

** Please Return the completed form with each lens **



PRECISION LENS

**Clinical Requisition Medical Device Reporting
Form - Intraocular Lens (IOL)**

Toll Free: 800-514-1095

Main: 952-358-0414

Fax : 952-881-2453

| | | | |
|---|--|---------------------|----------------------|
| Date of Event: | Account Number: | RGA Number: | |
| PRODUCT INFORMATION AND EVENT SPECIFICS - CARTRIDGE /IOL | | | |
| IOL Model Number & Diopter | IOL Serial Number | Cartridge Type Used | Cartridge Lot Number |
| <input type="checkbox"/> Opened/not used (not product issue/doctor changed mind) | | | |
| Did the lens or cartridge contact the patient's eye? | <input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> cartridge only; <input type="checkbox"/> Lens; <input type="checkbox"/> customer does not know | | |
| Extent of patient contact with lens: | Was the lens explanted in secondary surgical procedure? <input type="checkbox"/> Yes <input type="checkbox"/> No | | |
| <input type="checkbox"/> Fully inserted <input type="checkbox"/> Partially inserted | Implant Date: | Explant Date: | |
| Was the lens removed and replaced in same procedure? | Was the procedure completed using another IOL? If yes provide: | | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Model: | SN: | |

EVENT COMPLICATIONS (PLEASE CHECK ALL BOXES THAT APPLY)

Product Related

| | | | |
|--|--|---|--|
| <input type="checkbox"/> Loading Issue | <input type="checkbox"/> Bent / Broken Haptic | <input type="checkbox"/> IOL Torn. | <input type="checkbox"/> Lens Stuck in Cartridge |
| <input type="checkbox"/> Folding Issue. | <input type="checkbox"/> Missing / Detached Haptic | <input type="checkbox"/> Debris on Lens. | <input type="checkbox"/> Cartridge Broke / Cracked |
| <input type="checkbox"/> IOL missing | <input type="checkbox"/> Lens Scratched | <input type="checkbox"/> Handling problem/ Use error. | <input type="checkbox"/> Tip Cracked/Deformed |
| <input type="checkbox"/> IOL Rotation > or equal to 10 degrees | <input type="checkbox"/> Lead Haptic not Folded | <input type="checkbox"/> Trailing Haptic not Folded | |

Other, please describe:

Medical Related

| | | | | |
|--|--|---|---|--|
| <input type="checkbox"/> Capsule Tear / Collapse | <input type="checkbox"/> Infection / Inflammation | <input type="checkbox"/> Halos / Glare | <input type="checkbox"/> Incision enlargement | <input type="checkbox"/> Unplanned sutures |
| <input type="checkbox"/> Vitrectomy. | <input type="checkbox"/> Unexpected Post-op Refraction | <input type="checkbox"/> Other Visual Disturbance | <input type="checkbox"/> NA | |

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|-------------------|------------------------|
| Summary of Event: | Date of symptom onset? |
| | Symptoms: |

When problem Observed

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|--|---|---|--|--|
| <input type="checkbox"/> Upon Opening Package | <input type="checkbox"/> During handling prior to insertion | <input type="checkbox"/> While Inserting into the eye | <input type="checkbox"/> After Insertion | <input type="checkbox"/> During post- exam |
| Was product returned to Precision Lens? <input type="checkbox"/> Yes <input type="checkbox"/> No | | Reason for no return? <input type="checkbox"/> Discarded <input type="checkbox"/> Still implanted | | |

FACILITY CONTACT /PATIENT INFORMATION

| | | | |
|------------------------|--|---------------------------|--|
| Name of Account: | | Facility Address: | |
| Facility City/State | | Phone number: | |
| Physician/Surgeon: | | Attending Nurse/Tech: | |
| Gender: Male or Female | Intersex, Transgender, No info, Prefer not to Disclose | DOB : Patient Initial; | Eye affected: <input type="checkbox"/> Left (OS) <input type="checkbox"/> Right (OD) <input type="checkbox"/> Both |

| | |
|--|-------------------|
| Outcome significantly inter feres with activities of daily life: <input type="checkbox"/> YES <input type="checkbox"/> NO | Weight in Pounds: |
|--|-------------------|

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|---|--|
| Ethnicity: (Hispanic/Latino or Not Hispanic/Latino: | Race: Black or African American, American Indian or Alaska Native, Asian, Native Hawaiian, Pacific Islander or White |
|---|--|

| | | | |
|-------------------------|---|--|----------------------------------|
| Current Patient Status: | <input type="checkbox"/> Permanent Impairment | <input type="checkbox"/> Patient Has Recovered | <input type="checkbox"/> Unknown |
|-------------------------|---|--|----------------------------------|

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|---|---------------|
| *Required for All Reports, Completed By (Please Print): | Phone Number: |
|---|---------------|