URGENT FIELD SAFETY NOTICE: PFAA_1774317

Version 1

Field Safety Corrective Action

Affected Product:
T2 Ankle Arthrodesis / Femur / Tibia / Recon / Greater Trochanter Nails

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

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<th>Product No</th>
<th>Product Description</th>
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Lot #: 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
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:

<table>
<thead>
<tr>
<th>Product description</th>
<th>Product Reference</th>
<th>Lot Number</th>
<th>Qty</th>
<th>Qty Quarantined</th>
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We have not located any of these devices in our inventory:
(please delete if not applicable)

We have located the following devices:

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We have further distributed subject devices to the following organisations:

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<th>Facility Name</th>
<th>Facility Address</th>
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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.
<table>
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18281230S  Femoral Nail, A/R, R1500 T2 Femur Ø12x300 mm  K07AFF5
18281230S  Femoral Nail, A/R, R1500 T2 Femur Ø12x300 mm  K07AFF5
18281236S  Femoral Nail, A/R, R1500 T2 Femur Ø12x360 mm  K076A7C
18281236S  Femoral Nail, A/R, R1500 T2 Femur Ø12x360 mm  K076A7C
18281238S  Femoral Nail, A/R, R1500 T2 Femur Ø12x380 mm  K08327F
18281238S  Femoral Nail, A/R, R1500 T2 Femur Ø12x380 mm  K08327F
18281238S  Femoral Nail, A/R, R1500 T2 Femur Ø12x380 mm  K08327F
18460940S  Reconstruction Nail R2.0, Ti, LEFT T2 Recon Ø9x400 mm x 125°  K07F870
18470940S  Reconstruction Nail R2.0, Ti, RIGHT T2 Recon Ø9x400 mm x 125°  K078C6D
18470940S  Reconstruction Nail R2.0, Ti, RIGHT T2 Recon Ø9x400 mm x 125°  K078C6D
18470940S  Reconstruction Nail R2.0, Ti, RIGHT T2 Recon Ø9x400 mm x 125°  K078C6D
18470940S  Reconstruction Nail R2.0, Ti, RIGHT T2 Recon Ø9x400 mm x 125°  K078C6D
18470940S  Reconstruction Nail R2.0, Ti, RIGHT T2 Recon Ø9x400 mm x 125°  K078C6D
18470940S  Reconstruction Nail R2.0, Ti, RIGHT T2 Recon Ø9x400 mm x 125°  K078C6D
18470940S  Reconstruction Nail R2.0, Ti, RIGHT T2 Recon Ø9x400 mm x 125°  K078C6D
18470940S  Reconstruction Nail R2.0, Ti, RIGHT T2 Recon Ø9x400 mm x 125°  K078C6D
18471336S  Reconstruction Nail R2.0, Ti, RIGHT T2 Recon Ø13x360 mm x 125°  K0748D1
18471336S  Reconstruction Nail R2.0, Ti, RIGHT T2 Recon Ø13x360 mm x 125°  K0748D1
18501036S  Femoral Nail, LEFT T2 GTN Ø10x360 mm  K08D58D
18501036S  Femoral Nail, LEFT T2 GTN Ø10x360 mm  K08D58D
18501036S  Femoral Nail, LEFT T2 GTN Ø10x360 mm  K08D58D
18501036S  Femoral Nail, LEFT T2 GTN Ø10x360 mm  K08D58D
18501036S  Femoral Nail, LEFT T2 GTN Ø10x360 mm  K08D58D
18501036S  Femoral Nail, LEFT T2 GTN Ø10x360 mm  K08D58D
18501236S  Femoral Nail, LEFT T2 GTN Ø12x360 mm  K081650
18501236S  Femoral Nail, LEFT T2 GTN Ø12x360 mm  K081650
18501236S  Femoral Nail, LEFT T2 GTN Ø12x360 mm  K081650
18501236S  Femoral Nail, LEFT T2 GTN Ø12x360 mm  K081650
18501430S  Femoral Nail, LEFT T2 GTN Ø14x300 mm  K078C74
18510932S  Femoral Nail, RIGHT T2 GTN Ø9x320 mm  K076A80
18510932S  Femoral Nail, RIGHT T2 GTN Ø9x320 mm  K076A80
18510932S  Femoral Nail, RIGHT T2 GTN Ø9x320 mm  K076A80
18511446S  Femoral Nail, RIGHT T2 GTN Ø14x460 mm  K0748D3
18511446S  Femoral Nail, RIGHT T2 GTN Ø14x460 mm  K0748D3
18511446S  Femoral Nail, RIGHT T2 GTN Ø14x460 mm  K0748D3
18511446S  Femoral Nail, RIGHT T2 GTN Ø14x460 mm  K0748D3