AROA ECM™

Myriad Matrix™

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Soft Tissue Bioscaffold

Instructions For Use

AROA™

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Myriad Matrix™

Soft Tissue Bioscaffold

Product description

Myriad Matrix™ is an intact extracellular matrix (ECM) derived from ovine (sheep) forestomach tissue.
This advanced ECM scaffold is non-reconstituted collagen, thus it retains the innate biological structure and function of the native ECM associated macromolecules including elastin, fibronectin, glycosaminoglycans and laminin.

Myriad Matrix transforms into a soft conforming sheet, which is incorporated into the surrounding tissue over time. The device is supplied sterile and dry in a variety of sizes and thicknesses, which can be trimmed to size or applied whole to meet the individual patient's needs. Multiple sheets can be used if required.

Myriad Matrix is restricted to sale by or on the order of a licensed healthcare practitioner.

Not made with natural rubber latex.

Intended use

Myriad Matrix is intended to cover, protect, and provide a moist wound environment.

Indications for use

Myriad Matrix is indicated for the management of acute and chronic wounds, including:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunnelled/undermined wounds
- 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)
- Draining wounds

Contraindications

- **Myriad Matrix** is derived from an ovine (sheep) source and should not be used on patients with known sensitivity to ovine (sheep) derived material.
- **Myriad Matrix** is not indicated for use on third degree burns.
- **Myriad Matrix** is not indicated for use in pelvic floor prolapse repair surgery.

Risk statements

PRECAUTIONS

- Do not apply **Myriad Matrix** in the presence of uncontrolled clinical infection, acute inflammation, excessive exudate, or bleeding.
- **Myriad Matrix** is supplied sterile. Do not use if the pouch is damaged.
- Discard the device if mishandling has caused possible damage or contamination.
- Single use product. Do not resterilise. Discard all unused portions. Do not reuse. Reuse may contribute to wound infection.
- Minimise manipulation of **Myriad Matrix** during rehydration and placement.
- Always handle **Myriad Matrix** using aseptic technique.

POTENTIAL COMPLICATIONS

The following complications are possible. If any of the complications occur and cannot be resolved, consider removal of the device:

- Infection
- Acute or chronic inflammation
- Allergic reaction

Storage

Myriad Matrix should be stored at room temperature in a clean and dry area.

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.

Myriad Matrix can be used in conjunction with compression therapy and negative pressure wound therapy under the supervision of a health care provider.

1. Rehydrate the device in sterile saline or sterile Lactated Ringer's solution for a minimum of 5 minutes.
2. Trim the device to fit, if necessary, providing an allowance for overlap. Position the device to achieve maximum contact between the device and surrounding tissue to facilitate cell migration and tissue ingrowth.
3. If desired, fix in place using standard techniques, avoiding excess tension. It is recommended the device is covered using a non-adherent primary dressing and an appropriate secondary dressing.
4. The biodegradable **Myriad Matrix** device is incorporated into the wound over time. It is not necessary to remove any residual **Myriad Matrix**. 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. For best results, ensure **Myriad Matrix** remains hydrated.
5. Reapply as needed when **Myriad Matrix** has been incorporated into the wound.
6. Discard any unused portions according to institutional guidelines for medical waste.

Symbols glossary

Symbols contained in **ISO 15223-1 Medical devices** – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements are indicated below.

	5.1.1	Manufacturer
	5.1.3	Date of manufacture
	5.1.4	Use by/Expiration date
LOT	5.1.5	Lot number
REF	5.1.6	Catalog number
	5.1.8	Importer
STERILE EO	5.2.3	Sterilised using ethylene oxide
	5.2.6	Do not resterilise
	5.2.8	Do not use if packaging is damaged and consult instructions for use
	5.2.12	Double sterile barrier system
	5.3.4	Keep dry
	5.4.2	Do not reuse
	5.4.3	Consult instructions for use
BIO	5.4.8	Contains biological material of animal origin
MD	5.7.7	Medical Device
	-	Number of units
	-	Number of layers