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 CoCeBER 2023-002
Date: 2023-03-03

URGENT/IMMEDATE ACTION REQUIRED:
FIELD SAFETY CORRECTIVE ACTION (FSCA)
RECALL intraocular lenses AT TORBI 709MP batch 1R220240

Dear Customer,

You are using our intraocular lenses **AT TORBI 709MP** 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 an AT TORBI 709MP sph +9.5 cyl +4.0 diopter, manufactured in the batch affected by this recall. The subsequent internal investigation suggests that lenses from the batch 1R220240 could have been mixed up.

In consequence, we, Carl Zeiss Meditec AG, have decided to recall all IOLs from this batch, 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
.AT TORBI 709MP DPT 22.0 CYL 02.5	1R220240E001
.AT TORBI 709MP DPT 22.0 CYL 02.0	1R220240E003
.AT TORBI 709MP DPT 22.5 CYL 02.0	1R220240E004
.AT TORBI 709MP DPT 22.5 CYL 02.0	1R220240E005
.AT TORBI 709MP DPT 16.5 CYL 03.0	1R220240E011
.AT TORBI 709MP DPT 18.0 CYL 01.0	1R220240E017
.AT TORBI 709MP DPT 23.0 CYL 02.0	1R220240E019
.AT TORBI 709MP DPT 21.5 CYL 03.0	1R220240E025

Germany:

Product name	Serial number
.AT TORBI 709MP DPT 18.5 CYL 01.0	1R220240E013
.AT TORBI 709MP DPT 10.0 CYL 02.5	1R220240E014

Belgium:

Product name	Serial number
.AT TORBI 709MP DPT 22.0 CYL 02.0	1R220240E002
.AT TORBI 709MP DPT 16.5 CYL 03.0	1R220240E012
.AT TORBI 709MP DPT 23.0 CYL 02.0	1R220240E020
.AT TORBI 709MP DPT 21.5 CYL 02.5	1R220240E021
.AT TORBI 709MP DPT 21.5 CYL 02.5	1R220240E022
.AT TORBI 709MP DPT 19.0 CYL 03.5	1R220240E023

Ireland:

Product name	Serial number
.AT TORBI 709MP DPT 10.0 CYL 02.5	1R220240E015

Italia:

Product name	Serial number
.AT TORBI 709MP DPT 14.5 CYL 04.0	1R220240E008

Singapore:

Product name	Serial number
.AT TORBI 709MP DPT 06.0 CYL 02.0	1R220240E006
.AT TORBI 709MP DPT 13.0 CYL 01.0	1R220240E009
.AT TORBI 709MP DPT 13.0 CYL 01.0	1R220240E010

United Kingdom:

Product name	Serial number
.AT TORBI 709MP DPT 20.0 CYL 01.0	1R220240E007
.AT TORBI 709MP DPT 18.0 CYL 01.0	1R220240E018

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.

Tutelea Paulina Narcisa VIPTUTEL

Digitally signed by Tutelea Paulina Narcisa VIPTUTEL
Date: 2023.03.03 12:02:15 +01'00'

Paulina Tutelea
Head of Complaint Management & Vigilance
ZEISS Medical Technology Segment

Carl Zeiss Meditec AG
i.V.

Ortega Sophie FISOR

Signature numérique de Ortega Sophie FISOR
Date : 2023.03.03 12:16:25 +01'00'

Sophie Ortega
Complaint & Vigilance Manager
Implants & Consumables
ZEISS Medical Technology Segment

Annex

Appendix 1: Confirmation sheet

RECALL AT TORBI 709MP – FSCA CoCeBER 2023-002_709MP

I have read and understood the FSCA-RECALL related to AT TORBI 709MP batch 1R220240.

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**
AT TORBI 709MP		

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