PROFESSIONAL FITTING AND INFORMATION GUIDE

Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens

CAUTION: Federal Law Prohibits Dispensing Without a Prescription

Nonsterile. Clean and condition lenses prior to use.

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INTRODUCTION

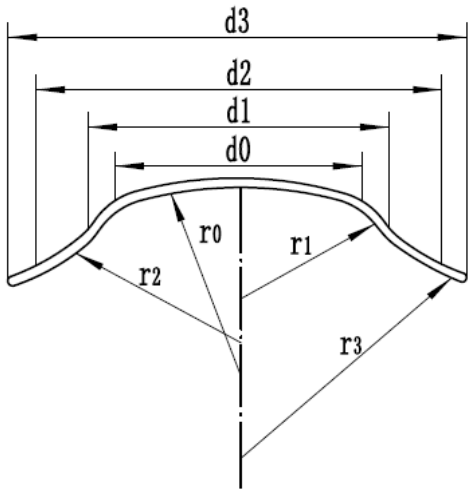
Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses produce a temporary reduction of myopia by reversibly altering the curvature of the cornea. A slight reduction of the curvature of the cornea can reduce the excessive focusing power of the myopic eye. If the amount of corneal reshaping is precisely controlled as is the objective of the Dilight™ lens design, it is possible to bring the eye into correct focus and completely compensate for myopia. The lens is designed to be worn overnight with removal during the following day. The lenses must be worn at night on a regular schedule to maintain the corneal reshaping, or the pre-treatment myopia will return.

PRODUCT DESCRIPTION

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens is a lathe cut contact lens manufactured from the rigid gas permeable material roflufocon E, which is a fluorosilicone acrylate contact lens material registered with the United States Adopted Names (USAN) Council.

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens is designed with anti-geometric shape. The lens consists of four arcs (or curves): base arc, reverse arc, fitting arc and side arc. The basal arc region, located in the center and relatively flat in shape, is the treatment area and exerts slight pressure on the cornea. The second is the inverted arc region, which is steeper and provides space for corneal epithelium and tear fluid. The fitting arc zone is then used to provide pressure in the middle and periphery of the cornea and improve center positioning. The lateral arc is the site of tear exchange.

Figure 1 Schematic Diagram of Shaft Section of Orthokeratology



Where,
r_0 ——BC Base Arc Radius;
r_1 —— Reverse Arc Curvature Radius;
r_2 ——Adaptive Arc Curvature Radius;
r_3 ——Edge Arc Curvature Radius;
d_0 ——Base Arc Diameter;
d_1——Reverse Arc Diameter;
d_2——Adaptive Area Diameter;
d_3——Total Diameter;

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens incorporates a visibility tint to make the lens more visible for handling. The tinted lenses are available in blue and gray and contain one or more of the following color additives: D&C Green No.6, C.I. Solvent yellow No. 18, and FD&C Red No. 17.

LENS PARAMETERS AVAILABLE

Table #1 - Delight (roflufocon E) Lens Parameters and Properties

Parameter or Property	Specification	Tolerance Limit
Radius of Base Arc Curvature	7.50-9.93 mm, Step Size 0.01mm	±0.05 mm
Total Diameter	9.60-11.60 mm, Step Size 0.10 mm	±0.10 mm
Central Thickness	0.15-0.30 mm, Step Size 0.01 mm	±0.02 mm
Back Focal Power F'v	$\|F'v\| \leq 5.00D$ $5.00D < \|F'v\| \leq 10.00D$	±0.12D ±0.18D
Prismatic Power (Residual)	$\|F'v\| \leq 6.00D$ $\|F'v\| > 6.00D$	±0.25cm/m ±0.50cm/m
Oxygen Permeability	94×10^{-11} (cm^2/s) [$mLO_2/(mL\cdot hPa)$] @35℃	± 20%
Refractive Index	1.432	± 0.001
Specific Gravity	1.15	-
Light Transmittance	94 %	± 5%
Contact Angle	46°	± 15%
Water Absorption	Less than 0.5% by weight	-

ACTIONS

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens 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 the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens 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 Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens 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 Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens is indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lens is indicated for overnight wear for the temporary reduction of myopia up to 4.00 diopters (manifest spherical equivalent) in eyes with astigmatism up to 1.50 diopters. The lenses may only be disinfected using a chemical disinfection system.

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

CONTRAINDICATIONS (REASONS NOT TO USE)

Reference "***Contraindications"*** found in the enclosed Package Insert

WARNINGS

Reference "***Warnings"*** found in the enclosed Package Insert

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

Reference ***"Adverse Effects (Problems and what to do)"*** found in the enclosed Package Insert

PRECAUTIONS

Reference ***"Precautions"*** found in the enclosed Package Insert

SELECTION OF PATIENTS

Patients are selected who have a demonstrated need and desire for a refractive reduction by orthokeratology with rigid gas permeable contact lenses and who do not have any of the contraindications for contact lenses described above.

Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses are indicated for myopic patients who desire to have time periods during the day in which they do not need to wear their contact lenses, but still need to see clearly.

Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses are primarily intended for patients who are within the following parameters.

Refractive error: -1.00 to –4.00 diopters with up to 1.50 diopters of astigmatism
Keratometry 40.00 to 46.00 diopters

FITTING CONCEPT

Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses are designed to be fit so that they flatten the central cornea and thereby reduce myopia. This goal is accomplished by the lens design and the manner in which the lens is fitted. The goal in fitting is a well-centered lens having a base curve that is flatter than the flattest meridian of the cornea by at least the attempted treatment power in that meridian. A well fit lens will have the proper sagittal depth to prevent vaulting off the central corneal apex and prevent excessive bearing in the alignment zone(s). There should be adequate edge lift to allow for proper tear exchange.

Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses have four zones: A Base Curve Zone for optical properties, a Reverse Curve Zone which provides the proper positioning of the Base Curve to the apex of the eye, an Alignment Curve Zone which allows the lens to properly center on the eye, and a Peripheral Curve Zone that provides edge lift and tear exchange.

The default parameters for a lens with an overall diameter of 10.5 mm would be:

Base Curve Optical Zone	6.0 mm
Reverse Curve Width (Fitting Curve)	0.75 mm
Alignment Curve Width	1.0 mm
Peripheral Curve Width	0.5 mm
Overall Diameter	10.5 mm

The default parameters for a lens with an overall diameter of 11.0 mm would be:

Base Curve Optical Zone	6.0 mm
Reverse Curve Width (Fitting Curve)	0.75 mm
Alignment Curve Width	1.25 mm
Peripheral Curve Width	0.5 mm
Overall Diameter	11.0 mm

PREDICTING LENS RESULTS:

The clinical results for the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens study show that the lens design is effective and predictable for correcting myopia between the range of –1.00 to –4.00 diopters.

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses will produce a temporary reduction of all or part of a patient's myopia. The amount of reduction will depend on many factors including the amount of myopia, the elastic characteristics of the eye and the way that the contact lenses are fit. Average amounts of reduction have been established by clinical studies but the reduction for an individual patient may vary from the averages.

CLINICAL STUDY DATA

Reference the ***"Clinical Study Data"*** found in the enclosed Package Insert.

Risk Analysis

There is a small risk involved when any contact lens is worn. It is not expected that the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses will provide a significant risk that is greater than other overnight wear rigid gas permeable contact lenses. Additionally, orthokeratology patients may experience episodes of blurry distance vision or visual flare and/or ghosting.

The two most common side effects that occur in 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 Dilight™ (roflufocon E) Overnight Orthokeratology Lenses. Other side effects, which sometimes occur in all hard lens wearers, are pain, redness, tearing, irritation, discharge, abrasion of the eye or distortion of vision. These are usually temporary conditions if the contact lenses are removed promptly 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. The benefits and risks of overnight wear lenses should be carefully discussed with your patient. Your patient should be instructed to remove the contact lenses if any abnormal signs are present.

FITTING PROCEDURES**:**

The specifications of the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses are the flat keratometer reading, the refractive power you are trying to correct, and the cornea diameter.

1. Pre-fitting Examination:

1.1. Complete refraction and visual health examination should be performed.

1.2. Pre-fitting patient history and examination are necessary to:

Determine whether a patient is a suitable candidate for The Dilight^{TM} (roflufocon E) Overnight Orthokeratology Contact Lens (consider patient hygiene and mental and physical state).

Collect and record baseline clinical information to which post-fitting examination results can be compared.

2.Initial Lens Power Selection:

The Back Vertex Power of the Dilight^{TM} (roflufocon E) Overnight Orthokeratology Contact Lens is calculated by subtracting the amount of myopia you want to correct from the spectacle refraction and adding an appropriate correction constant.

Rx = -2.75 diopters
Desired correction is the full –2.75 diopters
BVP = -2.75 – (-2.75) + 1.25= +1.25 diopters

The additional 1.25 diopters compensates for a small regression in the unaided visual acuity when the lens is first removed.

3. Initial Lens Diameter Selection:

Usually, We recommend selecting 10.5mm and 11.0mm as the initial lens diameter.

If HVID is between 10.5 and 11.2 mm choose a 10.5 mm lens.

If HVID is greater than 11.2 mm, choose the 11.0 mm lens

This guide is only a general recommendation and the specification for an individual patient will depend on the eye care practitioner's professional judgment.

4. Initial Lens Base Curve Selection:

The Base Curve of the Lens is expected to be flatter than the corneal keratometer readings and the alignment curves. R_{BC} refers to posterior apical radius measured in mm. The correction constant is an additional amount of flattening that is figured into the Base Curve to overcome a slight amount of initial rebound of the cornea when the lens is first removed. The correction constant is typically 1.25 diopters.

The R_{BC} is calculated by:

R_{BC} = (337.5 / (Flat K + Target Correction - Correction Constant))

For a Flat K of 44.00 and a Target Correction of –2.75

R_{BC} = (337.5 / (44.00 + (-2.75) - 1.25) = 337.5 / 40 = 8.438mm

5. Initial Lens Evaluation:

5.1 Static Fit - Fluorescein Pattern Assessment

Observe the fluorescein pattern with your slit lamp using the Cobalt blue light with a yellow Wratten filter attached. Hold the eyelids apart and manipulate the lens to a central position

for the best assessment of lens alignment to observe the NaFl pattern.

Central
The lenses should have sufficient sagittal height to never bear centrally on the cornea. Correct sagittal height will avoid central staining and prevent lateral decentration.

Mid-peripheral
The lens-cornea bearing must be balanced over the horizontal meridian of the mid-peripheral cornea. This allows for optimal lens centration and stability.

Edge
The horizontal edge lift should be sufficient to allow for tear flow and allow lid attachment.

5.2 Dynamic Assessment
Centration
The lens should be well centred on the cornea and cover the pupil. It is typical to see the lens be decentered slightly inferior temporal. This would have minimal effects on corneal reshaping but may induce aberrations.

Coverage
The size of the lens should almost cover the whole cornea but should never overlap the limbus.

Movement
The lens should move smoothly but not greater than 1.5 mm in any direction. Ideally the lens will move vertically due to superior eyelid interaction.

TRIAL LENSES:

Trial Lens Fitting:
Trial lens fitting may be helpful in lens selection. Trial lens fitting may allow a more accurate determination of lens specification for the lens fit and power. Choose the first lens according to the procedure given for lens selection. Trial lenses are very helpful in fitting patients whose corneal topography has been distorted by previous contact lens wear.

Trial Lens Set:
To evaluate just the fitting characteristics of the lens, a trial lens set would consist of a multiple of 20 lenses. The lenses would be labeled according to the flat keratometer reading or individual base curves. A trial lens set will allow evaluation of the lens centration on the cornea. This is a valuable tool and is particularly useful for fitting the astigmatic cornea.

CAUTION: Non-sterile lenses. Clean and condition lenses prior to use.

Eye care practitioners should educate contact lens technicians concerning proper care of trial lenses. Each contact lens is shipped non-sterile in a case with no solution (dry). Therefore in order to insure disinfection, clean and condition lenses prior to use. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, lenses should be surface cleaned and disinfected, following the manufacturer's instruction.

Trial Lens Procedure
Select a trial lens and place the lens upon the eye. Evaluate the lens using white light for the following:

1. Centering
   Lens should center as well or better than a regular RGP lens. The lens should be fitted according to the interpalpebral fitting philosophy. Lenses fitted according to the "lid attachment" philosophy, in which the lens purposely rides in a high position should be avoided.

2. Movement
   Lens movement should be equivalent to or slightly less than a regular RGP lens, fitted according to the interpalpebral philosophy.

Evaluate the fluorescein pattern. The fluorescein pattern should show a lens with definite central touch, approximately 4.0 mm to 6.0 mm in diameter with a surrounding area of pooling. The pattern should show alignment in the mid-periphery and there should be normal clearance at the edge.

The area of pooling near the transition between the base curve and secondary curve serves as a reservoir for tears and as a potential space for corneal shifting during the flattening process of orthokeratology. The cornea adapts by flattening in the central area, which reduces the space near the transition reservoir. The size of the transition reservoir, as observed from the fluorescein pattern, is a good indicator not only of the initial fit of the lens but also of the progress of corneal flattening over time as the lens is worn.

The fluorescein pattern provides a good method for monitoring the fit of the contact lens over time. As the cornea flattens, the area of pooling at the transition becomes less.

ORTHO-K PROBLEM SOLVING:

Tight lens or no movement:
Cause: It is usually caused by the alignment curve too steep or diameter too large.
Solution: Loosen (flatten) the alignment curves or reduce the diameter.

Loose Lens:
Cause: It is usually caused by a low amount of flattening of the peripheral cornea or from an asymmetrical corneal shape.
Solution: If the lens is too loose, tighten (steepen) the alignment curves.

High Riding Lens:
Cause: It is usually caused by either from the lens being too loose or from an asymmetrical corneal shape.

Solution: If the lens is too loose, tighten (steepen) the alignment curves.

Low Riding Lens:
A slight low riding lens is ideal for the position of the dispensing. The lens will then center with the eye closed. Do not make a change unless the lens is chronically low riding with eyelid closed (as demonstrated by topography) or if unacceptable ghosting persists.
Cause: The cornea becomes flatter from the apex to the rim. This degree of corneal flattening is different for everyone, with some corneas having a greater or lesser degree of flattening. If the flattening is too great, the alignment curves will be too steep.
Solution: Loosen (flatten) the alignment curves or reduce the diameter.

Lateral Riding Lens:
Cause: Lateral decentration can occur either nasally or temporally can occur due to various reasons such as lens design, eyelid anatomy or irregular baseline topographies.
Solution: All these factors must be considered when troubleshooting a lens with lateral decentration. Alleviating lateral decentration can be challenging however increasing the lens diameter may increase cornea coverage. Other options include tighten (steepen) or adjusting the alignment curves (possibly considering toric alignment curves if rotationally symmetrical lens was previously used).

Vaulting:
Cause: The main cause of central vaulting is an alignment curve that is too steep. The farther away from the top of the cornea, the harder it is to predict how fast the cornea will flatten. When the alignment curve is too steep, the central portion of the lens will rise up, preventing it from applying compression to the center of the cornea. The few cause of central vaulting is a reverse curve that is too steep
Solution: Loosen (Flatten) the alignment curves. The risk is that by loosening the alignment curves too much, centering problems can develop. If the lens is well centered, and does not appear tight in the alignment curve area, loosen (Flatten) the reverse curve.

Ghosting At Night:
Cause: The main cause of ghosting is when the reduced illumination at night causes the pupil to become larger than the central correction area of the cornea. This might occur even with a well-centered lens. Patients with smaller pupils will not experience this to the extent of patients with very large pupils. Another cause is a decentered lens. This can also cause ghosting during the day. Central islands can also give the same subjective complaints as ghosting.
Solution: Time is the answer for normal ghosting. If the lens is not centered, then follow the methods used to center the lens. The optical region of the lens can be enlarged. However, this might lead to a decrease in the holding time. It is recommended that you wait 1 month before increasing the size of the optical zone.

Under-responders:
An under-responder is a patient whose myopia does not reduce as anticipated. An example is a –3.00, which was reduced to –1.00 after one month of wear and has not changed for 3 weeks. You will be able to refract the patient, without the lenses in, to 20/20 or better.
Cause: Typically, the under-responder will have vaulting in the center. Some patients will, however, respond slower than others perhaps due to different cell structure of the cornea. You do not want to rush into making a change if the exam figures are correct.

Solution: Follow the same solutions for vaulting. If no vaulting is present, recheck the original exam figures. If the fluorescein pattern looks good, wait a while longer, typically one month to allow for slow responders. If there is still no further reduction on the unaided visual acuity, increase the target power .

Central Staining:
Cause: It is usually caused by central staining is a coated lens. Because of the steep reverse curve, it is difficult to clean the central posterior surface of the lens. This will create an irritating surface, which in turn causes the staining and a tendency for lens adherence. If the base curve is too flat, the reduced mechanical pressure can also cause irritation. A few causes of central staining are reduced oxygen supply.
Solution: Make sure the posterior surface of the lens is clean first. Review the cleaning solution used. Make sure there are no dry spots. If the staining remains, steepen the BC.

FOLLOW-UP CARE:

General Information:
Follow-up examinations, as recommended by the eye care practitioner, are necessary to ensure continued successful contact lens wear. Follow-up examinations should include an evaluation of lens movement, centering, comfort, and fluorescein pattern. Lens movement will decrease as tear volume is diminishing during adaptation. The patient should also begin to feel more comfortable. An assessment of vision and eye health, including inspection of the cornea for edema and/or staining should be performed.

Follow-Up Time:
On the first morning following overnight wear, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The patient should be asked to identify any problems, which occur that are related to contact lens wear.

Evaluation:
With lenses in place on the eyes, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the cornea flattens rapidly there will be a larger area of central touch and the pooling at the lens transition will be reduced. The lens will usually show reduced movement.

After the lens is removed, conduct a thorough slit-lamp examination to detect the following:

1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization. These conditions are indicative of excessive corneal edema.
2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of a reaction to solution preservatives, excessive lens wear, and/or an improperly fitted lens.

Follow-Up Frequency:
You need to get a good evaluation of the patient early on in the process to see how they are reacting to Dilight^{TM} (roflufocon E) Overnight Orthokeratology Lenses and to optimize the improvement in their unaided visual acuity. After vision has stabilized, the patient should

probably be recalled every 3 months to check on progress. The follow-up schedule is determined by the eyecare practitioner for each patient.

Corneal Topography:
A corneal topographer is a valuable tool to use for evaluating any fitting of overnight wear lenses and particularly the Dilight™ (roflufocon E) Overnight Orthokeratology Lenses. Since you are not able to evaluate the fit of the lenses when they are being worn at night, a corneal topographer can give you a picture of the resulting changes that have taken place. A corneal topographer will give you an accurate view of how the lens centered on the eye the previous night.

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 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. The patient should place the lens(s) in their 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 on your 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 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, the patient may be instructed to continue overnight wear of the lenses until the next scheduled follow-up visit.

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

Myopic Reduction Maintenance Lens (Retainer Lens) Schedule

After a period of several days, or when the eye care practitioner is satisfied that the patient has adapted to the Dilight™ (roflufocon E) Overnight Orthokeratology 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.

HANDLING OF LENSES

Standard procedures for rigid gas permeable lenses may be used.

CAUTION: Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses are shipped to the practitioner nonsterile. Clean and condition lenses prior to use.

PATIENT LENS CARE RECOMMENDATIONS

Please see list of lens care products in Package Insert

VERTEX DISTANCE & KERATOMETRY CONVERSION CHARTS

Standard charts may be used.

HOW SUPPLIED

Each lens is supplied non-sterile in an individual plastic case. The case, packing slip or invoice is marked with the base curve, power in diopters, diameter, center thickness, [color] and Lot #.

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.

Manufactured by

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Tianjin. P.R. China
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