

U.S. Testing and Treatment Information for ASR Hip Patients

Overview

DePuy recommends following the guidelines provided in the April 22, 2010 and the May 25, 2010 UK Medicines and Healthcare products Regulatory Agency (MHRA) Device Alerts, which include the following:

- Patients who received the ASR Hip System should be instructed to return to the surgeons' office for a follow up visit including clinical assessment and radiographic evaluation. If any radiographic change is indicative of product failure, the patient should be treated as per the surgeons' discretion.
- If surgeons or patients are concerned about the hip, blood testing for cobalt and chromium ion levels in whole blood may be performed as part of the follow up, and/or an MRI or ultrasound if necessary as per the guidelines and schedule below.
 1. An initial blood test should be performed. Cobalt and chromium ion levels should be 7 parts per billion (ppb) or below. If the patient is having symptoms, an MRI or ultrasound should also be considered at this time.
 2. If either metal ion concentration is above 7 parts per billion (ppb), a second blood metal ion test (both cobalt and chromium) should be performed three months after the first if no symptoms are present.
 3. If the metal ion concentration is again above 7ppb, the surgeon should consider MRI or ultrasound.
 4. If MRI or ultrasound scan reveals soft tissue reactions, fluid collections or tissue masses, then revision surgery should be considered.
 5. If metal ions are less than 7ppb and/or MRI or ultrasound are within normal values, patients should be evaluated on an annual basis for the first five years. These evaluations should be conducted according to the surgeons' normal procedures.
 6. If the surgeon or patient continues to be concerned about the hip, metal ion testing may be conducted on an annual basis at the surgeons' discretion.

Metal Ion Testing

Metal ion testing requires specialized equipment that is not widely available. Instructions for metal ion testing in EMEA and ASPAC will be available shortly. In North America, DePuy recommends working with LabCorp for this testing.

- If the surgeons' office has an account with LabCorp, Panel Code 284418 should be ordered.
- If the surgeons' office does not have an account with LabCorp, the patient should be provided with a prescription requesting Cobalt and Chromium in whole blood – Panel Code 284418 – and instructed to go to a LabCorp patient service center.

Cobalt and Chromium in whole blood will need to be drawn at a LabCorp patient service center. When sending patients to LabCorp, please provide the following information:

- Patient's name
- Patient's Date of Birth
- DePuy ASR Claim number (the patient will receive this after contacting the claims processor)
- Billing Account Number: 13103875
- Panel code: 284418 (Cobalt and Chromium in whole blood)
- Surgeon's first and last name
- Surgeon's fax number (results will be faxed to this number)
- Surgeon's LabCorp account number (if applicable)

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Locating a local LabCorp Office for the U.S. and Canada

Visit www.labcorp.com and click on “find a lab.”

Special Patient Instructions for Metal Ion Testing

Patients should be advised to refrain from taking mineral supplements, vitamin B-12 or vitamin B complex at least three days prior to specimen collection.

Locating an Alternative Testing Facility

If there is no LabCorp Patient Service Center in the area, patients should be directed to Quest Diagnostics with a detailed prescription containing: **Special Miscellaneous test: Cobalt and Chromium in whole blood.** Website:

www.questdiagnostics.com/hcp/psc/jsp/hcp_psc_index.jsp

Metal Ion Testing for Non-ASR Patients

Metal ion testing for patients without an ASR Hip should be done at the surgeons' discretion based on standard protocol. Please note that the cost of ion testing is typically not reimbursed through insurance and would be an out-of-pocket expense for patients. DePuy will only reimburse this expense for patients who have an ASR Hip.

MRI Protocol

Surgeons should order a MARS MRI. Guidance regarding this protocol will be available shortly.

Alternatives to MRI Testing

Ultrasound is an alternative option and recommendations regarding the ultrasound procedure will be available shortly.

Blood Storage

There's no need to store blood in the U.S.

Ion Levels

According to the British Orthopaedic Association (BOA) posting titled, **Metal on Metal Hip Replacement and Hip Resurfacing Arthroplasty: What does the MHRA Medical Device Alert Mean:** “It is likely that Cobalt and Chromium levels may be useful for screening but they are not well understood at present. High levels may start as low as 7ppb for either metal. High levels have a higher correlation with revision, pain and soft tissue reactions, but the correlation is not absolute in the short term.”