

IMPLEYE[®]
Scleral GP

**Professional Fitting
Instructions**

KEY FITTING CONCEPT:

Only one Dx lens application is required for on-eye assessment!

Follow our efficient diagnostic fitting system for SIGNIFICANT CHAIR TIME SAVINGS.

The intelligently designed Ampleye diagnostic set includes the optimal number of lenses to fit all types of patients - from a highly prolate bulging graft to a low sag oblate cornea. The incorporated 150 micron toric haptic provides rotational stability, ensures accurate trial assessment, and eliminates guesswork on Rx orders. The consistent Limbal Lift and Scleral Landing Zones mean that only one Dx lens application is required for on-eye assessment, reducing stress for the patient and saving valuable chair time for the practice.

Experience In Practice:

My experience with AMPEYE has been nothing short of awesome! It offers a simplified fitting approach to a highly customizable lens that can manage my early to advanced cones, PMD, and PK patients. Having standard toric haptics in the trial set really helps simplify one of the biggest challenges in scleral lens fittings, landing the lens. Also, the ability to change saggital height without changing the base curve helps with consistency in vision with lens ordering. - Nicholas Lawrence, OD | Howland, OH

I love my Ampleye fitting kit because I am able to fit patients with the first trial! I have previous scleral experience but really appreciate how well Ampleye works! - Steve Onorato, OD | Lakewood, CO

I have found my clinic's go-to scleral lens in Ampleye. The intuitive design, complimented by the toric haptic system, has allowed me to greatly reduce my chair time and minimize refits, which allows me to see more patients. This lens has been a practice builder.

-Joshua Davidson, OD | Baton Rouge, LA

I was excited to try Ampleye with the incorporated toric haptic system. In the past few months I have put all my new scleral fits into the Ampleye lens. It has been the best new product I have tried in many years. The fitting takes less time, and I have needed fewer follow-up visits to arrive at my final prescription.

Andrea Palardy Nielsen, OD | Royal Oak, MI

Ampleye makes fitting scleral lenses quicker and easier than I ever could have imagined. The process is straightforward, even the first time through.

My most challenging patients now have clear vision and feel great.

- Brad Kampschroeder, OD | Naperville, IL

Introduction

Ampleye is a 4-Zone scleral lens designed to vault the cornea and limbus completely, and land gently on the sclera with 360 degrees of alignment, reducing movement and increasing patient comfort.



Ampleye employs **Spline Science Technology** and advanced curve fitting algorithms to connect and smooth the lens junctions, making each zone independently adjustable for ultimate control of the complete fit.

Patient Considerations

Ampleye is an excellent option for any patient with an irregular cornea, or for those with lens stability issues or corneal GP intolerance. The locked-in hydration chamber secures fluid to keep the cornea moist, relieving symptoms of dry eye and ocular surface disease.

Defining the Ampleye Zones

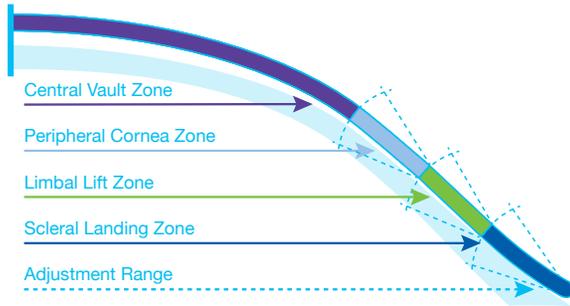
Central Vault Zone (CVZ)

The CVZ controls the sagittal depth (sag) required to vault the central cornea. Pre-settling, the ideal clearance should range between 250-400 microns (μm). This zone is listed in both sag and base curve measurements. The sag is used to control clearance, while the primary function of the base curve is to aid in determining overall lens power. The Ampleye Diagnostic Set employs only a limited number of base curves to reduce unpredictable over-refraction outcomes when switching from one sag to the next.



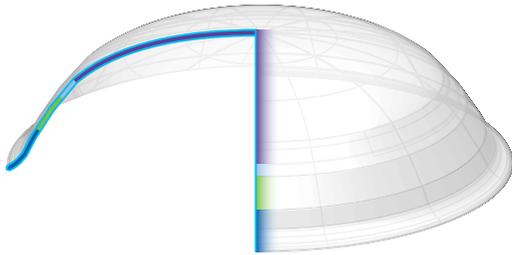
Peripheral Cornea Zone (PCZ)

The PCZ works like a hinge that lifts or lowers the CVZ. This zone is used to increase the vault in bulging eyes when the lens lays itself down on the peripheral corneal surface or to raise or lower the apical clearance when smaller sag adjustments are required (<200µm). Altering the base curve can perform a similar function; however, base curve changes can result in unpredictable over-refractions, whereas raising or lowering the PCZ specifically alters the sagittal height of the Ampleye lens. In the diagnostic set, the PCZ varies as the sag values change.



Limbal Lift Zone (LLZ)

The LLZ is used to adjust the limbal vault and should completely clear the limbus 360° to avoid any insult to the limbal tissue. Changing this zone aids in adjusting the overall sagittal height. The LLZ remains constant in all diagnostic lenses.



Scleral Landing Zone (SLZ)

The role of the SLZ is to spread the lens bearing evenly and over as broad a scleral area as possible. The SLZ should come to rest with uniform bearing on the sclera without excessive impingement. This zone can be altered to increase and decrease edge lift when necessary to avoid compression of the conjunctiva and its blood vessels. The SLZ remains constant in all diagnostic lenses.

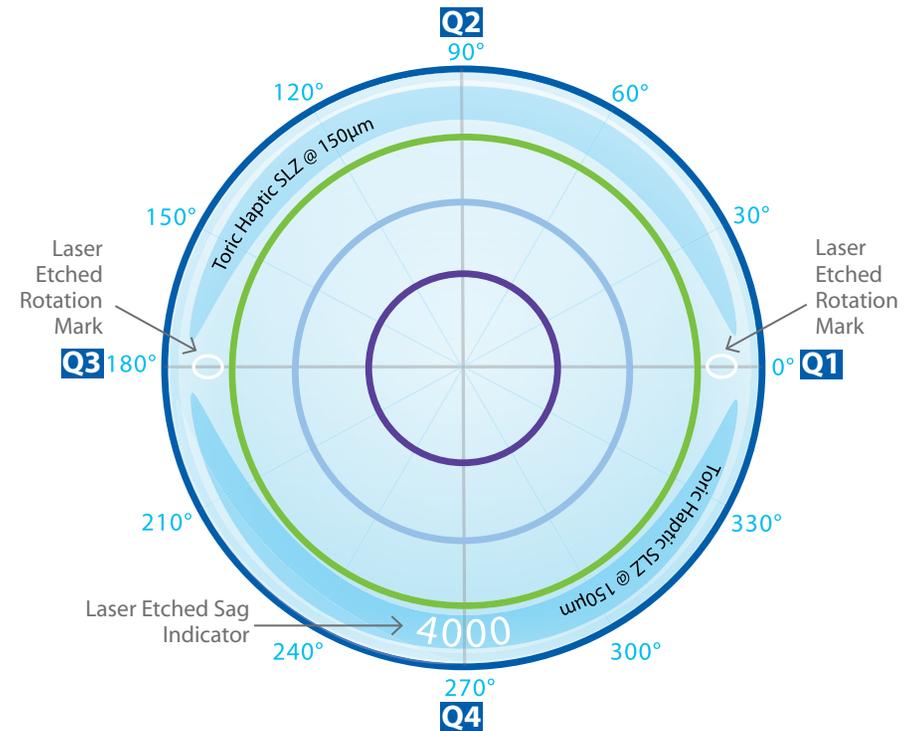
NOTE: All positive (+) step zone adjustments increase the overall depth of the lens. Conversely, all negative (-) step adjustments to the zones decrease the overall sagittal depth of the lens.

Lens Thickness

The standard center thickness (CT) of the Ampleye Scleral GP is .30mm or 300 microns (µm).

Lens Markings

Because Ampleye is not meant to sit on any specific axis, it is important to document the location of the diagnostic markings during the trial fit and at any follow-up visit. The rotation marks denote the flat axis of the lens while the sag indicator denotes the steep axis of the lens. As seen in the diagram, the sag indicator is laser etched at 6 o'clock and the rotation marks are at 3 and 9 o'clock. However, upon insertion, Ampleye will automatically find the flattest and steepest meridian of the sclera and remain rotationally stable. Noting the axis of the flat and/or steep meridian insures that the correct axis is compensated for when front surface cylinder is required and proper toric haptic adjustments are made to the scleral landing. On Ampleye patient Rx lenses, the sag indicator will be replaced with an "R" on right lenses and "L" on left lenses. They can be used in the same method as the diagnostic markings to reference rotation.



NOTE: 15.0mm Dx lenses have a spherical periphery and a 2-digit sag indicator (ie: 40).
15.5mm Dx lenses have a 125µm toric haptic periphery and a 2-digit+T sag indicator (ie: 40T).
16.5mm Dx lenses have a 150µm toric haptic periphery and a 4-digit sag indicator (ie: 4000).

About the Toric Haptic

Ampleye diagnostic and custom lenses in the primary diameter ranges have a toric haptic periphery. This is not a toric base curve, only the Scleral Landing Zone (SLZ) is toric. The inclusion of the toric haptic provides alignment on the sclera, aids in lens centration, and serves as an axis stabilizer if a cylinder correction is required. SLZ toricity is adjustable from 0-375µm.

Fitting Ampleye

The Ampleye Scleral GP is designed to vault the whole cornea, coming to rest only on the sclera. Because of the vaulting, the posterior lens surface does not interact with the cornea, therefore, the typical measurements from keratometry and topography are not useful and diagnostic fitting is required.

Initial trial lenses are selected by patient condition, as opposed to K-readings. The depth of the eye determines the initial depth of the trial lens. Lenses are labeled, selected and ordered according to their sagittal depth as opposed to base curve.

Getting Started

Perform Ocular Assessment & Select Initial Diagnostic Lens Based on the Patient's Condition

- Determine if the cornea is normal, median, or high sagittal depth.



- Choose the initial diagnostic lens that corresponds to the corneal depth.

INITIAL DIAGNOSTIC LENS SELECTION GUIDE				
Ocular Assessment	Lens Dia	Sag µm	BC mm/D	Power D
NORMAL DEPTH Normal Eyes/Oblate Corneas	15.0/15.5 mm 16.5 mm	3400 4000	8.65/39.00D 8.44/40.00D	+4.00 PLANO
MEDIAN DEPTH Keratoconus/PMD	15.0/15.5 mm 16.5 mm	3800 4400	8.04/42.00D 8.04/42.00D	PLANO -4.00
HIGH DEPTH PK or Advanced/Bulging Keratoconus	15.0/15.5 mm 16.5 mm	4200 4800	7.03/48.00D 8.04/42.00D	-6.00 -8.00

Prepare the Diagnostic Lens(es) - To prep the lenses to be used on your particular patient, follow one of these methods:

Quick Start - when the patient is present: Once the initial trial lens is selected, open the lens case and clean the lens with a laboratory cleaner or a lens cleaner acceptable for use with GP lenses. After following instructions for the cleaning solution you have used, apply conditioning solution to both surfaces and gently rub the lens to pre-condition the surfaces. This should assist in activating surface wetting to allow sufficient observation of the fitting characteristics. Rinse thoroughly with preservative-free saline. If the lens exhibits dry spots while on the eye, remove the lens and repeat the cleaning, conditioning and rinsing steps.

Pre-Conditioning - prior to patient arrival: Once the initial trial lens is selected, open the lens case and clean the lens with a laboratory cleaner or a contact lens cleaner acceptable for use with GP lenses. After following the cleaning instructions for the cleaning solution you have used, return the lens to the case and fill it with conditioning solution. For the most optimal wetting surface, soak the lens in conditioning solution for a minimum of 4 hours before the patients' scheduled fitting.



Trial Lens Application:

- Remove the initial prepared lens from the lens case and rinse with preservative free saline.
- Place the lens on a large DMV suction cup.
- Completely fill the bowl of the lens with preservative free saline and instill a generous amount of fluorescein. The lens is now ready for application.
- With the patient leaning forward (seated or standing), have the patient position the plane of the face parallel to the plane of the floor.
- Have the patient pull down on the lower lid.
- The practitioner should reach around the top of the head and pull up on the upper lid with one hand while bringing the lens straight up to the eye surface with the other.
- Gently but firmly place the lens on eye, squeezing the excess fluid out so the lens lands on the bulbar conjunctiva.
- Check lens placement with a hand-held cobalt blue light to assure there are no bubbles present.
- If bubbles are present, remove and reinsert lens.



To avoid insertion bubbles:

- Ensure the bowl of the lens is full of fluid.
- Open the fissure up as wide as possible to avoid hitting the lids or lashes as the lens is being placed on eye causing fluid to leak out.



- Place the lens on eye only when the eye is quiet and fixation into the bowl of the lens is maintained.
- If the lens doesn't land on the scleral 360 degrees around, the fluid leaks out and bubbles fill the space as the lens moves onto the center of the eye.

Evaluate the Lens Fit:

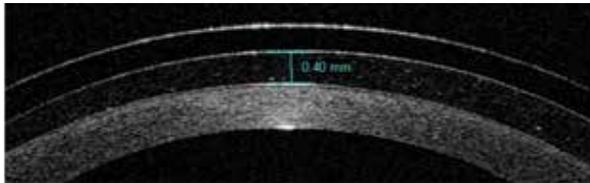
- Allow lens to settle on eye for a minimum of 20 minutes* before evaluating.
- Use slit lamp optic section and compare the center thickness of the trial lens (300µm) to the posterior tear layer to measure central vault while ensuring limbal clearance.

**An important note about settling: Vaulting scleral lenses, like Ampleye, land on the spongy bulbar conjunctiva resulting in moderate to significant sinking of the lens into the soft tissue. Allowing the lens to optimally settle ensures a definitive understanding of any modifications that might be needed in the custom lens.*

Ideal Central Vault*:

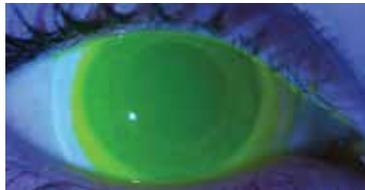
Diagnostic Fitting = 250-400µm

Post-Settling (8 hrs) = 125-275µm



> 400µm of central vault: note the amount of excess clearance and adjust on the Rx lens order.

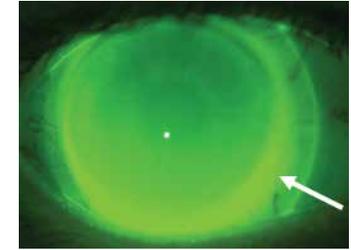
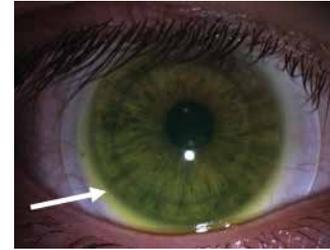
< 250µm of central vault but not touching: note the amount of clearance and adjust on the Rx lens order. If touch is present, select a trial lens with a sag that is 400µm higher than the current lens.



**should be achieved over the highest point of the cornea*

Limbal Vault Observation:

Make sure there is limbal vault as opposed to limbal touch. Fluorescein should be evident throughout the limbus and around 100% of the visible limbal region as demonstrated below. If there is limbal touch, adjust the Limbal Lift Zone (LLZ) on the Rx order.



Edge Evaluation:

The ideal peripheral alignment of the Scleral Landing Zone (SLZ) is noted by landing with all of its weight on the sclera as demonstrated below. View the SLZ to determine if there is excessive edge lift or excessive tightening or blanching. Order a modified SLZ if edge changes are necessary.



Over-Refract:

- Perform sphero-cylinder over-refraction.
- If front cylinder is required, observe sag indicator location. If sag indicator is not at 270° (6:00), compensate for any rotation using LARS.

Order the Rx Lens by calling Art Optical & Providing:

- Sag of trial lens
- Over-refraction
- Clock position of sag indicator on trial if cylinder is required.

Employing Custom Aligned Optics for AMPLEYE® Scleral GP Multifocals

Due to scleral elevation differences, lens mass and superior lid interaction, scleral lenses often decenter infero-temporal. While the spherical aberration control built into the Ampleye design corrects for visual symptoms that lens decentration can cause, it cannot correct for the optical displacement seen with multifocals. In many cases, the combination of lens decentration and angle kappa cause the center near optics to be out of reach. Employing custom aligned optics places the multifocal add directly in front of the pupil to provide presbyopic patients all-range acuity.

Getting Started:

- ✓ Using your standard Ampleye Fitting set, follow the normal fitting procedures and be sure to document trial lens rotation by identifying the clock location of the rotation marks or SAG indicator.
- ✓ Order an Ampleye Multifocal lens based on your trial fit information using the recommended Standard Decentration with a 2.50 mm center near zone:
 - OD 0.75mm towards axis 45
 - OS 0.75mm towards axis 135 (see image 1 and 2)

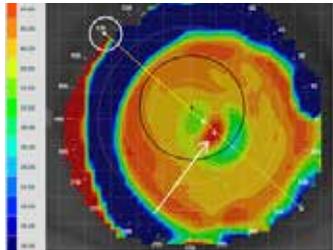


Image 1 - Multifocal without Custom Aligned Optics (left eye)

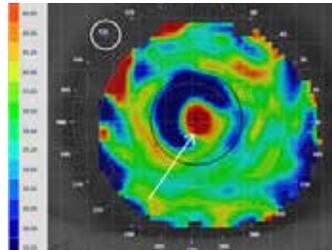


Image 2 - Multifocal with Custom Aligned Optics using Standard Decentration (OS 0.75mm towards axis 135)

Follow-up:

- ✓ Perform Topography over Multifocal lens
 - Perform topography over the lens in-situ with the patient looking directly down the center of the instrument
 - Select the Tangential Power Map and customize the dioptric scale to decrease the dioptric range. In most cases, shrinking the span of the scale to 3-4 diopters from the steepest central reading works well (ie. steepest central reading is 40.00 so scale range should be around 38.00-41.00 (see image 3 and 4).

- If the optics still appear to be mis-aligned, forward topography to a fitting consultant to evaluate and discuss recommendations. Alternatively, using the ruler or measuring feature on your topographer, measure the distance between the center of the near optics to the center of the pupil and note the axis direction. Provide this information to a fitting consultant who can assist in fine-tuning the position of the center near optics.

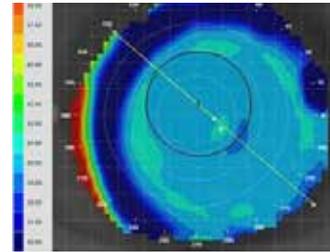


Image 3 - Tangential map with Standard power (35.00-50.00)

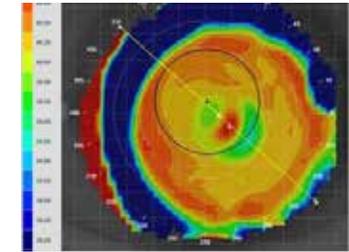


Image 4 - Tangential map with Custom scale (38.00-41.00)

Fine tune:

- ✓ Measure pupil diameter in normal room lighting
 - The standard 2.50mm center near zone can be decreased or increased according to pupil size
- ✓ Lens diameter
 - If excessive lens decentration with the standard 16.5 diameter is noted upon slit lamp examination or topographical findings, a decrease in the diameter may improve lens position and assist in centering the optics.

Lens markings and insertion:

- ✓ Document lens rotation
 - It is crucial to document the location of the lens markings during the trial fit and at all follow-up visits to ensure that the optics can be aligned in the correct direction
- ✓ Lens insertion
 - Directional lens insertion is required in order for the patient to achieve proper vision
 - Correct insertion will be assisted by a black dot located along the steep meridian placed 180 degrees from the engraved R/L (see image 5). Placement depends on the documented lens rotation but in most cases the black dot should be inserted superiorly.

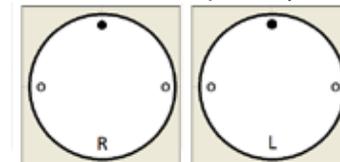
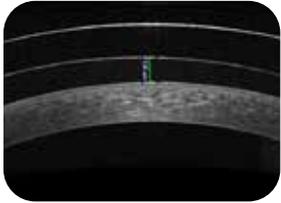


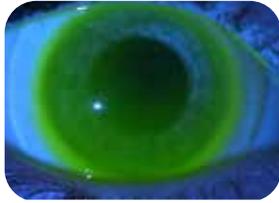
Image 5

FITTING REFERENCE IMAGES

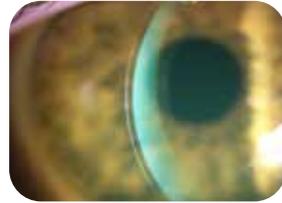
Central Vault Zone (CVZ)



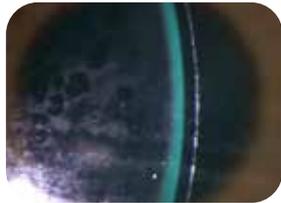
Adequate Central Clearance



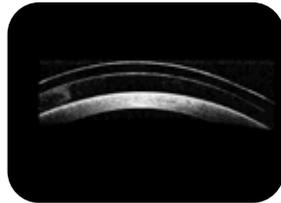
Inadequate Superior Central Clearance
(trial fit higher SAG)



Excessive Central Vault
(approx 900 microns, order SAG three steps lower)

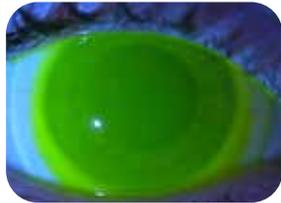


Minimal Central Clearance
(approx 200-250 microns, raise PCZ +4)

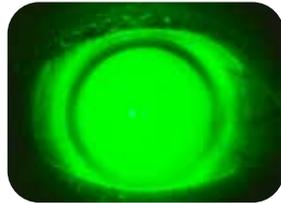


Excessive Central Vault
(approx 500 microns, order SAG one step lower)

Peripheral Corneal Zone (PCZ)



360° Appropriate Peripheral Corneal Clearance

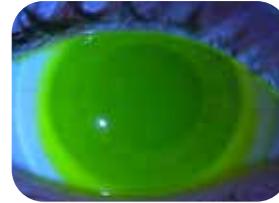


360° Inadequate Peripheral Corneal Clearance
(raise PCZ +5)

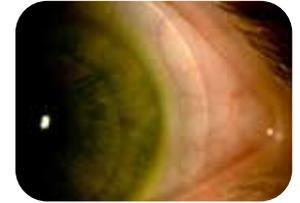


Heavy Peripheral Corneal Touch
(raise PCZ +10)

Limbal Lift Zone (LLZ)



Good Limbal Clearance
(more inferior due to inferior decentration)

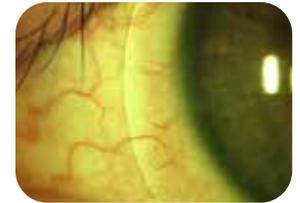


Good Limbal Clearance

Scleral Landing Zone (SLZ)



Appropriate Scleral Landing



Edge Blanching/Toeing
(lift SLZ -1.00 or adjust toric haptic)



Heel Blanching/Heeling
(reduce LLZ -2.00 and tighten SLZ +1.00)



Edge Lift
(tighten SLZ +1.00 or adjust toric haptic)

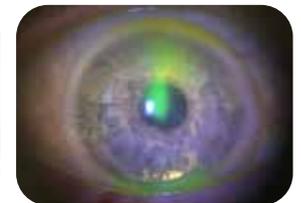
Miscellaneous



Conjunctival Prolapse
(reduce LLZ -2.00)



Limbal Injection
(reduce LLZ -2.00)



Fluorescein Tap Test
(adjust toric haptic)

TROUBLESHOOTING

FIT OBSERVATION

Excessive Central Vault Clearance (CVZ)

Insufficient Central Vault Clearance (CVZ)

Insufficient Mid-Peripheral Clearance (PCZ)

Excessive Limbal Clearance (LLZ)

Insufficient Limbal Clearance (LLZ)

Loose Edge or Scleral Standoff

Tight Edge, Scleral Edge Blanching or Compression

Scleral Heel Blanching

Cylinder Over-Refraction

RESOLUTION

Order Rx lens with lower sag to decrease by 200µm or adjust the PCZ of Rx lens in -1 step increments to decrease by 25µm.

Order Rx lens with higher sag to increase by 200µm or adjust the PCZ of the Rx lens in +1 step increments to increase by 25µm.

Order in +1 step changes in the PCZ to increase the mid-periphery 25µm. Suggested to change in +5 step increments. Extreme bearing should go +10 steps (250µm).

Order in -1 step changes in the LLZ to decrease by 25µm. Suggested to change in -3 step increments (75µm). Adjust PCZ in same amount of positive (+) steps to maintain same central vault.

Order in +1 step changes in the LLZ to increase by 25µm. Suggested to change in +3 step increments (75µm). Adjust PCZ in same amount of negative (-) steps to maintain same central vault.

360° mild edge lift, order SLZ +1
360° moderate edge lift, order SLZ +2
Lift off at rotation marks, decrease toric haptic. Lift off at laser sag indicator, increase toric haptic.

360° mildly tight edge, order SLZ -1
360° moderately tight edge, order SLZ -2
Edge blanching at rotation marks, increase toric haptic.
Edge blanching at laser sag indicator, decrease toric haptic.

Reduce LLZ -2 and order SLZ +1

Order a Front Toric.

FIT OBSERVATION

Lens Fogging or Clouding During Wear

Bulging Keratoplasty

Pingueculas Pterygiums

Oblate cornea

RESOLUTION

Check for excessive central vault and/or add non-preserved artificial tears upon insertion.

Check for tear exchange by tapping fluorescein on the front surface of settled lens and watch for uptake under the lens. Note clock hour of uptake to adjust fit.

Adjust the PCZ in + steps for better mid-peripheral vault. Increase diameter by .50.

Adjust diameter +/- .50
Adjust Toric Haptic
Employ Quadrant Control.

Flatten base curve to reduce central clearance while maintaining peripheral corneal clearance

Additional Ampleye Fitting Resources:

Visit www.artoptical.com/ampleye to view:

- Ampleye Scleral Quick Fit Demo
- Ampleye Virtual Consultant Tool
- Ampleye Initial Rx Lens Calculator
- Compensating Cylinder Axis for Rotation with Ampleye
- Ampleye Virtual Trial Set Demonstration & Training Tool
- Ampleye Case History Archive

Contact a certified fitting consultant @ 800.566.8001:

- Large staff of professionals
- Real-time fitting assistance
- Monday - Friday 9:00 am to 6:00 pm EST

Did You Know?

AMPLEYE is FDA indicated for the effective management of Ocular Surface Disease and Dry Eye?

For enhanced surface properties and increased lens wearing time, be sure to request



DIAGNOSTIC SETS & ACCESSORIES



Ampleye Scleral Standard Diagnostic Set Item# R1602 - \$200

9 Ampleye Dx Lenses with 16.5mm diameter and toric haptic. *INCLUDES:* Sagittal depths of 3800, 4000, 4200, 4400, 4600, 4800, 5000, 5200, & 5600 in storage case with fitting instructions and accessories - large DMV, small DMV, hand-held cobalt blue light, wrattan filter, & starter supply of non-preserved saline.

Ampleye Scleral 15.0/15.5 Diagnostic Set Item# R1603 - \$200

4 Ampleye Dx Lenses with 15.0mm diameter and 5 Ampleye Dx Lenses with 15.5mm diameter and toric haptic. *INCLUDES:* Sagittal depths of 3400, 3800, 4200, 4600 in both diameters and 4800 in 15.5mm in storage case with fitting instructions and accessories - large DMV, small DMV, hand-held cobalt blue light, wrattan filter, and starter supply of non-preserved saline.



Ampleye Scleral 15.0/15.5/16.5 Combo Diagnostic Set Item# R1605 - \$350

18 Ampleye Dx Lenses with 15.0/15.5/16.5mm diameter. *INCLUDES:* 1 lens of 3400, 3800, 4200, 4600 in both 15.0 & 15.5 diameters and 4800 in 15.5mm, as well as, one each of sag depths 3800, 4000, 4200, 4400, 4600, 4800, 5000, 5200, & 5600 in 16.5mm. Shipped in storage case with fitting instructions and accessories - large DMV, small DMV, hand-held cobalt blue light, wrattan filter, and starter supply of non-preserved saline.



Ampleye Scleral Diagnostic Set Extensions Item# R1602EXT or R1603EXT - \$150

Sold as add-ons to Ampleye R1602 or R1603 9-lens sets. **R1602EXT** includes duplicate 16.5mm lenses with 3800, 4000, 4200, 4400, 4800 and 5400sag, all with toric haptic, and spherical lenses of 4000, 4200 & 4400sag. **R1603EXT** includes (4) 15.0mm spherical lenses & (5) 15.5mm w/toric haptic in 3400, 3800, 4200, 4600sag, plus 4800sag in 15.5mm. Lenses will ship with an 18-lens foam insert that fits the original storage case.



Ampleye Individual Trial Lens - Item# R1602IRL - \$25
Available to order by diameter & sag for existing set-holders.



Ampleye Patient Starter Kit Item# R1130 - \$8

INCLUDES: deep well lens case, large DMV for lens insertion, traditional DMV for lens removal, pocket mirror, starter supply of non-preserved saline, & instructions in clear carrying case.

Nutrifill - Item# R1128

Preservative free rinsing & insertion solution for scleral lenses. Formulated with 5 electrolytes to mimic natural tears. Limited sample quantities available for S&H fee. Wholesale and patient supplies available @ nutrifill.com. Made in USA.



Addipak Sterile Saline - Item# R1126 - \$20

5ml Unit Dose Vials Sterile 0.9% NaCl - 100 Ct Box. Single use saline vials, preservative free, sterile.



Menicon LacriPure Saline Solution Item# R1127 - \$20

98 Count Box - 5ml vials. FDA approved non-preserved saline solution indicated for rinsing soft, hybrid, or GP lenses and for scleral lens insertion.



Progent by Menicon

Item# R1730 - Single Treatment - \$6²⁵

Item# R1732 - 7 Treatment Pack - \$22⁵⁰

For biweekly cleaning of scleral and corneal GP lenses. Cleans, loosens and removes surface deposits after a short soak without manual rubbing. Includes lens case.



Progent by Menicon Scleral Lens Case - Item# R1746 - \$8 ea.

For Progent treatment of large diameter lenses (11-23mm).



DMV Traditional RGP Lens Removers

Item# R3100 - \$2 ea.

Small suction cup for removing gas permeable lenses from the eye.



DMV Scleral Cup - Item# R3130 - \$3 ea.

Large diameter GP lens insertion tool.



EZI Scleral Lens Applicator

Item# R3135 - \$10

Scleral lens insertion ring allows for one finger application, lens self-positioning, and less air entrapment.



Featured Materials:

OPTIMUM

by Contamac[®]

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