

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

DePuy makes patient safety and health a top priority and is continually evaluating data about its products. 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 experienced pain and other symptoms that led to a second hip replacement surgery, called a revision surgery.

For this reason, DePuy Orthopaedics is recalling its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System. This recall means additional testing and monitoring may be necessary to ensure your hip implant is functioning well. In some cases patients may need additional surgery.

New data shows that five years after implantation, 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.

If you have received an ASR Hip Replacement or 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.

WHAT HAPPENS TO THE ASR IMPLANT AND WHAT SYMPTOMS SHOULD I WATCH FOR?

The patients who reported problems in the first five years and had revision surgery reported a variety of symptoms. These symptoms included pain, swelling and problems walking. These symptoms are normal if you have just had a hip replacement. But if the symptoms continue or come back, it is a sign that there may be a problem such as:

- Loosening, when the implant does not stay attached to the bone in the right position
- Fracture, where the bone around the implant may have broken; and
- Dislocation where the two parts of the implant that move against each other are no longer aligned.

Your hip implant is made up of ball and socket components that move against each other. These components are made of metal that wears over time and generates very small particles that can only be seen with a microscope. This is an expected process. Different people respond to the particles in different ways. 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.

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

WHAT DOES THE RECALL MEAN FOR ME?

Please contact the surgeon who performed your hip implant to determine if you received the ASR System. Most people with ASR hip implants do not experience problems. However, it is important that you follow up with your surgeon on an annual basis for the first 5 years after your ASR hip surgery – even if you are not experiencing symptoms – to ensure that your hip continues to work well. In some cases, your surgeon may order additional blood testing or imaging to evaluate how your hip is functioning. Your surgeon will determine the best monitoring plan for you and discuss treatment solutions should they be needed.

If you don't know who performed your hip replacement surgery, ask your primary care physician or the hospital where the surgery took place.

DePuy Can Help: If you are unable to determine the type of hip implant you received, we can help. Please fill out the release form available on www.DePuy.com.
U.S. patients should mail a completed form to DePuy Orthopaedics, Customer Quality Department, PO Box 988, 700 Orthopaedic Drive, Warsaw, IN 46581.
Patients outside of the U.S. should mail a completed form to DePuy International Limited, Complaints and Vigilance Department, St. Anthony's Road, Leeds, LS11 8DT. This will allow DePuy to contact your surgeon or hospital on your behalf.

If you received the ASR™ XL Acetabular System or DePuy ASR™ Hip Resurfacing System, you should take the following steps:

- Schedule an appointment with your surgeon. Your surgeon will be able to evaluate how your ASR hip is functioning.
- If you are experiencing pain, difficulty walking, or other symptoms, your surgeon may want to take x-rays of your hip. X-rays will allow your surgeon to evaluate how the ASR hip is positioned, if there is any damage to the bone and if the ASR hip has remained attached to the bone. If the x-rays show problems with your ASR hip, your surgeon may recommend surgery to replace it.
- In some cases, your surgeon may order additional blood testing or imaging to ensure your ASR hip is functioning well.
- The evaluation may include a blood test that indicates the level of microscopic metal particles around your hip. If the blood test indicates a high level of these particles, your surgeon may want to do a second blood test three months later. These levels may be high even if you are not experiencing any symptoms, so this blood testing is very important.
- If the second blood test still indicates a high level of these particles, your surgeon may want to do an MRI or ultrasound test of your ASR hip. If such tests show a reaction to the particles, your surgeon may recommend surgery to replace your

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implant. This is a decision that you and your surgeon need to discuss based on your own personal health needs.

- 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 continued follow-up.
- If you do need to have an additional surgery, several options are available and your surgeon will select the appropriate implant system for you.

WHO WILL PAY FOR MY TESTING AND TREATMENT?

Your safety and health is important to DePuy and we do not want cost to be a barrier to treatment. DePuy intends to cover reasonable and customary costs of testing and treatment if you need services, including revision surgery, associated with the recall of ASR. Bills for services should first be submitted to your insurance company or Medicare in the usual manner and DePuy will then reimburse you for your out of pocket expenses. Detailed information about the reimbursement process will be available shortly. Please visit our web site at www.depu.com or call the ASR Help Line at the number below.

WHO CAN I SPEAK WITH?

We recommend contacting your orthopaedic surgeon directly.

DePuy Can Help:

Additional questions? We are here to help. Do not hesitate to call the DePuy ASR Help Line beginning August 27, 2010.

Patients in the U.S. and Canada: Callers from the U.S. and Canada should dial the toll-free number 888-627-2677. The U.S. and Canada call center will be active from 8 a.m. to 9 p.m. EST, Monday through Saturday.

Patients outside of the U.S.: Please secure an operator and instruct them that you need to place a collect call to the United States at 813-287-1651. The operator will make the connection and transfer you to a representative who will greet you in English. Please respond in your preferred language to the representative. You will be transferred to a translator who speaks your language. The transfer to the translator may take up to two minutes. DePuy appreciates your patience while the call is being transferred. The OUS call center will be active 24 hours a day, 7 days a week.

Additional information is also available at www.depu.com.

Please check depu.com on a regular basis for additional updates and information.

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