Recall Letter

URGENT: MEDICAL DEVICE RECALL (2227937) Version 1

Affected Product:
External Fixation System Hoffmann II Compact - Pin To Rod Coupling 5/3-4mm

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19. October 2019

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

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

Type of Action: Removal

PFA Identifier: PFA_2227937

Identification of the Affected Product(s):
Pin To Rod Coupling Hoffmann II Compact products are used in external fixation procedures.

Catalogue #	Manufacturer Part Name	Lot #
49401020	Pin To Rod Coupling Hoffmann II Compact 5/3-4mm	D30875

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. The products were distributed to customers from 17. June 2019 – 01. July 2019 ([1] Attachment 1 includes a list of all products affected by this recall, and it may include products your account did not receive.) Please refer above for Part and Lot Number that was identified as shipped to distributors and end users.

Reason for Voluntary Recall
Stryker received a complaint for a Pin To Rod Coupling Hoffmann II Compact 5/3-4mm. The hospital reported that the Pin To Rod Coupling could not clamp the pin and rod as intended. The situation caused a surgical delay of 15 minutes, however the procedure was completed by using a product with a different lot number.
The non-functioning coupling was returned to the manufacturer, the investigation of the situation revealed that the coupling of the reported lot number is wrongly assembled by the manufacturer. The pin component of the lot number above is mixed up with the rod component (see Figure 1). Therefore, the coupling is not functional. The non-conformance is limited to one lot number.

Figure 1. Left: wrongly assembled, Right: Coupling assembled correctly.

Potential hazard
Non-functioning Pin To Rod Coupling Hoffmann II Compact 5/3-4mm (Cat# 49401020, Lot# D30875)

Risk to Health
The deviation can cause a prolongation of surgery time, a change of surgery method and potentially a revision surgery. Conservative fracture treatment with plaster cast is usually available and could complete the fracture treatment.
The defect is not easily recognizable for the user. The wrongly assembled Pin to Rod Coupling looks very similar to a correctly assembled coupling. However, it can be recognized, if functionality is tested before the surgery.

Mitigating Factors
Following can potentially solve the situation during surgery to complete the surgery successfully:
a. A spare Kit is available
b. Spare Pin to Rod couplings are available
c. Another external fixator system is available
d. Conservative fracture treatment with plaster cast is available

Recommendations for patients already treated with an affected device
N/A as the coupling either works or does not work.

Potential Alternative Products
The removal affects only one Lot number. Not affected Lots can be ordered.

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. 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.

This recall is being made with the knowledge of the Food and Drug Administration.

Product and Distribution Information

Product and Distribution Information Table						
Product Name	**Manufacturer's Product Number/Catalog Number**	**Lot/Serial Number**	**Manufacturing /Distribution Dates**	**Expiration Date (MM/DD/YYYY)**	**Quantity**	**Unique Device Identifier**
Pin To Rod Coupling Hoffmann II Compact 5/3-4mm	49401020	D30875	Batch release: 17. May 2019. Distribution: from 17. June 2019 to 01. July 2019	N/A, unsterile device	100	(01)07613327089158(10)D30875

Type of Action by the Company:
Removal

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: Dominik Blaser

Position: Lead Product Field Action Specialist

Address: Bohnackerweg 1, 2545 Selzach, Switzerland

Email: [redacted]

Telephone: [redacted]

Fax: +41 32 614 66 60

Yours Sincerely,
Dominik Blaser

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form

Response is Required

Customer Information:
Customer Name
Street Address
Town, State, Zip Code

Pin To Rod Coupling Hoffmann II Compact

PFA Identifier: Product Field Action PFA_2227937

Type of Action: Removal

Legal Manufacturer Stryker GmbH, Bohnackerweg 1
2545 Selzach, Switzerland

Product name: Pin To Rod Coupling Hoffmann II Compact 5/3-4mm
Catalogue # 49401020
Lot # D30875

I acknowledge receipt of the Recall Letter and can confirm that:

We have not located any of these devices in our inventory: ***(please delete if not applicable)***				
We have located the following devices:				
Product description	**Product Reference**	**Lot Number**	**Qty**	**Qty Quarantined**
We have further distributed subject devices to the following organisations:				
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

Any adverse events associated with recalled product? ☐Yes ☐No

If yes, please explain:
_____
_____
_____
_____

Was this device implanted? (If yes, please specify the implant dates, the quantities implanted, and provide available tracking information).

Return Response Box:

Please provide any additional information, if applicable.

Date_____Signature of Receipt _____

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