

Description

PuraPly® Micronized Wound Matrix consists of micronized porcine collagen intended for the management of wounds. PuraPly® Micronized Wound Matrix is supplied as a dry powder, particle size of $\leq 1000\mu\text{m}$. The device is sterile and packaged in a vial sealed in a single pouch.

Indications

PuraPly® Micronized Wound Matrix is intended for the management of wounds that include:

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

The device is intended for single patient use only.

Do not reuse. Do not implant.

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.

Precautions

- **Do not re-sterilize.** Discard all open and unused portions of PuraPly® Micronized 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® Micronized 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 this device. If any of these conditions occur, the device should be removed.

- Worsening infection
- Chronic inflammation (Initial application of 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 sell by or on the order of a physician or properly licensed practitioner.

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

Always handle PuraPly® Micronized 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. Using aseptic technique, open device outer pouch and remove container. Uncap container and lightly apply product over the desired wound area. Product can be poured directly from the container. If the wound is larger than a single device can cover, then multiple devices may be used.
3. Alternatively, PuraPly Micronized Wound Matrix can be hydrated with sterile solution to form a paste to aid in the application of the device where the location or geometry of the wound may make it difficult to apply the dry product. Hydration can be performed by transferring the product into an appropriately sized sterile container. Slowly add sterile solution until the desired consistency is obtained and then apply directly to the wound bed.

CAUTION: Do not tap or bang on the container to recover product.

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

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® Micronized Wound Matrix may gradually flake and may be removed during dressing changes. Do not forcibly remove PuraPly® Micronized Wound Matrix that may have adhered to the wound. Alternatively, the PuraPly® Micronized Wound Matrix may form into a caramel-colored gel, which can be rinsed away with gentle irrigation. On inspection, if PuraPly® Micronized Wound Matrix is no longer covering the wound, apply additional PuraPly® Micronized Wound Matrix over the wound. The wound should be reevaluated on a weekly basis for PuraPly Micronized reapplication.

Note: The device use should not be used for greater than 30 days in total.

Storage

Do not freeze or expose to excessive heat.

Sterilization

This device has been sterilized with gamma irradiation.

Symbols used on labeling



Sterilized using Irradiation



Use by date



Batch Code



Consult instructions for use

Manufactured and Distributed by:

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Empowering Healing

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