

1-2-3 FIT GUIDE & LENS DESIGN OPTIONS



Atlantis™
SCLERAL



Image courtesy of: Dr. Edward Carmona, Venezuela

Contact X-Cel Specialty Contacts Customer Service to order replacement fitting set or patient supplies*.

Preservative-free single use saline

Application and Removal DMV's

Fluorescein Strips

Patient Care Guides

In-Office Patient Brochures with Holder

*Supplies are only available for U.S territories.

This product is not sterile; prior to fitting your patient, clean and disinfect the selected lens according to the appropriate lens care regimen. The contact lens should always be inspected before being placed on the eye to ensure edge integrity.

Voluntary or involuntary exposure to extreme heat could damage or warp the contact lens.

Label Symbol definition:

	Manufacturer
	Device Identifier
	Product Identifier
	Consult instructions for use

Reporting of adverse reactions: All serious adverse experiences and adverse reactions observed in patients wearing the daily wear RGP contact lens(es) should be reported immediately to:

X-Cel Specialty Contacts

2775 Premiere Pkwy Ste. 600

Duluth, GA 30097

Telephone: 800.241.9312

Or to the material manufacturer detailed in your package insert.

Rx only. Please read the complete package insert for indications, instructions for insertion, removal, cleaning and maintenance of lens case, contraindications, warnings, precautions, known adverse reactions, side effects and instructions on actions to be taken when a problem occurs.

Package inserts can be found at xcelspecialtycontacts.com.

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PATIENT APPLICATIONS

- Keratoconus
- Post Surgical
- Pellucid Marginal Degeneration
- Dry Eye Syndrome*/Corneal Surface Disease
- Stevens-Johnson Syndrome
- Intolerance
- Keratoglobus
- Astigmatism
- Post-corneal Transplant
- Sjögren's Syndrome
- Graft versus Host Disease
- Presbyopia
- Corneal GP and Soft Lens

The following materials marked with an * are indicated for the management of dry eye disease. Material indication data was obtained and it is available from the material manufacturer package insert.

LENS PARAMETERS

Base Curve	6.50 to 9.12 mm
Diameter	14.0 to 17.5 (in 0.5 steps)
Power	+20.00 to -20.00D in 0.25D steps
Central Sagittal Depth Adjustment	Up to 200 microns decrease (in 25µm steps) Up to 200 microns increase (in 25µm steps) This will not affect the other 2 zones
Limbal Vault Zone	Up to 200 microns decrease Up to 200 microns increase Quadrant specific control
Scleral Zone	1 flat to 8 flat, 1 steep to 8 steep in 25µm increments
Toric Scleral Zone	Bi-meridian control Quadrant specific control
Cylinder Power	-0.75D to -5.00D in 0.25D steps
Axis	0 to 180°
Multifocal Distance Zones	3.6, 4.0, 4.4
Multifocal Add Power	+0.75D to +4.00D
Materials	Optimum Extra*, Optimum Extreme*, Optimum Infinite, Boston XO*, Boston XO2*, and Paragon HDS NOTE: Materials with an asterisk (*) are indicated for the management of dry eye disease.
Warranty	Unlimited exchanges and cancellation within 120 days of original invoice.
Tangible Hydra-PEG	Recommended for all design options and available materials.
PlasmaEYEZ	All Atlantis lenses are plasma treated free of charge.

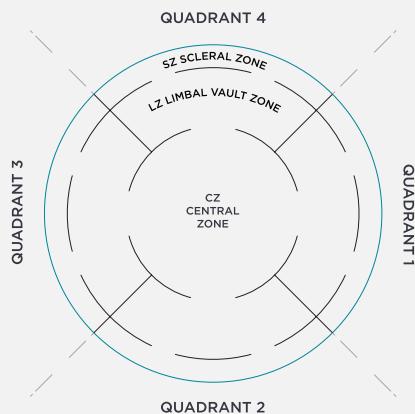
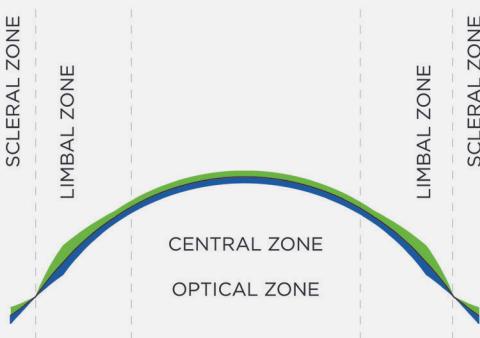
EASE OF FIT WITH THREE ZONES

The Atlantis scleral design has 3 truly independent zones.

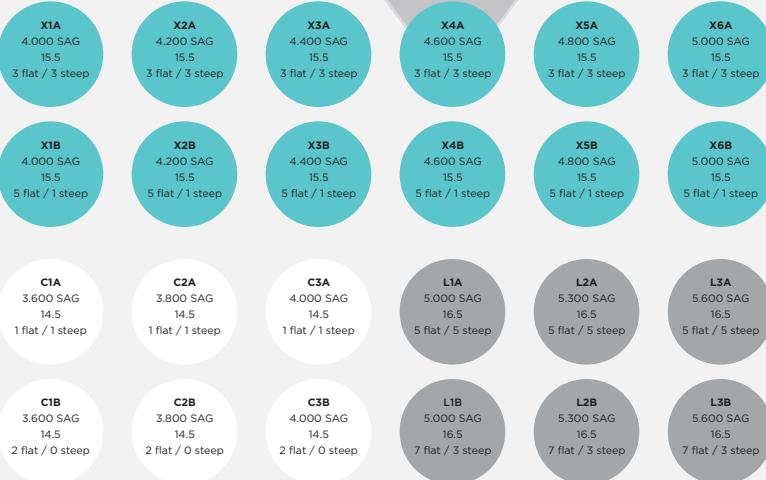
Central Zone- This is the optic zone and increases with a diameter increase. On the 15.5 the optic zone is an 8.5. Each individual central SAG can be increased or decreased by a total of 200 microns in 25 micron steps. This will not affect the other 2 zones.

Limbal Vault Zone –This zone extends from the outside of the central zone to the inside of the scleral zone and the width of this zone is consistent with each diameter. The SAG of this zone can be increased (up to 200 **microns**) or decreased (down 200 microns) with no effect on the other 2 zones. The highest point of this zone can also be adjusted out towards the edge of the lens or in towards the optic zone of the lens. Changes are made in 25 micron steps.

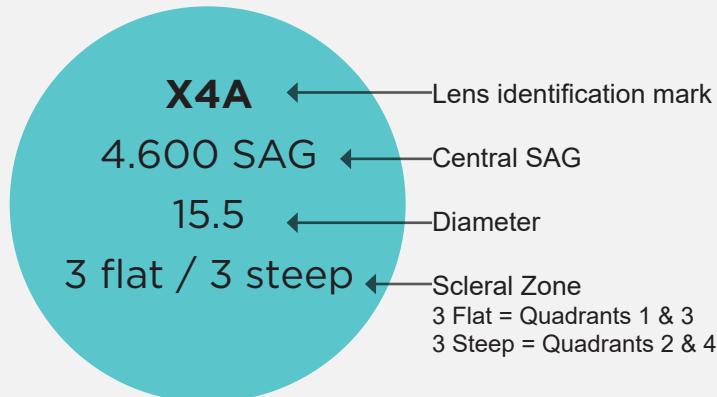
Scleral Zone – This is the edge of the lens and is roughly 1mm wide. This zone can be manipulated to increase or decrease the SAG of just this zone by 200 microns in each meridian or any quadrant. The changes are done in 25 micron steps and will not affect the central zone SAG or the limbal zone SAG.



FIT SET AND MARKINGS



Vial Cap Label



Other lens information is on the vial label.

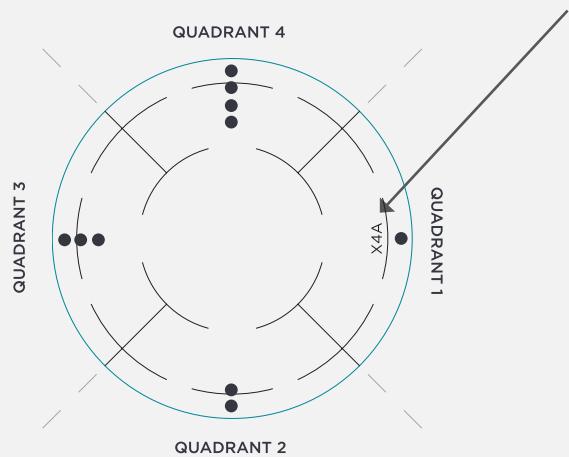
FIT SET AND MARKINGS

Diameter	SAG	Total Toricity of Scleral Zone	LENS 1		LENS 2	
			Power	CT	Scleral Zone	Scleral Zone
* 15.5	4.000	0.150	-3.00	0.300	3 flat / 3 steep X1A	5 flat / 1 steep X1B
* 15.5	4.200	0.150	-3.00	0.300	3 flat / 3 steep X2A	5 flat / 1 steep X2B
* 15.5	4.400	0.150	-3.00	0.300	3 flat / 3 steep X3A	5 flat / 1 steep X3B
* 15.5	4.600	0.150	-3.00	0.300	3 flat / 3 steep X4A	5 flat / 1 steep X4B
* 15.5	4.800	0.150	-3.00	0.300	3 flat / 3 steep X5A	5 flat / 1 steep X5B
* 15.5	5.000	0.150	-3.00	0.300	3 flat / 3 steep X6A	5 flat / 1 steep X6B
14.5	3.600	0.050	-3.00	0.300	1 flat / 1 steep C1A	2 flat / 0 steep C1B
14.5	3.800	0.050	-3.00	0.300	1 flat / 1 steep C2A	2 flat / 0 steep C2B
14.5	4.000	0.050	-3.00	0.300	1 flat / 1 steep C3A	2 flat / 0 steep C3B
16.5	5.000	0.250	-3.00	0.300	5 flat / 5 steep L1A	7 flat / 3 steep L1B
16.5	5.300	0.250	-3.00	0.300	5 flat / 5 steep L2A	7 flat / 3 steep L2B
16.5	5.600	0.250	-3.00	0.300	5 flat / 5 steep L3A	7 flat / 3 steep L3B

*This group of lenses make up the 12-lens fitting set.

Fitting Set Markings

Lens identification marking



RECOMMENDED STARTING POINT

The Atlantis design provides customizable zone options to provide a simple, streamlined fitting process that reduces chair time. A single fitting set will provide the necessary coverage to fit any corneal SAG or scleral shape.

When using the diagnostic kit to fit the Atlantis scleral lens, we recommend (regardless of K readings or condition) starting with the "X4A" lens.

15.5

X
Starting
point

This is the lens that will be most appropriate for most applications where scleral lenses are used.

Lenses in the 15.5 size provide a wide range of clearance and edge fitting options to handle the majority of cases.

Oblate corneas | Irregular corneas | Normal corneas with larger HVID > 11.5 needing more limbal clearance

14.5

C
Compact

The ideal lens for patients who would benefit from a slightly smaller lens design.

Normal corneas | Presbyopic patients | Smaller than average corneas with HVID < 11.5 | Tight lids or small fissures

16.5

L
Large

A great lens size to move to when the 15.5 Dia. lens is not adequate to fit pronounced corneas.

More SAG than the 15.5 will provide | Extra-large HVID needing limbal clearance

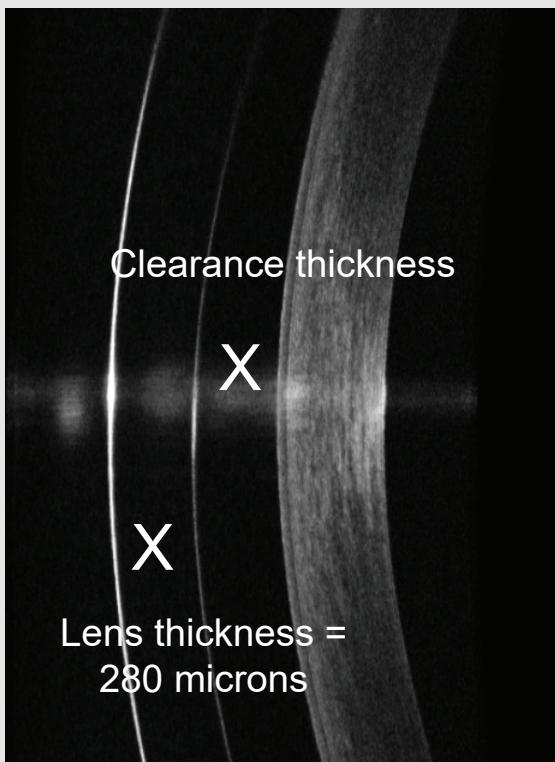
FITTING & CENTRAL ZONE EVALUATION

- a. Apply the diagnostic lens with non-preserved saline and **fluorescein**.
- b. Using the CLS evaluation process
(Central - 1, Limbal - 2, Scleral - 3)



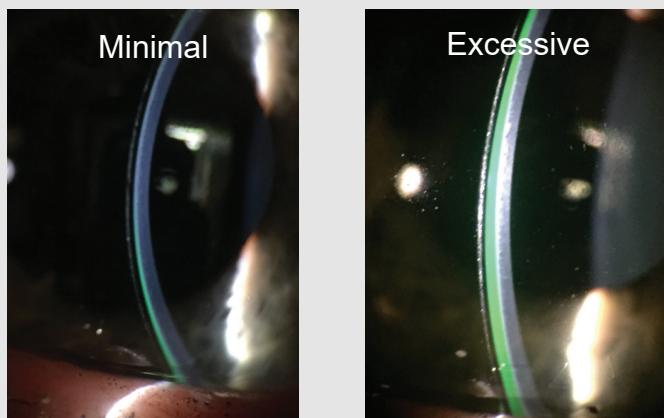
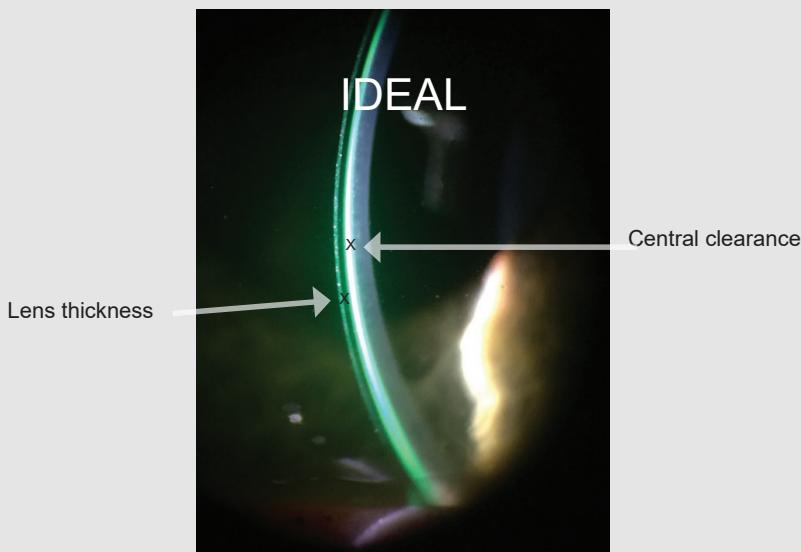
The ideal fitting relationships are:

1. CZ - completely vault the cornea, approximately 200 to 400 microns of clearance over the most elevated portion of the cornea. A decrease in clearance will occur with wearing time (loss can range from 50 - 150 microns).



FITTING & CENTRAL ZONE EVALUATION

To evaluate approximate clearance, compare the clearance to either the corneal thickness or the lens thickness (lens thickness is represented on the lens vial). Example: .28 thickness = 280 microns.



For issues see Troubleshooting in the appendix.

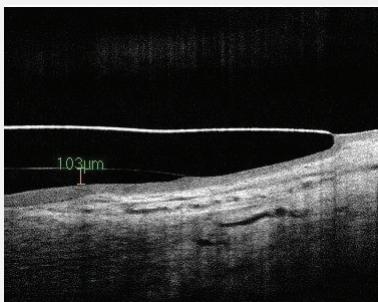
FITTING & LIMBAL ZONE EVALUATION

2. Limbal Vault Zone - completely vault the limbus. Avoid limbal touch while keeping clearance at a minimum (approx 100 mm of clearance)

Small, stagnate bubbles may be acceptable in the Limbal Vault Zone and may resolve over time.



Limbal Vault



OCT Limbal Vault

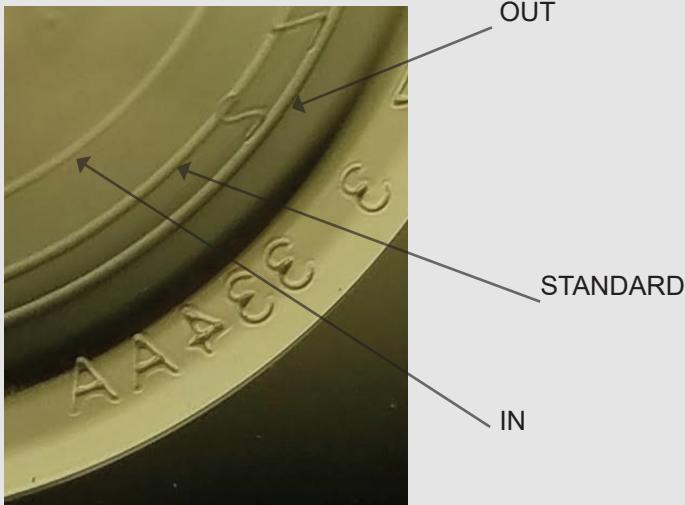


Insufficient Limbal Vault

LIMBAL VAULT OPTIONS

This revolutionary enhancement allows the limbal sag apex to be adjusted in/out or up/down, optimizing mid-peripheral clearance.

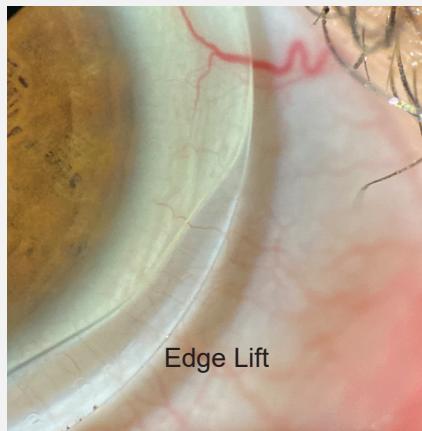
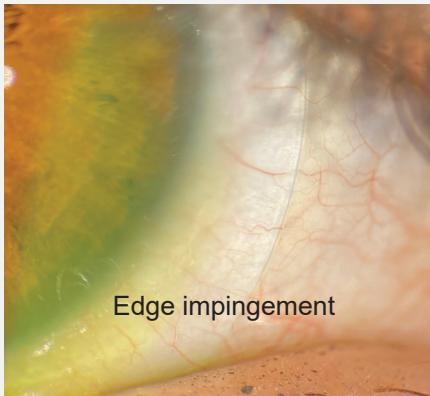
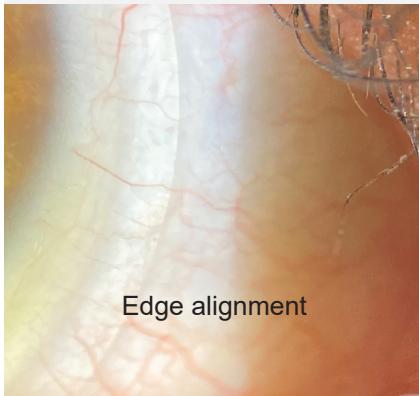
This design feature allows custom enhancements for multiple corneal conditions, such as; oblate (post myopic lasik, RK, etc...) and prolate (ectasias, trauma, etc...). This design feature can be fit utilizing the standard Atlantis fit set.



FITTING & SCLERAL ZONE EVALUATION

3. Scleral Zone - uniform alignment 360°

Look for disruption of vessels at the edge, blanching, impingement, and/or edge lift.



ASYMMETRIC SCLERAL ZONES

Studies have shown that as you move further away from the limbal area, the sclera often has more toricity and in some cases quadrant asymmetry.

With the Atlantis design, you have the ability to adjust the scleral zone by quadrant to better align with the sclera. Whether the scleral shape is with the rule, against the rule or oblique, the laser marks will align with the steeper of the two meridians.



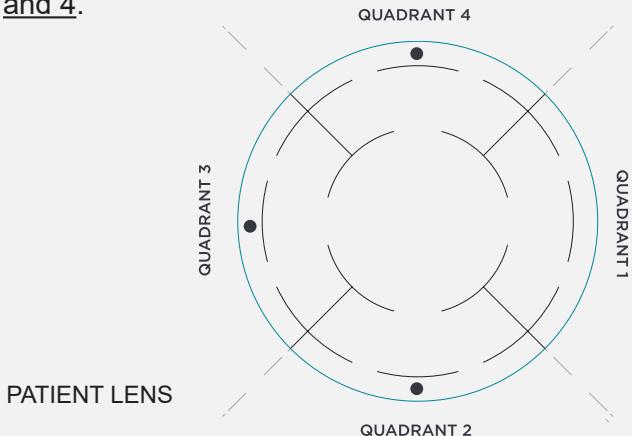
Inferior edge standoff



Nasal blanching

Images on this page are courtesy of Buddy Russell, COMT, FCLSA, FSLs

For toric or quadrant specific scleral zones, patient lenses will be marked with three dots always representing quadrants 2, 3, and 4.



FLEXURE & RESIDUAL ASTIGMATISM

It is best to determine if the residual astigmatism is due to any lens flexure prior to ordering front toric optics.

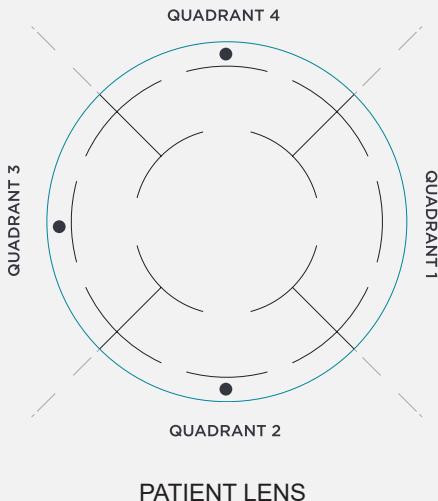
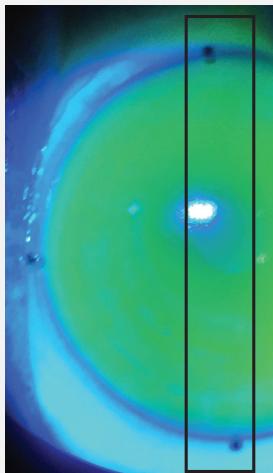
Determine if lens flexure is present. With the scleral lens on the eye, simply perform keratometry or topography. If keratometric readings (or Sim K) are NOT spherical, increase the center thickness by .10 and stay with spherical optics.

If trial lens on eye shows residual cylinder of 0.75D or greater and does not have a toric scleral zone, order spherical equivalent lens with the following amount of scleral toricity:

- 14.5 start with 50 microns of toricity
- 15.0 start with 100 microns of toricity
- 15.5 start with 150 microns of toricity
- 16.0 start with 200 microns of toricity
- 16.5 start with 250 microns of toricity

If trial lens or patient lens has a toric scleral zone and residual cylinder is still greater than 0.75D:

- o Use slit lamp reticule to determine steep meridian axis
- o Quadrants 2 and 4 marks steep meridian



FRONT TORIC CALCULATION

1. Call Consultant with steep meridian axis, over refraction, and trial or patient lens information for final lens parameters.
2. Use the following examples to determine final lens power.

Algorithm for calculating cylinder axis on lenses:

A = Over refraction axis (x130 in example below)

B = Steep axis of scleral (x20 in example below)

Example 1 - If A - B is positive, then lens cylinder axis = A - B (130 - 20)

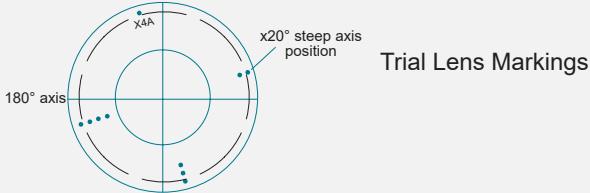
Example 2 - A - B is negative, then lens cylinder axis = 180 + A - B (130 - 150)

Example 1:

Over refraction: -3.00 -1.50 x130

Steep axis x20 = -3.00 -1.50 x130 - x20

Final lens power and axis = -3.00 -1.50 x110



LARS: Left Add, Right Subtract

Evaluating from the 0/180 meridian, determine steep meridian (Quadrants 2 and 4) using slit lamp reticule.

Using LARS method, each clock hour represents 30 degrees.



FRONT TORIC CALCULATION

Example 2:

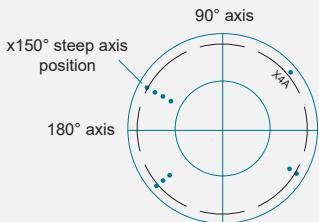
If OR axis is less than steep axis

OR -3.00 -1.50 x130

Steep axis after settling from reticule measurement x150

-3.00 -1.50 x (180 + (130 - 150))

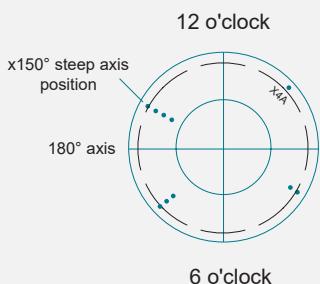
Final lens power and axis = -3.00 -1.50 x160



LARS: Left Add, Right Subtract:

Evaluating from the 0/180 meridian, determine steep meridian (Quadrants 2 and 4) using slit lamp reticule.

Using LARS method, each clock hour represents 30 degrees



Lens rotated 30° to the left.

OR -3.00 -1.50 x130

Left Add

130 + 30 = 160

The steep axis marks on the lens should be in the exact same position as those of the first diagnostic lens. LARS is used to eliminate the axis misalignment resulting from lens rotation and NOT TO ELIMINATE THE ROTATION.

ATLANTIS MULTIFOCAL

The Atlantis also offers a center distance scleral lens **multifocal** option. No additional diagnostic kit is needed. The only additional parameters to determine is the distance zone diameter and add power. The bi-aspheric multifocal design does not alter the fit of the lens as the sagittal depth is unchanged compared to the single vision Atlantis lens.

Three different distance zone diameters are available:

4.4 mm, 4.0 mm, 3.6 mm

Fitting the Atlantis Scleral Multifocal

1. Determine the dominant eye.
2. Determine pupil diameter under normal lighting conditions.
3. Standard distance zone is 4.0 mm. For larger pupil diameters order the 4.4mm and smaller diameters 3.6mm.
4. Order add power determined by refraction.

Pointers for achieving best vision in the Atlantis Multifocal:

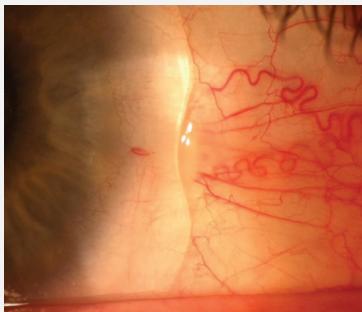
1. Desires better distance vision.
- change distance zone of dominant eye only to 4.4mm
2. Desires better near vision.
- change distance zone of non-dominant eye only to 3.6mm
3. Desires BEST distance vision
- use 4.4 mm OU
4. Desires BEST near vision
- use 3.6 mm OU

CONJUNCTIVAL ELEVATIONS

For those patients with a scleral elevation such as a conjunctival bleb, pinguecula, or pterygium, a final fit lens can be “notched” around the conjunctival irregularity.

Lens design options:

- *Smaller diameter that lands before the elevation
- *Larger diameter to completely vault the elevation
- *Lens Notching



Dr. Luis Noriega



Dr. Mauricio Pulido

Determining the size of a lens notch is optimized by sending a picture to our consultation team. Physically marking the lens with a sharpie marker or estimating the depth and width in millimeters can also be utilized.

DISPENSING VISIT AND FOLLOW-UP EVALUATION

Dispensing Visit

Patient should wear lenses for a minimum of 45 - 60 minutes prior to evaluation. Instruct application and removal, provide appropriate care system, care instructions and discuss increasing wearing time.

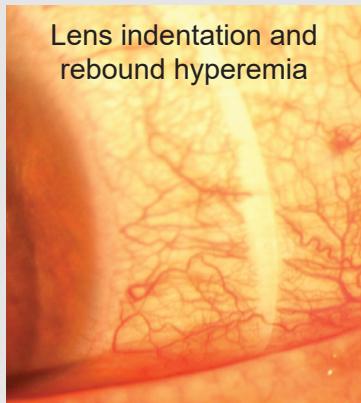
At the dispensing visit be sure to discuss warnings and precautions while referring the patient to the package insert and patient instructions for use.

Lens movement will be minimal (similar or less than a soft lens) and there will be very little tear exchange behind the lens.

1. Have patient arrive for follow-up preferably mid-morning to mid-afternoon after applying lenses in the morning.
2. Questions to patient:
 - a. How many hours a day are you wearing the lenses?
 - b. How is the comfort throughout the day?
 - c. How is your vision throughout the day?
 - d. Upon removal is there any discomfort or redness?
3. Determine if adequate central and limbal clearance is present with high magnification and optic section illumination and white light (or OCT).

DISPENSING VISIT AND FOLLOW-UP EVALUATION

4. For scleral zone evaluation determine if blanching is present. Evaluate edge clearance (none/adequate/excessive) in all meridians.
5. Remove the lens and evaluate the ocular surface for ocular insult.



Recommended Follow-up Visit Schedule

- 2 weeks
- 1 month
- 3 months
- 6 months
- **1 year

**It is recommended that scleral lenses be replaced on an annual basis.

TROUBLESHOOTING

Observation	Plan
Impingement Blanching (at the edge)	<ul style="list-style-type: none"> - Determine Quadrant and flatten SZ 1 step (25µm) accordingly - Circular – Flatten all quadrants by 1 step (25µm)
Compression Blanching (inside the edge)	<ul style="list-style-type: none"> - Determine quadrant and steepen SZ 1 step accordingly (25µm) -Larger lens diameter
Edge Lift	<ul style="list-style-type: none"> - Determine quadrant and steepen SZ 1 (25µm) step accordingly - Circular – Steepen all quadrants 1 step (25µm)
Excessive lens movement	<ul style="list-style-type: none"> - Steepen entire SZ by 1 step (25µm) - Increase diameter
Inferior Decentration (common and acceptable if mild)	<ul style="list-style-type: none"> - Increase SZ toricity by 1 step (25µm) in each meridian - Increase lens diameter by .5mm
Limbal bearing	<ul style="list-style-type: none"> - To the edge -steepen LZ by 2 steps (50µm) and OUT position - All other areas steepen the LZ by 2 steps (50µm) <p>*Quadrant specific changes available through consultation</p>
Paracentral bearing	<ul style="list-style-type: none"> - Outside OZ - Steepen LZ by 2 steps (50µm) and the IN position - All other areas steepen LZ by 2 steps (50µm) <p>*Quadrant specific changes available through consultation</p>
Residual astigmatism	<ul style="list-style-type: none"> - Refer to front toric section of fitting guide

TROUBLESHOOTING

Observation	Plan
Debris/Cloudy in tear/saline layer	<ul style="list-style-type: none"> - Reduce CZ clearance if excessive (25μm per step) - Increase SZ toricity by meridian or quadrant - Decrease LZ if clearance is excessive - Address solution use and cleaning process with patient
Lens discomfort	<ul style="list-style-type: none"> - Check for SZ lift and steepen by 1 step (25μm) in each quadrant - Check for limbal area clearance and steepen LZ accordingly - Possible limbal obstruction-refer to lens notching section - Add Tangible Hydra-PEG
Blurry vision (under achieving BCVA)	<ul style="list-style-type: none"> - Check surface quality - If lens build-up order with Tangible Hydra-PEG - Check for lens flexure with Over Ks or Topography
Bubbles under lens	<ul style="list-style-type: none"> - Check for proper application process - Flatten CZ vault (25μm steps) - Check for edge lift by quadrant and steepen by 1 step accordingly
Desires better distance vision	<ul style="list-style-type: none"> - Change distance zone of dominant eye only to 4.4mm
Desires better near vision	<ul style="list-style-type: none"> - Change distance zone of non-dominant eye only to 3.6mm
Desires BEST distance vision	<ul style="list-style-type: none"> - Use 4.4mm OU
Desires BEST near vision	<ul style="list-style-type: none"> - Use 3.6mm OU

NCLE CERTIFIED CONSULTANTS

X-Cel Specialty Contacts has enjoyed a reputation for our unparalleled customer service while being committed and passionate to manufacturing innovative and quality gas permeable and custom soft lenses. With our NCLE certified consultants offering over 200 years of experience to assist you with your specialty contact lens patients, we feel there is no fit too challenging. We believe your patient is our patient too so we are happy to assist you with all of your contact lens patients.

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Bruce Ballweg	bballweg@xcelspecialtycontacts.com	800.426.6241	WA

NO RISK WARRANTY

Unlimited exchanges and cancellation within 120 days of original invoice.

With our **Paperless Credit Policy**, there is no need to return lenses. Upon exchange, you can request credit at that time. Or, simply submit on our website under Paperless Credits, fax or email your account number, invoice number, patient name, and quantity. We will process your credit and it will appear on your monthly statement.

With the paperless system, you save valuable time and more importantly, costs you incur with packaging and return postage.

SUPPLIES FOR SCLERAL FITTING

When you need more fitting or marketing supplies for your practice, we are your one stop shop. Call 800.241.9312 to place an order for these supplies:

Addipak unpreserved single-use saline

ScleralFil preservative-free saline

Large black contact lens cases

Fluorescein

Care systems

DMV plungers

Lap towels

Pen lights

Insertion & Removal guides

Patient travel kits

Consumer brochures

Waiting room/Exam room consumer poster



Atlantis Patient Travel Kit

NOTES