EVO Visian ICL™

PATIENT SELECTION

EVO Visian ICL family of lenses ("EVO")* are indicated for use in phakic eye treatment in patients 21–45 years of age who meet the criteria listed below:

- Correction or reduction of myopia with or without astigmatism with spherical power ranging from -3.0 D to -20.0 D and cylinder power from 1.0 to 4.0 D at the spectacle plane
- With an anterior chamber depth (ACD) equal to or greater than 3.00 mm, as measured from the corneal endothelium to the anterior lens capsule
- Stable refractive history (within 0.5 D one year prior to implantation)

EVO candidates may include:

- Myopes starting as low as -3.0 D through to -20.0 D
- Patients being considered for laser vision correction procedures
- Patients with thinner corneas[1]
- Patients with dry eye risk factors[2]
- Patients whose corneal topography is less suited for laser vision correction

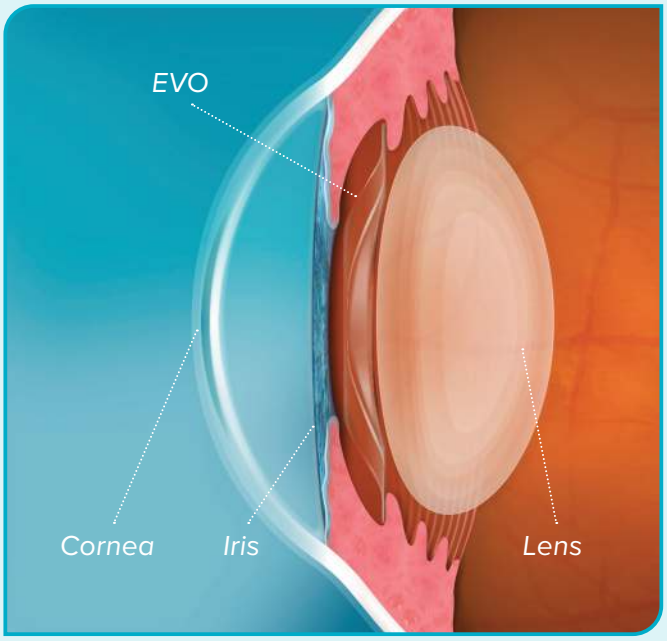
Patients NOT suitable for EVO include those:

- With an ACD of < 3.00 mm
- With anterior chamber angle < Grade III as determined by gonioscopic examination
- Who are pregnant or nursing
- Who are less than 21 years of age
- Who do not meet the minimum endothelial cell density

*EVO Visian ICL family of lenses include EVO Visian ICL, EVO+ Visian ICL, EVO Visian Toric ICL, EVO+ Visian Toric ICL

HOW DOES IT WORK?

- EVO is placed directly behind the iris and in front of the natural crystalline lens. In this position, EVO helps the eye to focus light properly onto the retina to create clear distance vision. The addition of the central port to EVO facilitates the flow of aqueous humor through the lenses, eliminating the need for peripheral iridotomies (PIs) prior to implantation.



BENEFITS

Made with Collamer® biocompatible material that works in harmony with the natural eye

Does not induce dry eye syndrome[2]

Permanent yet removable, if necessary

Excellent vision day and night[3,4]

99.4% of patients would have the procedure again[5]

UV protection

Evolution in Visual Freedom™

PREOPERATIVE INFORMATION

PATIENT WORK UP

- A standard, full ophthalmic exam should be performed
- Measurements needed for performing EVO calculations in the Online Calculation and Ordering System (OCOS)
  Screenshot of OCOS data entry tab shown to the right

MEASUREMENTS RECOMMENDED FOR PATIENT ASSESSMENT AND RECORDS

- Corneal Endothelial Cell Density (ECD) assessment
- Gonioscopic assessment of the angle, Grade III or higher
- Axial length
- Accurate and stable refraction

Calculate For	ICL • Toric ICL	
Patient ID	EVOPATIENT005	
Operative Eye	• OD OS	
DOB	1995.01.01	
Back vertex distance — BVD	12	
Manifest and/or cycloplegic refraction — Sphere	-5.50	
Cylinder	+2.00	
Axis	90	
	Power	**Degrees**
Keratometry — K1	42	@ 0
K2	44	@ 90
*True anterior chamber depth** — True ACD	3.0	
Corneal thickness — CT	0.5	
White to white — WW	11.8	
Contact lens over refraction sphere (optional) — CL Sphere	0	

**True ACD does not include Corneal Thickness*

POSTOPERATIVE INFORMATION

RECOMMENDED PATIENT POSTOPERATIVE ASSESSMENT[6]

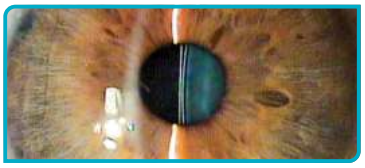
Postoperative same day,* 1 day, 7 day and beyond

- Visual acuity
- Intraocular pressure*
- Assess the ICL to crystalline lens vault
- Biomicroscopy to assess
  - EVO centration
  - Inflammation

MEASURING THE VAULT

Although the postoperative vault of EVO is intended to be approximately equal to the central corneal thickness, the optimal vault should be between 50% and 150% of central corneal thickness, this being equivalent to a range of 250 to 900 microns. However, in the absence of symptoms, lens vault outside this range may not necessarily require exchange or removal.

NORMAL VAULT



SHALLOW VAULT

HIGH VAULT

EVO models available:

Models	Spherical Power (D)	Cylindrical Power (D) (For EVO/EVO+ Toric)	Overall Diameters (mm)
EVO+	-3.0 to -14.0 -3.5 to -14.0** (EVO+ Toric)	1.0 to 4.0	12.1 12.6 13.2 13.7
EVO	-14.5 to -16.0 -14.5 to -18.0** (EVO Toric)		

***Product is unavailable if Spherical Equivalent (SEQ) is outside the -3.0 D to -16.0 D range*
Spherical and Cylindrical Powers available in 0.5 D steps
The EVO+ model offers an increase in optic diameter of 0.1 mm to 0.5 mm larger than the available EVO model

References:

1. Parkhurst GD, Psolka M, Kezirian GM. Phakic intraocular lens implantation in United States military warfighters: a retrospective analysis of early clinical outcomes of the Visian ICL. Journal of refractive surgery (Thorofare, NJ : 1995). 2011;27(7):473-81. **2.** Naves, J. Carracedo, G. Cacho-Babillo, I. Diadenosine Nucleotid Measurements as Dry-Eye Score in Patients After LASIK and ICL Surgery. Presented at American Society of Cataract and Refractive Surgery (ASCRS) 2012. **3.** Parkhurst GD. A prospective comparison of phakic collamer lenses and wavefront-optimized laser-assisted in situ keratomileusis for correction of myopia. Clinical ophthalmology (Auckland, NZ). 2016;10:1209-15. **4.** Martínez-Plazs E, López-Miguel A, López-De La Rosa A, et al. Effect of the EVO+ Visian Phakic Implantable Collamer Lens on Visual Performance and Quality of Vision and Life, Am J Ophthalmol 2021;226: 117–125. **5.** Packer M. The Implantable Collamer Lens with a central port: review of the literature. Clinical ophthalmology (Auckland, NZ). 2018;12:2427-38. **6.** Chuck RS, Jacobs DS, Lee JK, Afshari NA, Vitale S, Shen TT, *et al.* Refractive Errors & Refractive Surgery Preferred Practice Pattern®. Ophthalmology. 2018;125(1):P1-p104.

Important Safety Information for the Visian ICL Product Family:

The EVO Visian ICL is indicated for phakic patients 21-45 years of age to correct/reduce myopia with up to 4.00 D of astigmatism with a spherical equivalent ranging from -3.00 to -20.0 D and with an anterior chamber depth (ACD) 3.0 mm or greater. The EVO Visian ICL is contraindicated in patients with a true ACD of <3.00mm; with anterior chamber angle less than Grade III; who are pregnant or nursing; less than 21 years of age; and who do not meet the minimum endothelial cell density (ECD) listed in the Directions For Use (DFU). A summary of the relevant warnings, precautions and side effects: Endothelial cell loss, corneal edema, cataract, narrowing of the anterior chamber angle, pupillary block, increased intraocular pressure, glaucoma, secondary surgery to reposition, replace or remove the ICL, loss of BSCVA, increase in refractive astigmatism, glare and/or halos, pigment dispersion, iris transillumination defects, endophthalmitis, hypopyon, corneal endothelial damage, ICL dislocation, cystoid macular edema, iritis, retinal detachment, vitritis, and iris prolapse. Please review the DFU for complete safety and other information before performing the clinical procedure.

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