

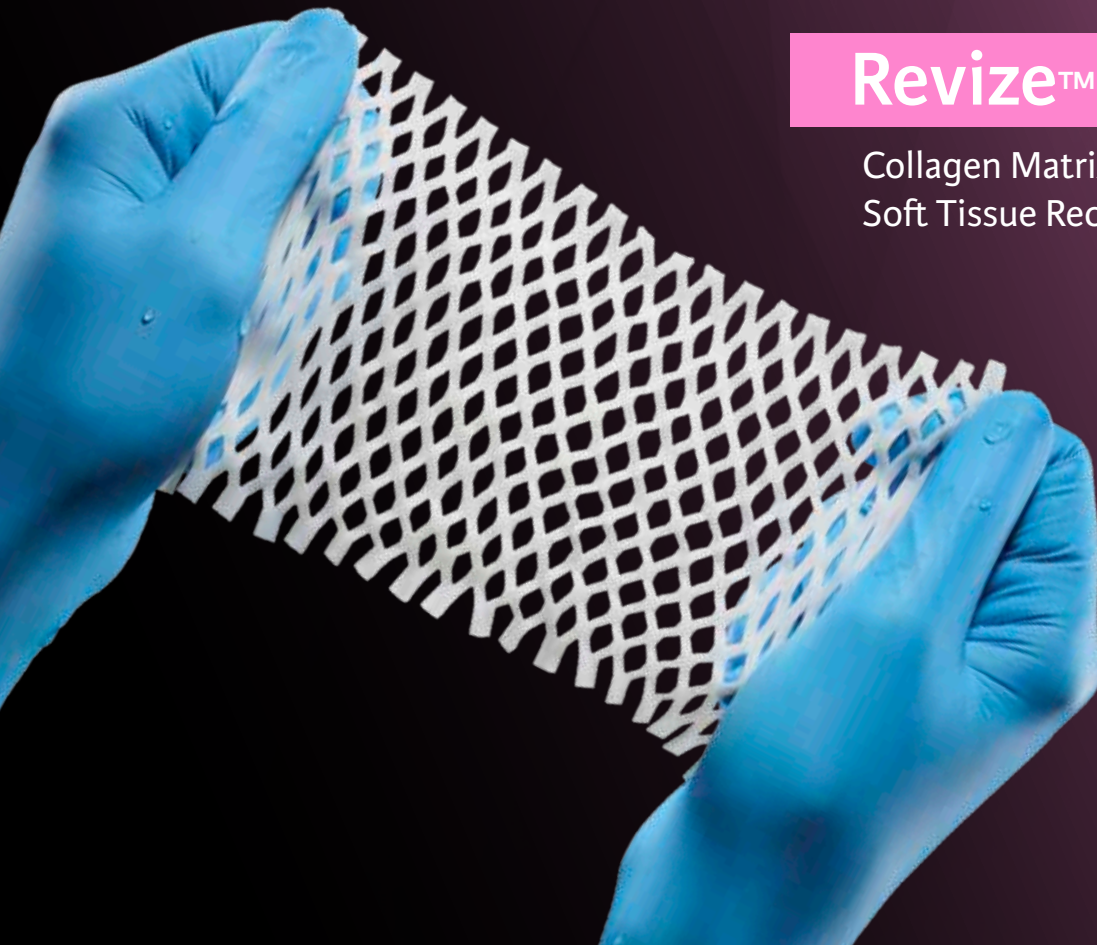
# Revize™

Collagen Matrix for  
Soft Tissue Reconstruction



# Revize™-X

Collagen Matrix for  
Soft Tissue Reconstruction



# Revize™ and Revize™-X are acellular collagen matrices for plastic & reconstructive surgery, derived from fetal bovine dermis, rich in Type III collagen.

**Revize and Revize-X** are derived from fetal bovine dermis, which is rich in Type III collagen.<sup>1</sup> Type III collagen has shown to mediate tissue healing and regrowth while inhibiting scarring.<sup>2,3</sup>

**Revize and Revize-X** are without preservatives, denatured proteins, artificial chemical crosslinks, cells, lipids, carbohydrates and other constituents, all of which can induce inflammation. It is terminally sterilized – never treated with potentially antigenic antibiotics. As a result, it does not elicit a foreign body inflammatory response upon implantation.<sup>4,5</sup>

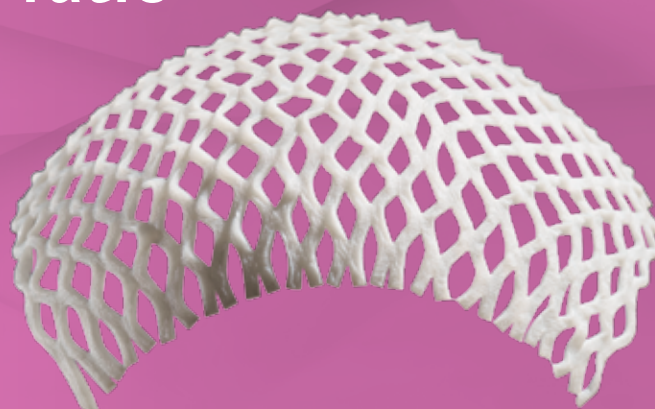
Feature	Description
Composition	Native, bovine dermal tissue
Collagen source	Bovine dermis
Appearance	Flat, solid or meshed, dry sheet of uniform thickness and color
Thickness <sup>6</sup>	1 mm
Storage	Room temperature storage
Chemical crosslinkers	None
Rehydration	Approximately 60 seconds in room temperature saline <sup>7</sup>
Intraoperative handling	Can be trimmed to size (wet or dry) and placed in any orientation, with either side up
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 International regulatory requirements
Sterilization	Via exposure to ethylene oxide gas; sterility assurance level of $10^{-6}$ with undetectable ethylene oxide residuals

## Revize-X expands at a 2:1 ratio

**Revize-X** is an expandable matrix that provides up to **2X** the initial coverage area once hydrated and fully expanded.<sup>8</sup>

It features a meshing pattern which allows for:

- Vascular ingrowth
- Increased conformability



# Revize™

## Ordering Information

Reference	Description	Thickness <sup>6</sup>
611-001-002	4 cm x 12 cm Solid	1 mm
611-001-003	4 cm x 16 cm Solid	1 mm
611-001-001	10 cm x 10 cm Solid	1 mm



611-001-001



611-001-002



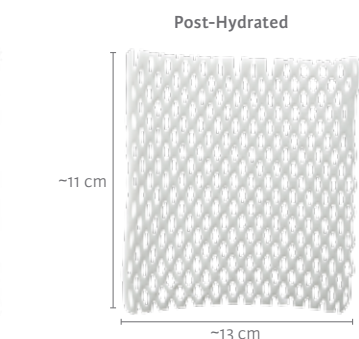
611-001-003



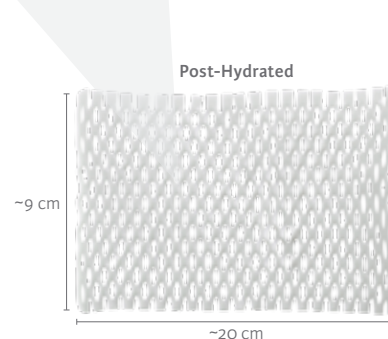
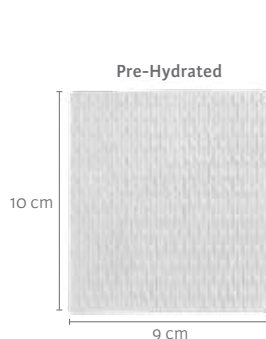
# Revize™-X

## Ordering Information

Reference	Description	Thickness <sup>6</sup>
611-005-001	12 cm x 6 cm Meshed <i>Expands to ~11 cm x 13 cm<sup>8</sup></i>	1 mm
611-005-002	10 cm x 9 cm Meshed <i>Expands to ~9 cm x 20 cm<sup>8</sup></i>	1 mm

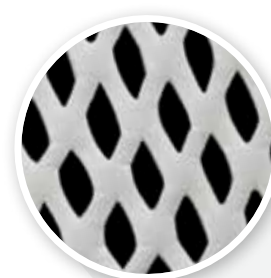


611-005-001



611-005-002

All product Images are not to scale



- Ramshaw J. Distribution of type III collagen in bovine skin of various ages. Connective Tissue Research. 1986; 14:307-314.
- Larson et al. Scarless fetal wound healing: a basic science review. Plast Reconstr Surg. 2010;126:1172-1180.
- Volk et al. Diminished type III collagen promotes myofibroblast differentiation and increases scar deposition in cutaneous wound healing. Cells Tissues Organs. 2011;194:25-37.
- Cornwell K, Landsman A, James K. Extracellular matrix biomaterials for soft tissue repair. Clin Podiatr Med Surg. 2009 Oct; 26(4):507-23.
- Data on file, Internal testing PDR 252.
- Nominal thickness.
- Revize and Revize-X are specified to hydrate in ≤ 3 minutes; typically, it hydrates in ~60 seconds.
- When hydrated and fully expanded, refer to package insert for expansion instruction.

## Indications

Revize™ / Revize™-X is intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes. Revize / Revize-X is specifically indicated for plastic and reconstructive surgery.

## Contraindications

Revize / Revize-X should not be used for patients with a known history of hypersensitivity to collagen or bovine products.

## Warnings and Precautions

**CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.**

- 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 device.
- Do not use the device in contaminated or infected surgical sites. Treat any existing infection appropriately. If used in contaminated or infected wounds, collagen-based implants can weaken or break down.
- The device is for single patient use only.
- Do not use the device if the foil seal is broken.
- Discard all opened and unused portion(s) of the device.
- Do not resterilize the device.
- The device has not been evaluated for use in pregnant women.
- The patient's medical condition may adversely impact healing of the deficient tissue. These conditions may include, but are not limited to: obesity, smoking, diabetes, insufficient blood supply at the implant site, and exposure of the implant site to radiotherapy and chemotherapy.
- Do not use the device past the expiration date.
- Do not mesh or fenestrate Revize-X.
- The device is not indicated for use in hernia repair.

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:**

USA 877-444-1122 ■ 866-800-7742 fax  
International +1 617-268-1616 ■ +1 617-268-3282 fax  
[integralife.com/contact](http://integralife.com/contact)



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