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]

April 08, 2013

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

Reference: R-2013-04
Concerned Devices: Four lots of BIOSURE™ Driver and one lot of BIOSURE™ Ratchet Driver

Product No.	Description	Batch No.			
72201887	BIOSURE™ Driver	50399964	50404491	50407175	50409038
72201888	BIOSURE™ Ratchet Driver	50410950			

Dear Dr.

This letter is to inform you of a field action regarding specific batches of the above mentioned products. This field action has been reported to the relevant competent authorities.

Product	**Four lots of BIOSURE™ Driver and one lot of BIOSURE™ Ratchet Driver (see article and lot information above)**
Reason for this Field Action	Smith & Nephew, Inc. is initiating a voluntary Field Safety Corrective Action of the above product numbers and batches to remove all potentially affected devices from the market. We have become aware that five lots of the device were manufactured larger than the specified print dimension and could result in an improper fit with the screw.
Risks to Health	In the most likely scenario, during an Anterior or Posterior Cruciate Ligament repair, as the surgeon is using the driver to insert the screw into the bone, the screw becomes stuck on the driver and the two components cannot be removed from one another. In the worst case scenario, the distal tip of the screw cracks during insertion and the surgeon is able to retrieve all the pieces of the broken screw. In both scenarios, a backup device from another lot is available and the surgery is completed successfully. There is no additional patient follow-up required.
Actions to be	1. Locate and quarantine affected devices immediately.

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

taken by the user	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.
Other Information	The concerned product is manufactured by Smith & Nephew, Inc. Within the European Economic Area and Switzerland the field action 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 28 79 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 enquires.

☐ We confirm the receipt of this Field Safety Notice.

☐ In our facility we have _____ concerned devices which we will return.

☐ _____ concerned devices have been discarded in our facility.

Institution: _____ Reference: R-2013-04

Name: _____ Date / Signature: _____