

[Recipients Address]

October 4, 2018

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

Reference: R-2018-33

Concerned Devices: GII Distal Cutting Blocks

Product No.	Description	Batch No. / UDI No.
71441147	GII MIS DCF DISTAL CUT BLOCK	17GM05508
		17HM02186
		17HM14046
		17LM01753
		18BM18910
		18CM18091A
		18CM18091
		16KM03417

Dear Customer:

This letter is to inform you that Smith & Nephew Inc., have voluntarily initiated a recall to remove multiple lots of GII MIS DCF CUTTING BLOCKS due to a manufacturing error. The tab thickness on the GII Distal cutting block was manufactured too small and will not allow the instrument to lock with the GII Distal Alignment guide.

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

Risks to Health	In the event the affected device is presented for use, the cutting block will not lock and a backup device will be used to complete the procedure. However, in the worst case if a backup device is not available the cutting block would be used without the locking mechanism, potentially causing procedural problems.
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

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-2018-33

Name: _____ Date / Signature: _____