الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

ذكر المحروقات: 056
13/1/2014
بيروت، في: 2 - آب 2012

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز نظير معروف
Intraocular Lens Intraocular. T-flex Aspheric: 620H, 573T and 623T

الجهاز المعين. للمتابعة:
- Trade Mark: Rayner Intraocular Lenses Ltd
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية
Medicine and Health Care Products Regulatory Agency (UK) MHRA
والتصويت الصادرة عن الشركة المصنعة والتي تتضمن وجود خلل في عمل الصفح الموارد
أعلان نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربط:
التوصية الصادرة عن الشركة المصنعة
- مراجع
- دائرة البرامج والمشاريع
- المسابقات الحكومية
- المحروقات

مدير عام المستشفيات
د. وليد عمكر
Urgent – Field Safety Notice (FSN)

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:

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Device Model Number</th>
<th>Device Lot Number</th>
<th>Quantity</th>
<th>Date of Sale</th>
</tr>
</thead>
<tbody>
<tr>
<td>T-flex Aspheric</td>
<td>623T</td>
<td>05364769801</td>
<td>1</td>
<td>30/05/2013</td>
</tr>
<tr>
<td>T-flex Aspheric</td>
<td>623T</td>
<td>05364769802</td>
<td>1</td>
<td>30/05/2013</td>
</tr>
<tr>
<td>T-flex Aspheric</td>
<td>623T</td>
<td>05364769901</td>
<td>1</td>
<td>30/05/2013</td>
</tr>
<tr>
<td>T-flex Aspheric</td>
<td>623T</td>
<td>05364769902</td>
<td>1</td>
<td>30/05/2013</td>
</tr>
</tbody>
</table>

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.

2. Complete and return the enclosed ‘Rayner Intraocular Lenses Limited Field Safety Notice Response Form’ by e-mail to feedback@rayner.com or by fax to +44 (0) 1273 324623 Attention: Jodie Neal.

3. Return the affected items to Rayner Intraocular Lenses Limited. Returns must be clearly identified as “returned due to recall” and sent to the following address:

   FAO: Jodie Neal
   Rayner Intraocular Lenses Limited
   1-2 Sackville Trading Estate
   Sackville Road
   Hove
   East Sussex
   BN3 7AN
   England

Rayner Intraocular Lenses Limited’s Customer Commitment

Rayner Intraocular Lenses Limited sincerely apologises for any inconvenience this action may cause you. Replacement free of charge lenses will be issued to you at the earliest opportunity. If there is a scheduled operation date please advise us of this date and we will do our utmost best to ensure that your order is fulfilled before this time.

Rayner Intraocular Lenses Limited is committed to ensuring that our products are manufactured to the highest standard and wish to inform you that we take all such matters extremely seriously.

Notification to Competent Authorities

By copy of this letter, Rayner Intraocular Lenses Limited wishes to inform you that the National Competent Authority (NCA) has been notified of this Field Safety Corrective Action (FSCA).

Should you have any questions regarding this field action, please do not hesitate to contact me or your Rayner representation.

Yours Faithfully,

J Neal 04/06/12

Jodie Neal
Quality and Regulatory Affairs Associate
Rayner Intraocular Lenses Limited
## Rayner Intraocular Lenses Limited Field Safety Notice Response Form

**Facility Name:** Optimax  
**Country:** United Kingdom  
**Date of Issue:** 7th June 2013

<table>
<thead>
<tr>
<th>Device Name/Model</th>
<th>LOT Number</th>
<th>Quarantined</th>
<th>Implanted</th>
<th>Date of Implantation (DD/MM/YYYY)</th>
<th>Follow Up Action Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>T-flex Aspheric 623T</td>
<td>053E4769801</td>
<td>Yes No</td>
<td>Yes No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T-flex Aspheric 623T</td>
<td>053E4769802</td>
<td>Yes No</td>
<td>Yes No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T-flex Aspheric 623T</td>
<td>053E4769901</td>
<td>Yes No</td>
<td>Yes No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T-flex Aspheric 623T</td>
<td>053E4769902</td>
<td>Yes No</td>
<td>Yes No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Name of Person Completing Form:**

**Title of Person Completing Form:**

**Date of Completion:**

☐ I have read and understood the contents of this Field Action.

☐ I have notified all affected persons of this Field Action.

☐ I confirm that the affected devices in my possession will be returned to Rayner Intraocular Lenses. Please specify “N/A” if not applicable.

**Signature:**

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*Please return the completed form by e-mail to feedback@rayner.com or by fax to +44 (0) 1273 324623 for the attention of Jodie Neal.*