



Carl Zeiss Meditec AG 10589 Berlin

To whom it may concern

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Your ref.: N/A

Yours of: N/A

Our ref.: FSCA BER 2025-01

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ADVISORY NOTICE
on Field Safety Corrective Action of
Toric Intraocular Lenses (repacked units)

Dear colleagues,

Problem description:

In case intraocular lenses (IOL) are returned from the field (customers, dealers), cosmetic issues with the outer packaging may occur and Carl Zeiss Meditec AG performs repacking of the secondary packaging (IOL box).

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 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.

Our databases indicate that the lenses referenced hereafter are involved in the FSCA action:

Serial Number	IOL Description	Country
1S221604E104	AT Lisa Tri Toric 939MP dpt 24.5 cyl01.0	AU
1S231344E019	AT TORBI 709MP DPT -00.5 CYL 01.0	AU
1S221253E122	AT TORBI 709MP DPT 20.5 CYL 02.0	BE
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
1S221210E047	AT Lisa Tri Toric 939MP dpt 13.0 cyl04.0	BR
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

Serial Number	IOL Description	Country
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
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

Serial Number	IOL Description	Country
1S241026E027	AT TORBI 719M SE+16.00 CYL06.0	FR
1S241825E016	AT TORBI 719M SE+22.00 CYL08.0	FR
1S212638E103	AT TORBI 719M SE+28.00 CYL05.5	IT
1S232807E207	AT LISA TRI TORIC 949MP SE+15.00 CYL01.0	IT
1S221783E256	AT TORBI 709MP DPT 25.0 CYL 02.0	MX
1S231589E156	AT TORBI 709MP DPT 20.5 CYL 02.0	MY
1S233096E005	AT LISA TRI TORIC 949MP SE+19.50 CYL01.5	NO
1S231589E208	.AT TORBI 709MP DPT 21.0 CYL 01.5	NZ
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
1S233615E057	AT LISA TRI TORIC 949MP SE+26.00 CYL01.0	RO
1S231431E186	AT TORBI 709MP DPT -03.0 CYL 01.0	SG
1S220970E279	AT TORBI 709MP DPT 24.5 CYL 02.0	TH
1S221506E314	AT TORBI 709MP DPT 18.0 CYL 02.0	TH
1S232128E022	AT LISA TRI TORIC 949MP SE+15.50 CYL01.5	TW
1S232940E212	AT TORBI 719M SE+15.50 CYL04.5	TW

Risk for patient, users or thirds

Inaccurate information on the secondary label leads to implantation of a lens with an incorrect power, the patient may have an unintended outcome of refraction as well as visual acuity. In this case an IOL exchange, an add on IOL, refractive laser surgery or wearing glasses would be required.

Advise on action to be taken:

We thank you sincerely for carrying out the following actions:

- checking the status and localisation of affected IOLs shipped to your customer
- contacting immediately your customers who have received the affected products:
 - if the device is not yet implanted, ask them to place the product into quarantine
 - if the device has been implanted, ask them to report any adverse patient impact, patient data and specific follow-up information, such as IOL exchange

- sending back the **non-implanted** affected products to Berlin site:

Carl Zeiss Meditec AG
Quality Control: Heike Joithe
Max-Dohrn-Strasse 8-10
10589 Berlin, Germany

Contact: Heike Joithe, Phone: +49 30 854001 315, heike.joithe@zeiss.com

- **For crediting the products, please create regulation-return-purchase-order with issuing storage location 5400. Add FSCA number (FSCA BER 2025-01) at Document Header Text.**
- Inform us via mail about every return. Please avoid collecting the IOLs unreasonably and return it asap.
- Personally notifying your customer of the field safety corrective action and forwarding the Urgent Field Safety Notice (customer letter) you receive from us to your customer.
- Sending us the customer's notification (see appendix of customer letter) back to us.

We sincerely regret the inconvenience caused.

Yours sincerely,

Carl Zeiss Meditec AG
i.V.

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