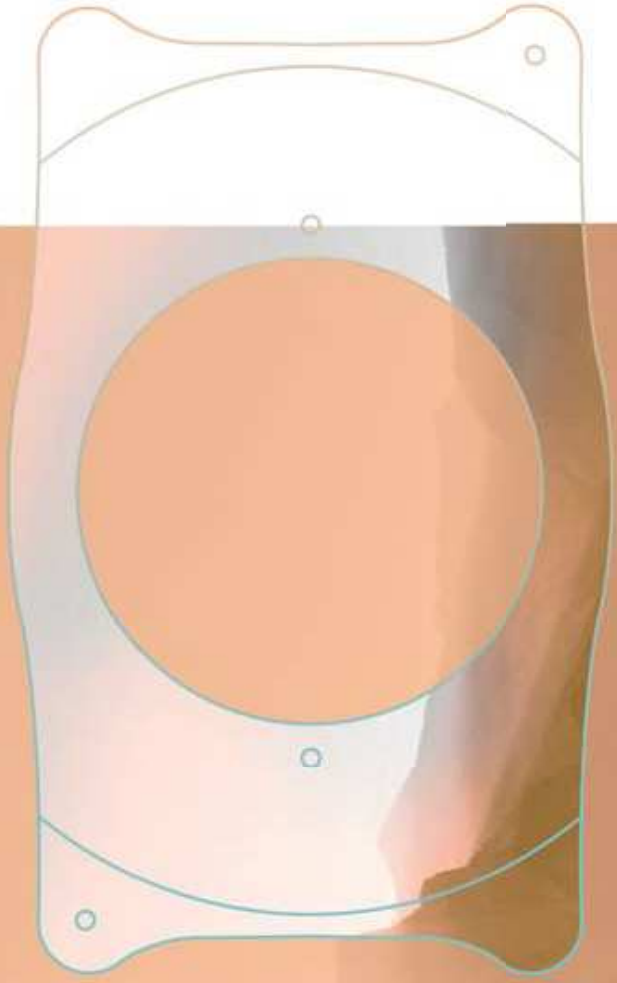


# Visian ICL™



P H A K I C   I N T R A O C C U L A R   L E N S



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

For the correction/reduction of moderate to high myopia 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 Ave.  
 Monrovia, CA 91016  
 USA  
 Tel: (800) 352-7842  
 Fax: (800) 952-4923

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

**PRODUCT INFORMATION**

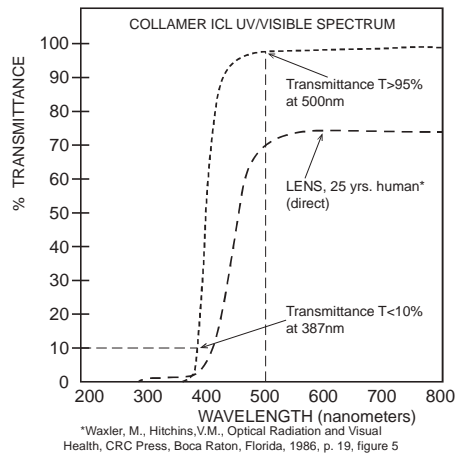
Please review this product information completely before performing your initial clinical procedure. All physicians must complete the STAAR Surgical Visian ICL Physician Certification Program prior to use.

**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   |



**INDICATIONS**

The Visian ICL is indicated for use in adults 21-45 years of age:

1. For the correction of myopia in adults with 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 in adults with 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 3.00mm 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 <3.00mm\*;
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 <sup>2</sup> | 3800 cells/mm <sup>2</sup> | 3250 cells/mm <sup>2</sup> |
| 26-30 | 3425 cells/mm <sup>2</sup> | 3375 cells/mm <sup>2</sup> | 2900 cells/mm <sup>2</sup> |
| 31-35 | 3025 cells/mm <sup>2</sup> | 2975 cells/mm <sup>2</sup> | 2625 cells/mm <sup>2</sup> |
| 36-40 | 2675 cells/mm <sup>2</sup> | 2625 cells/mm <sup>2</sup> | 2350 cells/mm <sup>2</sup> |
| 41-45 | 2350 cells/mm <sup>2</sup> | 2325 cells/mm <sup>2</sup> | 2100 cells/mm <sup>2</sup> |
| >45   | 2075 cells/mm <sup>2</sup> | 2050 cells/mm <sup>2</sup> | 1900 cells/mm <sup>2</sup> |

\*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<sup>2</sup> at 75 years of age. Spectacular microscopy should be performed preoperatively and ECD should be monitored periodically at intervals dictated by the physician's medical judgment.

#### WARNINGS

- 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.
- 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.
- 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.
- 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.
- Do not attempt to sterilize or repackage the Visian ICL.
- 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.
- 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.
- 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.

- Patients with higher degrees of myopia experience lower efficacy and higher rates of adverse events (AEs) and complications.
- The effect of pupil size on visual symptoms is not known.
- Inadequate flushing of the viscoelastic from the eye may lead to IOP spikes. IOP should be checked 24 hours postoperatively.
- The effectiveness of ultraviolet (UV) absorbing intraocular lenses (IOLs) in reducing the incidence of retinal disorders has not been established.

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 / >10mmHg change from baseline at last visit (0.2%), 1 macular hemorrhage (0.2%) and 1 subretinal hemorrhage (0.2%).

There were 20 cases of failed 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 (0 Years) % (n/N) | FDA Grid % |
|--------------------------------------|--------------------|------------|------------------------------|------------|
| Endophthalmitis                      | 0% (0/526)         | 0.1%       | 0% (0/526)                   | —          |
| Hypohemia                            | 0% (0/526)         | 2.2%       | 0% (0/526)                   | —          |
| Hyphema                              | 0% (0/526)         | 0.3%       | 0% (0/526)                   | —          |
| IOL Dislocation                      | 0% (0/526)         | 0.1%       | 0% (0/526)                   | —          |
| Cyclitic 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 <sup>1</sup> | 6.8% (36/526)      | 0.8%       | —                            | —          |
| Corneal Edema (after 1 week)         | 0% (0/526)         | —          | 0% (0/526)                   | 0.3%       |
| Intit <sup>2</sup> (after 1 week)    | 0% (0/526)         | —          | 0% (0/526)                   | 0.3%       |

#### Surgical Treatments Not Mentioned in FDA Grid

| Refractive Procedures     | 3.9% (20/526) | — | —          |
|---------------------------|---------------|---|------------|
| Iris Prostaglandin 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 intits. 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 (>20 D) 35.0% in myopes >20 D, and 0.0% for 25+ in pseudophakic eyes with high axial myopia.

Ogawa A, Tanaka M. The relationship between refractive errors and retinal detachment. *Japan J Ophthalmol* 32:2110-1988.  
 DeAngelis-Larkin G, Deane CA. Retinal detachment. Available at: [http://www.amedia.com/emergtopics04.htm](http://www.amedia.com/emedicine.com/emergtopics04.htm)  
 DeAngelis-Larkin G, Deane CA. Retinal detachment in high myopia. *Retina* 19:103-107, 1999.  
 J Cat Ref Surg 23, 1955:1937. Refractive procedures include AK and LASK

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  | %    |
|---------------------------------------|----|------|
| 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)

| N                | 12 Months |       | 36 Months |       |
|------------------|-----------|-------|-----------|-------|
|                  | 240       | 189   | 240       | 189   |
| 20/20 or better  | 65.4%     | 63.3% | 65.4%     | 63.3% |
| 20/40 or better  | 95.7%     | 94.7% | 95.7%     | 94.7% |
| 20/80 or better  | 98.6%     | 98.9% | 98.6%     | 98.9% |
| Worse than 20/80 | 0.4%      | 1.1%  | 0.4%      | 1.1%  |

#### 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 postop in 14 eyes (2.7%). 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%).

### 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 | 95.5%     | 96.4%     |
| 20/25 or better | 99.7%     | 100%      |
| 20/40 or better | 100%      | 100%      |

### Predictability of Refraction

The refraction was predictable with 90.3% of subjects achieving  $\pm 1.0D$  from target at the 12 month examination.

### Spherical Equivalent (Target Variance) Distribution

|             | 12 Months | 36 Months |
|-------------|-----------|-----------|
| N           | 455       | 363       |
| $\pm 0.50D$ | 89%       | 88.3%     |
| $\pm 1.0D$  | 91.6%     | 89.5%     |

### Stability

The refraction was stable with 97.6% of eyes achieving less than or equal to  $\pm 1.0D$  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          |
| $\pm 0.25D$ | 75.5%       | 76.8%        | 75.1%        |
| $\pm 0.5D$  | 91.0%       | 89.8%        | 90.2%        |
| $\pm 1.0D$  | 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 Vision ICL implantation compared to before the Vision 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 (88.6%)                 |
| Double Vision              | 345/351 (98.3%)                 |
| Night Vision               | 308/350 (88.0%)                 |
| Night Driving Difficulties | 30/1335 (89.8%)                 |

### Additional Clinical Outcomes

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

### MRSE vs. Intended Target' by Preoperative MRSE

| Lens Group             | Exam Interval          | n                      | $\pm 0.5D$ | $\pm 1.0D$ | $\pm 2.0D$ |       |       |
|------------------------|------------------------|------------------------|------------|------------|------------|-------|-------|
| Study Cohort           | 1 Week                 | 501                    | 64.7%      | 87.4%      | 97.2%      |       |       |
|                        | 1 Month                | 506                    | 66.0%      | 87.5%      | 97.8%      |       |       |
|                        | 3 Months               | 485                    | 63.5%      | 86.7%      | 97.5%      |       |       |
|                        | 6 Months               | 479                    | 66.8%      | 88.9%      | 98.1%      |       |       |
|                        | 12 Months              | 465                    | 67.7%      | 90.3%      | 98.2%      |       |       |
| New Calculation Method | 1 Week                 | 465                    | 67.7%      | 90.3%      | 98.2%      |       |       |
|                        | 1 Month                | 465                    | 67.7%      | 90.3%      | 98.2%      |       |       |
|                        | 3 Months               | 363                    | 67.5%      | 88.2%      | 95.1%      |       |       |
|                        | 6 Months               | 366                    | 70.0%      | 88.3%      | 95.3%      |       |       |
|                        | 12 Months              | 366                    | 70.0%      | 88.3%      | 95.3%      |       |       |
| <-7D Cohort            | 36 Months              | 72                     | 64.7%      | 97.2%      | 100%       |       |       |
|                        | New Calculation Method | 36 Months              | 72         | 66.1%      | 97.2%      | 100%  |       |
|                        | >-7 to <-10D Cohort    | 36 Months              | 131        | 71.0%      | 93.1%      | 100%  |       |
|                        |                        | New Calculation Method | 36 Months  | 131        | 70.2%      | 92.4% | 100%  |
|                        |                        | >-10D to <-15D Cohort  | 36 Months  | 130        | 64.6%      | 88.2% | 98.5% |
| New Calculation Method |                        |                        | 36 Months  | 130        | 70.0%      | 88.5% | 98.2% |
| >-15D Cohort           |                        |                        | 36 Months  | 30         | 23.3%      | 53.3% | 83.3% |
|                        | New Calculation Method |                        | 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 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       | 51.5%           | 95.0%            |                  |
|               | 3 Months       | 248       | 50.8%           | 94.8%            |                  |
|               | 6 Months       | 248       | 60.9%           | 96.4%            |                  |
|               | 12 Months      | 240       | 65.4%           | 96.7%            |                  |
| >-7D to <-10D | 36 Months      | 58        | 72.4%           | 98.3%            |                  |
|               | >-10D to <-15D | 36 Months | 83              | 62.7%            | 92.8%            |
|               | >-15D          | 36 Months | 48              | 37.5%            | 93.8%            |
|               | >-15D          | 36 Months | 0               | NA% <sup>1</sup> | NA% <sup>2</sup> |
|               | >-15D          | 36 Months | 0               | NA% <sup>1</sup> | NA% <sup>2</sup> |

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: 4.9mm, 5.2mm, 5.5mm and 5.8mm. Glare was absent/mild in 82.4% of subjects in the 4.9mm, 90.3% in the 5.2mm, 91.8% in the 5.5mm and 89.9% in the 5.8mm groups. Marked/severe glare occurred in 3.3% of eyes with the 4.9mm, 2.8% with the 5.2mm, 4.1% with the 5.5mm and 1.4% 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% of subjects in the 4.9mm, 87.3% in the 5.2mm, 89.8% in the 5.5mm and 87.8% in the 5.8mm. Marked/severe halo was dependent upon the Vision ICL optic diameter and was 9.9% with the 4.9mm, 2.8% with the 5.2mm, 4.1% with the 5.5mm and 1.4% with the 5.8mm.

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 4.9mm, 98.6% with the 5.2mm, and 98.0% 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 were reported in 16.7% of eyes in the 4.9mm group compared to 0% with the 5.8mm. Night driving difficulties were absent/mild in 71.1% of eyes using the 4.9mm, 83.8% with the 5.2mm, 85.4% with the 5.5mm, and 91.9% 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 of marked/severe night vision difficulties occurred with the 5.8mm. Subjective night vision difficulties 36 months after Vision ICL insertion were absent/mild in 73.6% of eyes with 4.9mm, 84.7% with the 5.2mm, 83.7% with the 5.5mm, and 90.6% with the 5.8mm.

### 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 Vision 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" column.

**Accountability (all implanted eyes, N=229)**

|                               | 12 Months | 24 Months | 38 Months | 48 Months | 60 Months | ≥ 60 Months |
|-------------------------------|-----------|-----------|-----------|-----------|-----------|-------------|
| Available for Analysis        | 472       | 469       | 384       | 248       | 225       | 335         |
| Discontinued (ICL Removals)   | 0         | 1         | 5         | 5         | 10        | 11          |
| Missed Visit/CRF not Received | 40        | 44        | 84        | 132       | 176       | NA          |
| Missing                       | 0         | 0         | 0         | 1         | 4         | NA          |
| Lost to Follow-up             | 14        | 22        | 53        | 80        | 111       | 180         |
| <b>% Accountability</b>       | 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)

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

**Adverse Events<sup>1</sup>**

| Adverse Event                     | Cumulative n/526 (%) | ≤ 12 Mo n/526 (%) | >12-24 Mo n/462 (%) | >24-38 Mo n/276 (%) | >38-48 Mo n/176 (%) | >48-60 Mo n/136 (%) | ≥ 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%)          |
| ICL 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 Reintention <sup>2</sup> | 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 Reintentions.

**Surgical Reintentions**  
A total of 43 eyes (8.2%) underwent surgical reintention 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 Adjuvant Surgery**

|                               | Cumulative n/526 (%) | ≤ 12 Mo n/526 (%) | >12-24 Mo n/462 (%) | >24-38 Mo n/276 (%) | >38-48 Mo n/176 (%) | >48-60 Mo n/136 (%) | ≥ 60 Months 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%)            | 0 (0.0%)            | 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  | 20 (3.8%)            | 20 (3.8%)         | 0 (0.0%)            | 0 (0.0%)            | 0 (0.0%)            | 0 (0.0%)            | 0 (0.0%)              |
| <b>TOTAL</b>                  | 43 (8.2%)            | 28 (5.3%)         | 4 (0.9%)            | 4 (0.9%)            | 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.

| Relative Procedure | ≤ 12 Mo % (n/N) | >12-24 Mo % (n/N) | >24-38 Mo % (n/N) | >38-48 Mo % (n/N) | >48-60 Mo % (n/N) | ≥ 60 months % (n/N) | Total         |
|--------------------|-----------------|-------------------|-------------------|-------------------|-------------------|---------------------|---------------|
| LASIK              | 15/26 (5.9%)    | 15/24 (6.2%)      | 0/48 (0.0%)       | 0/256 (0.0%)      | 0/231 (0.0%)      | 11/17 (6.5%)        | 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. The remaining 7 eyes reported no change or improvement. 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 either 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 (%) | 38 Mo n/N (%) | 48 Mo n/N (%) | 60 Mo n/N (%) | ≥ 60 Mo n/N (%) |
|-------------------|---------------|---------------|---------------|---------------|---------------|-----------------|
| Decrease ≥2 Lines | 14/69 (0.2%)  | 24/65 (0.4%)  | 33/84 (0.8%)  | 12/42 (0.4%)  | 12/22 (0.4%)  | 2/33 (0.6%)     |
| Decrease <2 Lines | 24/69 (0.4%)  | 34/65 (0.6%)  | 13/84 (0.3%)  | 12/42 (0.4%)  | 2/22 (0.8%)   | 2/33 (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.

**Any Anterior Subcapsular Opacity (ASC)**

| Cataract Type               | Preop n/N (%) | 12 Mo n/N (%) | 24 Mo n/N (%) | 38 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 (0.4%)  | 2/472 (0.4%)  | 1/457 (0.8%)  | 3/381 (0.8%)  | 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%)  | 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%)  | 0/225 (0.0%)  | 2/334 (0.6%)    | 4                         |
| Anterior Subcapsular        | 0/526 (0.0%)  | 0/526 (0.0%)  | 0/472 (0.0%)  | 0/457 (0.0%)  | 2/381 (0.5%)  | 0/225 (0.0%)  | 2/334 (0.6%)    | 4                         |
| <b>Total Number of Eyes</b> | 6             | 13            | 3             | 5             | 8             | 9             | 2               | 5                         |

\* 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 (NO) 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.

**Intraocular Pressure (IOP)**

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

| 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 (%) |
|-----------------------|---------------|---------------|---------------|---------------|--------------|--------------|---------------|---------------|---------------|---------------|-----------------|
| >10mmHg over Baseline | NA            | 23/526 (0.3%) | 20/526 (0.3%) | 12/524 (2.3%) | 25/22 (0.4%) | 0/511 (0.0%) | 25/21 (0.4%)  | 24/69 (0.4%)  | 14/10 (0.4%)  | 24/69 (0.4%)  | 6/262 (2.3%)    |
| >25mmHg               | 0/526 (0.0%)  | 0/526 (0.0%)  | 0/526 (0.0%)  | 0/526 (0.0%)  | 0/526 (0.0%) | 0/526 (0.0%) | 0/526 (0.0%)  | 0/526 (0.0%)  | 0/526 (0.0%)  | 0/526 (0.0%)  | 0/526 (0.0%)    |

1. Refer to section on Intraocular Pressure for details.

2. Refer to section below for details on Surgical Reintentions.

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% Con. Interval | 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<br>N=175 | 36 Mo<br>N=132 | ≥60 Mo<br>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)

| Endothelial Cell Density                       | For all eyes with ECD data at both visits: |                              |   |
|--|--|------------------------------|---|
|  | 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 (7.99)                               | -5.04 (8.09)                 | -4.74 (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 to -42.94                            | 11.62 to -23.15              | 4.27 to -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-operative data is approximately 1.9% per year.

#### Predicted Percent Endothelial Cell Loss

| Time from procedure | 90% prediction interval* |       |
|---------------------|--------------------------|-------|
|                     | Lower                    | Upper |
| 3 months            | -20%                     | 23%   |
| 1 year              | -18%                     | 25%   |
| 2 years             | -16%                     | 27%   |
| 3 years             | -14%                     | 28%   |
| 4 years             | -12%                     | 31%   |
| 5 years             | -10%                     | 33%   |
| 10 years            | -2%                      | 40%   |
| 15 years            | 6%                       | 50%   |
| 20 years            | 13%                      | 57%   |
| 25 years            | 19%                      | 64%   |
| 30 years            | 25%                      | 70%   |
| 35 years            | 30%                      | 75%   |
| 40 years            | 35%                      | 80%   |
| 45 years            | 42%                      | 84%   |
| 50 years            | 43%                      | 88%   |
| 55 years            | 46%                      | 92%   |

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

**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**  
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                                | 6.2 Mo        | None                  | None               | None                      | Normal      |
| 2 (1 subject) | Unspecified                                | 5 Mo, 12 Mo   | Yes                   | None               | None                      | Normal      |
| 2 (1 subject) | Open Angle                                 | 3.7 Mo, 51 Mo | Yes                   | None               | None                      | Normal      |
| 2 (1 subject) | Open Angle, possibly 2° pigment dispersion | 7.1 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                        | 95.05% (104)      | 0.95% (1) | 105    | 99.66% (293)          | 0.34% (1)  | 294    |
| Abnormal Pigment Suggestive of Pigmentary Dispersion | 95.26% (101)      | 4.72% (5) | 106    | 94.00% (282)          | 6.00% (18) | 300    |
| Angle Depth  | 99.05% (104)      | 0.95% (1) | 105    | 100% (298)            | 0.00% (0)  | 298    |

\* Total number of eyes with gonioscopy was 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/N)       | % (n/N)      | % (n/N)      | % (n/N)      | % (n/N)      | % (n/N)      | % (n/N)       | % (n/N) | % (n/N) | % (n/N) | % (n/N)      |  |
| Pigment on cornea         | 0.0%          | 0.0%         | 0.0%         | 0.0%         | 0.0%         | 0.0%         | 0.0%          | 0.0%    | 0.0%    | 0.0%    | 1.2% (4/353) |  |
| Pigment on ICL            | 2.5% (13/526) | 0.4% (2/472) | 0.4% (2/472) | 2.0% (9/459) | 1.8% (7/384) | 2.0% (8/248) | 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     | 223     | 86      | 44      |
| Eyes with readable ECD (95.5%)               | 192  | 209     | 220     | 174     | 146     | 113     | 37      | 27      |
| Eyes with both Preop and postop readable ECD | NA   | 162     | 175     | 151     | 132     | 109     | 85      | 19      |
|  |      | (37.1%) | (32.9%) | (34.4%) | (44.0%) | (37.8%) | (17.4%) | (41.2%) |

## Other Complications

No cases of endophthalmitis, hyphema, hypopyon, cystoid macular edema or corneal ulcer were reported during the study. Corneal haze, corneal edema or iris 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 -10.66D (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 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 MicroSTAAR® Injector system (Models MS1TF and MS1PF 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 ACD. The ACD measurement is defined as the distance from the apex of the anterior corneal surface to the apex of the anterior crystalline lens surface and therefore includes the thickness of the cornea.

#### Visian ICL 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 + corneal thickness). For eyes with ACD measurements of  $\leq 3.5$ mm, 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  $\leq 3.5$ 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

| White-to-White (mm) | ACD (mm)        |                 |
|---------------------|-----------------|-----------------|
|                     | AI              | $\leq 3.5$      |
| $< 10.5$            | Not Recommended | $> 3.5$         |
| 10.5-10.6           | Not Recommended | 12.1            |
| 10.7-11.0           | 12.1            | Not Recommended |
| 11.1                | 12.1            | 12.6            |
| 11.2-11.4           | 12.6            | 13.2            |
| 11.5-11.6           | 13.2            | 13.7            |
| 11.7-12.1           | 13.7            | Not Recommended |
| 12.2                | 13.7            | Not Recommended |
| 12.3-12.8           | 13.7            | Not Recommended |
| $\geq 13$           | Not Recommended | 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 biometry (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 (0.5mm; 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 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.ocs.staar.com](http://www.ocs.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 MICROSTAAR® Injectors, Model MSI-TF or MSI-PF with SFC-45 or SFC-45 FP Cartridge. For detailed loading instructions see Directions For Use for 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<br>Manufacturer           | Medical device manufacturer                                       |
|         | 5.1.4<br>Use by date            | Use by (YYYY-MM-DD)   |
|         | 5.1.7<br>Serial number          | Serial number   |
|         | 5.2.1<br>Sterile                | Sterile   |
|         | 5.2.5<br>Sterilized using steam | Sterilized using steam  |
|         | 5.4.2<br>Do not reuse           | Do not reuse  |
|         | 5.4.4<br>Caution                | Consult instructions for use for important cautionary information |

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