



رقم المحفوظات: ٣٨/٢٥
رقم الصادر: ١٣/١/٢٧١٢
بيروت، في: ٢٢ كانون الثاني ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Liko Standard Slingbar 450

الجهاز المعنى بالمتابعة:

- Liko Standard Slingbar 450
- Trade Mark: Hill Rom Inc
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA
الذي يحذر فيه من استعمال الصنف المذكور أعلاه بسبب وجود خلل في عمله مما قد يؤثر على
سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

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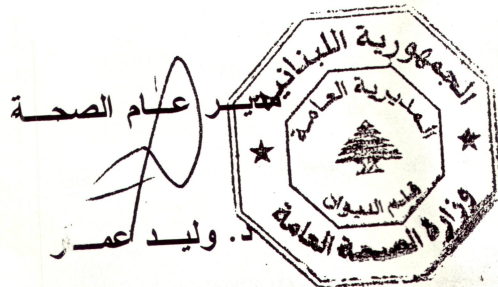
- التقرير الصادر عن وكالة ال FDA

يبلغ:

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- المستشفيات الحكومية

- المحفوظات



وثيقة مطابقة للأصل
تمت في ٢٦ كانون الثاني ٢٠١٣
رئيس قسم الدروس والتدريب
والعلاقات الصحية والتوليد
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Medical & Radiation Emitting Device Recalls

U.S. Food & Drug Administration

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1
2
3
4
5
6

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510(k)⁷ | Registration & Listing⁸ | Adverse Events⁹ | Recalls¹⁰ | PMA¹¹ | Classification¹² | Standards¹³ |
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Class 2 Recall Liko Standard Slingbar 450.

Date Posted	December 31, 2012
Recall Number	Z-0622-2013
Product	Liko Standard Slingbar 450. The Standard Slingbar 450 is a versatile sling bar which can be used for most lifting situations. It can be used with different Liko ceiling and mobile lifts.
Code Information	The Liko Standard Slingbar 450 accessory has been supplied under multiple product numbers and combined with the sale of mobile lifts. The Standard Slingbar 450 is not serialized and has been distributed between January 1980 and the present. Here are the different Product Numbers in which the Slingbar has been shipped under: Standard Slingbar 450: 20090029, 20190024, 20190041, 31190015, 31290017, 31290043, 3156001, 3156003, 3156007, 3156014, 3156016, 31590043, and 5019013. Packaged with Golvo up to April of 2005: 2000001, 2000003, 2000005, 2000006, 2000007, 2000008, 2000009, 2000009CH, 2000009D, 2000009DK, 2000009EU, 2000009F, 2000009FIN, 2000009J, 2000009N, 2000009NL, 2000009UK, 2000009U5, 2000010, 20000100, 20000100K, 2000010EU, 2000010F, 2000010FIN, 2000010H, 2000010J, 2000010N, 2000010NL, 2000010UK, 2000010U5, 2000050, 2000051, 2000061, IN8000, and IN8061. Packaged with Viking up to December of 2004: 2040003, 2040003L, 2040004, 2040005, 2040006, 2040007, 2040013, 2040014, 2040015, 2040033, 2040034, and 2040035. Packaged with LikoLight up to December of 2004: 2030001 and 2030001H. Packaged with Uno lifts up to present: 2010001, 2010002, 2010003, 2010003D, 2010003EU, 2010003F, 2010003H, 2010003N, 2010003UK, 2010003US, 2010004, 2010004D, 2010004EU, 2010004F, 2010004H, 2010004N, 2010004UK, 2010004US, 2010005, 20100050, 2010005EU, 2010005F, 2010005N, 2010005UK, 2010005U5, 2010011, 2010012, 5E2010004, and 5E2010011. Packaged with Caroli lifts up to present: 5011001.
Recalling Firm/ Manufacturer	Hill-Rom, Inc. 1069 State Route 46 East Batesville, Indiana 47006-7520
Reason for Recall	Liko/Hill-Rom has received reports from facilities which indicate that serious injuries have been received related to the Standard Sling bar 450. There have been 6 complaints of injury related to the product over the past 32 years (6 out of 838,687,856 estimated patient uses). One of the injuries was associated with a patient during use, four injuries occurred when the slingbar was not in use wher
Action	Hill-rom sent an URGENT MEDICAL DEVICE RECALL notification letter dated December 6, 2012, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. Customers were requested to please read, fill in completely, and return the Response Form to Hill-Rom immediately. This information will be compiled and reported to the applicable regulatory governing bodies. If we do not receive your response we will be required to contact you asking for your response. Continue to follow safe lifting practices, and do not allow unauthorized persons, especially children, to play around or operate the lift. If you have any questions concerning this Customer Safety Notification, please contact Hill-Rom Technical Support at 800-445-3720.
Quantity in Commerce	261 units
Distribution	Worldwide Distribution -- US (nationwide) including the states of AR, AZ, CA, CO, FL, GA, HI, IA, IL, IN, KS, KY, MA, ME, MI, MN, MO, MS, NC, NE, NJ, NM, NV, NY, OK, OR, PA, TN, TX, UT, WA, WV, and WY, and the country Canada. We have not yet defined our European or International facilities at this time.

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7. [../cfPMN/pmn.cfm](..../cfPMN/pmn.cfm)