Field Safety Notice (FSN)

Rayner Intraocular Lenses Limited

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Ref: 2015-02

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.

Internal quality checks have revealed that certain products released to market may contain a higher than usual level of residual polishing compound (aluminium oxide) that is used in the manufacturing process of intraocular lenses (IOLs).

Rayner maintains extremely high levels of product quality and has set stringent internal limits for residual aluminium oxide levels. There is a possibility that certain products released to market may contain levels that slightly exceed these limits.

As a precaution, and because clinically significant levels of aluminium oxide have, on rare occasions been linked to cases of Toxic Anterior Segment Syndrome (TASS) in published literature [1], Rayner Intraocular Lenses Limited has initiated a voluntary recall of these products.

Product sold to Denmark:

Product Name and Model Number	Batch Number	Power
Sulcoflex Aspheric 653L	105E77021	-0.5D

Information for stock control managers and healthcare facilities:

All listed batches (Lots) should be immediately quarantined in the first instance and then returned as promptly as possible (please refer to instructions below).

Rayner Intraocular Lenses Limited offers free replacement, reimbursement or substitution.

Information for Healthcare professionals and surgeons:

If a lens with an indicated serial number has already been implanted, it is recommended that as a precaution, you monitor for symptoms of TASS post operatively for up to a month in case of late onset presentation.

If cases of TASS do arise, please promptly report these cases to us and / or directly to your Health Authority.

Return contact details:

Return the completed response form and any product for replacement, reimbursement or substitution to:

FAO: Vigilance Department

Rayner Intraocular Lenses Limited

The Ridley Innovation Centre

10 Dominion Way

Worthing

BN14 8AQ

United Kingdom

The completed form may also be returned to Rayner via e-mail to feedback@rayner.com or by fax to +44 (0) 1903 258901.

Rayner Intraocular Lenses Limited's Customer Commitment

Rayner Intraocular Lenses Limited sincerely apologises for any inconvenience this action may cause you. Replacement, reimbursement or substitution 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,

Eleanor Rees

Regulatory Vigilance Manager
Rayner Intraocular Lenses Limited

Ref:

[1]*Don Calogero, MS et al;* Evaluation of Intraocular Reactivity to Metallic and Ethylene Oxide Contaminants of Medical Devices in a Rabbit Model; *Ophthalmology 2012;119:e36–e42*

Rayner Intraocular Lenses Limited

Field Safety Notice Response Form

Device Name/Model	LOT Number	Implanted	Returned to Rayner
		Yes ☐ No ☐	Yes ☐ No ☐
		Yes ☐ No ☐	Yes ☐ No ☐
		Yes ☐ No ☐	Yes ☐ No ☐
		Yes ☐ No ☐	Yes ☐ No ☐
		Yes ☐ No ☐	Yes ☐ No ☐
		Yes ☐ No ☐	Yes ☐ No ☐
		Yes ☐ No ☐	Yes ☐ No ☐
		Yes ☐ No ☐	Yes ☐ No ☐
		Yes ☐ No ☐	Yes ☐ No ☐

Name and title of person completing form:	
Facility name:	
☐ I have read and understood the contents of this Field Action.	
☐ I have notified all affected persons of this Field Action.	
Signature:	**Date:**

E-mail to feedback@rayner.com

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