National Patient Safety Alert

Medicines & Healthcare products Regulatory Agency

NIDEK EyeCee One preloaded and EyeCee One Crystal preloaded Intraocular Lenses (IOLs): risk of increased intraocular pressure

Date of Issue:	1-Feb-23	Reference No:	NatPSA/2023/003/MHRA

This alert is for action by: all providers of ophthalmic surgery and community optometrists

This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by an executive leader (or equivalent role in organisations without executive boards) and supported by the clinical lead for ophthalmology.

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 U.K. Ltd.

Increased intraocular pressure can lead to optic nerve damage and vision loss if left untreated.

A Device Safety Information notification (DSI/2023/001) was issued on 26 January 2023 stating that users should stop using these products immediately and quarantine all preloaded EyeCee One and EyeCee One Crystal IOLs, pending the results of further investigations.

The root cause of the increased intraocular pressure has not been identified and further investigations are ongoing with the manufacturer. A Field Safety Notice (FSN) has been disseminated by Nidek and should be followed.

To protect patient safety, healthcare professionals / teams should contact patients who have received implants with the preloaded EyeCee IOLs since 1 October 2022 (preferably by telephone) and advise them to have the pressure in their eye tested. Local arrangements for intraocular pressure testing should be agreed and made clear to patients affected.

This advice is only relevant to patients who have received preloaded EyeCee One and EyeCee One Crystal IOLs.

Actions required

Actions should be fully completed in 2 weeks (by 16 February 2023)

Providers of ophthalmic surgery:

1. Urgently identify whether you have implanted any EyeCee One preloaded and EyeCee One Crystal preloaded intraocular lenses (IOLs) since 1 October 2022.
2. Confirm with the nominated person as indicated in the DSI that you have immediately stopped using these products, that any unused product has been quarantined, and you have actioned the FSN and returned the FSN Acknowledgement Form.
3. Contact any patients (preferably by telephone) who have received these lenses since 1 October 2022 and undertake a patient-centred risk assessment to determine the appropriate clinical follow-up required (see additional information, including a suggested template communication).
4. Put in place an action plan for a rapid access pathway to the cataract surgery provider for those patients found at screening to have high intraocular pressures. The cataract provider will undertake further assessment.
5. When changing to a suitable alternative IOL ensure you have undertaken a local risk assessment, paying particular care to biometry calibration requirements.
6. Report occurrences of high intraocular pressure associated with these products through your healthcare institution's local incident reporting system and/or your national incident reporting authority as appropriate: (England, Scotland, Wales, and Northern Ireland) and Bausch + Lomb U.K. Ltd.

Community optometrists:
Ensure there is sufficient capacity to carry out urgent testing for identified patients.

For any enquiries about this alert contact: info@mhra.gov.uk

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

Information on adverse incidents

The MHRA is aware of 4 centres experiencing reports of high intraocular pressure with some patients. One site has experienced a rate of approximately 2-4% and most affected patients experienced minimal symptoms. The time to onset of raised pressure is also variable from days to a few weeks. No patient group has been observed to be at higher risk of experiencing high intraocular pressure, although pre-existing ocular hypertension and glaucoma may be pertinent. The MHRA is not aware of any reports of this issue prior to October 2022. There have also been similar reports in other countries.

Clinical risk assessment and follow-up

Patients who were implanted with these devices from 1 October 2022 should be contacted by the centre who implanted the device (preferably by telephone) and advised of the issue and given advice on what to do.

To support centres in contacting patients, a template for patient communication is available, which has been developed with stakeholders. This information should be provided in a patient-centric manner, depending on the risk assessment for that patient. Arrangements for testing should be agreed locally and can be inserted into the communication as needed, but should include a telephone number and email address to enable timely contact between the testing provider and the cataract provider.

The pathway for patients to have their intraocular pressures tested within 2 weeks are:

- **Private patients**: private cataract providers should recall patients for pressure checks

In England, Wales and Northern Ireland

- **Patients aged 60 and under**, including children: these patients should be asked to attend their secondary care cataract provider team for pressure checks.
- **All other patients:** the options include referral to a local optometrist or an appointment back with the centre implanting the device.

In Scotland

- **All patients:** the options include referral to a local optometrist or an appointment back with the centre implanting the device.

Any patients with high intraocular pressure, >22mmHg, require a rapid access pathway back to the cataract provider team who undertook the procedure. The mechanism to do this should be clearly set out, including provision to the optometrist of contact routes to the cataract provider team at the time of testing. All affected patients should be tested within 2 weeks of this alert. Follow-up should be made with patients who have not responded or been reached by telephone.

The outcome of the optometric examination and intraocular pressure testing should be notified to the cataract provider team (whether normal or not) as soon as possible, via an agreed process that includes contact details and be recorded in the patient's clinical records (both optometry and hospital).

Stakeholder engagement

The MHRA has consulted with NHS England and representatives from the Scottish and Welsh Governments and the Department of Health Northern Ireland. The MHRA has also consulted with the Royal College of Ophthalmologists, the College of Optometrists, and the NHS National Clinical Director for Eye Care.

Please check website for when actions should be ceased or advice to check for date restriction are lifted.