Medicines & Healthcare products Regulatory Agency

# EyeCee One preloaded and EyeCee One Crystal preloaded intraocular lenses (IOLs): stop using immediately and quarantine all preloaded EyeCee One lenses DSI/2023/001

## Devices Details

Device Name: EyeCee One preloaded and EyeCee One Crystal preloaded Intraocular lenses (IOLs)
Affected lot numbers/serial numbers: All
Manufactured by Nidek and distributed by Bausch + Lomb

## Summary

The MHRA is aware of reports of increased intraocular pressure in patients recently implanted with EyeCee One preloaded and EyeCee One Crystal preloaded intraocular lenses (IOLs).

## Explanation of identified safety issue

The MHRA is aware of cases of increased intraocular pressure in patients recently implanted with EyeCee One preloaded and EyeCee One Crystal preloaded intraocular lenses (IOLs), which are manufactured by NIDEK and distributed by Bausch + Lomb.

The root cause has not been identified and further investigations are ongoing with the manufacturer. A Field Safety Notice has been disseminated by Nidek.

Due to the potential risks for patient safety, you should stop using these IOLs and quarantine remaining stock immediately pending the results of further investigations. Additional communications will be issued shortly advising clinicians and affected patients on the next steps.

## Actions for ophthalmology, ophthalmic theatres, and Medical Devices Safety Officers. To be completed 26 January 2023

Please take the following actions immediately:

1. Nominate a lead person to take responsibility for completing these actions. Note – we recommend including colleagues in purchasing, supplies, and the Medical Device Safety Officer (MDSO).
2. Identify if your organisation uses these IOLs
3. Stop using these impacted products immediately
4. Quarantine these impacted IOLs until further notice.
5. Consider using a suitable alternative product if available following local risk assessment
6. Immediately notify any other departments who need to be aware of this notice.

## Advice for patients

The advice in this notice is aimed at the healthcare teams who are responsible for providing and monitoring lenses used in cataract surgery. The MHRA is urgently investigating this issue and will be advising healthcare professionals on next steps, including the need to contact patients who may be affected, as soon as more information is available. If you are affected, your healthcare professional will contact you in due course. If you or somebody in your care had cataract surgery recently and are concerned, please contact the hospital where you had surgery for advice.

Published 26 January 2023