



URGENT FIELD SAFETY NOTICE
All Lots of Preloaded EyeCee One IOLs

January 3, 2023

Dear Customer,

We are writing to inform you of a Field Safety Notice for all lots of preloaded versions of EyeCee One intraocular lenses (IOLs) that are manufactured by NIDEK and distributed by Bausch + Lomb (a full list of affected products is in attachment A).

NIDEK has issued this field safety notice while it undergoes a full investigation, in collaboration with Bausch + Lomb, due to a limited number of reports of high ocular hypertension in patients who were implanted with one of these lenses.

A preliminary investigation has thus far not established a link between these preloaded EyeCee One IOLs and the reports of high ocular hypertension or identified a root cause. Nidek and Bausch + Lomb are continuing to investigate this issue to definitively determine the root cause of these reports and whether a link to these products exists.

Please take the following actions immediately:

1. Stop using these impacted products (a full list of affected products is in attachment A).
2. Quarantine these impacted IOLs until further notice.
3. Immediately forward this information to any recipients who may have distributed these impacted IOLs.

NIDEK has notified health authorities of these actions.

NIDEK will provide an update on its investigation, as well as the actions customers should take with the quarantined products once the investigation has been completed.

We are committed to ensuring patient safety and we appreciate your prompt attention to this matter.

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 NIDEK sales representative:

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Sincerely,

Name

Title

NIDEK