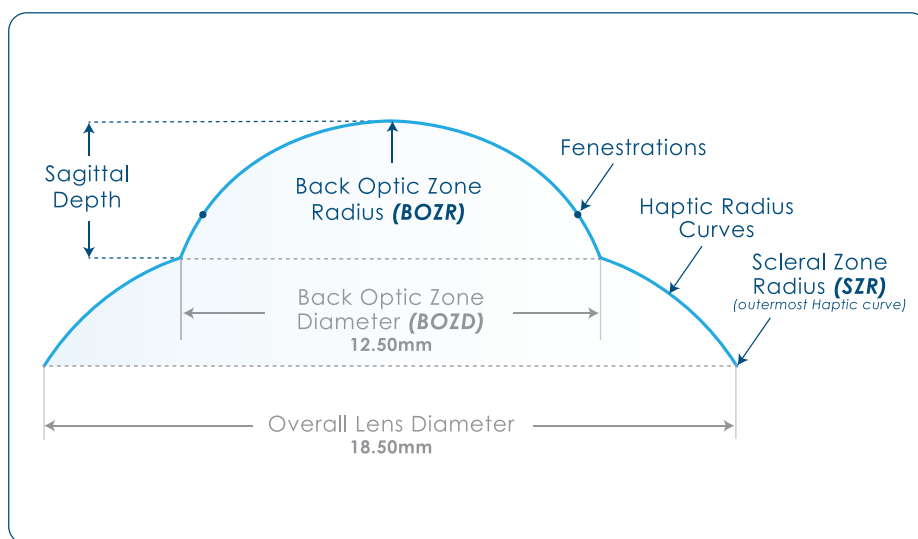


INTRODUCTION

The *CTE Scleral* lens is a fenestrated non-sealed lens. The lens is designed to have a continuous tear flow behind the lens providing better corneal health when compared to a sealed scleral lens.

The intended uses for the *CTE Scleral* lens include: all irregular corneas, Keratoconus, corneal transplant, trauma, high refractive powers or astigmatism, corneal protection against Trichiasis, Ptosis, Pellucid marginal degeneration, Keratoglobus, Post-LASIK Ectasia, Corneal scars, Terrien's marginal degeneration, anterior corneal dystrophies, post intacts and post cross-linking procedures.

CTE SCLERAL LENS DIAGRAM



INITIAL FITTING

The *CTE Scleral* set is comprised of 20 fitting lenses. The set has 3 different *Scleral Zone Radii*.

A SERIES =
13.75mm

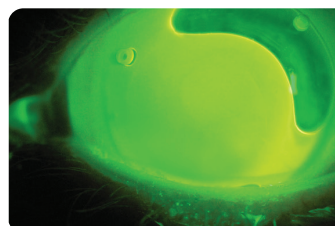
B SERIES =
14.50mm

C SERIES =
15.25mm

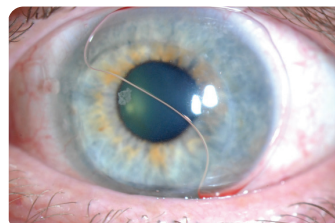
The Back Optic Zone Diameter (BOZD) in all fitting lenses is 12.50mm. In each series of fitting lenses there will be a range of Back Optic Zone Radii (BOZR) and Scleral Zone Radii (SZR). Since the most common SZR will be 14.50mm, it is recommended to start with the B series of fitting lenses.

When unsure of which lens to start with, it is recommended to use the mid range B4 (7.70/14.50) lens. The *CTE Scleral* lens does not need to be prefilled with solution, as is required with a sealed scleral lens. The patient's natural tear film will fill the lens. Once the fitting lens is inserted, allow a few minutes for the lens to settle and fill with tear. The optimal lens vault is determined by an on-eye evaluation of the fitting lens. A drop of fluorescein is required to aid in the evaluation.

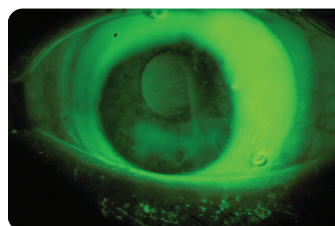
Once the corneal fit is satisfactory the lens should sit on the eye for 30 minutes. The scleral fit is very important. A proper fit allows for a continuous tear exchange to occur behind the lens. Excessive scleral edge stand off of the lens rim is contraindicated. If there is scleral edge stand off, a steeper SZR is needed. You must check to ensure there is no blood flow obstruction on the sclera (blanching or vascular congestion). If any pressure on blood vessels is observed, a flatter SZR is needed.



A **proper fit** will have a crescent shaped air bubble present outside of the pupil in the mid peripheral area of the lens.



A large air bubble that covers the pupil in anyway will indicate a **flatter Back Optic Zone Radius is required**.



If any corneal touch is present or if no air bubble is present then a **steeper Back Optic Zone Radius is required**.

Once an acceptable fit has been determined, an over refraction should be taken over the fitting lens. The fitting lens and the over refraction will then be provided to the lab and the patient's lens will be made.

LENS DISPENSING APPOINTMENT

During the lens dispensing appointment, insert the lens and have the patient wear the lens for 30 minutes. Insert a drop of fluorescein in the patient's eye and check that a crescent shaped air bubble is present. Be aware that this bubble will be slightly larger than the bubble that was observed during the fitting exam. As non sealed lenses have a tendency to set back when the lens is initially worn, the lab has made an adjustment to the lens to allow for this set back. This bubble should not impede into the pupil. Check visual acuity. Also check the scleral portion of the lens. As with the initial fitting, ensure that no vascular blood flow obstruction is occurring (blanching or vascular congestion). Check that no corneal touch is present. Instruct the patient on proper lens insertion and lens care. Also instruct the patient to start wearing the lens for two hours, and to increase lens wear time by an hour each day until a full wearing schedule is reached.

1-WEEK FOLLOW UP EXAMINATION

During the follow up examination, after one week of wear, recheck the scleral fit of the lens to again ensure that no vascular blood flow obstruction is occurring. Check to ensure no corneal touch is occurring as some lens set back has most likely occurred. The air bubble should be reduced in size from the initial lens dispensing and resemble the size of the air bubble during the initial fitting, with the fitting lens. Check visual acuity. Have the patient remove the lens and check the lens itself to make sure the patient is properly cleaning the lens and that the fenestrations are clean and clear. Carefully check the condition of the cornea using a slit lamp to ensure the cornea appears normal and healthy. If any abnormal corneal conditions are observed, have the patient discontinue wearing the lens and report the findings to the lab immediately.

TECHNICAL INFORMATION

Material: *Harmony Plus Dk 97.*

This material has a hydrophilic monomer blended into the matrix of the material.

This material provides excellent surface wettability along with high oxygen permeability.

Overall Lens Diameter: 18.50mm

Back Optic Zone Diameter (BOZD): 12.50mm

Lens	Back Optic Zone Radius (BOZR)	Scleral Zone Radius (SZR)	Power (PWR)	Sag
A1	6.80	13.75	-8.00	7.250
A2	7.00	13.75	-6.50	6.874
A3	7.30	13.75	-4.50	6.422
A4	7.70	13.75	-2.00	5.944
A5	8.00	13.75	+0.00	5.669
A6	8.40	13.75	+1.12	5.355
B1	6.80	14.50	-7.25	7.157
B2	7.00	14.50	-6.00	6.777
B3	7.30	14.50	-3.50	6.331
B4	7.70	14.50	-1.50	5.852
B5	8.00	14.50	+0.50	5.577
B6	8.40	14.50	+2.00	5.253
B7	8.80	14.50	+3.50	4.999
C1	6.80	15.25	-6.50	7.081
C2	7.00	15.25	-5.25	6.701
C3	7.30	15.25	-2.75	6.234
C4	7.70	15.25	-0.75	5.767
C5	8.00	15.25	+0.75	5.482
C6	8.50	15.25	+2.25	5.101
C7	9.00	15.25	+4.50	4.791

IMPORTANT

This lens is not fitted as per typical sealed scleral lenses. The air bubble is the most important factor in determining the appropriate BOZR and not the fluorescein pattern.

Select and fit a lens

Start with your selected fitting lens

If unsure, start with lens **B4**

Fit lens and allow to fill with patient's natural tear

Evaluate the fit

Administer fluorescein

Indication of blanching or vascular congestion

Yes

Select a fitting lens with a **flatter SZR**

No

Excessive standoff of the lens rim

Yes

Select a fitting lens with a **steeper SZR**

No

Corneal touching or too small/no air bubble present

Yes

Select a fitting lens with a **steeper BOZR**

No

Air bubble infringing on the pupil

Yes

Select a fitting lens with a **flatter BOZR**

Allow to sit on the eye for **30 minutes**

Good fit with crescent shaped air bubble present

No

Select another more appropriate fitting lens

Yes

Order the lens

Determine over refraction

Inform the Lab of fitting lens determined and over refraction required