[Recipients Address]

Device Field Safety Notice for Recall

Reference: R-2018-09
Concerned Devices: Intertan 11.5MM x 18CM 125D

Product No.	Description	Batch No. / UDI No.
71675202	INTERTAN 11.5MM X 18CM 125D	16GT73730

Dear Customer:

This letter is to inform you that Smith & Nephew Inc., have initiated a voluntary field action to remove a single lot of INTERTAN 11.5MM X 18CM nails due to a laser mark labeling error. The 11.5mm nail was incorrectly laser marked as a 10mm nail.

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

Risks to Health	In the event the nail is selected based on the correct outer label, the device will perform as indicated. However, if the user notices the laser mark error; they may elect to replace the device. Replacing the affected device could potentially lead to a slight surgical delay.
Actions to be taken by the user	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-2018-09

Name: _____ Date / Signature: _____