**Informed Consent for Ortho-Keratology Overnight Contact Lens Therapy**

Your child has been diagnosed with myopia (nearsightedness), a condition causing blurry distance vision. Myopia may increase the risk of several sight-threatening diseases such as myopic macular degeneration, cataracts, glaucoma, retinal holes and retinal detachments.

We are recommending the use of Ortho-keratology lenses (also known as OK, OrthoK, Corneal Reshaping, Corneal Refractive Therapy, CRT and some other names) as a treatment option for myopia. These lenses are meant to be worn overnight during sleep and removed upon awakening. As the cornea (clear outer window of the eye) is reshaped, light is focused on the back of the eye differently than with conventional contact lenses, which has been shown to slow down the progression of nearsightedness.

When ortho-keratology lenses are removed, vision should be clear, similar to your child wearing conventional eyeglasses or contact lenses. This clear vision effect is temporary. If ortho-keratology lens wear is discontinued, the myopia management effect, as well as the clear uncorrected vision, will cease.

Risks associated with Ortho-keratology lenses include:

* Microbial infections – serious eye infections can occur when wearing *any* contact lenses. Using lenses overnight can increase the risk of these infections, especially when lenses are not properly cared for.
* Acanthamoeba keratitis – Acanthamoeba is an organism which may be found in tap water, pools, lakes, rivers, hot springs, sea water, etc. Infections from acanthamoeba can be serious and lead to permanent vision loss. **Under no circumstances should tap water be used with the ortho-keratology lenses we have prescribed.**  You should only use the ortho-keratology lens care cleaning regimen we have recommended, precisely follow the instructions we have given, and not make any changes without calling us first. This cleaning regimen may vary from patient to patient.

Although rare, the most common side effects from Ortho-keratology lenses are:

* Blurry vision – This is usually worse initially as the prescription is decreasing from the initial prescription to the state of temporarily reduced myopia.
* Halos around lights – this is rare, may be present initially and is eliminated if lens wear stops.
* Lens awareness or discomfort – This is mild when starting ortho-keratology lens wear and usually disappears after a few nights of wear.

To help ensure the best possible outcome, it is critical that you keep all scheduled appointments and alert our office immediately if you or your child is experiencing any side effects from the ortho-keratology lenses. These side effects are very rare and if they do occur, they do so in varying degrees with different patients. Stopping the use of ortho-keratology lenses usually eliminates the side effects. Should your child experience any side effects from the ortho-keratology lenses, you should contact our office immediately and discontinue further use until you speak to a doctor.

Office visits during the first year of treatment will usually be scheduled as follows:

* After the first night of wear
* 1 week
* 1 month
* 3 months
* 6 months following the first visit

Depending on the rate of myopic progression, additional visits may be required and will be determined by a provider on a case by case basis.

After the first year, an annual examination and ortho-keratology lens evaluation is required to ensure ongoing optimal visual health and the stability of the therapeutic effect. Three to six-month monitoring visits will be scheduled on an ongoing basis as required.

Although Orthokeratology contact lenses have been approved by the FDA, the FDA has not specifically approved their use for slowing the progression of myopia. However, Orthokeratology lenses have been shown to be effective in slowing the progression of myopia. The use of a medication or device for purposes for which they are not intended is a common practice in medicine and is referred to as “off label” use.

There are alternative treatments available that may slow the rate of the progression o myopia. These include atropine eye drops and certain soft contact lenses. Each of these has its own unique advantages, disadvantages, risks, and benefits. While conventional glasses or contact lenses compensate for the blurred vision from myopia, their use has not been shown to effectively slow myopic progression.

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, agree to have my child/ward treated with OrthoK Lenses for the treatment of pediatric myopia and I acknowledge the following:

* + - I have been informed of the purpose, risks, and benefits of treatment with OrthoK Lenses and have been informed of other treatment options.
* All of my questions have been addressed and answered to my satisfaction and understanding.
* Not attempting to slow down the progression of myopia may also carry with it certain risks, including permanent vision loss, particularly later in life and in higher degrees of myopia.
* The use of OrthoK Lenses are being used as an “off label” use.
* No guarantee or assurance has been given by anyone as to the specific results that may be obtained by using OrthoK Lenses.
* I agree to follow the treatment regimen required for OrthoK Lenses.
* I will contact the office immediately in the event of the presence of any of the side effects listed above or in the case of an emergency.
* I will keep all scheduled appointments, as per the protocol.

My signature below confirms my understanding of the requirements for treatment with OrthoK Lenses. I further understand that failure to comply with the requirements may lead to termination from the treatment program.

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Parent/Guardian Signature Date

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Doctor Signature Date