Wednesday, September 20, 2017

[Contact Name]

Andrew Lindsay– QM Manager

[Business Name]
[Customer Address]
[City, State, Zip Code]

Carl Zeiss Ltd.
509 Coldhams Lane
Cambridge
Cambridgeshire
CB1 3JS
U.K.

URGENT: MEDICAL DEVICE RECALL

RE: Recall of Aaren Scientific, Inc. EC-3 Intraocular Lenses +10.0D

Dear [Customer Contact Name],

This voluntary action reflects Carl Zeiss Meditec's commitment to high quality standards and ensuring that our products fully meet your expectations. Carl Zeiss Meditec remains fully committed to serving you and your patients with safe and effective products.

Carl Zeiss Meditec is initiating this action due to detection of a potential labeling error that resulted in a total of Three (3) units being mislabeled with the wrong dioptric power. This may lead to myopic or hyperopic post-operative refractive outcomes, and potential explantation of the lens. Continued use of the serial number listed below is not recommended.

Our records show that you were shipped the following EC-3 Posterior Chamber Hydrophobic Acrylic Lens impacted by this action. We have listed the affected serial numbers below:

Part Number	Material Description	Diopter	Serial Number	Expiration Date
003500-0019-168	EC-3 Hydrophobic Lens	+10.0 D	3S1605000024	03/04/2021
003500-0019-168	EC-3 Hydrophobic Lens	+10.0 D	3S1605000026	
003500-0019-168	EC-3 Hydrophobic Lens	+10.0 D	3S1605000027	

]

The serial number(s) can be found at the top of each individual carton, please see page 3 for labeling example. The serial number is also present on the Tyvek pouch within the package.

Please undertake the following actions:

1. Compare your inventory against the above list.

2. **STOP** using and **REMOVE** from your inventory **all affected** EC-3 IOL Lenses listed above.
3. Complete and return the attached Customer Reply Form **EVEN IF YOU HAVE NO INVENTORY** affected by this recall, to Carl Zeiss Ltd., Quality Management at +44 1233 403 741 or email to andrew.lindsay@zeiss.com within **3 business days of receipt of this letter**.

Upon notification, Carl Zeiss Meditec will supply you will a Return Good Authorization Number to replace all remaining customer inventory of the affected product immediately.

Carl Zeiss Meditec requires this information for reconciliation purposes with regulatory agencies. No other Carl Zeiss Meditec EC-3 Posterior Chamber Hydrophobic Acrylic Lens are affected by this action.

This notice should be shared with anyone who needs to be aware within your organization or to any organization where the potentially affected products have been transferred. If you have inventory of any of the EC-3 Posterior Chamber Hydrophobic Acrylic Lens with the serial numbers listed, please contact your local ZEISS Sales Representative or Andrew Lindsay, Quality Manager at +44 1233 403 741 or email to andrew.lindsay@zeiss.com to arrange pick up of lenses to be returned.

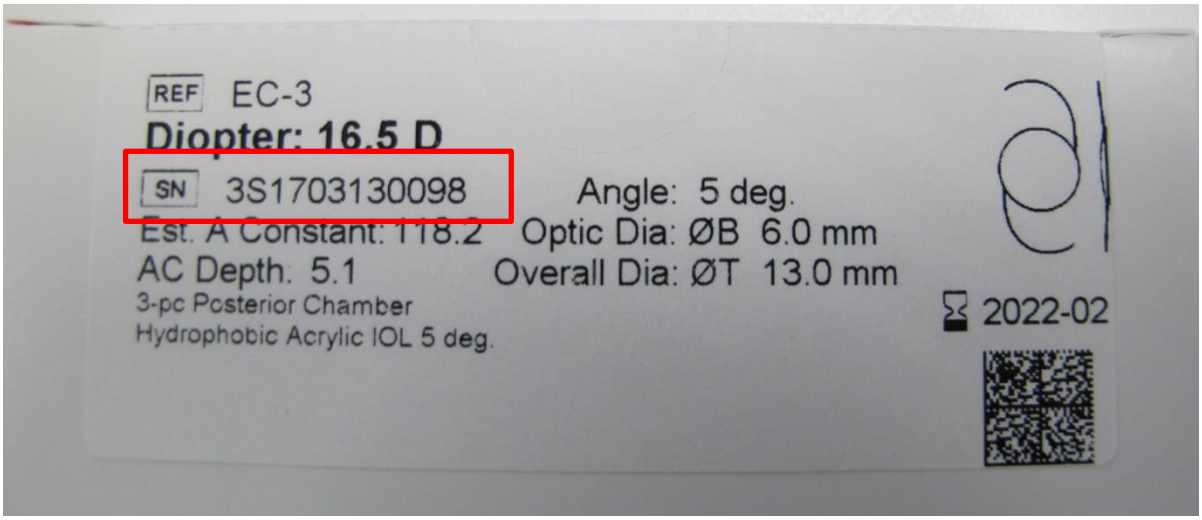
If you have product complaints or adverse events to report regarding the use of the EC-3 Posterior Chamber Hydrophobic Acrylic Lens, please inform Carl Zeiss Meditec. If you do report a complaint, please provide the EC-3 Posterior Chamber Hydrophobic Acrylic Lens serial number and, if a patient was involved, the date of surgery, and a description of the event and patient outcome.

We recognize the inconvenience this causes you and appreciate your assistance in expediting the return of this product.

Andrew Lindsay
Quality Manager
Carl Zeiss Ltd.
509 Coldhams Lane
Cambridge
Cambridgeshire
CB1 3JS
U.K.
Phone: +44 (0) 1223 403 741

EC-3 IOL Unit Carton Label Example

Serial Number Location



AAREN SCIENTIFIC, INC. EC-3 IOL RECALL CUSTOMER REPLY FORM

Please complete and return immediately **EVEN IF YOU HAVE NO STOCK**

Please send the form via Fax: 44 1223 403 756 or email to: andrew.lindsay@zeiss.com

Place an "X" in one of the boxes below:

☐ We have no stock of EC-3 Lenses involved in the recall.

☐ All affected EC-3 Lenses have been implanted or discarded.

☐ We are returning affected EC-3 Lenses

Model	Serial Number	Status of Z28 Cartridges (*Please check one (1) box for EACH Serial Number*)		
		Implanted	**Discarded**	**To be Returned**
EC-3 IOL	3S1605000024			
	3S1605000026			
	3S1605000027			

Person completing this form acknowledges the receipt and understanding of the actions, as stated in the Field Safety Notice:

Customer Account Number: _____

Account Name: _____

Address: _____

City, State, Zip Code _____

Telephone Number:

Name (print): _____

Title/Position: _____

Signature: _____

Date: _____