Carl Zeiss Meditec AG 10589 Berlin

To whom it may concern

Carl Zeiss Meditec AG

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Division/Dept.: Complaint Management & Vigilance
Your contact: Dr. Lucia Püttmann, Sophie Ortega

Your ref.: N/A
Yours of: N/A
Our ref.: FSCA CoCe8 2022-003
Date: 2022-10-17

URGENT/IMMEDATE ACTION REQUIRED:
FIELD SAFETY CORRECTIVE ACTION (FSCA)
RECALL intraocular lenses CT ASPHINA 409M 15.5D & 24.5D

Dear Customer,

You are using our intraocular lenses **CT ASPHINA 409M** and we thank you for your loyalty and trust in our products.

At ZEISS, the quality and safety of all our products is our highest priority. Unfortunately, with this letter, we must inform you, that we detected a possible labelling error on a production order of the above-mentioned IOLs and that we will therefore perform a Field Safety Corrective Action. In the following, we will give you a precise description of the situation and provide clear guidance on how to avoid any inconveniences for your patients.

Problem description
A customer informed us of an unexpected refractive outcome in one of their patients with a CT ASPHINA 409M 15.5D, manufactured in one the production orders affected by this recall. The subsequent internal investigation suggests that lenses from two production orders could have been mixed up.

In consequence, we, Carl Zeiss Meditec AG, have decided to recall all IOLs from these two production orders, to inform customers and prevent further implantation of an IOL with the wrong diopter to avoid further harm to patients.

Affected products

Our database indicates that you have received the lenses referenced hereafter:

France:

Product name	**Serial number**
CT ASPHINA 409M DPT 24.5	6S220302E497
CT ASPHINA 409M DPT 24.5	6S220302E507
CT ASPHINA 409M DPT 24.5	6S220302E508

Germany:

Product name	**Serial number**
CT ASPHINA 409M DPT 15.5	6S220302E464
CT ASPHINA 409M DPT 15.5	6S220302E466
CT ASPHINA 409M DPT 15.5	6S220302E472
CT ASPHINA 409M DPT 15.5	6S220302E467
CT ASPHINA 409M DPT 15.5	6S220302E468
CT ASPHINA 409M DPT 15.5	6S220302E469
CT ASPHINA 409M DPT 15.5	6S220302E471
CT ASPHINA 409M DPT 15.5	6S220302E473
CT ASPHINA 409M DPT 15.5	6S220302E474
CT ASPHINA 409M DPT 15.5	6S220302E476
CT ASPHINA 409M DPT 15.5	6S220302E478
CT ASPHINA 409M DPT 15.5	6S220302E479
CT ASPHINA 409M DPT 15.5	6S220302E480

Product name	Serial number
CT ASPHINA 409M DPT 15.5	6S220302E481
CT ASPHINA 409M DPT 24.5	6S220302E486
CT ASPHINA 409M DPT 24.5	6S220302E487
CT ASPHINA 409M DPT 24.5	6S220302E488
CT ASPHINA 409M DPT 24.5	6S220302E489
CT ASPHINA 409M DPT 24.5	6S220302E490
CT ASPHINA 409M DPT 24.5	6S220302E491
CT ASPHINA 409M DPT 24.5	6S220302E492
CT ASPHINA 409M DPT 24.5	6S220302E493
CT ASPHINA 409M DPT 24.5	6S220302E494
CT ASPHINA 409M DPT 24.5	6S220302E495
CT ASPHINA 409M DPT 24.5	6S220302E499
CT ASPHINA 409M DPT 24.5	6S220302E500
CT ASPHINA 409M DPT 24.5	6S220302E501
CT ASPHINA 409M DPT 24.5	6S220302E503
CT ASPHINA 409M DPT 24.5	6S220302E505
CT ASPHINA 409M DPT 24.5	6S220302E506

Slovenia:

Product name	Serial number
CT ASPHINA 409M DPT 15.5	6S220302E463
CT ASPHINA 409M DPT 15.5	6S220302E465
CT ASPHINA 409M DPT 15.5	6S220302E483
CT ASPHINA 409M DPT 24.5	6S220302E496

Romania:

Product name	Serial number
CT ASPHINA 409M DPT 24.5	6S220302E498
CT ASPHINA 409M DPT 24.5	6S220302E502
CT ASPHINA 409M DPT 24.5	6S220302E504

Hazard description
Consequently, the implantation of a wrong lens could lead to a refractive error of the patient.

If you have already implanted this device, please review the refractive outcome for the patient. In case of a wrong refraction results, an additional surgery may be required 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.

Actions & Recommendation:
Please check the status of all affected products you have:

- If you have still one of these 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 the affected lenses, please review the refractive outcome of your patient.

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

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 for your careful attention, your consequent verifications, and your continuous support. We sincerely regret the inconvenience caused and thank you for addressing the matter promptly. We remain at your disposal.

Yours sincerely,

Carl Zeiss Meditec AG
i.V.

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Dr. Lucia Püttmann
Head of Complaint Management & Vigilance
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Carl Zeiss Meditec AG
i.V.

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Dr. Constantin Brachtendorf
Head of Product Management Routine Cataract Implants & Consumables
ZEISS Ophthalmic Devices

Annex

Appendix 1: Confirmation sheet

RECALL CT ASPHINA 409M – FCA CoCe8 2022-003

I have read and understood the FSCA-RECALL related to CT ASPHINA 409M 15.5D & 24.5D.

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

Status of the affected lenses:

Product Name and Dioptre (D)	**Serial Number(s)**	**Lens Status:** • **Blocked/Sent back to ZEISS** • **Implanted/Patient outcome**
CT ASPHINA 409M 15.5D		
CT ASPHINA 409M 24.5D		

Confirmation:

Signature:_____ Date:_____

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

Please send back this confirmation form via e-mail to

- dl.med-complaints-lrb.all@zeiss.com