Carl Zeiss Meditec AG 10589 Berlin

To whom it may concern

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

Division/Dept.: Complaint Management & Vigilance
Your contact: Paulina Tutelea, Claudia Minke

Your ref.: N/A
Yours of: N/A
Our ref.: FSCA BER 2023-003
Date: 2023-07-04

URGENT/IMMEDATE ACTION REQUIRED:

FIELD SAFETY CORRECTIVE ACTION (FSCA)

RECALL intraocular lens AT LISA 809M and AT LISA tri 839MP

Dear Customer,

You are using our intraocular lenses **AT LISA 809M and/ or AT LISA tri 839MP** 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 LISA 809M sph +14.0 diopter, manufactured in batch 1S222100, affected by this recall. The subsequent internal investigation suggests that lenses from different batches could have been mixed up.

In consequence, we, Carl Zeiss Meditec AG, have decided to recall the affected work order of AT LISA 809M + 14.0D IOLs from batch 1S222100, to inform customers and prevent further implantation of an IOL with the wrong diopter and to avoid further harm to patients. Two (2) other work orders have been identified to be potentially affected: 839MP +6,0 diopter in batch 1S222105 and 809M +6.0 diopter in batch 1S222089. These will be included in the recall.

Affected products

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

China:

Batch	Material	Description	Serial Number
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890066
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890067
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890068
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890069
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890070
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890071
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890072
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890073
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890074
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890075
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890076
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890077
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890078
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890079
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890080
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890081
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890082
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890083
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890084
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890085
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890086
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890087
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890088
1S222089	000000-1919-408	.AT LISA 809M CN dpt 06.0	1S2220890089

France:

Batch	Material	Description	Serial Number
1S222100	003500-0000-277	.AT LISA 809M DPT 14.0	1S222100E333
1S222100	003500-0000-277	.AT LISA 809M DPT 14.0	1S222100E320
1S222100	003500-0000-277	.AT LISA 809M DPT 14.0	1S222100E327
1S222100	003500-0000-277	.AT LISA 809M DPT 14.0	1S222100E330
1S222100	003500-0000-277	.AT LISA 809M DPT 14.0	1S222100E334

Germany:

Batch	Material	Description	Serial Number
1S222105	003500-0006-019	AT LISA TRI 839MP DPT 06.0	1S222105E090

Great Britain:

Batch	Material	Description	Serial Number
1S222105	003500-0006-019	AT LISA TRI 839MP DPT 06.0	1S222105E080

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.

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.A.

Tutelea Paulina Narcisa VIPTUTEL

Digitally signed by Tutelea Paulina Narcisa VIPTUTEL
Date: 2023.07.04 15:35:18 +02'00'

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

Carl Zeiss Meditec AG
i.V.

Minke Claudia OGCMIN

Digital unterschrieben von Minke Claudia OGCMIN
Datum: 2023.07.04 15:31:32 +02'00'

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

Annex

Appendix 1: Confirmation sheet

Field Safety Corrective Action AT LISA 809M / AT LISA tri 839MP
Reference: FSCA BER 2023-003_809M_839MP

I have read and understood the notification related to the **Field Safety Corrective Action** of AT LISA 809M and AT LISA tri 839MP.

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