

[Recipients Address]

October 10, 2014

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

Reference: R-2014-15

Concerned Devices: TRIGEN® INTERTAN® Lag Screw Length Gauge

Product No.	Description	Batch No. / UDI No.
71674558	INTERTAN Lag Screw Length Gauge	14AM04290; 14FM20562; 14FM20562A; 14FM20563; 14FM20565; 14GM03897; 14GM03898; 14GM03899; 14GM07262; 14GM07264; 14GM07282

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action of several batches of the TRIGEN INTERTAN Lag Screw Length Gauge due to a manufacturing error. Specifically, the gauge lines were not laser etched in the correct position.

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

<b>Risks to Health</b>	In the event the surgeon does not use fluoroscopy and the gauges are used for the smaller size lag screws 70 mm through 85 mm, there is a low risk that the lag screw could potentially penetrate the femoral head and damage the cartilage on the acetabulum.
<b>Actions to be taken by the user</b>	<ol style="list-style-type: none"> <li>1. Locate and quarantine affected unused devices immediately.</li> <li>2. Return quarantined product to your national Smith &amp; Nephew agency/distributor.</li> <li>3. Complete the return slip and fax it to your national Smith &amp; Nephew agency/distributor.</li> <li>4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization.</li> <li>5. Please maintain awareness on this notice and resulting action until the Field Safety Corrective Action is terminated to ensure effectiveness of the action.</li> </ol>
<b>Other Information</b>	The concerned product is manufactured by Smith & Nephew, Inc. Within the European Economic Area, Switzerland and Turkey the field action is coordinated by Smith & Nephew Orthopaedics AG (Switzerland).

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.

In our facility we have \_\_\_\_\_ *(Qty)* concerned devices which we will return.

\_\_\_\_\_ *(Qty)* concerned devices have been discarded in our facility.

Institution: \_\_\_\_\_ Reference: R-2014-15

Name: \_\_\_\_\_ Date / Signature: \_\_\_\_\_