DePuy Orthopaedics Voluntarily Recalls ASRâ„¢ Hip System

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WARSAW, Ind., Aug. 26 /PRNewswire/ -- DePuy Orthopaedics, Inc., announced it is voluntarily recalling the ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery due to the number of patients who required a second hip replacement procedure, called a revision surgery.

The majority of ASR hip replacement surgeries have been successful. However, the company is advising patients with an ASR device to visit their surgeons for evaluation of their implant performance. Yearly monitoring is recommended to ensure the ASR hip replacement is functioning well, even in the absence of symptoms.

New, unpublished 2010 data from the National Joint Registry (NJR) of England and Wales shows a five-year revision rate of approximately 12% for the ASR™ Hip Resurfacing System and approximately 13% for the ASR™ XL Acetabular System. These revision rates are across the entire size range. The risk for revision was highest with ASR head sizes below 50 mm in diameter and among female patients. Previous post-market surveillance data from a variety of sources – including national joint replacement registries, published literature, company sponsored clinical trials, internal complaints data and unpublished clinical research reports – had shown lower revision rates and that the ASR hip was performing in line with other devices in its class.

"We regret that this recall will be concerning for patients, their family members and surgeons," said David Floyd, president, DePuy Orthopaedics. "We are committed to assisting patients and health care providers by providing information through multiple channels and paying for the cost of doctor visits, tests and procedures associated with the recall."

DePuy intends to cover reasonable and customary costs of monitoring and treatment for services, including revision surgeries, associated with the recall of ASR.

DePuy is

SOURCE [1]

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Links:
[1] http://www.bio-medicine.org/medicine-technology-1/DePuy-Orthopaedics-Voluntarily-Recalls-ASR-u2122-Hip-System-10410-1/