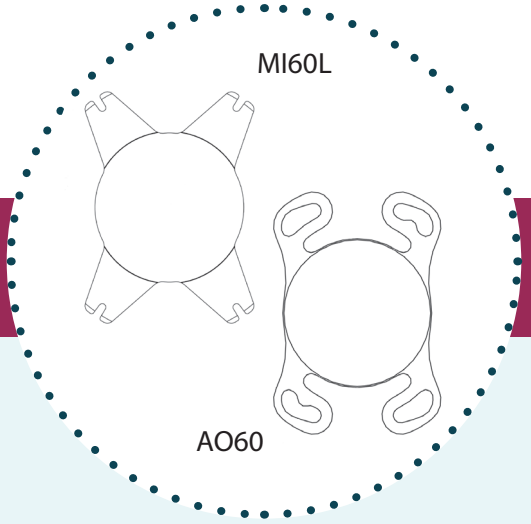
Akreos® 1.8 MICS™
AO Micro Incision Lens

Akreos®
Advanced Optics Aspheric Lens



Akreos AO provides quality of vision and contrast sensitivity with advanced optics [1, 3, 4]

- Manufactured to have a high degree of flexibility to allow for an incision size as small as 1.8 mm [6]
- Three lengths for excellent fit[2] and four-point haptic design for excellent centration and stability[2, 5]
- Minimized reflected light through a design using equi-biconvex and low refractive index material[7]

Model	Recommended Starting A-Constant	Overall Diameter	Diopter Powers
AO60	118.5*	11.0 mm (+0 to +15 D) 10.7 mm (+15.5 to +22 D) 10.5 mm (+22.5 to +30 D)	+0 D to +9 D in 1.0 D steps +10 D to +30 D in 0.5 steps
MI60L	119.1*	11.0 mm (+0 to +15 D) 10.7 mm (+15.5 to +22 D) 10.5 mm (+22.5 to +30 D)	+0 D to +9 D in 1.0 D steps +10 D to +30 D in 0.5 D steps
Incision Size	As small as 1.8 mm		
Optic Shape	Aspheric		
Material—Optic and Haptics	Hydrophilic Acrylic with UV Blocker		
Refractive Index at 35°C	1.458		

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

	Model AO60			Model MI60L
Optic Body Diameter	6.2 mm (+0 to +9 D) 6.0 mm (+10 to +30 D)			6.2 mm (+0 to +15 D) 6.0 mm (+15.5 to +22 D) 5.6 mm (+22.5 to +30 D)
Delivery Systems	VIS100	AI-28	INJ100	VIS100

INDICATIONS: Akreos® posterior chamber intraocular lenses are indicated for primary implantation for correction of aphakia in adult patients in whom a cataractous lens has been removed by phacoemulsification. The lens is intended for placement in the capsular bag. PRECAUTIONS: Do not resterilize these lenses. Do not reuse the IOL. Do not store the device in direct sunlight or at a temperature below freezing (<0°C). Store at room temperature. Avoid high temperatures (>45°C). Do not implant the IOL if the outer pouch or vial is opened or damaged. Do not reuse the IOL. Do not soak or rinse lenses in solutions other than balanced salt solution or equivalent. The IOL should be used in the shortest possible time after opening the vial. Do not implant the IOL if the lens is not completely immersed in solution under any vial orientation. Akreos® lenses can absorb substances that they contact (disinfectant, drug). Do not place the lens in contact with surfaces where such contamination can occur. If YAG laser posterior capsulotomy is performed, assure that the laser beam is focused slightly behind the posterior capsule. WARNINGS: Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio: Patients with recurrent severe anterior or posterior segment inflammation or uveitis; patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases; surgical difficulties at the time of cataract extraction, which may increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss); a compromised eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible; circumstances that would result in damage to the endothelium during implantation; suspected microbial infection; patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL; children under the age of 2 years are not suitable candidates for intraocular lenses. Since the clinical study for the Akreos® intraocular lens was conducted with lens being implanted in the capsular bag, there is insufficient clinical data to demonstrate its safety and efficacy for placement in the ciliary sulcus. YAG posterior capsulotomies should be delayed until at least 12 weeks after the implant surgery. The posterior capsulotomy opening should be kept as small as possible. There is an increased risk of lens dislocation and/or secondary surgical intervention with early or large capsulotomies. Improper handling may cause damage to the haptic or optic portions of Akreos® foldable lenses. If lenses are not handled appropriately, optic tears may result. Physicians should not attempt to implant lenses that have radial optic tears or separations at the optic/haptic interface. Use of folding instruments other than those validated and recommended in the labeling might result in IOL damage (optic tears, haptic damage) that might require IOL explantation To avoid the creation of permanent forceps marks in the central optic zone, exercise care during handling and insertion of the lens. ADVERSE EVENTS: The incidence of adverse events experienced during the clinical trial was comparable to or lower than the incidence reported in the historic control ("FDA grid") population. As with any surgical procedure, risk is involved. The most frequently reported cumulative adverse event that occurred during the clinical trial of the Akreos® was cystoid macular edema, which occurred at a rate of 1.4%. Persistent adverse events included macular edema (0.3%) and iritis (0.3%), were comparable to or lower than the incidence reported in the historic control ("FDA grid") population, as well as corneal edema (0.9%) and raised IOP requiring treatment (0.6%), which were higher than the incidence reported in the FDA grid. 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. Jorge L. Alió, MD, PhD, David P. Piñero , MSc, Dolores Ortiz, PhD, Raúl Montalbán, OD. Clinical outcomes and postoperative intraocular optical quality with a microincision aberration-free aspheric intraocular lens. J Cataract Refract Surg 2009; 35:1548-1554.
2. Akreos MICS DFU
3. Izzet Can, Tamer Takmaz, Yelda Yildiz, Hasan Ali Bayhan, Gulizar Soyugelen, Basak Bostanci. Coaxial, microcoaxial, and biazial microincision cataract surgery. J Cataract Refract Surg 2010; 36:740-746.
4. Marcony R. Santhiago, Marcelo V. Netto, Jackson Barreto Jr, Beatriz A. F. Gomes, Adriana Mukai, Ana Paula Calil Guermandi, Newton Kara-Junior. Wavefront Analysis, Contrast Sensitivity, and Depth of Focus After Cataract Surgery With Aspherical Intraocular Lens Implantation. American Journal of Ophthalmology, March 2010, Vol. 149, No. 3.
5. Phillip J. Buckhurst, James S. Wolffsohn, Shehzad A. Naroo, Leon N. Davies. Rotational and centration stability of an aspheric intraocular lens with a simulated toric design. J Cataract Refract Surg 2010; 36:1523-1528.
6. Data on file: Recommended incision size memo
7. Eric JC et al. Analysis of postoperative glare and intraocular lens design. J Cataract Refract Surg. 2001; 27:614-21