Smith & Nephew Orthopaedics AG
Schachenallee 29
5001 Aarau
Switzerland

T +41 (0)62 832 06 06
F +41 (0)62 832 06 07
www.smith-nephew.com

[Recipients Address]

January 31, 2012

URGENT FIELD SAFETY NOTICE: Medical Device Field Safety Corrective Action

Reference: R1109
Concerned Devices: SpatialFrame.com Software Version 4.1.1

Description	Catalog Number	Version
SpatialFrame.com Software	71070401	4.1.1

Dear Dr.

This letter is to inform you of a field action regarding a specific version of the SpatialFrame.com Software. This field action has been reported to the relevant competent authorities.

Product	SpatialFrame.com Software Version 4.1.1
Reason for this Field Action	It was determined that under certain rare conditions the software could produce a strut adjustment schedule with a duration longer than anticipated. Strut adjustment schedules which were printed after selecting “Save As”, selecting the “Prescription” tab and selecting “Printable PDF Version” between March 19, 2011 and August 14, 2011 may be affected. Initial and Final Strut values are correct, only the duration of the strut adjustment schedule can be affected. The issue has been corrected.
Risks to Health	In the worst case, if the extended strut adjustment schedule goes unnoticed, the bone may consolidate sooner than anticipated and may require additional surgery.
Actions to be taken by the user	1. Review unfinished procedures based on schedules prepared with the SpatialFrame.com Software. If there appear to be unexpectedly long strut adjustment schedules, open and reprint the schedules.

Smith & Nephew Orthopaedics AG
Schachenallee 29
5001 Aarau
Switzerland

T +41 (0)62 832 06 06
F +41 (0)62 832 06 07
www.smith-nephew.com

	2. Acknowledge receipt of the notification you received by e-mail, or complete the below return slip and fax it to your national Smith & Nephew agency/distributor. 3. Please make sure this safety information is passed on to all those who need to be aware of it within your organization. 4. Please maintain awareness on this notice and resulting action until the Field Safety Corrective Action is terminated to ensure effectiveness of the action.
Other Information	In Europe, this field action of Smith & Nephew, Inc. (Memphis, US) is coordinated by Smith & Nephew Orthopaedics AG.

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 phone number: +41 62 832 07 43 or by e-mail: european.complaint@smith-nephew.com.

Contact Details of Subsidiary / Distributor

Return Slip

Please complete and return this feedback information to the contact specified above to prevent repetitive enquiries.

☐ We confirm the receipt of this Field Safety Notice

Institution: _____ Reference: R1109

Name: _____ Date / Signature: _____