

US Pat. 6,576,265; 6,849,273; 6,861,074;
6,890,564; 6,887,495; 9,265,860; 9,433,701

AU Pat. 777,652; 2005200350

CA Pat. 2,393,468

CN Pat. 200920004482.2

EU Pat. 1239897

JP Pat. 3824537; 4942908

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LBL-1004.0

REF PSM0412; PSM0505; PSM0615; PSM0710;
PSM0715; PSM1015

SYMBOLS GLOSSARY

| | Title of Symbol/ Explanatory Text | ISO 7000 Reference Number |
|--|--------------------------------------|---------------------------------|
|  | 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 |

Gentrix™

SURGICAL MATRIX

Thin

INSTRUCTIONS FOR USE

Rx Only

Above symbols conform with the following standards:

ISO 15223 —1:2012 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



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MADE IN USA

DEVICE DESCRIPTION

Gentrix™ Surgical Matrix Thin (3-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 Thin is intended for implantation to reinforce soft tissue where weakness exists in patients requiring urological, gastroenterological, or plastic & reconstructive surgery. Reinforcement of soft tissue within urological, gastroenterological, and plastic & reconstructive surgery includes, but is not limited to, the following procedures: hernia and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair.

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. Do not use for high stress applications, such as large, high tension ventral hernias, repair of pelvic organ prolapse, and sacrocolposuspension 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

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

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 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, tender scars, adhesions, seroma formation, fistula formation, hematoma, recurrence of tissue defect, 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.

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 Thin. The provided suggestions are not intended to supersede internal institutional protocols and sound clinical judgment.

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

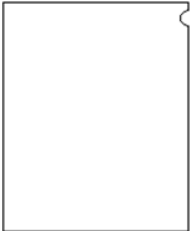
3. Prepare defect site using standard surgical techniques. Place device into well vascularized tissue.

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 10 mm port or larger.
5. **Insert through port only once.**