STAAR®
SURGICAL

COLLAMER® ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER THREE PIECE FOLDABLE INTRAOCULAR LENS

For the replacement of the human lens in the visual correction of aphakia

STAAR Surgical Company Quality System complies with ISO 13485:2003 and its CE Mark products comply with the Medical Device Directive 93/42EEC requirements

DIRECTIONS FOR USE

STAAR Surgical Company
1911 Walker Avenue
Monrovia, CA 91016, U.S.A.
Tel: (800) 352-7842
Fax: (800) 952-4923

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION
STAAR Surgical's Collamer® Ultraviolet-Absorbing Posterior Chamber Three Piece Foldable Intraocular Lenses (Collamer 3P IOL) are available as biconvex optical lenses designed to be implanted in the ciliary sulcus or the capsular bag following extracapsular cataract extraction. The IOL can either be folded and inserted through an incision or injected using the recommended STAAR Injector and Cartridge. However, accommodation will not be replaced.

INDICATION
The Collamer Ultraviolet-Absorbing Posterior Chamber Three Piece Foldable Intraocular Lenses are generally indicated for primary implantation for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by cataract extraction.

MODE OF ACTION
When implanted, the Collamer 3P IOL replaces the natural lens of the eye and functions as a refracting medium in the correction of aphakia.

PRECAUTIONS
1. Do not attempt to resterilize the Collamer 3P IOL by any method as this can produce undesirable side effects.
2. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
3. Do not store the IOL in direct sunlight or at a temperature greater than 40° C. Do not autoclave the intraocular lens.
4. The IOL may take up to 24 hours to reach it's final optical power when in situ.

WARNINGS
Physicians considering IOL implantation under any of the following circumstances should weigh the potential risk/benefit ratio:
1. Recurrent severe anterior or posterior segment inflammation or uveitis.
2. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment disease.
3. Surgical difficulties at the time of cataract extraction which might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
4. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
5. Circumstances that would result in damage to the endothelium during implantation.
6. Suspected microbial infection.
7. Children are not suitable candidates for intraocular lenses.
8. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.
9. One or more iridectomies at the time of IOL implantation may prevent the need for second ary iridectomies for pupillary block.
10. Existence of: Corneal endothelial dystrophy, Glaucoma, Active chronic anterior or posterior uveitis, Rubeosis iridis, Synechiae and short anterior segment.

ADVERSE EVENTS
The Food and Drug Administration has identified, as potentially sight-threatening, eleven (11) complications which may occur following cataract extraction and/or intraocular lens implantation. The following is a summary of cases who completed the study (Cohort) and who were reported with these sight-threatening complications during the study of the Model CC4203VF IOL:

Potentially Sight-Threatening Complications by Time Frame-Cohort Cases

Complication	Time Frame (Form#) Form 1 n=499 #	%	Form 2 n=461 #	%	Form 3 n=474 #	%	Form 4 n=457 #	%	Form 5 n=383 #	%	Form 6 n=502 #	%	Cumulative Cases* n=502 #	%
Macular Edema	1	0.2	5	1.1	5	1.1	5	1.1	0	0.0	0	0.0	12	2.4
Iritis[1]	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.2	1	0.2
Corneal Edema[1]	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.2	1	0.2
Hyphema	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Pupillary Block	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Secondary Glaucoma	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Cyclitic Membrane	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Vitritis	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Endophthalmitis	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Retinal Detachment	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
IOL Dislocation	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

*Cumulative % is based on the ratio of the number of cases with any postop occurrence to the number of cases enrolled.
[1]Reported as Mild or Greater. Only persistent reports of Iritis and Corneal Edema are defined as "sight-threatening".

Adverse events were reported at the following rate for the model CC4204VF IOLs in the clinical study:

Time Frame (Form#)

Complication	Form 1 n=678 #	%	Form 2 n=610 #	%	Form 3 n=639 #	%	Form 4 n=577 #	%	Form 5 n=482 #	%	Form 6 n=502 #	%	Cumulative Cases* n=685[2] #	%
Hypopyon	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Intraocular Infection	0	0.0	1	0.2	0	0.0	0	0.0	0	0.0	0	0.0	1	0.1
Acute Corneal Decompensation	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Secondary Surgical Interventions:														
Aspiration to Relieve Capsular Block	1	0.1	1	0.2	0	0.0	0	0.0	0	0.0	0	0.0	2	0.3
Removal/Replace IOL Due to Wrong Power[1]	0	0.0	0	0.0	1	0.2	0	0.0	0	0.0	0	0.0	1	0.1
Remove IOL Due to Unresolved Optic Tilt[1]	0	0.0	0	0.0	1	0.2	0	0.0	0	0.0	0	0.0	1	0.1

*Cumulative % is based on the ratio of the number of cases with any postop occurrence to the number of cases enrolled.
[1]Same case had two IOL removal/replacements.
[2]One patient deceased after Form 1.

As March 1, 2000, there were 686 implants and the overall incidence of reported adverse events is 0.9%.

CLINICAL TRIAL

Summary Findings of the Clinical Studies:
The Model CC4203VF IOL was found to be safe and effective at correcting aphakia after cataract removal in patients 60 years of age or older.

Description of the Clinical Trial
The clinical trial of the Model CC4203VF began on March 7, 1996. The study was designed to determine the safety and effectiveness of the IOL in correcting aphakia after cataract removal. The clinical study consisted of two phases. In the first phase, 125 cases were enrolled and followed through 4-6 months postoperative after which their results were assessed by FDA to determine whether the study should be allowed to expand into its second phase. The second phase began on January 13, 1997 during which 561 additional cases were enrolled.

The clinical study design featured enrollment of eligible cases in a non-randomized fashion at 15 clinical sites with their results compared to literature controls, namely the FDA "Grid" of cataract surgery results. Criteria for inclusion in the study were male or female aphakic patients age 60 years or older who underwent primary cataract extraction via phacoemulsification after successful circular tear anterior capsulotomy and the posterior capsule remained intact. Minor scratches on the IOLs were noted after injection in 11 (2.1%) of the study cases which the Sponsor believes can be attributed to the investigators' learning curve while adapting the use of this injector. All of these patients achieved Best Corrected Visual Acuity of 20/40 or better.

As of the date of database cut-off, August 17, 1998, 502 of the enrolled cases had completed the study (the "Cohort"). Of the remaining 184 cases, 133 had reported enough interim examinations to otherwise qualify for the Cohort but had not completed the Form 6 exam (12 months) by the date of the database cut-off (Continuing group); 34 had discontinued from the study and were lost-to-follow-up (Lost-to-Follow-Up group) and 17 had deceased prior to completion of the Form 6 exam.

Case Population
Baseline (Preoperative) Demographic Characteristics of Study Cases

N= 686

Sex		
	Male	40.1%
	Female	59.9%
Ethnic Origin		
	Caucasian	91.4%
	Black	4.1%
	Other	4.5%
Mean Age		72.5 years

Best Spectacle Corrected Visual Acuity
The following is a summary of best spectacle corrected visual acuity results reported at the Form 6 or later (12 or more months) postoperative exam for the 338 cases who completed the clinical study as of the date of the database cut-off.

Best Corrected Visual Acuity at Form 6 or Later - Model CC4203VF IOLs
Subjects without any Pre-Existing Ocular Pathology or Postoperative Macular Degeneration
(n= 338)

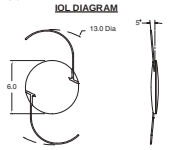
	Total #	%	Age <50 #	%	50-59 #	%	60-69 #	%	70-79 #	%	>80 #	%
20/20 or better	147	43.5	2	66.7	17	89.5	52	51.0	66	38.4	10	23.8
20/21 to 20/25	89	26.3	0	0.0	2	10.5	24	23.5	50	29.1	13	31.0
20/26 to 20/30	64	18.9	1	33.3	0	0.0	17	16.7	34	19.8	12	28.6
20/31 to 20/40	25	7.4	0	0.0	0	0.0	6	5.9	14	8.1	5	1.9
20/41 to 20/80	13	3.8	0	0.0	0	0.0	3	2.9	8	4.7	2	4.8
20/81 to 20/100	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
20/101 to 20/200	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
>20/200	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Total	338	100.0	3	100.0	19	100.0	102	100.0	172	100.0	42	100.0
20/40 or better	325	96.2	3	100.0	19	100.0	99	97.1	164	95.3	40	95.2

STABILITY TESTING / SHELF LIFE STUDY
A 2 year real time testing was done for Collamer IOL in 5ml Vial and Tyvek pouch. The study indicated that the samples of Collamer CQ 2005 V, 3P IOL, Low, Medium and High Diopter ranges in BSS media were used and the results indicated that the package remains adequate for the storage of the Collamer IOL and the IOL doesn't change during the 2 year real time period.

DETAILED DEVICED DESCRIPTION

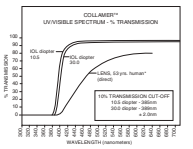
Optic:	
Material	Collamer
Light Transmittance	95% ±5% in the visible region of the light spectrum (400-750 nm); 10% transmission at 387 nm.
Specific Gravity	1.21
Index of Refraction	1.442 (35°C)
Body Optic Shape	Biconvex, Equi-Aspheric
Body Diameter	6.0 mm
Dioptric Power (D)	+10.5 to +30.5
Haptics:	
Configuration	3-Piece modified C-Loop, 5° angulation
Material	Polyimide
Color	Gold
Overall Diameter	13.0 mm

IOL DIAGRAM



Model CQ2015A

The light transmittance characteristics of the STAAR Collamer IOLs are shown below:



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

INSTRUCTIONS FOR USE

IOL Preparation and Usage:
1. Prior to implantation, examine the IOL package for type, power, and proper configuration.
2. Open the peel pouch and remove the IOL in a sterile field.
3. Examine the lens thoroughly to ensure particles have not become attached to it, and exam ine the lens optical surfaces for other defects.
4. Hold the vial right-side up, carefully lift the metal tab away from you and then twist clockwise until the cap separates at the perforations. Continue to twist until the ring is released. Using a pair of blunt forceps, remove the IOL from the vial. The IOL may be transferred into a container of normal saline solution or Balanced Salt Solution before insertion. The solution should be kept at room temperature. The IOL should not be exposed to a dry environment (air) for more than one minute.
5. Record the Control number on operative report to retain traceability.
6. Complete the Lens Accountability Form (Postcard) that is enclosed in the IOL box and mail to STAAR Surgical.
7. STAAR recommends using only the MICROSTAAR® MSI-PM, MSI-TM injector with the CQ Cartridge-FP delivery system to insert the Collamer 3P IOL in the folded state. The IOL is for single use only.

CAUTION: Do not use IOL if package has been opened or damaged. The sterility of the IOL may have been compromised.

IOL POWER CALCULATIONS
The physician should determine preoperatively the power of the IOL to be implanted. IOL power calculation methods are described in the following references:

Hoffer, K.J., "The Hoffer Q formula: a comparison of theoretic and regression formulas," Journal of Cataract and Refractive Surgery, Vol. 19, pp. 700-712, 1993; ERRATA, Vol. 20, pp. 677, 1994.
Holladay, J.T., Musgrove, K.H., Prager, T.C., Lewis, J.W., Chandler, T.Y., and Ruiz, R.S., "A three-part system for refining intraocular lens power calculations," Journal of Cataract and Refractive Surgery, Vol. 14, pp. 17-24, 1988.
Holladay, J.T., "Standardizing Constants for Ultrasonic Biometery, Keratometry and Intraocular Lens Power Calculations"; Journal of Cataract and Refractive Surgery, Vol. 23, pp. 1356-1370, 1997.
Norrby, N.E.S., "Unfortunate Discrepancies," Letter to the Editor and Reply by Holladay, J.T., Journal of Cataract and Refractive Surgery, Vol. 24, pp. 433-434, 1998.
Olsen T., Olesen H., Thim K., and Corydon, L., "Prediction of pseudophakic anterior chamber depth with the newer IOL calculation formulas," Journal of Cataract and Refractive Surgery, Vol. 18, pp. 280-285, 1992.
Retzlaff, J.A., Sanders, D.R., Kraff, M.C., Development of the SRK/T intraocular lens implant power calculation formula. "Journal of Cataract and Refractive Surgery," Vol. 16, pp. 333-340, 1990; ERRATA, Vol. 16, pp. 528, 1990

Physicians requiring additional information on IOL power calculation may contact STAAR Surgical Clinical Affairs Department at (800) 292-7902.

SURGICAL PROCEDURE
Proper Surgical technique is the responsibility of the individual surgeon. The surgeon must determine the suitability of any particular procedure based upon his or her medical training and experience.

PATIENT REGISTRATION
Each patient who receives a STAAR Surgical Company Collamer Ultraviolet-Absorbing Posterior Chamber Three Piece Foldable Intraocular Lens must be registered with STAAR at the time of IOL implantation.

Registration is accomplished by completing the Lens Accountability Form (postcard) that is enclosed in the IOL 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 IOL package. This card must be given to the patient with instructions to keep it as a permanent record of the implant and to show the card to any eye care practitioner seen in the future.

REPORTING
Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as IOL related and that were not previously expected in nature, severity or degree of incidence should be reported to STAAR Surgical at:

USA/Canada Phone: (800) 352-7842
Fax: (800) 952-4923

This information is being requested from all implant surgeons in order to document potential long-term effects on intraocular lens implantation.

HOW SUPPLIED
The Collamer 3P IOLs are supplied sterile and in nonpyrogenic glass vials. The vials are sealed within a pouch and placed in a unit box with labels and product information. The pouch containing the vial of Collamer 3P IOL is sterilized with steam and should be opened only under sterile conditions.

EXPIRATION DATE
The expiration date on the IOL package is the sterility expiration date. In addition, there is a sterility expiration date that is clearly indicated on the outside of the shelf-pack. Sterility is assured if the bag seals or pouch and vial seals are not punctured or damaged until the expiration date. This IOL should not be implanted past the indicated sterility expiration date. The Collamer 3P IOLs are steam sterilized (autoclaved).

WARNING
STAAR Surgical Collamer® IOLs 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 IOLs
Contact STAAR Surgical. The intraocular lens must be returned dry. Do not try to rehydrate.

LENS (IOL) SPECIFICATIONS OF LIABILITY
STAAR recommends using IOL folding forceps or STAAR approved delivery systems for implanting the Collamer 3P IOL in the folded state.

WARRANTY AND LIMITATIONS 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 Collamer IOL 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 or merchantability or fitness for use.

STORAGE:
Store the Collamer 3P IOL at room/ambient temperature.

WARNING:
Do not attempt to resterilize nor repackage the IOL. Do not autoclave the IOL. Do not freeze. Do not expose to temperature greater than 40° C. If temperature requirements are not met, return IOL to STAAR Surgical.

BIBLIOGRAPHY
1. Willis et al.: Opthalmic Surgery, Vol. 16, No. 2, February, 1985.
2. Stark, W.J. et al.: The FDA Report on Intraocular Lenses. Ophthalmology 90(4):311-317.

SYMBOLS GLOSSARY:
All symbols, titles and reference numbers taken from ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.

STERILE — ***Sterilized using steam*** Sterilized using steam (5.2.5)
Do not re-use Do not reuse (5.4.2)
Do not resterilize Do not resterilize (5.2.6)
Use-by date Use by (YYYY-MM-DD) (5.1.4)
SN — ***Serial number*** Serial number (5.1.7)
Consult instructions for use Consult instructions for use (5.4.3)
Caution Consult instructions for use for important cautionary information (5.4.4)
Manufacturer Manufacturer (5.1.1)
EC REP — ***Authorized representative in the European Community*** Authorized representative in the European Community (5.1.2)

Latest Revision: 2016-12-06
11 0429 30/3