CAUTION: Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.
DEVICE DESCRIPTION
MatriStem® Surgical Matrix PSMX (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 devices are terminally sterilized using electron beam irradiation.

INDICATIONS
MatriStem® Surgical Matrix PSMX (6-layer) 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 procedures: hernia and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair.

CONTRAINdications
Not for patients with known sensitivity or allergy to porcine materials.

WARNINGS
1. Do not use via transvaginal placement for treatment of pelvic organ prolapse or stress urinary incontinence.
2. Exposure to contaminated or infected field can lead to weakening or breakdown of device.
3. If active infection is present, treat patient to resolve infection prior to device implantation.
4. Do not re-use or re-sterilize; can damage the device and lead to device failure and/or patient injury.
5. Do not use after printed expiration date.
6. Do not use if package is compromised, which may indicate loss of device sterility.
7. Do not use device 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.

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, fistula formation, hematoma, 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

STORAGE
Store in a clean, dry environment between 15-35°C (59-95°F) in unopened and undamaged package. Protect from freezing, excessive heat and high humidity.

STERILIZATION
MatriStem® devices are supplied sterile by electron beam irradiation in double peel-open packages. Device is sterile if package is unopened and undamaged.

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. Rehydrate device prior to use in sterile dish by submerging completely in room temperature sterile saline solution (0.9%):

Minimum hydration time: 20 min
Maximum recommended 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 reuse 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.