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

ACell® is a registered trademark of ACell, Inc.

LBL-1003.0

REF PFM0412; PFM0505; PFM0710; PFM0912; PFM1015

SYMBOLS GLOSSARY

	Title of Symbol/ Explanatory Text	ISO 7000 Reference Number
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
SN	Serial Number	2498
STERILE R	Sterilized Using Irradiation	2502
	Use By Date	2607

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

Pelvic Floor Matrix

INSTRUCTIONS FOR USE

Rx Only

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

DEVICE DESCRIPTION

ACell® Pelvic Floor 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

ACell Pelvic Floor Matrix (6-layer) is intended for implantation to reinforce soft tissue where weakness exists in patients requiring urological or gynecological surgery. Reinforcement of soft tissue within urological and gynecological surgery includes, but is not limited to, the following procedures: pubourethral support, urethral and vaginal prolapse repair, reconstruction of pelvic floor, and bladder support. By providing pubourethral support, ACell Pelvic Floor Matrix may be used for the treatment of urinary incontinence resulting from urethral hypermobility and intrinsic sphincter deficiency.

CONTRAINDICATIONS

Patients with known sensitivity or allergy to porcine materials.

WARNINGS

1. Exposure to contaminated or infected field can lead to rapid breakdown of device.
2. If active infection is present, treat patient to resolve infection prior to device application.
3. 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.

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, 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

STERILIZATION

ACell device is supplied sterile by electron beam irradiation in double peel-open pouches. Device is sterile if device pouch is unopened and undamaged.

The following procedures only serve as a suggested guideline for the application of ACell Pelvic Floor Matrix. 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: 20 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 defects 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.**