STAAR™ SURGICAL

Visian ICL™

eDFU-0045/1

Phakic Intraocular Lens

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STAAR™ SURGICAL

Visian™ Implantable Collamer™ Lens (Visian ICL™)

DIRECTIONS FOR USE

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; special attention is placed on sizing methodologies for determination of Visian ICL overall diameter. Improper ICL size may lead to adverse events ranging from mild to severe.

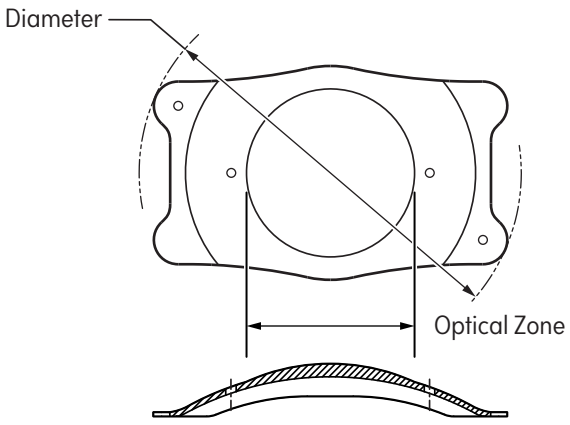
DEVICE DESCRIPTION

The Visian Implantable Collamer Lens (Visian ICL) features a single piece lens design with a central, concave/convex optical zone of 5.8mm diameter. The lens is manufactured in four overall diameters, 11.6, 12.1, 12.6, 13.2mm to accommodate different eye sizes. The lenses are capable of being folded and implanted through an incision of 3.5mm or less. The lenses are manufactured from a proprietary ultraviolet (UV) radiation absorbing polymer containing hydroxyethylmethacrylate (HEMA) and porcine collagen. The 10% UV cut-offs for STAAR's phakic IOL lens family are:

- 377nm for the thinnest central thickness lens, -5.5D, and
- 388nm for the thickest central thickness lens, +10.0D.

Table 1: VICH Models

Brand Name	Model Name	Dioptric Power (D)	Overall Diameter (mm)	Optic Diameter (mm)	Haptic Design
Visian ICL	VICH 11.6	+0.5 to +10.0	11.6	5.8	Flat, plate
Visian ICL	VICH 12.1	+0.5 to +10.0	12.1	5.8	Flat, plate
Visian ICL	VICH 12.6	+0.5 to +10.0	12.6	5.8	Flat, plate
Visian ICL	VICH 13.2	+0.5 to +10.0	13.2	5.8	Flat, plate



VICH Diagram

INDICATIONS

Visian ICL is indicated for use in phakic eye treatment in patients 21-45 years of age for:

- The correction/reduction of hyperopia in patients ranging from +0.5D to +16.0D at the spectacle plane.
- With an anterior chamber depth (ACD) equal to or greater than 3.0mm, as measured from the corneal endothelium to the anterior lens capsule.

MODE OF ACTION

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 correct/ reduce hyperopia.

CONTRAINDICATIONS

Visian ICL is contraindicated in the presence of any of the following circumstances and/or conditions:

1. Patients with low/abnormal corneal endothelial cell density, Fuchs' dystrophy or other corneal pathology
2. Ocular hypertension in either eye
3. Any cataract in the operative eye or non-traumatic cataract in the fellow eye.
4. Persons under the age of 21 years.
5. Primary Open Angle or Narrow Angle Glaucoma.
6. Narrow anterior chamber angles (i.e. less than Grade III as determined by gonioscopic exam).
7. Pregnant or nursing.
8. Previous or pre-existing ocular disease that would preclude post-operative visual acuity of 0.477 logMAR (20/60 Snellen) or better.
9. Patients who are amblyopic or blind in the fellow eye.
10. Implantation of a lens in an eye with an anterior chamber depth (ACD), as measured from the corneal endothelium to the anterior lens capsule, less than 3.0mm.

COMPLICATIONS AND ADVERSE REACTIONS

Adverse reactions and complications due to, or following surgery and implantation of any Visian ICL may include, but are not limited to: Hyphema, Non-reactive Pupil, Pupillary Block, Additional YAG Iridotomy, Secondary Glaucoma, Cataract, Intraocular Infection, Uveitis/ Iritis, Retinal Detachment, Vitritis, Corneal Edema, Macular Edema, Corneal Decompensation, Over/Under Correction, Significant Glare and/or Halos (under night driving conditions), Hypopyon, Increased Astigmatism, Loss of BSCVA, Decentration/Subluxation, IOP Elevation from Baseline, Corneal Endothelial Cell Loss, Iris Pigment Dispersion, Secondary Surgical Intervention to Remove/ Replace/ Reposition the Lens, Peripheral Anterior Synechia (PAS), Iris Synechia to Implant, Conjunctival Irritation, Vitreous Loss.

PRECAUTIONS

1. Do not attempt to sterilize.
2. Do not autoclave.
3. The lens should not be exposed to any solutions other than the normally used intraocular irrigating solutions (e.g. isotonic saline, Balanced Salt Solution (BSS), viscoelastic, etc.).
4. The lens should be handled carefully. No attempts should be made to reshape or cut any portion of the lens or to apply undue pressure to the lens optical portion with a sharp object.
5. Do not allow the lens to dry in air. The lens should be stored in sterile BSS solution during surgery.
6. The long-term effect of the lens has not been determined. Therefore, physicians should continue to monitor implant patients postoperatively on a regular basis.
7. Safety and effectiveness of the lens has not been established in patients with: unstable refractive error in either eye, keratoconus, history of clinical signs of iritis/uveitis, synechia, pigment dispersion syndrome, pseudoexfoliation, insulin- dependent diabetes or diabetic retinopathy, history of previous ocular surgery including refractive corneal surgery.
8. Implantation of a lens may result in a decrease in corneal endothelial cell density.

CALCULATION OF LENS POWER AND SIZING

The lens power and size calculation should be performed by the surgeon using the STAAR Calculation Software. Using the software potentially prevents calculation errors that may result in secondary surgery due to refractive surprise, excessive vaulting, lens rotation, IOP elevation from baseline, etc. During the U.S. FDA trial for the ICM/TICM, the white to white and ACD (from the corneal endothelium to the anterior lens capsule) were used to determine the ICL overall diameter. There are some reports suggesting that white to white corneal measurements do not correlate with sulcus to sulcus measurements. Recent publications indicate that new imaging technologies may provide optimal visualization and measurement of the intraocular dimensions involved in phakic intraocular lens implantation.

LENS PREPARATION

Verify that the level of the liquid fills at least 2/3 of the vial. The thermoformed tray and vial should be opened in a sterile field. Record serial number on operative report to retain traceability of the lens. Remove the aluminum cap and stopper from the vial. Remove the lens from the vial. The lens should not be exposed to a dry environment (air) for more than one minute.

CAUTION: Do not use if package has been opened or damaged.

CAUTION: Do not allow the lens to dry after removal from the glass vial.

ADMINISTRATION AND INSTRUCTION FOR USE

Implantation of Visian ICL should only be attempted by a surgeon who is highly skilled in the required surgical technique. The following procedure is recommended for implantation of Visian ICL. Two YAG iridotomies, (0.5 to 0.8mm; placed superiorly, 90 degrees apart) should be performed 1 to 2 weeks prior to surgery with confirmation of patency prior to lens implantation. The patient should be prepared for surgery according to the surgeon's standard operating procedure. A clear scleral or corneal tunnel wound incision of 3.5mm or less should be used, followed by filling of the anterior and posterior chamber with an appropriate viscoelastic. The lens is then folded using a MICROSTAAR™ injector MSI-PF or MSI-TF with SFC-45 cartridge and injected into the anterior chamber of the eye. Please refer to the product insert or loading guide provided with the injector for instructions regarding proper loading and injection of the lens using the MICROSTAAR injection system. Verify correct orientation of the lens in the eye and that the lens is not inverted. If the pupil remains sufficiently dilated, the lens should be well centered and positioned under the iris in front of the natural lens so that the footplates are placed in the sulcus. Complete removal of the viscoelastic material from the eye must be performed after completion of the surgical procedure and before the eye is closed (without sutures). From this point the operation can proceed according to the surgeon's standard procedure. Dispose of any single use accessories that may have become contaminated with bodily fluids during the procedure as biohazardous waste according to standard surgical biohazard waste disposal procedure. Postoperative medical care of the patient should also follow the surgeon's standard procedure.

WARNINGS

1. Check the label of the lens package for proper lens model and power.
2. Open the package to verify the dioptric power of the lens.
3. Handle the lens by the haptic portion. Do not grasp the optic with forceps and never touch the center of the optic once the lens is placed inside the eye.
4. 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.
5. STAAR Surgical recommends using the MICROSTAAR MSI-PF or MSI-TF with SFC-45 cartridge injection systems to insert the lens in the folded state.

NOTE: The primary viscoelastic used during the US FDA clinical trial was a low molecular weight 2% hydroxypropyl methylcellulose preparation.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

A Summary of Safety and Clinical Performance (SSCP) for the ICL family of lenses can be found in the European database on medical devices (Eudamed) at https://ec.europa.eu/tools/eudamed. The Basic UDI-DI (BUDI-DI) used to search for the for the ICL family of lenses on the website is 764013516ICLGV.

CLINICAL TRIAL ICH:

Summary Findings of the Implantable Collamer Lens for Hyperopia Clinical Study Model ICH:

Table 2: Patient Demographics

327 Eyes Treated of 197 Patients

Sex		
Male	105	(53.3%)
Female	92	(46.7%)
Ethnic Origin		
Caucasian	175	(88.8%)
Black	6	(3.0%)
Hispanic	6	(3.0%)
Other	10	(5.1%)

Table 3: Adverse Events

A summary of adverse events reported in the 327 eyes enrolled during the clinical trial (at any postoperative exam) is presented below:

Adverse event	N	%
ICL Removal Due to Elevated IOP	1	0.3
ICL Replacement (Due to Incorrect Sizing)	3	0.9
ICL Repositioning	2	0.6
ICL Removal Due to Cataract	8	2.4
Other Secondary Surgical Interventions	0	0.0

Table 4: Best Spectacle Corrected Visual Acuity with Time for Patients with PREOP BSCVA 20/20 or better
The Implantable Collamer Lens for Hyperopia

	Preop n%	1 Week n%	1 Month n%	3 Months n%	6 Months n%	12 Months n%	24 Months n%
≤20/20	214/214 (100.0%)	158/202 (78.2%)	160/192 (83.3%)	145/171 (84.8%)	130/158 (82.3%)	84/107(78.5%)	32/40 (80.07%)
≤20/25	214/214 (100.0%)	186/202 (92.1%)	182/192 (94.8%)	166/171 (97.1%)	155/158 (98.1%)	103/107 (96.3%)	37/40 (92.5%)
≤20/32	214/214 (100.0%)	196/202 (97.0%)	190/192 (99.0%)	171/171 (100.0%)	156/158 (98.7%)	107/107 (100.0%)	39/40 (97.5%)
≤20/40	214/214 (100.0%)	202/202 (100.0%)	192/192 (100.0%)	171/171 (100.0%)	158/158 (100.0%)	107/107 (100.0%)	39/40 (97.5%)
≤20/80	214/214 (100.0%)	202/202 (100.0%)	192/192 (100.0%)	171/171 (100.0%)	158/158 (100.0%)	107/107 (100.0%)	40/40 (100.0%)
≤20/200	214/214 (100.0%)	202/202 (100.0%)	192/192 (100.0%)	171/171 (100.0%)	158/158 (100.0%)	107/107 (100.0%)	40/40 (100.0%)
>20/200	0/214 (0.0%)	0/202 (0.0%)	0/192 (0.0%)	0/171 (0.0%)	0/158 (0.0%)	0/107 (0.0%)	0/40 (0.0%)
Not Reported	0	7	4	2	4	2	0
Total	214	207	194	172	161	108	40

Table 5: UCVA Stratified by PREOP SEQ for Patients with PREOP BSCVA 20/20 or better
The Implantable Collamer Lens for Hyperopia

	Preop n/N%		1 Week n/N%		1 Month n/N		3 Months n/N%	
	Hyperopia<5D	Hyperopia>5D	Hyperopia<5D	Hyperopia>5D	Hyperopia<5D	Hyperopia>5D	Hyperopia<5D	Hyperopia>5D
≤20/20	3/93 (3.2%)	2/121 (1.7%)	31/91 (34.1%)	29/114 (25.4%)	40/88 (45.5%)	28/107 (26.2%)	39/80 (48.8%)	32/93 (34.4%)
≤20/25	5/93 (5.4%)	3/121 (2.5%)	48/91 (52.7%)	64/114 (56.1%)	58/88 (65.9%)	57/107 (53.3%)	55/80 (68.8%)	57/93 (61.3%)
≤20/32	7/93 (7.5%)	3/121 (2.5%)	69/91 (75.8%)	86/114 (75.4%)	75/88 (85.2%)	79/107 (73.8%)	66/80 (82.5%)	75/93 (80.6%)
≤20/40	13/93 (14.0%)	4/121 (3.3%)	78/91 (85.7%)	103/114 (90.4%)	81/88 (92.0%)	99/107 (92.5%)	72/80 (90.0%)	86/93 (92.5%)
≤20/80	44/93 (47.3%)	19/121 (15.7%)	87/91 (95.6%)	114/114 (100.0%)	88/88 (100.0%)	107/107 (100.0%)	80/80 (100.0%)	93/93 (100.0%)
≤20/200	76/93 (81.7%)	40/121 (33.1%)	90/91 (98.9%)	114/114 (100.0%)	88/88 (100.0%)	107/107 (100.0%)	80/80 (100.0%)	93/93 (100.0%)
>20/200	17/93 (18.3%)	81/121 (66.9%)	1/91 (1.1%)	0/114 (0.0%)	0/88 (0.0%)	0/107 (0.0%)	0/80 (0.0%)	0/93 (0.0%)
Not Reported	0	0	0	2	0	0	0	0
Total	93	121	91	116	88	107	80	93

	6 Months n/N%		12 Months n/N%		24 Months n/N%	
	Hyperopia<5D	Hyperopia>5D	Hyperopia<5D	Hyperopia>5D	Hyperopia<5D	Hyperopia>5D
≤20/20	30/68 (44.1%)	33/93 (35.5%)	25/48 (52.1%)	21/60 (35.0%)	8/16 (50.0%)	7/24 (29.2%)
≤20/25	47/68 (69.1%)	53/93 (57.0%)	34/48 (70.8%)	34/60 (56.7%)	11/16 (68.8%)	15/24 (62.5%)
≤20/32	57/68 (83.8%)	80/93 (86.0%)	40/48 (83.3%)	45/60 (75.0%)	12/16 (75.0%)	19/24 (79.2%)
≤20/40	60/68 (88.2%)	88/93 (94.6%)	42/48 (87.5%)	54/60 (90.0%)	15/16 (93.8%)	21/24 (87.5%)
≤20/80	67/68 (98.5%)	93/93 (100.0%)	48/48 (100.0%)	59/60 (98.3%)	16/16 (100.0%)	24/24 (100.0%)
≤20/200	68/68 (100.0%)	93/93 (100.0%)	48/48 (100.0%)	60/60 (100.0%)	16/16 (100.0%)	24/24 (100.0%)
>20/200	0/68 (0.0%)	0/93 (0.0%)	0/48 (0.0%)	0/60 (0.0%)	0/16 (0.0%)	0/24 (0.0%)
Not Reported	0	0	0	0	0	0
Total	68	93	48	60	16	24

Table 6: Manifest Refraction Spherical Equivalent with Time
The Implantable Collamer Lens for Hyperopia

Spherical Equivalent (D)	Preop n%	1 Week n%	1 Month n%	3 Months n%	6 Months n%	12 Months n%	24 Months n%
>4.00	254 (77.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.4%)	0 (0.0%)	0 (0.0%)
+4.00 to +3.01	60 (18.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
+3.00 to +2.01	11 (3.4%)	3 (1.0%)	3 (1.0%)	2 (0.8%)	1 (0.4%)	3 (1.9%)	1 (1.7%)
+2.00 to +1.01	2 (0.6%)	16 (5.3%)	20 (6.9%)	18 (6.8%)	21 (8.9%)	13 (8.3%)	5 (8.5%)
+1.00 to +0.01	0 (0.0%)	82 (27.1%)	82 (28.2%)	96 (36.4%)	79 (33.3%)	66 (42.3%)	29 (49.2%)
0.00 to -1.00	0 (0.0%)	164 (54.1%)	152 (52.2%)	123 (46.6%)	121 (51.1%)	69 (44.2%)	23 (39.0%)
-1.01 to -2.00	0 (0.0%)	31 (10.2%)	34 (11.7%)	22 (8.3%)	12 (5.1%)	5 (3.2%)	1 (1.7%)
-2.01 to -3.00	0 (0.0%)	5 (1.7%)	0 (0.0%)	2 (0.8%)	1 (0.4%)	0 (0.0%)	0 (0.0%)
≤3.00	0 (0.0%)	2 (0.7%)	0 (0.0%)	1 (0.4%)	1 (0.4%)	0 (0.0%)	0 (0.0%)
Total	327 (100.0%)	303 (100.0%)	291 (100.0%)	264 (100.0%)	237 (100.0%)	156 (100.0%)	59 (100.0%)
Mean	5.763	-0.197	-0.103	-0.032	0.016	0.147	0.326

ADVERSE EVENT REPORTING

Adverse Reactions and/or potentially sight-threatening complications that may reasonably be regarded as lens related must be reported immediately to STAAR Surgical and, if applicable, the competent authority of the EU Member State where the patient is established. This information is being requested from surgeons in order to document potential long-term effects of Visian ICL implantation

HOW SUPPLIED

Each Visian ICL is supplied sterile and non pyrogenic in a sealed vial containing BSS. The vial is sealed within a thermoformed tray placed in a box with labels and product information. Sterility is assured until the expiration date indicated on package label, if the tray and vial seal are not punctured or damaged. Visian ICL is steam sterilized. A Patient Implant Card and labels are supplied in the unit package. This card, which includes a link to important safety information regarding the implanted lens, should be completed by the healthcare provider and given to the patient to keep as a permanent record of the implant, and a resource to show to any eye care practitioner seen in the future.

EXPIRATION DATE

The expiration date on the device package is the sterility expiration date. This device must not be used past the indicated sterility expiration date.

RETURN POLICY FOR STAAR VISIAN ICL

Contact STAAR Surgical. Visian ICL must be returned dry. Do not attempt to re-hydrate the lens.

WARRANTY AND LIMITATION OF LIABILITY

STAAR Surgical warrants that reasonable care was taken in making this product. STAAR Surgical shall not be responsible for any incidental or consequential loss, damage, or expense which arises directly or indirectly from the use of this product. To the extent permitted by law, STAAR Surgical's sole liability from any and all causes pursuant to Visian ICL shall be limited to the replacement of Visian ICL which is returned to and found to be defective by STAAR Surgical. 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, or any implied merchantability or fitness for use.

STORAGE

Store the lens at room / ambient temperature.

CAUTION

- Do not autoclave the lens. Do not store the lens at temperatures greater than 40°C. Do not freeze. If temperature requirements are not met, return the lens to STAAR Surgical.
- STAAR Surgical ICLs and disposable accessories are packaged and sterilized for single use only. Cleaning, reuse and/or resterilization are not applicable to these devices. If one of these devices were reused after cleaning and/or resterilization, it is highly probable that it would be contaminated and the contamination could result in infection and/or inflammation.

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SYMBOL GLOSSARY

STERILE	Sterilized using steam
2	Do not re-use
2 STERILIZE	Do not resterilize
SN	Serial Number
REF	Catalogue number
	Use-by date
edfu.staar.com +1-800-352-7842 +41 32 332 8888	Consult electronic instructions for use
	Caution
	Manufacturer
	Date of manufacture
0°C 40°C RT	Store at room/ambient temperature. Do not freeze. Do not expose to temperature greater than 40°C
	Do not use if the product sterile barrier system or its packaging is compromised
US	Country of manufacture – United States
CH	Country of manufacture - Switzerland
D	Diopter
∅	Overall diameter
$\varnothing_B$	Body Diameter (Optic Diameter)
Rx Only	U.S. (Federal) law restricts this device to sale by or on the order of a physician
MD	Medical device
UDI	Unique device identifier
BIO	Contains biological material of animal origin
	Single sterile barrier system with protective packaging outside
31	Date
	Patient identification
	Patient information website
	Health care center or Doctor
OD	Right eye
OS	Left eye
EC REP	Authorized representative in the European Community
CE	CE conformity marking per European Council Directive 93/42/EEC or European Council Regulation (EU) 2017/745