Carl Zeiss Meditec AG 10589 Berlin

Carl Zeiss Meditec AG
Berlin Site
Max-Dohrn-Strasse 8-10
10589 Berlin, Germany

[redacted]

e-mail: katrin.krause@zeiss.com

Your ref.:

Division/Dept.: QM

Yours of:

Your contact: Gildas Lorec, Claudia Minke

Our ref.:FCACoCe8 2017-01

Date: 01/02/2017

URGENT/IMMEDATE ACTION REQUIRED: FIELD SAFETY CORRECTIVE ACTION (FSCA)

RECALL intraocular lenses CT ASPHINA 409MP batch 1S162290

Dear Customer,

You are using our intraocular lenses **CT ASPHINA 409MP** and we thank you for your loyalty to our products.
As you know, high quality and innovation is our main goal, but your safety and satisfaction is our first priority.
To ensure that you are able to continue reliably use of our system/products with the level of high quality you expect, Carl Zeiss Meditec is planning to perform a Field Safety Corrective Action.

With this letter, we would like to inform you that we have detected a potential labeling error on a production order of the above-mentioned IOLs. We want to give you a precise description of the situation and provide clear guidance on how to avoid any inconveniences with your patients and in your center.

Problem description:

A labeling error has been detected on a lot of 23 lenses CT ASPHINA 409MP 20.0D. It was detected that the lens inside the primary packaging could be trifocal lens with a lower diopter.

All necessary actions have been done that no other batch is affected.

Hazard description:

As a consequence, it could lead a wrong implantation and post-operative refraction error for the patient.

If you have already implanted this device, please review the refractive outcome for the patient. In the case of a myopic shift, you may require additional surgery to correct the error, based on your judgement of the benefit / risk for the patient:

- either an explantation /reimplantation of a new IOL,

- or a secondary IOL implantation in sulcus,
- or an additional refractive surgery,
- or eyeglasses/contact lenses correction prescription.

Affected product:

23 intraocular lenses have been identified to be affected.

Our traceability records indicate that you have received the following affected lenses :

Product Name	Diopter (D)	Serial Number

Actions & Recommendation:

Please check the status of all affected products you have:

If you have still the lenses in stock, please place them immediately in quarantine and contact your local ZEISS representative. These lenses have to be shipped back to ZEISS.

If you have implanted affected lenses, please review the refractive outcome of your patient.

Please inform the relevant persons within your healthcare structure who are involved in the above mentioned ZEISS intraocular lenses use.

We kindly ask you to send back to us the acknowledge receipt of the letter which you will find in Appendix 1.

This Field Safety Corrective Action will be reported to your local Health Authorities in accordance with the European regulations.

We thank you very much for your careful attention, your consequent verifications and your continuous support. We apologize for any inconveniences this situation might cause, and remain at your disposal.

Yours sincerely,

[redacted]

Appendix 1: Confirmation sheet

RECALL CT ASPHINA 409MP – FCA CoCe8 2017-01

I have read, understood the FSCA-RECALL related to CT ASPHINA 409MP 20.0D

I have transmitted the information to the relevant persons within my healthcare structure.

Status of the affected lenses :

Product Name	Diopter (D)	Serial Number	Lens Status : -Blocked/sent back to ZEISS -Implanted/Patient outcome

Confirmation:

Signature:_____ Date:_____

Name:	
Function:	
Address:	
Phone:	
E-mail address:	

Please send back this confirmation form:
By e-mail to claudia.minke@zeiss.com or gildas.lorec@zeiss.com
or by FAX +49 30 854001-123