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

ACell® is a registered trademark of ACell, Inc.

Gentrix is a registered trademark of ACell, Inc. in the U.S. and may be registered or pending in other countries.

REF PSMX0505; PSMX0710; PSMX1015

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
LOT	Batch Code	2492
REF	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
SN	Serial Number	2498
STERILE R	Sterilized Using Irradiation	2502
	Use By Date	2607
Rx Only	CAUTION! Federal (US) law restricts this device to sale by or on order of a licensed healthcare practitioner.	21 CFR 801

LBL-1006.02
02/2019

Gentrix™
SURGICAL 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™ Surgical Matrix (6-layer) is composed of a porcine-derived extracellular matrix, also known as urinary bladder matrix. The device is supplied in a multi-layer sheet configuration in sizes up to 10 cm x 15 cm and packaged in double peel-open pouches. The device is terminally sterilized using electron beam irradiation.

INDICATIONS

Gentrix Surgical Matrix is intended for implantation to reinforce soft tissue where weakness exists in patients requiring gastroenterological or plastic & reconstructive surgery. Reinforcement of soft tissue within gastroenterological and plastic & reconstructive surgery includes, but is not limited to, the following open or laparoscopic procedures: hernia (e.g. hiatal/ diaphragmatic) and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair. Gentrix Surgical Matrix minimizes tissue attachment to the device in case of direct contact with viscera.

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.
2. Device is not intended for bridging hernia defects.
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

1. Always use aseptic technique when handling device.
2. No studies have evaluated reproductive impact of clinical use of device.

MRI SAFETY INFORMATION

Gentrix Surgical 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 Surgical Matrix 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, tender scars, adhesions, seroma formation, fistula formation, hematoma, recurrence of tissue defect, bowel stricture, anastomotic stricture formation and leaks, dyspareunia, vaginal shortening, vaginal bleeding, atypical vaginal discharge, groin and/or buttock and/or leg pain, urinary or fecal incontinence, delayed or failed incorporation of graft, failure to repair a prolapse, recurrent prolapse, mesh or suture erosion or extrusion, and injury to the bladder, bowel, blood vessels, and/or nerves of the pelvis. Mesh at the hiatus has the potential to cause erosion into the esophagus with stricture formation, abscess, dysphagia and the need for esophageal resection with reconstruction.

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 Surgical Matrix. The use of mesh for reinforcement at the hiatus or other soft tissue defect should be based on internal institutional protocol, sound clinical judgment and the adequacy of the tissue available for closure.

DEVICE APPLICATION

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

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

2. Hydrate device in a sterile dish with room temperature sterile saline (0.9%):

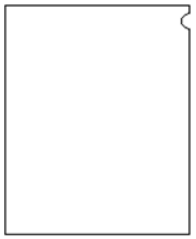
   Minimum hydration time: 10 min
   Maximum hydration time: 60 min

3. Prepare defect site using standard surgical techniques. Place device into well vascularized tissue.
4. Allow sufficient overlap of device to cover defect. Trim device as needed.

CAUTION: Cutting device too small could create excess stress on the suture line or device resulting in recurrence of defect or new defect in adjacent tissues.

5. Using aseptic technique, transfer device into defect site and secure into place.

NOTE: Place epithelial basement membrane side of device away from defect. When sidedness indicator (notch) is in location shown in image, epithelial basement membrane side of device is facing up.



Recommended suture bite depth: 10 mm

NOTE: Interrupted sutures can provide additional security against recurrence of defect in event of suture failure.

6. Ensure device maintains close tissue approximation.
7. Complete standard surgical procedure.
8. Discard any unused portions of device. Do not re-use or re-sterilize any unused portions of device.

Laparoscopy

When performing laparoscopic procedures using device:

1. Properly hydrate device prior to loading.
2. Grasp device along width or at any of the four corners. Avoid grasping along length of device.
3. Fold device at grasping site and roll along width of device prior to insertion.
4. Load device through 12 mm port or larger.
5. **Insert through port only once.**

Hiatal/Diaphragmatic

When performing hiatal/diaphragmatic repairs using the device:

1. Ensure that a rim of native hiatal tissue separates the mesh from the wall of the esophagus so as to not constrict the esophagus.
2. Ensure that the mesh is anchored securely to avoid mesh migration and erosion in to the esophagus or adjacent organs.