

REPUBLIC OF LEBANON

MINISTRY OF PUBLIC HEALTH

THE DIRECTOR GENERAL



الجمهورية اللبنانية

وزارة الصحة العامة

المدير العام

رقم المحفوظات: ٤٧/٢٥
رقم الصادر: ١٢/١٣٢٢٨٦
بيروت، في: ٣ تموز ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Wheelchairs, powered tilt/recline

الجهاز المعنى بالمتابعة:

- Wheelchairs, powered tilt/recline
- Trade Mark: Pride Mobility Products Ltd
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف الوارد أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

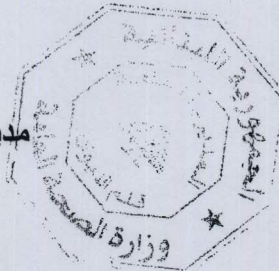
- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة

د. وليد عمار





Rev 1

32 Wedgwood Road
Bicester, Oxfordshire OX26 4UL

**Correction for model R40PED with MBL, LL-1000 power seat tilt actuator
manufactured from April 26th, 2012 to May 20th, 2013**

August 22nd 2013

**Urgent Field Safety Notice
Pride R40PED Powerchair**

Dear Dealer:

This letter is to inform you of a product safety correction on the on the R40PED (Sparky) powerchairs with tilt seating system manufactured by ANI from April 26th, 2012 to May 20th, 2013.

After evaluation of this unit, Pride has found that there is a potential for the stop bushing on the seating tilt actuator to fail. This may lead to a separation of the actuator's internal components and the seat tilting backwards to a degree much greater than intended. Furthermore, the end user may not have any means of detection for this failure mode prior to such an event.

Pride has received 2 consumer complaints on this issue. We acknowledge the potential that such a malfunction in the product can occur and could lead to serious personal injury and/or death.

In order to alleviate any potential for this type of malfunction, Pride will replace the actuator, part # LL-1000 manufactured by MBL, with a new assembly that has a more robust and proven stop bushing.

You will need to perform the following:

1. Locate any potentially affected R40PED (Sparky) powerchairs from the provided list of serial numbered units.
2. Contact the patient(s) and inform them of the product correction. **We have provided a sample letter that you may distribute to your users (consumers) alerting them to the device correction (see attached).**
3. Contact Pride to order the replacements parts (please have the serial number of the unit available).
4. Make an appointment with the consumer and replace the existing part.
5. Complete and return Pride's correction completion card that has been submitted to you. This card notifies Pride that you have completed the upgrade. The card must be completed in its entirety.

We apologize for any inconvenience this action may have caused you or your patient(s). Please be assured that Pride's efforts in this matter are intended to demonstrate our continued commitment to manufacturing safe, high quality products. Thank you for your continued support.

Contact reference person:
Brett Goddard
Pride Mobility Products Limited
32 Wedgwood Road
Bicester, Oxfordshire OX26 4UL
Telephone: 01869 324600 / Fax: 01869 323070

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

Thank you

Pride Mobility Product, Corporation