

INFORMATION FOR HIP REPLACEMENT PATIENTS WHO HAVE DEPUY BRAND IMPLANTS

Total hip replacement remains one of the most successful and life -changing operations available for patients with incapacitating hip arthritis. Over 30,000 hip replacements are performed annually in Australia. The vast majority of implants used In Australia are highly successful.

The ASR[™] Hip is one of many hip replacement implants available from Johnson & Johnson Medical and DePuy Orthopaedics, Inc. ('DePuy'). Recently, information received by the company has shown that more people than expected who have an ASR Hip System have experienced pain and other symptoms that have led to a second hip replacement surgery, called a revision surgery.

For this reason, DePuy has recalled its ASR[™] XL Acetabular System and DePuy ASR[™] Hip Resurfacing System.

If you had your hip surgery *before* July 2003, the hip you received will not be one of the hips being recalled.

If you had your hip surgery *after* July 2003 you may not be aware of what brand of implant you have, so DePuy has advised you to check with your surgeon or hospital as to what brand of hip implant you have received.

Once you have this information:

If you have confirmed that you have an ASR Hip implanted, what it means:

- Your hip implant has been recalled
- Regular testing and treatment may be necessary to make sure that your hip implant is working well
- DePuy plans to cover reasonable and customary costs of testing and treatment, including revision surgery if it is necessary, associated with the ASR recall.

Even if you do not yet have out-of-pocket medical expenses (ie expenses you have to pay personally), please contact the DePuy ASR Help Line on 1800 665 460 so that you may be given a registration number. This will allow DePuy to process all reasonable costs, such as lost work time and travel expenses. These expenses are subject to review by DePuy.

SYMPTOMS, CAUSES AND TESTING

You may experience a number of symptoms which could indicate a problem with your ASR Hip implant. These include pain, swelling and problems walking. If you have just had a hip replacement these things could be normal but if they continue or return, you should contact your orthopaedic surgeon.

The ASR Hip is made up of ball and socket components that move against each other. Over time the metal parts wear away and very small particles that can only be seen with a microscope are produced. This is a normal wear process. These particles do not cause problems for most patients, but a small number of patients may react to these particles. This reaction causes fluid to collect in the joint and in the muscles around the joint. At first the reaction may be painless, but if it is left untreated, it may cause pain and swelling around the joint and could also damage some of the muscles, bones and nerves around the hip.

Your surgeon may need to do tests to determine if your hip is working as it should be and whether you are having a reaction to the metal particles. These tests may include X-rays of your hip, a blood test to indicate the level of metal particles around your hip, an ultrasound or an MRI scan to see if you are having a reaction to the metal particles. Your surgeon will decide the best follow-up plan for you and talk to you about further treatment.

UNDERSTANDING THE ASR HIP RECALL

If you had an ASR XL Acetabular System or DePuy ASR Hip Resurfacing System implanted, you should schedule an appointment with your orthopaedic surgeon. Your surgeon will be able to examine you and see how your ASR Hip System is working.

The 'recall' of the ASR Hip does not mean that all patients need to have their hip implants removed. However, it is currently recommended that you follow up with your surgeon on a yearly basis for the first five years after your ASR Hip surgery—even if you are not having symptoms—to make sure that your hip continues to work well.

WHAT TO EXPECT AT YOUR NEXT SURGEON VISIT

- Your surgeon will examine you to see how your ASR Hip System is working.
- If you are having pain, difficulty walking, or other symptoms, your surgeon may want to take x-rays of your hip and perform other tests as listed above.
- If you do not have any symptoms or test results that suggest a potential problem with your implant, then you should follow your surgeon's recommendations for regular follow-up.
- If you require further surgery, there are a number of choices available and your surgeon will discuss them with you.

PAYING FOR TESTING AND TREATMENT

DePuy plans to cover reasonable and customary costs of care if you need them, including revision surgery if it is necessary, associated with the ASR recall.

DePuy is finalising the process of how your costs will be reimbursed and how the claims centre will work in Australia. Where possible, DePuy plans to pay your surgeon or hospital directly for costs of your care, including if you have to have revision surgery. The claims centre will also help you if you have already had revision surgery for the ASR implant and paid for the surgery. Please call the *ASR Help Line on 1800 665 460 or visit www.depuy.com.

Please check the Australian page on <u>www.depuy.com</u> on a regular basis for additional updates and information.

* Please note: Calls to the ASR Help Line will be free of charge. Outside operational hours there will be either an answering service or a recording which redirects callers to an emergency 24-hour number.

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