

For Immediate Release

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## DePuy Orthopaedics Voluntarily Recalls ASR<sup>™</sup> Hip System

WARSAW, IN, August 26, 2010 – DePuy Orthopaedics, Inc., announced it is voluntarily recalling the ASR<sup>™</sup> XL Acetabular System and DePuy ASR<sup>™</sup> 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New, unpublished 2010 data from the National Joint Registry (NJR) of England and Wales shows a five-year revision rate of approximately 12% for the ASR<sup>™</sup> Hip Resurfacing System and approximately 13% for the ASR<sup>™</sup> 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joint replacement registries, published literature, company sponsored clinical trials, internal complaints data and unpublished clinical research reports – had shown lower revision rates and that the ASR hip was performing in line with other devices in its class.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 providing hospitals, surgeons and patients with comprehensive information about the recall to help them determine next steps. Patients and health care professionals with questions related to this recall should visit depuy.com. As of August 27, patients in the U.S. and Canada can contact DePuy by calling 888-627-2677 Monday-Saturday, 8 a.m. to 9 p.m. EST. Patients in other countries can place a collect call to the U.S. at +1 813-287-1651 24 hours a day, seven days a week.

The ASR device is part of a class of large diameter, monoblock hip resurfacing and replacement devices often selected by surgeons for younger patients who may benefit from a more stable device that can reduce the chances of dislocation after surgery. The DePuy ASR<sup>™</sup> Hip Resurfacing System was introduced in 2003 and is only approved for use outside the U.S. The ASR<sup>™</sup> XL Acetabular System was first launched in 2004 and has been available worldwide.

Very few devices remain on the worldwide market. DePuy decided in 2009 that it would be discontinuing the ASR System as a result of declining demand and the intention to focus on the development of next generation hip replacement and resurfacing technologies that best meet the needs of surgeons and patients.

DePuy has notified the U.S. Food and Drug Administration and other regulatory agencies globally of the voluntary recall.

## About the DePuy Companies

DePuy Orthopaedics, Inc., a Johnson & Johnson company, is a leading global provider of orthopaedic devices for hip, knee, extremities and trauma, as well as bone cement and operating room products. It is part of the DePuy Family of Companies, which has a rich heritage of pioneering a broad range of products and solutions across the continuum of orthopaedic and neurological care. These companies are unified under one vision – Never Stop Moving<sup>™</sup> – to express their commitment to bring meaningful innovation, shared knowledge and quality care to patients throughout the world. Visit www.depuy.com for more information.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from *DePuy Orthopaedics, Inc.* and/or Johnson & Johnson's expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2010. Copies of this Form 10-K, as well as subsequent filings, are available online at <u>www.sec.gov</u>, <u>www.jnj.com</u> or on request from Johnson & Johnson. Neither *DePuy Orthopaedics, Inc.* nor Johnson a Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)

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