

URGENT: MEDICAL DEVICE FIELD SAFETY NOTICE (UPDATE)

Stella 2.0 Implant Orientation Diagram (IOD)

June 4, 2026

Dear Doctor:

Purpose of this Letter

The purpose of this letter is to provide an update on a voluntary Field Safety Notice that STAAR Surgical Company (STAAR) issued on April 20, 2026 via email and overnight mail delivery. Some affected customers were notified that, during the period from April 13 to 16, 2026 starting with the rollout of Stella 2.0, there was the possibility of an error with the Implant Orientation Diagram (IOD) generation used for the implantation of Toric EVO/EVO+ Implantable Collamer Lenses (ICLs). Specifically, when users created multiple Toric lens line items with different axis values on the same patient eye, such as with backup or secondary lens reservations, there was the possibility of an incorrect rotation value because it was referencing the rotation from another IOD from the same eye. We also indicated that any IOD printed from Stella 2.0 after 5:30pm US PDT on April 16, 2026 was not affected by this issue.

Based on our review of internal records in Stella 2.0 at the time, only surgeons who had multiple reservations made on lenses on the same patient eye had received the Field Safety Notice starting on April 20, 2026. However, all active ICL surgeons are now receiving this update.

Reason for the Update

The software correction implemented on April 16, 2026 has been effective in addressing the identified root cause associated with the generation of multiple Toric lens line items containing different axis values for the same patient eye. However, since implementation of that correction on April 16, 2026, STAAR has become aware of additional issues that may affect information displayed on the generated IOD. While these issues are unrelated to the original root cause, and corrections have been implemented, they were identified and corrected after the original Field Safety Notice. A summary of these additional issues is provided below:

- Expected refraction, spherical equivalent, and/or model/version values may be incorrect on the generated IOD;
- If the sphere value for a Toric lens reservation is null, Stella 2.0 will default to indicate a rotation value of 90° on the IOD.

In addition, users' local office network firewall settings may block Stella 2.0 web browser functionality, impacting the IOD display. Given concerns that local firewall settings within certain user environments may affect the ability to successfully generate an IOD, we will temporarily disable the IOD generation functionality within Stella 2.0 on June 7, 2026 (US time). This precautionary measure is being taken to ensure that IODs are generated and provided without the risk of incomplete or incorrect information resulting from blocked connectivity or communication issues.

The functionality will remain disabled while we further evaluate the process, identify any potential vulnerabilities, and implement appropriate mitigations. Once these activities have been completed and the effectiveness of the corrective actions has been verified, the IOD generation feature will be re-enabled and users will be notified accordingly.

Effective May 29, 2026, IOD printouts have been provided in paper format and shipped along with the product. These printouts will be included in the shipping box; if the shipping box includes more than one Toric lens requiring an IOD, users must verify that the correct IOD printout is matched to the

corresponding product by confirming the serial number listed on both the IOD and the product packaging prior to use.

For orders shipped without a printed IOD diagram, contact your Sales Representative. Also, our Customer Service team remains available to you if you have questions.

Root Cause and Corrective Actions

The root cause of these issues will be re-evaluated. In addition, we have initiated a comprehensive review of the IOD generating process within the Stella 2.0 software to ensure that these and other potential issues leading to the incorrect information printed on the IOD are mitigated in the future. Upon completion of this review and implementation of any necessary corrective actions, the IOD functionality within Stella 2.0 will be re-enabled. We will provide notification once the review has been completed and the IOD functionality has been restored.

Risk to Health

If a Toric EVO/EVO+ device was implanted using an incorrect IOD diagram, there is the potential for the following adverse events:

- Refractive surprise
- Blurred vision
- Glares/Halos
- Other visual disturbances.

Removal or repositioning of the lens may need to be considered in these cases.

Actions to Take

We continue to inform you so that a proper clinical decision can be made regarding patient management and follow-up, based on your assessment of the clinical outcome.

Adverse reactions or quality problems experienced with the use of this product should be reported to STAAR's Complaint Handling Department (complaints.ag@staar.com).

We are deeply sorry for the inconvenience this may cause you, your staff, and your patients. Please be assured that patient safety and product quality remain the highest priority at STAAR. Should you have any questions, please contact your STAAR Sales Representative or Customer Service at customerservice.ag@staar.com or by phone at **+41323328888** Monday through Friday, 8:00am to 5:00pm CET.

Thank you for your support of STAAR products and your cooperation with this matter.

Sincerely,



Philip Tsung
Vice President, Global Quality