STAAR® SURGICAL

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# COLLAMER® ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER SINGLE PIECE FOLDABLE INTRAOCULAR LENS

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

DIRECTIONS FOR USE

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

## DEVICE DESCRIPTION

STAAR Surgical's Collamer® Ultraviolet-Absorbing Posterior Chamber Single Piece Foldable Intraocular Lenses (Collamer 1P IOL) are available as biconvex optical lenses designed to be implanted completely within 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.

## INDICATIONS

The Collamer Ultraviolet-Absorbing Posterior Chamber Single Piece Foldable Intraocular Lenses are intended to correct aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by cataract extraction. The IOL is to be implanted in the posterior chamber and in the capsular bag through a tear-free capsulorhexis (circular tear anterior capsulotomy).

## MODE OF ACTION

When implanted, the Collamer 1P IOL replaces the natural lens of the eye and functions as a refracting medium in the correction of aphakia.

## CONTRAINDICATIONS

The STAAR Surgical Company Collamer 1P IOLs are contraindicated under the following circumstances:

1. Capsulotomy by any technique other than circular tear.
2. The presence of radial tears known or suspected at the time of surgery.
3. Situations in which the integrity of the circular tear cannot be confirmed by direct visualization.
4. Cataract extraction by techniques other than phacoemulsification.
5. In any patient in whom the need for a large capsulotomy can be anticipated (e.g., diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.).

## PRECAUTIONS

1. STAAR Surgical Collamer IOLs are packaged and sterilized for single use only, and should not be resterilized and/or reused. Safety and functionality of these devices after resterilization and/or during reuse has not been investigated and is unknown. STAAR Surgical strongly opposes the reuse, cleaning, refurbishing, and/or resterilization of all Collamer IOLs. Do not attempt to resterilize the Collamer 1P IOL by autoclaving or any other method.
2. Store the Collamer IOL at the specified temperature conditions. Do not store the IOL in direct sunlight or expose to a temperature greater than 40 °C. Do not freeze. If temperature requirements are not met, return the device to STAAR Surgical.
3. Use only sterile intraocular irrigating solutions (e.g., balanced salt or normal saline solution) to rinse and/or soak IOLs.
4. The IOL may take up to 24 hours to reach it's final optical power when in situ.
5. **Do not use IOL if the package has been opened or damaged, or if there is any evidence that the sterility of the IOL may have been compromised.**

## WARNINGS

1. This IOL should not be implanted if the posterior capsule is ruptured or if a primary posterior capsulotomy is to be performed.
2. Since the study of the Model CC4203VF IOL was conducted with the IOL being implanted in the capsular bag only, there are insufficient clinical data to demonstrate its safety and efficacy for placement in the ciliary sulcus.
3. Physicians considering IOL implantation under any of the following circumstances should weigh the potential risk/benefit ratio:
   a. Recurrent severe anterior or posterior segment inflammation or uveitis.
   b. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment disease.
   c. 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).
   d. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
   e. Circumstances that would result in damage to the endothelium during implantation.
   f. Suspected microbial infection.
   g. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.
   h. Children are not suitable candidates for intraocular lenses.
   i. One or more iridectomies at the time of IOL implantation may prevent the need for secondary iridectomies for pupillary block.
   j. Existence of: Corneal endothelial dystrophy, Glaucoma, Active chronic anterior or posterior uveitis, Rubeosis iridis, Synechiae and short anterior segment.
4. Refractive change toward hyperopia, (that may be successfully relieved by anterior YAG capsulotomy) has occurred in a small number of cases potentially due to posterior displacement of the IOL/capsular fibrosis. (Not reported when larger than 5.5mm diameter capsulorhexis performed).

## STABILITY TESTING / SHELF LIFE STUDY

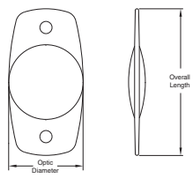
A 2 year real shelf life study on Collamer 1P IOL stored in BSS and packaged in 2ml Vials and Thermoform Tray was done. Based upon the results, it passed the acceptance criteria stated in protocol and the Collamer 1P IOL is validated for a 2 year shelf life.

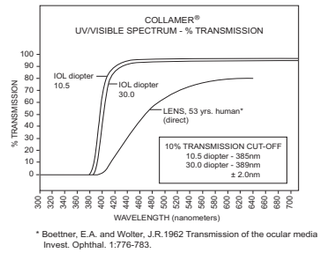
## DETAILED DEVICE DESCRIPTION

| | |
|---|---|
| Material | Collamer |
| Configuration | Flat Plate |
| Specific Gravity | 1.21 |
| Index of Refraction | 1.442 (35°C) |
| Body (Optic) Shape | Biconvex, Equi-Aspheric * |
| Optic Diameter | 6.0mm |
| Overall Diameter | 10.8mm |
| Dioptric Power (D) | +10.5 to +30.5 |
| Fenestration | 0.9mm (one on each haptic) |
| Light Transmittance | 95 ± 5% in the visible region of the light spectrum (400-750 nm); 10% transmission at 387 nm. The light transmittance characteristics are shown in the graph below. |

* The effect(s) of this aspheric design feature have not been clinically assessed.

Model **CC4204A**




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

## INSTRUCTION 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 or tyvek lid and remove the IOL in a sterile field.
3. Hold the vial right-side up, remove the aluminum cap and stopper. 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.
4. Examine the IOL thoroughly to ensure particles have not become attached to it, and examine also the IOL's optical surfaces for other defects.
5. STAAR recommends using the MicroSTAAR Injector MSI-TF and MSI-PF with SFC-45 cartridges, MSI-Indigo-P with SFC-25 and the nanoPOINT delivery system to insert the Collamer 1P IOL in a folded state.
6. Record the Control number on operative report to retain traceability.
7. Complete the Lens Accountability Form (postcard) that is enclosed in the IOL box and mail it to STAAR Surgical.

### IOL POWER CALCULATION:

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 calculations 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 Single 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.

### 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 CC4203VF IOLs in the clinical study.

| Complication | Time Frame (Form#) 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 of March 1, 2000, there were 686 implants and the overal incidence of reported adverse events was 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 | Mean Age | Ethnic Origin |
|---|---|---|
| 40.1% Male | 72.5 Years | Caucasian 91.4% |
| 59.9% Female | | Black 4.1% |
| | | Other 4.5% |

### Best Spectacle Corrected Visual Acuity

The following is a summary of best spectacle corrected visual acuity results reported on 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 on Form 6 or Later - Model CC4203VF Lens**

**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 | 11,9 |
| 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 |

## 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 |
| International | Phone: | +(41) 32 332 8888 |

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 1P IOLs are supplied sterile and in nonpyrogenic glass vials. The vials are sealed within a plastic tray or pouch and placed in a unit box with labels and product information. The plastic tray or pouch containing the vial of the Collamer 1P 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 tray 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 1P IOLs are steam sterilized (autoclaved).

## RETURN POLICY FOR STAAR IOLs

Contact STAAR Surgical. The intraocular lens must be returned dry. Do not try to re-hydrate.

## 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 warranties or merchantability or fitness for use.

## STORAGE

Store the Collamer 1P IOL at room/ambient temperature.

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## BIBLIOGRAPHY


1. Willis et al.: Ophthalmic 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) | *Consult instructions for use* Consult instructions for use (5.4.3) | *Manufacturer* Manufacturer (5.1.1) |
| *Do not re-use* Do not reuse (5.4.2) | *Caution* Consult instructions for use for important cautionary information (5.4.4) | *Date of manufacture* Date of manufacture (5.1.3) |
| *Do not resterilize* Do not resterilize (5.2.6) | *Authorized representative in the European Community* Authorized representative in the European Community (5.1.2) | *Use-by date* Use by (YYYY-MM-DD) (5.1.4) |
| SN — *Serial number* Serial number (5.1.7) | | |

Latest Revision: 2017/06/06

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