Symphony™

Proliferative Bioscaffold

	5.3.4	Keep dry
	5.3.6	Upper limit of temperature
	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
Rx Only	-	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

Instructions For Use

Proliferative Bioscaffold

Symphony™

AROA ECM™

AROA™

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Symphony™

Proliferative Bioscaffold

Product description

Symphony is a sterile, single use wound care device manufactured by incorporating a layer of glycosaminoglycans between three sheets of ovine forestomach-derived extracellular matrix.

Intended use

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

Indications for use

Symphony 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, second-degree burns, and skin tears)
- Draining wounds

Contraindications

- Do not use the device in patients with a known sensitivity to materials of ovine (sheep) origin or to hyaluronan.
- **Symphony** is not indicated for use on third degree burns.

Risk Statements

PRECAUTIONS

- **Symphony** is intended for use in a hospital or professional healthcare environment only.
- Do not apply to wounds with uncontrolled clinical infection, acute inflammation, excessive exudate or bleeding.
- Always handle **Symphony** using aseptic technique.
- **Symphony** is supplied in a blister tray with a sterile lid and a protective foil lid. Do not use if any of the packaging is compromised or if either of the seals are broken.
- 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 result in device failure and/or patient injury.
- Discard **Symphony** if past its expiration date.
- Excessive rehydration (>10 mins) may cause damage to the device.
- Minimize manipulation of the device during rehydration and application.

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 consider removal of the device.

Storage

Symphony should be stored at less than 25°C/77°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. **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**

- Select a device size which is slightly larger than the wound. **Symphon**y can be applied as a whole sheet or trimmed so that it contacts the wound margins.
- Inspect the packaging to ensure it is intact and undamaged.
- Peel back both the foil and sterile layer of the blister tray. Using aseptic technique, carefully remove the **Symphony** device from the tray.
- Rehydrate the device prior to placement with sterile saline or Ringer's solution. Do not hydrate for longer than 10 minutes or use a hydration solution exceeding a temperature of 37°C/98°F. The device can be hydrated in the tray if required. Alternatively, the dry device can be placed in the wound and rehydrated. Once placed, the device will transform into a soft conforming sheet.
- Ensure that **Symphony** conforms to the underlying wound bed. Place the device in maximum contact with healthy, well-vascularized tissue for best results.
- **Symphony** can be secured by mechanical means, at the discretion of the physician. If suturing or stapling, ensure that all layers of the device are secured.
- Protect **Symphony** using an appropriate secondary dressing. The overlying dressing should be changed according to standard of care taking into account the level of exudate.
- To protect **Symphony** from adhering to the secondary dressing, consider applying a non-adherent dressing over the device to help protect the tissue while facilitating an optimal moist wound healing environment.

3. **Reapplication**

- **Symphony** is incorporated into the wound over time.
- Carefully cleanse the wound in accordance with established procedures. It is not necessary to remove residual **Symphony**.
- Reapply **Symphony** as needed, until the wound has re-epithelialized. Duration of treatment is determined by the physician and depends upon the wound type and conditions.
- Change the cover dressings as needed and when **Symphony** is reapplied.

Symbols

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 resterilize
	5.2.8	Do not use if packaging is damaged
	5.2.14	Single sterile barrier system with protective packaging outside