Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for Overnight Wear

PACKAGE INSERT
IMPORTANT
Please read carefully and keep this information for future use.

This package insert is intended for the eye care practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

CAUTION:
Federal Law Prohibits Dispensing Without a Prescription

Contact lenses for overnight orthokeratology should be fitted only by a contact lens fitter trained and certified in the fitting of conventional and sigmoid geometry contact lenses.

Nonsterile. Clean and condition lenses prior to use.

WARNING:
The practitioner should provide this warning to the patient:

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. IT IS ESSENTIAL THAT YOU FOLLOW YOUR EYE CARE PRACTITIONER'S DIRECTIONS AND ALL LABELING INSTRUCTIONS FOR PROPER USE OF YOUR CONTACT LENSES AND LENS CARE PRODUCTS. EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, REDNESS OF THE EYE, OR OTHER PROBLEMS WITH YOUR EYES, IMMEDIATELY REMOVE YOUR LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER OR ATTENDING HOSPITAL EMERGENCY ROOM PHYSICIAN.

DESCRIPTION:
Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for the Temporary Reduction of Myopic Refractive Error (Sigmoid Proximity Control Design):

Optimum Infinite (tisilfocon A) Orthokeratology Lenses II are manufactured from Optimum Infinite material (tisilfocon A). The lenses are designed to have congruent anterior and posterior surfaces each consisting of three zones:

1. The central spherical zone (BC).
2. A mathematically designed sigmoid corneal proximity "Return Zone" (W).
3. A non-curving "Landing Zone" (LZW).

The lens design also includes a convex elliptical edge terminus smoothly joining the anterior and posterior surfaces (P).

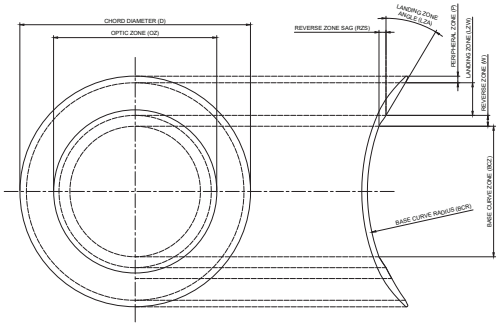
Optimum Infinite (tisilfocon A) Orthokeratology Lenses II are to be worn overnight with removal during all or part of each following day. The lens material (tisilfocon A) is a thermoset copolymer derived from fluoromethacrylate and siloxanylstyrene, bound by crosslinking agents. The lenses are available as lathe-cut contact lenses with a blue, green, red or yellow tint. The blue tinted lens contains D&C Green #6. The green tinted lens contains D&C Green #6 and D&C Yellow #18. The red tinted lens contains D&C Red #17 and D&C Yellow #18. The yellow tinted lens contains D&C Yellow #18. Also, a UV absorber (Benzophenone) is added during the manufacturing process.

Table 1. Optimum Infinite (tisilfocon A) Orthokeratology Lenses II Parameters

Parameter	Range
Diameter (D)	9.5 to 12.0 mm
Central Base Curve Radius (BC)	6.50 to 10.50 mm
Optical Zone Semi Chord (OZ)	2.50 to 3.50 mm
Return Zone Width (w)	0.75 to 1.5 mm
Return Zone Depth (△)	to 1.0 mm
Return Zone Radius	to infinity
Landing Zone Angle (°)	-25° to -50°
Landing Zone Width (LZW)	0.5 to 2.75 mm
Peripheral Edge Curve Width (P)	0.04 mm to LZW
Dioptric Powers	-2.00 to +2.00 Diopters

Table 2. Optimum Infinite (tisilfocon A) Orthokeratology Lenses II Properties

Property	Optimum Infinite (tisilfocon A) Orthokeratology Lenses II
Refractive Index (dry)	1.434
Modulus (MPa)	1416
Hardness (Shore D)	81
Specific Gravity	1.20
Surface Character	Hydrophobic
Oxygen Permeability (Dk)	180 x 10 11 (cm2/sec) (ml O2/ml x mm Hg @ 35°C)
Color Additives	Visibility Tints – D&C Green #6, Solvent Yellow #18, D&C Red #17



ACTIONS:
The Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight wear produces a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and completely compensate for myopia.

The posterior surface of regular contact lenses generally aligns with the central cornea and rests directly on the corneal tear layer. Regular contact lenses are designed to cause little or no effect on the cornea but Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight wear is designed to purposely flatten the shape of the cornea by applying slight pressure to the center of the cornea when the patient is asleep.

After the lens is removed, the cornea retains its altered shape for all or most of one's waking hours. The lenses are designed to be worn overnight with removal during the following day. The Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight wear must be worn at night on a regular schedule to maintain the orthokeratology effect, or the myopia will revert to the pretreatment level.

INDICATIONS:
The Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight wear are indicated for use in the reduction of refractive error in non-diseased eyes. The lenses are indicated for overnight wear for the temporary reduction of myopia up to 6.00 diopters with eyes having astigmatism up to 1.75 diopters. The lenses may only be disinfected using a chemical disinfection system.

Note: To maintain the Orthokeratology effect of myopia reduction, overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving) and cause visual fluctuations and changes in intended correction.

CONTRAINDICATIONS (REASONS NOT TO USE):
Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight wear **SHOULD NOT BE USED** when any of the following conditions exist:

- Acute and sub-acute inflammations or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva or eyelids.
- Severe insufficiency of tears (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa which may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the contact lens.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes are red or irritated.

WARNINGS:
The practitioner should provide this warning to the patient.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.

It is essential that the patient follows the directions of the eye care practitioner and all labeling instructions for proper use of contact lenses and lens care products.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF THE PATIENT EXPERIENCES:

- Eye Discomfort,
- Excessive Tearing,
- Vision Changes,
- Loss of Vision,
- Redness Of The Eye,
- Or Other Problems with their Eyes,

THEY SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THEIR EYE CARE PRACTITIONER.

> The risk of ulcerative keratitis has been shown to be greater among wearers of extended wear lenses than among wearers of daily wear lenses. The risk among extended wear lens wearers increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning the storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers. It is recommended that contact lens wearers see their eye care practitioners twice each year or, if directed, more frequently.

Optimum Infinite (tisilfocon A) Orthokeratology Lenses II are to be worn overnight with removal during all or part of each following day. Wearing the lenses continuously (extended wear) presents increased risk, which increases with the number of consecutive days that the lenses are worn between removals. Although the lens is prescribed for use only overnight wear with removal during waking hours, and although the safety risks of overnight wear with removal upon wakening may not be as great as with extended wear, there is still increased risk beginning with the first overnight period.

To avoid serious eye infections, vision loss or blindness, please be aware of the following warnings...

- **Inadequate rubbing, rinsing, and disinfecting of your lenses may cause serious eye infections, vision loss or blindness. Failure to complete the recommended lens rubbing and rinsing times in the labeling to adequately disinfect lenses and reduce the risk of contact lens infection can cause severe infection, vision loss or blindness.**
- **Do not reuse or "top off" old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-Off" is the addition of fresh solution to solution that has been sitting your case.**
- **Never use water, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.**
- **Do not expose your contact lenses to water while you are wearing them.**
- **If your lenses have been submersed in water when swimming in pools, lakes, or oceans, you should discard them and replace them with a new pair. Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. Ask your eye care professional for recommendations about wearing your lenses during any activity involving water.**
- **Do not use your multi-purpose solution beyond the expiration and/or discard date because it could result in contamination of the solution and can lead to severe infection, vision loss or blindness**
- **Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh multi-purpose solution (or sterile saline solution) so you do not contaminate your lenses or lens case.**

PRECAUTIONS:
Eye care Practitioner

Clinical studies have demonstrated that Optimum Infinite (tisilfocon A) Orthokeratology Lenses II are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in the material. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all factors that affect lens performance and the patient's ocular health; including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter. The potential impact of these factors on the patient's ocular health should be weighed against the patient's need for refractive reduction; therefore, the continuing ocular health of the patient, and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

Overnight orthokeratology lenses in adults has been shown to induce optical aberrations, increase corneal irregularity and ocular high-order aberrations and reduce the eye's contrast sensitivity function to a degree correlated with myopic correction achieved, even in clinically successful orthokeratology cases. This may cause bothersome symptoms in vision such as: i.e.: double vision, glare, halos, blurring, and night vision problems.

Patient

Patients should be informed of the following precautions

Solution Precautions
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions with the contact lenses.
- Do not heat the wetting/soaking solution and lenses.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts of the contact lens solutions used.
- Use only a chemical lens care system. Use of a heat (thermal) lens care system can cause damage by warping Optimum Infinite (tisilfocon A) Orthokeratology Lenses II.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored).

Handling Precautions
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Be certain that fingers and hands are free of foreign material before touching the contact lenses. Microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by the eyecare practitioner.
- Always handle the lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.
- Do not touch the lens with fingernails.
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

Lens Wearing Precautions
- CAUTION: Non-sterile. Clean and condition lenses prior to use.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens in the "Instructions for Wearers" booklet. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, patients should immediately consult with the eye care practitioner.
- Never wear contact lenses beyond the period recommended by the eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products such as sprays are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions
- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty, clean, and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.

Topics to Discuss with the Eyecare Practitioner
- Ask your eyecare practitioner about wearing your lenses during sporting activities.
- Always contact your eyecare practitioner before using any medicine in your eyes.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.

Who Should Know That the Patient is Wearing Contact Lenses
- Inform your doctor (health care practitioner) about being a contact lens wearer.
- Always inform your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear contact lenses.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO):
Patients should be informed that the following problems might occur:

- Eyes stinging, burning, itching (irritation), or other eye pains.
- Comfort is less than when lens was first placed on eye.
- Feeling of something in the eye, such as a foreign body or scratched area.
- Excessive watering (tearing) of the eyes.
- Unusual eye secretions.
- Redness of the eyes.
- Reduced sharpness of vision (poor visual acuity).
- Blurred vision, rainbows, or halos around objects.
- Sensitivity to light (photophobia).
- Dry eyes.

Please refer to the Clinical Study Section of this package insert for adverse effects observed during the study.

If the patient notices any of these conditions, the patient should be instructed to **IMMEDIATELY REMOVE THE LENSES.**
The patient should be advised to follow these instructions:

- If the discomfort or problem stops, then look closely at the lens.
- If the lens is in any way damaged, **DO NOT** put the lens back on the eye. Place the lens in the storage case and contact the eye care practitioner.
- If the lens has dirt, an eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens; then reinsert it.
- If the problem continues, **IMMEDIATELY** remove the contact lenses and consult the eye care practitioner.

When any of the above problems occur, a serious condition such as Acanthamoeba Keratitis, infection, corneal ulcer, neovascularization, iritis, persistent stromal edema or GPC (Giant Papillary Conjunctivitis) may be present. The patient should be instructed to keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage including corneal scarring , opacification, blindness or loss of eye.

SUMMARY OF CLINICAL STUDY DATA:
For clinical study data relevant to Optimum Infinite (tisilfocon A) Orthokeratology Lenses II, please see the following summary, which presents clinical data from PMA approval P050031.

Introduction

Two hundred and four eyes of 102 patients are presented in this report of a study of myopia and myopia astigmatism treatment with overnight wear of orthokeratology lenses in tisilfocon A material in a protocol-controlled investigation at nine U.S. sites. The objective of this investigation was to determine the safety and effectiveness of the lenses in the population defined in the protocol.

Demographic Information

The data presented in this report were collected and analyzed from the 204 eyes of 102 enrolled subjects of which 196 eyes of 98 subjects were treated at nine U.S. centers. The mean age of the full cohort of patients was 34.56 ± 11.6 years (range 11-57). There were 67 female and 31 male subjects enrolled and treated. The data for 72 patients (144 eyes) were analyzed for effectiveness following 6 months of treatment. The mean age of these patients was 34.97 ± 12.0 years (range 11 to 57). A waiver was granted for one subject that was age 11 years 8 months at the baseline visit. There were 10 adolescent subjects enrolled, 2 withdrew prior to treatment. There were 48 female and 24 male subjects of these 47 were classified Caucasian, 3 were African American, 14 were Asian/Pacific Islander, 1 was American Indian/ Aleut Eskimo, and 5 were classified Hispanic.

Effectiveness Outcomes

The average amount of myopia that can be expected to be corrected is shown in the following table. These values assessed on 137 eyes on which full correction was attempted are only averages and some patients can be expected to achieve more or less than these averages. Seven patients were given a monovision treatment in which one eye was targeted for emmetropia and one targeted to remain myopic, in order to provide near vision.

AVERAGE REDUCTION IN MYOPIA (DIOPTERS) N=137*

Refractive Range and Count	Average Subjective Refraction (MRSE)	Average Myopia Reduction (MRSE)	Average Residual Subjective Refraction (MRSE)
-0 25>-1.00 N=8	-0.89	0.81 ± -0.48	-0.08 ± -0.38
-1.25>-2.00 N=40	-1.63	1.49 ± -0.45	-0.13 ± -0.40
-2.25>-3.00 N=46	-2.57	2.37 ± -0.62	-0.20 ± -0.57
-3.25>-4.00 N=25	-3.67	3.23 ± -0.67	-0.44 ± -0.62
-4.25>-5.00 N=13	-4.40	3.88 ± -0.67	-0.52 ± -0.60
-5.25>-6.00 N=5	-5.50	5.65 ± -0.55	0.15 ± -0.55

* All completed eyes targeted for emmetropia

Uncorrected Visual Acuity (UCVA)

Post treatment visual acuity was assessed on 137 eyes on whom full correction was attempted. Of these eyes 41.5% obtained 20/20 or better uncorrected visual acuity and 94.8% obtained 20/40 or better visual acuity at 6 months. See the following table.

Orthokeratology treatment provided a temporary full reduction in some patients with up to -5.5 diopters of myopia. For patients with greater than -5.5 diopters of myopia only a partial reduction of myopia can be expected. The percentage of patients that can be expected to achieve full or partial temporary refractive reduction based on 144 treated eyes is shown in the following table.

PERCENT OF COMPLETED EYES THAT ACHIEVED FULL OR PARTIAL TEMPORARY REDUCTION OF MYOPIA

INITIAL MYOPIA	FULL REDUCTION ± 0.50 D from Target*	PARTIAL REDUCTION ± 1.00 D from Target*	FINAL V.A. 20/20 or better**	FINAL V.A. 20/40 or better**
1.00 D or less	88%	N/A	50%	100%
-1.25 to -2.00 D	83%	100%	60%	95%
-2.25 to -3.00 D	81%	95%	39%	93%
-3.35 to -4.00 D	70%	93%	24%	92%
-4.25 to -6.00 D	79%	86%	23%	100%
-5.25 to -6.00 D	33%	83%	33%	100%

* N=144 for reduction (all efficacy qualified eyes)
** N=137 for Final V.A. (only eyes targeted for emmetropia)

Accuracy

Accuracy of outcome was evaluated by analysis of attempted versus achieved manifest refraction spherical equivalent. At the 6 month visit, 77.6% (111/144) of 6-month completed eyes were within 0.50 D attempted spherical equivalent correction, and 95.1% (136/144) or eyes were within 1.00 D of attempted correction. In this clinical study the higher the initial myopia the lower the percentage of patients achieved full correction and/or 20/20 vision.

Wearing Time

The lenses were used for overnight wear only. They were applied within 30 minutes of sleep and removed within 30 minutes of awakening. The average wearing time was 6 to 8 hours and reflected the expected distribution of night-sleep time. There was no apparent relationship between the number of hours of wear during sleep and the visual acuity outcome for any amount of pretreatment myopia.

Regression Of Visual Acuity

To help you assess the change over time following lens removal, subjects in the clinical study were evaluated at 8, 24, 48, and 72 hours after removal of their lenses following either the six or nine month scheduled visit. Remember that the times given are averages, many patients will do better, many will not fare as well. The 1 Diopter regression point was chosen because it approximately corresponds to 20/40 unaided vision, the legal requirement for driving in many states.

The following guidance table is intended for counseling patients regarding the stability of their vision throughout the day. Values in the table represent the number or hours from the time of lens removal before the average patient's vision will have regressed to the point that his/her refraction is -1.0 Diopter (roughly corresponding to 20/40).

To use the chart, find the patient's original pretreatment Manifest Refractive Spherical Equivalent (MSRE) in the 3rd horizontal row then move down that column to the row where the refraction (in column 2) matches the refraction your patient achieves immediately on lens removal alter a night's wear. The bold value found in the cell identified in this way represents the average number of hours that similar patients have experienced before their refractive error has regressed to approximately -1.0 Diopter. Beneath that value is the minimum projected time for any subject in the study. This is only a guideline; every patient should test his/her vision as it relates to the requirements of their own daily schedules.

BE SURE TO MAKE YOUR PATIENTS AWARE OF THESE LIMITATIONS OF ORTHOKERATOLOGY TREATMENT AND THE OPTIONS AVAILABLE TO THEM WHEN A PROBLEM ARISES.

AVERAGE AND MINIMUM HOURS UNTIL REGRESSION TO -1.0 DIOPTER OR WORSE (estimated for all subjects with pretreatment MRSE > -1.0 D targeted for emmetropia and corrected to better than -1.0 D MRSE N=79)							
			-1.12 to -2.00	-2.12 to -3.00	-3.12 to -4.00	-4.12 to -5.00	-5.12 to -6.00
Refraction At Lens Removal	+0.50	Mean	163.7 Hrs	52.6 Hrs	19.8 Hrs	12.1 Hrs	16.9 Hrs
		Minimum	9.3 Hrs	3.7 Hrs	4.3 Hrs	5.3 Hrs	5.5 Hrs
	+0.25	Mean	162.3 Hrs	51.6 Hrs	18.9 Hrs	11.4 Hrs	15.9 Hrs
		Minimum	9.3 Hrs	3.5 Hrs	4.1 Hrs	4.9 Hrs	5.1 Hrs
	0.00	Mean	159.4 Hrs	49.9 Hrs	17.5 Hrs	10.5 Hrs	14.4 Hrs
		Minimum	9.2 Hrs	3.2 Hrs	3.9 Hrs	4.4 Hrs	4.7 Hrs
	-0.25	Mean	153.5 Hrs	46.9 Hrs	15.5 Hrs	9.1 Hrs	12.3 Hrs
		Minimum	9.1 Hrs	2.8 Hrs	3.4 Hrs	3.8 Hrs	4.1 Hrs
	-0.50	Mean	139.7 Hrs	41.1 Hrs	12.3 Hrs	7.1 Hrs	9.5 Hrs
		Minimum	8.5 Hrs	2.2 Hrs	2.8 Hrs	2.9 Hrs	3.1 Hrs
	-0.75	Mean	103.9 Hrs	28.8 Hrs	7.5 Hrs	4.3 Hrs	5.5 Hrs
		Minimum	5.1 Hrs	1.2 Hrs	1.6 Hrs	1.6 Hrs	1.8 Hrs

Effects on Astigmatism

Orthokeratology does not predictably affect the magnitude of pretreatment astigmatism. Either increases or decreases in astigmatism may occur following Orthokeratology Treatment. Of the eyes that completed the nine-month clinical study, 27% showed no change in refractive astigmatism, 49% showed a decrease of one diopter or less and 1% showed a decrease more than one diopter, while 23% showed an increase of one diopter or less and 1% showed an increase greater than one diopter of refractive astigmatism.

OVERNIGHT WEAR SAFETY SUMMARY:

In this trial, 196 eyes from 98 patients were evaluated for safety during six months overnight orthokeratology when treating myopia and myopia with astigmatism. In this study analysis of safety outcomes was performed for BSCVA losses, adverse events, complications, intraocular pressure, slit lamp findings and symptoms problems and complaints. The analysis was completed for all eyes that reported at all visits.

Best Spectacle-Corrected Visual Acuity (BSCVA)

The BSCVA change analyzed in this trial is the difference between the baseline acuity with best subjective refraction and the acuity with the subjective refraction at the specified visit. Seventy percent of completed eyes (101/144) experienced no change in BSCVA at 6 months, while 15 % (22/144) experienced one line of improved BSCVA and 10% (14/144) eyes experienced one line of diminished BSCVA. Five completed eyes, 3.5% (5/144) manifested a transient loss of two or more lines of BSCVA at the six-month visit. All losses except one were found to be transient as they were not found to be present at the post-removal visits. In one case recovery was not documented before the eye was lost to follow-up. There was one eye with BSCVA worse than 20/40 at the six month visit. At prior visits, with the exception of 3 cases, eyes measuring worse than 20/40 BSCVA were re-tested with a contact lens in place. In those cases retested with a lens, the acuity improved to within one line of vision, indicating that the loss was due to higher order aberration in the anterior corneal plane. In the cases when the test was mistakenly omitted, the BSCVA loss improved to within one line of vision by the next scheduled visit. There is a pattern of transient BSCVA loss at each visit and a trend toward a decreasing percentage with time.

After passing the dispensing and a successful day one visit, of the 204 eyes originally enrolled in the study, 35 were found, at one point or another, to have temporarily lost 2 lines or more of BSCVA from baseline. In one case recovery was not documented before the eye was lost to follow-up. Additionally, eight subjects were observed to temporarily have BSCVA's of 20/40 or worse.

Absence of Persistent Corneal Change

The protocol stipulates that all treated eyes of subjects who discontinued the clinical trial must be followed one month post discontinuation and every one month thereafter until there was no difference greater than 0.50 D in either of the keratometric meridians from the baseline measures. Of the 58 discontinued eyes of the 29 discontinued subjects, 39 eyes of 20 subjects were within 0.50 D of the baseline measurements at the discontinuation visit. One of the discontinued subjects (2 eyes) was lost to follow-up during the investigation. Eleven eyes of 6 subjects were measured to be within 0.50 D of their baseline visit at a post discontinuation visit. Two enrolled subjects were not dispensed.

Slit Lamp Findings

There were no grade 2 or 3 observations at baseline. There were 1578 observations for all scheduled and unscheduled follow-up visits. There were 61 grade 2 (mild) observations (3.9%) during treatment and 7 grade 3 (moderate) observations (< 0.5%) reported. There were no grade 4 (severe) observations reported that would constitute adverse events.

Of the 8 grade 3 reports five were for staining, one for injection and two were for other and described as corneal infiltrates. All 8 cases resolved without further complication. These occurred in 4 subjects. In each case lens wear was discontinued. Two subjects discontinued the study and 2 completed. All cases resolved without further complication.

Symptoms, Complaints and Discontinuations

One hundred two subjects underwent baseline evaluation in the study. Of these, 98 subjects (196 eyes) had lenses dispensed and wore them for at least one night of treatment. The safety analysis was conducted on all 196 treated eyes of the 98 subjects. Seventy-two subjects, 73.5% (144/196 eyes), completed six months of treatment. The efficacy analysis was conducted on all 72 subjects (144 eyes) that completed six months of treatment. Of the 98 subjects, 29 were discontinued prior to the six-month visit. The table below reports the tabulation of subjects that were discontinued prior to the six-month visit and the reason for discontinuation.

REASON FOR DISCONTINUATION (N=102 ENROLLED SUBJECTS)	
Reason for Discontinuation	Number of Patients
Unacceptable Visual Acuity	13
Other	6
Lack of Comfort	3
Lack of Interest	5
Protocol Violation	2
Missed Visits	0
Pathology	0

The reasons given for "other" include two subjects who reported lens adherence, one that reported "lens slipping" at night, one who had back surgery and could not attend visits, and two not dispensed. The protocol violation listing includes two subjects who stopped wear of the lenses for long periods during the study.

The clinical reasons for discontinuation are unacceptable vision, lack of comfort, lens adherence and lens slipping that account for 13 % (13/98), 3 % (3/98), 2% (2/98) and l % (l/98) respectively. The total discontinuation rate for clinical reasons was 19 %.

PERCENT OF EYES EXHIBITING COMPLAINT OR SYMPTOM AT VISIT						
Visit	Unscheduled	2-Week	1-Month	2-Month	3-Month	6-Month
Total Eyes at Visit	260	168	158	164	160	144
None	39%	44%	63%	68%	69%	81%
Discomfort	24%	20%	15%	14%	15%	8%
Itching/ Burning	6%	4%	0%	4%	1%	0%
Blurred Vision	26%	20%	8%	4%	4%	5%
Dryness/ Scratch	6%	3%	6%	7%	3%	5%
Redness	5%	2%	1%	0%	0%	0%
Variable Vision	12%	15%	4%	2%	4%	3%
Photophobia	3%	1%	0%	0%	1%	0%
Halos	4%	11%	8%	5%	3%	1%
Ghost Images	0%	1%	1%	1%	0%	1%
Lens Adhesion	5%	2%	1%	0%	1%	1%
Lens Need Cleaning	2%	5%	1%	3%	0%	1%
Other	6%	3%	1%	1%	0%	2%

Adverse Events and Complications

Study related complications were reported, along with other clinical findings throughout the course of the study. Investigators were encouraged to report all clinical findings, regardless of severity or frequency. As these events were brought to the attention of the study monitors, appropriate information was examined regarding the treatment and post-treatment course of each individual eye. Often this information included but was not limited to BSCA, UCVA, refraction, slit lamp findings and videokeratography.

These reports were followed up, where necessary, with a phone call to the investigator. One subject was found to have suffered a loss of greater than 2 lines of acuity from his baseline BSCVA and it was lost to follow-up. Although recovery was not documented, this subject had no significant ocular pathology observed at any visit. Another subject was found to have a similar loss and was not documented to have recovered for 216 days. One subject experienced a loss of acuity in one eye to worse than 20/40 whose recovery was not documented for 89 days.

There were three events reported on Adverse Event Forms. Two were rated as moderate and one as mild. No serious adverse events were reported.

The following is the description of the adverse events. One subject experienced a peripheral corneal infiltrate, discontinued lens wear, administered medication, and the infiltrate resolved in 7 days. A second subject experienced two incidents of corneal infiltrates, discontinued lens wear, administered medication, and each occurrence resolved in 6 days.

Lens adherence was reported in two subjects who discontinued and was listed as a study related complication. It was also reported as a symptom, problem or complaint. There were twenty-one positive reports of lens adherence in thirteen eyes of nine subjects. The right eye of one subject was the only eye to report persistent lens adherence (at multiple sequential visits). It is noteworthy that this eye was also reported to have a moderate adverse event.

There were no slit lamp findings graded at level 4 (severe). All grade 2 or greater measures resolved without complication. The remaining study related complications were restricted to the transient losses of two or more lines of BSCVA, reductions to ≤ 20/40 and to slit lamp findings graded at level 3 (moderate). For subjects completing at least a day 1 visit there were 63 occurrences in 50 eyes of temporary loss of 2 or more lines of visual acuity. Of 186 subject eyes that continued to scheduled visits beyond day 1, and excluding observations at day 1 visits, there were 35 occurrences of temporary loss of 2 or more lines of visual acuity.

Of these occurrences 15 occurred on scheduled visits beyond the early fitting period*, and 7 were at Unscheduled or Discontinuation visits. The average duration for all occurrences until the investigator was able to bring the subject in and document recovery to better than 2 lines from baseline was 31.4 days. Although the range of durations until documented recovery** was 0 to 216 days (one subject could not be returned for documentation), the median duration was 18 days. Of the 15 occurrences beyond the early fitting period none were bilateral and the average logMAR acuity at the time of the first observation was 0.17 (better than 20/32 in that eye). Only two of these eyes demonstrated visual acuities worse than 20/40 when first observed and they were documented to have been resolved at their next follow-up visit in 7 and 21 days respectively.

* Period from dispense through successful 2-week visit
** Actual Recovery may have occurred earlier

Eight subjects presented with acuities of ≤20/40 during the course of the study. Two were observed only at the day 1 visit. One subject placed lens cleaner in his eye just after the 3-month visit but was not documented to have recovered until the 6-month visit, 89 days later. Excluding the subject who put cleaner in his eye, the range for time to documented recovery was 0.3 to 21 days with a median of 11 days.

There were no slit lamp findings graded at level 4 (severe). All grade 2 or greater measures resolved without complication.
Three subjects (5 eyes) experienced grade 3 staining. No subjects with grade 1 staining required antibiotic treatment or lens wear discontinuation equal to two weeks. The table below summarizes the findings related to these events.

Eye	Date	Visit	Treatment for Grade 3 Staining
OD	06/10/04	Two Wk	Discontinued lens wear for 6 days
OS	06/10/04	Two Wk	Discontinued lens wear for 6 days
OD	05/27/04	Day One	Discontinued lens wear for 24 hours
OD	07/15/04	Day One	Not contact lens related – discontinued lens wear for 1 week
OS	07/15/04	Day One	Not contact lens related – discontinued lens wear for 1 week

A summary of key safety variables is presented in the following table:

Summary of Key Safety Variables*																
Criteria	1 Day n	%	2 Weeks n	%	1 Month n	%	2 Months n	%	3 Months n	%	6 Months n	%	Un-scheduled n	%
n	196		168		158		164		160		144		210	
Adverse events													3	1.4
Loss of ≥ 2 lines BSCVA ***	32 *****	16.3	9	5.4	4	2.5	2	1.2	4	2.5	5	3.5	7	3.3
BSCVA worse than 20/40 ***	4	2.0	3	1.8	1	0.6	0	0	1	0.6	1	0.7	2	1.0
Increase of > 1D of Refractive Cyl	2	1.0	4	2.4	2	1.3	1	0.6	0	0	0	0	6	2.9
Increase of > 2D of Refractive Cyl ****	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Increase of > 1 D Corneal Cyl	16	8.2	8	4.8	5	3.2	7	4.3	12	7.5	10	6.9	12	5.7
Increase of > 2 D Corneal Cyl *****	0	0	4	2.4	0	0	2	1.2	3	1.9	1	0.7	0	0

* Includes multiple interim observations of some events
** Includes Discontinuation visits and regression study visits
*** There were 35 incidents of loss ≥ 2 lines of vision (all documented to be temporary except one)
**** All cylinder increases of ≥ 2 Diopters were temporary
***** On the 32 day-one observations, 4 of these observations were still observed at the 2-week visit (in addition to the 9 new cases at 2 week noted in the table)

Patient Satisfaction

Fifty-nine of the 72 completed subjects (85.3%) rated their overall satisfaction with their unaided vision equivalent to very good or excellent at the 6 month visit compared to no subjects (0.0%) for the same equivalent rating pretreatment.

FITTING:
For a description of fitting techniques, refer to the Fitting Guide for Optimum Infinite (tisilfocon A) Orthokeratology Lenses II. Copies of the fitting guide are available from:

Contamac, Ltd.
Carlton House
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Saffron Walden
Essex CB11 3AU
Phone (UK): 01799 514800
+1-866 US CONTAMAC
Contamac.com

RECOMMENDED WEARING SCHEDULE:
Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to limit the wearing schedule as recommended by their eye care practitioner regardless of how comfortable the lenses feel.

Wearing Schedule: On the initial night of wearing (first overnight wear), lenses should be inserted at a time early enough to achieve 8 to 10 hours of closed eye wearing time (sleep). A well fit lens provides for centration with the eye closed. The effects of lid interaction on blinking and gravity may result in lens decentration during open eye wear. The patient should place the lens(s) in their eye 15 to 20 minutes before going to sleep.

Be aware "when in doubt, take it out". It is important that the new wearer not sleep in a lens that has a significant foreign body sensation. In the event of foreign body sensation, instruct the patient to remove the lens, clean and re-wet it; and again place the lens in the eye. If the sensation continues, remove the lens. The lens should not be worn.

Appointment Schedule: The patient should report for follow-up evaluation the morning after the first overnight wear. The visit is best scheduled within a few hours of awakening and the patient should report with lenses in place. This visit provides an excellent opportunity to evaluate lens centration and potential lens adherence.

Upon the absence of clinical signs and complications, the patient may be instructed to continue overnight wear of the lenses until the next scheduled follow-up visit. An alternate daytime wear schedule may be offered at the practitioner's discretion.

Myopic Reduction Maintenance Lens (Retainer Lens) Schedule

After a period of several days, or when the eyecare practitioner is satisfied that the patient has adapted to the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II, the eyecare practitioner may optimize the wearing schedule for an individual patient to monitor the duration of visual improvement. This may continue as long as the patient can see clearly. When it is found that the patient experiences a visual decrement following lens removal, the schedule of overnight wear must be modulated to maintain visual performance.

LENS CARE DIRECTIONS:
The lens care products listed below are recommended for use with the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II.

Chemical Lens Care System

- **CLEAR CARE® Cleaning & Disinfecting Solution by Alcon**
- **Unique pH® Multi-Purpose Solution by Menicon Co., Ltd**
- **Boston Simplus Multi-Action Solution by Bausch & Lomb, Inc.**

The directions found in the package inserts from these products should be followed. Failure to adhere to these procedures may result in the development of serious ocular complications. A patient should not switch from one care system to another unless it has been determined by the eye care practitioner that this is necessary. Do not mix or alternate the disinfection and storage systems unless so indicated on the product label.

Inform the patient of the following lens care suggestions:

- Always wash and rinse your hands before handling your contact lenses
- Never use tweezers or other tools to remove your lenses from the lens container. Pour the lens into your hand.
- Optimum Infinite (tisilfocon A) Orthokeratology Lenses II must be both cleaned and disinfected each time you remove them. One procedure does not replace the other. Cleaning is necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs. To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.
- Clean one lens first. The recommended procedure is to always clean the same lens first to avoid mix-ups. Rinse the lens thoroughly to remove the cleaning solution. Place the lens into the correct storage chamber and fill the chamber with the recommended disinfecting solution as recommended by your eye care practitioner. Clean and rinse the other lens in the same manner and place it in its chamber.
- Tightly close the top of each chamber of the lens storage case.
- To disinfect your lenses, leave them in the solution for at least the period indicated on the product label.
- Leave the lenses in the closed storage case until you are ready to put them in your eye.

LENS CASE CLEANING AND MAINTENANCE:

Clean contact lens cases with digital rubbing with fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Air-drying or recapping the lens case lids after use without any additional cleaning methods should be discouraged. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.

ENZYME CLEANING:
The eye care practitioner may recommend enzyme cleaning. Enzyme cleaning does not replace routine cleaning and disinfecting. The patient should carefully follow the instructions in the enzymatic cleaning labeling.

EMERGENCIES:
If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should flush eyes immediately with tap water and then remove lenses promptly. The patient should **CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

HOW SUPPLIED:
CAUTION: Nonsterile lenses. Clean and condition lenses prior to use. Each Optimum Infinite (tisilfocon A) Orthokeratology Lenses II is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped in Boston SIMPLUS solution, or Menicon Unique pH solution. Boston Simplus Solution contains poloxamine, hydroxyalklphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%). Menicon Unique pH contains hydroxypropyl guar, polyethylene glycol, poloxamine, boric acid, propylene glycol, and is preserve with polyquaternium-1 (0.0011%), and edetate disodium (0.01%).

The case, packing slip or invoice is marked with the central base curve radius, dioptric power, overall diameter, return zone depth, landing zone angle, center thickness, serial number, ship date and the color of the lens. If the patient has experienced a prior history of allergy to any of these ingredients, remove the lens from the solution and soak the lens 24 hours in sterile unpreserved saline prior to cleaning, disinfecting and dispensing.

Never reuse the solution. You may store the lens in the unopened container until ready to dispense, up to a maximum of thirty (30) days from the Ship Date (see Packing Slip). When a lens has been stored for 30 days in its original packaging solution, it should be cleaned and disinfected. Follow the directions on the selected disinfecting solution regarding prolonged storage.

REPORTING OF ADVERSE REACTIONS:
All serious adverse experiences and adverse reactions observed in patients wearing or experienced with the lenses should be reported immediately to the manufacturer.

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℞ Prescription Use Only

Use-by date

LOT Batch code

Date of Manufacturer

Consult instructions for use

Printed 02/2026

PATIENT INFORMATION BOOKLET FOR POTENTIAL USERS OF Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for Overnight Wear

CAUTION:
Federal Law Prohibits Dispensing Without a Prescription

Nonsterile. Clean and condition lenses prior to use.

LIST OF CONTENTS:

INTRODUCTION:
The information in this booklet is to help you decide whether or not to be fitted with the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II. Orthokeratology is a fitting procedure that temporarily corrects or greatly reduces nearsightedness (known by the medical name, myopia) with or without astigmatism after contact lenses have been removed. By temporary, it is meant that the contact lenses are worn while sleeping (overnight) and then removed upon awakening; whereupon the nearsightedness remains corrected or greatly reduced for all or most of your waking hours. The exact time period over which the myopia remains corrected varies with each patient. Generally, Optimum Infinite (tisilfocon A) Orthokeratology Lenses II must be worn each night to maintain the effect.

HOW THE EYE FUNCTIONS:
The eye is very much like a camera and must be in good focus to see objects clearly. The focusing power of the eye comes from two eye structures, the cornea and the lens.

The cornea is the clear, bubble-like structure on the front of the eye, where light first enters the eye. It provides about two thirds of the eye's focusing power, and the lens inside the eye provides the other third. In a normal eye, light focuses at the retina, at the back of the eye, which acts like the film in a camera. Some eyes focus, or refract, the light too much, so that the images of distant objects are formed in front of the retina, and the image on the retina is blurred, producing myopia.

Myopia usually starts in childhood and gets progressively worse through adolescence. It normally stops increasing by the late teens, but it can sometimes continue to get worse into the mid-twenties.

HOW THE OPTIMUM INFINITE (TISILFOCON A) ORTHOKERATOLOGY LENSES II FUNCTIONS:
The Optimum Infinite (tisilfocon A) Orthokeratology Lenses II produces a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Contact lenses rest directly on the cornea, separated only by a layer of tears, and can influence the corneal shape. Regular contact lenses are designed to nearly match the shape of the cornea and thereby cause little or no flattening effect.

Optimum Infinite (tisilfocon A) Orthokeratology Lenses II are designed to purposely not match the shape of the cornea but instead apply slight pressure to the center of the cornea, in a design known as reverse geometry.

Pressure is produced when the lens is less curved than the cornea, which places more of the lens weight on the center of the cornea. If the cornea is flattened, this reduces the focusing power of the eye, and if the amount of corneal flattening is sufficient, it is possible to bring the eye into correct focus and compensate for myopia. After the lens is removed, the cornea retains its altered shape for all or part of the remainder of the day.

Optimum Infinite (tisilfocon A) Orthokeratology Lenses II are indicated for patients who desire to have time periods during the day in which they do not need to wear their contact lenses, but still be able to see clearly. Some patients are content to wear their contact lenses for normal activities during part of the day and remove them for evening activities.

These contact lenses for Orthokeratology produce a temporary reduction of all or part of your myopia. The amount of reduction will depend on many factors, including the amount of your initial myopia, the elastic characteristics of your eye and the way that the contact lens fits your eye.

ALTERNATIVE WAYS TO CORRECT MYOPIA:
Myopia can be corrected by any method that reduces the focusing power of the eye. The most common methods of reduction are by glasses or regular daily wear or extended wear contact lenses. These represent a means of correcting myopia only during the time that the glasses or regular contact lenses are worn, with no lasting effect on the myopia. Other methods of correcting myopia involve various surgical procedures such as LASIK.

RISK ANALYSIS:
There is a small risk involved when any contact lens is worn. It is not expected that the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II will provide a risk that is greater than other overnight wear rigid gas permeable contact lenses. The most common patient symptoms concerned poor distance vision and flare/ghosting (visual disturbances). The incidence of these symptoms tends to decrease over time in orthokeratology treatment, and they will go away if lens wear is discontinued.

The two most common side effects which occur in general rigid contact lens wearers are corneal edema and corneal staining. It is anticipated that these two side effects will also occur in some wearers of Optimum Infinite (tisilfocon A) Orthokeratology Lenses II. Other side effects, which sometimes occur in all hard lens wearers, are pain, redness, tearing, irritation, discharge, or abrasion of the eye. These are usually temporary conditions if the contact lenses are removed promptly and professional care is obtained. When overnight orthokeratology lenses dislocate during sleep, transient distorted vision may occur the following morning after removal of the lenses. This distortion may not be immediately corrected with spectacle lenses. The duration of the distorted vision would rarely be greater than the duration of the daily visual improvement normally achieved with the lenses.

In rare instances, there may occur permanent corneal scarring, and resulting permanent decreases in vision may occur. The risk of serious problems (such as corneal ulcers and vision loss) is greater when lenses are worn overnight. In addition, studies have shown that smoking increases the risk of corneal ulcers, for those who wear lenses overnight. You should carefully discuss the benefits and risks of overnight wear lenses with your eye care professional. You should remove your contact lenses if any abnormal signs are present.

INDICATIONS:
The Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight wear are indicated for use in the reduction of refractive error in non-diseased eyes. The lenses are indicated for overnight wear for the temporary reduction of myopia up to 6.00 diopters with eyes having astigmatism up to 1.75 diopters. The lenses may only be disinfected using a chemical disinfection system.

Note: To maintain the Orthokeratology effect of myopia reduction, overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving) and cause visual fluctuations and changes in intended correction.

PRECAUTIONS:
General

Clinical studies have demonstrated that Optimum Infinite (tisilfocon A) Orthokeratology Lenses II are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in the material. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all factors that affect lens performance and the patient's ocular health; including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter. The potential impact of these factors on your ocular health should be weighed against the need for refractive reduction; therefore, your continuing ocular health, and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

Overnight orthokeratology lenses in adults has been shown to induce optical aberrations, increase corneal irregularity and ocular high-order aberrations and reduce the eye's contrast sensitivity function to a degree correlated with myopic correction achieved, even in clinically successful orthokeratology cases. This may cause bothersome symptoms in vision such as: i.e.: double vision, glare, halos, blurring, and night vision problems.

Each Optimum Infinite (tisilfocon A) Orthokeratology Lens II is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped in Boston SIMPLUS solution, or Menicon Unique pH solution. Boston Simplus Solution contains poloxamine, hydroxyalklphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%). Menicon Unique pH contains hydroxypropyl guar, polyethylene glycol, poloxamine, boric acid, propylene glycol, and is preserve with polyquaternium-1 (0.0011%), and edetate disodium (0.01%).

The case, packing slip or invoice is marked with the central base curve radius, dioptric power, overall diameter, return zone depth, landing zone angle, center thickness, serial number, ship date and the color of the lens. If the patient has experienced a prior history of allergy to any of these ingredients, remove the lens from the solution and soak the lens 24 hours in sterile unpreserved saline prior to cleaning, disinfecting and dispensing.

Never reuse the solution. You may store the lens in the unopened container until ready to dispense, up to a maximum of thirty (30) days from the Ship Date (see Packing Slip). When a lens has been stored for 30 days in its original packaging solution, it should be cleaned and disinfected. Follow the directions on the selected disinfecting solution regarding prolonged storage.

Patient
You should be aware of the following precautions

Solution Precautions
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions with the contact lenses.
- Do not heat the wetting/soaking solution and lenses.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts of the contact lens solutions used.
- Use only a chemical lens care system. Use of a heat (thermal) lens care system can cause damage by warping Optimum Infinite (tisilfocon A) Orthokeratology Lenses II.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored).

Handling Precautions
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Be certain that your fingers and hands are free of foreign material before touching your contact lenses. Microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by your eyecare practitioner.
- Always handle your lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour your lens into your hand.
- Do not touch the lens with your fingernails.
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

Lens Wearing Precautions
- CAUTION: Nonsterile. Clean and condition lenses prior to use.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens in the Instructions for Wearers Booklet. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, you should immediately consult your eye care practitioner.
- Never wear your contact lenses beyond the period recommended by your eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products such as sprays are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions
- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty, clean, and rinse the lens case with fresh, sterile rinsing solution and allow to air dry. Do not use water.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eyecare practitioner.

Discuss these Topics with your Eye Care Practitioner

- During initial weeks of treatment, some patients may experience changes in vision that may require temporary alternate corrective eyewear. This should be discussed with your eye care practitioner.
- Wear of contact lenses during sporting activities.
- Use of any medication in your eye(s).
- Importance of adhering to the recommended follow-up schedule to assure the continuing health of your eyes.
- Informing your doctor (health care practitioner) about being a contact lens wearer.
- Informing your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear contact lenses during work hours.

CONTRAINDICATIONS (REASONS NOT TO USE)
Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight wear **SHOULD NOT BE USED** when any of the following conditions exist:

- Acute and sub-acute inflammations or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva or eyelids.
- Severe insufficiency of tears (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa which may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the contact lens.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes are red or irritated.

WARNINGS:
Incorrect use of contact lenses and lens care products can result in serious injury to the eye. It is essential that you follow the eye care practitioner's directions and all labeling instructions for proper use of contact lenses and lens care products. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, immediately remove the lenses and do not wear them until instructed to do so by the eye care practitioner. All contact lens wearers must see their eye care practitioner according to the schedule given to them.

Optimum Infinite (tisilfocon A) Orthokeratology Lenses II are to be worn overnight with removal during all or part of each following day. Wearing the lenses continuously (extended wear) presents increased risk, which increases with the number of consecutive days that the lenses are worn between removals. Although the lens is prescribed only for overnight wear with removal during waking hours, and although the safety risks of overnight wear with removal upon awakening may not be as great as with uninterrupted extended wear, there is still increased risk beginning with the first overnight period.

WARNING
The risk of ulcerative keratitis has been shown to be greater among wearers of extended wear lenses than among wearers of daily wear lenses. The risk among extended wear lens wearers increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning the storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers. It is recommended that contact lens wearers see their eye care practitioners twice each year or, if directed, more frequently.

To avoid serious eye infections, vision loss or blindness, please be aware of the following warnings...

- **Inadequate rubbing, rinsing, and disinfecting of your lenses may cause serious eye infections, vision loss or blindness. Failure to complete the recommended lens rubbing and rinsing times in the labeling to adequately disinfect lenses and reduce the risk of contact lens infection can cause severe infection, vision loss or blindness.**
- **Do not reuse or "top off" old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-Off" is the addition of fresh solution to solution that has been sitting your case.**
- **Never use water, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.**
- **Do not expose your contact lenses to water while you are wearing them.**
- **If your lenses have been submersed in water when swimming in pools, lakes, or oceans, you should discard them and replace them with a new pair. Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. Ask your eye care professional for recommendations about wearing your lenses during any activity involving water.**
- **Do not use your multi-purpose solution beyond the expiration and/ or discard date because it could result in contamination of the solution and can lead to severe infection, vision loss or blindness.**
- **Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh multi-purpose solution or sterile saline solution so you do not contaminate your lenses or lens case.**

ADVERSE EFFECTS:
You should be informed that the following problems might occur:

- Eyes stinging, burning, itching (irritation), or other eye pains.
- Comfort is less than when lens was first placed on eye.
- Feeling of something in the eye, such as a foreign body or scratched area.
- Excessive watering (tearing) of the eyes.
- Unusual eye secretions.
- Redness of the eyes.
- Reduced sharpness of vision (poor visual acuity).
- Blurred vision, rainbows, or halos around objects.
- Sensitivity to light (photophobia) .
- Dry eyes.

If you notice any of the above, **IMMEDIATELY REMOVE YOUR LENSES.**

- If the discomfort or problem stops, then look closely at the lens.
- If the lens is in any way damaged, **DO NOT** put the lens back on your eye. Place the lens in the storage case and contact your eye care practitioner.
- If the lens has dirt, an eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse and disinfect the lens; then reinsert it.
- If the problem continues, you should **IMMEDIATELY** remove the contact lenses and consult your eye care practitioner.

When any of the above problems occur, a serious condition such as Acanthamoeba Keratitis, infection, corneal ulcer, neovascularization, iritis, persistent stromal edema or GPC (Giant Papillary Conjunctivitis) may be present. The patient should be instructed to keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage including corneal scarring , opacification, blindness or loss of eye.

SUMMARY OF CLINICAL STUDY DATA:
For clinical study data relevant to Optimum Infinite (tisilfocon A) Orthokeratology Lenses II, please see the following summary, which presents clinical data from PMA approval P050031.

Introduction

Two hundred and four eyes of 102 patients are presented in this report of a study of myopia and myopia astigmatism treatment with overnight wear of contact-lens orthokeratology lenses in tisilfocon A material in a protocol-controlled investigation at nine U.S. sites. The objective of this investigation was to determine the safety and effectiveness of the lenses in the population defined in the protocol.

Demographic Information

The data presented in this report were collected and analyzed from the 204 eyes of 102 enrolled subjects of which 196 eyes of 98 subjects were treated at nine U.S. centers. The mean age of the full cohort of patients was 34.56 ± 11.6 years (range 11-57). There were 67 female and 31 male subjects enrolled and treated. The data for 72 patients (144 eyes) were analyzed for effectiveness following 6 months of treatment. The mean age of these patients was 34.97 ± 12.0 years (range 11 to 57). A waiver was granted for one subject that was age 11 years 8 months at the baseline visit. There were 10 adolescent subjects enrolled, 2 withdrew prior to treatment. There were 48 female and 24 male subjects of these 47 were classified Caucasian, 3 were African American, 14 were Asian/Pacific Islander, 1 was American Indian/ Aleut Eskimo, and 5 were classified Hispanic.

Effectiveness Outcomes

The average amount of myopia that can be expected to be corrected is shown in the following table. These values assessed on 137 eyes on which full correction was attempted are only averages and some patients can be expected to achieve more or less than these averages. Seven patients were given a monovision treatment in which one eye was targeted for emmetropia and one targeted to remain myopic, in order to provide near vision.

AVERAGE REDUCTION IN MYOPIA (DIOPTERS) N=137*

Refractive Range and Count	Average Subjective Refraction (MRSE)	Average Myopia Reduction (MRSE)	Average Residual Subjective Refraction (MRSE)
-0 25>-1.00 N=8	-0.89	0.81 ± -0.48	-0.08 ± -0.38
-1.25>-2.00 N=40	-1.63	1.49 ± -0.45	-0.13 ± -0.40
-2.25>-3.00 N=46	-2.57	2.37 ± -0.62	-0.20 ± -0.57
-3.25>-4.00 N=25	-3.67	3.23 ± -0.67	-0.44 ± -0.62
-4.25>-5.00 N=13	-4.40	3.88 ± -0.67	-0.52 ± -0.60
-5.25>-6.00 N=5	-5.50	5.65 ± -0.55	0.15 ± -0.55

* All completed eyes targeted for emmetropia

Uncorrected Visual Acuity (UCVA)

Post treatment visual acuity was assessed on 137 eyes on whom full correction was attempted. Of these eyes 41.5% obtained 20/20 or better uncorrected visual acuity and 94.8% obtained 20/40 or better visual acuity at 6 months. See the following table.

Orthokeratology treatment provided a temporary full reduction in some patients with up to -5.5 diopters of myopia. For patients with greater than -5.5 diopters of myopia only a partial reduction of myopia can be expected. The percentage of patients that can be expected to achieve full or partial temporary refractive reduction based on 144 treated eyes is shown in the following table.

PERCENT OF COMPLETED EYES THAT ACHIEVED FULL OR PARTIAL TEMPORARY REDUCTION OF MYOPIA

INITIAL MYOPIA	FULL REDUCTION ± 0.50 D from Target*	PARTIAL REDUCTION ± 1.00 D from Target*	FINAL V.A. 20/20 or better**	FINAL V.A. 20/40 or better**
1.00 D or less	88%	N/A	50%	100%
-1.25 to -2.00 D	83%	100%	60%	95%
-2.25 to -3.00 D	81%	95%	39%	93%
-3.35 to -4.00 D	70%	93%	24%	92%
-4.25 to -6.00 D	79%	86%	23%	100%
-5.25 to -6.00 D	33%	83%	33%	100%

* N=144 for reduction (all efficacy qualified eyes)
** N=137 for Final V.A. (only eyes targeted for emmetropia)

Accuracy

Accuracy of outcome was evaluated by analysis of attempted versus achieved manifest refraction spherical equivalent. At the 6 month visit, 77.6% (111/144) of 6-month completed eyes were within 0.50 D attempted spherical equivalent correction, and 95.1% (136/144) or eyes were within 1.00 D of attempted correction. In this clinical study the higher the initial myopia the lower the percentage of patients achieved full correction and/or 20/20 vision.

Wearing Time

The lenses were used for overnight wear only. They were applied within 30 minutes of sleep and removed within 30 minutes of awakening. The average wearing time was 6 to 8 hours and reflected the expected distribution of night-sleep time. There was no apparent relationship between the number of hours of wear during sleep and the visual acuity outcome for any amount of pretreatment myopia.

Regression Of Visual Acuity

To help you assess the change over time following lens removal, subjects in the clinical study were evaluated at 8, 24, 48, and 72 hours after removal of their lenses following either the six or nine month scheduled visit. Remember that the times given are averages, many patients will do better, many will not fare as well. The 1 Diopter regression point was chosen because it approximately corresponds to 20/40 unaided vision, the legal requirement for driving in many states.

The following guidance table is intended for counseling patients regarding the stability of their vision throughout the day. Values in the table represent the number or hours from the time of lens removal before the average patient's vision will have regressed to the point that his/her refraction is -1.0 Diopter (roughly corresponding to 20/40).

To use the chart, find the patient's original pretreatment Manifest Refractive Spherical Equivalent (MSRE) in the 3rd horizontal row then move down that column to the row where the refraction (in column 2) matches the refraction your patient achieves immediately on lens removal alter a night's wear. The bold value found in the cell identified in this way represents the average number of hours that similar patients have experienced before their refractive error has regressed to approximately -1.0 Diopter. Beneath that value is the minimum projected time for any subject in the study. This is only a guideline; every patient should test his/her vision as it relates to the requirements of their own daily schedules.

BE SURE TO MAKE YOUR PATIENTS AWARE OF THESE LIMITATIONS OF ORTHOKERATOLOGY TREATMENT AND THE OPTIONS AVAILABLE TO THEM WHEN A PROBLEM ARISES.

AVERAGE AND MINIMUM HOURS UNTIL REGRESSION TO -1.0 DIOPTER OR WORSE (estimated for all subjects with pretreatment MRSE > -1.0 D targeted for emmetropia and corrected to better than -1.0 D MRSE N=79)							
			-1.12 to -2.00	-2.12 to -3.00	-3.12 to -4.00	-4.12 to -5.00	-5.12 to -6.00
Refraction At Lens Removal	+0.50	Mean	163.7 Hrs	52.6 Hrs	19.8 Hrs	12.1 Hrs	16.9 Hrs
		Minimum	9.3 Hrs	3.7 Hrs	4.3 Hrs	5.3 Hrs	5.5 Hrs
	+0.25	Mean	162.3 Hrs	51.6 Hrs	18.9 Hrs	11.4 Hrs	15.9 Hrs
		Minimum	9.3 Hrs	3.5 Hrs	4.1 Hrs	4.9 Hrs	5.1 Hrs
	0.00	Mean	159.4 Hrs	49.9 Hrs	17.5 Hrs	10.5 Hrs	14.4 Hrs
		Minimum	9.2 Hrs	3.2 Hrs	3.9 Hrs	4.4 Hrs	4.7 Hrs
	-0.25	Mean	153.5 Hrs	46.9 Hrs	15.5 Hrs	9.1 Hrs	12.3 Hrs
		Minimum	9.1 Hrs	2.8 Hrs	3.4 Hrs	3.8 Hrs	4.1 Hrs
	-0.50	Mean	139.7 Hrs	41.1 Hrs	12.3 Hrs	7.1 Hrs	9.5 Hrs
		Minimum	8.5 Hrs	2.2 Hrs	2.8 Hrs	2.9 Hrs	3.1 Hrs
	-0.75	Mean	103.9 Hrs	28.8 Hrs	7.5 Hrs	4.3 Hrs	5.5 Hrs
		Minimum	5.1 Hrs	1.2 Hrs	1.6 Hrs	1.6 Hrs	1.8 Hrs

Effects on Astigmatism

Orthokeratology does not predictably affect the magnitude of pretreatment astigmatism. Either increases or decreases in astigmatism may occur following Orthokeratology Treatment. Of the eyes that completed the nine-month clinical study, 27% showed no change in refractive astigmatism, 49% showed a decrease of one diopter or less and 1% showed a decrease more than one diopter, while 23% showed an increase of one diopter or less and 1% showed an increase greater than one diopter of refractive astigmatism.

OVERNIGHT WEAR SAFETY SUMMARY :

In this trial, 196 eyes from 98 patients were evaluated for safety during six months overnight wear orthokeratology when treating myopia and myopia with astigmatism. In this study analysis of safety outcomes was performed for BSCVA losses, adverse events, complications, intraocular pressure, slit lamp findings and symptoms problems and complaints. The analysis was completed for all eyes that reported at all visits.

Best Spectacle-Corrected Visual Acuity (BSCVA)

The BSCVA change analyzed in this trial is the difference between the baseline acuity with best subjective refraction and the acuity with the subjective refraction at the specified visit. Seventy percent of completed eyes (101/144) experienced no change in BSCVA at 6 months, while 15 % (22/144) experienced one line of improved BSCVA and 10% (14/144) eyes experienced one line of diminished BSCVA. Five completed eyes, 3.5% (5/144) manifested a transient loss of two or more lines of BSCVA at the six-month visit. All losses except one were found to be transient as they were not found to be present at the post-removal visits. In one case recovery was not documented before the eye was lost to follow-up. There was one eye with BSCVA worse than 20/40 at the six month visit. At prior visits, with the exception of 3 cases, eyes measuring worse than 20/40 BSCVA were re-tested with a contact lens in place. In those cases retested with a lens, the acuity improved to within one line of vision, indicating that the loss was due to higher order aberration in the anterior corneal plane. In the cases when the test was mistakenly omitted, the BSCVA loss improved to within one line of vision by the next scheduled visit. There is a pattern of transient BSCVA loss at each visit and a trend toward a decreasing percentage with time.

After passing the dispensing and a successful day one visit, of the 204 eyes originally enrolled in the study, 35 were found, at one point or another, to have temporarily lost 2 lines or more of BSCVA from baseline. In one case recovery was not documented before the eye was lost to follow-up. Additionally, eight subjects were observed to temporarily have BSCVA's of 20/40 or worse.

Absence of Persistent Corneal Change

The protocol stipulates that all treated eyes of subjects who discontinued the clinical trial must be followed one month post discontinuation and every one month thereafter until there was no difference greater than 0.50 D in either of the keratometric meridians from the baseline measures. Of the 58 discontinued eyes of the 29 discontinued subjects, 39 eyes of 20 subjects were within 0.50 D of the baseline measurements at the discontinuation visit. One of the discontinued subjects (2 eyes) was lost to follow-up during the investigation. Eleven eyes of 6 subjects were measured to be within 0.50 D of their baseline visit at a post discontinuation visit. Two enrolled subjects were not dispensed.

Slit Lamp Findings

There were no grade 2 or 3 observations at baseline. There were 1578 observations for all scheduled and unscheduled follow-up visits. There were 61 grade 2 (mild) observations (3.9%) during treatment and 7 grade 3 (moderate) observations (< 0.5%) reported. There were no grade 4 (severe) observations reported that would constitute adverse events.

Of the 8 grade 3 reports five were for staining, one for injection and two were for other and described as corneal infiltrates. All 8 cases resolved without further complication. These occurred in 4 subjects. In each case lens wear was discontinued. Two subjects discontinued the study and 2 completed. All cases resolved without further complication.

Symptoms, Complaints and Discontinuations

One hundred two subjects underwent baseline evaluation in the study. Of these, 98 subjects (196 eyes) had lenses dispensed and wore them for at least one night of treatment. The safety analysis was conducted on all 196 treated eyes of the 98 subjects. Seventy-two subjects, 73.5% (144/196 eyes), completed six months of treatment. The efficacy analysis was conducted on all 72 subjects (144 eyes) that completed six months of treatment. Of the 98 subjects, 29 were discontinued prior to the six-month visit. The table below reports the tabulation of subjects that were discontinued prior to the six-month visit and the reason for discontinuation.

REASON FOR DISCONTINUATION (N=102 ENROLLED SUBJECTS)	
Reason for Discontinuation	Number of Patients
Unacceptable Visual Acuity	13
Other	6
Lack of Comfort	3
Lack of Interest	5
Protocol Violation	2
Missed Visits	0
Pathology	0

The reasons given for "other" include two subjects who reported lens adherence, one that reported "lens slipping" at night, one who had back surgery and could not attend visits, and two not dispensed. The protocol violation listing includes two subjects who stopped wear of the lenses for long periods during the study.

The clinical reasons for discontinuation are unacceptable vision, lack of comfort, lens adherence and lens slipping that account for 13 % (13/98), 3 % (3/98), 2% (2/98) and l % (l/98) respectively. The total discontinuation rate for clinical reasons was 19 %.

PERCENT OF EYES EXHIBITING COMPLAINT OR SYMPTOM AT VISIT						
Visit	Unscheduled	2-Week	1-Month	2-Month	3-Month	6-Month
Total Eyes at Visit	260	168	158	164	160	144
None	39%	44%	63%	68%	69%	81%
Discomfort	24%	20%	15%	14%	15%	8%
Itching/ Burning	6%	4%	0%	4%	1%	0%
Blurred Vision	26%	20%	8%	4%	4%	5%
Dryness/ Scratch	6%	3%	6%	7%	3%	5%
Redness	5%	2%	1%	0%	0%	0%
Variable Vision	12%	15%	4%	2%	4%	3%
Photophobia	3%	1%	0%	0%	1%	0%
Halos	4%	11%	8%	5%	3%	1%
Ghost Images	0%	1%	1%	1%	0%	1%
Lens Adhesion	5%	2%	1%	0%	1%	1%
Lens Need Cleaning	2%	5%	1%	3%	0%	1%
Other	6%	3%	1%	1%	0%	2%

Adverse Events and Complications

Study related complications were reported, along with other clinical findings throughout the course of the study. Investigators were encouraged to report all clinical findings, regardless of severity or frequency. As these events were brought to the attention of the study monitors, appropriate information was examined regarding the treatment and post-treatment course of each individual eye. Often this information included but was not limited to BSCA, UCVA, refraction, slit lamp findings and videokeratography.

These reports were followed up, where necessary, with a phone call to the investigator. One subject was found to have suffered a loss of greater than 2 lines of acuity from his baseline BSCVA and it was lost to follow-up. Although recovery was not documented, this subject had no significant ocular pathology observed at any visit. Another subject was found to have a similar loss and was not documented to have recovered for 216 days. One subject experienced a loss of acuity in one eye to worse than 20/40 whose recovery was not documented for 89 days.

There were three events reported on Adverse Event Forms. Two were rated as moderate and one as mild. No serious adverse events were reported.

The following is the description of the adverse events. One subject experienced a peripheral corneal infiltrate, discontinued lens wear, administered medication, and the infiltrate resolved in 7 days. A second subject experienced two incidents of corneal infiltrates, discontinued lens wear, administered medication, and each occurrence resolved in 6 days.

Lens adherence was reported in two subjects who discontinued and was listed as a study related complication. It was also reported as a symptom, problem or complaint. There were twenty-one positive reports of lens adherence in thirteen eyes of nine subjects. The right eye of one subject was the only eye to report persistent lens adherence (at multiple sequential visits). It is noteworthy that this eye was also reported to have a moderate adverse event.

There were no slit lamp findings graded at level 4 (severe). All grade 2 or greater measures resolved without complication. The remaining study related complications were restricted to the transient losses of two or more lines of BSCVA, reductions to ≤ 20/40 and to slit lamp findings graded at level 3 (moderate). For subjects completing at least a day 1 visit there were 63 occurrences in 50 eyes of temporary loss of 2 or more lines of visual acuity. Of 186 subject eyes that continued to scheduled visits beyond day 1, and excluding observations at day 1 visits, there were 35 occurrences of temporary loss of 2 or more lines of visual acuity.

Of these occurrences 15 occurred on scheduled visits beyond the early fitting period*, and 7 were at Unscheduled or Discontinuation visits. The average duration for all occurrences until the investigator was able to bring the subject in and document recovery to better than 2 lines from baseline was 31.4 days. Although the range of durations until documented recovery** was 0 to 216 days (one subject could not be returned for documentation), the median duration was 18 days. Of the 15 occurrences beyond the early fitting period none were bilateral and the average logMAR acuity at the time of the first observation was 0.17 (better than 20/32 in that eye). Only two of these eyes demonstrated visual acuities worse than 20/40 when first observed and they were documented to have been resolved at their next follow-up visit in 7 and 21 days respectively.

* Period from dispense through successful 2-week visit
** Actual Recovery may have occurred earlier

Eight subjects presented with acuities of ≤20/40 during the course of the study. Two were observed only at the day 1 visit. One subject placed lens cleaner in his eye just after the 3-month visit but was not documented to have recovered until the 6-month visit, 89 days later. Excluding the subject who put cleaner in his eye, the range for time to documented recovery was 0.3 to 21 days with a median of 11 days.

There were no slit lamp findings graded at level 4 (severe). All grade 2 or greater measures resolved without complication.
Three subjects (5 eyes) experienced grade 3 staining. No subjects with grade 1 staining required antibiotic treatment or lens wear discontinuation equal to two weeks. The table below summarizes the findings related to these events.

Eye	Date	Visit	Treatment for Grade 3 Staining
OD	06/10/04	Two Wk	Discontinued lens wear for 6 days
OS	06/10/04	Two Wk	Discontinued lens wear for 6 days
OD	05/27/04	Day One	Discontinued lens wear for 24 hours
OD	07/15/04	Day One	Not contact lens related – discontinued lens wear for 1 week
OS	07/15/04	Day One	Not contact lens related – discontinued lens wear for 1 week

A summary of key safety variables is presented in the following table:

Summary of Key Safety Variables*																
Criteria	1 Day n	%	2 Weeks n	%	1 Month n	%	2 Months n	%	3 Months n	%	6 Months n	%	Un-scheduled n	%
n	196		168		158		164		160		144		210	
Adverse events													3	1.4
Loss of ≥ 2 lines BSCVA ***	32 *****	16.3	9	5.4	4	2.5	2	1.2	4	2.5	5	3.5	7	3.3
BSCVA worse than 20/40 ***	4	2.0	3	1.8	1	0.6	0	0	1	0.6	1	0.7	2	1.0
Increase of > 1D of Refractive Cyl	2	1.0	4	2.4	2	1.3	1	0.6	0	0	0	0	6	2.9
Increase of > 2D of Refractive Cyl ****	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Increase of > 1 D Corneal Cyl	16	8.2	8	4.8	5	3.2	7	4.3	12	7.5	10	6.9	12	5.7
Increase of > 2 D Corneal Cyl *****	0	0	4	2.4	0	0	2	1.2	3	1.9	1	0.7	0	0

* Includes multiple interim observations of some events
** Includes Discontinuation visits and regression study visits
*** There were 35 incidents of loss ≥ 2 lines of vision (all documented to be temporary except one)
**** All cylinder increases of ≥ 2 Diopters were temporary
***** On the 32 day-one observations, 4 of these observations were still observed at the 2-week visit (in addition to the 9 new cases at 2 week noted in the table)

Patient Satisfaction

Fifty-nine of the 72 completed subjects (85.3%) rated their overall satisfaction with their unaided vision equivalent to very good or excellent at the 6 month visit compared to no subjects (0.0%) for the same equivalent rating pretreatment.

MAINTAINING EFFECTS OF OPTIMUM INFINITE (TISILFOCON A) ORTHOKERATOLOGY LENSES II:

The long-term wear of Optimum Infinite (tisilfocon A) Orthokeratology Lenses II does not eliminate the need to continue wearing contact lenses to produce the reduction in myopia. After the cornea has been changed by wearing these contact lenses, you must continue overnight wear of the lenses to maintain the results. Usually the treatment lenses will continue to be the lenses worn after successful treatment. In unusual circumstances, new lenses may be prescribed that are Myopic Reduction Maintenance Lenses or Retainer Lenses. Such Retainer Lenses would be only a slight modification of the patient's prescription.

The wearing schedule for Optimum Infinite (tisilfocon A) Orthokeratology Lenses II or Retainer Lenses may vary from the schedule prescribed during treatment. In cases of low pretreatment myopia, the effect may last for more than one day.

GLOSSARY:

Adnexa	Tissues near the eye
Adverse effects	Undesirable effects
Aphakia	Eye that does not have a lens structure
Astigmatism	Eye condition in which one or more surfaces of the cornea or lens has a shape that is not round but more like that of a football
Best Spectacle Corrected Visual Acuity	Best vision you can achieve wearing glasses in your exact prescription under optimum viewing conditions
Contact Lens Sticking	Lack of movement of a contact lens on the cornea
Cornea	The clear, bubble-like structure on the front of the eye, where light first enters the eye.
Corneal abrasion	Loss of cells on the corneal surface due to mechanical trauma
Corneal edema	Accumulation of fluid in the cornea
Corneal hypoesthesia	Partial loss of sensitivity to touch in the cornea
Corneal staining	Bright areas on the cornea where dye collects. Indicates an abrasion or other disturbance of the cornea
Corneal ulcer	Small area of tissue loss in the cornea
Disinfection	Destruction of bacteria and viruses but not some spores
Diopter	Unit of power for glasses or contact lenses
Enzyming contact lenses	Placing contact lenses in a solution that contains an enzyme that dissolves proteins on the surface of the lens
Hypoesthesia	Reduced corneal sensitivity to touch
Iritis	Infection of the iris or colored portion of the eye
Lacrimal secretion	Generation of tears
Manifest Refraction Spherical Equivalent	A measure of vision correction requirements (in diopters), which combines your myopia and your astigmatism
Myopia	Medical term for nearsightedness
Myopic Reduction Maintenance Lens	A modification of the orthokeratology contact lens design in which the central portion of the lens applies just enough pressure to the cornea to maintain the corneal flattening achieved but with no additional corneal flattening
Neovascularization	New vessel growth in the cornea
Orthokeratology	Contact lens fitting procedure that temporarily reduces myopia after contact lenses have been removed
Refract	Bending of light in order to make it focus
Refractive anomalies	Eye conditions leading to blurred vision including myopia (nearsightedness), hyperopia (farsightedness) and astigmatism
Retainer Lenses	Another name for the Myopic Reduction Maintenance Lens
Retina	Structure at the back of the eye that receives the light image
Rewetting contact lenses	Placing a solution in the eye while contact lenses are worn that acts as an artificial tear to wet the lens
Sticking lens	Lens on the cornea that does not move

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After Your Optimum Infinite (tisilfocon A) Orthokeratology Lenses II Have Been Fitted

Instructions for Wearers of Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for Overnight Wear

CAUTION:
Federal Law Prohibits Dispensing Without a Prescription

Nonsterile. Clean and condition lenses prior to use.

Instructions for Wearers of Optimum Infinite (tisilfocon A) Orthokeratology Lenses II

Patient Name.....
.....

Prescribed Lens.....

Doctor.....

Address.....
.....
.....

Phone.....

LIST OF CONTENTS:

PRECAUTIONS:
General

Clinical studies have demonstrated that Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight wear are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in the material. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all factors that affect lens performance and your ocular health; including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter. The potential impact of these factors on the patient's ocular health should be weighed against your need for refractive reduction; therefore, your continuing ocular health and lens performance on the eye should be carefully monitored by your prescribing eye care practitioner.

Each Optimum Infinite (tisilfocon A) Orthokeratology Lens II is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped in Boston SIMPLUS solution, or Menicon Unique pH solution. Boston Simplus Solution contains poloxamine, hydroxyalklphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%). Menicon Unique pH contains hydroxypropyl guar, polyethylene glycol, poloxamine, boric acid, propylene glycol, and is preserve with polyquaternium-1 (0.0011%), and edetate disodium (0.01%).
The case, packing slip or invoice is marked with the central base curve radius, dioptric power, overall diameter, Return Zone Depth, Landing Zone Angle, center thickness, serial number, ship date and the color of the lens. If the patient has experienced a prior history of allergy to any of these ingredients, remove the lens from the solution and soak the lens 24 hours in sterile unpreserved saline prior to cleaning, disinfecting and dispensing.
Never reuse the solution. You may store the lens in the unopened container until ready to dispense, up to a maximum of thirty (30) days from the Ship Date (see Packing Slip). When a lens has been stored for 30 days in its original packaging solution, it should be cleaned and disinfected. Follow the directions on the selected disinfecting solution regarding prolonged storage.

Patient

Solution Precautions
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions with the contact lenses.
- Do not heat the wetting/soaking solution and lenses.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts of the contact lens solutions used.
- Use only a chemical lens care system. Use of a heat (thermal) lens care system can cause damage by warping Optimum Infinite (tisilfocon A) Orthokeratology Lenses II.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored).

Handling Precautions
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Be certain that your fingers or hands are free of foreign material before touching your contact lenses. Microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by your eyecare practitioner.
- Always handle your lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour your lens into your hand.
- Do not touch the lens with your fingernails.
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

Lens Wearing Precautions
- CAUTION: Nonsterile. Clean and condition lenses prior to use.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens in the Instructions for Wearers Booklet. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, you should immediately consult your eye care practitioner.
- Never wear your contact lenses beyond the period recommended by your eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products such as sprays are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions
- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty, clean, and rinse the lens case with fresh, sterile rinsing solution and allow to air dry. Do not use water.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eyecare practitioner.

To avoid serious eye infections, vision loss or blindness, please be aware of the following warnings...
- **Inadequate rubbing, rinsing, and disinfecting of your lenses may cause serious eye infections, vision loss or blindness. Failure to complete the recommended lens rubbing and rinsing times in the labeling to adequately disinfect lenses and reduce the risk of contact lens infection can cause severe infection, vision loss or blindness.**
- **Do not reuse or "top off" old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-Off" is the addition of fresh solution to solution that has been sitting your case.**
- **Never use water, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.**
- **Do not expose your contact lenses to water while you are wearing them.**
- **If your lenses have been submersed in water when swimming in pools, lakes, or oceans, you should discard them and replace them with a new pair. Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. Ask your eye care professional for recommendations about wearing your lenses during any activity involving water.**
- **Do not use your multi-purpose solution beyond the expiration and/or discard date because it could result in contamination of the solution and can lead to severe infection, vision loss or blindness.**
- **Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh multi-purpose solution (or sterile saline solution) so you do not contaminate your lenses or lens case.**

Discuss these topics with your eye care practitioner
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.
- During initial weeks of treatment, some patients may experience changes in vision that may require temporary alternate corrective eyewear. This should be discussed with your eye care practitioner.
- Once your vision is fully corrected, you may experience some hours of fluctuation of vision late in the day. If these are bothersome, discuss with your practitioner the possibility of wearing your contact lenses during those times.
- Ask your eyecare practitioner about wearing contact lenses during sporting activities.
- Ask your eyecare practitioner about use of any medication in your eye.

Who Should Know That You Are Wearing Contact Lenses?
- Inform your doctor (health care practitioner) about being a contact lens wearer.
- If you choose to wear your lenses while at work always inform your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear contact lenses during work hours.

ADVERSE EFFECTS:
You should be informed that the following problems might occur:
- Eyes stinging, burning, itching (irritation), or other eye pains.
- Comfort is less than when lens was first placed on eye.
- Feeling of something in the eye, such as a foreign body or scratched area.
- Excessive watering (tearing) of the eyes.
- Unusual eye secretions.
- Redness of the eyes.
- Reduced sharpness of vision (poor visual acuity).
- Blurred vision, rainbows, or halos around objects.
- Sensitivity to light (photophobia).
- Dry eyes.

If you notice any of the above, **IMMEDIATELY REMOVE YOUR LENSES.**
- If the discomfort or problem stops, then look closely at the lens.
- If the lens is in any way damaged, **DO NOT** put the lens back on your eye. Place the lens in the storage case and contact your eye care practitioner.
- If the lens has dirt, an eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse and disinfect the lens; then reinsert it.
- If the problem continues, you should **IMMEDIATELY** remove the contact lenses and consult your eye care practitioner.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, iritis, persistent stromal edema or GPC (Giant Papillary Conjunctivitis) may be present. You should be instructed to keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS FOR LENS HANDLING
Preparing the Lens for Wearing:

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substance when you handle your lenses. The procedures are:

- Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- To avoid damaging your lenses, handle them with your fingertips, and be careful to avoid contact with your fingernails. It is helpful to keep your fingernails short and smooth.
- Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

Handling the Lenses
- Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks and tears.

Placing the Lens on the Eye
- Work over a table, upon which is placed a clean towel.
- Do not place lenses on the eye while working over a sink.

For the RIGHT EYE
- Wet the forefinger of the right hand with a drop of conditioning solution and place the contact lens on the forefinger of the right hand.
- Place the second finger of the left hand on the middle of the upper lid and press upward firmly.
- Place the second finger of the right hand on the lower lid and press downward firmly.
- Stare into a mirror as though looking through the forefinger holding the contact lens. You will later learn to do this without a mirror.
- Slowly move the hand to advance the forefinger with the contact lens towards the cornea until the lens touches the cornea and release the lids.
- Release the lid and close the eye for a few seconds.

Repeat for the LEFT EYE
There are other methods of lens placement. If the above method is difficult for you, your eyecare practitioner will provide you with an alternate method.

Note: If after placement of the lens your vision is blurred, check for the following:

The lens is not centered on the eye (see "Centering the Lens", next section in this booklet).

If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:

- Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
- The lens is on the wrong eye.

If you find that your vision is still blurred after checking the above possibilities remove both lenses and consult your eyecare practitioner.

Centering the Lens
Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens follow the procedure below.

- First, locate the lens by pulling away the lids.
- After the lens is found gently press on the lid over the lens while looking away from the direction of the lens.
- Next, look back towards the lens. The lens should center on the cornea.

Removing the Lens
- Always remove the same lens first.
- Wash, rinse, and dry your hands thoroughly.
- Work over a table with a clean towel. Do not remove lenses over a sink unless you have first placed a clean towel over the drain.
- Place the right index finger of the right hand at the outer corner of the eye.
- Place the left hand cupped below the eye.
- Open the eyes wide as if to stare.
- Continue to keep the eyes open and pull the lids sideways away from nose.
- Blink quickly and firmly.
- Remove the other lens by following the same procedure.
- Follow the required lens care procedures described under the heading: Caring for your lenses ("Cleaning", "Rinsing", "Disinfecting", "Enzyming", "Storing" and "Rewetting/Lubricating").

Note: If this method of removing your lens is difficult for you, your eye care practitioner will provide you with an alternate method.

CARING FOR YOUR LENSES:
Basic Instructions

For continued safe and comfortable wearing of your lenses, it is important that you clean and rinse, then disinfect your lenses after each removal using the care regimen recommended by your eyecare practitioner. Cleaning and rinsing are necessary to remove mucus, secretions, films, or deposits that may have accumulated during wearing. The ideal time to clean, rinse, and disinfect your lenses is immediately after wearing them. Disinfecting is necessary to destroy harmful germs.

You should adhere to a recommended care regimen.

Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS section above.

When you first receive your lenses, practice how to put the lenses on and removing them while you are in your eyecare practitioner's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfection. Your eyecare practitioner should instruct you about appropriate and adequate procedures and products for your use.
For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh unexpired lens care solutions.

Use the recommended system of lens care, which is chemical (not heat) and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling.**

Always remove, clean, rinse, enzyme and disinfect your lenses according to the schedule prescribed by your eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.

To avoid contamination, do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.

The lens care products listed below are recommended for use with your Optimum Infinite (tisilfocon A) Orthokeratology Lenses II.

Chemical Lens Care System

- **CLEAR CARE® Cleaning & Disinfecting Solution by Alcon**
- **Unique pH® Multi-Purpose Solution by Menicon Co., Ltd**
- **Boston Simplus Multi-Action Solution by Bausch & Lomb, Inc.**

Note: Some solutions may have more than one function, which will be indicated, on the label. Read the label on the solution bottle and follow instructions.

Always wash and rinse your hands thoroughly before handling your contact lenses.

Clean
Clean one lens first (always start with the same lens first to avoid mix-ups). Place the lens, front side down, in the palm of the hand and apply several drops of cleaning solution. Using the index finger of the other hand, apply slight pressure in a swirling motion for about 5 seconds. Do not clean the lens by rubbing it between the thumb and index fingers, as this may cause lens warpage.

Rinse
Rinse the lens thoroughly with clean tap water or saline, as directed by your eyecare practitioner, to remove the cleaning solution, mucus, and film from the lens surface. Place that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

Disinfect
After cleaning and rinsing the lens, disinfect them by using the system recommended by your eye care practitioner and/or the lens manufacturer. Follow the instructions provided in the disinfection solution labeling.
Note: Optimum Infinite (tisilfocon A) Orthokeratology Lenses II cannot be heat (thermally) disinfected.

Storage
To store lenses, disinfect and leave them in the closed case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the storage solution package insert or your eyecare practitioner for information on storage of your lenses.

Always keep your lenses completely immersed in a recommended disinfecting / conditioning solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your eyecare practitioner for a recommendation on how to store your lenses.

Care of Your Lens Case
Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty, clean, and rinse the lens case with fresh, sterile rinsing solution and allow to air dry. Do not use water. When the case is used again, refill it with fresh disinfecting solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

Lubricating / Re-wetting
Your eye care practitioner will recommend a lubricating / re-wetting solution for your use. Lubricating / Re-wetting solutions can be used to re-wet (lubricate) your lenses while you are wearing them to make them more comfortable.

Lens Deposits and Use of Enzymatic Cleaning Procedure
Enzyme cleaning may be recommended by your eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of your lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does not replace routine cleaning and disinfecting. For enzyme cleaning, you should carefully follow the instructions in the enzymatic cleaning labeling.

Care for a Sticking (Non-Moving) Lens
If the lens is stuck (stops moving) or cannot be removed, you should apply 5 drops of the recommended lubricating or re-wetting solution directly to the eye. Wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 30 minutes, you should **IMMEDIATELY** consult your eye care practitioner.

EMERGENCIES:
If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should:

- FLUSH EYES IMMEDIATELY WITH TAP WATER
- REMOVE YOUR LENSES
- IMMEDIATELY CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

WEARING AND APPOINTMENT SCHEDULE:
Wearing Schedule: On night one lenses should be inserted at a time early enough to achieve 8 to 10 hours of closed eye wearing time (sleep). A well fit lens provides for centration with the eye closed. The effects of lid interaction on blinking and gravity may result in lens decentration during open eye wear. You should place the lens(s) in your eye 15 to 20 minutes before going to sleep. Your eye care practitioner will advise you if the wearing schedule needs to be changed. Be aware "when in doubt, take it out". It is important that the new wearer not sleep in a lens that has a significant foreign body sensation. In the event of foreign body sensation, remove the lens, clean and re-wet it; and again place the lens in your eye. If the sensation continues, remove the lens. The lens should not be worn.

Appointment Schedule: Your eye care practitioner will schedule a follow-up evaluation after the first overnight wear. The visit is best scheduled within a few hours of awakening and you should report with your lenses in place. This visit provides an excellent opportunity to evaluate lens centration and potential lens adherence.

Assuming the absence of clinical signs and complications, you will be instructed to continue overnight wear of the lenses until the next scheduled follow-up visit. Keeping these appointments is important to maintain good eye health.

Appointment Dates
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The cornea normally changes within five to eight hours of wear. Your practitioner should modulate your wearing time to determine the MINIMUM wear required for myopic reduction. The average wearing time is between 8 and 10 hours. Attempt to maintain wearing time at this minimal level.

MYOPIC REDUCTION MAINTENANCE LENS (RETAINER LENS) SCHEDULE:
The Retainer Lens schedule should be customized for each patient. The Retainer Lens wearing time begins with the same wearing time required for the last fitted Optimum Infinite (tisilfocon A) Orthokeratology Lenses II. After a period of several days, or when the eyecare practitioner is satisfied that the patient has adapted to the Retainer Lenses, the patient may attempt to skip a night of wear to monitor the duration of visual improvement. This may continue as long as the patient can see clearly. When it is found that the patient experiences a visual decrement following lens removal, the schedule of overnight wear must be modulated to maintain visual performance.

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