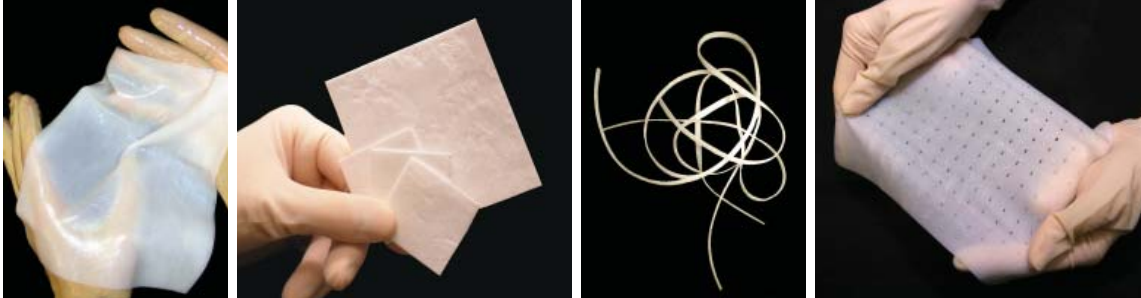


PriMatrix™

Dermal Repair Scaffold



TEI

BIOSCIENCES

Repair | Reinforce | Regenerate

Product Overview

PriMatrix is a novel acellular collagen matrix derived from fetal bovine dermis. An ideal material for the management of numerous types of wounds, this biologic matrix provides an environment that supports the cell repopulation and revascularization processes essential to wound healing. In addition to non-denatured Type I collagen, PriMatrix is rich in Type III collagen, a natural component of fetal dermis; Type III collagen is active in developing and healing tissues. The product is designed to deliver and incorporate collagen into the wound bed, stimulating rapid tissue granulation and supporting native collagen production.

TEI Biosciences manufactures PriMatrix using a patented process designed to remove cellular components and potentially infectious agents from the raw material, while preserving the biological properties and structure of native collagen.

PriMatrix is offered in a variety of sizes and configurations for use in both hospital and office settings. Small pieces, with or without fenestrations, may be applied in the case of post-Mohs surgery or for small skin ulcers. Sizes as large as 20 x 25 cm are available for more challenging wounds and second-degree burns. PriMatrix strips are also available to efficiently fill deep or tunneled wounds. All configurations of PriMatrix may be used in conjunction with vacuum-assisted wound healing systems.



PriMatrix provides an environment to support wound healing and new tissue development.

Skin ulcers

Second degree burns

Surgical wounds

Trauma wounds

Post-Mohs surgery

Tunneled wounds

PriMatrix at a Glance

Composition	Native, non-denatured collagen
Collagen source	Fetal bovine dermis
Appearance	Flat, dry sheet of uniform thickness and color, available with or without fenestrations (select sizes only)
Color	White
Dry thickness	0.20 - 1.04 mm, nominally ~ 0.65 mm
Pyrogens	Non-pyrogenic
Storage and shelf life	Room temperature storage for up to three years
Chemical crosslinkers	None
Intraoperative handling	Can be trimmed to size wet or dry and placed in any orientation, with either side up
Rehydration	Approximately 60 seconds in room temperature saline
Viral safety	Manufacturing process includes validated viral-inactivation steps
Transmissible Spongiform Encephalopathy (TSE) safety	TSE safety certification by European Directorate for the Quality of Medicines; source tissue selected and processed in accordance with strict US and European regulatory requirements
Sterilization	Via exposure to ethylene oxide gas; sterility assurance level of 10 ⁻⁶ with undetectable ethylene oxide residuals

Coding and Reimbursement

Medicare Hospital Outpatient Coding – J7349 – *Dermal (substitute) tissue of non-human origin, with or without other bioengineered or processed elements, without metabolically active elements (PriMatrix) per square centimeter (effective January 1, 2008)*

Hospital Outpatient Payment – *Made under APC 1141*

Physician Office Payment – *Made based on quarterly reported Average Sales Price*

Ordering Information

Size (cm)	Fenestrations	Product Number
4 x 4	No	607-001-440
4 x 4	Yes	607-004-440
6 x 6	No	607-001-660
6 x 6	Yes	607-004-660
8 x 8	No	607-001-880
8 x 8	Yes	607-004-880
8 x 12	No	607-001-812
10 x 12	No	607-001-112
10 x 25	No	607-001-125
20 x 25	No	607-001-225
0.2 x 26.5*	No	607-001-009

* Sold as set of three individually packaged units.

Features & Benefits

- Biologic, acellular collagen matrix derived from fetal bovine dermis – rich in Type III collagen, the active collagen found in developing and healing tissues
- Superior handling characteristics
- Available in several sizes, with select sizes offered in both fenestrated and non-fenestrated versions
- Three-year shelf life
- Room temperature storage
- Minimal preparation time – rehydrates in about 60 seconds
- Biocompatible and cell-friendly with no artificial chemical crosslinking – promotes rapid revascularization and integration with host tissue
- Terminally sterilized



About TEI Biosciences

A leading, privately held biomedical company, TEI Biosciences has applied its expertise in regenerative medicine to develop and commercialize novel biologic products for a broad spectrum of soft tissue repair and reinforcement applications - from dura, tendon, and hernia repair to wound management and plastic and reconstructive surgery. TEI sells its products directly and through partnerships with some of the world's major medical device companies.



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