

MicroLyte AG

Wound Dressing

INSTRUCTIONS

2" x 2" (5cm x 5cm)



MicroLyte™ AG Wound Dressing

DESCRIPTION: MicroLyte™ Ag wound dressing is a sterile, single use unsupported synthetic absorbent polyvinyl alcohol hydrogel sheet with a polymeric surface coating containing ionic and metallic silver. It has very low amounts of silver, with a maximum of 0.4 mg of silver in a 2 inch x 2 inch dressing, equivalent to 0.1 mg/sq. inch.

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

INTENDED USE: MicroLyte™ Ag wound dressing is indicated for the management of wounds and can be used over-the-counter for minor wounds such as abrasions and lacerations, minor cuts, and minor scalds and burns. Under the direction of a healthcare professional, MicroLyte™ Ag may be used for more serious wounds such as 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™ Ag wound dressing may be used over debrided and grafted partial thickness wounds.

INDICATIONS FOR USE: *Under the supervision of a healthcare professional, MicroLyte™ Ag wound dressing 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 the dressing to size slightly larger than the wound. Multiple sheets can be used to tile the entire wound area.
- Apply the dressing directly to wound bed. When placed on a moist wound bed, the dressing forms a soft conforming sheet.
- This primary dressing should be used with a secondary cover dressing. Cover with a moisture retentive dressing, such as, a film dressing, foam dressing, wet-to-dry gauze or other appropriate dressing. See individual cover dressing package inserts for complete instructions for use.
- All wounds should be inspected daily.
- Reapply MicroLyte™ Ag dressing every 3 days, depending on the wound and the healing progression, or when clinically indicated (e.g. leakage, excessive bleeding, increased pain).

- To reapply, carefully remove the secondary cover dressing. Microlyte Ag is normally removed with the secondary cover dressing. Any remaining Microlyte™ Ag will be removed with normal wound cleansing.
- Change the secondary cover dressing as needed or when Microlyte™ Ag is re-applied.
- 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 iodophore containing products that may reduce the effectiveness of silver in the dressing.
- The wound should be inspected during 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) hypergranulation (excessive tissue formation), (g) sensitivity (allergic reaction), (h) no signs of healing.
- Secondary dressings should be used as stated in the “Directions For Use” section.
- This wound dressing 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.

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 granulated 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™ Ag wound dressings. The biocompatibility of the dressing has been demonstrated through appropriate *in vitro* and *in vivo* tests, including cytotoxicity, acute systemic toxicity, subacute/subchronic toxicity, acute intracutaneous reactivity, skin sensitization, and tissue implantation tests. Antimicrobial activity has been demonstrated by relevant standard *in vitro* microbiological assays. Microlyte™ Ag was shown to be effective against microbes most frequently associated with wound infections, including, *Staphylococcus aureus* (ATCC 6538), MRSA (ATCC 33591), VRE (ATCC 55175), *Pseudomonas aeruginosa* (ATCC 9027), *Escherichia coli* (ATCC 8739), *Klebsiella pneumoniae* (ATCC 4352), *Candida tropicalis* (ATCC 750) and *Candida albicans* (ATCC 10231). The product has been determined as being non-pyrogenic.

CONTRAINDICATIONS: Do not use on individuals who are sensitive to silver or who have had an allergic reaction to the dressing 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™ Ag wound dressings are individually packaged in a sterile foil pouch. Supplied in boxes of individually packaged sterile dressings. Sterilization by E-beam radiation. Sterility is guaranteed unless pouch is damaged or opened. Single use only.

REF. 91001 2 inch x 2 inch (5 cm x 5 cm)

MANUFACTURED BY

Imbed Biosciences Inc.

5520 Nobel Dr, Suite 100, Madison, WI 53711

Ph: 608.237.1525 | Fax: 608.237.1271

www.imbedbio.com

Made in USA

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Explanation of symbols



Batch code



Part Number



Caution, consult document



Sterilization using E-beam radiation



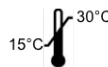
Re-use is not allowed



Do not use if package is damaged



Use by date



Store between 15°C/59°F - 30°C/86°F

Rx Only

Caution: Federal law restricts sale of the device to or on the order of a licensed practitioner



Latex-free



Manufacturer