

Visian ICL™

eDFU-0049/1

Phakic Intraocular Lens




STAAR Surgical AG
Hauptstrasse 104
CH-2560 Nidau
Switzerland
Tel: +41 32 332 8888



Visian Implantable Collamer® Lens (VICL™) For the correction/reduction of Myopia and Hyperopia

DIRECTIONS FOR USE

PRODUCT INFORMATION

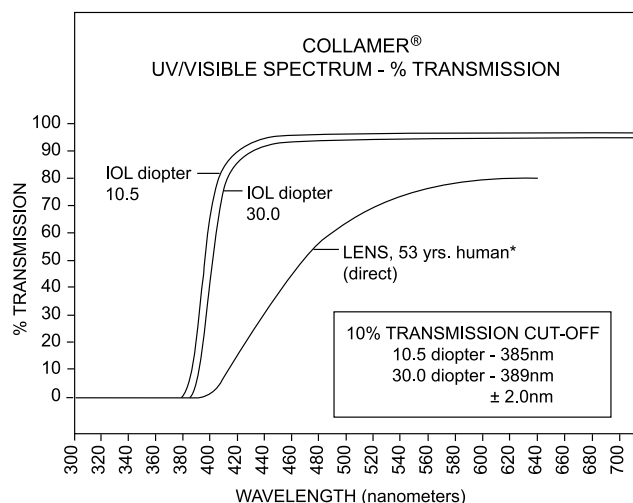
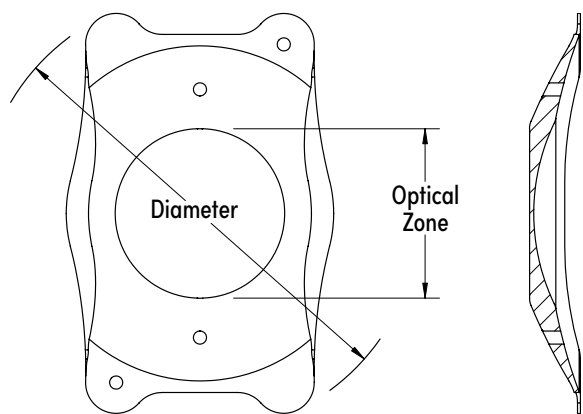
Please review this product information completely before performing your initial clinical procedure. All physicians must complete the STAAR Surgical Visian® ICL Physician Certification Program prior to use. All physicians must complete the STAAR Surgical Visian® TICL Physician Certification Program prior to use. During this training program, especial attention is placed on sizing methodologies for determination of the Visian ICL overall diameter. Improper ICL size may lead to adverse events ranging from mild to severe.

DEVICE DESCRIPTION

The Visian® Implantable Collamer® Lens (VICL) features a single piece lens design with a central, concave/convex optical zone of 4.9 to 5.8 mm diameter (according to model and diopter). The lens is manufactured in five overall lengths, 11.6*, 12.1, 12.6, 13.2, 13.7** mm to suit different eye sizes (*only hyperopia; **only myopia). The lenses are manufactured from a proprietary porcine collagen/ HEMA polymer material with a refractive index of 1.442 at room temperature in BSS. 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.

Table 1: VICL Models available on International market

Model Number	Dioptic Power (D)	Overall Diameter (mm)	Optic Diameter (mm)	Haptic Design
VICM 12.1	-0.5 to -18.0	12.1	4.9 to 5.8	Flat, plate
VICM 12.6	-0.5 to -18.0	12.6	4.9 to 5.8	Flat, plate
VICM 13.2	-0.5 to -18.0	13.2	4.9 to 5.8	Flat, plate
VICM 13.7	-0.5 to -18.0	13.7	4.9 to 5.8	Flat, plate
VICH 11.6	+0.5 to +10.0	11.6	5.8	Flat, plate
VICH 12.1	+0.5 to +10.0	12.1	5.8	Flat, plate
VICH 12.6	+0.5 to +10.0	12.6	5.8	Flat, plate
VICH 13.2	+0.5 to +10.0	13.2	5.8	Flat, plate



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

INDICATIONS

Visian® Implantable Collamer® Lenses (VICL) are indicated for use in phakic eye treatment in adults 21-45 years of age for:

- The correction/reduction of myopia in adults with myopia ranging from -0.5D to -20.0D at the spectacle plane
- The correction/reduction of hyperopia in adults with hyperopia ranging from +0.5D to +16.0D at the spectacle plane.
- 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.

MODE OF ACTION

The VICLs 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 myopia and hyperopia.

CONTRAINDICATIONS

VICL's are contraindicated in the presence of any of the following circumstances and/or conditions:

1. Patients with low/abnormal corneal endothelial cell density, Fuch's dystrophy or other corneal pathology
2. Ocular hypertension in either eye
3. Any cataract in the operative eye or nontraumatic cataract in the fellow eye.
4. Person 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 20/60 Snelleor better.

9. Patients who are amblyopic or blind in the fellow eye.

10. Keratoconus

11. 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 3.0 mm.

COMPLICATIONS AND ADVERSE REACTIONS

Adverse reactions and complications due to, or following surgery and implantation of any VICL may include, but are not limited to: Hyphema, Non-reactive Pupil, Pupillary Block, Vault, 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), hypopion, increased astigmatism, loss of BSCVA, decentration/subluxation, IOP elevation from baseline, corneal endothelial cell loss, severe intraocular inflammation, secondary surgical intervention to remove/ replace the lens, synechia to implant, Conjunctival Irritation, Vitreous Loss.

PRECAUTIONS

1. Do not attempt to sterilize (see warning).
2. Do not autoclave (see warning).
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 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, 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 can be performed by the surgeon using the STAAR Visian ICL calculation software, or, on request, performed by STAAR Surgical AG department of Clinical Research. During the US 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 reports suggesting that this white to white distance has a poor correlation with sulcus to sulcus distance. Latest publications indicate that new imaging technologies provide an optimal visualization and measurement of the intraocular dimensions involved in phakic Intraocular lens implantation. In particular, Ultrasound Biomicroscopy Microscopy (UBM) has been suggested to provide measurement of the sulcus to sulcus distance.

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 stopper. Using the foam tip plunger, 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 VICLs. 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 operating procedure. A clear scleral or corneal tunnel wound incision of 3.5 mm or less should be used, followed by filling of the anterior and posterior chamber with an appropriate viscoelastic. The lens 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 lens using the MICROSTAAR® injection system. Verify correct orientation of the lens 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 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 and never touch the center of the optic once the lens is placed inside the eye.
- 4. STAAR Surgical recommends using only the STAAR approved delivery system to insert the lens in the folded state.
- 5. Complete removal of viscoelastic from the eye after completion of the surgical procedure is essential. Viscoelastic devices that may be difficult to aspirate should not be used. Note: the primary viscoelastic used with the lens during 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 ICM AND ICH:

Summary Findings of the Clinical Studies:

The Model ICM Implantable Collamer Lenses were found to be safe and effective as refractive elements to optically reduce moderate to high myopia

Table 2: Adverse Events

A summary of adverse events reported in the 696 eyes enrolled during the clinical trial (at any postoperative exam) is presented below:

Adverse event	N	%
ICL Removal Due to Elevated IOP	2	0.3
ICL Replacement (Due to Incorrect Sizing)	6	0.9
ICL Repositioning	4	0.6
ICL Removal Due to Cataract	5	0.7
Other Secondary Surgical Interventions	6	0.8

Table 3: Patient Demographics
696 Eyes Treated of 404 Patients

Sex		
Male	158	(39.1%)
Female	246	(60.9%)
Ethnic Origin		
Caucasian	348	(86.1%)
Black	6	(1.5%)
Hispanic	26	(6.4%)
Other	24	(5.9%)

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	439/439 (100.0%)	376/417 (90.2%)	403/419 (96.2%)	391/404 (96.8%)	368/386 (95.3%)	270/280 (96.4%)	76/82 (92.7%)
≤20/25	439/439 (100.0%)	408/417 (97.8%)	416/419 (99.3%)	403/404 (99.8%)	384/386 (99.5%)	279/280 (99.6%)	82/82 (100.0%)
≤20/32	439/439 (100.0%)	414/417 (99.3%)	419/419 (100.0%)	404/404 (100.0%)	386/386 (100.0%)	279/280 (99.6%)	82/82 (100.0%)
≤20/40	439/439 (100.0%)	416/417 (99.8%)	419/419 (100.0%)	404/404 (100.0%)	386/386 (100.0%)	279/280 (99.6%)	82/82 (100.0%)
≤20/80	439/439 (100.0%)	417/417 (100.0%)	419/419 (100.0%)	404/404 (100.0%)	386/386 (100.0%)	280/280 (100.0%)	82/82 (100.0%)
≤20/200	439/439 (100.0%)	417/417 (100.0%)	419/419 (100.0%)	404/404 (100.0%)	386/386 (100.0%)	280/280 (100.0%)	82/82 (100.0%)
>20/200	0/439 (0.0%)	0/417 (0.0%)	0/419 (0.0%)	0/404 (0.0%)	0/386 (0.0%)	0/280 (0.0%)	0/82 (0.0%)
Not Reported	0	11	4	3	5	0	1
Total	439	422	421	405	391	280	83

Table 5: Uncorrected Visual Acuity over Time for Patients with PREOP BSCVA 20/20 or better
The Implantable Collamer® Lens for Myopia

	Preop n%	1 Week n%	1 Month n%	3 Months n%	6 Months n%	12 Months n%	24 Months n%
≤20/20	0/439 (0.0%)	162/421 (38.5%)	197/421 (46.8%)	210/404 (52.0%)	200/391 (51.2%)	158/278 (56.8%)	33/83 (39.8%)
≤20/25	0/439 (0.0%)	248/421 (58.9%)	278/421 (66.0%)	281/404 (69.6%)	274/391 (70.1%)	206/278 (74.1%)	44/83 (53.0%)
≤20/32	0/439 (0.0%)	316/421 (75.1%)	351/421 (83.4%)	338/404 (83.7%)	323/391 (82.6%)	235/278 (84.5%)	63/83 (75.9%)
≤20/40	0/439 (0.0%)	364/421 (86.5%)	377/421 (89.5%)	369/404 (91.3%)	346/391 (88.5%)	253/278 (91.0%)	71/83 (85.5%)
≤20/80	0/439 (0.0%)	408/421 (96.9%)	409/421 (97.1%)	397/404 (98.3%)	382/391 (97.7%)	271/278 (97.5%)	80/83 (96.4%)
≤20/200	0/439 (0.0%)	421/421 (100.0%)	421/421 (100.0%)	404/404 (100.0%)	391/391 (100.0%)	278/278 (100.0%)	83/83 (100.0%)
>20/200	439/439 (100.0%)	0/421 (0.0%)	0/421 (0.0%)	0/404 (0.0%)	0/391 (0.0%)	0/278 (0.0%)	0/83 (0.0%)
Not Reported	0	3	1	3	1	3	0
Total	439	422	421	405	391	280	83

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

Spherical Equivalent (D)	Preop n%	1 Week n%	1 Month n%	3 Months n%	6 Months n%	12 Months n%	24 Months n%
≥1.01	0 (0.0%)	4 (0.6%)	7 (1.1%)	6 (1.0%)	5 (0.8%)	4 (0.9%)	0 (0.0%)
+1.00 to +0.01	0 (0.0%)	97 (15.0%)	119 (18.1%)	121 (19.6%)	104 (17.5%)	68 (15.2%)	14 (10.3%)
0.00 to -1.00	0 (0.0%)	399 (61.8%)	405 (61.7%)	374 (60.6%)	356 (59.8%)	283 (63.3%)	75 (55.1%)
-1.01 to -2.00	0 (0.0%)	103 (15.9%)	81 (12.3%)	81 (13.1%)	91 (15.3%)	58 (13.0%)	36 (26.5%)
-2.01 to -6.00	0 (0.0%)	40 (6.2%)	41 (6.3%)	31 (5.0%)	36 (6.1%)	32 (7.2%)	11 (8.1%)
-6.01 to -10.00	284 (40.8%)	3 (0.5%)	3 (0.5%)	4 (0.6%)	3 (0.5%)	2 (0.4%)	0 (0.0%)
-10.01 to -15.00	318 (45.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
-15.01 to -20.00	88 (12.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
≤ 20.00	6 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Total	696 (100.0%)	646 (100.0%)	656 (100.0%)	617 (100.0%)	595 (100.0%)	447 (100.0%)	136 (100.0%)
Mean	-11.408	-0.658	-0.566	-0.526	-0.580	-0.623	-0.857

Table 7: 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 8: 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 9: 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 10: 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

**Table 10: UCVA Stratified by PREOP SEQ for Patients with PREOP BSCVA 20/20 or better
The Implantable Collamer® Lens for Hyperopia**

	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

**Table 11: 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 to STAAR Surgical AG immediately. This information is being requested from all surgeons in order to document potential long-term effects of Visian® ICL implantation

HOW SUPPLIED

Each Collamer® implant is provided sterile and non-pyrogenic in sealed vials containing BSS. The vials are sealed within a sterile thermoform tray placed in a box with labels and product information (Directions for Use). Sterility is assured until the expiration date indicated on package label, if the tray seal and vial seal are not punctured or damaged. VICL's are sterilized using steam. Patient Card Instructions: 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 to any eye care practitioner seen in the future.

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.

RETURN POLICY FOR STAAR VISIAN ICL

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

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 lens 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 lens at room / ambient temperature.

WARNING: 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 AG.

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, &/or resterilization, it is highly probable that it would be contaminated and the contamination could result in infection and/or inflammation.

REFERENCES / BIBLIOGRAPHY

1. Sanders DR, Vukich JA, Doney K, Gaston M. U.S. Food and Drug Administration Clinical Trial of the Implantable Contact Lens for Moderate to High Myopia, Ophthalmology 2003;110:255-266
2. Sanders DR, Doney K, Poco M. U.S. Food and Drug Administration Clinical Trial of the Implantable Collamer lens for Moderate to High Myopia, Three-Year Follow-up. Ophthalmology 2004;111:1683-1692

3. Sanders DR, Schneider D, Martin R, Brown D, Dulaney D, Vukich J, Slade S, Schallhorn S. Toric Implantable Collamer Lens for Moderate to High Myopic Astigmatism. *Ophthalmology* 2007;114:54-61
4. Sanders DR, Anterior Subcapsular Opacities and Cataracts 5 Years After Surgery in the Visian Implantable Collamer Lens FDA Trial. *J Refract Surg* 2008;24:566-570
5. Edelhauser HF, Sanders DR, Azar R, Lamielle H, Corneal endothelial assessment after ICL implantation. *J Cataract Refract Surg* 2004;30:576-583
6. Postoperative Inflammation after Implantation of the Implantable Contact Lens. *Ophthalmology* 2003;110:2335-2341
7. Sanders DR. Matched Population Comparison of the Visian Implantable Collamer Lens and Standard LASIK for Myopia of -3.00 to -7.88 Diopters. *J Refract Surg*. 2007;23:537-553
8. Sanders DR, Arver EJ. Standardized Analyses of Correction of Astigmatism With the Visian Toric Phakic Implantable Collamer Lens. *J Refract Surg*. 2007;23:649-660
9. Schallhorn S, Tanzer D, Sanders DR, Sanders ML. Randomized Prospective Comparison of Visian Toric Implantable Collamer Lens and Conventional Photorefractive Keratectomy for Moderate to High Myopic Astigmatism. *J Refract Surg*. 2007;23:853-867
10. Sanders DR, Sanders ML. Comparison of the Toric Implantable Collamer Lens and Custom Ablation LASIK for Myopic Astigmatism. *J Refract Surg*. 2008;24:773-778
11. Bylsma SS, Zalta AH, Foley E, Osher RH. Phakic posterior chamber intraocular lens pupillary block. *J Cataract Refract Surg*. 2002;28:2222-2228
12. Sanders DR, Actual and theoretical risks for visual loss following use of the implantable contact lens for moderate to high myopia. *J Cataract Refract Surg*. 2003;29:1323-1332
13. Sanders DR, Bernitsky DA, Harton PJ, Rivera RP. The Visian Myopic Implantable Collamer Lens Does Not Significantly Affect Axial Length Measurement With the IOL Master. *J Refract Surg*. 2008;24:957-959
14. Lege BAM, Haigis W, Neuhann TF, Bauer MH. Age-related behavior of posterior chamber lenses in myopic phakic eyes during accommodation measured by anterior segment partial coherence interferometry. *J Cataract Refract Surg*. 2006;32:999-1006
15. Pesando PM, Ghiringhello MP, Di Meglio G, Fanton G. Posterior chamber phakic intraocular lens (ICL) for hyperopia: Ten-year follow-up. *J Cataract Refract Surg*. 2007;33:1579-1584
16. Chung TY, Park SC, Lee MO, Ahn K, Chung ES. Changes in Iridocorneal Angle Structure and Trabecular Pigmentation With STAAR Implantable Collamer Lens During 2 Years. *J Refract Surg*. 2009;25:251-258
17. Allan B, Argeles-Sabate I, Mamalis N. Endophthalmitis rates after implantation of the intraocular Collamer lens: Survey of users between 1998 and 2006. *J Cataract Surg*. 2009;35:766-769.

SYMBOL GLOSSARY



Medical device



Do not re-use



Do not re-sterilize



Do not use if the product sterile barrier system or its packaging is compromised



Body diameter (Optic diameter)



Overall diameter



Single sterile barrier system with protective packaging outside



Use-by date



Diopter



Date



Caution



Contains biological material of animal origin



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



Store at room/ambient temperature. Do not freeze. Do not expose to temperature greater than 40°C



Sterilized using steam



Authorized representative in the European Community



CE conformity marking per European Council Directive 93/42/EEC or European Council Regulation (EU) 2017/745



Manufacturer



Date of manufacture



Country of manufacture—United States



Country of manufacture—Switzerland



Unique Device Identifier



Catalogue number



Right eye



Left eye



Serial number



Consult electronic instructions for use



Health care center or Doctor