HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Raindrop Near Vision Inlay

Priority 2 – Warning

HPRA Safety Notice: SN2019(01) **Issue Date: 16 January 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
ReVision Optics	V38358

ISSUE

The U.S. Food and Drug Administration (FDA) has recently published a Safety Communication concerning the Raindrop Near Vision Inlay. The communication alerts eye care providers and patients who have had this device implanted or who have previously had this device explanted, of the increased risk of corneal haze (a type of cloudiness in the cornea due to inflammation) associated with this device.

ReVision Optics, the manufacturer of this device, ceased trading in 2018. The HPRA is issuing this Safety Notice as we do not have oversight of the distribution network for the Irish market. However, we are aware that these devices have been implanted in at least one centre in Ireland.

Based on this FDA communication, the HPRA is recommending that users cease implanting Raindrop Near Vision Inlays and that patients who have previously received this implant be monitored for corneal haze development.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1 Check your inventory to determine if you are in possession of these devices.

2 Discontinue implantation of Raindrop Near Vision Inlays.

3 Monitor patients who have the inlay implanted or have previously had the device explanted for the development of corneal haze.

4 If your organisation is in possession of these devices, please contact the HPRA using the contact details below.

5 Report any incidents or complaints to the HPRA using the contact details below.

TARGET GROUPS	
Ophthalmic nurses Ophthalmologists General Practitioners	Eye Clinics Ophthalmology departments

BACKGROUND

The FDA has published a Safety Communication which details new clinical data concerning the Raindrop Near Vision Inlay. The manufacturer of this device ReVision Optics ceased trading in 2018 and we have been informed that the device is no longer being sold.

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

Therefore, the HPRA strongly recommends not implanting the Raindrop Near Vision Inlays. Patients already implanted with the Raindrop Inlay should attend follow-up appointments regularly and be monitored for the development of corneal haze.

Please visit the FDA website for further information:
Increased Risk of Corneal Haze Associated with the Raindrop Near Vision Inlay: FDA Safety Communication.

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
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Earlsfort Terrace
Dublin 2

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