Organogenesis

PuraPly® AM

Antimicrobial Wound Matrix

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Description

PuraPly® Antimicrobial Wound Matrix 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 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 intended 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

The device is intended for single patient use only. Do not reuse.

Contraindications

- This device is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.
- The device 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.
- Device is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- The device must be used prior to the expiration date.
- Discard device 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 complications are possible with the use of the device. If any of these conditions occur, the device should be removed.

- Worsening infection
- Chronic inflammation (Initial application of the device 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.

The product can be applied from the onset and for the duration of the wound, weekly or at the discretion of the health care practitioner.

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 the dry sheet to the outline of the wound area. If the wound is larger than a single sheet, then multiple sheets may be used. Overlap adjoining sheets 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 the sheet in contact with the intact tissue. Smooth PuraPly® Antimicrobial Wound Matrix into place to ensure the sheet is in contact with the underlying wound bed. The sheet may be fixed to the wound using sutures or other fixation method. The optimum fixation method is determined by wound location, size, depth and user preference.

4. Apply a non-adherent dressing followed by secondary dressings as appropriate for the type and stage of wound.

NOTE: If excess exudate collects under the sheet, small openings can be cut in the sheet to allow the exudates to drain.

IMPORTANT: After application, use an appropriate, non-adherent dressing to maintain a moist wound environment. The optimum 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. Frequency of secondary dressing change will be dependent upon volume of exudate produced and type of dressing used. As healing occurs, sections of PuraPly® Antimicrobial Wound Matrix may gradually peel and may be removed during dressing changes. Do not forcibly remove sections of PuraPly® Antimicrobial Wound Matrix that may adhere to the wound. Alternatively, the PuraPly® Antimicrobial Wound Matrix may form into a caramel-colored gel, which can be rinsed away with gentle irrigation. On inspection, if PuraPly® Antimicrobial Wound Matrix is no longer covering the wound, place an additional piece of PuraPly® Antimicrobial Wound Matrix over the wound. The wound should be reevaluated on a weekly basis for PuraPly® Antimicrobial reapplication.

Storage

Do not freeze or expose to excessive heat.

Sterilization

This device has been sterilized with gamma irradiation.

Symbols Used on Labeling

STERILE R	Sterilized using irradiation		Use by date
	Consult instructions for use	LOT	Batch Code

Manufactured and Distributed by:

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