IRISH MEDICINES BOARD
SAFETY NOTICE

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ASR™ Articular Surface Replacement and ASR™ XL Acetabular System

IMB Safety Notice: SN2010(10)
Circulation Date: 27 August 2010

MANUFACTURER/SUPPLIER
DePuy International Ltd.

TARGET GROUPS
Orthopaedic surgeons
Orthopaedic theatre staff
Orthopaedic registrars
Risk managers
Hospital CEOs
General Practitioners

ISSUE

Recall of DePuy's ASR™ Hip Implant System due to higher than expected revision rate.

BACKGROUND

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 This decision is based on new, unpublished data from the National Joint Registry (NJR) of England and Wales.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.

ENQUIRIES

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

SAFETY NOTICE

Irish Medicines Board
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Earlsfort Terrace
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