

[Recipients Address]

June 15, 2016

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

Reference: R-2016-27

Concerned Devices: TWINFIX QUICK-T KNOT PUSHER SUTURE CUTTERS

Product No.	Description	Batch No.
7209417	TWINFIX QUICK-T KNOT PUSHER SUTURE CUTTERS	50412843 50477278 50527184

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action of all TWINFIX QUICK-T KNOT PUSHER SUTURE CUTTER devices due to a packaging design issue. Based on internal testing, Smith & Nephew has identified that this device could be subject to breaches of its sterile packaging. Smith & Nephew has received no customer complaints indicating a packaging breach or a post-operative infection.

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

Risks to Health	In the event the device is presented for use and a breach in the sterile barrier is not noticed, a non-sterile device could enter the surgical field.
Actions to be taken by the user	<ol style="list-style-type: none">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 hereby confirm that we are aware of this Field Safety Notice concerning the TWINFIX QUICK-T KNOT PUSHES SUTURE CUTTERS. The Field Safety Notice was communicated within our organisation.

Please mark accordingly:

☐ In our facility we do not have any of the affected product in stock
or

☐ We will return the following products:

Product No.	Description	Batch No.	Quantity to be Returned
7209417	TWINFIX QUICK-T KNOT PUSHES SUTURE CUTTERS	50412843	
7209417	TWINFIX QUICK-T KNOT PUSHES SUTURE CUTTERS	50477278	
7209417	TWINFIX QUICK-T KNOT PUSHES SUTURE CUTTERS	50527184	

Institution: _____ Reference: R-2016-27

Name: _____ Date / Signature: _____