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[Recipients Address]

July 22, 2020

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

Reference: R-2020-14
Concerned Devices: POLARSTEM Collar Reamer Guide

Product No.	Description	Batch No.
75102205	POLARSTEM COLLAR Reamer Guide	A56281, A57539, A58660, A60630, A61590, A62616 & A62689

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc. has initiated a field safety corrective action to voluntarily remove multiple lots of POLARSTEM COLLAR Reamer Guides due to a product design issue. The POLARSTEM Collar Reamer Guide was designed to be clipped onto the trial rasp and guide the calcar reamer when preparing the proximal femur for a collared POLARSTEM. The design included a smaller clearance at the connection site between the reamer guide hook and the calcar reamer. The smaller clearance increases the risk of interference with the calcar reamer when bone debris is present at the connection site.

Risks to Health	In the most likely event, the instrument functions and the procedure is completed as intended. In the worst case, breakage of the reamer guide could occur due to interference with the calcar reamer when bone debris is present at the connection site. Broken fragments could potentially remain in the wound, necessitating additional surgical intervention.
Actions to be taken by the user	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 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-2020-14

Name: _____ Date / Signature: _____