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[Recipients Address]

July 31, 2019

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

Reference: R-2019-17
Concerned Devices: 4.5MM FULL RADIUS CONCAVE LONG BLADES

Product No.	Description	Batch No.
7205335	4.5MM FULL RADIUS CONCAVE CURVE LONG BLADE	50779861

Dear Customer:
cc: Chairman Medical Board and relevant Head of Departments

This letter is to inform you that Smith & Nephew, Inc. has voluntarily initiated a recall to remove a single lot of 4.5MM FULL RADIUS; CONCAVE CURVE LONG BLADES due to a manufacturing error. The Full Radius Concave blades were manufactured with an incorrect bend orientation, the affected blades are convex instead of concave.

Risks to Health	In the event the blades are presented for use, the surgeon would need to replace the blade to ensure appropriate access to the targeted anatomy. The device replacement could potentially result in a slight delay with negligible impact to the patient and or 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:

Smith & Nephew Pte Ltdd

Contact No: 6270 0552

Email: singapore.surgicalsale@smith-nephew.com

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-2019-17

Name: _____ Date / Signature: _____