STRYKER Trauma GmbH (Trauma & Extremities Division)

May/19/2021

Recall Letter

URGENT: MEDICAL DEVICE RECALL 2644769 Version 1

Affected Product:
SPI Elast. Sleeve 8-13 and SPI Elast. Sleeve 8-11

19.May.2021

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_2644769

Identification of the Affected Product(s):

Catalog #	Manufacturer Part Name	Lot #
18061407S	SPI Elast. Sleeve 8-13	K03CC50
18061406S	SPI Elast. Sleeve 8-11	K03CC4F

Dear Customer,

Purpose of this letter
The purpose of this notification is to advise you that Stryker Trauma GmbH (Trauma & Extremities Division) is conducting a voluntary recall. The above-referenced products were distributed to customers from August 2020 – November 2020

Reason for Voluntary Recall
Stryker Trauma GmbH (Trauma & Extremities Division) determined through its quality system that two specific lots of T2 Nail Insertion Sleeve instrument, referenced in the table above, contain devices that have a different inner diameter than the diameter specified on the outer box label. Specifically, the products in: (i) lot number K03CC50 contained products with an inner diameter that was 2mm smaller than the label indicates; and (ii) lot number K03CC4F contained products with an inner diameter that was 2mm larger than the label indicates. As a result of this discrepancy, surgeons using the products from the above-referenced lots could open a sleeve which is 2mm smaller or 2mm larger than intended.

Potential Risk to Health
If a surgeon identifies the discrepancy in sizing prior to implantation, the surgeon could use an alternate product of the correct size. This could result in additional time under anesthesia for the patient due to prolongation of surgery.

The use of a nail insertion sleeve with a smaller or larger inner diameter than intended could result in the following:

- Additional time under anesthesia for the patient due to prolongation of surgery,
- Soft / Hard tissue damage,
- Foreign body response if the sleeve has collision with a drill bit

Mitigating Factors

- Except for the outer box label, the products were manufactured in conformance with their specifications and are identifiable by the correct markings on the impacted product.

- Fluoroscopy is used during the procedure to verify. the position of the guide wires, entry point of the implant and to perform the operation which can be completed with or without the nail insertion sleeve.

Recommendations for patients already treated with an affected device
A medical risk assessment concluded that the use of an inner sleeve with a diameter that is 2mm larger or smaller than anticipated does not represent a significant medical risk to the patient.

Potential Alternative Products
The non-conforming label is lot specific. Products from other T2 Nail Insertion Sleeve instrument lots are accurately labelled 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 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.
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

   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.
5. Please complete the attached customer response form (acknowledgement form). It is possible that that you no longer have any physical inventory of the impacted products 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 the customer response form even if you no longer have any of the subject devices in your physical inventory**.
6. Return the completed form to your nominated Stryker Representative (indicated below) for this action.

We request that you **please respond to this notice within 7 calendar days** from the date of receipt. A Stryker Representative will contact you to facilitate the actions described within this section. We appreciate your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter.

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form

Response is Required

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

T2 Nail Insertion Sleeve SPI

PFA Identifier: Product Field Action PFA_2644769

Type of Action: Removal

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

Catalog #	Manufacturer Part Name	Lot #
18061407S	SPI Elast. Sleeve 8-13	K03CC50
18061406S	SPI Elast. Sleeve 8-11	K03CC4F

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