

**Notice Information: - Advisory
27 August 2010**

Part 1. Product Information

- a) Title: ASR™ Articular Surface Replacement and ASR™ XL Acetabular System
- b) Product Name/Type: ASR™ Articular Surface Replacement and ASR™ XL Acetabular System
- c) Reference: IMB Safety Notice: SN2010(10)
- d) Manufacturer/Supplier: DePuy International Ltd

Part 2. Target Audience

- a) Target Audience:
- Orthopaedic surgeons
 - Orthopaedic theatre staff
 - Orthopaedic registrars
 - Risk managers
 - Hospital CEOs
 - General Practitioners

Part 3. Problem/Issue

- a) Problem/Issue: Recall of DePuy's ASR™ Hip Implant System due to higher than expected revision rate.

Part 4. Background Information

a) Background Information:

On 26th August 2010, DePuy announced a worldwide recall of the ASR™ Hip System. This decision is based on new, unpublished data from the National Joint Registry (NJR) of England and Wales. The data shows the five year revision rate for the ASR™ Articular Surface Replacement is approximately 12% and for the ASR™ XL Acetabular System is approximately 13%. 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.

DePuy circulated a field safety notice (FSN) on 26th August 2010 to advise customers of this recall. DePuy has advised the IMB that there is no stock currently held at Irish hospitals.

The Irish Medicines Board (IMB) is working with the HSE and orthopaedic surgeons regarding recommendations for patient review.

Patients who received the ASR™ XL Acetabular System or DePuy ASR™ Hip Resurfacing System will be contacted to schedule a review. However, if patients are experiencing pain, difficulty walking or other symptoms, they should contact their GP or orthopaedic consultant for advice.

Part 5. Enquiries

a) All enquiries should be made to:

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

Enquiries should be addressed to:

Manufacturer:

DePuy International Ltd

St Anthony's Road

Leeds LS11 8DT

England

Contact Person: Paul Arnott

Tel: 07771 971 930

Fax: 0113 387 6087

Email: parnott@its.jnj.com

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