DFU UPDATE: NEW DELIVERY SYSTEM INFORMATION INCLUDED. READ NOW

Visian ICL™

STAAR® SURGICAL

Visian® ICL™
(Implantable Collamer® Lens) for Myopia

For the correction/reduction of
moderate to high myopic astigmatism
STAAR Surgical Company operates in compliance with the
Medical Device Directive 93/42/EEC and ISO 13485

DIRECTIONS FOR USE

Manufactured and Distributed By:

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CAUTION: U.S. (Federal) law restricts this device to sale by or on the order of a physician.

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PRODUCT INFORMATION

Please review this product information completely before performing your initial clinical procedure. All physicians must complete the STAAR Surgical Visian ICL Physician Certification Program prior to use.

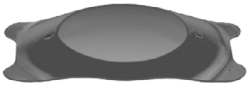
DEVICE DESCRIPTION

The Visian ICL (Implantable Collamer Lens), is an intraocular implant manufactured from Collamer, a proprietary hydroxyethyl methacrylate (HEMA)/porcine- collagen based biocompatible polymer material. The Visian ICL contains a UV absorber made from a UV absorbing material. The lens features a plate-haptic design with a central convex/concave optical zone and incorporates a forward vault to minimize contact of the Visian ICL with the central anterior capsule.

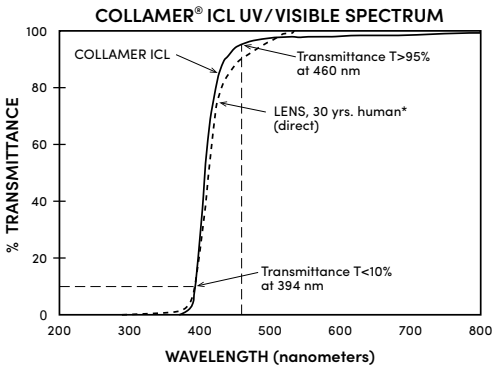
The Visian ICL features an optic diameter that varies with the dioptric power; the smallest optic diameter being 4.9mm and the largest 5.8mm. All descriptions of optic diameter, overall diameter or power refer to measurements in BSS unless otherwise noted. The Visian ICL is capable of being folded and inserted into the posterior chamber through an incision of 3.5mm or less. The Visian ICL is intended to be placed entirely within the posterior chamber directly behind the iris and in front of the anterior capsule of the human crystalline lens. When correctly positioned, the Visian ICL functions as a refractive element to optically reduce moderate to high myopia.

Model Number	Dioptric Power (D)	Overall Diameter (mm)	Optic Diameter (mm)	Haptic Design
MICL 12.1	-3.0 to -16.0D	12.1	4.9 – 5.8	Flat, plate
MICL 12.6	-3.0 to -16.0D	12.6	4.9 – 5.8	Flat, plate
MICL 13.2	-3.0 to -16.0D	13.2	4.9 – 5.8	Flat, plate
MICL 13.7	-3.0 to -16.0D	13.7	4.9 – 5.8	Flat, plate

Visian ICL



Visian ICL positioned in the eye



*Artigas J. M., Felipe A., Navea A., et al. Spectral Transmission of the Human Crystalline Lens in Adult and Elderly Persons: Color and Total Transmission of Visible Light. Investigative Ophthalmology & Visual Science. 2012; 53 (7):4076- 4084.

INDICATIONS

The Visian ICL is indicated for use in patients 21–45 years of age:

1. for the correction of myopia ranging from -3.0D to ≤-15.0D with less than or equal to 2.5D of astigmatism at the spectacle plane;
2. for the reduction of myopia ranging from greater than -15.0D to -20.0D with less than or equal to 2.5D of astigmatism at the spectacle plane;
3. with an anterior chamber depth (ACD) of 3.00 mm or greater, and a stable refractive history (within 0.5D for 1 year prior to implantation).

MODE OF ACTION

The Visian ICL functions as a refractive element to optically reduce moderate to high myopia. The Visian ICL is intended for placement in the posterior chamber of the phakic eye.

CONTRAINDICATIONS

The Visian ICL is contraindicated in patients:

1. with a true ACD of <3.00 mm*;
2. with anterior chamber angle less than Grade III as determined by gonioscopic examination;
3. who are pregnant or nursing;
4. less than 21 years of age;
5. who do not meet the minimum endothelial cell density (ECD).

Minimum Endothelial Cell Density for Age and True ACD*

Age	Minimum ECD ACD≥3.0mm	Minimum ECD ACD≥3.2mm	Minimum ECD ACD≥3.5mm
21–25	3875 cells/mm^2	3800 cells/mm^2	3250 cells/mm^2
26–30	3425 cells/mm^2	3375 cells/mm^2	2900 cells/mm^2
31–35	3025 cells/mm^2	2975 cells/mm^2	2625 cells/mm^2
36–40	2675 cells/mm^2	2625 cells/mm^2	2350 cells/mm^2
41–45	2350 cells/mm^2	2325 cells/mm^2	2100 cells/mm^2
>45	2075 cells/mm^2	2050 cells/mm^2	1900 cells/mm^2

* The true ACD is defined as the distance from the apex of the **posterior** corneal surface to the apex of the anterior crystalline lens surface. Many measuring devices provide an ACD measurement defined as the distance from the apex of the **anterior** corneal surface to the apex of the anterior crystalline lens surface. If the surgeon is using an instrument that measures from the anterior corneal surface, the thickness of the cornea must be subtracted to get the true ACD.

The table indicates the minimum ECD per age group at time of implantation for three different ACD ranges. This table was developed using rates of 2.47%. 2.44% and 2.15% (the upper 90% confidence interval of the average cell loss for eyes with the specified ACD) for the ≥3.0mm, ≥3.2mm and ≥3.5mm groups, respectively. (These rates were calculated from the original PMA clinical study data). It sets minimum ECD criteria, as functions of age that should result in at least 1000 cells/mm^2 at 75 years of age. Specular microscopy should be performed preoperatively and ECD should be monitored postoperatively at intervals dictated by the physician's medical judgment.

WARNINGS

1. Some subjects in the clinical study demonstrated endothelial cell loss >30% (range, 30.9% to 42.6%) at 5-7 years postoperatively. The long term effects on the corneal endothelium have not been established. Patients should be advised about the potential risk of corneal edema, possibly requiring corneal transplantation. Patients' ECD should be monitored periodically as long as they remain implanted with the ICL.
2. Secondary to implantation of the ICL, patients have increased risk of development of cataract, including visually significant cataract that continues to increase with each year. The physician should monitor the patient for cataract periodically. The long term risk of visually significant cataract and related secondary surgery may be higher in older patients and those with higher myopia. The long-term rate (beyond 5-7 years) of cataract formation secondary to implantation, removal and/or replacement of the Visian ICL is unknown.
3. The potential of the lens to alter intraocular pressure (IOP) and the long-term risks of glaucoma, peripheral anterior synechiae and pigment dispersion are unknown.
4. Two basal iridotomies must be performed 90° apart using a YAG laser at least 2 weeks before implantation of the Visian ICL, with confirmation of the patency of the iridotomies prior to implantation. The patients should not be taking topical steroid medication at the time of Visian ICL implantation.
5. Do not attempt to resterilize or repackage the Visian ICL.
6. Do not autoclave the Visian ICL. Do not expose to temperature greater than 40°C. Do not freeze. If temperature requirements are not met, return the Visian ICL to STAAR Surgical.
7. The iridocorneal angle distance may decrease after implantation of the Visian ICL. Iridocorneal angle should be assessed 1 week after implantation and monitored if the angle is extremely narrow.
8. Complete removal of viscoelastic from the eye after completion of the surgical procedure is essential. STAAR Surgical recommends a low molecular weight 2% hydroxypropyl methylcellulose or dispersive, low viscosity ophthalmic viscosurgical device. Do not use short chain sodium hyaluronate acids (viscoelastics) due to increased risk of cataract formation related to trapped viscoelastic.

NOTE: The primary viscoelastic used with the Visian ICL during the clinical trial was a low molecular weight 2% hydroxypropylmethylcellulose preparation.

PRECAUTIONS

Prior to surgery, the surgeon must provide prospective patients with a copy of the patient information booklet for this product and inform these patients of the possible benefits and complications associated with the use of this device.

1. Patients with higher degrees of myopia experience lower efficacy and higher rates of adverse events (AEs) and complications.
2. The effect of pupil size on visual symptoms is not known.
3. Inadequate flushing of the viscoelastic from the eye may lead to IOP spikes. IOP should be checked 24 hours postoperatively.
4. The effectiveness of ultraviolet (UV) absorbing intraocular lenses (IOLs) in reducing the incidence of retinal disorders has not been established.
5. The relationship between the Visian ICL and retinal detachment is undetermined.
6. If a method of power calculation different from that used in the ICL clinical study (i.e., lens power calculated by STAAR Surgical using STAAR's propriety software) is used, the effectiveness of the Visian ICL for myopia may not be consistent with the results reported in the Visian ICL clinical study results section.
7. The accuracy of ultra-sound based measurement of axial length in an eye with a Visian ICL is unknown. Axial length measurements based upon partial coherence laser interferometry appear to not be significantly affected by implantation of the Visian ICL. See section on "Post-Approval Study of the Effect of the Visian ICL on Axial Length Measurement."

The safety and effectiveness of the Visian ICL for the correction of moderate to high myopia has **NOT** been established in patients with:

1. Greater than 20D of myopia;
2. Greater than 2.5D of astigmatism;
3. Unstable or worsening myopia;
4. A diagnosis of ocular hypertension or glaucoma;
5. Pseudoexfoliation;
6. Pigment dispersion;
7. History or clinical signs of iritis/uveitis;
8. Insulin-dependent diabetes or diabetic retinopathy;
9. History of previous ocular surgery;
10. Progressive sight-threatening disease other than myopia;
11. Serious (life-threatening) non-ophthalmic disease.

CLINICAL TRIALS AND RESULTS

The Visian ICL was evaluated in a prospective nonrandomized study and three post-approval studies: (1) extended follow-up of the pre-approval cohort to further characterize safety; (2) a new enrollment patient survey study to collect safety information from patients, and; (3) a post-approval study to assess the effect of the ICL on axial length measurement.

PMA CLINICAL TRIAL AND RESULTS–VISIAN ICL FOR MYOPIA

The Visian ICL was evaluated in a prospective nonrandomized study of 526 eyes of 294 subjects, 470 of which were followed for 1 year and 369 followed for 3 years. Demographics for the Study Cohort are presented in the following table:

Demographics: 526 Eyes of 294 Subjects

Age	
Average	36.55 ±5.8 years
Range	22 to 45 years
Race	
Black	2.0%
Caucasian	84.7%
Hispanic	7.8%
Other	5.4%
Gender	
Female	60.5%
Male	39.5%

In the study, surgeons supplied the following parameters to STAAR: manifest refraction–sphere, cylinder, axis; back vertex distance in millimeters; ACD in millimeters (posterior surface of the cornea to the anterior surface of the crystalline lens); and corneal thickness in millimeters. STAAR calculated the appropriate ICL power using proprietary software.

Adverse Events

A total of 526 eyes of 294 subjects were evaluated in the clinical trial to determine the safety of the Visian ICL. Anterior subcapsular opacities, not all clinically significant, were observed postoperatively in 14 eyes (2.7%). An increase in postoperative cylinder >2D at 3 years from surgery was present in 0.4% of eyes. Loss of best spectacle corrected visual acuity (BSCVA) >2 lines occurred in 4 eyes (0.8%) and a 2 line loss in 6 eyes (1.2%).

The AEs/complications experienced during the clinical study of the Visian ICL (between 1 and 36 months) included 3 retinal detachments (0.6%), 2 cases of glaucoma (0.4%), clinically significant cataract (2 anterior (0.4%); 5 nuclear (1%)), 1 case of elevated IOP >25 mmHg / >10 mmHg change from baseline at last visit (0.2%), 1 macular hemorrhage (0.2%) and 1 subretinal hemorrhage (0.2%).

There were 20 cases of raised IOP requiring secondary surgical intervention in the early postoperative time period. Of these, 17 eyes were treated with YAG laser iridotomy for pupillary block, and 3 eyes were treated with repeat irrigation and aspiration for removal of retained viscoelastic. There were 16 cases of secondary surgical intervention for ICL removal, replacement, or repositioning. In addition, most patients experienced some degree of endothelial cell loss after ICL implantation.

Incidence of AEs/complications (compared with the FDA Grid for cataract extraction and posterior chamber IOL implantation) and incidence of surgical reinterventions are shown in the following tables:

Adverse Event	Cumulative % (n/N)	FDA Grid %	Persistent (36 Mo) % (n/N)	FDA Grid %
Endophthalmitis	0% (0/526)	0.1%	0% (0/526)	---
Hyphema	0% (0/526)	2.2%	0% (0/526)	---
Hypopyon	0% (0/526)	0.3%	0% (0/526)	---
IOL Dislocation	0% (0/526)	0.1%	0% (0/526)	---
Cystoid Macular Edema	0% (0/526)	3.0%	0% (0/526)	0.5%
Pupillary Block	3.2% (17/526)	0.1%	0% (0/526)	---
Retinal Detachment	0.6% (3/526)	0.3%	0% (0/526)	---
Surgical Reintervention[1]	6.8% (36/526)	0.8%	0% (0/526)	---
Corneal Edema (after 1 week)	0% (0/526)	---	0% (0/526)	0.3%
Iritis[2] (after 1 week)	0% (0/526)	---	0% (0/526)	0.3%
Surgical Treatments Not Monitored in FDA Grid				
Refractive Procedures	3.9% (20/526)	---	---	---
Iris Prolapse Repair	0.2% (1/526)	---	0% (0/526)	---

[1] Refer to table below for details on Surgical Reinterventions.

[2] There is no FDA Grid Rate for cumulative iritis. Comparison should be made to literature for retinal detachment rates for high myopia. Retinal detachment rates increase with increasing myopia. The risk of retinal detachment within one year of implantation of this device is 0.2%. The risk of retinal detachment for high myopes following implantation is more than 10 times the risk without surgery, i.e., greater than 10 fold the background rate of retinal detachment for high myopes (>-3D) 5.0% in myopes >-6D and 0.8% to7.5% in pseudophakic eyes with high axial myopia.

Ogawa A, Tanaka, M. The relationship between refractive errors and retinal detachment, Jpn J Ophthalmolo 32;310:1988.

Dellone-Larkin G, Dellona CA. Retinal detachment. Available at: http://www.emedicine.com/emerg/topic504.htm

Jacobi F, Hessemer V. Pseudophakic retinal detachment in high axial myopia. J Cat Ref Surg 23; 1095:1997.

Refractive procedures include: AK and LASIK

Surgical reinterventions (see table below) were not shown to have an impact on efficacy. Surgical reinterventions occurred in 6.8% of cases.

Visian ICL Related Additional Surgery	n	%[1]
Visian ICL Repositioning	4	0.8%
Visian ICL Replacement, then Removal	1	0.2%
Visian ICL Replacement	8	1.5%
Visian ICL Removal	3	0.6%
Raised IOP Requiring Surgery	20	3.8%
TOTAL	**36**	**6.8%**

[1] Total Study Cohort (n=526)

Refer to the Section "POST-APPROVAL CONTINUATION OF THE VISIAN ICL CLINICAL STUDY" for a detailed discussion of AEs and complications that occurred in the PMA study cohort from day of surgery throughout the long-term post-approval phase of the study.

Visual Acuity

The postoperative results demonstrated that the Visian ICL can provide full correction for high myopia up to -15D and only partial correction up to -20D. The visual acuities at 12 and 36 months are described in the following tables:

Uncorrected Distance Visual Acuity (UCDVA)

(Where emmetropia was the goal (±0.50D) and Preoperative Best Spectacle Corrected Visual Acuity (BSCVA) better than or equal to 20/20)

	12 Months	36 Months
N	240	189
20/20 or better	65.4%	59.3%
20/40 or better	96.7%	94.7%
20/80 or better	99.6%	98.9%
Worse than 20/80	0.4%	1.1%

Best Corrected Distance Visual Acuity (BCDVA), Snellen

(Eyes with Preoperative BCVA 20/20 or better)

	12 Months	36 Months
N	321	253
20/20 or better	95.6%	96.4%
20/25 or better	99.7%	100%
20/40 or better	100%	100%

Predictability of Refraction

The refraction was predictable with 91.6% of subjects achieving ±1.0D from target at the 12 month examination.

Spherical Equivalent (Target Variance) Distribution

	12 Months	36 Months
N	455	363
±0.50D	69%	68.3%
±1.0D	91.6%	89.5%

Stability

The refraction was stable with 97.6% of eyes achieving less than or equal to ±1.0D of shift at 36 months.

Manifest Refraction Spherical Equivalence (MRSE) Change between Visits

	6-12 Months	12-24 Months	24-36 Months
N	424	413	337
±0.25D	75.5%	76.8%	75.1%
±0.5D	91.0%	89.8%	90.2%
±1.0D	97.6%	97.6%	97.6%
>1.0D	2.4%	2.4%	2.4%

Optical Visual Symptoms

The following table reports the subjective optical visual symptoms reported by subjects during this clinical study after Visian ICL implantation compared to before the Visian ICL surgery:

Subjective Symptoms-Improvement/No Change Compared to Preoperative

Symptom	Improved/No Change at 36 Months
Glare	317/351 (90.4%)
Halos	310/350 (88.5%)
Double Vision	345/351 (98.3%)
Night Vision	308/350 (88.0%)
Night Driving Difficulties	301/335 (89.8%)

Additional Clinical Outcomes

The following table provides predictability of intended refraction (±0.50D and ±1.0D) for all eyes and by the level of preoperative refraction.

MRSE vs. Intended Target[1] by Preoperative MRSE

Lens Group	Exam Interval	n	±0.5D	±1.0D	±2.0D
Study Cohort	1 Week	501	64.7%	87.4%	97.2%
	1 Month	506	68.0%	87.9%	97.8%
	3 Months	485	63.9%	88.7%	97.9%
	6 Months	479	66.8%	88.9%	98.1%
	12 Months	455	67.7%	90.3%	98.2%
	24 Months	443	66.1%	90.1%	98.0%
	36 Months	363	67.5%	88.2%	98.1%
New Calculation Method[3]	36 Months	363	70.0%	89.3%	98.3%
≤-7D Cohort	36 Months	72	84.7%	97.2%	100%
New Calculation Method[3]	36 Months	72	86.1%	97.2%	100%
>-7D to -10D Cohort[2]	36 Months	131	71.0%	93.1%	100%
New Calculation Method[3]	36 Months	131	70.2%	92.4%	100%
>-10D to -15D Cohort	36 Months	130	64.6%	86.2%	98.5%
New Calculation Method[3]	36 Months	130	70.0%	88.5%	99.2%
>-15D Cohort	36 Months	30	23.3%	53.3%	83.3%
New Calculation Method[3]	36 Months	30	30.0%	60.0%	83.3%

[1] All Study Cohort Eyes
[2] Note % lower with new Power Calculation Method
[3] The new calculation method was used to correct for a change in power labeling to allow standard phakic IOL power formulas to be used without modification. It is a theoretical calculation only.

The following table shows the UCVA for all eyes and by the level of preoperative refraction for all eyes implanted that were targeted for emmetropia and had a BSCVA of 20/20 or better preoperatively.

UCVA[1] by Preoperative MRSE

Lens Group	Exam Interval	n	20/20 or Better	20/40 or Better
Study Cohort	1 Week	259	49.8%	91.9%
	1 Month	262	56.5%	95.0%
	3 Months	251	63.7%	96.4%
	6 Months	248	60.9%	96.4%
	12 Months	240	65.4%	96.7%
	24 Months	228	59.6%	93.4%
	36 Months	189	59.3%	94.7%
≤-7D	36 Months	58	72.4%	98.3%
>-7D to -10D	36 Months	83	62.7%	92.8%
>-10D to -15D	36 Months	48	37.5%	93.8%
>-15D	36 Months	0	NA%[2]	NA%[2]

[1] Eyes with preoperative BSCVA 20/20 or better and emmetropia targeted correction
[2] No Eyes >-15D group with this preoperative status

Subjective Quality of Vision

Subjective Quality of Vision – All eyes

Quality of Vision Grading	Preoperative	36 months
Very Good/Excellent	288 (55.0%)	267 (77.0%)
Poor/Very Poor	61 (11.6%)	20 (5.8%)

Subjective Symptoms Stratified by Optic Diameter

Subjective symptoms reported by subjects were stratified into 4 groups based on the optic diameter: 4.9 mm, 5.2 mm, 5.5 mm and 5.8 mm. Glare was absent/mild in 82.4% of subjects in the 4.9 mm, 90.3% in the 5.2 mm, 91.8% in the 5.5 mm and 89.9% in the 5.8 mm groups. Marked/severe glare occurred in 3.3% of eyes with the 4.9 mm, 2.8% with the 5.2 mm, 4.1% with the 5.5mm and 1.4% with the 5.8 mm optic at 36 months postoperatively.

The smaller the optic diameter, the greater the incidence of halos. Halos were absent/mild in 80.2% of subjects in the 4.9 mm, 87.3% in the 5.2 mm, 89.8% in the 5.5 mm and 87.8% in the 5.8 mm. Marked/severe halo was dependent upon the Visian ICL optic diameter and was 9.9% with the 4.9 mm, 2.8%with the 5.2 mm, 4.1% with the 5.5 mm and 1.4% with the 5.8 mm.

Double vision was absent in all eyes with the 5.8mm optic diameter. Double vision was reported as absent in 95.6% of the subjects with the 4.9 mm, 98.6% with the 5.2 mm, and 98.0% with the 5.5 mm at 36 months. The incidence of marked/severe night driving difficulties negatively correlated with the optic diameter. Marked/ severe night driving difficulties was reported in 16.7% of eyes in the 4.9 mm group compared to 0% with the 5.8 mm. Night driving difficulties were absent / mild in 71.1% of eyes using the 4.9 mm, 83.8% with the 5.2 mm, 85.4% with the 5.5 mm, and 91.9% with the 5.8 mm.

A similar trend between the subjective symptom and the 36-month follow-up shows a negative correlation between the incidence/severity of night vision difficulties and the optic diameter. No cases of marked/severe night vision difficulties occurred with the 5.8 mm. Subjective night vision difficulties 36 months after Visian ICL insertion were absent/mild in 73.6% of eyes with 4.9 mm, 84.7% with the 5.2 mm, 83.7% with the 5.5 mm, and 90.6% with the 5.8 mm.

POST-APPROVAL CONTINUATION OF THE PMA CLINICAL TRIAL

As a condition of approval, STAAR Surgical was required to follow subjects of the original PMA study cohort through 60 months (5 years) after lens implantation with the specific objective of collecting long-term data on endothelial cell loss and on AEs/complications.

Study Objective

The objective of this post-approval study was to collect new long-term data on endothelial cell loss and on AEs/complications in order to assess long-term safety of the lens. Only data on these safety parameters are updated in this section.

Study Design

This post-approval study consisted of the extended follow-up of the original PMA study cohort. It was a single-arm study with follow-up visits scheduled at 48 and 60 months (4 and 5 years) post-implantation.

Total Number of Enrolled Study Sites and Subjects

Of the 526 eyes (294 subjects) enrolled at 14 sites in the United States in the original PMA study, 335 eyes of 192 subjects were seen at 60 months (5 years) or later, as shown in the following table. However, since this post-approval study was initiated a number of years after the first implants of the Visian ICL in the original PMA study, some subjects were more than 60 months postoperative at the time of initiation of the post-approval study. These subjects were seen for a final visit and are included in the "≥60 Months" columns.

Accountability (all implanted eyes, N=526)	12 Months	24 Months	36 Months	48 Months	60 Months	≥60 Months
Available for Analysis	472	459	384	248	225	335
Discontinued (ICL Removals)[1]	0	1	5	5	10	11
Missed Visit/CRF not Received	40	44	84	192	176	NA
Missing	0	0	0	1	4	NA
Lost to Follow-up	14	22	53	80	111	180
% Accountability[2]	89.7%	87.4%	73.7%	47.7%	43.9%	65.6%

[1] Cumulative total number of eyes discontinued is 11

[2] % Accountability is equal to (Available for analysis)/(All Implanted Eyes-Discontinued-Missing)

Adverse Events and Complications

The incidence of AEs, complications and surgical reinterventions reported from time of surgery through the end of the post-approval study period (≥60 months), are shown in the tables below:

Adverse Events[1]

Adverse Event	Cumulative n/526 (%)	≤12 Mo n/526 (%)	>12-24 Mo n/462 (%)	>24-36 Mo n/426 (%)	>36-48 Mo n/276 (%)	>48-60 Mo n/346 (%)	≥60 Mo n/348(%)
Endophthalmitis	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)
Hyphema	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)
Hypopyon	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)
IOL Dislocation	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)
Cystoid Macular Edema	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)
Pupillary Block	17, (3.2%)	17, (3.2%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)
Retinal Detachment	3, (0.6%)	1, (0.2%)	1, (0.2%)	1, (0.2%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)
Surgical Reintervention[2]	43, (8.2%)	28, (5.3%)	4, (0.9%)	4, (0.9%)	2, (0.7%)	4, (1.2%)	1, (0.3%)
Corneal Edema (after 1 week)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)
Iritis (after 1 week)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)
Iris Prolapse Repair	1, (0.2%)	1, (0.2%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)	0, (0. 0%)

[1] Loss of VA, cataract development, raised IOP requiring pharmacologic intervention, endothelial cell loss and other unclassified complications are not included in the table but are discussed in the sections below.

[2] Refer to section below for details on Surgical Reinterventions.

Surgical Reinterventions

A total of 43 eyes (8.2%) underwent surgical reintervention during the study. Of these, 23 (4.4%) eyes had repositioning (4 eyes), removal (10 eyes) or replacement (8 eyes) of the ICL, and 1 eye had ICL replacement and then removal. Each case of ICL removal during the study was performed in conjunction with cataract surgery. An additional 20 eyes (3.8%) underwent repeat YAG iridotomy or additional irrigation/aspiration during the early postoperative time period. Of these, 17 eyes were treated with YAG laser iridotomy for pupillary block, and 3 eyes were treated with repeat irrigation and aspiration for removal of retained viscoelastic.

ICL Related Additional Surgery	Cumulative n/526 (%)	≤12 Mo n/526 (%)	>12-24 Mo n/462 (%)	>24-36 Mo n/426 (%)	>36-48 Mo n/276 (%)	>48-60 Mo n/346 (%)	≥60 Mo n/348(%)
ICL Repositioning	4 (0.8%)	4 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ICL Replacement, then Removal	1 (0.2%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ICL Replacement	8 (1.5%)	4 (0.8%)	2 (0.4%)	2 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ICL Removal	10 (1.9%)	0 (0.0%)	2 (0.4%)	1 (0.2%)	2 (0.7%)	4 (1.2%)	1 (0.3%)
Raised IOP Requiring Surgery[1]	20 (3.8%)	20 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TOTAL	43 (8.2%)	28 (5.3%)	4 (0.9%)	4 (0.8%)	2 (0.7%)	4 (1.2%)	1 (0.3%)

[1] Refer to section on Intraocular Pressure for details.

Refractive Procedures

A total of 22 eyes (4.2%) underwent refractive procedures during the study; this consisted of 17 LASIK (3.2%) procedures and 5 Arcuate Keratotomy (AK) (1.0%) procedures, as seen in the following table.

Refractive Procedure	≤12 Mo % (n/N)	>12-24 Mo % (n/N)	>24-36 Mo % (n/N)	>36-48 Mo % (n/N)	>48-60 Mo % (n/N)	≥60 Mo % (n/N)	Total
LASIK	15/526 (2.9%)	1/524 (0.2%)	0/448 (0.0%)	0/256 (0.0%)	0/231 (0.0%)	1/117 (0.9%)	17/526 (3.2%)
AK	3/526 (0.6%)	2/524 (0.4%)	0/448 (0.0%)	0/256 (0.0%)	0/231 (0.0%)	0/117 (0.0%)	5/526 (1.0%)

Best Spectacle Corrected Visual Acuity (BSCVA) Loss

Eighteen eyes of 16 subjects reported a significant vision loss of ≥2 lines in BSCVA between 12 months and ≥60 months. Reasons for significant vision loss included cataract development (9 eyes), myopic degeneration (1 eye), retinal detachment (1 eye) and unknown etiology was reported for 4 eyes. For 3 eyes, decrease in BSCVA was transient without intervention.

At the final study visit (which ranged from 18 to 62 months), 11 of these 18 eyes reported an improvement in BSCVA of 2 to 10 lines compared to preoperative BSCVA, attributed to cataract surgery, refractive surgery or reversal of transient vision loss. In the remaining 7 eyes, vision loss of ≥2 lines was persistent at the final study visit (which ranged from 36 to 60 months).

The number of eyes reporting a decrease in either 2 lines or >2 lines is reported in the table below:

Decrease in BSCVA	12 Mo n/N (%)	24 Mo n/N (%)	36 Mo n/N (%)	48 Mo n/N (%)	60 Mo n/N (%)	≥60 Mo n/N (%)
Decrease >2 Lines	1/469 (0.2%)	2/456 (0.4%)	3/384 (0.8%)	1/242 (0.4%)	1/222 (0.4%)	2/331 (0.6%)
Decrease =2 Lines	2/469 (0.4%)	3/456 (0.6%)	1/384 (0.3%)	1/242 (0.4%)	2/222 (0.8%)	2/331 (0.6%)

Lens Opacity and Visually Significant Cataract Formation

The table below provides the type of cataracts of grade trace or greater that developed over time for the PMA Study cohort. The long-term incidence of anterior subcapsular opacity secondary to implantation of the Visian ICL has been studied in 526 eyes of 294 subjects followed for up to 7.5 years, with 334 eyes available for analysis at 5 or more years. A total of 31 eyes developed an anterior subcapsular opacity.

Cataract Type	Preop n/N (%)	<12 Mo n/N (%)	12 Mo n/N (%)	24 Mo n/N (%)	36 Mo n/N (%)	48 Mo n/N (%)	60 Mo n/N (%)	≥60 Mo n/N (%)	Cumulative Number of Eyes
Nuclear	4/526 (0.8%)	4/526 (0.8%)	2/472 (0.4%)	1/457 (0.2%)	3/381 (0.8%)	0/245 (0.0%)	0/225 (0.0%)	3/334 (0.9%)	13
Cortical	2/526 (0.4%)	2/526 (0.4%)	0/472 (0.0%)	1/457 (0.2%)	4/380 (1.1%)	1/245 (0.4%)	0/225 (0.0%)	0/334 (0.0%)	8
Posterior Subcapsular	0/526 (0.0%)	0/526 (0.0%)	0/472 (0.0%)	0/457 (0.0%)	2/381 (0.5%)	0/245 (0.0%)	0/225 (0.0%)	2/334 (0.6%)	4
Anterior Subcapsular	0/526 (0.0%)	8/526 (1.5%)	3/472 (0.6%)	4/457 (0.9%)	2/381 (0.5%)	8/245 (3.3%)	2/225 (0.9%)	4/335 (1.2%)	31
Total Number of Eyes*	6	13	3	5	8	9	2	5	45

* Final row may not sum to number of nuclear, cortical or subcapsular cataracts, as some eyes had multiple types of cataracts.

Visually significant cataracts of all types, involving a vision loss of ≥2 lines in BSCVA, were reported in 9 eyes (1.7%) through the extended follow-up study period: 1 anterior subcapsular cataract (ASC) at 18 months, 3 ASC at 48 months and 1 surgically induced ASC which was reported to have a 2 line loss of BSCVA at 24 months after ICL implantation; 1 nuclear cataract (NC) at 12 months, 1 at 30 months, 2 at 36 months.

Per eye, the risks of developing any anterior subcapsular opacity, developing a visually significant anterior subcapsular opacity, or of having cataract surgery for any type of cataract were calculated using Kaplan-Meier analyses. As provided in the table below, these risks were 6.1%, 1.2% and 3.1% at 60 months and 12.4%, 1.2% and 3.1% at 84 months, respectively.

	≤12 Mo	>12-24 Mo	>24-36 Mo	>36-48 Mo	>48-60 Mo	≥60 Mo
Any Anterior Subcapsular Opacity (ASC)						
Number at risk at period start	526	499	477	441	366	251
Events during period	9	4	3	4	7	4
Survival estimate at period end	98.3%	97.5%	96.9%	95.9%	93.9%	87.6%
1-survial estimate (risk)	1.7%	2.5%	3.2%	4.1%	6.1%	12.4%
Visually Significant ASC						
Number at risk at period start	526	507	487	450	379	261
Events during period	1	1	0	0	3	0
Survival estimate at period end	99.8%	99.6%	99.6%	99.6%	98.8%	98.8%
1-survial estimate (risk)	0.2%	0.4%	0.4%	0.4%	1.2%	1.2%
Cataract Surgery for Any Type of Cataract						
Number at risk at period start	526	505	484	448	376	258
Events during period	3	3	2	3	3	0
Survival estimate at period end	99.4%	98.8%	98.4%	97.7%	96.9%	96.9%
1-survial estimate (risk)	0.6%	1.2%	1.6%	2.3%	3.1%	3.1%

Intraocular Pressure (IOP)

a) *Changes in IOP from Baseline*

Postoperatively, IOP >25 mmHg or an increase of >10 mmHg over preoperative was reported in 14 eyes (2.7%) of the Visian ICL PMA cohort through ≥60 months.

b) *Raised IOP Requiring Surgery*

IOP (mmHg)	Preop n/N (%)	1 D n/N (%)	14 D n/N (%)	1 Mo n/N (%)	3 Mo n/N (%)	6 Mo n/N (%)	12 Mo n/N (%)	24 Mo n/N (%)	36 Mo n/N (%)	48 Mo n/N (%)	60 Mo n/N (%)	≥60 Mo n/N (%)
>10 mmHg over Baseline	NA	23/526 (4.4%)	20/526 (3.8%)	12/524 (2.3%)	2/522 (0.4%)	0/511 (0%)	2/501 (0.4%)	2/469 (0.4%)	1/410 (0.2%)	2/348 (0.6%)	6/262 (2.3%)	4/263 (0.4%)
>25mm Hg	0/526 (0%)	23/526 (4.4%)	16/526 (3.0%)	11/524 (2.1%)	2/522 (0.4%)	0/511 (0%)	2/501 (0.4%)	2/469 (0.4%)	1/410 (0.2%)	3/348 (0.9%)	7/262 (2.7%)	4/263 (0.4%)

A total of 20 eyes (3.8%) experienced raised IOP requiring intervention. An additional YAG iridotomy was performed on 17 of the eyes for pupillary block and 3 eyes had repeat irrigation and aspiration at 1 day postoperative to remove retained viscoelastic. All of these events occurred in the early postoperative period, most frequently at 1 to 2 days postoperative.

c) *Raised IOP Requiring Pharmacologic Intervention*

A total of 7 eyes of 4 subjects in the PMA cohort developed glaucoma during the clinical trial. Open angle glaucoma was diagnosed for 4 eyes (2 subjects) and the remaining 3 eyes of 2 subjects the type of glaucoma was not specified. None of these eyes required secondary surgical intervention for treatment of IOP during the study.

Upon gonioscopic examination, no anterior synechiae, transillumination defects, or abnormal angle depth was observed in any of these 7 eyes. However, abnormal pigmentation was observed in 6 eyes, with 2 eyes of a single subject diagnosed with open angle glaucoma and possible secondary pigment dispersion at 6 years postoperatively.

No. of Eyes	Type of Glaucoma	Onset	Abnormal Pigmentation	Anterior Synechiae	Transillumination Defects	Angle Depth
1 (1 subject)	Unspecified	62 Mo	None	None	None	Normal
2 (1 subject)	Unspecified	5 Mo, 12 Mo	Yes	None	None	Normal
2 (1 subject)	Open Angle	37 Mo, 53 Mo	Yes	None	None	Normal
2 (1 subject)	Open Angle, possibly 2° pigment dispersion	71 Mo, 73 Mo	Yes	None	None	Normal

Gonioscopic Findings

In the post-approval study, investigators were asked to perform gonioscopy at the 48 Month (Form 9) and/or > 60 Month (Form 10) study visits. Specifically, investigators were to report on the absence or presence of peripheral anterior synechiae, the absence or presence of abnormal pigment suggestive of pigment dispersion and normal or abnormal angle depth.

Finding	48 Month (Form 9)			≥ 60 Months (Form 10)		
	Absent	Present	Total*	Absent	Present	Total*
Peripheral Anterior Synechiae	99.05% (104)	0.95% (1)	105	99.66% (293)	0.34% (1)	294
Abnormal Pigment Suggestive of Pigmentary Dispersion	95.28% (101)	4.72% (5)	106	94.00% (282)	6.00% (18)	300
	Normal	Abnormal	Total	Normal	Abnormal	Total
Angle Depth	99.05% (104)	0.95% (1)	105	100% (298)	0.00% (0)	298

* Total number of eyes with gonioscopy performed at that visit

Other Findings

At the 48 month visit, no "other findings" were reported. At the ≥60 month visit, there were a total of 24 comments reported under "other findings". They were: "Heavy Pigment" (n=8); "Moderate Pigment" (n=8); "Light Pigment" (n=4); "Transillumination defects" (n=2) and "Myopic Degeneration and Pigment Changes in Macula" (n=2).

Slit Lamp Findings

The table below summarizes the incidence of pigment on cornea, pigment on ICL and transillumination defects that occurred at different time points reported throughout the study follow-up period:

Finding/Onset	<12 Mo % (n/N)	12 Mo % (n/N)	24 Mo % (n/N)	36 Mo % (n/N)	48 Mo % (n/N)	≥60 Mo % (n/N)
Pigment on cornea	0.0%	0.0%	0.0%	0.0%	0.0%	1.2% (4/335)
Pigment on ICL	2.5% (13/526)	0.4% (2/472)	2.0% (9/459)	1.8% (7/384)	2.0% (5/248)	5.1% (17/335)
Transillumination defects	0.6% (3/526)	0.0% (0/472)	0.2% (1/459)	0.3% (1/384)	0.4% (1/248)	0.9% (3/335)

Endothelial Cell Density

Specular microscopy was performed on a subgroup of the original PMA study cohort with data available through ≥60 months postoperatively. A central reading center was used to minimize the inherent variability associated with endothelial cell counts.

The table below provides detail on the number of readable specular microscopy images captured at each time point in the study.

	Preop	3 Mo	12 Mo	24 Mo	36 Mo	48 Mo	60 Mo	72 Mo	84 Mo
Total Cohort	526		472	459	384	248	225	86	44
Eyes with readable ECD	192 (36.5%)	209	246 (52.1%)	220 (47.9%)	174 (45.3%)	146 (58.9%)	113 (50.2%)	37 (43.0%)	27 (61.4%)
Eyes with both Preop and Postop readable ECD	NA	162	175 (37.1%)	151 (32.9%)	132 (34.4%)	109 (44.0%)	85 (37.8%)	15 (17.4%)	19 (43.2%)

The analysis of ECD over time was conducted on eyes with both pre and postoperative ECD counts. Mean ECD results from clinical trial subjects are shown in the following table:

Visit	Mean	SD	90% Confidence Limits
Preop	2657	290	2622 to 2692
3 Mo	2570	340	2532 to 2609
12 Mo	2548	349	2511 to 2584
24 Mo	2479	357	2439 to 2518
36 Mo	2454	348	2411 to 2498
48 Mo	2396	367	2346 to 2447
≥60 Mo	2298	354	2252 to 2345

During the PMA trial and subsequent long-term follow-up of the PMA cohort, 13 eyes of 10 subjects (11.3% of those available for evaluation ≥60 months after surgery) reported significant endothelial cell loss (>30% loss of central ECD). Of these 13 eyes, 3 eyes of 3 subjects experienced this level of endothelial cell loss (30.8–45.6%) between baseline and the first 12 months of follow-up, and it was presumed to be the result of surgery; the remaining 10 eyes of 7 subjects had this level of endothelial cell loss (30.9–42.6%) at the final study visit (≥60 months, between 5.0 and 6.7 years).

ECD loss from Preoperative Values–Summary

ECD loss from Preop (%)	12 Mo N=175	36 Mo N=132	≥60 Mo N=115
≥10%	22 (12.6%)	44 (33.3%)	77 (67.0%)
≥15%	8 (4.6%)	22 (16.7%)	50 (43.5%)
≥20%	4 (2.3%)	12 (9.1%)	30 (26.1%)
≥30%	3 (1.7%)	2 (1.5%)	13 (11.3%)

The available data from the clinical study demonstrate a mean percentage change from baseline to 60 months of 12.3% (SD 9.4%), based on subjects with data at both baseline and ≥60 months.

The table below provides the mean, standard deviation, median, interquartile range, and range of percent change in ECD. These data represent changes in ECD between:

- The preoperative visit and the 12 month visit (for all eyes with ECD data at both visits);
- The 1 year visit to the 3 year visit (for all eyes with ECD data at both visits); and
- The 3 year visit to the final visit at 5 years or later (for all eyes with ECD data at both visits)

	For all eyes with ECD data at both visits:		
Endothelial Cell Density	Preoperative visit to 12 month visit	1 year visit to 3 year visit	3 year visit to final visit at 5 years or later
N (ECD observations with data at both visits)	175	150	108
Mean (SD) % Change in ECD	-3.19 (7.59)	-5.04 (8.09)	-6.74 (5.15)
Median % Change in ECD	-2.45	-4.27	-6.24
Interquartile Range % Change in ECD (Q1 to Q3)	0.97 to -2.45	-1.41 to -4.27	-3.04 to -9.93
Range (Min, Max) % Change in ECD	16.22,-42.94	11.62, -23.15	4.27, -22.52

The following table provides the predicted percent endothelial cell loss, by year, for a hypothetical patient with preoperative ECD equal to the mean level in the clinical study. For this hypothetical patient, there is 90% confidence that the endothelial cell loss will be between the lower and upper prediction interval bounds at each point in time. The entries in this table are calculated assuming a bi-exponential loss in ECD, i.e., a rapid initial phase of cell loss in the early postoperative period related to surgical trauma, followed by a slow, chronic phase of cell loss thereafter. Rates of predicted long term loss are derived from clinical data collected through 5 to 7 years postoperatively. The calculated chronic rate of loss from this post-approval data is approximately 1.8% per year.

Predicted Percent Endothelial Cell Loss

Time from procedure	Predicted Percent Cell Loss	90% prediction interval*	
		Lower	Upper
3 months	1%	-20%	23%
1 year	4%	-18%	25%
2 years	5%	-16%	27%
3 years	8%	-14%	29%
4 years	9%	-12%	31%
5 years	11%	-10%	33%
10 years	20%	-2%	42%
15 years	28%	6%	50%
20 years	35%	13%	57%
25 years	42%	19%	64%
30 years	47%	25%	70%
35 years	53%	30%	75%
40 years	57%	35%	80%
45 years	62%	39%	84%
50 years	66%	43%	88%
55 years	69%	46%	92%

**Note:* Positive values represent levels of % ECD loss; negative values represent levels of % ECD gain

Other Complications

No cases of endophthalmitis, hyphema, hypopyon, cystoid macular edema or corneal ulcer were reported during the study. Corneal haze, corneal edema or iritis were not reported after the 1 week visit. One case each of iris prolapse (0.2%), macular hemorrhage (0.2%) and subretinal hemorrhage (0.2%) were reported at 1 day, 1 week and 3 months postoperative, respectively. Retinal detachment was reported in 3 eyes (0.6%) at 4, 22 and 31 months after Visian ICL implantation.

A case of anisocoria (unequal pupil size) has been reported for a subject implanted with an ICL in another clinical trial.

Study Strengths and Limitations

This post-approval study uses the original IDE study cohort, following patients who had already completed 36 months of follow-up; therefore, long-term data (60-months or later) is available sooner as opposed to a new-enrollment study. Additionally, this is the only post-approval sub-study that collected ECD data. However, the 60 month follow-up rate of 65.3% is less than optimal. Biases could have been introduced into the study results because of the loss to follow-up, which could limit the generalizability of the study results.

POST-APPROVAL STUDY OF THE EFFECT OF THE VISIAN ICL ON AXIAL LENGTH MEASUREMENT

The Visian ICL was evaluated in a prospective, non-randomized study of 30 eyes of 30 subjects to assess the effect of the lens on the measurement of the eye's axial length, and to determine whether the ICL affects this measurement. Study inclusion criteria were:

- Moderate to high myopia (-3D to -20D measured as spherical equivalent of the manifest refraction) scheduled to undergo implantation of the commercially available Myopic Visian ICL.
- Subject meets all of the Indications for Use criteria for the commercially available Myopic Visian ICL.
- Ability to be measured with the IOL Master Axial Length measurement device.
- Willingness to comply with the sub-study preoperative and postoperative visit requirements.

There were no study exclusion criteria.

The subjects underwent implantation of the commercially available Visian ICL. The axial length was measured preoperatively and between one week and one month postoperatively. All axial length measurements were obtained using a Carl Zeiss IOL Master, a non-contact partial coherence laser interferometer. The difference in the pre and postoperative axial length was calculated individually for each eye.

Of the 30 subjects, 11 were male, 19 female, 29 Caucasian and 1 Asian. The ICL power of the lens implanted averaged -10.68D (range -3.50D to -16.00D). The preoperative axial length averaged 27.28 mm (range 23.69 mm to 34.32 mm) and the postoperative axial length averaged 27.28 mm (range 23.72 mm to 34.51 mm). The average difference in preoperative and postoperative axial lengths is -0.02 mm (range -0.23 mm to +0.19 mm).

The correlation coefficient was calculated based on a regression analysis on the pre and postoperative data. The results of the analysis show that the variance preoperative is statistically equivalent to the variance postoperative at 95% confidence. The average difference of -0.02 mm in axial length measurement pre and postoperative would change IOL power prediction by 0.05D, which is well below the measurement of error of IOL power manufacturers.

The data in this study suggests that the ICL has a negligible influence on axial length measurements for IOL power calculations, when measurements are based on partial coherence laser interferometry. The accuracy of ultrasound-based measurement of axial length is unknown.

Study strengths include its representative sample (no exclusion criteria) and relevance to clinical questions surrounding axial measurement. Study limitations include its applicability only to laser interferometry-based measurement and not to ultrasound measurement of axial length, and the use of only 2 investigational sites.

POST APPROVAL ADVERSE EVENT STUDY - VISIAN ICL FOR MYOPIA

A survey study was conducted in the US after Visian ICL for Myopia was approved by the FDA. The goal of this study was to collect safety information from patients who had ICL surgery in the general population. All patients who consented to participate were asked to complete surveys at scheduled times up to 5 years after their Visian MICL surgery. The surveys asked patients to report any complications or additional eye surgeries because of the MICL.

Description of the Study Patient Group:

- 2999 eyes of 1547 patients implanted with the Visian MICL participated;
- Most patients were white (Caucasian) and over half of the patients were female;
- Patients ranged from 17 to 77 years of age at time of surgery.

The surveys asked for information about the following adverse events:

- Problems with endothelial cells;
- Cataract formation;
- Medical treatment for inflammation inside the eye;
- Medical treatment for intraocular pressure and damage to the optic nerve caused by glaucoma;
- Surgery because of retinal detachment;
- Surgery to remove, replace or reposition the Visian ICL;
- Other complications in the eye.

The cumulative incidence per eye for each of the events assessed in the survey in addition to the cumulative incidence of the same events from the PMA clinical study for comparison are presented in the table below.

Cumulative Adverse Events, Comparison to PMA Clinical Study

	Survey Questionnaire	PMA Study
	60 months-Cumulative	>60 months-Cumulative
1-Corneal problems	0.3%, (5/2999)	0%, (0/526) Corneal Edema (after 1 week)
2-Cataract development	5.1%, (154/2999)	8.6%, (45/526)
3-Treated intraocular inflammation	0.5%, (14/2999)	0.0%, (0/526)
4-Treated IOP or glaucoma	1.6%, (47/2999)	1.3%, (7/526)
5-Retinal Detachment Surgery	0.4%, (13/2999)	0.6%, (3/526)
6-Remove, replace or reposition ICL	4.2%, (126/2999)	4.3%, (23/526)

The MICL PMA clinical study only enrolled subjects ≤ 45 years of age. A comparison of the cumulative incidence of the events between the PMA Clinical Study and the survey questions for patients ≤45 years of age at the time of ICL surgery are provided in the table below.

Cumulative Adverse Events, Comparison to PMA Clinical Study
(Ages ≤45 yrs old at time of Surgery)

	Survey Questionnaire	PMA Study
	60 months-Cumulative	>60 months-Cumulative
1-Corneal problems	0.0%, (0/2527)	0%, (0/526) Corneal Edema (after 1 week)
2-Cataract development	3.0%, (75/2527)	8.6%, (45/526)
3-Treated intraocular inflammation	0.5%, (13/2527)	0.0%, (0/526)
4-Treated IOP or glaucoma	1.5%, (38/2527)	1.3%, (7/526)
5-Retinal Detachment Surgery	0.3%, (7/2527)	0.6%, (3/526)
6-Remove, replace or reposition ICL	2.9%, (74/2527)	4.3%, (23/526)

Glare was reported for 2.8% (85/2999) and halos were reported for 5.2% (156/2999) of all implanted eyes in the survey study. The cumulative per eye incidence of glare and halo at 36 months after surgery from the survey questionnaire was compared to the MICL PMA clinical study data on worsening of glare and halo at 36 months compared to baseline. The comparison between the studies is made for patients ≤ 45 years of age at the time of ICL surgery and is provided in the following table.

Cumulative reports of Glare and Halos at 36 Months,
Comparison to PMA Study, (Ages ≤ 45 yrs old at time of Surgery)

	Survey Questionnaire	PMA Study
Glare	2.6%, (66/2527)	9.6%, (34/351)
Halos	5.6%, (142/2527)	11.5%, (40/350)

Overall, patient responses to surveys provided similar information to what was found in the FDA safety and effectiveness clinical study of 526 eyes of 294 patients. This study included patients over 45 years of age. This age group was not included in the FDA safety and effectiveness study of the Visian ICL. These older patients reported a higher rate of cataracts and need for a second surgery than patients who were 45 or younger at the time of initial Visian ICL surgery.

INSTRUCTIONS FOR USE

CAUTION

Implantation of a Visian ICL should only be attempted by a surgeon who is highly skilled in the required surgical technique and has completed the Visian ICL Certification Program.

CAUTION

Do not use Visian ICL if package has been opened or damaged. The sterility of the lens may be compromised.

Visian ICL Handling Precautions

1. Choice of the proper Visian ICL size should be carefully considered prior to surgery.
2. Check the label of the Visian ICL package for proper lens model and power.
3. Open the package to verify the dioptric power of the lens.
4. Handle the Visian ICL by the haptic portion. Do not grasp the optic with forceps as this could potentially lead to damage to the smooth anterior and posterior optical surfaces.
5. Never touch the center of the optic with instruments once the Visian ICL is placed inside the eye. Inadvertent pressure through the optic could potentially damage the central crystalline lens resulting in a lens opacity.
6. STAAR Surgical recommends using only the LIOLI-24 and MicroSTAAR® Injector system (Models MSI-TF and MSI-PF with SFC-45 or SFC-45 FP Cartridge) to insert the Visian ICL in the folded state.
7. The Visian ICL should be carefully examined in the operating room prior to implantation.
8. The Visian ICL should not be exposed to any solutions other than the normally used intraocular irrigating solutions (e.g., isotonic saline, BSS, viscoelastic, etc.)
9. Keep the Visian ICL moist. It is recommended that the Visian ICL be held in sterile BSS solution prior to implantation.
10. The Visian ICL should be handled carefully. No attempt should be made to reshape or cut any portion of the lens. Do not apply undue pressure to the Visian ICL optical portion with a sharp object since this could perforate the optic.
11. The intended location of the Visian ICL is behind the iris within the posterior chamber and in front of the anterior capsule of the crystalline lens.
12. Complete irrigation and aspiration of viscoelastic from the eye after completion of the surgical procedure is essential. Viscoelastic products that may be difficult to aspirate should not be used.

NOTE

The long term effects of phakic IOL implantation have not been determined. Physicians should continue to monitor implant patients postoperatively on a regular basis.

SURGICAL PRECAUTIONS/INFORMATION

Preoperative Information

Preoperative ECD Measurements

An ECD measurement should be performed preoperatively to determine if candidates meet the minimum ECD requirements based upon age and true ACD. The true ACD is defined as the distance from the apex of the **posterior** corneal surface to the apex of the anterior crystalline lens surface. Many measuring devices provide an ACD measurement defined as the distance from the apex of the **anterior** corneal surface to the apex of the anterior crystalline lens surface. If the surgeon is using an instrument that measures from the anterior corneal surface, the thickness of the cornea must be subtracted to get the true ACD.

Visian ICL Length Determination

During the original US PMA clinical study, sizing of the Visian ICL myopic lenses (12.1 mm to 13.7 mm) was determined by the horizontal white-to-white and the ACD measurements (true ACD, defined as the distance from the apex of the posterior corneal surface to the apex of the anterior crystalline lens surface). For eyes with ACD measurements of ≤3.5 mm, the lens size was calculated by adding 1.1 mm to the horizontal white-to-white measurement. Eyes exhibiting an ACD greater than 3.5 mm required the addition of up to 1.6 mm to the white-to-white measurement, up to a maximum length of 13.7 mm. Calculated lens sizes between the available lens diameters (in 0.5 mm steps) were generally rounded down if the ACD was ≤3.5 mm and rounded up if the ACD was >3.5 mm.

Analyses of all of the collected clinical data resulted in slightly modified recommendations for sizing of the Visian ICL as compared to those used in the clinical trial. A table of recommended ICL lengths based upon white-to-white and ACD measurements is given below.

Table of Recommended Visian ICL Overall Diameter by White-to-White and ACD Measurements

	ACD (mm)		
White to White (mm)	All	≤3.5	>3.5
<10.5	Not Recommended	–	–
10.5-10.6	–	Not Recommended	12.1
10.7-11.0	12.1	–	–
11.1	–	12.1	12.6
11.2-11.4	12.6	–	–
11.5-11.6	–	12.6	13.2
11.7-12.1	13.2	–	–
12.2	–	13.2	13.7
12.3-12.9	13.7	–	–
≥ 13	Not Recommended	–	–

White-to-White Measurements

The white-to-white measurement is an indirect measurement and does not correlate with sulcus-to-sulcus measurements. Newer advancements in the direct measurement of the ciliary sulcus such as ultrasonic biomicroscopy (UBM) should be considered as alternative methods for the determination of the desired Visian ICL overall diameter. At present there is no large series study demonstrating the effectiveness of UBM in Visian ICL sizing.

Peripheral Iridectomy

Two YAG iridotomies (0.5 mm; placed superiorly, 90 degrees apart) should be performed 2 to 3 weeks prior to surgery with confirmation of the patency of the iridotomies prior to lens implantation.

Learning Curve / Individual Surgeon Variability Issues

A learning curve and individual surgeon variability was seen in the clinical trial in terms of early anterior subcapsular lens opacities, removals and reinsertions of the Visian ICL at the time of surgery, and Visian ICL replacements due to sizing.

Visian ICL Power Calculation

Implantation of the Visian ICL requires that a preoperative determination of the dioptric power of the implanted lens be calculated. Achievement of emmetropia is not necessarily a desirable postoperative goal and factors such as visual status of the fellow eye and patient lifestyle should be considered when determining the lens power to be used.

In order to achieve refractive results similar to those found in the PMA study, ICL power and size calculation should be performed using the STAAR Visian ICL Calculation Software (www.ocos.STAAR.com).

Intraoperative Information

Preparation of the lens for use

CAUTION

Perform the following steps in a sterile field.

- Inspect the lens vial. Ensure that it is not damaged.
- While keeping the vial in a vertical position, remove the aluminum seal and remove the cap.
- Carefully remove the lens from the vial.
- Examine the lens carefully under the microscope for damage or particulate matter.

CAUTION

Do not allow the Visian ICL to dry after removal from the glass vial.

Delivery System

STAAR Surgical recommends using only the LIOLI-24 and MICROSTAAR® Injectors, Model MSI-TF or MSI-PF with SFC-45 or SFC-45 FP Cartridge. For detailed loading instructions see information provided with the MSI delivery system, or with the lens for the LIOLI-24 delivery system.

CAUTION

The ICL should be injected within 1-2 minutes after loading. Viscoelastic materials tend to lose their lubricity if exposed to air too long.

Viscoelastic Usage

Complete removal of viscoelastic from the eye after completion of the surgical procedure is essential. STAAR Surgical recommends a low molecular weight 2% hydroxypropyl methylcellulose (HPMC) or dispersive, low viscosity ophthalmic viscosurgical device. Do not use short chain sodium hyaluronate acids (viscoelastics) due to increased risk of cataract formation related to trapped viscoelastic.

Inadequate flushing of the viscoelastic from the eye may lead to IOP spikes. IOP should be checked 24 hours postoperatively.

Postoperative Information

Visian ICL Removal

It is recommended that the Visian ICL be removed in cases where the vault is insufficient and the patient exhibits early anterior subcapsular cataract. Removal of the Visian ICL may be necessary in cases where the vault is excessive causing narrowing of the anterior chamber angle, thus decreasing aqueous flow. Visian ICL removal may also be necessary for other reasons on an individual basis. The risks involved in Visian ICL replacement have not been studied and are unknown.

Axial Length Measurement Correction for Intraocular Lens (IOL) Power Calculation

The accuracy of ultra-sound based measurement of axial length in an eye with a Visian ICL is unknown. Axial length measurements based upon partial coherence laser interferometry appear to not be significantly affected by implantation of the Visian ICL. See section on "Post-Approval Study of the Effect of the Visian ICL on Axial Length Measurement."

NOTE

More detailed information regarding the recommended Surgical Technique is provided in conjunction with STAAR's Visian ICL Physician Certification Program.

SURGICAL PROCEDURE

All physicians must complete the STAAR Surgical Visian ICL (Visian ICL) Physician Certification Program prior to using the Visian ICL in a clinical setting.

PATIENT REGISTRATION

Each patient who receives a Visian ICL must be registered with STAAR Surgical at the time of lens implantation. Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens package and mailing it to STAAR Surgical. Patient registration is essential to STAAR Surgical's long term patient follow-up program and will assist STAAR Surgical in responding to Adverse Reaction Reports and/or potentially sight-threatening complications. An Implant Identification Card is supplied in the unit package. This card should be given to the patient with instructions to keep it as a permanent record of the implant and to show the card to any eye care practitioner seen in the future.

REPORTING

Adverse Reactions and/or potentially sight-threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature, severity or degree of incidence should be diligently reported to STAAR Surgical immediately at:

USA Phone: (800) 352-7842
Fax: (800) 952-4923

This information is being requested from all surgeons in order to document potential long-term effects of Visian ICL implantation, especially in younger patients. Physicians must report these events in order to aid in identifying emerging or potential problems with the Visian ICL.

HOW SUPPLIED

Each Visian ICL is provided sterile and non-pyrogenic in sealed vials within a sterile thermoform tray placed in a box with labels and product information. The tray and vial containing the Visian ICL are sterilized with steam and should be opened only under sterile conditions.

EXPIRATION DATE

The expiration date on the device package and unit box is the sterility expiration date. If the tray seal and vial seal are not punctured or damaged, sterility is assured until the expiration date indicated on the package label. This device should not be used past the indicated sterility expiration date.

RETURN POLICY FOR STAAR VISIAN ICLs

Contact STAAR Surgical. The Visian ICL should be returned dry. Do not attempt to rehydrate.

LENS SPECIFIC RECOMMENDATION

The physician must use the STAAR recommended Injector and Cartridge delivery system for implanting the Visian ICL in the folded state.

WARRANTY AND LIMITATION OF LIABILITY

STAAR Surgical Company warrants that reasonable care was taken in making this product. STAAR Surgical Company shall not be responsible for any incidental or consequential loss, damage, or expense which arises directly or indirectly from the use of this product. Any liability shall be limited to the replacement of any STAAR Visian ICL which is returned to and found to be defective by STAAR Surgical Company.

This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including but not limited to, any implied merchantability or fitness for use.

STORAGE

Store the Visian ICL at room/ambient temperature.

WARNING

Do not autoclave the Visian ICL. Do not expose to temperature greater than 40°C. Do not freeze. If temperature requirements are not met, return the Visian ICL to STAAR Surgical.

SYMBOLS GLOSSARY

Symbol*	Reference Number and Title	Explanatory Text
	5.1.1 Manufacturer	Medical device manufacturer
	5.1.3 Date of manufacture	Date of manufacture
	5.1.4 Use by date	Use by (YYYY-MM-DD)
	5.1.7 Serial number	Serial number
	5.2.1 Sterile	Sterile
	5.2.5 Sterilized using steam	Sterilized using steam
	5.2.6 Do not resterilize	Medical device is not to be resterilized
	5.4.2 Do not re-use	Do not reuse
	5.2.8 Do not use if package is damaged	Do not use if the product sterile barrier system or its package is compromised
	5.4.4 Caution	Consult instructions for use for important cautionary information
 edfu.staar.com (800) 352-7842	5.4.3 Consult instructions for use	Consult electronic instructions for use

* ISO 15223-1 Medical devices – Symbols to be use with medical device labels, labelling and information to be supplied - Part 1: General requirements.

Latest Revision: 2019/09/27 eDFU-0006/1