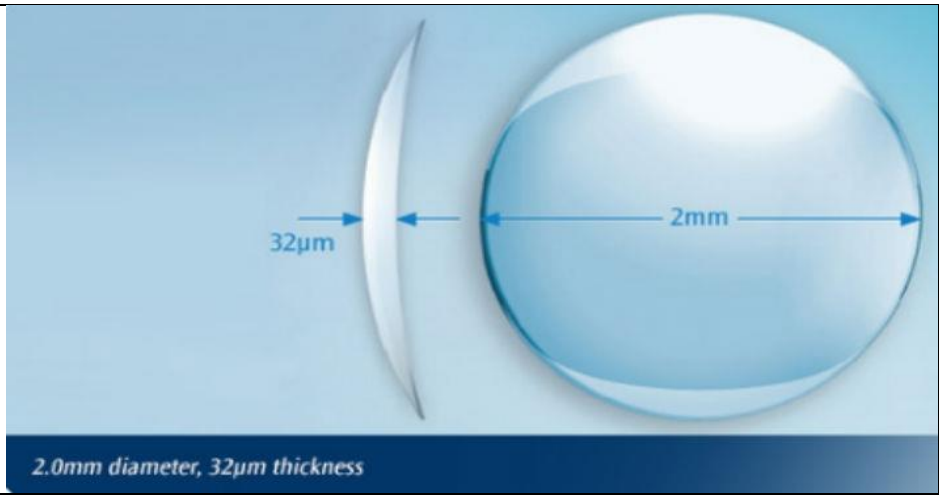
المركز الوطني للبلاغات عن الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Urgent Safety Communication

Increased Risk of Corneal Haze Associated with the (Raindrop Near Vision Inlay)

Device/ Product Name:	Raindrop Near Vision Inlay
Lot numbers/Serials:	Raindrop Near Vision Inlay
Manufacturer:	Revision Optics Inc. RVO 2.0 (Optics Medical)
Problem:	Saudi FDA would like to bring to your attention with regard to the device (Raindrop Near Vision Inlay). People who undergo implantation of the Raindrop Near Vision Inlay device are at risk for the development of corneal haze that can affect clear vision. Haze can cause blurry vision or glare by clouding the cornea, or by changing the focusing power of the eye. The impact of haze on the patient's vision is dependent on the severity of haze and its location in the cornea.
Recommendation/Actions:	**Recommendations for Patients:** - patients should not receive the Raindrop Near Vision Inlay device. - If already implanted with the device, be sure to keep your regularly scheduled appointments with your eye care provider. **Recommendations for Eye Care Providers:** - Do not implant Raindrop inlays. - Monitor patients with the implant for the development of corneal haze. - Monitor patients whose device has been explanted for the development of corneal haze. - Contact SFDA for further information.

Devices/Products photo:	

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2412
Fax: +966 (11) 2757245

Or

Saudi Vigilance
https://ade.sfda.gov.sa/Home/Report

For latest published Recalls/Alerts, please visit (NCMDR Website)

Sincerely,
NCMDR Team