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Dear Doctor:

Hazard Alert: Metal Liner Components of the R3™ Acetabular System

Smith & Nephew's highest priority is to design safe and effective medical technology for the benefit of patients. In alignment with these values, we are taking the precautionary step of withdrawing the optional metal liner within the R3 Acetabular System from the market. This action has been taken following a review of the most recent data as we are not satisfied with its clinical performance.

The most recent data sources related to the performance of the metal liner in the R3 System includes:

- The United Kingdom's National Joint Registry, which shows a revision rate of 6.3% at 4 years.
- The Australian Orthopaedic Association's National Joint Replacement Registry, which shows a revision rate of 2.48/100 observation years.

While we continue to study this, the data does not indicate that there is a single, dominant reason why this liner isn't performing to our standard—such as metallurgy or a manufacturing process. For instance, in the Australian Registry, there's a range of diagnoses, including infection, dislocation, metal sensitivity, loosening/lysis and fracture.

This precautionary step affects only the metal liner component of the R3 System. The R3 System's cross-linked polyethylene liners and BIOLOX Delta liners are unaffected by this market withdrawal.

We advise that physicians should contact their patients who have been implanted with the metal liner to inform them of the current alert and maintain their usual follow-up protocols for patients who have undergone hip replacement or resurfacing surgery. In addition we support the various regulatory agencies' guidelines for the clinical follow-up of MoM hip replacements (<http://www.medsafe.govt.nz/profs/device-issues.asp#17April2012>) and are not suggesting more is required for patients who have this component. If you or your patients would like to read more about our action, they can visit <http://R3.Smith-Nephew.com>.

If I can be of any help to you during this transition to other bearing options, or if I can provide additional information on the clinical performance of our devices, please be in touch directly. My email address is andy.weymann@smith-nephew.com.

Sincerely,

Andy Weymann, MD
Chief Medical Officer
Smith & Nephew