

Smith & Nephew Surgical Ltd
Reg No: 28254520
Unit 1a, Charann Place
Avondale NI 1348
PO Box 19045
Avondale NI
New Zealand

T 0800 778 104
F 0800 775 744
www.smith-nephew.com



XX XXXXXX 2012

<ADDRESSEE>
<ADDRESS 1>
<ADDRESS 2>
<ADDRESS 3>

Dear Doctor:

Hazard Alert: BIRMINGHAM HIP™ Modular Head

Following a review of the most recent data regarding the clinical performance of the BIRMINGHAM HIP™ Modular Head (BMMH) (under the existing indications for use) a higher than expected revision rate when compared to all other conventional hip replacements has been identified. Amongst other reasons, the leading causes for revision include metal sensitivity, loosening and lysis and infection. The BMMH will no longer be available for primary hip replacement surgery.

Please note that this Hazard Alert does not apply to Smith & Nephew's BIRMINGHAM HIP™ Resurfacing (BHR) implants.

Actions Required

1. Please note the contents of this letter and contact your patients who have been implanted with the BMMH to advise them of the alert.
2. Please complete the attached acknowledgement form and return it to Smith & Nephew by 26 October 2012.
3. Surgeons are advised to implement appropriate follow-up protocols for their patients such as the MHRA advice about the management and monitoring of patients implanted with metal-on-metal (MoM) hip replacements < <http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON155761>> or the Medsafe guidance <http://www.medsafe.govt.nz/profs/device-issues.asp#17April2012> or the Australian Therapeutic Goods Administration (TGA)'s guidance released on 20 September 2012 < <http://www.tga.gov.au/hp/information-devices-mom-hip-implants.htm>>
4. The need for follow-up should be determined on a case-by-case basis following a detailed assessment of your patient's particular set of circumstances. The necessity for diagnostic imaging and blood tests will need to be determined in consultation with your patient.

Risks to Health

While the causes of the elevated revision rate are not known the potential risks that may result from use of the device have not changed. They may include pain and limited mobility, potentially leading to revision surgery.

Females of child bearing age are at greater risk with metal-on-metal implants. Severely overweight individuals have been observed to be at greater risk of revision surgery (as set out in the product IFU).

Reason for this Hazard Alert

The BMMH is a Metal on Metal (MoM) replacement system that consists of a Birmingham Acetabular cup, a conventional stem and a Birmingham modular head. The Acetabular cup and the modular head is the MoM articulation. There have been 39 different types of conventional stems used with this articulation. The revision rate for the BMMH with all stems is:

- 1.29 (95% CI 1.11, 1.49) revisions per 100 observation years in the NJREW; and
- 1.13 (95% CI 0.94, 1.34) revisions per 100 observation years in the NJRR.

The revision rate in the NJREW exceeds the 1% benchmark established by the UK's National Institute for Health and Clinical Excellence (NICE). However, the rate of revision for the more popular stem, the Smith and Nephew uncemented SYNERGY™ femoral stem, is 1.07 (95% CI 0.88-1.27) in the NJREW and 0.94 (95% CI 0.65, 1.33) in the NJRR.

The rate of revision for the BMMH is relatively low until the third year of implantation where it appears that revisions for metal sensitivity in particular are higher than the rate for other total conventional hip replacements. According to the NJRR, the Cumulative Percent Revision for BMMH at 3 years is 3.1% compared to 2.8% for other total conventional hip implants. However the Cumulative Percent Revision for BMMH at 7 years is approximately 9% compared to 5% for other total conventional hip implants.

Other Information

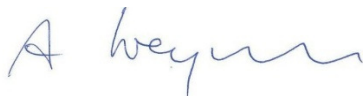
The manufacturer Smith & Nephew Orthopaedics Limited has revised the instructions for use for the BMMH. As a result of the changes to the IFU, the BMMH will no longer be available for primary surgery. Smith & Nephew will restrict indications to BHR resurfacing revision procedures only where a BIRMINGHAM HIP acetabular cup is well fixed and positioned, and where there are no signs of metal sensitivity. The femoral component is to be revised to an uncemented SYNERGY® stem.

Smith & Nephew is committed to distributing only products of the highest quality standards and to providing support to surgeons and patients who use those products.

If you or your patients would like further information about our actions, please visit <http://BMMH.Smith-Nephew.com>.

This letter is being sent following consultation with Medsafe.

Sincerely,



Andy Weymann, MD
Chief Medical Officer
Smith & Nephew