

Health Care Professional Letter

August 24, 2010

ATTN: DePuy Customers

I am writing to share urgent and important information about DePuy's decision to voluntarily recall the ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System. *(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.)* The official recall notice is attached.

Most ASR hip replacement surgeries have been successful. However, data recently received by DePuy shows that more people than expected who received the ASR hip require revision surgery.

For this reason, DePuy Orthopaedics is voluntarily recalling its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System. This recall means additional testing and monitoring may be necessary to ensure your patients' hips are functioning well. In some cases, patients may need revision surgery.

Our goal is to help you answer your patients' questions and support their prompt follow up care and treatment. Please contact your patients and request that they schedule a follow up appointment for evaluation.

Included with this letter are several documents that you may use to communicate with patients, including:

- Sample patient cover letter
- Information for Patients
- Medical Release Form

The recommended patient follow up protocol is that patients with radiographic changes indicative of product failure should be treated 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 without exhibiting any symptoms. 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, so metal ion testing is extremely important. Therefore, metal ion testing should be considered in cases where the surgeon is concerned about the hip replacement even if the patient is asymptomatic.

It is important to note that 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 you have concerns about a patient with the ASR System, even when they're asymptomatic. 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.

The completion of the patient release form will allow you to share information about this patient's case with DePuy and will allow DePuy to provide information directly to patients regarding the ASR Hip System. DePuy will also use this information to process claims efficiently and to help DePuy to better understand the causes of the problems with the ASR Hip System. Patients should complete the form and bring it with them to the appointment.

We will provide you with a brief form to be completed for each patient, including date of surgery, components implanted, follow up status and the results of any metal ion testing. We appreciate your assistance with this process, and we will provide compensation at a rate of \$50 per patient for each completed form that is submitted to DePuy.

You can access the latest information about the recall by visiting our website at www.DePuy.com. If you have additional questions, please contact the physicians listed below:

U.S./Canada/Latin America

Rodrigo Diaz, Scientific Information Officer, 574-372-7401
Mikhail Chkolnik, Project Leader, Clinical Research, 1-888-554-2482

EMEA

Jens Krugmann, Director Product Safety and Risk Management, +353 87 6123 872
Dirk Parwis Ghadamgahi, Manager, Customer Education, +49172 446 6209
Greg Medalla, Manager Clinical Research, +44 113 387 7017

ASPAC

Aran Maree, Vice President Strategic Medical Affairs, +65 6827 6015

Thank you for your assistance during this recall process.

Sincerely,



Pamela L. Plouhar, Ph.D.
VP, Worldwide Clinical Affairs