



Carl Zeiss Meditec AG 10589 Berlin

To whom it may concern

Division/Dept.: Complaint Management & Vigilance
Your contact: Dr. Lucia Puettmann, Claudia Minke

Carl Zeiss Meditec AG

Berlin location
Max-Dohrn-Strasse 8-10
10589 Berlin
Germany

Phone: N/A
Fax: N/A
E-mail: dl.med-complaints-lrb.all@zeiss.com

Your ref.: N/A
Yours of: N/A
Our ref.: FSCA ONT 2024-002
Date: 2024-06-14

URGENT/IMMEDIATE ACTION REQUIRED:

**FIELD SAFETY CORRECTIVE ACTION (FSCA)
RECALL intraocular lens CT LUCIA 221P 23.0D & 28.5D**

Dear Customer,

You are using our intraocular lenses **CT LUCIA 221P** 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 two patients with an CT LUCIA 221P 23,0 diopter, manufactured in batch 3S231095. The subsequent internal investigation suggests that lenses from different batch could have been mixed up.

A potential partial mix-up of IOLs within another work order from IOLs manufactured in parallel in one manufacturing step could be the root cause: A potential mix-up work order (CT LUCIA 221P 28.5D) has been identified. It explains the refractive error from both complaints.

Address of Record:
Goeschwitzer Strasse 51 - 52
07745 Jena, Germany

Address for Delivery:
Carl Zeiss Meditec AG
Max-Dohrn-Strasse 8 - 10
10589 Berlin, Germany

Banks:
Deutsche Bank Jena
Account: 624536900 (BIC 820 700 00)
IBAN: DE90 8207 0000 0624 5369 00
BIC/ SWIFT: DEUT DE 8EXXX

Commerzbank Jena
Account: 258072800 (BIC 820 400 00)
IBAN: DE31 8204 0000 0258 0728 00
BIC/ SWIFT: COBADEFFXXX

Commercial Register:
Local Court Jena HRB 205623

VAT-ID No.: DE 811 922 737
WEEE-Reg.-No.: DE55298748

Chairman of the Supervisory Board:
Dr. Karl Lamprecht

Board of Management:
Dr. Markus Weber (CEO)
Justus Felix Wehmer

In consequence, we, Carl Zeiss Meditec AG, have decided to initiate a Field Safety Corrective Action for all IOLs from these two work 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 may have received the lenses referenced hereafter:

Germany:

Material	Description	Serial Number	Batch
003500-0034-865	CT LUCIA 221P TIP2.2 DPT 23.0	3S2310950281	3S231095
003500-0034-865	CT LUCIA 221P TIP2.2 DPT 23.0	3S2310950282	3S231095
003500-0034-865	CT LUCIA 221P TIP2.2 DPT 23.0	3S2310950283	3S231095
003500-0034-865	CT LUCIA 221P TIP2.2 DPT 23.0	3S2310950285	3S231095
003500-0034-865	CT LUCIA 221P TIP2.2 DPT 23.0	3S2310950292	3S231095
003500-0034-865	CT LUCIA 221P TIP2.2 DPT 23.0	3S2310950284	3S231095
003500-0034-865	CT LUCIA 221P TIP2.2 DPT 23.0	3S2310950290	3S231095
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960224	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960225	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960226	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960228	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960229	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960231	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960232	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960233	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960236	3S231096

Italy:

Material	Description	Serial Number	Batch
003500-0034-865	CT LUCIA 221P TIP2.2 DPT 23.0	3S2310950286	3S231095
003500-0034-865	CT LUCIA 221P TIP2.2 DPT 23.0	3S2310950287	3S231095
003500-0034-865	CT LUCIA 221P TIP2.2 DPT 23.0	3S2310950288	3S231095
003500-0034-865	CT LUCIA 221P TIP2.2 DPT 23.0	3S2310950289	3S231095
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960234	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960243	3S231096

Czech Republic:

Material	Description	Serial Number	Batch
003500-0034-865	CT LUCIA 221P TIP2.2 DPT 23.0	3S2310950291	3S231095
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960230	3S231096

Turkey:

Material	Description	Serial Number	Batch
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960194	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960203	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960204	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960205	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960206	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960207	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960208	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960209	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960210	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960211	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960212	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960213	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960214	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960215	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960216	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960217	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960218	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960219	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960220	3S231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960221	3S231096

El Salvador:

Material	Description	Serial Number	Batch
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	3S2310960222	3S231096

Mexico:

Material	Description	Serial Number	Batch
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960195	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960196	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960197	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960198	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960199	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960200	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960201	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960202	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960223	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960227	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960235	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960237	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960238	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960239	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960240	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960241	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960242	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960244	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960245	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960246	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960247	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960248	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960249	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960250	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960251	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960252	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960253	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960254	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960255	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960256	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960257	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960258	35231096
003500-0034-876	CT LUCIA 221P TIP2.4 DPT 28.5	352310960259	35231096

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 must 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 or Local 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.

Carl Zeiss Meditec AG
i.V.

Dr. Lucia Puettmann
Head of Complaint Management & Vigilance
ZEISS Medical Technology Segment

Claudia Minke
Complaint & Vigilance Manager
Implants & Consumables
ZEISS Medical Technology Segment

Annex

Appendix 1: Confirmation sheet

RECALL CT LUCIA 221P 23.0D & 28.5D – FSCA ONT 2024-002_CT LUCIA 221P

I have read and understood the FSCA-RECALL related to CT LUCIA 221P 23.0D & 28.5D

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

Status of the affected lenses:

Product Name and Diopter (D)	Serial Number(s)	Lens Status: <ul style="list-style-type: none"> • Blocked/Sent back to ZEISS • Implanted/Patient outcome

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