Microlyte® MATRIX

INSTRUCTIONS

DESCRIPTION: Microlyte® Matrix is a sterile, single use absorbent polymeric wound matrix composed primarily of bioresorbable polyvinyl alcohol with a polymeric surface coating containing ionic and metallic silver. It has very low amounts of silver, with a maximum of 0.16 mg/in^2.

MECHANISM OF ACTION: Microlyte® Matrix absorbs wound fluid and forms a soft matrix that conforms to the wound surface and maintains a moist environment. The matrix contains silver only to prevent or minimize microbial growth within the matrix.

INTENDED USE: Under the direction of a healthcare professional, Microlyte® Matrix may be used for partial and full thickness pressure ulcers, venous stasis ulcers, diabetic ulcers, first and second-degree burns, abrasions and lacerations, donor sites and surgical wounds. Microlyte® Matrix may be used over debrided and grafted partial thickness wounds.

INDICATIONS FOR USE:

Under the supervision of a healthcare professional, Microlyte® Matrix may be used for the management of:

- Wounds,
- Partial and full thickness wounds including pressure ulcers, venous stasis ulcers, diabetic ulcers, first and second-degree burns, abrasions and lacerations, donor sites and surgical wounds,
- May be used over debrided and grafted partial thickness wounds.

DIRECTIONS FOR USE:

- Clean the wound area using sterile saline solution.
- If the wound is dry, moisten it with sterile saline and remove excess saline with sterile gauze.
- Avoid contact with wet surfaces until placed on a moist wound bed.
- Cut Microlyte® Matrix to size slightly larger than the wound. Multiple sheets can be used to cover the entire wound area.
- Apply Microlyte® Matrix directly to wound bed. When placed on a moist wound bed, the matrix conforms to the wound bed. Mechanical fixation of Microlyte® Matrix may be accomplished with the physician's choice of fixation, if necessary.
- Microlyte® Matrix should be covered with a non-adherent dressing. Cover with a moisture retentive dressing such as, a film dressing, foam dressing, or other appropriate dressing. See individual cover dressing package insert for complete instructions for use. All dressing site areas should be inspected daily.
- Microlyte® Matrix can be applied from the onset and for the duration of the wound, every 3 days or at the discretion of the health care practitioner depending on the wound and the healing progression, or when clinically indicated (e.g. leakage, excessive bleeding, increased pain).
- The wound should be re-evaluated on a weekly basis.
- To reapply, carefully remove the cover dressing(s). Gently irrigate wound with sterile saline to remove necrotic tissue. It is not necessary to remove any residual Microlyte® Matrix observed during cover dressing changes.
- Change the cover dressing as needed or when Microlyte® Matrix is reapplied.
- Duration of treatment depends on wound type and healing conditions.

PRECAUTIONS FOR USE:

- Warning: Frequent or prolonged use of this product may result in permanent discoloration of skin.
- Warning: Avoid use with iodophor containing products that may reduce the effectiveness of silver in the dressing.

Imbed BIOSCIENCES

- The wound should be inspected during cover dressing changes. Consult a healthcare professional if you see (a) signs of infection (increased pain, increased redness, wound drainage), (b) bleeding, (c) a change in wound color and/or odor, (d) irritation (increased redness and/or inflammation), (e) maceration (skin whitening), (f) hyper-granulation (excessive tissue formation), (g) sensitivity (allergic reaction), (h) no signs of healing.
- Cover dressings should be used as stated in the "Directions for Use" section.
- Microlyte® Matrix should not be used with other wound care products other than those listed in the "Directions for Use" section without first consulting a healthcare professional.
- This product contains <1.1 mg/in^2 polyethylene glycol (400 Da).

For pressure ulcers, venous stasis ulcers, diabetic ulcers, first-and second-degree burns, donor sites, skin grafts and surgical wounds:

- Treatment of wounds listed above should be under the supervision of a healthcare professional.
- Appropriate supportive measures should be taken where indicated. For example, use of graduated compression in the management of venous leg ulcers, or pressure relief measures in the management of pressure ulcers, systemic antibiotics and frequent monitoring in the treatment of wound infection, control of blood glucose for diabetic ulcers, etc.

SAFETY & EFFECTIVENESS: Preclinical testing has been performed on Microlyte® Matrix and its biocompatibility has been demonstrated through appropriate in vitro and in vivo tests, including cytotoxicity, acute systemic toxicity, subacute/sub-chronic toxicity, acute intracutaneous reactivity, skin sensitization, and tissue implantation tests. Sustained antimicrobial activity for up to 3 days has been demonstrated by relevant standard in vitro microbiological assays in simulated wound fluid. Microlyte® Matrix was shown to be effective in killing more than 4 log10 CFUs of microbes most frequently associated with wound infections, including, *S. aureus* (ATCC 6538), MRSA (ATCC 33591), VRE (ATCC 55175), *P. aeruginosa* (ATCC 9027), *E. coli* (ATCC 8739), *K. pneumoniae* (ATCC 4352), *C. tropicalis* (ATCC 750) and *C. albicans* (ATCC 10231). The product has been determined to be non-pyrogenic.

CONTRAINDICATIONS: Do not use on individuals who are sensitive to silver or who have had an allergic reaction to Microlyte® Matrix or one of its components.

STORAGE CONDITIONS: Store at room temperature (15°C/59°F – 30°C/86°F). Keep dry. If further information is needed, please contact Imbed Biosciences Inc.

HOW SUPPLIED: Microlyte® Matrix is individually packaged in foil pouches. Sterilization by E-beam radiation. Do not use if the sterile barrier system is compromised

Single use only.

MANUFACTURED BY Imbed Biosciences, Inc.
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Made in USA

EXPLANATION OF SYMBOLS

LOT	Batch code		Do not use if package is damaged
REF	Part number		Use by date
	Caution, consult documentation	15°C 30°C	Store between 15°C/59°F and 30°C/86°F
STERILE R	Sterilized using e-beam radiation	LATEX	Latex-free
	Re-use is not allowed		Manufacturer
Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner		Non-pyrogenic

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