

URGENT FIELD SAFETY NOTICE

STAAR Japan Preloaded Acrylic Intraocular Lens (Model KS-SP)

March 28, 2023

Dear Customer,

Recently, Nidek issued a Field Safety Notice for all lots of the Bausch + Lomb preloaded EyeCee One intraocular lens (IOL) manufactured by Nidek and distributed by Bausch + Lomb (<https://mhra-gov.filecamp.com/s/d/MWjGnAVxprpOgwQl>). The Notice was issued due to “a limited number of reports of high ocular hypertension in patients who were implanted with one of these lenses.”

The STAAR Japan preloaded KS-SP intraocular lens is also manufactured by Nidek in the same facility from the same or similar manufacturing and materials as the Bausch + Lomb IOL.

STAAR Japan has received one (1) report of high intraocular pressure following use of the KS-SP IOL in Japan, and continues to closely monitor the situation to ensure patient safety.

STAAR Japan has joined the Nidek and Bausch + Lomb investigation to help identify the root cause of the “high ocular hypertension”. At this time the definitive root cause has not been identified, nor why some IOLs have this response while others do not.

Due to the significance of the reports and the lack of a known root cause at this time, as a precautionary measure, STAAR Japan is asking that you:

- **STOP USING the STAAR Japan KS-SP IOL until further notice.**
- Account for and quarantine all KS-SP IOLs in your inventory.
- Complete the attached Accountability Form for KS-SP IOLs and return to STAAR AG (acting on behalf of STAAR Japan), even if the amount in your inventory is zero (0).

STAAR Japan is committed to ensuring patient safety and appreciates your prompt attention and actions.

STAAR Japan has notified the Health Authorities of these actions.

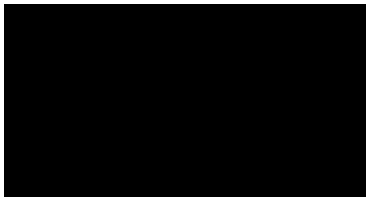
We apologize for the inconvenience to you, your patients and your staff, and appreciate your patience. STAAR Japan will continue to assist in the investigation and will provide an update, and further instructions for the quarantined IOLs.

The completed Accountability Form for STAAR Japan KS-SP IOLs should be sent to:

customerservice.ag@staar.com

Should you have questions regarding this notice please contact your STAAR AG Country Manager or Customer Service at the above email.

Sincerely,



Attachment:

Accountability Form