

POST-OPERATIVE CARE RECOMMENDATIONS

1. Proper post-operative care may include the use of appropriate drainage and negative pressure therapy.
2. As with any post-operative care, aseptic technique should be practiced when required to minimize contamination to the surgical wound.

DEFINITIONS

 FIRM	 CONTENTS	 OPEN HERE
 DO NOT USE IF PACKAGE IS DAMAGED	 INNER POUCH	 OUTER POUCH
 CORRECT SETTING	 INCORRECT SETTING	 MANUFACTURED BY
 ATTENTION, SEE INSTRUCTIONS FOR USE	 STERILIZED USING IRRADIATION	 DO NOT RE-STERILIZE
 FOR SINGLE USE ONLY	 TEMPERATURE LIMITATIONS 30°C -8°C	 USE BY DATE
 CATALOG NUMBER	 LOT NUMBER	RxONLY CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
 AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	 PERFORATED	

CUSTOMER SUPPORT

For product complaints and potential adverse events, please contact your local Sales Representative, or 1-800-433-8871.

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Manufactured by:
LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876 USA



STRATTICE™ Reconstructive Tissue Matrix Perforated

Surgical Mesh

DEVICE DESCRIPTION

STRATTICE™ Reconstructive Tissue Matrix Perforated (“STRATTICE™ TM” or “the surgical mesh”) is a surgical mesh that is derived from porcine skin and is processed and preserved in a patented phosphate buffered aqueous solution containing matrix stabilizers. This device is designed to perform as a surgical mesh for soft tissue repair while presenting a scaffold to the patient. The structural properties minimize tissue attachment to the mesh. STRATTICE™ TM consists of a terminally sterilized sheet of processed porcine dermal matrix. This device is provided in prescribed geometric configurations and packaged in a double pouch configuration.

Use of STRATTICE™ TM provides for an implant which is strong, biocompatible and will incorporate into the recipient tissue with associated cell and microvascular ingrowth.

Animal studies show a low incidence in adhesion to the STRATTICE™ TM surgical mesh based on observation of minimal visceral tissue attachment.

INDICATIONS FOR USE

STRATTICE™ TM is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.

STRATTICE™ TM is intended for single patient one-time use only.

CONTRAINDICATIONS

- STRATTICE™ TM is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.
- Polysorbate 20 is a component of the aqueous phosphate buffered solution and therefore the surgical mesh should not be used in patients with a known sensitivity to this material.

RxONLY CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



WARNINGS

- **Do not resterilize.** Discard all open and unused portions of the device.
- **Do not use** if the package is opened or damaged.
- **Do not use** if seal is broken or compromised.
- **Do not use** if the temperature monitoring device does not display “OK”.
- **Do not reuse** once the surgical mesh has been removed from the packaging and/or is in contact with a patient. This increases risk of patient-to-patient contamination and subsequent infection.
- After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

PRECAUTIONS

- Discard the surgical mesh if mishandling has caused possible damage or contamination.
- Discard if the surgical mesh is past its expiration date.
- Ensure that the surgical mesh is placed in a sterile basin and covered with room temperature sterile saline or room temperature sterile lactated Ringer’s solution for a **minimum of 2 minutes** prior to implantation in the body.
- Place the surgical mesh in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.
- The surgical mesh should be hydrated and moist when the package is opened. If the surgical mesh is dry, do not use.
- If a tissue punch-out piece is visible, remove using aseptic technique before implantation.
- Certain considerations should be used when performing surgical procedures using a surgical mesh product:
 - Consider the risk/benefit balance of use in patients with significant co-morbidities; including but not limited to, obesity, smoking, diabetes, immunosuppression, malnourishment, poor tissue oxygenation (such as COPD), and pre- or post-operative radiation.
 - Presence of a significant microbial load may affect overall performance of surgical mesh. Utilize bioburden-reducing techniques to minimize contamination levels at the surgical site, including, but not limited to, appropriate drainage, debridement, negative pressure therapy, and/or antimicrobial therapy.
 - In large abdominal wall defect cases where midline fascial closure cannot be obtained, with or without separation of components techniques, utilization of the surgical mesh in a bridged fashion is associated with a higher risk of hernia recurrence than when used to reinforce fascial closure.

STORAGE

- STRATTICE™ TM is a sterile medical device that should be stored in a clean, dry location at room temperature.
- Store in original packaging.
- Refer to the temperature monitor located on the product carton to ensure that the product has been stored within its temperature limits. Only use the product if the included temperature monitor displays “OK” on the screen. If screen displays anything other than “OK”, do not use the product.

- The expiration date of the product is indicated as 4 digit year, 2 digit month, and 2 digit day (YYYY-MM-DD).

STERILIZATION

- This product is sterilized by electron beam irradiation.

INSTRUCTIONS FOR PREPARING STRATTICE™ TM FOR SURGICAL USE

These instructions are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care. Users should be familiar with surgical procedures and techniques involving surgical mesh before using STRATTICE™ TM.

REQUIRED MATERIALS

- Sterile forceps
- Soaking fluid: room temperature sterile saline or room temperature sterile lactated Ringer’s solution
- One sterile basin per piece of surgical mesh.

PREPARATION INSTRUCTIONS

1. Open the carton and remove the foil package.
2. Peel open the outer foil package and remove the inner foil pouch using aseptic technique. The inner foil pouch is sterile and may be placed directly into the sterile field.
3. Open the inner pouch carefully and aseptically remove the surgical mesh. Always use sterile gloved hands or forceps when handling the surgical mesh.
4. Soak the device for a **minimum of 2 minutes** using a sterile basin and sufficient room temperature sterile saline or room temperature sterile lactated Ringer’s solution to cover the surgical mesh.
5. Store the surgical mesh in the room temperature sterile solution until ready for implantation. Device can be stored in sterile solution for a maximum of 4 hours.

IMPLANTATION INSTRUCTIONS

1. Prepare the surgical site using standard techniques. As with any surgical implant, careful aseptic technique should be practiced and contact of the mesh with patient’s skin should be minimized.
2. The surgical mesh may be folded, trimmed or cut as required to fit the surgical site using aseptic technique, ensuring allowance for overlap.
3. Transfer the surgical mesh to the surgical site using sterile gloved hands or forceps.
4. Suture the surgical mesh into place.

NOTE: Tension and suture placement are application dependent. For hernia repair applications, surgical experience with soft tissue implants indicates that suturing STRATTICE™ TM under physiologic tension with a minimum of 3cm–5cm overlap or as much as required to reach healthy adjacent tissues, may produce improved outcomes. Use of permanent sutures is recommended.

5. Complete the standard surgical procedure.
6. Discard any unused portions of the surgical mesh as per institutional procedures.