Application Guide for Full-Thickness Wounds

**PriMatrix®**
Dermal Repair Scaffold

**PriMatrix® Ag**
Antimicrobial Dermal Repair Scaffold
Prior to application of PriMatrix, the wound bed and margins must be prepared.

**PriMatrix®** is a unique dermal repair scaffold for the management of the most challenging wounds. PriMatrix is offered in solid, fenestrated, and meshed configurations, in a range of sizes available for burns, trauma, and other challenging partial and full-thickness wounds.

The following instructions serve as general guidelines for the application of PriMatrix for full-thickness wounds.

---

**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.

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 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

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

Range of motion can begin.

**Day 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.

**Day 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 should not be used for patients with a known history of hypersensitivity to collagen or bovine products.

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.
- PriMatrix should not be applied directly on third degree burns.
Ordering Information

**PriMatrix Dermal Repair Scaffold**

<table>
<thead>
<tr>
<th>Reference</th>
<th>Description</th>
<th>Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>607-001-660</td>
<td>6 cm x 6 cm</td>
<td>Solid</td>
</tr>
<tr>
<td>607-004-660</td>
<td>6 cm x 6 cm</td>
<td>Fenestrated</td>
</tr>
<tr>
<td>607-005-660</td>
<td>6 cm x 6 cm</td>
<td>Meshed</td>
</tr>
<tr>
<td>607-001-880</td>
<td>8 cm x 8 cm</td>
<td>Solid</td>
</tr>
<tr>
<td>607-004-880</td>
<td>8 cm x 8 cm</td>
<td>Fenestrated</td>
</tr>
<tr>
<td>607-005-880</td>
<td>8 cm x 8 cm</td>
<td>Meshed</td>
</tr>
<tr>
<td>607-001-812</td>
<td>8 cm x 12 cm</td>
<td>Solid</td>
</tr>
<tr>
<td>607-005-812</td>
<td>8 cm x 12 cm</td>
<td>Meshed</td>
</tr>
<tr>
<td>607-001-112</td>
<td>10 cm x 12 cm</td>
<td>Solid</td>
</tr>
<tr>
<td>607-001-125</td>
<td>10 cm x 25 cm</td>
<td>Solid</td>
</tr>
<tr>
<td>607-005-125</td>
<td>10 cm x 25 cm</td>
<td>Meshed</td>
</tr>
<tr>
<td>607-001-225</td>
<td>20 cm x 25 cm</td>
<td>Solid</td>
</tr>
<tr>
<td>607-005-225</td>
<td>20 cm x 25 cm</td>
<td>Meshed</td>
</tr>
</tbody>
</table>
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 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.
- PriMatrix Ag Antimicrobial is for single patient use only.
- 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.
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.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Description</th>
<th>Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>607-101-660</td>
<td>6 cm x 6 cm</td>
<td>Solid</td>
</tr>
<tr>
<td>607-104-660</td>
<td>6 cm x 6 cm</td>
<td>Fenestrated</td>
</tr>
<tr>
<td>607-105-660</td>
<td>6 cm x 6 cm</td>
<td>Meshed</td>
</tr>
<tr>
<td>607-101-880</td>
<td>8 cm x 8 cm</td>
<td>Solid</td>
</tr>
<tr>
<td>607-104-880</td>
<td>8 cm x 8 cm</td>
<td>Fenestrated</td>
</tr>
<tr>
<td>607-105-880</td>
<td>8 cm x 8 cm</td>
<td>Meshed</td>
</tr>
<tr>
<td>607-101-812</td>
<td>8 cm x 12 cm</td>
<td>Solid</td>
</tr>
<tr>
<td>607-104-812</td>
<td>8 cm x 12 cm</td>
<td>Fenestrated</td>
</tr>
<tr>
<td>607-105-812</td>
<td>8 cm x 12 cm</td>
<td>Meshed</td>
</tr>
<tr>
<td>607-101-112</td>
<td>10 cm x 12 cm</td>
<td>Solid</td>
</tr>
<tr>
<td>607-105-112</td>
<td>10 cm x 12 cm</td>
<td>Meshed</td>
</tr>
<tr>
<td>607-101-125</td>
<td>10 cm x 25 cm</td>
<td>Solid</td>
</tr>
<tr>
<td>607-104-125</td>
<td>10 cm x 25 cm</td>
<td>Fenestrated</td>
</tr>
<tr>
<td>607-105-125</td>
<td>10 cm x 25 cm</td>
<td>Meshed</td>
</tr>
<tr>
<td>607-101-225</td>
<td>20 cm x 25 cm</td>
<td>Solid</td>
</tr>
<tr>
<td>607-104-225</td>
<td>20 cm x 25 cm</td>
<td>Fenestrated</td>
</tr>
<tr>
<td>607-105-225</td>
<td>20 cm x 25 cm</td>
<td>Meshed</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.

- 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.
- Consult product labels and inserts for any indication, contraindications, hazards, warnings, precautions, and instructions for use.

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