INTEGRA®

PriMatrix® Ag

Antimicrobial Dermal Repair Scaffold

Instructions for Use

PriMatrix® Ag Antimicrobial Dermal Repair Scaffold

Description
PriMatrix® Ag Antimicrobial is an acellular dermal tissue matrix derived from fetal bovine dermis. The device is supplied sterile in a variety of sizes to be trimmed by the surgeon to meet the individual patient's needs. The Ionic Silver content is intended to prevent microbial colonization of the device.

Ionic silver is a broad spectrum antimicrobial. PriMatrix® Ag Antimicrobial has been shown in CLSI Disc Susceptibility testing to be effective against a range of bacteria, including: Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Methicillin-Resistant Staphylococcus aureus (MRSA), Enterococcus faecium, Klebsiella pneumoniae, Listeria monocytogenes, Vancomycin-Resistant Enterococcus faecalis (VRE), Acinetobacter baumanni, and Streptococcus pyrogenes (Group A).

Indications
PriMatrix® Ag Antimicrobial is intended for the management of wounds that include:
- Partial and full thickness wounds
- Pressure, diabetic, and venous ulcers
- Second-degree burns
- Surgical wounds—donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence
- Trauma wounds —abrasions, lacerations, and skin tears
- Tunneled/undermined wounds
- Draining wounds

Contraindications
- PriMatrix® Ag Antimicrobial should not be used for patients with a known history of hypersensitivity to silver, collagen, or bovine products.
- This device is not indicated for use in third-degree burns.

Warnings and precautions
- Do not expose to chemicals or substances other than sterile, room temperature 0.9% saline.
- Excessive heat can damage collagen. Do not hydrate in 0.9% saline warmed above room temperature. If, when hydrated, the product shrinks in size, DO NOT use the product as it may be damaged.
- PriMatrix® Ag Antimicrobial should be used with caution in regions where an infection exists or is suspected. Treat any existing infection appropriately.
- PriMatrix® Ag Antimicrobial is for single use only. Do not resterilize as this may damage PriMatrix® Ag Antimicrobial.
- Do not use product if past the date of expiration indicated on the product label.
- PriMatrix® Ag Antimicrobial is available in meshed, fenestrated, and solid forms. Meshing of meshed and fenestrated PriMatrix® Ag Antimicrobial is not recommended.
- Silver-containing compounds are known to cause a condition known as argyria, a silver induced darkening of the skin. Frequent or prolonged use of PriMatrix® Ag Antimicrobial may result in skin discoloration.

Potential complications
The following complications are possible. If any of these conditions occur, the device should be removed.
- Infection
- Chronic inflammation
- Allergic reaction
- Excessive redness, pain, swelling, or blistering

PHYSICIANS NOTE: The physician must convey the indications, contraindications, warnings and precautions, and potential complications given in this document to the patient.

Instructions for Use
These suggested instructions are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

- Always handle PriMatrix® Ag Antimicrobial using aseptic techniques.
- Prepare the wound area using standard non-enzymatic methods ensuring that the wound is free of debris and necrotic tissue. An initial debridement of the wound may be necessary to ensure the wound edges contain viable tissue.
- Inspect packaging and reject product if packaging is previously damaged or opened.
- Peel open outer foil package and aseptically deliver inner, sterile package to sterile field.
- Rinse surgical gloves, if necessary, to remove any glove powder prior to touching product.
- Cut PriMatrix® Ag Antimicrobial to the desired size. Multiple pieces may be used.
- For ease of handling, rehydrate PriMatrix® Ag Antimicrobial in room temperature 0.9% sterile saline until hydrated (typically less than one minute). Hydration is indicated by a color change from white (dry) to gray (wet). To facilitate hydration, pressure can be applied with gloved fingers across the surface of the device until PriMatrix® Ag Antimicrobial has a uniform wet appearance.
- Apply directly to the wound, covering the entire wound bed. PriMatrix® Ag Antimicrobial may be secured with mechanical means, if necessary.
- Use an appropriate, non-adherent, secondary dressing(s) to maintain a moist wound environment. Change the secondary dressing(s) as needed to maintain a moist, clean wound area. Do not forcibly remove sections of PriMatrix® Ag Antimicrobial that may adhere to the wound.
- Discard any unused pieces of PriMatrix® Ag Antimicrobial.

Safety

- PriMatrix® Ag Antimicrobial is manufactured from fetal bovine skin, one of the purest sources of collagen available. The source material is processed and solely derived from cattle in compliance with United States and European regulatory requirements.
- PriMatrix® Ag Antimicrobial has been demonstrated MR safe in up to a 3T field.
- PriMatrix® Ag Antimicrobial contains silver at an average per-unit content of up to 165 micrograms/cm2 and releases Ionic Silver.
- Reduction in colonization or microbial growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed.

Storage

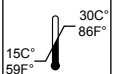
- Store at room temperature: 15 - 30°C (59 - 86°F).
- Keep away from heat sources.
- Keep away from direct sunlight.

How Supplied

- PriMatrix® Ag Antimicrobial is supplied sterile in single use, double-peel packages in a variety of sizes and in meshed, fenestrated, and solid forms.
- As long as the package has not been damaged or opened, the contents are guaranteed sterile and nonpyrogenic.

Appearance
This product, like other silver-containing products, may darken upon storage, after hydration in saline, when exposed to light, or when in contact with body fluids and tissues. This darkening does not affect product performance.

Symbols Used on Labeling

Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner		Do Not Re-Use
	Sterilized using Ethylene Oxide		Do Not Re-sterilize
	Manufacturer		Catalog Number
	Consult Instructions For Use		Lot Number
	Temperature Limitation		Quantity
	Do Not Use if Package is Damaged		Expiration date (YYYY-MM-DD)

Manufactured by:
TEI Biosciences Inc.
7 Elkins Street
Boston, MA 02127 n USA
Tel: (866) 524-0022 n Fax: (888) 623-2259
integralife.com

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