



The Canadian Orthopaedic Association
L'Association Canadienne d'Orthopédie



**Withdrawal of DePuy ASR Resurfacing and XL metal-on-metal bearings –
Information for and Advice to Surgeons from the Subsection of Arthroplasty of
the COA and the Canadian Orthopaedic Association**

November 2010

The ASR Device has now been withdrawn from Canada as well as the United Kingdom, Australia, United States, New Zealand and South Africa due to adverse results and higher than expected revision rates on the UK NJR and Australian Registries. The revision rate at 5 years in the NJR is 12% for ASR Resurfacing and 13% for Stemmed ASR Components. Consensuses among the orthopaedic organizations from the countries mentioned above have suggested that the following may aid patient care.

All patients with these components should be identified and should be informed that they have a hip replacement device that has been withdrawn, and require close clinical follow-up and surveillance. The patients should be registered with Depuy so that any associated costs of consultation, investigation or subsequent treatment can be paid for by Depuy. This requires the patient's consent, copies of the stickers of the implant used (from the hospital file) and the patient's name, birth date and address. No other healthcare information is required.

Some form of follow-up should be performed at least annually and patients should be given contact information so that they can be reviewed quickly should they have worsening pain or deteriorating clinical function. All of the organizations and their arthroplasty subspecialty groups have suggested that follow-up should continue for the life of the implant, until more data is available.

At present it is felt that "no specific investigations" are required in the absence of pain and with implants that are performing well, apart from regular yearly follow-up.

However x-rays that show that the components have come to lie in a position associated with high wear (Vertical acetabular cup > 50 degrees) will need to be followed up more closely.

With a painful implant, further investigations should be performed. Other causes of pain such as infection, loosening of components, soft tissue / psoas impingement, fracture, osteonecrosis, referred pain from the spine, pelvis or adnexae should be excluded.

If no other reasonable cause of the symptomatic hip is uncovered, Blood Cobalt and Chromium ions should be measured as these are an indicator of surface wear. They are usually surprisingly low in well functioning components. The British MHRA has suggested that whole blood levels of either Cobalt or Chromium above 7ppb may be significant. Below this level significant soft tissue reaction and tissue damage is less likely leading to a lower risk of implant failure. Above this level, patients will require closer observation. Blood ions done yearly, or more frequently, at the discretion of the surgeon along with an MRI, (with metal artefact reduction sequences) to look for soft tissue pseudotumour would be indicated. If these tests were grossly positive and linked to the symptoms of the patient, revision hip surgery maybe indicated. It should be clearly noted, there is no hard evidence that above a certain metal ion concentration, revision surgery must be performed. There is a relationship but it is not predictive.

The other useful investigation is cross sectional imaging, either MRI with metal artefact reduction sequences (MARS) or ultrasound. These are capable of giving clear images of fluid collections or solid lesions ('pseudotumour') around the hip. It is still thought that significant soft tissue reactions are unlikely in the absence of pain. Some "asymptomatic patients" may seek further reassurance, in such cases blood ion levels and imaging may be performed but caution should be exercised in acting on the findings in the asymptomatic patient. It is recommended if the tests are abnormal then more frequent follow-up should be instituted with the tests repeated at intervals (6 to 12 months). It is the trend of the tests that is more important than absolute values. If the patient remains asymptomatic but the blood ion levels and more importantly the MRI signs of pseudotumor become progressively more abnormal, revision surgery may need to be considered. It should be noted that the clinical indicators (pain and limp) are still the best to date.

The decision on when to advise revision surgery remains clinical. It is thought that worsening or severe pain, rising metal ions or increasing size of a solid mass are concerning and may require revision surgery. It is the recommendation of all the associations that a second orthopaedic opinion be sought prior to proceeding on to a revision in these cases.

Cystic lesions on MRI should be noted and followed. There is however increasing evidence that solid masses are more concerning than cystic ones. There is also evidence that cystic masses are found adjacent to well functioning hips. Research and audit will improve future guidance in this area.

Revision surgery may be challenging in the presence of pseudotumour, often requiring difficult debridements and reconstructions. It is considered important to do a thorough debridement of the abnormal tissue akin to the treatment of infection. MRI and / or CT should be performed preoperatively to allow a thorough appreciation of the extent of the soft tissue lesion.

In the case of an asymptomatic joint with normal investigations (if investigations have been performed), then yearly follow-up with the treating surgeon with the routine examination and x-rays is all that is indicated. The patient should be advised to report back urgently should symptoms develop in the interim.

In any case where revision surgery is clinically indicated, a second opinion from another experienced surgeon to confirm and support the appropriateness of the treatment plan should be considered. This plan may either be watchful waiting in the presence of equivocal symptoms or equivocal abnormal investigation; or the decision to intervene and revise the hip. Retrieved implants at revision surgery should be retained and either given to the patient or sent to a central or local storage unit and sent to an independent assessment facility for investigation. This independent retrieval lab will also store the component, unless otherwise directed by the patient or his/her advocate. The patient needs to be informed that the implant can be stored by an independent storage area, should it be required later as evidence for legal proceedings. The COA will have further information on this as it becomes available from Depuy and our storage areas.

If you are asked to send patient data or imaging to any commercial company, the commercial company needs to obtain the patient's written consent in every case. Doing so may have legal implications for the patient and they should obtain legal advice prior to sending any information to the company.

Decision Tree

1. Identify patients with ASR Implants (medical or hospitals records or via National Joint Registry).
2. Contact patients and explain they require close follow-up and they should contact Depuy : by calling patient contact number 1-888-627-2677 8am - 9pm Mon-Sat. or visit DePuy's website at <http://asrrecall.depuy.com/asrcanadaenglish> or <http://asrrecall.depuy.com/node/20463> for French information.
3. Arrange out patient consultation
 - **If asymptomatic with normal examination and satisfactory x-rays:**
 - they just require the usual follow-up of any joint replacement in one year.
 - **If asymptomatic with normal examination but x-rays show components may have come to lie in a position associated with high wear perform blood ion levels and/or imaging:**
 - 1) If tests normal follow-up in 12 months and repeat tests.
 - 2) If tests equivocal repeat after 6 to 12 months* (if deteriorating consider revision if the clinical symptoms support this action)
 - 3) If tests are abnormal, repeat the tests in 6 to 12 months and consider revision. If a pseudotumor is felt to be increasing in size, a revision should be considered if clinically indicated (a second opinion is strongly advised prior to revision surgery).
 - 4) Increasing metal ions alone are not predictive at this time.
 - **If asymptomatic with normal examination and satisfactory x-rays but patient worried wanting reassurance about their hip consider doing blood ions and/or imaging:**
 - 1) If tests normal follow-up in one year.
 - 2) If tests equivocal repeat after 6 to 12 months* (if deteriorating consider revision if clinically indicated.
 - 3) If tests are grossly abnormal consider revision if clinically indicated.

A second surgical opinion is strongly advised prior to proceeding to revision surgery*.
 - **If symptomatic exclude other causes of pain and do blood ions and/or imaging:**
 - 1) If symptoms mild but tests normal repeat follow-up and tests in 6 to 12 months*.
 - 2) If symptoms mild but tests abnormal consider revision if clinically indicated*.

- 3) If symptoms are severe or worsening but tests normal, a revision should be considered as would be the case for any painful total joint arthroplasty.
- 4) If symptoms are severe or worsening and tests abnormal the Associations agree that relatively expedited surgery should be considered within a maximum of three months- or sooner if clinically possible*.

Notes

* Treatment decisions should be confirmed with an (another) experienced revision surgeon. It is important that the patient receives the best possible advice under these difficult and evolving circumstances. The decision-making and the performance of subsequent revision may come under close scrutiny. All revision cases should be logged with the CJRR (the Canadian Joint Replacement Registry) with patient consent. The CJRR is independent and will be able prospectively to audit the cases and the situation as it develops.

Patients should have open access to return to clinic at any time if symptoms deteriorate.

Revision surgery may be complex and has involved major acetabular deficiencies in the past.

Revision should be performed expeditiously when indicated to avoid progressive tissue damage.

Blood ion tests need to be performed by accredited laboratory. The laboratory(s) so defined will be described on the COA web site.

Ultrasound or MARS MRI scans need to be performed and more importantly read by musculoskeletal sub specialized radiologists when possible.

Implants retrieved should either be given to the patient to store personally or more preferably sent to a central storage unit to be named by the COA at a later date

This storage area and its funding is still being discussed with Depuy at this time.

Information should not be sent to a commercial company without patient consent.

Depuy will provide funding for follow-up, investigations and revision surgery if indicated.

This guidance represents best current practice (Nov 2010) to protect patients but may change with experience.

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A link on the Canadian Orthopaedic Association, the [American Academy of Orthopaedic Surgeons](#), the [American Orthopaedic Association](#), the [British Hip Society](#) and the [British Orthopaedic Association](#) web sites will be available to provide further information on protocols, points of contact and examples of common findings.