STRATTICE™ Reconstructive Tissue Matrix Extra Thick

Surgical Mesh

DEVICE DESCRIPTION

STRATTICE™ Reconstructive Tissue Matrix Extra Thick ("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.

USE BY DATE

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
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.
5. Complete the standard surgical procedure.
6. Discard any unused portions of the surgical mesh as per institutional procedures.