Refractec

ViewPoint™ CK System

PROFESSIONAL USE INFORMATION MANUAL FOR TREATMENT OF HYPEROPIA UTILIZING THE CONDUCTIVE KERATOPLASTY℠ (CK℠) PROCEDURE

PHYSICIAN'S REFERENCE GUIDE

For Hyperopia from +0.75 to +3.25 D

CAUTION

Restricted Device: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. U.S. Federal Law restricts the use of this device to practitioners who have been trained in its operation and who have experience in the surgical management and treatment of refractive errors.

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I. GENERAL WARNINGS

"WARNING!"

Identifies conditions or practices that could result in damage to equipment or other property, personal injury or loss of life.

WARNINGS:

WARNING! This document provides information concerning the intended clinical use of the Refractec ViewPoint™ CK System. For complete information concerning system components, safety instructions, installation, maintenance, and troubleshooting, refer to the Refractec ViewPoint™ CK System *Operator's Manual.*

WARNING! Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient and/or user complications.

WARNING! Any adjustments to controls or calibration other than those specified herein may result in damage or injury to the patient or the user.

WARNING! Never operate the device in the presence of flammable anesthetics or other volatile substances, such as alcohol.

WARNING! All patients must be given the opportunity to read and understand the Patient Information Booklet, and to have all of their questions answered to their satisfaction before giving consent to the Conductive Keratoplasty℠ (CK℠) procedure or the use of the Refractec ViewPoint™ CK System.

II. INTRODUCTION

The ViewPoint™ CK System is designed to treat spherical, previously untreated hyperopia of 0.75 to 3.25 D through a procedure known as Conductive Keratoplasty℠ (CK℠).

Conductive Keratoplasty℠ utilizes low energy, delivered directly into the corneal stroma through a handpiece and Keratoplast™ Tip, to effect refractive change in the cornea. As a result of conducting a controlled amount of radiofrequency (RF) energy into the corneal stroma, the desired collagen shrinkage temperature is achieved. The peripheral application of this treatment in a predetermined pattern, creates a band of tightening and results in a steepening of the central cornea (Figure 1). This steepening results in the desired refractive effect.

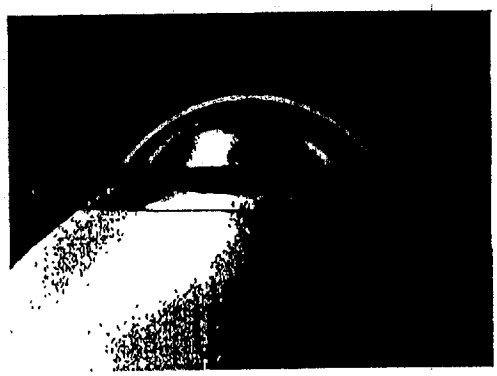

Figure 1

Conductive Keratoplasty℠

Conductive Keratoplasty℠ increases the curvature of the central cornea to decrease hyperopia.

III. DEVICE DESCRIPTION

The ViewPoint™ CK℠ System (Figure 2) used to perform the CK℠ procedure consists of the following components:

- Radiofrequency energy-generating console
- Reusable corneal marker
- Reusable lid speculum (Figure 3) with cable and connector
- Reusable hand-held, pen-shaped handpiece with cable and connector
- Footpedal
- Disposable Keratoplast™ Tip
- Patient treatment card

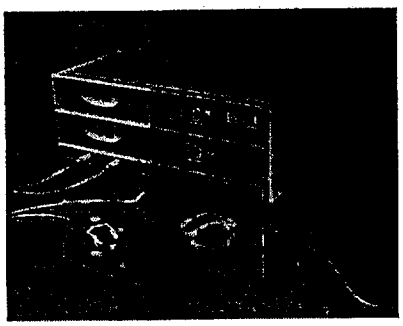

Figure 2
ViewPoint™ CK System

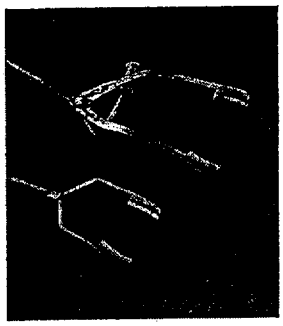

Figure 3
CK Lid Specula
Lancaster type (top)
Barraquer type (bottom)

ViewPoint™ CK℠ System Console

A patient treatment card is inserted into the console to activate the system. The energy level is set at 60% power (0.6W) with a treatment time of 0.6 seconds. Selection of parameters outside the default settings is not allowed in this version of the Viewpoint™ CK℠ System. An AC powered, portable, low power, energy source provides regulated radiofrequency energy through the handpiece to the Keratoplast™ Tip.

Handpiece

The handpiece is a hand-held, reusable, pen-shaped instrument attached by a removable cable and connector to the console. The radiofrequency energy is delivered by means of the Keratoplast™ Tip, which attaches to the handpiece.

Keratoplast™ Tip

A sterile, disposable, stainless steel, Keratoplast™ Tip (Figure 4), 90 µm in diameter and 450 µm long, that delivers radiofrequency energy directly to the corneal stroma, is attached to the handpiece. The Keratoplast™ Tip has a proximal bend of 45° and a distal bend of 90° to allow access to the cornea over the patient's brow and nasal regions. A Teflon® stop at the very distal portion of the stainless steel tip assures correct depth of penetration. The Keratoplast™ Tip must not be used on fellow eyes or subsequent patients.

Figure 4

CK℠ Keratoplast™ Tip

Lid Speculum

The lid speculum serves as the return (dispersive) electrode for the radiofrequency energy being delivered through the Keratoplast™ Tip. Two types of specula are offered: Barraquer type and Lancaster type. The Barraquer type is a small, malleable wire-speculum and the Lancaster is a locking speculum. The Lancaster lid speculum was not used in the clinical investigation of the device.

Footpedal

The footpedal attaches to the console and controls the release of radiofrequency energy.

Patient Treatment Card

A patient treatment card is inserted into the console to activate the system.

Safety Features

The ViewPoint™ CK℠ System has numerous safety features to assure proper operation. The ViewPoint™ CK℠ System includes safety checks at start-up and monitors output during treatment.

Software

The ViewPoint™ CK℠ System software controls the user interface, and provides the user with system diagnostics and error messages in the event of a device anomaly. Additionally, the software saves all error messages on to the patient treatment card to assist in the diagnosis technical issues.

Note: Additional details regarding operation of this device can be found in the Refractec ViewPoint™ CK℠ System Operator's Manual.

IV. INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE EVENTS

A. INDICATIONS FOR USE

The ViewPoint™ CK℠ System / Conductive Keratoplasty℠ (CK℠) Procedure is indicated for the temporary reduction of spherical hyperopia in patients who have 0.75 D to 3.25 D of cycloplegic spherical hyperopia, less than or equal to 0.75 D of refractive astigmatism (minus cylinder format), a cycloplegic spherical equivalent of 0.75 D to 3.00 D, and are 40 years of age or greater with a documented stability of refraction for the prior 12 months, as demonstrated by a change of less than 0.50 D in spherical and cylindrical components of the manifest refraction. The magnitude of correction with this treatment diminishes over time, with some patients retaining some or all of their intended refractive correction.

NOTE: Refer to the preceding General Warnings section of this *Physician's Reference Guide*, in addition to the warnings and precautions found in this section.

B. CONTRAINDICATIONS

The Refractec ViewPoint™ CK℠ System / Conductive Keratoplasty℠ (CK℠) Procedure should not be used in:

- Patients with a peripheral pachymetry reading, measured at the 6 mm optical zone, of less than 560 μm.
- Patients who have had previous strabismus surgery or are likely to develop strabismus following the CK℠ procedure.
- Patients with a history of Herpes zoster or Herpes simplex keratitis.
- Patients who have diabetes, diagnosed autoimmune disease, connective tissue disease, or clinically significant atopic syndrome.
- Patients who are being treated with chronic systemic corticosteroid or other immunosuppressive therapy that may affect wound healing, and any immunocompromised patients.
- Patients who are pregnant or lactating.
- Patients with keratoconus.
- Patients with a history of keloid formation.
- Patients with intractable keratoconjunctivitis sicca.
- Patients with implantable electrical devices (pacemakers, defibrillators, cochlear implants, etc).
- Patients with narrow angles.

C. WARNINGS

- The Refractec ViewPoint™ CK℠ System / Conductive Keratoplasty (CK℠) Procedure is **NOT** recommended in:
  - Patients with nystagmus or other condition that prevents a steady gaze, which is required during surgery.
  - Patients with unstable refraction over the year prior to examination.

- Patient related warnings:
  - Patients must refrain from wearing contact lenses 2 to 3 weeks before his or her eye exam (2 weeks prior for soft; 3 weeks prior for hard or gas permeable lenses). Failure to do so may produce poor surgical results.
  - CK℠ may induce myopia in the early post-treatment period, which may necessitate temporary spectacle correction for tasks such as driving.

D. PRECAUTIONS

Specific training from Refractec, Inc. is required before anyone is qualified to operate the Refractec ViewPoint™ CK System. Read and understand this manual and the Operator's Manual prior to operating the system.

The safety and effectiveness of the ViewPoint™ CK System / Conductive Keratoplasty℠ (CK℠) Procedure have **NOT** been established in:

- Patients under 40 years of age.
- Patients with progressive hyperopia, ocular disease, corneal abnormality, or trauma in the treatment area.
- Patients with greater than 3.25 D of hyperopia, 0.75 D of astigmatism, or CRSE greater than 3.00 D.
- Patients with more than 0.50 D difference between preoperative manifest refraction spherical equivalent (MRSE) and cycloplegic refraction spherical equivalent (CRSE).
- Patients who have had prior intraocular or corneal surgery.
- Eyes previously treated with other refractive surgical procedures.
- Retreatments (NOTE: Suitability for future refractive procedures by any modality is unknown).
- CK℠ treatments performed at the slit lamp.

E. ADVERSE EVENTS

Adverse events, complications, and ocular findings reported in the U.S. clinical studies for the Refractec ViewPoint™ CK℠ System / Conductive Keratoplasty℠ (CK℠) procedure for the correction of hyperopia with or without astigmatism are summarized in Table 1.

Table 1
Adverse Event Summary

	Month 1	Month 3	Month 6	Month 9	Month 12
Late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BSCVA	0%	0%	0%	0%	0%
Decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction at 6 months	0%	0%	0%	0%	<1%
Any corneal epithelial defect involving the keratectomy site at 1 month or later	0%	0%	0%	0%	0%
Corneal infiltrate or ulcer	0%	0%	0%	0%	0%
Corneal edema at 1 month or later	0%	0%	0%	0%	0%
Corneal perforation	0%	0%	0%	0%	0%
Corneal microbial infection	0%	0%	0%	0%	0%
Corneal decompensation	0%	0%	0%	0%	0%
Corneal scar in visual axis	0%	0%	0%	0%	0%
Uncontrolled IOP with increase of > 5 mm Hg above baseline and any reading above 25 mm Hg	0%	0%	0%	0%	0%
IOP >25 mm Hg	0%	0%	1%	<1%	<1%
Intraocular infection	0%	0%	0%	0%	0%
Hypopyon	0%	0%	0%	0%	0%
Hyphema	0%	0%	0%	0%	0%
Onset of cataract unrelated to age, systemic disease, or trauma	0%	0%	0%	0%	0%
Retinal detachment	0%	0%	0%	0%	0%
Retinal vascular accidents	0%	0%	0%	0%	0%
Secondary surgical intervention other than CK treatment	0%	0%	0%	0%	<1%
Death	0%	0%	0%	0%	0%
Other	1%	1%	<1%	1%	1%

No serious or sight-threatening adverse events were reported for the clinical trial population. A total of 13 patients (18 eyes) experienced an adverse event. Of the reported adverse events, six were non-ophthalmic. Intraoperative ocular adverse events include one eye that had a corneal perforation, the CK^{SM} procedure was terminated, and successfully completed several weeks later with good visual outcome. In two eyes, the procedure could not be performed and had to be rescheduled due to technical difficulties with the CK^{SM} device.

During the postoperative follow-up period, three eyes (two subjects) were reported with intraocular pressure greater than 25 mm Hg. However, one of the two affected subjects with reports of IOP >25 mm Hg had presented with IOP of 25 mm Hg at the time of enrollment, and was therefore ineligible for enrollment in the study. This eye was evaluated by a glaucoma specialist who determined that the IOP elevation likely reflected early onset of glaucoma. The subject is being managed by close monitoring. The increased IOP in the other two eyes resolved without sequelae.

Mild iritis was reported in one eye at the 7-day visit, and this resolved uneventfully. One eye presented with a "retinal break" approximately 15 months post-CK; argon laser photocoagulation was performed successfully, and the event was considered to have resolved.

V. CLINICAL STUDY

A. INTRODUCTION

A prospective, multi-center clinical study was conducted to evaluate the safety and efficacy of the Refractec ViewPoint™ CK℠ System used to correct hyperopia with the Conductive Keratoplasty℠ (CK℠) Procedure.

Eligibility criteria for subjects included: ≥ 21 years of age; eyes with 0.75 D to 3.25 D of hyperopia, who have less than or equal to 0.75 D of refractive astigmatism (cylinder) and a spherical equivalent of 0.75 D to 3.00 D; best spectacle corrected visual acuity of 20/40 or better in both eyes, spherical equivalent manifest refraction and spherical equivalent cycloplegic refraction that did not differ by more than 0.50 D; hard contact lens wearers must have had two (2) central keratometry readings and two (2) manifest refractions (taken at least one week apart), that do not differ from each other by more than 0.50 D in either meridian and mires must have been regular in the eye to be treated. Contact lens wearers had to abstain from contact lens use prior to baseline examination for two to three weeks.

Study exclusion criteria included: previous strabismus, intraocular or corneal surgery; anterior segment pathology; eyelid disease; corneal abnormality; signs of progressive or unstable hyperopia; latent hyperopia; blindness of the fellow eye; history of Herpes zoster, Herpes simplex keratitis, steroid-responsive rise in IOP, glaucoma or preoperative IOP > 21mm Hg; risk for angle closure or a potentially occludable angle; diabetes, autoimmune disease, connective tissue disease, significant atopic syndrome, chronic systemic corticosteroid use, distorted or unclear keratometric mires, a history of keloid formation, intractable keratoconjunctivitis sicca, or pregnancy or lactation.

B. DEMOGRAPHICS

Table 2
Demographics
All Eyes Enrolled

401 Eyes of 233 Enrolled Subjects

Gender	Male	42%
	Female	58%
Race	Caucasian	81%
	Black	9%
	Asian	2%
	Other	9%
Eye	Left	49%
	Right	51%
Age (yrs)	N	233
	Mean	55.3
	95% Confidence Interval	54.5, 56.1
	Standard Deviation	6.36
	Median	55.6
	Range	40.2, 73.9
Range of Treatment - CRSE	N	401
	Mean	1.86
	95% Confidence Interval	1.80, 1.92
	Standard Deviation	0.628
	Median	1.75
	Range	0.75, 4.00

Demographic information on the study population of 401 eyes of 233 subjects is summarized in Table 2. Of the 233 enrolled subjects, 58% were female and 42% male, with a mean age of 55.3 years (S.D. 6.36, range 40.2, 73.9). The majority of the subjects were Caucasian (81%); 9% of the study population were Black, 2% Asian, and the remaining 9% of subjects were identified as "Other Race."

Mean hyperopia at baseline in this population of eyes, reported as cycloplegic refractive spherical equivalent (CRSE), was 1.86 D (S.D. 0.628 D) and ranged from 0.75 D to 4.00 D.

The protocol was amended after enrollment of the initial cohort of 54 eyes to reflect a decrease in the maximum spherical hyperopia to be corrected by CK[SM]. A modified nomogram that shifted the treatment ranges and number of spots also reduced the maximum CK[SM] treatment from 4.00 D to 3.25 D spherical hyperopia (CRSE $\leq$ 3.00 D). Thus, the nomogram identified as "current nomogram" specifies a treatment range of 0.75 D to 3.25 D spherical hyperopia, a spherical equivalent of 0.75 D to 3.00 D, and no more than 0.75 D absolute cylinder.

Of the 54 eyes that underwent CK[SM] during the first phase of study, only 25 eyes fit into the modified CK[SM] nomogram. The remaining 29 eyes fell outside of the treatment ranges defined in the modified nomogram, identified throughout this report as the "current nomogram", which was used for the remainder of the study. Since these 29 eyes were not treated with the current nomogram, their refractive outcomes do not reflect the effectiveness of the current nomogram, and on this basis, they have been excluded from the effectiveness outcomes, i.e., uncorrected visual acuity, accuracy of intended (target) to achieved refraction, expressed as spherical equivalent manifest refraction or MRSE, and mean postoperative refraction, also expressed as MRSE. An additional 9 eyes were treated outside the current nomogram as a result of protocol deviations or surgeon error, and have also been excluded from analyses of effectiveness. All eyes have been included in analyses of the stability and safety parameters.

C. BASELINE PARAMETERS

Table 3
Preoperative Refractive Parameters
Eyes Treated with Current Nomogram

		Primary Eyes		Fellow Eyes		All Eyes	
Spherical Equivalent (MRSE) *	0.0-0.99 D	11	6%	11	7%	22	6%
	1.0-1.99 D	121	61%	84	52%	205	57%
	2.0-2.99 D	62	31%	63	39%	125	35%
	3.0-4.00 D	5	3%	4	2%	9	2%
	Total	199	100%	162	100%	361	100%
Cylinder (manifest) **	0.00 D	69	35%	57	35%	126	35%
	0.25 D	41	21%	38	23%	79	22%
	0.50 D	59	30%	49	30%	108	30%
	0.75 D	28	14%	18	11%	46	13%
	1.00 D	3	2%	1	1%	4	1%
	1.25 D	0	0%	0	0%	0	0%
	Total	200	100%	163	100%	363	100%
Spherical Equivalent (CRSE) **	0.0-0.99 D	8	4%	9	6%	17	5%
	1.0-1.99 D	117	59%	85	52%	202	56%
	2.0-2.99 D	65	33%	60	37%	125	34%
	3.0-4.00 D	10	5%	9	6%	19	5%
	Total	200	100%	163	100%	363	100%
Cylinder (cycloplegic) **	0.00 D	69	35%	67	41%	136	37%
	0.25 D	29	15%	36	22%	65	18%
	0.50 D	75	38%	39	24%	114	31%
	0.75 D	26	13%	21	13%	47	13%
	1.00 D	1	1%	0	0%	1	<1%
	1.25 D	0	0%	0	0%	0	0%
	Total	200	100%	163	100%	363	100%

* Excludes two ineligible eyes with minus MRSE; these eyes are included in the cylinder analysis.

** Includes one ineligible eye with > 0.75 D cycloplegic cylinder.

Preoperative refractive parameters for the population of 363 eyes in the current nomogram group are shown in Table 3. It should be noted that while Table 3 shows a number of eyes with 1.00 D and 1.25 D of manifest cylinder, only one eye was ineligible based on the protocol entry criterion of no more than 0.75 D cylinder measured with cycloplegic refraction. (Note: The protocol did not establish an entry criterion for the magnitude of manifest cylinder.)

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D. ACCOUNTABILITY

Table 4
Accountability
Eyes Treated with Current Nomogram

	Month 1		Month 3		Month 6		Month 9		Month 12	
Available for Analysis	354/363	98%	358/363	99%	352/363	97%	350/363	96%	344/363	95%
Discontinued	1/363	<1%	1/363	<1%	1/363	<1%	1/363	<1%	1/363	<1%
Missed Visit	8/363	2%	4/363	1%	10/363	3%	10/363	3%	0/363	0%
Not yet eligible for interval	0/363	0%	0/363	0%	0/363	0%	0/363	0%	14/363	4%
Lost to Follow-up	0/363	0%	0/363	0%	0/363	0%	2/363	1%	4/363	1%
Accountability	354/363	98%	358/363	99%	352/363	97%	350/363	96%	344/349	99%

As shown in Table 4, accountability was excellent. For eyes treated with the current nomogram enrolled (n=363), follow-up was available for 98% of eyes at 1 month, 99% at 3 months, 97% at 6, 96% at 9 and 95% at 12 months. No more than 3% of patients missed a scheduled follow-up visit (0% to 3% at each interval), only a single patient was discontinued from the study, and no patients were lost-to-follow-up at the 1 month, 3 months and 6 months postoperative intervals. Accountability, i.e., the proportion of eyes eligible for the examination window and not discontinued or lost to follow up was 96% or greater at every study interval.

E. SAFETY AND EFFICACY RESULTS

Table 5
Summary of Key Safety and Efficacy Variables
Efficacy variables: Eyes Treated with Current Nomogram
Safety variables: All Eyes Treated

	Month 1	Month 3	Month 6	Month 9	Month 12
Efficacy Variables					
UCVA 20/20 or better	29%	40%	45%	49%	56%
UCVA 20/25 or better	51%	63%	64%	73%	75%
UCVA 20/40 or better	79%	86%	90%	93%	92%
MRSE ≤ 0.50 D	47%	56%	61%	63%	62%
MRSE ≤ 1.00 D	75%	83%	88%	87%	89%
MRSE ≤ 2.00 D	94%	97%	99%	99%	99%
Safety Variables					
Loss of 2 lines BSCVA	6%	5%	4%	3%	2%
Loss of > 2 lines BSCVA	2%	1%	1%	1%	0%
BSCVA worse than 20/40	0%	0%	0%	0%	0%
Increase > 2 D cylinder	3%	2%	1%	<1%	<1%
BSCVA worse than 20/25 if 20/20 or better preoperatively	4%	2%	1%	1%	0%

Key safety and efficacy variables are summarized in Table 5; safety information is presented for all treated eyes, while efficacy data are presented for the population of eyes treated with the current nomogram. Uncorrected visual acuity and MRSE within 0.50, 1.00 and 2.00 D are provided for eyes with intended correction of plano. The proportion of eyes with uncorrected visual acuity of 20/20 was reported as 29% at 1 month, 40% at 3 months, 45% at 6 months, 49% at 9 months, and 56% at 12 months. The percentage of eyes with UCVA of 20/40 or better improved from 79% at 1 month, to 86% at 3 months, 90% at 6 months, 93% at 9 months, and 92% at 12 months. These visual acuity results exceed the effectiveness parameter identified in the study protocol at the postoperative interval at which stability has been established.

With regard to manifest refractive spherical equivalent, 47% at 1 month, 56% at 3 months, 61% at 6 months, 63% at 9 months and 62% of eyes at 12 months were within 0.50 D of the intended correction. Consistent with the improvement in uncorrected visual acuity over the course of the study, the proportion of eyes within 1.00 D of emmetropia

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increased from 75% at 1 month, to 83% at 3 months, 88% at 6 months, 87% at 9 months, and further improved to 89% at 12 months. These outcomes either approximate or exceed the requirements defined in the study protocol at the point of stability and beyond. From 6 to 12 months 99% of eyes were within 2.00 D of emmetropia.

Target outcomes for safety parameters were similarly achieved in the study population. From 3 months, loss of more than 2 lines of BSCVA was reported in $\leq$ 1% of eyes; 2 eyes were reported to have a loss of more than 2 lines of BSCVA at 9 months, and there were no eyes with loss of more than 2 lines at 12 months. There were also no eyes with BSCVA worse than 20/40 at the 1, 3, 6, 9 or 12-month examinations. Induced cylinder of more than 2.00 D was reported for only 2% of the study eyes at the 3 month examination, decreasing to $\leq$ 1% at all intervals thereafter. Similarly, from the 6-month examination, $\leq$ 1% of eyes with BSCVA 20/20 or better at baseline reported a decrease in BSCVA to worse than 20/25 following CK^{SM}.

Sufficient data beyond 12 months is not currently available.

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Table 6
Summary of Key Safety and Efficacy Variables at 12 Months
Preoperative MRSE Stratified by Dioptric Group
Efficacy variables: Eyes Treated with Current Nomogram
Safety variables: All Eyes Treated

	0.00 to 0.99 D	1.00 to 1.99 D	2.00 to 3.25 D
Efficacy Variables			
UCVA 20/20 or better	64%	59%	48%
UCVA 20/25 or better	73%	77%	72%
UCVA 20/40 or better	91%	94%	90%
MRSE ≤ 0.50 D	82%	68%	50%
MRSE ≤ 1.00 D	100%	94%	78%
MRSE ≤ 2.00 D	100%	100%	98%
Safety Variables			
Loss of 2 lines BSCVA	0%	3%	1%
Loss of > 2 lines BSCVA	0%	0%	0%
BSCVA worse than 20/40	0%	0%	0%
Increase > 2 D cylinder	0%	<1%	0%
BSCVA worse than 20/25 if 20/20 or better preoperatively	0%	0%	0%

Table 7
Summary of Key Safety and Efficacy Variables at 12 Months
Stratified by Treatment Spots Applied
Efficacy variables: Eyes Treated with Current Nomogram
Safety variables: All Eyes Treated

	8 Spots*	16 Spots*	24 Spots*	32 Spots*
Efficacy Variables				
UCVA 20/20 or better	67%	63%	49%	49%
UCVA 20/25 or better	80%	77%	73%	71%
UCVA 20/40 or better	93%	96%	92%	87%
MRSE ≤ 0.50 D	100%	70%	60%	41%
MRSE ≤ 1.00 D	100%	96%	92%	67%
MRSE ≤ 2.00 D	100%	100%	100%	97%
Safety Variables				
Loss of 2 lines BSCVA	0%	3%	3%	0%
Loss of > 2 lines BSCVA	0%	0%	0%	0%
BSCVA worse than 20/40	0%	0%	0%	0%
Increase > 2 D cylinder	0%	1%	0%	0%
BSCVA worse than 20/25 if 20/20 or better preoperatively	0%	0%	0%	0%

* 8 spots = CRSE 0.75 to 0.875 D
16 spots = CRSE 1.00 to 1.625 D
24 spots = CRSE 1.75 to 2.25 D
32 spots = CRSE 2.375 to 3.00 D

Table 6 shows key safety and efficacy variables stratified by dioptric group at 12 months. This is followed by the key safety and efficacy variables stratified by the number of treatment spots applied, shown in Table 7. Because the stratification by dioptric group represents a slightly different distribution of eyes than the stratification by the treatment pattern applied, minor differences can be observed between these two tables with regard to the key safety and efficacy variables. However, in general, key safety and efficacy outcomes were similar when comparing stratification by dioptric group and by treatment pattern. As demonstrated by Tables 6 and 7, effectiveness decreases with increasing preoperative refractive error.

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1. Induced Manifest Refraction Cylinder

Table 8
Absolute Change in Refractive Cylinder
All Eyes Treated

Astigmatism	Month 1	Month 3	Month 6	Month 9	Month 12
Increase > 2.00 D	3%	2%	1%	<1%	<1%
Increase > 1.00 D	21%	15%	14%	7%	6%

Table 9
Comparison of Eyes with > 1.00 D Induced Cylinder
and Eyes with ≤ 1.00 D Induced Cylinder
All Eyes Treated

	≤ 1.00 D Induced Cylinder		> 1.00 D Induced Cylinder	
	Month 9	Month 12	Month 9	Month 12
Loss of ≥ 2 lines BSCVA	4%	3%	4%	0%
No Change (± 1 line)	93%	94%	96%	96%
Increase of ≥ 2 lines BSCVA	3%	4%	0%	5%
UCVA 20/20 or better	52%	57%	9%	35%
UCVA 20/25 or better	75%	76%	43%	47%
UCVA 20/40 or better	93%	94%	83%	71%
UCVA				
N	327	327	23	17
Mean	26.22	25.75	40.13	34.41
95% Confidence Interval	24.81,27.63	24.30,27.20	25.23,55.03	25.83,42.99
Standard Deviation	13.034	13.460	36.462	18.056
Median	20.00	20.00	32.00	30.00
Range	12.50,100.00	12.50,100.00	20.00,200.00	16.00,80.00

Table 10
Absolute Shift in Axis
All Eyes Treated

Induced Shift	Month 6	Month 9	Month 12
0° to 15°	34%	37%	39%
16° to 30°	19%	16%	16%
31° to 45°	11%	10%	9%
46° to 60°	11%	12%	10%
61° to 75°	12%	12%	15%
76° to 90°	15%	14%	10%

The incidence of induced cylinder is reported in Table 8. At 6 months, 1% of eyes experienced an increase in cylinder of > 2.00 D and <1% of eyes had an increase in cylinder at months 9 and 12. 14% of eyes experienced induced cylinder of > 1.00 D at 6 months, decreasing to 7% at 9 months and 6% at 12 months, which indicates that induced cylinder resolves over time.

Table 9 demonstrates a comparison of eyes with ≤ 1.00 D and > 1.00 D induced cylinder. Both of these groups experienced an improvement in mean postoperative UCVA when compared to mean preoperative UCVA. At 12 months, eyes with ≤ 1.00 D induced cylinder had a mean postoperative UCVA of 20/25.75, while eyes with > 1.00 D induced cylinder had a mean postoperative UCVA of 20/34.41. However, for the eyes with > 1.00 D induced cylinder at 12 months the proportion with UCVA 20/20 or better was 35% and the proportion with UCVA 20/40 or better was 71%, while for the eyes with ≤ 1.00 D induced cylinder at 12 months the proportion with UCVA 20/20 or better was 57% and the proportion with UCVA 20/40 or better was 94%.

As shown in Table 10, when cylinder is present, axis shift is probable and the precise direction of cylinder axis shift is not predictable. The stability of cylinder axis has not been determined.

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2. Change in Best Spectacle Corrected Visual Acuity

Table 11
Change in Best Spectacle Corrected Visual Acuity
All Eyes Treated

	Month 1	Month 3	Month 6	Month 9	Month 12
Decrease > 2 lines	2%	1%	1%	1%	0%
Decrease 2 lines	6%	5%	4%	3%	2%
Decrease 1 line	29%	27%	27%	22%	22%
No Change	48%	51%	51%	54%	54%
Increase 1 line	12%	13%	16%	18%	18%
Increase 2 lines	2%	3%	1%	2%	4%
Increase > 2 lines	0%	0%	1%	0%	0%

As shown in Table 11, at 6 months, 95% of eyes reported no significant loss of BSCVA. Only 5% (18/387) of eyes reported greater than or equal to 2 lines loss of BSCVA. Of these 18 eyes, 39% (7/18) reported a BSCVA of 20/20 and 78% (14/18) had a BSCVA of 20/25 or better. All but one eye (17/18) had 20/32 or better with no eye worse than 20/40. In regards to patient satisfaction specifically for these 18 eyes, half (9/18) reported being "Satisfied" or "Very Satisfied" while 28% or 5 eyes reported being "Dissatisfied" or "Very Dissatisfied".

3. Change in Manifest Refraction Over Time

Table 12
Stability of Manifest Refraction through 12 Months
Patients with Consecutive visits
All Eyes Treated

	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
Change in MRSE ≤ 0.50 D	74%	89%	88%
Change in MRSE ≤ 0.75 D	87%	95%	96%
Change in MRSE ≤ 1.00 D	93%	98%	97%
Change in MRSE			
Mean	0.26	0.10	0.14
95% Confidence Interval	0.20,0.32	0.06,0.14	0.10,0.18
Standard Deviation	0.493	0.372	0.362
Change in MRSE per Month			
Mean	0.09	0.03	0.05
95% Confidence Interval	0.07,0.11	0.01,0.05	0.03,0.07
Standard Deviation	0.164	0.124	0.121

Table 13
Mean MRSE by Visit
12 Month Cohort
Eyes Treated with Current Nomogram

	Baseline	1 Month	3 Months	6 Months	9 Months	12 Months
N	325	325	323	325	325	325
Mean	1.77	-0.56	-0.29	-0.04	0.05	0.19
95% Confidence Interval	1.71,1.83	-0.66,-0.46	-0.37,-0.21	-0.12,0.04	-0.03,0.13	0.11,0.27
Standard Deviation	0.587	0.889	0.781	0.727	0.692	0.662

Stability of manifest refraction for groups of eyes with consecutive visits (i.e., 3 and 6 months, or 6 and 9 months, or 9 and 12 months) is shown in Table 12. A total of 383 eyes had a 3 and 6 month visit, 380 eyes had a 6 and 9 month visit and 371 eyes were evaluated at both 9 and 12 months. A change in MRSE of ≤ 1.00 D was reported for 93% of eyes between 3 and 6 months, for 98% of eyes between 6 and 9 months, and 97% of eyes between 9 and 12 months. The proportion of eyes with a change in MRSE of ≤ 0.75 D was also very high: 87% between 3 and 6 months, 95% between 6 and 9

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months, and 96% between 9 and 12 months. Most importantly, a change in MRSE of ≤ 0.50 D was reported for a large majority of eyes, i.e., 74% between 3 and 6 months, 89% between 6 and 9 months, and 88% between 9 and 12 months. The mean difference in MRSE was 0.26 D (95% CI 0.20, 0.32) between 3 and 6 months, 0.10 D (95% CI 0.06, 0.14) between 6 and 9 months, increasing to 0.14 (95% CI 0.10, 0.18) between 9 and 12 months. The rate of change in MRSE per month was 0.09 D (95% CI 0.07, 0.11) between 3 and 6 months, 0.03 D (95% CI 0.01, 0.05) between 6 and 9 months, and increasing to 0.05 D (95% CI 0.03, 0.07) between 9 and 12 months.

As shown in Table 13, the mean MRSE at baseline for the cohort of all eyes with a 12 month visit was 1.77 D. The mean MRSE at 1 month was –0.56 D demonstrating the intentional overcorrection associated with the CK procedure. At 3 months the mean MRSE was –0.29 D and at 6 months it approximated emmetropia with a mean of –0.04 D. The mean MRSE for this population was 0.05 D at 9 months and 0.19 D at 12 months demonstrating a hyperopic drift with an 11% loss of surgical effect in relation to the intended target of emmetropia.

Data beyond 12 months is unavailable and the duration of the hyperopic drift is unknown.

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VI. PATIENT SATISFACTION AND PATIENT SYMPTOMS

A. PATIENT SATISFACTION

Subjects were asked to rate their quality of vision as compared to the quality of vision before Conductive Keratoplasty℠ (CK℠) surgery. The percentage of patients that rated each condition as improvement that was "extreme," "marked," "moderate," "slight," or "no improvement" is shown in Table 14.

Table 14
Quality of Vision

	Month 1	Month 3	Month 6	Month 9	Month 12
Extreme Improvement	24%	24%	29%	31%	30%
Marked Improvement	42%	44%	44%	39%	43%
Moderate Improvement	19%	22%	15%	18%	17%
Slight Improvement	10%	6%	8%	8%	7%
No Improvement	5%	4%	3%	3%	3%

Over 65% of all subjects reported a "marked" or "extreme" improvement following the CK℠ procedure. At least a moderate improvement in vision was reported for approximately 88% of eyes at 6, 9, and 12 months. Approximately 10% of subjects reported "no" or "slight" improvement in quality of vision at 6, 9 and 12 months (Table 14).

Overall patient satisfaction was assessed on a patient survey at 1, 3, 6, 9, and 12 months post-treatment using a 5-point grading scale from "very satisfied" to "very dissatisfied."

Table 15
Patient Satisfaction

	Month 1	Month 3	Month 6	Month 9	Month 12
Very Satisfied	45%	46%	46%	49%	50%
Satisfied	31%	33%	36%	30%	31%
Neutral	16%	15%	9%	11%	9%
Dissatisfied	4%	3%	5%	6%	7%
Very Dissatisfied	3%	2%	3%	3%	2%

When asked to rate satisfaction (Table 15), over 80% of subjects indicated that they were "satisfied" or "very satisfied" with the results of treatment. A "dissatisfied" or "very

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dissatisfied" rating was reported by 8% of subjects at month 6, 9% at month 9, and 9% at month 12.

Table 16
Need for Distance Correction

	Month 1	Month 3	Month 6	Month 9	Month 12
No	84%	89%	87%	82%	82%
Yes	16%	11%	13%	18%	18%

Table 16 demonstrates the proportion of eyes needing postoperative distance correction. At 12 months, 82% of eyes did not require distance correction, while 18% wore spectacles or contact lenses for distance.

B. PATIENT SYMPTOMS

Subjects were asked to complete a questionnaire that allowed them to report any symptoms or complaints they had regarding their vision or ocular comfort following the procedure. Results for the subjective responses to these questionnaires at 6, 9, and 12 months post treatment are provided in Table 17. Symptoms were evaluated for severity and classified as follows: "none," "mild," "moderate," "marked," and "very severe."

Table 17
Patient Symptoms
All Eyes Treated

	None	Mild	Moderate	Marked	Very Severe
Light Sensitivity					
Preop	69%	17%	9%	4%	1%
Month 6	52%	33%	11%	3%	1%
Month 9	57%	28%	12%	3%	1%
Month 12	54%	31%	10%	3%	1%
Headaches					
Preop	84%	12%	2%	1%	1%
Month 6	84%	10%	4%	1%	1%
Month 9	84%	9%	4%	1%	2%
Month 12	85%	10%	4%	1%	1%
Pain					
Preop	95%	4%	1%	0%	0%
Month 6	91%	7%	1%	1%	1%
Month 9	92%	6%	1%	0%	1%
Month 12	96%	3%	0%	1%	1%
Redness					
Preop	83%	13%	3%	<1%	1%
Month 6	81%	13%	4%	1%	1%
Month 9	77%	15%	6%	2%	1%
Month 12	83%	13%	3%	1%	<1%
Dryness					
Preop	77%	15%	8%	1%	0%
Month 6	58%	28%	8%	6%	1%
Month 9	60%	27%	8%	5%	1%
Month 12	61%	27%	7%	4%	1%
Excessive Tearing					
Preop	87%	6%	4%	2%	1%
Month 6	85%	9%	3%	2%	1%
Month 9	83%	11%	3%	1%	2%
Month 12	89%	6%	3%	1%	1%

Table 17
Patient Symptoms
All Eyes Treated
(Continued)

	None	Mild	Moderate	Marked	Very Severe
Burning					
Preop	88%	9%	2%	1%	<1%
Month 6	83%	12%	3%	2%	<1%
Month 9	82%	11%	5%	2%	<1%
Month 12	85%	12%	2%	1%	0%
Gritty, Scratchy, or Sandy Feeling					
Preop	83%	14%	2%	0%	0%
Month 6	79%	13%	4%	3%	0%
Month 9	82%	14%	3%	1%	1%
Month 12	81%	14%	4%	0%	1%
Glare					
Preop	74%	18%	6%	1%	1%
Month 6	56%	28%	11%	5%	1%
Month 9	58%	28%	8%	4%	2%
Month 12	60%	25%	11%	2%	2%
Halos					
Preop	90%	7%	2%	2%	<1%
Month 6	63%	21%	8%	5%	2%
Month 9	66%	21%	9%	2%	2%
Month 12	65%	21%	8%	3%	2%
Blurred Vision					
Preop	67%	13%	11%	7%	2%
Month 6	52%	28%	12%	6%	3%
Month 9	59%	22%	12%	5%	2%
Month 12	63%	22%	10%	4%	1%
Double Vision					
Preop	90%	5%	5%	1%	0%
Month 6	67%	17%	8%	6%	3%
Month 9	74%	13%	7%	4%	1%
Month 12	77%	14%	5%	3%	1%

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Table 17
Patient Symptoms
All Eyes Treated
(Continued)

	None	Mild	Moderate	Marked	Very Severe
Fluctuation of Vision					
Preop	84%	12%	3%	1%	0%
Month 6	54%	29%	8%	7%	1%
Month 9	60%	25%	7%	5%	3%
Month 12	60%	28%	7%	4%	1%
Variation in Vision in Bright Light					
Preop	74%	16%	8%	2%	<1%
Month 6	55%	30%	10%	3%	1%
Month 9	62%	24%	8%	5%	1%
Month 12	58%	28%	9%	4%	1%
Variation in Vision in Normal Light					
Preop	85%	11%	4%	<1%	<1%
Month 6	70%	19%	9%	1%	1%
Month 9	71%	17%	8%	3%	1%
Month 12	70%	22%	6%	2%	1%
Variation in Vision in Dim Light					
Preop	75%	14%	8%	1%	1%
Month 6	54%	26%	13%	5%	1%
Month 9	60%	19%	12%	5%	3%
Month 12	57%	25%	11%	4%	3%
Night Driving Vision Problems					
Preop	64%	19%	12%	2%	2%
Month 6	55%	24%	12%	6%	4%
Month 9	59%	23%	7%	6%	4%
Month 12	60%	24%	7%	5%	4%
Other Symptoms					
Preop	96%	1%	2%	1%	0%
Month 6	96%	2%	1%	<1%	1%
Month 9	97%	2%	1%	0%	<1%
Month 12	96%	1%	1%	1%	<1%

NOTE: At the 12 month interval, ≥ 5% of patients reported a postoperative increase in moderate to marked ratings for the following symptoms: glare, halos, fluctuation of vision, and variation in vision in dim light. There was no significant increase (≥ 5%) in symptoms with very severe rating.

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VII. SURGICAL PLANNING AND PROCEDURES

A. PATIENT SELECTION

In addition to the information listed in the indications, contraindications, precautions, and warnings section of this booklet, consideration should be given to the following in determining the appropriate patients for the Conductive Keratoplasty℠ (CK℠) procedure:

- Patients who are hard contact lens wearers should have two (2) central keratometry readings and two (2) manifest refractions taken at least one week apart, the last of which should not differ from the previous values by more than 0.50 D in either meridian; mires must be regular in the eye to be treated.
- The patient should have the ability to tolerate topical anesthesia.
- The patient must be able to fixate steadily and accurately for the duration of the CK℠ procedure.
- Patients should sign and be given a copy of the written Informed Consent Form.
- Patients should be clearly informed of all alternatives for the correction of their hyperopia by use of spectacles, contact lenses, and other refractive surgeries such as LTK, PRK and LASIK.

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B. SYSTEM PREPARATION

- Plug the main power cord into the main power source. Switch the system on using the Power Switch located next to the Power Cord Receptacle. The Green System-Busy Light should illuminate for approximately 3 seconds and then blink until the system self-tests have been completed and a valid treatment card has been inserted into the Patient Treatment Card slot. The light will extinguish when the system is ready to operate.
- Insert the Lid Speculum cable connector into the blue connector on the front panel. Insert the Handpiece cable connector into the gray connector on the front panel.
- Carefully remove the Keratoplast™ Tip from it's packaging. To avoid damage to the Teflon® tip, follow the illustrations on the Keratoplast™ Tip labeling.
- Insert the new Keratoplast™ Tip into the handpiece, taking care to avoid touching the distal end of the tip.

WARNING! Touching the tip to any surface may damage the tip. Verify that the tip is undamaged prior to the beginning of the procedure.

- Insert a Patient Treatment Card into the Patient Treatment Card slot. Align the arrow on the card with the arrow on the front panel and press the card firmly until it stops. The card will insert to approximately 2/3 of its length. With proper insertion of a valid Patient Treatment Card, the system will sound several short beeps, the display will show P1, and the green system-busy light will stop flashing and turn off. The display signifies that one treatment is available on the card. If the card is invalid or cannot be read, the green system-busy light will continue to blink.

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- Upon initiation, the power defaults to the recommended 60% level, and the duration defaults to the recommended 0.6 seconds. These settings may not be adjusted.
- If a system error occurs, a tone will sound and an error message will be displayed in the front panel displays. The error code will also be written on the Patient Treatment Card. Error codes are defined in the Error Messages section of the Operator's Manual included with the ViewPoint™ CK℠ System. If an error occurs that requires service of the ViewPoint™ CK℠ System, please return the Patient Treatment Card that was used when the error occurred.

C. PROCEDURE

- Ensure a minimum of 560 μm corneal thickness at the 6 mm optical zone.
- Determine surgical plan based on the nomogram. Correct only the patient's full cycloplegic spectacle refraction. Do not correct for vertex.
- Administer 1 drop of topical anesthetic 3 times at intervals of 5 minutes. Monitor the patient appropriately for the degree of anesthesia.
- Do not use pilocarpine; the patient's pupil should be a normal non-pharmacologic pupil.
- Assure that the new Keratoplast™ Tip is inserted into the handpiece and inspect the tip under scope.
- Insert the CK℠ lid speculum into the operative eye.

WARNING! Do not use an eye drape. The speculum must have direct contact with lids to ensure the flow of energy. Poor contact of the lid speculum may result in inadequate application of energy.

- Position the microscope over or in front of the eye to be treated.

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- Dampen the CK[SM] marker with gentian violet, rose bengal, or methylene blue stain. Be sure to center the marker's cross hair on the patient's line of sight. Apply even downward pressure to the marker and ensure a complete and crisp corneal mark (Figures 5 & 6). Irrigate with balanced salt solution to remove excess ink or stain.

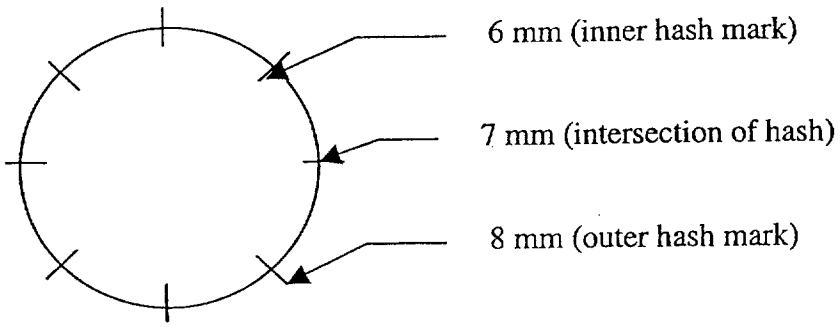

Figure 5
Corneal Marking

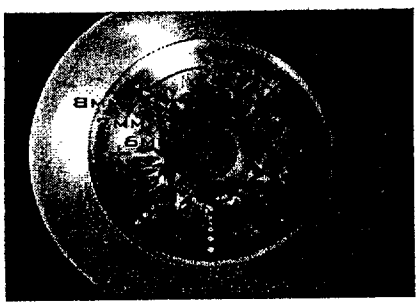

Figure 6
Corneal Marking

- Dry the surface of the cornea thoroughly with a fiber-free sponge to avoid dissipation of applied energy by a wet or damp ocular surface.
- Apply treatment spots according to surgical plan and observe the following:
  - Concentrate on **precise tip placement** to ensure symmetrical treatment pattern.
  - Achieve **perpendicularity** of tip to ocular surface before penetrating the cornea.

- Apply and maintain **uniform downward pressure** to ensure that the tip is fully seated before applying energy. (Cornea should be dimpled).
- Apply energy by depressing / holding footpedal **until audible tone ceases.**
- Pull tip straight out and **inspect.** If necessary, use a lint-free sponge to remove debris. Replace a bent or damaged tip before proceeding.
- For 8 spot treatment, apply all spots at 7 mm optical zone.
- For 16, 24, or 32 spot treatments, begin at 6 mm optical zone, then proceed to 7 mm, then to 8 mm, and finally place the intermediate 7 mm series as necessary. **Note: Ideal procedure time is equal to one minute or less per series of 8 spots.**
- Remove speculum and administer 1 drop of topical ophthalmic antibiotic solution and one drop of NSAID. Artificial tears may be used to promote patient comfort.
- If bilateral treatment is being performed, the procedure described above is repeated for the fellow eye utilizing a new Keratoplast™ Tip.

WARNING!

The Keratoplast™ Tip must not be used on fellow eyes or subsequent patients.

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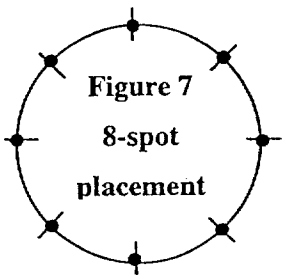
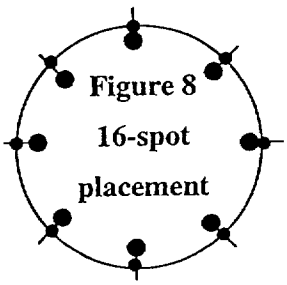
The appropriate treatment parameters are set on the ViewPoint™ CK℠ System console, as per the following table, which establishes specified parameters based on the planned spherical correction:

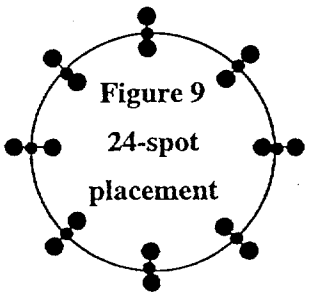
Table 18
Treatment Parameters

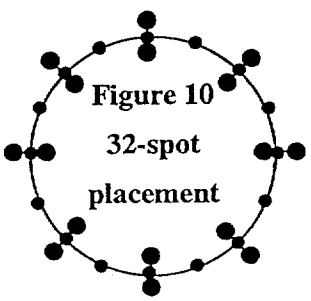
Application Spots	Diameter	Power	Duration	Preop CRSE
8 (Fig. 7)	7 mm	60 Percent	0.6 Seconds	0.75 D to 0.875 D
16 (Fig. 8)	6 & 7 mm	60 Percent	0.6 Seconds	1.00 D to 1.625 D
24 (Fig. 9)	6, 7, 8 mm	60 Percent	0.6 Seconds	1.75 D to 2.25 D
32 (Fig. 10)	6, 7, 8 and in between at 7 mm	60 Percent	0.6 Seconds	2.375 D to 3.00 D

It should be noted that the data collected to date does not present definitive evidence of an age effect, and only a trend of greater correction (MRSE) with increasing age. These data are not adequately strong to warrant inclusion of age as an adjustment in the surgical nomogram, since there was no effect of age on UCVA and inconsistent effect of age on predictability of MRSE. Additional data must be collected before age can be included as an adjusting factor in the nomogram.









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Begin at patient's 12 o'clock, then proceed to 6 o'clock. Continue to follow the pattern as demonstrated in Figure 11. Repeat this pattern at each optical zone.

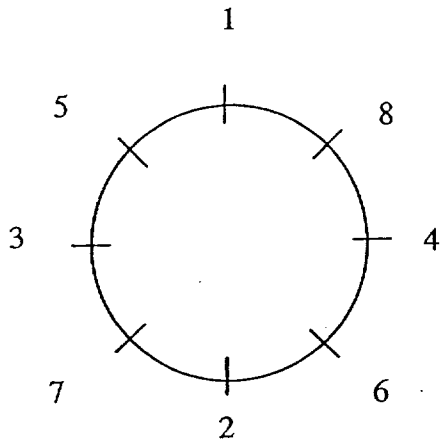

Figure 11

Sequence of spot placement

D. POSTOPERATIVE CARE

Following the CK[SM] procedure, the surgeon may follow his or her usual refractive surgery postoperative care regimen. Refractec recommends administration of one drop of a topical ophthalmic antibiotic solution and one drop of an ophthalmic NSAID, continued according to product labeling. CK[SM] induces myopia in the early post-treatment period, which may necessitate temporary spectacle correction for tasks such as driving.

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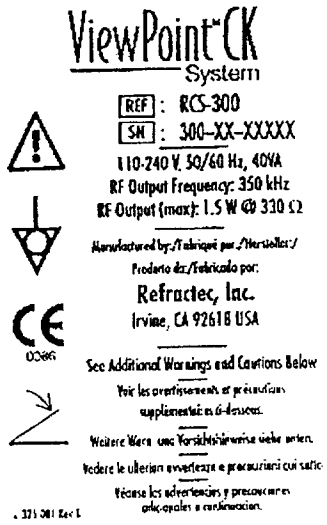
VIII. DEVICE LABELS



L-325-001
RCS-300 Console Back Panel Label

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ViewPoint CK System

REF: RCS-300

110-240 V, 50/60 Hz, 40VA

RF Output Frequency: 350 kHz
RF Output (max): 1.5 W @ 330 Ω

WARNING

For continued protection against fire hazard, replace only with same type and rating of fuse

110 - 120 VAC: T4A 2.5A, 3AG, SB
220 - 240 VAC: T2A 2.5A, 5x20mm, FI

Hospital grade receptacle required for ground reliability

Covered by one or more International and U.S. Patents including: US Pat 5,533,999; 5,634,921; 5,749,871

ViewPoint CK System

REF: RCS-300

110-240 V, 50/60 Hz, 40VA

Fréquence de sortie RF: 350 kHz
Sortie RF (max): 1,5 W à 330 Ω

AVERTISSEMENT

Pour éviter les risques d'incendie, ne remplacer que par un fusible du même type et des mêmes spécifications

110 - 120 V~ : 1 à 2,5A, 3AG, SB
220 - 240 V~ : 2 à 2,5A, 5x20mm, FI

Prise pour usage hospitalier requise pour une mise à la terre fiable

Protégé par un ou plusieurs brevets internationaux et américains (États-Unis), y compris 5,533,999; 5,634,921; 5,749,871

ViewPoint CK System

REF: RCS-300

110 240 V, 50/60 Hz, 40VA

HF-Ausgangsfrequenz: 350 kHz
HF-Ausgang (max.): 1,5 W bei 330 Ω

WARNUNG

Um kontinuierlichen Schutz gegen Brandgefahr sicherzustellen, nur mit Sicherung des gleichen Typs oder der gleichen Nennleistung ersetzen

110 - 120 V~ : 1 bei 2,5A, 3AG, SB
220 - 240 V~ : 2 bei 2,5A, 5x20mm, FI

Für zuverlässige Erdung ist eine Krankenhaus-Spezial Schutzsteckdose erforderlich.

Durch ein oder mehrere internationale und US-Patente geschützt, einschließlich: US-Pat. 5,533,999; 5,634,921; 5,749,871

ViewPoint CK System

REF: RCS-300

110-240 V, 50/60 Hz, 40VA

Frequenza uscita RF: 350 kHz
Uscita RF (max): 1,5 W a 330 Ω

AVVERTENZA

Per garantire l'ininterrotta protezione del pericolo di incendio, sostituire il fusibile solo con uno di tipo e caratteristiche nominali uguali

110 - 120 V~ : 1 da 2,5A, 3AG, SB
220 - 240 V~ : 2 da 2,5A, 5x20mm, FI

Per l'affidabilità della messa a terra, collegare a una presa per uso ospedaliero.

Tutelato da uno o più brevetti statunitensi e internazionali, inclusi i brevetti USA 5,533,999; 5,634,921; 5,749,871

ViewPoint CK System

REF: RCS-300

110-240 V, 50/60 Hz, 40VA

Frecuencia de salida de la señal de radio: 350 kHz
Salida de radiofrecuencia (máx.): 1,5 W a 330 Ω

ADVERTENCIA

Para mantener una protección continua contra el peligro de incendio, reemplace el fusible sólo con otro del mismo tipo y clasificación

110 - 120 V~ : 1 a 2,5A, 3AG, SB
220 - 240 V~ : 2 a 2,5A, 5x20mm, FI

Para asegurar una buena conexión a tierra se requiere un enchufe de tipo clasificado para uso en hospitales.

Cubierto por uno o más patentes internacionales y estadounidenses, entre ellas los patentes estadounidenses 5,533,999; 5,634,921; 5,749,871

L-325-021
RCS-300 Console Bottom Panel Label

Refractec

For use with the RCS-200 and ViewPoint™ CK System

REF: RCS-KTP-450
Keratoplast™ Tip

LOT:

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

STERILE EO

Contents Sterile In Unopened, Undamaged Package

For Single Use Only

Manufactured by:
Refractec, Inc., Irvine, CA 92618 USA
+1.949.784.2600; +1.800.752.9544; +1.949.784.2601 Fax

European Union Authorised Representative:
M. Devices Group, Marlborough House, Fiding Street
Southport, PR8 1EW, UK
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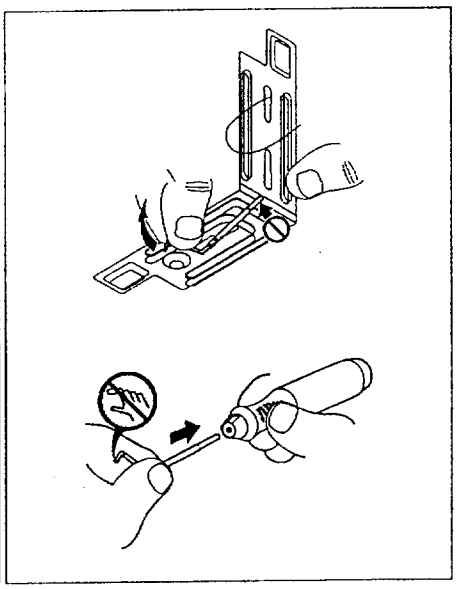
CE 0086

A-001274 P-425-1 REV 2001
L-325-036 Rev B



L-325-036
Disposable Keratoplast™ Tip Label

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