

# DePuy Hip Implants: Another Johnson & Johnson Recall

DePuy Orthopaedics, a subsidiary of Johnson & Johnson, has voluntarily recalled two of its hip replacement systems after a staggering number of patients were forced to undergo revision surgeries as a result of device failure and premature deterioration of the devices. This recall comes on the heels of several others recently issued by the healthcare products conglomerate (eleven total recalls since September 2009), leading to some serious questions about their quality control.

A spokesperson for the company has advised that any patient who has an ASR XL Acetabular System or the ASR Hip Resurfacing System should consult with their surgeon for immediate evaluation of the device's performance and for enhanced monitoring. The recall may affect up to 93,000 patients worldwide who have been implanted with one of the 29 various models of these defective hip devices. The ASR XL Acetabular System, released

in 2004, was available worldwide, while the ASR Hip Resurfacing System, launched in 2003, had only been approved for use outside the United States. Approximately one in eight patients implanted with ASR products have required corrective surgery within the first five years after the initial implant. According to the National Joint Registry of England and Wales, the failure rates of 13% and 12% respectively are about twice the industry average for similar devices.

On July 17, 2010, the FDA categorized DePuy's actions with regard to these hip implants as a Class II medical device recall due to the new revision rate data transmitted to physicians, which contradicts the manufacturer's initial statements that the ASR products were being discontinued due to low sales figures and declining demand rather than safety and performance issues. Class II recalls are issued when a product has a lower probability of causing serious injuries or death than Class I recalls (the most serious level of a product recall), but where there is still,

nevertheless, the possibility of severe enough adverse events to cause irreversible damages.

The hip systems consist of metal ball and socket components - the socket portion is at the outer edge of the pelvis and the ball portion atop of the femur, which fits into the socket. These components wear over time as they move against each other, causing microscopic metallic particles to break away from the devices. Some patients have experienced inflam-



matory reactions to these metallic shavings. Those who reported adverse events and underwent surgical intervention reported symptoms such as pain, swelling, and difficulty walking. While these symptoms are considered normal for patients who have recently received a hip replacement, they can also signal a problem when the symptoms persist or worsen over time. According to DePuy's website, prolonged complaints of these symptoms may be a sign of loosening of the

hardware (when the implant does not stay attached to the bone in the correct position), fracture (where the bone around the implant may have broken), or dislocation (where the two parts of the implant that move against each other are no longer aligned).

In recent months, a number of lawsuits have been filed over faulty DePuy hip implants. The mass torts lawyers at **Searcy Denney Scarola Barnhart & Shipley, P.A.** are proud to represent clients who have suffered injuries as a result of defective DePuy hip implants as well as other defective medical devices, drugs, and consumer products. ♦

This recall comes on the heels of several others recently issued by the healthcare products conglomerate (eleven since September 2009).

**“That leads to serious questions about their quality control.”**