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**URGENT FIELD SAFETY NOTICE: FSCA 1774317**

Field Safety Corrective Action

Affected Product:

T2 Ankle Arthrodesis / Femur / Tibia / Recon / Greater Trochanter Nails

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27.04.2018

**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:** FSCA 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: **List of products affected by FSCA 1774317 globally**

## STRYKER Trauma GmbH (Trauma & Extremities Division)

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. No affected lots can be ordered nor 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

## STRYKER Trauma GmbH (Trauma & Extremities Division)

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:* Sara Rodriguez Jato

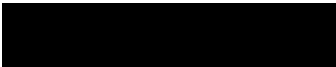
*Position:* QA lead

*Email:* [ASEAN.PMS@stryker.com](mailto:ASEAN.PMS@stryker.com)

*Telephone:* +84 28 3827 5399

*Fax:* +84 28 3827 5398

Yours Sincerely,



## STRYKER Trauma GmbH (Trauma & Extremities Division)

**Attachment 1:** List of products affected by FSCA 1774317 globally

Brand	Sub-brand	PN	Product description	Lot No.
T2	ANKLE ARTHRODESIS NAIL	18181130S	Ankle Arthrodesis Nail, left T2 Ankle Ø11x300mm	K07AFEA
T2	ANKLE ARTHRODESIS NAIL	18191130S	Ankle Arthrodesis Nail, right T2 Ankle Ø11x300mm	K081639
T2	ANKLE ARTHRODESIS NAIL	18191030S	Ankle Arthrodesis Nail, right T2 Ankle Ø10x300mm	K078C7E
T2	FEMORAL NAILS - R/A	18251240S	Femoral Nail, A/R T2 Femur Ø12x400 mm	K07F86C
T2	FEMORAL NAILS - R/A	18251144S	moral Nail, A/R T2 Femur Ø11x440 mm	K078C77
T2	FEMORAL NAILS - R/A	18281230S	Femoral Nail, A/R, R1500 T2 Femur Ø12x300 mm	K07AFF5
T2	FEMORAL NAILS - R/A	18251136S	Femoral Nail, A/R T2 Femur Ø11x360 mm	K076AA1
T2	FEMORAL NAILS - R/A	18251032S	Femoral Nail, A/R T2 Femur Ø10x320 mm	K081642
T2	FEMORAL NAILS - R/A	18251034S	Femoral Nail, A/R T2 Femur Ø10x340 mm	K0957B1
T2	FEMORAL NAILS - R/A	18251232S	Femoral Nail, A/R T2 Femur Ø12x320 mm	K0957B5
T2	FEMORAL NAILS - R/A	18251236S	Femoral Nail, A/R T2 Femur Ø12x360 mm	K083278
T2	FEMORAL NAILS - R/A	18281032S	Femoral Nail, A/R, R1500 T2 Femur Ø10x320 mm	K08327D
T2	FEMORAL NAILS - R/A	18281136S	Femoral Nail, A/R, R1500 T2 Femur Ø11x360 mm	K0816EE
T2	FEMORAL NAILS - R/A	18281236S	Femoral Nail, A/R, R1500 T2 Femur Ø12x360 mm	K076A7C
T2	FEMORAL NAILS - R/A	18251524S	Femoral Nail, A/R T2 Femur Ø15x240 mm	K078C70
T2	FEMORAL NAILS - R/A	18281238S	Femoral Nail, A/R, R1500 T2 Femur Ø12x380 mm	K08327F
T2	GTN	18501036S	Femoral Nail, LEFT T2 GTN Ø10x360 mm	K08D58D
T2	GTN	18501236S	Femoral Nail, LEFT T2 GTN Ø12x360 mm	K081650
T2	GTN	18510932S	Femoral Nail, RIGHT T2 GTN Ø9x320 mm	K076A80
T2	GTN	18501430S	Femoral Nail, LEFT T2 GTN Ø14x300 mm	K078C74
T2	GTN	18511446S	Femoral Nail, RIGHT T2 GTN Ø14x460 mm	K0748D3
T2	RECON NAILS	18460940S	Reconstruction Nail R2.0, Ti, LEFT T2 Recon Ø9x400 mm x 125°	K07F870
T2	RECON NAILS	18470940S	Reconstruction Nail R2.0, Ti, RIGHT T2 Recon Ø9x400 mm x 125°	K078C6D
T2	RECON NAILS	18471336S	Reconstruction Nail R2.0, Ti, RIGHT T2 Recon Ø13x360 mm x 125°	K0748D1
T2	TIBIAL NAILS - STD	18221231S	Tibial Nail, Standard T2 Tibia Ø12x315 mm	K074846
T2	TIBIAL NAILS - STD	18220933S	Tibial Nail, Standard T2 Tibia Ø9x330 mm	K08163B

## 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:** T2 Arthrodesis / Femur / Tibia / Recon / Greater Trochanter Nails

**Catalogue #** See attachment I

**Lot #** See attachment I

I acknowledge receipt of the Field Safety Notice for PFAA\_1774317 and can confirm that:

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

**Contact Name** \_\_\_\_\_ **Contact Facility** \_\_\_\_\_

**Contact address** \_\_\_\_\_ **Contact Position** \_\_\_\_\_

\_\_\_\_\_ **Contact Tel No** \_\_\_\_\_

\_\_\_\_\_ **Contact Fax No** \_\_\_\_\_

\_\_\_\_\_ **Contact e-mail** \_\_\_\_\_

PLEASE COMPLETE AND EMAIL TO ASEAN.PMS@stryker.com.