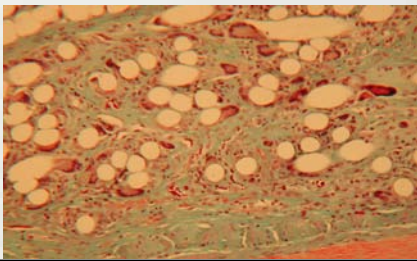


Material and Structure: a next generation non-woven, microfiber polypropylene mesh for all types of hernia repair available in two configurations: WN for non-visceral contact mesh repairs and XB for visceral contact mesh repairs. Being a low weight mesh with a high degree of flexibility and a reduced thickness of ~0.5 mm, SURGIMESH provides ease of handling and maneuverability during surgical procedures along with superior patient comfort and lower complication rates long term¹⁾. Due to its non-woven nature and small fiber size (0.02 mm - up to 10 times smaller), SURGIMESH presents an appropriately sized interconnecting pore structure which results in low levels of inflammation and completeness of incorporation in very short periods of time. Composed of a random network of high strength fibers, SURGIMESH exceeds FDA reviewed mesh strength levels.



Non-woven, microfiber structure of SURGIMESH material.

Incorporation: as a result of its small fiber size and optimal interconnecting pore structure, analysis of SURGIMESH implants demonstrated complete incorporation by 12 days post-operatively in experimental studies²⁾. The incorporation was primarily collagenous with low levels of inflammation and very thin fiber granuloma formation as seen in the histological section to the left. Upon complete incorporation, the SURGIMESH material demonstrates healthy vascularization throughout the non-woven, microfiber structure²⁾. Associated with these low levels of inflammation, in clinical use SURGIMESH has not exhibited noticeable levels of shrinkage at hernia repair sites^{3, 5)}. Clinical experience with SURGIMESH has shown minimal infective complication once full incorporation has occurred⁴⁾. A prospective, randomized open inguinal hernia repair comparison of SURGIMESH to heavy weight knitted polypropylene and e-PTFE meshes found significantly less patient pain and a reduced rate of complication over a five year follow-up¹⁾.



Full tissue incorporation and low inflammation shown in SURGIMESH WN after 12 days in a porcine abdominal wall repair model

Visceral Contact: the XB Tintra configuration of SURGIMESH possesses a very thin (~0.2 mm) layer of integrated medical grade silicone elastomer on one surface to minimize visceral tissue attachment in laparoscopic and open minimally invasive hernia repairs. The silicone surface, being a permanent barrier to tissue attachment, provides consistent minimization of tissue attachment³⁾ long term. This is shown in the picture to the right where the visceral surface of a ventral hernia repair performed with SURGIMESH XB demonstrates secure healing to the abdominal wall with no visceral adhesion formation after 75 days⁴⁾. With the XB Tintra configuration the peritoneal surface has small 1 mm holes for serous drainage post operatively. These holes heal over early in the post operative period. Clinical feedback on use of SURGIMESH for minimally invasive hernia repair has found the mesh to provide superior handling and ease of use for surgeons while demonstrating improved patient comfort and outcome^{1, 3, 4)} in open and laparoscopic hernia repairs.



75 day laparoscopic re-look of a ventral hernia repair with SURGIMESH XB in a gastric bypass patient.

References:

- 1) Smietanski, M., et. al., Five-year results of a randomized controlled multi-centre study comparing heavy-weight knitted versus low-weight, non-woven polypropylene implants in Lichtenstein hernioplasty, *Hernia*, v. 15, p. 495, Oct 11
- 2) Aspide Medical, ITAQ330 Implantation Test Summary, November 2003
- 3) Mechanical and Histomorphometric Assessment of Surgical Meshes, Dartmouth Surgical Research Lab, Data on file
- 4) Yunis, J, Safety and Efficacy of Non-Woven PP with Silicone Barrier in LVHR, ACOS Annual ACA, Sep. 11
- 5) Mann, KE, PNMC, Case Report – SURGIMESH XB in Ventral Hernia Repair Re-look Procedure, October 2009