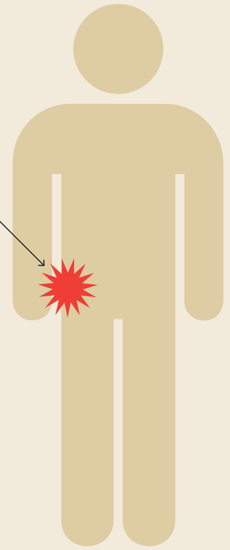
DEPUY ASR ACETABULAR HIP REPLACEMENTS
WHAT HAPPENED AND WHEN?

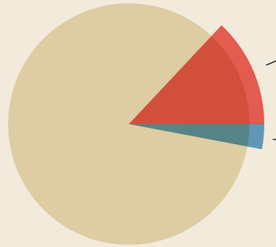
DePuy released insufficiently tested hip implants that have caused serious problems in an inordinately large percentage of hip replacement surgery patients, including metal poisoning (metalosis), bone deterioration, and increased risks for future surgeries and implants. DePuy is offering to replace the ASR™ hip implants at their cost in hopes that patients will waive their right to further damages. That means if you accept their offer, you will not receive any compensation for future medical bills, disability, lost wages, or your pain and suffering incurred to date.

If you received a DePuy hip implant since 2003 or think you have a DePuy hip implant and would like to know more about this case, give our offices a call at 1-800-677-7095. We have people to help answer your questions and explain how we can help.

FAILED DEPUY ASR ACETABULAR IMPLANT:

- Pain, Swelling, Difficulty Walking
- Metal Poisoning (Metalosis)
- Bone Deterioration
- Tissue Damage
- Pseudotumors
- Necrosis





13%
The failure rate of the DePuy ASR Acetabular System within 5 years

.5% - 3%
The standard industry revision rate for hip replacement within 5 years

KNOWN FAILURE
DePuy knew about these high failure rates as early as 2007, three years before issuing a recall in 2010.

"REVISION"

A "revision" is a surgery where the orginal hip replacement is removed and a new hip replacement is put in.

The number of complaints filed with the FDA between 2006 and 2010.

887

2004

DePuy introduces their ASR Acetabular System

2005

DePuy files for a FDA 510k Application of Approval for ASR Acetabular System saving DePuy time and money. Filing for a 510k costs $4,400, versus filing for a FDA Permanent Application of Approval costing $250,000+.

- August 5 – FDA 510k approval of DePuy ASR Acetabular System (cup sizes 44mm – 62mm)[2]

2006

12

The number of complaints to FDA regarding the DePuy ARS Acetabular System in 2006.[3]

- March 24 – First complaint to FDA of ASR Acetabular malfunction – ASR failed during surgery while being checked by surgeon.[3]

2007

87

The number of complaints to FDA regarding the DePuy ARS Acetabular System in 2007.[3]

- Australian Orthopaedic's National Joint Replacement Registry (NJRR) reports the revision rate for DePuy ASR Acetabular System is over 2 times the normal rate.[4]
- September 27 – DePuy settles case paying $84,796,800 for bribing surgeons to use DePuy devices. DePuy signs Corporate Integrity Agreement with Department of Health and Human Services.[5,6]

2008

239

The number of complaints to FDA regarding the DePuy ARS Acetabular System in 2008.[3]

- DePuy files 510k with FDA for ASR XL Modular Acetabular System (cup sizes 64mm – 70mm)
- July 2 – FDA approval on ASR XL Modular Acetabular System
- Australia's NJRR re-identifies DePuy ASR still having a higher than normal revision rate[4]
- National Joint Registry of England and Wales reports that over 3 years DePuy's ASR system has worst revision rate at 7.5% versus a 4.5% average[7]

2009

424

The number of complaints to FDA regarding the DePuy ARS Acetabular System in 2009.[3]

- DePuy sends brochure to doctors describing importance of proper cup position for its ASR system. But does not address any specific concerns for its ASR system
- Australia's NJRR continues to report DePuy ASR still having a higher than normal revision rate[5]
- DePuy withdraws ASR from Australian market for "comercial reasons"
- DePuy announces it will discontinue the ASR system based on claims of "declining demand" but does not device

2010

125

The number of complaints to FDA regarding the DePuy ARS Acetabular System in 2010.[3]

- In a February interview with New York Times DePuy states ASR's performance is equal to that of competition
- DePuy issues formal recall in the United States of their ASR Systems in a letter dated March 6
- April 10 – DePuy maintains in the New York Times the ASR System is safe despite the recall
- May 25 – FDA issues alert on DePuy ASR Systems
- August 24 – Johnson & Johnson announce that DePuy issues worldwide recall on their ASR Systems, 5 months after U.S. recall of product

[1] http://asrrecall.depuy.com/usmedia
[2] FDA 510k Summary of DePuy ASR Modular Acetabular Cup System
[3] FDA MAUDE search http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
[4] DePuy ASR Hip Implant Recall - What did DePuy Know, and When? http://mccarthy.ie/depuy-asr-hip-implant-recall-what-did-depuy-know-and-when/
[5] http://www.justice.gov/usao/nj/press/files/pdffiles/DePuyCivilSettlement.pdf
[6] http://www.justice.gov/usao/nj/press/files/pdffiles/DePuyCIA92707.pdf
[7] Focus on Hip Resurfacing Antroplasty; The Journal of Bone and Joint Surgery, 2010

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