HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Liko Universal Slingbar 350, Slingbar 450, and Slingbar 600

Priority 2 – Warning

HPRA Safety Notice: SN2017(34) **Issue Date: 19th October 2017**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Hill-Rom	V26895

ISSUE
The Health Products Regulatory Authority (HPRA) has been informed of an issue in relation to Liko® Universal SlingBar 350, SlingBar 450 and SlingBar 600 devices. Hill-Rom has become aware of several complaints of the center bolt of the sling bars failing during use. The Universal Slingbars listed above may be used with the following mobile patient lifts: Golvo™, Uno™, LikoLight™, Likorall™, Multirall™ and Viking™ XS/S/M/L. Hill-Rom has advised that there is a potential risk for breakage of the sling bar with the result of a free fall of the patient if the device is not used as per the instructions for use (IFU) This hazard could cause potentially minor to catastrophic injuries to a patient.

Hill-Rom is requesting that customers inspect their Universal Slingbars within the serial number range 1200101 to 1370151.
Models affected are:
Universal SlingBar 350, p/n 3156074, 3156084 and 3156094
Universal SlingBar 450, p/n 3156075, 3156085 and 3156095
Universal SlingBar 600, p/n, 3156076 and 3156086

Hill-Rom have issued a field safety notice (FSN) which outlines instructions for identifying affected devices, and how to inspect them for damage.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Refer to the accompanying FSN and follow the instructions provided by the manufacturer.

2. Complete the response form and return it to the manufacturer.

3. Forward a copy of this Safety Notice and FSN to all relevant personnel within your organisation, or any person/s or organisation to whom/which this device has been transferred.

4. Report any adverse events associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Carers	Occupational Therapists
Community Care Centres	Procurement Managers
Community Nurses	Risk Managers
General public	Supplies Managers
Health Visitors	

BACKGROUND

Hill-Rom has received complaints advising that the centre bolt of the sling bar, which connects the bar to the patient lift, has failed during use. The potentially affected sling bars have been produced until May 2014.

The manufacturer has confirmed that if the Universal Slingbars are not used in accordance with the IFU, the center bolt of the device may become weakened, which could lead to the potential risk for breakage with the result of the free fall of the patient.

Hill-Rom has advised that there is no risk of this issue occurring if the device is used as intended, and in accordance with the IFU

Hill-Rom is requesting that users inspect the device in accordance with the accompanying FSN and Inspection Point Instruction sheet. If the device fails the tests, Hill-Rom will replace the sling bar free of change.

Hill-Rom continues to contact customers to that have not yet responded.

The HPRA is issuing this safety notice to raise awareness of this issue.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Liko AB
Nedre Vägen 100
Luleå
Sweden.

Telephone: +46 920 474700
Fax: +46 920 474701
E-mail: se.quality@hill-rom.com
Website: www.hillrom.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie