

Thank you for choosing Paragon CRT®, the world leader in contact lens corneal reshaping. By reviewing the basic fitting dynamics of Paragon CRT and taking the certification test that follows, you will join thousands of practitioners who have made the choice to prescribe Paragon CRT. Thank you for your support, and welcome to the exciting new modality of Corneal Refractive Therapy!

## MARKETING & PRACTICE MANAGEMENT TOOLS

David Thomas Contact Lenses provides marketing and practice management tools that can easily be integrated into your practice. By simply handing each patient a Paragon CRT brochure when they check in, your staff will stimulate interest and enhance communication with potential candidates. Build on this person-to-person communication by fitting a key staff member with Paragon CRT. A staff member wearing Paragon CRT will provide an immediate benefit to patients with questions about the procedure through their personal experience. To assist you, Paragon provides you with two free staff member fits. By following the simple step-by-step marketing techniques included in your Paragon CRT Practice Management Kit, you will realize substantial practice growth.



Remember, the Paragon CRT system features a 90-day **"Risk Free Test Drive"** with 30-60-90 day billing increments.



*"With Paragon CRT, I received a comprehensive support system that has enhanced my practice."*

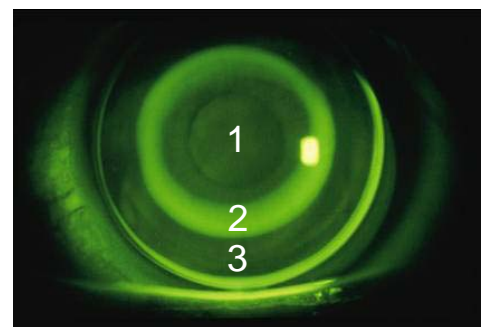
Bruce Bridgewater, O.D.  
Scottsdale, Arizona

## 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 $\mu$  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 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. The BC should be centered over the pupil with a Refraction Over Lens (ROL) of Plano for maximum results. To reduce myopia, this 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.

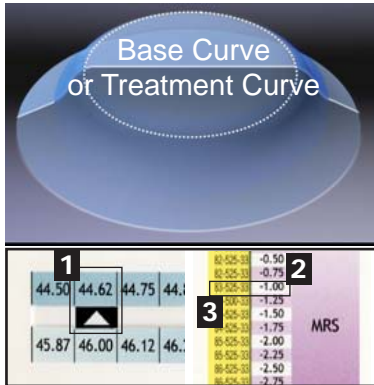
### 3. LZA: Landing Zone Angle

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.

# THE FITTING PROCESS

## BC: BASE CURVE/TREATMENT ZONE

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). You will need the patient's flat Keratometric (K's) 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:



1. Slide the tab until the arrow appears pointing either up or down at the correct Flat "K".
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).

## 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 is necessary to achieve centration (i.e. greater sagittal depth) a smaller central applanation may be acceptable. RZD can be adjusted in 25 micron steps.

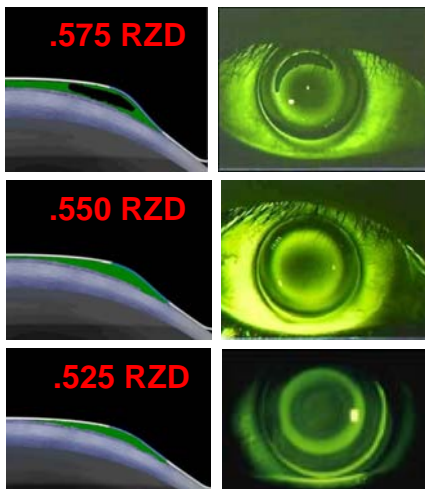
An RZD that is too shallow will exhibit apical touch but have insufficient tear interaction in the periphery and the lens will most likely decenter. An RZD that is too great will not demonstrate the desired 3-4mm area of central applanation.

In both cases, the solution is to increase or decrease the sagittal depth by changing the RZD.

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

## 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 vision correction 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.



**PROBLEM:** 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 applate to the central cornea to a 3-4mm treatment zone.

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

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.\*

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

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.

**Most common RZD range is 525-575μ.**

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

# LZA: LANDING ZONE ANGLE

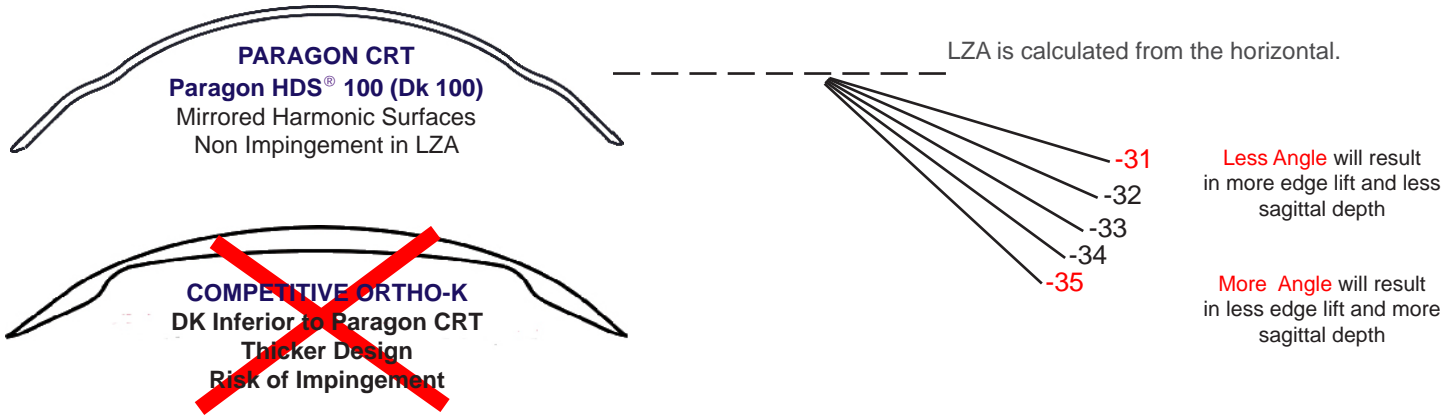
Landing Zone Angles are available in varying degrees to provide appropriate tear film touch in the periphery of the cornea and adequate edge lift.



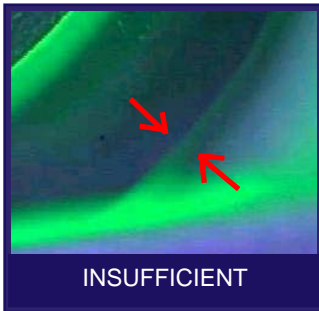
The primary function of the Landing Zone Angle is to provide appropriate edge lift. If the LZA suggested by the Slide Rule demonstrates edge lift that is not optimum, the LZA (Landing Zone Angle) can be adjusted in one degree steps.\*

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.

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.



\*A one degree LZA angle change affects overall sagittal depth by 15 microns. See: SOLVING LENS DECENTRATION PROBLEMS.



**PROBLEM:** The LZA chosen for this fit is not allowing enough fluid underneath the edge of the lens.

**SOLUTION:** Allow for more edge lift.

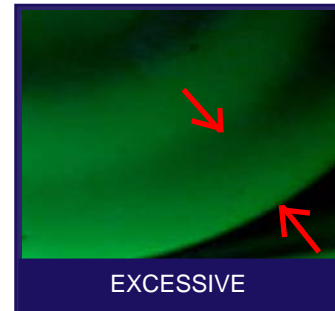
**Decrease the LZA** one degree\* until the appropriate amount of edge lift is present.

Example: Change from a -34 LZA to a -33 LZA



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:** The LZA chosen for this fit is allowing too much fluid underneath the edge of the lens.

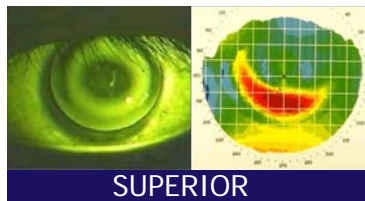
**SOLUTION:** Reduce the edge lift.

**Increase the LZA** one degree\* until the appropriate amount of edge lift is present.

Example: Change from a -32 LZA to a -33 LZA

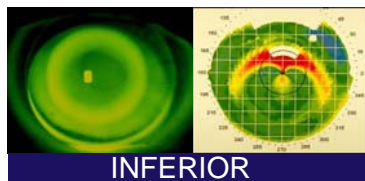
\*Each degree of LZA affects overall sagittal depth by approximately 15 microns.

## SOLVING LENS DECENTRATION PROBLEMS



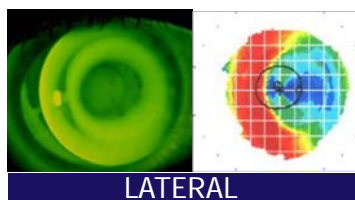
**PROBLEM:** Just as in standard GP fitting, lenses that are too shallow in overall sagittal depth will tend to decenter. In order to center the lens, an increase in overall sagittal depth is necessary. Any increase in the number value of either RZD or LZA will increase overall sagittal depth.

- SOLUTION: Increase Sagittal Depth**
1. Increase RZD one step (25 microns)
  2. Increase LZA one degree (~15 microns)
  3. Increase overall diameter



**PROBLEM:** 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. -33), 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 the RZD or LZA will decrease overall sagittal depth.

- SOLUTION: Decrease Sagittal Depth**
1. Decrease LZA one degree (~15 microns) or go back to initial LZA and
  2. Decrease RZD one step (25 microns) with the initial LZA



**PROBLEM:** Similar to lenses that displace superiorly, in order to re-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. A diameter increase may also be indicated.

- SOLUTION: Increase Sagittal Depth**
1. Increase RZD one step (25 microns)
  2. Increase LZA one degree (~15 microns)
  3. Increase overall diameter

## RECOMMENDED FOLLOW-UP & LENS REPLACEMENT SCHEDULE

### Follow-Up Schedule

- Visit 1: First Morning
- Visit 2: One Week
- Visit 3: Two Weeks
- Visit 4: One Month
- Visit 5: Two Months
- Visit 6: One Year

**NOTE:** Adolescent patients should be seen quarterly.

Replace dispensed lenses at two-week to one-month visit.

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 Lenses (ROL).
  - 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.

The patient's treatment may 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 likely be needed during the 7-14 day treatment period. The patient will always see clearly with their Paragon CRT lenses on, provided the BC and ROL 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 exclusively recommends Menicon Progent for in-office only disinfection and protein removal for fluorosilicone acrylate GP lenses.



Paragon CRT® is the only FDA approved overnight corneal reshaping system with Proximity Control Technology®. And with the number of patients wearing Paragon CRT in the tens of thousands, practitioners fitting Paragon CRT are experiencing tremendous practice growth!

Paragon CRT practitioners who have successfully integrated Paragon CRT into their practices are reporting they have minimized the negative effects of managed care and the competitive pressures from large optical chains, as well as telephone and Internet contact lens marketers on their practices. They have also increased patient loyalty and retention.

Now it's your turn to enjoy the benefits Paragon CRT can have on your practice. And at the same time, your patients will enjoy a new lease on life with the visual freedom Paragon CRT provides. Getting started is easy!

Becoming a Certified Paragon CRT Practitioner:

1. Review the Paragon CRT Certification Training Information booklet and complete the 18-Question Certification Test.
2. Choose to order the Diagnostic Dispensing System (DDS), or enroll in the SUREFIT Guarantee™ Program.
3. Fax your completed order form to +44 (0) 1604 790366.

## THE DIAGNOSTIC DISPENSING SYSTEM & SUREFIT GUARANTEE



Once you've completed your Certification Test, a Paragon representative will contact you to verify the purchase of the Paragon CRT Diagnostic Dispensing System (DDS), or enroll you in the SUREFIT Guarantee™ Program.

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, reviewing the following information is required: Paragon CRT Clinical Manual and Dispensing Guide, Paragon CRT Fitting Guide, Paragon CRT Welcome Book, and the Paragon CRT Package Insert and Instructions for Wearers.



The SUREFIT Guarantee Program allows Certified Practitioners with a DDS the ability to fit outside the standard DDS parameters by ordering empirically or with the Slide Rule. SUREFIT Guarantee provides one free exchange within 90 days.

The DDS provides the Certified Practitioner the ability to trial fit patients and dispense properly fitted CRT lenses on the day of their visit. While Certified Practitioners without a DDS can order empirically under the SUREFIT Guarantee Program, the DDS remains the suggested method for dispensing CRT.

## AQUACOMFORT PLASMA TREATMENT



With AquaComfort™ Plasma Treatment, Paragon CRT lenses have reached an exciting new level of wettability and patient comfort. AquaComfort Plasma Treatment is an FDA approved process designed to enhance patient comfort and increase the wettability of lenses made from the Paragon HDS Technology family of materials, including Paragon CRT.

## PARAGON CRT SUPPORT TOOLS



As a Paragon CRT certified practitioner, you will receive the following tools with your DDS to assist you and your staff in integrating Paragon CRT into your practice:

- Paragon CRT Certificate
- Paragon CRT Initial Lens Selector Slide Rule & Yellow Wratten Filter
- Paragon CRT Patient Care Kit
- Practice Listing on [www.paragoncrt.com](http://www.paragoncrt.com)
- Basic and Advanced Clinical and Practice Management Training via Web Seminars
- Paragon CRT Practice Management Kit containing Patient Education Materials, Staff Training, Referral and Patient Testimonial Programs



PRACTITIONER NAME (MD / OD / OTHER)

PRACTICE NAME

ADDRESS

CITY / STATE / ZIP

PHONE FAX EMAIL

TOPOGRAPHY BRAND

Only practitioners who successfully complete the certification test are permitted, by FDA regulation, to fit Paragon CRT lenses for Corneal Refractive Therapy. As with any medical device, only licensed practitioners may purchase Paragon CRT lenses. **Circle your answers below**

- What is the approximate thickness of the corneal epithelium?  
 A. 130 microns B. 50 microns C. 80 microns
- What is the fixed Optic Zone diameter in the BC of Paragon CRT?  
 A. 5.0mm B. 7.0mm C. 6.0mm
- Which parameter in Paragon CRT is never adjusted to change the fit or centration of the lens?  
 A. LZA B. BC C. RZD
- What is the target ROL (Refraction Over Lens) with Paragon CRT?  
 A. -0.50 B. Plano C. +0.50 to -0.50
- If the ROL is -1.00D, what adjustment should be made in the BC to achieve a Plano ROL?  
 A. Steepen .20mm B. Flatten .10mm C. Flatten .20mm
- Which of the following would indicate the Paragon CRT lens with the greatest sagittal depth?  
 A. 8.6 .550 -33 B. 8.6 .550 -32 C. 8.6 .575 -33
- Of the following, which is the best option to improve the centration of a superiorly positioned Paragon CRT lens?  
 A. Increase RZD B. Decrease RZD C. Steepen BC
- Of the following, which is the best option to improve the centration of an inferiorly positioned Paragon CRT lens?  
 A. Increase LZA B. Decrease LZA C. Flatten BC
- Return Zone Depths are available in micron increments of:  
 A. 15 microns B. 7 microns C. 25 microns
- A one degree change in LZA affects overall sagittal depth by  
 A. 15 microns B. 25 microns C. 7 microns
- At dispensing, the LZA reflects an excessive amount of edge lift. What adjustment is needed?  
 A. Decrease LZA B. Increase LZA C. Make no adjustment
- At dispensing, the LZA reflects an insufficient amount of edge lift. What adjustment is needed?  
 A. Decrease LZA B. Increase LZA C. Make no adjustment
- What is the age restriction for prescribing Paragon CRT?  
 A. No restriction B. Must be over 18 C. Must be over 21
- After dispensing, when should you see the patient for their follow up visit to ensure proper centration and applanation?  
 A. 1 Week B. 1 Day C. 1 month
- How long is the average treatment period for a new Paragon CRT lens wearer?  
 A. 7 to 14 days B. 1 Month C. 2 Months
- When using the Slide Rule, what two components are needed to determine the initial Paragon CRT lens?  
 A. Steep K / Manifest Refraction Sphere  
 B. Flat K / Spherical Equivalent  
 C. Flat K / Manifest Refraction Sphere
- The design of the Landing Zone will allow:  
 A. Impingement on the underlying cornea  
 B. Tear film touch in the periphery of the cornea  
 C. Varying radius of curvature
- When presenting Paragon CRT to your patients, who would be considered a candidate for the procedure based on our FDA approval?  
 A. Up to -8.00D myopia, with or without up to -2.50D astigmatism  
 B. Up to -6.00D myopia, with or without up to -2.00D astigmatism  
 C. Up to -6.00D myopia, with or without up to -1.75D astigmatism

**TO COMPLETE YOUR CERTIFICATION & ORDER, PLEASE INITIAL ONE OF THE FOLLOWING OPTIONS:**

- A)  I am a licensed practitioner seeking Paragon CRT Certification. **By signing below, I am ordering the "Risk Free" Paragon CRT Diagnostic Dispensing System (DDS) for my use. (Check)  Please send me the Paragon CRT DDS for £1175.**  
 I agree to keep the DDS filled for a 2-year period and agree to permit periodic access to my DDS by an Authorized David Thomas Representative so they may audit the DDS and place necessary lens replacement orders to meet the set requirement of 100 lenses.
- B)  I am a licensed practitioner seeking Paragon CRT Certification. **By signing below, I am eligible to order Paragon CRT under the SUREFIT Guarantee™ Program. I understand I will be billed £66.50 for the Technical Kit.** I understand the DDS is the preferred method of fitting and I am eligible to order the DDS at anytime once I am Certified.
- C)  I am a licensed practitioner or state certified contact lens fitter seeking Paragon CRT Certification and will be utilizing the following Paragon CRT Certified practitioners Diagnostic Dispensing System (DDS).
- D)  I am an Optometric student seeking Paragon CRT Certification. I attend \_\_\_\_\_ college & will graduate in \_\_\_\_\_ month / \_\_\_\_\_ year.
- E)  I am a licensed practitioner seeking Paragon CRT Certification and practice outside of the USA & Canada.

**Practitioner Name / GOC #**

**City / State / Telephone #**

SIGNATURE GOC # DATE