Strattice™ Reconstructive Tissue Matrix

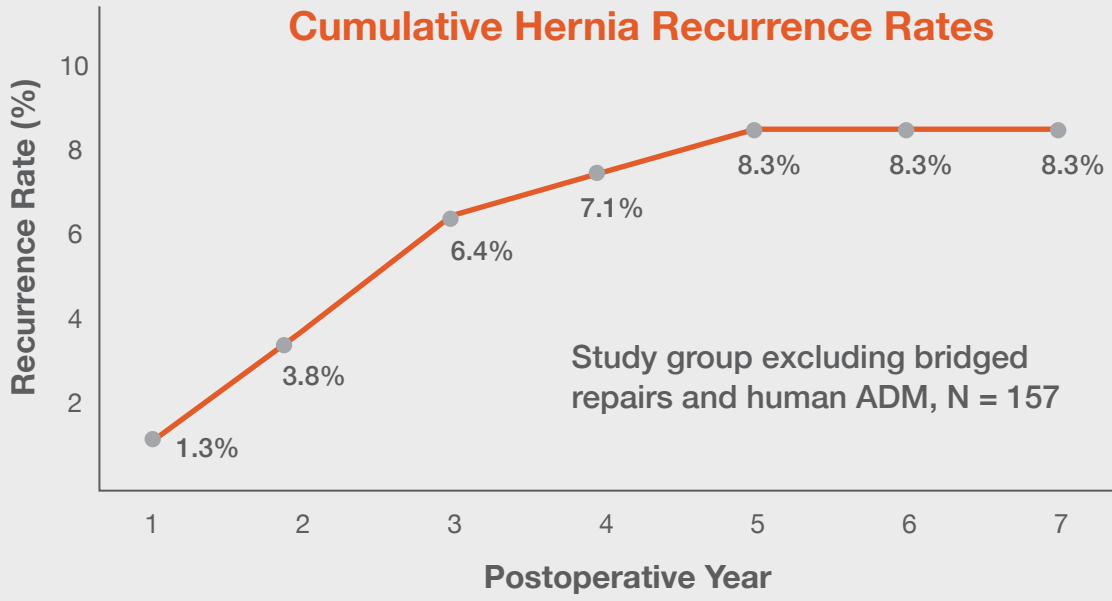
BECAUSE EVIDENCE MATTERS

In the study, STRATTICE™ Reconstructive Tissue Matrix (RTM) provided "durable long-term outcomes in complex AWR"[1]

Study Setup

- Analysis sample of 191 patients, with a median follow-up of 52.9 months (range 36-104 months) and 23 surgeons. Majority of nonhuman ADMs were STRATTICE™ RTM (109/169)
- Primary outcomes measure was hernia recurrence. Secondary outcomes measure was surgical site occurrence, defined as the presence of 1 or more of the following postoperative surgical complications: bulging or laxity of the abdominal wall, wound dehiscence, skin/fat necrosis, cellulitis/abscess, hematoma, and seroma
- Follow-up for hernia recurrence was performed on all patients by physical examination and confirmed by CT scan in 88%
- Limitations of study included retrospective nature, noncomparative and nonrandomized design, and the potential for selection bias
- Study conducted at a single center—The University of Texas MD Anderson Cancer Center, Houston, TX

Hernia recurrence rates achieved stasis in years 5 through 7 when bridged repair and human ADM patients were excluded*



*Adapted from Garvey et al., Table 4, Fig 3 (1 hernia recurrence-free probability). The cumulative hernia recurrence rates were estimated by using the Kaplan-Meier product limit method.

ADM = acellular dermal matrix; AWR = abdominal wall reconstruction.

HUMAN ADM WAS ASSOCIATED WITH HIGHER HERNIA RECURRENCE RATES

- Human ADMs and bridged repair were significantly predictive of developing a hernia recurrence
- Use of a human ADM resulted in a hazard ratio of 3.3 (95% CI = 1.3-8.5, p = 0.01)

THE AUTHORS FOUND THAT HERNIA RECURRENCE RATES WITH ADMS COMPARED FAVORABLY TO THOSE REPORTED IN LITERATURE OF SYNTHETIC MESH AND ACHIEVED LOWER INFECTION AND EXPLANTATION RATES

- These data demonstrated that avoiding a bridged repair and employing xenograft rather than human allograft can help improve hernia recurrence rates
- Rates of postoperative infection and mesh removal experienced by the ADM cohort were among the lowest reported in published literature for AWR

INDICATIONS

STRATTICE™ Reconstructive Tissue Matrix (RTM), STRATTICE™ RTM Perforated, STRATTICE™ RTM Extra Thick, and STRATTICE™ RTM Laparoscopic are intended for use as soft tissue patches to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use of these products 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™ RTM Laparoscopic is indicated for such uses in open or laparoscopic procedures. These products are supplied sterile and are intended for single patient one-time use only.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

These products should not be used in patients with a known sensitivity to porcine material and/or Polysorbate 20.

WARNINGS

Do not resterilize. Discard all open and unused portions of these devices. **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.

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.

For STRATTICE™ RTM Extra Thick, **do not use** if the temperature monitoring device does not display "OK."

PRECAUTIONS

Discard these products if mishandling has caused possible damage or contamination, or the products are past their expiration date. Ensure these products are 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 these products in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.

These products 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.

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.

For STRATTICE™ RTM Perforated, if a tissue punch-out piece is visible, remove using aseptic technique before implantation.

For STRATTICE™ RTM Laparoscopic, refrain from using excessive force if inserting the mesh through the trocar.

STRATTICE™ RTM, STRATTICE™ RTM Perforated, STRATTICE™ RTM Extra Thick, and STRATTICE™ RTM Laparoscopic are available by prescription only.

For more information, please see the Instructions for Use (IFU) for all STRATTICE™ RTM products available at https://hcp.stratticetissuematrix.com or call 1.800.678.1605.

To report an adverse reaction, please call Allergan Aesthetics at 1.800.367.5737.

Reference: 1. Garvey PB, Giordano SA, Baumann DP, Liu J, Butler CE. Long-term outcomes after abdominal wall reconstruction with acellular dermal matrix. *J Am Coll Surg*. 2017;224(3):341-350.

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