MHRA Device Safety Information

Reference: MDSI2307 **Issued:** 03 August 2023 **Review Date:** 23 August 2023

EyeCee One and EyeCee One Crystal preloaded intraocular lenses (IOLs): update of previous quarantine advice after identification of likely cause

Summary

The MHRA is providing an update on the issue of increased intraocular pressure in patients implanted with EyeCee One preloaded and EyeCee One Crystal preloaded intraocular lenses.

Action

- Identify the IOLs affected by the updated Field Safety Notice and follow the actions in the notice to retain these for manufacturer recall
- All other EyeCee One and EyeCee One Crystal preloaded IOLs within their expiry date can now be used.
- Report adverse incidents to your local incident recording system and to the Incident Reporting & Investigation Centre (IRIC) using the following link:
  https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/report-an-incident/

Equipment details

Device Name: EyeCee One and EyeCee One Crystal preloaded intraocular lenses (IOLs)
Affected lot numbers/serial numbers: see Field Safety Notice
Manufactured by NIDEK and distributed by Bausch + Lomb

Background

New advice

This MHRA Device Safety Information replaces advice in MDSI2301 which should no longer be followed.

On 13 July 2023, NIDEK published an updated Field Safety Notice, which states that only EyeCee One and EyeCee One Crystal preloaded intraocular lenses (IOLs) manufactured between September 2021 and November 2022 are affected by a manufacturing problem that they attribute as the likely causal factor of increased intraocular pressure (IOP) in some patients. NIDEK has now recalled specific affected batches as listed in the Field Safety Notice.

The likely cause has now been identified and found to only affect those IOLs manufactured between September 2021 and November 2022. Therefore all other IOLs within their expiry date can now be removed from quarantine and used in patients, as they are unaffected by this issue.

Background to this safety issue

In January 2023, cases were reported of increased intraocular pressure in patients recently implanted with EyeCee One preloaded and EyeCee One Crystal preloaded IOLs.

NIDEK published a Field Safety Notice quarantining all EyeCee One and EyeCee One Crystal preloaded IOLs. The MHRA also published a Device Safety Information (DSI/2023/001) quarantining these devices. This was published in Scotland as MDSI2301. On 1 February, MHRA issued a National Patient Safety Alert (NatPSA/2023/003/MHRA) asking that all patients implanted with these devices since October 2022 be recalled to have their intraocular pressure checked.

Further advice on patient monitoring

Patients who were found to have normal intraocular pressure do not require further follow-up, as the increased pressure occurs in the period covered by general postoperative management after cataract surgery. They should continue to have regular sight tests with their optometrist. Patients who were found to have high intraocular pressure should continue to be seen by an appropriate specialist for treatment and monitoring.

Suggested onward distribution

Ophthalmology, ophthalmic theatres and other relevant departments

References

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 and the College of Optometrists.

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

Accessibility: Please contact us using the above details if you are blind or have a sight impairment and would like to request this alert in a more suitable format.

IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in CEL 43 (2009), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities,* issued 30 October 2009.

Report an incident: Information on how to report an adverse incident

NHS National Services Scotland is the common name for the Common Services Agency for the Scottish Health Service https://www.nss.nhs.scot/