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Urgent Field Safety Notice

Affected Product:	**BIRMINGHAM HIP® RESURFACING Extraction Kit (instrument)**
FSCA reference:	R-2016-17
FSCA action:	Product Recall
Date:	March 28, 2016
Details of affected product:	See below

Dear Doctor

This letter is to inform you of a voluntary Field Safety Corrective Action (FSCA) regarding the recall of a sterile single-use Extraction Kit instrument used with the BIRMINGHAM HIP® RESURFACING (BHR) System, manufactured by Smith & Nephew Orthopaedics Ltd., Leamington Spa, UK.

This field action does not affect the market availability of the BHR System.

Background

During a recent audit of the Smith & Nephew Orthopaedics Ltd. site by our Notified Body, it was noted that additional documentation was required to complete the necessary conformity assessment procedure for the Extraction Kit.

The kit, which can be used intraoperatively to remove the BHR acetabular cup during a revision procedure, is supplied in terminally sterilised packaging.

Reason for this FSCA

In consultation with the Notified Body, and considering the inadequacy of the documentation required to maintain the Extraction Kit on the market, Smith & Nephew is voluntarily recalling this device.

There have been only 2 complaints concerning the Extraction kits from 2009-2016 (a 0.003% failure rate) with no adverse health consequences for the patients. Furthermore, a health hazard evaluation conducted for this device has identified no known concerns around the safety of patients on whom the Extraction Kit would have been used.

Information relating to patient safety

The Extractions Kits are single-use instruments provided to remove the BHR acetabular cups during revision surgery. Other instruments, such as acetabular cup extractors, which are supplied by Smith & Nephew, can also be used for the same purpose as the kit.

Actions to be taken by the user

1. Immediately identify and quarantine any Extraction Kits currently held in stock.
2. Return all unused product to Smith & Nephew directly.

3. Complete the return slip and forward it to your national Smith & Nephew agency / distributor to confirm receipt of this Field Safety Notice.
4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization.
5. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Affected Products

This FSCA is only applicable to the following product:

Product Description	Catalogue Numbers	Batches/Lots
BIRMINGHAM HIP® RESURFACING Extraction Kit	900201	All Batches/Lots

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 contact us on the following phone number: +41 62 832 27 15 or by e-mail: fieldactions@smith-nephew.com.

Yours Sincerely,

Manoja Ranawake
Group Director Regulatory Affairs – Europe & Canada
Smith & Nephew Plc

Contact Details:

Smith & Nephew Advanced Surgical Devices UK & I
Fax: ***+ 44 (0)1480 423 201****, or*
Email: ***anica.alcala@smith-nephew.com*** *or* ***greg.williams@smith-nephew.com***

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Return Slip

Please complete and return this feedback information 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 recall of the BHR Extraction Kit.

Institution: _____ Reference: R-2016-17

Name: _____ Date/Signature: _____

Tel: _____