Smith & Nephew Inc
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IMPORTANT ADVISORY NOTICE
PERFORMANCE DATA - SMITH & NEPHEW MODULAR FEMORAL HEAD

Affected Product: Smith & Nephew Modular Femoral Head

March 19, 2015

Dear Dr.

Smith & Nephew wishes to share important information with you regarding the ongoing performance of the Smith & Nephew Modular Femoral Head (MFH), sold in the United States by Smith & Nephew Inc., Memphis TN ('Smith & Nephew'). It should be noted that this field action does not affect the BIRMINGHAM HIP° Resurfacing System.

Background
The MFH is no longer available for sale. The decision to phase out the product from the market was taken in mid-2014 due to a decline in sales of the product. There are no MFH remaining in the field and all products that had been formerly distributed are under the control of Smith & Nephew.

In late 2014, after the decision to phase out the product was made, Smith & Nephew became aware of the results of a clinical study relating to the performance of another of its hip implant products, which have been determined to be relevant to ongoing post-market surveillance of the MFH's performance.

Following a careful analysis of these data, Smith & Nephew has determined to inform customers of a potential decline in clinical performance in patients implanted with the MFH. Due to the potential risk identified with the product, this notice also is being sent to all customers who have used the MFH since its market launch in 2006.

This information is being reported to the FDA.

Context and reasons for this advisory notice
In late November of 2014, Smith & Nephew received a report of a study conducted in the UK analyzing the clinical results of a cohort of patients with sleeved BIRMINGHAM HIP° Modular Heads (BHMH) and uncemented SYNERGY° stems. The BHMH is a total hip arthroplasty system that uses a metal on metal (MoM) bearing. It has never been marketed in the U.S.

This study showed elevated levels of cobalt ions in the blood, a phenomenon believed to be linked to taper corrosion. Taper corrosion has been a focus of discussion in recent literature and has been known for some time to be associated with certain total hip arthroplasty systems.

This study indicated that there is a potential increased risk of fretting corrosion and accelerated release of metal debris and ions at the taper junctions of the Modular Taper Sleeve, with which the MFH is used, at its interfaces with the stem and with the head.

In parallel, in post-market surveillance, Smith & Nephew has noted a decline in the performance data of the BHMH in the national joint registries of Australia and England and Wales.

There are no equivalent data in the United States for the MFH, in its cleared indication for hemi-arthroplasty. Moreover, the study to which we refer above was a single center study featuring a small cohort of patients. However, out of an abundance of caution, Smith & Nephew concludes that the data from the study concerning BHMH are worthy of consideration with respect to the performance of the MFH in patients already implanted with the device.

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The MFH was indicated for use for hemi-arthroplasty of the hip, where the prosthetic metal femoral head articulates with the patient's native acetabular cartilage and thus was not a MoM construct. However, the MFH shares a number of similar design features with the BHMH. Specifically, it uses the Morse tapers with the same geometry and design as the BHMH.

It is for these reasons that, as a precautionary measure, Smith & Nephew is sharing this information with past MFH users.

We are recommending that physicians maintain their routine follow-up protocol for patients who have undergone hip arthroplasty. The need for any additional follow-up should be determined on a case-by-case basis following a detailed assessment of the patients' clinical circumstances.

Please fill in the acknowledgement of receipt enclosed in this notice and make sure this safety information is passed on to all those who need to be aware of it within your organization.

Affected Products
This notice is applicable to the following products:

Smith & Nephew Modular Femoral Head

74122538	Smith & Nephew Modular Femoral Head 38MM
74122540	Smith & Nephew Modular Femoral Head 40MM
74122542	Smith & Nephew Modular Femoral Head 42MM
74122544	Smith & Nephew Modular Femoral Head 44MM
74122546	Smith & Nephew Modular Femoral Head 46MM
74122548	Smith & Nephew Modular Femoral Head 48MM
74122550	Smith & Nephew Modular Femoral Head 50MM
74122552	Smith & Nephew Modular Femoral Head 52MM
74122554	Smith & Nephew Modular Femoral Head 54MM
74122556	Smith & Nephew Modular Femoral Head 56MM
74122558	Smith & Nephew Modular Femoral Head 58MM

12/14 Modular Taper Sleeve

74222100	12/14 Modular Taper Sleeve -4MM 12/14
74222200	12/14 Modular Taper Sleeve 0MM 12/14
74222300	12/14 Modular Taper Sleeve +4MM 12/14
74222400	12/14 Modular Taper Sleeve +8MM 12/14

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

If you have any questions, please contact Debbie Phillips at 901-399-5635 or by e-mail: fieldactions@smith-nephew.com.

Yours sincerely,

Andy Weymann, MD
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Contact Details of Subsidiary / Distributor

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☐ We confirm the receipt of this Advisory Notice

Institution: _____ Reference: R-2015-03

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