Stryker Osteonics SA – Dubai Rep. Office
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stryker®

Middle East & Africa

21st June 2012

URGENT FIELD SAFETY NOTICE: RA2011-070

Dear Customer

Description: GoBed+, GoBed II, Rose, and MA204

Catalog # FL20E, FL28C & FL28EX, FL14E3, and FL25E

Lot # All models manufactured from 1st March 2002 to 30th June 2008.

Please find attached details of a Product Field Action that has been initiated by Stryker medical concerning the above referenced devices.

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action. It may be that you no longer have any physical inventory on site. In this case you are receiving the notice because you have potentially received non-conforming devices in the past and as a responsible manufacturer we feel that it is our duty to ensure that you are aware of the information contained within the manufacturer's Field Safety Notice.

This action has been taken to ensure that users are aware of important Information for inspection of the devices listed above. You are required only to read the attached Field Safety Notice and then sign and return the customer response form confirming that you have completed the actions requested by the manufacturer.

Completing the Customer Response 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.

We request that you respond to this notice within seven calendar days from the date of receipt. The target date for completion of this action is 15th Dec 2012 and your timely response will enable us to ensure that we meet this target and ensure that non conforming devices are removed from the market as quickly as possible.

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: Azza Ibrahim
Position: RAQA Manager MEA
E-mail: azza.ibrahim@stryker.com
Tel: +971 42222842
Fax: +971 42247381

On behalf of Stryker we thank you sincerely for your help and support in completing this action within 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,
Azza Ibrahim
RAQA Manager MEA

Azza Ibrahim
21/06/2012

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URGENT Field Safety Notice: RA2011-070

Dear Customer

Description: GoBed+, GoBed II, Rose, and MA204
Catalogue No: FL20E, FL28C & FL28EX, FL14E3, and FL25E
Lot No: All models manufactured from 1st March 2002 to 30th June 2008.

Stryker® Medical has initiated a Product Field Action for the devices identified above. The purpose of this letter is to list the hazards potentially associated with the Product Field Action.

Issue
Stryker Medical has received complaints regarding scales and/or bed exit systems on GoBed+, GoBed II, Rose and MA204 beds. The units cited were manufactured between March 1, 2002 thru June 30, 2008. Investigation identified that the reported issues could be attributed to load cell malfunctions.

Potential Hazards

- Patient falls to the floor of the hospital room without the knowledge of the hospital staff.
- A patient has been incorrectly medicated with either a larger, or smaller, dose of medication than prescribed by a clinician. (Excludes Rose bed as Scales are not offered.)
- A patient's physical condition is incorrectly assessed by a clinician based upon erroneous weight tracking. (Excludes Rose bed as Scales are not offered.)

These hazards could lead to serious injury for patients. The probability of actual occurrence has been determined to be remote.

To-date, Stryker is not aware of any injuries or adverse events been associated with these reported events.

Risk Mitigation
A 50% drop in patient weight detected by the system triggers a bed exit alarm, regardless of whether the patient has breached a Zone 'fence'.
Initial investigation has shown that the load cells fluctuate in a negative and positive direction and can fluctuate by as much as 100 – 150 pounds every 3 seconds. If the patients' weight is off by this order of magnitude, it would be apparent to the caregiver that the scale is providing an unreliable reading.
If the bed cannot communicate with any one of the load cells due to a completely broken connection anywhere in the wiring, a scale error will be displayed.

Type of Action
Immediate Inspection of subject devices.
We are issuing this Field Safety Notice to inform you of this potential situation and to request that you inspect your beds and confirm that the scale and bed exit alarm functions are working as intended.

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Immediate actions

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. Immediately locate and inspect all subject devices:
    a. If equipped with scales, ensure that weight displays properly.*
        i. No fluctuating weights
        ii. No error codes displayed
    b. If equipped with bed exit functionality, ensure that bed exit can be set properly for all available zones.*
        i. Bed exit can be set – no error message displayed;
        ii. Bed exit alarms if weight is removed;

2. Continue to periodically inspect scale and bed exit functionality, as specified in the Preventive Maintenance Checklist in the product's maintenance manual.
3. Ensure that this notice is forwarded internally to all appropriate personnel
4. Complete the customer response form attached indicating the number of units located and inspected
5. Return the completed response form to your local Stryker distributor. Contact details indicated on the form.
    a. On receipt of the completed notice a Stryker representative will contact you to arrange for replacement of any non conforming devices.
    b. Please return this notice within five working days. This will enable us to order any replacement devices that you may need in a timely manner.
6. Please respond to this notice even if you do not currently have any subject devices. This will negate the need for us to send any reminder notices.
7. Inform Stryker of any adverse events associated with use of subject devices
    a. Please comply with any local regulations concerning the reporting of adverse events to the Kingdom of Saudi Arabia Food & Drug Authority.

*For additional information, please, refer to the product's operations and/or maintenance manuals.

We sincerely regret any inconvenience that this action may cause you and on behalf of Stryker would like to thank you for your help and support in completing this action in a timely manner.

Should you have any queries on this matter please do not hesitate to contact the undersigned.

Yours faithfully,
Azza Ibrahim
RAQA Manager MEA

Azza Ibrahim
21/06/2012

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RA2011-070: PFA ACKNOWLEDGMENT FORM

Description: GoBed+, GoBed II, Rose, and MA204
Catalogue No: FL20E, FL28C & FL28EX, FL14E3, and FL25E
Lot No: All models manufactured from 1st March 2002 to 30th June 2008.

I acknowledge receipt of the Field Safety Notice for RA2011-070 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 Inspected**
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** _____

Please return the completed form to:
azza.ibrahim@stryker.com

Stryker Osteonics SA