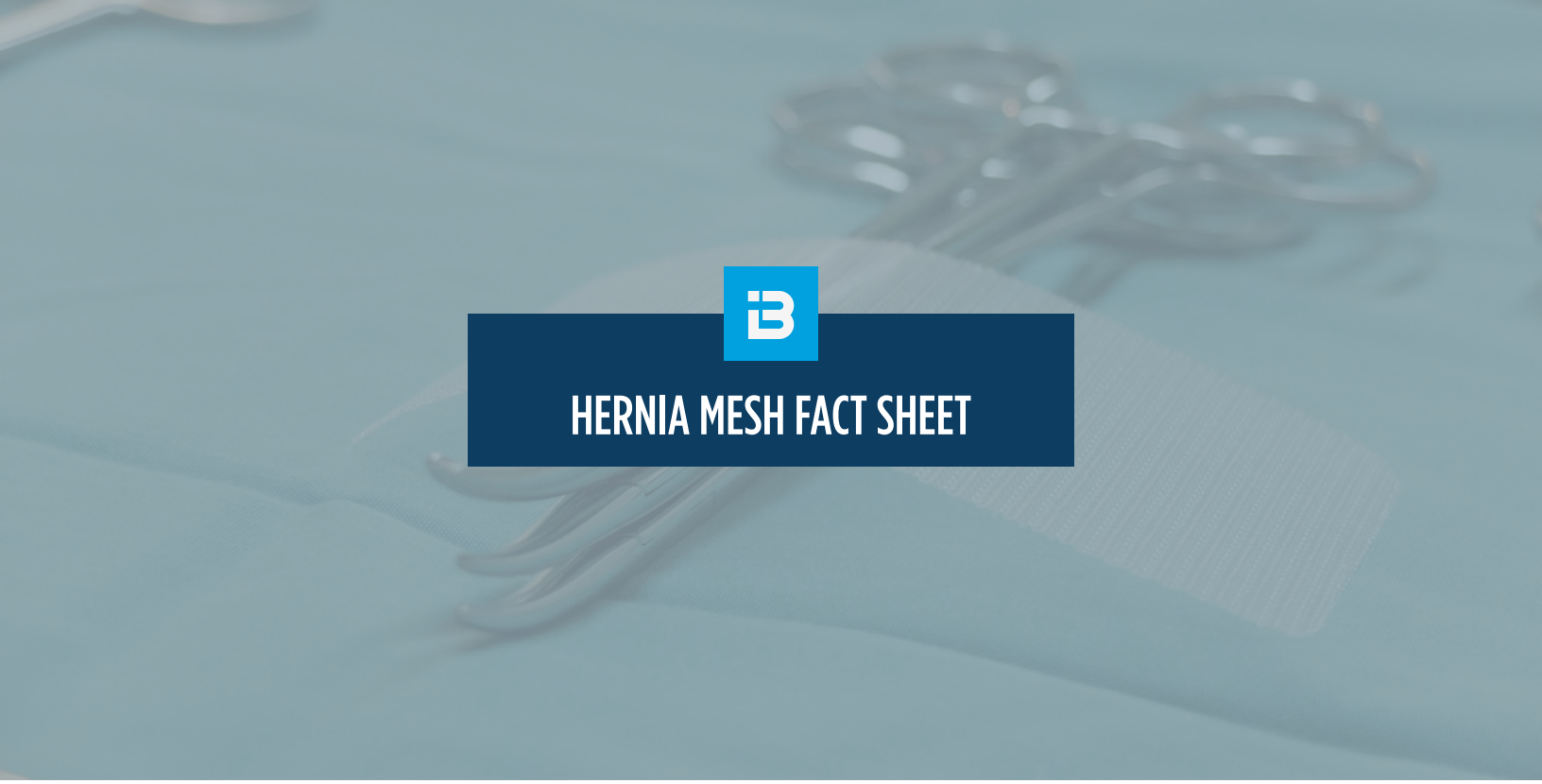

HERNIA MESH FACT SHEET

When first speaking with a potential client about problems with a hernia mesh implant, you might encounter common questions as to the device, known problems and/or the rate of failure. The following information should prove helpful in answering many of these inquiries as well as offer a better understanding of why certain hernia mesh devices are prone to severe problems, why these issues should have been caught sooner, and why manufacturers were reluctant to make any corrective actions.

WHAT ARE THE SYMPTOMS OF HERNIA MESH FAILURE?

While a hernia mesh implant can fail for any number of reasons, poor or defective product material or device design are often the culprits. These factors can lead to surgical site infection, adhesion to other organs or body tissue, bowel obstruction or even a hernia recurrence. Below are some indications of a hernia mesh failure of which patients should be aware:

- Pain, discomfort, bruising or swelling in the abdomen or groin
- A noticeable lump in or around the original hernia site
- Redness, soreness and warmth in the area of the surgical incision
- Abdominal bloating or Inability to pass stools
- Fluid build-up near the surgical site
- Fever, nausea and vomiting

HOW DO I FIND OUT WHAT TYPE OF HERNIA MESH DEVICE WAS USED IN MY SITUATION?

In some cases, certain surgical mesh devices used in specific applications don't fall within the parameters of ongoing mass tort lawsuits—thus, it's important to ascertain details regarding the device in question, its manufacturer and its implementation by the surgeon.

It's important that you complete the following steps:

- Contact the surgeon who performed the operation
- Request medical records from the hospital (will need authorization pursuant to HIPPA)
- Crosscheck device name with list of applicable manufacturers and products (page 2-3)

WHO IS AT RISK FOR COMPLICATIONS WITH A HERNIA MESH IMPLANT?

Anyone who has undergone laparoscopic surgery to repair a hernia may be at risk for developing complications—especially if the surgery occurred in the past 15 years. The side effects that one may experience are not limited to pain, fever, signs of infection or swelling in the area. In fact, many patients could experience a partial or complete failure of a hernia mesh device with mild to no symptoms that might be attributed to other more common maladies.

WHY DID IT TAKE SO LONG TO REVEAL ISSUES WITH HERNIA MESH?

In an effort to be more competitive with sales of hernia mesh, some companies released "new and improved" products that might not have been fully tested over a long enough period of time. Many of the newer synthetic meshes, such as Ethicon's Physiomesh and C-QUR by Atrium, were approved via the FDA's 510(k) process–a fast-track review developed for new devices that are deemed to be similar to an already approved medical device.

Because these meshes were considered comparable to another product that simply utilized a newer synthesized material, they were not subject to the same stringent safety testing as new products nor were they tested in specific applications, such as being used to repair the abdominal wall. Subsequent studies have now shown the synthetic polypropylene material used by many manufacturers—along with the biocoating some used to combat inflammation within the body—has caused many of the problems with these newer products.

WHY MIGHT A HERNIA MESH DEVICE BE RECALLED?

While all surgical devices, such as hernia mesh, must be approved by the FDA for safe use, some problems do not appear until after some time following the implant of the product. For most hernia mesh devices, the problems that have surfaced over time include the following:

Migration – When the hernia mesh moves within the body

Contraction – The mesh will actually collapse on itself, no longer covering the hernia location

Adhesion – Development of scar-like tissue that causes organs, muscle and body tissue to stick together

Fistula – An abnormal connection between organs or the intestinal tract, the latter allowing for leakage into body cavity or through the skin

Obstruction – The hernia mesh device can cause a blockage in the large or small intestine

Perforation – Irritation or abrasion from the mesh causes a hole in bowels or neighboring organ

WHY DO SURGEONS USE HERNIA MESH?

Before the advent of surgical mesh, hernias were repaired with sutures—basically the doctor would stitch the torn tissue back together. This process would simply patch together tissue or muscle that had already been weakened to the point of rupturing or tearing, thus increasing the chance of a recurrence in the future.

By introducing a new, stronger material (hernia mesh) into the repair, doctors successfully reduced the risk of a recurring hernia—yet the new devices introduced complications that can be more debilitating than the hernia itself.

WHICH HERNIA MESH PRODUCTS HAVE BEEN RECALLED BY THE FDA?

The FDA has issued the following hernia mesh recalls—accounting for hundreds of thousands of implanted devices since 2005:

COMPOSIX KUGEL MESH BY BARD DAVOL

Specifically designed to prevent the occurrence of incisional hernias, the Composix mesh was designed with a "recoil ring" built in that allowed the mesh patch to be inserted into the body while folded up—the ring then allowing the patch to be fully opened once in place behind/under the incision. This design proved to be a critical flaw over time, as the ring can break apart and migrate throughout the body—ultimately puncturing internal organs and causing other damage.

C-QUR BY ATRIUM MEDICAL

Able to be used in more than just ventral and inguinal hernias, the C-QUR used an all-natural Omega 3 fatty acid gel coating that was made from purified pharmaceutical grade fish oil. The coating was intended to prevent adhesions with the polypropylene material, but in actual use, the coating caused adverse reactions and severe side effects with some patients almost immediately, while others who tolerated the coating later experienced internal organ damage as the coating separated from the mesh over time.

PROCEED BY ETHICON (JOHNSON & JOHNSON)

Made to patch hernias that rupture the abdominal wall, the Proceed hernia mesh was constructed out of a lightweight polypropylene mesh called Prolene. This soft mesh was then coated with oxidized regenerated cellulose (ORC) to prevent injury within the body. Unfortunately, the entire device was radiated to make the coating resorbable—unknowingly starting a degradation process to the mesh polymer beneath, which caused product shrinkage, disintegration and migration throughout the body.

PHYSIOMESH BY ETHICON (JOHNSON & JOHNSON)

While never recalled by the FDA—it was "voluntarily" withdrawn from world markets in 2016—Physiomesh has probably affected the most people with its serious defects that included premature breakdown/disintegration; failure to incorporate into the abdominal wall; adhesion to the bowels; folding over after implantation; and prone to perforations and tears while still in the packaging. The manufacturers were so aware of ongoing issues that they brought a revision to market in 2014 called Physiomesh Open, yet it never gained traction in the market before the company decided to withdraw all Physiomesh products.

DURING WHAT TIME PERIOD HAVE THESE DEFECTIVE HERNIA MESH PRODUCTS BEEN EMPLOYED?

Using surgical mesh for hernia repairs has been possible for many decades, but usually with mixed results due to rejection and infection. With the advent of new materials in the 1980s, mesh-based repairs became more popular. As an example, by the 2000s, more than 90 percent of all groin hernia repairs relied on mesh-based repairs. For most manufacturers, the mid-2000s witnessed the widespread use of synthetic polypropylene mesh for repairing numerous types of hernias.

PHYSIOMESH

- First approved by the FDA for the U.S. marketplace in 2010
- Voluntarily withdrawn by Ethicon (Johnson & Johnson) in 2016
- Estimated more than 300,000 hernia patients have received a Physiomesh implant in the U.S. alone
- Currently 1,439 Physiomesh lawsuits filed in federal courts nationwide

ATRIUM C-QUR MESH

- Entered U.S. market in 2006 with FDA approval
- Received an FDA warning regarding unaddressed complaints in October 2012
- The FDA issued a Class II recall of the C-QUR Edge product in August 2013—a designation reserved for situations where use of product may cause health consequences that are most likely medically reversible with a remote chance of more serious, irreversible side effects

COMPOSIX KUGEL BY DAVOL

- The Composix Kugel mesh patch was first approved by the FDA in 2002
- An FDA Class I recall began in 2005—the highest level of recall that indicates a reasonable probability of injury—with over 100,000 units covered by the last expansion in January 2007
- 34 reports of ring breakage leading to recall including one death due to the defect
- Nearly 2,000 Composix Kugel Mesh lawsuits have been consolidated in Rhode Island state court

WHICH SPECIFIC HERNIA MESH DEVICES OR PRODUCTS COULD POSE PROBLEMS?

Below is a comprehensive list of brands and device models that have reported adverse events and/or are currently the subject of multiple lawsuits. It is possible that other products manufactured by these companies could be causing similar problems but might require more research.

ATRIUM MEDICAL

- C-QUR Mesh
- C-QUR TacShield
- C-QUR V-Patch
- C-QUR Edge
- C-QUR Lite Mesh V-Patch
- C-QUR Edge Mesh V-Patch
- C-QUR V-Patch Mesh
- C-QUR OVT Mesh
- C-QUR RPM Mesh
- C-QUR Mosaic
- C-QUR FX
- C-QUR CentriFX

COVIDIEN (Medtronic subsidiary)

- Parietex Composite Mesh
- Surgipro Mesh
- Monofilament Mesh
- Composite Mesh
- Optimized Composite Mesh
- ProGrip Self-Fixating Mesh
- Parietex Plug and Patch System
- Symbotex Composite Mesh

DAVOL (C.R. Bard subsidiary)

- Composix Kugel Mesh
- Composix E/X Mesh
- Composix L/P Mesh
- Perfix Plug
- 3DMax
- Sepramesh IP Composite
- Ventralex Hernia Patch
- Ventralex ST Hernia Patch
- Ventrio Hernia Patch
- Ventrio ST Hernia Patch
- Visilex
- Marlex
- Spermatix

GORE

- DualMesh
- DualMesh Plus

ETHICON (Johnson & Johnson subsidiary)

- Physiomesh
- Prolene Plug
- Prolene PHS
- Proceed Surgical Mesh
- Prolene 3D Patch
- Ultrapro Lightweight Mesh