--- URGENT ---
FIELD ACTION NOTICE for Recall

GII Tibial Punch

Please see product detail below / in the attached list

Product No.	Description	Batch No. / UDI No.	Shipment Dates
71440408	GENESIS II 13MM TIBIAL PUNCH	15FM16181	June 27, 2017 through December 11, 2017

FSCA no.: R-2018-22
5/4/2018

DESCRIPTION OF THE PROBLEM

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.

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.

REPORTING TO NATIONAL COMPETENT AUTHORITIES

The respective RA/QA personnel in Spain are to report this FSCA to its national competent authority. Please provide the Field Action Coordinator with copies of the respective reporting documents (initial and final report).

In, United American Emirate and Mexico, reportability of this Field Action is to be determined by the respective RA/QA peronnel. Please provide the Field Action Coordinator with copies of the respective reporting documents (initial and final report).

If any subsidiary/distributor has further distributed the mentioned devices to other countries, please indicate asap to the Field Action Coordinator (FAC), including the information whether you will notify the consignee and the respective competent authority yourself or if you require support of the FAC.

ACTIONS TO BE TAKEN BY THE DISTRIBUTOR

- Identify and quarantine the devices in your warehouse.
- Identify and inform all users, which have received affected products with the attached Field Safety Notice for Recall.
- Collect return slips of the Field Action Notice for Recall (to confirm awareness of all affected users) and forward them to the specified contact below. If acknowledgement is not provided by any of the affected users provide evidence of three attempts to notify these users.
- Complete the acknowledgment section on page 3 and return it to the specified contact below.
- Return collected devices as instructed below.

Please maintain awareness on this notice and resulting action until the Field Action is terminated to ensure effectiveness of the action. This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

DISTRIBUTION

Country	Product No.	Batch No. / UDI No.	Distribution Qty.
Mexico	71440408	15FM16181	1
Spain	71440408	15FM16181	3
United American Emirate	71440408	15FM16181	1

RETURN INSTRUCTIONS

Please contact Smith & Nephew's Global Field Actions Department via e-mail at FieldActions@smith-nephew.com or fax +41 62 832 06 07 to obtain a return authorization (RA) number.

Please write the **RA number on the outside of your shipping container and on the documents attached** for efficient and accurate processing of the returned devices. Devices returned under these procedures should not be mixed with other stock and **must be returned within 30 days from the date of the initial notification**.

Shipping address:
Smith & Nephew Memphis | Attn: Quality Hold and Field Action Returns Department | Building G | 1450 Brooks Road East, Memphis, TN 38116

CONTACT PERSON

For questions, please contact:
Garry Smith / Field Action Manager
P: 1 901 399 1970
F: 1 901 566 7975
fieldactions@smith-nephew.com

ACKNOWLEDGMENT SECTION

Please complete and return this feedback information by fax or e-mail to the contact specified above to prevent repetitive enquiries.

Product No.	Description	Batch No.	Quantity to be Returned	No Product to Return
				☐

■ _____ [Qty] customers in my territory have provided written acknowledgement of receipt of the FSN.

■ _____ [Qty] customers have not provided written feedback after three notification attempts.

■ Comments: _____

---------- *For those advised above to perform national competent authority (NCA) reporting:* ----------

■ NCA reporting has been performed as instructed above and copies of the respective reporting documents (initial and final report) are provided to the Field Action Coordinator. YES ☐ NO ☐

Rationale if NO: _____

Name/Title (please print): _____ Reference: R-2018-22

Date / City: Signature: