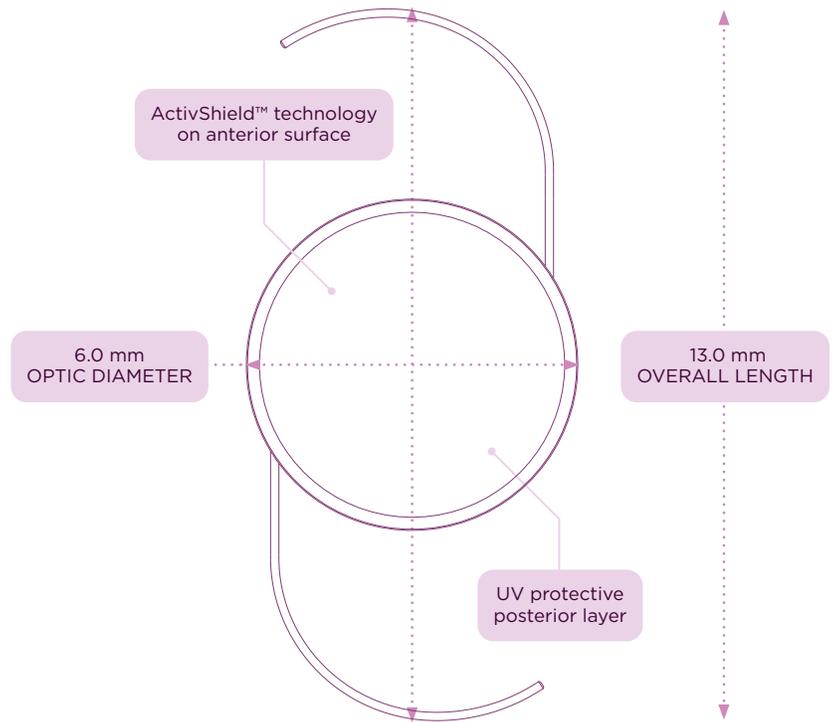


Light Adjustable Lens™

Photo Reactive UV Absorbing Silicone

- 10° haptic angulation
- Squared posterior edge
- Rounded anterior edge



OPTIC CHARACTERISTICS

LAL® Powers	+4.0D to +15.0D - 1D increments +16.0D to +24.0D - 0.5D increments +25.0D to +30.0D - 1D increments
Diameter	6.0 mm
Shape	Biconvex
Material	Silicone
Refractive Index	1.43
Edge Design	Square posterior edge/round anterior edge
Anterior Surface	ActivShield redundant UV protection
Posterior Surface	UV protective back layer
Transmissibility	UV cut-off at 10% T 392 nm for all lens powers

OPTICAL BIOMETRY

A-Constant	119.1
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HAPTIC CHARACTERISTICS

Overall Length	13.0 mm
Configuration	Modified C
Material	Bluecore PMMA
Design	10° haptic angulation

RECOMMENDED INSERTION INSTRUMENTS

Proprietary RxSight Insertion Device - titanium screw style hand piece and disposable cartridge

Proprietary RxSight Single Use Injector - disposable, sterile instrument with a fixed non-pyrogenic cartridge

INDICATIONS FOR USE AND IMPORTANT SAFETY INFORMATION

INDICATIONS: The Light Adjustable Lens™ (LAL®) and Light Delivery Device™ (LDD™) system is indicated for the reduction of residual astigmatism to improve uncorrected visual acuity after removal of the cataractous natural lens by phacoemulsification and primary implantation of the intraocular lens in the capsular bag in adult patients with preexisting corneal astigmatism of ≥ 0.75 diopters and without preexisting macular disease. The system also reduces the likelihood of clinically significant residual spherical refractive errors.

CONTRAINDICATIONS: The LAL is contraindicated in patients who are taking systemic medication that may increase sensitivity to ultraviolet (UV) light as the LDD treatment may lead to irreversible phototoxic damage to the eye; patients who are taking a systemic medication that is considered toxic to the retina (e.g., tamoxifen) as they may be at increased risk of retinal damage during LDD treatment; patients with a history of ocular herpes simplex virus due to the potential for reactivation from exposure to UV light; patients with nystagmus as they may not be able to maintain steady fixation during LDD treatment; and patients who are unwilling to comply with the postoperative regimen for adjustment and lock-in treatments and wearing of UV protective eyewear.

WARNINGS: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting an IOL in a patient with any of the conditions described in the LAL and LDD Professional Use Information document. Caution should be used in patients with eyes unable to dilate to a pupil diameter of ≥ 7 mm to ensure that the edge of the LAL can be visualized during LDD light treatments; patients who the doctor believes will be unable to maintain steady fixation that is necessary for centration of the LDD light treatment; and patients with sufficiently dense cataracts that preclude examination of the macula as patients with preexisting macular disease may be at increased risk for macular disease progression. Patients at high risk for future vitreoretinal disease that may require silicone oil as part of therapy. The LAL must be implanted in the correct orientation with the back layer facing posteriorly. There is no clinical data to demonstrate the safety and effectiveness of ciliary sulcus placement of the LAL. Patients with any of the following conditions may not be suitable candidates for the LAL: recurrent severe anterior or posterior segment inflammation or uveitis of unknown origin, or any disease producing an inflammatory reaction in the eye; surgical difficulties at the time of cataract surgery before LAL implantation; a compromised eye; eyes with neither the posterior capsule nor the zonules are intact enough to provide support for the LAL.

PRECAUTIONS: The long-term effect on vision due to exposure to UV light that causes erythropsia (after LDD treatment) has not been determined. The implanted LAL MUST undergo a minimum of 2 LDD treatments (1 adjustment procedure plus 1 lock-in treatment) beginning at least 17-21 days post-implantation. All clinical study outcomes were obtained using LDD power adjustments targeted to emmetropia post-LDD treatments. The safety and performance of targeting to myopic or hyperopic outcomes have not been evaluated. The safety and effectiveness of the LAL and LDD have not been substantiated in patients with certain preexisting ocular conditions and intraoperative complications. Patients must be instructed to wear the RxSight-specified UV protective eyewear during all waking hours after LAL implantation until 24 hours post final lock-in treatment. Unprotected exposure to UV light during this period can result in unpredictable changes to the LAL, causing aberrated optics and blurred vision, which might necessitate explantation of the LAL. Concurrent light treatments in both eyes after bilateral LAL implantation was not performed in the clinical study. Poorer refractive results may occur with the use of corneal sutures if refractive stability is not achieved prior to LDD treatments. Light treatments should be delayed in the case of an ocular adverse event that could be negatively impacted by light treatment or negatively impact the effectiveness or safety of a light treatment.

ADVERSE EVENTS: The most common adverse events (AEs) reported in the randomized pivotal trial included cystoid macular edema (3 eyes, 0.7%), hypopyon (1 eye, 0.2%), and endophthalmitis (1 eye, 0.2%). The rates of AEs did not exceed the rates in the ISO historical control except for the category of secondary surgical interventions (SSI); 1.7% of eyes (7/410) in the Light Adjustable Lens group had an SSI ($p < .05$). AEs related to the UV light from the LDD include phototoxic retinal damage causing temporary loss of best spectacle corrected visual acuity (1 eye, 0.2%), persistent induced tritan color vision anomaly (2 eyes, 0.5%), persistent induced erythropsia (1 eye, 0.3%), reactivation of ocular herpes simplex Infection (1 eye, 0.3%), and persistent unanticipated significant increase in manifest refraction error (≥ 1.0 D cylinder or MRSE) (5 eyes, 1.3%).

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Please see the Professional Use Information document for a complete list of contraindications, warnings, precautions, and adverse events.