

INSTRUCTIONS FOR USE

TheraGENESIS®

TheraGenesis® Meshed Bilayer Wound Matrix

DEVICE DESCRIPTION

TheraGenesis® Meshed Bilayer Wound Matrix is a collagen-based wound dressing that consists of two layers: a porcine tendon-derived atelocollagen sponge layer and a silicone film layer. It contains a non-adhesive gauze (TRES™) to reinforce the silicone film, and slits to aid in the drainage of exudate. The biodegradable collagen matrix provides a scaffold for cellular invasion and capillary growth.

INDICATIONS FOR USE

TheraGenesis Meshed Bilayer Wound Matrix is indicated 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-Moh's surgery, post-laser surgery, podiatric, wound dehiscence),
- trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears), and
- draining wounds.

TheraGenesis Meshed Bilayer Wound Matrix may be used in conjunction with negative pressure wound therapy. The device is intended for one-time use.

CONTRAINDICATIONS

- TheraGenesis Meshed Bilayer Wound Matrix may exacerbate conditions in patients showing sensitivity to porcine-derived products (such as insulin), or silicone materials.
- Do not use in patients with a history of hypersensitivity to proteins of animal origin.
- Do not use in infected wound sites.
- This device is not indicated for use in third-degree burns.
- When used with negative pressure wound therapy (NPWT), follow Contraindications for the specific NPWT device utilized, such as in the presence of exposed arteries, veins, organs, anastomotic sites or nerves, malignancy in the wound, untreated osteomyelitis, untreated malnutrition, necrotic tissue (with or without eschar present), non-enteric and unexplored fistulas, and sensitivity to silver (if silver dressings are used).

WARNINGS AND PRECAUTIONS

CAUTION: Federal law restricts this device to sale by or on the order of a physician or practitioner.

- Caution should be exercised in patients susceptible to such allergic symptoms as bronchial asthma or urticaria.
- TheraGenesis Meshed Bilayer Wound Matrix has no antibacterial activity and care must be taken regarding bacterial infection. For example, if infected wounds are present near the application site, adequate disinfection should be performed at the time of operation. If infection does occur, it should be treated in accordance with local clinical practice.
- Discard device if mishandling has caused possible damage or contamination.
- TheraGenesis Meshed Bilayer Wound Matrix should not be applied until excessive exudates, bleeding and acute swelling are controlled, and no infection is observed.

- Use TheraGenesis Meshed Bilayer Wound Matrix when exudates are expected to be emitted from the wound and therefore adequate drainage is necessary. The excessive exudates may separate the matrix from the wound surface, causing infection.
- The following complications are possible with the use of wound dressings. If any of the following conditions occur, TheraGenesis Meshed Bilayer Wound Matrix should be removed: infection, wound colonization, sepsis, chronic inflammation (initial application of the device may be associated with transient, mild, localized inflammation), allergic reaction, excessive redness, pain or swelling.
- Do not re-sterilize. Discard all opened and unused portions of TheraGenesis Meshed Bilayer Wound Matrix.
- Device is sterile if the package is unopened and un-damaged. Do not use if the package seal is broken.
- Do not stretch, expand, spread, or re-mesh the device.
- Use immediately after opening.
- Do not use after expiration date.
- When used with NPWT, follow Warnings and Precautions for the specific NPWT device utilized, such as:
 - Precautions for patients who are or may be receiving anticoagulant therapy or suffering from difficulty in hemostasis;
 - Excessive bleeding is a serious risk associated with the application of suction to wounds and may result in death or serious injury. Careful patient selection, in view of the above-stated Contraindications, Warnings and Precautions, is essential. Carefully monitor the wound and collection circuit for any evidence of a change in the blood loss status of the patient. Notify the physician of any sudden or abrupt changes in the volume or the color of exudate.

INSTRUCTIONS FOR USE

PRE-APPLICATION

1. Immerse TheraGenesis Meshed Bilayer Wound Matrix in sterile physiological saline for 5 minutes to adequately saturate the collagen sponge layer.
2. Prepare the wound bed using standard methods to ensure wound is free of debris and necrotic tissue that may cause infection. If necessary, surgically debride the wound to ensure the wound edges contain viable tissue. Perform adequate hemostasis, clean and disinfect the wound surface, without leaving hematoma.

APPLICATION

1. Cohesively apply one or more sheets, depending on the size of the wound surface.
2. Apply the collagen sponge surface to the wound surface. Do not mistake the back and front. The silicone film side has a glossy surface.
3. Fix the product to the periphery of the wound with surgical staples, sutures or other mechanical means. When using multiple sheets, fix the sheets together in the same manner.

Note: Use of TheraGenesis Meshed Bilayer Wound Matrix is limited to the use of the two largest sheets (20 cm x 24 cm) as the endotoxin per dose is limited to 20 EU. In addition, it is limited to the use of three and a half sheets of 8.2 cm x 12 cm for pediatrics (weight: 10 kg), and two and a half sheets of 8.2 cm x 6 cm for neonates (weight: 3.5 kg).

[With Negative Pressure Wound Therapy (NPWT)]

1. Place foam dressings over the TheraGenesis Meshed Bilayer Wound Matrix, and utilize drapes and other appropriate equipment according to instructions for use of the NPWT device.
2. Apply NPWT according to manufacturer's instructions for use, paying specific attention to Contraindications, Warnings and

Precautions. TheraGenesis Meshed Bilayer Wound Matrix has only been tested for use in conjunction with the InfoV.A.C. NPWT System in continuous and intermittent mode. The wound should be monitored. Where applicable, follow instructions for “Meshed Grafts and Bioengineered Tissues.”

- For pressure settings, refer to instructions for use for the specific device utilized and type of wound, if applicable.
- During dressing changes, carefully remove the NPWT device and secondary dressing, foam or film, using caution not to disrupt the TheraGenesis Meshed Bilayer Wound Matrix.
- Discontinue NPWT when the collagen matrix has been integrated and the silicone has separated from the wound (typically 14-21 days). When using NPWT, this time frame may be reduced.

[Without NPWT]

- After application, use appropriate secondary dressings to maintain device adherence and protect the wound area. Excessive pressure, dead spaces or deviation from the wound surface prevents the cellular invasion and capillary growth and might result in insufficient formation of new dermis-like tissue. The optimal secondary dressing is determined by wound location, size, depth and user preference.
- Change the secondary dressing as required. Frequency of the secondary dressing change will be dependent upon the volume of exudates produced, type of dressing used and the clinician’s need to inspect the wound bed for signs of infection or healing.
- As healing occurs, sections of the silicone film may gradually peel off and may be removed during dressing changes. Remove the silicone film when the tissue underneath is healed, typically 14 to 21 days. Do not forcibly remove the silicone film that may adhere to the wound, causing separation of the product from the wound bed.

HOW SUPPLIED

TheraGenesis Meshed Bilayer Wound Matrix is supplied sterile, in single use, double peel packages. The product is available in the following sizes:

TheraGenesis® Meshed Bilayer Wound Matrix

Code	Size* (cm × cm)	Size (inch × inch)	Quantity (sheet/box)
TG-M4030	4 × 3	1.6 × 1.2	1
TG-M4060	4 × 6	1.6 × 2.4	1
TG-M8260	8.2 × 6	3.2 × 2.4	1
TG-M8290	8.2 × 9	3.2 × 3.5	1
TG-M82120	8.2 × 12	3.2 × 4.7	1
TG-M120240	12 × 24	4.7 × 9.4	1
TG-M200240	20 × 24	7.9 × 9.4	1

* Product size specifications are in centimeters.

STORAGE

Store in a dry place. Avoid exposure to high temperature and protect from freezing (1°C / 34°F – 30°C / 86°F). Keep away from sunlight. Do not use beyond expiration date indicated on the outer packaging.

DISPOSAL

Product needs to be disposed according to institutional procedures.

SYMBOL GLOSSARY DEFINITIONS

Symbol	Symbol Title	Standard ¹ or Regulation Reference ²
	Manufacturer	ISO 15223-1 Clause 5.1.1
	Use-by date	ISO 15223-1 Clause 5.1.4
	Batch code	ISO 15223-1 Clause 5.1.5
	Catalogue number	ISO 15223-1 Clause 5.1.6
	Sterilized using ethylene oxide	ISO 15223-1 Clause 5.2.3
	Do not resterilize	ISO 15223-1 Clause 5.2.6
	Do not use if package is damaged and consult instructions for use	ISO 15223-1 Clause 5.2.8
	Single sterile barrier system with protective packaging inside	ISO 15223-1 Clause 5.2.13
	Single sterile barrier system with protective packaging outside	ISO 15223-1 Clause 5.2.14
	Keep away from sunlight	ISO 15223-1 Clause 5.3.2
	Keep dry	ISO 15223-1 Clause 5.3.4
	Temperature limit	ISO 15223-1 Clause 5.3.7
	Do not re-use	ISO 15223-1 Clause 5.4.2
	Consult instructions for use	ISO 15223-1 Clause 5.4.3
	Caution	ISO 15223-1 Clause 5.4.4
	Not made with natural rubber latex	ISO 15223-1 Clause 5.4.5 Annex B.2
	Contains biological material of animal origin	ISO 15223-1 Clause 5.4.8
	Prescription only	21 CFR 801.109

¹ ISO 15223-1:2021 Medical Devices – Symbols to be used with information to be supplied by the manufacture – Part 1: General Requirements

² 21 CFR 801.109 Prescription devices



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INSTRUCTIONS FOR USE

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INDICATIONS FOR USE

TheraGenesis Non-Meshed Bilayer Wound Matrix is indicated 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-Moh's surgery, post-laser surgery, podiatric, wound dehiscence),
- trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), and
- draining wounds.

The device is intended for one-time use.

CONTRAINDICATIONS

- TheraGenesis Non-Meshed Bilayer Wound Matrix may exacerbate conditions in patients showing sensitivity to porcine-derived products (such as insulin), or silicone materials.
- Do not use in patients with a history of hypersensitivity to proteins of animal origin.
- Do not use in infected wound sites.
- This device is not indicated for use in third-degree burns.

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- Discard device if mishandling has caused possible damage or contamination.
- TheraGenesis Non-Meshed Bilayer Wound Matrix should not be applied until excessive exudates, bleeding and acute swelling are controlled, and no infection is observed.

- Use TheraGenesis Meshed Bilayer Wound Matrix when exudates are expected to be emitted from the wound and therefore adequate drainage is necessary. The excessive exudates may separate the matrix from the wound surface, causing infection.
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- Do not re-sterilize. Discard all opened and unused portions of TheraGenesis Non-Meshed Bilayer Wound Matrix.
- Device is sterile if the package is unopened and undamaged. Do not use if the package seal is broken.
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POST-APPLICATION

1. After application, use appropriate secondary dressings to maintain device adherence and protect the wound area. Excessive pressure, dead spaces or deviation from the wound surface prevents the cellular invasion and capillary growth and might result in insufficient formation of new dermis-like tissue. The optimal secondary dressing is determined by wound location, size, depth and user preference.

2. Change the secondary dressing as required. Frequency of the secondary dressing change will be dependent upon the volume of exudates produced, type of dressing used and the clinician's need to inspect the wound bed for signs of infection or healing.

Note: if hematoma or excess exudates gather under the silicone film, small openings can be cut in the sheet to allow the fluid to drain.

3. As healing occurs, sections of the silicone film may gradually peel off and may be removed during dressing changes. Remove the silicone film when the tissue underneath is healed, typically 14 to 21 days. Do not forcibly remove the silicone film that may adhere to the wound, causing separation of the product from the wound bed.

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