## Hernia Mesh Lawsuit Filed Against Atrium Medical Corporation

## By Dan C. Bolton and Farid Zakaria, Keller, Fishback & Jackson LLP

The law firm of Keller, Fishback & Jackson LLP recently filed a lawsuit in California federal court on behalf of a forty-six year old man injured by a hernia mesh product. The lawsuit alleges claims of product liability, negligence, and fraud against Atrium Medical Corporation (Atrium), the mesh manufacturer, and seeks compensatory and punitive damages. This is believed to be the first case in California filed against Atrium for one of its hernia mesh products.

The plaintiff, a resident of New Jersey, underwent double inguinal hernia repair in 2011 with the ProLoop, a surgical mesh made of a type of plastic called polypropylene. He suffered serious complications after the surgery, including constant and excruciating pain in his groin, pelvic organ damage, nerve damage, the inability to have sexual intercourse, as well as anxiety and depression. Despite undergoing additional surgery some 18 months later to remove the implants, today he still suffers from lasting health problems.

The ProLoop mesh is a non-absorbable three-dimensional plug composed of knitted rows of polypropylene with multiple protruding loops. Polypropylene hernia mesh presents many of the same risks as transvaginal mesh, another dangerous medical device impacting thousands of women in the United Stated and currently the subject of nationwide litigation. Both products have undergone minimal regulatory scrutiny under <u>a legal framework</u> that does not require the submission of safety and efficacy data to the Food and Drug Administration.

The lawsuit points out that Atrium's warnings concerning Proloop are grossly inadequate and violate the manufacturer's duty to warn of the dangers of mesh. In the Instructions for Use, Atrium states only that inflammation, infection, mechanical disruption, and adhesion are potential side effects.

Polypropylene hernia mesh is frequently used in hernia repair surgery, though it is not always necessary given the high likelihood of complications. Despite relentless marketing by manufacturers, many doctors steer away from polypropylene mesh and use a mesh free procedure called the Shouldice technique to repair hernia. The Shouldice technique has been used for decades and has low rates of failure.

Manufacturers have touted mesh for hernia repair as safe and effective, but published research has found high rates of serious complications. One researcher observed there have been many "reports of various degrees of degradation ... stress cracking and mesh shrinkage along with infection, chronic inflammation and the stimulation of sclerosis [hardening of tissue]." The researcher concluded, "Based on available evidence the polypropylene used for surgical treatment of various structural defects is not inert after implantation in the human body."

In fact, a debilitating consequence of hernia repair with mesh is inguinodynia, or chronic groin pain. This condition results from the deformation of mesh following implantation, the

persistent foreign body reaction to mesh, and nerve entrapment in the mesh. The medical literature reports an extraordinarily high rate of chronic groin pain after hernia repair with mesh – in some reports approaching 50%, and even higher in others. Moreover, as the mesh degrades in the human body, small flakes of polypropylene can lead to infection and irritation, and severe pain as the body tries to rid itself of the foreign material.

Despite the abundance of scientific and medical information published in the literature relating to the dangerous properties and serious risks of polypropylene mesh, the plaintiff asserts that the defendants have made a deliberate decision to ignore these dangers, to aggressively market the ProLoop, and to paint a misleading picture of its safety and efficacy in the product literature.

Dan C. Bolton is Of Counsel and Farid Zakaria is an associate in the Los Angeles office of <u>Keller</u>, <u>Fishback & Jackson LLP</u>. The firm represents plaintiffs nationwide in pharmaceutical and medical device cases, including hernia and transvaginal mesh litigation. Mr. Bolton oversees the pharmaceutical and medical device practice. Mr. Zakaria has a background in molecular and cell biology.