

DePuy Orthopaedics
ASR™ Hazard Alert Reference
Guide for Healthcare Professionals

This ASR™ Hazard Alert Reference Guide is being provided to share the latest information about the ASR Hazard Alert and the recommendations for care and treatment of patients with an ASR System, along with the reimbursement process associated with these services. Johnson & Johnson Medical and DePuy Orthopaedics, Inc. (“DePuy”) are committed to sharing new information with customers as it becomes available but please do not hesitate to contact your DePuy representative with any questions.

Information to Assist Surgeons when Talking with Patients

Surgeon Communication Resources

DePuy is making available a range of documents to help with patient communications.

These include:

- Sample patient letter
- Sample non-ASR patient letter
- Patient information sheet
- Patient consent form for disclosure of records
- Additional information about the patient consent form
- Talking points for office managers

1. Patient Consent Form

DePuy has retained Crawford & Company (“Crawford”), a third party claims processor that manages the ASR Help Line and patient claims process. This company will provide a Patient Consent Form directly to patients to fill out when a claim is initiated with the call centre. In early October country-specific patient consent forms will also be available on www.depu.com.

The completion of the Patient Consent Form will allow surgeons to share information about the patient’s case with DePuy and Crawford, and will allow DePuy to provide information directly to patients regarding the ASR Hip System. Crawford will also use this information to process claims efficiently. Access to this data (blood testing results, results of imaging and revision data) will help DePuy better understand the causes of the higher than expected revision rates with the ASR Hip System.

If the surgeon anticipates contacting the ASR Help Line to initiate a claim for a patient, the Patient Consent Form will need to be completed and faxed to Crawford before the claim can be initiated. Crawford cannot accept patient information from the surgeon’s office without a copy of the Patient Consent Form with the patient’s signature. The only exception is if the surgeon is providing a claim related to a past or planned revision surgery. In that case, there is preliminary information that may be shared by the surgeon.

No patient is required to sign the Patient Consent Form or to provide their medical information. If a patient does not wish to sign the Patient Consent Form or to provide their medical information to Crawford or DePuy, we will still endeavor to investigate their claim for reimbursement. However, in this situation a surgeon cannot initiate a claim on behalf of a patient – the patient will need to call the ASR Help Line directly. And we regret that without access to the appropriate medical information, it is unlikely that we will be able to consider the patient’s claims for reimbursement and prompt resolution of their claim may not be possible.

It is important to note that the patient does not waive his/her right to pursue legal action by signing the Patient Consent Form or by providing the medical information to DePuy.

2. Identifying ASR Patients

Please note that DePuy does not track patients who receive implants, so the ASR Help Line will not be able to advise a patient what implant they received. As you are aware, information regarding the specific implant a patient received is typically part of the patient record at the surgeons' office or in the hospital. Therefore patients who call the ASR Help Line and who do not know this information will be referred to their surgeon or hospital to confirm their implant details.

3. Contacting Patients

DePuy does not collect complete contact information for patients who receive DePuy implants, so DePuy is unable to notify patients directly. To the extent ASR product information is available in our records we may provide this to surgeons to assist them with verification and patient care.

DePuy Assisting Customers with Notifying Patients

DePuy is evaluating how we can assist customers compliantly and will provide more information shortly.

4. Patient Testing

Testing and Treatment Recommendations for ASR Hip Patients

In DePuy's global communications it was recommended that surgeons follow the guidelines provided in the April 22, 2010 and the May 25, 2010 UK Medicines and Healthcare products Regulatory Agency (MHRA) Device Alerts. Should surgeons wish to follow these guidelines, they are available for download on the DePuy website www.depuy.com. Surgeons can also contact Dr. Leanne Wall on +61 2 9815 3661 for further information.

DePuy (Australia & New Zealand) draws your attention to the guidelines provided to members of the Australian Orthopaedics Association (AOA), dated 14 September 2010, for managing patients with an implanted ASR. The New Zealand Orthopaedic Association concurs with the AOA recommendations.

The AOA's recommendations are summarised as follows:

- All patients with an implanted ASR should be notified of the company's concerns
- All patients with an implanted ASR should be reviewed at least annually or sooner if symptoms of a painful hip arise
- Standard x-rays and ultrasound would be the investigations of choice, with any decision to revise being based on evidence of x-ray and ultrasound showing appearance of bone destruction and muscle or soft tissue damage.

In addition, the AOA did not endorse the concept of metal ion and MRI testing, as recommended by the MHRA in its April 22, 2010 and May 25, 2010 Device Alerts, in any decision-making about potential revision surgery.

The decision to prescribe any particular course of treatment or testing is up to each surgeon's own medical expertise and experience. In the event that surgeons wish to conduct this testing, DePuy intends to reimburse for these costs related to the ASR recall.

5. Reimbursement

DePuy's ASR Reimbursement Policy

DePuy intends to cover reasonable and customary costs for testing and treatment of patients, including revision surgery if necessary, associated with the ASR™ Hip System recall.

ASR Revisions Performed Prior to the Recall

ASR revisions associated with the ASR recall, whether or not they occurred before the recall, will be covered, subject to DePuy's review as well as certain limited exclusions defined below or other reasons unrelated to the recall.

Timing

DePuy will reimburse if the ASR revision occurs within 7 years after the initial implantation. DePuy will reimburse for blood ion tests/MRI/ultrasound scans if the investigation occurs within 5 years from the date of the recall.

Patient Out-of-Pocket Expenses

Patients will be covered for out-of-pocket costs for reasonable and documented expenses, which may include, but are not limited to travel expenses and other reimbursable expenses.

Medical Treatment Expenses

DePuy will provide reimbursement for the reasonable and customary costs of tests and treatments related to the ASR recall pursuant to the eligibility criteria set out in this note and subject to review. This may include but is not limited to, blood testing, CT scans, ultrasound scans, MRI scans, x-rays, and revision surgery costs if surgery is necessary. These expenses should be submitted through Crawford for review of eligibility. A claim number and handler will be assigned so the claims can be processed.

Patient Eligibility for Reimbursement

Reimbursement is subject to the completion and submission of required documentation to Crawford to confirm eligibility. Eligibility will be determined, in part, by validation that the patient has an ASR component implanted and that the treatment is associated with the ASR Hazard Alert. To facilitate this validation, we are asking for the patient to consent to provide DePuy/Crawford with x-rays, explants and other related medical information after the revision surgery.

Reimbursement Process

DePuy is in the process of finalising the reimbursement process and claims centre procedures in New Zealand. DePuy intends to provide eligible patients with pre-approval of costs for treatment and follow-up (subject to final confirmation of an ASR implant) and may, where appropriate, effect payments direct to healthcare providers so that patients are not required to fund the reimbursable costs associated with treatment and follow-up, including revision surgery. The claims centre will also handle retrospective claims for eligible patients who have already had revision surgery for the ASR implant.

Detailed information about the reimbursement process will be provided to customers as soon as it is available.

Exclusions

The following surgeries may not be covered, subject to review by DePuy:

- size mismatches
- traumatic injury where there is no evidence of soft tissue reaction at the time of surgery
- femoral neck fractures, providing that the fracture occurred within three months of primary surgery, and subject to review on a case-by-case basis
- where infection is the cause of the revision, as confirmed by positive culture.

6. Contact Us

Recall Process and Reimbursement Questions:

An ASR Help Line has been set up in New Zealand to assist in answering general questions about the recall and to register claims for reimbursement. Toll Free Number **0800 660 026**

Clinical Questions:

- Dr Marc Thomas, Marketing Director, DePuy (Australia & New Zealand) Tel: +61 429 210 365
- Dr Leanne Wall, Medical Affairs Director, Johnson & Johnson Medical (Australia & New Zealand), Tel: +61 419 292 651
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