Monday, August 13, 2018

[Fill Customer Contact Name]

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

Your name here – QM Manager

Add your address here.

URGENT: MEDICAL DEVICE RECALL

RE: Recall of Carl Zeiss Meditec AG 611P CT Lucia Intraocular Lenses | +11.5 D

Dear [Customer Contact Name],

This Recall 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 Two (2) units that were possibly mislabeled with the wrong dioptric power. This may lead to myopic or hyperopic post-operative refractive outcome 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 611P CT Lucia Hydrophobic Acrylic Posterior Chamber Intraocular Lens impacted by this action. We have listed the affected serial numbers below:

Part Number	Material Description	Diopter	Serial Number	Expiration Date
003500-0026-367	611P CT LUCIA Hydrophobic Lens	+11.5 D	3S1610660163	2019-03-31
003500-0026-367	611P CT LUCIA Hydrophobic Lens	+11.5 D	3S1610660174	

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. If the lenses have been implanted and there were no issues noted, **No further actions are needed to be taken.**
3. If you, identify that any of the listed serial numbers are still within your inventory **STOP** using and **REMOVE** from your inventory.

4. Complete the Customer Reply Form and fax or send to your CZM VG mbH, Quality Management at +49 7364 205499 or email at juergen.ott@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 611P CT Lucia 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 611P CT Lucia Posterior Chamber Hydrophobic Acrylic Lens with the serial numbers listed, please contact your local ZEISS Sales Representative or **Your name here,** Quality Manager at **Please add your Fax number** or email to **juergen.ott@zeiss.com** in order to arrange pick up of lenses to be returned.

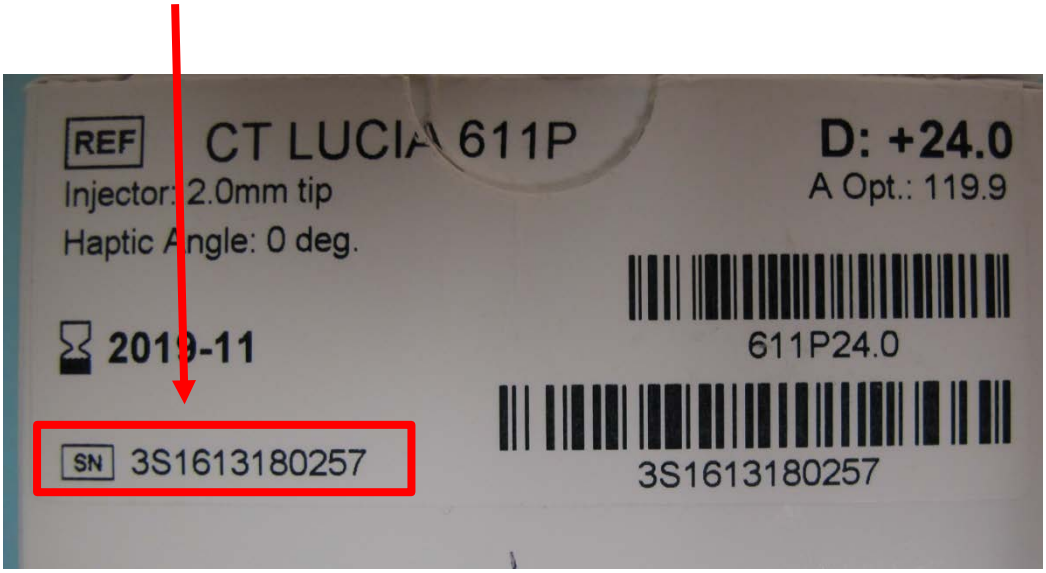
If you have product complaints or adverse events to report regarding the use of the 611P CT Lucia Posterior Chamber Hydrophobic Acrylic Lens, please inform Carl Zeiss Meditec Production, LLC. If you do report a complaint, please provide the 611P CT Lucia Posterior Chamber Hydrophobic Acrylic Lens serial 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.

Your name here
Quality Manager
[QM Contact Information Here]

CT Lucia Hydrophobic IOL Unit Carton Label Example

Serial Number Location



CARL ZEISS MEDITEC 611P CT LUCIA IOL RECALL CUSTOMER REPLY FORM

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

Please send the form via Fax: +49 7364 20 4959 or email: juergen.ott@zeiss.com

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

☐ We have no stock of 611P CT Lucia IOL involved in the recall.

☐ All affected 611P CT Lucia IOL have been implanted or discarded.

☐ We are returning affected 611P CT Lucia IOL

Model	**Serial Number**	**Status of 611P CT Lucia Hydrophobic Acrylic IOL** ***(Please check one (1) box for EACH serial number)***		
		Implanted	**Discarded**	**To be Returned**
611P CT Lucia IOL	3S1610660163			
	3S1610660174			

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: _____