**PACKAGE INSERT**
**STAAR SURGICAL COMPANY**
**COLLAMER™ ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS**

## DEVICE DESCRIPTION

STAAR Surgical Company's Model CC-4203BF/CC-4230VF COLLAMER™ Ultraviolet-Absorbing Posterior Chamber Intraocular Lenses (COLLAMER IOL™) are available as biconvex optical lenses designed to be implanted completely within the capsular bag. The optical portion has the capability of being folded prior to insertion, allowing the lens to be inserted through an incision of approximately 3.5 mm or smaller rather than 6.0 mm or larger, while preserving a full size lens body after implantation.

The available powers for the COLLAMER™ IOL are -3.0 to +5.0 diopters in 1.0 diopter increments; +10.5 to +34.0 in 0.5 diopter increments.

## INDICATIONS

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

## CONTRAINDICATIONS

The STAAR Surgical Company COLLAMER™ Ultraviolet-Absorbing Posterior Chamber Intraocular Lenses are contraindicated under the following circumstances:

a) capsulotomy by any technique other than a circular tear,
b) the presence of radial tears known or suspected at the time of surgery,
c) situations in which the integrity of the circular tear cannot be confirmed by direct visualization,
d) cataract extraction by techniques other than phacoemulsification,
e) 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. Do not resterilize this intraocular lens by any method. **(SEE RETURN LENS POLICY)**
2. Do not store lenses at temperatures over 115° Fahrenheit.
3. Use only sterile intraocular irrigating solutions (e.g., balanced salt or normal saline solution) to rinse and/or soak lenses.

## WARNINGS

1. This lens 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 CC-4203VF lens was conducted with the lens 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 lens 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 under the age of 2 years are not suitable candidates for intraocular lenses.

## 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 CC-4203VF lens:

**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 | |
| | n | % | n | % | n | % | n | % | n | % | n | % | n | % |
| Iritis[1] | 159 | 31.9 | 20 | 4.3 | 14 | 3.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 | 135 | 26.9 |
| Corneal Edema[1] | 60 | 12.0 | 14 | 3.0 | 3 | 0.6 | 1 | 0.2 | 1 | 0.3 | 1 | 0.2 | 69 | 13.7 |
| Macular Edema | 1 | 0.2 | 5 | 1.1 | 5 | 1.1 | 5 | 1.1 | 0 | 0.0 | 0 | 0.0 | 12 | 2.4 |
| 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 |
| Lens 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 CC-4203VF lenses in the clinical study:

**Adverse Events by Time Frame**

| 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] | |
| | n | % | n | % | n | % | n | % | n | % | n | % | n | % |
| 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 lens removal/replacements
[2] One patient deceased after Form 1.

As of 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 CC-4203VF 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 CC-4203VF 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 lenses 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 to 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 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% |
| Race | | |
| | Caucasian | 91.4% |
| | Black | 4.1% |
| | Other Races | 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 CC-4203VF Lens**
**Subjects without any Pre-Existing Ocular Pathology or Postoperative Macular Degeneration**
(n= 338)

| | | | Age Decade | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | TOTAL | | < 50 | | 50 - 59 | | 60 - 69 | | 70 - 79 | | ≥ 80 | |
| | n | % | n | % | n | % | n | % | n | % | n | % |
| **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 |
| **Worse than 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 |

## DETAILED DEVICE DESCRIPTION

| | |
|---|---|
| Material | COLLAMER™ porcine collagen/HEMA copolymer |
| 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 | 1.450 (35°C) |

| Optic Shape/ Diameter (mm) | Dioptric Power (D) | Overall Length (mm) | Haptic Fenestration (mm) Design | Haptic (One on each plate haptic) |
|---|---|---|---|---|
| Convex-Concave/ 6.3 - 6.5 | -3.0 to +5.0 (1.0 D Increments) | 11.3 | Flat Plate | 0.9 |
| Biconvex/6.3 | +5.5 to +10.0 (1.0 D Increments) | 11.0 | Flat Plate | 0.9 |
| Biconvex/5.5 | +10.5 to +34.0 (0.5 D Increments) | 10.8 | Flat Plate | 0.9 |

The COLLAMER™ Ultraviolet-Absorbing Posterior Chamber Intraocular Lenses are steam sterilized (autoclaved).

ADD UV CURVE HERE

## DIRECTIONS FOR USE

Lens Preparation:

1. Prior to implantation, examine the lens package for type, spherical-equivalent power and proper configuration.
2. The peel pouch should be opened onto the sterile field for a sterile presentation of the tray.
3. Record the control number on operative report to retain traceability.
4. Hold tray label side up and peel open seal, transfer the lens into a container of normal saline or Balanced Salt Solution. NOTE: The lens may pick up an electrostatic charge upon opening the package. The lens should be carefully examined to ensure that particles have not been attracted to it.

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

## CALCULATION OF LENS POWER

The physician should determine preoperatively the power of the lens to be implanted. Lens power calculation methods may be described in the following references:

1. Binkhorst, R.D., Intraocular Lens Power Calculation Manual, New York, Richard D. Binkhorst; 1978.
2. Retzlaff, J., Sanders, D., Kraff, M. Development of the SRK/T intraocular lens implant power calculation formula. J Cat Ref Surg 1990 (16): 333-340
3. Retzlaff, J., Sanders, D., Kraff, M. Lens Implant Power Calculation - A Manual for Ophthalmologists and Biometrists. SLACK Inc., Thorofare, NJ, 1990.
4. Holladay, J., Musgrove K., Prager, T., et al. A three-part system for refining intraocular lens power calculations. J Cat Ref Surg, 1988 (14):17-24.
5. Hoffer K. The Hoffer Q formula: a comparison of theoretic and regression formulas. J Cat Ref Surg, 1993 (19):700-712; ERRATA, 1994 (20):667.
6. Olsen T, Olesen H., Thim K., et al. Prediction of pseudophakic anterior chamber depth with the newer IOL calculation formulas. J Cat Ref Surg, 1992 (18):280-85.

INSTRUCTIONS FOR USE

1. STAAR recommends using only the MicroSTAAR™ Injector (or equivalent) insertion instrument to insert the COLLAMER™ Ultraviolet-Absorbing Posterior Chamber Intraocular Lens in the folded state. All but one of the lenses placed in the study cases (99.9%) were inserted using the MicroSTAAR™ injector.

NOTE: Please refer to the Directions for Use insert with the folding instrument for additional information.

## PATIENT REGISTRATION INSTRUCTIONS AND REPORTING

Registration

Each patient who receives a STAAR Surgical Company (STAAR) COLLAMER™ Ultraviolet Absorbing Posterior Chamber Intraocular Lens must be registered with STAAR at the time of lens implantation.

Registration is accomplished by completing the Lens Accountability Form (postcard) that is enclosed in the lens box and mailing it to STAAR Surgical Company. Patient registration is essential for STAAR Surgical Company'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 lens 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.

Reporting

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

National Toll Free: (800) 292-7902
Local: (626) 303-7902
FAX: (626) 303-2962

## HOW SUPPLIED

The COLLAMER™ Ultraviolet Absorbing Posterior Chamber Intraocular Lenses are supplied sterile and nonpyrogenic in glass vials. The vials are sealed within a plastic tray and placed in a unit box with labels and product information. The lenses have been steam sterilized.

## EXPIRATION DATE

The expiration date on the lens 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 and vial seals are not punctured or damaged until the expiration date. This lens should not be implanted past the indicated sterility expiration date.

## RETURN LENS POLICY

Contact STAAR Surgical Company.

## CAUTION

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

## 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.


ADD LENS DRAWING HERE

# CE 0124

STAAR SURGICAL COMPANY OPERATES IN COMPLIANCE WITH THE MEDICAL DEVICE DIRECTIVE 93/42/EEC AND (APPLICATION NORM TO EN 9001) AND EN46001.


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