Friday, February 02, 2018

Carl Zeiss Meditec Production, LLC.
1040 South Vintage Avenue, Bldg. A
Ontario, CA 91761-3631
USA

URGENT: MEDICAL DEVICE RECALL

RE: Recall of Carl Zeiss Meditec AG 611P CT Lucia Intraocular Lenses | +19.5 D

Carl Zeiss Meditec Production, LLC is initiating a recall due to the detection of a potential labeling error made during the production of Carl Zeiss Meditec AG CT LUCIA 611P, +19.5D lenses. This resulted in a total of 57 Lenses that were potentially mislabeled with the incorrect diopter. Please find below the product description of the affected product(s):

Affected Product By This Recall:

Product Name: 611P CT LUCIA Posterior Chamber Hydrophobic Acrylic Lens
Model Number: 611P CT LUCIA
Intended Use: Carl Zeiss 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 III
Classification Rule: MDD 93/42/EEC Annex II, Section 4
EC Number: CE 0257 (Registration Number 263168-MR2)
Part Number: 003500-0026-383
Material Description: CT LUCIA 611P Hydrophobic Lens
Diopter: +19.5D
Serial Numbers Affected:

3S1609150722	3S1609150738	3S1609150754	3S1609150770
3S1609150723	3S1609150739	3S1609150755	3S1609150771
3S1609150724	3S1609150740	3S1609150756	3S1609150772
3S1609150725	3S1609150741	3S1609150757	3S1609150773
3S1609150726	3S1609150742	3S1609150758	3S1609150774
3S1609150727	3S1609150743	3S1609150759	3S1609150775
3S1609150728	3S1609150744	3S1609150760	3S1609150776
3S1609150729	3S1609150745	3S1609150761	3S1609150777
3S1609150730	3S1609150746	3S1609150762	3S1609150778
3S1609150731	3S1609150747	3S1609150763	3S1609150779
3S1609150732	3S1609150748	3S1609150764	3S1609150780
3S1609150733	3S1609150749	3S1609150765	3S1609150781
3S1609150734	3S1609150750	3S1609150766	3S1609150782
3S1609150735	3S1609150751	3S1609150767	3S1609150783
3S1609150736	3S1609150752	3S1609150768	
3S1609150737	3S1609150753	3S1609150769	

Recalling Firm and Recall Coordinator Information:

Company Name:	Carl Zeiss Meditec AG
CE Number:	CE 0257
Company Address:	Goeschwitzer Strasse 51 – 52, Jena, Germany 07745
Company Type:	Legal 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

Carl Zeiss Meditec AG is initiating this action due to detection of a potential labeling error that may have resulted in a mislabeling of 57 units of 611P CT LUCIA Hydrophobic Lenses. It has been identified that a potential labeling mix-up may have caused finished product labeled as +19.5 Diopter to potentially contain a +34.0D intraocular lens.

Implantation of a mislabeled lens is considered to potentially cause a refractive power impairment. This likely may result in the need of 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:	January 22nd, 2018
Number of Complaints:	One (1)
Number of MDRs:	One (1)
Number of Reportable Incidents:	One (1)

Carl Zeiss Meditec Production, LLC has received a complaint, which was deemed as a reportable adverse event relating to this identified problem. This potential labeling error was discovered when the explanted lens was returned for analysis, measured and confirmed to be a +34.0D.

Volume of Product Affected:

Total Quantity Produced:	57 Units
# of Units Sold:	33 Units
# of Units Still in Stock:	24 Units
# of Customers Sold To:	Please See Attachment 1 - Consignee List
User-Level of Distribution:	User Level (i.e. surgery center(s), hospital(s), etc.)
Area(s) of Distribution:	Austria | Finland | France | Germany | Italy | Spain | United Kingdom | Sweden |Switzerland

Health Hazard Evaluation

Description of potential health hazard:

A potential labeling error resulted in the mislabeling of 57 units of 611P CT LUCIA Hydrophobic Lenses. It has been identified that a potential labeling mix-up has caused +19.5 Diopter lenses to possibly contain +34.0D intraocular lenses.

Factors that may have caused or contributed to the adverse event or potential health hazard: Product labeling error within production at the manufacturing site may occur during the final diopter verification before loading the lens into the injector assembly and/ or during final packaging of the device. Additionally, the operators are required to follow general line clearance process with respect to all products to eliminate any potential product mix-up. However, if this is not followed it may lead to product mix-up.

Use related or human performance contributing factors:
There are no human factors from the surgeon or nurse which would contribute to this risk.

Likelihood of Occurrence:
Rare – This is determined as rare due to the fact that only One (1) recorded complaint has been noted to have cause a myopic (-) refractive outcome, post-surgery. The root cause of the problem has been identified to a labeling error within the production process, which makes the likelihood high as well.

Probability of Injury Occurring:
Likely – The labeling error which has been identified to potentially have been caused in our production process and has led to lenses being labeled with the wrong diopter is extremely likely to cause injury. This is due to the fact that implantation of the wrong diopter will result in the need for additional medical intervention.

Severity of the Injury:
Moderate – As implantation of the wrong diopter will result in unwanted (- or +) refractive outcomes that will cause optical complications. These impairments are considered significant but temporary as they are reversible with additional surgery to correct.

Recall Strategy

Recall Level: End-User (Hospital/Surgery Centers)
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.
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 Carl Zeiss Meditec Production, LLC to the following Recall Coordinators:

Recall Coordinator Information

Owen J. Bry, Sr. Quality Manager
Email: owen.bry@zeiss.com
Phone: +1 909.906.5119

Aileen Sanchez, Complaint Manager
Email: 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_2018-01
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 611P CT LUCIA Hydrophobic Lenses listed on page 1 and 2 of this letter.

Carl Zeiss Meditec Production, LLC 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 un-answered. 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

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

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