

January 21<sup>st</sup>, 2019**URGENT Field Safety Notice: PFA 1982723** Version 1

**Legal Manufacturer:** Stryker Trauma GmbH, Professor-Küntschers-Strasse 1-5  
24232 Schönkirchen, Germany

**Recipients:** Health Care Professionals and Operators of Medical Devices working with the T2 IM Nailing System

**Type of Action:** Product Field Action

**PFA Identifier:** PFA\_1982723

**Identification of the Voluntary Affected Product(s):**  
T2 Instruments

Product Ref #	Product Name	Lot Code (packaging)	Vendor code engraved on item
18069900	Instrument Tray, Basic T2 Femur Long	K026ACE	KU97181

Dear Customer,

**Purpose of this letter**

The purpose of this notification is to advise you that Stryker Trauma GmbH is conducting a voluntary Product Field Action for a specific lot of the product **Instrument Tray, Basic T2 Femur Long**.

These products were distributed to customers from Oct. 18<sup>th</sup>, 2018 to Oct. 22<sup>nd</sup>, 2018. Please refer above for Part and Lot Number that were identified as shipped to distributors and end users.

**Reason for Corrective Action**

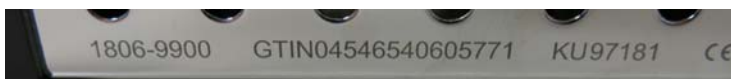
The manufacturer has discovered that the faceplates may incorrectly identify the T2 Basic **Long** Instrument Set as T2 Basic **Short** Instrument Set.



Correctly labeled



Wrongly labeled



Identification of affected batch by vendor code KU97181

**Risk to Health**

Due to the wrong labeling on the tray there is possibility that the wrong and not adequate content is not suitable for a certain intervention. It cannot be excluded that in certain cases and under unfavorable circumstances an operation which has been started or which is planned cannot be adequately executed.

**Mitigating Factors**

None

**Potential Alternative Products**

All correctly labeled trays can be used.

**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 action.
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 devices affected by this Product Field Action.
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 organizations.
  - 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.

We request that you **respond to this notice within 7 calendar days** from the date of receipt. On receipt of the Acknowledgement Form, a Stryker Representative will contact you to organize any applicable actions. We appreciate your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter.

**OTHER INFORMATION:**

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:

Telephone:

E-mail:



On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours faithfully,

Name

Job Title

## **PFA 1982723: Acknowledgement Form**

**FSCA Identifier:** Product Field Action PFAA\_1982723

**Type of Action:** Product Field Action

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

**Identification of the Voluntary Affected Product(s):**

T2 Instruments

Product Ref #	Product Name	Lot Code (packaging)	Vendor code engraved on item
18069900	Instrument Tray, Basic T2 Femur Long	K026ACE	KU97181

I acknowledge receipt of the Field Safety Notice for PFA 1982723 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>				

<b>Contact Name</b>	_____	<b>Contact Facility</b>	_____
<b>Contact address</b>	_____	<b>Contact Position</b>	_____
	_____	<b>Contact Tel No</b>	_____
	_____	<b>Contact Fax No</b>	_____
	_____	<b>Contact e-mail</b>	_____

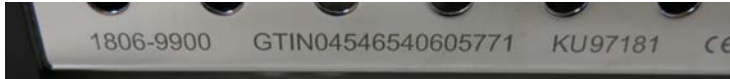
**PLEASE COMPLETE AND FAX THIS FORM TO X  
OR EMAIL TO X.**

(This Form is to be filled by Stryker Representative)

**PFA 1982723: Instruction and Response Form Stryker Representative**

Instructions for inspection of the products affected by PFA 1982723 at the customer performed by Stryker Representative:

1. Identify the product by catalogue number and vendor code which is engraved on the long side of the instrument tray (see photo).



Identification of affected batch by vendor code KU97181

2. Check the front panel labels at both ends of the instrument tray (see photos):



Correctly labeled



Wrongly labeled

3. Document the result of the inspection conducted at Hospital:  
Hospital name:

Hospital address:

Product Ref #: 18069900

Lot Code: KU97181

Qty: ....

Results of inspection at hospital:

Labels correct at both sides ☐

Labels wrong at both sides ☐

Label wrong at one side ☐

4. Product exchange: In case a wrong label was found, please exchange the instrument tray and return the nonconforming product to the manufacturer. Instrument trays with correct labels on both sides can be used as intended. Ensure the availability of replacement trays.

Wrong tray was exchanged: ☐

Tray is in specification: ☐

(Customer was informed that instrument tray can be used as intended)

Name of Stryker Representative:

Date: