

FITTING & TROUBLESHOOTING GUIDE

SPECTRUM



A Life Changing Product

The **SmartLens PRO** lens is a scleral lens design used in the treatment for restoration of vision and corneal health in patients with dry eye and corneal irregularities.

Ability

- Restore vision in a compromised cornea.
- Create an artificial tear layer to help and improve dry eye symptoms.
- Provide exceptional optics through advancements of computer controlled equipment & 3-D design software.
- Change the life of your patients through better vision, lens comfort and patient care.
- Comfort is unsurpassed no matter how irregular the cornea

Fitting Set Prep & Cleaning

Trial Lens Preparation

- 1. Wash hands well with contact lens approved hand soap.
- 2. Clean lens thoroughly with RGP multipurpose lens solution.
- 3. Rinse lens well with saline.
- 4. Completely massage saline solution onto lens. Focus on the front surface and absorption. Do not rinse off.
- 5. Fill concave surface with non-preserved saline and Flourescein.
- 6. Insert lens with patients head parallel to the floor.

Recommended Disinfecting Protocol

Clean trial lens with RGP multipurpose lens solution. Rinse with saline. Place lens in contact lens case. Fill with hydrogen peroxide solution, 3%. Allow soaking for 10 minutes. Rinse lens and lens case with saline (no water). Store lens in RGP multipurpose lens solution for up to 1 month. Cases should be replaced yearly.

Concept

Our **SmartLens PRO** lens concept is simple. By adjusting the optical zone you can obtain the ideal clearance over the apex of the cornea out to the limbal region of the eye. In turn, this creates a reservoir of fluid under the lens maintaining corneal health.

Additionally, the scleral landing area is designed to smoothly transition onto the conjunctiva creating a stable well fitting lens.

The standard SmartLens PRO trial set includes 18 diagnostic lenses in 3 different diameters with varying optic zones and saggital depth. This set usually will correct multiple types of corneal disorders.

The SmartLens PRO scleral lens can be custom designed for any patient and eye disorder

Lens Design

SmartLens PRO scleral lens performs exceptionally well on dry eyes and irregular corneas including keratoconus, corneal trauma, pellucid marginal degeneration, penetrating keratoplasties, post LASIK and RK patients. It incorporates a proprietary multiple posterior curve system to obtain corneal alignment. Patients who wear SmartLesn PRO will have unsurpassed comfort and clarity throughout the day. The standard trial lens set contains 15.5 mm, 16.0 mm and 16.5 mm diameters.

Pre-Fitting Examination

It is recommended that corneal topography be done, taking note to the symmetry of the cornea. Your initial base curve should mimic the cornea's shape (steep cornea steeper base curve; flat cornea flatter base curve). Corneal elevation and most importantly, corneal diameter, should be noted.



STEP 1 Limbal Clearance

Selecting Lens Size

Trial lenses come with "LCI" limbal curve indicator markings. These markings will assist in determining proper lens diameter. It is recommended that for patients with normal or smaller than normal size corneas, (11.5mm or less), a 16.0mm trial lens should be a first choice. Patients with larger corneas, (12.0mm or greater), should be fit in the 16.5mm lens. Once on the eye, observe the "LCI" markings in **temporal quadrant**. If A and or B are over the limbus the diameter is ideal (Fig. A). If the limbus sits beyond B to C, fit a lens .5mm larger (Fig. B). If the limbus sits beyond the third line reference C fit a lens 1.0mm larger.



Figure A: Lens is within target no change in diameter.



Figure B: Lens too small go 0.5mm larger in diameter.

Unacceptable limbal bearing









STEP 2 Central Clearance

Choosing Base curve & SAG

The most difficult parameter to determine on a distorted corneal is the initial trial lens. The SmartLens PRO lens is fit by SAG value and not base curve. However, the base curve does need to mimic the cornea. i.e.: use a steeper base curve on steeper corneas and flatter base curves on flatter asymmetric corneas such as Pellucid, LASIK, and RK eyes. Below is a suggested initial base curve / SAG guide.

Moderate Cone	Severe Cone	Pellucid	Post Surgical	Post Surgical
Advanced Cone	Globus Cone		(Sunken - Lasik/RK/PK)	(Bulging) PK
7.50 BC/16.0/4.72 SAG	7.34 BC/16.5/5.39 SAG	7.50 BC/16.0/4.72 SAG	7.85 BC/16.5/4.80 SAG	7.34 BC/16.5/5.39 SAG

Fluorescein Pattern

Lens selection should be aided by an examination of the fluorescein pattern. Place the fluorescein in the bowl of the lens at insertion. If there is central bearing the SAG value should be increased by 0.1mm for every 1.0mm of touch. The ideal pattern will align cornea to the limbus and will vault the steepest part of the cornea by at least 250 microns at insertion. Once that is obtained, a close evaluation of the periphery is needed. There should not be any excessive edge lift or worse impingement into the conjunctiva. If there is excessive lift or impingement in the periphery, the lens edge should be adjusted.

2mm touch/4.20 SAG



No touch/4.40 SAG



Too flat/Heavy central bearing with Limbal Bubble Increase SAG value by 0.3-0.4mm



A properly fit lens will have alignment over the cornea. The ideal vault will have at least 250 microns of clearance over the steepest part of the cornea at initial insertion. Your goal is to find the minimum SAG Value that vaults the cornea over the limbus with no apical bearing. Upon settling the ideal vault will have settled and will be approximately 150 microns.





STEP 3 Peripheral Edge Alignment

A proper edge should not lift off of the sclera or more importantly, impinge into it. An edge that lifts excessively will cause lens awareness while an edge that impinges can cause redness and discomfort. If the edge is not aligned with the sclera recheck to make sure that you have an appropriate SAG that vaults the cornea. If you do have the appropriate SAG with an incorrect edge, call our consultation department for advice on peripheral curve changes.

Good edge alignment



Excessive edge lift



Lens impingement



Toric Haptic

Toric Haptic designs allow the lens edge to align more precisely to any scleral asymmetry. This improved alignment can help centration, comfort and/or debris under the lens. Standard toric haptic lens designs have approximately 200um steep differential.



STEP 4 Over Refract

Calculating Lens Power

Lens power is best determined by over-refraction. The spherical and or the cylinder value of the overrefraction are simply added to the trial lens power to determine the correct power.

Ideal Fit

In a properly fit SmartLens PRO lens the tear reservoir should thin gradually over the limbus until the lens comes down to rest on the conjunctival surface. Alignment with the conjunctiva should be to provide a seal, prevent the introduction of bubbles and avoid awareness of the lens edge. It should not compress the ocular surface to the extent that it causes conjunctival vessel blanching, redness beyond the lens edge,

displacement/bunching of the conjunctiva and discomfort. The lens should center and should not move significantly on blink.

Ideal 150 micron clearance after setting















Multifocal Lens Designs

The SmartLens PRO lens is available in numerous multifocal designs. The most common are an aspheric multifocal and a periscopic center add multifocal. Both work exceptionally well when prescribed for the proper patient. First and foremost, obtain a proper physical fit. Once obtained, then evaluate the overall refraction making sure not to over minus in the correction.



LENS DESIGN AMF dual aspheric multifocal



LENS DESIGN CENTER NEAR PERISCOPIC off-center near zone





LENS DESIGN ALTERNATING ZONE multifocal near and distant

On Point

On Point Alignment Technology is laser-marked diagnostic lenses. The laser alignment grid gives precise output to the angle and the amount of offset needed for a custom optic. No guessing and no "ONE-Size-Fits-All". A truly customized optic for each patient





Benefits

Curve Specific Design Modify only the curves you want

Simplistic Fitting Minimize patient chair time

Warranty 5 month with unlimited exchanges Make sure your patient understands the importance of proper insertion and removal. When inserting a SmartLens PRO it is important that the concave surface be fully filled with saline so as to reduce the risk of induced unwanted bubbles. Most patients find that holding the lens between the index and middle finger or using a lens insertion tool works best. Since SmartLens PRO tends to settle on the eye, it needs to be pre-loosened before removal. We recommend irrigating with saline and massaging the lens prior to removing the lens with a DMV suction cup. (Refer to our care and handling video on our website for more detailed instructions).

Bubbles

Sometimes at insertion a false bubble can be induced. It is very important when inserting the lens that it be filled fully with saline and placed on the eye with the head down and parallel with the table top. You do not want any bubbles as they will cause the cornea to become dry within those areas.

Proper Position





Insertion Tool



Induced Bubbles

While not common, corneal edema may occur in some patients. A lens with too much vault can cause this. Make sure to re-evaluate your SAG value. It should be the minimum SAG that vaults with no apical bearing (100-150 microns after settling). Another cause may be that the periphery of the lens is impinging into the conjunctiva. If this occurs flattening the PC's while maintaining the appropriate SAG is indicated. Lens awareness can occur if there is too much edge lift. Excessive edge lift is caused by either the PC's being too flat or the lens SAG being too low. If excessive edge lift is observed you should first determine if the SAG is appropriate. Often when the SAG is increased, the edge will improve. If the lens SAG is correct, then a steeper periphery is indicated.

The two most common causes for SPK are either from preservatives in the solution or excessive bearing on the apex. Because these lenses have very little or no movement, tear exchange is very slow to occur. Therefore, it is very important that a non-preserved saline be used when inserting. This will eliminate any possibility of chemical irritation. On rare occasions metabolic debris accumulation can be an issue. Usually the patient will complain of decrease acuity after eight to ten hours wear. If this occurs reorder with toric pc's. Excessive redness can be a sign that the lens is fitting tight. Patients may complain that their wearing time is limited to only a few hours a day. Recheck the SAG to make sure it is at 150 micron apical vault – (after settling) and adjust if necessary. If the SAG is appropriate then re-design with a flatter periphery.

Issue	Cause	Resolve	
Corneal Edema	To much vault	Re-evaluate lens SAG with fluorescein. Decrease SAG	
Corneal Edema	Lens edge impingement	Flatten PCs/maintain appropriate SAG	
Excessive Edge Lift	Low SAG	Re-evaluate lens SAG with fluorescein. Increase SAG	
Excessive Edge Lift with correct SAG	Flat PCs	Steepen PCs	
SPK	A preservative solution has been used	Must use preservative free solutions	
SPK	Excessive bearing on the corneal apex	Re-evaluate lens SAG with fluorescein. Increase SAG	
Decreased Acuity	Metabolic debris	Reorder with Toric PCs	
Excessive Redness	Tight fit/excessive SAG	Re-evaluate lens SAG with fluorescein. Decrease SAG	
Excessive Redness with correct SAG	Tight PCs Flatten PCs		

Troubleshooting

Fitting Pearls

- Mimic the shape of the cornea.
- Clear the apex and limbus
- Central bearing, edge lift and\or limbal bubbles indicate a flat fit.
- Increase SAG value if there is a central bearing (0.1mm for every 1.0mm of bearing).
- Deep central pooling or central bubbles indicate a steep fit.
- Decrease SAG value if you have a steep fit.
- Ideal fluorescein pattern will be aligned at 150 microns of clearance after settling.
- Edge should not impinge or lift excessively off of the sclera.

*Your goal is to find the minimum SAG Value that vaults the cornea with no apical bearing (150 microns after settling / 250 microns at insertion).

Quick Fit Guide

STEP 1 Make sure the lens is large enough to clear the limbus

STEP 2 Determine the minimum SAG value that vaults the cornea with no apical touch. If there is apical touch, increase the SAG value (.1mm SAG for every 1.0mm of touch) until the lens vaults the cornea at least 250 microns. (Clearance is best seen with a thin white slit beam. The green fluorescein band should be 1/2 as thick as a normal corneal thickness.)

STEP 3 Check the edge. It should not impinge or lift excessively off the sclera.

STEP 4 Over refract for final correction.

Moderate Cone	Severe Cone	Pellucid	Post Surgical	Post Surgical
Advanced Cone	Globus Cone		(Sunken - Lasik/RK/PK)	(Bulging) PK
7.50 BC/16.0/4.72 SAG	7.34 BC/16.5/5.39 SAG	7.50 BC/16.0/4.72 SAG	7.85 BC/16.5/4.80 SAG	7.34 BC/16.5/5.39 SAG



ADVANCE FITTING GUIDE

SPECTRUM

Diagnostic Lens

All **SmartLens PRO** diagnostic lenses have several laser marks to assist in proper fittings.

- The lens parameters are etched on the lens to ensure that all lenses are stored properly and organized to avoid any confusion.
- LCI- Limbal Curve Indicator are etchings on the nasal and temporal side to evaluate proper limbal clearance. Please see fitting guide.
- OnPoint Laser Technology- Laser grid to evaluate decentration and reference quadrant specific changes at corresponding axis.
- All lenses have an asterisk at 270° to reference steep meridian.

Custom Lens

All **SmartLens PRO** lenses will have an laser-etched asterisk. The asterisk is always in the 6 o'clock (270°) position for proper alignment of the haptic toric and/ or front toric.



Pro-Tip

Small HVIDs (<=11.8) or smaller use the 16.0mm lenses Larger HVIDs (>=12.0mm) or larger use 16.5mm lens

Lens Alignment Process

All **SmartLens PRO** lens designs are FIRST customized by aligning the back surface of the lens to the sclera. It is essential to stabilize the lens first before any other customizations can be made to ensure successful optics, vaults and SAG changes. Back surface alignment will ensure the asterisk is brought back to the 270° position on each lens.

All **SmartLens PRO** fitting sets are standard with toric haptics. Each trial lens has 200µ toricity. The STEEP will always align to the STEEP part of the sclera and the asterisk is marked on steep at 270°.

The asterisk should inserted at the 270° position. Notate the position of the asterisk and any rotation of the lens. This must be told to consultation when ordering.



- Confirm rotation by manually rotating the lens back to 270° on the eye several times.
- Please note: The rotation of the back surface will allow the addition of front surface cylinder without the need for LARS compensation.

Custom Lens Diameter - LCI

Limbal Curve Indicators are laser markings on the horizontal meridian of all trial lenses. LCI are to assess the the overal correct lens diameter and limbal clearance for every patient.



0

Evaluate the Temporal Edge when assessing LCI.

2

Limbus will ideally land between the two "inner" lines A & B



In this image, the lens is too small. Use a larger diagnostic lens diameter and/or tell consultation for modifications.

Quadrant Specific / Free Form

SmartLens PRO lenses can be modified independently in the Central Zone, Limbal Zone and Peripheral Curves in each corresponding quadrant.



- Place all diagnostic **SmartLens PRO** lenses with the asterisk at 270°. The Limbal Curve Indicators are on the horizonal meridian.
- Communicate modifications needed in each zone by referring to superior, inferior, nasal and temporal zones. (180° OD- temporal 180° OS -Nasal)
- All peripheral curves can be modified in each quadrant. 1 step= 70µ to correct edge alignment.

SmartVault & Dual SmartVault

This customization allows vaulting high sections on the sclera due to pterygium, pinguecula, shunts or scars. **SmartLens PRO** can be made with two Smartvaults. Standard vaults are 3.5mm width/300µ depth

A radicle overlay is ideal to calculate precisely the position of the vault.





SmartLens PRO - FreeForm lens with small SmartVault

Case Report Example:

SmartLens PRO lens designed with Eaglet Scan over a Trabeculectomy Bleb. Both Patient and Surgeon are happy. Patient been wearing lens for 6 months.



Oblique Zone / Excessive inferior Clearance

SmartLens PRO lens can be modified independently in the Central Zone, Limbal Zone and Peripheral Curves in each corresponding quadrant.



A solution to excessive inferior clearance in scleral lenses due to Pellucid, Steep Corneas, and decentration.

SmartLens PRO design algorithm minimizes inferior clearance by modifying zones in the 270° position to reduce excess vault and contour to this steep area of the cornea.

More Available Features

Add-on or Additional Options

- Hydra-Peg
- Notching
- HD optics
- Fenestration / Truncation
- Inverse (Aspheric Limbal Curves)
- Any Diameter (14.5mm-20.0+mm)
- Multi-Focals and Optics
 - Front Surface Cylinder
 - Aspheric Center Distance
 - Center Near
 - Center Near Displaced Optics
 - Custom Zone Size
 - Custom Add Power
- Front Surface Cylinder Multifocal
- Combination of Optics

Fitting Principles

- Identify trial with best lens fit
- Evaluate LCI
- Evaluate Central Clearance the ideal is 300um at insertion over steepest area of cornea. (Trial lenses are 300µ thick).
- Notate haptic alignment in all 4 quadrants.
- Perform a spherical over-refraction to determine lens power. Some patients will need sphero-cylindrical refraction over the final diagnostic lens.
- Notate any lens rotation.
- Order lens with all modifications.

Troubleshooting Guide

ISSUES	CAUSE	SOLUTION	
• Excessive Clearance	• Too Steep Central Zone	Lower SAG/Flatter BC/ Flatten Central Zone	
• Minimal Clearance	• Too Flat Central Zone	• Increase SAG/Steeper BC	
• Excessive Decentration	• Too much vault/Vertical meridian too flat	 Reduce Central Zone/steepen vertical PCs 1-2 steps 	
• Conjunctival prolaps	• Too much limbal clearance	• Flatten Limbal Zone	
 Blanching at edges 	• Scleral Zone too steep	 Flatten Pcs/1 step 70 microns 	
 Impingement outside limbus 	 Too steep landing zone/ too flat Scleral Zone 	 Flatten Landing Zone/steepen Pcs 	
• Cloudy vision <4 hours	• Tear exchange under the lens	 Do NaFl test to confirm what quadrant is flat/lens stand off and steepen SLZ 	



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