26 August 2010

Dr. Name
Position
Address
Address
Address

HAZARD ALERT

DePuy ASR™ Articular Surface Replacement and ASR™ XL Acetabular System

Dear Dr. Name

In consultation with MedSafe, Johnson and Johnson Medical is issuing a Hazard Alert regarding the DePuy ASR™ Articular Surface Replacement and ASR™ XL Acetabular System. The ASR™ System was withdrawn from New Zealand in December 2009. Stock available for revision purposes will no longer be supplied.

As part of the post-market surveillance program, DePuy continually evaluates 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joint replacement registries, published literature, company sponsored clinical trials, internal complaints data and unpublished clinical research reports.

Johnson and Johnson Medical issued a Safety Alert Notice in March 2010 after receiving new data from the United Kingdom 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DePuy has just received new, unpublished 2010 data from the National Joint Registry (NJR) of England and Wales.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.

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.

ACTIONS

Patient Follow Up

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 you concerned about the hip replacement.

Patients who received the ASR™ System should be informed of this Hazard Alert and instructed to return for a follow up visit.
Patients with radiographic changes indicative of product failure should be managed according to normal procedures. All other patients should be managed as follows:

Johnson & Johnson (New Zealand) Ltd.
13a Gabador Place, Mt Wellington; Auckland 1060, New Zealand
PO Box 62185, Mt Wellington, Auckland 1641, New Zealand
Tel: +64 9 574 1783 Fax: +64 9 573 6234 Toll Free: 0800 433 789

- Review 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 Magnetic Resonance Imaging (MRI) or ultrasound scans;
  - If metal ion levels in whole blood are elevated above 120 nmol/L cobalt or 135 nmol/L chromium i.e. 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.

Addition information regarding trace element testing will be provided shortly, should you be considering this option.

Financial Support for Patient Follow Up

Johnson and Johnson Medical intend to cover reasonable and customary costs of monitoring and treatment for patients who might need such services associated with the recall of ASR.

Diagnostic testing, as recommended, may be used when surgeons have concerns about a patient with the ASR System. If, based on patient symptoms and/or the results of the diagnostic testing, the surgeon recommends a revision procedure; Johnson and Johnson Medical will provide this reimbursement.

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 Johnson and Johnson and DePuy with x-rays, explants and any other requested medical information after the revision surgery. Please find attached a patient consent form for signature. Additional information will be provided in relation to financial support shortly.

Please complete the attached reply document and email or fax it back to Johnson & Johnson Medical to confirm your receipt of this letter.

If you require additional information regarding this matter, please contact:

Dr. Marc Thomas, MBBS, Director of Marketing, DePuy Australia, +61 (0)429 210 365
Dr. Leanne Wall, MBBCh, Medical Director, Johnson & Johnson Medical Australia, +61 (0)419 292 651
Dr. Aran Maree, MB, ChB, MRCP Vice President, Strategic Medical Affairs, Johnson & Johnson Medical Asia Pacific, +65 97 226 099

Yours sincerely

Dr. Leanne Wall
Medical Director
JOHNSON & JOHNSON MEDICAL PTY LTD

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DePuy

NEW ZEALAND HAZARD ALERT RESPONSE

RETURN TO	:	**Fiona Smith**
		Quality Director
		Johnson & Johnson Medical
EMAIL	:	**fsmith2@its.jnj.com**
FAX NO	:	**0800 364 444**
FROM	:	**Dr Name**

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HAZARD ALERT

DePuy ASR™ Articular Surface Replacement and
ASR™ XL Monoblock Metal-on-Metal System

This document is an enclosure with the August, 2010 Safety Alert Letter. I have read and understand the Safety Alert.

NAME: _____ (Please Print Your Name)

SIGN: _____

DATE: _____

Johnson & Johnson MEDICAL

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