Smith & Nephew Inc
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www.smith-nephew.com

We are smith&nephew

[Recipients Address]

August 15, 2015

URGENT FIELD SAFETY NOTICE: Medical Device Field Safety Corrective Action / Recall

Reference: R-2015-12
Concerned Devices: TRIGEN 8/7MM X 24CM HUMERAL NAIL

Product No.	Description	Batch No.
71770824	TRIGEN 8/7MM X 24CM HUMERAL NAIL	14GM18639

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action of single batch of TRIGEN 8/7MM X 24CM HUMERAL NAIL due to a manufacturing error. The packaged devices contained the incorrect ChartStik® labels. The Devices contained a ChartStik label for an OXINIUM Femoral Head.
This field action has been reported to the relevant competent authorities.

Risks to Health	In the event the device is presented for surgery; the devices will perform as indicated. Therefore the procedure is completed as intended. However, if the error is not recognized; the device traceability in the patient records could potentially be compromised.
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 Corrective Action 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.

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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.

In our facility we have _____ *[Qty]* concerned devices which we will return.

_____ *[Qty]* concerned devices have been implanted in our facility.

Institution: _____ Reference: R-2015-12

Name: _____ Date / Signature: _____