Emerging Litigation: Hernia Mesh Criteria and Venue

Defective hernia mesh is becoming an increasingly popular, main stream mass tort case. As advertising increases across the country, it is likely that attorneys who do not typically handle mass tort cases, will have a client inquire about hernia mesh complications. Workers Compensation, Social Security Disability, and other personal injury clients that your firm previously represented or is currently representing could have a hernia mesh implanted from a workplace or other injury that resulted in a hernia. We have discovered and accepted referred clients that were previously retained for other cases that fall into this category and have hernia mesh implanted that is causing severe complications or have previously had hernia mesh removed.

There are dozens of hernia mesh products made out a variety of materials and many have differing "signature defects". These defects are responsible for causing clients severe complications and even secondary revision surgeries to remove or repair the mesh. The key to these cases is being able to identify which complications are caused from a mesh product and which complications are just a bi-product of a hernia repair surgery. There are currently four hernia mesh manufacturers subject to litigation and below is a brief overview of each.

Ethicon Physiomesh

Ethicon Physiomesh is a flexible composite mesh made out of polypropylene created for use in laparoscopic hernia repair surgeries.[1] After reports of increased hernia recurrence rates and other device failures, Ethicon Physiomesh was voluntarily withdrawn from the market on May 25, 2016.[2] Ethicon also released a version of Physiomesh for use in open hernia repair surgeries which was not included in the voluntary withdrawal.[3] Cases against Ethicon for injuries from its laparoscopic Physiomesh product are currently pending in a multidistrict litigation, *In Re: Ethicon Physiomesh Flexible Composite Hernia Mesh Products Liability Litigation*, in the United States District Court for the Northern District of Georgia and are organized under the Honorable Richard W. Story. The defect in Physiomesh is that the lightweight mesh rips, rolls up, or does not incorporate resulting in higher hernia recurrence rates.[4]

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[1] *Lawsuits Scheduled for Ethicon's Physiomesh Hernia Mesh*, Meshnewsdesk, https://www.meshmedicaldevicenewsdesk.com/lawsuits-scheduled-ethicons-physiomesh-hernia-mesh/ (October 25, 2016).

[2] *Ethicon Urgent: Field Safety Notice Ethicon Physiomesh Flexible Composite Mesh (All Product Codes)*, p. 1, https://www.igz.nl/Images/IT1027122-Ethicon_PHYSIOMESH-algepublic._tcm294-375822.pdf (May 25, 2016).

[3] *ETHICON PHYSIOMESH™ Open Flexible Composite Mesh Device*, p. 2, www.Ethicon.com, http://hostedvl106.quosavl.com/cgi-isapi/server.dll?8080?IFUs?.cmt1bWFyMTJAaXRzLmpuai5jb20=?GetOneDocPureFullTxt?d293k961t6d457bobbvpa9lkh8?8 (last visited February 19, 2015).

[4] Pawlak, Hilgers, Bury, et al., *Comparison of two different concepts of mesh and fixation technique in laparoscopic ventral hernia repair: a randomized controlled trial*, NCBI, *https://www.ncbi.nlm.nih.gov/pubmed/26139491* (July 3, 2015); *MAUDE Adverse Event Report: ETHICON, INC. PHYSIOMESH MESH, SURGICAL*, FDA PHY2025V, *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=2639885* ("It was reported that

Atrium Medical C-QUR

Atrium C-QUR mesh is an omega 3 fatty acid coated, polypropylene mesh created to minimize tissue attachment to the mesh.[5] However, increased incidents of mesh failure have been reported.[6] In or about February 2015, a permanent Federal Court injunction was entered against Atrium Medical Corporation, and its parent companies, to stop the distribution of adulterated and misbranded products, including surgical meshes.[7] Cases against Atrium Medical for injuries from its C-QUR products are currently pending in a multidistrict litigation, *In Re: Atrium Medical Corp. C-QUR Mesh Products Liability Litigation*, in the District of New Hampshire and are organized under the Honorable Landya B. McCafferty. The defect in C-QUR mesh is that the baked-on fish oil compound creates an adverse tissue reaction and sometimes an infection, resulting in the need for revision surgeries.

Bard Hernia Mesh

Bard hernia mesh products have not been withdrawn from the market and there is not currently a multidistrict litigation involving these products. However, there is a consolidated litigation in Rhode Island State Court, *In Re: Davol/C.R. Bard Hernia Mesh Multi-Case Management*, where Bard's subsidiary, Davol, is located. Bard has a large share of the hernia mesh product market and only some of the products manufactured by Bard are involved in this litigation. We have seen Bard hernia mesh products cause complications such as adhesions, fistulas, abscess formation/infection, bowel obstruction, organ perforation, seromas, and severe pain.

Covidien Parietex

Covidien Parietex hernia mesh is another product that has not been withdrawn from the market and is not a part of multidistrict litigation. However, there is a consolidated State Court litigation in Massachusetts where an increasing number of these case are being filed. Unlike many of the other hernia mesh products, Parietex is made out of polyester. We have seen Covidien Parietex

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a patient underwent a laparoscopic hernia repair procedure on (b)(6) 2012 and mesh was used. Twenty days post operatively, the patient experienced severe inflammation due to the foreign body mesh and developed an recurrent incisional hernia. The patient underwent a reoperation on (b)(6) 2012….The mesh was completely and easily removed because it was ***not integrated at all***") (emphasis added).

[5] Pierce, Perrone, Nimeri, et al., *120-day comparative analysis of adhesion grade and quantity, mesh contraction, and tissue response to a novel omega-3 fatty acid bioabsorbable barrier macroporous mesh after intraperitoneal placement Surg Innov.*, Pub Med, https://www.ncbi.nlm.nih.gov/pubmed/19124448 (January 4, 2009).

[6] *MAUDE Adverse Event Report: ATRIUM MEDICAL CORPORATION C-QUR MESH MESH, SURGICAL, POLYMERIC*, FDA, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=5201119 ("Patient had laparoscopic hernia repair approximately one year ago….. Patient developed wound complications, cellulitis, abdominal pain and discharge. Surgeon took patient back into the operating room and mesh was completely intact with no incorporation into surrounding tissue. Described mesh as being like it was tofu/green in color and lumpy. Mesh was removed.").

[7] *District Court Enters Permanent Injunction Against New Hampshire Company and Senior Executives to Stop Distribution of Adulterated and Misbranded Products*, The United states Department of Justice, https://www.justice.gov/opa/pr/district-court-enters-permanent-injunction-against-new-hampshire-company-and-senior (February 3, 2015).

cause complications such as chronic inflammation, fibrosis, shrinkage, tears, and mesh migration.

Conclusion

With over a million hernia surgeries a year, it is likely a client, friend, or family member has had a hernia repair surgery using mesh.[8] It is important to note that not all mesh products are subject to litigation and several of the products are being relied upon as a reasonable alternative design. With this in mind, case selection and filing only clear defect cases is important.

If you have any further questions on any of the current mesh litigations or case criteria, feel free to email me at jgebelle@yourlegalhelp.com.

[8] *Hernia Surgical Mesh Implants*, FDA, https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/HerniaSurgicalMesh/default.htm (last updated April 4, 2017).