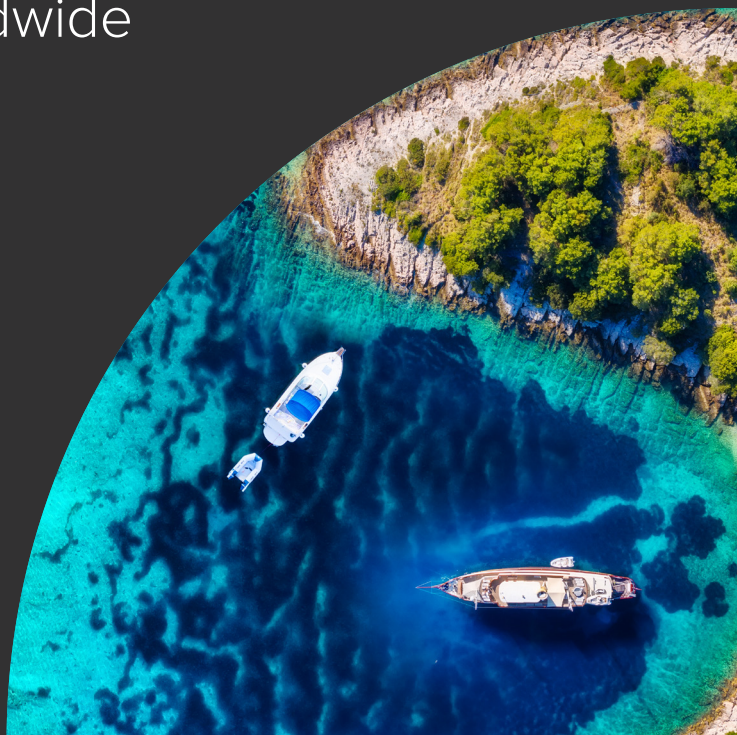
EVO ICL™

THERE'S ONLY ONE

Collamer™ is the one-of-a-kind material that defines EVO ICL™ worldwide



STAARSURGICAL™

What matters in ICL

EVO ICL™

Outcomes matter

- Outstanding postoperative uncorrected visual acuity[1]
- Superb quality of vision[1]
- Excellent night vision[2]
- Improved quality of life[2]

Innovation matters

- Preserves the cornea and crystalline lens[3]
- No preoperative peripherial iridotomies (PIs)
- Collamer material is biocompatible, providing a flexible and stable phakic lens
- Advanced manufacturing drives high quality

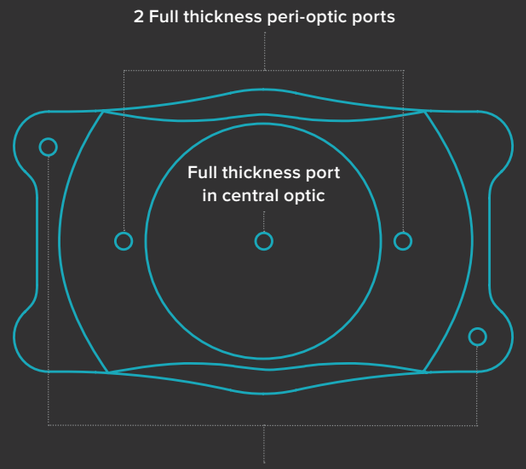
Trust matters

- Low rate of adverse events[1]
- Outstanding safety and effectiveness[1-4]
- High rate of patient satisfaction[1]
- Over 3 million ICLs have been distributed worldwide

Experience matters

- Celebrating 30 years of delivering visual freedom
- First to market with ICL technology
- Has set high standards for ICL efficacy and safety since 1993
- More clinical studies than any other phakic implantable lens

Only one with AquaPORT®



The novel 0.36 mm diameter central port design:[5]

- Functions effectively to allow physiologic aqueous flow resulting in
  - Reduced risk of pupillary block and anterior subcapsular cataract[6]
- Eliminates the requirement for preoperative PIs

Only one with Collamer™

Collamer is derived from two words that describe the composition of the material: “Collagen” and “Co-polymer.”

Collamer is a co-polymer of poly-HEMA and collagen, that offers UV protection.

3M

Collamer has a proven history of over 30 years with more than 3 million ICL lenses distributed worldwide.

Collamer minimizes inflammation, flare and cellular reaction.[7,8]

Works in harmony with the eye

Effectiveness

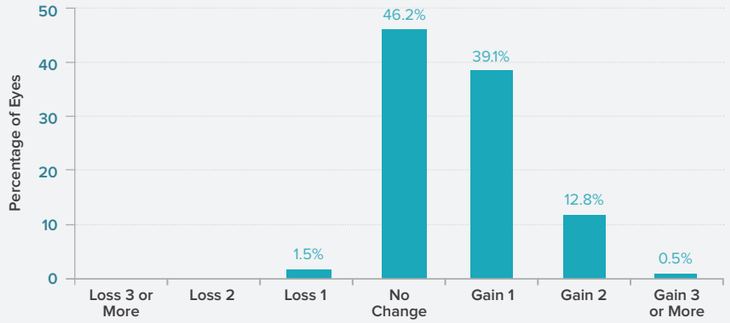
The effectiveness of EVO is demonstrated by the high levels of postoperative uncorrected visual acuity, refractive predictability and stability[1] enjoyed by patients.

Efficacy Index is defined as UCVA (Uncorrected Visual Acuity) after treatment divided by CDVA (Corrected Distance Visual Acuity) before treatment (UCVA post/CDVA pre).

	Eyes (n)	Follow Up	Efficacy Index	UDVA	Accuracy within ± 0.50 D	Accuracy within ± 1.0 D
Published Literature[1]	**n = 1,905**	**Up to 5 years**	**1.04**	-0.02 logMAR	90.8%	98.7%
FDA Clinical Trial[5]*	**n = 629**	**6 months**	**1.06**	-0.059 logMAR	90.5%	98.9%

*619 eyes (98.4%) were available for analysis at the 6-month visit.

Change in Corrected Distance Visual Acuity



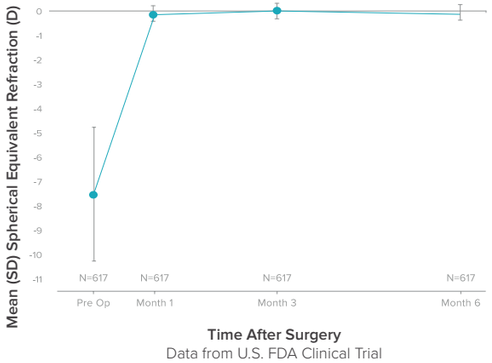
98.5%
of eyes were the same or better.[4]

52.3%
of eyes gained one or more lines of CDVA.[5]

Figure adapted from Packer. 2022.[5]

Refractive Stability

Excellent refractive stability.



Note: Consistent cohort of subjects with all visits are used.
Figure adapted from Packer. 2022.[5]

IOP Stability

Intraocular pressure (IOP) is well controlled.

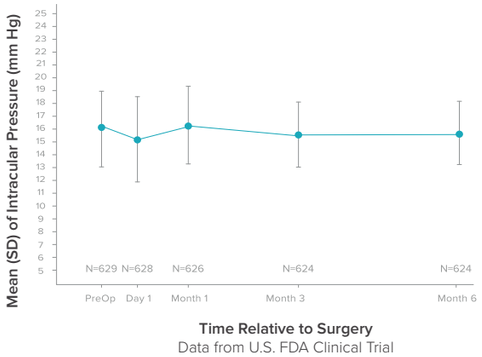
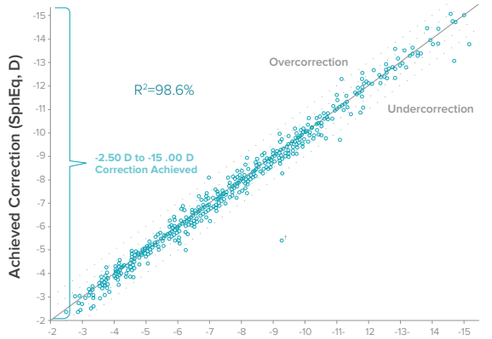


Figure adapted from Packer. 2022.[5]

Predictability

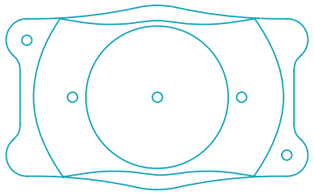
High predictability across a large diopter range.



† In the U.S. FDA clinical trial, one eye experienced myopic shift due to nuclear sclerosis
Figure adapted from Packer. 2022.[5]

Rotational Stability

Of 629 eyes implanted with EVO, only one eye with a toric lens required surgical repositioning for residual astigmatism.[5]



Data from U.S. FDA Clinical Trial

Excellent Night Vision

EVO provides postoperative improvement in mesopic contrast sensitivity (CS) with and without glare.[2]

EVO Performance in Mesopic (Twilight) Conditions with Halogen and Xenon Glare

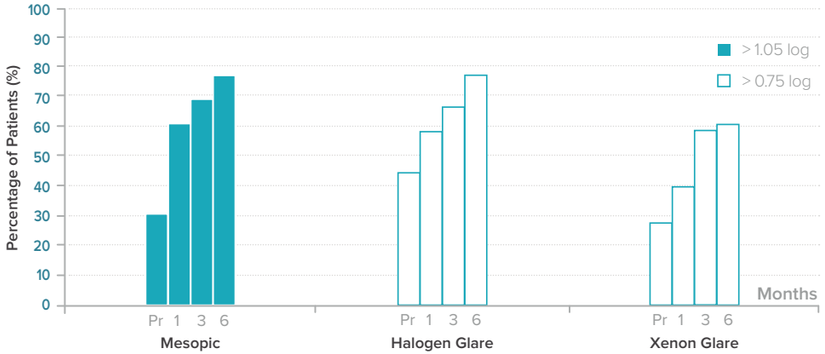


Figure adapted from Martinez-Plaza et al. 2021.[2]

Low Higher-Order Aberrations

Low induction of coma-like, spherical-like and total higher-order aberrations (HOA).[9]

Higher-Order Aberrations

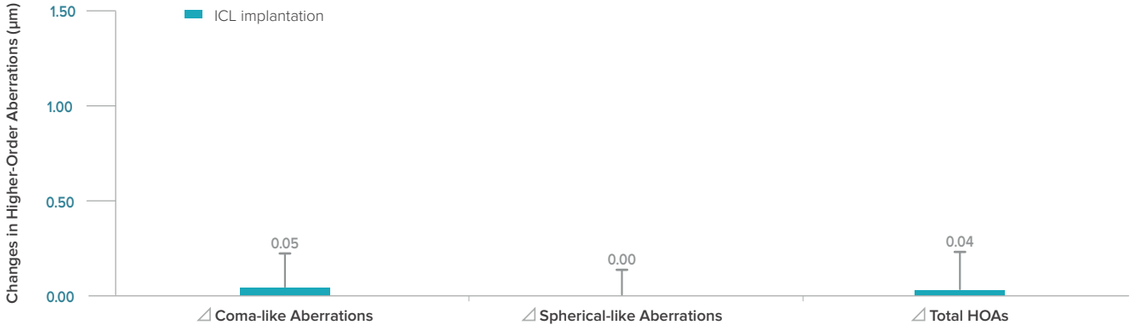


Figure adapted from Igarashi. 2019.[9]

Proven Safety

Safety data suggest reduced rates of anterior subcapsular cataract and pupillary block relative to earlier models.[1,5]

Safety Index is defined as CDVA after treatment divided by CDVA before treatment (CDVA post/CDVA pre).

	Eyes (n)	Follow Up	Safety Index	ASC Cataract	Pupillary Block	Pigment Dispersion
Published Literature[1]	n = 4,196	Up to 5 years	1.15	0.00% (n = 0)	0.02% (n = 1)**	0.00% (n = 0)
FDA Clinical Trial[8]*	n = 629	6 months	1.24	0.00% (n = 0)	0.00% (n = 0)	0.00% (n = 0)

*619 eyes (98.4%) were available for analysis at the 6-month visit.
**Due to retained viscoelastic.[1]

EVO offers patients an exciting and safe option in refractive surgery.

Does not induce dry eye syndrome[10]

Rapid visual recovery[3,11]

No risk of ectasia[11]

Available Models of the EVO Family of Lenses

Models	Spherical Power (D)	Cylindrical Power (D) (for EVO/EVO+ Toric)	Overall Diameters (mm)
EVO+	-0.5 to -14.0	0.5 to 6.0	12.1 12.6 13.2 13.7
EVO	-0.5 to -18.0		

EVO ICL spherical models available in 0.25 D increments from -0.5 to -3.0 D, and 0.5 D increments from -3.0 D to -18.0 D; toric models are available in 0.5 D increments.

IMPORTANT SAFETY INFORMATION FOR THE EVO/EVO+ ICL

All physicians must complete the STAAR Surgical Visian ICL Physician Training Certification Program prior to using the EVO/EVO+ ICL in a clinical setting. Please review the EVO/EVO+ ICL Directions For Use (DFU) completely before performing a clinical procedure.

INDICATIONS: The EVO/EVO+ ICL is indicated for phakic patients 21-60 years, with an anterior chamber depth (ACD) 2.8 mm or greater to correct/reduce myopia ranging from -0.5 diopters to -20.0 diopters with up to 6.0 D of astigmatism. The EVO/EVO+ ICL is intended for placement in the posterior chamber of the eye.

WARNING/PRECAUTION: 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.

ATTENTION: Reference the EVO/EVO+ ICL DFU available at https://edfu.staar.com/edfu/ for a complete listing of indications, contraindications, warnings and precautions.

REFERENCES

1. Packer M. The Implantable Collamer Lens with a central port: review of the literature. Clinical ophthalmology (Auckland, NZ). 2018;12:2427-38. **2.** Martínez-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;226:117-25. **3.** Kohnen T. Phakic intraocular lenses: Where are we now? *J Cataract Refract Surg*. 2018;44(2):121-3. **4.** Kamiya K, Shimizu K, Igarashi A, Kitazawa Y, Kojima T, Nakamura T, et al. Posterior chamber phakic intraocular lens implantation: comparative, multicentre study in 351 eyes with low-to-moderate or high myopia. *Br J Ophtalmol*. 2018;102(2):177-81. **5.** Packer M. Evaluation of the EVO/EVO+ Sphere and Toric Visian ICL: Six month results from the United States Food and Drug Administration clinical trial. Clinical Ophthalmology. 2022;16:1541-53. **6**. Data from the US EVO FDA clinical study. **7.** Schild G, Amon M, Abela-Formanek C, Schauersberger J, Bartl G, Kruger A. Uveal and capsular biocompatibility of a single-piece, sharp-edged hydrophilic acrylic intraocular lens with collagen (Collamer®): 1-year results. *J Cataract Refract Surg* 2004;30(6):1254-8. **8.** Brown DC, Ziemba SL. Collamer® intraocular lens: clinical results from the US FDA core study. *J Cataract Refract Surg*. 2001;27(6):833-40. **9.** Igarashi A. Posterior chamber phakic iols vs. Lasik: Benefits and complications. Expert Review of Ophthalmology. 2019;14(1):43-52. **10.** 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*. (Auckland, NZ). 2017;11:1253-63. **11.** Wei R, Li M, Zhang H, Aruma A, Miao H, Wang X, et al. Comparison of objective and subjective visual quality early after implantable collamer lens V4c (ICL V4c) and small incision lenticule extraction (SMILE) for high myopia correction. *Acta Ophthalmol*. 2020;98(8):e943-e50.

STAARSURGICAL™

STAAR Surgical Company
25651 Atlantic Ocean Drive
Lake Forest, CA 92630
(800) 352-7842

DISCOVER MORE ABOUT EVO TODAY!

evo.staar.com