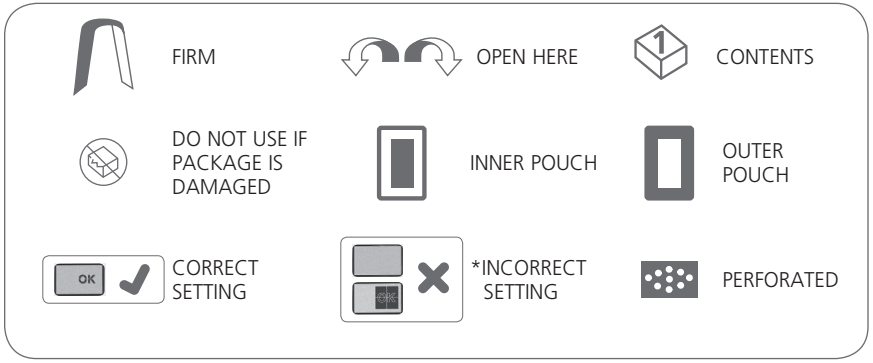
DEFINITIONS



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This product and certain methods are covered by patents and patents pending, including: US 8,905,826; US 8,735,054; US 8,469,779; US 8,323,352; US 8,007,531; and US 7,476,249.

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Strattice™ Surgical Mesh

RECONSTRUCTIVE TISSUE MATRIX
PERFORATED

DEVICE DESCRIPTION

Strattice™ Reconstructive Tissue Matrix Perforated (Strattice TM or the device) 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. The device consists of a terminally sterilized sheet of the processed porcine dermal matrix provided in prescribed geometric configurations and thicknesses 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™ Reconstructive Tissue Matrix Perforated 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™ Reconstructive Tissue Matrix Perforated is intended for single patient one-time use only.

CONTRAINDICATIONS

- This device is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.
- This device contains Polysorbate 20.

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

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WARNING

- **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.
- 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 device if mishandling has caused possible damage or contamination, or the device is past its expiration date.
- Soak the device for a minimum of 2 minutes using a sterile basin and room temperature sterile saline or room temperature sterile lactated Ringer's solution to cover the mesh.
- Place device in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.
- Strattice TM should be hydrated and moist when the package is opened. If Strattice TM is dry, do not use.
- If a tissue punch-out piece is visible, remove using aseptic technique before implantation.

STORAGE

- Strattice TM is a sterile medical device that should be stored in a clean, dry location at room temperature.
- It is to be stored in its original packaging.
- The expiration date of the product is indicated as 4 digit year, 2 digit month, and 2 digit day (YYYY-MM-DD).

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 Strattice TM

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 device. Always use sterile gloved hands or forceps when handling Strattice TM.
4. Soak the device for a minimum of 2 minutes using a sterile basin and room temperature sterile saline or room temperature sterile lactated Ringer's solution to cover the mesh.
5. Store device 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.
2. Strattice TM may be folded, trimmed or cut as required to fit the surgical site using aseptic technique, ensuring allowance for overlap.
3. Transfer Strattice TM to the surgical site using gloved hands or forceps.
4. Suture Strattice TM 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 underlay 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 Strattice TM as per institutional procedures.