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

PATIENT INFORMATION BOOKLET

For Farsightedness (Hyperopia)

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.

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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Glossary

This glossary contains definitions of terms used in this information booklet. If you have any questions about these terms, please ask you 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 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 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 medical procedure, which utilizes radio frequency energy to gently heat and reshape the cornea. This procedure was designed to correct farsightedness (hyperopia) without cutting or removing corneal tissue.

**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 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 near vision. The cornea and 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.
Hyperopic Astigmatism: an eye that combines hyperopia and astigmatism. The cornea and the 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 flap is folded back, an excimer laser beam is directed to the corneal surface exposed beneath the flap to remove tissue for a refractive correction, after which the 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.

Non-Steroidal Anti-inflammatory Drug (NSAID): a type of drug that reduces inflammation or the body’s reaction to injury or disease. Your doctor may prescribe this type of medication after the procedure.

Ocular Hypertension: an increase in the pressure inside the eye.

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.

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

Do you need to wear glasses or contact lenses to help you to see clearly? One 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, the laser energy is applied to the inner layers of the cornea. This procedure uses a device called a microkeratome to create a thin slice of tissue on the surface of the cornea at the beginning of the LASIK procedure. The corneal flap is folded back and the laser is applied to the inner layers of the cornea. Afterwards, the 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 temporarily treat hyperopia.

Conductive Keratoplasty (CK) is a procedure designed to reduce farsightedness without using a laser. Radio Frequency (RF) energy is used to gently heat the corneal tissue and reshape the cornea. This process shrinks the collagen tissue at specific treatment spots to create a band of tightening. It is the band of tightening that steepens the cornea and corrects the point of focus so that light focuses properly on the retina, to correct your vision. CK is less invasive than LASIK surgery, and does not require creation of a corneal flap using a microkeratome.

The ViewPoint™ CK System is the device used to perform the CK procedure. A handpiece with a Keratoplast™ Tip delivers RF energy into the cornea.
Please read this information carefully and discuss any questions 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/military pilots, may not be met by having CK, LASIK, LTK, or PRK.
How Does CK Correct Hyperopia?

The human eye functions like a camera. The lens in a camera focuses light into images onto film. In the same way, the cornea and the lens inside the eye focus light into 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 better in the distance than at near. The cornea and 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 cause a blurred image.

**DIAGRAM 2: HYPEROPIA**
CK can change how the eye focuses light by reshaping the cornea to correct hyperopia. CK uses RF energy to gently 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 3 shows how CK can reshape the cornea to provide clearer vision.
What Are the Benefits of CK?

CK may reduce farsightedness. CK may also reduce or eliminate the need to wear glasses or contact lenses to see clearly.

The CK procedure performed with the ViewPoint™ CK System is effective in reducing hyperopia between 0.75 and 3.00 diopters.

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 9 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
AT 9 MONTHS AFTER THE CK PROCEDURE

<table>
<thead>
<tr>
<th></th>
<th>Hyperopia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
</tr>
<tr>
<td>Visual Acuity 20/20 or better <strong>without</strong> glasses</td>
<td>170/340</td>
</tr>
<tr>
<td>Visual Acuity 20/25 or better <strong>without</strong> glasses</td>
<td>250/340</td>
</tr>
<tr>
<td>Visual Acuity 20/40 or better <strong>without</strong> glasses</td>
<td>315/340</td>
</tr>
<tr>
<td>Visual Acuity 20/20 or better <strong>with</strong> glasses</td>
<td>346/376</td>
</tr>
<tr>
<td>Visual Acuity 20/25 or better <strong>with</strong> glasses</td>
<td>370/376</td>
</tr>
<tr>
<td>Visual Acuity 20/40 or better <strong>with</strong> glasses</td>
<td>376/376</td>
</tr>
<tr>
<td>Loss of <strong>more</strong> than 2 lines of visual acuity <strong>with</strong> glasses</td>
<td>2/376</td>
</tr>
</tbody>
</table>
At 9 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 9 MONTHS

Subjective responses rated as “none,” “mild,” “moderate,” “marked” or “very severe”

<table>
<thead>
<tr>
<th>Subjective Responses</th>
<th>None %</th>
<th>Mild %</th>
<th>Moderate %</th>
<th>Marked %</th>
<th>Very Severe %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blurred vision</td>
<td>58</td>
<td>23</td>
<td>12</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Burning</td>
<td>82</td>
<td>11</td>
<td>5</td>
<td>2</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Double vision</td>
<td>74</td>
<td>13</td>
<td>7</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Dryness</td>
<td>60</td>
<td>26</td>
<td>8</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Excessive tearing</td>
<td>83</td>
<td>11</td>
<td>3</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Fluctuation of vision</td>
<td>60</td>
<td>25</td>
<td>7</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Glare</td>
<td>58</td>
<td>28</td>
<td>8</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Gritty, scratchy, or sandy feeling</td>
<td>81</td>
<td>14</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Halos</td>
<td>65</td>
<td>21</td>
<td>9</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Headache</td>
<td>84</td>
<td>9</td>
<td>4</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Light sensitivity</td>
<td>57</td>
<td>27</td>
<td>12</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Night driving vision problems</td>
<td>59</td>
<td>23</td>
<td>8</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Pain</td>
<td>92</td>
<td>5</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Redness</td>
<td>77</td>
<td>15</td>
<td>6</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Variation of vision in bright light</td>
<td>63</td>
<td>24</td>
<td>8</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Variation of vision in normal light</td>
<td>71</td>
<td>17</td>
<td>8</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Variation of vision in dim light</td>
<td>60</td>
<td>19</td>
<td>12</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>
Patients also reported on a questionnaire their satisfaction with their results at 9 months after the procedure, which was rated as “very satisfied,” “satisfied,” “neutral,” “dissatisfied,” or “very dissatisfied.” Approximately 80% of the patients surveyed were satisfied or very satisfied with their CK results. “Dissatisfied” or “very dissatisfied” was reported for 9% of the patients surveyed.

### U.S. CLINICAL STUDY

**PATIENT SATISFACTION RESULTS AT 9 MONTHS**

<table>
<thead>
<tr>
<th>Hyperopia</th>
<th>n/N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very satisfied</td>
<td>176/357</td>
<td>49%</td>
</tr>
<tr>
<td>Satisfied</td>
<td>107/357</td>
<td>30%</td>
</tr>
<tr>
<td>Neutral</td>
<td>42/357</td>
<td>12%</td>
</tr>
<tr>
<td>Dissatisfied</td>
<td>21/357</td>
<td>6%</td>
</tr>
<tr>
<td>Very dissatisfied</td>
<td>11/357</td>
<td>3%</td>
</tr>
</tbody>
</table>
Contraindications

You should **NOT** have the CK procedure if:

- **You are pregnant or nursing** — due to the potential for temporary fluctuation in refraction.
- **You show signs of 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 infection in your eye.**
- **You have severe, untreatable dry eye.**
Warnings

Discuss with your doctor if:

- You have had changes in your vision over the previous 6 to 12 months.
- You have nystagmus (uncontrolled eye movements) or another condition that prevents a steady gaze, which is required during the CK procedure.
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 CK surgery.

Also, you should be aware that the safety and effectiveness of retreatments performed with the ViewPoint™ CK System has not been established.
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, some patients experience pain, discomfort, blurry vision, tearing, and/or light sensitivity as the cornea heals. During the first 2-9 months after the procedure, some patients experience changes in vision.

On the Day of the CK Procedure

In clinical studies of the ViewPoint™ CK System, the following complication was reported on the day of the procedure (n = 401) 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; the procedure could not be performed and had to be rescheduled due to technical difficulties with the ViewPoint™ CK System.

The First Week Following the CK Procedure

- You may experience some pain, discomfort, and a feeling of something in the eye which may last from 1 up to 3 days after the procedure.
- Swelling of the cornea.
- In clinical studies of the ViewPoint™ CK System, each of the following complications were reported at the 1 week visit (n = 391) at a rate of less than 1%: blurred vision; conjunctivitis; double vision; eyelid inflammation or a stye. The following adverse reaction was reported at 1 week at a rate of less than 1%: mild iritis or inflammation.
The First Month Following the CK Procedure

- You may notice some glare, sensitivity to light, and difficulty driving at night.

- Some patients experience small changes in their vision. For example, their vision may improve or worsen. These changes may occur up to 3 months or more after the procedure.

Summary of Adverse Events and Complications – 9 Months After the CK Procedure

In U.S. clinical studies of the ViewPoint™ CK System, the following adverse events and complications related to the CK procedure were reported.

**FDA Safety Criteria**

- Loss of more than 2 lines of best corrected vision on eye chart (best possible vision with glasses or contacts) 1%
- Eyes worse than 20/40 (best possible vision with glasses or contacts); level in most states required to pass driving test 0%
- Eyes with significant astigmatism 1%

**Adverse Events**

- Increase in intraocular pressure (> 25 mm Hg) 1%

**Complications**

- Corneal erosion 0%
- Double vision 1%
- Pain 0%
- Foreign Body Sensation <1%
U.S. clinical studies of the ViewPoint™ CK System have shown the following conditions may occur after the CK procedure. At 9 months after the procedure, patients noted on a questionnaire that these conditions were “none,” “mild,” “moderate,” “marked,” or “very severe,” as shown in the table below. Most of these conditions rated “marked” to “very severe” are not significantly different than what was reported prior to having the CK procedure. At least 5% of the study patients reported a postoperative increase in the following symptoms: glare, halos, and fluctuation in vision.

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<td>3</td>
</tr>
</tbody>
</table>
Are You A Good Candidate for CK?

If you are considering CK, you must:

• Be at least 40 years of age
• Have healthy eyes with no eye disease or corneal abnormality
• Have farsightedness between 0.75 and 3.00 diopters with up to 0.75 diopter 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

CK may not be appropriate for individuals with unrealistic expectations. Patients who expect perfect results, perfect vision under all light conditions, or an instant change in vision may be poor candidates for CK. As with any refractive procedure, CK does not guarantee perfect results. Vision usually stabilizes 6 to 9 months after the procedure. During this time, your vision may not be perfect and you may need to wear glasses or contact lenses.
What Should You Expect During the CK Procedure?

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

Before the CK Procedure

First, if you have an interest in CK, you will need to have a preoperative examination 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.

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 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, please tell your doctor if you take any medications or have any allergies. Also, talk with your doctor about eating or drinking right before the procedure. You should also 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 bed. Your doctor will place anesthetic (numbing) drops into your eye. 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.

Overall, the procedure takes about 5 minutes. The microscope will be positioned over your eye and the surgeon will ask you to fixate on the microscope’s light. The surgeon will mark your cornea. The Keratoplast™ Tip will be placed on your eye and the ViewPoint™ CK System will deliver energy to reshape your cornea. It is important to continue looking at the microscope’s light throughout the treatment. The surgeon will measure your correction and will apply additional treatment if necessary.

After the procedure is complete, your doctor will place drops into your eye. The procedure is painless because of the numbing drops. The numbing drops will wear off in about 45-60 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 after the procedure. 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 your 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.

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. As you heal, you should no longer see these spots.
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 in 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 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.
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.

<table>
<thead>
<tr>
<th>Question</th>
<th>TRUE</th>
<th>FALSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Refractive surgery is risk free.</td>
<td></td>
<td>☐</td>
</tr>
<tr>
<td>2. It does not matter if I wear my contact lenses when my doctor told me not to wear them.</td>
<td></td>
<td>☐</td>
</tr>
<tr>
<td>3. After the CK procedure, there is a good chance that I will be less dependent on eyeglasses.</td>
<td></td>
<td>☐</td>
</tr>
<tr>
<td>4. I may need reading glasses after the CK procedure.</td>
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<td>☐</td>
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<tr>
<td>5. There is a risk that I may lose some vision after the CK procedure.</td>
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<td>☐</td>
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<tr>
<td>6. It does not matter if I am pregnant or nursing.</td>
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<tr>
<td>7. If I have an autoimmune disease, I am still a good candidate for CK.</td>
<td></td>
<td>☐</td>
</tr>
</tbody>
</table>

Answers to Self-Test Questions:
1. False (see Risks on Page 17); 2. False (see Before the CK Procedure on Page 21); 3. True (see Benefits on Page 10); 4. True (see Introduction on Page 7); 5. True (see Risks on Page 18); 6. False (see Contraindications on Page 14); 7. False (see Contraindications on Page 14).
Summary of Important Information

- CK is a permanent procedure and 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/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.
Patient Assistance Information

PRIMARY EYE CARE PROFESSIONAL

Name: _________________________________________
Address: _______________________________________
Phone: _________________________________________

CK SURGEON

Name: _________________________________________
Address: _______________________________________
Phone: _________________________________________

TREATMENT LOCATION

Name: _________________________________________
Address: _______________________________________
Phone: _________________________________________

MEDICAL DEVICE MANUFACTURER

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