

[Recipients Address]

June 24, 2020

URGENT FIELD SAFETY NOTICE: Medical Device Field Safety Notice for Recall

Reference: R-2020-10

Concerned Devices: TRIGEN[◊] META-NAIL[◊] Tibial Nail 10mm X 39cm

Product No.	Description	Batch No.
71655139	TRIGEN META-NAIL Tibial Nail 10mm X 39cm	19BM13592A

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc. has initiated a field safety corrective action to voluntarily remove a single lot of TRIGEN META-NAIL TIBIAL NAIL 10MM x 39CM due a manufacturing error which resulted in the re-sterilization of the ultra-high-molecular-weight polyethylene (UHMWPE) sleeve. The sleeve, intended to provide resistance for screw backout, is not intended to be re-sterilized. Re-sterilization of the sleeve could potentially lead to the loss of system functionality.

Risks to Health	In the event the device is presented for use with a re-sterilized sleeve, the sleeve could break resulting in the potential for patient injury.
Actions to be taken by the user	<ol style="list-style-type: none">1. Locate and quarantine affected unused devices immediately.2. Return quarantined product to your national Smith+Nephew agency/distributor.3. Complete the return slip and e-mail or fax it to your national Smith+Nephew agency/distributor.4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization.5. Please maintain awareness on this notice and resulting action until the Field Safety Notice for Recall is terminated to ensure effectiveness of the action.

Smith+Nephew is committed to distribute only products of the highest quality standards and to provide any required support. We regret that this has occurred and any inconvenience it may cause or has caused you, your patients, or your staff.



If you have any questions please feel free to contact us under the following contact details:

Contact Details of Subsidiary / Distributor

Return Slip

Please complete and return this feedback information to the contact specified above to prevent repetitive enquires.

We hereby confirm the receipt of this Field Safety Notice for Recall.

In our facility we have _____ [Qty] concerned devices which we will return.

_____ [Qty] concerned devices have been discarded in our facility.

Institution: _____ Reference: R-2020-10

Name: _____ Date / Signature: _____