

Myriad Morcells™

Morcellized Bioscaffold

EN Product description

Myriad Morcells™ is derived from an extracellular matrix (ECM) composed of 100% w/w ovine (sheep) collagen.

Not made with natural rubber latex.

Intended use

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

Clinical benefit

The extracellular matrix provides a scaffold for the patient's own cells to build granulation tissue

Indications for use

Myriad Morcells is indicated for use in the management of the following wounds:

- 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)
- Trauma wounds (abrasions, lacerations, partial-thickness burns, and skin tears)
- Draining wounds

Contraindications

- Do not use the device in patients with a known sensitivity to materials of ovine (sheep) origin. Use of the device in this patient population may result in an allergic or immunological reaction.
- **Myriad Morcells** is not indicated for use on third degree burns.

Risk statements

PRECAUTIONS

- Do not apply to wounds with uncontrolled clinical infection, acute inflammation, excessive exudate, or bleeding.
- Always handle **Myriad Morcells** using aseptic technique.
- **Myriad Morcells** is supplied sterile. Do not use if the pouch seal is broken.
- **Myriad Morcells** is packaged in an outer sterile barrier pouch. Aseptically present the blister tray into the sterile field.
- Discard the device if mishandling has caused possible damage or contamination.
- Single use product. Do not reuse. Do not re-sterilize. Reuse, re-sterilization, reprocessing and/or repackaging may compromise the essential material characteristics that are critical to the overall performance of the device.
- Discard **Myriad Morcells** if the product is past its expiration date.

POTENTIAL COMPLICATIONS

Allergic reaction, infection, and/or inflammation are possible with the use of this device. If any of the complications occur and cannot be resolved, the healthcare provider should discontinue use.

Storage

Myriad Morcells 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.

1. Wound Preparation

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

2. Application















- Apply **Myriad Morcells** directly to the wound bed, lightly covering the entire wound. Product can be poured directly from the container.
- Alternately, **Myriad Morcells** can be hydrated with sterile saline either in the tray or a separate sterile container to form a paste to aid in the application where the location or geometry of the wound may make it difficult to apply the dry device. To make a paste, remove the lid of the tray provided or dispense **Myriad Morcells**. Slowly add sterile saline until desired consistency is obtained.
- When applied, **Myriad Morcells** should cover the entire wound bed and contact the wound margins.
- **Myriad Morcells** will be incorporated into the wound over time and may be visibly present for up to 7 days. In vivo animal testing in an intramuscular implant study using histological methods showed complete degradation of the device material after 17 weeks.
- To protect **Myriad Morcells** from adhering to the secondary dressing, consider applying a non-adherent dressing to help protect the tissue while facilitating an optimal moist wound healing environment. The overlying dressing should be changed according to standard of care taking into account the level of exudate.

3. Re-application

- Carefully cleanse the wound in accordance with established procedures. It is not necessary to remove residual **Myriad Morcells**.
- Reapply **Myriad Morcells** as needed. Duration of treatment is determined by the physician.
- Change the cover dressings as needed, and when **Myriad Morcells** is re-applied.

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
	5.1.5	Lot number
	5.1.6	Catalog number
	5.2.3	Sterilized using ethylene oxide
	5.2.6	Do not re-sterilize
	5.2.8	Do not use if packaging is damaged and consult instructions for use
	5.2.13	Single sterile barrier system with protective packaging inside
	5.3.4	Keep dry
	5.4.2	Do not reuse
	5.4.3	Consult instructions for use
	5.4.8	Contains biological material of animal origin
	5.7.7	Medical device
Rx Only	-	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner

Instructions For Use



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AROA ECM™



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