

UPDATED URGENT FIELD SAFETY NOTICE*Recall of EyeCee ONE Preloaded and EyeCee ONE Crystal Preloaded***Month XX, 2023**

Dear Customer,

NIDEK is conducting a voluntary recall of specific lots of EyeCee ONE preloaded and EyeCee ONE crystal preloaded intraocular lenses (IOLs) globally in countries where affected IOLs were shipped. A complete list of affected IOLs is attached (see Attachment A).

This recall is the result of NIDEK and Bausch + Lomb having received reports of elevated intraocular pressure (IOP) in patients who were implanted with one of these IOLs. During the period of quarantine, NIDEK carried out an internal investigation, and identified that specific material lot used in the coating process is the causal factor.

On the nozzle portion of the injector, a coating agent (PVP) is used for smoothness of the IOL injection. As result of investigation NIDEK identified SPECIFIC PVP LOTS of the injector have physically obstructed the drainage pathway of aqueous humor. This will likely result as occurrence of abnormally elevated IOP.

Use of these products may pose a risk of sustained, elevated IOP and patients who have had these lenses implanted should be closely monitored for IOP. Any high IOP cases will require immediate attention and treatment by the surgeon or other appropriate healthcare professional.

The health and safety of everyone who uses our products is of our utmost priority, and we take matters such as this very seriously, which is why we are taking this voluntary action.

All appropriate regulatory bodies have been informed of this action. Details regarding this recall are included in this document; therefore, no further information will be distributed.

Action to be Taken by User

According to the records retained at NIDEK, your facility was shipped and had received the products subject to this recall. You are kindly requested to conduct following actions in response to this Field Safety Notice:

- Review your inventory for all products impacted by this recall.
- Please quarantine all the products subject to this recall at your facility.
(For details of products subject to this recall, please refer to attached "Attachment A")
- As for filling up of "Customer Verification Form" and return of the products subject to recall, you will be contacted from authorized distributor of NIDEK. Until further contact from the distributor, please quarantine and retain all the products subject to recall.
- Please forward this message to whom that you may have distributed the intraocular lenses subject to this recall
- Please ensure in your organization that all users of the affected products and other persons are made aware of this Urgent Field Safety Notice. Please keep this information at least until the measure has been completed.

Contact Information

We appreciate your patience regarding this matter and apologize for any inconvenience it may cause. In the meantime, if you have any questions regarding this issue, please contact your local sales representative:

FRANCE

Surgical: service-clients.france@bausch.com

☎ +33 (0) 4 67 13 47 49

ITALY

Surgical: servizio_clienti@bausch.com

☎ 02 91483851

SPAIN

Surgical: Servicio.Clientes@bausch.com

☎ +34 902 381 010

PORTUGAL

Surgical: Servicio.Clientes@bausch.com

☎ +351 808 203 178

NETHERLANDS, BELGIUM

Surgical: csbenelux@bausch.com

☎ Netherlands+31 (0) 20 203 54 01; Belgium +32 3 280 82 40.

REPUBLIC OF IRELAND

Surgical: uksurgorders@bausch.com

☎ +44(0)208 781 0000

SWEDEN, NORWAY, DENMARK, FINLAND, ICELAND

Surgical: customerservice.nordic@bausch.com

☎ Sweden & Iceland: +46 08 616 9570; Norway +47 800 104 40; Denmark +45 808 809 90;

Finland +358 0800 118 011

POLAND

Surgical: zamowienia.chirurgia@bausch.com

☎ +48 801 080 023

GERMANY, AUSTRIA

Surgical: kundenservice@bausch.com

☎ Germany +49 (0) 800 589 3114; Austria +43 (0) 800 241015

CEE (Bulgaria, Cyprus, Czechia, Estonia, Greece, Croatia, Hungary, Lithuania, Romania)

Surgical: ELC_EASTERN_EUROPE@bausch.com

☎ +31 206582728

Authorized Representative of NIDEK in EU member states:

Audrey_guillou@nidek.fr

☎ +33 (0) 1 49 80 97 97

Sincerely,

Name : Katsuaki Tohyama



Title : Senior Manager

Quality Assurance Department

NIDEK

Updated Urgent Field Safety Notice

Label Examples

Serial No. on outer package	Serial No. on sterilized packaging
 <p>Label on outer package showing: SZ-1 +23.5D SN UJX05300 2027-11 (01) 04987669585351 (17) 271100 (21) UJX05300</p>	 <p>Label on sterilized packaging showing: NIDEK CO., LTD. 34-14, Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan SZ-1 BAUSCH+LOMB +23.5D SN UJX05300 EyeCee[®] ONE preloaded 78400-P376-E0</p>

On label of outer package and sterilized package, S/No are written for identification of the product. Prefix 2 digits shows production year and month of the product. For details, please see the table in the next page.

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Production Year	Production Month	First Digit	Second Digit	Production Year	Production Month	First Digit	Second Digit
2019	5	P	F	2021	9	R	3
2019	6	P	G	2021	10	R	4
2019	7	P	H	2021	11	R	5
2019	8	P	J	2021	12	R	6
2019	9	P	K	2022	1	R	7
2019	10	P	L	2022	2	R	8
2019	11	P	M	2022	3	R	9
2019	12	P	N	2022	4	R	0
2020	1	R	A	2022	5	U	A
2020	2	R	B	2022	6	U	B
2020	3	R	C	2022	7	U	C
2020	4	R	E	2022	8	U	E
2020	5	R	F	2022	9	U	F
2020	6	R	G	2022	10	U	G
2020	7	R	H	2022	11	U	H
2020	8	R	J	2022	12	U	J
2020	9	R	K	2023	1	U	K
2020	10	R	L	2023	2	U	L
2020	11	R	M				
2020	12	R	N				
2021	1	R	P				
2021	2	R	R				
2021	3	R	T				
2021	4	R	U				
2021	5	R	W				
2021	6	R	Y				
2021	7	R	1				
2021	8	R	2				

IMPORTANT : Production lots during September 2021 to November 2022 are subject to recall (Yellow Highlighted). For details of Serial Numbers subject to recall, please refer to “Attachment A” (Example : Because UJX05300 is production of December 2022, it is our of recall scope)

Products of specific production period are the cause of the problem. Therefore, the products that are out of recall scope can be used.

Updated Urgent Field Safety Notice Acknowledgement Form

This is to acknowledge receipt of the above referenced recall notification dated Month XX, 2023.

In accordance to the instructions by NIDEK's distributor, please fill up the form and return.

Afterwards, you will be paid back upon your returning of the products subject to recall.

Please kindly note that, In cases where your product returning is not in accordance to the instructions, such as returning without this form, paying back to you may delay.

Product Details:

EyeCee ONE preloaded and EyeCee ONE crystal preloaded IOLs

Please review and acknowledge (X) the following statement below:

☐ We have reviewed the attached field safety notice and acknowledge the alert.

Please review and acknowledge (X) one of the statements below that applies to your facility:

☐ We do not have any of these impacted IOLs in our inventory.

☐ We do have these impacted IOLs in our inventory. If checked, please fill out chart below.

Please insert the total number of IOLs impacted by this recall identified at your facility:

Product Name	Lot No.	Quantity Used	Quantity Returning

To obtain a Return Material Authorization Number (RMA) and arrange for a pickup of the identified product, please contact authorized distributor of NIDEK in your country/region at numbers indicated as contact information.

I hereby certify that I have quarantined the above listed product to prevent use and am awaiting pick up.

Date

Name (Print)

Account Number

Signature

Facility Name

Telephone Number

Please complete, sign and return this form to authorized distributor of NIDEK in your country/region at e-mail address indicated in the contact information.

Confidentiality Agreement: The information contained in this message is confidential information intended for the use of the address listed above. If you are neither the intended recipient nor the employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any disclosure, copying, distribution or the taking of any action in reliance on the contents of the information is strictly prohibited. If you have received this in error, please immediately notify us by telephone to arrange for the return of the original document to us.