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## Surgeons Warned Against Using Surgical Mesh in Pelvic Surgeries

On July 13, 2011, the FDA issued a new advisory warning about plastic surgical mesh utilized during transvaginal surgeries to correct common female gynecological problems. The surgical mesh is made from porous synthetic material and is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat stress urinary incontinence. U.S. physicians perform about 75,000 surgeries utilizing these mesh products each year. From 2008 to 2010, the FDA received more than 1,500 Adverse Event Reports related to complications associated with the plastic mesh. Surgeons Warned Against Using Surgical Mesh in Pelvic Surgeries.

Serious Complications Associated with Surgical Mesh Products Include:

- Infection
- Extreme Pelvic Pain
- Bleeding
- Dyspareunia (painful intercourse)
- Erosion/Protrusion of Mesh through the Vaginal Wall
- Vaginal Scarring/Deformity
- Multiple Surgeries to Remove Imbedded Mesh
- Urinary Problems

Recent studies indicate that about 10% of women who have the mesh placed transvaginally experience mesh erosion within 12 months of surgery and more than half require additional surgeries to remove the mesh. Mesh erosion can require multiple surgeries to repair and can be debilitating for some women. In some cases, even multiple surgeries will not resolve the complications.



Thousands of women suffering pelvic organ prolapse are treated with plastic mesh each year, but reports indicate surgery can often be performed safely and effectively without the need for mesh. The FDA plans to convene an advisory committee of experts this Fall to determine whether to ban the mesh. Under the FDA's controversial 510(k) approval process, the agency granted approval for use of the mesh in vaginal procedures in 2002 without requiring new studies demonstrating their safety or effectiveness since mesh products were already in widespread use and were "substantially equivalent" to mesh products already on the market.

Kirk-Pinkerton is currently accepting referrals of women who have suffered serious complications following mesh repair surgery for pelvic organ prolapse or stress urinary incontinence. Please contact Injury Attorney Bill Robertson for more information.