INTEGRA®
LIMIT UNCERTAINTY

PriMatrix®

Dermal Repair Scaffold

PriMatrix Design

PriMatrix was designed to satisfy the demand for a safe, consistent, unique dermal repair scaffold for use in a broad range of wounds. It has become the product of choice for podiatric, trauma, plastic & reconstructive, and burn care surgeons.

PriMatrix is an dermal repair scaffold derived from fetal bovine dermis, one of the purest sources of collagen available.

The proprietary technology used to process PriMatrix products preserves the beneficial properties of the natural collagen fibers and generates a tissue matrix free of contaminants and artificial chemical crosslinks. The scientific mechanism behind tissue generation with PriMatrix has been attributed to the purity and nativity of the matrix.

Sterility Assurance

PriMatrix is terminally sterilized via exposure to ethylene oxide gas. The cycle has been validated to provide a sterility assurance level of 10^{-6} with undetectable levels (<0.01 mg per device) of ethylene oxide chemical residuals. So long as the product package has not been damaged or opened, the contents are guaranteed sterile.

Viral Safety

The PriMatrix manufacturing process includes a chemical viral inactivation step validated to ensure inactivation of potentially contaminating virus classes including:

- Enveloped & non-enveloped RNA viruses
- Enveloped & non-enveloped DNA viruses

Biocompatibility

The biocompatibility of PriMatrix has been evaluated by a third-party laboratory in accordance with ISO 10993, the internationally recognized standard for medical implants intended for long-term use. The results of these tests are summarized in the table on the following page.

TSE Safety

PriMatrix has been specifically designed to safeguard against the possibility of transmitting prion-related Transmissible Spongiform Encephalopathy (TSE) diseases, including variant Creutzfeldt Jakob Disease (vCJD), the human form of Bovine Spongiform Encephalopathy (BSE).

The product is derived from fetal bovine dermis which has been designated safe by the World Health Organization and EU scientific committees as no detectable levels of infectivity have been identified for this type of tissue.[1]

The source tissues for PriMatrix are selected and processed in accordance with strict US and international regulatory requirements. The products have also passed the rigorous criteria for TSE safety certification by the European Directorate for the Quality of Medicines.[2]

Packaging & Shipping

Each PriMatrix unit is packaged dry within a Tyvek-laminate pouch that may be passed directly into the sterile field. The inner pouch is sealed within a foil pouch that acts as a light and moisture barrier, allowing for long-term storage.

Storage & Shelf Life

Upon receipt, PriMatrix should be stored at room temperature, away from direct heat sources; refrigeration is not necessary. The product has a shelf life of up to five years. The expiration date is indicated on the device label.

Hydration

Packaged dry, PriMatrix requires hydration for approximately one minute in room temperature, sterile 0.9% saline prior to use. The product must not be hydrated in solutions warmed above room temperature, as excessive heat may damage the collagen.

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.

1 - WHO (World Health Organization) Tables on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies — Geneva, Switzerland, (2010).

2 - EDQM Certificate No. R1-CEP 2004-116 Rev. 00 for Collagen Matrix, Strasbourg, 23 November 2004.

PriMatrix® Biocompatibility Summary[3]

Test Performed	Standard	Result
Cytotoxicity, MEM Elution	ISO 10993-5	No evidence of causing cell lysis or toxicity
Sensitization, Maximization	ISO 10993-10	No evidence of causing delayed dermal contact sensitization
Acute Intracutaneous Reactivity	ISO 10993-10	No evidence of significant irritation
Acute Systemic Toxicity	ISO 10993-11	No mortality or evidence of systemic toxicity
Genotoxicity, AMES Bacterial Reverse Mutation	ISO 10993-11	Nonmutagenic to Salmonella typhimurium test strains TA98, TA100, TA1535, TA1537, and Escherichia coli strain WP2uvrA
In Vitro Hemolysis, Modified ASTM Direct Contact Method	ISO 10993-3	Nonhemolytic
In Vitro Hemolysis, Modified ASTM Extraction Method	ISO 10993-4	Nonhemolytic
Surgical Muscle Implantation, 4 & 12 Weeks	ISO 10993-6	Macroscopically and microscopically classified as a nonirritant as compared to negative control plastic

3 - Data on file, TEI Biosciences Inc.

Frequently Asked Questions

What impact will hydration in hot saline have on PriMatrix?

Heated saline solutions may damage the product, potentially eliciting an inflammatory response upon implantation. Always verify that the saline is at room temperature (15-30°C; 59-86°F) prior to hydration.

Can the hydration process be sped up in the operating room?

Yes. As described in the Instructions for Use, you may speed hydration somewhat by applying light pressure with sterile-gloved fingers to squeeze out any bubbles trapped within the matrix.

Should the product be cut to size while dry, or following hydration?

PriMatrix may be cut to size to meet the individual patient's needs in either its dry or its hydrated state.

Does PriMatrix have to be implanted with a specific side up?

No. There is no sidedness associated with PriMatrix. It may be placed in any orientation.

Is a bovine sensitivity skin test required prior to implantation of PriMatrix?

No. This test is associated with other collagen preparations, e.g. injectable collagen, and is not required for PriMatrix.

How should PriMatrix be secured to the wound?

Secure PriMatrix to the wound by mechanical means, such as suturing, stapling, or bolstering. Adhesive strips should be used only on the peri-ulcer skin over a non-adherent dressing.

Can PriMatrix be used in infected wounds?

PriMatrix should be used with caution in regions where infection exists. Collagen is susceptible to break-down in the presence of bacterial enzymes. Please refer to the Instructions for Use included with each device for complete warnings and contraindications.

When should PriMatrix be reapplied?

Reapply PriMatrix if the wound has not decreased in size within two weeks, if PriMatrix is no longer visible, or if PriMatrix has been displaced from the wound.

Can PriMatrix be resterilized?

No. The product is ethylene oxide sterilized for single-patient use only. Resterilization can damage PriMatrix.

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

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