

Safety Notice

Medical Devices

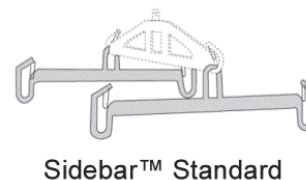
Liko SlingBar 350, SlingBar 360, SlingBar Wide 670, SideBar Standard

Part Numbers: 3156015, 3156002, 3156008,
3156004, 3156013, 3156012, 3156017 or
3156011

Distributed between April 1998 and May
2008.

Priority 2 – Warning

HPRA Safety Notice: SN2014(38)



Issue Date: 26th September 2014

| MANUFACTURER / SUPPLIER | HPRA CASE REFERENCE |
|---|---------------------|
| Manufacturer: Liko / Hill-Rom | V19001 |

| ISSUE |
|---|
| <p>The Health Products Regulatory Authority (HPRA) has been notified of an impalement risk on Liko SlingBar 350, SlingBar 360, SlingBar Wide 670 and SideBar Standard which can be attached to various Liko overhead and mobile lifts. The sling hook of the sling bar could pierce a body structure, such as the head, shoulder, or groin. The affected sling bars were distributed between April 1998 and May 2008. Liko/Hill-Rom is providing replacement sling bars to mitigate this impalement risk. The attached Field Safety Notice was issued to all potentially affected centres in October 2013. The exact quantity of devices placed on the Irish market during this period cannot be verified by the manufacturer. This Safety Notice has been issued as full reconciliation of affected units has not been achieved.</p> |

ACTION OR RECOMMENDATIONS

HPRA advises users to:

- 1 Follow the instructions in the manufacturer's field safety notice (FSN).
- 2 Determine the number of replacement sling bars you require.
- 3 Complete and return the Response Form included with the field safety notice.
- 4 Once replacement sling bars are received, discard the old ones.
- 5 Ensure relevant personnel receive a copy of the attached field safety notice.
- 6 Forward the FSN and this safety notice to any other persons/organisations where these devices have been transferred.

TARGET GROUPS

| | |
|--|-------------------------|
| HSE Hospital Staff | Purchasing Managers |
| Private Hospital Staff | Supplies Managers |
| Nursing Home Staff | Relevant Wards |
| Hospital Chief Executive Officers | Risk Managers |
| Clinical Engineers / Biomedical Engineer | Physiotherapists |
| Community Care Centres | Health Visitors |
| Occupational Therapists | Community Care Managers |
| Carers | |

BACKGROUND

No serious injuries or deaths have resulted from patients, caregivers, or bystanders tripping or falling into these sling bars. However Hill-Rom have previously replaced Standard Sling Bar 450 sling bar of similar design.

Product numbers 3153012 and 3156017 may also be bundled with mobile lifts:
Viking® 300 serial number 800000 through 800508 and
Viking® XL serial number 800509 through 800774.

MANUFACTURER CONTACT INFORMATION

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

Jody Smith
Hill-Rom Technical Support
Clinitron House,
Ashby Park,
Ashby De La Zouch,
Leicestershire, LE651JG
United Kingdom

Telephone: +44 (0) 1530562167
Fax: +44 (0) 1530411555
E-mail: UKCustomerCare@hill-rom.com
Website: www.hill-rom.co.uk

HPRA CONTACT INFORMATION

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

| | | |
|--------------------------------------|------------|--|
| Health Products Regulatory Authority | Telephone: | +353-1-6764971 |
| Kevin O'Malley House | Fax: | +353-1-6344033 |
| Earlsfort Centre | E-mail: | devicesafety@hpra.ie |
| Earlsfort Terrace , Dublin 2 | Website: | www.hpra.ie |