**Informed Consent**

**Soft Multifocal Contact Lenses**

You or your child have 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 Soft Multifocal Contact Lenses (SMFCL) as a treatment option for myopia. These lenses are meant to be worn during the day and removed for sleeping. The lenses focus light on the back of the eye differently than conventional contact lenses, which is believed to slow down the progression of nearsightedness.

Risks associated with SMFCL include:

* Microbial infections – serious eye infections can occur when wearing *any* contact lenses, 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 soft multifocal contact lenses prescribed.** You should only use the SMFCL Lens care cleaning regimen (if there is one required with your lenses) we have recommended, precisely follow the instructions we have given, and not make any changes without calling us first.

Although rare, the most common side effects from SMFCL are:

* Blurry vision – This is usually worse initially and resolves in a few days
* Halos around lights – this may be present initially and resolves in a few days. This usually is eliminated if lens wear stops.
* Lens awareness or discomfort – This is mild when starting SMFCL wear and usually disappears within a few hours or after a few days 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 SMFCL. These side effects are very rare and if they do occur, they do so in varying degrees with different patients. Stopping the use of SMFCL usually eliminates the side effects. Should your child experience any side effects from the SMFCL, 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:

* 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 the provider on a case by case basis.

After the first year, an annual examination and SMFCL 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 SMFCL have been approved by the FDA, the FDA has not specifically approved all the various brands for slowing the progression of myopia. However, SMFCL 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 of myopia. These include atropine eye drops and certain rigid overnight contact lenses, commonly referred to as orthokeratology 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 treated with SMFCL for the treatment of pediatric myopia and I acknowledge the following:

* + - I have been informed of the purpose, risks, and benefits of treatment with SMFCL 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 certain brands of SMFCL 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 SMFCL.
* I agree to follow the treatment regimen required for SMFCL.
* 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 SMFCL. 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