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SAFETY ALERT

Considerations for the safe and effective use of DePuy ASR™ - Hip Resurfacing Arthroplasty

September 28, 2007

Dear Doctor

This letter is being sent to ensure that you are aware of the importance of correct patient selection and appropriate surgical technique in the use of the DePuy ASR™ articular surface replacement system.

As part of our routine post market surveillance activities, ongoing analysis of data collected on revision cases indicates that the revision rate of the DePuy ASR™ system is 3.2 revisions per 100 patient years. When reviewing these cases it was found that in 80% where cause was determined, sub-optimal patient selection and surgical technique have contributed to premature failure or have been the major contributors to premature failure.

Over 850 DePuy ASR™ systems have been sold in Australia. Of the revisions reported on the Australian Orthopaedic Association National Joint Replacement Registry the following reasons for revision have been stated:

Reason for revision	Frequency
Avascular necrosis	1
Dislocation of the prosthesis	1
Fractured neck of femur	12
Infection	1
Loosening	3
Metal sensitivity	1

It is important, therefore, that in accordance with the DePuy ASR™ instructions for use and surgical technique that **only those patients who have good bone quality and appropriate bone geometry are treated with surface replacement.**

During surgery close attention must be afforded to component positioning. The femoral component must be fully seated and neck notching must be avoided. The acetabular component must be implanted at the correct inclination (35-45 degrees). An appropriate cementing technique must be employed.

In the near future your local DePuy representative will be contacting you to discuss this matter and to update you on a series of further measures we are undertaking to support you in ensuring optimal patient outcomes with hip resurfacing arthroplasty. In the meantime, we ask that you adhere to the appropriate patient selection criteria and surgical technique for the DePuy ASR™ system, should you require further copies of the surgical technique please contact your local DePuy representative or the undersigned.

In accordance with our responsibilities as Sponsor of the DePuy ASR™ system in Australia, Johnson & Johnson Medical Australia have engaged in regular discussions with the Therapeutic Goods Administration (TGA) who are aware of our actions and have been briefed on the detailed technical investigations conducted and our ongoing activities.

Please feel free to contact me on (612) 9815 3895 or 0420 302 574 if you require any further information.

Yours sincerely,

Dr Aran Maree MB, ChB, MRCP (Irl)
Medical Director – Australia and New Zealand