smith&nephew

[Recipients Address]

January 13, 2014

URGENT FIELD SAFETY NOTICE: Medical Device Field Safety Corrective Action

Reference: R-2014-12
Concerned Devices: BIRMINGHAM HIP® Resurfacing System (BHR)
FSCA action: Revision of the Instructions for Use (IFU)

Concerned Document: Instructions for Use Lit. No. 81036947 Rev E 11/14

Dear Dr.

This letter is to inform you of a field safety corrective action that Smith & Nephew is conducting to update the Instructions for Use (IFU) for the BIRMINGHAM® HIP Resurfacing (BHR®) System. The revisions to the IFU include an expansion of the warnings for certain population sub-groups, in line with available sources including registry data.

This field action has been reported to the relevant competent authorities.

Risks to Health	If a patient from the following population sub-groups is fitted with a BHR System, the patient is at greater risk of requiring a revision surgery earlier than expected: • Females • Males aged 65 or greater • Patients requiring an implant head size ≤48mm Patients who experience symptoms including pseudotumors, tissue masses, fluid collections, enlarges bursae, pain and swelling local buildup of excessive metal particles or metal hypersensitivity, may require revision surgery, with attendant risks and the potential for impaired function.
Actions to be taken by the user	1. Use the BIRMINGHAM HIP Resurfacing System only in accordance with the warning statement and indications for use in the IFU as set out below. 2. Complete the return slip and forward it to your national Smith & Nephew agency / distributor to confirm receipt of this Field Safety Notice. 3. Please make sure this safety information is passed on to all those who need to be aware of it within your organization. 4. Please maintain awareness on this notice and resulting action for an appropriate period

	to ensure effectiveness of the corrective action.
Adjustment in the Instructions for Use	In order to mitigate the performance observed in the patient sub-populations, the IFU has been updated to include a warning stating that based on literature reports together with the manufacturer's post-market data, the following were identified as risk factors for early revision: • Patients who are female; • Patients who: receive a smaller component size (≤48mm); • Male patients who are aged 65 or older; • Patients who have a diagnosis of avascular necrosis; and • Patients who have congenital dysplasia; The IFU has also been updated to note that, the more risk factors a patient has, the greater the risk of procedure failure requiring a revision of the hip.
Other Information	The concerned product is manufactured by Smith & Nephew Orthopaedics Ltd. Within the European Economic Area, Switzerland and Turkey the field action is coordinated by Smith & Nephew Orthopaedics AG (Switzerland).

Please see product details below:

Description	Catalog Numbers	Batch No
BHR Resurfacing Head	74121138, 74123140, 74121142, 74123144, 74121146, 74123148, 74121150, 74123152, 74121154, 74123156, 74121158, 74123160, 74123162	All Batches
BHR Acetabular Cup	74120144, 74120146, 74122146, 74122148, 74120148, 74120150, 74122050, 74122152, 74120152, 74120154, 74122154, 74122156, 74120156, 74120158, 74122158, 74122160, 74120160, 74120162, 74122162, 74122164, 74120164, 74120166, 74122166, 74122168	
BHR Dysplasia Cup	74120246, 74122248, 74120250, 74122252, 74120254, 74122256, 74120258, 74122260, 74120262, 74122264, 74120266	

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 have any questions please feel free to contact us under the following contact details:

Contact Details of Subsidiary / Distributor

Yours sincerely,

[redacted]
Chief Medical Officer
Advance Surgical Devices Division
Smith & Nephew

Return Slip

Please complete and return this feedback information before January 31, 2015 to the contact specified above to prevent repetitive enquiries.

☐ We confirm the receipt of this Field Safety Notice and confirm that we are aware of the change in the Instructions for Use.

Institution: _____ Reference: R-2014-12

Name: _____ Date / Signature: _____