Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/007 Issued: 13 February 2019 at 12:00 Valid until: February 2020

Ophthalmic implant Raindrop Near Vision Inlay – risk of corneal haze.

Summary

Manufactured by ReVision Optics, Inc – patients implanted with this device have an increased risk of corneal haze.

Action

- Do not implant Raindrop Near Vision Inlays.
- Identify all unused stock of Raindrop Near Vision Inlays and dispose of them.
- Monitor patients who have the inlay implanted or have previously had the device explanted for the development of corneal haze. The frequency of follow up should be determined by individual patient risk assessment.
- Report adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales.

Action by
All healthcare professionals who are responsible for or who use these devices.

Deadlines for actions
Actions underway: 27 February 2019
Actions complete: 10 April 2019

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device

The device is a corneal inlay (corneal implant) used to improve near vision.

Problem / background

The USA's Food and Drug Administration (FDA) issued a safety communication informing users that implantation of this device has led to an increased occurrence of corneal haze.

The cited study shows that 75% of 150 enrolled patients developed corneal haze. In 42% of patients, the corneal haze has been present in the central region of the cornea.

There is no specific guidance regarding frequency of follow-up from the manufacturer; the clinician should assess the risk of corneal haze in individual patients.

It is unknown how many Raindrop Near Vision Inlay devices may be placed on the market in the UK.

Manufacturer contacts

ReVision Optics, the manufacturer of this device, ceased operations in 2018 and no contacts are available. Due to the lack of information on the distribution of this device, the MHRA is publishing this alert as a precautionary notice.

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Community hospitals
- Minor injury units
- NHS walk-in centres
- Nursing executive directors
- Operating department practitioners
- Ophthalmic nurses
- Ophthalmologists
- Ophthalmology departments
- Ophthalmology, directors of
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Walk-in centres

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- Community optometrists
- Dispensing opticians

- General practitioners
- Optometrists
- General practice managers
- General practice nurses

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/007** or **2018/012/017/487/001**.

Technical aspects
Jonathan Fox, MHRA
Tel: 020 3080 6000
Email: DSS-TM@mhra.gov.uk

Clinical aspects
Devices Clinical Team, MHRA
Tel: 020 3080 7274
Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland
Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health, Social Services and Public Safety
Tel: 0208 9052 3868
Email: niaic@health-ni.gov.uk
To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.
Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 250986 / 03000 255510

Email: haz-aic@wales.gov

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).