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[Recipients Address]

September 16, 2019

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

Reference: R-2019-19
Concerned Devices: RT-PLUS◇ MODULAR FEMORAL BLOCKS

Product No.	Description	Batch No.
75005579	RT-PLUS Mod Femoral Block Dist. 4/15 cem.	D1416197
75005585	RT-Plus Mod Femoral Block Dist. 8/15 cem	D1416198
75005587	RT-PLUS Mod Femoral Block Dist. 10/10 cem.	D1416199

Dear Customer:

This letter is to inform you that Smith+Nephew Orthopaedics AG has voluntarily initiated a recall to remove multiple lots of RT-PLUS MODULAR FEMORAL BLOCKS due to a manufacturing error. The pre-assembled screw to the femoral block might be either too long or too short. As a result, the block will not assemble to the femoral component as intended.

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

Risks to Health	In the event the blocks are presented for use, most likely the surgeon will notice the too long screw, open another block to find the appropriate screw and the procedure is completed as intended. In the rare event, an appropriate screw cannot be located the surgeon would resect more bone to upsize to a larger block potentially resulting in a surgical delay.
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-2019-19

Name: _____ Date / Signature: _____