BostonSight® SCLERAL

Your partner in saving sight.

SPECTRUM INTERNATIONAL

FitGuide™

For 16-19mm scleral lenses

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

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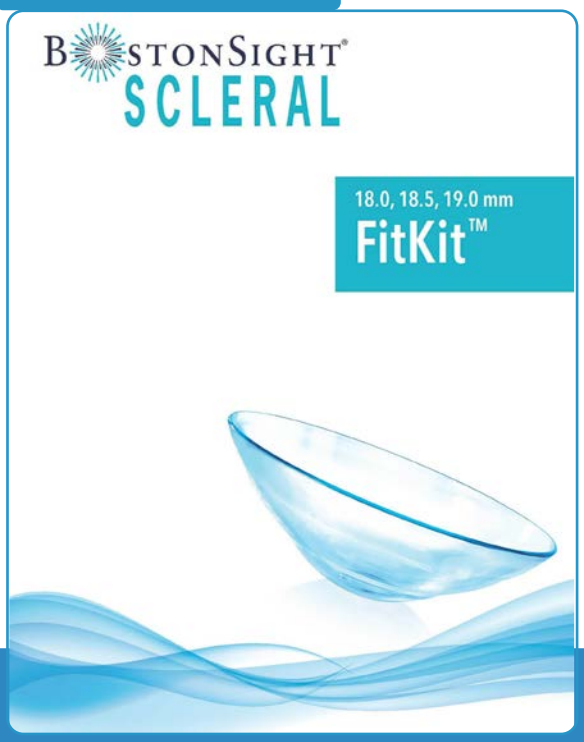
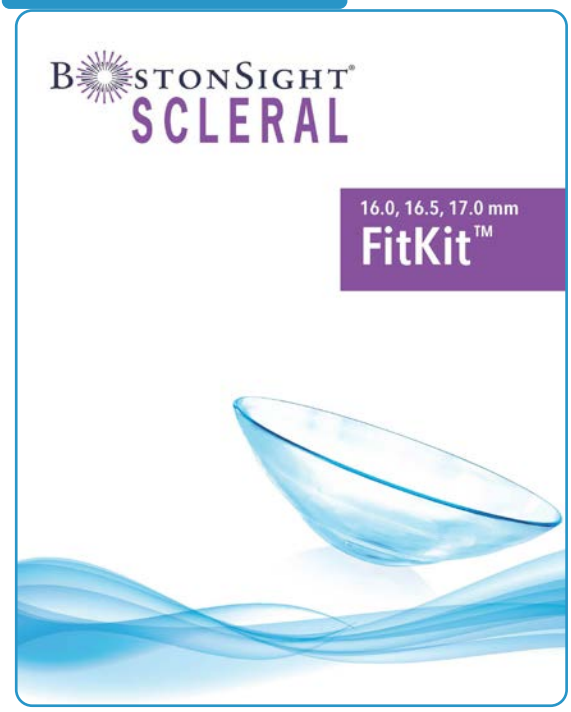
Diagnostic lens sets come with three specific diameters and include nine fitting lenses for each eye.

18.0, 18.5, and 19mm



16, 16.5, and 17mm



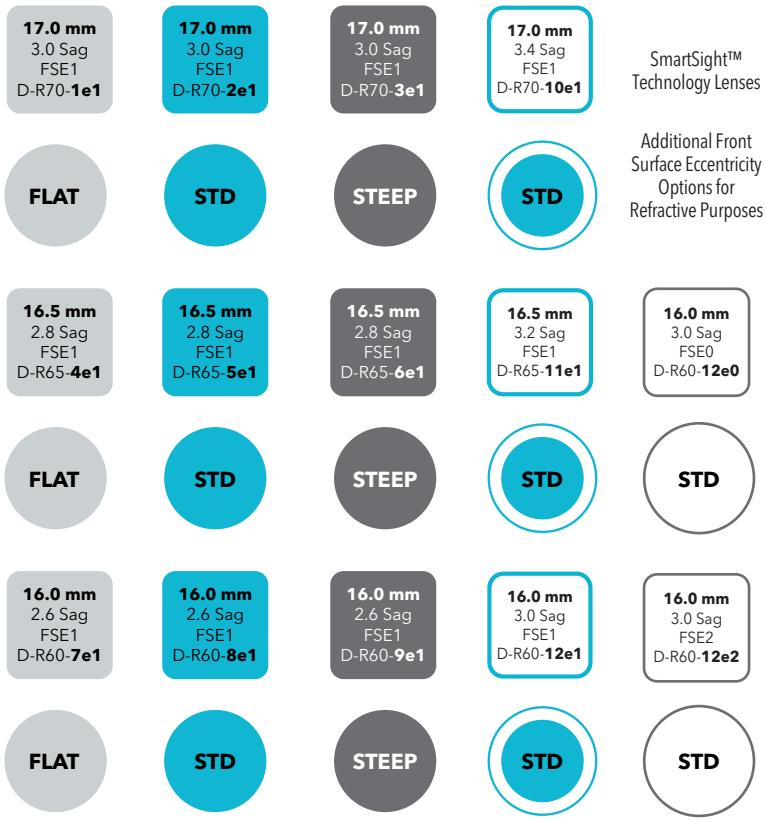
DIAGNOSTIC LENS SET

Each BostonSight SCLERAL FitKit™ includes a total of 28 diagnostic lenses. Nine lenses for each eye constitute the primary fitting set, with one additional sagittal depth option for each diameter; an additional two lenses per eye are included for residual high aberration control to achieve best corrected visual acuity. Diagnostic sets come with three specific diameters: 16, 16.5 and 17mm or 18, 18.5 and 19mm.

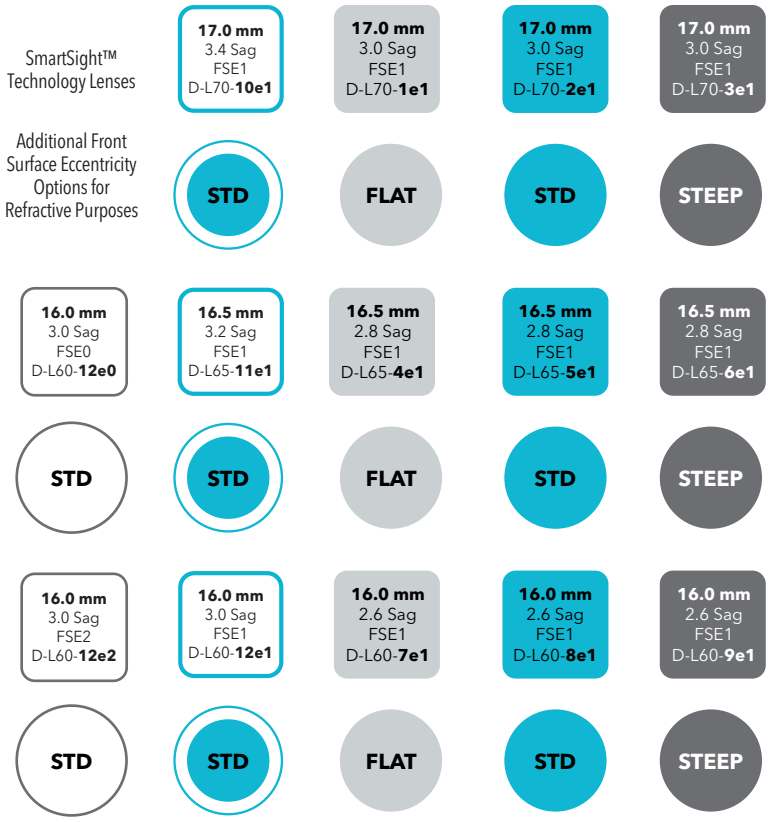
Lens selection and fitting is designed to simplify the fitting process as described in the schematic on the next page. Our fitting system is based on scleral anatomy and driven by clinical data. Specific lenses are provided for the left and right eye.

16, 16.5 and 17mm FitKit™

Fitting Lenses RIGHT

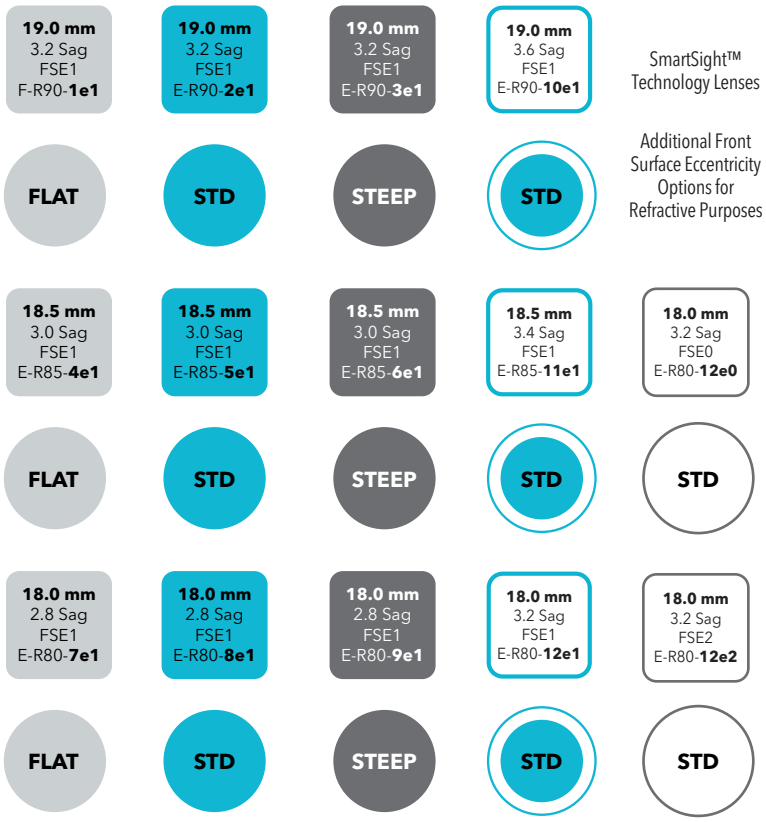


Fitting Lenses LEFT

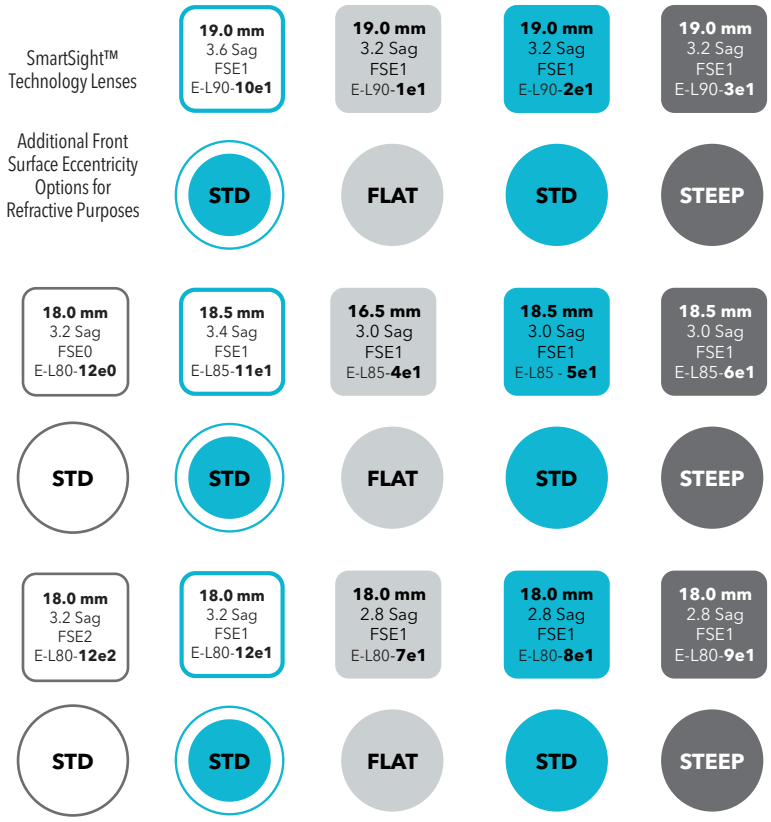


18, 18.5 and 19mm FitKit™

Fitting Lenses RIGHT



Fitting Lenses LEFT



FITTING PRINCIPLES OF THE BOSTONSIGHT SCLERAL LENS

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.
The steps are as follows:

1. Identify the trial lens having the best initial fit.
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 sphero-cylindrical refraction over the final diagnostic lens.
6. Order the lens with any modifications as needed.

E-R80-1e1

LENS SET SERIES	EYE R vs. L	DIAMETER	LENS NUMBER 1-12	ECCENTRICITY FSE0, FSE1 OR FSE2
E	R	80	1	e1

Easy diagnostic lens ID with unique laser-engraved model number

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

Laser-engraved model number location

FITTING ALGORITHM SCHEMATIC

Choose diameter.

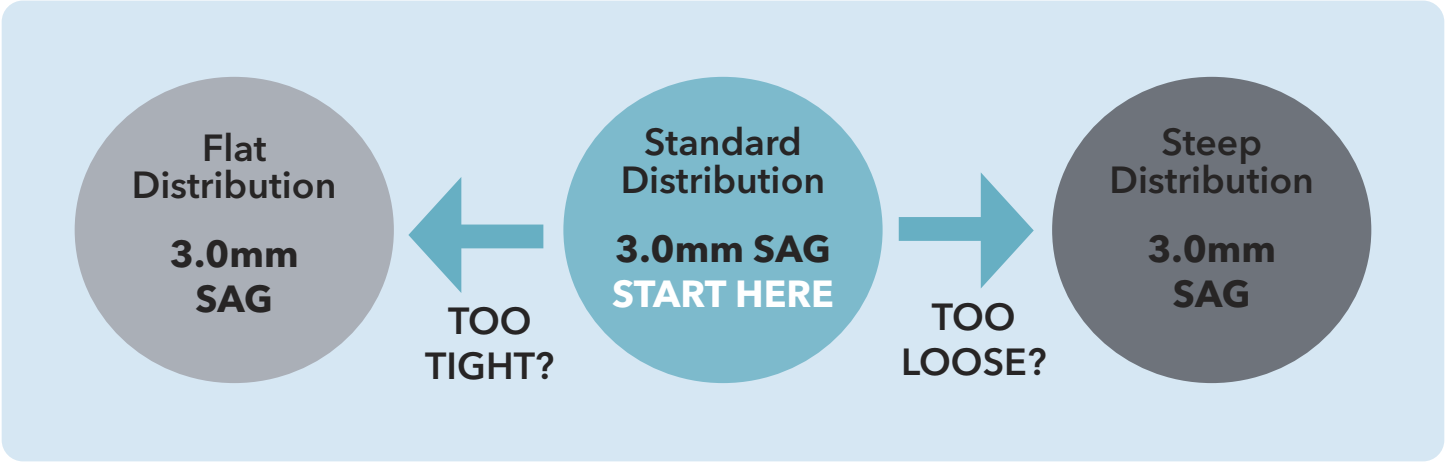
Start at the center with s Standard Distribution lens and standard sagittal height at each given diameter.

If the Standard Distribution lens fits loose, choose the Steep Distribution lens.

If the Standard Distribution lens fits tight, choose the Flat Distribution lens.

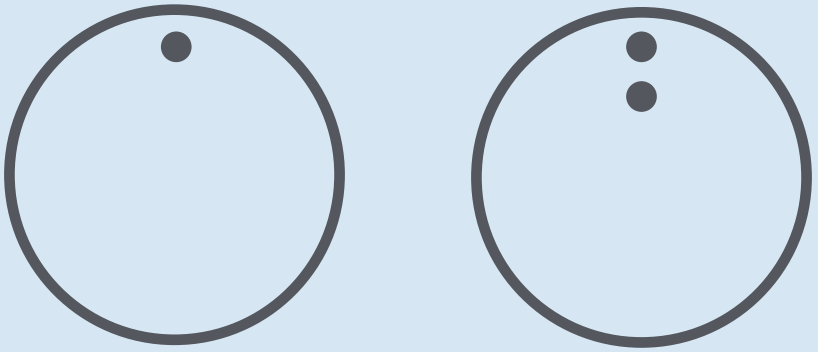
Once the best diagnostic lens is identified, sagittal height and individual hemi-meridians can be modified as needed for design customization.

Fitting guide is based on a simplified system for each eye.



LENS MARKINGS - USING DOTS TO IDENTIFY RIGHT AND LEFT LENSES

Right vs. left lens identification

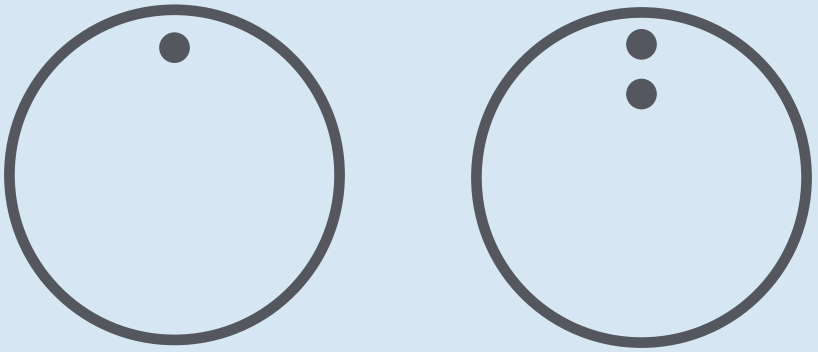


One dot = RIGHT lens

Two dots = LEFT lens

Expected lens positioning in the eye

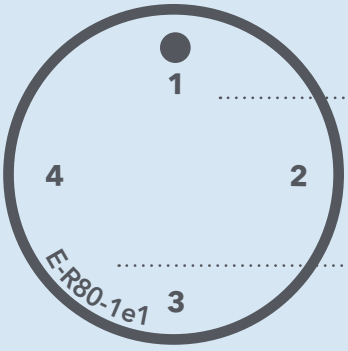
60-85% of the time



15-40% of the time

LENS MARKINGS (continued)

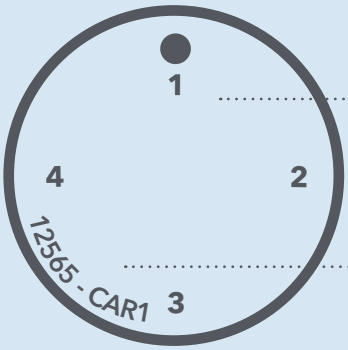
DIAGNOSTIC LENS



Easy ID with Arabic numerals to identify each individual hemi-meridian

Diagnostic lens model number laser-engraved for positive ID

PATIENT'S LENS



Easy ID with Arabic numerals to identify each individual hemi-meridian

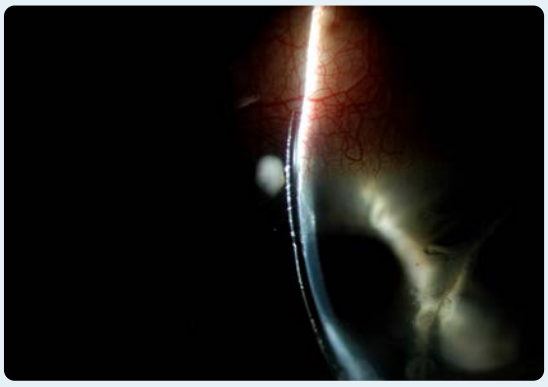
Laser-engraved unique identifier = order number + first 3 letters of patient's last name + lens number

DIAMETER SELECTION

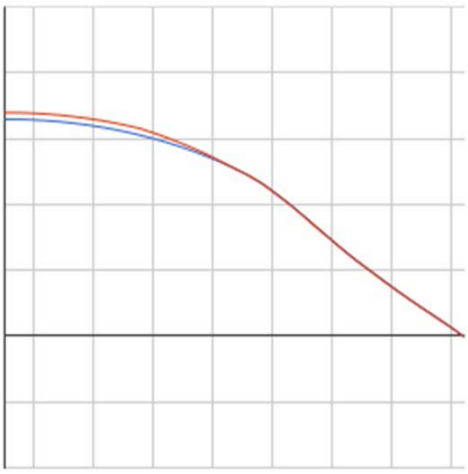
Smaller diameter lenses are suitable for smaller HVIDs, regular corneas, smaller apertures, and/or tighter lids. As lens diameter is decreased, the haptic bearing surface area becomes smaller. This is less significant for lenses having diameters 18.0mm or larger. Larger sizes, i.e. 19.0 mm, are useful for large globes such as those with significant keratoectasia, high myopia, and large horizontal visible iris diameters (HVID's) and for cases of chronic exposure and fragile and compromised ocular surfaces and disease eyes.

SAGITTAL HEIGHT

Sagittal height should be modified with the goal of achieving the suggested 200 - 3000µ clearance. For reference, refer to the center thickness of the lens, which is 300µ. Our recommended starting point is the Standard Distribution sagittal height lens. Once the best trial diagnostic lens for both haptic alignment and sagittal height is determined, proceed to make 50 micron adjustments as needed. For example, if you note corneal touch as shown below, for a desired 200µ clearance, increase sag value by 200µ as shown.



Example of corneal touch



− 200 +

Sag increase by 200µ

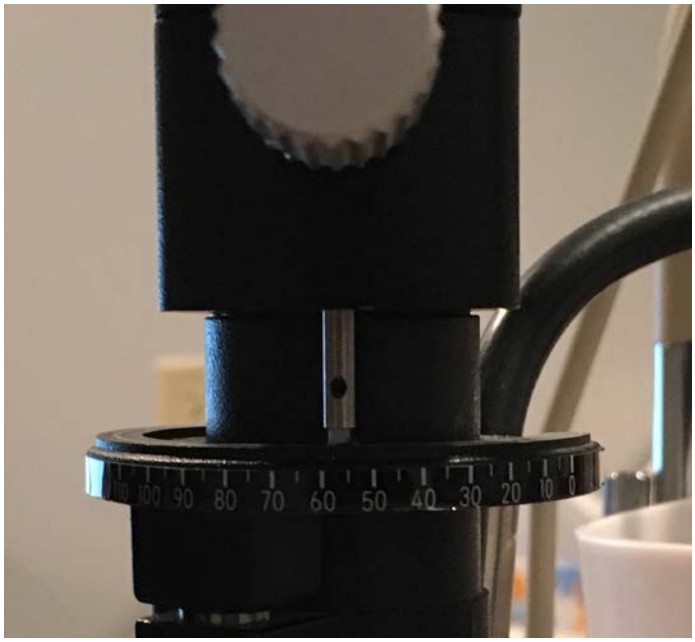
FRONT SURFACE OPTICS

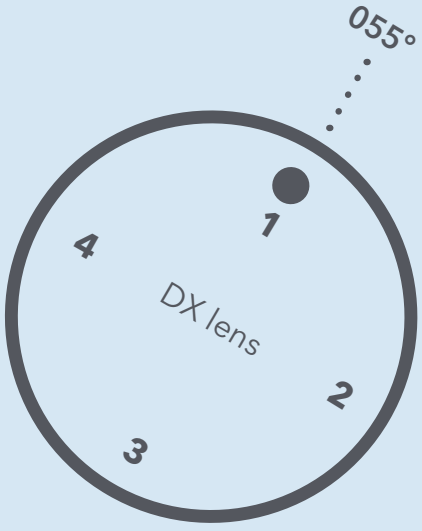
Multiple front surface eccentricity options are provided. For optimal best corrected visual acuity results, it is imperative that the best fitting trial diagnostic lens has been identified and assessed before proceeding to fine-tune best corrected visual acuity. Once a rotationally stable diagnostic 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 front surface eccentricity lens options provided, FSEO or FSE2. If best-corrected vision is improved, proceed to order the lens based on the best fitting diagnostic lens and choose the best front surface eccentricity option (FSE1, FSE2, or FSE0) from the drop down menu in the order sheet.

BostonSight SCLERAL lenses in astigmatic powers up to 6D are available for order. If the patient is unable to achieve satisfactory vision after attempting all front surface eccentricity options, then it is important to check for residual astigmatism. Astigmatic corrections can only be applied to rotationally stable lenses. 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 example below). The latter measurement in degrees is crucial in order to obtain accurate results.

Scenario | Residual astigmatism correction

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



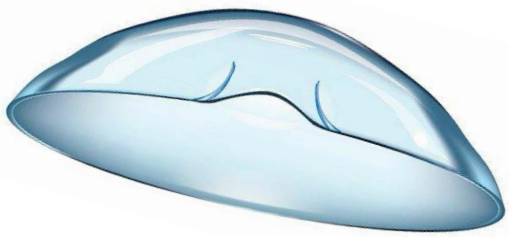


① Measure the location of lens dot in degrees using your slit-lamp as shown above (in this example, dot location is at 055°)

② Provide sphero-cylindrical value and lens dot location.

SmartChannel™ TECHNOLOGY

With BostonSight SCLERAL SmartChannel Technology, you can easily customize your lens to facilitate fits over anatomical obstacles, promote tear exchange and reduce suction.



VAULTING OVER ANATOMICAL OBSTACLES: 3 Easy Steps

1. Adequately fit the lens until you achieve a rotational stable fit with aligned peripheral haptics.

2. Notate the location of the dot in degrees using the slit rotation control ring in your slit lamp. The channel will be adequately positioned regardless of where the dot is resting on the eye.

3. Determine the position of the dot (in degrees), the width (in degrees) and the depth of the channel (mm) required to vault the anatomical obstacle. You can request up to 4 SmartChannels per lens, and they can be positioned in any location in the lens. If you need to add another Smartchannel, note the start point in degrees, the end point in degrees and the depth, and submit to your representative using your order form.

Cuadrantes Zona Escleral (Hápticas) [Aplanar = (+) Encurvar = (-)]

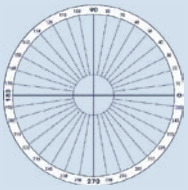
Δμm

Cuadrante 1

Cuadrante 2

Cuadrante 3 ___

Cuadrante 4 ___



Indicar las posición de los puntos en grados

Clearance Periferal/Limbal

Cuadrante 1

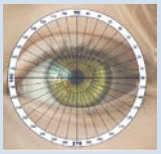
Cuadrante 2 ___

Cuadrante 3

Cuadrante 4

Canales Inteligentes (SmartChannels™)

Canal	Comienzo (°)	Final (°)	Profundidad (mm)
1			
2			
3			
4			



Localización de los puntos en grados (0-360)

Cambio de Altura Sagita Central

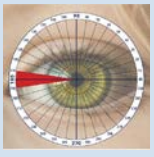
SAG 0

Comentarios

Ejemplo:

Canal	Comienzo	Final	Profundidad
1	170	190	0.2

Localización de los puntos en grados (0-360) 65



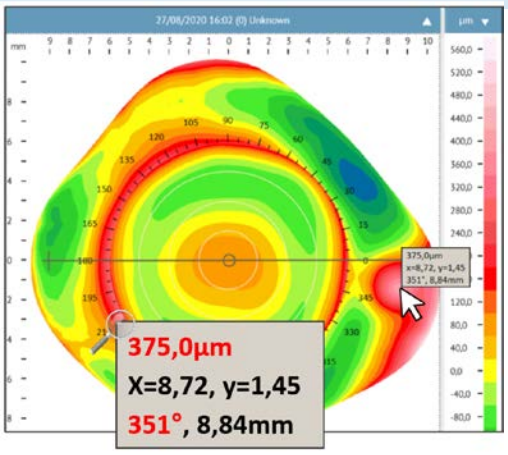
NOTE: If you have a scleral topographer, move the cursor to the area of elevation to find out information about location and the depth, and determine your starting point and endpoint of your SmartChannel in degrees. **We recommend adding 10° to each side, as shown below.**

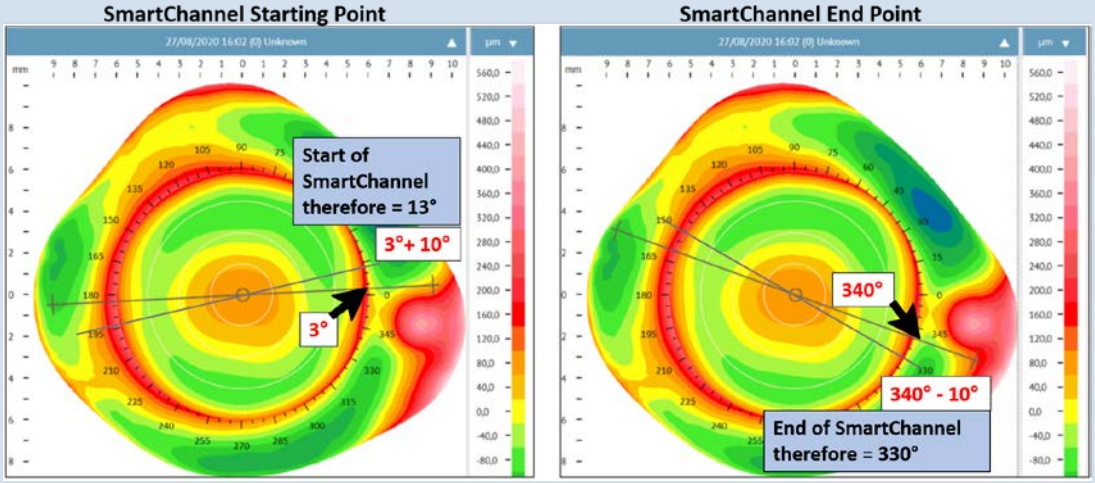
Pinguecula example.
Data obtained from Eaglet Eye's ESP:

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 Smart-Channel in degrees.





PROMOTING TEAR EXCHANGE AND REDUCING SUCTION

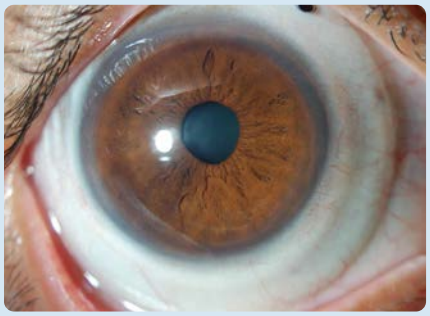
The same 3 steps as described on page 9 apply when designing SmartChannels to promote tear exchange and reduce suction. The only difference is the width and depth.

① The standard initial width is 20-30 degrees and depth is 150-200

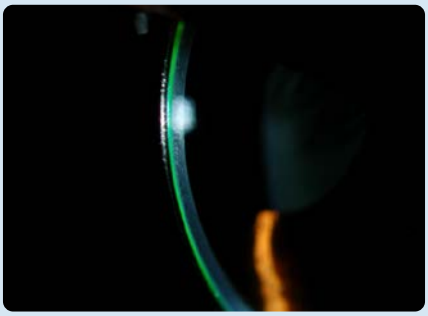
② Typically, channels to relieve suction are added in the temporal and nasal locations in the eye (180 deg and 0 deg). If more channels are needed, a total maximum of 4 total channels can be added.

FITTING GOALS FOR BostonSight SCLERAL

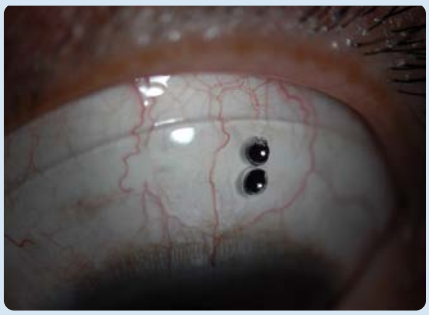
After lens has settled for 20-30 minutes



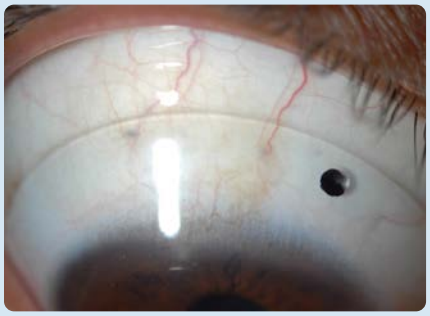
The lens centers well and is virtually motionless on blinking. Air bubbles do not intrude under the haptic or optic zone after the lens has been applied.



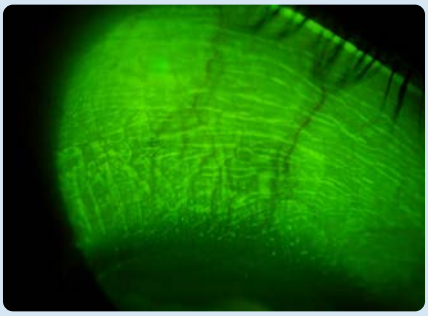
Corneal clearance: The thickness of the fluid compartment over the corneal apex is approximately 200µ to 300µ (in comparison, the center thickness (CT) of the lens is 300µ). Also, vaulting should occur at the limbal area.



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.

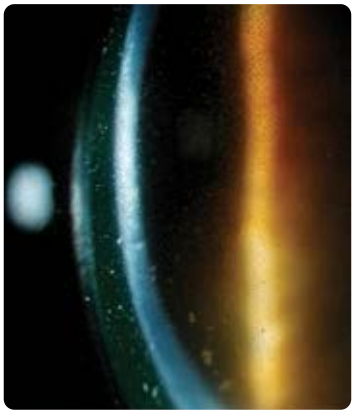


There should be minimal to no imprint of the edge of the lens on the bulbar conjunctiva upon lens removal.

TROUBLESHOOTING

Accumulation of debris in the fluid reservoir

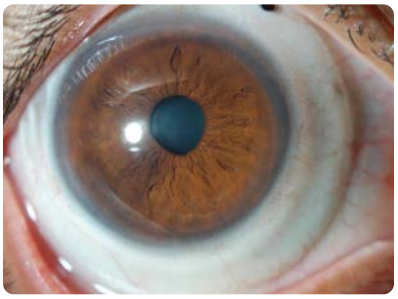
This is common in eyes with distorted corneas that also have a dry eye component, or in ocular surface disease. This should be managed stepwise as suggested below:



1. Apply flourescein 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.
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.

Hooding of the limbal bulbar conjunctiva

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.



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.

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.

TROUBLESHOOTING (continued)

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.

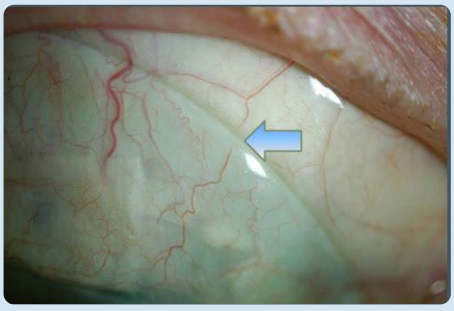
Edge Impingement

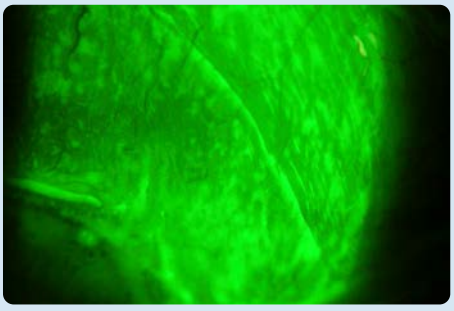
The following are possible causes of localized peripheral edge impingement:

Sectorial/meridional localized edge impingement. This is usually resolved by flattening the haptic in the specified meridian. If you notice edge impingement in a specific me ridian, first identify the meridian: 1, 2, 3, or 4, and flatten accordingly in 50µ steps

If the impingement noted looks like the one below, and upon lens removal, there's conjunctival staining similar to the image below, the minimal suggested amount of haptic flattening is **200µ if working with the 18-19mm FitKit and 100µ if working with the 16-17mm FitKit.**

Example shown is for 18-19mm FitKit.

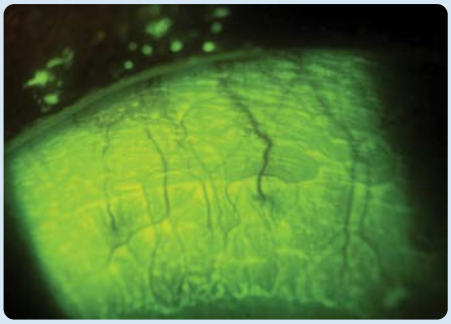




For example, if the amount of impingement noted and the conjunctival staining pattern after lens removal looks like the picture above, and it corresponds to Meridian 1, then the haptic should be flattened by at least 200µ at Meridian 1.

TROUBLESHOOTING (continued)

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

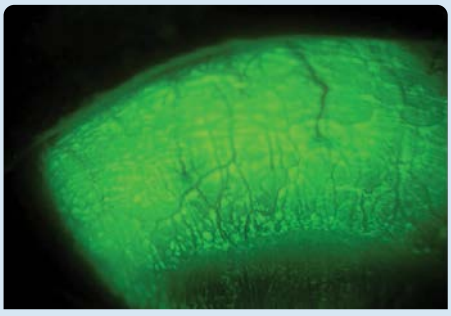


Staining pattern upon lens removal

Example shown is for 18-19mm FitKit.

− 150 +

Flatten haptics by 150µ



Fitting endpoint after modification:
No conjunctival staining

TROUBLESHOOTING (continued)

Edge Lift

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

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

Example shown is for 18-19mm FitKit.

Edge lift scenario

− -150 +

Steepen haptics by 150µ

Fitting endpoint after modification: Edge alignment

Lens parameters and availability

DIAMETERS	16.0mm, 16.5mm and 17.0mm,18.0mm, 18.5mm and 19.0mm
SPHERE POWER	-20.00 Diopters to +20.00 Diopters
SAGITTAL HEIGHT	2.0mm to 6.0mm in 0.1mm (50µm) steps
CYLINDER AND AXIS	-0.50 to 6.00 Diopters, 5° to 180° in 5° increments
CENTER THICKNESS	0.30mm, unless otherwise noted
PERIPHERAL HAPTIC SYSTEM (PHS™)	Customizable
POLYMER MATERIAL	Optimum Extra, Optimum Extreme, Optimum Infinite, Boston Equalens, Boston XO_2
OPTIONS	Quadrant-specific toric PHS™; Front Surface Eccentricity (FSE), Front-surface toric Rx, SmartChannels™

BostonSight® SCLERAL

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