US Pat. 6,576,265; 6,849,273; 6,861,074; 6,890,564; 6,887,495; 9,265,860; 9,433,701

AU Pat. 777,652; 2005200350

CA Pat. 2,393,468

CN Pat. 200920004482.2

EU Pat. 1239897

JP Pat. 3824537; 4942908

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LBL-1001.0

REF MM0020; MM0030; MM0060; MM0100; MM0100F; MM0200; MM0200F; MM0500; MM1000

SYMBOLS GLOSSARY

	Title of Symbol/ Explanatory Text	ISO 7000 Reference Number
LOT	Batch Code	2492
REF	Catalogue Number	2493
	Consult Instructions for Use	1641
	Do Not Re-sterilize	2608
	Do Not Reuse	1051
	Do Not Use if Package is Damaged	2606
	Manufacturer	3082
SN	Serial Number	2498
STERILE R	Sterilized Using Irradiation	2502
	Use By Date	2607

Above symbols conform with the following standards:

ISO 15223 — 1:2012 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

ISO 7000 — Graphical symbols for use on equipment — Registered symbols

MicroMatrix®

INSTRUCTIONS FOR USE

Rx Only

ACell, Inc.
6640 Eli Whitney Drive
Columbia, MD 21046
www.acell.com
800-826-2926
MADE IN USA

DEVICE DESCRIPTION

MicroMatrix® is composed of a porcine-derived extracellular matrix known as urinary bladder matrix. The device is supplied in a particle form in units up to 1000mg and packaged in a glass vial and peel-open pouch. The device is 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

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

WARNINGS

1. If active infection is present, treat patient to resolve infection prior to device application.
2. Do not use glass vial if cracked, broken, or otherwise damaged.

PRECAUTIONS

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 at room temperature 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.

Any adverse reaction should be reported to ACell:
US Toll-Free: 1-800-826-2926

STERILIZATION

MicroMatrix device is supplied sterile by electron beam irradiation in a glass vial and a peel-open pouch. Device is sterile if device pouch is unopened and undamaged.

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

DEVICE APPLICATION

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 pouch and remove glass vial. Carefully open the glass vial.
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

1. Inspect primary dressing at least every 7 days.

   - 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.