

Natural Dermal Template

EN Product description

Endoform® Natural Dermal Template is a collagen dressing with an intact extracellular matrix (ECM). Derived from ovine (sheep) forestomach tissue, this advanced wound care dressing is non-reconstituted collagen, thus it retains the innate biological structure of the native ECM associated macromolecules including elastin, fibronectin, glycosaminoglycans and laminin. When rehydrated with wound exudate or sterile saline, Endoform Natural Dermal Template transforms into a soft conforming sheet, which is naturally incorporated into the wound over time.

Not made with natural rubber latex.

Intended use

Endoform® Natural Dermal Template is a sterile, single use ovine forestomach-derived extracellular matrix intended to cover, protect, and provide a moist wound environment.

Indications for use

Endoform® Natural Dermal Template is indicated for the management of wounds including:

- Partial and full thickness wounds
 - Pressure ulcers
 - Venous ulcers
 - Diabetic ulcers
 - Chronic vascular ulcers
 - Tunneled/undermined wounds
 - Surgical wounds (donor sites, grafts, post Moh's surgery, post laser surgery, podiatric, wound dehiscence)
 - Traumatic wounds (abrasions, lacerations, first and second-degree burns, and skin tears)
 - Draining wounds
- Rx** Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Contraindications

- **Endoform® Natural Dermal Template** is derived from an ovine (sheep) source and should not be used on patients with known sensitivity to ovine (sheep) derived material.
- **Endoform® Natural Dermal Template** is not indicated for use on third degree burns.

Precautions

- Do not apply to wounds with uncontrolled clinical infection, acute inflammation, excessive exudate, or bleeding
- **Endoform® Natural Dermal Template** is supplied as a sterile dressing. Do not use if the pouch seal is broken.
- Discard the device if mishandling has caused possible damage or contamination.
- Single use product. Do not attempt to re-sterilize. Discard all unused portions. Do not reuse.
- Always handle **Endoform® Natural Dermal Template** using aseptic technique.

Storage

Endoform® Natural Dermal Template should be stored between 15°C/59°F–40°C/104°F in a clean and dry area.

How supplied

Product Code	Description
529311	Endoform® Natural 2" x 2" / (5 cm x 5 cm)
529312	Endoform® Natural 2" x 2" / (5 cm x 5 cm), Fenestrated
529313	Endoform® Natural 4" x 5" / (10 cm x 12.7 cm)
529314	Endoform® Natural 4" x 5" / (10 cm x 12.7 cm), Fenestrated

Directions for use

These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

1) Wound Preparation

- Prepare the wound bed by cleansing, irrigation and if necessary debridement to ensure the wound is free of debris, necrotic tissue or infected tissue.











2) Dressing Application

- Select a sheet of the dermal template which is slightly larger than the wound and apply aseptically.
- Endoform® Natural Dermal Template** can be applied as a whole sheet or trimmed so that it contacts the wound margins. Multiple sheets can be used to cover the entire wound bed.
- For ease of handling, apply the dermal template by placing the dry material in the wound and rehydrating with exudate or sterile saline. When hydrated **Endoform® Natural Dermal Template** transforms into a soft conforming sheet. Ensure that the dermal template conforms to the underlying wound bed.
- To protect **Endoform® Natural Dermal Template** from adhering to the secondary dressing, consider applying a non-adherent dressing over the dermal template to help protect the tissue while facilitating an optimal moist wound healing environment.
- Secure the dermal template using an appropriate secondary dressing. The overlying dressing should be changed according to standard of care taking into account the level of exudate.
- The biodegradable **Endoform® Natural Dermal Template** is naturally absorbed and incorporated into the wound over time. **Endoform® Natural Dermal Template** may last up to 7 days in the wound, depending on the wound environment.
- Endoform® Natural Dermal Template** can be used in conjunction with compression therapy and negative pressure wound therapy under the supervision of a health care provider.

3) Dressing Changes

- Duration of treatment and reapplication is determined by the physician and depends upon the wound type and conditions.
- Reapply when the dermal template has been incorporated into the wound. It is recommended to assess the wound within 72 hours. **Endoform® Natural Dermal Template** may last up to 7 days in the wound, depending on the wound environment.
- Carefully cleanse the wound surface in accordance with established procedures. Do not attempt to remove the off-white to golden gel that forms from residual **Endoform® Natural Dermal Template** in the wound as it contains extracellular matrix components that assist in wound healing.
- If areas of the dermal template are dry upon inspection, rehydrate with sterile saline and leave in place.
- It is not necessary to remove any residual **Endoform® Natural Dermal Template** during dressing changes. However, if the product has been overlapped onto the peri-wound area, the remaining loose product that has not incorporated into the wound may be gently removed around the edges if desired.
- Change the secondary dressings as needed, and when **Endoform® Natural Dermal Template** is re-applied.

Symbols

ISO 15223-1: 2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements		
	5.4.2	Do not reuse
	5.2.6	Do not re-sterilize
	5.2.8	Do not use if package is damaged
	5.1.4	Use by expiration date YYYY/MM/DD
	5.3.4	Keep dry
	5.2.3	Sterilized with ethylene oxide
	5.3.7	Store at room temperature
	5.4.3	Consult instructions for use
	5.3.2	Keep away from heat and light
	-	Number of Units



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