

**SUMMARY OF SAFETY AND
EFFECTIVENESS DATA (SSED)**

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I. GENERAL INFORMATION

Device Generic Name: Endocapsular Tension Ring

Device Trade Name: Oculaid™ Capsular Tension Ring (Model 275 10/12 mm and Model 276 11/13 mm), or Stableyes™ Capsular Tension Ring (Model 275 10/12 mm and Model 276 11/13 mm)

Applicant's Name and Address: OPHTEC USA, Inc
6421 Congress Avenue, Suite 112
Boca Raton, FL 33487

Date of Panel Recommendation: None

Premarket Approval (PMA)
Application Number: P030023

Date of Notice of Approval
To Applicant: April 27, 2004

II. INDICATIONS FOR USE

CTRs are indicated for the stabilization of weakened, broken or missing zonules that are suspected or observed during cataract extraction using phacoemulsification and continuous curvilinear capsulorhexis techniques in adults.

III. CONTRAINDICATIONS

CTRs should not be used in the presence of a torn or compromised capsular bag or significant, progressive pseudoexfoliation. CTRs should not be used in patients 12 years old or younger due to the developing eye.

IV. WARNINGS AND PRECAUTIONS

Please refer to the device labeling for a list of warnings and precautions.

V. DEVICE DESCRIPTION

Oculaid™ (Stableyes™) CTRs are semicircular rings made of Perspex CQ UV® (ultraviolet light absorbing polymethylmethacrylate, PMMA) designed for permanent placement into the equator of the lens capsular bag during cataract extraction using continuous curvilinear capsulorhexis and phacoemulsification techniques.

The device is available in two sizes, Model 275 and Model 276. Model 275 has an uncompressed diameter of 12.0 mm and a compressed diameter of 10.0 mm. Model 276 has an uncompressed diameter of 13.0 mm and a compressed diameter of 11.0 mm.

Model 275 and Model 276 have the same cross-sectional dimensions (0.15 to 0.20 mm). These dimensions are similar to the haptic dimensions of standard single piece PMMA intraocular lenses. The CTRs are uniplaner (no anterior or posterior angulation) and have two 0.40 mm manipulation eyelets; one located at each end of the device.

CTRs can be inserted into the capsular bag equator either immediately following the capsulorhexis and hydrodissection (prior to phacoemulsification) or following phacoemulsification. Surgeon preference and experience determines the model/size of the CTR used.

CTRs can be inserted into the capsular bag using forceps to manipulate the device into position or by using an OPHTEC Tension Ring Inserter. The Inserter method is the technique used most often. Instructions for loading and injecting the CTRs using an OPHTEC Tension Ring Inserter are included with each Inserter.

CTRs are sterilized using (ethylene oxide,EO) and are provided in Tyvek® sealed containers.

VI. ALTERNATIVE TREATMENTS

For the management of weakened or damaged zonules, the haptics of conventional C-Loop intraocular lenses (IOLs) may provide similar, but limited support. Other alternatives in the case of significantly compromised zonules or capsular bag integrity include transscleral suturing the IOL in the sulcus of the posterior chamber or placing an anterior IOL into the angle of the anterior chamber.

VII. MARKETING HISTORY

The Oculaid™ CTR has been marketed and used in 45 countries including the following regions and countries: Europe, The Middle East, South

America, Australia, Canada, Mexico, South Korea, and South Africa. The devices have not been withdrawn from any country for reasons relating to safety and effectiveness of the devices.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Although no adverse events related to device failure were reported during the clinical study, potential adverse events include, but are not limited to, those related to intraocular lens surgery, inadequate support postoperatively allowing the device to dislocate into the vitreous, inadequate support allowing the IOL to become decentered, and capsule rupture causing vitreous loss. Refer to the clinical summary section for details.

IX. SUMMARY OF PRECLINICAL STUDIES

With the exception of sections related to optic testing, the applicant conducted pre-clinical testing in accordance with the recommendations in FDA's draft intraocular lens guidance document.

The applicant conducted a battery of in-vivo and in-vitro acute and chronic toxicity tests that establish the biocompatibility of the lens materials. These tests did not include a 1-year animal implantation study. The 1-year animal implantation study was not considered necessary because of the availability of information in the public domain that demonstrates that the material is biocompatible.

These studies, combined with data from chemistry and engineering analyses, demonstrate the suitability of the material for use in capsular tension rings. The adequacy of the manufacturing processes, including sterilization, was established through a review of the manufacturing information in the PMA as well as thorough on-site inspections. Non-clinical testing demonstrates the safety and effectiveness of this device from microbiology, toxicology, engineering, and manufacturing perspectives.

X. SUMMARY OF CLINICAL STUDIES

The applicant performed a multi-center clinical study using the Oculaid™ CTR in the US under an Investigational Device Exemption.

A. Study Objective

The objective of the Oculaid™ study was to evaluate the relative safety and effectiveness of the device when used as indicated.

B. Study Design

The US Oculaid™ CTR study was an unmasked, prospective multi-center study. No control population was studied. Initial eyes and fellow eyes were enrolled into the study; however, the safety and effectiveness analysis was performed on initial eyes only.

C. Inclusion / Exclusion Criteria

Subject inclusion criteria were:

- 21 years old or older
- Required cataract surgery with IOL implantation
- Had observed or suspected weakened, torn, missing or otherwise compromised zonules (torn or missing not to exceed 33% of the capsular bag diameter) due to Pseudoexfoliation Syndrome, Marfan's Syndrome, trauma or other zonular compromising condition, and possessed an intact lens capsule during insertion.

Subjects were generally excluded for the following conditions:

- One functional eye
- Capsular bag tearing or significant zonular dialysis during surgery
- Preoperative ocular infection
- Ocular inflammation or uveitis
- Amblyopia
- Aniridia
- Congenital cataracts
- Cataracts due to rubella
- Corneal disease
- Diabetes
- Glaucoma
- Iritis
- Iris atrophy
- Pseudophakic lens exchange
- Microphthalmia
- Optic atrophy
- Macular degeneration
- Retinal disease (detachment, degeneration)
- Vitritis
- Flat anterior chamber
- Various other compromising conditions.

D. Study Plan, Patient Assessments, and Safety and Efficacy Criteria

Subjects were evaluated preoperatively and postoperatively at the following intervals; 1 week, 1 month, 3 months, 6 months and 12 months.

The following objective parameters were collected from each subject preoperatively and postoperatively:

| | Preop | 1 week | 1 month | 3 months | 6 months | 12 months |
|-------------------|-------|--------|---------|----------|----------|-----------|
| Dilated Slit lamp | X | | | X | X | X |
| BSCDVA* | X | X | X | X | X | X |
| UCDVA† | | X | X | X | X | X |
| IOP‡ | X | X | X | X | X | X |
| Dr. Questionnaire | X | | | X | X | X |

. Intraoperative and postoperative complications / adverse events were reported when observed.

E. Study Period, Investigational Sites, and Demographics

1. Study Periods

The study was designed to follow at least 100 subjects for at least 12 months. Subjects were seen at the intervals specified in Section D above.

2. Subject Accountability

Study enrollment began on May 30, 2001 and ended on April 30, 2004. The primary analysis was performed on subjects/eyes that were eligible for their 12 month postoperative exam. This group included 114 subjects (initial eyes) and 133 eyes (includes 114 initial eyes and 19 fellow eyes). An additional 94 subjects (104 eyes including fellow eyes) were enrolled during this timeframe but were not yet eligible for their 12 month follow up visit and therefore were not included in the cohort analysis.

Of the primary cohort group (114 initial eyes), 93 (81.6%) were available for examination at 12 months. Two subjects (1.8%) were hospitalized and not able to undergo examination

* BSCDVA = Best Spectacle Corrected Distance Visual Acuity

† UCDVA = Uncorrected Distance Visual Acuity

‡ IOP = Intraocular Pressure

at the close of the database; 12 (10.5%) were not able to be contacted at the close of the database; 2 (1.8%) had died; and 5 (4.4%) had not yet been examined (interval still open).

| Study Accountability | Initial Eyes | Fellow Eyes | Total |
|---|--------------|-------------|-------|
| Total eyes implanted during the study | 208 | 29 | 237 |
| Eyes not yet eligible for 12 month visit (still active) | 94 | 10 | 104 |
| Total Initial Eyes eligible for 12 month visit (Study Cohort) | 114 | 19 | 133 |
| | | | |
| | | | |
| Cohort Accountability | 114 | | |
| Died | -2 | | 112 |
| Hospitalized | -2 | | 110 |
| Not able to contact | -12 | | 98 |
| Eligible, but not yet seen | -5 | | 93 |

3. Investigational sites

Eleven (11) investigators from 8 investigational sites contributed to the enrollment of the cohort population. The sites were geographically dispersed throughout the United States.

4. Subject Demographics

The demographics related to this study are provided in the following table.

| | | |
|---------|------------|---------|
| Age: | Mean: | 68.43 |
| | St Dev: | 16.72 |
| | Range: | 20 – 99 |
| Gender: | Female: | 49.12% |
| | Male: | 50.88% |
| Race: | Caucasian: | 91.23% |
| | Negro: | 6.14% |
| | Asian: | 0.88% |
| | Other: | 1.75% |

F. Data Analysis and results

Table 1. Preoperative condition justifying the use of a CTR

| | | |
|-------------------|----|--------|
| Marfans Syndrome | 2 | 1.75% |
| Surgical Trauma | 8 | 7.02% |
| Other Trauma | 20 | 17.54% |
| Weak/Lax Zonules | 38 | 33.33% |
| Pseudoexfoliation | 46 | 40.35% |

Table 2. Preoperative condition of zonule

| | | |
|----------|----|-------|
| Broken | 20 | 17.5% |
| Weak/Lax | 94 | 82.5% |

Table 3. Preoperative percent of zonule broken, when reported broken

| | | |
|------------|---|--------|
| < 5 % | 1 | 5.0 % |
| 5 to 10 % | 4 | 20.0 % |
| 11 to 15 % | 1 | 5.0 % |
| 16 to 20 % | 4 | 20.0 % |
| 21 to 25 % | 6 | 30.0 % |
| 26 to 30 % | 2 | 10.0 % |
| 31 to 33 % | 2 | 10.0 % |

Table 4. Use of the CTR Inserter to place the CTR

| | | |
|-------------------|-----|---------|
| Inserter used | 111 | 97.37 % |
| Inserter not used | 3 | 2.63 % |

Table 5. When CTR was inserted

| | | |
|--|----|---------|
| Prior to cataract extraction | 26 | 22.81 % |
| Following cataract extraction | 87 | 76.32 % |
| Separate procedure following cataract extraction | 1 | 0.88 % |

Table 6. Intraoperative complications

| | | |
|------------|-----|---------|
| None | 111 | 97.37 % |
| PC Rupture | 3 | 2.63 % |

Table 7. Surgeon’s determination of the effectiveness of the device (rating from 1 to 10, 1 = not effective, 10 = effective)

| Rating | | |
|--------|-----|---------|
| 3 | 1 | 0.88 % |
| 7 | 1 | 0.88 % |
| 9 | 2 | 1.75 % |
| 10 | 110 | 96.49 % |

Table 8. IOL centration at 12 months postoperative

| | | |
|--------------|----|---------|
| Centered | 91 | 97.85 % |
| Not Centered | 2 | 2.15 % |

Table 9. Integrity of posterior capsule at 12 months postoperative

| | | |
|-------------------------|----|---------|
| Capsular bag intact | 88 | 94.62 % |
| Capsular bag not intact | 5 | 5.38 % |

Table 10. Subjects that had undergone YAG Laser posterior capsulotomies by the 12 month interval

| | | |
|---------------------------|----|--------|
| No YAG Capsulotomy | 87 | 93.5 % |
| Underwent YAG Capsulotomy | 6 | 6.5 % |

Table 11. Postoperative complications by reporting interval

| | 1 Week | | 1 Month | | 3 Months | | 6 Months | | 12 Months | |
|----------------------|--------|--------|---------|--------|----------|--------|----------|--------|-----------|--------|
| | # | % N | # | % N | # | % N | # | % N | # | % N |
| None | 110 | 96.49% | 107 | 98.17% | 99 | 97.06% | 78 | 91.76% | 84 | 90.32% |
| High IOP | 1 | 0.88% | | | | | | | | |
| IOL Decentered | | | 1 | 0.92% | | | | | | |
| PCO | 1 | 0.88% | | | 2 | 1.96% | 5 | 5.88% | 6 | 6.45% |
| Epi Retinal Membrane | | | 1 | 0.92% | | | | | | |
| Other | 2 | 1.75% | | | 1 | 0.98% | 2 | 2.35% | 3 | 3.23% |

Table 12. Adverse Events

No Adverse Events were reported in the cohort group.

Table 13. Postoperative uncorrected distant visual acuity by reporting interval

| 20/ 15 20 25 30 40 50 60 70 80 100 125 150 160 200 300 400 Vision not recorded | 1 Week | | 1 Month | | 3 Months | | 6 Months | | 12 Months | |
|--|--------|--------|---------|--------|----------|--------|----------|--------|-----------|--------|
| | # | % | # | % | # | % | # | % | # | % |
| 15 | 1 | 0.91% | 4 | 3.67% | 3 | 2.75% | 4 | 5.19% | 0 | 0.00% |
| 20 | 13 | 11.82% | 9 | 8.26% | 10 | 9.17% | 12 | 15.58% | 17 | 19.54% |
| 25 | 7 | 6.36% | 13 | 11.93% | 16 | 14.68% | 6 | 7.79% | 9 | 10.34% |
| 30 | 12 | 10.91% | 11 | 10.09% | 12 | 11.01% | 15 | 19.48% | 13 | 14.94% |
| 40 | 8 | 7.27% | 18 | 16.51% | 11 | 10.09% | 7 | 9.09% | 10 | 11.49% |
| 50 | 11 | 10.00% | 5 | 4.59% | 9 | 8.26% | 5 | 6.49% | 5 | 5.75% |
| 60 | 10 | 9.09% | 5 | 4.59% | 5 | 4.59% | 4 | 5.19% | 6 | 6.90% |
| 70 | 10 | 9.09% | 3 | 2.75% | 0 | 0.00% | 1 | 1.30% | 0 | 0.00% |
| 80 | 1 | 0.91% | 8 | 7.34% | 3 | 2.75% | 1 | 1.30% | 0 | 0.00% |
| 100 | 6 | 5.45% | 5 | 4.59% | 5 | 4.59% | 1 | 1.30% | 2 | 2.30% |
| 125 | 2 | 1.82% | 1 | 0.92% | 1 | 0.92% | 1 | 1.30% | 1 | 1.15% |
| 150 | 0 | 0.00% | 2 | 1.83% | 1 | 0.92% | 2 | 2.60% | 1 | 1.15% |
| 160 | 3 | 2.73% | 1 | 0.92% | 2 | 1.83% | 2 | 2.60% | 0 | 0.00% |
| 200 | 8 | 7.27% | 8 | 7.34% | 6 | 5.50% | 5 | 6.49% | 10 | 11.49% |
| 300 | 0 | 0.00% | 0 | 0.00% | 1 | 0.92% | 0 | 0.00% | 0 | 0.00% |
| 400 | 18 | 16.36% | 16 | 14.68% | 13 | 11.93% | 11 | 14.29% | 13 | 14.94% |
| Vision not recorded | 4 | 3.64% | 0 | 0.00% | 4 | 3.67% | 8 | 10.39% | 5 | 5.75% |

A significant number of subjects in this study had compromised vision and were not expected to achieve improved uncorrected visual acuity in accordance with the FDA Grid.

Table 14. Postoperative best spectacle corrected distance visual acuity by reporting interval

| 20/ | 1 Week | | 1 Month | | 3 Months | | 6 Months | | 12 Months | |
|---------------------|--------|--------|---------|--------|----------|--------|----------|--------|-----------|--------|
| | # | % | # | % | # | % | # | % | # | % |
| 15 | 1 | 1.01% | 9 | 8.65% | 9 | 9.28% | 13 | 16.05% | 7 | 7.69% |
| 20 | 23 | 23.23% | 31 | 29.81% | 31 | 31.96% | 22 | 27.16% | 25 | 27.47% |
| 25 | 11 | 11.11% | 10 | 9.62% | 16 | 16.49% | 13 | 16.05% | 20 | 21.98% |
| 30 | 16 | 16.16% | 19 | 18.27% | 13 | 13.40% | 12 | 14.81% | 14 | 15.38% |
| 40 | 9 | 9.09% | 10 | 9.62% | 9 | 9.28% | 2 | 2.47% | 3 | 3.30% |
| 50 | 8 | 8.08% | 2 | 1.92% | 2 | 2.06% | 2 | 2.47% | 1 | 1.10% |
| 60 | 7 | 7.07% | 3 | 2.88% | 2 | 2.06% | 3 | 3.70% | 2 | 2.20% |
| 70 | 6 | 6.06% | 1 | 0.96% | 0 | 0.00% | 2 | 2.47% | 2 | 2.20% |
| 80 | 4 | 4.04% | 4 | 3.85% | 1 | 1.03% | 1 | 1.23% | 1 | 1.10% |
| 100 | 2 | 2.02% | 2 | 1.92% | 3 | 3.09% | 0 | 0.00% | 3 | 3.30% |
| 125 | 0 | 0.00% | 1 | 0.96% | 1 | 1.03% | 1 | 1.23% | 1 | 1.10% |
| 150 | 0 | 0.00% | 2 | 1.92% | 1 | 1.03% | 1 | 1.23% | 1 | 1.10% |
| 160 | 2 | 2.02% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% |
| 200 | 1 | 1.01% | 1 | 0.96% | 1 | 1.03% | 2 | 2.47% | 2 | 2.20% |
| 300 | 1 | 1.01% | 0 | 0.00% | 1 | 1.03% | 1 | 1.23% | 1 | 1.10% |
| 400 | 8 | 8.08% | 9 | 8.65% | 7 | 7.22% | 6 | 7.41% | 8 | 8.79% |
| Vision not Recorded | 15 | 15.15% | 5 | 4.81% | 5 | 5.15% | 4 | 4.94% | 2 | 2.20% |

A significant number of subjects in this study had compromised vision and were not expected to achieve improved uncorrected visual acuity in accordance with the FDA Grid.

Table 15. Best spectacle corrected distance visual acuity at 12 months for subjects who were expected to achieve 20/40 postoperatively regardless of their preoperative pathology

| 20 / | n = | % | | n = | % |
|------|-----|--------|------------------|-----|--------|
| 15 | 8 | 10.00% | 20/15 or better | 8 | 10.00% |
| 20 | 28 | 35.00% | 20/20 or better | 36 | 45.00% |
| 25 | 26 | 32.50% | 20/25 or better | 62 | 77.50% |
| 30 | 12 | 15.00% | 20/30 or better | 74 | 92.50% |
| 40 | 5 | 6.25% | 20/40 or better | 79 | 98.75% |
| 50 | 0 | 0.00% | Worse than 20/40 | 1 | 1.25% |
| 60 | 0 | 0.00% | | | |
| 70 | 0 | 0.00% | | | |
| 80 | 0 | 0.00% | | | |
| 100 | 0 | 0.00% | | | |
| 125 | 0 | 0.00% | | | |
| 200 | 0 | 0.00% | | | |
| 300 | 0 | 0.00% | | | |
| 400 | 1 | 1.25% | | | |

N=80

Table 16. Best spectacle corrected distance visual acuity at 12 months for subjects who were not expected to achieve 20/40 postoperatively due to their preoperative pathology

| 20 / | n = | % | | n = | % |
|------|-----|--------|------------------|-----|--------|
| 15 | 0 | 0.00% | 20/15 or better | 0 | 0.00% |
| 20 | 2 | 6.45% | 20/20 or better | 2 | 6.45% |
| 25 | 1 | 3.23% | 20/25 or better | 3 | 9.68% |
| 30 | 2 | 6.45% | 20/30 or better | 5 | 16.13% |
| 40 | 0 | 0.00% | 20/40 or better | 5 | 16.13% |
| 50 | 2 | 6.45% | Worse than 20/40 | 26 | 83.87% |
| 60 | 3 | 9.68% | | | |
| 70 | 2 | 6.45% | | | |
| 80 | 2 | 6.45% | | | |
| 100 | 4 | 12.90% | | | |
| 125 | 1 | 3.23% | N=31 | | |
| 200 | 2 | 6.45% | | | |
| 300 | 1 | 3.23% | | | |
| 400 | 8 | 25.81% | | | |

XI. CONCLUSIONS DRAWN FROM THE CLINICAL STUDY

The data in this application provide a reasonable level of safety and effectiveness for Oculaid™ (Stableyes™) Models 275 and 276 when used for the management of weak or broken zonules in adult patients who undergo cataract extraction using phacoemulsification and continuous curvilinear capsulorhexis techniques.

Regardless of the model selected or technique used to insert the rings, zonular support, capsular bag stability and IOL centration are typically attained postoperatively. Postoperative posterior capsule opacification undergoing treated with a YAG laser does not appear to compromise the stability of the capsular bag or CTR. Surgeon satisfaction levels related to the performance of the device are very high.

XII. PANEL RECOMMENDATION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH DECISION

The Center for Devices and Radiological Health (CDRH) reviewed the PMA and concluded that the PMA contained sufficient valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the device under the prescribed indications for use. CDRH approved this PMA in a letter to the PMA applicant dated April 27, 2004 and signed by the Director, Division of Ophthalmic and Ear, Nose and Throat Devices, Office of Device Evaluation. The applicant's manufacturing facilities were inspected and found to be in compliance with the Quality System Regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See product labeling

Hazards to health from the use of the device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in Labeling.
Postapproval Requirements and Restrictions: See approval order.