

“Improving Upon Historical Hernia Mesh Failure Modes” Marketing Initiative Successfully Launched to Engage Hernia Surgeons In Reviewing Knitted, Expanded and Non-Woven Mesh Experimental and Clinical Performance

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In 2005 due to the range of complications hernia surgeons had been experiencing, authors from two prestigious medical institutions published summaries describing analyses performed on clinically removed hernia meshes and on mesh adverse event data being collected by the Food and Drug Administration^{1,2}. These publications reported the reasons for hernia mesh removal and, in one publication, analyzed the retrieved mesh samples. Reasons for removal included hernia recurrence, mesh mechanical failure, chronic pain at hernia site, reaction at site of mesh, infection of hernia mesh or site, adhesions to mesh or site, fistula formation or erosion to mesh and seroma formation at the hernia site.

Both publications concluded that some reasons for removal were related to specific knitted and expanded mesh material characteristics. The reasons included mesh mechanical failure, chronic pain at hernia site, reaction at site of mesh, infection of hernia mesh or site, adhesions to mesh or site and fistula formation or erosion at the hernia site. Alternatively, experimental³ and clinical^{4,5} experience with SURGIMESH® non-woven, microfiber polypropylene matrix hernia meshes has shown that these same potential mesh failure modes are either eliminated or significantly reduced when SURGIMESH hernia mesh is used.

Hernia surgeon response to this initiative has been very positive with many appreciating the comprehensive approach and subsequently trialing SURGIMESH WN and XB hernia meshes in clinical hernia repair. For additional information on SURGIMESH hernia repair configurations visit the www.surgimesh.com web site.

References:

- 1) Klosterhalfen, B, et.al., The lightweight and large porous mesh concept for hernia repair, Expert Review Medical Devices, vol. 2, p. 1-15, Feb. 2005
- 2) Robinson, TN, et.al., Major mesh-related complications following hernia repair, Surgical Endoscopy, vol. 19, p. 1556-1560, Dec 2005
- 3) Hoopes, PJ, et.al., Mechanical and Histomorphometric Assessment of Surgical Meshes, Dartmouth Surgical Research Lab, data on file
- 4) Yunis, J., Laparoscopic Ventral Hernia Repairs with SURGIMESH presentation, ACAOS Meeting, September 2011
- 5) <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>

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BG Medical is the exclusive US distributor for SURGIMESH and other advanced medical device technologies.

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