

Depuy® ASR Hip Implant Recall

The Facts

Recalled Devices:

ASR XL Acetabular System—on the market since 2004, and sold worldwide.

ASR Hip Resurfacing System—on the market since 2003, and sold exclusively outside the United States.

Dates of Implant:

July 2003 to 2010

Design Defect:

The shallow nature of the cup is different than other metal-on-metal (“MOM”) devices.

A) Causes excessive heat and friction between the metal cup and the metal ball.

B) Size, design and location of the resurfacing cup are three important factors that relate to the release of metal ions in the body. The design at issue here increases friction at multiple contact points between the femoral head and the acetabular cup.

Cause of Recall:

According to DePuy, the 5-year revision rate for the ASR implants is 12-13%. We expect that ultimately it will be revealed that the revision rate is in fact much higher. It is important to note that the revision rate for 6 years or more from implantation is not known at this time.



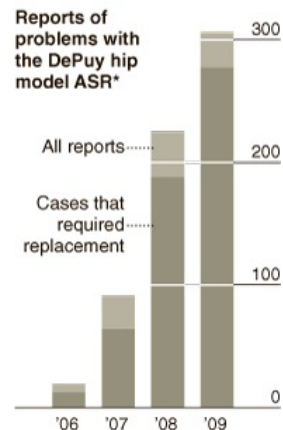
Problems with DePuy® Implants: Loosening, Misalignment & Fracture

A) Common Symptoms and Difficulties Associated with Loosening

- Difficulty standing or walking
- Crunching or popping noises
- Hip fractures or dislocation
- Tissue inflammation, infection, necrosis (this can cause the need for additional surgeries within a couple of months after implant)
- Severe Pain

Reported Problems

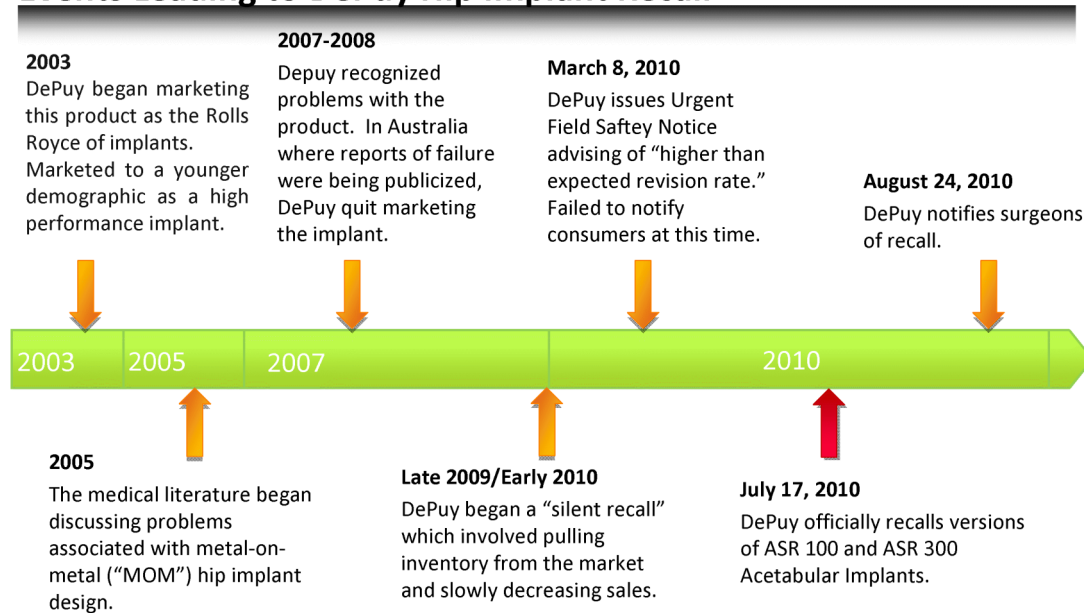
Between 2006 and 2009, reports of problems with the DePuy model ASR hip replacement device rose sharply. Of the problems reported in 2009, over 90 percent required replacement.



*Includes reports to F.D.A. of some cases outside the U.S.

Source: F.D.A.

Events Leading to DePuy Hip Implant Recall



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B) Common Symptoms and Difficulties Caused by Misalignment

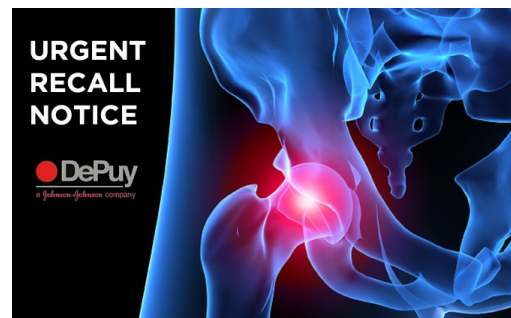
Metallosis is a common problem caused by metallic particles being released into surrounding tissue and into the bloodstream. The excessive heat and friction between the metal cup and the metal ball creates these metallic particles. The friction results in ions of chromium and cobalt being released into the body. As a result, patients are experiencing Aseptic Lymphocytic Vasculitis Associated Lesions (“ALVAL”) from heavy metal toxicity.



Symptoms of Metallosis:	Metallosis Results in Long-Term Injuries such as:
<ul style="list-style-type: none"> • Swelling in and around Implant Site • Spontaneous Dislocation • Nerve Palsy • Noticeable Mass or Rash • Groin Pain / Thigh Pain • Fatigue • Intense Pain at the Site of the Hip Replacement 	<ul style="list-style-type: none"> • Metal staining, black tissue and pseudo tumors around prosthesis. • Bone deterioration (and progressive bone deterioration) • Site area tissue and / or muscle necrosis • Brownish Fluid Developing in Both Hips • Other Infections • Potentially cancerous

C) Fractures

- Inhibited “Boney In-Growth” due to metal ions stunting bone growth.
- Lack of bone growth can cause loosening since this product does not use screws.
- Loosening leads to fractures.



Frequently Asked Questions

What is the DePuy ASR XL Acetabular System?

The ASR XL Acetabular System is a 3 component system comprised of: the femoral stem (which is inserted inside the femur); the femoral head (or ball) that connects to the stem; and then fits inside the acetabulum (cup). A unique characteristic of the ASR XL Acetabular system is that it is a metal-on-metal device meaning both the femoral ball and acetabula cup portion of the implant are metal.

What are the Common Problems/Symptoms with the ASR XL Acetabular System?

Swelling, component loosening, component misalignment, infections, bone fractures, dislocation, loss of muscle mass, unexplained hip pain, thigh and groin pain, pain when walking or rising from seated position, and clicking sounds. X-rays can also reveal metal debris, which can ultimately lead to inflammation of the surrounding tissue.

What Should I Do if I Received a Defective DePuy ASR XL Hip Replacement?

Always consult your doctor or physician regarding health-related issues, but if you or someone you care about received defective joint replacement components, we would like to speak with you right away. **DO NOT SIGN A RELEASE FROM THE SURGEON OR DePUY.** It is imperative that you do NOT sign the release sent to you by your physician on behalf of DePuy. These releases will allow DePuy complete access to your medical records and allow them to obtain possession of the defective implant in the event it is removed.

When were these problems discovered?

The defects were first documented by the Australian National Joint Replacement Registry in early 2008. The evidence presented clearly demonstrated a very high rate of failure concerning this device. Australia withdrew this device from the market in December 2009. Researchers from a British study also reported problems with the metal-on-metal implants causing adverse soft tissue reactions resulting from the friction of the metal-on-metal surfaces. These patients showed higher rates of wear and tear and soft tissue damage. The United States Food and Drug Administration did not participate in a recall despite this information.

Should I return to my physician who contacted me?

Perhaps. In our experience, most doctors have been very

supportive of their patients. Doctors are ordering X-rays, MRIs, blood tests, and bone density tests. These tests are important.

Should I sign the documents my doctor gave me?

ABSOLUTELY NOT!!!! There are different versions of this document, but they allow DePuy to obtain your medical records and in some cases, obtain your defective device if it is removed. Your information will also be provided to DePuy's adjusters handling the claims.

What do I need to be doing?

First and foremost, continue your treatment regimen. Additionally, consider keeping a journal. We have found this to be extremely helpful in representing clients and it assists us in personalizing your claims when we have to present them for settlement or trial.

Do I have to go back to my doctor for this to be covered?

No: In fact, a class action has been filed against DePuy claiming they are misleading consumers. In that complaint, it is alleged:

"In our opinion, DePuy's 'offer' may deceive potential claimants into believing that the company has actually agreed to advance or reimburse their costs for medical monitoring or revision surgery. In fact, no specific offer to pay medical costs has been made and no specific plan for reimbursement has been announced. Moreover, DePuy has stated that before reimbursement of expenses will be provided, it will review the patient's medical records to determine if the patient meets DePuy's criteria for payment. According to DePuy, the medical records must confirm that the revision is related to the ASR recall and 'not some other type of cause, such as a traumatic fall.' Blaming the device failure on a fall, or another cause, such as physician error, patient misuse, pre-existing condition or underlying diseases is a standard litigation defense in these types of cases. Thus a patient who releases medical records to DePuy may do nothing but provide DePuy with a jump start on litigation defenses."

Even if you are currently not experiencing adverse effects of this defective hip implant, be careful letting DePuy dictate your care. Contact us immediately for a consultation.



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