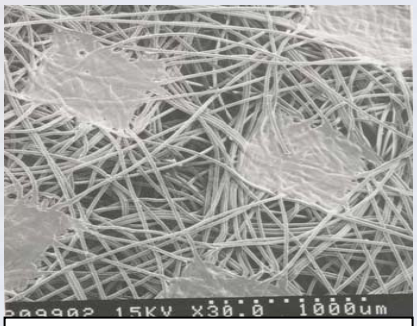
SURGIMESH® Hernia Mesh

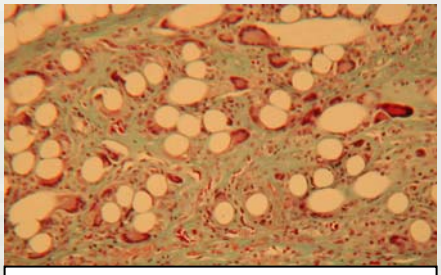
Product Summary

Material and Structure: a next generation non-woven, microfiber polypropylene mesh for all types of hernia repair available in two configurations for either open hernia – WN – or barrier mesh applications – XB Tintra. With a high degree of flexibility, a reduced thickness of ~0.5 mm and being a light weight mesh, SURGIMESH provides ease of handling and maneuverability during surgical procedures along with superior patient comfort and lower complication rates long term[1)]. Due to it's 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 lower levels of inflammation and completeness of incorporation in very short periods of time. Composed of a random network of high strength fibers, SURGIMESH is 1.6 times the FDA standard for hernia mesh strength.



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 studies[2)]. 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. Associated with these low levels of inflammation, in clinical use SURGIMESH has not exhibited noticeable levels of shrinkage at hernia repair sites[3, 4)]. US clinical experience with SURGIMESH has shown minimal infective complication once full incorporation has occurred. Upon complete incorporation, the SURGIMESH material demonstrates healthy vascularization throughout the non-woven, microfiber structure[2)]. 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 in the first year of follow-up[1)].



Full tissue incorporation and low inflammation is found 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 prevent visceral adhesion formation in laparoscopic and open minimally invasive hernia repairs. The silicone surface, being an absolute barrier to adhesion formation, significantly reduces adhesions to visceral structures. This is shown in the picture to the right where the visceral surface of a ventral hernia repair performed with SURGIMESH XB demonstrates firm healing to the abdominal wall with no visceral adhesion formation[4)] after 75 days implant duration. With the XB Tintra configuration, to assist in managing post-operative seromas, the peritoneal surface has small 1 mm holes for serous drainage. These holes heal over shortly post-operatively. 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 outcome[1, 3, 4)] in open and laparoscopic hernia repairs.

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

References:

1) Paradowski, T, et.al., Polypropylene vs. ePTFE vs. WN mesh for Lichtenstein inguinal hernia repair – a prospective, randomized, double blind pilot study of one-year follow-up, VideoSurg, Vol. 4, p. 6, April 2009
2) Aspide Medical, ITAQ330 Implantation Test Summary, November 2003
3) Francois, JY, et.al., Short Term WN Result In Laparoscopic Inguinal Hernia Repair in Adults, Aspide Medical, June 2003
4) Mann, KE, Portsmouth Naval MC, Case Report – 75 Day Re-look Laparoscopy - Umbilical Repair, October 2009