smith&nephew

[Recipients Address]

April 30, 2015

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

Reference: R-2015-04
Concerned Devices: ULTRA FAST-FIX® Knot Pusher/Suture Cutter, Straight

Product No.	Description	Batch No. / UDI No.
72201537	ULTRA FAST-FIX Knot Pusher/Suture Cutter, Straight	All batches manufactured from April 2010 to April 2014 which have corresponding expiration dates of April 2015 to April 2019

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action of all batches of ULTRA FAST-FIX Knot Pusher Suture Cutters manufactured from April 2010 to April 2014 (which have corresponding expiration dates of April 2015 to April 2019) due a packaging defect. A Smith & Nephew internal investigation found the packaging material and design to be insufficient to prevent the ULTRA FAST-FIX Knot Pusher Suture Cutter's sharp edges from potentially puncturing the pouch and rendering the device unsterile.
To date there have been no complaints or adverse effects associated with this issue.
This field action has been reported to the relevant competent authorities.

Risks to Health	Smith & Nephew conducted a Health Hazard Evaluation which found the most likely scenario to be that damage to the sterile barrier packaging (pouch) will be visible to the user prior to use and the device discarded. However, the worst case scenario is that defects in the packaging are not detected and an unsterile device is used during an arthroscopic repair. This could potentially lead to a post-operative 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 contact Bill Aubrey on the following phone number +44 7983 598299 or by e-mail: fieldactions@smith-nephew.com.

Please complete this declaration and return to Smith & Nephew Advanced Surgical Devices by fax: ***01480 423 201****, or email:* ***greg.williams@smith-nephew.com*** *or* ***anica.alcala@smith-nephew.com*** *or* ***UK.ServiceOperations@smith-nephew.com***

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 used in our facility.

Institution: _____ Reference: R-2015-04

Name: _____ Date / Signature: _____