WHITNEYMOORE

DePuy Orthopaedics Hip Implant Recall

The recall on 26 August 2010 by DePuy Orthopaedics of its ASR hip implants due to higher than normal failure rates is a cause of major concern for patients who have received the device – whether or not they are experiencing problems. All such patients are advised to consult their surgeons and to undergo certain tests on a regular basis. Apart from the medical concerns there are serious legal issues involved in relation to which patients should also obtain immediate expert advice.

Background

Following the study of data from Australia and the National Joint Registry for England and Wales which revealed higher than normal failure rates, DePuy Orthopaedics (a subsidiary of pharmaceutical giant Johnson & Johnson) has recently announced the worldwide recall of its ASR System hip replacement implants.

The metal ball and socket components of the ASR system have been used in both hip replacement and hip resurfacing procedures since July 2003. Some 93,000 patients worldwide have been implanted using the ASR system, including 3,500 recipients in Ireland. The data has shown a 13% failure rate in the ASR system used in hip replacements and a 12% failure rate in the ASR resurfacing system.

The Problem

The articulation of any metal on metal implant can create microscopic debris that is absorbed into the patient's body. It would appear that the higher failure rates in the DePuy prostheses result from excessive amounts of metal debris arising from the particular design of the socket component which is shallower than those made by other manufacturers. According to one leading orthopaedic surgeon, the design of the DePuy system makes it difficult to achieve optimal alignment of the metal ball component and the metal socket resulting in greater wear. This is particularly so for the smaller sizes, which explains why the failures are more evident in women than in men.

Symptoms

Excessive amounts of metal debris can cause inflammatory reactions, soft tissue damage, and loss of bone, resulting in severe pain and, in many cases, failure of the implant itself. Patients whose hip implants have failed or who have presented with these symptoms will need to undergo revision surgery. In the words of another leading orthopaedic surgeon, "such hips need revising sooner rather than later. Diagnosing what is wrong early and accurately is important. Knowing how to fix the situation even more so."

Medical Issues

With failure rates of 12% and 13%, or one in eight, it is anticipated that in Ireland as many as 400 of the 3,500 Irish ASR implant recipients will require remedial surgery within five years of their original hip replacement surgery.

In a statement issued on 30 August 2010 the HSE indicated that arrangements were being put in place with hospitals to identify patients in Ireland who had received the affected implants and that they would be contacting those patients in the coming weeks and would take "all steps necessary to ensure patients

receive appropriate follow-up." The statement goes on to say that "each patient affected will be given an appointment to visit their surgeon. The surgeon may need to order a blood test and an x-ray."

In its Medical Device Alert (Ref: MDA/2010/069 issued on 7 September 2010) the UK's Medicines and Healthcare products Regulatory Agency (MHRA) recommends that orthopaedic surgeons should –

- for all patients implanted with ASR hip replacements follow up with clinical examinations at least annually;
- for those already presenting with symptoms of abnormal pain, limping, swelling around the hip, deteriorating hip function or radiological abnormality–
    - Consider measuring cobalt and chromium ion levels in whole blood and/or performing cross sectional imaging including MRI or ultrasound scan
    - If metal ion levels in whole blood are elevated above 7 parts per billion for either metal ion, a second test should be performed three months after the first in order to identify patients who require closer surveillance, which may include cross sectional imaging
    - If MRI or ultrasound scan reveals soft tissue reactions, fluid collections or tissue masses then consider revision surgery.

Legal Issues

Despite the recall of the implants, there has, to date, been no admission of liability or negligence on the part of DePuy Orthopaedics and there are potentially very serious legal issues arising from the recall. Whilst in its Recall Notice DePuy indicates that it will cover the reasonable and customary costs of testing and treatment, including revision surgery if required, it is far from clear how this process will work and what exactly will be covered.

There is no reference to the payment of any compensation to patients for the pain and suffering they will endure as a result of the defective implant or of having to undergo revision surgery; for any loss of functionality in their hip joints following revision surgery; for loss of earnings during any absence from work necessitated by tests, surgery or recovery periods. DePuy is also imposing on patients, as a condition of the payment of any costs and expenses, a requirement that they sign consent forms releasing information to the company and the explanted device. Under no circumstances should any documentation be signed without proper legal advice.

There are strict limitation periods within which legal proceedings must be taken, after which any proceedings may be statute barred. For some patients that clock may already be ticking. It is imperative, therefore, that in addition to seeking immediate medical advice, patients who have received a DePuy ASR hip implant should seek urgent advice as regards their legal rights and entitlements.

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