Visian ICL™ (Implantable Collamer Lens) For Myopia

Product Information

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

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician.

Device Description

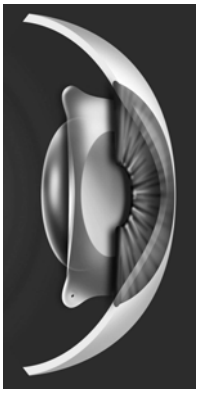
The STAAR Surgical Visian ICL (Implantable Collamer Lens) is an intraocular implant manufactured from a proprietary hydroxyethyl methacrylate (HEMA)/porcine-collagen based biocompatible polymer material. The Visian ICL contains a UV absorber made from a UV absorbing material. The Visian ICL features 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 with an overall diameter that varies with the dioptric power; the smallest optic/overall diameter being 4.9 mm/12.1 mm and the largest 5.8 mm/13.7 mm. All descriptions of optic diameter, overall diameter or Visian ICL power refer measurements in BSS unless otherwise noted. The lenses are capable of being folded and inserted into the posterior chamber through an incision of 3.5 mm 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 lens 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
MICL12.1	-3.0 to –16.0 D	12.1	4.9- 5. 8	Flat, plate
MICL12.6	-3.0 to –16.0 D	12.6	4.9- 5. 8	Flat, plate
MICL13.2	-3.0 to –16.0 D	13.2	4.9- 5. 8	Flat, plate
MICL13.7	-3.0 to –16.0 D	13.7	4.9- 5. 8	Flat, plate

STAAR Visian ICL VERSION 4



STAAR Visian ICL positioned in the eye.

Indications

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

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

The Visian ICL is intended for placement in the posterior chamber of the phakic eye.

Contraindications

The ***Visian ICL is contraindicated in patients:***

- With an anterior chamber depth (ACD) < 3.00 mm
- With anterior chamber angle less than Grade II as determined by gonioscopic examination.
- Who are pregnant or nursing.
- Who do not meet the minimum endothelial cell density

Endothelial Cell Density

Age	Minimum ECD – ACD ≥ 3.0 mm	Minimum ECD – ACD ≥ 3.2 mm	Minimum ECD – ACD ≥ 3.5 mm
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 table indicates the minimum endothelial cell density (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 ≥ 3.0 mm, ≥ 3.2 mm, and ≥ 3.5 mm groups, respectively . It sets minimum endothelial cell density criteria as functions of age that should result in at least 1000 cells/mm^2 at 75 years of age. The patient's ECD should be monitored periodically at the physician's discretion.

Warnings

- The long-term effects on the corneal endothelium have not been established. Patients should be advised about potential risk of corneal edema, possibly requiring corneal transplantation.

- The long-term rate 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 90º 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 re-sterilize or repackage this lens.

- Do **not** autoclave the Visian ICL. Do not freeze; do not expose to temperature greater than 40 degrees Celsius.

Precautions

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

1. Patients with higher degrees of myopia experience lower efficacy and higher rates of adverse events and complications.

2. The effect of pupil size on visual symptoms is not known.

3. Inadequate flushing of the viscoelastic from the eye may lead to intraocular pressure (IOP) spikes. IOP should be checked 24 hours postoperatively.

4. The effectiveness of ultraviolet absorbing lenses in reducing the incidence of retinal disorders has not been established.

5. The relationship between the Visian ICL and future lens opacities and retinal detachment is undetermined.

6. The accuracy of measurement of axial length in an eye with a Visian ICL is unknown

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

a) greater than 20D of myopia ;

b) greater than 2.5D of astigmatism

c) unstable or worsening myopia

d) a diagnosis of ocular hypertension or glaucoma

e) pseudoexfoliation

f) pigment dispersion

g) history or clinical signs of iritis/uveitis

h) insulin-dependent diabetes or diabetic retinopathy

i) history of previous ocular surgery

j) progressive sight-threatening disease other than myopia

k) serious (life-threatening) non-ophthalmic disease

Adverse Events and Complications 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 postop cylinder (>2 D) at 3 years (0.4%). Loss of BSCVA > 2 lines occurred in 4 eyes (0.8%); =2 line loss in 6 eyes (1.2%).

The adverse events/complications experienced during the clinical study of the Visian ICL (between 1 and 36 months) all occurring in ≤ 1% of cases (cumulative) and included 3 retinal detachments (0. 6%), 2 cases of glaucoma (0.4%), clinically significant cataract (2 anterior (0.4%); 5 nuclear (1%)), 1 case of elevated IOP > 25 mmHg /> 10 mmHg change from baseline at last visit (0.2%), 1 macular hemorrhage (0.2%) and 1 subretinal hemorrhage (0.2%). Corneal edema and iritis were not reported after the 1 week visit. No cases of macular edema, endophthalmitis, corneal ulcer, corneal haze/edema (after 1 week), hypopyon, hyphema or persistent corneal edema were reported during the study.

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

Adverse Event	Cumulative % (n/N)	FDA Grid %	Persistent (3 Years) % (n/N)	FDA Grid %
Endophthalmitis	0% (0/526)	0.1%	0% (0/526)	---
Hyphema	0% (0/526)	2.2%	0% (0/526)	---
Hypopyon	0% (0/526)	0.3%	0% (0/526)	---
IOL Dislocation	0% (0/526)	0.1%	0 (0/526)%	---
Cystoid Macular Edema	0% (0/526)	3.0%	0% (0/526)	0.5%
Pupillary Block	0% (0/526)	0.1%	0% (0/526)	---
Retinal Detachment	0.6% (3/526)	0.3%	0% (0/526)	---
Surgical Reintervention	3.1% (16/526)	0.8%	0% (0/526)	---
Corneal Edema (after 1 week)	0% (0/526)	---	0% (0/526)	0.3%
Iritis[1] (after 1 week)	0% (0/526)	---	0% (0/526)	0.3%
Raised IOP Requiring Intervention	3.8% (20/526)	---	0.4% (2/526)	0.4%
SURGICAL TREATMENTS NOT MONITORED IN FDA GRID				
Refractive Procedures	20/526 (3.9%)	---	---	---
Iris Prolapse Repair	0.2% (1/526)	---	0% (0/526)	---

1.There is no FDA Grid Rate for cumulative iritis.
Comparison should be made to literature for retinal detachment rates for high myopia.
Retinal detachment rates increase with increasing myopia. The risk of retinal detachment within one year of implantation of this device is 0.2%. The risk of retinal detachment for high myopes following implantation is more than 10 times the risk without surgery, i.e., greater than 10 fold the background rate of retinal detachment for high myopes (greater than minus 3 diopters).5.0% in myopes > -6 D and 0.8% to 7.5 % in pseudophakic eyes with high axial myopia.

Ogawa A, Tanaka, M., The relationship between refractive errors and retinal detachment. Jpn J Ophthalmolo 32**;**310:1988.
Dellone-Larkin G, Dellona CA. Retinal detachment. Available at: *http://www.emedicine.com/emerg/topic504.html*
Jacobi F, Hessemer V. Pseudophakic retinal detachment in high axial myopia. J Cat Ref Surg 23;1095:1997.
Refractive procedures include: AK and LASIK

Surgical reinterventions (see table below) were not shown to have an impact on safety or efficacy. Surgical reinterventions occurred in 3.1% 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%
TOTAL	16	3.1%

*Total Study Cohort (n = 526)

Other Complications:

Postoperatively IOP > 25 mmHg during follow-up or an increase of > 10 mmHg over preoperative took place in 5 cases through 3 years (only 1 persisted at last visit); 1.4% of the Visian ICL PMA Cohort. Only 2 cases (0.4%) in the entire cohort were diagnosed with ocular hypertension and started on pressure lowering medication. No cases (0.0%) in this study exhibited optic nerve or visual field changes characteristic of glaucoma.

Clinical Results

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

Demographics: 526 Eyes of 294 Subjects

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

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 1 and 3 years are described in the following tables:

UCDVA = Uncorrected Distance Visual Acuity, Snellen
(Where emmetropia was the goal (± 0.50 D) and Pre-op Best Spectacle Corrected Visual Acuity (BSCVA) better than or equal to 20/20)

	1 Year	3 Year
N	240	189
20/20 or better	65.4%	59.3%
20/40 or better	96.7%	94.7%
20/80 or better	99.6%	98.9%
Worse than 20/80	0.4%	1.1%

BCDVA = Best Corrected Distance Visual Acuity, Snellen
(Eyes with Preoperative BCVA 20/20 or better)

	1 Year	3 Year
N	321	253
20/20 or better	95.6%	96.4%
20/25 or better	99.7%	100%
20/40 or better	100%	100%

Predictability of Refraction

The refraction was predictable with 90.3% of patients achieving ± 1.0 D from target at the 1 year examination.

Spherical Equivalent (Target Variance) Distribution

	1 Year	3 Year
N	455	363
± 0.50 D	69%	68.3%
± 1.0 D	91.6%	89.5%

Stability

The refraction was stable with 97.6% of eyes achieving less than or equal to ± 1.0D of shift at 3 years.

Manifest Refraction Spherical Equivalence (MRSE)
Change between Visits

	6 Month to 1 Year	1 Year to 2 Year	2 Year to 3 Year
N	424	413	337
± 0.25 D	75.5%	76.8%	75.1%
± 0.5 D	91.0%	89.8%	90.2%
± 1.0 D	97.6%	97.6%	97.6%
> 1.0 D	2.4%	2.4%	2.4%

Endothelial Cell Density

Endothelial cell density was performed using a single reading center to minimize standard deviations inherent in this test method. A percent change from baseline to 3 years of 8.9% (SD 8.5%), and from baseline to 4 years of 10.6% (SD 9%) was found. Endothelial cell loss over time in patients with extremely high myopia is unknown.

Mean EC density results are shown in the following table:

Visit	Mean	Standard Deviation	90% Confidence Limits
Pre-op	2657	286	2625 to 2689
6 Months	2571	337	2534 to 2608
1 Yr	2544	352	2508 to 2580
2 Yr	2476	356	2438 to 2514
3 Yr	2434	359	2393 to 2475
4 Yr	2387	399	2327 to 2447

The available data from the clinical study indicates a continual steady loss of endothelial cell density of -2.2% per year and this rate has not been established as safe..

The following table provides the predicted percent endothelial cell loss, by year, for an individual patient with pre-operative endothelial cell density equal to the mean level in

the clinical study. For this individual patient and time, we are 90% confident that the endothelial cell loss will be between the lower and upper prediction interval bounds. The entries in this table are calculated assuming a constant linear loss in endothelial cell density from three months after the procedure.

Years from procedure	Predicted Percent Cell Loss	90% prediction interval	
		Lower	Upper
3 months	3%	-18%	24%
1	5%	-17%	26%
2	7%	-15%	28%
3	9%	-13%	30%
4	11%	-11%	32%
5	13%	-9%	34%
10	23%	1%	45%
15	34%	11%	56%
20	44%	20%	68%
25	54%	29%	80%
30	65%	38%	92%
35	75%	46%	100%
40	85%	54%	100%
45	96%	63%	100%
50	100%	71%	100%
55	100%	79%	100%
60	100%	86%	100%

Optical Visual Symptoms

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

Subjective Patient Symptoms-Improvement/No Change Compared to Pre-op

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

Additional Clinical Outcomes

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

MRSE *vs.* Intended Target[1] by Pre-op MRSE

Lens Group	Exam Interval	*N*	± 0.50 D	± 1.0 D	± 2.0 D
Study Cohort	1 Week	501	64.7%	87.4%	97.2%
	1 Month	506	68%	87.9%	97.8%
	3 Months	485	63.9%	88.7%	97.9%
	6 Months	479	66.8%	88.9%	98.1%
	1 Year	455	67.7%	90.3%	98.2%
	2 Year	443	66.1%	90.1%	98%
	3 Year	363	67.5%	88.2%	98.1%
New Calculation Method[3]	3 Year	363	70.0%	89.3%	98.3
≤ -7 D Cohort	3 Year	72	84.7%	97.2%	100%
New Calculation Method[3]	3 Year	72	86.1%	97.2%	100%
> -7 to -10 D Cohort	3 Year	131	71.0%	93.1%	100%
New Calculation Method[3]	3 Year	131	70.2%[2]	92.4%[2]	100%
> -10 D to -15 D Cohort	3 Year	130	64.6%	86.2%	98.5%
New Calculation Method[3]	3 Year	130	70%	88.5%	99.2%
> -15 D Cohort	3 Year	30	23.3%	53.3%	83.3%
New Calculation Method[3]	3 Year	30	30%	60%	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	56.5%	95%
	3 Months	251	63.7%	96.4%
	6 Months	248	60.9%	96.4%
	1 Year	240	65.4%	96.7%
	2 Year	228	59.6%	93.4%
	3 Year	189	59.3%	94.7%
≤ -7 D	3 Year	58	72.4%	98.3%
> -7 D to -10 D	3 Year	83	62.7%	92.8%
> -10 D to -15 D	3 Year	48	37.5%	93.8%
> -15 D	3 Year	0	NA%**	NA**%

*Eyes with Preoperative BSCVA 20/20 or Better and Emmetropia Targeted Correction
** No Eyes > -15 D group with this Preop Status

Subjective Quality of Vision

Subjective Quality of Vision-All Eyes

Quality of Vision Grading	Pre-op	36 months
Very Good/Excellent	288 (55%)	267 (77%)
Poor/Very Poor	61 (11.6%)	20 (5.8%)

Subjective Patient Symptoms Stratified by Optic Diameter

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

The incidence/severity of halos increased, the smaller the optic diameter. Halos were absent/mild in 80.2% of patients in the 4.9 mm, 87.3% in the 5.2 mm, 89.8% in the 5.5

mm and 87.8% in the 5.8 mm. Marked/severe halo was dependent upon the Visian ICL optic diameter and was 9.9% with the 4.9 mm, 2.8%with the 5.2 mm, 4.1% with the 5.5 mm and 1.4% with the 5.8 mm.

Double vision was absent in all eyes with the 5.8 mm optic diameter. Double vision was reported as absent in 95.6% of the patients with the 4.9 mm, 98.6 with the 5.2 mm, and 98.0% with the 5.5 mm at 36 months.

The incidence of marked/severe night driving difficulties negatively correlated with the optic diameter. Marked/severe night driving difficulties was reported in 16.7% of eyes in the 4.9 mm group compared to 0% with the 5.8 mm. Night driving difficulties were absent/mild in71.1% of eyes using the 4.9 mm, 83.8% with the 5.2 mm, 85.4% with the 5.5 mm, and 91.9% with the 5.8 mm.

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

Administration and Instructions for Use

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 Training Certification Program. The following procedures are recommended for implantation of the Visian ICL.

Directions for Use

Visian ICL Handling Precautions

- Choice of the proper Visian ICL size should be carefully considered prior to surgery.

- Check the label of the Visian ICL package for proper lens model and power.

- Open the package to verify the dioptric power of the lens.

- Handle the lens 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.

- 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.

- STAAR Surgical recommends using only the MICROSTAAR™ ® injector system (Models MSI-TF and MSI-PF) to insert the Visian ICL in the folded state.

- The Visian ICL should be carefully examined in the operating room prior to implantation.

- 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.)

- Keep the Visian ICL moist. It is recommended that the Visian ICL be held in sterile BSS solution prior to implantation.

- 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.

- 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.

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

The long terms effects of phakic intraocular lens implantation have not been determined. Therefore, physicians should continue to monitor implant patients postoperatively on a regular basis.

Visian ICL Surgical Procedure

The following represent a brief 'Directions for Use'. More detailed information regarding the recommended Surgical Technique will be provided in conjunction with STAAR's Visian ICL Physician Training Certification Program.

1. Check the label on the lens package for proper lens model, dioptric power and expiration date.
2. Inspect the blister pack. Ensure that it is not damaged.
3. Tap lightly on the lid before opening the lens container.
4. While keeping the container in a horizontal position, unscrew the cap and lift it.
5. Grasp the lens gently with forceps.
6. Examine the lens carefully under the microscope for damage or particulate matter.

DO NOT ALLOW THE LENS TO DRY AFTER REMOVAL FROM THE GLASS VIAL.

Key Visian ICL Surgical Points

Endothelial Cell Density (ECD) Preoperative Measurements: An ECD measurement should be performed preoperatively to determine if candidates meet the minimum ECD requirements based upon age and ACD.

Visian ICL Replacement: It is recommended that the Visian ICL be replaced in cases with poor vault that exhibit early anterior subcapsular cataract with UCVA worse than 20/50. Visian ICL replacement may also be necessary for other reasons on an individual case basis.

Injectors: The Visian ICL should be inserted with the MICROSTAAR ™ ® Models MSI-TF or MSI-PF.

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.

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.

Postoperative Intraocular Pressure Monitoring: Intraocular pressure (IOP) should be checked 24 hours postoperatively.

Viscoelastic Usage: Inadequate flushing of the viscoelastic from the eye may lead to intraocular pressure (IOP) spikes. IOP should be checked 24 hours postoperatively.

Visian ICL Length Determination: During the U.S. multi-center clinical study, sizing of the Visian ICL myopic lenses (12.1 to 13.7mm) was determined by the horizontal white-to-white and the anterior chamber depth (ACD) measurements. 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 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)	Recommended ICL Length
<10.5	All	Not Recommended
10.5-10.6	<=3.5	Not Recommended
10.5-10.6	>3.5	12.1
10.7-11.0	All	12.1
11.1	<=3.5	12.1
11.1	>3.5	12.6
11.2-11.4	All	12.6
11.5-11.6	<=3.5	12.6
11.5-11.6	>3.5	13.2
11.7-12.1	All	13.2
12.2	<=3.5	13.2
12.2	>3.5	13.7
12.3-12.9	All	13.7
>=13	All	Not Recommended

W-to-W Measurements: Are an indirect measurement and poorly correlate with sulcus measurements. Newer advancements in the direct measurement of the ciliary sulcus such as ultrasonic biomicroscopy (UBM) should be considered as alternative methods for the determination of the desired Visian ICL overall diameter. At present there is no large series demonstrating the effectiveness of UBM in Visian ICL sizing.

Replacement of Visian ICL

It is recommended that the Visian ICL be replaced in cases with poor vault that exhibit early anterior subcapsular cataract with UCVA worse than 20/50. Visian ICL replacement may also be necessary for other reasons on an individual case basis.

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

The accuracy of measurement of axial length in an eye with a Visian ICL is unknown. 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. Physicians requiring information on lens power calculation may contact STAAR Surgical Company, Customer Service, Monrovia, California; telephone # (800) 352 7842.

Patient Registration Instructions and Reporting 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.

Adverse Event 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. 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 STAAR Visian ICL's.

Customers should use the following telephone/FAX numbers when reporting adverse reactions or potentially sight-threatening complications involving Visian ICL: Telephone; (800) 352 7842 FAX: (800) 952 4923

How Supplied

Each Visian ICL is provided sterile and non-pyrogenic in sealed vials within a sterile thermoform tray placed in a box with labeling. 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 was steam sterilized.

Distributed by
STAAR Surgical Inc.
1911 Walker Avenue
Monrovia, CA 91016 USA
Tel: (626) 303-7902
FAX: (626) 303-2962

Expiration Date

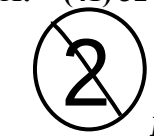
The expiration date on the device package and unit box is the sterility expiration date. Sterility is assured if the tray seal is not punctured or damaged until the expiration date. This device should not be used past the indicated sterility expiration date.

Return Policy

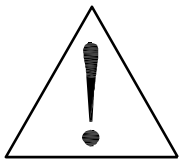
Contact STAAR Surgical. Lens should be returned dry. Do not attempt to re-hydrate.

Manufactured By

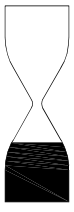
STAAR Surgical AG.
Hauptstrasse 104
CH2560 Nidau, Switzerland
Tel: + (41) 32 332 8888
FAX: + (41) 32 332 8899



Do not reuse



See instruction for use



Use by

Store at Room Temperature/Ambient