EUROPA SCLERAL

UNIVERSAL FIT TECHNOLOGY

Fitting Guide

SPECTRUM INTERNATIONAL

TABLE OF CONTENTS

WHAT TO TELL SPECTRUM INTERNATIONAL

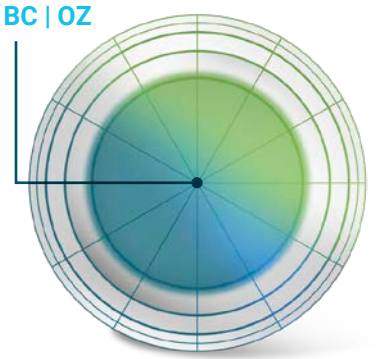
Throughout this Guide, we will be giving shortcut sections that summarize the information that is extremely beneficial to communicate to us, depending on your clinical findings and customization option(s) required.

Contact our Consultation Team at any time at sales@spctinternational.com

CLINICAL TIPS & PEARLS

This icon will indicate tailored troubleshooting tips from our experienced Consultation Team.

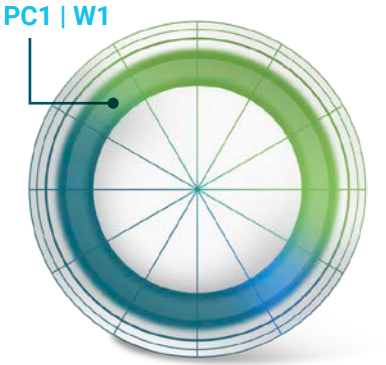
EUROPA SCLERAL DESIGN ZONES



CENTRAL ZONE

Base Curve (BC) / Optical Zone (OZ)

The BC parameter controls how much the lens vaults over the cornea and plays a primary role in the overall sag of the lens (although all curves play a part in the sag calculation). We label and communicate the BC (radius of curvature) in both diopters (D) and mm format, dependent on Practitioner preference. The posterior optical zone (OZ) is labeled in diameter (mm) and the anterior OZ houses the optics (power) of the lens.

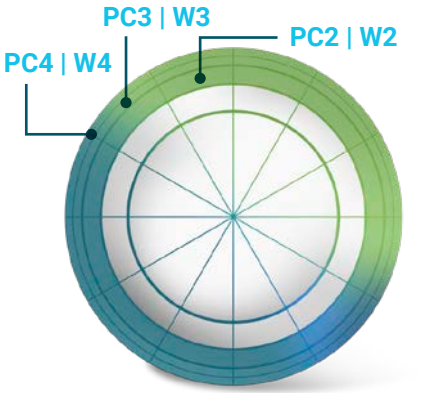


LIMBAL ZONE

Peripheral Curve 1 (PC1)
Peripheral Curve Width 1 (W1)

Mid-peripheral | Transition Zone

The Europa's PC1 reverse curve controls your limbal clearance and has a very direct relationship with the BC. Typically, they are modified together unless thin limbal clearance is observed. We label and communicate **the flat meridian** of PC1 in both diopter (D) and mm radius of curvature format. Unlike OZ, W1 (the width of the curve) is labeled in radius on either side in millimeters, not diameter.



SCLERAL ZONE

Curves: PC2, PC3, PC4
Widths: W2, W3, W4

Haptic | Landing Zone

We label and communicate **the flat meridian** of our peripheral curves in mm radius of curvature format. The Europa becomes progressively flatter as you move to the outer edge of the lens. Unlike OZ, W2 - W4 (the width of these curves) is labeled in radius on either side in millimeters, not diameter.

SCLERAL FITTING PROCESS
CENTRAL

OPTIMAL VAULT & LENS SETTLING

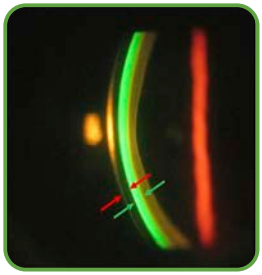
After initial application, the Europa Scleral, should completely vault the central cornea between 200 - 300 microns (µ). The lens will settle on average 100µ for an ideal vault between 100 - 200µ post-settling.

When possible, schedule your post-fit scleral evaluations later in the day.

Analyzing your patient's current fit after they have been wearing the lens for an extended period of time will allow you to see the fit 'at its worst' & better pinpoint what, if anything, needs adjusting. Minimal wear time should be 4 hours.

EVALUATION

Directly after lens application, check for insertion bubbles. The immediate presence of bubbles upon insertion usually does not indicate an improper fit but rather improper insertion technique. If they are present, remove immediately and reinsert. Allow the lens to settle for as long as feasible (at least 10-15 minutes if possible). Compare the thickness of the Europa Scleral lens (1) to the thickness of the fluid reservoir (2). Use your optic section view (white light) at a 45° angle. Use the Ferris State Scleral Lens Fit Scales as a reference tool for analyzing clearance. OCT Imaging can also be used to assess clearance (not required for scleral fitting).



Our patient (Rx) lenses default to a standard CT = 350µ; this is customizable upon request.

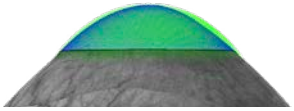
Our standard Europa Scleral Fitting Set has a CT = 400µ

LENS ADJUSTMENTS

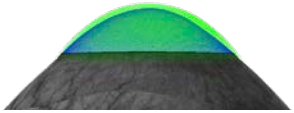
Steepening the BC increases the sag and corneal clearance of the lens. A change in the sag value will result in a 1:1 change in central clearance. Our Consultants typically modify BC & PC1 together unless limbal clearance is a concern or a reverse geometry design is required (in those cases, BC & PC1 are modified separately).

BC & PC1 Flattening/Steepening *[Consultation approximations]* **1 step = 1 Diopter (D)**	**50µ** | 1 step change in BC, only **50µ** | 1 step change in PC1, only **100µ** | 1 step change in BC & PC1

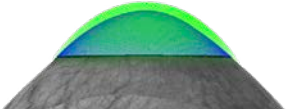
BC | PC1 (Too Flat)
1 STEP FLAT



BC | PC1 (Optimal)



BC | PC1 (Too Flat)
1 STEP STEEP



- *How much central clearance you want to gain or lose.*
- *If limbal clearance is thin or excessive.*
- *If the periphery is tight.*

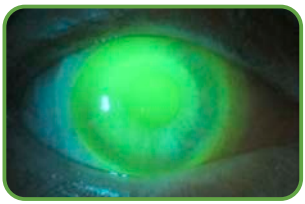
SEND PICTURES!

SCLERAL FITTING PROCESS
LIMBAL

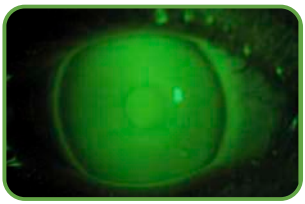
LIMBAL CLEARANCE - WHY IS IT IMPORTANT?

Stem cells are located in the limbal area and are crucial for corneal health - avoid bearing or pressure on the limbal area. Evaluating fluorescein patterns & using OCT (if available) are the best methods of trying to assess this hard to measure but important area.

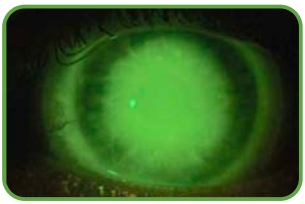
Good Limbal Clearance



Area of Limbal Touch



Poor Limbal Clearance 360°



LENS ADJUSTMENTS

For thin limbal clearance, the most effective adjustment is to widen W1. Since this PC1 reverse curve is our steepest curve, by widening it we improve clearance. Alternatively, we can steepen or flatten PC1; however, our Consultation Team does not find that to be as effective as increasing the width of that PC1 curve (W1). We typically recommend decreasing the diameter of the lens if the fit is exhibiting excessive limbal clearance.

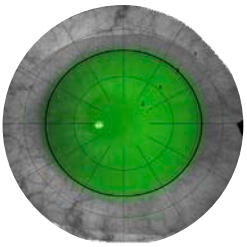
For thin limbal clearance, increase limbal curve width (W1)

Our Consultation Team typically increases W1 by 0.25mm (a 0.5mm diameter increase). While the Δ sag between the 2 lenses might be a little higher, you should effectively see 100μ central clearance increase.

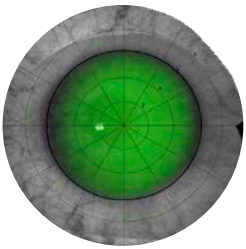
If you do not want to see a diameter increase, please contact our Consultation Department to discuss other options. We do see the best success when the diameter is increased slightly.

The simulated fluorescein images below depict optimal limbal clearance (left image) and thin limbal clearance with an approximate severity = moderate (right image). The resolution for the thin limbal clearance would be to increase W1 (with a resulting diameter increase).

OPTIMAL
Limbal Clearance



THIN
Moderate Severity



Limbus = black circle

- *What is your central clearance? We will compensate as needed.*
- *If limbal clearance inadequate, note severity (mild, moderate, severe).*
- *If you do not want diameter to increase.*
- *If the periphery is tight.*

SEND PICTURES!

SCLERAL FITTING PROCESS
SCLERAL

ASSESSING THE SCLERAL ZONE

Use a diffuse white light in low illumination to observe the haptic portion of the lens. The haptic should rest evenly on the sclera without compression or impingement. Avoid conjunctival blanching: localized areas of the conjunctiva surrounding the limbus can be 'whitened' because compression of the lens restricts blood flow. A well fit lens should semi-seal to the eye with little to no movement. The Europa's edges are designed to rest evenly on the conjunctiva and to avoid edge impingement (digging in). If the edge of the lens is too tight, it can focally pinch the conjunctival tissue. This can be observed via both slit lamp and OCT. The suggested adjustments below are for 360° findings. If your observations are in a single meridian, please see our Toric Haptics (p09) section.

For 360° tightness in the haptic

Our Consultation Team typically flattens PC2 & PC3 by 1 step. Note that you will LOSE approximately 100µ of central clearance; we will compensate as needed.

PC2 & PC3 Flattening Steepening

[Consultation approximations]

1 step = 0.5 (mm)

Δ 100µ central clearance =
1 step change in PC2 & PC3

- *What is your central/limbal clearance? We will compensate as needed.*
- *The severity of the blanching and compression (mild, moderate, severe).*

SEND PICTURES!

DIAMETER CHANGES

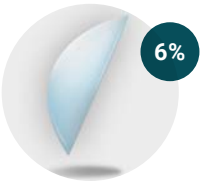
When increasing the diameter of a lens (typically using W1), the overall sag of that lens and central clearance will increase; when decreasing diameter, the sag and clearance will decrease. Note that there is no absolute and the expected change in clearance is usually 100µ; depending on the individual shape of the sclera and the specific lens parameters being modified.

Δ 0.5 (mm) in Diameter = 100µ increase/decrease clearance

TREATMENT OF ASYMMETRIC COMPRESSION, IMPINGEMENT, EDGE LIFT

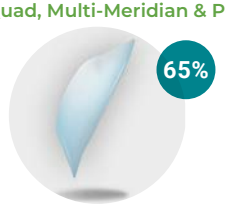
The sclera is not spherical in the majority of cases. Europa Scleral has analyzed more scleral topography data than any other contact lens manufacturer and has become leading experts in the field of scleral shape.*

SPHERICAL



TORIC
See Toric Haptics

ASYMMETRIC
See Quad, Multi-Meridian & P-Lift



* Qualitative Assessment of Scleral Shape Patterns The SSSG Study
J Cont Lens Res Sci Vol 1(1):12-22; November 16, 2017. © 2017

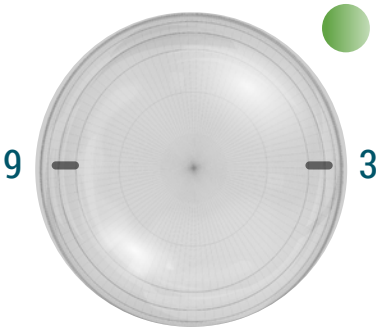
LENS MARKINGS
STEEP AXIS

Note where your hashmarks rotate to (clock hrs or degrees)

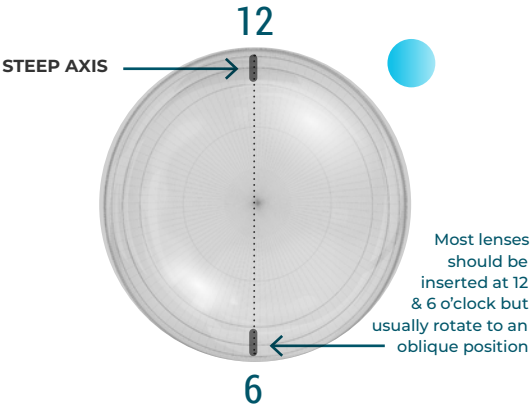
It is important to make note of and communicate if any rotation is observed.

This will be especially helpful if you incorporate front toricity at any point during the fit.

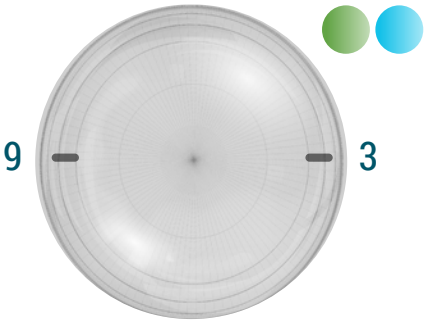
FRONT TORIC, ONLY



BACK TORIC (TPC), ONLY

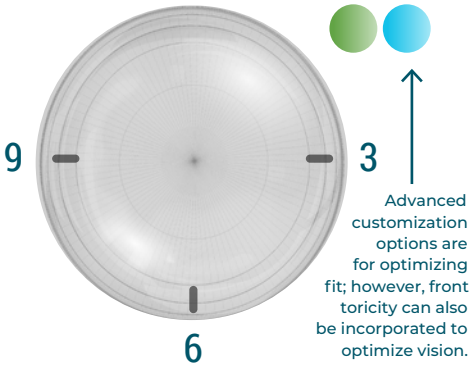


FRONT & BACK (TPC)



ADVANCED CUSTOMIZATION

Quad-Specific, Multi-Meridian, Precision Lift



Front Toricity | OPTICS FEATURE

Front surface toricity is utilized when astigmatism is measured with sphero-cylindrical over-refraction.

Back Toricity | FITTING FEATURE

Scleral toricity is integrated into the haptic (i.e. peripheral system/scleral zone)

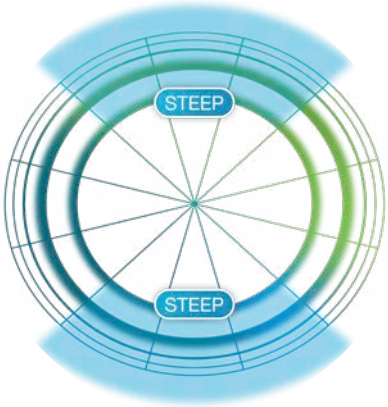
Amount of toricity in our lens designs increases as you move away from the limbus

You may request additional black or white drill dot(s) at 6 o'clock to make insertion and OD/OS differentiation easier.

SCLERAL ASYMMETRY
TORIC HAPTICS

TORIC HAPTICS - WHAT ARE THEY & WHY USE THEM?

What is a toric haptic? It is the steepening of one meridian compared to the other meridian that is 90° away (i.e. 12 & 6 o'clock steepened by 200µ compared to 3 & 9 o'clock). These are also referred to as toric peripheral curves or TPCs. Why do we use them? Simply put, we use them to better align the lens to the patient's sclera. **The advantages of adding scleral toricity when indicated include better patient comfort, elimination of edge lift, decrease in debris build-up under the lens (mid-day fogging), and increased lens stability.**



Don't assume you need TPCs on ALL PATIENTS

Unlike other labs, we do not recommend TPCs as a default on all fits. These should be incorporated based on clinical evaluation. The conjunctiva can be very forgiving. We see successful spherical fits every day!

Having said that, the potential advantages of toric haptics are numerous & include:

improved comfort | elimination of edge lift
elimination of mid-day fogging
elimination of bubbles | decrease in debris
increased lens stability

HOW TO USE TPC LENSES IN OUR FITTING SET

Our new comprehensive Europa fitting sets offer two levels of toricity: 200µ and 300µ. Our thorough and expansive analysis on scleral shape patterns showed an average of 200µ of scleral toricity in a standard patient population. If 200µ doesn't alleviate the blanching or edge lift, move up to the 300µ options.

Rotate & observe hashmarks

With a TPC lens on the eye, rotate the lens 30-60° & see if the lens rotates back into place. If yes, that is a good indication that the sclera is toric & TPCs are a great choice.

Start with spherical lens (5)
If isolated areas of blanching or edge lift, try 200µ (T2).
If unresolved, try 300µ (T5).

5 46 4660 -2.0

T2 46 4660 -2.0 200µ

T5 46 4660 -2.5 300µ

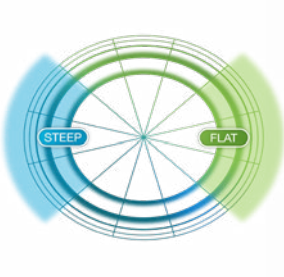
- *Describe what you are seeing and where (edge lift at 12 & 6 or blanching at 3 & 9).*
- ***IMPORTANT:** Let us know where the hashmarks settle.*
- *When in doubt, we recommend starting with 200µ of toricity and moving in 100µ steps (we can, however, make changes as small as 25µ microns based on Practitioner preferences).*

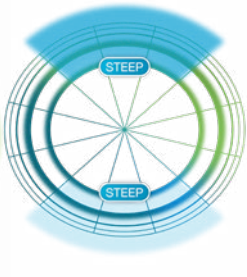
DID WE MENTION TO SEND PICTURES?

SCLERAL ASYMMETRY
QUADRANT & MULTI-MERIDIAN

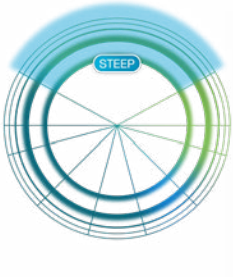
Our Multi-Meridian option is our most advanced option and encapsulates both quadrant-specific and multimeridian lenses (no limitations to the standard 90° quadrants). When toric haptics do not resolve periphery fitting issues, often due to asymmetry within a meridian, the next step is to explore the option that allows for independent adjustments in the haptic.

QUADRANT-SPECIFIC





MULTI-MERIDIAN



If the lens exhibits **asymmetric tightness (compression)**, our Consultation Team will flatten the quadrant (decreasing sag of that area).

If the lens exhibits **asymmetric lift (edge lift)**, our Consultation Team will steepen the quadrant (increasing sag of that area).

Severity Scale and correlating micron (µ) adjustment

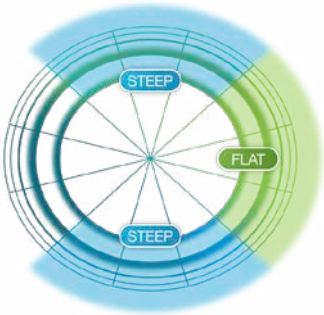
MILD (+/- 200 µ) | MODERATE (+/- 300 µ) | SEVERE (+/- 400 µ) | OTHER (customized)

Modification should be made in 50µ steps (minimally 25µ, by Practitioner request only).

- *If the current (or Dx) lens has scleral toricity incorporated, confirm where the hashmarks are located once the lens is allowed to settle.*
- *Which quadrants you need adjusting,whether they need to be flattened or steepened and note severity.*

Where are we seeing these used most successfully?

Our Consultation Team can use our Multi-Meridian technology to greatly improve decentration, which is inherently evident in scleral lens fitting. We have also been incorporating quad-specific flattening into the nasal quadrant in addition to an already existing TPC (steepening superior & inferior quadrant, flattening nasal). The possibilities are endless!



**this example is based on a right eye (OD)*

SCLERAL OBSTACLES
NOTCH & PRECISION LIFT

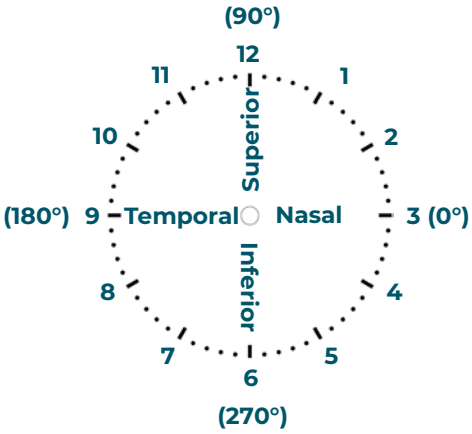
We offer two different methods of addressing scleral obstacles - you can either vault over (Precision Lift) or go around (Notch) scleral obstacles of any shape or size. Notching & Precision Lifts are helpful when patients have conditions such as pingueculas, pterygiums, and conjunctival blebs for glaucoma management. Choosing which option to utilize is Practitioner and Patient dependent. Our Consultation Team has seen great success using either. Our Precision Lift technology is one of our newer and most advanced options.

NOTCH
Around the Obstacle

PRECISION LIFT
Vault Over the Obstacle

Here is what we need to know to optimally design these scleral obstacle-related customizations. (All of the below items can be provided in either degrees or clock hours):

- *If the current (or Dx) lens has scleral toricity incorporated, confirm where the hashmarks are located once the lens is allowed to settle.*
- *Location of the area that needs to be notched around or lifted over an elevation.*
- *Width of the area that needs to be notched around or lifted over an elevation. When estimating, 30° is a good starting point.*
- *Depth of the area that needs to be notched around or lifted (how far into the lens, usually in mm).*
- *Estimation of how high the elevation is that the Precision Lift is vaulting over. Precision Lift only - when estimating, 200µ is a good starting point.*



*this example is based on a right eye (OD)

Send pictures or sketches!

No judgement will be made on your artistic ability.

Why is our Precision Lift unique?

We can elevate all the way into the midperipheral or limbal zone (through PC1). Other scleral lens manufacturers are limited to the edge of the lens when vaulting.

We can also do multiple Precision Lifts on one lens. A more common example of utilizing two Precision Lifts would be the presence of both nasal and temporal pinguecula.

OPTICAL PERFORMANCE
POWER, TORICITY & PRESBYOPIA

FINAL POWER CALCULATION

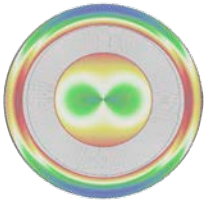
Spectrum International strongly recommends that you allow us to calculate the final power by providing us with the overrefraction. Keep in mind that both vertexing and Base Curve (BC) compensation is required to correctly calculate a final power. Vertex conversion occurs at +/- 4 sphere and for every change in BC of 1D, there is a corresponding change in sphere of the lens. The SAMFAP rule can be utilized - steep add minus, flat add plus. The good news is that we will take care of all of that for you! If we are provided with a 'Final Power' only, it is assumed that the Practitioner has completed these adjustments.

Double vision

We will typically increase the size of the front optic zone (OZ) to eliminate double vision symptoms (assuming good overall fit).

Lens surface deposits

Check and optimize lens care and cleaning regimen. Check and treat OSD (lid care regimen, etc.); Consider adding Hydra-PEG™ coating.



DOUBLE SLAB-OFF

FRONT TORICITY

Not only is the Europa available with astigmatic correction (front toric) but you can also integrate front toricity with back toricity (TPC, Quad/Multi- Meridian, or Precision Lift) and even add a presbyopic correction on top of that. Astigmatic corrections can only be applied to rotationally stable lenses. For lenses with front toricity only (spherical back surface), we use a double slab-off ballasted design for stability.

Recommended steps for ordering a Front & Back Toric Lens

- *Finalize the fit of the back surface of the lens first. If you have one of our newer Dx sets, utilize the TPC lenses as needed to confirm whether back toricity is required.*
- *If your patient's fit has any form of scleral toricity incorporated (from TPC to our advanced customization options), NOTATE WHERE THE HASHMARKS SETTLE (see **Lens Markings** (p7). Please allow as much time as possible for the lens to settle before evaluating final position.*
- *Perform sphero-cylindrical over-refraction and evaluate for any lens flexure.*

- ***IMPORTANT:** let us know where the hashmarks settle on any back toric lenses.*
- *The sphero-cylindrical over-refraction.*

PRESBYOPIA

Our presbyopia option is designed to offer simultaneous near and distance vision. It is a concentric bifocal design with a near or distance center. We default to a 2.0mm center zone; however this is customizable. See Parameters (p 15) for more information on this fully customizable option.

- *Add powers requested & dominant eye.*
- *Any requested modifications to the center zone size.*

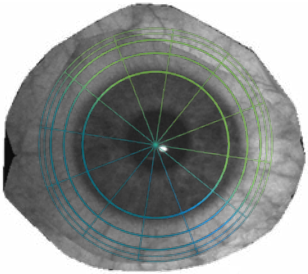
FAQS - Q&A

DO I NEED AN SMAP3D™ SCLERAL TOPOGRAPHER TO SUCCESSFULLY FIT THE EUROPA SCLERAL?

No. We are learning so much about scleral shape and informing our design and remake process with the data that we collect and analyze. Whether you own an sMap3D™ or not, you and your patients benefit from this vast store of knowledge.

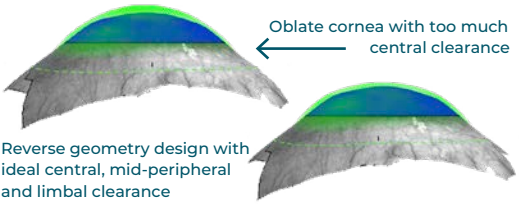
Is it an amazing instrument? Absolutely. The sMap3D™ provides invaluable data such as the sag of the eye and the exact amount & location of scleral toricity. It also helps us make incredibly informed and quantitatively-driven customized lenses - namely Multi-Meridian and Precision Lift designs. While our advanced customization is available on all Europa lenses, scleral topography data is helpful, to say the least.

Throughout this guide, you will notice the use of sMap3D™ enhanced visual assessment tools, including virtual fluorescein simulations and 3D lens elevation views showing the Europa lens over the eye.



WILL ALL OF MY VISIONARY OPTICS LENSES BE COMPLEX OR INVOLVE AN ADVANCED LEVEL OF CUSTOMIZATION?

No. Our scleral lenses offer a unique combination: they're user-friendly and straightforward to fit, but also come with the most advanced customization options available. We are firm believers in not overcomplicating what can already be a complex fitting process. Unless topography data or clinical observation/experience warrant it, our team will always suggest a more conservatively designed lens to begin with. But when needed, our design features, backed by data and experience, can help you solve the most challenging fits-ones that could not be resolved with previous lens designs.



DOES VISIONARY OPTICS HAVE A SPECIFIC OBLATE EUROPA LENS DESIGN?

This is not necessary. Our Europa Scleral lens has been uniquely designed to fit a wide variety of corneal and scleral geometries. Multiple fitting sets are not needed to separately fit oblate and prolate corneas, as is often the case with other scleral lens designs. Simply apply the flattest lens in the fitting set that will give you the best central clearance possible. Our Consultation Team can then manipulate the BC & PC1 relationship to obtain an optimal fit on an oblate cornea. As always, send pictures!

CLEANING, CARE, & STORAGE

PREPARING PATIENT (RX) LENSES FOR PATIENT FITTING

Our patient lenses are shipped in approved GP multipurpose solution, depending on the material that is specified on each individual order. Since these are not shipped sterile, we recommend cleaning and rinsing them prior to insertion. Remember to only use approved solutions for lenses that are coated with Hydra-PEG™ technology (no enzymatic, abrasive or alcohol-based cleaners).

PREPARING DIAGNOSTIC (DX) LENSES FOR PATIENT FITTING

Our Europa Scleral Fitting Set lenses are shipped dry. The lenses need to be thoroughly cleaned and conditioned before use for patient fitting. Conditioning will ensure the lens wets well, which is particularly important for over-refraction purposes. Use a GP conditioning solution and rub the surface of the lens really well in the palm of your hand. Be liberal with the solution and try to spend at least a few minutes rubbing the lens. If you are still experiencing wettability issues, utilize an extra strength GP cleaner (example: Lobob Optimum Extra Strength cleaner) followed by rubbing the surface with the conditioning solution.

Tip: Squeegee Method

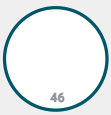
Once you have evaluated the fit and are preparing to over-refract, consider using either the edge of a DMV remover or a Q-Tip to 'squeegee' the front OZ (center) of the lens if you see beading of solution/tears on the front surface. Put a drop of solution on the DMV or Q-Tip and gently rub the front of the lens. A Weck-Cel® sponge (or similar product) also works well.

CLEANING & CARE PROTOCOL FOR DIAGNOSTIC (DX) LENSES

After use, we recommend utilizing a hydrogen peroxide system. Follow the directions for the care system being utilized. Once disinfected and cleaned, lenses should be thoroughly dried prior to being placed back into the Dx packaging. You can always verify lenses prior to placing them back into the set by checking the BC and TPC (if any) laser marks that are located at the edge of the lenses. Alternatively, you can store your lenses in a conditioning solution. However, please ensure you have a process in place to guarantee appropriate cleaning and replacement of solution.

SPHERICAL LENSES 1 - 14
TORIC HAPTIC LENSES T1-T6

46(7.34) — Base Curve D (mm)
4660 — Sag (µ)
-2.0 — Sphere Power (D)
200µ & 300µ — Toric haptic (µ)
STEEP AXIS marking



-2: 200 -3: 300

We lasermark the Base Curve (D) and Toric Haptic (µ) on all Dx lenses.

PARAMETERS, INSTRUCTIONS FOR USE, & RESOURCES

ADVANCED CUSTOMIZATION WITH NO LIMITATIONS

Full Customization | Base Curve, Sag, Power, CT, Peripheral Curves
Toric Haptic | Up to 800µ in 25µ steps
Diameter | 15.0 - 22.0mm
Material | Full range of material (Dk 100+)
Plasma | All lenses are plasma-treated
Hydra-PEG | Tangible Hydra-PEG™ available upon request
Presbyopia Add Power | +1.00 to +3.50D in 0.50D steps
Presbyopia Add Zone | 2mm near (or distance) center zone 1.0 to 3.5mm in steps of 0.5mm

FDA 510(K) CLEARANCE INDICATION FOR USE STATEMENT

The Europa Scleral Contact Lens for daily wear is indicated for use for the management of multiple ocular conditions, such as degenerations that lead to an irregular corneal shape (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's Nodular Degeneration), dystrophies (e.g. Cogan's dystrophy, Granular Corneal Dystrophy, Lattice Corneal Dystrophy), post-surgery (e.g. corneal transplant, LASIK, radial keratotomy), and corneal scarring from infection or trauma.

The Europa Scleral Contact Lens for daily wear is also indicated for therapeutic management of ocular surface disease including dry eye (e.g. ocular manifestations of Graft-versus-Host disease, Sjogren's syndrome, dry eye syndrome), limbal stem cell deficiency (e.g. Stevens-Johnson syndrome, chemical and thermal burns, radiation, filamentary keratitis), epidermal ocular disorders, disorders of the skin (e.g. atopy, ectodermal dysplasia), neurotrophic keratitis (e.g. Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g. anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for distorted cornea or ocular surface disease, the Europa Scleral Contact Lens may incidentally provide correction of refractive error in persons with myopia, hyperopia, astigmatism or presbyopia.

Eye care practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

WE ARE DESIGNING YOUR SCLERAL SUCCESS TODAY

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