RÉPUBLIQUE LIBANAISE
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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٥٠/٣٧١
رقم الصادر : ١٠/١١٩/١/١٢
بيروت، في : ١٩ تشرين الثاني ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي   Hoists, overhead/wall track system,

الجهاز المعني بالمتابعة:
- Hoists, overhead/wall track system, transfer hook - Trade Mark: Handicare

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود خلل في تصنيع الجهاز المذكور أعلاه مما يشكل خطرا" على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات.

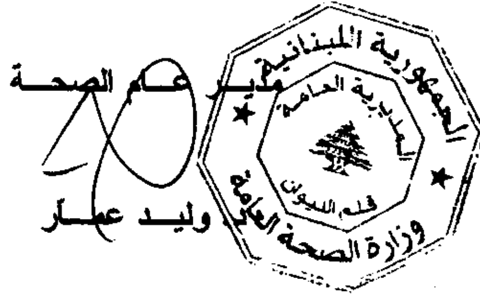
مرفق ربطا:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
وليد عمار



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handicare

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October 18, 2012

To our partners

Urgent field safety notice

Regarding RoomTransferHook 70200010

Affected devices
RoomTransferHook (RTH) distributed from Handicare AB before March 30, 2012. The design of **the affected hook does not include spring plungers**, red marked in figure 1.

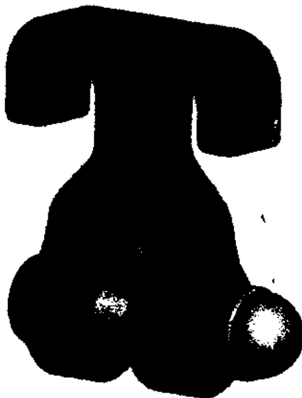

Fig. 1 Correct design of the double hook in RoomTransferHook 70200010.

Background information and reason for the Field safety corrective action
When manoeuvring a patient from one ceiling lift unit to another using an RTH, a critical point is the actual transfer of the RTH between the H-adapters at the end of the lift straps (Fig. 2). If the RTH is not correctly attached to the H-adapter, the RTH could slide out of the adapter, causing the patient to fall to the floor.

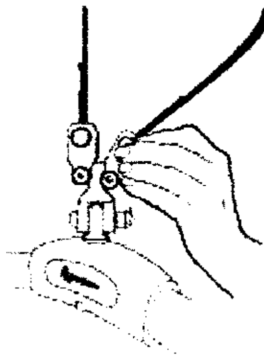

Fig. 2 Correct attachment of RTH to H-adapters.

handicare

The first models of Handicare's RTH did not include the spring plungers, but had other solutions. To further reduce the risk of incorrect use, the spring plunger was introduced as from March 30, 2012. As an act of precaution Handicare has now decided to replace all RTHs of the old design.

Actions to be taken by our partners

A check of the RTHs should be performed without any delay. Inspect your installations, warehouses etc and remove affected devices. Be sure to take them out of service and dispose of them properly.

Confirm that you have received this information and report back to Handicare AB's technical support as soon as possible, contact information below.

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Further information and technical advice

Handicare AB will provide new RTHs for replacement of the affected ones. These will be sent to you as soon as Handicare AB has them in stock, which will be within 2-4 weeks.

For confirmation, report, questions and technical advice regarding this issue, please contact:

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Handicare AB sincerely apologizes for any inconvenience this may cause our partners.

This notice has been notified the appropriate Regulatory Agency.

For and on behalf of
Handicare AB

Malin Wallström
Quality and environment manager