

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 System 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™ 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.

How to find out if you have an ASR hip implant

Please contact your orthopaedic surgeon to determine whether you received an ASR hip implant. If you don't know who performed your hip replacement surgery, ask your primary care physician or the hospital where the surgery took place. If you are unable to determine the type of hip implant you received, fill out the release forms available below and mail them to the address on the form. This will allow DePuy to contact your surgeon or hospital on your behalf.

[Download Authorization Form \(Medical Release for United States\)](#)

[Download Authorization Form \(Medical Release for Outside of the United States\)](#)

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. 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.

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 Hip 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, fill out the release form available below.

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.

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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 System 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 System is positioned, if there is any damage to the bone and if the ASR Hip System has remained attached to the bone. If the x-rays show problems with your ASR Hip System, 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 System 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 System. If such tests show a reaction to the particles, your surgeon may recommend surgery to replace your 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 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.

**Authorization to Use or Disclose Information
(Medical Release Form)**

I hereby authorize the use or disclosure of my individually identifiable health information as described below. I understand this authorization is voluntary. I understand that if the organization or persons authorized to receive the information is not a health plan or health care provider, then the released information may no longer be protected by federal privacy regulations.

Patient Name:	
Patient Address:	
Patient Date of Birth:	

Persons/organizations providing the information (Doctor/Office Name or Hospital and Address):

Persons/organizations receiving the information:
DePuy Orthopaedics, Inc., Customer Quality Department
PO Box 988, 700 Orthopaedic Drive, Warsaw, IN 46581

Specific description of information to be used or disclosed, including date(s):

<p>All medical records and x-rays of <u>(name)</u> regarding his/her initial implant surgery that occurred on or about <u>(date)</u>, and subsequent revision surgery that occurred on or about <u>(date)</u>, and all follow up visits and records. Doctor office records should include but not be limited to new patient intake form, progress record, telephone message slips, copies of lab work, radiography, consultation reports, physical therapy reports, product code and lot number of components implanted; and all records relating to these surgeries and all follow up visits and records.</p>

Reason for use or disclosure of information: Manufacturer's Investigation

- I understand that I will not be denied health care or health plan coverage, as the case may be, if I do not sign this form.
- I understand that I may see and copy the information described on this form if I ask for it, and that I get a copy of this form after I sign it.
- I understand that this authorization will expire six months from date of signature.
- I understand that I may revoke this authorization at any time by notifying the person or organization providing the information in writing, but if I do it won't affect any actions taken before the revocation is received.

Signature of Patient or Patient's representative

Date