# Fitting Guide

## Applications

- Normal Prolate Corneas
- Presbyopia
- Astigmatism
- Emergent or Frusté Keratoconus
- Soft Contact Lens Intolerant
- Small Diameter GP Lens Intolerant
- Post-RK, Post-LASIK
- Nipple Cones
- Oval Cones
- Irregular Corneas
- Ectatic Corneas
- Ocular Surface Disease

## Design Options

- Spherical
- Multifocal
- Sym-Toric (Front Toric)
- Toric Haptic
- Oblate
- Oblate Multifocal
- Asian Design
- Extra Limbal Clearance
- Quadrant Specific
- Controlled Peripheral Recess (CPR)
INTRODUCTION

The Onefit Scleral Lens is unique and simplifies the fitting process for a wide range of applications. Corneas with normal prolate profile, astigmatism, post grafts, as well as mild to moderately irregular corneas will benefit from this proprietary geometry. The design serves as a platform from which the Multifocal, Oblate, Sym-Toric (Front Toric), Toric Haptic, Quadrant Specific, Controlled Peripheral Recess, and Extra Limbal Clearance designs can be ordered.

Onefit minimizes both lens thickness and tear layer required to support the lens, maximizing oxygen transmission to the cornea and stem cells, while eliminating fitting issues associated with larger scleral lenses (fogging, conjunctival pro-lapse, etc).

Onefit is designed to vault a given topography with an optimal sag height, and is specified by the value of the base curve in mm; simplifying the fitting process and making it more user-friendly. Patient handling is simplified as the Onefit standard diameter is similar to most soft lenses.

The Onefit Asian design (Onefit A) embraces the same minimalist approach to fitting scleral lenses described in this fitting guide, while addressing the physiological nuances of the Asian eye. Onefit A lenses need to be ordered from the Onefit A fitting set. Since Onefit A addresses the physiological specificities of the Asian eyes, with a smaller standard diameter and different paracentral edge geometry, a different fitting set is required to reflect with exactitude those nuances.

FITTING PHILOSOPHY

Onefit is supported by the conjunctiva and the fluid layer under the lens, rather than by the cornea. It is designed to vault the entire corneal surface including the limbal area. However, the clearance over the cornea varies from center to the periphery to optimize oxygen transmission to the tissue, especially over the limbus where the stem cells are located.

Onefit was designed to maximize oxygen transmission when combining the lens and tear layer thickness. For this reason the lens is thinner over the limbus compared to other designs. Its unique geometry reduces the tear layer from the center out to the limbal area. Optimum results in fit and corneal health are achieved with a clearance of 150 to 175 microns (4+ hours of wear) at the point of highest corneal elevation, with limbal clearance not exceeding 40 to 60 microns. The lens peripheral edge should align with the conjunctiva. Onefit is manufactured in materials offering a minimum permeability of 100 DK.

Based on clinical trials, every 0.10 mm change in the base curve value results in an average variation in central clearance of 50 microns. For example, if the base curve is steepened by 0.10 mm the apical clearance will increase by 50 microns. On the other hand, if the base curve is flattened by 0.10 mm the apical clearance will be reduced by approximately 50 microns.

FITTING PROCESS

Onefit lenses are simple and easy to fit, providing consistent reproducible results.

6 Step Fitting Process

01 Initial base curve and diameter selection
02 Evaluate clearance at the point of highest corneal elevation
03 Evaluate limbal clearance
04 Evaluate conjunctival alignment
05 Evaluate resistance
06 Over-refraction

LENS ASSESSMENT

Evaluate fitting characteristics from the inside out. Onefit scleral lenses will recess on average 100 microns during a full day of wear, with roughly 50% happening within the first 30 minutes of application. This is why clearance evaluated at application, after 30 minutes and 4 plus hours of wear will vary accordingly. Consideration should be given to amount of time the lenses have been in-situ when evaluating for optimal central clearance.

See the decision tree on page 18, for an easy and intuitive step-by-step approach to fitting the optimal lens.

COMPENSATING FOR DIAMETER CHANGES

Diameter changes will be compensated with a change in base curve and accompanying change in final lens power. For an increase in diameter of 0.3 mm, flatten the base curve 0.3 mm and adjust the power accordingly (use the Onefit Fitting Tool on the Blanchard web site; www.blanchardlab.com, for an accurate calculation of the new lens power).

Note: The diameter/base curve relationship stated in section 01, is accurate for the majority of patients but results may vary according to each individual’s scleral shape.
Diameter Selection Chart

**BASE CURVE**
Select a base curve that is equal to flat K.

**DIAMETER**
The horizontal visible iris diameter (HVID) is the main factor to consider in determining the lens diameter. The unique peripheral curve system of Onefit is optimized with the use of the standard diameter.

The standard lens diameter will cover > 90% of the cases. For smaller corneas, it is recommended to select a smaller lens (0.3 mm). For a larger cornea, a larger diameter could be considered.

**Diameter Selection Chart**

<table>
<thead>
<tr>
<th>Onefit Platform</th>
<th>HVID</th>
<th>DIAMETER</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Less than 11.5 mm</td>
<td>14.6 mm or less (custom)</td>
</tr>
<tr>
<td></td>
<td>Between 11.5 mm and 12.0 mm</td>
<td>14.9 mm (standard)</td>
</tr>
<tr>
<td></td>
<td>12.0 mm - 12.3 mm</td>
<td>15.2 mm</td>
</tr>
<tr>
<td>Onefit A - for the Asian Eye</td>
<td>HVID</td>
<td>DIAMETER</td>
</tr>
<tr>
<td></td>
<td>Less than 11.3 mm</td>
<td>14.4 mm or less (custom)</td>
</tr>
<tr>
<td></td>
<td>Between 11.3 mm and 11.8 mm</td>
<td>14.7 mm (standard)</td>
</tr>
<tr>
<td></td>
<td>11.8 mm - 12.1 mm</td>
<td>15.0 mm</td>
</tr>
</tbody>
</table>

**Evaluate Apical Clearance**

**Highest Corneal Elevation**

*Before applying the lens, fill the bowl with non-preserved solution tinted with fluorescein dye.*

**Evaluate Apical Clearance First. Ignore Peripheral Fit at This Time.**

*At application, look for clearance of 200 to 225 microns at the point of highest corneal elevation. According to the clearance observed, make changes to the base curve. Applying a lens that is 0.5 mm steeper will increase apical clearance by 50 microns on average. Applying a lens that is 0.5 mm flatter will reduce apical clearance by 50 microns on average.

*Tip: Use the diagnostic lens thickness specified with lens parameters on the diagnostic lens case as a reference to evaluate clearance.*

Evaluate the cornea/lens relationship under white light (optic section) at the stilt lamp, using no more than a 40° angle. Using the blue filter will not help determine the actual thickness of the fluid layer under the lens. Utilizing an anterior segment OCT gives you a more accurate reading of the fluid layer thickness, particularly at the limbal level.

After the lens has settled for 30 minutes, look for clearance of 200 to 225 microns at the point of highest corneal elevation.

The ideal clearance after +4 hours of wear is 175 to 215 microns at the point of highest corneal elevation.

**Evaluate Limbal Clearance**

Onefit is designed to minimize clearance at the limbal level in order to maximize oxygen transmission over this very sensitive area where the stems cells are located, as well as allow for a smooth landing on the adjacent conjunctiva. Evaluate clearance in the limbal area under white light (optic section) at the stilt lamp. As it is with the cornea, allow no touch on the limbus. At this stage, the blue filter can be used to confirm the presence of fluorescein at the limbal level. Remember if the clearance is less than 25 microns, fluorescein may not be seen, particularly with smaller diameter lenses.

Ideally, OCT scans will reveal whether or not there is clearance at the limbus. Otherwise, evaluate the lens fitting characteristics during follow up visits. Lack of staining at the limbal level indicates that clearance is adequate and there is no need to make a change.

**Insufficient Vault** (after 4+ hours of wear) resulting in a touch on the cone. Note the accumulation of mucus deposits on this area, illustrating a lack of tear exchange under the lens. Base curve should be steepened by at least 0.5 mm, which will result in a 250 micron increase to clearance.

**Ideal Clearance** (4+ hours of wear) of 225 microns (25 of the lens thickness or 25 of the corneal thickness). Measured with optic section using white light at a 40° angle.

**Anterior Segment OCT** gives you a more accurate reading of the fluid layer thickness.

**Increased Limbal Clearance**

Limited limbal clearance
Increased limited limbal clearance
Limited limbal clearance with an Extra Limbal Clearance design option
Limited limbal clearance with a standard diameter lens
Limited limbal clearance with a larger diameter (0.3 mm larger than standard)

On the other hand, ring staining pattern or any signs of tissue compression at the limbal level, are an indication that the lens is too close to the surface and the vault in that area must be increased. First, order a lens with Extra Limbal Clearance. This option will increase clearance over the limbal area by 50 microns, without affecting the lens behavior on the eye. Second, try a lens with a diameter 0.3 mm larger. The modified geometry of the larger lens will increase the vault over the limbal area.

*The Asian design already incorporates the Extra Limbal Clearance option. If the vault over the limbal area needs to be increased, try a lens with a diameter 0.3 mm larger.*

**Note:** The base curve and power need to be compensated when making a diameter change, please refer to Compensating for Diameter Changes on page 3 in this guide.

**Fitting Tip:** When the base curve/diameter selection leads to optimal limbal clearance, but excessive central clearance, the Onefit Oblate series can be used to re-establish an appropriate central clearance. Please refer to the Onefit Oblate on page 12 in this guide.
04 EVALUATE CONJUNCTIVAL ALIGNMENT

After selecting the base curve that provides optimal clearance (between 200 and 225 microns after 30 minutes of wear), evaluate edge lift. Look for conjunctival alignment; ensure there is no edge stand-off or peripheral seal off.

This represents an optimal conjunctival alignment with no edge stand-off or peripheral seal (blanching).

Optimal edge landing on the conjunctiva (OCT view).

Excessive edge stand-off, causing discomfort (OCT view).

Edge too steep, causing conjunctival compression with a potential for peripheral seal off and blanching (OCT view).

A simple test to demonstrate good conjunctival alignment is to apply a gentle pressure on the conjunctiva and observe how easily it is to create a gap with the back surface of the lens. Careful: applying too much pressure may create a gap with the back surface of the lens. If there is no movement, re-assess the fit. Release the pressure and watch the conjunctiva re-align itself with the back surface of the lens.

CONJUNCTIVAL GAP CREATED WITH GENTLE PRESSURE, INDICATING OPTIMAL LENS LANDING ON THE CONJUNCTIVA

TORIC HAPTIC (PC)

If the fit indicates a toric haptic is needed; the haptic itself will stabilize the lens on the surface of the eye. To ensure proper stabilization of a lens with an anterior toric optics, a minimum of two (2) steps difference between flat and steep meridian is needed. For example: Flat 1 (Steep 1 or Flat 2 (Steep 2).

When dispensing a Onefit toric haptic lens, confirm stability of the axis orientation by manually rotating the lens 90 degrees, clockwise and counter-clockwise, and observe if the lens always come back to the same habitual axis orientation. If the axis orientation is not stable, consider increasing the difference between the flat and steep meridians.

Use the Axis Compensation Tool-LARS (Left Add, Right Subtract) available in Custom Tools at blanchard.com to compensate for misaligned axis.

Lenses with a toric haptic are etched with double hashmarks at 3 o'clock to indicate the flattest meridian.

Anterior toric lenses with toric haptics are etched with double hashmarks at 3, 6, and 9 o'clock.

This represents an optimal toric landing on the conjunctivae (OCT view).

QUADRANT SPECIFIC

Although rarely needed due to the diameter of the lens, sometimes the asymmetry of the sclera requires that each quadrant has their own unique specifications. Therefore, we have added a Quadrant Specific tool to the Custom Tools section at blanchardlab.com to help you design each quadrant.

QUADRANT SPECIFIC CONTINUED...

To find the Quadrant Specific tool at blanchardlab.com, click on the green "Tools and Order Form" button in the upper right corner of the home page. From there you will see a link to "Custom Tools".

EDGE STAND-OFF

Edge stand-off will cause: tear meniscus to break-up at the edge of the lens, excessive movement when performing the Push-In Test (section 05), discomfort to the patient, and finally air bubble(s) which can invade the area under the lens edge when blinking.

To remedy the situation, start by re-assessing apical clearance to make sure it is optimal. If central clearance is optimal, order a lens with an edge lift that is Steep 1 or Steep 2 according to the severity of the stand-off. If the central clearance is insufficient, first, re-fit a lens with a steeper base curve and re-assess apical clearance to be optimal. If the problem persists, order a lens with an edge lift that is Steep 1 or Steep 2 according to the severity of the stand-off.

PERIPHERAL SEAL OFF

Peripheral seal off can cause vessel compression, blanching, and high resistance, or no movement at all with the Push-In Test (see section 05). Upon application, a tight peripheral edge will feel comfortable, but will cause a tight lens syndrome within a few hours of wear (see Troubleshooting on page 16).

PERIPHERAL SEAL OFF SYMPTOMS / REMEDY

To remedy the situation, start by re-assessing apical clearance to make sure it is optimal. If central clearance is optimal, order a lens with an edge lift that is Flat 1. If central clearance is excessive, first, re-fit a lens at an even less steep curve and re-assess apical clearance to be optimal. If the problem persists order a lens with an edge lift that is Flat 1.

To remedy the situation, start by re-assessing apical clearance to make sure it is optimal. If central clearance is optimal, order a lens with an edge lift that is Flat 1. If central clearance is excessive, first, re-fit a lens at a less steep curve and re-assess apical clearance to be optimal. If the problem persists order a lens with an edge lift that is Flat 1.

Apply gentle pressure on the conjunctiva and then push the lens up. The lens should offer little resistance and exhibit 0.5 mm to 2.0 mm movement (not on blinking, but under the push-up pressure).

PUSH-IN TEST

In addition to this test, observe if the lens rotates freely on the eye. Put your finger on the lens at 6 o'clock and rotate the lens back and forth from the temporal to nasal side. If there is no resistance, then conjunctival alignment should be considered optimal. It is easy to see the rotation of the diagnostic lens by looking at the laser marks at the periphery of the lens.

LENS ROTATION

If with the push-up pressure the lens moves excessively or not at all, re-assess the fit.

EVALUATE RESISTANCE (PUSH-IN TEST)

05 EVALUATE RESISTANCE (PUSH-IN TEST)

The Push-In Test is performed by applying gentle pressure on the conjunctiva and then pushing the lens up. It is a simple test to evaluate the overall fit of the lens. The lens should offer no or very little resistance and exhibit 0.5 mm to 2.0 mm movement (not on blinking, but under the push-up pressure).
**OVER-REFRACTION**

As is the case for all specialty contact lenses, perform over-refraction after the optimal lens is settled on the eye, to determine the appropriate parameters. Retinoscopy is recommended to begin the over-refraction, followed by sphero-cylindrical over-refraction, monocularly then binocularly.

This lens is designed to mask up to -0.75D of corneal cylinder. However, some individual corneal profiles will not be completely compensated by the fluid under the lens.

**ANTERIOR TORIC DESIGNS**

Residual astigmatism greater than -0.75D should be incorporated into an anterior toric design, using either Sym-Toric or Toric Haptic as stabilization method.

**Sym-Toric (Front Toric) - Preferred stabilization method**

In smaller lenses such as Onefit, scleral asymmetry is not always sufficient to stabilize a lens with Toric Haptic. For this reason, the Onefit Sym-Toric was developed. Sym-Toric relies on corneal shape rather than scleral asymmetry to stabilize the lens on the surface of the eyes.

No additional trial lenses are needed to fit Onefit Sym-Toric lenses.

Fit the lens as if it were a spherical Onefit lens. If you have residual cylinder, incorporate the cylinder and axis into the Rx and specify Onefit Sym-Toric as your lens choice.

Note: If the fit indicates a toric haptic is needed, please see the following section for instructions on fitting our toric haptic design.

When you dispense the Sym-Toric lens, have the patient insert the lens with the orientation dot at or near 6 o'clock. Let the lens settle for 2 or 3 minutes and note the axis at which the lens has settled (habitual position). To confirm stability of axis orientation, manually rotate the lens 30 degrees, clockwise and counter-clockwise, and observe if the lens always come back to the same habitual axis orientation. If the axis orientation is not stable, consider increasing the difference between the flat and steep meridians.

**Toric Haptic (PC)**

If the dot is not at 6:00 o'clock and the vision is not optimal, manually rotate the lens so that the dot is at 6:00 o'clock and re-evaluate vision. If vision is optimal when the dot is at 6:00 o'clock, compensate for the "habitual cylinder axis orientation" using LARS - or LARS online tool.

If the fit indicates a toric haptic is needed; the haptic itself will stabilize the lens on the surface of the eye. To ensure proper stabilization of a lens with an anterior toric optic(s), a minimum of two (2) steps difference between flat and steep meridian is needed. For example: Flat 5 steps or Flat 2 steps.

When dispensing a Onefit toric haptic lens, confirm stability of the axis orientation by manually rotating the lens 30 degrees, clockwise and counter-clockwise, and observe if the lens always come backs to the same habitual axis orientation. If the axis orientation is not stable, consider increasing the difference between the flat and steep meridians.

Use the Axis Compensation Tool-LARS (Left Add, Right Subtract) available in Custom Tools at blanchard.com to compensate for misaligned axis.

**LENS PROFILE**

Onefit Multifocal is a simultaneous vision, near-centered aspheric multifocal system. The system combines a distance lens profile (D Lens) for the dominant eye and a near lens profile (N Lens) for the non-dominant eye.

The near lens profile (N Lens) is specifically designed to enhance vision for computer and smart phone range. The two lenses work in tandem; the aspheric power profile, central add and power distribution of each lens profile complement each other to optimize selection of the image of regard, alleviating shadowing and confusion.

**FITTING PROCESS AND ORDERING**

**First**

Follow the recommendations in this guide for fitting monofocal Onefit.

**Second**

Use the lens fogging technique (+2.00 lens), to determine which eye is dominant at distance.

**Third**

Use the information obtained from the first and second steps above to order the lenses based on the following chart.

<table>
<thead>
<tr>
<th>ADD</th>
<th>Dominant Eye</th>
<th>Non-Dominant Eye</th>
</tr>
</thead>
<tbody>
<tr>
<td>+1.00 to +1.50</td>
<td>D Lens</td>
<td>D Lens</td>
</tr>
<tr>
<td>+1.75 to +2.25</td>
<td>D Lens</td>
<td>N Lens</td>
</tr>
<tr>
<td>+2.50 and up</td>
<td>N Lens</td>
<td>N Lens</td>
</tr>
</tbody>
</table>

Note: Consider 2 N lenses for pupils that are 5.0 mm and larger.
**DISPENSING AND OVER-REFRACTION**

**DISTANCE VISION**

Monocular over-refraction is first done at distance (maximum convex approach) to reach optimal BCVA (Best Corrected Visual Acuity) for each eye; next, equilibrate both eyes. Hand held lenses are preferred over a phoropter. Starting your over-refraction with retinoscopy will rapidly determine if there is any toricity in play.

**NEAR VISION**

Place the results of the distance over-refraction in a trial frame and evaluate the near vision on a binocular basis. Again, hand held trial lenses are preferred over a phoropter. Be sure that lighting is sufficient for reading during the evaluation. The reading card can be used to evaluate near vision. It is recommended that the patient perform normal near tasks, such as using a computer or a smartphone. If near vision is not optimal, add more convex (plus) power over the D-lens first, then over the N-lens. Distance vision should be re-evaluated each time convex (plus) power is changed. If distance vision is compromised, balance distance vision and near vision by removing the convex (plus) power over the D-lens, leaving the over-correction convex (plus) power over the N-lens only. Re-check vision at both distances before ordering.

**NOTE**

Similar to other simultaneous lens designs, vision at all distances will improve over time for most patients. If the binocular vision is serviceable at the dispensing visit (distance, computer and cell phone), then instruct the patient to wear the lenses for up to two weeks. It is important to do this before making any changes to the Rx.

**RESIDUAL ASTIGMATISM**

OneFit Multifocal lenses are not available in a toric lens design.

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**ONEFIT OBLATE LENSES**

The existing Onefit diagnostic fitting set serves as the platform from which Onefit Oblate lenses are ordered. No additional diagnostic fitting lenses are required to fit Onefit Oblate lenses.

**CONCEPT**

When the base curve/diameter selection of a Onefit leads to optimal limbal clearance and scleral edge landing, but excessive central clearance (> 250 microns), the oblate series - using reverse geometry - allows the practitioner to re-establish a healthy central clearance level (100-125 microns after 4+ hours of wear) by specifying one of four values of Central Clearance Reduction (CCR) - 70 microns, 110 microns, 150 microns and 190 microns - without altering limbal clearance and the way the lens lands on the sclera. (See illustrations below).

Specifically designed for oblate corneas (RK, PRK, Post LASIK), the oblate series can be used on any corneal shape to reduce central clearance to the desired level.

**POWER COMPENSATION OF OBLATE LENSES**

The central clearance reduction of the Onefit Oblate lenses is achieved by flattening the radius of the central base curve.

As the tear lens power is modified with every CCR change, the power of the lens must be compensated for as follows:

- CCR 70: +2.00 D
- CCR 110: +4.00 D
- CCR 150: +6.00 D
- CCR 190: +8.00 D

**NOTE:** Use the Fitting Tool, located on the Onefit product page at blanchardlab.com

**IMPORTANT:** The power specified when ordering a Onefit Oblate lens must be the compensated power. For example a Onefit lens with a power of -6.00 (including over-refraction), if ordered with a CCR 110, would be ordered as -2.00 (-6.00 +4.00 = -2.00).
FITTING

OBLATE CORNEAS

01. Select base curve (ignore central clearance at this stage)
Starting from the regular Onefit diagnostic fitting set; select a lens that gives optimal mid-peripheral/limbal clearance as well as conjunctival alignment. A good starting point would be to select a lens that is 0.2mm to 0.3mm flatter than ‘Sim K’ reading just outside the treatment zone or host graft junction (approximately 4.2mm radius from the central visual axis). Ignore central clearance at this point.

02. Measure central clearance
The proper base curve selection as determined above will most inevitably lead to excessive central clearance (oblate cornea). Measure the central clearance using an optic section, comparing the central clearance to the lens thickness. OCT may be used as well.
Note: Lenses will recess on average 100 microns over a period of 4 hours from application. Central clearance will vary accordingly. Consideration should be given to amount of time the lenses have been in-situ when evaluating for optimal central clearance.

03. Over-refract
Over-refract and incorporate your findings to the Onefit diagnostic lens power.

04. Determine Central Clearance Reduction value (CCR)
From your measurement of the central clearance, determine by how much you need to decrease central clearance to achieve optimal central clearance level (150-175 microns after 4 hours of wear). Select the 70, 110, 150 or 190 CCR value and compensate the power for the appropriate Oblate lens order.

LENS IDENTIFICATION

The Oblate lens will be identified with the same base curve value in millimeters, as the regular Onefit, with the addition of the CCR value (70 / 110 / 150 / 190).

For example: Onefit 7.80mm with a CCR value of 110 microns would be identified as 7.8/110. A Onefit 7.80mm with a CCR value of 150 microns would be identified as 7.8/150.

LENS MARKING

Oblate lenses are engraved with the CCR value as follows: OB/70

NORMAL CORNEA

In an effort to provide sufficient limbal clearance, fitting guidelines point to steeper base curve and/or larger diameter lenses. If the recommended changes eliminate the presence of limbal bearing, but result in excessive central clearance (> 250 microns), the Oblate series can be used to correct the situation, and bring central clearance back to a healthy level (150-175 after 4+ hours of wear).

Please refer to steps 1-6 of this fitting guide for optimal fitting characteristics.

AVAILABILITY

The Oblate series can be ordered in the following designs:
- Spherical
- Multifocal
- Front Toric
- Toric Haptic
- Quadrant Specific
- Controlled Peripheral Recess (CPR)

CONTROLLED PERIPHERAL RECESS (CPR)

Controlled Peripheral Recess, or “CPR”, is a manufacturing process that creates a precise, controlled and reproducible peripheral recess to accommodate pingueculas, scleral shunts, and other scleral elevations that may contribute to lens discomfort and/or poor lens centration. CPR technology is available in Spherical, Front Toric, Toric Haptic and Quadrant Specific specifications.

The extremely user-friendly CPR Tool at blanchardlab.com keeps you in total control of CPR placement and size, simplifies the design and ordering process, and provides a visual representation of the lens design.

LENS IDENTIFICATION

The Oblate lens will be identified with the same base curve value in millimeters, as the regular Onefit, with the addition of the CCR value (70 / 110 / 150 / 190).

For example: Onefit 7.80mm with a CCR value of 110 microns would be identified as 7.8/110. A Onefit 7.80mm with a CCR value of 150 microns would be identified as 7.8/150.

LENS MARKING

Oblate lenses are engraved with the CCR value as follows: OB/70
Onefit scleral lenses are perhaps the most hydrating and oxygenating scleral lens on the market, providing patients with excellent comfort and long-term corneal health. However, many patients can benefit from a Tangible Hydra-PEG coating, which improves the lenses wettability, surface water retention, lubricity and minimizes protein and lipid deposits — providing the ultimate in comfort and extended wear. Contamac's Optimum and Hexa 100 materials have FDA 510(k) clearance for therapeutic applications, including treatment of Dry Eye. Consider adding Hydra-PEG to your Onefit lenses manufactured in Contamac™ Optimum or Hexa 100 materials.

**COMFORT VS LENS AWARENESS**

This lens was designed to be as comfortable as a soft lens after adaptation. At the initial trial you can expect some lens awareness, particularly for patients with no prior lens experience, or those with prior soft lens wearing experience. However, true discomfort is a certain sign of a bad fit.

The primary cause of lens discomfort is edge stand-off. After 30 minutes, if the patient is not comfortable, access apical clearance to be optimal (after 30 minutes of wear, look for 200-225 microns of clearance). If the central clearance is insufficient, first, re-fit a lens with a steeper base curve and/or peripheral curves to optimize tear exchange. This is very rare with mini scleral lenses (≤ 15.0 mm) but could be an issue with larger lenses. The likely cause of this accumulation is a restriction of the tear flow under the lens. Consider selecting flatter base curve lenses and/or select flatter peripheral curves (keeping apical clearance at a minimum of 170 microns after lens equilibration).

**HANDLING**

Similar to other corneo scleral and mini scleral lenses, lens application requires the bowl to be filled with solution. Non-preserved saline solution or non-preserved artificial tears are preferable. It is recommended that the patient tilt their head forward and bring the lens up to the eyeball. There should never be a bubble under the lens after application of the lens on the eye. Mishandling is the number one reason for failure with this type of lens. Typically bubbles are the result of application error.

Refer patients to application and removal videos at www.onefitlenses.com.

**HYDRA-PEG**

Onefit scleral lenses are perhaps the most hydrating and oxygenating scleral lens on the market, providing patients with excellent comfort and long-term corneal health. However, many patients can benefit from a Tangible Hydra-PEG coating, which improves the lenses wettability, surface water retention, lubricity and minimizes protein and lipid deposits — providing the ultimate in comfort and extended wear. Contamac’s Optimum and Hexa 100 materials have FDA 510(k) clearance for therapeutic applications, including treatment of Dry Eye. Consider adding Hydra-PEG to your Onefit lenses manufactured in Contamac™ Optimum or Hexa 100 materials.
DIAGNOSTIC LENSES

<table>
<thead>
<tr>
<th>Onefit (14 lenses)</th>
<th>Onefit A (Asian design - 14 lenses)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Base Curve</strong></td>
<td>7.00 mm, 8.00 mm (by 0.10 mm inc.)</td>
</tr>
<tr>
<td></td>
<td>8.20 mm, 8.40 mm, 8.60 mm</td>
</tr>
<tr>
<td><strong>Diameter</strong></td>
<td>14.9 mm</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td>Varies with base curve</td>
</tr>
<tr>
<td></td>
<td>( plano to -6.00D)</td>
</tr>
<tr>
<td><strong>Edge Lift</strong></td>
<td>Standard</td>
</tr>
<tr>
<td><strong>Center Thickness</strong></td>
<td>Varies with power (0.20 mm to 0.25 mm)</td>
</tr>
</tbody>
</table>

Note: Diagnostic lenses of the Onefit platform are marked with numbers identifying the geometry, which indicate the diameter and base curve value. For example, a Onefit with a base curve of 7.50 mm and a diameter of 14.9 mm would be laser marked as follows: PA2 14.9 7.5.

Onefit A diagnostic lenses are marked with the letter A identifying the geometry, followed by the base curve value, the edge configuration and diameter. For example, a Onefit A lens with a base curve of 7.80 mm, with a standard edge and diameter would be laser marked as follows: A 7.8 Std 7.

CONDITIONING DIAGNOSTIC LENSES BEFORE EACH USE

Diagnostic lenses are stored dry in their respective cases. Before each use it is imperative that you clean and condition each lens thoroughly. To clean, apply a few drops of an approved GP lens cleaner on both surfaces and gently rub the lenses between your fingers or in the palm of your hand for 10 to 15 seconds. Rinse off the cleaner with saline and proceed with conditioning. To condition, use the same method as cleaning, apply a few drops of an approved GP conditioning solution and rub each lens for 15 to 20 seconds. Rinse lens with non-preserved saline solution. The diagnostic lens is now ready for use.

PARAMETERS AVAILABLE

<table>
<thead>
<tr>
<th>Onefit (14 lenses)</th>
<th>Onefit A (Asian design - 14 lenses)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Base Curve Range</strong></td>
<td>6.0 mm to 9.4 mm in 0.10 mm increments.</td>
</tr>
<tr>
<td></td>
<td>6.0 mm to 9.0 mm in 0.10 mm increments.</td>
</tr>
<tr>
<td><strong>Diameter</strong></td>
<td>14.6 mm, 14.9 mm (standard), 15.2 mm</td>
</tr>
<tr>
<td></td>
<td>14.4 mm, 14.7 mm (standard), 15.0 mm</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td>+20.00D to -20.00D in 0.25D increments.</td>
</tr>
<tr>
<td></td>
<td>+20.00D to -20.00D in 0.25D increments.</td>
</tr>
<tr>
<td><strong>Cylinder</strong></td>
<td>-0.50D to -5.00D in 0.25D increments.</td>
</tr>
<tr>
<td></td>
<td>-0.50D to -5.00D in 0.25D increments.</td>
</tr>
<tr>
<td><strong>Axis</strong></td>
<td>Any</td>
</tr>
<tr>
<td><strong>ADD</strong></td>
<td>D Lens (Dominant), N Lens (Non-Dominant)</td>
</tr>
<tr>
<td></td>
<td>D Lens (Dominant), N Lens (Non-Dominant)</td>
</tr>
<tr>
<td><strong>Edge Lift Values</strong></td>
<td>Standard, Steep 1, Steep 2, Flat 1 and Flat 2</td>
</tr>
<tr>
<td></td>
<td>Standard, Steep 1, Steep 2, Flat 1 and Flat 2</td>
</tr>
<tr>
<td><strong>Oblate</strong></td>
<td>CCR 70, CCR 110, CCR 150, CCR 190</td>
</tr>
<tr>
<td></td>
<td>CCR 70, CCR 110, CCR 150, CCR 190</td>
</tr>
<tr>
<td><strong>Extra Limbal Clearance</strong></td>
<td>Available</td>
</tr>
<tr>
<td></td>
<td>Not available</td>
</tr>
</tbody>
</table>

ORDERING

Specify: Base Curve, Power, Diameter, Edge, Multifocal Profile, CCR Value, and Extra Limbal Clearance if any.

DETECTION TREE

[Diagram showing decision tree for diagnosing and fitting diagnostic lenses]

Photos courtesy of Dr. Langis Michaud O.D. M.SC. FAAO (dipl) – Clinical research project Blanchard Université de Montréal.
1. **Evaluate Clearances at the Point ofHighest Corneal Elevation**

View with white light optic section, narrow beam at 30°-40°. Clearance will vary as lens settles (see ideal fit above). For a lens exhibiting insufficient clearance, refit a lens with a steeper base curve. For a lens exhibiting excessive clearance, refit a lens with a flatter base curve. A 0.10mm change in base curve value will result in an average variation in central clearance of 50 microns.

2. **Evaluate Limbal Clearance**

Assess fluorescein coverage at the limbal level and allow no touch on the limbus, as with the cornea. If the clearance is less than 25 microns fluorescein may not be seen. If the central clearance seems appropriate (see ideal fit above) but the limbal area presents with a bearing, indicated by staining at the follow-up visit, order a lens with the Extra Limbal Clearance. This option will increase clearance over the limbal area by 50 microns, without affecting the lens behavior on the eye. Second, try a lens with a diameter 0.3 mm larger. The modified geometry of the larger lens will increase the vault over the limbal area.

3. **Evaluate Conjunctival Alignment**

Look for conjunctival alignment; ensure there is no edge stand off or peripheral seal. Edge Stand-off: excessive movement or excessive lens awareness. If the central clearance is insufficient, first, re-fit a lens with a steeper base curve and re-assess apical clearance to be optimal. If the problem persists, order a lens with an edge lift that is Steep 1 or Steep 2 according to the severity of the stand-off.

Peripheral Seal-off: if central clearance is excessive, first, re-fit a lens with a flatter base curve and re-assess apical clearance to be optimal. If the problem persists, order a lens with an edge lift that is Flat 1.

4. **Evaluate Resistance**

The Onefit lens should offer no or very little resistance and exhibit 0.5 mm to 1.0 mm movement (not on blinking, but under the push-up pressure).

5. **Over-Refracting**

Residual cylinder (e.g., >0.75D that cannot be corrected with additional central clearance should be incorporated into an anterior toric design. Simply give the laboratory your over-refraction when ordering.

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### Ordering

Specify: Base Curve, Power, Diameter, Edge, Extra Limbal Clearance, Multifocal Profile and CCR Value, if any.