Central Drugs Standard Control Organization

Directorate General of Health Services
Government of India (Medical Device Division)
Food & Drugs Administration Bhavan, Kotla Road, New Delhi

File No: 31-132-MD/2006-DC (Re Reg 2009) **Date: 09.12.2013**

MEDICAL DEVICE ALERT

DEVICE

ASR XL Acetabular System & DePuy ASR Hip Resurfacing system.

BACKGROUND

The DePuy ASR™ XL Acetabular System is used in hip replacement surgeries for people with hip joint damage from arthritis or injuries. It comprises of the acetabular cup, which is a metal liner that replaces the socket portion of the pelvis, known as the acetabulum.

The DePuy ASR™ Hip Resurfacing System consists of two components, (i) a cap which is placed over the femoral head and (ii) the acetabular cup. Unlike in conventional hip replacement surgery where the femoral head is replaced, resurfacing of the hip preserves the femoral bone by placing a metal cap over the surface of the femoral head. The femoral head and neck are not removed. The acetabulum is replaced with the acetabular cup as in a total hip replacement surgery.

DePuy Orthopaedics issued a notification or 'Field Safety Notice'.

PROBLEM

Recall of ASR hip replacement implants due to increased rates of revision.

ACTION BY

- Medical directors/ Healthcare Professionals
- Orthopaedic surgeons.
- Staff involved in the management of patients with joint replacement implants.

ACTION

- Do not implant DePuy ASR hip replacements.
- Return all unused ASR hip replacement implants to the manufacturer.
- Inform all patients implanted with ASR hip replacements about this recall and schedule them for a follow-up visit.
- Follow up all patients implanted with ASR hip replacements with clinical examination at least annually.
- For patients presenting with symptoms of abnormal pain, limping, swelling around the hip, deteriorating hip function or radiological abnormality:
  - consider measuring cobalt and chromium ion levels in whole blood and/or performing cross sectional imaging including MRI or ultrasound scan.
  - If metal ion levels in whole blood are elevated above 120 nmol/L (cobalt) or 135 nmol/L (chromium) [ie seven 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 consider revision surgery.

ADVERSE EFFECTS

Patients who reported problems with the DePuy ASR™ systems and required revision surgeries within the first five years post-surgery presented with a variety of symptoms including pain, swelling and difficulty in walking. A small number of patients implanted with these systems may also develop progressive soft tissue reactions to the metal debris generated as the metal components wear out over time. While this condition may initially be painless, if left untreated, this reaction may cause pain and swelling around the joint and could damage some of the muscles, bones and nerves around the hip.

To date 15,829 units of ASR XL Acetabular System & DePuy ASR Hip Resurfacing system has been imported in India of which 1295 unused product has been returned to source company.

Patients and Healthcare professionals are advised to report adverse events suspected to be associated with the ASR XL Acetabular System & DePuy ASR Hip Resurfacing system or other medical device to the Manufacturer and CDSCO.

CONTACTS

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