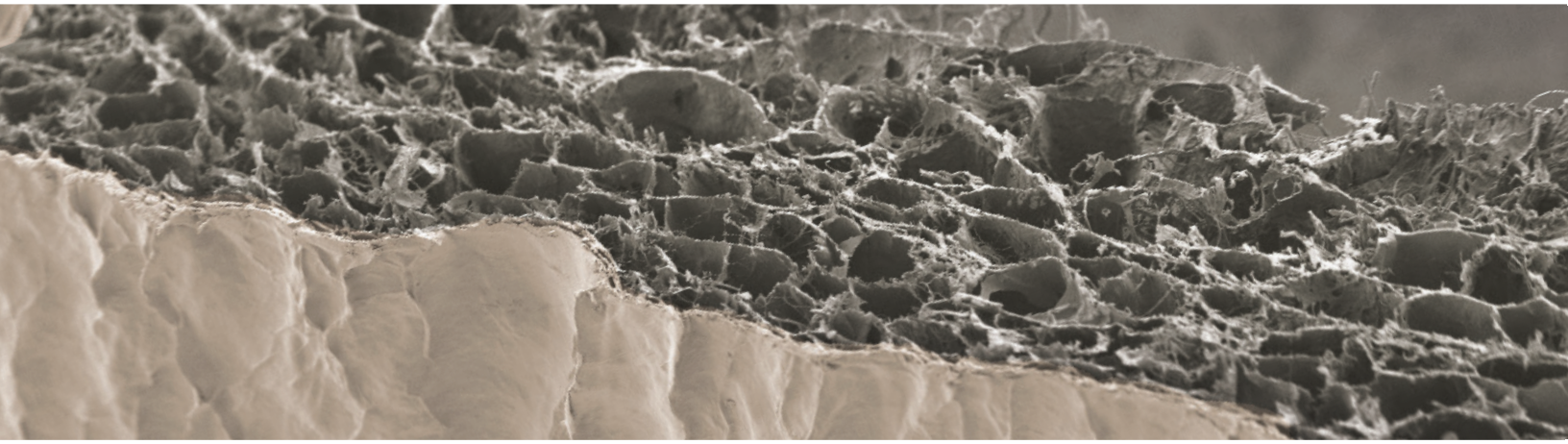
Gentrix® Surgical Matrix

Complex Hernia Repairs

Ventral | Parastomal | Hiatal

ACell®

Not Your Ordinary ECM



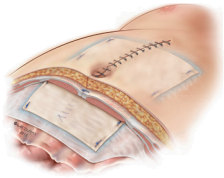
ACell's Gentrix® Surgical Matrix devices are an extracellular matrix scaffold which has been shown to facilitate the body's ability to remodel site-appropriate, biomechanically functional tissue where scarring would be expected[1-3]. Our product has demonstrated positive patient outcomes with minimal complications[4].

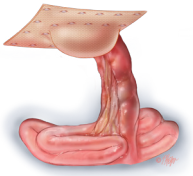
Gentrix Surgical Matrix Devices:

- Are fully resorbable, non-crosslinked, biologically-derived extracellular matrices (ECMs).
- Contain intact epithelial basement membrane and numerous collagens.
- Minimize the risk of costly complications such as foreign body response, erosion, and infection that can occur with synthetic alternatives[5-9].
- Deliver a functional host response, thereby optimizing the strength of repair.
- Offer ease in handling and securing.

Appropriate for a Range of Hernia Procedures:

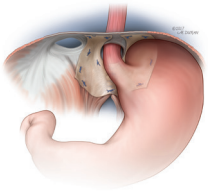
VENTRAL
HERNIA





PARASTOMAL
HERNIA

HIATAL
HERNIA



Product Composition

Gentrix Surgical Matrix products are medical devices engineered using ACell's proprietary MatriStem UBM™ (Urinary Bladder Matrix) technology and are intended to reinforce soft tissue where weakness exists. Gentrix devices contain multiple types of carbohydrates, collagens, proteins, and other components. These product characteristics facilitate a remodeling process by the body that leads to the formation of site-appropriate, biomechanically functional tissue. These features represent key competitive advantages over other treatment modalities for a range of surgical procedures.

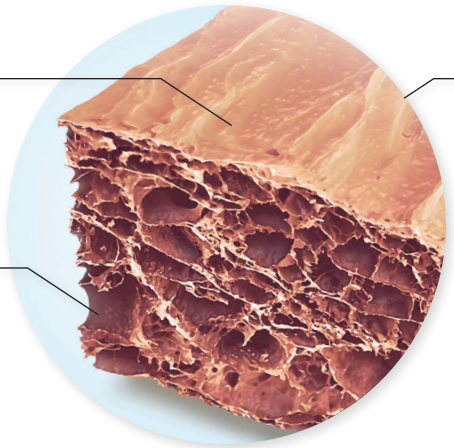
MatriStem UBM Technology

Epithelial Basement Membrane

The epithelial basement membrane can contribute to epithelial and progenitor cell attachment and proliferation.

Lamina Propria

The lamina propria surface is conducive for integration of host connective tissue into the scaffold.



Contains:

Glycosaminoglycans

Collagen Type I

Collagen Type III

Collagen Type IV

Collagen Type VII

Laminin

ACell's Proprietary Process

Many biologically-derived products are processed with harsh chemicals and detergents, while ACell uses a gentle method to preserve the ECM in its most natural state. The natural scaffold allows the body to remodel tissue while minimizing the foreign body response. Gentrix is a non-synthetic device, which can minimize the risk of costly complications often associated with synthetic products.

MatriStem UBM 8 Hours	Dermis[10] 1 Week*
Stretching	Scalding
Delamination	Lime
Scraping	0.25% Trypsin
PAA/EtOH	70% Ethanol
Saline	3% H_2O_2
Water	0.1% SDS
	1% Triton X-100
	PAA/EtOH

*Representative processing for dermal products for reference use only. Does not represent any single, specific product processing protocol.

Positive Patient Outcomes with Minimal Complications

Gentrix Surgical Matrix devices have been shown to facilitate an enduring repair with restoration of anatomical functionality. Pre-clinical and clinical data show that Gentrix devices reinforce hernia repairs by facilitating the deposition of biomechanically functional, site-appropriate tissue capable of sustaining the physiologic mechanical loading at the defect site over time.

In a recent study, 64 patients underwent complex incisional hernia repair utilizing Gentrix as a reinforcement graft. The patient population was complex, with 84% classified as "severe" (Slater severity classification system[11]). At a median follow-up of 36 months, **the total recurrence rate was 15.6%[4].**

The same study demonstrates long-term clinical results with a low rate of complications, despite the severity of the patient population. There were no cases of erosion, fistulation, or bowel obstruction observed in any of the 64 patients in this study.

Results (Long term clinical follow-up after complex ventral incisional hernia repair[4])

Median follow-up time	36 mos (12-70 mos)
Total Recurrences	10 (15.6%)
Median time to hernia recurrence	32 mos (4-51 mos)
Surgery for repair of hernia recurrence	9 (14%)
Seroma	12 (19%)
Major wound care	13 (20%)
Median Carolina Comfort Score (CCS)	16 (115 max. points)

This study compares favorably to other recently published studies utilizing biologically-derived ECMs in hernia repair with similar patient populations and shorter follow-up periods. Two of the most comparable studies had recurrence rates of **23%** and **31.8%** at **24 months** and **18 months**, respectively[12,13].

A **4% recurrence rate** was displayed at **24 months*[4]**

* Kaplan-Meier Freedom from Recurrence statistical analysis.

Radiographic and Histological Evidence of Enduring Repair

In the same study, radiographic evidence of fascia repair, either by CT scan or abdominal wall ultrasound, was obtained in a subset of 28 patients. Histological analysis of the repaired fascia was obtained from three patients during the course of the study.

In the patients evaluated with ultrasound, all cases without clinical hernia recurrence showed an intact, defined fascial layer without reherniation (Figure 1). CT scans also demonstrated an intact fascia of the abdominal wall (Figure 2).

In each case where a full-thickness fascial biopsy was obtained, closer examination revealed an intact repair with a visual and tactile sense of strength equivalent to native fascia. Histologically, each case showed that the UBM implant region exhibited functional remodeling of site-appropriate connective tissue (Figure 3)[4].

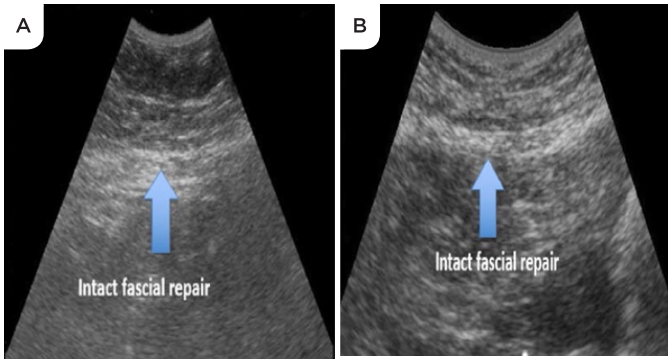


Figure 1. Abdominal wall ultrasound imaging depicting repaired fascia demonstrating a recognizable, robust, intact fascial layer without recurrent herniation. **(A)** Ultrasound of abdominal wall two and a half years after ventral hernia repair with Gentrix reinforcement. **(B)** Ultrasound of abdominal wall in a separate patient three years after ventral hernia repair with Gentrix reinforcement.

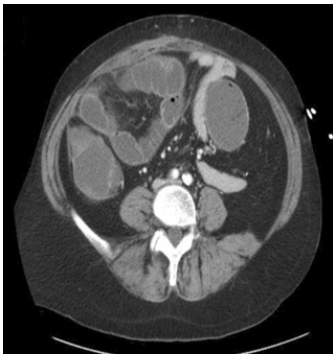


Figure 2. Axial CT scan demonstrating intact fascia patient after retrorectus repair prior to exploration for bowel obstruction. Some thickening of right and mid-abdominal wall noted from repair 14 months prior.

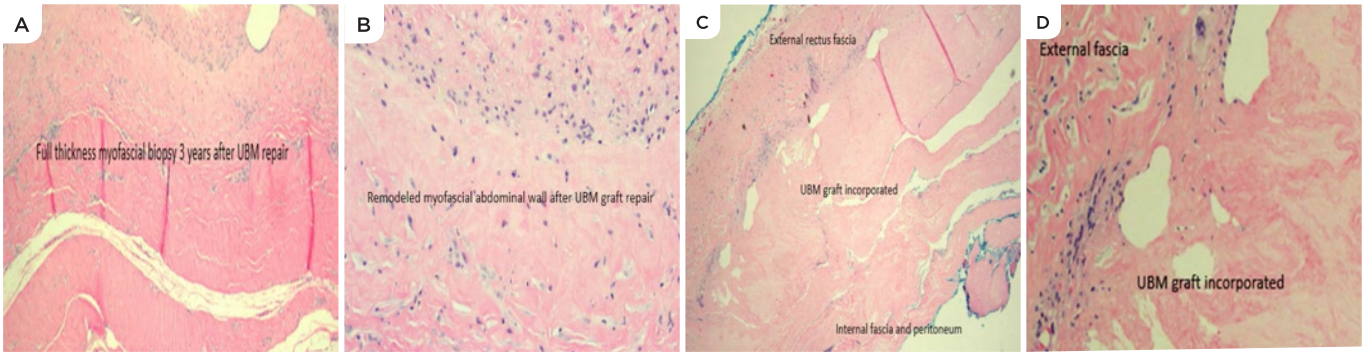
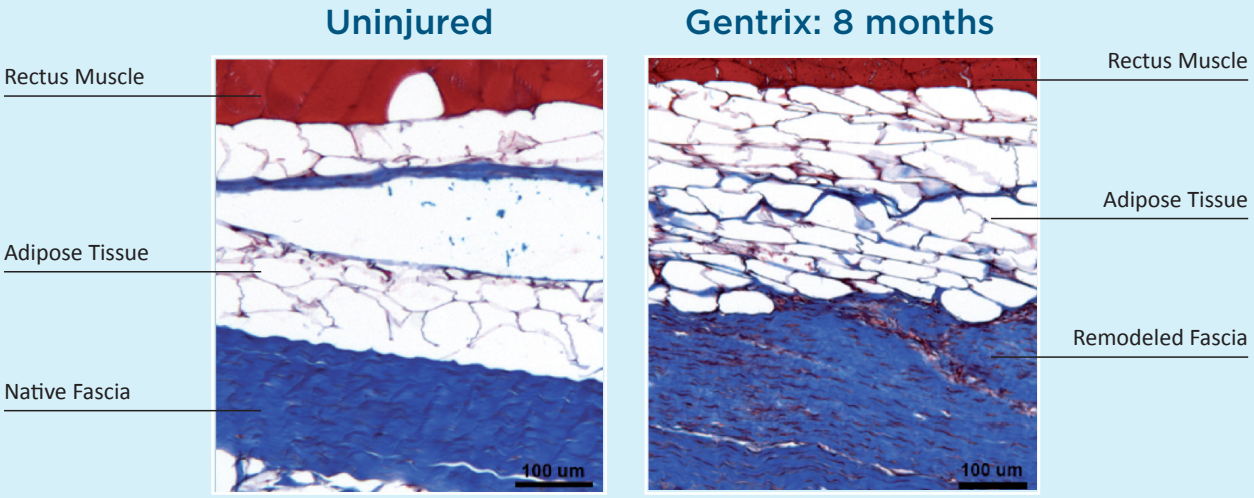


Figure 3. (A) Full-thickness myofascial biopsy three years after Gentrix repair of ventral hernia at 4x power. **B)** 10x power and full-thickness myofascial biopsy three years following intraperitoneal repair. **(C)** 4x power myofascial biopsy 32 months after retrorectus repair of incisional hernia. **(D)** 4x power myofascial biopsy 32 months after retrorectus repair of incisional hernia at interface of external native fascia and remodeled Gentrix.

Functional Healing Response

Gentrix Surgical Matrix devices have been shown to facilitate the remodeling of site-appropriate, biomechanically functional tissue. In a pre-clinical large animal ventral hernia study, animals reinforced with Gentrix devices were associated with a positive tissue remodeling response, and the remodeled tissue largely resembled a thickened posterior fascia[14].

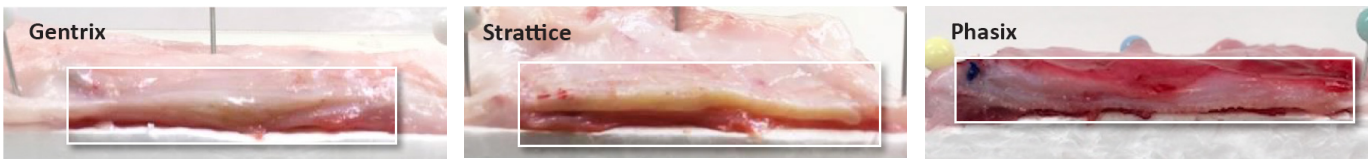
Animals reinforced with Gentrix devices were also characterized by an infiltration of fibroblasts and mesenchymal cells, as well as the presence of small blood vessels at the 3-month time point[14].



Remodeled tissue mimicked that of uninjured tissue

Gentrix Surgical Matrix devices can be rapidly repopulated and revascularized by the host, leading to a more favorable remodeling response. Reinforcement with Gentrix devices has been shown to reduce scarring and encapsulation by facilitating site-appropriate, biomechanically functional tissue remodeling.

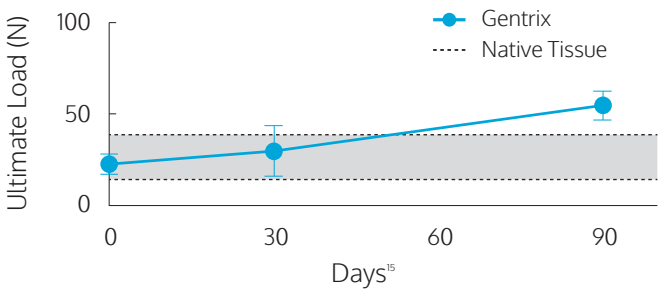
In a pre-clinical ovine study, the remodeling response of Gentrix was compared to that of Strattice® and Phasix®. At three months, the Gentrix device was fully remodeled into site-appropriate connective tissue, while the Strattice and Phasix devices were easily identifiable from surrounding tissue[15].



Provides Optimal Strength

Gentrix Offers a Durable Repair

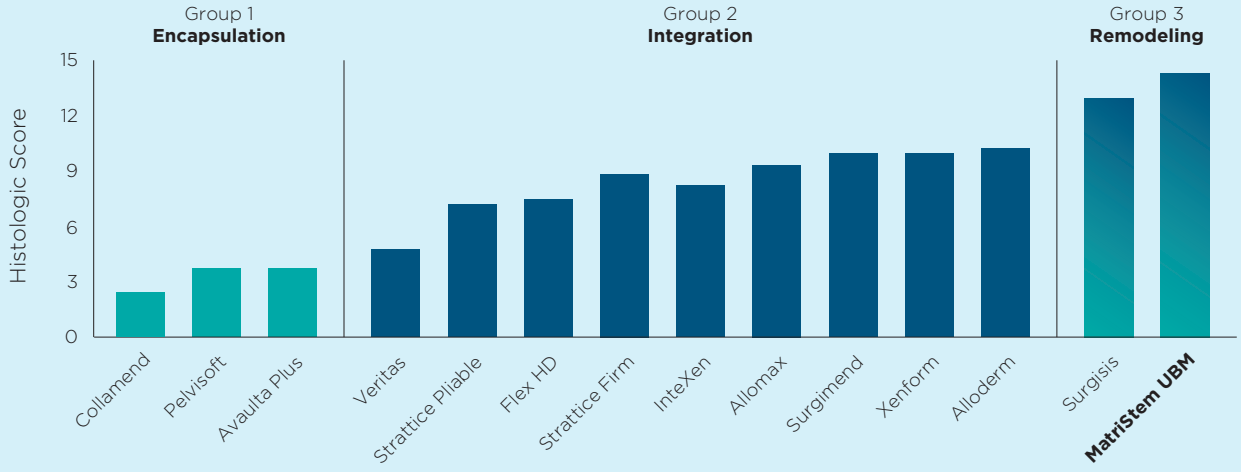
When Gentrix devices were implanted into an ovine fascia lata defect, the devices showed full remodeling at three months and had been replaced with vascularized tissue. When studied at time of implantation, 30 days, and 90 days, **the strength of the remodeled fascia displayed an increasing trend.** Gentrix maintained a mechanical strength and stiffness that was similar to native, uninjured fascia throughout the study[15].



Evidence of Tissue Remodeling

Brown et al.[2] described the tissue remodeling response to 14 different commercially available biologic surgical mesh devices in a rat model of abdominal wall repair. Higher scores are more indicative of a site-appropriate tissue remodeling response, while low scores are more indicative of a scar tissue or foreign body response. Of the 14 different commercially available ECMs tested, MatriStem UBM technology had the most favorable host remodeling response at both 14 and 35 days post-implantation.

Histological Score - 35 Days Post Application



Encapsulation - Chronic inflammation and foreign body response resulting from chemically crosslinked materials

Integration - Early inflammatory cell infiltration with decreased cellularity and little evidence of site-appropriate tissue resulting from dermis-derived materials

Remodeling - Early infiltration by inflammatory cells and signs of site-appropriate tissue

Product	Item Number	Size	Quantity
Gentrix Surgical Matrix Thin	PSM0505	5 x 5 cm	1/box
Gentrix Surgical Matrix Thin	PSM0412	4 x 12 cm	1/box
Gentrix Surgical Matrix Thin	PSM0710	7 x 10 cm	1/box
Gentrix Surgical Matrix Thin	PSM0615	6 x 15 cm	1/box
Gentrix Surgical Matrix Thin	PSM0715	7 x 15 cm	1/box
Gentrix Surgical Matrix Thin	PSM1015	10 x 15 cm	1/box
Gentrix Surgical Matrix	PSMX0505	5 x 5 cm	1/box
Gentrix Surgical Matrix	PSMX0710	7 x 10 cm	1/box
Gentrix Surgical Matrix	PSMX1015	10 x 15 cm	1/box
Gentrix Surgical Matrix Plus	MSPL0507	5 x 7 cm	1/box
Gentrix Surgical Matrix Plus	MSPL0710	7 x 10 cm	1/box
Gentrix Surgical Matrix Plus	MSPL1010	10 x 10 cm	1/box
Gentrix Surgical Matrix Plus	MSPL1015	10 x 15 cm	1/box
Gentrix Surgical Matrix Thick	PSMT1020	10 x 20 cm	1/box
Gentrix Surgical Matrix Thick	PSMT1620	16 x 20 cm	1/box
Gentrix Surgical Matrix Thick	PSMT2020	20 x 20 cm	1/box
Gentrix Surgical Matrix Thick	PSMT2025	20 x 25 cm	1/box
Gentrix Surgical Matrix Thick	PSMT2030	20 x 30 cm	1/box
Gentrix Surgical Matrix Thick	PSMT3030	30 x 30 cm	1/box
Gentrix Surgical Matrix Thick	PSMT3040	30 x 40 cm	1/box
Gentrix Hiatal	HIAT0706	6 x 7.5 cm	1/box

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ACell Employee | § Former ACell Employee | ▲ Consultant

Rx ONLY Refer to IFU supplied with each device for indications, contraindications, and precautions.
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