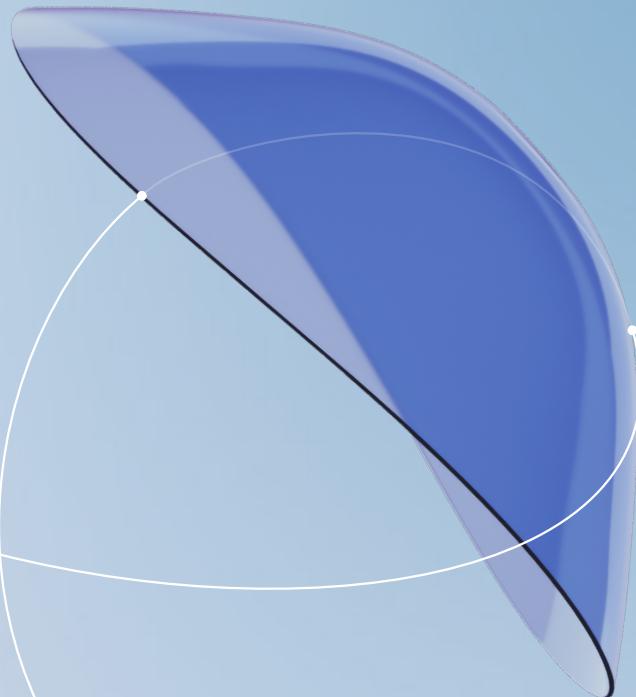




Your partner in saving sight.®



FitGuide®

FOR 16-19mm SCLERAL LENSES

Achieve a smart, efficient, and predictable fit that provides optimal vision, comfort, and long-term health for your patients.

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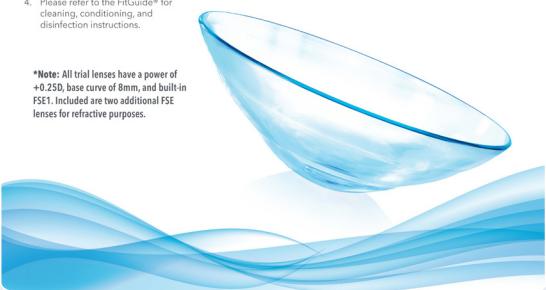
16, 16.5, AND 17mm

BOSTONSIGHT[®]
SCLERAL

16.0, 16.5, 17.0 mm
FitKit[®]

1. Wash your hands thoroughly with non-moisturizing soap and water before handling lenses.
2. Upon receiving your lenses, please inspect them for damage.
3. If a lens breaks or arrives damaged, order a replacement.
4. Please refer to the FitGuide[®] for cleaning, conditioning, and disinfection instructions.

*Note: All trial lenses have a power of +0.25D, base curve of 8mm, and built-in FSE1. Included are two additional FSE lenses for refractive purposes.



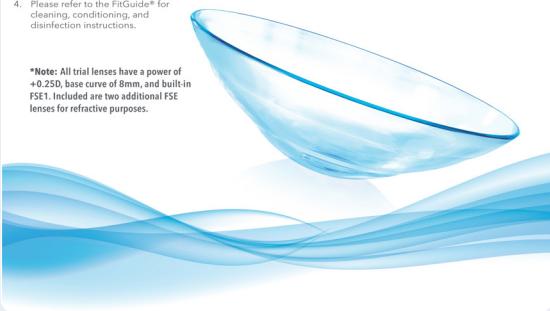
18, 18.5, AND 19mm

BOSTONSIGHT[®]
SCLERAL

18.0, 18.5, 19.0 mm
FitKit[®]

1. Wash your hands thoroughly with non-moisturizing soap and water before handling lenses.
2. Upon receiving your lenses, please inspect them for damage.
3. If a lens breaks or arrives damaged, order a replacement.
4. Please refer to the FitGuide[®] for cleaning, conditioning, and disinfection instructions.

*Note: All trial lenses have a power of +0.25D, base curve of 8mm, and built-in FSE1. Included are two additional FSE lenses for refractive purposes.



DIAGNOSTIC LENS SET

The BostonSight SCLERAL FitKit[®] is designed to simplify the fitting process. Our fitting system is based on scleral anatomy and driven by clinical data. Specific lenses are provided for the left and right eye.

Each FitKit includes a total of 28 diagnostic lenses: nine lenses for the right eye and nine lenses for the left eye, with one additional sagittal depth option for each diameter and an additional two lenses per eye are included for residual higher aberration control to achieve best corrected visual acuity without the need for an aberrometer. Diagnostic sets come with three diameters: 16, 16.5, and 17mm or 18, 18.5, and 19mm.

FREE-FORM FITTING WITH SMART360[®]

Design a custom lens for your patient, with no trial lenses required. BostonSight's Smart360 feature integrates your profilometer with FitConnect[®] to transfer scan data to BostonSight's manufacturing lab. Our fitting philosophy remains the same and you may use this guide for troubleshooting.

Diameter Recommendations

You know your patients best, however it can be helpful to have a quick reference for which diameter may work well for your case. The following are general guidelines.

16, 16.5, AND 17mm

Small HVIDs
(<=11.0mm)

Small apertures

Tight lids

Regular corneas

Pediatric
patients

Difficulty
handling lenses

18, 18.5, AND 19mm

Large HVIDs
(≥ 11.5 mm)

Compromised
ocular surface

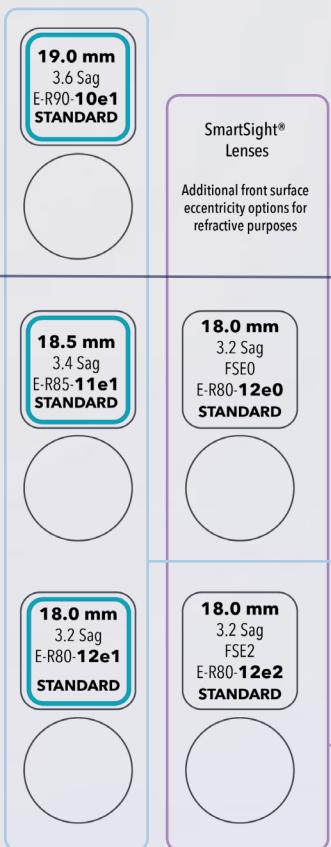
Highly ectatic corneas

Chronic
exposure

Compromised/
fragile grafts

Severe dry eye

18, 18.5, and 19mm FitKit®



FITTING LENSES / RIGHT

All trial lenses have a power of +0.25D, base curve of 8mm, built-in FSE1, and built-in oval optic zones.

Nine core lenses

Additional sag lenses

Additional front surface eccentricity (FSE) lenses for refractive purposes. See SmartSight® on page 12.



FITTING LENSES / LEFT

16, 16.5, and 17mm FitKit®

FITTING LENSES / RIGHT

All trial lenses have a power of +0.25D, base curve of 8mm, built-in FSE1, and built-in oval optic zones.

17.0 mm 3.0 Sag D-R70-1e1 FLAT	17.0 mm 3.0 Sag D-R70-2e1 STANDARD	17.0 mm 3.0 Sag D-R70-3e1 STEEP	17.0 mm 3.4 Sag D-R70-10e1 STANDARD	SmartSight® Lenses Additional front surface eccentricity options for refractive purposes
16.5 mm 2.8 Sag D-R65-4e1 FLAT	16.5 mm 2.8 Sag D-R65-5e1 STANDARD	16.5 mm 2.8 Sag D-R65-6e1 STEEP	16.5 mm 3.4 Sag D-R65-11e1 STANDARD	16.0 mm 3.0 Sag FSE0 D-R60-12e0 STANDARD
16.0 mm 2.6 Sag D-R60-7e1 FLAT	16.0 mm 2.6 Sag D-R60-8e1 STANDARD	16.0 mm 2.6 Sag D-R60-9e1 STEEP	16.0 mm 3.0 Sag D-R860-12e1 STANDARD	16.0 mm 3.0 Sag FSE2 D-R60-12e2 STANDARD

FITTING LENSES / LEFT

SmartSight® Lenses Additional front surface eccentricity options for refractive purposes	17.0 mm 3.4 Sag D-L70-10e1 STANDARD	17.0 mm 3.0 Sag D-L70-1e1 FLAT	17.0 mm 3.0 Sag D-L70-2e1 STANDARD	17.0 mm 3.0 Sag D-L70-3e1 STEEP
	16.0 mm 3.0 Sag FSE0 D-L60-12e0	16.5 mm 3.2 Sag D-L65-11e1 STANDARD	16.5 mm 2.8 Sag D-L65-4e1 FLAT	16.5 mm 2.8 Sag D-L65-5e1 STANDARD
	16.0 mm 3.0 Sag FSE2 D-L60-12e2	16.0 mm 3.0 Sag D-L60-12e1 STANDARD	16.0 mm 2.6 Sag D-L60-7e1 FLAT	16.5 mm 2.8 Sag D-L65-6e1 STEEP

Lens Handling and Conditioning

Trial lenses in the FitKit will be shipped wet to ensure proper wetting. The conditioning solution must be replaced with fresh solution (i.e. Boston Simplus) upon FitKit receipt and must be replaced every 30 days. Proper cleaning, disinfection and handling is required before each use.

- ① Wash hands thoroughly with non-moisturizing soap and water before handling lenses.
- ② Place one lens in the palm of your hand. Place one or two drops of your daily cleaning solution on the outside surface of the lens and rub gently for 15 seconds. Flip the lens over and do the same on the inside surface of the lens.
- ③ Rinse the lens thoroughly with preservative-free saline.
- ④ Place lens in conditioning solution, such as Boston Simplus, for at least 1 hour before use.

Your BostonSight SCLERAL trial lens is now ready for patient application.

Fitting Algorithm Schematic Based on Scleral Shape

- ① Choose diameter.
- ② Start at the center with a Standard shape lens and standard sagittal depth at each given diameter.
- ③ If the Standard shape lens fits loose, choose the Steep shape lens.
- ④ If the Standard shape lens fits tight, choose the Flat shape lens.



Fitting Principles

The process of fitting the BostonSight SCLERAL lens is based on identifying the best fitting trial lenses and adapting their geometries and power to create eye-specific lenses.

- ① Identify the trial lens having the best initial fit using the fitting algorithm.
- ② Re-evaluate the fit after the appropriate settling time.
- ③ When indicated, replace with one having more appropriate parameters.
- ④ Repeat the process until the best fitting trial lens is identified.
- ⑤ Perform spherical over-refraction to determine lens power. Vision may be optimized using a different trial with different front eccentricity values or by performing spherocylindrical refraction over the final diagnostic lens.
- ⑥ Order the lens with any modifications as needed in FitConnect®.

Lens Identification

Easy diagnostic lens ID with unique laser-engraved model number

E-R 80-1 e1

LENS SET
SERIES

EYE
R VS. L

DIAMETER

LENS
NUMBER
1-2

ECCENTRICITY
FSEO, FSE1 OR
FSE2



Laser engraved model
number location

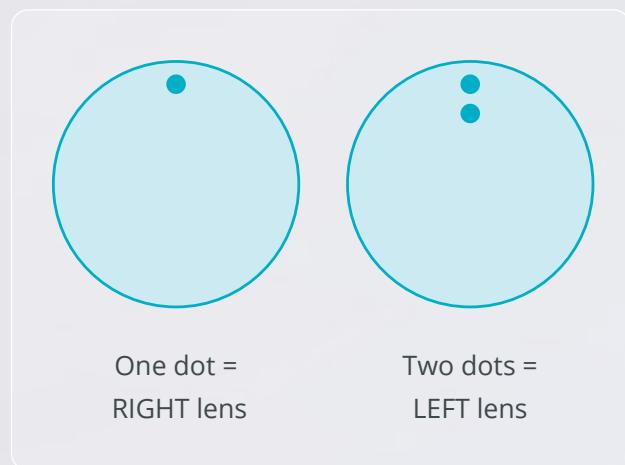
Example Shown:

Lens Set Series: E
Right Lens
18.0mm diameter
Lens #1
FSE1

Lens Markings

USING DOTS TO IDENTIFY RIGHT AND LEFT LENSES

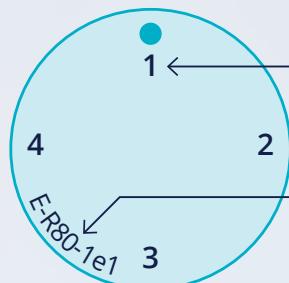
Right vs. left lens identification



Expected lens positioning in the eye



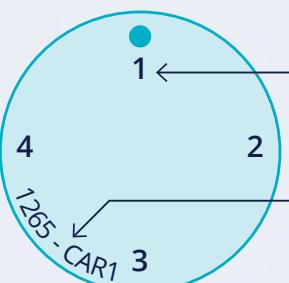
Diagnostic lens



Easy ID Arabic numerals
to identify each quadrant

Diagnostic lens model number
laser-engraved for positive ID

Patient's lens



Easy ID Arabic numerals
to identify each quadrant

Laser-engraved unique identifier =
order number + first 3 letters of
patient's last name + lens number

Adjusting Optics

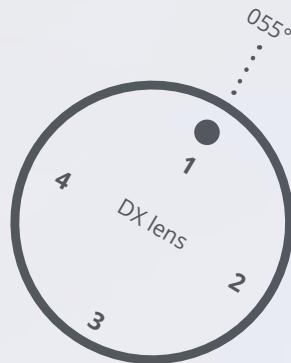
FRONT SURFACE OPTICS WITH SMARTSIGHT® AND SMARTSIGHT HOA®

Astigmatism

BostonSight SCLERAL lenses in astigmatic powers up to 8D are available for order. If the patient is unable to achieve satisfactory vision after attempting all front surface eccentricity options (see SmartSight® FSE), then it is important to check for residual astigmatism. Astigmatic corrections can only be applied to rotationally stable lenses (see SmartSight). To measure astigmatic power, use trial diagnostic lens that provides best haptic alignment and perform sphero-cylindrical over-refraction. Document both the sphero-cylindrical over-refraction and the location of the lens dot in degrees using the slit rotation control ring in your slit lamp (see figure 1). The latter measurement in degrees is crucial in order to obtain accurate results.

Fig. 1: Residual astigmatism correction scenario

Example One
Sphero-cylindrical over-refraction
—1.00 —1.25 x 075

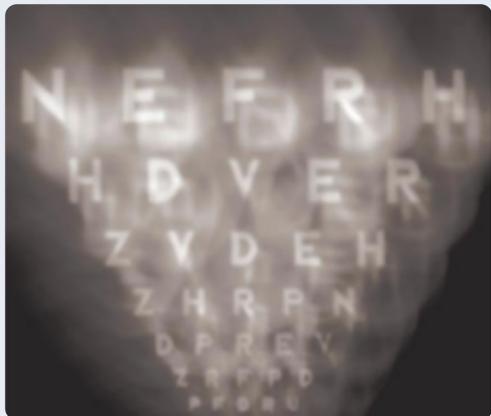


- ① Measure the location of lens dot in degrees using your slit-lamp as shown above (in this example, dot location is at 055°)
- ② Enter sphero-cylindrical value and lens dot location in the order screen of FitConnect

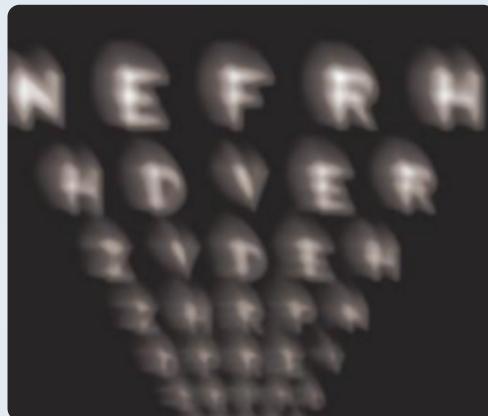
SmartSight® FSE

Multiple front surface eccentricity (FSE) options are provided. For optimal results, it is imperative that the best fitting trial diagnostic lens has been identified and assessed before proceeding to fine-tune best corrected visual acuity. Once a rotationally stable diagnostic lens has been identified, perform spherical over-refraction. If spherical over-refraction does not achieve expected visual acuity with the built-in FSE1 value, then attempt over-refraction with the other front surface eccentricity lens options provided: FSE0 or FSE2. If best-corrected vision is improved, proceed to order the lens based on the best fitting diagnostic lens, choosing the best front surface eccentricity option (FSE1, FSE2, or FSE0) from the drop-down menu provided in FitConnect, and enter over-refraction obtained with the determined best FSE value.

Without SmartSight FSE



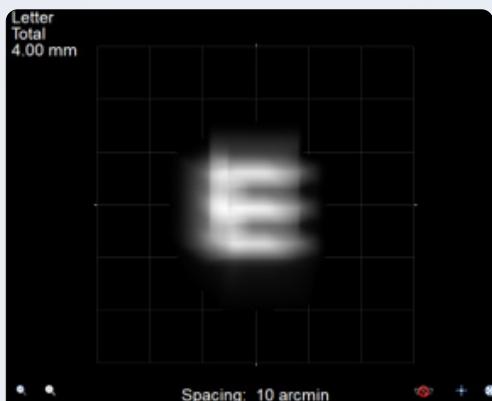
With SmartSight FSE



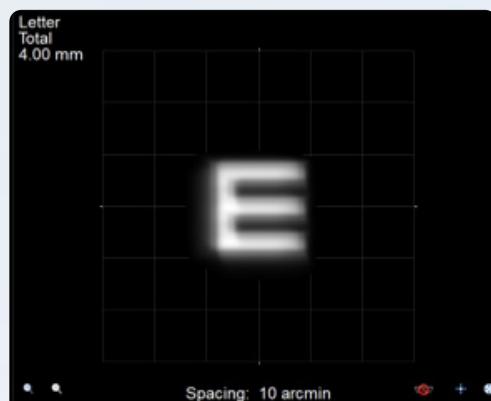
SmartSight HOA®

For the most significant HOA cases, we recommend SmartSight HOA®. Our open aberrometer platform means if you have an aberrometer, you can harness the power of SmartSight HOA. However, we recommend that you are already comfortable with the traditional fitting of BostonSight SCLERAL lenses before adding SmartSight HOA. Please review our SmartSight HOA fitting videos based on your aberrometer. **SmartFocus cannot be combined with SmartSight HOA.*

Without SmartSight HOA



With SmartSight HOA



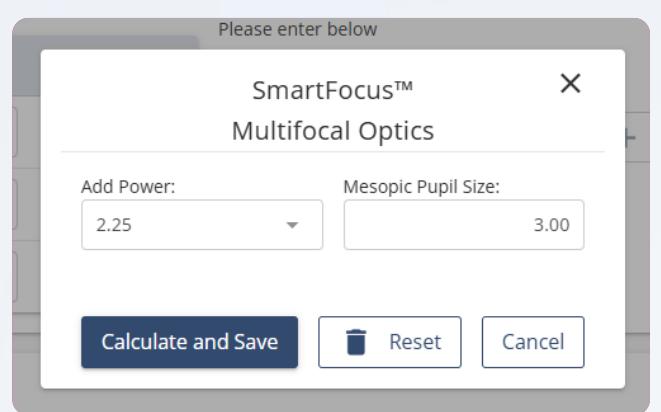
SmartFocus™ Multifocal

Currently multifocal optics are available in 16-17 mm lenses. Before adding multifocal optics to your lens, optimize the distance visual acuity prescription and get the fit as close to final as possible.

On the Optics screen in FitConnect, click +SmartFocus. Enter the ADD Power and Mesopic Pupil Size for each eye as shown in figure 2. Click Calculate and Save. You will know your multifocal option was added by looking at the right side of your order screen in the Order Summary. SmartFocus optics will be listed under "ADD." (See pg. 23 for troubleshooting tips.)

**SmartFocus cannot be combined with SmartSight HOA or Quad-Elevation™.*

Fig. 2



Fitting Modifications

Sagittal depth

Sagittal depth should be modified in FitConnect with the goal of achieving the suggested 200 – 300 μ clearance, pre-settling. For reference, refer to the center thickness of the lens, which is 300 μ . Our recommended starting point is the standard sagittal depth lens. Once the best trial diagnostic lens for both haptic alignment and sagittal depth is determined, proceed to make 50-micron adjustments in FitConnect as needed. For example, if you note corneal touch as shown in figure 3, for a desired 200 μ clearance, increase sag value by 200 μ in your FitConnect account as shown in figure 4.



Fig. 3: Example of corneal touch

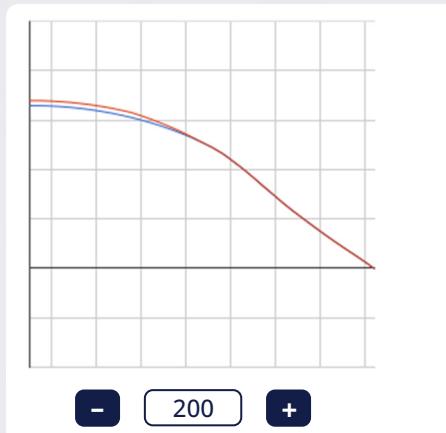


Fig. 4: Sag increase by 200 μ in FitConnect

Quad-Specific changes

HAPTIC CHANGES

Lens haptics can be modified in a quadrant-specific manner to achieve a rotationally stable fit, properly align the conjunctival-scleral surface, and obtain a physiological endpoint.

Edge Impingement

The minimum suggested micron changes to decrease edge lift or minimize impingement is 100 μ m. If working with the 16-17mm designs, and significant edge lift or impingement is noted, then go with 150 μ m changes or more as needed. **If working with the 18-19mm designs and significant edge lift or impingement is noted, then go with 200 μ m changes or more as needed.** 50 μ m changes should be used only to address symptoms of edge awareness – which most of the time will dissipate without the need for change and after lens adaptation.

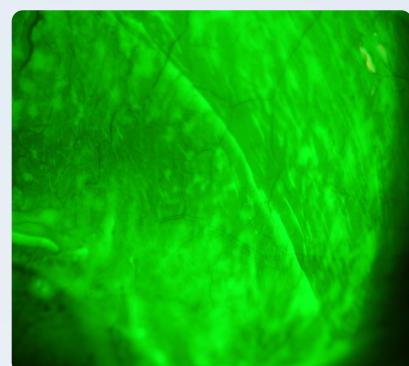
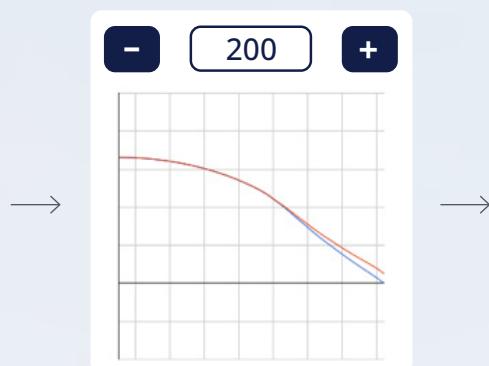
Edge Impingement, cont.

The following are possible causes of localized peripheral edge impingement:

Sectorial/meridional localized edge impingement. This is usually resolved by flattening the haptic in the specified quadrant. If you notice edge impingement in a specific quadrant, first identify the quadrant: 1, 2, 3, or 4, and flatten accordingly using FitConnect.

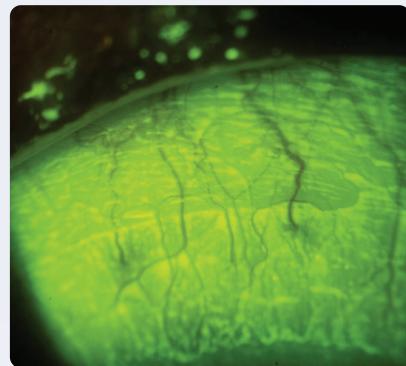
If the impingement noted looks like figure 5, and upon lens removal, there's conjunctival staining similar to the image below, the minimal suggested amount of haptic flattening is **200 μ** if working with the 18-19mm FitKit and **150 μ** if working with the 16-17mm FitKit.

Fig. 5: Example shown is for 18-19mm FitKit.

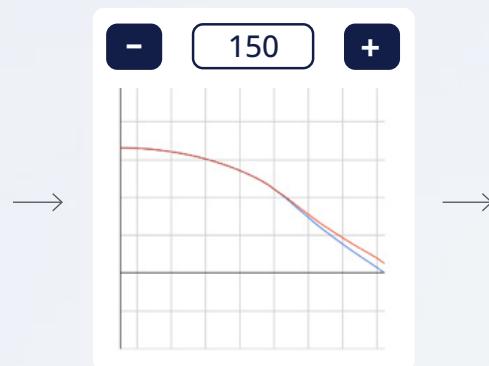


If the impingement noted looks like figure 6 upon lens removal, then the amount to flatten haptic is **150 μ** if working with the 18-19mm FitKit and **100 μ** if working with the 16-17mm FitKit.

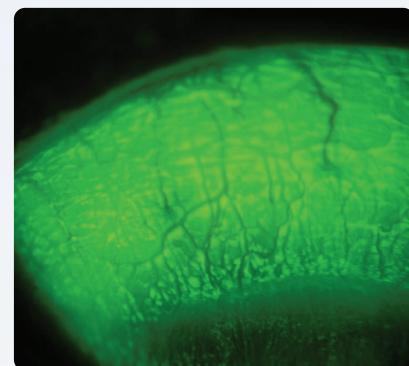
Fig. 6: Example shown is for 18-19mm FitKit.



Staining pattern upon lens removal



Flatten haptics by 150 μ



Fitting endpoint after modification: No conjunctival staining

Fitting Modifications, cont.

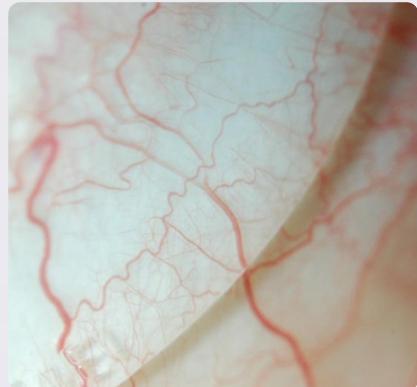
Edge Lift

If edge lift occurs, the haptic should be steepened in the corresponding haptic. First identify which quadrant corresponds to the observed edge lift: 1, 2, 3, or 4.

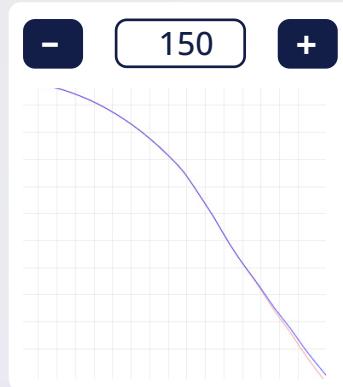
For example, if the amount of edge lift noted looks like figure 7, and it corresponds to quadrant 1, then haptic should be steepened by at least 150 μ at quadrant 1 for 18-19mm FitKit and 100 μ for the 16-17 FitKit.

Log in to your FitConnect account and use the graphical representation at quadrant 1 as shown in figure 7.

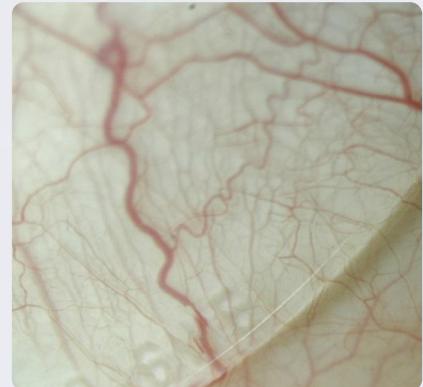
Fig. 7: Example shown is for 18-19mm FitKit.



Edge lift scenario



Steepen haptics
by 150 μ



Fitting endpoint after
modification

QUAD-LIMBAL™

Change Limbal Clearance in a quadrant-specific manner with Quad-Limbal™.

Standard

The default choice in FitConnect is based on our data-driven design with built-in oval optic zone. However, if you need to modify in any given quadrant because of touch or over-vaulting, then we have created a simple STEP system for you to address limbal clearance changes in a quadrant-specific manner as shown in figure 8.

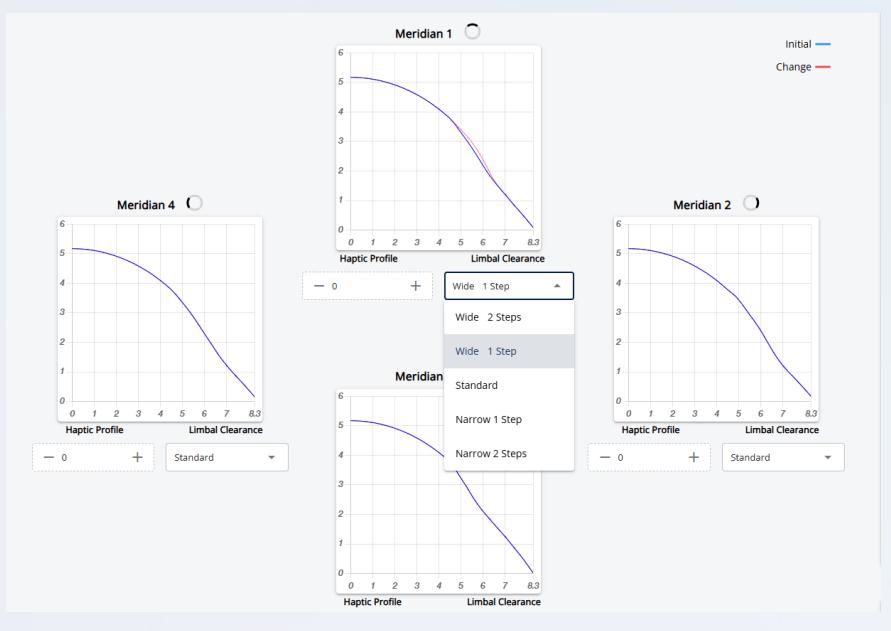
Narrow 1/Wide 1 Step

If HVID is between 11-12mm and/or you need to decrease the limbal clearance by ~100-140µm, choose Narrow 1 step. If HVID is between 12-13mm and/or you need to increase the limbal clearance by ~100-140µm, choose the Wide 1 step.

Narrow 2/Wide 2 Step

If HVID is <11mm and/or you need to decrease the clearance by ~150-200µm choose the Narrow 2 step. If HVID is > 13mm and/or you need to increase the clearance by ~150-200µm choose the Wide 2 Step.

Fig. 8



Fitting Modifications, cont.

QUAD-ELEVATION™ — MID-PERIPHERAL CORNEAL ADJUSTMENTS

Quad-Elevation allows you to modify the mid-peripheral corneal zone by manipulating the base curve (BC) independently in each quadrant. In the BostonSight SCLERAL lens design, BC changes only affect the mid-peripheral corneal zone. This feature is particularly important to avoid touch in the mid-peripheral corneal zone in any given quadrant.

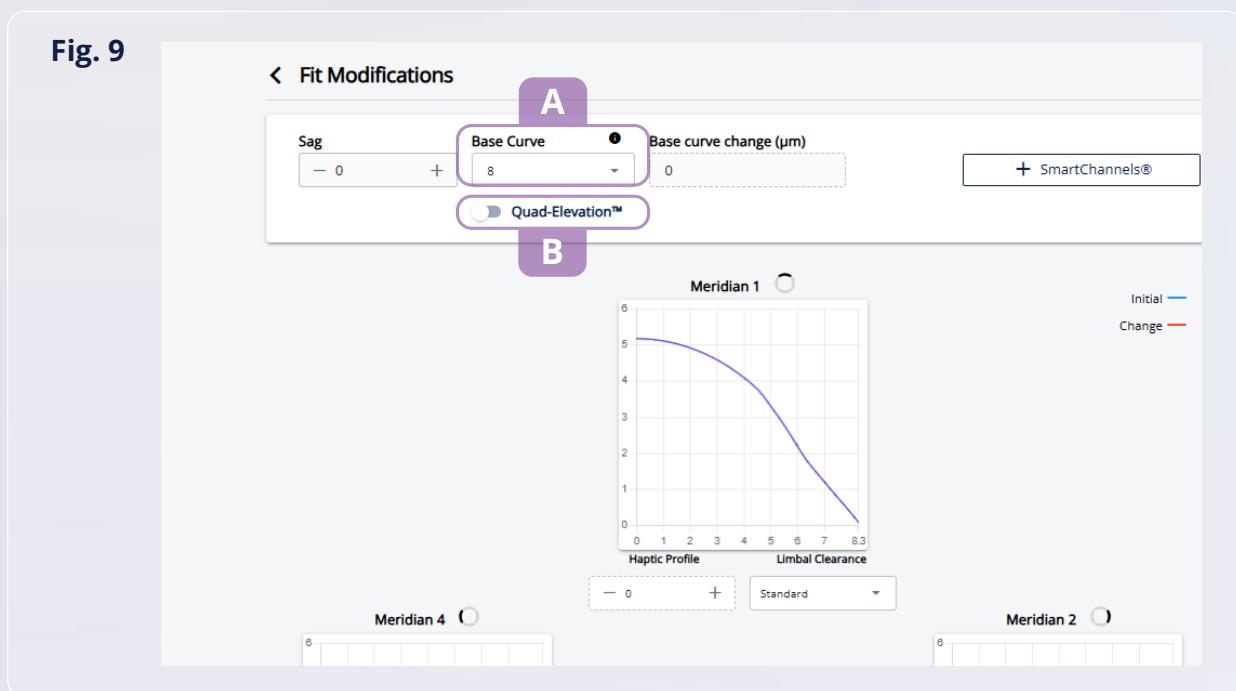
Modifying the BC (marked with A in figure 9) changes the BC around the entire lens.

To change BC in a quadrant-specific manner, toggle on Quad-Elevation™ (marked with B in figure 9). A selection box appears under each meridian as shown in figure 10.

NOTE: Quad-Elevation is available to toggle on only when spherical changes are made to the lens. If you change the cylinder or axis of the lens, Quad-Elevation will not be available.

* *SmartFocus cannot be combined with Quad-Elevation.*

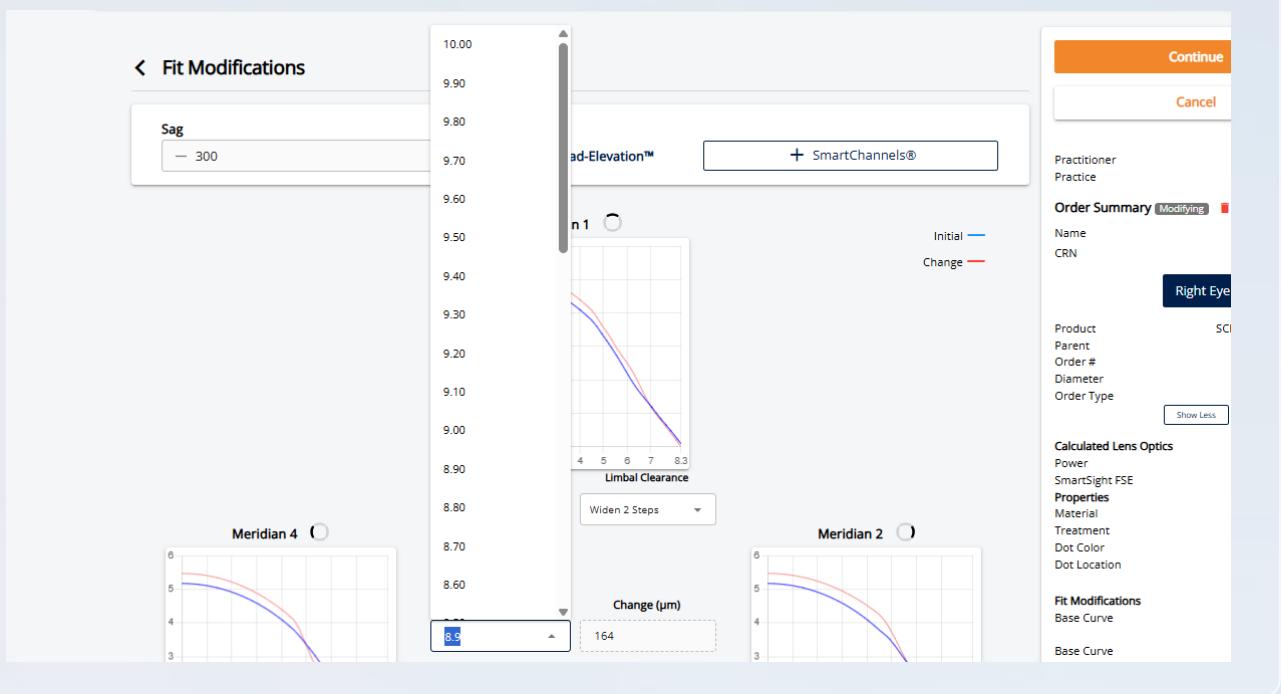
Fig. 9



Choose the BC value that corresponds to the micron amount by which you need to increase or decrease the mid-peripheral corneal zone as shown in figure 10. The lens design will change accordingly showing the chosen micron change in the adjacent micron conversion calculator and in your Order Summary column on the right.

- To increase the clearance at the mid-periphery, select a value **greater** than 8.0 BC.
- To decrease the clearance at the mid-periphery, select a value **less** than 8.0 BC.

Fig. 10



Note that if you do NOT change the BC in a particular quadrant, the Order Summary screen will show 0 in the corresponding quadrant. This does not mean the BC is 0. This indicates that the BC remains the same as the parent order.

Click the meridian wheel icon above each quadrant to zoom in on real-time graphical changes as indicated in figure 11.

Fig. 11



Fitting Modifications, cont.

SmartChannels®

With BostonSight SCLERAL SmartChannel Technology, you can easily customize your lens to facilitate fits over anatomical obstacles, promote tear exchange, and reduce suction. You can add up to four (4) SmartChannels per lens, and they can be positioned in any degree location in the lens.

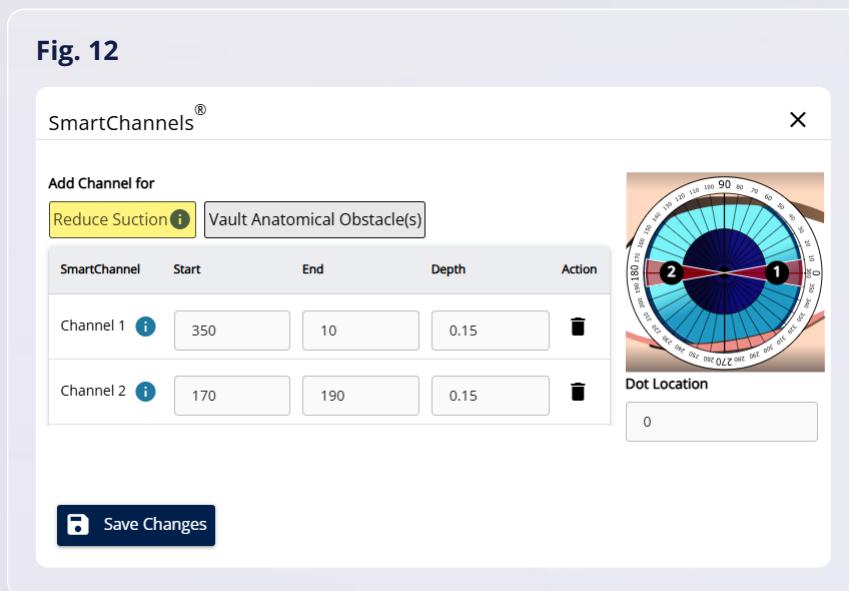
Now, you have the option of selecting the application for which you'd like to use SmartChannels for, making it easier and more efficient to design lenses!

REDUCING SUCTION

FitConnect powers the "Smart" in lens design with its new auto-design feature, providing built-in efficiency for providers. If reducing suction is your primary goal for adding SmartChannels, simply click the REDUCE SUCTION tab in FitConnect and leverage the auto-design feature (see figure 12). Two (2) channels will be added in the horizontal axis with default depths and widths. To add two additional channels, click REDUCE SUCTION again, and two more channels will be added in the vertical axis, for a total of four (4), the maximum.

You can still modify the Channel location, width, or depth by typing in the box.

Fig. 12



VAULTING OVER ANATOMICAL OBSTACLES

- ① Adequately fit the lens until you achieve a rotational stable fit with aligned peripheral haptics.
- ② Note the location of the dot in degrees using the slit rotation control ring in your slit lamp. FitConnect will compensate for the lens rotation; the channel will be adequately positioned regardless of where the dot is resting on the eye.
 - Determine the start and end position of the channel (in degrees), the width (in degrees), and the depth of the channel (mm) required to vault the anatomical obstacle.
- ③ Utilizing CSP or ESP data to design a SmartChannel:
 - Move the cursor to the area of elevation to find information about location and depth and determine starting point and end point of your SmartChannel in degrees.
 - We recommend adding 10° to each side, as shown in figure 13.

Fig. 13

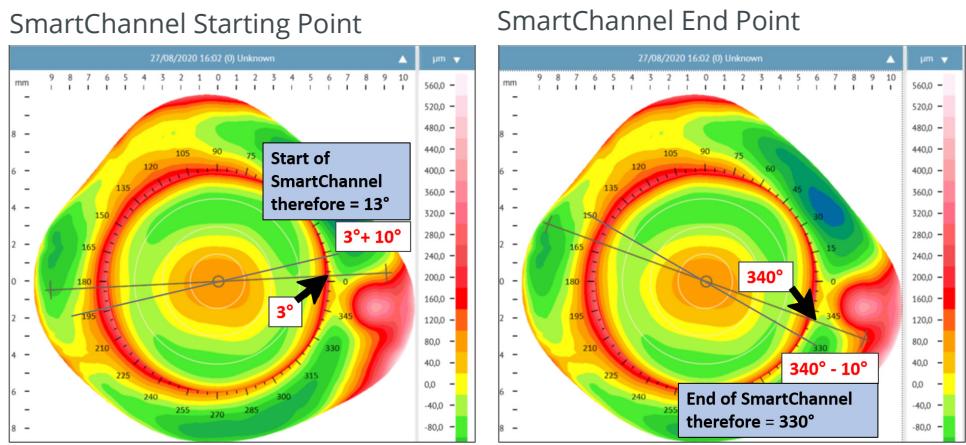
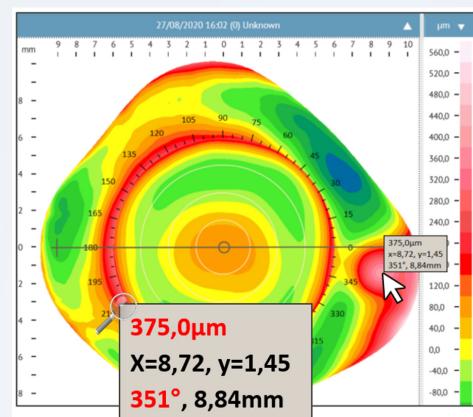


Fig. 14: Pinguecula example

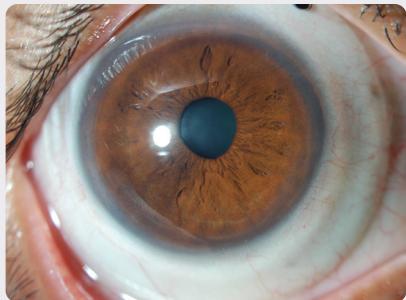
Data obtained from Eaglet Eye's ESP:

- ① Location: 351°
- ② Depth: 375μ
- ③ Move cursor to the superior and inferior edge of the pinguecula to determine starting point and end point of SmartChannel in degrees.



Fitting Goals

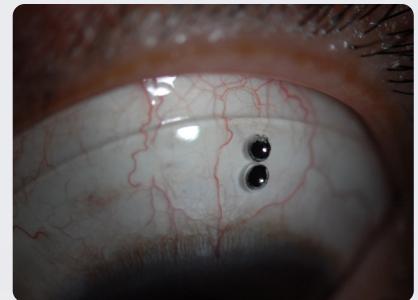
After lens has settled for 20-30 minutes.



The lens centers well and is virtually motionless on blinking. Air bubbles do not intrude under the haptic or optic zone after the lens has been applied.



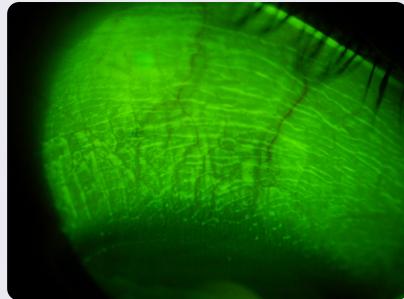
Corneal clearance: The thickness of the fluid compartment over the corneal apex is approximately 200μ to 300μ (in comparison, the center thickness (CT) of the lens is 300μ). Also, vaulting should occur at the limbal area.



Episcleral blood vessels underlying the haptic are not compressed for adequate haptic scleral alignment.



The edge of the lens does not impinge on the bulbar conjunctiva.



There should be minimal-to-no imprint of the edge of the lens on the bulbar conjunctiva upon lens removal.

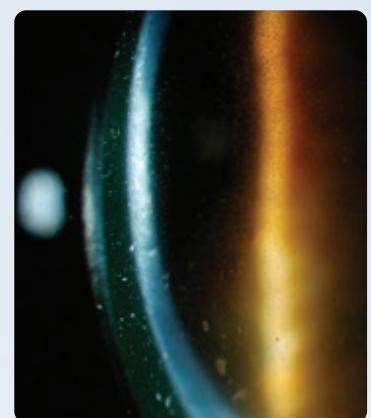
Troubleshooting

ACCUMULATION OF DEBRIS IN THE FLUID RESERVOIR (figure 15)

This is common in eyes with distorted corneas that also have a dry eye component, or in ocular surface disease. This should be managed stepwise, as suggested below:

- ① Apply fluorescein over the device to determine excessive exchange or vector for debris intake. If this occurs, then re-evaluate the haptic toricity distribution and steepen haptics as needed, using the graphical representations for each individual quadrant in your FitConnect account.
- ② Minimize central sagittal depth if excessive.
- ③ Consider the use of more viscous fluid in the lens reservoir, such as preservative-free Refresh Celluvisc mixed with preservative-free saline.

Fig. 15



HOODING OF THE LIMBAL BULBAR CONJUNCTIVA (figure 16)

Loose bulbar conjunctiva is often seen overlapping the peripheral cornea during lens wear. This can be quite impressive. Nevertheless, if the redundant conjunctival tissue is flat, the condition is benign. However, if it is a function of excessive lens suction, this requires a re-design to establish adequate venting by improving haptic scleral alignment. More commonly this is associated to high limbal clearance. Proceed to reduce limbal clearance in the corresponding meridian in FitConnect following the step system, as described above.

Fig. 16



DIFFUSE, FINE SPK

(The following should be ruled out for lens related causes.)

- ① Residual hydrogen peroxide. This is always associated with stinging on lens application and may indicate the need for a more thorough saline rinse prior to lens application, or the need to replace the platinum catalyst, if this system is used for neutralization.
- ② Sensitivity to wetting/soaking solution used for overnight storage (if any). In these cases, overnight hydrogen peroxide disinfection is recommended.

Troubleshooting, cont.

DEVELOPMENT OF HYPERTROPHIC BULBAR CONJUNCTIVAL LESION COINCIDENT WITH THE EDGE OF THE LENS

This may be due to chronic edge impingement and its resolution requires a significant flattening of haptic or change in the lens diameter — either smaller by at least 1mm if this avoids any edge impingement in this area, or larger so that the lens rides over the hypertrophic tissue.

DISCRETE ROUND OR OVAL DEPRESSION OF THE CORNEAL SURFACE PRESENT IMMEDIATELY AFTER LENS REMOVAL

If it pools fluorescein dye, does not stain, and resolves rapidly, it is most likely a dellen due to a sequestered air bubble during lens wear.

RIPPLED TEXTURE OF THE CORNEAL SURFACE IMMEDIATELY AFTER LENS REMOVAL

This is common and benign. It probably is due to the absence of the normal shearing forces of blinking that serve, among other things, to smooth the mucin layer on the corneal surface.

LENS-RELATED BULBAR CONJUNCTIVAL INJECTION

Common causes include:

- ① Pinguecula, especially the more diffuse type.
- ② Excessive haptic compression and/or edge impingement, most often evaluated upon lens removal as rebound injection.
- ③ Inadequate neutralization of hydrogen peroxide.
- ④ Sensitivity to constituents of contact lens wetting solutions if used for lens soaking.

Troubleshooting, cont.

SMARTFOCUS™

When and if SmartFocus troubleshooting is required, please do the following:

- ① Ensure Distance Rx is accurate
- ② Ensure mesopic pupil size was correctly measured for each eye
- ③ Ensure ADD power is correct
- ④ Hold for Consultation
- ⑤ Enter DVA OU, NVA OU, DVA OD/OS, and NVA OD/OS

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LENS PARAMETERS

DIAMETERS	16.0mm, 16.5mm, 17.0mm, 17.5mm with Smart360, 18.0mm, 18.5mm, and 19.0mm
SPHERE POWER	-20.00 Diopters to +20.00 Diopters
SAGITTAL DEPTH	2.0mm to 6.0mm in 0.1mm (50 μ) steps
CYLINDER AND AXIS	-0.50 to 6.00 Diopters, 5° to 180° in 5° increments
CENTER THICKNESS	0.3mm, unless otherwise noted
PERIPHERAL HAPTIC SYSTEM	Customizable
OPTIONS	Quadrant-specific toric PHS; Front-surface toric Rx, SmartSight® FSE, SmartSight HOA®, SmartChannels®, SmartFocus™, Tangible Hydra-PEG (incurs additional fee)

LENS MATERIALS

PRODUCT	MATERIAL	DK
Contamac	Optimum Extra	100
Contamac	Optimum Extreme in clear or ice blue	125
Contamac	Optimum Infinite	180
Bausch + Lomb	Boston® EQII (cannot be used with Hydra-PEG)	85
Bausch + Lomb	Boston® XO2 in clear or ice blue	141



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