Integra®

PriMatrix® Dermal Repair Scaffold

Limiting uncertainty with this dermal scaffold that can help manage challenging wounds.

PriMatrix® is a dermal repair scaffold for the management of challenging wounds. Derived from fetal bovine dermis, PriMatrix® Dermal Repair Scaffold is particularly rich in Type III collagen, which is associated with healing process and tissue development.

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

Features and Benefits

- An acellular collagen matrix derived from fetal bovine dermis
- Rich in Type III collagen, collagen that is associated in developing and healing tissues
- Excellent handling characteristics
- Available in several sizes in meshed, fenestrated, and solid configurations
- Five-year shelf life
- Room temperature storage
- Minimal preparation time–rehydrates in about 60 seconds
- Biocompatible and cell-friendly with no artificial chemical crosslinking
- Terminally sterilized
- No significant foreign body inflammatory response[1]

1 http://www.primatrix.com/file-assets/primatrix-safety-handling1.pdf

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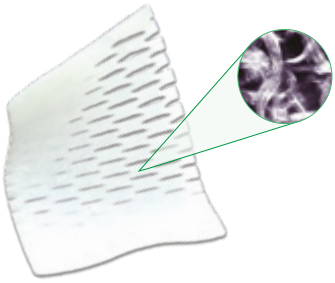

The PriMatrix® proprietary processing technology preserves the beneficial features of the natural dermal collagen fibers and generates a tissue matrix free of contaminants and artificial chemical crosslinks. When applied to the patient's wound PriMatrix® Dermal Repair Scaffold fills with blood, absorbs cell and growth factors. The dermal collagen fibers support cellular repopulation and revascularization processes critical in wound healing.

Ordering Information

Size	Solid	Fenestrated	Meshed
3x3cm	-	-	607-005-330
4x4cm	607-001-440	607-004-440	607-005-440
5x5cm	-	-	607-005-550
6x6cm	607-001-660	607-004-660	607-005-660
8x8cm	607-001-880	607-004-880	607-005-880
8x12cm	607-001-812	-	607-005-812
10x12cm	607-001-112	-	-
10x25cm	607-001-125	-	607-005-125
20x25cm	607-001-225	-	607-005-225

Description

PriMatrix® Dermal Repair Scaffold 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.

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.

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

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 indications, contraindications, hazards, warnings, precautions, and instructions for use.

Products mentioned in this document are CE class III devices. Please contact Integra customer service should you need any additional information on devices classification. All the medical devices mentioned on this document are CE marked in accordance with the applicable European laws, unless specifically identified as "NOT CE MARKED".

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