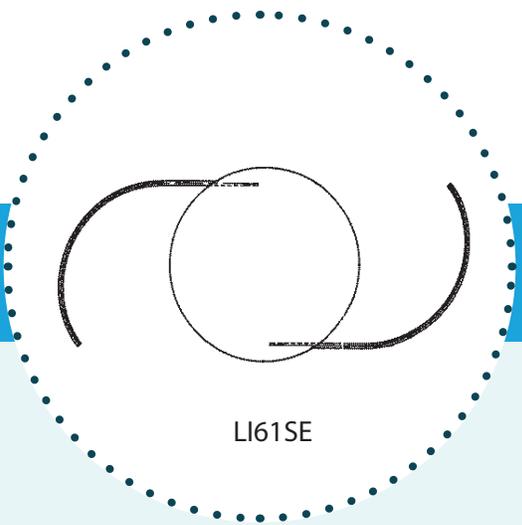


SofPort is a truly surgeon-friendly IOL that unfolds gently and controllably within the eye¹

- SofPort AO is neutral to the induction of positive or negative spherical aberrations and does not induce significant high-order aberrations²
- SofPort AO optic is less sensitive to the effects of misalignment or decentration than non-AO lenses.²
- Designed with a sharp 360° square posterior edge, a feature that has been shown to result in reduced PCO compared to round edged IOLs³



Model	Recommended Starting A-Constant	Overall Diameter	Diopter Powers
LI61AO	118.7*	13.0 mm	+0 D to +4 D in 1.0 D steps +5 D to +30 D in 0.5 D steps +31 D to +34 D in 1.0 D steps
LI61SE			
Incision Size		As small as 2.4 mm	
Optic Shape		Biconvex	
Material—Optic		Silicone; 10% cutoff at 410 nm	
Material—Haptics		Polymethylmethacrylate (PMMA) Monofilament	
Refractive Index at 35°C		1.429	
Optic Body Diameter		6.0 mm	
Delivery System		EZ-28 and EZ-24	

*A-constants are optical biometry estimates only. It is recommended that each surgeon develop his or her own values.

INDICATIONS: The LI61AO and LI61SE SofPort® lenses are intended to be used for primary implantation for the visual correction of aphakia in adult patients where a cataractous lens has been removed by extracapsular cataract extraction methods (see WARNINGS). They are intended for placement in the ciliary sulcus or capsular bag. **NOTE:** Implantation of intraocular lenses should not be performed in patients under 18 years of age. **PRECAUTIONS:** Do not resterilize these lenses by any method. Do not store lenses at temperatures over 45°C. Use only sterile intraocular irrigating solutions, e.g., balanced salt or normal saline solution, to rinse and/or soak lenses. The lens should be handled carefully. Do not use serrated or toothed instruments or apply undue pressure when handling silicone lenses as doing so may damage the lenses. The lens must be discarded if it remains in the folding instrument longer than 15 minutes. Special consideration should be given to the dimensions of lenses at the extreme ends of the power range in relation to the anatomical clearances in the patient's eye. The potential impact of factors such as optic central thickness, optic edge thickness, and overall lens size on the patient's long-term clinical outcome should be carefully weighted against the potential benefit associated with the implantation of an intraocular lens. This is particularly true for anterior chamber lenses. The patient's clinical progress should be carefully monitored. Do not use forceps to fold lenses with more than 30.0 diopters due to the high central thickness. Lenses can be inserted flat with forceps, or with an approved injector. **WARNINGS:** As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include but are not limited to the following: lens dislocation, manifestations of inflammation, corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary or cyclitic membrane, iris prolapse, hypopyon, and transient or persistent glaucoma. The safety and efficacy of these posterior chamber lenses have not been established if placed in the anterior chamber. Pupillary block may be prevented by one or more iridectomies performed at the time of implantation. Undesirable optical effects such as glare, halos, etc. have been reported by some patients after intraocular lens implantation. These phenomena are not completely understood but are thought to be related to positioning holes and edge effects. The effectiveness of these lenses in reducing the incidence of retinal disorders has not been established. The safety of intraocular lenses has not been substantiated in patients with pre-existing ocular conditions (chronic drug miosis, glaucoma, amblyopia, diabetic retinopathy, previous corneal transplant, previous retinal detachment, iritis, etc.). Physicians considering lens implants in such patients should explore the use of alternative methods of aphakic correction and consider lens implantation only if alternatives are deemed unsatisfactory to meet the needs of the patient. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The physician must determine the benefits to be derived from lens implantation when such conditions exist. Patients who experience surgical complications associated with the cataract extraction procedure (posterior capsule rupture, detached Descemet's membrane, anterior chamber bleeding, iris damage, or vitreous bulge or loss) may experience poorer visual acuity. Medical judgment must be exercised to determine if a lens should be implanted when surgical problems occur. Patients who experience postoperative complications, particularly macular edema, may have a slightly higher risk of experiencing poorer visual outcome than patients without sight-threatening complications. This lens is not intended, nor should be used, for a clear lens exchange. **ADVERSE EVENTS:** The most frequently reported adverse events that occurred during the clinical trial of the SofPort® were hypopyon, intraocular infection and acute corneal decompensation all of which occurred at a rate of <0.5%. Other reported events occurring in less than 1% of patients were secondary surgical interventions. **CAUTION:** Federal law restricts this device to sale by or on the order of a physician. **ATTENTION:** Reference the Directions for Use labeling for a complete listing of indications and important safety information.

1. Lisa B. Samalonis. Review of Ophthalmology 15 of June 2005. Aspheric IOLs: from Theory to Practice.
 2. Altmann GE, Nichamin LD, Lane SS, Pepose JS. Optical performance of 3 intraocular lens designs in the presence of decentration. J Cataract Refract Surg. 2005;31:574-585.
 3. Buehl W et al., Effect of intraocular lens design on posterior capsule opacification. J Cataract Refract Surg 2008; 34: 1976-1985 ASCRS and ESCRS