

[Recipients Address]

March 4, 2019

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

Reference: R-2019-06

Concerned Devices: R3 Variable Angle Drill Guide

Product No.	Description	Batch No. / UDI No.
71364477	R3 VARIABLE ANGLE DRILL GUIDE	18FM16595

Dear Customer:

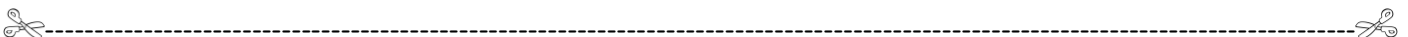
cc: Chairman Medical Board and relevant Head of Departments

This letter is to inform you that Smith & Nephew, Inc. has voluntarily initiated a recall to remove a single lot of R3 VARIABLE ANGLE DRILL GUIDES. The drill guide label incorrectly identifies the country of origin as China. The affected instruments were manufactured in Switzerland.

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

Risks to Health	The affected devices were manufactured within the relevant specification and will perform as intended. The use of or exposure to the device is not likely to cause additional adverse health consequences.
Actions to be taken by the user	<ol style="list-style-type: none">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 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

Smith & Nephew Pte. Ltd.

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-2019-06

Name: _____ Date / Signature: _____