

***Urgent – Medical Device Market Removal 1<sup>st</sup> Notification – Urgent  
3005975929-6/3/15-002-R  
Internal Reference R-2015-08***

***BIRMINGHAM HIP<sup>®</sup> RESURFACING (BHR) SYSTEM***

June 3, 2015

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<sup>®</sup> 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:

<b>Product</b>	<b>Catalogue Numbers</b>
BHR <sup>®</sup> 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

**Potential Risk with Use of the Product**

As part of its post market surveillance (PMS) and post-marketing clinical follow-up processes, 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).

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 may present with pain and limited mobility, potentially leading to a greater risk of revision surgery. Patients who experience symptoms including 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 for Hospital Representatives:**

1. Please inspect your inventory and locate any unused devices from the above listed product and batch numbers, and quarantine them immediately.
2. Complete the last two columns in the Inventory Return Certification Form on the following page, indicating the quantities that need to be returned, and include your phone and fax number in the spaces provided. If you do not have product to return, please place an "x" in the column "No product to return".
3. Please contact Smith & Nephew's Field Action Department via email at [REDACTED] or fax [REDACTED] to obtain a return authorization (RA) number.
4. Return any affected product to the address listed on the Inventory Return Certification Form. Please indicate the RA number on your return shipment.

**Actions for Smith & Nephew Inventory Specialists**

1. Carry out a physical count of all affected product in your territory and record this data on the Inventory Return Certification Form on the following page.
2. If you do not have product to return, please place an “x” in the column “No Product to Return”, and then fill in the Acknowledgement of Responsibility at the bottom of the form.
3. Fax or email a copy of the completed Inventory Return Certification Form to: [REDACTED] or email to: [REDACTED]
4. Return any affected product to the address listed on the Inventory Return Certification Form. Please indicate the RA number on your return shipment.

If you or your patients would like to read more about our action, further information is available at [REDACTED]

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 [REDACTED]

Yours sincerely,

[REDACTED]

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

cc: Local Distributor/Agent



## Inventory Return Certification Form

DATE: \_\_\_\_\_

**BIRMINGHAM HIP° RESURFACING (BHR) SYSTEM**  
**3005975929-6/3/15-002-R**  
**Internal Reference R-2015-08**

Product No	Description	Batch No	Individual Units to be Returned	No Product to Return
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			

### Actions for Smith & Nephew Affiliates/Distributors

1. Send this letter to your customers and ask them to return the recalled product.
2. Please inspect your inventory and locate any unused devices from the above listed product and batch numbers.
3. Complete the last two columns in the Inventory Return Certification Form above, indicating the quantities and lot numbers that need to be returned, and include your phone and fax number in the spaces provided. If you do not have product to return, please place an "x" in the column "No Product to Return".
4. Fax or email a copy of the completed Inventory Return Certification Form to: [REDACTED] or email to: [REDACTED]
5. You will receive an additional communication from Smith & Nephew in order to coordinate the replacement of your devices.

### For Hospital Representatives or Sales Offices with Consumed Products

Name (Print) \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_  
 Facility Name \_\_\_\_\_  
 Facility Address \_\_\_\_\_  
 Contact Phone \_\_\_\_\_ Fax \_\_\_\_\_  
 Smith & Nephew RA Number \_\_\_\_\_  
 Smith & Nephew Account No. \_\_\_\_\_

### For Smith & Nephew Affiliates/Distributors

Name (Print) \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_  
 Name of Organization \_\_\_\_\_  
 Contact Phone # \_\_\_\_\_ Fax \_\_\_\_\_

Return affected product to: Smith & Nephew | Attn: Global Field Actions | Global Distribution Center | 3303 East Holmes Road | Memphis, TN 38141-8101