STRYKER Trauma GmbH (Trauma & Extremities Division)

Generic: URGENT FIELD SAFETY NOTICE: PFAA_1774317 Version 1

Field Safety Corrective Action
Affected Product:
T2 Ankle Arthrodesis / Femur / Tibia / Recon / Greater Trochanter Nails

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23.04.2018

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: PFAA_1774317

Identification of the Affected Product(s):

Description: T2 Arthrodesis / Femur / Tibia / Recon / Greater Trochanter Nails

Brand	Product No	Product Description
T2	18181130S	Ankle Arthrodesis Nail, left T2 Ankle Ø11x300mm
T2	18191030S	Ankle Arthrodesis Nail, right T2 Ankle Ø10x300mm
T2	18191130S	Ankle Arthrodesis Nail, right T2 Ankle Ø11x300mm
T2	18220933S	Tibial Nail, Standard T2 Tibia Ø9x330 mm
T2	18221231S	Tibial Nail, Standard T2 Tibia Ø12x315 mm
T2	18251032S	Femoral Nail, A/R T2 Femur Ø10x320 mm
T2	18251034S	Femoral Nail, A/R T2 Femur Ø10x340 mm
T2	18251136S	Femoral Nail, A/R T2 Femur Ø11x360 mm
T2	18251144S	Femoral Nail, A/R T2 Femur Ø11x440 mm
T2	18251232S	Femoral Nail, A/R T2 Femur Ø12x320 mm
T2	18251236S	Femoral Nail, A/R T2 Femur Ø12x360 mm
T2	18251240S	Femoral Nail, A/R T2 Femur Ø12x400 mm
T2	18251524S	Femoral Nail, A/R T2 Femur Ø15x240 mm
T2	18281032S	Femoral Nail, A/R, R1500 T2 Femur Ø10x320 mm
T2	18281136S	Femoral Nail, A/R, R1500 T2 Femur Ø11x360 mm
T2	18281230S	Femoral Nail, A/R, R1500 T2 Femur Ø12x300 mm
T2	18281236S	Femoral Nail, A/R, R1500 T2 Femur Ø12x360 mm
T2	18281238S	Femoral Nail, A/R, R1500 T2 Femur Ø12x380 mm
T2	18460940S	Reconstruction Nail R2.0, Ti, LEFT T2 Recon Ø9x400 mm x 125°
T2	18470940S	Reconstruction Nail R2.0, Ti, RIGHT T2 Recon Ø9x400 mm x 125°
T2	18471336S	Reconstruction Nail R2.0, Ti, RIGHT T2 Recon Ø13x360 mm x 125°
T2	18501036S	Femoral Nail, LEFT T2 GTN Ø10x360 mm
T2	18501236S	Femoral Nail, LEFT T2 GTN Ø12x360 mm
T2	18501430S	Femoral Nail, LEFT T2 GTN Ø14x300 mm
T2	18510932S	Femoral Nail, RIGHT T2 GTN Ø9x320 mm
T2	18511446S	Femoral Nail, RIGHT T2 GTN Ø14x460 mm

Lot #s: Only specific lot numbers are affected!
For details please see attachment: **PFAA_1774317 affected products list**

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 28.03.2018 – 10.04.2018. 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
The manufacturer has discovered that potentially out-of-specification products may have left the factory. Non-conforming cannulation of the nails may result in reduced component strength and potentially premature nail breakage.

Potential Hazards
Premature nail breakage.

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 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 PFAA_1774317

Type of Action: Field Safety Corrective Action

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

Product name:
Catalogue #
Lot #

I acknowledge receipt of the Field Safety Notice for PFAA_1774317 and can confirm that:

We have not located any of these devices in our inventory: ***(please delete if not applicable)***				
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.