

CRT® Certification and Information Guide



www.artoptical.com | 800-253-9364



www.paragoncrt.com | 800-528-8279

#### **Welcome To The World of Corneal Reshaping**

I want to personally thank you for your interest in Paragon CRT®; the benchmark in corneal reshaping. It's an exciting time to get involved in one of the fastest growing modalities in the contact lens market.

Corneal reshaping is quickly entering the mainstream of contact lens fitting, and practices around the world have begun capturing new market share, while enjoying the incremental revenue that CRT can provide. With mainstream practices focusing on increased profit-per-patient, CRT provides a seamless way to achieve higher profit margins while minimizing chair time.

There are two key areas where CRT is making a strong impact:

First, teens and tweens, referred to as the "8-to-18" market need the freedom to be children. During school and daytime activities, contact lenses and glasses can get in a child's way of learning and playing. With CRT, mom and dad have comfort knowing their children are seeing well at school, versus wondering if they are wearing or breaking their glasses, or losing contact lenses. Parents also have the convenience to help manage the care and handling of CRT lenses at home, just before bedtime and upon awakening.

Second, soft contact lens wearers that are experiencing discomfort, manifested as feelings of dryness or scratchiness. These people are struggling with daytime discomfort, but are making every attempt not to return to wearing glasses. By providing total freedom from contacts during waking hours, CRT is simply removing the problem; lens discomfort. Having no lenses on their eyes during waking hours allows a healthy and comfortable 16 hours of unobstructed access to oxygen.

Paragon recently conducted a survey regarding chair time and the use of staff members when fitting CRT. Of the surveyed CRT Certified Practitioners:

- 70% require 30-60 minutes for the initial CRT fitting visit.
- 93% take between 15 to 30 minutes for each CRT follow-up appointment.
- 78% report using a technician to assist on CRT fitting.
- 50% use a technician for lens insertion.

Paragon has made it easier than ever to get involved in CRT. If you are considering offering CRT in your practice, I encourage you to take our 90-day Risk Free Test Drive with the 100-Lens DDS, or begin fitting with our patent-pending CRT® SureFIT® system that does not require a lens inventory. I sincerely thank you for your interest in CRT and welcome you to the world of corneal reshaping.

Best regards,

Joe Sicari, President & CEO

Paragon Vision Sciences - Paragon CRT



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#### Overview of the Paragon CRT® Design

On June 13, 2002, Paragon Vision Sciences received FDA approval for overnight Corneal Refractive Therapy using Paragon CRT. The approval includes up to -6.00D myopia, with or without -1.75D astigmatism. There is no age restriction when prescribing Paragon CRT.

As presently understood, fluid forces arising from tear interaction with the lens periphery exert a "pulling" force on the lens. This force is applied at the point of apical touch and gently reshapes the 50 micron thick epithelial layer to conform to the shape of the lens Base Curve. Reshaping the epithelium is accomplished by a combination of compression and redistribution of fluids within the epithelial cells. The effect is completely reversible.

#### 1. BC: Base Curve/Treatment Curve

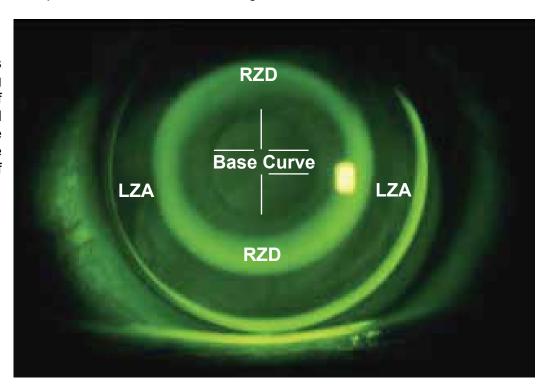
The central 6.0 mm (fixed Optic Zone) of the Paragon CRT design contains the Base Curve. The BC (or Treatment Curve) is the radius of curvature that flattens the cornea to reduce the patient's myopia. For best results, the BC should be centered over the pupil, and the patient's Refraction Over Lens (ROL) should be Plano. To reduce myopia, the BC will be flatter than the underlying corneal apex. Manipulation of the BC is not used for centration purposes.

#### 2. RZD: Return Zone Depth

The key elements to successful Corneal Refractive Therapy are centration and central applanation. Both are accomplished through precise control of sagittal depth utilizing the RZD. It is the Return Zone Depth that is the primary variable parameter used to vary the sagittal depth of the Paragon CRT lens. Since the base curve will deviate from the cornea at the periphery of the Optical Zone, it is necessary to redirect the lens back toward the cornea. This is accomplished by a 1.0 mm wide sigmoid curve which is called the Return Zone. The depth of the Return Zone can be varied by the prescriber in 25-micron increments, providing precise applanation or pressure to the cornea, resulting in effective treatment.

#### 3. LZA: Landing Zone Angle

The peripheral portion of the lens is called the Landing Zone. The Landing Zone is a flat surface with a radius of infinity and can only meet the curved corneal surface tangentially. The prescriber selects the angle of the Landing Zone to adjust the amount of edge lift.



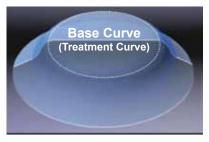


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#### **Overview of the Paragon CRT® Design**

#### 1. BC: Base Curve/Treatment Curve

The radius of the BC (or Treatment Curve) is determined by using the Paragon CRT Lens Selector Slide Rule, provided in your Diagnostic Dispensing System (DDS) or Technical Kit. You will need the patient's flat "K" Reading and Manifest Refraction Sphere (MRS). When using the Lens Selector Slide Rule, following these simple steps will ensure the proper lens will be selected:



42.50 42.62 42.75 42.87



- 2. Find the MRS (not spherical equivalent) to the right of the window.
- 3. Identify the recommended initial Paragon CRT lens parameters in the window immediately next to the MRS.
- 4. Prior to insertion of the lens, a topical anesthetic should be applied to reduce tearing and maximize patient comfort during the fitting process.
- 5. Perform a Refraction Over Lens (ROL) to determine if the BC selected is correct and will treat the prescription fully. The ROL should be Plano for maximum results.



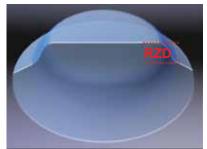
The Slide Rule algorithm is designed to create a half diopter overcorrection. This is compensated for by having all lenses in the Lens Diagnostic Dispensing System (DDS) be +0.50D in power. If the ROL yields a "minus power over refraction", the BC is too steep and should be flattened in .10mm steps for every -0.50D over refraction until the patient achieves a Plano ROL. Conversely, if the ROL yields a "plus power over refraction", the BC is too flat and should be steepened in .10mm steps for every +0.50D ROL. Each Paragon CRT lens is laser marked for authenticity and parameter identification (Base Curve, Return Zone & Landing Zone).

#### 2. RZD: Return Zone Depth

The goal in selecting the appropriate RZD is to select the "shallowest" RZD that keeps the lens centered. A 3-4mm area of central applanation is ideal. However, if a greater Return Zone (i.e., 550 microns versus 525 microns) is necessary to achieve centration (i.e., greater sagittal depth) a smaller central applanation may be acceptable. The RZD can be adjusted in 25 micron steps.

An RZD that is too shallow will exhibit apical touch but have insufficient tear interaction in the periphery and the lens will most likely decenter. An RZD that is too great will not demonstrate the desired 3-4mm area of central applanation.

In both cases, the solution is to increase or decrease the sagittal depth by changing the RZD. See the following page for RZD problem solving techniques as it relates to overall sagittal depth.





Remember: Base Curve changes should not be used to alter or change the sagittal depth.



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#### Overview of the Paragon CRT® Design

#### 2. RZD: Return Zone Depth In Relation To Overall Sagittal Depth

Below are three different RZDs on the same cornea. In each case, the only varied parameter is a 25-micron RZD adjustment. The most critical variable to treatment and patient satisfaction is centration.

Once the Paragon CRT lens has been well-centered in the course of the fitting process, adjustments to the RZD may be required to achieve the desired 3-4mm zone of applanation as indicated below.

# Excessive cl

Excessive clearance, bubble in the RZD, lack of central applanation due to the RZD being too "great". If the depth

of the RZD is too great, creating too much sagittal depth, the BC (or Treatment Zone) will not applanate the central cornea to a 3-4mm treatment zone.

**SOLUTION:** Reduce the RZD 25 microns (Example: move from 575 to 550)

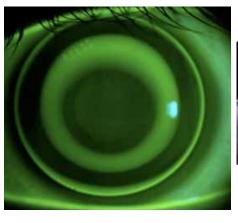


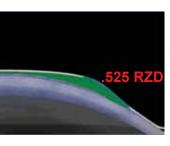


While the reduction of the RZD by 25 microns resulted in the loss of the bubble, there is still not enough applanation in the center of the cornea. A further reduction in sagittal depth is required to provide the applanation needed.

Note: If the reduction in the RZD (minus 25 microns) results in a decentered lens, return to the previous RZD that provided centration.

**SOLUTION:** Reduce the RZD 25 microns (Example: move from 550 to 525)





This fluorescein pattern is excellent. The lens is centered (BC or Treatment Zone is over the pupil) and there is 3-4mm central applanation. This RZD is the correct choice. The next step in lens evaluation is the Landing Zone Angle, which is covered in the next section.

Note: The most common RZD range is 525 to 575.



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#### Overview of the Paragon CRT® Design

#### 3. LZA: Landing Zone Angle

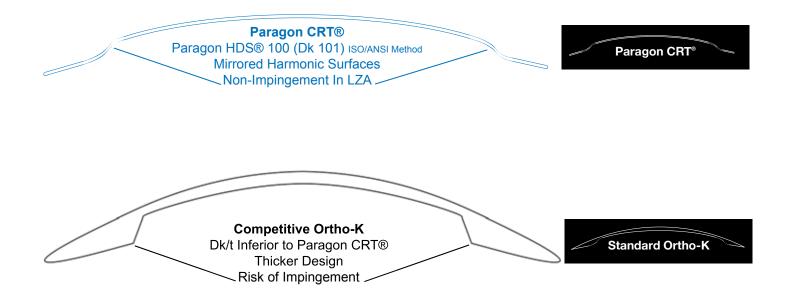
The primary function of the Landing Zone Angle is to provide appropriate edge lift. If the LZA suggested by the Slide Rule demonstrates edge lift that is not optimum, the LZA (Landing Zone Angle) can be adjusted in one degree steps.

The LZA is a flat surface with a radius of infinity, which means it can only meet the curved peripheral corneal surface tangentially. This tangential relationship between the LZA and the cornea reduces the possibility of trauma to the peripheral corneal tissue often seen in reverse-geometry designs. Lens impingement is nearly impossible with Paragon CRT due to the tangential, flat surface of the LZA.



Landing Zone Angles are available in varying degrees to provide appropriate tear film touch in the periphery of the cornea and adequate edge lift.

The Paragon CRT design features "harmonic surfaces", where the front surface mirrors the back surface. The advantage of this technologically advanced design provides a thinner, lighter design and up to 30% greater oxygen transmission.

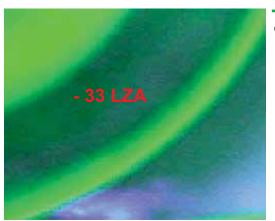


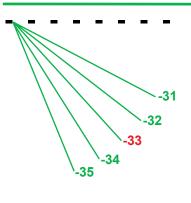


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#### Overview of the Paragon CRT® Design

#### 3. LZA: Landing Zone Angle In Relation To Appropriate Edge Lift



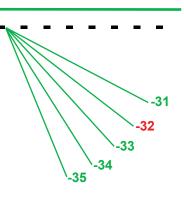


#### APPROPRIATE EDGE LIFT:

In this example, an appropriate LZA will result in the proper amount of tear film touch in the peripheral cornea, while allowing sufficient edge lift.

When diagnostic fitting, always choose the lesser of the two angles when deciding between two options.

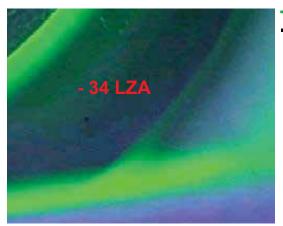


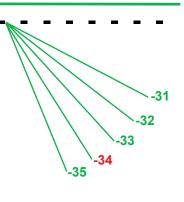


#### PROBLEM: EXCESSIVE EDGE LIFT

In this example, the LZA chosen for this fit is allowing too much fluid underneath the edge of the lens.

An increase in the LZA number will reduce the edge lift. (Example: change from a -32 to a -33 LZA.)





#### PROBLEM: INSUFFICIENT EDGE LIFT

In this example, the LZA chosen for this fit is not allowing enough fluid underneath the edge of the lens.

A decrease in the LZA number will increase the edge lift. (Example: change from a -34 to a -33 LZA.)

Each degree of LZA affects the overall sagittal depth by approximately 15 microns.

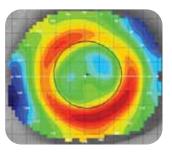


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#### Overview of the Paragon CRT® Design

#### **Solving CRT Lens Decentration Problems**

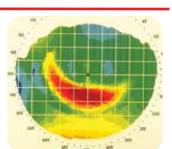




#### **BULL'S-EYE FLUORESCEIN PATTERN:**

The Base Curve (Treatment Curve) should be well centered over the pupil, exhibit 3-to-4 mm of central touch, or applanation, with appropriate edge lift. A Plano/+0.50D ROL (Refraction Over Lens) will provide the patient with maximum treatment results.



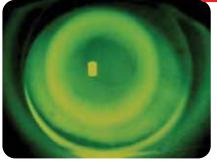


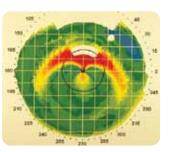
#### PROBLEM: SUPERIOR POSITIONING

Just as in standard Gas Permeable lens fitting, lenses that are too shallow in overall sagittal depth will tend to decenter. In order to center the lens, an increase in overall sagittal depth is necessary. Any increase in the number value of either RZD or LZA will increase overall sagittal depth.

**SOLUTION**: Increase Sagittal Depth

- 1. Increase RZD one step (25 microns)
- 2. Increase LZA one degree (~15 microns)
- 3. Increase Overall Diameter



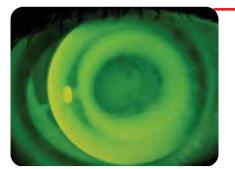


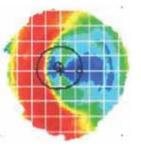
#### PROBLEM: INFERIOR POSITIONING

Lenses that are too deep in sagittal depth tend to decenter inferiorly. A common reason for inferior decentration is when the LZA is too great (-34 vs. -35), which drives the lens downward from a superior, flatter cornea. Often, lessening the LZA one degree will help in centration. However, any decrease in the number value of either RZD or LZA will decrease overall sagittal depth.

**SOLUTION:** Decrease Sagittal Depth

- 1. Decrease LZA one degree (~15 microns)
- 2. Stay with the initial LZA and decrease the RZD one step (25 microns)





#### PROBLEM: LATERAL POSITIONING

Similar to lenses that displace superiorly, an increase in overall sagittal depth is necessary to center the lens.

**SOLUTION:** Increase Sagittal Depth

- 1. Increase RZD one step (25 microns)
- 2. Increase LZA one degree (~15 microns)
- 3. Increase Overall Diameter



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#### Overview of the Paragon CRT® Design

## Recommended Follow-Up Schedule and Lens Replacement Schedule

On the first-morning follow-up visit, the patient should present wearing their Paragon CRT lenses.

- 1. With the lenses on, check visual acuity and perform a Refraction Over Lense (ROL). The results should be "Plano".
- 2. Perform a slit lamp evaluation to confirm lens centration and appropriate edge lift.
- 3. Remove the Paragon CRT lenses and check visual acuity.
- 4. Perform a manifest refraction to determine the amount of treatment achieved during the first night of therapy.



#### What To Expect After Day-1

The patient's treatment most likely will not last throughout their waking hours during the first day following overnight treatment. Management with Paragon CRT lenses during the day (or soft disposable lenses) will most likely be needed during the 7-14 day treatment period.

The patient will always see clearly with their Paragon CRT lenses on, provided the Base Curve and Refraction Over Lens are correct. Each morning when the lens is removed and stored in the practitioner-recommended lens care solution, the patient should notice that their unaided visual acuity maintains for a progressively longer duration throughout the day.

At the end of the treatment period, the patient should enjoy unaided visual acuity for all or most of their waking hours. Some patients may be able to skip a night between applications.

Replacement lenses should be ordered for your DDS, as well as a spare pair of lenses for the patient. Paragon Vision Sciences recommends Menicon Progent for in-office disinfection and protein removal for fluorosilicone acrylate GP lenses.





#### Follow-Up Schedule After The Fitting and Dispensing Visit

Visit 1: First-morning visit

Visit 2: One-week visit

Visit 3: Two-week visit

Visit 4: One-month visit

Visit 5: Two-month visit

Visit 6: One-year visit

Order replacement lenses to put back in your DDS at the two-week to one-month follow-up visit. This will ensure you have the appropriate CRT lens for your next patient.

SN 664073

Order replacement lenses for your patient.

Note: Adolescent patients should be seen quarterly.



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#### Overview of the Paragon CRT® Design

#### CRT® SureFit®. "As Easy As 1, 2, 3"

CRT® SureFit® provides certified practitioners a single-use, 3-lens per eye, fitting and dispensing system which will ensure a high probability of Day 1, first fit success. Currently, corneal reshaping patients qualify for CRT SureFit when they meet the following criteria:

- Flat keratometric readings of 41.00D to 45.00D
- Spectacle refraction (vertexed) of -4.00D and below (Spherical component of the spectacle Rx must be equal to or greater than the cylindrical component.)
- Up to -1.00D of corneal cylinder (Astigmatism should be "with the rule")





Certified CRT practitioners, with or without a 100-Lens Diagnostic Dispensing System, can order CRT SureFit from Authorized Paragon CRT Laboratories or directly from Paragon Vision Sciences using "K" Readings and Spectacle Rx.

#### When Your CRT® SureFIT® Order Arrives

CRT SureFit lenses are clearly identified, with directions on the proper sequence of fitting. Based upon a patient's pre-treatment "K" Readings and Spectacle Rx, the first lens in the CRT SureFit Delivery System (lens 1) is the lens that has the highest probability of first fit success. Should the first lens not be dispensable because of improper lens positioning and/ or under-treatment, the second and third lenses are pre-determined parameters (based on 8 years of CRT historical fitting data) that should provide a successful CRT fit for the patient.

#### Fitting The Patient With CRT® SureFIT®. "As Easy As 1, 2, 3"

For Flat "K" Readings Between 41.00D and 45.00D



**Step 1:** Open the lens labeled OD-1 and/or OS-1 and place on the patient's eye. A properly fitted CRT lens will show:

- Centered "bull's-eye" pattern (over the pupil)
- 3mm to 4mm central treatment zone (over the pupil)
- Acceptable edge lift
- Refraction Over Lens (ROL) should be Plano to +0.50D

If the lens(es) labeled OD-1 and OS-1 exhibit the qualities above, dispense the lens(es) and follow-up with the patient the next morning.

**Step 2:** If the lens labeled "1" shows displacement in a superior or lateral manner, either at the initial trial visit or upon first morning follow-up, remove lens "1" and apply lens "2".

If lens "2" exhibits the qualities of a properly fit CRT lens, dispense and follow-up the next morning or in 5 to 7 days. If lens "2" does not center well, call Paragon Vision Sciences' Consultation Department to determine if a fourth lens is required to achieve a successful fit: 800-528-8279 x 2.

**Step 3:** If the lens labeled "2" centers well after follow-up but the final treatment result is not achieved, remove lens "2" and apply lens "3". If lens "3" exhibits the qualities of a properly fit CRT lens, dispense and follow-up in 5 to 7 days. If the final treatment result is still not achieved, call Paragon Vision Sciences' Consultation Department to determine if a fourth lens is required to achieve a successful fit. In most cases, final treatment will take 10-to-14 days from the last CRT parameter worn.



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#### Overview of the Paragon CRT® Design

Once you've completed your Certification Test, the next step is to choose the best method to fit CRT in your practice. The 100-Lens Diagnostic Dispensing System (DDS) is the recommended method for integrating CRT in your practice. However, Paragon recognizes that all practices aren't the same and, therefore, we have two additional options; CRT SureFit, which is the second recommended method to integrate CRT in your practice, or you can choose to fit CRT empirically.



#### The 100-Lens Diagnostic Dispensing System (DDS):

- Up to 80% immediate dispensing
- Saves chair time & increases profitability
- Fewer patient visits, delivering improved convenience
- Immediate fit assessment with in-office lens changes
- 90-Day Risk Free Test Drive. 30/60/90 day billing
- Two staff members receive one complimentary pair of CRT lenses
- Up to three immediate family members receive half price CRT lenses (maximum of six lenses total)

## As a Certified CRT Practitioner, you will receive the following tools with your DDS:

- Paragon CRT Certificate
- · Paragon CRT Initial Lens Selector Slide Rule
- Yellow Wratten Filter
- CRT Patient Care Kits
- · Practice name listed on paragonert.com
- Innovative Practice Management & Marketing Support Kit:
  - 8-to-18 Consumer Brochures
  - 8-to-18 Recall Cards
  - 8-to-18 Patient Intake Forms
  - Contacts & Lifestyle Consumer Brochures
  - Contacts & Lifestyle Recall Cards
  - Staff Training Booklet

It is important to note Paragon CRT lenses are precision therapeutic lenses and as with other contact lenses, there are Indications, Contraindications, Warnings and Precautions. When your DDS arrives and prior to prescribing Paragon CRT, review of the following information is required: Paragon CRT Welcome Book, and the Paragon CRT Package Insert and Instructions for Wearers.



#### **CRT® SureFit® Dispensing System:**

- Three lenses per eye shipped with each CRT SureFit® order
- For patients that fall within the following parameters:
  - Flat "K" Readings between 41.00D and 45.00D
  - Spectacle Rx (vertexed power) up to -4.00D
  - Corneal Cylinder up to -1.00D
- Saves chair time & increases profitability
- Fewer patient visits
- Improves convenience for your patient and practice
- Immediate fit assessment with in-office lens changes, if needed
- Two staff members receive one complimentary pair of CRT lenses
- Practice name listed on paragonert.com

#### Marketing materials available upon request:

- 8-to-18 Consumer Brochures
- 8-to-18 Recall Cards
- 8-to-18 Patient Intake Forms
- Contacts & Lifestyle Consumer Brochures
- Contacts & Lifestyle Recall Cards
- Staff Training Booklet

#### **Traditional Warranty Program**

- Prescribe Paragon CRT by fitting empirically
- · Two free exchanges within 90 days, if needed
- Professionally trained consultants assist in parameter selection

Paragon recommends corneal topography for pre- and post-dispensing evaluations.

# PARAGOLERT® CORNEAL REFRACTIVE THERAPY

## **CRT®** Certification and

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E-Mail:		
Would You Like To Recei	ive Periodical E-Mail Updat	tes From Paragon? Yes, please. No thanks.
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First CRT Lab of Cho	oice:	Second CRT Lab of Choice:
Topographer Brand:		Do You Fit Other Corneal Reshaping Products? Y N
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UV Availability
Deposit Resistent
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Extended Wear
UV Availability
Deposit Resistent
Proven Stability
Promotes Corneal Health



23 Dk\*
Daily Wear
UV Availability
Deposit Resistent
Proven Stability
Superior Wettability



22 Dk\*
Highest Refractive Index Available
Ideal For Presbyopic Designs
Great For High Prescriptions
Daily Wear
Less Lens Mass
Thin Lens Profile







30 Dk\*
12.8 Wetting Angle
Daily Wear
UV Availability
Deposit Resistent
Structural Integrity
Superior Wettability



43 Dk\*
14.7 Wetting Angle
Daily Wear
Extended Wear
UV Availability
Deposit Resistent
Proven Stability



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