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

17 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	573T	053E4769701	1	30/05/2013
T-flex Aspheric	573T	053E4769702	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.

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: [redacted].

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: [redacted]

   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,

[redacted]
Quality and Regulatory Affairs Associate
Rayner Intraocular Lenses Limited

Rayner Intraocular Lenses Limited Field Safety Notice Response Form

Facility Name: Rayner Surgical Vertrieb GmbH

Country: Germany

Date of Issue: 7th June 2013

Device Name/Model	LOT Number	Quarantined	Implanted	Date of Implantation (DD/MM/YYYY)	Follow Up Action Taken
T-flex Aspheric 573T	053E4769701	Yes ☐ No ☐	Yes ☐ No ☐		
T-flex Aspheric 573T	053E4796702	Yes ☐ No ☐	Yes ☐ No ☐		
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*					
The form was translated into the following language(s) prior to distribution *Please specify translated l*anguage(s) or "N/A" if not applicable.) *If translated, please provide Rayner with a copy of the translation.*					
I confirm that the FSCA and FSN has been forwarded to the NCA *If no, please advise Rayner why the NCA was not notified.*				Yes ☐ No ☐	
Signature:					

Rayner

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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

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Yours Faithfully,

[redacted]

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

Device Name/Model	LOT Number	Quarantined	Implanted	Date of Implantation (DD/MM/YYYY)	Follow Up Action Taken
T-flex Aspheric 623T	053E4769801	Yes ☐ No ☐	Yes ☐ No ☐		
T-flex Aspheric 623T	053E4769802	Yes ☐ No ☐	Yes ☐ No ☐		
T-flex Aspheric 623T	053E4769901	Yes ☐ No ☐	Yes ☐ No ☐		
T-flex Aspheric 623T	053E4769902	Yes ☐ No ☐	Yes ☐ No ☐		
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.					
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Signature:					

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