

CRT Informed Consent Document

You are being fitted with rigid gas permeable (RGP) contact lenses, also known as Corneal Refractive Therapy (CRT). CRT refers to the use of specially designed RGP contact lenses to temporarily reshape the cornea (the clear lens on the front of the eye), allowing you to see clearly without the use of glasses or contacts during waking hours. The CRT contact lenses must be worn on a regular basis during sleep in order to reduce the need for glasses or contact lenses during the day. The CRT contact lenses also act as a retainer to keep the cornea from changing to help slow the progression of near-sightedness in young people. More than 70% of CRT patients are between the ages of 8 to 18 years old and the FDA has no age restriction on CRT.

Complications and side effects

CRT carries the same risks as other types of contact lenses, such as swelling of the cornea, scratching of the eye, irritation, infection, unusual eye discharge, excessive tearing, dry eyes, sensitivity to light, pain, redness and distorted vision. These risks are usually temporary if the contact lenses are removed promptly and if appropriate professional care is received. In some instances permanent corneal scarring, infection or blood vessel growth on the cornea may occur, which can lead to reduced sight in some rare cases. The risk of infection has been shown to be greater among patients who wear their contact lenses overnight than among those who do not sleep in their lenses. For these reasons, although many times contact lenses are viewed as a commodity, they are actually a medical device regulated by the FDA.

CRT also has risks that are not typically associated with other types of contact lenses, such as blurry or variable vision, especially later in the day. The blurry vision and how long it lasts each day should decrease with time. You may also experience distortions or ghost images, particularly outside at night which may affect night driving. For the first few weeks, the risk may be increased in patients with a high degree of correction or large pupils.

All risks are minimized if you follow the correct contact lens wearing schedules and care procedures, remove your lenses if problems occur and report to your optometrist as soon as possible. With any procedure there may be unforeseeable risks. If you experience any of the symptoms listed above, remove your lenses immediately. If the condition continues after lens removal, you should immediately call for an appointment or consultation with your optometrist who will provide the necessary treatment. For after hours consultation, call the number provided on the office answering service for emergencies.

I understand that if my condition requires a procedure not indicated by the FDA and deemed "off-label", I release all liability from Sans Pareil EyeCare and the practitioner(s) and accept treatment under my own volition.

Signature: _____

Lens wear Schedule: Your doctor will recommend a wearing schedule for you to follow. The wearing time necessary for CRT is typically 7 to 8 hours per night. Your doctor will also recommend a follow-up schedule to check your vision and contact lenses. It is important to attend every visit (with your lenses) that your optometrist recommends in order to maintain the health of your eyes.

Alternative to Corneal Refractive Therapy: Alternates to CRT include, among others, eyeglasses, traditional contact lenses and refractive surgery procedures.

Pregnancy: Pregnancy could adversely affect treatment results and CRT should not be started if pregnant or planning to soon be pregnant. If problems exist during pregnancy, you may need to temporarily discontinue CRT lens wear until after birth.

Patient Name: _____ Signature: _____ Date: _____

Legal Guardian: _____ Signature: _____ Date: _____

Attending Doctor/Witness: _____ Signature: _____ Date: _____