

Hip Implant Recovery

An informational newsletter from

Parker McDonald, P.C. & Harrison Davis Steakley Morrison, P.C.



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855-487-8447

DePuy Hip Implant Recall: The Whole Story

DePuy Orthopaedics has voluntarily recalled its defective metal-on-metal hip implant systems, including the ASR XL Acetabular device ("ASR"), which was used throughout the United States from 2005 through August 24, 2010. In this newsletter, we answer these questions: (1) how and why is the ASR implant device defective; (2) what did DePuy know about the nature and extent of the defect in the ASR; and (3) when did they know it.

Information About the Human Hip

The human hip is a ball-and-socket joint designed to allow for a wide range of motion. The hip is a complex joint which requires for normal function healthy soft tissue including ligaments, tendons, muscles, nerves, and blood vessels. The most prominent components of the hip, and the most susceptible to degenerative disease, are the "hipbones" and the joint.

The "hipbones" are the femur, commonly known as the thighbone, and the pelvis. On top of the femur is the femoral head. The femoral head is shaped like a ball and fits into a round socket, or "cup", on the side of the pelvis. This socket, or "cup", is called the acetabulum. Articular cartilage covers the surface of the femoral head and the acetabulum and is about one-quarter of an inch thick in the hip joint. This cartilage has a rubbery consistency and is slippery, allowing the surface of the femoral head to slide smoothly and easily within the joint formed in the acetabulum. This design allows for the smooth, wide range of motion needed for daily activities such as walking, climbing stairs, bending and sitting.

Hip Damage and Replacement

If damaged, a hip can be replaced.

The most common cause of damage to the hip joint that requires a hip implant is osteoarthritis. Osteoarthritis is a disease linked most commonly to aging. Osteoarthritis causes, among other things, degeneration of the articular cartilage and/or the underlying bones. Advanced osteoarthritis leaves the articular cartilage so rough and pitted that the femoral head no longer slides smoothly over the surface of the acetabulum causing severe pain and discomfort with virtually any movement within the hip joint. Other diseases such as osteonecrosis, which derives from a diminished blood flow to the femoral head, can also damage

the hip joint leading to the necessity of a hip replacement. Other factors, such as bone tumors and trauma, can also lead to the breakdown of the hip joint and necessity of a subsequent hip replacement surgery.

During the hip replacement procedure, the orthopedic surgeon makes an 8-inch incision over the side of the hip, separates the soft tissues in order to enter the joint capsule and then dislocates the femoral head from the acetabulum.



Two components of the ASR device.

The surgeon then removes diseased cartilage from the acetabulum and replaces it with the acetabular prosthesis – a new "cup" to hold a new femoral head. Next, the surgeon removes the entire diseased femoral head from the femur. The stem of the new femoral head prosthesis is inserted into the hollow center portion of the femur. To complete the procedure, the "ball" of the new femoral head is placed within the cup, proper alignment is confirmed and the incision is closed. The patient now has a new, artificial hip joint.

Hip replacement surgery is very common in the United States with significantly more than 90 percent of hip replacements considered successful in that they require no further surgical intervention. But, this has not been the case with the DePuy ASR.

DePuy's ASR Replacement Hip Implant System

So how is DePuy's recalled ASR hip implant different from other hip implants?

In 2003, DePuy released its ASR hip implant system. The DePuy ASR implant was a unique, metal-on-metal design. DePuy promoted the ASR implant as a breakthrough in design

that would last longer and provide patients more natural movement. Published reports suggest that the ASR hip implant was designed to last for 15 years.

Unfortunately, researchers have concluded that the DePuy ASR metal-

on-metal hip implant has major design defects and have expressed grave concerns about its safety. First, the acetabular prosthesis, the "cup", is so shallow it

is susceptible to so called "edge loading", a situation where the joint's ball strikes against the cup's edge, chiseling off debris.

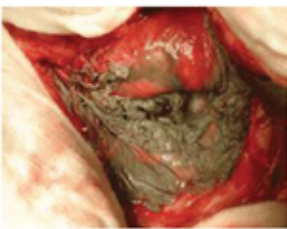
This defect leads to potentially severe complications. As the metal-on-metal surfaces of the implant parts rub together, microscopic ions of the heavy metals chromium and cobalt are released into the body. Elevated levels of chromium and cobalt can cause a potentially very dangerous condition known as metallosis. Metallosis is a reaction of the immune system to heavy metals in the body. Metallosis can cause severe complications such as destruction of surrounding bone and muscle. These complications can significantly increase the difficulty a doctor faces in performing a subsequent revision surgery to replace the defective DePuy ASR device.

Symptoms of metallosis include spontaneous dislocation of the joint, groin or thigh pain, fatigue, and intense pain at the site of the hip replacement. Questions have been raised whether metallosis may be a cause of heart irregularities and kidney disease. There is also concern that elevated levels of chromium and cobalt can have long-term effects including

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chromosomal damage and cancer.



Metallosis in hip joint.

Initial Approval; Current ASR Recall

DePuy obtained FDA approval for its ASR hip implant in 2005 through a shortcut process known as the 510(k) approval process. That process pre-approves any product that is deemed “substantially equivalent” to those products already marketed for sale and requires no clinical trials. DePuy gained its approval through this system by asserting that “the subject device does not raise any new issues of safety or effectiveness.”

On March 6, 2010, DePuy issued a warning to surgeons in the United States that its ASR hip implant had a higher than expected failure rate. This warning was finally provided a year after DePuy was presented with findings that the ASR implant was failing early and required revision surgery. Shockingly, the March warning letter came nearly three months after DePuy voluntarily withdrew the ASR hip implant from the Australian market in December 2009. DePuy continued to promote and sell the ASR hip implant in the United States for over six months after the Australian withdrawal before finally recalling the ASR device in the United States in August 2010.

The Consequences for ASR Patients

Estimates are that as many as 93,000 patients worldwide were implanted with the DePuy ASR hip implant. DePuy itself estimates that at least 13 per cent of these patients will experience product failure and will require revision surgery to remove and replace the defective hip implant device. Our review of anecdotal evidence suggests that as many as 30 per cent of patients may experience product failure and will require revision surgery. These procedures will be performed on a predominantly elderly patient population particularly susceptible to potentially severe complications such as deep vein thrombosis, systemic infection, implant dislocation, injury to the arteries or nerves of the leg, shortening of the leg, fat embolism, femur fracture, permanent loss of range of motion and intractable pain. These patients have substantial claims for damages for pain and suffering, mental anguish, physical incapacity, disfigurement, future medical expenses and costs of future care.

We Can Help

Parker McDonald and Harrison Davis Steakley Morrison have teamed together to form what we believe is the most dynamic and effective DePuy ASR hip implant litigation and trial team in the country. We have decades of experience and an outstanding record of many, excellent successes in representing victims of defective drugs and medical devices. We have committed the substantial financial and manpower resources of both our firms to the cause of the innocent vic-

tims of the DePuy ASR hip implant.

It is vital that patients with a DePuy ASR hip implant consult with us before revision surgery to remove and replace an ASR hip implant. It is critical that the patient does not sign the release that DePuy’s agent, Broadspire, may require as a condition of paying any part of the cost of revision surgery. On this issue, we stand ready to fund in full and in advance the entire cost of revision surgery in order that our clients have the surgery as soon as recommended by their orthopedic surgeon. In addition, it is important that the patient undergo blood tests for chromium and cobalt levels before revision surgery. Finally, it is also important that the patient provide the surgeon with written instructions concerning the preservation of tissue samples and the retention and possession of the explanted ASR device before the revision surgery.

The campaign on behalf of DePuy ASR hip implant victims will be long and challenging and will require special experience, knowledge, talent and resources. We would be honored to accept your referral of ASR hip implant clients. We pay customary referral fees to referring attorneys on all referrals.

Contact us today.

855-487-8447

Dan@ParkerMcDonaldLaw.com
www.HipImplantRecovery.com

PM Parker
McDonald
TRIAL LAWYERS

2317 Plaza Parkway
Bedford, Texas 76021
817-503-9200

**HARRISON
DAVIS
STEAKLEY
MORRISON, P.C.**
ATTORNEYS AT LAW
5 Ritchie Road
Waco, Texas 76712
254-761-3300

www.HipImplantRecovery.com

Hip Implant Recovery

2317 Plaza Parkway, Suite 100
Bedford, Texas 76021

ADDRESS SERVICE REQUESTED