

Malcomson Law Hip Recall Conference: Legal & Medical Engineering Expertise

Malcomson Law will be hosting an informational conference on **Saturday the 8th of January** in the **Gresham Hotel, Dublin**.

Managing Partner Raymond Bradley will speak about one's legal rights in relation to the recall, and the legal issues involved in bringing a claim.

He will be joined by **expert speakers Mr David J. Langton and Dr Thomas Joyce** from Newcastle University's School of Mechanical and Systems Engineering.

Mr Langton and Dr Joyce have published many scholarly articles on the design faults of the ASR Hip Replacement Systems and case studies of the problems experienced by people fitted with those implants. Mr Langton is an Orthopaedic Surgeon and Dr Joyce a mechanical engineer and reader in biotribology at Newcastle University.

Malcomson Law have invited several people who have made inquiries to the firm about the DePuy recall to come to the conference, where the expert speakers can inform them of the technical aspects of the hip implants, and the defects which led to their subsequent withdrawal from the market.

Malcomson Law's Hip Recall Legal Team

Managing Partner Raymond Bradley, and Solicitors Patricia Crosbie and Edel Sheerin, will be on-hand to advise attendees of the legal developments so far, and inform them of their legal rights and the issues involved in making a claim against DePuy.

If you have been affected by the circumstances surrounding the withdrawal of a faulty DePuy hip replacement implant/device then please feel free to contact **Malcomson Law** at **(01) 8744422** or complete an Online Enquiry Form at **www.mlaw.ie**

Health Law Department

We deal with all aspects of Health Law. If you require advice or further information then please contact the Health Law Department on 01 8744422

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MALCOMSON
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Medico-Legal Conference

Hip Replacement Recall

Saturday, 8th January 2011

Health Law Department

The specialist Health Law Team at Malcomson Law is headed by Raymond Bradley. He has extensive experience of taking health related cases in the Irish High Court, an unrivalled record of involvement in high-profile cases of medical negligence and in representing victims of health scandals at public inquiries and compensation tribunals.

DePuy Hip Replacement Recall

On the 27th of August 2010 DePuy recalled their ASR Hip Resurfacing System and ASR Total Hip Replacement products from the market. The company announced that, 5 years after implantation, 12% of patients who'd received the ASR Resurfacing System, and 13% of those fitted with the ASR Total Hip Replacement, needed a second or revision surgery.

In Ireland, the 3500 patients who received these implants will need to be reviewed—on the basis of the above figures, around 400 of those people will require revision surgery.

Hip Recall Timeline

- **2008:** The United States Food And Drug Administration (FDA) begins to receive notification of adverse reactions to the hip implants
- **December 2009:** The devices are voluntarily withdrawn from the Australian market
- **March 2010:** DePuy voluntarily withdraws the implants from the US market
- **27th August 2010:** A worldwide recall is put into effect after DePuy received revision surgery figures from the National Joint Registry of England and Wales
- **August 2010:** The Health Service Executive (HSE) writes to all Irish Hospitals' Orthopaedic Units, requesting them to recall or withdraw the ASR implants
- **28th September 2010:** Malcomson Law write to all Irish Orthopaedic Surgeons urging them not to comply with DePuy's request to be furnished with any removed implants
- **November 2010:** Irish hospitals write to patients to set up appointments with an Orthopaedic Team

What are the health implications?

Because of the earlier than expected failure rate of the implants, patients began experiencing intense pain and weakness of the hip, including swelling and problems with mobility. A lot of patients required further surgical intervention almost immediately. Women and people with weak bones seem to be inordinately affected by the defective implants.

The **ASR systems are metal-on-metal implants** as opposed to the older ceramic models. This has led to very specific problems, as the grinding of the movable metal parts of the implant have been shown to release metal ion particles (specifically, cobalt and chromium) into the bloodstream.

This **Cobalt Poisoning**, or **Metallosis**, can result in the formation of non-cancerous tumours, sinew damage, and aseptic lymphatic vascular and associated lesions. These conditions are a result of particularly aggressive necrotic erosion of living tissue and cells. Recent studies have shown that Cobalt Poisoning may also result in tinnitus, vertigo, deafness, blindness, optic nerve atrophy, fatigue, and cognitive decline.

Revision Surgery & Other Issues

Each of the Irish hospitals which performed hip replacement surgeries will be writing to patients so that they can attend the hospital and meet a specialised Orthopaedic Team.

- Patients should be advised as quickly as possible as to whether their implant is defective and requires a revision surgery.
- **Under no circumstances should patients sign DePuy's request form**, which would give DePuy access to their medical records and the original faulty implant.
- Patients should request that **blood tests** be undertaken to ascertain if the implant has released microscopic metal particles into their bloodstream
- If such particles are found, patients should request that an **MRI scan** be performed as a matter of priority as metal ions in the blood may cause neurological defects, as well as the side effects mentioned above.

What are the legal issues involved?

Malcomson Law have been contacted by many patients in relation to the hip replacement recall. As most evidence points to a defective design in the hip implants, Malcomson Law are receiving instructions to pursue a Defective Products Claim on behalf of those people affected. These claims fall under the ambit of the Liability for Defective Products Act, 1991. Anyone affected should be aware of the following legal issues:

- **Under no circumstances should you sign DePuy's request form**, which would give DePuy access to your medical records and the removed implant. Both the records and the excised implant may be required in any future Court proceedings
- That a **Limitations time period affects claims brought under the Defective Products Act**. You need to inform your Solicitor of all the relevant dates of procedures and surgeries, as these dates may affect when your claim would be time-barred.

Liability for Defective Products Act, 1991

The 1991 Act provides victims of defective products with an additional remedy against the producer of the defective product. The Act has profound implications for producers and manufacturers of goods in that it holds them strictly liable (without proof of fault) for the safety of their products. Under the Act, for the plaintiff to succeed, it will be required to prove that the damage or the injury caused was the result of a faulty product.

Under the terms of the 1991 Act a product is defective if it fails to provide the safety which a person is entitled to expect. Accordingly, to fall within the ambit of the 1991 Act the product must not only be defective it must also be unsafe.

The Act also makes extensive defences available to the producer.

Malcomson Law's Charity of the Year for 2010 is **Headway**, supporting people with Acquired Brain Injury