STAARSURGICAL™

DFU UPDATE: NEW DELIVERY SYSTEM INFORMATION INCLUDED. READ NOW

Visian ICL™

eDFU-0005/2

PHAKIC TORIC INTRAOCULAR LENS

TORIC

STAAR® SURGICAL

Visian® TORIC 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:

STAAR Surgical Company
1911 Walker Avenue
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USA
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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 TICL Physician Certification Program prior to use.

DEVICE DESCRIPTION

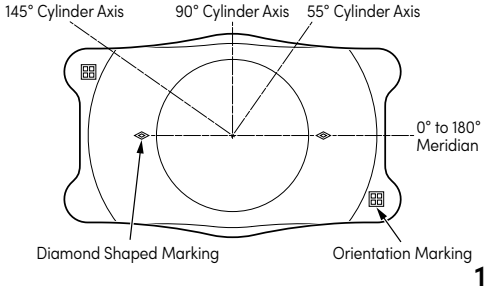
The Visian® TICL (Implantable Collamer® Lens), is an intraocular implant manufactured from Collamer®, a proprietary hydroxyethyl methacrylate (HEMA)/porcine-collagen based biocompatible polymer material. The Visian TICL contains a UV absorber made from a UV absorbing material.

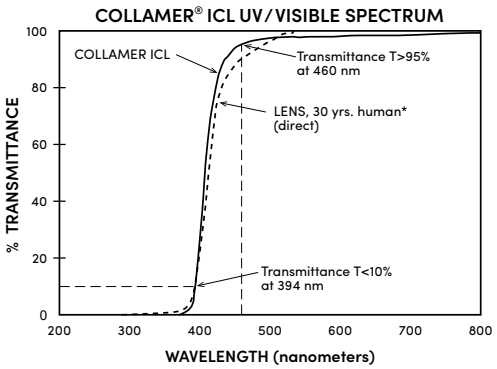
The Visian TICL lens features a plate-haptic design with a central convex/concave optical zone and incorporates a forward vault to minimize contact of the Visian TICL with the central anterior capsule.

The Visian TICL 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 TICL is capable of being folded and inserted into the posterior chamber through an incision of 3.5mm or less. The Visian TICL 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,

Model Number	Spherical Equivalent Dioptric Power (D)	Cylindric Dioptric Power (D)	Overall Diameter (mm)	Optic Diameter (mm)	Haptic Design
TMICL 12.1	-3.0 to -16.0D	1.0 to 4.0	12.1	4.9 – 5.8	Flat, plate
TMICL 12.6	-3.0 to -16.0D	1.0 to 4.0	12.6	4.9 – 5.8	Flat, plate
TMICL 13.2	-3.0 to -16.0D	1.0 to 4.0	13.2	4.9 – 5.8	Flat, plate
TMICL 13.7	-3.0 to -16.0D	1.0 to 4.0	13.7	4.9 – 5.8	Flat, plate

Visian TICL





*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.

the Visian TICL functions as a refractive element to optically reduce moderate to high myopic astigmatism.

The Visian TICL is labeled using a plus cylinder axis format. The lenses are labeled to the nearest degree and as such lenses of any axis between 1° to 180° may be held in inventory. The Visian TICL is designed to be rotated up to 22.5° clockwise or counterclockwise in order to align the lens axis at the preoperative plus cylinder axis. The lens has two diamond shaped markings, one on each side of the optic, these are to aid with the alignment of the lens. The markings indicate the meridian from which the cylinder axis is measured and do not indicate the cylinder axis of the lens.

The Visian TICL has orientation markings on the footplates to ensure the lens is implanted right side up. When correctly oriented the orientation markings will be on the leading right/trailing left footplates.

The sphere component of the Visian TICL label indicates the spherical power and not the spherical equivalent power.

INDICATIONS

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

1. for the correction of myopic astigmatism with spherical equivalent ranging from -3.0D to ≤-15.0D (in the spectacle plane) with cylinder (spectacle plane) of 1.0D to 4.0D.
2. for the reduction of myopic astigmatism with spherical equivalent ranging from greater than -15.0D to -20.0D (in the spectacle plane) with cylinder (spectacle plane) 1.0D to 4.0D.
3. with an anterior chamber depth (ACD) of 3.00mm or greater, when measured from the corneal endothelium to the anterior surface of the crystalline lens and a stable refractive history (within 0.5D for both spherical equivalent and cylinder for 1 year prior to implantation).
4. The Visian TICL is intended for placement in the posterior chamber (ciliary sulcus) of the phakic eye.

MODE OF ACTION

The Visian TICL functions as a refractive element to optically reduce moderate to high myopia with astigmatism.

CONTRAINDICATIONS

The Visian TICL is contraindicated in patients

1. with a true ACD of <3.00mm*;
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 data was developed as part of the STAAR Visian ICL for Myopia Clinical Study. 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. 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 STAAR Visian ICL for Myopia Clinical Study demonstrated endothelial cell loss >30% (range, 30.9% to 42.6%) at 5–7 years postoperatively. The longer-term effects (beyond 5–7 years) 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 TICL.
2. Secondary to implantation of the Visian 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. Implantation of the Visian ICL is associated with an elevated risk of early postoperative increase in intraocular pressure (IOP; usually associated with pupillary block) that requires secondary surgical intervention. The long-term risks of glaucoma, peripheral anterior synechiae and pigment dispersion are not well established.
4. Two basal iridotomies must be performed 90° apart using a YAG laser at least 2 weeks before implantation of the Visian TICL, 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 TICL implantation.
5. Do not attempt to resterilize or repackage the Visian TICL.
6. Do not autoclave the Visian TICL. Do not expose to temperature greater than 40°C. Do not freeze. If temperature requirements are not met, return the Visian TICL to STAAR Surgical.
7. The iridocorneal angle distance may decrease after implantation of the Visian TICL. Iridocorneal angle should be assessed 1 week after implantation and monitored if the angle is extremely narrow.
8. A patient with mesopic pupil size that is greater than the optic diameter of the Visian TICL may experience symptoms of glare and/or halos. Patients should be advised about this potential risk prior to TICL implantation.
9. 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 TICL during the clinical trial was a low molecular weight 2% hydroxypropyl methylcellulose 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 myopic astigmatism experience lower efficacy and higher rates of adverse events (AEs) and complications.
2. Inadequate flushing of the viscoelastic from the eye may lead to IOP spikes. IOP should be checked 24 hours postoperatively.
3. The effectiveness of ultraviolet (UV) absorbing intraocular lenses (IOLs) in reducing the incidence of retinal disorders has not been established.
4. The relationship between the Visian TICL and retinal detachment is undetermined.
5. If a method of power calculation different from that used in the Visian TICL clinical study is used, the effectiveness of the Visian TICL for myopic astigmatism may not be consistent with the results reported in the Visian TICL clinical study results section.
6. 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."
7. In the TICL clinical study, surgeons were instructed to create one or two side port incisions, 60–90˚ away from the main incision, which should always be made at the horizontal temporal position. A 3.2mm clear corneal tunnel incision was constructed parallel to the iris plane, with a tunnel length of 1.5 to 1.75mm. If the surgeon uses a method of incision which is different from that used in the TICL clinical study, the postoperative astigmatic results may not be consistent with the results reported for the TICL clinical study.

The safety and effectiveness of the Visian TICL for the correction of moderate to high myopic astigmatism has **NOT** been established in patients with

1. greater than 20.0D of myopia;
2. astigmatism less than 1.0D and greater than 4.0D;
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.

ADVERSE EVENTS

A list of adverse events associated with the TICL are provided below. Additionally, the location for specific adverse event data from the TICL PMA and Myopia ICL (MICL) clinical studies is provided. For some events, the greatest detail is provided in the section that includes the adverse event data from the MICL clinical studies (pre-approval study and extended follow-up post-approval study).

Adverse Events

Adverse Event	For more information please refer to:
Implantation of the TICL can be associated with insufficient TICL vaulting over the crystalline lens, which can lead to anterior subcapsular opacities or clinically significant cataracts	TICL PMA CLINICAL TRIAL AND RESULTS: Adverse Events and Complications • DFU, Pg. 4 MICL ADDITIONAL CLINICAL DATA: Lens Opacity and Visually Significant Cataract Formation • DFU, Pg. 8
Implantation of the TICL can be associated with excessive TICL vaulting, which can cause a narrowing of the anterior chamber angle, possible pupillary block, increased intraocular pressure and glaucoma	TICL PMA CLINICAL TRIAL AND RESULTS: Adverse Events and Complications • DFU, Pg. 4 MICL ADDITIONAL CLINICAL DATA: Adverse Events • DFU, Pg. 7 MICL ADDITIONAL CLINICAL DATA: Surgical Reinterventions • DFU, Pg. 8 MICL ADDITIONAL CLINICAL DATA: Intraocular Pressure • DFU, Pg. 9
Implantation of the TICL is associated with an increased rate of chronic corneal endothelial cell loss, which may, over a period of time, lead to corneal edema and possibly the need for a corneal transplant	TICL PMA CLINICAL TRIAL AND RESULTS: Adverse Events and Complications • DFU, Pg. 4 MICL ADDITIONAL CLINICAL DATA: Adverse Events • DFU, Pg. 7 MICL ADDITIONAL CLINICAL DATA: Endothelial Cell Density • DFU, Pgs. 9 – 10
TICL may move out of its appropriate position	TICL PMA CLINICAL TRIAL AND RESULTS: Visian TICL Related Additional Surgery • DFU, Pgs. 4 - 5 MICL ADDITIONAL CLINICAL DATA: Surgical Reintervention • DFU, Pg. 8
There may be a need for secondary surgery for TICL removal, replacement, or repositioning	TICL PMA CLINICAL TRIAL AND RESULTS: Visian TICL Related Additional Surgery • DFU, Pg. 4 MICL ADDITIONAL CLINICAL DATA: Surgical Reintervention • DFU, Pg. 8
There may be a need for other types of secondary surgical intervention to treat some adverse events	TICL PMA CLINICAL TRIAL AND RESULTS: Adverse Events and Complications • DFU, Pg. 4 MICL ADDITIONAL CLINICAL DATA: Surgical Reintervention • DFU, Pgs. 8 - 9
There may be a loss of best spectacle-corrected visual acuity	TICL PMA CLINICAL TRIAL AND RESULTS: Adverse Events and Complications • DFU, Pgs. 4 – 5 MICL ADDITIONAL CLINICAL DATA: Best Corrected Distance Visual Acuity (BCDVA) Loss • DFU Pg. 8
Implantation of the TICL may cause an increase in refractive astigmatism;	TICL PMA CLINICAL TRIAL AND RESULTS: Refractive Cylinder (Target Variance) Distribution • DFU, Pg. 6
The TICL may be associated with pigment dispersion and iris transillumination defects	MICL ADDITIONAL CLINICAL DATA: Slit Lamp Findings • DFU, Pg. 9
As with implantation of other types of intraocular lenses, potential adverse events can include, but are not limited to infection (endophthalmitis), hypopyon, corneal endothelial damage, IOL dislocation, cystoid macular edema, corneal edema, pupillary block, iritis, retinal detachment, transient or persistent glaucoma, vitritis, iris prolapse, secondary surgical intervention and increased visual symptoms related to the optical characteristics of the IOL including halos, glare and/or double vision	TICL PMA CLINICAL TRIAL AND RESULTS: Adverse Events and Complications • DFU, Pg. 4 TICL PMA CLINICAL TRIAL AND RESULTS: Optical Visual Symptoms • DFU, Pg. 6 TICL PMA CLINICAL TRIAL AND RESULTS: Subjective Symptoms Stratified by Optic Diameter • DFU, Pg. 12 MICL ADDITIONAL CLINICAL DATA: Surgical Reintervention • DFU, Pg. 8
Secondary surgical interventions may include, but are not limited to lens repositioning, lens replacement, vitreous aspiration, iridotomy/iridectomy for pupillary block, wound leak repair, retinal detachment repair and corneal transplantation	TICL PMA CLINICAL TRIAL AND RESULTS: Visian TICL Related Additional Surgery • DFU, Pgs. 4 – 5 MICL ADDITIONAL CLINICAL DATA: Surgical Reintervention • DFU, Pg. 8 MICL ADDITIONAL CLINICAL DATA: Other Complications • DFU, Pg. 10

CLINICAL TRIALS AND RESULTS

Data from a recent clinical study of the Visian TICL, and data from prior clinical studies of the parent Visian MICL are included to support the safety and effectiveness of the Visian TICL. These include the following:

A clinical study of the Visian TICL, demonstrating the safety and effectiveness of the modification of the previously approved Visian MICL model by the addition of a toric optic.

Clinical studies of the parent Visian MICL including the primary safety and effectiveness 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.

<u>Toric ICL Clinical Trial and Results</u>

The Visian TICL was evaluated in a prospective nonrandomized study of 210 eyes of 124 subjects, 194 eyes of which were followed for 12 months. Study Cohort demographics are as follows:

Demographics
N=124 (Subjects)

Age	
Mean (SD)	35.0 (6.8) yrs
Range	21 to 45 yrs
Race	**n/124, %**
Caucasian	102, 82.3%
Hispanic	10, 8.1%
Black	6, 4.8%
Other	6, 4.8%
Gender	
Female	69, 55.6%
Male	55, 44.4%

Adverse Events and Complications

A total of 210 eyes of 124 subjects were evaluated in the clinical trial of the Visian TICL. Anterior subcapsular opacities, not all clinically significant, were observed postoperatively in six eyes (2.9%). Two of these 6 cases (1.0%) had a clinically significant cataract. The remaining 4 cases were asymptomatic with 20/16 or better BCDVA and 20/25 or better UCVA at their last reported visit. There were no cases of greater than trace nuclear color, nuclear opalescence, cortical or posterior subcapsular changes preoperatively or at any postoperative visit.

A total of 3 eyes (1.4%) reported a loss of ≥2 lines of BCDVA between the preoperative and 12 month visit. A loss of >2 lines of BCDVA (20/25 to 20/50) occurred at the 12 month visit in one eye (0.5%) due to anterior subcapsular cataract. There was no information regarding treatment or resolution at the time of study closure. A loss of 2 lines of BCDVA was reported in two eyes (1.0%). In one eye, the preoperative BCDVA was 20/12.5 and at the 12 month visit the BCDVA was 20/20. There were no lens opacities noted at any visit and the patient consistently rated her satisfaction with the procedure as very satisfied. The other eye was amblyopic with preoperative BCDVA of 20/40 and postoperative BCDVA of 20/60 at both the 6 and 12 month visits. This patient was subsequently seen 5 months after the 12 month visit and BCDVA was within 1 line of preoperative BCDVA. No eyes (0%) had BCDVA worse than 20/40 (if preoperative BCDVA 20/20 or better) between 1 and 12 months postoperative.

Corneal edema and iritis were not reported after the 1 week visit. There was 1 case (0.5%) with a retinal detachment. One eye (0.5%) had increased IOP at one day postoperative, which was related to a pupillary block and resolved with an additional Nd:YAG iridotomy. IOP at the one day follow up visit after Nd:YAG iridotomy was 12 mmHg, At the final 12 month post op visit, the BCVA was 20/25 and IOP was 14mmHg. One eye (0.5%) experienced an IOP >25mmHg at 6 months postoperative, which dropped to 17mmHg at 12 months. Two eyes (1.0%) of two subjects experienced an increase of >10mmHg over preoperative IOP during the 12 month follow-up period. These eyes experienced IOP increases from 8mmHg to 21 mmHg and from 10 mmHg to 22mmHg. No treatment was reported in any of these cases. No cases of endophthalmitis, corneal ulcer, ocular hypertension, corneal haze/edema (after 1 week), or corneal melting were reported during the study. The 8 cases (3.8%) of surgical intervention all had improvement/no change in BCDVA or no significant loss in BCDVA (1 line in 1 case) at the last follow-up visit.

Incidence of key AEs/complications are provided in the table below. For a benchmark, they are compared with the ISO historical rate for posterior chamber IOLs for aphakia, implanted in the capsular bag (from ISO 11979-7). Details concerning the types of surgical reinterventions are shown in the following table.

Incidence of Key Adverse Events and/or Complications

Adverse Event	**Cumulative N=210 Eyes**	**ISO[1] Historical Rate**	**Persistent (12 Months)**	**ISO Historical Rate**
	n/210, %	**%**	**n/194, %**	**%**
Endophthalmitis	0, 0%	0.1%	0, 0%	–
Hyphema[4]	0, 0%	–	0, 0%	–
Hypopyon	0, 0%	0.3%	0, 0%	–
IOL Dislocation	0, 0%	0.1%	0, 0%	–
Cystoid Macular Edema	0, 0%	3.0%	0, 0%	0.5%
Raised IOP Requiring Treatment[4]	1, 0.5%	–	0, 0%	0.4%
Pupillary Block	1, 0.5%	0.1%	0, 0%	–
Retinal Detachment[2]	1, 0.5%	0.3%	0, 0%	–
Surgical Reintervention[3]	8, 3.8%	0.8%	0, 0%	–
BCDVA loss ≥ 2 lines[4]	3, 1.5%	–	3, 1.5%	–
Corneal Edema[4] (after 1 week)	0, 0%	–	0, 0%	0.3%
Iritis[4] (after 1 week)	0, 0%	–	0, 0%	0.3%
Anisocoria[4]	1, 0.5%	–	0, 0%	–

[1] ISO-11979-7: Ophthalmic implants–Intraocular Lenses Part 7: Clinical Investigations.
[2] 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 0.5%. The risk of retinal detachment for high myopes following implantation with the Visian MICL† 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% to 7.5% in pseudophakic eyes with high axial myopia.
† Visian MICL Clinical Trial.
[3] Refer to table below for details on Surgical Reinterventions.
[4] There is no ISO historical rate for cumulative hyphema, raised IOP requiring treatment, iritis (after 1 week), BCDVA loss ≥ 2 lines, corneal edema (after 1 week) and anisocoria.

Surgical reinterventions occurred in 3.8% of eyes.

Visian TICL Related Additional Surgery

	n/210*	**%**
TICL Repositioning	1	0.5%
Visian TICL Replacement (too long)	1	0.5%
Visian TICL Removal (no ICL or IOL replacement)	3	1.4%
YAG Iridotomy**	3	1.4%
TOTAL	**8**	**3.8%**

* Total Eye Cohort (N=210)

** Three cases (1.4%) underwent an additional iridotomy. One of these was performed on the day of surgery because the surgeon felt the previous YAG procedure was inadequate. The IOP was 14mmHg or less at all postoperative visits. The second case had an additional YAG iridotomy performed at 5 days postoperative to deepen the anterior chamber which was successful. This case was not associated with an increase in IOP. In the third case, the procedure was performed at 1 day postoperative to enlarge the preoperative iridotomy which was occluded by retained viscoelastic material, resulting in elevated IOP. Subsequent to the YAG procedure, the IOP returned to normal and stayed normal for the remainder of the follow-up.

Anterior subcapsular opacities, not all clinically significant, were observed postoperatively in six eyes (2.9%). Two of these six eyes (1.0%) had clinically significant cataracts. The remaining 4 subjects were asymptomatic with 20/16 or better BCDVA and 20/25 or better UCDVA at their last reported visit.

Decrease in Refractive Myopia and Cylinder

Reduction in refractive myopia and cylinder (manifest refraction spherical equivalent [MRSE] and cylinder) were the primary efficacy outcomes for the study. The tables below provide MRSE and cylinder over time, and a comparison between preoperative and 12 month MRSE and cylinder for the consistent cohort. The mean MRSE improved from -9.34D preoperative to 0.03D at the 12 month follow-up visit. There was a highly significant ($p < 0.001$) 1.43D mean decrease in cylinder from preoperative to 12 months postoperative (paired t-test).

MRSE over Time

	Preop	1 Week	1 Month	3 Months	6 Months	12 Months
N (eyes)	210	205	200	191	182	194
Mean (D)	-9.38	0.02	0.13	0.13	0.11	0.03
SD	2.67	0.45	0.43	0.39	0.49	0.46
Range (D)	-19.50 to -2.38	-1.50 to 1.38	-1.63 to 1.75	-1.25 to 1.25	-1.75 to 2.63	-2.25 to ±1.00

MRSE: Preoperative vs. 12 Months (consistent cohort)

	Preop	12 Months
N (eyes)	194	194
Mean (D)	-9.34	0.03
SD	2.63	0.46
Range (D)	-19.50 to -2.38	-2.25 to ±1.00

Manifest Refraction Cylinder over Time

Spherical Equivalent	Preop	1 Week	1 Month	3 Months	6 Months	12 Months
N (eyes)	210	205	200	191	182	194
Mean (D)	1.95	0.50	0.50	0.52	0.45	0.52
SD	0.84	0.54	0.49	0.49	0.45	0.48
Range (D)	1.00 to 4.00	0.00 to 3.00	0.00 to 3.00	0.00 to 3.00	0.00 to 2.00	0.00 to 3.00

Manifest Refraction Cylinder: Preoperative vs. 12 Months (consistent cohort)

	Preop	12 Months
N (eyes)	194	194
Mean (D)	1.95	0.52
SD	0.85	0.48
Range (D)	1.00 to 4.00	0.00 to 3.00

Visual Acuity

The visual acuities at 6 and 12 months are described in the following tables:

Uncorrected Distance Visual Acuity (UCDVA)

(Eyes with Preoperative BCDVA 20/20 or Better)

	Preoperative N=173 Eyes	6 Months N=155 Eyes	12 Months N=159 Eyes
UCDVA	**n/173, %**	**n/155, %**	**n/159, %**
20/12.5 or better	0, 0%	41, 26.5%	40, 25.2%
20/16 or better	0, 0%	117, 75.5%	101, 63.5%
20/20 or better	0, 0%	140, 90.3%	142, 89.3%
20/40 or better	0, 0%	155, 100%	159, 100%
20/50 or worse	173, 100%	0, 0.0%	0, 0.0%
20/200 or worse	173, 100%	0, 0.0%	0, 0.0%

Best Corrected Distance Visual Acuity (BCDVA)

(Eyes with Preoperative BCDVA 20/20 or better)

	6 Months N=155 Eyes	12 Months N=159 Eyes
BCDVA	**n/155, %**	**n/159, %**
20/12.5 or better	71, 45.8%	72, 45.3%
20/16 or better	141, 91.0%	143, 89.9%
20/20 or better	155, 100%	159, 100%
20/25 or better	155, 100%	159, 100%
20/40 or better	155, 100%	159, 100%

Comparison of Preoperative BCDVA to 12 Month Postoperative UCDVA

	Preop BCDVA N=193 Eyes	12 Month UCDVA N=193 Eyes
	n/N, %	**n/N, %**
20/12.5 or better	7, 3.6%	40, 20.7%
20/16 or better	79, 40.9%	104, 53.9%
20/20 or better	159, 82.4%	158, 81.9%
20/25 or better	181, 93.8%	175, 90.7%
20/32 or better	190, 98.4%	180, 93.3%
20/40 or better	193, 100.0%	184, 95.3%
20/80 or better	193, 100.0%	191, 99.0%
20/200 or better	193, 100.0%	193, 100.0%
Worse than 20/200	0, 0%	0, 0%

Predictability of Refraction

The MRSE of the refraction was predictable with 97.4% of eyes achieving within ± 1.0D from target at the 12 month examination.

Accuracy of MRSE to Target

	12 Months N=194 Eyes
	n/194, %
Within ± 0.50D	149, 76.8%
Within ± 1.0D	189, 97.4%

The manifest cylinder was predictable with 92.3% of eyes achieving within ± 1.0D from target at the 12 month examination.

Accuracy of Manifest Cylinder to Target*

	12 Months N=194 Eyes
	n/194, %
Within ± 0.50D	134, 69.1%
Within ± 1.0D	179, 92.3%

* At the corneal plane

The effect of a temporal corneal incision on corneal toricity was analyzed. On average, implantation of the TICL contributes less than 0.5D of "with-the-rule" astigmatism to the net corneal toricity.

Stability

MRSE was stable with 99.4% of eyes achieving less than or equal to ±1.0D of shift between 6 and 12 months after surgery.

MRSE Change between Visits

	1 Month to 3 Months	3 Months to 6 Months	6 Months to 12 Months
	N=184 Eyes	N=172 Eyes	N=177 Eyes
Change	**n/184, %**	**n/172, %**	**n/177, %**
Within ± 0.25D	136, 73.9%	129, 75.0%	139, 78.5%
Within ± 0.50D	169, 91.8%	159, 92.4%	167, 94.4%
Within ± 1.0D	184, 100%	170, 98.8%	176, 99.4%
> 1.0D	0, 0%	2, 1.2%	1, 0.6%
Mean Change	0.010	-0.009	0.081
SD	0.311	0.330	0.360
95% CI of the Mean	-0.04 to 0.05	-0.06 to 0.04	0.03 to 0.13

Manifest cylinder was stable with 97.2-98.8% of eyes achieving less than or equal to ±1.0D of shift between 6 to 12 months after surgery, depending on analysis method.

Manifest Cylinder Change Between Visits

Analysis Group	Exam Interval	N (Eyes)	Within ± 0.5D n/N, %	Within ± 1.0D n/N, %	Mean Change for Interval [95% Confidence Interval]
Vector Stability	1 to 3 Months	184	143/184, 77.7%	179/184, 97.3%	0.26D [0.23 to 0.3]
	3 to 6 Months	172	145/172, 84.3%	167/172, 97.1%	0.23D [0.19 to 0.26]
	6 to 12 Months	177	141/177, 79.7%	172/177, 97.2%	0.26D [0.22 to 0.29]
Vector Stability Consistent cohort	1 to 3 Months	167	130/167, 77.8%	162/167, 97.0%	0.26D [0.23 to 0.3]
	3 to 6 Months		140/167, 83.8%	162/167, 97.0%	0.23D [0.19 to 0.27]
	6 to 12 Months		134/167, 80.2%	163/167, 97.6%	0.24D [0.21 to 0.28]
Stability of Absolute Cylinder	1 to 3 Months	184	154/184, 83.7%	181/184, 98.4%	0.00D [-0.05 to 0.05]
	3 to 6 Months	172	153/172, 89.0%	170/172, 98.8%	-0.03D [-0.08 to 0.01]
	6 to 12 Months	177	151/177, 85.3%	174/177, 98.3%	0.04D [0 to 0.09]
Stability of Absolute Cylinder Consistent Cohort	1 to 3 Months	167	140/167, 83.8%	164/167, 98.2%	0.00D [-0.05 to 0.05]
	3 to 6 Months		148/167, 88.6%	165/167, 98.8%	-0.03D [-0.08 to 0.01]
	6 to 12 Months		143/167, 85.6%	165/167, 98.8%	0.03D [-0.02 to 0.07]

Study investigators were asked to examine the patient at the slit lamp and estimate the orientation of the long axis of the Visian TICL based upon the alignment markings or haptic edges if visible. The lens orientation was then recorded in clock hours. For instance, if the lens was oriented exactly horizontally it would be recorded as at either 3:00 or 9:00 (clock hour position). Rotation was evaluated based upon the change in clock hour orientation of the Visian TICL postoperatively. A change of a half clock hour would represent 15 degrees of rotation and a change of a quarter clock hour would represent 7.5 degrees of rotation.

Rotation of the TICL Between Visits (from direct observation of TICL)

	1 Day – 1 Week	1 Week – 1 Month	1 Month – 3 Months	3 Months – 6 Months	6 Months – 12 Months
N (Eyes)	121	155	148	136	140
Rotation	**n/121, %**	**n/155, %**	**n/148, %**	**n/136, %**	**n/140, %**
≤ 5°	118, 97.5%	148, 95.5%	141, 95.3%	133, 97.8%	132, 94.3%
≤ 10°	121, 100%	155, 100%	147, 99.3%	135, 99.3%	137, 97.9%

Optical Visual Symptoms

A standardized subjective patient questionnaire was administered across all investigative sites to all subjects in the Visian TICL Study Cohort preoperatively and after ICL implantation. Study subjects' subjective assessments of ocular symptoms of glare, halos, double vision, night vision and night driving difficulties were evaluated for each eye at the preoperative and at the 3 and 12 month postoperative follow-up visits. Subjects were asked to grade the level of the specific ocular symptom in one of five categories: Absent, Mild, Moderate, Marked or Severe.

Eyes with Symptoms Worse at 12 Months compared to Preoperative

Visual Symptom	Worse at 12 Months than Preoperative
	n/N, %
Glare	28/185, 15.1%
Halos	33/185, 17.8%
Double Vision	3/185, 1.6%
Night Vision	22/184, 11.9%
Night Driving Difficulties	24/182, 13.2%

Note: The questionnaire and methodology used to evaluate these subjective symptoms were not considered by the FDA to be validated.

Additional Clinical Outcomes

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

Accuracy of MRSE vs. Intended Target* by Preoperative MRSE

Lens Group	Exam Interval	N	Within ± 0.50D n/N, %	Within ± 1.0D n/N, %	Within ± 2.0D n/N, %
Study Cohort	1 Week	201	149/201, 74.1%	194/201, 96.5%	201/201, 100%
	1 Month	198	155/198, 78.3%	189/198, 95.5%	198/198, 100%
	3 Months	190	142/190, 74.7%	185/190, 97.4%	190/190, 100%
	6 Months	181	122/181, 67.4%	174/181, 96.1%	180/181, 99.4%
	12 Months	194	149/194, 76.8%	189/194, 97.4%	194/194, 100%
≤ -7D Cohort	12 Months	33	28/33, 84.8%	33/33, 100%	33/33, 100%
> -7 to -10D Cohort	12 Months	93	76/93, 81.7%	92/93, 98.9%	93/93, 100%
> -10D to -15D Cohort	12 Months	62	42/62, 67.7%	59/62, 95.2%	62/62, 100%
>-15D Cohort	12 Months	6	3/6, 50.0%	5/6, 83.3%	6/6, 100%

* All Study Cohort Eyes

Accuracy of Manifest Cylinder vs. Intended Target (Over Time)

Lens Group[1]	Exam Interval	N (Eyes)	Within 0.25D n/N[2], %	Within 0.50D n/N[2], %	Within 1.00D n/N[2], %	Within 2.00D n/N[2], %
Study Cohort	Preop	210	0/210, 0%	0/210, 0%	43/210, 20.5%	134/210, 63.8%
	1 Week	205	92/201, 45.8%	128/201, 63.7%	184/201, 91.5%	198/201, 98.5%
	1 Month	200	84/198, 42.4%	128/198, 64.6%	180/198, 90.9%	197/198, 99.5%
	3 Months	191	77/190, 40.5%	123/190, 64.7%	174/190, 91.6%	186/190, 97.9%
	6 Months	182	87/181, 48.1%	128/181, 70.7%	167/181, 92.3%	181/181, 100%
	12 Months	194	78/194, 40.2%	127/194, 65.5%	177/194, 91.2%	193/194, 99.5%

[1] All Study Cohort Eyes
[2] Eyes with non-missing data

Percent Reduction of Absolute (non-vector) Cylinder Attempted 'vs' Achieved

Spectacle Plane – All Eyes

Percent Reduction of Absolute Cylinder

Preoperative Cylinder	N=194 Eyes	Mean	Range	[% CI]
ALL	**n/194, %**	77.8	-62.7 to 151.9	[73.9 to 81.6]
> 0.5D to ≤ 1.0D	39, 20.1%	75.1	-26.4 to 125.2	[65.4 to 84.8]
> 1.0D to ≤ 2.0D	86, 44.3%	71.4	-62.7 to 137.3	[64.9 to 77.9]
> 2.0D to ≤ 3.0D	45, 23.2%	87.1	44.8 to 151.9	[82.2 to 91.9]
> 3.0D to ≤ 4.0D	24, 12.4%	87.6	29.0 to 125.6	[80.3 to 95]

The following table shows the UCDVA by the level of preoperative refraction for all eyes implanted that had a BCDVA of 20/20 or better preoperatively.

UCDVA* Over Time and by Preoperative MRSE

MRSE Group	Exam Interval	N Eyes	20/20 or Better n/N, %	20/40 or Better n/N, %
	1 Week	171	131/171, 76.6%	170/171, 99.4%
	1 Month	166	139/166, 83.7%	164/166, 98.8%
Study Cohort	3 Months	161	140/161, 87.0%	161/161, 100%
	6 Months	155	140/155, 90.3%	155/155, 100%
	12 Months	159	142/159, 89.3%	155/155, 100%
≤ -7D	12 Months	33	31/33, 93.9%	32/33, 97.0%
> -7D to -10D	12 Months	93	78/93, 83.9%	91/93, 97.8%
> -10D to -15D	12Months	61	47/61, 77.0%	59/61, 96.7%
> -15D	12Months	6	2/6, 33.3%	2/6, 33.3%

* In eyes with preoperative BCDVA of 20/20 or better

Subjective Quality of Vision

A standardized subjective patient questionnaire was administered across all investigative sites to all subjects in the Visian TICL Study preoperatively and after ICL implantation. Study subject's subjective assessments of their quality of vision were evaluated for each eye at the preoperative and at the 3 and 12 month postoperative follow-up visits. Subjects were asked to rate their level of quality of vision in one of five categories: Excellent, Very Good, Good, Poor or Very Poor.

Subjective Quality of Vision

All Eyes

Quality of Vision Grading	Preoperative	12 Months
	N=210	N=184
	n/210, %	**n/184, %**
Excellent /Very Good	135/210, 64.3%	174/184, 94.6%
Good	53/210, 25.2%	10/184, 5.4%
Poor/Very Poor	22/210, 10.5%	0/184, 0%

Note: The questionnaire and methodology used to evaluate these subjective symptoms were not considered by the FDA to be validated.

Visian ICL for Myopia (MICL) Clinical Trial and Results (Pre-approval Study and Post-approval Extended Follow-up Safety Data)

The Visian MICL was evaluated in a prospective nonrandomized safety and effectiveness study of 526 eyes of 294 subjects, 470 of which were followed for 1 year and 369 followed for 3 years. Of these, 335 eyes of 192 subjects were seen at 60 months (5 years) or later in a post-approval study with the specific objective of collecting long-term data on endothelial cell loss and AEs/complications in the original PMA cohort. Demographics for the original PMA Cohort are presented in the following table:

Demographics

N=294 (Subjects)

Age	
Mean (SD)	36.55 (5.8) yrs
Range	22 to 45 yrs
Race	**n/294, %**
Caucasian	249, 84.7%
Hispanic	23, 7.8%
Black	16, 5.4%
Other	6, 2.0%
Gender	
Female	178, 60.5%
Male	116, 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 and Complications in the MICL Study (including post-approval extended follow-up safety data).

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	≤12 Mo	>12-24 Mo	>24-36 Mo	>36-48 Mo	>48-60 Mo	≥60 Months
	N=526	N=526	N=462	N=426	N=276	N=346	N=348
	n/526, %	**n/526, %**	**n/462, %**	**n/426, %**	**n/276, %**	**n/346, %**	**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 table 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 Months N=348
	n/526, (%)	n/526 (%)	n/462 (%)	n/426 (%)	n/276 (%)	n/346 (%)	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	>12-24 Mo	>24-36 Mo	>36-48 Mo	>48-60 Mo	≥60 Months	Total
	N=526	N=524	N=448	N=256	N=231	N=117	N=526
	n/526, %	**n/524, %**	**n/448, %**	**n/256, %**	**n/231, %**	**n/117, %**	**n/526, %**
LASIK	15, 2.9%	1, 0.2%	0, 0.0%	0, 0.0%	0, 0.0%	1, 0.9%	17, 3.2%
AK	3, 0.6%	2, 0.4%	0, 0.0%	0, 0.0%	0, 0.0%	0, 0.0%	5, 1.0%

Best Spectacle Corrected Visual Acuity (BCDVA) Loss

Eighteen eyes of 16 subjects reported a significant vision loss of ≥2 lines in BCDVA 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 BCDVA 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 BCDVA of 2 to 10 lines compared to preoperative BCDVA, 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 BCDVA	12 Mo	24 Mo	36 Mo	48 Mo	60 Mo	≥60 Mo
	N=469	N=456	N=384	N=242	N=222	N=331
	n/469, %	**n/456, %**	**n/384, %**	**n/242, %**	**n/222, %**	**n/331, %**
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 Visian ICL for Myopia FDA 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=526	<12 Mo N=526	12 Mo N=472	24 Mo N=457	36 Mo N=381	48 Mo N=245	60 Mo N=225	≥60 Mo N=334	Cumulative of Eyes
	n/526, %	**n/526, %**	**n/472, %**	**n/457, %**	**n/381, %**	**n/245, %**	**n/225, %**	**n/334, %**	
Nuclear	4, 0.8%	4, 0.8%	2, 0.4%	1, 0.2%	3, 0.8%	0, 0.0%	0, 0.0%	3, 0.9%	13
Cortical	2, 0.4%	2, 0.4%	0, 0.0%	1, 0.2%	4, 1.1%	1, 0.4%	0, 0.0%	0, 0.0%	8
Posterior Subcapsular	0, 0.0%	0, 0.0%	0, 0.0%	0, 0.0%	2, 0.5%	0, 0.0%	0, 0.0%	0, 0.0%	4
Anterior Subcapsular	0, 0.0%	8, 1.5%	3, 0.6%	4, 0.9%	2, 0.5%	8, 3.3%	2, 0.9%	4, 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 BCDVA, 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 BCDVA 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

a) *Changes in IOP from Baseline*

The following table shows the number of eyes with postoperative IOP >25mmHg or an increase of >10mmHg over the preoperative value.

IOP (mmHg)	Preop	1 D	14 D	1 Mo	3 Mo	6 Mo	12 Mo	24 Mo	36 Mo	48 Mo	60 Mo	≥60 Mo
		N=526	N=526	N=524	N=522	N=511	N=501	N=469	N=410	N=348	N=262	N=263
	n/526, %	n/526, %	n/526, %	n/524, %	n/522, %	n/511, %	n/501, %	n/469, %	n/410, %	n/348, %	n/262, %	n/263, %
>10mmHg over Baseline	NA	23, 4.4%	20, 3.8%	12, 2.3%	2, 0.4%	0, 0%	2, 0.4%	2, 0.4%	1, 0.2%	2, 0.6%	6, 2.3%	4, 1.5%
>25mmHg	0, 0%	23, 4.4%	16, 3.0%	11, 2.1%	2, 0.4%	0, 0%	2, 0.4%	2, 0.4%	1, 0.2%	3, 0.9%	7, 2.7%	4, 1.5%

b) *Raised IOP Requiring Surgery*

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 Visian ICL for Myopia 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)		
	Total* (N)	Absent n/N, %	Present n/N, %	Total* (N)	Absent n/N, %	Present n/N, %
Peripheral Anterior Synechiae	105	104/105, 99.05%	1/105, 0.95%	294	293/294, 99.66%	1/294, 0.34%
Abnormal Pigment Suggestive of Pigmentary Dispersion	106	101/106, 95.28%	5/106, 4.72%	300	282/300, 94.00%	18/300, 6.00%
	Total	Normal	Abnormal	Total	Normal	Abnormal
Angle Depth	105	104/105, 99.05%	1/105, 0.95%	298	298/298, 100%	0, 0.00%

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

Endothelial Cell Density

Specular microscopy was performed on a subgroup of the original Visian ICL for Myopia 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.

Total Cohort (N)	Preop N=526	3 Mo	12 Mo N=472	24 Mo N=459	36 Mo N=384	48 Mo N=248	60 Mo N=225	72 Mo N=86	84 Mo N=44
	n/526, %		n/472, %	n/459, %	n/384, %	n/146, %	n/225, %	n/86, %	n/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 Visian ICL for Myopia 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

	12 Mo	36 Mo	≥60 Mo
ECD loss from Preop (%)	N=175	N=132	N=115
	n/175, %	**n/132, %**	**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 Visian ICL for Myopia 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.

Study Strengths and Limitations of Visian ICL for Myopia Post-Approval Follow-up of IDE Study Cohort

The post-approval study used the original Visian ICL for Myopia IDE study cohort, following subjects 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.

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

UCDVA, Snellen

(Where emmetropia was the goal (±0.50D) and Preoperative BCDVA better than or equal to 20/20)

	12 Months	36 Months
	N=240	N=189
UCDVA	**n/240, %**	**n/189, %**
20/20 or better	157, 65.4%	112, 59.3%
20/40 or better	232, 96.7%	179, 94.7%
20/80 or better	239, 99.6%	187, 98.9%
Worse than 20/80	1, 0.4%	2, 1.1%

BCDVA, Snellen

(Eyes with Preoperative BCDVA 20/20 or better)

	12 Months	36 Months
	N=321	N=253
BCDVA	**n/321, %**	**n/253, %**
20/20 or better	307, 95.6%	244, 96.4%
20/25 or better	320, 99.7%	253, 100%
20/40 or better	321, 100%	253, 100%

Predictability of Refraction

A total of 90.3% of eyes achieved within ±1.0D MRSE of target refraction at the 12 month examination.

Accuracy of MRSE to Target

	12 Months	36 Months
	N=455	N=363
	n/455, %	**n/363, %**
Within ±0.50D	308, 67.7%	245, 67.5%
Within ±1.0D	411, 90.3%	320, 88.2%

Stability

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

MRSE Change between Visits

	6-12 Months	12-24 Months	24-36 Months
	N=424	N=413	N=337
Change	**n/424, %**	**n/413, %**	**n/337, %**
Within ±0.25D	320, 75.5%	317, 76.8%	253, 75.1%
Within ±0.5D	386, 91.0%	371, 89.8%	304, 90.2%
Within ±1.0D	414, 97.6%	403, 97.6%	329, 97.6%
>1.0D	10, 2.4%	10, 2.4%	8, 2.4%

Optical Visual Symptoms

The following table shows the subjective optical visual symptoms reported for implanted eyes at 36 months after Visian ICL surgery compared to before surgery:

Subjective Symptoms-Improvement/No Change Compared to Preoperative

Symptom	Improved/No Change at 36 Months
	n/N, %
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 n/N, %	±1.0D n/N, %	±2.0D n/N, %
Study Cohort	1 Week	501	324/501, 64.7%	438/501, 87.4%	487/501, 97.2%
	1 Month	506	344/506, 68.0%	445/506, 87.9%	495/506, 97.8%
	3 Months	485	310/485, 63.9%	430/485, 88.7%	475/485, 97.9%
	6 Months	479	320/479, 66.8%	426/479, 88.9%	470/479, 98.1%
	12 Months	455	308/455, 67.7%	411/455, 90.3%	447/455, 98.2%
	24 Months	443	293/443, 66.1%	399/443, 90.1%	434/443, 98.0%
	36 Months	363	245/363, 67.5%	320/363, 88.2%	356/363, 98.1%
New Calculation Method[3]	36 Months	363	254/363, 70.0%	324/363, 89.3%	354/363, 98.3%
≤-7D Cohort	36 Months	72	61/72, 84.7%	70/72, 97.2%	72/72, 100%
New Calculation Method[3]	36 Months	72	62/72, 86.1%	70/72, 97.2%	72/72, 100%
>-7 to -10D Cohort[2]	36 Months	131	93/131, 71.0%	122/131, 93.1%	131/131, 100%
New Calculation Method[3]	36 Months	131	92/131, 70.2%	121/131, 92.4%	131/131, 100%
>-10D to -15D Cohort	36 Months	130	84/130, 64.6%	112/130, 86.2%	128/130, 98.5%
New Calculation Method[3]	36 Months	130	91/130, 70.0%	115/130, 88.5%	129/130, 99.2%
>-15D Cohort	36 Months	30	7/30, 23.3%	16/30, 53.3%	25/30, 83.3%
New Calculation Method[3]	36 Months	30	9/30, 30.0%	18/30, 60.0%	25/30, 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 UCDVA for all eyes and by the level of preoperative refraction for all eyes implanted that were targeted for emmetropia and had a BCDVA of 20/20 or better preoperatively.

UCDVA[1] by Preoperative MRSE

Lens Group	Exam Interval	N	20/20 or Better n/N, %	20/40 or Better n/N, %
Study Cohort	1 Week	259	129/259, 49.8%	238/259, 91.9%
	1 Month	262	148/262, 56.5%	249/262, 95.0%
	3 Months	251	160/251, 63.7%	242/251, 96.4%
	6 Months	248	151/248, 60.9%	239/248, 96.4%
	12 Months	240	157/240, 65.4%	232/240, 96.7%
	24 Months	228	136/228, 59.6%	213/228, 93.4%
	36 Months	189	112/189, 59.3%	179/189, 94.7%
<-7D	36 Months	58	42/58, 72.4%	57/58, 98.3%
>-7D to -10D	36 Months	83	52/83, 62.7%	77/83, 92.8%
>-10D to -15D	36 Months	48	18/48, 37.5%	45/48, 93.8%
>-15D	36 Months	0	NA%[2]	NA%[2]

[1] Eyes with Preoperative BCDVA 20/20 or Better and Emmetropia Targeted Correction
[2] No Eyes >-15D group with this Preop Status

Subjective Quality of Vision
Subjective Quality of Vision – All Eyes

Quality of Vision Grading	Preoperative N=524 n/N, %	36 months N=346 n/N, %
Very Good/Excellent	288/524, 55.0%	267/346, 77.0%
Poor/Very Poor	61/524, 11.6%	20/346, 5.8%

Subjective Patient Symptoms Stratified by Optic Diameter

Subjective symptoms were reported by each eye and stratified into 4 groups based on the optic diameter: 4.9mm, 5.2mm, 5.5mm and 5.8mm. Glare was absent/mild in 82.4% (75/91) of eyes in the 4.9mm, 90.3% (65/72 eyes) in the 5.2mm, 91.8% (45/49 eyes) in the 5.5mm and 89.9% (125/139 eyes) in the 5.8mm groups. Marked/severe glare occurred in 3.3% (3/91) of eyes with the 4.9mm, 2.8% (2/72 eyes) with the 5.2mm, 4.1% (2/49 eyes) with the 5.5mm and 1.4% (2/139 eyes) with the 5.8mm optic at 36 months postoperatively.

The smaller the optic diameter, the greater the incidence of halos. Halos were absent/mild in 80.2% (73/91) of eyes in the 4.9mm, 87.3% (62/71 eyes) in the 5.2mm, 89.8% (44/49 eyes) in the 5.5mm and 87.8% (122/139 eyes) in the 5.8mm. Marked/severe halo was dependent upon the Visian ICL optic diameter and was 9.9% (9/91 eyes) with the 4.9mm, 2.8% (2/71 eyes) with the 5.2mm, 4.1% (2/49 eyes) with the 5.5mm and 1.4% (2/139 eyes) with the 5.8mm.

Double vision was absent/mild in all (139/139) eyes with the 5.8mm optic diameter. Double vision was reported as absent in 95.6% (87/91) of eyes with the 4.9mm, 98.6% (71/72 eyes) with the 5.2mm, and 98.0% (48/49 eyes) with the 5.5mm 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% (15/90) of eyes in the 4.9mm group compared to 0% (0/135 eyes) with the 5.8mm. Night driving difficulties were absent/mild in 71.1% (64/90) of eyes using the 4.9mm, 83.8% (57/68 eyes) with the 5.2mm, 85.4% (41/48 eyes) with the 5.5mm, and 91.9% (124/135 eyes) with the 5.8mm.

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 (0/139 eyes) of marked/severe night vision difficulties occurred with the 5.8mm. Subjective night vision difficulties 36 months after Visian ICL insertion were absent/mild in 73.6% (67/91) of eyes with 4.9mm, 84.7% (61/72 eyes) with the 5.2mm, 83.7% (41/49 eyes) with the 5.5mm, and 90.6% (126/139 eyes) with the 5.8mm.

Visian ICL Implantable Collamer Lens Post-Approval Adverse Event Study

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.

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.
- Patient 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 27.28mm (range 23.69mm to 34.32mm) and the postoperative axial length averaged 27.28mm (range 23.72mm to 34.51mm). The average difference in preoperative and postoperative axial lengths is -0.02mm (range -0.23mm to + 0.19mm).

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 -0.02mm 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.

INSTRUCTIONS FOR USE

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

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

Visian TICL Handling Precautions

1. Choice of the proper Visian TICL size should be carefully considered prior to surgery.
2. Check the label of the Visian TICL package for proper lens model and power.
3. Open the package to verify the dioptric power of the lens.
4. Handle the Visian TICL 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 TICL 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 FP Cartridge), to insert the Visian TICL in the folded state.

7. The Visian TICL should be carefully examined in the operating room prior to implantation.
8. The Visian TICL 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 TICL 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 TICL optical portion with a sharp object since this could perforate the optic.
11. The intended location of the Visian TICL is behind the iris within the posterior chamber and in front of the anterior capsule of the crystalline lens.
12. The Visian TICL is manufactured so that rotation of no more than 22.5 degrees (2/3 clock hours) is necessary.
13. It is recommended that the surgeon not rotate the TICL more than 22.5 degrees from horizontal.
14. 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 measurement is defined as the distance from the apex of the posterior corneal surface to the apex of the anterior crystalline lens surface

Visian TICL Length Determination

During the original US PMA clinical study, sizing of the Visian ICL myopic lenses (12.1mm to 13.7mm) 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 ≤3.5mm, the lens size was calculated by adding 1.1mm to the horizontal white-to-white measurement. Eyes exhibiting an ACD greater than 3.5mm required the addition of up to 1.6mm to the white- to-white measurement, up to a maximum length of 13.7mm. Calculated lens sizes between the available lens diameters (in 0.5mm steps) were generally rounded down if the ACD was ≤ 3.5mm and rounded up if the ACD was >3.5mm.

Analyses of all of the collected clinical data resulted in a slightly modified recommendation 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 TICL overall diameter. At present there is no large series study demonstrating the effectiveness of UBM in Visian ICL sizing.

Peripheral Iridotomy

Two YAG iridotomies (0.5mm; 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 TICL at the time of surgery, and Visian TICL replacements due to sizing.

Refraction:

A cycloplegic refraction is recommended to confirm the accuracy of the manifest refraction.

Visian TICL Power Calculation

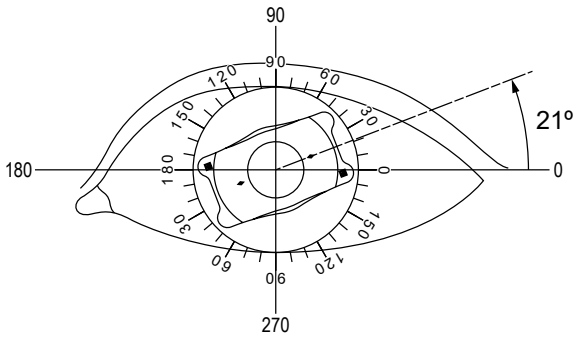
Implantation of the Visian TICL requires that a preoperative determination of the dioptric power of the implanted lens be calculated. Achievement of emmetropia is not necessarily a desirable postoperative goal and factors such as visual status of the fellow eye and patient lifestyle should be considered 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 TICL Calculation Software. (www.ocos.STAAR.com).

The TICL calculator will recommend a cylinder power and a range of spherical powers along with their expected postoperative values (i.e. residual sphere, cylinder, axis and spherical equivalent). Selection of lens power is based on the treatment plan of the surgeon for a given eye.

In all cases it is recommended the Visian TICL be implanted horizontally in the eye through a temporal incision.

As part of the implantation procedure, the Visian TICL may need to be rotated up to 22.5 degrees clockwise or counterclockwise from the 0°–180° meridian in order to align the lens axis at the preoperative plus cylinder axis. The surgeon should mark the horizontal axis (0°–180°) of the eye at the slit lamp prior to surgery. These horizontal axis marks will be used as reference points to mark the desired orientation of the lens under the operating microscope, using a suitable corneal axis marking device. For example, if the preoperative plus cylinder axis is at 136° and the lens selected has the cylinder axis at 115°, the lens will need to be rotated 21° counterclockwise from the temporal meridian in eye. In this case the desired axis marked on the cornea would be 21° counterclockwise from the 0°–180° meridian. The online ordering software for the Visian TICL is designed to generate an Implantation Orientation Diagram (IOD) to guide the surgeon in determining the amount and direction of rotation for the specific lens selected. See example below:



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 TICL 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 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 Visian TICL 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

Postoperative Visian TICL Vault

Lens vault (the distance between the anterior surface of the crystalline lens and the posterior surface of the Visian Toric ICL) should be assessed 24 hours postoperatively at a slit lamp. Although the postoperative vault of the Toric ICL is intended to be approximately equal to the central corneal thickness, we believe that the optimal vault should be between 50% and 150% of central corneal thickness, this being equivalent to a range of 250 to 900 microns. However, in the absence of symptoms, lens vault outside of this range may not necessarily require exchange or removal.

Visian TICL Removal

It is recommended that the Visian TICL be removed in cases where the vault is insufficient and the patient exhibits early anterior subcapsular cataract. Removal of the Visian TICL may be necessary in cases where the vault is excessive causing narrowing of the anterior chamber angle, thus decreasing aqueous flow. Visian TICL removal may also be necessary for other reasons on an individual basis. The risks involved in Visian TICL 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 TICL Physician Certification Program.

SURGICAL PROCEDURE

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

PATIENT REGISTRATION

Each patient who receives a Visian TICL 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 TICL implantation, especially in younger patients. Physicians must report these events in order to aid in identifying emerging or potential problems with the Visian TICL.

HOW SUPPLIED

Each Visian TICL 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 TICLs.

Contact STAAR Surgical. The Visian TICL 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 TICL 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 TICL 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 TICL at room/ambient temperature.

WARNING

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

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