.
- Do not tap glass vial with metal objects or handle in a way that may cause glass to break and contaminate wound.
- DermaForm is not intended to be solubilized and injected.
- The safety of using more than 2000 mg of DermaForm in a single application has not been evaluated.

Potential Complications

Complications and reactions are possible with any soft tissue repair, including but not limited to:

- Local inflammatory reaction or infection caused by the surgical procedure
- Chronic inflammation (the procedure may be associated with transient, mild, localized inflammation)
  - > *Local tissue necrosis*
  - > *Tissue healing disturbances*
  - > *Unplanned surgical interventions*
  - > *Scarring*
- 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 DermaForm.
- The device must be handled using sterile gloves and sterile instruments.
- The device 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.
- Do not use glass vial if cracked, broken, or otherwise damaged.

Packaging

DermaForm is packed in sterile double packaging and includes one vial.

Re-Order Number	Size
502092	DermaForm 500 mg

ISO 15223-1 Medical Devices Symbols Legend		
Symbol	ISO 15223 Reference Number and Definition	
	5.1.1	Manufacturer
	5.1.4	Use-by-date
STERILE R	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
Rx only		Prescription only
	5.2.6	Do not re-sterilize
15°C 25°C	5.3.7	Temperature limitation (15-25°C/ 59-77°F)
	5.3.2	Keep away from sunlight

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

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