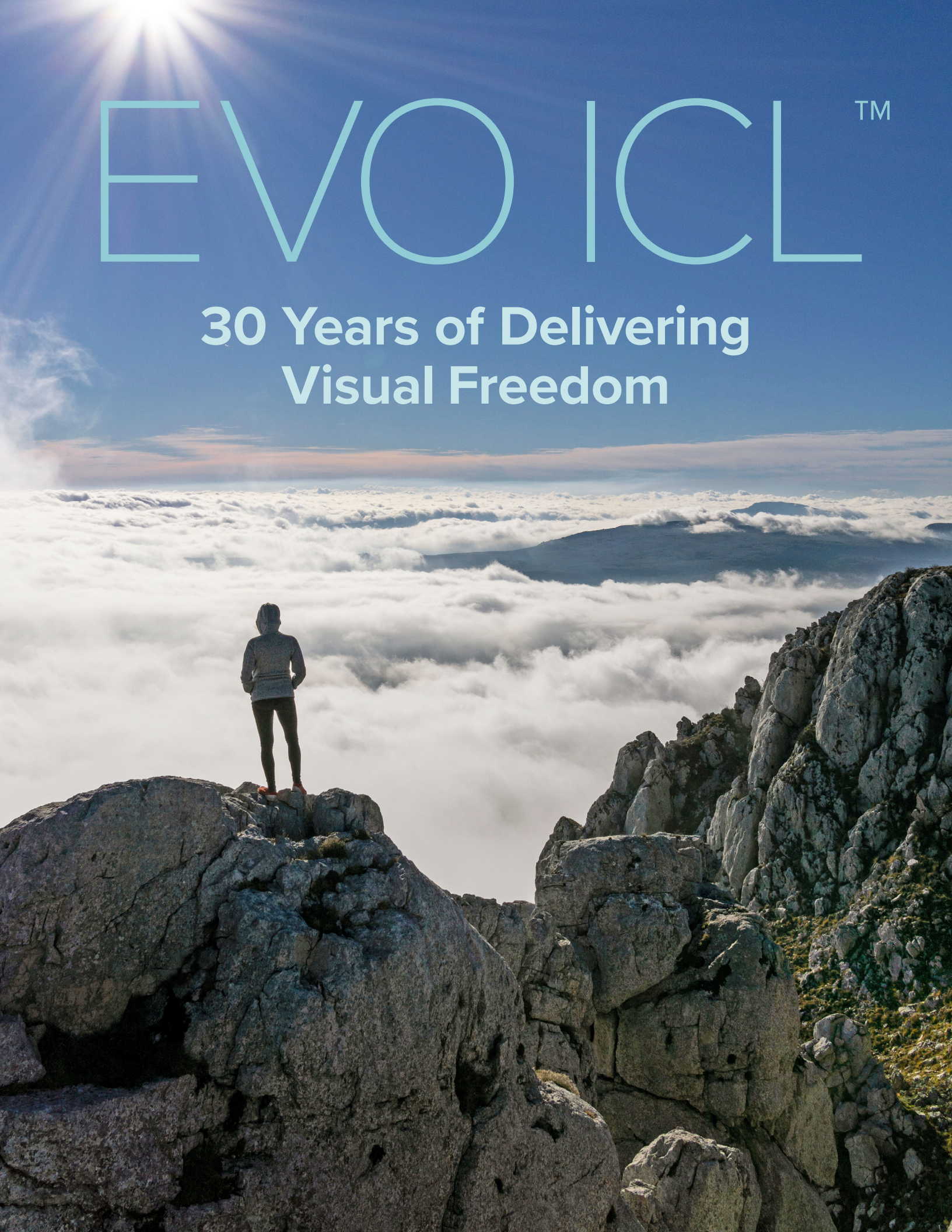
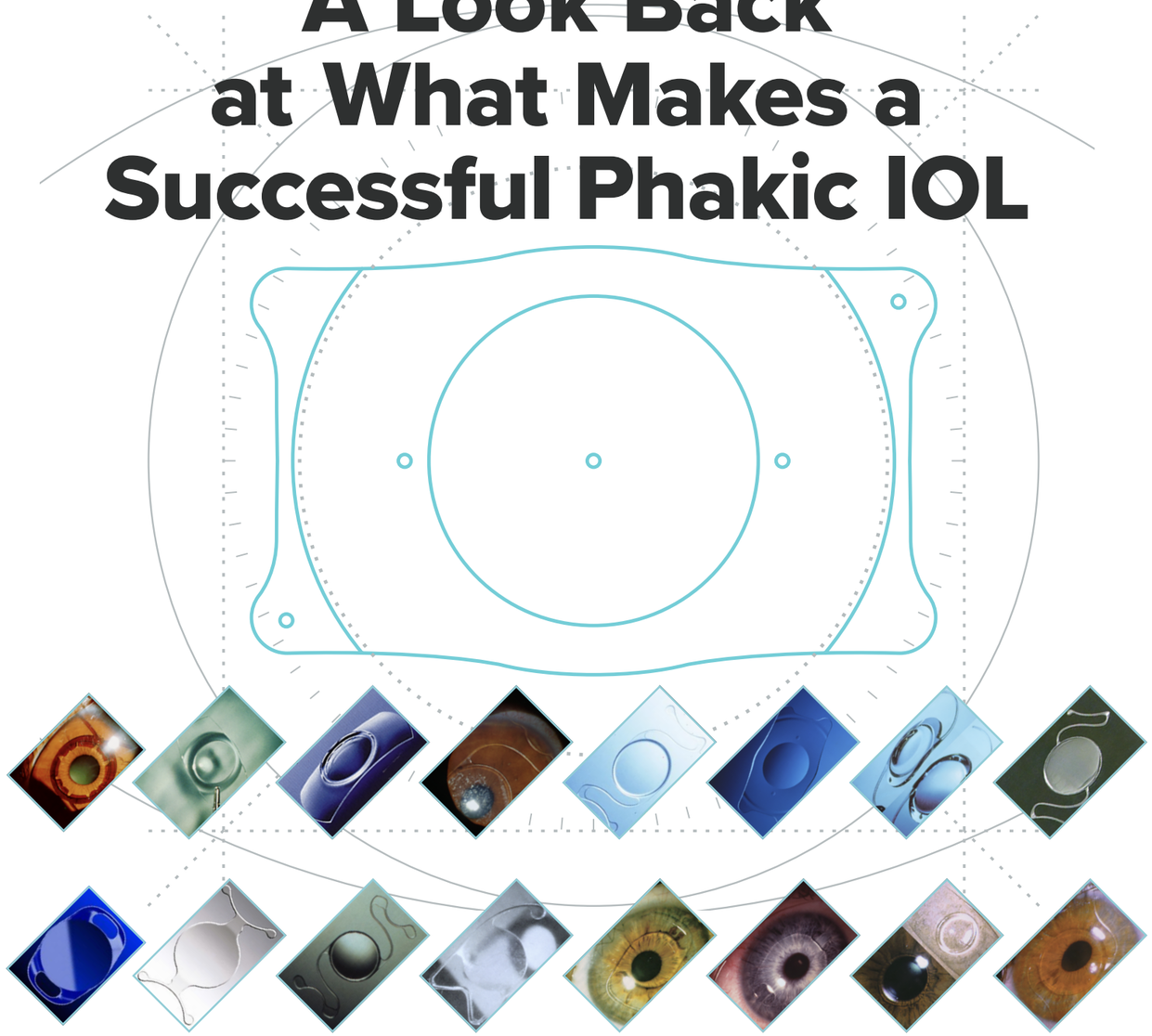

EVO ICL™
30 Years of Delivering
Visual Freedom

A Look Back at What Makes a Successful Phakic IOL



The use of phakic IOLs (pIOLs) is growing dramatically, with implantation of these lenses—primarily EVO ICL™—reaching a double-digit share of overall refractive procedures in many countries around the world. As the category grows and new pIOLs are introduced, it is important to understand the successes and failures of pIOL designs of the past in order to make the best choices for today's patients.

Phakic IOLs have all the same requirements as pseudophakic IOLs: biocompatibility, material clarity, reliable fixation and stability over time. However, lenses intended for correction of refractive error in younger adults have unique design challenges that go well beyond what is required of a lens for cataract surgery:

- They must last and remain clear for decades after implantation.
- In a phakic eye, there is less physical space for the implanted lens, which means it will sit in closer proximity to critical anatomical structures such as the crystalline lens, cornea, and iris. The long-term impact of these tissues' interactions with the phakic implant can only be assessed many years after surgery.
- They must be safely and easily removable—again, typically many years after the original surgery, when the patient eventually develops typical age-related cataracts.

For all these reasons, when adopting pIOL technologies, it is important to review long-term, peer-reviewed clinical results and ensure the lens has a long history of successful implantation in qualifying young patients.

Early history

Well before excimer lasers were used to reshape the cornea, innovators conceived of phakic IOLs as an ideal way to correct vision. The first pIOL, an angle-supported anterior chamber lens, was implanted by Benedetto Strampelli, MD, in 1953.[1] It was soon followed by other designs that relied on iris hooks or "claws" for fixation. These early anterior chamber pIOLs had unacceptable complication rates, including chronic endothelial cell loss (ECL), iris atrophy, pupil ovalization, uveitis, and glaucoma; most were explanted.[2]

Later, between the 1990s and 2010s, more than a dozen pIOL designs received regulatory approval in major markets based on early clinical results. Among these, for example, were foldable angle-supported pIOLs that could be implanted via small incisions, such as the Kelman Duet (Tekia) and Acrysof Cachet (Alcon) lenses. However, the proximity of angle-supported pIOLs to the corneal endothelium continued to cause long-term problems such as ECL[2-4] that eroded confidence in pIOLs; most of the anterior chamber pIOLs ultimately failed in the marketplace.

EVO ICL's origins

Posterior chamber pIOLs were developed with the goal of moving the phakic lens away from the endothelium to reduce the risk of corneal endothelial damage. The posterior chamber pIOL was first developed by refractive surgery pioneer Svyatoslav Fyodorov, MD, who developed a "mushroom" or "collar-button" style pIOL in 1986. Initial complications included corneal touch, decentration, pupillary block glaucoma, and cataract formation.[5] Other posterior chamber pIOLs made from a variety of materials were introduced, including the Phakic Refractive Lens (PRL, CibaVision). This ultrathin silicone pIOL was not well fixated in the posterior chamber and was eventually discontinued due to difficulties with zonular dehiscence and subluxation into the vitreous cavity.[6,7]

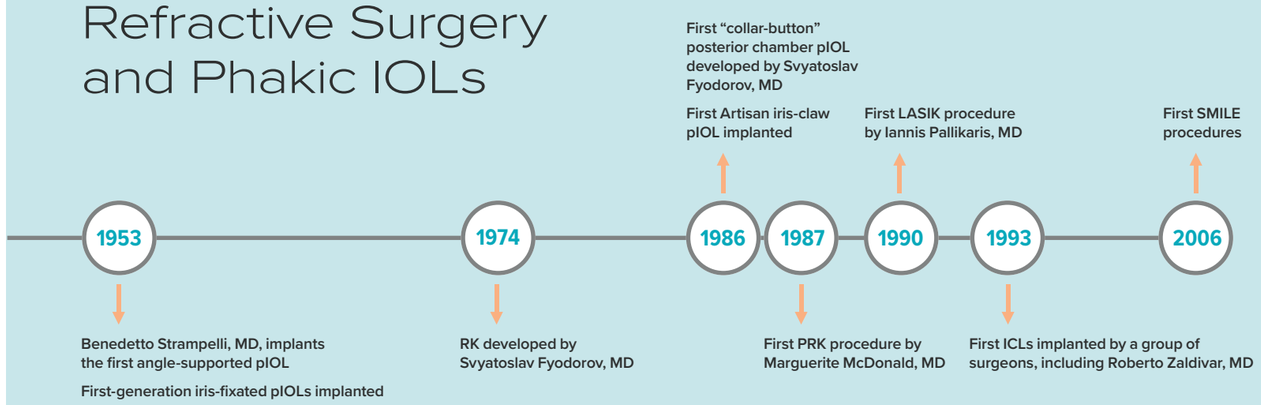
> "Speaking from my own experience of performing ICL surgery for about 23 years, EVO surgery has been thoroughly tested and proven for its long-term stability, effectiveness, and visual acuity." –Jong-Ho Lee, MD, Seoul, Korea

STAAR Surgical™ developed the Implantable Collamer® Lens, a posterior chamber pIOL designed for ciliary sulcus placement. First implanted in 1993, the ICL rapidly became the most widely used posterior chamber pIOL. Numerous studies showed that even early versions of the ICL were stable, safe, and predictable. However, complications such as cataract development and elevated IOP continue to be monitored.

> "With the ongoing development of customized implantation and precise preoperative measurement procedures, EVO ICL surgery is becoming more precise." –Xingtao Zhou, MD, Shanghai, China

Of all the anterior and posterior chamber pIOLs developed over the years, only a few remain on the market, which is now dominated by STAAR Surgical's EVO ICL family.[8] With excellent long-term results and the evolution of ICL technology detailed in the following pages, pIOLs have come full circle—from their origin as one of the earliest forms of refractive surgery to one of the most versatile mainstream refractive surgery options today.

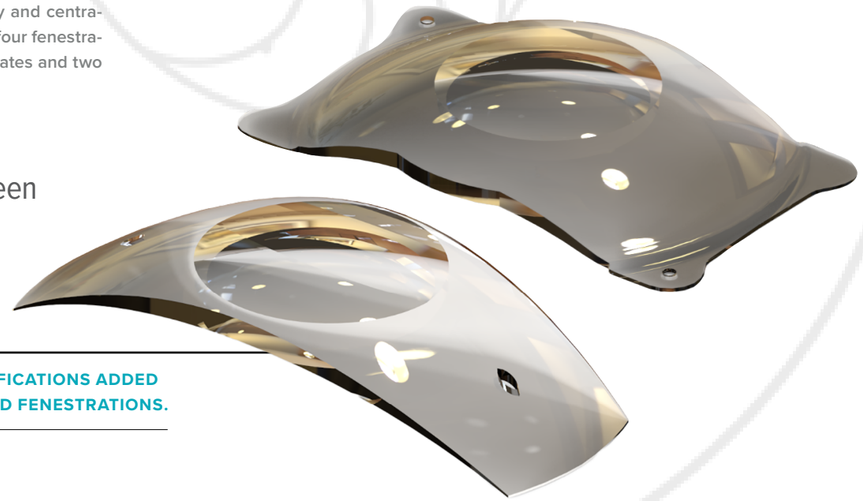
Refractive Surgery and Phakic IOLs



The Evolution of ICL Technology

One of the first STAAR Implantable Collamer Lenses was implanted by Roberto Zaldivar, MD, in 1993. It was a single-piece, plate haptic lens with two 0.9 mm fenestrations (one in each haptic). Between 1993 and 1995, the design was modified rapidly.[9] Distal footplates were added to improve stability and centration. And by 1995, the lens had four fenestrations or holes: Two in the footplates and two on either side of the optic.[9]

> "ICL with the CentraFLOW® has been a game changer."
> –Sanjay Chaudhary, MD, Delhi, India

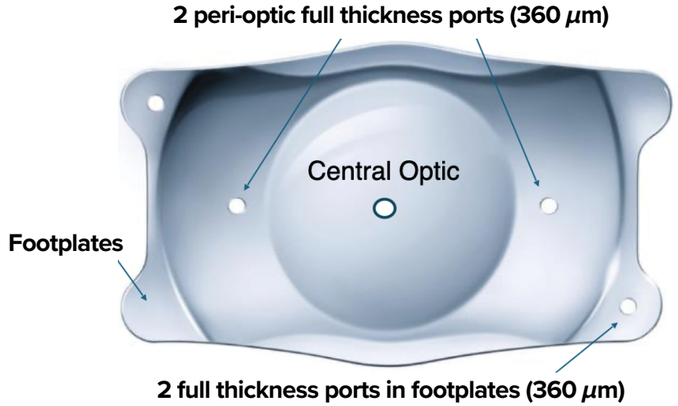


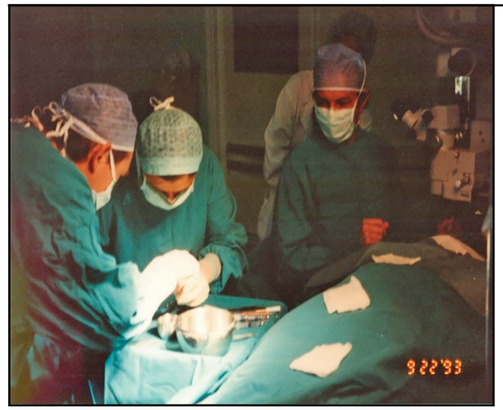
EARLY ICL MODIFICATIONS ADDED FOOTPLATES AND FENESTRATIONS.

The most important design refinement was the introduction of a central port. First discussed and patented in the 1990s, it was further refined with Kimiya Shimizu, MD, and finally launched as the ICL V4c, or EVO, in 2011 in Europe. The 0.36 mm central hole facilitates aqueous flow through the ICL, supporting corneal metabolism and reducing the likelihood of cataract development.[10] By eliminating the need for a preoperative peripheral iridotomy (PI), it has also simplified the surgical technique, shortened the preoperative process, and made the procedure more comfortable for patients. EVO ICL was approved in the European Union, Korea, China, Japan, and Canada by 2016, and in the U.S. in 2022.

Additional design changes have included a refinement of the injector system for easier loading and injection, and the introduction of the EVO+ ICL (V5), which has a larger optic diameter (6.1 mm maximum).

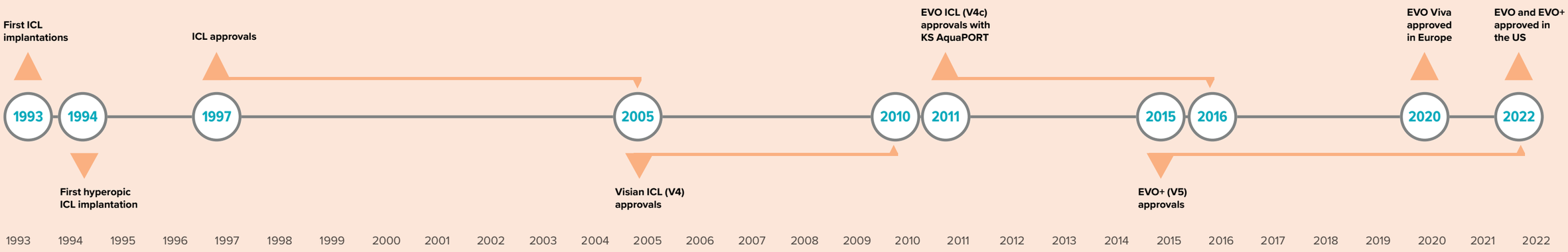
These innovations in ICL design, combined with advances in ICL planning software, further support surgeons in performing EVO ICL procedures. At the same time, surgeons around the world have also identified preferred approaches to patient evaluation for refractive surgery, incorporating new diagnostic and imaging technologies, such as optical coherence tomography and ultrasound biomicroscopy, to visualize and obtain measurements needed for procedure planning.[11]

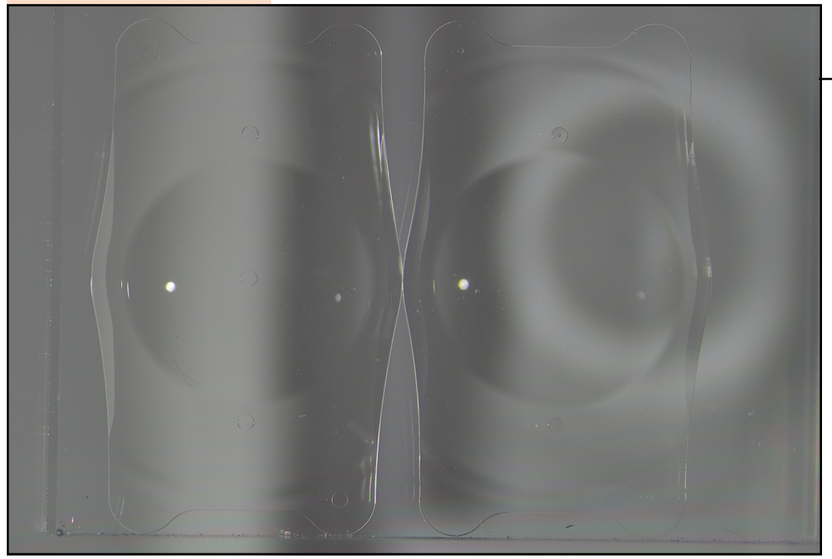




ROBERTO ZALDIVAR, MD, PERFORMS AN EARLY ICL IMPLANTATION.

The History of EVO ICL





AFTER 27 YEARS IN THE EYE, AN ICL (RIGHT IMAGE) EXPLANTED PRIOR TO CATARACT SURGERY IS DIFFICULT TO DISTINGUISH FROM A NEW, UNUSED EVO ICL (LEFT IMAGE).

The Unique Collamer Material

What has never changed over the past 30 years of ICL implantation is the use of the unique Collamer lens material. This copolymer of poly-hydroxyethyl methacrylate (HEMA) and porcine collagen with a chromophore that provides effective UV blocking was developed and patented by STAAR Surgical. The soft, flexible material attracts a fibronectin monolayer on the surface of the lens that inhibits aqueous protein binding.[2,5,12] It has a refractive index of 1.45 at 35°C, and an Abbe number (62) that is higher than that of the human lens (47) and most IOLs (37-55).[13] The refractive index and high Abbe number reduce chromatic aberration and provide excellent clarity and optical performance.

> “Our young pIOL patients must be able to tolerate the material inside their eyes for 30 or 40 years. And then, when it is time for cataract surgery, we should be able to remove it. That’s why we have to take the material so seriously.”
>
> –Roger Zaldivar, MD, Mendoza, Argentina

Evidence of the unique properties of the Collamer material can be found in the experience of surgeons who have explanted an ICL many years later, at the time of cataract surgery. A published report on 13 ICLs explanted after an average of 10.5 years demonstrated long-term stability of the ICL, with no lens changes on electron microscopy and similar light transmission characteristics between the explanted lenses and new, unused lenses.[14] Similarly, clinicians who have explanted lenses after more than 20 years in the eye have anecdotally reported finding no iris damage, no pigment dispersion, no inflammatory cells, and intact clarity, transparency, and elasticity of the material upon removal. The Collamer material can still be folded and manipulated after decades in these eyes.

Given that many other pIOLs have come and gone, including many that were withdrawn from the market due to unacceptable complication rates, the 30 years of proven safety and clinical performance of the ICL and the Collamer material is reassuring. EVO has a trusted reputation and a record of success.

> “EVO ICL is one of the few prostheses in all of medicine—not just in ophthalmology—that can maintain its material properties in the body over a long period of time. I know from personal experience that the ICL will look the same in 25 years as it does today.” –Daniel Elies, MD, Barcelona, Spain

EVO: Proven Results

EFFICACY

EVO ICL is a safe, effective, and predictable procedure widely used around the world for the correction of myopia and myopia with astigmatism, with stable outcomes and low rates of adverse event rates.[15-18] In the U.S., EVO ICLs may be used in a wide range of eyes with -3.0 to -20.0 D of myopia and up to 4.0 D of astigmatism at the spectacle plane. Candidates should have a history of stable refraction over the past year, an anterior chamber angle of Grade III or larger, and an anterior chamber depth of at least 3.0 mm in the U.S. A predicted postoperative vault of 250-900 µm, or 50% to 180% of corneal thickness, is considered optimal.

In the U.S. FDA clinical trial of EVO ICL (n=629 eyes), the mean manifest refraction spherical equivalent (MRSE) at 6 months was -0.08 ± 0.33 D.[18] Mean postoperative uncorrected (UDVA) and corrected (CDVA) distance visual acuity were -0.059 ± 0.10 and -0.13 ± 0.08 logMAR, respectively. MRSE was within 0.5 D of target refraction in 90.5% of eyes and within 1.0 D in 98.9% of eyes. More than half the eyes (52.3%) gained one or more lines of CDVA and no eyes lost more than one line of CDVA.[18] Fully 94.5% of eyes had 20/20 or better UDVA.

> “It’s not uncommon for patients to describe their vision with EVO ICL as being “high definition” compared to their previous experience with glasses or contact lenses.”
>
> –Alaa Eldanasoury, MD, FRCS, Jeddah, Saudi Arabia

Findings in a global review of the literature were similar.[16] The reported efficacy index, or the ratio of postoperative UDVA to preoperative CDVA, ranged from 0.90 to 1.35, with a weighted average of 1.04. The weighted average UDVA after EVO ICL implantation was 20/19 (logMAR -0.02), with a range from 20/12 to 20/27 (logMAR -0.20 to 0.14).[16] An evaluation of long-term results in 177 eyes implanted with the EVO ICL showed excellent safety, accuracy and stability at 8 years of followup.[19]

SAFETY

In the 2018 global literature review that analyzed 67 published papers and more than 4,000 eyes implanted with EVO ICL, there was one reported case of pupillary block (0.04%), 14 cases of secondary surgical intervention (0.47%), and no cases of pigment dispersion or anterior subcapsular cataract.[16] Mean endothelial cell loss was 2.6%. One study with longer follow-up reported mean ECL at 5 years to be only 0.5% ± 5.4%.[20]

Similarly, in the U.S. FDA trial at 6 months post-op, there were no cases of pupillary block, angle closure glaucoma, pigment dispersion or anterior subcapsular cataract.[18] The absence of this type of cataract development is particularly notable, given that cataract was previously considered the most significant complication of posterior chamber pIOLs.

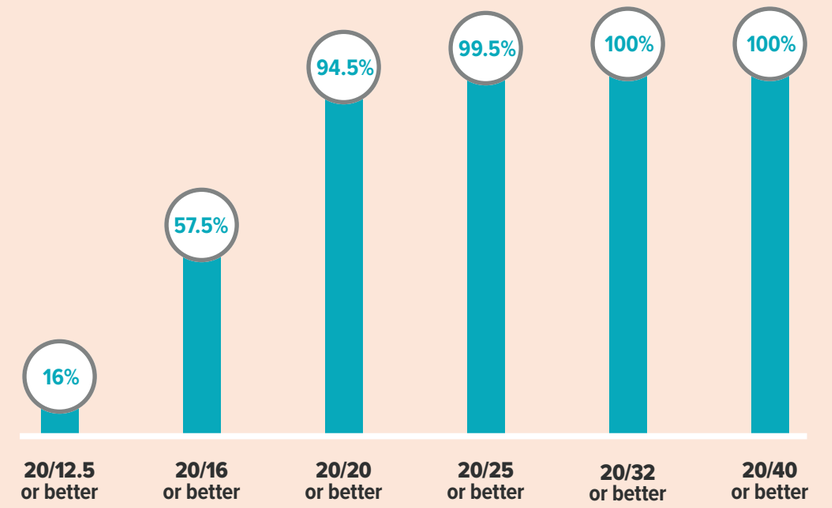
EVO lenses rarely need to be removed or repositioned. In the 2018 global literature review, the incidence of secondary surgical intervention was 0.47%.[16] In one large report of more than 10,000 consecutive ICL cases, only 22 eyes (0.21%) needed to undergo a secondary surgical intervention, such as realignment of toric ICLs or lens exchange.[21]

COMPLICATION RATES[16]

From a 2018 literature review of 4,196 EVO-implanted eyes with up to 5 years follow-up

- 0.00% **Anterior subcapsular cataract**
- 0.04% **Pupillary block**
- 0.00% **Pigment dispersion**
- 0.47% **Secondary surgical intervention**

UNCORRECTED VISUAL ACUITY AT MONTH 6 FOR 200 EYES WITH MODERATE MYOPIA[18]



Lens-Based Refractive Surgery in the Modern Practice

Today, 1 in every 3 people in the world is myopic, and that is expected to increase to 1 in every 2 people by 2050.[22]

Increasingly, refractive surgeons are offering EVO ICL to a much broader range of their myopic patients, including those with moderate myopia who are also eligible for laser refractive surgery. Phakic IOL surgery in general has enduring appeal because it is an additive procedure that offers rapid visual recovery, excellent refractive stability, improved visual acuity, and preservation of accommodation.[1]

> "ICL is an additive surgery that gives excellent results and does not damage the overall structure of the eye. Because of this, it is a leading refractive choice across a wide range of diopters."
>
> **–Zheng Wang, MD, Guangzhou, China**

> "One of the compelling reasons for using EVO ICL is it is reversible surgery, distinguishing it from competitive products like PRK, LASIK, and SMILE, which are irreversible refractive surgeries.
>
> **–Kimiya Shimizu, Md, PhD, Tokyo, Japan**

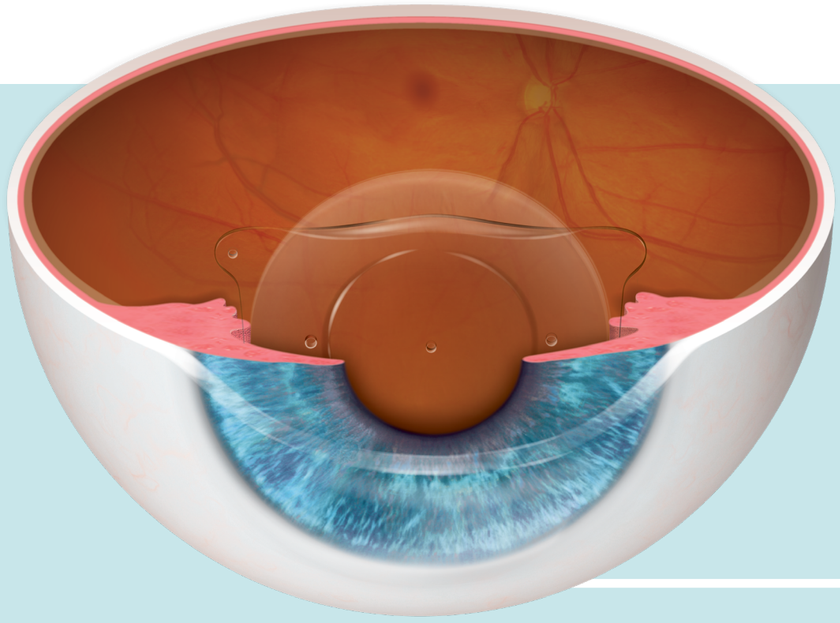
With more than 3 million ICLs distributed worldwide, STAAR Surgical is the undisputed leader in the phakic IOL marketplace. Patients are highly satisfied with the procedure: 99.4% of 1,542 EVO patients from the ICL Data Registry surveyed in 2018 said they would choose EVO again. The procedure represents an easy entry point to refractive surgery for cataract surgeons who may not have or regularly use an excimer laser for corneal refractive surgery.

The EVO ICL can be implanted through a small incision, so it has minimal impact on the cornea and is therefore an option for patients with dry eye risk factors or or corneas unsuitable for laser vision correction. Another key advantage of pIOLs over both laser vision correction and refractive lens exchange is reversibility. But true reversibility—especially many years after initial implantation—hinges on the material being biocompatible in the eye, as the EVO Collamer material has proven to be.

ICL patients undergoing cataract surgery can have biometry and lens power calculation performed as usual and the IOL can be implanted through a typical small incision, with very little change in the cataract surgical procedure. Patients' opportunity to choose multifocal or other advanced IOLs is typically not affected by having had an ICL. Axial length measurement is typically not affected by the ICL, although caution must be taken to correctly measure the anterior chamber depth.[23]

The ease and safety of performing ICL surgery without preoperative PIs since the introduction of EVO has made it a more mainstream procedure in many practices. Once reserved for high myopes, many now offer it as a premium refractive option for patients with moderate myopia. A recent evaluation of EVO ICL in 200 eyes with moderate (-3.00 to -6.00 D) myopia found excellent UDVA, gains in CDVA, and an excellent safety profile for patients in this range of myopia.[24]

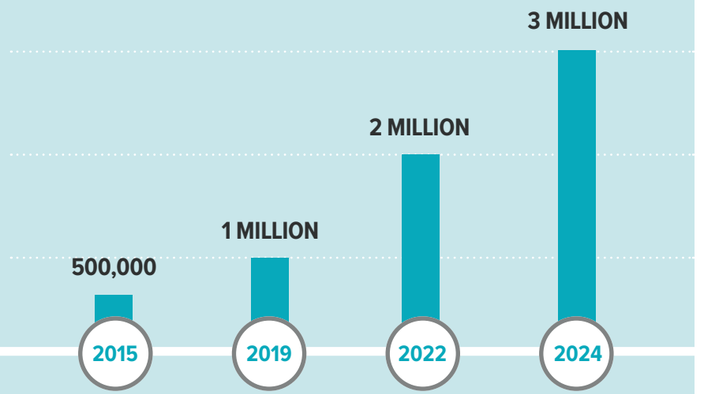
Consider adding EVO ICL to your refractive surgery practice today or expanding the pool of candidates for lens-based refractive surgery.



EVO ICL Advantages

- ADDITIVE PROCEDURE
- DOES NOT REQUIRE REMOVAL OF CORNEAL TISSUE
- RAPID VISUAL RECOVERY[18]
- REFRACTIVE STABILITY[18]
- SURGICALLY REVERSIBLE
- OFTEN IMPROVES BEST-CORRECTED VISUAL ACUITY
- OUTSTANDING OPTICAL QUALITY[18]
- ROTATIONALLY STABLE TORIC LENS[18,25]
- UV BLOCKING MATERIAL
- HIGH RATES OF PATIENT SATISFACTION[16]
- TYPICALLY COMFORTABLE PROCEDURE FOR PATIENTS
- TYPICALLY SHORT LEARNING CURVE FOR CATARACT SURGEONS
- AVOIDS CORNEAL TISSUE REMOVAL MYOPIC REGRESSION
- NO INCREASED RISK OF ECTASIA[21]
- NO INCREASED RISK OF DRY EYE[26]
- PRESERVES ACCOMMODATION
- PRESERVES FUTURE IOL CHOICE AND EASE OF IOL POWER CALCULATIONS

STAAR ICLs Distributed Worldwide (all models)



REFERENCES:

1. Kohnen T. Phakic intraocular lenses: Where are we now? *J Cataract Refract Surg.* 2018;44(2):121-123.
2. Guell JL, Morral M, Kook D, Kohnen T. Phakic intraocular lenses Part 1: Historical overview, current models, selection criteria, and surgical techniques. *J Cataract Refract Surg.* 2010;36:1976-1993.
3. Jonker SM, Berendschot TT, Ronden AE, Saelens IE, Bauer NJ, Nuijts RM. Long-term endothelial cell loss in patients iwth artisan myopia and artisan toric phakic intraocular lenses: 5 and 10 year results. *Ophthalmology.* 2018;125(4):486-494.
4. Kitazawa Y. Phakic intraocular lens for pathological myopia. Pathological myopia from the viewpoint of imaging diagnosis. *Clinical Practice.* 2017;(244-255.)
5. Lovisolo CF, Reinstein DZ. Phakic intraocular lenses. *Surv Ophthalmol.* 2005;50:549-587.
6. Donoso R, Castillo P. Correction of high myopia with the PRL phakic intraocular lens. *J Cataract Refract Surg.* 2006;32:1296-1300.
7. Srinivasan S. Phakic intraocular lenses: Lessons learned. *J Cataract Refract Surg.* 2019:1529-1530.
8. MarketScope. *2023 Refractive Surgery Market Report.* 2023.
9. Zaldivar R. ICL evolution. In: Fine IH, ed. *Clear Corneal Lens Surgery.* SLACK Inc.; 1999:291-293.
10. Kawamorita T, Shimizu K, Shoji N. Effect of hole size on fluid dynamics of a posterior-chamber phakic intraocular lens with a central perforation by using computational fluid dynamics. *Graefes Arch Clin Exp Ophthalmol.* 2016;254:739-744.
11. Thompson V, Cummings AB, Wang X. Implantable Collamer Lens Procedure Planning: A Review of Global Approaches. *Clin Ophthalmol.* 2024;18:1033-1043.
12. Rosen E, Gore C. STAAR Collamer posterior chamber phakic intraocular lens to correct myopia and hyperopia *J Cataract Refract Surg.* 1998;24:596-606.
13. Zhao H, Mainster MA. The effect of chromatic dispersion on pseudophakic optical performance. *Br J Ophthalmol.* 2007;91(9):1225-1229.
14. Nakamura T, Isogai N, Kojima T, et al. Long-term in vivo stability of posterior chamber phakic intraocular lens: Properties and light transmission characteristics of explants. *Am J Ophthalmol.* 2020;219:295-302.
15. Martínez-Plaza E, López de la Rosa A, López-Miguel A, Holgueras A, Maldonado M. EVO/EVO+ Visian Implantable Collamer Lenses for the correction of myopia and myopia with astigmatism. *Expert Rev Med Devices.* 2023;20(2):75-83.
16. Packer M. The implantable collamer lens with a central port: Review of the literature. *Clin Ophthalmol.* 2018;12:2427-2438.
17. Montés-Micó R, Ruiz-Mesa R, Rodríguez-Prats J, Tañá-Rivero P. Posterior-chamber phakic implantable collamer lenses with a central port: A review. *Acta Ophthalmol.* 2021;99(3):e288-e301.
18. 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. *Clin Ophthalmol.* 2022;16:1541-1553.
19. Kamiya K, Shimizu K, Takahashi M, Ando W, Hayakawa H, Shoji N. Eight-year outcomes of implantation of posterior chamber phakic intraocular lens with a central port for moderate to high ametropia. *Front Med* (Lausanne). 2021;(eCollection):799078.
20. Shimizu K, Kamiya K, Igarashi A, Kobashi H. Long-term comparison of posterior chamber phakic intraocular lens with and without a central hole (Hole ICL and Conventional ICL) implantation for moderate to high myopia and myopic astigmatism: Consort-compliant article. *Medicine.* 2016;95(14):e3270.
21. Wei R, Li M, Aruma A, et al. Factors leading to realignment or exchange after implantable collamer lens implantation in 10,258 eyes. *J Cataract Refract Surg.* 2022;48(10):1190-1196.
22. Holden B, Fricke T, Wilson D, et al. Global prevalence of myopia and high myopia and temporal trends from 2000 through 2050. *Ophthalmology.* 2016;123(5):1036-1042.
23. Sanders D, Bernitsky D, Harton PJ, al e. The Visian myopic implantable collamer lens does not significantly affect axial length measurement with the IOLMaster. *J Refract Surg.* 2008;24:957-959.
24. Packer M. The EVO ICL for moderate myopia: Results from the US FDA clinical trial. *Clin Ophthalmol.* 2022;16:3981-3991.
25. Lee H, Kang DSY, Choi JY, et al. Rotational stability and visual outcomes of V4c toric phakic intraocular lenses. *J Refract Surg.* 2018;34(7):489-496.
26. Zhang H, Deng Y, Ma K, et al. Analysis on the changes of objective indicators of dry eye after implantable collamer lens (ICL) implantation surgery. *Graefes Arch Clin Exp Ophthalmol.* 2024;262(7):2321-2328.

Important Safety Information for the EVO 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 <3.00 mm; with anterior chamber angle less than Grade III; who have moderate to severe glaucoma, 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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