NHS National Services Scotland

MHRA Device Safety Information

Reference: MDSI2301 **Issued:** 26 January 2023 **Review Date:** 26 January 2024

EyeCee One preloaded and EyeCee One Crystal preloaded intraocular lenses (IOLs): stop using immediately and quarantine

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 26 January 2023. The original webpage can be accessed here.

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).

Action

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 (and independent service providers to whom you have contracted out services) who need to be aware of this notice.
7. Report adverse incidents to your local incident management system and to IRIC:

Actions for ophthalmology, ophthalmic theatres, and Medical Devices Safety Officers (Incidents and alerts Safety Officers (ISOs) in Scotland). To be completed **26 January 2023**

Equipment details

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

Background

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.

Suggested onward distribution

Health & Safety
Ophthalmology
Operating Departments
Risk Management
Supplies/Procurement

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/