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
Cytal™ Burn Matrix is composed of a porcine-derived extracellular matrix also known as urinary bladder matrix. The device is supplied in a multi-layer sheet configuration in sizes up to 10 cm x 15 cm and packaged in double peel-open pouches. The device is terminally sterilized using electron beam irradiation.

INDICATIONS
Cytal Burn Matrix is intended for the management of wounds including: second-degree burns, 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, 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.

PRECAUTIONS
- Do not re-use or re-sterilize.
- Do not use after printed expiration date.
- Do not use device if package seal has been broken.
- Exposure to contaminated or infected field can lead to rapid breakdown of device.
- If active infection is present, treat patient to resolve infection prior to device use.

WARNINGS
- Do not use if cracked, broken, or otherwise damaged.

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

DEVICE APPLICATION
The following procedures only serve as a suggested guideline for the application of Cytal Burn Matrix. 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. 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: 2 min
   Maximum hydration time: 45 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. When sidedness indicator (notch) is in location shown in image, epithelial basement membrane side of device is facing up.

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

NOTE: Keep device and wound bed moist.

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

1. Inspect primary dressing approximately every 5-7 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. Inspect secondary dressings daily and change dressings as appropriate for the wound type.
   - During secondary dressing changes, do not remove any remaining device that is intact 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 intact.
4. Repeat wound care management process weekly until wound has epithelialized or until desired wound state is achieved.

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

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.