

27 June 2016

URGENT FIELD SAFETY NOTICE: 415836
Trochanteric Fixation Nail Advanced (TFNA) guide sleeve, yellow

Please distribute this information to appropriate personnel at your facility.

Dear Sir/Madam,

Part Description, Part and Lot Numbers

Part Description	Part Number	Lot Numbers
Guide Sleeve, yellow	03.037.017	See Attachment 1

Synthes GmbH is initiating a Field Safety Notice of the above mentioned Part and Lot Numbers of the Trochanteric Fixation Nail Advanced (TFNA) guide sleeve, yellow. These devices are specific to the Trochanteric Fixation Nail Advanced (TFNA) system. The TFNA Proximal Femoral Nailing System is for the treatment of intramedullary fixation of proximal femoral fractures.

Our records indicate that you may have inventory that is impacted by this recall or have been using affected product(s) from a loan set.

Reason for the Field Safety Notice

The affected lots of the Guide Sleeves (Part # 03.037.017) may have been manufactured with a slightly larger than specified outer diameter which could prevent the sleeve from going through the TFNA aiming arm properly. **Note: Only guide sleeves that do not pass functional testing will be removed from the field following the evaluation of your inventory for functionality of the aiming arms and guide sleeve described in attachment 2.**

Potential Patient Impact:

In the event that Guide Sleeve does not fit through the TFNA aiming arm properly, a surgical delay may occur.

Customer immediate actions:

1. Immediately review your inventory to identify and quarantine all affected products listed above in a manner that ensures the affected products will not be used.
2. Conduct functional testing. Refer to attachment 2 for instructions on how to perform the functional test. Please ensure every aiming arm is tested with every

guide sleeve within your control and, upon completion, only return the device if the product does not pass.

3. Review, complete, sign and return the attached reply form on page 3 of this letter to your local DePuy Synthes sales organization in accordance with the directions on the form within 5 business days of receipt of this notification.
4. Return any affected product as soon as possible, but within 30 business days. A credit note will be issued for the returned items.
5. Forward this notice to anyone in your facility that needs to be informed.
6. If any of the affected products has been forwarded to another facility, contact that facility to arrange for a functional test to be performed and for product that does not pass the functional testing to be returned.
7. Maintain awareness of this notice until all products listed below have been returned to DePuy Synthes.
8. Keep a copy of this notice.

We apologize for any inconvenience that this product recall may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Synthes sales consultant.

Thank you for your attention and cooperation.

Yours Sincerely,



Lee, Ching Hwee
Associate Manager, Regulatory Affairs

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Guide Sleeve, yellow	03.037.017	See Attachment 1

Please check (√) accordingly:

- We acknowledge receipt of this information, but do not have any identified product in stock; returned quantity is zero.
- We located the affected product in stock and our instrument has **passed** functional testing; Quantity of devices that passed functional testing is documented below.

Product Code	(Lot Number)	QUANTITY OF DEVICES THAT PASSED FUNCTIONAL TESTING (Number in "Eaches")

- We have located the affected product in stock and our product did not pass functional testing; returned quantity is documented below.

Product Code	(Lot Number)	RETURNED Quantity (Number in "Eaches")

Please sign, date and stamp below. Your signature provides confirmation that you have received and understood this notification.

Customer Name

Title

Signature & Date



Stamp (*Stamp shall bear facility name*)

Please complete this Verification Section and return to your Depuy Synthes representative or fax it to +65 6720 0750 within **(5) five business days** of receipt of the Field Safety Notice.

Attachment 1. Part Description, Part- and Lot Numbers subject to this field safety notice

Part Description	Part Number	Lot Numbers			
Guide Sleeve, yellow	03.037.017	9066399	9409791	9542998	9704087
		9066435	9409792	9554329	9718920
		9301183	9422885	9554330	9734863
		9301184	9428332	9569617	9734868
		9327510	9439269	9569618	9734876
		9339162	9469298	9574931	9763550
		9340629	9485532	9590744	9764854
		9347641	9485534	9590747	9768880
		9347642	9494322	9604306	9768881
		9351396	9501935	9604307	9768882
		9351397	9502768	9620447	9768883
		9356941	9505477	9641077	9768884
		9359339	9519303	9641078	9768886
		9359540	9519308	9651850	
		9371095	9533341	9661608	
		9409790	9542486	9661610	

Attachment 2: Functional Test for Guide Sleeve

<p>Step 1: Hold the TFNA Aiming Arm as shown in picture.</p> <p>Step 2: Insert the Guide Sleeve into the aiming arm as shown in picture.</p> <p>Note the correct orientation of the flat surface on the Guide Sleeve.</p>	
<p>Step 3: Hold the Guide Sleeve at the upper end and slide it through the hole in the Aiming Arm until stop.</p>	
<p>Step 4: Document the result (pass / not passed)</p>	<p>1) Passed Guide Sleeve slides through aiming arm.</p> <p>2) Not passed Guide Sleeve does not fit through aiming arm.</p>