

## Urgent Field Safety Notice

<b>Affected Product:</b>	<b>TC-PLUS<sup>®</sup> Advanced Femoral Trials</b>
<b>FSCA reference:</b>	R-2018-17
<b>Date:</b>	May 23 <sup>rd</sup> 2018
<b>FSCA action:</b>	Recall
<b>Details of affected product:</b>	See below

Dear Dr.

This letter is to inform you that Smith & Nephew Orthopaedics AG has initiated a voluntary Field Safety Corrective Action (FSCA) to recall the femoral trials of the TC-PLUS Advanced Knee system.

Following review of available data from a small number of complaints concerning this device, we identified that where a TC-PLUS Advanced Trial is used for a CR (Cruciate Retaining) Implant, wear can occur if drilling through the femoral holes is not done perpendicularly. Wear could lead to the formation of stainless steel debris.

A very small number of these devices has been released on the market and although Smith & Nephew has not received any complaints suggesting patients were adversely affected by this issue, we have taken the decision to issue this voluntary recall of TC-PLUS Advanced Femoral Trials, as there is a hypothetical risk that some debris could go unnoticed intraoperatively and remain in the joint.

### **Background**

The TC-PLUS Advanced Femoral Trials are used during Knee Replacement Surgery and are part of the standard instrumentation. A small number of these devices has been released on the market.

### **Context and reasons for this FSCA**

This FSN has been issued to recall the TC-PLUS Advanced Femoral Trials as we identified that when the device is used with a CR (Cruciate Retaining) Implant, drilling could result in the formation of stainless steel debris.

### **Information relating to patient safety**

In the small number of instances where Smith & Nephew Orthopaedics AG was made aware this issue has occurred, debris was removed through a thorough lavage of the surgical site, requiring an extension of the surgery by approximately 15 minutes. No further impacts on the patients were noted.

There is a hypothetical risk that in some cases, debris not visible intraoperatively could remain in situ. There have been no reports of such event made to Smith & Nephew. We consider that in this situation, which would be the worst-case scenario for this issue, any subsequent issues would be detected through regular

post-surgical patient follow-up. We are therefore not recommending that any particular patient follow-up measures be done for patients on which this device was used.

### **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. Ensure this safety information is passed on to all those who need to be aware of it within your organization.
5. Maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

### **Affected Products**

This FSCA is applicable to the following products:

<b>Product No.</b>	<b>Description</b>	<b>Batch No. / UDI No.</b>
75100715	TC ADV PRIM FEMORAL TRIAL RIGHT SIZE 2	A59271
75100716	TC ADV PRIM FEMORAL TRIAL RIGHT SZ 4/4S	A59272
75100717	TC ADV PRIM FEMORAL TRIAL RIGHT SZ 6/6S	A59273
75100718	TC ADV PRIM FEMORAL TRIAL RIGHT SZ 8/8S	A59274
75100719	TC ADV PRIM FEMORAL TRIAL RIGHT SIZE 10	A59275
75100720	TC ADV PRIM FEMORAL TRIAL RIGHT SIZE 12	A59276
75100722	TC ADV PRIM FEMORAL TRIAL LEFT SIZE 2	A59277
75100723	TC ADV PRIM FEMORAL TRIAL LEFT SIZE 4/4S	A59278
75100724	TC ADV PRIM FEMORAL TRIAL LEFT SIZE 6/6S	A59279
75100725	TC ADV PRIM FEMORAL TRIAL LEFT SIZE 8/8S	A59280
75100726	TC ADV PRIM FEMORAL TRIAL LEFT SIZE 10	A59281
75100727	TC ADV PRIM FEMORAL TRIAL LEFT SIZE 12	A59282

Smith & Nephew is committed to distributing only products of the highest quality standards and to providing support to customers who use those products.

If you have any questions, please contact Christoph Fankhauser, Director Global Marketing Knees, on the following phone number: +41 79 544 95 71 or by e-mail: [christoph.fankhauser@smith-nephew.com](mailto:christoph.fankhauser@smith-nephew.com).

Yours sincerely,



**Andy Weymann, MD**  
Chief Medical Officer

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 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-2018-17

Name : \_\_\_\_\_ Date / Signature: \_\_\_\_\_