Application Guide for Full Thickness Wounds

PriMatrix®
Dermal Repair Scaffold

PriMatrix® Ag
Antimicrobial Dermal Repair Scaffold
As the manufacturer of this device, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Step 1 • Prepare Viable Wound Bed

Remove all eschar, necrotic, and infected tissue.

The tissue bed and margins should contain skin edges with bleeding dermis, subcutaneous fat with punctuate bleeding, scored fascia and red/pink muscle.
Step 2 • Prepare PriMatrix®

Trim PriMatrix® to cover the prepared wound bed with minimal overlap.

Hydrate PriMatrix® in room temperature sterile saline.

Step 3 • Apply and Secure PriMatrix®

Expand and smooth PriMatrix® across the wound to ensure intimate contact with the wound bed.

Staple or suture PriMatrix® to wound edge with minimal overlap.

Staple or suture adjacent pieces of PriMatrix.
Step 4 • Apply Standard Dressings to PriMatrix®

Moist Wound Therapy

1. Apply a non-adherent contact layer directly over PriMatrix®.
2. Use appropriate products and secondary dressings to maintain moist wound healing.
3. Use dressings to bolster PriMatrix® to ensure contact between PriMatrix® and the wound bed.
Step 5 • Perform Standard Wound Care

**Moist Wound Therapy**

**Days 1–2:**
Remove dressings down to petrolatum gauze, replace ointment, absorbent dressings, and elastic bandage wrap.

Range of motion can begin.

**Days 3–5:**
Remove all dressings down to non-adherent contact layer (remove non-adherent contact layer when PriMatrix® has attached to the wound bed).

Replace dressings removed.

**Days 5+:**
Remove all dressings, staples and sutures.

Gently wash wound, and replace all dressings.
Step 6 • Assess Tissue Generation Post-PriMatrix® Application
Step 7 • Apply Split Thickness Skin Graft

Prepared Tissue

Prepare generated tissue for skin graft application using a gentle abrasion system. Harvest a 0.008 – 0.012 inch thick skin graft.

Skin Grafted Tissue

5 days post-STSG application

19 days post-STSG application
PriMatrix® Dermal Repair Scaffold

Description
PriMatrix® 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.

Indications
PriMatrix® 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® is not designed, sold, or intended for use except as indicated.  • PriMatrix® should not be used for patients with a known history of hypersensitivity to 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® should be used with caution in regions where an infection exists or is suspected. Treat any existing infection appropriately.  • Do not resterilize as this may damage PriMatrix®.  • Do not use if the product package is damaged or opened.  • PriMatrix® is for single patient use only.  • Rinse surgical gloves to remove glove powder prior to touching PriMatrix®.  • Do not use product if past the date of expiration indicated on the product label.  • Meshing of fenestrated PriMatrix® is not recommended.
## Ordering Information

**PriMatrix® Dermal Repair Scaffold**

<table>
<thead>
<tr>
<th>Size</th>
<th>Solid</th>
<th>Fenestrated</th>
<th>Meshed</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 x 8 cm</td>
<td>607-001-880</td>
<td>607-004-880</td>
<td>607-005-880</td>
</tr>
<tr>
<td>8 x 12 cm</td>
<td>607-001-812</td>
<td>-</td>
<td>607-005-812</td>
</tr>
<tr>
<td>10 x 12 cm</td>
<td>607-001-112</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>10 x 25 cm</td>
<td>607-001-125</td>
<td>-</td>
<td>607-005-125</td>
</tr>
<tr>
<td>20 x 25 cm</td>
<td>607-001-225</td>
<td>-</td>
<td>607-005-225</td>
</tr>
</tbody>
</table>

---

**Solid**

**Fenestrated**

**Meshed**
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 baumannii, and Streptococcus pyogenes (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 is not designed, sold, or intended for use except as indicated.  • PriMatrix® Ag should not be used for patients with a known history of hypersensitivity to 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.  • Do not resterilize as this may damage PriMatrix® Ag Antimicrobial.  • Do not use if the product package is damaged or opened.  • PriMatrix® Ag Antimicrobial is for single patient use only.  • Rinse surgical gloves to remove glove powder prior to touching PriMatrix® Ag Antimicrobial.  • Do not use product if past the date of expiration indicated on the product label.  • Meshing of fenestrated PriMatrix® Ag
Warnings and Precautions, Appearance, Ordering Information

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.

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

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.

Ordering Information

PriMatrix® Ag Antimicrobial Dermal Repair Scaffold

<table>
<thead>
<tr>
<th>Size</th>
<th>Solid</th>
<th>Fenestrated</th>
<th>Meshed</th>
</tr>
</thead>
<tbody>
<tr>
<td>8x8cm</td>
<td>607-101-880</td>
<td>607-104-880</td>
<td>-</td>
</tr>
<tr>
<td>8x12cm</td>
<td>607-101-812</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>10x12cm</td>
<td>607-101-112</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>10x25cm</td>
<td>607-101-125</td>
<td>-</td>
<td>607-105-125</td>
</tr>
<tr>
<td>20x25cm</td>
<td>607-101-225</td>
<td>-</td>
<td>607-105-225</td>
</tr>
</tbody>
</table>
Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Always refer to the appropriate instructions for use for complete clinical instructions.
- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.

For more information or to place an order, please contact:

United States, Canada, Asia, Pacific, Latin America
USA 844-774-6287 • 844-329-7746 fax
International +609-936-5400 • 609-750-4259 fax
integralife.com/contact

Manufacturer:

TEI Biosciences, a subsidiary of Integra LifeSciences Corporation
7 Elkins Street
Boston, MA 02127 • USA