Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

1-901-396-2121
1-800-821-5700
www.smith-nephew.com

Urgent Medical Device Recall Notice
R-2017-36

December 14, 2017

<Insert Address>

This letter is to inform you that Smith & Nephew, Inc. have initiated a field action to voluntarily remove a single lot of both the R3 0 Hole Acetabular Shell 50mm and R3 Constrained Acetabular Liner 52mm due to a labeling error. The affected devices were packaged and distributed with the wrong chartstik label.

Please see product details below:

Product Number	Description	Batch Number
71331850	R3 0 HOLE ACETABULAR SHELL 50MM	17CM22619
71339152	R3 CONSTRAINED ACET LINER 52MM	17CM08286

Shipment Date: April 22, 2017 through November 09, 2017

Potential Risk with Use of the Product

The use of the affected devices presents a negligible risk to patient health. The devices were manufactured in accordance with the relevant specification. In the event hip revision is warranted, the error could lead to confusion during revision surgery planning or surgeon annoyance.

Required Actions:

- Please follow the instructions on the attached Response Form.

Enclosure: Response Form

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PLEASE COMPLETE ALL ITEMS AND RETURN WITHIN 5 DAYS OF RECEIPT

Required Actions:

1. Please inspect your inventory and locate any unused devices from the listed product and batch numbers on the first page of this Field Action Notification, and quarantine them immediately.
    a. If you are a distributor, you must notify your customers of the field action and ensure that these actions are carried out.
2. If you have no product to return, please put an X in the appropriate location below.
3. If you have product to return, please list the batch numbers and quantities of each batch that you are returning in the appropriate boxes below.
4. Complete the remainders of the form sign and send to FieldActions@smith-nephew.com or fax to 901-566-7975.
   Please Note – even if you have no product to return, this form must be completed, signed and returned.
5. Once the form is received by Smith & Nephew, you will be sent a Return Authorization (RA) number.

If you have any questions or concerns regarding this recall please contact FieldActions@smith-nephew.com.

No Product to Be Returned ☐

Product Part Number	Batch Number (List Specific Batch #'s to be Returned)	Quantity of Units to be Returned

We hereby confirm that we are aware of this Medical Device Field Action and it has been communicated within our organization.

Printed Name (required): _____Title: _____

Signature (required):_____ Date (required):____/____/____

Email:_____ Telephone: (___) _____-_____

S&N Account Number: _____ RA Number (S&N use only):_____
Name of Organization(s) Covered by Response: _____

Return affected product to: Smith & Nephew | Attn: Global Field Actions | Building G, 1450 Brooks Rd. East |Memphis, TN 38116