Onefit™ SCLERAL LENS

OPTIMUM OXYGENATION FOR LONG-TERM CORNEAL HEALTH

FITTING GUIDE

Applications

- NORMAL PROLATE CORNEAS
- PRESBYOPIA
- ASTIGMATISM
- EMERGENT OR FRUSTE 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
- FRONT TORIC
- SYM-TORIC
- TORIC HAPTIC
- OBLATE
- OBLATE MULTIFOCAL
- ONEFIT™ SC - FOR SMALL CORNEAS
- EXTRA LIMBAL CLEARANCE
- QUADRANT SPECIFIC
- CONTROLLED PERIPHERAL RECESS (CPR)

CooperVision®

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INTRODUCTION

The **Onefit Scleral Lens** is unique and simplifies the fitting process for a wide range of applications. Corneas with normal prolate profile, astigmatism, 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 reducing fitting issues associated with larger scleral lenses (fogging, conjunctival pro-lapse, etc).

Onefit is designed to vault a given topography with an optimal fluid reservoir, 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 SC** scleral lens design was developed for smaller corneas, which tend to have less flattening towards the periphery. The design has increased lift over the limbus to accommodate the flattening profile, and are easier to handle for smaller palpebral fissures. Using this design for the right patients helps the fitter get to the optimal fit faster.

M | MADE TO MEASURE CONTACT LENSES

Onefit™
SCLERAL LENS PLATFORM

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. The lens is considered fully settled after 4 hours. 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.

01 INITIAL BASE CURVE AND DIAMETER SELECTION

BASE CURVE

Select a base curve that is equal to flat K.

DIAMETER

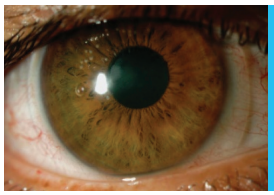
The horizontal visible iris diameter (HVID) is the main factor to consider in determining the lens diameter. The unique peripheral curve system of **Onefit** is optimized with the use of the standard diameter.

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 ordered (0.3 mm) - see table below or a Onefit MED or MED+ should be considered.

Diameter Selection Chart

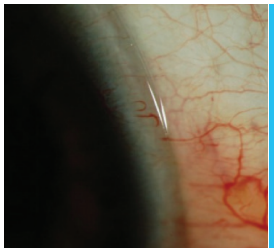
Onefit Platform	
HVID	**DIAMETER**
Less than 11.5 mm	14.6 mm or less (custom)
Between 11.5 mm and 12.0 mm	14.9 mm (standard)
12.0 mm - 12.3 mm	15.2 mm
>12.3 mm.	Consider Onefit MED or MED+

Onefit SC - for smaller corneas	
HVID	**DIAMETER**
Less than 11.3 mm	14.4 mm or less (custom)
Between 11.3 mm and 11.8 mm	14.7 mm (standard)
11.8 mm - 12.1 mm	15.0 mm



Ideal diameter

Lens exceeds HVID by at least 1.5 mm in each meridian, and limbal area is properly vaulted.



Diameter too small

Lens does not exceed HVID by at least 1.5 mm in each meridian, and limbal area is not properly vaulted.

DESIGN A LARGER LENS

02 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.

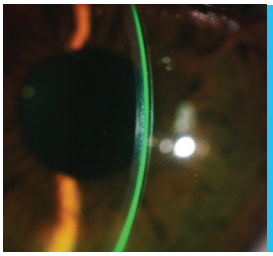
At application, look for clearance of 250 to 275 microns at the point of highest corneal elevation. According to the clearance observed, make changes to the base curve. Applying a lens that is 0.10mm steeper will increase apical clearance by 50 microns on average. Applying a lens that is 0.10mm flatter 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 slit lamp, using approximately a 45° 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 an exact measurment 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.

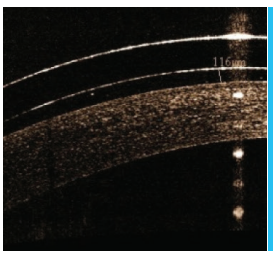
The ideal clearance **after 4 plus hours** of wear is 150 to 175 microns at the point of highest corneal elevation.



Ideal clearance (4+ hours of wear)

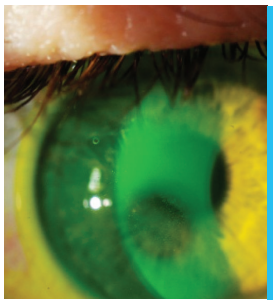
of 175 microns (2/3 of the lens thickness).

Measured with optic section using white light at a 45° angle



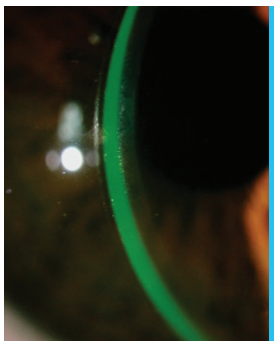
Anterior segment OCT

gives you an exact measurement of the fluid layer thickness.



INSUFFICIENT VAULT (after 4+ hours of wear) resulting in a touch on the cone.

Base curve should be steepened by at least 0.5 mm, which will result in a 250 micron increase to clearance.

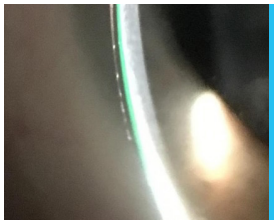


EXCESSIVE APICAL CLEARANCE (380 microns **after 4+ hours of wear**).

Base curve needs to be flattened by 0.4mm to reach the target of 175 microns when settled

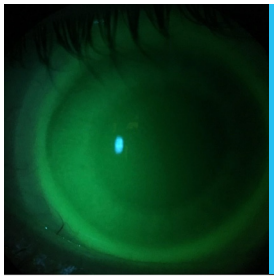
03 EVALUATE LIMBAL CLEARANCE

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 slit lamp. As is with the cornea, allow no touch on the limbus. At this stage, the blue filter can be used to confirm the presence of fluoresceine at the limbal level. Remember if the clearance is less than 25 microns, fluoresceine may not be seen, particularly with smaller diameter lenses.



Assessing Fluid Reservoir OPTIC SECTION:
Look for a visible green band as you approach the limbus.

Fluoresceine thinner than 25 microns will not be visible.



Assessing Fluid Reservoir BLUE LIGHT:
Look for a visible green band as you approach the limbus.
Note area of touch from 10-12.

Fluoresceine thinner than 25 microns will not be visible.

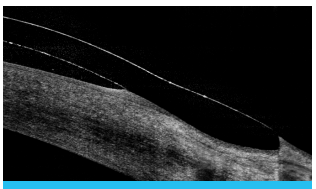
Ideally, OCT scans will reveal whether or not there is clearance at the limbus. Otherwise, evaluate the lens fitting characteristics during follow up visits. Lack of staining at the limbal level indicates that clearance is adequate and there is no need to make a change.

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, check to make sure that the lens diameter is adequate. If it is inadequate select a lens witha diameter 0.3mm larger. The modified geometry of the larger lens will increase the vault over the limbal area. Second order a lens with Extra Limbal Clearance (XLC). This option will increase clearance over the limbal area by 50 microns, without affecting the lens behavior on the eye.

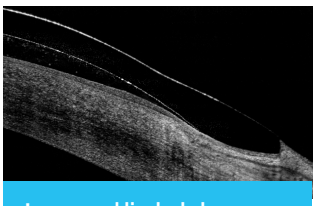
*The Onefit™ SC design already incorporates the Extra Limbal Clearance option. If the vault over the limbal area needs to be increased, try a lens with a diameter 0.3 mm larger.

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.

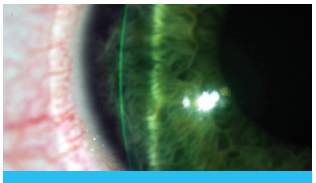
Fitting Tip: When the base curve/diameter selection leads to optimal limbal clearance, but excessive central clearance, the **Onefit** Oblate series can be used to re-establish an appropriate central clearance. Please refer to the **Onefit** Oblate on page 11 in this guide.



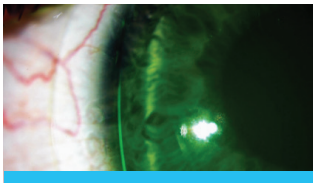
Limited limbal clearance with a standard mid-perripheral design



Increased limbal clearance with an Extra Limbal Clearance design option



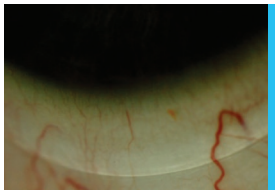
Limited limbal clearance with a standard diameter lens



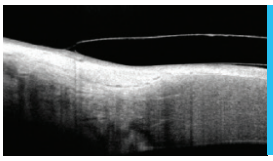
Increased limbal clearance with a larger diameter (0.3 mm larger than standard)

04 EVALUATE CONJUNCTIVAL ALIGNMENT

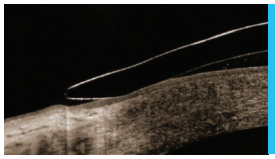
After selecting the base curve that provides optimal clearance (between 200 and 225 microns after 30 minutes of wear), evaluate edge lift. Look for conjunctival alignment; ensure there is no edge stand-off or peripheral seal off.



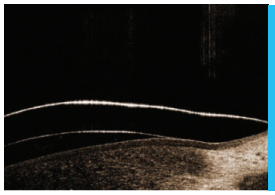
This represents an **optimal conjunctival aligment** with no edge stand-off or peripheral seal (blanching).



Optimal edge landing on the conjunctiva (OCT view).



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

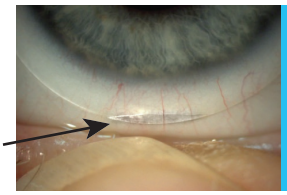


Edge too steep, causing conjunctival compression with a potential for peripheral seal off and blanching (OCT view).

05 EVALUATE RESISTANCE

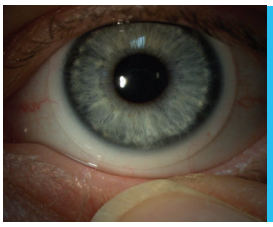
PUSH IN TESTS

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 1.0 mm movement (not on blinking, but under the push-up pressure).



Apply a gentle pressure on the conjunctiva and observe how easy it is to create a gap with the back surface of the lens.

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



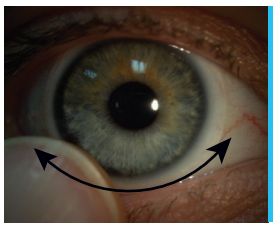
Apply gentle pressure on the conjunctiva and then push the lens up. The lens should offer little resistance and exhibit 0.5 mm to 1.0 mm movement.

When conducting a Push-In Test, you should also observe to see how easy it is to create a gap between the eye and the lens. If you can create a small gap with gentle pressure, the landing on the conjunctive is good.

Note: Be careful not to apply too much pressure on the conjunctiva, as air may seep under the lens causing bubbles.

LENS ROTATION

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. If the lens moves excessively, or not at all, re-assess the fit.



Put your finger on the lens at 6 o'clock and rotate the lens back and forth. The lens should rotate freely.

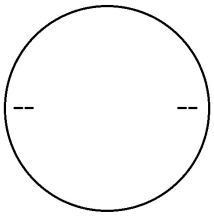
If with the push-up pressure the lens moves excessively or not at all, re-assess the fit.

TORIC HAPTIC (PC)

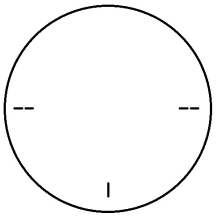
If the fit indicates a toric haptic is needed; the haptic itself will stabilize the lens on the surface of the eye. To ensure proper stabilization of a lens with anterior toric optics, a minimum of two (2) steps difference between the flat and steep meridians is needed. For example: Flat 1/Steep 1 or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

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 comes 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.



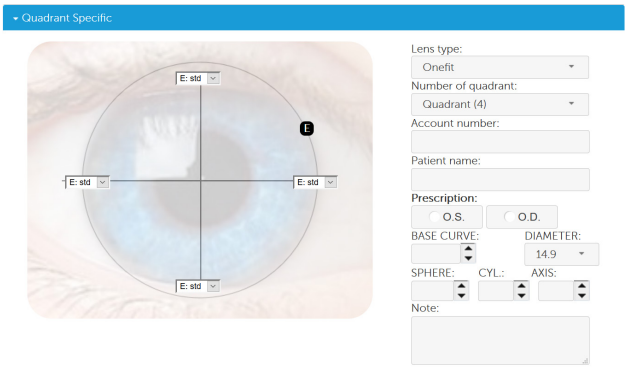
Lenses with a toric haptic are etched with double hashmarks at 3 and 9 o'clock to indicate the flattest meridian.



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

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.



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 SYMPTOMS / REMEDY

Edge stand-off will cause: tear meniscus to break-up at the edge of the lens, excessive movement when performing the **Push-In Test** (see section 5), 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.

TO TROUBLESHOOT PERIPHERAL CURVE ISSUES: FIRST, ASSESS CENTRAL CLEARANCE TO BE OPTIMAL, SECOND, CHANGE THE PERIPHERAL EDGE LIFT PROFILE.

PERIPHERAL SEAL OFF SYMPTOMS / REMEDY

Peripheral seal off can cause vessel compression, blanching, and high resistance, or no movement at all with the **Push-In Test** (see section 5). 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 15).

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 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.

06 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 has the potential to mask up to -3.50D of corneal cylinder. Note that some individual corneal profiles will not be completely compensated by the fluid under the lens.

FRONT TORIC DESIGNS

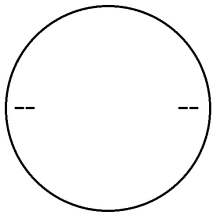
Residual astigmatism greater than -0.75D should be incorporated into an front toric design, using either Toric Haptic or Sym-Toric as stabilization method.

Toric Haptic (PC)

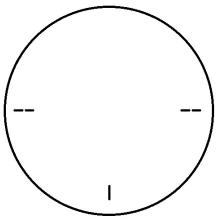
If the fit indicates a toric haptic is needed; the haptic itself will stabilize the lens on the surface of the eye. To ensure proper stabilization of a lens with front toric optics, a minimum of two (2) steps difference between flat and steep meridians is needed. For example: Flat 1/Steep 1 or Flat 2/Std.

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.



Lenses with a toric haptic are etched with double hashmarks at 3 and 9 o'clock to indicate the flattest meridian.



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

Sym-Toric (Front Toric)

In smaller lenses such as Onefit, toric haptics are not always needed for an optimum fit. 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 you would 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 previous 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 20 degrees clockwise and counter clockwise and observe if the lens always comes back to the same "habitual axis orientation". If the dot is not exactly at 6 o'clock, evaluate visual performance. If not affected, there is no need to make an axis change.

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

Sym-Toric lenses are etched with single hashmarks at 5, 6, and 7 o'clock, as well as a dot at 6 o'clock

One Hour = 30° Axis Rotation

LARS:

Rotation Left (↺) Add
Rotation Right (↻) Subtract

ONEFIT MULTIFOCAL

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

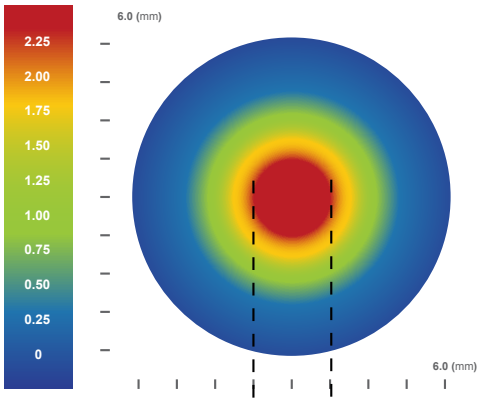
INTRODUCTION

Onefit lenses center well, have limited movement with blinking, remain stable at the center of the visual axis, and unlike soft lenses, do not dehydrate during wear. The unique characteristics of this scleral GP lens provide an excellent platform for a new generation of multifocal lenses, delivering superior comfort and excellent visual performance for today's active presbyopic patient!

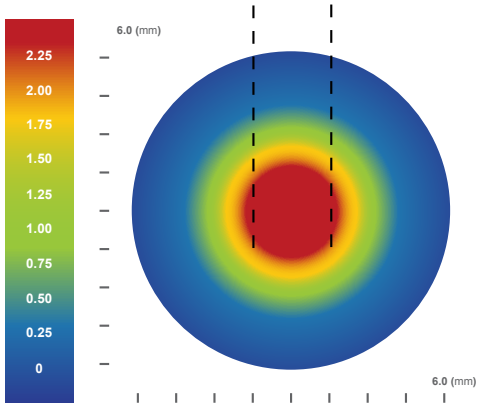
LENS PROFILE

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.

D Lens



N Lens



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.

ADD	Dominant Eye	Non Dominant Eye
+1.00 to +1.50	D Lens	D Lens
+1.75 to +2.25	D Lens	N Lens
+2.50 and up	N Lens	N Lens

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 smart phone. 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.

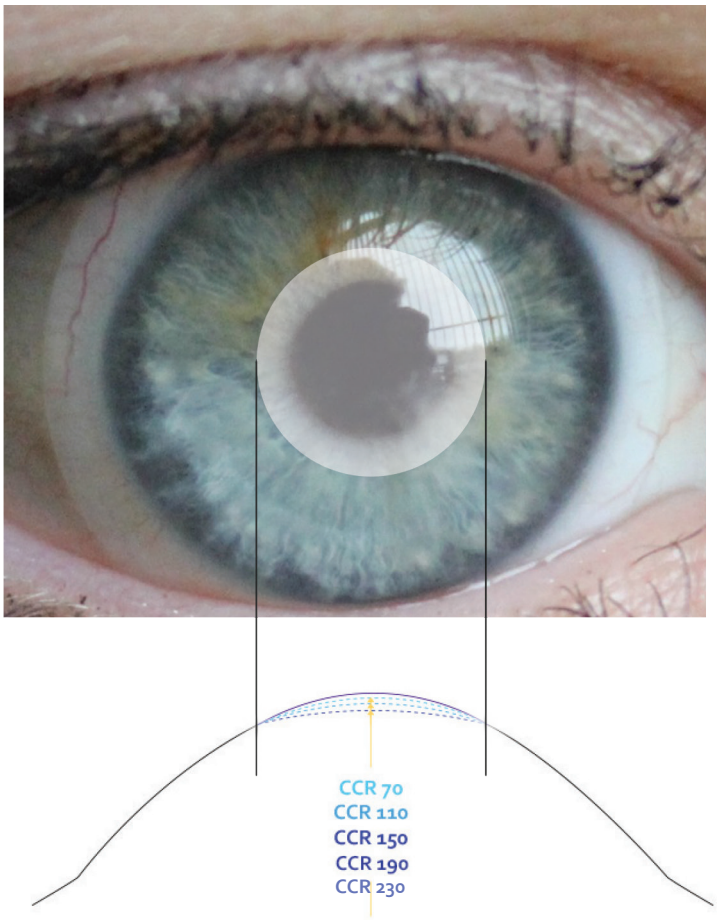
ONEFIT OBLATE LENSES

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 landing zone, but excessive central clearance (> 250 microns), the oblate series - using reverse geometry - allows the practitioner to re-establish a healthy central clearance level (150-175 microns after 4+ hours of wear) by specifying one of five values of Central Clearance Reduction (CCR) - 70 microns, 110 microns, 150 microns, 190 microns and 230 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: +2.00D
CCR 110: +4.00D
CCR 150: +6.00D
CCR 190: +8.00D
CCR 230: +10.00D

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, 190, or 230 CCR value and compensate the power for the appropriate Oblate lens order.

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.

AVAILABILTY

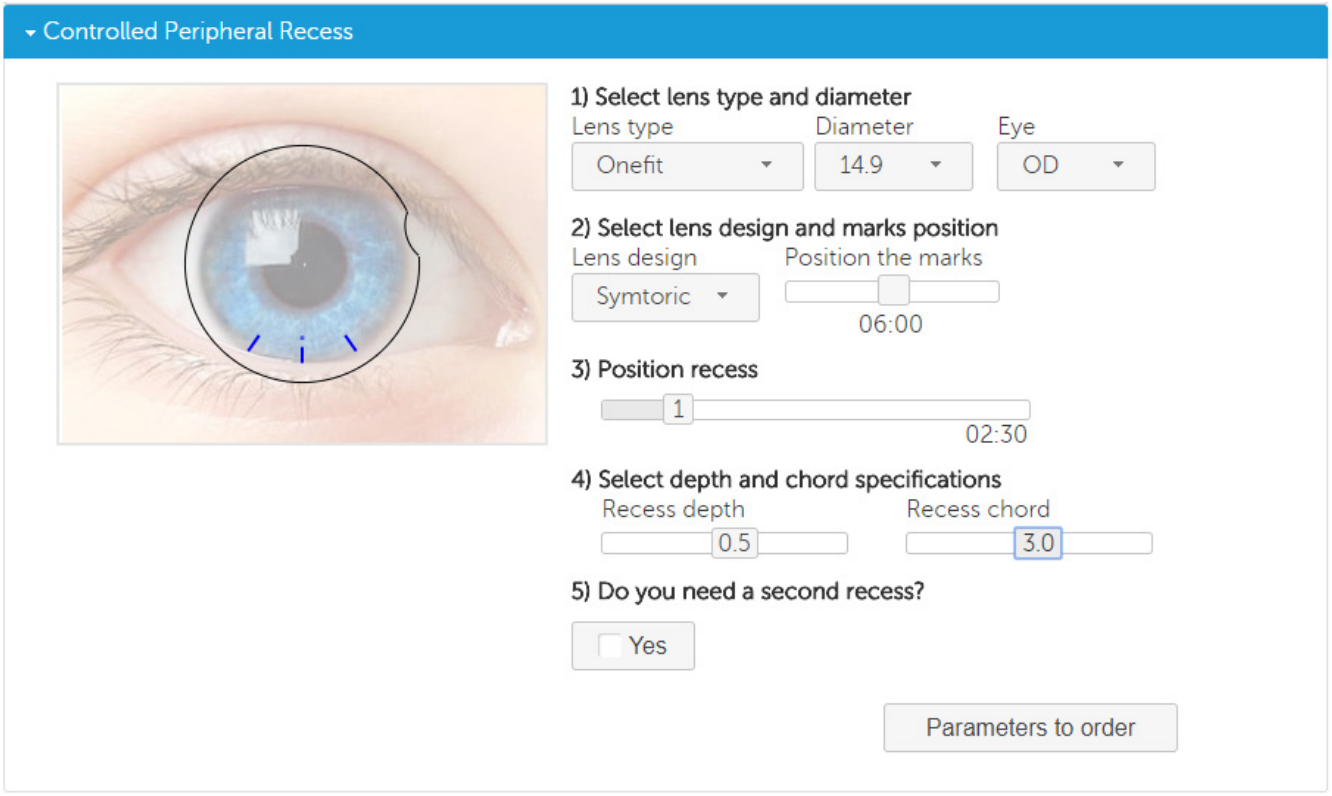
The Oblate series can be ordered in the following designs:

- 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, Multifocal, Toric Haptic and Quadrant Specific specifications.

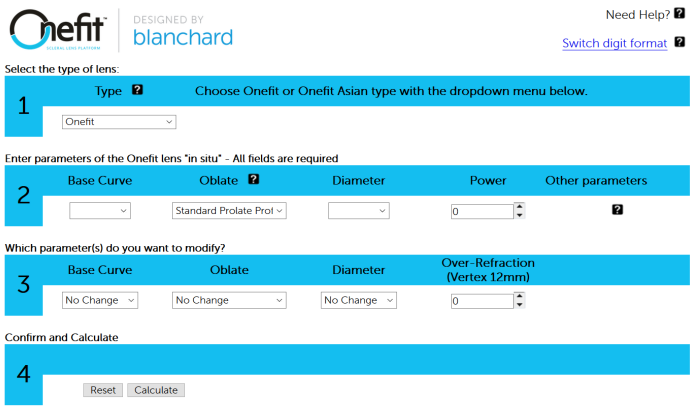
The extremely user-friendly CPR Tool at blanchardlab.com **keeps you in total control** of CPR placement and size, simplifies the design and ordering process, and provides a visual representation of the lens design.



You can connect directly to the CPR Tool, along with other innovative fitting tools, by clicking on "Tools and Order Forms" on the blanchardlab.com home page. From there, select "Custom Tools".

ONEFIT FITTING TOOL

To help determine the parameters of a new **Onefit** lens based on your observations of an existing fit, we recommend you always use the **Onefit** FittingTool available at **www.blanchardlab.com**



The **Onefit** Fitting Tool will automatically compensate any desired modification(s) to an existing fit, as well as recalculate the final lens power, taking into consideration any over-refraction.

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, assess if apical clearance is 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 re-access 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.

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.

TANGIBLE® 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 materials, as well as Boston's XO® and XO2® materials have FDA 510(k) clearance for therapeutic applications, including treatment of Dry Eye. Call the laboratory for a full list of materials approved for Tangible® Hydra-PEG.

TROUBLESHOOTING PROBLEMS

NOT ENOUGH CLEARANCE AT THE LIMBAL LEVEL

If central clearance seems appropriate (150-175 microns after 4+ hours of wear), but the limbal area presents with a bearing, indicated by staining at the follow-up visit, order a lens with the Extra Limbal Clearance (XLC) option. A larger diameter can also be used to increase the vault over the limbal area. If the larger compensated diameter lens leads to optimal limbal clearance but excessive central clearance, consider the **Onefit** oblate lens to re-establish adequate central clearance.

EYES BECOME RED AND PAINFUL AFTER A FEW HOURS OF WEAR

Referred to as "tight lens syndrome". Peripheries are creating a complete seal off at the peripheral level. Consider ordering a flatter base curve lens and/or select flatter peripheral curves (keeping apical clearance at a minimum of 170 microns after lens equilibration).

DEBRIS (MUCUS) ACCUMULATION UNDER THE LENS

This is very rare with mini scleral lenses (≤ 15.0 mm) but could be an issue with larger lenses. The likely cause of debris accumulation is non-optimal tear flow under the lenses, either inadequate or excessive tear exchange". "Evaluate the peripheral curves to optimize tear exchange. Toric haptics can be helpful in cases of excessive exchange.

BUBBLES ARE ALWAYS PRESENT ON APPLICATION

There is not enough fluid in the lens before application, or there was too much liquid that spilled off the lens during handling. Revisit the handling procedures with the patient. Mixing non-preserved saline with more viscous non-preserved artificial tear can help.

VISION IS NOT GOOD WITH THE LENS ON

Make sure that there are no bubbles under the lens, and check the wettability of the front surface. Perform over-refraction (spherical and cylindrical) to identify any residual astigmatism.

LENS IS DIFFICULT TO REMOVE OR STUCK ON THE EYE

This is a sign that the fit is either too small, creating a seal at the limbal level, or excessively steep, creating a seal at the peripheral level. Revisit contact lens fit. If the fit is good, ask the patient to look upward before removal and apply gentle pressure on the conjunctiva at the lens edge. This will allow some air to enter under the lens. Removal should be easy following this procedure. This could also happen on marginal dry eye patients after a full day of wear. Ask the patient to lubricate the ocular surface before removing the lenses.

LENS SEEMS OPTIMAL AT THE FIT BUT THERE IS NO CLEARANCE AFTER 8 HOURS OF WEAR

In this case, there is too much fluid exchange. Consider using a steeper base curve and/or steepening the peripheries to minimize this occurrence. If not possible, consider using a more viscous non-preserved solution to fill the bowl at application.

DIAGNOSTIC LENSES	Onefit (14 lenses)	Onefit SC (14 lenses)
Base Curve	7.00 mm, 8.00 mm (by 0.10 mm inc.) 8.20 mm, 8.40 mm, 8.60 mm	7.00 mm, 8.00 mm (by 0.10 mm inc.) 8.20 mm, 8.40 mm, 8.60 mm
Diameter	14.9 mm	14.7 mm
Power	Varies with base curve (plano to -6.50D)	Varies with base curve (-1.00D to -7.00D)
Edge Lift	Standard	Standard
Center Thickness	Varies with power (0.20 mm to 0.25 mm)	

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	Onefit (14 lenses)	Onefit SC (14 lenses)
Base Curve Range	6.0 mm to 9.4 mm in 0.10 mm increments.	6.0 mm to 9.0 mm in 0.10 mm increments.
Diameter	14.6 mm, 14.9 mm (standard), 15.2 mm	14.4 mm, 14.7 mm (standard), 15.0 mm
Power	+20.00D to -20.00D 0.25D increments.	+20.00D to -20.00D 0.25D increments.
Cylinder	-0.50D to -5.00D 0.25D increments.	-0.50D to -5.00D 0.25D increments.
Axis	Any	Any
ADD	D Lens (Dominant), N Lens (Non-Dominant)	D Lens (Dominant), N Lens (Non-Dominant)
Edge Lift Values	Standard, Steep 1, Steep 2, Flat 1 and Flat 2	Standard, Steep 1, Steep 2, Flat 1 and Flat 2
Oblate	CCR 70, CCR 110, CCR 150, CCR 190, CCR 230	CCR 70, CCR 110, CCR 150, CCR 190, CCR 230
Extra Limbal Clearance	Available	Not available

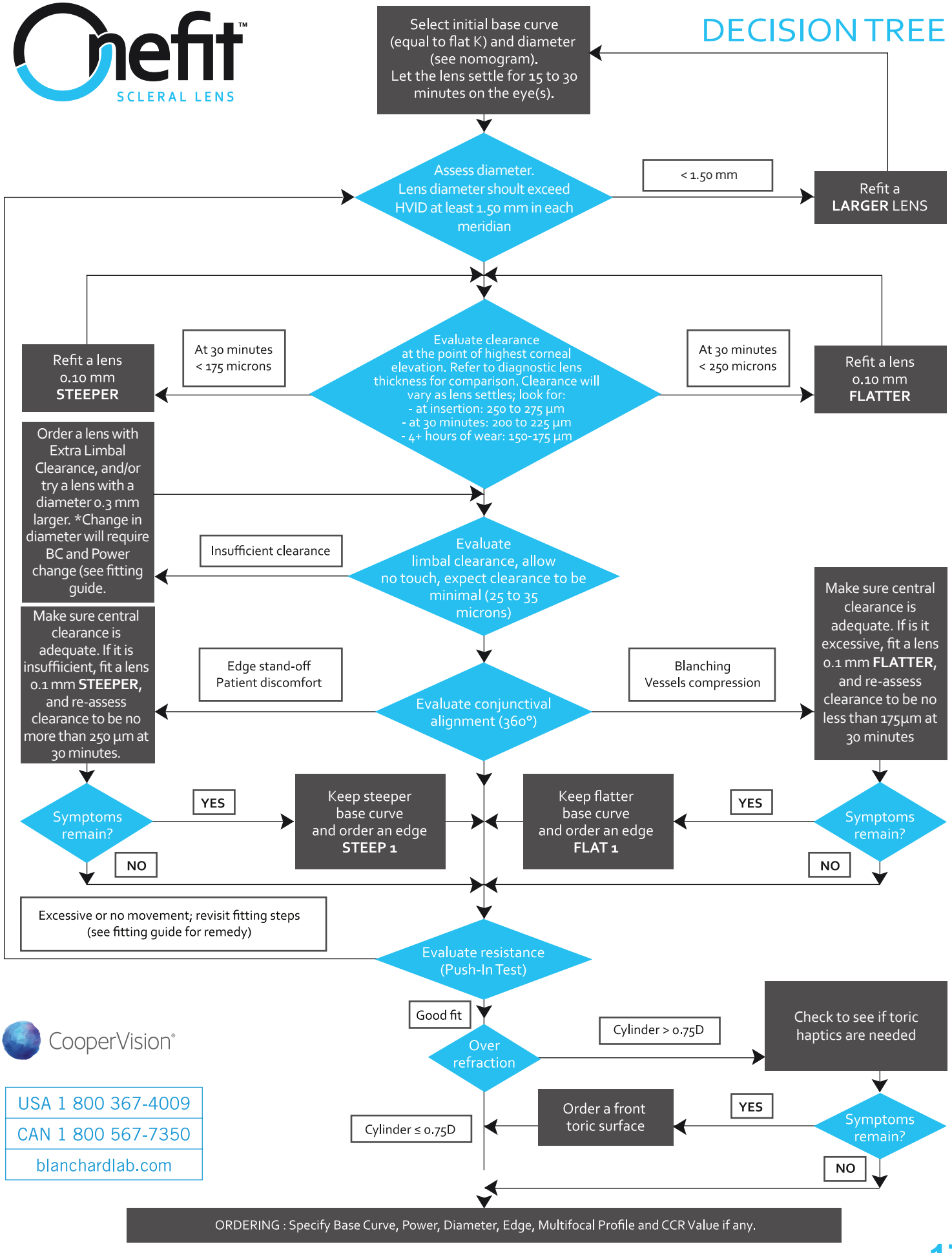
ORDERING

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

Photos courtesy of Dr. Langis Michaud O.D. M.SC. FAAO (dipl). – Clinical research project Blanchard-Université de Montréal.

Onefit™ SCLERAL LENS

DECISION TREE



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Onefit SCLERAL LENS 6 STEP SIMPLIFIED FITTING GUIDE

1 INITIAL BASE CURVE AND DIAMETER SELECTION

INDICATIONS	BASE CURVE SELECTION	DIAMETER SELECTION				IDEAL FIT
Normal prolate corneas Presbyopia Astigmatism Emergent or fruste keratoconus Soft or small diameter GP lens intolerant Post-RK, Post-LASIK Nipple cones Oval cones Irregular corneas Ectatic corneas OSD	Equivalent to Flat "K"	Lens diameter should exceed HVID at least 1.50 mm in each meridian				Evaluate clearance at the point of highest corneal elevation. Refer to diagnostic lens thickness for comparison. Clearance will vary as lens settles; look for: **- at insertion: 250 to 275 µm** **- at 30 minutes: 200 to 225 µm** **- 4+ hours of wear: 150-175 µm** Allow no corneal touch, especially on the cone as well as near the limbus.
		ONEFIT		ONEFIT SC		
		HVID	DIAMETER	HVID	DIAMETER	
		< 11.5 mm	14.6 mm	< 11.3 mm	14.4 mm	
		11.5 to 12.0 mm	**14.9 mm**	**11.3 to 11.8 mm**	**14.7 mm**	
		12.0 to 12.3 mm	15.2 mm	11.8 to 12.1 mm	15.0 mm	

For larger HVIDs, go to the Onefit MED or Onefit MED+

•• **ALWAYS FILL THE LENS BOWL WITH A NON-PRESERVED SOLUTION BEFORE APPLICATION. THIS WILL ELIMINATE BUBBLES TRAPPED BEHIND LENS. IF A BUBBLE PRESENTS, REMOVE LENS AND RE-FILL WITH SOLUTION AND RE-APPLY.** (INSERT NaFL INTO BOWL WITH SOLUTION TO BEGIN EVALUATION)

2 EVALUATE CLEARANCE AT THE POINT OF HIGHEST CORNEAL ELEVATION

VIEW WITH WHITE LIGHT OPTIC SECTION, NARROW BEAM AT 40° - 45°

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.

3 EVALUATE LIMBAL CLEARANCE

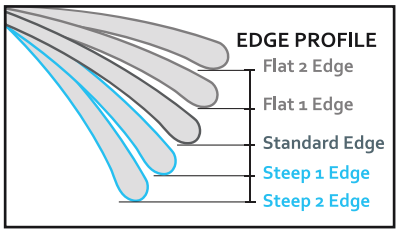
Assess fluorescein coverage at the limbal level and allow no touch on the limbus, as with the cornea. If the clearance is less than 25 microns fluorescein may not be seen. If the central clearance seems appropriate (see ideal fit above) but the limbal area presents with a bearing, indicated by staining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

4 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.



5 EVALUATE RESISTANCE (PUSH-IN TEST)

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).

6 OVER-REFRACTION

Residual cylinder >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.

ORDERING

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

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