US Pat No. 6,576,265; 6,849,273; 6,861,074

AUS Pat No. 777652

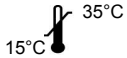
EU Pat No. 1239897; 1428540; 1749543

JPN Pat No. 3824537 ; 4942908



IFU-MM-001.2 09/2016

**SYMBOLS**

| | |
|---|---|
|  | Manufacturer |
|  | Catalogue Number |
|  | Batch Code |
|  | Quantity |
|  | Serial Number |
|  | Use By |
|  | Consult Instructions for Use |
|  | Do Not Reuse |
|  | Do Not Resterilize |
|  | Sterilized Using Irradiation |
|  | Temperature Limit |
|  | U.S. Prescription Device |
|  | Do Not Use If Package Is Damaged |

6640 Eli Whitney Drive
Columbia, MD 21046
US Toll-Free: 1-800-826-2926
www.acell.com


# MicroMatrix®

## INSTRUCTIONS FOR USE


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

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.

## DEVICE DESCRIPTION

MicroMatrix® is composed of a porcine-derived extracellular matrix known as urinary bladder matrix. The devices are supplied in a particle form in masses up to 1000mg, and packaged in a glass vial and a peel -open pouch. The devices are terminally sterilized using electron beam irradiation.

## INDICATIONS

MicroMatrix is intended for the management of topical wounds including: 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) and draining wounds. The device is intended for one-time use.

## CONTRAINDICATIONS

- Patients with known sensitivity or allergy to porcine materials.
- Third-degree burns.

## WARNINGS

1. If active infection is present, treat patient to resolve infection prior to device implantation.
2. Do not re-use or re-sterilize; can damage the device and lead to device failure and/or patient injury.
3. Do not use after printed expiration date.
4. Do not use if package is compromised, which may indicate loss of device sterility.
5. Do not use device if cracked, broken or otherwise damaged.

## PRECAUTIONS

1. Do not tap glass vial with metal objects or handle in a way that may cause glass to break and contaminate wound.

## STORAGE

Store in a clean, dry environment between 15-35°C (59-95°F) in unopened and undamaged package. Protect from freezing, excessive heat, and high humidity.

## POTENTIAL COMPLICATIONS

Complications and reactions are possible with any soft tissue repair, including but not limited to: infection, increased chronic inflammation, allergic reaction, unexplained fever or chills, excessive redness, pain or swelling.

If there is an adverse event, remove remaining device and inspect wound, and report the event to ACell:
US Toll-Free: 1-800-826-2926

## STERILIZATION

MicroMatrix® devices are supplied sterile by electron beam irradiation in a glass vial and a peel-open package. Device is sterile if package is unopened and undamaged.

## DEVICE APPLICATION

**The following procedures only serve as a suggested guideline for the application of MicroMatrix. The provided suggestions are not intended to supersede internal institutional protocols and sound clinical judgment.**

1. Clean wound bed and irrigate to remove exudate and debris.
2. Perform standard debridement procedures in line with internal institutional protocols.
3. Using standard aseptic/sterile technique, open device outer pouch and remove device from inner pouch.
4. Apply device directly to the wound bed, lightly covering the entire wound. Product can be poured directly from the container. Alternatively, MicroMatrix can be hydrated with sterile saline 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 device. Slowly add sterile saline until desired consistency is obtained

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

**CAUTION**: Discard any unused portions of device.

**NOTE:** If using a wound dressing sheet of similar composition (such as Cytal™ devices), in conjunction with MicroMatrix, apply MicroMatrix directly to wound prior to applying the sheet as described in the corresponding Instructions for Use.

5. Cover device with non-adherent dressing. Secure dressings to wound site.

   **Wet Wound** - Apply an absorptive dressing. Secure dressings to wound site.

   **Dry Wound** - Apply a hydrogel dressing to keep wound moist. Secure dressings to wound site.

## WOUND CARE MANAGEMENT

**The following procedures only serve as a suggested guideline for the management of treated wounds. The provided suggestions are not intended to supersede internal institutional protocols and sound clinical judgment.**

1. Inspect primary dressing approximately every other day.

   - Remove exudate and apply new device to any non-covered wound areas as necessary.
   - During new device application, cover device with a new and appropriate secondary dressing, as described above.

2. Change all secondary dressings as appropriate for the wound type.

   - During secondary dressing changes, do not remove any remaining device that is present on wound surface.
   - As device is resorbed and incorporated, it may form a caramel-colored gel and emit a pungent odor.

3. Rinse wound surface gently leaving any existing caramel-colored gel on wound surface.

4. Repeat wound care management process every other day until wound has epithelialized or until desired wound state is achieved.

**NOTE**: Maintain moist wound environment throughout wound care management procedures.