URGENT FIELD SAFETY NOTICE: RA2020 - 2367146

FSCA identifier: RA2020-2364176

Type of action: Field Safety Corrective Action: Correction

Legal Manufacturer: Stryker Medical-Kalamazoo, 3800 East Centre Avenue, Michigan, USA

Products affected:

Model numbers	Product description	Serial number(s)
6550-000-000	Power-PRO™ TL cot manufactured between Sept 9, 2019 and Nov 7, 2019	See Attachment

April 29, 2020

Dear Customer,

Stryker Medical has initiated a voluntary, lot-specific recall for the Power-PRO™ TL cot manufactured between Sept 9, 2019 and Nov 7, 2019. The intent of this letter is to list known hazards and harms, and to list any risk mitigation factors and actions required.

Product Description:

The Stryker Model 6550 Power-PRO™ TL cot is a powered ambulance cot that consists of a platform mounted on a wheeled X-frame designed to support and transport a maximum weight of 700 lb (318 kg) in pre-hospital and hospital environments.

Issue:

Stryker has identified that Riv-nuts on the outer rails on some PowerPRO TL cots manufactured between September 9, 2019 and November 7, 2019 may not be fully crimped due to a tooling issue. The reduced crimping may cause a reduction in retaining force of the Riv-nuts, which may impact the ability of the cot to pass the crash test standard BS EN 1789.

Potential Risk:

A Health Hazard Evaluation was completed which identified that, if the cot is released from the fastener, there is a potential risk of blunt force injury to the patient or ambulance staff. In its maximum severity, this potential injury could result in the need for medical or surgical intervention for the patient or caregiver. The risk is only present during an ambulance accident, and there have been no reported incidents.

Actions Needed:

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all subject devices pending to return to Stryker.

2. Circulate this Field Safety Notice internally to all interested/affected parties.

3. Maintain awareness of this notice internally until all required actions have been completed within your facility.

4. 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 inform Stryker of any adverse events concerning the use of the subject devices.

    Please comply with any local regulations concerning the notification of adverse events to your National or local Competent Authorities.

6. Return the enclosed business reply form to confirm receipt of this notification by fax or email XXXX or email XXXX the enclosed acknowledgement of this notification.

7. Upon receipt of the completed business reply form, Stryker will contact you to arrange for the modification/repair of your Power-PRO ™ TL cot.
    a. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

8. If you have loaned or sold any of the products listed in this letter, please forward a copy of this notice to the new users and advise us of their new location in the space provided on the business reply form.

9. If you have disposed of any of these units and they are no longer in use, please, advise us of their obsolescence by providing us with their serial number in the space provided on the business reply form.

We request that you respond to this notice within 7 calendar days from the date of receipt.

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:

In line with the recommendations of the Meddev Vigilance Guidance document Ref.2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

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 cause. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remaining on the market.

Yours Sincerely,

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I acknowledge receipt of the Field Safety Notice for RA2020-2367146 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:			
Catalog number	Description	Serial number	Qty
We have further distributed subject devices to the following organizations:			
Facility Name			
Facility Address			
Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE THIS FORM WITHIN 7 CALENDAR DAYS AND RETURN IT BY USING THE EMAIL, XX, OR FAX, XX.

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Attachment: List of affected products

Catalog Number	Serial
6550-000-000	1909003700051
6550-000-000	1909003700052
6550-000-000	1909003700053
6550-000-000	1909003700054
6550-000-000	1909003700055
6550-000-000	1909003700056
6550-000-000	1909003700057
6550-000-000	1909003700058
6550-000-000	1909003700059
6550-000-000	1909003700060
6550-000-000	1909003700061
6550-000-000	1909003700062
6550-000-000	1909003700063
6550-000-000	1909003700064
6550-000-000	1909003700065
6550-000-000	1909003700066
6550-000-000	1909003700067
6550-000-000	1909003700068
6550-000-000	1909003700069
6550-000-000	1909003700070
6550-000-000	1909003700071
6550-000-000	1909003700072
6550-000-000	1909003700073
6550-000-000	1909003700074