



رقم المحفوظات: ٤٨٤٥
رقم الصادر: ١٣/١/٢٥٧٩٢
بيروت، في: ٢ - آب - ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Intraocular Lens Intraocular. T-flex Aspheric: 620H,
573T and 623T

الجهاز المعني بالمتابعة:

- Intraocular Lens Intraocular. T-flex Aspheric: 620H, 573T and 623T.
- Trade Mark: Rayner Intraocular Lenses 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، 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 عمّار

Urgent – Field Safety Notice (FSN)

Rayner Intraocular Lenses Limited

1-2 Sackville Trading Estate
Sackville Road
Hove
East Sussex
England
BN3 7AN

Telephone: +44 (0) 1273 205401

Fax: +44 (0) 1273 324623

www.rayner.com

07 June 2013

Ref: 2013-06-06 PR

To whom it may concern,

Healthcare professionals and consumers are advised that Rayner Intraocular Lenses Limited is voluntarily recalling certain Hydrophilic Acrylic Single Use Intraocular Lenses (IOLs) that are in distribution. Rayner Hydrophilic Acrylic Single Use IOLs are indicated for the replacement of the crystalline lens following the development of cataract.

In June 2013 Rayner Intraocular Lenses Limited identified a potential weakness of the outer paper pouch chevron seal. Rayner Intraocular Lenses Limited has determined that as a result of this weakness the sterility of the primary pack (the IOL blister pouch) may be compromised.

As a result of the findings of our investigations, a precautionary recall has been initiated. A review of our distribution history identifies that you have received the following product:

Device Name	Device Model Number	Device Lot Number	Quantity	Date of Sale
T-flex Aspheric	623T	053E4769801	1	30/05/2013
T-flex Aspheric	623T	053E4769802	1	30/05/2013
T-flex Aspheric	623T	053E4769901	1	30/05/2013
T-flex Aspheric	623T	053E4769902	1	30/05/2013

Information for Healthcare Professionals

Rayner Intraocular Lenses Limited advises all healthcare professionals to stop usage of the identified models, to quarantine any product from the identified batches that remain in their stock and to distribute this notice to all affected persons within your facility.

Instructions for Healthcare Facilities/Distributors

1. Identify and quarantine the products listed above.



Registered Office: Lowndes House, The Bury, Church Street, Chesham, Buckinghamshire, HP5 1DJ, England. Reg. No. 615539



