smith&nephew

[Recipients Address]

April 22, 2014

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

Reference: R-2014-04
Concerned Devices: Packaging of RT-PLUS® Femoral Component

Product No.	Description	Batch No.
75005494 / 24102	RT-PLUS Femoral Component right Size 2	All batches produced since 2007
75005495 / 24104	RT-PLUS Femoral Component right Size 4	
75005496 / 24106	RT-PLUS Femoral Component right Size 6	
75005497 / 24108	RT-PLUS Femoral Component right Size 8	
75005498 / 24110	RT-PLUS Femoral Component right Size 10	
75005499/ 24122	RT-PLUS Femoral Component left Size 2	
75005500/ 24124	RT-PLUS Femoral Component left Size 4	
75005501 / 24126	RT-PLUS Femoral Component left Size 6	
75005502 / 24128	RT-PLUS Femoral Component left Size 8	
75005503 / 24130	RT-PLUS Femoral Component left Size 10	
Custom-made Allergy RT-PLUS Femoral Components (Please refer to enclosed list of product and batch information.)		

Dear Dr.

This letter is to inform you that Smith & Nephew Orthopaedics AG has initiated a voluntary field action of all batches of the RT-PLUS Femoral Components manufactured since 2007. Under certain shipping conditions, the stem can potentially pierce the inner peel pouches, compromising the sterile barrier. In some instances, the cardboard box is also visibly damaged.
This field action has been reported to the relevant competent authorities.

Risks to Health	Damage to the inner peel pouch may not be visibly obvious to the user. This could lead to an unsterile device being used, increasing the risk of infection.
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.

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-2014-04

Name: _____ Date / Signature: _____