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[Recipients Address]

October 07, 2019

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

Reference: R-2019-18
Concerned Devices: LAG SCREW 3.2 GUIDE PIN SLEEVE

Product No.	Description	Batch No.
71674032	LAG SCREW 3.2 GUIDE PIN SLEEVE	18DM11613A
		18HM02575
		18HM13327A
		18HM20956A

Dear Customer:

This letter is to inform you that Smith+Nephew, Inc. has voluntarily initiated a recall for a group of LAG SCREW 3.2 GUIDE PIN SLEEVE due to a manufacturing error. The detent balls in the guide pin sleeve were not drilled to the correct depth, which will cause them to not fully compress. This failure could cause the Lag Screw Guide Pin Sleeve to not mate with Lag Screw Drill Sleeve.
This field action has been reported to the relevant competent authorities.

Risks to Health	In the event the affected product is presented for use and no replacement is available, in the worst-case scenario the guide would need to be manually held in place and the assistance of radiographic visualization may need to be employed to support proper alignment of the lag screw. This could potentially result in compromised alignment of the lag screw placement as well as compromised fixation and alignment of the fracture. Smith & Nephew has not received any reports of this worst-case scenario occurring.
Actions to be taken by the user	1. Locate and quarantine affected devices immediately. 2. Return quarantined product to your national Smith+Nephew agency/distributor. 3. Complete the return slip and 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 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-2019-18

Name: _____ Date / Signature: _____