

Fitting Guide

Going Beyond the Fit[™] with a Data-Driven Lens Fitting System

- Lens diameters of 18.0mm, 18.5mm and 19.0mm
- Comprehensive 22-lens diagnostic set
- Right and Left anatomical designs
- Front Surface Eccentricity (FSE) options

Leveraging 6 years of patient data from approximately 7,000 eyes

BostonSight SCLERAL is the first scleral lens fitting system based on scleral anatomy and driven by clinical data

Our Goal: Provide your patients comfort and improved ocular health with an accurate and dependable fit through:

- Minimized modifications
- Reduced number of patient sessions





Diagnostic lens sets are available in three specific diameters and include nine fitting lenses for each eye

DIAGNOSTIC LENS SET

Each BostonSight SCLERAL fitting set includes a total of 22 diagnostic lenses. Nine lenses for each eye constitutes the primary fitting set and an additional two lenses per eye are included for residual high aberration control to achieve best corrected visual acuity. Diagnostic sets are available in three specific diameters: 18.0, 18.5, and 19.0mm.

Lens selection and fitting is designed to simplify the fitting process as described in schematic on the next page. Given our fitting system is based on scleral anatomy and driven by clinical data, each set is divided into lenses specifically intended to be used on the right or left eye.

| Flat P +0.25D FSE1 3.0mm SAG B-R80-1e1 | Standard P +0.25D FSE1 3.0mm SAG B-R80-2e1 | Steep P +0.25D FSE1 3.0mm SAG B-R80-3e1 | | | Fitting lenses RIGHT |
|--|--|---|--|--|--|
| Flat P +0.25D FSE1 2.8mm SAG B-R80-4e1 | Standard P +0.25D FSE1 2.8mm SAG B-R80-5e1 | Steep P +0.25D FSE1 2.8mm SAG B-R80-6e1 | Standard P +0.25D FSE0 2.8mm SAG B-R80-5e0 | Standard P +0.25D FSE2 2.8mm SAG B-R80-5e2 | Best corrected vision / HOA lenses RIGHT |
| Flat P +0.25D FSE1 2.6mm SAG B-R80-7e1 | Standard P +0.25D FSE1 2.6mm SAG B-R80-8e1 | Steep P +0.25D FSE1 2.6mm SAG B-R80-9e1 | | | |
| Flat P +0.25D FSE1 3.0mm SAG B-L80-1e1 | Standard P +0.25D FSE1 3.0mm SAG B-L80-2e1 | Steep P +0.25D FSE1 3.0mm SAG B-L80-3e1 | | | Fitting lenses LEFT |
| Flat P+0.25D FSE1 2.8mm SAG B-L80-4e1 | Standard P +0.25D FSE1 2.8mm SAG B-L80-5e1 | Steep P +0.25D FSE1 2.8mm SAG B-L80-6e1 | Standard P +0.25D FSE0 2.8mm SAG B-L80-5e0 | Standard P +0.25D FSE2 2.8mm SAG B-L80-5e2 | Best corrected vision / HOA lenses LEFT |
| Flat P +0.25D FSE1 2.6mm SAG | Standard P +0.25D FSE1 | Steep P+0.25D FSE1 | | | |



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 the eye-specific lens. The steps are as follows:

- ① Identify the trial lens having the best initial fit (process described below).
- ② Re-evaluate the fit after the appropriate settling time.
- ③ When indicated, replace it 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.
- Order the lens via your FitConnect[™] account at:
 BostonSightSCLERAL.org/orders with any modifications as needed.





Laser-engraved model number location



FITTING ALGORITHM SCHEMATIC

The selection process *always* starts at the center with a **Standard Distribution lens** and standard 2.8 mm sagittal height. The next lens is chosen by going either up or down in sagittal height choices in order to achieve adequate corneal clearance.

If the Standard Distribution lens fits loose, choose the Steep Distribution lens with associated sagittal height.

If the Standard Distribution lens fits tight, choose the Flat Distribution lens with associated sagittal height.

Once the best diagnostic lens is identified, individual hemi-meridians can be modified as needed for design customization, using the graphical representations for each individual hemi-meridian provided in your FitConnect account.



Fitting guide is based on a simplified 3x3 matrix system for each eye



DIAMETER SELECTION

As a lens diameter is decreased, the area of its haptic bearing surface becomes smaller. Smaller bearing surfaces can increase scleral compression. 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).

SAGITTAL HEIGHT

Sagittal height should be modified in FitConnect[™] with the goal of achieving the suggested 200-300um clearance. For reference, refer to the center thickness of the lens, which is 250µm. Our recommended starting point is a 2.8mm sagittal height with the Standard Distribution Lens (Lens number 5 in each set). Choose the trial diagnostic lens on the top row or bottom row, for each distribution, to assess either higher or lower sagittal height values. Once the best trial diagnostic lens for both haptic alignment and sagittal height is determined, proceed to make 100 micron adjustments in FitConnect as needed. For example, if you note corneal touch as shown to the right, for a desired 200um clearance, increase sag value by 200um in your FitConnect account as shown to the right.



Example of corneal touch



FitConnect Login/Register: fitconnect.bostonsightSCLERAL.org



Sag increase by 200um in FitConnect



FRONT SURFACE OPTICS

Multiple front surface eccentricity options are available for trial. 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, FSE0 or FSE2. If best-corrected vision is improved, proceed to order lens based on the best fitting diagnostic lens (lens 1-9) and choose the best front surface eccentricity option (FSE1, FSE2, or FSE0) from the drop down menu provided in FitConnect.

BostonSight SCLERAL lenses are also available for order in astigmatic powers up to 6D. 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 examples on the next page). 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



 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 your FitConnect account at BostonSightSCLERAL.org/orders



Fitting goals for BostonSight SCLERAL lens

The following are the fitting goals of the BostonSight SCLERAL lens after it 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 250μ). 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.







60-85% of the time



15-40% of the time

Expected lens positioning in the eye



Lens markings







TROUBLESHOOTING

Accumulation of debris in the fluid reservoir

This is common in eyes with distorted corneas which 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, using the graphical representations for each individual hemi-meridian 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.



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)

- a. 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.
- b. 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.

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:

- a. Pinguecula, especially the more diffuse type.
- b. Excessive haptic compression and/or edge impingement, most often evaluated upon lens removal as rebound injection.
- c. Inadequate neutralization of hydrogen peroxide.
- d. 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 meridian, first identify the meridian: 1, 2, 3, or 4, and flatten accordingly using your FitConnect account.

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 m.



Login to your FitConnect account and use the graphical representations at each meridian to help guide your decision.

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 m at Meridian 1. Refer to the graphical representation to the right.

Meridian 1





If the impingement noted looks like the one below upon lens removal, then the amount to flatten haptic is $150\mu m$ using your FitConnectTM account.



Staining pattern upon lens removal



Flatten haptics by 150um

> Fitting endpoint after modification: No conjunctival staining



Edge Lift

If there's edge lift, 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 m at Meridian 1.

Login to your FitConnect account and use the graphical representation at Meridian 1 as shown below:



Fitting endpoint after modification: Edge alignment





| Lens parameters and availability | | | |
|----------------------------------|--|--|--|
| DIAMETERS | 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 (100 μ m) steps | | |
| CYLINDER AND AXIS | -0.50 to -6.00 Diopters, 5° to 180° in 5° increments | | |
| CENTER THICKNESS | 0.25mm, unless otherwise noted | | |
| PERIPHERAL HAPTIC SYSTEM (PHS™) | Customizable | | |
| POLYMER MATERIAL | Optimum Extra, Optimum Extreme, Boston® Equalens II, Boston® XO2 | | |
| OPTIONS | Quadrant-specific toric PHS™ Front Surface Eccentricity (FSE) Front-surface toric Rx | | |



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