


















DEFINITIONS

	PLIABLE		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		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.

CUSTOMER SUPPORT

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


Patented in the US. Please see www.allergan.com/patents. Additional patents may be pending or granted in the US and elsewhere.

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 Manufactured by:
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STRATTICE™ BPS Reconstructive Tissue Matrix

Surgical Mesh

DEVICE DESCRIPTION

STRATTICE™ BPS Reconstructive Tissue Matrix (“STRATTICE™ BPS” 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 for cellular and microvascular ingrowth. STRATTICE™ BPS consists of terminally sterilized sheet of processed porcine dermal matrix provided in prescribed geometric configurations and packaged in a double pouch configuration.

Use of STRATTICE™ BPS provides for an implant that is strong and biocompatible for its intended use and which will incorporate into the recipient tissue with associated cellular and microvascular in-growth.

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

INDICATIONS FOR USE

STRATTICE™ BPS 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 which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The implant is intended for reinforcement of soft tissue in plastic and reconstructive surgery.

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

CONTRAINDICATIONS

- STRATTICE™ BPS 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.
- 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.
 - As standard practice, bioburden-reducing techniques should be utilized in significantly contaminated or infected cases to minimize contamination levels at the surgical site, including, but not limited to, appropriate drainage, debridement, negative pressure therapy, and/or antimicrobial therapy prior and in addition to implantation of the surgical mesh.

STORAGE

- STRATTICE™ BPS 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™ BPS 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™ BPS.

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 the 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. Secure the surgical mesh into place.
5. The surgical mesh should be placed in good approximation with healthy adjacent tissues without leaving potential spaces for fluid accumulation between the mesh and the adjacent tissues. Care should be taken to avoid placing the mesh adjacent to ischemic or poorly vascularized tissues whenever possible.
6. Complete the standard surgical procedure.
7. Discard any unused portions of the surgical mesh as per institutional procedures.

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.