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

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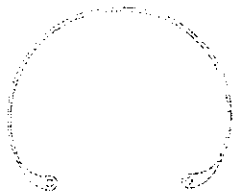
STERILE | EO



Manufactured by:
OPHTEC BV
15 Schweitzerlaan
9728 NR Groningen
The Netherlands
Tel 31-50-525-1944

# Oculaid™ Capsular Tension Ring

**Instructions for use**

**Description**: The Oculaid™ Capsular Tension Ring (CTR) semi-circular ring is made entirely of Perspex® CQ UV (ultraviolet light absorbing polymethylmethacrylate, PMMA) with one manipulation eyelet at each end of the ring. The CTR is intended for placement into the equator of the capsular bag during cataract surgery by using either forceps or a specially designed insertion instrument. CTRs are available in 2 sizes, Model 275 (12 mm diameter) and Model 276 (13 mm diameter).

**Indications**: 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.

**Contraindications**: CTRs should not be use 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.

**Warnings**: The long-term effects of progressive zonular stability following implantation of a CTR are not known.

Patients with pseudoexfoliation syndrome or an otherwise compromised zonule due to trauma exhibit a wide variety and degree of intraoperative and postoperative complications that must be taken into consideration by the surgeon prior to using the CTR. All subjects with a compromised zonule may not be suitable to receive a CTR.

The medical literature has reported that eyes with pseudoexfoliation syndrome and a shallow (below average) anterior chamber depth may exhibit a greater tendency to develop zonular instability, intraoperative and postoperative complications.

The use of a CTR in patients less than 18 years of age may increase the risk of radial tears of the capsulorhexis as reported in the medical literature.
The safety of the CTR in cases of zonulolysis greater than 33% has not been established.

**Precautions:**
The CTR is for single use only
This device may not be reused
This device may not be resterilized
Product is sterile and must remain in its original package until ready for use
Use sterile technique and remain in a sterile field when handling the product
Do not use after expiration date
Do not use if the package is opened or damaged
Inspect product prior to use. Do not use damaged products
Surgeons should be familiar with the CTR insertion technique prior to use
Store between 50 and 85 degrees F

**How Supplied:** The CTR is supplied as a single unit in a dry, sterile, primary package. The primary package is contained within a cardboard shelf package along with administrative labels and a patient identification card. This product is sterilized with ethylene oxide.
Store Tension Rings in a dry area out of direct sunlight. Avoid extreme temperatures.

**Directions for use**: The CTR may be inserted into the capsular bag either immediately following continuous curvilinear capsulorhexis (prior to phacoemulsification) or following cataract extraction (just prior to the insertion of an intraocular lens). The surgeon is responsible for determining the appropriate time to insert the CTR, depending on the needs of each individual case. The CTR can be inserted with forceps or with an Oculaid™ CTR Inserter (instructions are provided with the Inserter).

To insert the CTR, the leading edge of the ring is placed through the capsulorhexis and guided toward the periphery of the capsular bag. The ring is then slowly fed along the circumference of the capsular bag, while insuring that the ring does not perforate or otherwise damage the capsular bag or entrap lens cortex. To complete the insertion, the trailing end of the ring is rotated into place with a positioning hook.

Selection of CTR Model (size): CTR Models 275 and 276 have identical cross sectional dimensions. The difference between these designs is the overall diameter of the ring. Model 275 has an uncompressed diameter of 12.0 mm and is designed for placement in all eyes except those with a large capsular bag diameter (as may be found in highly myopic eyes). Model 276 has an uncompressed diameter of 13.0 mm and was designed for capsule bags with a large diameter (as may be found in highly myopic eyes).

Following implantation of the CTR, the surgeon should provide the patient with the implant identification card and complete the implant registration card before returning the registration card to OPHTEC.

**Clinical Results:**

The clinical study of the Oculaid™ CTR was designed to determine the relative safety and effectiveness of the device when used to manage weak or broken zonules during cataract surgery. The study began in May 2001 and concluded in May 2003. Eleven (11) surgeons at 8 sites implanted 133 CTRs (114 initial eyes and 19 fellow eyes). Preoperatively, 17.5% of the cases treated had broken zonules, while 82.5% were reported as having weakened zonules. The CTR Inserter was used to insert CTRs in 97.4% of cases, while 2.6% used a manual insertion technique. CTRs were inserted prior to cataract extraction 22.8% of the time, and 77.2% of the time following cataract removal. The percentage of cases requiring intraoperative vitrectomy unrelated to the CTR was 2.6%. At 12 months postoperatively, 97.8% of cases reported the IOL to be centered and 94.6% reported that the capsular bag integrity was intact. Thirteen (13) cases (11.4%) were treated for secondary posterior capsule opacity using an Nd:YAG laser. The results achieved by the patients followed for one year provide reasonable assurance that the CTR is a safe and effective device for the management of a compromised zonule.

**Patient Population**

The patient population in the study consisted of 49.1% females and 50.9% males, 91.2% Caucasians. 6.1% Blacks, 0.9% Asians, and 1.7% Other. The mean age for this population was 68.4 years old.

**Visual Acuity**

All subjects (n=114) in the study underwent simultaneous cataract extraction and CTR insertion. Subjects receiving a CTR had preexisting pathologies that varied in type and degree, which in many cases limited their potential postoperative visual acuity. CTRs are not indicated for the correction of visual acuity.

**Table 1**: Percentage of the zonule with preoperative dehiscence

| | N=114 n= | % |
|---|---|---|
| None | 98 | 85.9% |
| 1 to 5 % | 1 | 0.8 % |
| 5 to 10 % | 4 | 3.5 % |
| 11 to 15 % | 1 | 0.8 % |
| 16 to 20 % | 4 | 3.5 % |
| 21 to 25 % | 6 | 5.2 % |
| 26 to 30 % | 2 | 1.7 % |
| 31 to 33 % | 2 | 1.7 % |

**Table 2:** Best Corrected Visual Acuity at 12 months postoperative (all subjects regardless of preoperative pathology)

| | N=114 1 Week | | N=109 1 Month | | N=101 3 Months | | N=85 6 Months | | N=93 12 Months | |
|---|---|---|---|---|---|---|---|---|---|---|
| | n= | % | n= | % | n= | % | n= | % | n= | % |
| 20/40 or better | 60 | 52.6% | 79 | 72.5% | 77 | 76.2% | 62 | 72.9% | 69 | 74.2% |
| Worse than 20/40 | 39 | 34.2% | 25 | 33.9% | 19 | 18.8% | 19 | 22.4% | 22 | 23.6% |
| Vision not Recorded | 15 | 13.2% | 5 | 4.6% | 5 | 4.9% | 4 | 4.7% | 2 | 2.2% |

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. Not all subjects were available for all visits.

**Table 3.** Best spectacle corrected distance visual acuity at 12 months for subjects who were expected to achieve 20/40 postoperatively regardless of their preoperative pathology

| | N=80 n = | % |
|---|---|---|
| 20/40 or better | 79 | 98.8% |
| Worse than 20/40 | 1 | 1.2% |

**Table 4:** Best Corrected Visual Acuity at 12 months of subjects with preoperative pathologies

| | N=31 n = | % |
|---|---|---|
| 20/40 or better | 5 | 16.1% |
| Worse than 20/40 | 26 | 83.9% |

**Table 5:** Best Corrected Visual Acuity at 12 months of Subjects with Preoperative Pathology that were not expected to achieve Acuity of 20/40 or Better by pathology

| N=26 | 20/40 or Better | % | Worse than 20/40 | % |
|---|---|---|---|---|
| Glaucoma | 1 | 3.8% | 2 | |
| Corneal Scar | | | 1 | 3.8% |
| Diabetic Retinopathy | | | 1 | 3.8% |
| Keratoconus | | | 1 | 3.8% |
| Lens Subluxation | | | 1 | 3.8% |
| Macular Degeneration | | | 7 | 26.9% |
| Macular Hole | | | 2 | 7.7% |
| Nystagmus | | | 1 | 3.8% |
| Central Retinopathy | | | 2 | 7.7% |
| Corneal Transplant | | | 3 | 11.5% |
| Previous Retinal Surgery | 1 | 3.8% | 2 | 7.7% |
| Trauma | 1 | 3.8% | | |
| Retinitis Pigmentosis | | | | |

**Table 6. Complications that occurred at anytime during the study**

N=133

| Type | n= | % |
|---|---|---|
| None | 114 | 85.7 |
| PCO requiring YAG | 13 | 9.8 |
| Transient increased IOP | 1 | 0.7 |
| Decentered IOL | 1 | 0.7 |
| Epi retinal Membrane | 1 | 0.7 |

**Table 7. Adverse Events**

Adverse Events / Anticipated Serious Complications (occurring at anytime during the study)

Subjects receiving CTRs experienced complications consistent with their preoperative pathologies in variety and degree. The listing below includes anticipated serious complications following cataract surgery with a CTR, that would otherwise (under normal conditions) be considered adverse events. For consistency, these serious complications are titled Adverse Events.

N=133

| Type | n= | % |
|---|---|---|
| None | 127 | 95.5 |
| Intraoperative vitreous loss requiring vitrectomy | 3 | 2.2 |
| Zonular dehiscence requiring suturing of IOL | 1 | 0.7 |
| Corneal transplant rejection/regraft | 1 | 0.7 |
| Retinal detachment | 1 | 0.7 |

Report all adverse events to:

OPHTEC USA, Inc.
6421 Congress Ave., Ste 112
Boca Raton, FL 33487
(561) 989-8767

Manufactured by OPHTEC BV, Schweiterzlaan 15, 9728 NR, Groningen, The Netherlands

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

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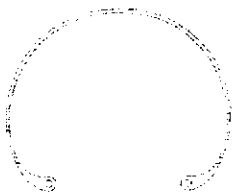

Manufactured for:
Advanced Medical Optics, Inc
Santa Ana, CA 92799
(800) 366-6554

# StabilEyes™ Capsular Tension Ring

**Instructions for use**

**Description**: The StabilEyes™ Capsular Tension Ring (CTR) semi-circular ring is made entirely of Perspex® CQ UV (ultraviolet light absorbing polymethylmethacrylate, PMMA) with one manipulation eyelet at each end of the ring. The CTR is intended for placement into the equator of the capsular bag during cataract surgery by using either forceps or a specially designed insertion instrument. CTRs are available in 2 sizes, Model STBL12US (12 mm diameter) and Model STBL13US (13 mm diameter).

**Indications**: 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.

**Contraindications**: CTRs should not be use 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.

**Warnings**: The long-term effects of progressive zonular stability following implantation of a CTR are not known.

Patients with pseudoexfoliation syndrome or an otherwise compromised zonule due to trauma exhibit a wide variety and degree of intraoperative and postoperative complications that must be taken into consideration by the surgeon prior to using the CTR. All subjects with a compromised zonule may not be suitable to receive a CTR.

The medical literature has reported that eyes with pseudoexfoliation syndrome and a shallow (below average) anterior chamber depth may exhibit a greater tendency to develop zonular instability, intraoperative and postoperative complications.

The use of a CTR in patients less than 18 years of age may increase the risk of radial tears of the capsulorhexis as reported in the medical literature.
The safety of the CTR in cases of zonulolysis greater than 33% has not been established.

**Precautions:**
The CTR is for single use only
This device may not be reused
This device may not be resterilized
Product is sterile and must remain in its original package until ready for use
Use sterile technique and remain in a sterile field when handling the product
Do not use after expiration date
Do not use if the package is opened or damaged
Inspect product prior to use. Do not use damaged products
Surgeons should be familiar with the CTR insertion technique prior to use
Store between 50 and 85 degrees F

**How Supplied:** The CTR is supplied as a single unit in a dry, sterile, primary package. The primary package is contained within a cardboard shelf package along with administrative labels and a patient identification card. This product is sterilized with ethylene oxide.
Store Tension Rings in a dry area out of direct sunlight. Avoid extreme temperatures.

**Directions for use**: The CTR may be inserted into the capsular bag either immediately following continuous curvilinear capsulorhexis (prior to phacoemulsification) or following cataract extraction (just prior to the insertion of an intraocular lens). The surgeon is responsible for determining the appropriate time to insert the CTR, depending on the needs of each individual case. The CTR can be inserted with forceps or with a StabilEyes™ CTR Micro Inserter Model STBLNSUS (instructions are provided with the Inserter).

To insert the CTR, the leading edge of the ring is placed through the capsulorhexis and guided toward the periphery of the capsular bag. The ring is then slowly fed along the circumference of the capsular bag, while insuring that the ring does not perforate or otherwise damage the capsular bag or entrap lens cortex. To complete the insertion, the trailing end of the ring is rotated into place with a positioning hook.

Selection of CTR Model (size): CTR Models STBL12US and STBL13US have identical cross sectional dimensions. The difference between these designs is the overall diameter of the ring. Model STBL12US has an uncompressed diameter of 12.0 mm and is designed for placement in all eyes except those with a large capsular bag diameter (as may be found in highly myopic eyes). Model STBL13US has an uncompressed diameter of 13.0 mm and was designed for capsule bags with a large diameter (as may be found in highly myopic eyes).

Following implantation of the CTR, the surgeon should provide the patient with the implant identification card and complete the implant registration card before returning the registration card to Advanced Medical Optics.

**Clinical Results:**

The clinical study of the StabilEyes CTR was designed to determine the relative safety and effectiveness of the device when used to manage weak or broken zonules during cataract surgery. The study began in May 2001 and concluded in May 2003. Eleven (11) surgeons at 8 sites implanted 133 Rings (114 initial eyes and 19 fellow eyes). Preoperatively, 17.5% of the cases treated had broken zonules, while 82.5% were reported as having weakened zonules. The CTR Inserter was used to insert CTRs in 97.4% of cases, while 2.6% used a manual insertion technique. CTRs were inserted prior to cataract extraction 22.8% of the time, and 77.2% of the time following cataract removal. The percentage of cases requiring intraoperative vitrectomy unrelated to the CTR was 2.6%. At 12 months postoperatively, 97.8% of cases reported the IOL to be centered and 94.6% reported that the capsular bag integrity was intact. Thirteen (13) cases (11.4%) were treated for secondary posterior capsule opacity using an Nd:YAG laser. The results achieved by the patients followed for one year provide reasonable assurance that the CTR is a safe and effective device for the management of a compromised zonule.

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1700 East St. Andrew Place
Santa Ana, CA 92705
(800) 366-6554