



رقم المحفوظات: ٧٧/٢٠٠
رقم الصادر: ١٢/٢٢٢٧٢
بيروت، في:

٣ تموز ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Walking aids, rollators frame. X-Fold Rollator

الجهاز المعني بالمتابعة:

- Walking aids, rollators frame. X-Fold Rollator
- Trade Mark: Drive Medical Ltdv
- 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 ربطا:

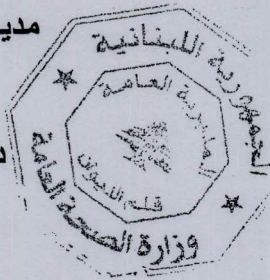
- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة

د. وليد عمار



Urgent Field Safety Notice

X-Fold Rollator
FSN WA018 16/08/13
Type of action : Backrest Replacement

drive™

Date: 16 Aug 2013

Attention: Drive Medical Stockists

Details on affected devices:

WA018 (X-Fold Rollator – pictured right)

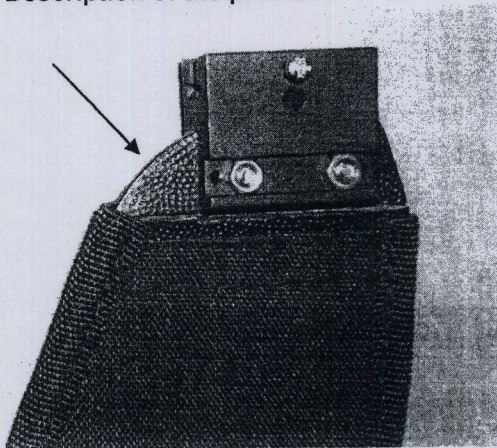
Batch 29486 with serial numbers: 2G121200401 TO 2G121200600

Batch 29763 with serial numbers: 2G121200001 TO 2G121200100

Dispatched from Feb 2013 to Aug 2013



Description of the problem:



The backrest on the above batches has an exposed plastic section on both the front and rear of the backrest (arrowed left).

If this section is bent or flexed repeatedly then it can break resulting in the backrest failing.

This could cause user injury.

This backrest design has only been fitted to rollators in the serial number series above and other X-Fold rollators are unaffected.

Advise on action to be taken by the dealer / user:

Drive Medical dealers should contact their customers with this information.

Affected backrests should be taken out of service and the serial numbers recorded on the sheet overleaf. The feedback sheet should be completed and sent back to Drive Medical who will issue replacement backrest(s). Upon receipt of the replacement part(s), the backrest should be installed and the faulty backrest disposed off.

Transmission of this Field Safety Notice: (if appropriate)

Distributed to Drive Medical Stockists and Issuers who have sold the rollators.

Contact reference person:

Paul Kendall
Drive Medical Ltd,
Ainley's Industrial Estate,
Elland, West Yorkshire HX5 9JP.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

P Kendall