THREE MESH CASES: Two defense verdicts; one large award

Transvaginal mesh not properly placed

IN JANUARY 2007, polypropylene mesh (Gynecare Prolift Transvaginal Mesh; Ethicon) was inserted in a 57-year-old woman to treat bladder and rectal prolapse. The patient developed small-intestine obstruction, bladder contraction, and a large pelvic abscess. Surgical treatment of the complications included creation of a colostomy. She required daily self-catheterization. The patient died of unrelated causes after the suit was filed.

ESTATE'S CLAIM The gynecologist did not properly insert the mesh and did not fully inform the patient of possible complications.

PHYSICIAN'S DEFENSE The mesh was properly inserted. The patient developed an unpreventable adverse reaction to the mesh. Proper consent was obtained.

VERDICT A New York defense verdict was returned.

Polypropylene mesh removed due to pain

POLYPROPYLENE MESH (Obtryx Transobturator Midurethal Sling system, Boston Scientific Corporation [BSC]) was used to treat a woman's stress urinary incontinence (SUI) in 2008. Following surgery, the patient reported pain. The mesh was partially removed in 2011. The patient has continuing pain and complications caused by remaining pieces of the mesh that the surgeon believes cannot be removed safely.

PATIENT'S CLAIM Although BSC warned that the material could oxidize and become brittle, the surgeon used it anyway. The mesh eroded through the urethra, causing permanent damage. BSC was negligent in the design, marketing, and instructions for Obtryx.

DEFENDANTS' DEFENSE The surgeon read the instructions and felt the product was safe. BSC claimed the mesh is safe for SUI use. Directions for use clearly warn of possible erosion. A BSC engineer admitted that the tissue that surrounds the mesh can shrink, encapsulating nerves and causing chronic pain.

VERDICT A Massachusetts defense verdict was returned.

Abscesses, nerve damage: $73M

A 42-YEAR-OLD WOMAN reported SUI to her gynecologist. In January 2011, the gynecologist placed polypropylene pelvic mesh (Obtryx Transobturator Midurethal Sling system, BSC). Following surgery, the patient reported pain and fever; pelvic abscesses were found.

Multiple procedures partially removed the mesh and treated the infection. During one procedure, her femoral and obturator nerves were damaged; she walks with a limp. Dyspareunia and pain continue. Additional operations will be needed to remove more mesh and treat continuing infection.

PATIENT'S CLAIM BSC was negligent in the product's design and marketing. Warnings for use were inadequate concerning the nature and extent of possible permanent injuries: groin and pelvic pain, dyspareunia, nerve damage, and chronic urinary tract infections. BSC withheld or concealed clinical trial information and did not perform and report proper postmarket surveillance.

When pivotal study results were published in 2009, indicating that further research was needed to confirm that Obtryx was appropriate for treating SUI, the BSC sales department received an email telling them to not share this information with physicians.

At trial, BSC corporate executives knew little about system design and warnings regarding its use. Data that BSC provided to document the safety of Obtryx were not about that product.

MANUFACTURER'S DEFENSE Both sides agreed not to introduce discussion of the FDA and 510(k) process. BSC blamed a call-center for not passing along complaints from customers in a timely manner.

VERDICT A $73,465,000 Texas verdict was returned against BSC. The jury determined that the manufacturer displayed gross negligence; the design of the Obtryx system is faulty. The award included $50 million for exemplary damages, which the judge reduced to $11.2 million due to state caps, for a total award of $34.6 million.

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