

**Informed Consent for Corneal Reshaping- Refractive Therapy**  
Prepared By Hopewell – Lambertville Eye in Association with Paragon CRT  
For more details see [paragoncrt.com](http://paragoncrt.com)

Now you can be free of daytime contact lenses and glasses during your daily activities without undergoing surgery and enjoy great vision! Recent clinical research combined with the latest corneal surface mapping technology, computerized manufacturing and space age oxygen-breathing materials have brought new science to corneal reshaping.

Corneal Refractive Therapy is a non-surgical process clinically developed to reshape the cornea while you sleep. The result is the temporary correction of myopia with or without moderate astigmatism.

Similar in appearance to standard contact lenses, Paragon CRT therapeutic lenses gently reshape the corneal surface during sleep and provide clear, natural vision when the lenses are removed upon waking.

Because Paragon CRT offers freedom from glasses and the hassle of wearing contact lenses during the day, this leading-edge technology can enhance the lifestyle of those requiring vision correction. Active individuals can freely participate in sports without the interference of glasses or bother of contacts. Eye irritation or dryness, sometimes associated with contact lens wear due to outside dust and pollutants, is eliminated.

**How Paragon CRT® works?** In the myopic eye, the focusing power is too great. Light focuses in front of the retina, making distant objects appear blurry. When eyeglasses or contacts are worn, light is focused on the retina so you can see clearly.

Laser surgery is another way to correct myopia. It permanently alters the cornea and corrects the focal point, producing clear vision.

Today, Corneal Refractive Therapy provides a new option for patients. Paragon CRT lenses correct myopia, with or without low or moderate astigmatism, by gently reshaping the cornea while you sleep. When the Paragon CRT lenses are removed in the morning, the treated cornea allows light to focus on the retina. The result is clear, natural vision for all or most of your waking hours

#### FREQUENTLY ASKED QUESTIONS

**1. What is Paragon CRT®?**

Paragon CRT is a specially designed oxygen permeable therapeutic contact lens used in Corneal Refractive Therapy. Corneal Refractive Therapy is a sophisticated, non-surgical process, which reshapes the cornea while you sleep. You remove the lenses when you awake and are able to go throughout the day without any other correction.

**2. How new is Paragon CRT?**

Contact lens corneal reshaping is not a new concept. Previous corneal reshaping designs were only as successful as technology allowed. Paragon Vision Sciences has taken the recent advancements in computerized corneal mapping, computerized manufacturing, and oxygen permeable contact lens materials and produced a therapeutic contact lens design that is like no other. This has allowed Paragon CRT to become the one corneal reshaping modality that truly stands out and the first to earn FDA approval for nighttime Corneal Refractive Therapy.

**3. Is Corneal Refractive Therapy Permanent?**

No. It's temporary. If you stop wearing the lenses regularly while you sleep, your vision will return to its original state in as little as 72 hours.

**4. Can everyone wear Paragon CRT?**

Not everyone can wear Paragon CRT. This lens is designed for individuals with low to moderate myopia (nearsightedness up to -6.00 diopters) with or without astigmatism (up to -1.75 diopters). Paragon CRT therapeutic lenses are not yet available in bifocal prescriptions for presbyopia (which requires reading glasses or bifocals). At your doctor's discretion you may be fitted in a monovision mode (one eye corrected for near vision and one corrected for distance vision). You might still need reading glasses. However, since there are variations in patient physiology and visual needs, the decision for CRT, *at any age*, can only be made after a thorough eye exam and the recommendations of the eye care professional. At this time, hyperopia (farsightedness) is not correctable with CRT.

**5. How long does it take to reach good vision?**

Most patients have rapid improvement in the first few days of treatment and achieve nearly their optimum vision in 10 to 14 days.

**6. What do I do to see adequately in the period of time between when I start Corneal Refractive Therapy with Paragon CRT and when I achieve full treatment?**

It's important to understand that for a time after you have begun treatment, but before sufficient treatment is realized, your old glasses or contacts will no longer be the appropriate prescription. It may involve insertion of your Paragon CRT lenses for part of the day or some use of temporary soft lenses in different prescriptions as an option. Your eye care practitioner will discuss your options for visual correction during that transitional period of time.

**7. Are there any risks involved with wearing Paragon CRT?**

There is a small risk involved when any contact lens is worn. It is not expected that the Paragon CRT lenses for contact lens Corneal Refractive Therapy will provide a risk that is greater than other contact lenses. There were no serious adverse events reported in the Paragon CRT FDA clinical study.

There is a small risk involved when any contact lens is worn. It is not expected that the Paragon CRT Contact Lenses for Corneal Refractive Therapy will provide a risk that is greater than other rigid gas permeable contact lenses. Because this procedure is reversible some patients may notice changes in their vision late in the day.

The two most common side effects that occur in rigid contact lens wearers are corneal edema and corneal staining. It is anticipated that the same side effects will also occur in some wearers of Paragon CRT. Other side effects that sometimes occur in all contact lens wearers are pain, redness, tearing, irritation, discharge, abrasion of the eye or distortion of vision. These are usually temporary conditions if the contact lenses are removed promptly.

In very rare instances, infections of the eye, corneal ulcer, iritis, or neovascularization, corneal scarring, permanent decreased vision may occur. The occurrence of these side effects should be minimized or completely eliminated if proper lens care is exercised.

**8. Can I see with my Paragon CRT lenses in?**

Yes. One of the great features of the Paragon CRT lens is that if you have to get up in the middle of the night, you will be able to see where you are going. Or, if during the initial treatment phase, you find you need some form of vision correction, you can put in your Paragon CRT lenses and see clearly.

**9. How often will I have to replace my Paragon CRT lenses?**

Generally speaking the Paragon CRT lenses will have to be replaced once a year. However, depending on factors such as protein build-up, how well the lenses are taken care of, etc., the lenses may have to be replaced more frequently.

**10. How do I care for my Paragon CRT lenses?**

Your lenses should be chemically disinfected after every use (not heat). Your eye care practitioner will instruct you about which care system is best for you.

**11. How much does Corneal Refractive Therapy with Paragon CRT cost? See end of consent.**

**12. Is Corneal Refractive Therapy painful?**

The therapy is not painful. Initially, you may have a slight awareness of the therapeutic lens. You will not feel the lenses when you sleep and there is no sense of physical corneal change.... just visual improvement when the lenses are removed.

**13. Is Corneal Refractive Therapy or Paragon CRT FDA approved?**

Paragon CRT is the first therapeutic lens design approved by the FDA for overnight contact lens Corneal Refractive Therapy for the temporary reduction of myopia. Paragon Vision Sciences, the manufacturer of Paragon CRT, received the final written approval on June 13, 2002. The issuance of this approval is the culmination of the most extensive clinical study to date to establish the safety and efficacy of contact lens corneal reshaping in overnight use.

**14. What is the difference between Corneal Refractive Therapy and Paragon CRT?**

Corneal Refractive Therapy is the *process* of using a therapeutic contact lens to reduce myopia by reshaping the corneal surface while you sleep. Paragon CRT is the *product* for this therapy.

**15. Are there age restrictions for Corneal Refractive Therapy with Paragon CRT?**

No. The FDA placed no age restrictions on candidates for Corneal Refractive Therapy with Paragon CRT. CRT is being successfully performed on children 12 years old and younger. It can be a great option for children and teens that are active in sports activities or any other extra curricular activities.

Those who are older and presbyopic (requiring reading glasses or bifocals) may still be candidates for CRT. They may correct their distance vision with CRT and wear near-vision reading glasses for close work. At the doctor's discretion you may be fitted in a monovision mode (one eye corrected for near vision and one corrected for distance vision).

Visual requirements due to age or activities can only be assessed after a thorough eye exam. Your Paragon CRT certified eye care professional will recommend what is best for you.

**16. Are the Paragon CRT lenses difficult to insert or remove?**

These lenses are generally no more difficult to insert or remove than any other similar contact lens. You may want to instill comfort or rewetting drops prior to insertion of the lenses and immediately upon waking. The lenses must move freely prior to removal. If you have difficulty removing the Paragon CRT lens, there are lens removal aids available to assist this process.

**17. If I discontinue CRT, will my vision to return to normal?**

There are no recorded permanent corneal changes post-treatment. Generally, the more myopia being reduced, the longer it will take for the corneal curvature to return to normal. For instance, if your pretreated correction was - 4.50D, it would take a few days longer to return to normal than if the pretreated correction was -1.50D.

**18. My driver's license is marked that I need corrective lenses to operate a motor vehicle. What do I do about that?**

Your eye care professional will supply you with a document that states you are participating in a visual therapy program that eliminates the need for corrective lenses during working hours. The document should have an expiration date and you should have your driver's license updated with a new vision screening through your local DMV office to reflect this change, before the expiration date.

**19. What happens if I lose or damage a lens?**

Corneal Refractive Therapy is different than wearing regular contact lenses. If you discontinue wear for one night, your vision may be impaired the next day. Previously worn glasses or contact lenses may not help. Immediate replacement is necessary! Having a spare pair of lenses is strongly recommended.

**20. Do benefit programs cover Corneal Refractive Therapy?**

This is an elective procedure, and to the best of our knowledge is not usually covered by benefit programs. If regular contact lenses are covered under your vision care plan, Corneal Refractive Therapy may be partially covered. You should check with your benefits plan administrator.

**21. I suffer from "dry" eyes, am I a candidate for Corneal Refractive Therapy?**

Only your eye care professional can determine if you are a CRT candidate. Many patients with slightly dry eyes do well with CRT. Since you are wearing the lenses only while sleeping, the closed eye state minimizes evaporative loss of tears and can give dry-eye patients suitable vision without compromising the ocular surface.

**22. I used to wear contact lenses, but stopped due to discomfort. Am I a candidate for Corneal Refractive Therapy?**

Paragon CRT lenses are worn at night while you are sleeping. This greatly reduces any discomfort normally experienced while wearing contact lenses during the day.

**23. I have astigmatism. Am I a candidate for Corneal Refractive Therapy?**

Paragon CRT is designed to correct myopia with to 1.25 diopters of astigmatism. Each individual should be evaluated by a certified eye care professional to determine if CRT is right for your visual requirements.

**24. I wear glasses. Am I a candidate for Corneal Refractive Therapy?**

The transition from wearing only glasses to Paragon CRT should not be a concern. About 18% of the patients in the FDA study were non-contact lens wearers. The dropout rate related to discomfort was only 3.9%.

**25. How can I tell if I have the original Paragon CRT lenses?**

Each lens is laser marked to assure you and your eye care practitioner that you have the original Paragon CRT therapeutic contact lens.

**26. How much does Corneal Refractive Therapy with Paragon CRT cost?**

The cost for your initial fitting, professional care, follow-up and Paragon CRT therapeutic lenses varies by practitioner. After your first year, the annual cost of CRT is about the same as wearing contact lenses or glasses. You may also consult want to consult with your employer about **Flexible Spending Accounts**.

Any expense that is considered a deductible medical expense by the IRS and is not reimbursed through your insurance can be reimbursed through the FSA. These include most elective surgery, corneal refractive therapy, laser vision correction, deductibles, eyeglasses, and prescription drug co-payments.

Not all employers participate in FSA programs. It is recommended you check with your Benefits Manager to see if your employer participates. It is important to calculate how much money to contribute for the year. If you put in more money than you need, by law, you lose it. For Corneal Refractive Therapy, it's recommend you have a consultation first to determine candidacy prior to making any allocations to your Flexible Spending Account.

**Charges: The charges for CRT are based on complexity. (Insurance and Vision Plans can not be used with CRT)**

<b>Professional Fees based on complexity of fit</b>	<b>\$1500 to \$1900</b>
<b>Initial Lenses (warranted lens – custom fabrication)</b>	<b>\$750 to \$900 (custom made) per pr.</b>
<b>Replacement Lenses (non warranted)</b>	<b>\$275 to \$325 (no exchanges) per lens</b>
<b>Yearly Aftercare: professional fees</b>	<b>Annual Exam plus Topography/ Aberrometry</b>

Note: If the patient is unsuccessful with CRT lenses, the patient is responsible for a portion of the professional fee and cancellation fee on custom made lenses of \$275.

Note: re-fit is defined as visits associated to re-evaluate the fit or be re-fit into a different lens modality after the successful completion and dispensing of final CRT lenses.

If the patient has a material benefit for contact lenses via an insurance or vision plan, this maybe applied to the CRT lenses, but if the lenses are discontinued – the material benefit can not be refunded nor applied to spectacles, only the purchase of additional contact lenses. Visits not related to the fitting of the CRT or medical concerns, these visits would be billed to the patient's insurance carrier.

We hope this information is sufficient to help you decide whether to go ahead with the fitting and use of CRT lenses. Don't worry about asking questions. Our staff will be happy to answer them. Our contact telephone numbers are:

**Hopewell Eye: 609-466-0055 Lambertville Eye: 609-397-7020 After Hours: 609-213-5008**

**I have read and understand the above information and acknowledge and take full financial responsibility for the fitting and dispensing of CRT lenses this by signing below:**

\_\_\_\_\_  
**Patient Signature /date**

\_\_\_\_\_  
**Doctor's Signature /date**

\_\_\_\_\_  
**Witness Signature /date**