

STRYKER Trauma GmbH (Trauma & Extremities Division)

Generic: URGENT FIELD SAFETY NOTICE: PFA 1821294 Version 1

Field Safety Corrective Action

Affected Product:

T2 Ankle Arthrodesis Nails / Proximal Humeral Nails

15.06.2018

Legal Manufacturer: Stryker Trauma GmbH, Professor-Küntscher-Straße 1-5
24232 Schönkirchen, GERMANY

Recipients: Health Care Professionals, Operators of Medical Devices, Distributors

Type of Action: Field Safety Corrective Action

FSCA Identifier: PFA 1821294

Identification of the Affected Product(s):

Description: T2 Ankle Arthrodesis Nails / Proximal Humeral Nails

Brand	Product Nr.	Product Description
T2	18181115S	Ankle Arthrodesis Nail, left T2 Ankle Ø11x150mm
T2	18191020S	Ankle Arthrodesis Nail, right T2 Ankle Ø10x200mm
T2	18191220S	Ankle Arthrodesis Nail, right T2 Ankle Ø12x200mm
T2	18321045S	Proximal Humeral Nail, cannulated, RIGHT T2 Prox. Hum. Ø8 x 150 mm
T2	18322824S	Proximal Humeral Nail Long, LEFT T2 Prox. Hum. Ø8x240 mm
T2	18322828S	Proximal Humeral Nail Long, LEFT T2 Prox. Hum. Ø8x280 mm
T2	18323826S	Proximal Humeral Nail Long, RIGHT T2 Prox. Hum. Ø8x260 mm

Lot #s: K0ACFED, K0B9038, K0B906C, K0BF6C6, K0BF6D2, K0CAEC4, K0CC741, K0CC742, K0CC743, K0CC744

Only specific lot numbers are affected!

For details please see attachment: **PFA 1821294 affected products_rev1**

Dear Customer,

The purpose of this notification is to advise you that Stryker Trauma GmbH (Trauma & Extremities Division) is conducting a voluntary recall for specific lots of the T2 Nailing System. These products were distributed to customers from 11.05.2018 – 18.05.2018. Attachment 1 includes a list of all products affected by this FSCA, and it may include products your account did not receive. Please refer above for Part and Lot Numbers that were identified as shipped to distributors and end users.

Reason for Voluntary Recall

Stryker Corporation investigated a nonconformance with a supplier. The manufacturer has determined that products have left the factory where the quality of the sealed seam of the sterile packaging did not correspond to the specification. During the sealing process, a Tyvek lid stuck to the sealing plate. The subsequently packaged products were sealed with the lid sticking to the seal plate.

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Though testing of the sealed seam confirmed that the integrity of the sterile barrier is intact, integrity of the sterile barrier cannot be assured over 5 years shelf life.

Risk to Health

Integrity of the sterile barrier cannot be assured over 5 years shelf life. Therefore, a risk of infection due to the use of an improperly sealed device cannot be excluded.

Mitigating Factors

None

Recommendations for patients already treated with an affected device

There are no additional follow-ups recommended for patients with an implanted product, this is based upon the fact that no additional harms have been identified. It is recommended that the surgeons continue to evaluate their patients through routine follow-ups. This is not a recall to explant the nail.

Potential Alternative Products

The removal of the products is lot specific. Not affected lots can be ordered and are available.

Actions to be taken by the Customer/User:

Our records indicate that you may have received one or more of the subject devices. It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication. We therefore request that you read this notice carefully and complete the following actions.

1. Inform individuals within your organization who need to be aware of this device recall.
2. Immediately check all stock areas and/or operating room storage to determine if any devices from the affected product list are at your facility. **Response is required, even you may not have any physical inventory on site anymore.**
3. Quarantine and discontinue use of the recalled devices.
4. Maintain awareness of this notice internally until all required actions have been completed within your facility
5. Inform Stryker if any of the subject devices have been distributed to other organisations.
 - a) Please provide contact details so that Stryker can inform the recipients appropriately.
 - b) If you are a Distributor, note that you are responsible for notifying your affected customers.
6. Please inform Stryker of any adverse events concerning the use of the subject devices?
7. Please comply with any local regulations concerning the notification of adverse events to your National or local Competent Authorities.
8. Complete the attached customer response form (acknowledgement form). It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore, please complete even if you no longer have any of the subject devices in your physical inventory.
9. Return the completed form to your nominated Stryker Representative (indicated below) for this Action.

We request that you **respond to this notice within 7 calendar days** from the date of receipt. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions. We appreciate

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your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly

Name:

Position:

Email

Telephone

Fax

Yours Sincerely,

Signature

STRYKER Trauma GmbH (Trauma & Extremities Division)

ACKNOWLEDGMENT FORM (FSCA)

FSCA Identifier: Product Field Action PFA 1821294

Type of Action: Field Safety Corrective Action

Legal Manufacturer Stryker Trauma GmbH, Professor-Küntschers-Straße 1-5
24232 Schönkirchen, GERMANY

Product name:

Catalogue #

Lot #

I acknowledge receipt of the Field Safety Notice for PFA 1821294 and can confirm that:

We have not located any of these devices in our inventory: <i>(please delete if not applicable)</i>				
We have located the following devices:				
Product description	Product Reference	Lot Number	Qty	Qty Quarantined
We have further distributed subject devices to the following organisations:				
Facility Name				
Facility Address				
Form completed by:				

Contact Name _____ Contact Facility _____
Contact address _____ Contact Position _____
_____ Contact Tel No _____
_____ Contact Fax No _____
_____ Contact e-mail _____

PLEASE COMPLETE AND FAX THIS FORM TO X
OR EMAIL TO X.