

# Florida woman sues DePuy Orthopedics over hip implant

Mass Device

DePuy Orthopaedics is facing the first of what might be an avalanche of lawsuits over one of its hip implants, after a Florida woman sued the company over an allegedly faulty hip implant.

Kathleen Margenau was implanted with a DePuy ASR acetabular cup in March 2008, according to court documents. Following the surgery, Margenau began experiencing pain and "extreme weakness in her hip and quadriceps," according to the lawsuit. Little more than a year later, her surgeon explanted the device and found that the device had "catastrophically failed." Another device made by one of the Johnson & Johnson (NYSE:JNJ) subsidiary's competitors was implanted and Margenau returned to her active lifestyle, according to the document.

DePuy, which introduced the ASR in the U.S. in 2005 after winning 510(k) clearance from the Food & Drug Administration, allegedly knew of design problems with the cup but failed to adequately warn physicians, according to the lawsuit.

"During this time, defendant DePuy was aware of a high rate of failures of its ASR cups, but did not provide this information to [Margenau's surgeon]," the lawsuit alleged. "As a result of defendant DePuy failing to provide this crucial information to plaintiff's orthopedic surgeon, [he] had little reason to suspect that the source of plaintiff's ongoing pain and weakness was the result of the failure of the ASR cup."

DePuy discontinued the cup and had phased it out by March of this year, sending a letter to doctors that month warning that data from the Australian medical device registry showed a "higher-than-expected" failure rate in traditional hip replacements, especially in smaller patients or those with weak bones.

Those moves followed two years of reports that the implant was prone to early failure, according to the [New York Times](#) [1]. Dr. Stephen Graves, the director of the Australian database, told the newspaper that the company was too slow in pulling the device from the market. The FDA received about 300 complaints about the ASR cup since 2008, according to the *Times*, with most complainants undergoing revision surgeries to replace the device. And the device's co-developer, Dr. Thomas Schmalzried, said he and DePuy officials realized that the ASR cup might be more of a challenge to implant properly than competing cups.

"The window for component position that is consistent for good, long-term clinical function is smaller for the ASR," than other cups, Schmalzried told the newspaper, which reported that he received \$3.4 million from DePuy for his work on the ASR and other devices.

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DePuy acceded that the device posed "a theoretical potential" to "be more sensitive to component position," but cited data from other studies and examinations of explanted devices that contradicted that finding.

Margenau is seeking a jury trial, compensatory damages and legal fees. The consortium of law firms that's representing her [said](#) [2] it believes the lawsuit is the first to involve the ASR device.

[SOURCE](#) [3]

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[1] <http://www.nytimes.com/2010/03/10/business/10device.html>

[2] <http://www.prweb.com/releases/depuy-asr-hip-replacement/lawsuit/prweb4130564.htm>

[3] <http://www.massdevice.com/news/florida-woman-sues-depuy-orthopedics-over-hip-implant>