FACTS YOU NEED TO KNOW ABOUT the ViewPoint™ CK System and the Conductive Keratoplasty℠ (CK℠) Procedure

PATIENT INFORMATION BOOKLET

For Farsightedness (Hyperopia)
from +0.75 to +3.25 D

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.

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.

Refractec, Inc.
5 Jenner, Suite 150
Irvine, CA 92618
USA
Tel: 800.752.9544
Fax: 949.784.2601
www.refractec.com

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Glossary

This glossary contains definitions of terms used in this information booklet. If you have any questions about these terms, please ask your doctor. Your doctor can answer your medical questions.

Astigmatism: an eye condition that results in blurred distance and/or near vision. Typically, this is due to the front of the eye (cornea) being shaped like a football. The light rays are then focused at different points inside the eye causing blurred or distorted vision.

Antibiotic Medication: a drug that treats or prevents infection. Your doctor may prescribe this type of medication after the procedure.

Anti-inflammatory Medication: a drug that reduces inflammation or the body's reaction to injury or disease. A procedure that alters the eye, such as CK℠, can also cause inflammation. Your doctor may prescribe this type of medication after the procedure.

Autoimmune Disease: a medical condition in which the body attacks itself that may result in inflammation or swelling of parts of the body; such as muscles, joints, and blood vessels. Examples of this condition are rheumatoid arthritis and multiple sclerosis. If you have this type of condition, you should not have the CK℠ procedure.

Cataract: a clouding of the crystalline lens inside the eye that can cause a loss of vision. This clouding tends to develop with older age and may affect different parts of the crystalline lens.

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 8 to 32 times into the cornea in a circular pattern, which results in an increased curvature of the cornea. This procedure was designed to treat farsightedness (hyperopia) without cutting or removing corneal tissue.

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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 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.

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

Diopter: a unit of measurement for determining the amount of hyperopia, myopia, and/or astigmatism of an eye.

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.

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

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better at distance than at near without glasses or contact lenses, but usually require correction for both distances.

Hyperopic Astigmatism: an eye that combines hyperopia and astigmatism. The cornea and the crystalline lens focus the light rays at different points behind the retina and results in blurred distance and near vision.

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.

Laser Thermal Keratoplasty (LTK): a medical procedure in which laser energy is applied to the cornea to reshape the cornea to reduce farsightedness.

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.

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

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

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Introduction

This brochure provides information to help you decide whether or not to have Conductive Keratoplasty℠ (CK℠) for the correction of your farsightedness (hyperopia). Please read this brochure carefully and discuss the information with your ophthalmologist and his or her staff. Your ophthalmologist can determine if you are a candidate for CK℠.

CK℠ is NOT required to correct farsightedness. You can wear glasses or contact lenses to correct your vision. Another option to see more clearly is to correct your vision with surgery. Some types of surgery correct vision by reshaping the front surface of the eye, the cornea. One type of surgery that reshapes the cornea is photorefractive keratectomy (PRK). PRK uses a laser to shape the corneal surface. Laser in-situ keratomileusis (LASIK) is another surgical procedure that uses a laser to correct farsightedness. In the LASIK procedure, a corneal flap is created and folded back and the laser energy is then applied to the inner layers of the cornea. Afterwards, the corneal flap is folded back into place on the cornea. Another procedure that uses a laser is laser thermal keratoplasty (LTK), which reshapes the cornea to treat hyperopia.

If you choose to have CK℠ to correct your farsightedness, you may benefit from having both of your eyes treated with CK℠ during the same appointment. Sometimes, however, it is better to have only one eye treated at a time with CK℠. This is something you should discuss with your ophthalmologist.

You are the only one who can decide whether CK℠ is right for you. The information in this brochure should help you make your decision. Make sure that all of your questions have been answered by your ophthalmologist before deciding to have CK℠.

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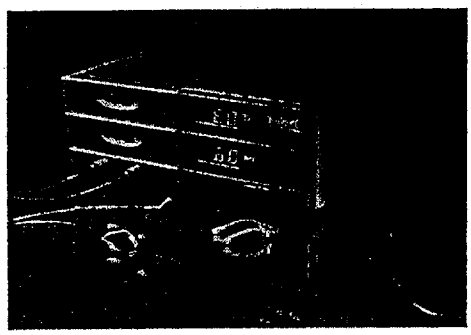
Conductive Keratoplasty℠ (CK℠) is a procedure designed to treat farsightedness without using a laser. The CK℠ treatment utilizes a controlled release of radiofrequency (RF) energy to increase the temperature of corneal tissue. The treatment is applied with a probe that is introduced 8 to 32 times into the cornea in a circular pattern, which results in an increased curvature of the cornea to correct your vision.

The **ViewPoint™ CK℠ System** is the device used to perform the CK℠ procedure. A handpiece with a Keratoplast™ Tip (a sterile, stainless steel probe about the size of a human hair) delivers radiofrequency energy into the cornea.



ViewPoint™ CK℠ System

CK℠ Keratoplast™ Tip Compared To A Human Hair

Please read this patient information booklet carefully and discuss any questions you may have with your doctor. It is important that you make an informed decision about CK℠ with the help of your doctor.

Although vision without glasses is improved after CK℠, some people still need glasses or contact lenses for some tasks. CK℠ does not eliminate the need for reading glasses. In addition, the vision requirements of some occupations, such as airplane or military pilots, may not be met by having CK℠, LASIK, LTK, or PRK.

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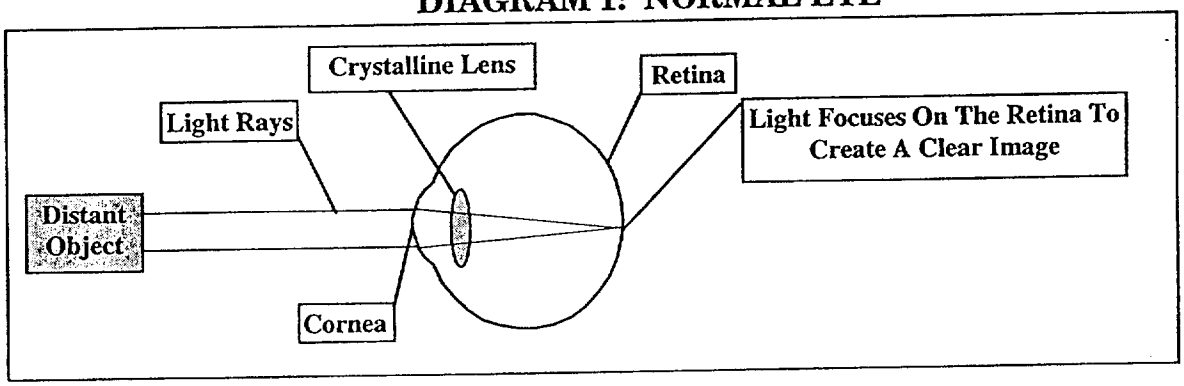
How Does CK℠ Correct Hyperopia?

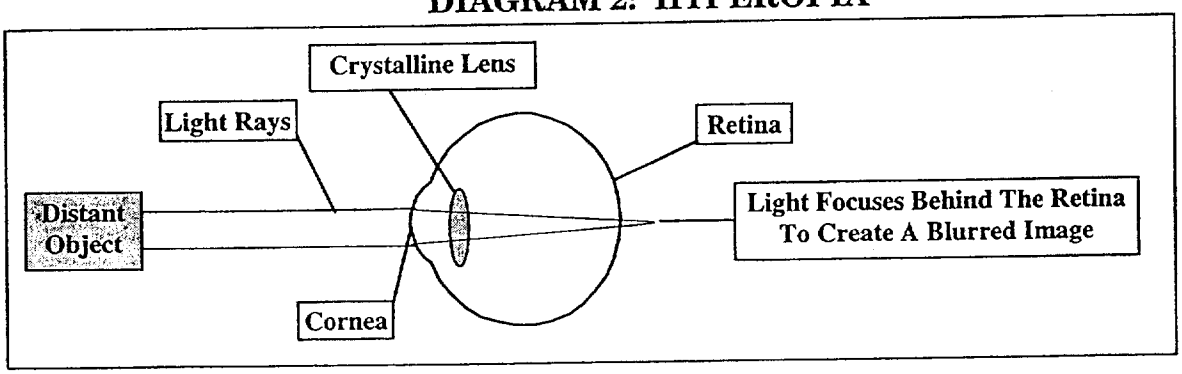
The human eye functions like a camera. The lens in a camera focuses light images onto film. In the same way, the cornea and the crystalline lens inside the eye focus light images on the retina, the back surface of the eye (see Diagram 1). Blurred vision occurs when the light does not focus precisely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

DIAGRAM 1: NORMAL EYE



Hyperopia (farsightedness) is an eye condition where people may see objects better in the distance than near. The cornea and crystalline lens focus light rays from distance and near objects behind the retina. Diagram 2 shows how light from distance objects focus behind the retina to create a blurred image.

DIAGRAM 2: HYPEROPIA



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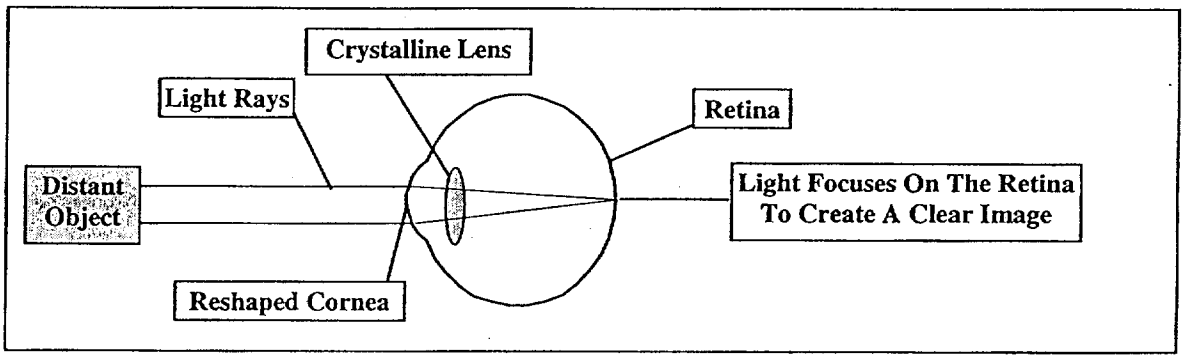
CK[SM] can change how the eye focuses light by reshaping the cornea to correct hyperopia. CK[SM] uses a controlled released of radiofrequency energy to heat and shrink the corneal tissue, which steepens the cornea. This steepening corrects the point of focus so that light focuses properly on the retina. CK[SM] reshapes the cornea without changing any other parts of the eye. Diagram 3 shows how CK[SM] can reshape the cornea to provide clearer vision.

DIAGRAM 3: CORRECTION OF VISION AFTER CK[SM]



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Precautions

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

- Eyes with diseases of the cornea (for example, scar, infection, etc.)
- Eyes with previous surgery or injury to the center of the cornea where CK℠ will reshape the cornea
- Eyes with previous intraocular or corneal surgery (for example, cataract surgery)
- 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)
- Patients under 40 years of age
- Eyes with more than 3.00 diopters of farsightedness
- Eyes with more than 0.75 diopters of astigmatism
- Eyes with previous refractive surgery (including previous CK℠ surgery)

If you have any of the above, 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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What Are the Benefits of CK[SM]?

CK[SM] has many benefits including its ability to improve your uncorrected distance vision (your vision without glasses or contact lenses used to see objects at a distance). CK[SM] is also 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[SM] include:

- CK[SM] can treat between 0.75 and 3.25 diopters of hyperopia or farsightedness.
- CK[SM] can greatly reduce your need for glasses or contact lenses used to see in the distance.
    - o You may find, after having CK[SM], that you wear your glasses less during the day or only during certain activities.
- CK[SM] may even eliminate your need for glasses or contact lenses used to see in the distance.

What Are the Risks of CK℠?

CK℠ is a refractive procedure and as such, carries potentially serious risks. Please review this booklet and discuss the risks with your doctor.

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.

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 be nearsighted for the first few months after CK℠. This is mild and temporary, but you may require glasses for tasks such as driving. Some patients also experience an increase in astigmatism, which may affect their vision.

In clinical studies of the ViewPoint™ CK℠ System, the following complication was reported on the day of the procedure at a rate of less than 1%:

- Corneal scratch

The following adverse events were reported on the day of the procedure at a rate of less than 1%:

- Corneal perforation (later resolved and the patient was treated successfully)
- Procedure could not be performed and had to be rescheduled due to technical difficulties with the ViewPoint™ CK℠ System

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At the 1 week visit, each of the following complications were reported at a rate of less than 1%:

- Blurred vision
- Conjunctivitis (discharge, redness, and swelling)
- Double vision
- Eyelid inflammation (stye)

The following adverse event was reported at 1 week at a rate of less than 1%:

- Inflammation (mild iritis)

Are You A Good Candidate for CK℠?

CK℠ is indicated for the temporary reduction of farsightedness. 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 farsightedness between 0.75 and 3.00 diopters with up to 0.75 diopters of astigmatism
- 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

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Things to consider:

- CK℠ 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.
- Your vision may continue to change over time.
- Your improved vision after the CK℠ treatment may diminish over time. Based on existing information from the clinical trial, approximately 11% of the correction seen at 6 months is gone at 12 months, with some patients retaining some or all of their correction.
- If your results with CK℠ are not satisfactory and you desire a second procedure, it is unproven 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.
- You may experience improvement in your near vision such as being able to see objects close up, like reading a book without glasses, as well as an improvement in distance vision. However, most likely this improvement in near vision will go away over time while the improvement in distance vision may last longer.
- The goal of CK℠ is to improve your ability to see objects at a distance, not improve your ability to see objects close up.

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What to Expect

The CK[SM] procedure can be performed on one eye at a time or on both eyes during the same session.

Before the CK[SM] Procedure

First, if you have an interest in CK[SM], you will need to have a preoperative examination to determine if your eye is healthy and suitable for CK[SM]. 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.

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.

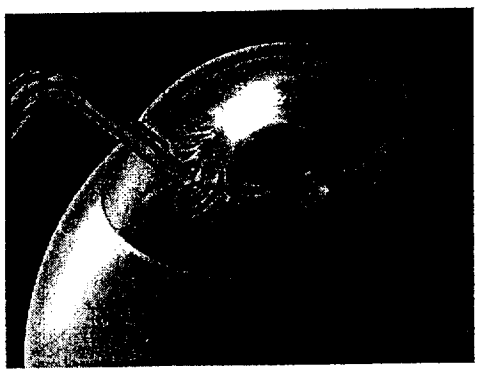
Before the procedure:

- 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 may 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 8 to 32 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

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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 mildly 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.

DO NOT rub your eyes for the first 3 to 5 days. Your doctor can also 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 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 of CK℠?*" for information on the complications and adverse reactions that may occur in the first few weeks after the procedure.

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.

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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 of CK℠?*" for information on visual outcomes in the clinical study.

The First Week 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.

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Contraindications

You should **NOT** have the CK[SM] procedure 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 cornea that is too thin for the procedure to be completed safely.**
- **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 have a tendency to form scars.**
- **You have a history of Herpes simplex or Herpes zoster in your eye.**
- **You have severe, untreatable dry eye.**
- **You have an implantable electrical device such as a pacemaker, defibrillator, or cochlear implant.**
- **You have narrow angles** – since 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[SM] procedure.**

Warnings

Discuss with your doctor if:

- You have had changes in your vision over the previous 12 months. Unstable vision may result in poor treatment results.
- You have uncontrolled eye movements (nystagmus) or another condition that prevents a steady gaze, which is required during the CK℠ procedure.

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Summary of Important Information

- CK℠ is not reversible.
- CK℠ may not eliminate the need for reading glasses.
- Your vision must be stable for at least one year before the CK℠ procedure. You will need written evidence that your farsightedness has not changed more than 0.50 diopters.
- 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 *Benefits* and *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, PRK, or LTK.
- 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.

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Questions to Ask Your Doctor

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

- Which type of refractive condition do I have?
- What other options are available to correct my farsightedness?
- 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 farsightedness?
- 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℠?
- Should I have the CK℠ procedure on my other eye?
- 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 treatment.

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Self-Test

Are You an Informed and Educated Patient?

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

	TRUE	FALSE
1. Refractive procedures, such as CK℠, PRK, LASIK, and LTK, are risk free.	☐	☐
2. It does not matter if I wear my contact lenses when my doctor told me not to wear them.	☐	☐
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 Self-Test Questions:
1. False (see "What Are the Risks of CK" on Page 12); 2. False (see "Before the CK Procedure" on Page 16);
3. True (see "What Are the Benefits of CK" on Page 11); 4. True (see "Introduction" on Page 6);
5. True (see "What Are the Risks of CK" on Page 12); 6. False (see "Contraindications" on Page 20);
7. False (see "Contraindications" on Page 20)

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Summary of Clinical Study Data

The results listed in the following section are from U.S. clinical studies of the ViewPoint™ CK℠ System.

The following table lists the vision outcomes at 12 months after the procedure. The information includes the percentage of patients who achieved each level of vision with and without glasses.

U.S. CLINICAL STUDY RESULTS
12 MONTHS AFTER THE CK℠ PROCEDURE

	n/N	%
Visual Acuity 20/20 or better **without** glasses	191/344	56%
Visual Acuity 20/25 or better **without** glasses	257/344	75%
Visual Acuity 20/40 or better **without** glasses	318/344	92%
Visual Acuity 20/20 or better **with** glasses	356/381	93%
Visual Acuity 20/25 or better **with** glasses	377/381	99%
Visual Acuity 20/40 or better **with** glasses	381/381	100%
Loss of **more** than 2 lines of visual acuity **with** glasses	1/381*	<1%

* Not related to the CK℠ procedure

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In U.S. clinical studies of the ViewPoint™ CK℠ System, the following adverse events and complications related to the CK℠ procedure were reported at 12 months after treatment.

Adverse Events

Late onset of haze with loss of vision	0 in 381 eyes
Loss of more than 2 lines of best corrected vision on eye chart (best possible vision with glasses or contacts)	1 in 381 eyes*
Corneal ulcer	0 in 381 eyes
Corneal edema at 1 month or later (swelling)	0 in 381 eyes
Corneal infection	0 in 381 eyes
Corneal scar	0 in 381 eyes
Uncontrolled intraocular pressure	0 in 381 eyes
Increase in intraocular pressure > 25 mm Hg	1 in 381 eyes
Onset of cataract unrelated to age	0 in 381 eyes
Retinal detachment (torn layer in the back of the eye)	0 in 381 eyes
Retinal vascular accident (stroke in back of eye)	0 in 381 eyes
Secondary surgical intervention	1 in 381 eyes*

* Not related to the CK℠ procedure

Complications

Peripheral corneal epithelial defect	1 in 381 eyes
Corneal edema between 1 week and 1 month	0 in 381 eyes
Corneal erosion (loss of outer most layer of eye)	0 in 381 eyes
Double/ghost images	4 in 381 eyes
Foreign body sensation	0 in 381 eyes
Pain	0 in 381 eyes

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At 12 months after the procedure, patients completed a questionnaire for the symptoms shown in the table below. Each symptom was rated as "none," "mild," "moderate," "marked," or "very severe." As you can see in the table below, most of the patients rated these symptoms as "none" or "mild."

U.S. CLINICAL STUDY PATIENT QUESTIONNAIRE RESULTS AT 12 MONTHS

Subjective Responses	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%

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Subjective Responses	None	Mild	Moderate	Marked	Very Severe
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%
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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Subjective Responses	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 Symptom					
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 least 5% of the study patients reported a postoperative increase in glare, halos, fluctuation of vision, and variation in vision in dim light at 12 months.

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Patients also reported their satisfaction with their results on a questionnaire 12 months after the procedure, which was rated as "very satisfied," "satisfied," "neutral," "dissatisfied," or "very dissatisfied." Over 80% of the patients surveyed were "satisfied" or "very satisfied" with their CK[SM] results. "Dissatisfied" or "very dissatisfied" was reported for 9% of the patients surveyed.

U.S. CLINICAL STUDY
PATIENT SATISFACTION RESULTS AT 12 MONTHS

	n/N	%
Very satisfied	185/369	50%
Satisfied	115/369	31%
Neutral	34/369	9%
Dissatisfied	27/369	7%
Very dissatisfied	8/369	2%

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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
U.S.
Tel: (800) 752-9544
Fax: (949) 784-2601
www.refractec.com

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