

STRYKER Trauma GmbH (Trauma & Extremities Division)

Recall Letter

URGENT: MEDICAL DEVICE RECALL

PFA_2219868 Version 1

Medical Device Recall

Affected Product: T2 Alpha Delta Strike Plate IMN Instruments

25th November 2019

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: Removal

PFA Identifier: PFA_2219868

Identification of the Affected Product(s):

Catalog #	Manufacturer Part Name	Lot #
23510050	Delta Strike Plate IMN Instruments	All

Dear Customer,

Purpose of this letter

The purpose of this notification is to advise you that Stryker GmbH (Trauma & Extremities Division) is conducting a voluntary recall. These products were distributed to customers from November 2018 – August 2019. Please refer above for the catalog number that was identified as shipped to distributors and end users.

Reason for Voluntary Recall

The manufacturer has discovered that the instrument can break at the level of the thread when being exposed to high forces during nail implantation or removal.

Risk to Health

Surgeon or patient could be hit by a fragment causing laceration or abrasive wound. Due to the loss of the strike plate the operative intervention cannot be finished as planned. A change of the surgery method might in very rare occasions be the consequence.

Mitigating Factors

None

Recommendations for patients already treated with an affected device

There is no recommendation. A breakage of the instrument will be obvious to the user, who will react to complete the surgery successfully.

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Potential Alternative Products

The Strike Plate T2 Femur Catalogue number 18060150 can be used in combination with the Universal Rod Catalogue number 18060110 of the T2 Nailing System.

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 if 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 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. 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.
7. 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.

We confirm that the competent national authorities in your country have been informed of this safety corrective action in accordance with regulatory requirement in your country.

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:

Yours Sincerely,

Signature

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form

Response is Required

T2 Alpha Delta Strike Plate IMN Instruments

PFA Identifier: Product Field Action PFA_2219868

Type of Action: Removal

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

Product name: Delta Strike Plate IMN Instruments

Catalogue # 23510050

Lot # all

I acknowledge receipt of the Recall Letter 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 organizations:					
Facility Name					
Facility Address					
Form completed by:					

Contact Name _____ **Contact Facility** _____

Contact address _____ **Contact Position** _____

_____ **Contact Tel No** _____

_____ **Contact Fax No** _____

_____ **Contact e-mail** _____

I have read and understand the recall instructions provided in the <date of> letter. Yes No

Date _____ Signature of Receipt _____

PLEASE FAX COMPLETED RESPONSE FORM TO: Tel. # _____, ATTN: _____
OR MAIL TO: FIRM NAME AND ADDRESS