

**ASR™ XL Acetabular System and
DePuy ASR™ Hip Resurfacing System Hazard Alert**
Information for Patients

DePuy makes patient safety and health a top priority and is continually evaluating data about its products. The ASR™ Hip is one of many hip implants available from Johnson & Johnson Medical and DePuy Orthopaedics, Inc. (“DePuy”). Most ASR hip replacement surgeries have been successful. However, data recently received by the company shows that more people than expected who received the ASR Hip System experienced pain and other symptoms that led them to have a second hip replacement surgery, called a revision surgery. New data shows that five years after having the hip implanted, approximately 12% of patients (1 in 8) who had received the ASR resurfacing device and 13% of patients (1 in 8) who had received the ASR total hip replacement needed to have a revision surgery.

For this reason, DePuy Orthopaedics has recalled its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System. We understand that you may be concerned by this recall. There are many different brands of hip implants available and you may not be aware of what brand of implant you have. DePuy Orthopaedics encourages you to check with your surgeon or hospital to determine what brand of hip implant you have received.

If you have received an ASR™ XL Acetabular System or DePuy ASR™ Hip Resurfacing System (both of which will be referred to as your hip implant), the following information will help you understand what this recall means to you and the steps you should take.

FINDING OUT IF YOU HAVE AN ASR HIP AND NEXT STEPS

The hip systems DePuy is recalling—the ASR™ XL Acetabular Head System and DePuy ASR™ Hip Resurfacing System—became available in July 2003.

If you had your hip surgery **before July 2003**, the hip you received will not be one of the hips being recalled. Please speak to your orthopaedic surgeon about any questions you may have about your hip replacement.

If you had hip surgery **after July 2003**:

- DePuy is not allowed to maintain a list of patients who received an ASR due to reasons of Patient Privacy. Please contact your orthopaedic surgeon or the hospital where your hip replacement surgery was done to check whether you received an ASR Hip. It may take time for the surgeon or hospital to find this information for you. If you recall the date on which you had your hip surgery, please make a note of this, as this may help them find your information.
- For Patient Privacy reasons, your orthopaedic surgeon or the hospital where you had your surgery may ask you to come in person to collect this information.
- Once you have this information:

If you have confirmed that you have an ASR Hip implanted, please contact the DePuy ASR Help Line on **0800 660 026**

- This recall means that other 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 i.e. expenses you have to pay personally, please contact the DePuy ASR Help Line so that you may be given a claim number. This will allow DePuy to process other reasonable costs, such as lost work time and travel expenses, subject to review by DePuy.
- If you have not received an ASR Hip, the hip you received is not part of this recall. Please speak to your orthopaedic surgeon about any questions you may have about your hip replacement.

SYMPTOMS, CAUSES AND TESTING

There are a number of symptoms which may indicate a problem with your ASR hip implant. These include pain, swelling and problems walking. These symptoms may be normal if you have just had a hip replacement. If the symptoms continue or come back, we recommend that you contact your orthopaedic surgeon or hospital for further instructions.

The ASR Hip is made up of ball and socket components that move against each other. These metal components wear over time and generate very small particles that can only be seen with a microscope. This is an expected process. These particles do not cause problems for most patients, but a small number of patients may react to these particles, causing fluid to collect in the joint and in the muscles around the joint. 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.

Tests may help your surgeon determine if your hip is working as it should and whether you are having a reaction to the metal particles. Your surgeon may take X-rays of your hip. Also, a blood test may be done to indicate the level of microscopic metal particles around your hip. Your surgeon may also use an ultrasound or an MRI scan to evaluate if you are having a reaction to the metal particles.

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 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. Most people with ASR hip implants do not have problems. 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.

In some cases, your surgeon may order other blood testing or imaging, such as x-rays or ultrasound, to see how well your hip is working. Your surgeon will decide the best monitoring plan for you and talk to you about further treatment.

If you don't know who performed your hip replacement surgery, ask your general practitioner (GP) or the hospital where the surgery took place and please make a note of the date.

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. If the x-rays show problems with your ASR Hip System, your surgeon may recommend surgery to replace it.
- If you do not have any symptoms or test results that suggest you may need to have your implant replaced, then you should follow your surgeon's recommendations for follow-up.
- If you do need to have another surgery, there are a number of choices available and your surgeon will choose the right implant system for you.

PAYING FOR TESTING AND TREATMENT

Your safety and health is important to DePuy, and we do not want cost to be a reason that you do not have 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 New Zealand. 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 **0800 660 026** or visit www.depuy.com.

Please check the New Zealand page on www.depuy.com on a regular basis for additional updates and information. This page will be available in October 2010.

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