



Tuesday, September 05, 2017

## URGENT: FIELD SAFETY NOTICE

### RE: Recall of Aaren Scientific, Inc. EC-3 9.5D, 10.0D, 10.5D and 24.0D Intraocular Lenses

Report #: FCACOCE09\_2017-002-001

To Whom It May Concern,

Aaren Scientific, Inc. is initiating a recall due to the detection of a potential labeling error made during the production of our lenses. This resulted in a total of 27 EC-3 Lenses being mislabeled with the incorrect diopter. Please find below the product description of the affected product(s):

#### Affected Product By This Recall:

**Product Name:** EC-3 Posterior Chamber Hydrophobic Acrylic Lens  
**Model Number:** EC-3  
**Intended Use:** Aaren Scientific Lenses are intended for primary implantation in the posterior chamber in patients where a cataractous lens has been removed by cataract extraction. It is recommended that the use of the intraocular lens be initially limited to one eye. Use of the lenses is especially appropriate in patients who cannot tolerate contact lenses, those who would not be candidates for cataract spectacles, or for patients requiring an intraocular lens for occupational or other reasons.  
**Device Class:** Class IIb  
**Classification Rule:** MDD Annex IX, III, Rule 8  
**EC Number:** CE 0050 (Registration Number 252.646)

#### Volume of Product Affected:

**Total Quantity Produced:** 27 Units  
**# of Units Sold:** 24 Units  
**Distribution Level:** Distributors  
**Area(s) of Distribution:** Netherlands | Germany | Spain | Malaysia | United Kingdom | Belgium | Poland | Sweden | Switzerland

Part Number	Material Description	Diopter	Serial Number	Expiration Date
003500-0019-228	EC-3 Hydrophobic Lens	+9.5 D	3S1605000143	03/04/2021
003500-0019-228	EC-3 Hydrophobic Lens	+9.5 D	3S1605000144	03/04/2021
003500-0019-168	EC-3 Hydrophobic Lens	+10.0 D	3S1605000031	03/04/2021
003500-0019-168	EC-3 Hydrophobic Lens	+10.0 D	3S1605000025	03/04/2021
003500-0019-168	EC-3 Hydrophobic Lens	+10.0 D	3S1605000026	03/04/2021
003500-0019-168	EC-3 Hydrophobic Lens	+10.0 D	3S1605000030	03/04/2021
003500-0019-168	EC-3 Hydrophobic Lens	+10.0 D	3S1605000028	03/04/2021
003500-0019-168	EC-3 Hydrophobic Lens	+10.0 D	3S1605000024	03/04/2021



003500-0019-168	EC-3 Hydrophobic Lens	+10.0 D	3S1605000027	03/04/2021
003500-0019-168	EC-3 Hydrophobic Lens	+10.0 D	3S1605000023	03/04/2021
003500-0019-168	EC-3 Hydrophobic Lens	+10.0 D	3S1605000022	03/04/2021
003500-0019-168	EC-3 Hydrophobic Lens	+10.0 D	3S1605000020	03/04/2021
003500-0019-168	EC-3 Hydrophobic Lens	+10.0 D	3S1605000021	03/04/2021
003500-0019-168	EC-3 Hydrophobic Lens	+10.0 D	3S1605000029	03/04/2021
003500-0019-169	EC-3 Hydrophobic Lens	+10.5 D	3S1605000131	03/04/2021
003500-0019-196	EC-3 Hydrophobic Lens	+24.0 D	3S1605000043	03/04/2021
003500-0019-196	EC-3 Hydrophobic Lens	+24.0 D	3S1605000044	03/04/2021
003500-0019-196	EC-3 Hydrophobic Lens	+24.0 D	3S1605000047	03/04/2021
003500-0019-196	EC-3 Hydrophobic Lens	+24.0 D	3S1605000048	03/04/2021
003500-0019-196	EC-3 Hydrophobic Lens	+24.0 D	3S1605000050	03/04/2021
003500-0019-196	EC-3 Hydrophobic Lens	+24.0 D	3S1605000051	03/04/2021
003500-0019-196	EC-3 Hydrophobic Lens	+24.0 D	3S1605000052	03/04/2021
003500-0019-196	EC-3 Hydrophobic Lens	+24.0 D	3S1605000054	03/04/2021
003500-0019-196	EC-3 Hydrophobic Lens	+24.0 D	3S1605000045	03/04/2021
003500-0019-196	EC-3 Hydrophobic Lens	+24.0 D	3S1605000046	03/04/2021
003500-0019-196	EC-3 Hydrophobic Lens	+24.0 D	3S1605000049	03/04/2021
003500-0019-196	EC-3 Hydrophobic Lens	+24.0 D	3S1605000053	03/04/2021

**Recalling Firm and Recall Coordinator Information:**

**Company Name:** Aaren Scientific, Inc.  
**CE Number:** CE 0050  
**Company Address:** 1040 S Vintage Ave, Ontario, CA 91761  
**Company Type:** Manufacturer  
**Recall Coordinator Contact:** Owen J. Bry, Senior Quality Manager  
**Recall Coordinator Phone #:** 909.906.5119  
**Recall Coordinator Fax #:** 909.937.1088  
**Recall Coordinator Email:** owen.bry@zeiss.com

**Reason for Initiating the Voluntary Recall**

Aaren Scientific, Inc. is initiating this action due to detection of a potential labeling error that may have resulted in a mislabeling of 27 units of EC-3 Hydrophobic Lenses being affected. It has been identified that the labeling mix-up has caused finished product labeled as +10.0 Diopter to actually contain +24.0D intraocular lenses and vice versa.

Implantation of a mislabeled lens is considered to potentially cause a refractive power impairment. This could possibly result in the need for an additional surgery which is based on the surgeon’s discretion and expertise. This may include, but not limited to:

1. Explant of the lens if the patient has a high refractive surprise post-operatively
2. Piggyback lens implantation to correct the post-operative refractive surprise
3. Other technique the surgeon may need to perform due to patient history and pathology

These are all considered as a severe risk, with a high probability the surgeon may need to perform an additional surgery to correct the problem and prevent any injury from occurring.

**Date Identified:** August 22<sup>nd</sup>, 2017  
**Number of Complaints:** Two (2)  
**Number of MDRs:** Two (2)  
**Number of Reportable Incidents:** Two (2)



Aaren Scientific, Inc. has received Two (2) complaints, which were deemed as reportable adverse events relating to this identified problem. This potential labeling error was discovered by our Complaint Manager during the investigation of both of these complaints.

## Recall Strategy

**Recall Level:** Distributor  
**Method of Notification:** Mail, E-Mail, and Facsimile  
**Mail to be Sent By:** Overnight

### Actions to be performed by the Sales and Service Centers (SSC):

1. ***Immediately*** trace the status and location of all serial numbers listed above.
2. ***Immediately*** contact ***ALL*** customers by Phone, Mail, and E-Mail asking them to quarantine the product and ***DO NOT*** implant the product.
3. ***Immediately*** contact ***ALL*** customers by Phone, Mail, and E-Mail and provide the Customer Notification Letter provided in Attachment 2.
4. Keep record of customer notifications performed for the following information:
  - a. Date of Contact
  - b. Form of Contact (Phone, E-mail, Mail, ZEISS Sales Rep. Visit)
  - c. Person spoke with (if by Phone or Visit)
  - d. Traceability Information (i.e. email communication and/or tracking number of Customer Notification Forms)
  - e. Return Goods Authorizations issued to Customer (if applicable)
5. Customers shall be required to complete the Customer Reply Form (see Customer Notification Letter) and return a signed copy back to the SSC and/or ZEISS Sales Representative.

NOTE 1: Every attempt shall be made by the SSC or ZEISS Sales Representative to make contact with the customer and reconcile all sold/shipped lenses. (SSC)

NOTE 2: If the ZEISS Sales Representative is able to confirm via telephone or in person the status of all serial numbers shipped to the customer, they may complete the Customer Reply Form and send it back for the customer.

6. The Sales and Service Centers shall send all Customer Reply Forms back to Aaren Scientific, Inc. to the following Recall Coordinators:

### Recall Coordinator Information

Owen J. Bry, Sr. Quality Manager  
Email: [owen.bry@zeiss.com](mailto:owen.bry@zeiss.com)  
Phone: +1 909.906.5119

Aileen Sanchez, Complaint Manager  
Email: [aileen.sanchez@zeiss.com](mailto:aileen.sanchez@zeiss.com)  
Phone: +1 909.906.5165

### Returning Affected Product:

All product which is returned to the SSC, shall be immediately shipped to the address below:

Carl Zeiss Meditec AG  
REF: FCA\_COCE09\_2017-02  
Attn. Claudia Minke  
Max-Dohrn-Strasse 8-10  
10589 Berlin, Germany



### **Effectiveness Checks of the Recall**

Both the SSC and CoCe (manufacturing site) are responsible for checking the effectiveness of the recall until all product has been reconciled. Customer Reply forms must be obtained from ALL customers which have been sold the EC-3 Hydrophobic Lenses listed on page 1 and 2 of this letter.

Aaren Scientific, Inc. will schedule *Monthly* meetings with each SSC Quality Manager to receive an update on the status of the recall.

Customers which the SSC has tried to make contact with to obtain information on the status of the lenses affected may be deemed out of business, IF three (3) consecutive letters, e-mails, and facsimiles go unanswered. Three (3) final attempts shall be made by the SSC to contact the customer by last known phone number. The use of search engines should be used to identify customers which may have moved facilities, or changed phone numbers. If all of these attempts have resulted in the customer not providing a documented response to any forms of initial contact, the SSC may be able to identify these customers as out of business in future recall effectiveness communication.

If you have product complaints or adverse events to report regarding the use of the EC-3 Posterior Chamber Hydrophobic Acrylic Lens, please inform Carl Zeiss Meditec. If you do report a complaint, please provide the EC-3 Posterior Chamber Hydrophobic Acrylic Lens serial number and, if a patient was involved, the date of surgery, and a description of the event and patient outcome.

We recognize the inconvenience this causes you and appreciate your assistance in expediting the return of this product.

Owen Bry  
Senior Quality Manager  
CoCe IOLs & Biomaterials Ontario  
Medical Technology Business Group

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