

Myriad

Product description

Myriad is a collagen matrix with an intact extracellular matrix (ECM). Derived from ovine (sheep) forestomach tissue, this advanced matrix 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 transforms into a soft conforming sheet, which is naturally 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 meet the individual patient's needs.

Not made with natural rubber latex.


Intended use

Myriad is intended for applications in plastic and reconstructive surgery or to cover, protect, and provide a moist wound environment. The device may be fixed, via sutures, staples, or tacks to the surrounding tissue, if desired.

Indications for use

Myriad is indicated for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery, or for 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, first and second-degree burns, and skin tears)
- Draining wounds

 Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Contraindications

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

Precautions

- **Myriad** may not have sufficient strength to support stresses encountered in some ventral hernias or large-area, body-wall repairs. **Myriad** is not intended to augment breast reconstruction.
- Do not apply **Myriad** in the presence of uncontrolled clinical infection, acute inflammation, excessive exudate, or bleeding
- **Myriad** is supplied sterile. 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.
- Minimize manipulation of **Myriad** during rehydration and placement.
- Always handle **Myriad** 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
- Seroma formation

Storage











Endoform™ Myriad should be stored between 15°C/59°F–40°C/104°F 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) 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, an overlap of 3-5 cm with healthy well-vascularized tissue is suggested.
- 3) If desired, suture, staple, or tack into place**, avoiding excess tension. Alternately, the device can be secured using an appropriate secondary dressing.
- 4) Discard any unused portions** according to institutional guidelines for medical waste.

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 between 15°C/59°F - 40°C/104°F
	5.4.3	Consult instructions for use
	5.3.2	Keep away from heat and light
	-	Number of Units

