

# PATIENT SELECTION

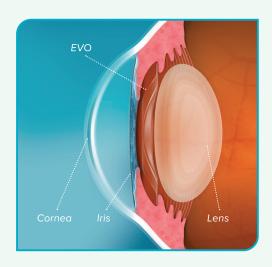


The EVO ICL family of lenses\* (EVO) is indicated for use in phakic eye treatment in patients 21-60 years of age who meet the criteria listed below:

- The correction/reduction of myopia with or without astigmatism
- Requiring a lens with sphere power of -0.5 D to -18.0 D and cylinder power up to +6.0 D
- With an anterior chamber depth (ACD) equal to or greater than 2.8 mm, as measured from the corneal endothelium to the anterior lens capsule

#### 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.



## **EVO** candidates may include:

- Myopes starting as low as -0.5 D to -18.0 D
- · Patients being considered for laser vision correction procedures
- · Patients with thinner corneas1
- Patients with dry eye risk factors<sup>2</sup>
- · Patients whose corneal topography is less suited for laser vision correction

#### Patients NOT suitable for EVO include those:

- With an ACD of < 2.8 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
- With low/abnormal corneal endothelial cell density, Fuch's dystrophy or other corneal pathology
- With any cataract in the operative eye or nontraumatic cataract in the fellow eye
- · With primary open angle or narrow angle glaucoma
- · With previous or pre-existing ocular disease that would preclude post operative visual acuity of 0.477 (logMAR), 20/60 (Snellen), 0.33 (Decimal), or better
- · Who are amblyopic or blind in the fellow eye
- · With ocular hypertension in either eye

## PATIENT ADVANTAGES



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





Does not induce dry eye syndrome 2,3

99.4%

of patients surveyed would have the procedure again 6



Permanent yet removable by a doctor, if necessary



protection

<sup>\*</sup>EVO ICL family of lenses include EVO ICL, EVO+ ICL, EVO Toric ICL, EVO+ Toric ICL

## PREOPERATIVE INFORMATION

### **PATIENT WORK UP**

- · A standard, full ophthalmic exam should be performed
- Measurements needed for performing EVO calculations using the Stella<sup>TM</sup> ordering system.

See Pre-Op Data Valid Values table 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

Back vertex distance
Manifest and/or cycloplegic refraction
Keratometry

Contact lens over refraction sphere (optional)

	Pre-Op Data Valid Values	
1	BVD*	4.00 mm to 17.00 mm
1	Sphere	-20.00 D to -0.25 D
	Cylinder	-4.00 D to 4.00 D
	Axis	0 to 180°
	Keratometric Power (K1)	30.00 D to 60.00 D
	K1 axis	0 to 180°
	Keratometric Power (K2)	30.00 D to 60.00 D
	K2 axis	0 to 180°
	True ACD**	3.00 mm to 4.50 mm
	Corneal Thickness (CCT)***	300 μm to 900 μm
	White to White	10.50 mm to 12.90 mm
1	CL Sphere	-20.0 D to 0.00 D

- \*BVD defaults to 12.00 mm
- \*\*True ACD does not include CCT
- \*\*\*CCT is in micrometers

## POSTOPERATIVE INFORMATION

## RECOMMENDED PATIENT POSTOPERATIVE ASSESSMENT 6

Postoperative same day, day 1, day 7 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+	-0.5 to -14.0	05+260	12.1 12.6
EVO	-0.5 to -18.0	0.5 to 6.0	13.2 13.7

Spherical models available in 0.25 D increments from -0.5 D to -3.0 D and 0.50 D increments from -3.0 D to -18.0 D Toric models are only available in 0.5 D increments

#### 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. Ganesh S, Brar S, Pawar A. Matched population comparison of visual outcomes and patient satisfaction between 3 modalities for the correction of low to moderate myopic astigmatism. Clin Ophthalmol. 2017;11:253-63. 3. Zhang H, Deng Y, Ma K, Yin H, Tang J. Analysis on the changes of objective indicators of dry eye after implantable collamer lens (ICL) implantation surgery. Graefes Arch Clin Exp Ophthalmol. 2024 Jul;262(7):2321-2328. 4. Parkhurst GD. A prospective comparison of phakic collamer lenses and wavefront-optimized laser-assisted in situ keratomileusis for correction of myopia. Clinical ophthalmology. 2016;10:1209-15. 5. Martinez-Plaza 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. 6. Packer M. The Implantable Collamer Lens with a central port: review of the literature. Clinical ophthalmology. 2018;12:2427-38. 7. Chuck RS, Jacobs DS, Lee JK, Afshari NA, Vitale S, Shen TT, et al. Refractive Errors & Refractive Errors Current Practice Pattern\*. Ophthalmology. 2018;125(1):P-p104.

### Important Safety Information for the EVO/EVO+ ICL:

The EVO/EVO+ ICL is indicated for phakic patients 21-60 years with an anterior chamber depth (ACD) 2.8 mm or greater and are available in spherical powers ranging from -3.0 D to -18.0 D for the correction/ reduction of myopia with or without a cylinder power range from 1.0 D to 6.0 D. Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/ benefit ratio before implanting a lens in a patient with any of the conditions described in the DFU. Prior to surgery, physicians should inform prospective patients of possible risks and benefits associated with the EVO/EVO+ ICL. Reference the EVO/EVO+ ICL DFU available at https://edfu.staar.com/edfu/ for a complete listing of indications, contraindications, warnings and precautions.