URGENT INFORMATION - RECALL NOTICE

August 24, 2010

ASR™ XL Acetabular System/DePuy ASR™ Hip Resurfacing System

Dear Clinicians:

As part of our ongoing post-market surveillance of all products, DePuy is continually evaluating 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joint replacement registries, published literature, company sponsored clinical trials, internal complaints data and unpublished clinical research reports.

DePuy Orthopaedics issued a Field Safety Notice in March 2010 after receiving new data from the UK that demonstrated the ASR™ System had a higher than expected revision rate at 8-9 percent at three years when used with smaller head sizes (less than 50 mm diameter). The overall revision rate for ASR continued to be in line with the class of metal-on-metal monoblock systems based on the data available to DePuy at that time.

DePuy has just received new, unpublished 2010 data from the National Joint Registry (NJR) of England and Wales. The data shows the five year revision rate for the ASR™ Hip Resurfacing System is approximately 12 percent and for the ASR™ XL Acetabular System is approximately 13 percent. 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.

Because the new NJR data shows a higher than expected revision rate at five years, **DePuy is issuing a voluntary recall of all ASR products**.

Reasons for revision identified within the datasets are consistent with those previously reported for ASR and include component loosening, component malalignment, infection, fracture of the bone, dislocation, metal sensitivity and pain.

Note: The DePuy ASR™ Hip Resurfacing System was only approved for use outside the U.S. and the ASR™ XL Acetabular System was available worldwide.

Please share this notice with your organization and any organization where the ASR products may have been transferred. **Do not implant the ASR devices.** Your DePuy representative will assist with returns of any remaining inventory.

Patient Follow Up
Patients who received the ASR System should be informed of this recall and instructed to return for a follow up visit.

Patients with radiographic changes indicative of product failure should be addressed according to normal procedures. All other patients should be followed according to the April 22, 2010 and the May 25, 2010 UK Medicines and Healthcare products Regulatory Agency (MHRA) Device Alerts.[1, 2] Per the April 22, 2010 Device Alert, a small number of patients may develop progressive soft tissue reactions to metal wear debris. The debris can cause soft tissue damage which may compromise the results of the revision surgery. Early revision of poorly performing hip replacements that generate metal debris should give a better revision outcome. Therefore metal ion testing should be considered in cases where the surgeon is concerned about the hip

replacement. The May 25, 2010 Alert specifies the following actions specific to the ASR:

- Follow up all patients implanted with ASR acetabular cups at least annually for five years postoperatively. Beyond five years, follow up in accordance with locally agreed protocols.
- For patients who are symptomatic or implanted with a cup angle greater than 45°, particularly where a small component has been implanted:
    - Consider measuring cobalt and chromium ion levels in whole blood and/or performing cross sectional imaging including MRI or ultrasound scans
    - If metal ion levels in whole blood are elevated above 7 parts per billion (ppb) for either metal ion, a second test should be performed three months after the first in order to identify patients who require closer surveillance, which may include cross sectional imaging
    - If MRI or ultrasound scan reveals soft tissue reactions, fluid collections or tissue masses, then revision surgery should be considered.

Financial Support for Patient Follow Up

DePuy intends to cover reasonable and customary costs of monitoring and treatment for services, including revisions, associated with the recall of ASR. Diagnostic testing, as recommended by the MHRA, may be used when surgeons have concerns about a patient with the ASR System. The procedure for the reimbursement process will be provided to you at a later date, but fees for services should first be submitted to payors in the usual manner and DePuy will then reimburse patients and payors for out of pocket reasonable and customary expenses.

Reimbursement is subject to the completion and submission of required documentation to DePuy to confirm eligibility. Eligibility will be determined, in part, by validation that the patient has an ASR component implanted and has consented to provide DePuy with x-rays, explants and any other requested medical information after the revision surgery.

Further details and procedures regarding this guidance will be provided in the near future. For additional information, please contact the following physicians:

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Sincerely,

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References:

1. Medical Device Alert: All metal-on-metal (MoM) hip replacements. http://www.mhra.gov.uk/ Publications/ Safetywarnings/MedicalDeviceAlerts/CON079157
2. Medical Device Alert: DePuy ASR™ acetabular cups used in hip resurfacing arthroplasty and total hip replacement. http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/ CON082089