



ONEFIT™ MED PUTS YOU IN CONTROL:

Full customization when a larger diameter is needed for highly irregular, medically indicated or normal corneas.

FITTING GUIDE

| Applications | Design Options |
|---|--|
| IRREGULAR CORNEAS ECTATIC CORNEAS NIPPLE CONES OVAL CONES POST-RK, POST-LASIK PELLUCID MARGINAL DEGENERATION OCULAR SURFACE DISEASE SMALL GP AND SOFT CONTACT LENS INTOLERANT ASTIGMATISM PRESBYOPIA NORMAL PROLATE CORNEAS POST-GRAFT | SPHERICAL MULTIFOCAL FRONT TORIC TORIC HAPTIC OBLATE OBLATE MULTIFOCAL QUADRANT SPECIFIC CONTROLLED PERIPHERAL RECESS |

INTRODUCTION

Onefit MED is an intuitive and easy to use scleral lens that allows practitioners to customize the ideal lens for a wide range of applications — when a larger diameter is needed for a healthy, highly irregular or medically indicated cornea. Designed to put the practitioner in control of the design and fit, adjustment can be made in four (4) separate zones of the lens (Central, Mid-Peripheral, Limbal and Edge). To easily find the exact location of the Mid-Peripheral and Limbal zones, the Dx lenses are etched with solid lines that can be observed at the slit lamp or OCT image. **Onefit MED** minimizes both lens thickness and tear layer, maximizing oxygen transmission to the cornea and stem cells. The design serves as its own platform from which Multifocal, Oblate, Front Toric, Toric Haptic, Quadrant Specific and Controlled Peripheral Recess can be ordered.

Onefit MED is very predictable and the final lens parameters can be determined, as well as visualized, using the **Onefit MED** Fitting Tool available at www.blanchardlab.com. A DK/T tool is also available in conjunction with the Fitting Tool to estimate oxygen transmission of the lens you are designing.

Onefit MED puts you in the driver seat, is extremely easy to fit, saves you chair time and provides the patient with exceptional visual acuity, comfort and optimal oxygen to the cornea for long-term corneal health.



PARAMETERS AVAILABLE

| Parameter | Range |
|--------------------------|---------------------------------|
| Sag Height / Diameter | |
| 15.6 mm standard | 3800 to 6200 in 50 micron steps |
| 16.0 mm | 3800 to 6600 in 50 micron steps |
| 16.4 mm | 4000 to 6600 in 50 micron steps |
| Mid-Peripheral Value (M) | +200 to -200 in 25 micron steps |
| Limbal Value (L) | +200 to -200 in 25 micron steps |
| Edge (E) | +250 to -250 in 25 micron steps |



FITTING PHILOSOPHY

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

Ideal clearance after four (4) plus hours of wear are as follows for each zone:

Central, or point of highest elevation: 150 to 175 microns

Mid-Peripheral: 100 to 125 microns

Limbal: 50 to 75 microns

Edge: aligned to the conjunctiva

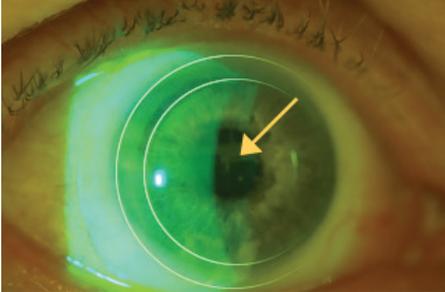
Note: **Onefit MED** lenses will recess on average 100 microns during a full day of wear, with roughly 50% happening within the first 30 minutes of application. Therefore, clearance evaluated at application, after 30 minutes, and 4 plus hours of wear will vary accordingly. Consideration should be given to amount of time the lenses have been in-situ when evaluating for optimal clearance.

EVALUATING YOUR FIT

01 DIAMETER

The standard 15.6 mm diameter will fit the vast majority of corneas. Rarely will the larger diameters (16.0 mm and 16.4 mm) be used, unless you encounter a severely protruded graft, severe keratoconus or an unusually large cornea (12.3 mm and over). However, when a larger diameter is needed, the transition from the standard 15.6 mm is easy and does not require the patient to be trial fitted again. The **Onefit MED** Fitting Tool will calculate the required adjustments for you. (See page 11 for more on the Fitting Tool).

02 CENTRAL (SAG VALUE)



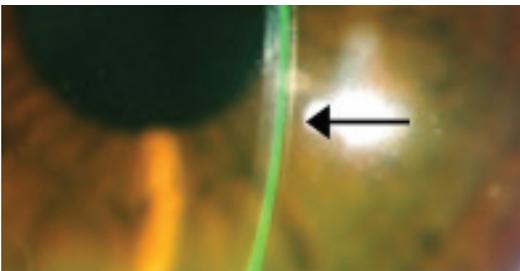
At application, look for clearance of 250 to 275 microns at the point of highest corneal elevation. According to the clearance observed, make changes to the sag height of the lens (50 microns steps).

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

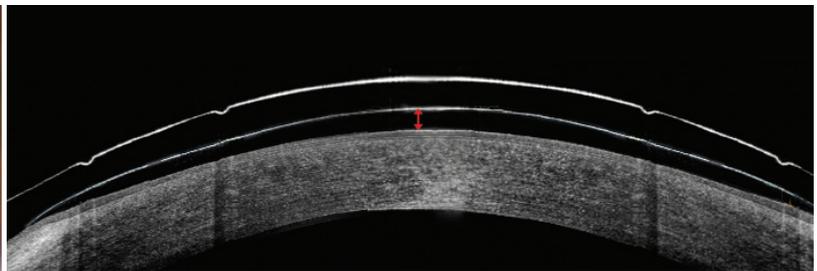
Evaluate the corneal/lens relationship under white light (optic section) at the slit lamp, using no more than a 40° angle. Using a blue filter will not help determine the actual thickness of the fluid layer under the lens. Utilizing an anterior segment OCT gives you a more accurate reading of the fluid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

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

IDEAL CLEARANCE AFTER 4 PLUS HOURS OF WEAR IS 150 TO 175 MICRONS AT THE POINT OF HIGHEST ELEVATION.

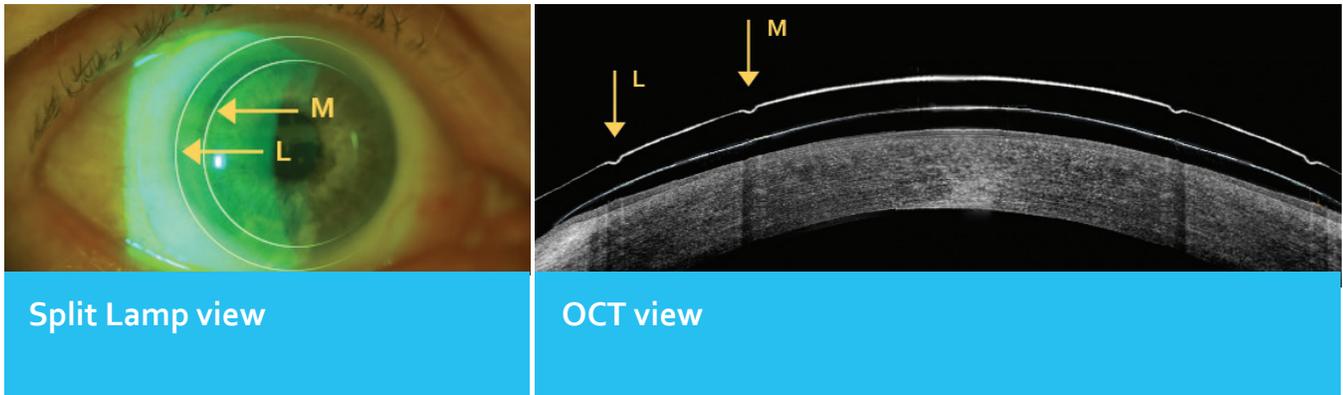


Split Lamp view



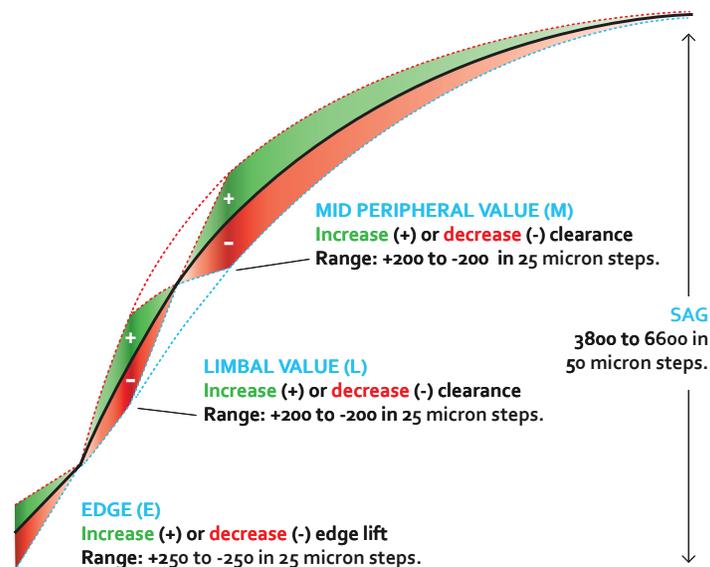
OCT view

03 MID-PERIPHERAL (M) AND LIMBAL (L) CLEARANCE



To easily find the exact location of the Mid-Peripheral and Limbal zones, Dx lenses are etched with solid lines that can be observed at the slit lamp or OCT image.

The amplitude of change offered by the M and L values (+200 microns to -200 microns in 25 micron steps) allows the practitioner to truly customize the fit to maximize oxygenation and performance of the lens. The M and L values can be adjusted independently of each other. For example, a lens can be ordered with increased clearance (+) in the mid-peripheral zone, but decreased clearance (-) in the limbal zone. Or, the M and the L values can be ordered with both increased or decreased clearance (see below).



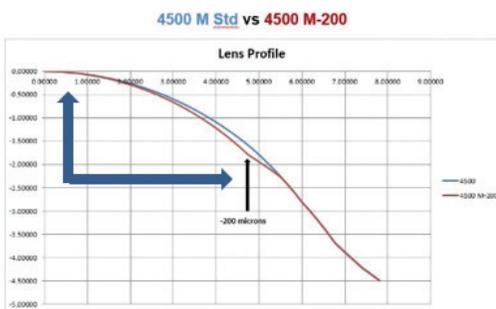
Note: To simplify the fitting, any modifications of the M, L and E values are automatically compensated for sag height, via a proprietary geometry.

Specify the Mid-Peripheral (M) and Limbal (L) clearance values in microns as follows:

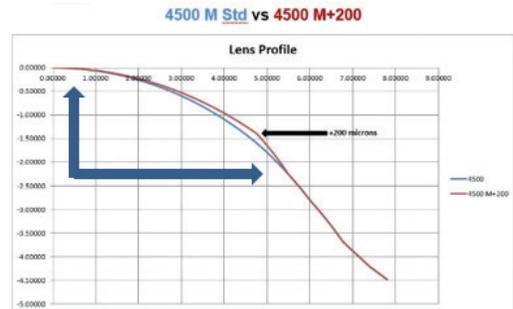
| Value | Standard | Increased Clearance (+) | Decreased Clearance (-) |
|-------|----------|---|---|
| M | M Std | M+25 to M+200 25 micron steps | M-25 to M-200 25 micron steps |
| L | L Std | L+25 to L+200 25 micron steps | L-25 to L-200 25 micron steps |

Important

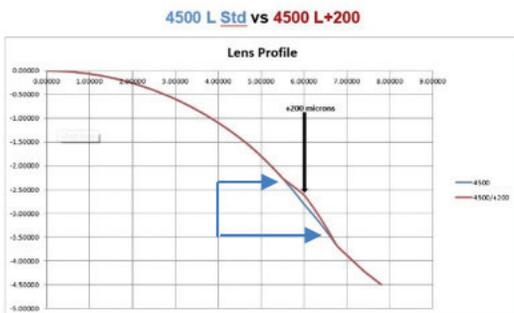
A modification of the M value; increased clearance (+) or decreased clearance (-), changes the base curve radius of the lens. Therefore, as with any rigid lenses, the power of the lens will need to be modified accordingly to reflect the new tear lens power. The **Fitting Tool**, will automatically re-calculate the final lens power according to the M value selected. (See page 11 for more on the Fitting Tool.)



Modifications of the M value changes the base curve radius of the lens, requiring an adjustment in final lens power.



A modification in the L value increased clearance (+) or decreased clearance (-) will not affect final lens power, as the change is not within the optical zone.

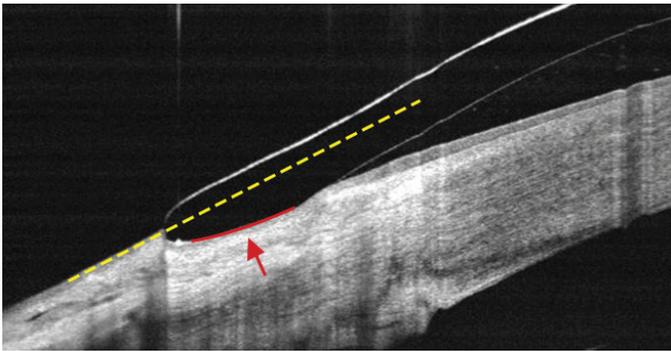


Modification of the L value does not affect final lens power, as the change is not within the optical zone.



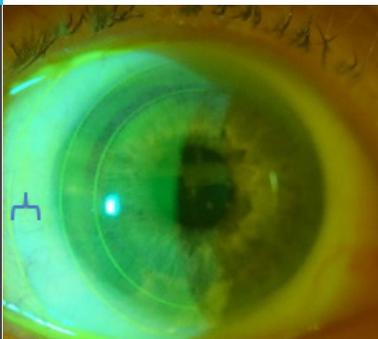
04 EDGE (E) VALUE

The Edge (haptic) of the **Onefit MED** is unique and is a combination of peripheral curves and tangent lathing technology, providing enhanced support within the lens peripheral landing zone beyond the limbus. Modifications of the edge lift is specified in microns of change. The range is from -250 microns (decreased clearance) to +250 microns (increased clearance) in 25 micron steps.



The edge of Onefit MED combines curves and tangent lathing technology (arrow) to ensure a smooth landing on the conjunctiva/sclera. Look for edge angle to approximate conjunctiva/sclera angle (dashed line).

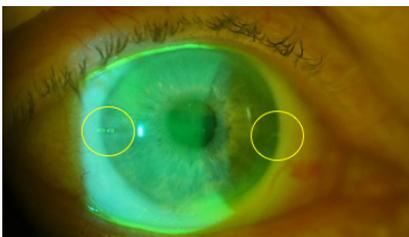
Increased Edge Clearance (+)



Decreased Edge Clearance (-)



TORIC HAPTIC



Toric Haptic allows the lens edge to align to scleral asymmetry for improved edge alignment and/or better lens centration. Lenses with a Toric Haptic are etched to indicate the flattest meridian.

Note: A lens with a Toric Haptic will find its equilibrium on the conjunctiva (point of least resistance) which is not necessarily the 0-180 meridian.

Specify the Edge (E) value in microns as follows :

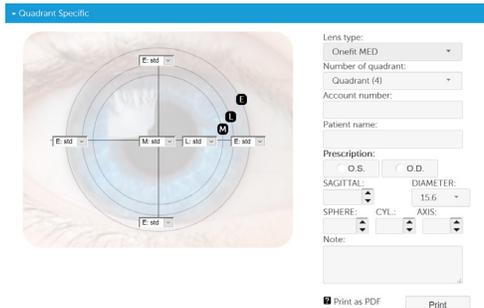
| Value | Standard | Increased Clearance (+) | Decreased Clearance (-) |
|-------|----------|----------------------------------|----------------------------------|
| E | E Std | E+25 to E+250 25 micron steps | E-25 to E-250 25 micron steps |

Note: For Toric Haptic, specify both the flat and steep meridian. **Example:**

| E Value | Flat Meridian Value | Steep Meridian Value |
|--------------|---------------------|----------------------|
| E std / -100 | Standard | -100 |
| E +100 / +25 | +100 | +25 |
| E -25 / -150 | -25 | -150 |

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”.

OVER-REFRACTION

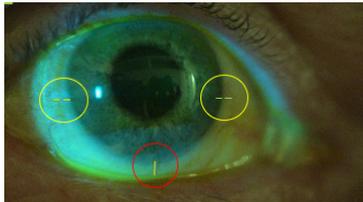
As is the case for all specialty contact lenses, you should perform over-refraction after the optimal lens is settled on the eye, to determine the appropriate parameters. Retinoscopy is recommended to begin the over-refraction, followed by sphero-cylindrical over-refraction, monocularly then binocularly. This lens is designed to mask up to -3.50D of corneal cylinder. However, some individual corneal profiles will not be completely compensated by the fluid under the lens.

RESIDUAL ASTIGMATISM

Residual astigmatism greater the -0.75D should be incorporated into the anterior toric design. **Toric Haptic** is the preferred design option to stabilize **Onefit MED** lenses with toric optics.

Note: When prescribing anterior toric lenses, a **minimum of 100 microns** difference between flat and steep meridian is needed to ensure good stabilization of the lens on the eye.

For example: flat meridian with increased clearance of +50 microns and the steep meridian with a decreased clearance of -50 microns (E+50/-50).



Anterior toric lenses are etched with an additional line (|) at 6 o'clock

Use LARS (Left Add, Right Subtract) to compensate for misaligned axis. One (1) hour of rotation represents 30 degrees of rotation. A lens that aligns at 2, 5 and 8 o'clock is rotated 30 degrees to the right. A lens that aligns at 4, 7 and 10 o'clock is rotated 30 degrees to the left. Use the Axis Compensation Tool – LARS, available in Custom Tools at blanchardlab.com

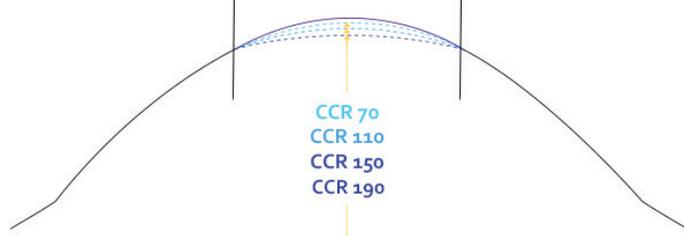
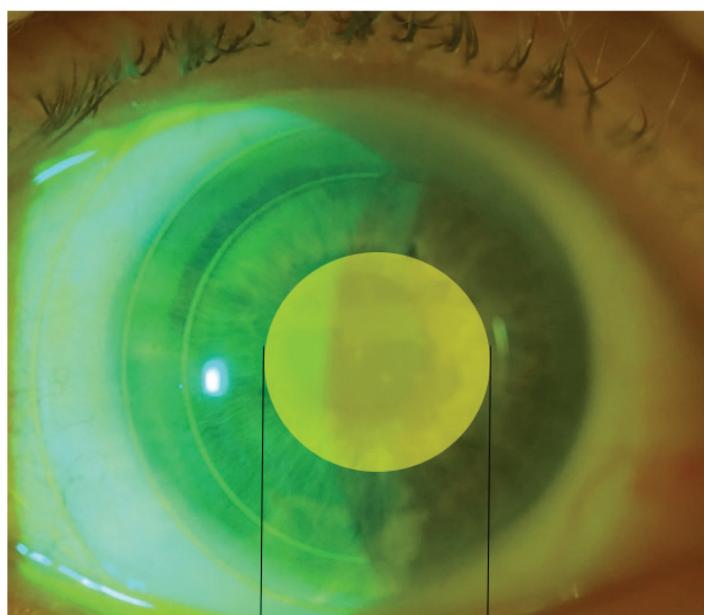
TIP: Each trial set come with four (4) lenses with a toric haptic (E+75/-75). Select a sag height that provides sufficient clearance of the cornea and limbus (no touch). Apply the lens and let it settle for 10 minutes. After the lens has found its point of least resistance, locate the etch marks indicating the flattest meridian and compensate your axis accordingly using LARS.

ONEFIT MED OBLATE LENSES

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

CONCEPT

Specifically designed for oblate corneas (PK, PRK, post LASIK) the Onefit MED Oblate geometry allows the practitioner to re-establish a healthy **central clearance level** (150-175 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** mid-peripheral, limbal clearance and the way the lens lands on the sclera.



POWER COMPENSATION OF OBLATE LENSES

The central clearance reduction of the Onefit MED 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

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

IMPORTANT: The power specified when ordering a Onefit MED Oblate lens must be the compensated power. For example, Onefit MED 4500 with a power of -6.00 (including over-refraction), if ordered with a CCR 110, would be ordered as -2.00 ($-6.00 + 4.00 = -2.00$).

For more details on Onefit MED Oblate lenses please consult the Onefit Fitting Guide.

ONEFIT MED MULTIFOCAL LENSES

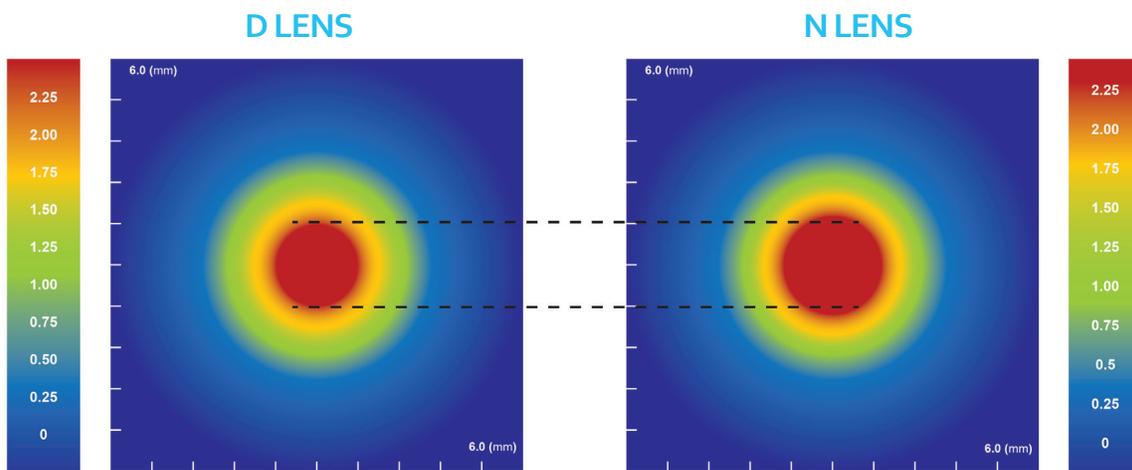
The existing Onefit MED diagnostic fitting set serves as the platform from which Onefit MED Multifocal lenses are ordered. No additional diagnostic lenses are required to fit Onefit MED Multifocal lenses.

INTRODUCTION

Onefit MED 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 MED Multifocal is a simultaneous vision, near-centered, aspheric multifocal. 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 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 in view, alleviating shadowing and confusion.



FITTING PROCESS

- 01 Follow the recommendations in this guide for fitting monofocal **Onefit MED**.
- 02 Use the lens fogging technique (+2.00 lens), to determine which eye is dominant at distance.
- 03 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 |

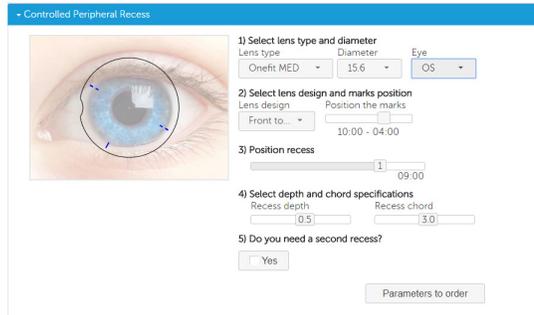
Note: Consider 2 N lenses for pupils that are 5.0mm and larger

For more information on the **Onefit MED** Multifocal lenses and fitting, please consult the Onefit Fitting Guide.

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, 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.



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 MED FITTING TOOL

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

Onefit MED Fitting Tool

Need help? Navigator compatibility?

Reset

1- Enter parameters of the Onefit MED lens "in situ" - All fields are required

| SAG | OBLATE | M | L | Toric PC? | EDGE | POWER | DIAMETER |
|--------|-------------|-----|-----|-----------|------|-------|----------|
| A 4300 | Std Prolate | std | std | No | std | -1.50 | 15.6 |

2- Which parameter(s) do you want to modify? - All fields are required

| SAG | OBLATE | M | L | Toric PC? | EDGE | OVER-REFRACTION | DIAMETER |
|--------|--------|-----------|-----------|-----------|------|---|----------|
| B 4450 | CCR 70 | No change | No change | No change | -75 | -3.50 <small>(vertex 12.0mm)</small> | 15.6 |

3- Use the button to calculate the lens to order

Calculate

On Line A: Enter the exact parameters of the lens in situ (see above for example).

On Line B: Enter the parameters you would like to change as well as any over-refraction. For example, among other modifications requested, a new sag at 4450 is specified.

Hit Calculate: You get the parameters of the new lens to order, as well as a graph comparing the lens in situ (line A), with the proposed lens (line B). See graphic on following page.

4- New Onefit MED Lens to Order

| | |
|--------------------------|------------|
| SAG | 4450 |
| Oblate (CCR) | 70 |
| M | std |
| L | std |
| EDGE (Spherical): | -75 |
| | |
| Diameter | 15.60 |
| Power | -4.5 |



DIAGNOSTIC LENSES (20 LENSES)

| | 16 Lenses with Spherical Haptic | 4 Lenses with Toric Haptic |
|------------|--|--|
| Sag Height | 4000, 4200, 4400 to 5400 (0.10 inc.) 5600, 5800, 6000 | 4500, 5000, 5500, 6000 |
| Diameter | 15.6mm | 15.6mm |
| M Value | Standard | Standard |
| L Value | Standard | Standard |
| E Value | Standard | +75 / -75 |
| | Dx lenses are etched with their respective sag value and the letters STD indicating that the M, L and E values are standard i.e 4500 STD | Dx Toric Haptic lenses are etched with their respective sag value and the letters STD/ Toric Haptic indicating that the M and L values are standard and the E value is +75 / -75 |

CONDITION 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.

ORDERING

7 VALUES TO SPECIFY. EXAMPLES:

| | | |
|-----------------|-----------------------------|-------------------|
| 1- Sag Height | 4500 | |
| 2- Oblate (CCR) | 110 | |
| 3- M Value | +75 | |
| 4- L Value | -50 | |
| 5- E Value | Spherical | +25 |
| | Toric Haptic (Flat / Steep) | +75 / -75 |
| 6- Diameter | 15.6 | |
| 7- Power | Spherical | -4.50 |
| | Anterior toric | -2.50 -1.75 x 180 |

IMPORTANT: Section 4 of the Onefit MED Fitting Tool gives you all 7 parameters to order. We recommend you always use the Fitting Tool when ordering Onefit MED lenses. Remember, any change you make in the Sag Value and/or M Value will affect the final power of the lens. Let the Fitting Tool do the math for you!

The Onefit MED fitting tool is located on the Onefit MED product page at blanchardlad.com

Onefit™ MED

SCLERAL LENS



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