












Patents and patents pending see:  
www.acell.com/patents

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**REF** LRM0406; LRM0410; LRM0415; LRM0615

SYMBOLS GLOSSARY		
The below symbols conform with the following standards:		
ISO 15223 —1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements		
ISO 7000 — Graphical symbols for use on equipment — Registered symbols		
Title of Symbol/ Explanatory Text		ISO 7000 Reference
	Batch Code	2492
	Catalogue Number	2493
	Consult Instructions for Use	1641
	Do Not Re-sterilize	2608
	Do Not Reuse	1051
	Do Not Use if Package is Damaged	2606
	Manufacturer	3082
	Non- Pyrogenic	2724
	Serial Number	2498
	Sterilized Using Irradiation	2502
	Use By Date	2607
<b>Rx Only</b>	CAUTION! Federal (US) law restricts this device to sale by or on order of a licensed healthcare practitioner.	21 CFR 801



LBL-1148.02  
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# Gentrix®

## Incisional Matrix

### INSTRUCTIONS FOR USE

### Rx Only

 ACell, Inc.  
6640 Eli Whitney Drive  
Suite 200  
Columbia, MD 21046  
USA  
www.acell.com  
800-826-2926  
MADE IN USA



## DEVICE DESCRIPTION

Gentrix<sup>®</sup> Incisional Matrix is composed of a porcine-derived extracellular matrix, also known as urinary bladder matrix. The device is supplied in a single layer sheet configuration in sizes up to 6 cm x 15 cm and packaged in double peel-open pouches. The device is terminally sterilized using electron beam irradiation.

## INDICATIONS

Gentrix Incisional Matrix is intended for implantation to reinforce soft tissue.

## CONTRAINDICATIONS

Patients with known sensitivity or allergy to porcine materials.

## WARNINGS

1. Device is not intended for transvaginal placement or treatment for pelvic organ prolapse or stress urinary incontinence, bladder support, transabdominal sacrocolposuspension, reconstruction of the pelvic floor, or pubourethral support as device has not been evaluated for these indications and may not provide sufficient support.
2. Device is not intended for high stress applications, such as large, high tension ventral hernias and bridging fascial defects as the device may not provide sufficient support.
3. Exposure to contaminated or infected field can lead to weakening or breakdown of device.
4. If active infection is present, treat patient to resolve infection prior to device implantation.
5. Do not use if cracked, broken, or otherwise damaged.

## PRECAUTIONS

Always use aseptic technique when handling device.

## MRI SAFETY INFORMATION

Gentrix Incisional Matrix is MR safe.

## STORAGE

Store in a clean, dry environment at room temperature in unopened and undamaged package. Protect from freezing, excessive heat, and high humidity.

## STERILIZATION

Gentrix Incisional Matrix device is supplied sterile by electron beam irradiation in double peel-open pouches. Device is sterile if package is unopened and undamaged.

## POTENTIAL COMPLICATIONS

Complications and reactions are possible with any soft tissue repair, including but not limited to: infection, increased chronic inflammation, allergic reaction, unexplained fever or chills, excessive redness, acute and chronic pain, swelling, seroma, and dehiscence.

Any adverse reaction should be reported to ACell:  
US Toll-Free: 1-800-826-2926

**The following procedures only serve as a suggested guideline for the application of Gentrix Incisional Matrix. The provided suggestions are not intended to supersede internal institutional protocols and sound clinical judgment.**

## DEVICE APPLICATION

Gentrix Incisional Matrix may be used for soft-tissue reinforcement for intraoperative and/or incisional applications.

1. Remove device from packaging using standard aseptic/sterile technique.

**NOTE:** Slight variations in thickness may be present due to natural ECM variability.

2. Allow sufficient overlap of device to cover defect. Trim device as needed.

**CAUTION:** Cutting device too small may not provide optimal reinforcement at site of implantation.

3. Using aseptic technique, transfer device into defect site and secure into place.
4. Complete standard surgical procedure.
5. Discard any unused portions of device. Do not re-use or re-sterilize any unused portions of device.