Organogenesis

PuraPly® AM

Antimicrobial Wound Matrix

# PuraPly® Antimicrobial Wound Matrix

**Description**

PuraPly Antimicrobial Wound Matrix is a cross-linked extracellular matrix (ECM) scaffolding that consists of a collagen sheet coated with 0.1% polyhexamethylenebiguanide hydrochloride (PHMB) intended for the management of wounds. PuraPly Antimicrobial Wound Matrix is supplied dry in sheet form. The device is packaged in sterile, sealed single pouches. The device is white to off white in color. Variability in the appearance across the surface and in the level of translucency is normal for this native collagen tissue matrix.

**Indications**

PuraPly Antimicrobial Wound Matrix is indicated for the management of wounds and as an effective barrier to resist microbial colonization within the device and reduce microbes penetrating through the device. PuraPly Antimicrobial Wound Matrix is indicated for the management of:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled/undermined wounds
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, second- degree burns, skin tears)
- Draining wounds

**This device is intended for one-time use. The device is intended for single patient use only. Do not reuse.**

**Contraindications**

- PuraPly Antimicrobial Wound Matrix is derived from a porcine source and should not be used in patients with known sensitivity to porcine materials.
- PuraPly Antimicrobial Wound Matrix is not indicated for use in third degree burns.
- Do not use on individuals with a known sensitivity to polyhexamethylenebiguanide hydrochloride (PHMB).

**Precautions**

- **Do not resterilize**. Discard all open and unused portions of PuraPly Antimicrobial Wound Matrix.
- PuraPly Antimicrobial Wound Matrix is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- PuraPly Antimicrobial Wound Matrix must be used prior to the expiration date.
- Discard PuraPly Antimicrobial Wound Matrix if mishandling has caused possible damage or contamination.
- PuraPly Antimicrobial Wound Matrix should not be applied until excessive exudate, bleeding, acute infection and significant swelling are controlled.

**Potential Complications**

The following are possible with the use of PuraPly Antimicrobial Wound Matrix. If any of these conditions occur, PuraPly Antimicrobial Wound Matrix should be removed.

- Worsening Infection
- Chronic inflammation (Initial application of PuraPly Antimicrobial Wound Matrix may be associated with transient, mild, localized inflammation)
- Allergic reaction
- Excessive redness, pain, swelling or blistering

**Instructions for Use**

***Note:*** *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.*

**CAUTION: Federal (U.S.A) law restricts this device to sale by or on the order of a physician or properly licensed practitioner.**

PuraPly Antimicrobial Wound Matrix can be applied from the onset and for the duration of the wound, with subsequent application at the discretion of the health care practitioner. PuraPly Antimicrobial Wound Matrix will naturally be broken down and resorbed into the wound and is not intended to be removed.

**Always handle PuraPly Antimicrobial Wound Matrix using aseptic technique.**

1. Prepare wound area using standard methods to ensure wound is free of debris and necrotic tissue. If necessary, surgically debride the wound to ensure the wound edges contain viable tissue.
2. To apply, cut PuraPly Antimicrobial Wound Matrix to the outline of the wound area. If the wound is larger than a single PuraPly Antimicrobial Wound Matrix, then multiple PuraPly Antimicrobial Wound Matrix may be used. Overlap adjoining PuraPly Antimicrobial Wound Matrix to provide coverage of the entire wound. For ease of handling apply PuraPly Antimicrobial Wound Matrix by placing in a dry state over the wound and rehydrate the sheet using sterile saline or other isotonic solution.
3. Place the edge of PuraPly Antimicrobial Wound Matrix in contact with the intact tissue. Smooth PuraPly Antimicrobial Wound Matrix into place to ensure it is in contact with the underlying wound bed. Anchor PuraPly Antimicrobial Wound Matrix using preferred fixation method such as sutures or adhesive strips. The optimal fixation method is determined by wound location, size, depth and user preference.
4. Apply a non-adherent dressing followed by a secondary dressing as appropriate for the type and stage of wound.

**NOTE: If excess exudate collects under PuraPly Antimicrobial Wound Matrix, small openings can be cut in PuraPly Antimicrobial Wound Matrix to allow the exudate to drain.**

**IMPORTANT:** After application, use an appropriate, non-adherent dressing to maintain a moist wound environment. The optimal secondary dressing is determined by wound location, size, depth and user preference. Change the secondary dressing as needed to maintain a moist, clean wound area. Take care to avoid removing PuraPly Antimicrobial Wound Matrix when the secondary dressing is changed. Frequency of secondary dressing change will be dependent upon volume of exudate produced and type of dressing used. PuraPly Antimicrobial Wound Matrix is not intended to be removed. PuraPly® Antimicrobial Wound Matrix will gradually resorb and may form into a caramel-colored gel. As healing occurs, do not forcibly remove PuraPly Antimicrobial Wound Matrix that adheres to the wound. The wound should be reevaluated on a weekly basis. Subsequent application of PuraPly Antimicrobial Wound Matrix is at the discretion of the health care practitioner.

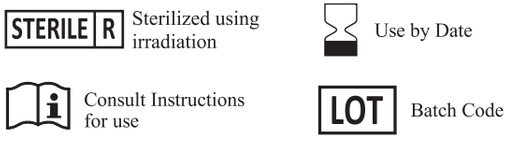
**Storage**

Do not freeze or expose to excessive heat.

**Sterilization**

PuraPly Antimicrobial Wound Matrix has been sterilized with gamma irradiation.

**Symbols Used on Labeling**

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