Smith & Nephew Inc
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Urgent Medical Device Market Removal

June 3, 2015

Affected Product:	**BIRMINGHAM HIP® RESURFACING (BHR) SYSTEM**
Reference:	3005975929-6/3/15-002-R (Internal Reference R-2015-08)
Action:	Device Removal and Labeling Changes Being Effected
Details of affected product:	See below

Dear Dr.

This letter is to inform you of a voluntary removal from the market of all lots of 46mm diameter and smaller femoral heads and corresponding acetabular cup components of the BIRMINGHAM HIP® Resurfacing (BHR) System due to observed revision rates which are higher than established benchmarks. Additionally, new information suggests that certain patient groups may also be at increased risk of early revision. These components are manufactured by Smith & Nephew Orthopaedics Ltd., Leamington Spa, United Kingdom and distributed in the US by Smith & Nephew, Inc.

Our records indicate that you/your facility received one of the following affected devices:

Product	Catalogue Numbers
BHR® Resurfacing Head	74121138, 74123140, 74121142, 74123144, 74121146
BHR Acetabular Cup	74120144, 74120146, 74122146, 74122148, 74120148, 74120150, 74122150, 74122152, 74120152, 74120154
BHR Dysplasia Cup	74120246, 74122248, 74120250, 74122252, 74120254

Reasons for this Voluntary Removal

As part of its post market surveillance (PMS) and post-marketing clinical follow-up, Smith & Nephew has conducted an analysis of recent National Joint Registry of England and Wales (NJREW) data, (the largest arthroplasty registry cohort of BHR patients). The NJREW data indicate that the BHR System continues to perform well in the male population requiring femoral head components 50mm in diameter and larger. However, the revision rates associated with the female gender and smaller femoral head sizes (46mm and smaller) and corresponding cup sizes regardless of gender, perform less well and exceed the current revision rate benchmark established by the UK National Institute for Health and Care Excellence (NICE).

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Information relating to patient safety

As a result of the increased risk of revision observed in these data, the following actions are being taken:

- BHR will now be contraindicated for all female patients. Pending regulatory approval, corresponding changes will be made to the Instructions for Use (IFU).
- Femoral head components sized 46mm in diameter and smaller, and their corresponding cup sizes, should no longer be used and are therefore being removed from the market.
- Pending regulatory approval, a warning will be added to the IFU stating that patients who, from plain radiograph pre-operative templating, appear to require 48mm femoral heads should not be considered as candidates for BHR implantation. Patients requiring a 48mm femoral head size are at a moderately elevated risk of requiring revision surgery earlier than expected. While Smith & Nephew concluded that the increased risk associated with this head size does not outweigh the potential benefit to the patient in specific circumstances of intra-operative downsizing from a pre-operatively template 50mm to a measurement of 48mm at the time of surgery, surgeons should use their best medical judgment to consider this information relative to the patient's overall medical history and prognosis in determining its appropriateness as a surgical treatment.

This market removal does not change current practices for patient follow-up care for this device: Smith & Nephew is not advising that female patients fitted with a BHR, or patients of either gender who are fitted with a BHR with a femoral head size of 48mm or less, should be proactively revised, unless this is required in the clinical judgment of each such patient's treating physician.

We are recommending that physicians maintain their routine follow-up protocol for patients who have undergone hip resurfacing arthroplasty. Patients who experience symptoms including limited mobility, pain, swelling, enlarged bursae, pseudotumors, tissue masses, fluid collections, or local build-up of excessive metal particles or metal hypersensitivity, may require revision surgery, with attendant risks and the potential for impaired function. The need for any additional follow-up, including the necessity for diagnostic imaging and blood tests, should be determined on a case-by-case basis following a detailed assessment of the patients' clinical circumstances.

Actions to be taken by the user

1. Discontinue all use of the affected catalog numbers immediately.
    a. NOTE: The Risk Management Department of your institution has also been contacted to inspect your inventory, locate any unused affected devices and quarantine them immediately for return to Smith & Nephew.
2. Ensure this safety information is passed on to all those who need to be aware of it within your organization.
3. Complete and return the attached form confirming your receipt of this Notification.

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If you or your patients would like to read more about our action, further information is available at www.smith-nephew.com/BHR.

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

If you have any questions regarding this Notification, please contact Garry Smith at 901-399-1970.

Yours sincerely,

A Weymann

Andy Weymann, MD
Chief Medical Officer
Advanced Surgical Devices Division
Smith & Nephew

cc: Local Distributor/Agent