Rayner

Rayner Intraocular Lenses Limited

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Hove
East Sussex
England
BN3 7AN

Telephone: +44 (0) 1273 205401
Fax: +44 (0) 1273 324623

www.rayner.com

[redacted]

Rayner Surgical Vertrieb GmbH

[redacted]

Germany

[redacted]

Urgent Field Safety Notice

Rayner Intraocular Lenses - Sulcoflex Aspheric (653L)
Batch – 050E10936
Type of action - Recall

Date: 31 March 2011

Dear Valued Customer,

Details of affected devices:
Product Name: Sulcoflex Aspheric
Product Model: 653L
Batch Number: 050E10936
Serial numbers of lenses delivered to you as follows:

February 2011: **050E1093623, 050E1093624, 050E1093630,**

March 2011: **050E1093636, 050E1093637**

Description of the problem:
It has come to the attention of Rayner Intraocular Lenses Limited that the labels of the affected batch are missing a plus (+) symbol prefixing the power value of 1.5D. The correct power value for this batch is +1.5D.

There is the potential for confusion as to whether the lens has a +1.5D value or a -1.5D value. If the lens were implanted, assuming it to be a -1.5D lens, this is likely to result in the patient having an incorrect post-operative refractive outcome. This may lead to the need for a further surgical procedure to explant the lens and implant a lens of the correct power.

Advice on action to be taken by the user:
You are asked to take the following steps to return the above mentioned product to us at our expense:

- Search all stocks for product of the above description and isolate it.
- Return to Rayner by the fastest possible means.

- Advise Rayner of lenses from the recall batch that have been implanted, using the attached form.
- Advise Rayner in writing of the action taken, using the attached form.

Upon receipt of your notification and returned product, credit will be issued for the invoiced cost of the products, plus any carriage and insurance charges. Please use the enclosed form to notify us. In the event that an immediate replacement of the product is required, Rayner Intraocular Lenses will honour a request by telephone or any other means, to ensure immediate shipment of a replacement or replacements.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Juliette Cook
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
E-mail: feedback@rayner.com

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Thank you for your attention to this letter. We appreciate your immediate co-operation.

Yours sincerely,

[redacted]

Juliette Cook
Head of Quality and Regulatory Affairs
Rayner Intraocular Lenses Limited

Attached: Customer Response Form

Recall of Sulcoflex Aspheric IOL model 653L (C11115/6)
Lot number: 050E10936
31st March 2011

Please submit form to:

Att: Juliette Cook
Rayner Intraocular Lenses Limited
1-2 Sackville Trading Estate
Sackville Road
Hove
East Sussex
BN3 7AN
Telephone: +44 (0) 1273 205 401
Fax: +44 (0) 1273 324623
e-mail: feedback@rayner.com

Customer Response – tick box and include details as appropriate.

In accordance with your instructions of 30th March 2011 we advise you that the following action has been taken:

☐ (Quantity) products have been returned to you with the product lot numbers identified as follows:

☐ The lenses with the following product lot numbers have been implanted and are not considered to be retrievable: (If applicable):

☐ The following surgeons have been notified of the nature of this recall, and have been asked to evaluate risk to individual patients (please state name of surgeon and hospital name and address):

Submitted by: (Name)

Job Title:

Signature:

Address:

Date: