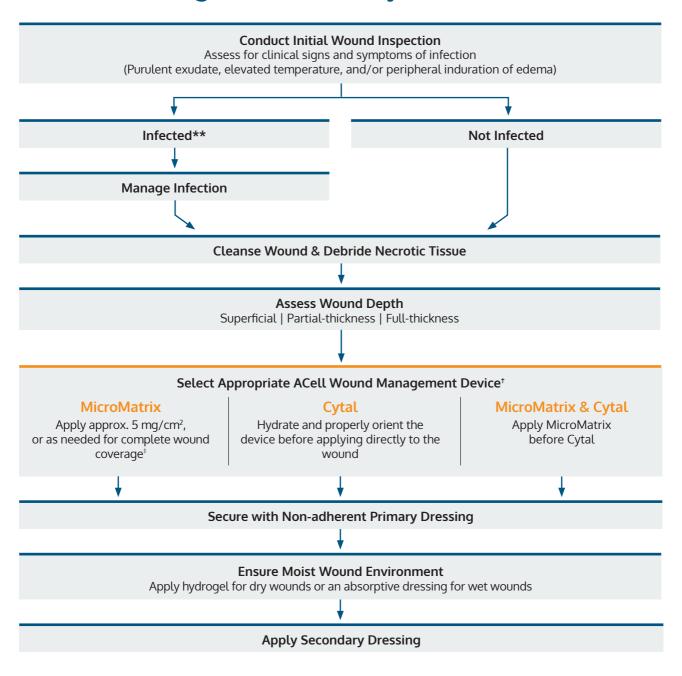


Cytal®/MicroMatrix®

Product Usage & Application Guide



Wound Management with Cytal and MicroMatrix



Selecting Which Device to Use

Intended to provide tailored wound management options for your patient, ACell's comprehensive product portfolio offers devices in multiple sizes and thicknesses. Use the following guide to help you select the device best suited for your patient's case[†]. For specific questions, please contact your ACell Representative.

Determine Device Size

The following is a general guideline to assist you in determining the amount of product needed for your patient. More product may be needed depending on the complexity and depth of the wound, as well as your follow up care plan.

Cytal® Wound Matrix MicroMatrix[®] Divide the surface area of the wound by the total sheet Use approximately 5 mg per cm² for complete wound area (below). bed coverage[‡]. • $3 \times 3.5 \text{ cm} = 10.5 \text{ cm}^2 \text{ coverage}$ • $100 \text{ mg} \approx 20 \text{ cm}^2 \text{ coverage}$ 200 mg ≈ 40 cm² coverage $5 \times 5 \text{ cm} = 25 \text{ cm}^2 \text{ coverage}$ $7 \times 10 \text{ cm} = 70 \text{ cm}^2 \text{ coverage}$ $500 \text{ mg} \approx 100 \text{ cm}^2 \text{ coverage}$ $10 \times 15 \text{ cm} = 150 \text{ cm}^2 \text{ coverage}$ • 1,000 mg \approx 200 cm² coverage $16 \times 25 \text{ cm} = 400 \text{ cm}^2 \text{ coverage}$ $16 \times 35 \text{ cm} = 560 \text{ cm}^2 \text{ coverage}$

Determine Device Thickness

The thicker the device, the longer it will persist in the wound bed. Having a longer persistence may be advantageous for deep wounds with more tissue loss. Thicker devices will take longer to resorb and may reduce the need for multiple applications and dressing changes. Thinner devices may be advantageous for superficial wounds, providing conformability with shorter resorption times.

Tip

When using concomitantly, apply MicroMatrix before you apply the Cytal Wound Matrix sheet. MicroMatrix will fit into irregular, tunneling, and undermining wound bed surfaces, and resorb faster than the Cytal sheet device.

Product	Configuration (Thickness)	 rsistence in Wound Bed	Wound Depth	Potential Examples of Wound Types*
MicroMatrix	Particulate	Shortest	Superficial to deep, full-thickness wounds	Irregular, tunneling, and undermining wounds
Cytal Wound Matrix	1-Layer Sheet		Superficial to partial-thickness wounds	Donor site repairs
Cytal Wound Matrix	2-Layer Sheet		Deep, partial-thickness wounds and second degree burns	Surgical resection
Cytal Wound Matrix	3-Layer Sheet		Full-thickness wounds	Traumatic wounds with exposed bone, tendon, hardware
Cytal Wound Matrix	6-Layer Sheet	Longest	Full-thickness wounds	Stage III & IV pressure injuries with exposed avascular structures

^{*} Refer to the approved device labeling IFU (instructions for use) for the full list of wound indications. The list of potential examples of wound types in the chart above is for guidance, however, it is the responsibility of the treating health care provider to determine which configuration(s) are ultimately used based upon his/her medical judgment.

Applying Cytal and MicroMatrix

Note: Refer to the approved device labeling IFU (instructions for use) for the full list of wound indications.



1. Wound Bed Preparation**

Before using ACell's wound management devices, the wound must first be debrided of necrotic or non-viable tissue and any infection must be managed.



2. Device Preparation

MicroMatrix

The product may be applied dry or may be mixed with saline to form a paste. A paste may be helpful for wounds that are difficult to access or where dry application would not be possible. To hydrate, slowly add sterile saline until desired consistency is obtained.

Cytal

Hydrate the device(s) with room temperature, sterile saline or Ringer's solution.

- Cytal 1- or 2-Layer approximately 2 minutes to hydrate
- Cytal 3- or 6-Layer approximately 5 minutes to hydrate

Note: Cytal sheets may be cut to fit irregular shaped wounds prior to hydrating the device.



3. Device Orientation

Cvtal

When the notched edge is in the upper right corner, the smooth basement membrane side of the device is facing up. Place the basement membrane side facing up and the lamina propria side on the wound.

Note: Device orientation is not applicable for Cytal 1-Layer sheets due to faster resorption rate.

How to Properly Open the MicroMatrix Cap



- 1. Lift the edge of the inset circle tab at the back of the arrow.
- 2. Pull the blue metal tab in the direction of the arrow.
- 3. While pulling the tab down the side of the cap, gently pull to the right and around the rim.
- 4. Discard the cap and remove the rubber stopper. Excess product may be trapped in the rubber stopper. The vials are slightly overfilled to account for any product loss due to packaging.

Note: Do not tap the vial with metal objects or handle it in a way that may cause the glass to break.







4. Device Application

MicroMatrix

Apply the powder or paste directly to the wound bed, covering the entire wound with an even distribution of product. Always apply MicroMatrix first if also using Cytal.

Cytal

Apply the device(s) directly to the wound. Excess product that overlaps healthy tissue may be left in place. Cytal may be secured by sutures, staples, or steristrips, if necessary.

Note: For large wounds, more than one Cytal sheet may be necessary to obtain complete coverage. Slightly overlap device edges to ensure complete wound coverage.





5. Wound Dressing

Primary Dressing

Cover the device(s) with a non-adherent dressing. The dressing may be sutured or stapled in place to protect the device. If the wound is dry or in an area that is prone to dryness, apply a moisture-adding dressing such as hydrogel to sufficiently hydrate the wound. If the wound is heavily exudative, apply an absorptive dressing on top of the non-adherent dressing.

Secondary Dressing

Secure the primary dressing in place with a secondary dressing that will bolster and protect the wound.

How to Manage the Wound Post-device Application

- In accordance with the IFUs, inspect the wound/primary dressing at least every 7 days when using Cytal (alone) or Cytal and MicroMatrix (concomitantly). Inspect the wound/primary dressing every 2-7 days when using MicroMatrix only.
- The wound may have an unpleasant odor and form a caramel-colored gel as the product absorbs into the wound.
- Keep the wound area moist throughout the healing process.
- · During dressing changes, gently rinse the wound surface to remove exudate, but leave the caramel-colored gel intact.
- As needed, reapply product to areas where the device is no longer visible and further remodeling is desired.
- · Repeat the wound care follow up process as needed until the wound has epithelialized or desired outcome has been achieved.

Cytal Wound Matrix and MicroMatrix are engineered using ACell's proprietary MatriStem UBMTM (Urinary Bladder Matrix) technology, which has been shown to facilitate the body's ability to remodel site-appropriate tissue. The fully resorbable, porcine-derived UBM devices are designed to work independently or together to offer a wide range of treatment options for partial- and full-thickness wounds.





MicroMatrix



20 mg	MM0020
30 mg	MM0030
60 mg	MM0060
100 mg	MM0100
100 mg (fine)	MM0100F
200 mg	MM0200
500 mg	MM0500
1000 mg	MM1000

Cytal Wound Matrix 1-Layer



3 x 3.5 cm	WS0303
3 x 7 cm	WS0307
7 x 10 cm	WS0710
10 x 15 cm	WS1015

Cytal Wound Matrix 2-Layer



5 x 5 cm	WSM0505
7 x 10 cm	WSM0710
10 x 15 cm	WSM1015

Cytal Wound Matrix 3-Layer



5 x 5 cm	WSR0505
$7 \times 10 \text{ cm}$	WSR0710
10 x 15 cm	WSR1015
16 x 25 cm	WSR1625
16 x 35 cm	WSR1635

Cytal Wound Matrix 6-Layer



5 x 5 cm	WSX0505
7 x 10 cm	WSX0710
10 x 15 cm	WSX1015

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This is a suggested guideline for wounds managed with ACell wound devices. The provided suggestions are not intended to supersede internal institutional protocols and sound clinical judgment.



^{**} If active infection is present, treat patient to resolve infection prior to device application.

[†] The decision of which techniques or products to use in a particular clinical application lies with the physician based on patient profile, particular circumstances surrounding the procedure, and previous clinical experiences.

[‡] Based on Cytal® Wound Matrix 1-Layer device particulate mass conversion and safety data on file (TP-0012). Product usage quantity is a recommendation only and does not reflect wound depth, which may adjust product need.