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www.acell.com/patents

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REF WSR0505, WSR0710, WSR1015,
WSR1625; WSR1635

SYMBOLS GLOSSARY		
The below symbols conform with the following standards:		
ISO 15223 —1:2016 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		
Title of Symbol/ Explanatory Text	ISO 7000 Reference	
 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
	Non- Pyrogenic	2724
	Open Here	3079
 SN	Serial Number	2498
	Sterilized Using Irradiation	2502
	Use By Date	2607
Rx Only	CAUTION! Federal (US) law restricts this device to sale by or on order of a licensed healthcare practitioner.	21 CFR 801

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Cytal®

Wound Matrix 3-Layer
INSTRUCTIONS FOR USE

Rx Only

 ACell, Inc.
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www.acell.com
800-826-2926
MADE IN USA

 **ACELL®**

DEVICE DESCRIPTION

Cytal® Wound Matrix 3-Layer is composed of a porcine-derived extracellular matrix also known as urinary bladder matrix. The devices are supplied in a fenestrated sheet configuration in sizes up to 16 cm x 35 cm and packaged in double peel-open pouches. The devices are terminally sterilized using electron beam irradiation.

INDICATIONS

Cytal Wound Matrix 3-Layer is intended for the management of 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. Exposure to contaminated or infected field can lead to rapid breakdown of device.
2. If active infection is present, treat patient to resolve infection prior to device application.
3. Do not use if cracked, broken, or otherwise damaged.

PRECAUTIONS

Always use aseptic technique when handling device.

STORAGE

Store in a clean, dry environment at room temperature in unopened and undamaged package. Protect from freezing, excessive heat, and high humidity.

STERILIZATION

Cytal devices are supplied sterile by electron beam irradiation in double peel-open pouches. Device is sterile if device pouch is unopened and undamaged.

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

The following procedures only serve as a suggested guideline for the management of wounds with Cytal Wound Matrix 3-Layer. 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 pouches and remove device from inner pouch.
4. Hydrate device in a sterile dish with room temperature sterile saline (0.9%) or sterile lactated Ringer's solution prior to use.
Minimum hydration time: 5 min
Maximum hydration time: 60 min
5. Cut device to the desired size, ensuring complete wound coverage.

NOTE: If using MicroMatrix® in conjunction with a Cytal device, apply MicroMatrix directly to wound as described in the corresponding Instructions for Use prior to applying the Cytal device.

6. Apply device directly to the wound bed.

Large Wound - More than one device may be necessary to obtain complete coverage. Overlap device edges slightly to assure coverage of entire wound.

NOTE: Place epithelial basement membrane side of device away from defect.

Figure 1 shows the fenestration pattern for devices up to 10x15 cm, and Figure 2 shows the fenestration pattern for devices 16 x 25 cm and larger.

When sidedness indicator (notch) is in location shown in Figure 1 & Figure 2, epithelial basement membrane side of device is facing up.

Additionally for device sizes 16 x 25 cm and 16 x 35 cm only (Figure 2), epithelial basement membrane side of device is facing up when the arrow fenestration pattern is pointing to the upper right.



Figure 1

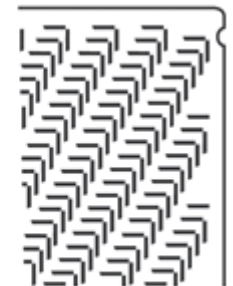


Figure 2

7. 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.

8. Discard any unused portion of the device.

NOTE: Keep device and wound bed moist.

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 weekly until wound has epithelialized or until desired wound state is achieved.

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