Introduction

Ampleye is a 4-Zone, 16.5mm scleral lens designed to vault the cornea and limbus completely. It should land 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-setting, 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 in curvature as the sag values change.

Limbal Lift Zone (LLZ)
The LLZ is used to adjust the limbal vault and should completely clear the limbus 360º to avoid any insult to the limbal tissue. Changing the curvature of 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).
**About the Toric Haptic**

Standard Ampleye diagnostic and custom lenses have a toric haptic periphery of 150µm. 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. Recent studies by Pacific University indicate that up to 90% of scleral surfaces are toric and found 150µm ideal for a 16.5mm lens. SLZ toricity is adjustable from 0-375µm.

**Lens Markings**

Because Ampleye is not meant to sit on any specific axis, the rotation indicating hash marks denote the flat axis of the lens. Upon insertion, Ampleye will automatically find the flattest meridian of the sclera and remain rotationally stable on that axis. The majority of the time, the scleral flat meridian will not line up with the flat K or refractive axis, so it is important to note the axis where the lens finds its rotational stability. Noting the axis of the flat meridian insures that the correct axis is compensated for when front surface cylinder is required. The lens sag is laser etched at 6:00 and serves as a reference to help locate the laser etched rotation marks.

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**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.

### INITIAL DIAGNOSTIC LENS SELECTION GUIDE

<table>
<thead>
<tr>
<th>Ocular Assessment</th>
<th>Sag µm</th>
<th>BC mm/D</th>
<th>Power D</th>
</tr>
</thead>
<tbody>
<tr>
<td>NORMAL DEPTH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal Eyes, Oblate Corneas</td>
<td>4000</td>
<td>8.44/40.00D</td>
<td>Plano</td>
</tr>
<tr>
<td>MEDIAN DEPTH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keratoconus, PMD</td>
<td>4400</td>
<td>8.04/42.00D</td>
<td>-4.00</td>
</tr>
<tr>
<td>HIGH DEPTH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advanced/Bulging Keratoconus, PK</td>
<td>4800</td>
<td>8.04/42.00D</td>
<td>-8.00</td>
</tr>
</tbody>
</table>

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**Getting Started**

Perform Ocular Assessment & Select Initial Diagnostic Lens Based on 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.

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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 the 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. Repeat this cleaning and soaking process for the next higher and lower sag depth lenses as well. If during the diagnostic fitting, a lens other than the 3 that have been prepared is needed, remove it from the lens case, and follow the quick start lens prep method.

**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.
- Fill the bowl of the lens with preservative free saline and instill a generous amount of fluorescein.
- Top the lens up with additional preservative free saline to ensure the lens is full of fluid. 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 arm 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 to 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 settle for 60 minutes is ideal and ensures a definitive understanding of any modifications that might be needed in the custom lens. If ideal settling time is not possible, be aware that modifications may be required to one or more of the Ampleye zones to optimize the fit following settling.
**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. If there is limbal touch, adjust the Limbal Lift Zone (LLZ) on the Rx order.

**Edge Evaluation:**
The ideal peripheral alignment of the SLZ is noted by landing with all of its weight on the sclera. 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, an axis adjustment may be necessary to compensate for any rotation observed when assessing the position of the hash marks on-eye. *(Perform keratometry or topography over lens to ensure no flexure is occurring).*

**Order the Rx Lens by calling Art Optical & Providing:**
- Sagittal depth of best-fitting trial lens
- Sphero-cylinder over-refraction
- Axis position of toric hash marks if cylinder is required

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### Available Parameters

| Peripheral Cornea Zone (PCZ) | Standard = 0  
Adjustable in 1.0 steps to +/-15.00  
Each step = 25µm of change |
|-----------------------------|---------------------------------|
| Limbal Lift Zone (LLZ)      | Standard = 0  
Adjustable in 1.0 steps to +/-15.00  
Each step = 25µm of change |
| Scleral Landing Zone (SLZ)  | Standard = 0  
Adjustable in 1.0 steps to +/-15.00  
Each step = 25µm of change |
| Sphere Power                | +/-20.00° in 0.25D steps  
*c*can be extended on order of practitioner |
| Cylinder Power Cylinder Axis| Up to -5.00D in -0.25 steps  
1° to 180° in 1° steps |
| Diameter                    | Standard = 16.5mm;  
16.0mm, 17.0mm available |
| Thickness                   | Standard = .30mm  
Adjustable in .01mm steps to .50mm |
| SLZ Quadrant Control        | Standard Q1 & Q3 = 0  
Standard Q2 & Q4 = 150µm  
Each quadrant is adjustable in +/- steps of 1-15. Each step = 25µm of change |

### SAGITTAL DEPTH & BASE CURVE

<table>
<thead>
<tr>
<th>SAGITTAL DEPTH</th>
<th>BASE CURVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>3,800</td>
<td>8.44</td>
</tr>
<tr>
<td>4,000</td>
<td>8.44</td>
</tr>
<tr>
<td>4,200</td>
<td>8.04</td>
</tr>
<tr>
<td>4,400</td>
<td>8.04</td>
</tr>
<tr>
<td>4,600</td>
<td>8.04</td>
</tr>
<tr>
<td>4,800</td>
<td>8.04</td>
</tr>
<tr>
<td>5,000</td>
<td>7.34</td>
</tr>
<tr>
<td>5,200</td>
<td>7.34</td>
</tr>
<tr>
<td>5,400</td>
<td>6.04</td>
</tr>
<tr>
<td>5,800</td>
<td>6.04</td>
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</tbody>
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*Standards as listed for central sag and base curve radius. Once the sag is set centrally, the base curve can be adjusted flatter or steeper while maintaining the same sag but it will affect the final resulting depth (+/-) by the amount of base curve radius change input (+/-). The range in adjustment is from 8.44mm (40.00D) to 6.04mm (60.00D). Each diopter of base curve change = 50µm*
<table>
<thead>
<tr>
<th>FIT OBSERVATION</th>
<th>RESOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excessive Central Vault Clearance (CVZ)</td>
<td>Go to the next lower sag diagnostic or adjust the PCZ of Rx lens in -1 step increments to decrease by 25µm.</td>
</tr>
<tr>
<td>Insufficient Central Vault Clearance (CVZ)</td>
<td>Go to next diagnostic lens that is 400µm higher than current, or adjust the PCZ of the Rx lens in +1 step increments to increase by 25µm.</td>
</tr>
<tr>
<td>Insufficient Mid-Peripheral Clearance (PCZ)</td>
<td>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).</td>
</tr>
<tr>
<td>Excessive Limbal Clearance (LLZ)</td>
<td>Order in -1 step changes in the LLZ to decrease the mid-periphery 25µm. Suggested to change in 5 step increments (125µm). Adjust PCZ in same amount of positive (+) steps to maintain apical clearance.</td>
</tr>
<tr>
<td>Insufficient Limbal Clearance (LLZ)</td>
<td>Order in +1 step changes in the LLZ to increase the mid-periphery 25µm. Suggested to change in 5 step increments (125µm). Adjust PCZ in same amount of negative (-) steps.</td>
</tr>
<tr>
<td>Loose Edge or Scleral Standoff</td>
<td>360° mild edge lift, order SLZ +1 360° moderate edge lift, order SLZ +2 Lift off 90° from laser sag, increase toric haptic; Lift at laser sag, decrease toric haptic.</td>
</tr>
<tr>
<td>Tight Edge, Scleral Bearing, Blanching or Compression</td>
<td>Mildly tight lens, order SLZ -1 Moderately tight lens, order SLZ -2 Severely tight lens, order SLZ -3 Adjust PCZ in same amount of positive (+) steps.</td>
</tr>
<tr>
<td>Cylinder Over-Refraction</td>
<td>Order a Front Toric.</td>
</tr>
<tr>
<td>Fogging or Clouding</td>
<td>Check for excessive central vault and/or add non-preserved artificial tears upon insertion.</td>
</tr>
<tr>
<td>Bulging Keratoplasty</td>
<td>Adjust the PCZ in + steps for better mid-peripheral vault. Increase diameter by .50.</td>
</tr>
<tr>
<td>Pingueculas Pterygiums</td>
<td>Adjust diameter +/- .50 Quadrant Control required.</td>
</tr>
<tr>
<td>Oblate cornea</td>
<td>Decrease PCZ accordingly.</td>
</tr>
</tbody>
</table>

### Additional Ampleye Fitting Resources

Visit [www.artoptical.com](http://www.artoptical.com) to view:

- Ampleye Introductory Webinar
- Ampleye Virtual Trial Set Demonstration & Training Tool
- Ampleye Case History Archive
- & More!

Contact a certified fitting consultant @ 800.566.8001:

- Large staff of professionals
- Real-time fitting assistance
- Monday - Friday 8:30-5:30 pm EST

Notes:

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