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-2018-22

May 4, 2018

<Insert Address>

This letter is to inform you that Smith & Nephew Inc., have initiated a field action to voluntarily remove a single lot of a GENESIS II 13MM TIBIAL PUNCH due to a manufacturing error. The affected trial punches are dimensionally incorrect; the affected punches are 2mm smaller than specification.

Please see product details below:

Product Number	Description	Batch Number
71440408	GENESIS II 13MM TIBIAL PUNCH	15FM16181

Shipment Date: June 27, 2017 through December 11, 2017

Potential Risk of Use of the Product

In the event, the affected device is presented for use most likely the size discrepancy would be noticed through the routine presurgical inspection. However in the worst case, if the non-conforming device is used during preparation of the medullary canal with sclerotic bone, an insufficient fit of the tibial implant could occur.

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