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Global Field Actions
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[Recipients Address]

December 16, 2019

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

Reference: R-2019-12
Concerned Devices: LEGION◇ AP FEMORAL CUTTING BLOCKS

Product No.	Description	Batch No.
71434409	LEGION AP Femoral Cutting Block Size 4	17LM05399, 17LM07852 & 17LM07852A
71434411	LEGION AP Femoral Cutting Block Size 6	17LM05397, 17LM05398 & 17LM07849
71434412	LEGION AP Femoral Cutting Block Size 7	17LM01746, 17LM05390, 17LM05394 & 17LM07851
71434413	LEGION AP Femoral Cutting Block Size 8	17LM08442

Dear Customer:

This letter is to inform you that Smith+Nephew Inc., has voluntarily initiated a recall to remove several lots of the LGN AP FEMORAL CUTTING BLOCKS due to a manufacturing error. Complaints were received indicating the spring plunger dis-assembled for four different size cutting blocks. The spring plunger hole was manufactured out of tolerance due to tool wear.

This field action has been reported to the relevant competent authorities.

Risks to Health	In the most likely event, the plunger will disassemble from the cutting block and another instrument is used to complete the procedure. In the worst case the disassembled plunger goes unnoticed in the wound throughout the remainder of the procedure.
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-2019-12

Name: _____ Date / Signature: _____