

LABELING

JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear

IMPORTANT:

The following basic information about contact lens wear and JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear is provided for you. If you are interested in JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear, please see a licensed eye care professional trained and certified in fitting the product. Based on your individual needs, your certified professional will determine if JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear are right for you.

What are JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear?

JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear are a unique rigid gas permeable contact lens design that temporarily corrects myopia (nearsightedness) by gently reshaping your cornea while you sleep. You may then be able to go throughout the day without any lenses. JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear is made from an approved extended wear contact lens material in a special design intended for this purpose.

Can everyone wear JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear?

Not everyone can wear JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear. These lenses are intended for individuals with low to moderate myopia (nearsightedness up to -5 diopters) and moderate astigmatism (1.50 diopters or less).

How likely is it that JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear will work for me?

Of the 210 eyes that completed the study with complete efficacy data (core cohort), 73% obtained 20/20 or better without other correction and 95% obtained 20/40 or better at 9 months. Visual acuity of 20/40 is required in most states to drive without glasses. One hundred and ten out of 374 enrolled eyes were discontinued, primarily due to unacceptable vision, loss to follow-up, or unacceptable comfort (in decreasing order).

Is orthokeratology treatment permanent?

No, it is temporary. If you stop wearing the lenses regularly, your lens-free vision will decline.

Who should not wear JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear?

Persons who exhibit any of the following conditions:

- Inflammation or infection of the eye
- Any eye disease, injury, or abnormality that affects the cornea or surrounding tissue
- Any systemic disease that may affect the eye or be worsened by wearing contact lenses

- Allergic reactions of eye which may be caused or exaggerated by wearing contact lenses or use of contact lens solutions
- Eyes that are red or irritated, or suffer severe dryness
- The JSZ Orthokeratology (oprifocon A) Contact Lenses have not been clinically studied in adolescent and pediatric subjects.

What are the risks of wearing JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear?

There is a small risk involved when any contact lens is worn. It is not expected that the JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear will provide a risk that is greater than other overnight wear rigid gas permeable contact lenses. Because this procedure is temporary, some patients may notice changes in their vision late in the day. 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 that occur in general rigid contact lens wearers are corneal edema and corneal staining. It is anticipated that the same side effects will also occur in some wearers of JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear. Other side effects that sometimes occur in all contact 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.

In very rare instances, infections of the eye, corneal ulcer, inflammation within the eye (iritis), new blood vessel growth into the cornea (neovascularization), and 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.

How do I care for my lenses?

Your lenses should be chemically disinfected after every use (not heat). Your eye care practitioner will instruct you about what care system is best for you. Your lenses should be replaced as your eye care practitioner sees fit.

How long does it take to reach good vision?

Most patients have rapid improvement in the first few days of treatment and have achieved nearly their optimum vision within about 1 month. Most eyes seem to be stable by 3 to 9 months. A small percentage of patients will not improve enough to function under all conditions without additional correction (glasses or daytime contact lens wear).

What do I do in the period of time between when I start orthokeratology treatment and when I achieve good vision?

It is important to understand that for a time after you have begun treatment but before sufficient visual change is realized, your old glasses will no longer be the appropriate prescription. Your eye care professional will discuss what your options are for visual correction during that period of time.

What are some important things for me to remember?

If you feel like you are having a problem with your vision or contact lenses, immediately remove your lenses and call your eye care professional. Always follow the instructions your eye care professional has given you about lens wear, follow-up and care systems.

What if I have questions about JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear?

It is essential that you discuss any issues you may have about your eye health or contact lens wear with your eye care professional. If you need any further information about JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear, please contact your eye care professional.

For more information, please call 1-800-645-0996.

JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear are:

Manufactured for
Szabocsik and Associates
203 N. Wabash Ave, Ste 1200
Chicago, IL 60601
800-645-0996 (phone)
800-827-0602 (fax)

and

Manufactured by
Euclid Systems Corporation
2810 Towerview Rd
Herndon, Virginia 20171

PACKAGE INSERT

JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear

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 restricts this device to sale by, or on the order of a licensed practitioner.

JSZ Orthokeratology (oprifocon A) Contact Lenses should be fitted only by a contact lens fitter trained and certified in the fitting of conventional (non-reverse geometry) and reverse geometry contact lenses.

Nonsterile. Clean and condition lenses prior to use.

JSZ Orthokeratology (oprifocon A) Contact Lenses
for Overnight Wear

DESCRIPTION

JSZ Orthokeratology (oprifocon A) Contact Lenses are lathe cut contact lenses with spherical posterior surfaces in blue, green, red and yellow tinted versions. The posterior curve is selected to properly fit an individual eye for orthokeratology and the anterior curve is selected to provide the necessary optical power for a temporary reduction of myopia. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

JSZ Orthokeratology (oprifocon A) Contact lenses are made from Boston® Equalens®II (oprifocon A) polymer with a water content of less than 1 percent. The material contains an ultraviolet absorber, Uvinul D-49. The blue tinted lenses contain D&C Green #6 as a color additive. The green tinted lenses contain D&C Green #6 and D&C Yellow #18. The red tinted lenses contain D&C Red #17 as a color additive. The yellow tinted lenses contain D&C Yellow #18 as a color additive.

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LENS PARAMETERS AVAILABLE

| | |
|--------------------|---|
| Chord Diameter | 9.6mm to 11.6mm |
| Center Thickness | |
| For low minus lens | .20mm to .32mm |
| For plus lenses | .20mm to .32mm |
| Base Curve | 7.30mm-10.15mm |
| Reverse Curve | 5.0 to 9.0 mm. Steeper than the base curve in proportion to the amount of correction |
| Alignment Curve 1 | 7.0 to 9.0 mm. Steeper than the base curve but flatter than the Reverse curve. Generally equal to the Flat K of the cornea being fit. |
| Alignment curve 2 | 7.25 to 9.25 mm. Steeper than the base curve but flatter than AC1 and Reverse curve |
| Peripheral curves | 9.00mm to 15.00mm |
| Back Vertex Power | +1.50 to -5.00 Diopters |

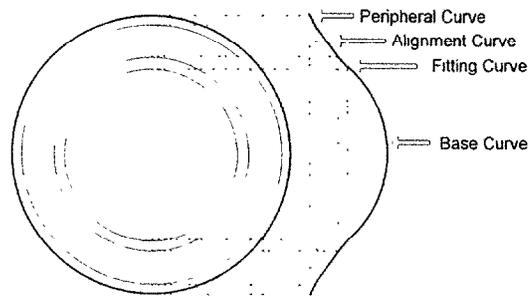


Figure 1: Representation of the reverse geometry lens design.

PHYSICAL PROPERTIES

The physical properties of oprifocon A

| | |
|--|------------------------------|
| Refractive index | 1.423 |
| Light Absorbance (absorbance units/inch) | |
| Blue(640nm) | 10.0 |
| Green(640nm) | 4.8 |
| Yellow(420nm) | 10.3 |
| Red(525nm) | 2.5 |
| Wetting Angle | 30 degrees by Captive Bubble |
| Specific Gravity | 1.24 |
| Hardness | 114 Rockwell |
| Water Content | less than 1% |
| Oxygen Permeability | 85 by Iso/Fatt |

ACTIONS

The JSZ Orthokeratology (oprifocon A) Contact Lenses produce 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 JSZ Orthokeratology (oprifocon A) Contact lenses are 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 JSZ Orthokeratology (oprifocon A) Contact Lenses must be worn at night on a regular schedule to maintain the orthokeratology effect, or the myopia will revert to the pretreatment level.

INDICATIONS

JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear are indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lenses are indicated for overnight wear for the temporary reduction of myopia up to 5.00 diopters with eyes having astigmatism up to 1.50 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), visual fluctuations and changes in intended correction.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the JSZ Orthokeratology (oprifocon A) Contact Lenses 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 your JSZ Orthokeratology (oprifocon A) Contact Lenses.
- 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.

JSZ Orthokeratology (oprifocon A) Contact Lenses 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 JSZ overnight orthokeratology prescribes only overnight wear with removal during waking hours, and although the safety risks of overnight wear with removal upon waking may not be as great as with extended wear, there is still increased risk beginning with the first overnight period.

PRECAUTIONS

Eye care Practitioner

Clinical studies have demonstrated that JSZ Orthokeratology (oprifocon A) Contact Lenses 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 safety and effectiveness of the JSZ Orthokeratology (oprifocon A) Contact Lenses **have not** been clinically studied in adolescent and pediatric subjects.

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.

JSZ Orthokeratology (oprifocon A) Contact Lenses are supplied non-sterile in an individual plastic case. The lens is shipped dry and must be cleaned and conditioned prior to use.

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 JSZ Orthokeratology (oprifocon A) Contact Lenses.
- 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 or 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 and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care practitioner.

Discuss these topics with each patient:

- Wear of contact lenses during sporting activities
- Use of any medication in the eye
- Importance of adhering to the recommended follow-up schedule to assure the continuing health of the eyes.
- Informing health care practitioner about being a contact lens wearer
- Informing employers of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that contact lenses not be worn during work hours.
- What should be done if vision is inadequate during the day.

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 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.

CLINICAL STUDY DATA*

Demographic Information

A total of 378 eyes (191 patients) were enrolled in the clinical study with 264 eyes (134 patients) completing a minimum of 9 months of contact lens wear. Data on 210 eyes (eyes with more complete effectiveness data) were analyzed for safety and effectiveness after 9 months of wear (the “core” group). In addition to this core group, 54 eyes were analyzed for safety data (the “adjunct” group). The entire population consisted of 128 females and 63 males, ranging in age from 17 to 64.

Effectiveness Outcomes

The average amount of myopia that can be expected to be corrected is shown in the following table. These values are only averages and some patients can be expected to achieve more or less than these averages.

*Data based on Euclid Systems Orthokeratology (oprifocon A) Contact Lens for overnight wear 9 month clinical study.

Average Reduction in Myopia (Diopters)
(210 Core Eyes)

| Initial Myopia | Mean Reduction (D) | Mean Residual (D) |
|-----------------|--------------------|-------------------|
| 0 to -1.00 | 1.15 | 0.21 |
| >-1.00 to -2.00 | 1.52 | -0.15 |
| >-2.00 to -3.00 | 2.39 | -0.13 |
| >-3.00 to -4.00 | 3.29 | -0.22 |
| >-4.00 to -5.00 | 3.85 | -0.57 |
| >-5.00 to -6.00 | 4.67 | -0.68 |
| >-6.00 | 4.88 | -1.25 |

Uncorrected Visual Acuity (UCVA)

The primary efficacy endpoint for the core group was the number of eyes achieving at **least 2 lines of improvement in uncorrected visual acuity with at least 20/40 vision**. For the 210 Core eyes available at 9 months, 199 eyes (95%) met these criteria of success, while 11 eyes did not achieve this successful outcome.

**PRIMARY EFFICACY ENDPOINT AT 9 MONTHS
STRATIFIED BY PRE-TREATMENT MYOPIA
CORE EYES (210)**

| | PRETREATMENT MYOPIA (MRSE) | | | | | | | Total |
|---|----------------------------|--------------------|---------------------|---------------------|---------------------|---------------------|---------------------|-------|
| | 0 to -1.00D* | <-1.00to -2.00D | <-2.00 to -3.00D | <-3.00 to -4.00D | <-4.00 to -5.00D | <-5.00 to -6.00D | <-6.00 to -7.00D | |
| | n | n | n | n | n | n | n | |
| A. #eyes at 9 months with 2 lines improvement and 20/40 or better | 5 | 60 | 72 | 34 | 22 | 5 | 1 | 199 |
| B. #eyes at 9 months not meeting above criteria, data available | 1 | 3 | 4 | 0 | 3 | 0 | 0 | 11 |
| C. #eyes enrolled and available at 9 months | 6 | 63 | 76 | 34 | 25 | 5 | 1 | 210 |
| % eyes at visit with Acuity "Success" (A/Dx100) | 83.3 | 95.2 | 94.7 | 100.0 | 88.0 | 100.0 | 100.0 | 94.8 |
| MRSE Mean | 0.21 | -0.15 | -0.13 | -0.22 | -0.57 | -0.68 | -1.25 | |
| Std. Dev. | 0.17 | 0.64 | 0.50 | 0.51 | 1.14 | 0.68 | 0.0 | |

*only 1 eye had an MRSE <-1.00 (0.63)

Post-treatment visual acuity was assessed on the 210 analyzed core eyes. Seventy-three percent achieved 20/20 or better, 95% achieved 20/40 or better.

Accuracy

At 9-months, 80 percent of the core eyes achieved a reduction of myopia to within 0.50 D of target and 93% achieved a reduction to within 1.00 D of target. The accuracy of the temporary reduction in myopia is given in the following table, which also shows the final acuity without lenses. However, accuracy of correction is less with correction higher than 4.00D than with those less than 4.00D.

**VISUAL OUTCOME
ACCURACY OF THE
TEMPORARY REDUCTION OF MYOPIA,
FINAL ACUITY WITHOUT CONTACT LENSES
(Core Eyes at 9-Months)**

| Initial Myopia** | % Within 0.50 D of Target* | % Within 1.00 D of Target* | % With Final VA 20/20 or better* | % With Final VA 20/40 or better* |
|------------------|----------------------------|----------------------------|----------------------------------|----------------------------------|
| <0.00 to -1.00D | 100% | 100% | 100% | 100% |
| -1.25 to -2.00D | 81% | 93% | 82% | 94% |
| -2.25 to -3.00D | 87% | 96% | 77% | 94% |
| -3.25 to -4.00D | 79% | 94% | 71% | 100% |
| -4.25 to -5.00D | 60% | 88% | 64% | 95% |

*100x# reported/# in category

** Manifest Refraction Spherical Equivalent

Wearing Time

The lenses were intended for overnight wear only. The average wear time was reported to be between 8 and 10 hours per night, and there was no apparent relationship between the number of hours of wear and the visual outcome, for any amount of pretreatment myopia.

Analysis of Post Lens Removal Uncorrected Visual Acuity (UCVA) Regression

The effects of wearing your lenses at night are not permanent and slowly diminish after you remove your lenses. While this does not present a problem for most wearers, it is important to realize for some patients their vision at the end of the day may not be fully satisfactory for highly demanding visual tasks. Although this may not be an issue for most wearers, the eye care practitioner should consider each patient's "late in the day" circumstance to discuss what steps the patient should take if this is a concern.

The data collected during the clinical study for the regression of UCVA following lens removal were incomplete. A postapproval study to evaluate the stability of treatment post lens removal will be conducted.

Effects on Astigmatism

Either increases or decreases in astigmatism may occur following orthokeratology. Of the 210 analyzed eyes, 35% showed no change in refractive astigmatism, 41% showed a decrease of one diopter or less, 2% showed a decrease greater than one diopter, 20% showed an increase of one diopter or less, and 2% showed an increase greater than one diopter.

OVERNIGHT WEAR SAFETY SUMMARY

In this study all eyes were evaluated for safety of overnight wear for orthokeratology to treat myopia and myopia with astigmatism. Two hundred and sixty-four eyes were followed for 9 months. The data on best corrected acuity, adverse events, slit lamp findings and symptoms provide reliable indications of the safety of oprifocon A in this treatment modality.

Best Spectacle Corrected Visual Acuity (BSCVA)

The majority of core eyes (those eyes with more complete effectiveness data upon which the primary effectiveness determinations can be made), 73% had no change in BSCVA from baseline. 18 % had a gain of 1 line, <1% had a gain of 2 lines, and 1 % had a gain of >2 lines in BSCVA as compared to baseline. Concurrently, 8% had a loss of >1 line as compared to baseline. No core eyes had a loss of ≥ 2 lines of BSCVA.

For the 54 completed adjunct eyes (those subjects for which incomplete data was collected but enough data is provided to use as safety data) the change in lines of BSCVA at the 9-month post-treatment interval showed 41% had no change in BSCVA from baseline, and 1% gained 1 line. There were 4% with loss of 1 line in BSCVA. Data were not reported for 29 eyes.

When considering all eyes entered into the study, there were a total of 42 incidents (in 34 eyes) of at least a temporary reduction of ≥ 2 lines of BSCVA during the course of the

study. Only 12 of the 42 incidents occurred after 3 months. Duration of the vision loss was not accurately determined in all cases, but for incidents in which there is some documentation and recovery was demonstrated, length of time to documented recovery varied from 1 day to 9 months. Thirty-three eyes had a duration of reduced vision of > 7 days.

Four eyes in 3 patients showed a reduction of ≥ 2 lines of best corrected acuity from initial visit to last study visit. One of these eyes was subsequently documented to return to normal acuity. No significant ocular abnormalities were observed in these eyes with biomicroscopy at the time of study exit.

Slit Lamp Findings

For 2,907 eye exams, there were 14 exams showing slit lamp findings greater than grade 2 reported as follows: grade 3 for staining (3 incidents); grade 4 for staining (2 incidents); grade 3 for injection (2 incident); grade 3 “other” (4 incidents); and ungraded (3 incidents: 2 staining and 1 tarsal abnormality). All findings greater than grade 2 resolved without further complications. There were 5 slit lamp findings > Grade 2 or ungraded, in the Core, and 9 in the adjunct. The most significant of the > Grade 2 findings, were 3 Grade 3 Corneal Staining cases, 2 Grade 4 Corneal Staining cases, 1 case of Corneal Infiltrates (grade 3) and 2 Cases (2 eyes of 1 subject) of trace Iritis

Symptoms, Problems and Complaints

Subjects were asked to report symptoms and complaints at each follow-up visit. For core and completed adjunct eyes, poor distance vision was reported for 17% (389/2389), flare or ghosting were reported for 9% (216/2389), and all other symptoms (poor near vision, red eye, excessive lens awareness/pain, excessive discharge, burning/itching, and photophobia) were reported for 8% (188/2389) throughout the study. It appears that the eyes with initial myopia above 3.00D had a higher incidence of these visual disturbances.

Discontinuations

Of the 90 adjunct subjects, 55 subjects (110 eyes) discontinued before completing 9 months of wear, for reasons as listed in the following table.

| REASONS FOR DISCONTINUATION | | |
|-----------------------------|--------|---------------|
| Clinical Reason* | # eyes | % of all eyes |
| Unacceptable vision | 52 | 14% |
| Lack of Comfort | 28 | 8% |
| Unacceptable physiology | 12 | 3% |
| Non-clinical Reasons | | |
| Lost-to-follow-up | 38 | 10% |
| Other** | 10 | 3% |

*Several subjects reported more than 1 reason for discontinuation, without giving

any priority to the reasons.

***"Other" included returned to spectacles (2 eyes), night vision bothered (2 eyes), wanted prior uncorrected near vision (2 eyes), financial (2 eyes), and could not maintain visit schedule (2 eyes).

Adverse Events and Complications

There were 12 significant lens-related adverse events reported in 10 subjects. Two eyes had bilateral grade 4 staining with significant decrease in vision to 20/80. One eye had grade 3 corneal staining secondary to a dislodged lens. One eye had significant corneal distortion with reduced vision to 20/200 and rippling on the cornea. Two eyes had bilateral iritis with trace cells and flare in both eyes. One eye had corneal infiltrates. Two eyes had abrasion (grade 3 staining). One eye had reduction of BSCVA to 20/50 secondary to a decentered lens. One eye had reduction of BSCVA to 20/60 due to central staining. One eye had reduction of BSCVA to 20/60 with no reason given.

All of these eyes that showed acuity reductions were documented as returning to normal vision, except two eyes of one subject with severe corneal staining that showed ≥ 2 lines loss of BSCVA. The return to pretreatment VA was not recorded on the case report form of this subject although the subject returned to soft contact lens wear and verbally reported that vision was normal. Of the 10 subjects for which adverse events were reported, 4 subjects discontinued the study. All adverse events resolved without further complications.

Change in Corneal Cylinder

The reduction in refractive error and improvement in unaided visual acuity is the result in part of a change in the corneal radius as measured by keratometry. The keratometer measures the corneal curvature in the two principal meridians at a chord diameter slightly less than 3 millimeters. The keratometer does not provide data of the local curvature inside or outside of the location of its measurement.

14% of all treated eyes manifested more than one diopter of increase in corneal cylinder from baseline to the nine month visit. The core group contained 26 eyes with greater than 1 D increase and the adjunct group contained of 24 eyes with greater than 1 D increase.

There were 7 eyes in the core group and 11 in the adjunct group that had increases (initial to patient's last visit) in corneal cylinder of >2 D. No eye with cylinder increase >1 D had a BSCVA at exit worse than 20/30.

Summary of Key Safety Variables

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

| Criteria | All Treated Eyes (364) | |
|--|---------------------------|----|
| | n | % |
| Significant Adverse Events | 12* | 3 |
| Loss of ≥ 2 lines BSCVA ^{† ‡} | 4 | 1 |
| BSCVA worse than 20/40 [†] | 1 | <1 |
| Increase of > 1 D Refractive Cylinder [†] | 12 | 3 |
| Increase of > 1 D Corneal Cylinder [†] | 50 | 14 |

*Includes 4 discontinued subjects (6 eyes).

[†] from baseline to exit visit

[‡] there were 42 incidents (in 34 eyes) of at least a temporary reduction of ≥ 2 lines of BSCVA during the course of the study. All except 4 discontinued eyes were documented as returning to normal during the study; one eye was documented to return to normal acuity after the study. No significant ocular abnormalities were observed in these eyes with biomicroscopy at the time of study exit.

FITTING

Caution: JSZ Orthokeratology (oprifocon A) Contact Lenses should be fitted only by a contact lens fitter trained and certified in the fitting of conventional (non-reverse geometry) and reverse geometry contact lenses.

Conventional methods of fitting rigid contact lenses for orthokeratology DO NOT APPLY to the JSZ Orthokeratology (oprifocon A) Contact Lens. For a description of fitting techniques, refer to the **Fitting Guide for JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear**. Copies of the Fitting guide are available from:

Szabocsik and Associates
203 N. Wabash Ave, Ste 1200
Chicago, IL 60601
(800) 645-0996
(800) 827-0602 (fax)

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.

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 JSZ Orthokeratology (oprifocon A) lenses, 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 by JSZ Corporation for use with the JSZ Orthokeratology (oprifocon A) Contact Lenses.

Chemical Lens Care System

Two Bottle System:

Boston ADVANCE® Cleaner **or** Boston® Cleaner

Boston ADVANCE® Comfort Formula Conditioning (soaking) Solution **or** Boston® Conditioning Solution

OR

One Bottle System:

Boston SIMPLICITY® Multi-Action Solution (Clean, Condition, Disinfect, Rinse, & cushion)

Boston®, Boston ADVANCE® and Boston SIMPLICITY® are registered trademarks of Polymer Technology Corporation.

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.
- JSZ Orthokeratology (oprifocon A) Contact Lenses 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

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the eye care practitioner.

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

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.

Szabocsik and Associates
203 N. Wabash Ave, Ste 1200
Chicago, IL 60601

800-645-0996
800-827-0602 (fax)

Printed mm/yy

PATIENT INFORMATION BOOKLET
FOR POTENTIAL USERS OF

JSZ Orthokeratology
(oprifocon A)

Contact Lenses for Overnight Wear

CAUTION: Federal law restricts this device to sale by, or on the order of a licensed practitioner.

JSZ Orthokeratology (oprifocon A) Contact Lenses should be fitted only by a contact lens fitter trained and certified in the fitting of conventional (non-reverse geometry) and reverse geometry contact lenses.

Nonsterile. Clean and condition lenses prior to use.

| | |
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Introduction

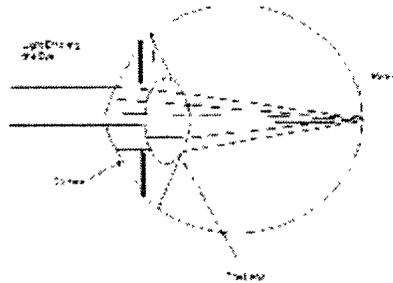
The information in this booklet is to help you decide whether or not to be fitted with the JSZ Orthokeratology lenses for Overnight wear. Orthokeratology is a fitting procedure that temporarily corrects or greatly reduces nearsightedness (known by the medical name, myopia) with or without astigmatism 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, JSZ Orthokeratology (oprifocon A) Contact Lenses must be worn each night to maintain the effect.

Note: JSZ Orthokeratology (oprifocon A) Contact Lenses should be fitted only by a contact lens fitter trained and certified in the fitting of reverse geometry contact lenses.

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.

Figure 1: Normal Eye



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.

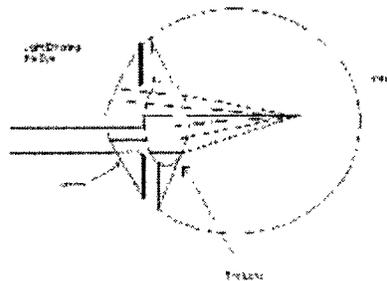


Figure 2: Nearsighted eye

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 JSZ Orthokeratology (oprifocon A) Contact Lens Functions

The JSZ Orthokeratology (oprifocon A) Contact Lens 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.

JSZ Orthokeratology (oprifocon A) Contact Lenses 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.

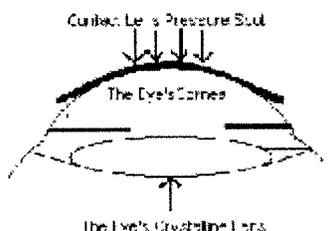


Figure 3: Eye Fitted with JSZ Orthokeratology (oprifocon A) Contact Lens

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.

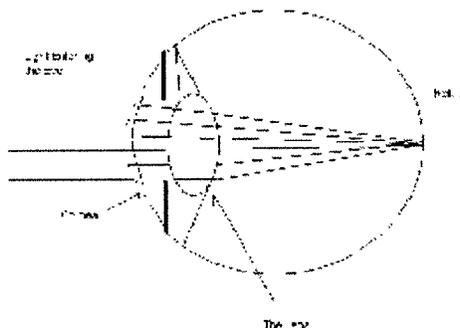


Figure 4: Nearsighted Eye after Orthokeratology

After the lens is removed, the cornea retains its altered shape for all or part of the remainder of the day.

JSZ Orthokeratology (oprifocon A) Contact Lenses 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 JSZ Orthokeratology (oprifocon A) lens 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 JSZ Orthokeratology (oprifocon A) Contact Lenses. 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

JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear are indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lenses are indicated for overnight wear for the temporary reduction of myopia up to 5.00 diopters with eyes having astigmatism up to 1.50 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), visual fluctuations and changes in intended correction.

Precautions

General

Clinical studies have demonstrated that JSZ Orthokeratology (oprifocon A) Contact Lenses 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 safety and effectiveness of the JSZ Orthokeratology (oprifocon A) Contact Lenses **have not** been clinically studied in adolescent and pediatric subjects.

The potential impact of these factors on the 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.

JSZ Orthokeratology (oprifocon A) Contact Lenses are supplied non-sterile in an individual plastic case. The lens is shipped dry and must be cleaned and conditioned prior to use.

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 JSZ Orthokeratology (oprifocon A) Contact Lenses.
- 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 and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- 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)

DO NOT USE your JSZ Orthokeratology (oprifocon A) Contact Lenses 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 your JSZ Orthokeratology (oprifocon A) Contact Lens.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes become 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.

JSZ Orthokeratology (oprifocon A) contact lenses 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 JSZ overnight orthokeratology prescribes only 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.

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.

CLINICAL STUDY DATA*

Introduction

JSZ Orthokeratology (oprifocon A) Contact Lenses may 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 your contact lens fits on your eye.

Demographic Information

A total of 378 eyes (191 patients) were enrolled in the clinical study with 264 eyes (134 patients) completing a minimum of 9 months of contact lens wear. Data on 210 eyes (eyes with more complete effectiveness data) were analyzed for safety and effectiveness after 9 months of wear (the “core” group). In addition to this core group, 54 eyes were analyzed for safety data (the “adjunct” group). The entire population consisted of 128 females and 63 males, ranging in age from 17 to 64.

Effectiveness Outcomes

The average amount of myopia that can be expected to be corrected is shown in the following table. These values are only averages and some patients can be expected to achieve more or less than these averages.

Average Reduction in Myopia (Diopters)
(210 Core Eyes)

| Initial Myopia | Mean Reduction (D) | Mean Residual (D) |
|-----------------|--------------------|-------------------|
| 0 to -1.00 | 1.15 | 0.21 |
| >-1.00 to -2.00 | 1.52 | -0.15 |
| >-2.00 to -3.00 | 2.39 | -0.13 |
| >-3.00 to -4.00 | 3.29 | -0.22 |
| >-4.00 to -5.00 | 3.85 | -0.57 |
| >-5.00 to -6.00 | 4.67 | -0.68 |
| >-6.00 | 4.88 | -1.25 |

Uncorrected Visual Acuity (UCVA)

Post-treatment visual acuity was assessed on the 210 analyzed eyes. 73% achieved 20/20 or better and 95% achieved 20/40 or better. 110 out of 374 enrolled eyes were discontinued, primarily due to unacceptable vision, loss-to-follow-up, or unacceptable comfort (in decreasing order).

*Data based on Euclid Systems Orthokeratology (oprifocon A) Contact Lens for overnight wear 9 month clinical study.

Accuracy

At 9 months, 80% of the core eyes achieved a reduction of myopia to within 0.50 D of target and 93% achieved a reduction to within 1.00 D of target. The accuracy of the temporary reduction in myopia is given in the following table, which also shows the final acuity without lenses. However, accuracy of correction is less with correction higher than 4.00D than with those less than 4.00D.

VISUAL OUTCOME ACCURACY OF THE TEMPORARY REDUCTION OF MYOPIA, FINAL ACUITY WITHOUT CONTACT LENSES (Core Eyes at 9-Months)

| Initial Myopia** | % Within 0.50 D of Target | % Within 1.00 D of Target | Final VA 20/20 or better | Final VA 20/40 or better |
|------------------|---------------------------|---------------------------|--------------------------|--------------------------|
| <0.00 to -1.00D | 100%* | 100% | 100% | 100% |
| -1.25 to -2.00D | 81% | 93% | 82% | 94% |
| -2.25 to -3.00D | 87% | 96% | 77% | 94% |
| -3.25 to -4.00D | 79% | 94% | 71% | 100% |
| -4.25 to -5.00D | 60% | 88% | 64% | 95% |

*100x# reported/# in category

** Manifest Refraction Spherical Equivalent

Wearing Time

The lenses were intended for overnight wear only. The average wear time was reported to be between 8 and 10 hours per night, and there was no apparent relationship between the number of hours of wear and the visual outcome, for any amount of pretreatment myopia.

Analysis of Post Lens Removal Uncorrected Visual Acuity (UCVA) Regression

The effects of wearing your lenses at night are not permanent and slowly diminish after you remove your lenses. While this does not present a problem for most wearers, it is important to realize for some patients their vision at the end of the day may not be fully satisfactory for highly demanding visual tasks. Although this may not be an issue for most wearers, you should consider your own late in the day circumstance to decide if it is a concern.

The data collected during the clinical study for the regression of UCVA following lens removal were incomplete. A postapproval study to evaluate the stability of treatment post lens removal will be conducted.

Effects on Astigmatism

Either increases or decreases in astigmatism may occur following orthokeratology. Of the 210 analyzed eyes, 35% showed no change in refractive astigmatism, 41% showed a decrease of one diopter or less, 2% showed a decrease greater than one diopter, 20% showed an increase of one diopter or less, and 2% showed an increase greater than one diopter.

OVERNIGHT WEAR SAFETY SUMMARY

In this trial all eyes were evaluated for safety and effectiveness of overnight wear for orthokeratology to treat myopia and myopia with astigmatism. There were 264 eyes of 134 subjects followed for 9 months and the data on best corrected acuity, adverse events, slit lamp findings and symptoms provide reliable indications of the safety of oprifocon A in this treatment modality.

Best Spectacle Corrected Visual Acuity (BSCVA)

The majority of core eyes, 73% had no change in BSCVA from baseline. Concurrently, 8% had a loss of >1 line as compared to baseline. No core eyes had a loss of ≥ 2 lines of BSCVA.

41% of the 54 completed adjunct eyes had no change in BSCVA from baseline to the 9-month post-treatment interval and 4% of eyes had a loss of 1 line of BSCVA. Data were not reported for 29 eyes.

When considering all eyes entered into the study, there were a total of 42 incidents (in 34 eyes) of at least a temporary reduction of ≥ 2 lines of BSCVA during the course of the study. Only 12 of the 42 incidents occurred after 3 months. Duration of the vision loss was not accurately determined in all cases, but for incidents in which there is some documentation and recovery was demonstrated, length of time to documented recovery varied from 1 day to 9 months. Thirty-three eyes had a duration of reduced vision of >7 days

Four eyes in 3 patients showed a reduction of ≥ 2 lines of best corrected acuity from initial visit to last study visit. One of these eyes was subsequently documented to return to normal acuity. No significant ocular abnormalities were observed in these eyes with biomicroscopy at the time of study exit.

Biomicroscope Exam

For 2,907 eye exams, there were 14 exams showing slit lamp findings greater than grade 2 (moderate or severe) which were reported as follows:

- moderate staining (3 incidents);
- severe staining (2 incidents);
- moderate injection (2 incidents);
- “other” (4 incidents); and,
- ungraded (3 incidents: 2 staining and 1 tarsal abnormality).

All findings greater than grade 2 resolved without further complications. There were 5 moderate, severe or ungraded findings, in the Core, and 9 in the adjunct. The most significant findings were 3 moderate Corneal Staining cases, 2 severe Corneal Staining cases, 1 moderate Corneal Infiltrates case and 2 cases (2 eyes of 1 subject) of trace Iritis.

The overall incidents of biomicroscope examination findings of subject's eyes reported moderate or severe findings for <1% of exams.

Symptoms, Problems and Complaints

Subjects were asked to report symptoms and complaints at each follow-up visit. For core and completed adjunct eyes, poor distance vision was reported at 17 %, flare or ghosting were reported for 10%, and all other symptoms (poor near vision, red eye, excessive lens awareness/pain, excessive discharge, burning/itching, and photophobia) were reported for 8% throughout the study. It appears that the eyes with initial myopia above 3.00D had a higher incidence of these visual disturbances.

Discontinuations

Of the 90 adjunct subjects, 55 subjects (110 eyes) discontinued before completing 9 months of wear, for reasons as listed in the following table.

| REASONS FOR DISCONTINUATION | | |
|-----------------------------|--------|---------------|
| Clinical Reason* | # eyes | % of all eyes |
| Unacceptable vision | 52 | 14% |
| Lack of comfort | 28 | 8% |
| Unacceptable physiology | 12 | 3% |
| | | |
| Non-clinical Reasons | | |
| Lost-to-follow-up | 38 | 10% |
| Other** | 10 | 3% |

*Several subjects reported more than 1 reason for discontinuation, without giving any priority to the reasons.

**"Other" included returned to spectacles (2 eyes), night vision bothered (2 eyes), wanted prior uncorrected near vision (2 eyes), financial (2 eyes), and could not maintain visit schedule (2 eyes).

Adverse Events and Complications

There were 12 significant lens-related adverse events reported in 10 subjects. Two eyes had bilateral staining; one eye had corneal staining and a dislodged lens; one eye had corneal distortion and rippling on the cornea; two eyes had iritis and flare; one eye had corneal infiltrates; two eyes had an abrasion; one eye had reduction of vision to 20/50 due to a decentered lens; one eye had reduction of vision to 20/60 due to central staining; and one eye had reduction of vision to 20/60 with no reason given.

All of these eyes that showed acuity reductions were documented as returning to normal vision, except two eyes of one subject with severe corneal staining that showed ≥ 2 lines loss of BSCVA. The return to pretreatment VA was not recorded on the case report form of this subject although the subject returned to soft contact lens wear and verbally

reported that vision was normal. Of the 10 subjects for which adverse events were reported, 4 subjects discontinued the study. All adverse events resolved without further complications.

Summary of Key Safety Variables

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

| SUMMARY OF KEY SAFETY VARIABLES | | |
|--|---------------------------|----|
| Criteria | All Treated Eyes (364) | |
| | n | % |
| Significant Adverse Events | 12* | 3 |
| Loss of ≥ 2 lines BSCVA ^{†‡} | 4 | 1 |
| BSCVA worse than 20/40 [†] | 1 | <1 |
| Increase of > 1 D Refractive Cylinder [†] | 12 | 3 |
| Increase of > 1 D Corneal Cylinder [†] | 50 | 14 |

*Includes 4 discontinued subjects (6 eyes).

† from baseline to exit visit

‡ there were 42 incidents (in 34 eyes) of at least a temporary reduction of ≥ 2 lines of BSCVA during the course of the study. All except 4 discontinued eyes were documented as returning to normal during the study; one eye was documented to return to normal acuity after the study. No significant ocular abnormalities were observed in these eyes with biomicroscopy at the time of study exit.

Maintaining Effects of JSZ Orthokeratology (oprifocon A) Lenses for Overnight Orthokeratology

The long-term wear of JSZ Orthokeratology (oprifocon A) Contact Lenses 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 JSZ Orthokeratology (oprifocon A) Contact Lens prescription.

The wearing schedule for JSZ Orthokeratology (oprifocon A) Contact Lenses 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.

Note: To maintain the JSZ 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), visual fluctuations and changes in intended correction.

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

JSZ Orthokeratology
(oprifocon A)

Contact Lenses for

Overnight Wear

Have Been Fitted

Instructions for Wearers of JSZ Orthokeratology (oprifocon A) Contact lenses for
Overnight Wear

CAUTION: Federal law restricts this device to sale by, or on the order of a
licensed practitioner.

**JSZ Orthokeratology (oprifocon A) Contact Lenses should be fitted
only by a contact lens fitter trained and certified in the fitting of
conventional (non-reverse geometry) and reverse geometry contact
lenses.**

Nonsterile. Clean and condition lenses prior to use.

Instructions for Wearers of
JSZ Orthokeratology (oprifocon A) Contact Lenses
For
Overnight Wear

Patient Name _____

Prescribed Lens _____

Doctor _____

Address _____

Phone _____

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Precautions

General

Clinical studies have demonstrated that JSZ Orthokeratology (oprifocon A) Contact Lenses 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 JSZ Orthokeratology (oprifocon A) Contact Lenses have not been clinically studied in adolescent and pediatric subjects. |
|--|

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.

JSZ Orthokeratology (oprifocon A) Contact Lenses are supplied non-sterile in an individual plastic case. The lens is shipped dry and must be cleaned and conditioned prior to use.

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 JSZ Orthokeratology (oprifocon A) Contact Lenses.
- 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 this 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 and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- 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:

- 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 by JSZ Corporation for use with your JSZ Orthokeratology (oprifocon A) Contact Lenses.

Chemical Lens Care System

Two Bottle System:

Boston ADVANCE® Cleaner **or** Boston® Cleaner

Boston ADVANCE® Comfort Formula Conditioning (soaking) Solution **or** Boston® Conditioning Solution

OR

One Bottle System:

Boston SIMPLICITY® Multi-Action Solution (Clean, Condition, Disinfect, Rinse, & cushion)

Boston®, Boston ADVANCE® and Boston SIMPLICITY® are registered trademarks of Polymer Technology Corporation.

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: JSZ Orthokeratology (oprifocon A) Contact Lenses 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 bacteria growth. After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer; then allow the lens case to air dry. 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

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 JSZ Orthokeratology (oprifocon A) Contact Lenses. 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.

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), visual fluctuations and changes in intended correction.

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PROFESSIONAL FITTING AND INFORMATION GUIDE

JSZ Orthokeratology (oprifocon A) Contact
Lenses

For

Overnight Wear

Rigid Gas Permeable
Contact Lenses

CAUTION: Federal law restricts this device to sale by, or on the order of a licensed practitioner.

JSZ Orthokeratology (oprifocon A) Contact Lenses should be fitted only by a contact lens fitter trained and certified in the fitting of conventional (non-reverse geometry) and reverse geometry contact lenses.

Nonsterile. Clean and condition lenses prior to use.

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INTRODUCTION

JSZ Orthokeratology (oprifocon A) 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 JSZ Orthokeratology 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 JSZ Orthokeratology lenses must be worn at night on a regular schedule to maintain the corneal reshaping, or the pre-treatment myopia will return.

PRODUCT DESCRIPTION

JSZ Orthokeratology (oprifocon A) Contact Lenses are lathe cut contact lenses with spherical posterior surfaces in blue, green, red and yellow tinted versions. The posterior curve is selected to properly fit an individual eye for orthokeratology and the anterior curve is selected to provide the necessary optical power for a temporary reduction of myopia. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

JSZ Orthokeratology (oprifocon A) Contact Lenses are made from Boston® Equalens®II (oprifocon A) polymer with water content of less than 1 percent. The material contains an ultraviolet absorber, Uvinul D-49. The blue tinted lenses contain D&C Green #6 as a color additive. The green tinted lenses contain D&C Green #6 and D&C Yellow #18. The red tinted lenses contain D&C Red #17 as a color additive. The yellow tinted lenses contain D&C Yellow #18 as a color additive.

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Detailed Description

The JSZ Orthokeratology (oprifocon A) Contact Lenses have a design known as reverse geometry. This means that the secondary curve on the posterior surface, next to the base curve, has a radius of curvature that is steeper (shorter radius) than the base curve (central curve). This curve is referred to as the "Fitting Curve" or the "Reverse Curve" (Figure 1).

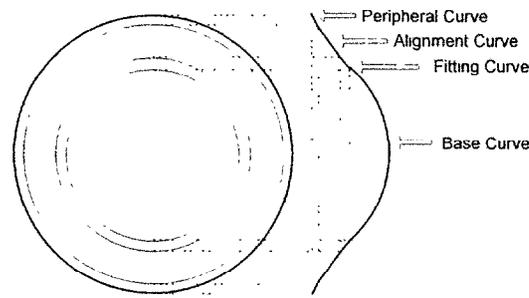


Figure 1: Representation of the reverse geometry lens design.

The Fitting Curve is surrounded by a flatter intermediate zone that is approximately equal in radius to the flat keratometer reading of the central cornea. This zone is referred to as the “Alignment Zone” or the “Alignment Curve”. In this way the geometry of the secondary curves are in the opposite relationship to the base curve, as occurs with standard RGP contact lens. Outside the Alignment Zone, at the edge of the lens, is a peripheral curve that allows for tear exchange under the lens to take place.

The function of the steep Fitting Curve, on the JSZ Orthokeratology (oprifocon A) Contact Lenses, is to allow the base curve to be fit in a flat relationship to the central cornea and still maintain lens stability on the cornea. With a regular RGP contact lens design that is fitted flat on the cornea there is only one support point for the contact lens, which occurs at the center of the lens. This lens will tend to rock and de-center on the cornea. With the JSZ Orthokeratology (oprifocon A) Contact Lenses, there is support for the lens at both the central cornea and in the area of the Alignment Zone. This will reduce lens rocking and aid in centering.

There is no fixed diopter relationship between the Base Curve and the Fitting curve for the JSZ Orthokeratology (oprifocon A) Contact Lenses. The Fitting Curve is calculated to control the sagittal depth of the optical zone, and control the amount of bearing the Base Curve will have on the central Cornea.

A lens design with an overall diameter of 10.2 or less will generally have one Alignment Curve. A larger diameter lens will generally have two alignment curves with the innermost curve approximately equal in radius to the flat keratometer reading, and the outermost Alignment Curve 1.0 diopters flatter than the first Alignment Curve.

LENS PARAMETERS AVAILABLE

| | |
|--------------------|--|
| Chord Diameter | 9.6mm to 11.6mm |
| Center Thickness | |
| For low minus lens | .20mm to .32mm |
| For plus lenses | .20mm to .32mm |
| Base Curve | 7.30mm-10.15mm |
| Reverse Curve | 5.0 to 9.0 mm. Steeper than the base curve in proportion to the amount of correction |

| | |
|-------------------|---|
| Alignment Curve 1 | 7.0 to 9.0 mm. Steeper than the base curve but flatter than the Reverse curve. Generally equal to the Flat K of the cornea being fit. |
| Alignment curve 2 | 7.25 to 9.25 mm. Steeper than the base curve but flatter than AC1 and Reverse curve |
| Peripheral curves | 9.00mm to 15.00mm |
| Back Vertex Power | +1.50 to -5.00 Diopters |

PHYSICAL PROPERTIES

The physical properties of oprifocon A

| | |
|--|------------------------------|
| Refractive index | 1.423 |
| Light Absorbance (absorbance units/inch) | |
| Blue (640nm) | 10.0 |
| Green (640nm) | 4.8 |
| Yellow (420nm) | 10.3 |
| Red (525nm) | 2.5 |
| Wetting Angle | 30 degrees by Captive Bubble |
| Specific Gravity | 1.24 |
| Hardness | 114 Rockwell |
| Water Content | less than 1% |
| Oxygen Permeability | 85 by Iso/Fatt |

ACTIONS

The JSZ Orthokeratology (oprifocon A) Contact Lenses produce 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 JSZ Orthokeratology (oprifocon A) Contact lenses are 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 JSZ Orthokeratology (oprifocon A) Contact Lenses must be worn at night on a regular schedule to maintain the orthokeratology effect, or the myopia will revert to the pretreatment level.

INDICATIONS

JSZ Orthokeratology (oprifocon A) Contact Lenses are indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lenses are indicated for overnight wear for the temporary reduction of myopia up to 5.00 diopters 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 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), 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.

JSZ Orthokeratology (oprifocon A) 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.

JSZ Orthokeratology (oprifocon A) Contact Lenses are primarily intended for patients who are within the following parameters.

Refractive error: -1.00 to -5.00 diopters with up to 1.50 diopters of astigmatism
Keratometry 40.00 to 46.00 diopters

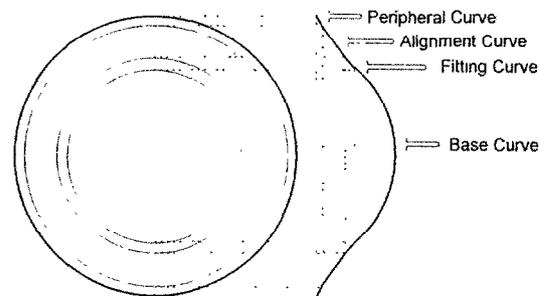
FITTING CONCEPT

JSZ Orthokeratology (oprifocon A) 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.

Define All Curve Widths & Zone Diameters

Defaults for the curve widths

The JSZ Orthokeratology (oprifocon A) Contact Lenses have four zones: A Base Curve Zone for optical properties, a Reverse Curve Zone (sometimes called the Fitting Curve) 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 a single curve in the Alignment Zone would be:

| | | |
|---------------------------------------|-----|---------|
| Base Curve Optical Zone | POZ | 6.2 mm |
| Reverse Curve Width (Fitting Curve) | FC | 0.6 mm |
| Alignment Curve Width | AC | 1.0 mm |
| Peripheral Curve Width | PC | 0.4 mm |
| Overall Diameter | OAD | 10.2 mm |

For a lens with an overall diameter greater than 10.2mm it is typical to split the alignment zone into two or more spherical curves. The default parameters for a larger lens would be:

| | | |
|---------------------------------------|------|---------|
| Base Curve Optical Zone | POZ | 6.2 mm |
| Reverse Curve Width (Fitting curve) | FC | 0.6 mm |
| Alignment Curve One | AC_1 | 0.7 mm |
| Alignment Curve Two | AC_2 | 0.6 mm |
| Peripheral Curve | PC | 0.4 mm |
| Overall Diameter | OAD | 10.6 mm |

The fitter will be able to adjust any or all of the default widths and zone diameters.

Defaults for the curve transitions - Fillets

In addition to the widths, each zone will be smoothly transitioned to its neighbor by use of a fillet curve. The default values are specified in the table below:

| | | |
|-------------------------------------|-------|---------|
| Base Curve to Fitting Curve | BC-FC | 0.05 mm |
| Fitting Curve to Alignment Curve | FC-AC | 0.10 mm |
| Alignment Curve to Peripheral Curve | AC-PC | 0.20 mm |

The fillet curve is calculated by scribing a circle which is tangent to each of the adjoining curves at the point described by traversing the distance given in this table along each of the curves.

The fitter will be able to adjust any or all of these default fillet widths.

Measure the Cornea

Topographic Data

- A topographic map that yields sagittal depth data from the apex out to a distance no less than the outermost diameter of the Alignment Curve Zone is desirable. Smaller samplings could be used, but the alignment curve would then be based on extrapolated data, similar to the K reading assumption below.

Keratometry Reading

- A standard K reading can be used to approximate the curvature of the eye.
- Fitter is allowed to enter any Keratometry value.

Select Alignment Curve - Radius and Position

The Alignment Curve should match to the corneal surface

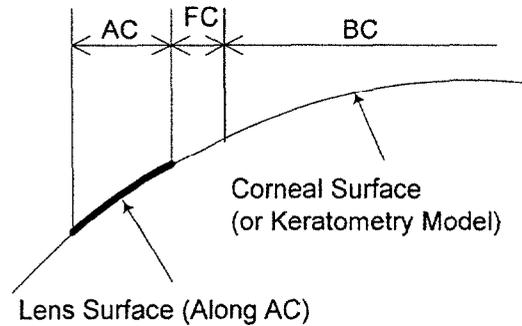
Topographic Data

- The Alignment Curve is determined by sampling the topographic values of the eye in the region where the curve will fit, and applying a least squares fitting algorithm to determine the best fit circle that can be scribed along that data. The radius of this circle is used for the Alignment Curve Radius.

Keratometric Data

- The Alignment Curve is equal to the radius derived from the Flat K reading.
- If more than one curve is used in the alignment curve zone, the radius of curvature will get progressively flatter from the inside to the outside

of the zone. Typically the first alignment curve radius is equal to the radius derived for the Flat K reading and the second alignment curves radius is 0.50 diopters flatter.



Fitter may be allowed to adjust the Alignment Curve

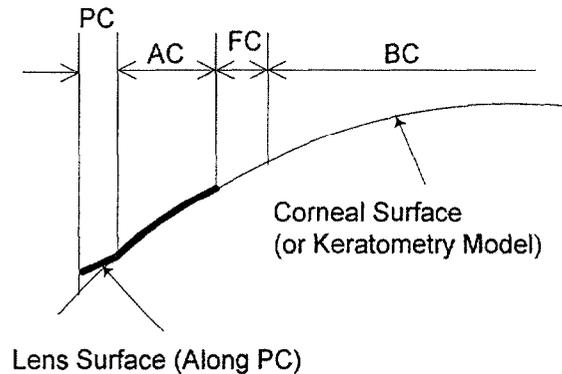
- Curve may be adjusted by steepening or flattening (e.g. based on clinical results showing too much movement, $AC = AC + 0.25D$.)

Select Peripheral Curve - Radius and Position

Peripheral Curve

The default radius of the Peripheral Curve is shown in the table below. It is also possible to apply a simple calculation to determine the peripheral curve (e.g. $AC + 2.5$ mm).

| | | |
|------------------|----|-----------------|
| Peripheral Curve | PC | 11.0 to 12.0 mm |
|------------------|----|-----------------|



Select Base Curve - Radius Only

“End Result” implies that the back surface of the Base Curve of the lens should be of the same curvature as required by the eye to give good vision. The lens should be constructed in a way that is close to the desired end result, but with a small additional flattening beyond the exact result desired.

If the cornea was somehow elasticized to attain the exact shape of the lens, then this additional flattening would not be required.

Topographic Data

- Central curvature is estimated based on topographic data in the method that generates the Sim-K value. Then this value for central curvature is used as if it were a K value. (see next)

Keratometry Reading

- The Base Curve Radius is determined by starting with the keratometry reading, then subtracting the desired power correction (in Diopters) and finally flattening further by a fixed increment (default = 0.75D)
- The Fitter can adjust the additional flattening increment if desired.

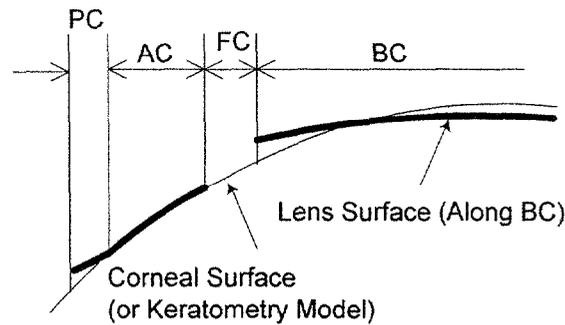
Select Base Curve - Position Only

Calculate Maximum Displacement of the Corneal Surface

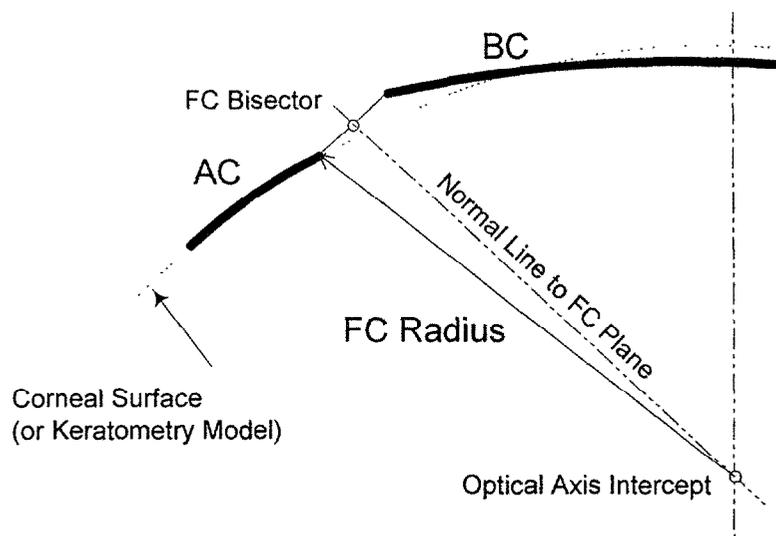
- The defined Base Curve is mathematically lowered into the space occupied by the corneal surface.
- The exact amount that the base curve is lowered into the corneal surface is a trade secret.
- The amount that the base curve is lowered into the corneal surface is related to Munnerlyn’s Formula used by excimer lasers for refractive surgery to determine the amount of tissue to be ablated to achieve the desired post-operative correction. In no case will this lowering (or push) of the base curve into the cornea exceed the displacement estimated by Munnerlyn’s Formula.

Position the Base Curve

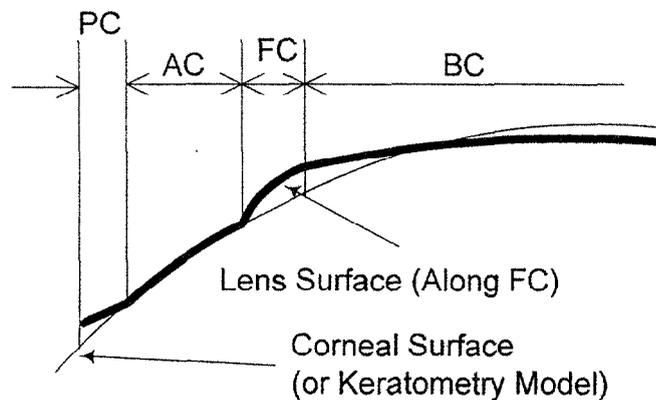
- From the position of maximum displacement, the Base Curve is then mathematically lifted up (or backed off) towards the apex of the cornea by a proprietary adjustable amount.
- The Fitter can adjust the amount of lift or push on the apex of the cornea.
- Once the Base Curve is placed in this position relative to the corneal surface, the sagittal depth values at the endpoints of the Base Curve Zone and the Alignment Curve Zone are known.



Determine Required Fitting Curve - Radius and Position



- Since the (x,y) coordinates of the Reverse Curve are determined by the inner diameter of the Alignment Curve Zone, and the outer diameter of the Base Curve Zone (POZ), these can be used to create a line between the two points.
- This line is bisected (a midpoint is found). And the slope is determined.
- Negating and Inverting the slope yields a line perpendicular to the Fitting Curve line.
- This perpendicular line is extended from the bisection point until it crosses the optical axis, this intersection point is noted.
- The radius from this intersection point to either endpoint of the Fitting Curve is determined, and this value becomes the Fitting Curve Radius.



This completely describes the back surface of the lens.

PREDICTING LENS RESULTS:

Various methods have been proposed for predicting the amount of corneal flattening that may be achieved for a given patient by orthokeratology. Other studies have not supported these conclusions, however, and further research is needed. It is not possible at this time to predict which patients will achieve the greatest corneal flattening with other orthokeratology designs.

The clinical results for the JSZ Orthokeratology (oprifoccon A) Contact Lenses Study show that the lens design is effective and predictable for correcting myopia between the range of -1.00 to -5.00 diopters.

The JSZ Orthokeratology (oprifoccon A) 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 JSZ Orthokeratology (oprifoccon A) 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 JSZ Orthokeratology (oprifocon A) Contact 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 JSZ Orthokeratology (oprifocon A) Contact Lenses may be fit using a modification of the standard techniques for rigid gas permeable contact lenses. A normal RGP contact lens is fit with the Base Curve in alignment with the central cornea. The JSZ Orthokeratology (oprifocon A) Contact Lenses are fit with the Alignment Curve in alignment with the peripheral cornea.

The specifications of the JSZ Orthokeratology (oprifocon A) Contact Lenses are the flat keratometer reading, the refractive power you are trying to correct, and the diameter.

1. Pre-fitting Examination:

- A. Complete refraction and visual health examination should be performed.
- B. Pre-fitting patient history and examination are necessary to:
 - Determine whether a patient is a suitable candidate for the JSZ Orthokeratology (oprifocon A) Contact Lenses (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 JSZ Orthokeratology (oprifocon A) Contact Lenses is calculated by subtracting the amount of myopia you want to correct from the spectacle refraction and adding a correction constant of 0.75 diopters.

Rx = -3.75 diopters
Desired correction is the full -3.75 diopters

$$\text{BVP} = -3.75 - (-3.75) + 0.75 = +0.75 \text{ diopters}$$

The additional 0.75 diopters compensates for a small regression in the unaided visual acuity when the lens is first removed. No compensation is made for vertex distance.

3. Initial Lens Diameter Selection:

We recommend selecting 10.6mm as the initial lens diameter.

Standard lens diameters for the JSZ Orthokeratology (oprifocon A) Contact Lenses are 10.2mm, 10.6mm, and 11.0mm. Lens diameters outside of this range are occasionally used for some eyes.

Select an initial diameter of 10.2mm if the flat keratometer readings are steeper than 45.00 diopters or if the corneal diameter is smaller than 11.5mm

Select an initial diameter of 11.0mm if the cornea is spherical or there is "Against the Rule" Astigmatism.

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. PAR 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 0.75 diopters.

The PAR is calculated by:

$$\text{PAR} = (337.5 / (\text{Flat K} + \text{Target Correction} - \text{Correction Constant}))$$

For a Flat K of 41.25 and a Target Correction of -3.75

$$\text{PAR} = (337.5 / (41.25 + (-3.75) - 0.75)) = 337.5 / 36.75 = 9.184\text{mm}$$

5. Initial Lens Evaluation:

Movement:

Blink induced lens movement should show downward lens movement with the lid motion and then upward with the lid motion as with a regular RGP contact lens. During the interblink period, the lens should have little or no motion (average less than one millimeter).

Positioning:

The lens should position centrally on the cornea when the eyelids are closed. To achieve this, in an open eye state, the lens should not ride more than 1.0 mm below center nor 1.0 mm above center. A slightly low position of the lens is preferred. A slightly low riding lens will center when the eyelids are closed.

Characteristics of a Tight (too steep) Lens:

A lens that is too tight will show reduced movement upon blinking and will show too much pooling of fluorescein in the center. The lens will be centered or decentered inferiorly and exhibit little or no movement. Bubbles may be detected behind the lens in the Fitting curve area.

Characteristics of a Loose (too flat) Lens:

A Loose lens will move excessively on the cornea following each blink. The lens may ride in either a position that is too high or too low or in an eccentric position. The fluorescein pattern will show too much clearance in the mid-periphery under the alignment curve. A loose lens is usually uncomfortable for the patient.

TRIAL LENSES:

Trial Lens Fitting:

Trial lens fitting may be helpful in determining 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 basic trial lens set would consist of fourteen (14) lenses. The lenses would be labeled by the flat keratometer reading, which corresponds to the alignment curve, the refractive power they will correct, and the diameter.

For Example: 44.25 / -3.75 10.6

A basic set this size will allow you to evaluate how well the lens will center on the cornea. This is a valuable tool and is particularly useful when there are more than two diopters of cylinder on the cornea. You will not need to over-refract to determine the BVP of the initial lens, since the JSZ Orthokeratology (oprifocon A) Contact Lenses is designed to have a BVP of +0.75 diopters and is to be worn at night.

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, rinsed and dried with a lint free towel prior to handling a lens.

Prior to reusing as a trial lens 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:

Centering

Lens should center as well or better than 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.

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:

Low Riding Lens:

A slight low riding lens is the ideal position upon 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 periphery. 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 by 0.10mm or reduce the Diameter by 0.50mm.

Loose Lens:

Cause: Generally 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 by 0.10mm.

High Riding Lens:

Cause: The high riding lens is usually caused 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 by 0.10mm.

Lateral Riding Lens:

Cause: Generally caused by a very spherical cornea or a cornea with against the rule cylinder.

Solution: Increase the diameter of the lens by at least 0.40mm. The recommended diameter would be 11.0mm.

Vaulting:

Vaulting occurs when excessive bearing is present in the peripheral regions causing reduced central bearing. This will be seen as central pooling or increased fluorescein under the center of the lens.

Cause: The major cause of central vaulting is an alignment curve that is too steep. The more peripheral one goes from the corneal apex, the more difficult it is to predict the rate of corneal flattening. 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. A fitting curve that is too steep can also cause central vaulting but is much less common.

Solution: Flatten the alignment curves by at least 0.10mm. 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, flatten the fitting curve by 0.10mm.

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, at least two to three weeks to allow for slow responders. If there is still no further reduction on the unaided visual acuity, increase the target power by 0.50D to 0.75D.

Central Islands:

Central islands are areas of distortion in the visual axis that are observed with corneal topography. If you do not use a corneal topographer in the follow-up exams, you will observe slightly distorted mires on the keratometer. This condition differs from the under-responder in that you will not be able to refract the patient, without the lenses in, to 20/20.

Cause: Generally caused by the fitting curve being too steep, causing the Base curve to lift off too much from the central cornea. Another cause is excessive astigmatism. With corneal astigmatism present, there are unequal bearing areas where the fitting curve comes into contact with the cornea.

Solution: Flatten the fitting curve by 0.05mm to 0.10mm. This will apply pressure that is more central and smooth out the central region. If the central disturbance is from astigmatism, then flattening the BC will help to correct this.

Target the spherical equivalent of the original refraction to be Plano to +1.00 assuming the patient will not have any accommodative symptoms.

Central Staining:

This is a complication due to either mechanical irritation or physiological problems.

Cause: One major cause of central staining is a coated lens. Because of the steep Fitting 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 BC is too flat, the reduced mechanical pressure can also cause irritation. Reduced oxygen availability can also cause central staining but this is a rare occurrence.

Solution: The first thing is to make sure the posterior surface of the lens is clean. Review the cleaning solution used. Make sure there are no dry spots. If the staining remains, steepen the BC by 0.5D.

Air Bubbles:

Air bubbles are a common occurrence and typically disappear after wear. Only when staining occurs under a persistent air bubble does the lens need to be changed.

Cause: Air bubbles form when not enough solution is under the fitting curve. Usually the upper lids will compress the lens to the cornea and the bubbles will disappear in the morning. The fitting curve has a steep configuration, which is sometimes difficult to fill with tears. Occasionally, the resultant air bubble can encompass 270 degrees around the FC. Any staining present is due to the air bubble where the cornea is not getting the lubrication or oxygen that it needs.

Solution: If the air bubble is less than 45 degrees in length upon insertion, just monitor the next day to see if any staining occurs. If the air bubble is greater than 45 degrees, have the patient remove the lens and fill the concave surface with solution and have the patient reinsert while looking down. If a large air bubble persists, monitor the next day to see if still present and if staining is present. If staining is present, monitor for three days to see if the bubble and staining recedes. If the bubble and staining persists then flatten the fitting curve 0.10mm. This will reduce the steepness of the fitting curve and reduce the air bubble. Air bubbles look bad but are usually a self-limiting condition, which require no change.

Reduced Holding Time:

This is when the unaided visual acuity does not hold an acceptable amount of time.

Cause: Generally caused by a lens that is not centered, with the steep area almost touching the visual axis. When the cornea normally regresses, the visual axis is impacted sooner because there is less distance between the visual axis and the edge of the peripheral steep ring. If some vaulting has occurred, there will be a smaller central visual zone with a corresponding wider concentric steep ring. The

cornea can only undergo a limited amount of change. Usually, the more induced change, the faster the cornea will regress. Therefore, if you have reduced -5.00 diopters of myopia, you should not expect the unaided visual acuity to hold all day. As a general rule, the lower the starting amount of myopia, the greater chance of holding all waking hours. The JSZ Orthokeratology (oprifocon A) Contact Lenses are not recommended for reducing myopia greater than -5.00 diopters.

Solution: If the lens is de-centered, make the appropriate modifications to the design to center the lens better. If vaulting is present, do what is required to reduce the vaulting. Flattening the BC by 0.50 diopters can also prolong the holding time by making the cornea change more before a decrease in UCVA is noticed. Flattening the base curve will only be effective for a patient that is able to accommodate the additional correction early in the day.

Ghosting At Night:

Night ghosting is a normal observation. This usually recedes with time but may always be present to some extent.

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 zone of the lens can also be enlarged to 6.2 to 6.5mm. 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.

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:

Follow-up examinations should be conducted at different times during the day to get a proper evaluation of unaided visual acuity throughout the day. 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 overnight wear of RGP contact lenses and to optimize the improvement in their unaided visual acuity. After vision has stabilized, the patient should probably be recalled every 6 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 JSZ Orthokeratology (oprifocon A) Contact 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.

We would recommend the use of the Euclid ET-800 Topographer because of its large field of view and because it gives a more accurate picture of the central cornea than a Placido Disk instrument. However, any 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 JSZ Orthokeratology (oprifocon A) Contact 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.

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

HANDLING OF LENSES

Standard procedures for rigid gas permeable lenses may be used.

CAUTION: JSZ Orthokeratology (oprifoconA) 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.

Szabocsik and Associates
203 N Wabash Ave, Ste 1200
Chicago, IL 60601

800-645-0996
800-827-0602 (fax)

Printed mm/yy

LENS CASE LABEL

Patient Name

Left

Right

BC

Pwr

Dia

CT

COLOR

JSZ Orthokeratology (oprifocon A) Contact
Lenses for Overnight Wear

CAUTION: Federal (USA) law restricts this
device to sale by or on the order of a licensed
practitioner

EXAMPLE OF PACKAGE LABEL

Order ID Number

Patient Name

Order Date

Contents: One/Two contact len(es)

Caution: The JSZ Orthokeratology (oprifocon A) Contact Lens(es) for Overnight Wear are not sterile when shipped. Prior to dispensing, clean, disinfect and **Hydrate** the len(es) according to the appropriate care regimen.

OD: Keratometry reading: 44.25/45.25 @180 Refraction: -3.00 sph

OS: Keratometry reading: 44.25/45.50 @180 Refraction: -3.00 -0.50 x 180

OD: JSZ oprifoconA Red (color) Lot # 01295PTC009

8.333 (base curve) 0.75(power) 10.2(diam)/6.2(oz) 0.50/6.66 (reverse curve width/radius)

1.0/7.627 (ac width/radius) 0.5/11.50 (pc width/radius) FS(front surface): Standard

OS: JSZ oprifoconA Yellow(color) Lot # 01295PTC007

8.333 (base curve) 0.75(power) 10.2(diam)/6.2(oz) 0.50/6.66 (reverse curve width/radius)

1.0/7.627 (ac width/radius) 0.50/11.50 (pc width/radius) FS(Front surface): Standard

Account #

Practitioner Name:

CAUTION: Federal(USA) law restricts this device to sale by or on the order of a licensed practitioner