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Refractec

Facts You Need To Know About the ViewPoint™ CK System and Conductive Keratoplasty® (CK®)

Patient Information Booklet

CK® (spherical hyperopic treatment of 1.00 to 2.25 D) to achieve a myopic endpoint (-1.00 D to -2.00 D) in one eye for the temporary improvement of near vision

Please read this entire booklet. Discuss its contents with your doctor so that all of your questions are answered to your satisfaction. Ask any questions you may have before you agree to the procedure.

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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 treatment and management of refractive errors.

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Introduction

Your doctor and Refractec, Inc. have provided the information in this booklet to help you decide whether to have *Conductive Keratoplasty®* (*CK®*) performed on one of your eyes to temporarily improve your near vision. It is temporary because the amount of correction may diminish over time. However, some patients retain some or all of their *CK®* correction. Please read this brochure carefully and discuss the information with your doctor and his or her staff. Your doctor can determine if you are a candidate for *CK®*.

The ViewPoint™ CK System is utilized to achieve the clinical technique called *monovision*. In *monovision*, one of your eyes is used for distance vision and your other eye is treated to provide an improvement in your near vision. Since not all patients can adapt to *monovision*, it is important that you complete a successful trial of *monovision* or have a history of *monovision* wear. Several alternatives to undergoing *CK®* for near vision improvement are available to you. You can wear eyeglasses (reading or *bifocals*), or *monovision* or bifocal contact lenses to correct your vision. In addition, there are other surgical procedures that can be used to correct your near vision, including the removal of the eyes' natural cataractous lens and replacement with a new lens (called a multi-focal or accommodative intraocular lens implant or IOL).

Although near vision without glasses is improved after the *CK®* procedure, some people still need glasses or contact lenses for some tasks. In addition, the vision requirements of some occupations, such as airplane or military pilots, may not be met by having *CK®*, *LASIK*, or *PRK*. You are the only one who can decide whether *CK®* is right for you. The information in this booklet should help you make your decision. Make sure that your doctor has answered all of your questions before you decide to have *CK®*.

Since this booklet uses many terms that may not be familiar to you, you can use the glossary provided at the end of the booklet for definitions of any word shown in italics.

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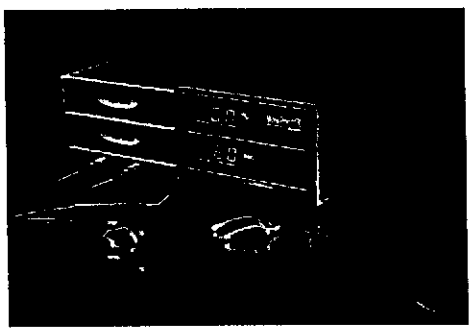
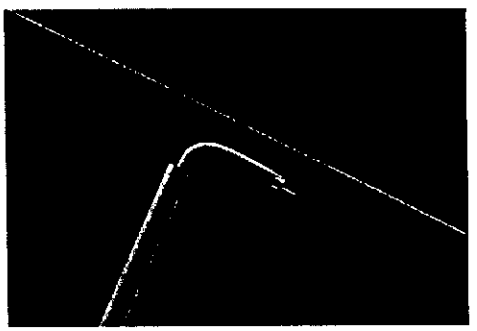
The ViewPoint™ CK System

The *CK*® treatment utilizes a controlled release of *radiofrequency (RF) energy* to increase the temperature of the corneal tissue, the clear tissue at the front of your eye. The treatment is applied with a probe called a Keratoplast™ Tip, which is a sterile, stainless steel probe about the size of a human hair. The Keratoplast™ Tip is introduced 16 to 24 times into the *cornea* in a circular pattern, to heat and shrink the corneal tissue. This results in an increased curvature of the *cornea* to create *monovision*, improving your near vision in the treated eye.



ViewPoint™ CK System

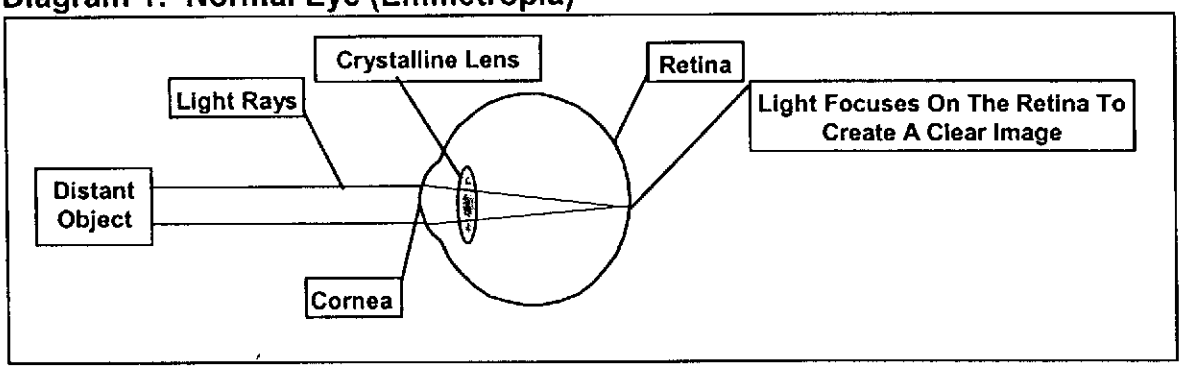


Keratoplast™ Tip Compared to a Human Hair

How the CK® Procedure Works

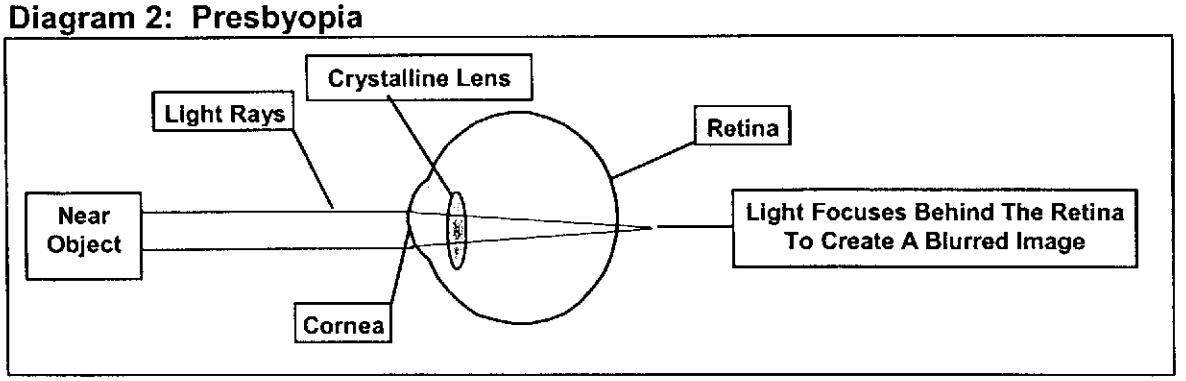
The human eye functions like a camera. The lens in a camera focuses light images onto film. In the same way, the *cornea* and the *crystalline lens* inside the eye focus light images on the *retina*, the back surface of the eye (see Diagram 1). Vision is blurred when the light does not focus precisely on the *retina*.

Diagram 1: Normal Eye (Emmetropia)



Presbyopia is an eye condition that affects people as they get older. This occurs because the lens inside the eye loses flexibility, leading to difficulty seeing objects up close. This loss of flexibility, or *accommodation*, causes the *cornea* and *crystalline lens* to focus light rays from near objects behind the *retina*. Diagram 2 shows how light from near objects focuses behind the *retina* to create a blurred image.

Diagram 2: Presbyopia



CK® can change how the eye focuses light by reshaping the *cornea* to improve near vision. *CK*® uses a controlled release of *radiofrequency energy* to heat and shrink the corneal tissue, which steepens the *cornea*. This steepening corrects the point of focus so that light focuses properly on the *retina*. *CK*® reshapes the *cornea* without changing any other parts of the eye. Diagram 3a shows how *CK*® can reshape the *cornea* to provide clearer near vision. *CK*® does not restore *accommodation* and the eye treated for near vision will have compromised distance vision (Diagram 3b).

Diagram 3a: Correction Of Vision After CK®

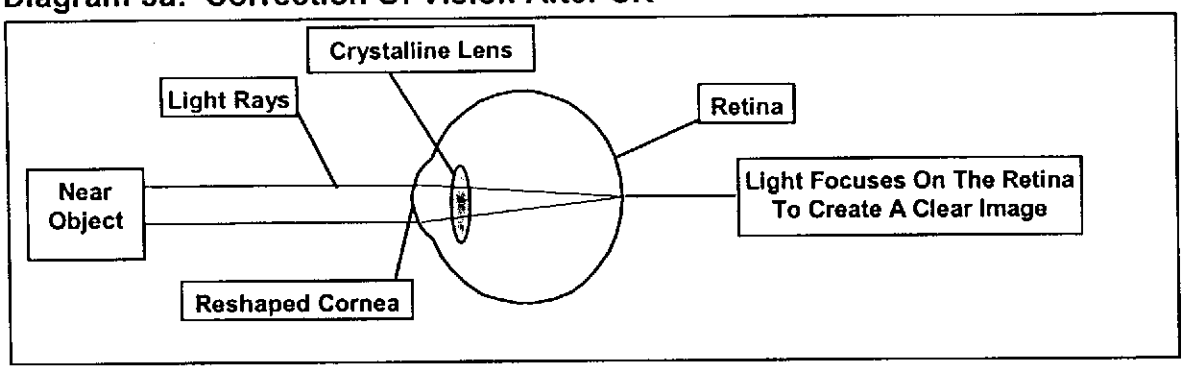
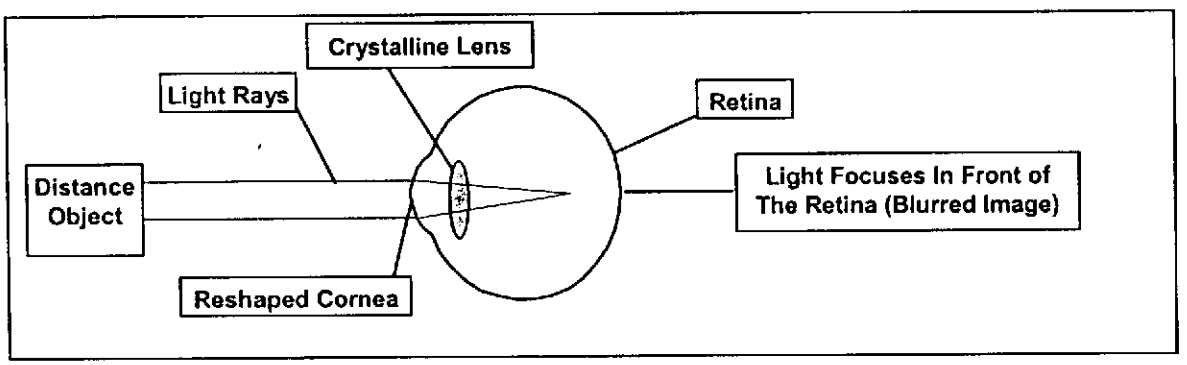


Diagram 3b: Correction Of Vision After CK®



WHAT ARE THE BENEFITS?

The benefit of *CK*® is its ability to improve your uncorrected near vision (your vision without glasses or contact lenses used to see objects up close). *CK*® is performed without the use of a laser and does not cut your eye. This is a perceived benefit for patients who are concerned about having a laser procedure performed on their eyes.

Additional benefits of *CK*® include:

- *CK*® can improve near vision in patients needing a refractive target of up to -2.00 *diopters.*
- *CK*® can reduce your need for glasses or contact lenses used to see up close. You may find, after having *CK*®, that you wear your glasses less during the day or only during certain activities.
- *CK*® may even eliminate your need for glasses or contact lenses used to see at near.

Clinical Study to Evaluate Benefits

A clinical study was conducted to evaluate the benefits and risks of the ViewPoint™ CK System when used to improve near vision. This study involved 150 subjects treated for near vision in one eye. The study results shown below and in the "Risks" section include all the available reported outcomes on the study patients.

To help you understand near visual acuity values (Jaeger), the tables below correlate Jaeger (J) to every day activities. Each table lists the number of eyes (n) for which data were available at the reported time interval. This number may vary since at the time this booklet was published not all subjects had completed all postoperative exams.

Study Patient Demographics

Table 1 lists the age, gender and race of subjects in this study.

Table 1 – Demographics of 150 Enrolled Subjects

Age	Average	52.9 years
	Range	43 to 70 years
Gender	Male	39%
	Female	61%
Race	Caucasian	96%
	Black	1%
	Asian	1%
	Other*	3%

* Other classification of race include: Egyptian and Hispanic.

Equivalent outcomes in non-Caucasians have not been determined.

Visual Acuity Without Glasses

Visual acuity measures the sharpness of vision using a letter chart. In this study, subjects were allowed to select a full or partial near correction to provide optimal clarity at their individual near vision preference (i.e. reading or computer distance). Of the 150 eyes treated, 133 eyes were fully corrected to achieve near (reading) vision. Table 2 shows that six months after treatment, 73% of study subjects saw J2 (20/30) or better without glasses in the eyes treated for near while 83% saw J3 (20/40) or better in the eyes treated for near. J2 (20/30) is considered to be the size of print found in want ads while J3 (20/40) is comparable to newspaper size print.

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Table 2 – Near Visual Acuity Without Glasses in the Eye Treated for Near

Near Visual Acuity *Without* Glasses	Before CK® n=81	6 Months n=81	12 Months n=53
J1+ (20/20) or better	0%	23%	13%
J1 (20/25) or better	0%	51%	38%
J2 (20/30) or better (want ads)	1%	73%	70%
J3 (20/40) or better (newspaper)	7%	83%	81%
J5 (20/50) or better	16%	94%	98%

Table 3 shows that six months after treatment, 81% of study subjects had near vision of J2 (20/30) or better without glasses with both eyes while 90% had near vision of J3 (20/40) or better with both eyes. 95% of study subjects had distance vision of 20/20 or better without glasses with both eyes while 100% had distance vision of 20/40 or better with both eyes. 20/20 is considered perfect distance vision.

Table 3 – Near and Distance Visual Acuity Using Both Eyes Without Glasses

Near Visual Acuity Using Both Eyes Without Glasses	Before CK® n=81	6 Months n=81	12 Months n=53
J1+ (20/20) or better	0%	28%	23%
J1 (20/25) or better	1%	56%	47%
J2 (20/30) or better (want ads)	7%	81%	77%
J3 (20/40) or better (newspaper)	15%	90%	89%
J5 (20/50) or better	37%	96%	98%
Distance Visual Acuity Using Both Eyes Without Glasses	**Before CK® n=91**	**6 Months n=91**	**12 Months n=62**
20/20 or better	92%	95%	97%
20/25 or better	98%	100%	98%
20/40 or better	100%	100%	100%

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WHAT ARE THE RISKS?

As with any surgical procedure there are risks associated with *CK*® performed to achieve *monovision*.

After the procedure you may experience mild to moderate pain, discomfort, blurry vision, tearing, and/or light sensitivity as the *cornea* heals. Some patients may experience fluctuation in their vision throughout the day. You may experience reduced sharpness of vision and reduced depth perception for distance and up close tasks. Symptoms such as mild blurred vision, headaches, and variable vision may be experienced for a short time or for several weeks as you adapt to *monovision*. You should avoid visually demanding tasks or situations for the first few weeks after your procedure. Your doctor will tell you when you can resume driving.

After the procedure, you may notice some glare, sensitivity to light, and difficulty driving at night. Some patients experience small changes in their vision. You may require glasses for tasks such as driving or reading. Some patients also experience an increase in *astigmatism*, which may affect their vision.

It is important to discuss these risks with your doctor before you make the decision to have treatment.

Contraindications – When Can't You Have CK®?

You should NOT have *CK*® if:

- You are pregnant or nursing – due to the potential for temporary fluctuation in your vision.
- You show signs of a cone shaped *cornea* (*keratoconus*) – since eyes with this condition may have unstable corneas.
- You have a *collagen vascular disease*, an *autoimmune disease*, *immunodeficiency disease*, immunocompromised status, clinically significant allergies or asthma, or insulin dependent diabetes – these are conditions that affect your immune response and your body's ability to heal, or result in *inflammation* or swelling of parts of the body, such as muscles, joints, and blood vessels – examples of these diseases are AIDS, lupus, rheumatoid arthritis, and multiple sclerosis.
- You are being treated with chronic systemic corticosteroid or other immunosuppressive therapy that may affect wound healing.
- You have an implantable electrical device such as a pacemaker, defibrillator, or cochlear implant – since the ViewPoint™ CK System may interfere with these devices.
- You have uncontrolled eye movements (nystagmus) or another condition that prevents a steady gaze – since a steady gaze is required during the *CK*® procedure.

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What Warnings and Other Information Do You Need to Know About?

Warnings

Be sure to talk to your doctor if:

- You have a tendency to form scars (keloids), because it is unknown whether the *CK*® procedure is safe and effective for you.
- You have a history of *Herpes simplex* or *Herpes zoster* in your eye, because the *CK*® procedure is more risky for you, if you have had a *Herpes simplex* or a *Herpes zoster* infection that affected your eyes, and have an infection now.
- You have severe, untreatable dry eye, because the *CK*® procedure may increase the dryness, which may or may not go away.
- You have narrow angles, because eyes with this condition are at risk of developing *glaucoma*.
- You have had previous *strabismus* surgery or are likely to develop *strabismus* following the *CK*® procedure, because it is unknown whether the *CK*® procedure is safe and effective for you.
- You have had changes in your vision over the previous 12 months. Unstable vision may result in poor treatment results.
- You have a *cornea* that is too thin for the procedure to be completed safely, because it is unknown whether the *CK*® procedure is safe and effective for you.
- You have not demonstrated the ability to adapt to *monovision* with contact lenses or spectacles, because it is unknown whether the *CK*® procedure is effective for you.
- You have not discontinued wearing contact lenses 2 to 3 weeks before your 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 variations of vision in the early post-treatment period, which may necessitate temporary spectacle correction for tasks such as driving, and monovision itself may permanently necessitate spectacles for tasks such as driving or reading fine print for long periods of time.

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Precautions

The safety and effectiveness of the ViewPoint™ CK System have NOT been established in:

- Eyes with progressive *hyperopia*, corneal disease or abnormality (for example, scar, infection, etc.), because it may affect the accuracy of the *CK®* treatment or the way your *cornea* heals after *CK®*. This may result in poor vision after *CK®*. If your eyes have an active disease, it is unknown whether *CK®* is safe and effective under this condition.
- Eyes with previous intraocular surgery (e.g., *cataract* surgery), corneal surgery, incisional keratotomy, or injury to the center of the *cornea* where *CK®* will reshape the *cornea*, because the *CK®* results may then be unpredictable and may result in poor vision after *CK®*.
- Patients with a history of *glaucoma* (a condition usually associated with high eye pressure that results in damage to the nerve in the eye and possible loss of vision), IOP greater than 21 mmHG, or steroid response IOP rise.
- Patients under 40 years of age.
- Eyes that require a correction of more than -2.00 D to achieve acceptable near vision.
- Eyes with more than 0.75 *diopters* of *astigmatism.*
- Eyes with previous refractive surgery (including previous *CK®* surgery).
- Eyes having a *dilated* refraction significantly different (> 0.50 D) from the non-*dilated* refraction.
- Eyes that cannot be corrected to 20/25 vision or better with glasses or contact lenses.
- Eyes that have previously been treated with *CK®*.
- Eyes of patients treated in the upright (sitting) position.
- Eyes treated with additional treatment spots; greater than 16 or 24-spot approved monovision treatments.
- The calculation of the intraocular lens power if you require future cataract surgery.
- Eyes that require < 1.00 D of treatment, because there were an insufficient number of eyes studied in the clinical trial to demonstrate safety and effectiveness.
- Eyes that require > 2.25 D of treatment, in particular, because effectiveness in the clinical trial was significantly below that of the approved indication.

There is no data available regarding the safety and effectiveness of other refractive procedures performed after *CK®*.

If you have any of the above conditions, you may not be a good candidate for *CK®* and you should discuss this with your doctor. Also, you should be aware that the safety and effectiveness of retreatments performed with the ViewPoint™ CK System have not been established.

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Important Things to Consider Regarding Monovision

- *Monovision* may not be appropriate for individuals with unrealistic expectations. Patients who expect perfect results, perfect vision under all light conditions, or an instant improvement in vision may be poor candidates for *CK®*. As with any refractive procedure, *CK®* does not guarantee perfect results. Your vision may not be perfect and you may need to wear glasses or contact lenses after the procedure.

- You should be aware that as with any type of vision correction there are advantages and compromises associated with *monovision* correction. The benefit of the improved near vision provided by *monovision* may be accompanied by compromised visual acuity and depth perception for distance and near tasks. Symptoms such as mild blurred vision, dizziness, headaches, and a feeling of slight imbalance may be experienced. The ability to adapt to these symptoms should be determined during a *monovision* contact lens trial period.

- You should successfully complete a *monovision* trial using glasses or contact lenses. It is important that you follow your doctor's suggestions for adaptation to *monovision* during this trial period. You should discuss any concerns that you may have during the adaptation period. It is in your best interest to assure that you are comfortable with the visual result of this *monovision* trial, since the *CK®* procedure is not reversible.

- The goal of the *Conductive Keratoplasty®* procedure for *monovision* is to improve your ability to see objects up close. Because you will have improved near vision in one eye and distance vision in the other, it is important to avoid too large of differences between your eyes, since this can result in symptoms such as reduced depth perception, blurred distance vision, and difficulties with night vision. Your doctor will limit the amount of effect you obtain with regard to near vision, to avoid inducing a large difference in *refraction* between your two eyes, and the associated visual symptoms.

- Some *monovision* patients require supplemental glasses to provide the clearest vision for important tasks and activities:

    - You may not be comfortable functioning under low levels of light, such as driving at night. You may want to discuss with your doctor having corrective lenses prescribed so that both eyes are corrected for distance when sharp *binocular* distance vision (vision using both eyes for distance) is required.

    - If you require very sharp near vision during prolonged close work, you may want to have additional corrective lenses prescribed so that both eyes are corrected for near when sharp *binocular* near vision is required.

- Occupational and environmental visual demands should be considered. If you require sharp vision (visual acuity and *stereopsis*, or good binocular vision) it must be determined during the *monovision* contact lens trial whether you can function adequately with the *monovision* created by CK. *Monovision* may not be optimal for activities such as:

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- Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities.
- Driving automobiles (e.g. driving at night). If you cannot pass your state driver's license requirements with *monovision* correction, you may require that additional over-correction (glasses) be prescribed.

- Your vision may continue to change over time. Your ability to read is a combination of your eye's current focusing ability and the power (add) used in your reading glasses. As you get older, your focusing abilities diminish, requiring stronger reading glasses to compensate. Therefore after the *CK*® treatment, as you continue to age and your focusing abilities diminish, your near vision may change over time with eventual need for glasses or contact lens correction.
- Your *presbyopia* will increase over time.
- Your improved vision after the *CK*® treatment may diminish over time. Based on existing information from the clinical trial, 87% (54/62) of eyes maintained their 6 month refractive effect at 12 months (within ± 0.50 D range). When stratified by refractive status at baseline, 89% (41/46) of *emmetropic* eyes maintained their 6 month refractive effect at 12 months, while 80% (12/15) of *hyperopic* eyes maintained their 6 month refractive effect at 12 months.
- If your results with *CK*® are not satisfactory and you desire a second procedure, it is unknown at this time whether retreatment procedures with *CK*® or other refractive procedures will be successful.
- Your vision may not be perfect and you may need to wear glasses or contact lenses for some activities even after having the *CK*® procedure.
- All patients do not function equally well with *monovision* correction. You may not perform as well for certain tasks with this correction as you may have with bifocal reading glasses. *Monovision* correction, as well as presbyopic contact lenses or other alternatives can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks.
- You may experience improvement in your near vision, such as being able to see objects close up, like reading a menu or checkbook without glasses. However, this improvement in near vision may diminish over time.
- The goal of *CK*® for *monovision* is to improve your ability to see objects up close and it is likely to result in a significant reduction in distance vision in the eye treated for near.
- The decision to undergo *CK*® for *monovision* is most appropriately left to you in conjunction with your doctor after carefully considering your vision needs.

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Clinical Study to Evaluate Risks

In the clinical study of *CK*® for *monovision*, visual acuity without glasses improved for all eyes treated.

To help you understand near visual acuity values (Jaeger), the tables below correlate Jaeger (J) to every day activities. Each table lists the number of eyes (n) for which data were available at the reported time interval. This number may vary since at the time this booklet was published not all subjects had completed all postoperative exams.

Visual Acuity With Glasses

Table 4 shows that six months after treatment, 100% of study subjects saw J2 (20/30) or better with glasses and 100% saw J3 (20/40) or better. J2 (20/30) is considered print similar to want ads while J3 (20/40) is newspaper print.

Table 4 – Visual Acuity With Glasses (Best Vision) in the Eyes Treated for Near

	Before CK® n=94	6 Months n=93	12 Months n=63
J2 (20/30) or better (want ads) with glasses	100%	100%	100%
J3 (20/40) or better (newspaper) with glasses	100%	100%	100%
J5 (20/50) or better with glasses	100%	100%	100%

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Change in Visual Acuity With Glasses After Treatment

Table 5 shows the change in visual acuity with glasses at 6 and 12 months compared to before treatment for the eyes treated for near in the clinical study.

A line of visual acuity is a line on the visual acuity chart, such as the 20/20 line. Loss of more than 2 lines of visual acuity means, for instance, going from 20/20 before *CK*® to 20/40 after *CK*®. A gain of lines means that patients could read 1 or more rows of letters on the eye chart (visual acuity chart) after treatment that they could not read before treatment.

Table 5 – Change in Visual Acuity With Glasses After Treatment Compared to Before Treatment in the Eyes Treated for Near

Change in Distance Vision With Glasses	6 Months n=93	12 Months n=63
Eyes with loss of > 2 lines	0%	0%
Eyes with loss of 2 lines	0%	0%
Eyes with loss of 1 line	3%	0%
Eyes with no change	77%	86%
Eyes with a gain of 1 line	17%	14%
Eyes with a gain of 2 lines	2%	0%
Eyes with a gain of > 2 lines	0%	0%

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Adverse Events and Complications

Some patients in the clinical study experienced adverse events and complications after the *CK*® procedure. Out of 146 eyes treated for near vision at six months, there was one adverse event reported, consisting of loss of more than 2 lines of best corrected vision (with glasses) on the eye chart. This was not related to *CK*®, but rather was the result of a possible technician error. There were a total of two complications at six months: one eye was reported to have double or ghost images and one eye was reported to have foreign body sensation. Out of 77 eyes treated for near vision at 12 months, no eyes reported adverse events and one eye was reported to have a complication of foreign body sensation (same eye as reported at 6 months).

None of the following adverse events were reported at any time during the study: *haze*, loss of more than 2 lines of best corrected vision (due to *CK*®), *corneal ulcer*, *corneal edema*, corneal infection, corneal scar, uncontrolled intraocular pressure (pressure in the eye), increase in intraocular pressure greater than 25 mmHg, onset of *cataract* unrelated to age, retinal detachment (torn layer in the back of the eye), retinal vascular accident (stroke in the back of the eye), or secondary surgical intervention.

None of the following complications were reported at any time interval during the study: peripheral *corneal epithelial defect*, *corneal edema*, *corneal erosion* (loss of the outer most layer of the eye) or pain.

Although none of the above mentioned adverse events and complications were reported during the clinical study, they are potential risks.

Patient Symptoms After the CK® Procedure

At several time points after the procedure, patients completed a questionnaire for the symptoms shown in the table below. Table 6a lists changes in patient symptoms reported as worse or significantly worse when comparing the severity of symptoms before treatment (preoperative) to 6 months (92 eyes) and 12 months (62 eyes) after treatment.

Table 6a – Comparison of Symptoms Before and After Treatment

	6 Months		12 Months	
Symptom	**Worse**	**Significantly Worse**	**Worse**	**Significantly Worse**
Light Sensitivity	3%	0%	5%	0%
Headache	1%	0%	0%	0%
Pain	1%	0%	0%	0%
Redness	1%	0%	0%	0%
Dryness	4%	0%	2%	0%
Excessive Tearing	0%	0%	0%	0%
Burning	1%	0%	0%	0%
Gritty, Scratchy, or Sandy Feeling	0%	1%	2%	0%
Glare	5%	1%	3%	3%
Halos	10%	1%	5%	3%
Blurred Vision	9%	2%	7%	3%
Double Vision	4%	1%	10%	2%
Fluctuation of Vision	9%	1%	7%	2%
Variation of Vision in Bright Light	4%	2%	5%	0%
Variation of Vision in Normal Light	1%	1%	5%	2%
Variation of Vision in Dim Light	2%	2%	5%	5%
Night Driving Vision Problems	2%	3%	2%	5%
Other Symptoms	4%	1%	0%	0%

Table 6b shows the incidence of "none," "mild," "moderate," "marked," and "very severe" for each symptom at baseline, 1 month, 6 months, and 12 months postoperative. While a clinically significant increase in postoperative symptoms was observed, the majority changed from "none" to "mild". The symptoms that reported a significant increase (>5%) from preoperative to 6 months or beyond in the "moderate" category are glare, *halos*, double vision, fluctuation of vision and variation of vision in dim light.

Table 6b – Patient Symptoms

Subjective Responses	None	Mild	Moderate	Marked	Very Severe
Light Sensitivity					
Preop	81%	15%	3%	1%	0%
Month 1	56%	31%	10%	2%	1%
Month 6	71%	23%	6%	0%	0%
Month 12	76%	19%	5%	0%	0%
Headaches					
Preop	92%	5%	0%	1%	1%
Month 1	94%	4%	1%	0%	0%
Month 6	94%	5%	1%	0%	0%
Month 12	94%	5%	2%	0%	0%
Pain					
Preop	98%	2%	0%	0%	0%
Month 1	93%	6%	1%	0%	0%
Month 6	97%	2%	1%	0%	0%
Month 12	100%	0%	0%	0%	0%
Redness					
Preop	94%	6%	0%	0%	0%
Month 1	92%	7%	1%	0%	0%
Month 6	96%	3%	1%	0%	0%
Month 12	97%	3%	0%	0%	0%
Dryness					
Preop	84%	14%	1%	0%	1%
Month 1	67%	24%	7%	1%	1%
Month 6	71%	24%	5%	0%	0%
Month 12	79%	19%	2%	0%	0%

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Table 6b – Patient Symptoms (continued)

Subjective Responses	None	Mild	Moderate	Marked	Very Severe
Excessive Tearing					
Preop	96%	2%	2%	0%	0%
Month 1	93%	7%	0%	0%	0%
Month 6	96%	3%	0%	1%	0%
Month 12	97%	3%	0%	0%	0%
Burning					
Preop	97%	1%	2%	0%	0%
Month 1	92%	6%	1%	1%	0%
Month 6	92%	6%	1%	0%	0%
Month 12	100%	0%	0%	0%	0%
Gritty, Scratchy or Sandy Feeling					
Preop	92%	6%	1%	0%	0%
Month 1	82%	13%	3%	1%	0%
Month 6	88%	11%	0%	1%	0%
Month 12	97%	2%	2%	0%	0%
Glare					
Preop	94%	5%	1%	0%	0%
Month 1	64%	23%	9%	3%	0%
Month 6	65%	27%	8%	1%	0%
Month 12	73%	21%	3%	3%	0%
Halos					
Preop	96%	3%	1%	0%	0%
Month 1	69%	17%	9%	3%	2%
Month 6	72%	15%	12%	1%	0%
Month 12	74%	16%	6%	3%	0%
Blurred Vision					
Preop	81%	12%	6%	0%	1%
Month 1	47%	32%	13%	7%	1%
Month 6	59%	27%	11%	3%	0%
Month 12	68%	19%	8%	5%	0%
Double Vision					
Preop	97%	3%	0%	0%	0%
Month 1	77%	13%	6%	4%	0%
Month 6	83%	12%	4%	0%	1%
Month 12	81%	8%	10%	2%	0%

Table 6b – Patient Symptoms (continued)

Subjective Responses	None	Mild	Moderate	Marked	Very Severe
Fluctuation of Vision					
Preop	94%	4%	2%	0%	0%
Month 1	51%	33%	12%	3%	0%
Month 6	65%	25%	10%	1%	0%
Month 12	69%	23%	6%	2%	0%
Variation in Vision in Bright Light					
Preop	86%	12%	2%	0%	0%
Month 1	63%	24%	9%	3%	0%
Month 6	70%	23%	2%	5%	0%
Month 12	84%	11%	3%	2%	0%
Variation in Vision in Normal Light					
Preop	95%	4%	1%	0%	0%
Month 1	70%	20%	9%	1%	0%
Month 6	75%	23%	1%	1%	0%
Month 12	81%	13%	5%	2%	0%
Variation in Vision in Dim Light					
Preop	86%	10%	3%	1%	0%
Month 1	61%	27%	9%	3%	0%
Month 6	62%	28%	5%	4%	0%
Month 12	65%	21%	10%	3%	2%
Night Driving Vision Problems					
Preop	86%	12%	2%	0%	0%
Month 1	61%	22%	10%	6%	1%
Month 6	66%	27%	4%	3%	0%
Month 12	82%	10%	3%	3%	2%
Other Symptom					
Preop	100%	0%	0%	0%	0%
Month 1	97%	0%	1%	2%	0%
Month 6	95%	1%	3%	1%	0%
Month 12	100%	0%	0%	0%	0%

During the first week after the procedure you may experience pain, discomfort, blurry vision, tearing, and/or light sensitivity as the *cornea* heals. After the procedure some patients may experience fluctuation in their vision throughout the day.

After *CK*® is performed, you may temporarily experience reduced sharpness of vision and reduced depth perception for distance and up close tasks. Symptoms such as mild blurred vision, headaches, and variable vision may be experienced for a short time or for several weeks as you adapt to *monovision*. You should avoid visually demanding tasks or situations for the first few weeks after your procedure. Your doctor will tell you when you can resume driving.

During the first month after the procedure, you may notice some glare, sensitivity to light, and difficulty driving at night. Some patients experience small changes in their vision. These changes may occur up to 3 months or more after the procedure. You may have blurred vision for the first few months after *CK*®. This is mild and temporary, but you may require glasses for tasks such as driving or reading. Some patients also experience an increase in *astigmatism*, which may affect their vision.

Are You A Good Candidate for CK®?

CK® is indicated for the temporary improvement of near vision in one eye. It is temporary because the amount of correction diminishes over time. However, some patients retain some or all of their *CK*® correction.

If you are considering *CK*®, you must:

- Be at least 40 years of age.
- Have healthy eyes with no eye disease, corneal abnormality or previous corneal or refractive surgery.
- Have *presbyopia* symptoms that require a refractive correction of up to -2.00 *diopters* to achieve acceptable near vision.
- Have a stable *refraction* for one year prior to the preoperative examination (no more than 0.50 *diopter* change).
- Be able to lie flat without difficulty.
- Be able to maintain steady fixation during the procedure.
- Be able to tolerate eye drops to numb your eye.
- Be informed of *CK*® risks and benefits.
- Be willing to sign an Informed Consent Form, if requested by your eye care professional.
- Discuss payment options with your doctor's office since *CK*® is not covered under most health insurance plans.

- Have successfully completed a *monovision* trial using spectacles or contact lenses. It is important that you follow your doctor's suggestions for adaptation to *monovision* during this trial period. You should discuss any concerns that you may have during the adaptation period.

Before the CK® Procedure

First, if you have an interest in *CK®*, you will need to have an examination before treatment to determine if your eye is healthy and suitable for *CK®*. This exam will include a complete medical and eye history, and a complete evaluation of both eyes. In addition, this examination will involve mapping your *cornea* with a computer to determine if it is smooth and properly shaped.

To determine your ability to adapt to the *monovision* resulting from *CK®*, in which one eye is used for near vision and the other eye is used for distance vision, you will complete a *monovision* trial or have a documented history of successful *monovision* wear. This assessment is important in determining whether *CK®* is appropriate for you.

WARNING:

If you wear soft contact lenses, it is very important to stop wearing them at least 2 weeks before the evaluation. If you wear hard or rigid gas permeable contact lenses you will need to stop wearing them at least 3 weeks before the evaluation. Failure to do this will produce poor results since it might affect the determination of your baseline refraction and amount of surgical correction needed.

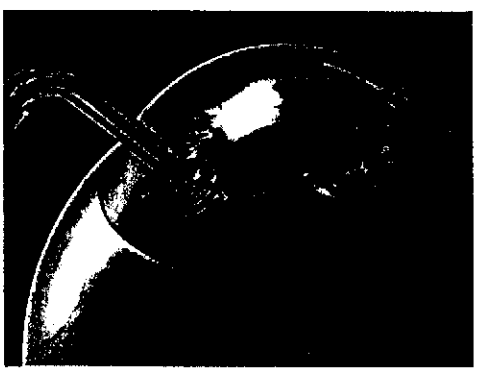
Before the procedure:

- Tell your doctor if you take any medications or have any allergies.
- Talk with your doctor about eating or drinking right before the procedure.
- Arrange for transportation, since you must not drive right after the procedure. Your doctor will tell you when you can resume driving.

The Day of the CK® Procedure

Before the *CK®* procedure, your doctor will ask you to lie on your back on a surgical bed. Your doctor will place anesthetic (numbing) drops into your eye to be treated. These drops ensure the painless application of treatment. Then, your doctor will place an instrument between your eyelids to hold them open during the *CK®* procedure. The eye not having the procedure will be taped shut.

The microscope will be positioned over your eye and the surgeon will ask you to look directly at the microscope's light. The surgeon will mark your *cornea* using an inked instrument. This instrument will provide the template, which will be used to guide the surgeon during treatment. It is important to continue looking at the microscope's light throughout the marking process and procedure to ensure proper treatment application. During the procedure, you may hear a series of beeps. These audible tones provide the surgeon with an indication that the appropriate energy has been delivered to your *cornea*. The Keratoplast™ Tip will be used to introduce the *radiofrequency energy* into your *cornea*. This will be repeated 16 to 24 times depending on the amount of treatment you require. Overall, the procedure takes about 5 minutes. The surgeon will measure your correction and will apply additional treatment if necessary.



CK® Procedure

After the procedure is complete, your doctor will place drops into your eye, which aid in the healing process. The numbing drops will wear off in about 30-45 minutes. After this time, you may experience some discomfort or pain for 1 to 3 days. You will be offered dark glasses to wear as needed.

The First Days After the CK® Procedure

You may be somewhat sensitive to light and have the feeling that something is in your eye for the first few days. Sunglasses may make you more comfortable during this time.

Your doctor can prescribe pain medication to make you more comfortable during this time. You should contact your doctor if you notice any pain (beyond the first week after the procedure) or any change or loss of vision in your eye.

IMPORTANT:

Use the *antibiotic* eye drops, non-steroidal *anti-inflammatory* eye drops and lubricants as directed by your doctor. Your results depend upon you following your doctor's directions.

Please refer to the section entitled "*What are the Risks*?" for information on the complications and adverse reactions that may occur in the first few weeks after the procedure.

The Weeks Following the CK® Procedure

During the first 24 to 48 hours after *CK®*, when you look in the mirror, you may be able to see the *CK®* treatment spots on your *cornea*. These spots will fade and you should not be able to see them in the mirror after 48 hours.

You may also experience blurred vision with or without glasses in the first week to one month after the procedure. Some patients may experience a reduction in their vision with glasses in the first week to one month as compared to before the procedure, but this tends to improve over time.

Some patients may experience small changes or fluctuations in their vision. For example, their vision may improve or worsen. These changes may occur for several months after the procedure. Your vision with and without glasses should become stable within the first few months after the procedure. Please refer to the section entitled "*What are the Benefits*?" for information on visual outcomes in the clinical study.

Visually demanding situations should be avoided during the adaptation period as described above. You may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that you be a passenger first to make sure that your vision is satisfactory for operating an automobile. Your doctor will tell you when you can resume driving.

Having supplemental glasses to wear for specific visual tasks, such as driving at night and reading fine print, may improve your success with the *CK®* procedure. Additionally, make use of proper illumination when carrying out demanding visual tasks.

Subjective Patient Questionnaire

At several time points after the procedure, patients completed a questionnaire for the symptoms shown in the table below. Table 7 lists patient symptoms reported as unchanged or better when comparing before treatment (preoperative) to 6 months (92 eyes) and 12 months (62 eyes) after treatment.

Table 7 – Comparison of Symptoms Before and After Treatment

	6 Months	12 Months
Symptoms	**Unchanged or Better**	**Unchanged or Better**
Light Sensitivity	97%	95%
Headache	99%	100%
Pain	99%	100%
Redness	99%	100%
Dryness	96%	98%
Excessive Tearing	100%	100%
Burning	99%	100%
Gritty, Scratchy, or Sandy Feeling	99%	98%
Glare	93%	93%
Halos	89%	92%
Blurred Vision	89%	90%
Double Vision	95%	89%
Fluctuation of Vision	90%	92%
Variation of Vision in Bright Light	93%	95%
Variation of Vision in Normal Light	98%	93%
Variation of Vision in Dim Light	96%	90%
Night Driving Vision Problems	95%	94%
Other Symptoms	95%	100%

Patients were asked to evaluate their quality of vision, satisfaction and quality of depth perception after *CK*®. Table 8 shows quality of vision results at 6 and 12 months after *CK*®. Quality of vision was evaluated on a scale of "no improvement" to "extreme improvement" ("worse" was not an option).

Table 8 – Quality of Vision After Treatment

	6 Months n=93	12 Months n=62
Extreme improvement	43%	39%
Marked improvement	32%	42%
Moderate improvement	14%	15%
Slight improvement	8%	3%
No improvement	3%	2%

Table 9 provides results for patients' satisfaction at 6 and 12 months after *CK*®.

Table 9 – Patient Satisfaction After Treatment

	6 Months n=93	12 Months n=62
Very satisfied	52%	56%
Satisfied	28%	27%
Neutral	17%	11%
Dissatisfied	3%	5%
Very dissatisfied	0%	0%

Table 10 lists the patient responses reported for their quality of depth perception before and after *CK*® (depth perception before *CK*® was assessed while wearing *monovision* contact lenses).

Table 10 – Quality of Depth Perception Before and After Treatment

	Before CK® n=81	6 Months n=93	12 Months n=61
Excellent	19%	24%	20%
Very good	37%	42%	39%
Good	38%	26%	34%
Fair	5%	6%	7%
Poor	1%	2%	0%

Tables 11 and 12 provide patient responses reported for their use of spectacles after *CK*®.

Table 11 – Spectacle Dependence for Near Vision

	6 Months n=93	12 Months n=63
Do you wear spectacles or contact lenses for near vision in your treated eye?	39%	52%
All near activities	15%	13%
Working on computer*	15%	16%
Reading	37%	52%

* Monitor distance and screen contrast not standardized.

Table 12 – Spectacle Dependence for Distance Vision

	6 Months n=93	12 Months n=63
Do you wear spectacles or contact lenses for distance vision in your treated eye?	2%	3%
Whenever driving	1%	2%
Night driving only	2%	2%
Watching TV or movies	0%	0%
Sporting events/activities only	0%	2%
All distance activities (full time)	0%	2%

Even in subjects who achieve good near vision without glasses post-operatively, some use of spectacles is likely to be required for certain tasks. The goal of *monovision* is to improve functional near vision. However, complete independence from spectacles for all near tasks is not a goal of this procedure and is unrealistic. The challenge of very fine point near tasks may be beyond the capability of this procedure, and perhaps of any *monovision* technique. Spectacle correction over *monovision* may be required for specific near point tasks, such as reading fine print or demanding visual tasks (i.e. reading which requires detail and persists for a long duration) where *binocular* near vision may be preferred.

Questions to Ask Your Doctor

You may want to ask the following questions to help you decide if *CK*® is right for you:

- What if I have uncontrolled eye movements (nystagmus) or another condition that prevents a steady gaze, which is required during the *CK*® procedure?
- Which type of refractive condition do I have?
- What other options are available to correct my *presbyopia*?
- Will I need to limit my activities after the *CK*® procedure? If yes, for how long?
- What are the benefits of *CK*® for my amount of *presbyopia*?
- What quality of vision can I expect in the first few months after the *CK*® procedure?
- If *CK*® does not correct my vision, what is the possibility that my glasses would need to be stronger than before? Could my need for glasses increase over time?
- If needed, will I be able to wear contact lenses after *CK*®?
- How is *CK*® likely to affect my need to wear glasses or contact lenses as I get older?
- Will my *cornea* heal differently if injured after having *CK*®?
- Do I need to have the *CK*® procedure on one or both of my eyes?
- Should I have the *CK*® procedure performed on both of my eyes at the same time?
- If applicable, how long will I have to wait before I can have the *CK*® procedure on my other eye?
- What vision problems might I experience if I have *CK*® performed only on one eye?
- What are the costs involved and the follow-up care requirements? Most health insurance policies do not cover refractive surgery.

Self-Test

Are you an informed and educated patient?

Take the test below and see if you can correctly answer these questions after reading this booklet.

	TRUE	FALSE
1. The *CK*® procedure is risk free.	☐	☐
2. It doesn't matter if I wear my contact lenses when my doctor told me not to.	☐	☐
3. After the *CK*® procedure, there is a good chance that I will be less dependent on eyeglasses.	☐	☐
4. I may need reading glasses after the *CK*® procedure.	☐	☐
5. There is a risk that I may lose some vision after the *CK*® procedure.	☐	☐
6. It does not matter if I am pregnant or nursing.	☐	☐
7. If I have an *autoimmune disease*, I am still a good candidate for *CK*®.	☐	☐

Answers to the Self-Test are found on page 33.

Summary of Important Information

- *CK®* is not reversible.
- Your improvement in near vision may diminish over time.
- *CK®* may not eliminate the need for glasses.
- Your vision must be stable for at least one year before the *CK®* procedure. You will need written evidence that your eyesight prescription has not changed more than 0.50 *diopters*.
- You must have demonstrated acceptance to *monovision* correction.
- Pregnant and nursing women should postpone the *CK®* procedure until they are no longer pregnant or nursing.
- You would not be a good candidate if you have *collagen vascular* or *autoimmune diseases*. If you have a condition that makes wound healing difficult, you would not be a good candidate.
- Surgery is not risk-free. Please read this entire booklet before you agree to the *CK®* procedure. Read the "What are the Benefits?" and "What are the Risks?" sections carefully.
- There are alternatives to the *CK®* procedure.
- The vision requirements of some occupations, such as airplane or military pilots, may not be met by having *CK®*, *LASIK*, or *PRK*.
- Before considering the *CK®* procedure you should have a complete eye examination and talk with at least one eye care professional about the time required for healing and the potential benefits, risks, and complications of the *CK®* procedure.
- The *CK®* procedure for improving near vision creates *monovision* (one eye for near vision and one eye for distance vision). This may result in a vision compromise in visually demanding situations.
- Even in subjects who achieve good near vision without glasses post-operatively, some use of spectacles is likely to be required for certain tasks. The goal of *monovision* is to improve functional near vision. However, complete independence from spectacles for all near tasks is not a goal of this procedure and is unrealistic. The challenge of very fine point near tasks may be beyond the capability of this procedure, and perhaps of any *monovision* technique. Spectacle correction over *monovision* may be required for specific near point tasks, such as reading fine print or demanding visual tasks (i.e. reading which requires detail and persists for a long duration) where *binocular* near vision may be preferred.
- There is not enough data to demonstrate the effectiveness of retreatments with *CK®*.

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Collagen Vascular Disease: a medical condition that may result in *inflammation* or swelling of parts of the body; such as muscles, joints, and blood vessels. Examples of this type of disease are lupus and rheumatoid arthritis. If you have this type of condition, you should not have the *CK®* procedure.

Conductive Keratoplasty® (CK®): a procedure that utilizes a controlled release of *radiofrequency energy* to increase the temperature of corneal tissue. The treatment is applied with a probe that is introduced 16 to 24 times into the *cornea* in a circular pattern, which results in an increased curvature of the *cornea*.

Contraindications: any special condition that results in the *CK®* procedure not being recommended.

Cornea: the clear front surface of the eye. Surgery such as *CK®*, *LASIK*, *PRK*, and RK reshape the *cornea* to correct vision.

Corneal Edema: see *Corneal Swelling*.

Corneal Epithelial Defect: area in the *epithelium* that is temporarily compromised.

Corneal Epithelium: the top layer of the *cornea*.

Corneal Erosion: temporary loss of tissue of the front, clear portion of the eye (*cornea*).

Corneal Flap: a thin slice of tissue on the surface of the *cornea* made with a microkeratome at the beginning of *LASIK* surgery. This *corneal flap* is folded back before the laser is applied to the inner layers of the *cornea*.

Corneal Swelling: an abnormal accumulation of fluid in the *cornea*. This condition is usually temporary and usually does not significantly affect vision.

Corneal Ulcer: an infection of the *cornea* that may result in a loss of vision.

Crystalline Lens: a structure inside the eye that helps to focus light onto the back of the eye.

Dilated: when eye drops instilled by your doctor are used to make your pupil larger and to prevent *accommodation*.)

Diopter: a unit of measurement of the power of the eye's lens (it determines the amount of *hyperopia*, myopia, and/or *astigmatism* of an eye).

Emmetropia: the condition where the eye is absent of refractive error.

Farsightedness: a term for *hyperopia* (see *hyperopia*).

Glaucoma: a condition usually associated with high eye pressure. This condition results in damage to the nerve at the back of the eye and possible loss of vision.

Halos: circular flares or rings of light that may appear around a headlight or other lighted objects. This symptom may occur after refractive surgery.

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Haze: a cloudiness of the *cornea* that may occur after refractive procedures.

Herpes simplex: a type of infection caused by a virus that can recur. This virus typically causes cold sores and/or vesicles to appear on the face or other parts of the body. You should discuss any history of this condition with your doctor before having the *CK*® procedure.

Herpes zoster: a type of infection caused by a virus that can recur. This condition is a reactivation of the chicken pox virus as an adult. Vesicles appear on only one side of the body. You should discuss any history of this condition with your doctor before having the *CK*® procedure.

Hyperopia: the medical term for *farsightedness*. An eye condition that may result in blurred distance and blurred near vision. The *cornea* and *crystalline lens* focus light rays from distant and near objects behind the *retina*. Farsighted eyes may see better at distance than at near without glasses or contact lenses, but usually require correction for both distances.

Immunodeficiency Disease: a medical condition that alters the body's ability to heal. An example is AIDS. If you have this type of condition, you should not have the *CK*® procedure.

Inflammation: the body's reaction to injury or disease. Procedures that alter the eye, such as *CK*®, can also cause inflammation.

Keratoconus: an eye condition that results in a thinning of the *cornea*. A change in corneal shape like a cone typically occurs. If you have this type of condition, you should not have the *CK*® procedure.

Laser In-Situ Keratomileusis (LASIK): a surgical procedure where a device called a microkeratome is used to surgically create a thin, hinged flap of corneal tissue. The *corneal flap* is folded back, an excimer laser beam is directed to the corneal surface exposed beneath the *corneal flap* to remove tissue for refractive correction, after which the *corneal flap* is brought back into place.

Monocular: located in or referring to one eye.

Monovision: a clinical technique in which one eye provides distance vision while the other eye is treated to provide near vision.

Photorefractive Keratectomy (PRK): a type of surgery used to correct vision by reshaping the surface of the *cornea* using an excimer laser. Tissue is removed from the outermost surface of the *cornea*.

Presbyopia: a condition that affects most people over the age of 40, as the aging process affects the eye's natural ability to bring near objects into focus. Occurs when the lens inside the eye loses flexibility, preventing accurate focusing on objects that are up close or near.

Radiofrequency Energy: a form of electrical energy (radio waves) utilized by the ViewPoint™ CK System and commonly used by other medical devices.

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Refraction: the act of determining the focal condition of the eye and its corrections by optical devices

Retina: the back surface of the inside of the eye. The retina takes focused light images and transfers them to the brain.

Stereopsis: three-dimensional vision possible only when you use both eyes together.

Strabismus: misalignment of the visual axes of the eyes (i.e., the eyes are not straight); commonly called crossed eyes.

Patient Assistance Information

Primary Eye Care Professional

Name: _____

Address: _____

Phone: _____

CK® Surgeon

Name: _____

Address: _____

Phone: _____

Treatment Location

Name: _____

Address: _____

Phone: _____

Medical Device Manufacturer:

Refractec, Inc.
5 Jenner, Suite 150
Irvine, CA 92618
USA
Tel: (800) 752-9544
Fax: (949) 784-2601
www.refractec.com