Report Form

Manufacturer's Field Safety Corrective Action Report

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 8)

1. Administrative information
To which NCA(s) is this report being sent? Vigilance on Medical Devices Ministry of Health Via Giorgio Ribotta 5 IT - 00144 Roma tel: +39 06 5994 2381 dgfdm@postacert.sanita.it, vigilance@sanita.it
Type of report ☒ Initial report ☐ Follow up report ☐ Final report
Date of this report 2016FEB15
Reference number assigned by the manufacturer MOD1238
FSCA reference number assigned by NCA
Incidence reference number assigned by NCA
Name of the co-ordinating national competent authority (if applicable)

2 Information on submitter of the report
Status of submitter ☒ Manufacturer ☐ Authorised representative within EEA, Switzerland and Turkey ☐ Others (identify the role):

3 Manufacturer information	
Name *Liko AB*	
Contact name Linnea Hedlund	
Address Nedre vägen 100	
Postcode 975 92	City Luleå
Phone +46(0)920-474700	Fax +46(0)920-474701
E-mail se.quality@hill-rom.com	Country Sweden

4 Authorised representative information
Name N/A
Contact name

N/A
Address N/A

Postcode N/A	City N/A
Phone N/A	Fax N/A
E-mail N/A	Country N/A

5 National contact point information

National contact point name -
Name of the contact person -
Address -

Postcode -	City -
Phone -	Fax -
E-mail E-mail See attached list for information about the national contacts	Country -

6 Medical device information

Class

☐	AIMD Active implants		
☐	MDD Class III	☐	IVD Annex II List A
☐	MDD Class IIb	☐	IVD Annex II List B
☐	MDD Class IIa	☐	IVD Devices for self-testing
☒	MDD Class I	☐	IVD General

Nomenclature system (preferable GMDN) GMDN	Nomenclature code 31169
Nomenclature text Lift patient transfer sling bar	
Commercial name/brand name/make Universal SlingBar	
Model number 3156074 3156084 3156094 3156075 3156085 3156095 3156076 3156086	Catalogue number N/A
Serial number(s) Serial number interval 1200101 to 1370151	Lot/batch number(s) N/A
Device Manufacturing date The Universal SlingBars have been manufactured since end of March 2004 to May 2014.	Expiry date N/A
Software version number (if applicable)	

N/A
Accessories/associated device (if applicable) N/A
Notified body (NB) ID- number N/A

7 Description of FSCA

Background information and reason for the FSCA

Hill-Rom has become aware of a potential safety issue related to the Universal SlingBar 350, SlingBar 450 and SlingBar 600 which could be attached to various Liko overhead and mobile patient lifts. Complaints have been received that the center bolt of the sling bar, which connects the bar to the patient lift, has failed during use.

Analysis has shown that the sling bar is reliable when used as intended with the sling bar level during the lift. However, if the sling bar is not used as intended, the bolt may be weakened. If the bolt is weakened there is a potential risk for breakage with the result of a free fall of the patient.

Non-approved usages include: lifting repeatedly with only one hook (a single side of the sling bar), lifting at angles, or using the sling bar to lift heavy equipment for servicing activities. Our design was not intended or indicated to withstand these uneven loads. Our test data indicates that on proper use of the sling bar, the bolt will not fail. It is important to highlight that the sling bar design is compliant with "ISO 10535: Hoists for the transfer of disabled persons—Requirements and test methods" and that the lift design requirement specifications (DRS) for symmetrical loading adhere to the specifications required by this international standard.

There are approximately 163 000 units on the field world wide

Description and justification of the action (corrective/preventive)

Hill-Rom is in the process to start sending customer notifications to all known potentially affected accounts. Confirmation of delivery will be collected. First mailing will start 31 March 2016.

Hill-Rom is conducting a correction in two phases:

Phase 1
Part of the customer letter, Hill Rom requests the customer to inspect all their Universal Slingbars within defined serial number interval, according to an inspection Point instruction. The customer will be able to identify their sling bar model according to attached Replacement Guide and fill in the attached response form to be returned to Docapost (Hill-Roms partner for distribution of safety instructions or information related to the Hill-Rom medical devices).

Phase 2
Customer responding that they have affected units will have new slingbars free of charge. Order number of shipped slingbars will be collected as proof of delivery.

The customers are requested to scrap the old sling bars.

Advice on actions to be taken by the distributor and the user

Hill-Rom requests customers to always load the sling bar evenly and always lift using both hooks of the sling bar. There are no hazards when using the device as intended. These are new instructions for users with a lift manufactured prior to 19 November 2013. Complete instruction guides are available from www.hill-rom.com

Progress of FSCA, together with reconciliation data (Mandatory for a Final FSCA)

First mailing will be sent out no later than 31 March 2016.

Attached please find	FSN Status
☒ Field Safety Notice (FSN) in English	☐ Draft
☐ FSN in national language	☒ Final

☐ Others (please specify):

Time schedule for the implementation of the different actions

The time to complete the correction is estimated to be 31 July 2017.

These countries within the EEA and Switzerland and Turkey are affected by this FSCA

Within EEA, Switzerland and Turkey:

☒ AT	☒ BE	☒ BG	☒ CH	☐ CY	☒ CZ	☒ DE	☒ DK	☐ EE	☒ ES
☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE	☒ IS	☒ IT	☒ LI	☒ LT
☒ LU	☒ LV	☒ MT	☒ NL	☒ NO	☒ PL	☒ PT	☒ RO	☒ SE	☒ SI
☒ SK	☒ TR								

Candidate Countries:

☒ HR

☐ All EEA, Candidate Countries, Switzerland and Turkey

Others:

BD, BN, HK, IN, ID, MY, PK, PH, SG, KR, LK, TW TH, AU, NZ, AR, BS, BM, BR, CL, CO, MX, PE, PR, UY, VE, IL, CN, JP, AO, AZ, BH, EG, IR, IQ, JO, KW, LB, LY, MA, OM, QA, RU, SA, RS, ZA, SY, TN, UA, AE, US, CA

8 Comments

FSN in national language will be sent on request.

I affirm that the information given above is correct to the best of my knowledge.

Linnea Hedlund

Signature

Linnea Hedlund	Luleå	15 February 2016
Name	City	Date

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.