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DePuy® ASR Hip Implant Recall Fact Sheet

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

- Screening Criteria:**
- a) If client did NOT receive recall letter, then the operative chart stick needs to be ordered.
 - b) Model numbers can be found on FDA website.

- 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.

Cause of Recall: According to its own admission, its 5-year revision rate is 12-13%. We expect that discovery will reveal that it is in fact much higher.



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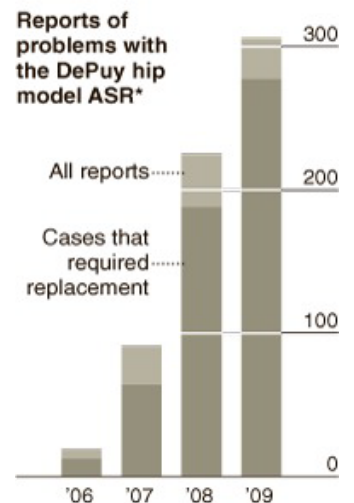
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Timeline of Events Leading to Recall

- 2003** DePuy began marketing this product as the Rolls Royce of implants. Marketed to a younger demographic. Marketed as high performance implant.
- 2005** By this time, the medical literature began discussing the problems with the metal-on-metal (“MOM”) design.
- 2007-08** DePuy recognized problems with the product in Australia and quit marketing the implant in Australia.
- Late '09 / Early '10** DePuy began a “silent recall” which involved pulling inventory from the market and slowly decreasing sales.
- March 8, 2010** DePuy issued Urgent Field Safety Notice advising of “higher than expected revision rate.” Failed to notify consumers at this time.
- July 17, 2010** DePuy officially recalls versions of ASR 100 and ASR 300 Acetabular Implants.
- August 24, 2010** DePuy notifies surgeons of recall.

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.



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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

b) Common Symptoms and Difficulties Caused by Misalignment

Metallosis is a common problem caused by the excessive heat and friction between the metal cup and the metal ball. 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">• 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) Fracture

- 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.



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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 ball and cup portion of the implant are metal.

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

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.

Who Discovered Problems and When?

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. Hospitals and hip surgeons in the United States had been warned about the defects of this device, but continued to use it anyway, until DePuy voluntarily recalled the product.

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Should I return to my physician who contacted me?

Perhaps. In my experience, most doctors have been very supportive of their patients. They are ordering X-rays, MRIs, blood tests, and bone density tests. These tests are important.

I have received several reports that certain physicians have only ordered X-rays, told their patients they were fine, and in one case, openly stated that the patient's pain onset occurred when they received the recall letter. The wife of this client reportedly quipped to the doctor that he obviously had not looked at her husband's chart in the two years since his surgery and certainly had not lived with him or he would know otherwise.

If your physician acts like this, I would not return and would find a surgeon who does hip revision surgery to evaluate your hip. If you are unable to locate a physician, let us know.

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. I have found this to be extremely helpful in representing clients and it assists me in personalizing your claims when I have to present them for settlement or trial.



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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."

Letting DePuy dictate your care may cost you in the future---in previous medical implant litigation I handled, patients were offered free medical care. What they were not told was that the manufacturer paid the doctors the bill rate as opposed to the insurance, Medicare or Medicaid reimbursement rate, which is much lower. When it came time to settle their claims, the manufacturer demanded credit from the settlement for what they paid, which was 3 or 4 times what the insurance carrier would have paid. This is a nice carrot used to keep some physicians happy.

What else do I need to know?

First, there is often a very close relationship between the makers of devices and the physicians who install them. Trips, seminars, catered lunches are not uncommon. Often the physicians and their orthopedic reps, as they are called, have close personal relationships. There is no doubt DePuy will seek to exploit this relationship, if it can be exploited, to obtain releases and medical records (to prepare their defense that the failure is unrelated). On the other hand, many physicians are patient advocates and some have even advised clients to seek legal representation.