Recalled medical devices received fast-track FDA approval, says New York Personal Injury Lawyer

A recently recalled medical device, the Axxent FlexiShield Mini, was originally approved by the U.S. Food and Drug Administration's 510(K) process.

NEW YORK, NEW YORK – Patients are at risk of life-threatening injuries from a device meant to protect healthy tissue from unwanted radiation during cancer treatment. The medical device, called the Axxent FlexiShield Mini, has been classified as the most serious type of recall.

According to the U.S. Food and Drug Administration (FDA), recalls of this level involve "situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death."

"Unsurprisingly, the shield was approved by the FDA via an abbreviated process used for devices that are considered substantially similar to products already on the market. This process, known as 510(K), allows a manufacturer to obtain market approval with little clinical testing and no testing on humans," said New York personal injury lawyer David Perecman, founder of the New York personal injury law firm, The Perecman Firm.

Most of the medical devices recalled for life-threatening or very serious hazards were cleared for market through the 510(K) process, according to a study published in 2011 in the *Archives of Internal Medicine*.

The drug agency cleared the Axxent FlexiShield Mini in June 2009. However, the device was flawed and left hundreds of particles of the metal tungsten in women's breasts. The tungsten particles could pose significant health risks for these women in the future, understands New York personal injury lawyer Perecman.

According to *The New York Times*, neither the manufacturer, iCAD Inc., nor the FDA could explain what went wrong with the shields.

They were taken off the market in February.

So far, 29 women are known to have been affected. Some of the women are considering having mastectomies to rid their bodies of the tungsten particles.

New York personal injury lawyer Perecman urges mammography and breast cancer patients to contact their doctors for follow up procedures.

If an individual has been injured by a defective medical device, he or she should contact an experienced New York personal injury lawyer to investigate whether or not they may be entitled to compensation.

About David Perecman and The Perecman Firm, PLLC:
For the past 30 years, the personal injury accident, auto accident, construction accident, and medical malpractice lawyers at The Perecman Firm, PLLC have championed all types of cases concerning personal injury. David Perecman, founder of the Firm, is a Board Director and the past Secretary and Treasurer of the New York State Trial Lawyers Association (NYSTLA) and a chair of its Labor Law Committee. Mr. Perecman's achievements have brought him recognition as an Honoree in the National Law Journal's Hall of Fame, in New York Magazine's "The Best Lawyers in America" and The New York Times Magazine "New York Super Lawyers, Metro Edition" for the years 2007-2010.

http://www.hrw.org/en/reports/2010/12/02/price-freedom

The Firm has recovered millions of dollars for its clients. Among the more recent victories, Mr. Perecman won a $15 million verdict* for a construction accident, a $5.35 million dollar verdict** for an automobile accident, and a $40 million dollar structured settlement for medical malpractice***.

*later settled while on appeal for $7.940 million

** later settled for $3.5 million

*** total potential payout

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