

Field Safety Notice (FSN)

Rayner Intraocular Lenses Limited

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www.rayner.com

26 January 2015

Ref: 2015-01

To whom it may concern,

Healthcare professionals and stock control managers are advised that Rayner Intraocular Lenses Limited is voluntarily recalling certain Hydrophilic Acrylic Single Use Intraocular Lens system packs that are in distribution.

It has come to our attention that certain products released to market contain an injector (individually wrapped within the product carton) that has a slightly shorter expiry date than the expiry date as shown on the outer carton.

The individually wrapped injector has its own expiry date marked on the tyvek lid.

The expiry date of the associated injectors is around one month prior to that shown on the outer carton.

These products are safe to be implanted. There is no immediate issue associated with the use of the product. The affected products will not expire for at least four years eight months.

The affected lots may have an expiry date (on the outer carton) of November 2019, December 2019 or January 2020.

Identified product distributed in Denmark:

Batch	System Pack name	Product Model No.
65122	Sulcoflex Aspheric	653L
65643	C-flex Aspheric with RaySert PLUS	RSP970C
65651	C-flex Aspheric with RaySert PLUS	RSP970C
65653	C-flex Aspheric with RaySert PLUS	RSP970C
65655	C-flex Aspheric with RaySert PLUS	RSP970C

Batch	System Pack name	Product Model No.
66099	C-flex Aspheric with RaySert PLUS	RSP970C

Information for Healthcare Professionals, stock control managers and healthcare facilities:

All listed batches are safe to use for at least four years eight months (depending on the expiry date).

Rayner Intraocular Lenses Limited offers free replacement of any of these products that are not intended to be used in the short term.

Please refer to the list of affected product.

By 1st July 2015 please indicate over the page which products you will be returning and send the form along with the returned stock. Alternatively, send the form separately by email or fax to the below contact details.

Return contact details:

Return the completed response form and any product for replacement to:

Rayner Vigilance Department

Rayner Intraocular Lenses Limited

1-2 Sackville Trading Estate

Sackville Road

Hove

East Sussex

BN3 7AN

England

E-mail to feedback@rayner.com

Fax to +44 (0) 1273 324623 for the attention of: Rayner Vigilance Department.

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.

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.

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

Yours Faithfully,

Jneal

Jodie Neal
Quality and Regulatory Affairs Associate
Rayner Intraocular Lenses Limited

Rayner Intraocular Lenses Limited
Field Safety Notice Response Form

Device Name/Model	LOT Number	Returned for free replacement
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
Name and title of person completing form:		
Facility name:		
<input type="checkbox"/> I have read and understood the contents of this Field Action.		
<input type="checkbox"/> I have notified all affected persons of this Field Action.		
<input type="checkbox"/> I confirm that the affected devices that are unlikely to be used in the short term will be returned <i>Please specify "N/A" if not applicable</i>		
Signature:		

E-mail to feedback@rayner.com

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