Carl Zeiss Meditec AG 10589 Berlin

To whom it may concern

Carl Zeiss Meditec AG

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Division/Dept.: Complaint Management & Vigilance

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Your ref.: N/A

Yours of: N/A

Our ref.: FSCA BER 2025-01

Date: 2025-01-15

URGENT/IMMEDATE ACTION REQUIRED:

FIELD SAFETY CORRECTIVE ACTION (FSCA)

RECALL of Toric Intraocular Lenses (repacked units)

Dear Customer,

You are using our intraocular lenses (IOL) 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:
During the repackaging process in production, it has been detected that some secondary labels showed an incorrect dataset for sphere and cylinder diopter. It is important to note that the primary label on the lens vial or barquette always contains the correct dataset of sphere and cylinder diopter.

We are performing repacking exclusively for toric IOLs; therefore, non-toric IOLs are not affected.

The potentially affected repacked toric IOLs have been identified. Until today we have not received complaints with any of these IOLs nor negative reports from dealers or SSCs. Nevertheless, it remains possible that a product with incorrect information on the secondary label has entered the market.

In consequence, we, Carl Zeiss Meditec AG, have decided to initiate a Field Safety Corrective Action for all IOLs identified, 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 one or multiple lenses referenced hereafter:

Serial Number	IOL Description	Country
1S231344E019	AT TORBI 709MP DPT -00.5 CYL 01.0	AU
1S232489E087	AT LISA TRI TORIC 949MP SE+24.50 CYL01.5	BE
1S232505E281	AT LISA TRI TORIC 949MP SE+23.50 CYL01.5	BE
1S232807E124	AT LISA TRI TORIC 949MP SE+23.50 CYL01.0	BE
1S233080E021	AT LISA TRI TORIC 949MP SE+23.50 CYL01.0	BE
1S232200E137	AT TORBI 719MP SE+17.00 CYL02.5	CH
1S212124E038	AT LISA TRI TORIC 949MP SE+21.00 CYL02.5	DE
1S212413E021	AT TORBI 719M SE+22.50 CYL02.5	DE
1S212413E022	AT TORBI 719M SE+22.50 CYL02.5	DE
1S223032E125	AT LISA TRI TORIC 949MP SE+10.50 CYL03.5	DE
1S230725E135	AT LISA TRI TORIC 949MP SE+23.50 CYL01.5	DE
1S230993E043	AT LISA TRI TORIC 949MP SE+13.50 CYL02.5	DE
1S231094E236	AT LISA TRI TORIC 949MP SE+18.00 CYL01.5	DE
1S231677E042	AT LISA TRI TORIC 949MP SE+09.50 CYL02.5	DE
1S232031E053	AT LISA TRI TORIC 949MP SE+26.00 CYL01.0	DE
1S232179E186	AT TORBI 719MP SE+20.50 CYL01.5	DE
1S232461E059	AT LISA TRI TORIC 949MP SE+19.00 CYL02.0	DE
1S232512E021	AT LISA TRI TORIC 949MP SE+26.00 CYL01.5	DE
1S232600E038	AT LISA TRI TORIC 949MP SE+25.00 CYL01.5	DE
1S232611E066	AT LISA TRI TORIC 949MP SE+19.00 CYL01.0	DE
1S232626E032	AT TORBI 719M SE+23.00 CYL08.0	DE
1S232672E051	AT LISA TRI TORIC 949MP SE+09.00 CYL01.5	DE
1S232728E102	AT LISA TRI TORIC 949MP SE+19.50 CYL01.5	DE
1S232872E029	AT TORBI 719M SE+33.00 CYL03.5	DE
1S232880E066	AT LISA TRI TORIC 949MP SE+26.00 CYL01.5	DE
1S232899E001	AT LISA TRI TORIC 949MP SE+15.00 CYL01.5	DE
1S232899E008	AT LISA TRI TORIC 949MP SE+15.00 CYL01.5	DE
1S232899E025	AT LISA TRI TORIC 949MP SE+14.00 CYL02.0	DE
1S232899E069	AT LISA TRI TORIC 949MP SE+13.50 CYL01.0	DE
1S232914E109	AT LISA TRI TORIC 949MP SE+21.50 CYL01.5	DE
1S232955E122	AT LISA TRI TORIC 949MP SE+16.50 CYL02.0	DE
1S233318E152	AT LISA TRI TORIC 949MP SE+22.00 CYL01.5	DE
1S233491E059	AT LISA TRI TORIC 949MP SE+25.00 CYL01.0	DE
1S233491E119	AT LISA TRI TORIC 949MP SE+22.00 CYL01.5	DE

Serial Number	IOL Description	Country
1S233615E044	AT LISA TRI TORIC 949MP SE+15.50 CYL01.0	DE
1S233655E018	AT TORBI 719M SE+25.50 CYL12.0	DE
1S233658E084	AT LISA TRI TORIC 949MP SE+27.00 CYL01.0	DE
1S240199E171	AT LISA TRI TORIC 949MP SE+25.00 CYL01.0	DE
1S240226E094	AT LISA TRI TORIC 949MP SE+20.50 CYL01.0	DE
1S240341E076	AT LISA TRI TORIC 949MP SE+22.00 CYL01.5	DE
1S240412E082	AT LISA TRI TORIC 949MP SE+21.50 CYL01.0	DE
1S240496E034	AT LISA TRI TORIC 949MP SE+24.00 CYL01.0	DE
1S240711E022	AT TORBI 719MP SE+02.50 CYL02.0	DE
1S240894E133	AT LISA TRI TORIC 949MP SE+27.00 CYL01.0	DE
1S240188E083	AT LISA TRI TORIC 949MP SE+20.00 CYL01.0	DK
1S240381E130	AT LISA TRI TORIC 949MP SE+20.00 CYL01.0	DK
1S240894E103	AT LISA TRI TORIC 949MP SE+20.00 CYL01.5	DK
1S212388E080	AT TORBI 719M SE+15.50 CYL02.5	ES
1S212614E085	AT TORBI 719M SE+25.50 CYL05.5	ES
1S231951E203	AT LISA TRI TORIC 949MP SE+21.50 CYL02.5	ES
1S232098E212	AT TORBI 719MP SE+15.50 CYL03.5	ES
1S240118E049	AT LISA TRI TORIC 949MP SE+19.50 CYL02.0	ES
1S241425E016	AT TORBI 719MP SE+05.00 CYL02.5	ES
1S212614E002	AT TORBI 719M SE+21.50 CYL05.0	FR
1S212638E025	AT TORBI 719M SE+25.50 CYL02.5	FR
1S231363E035	AT TORBI 719MP SE+18.00 CYL02.5	FR
1S231963E009	AT TORBI 719MP SE+18.00 CYL02.5	FR
1S232383E216	AT TORBI 719MP SE+28.00 CYL02.0	FR
1S232872E102	AT TORBI 719M SE+17.50 CYL04.5	FR
1S233261E026	AT TORBI 719MP SE+17.00 CYL02.5	FR
1S233310E012	AT TORBI 719M SE+18.50 CYL06.5	FR
1S233560E078	AT TORBI 719M SE+29.00 CYL04.5	FR
1S241026E027	AT TORBI 719M SE+16.00 CYL06.0	FR
1S241825E016	AT TORBI 719M SE+22.00 CYL08.0	FR
1S231589E156	AT TORBI 709MP DPT 20.5 CYL 02.0	MY
1S233096E005	AT LISA TRI TORIC 949MP SE+19.50 CYL01.5	NO
1S231241E090	AT LISA TRI TORIC 949MP SE+25.00 CYL01.5	PT
1S212404E004	AT LISA TRI TORIC 949MP SE+21.00 CYL02.5	RO
1S230915E030	AT LISA TRI TORIC 949MP SE+24.00 CYL03.5	RO
1S232430E166	AT LISA TRI TORIC 949MP SE+11.50 CYL02.5	RO
1S232430E170	AT LISA TRI TORIC 949MP SE+11.50 CYL02.5	RO
1S232512E096	AT LISA TRI TORIC 949MP SE+30.00 CYL02.5	RO

Serial Number	IOL Description	Country
1S233615E057	AT LISA TRI TORIC 949MP SE+26.00 CYL01.0	RO
1S231431E186	AT TORBI 709MP DPT -03.0 CYL 01.0	ID
1S221506E314	AT TORBI 709MP DPT 18.0 CYL 02.0	TH

Hazard description

Inaccurate information on the secondary label may lead to implantation of a lens with an incorrect power and the patient may have an unintended outcome of refraction as well as visual acuity.

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 already implanted one of the listed devices, please review the diopter information on the label in the patient's file which is giving the correct information about the IOL's power. In case the diopter on this label is not the intended IOL power, please review the refractive outcome of the 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 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.

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

Carl Zeiss Meditec SAS
i.V.

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

Annex

Appendix 1: Confirmation sheet

RECALL FSCA BER 2025-01

I have read and understood the RECALL information related to FSCA BER 2025-01.

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:** • **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