

[Recipients Address]

August 28, 2020

URGENT FIELD SAFETY NOTICE: Medical Device Field Safety Notice for Recall

Reference: R-2020-12 (R2)

Concerned Devices: T-FIX[®] RCG Sterile Drill

Product No.	Description	Batch No.
014771	T-FIX RCG Sterile Drill	2049408 (new)
014771	T-FIX RCG Sterile Drill	2042492

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc. has initiated a field safety corrective action to voluntarily remove a further lot of T-FIX RCG STERILE DRILL (1 DRILL & 2SL) due to a packaging configuration error. The T-Fix sterile package contained only one sleeve instead of two.

Risks to Health	In the most likely event, the failure mode is identified prior to use and a backup device is used to complete the surgical procedure. However, in the worst case there is no backup available and the device with one sleeve is used in a procedure, which could lead to a prolonged, more extensive surgery, potentially leading to longer exposure to anesthesia and the possible conversion from an arthroscopic to open procedure. We have received no complaints for the worst case.
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 e-mail 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 Notice for Recall 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 the receipt of this Field Safety Notice for Recall.

In our facility we have _____ [Qty] concerned devices which we will return.

_____ [Qty] concerned devices have been discarded in our facility.

Institution: _____ Reference: R-2020-12 (R2)

Name: _____ Date / Signature: _____