STAAR® SURGICAL

Visian ICL™

eDFU-0032/1

Phakic Intraocular Lens

STAAR® SURGICAL

UV-ABSORBING COLLAMER® IMPLANTABLE CONTACT LENS FOR HYPEROPIA

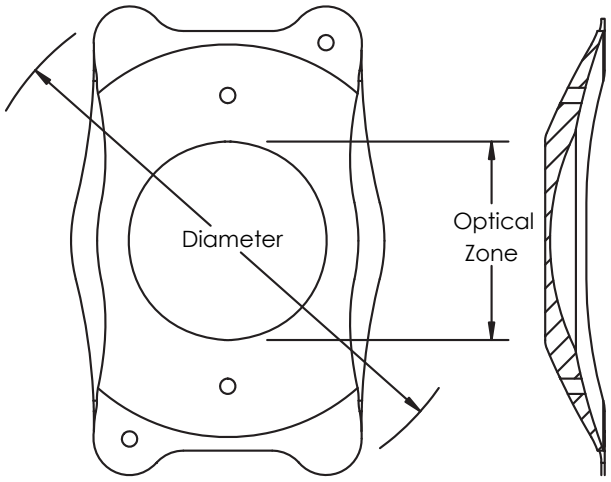
DIRECTIONS FOR USE

DEVICE DESCRIPTION

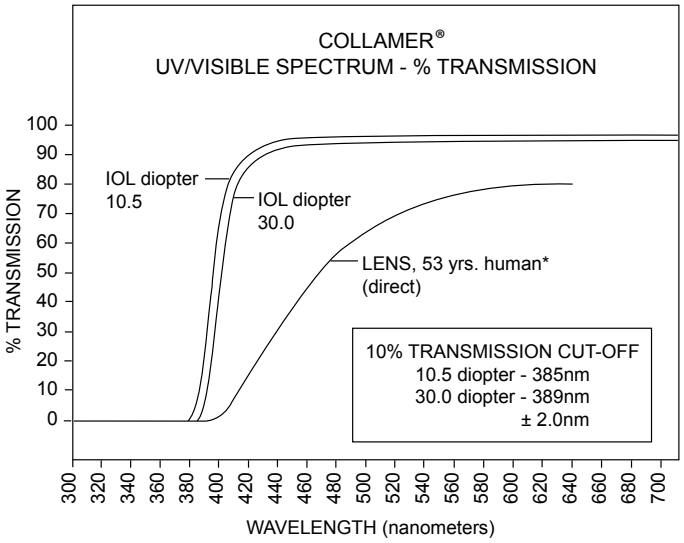
The Implantable Collamer® Lens (ICL™) features a single piece lens design with a central, concave/convex optical zone of 5.8 mm diameter. The lens is manufactured in various overall lengths for Hyperopia (stored in BSS) 11.6, 12.1, 12.6, and 13.2 mm, to suit different eye sizes. The lenses are manufactured from a proprietary porcine collagen/ HEMA polymer material with a refractive index of 1.453 at 35°C, a specific gravity of 1.21 and a durometer-hardness (shore A) of 45. The polymer material absorbs ultraviolet radiation, with light transmittance in the visible region of the spectrum of approximately 90% ±5%, with over 90% of ultraviolet radiation blocked below 387 nm wavelength. The lenses are capable of being folded and implanted through an incision of 3.5 mm or less.

ICL Models for Hyperopia available in Canada

Model Number	Dioptric Power (D)	Overall Length (mm)	Optic Diameter (mm)	Haptic Design
VICH11.6	+3.0 to +10.0	11.6	5.8	Flat, plate
VICH12.1	+3.0 to +10.0	12.1	5.8	Flat, plate
VICH12.6	+3.0 to +10.0	12.6	5.8	Flat, plate
VICH13.2	+3.0 to +10.0	13.2	5.8	Flat, plate



Model VICH (for Hyperopia)



* Boettner, E.A. and Wolter, J.R.1962 Transmission of the ocular media Invest. Ophthal. 1:776-783.

INDICATIONS

Implantable Collamer® Lenses (ICL™) are indicated for treatment of moderate to high hyperopia in phakic adults 21-45 years of age with an anterior chamber depth (ACD) of equal or greater than 3.0 mm, as measured from the corneal endothelium to the anterior lens capsule.

ICLs are available in powers ranging from +3.0 to +10.0 diopters for hyperopia.

MODE OF ACTION

The Implantable Collamer® Lenses are 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 hyperopia.

CONTRAINDICATIONS

Implantable Collamer® Lenses are contraindicated in the presence of any of the following circumstances and/or conditions:

1. Progressive Hyperopia (unstable refractive error in either eye).
2. Any previous corneal or refractive surgery.
3. A low endothelial cell count, Fuch's Dystrophy or other corneal pathology.
4. Keratoconus.
5. Primary Open Angle or Narrow Angle Glaucoma.
6. Any cataract in the operative eye or nontraumatic cataract in the fellow eye.
7. Previous history of iritis, synechia, pigment dispersion syndrome, pseudoexfoliation.
8. Patients with systemic collagen sensitivity.
9. Person under the age of 21 years.
10. Patients with any of the pre-existing conditions listed under "complications and adverse reactions" below, that will preclude postoperative visual acuity of 20/60 or better.
11. Narrow anterior chamber angles (i.e. Grade II or less).
12. Patients with low/abnormal corneal endothelial cell density.

COMPLICATIONS AND ADVERSE REACTIONS

Adverse reactions and complications due to, or following surgery and implantation of any Implantable Collamer®Lens may include, but are not limited to: Hyphema, Pupilary Block, Additional YAG Iridotomy Required, Cataract, Uveitis, Vitritis, Macular Edema Acute, Over/Under Correction, Non-reactive Pupil, Conjuctival Irritation, Secondary Glaucoma, Endophthalmitis, Retinal Detachment, Corneal Edema, Corneal Decompensation, Significant glare and/or halos (under night driving conditions)

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, BSS, viscoelastic, etc.).
4. The lens should be handled carefully. No attempts should be made to reshape or cut any portion of the lens nor 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 Implantable Collamer® Lens has not been determined. Therefore, physicians should continue to monitor implant patients postoperatively on a regular basis.
7. Safety and effectiveness of the ICL has not been established in patients with previous corneal refractive surgery.
8. Implantation of an ICL may result in a decrease in corneal endothelial cell density.

CALCULATION OF LENS POWER

Implantation of the Collamer® Lens requires that a preoperative determination of the dioptric power of the lens to be implanted be calculated. The lens power calculations can be performed by the surgeon using STAAR ICL calculation software,or, on request, performed by STAAR Surgical AG, Department of Clinical Research. Achievement of emmetropia is not necessarily a desirable postoperative goal, and factors such as visual status of the fellow eye and patient life style must be considered in determining the lens power tobe used. Physicians requiring information on lens power calculation may contact STAAR Surgical AG, Department of Clinical Research, Nidau.

LENS PREPARATION

Verify that the level of the liquid fills at least 2/3 of the vial. The thermoform tray and vial should be opened in a sterile field. Record control number on operative report to retain traceability. Remove the aluminum cap and septa. Using a pair of blunt forceps, 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 allow the lens to dry after removal from the glass vial.

ADMINISTRATION AND INSTRUCTION FOR USE

Implantation of any Collamer® lens should only be attempted by a surgeon who is highly skilled in the required surgical technique. The following procedure is recommended for implantation of STAAR Surgical AG Implantable Collamer® Lenses. Two YAG iridotomies, (0.5 to 0.8 mm; 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 standard procedure. A clear scleral or corneal tunnel wound incision of 3.0 to 4.0 mm should be with a viscoelastic. The ICL is then folded using an appropriate STAAR injector system and injected into the anterior chamber. Please refer to the product insert provided with the injector for instructions regarding proper loading and injection of the ICL using the STAAR approved delivery systems. Verify correct orientation of the ICL and that the lens is not ICL should be well centered and positioned under the iris in front of the natural lens so that the feet of the haptics are placed in the sulcus. Complete aspiration of the viscoelastic material must be performed before the eye is closed (without sutures). From this point the operation can proceed according to the surgeon's standard 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.
4. STAAR Surgical AG recommends using only the STAAR approved delivery systems to insert the Implantable Collamer® Lens in the folded state.
5. Complete aspiration of viscoelastic from the eye after completion of the surgical procedure is essential. Viscoelastic devices that may be the primary viscoelastic used with the ICL during the clinical trial was a low molecular weight 2% hydroxypropyl methylcellulose preparation.
6. Do not use short chain sodium hyaluronate acids (viscoelastics), e.g., Viscoat® (a Registered Trademark of Alcon), or other high viscous viscoelastics such as Healon GV® (a Registered Trademark of AMO). A long chain viscoelastic is suggested for use. Viscoelastics such as hydroxypropyl methylcellulose, e.g., Ocucoat® (a Registered Trademark of Bausch & Lomb), may also be used.

CLINICAL TRIAL

Summary Findings of the Clinical Studies:

The Model ICH Implantable Collamer® Lenses were found to be safe and effective as refractive elements to optically reduce hyperopia.

Description of the Clinical Trial

Patients were enrolled at 20 clinical centers in Canada and the United States. The Hyperopia Cohort was comprised of 197 patients with a total of 327 treated eyes who had preoperative hyperopia between +1.5 D and +11.5 D. Patients were primarily male and Caucasian with an average age of approximately 39 years. The effect of the ICL on Best Spectacle Corrected Visual Acuity (BSCVA), Uncorrected Visual Acuity (UCVA), planned versus achieved refraction and serious, sight-threatening complications was examined. A summary of patient demographics is shown below.

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%)

Mean Age 38.7 years

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

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

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<5 D	Hyperopia>5 D	Hyperopia<5 D	Hyperopia>5 D	Hyperopia<5 D	Hyperopia>5 D	Hyperopia<5 D	Hyperopia>5 D
≤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<5 D	Hyperopia>5 D	Hyperopia<5 D	Hyperopia>5 D	Hyperopia<5 D	Hyperopia>5 D
≤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

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

PATIENT REGISTRATION INSTRUCTIONS AND ADVERSE EVENT REPORTING REGISTRATION

Each patient who receives a STAAR Surgical (STAAR) ICL must be registered with STAAR at the time of device implantation. Registration is accomplished by completing the Device Accountability Form (postcard) that is enclosed in the unit box and mailing it to STAAR Surgical. Patient registration is essential for STAAR Surgical's long-term patient follow-up program and will assist STAAR in responding to Adverse Event 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 must be reported to STAAR Surgical AG. This information is being requested from all surgeons in order to document potential long-term effects of ICL implantation. For Canada the adverse event reporting must be sent to STAAR Surgical AG.

HOW SUPPLIED

Each Implantable Collamer® Lens is provided sterile and non-pyrogenic in sealed vials containing BSS solution. The vials are sealed within a sterile thermoform tray placed in a box with labels and product information (Direction for Use). Sterility is assured until the expiration date indicated on the package label, if the tray seal and vial seal are not punctured or damaged. ICL's are sterilized with steam.

EXPIRATION DATE

The expiration date on the device package is the sterility expiration date. In addition, there is a sterility expiration date that is clearly indicated on the outside of the unit box. 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.

WARNING

STAAR Surgical ICLs are packaged and sterilized for single use only. Cleaning, refurbishing and/or resterilization are not applicable to these devices. If one of these devices were reused after cleaning, refurbishing and/or resterilization, it is highly probable that it would be contaminated and the contamination could result in endopthalmitis and inflammation.

RETURN POLICY FOR STAAR ICLS

Contact STAAR Surgical AG. The Implantable Collamer® Lens must be returned dry. Do not try to re-hydrate.

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 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 ICL at room / ambient temperature.

WARNING

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

REFERENCES / BIBLIOGRAPHY

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SYMBOL GLOSSARY

MD	Medical device
	Do not re-use
STERILIZE	Do not resterilize
	Do not use if the product sterile barrier system or its packaging is compromised
B	Body diameter (Optic diameter)
	Overall diameter
	Single sterile barrier system with protective packaging outside
	Use-by date
D	Diopter
31	Date
	Caution
BIO	Contains biological material of animal origin
Rx Only	U.S. (Federal) law restricts this device to sale by or on the order of a physician
0°C 40°C RT	Store at room/ambient temperature. Do not freeze. Do not expose to temperature greater than 40°C
STERILE	Sterilized using steam
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
	Manufacturer
	Date of manufacture
US	Country of manufacture–United States
CH	Country of manufacture–Switzerland
UDI	Unique Device Identifier
REF	Catalogue number
OD	Right eye
OS	Left eye
SN	Serial number
edfu.staar.com +1-800-352-7842 +41 32 332 8888	Consult electronic instructions for use
	Health care center or Doctor