Synthes GmbH
Luzernstrasse 21
4528 Zuchwil
Switzerland

Tel. +41 32 720 40 60
Fax +41 32 720 40 61
http://www.depuysynthes.com/

DePuy Synthes
COMPANIES OF Johnson & Johnson

To all customers using Synthes Helical Blades for Trochanteric Fixation Nail (TFN), Titanium Alloy

PLEASE DISTRIBUTE THIS INFORMATION TO APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT THAT IS THE SUBJECT OF THIS NOTICE

27 September 2013

Urgent: Field Safety Notification
Helical Blade for TFN, Titanium Alloy

Part Description	Part Number	Lot Number
Helical Blade for TFN, Titanium Alloy	456.300 - 456.310 & 456.650	5615864 through 7423581
	456.300S - 456.310S & 456.650S	

Dear Sir/Madam:

Synthes is initiating a Field Safety Notification related to the Helical Blade for TFN, Titanium Alloy.

Through internal investigation Synthes identified the potential for non-conforming helical blades to be distributed to the field. Helical Blades, which are part of the TFN system, may have one or more dimensional features out of tolerance. The potential features that may be out of tolerance include the inner diameter of the Helical Blade where the guide wire passes and the dimensional features that allow for the Helical Blade and Insertion Instrument to mate. These non-conformances are not immediately apparent and the following is a summary of the potential outcomes that could occur if a patient is exposed to non-conforming product.

Potential hazard:
If during use a surgeon selects a Helical Blade with an inner diameter that is smaller than specified the Helical Blade will not pass over the 3.2 mm guide wire; resistance will be encountered. If resistance is encountered the surgeon should not try and force the Helical Blade over the guide wire and into the blade guide sleeve. Forcing the Helical Blade over the guide wire could result in the wire advancing beyond the proximal cortex of the head of the femur and into the acetabulum. Soft tissue damage and joint irritation may result if this scenario were to occur. In the presence of guide wire joint penetration unanticipated pain experienced by the patient may also result. If resistance is encountered the surgeon should remove the Helical Blade.

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***From this point the surgeon may proceed with the procedure following one of these options.

1. Prior to insertion and after the Helical Blade is in the sterile field a sterile operative team member may use a guide wire and attempt to pass it through the Helical Blade to ensure that the device will function as intended.

2. During insertion (following the standard procedure in the TFN technique guide using a guide wire), if resistance is encountered, you may remove the guide wire and reinsert the Helical Blade. Per the explained in TFN technique guide the guide wire is not required for Helical Blade insertion.

3. During insertion, if resistance is encountered, the guide wire may be left in place and the surgeon can remove the Helical Blade in order to exchange it with an additionally available Helical Blade.

Note: If resistance is encountered during the secondary insertion please remove the guide wire to ensure that it is not bent. A bent guide wire will not allow a Helical Blade to pass.

If during use a surgeon selects a Helical Blade with non-conforming features that impact the Helical Blade's ability to mate with the insertion instrument there is the potential for a surgical delay to result. These non-conforming features will not likely be identified until the operative personnel attempt to assemble the Helical Blade with the insertion instrument. If these features are out of specification it is likely that assembly will not be possible or that the assembled implant and insertion device connection will not be secure. If this scenario occurs the surgeon should select an alternatively available Helical Blade. The presence of this non-conformance may result in a surgical delay while an additional implant is procured.

Finally, adherence to the TFN technique guide and judicious use of intraoperative X-Ray are also recommended to ensure the best operative outcome for all patients.

Please take the following actions:

- Review the three (3) options provided above to clarify and mitigate the potential risk.
- If you **DO identify product that encounters resistance sliding over the guide wire or will not mate with the insertion instrument during surgery**, please take the following steps:
  - Please prepare the list of affected part and lot numbers and contact your local Synthes Trauma sales consultant.
  - Complete the Verification Section at the end of this letter by checking the appropriate box indicating affected product has been located. Also, please indicate the number of devices found. Please include your name, title, telephone number and signature in the spaces provided.
- Review, complete, sign and return the attached reply form to your local Synthes sales organisation in accordance with the directions on the form.
- Forward this Field Safety Notification to anyone in your facility that needs to be informed.
- Maintain awareness of this Field Safety Notification & maintain a copy.

The applicable regulatory agencies are being notified. Synthes GmbH is voluntarily taking this action.

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If you have any questions, please contact your Synthes Trauma consultant.

Thank you for your attention to this issue.

Sincerely,

Synthes GmbH

Claudia Allemann
Field Action Manager

Markus Wien
Director Quality Assurance Operations

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FIELD SAFETY NOTIFICATION FSN2013033

Synthes Helical Blade for TFN, Titanium Alloy

Verification Section

Part Description	Part Number	Lot Number
Helical Blade for TFN, Titanium Alloy	456.300 - 456.310 & 456.650	5615864 through 7423581
	456.300S - 456.310S & 456.650S	

☐ We have identified product with nonconforming features; returned quantity is documented below.

☐ We acknowledge receipt of this information but do not have the Helical Blade for TFN, Titanium Alloy

RETURNED DEVICES (including quantity) and/or COMMENTS:

_____

_____

_____

_____

_____

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____