



Carl Zeiss Meditec Vertriebsgesellschaft mbH 73447 Oberkochen

Monday, February 05, 2018

[Contact Name]

**Carl Zeiss Meditec
Vertriebsgesellschaft mbH**
ZEISS Gruppe

[Business Name]

Rudolf-Eber-Straße 11
73447 Oberkochen

[Customer Address]

[City, State, Zip Code]

URGENT: MEDICAL DEVICE RECALL

RE: Recall of Carl Zeiss Meditec AG 611P CT Lucia Intraocular Lenses | +19.5 D

Dear [Customer Contact Name],

This 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 Sixteen (16) 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	Dioptric	Serial Number	Expiration Date
003500-0026-383	611P CT LUCIA Hydrophobic Lens	+19.5 D	3S1609150722	2019-02-28
003500-0026-383	611P CT LUCIA Hydrophobic Lens	+19.5 D	3S1609150735	
003500-0026-383	611P CT LUCIA Hydrophobic Lens	+19.5 D	3S1609150736	
003500-0026-383	611P CT LUCIA Hydrophobic Lens	+19.5 D	3S1609150737	
003500-0026-383	611P CT LUCIA Hydrophobic Lens	+19.5 D	3S1609150739	
003500-0026-383	611P CT LUCIA Hydrophobic Lens	+19.5 D	3S1609150751	
003500-0026-383	611P CT LUCIA Hydrophobic Lens	+19.5 D	3S1609150752	
003500-0026-383	611P CT LUCIA Hydrophobic Lens	+19.5 D	3S1609150754	
003500-0026-383	611P CT LUCIA Hydrophobic Lens	+19.5 D	3S1609150756	
003500-0026-383	611P CT LUCIA Hydrophobic Lens	+19.5 D	3S1609150763	
003500-0026-383	611P CT LUCIA Hydrophobic Lens	+19.5 D	3S1609150764	
003500-0026-383	611P CT LUCIA Hydrophobic Lens	+19.5 D	3S1609150765	
003500-0026-383	611P CT LUCIA Hydrophobic Lens	+19.5 D	3S1609150766	
003500-0026-383	611P CT LUCIA Hydrophobic Lens	+19.5 D	3S1609150768	
003500-0026-383	611P CT LUCIA Hydrophobic Lens	+19.5 D	3S1609150769	



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** 611P CT Lucia IOL listed above.
3. Complete and return the attached Customer Reply Form **EVEN IF YOU HAVE NO INVENTORY** affected by this recall, to CZM VG mbH, Quality Management at +49 7364 204939 or email to qm.mvg.meditec.de@zeiss.com within **3 business days of receipt of this letter**.

Upon notification, Carl Zeiss Meditec will supply you with 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 Andreas Roth, Quality Manager at +49 7364 205499 or email to qm.mvg.meditec.de@zeiss.com to arrange to 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.

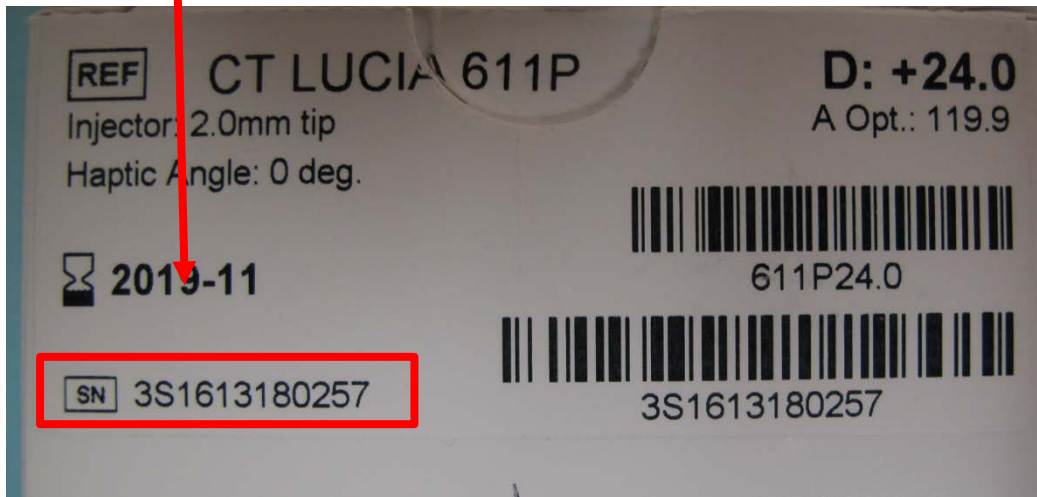


Quality Manager
[QM Contact Information Here]



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 4939 or email: qm.mvg.meditec.de@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)		
		Consumed	Discarded	To be Returned
611P CT Lucia IOL	3S1609150722			
	3S1609150735			
	3S1609150736			
	3S1609150737			
	3S1609150739			
	3S1609150751			
	3S1609150752			
	3S1609150754			
	3S1609150756			
	3S1609150763			
	3S1609150764			
	3S1609150765			
	3S1609150766			
	3S1609150768			
	3S1609150769			
	3S1609150774			

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: _____