

# STRYKER GmbH (Trauma & Extremities Division)

**Generic: URGENT FIELD SAFETY NOTICE: PFAA\_1761663** Version 1

Field Safety Corrective Action

Affected Product:

Farabeuf Clamp for 3.5mm Screws PRO– MATTA - PELVIC

25.04.2018

**Legal Manufacturer:** Stryker GmbH, Bohnackerweg 1  
2545 Selzach, Switzerland

**Recipients:** Health Care Professionals, Operators of Medical Devices, Distributors

**Type of Action:** Field Safety Corrective Action

**FSCA Identifier:** PFAA\_1761663

## Identification of the Affected Product(s):

Catalogue #	Manufacturer Part Name	Lot #
7705463	Farabeuf Clamp for 3.5mm Screws PRO	04857V

Dear Customer,

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 22.09.2017 – 31.01.2018. 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. The laser etching which indicates whether the device is in compression or distraction mode may be on the wrong side of the lever arm so that when set to **C** the device is distracting and when set to **D** the device is compressing.

### Potential Hazards

Loosening of fragment resulting in re-inspection and trial of clamp and repositioning of fragment resulting in prolongation of surgery <15 min and there is no possibility of soft tissue damage from a reversal of the laser markings.

There is no possibility of soft tissue damage or bleeding from a reversal of the laser markings. The clamp is still stable and the surgeon will immediately notice if the clamp distracts when he/she wants compression.

### Mitigating Factors

The failure is easily recognizable for the user.

### Recommendations for patients already treated with an affected device

The nonconformance does not represent a significant incremental Medical Risk to the patient.

## STRYKER GmbH (Trauma & Extremities Division)

### 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*

**STRYKER GmbH (Trauma & Extremities Division)**

Yours Sincerely,

*Signature*

STRYKER GmbH (Trauma & Extremities Division)

ACKNOWLEDGMENT FORM (FSCA)

FSCA Identifier: Product Field Action PFAA\_1761663

Type of Action: Field Safety Corrective Action

Legal Manufacturer Stryker GmbH, Bohnackerweg 1  
2545 Selzach, Switzerland

Product name:

Catalogue #

Lot #

I acknowledge receipt of the Field Safety Notice for RA2016-169 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 FAX THIS FORM TO X  
OR EMAIL TO X.