

Wednesday, 23 September 2026

Ref: 202609: FSN-RAOIFU

Field Safety Notice – RayOne IFU Update

Dear Valued Customer,

We wish to inform you of an update to the RayOne Preloaded Hydrophilic Acrylic IOL Injection System IFU and the RayOne Preloaded Hydrophobic Acrylic IOL Injection System IFU.

A precaution stating, **"Do not use if the device appears to be damaged"** has been added to the IFUs and is positioned below the existing precaution **"Do not use if the pack has been damaged."**

Affected models:

- RayOne Aspheric RAO600C
- RayOne Spheric RAO100C
- RayOne EMV RAO200E
- RayOne EMV Toric RAO210T
- RayOne Toric RAO610T
- RayOne Trifocal RAO603F
- RayOne Trifocal Toric RAO613Z
- RayOne Galaxy RAO605G
- RayOne Galaxy Toric RAO615X
- RayOne Hydrophobic Aspheric RAO800C
- RayOne Hydrophobic Aspheric BLF RAO850B

The IFU will enter production in Q4 2026. The updated precaution will be incorporated into:

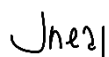
- Version 4 of the RayOne Preloaded Hydrophilic Acrylic IOL Injection System IFU
- Version 3 of the RayOne Preloaded Hydrophobic Acrylic IOL Injection System IFU

This update affects the IFU only. No changes have been made to the device, packaging, or manufacturing process. No action is required with physical product on hand at your facility. Please ensure relevant personnel are informed of this update.

Please complete and return the FSN Customer Response Form to feedback@rayner.com by 31-Oct-2026.

Should you have any questions, please do not hesitate to contact the Vigilance Team at feedback@rayner.com.

Yours faithfully,

A handwritten signature in black ink, appearing to read "Jodie Neal".

Jodie Neal
Vigilance Manager