URGENT FIELD SAFETY NOTICE: RA2018-1724060
Product: EMS – Power-LOAD® Cot Fastener

ATTN: Risk Management/ Fleet Manager

November 2018

FSCA identification: RA2018-1724060
Action type: Product correction
Catalogue Numbers: 6390-000-000
Product description: Power-LOAD® units manufactured between Jan 1, 2016 – Aug 16, 2017
Lots Numbers: See Attachment

The purpose of this letter is to advise you that Stryker Medical is voluntarily correcting specific serial numbers of EMS – Power-LOAD®

Reason for the Voluntary Recall:
After installation of the Power-LOAD, the Floor Plate Attachment Brackets (PN: 6390-101-108) which allow the Power-LOAD anchor to be secured to the Power-LOAD floor plate may be found to be broken after removing the anchor. All Power-LOAD units manufactured from January 1, 2016 to December 31, 2016, may potentially exhibit this issue.

Risk to Health:
A Health Hazard Evaluation was completed which identified the potential hazardous situation of a detached cot with fastener or detached fastener component. The highest possible severity for the patient and the user is death. There have been no reported performance issues to date or harms associated with this issue. Having completed our risk management assessment, we believe the probability of occurrence of harm to be negligible. However, we have chosen to replace the potentially affected parts on every Power-LOAD manufactured within the suspect time frame.

Actions to be taken by the Customer/User:

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. Locate the units listed on the attached business reply form and identify the address where they can be serviced
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 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.

5. Please inform Stryker of any adverse events concerning the use of the subject devices.
   a) Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
6. Complete the attached customer response 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. Upon receipt of your business reply form, a Stryker field service rep will contact you to arrange for the replacement of the Floor Plate Attachment Brackets on your Power-LOAD cot fastener.
8. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA

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 **XXX** 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: email:

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

Yours Sincerely,

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