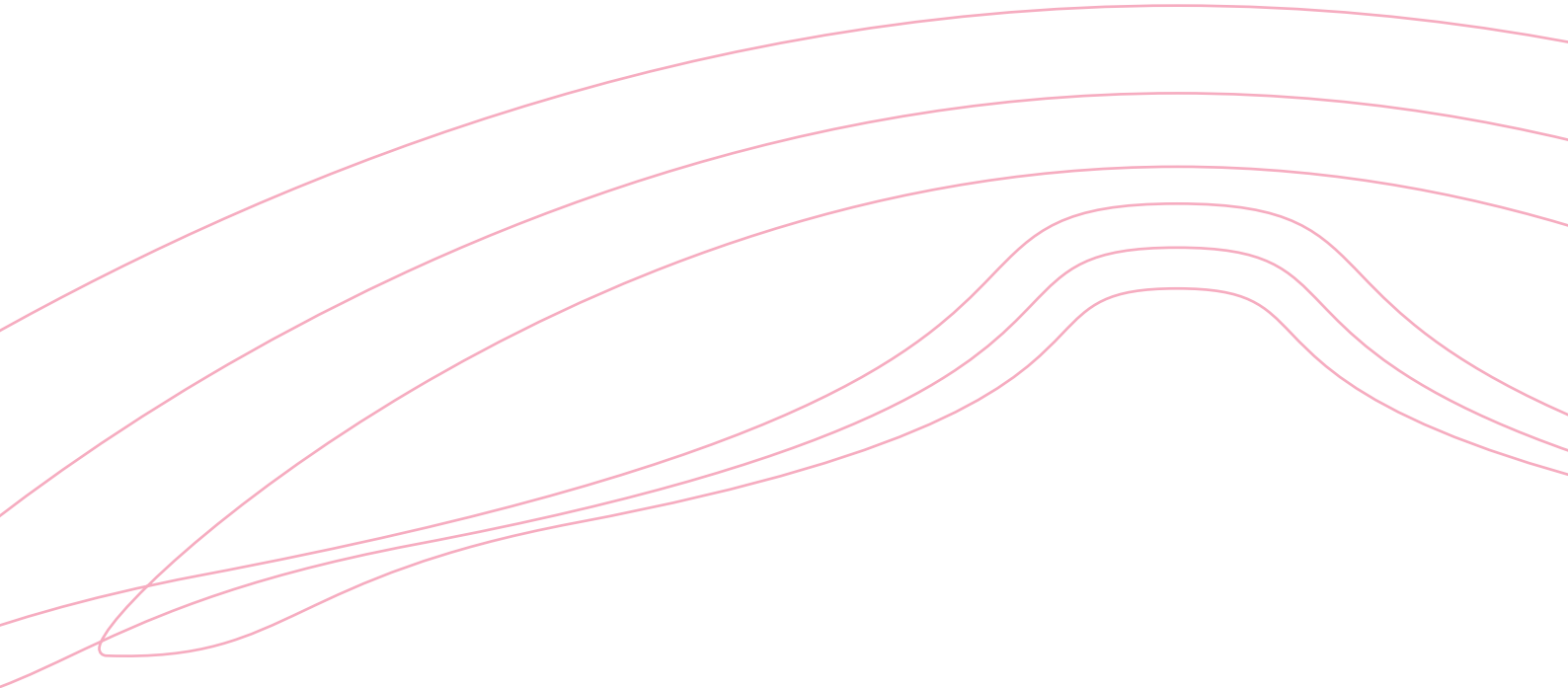




R O S E K



**ROSE K2 XL™**

# Practitioner's Fitting Guide

Corneo-scleral lens

The ROSE K contact lens closely mimics the cone-like shape of the cornea for every stage of the condition, fitting better over the patient's eye and leading to optimum corneal health and visual acuity.





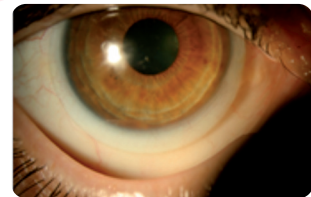
# ROSE K2 XL Corneo-scleral Lens

## Applications

- **Primary indications:** Keratoconus, Pellucid Marginal Degeneration (PMD), Post Graft, Post LASIK ectasia, any irregular corneal condition that cannot be successfully fitted within the limbus, rigid corneal lens intolerance
- **Secondary indications:** Polluted work conditions, stability for sport or working environment, Piggyback substitute, Dry Eye
- **Daily wear**

## Design

- Aspheric back optic zone that decreases as base curve (BC) steepens
- Front surface aberration control
- Precise edge lift control
- Reverse geometry in flatter base curves



### Parameter range

- BC range: 5.50 to 9.60mm
- Diameter range: 13.00 to 16.60mm
- Standard diameter: 14.60mm
- Power range: Varies depending on material
- Edge lifts: 25 options from -6.0 decreased lift to +6.0 increased lift in 0.50 steps  
5 standard lifts will optimally fit 90% of cases  
Other options are available on request

### Diagnostic Set

- 16 lenses
- BC: from 6.00 to 8.00mm
- Standard diameter: 14.60mm
- Edge lift: Standard Lift (0)

## Fitting Overview

Like all ROSE K2 designs, ROSE K2 XL follows the same simple, systematic five step fitting process:

### Step 1: Base Curve Selection

Select the flattest BC that shows no touch over the highest point on the cornea.

### Step 2: Peripheral Fit

Adjust the edge lift to optimize fluorescein circulation under the edge of the lens.

### Step 3: Diameter

Select the diameter such that the edge of the lens extends to approximately 1.3 to 1.5mm beyond the limbus.

### Step 4: Location

Adjust parameters such that the lens sits evenly around the limbus.

### Step 5: Movement

Adjust parameters to achieve movement on blink of 0.5 to 1.0mm.



# ROSE K2 XL Fitting Procedure

## Step 1: Base Curve selection

**Objective:** Select the **flattest BC that shows no touch** over the highest point on the cornea.

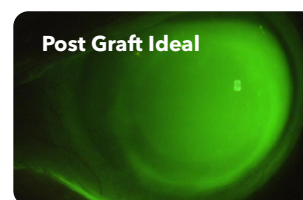
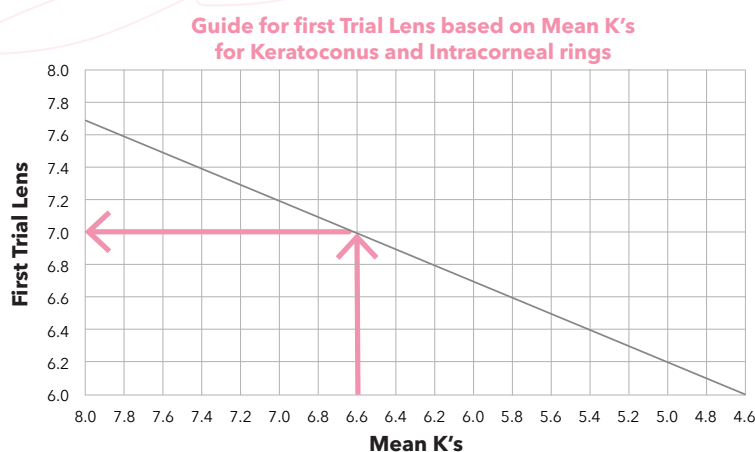
### Guide to first trial lens by condition

Keratoconus and intracorneal rings: See chart below

- PMD and Keratoglobus: 0.6mm steeper than mean K's
- Post Graft: 0.7mm steeper than mean K's
- Post LASIK: 0.7mm steeper than mean K's

If topography is unavailable to accurately identify the condition you are fitting, choose your first trial lens 0.2mm steeper than the mean K's.

NB: the above is only an approximate guide.



- Instill saline with fluorescein into the concave side of the lens and insert onto eye.
- Judge the central fit immediately after insertion.
- Try flatter or steeper BCs and select the **flattest BC which shows no touch** with fluorescein over the highest point on the cornea. (i.e. FDAFL- First Discernible Apical Clearance Lens)

NB: The highest point on the cornea may not be located centrally. In grafts, this is usually somewhere along the graft/host interface. With an OCT, the clearance between the cornea and back surface of the lens should be between 30 and 50 microns.

- **It is critical that the lens does not bear excessively at the HIGHEST point on the cornea otherwise corneal staining and lens binding may result.**
- To check that you have achieved the correct BC, insert a lens with a BC 0.1mm flatter and light feather touch should be observed at the highest point on the cornea.
- Once the correct BC is achieved, allow the lens to settle for a further 20 minutes then re-evaluate the fit.
- If further fluorescein is required, place it on the sclera at 12 o'clock just above the lens. Ask the patient to blink several times.
- If fluorescein does not circulate behind the lens, manipulate the lower and/or upper lid edge to encourage fluorescein to flush under the lens.
- With the correct BC, the "dark" landing zone band just inside the limbus should be between 1 to 1.5mm wide. If the landing zone is excessively wide, steepen the BC until the landing zone width is correct.

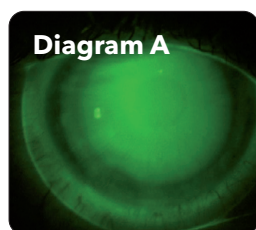
NB: An excessively wide landing zone will reduce lens movement.



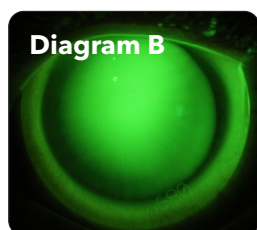
## Step 2: Peripheral Fit

**Objective:** Adjust the edge lift to optimize fluorescein circulation under the edge of the lens.

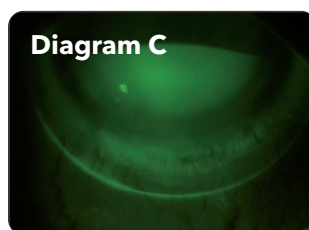
- Once the correct BC has been selected, observe the fluorescein pattern outside of the limbus at all positions around the clock.
- A peripheral fluorescein band with a minimum width of 0.8 to 1.0mm must be observed. **(see Diagram A)**
- Judge fluorescein immediately after lens insertion. Fluorescein will flush out from under the lens edge very quickly so more fluorescein needs to be applied if several minutes have elapsed. With the optimum edge lift, fluorescein should circulate under the edge of the lens.
- If the fluorescence under the lens edge is ideal **(see Diagram A)** but the band of fluorescein is too wide, consider decreasing the diameter.
- If the fluorescence under the lens edge is ideal **(see Diagram A)** but the band of fluorescein is too narrow, consider increasing the diameter.
- If the edge lift is excessive **(see Diagram B)** the lens will be uncomfortable, the fluorescein band will show dense fluorescence and may be too wide. The edge of the lens may lift off from the conjunctiva and cause subsequent bubbling under the edge of the lens. **DECREASE THE EDGE LIFT**
- If the edge lift is inadequate **(see Diagram C)**, the lens will be very comfortable on first insertion, but insufficient fluorescein or no fluorescein will be seen under the edge of the lens outside the limbus. **INCREASE THE EDGE LIFT**
- Fluorescein band may be irregular if peripheral astigmatism is present; refer to Toric and Asymmetric Options at the end of this guide.
- A tight edge lift may cause binding of the lens, which can cause blanching of the conjunctival vessels from the limbus to the edge of the lens and/or hyperemia of conjunctival vessels just outside the lens.



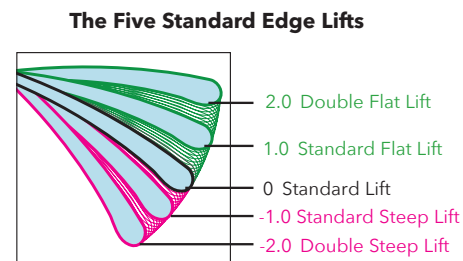
Ideal peripheral fit



Excessive edge lift



Insufficient edge lift



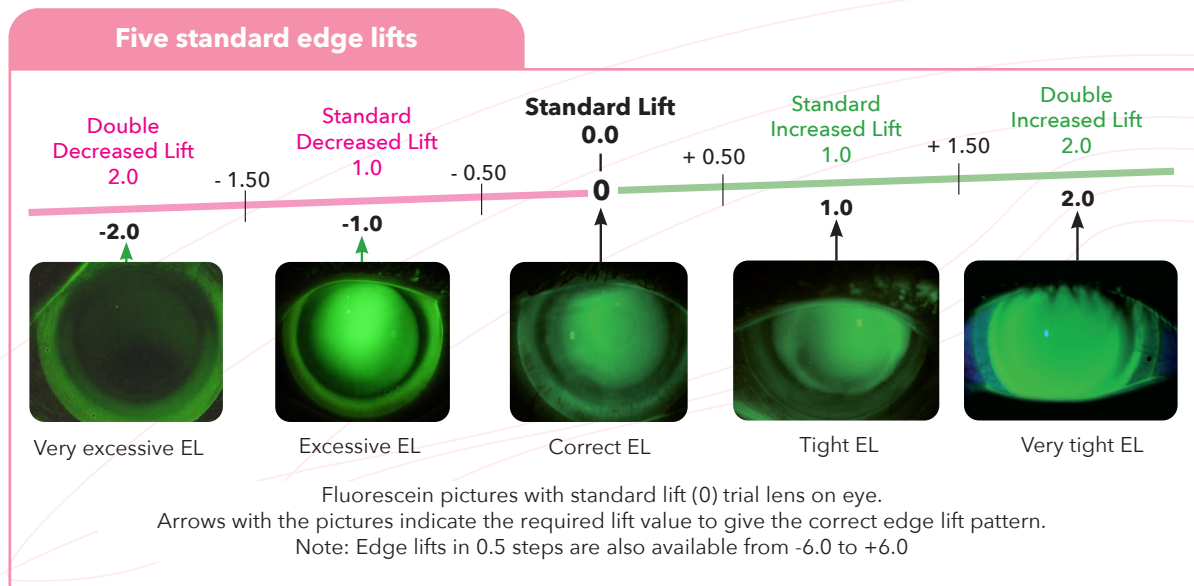
Edge lifts are available from -6.0 to +6.0 in 0.5 steps

### Fitting Tips

1. 50% of patients can be optimally fitted with the standard edge lift.
2. 90% of patients can be optimally fitted using the standard 5 edge lifts - Standard (0), Standard Increased (+1.00), Double Increased (+2.00), Standard Decreased (-1.00) and Double Decreased (-2.00).
3. Judge edge lift immediately after insertion and again after 20 minutes.
4. Lens discomfort on first insertion is most commonly associated with an excessive edge lift.
5. Discomfort experienced on lens removal often indicates a tight edge; increase the edge lift.
6. With the correct edge lift, with slight upward pressure on the edge of the lens at 6 o'clock via the lid, fluorescein should be seen to enter under the edge of the lens. Having to use excessive force indicates a tight edge.
7. Judging the correct choice of edge lift is a combination of interpretation of the following 5 points: the fluorescein pattern, movement, comfort, how easy the lens is to remove and how easily fluorescein enters under the lens edge with upward pressure on the lens lower edge.
8. Excessive force should not be required to remove the lens with a suction holder.
9. Changing the edge lift in most cases does not affect the fit over the cornea. However if the trial lens has an excessively tight edge causing the trial lens to bear mainly on the conjunctiva, increasing the edge lift may result in a flatter central fit than expected. To remedy, steepen the BC by 0.1 to 0.2mm.
10. With the correct amount of edge lift, the conjunctival vessels will still be observed through the fluorescein.



## Step 2: Peripheral Fit (Continued)



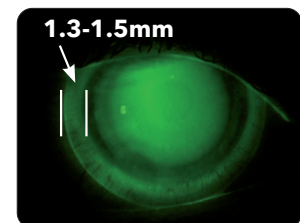
## Step 3: Diameter

**Objective:** The edge of the lens should extend to approximately 1.3 to 1.5mm beyond the limbus.

- Recommended standard diameter: 14.60mm (60% of fits).
- On an average sized cornea of 11.8mm, the lens should extend 1.3 to 1.5mm outside the limbus.
- For large corneas, increase the diameter to achieve 1.3 to 1.5mm outside the limbus.
- For small corneas, decrease the diameter to achieve 1.3 to 1.5mm outside the limbus.

### Fitting Tips

1. Decreasing the diameter may also assist with insertion and removal.
2. Making the lens larger will often make the lens more stable.
3. 0.3mm change in diameter can be significant.
4. The BC does not require any adjustment if you change the diameter.
5. If in doubt, it is better to leave the diameter slightly large rather than too small.



## Step 4: Location

**Objective:** The lens should sit evenly around the limbus.

- A decentered apex may cause the lens to locate inferiorly.
- To improve location, increase the diameter and/or flatten the BC.
- Slight decentration may not cause any major issues but may be slightly less comfortable.

## Step 5: Movement

**Objective:** On first insertion, the lens should move about 0.5 to 1.0mm on blinking.

- Judge movement at 6 o'clock by having the patient look up and blink.
- Judge the movement both on initial insertion and after the lens has settled for 20 minutes.
- After the lens settles, movement should be observed but it will be reduced from initial insertion (maximum of 0.5mm).
- Excessive movement makes the lens less comfortable.
- To decrease the movement: Decrease the edge lift, flatten the BC or use a combination of both.
- To increase the movement: Increase the edge lift, steepen the BC or use a combination of both.



# Evaluating Vision

An over-refraction can be performed immediately after the correct BC is determined however, it should be rechecked after 20 mins when the lens has settled further.

## Fitting Tips

1. Auto-refractors can give a useful starting guide for the refraction.
2. BCVA at the fitting is an accurate indication of the best BCVA that will be achieved.
3. For follow up visits, vision should always be checked first before any fluorescein is applied to the eye.
4. Going too steep centrally can reduce best vision. If the visual acuity is poor, try a flatter BC.

## Suggested wearing and follow-up schedule

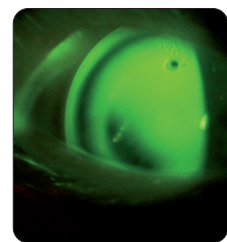
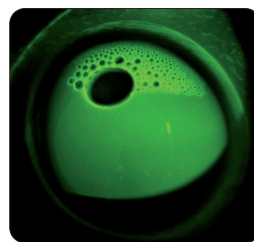
- **Day 1:** 3 hours maximum
- **From day 2 until first follow up visit:** Increase wearing time by 2 hours per day to a maximum of 8 hours per day
- **First follow up visit:** 2 weeks after dispensing lenses. If there are no problems at this visit, wearing time can be increased progressively 2 hours per day to a maximum of 12 hours
- **Second follow up visit:** 1 month after dispensing lenses
- **Third follow up visit:** 3 months after dispensing lenses
- **Ongoing follow up visits:** Every 6 months thereafter

## Fitting Tips

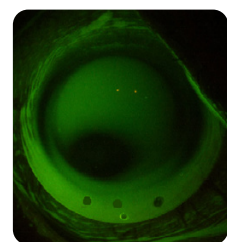
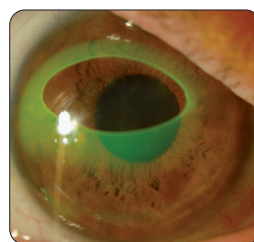
1. Ease of lens removal with a suction holder is a good indication of whether the edge lift is sufficient. With the method described here the lens should lift out easily from the eye.
2. Manipulating the lens over the cornea by using pressure on the lower lid and lifting the upper lid will give a good indication of whether the lens overall is too tight. The lens should move relatively easily. This is best observed with the patient looking straight ahead.
3. It is not uncommon to get slight fluorescein uptake on the cornea after a few hours of wear. This is generally a very superficial staining and should not cause any long-term issues.
4. Because of the reduced tear exchange over the cornea, some patients may report some discomfort or a dry feeling after 3 to 4 hours of wear. Removal of the lens, refilling with non-preserved saline and reinsertion will often alleviate this and give a further 3 to 4 hours comfortable wear. This should be performed routinely for new wearers for the first month of wear.
5. A tight edge on initial lens insertion gives much better comfort than a loose edge but may cause issues in the long term. Slight discomfort on first insertion, even with the correct edge lift, is not uncommon, and often settles after a few minutes. Initial comfort is not necessarily an indication of a good fitting lens. Because the ROSE K2 XL lens has a high edge lift, it may be slightly less comfortable on first insertion. Lens awareness is not uncommon for the first 2-3 days before settling.
6. Conjunctival indentation seen on lens removal may be eliminated by increasing the diameter, increasing the edge lift, steepening the BC or a combination of these to increase the movement.
7. Because of the comfort and reduced tear exchange, semiscleral lenses can cause corneal issues earlier than corneal lenses and often with fewer symptoms. Wearing time should be conservative until the first follow up at 2 weeks. Any issues will usually show up within the first month of wear. The patient should be advised to remove the lens and contact you IMMEDIATELY should they experience discomfort/pain, injection/hyperemia, photophobia, "cloudy/ misty" vision or any other issues they are concerned about.

## Bubbling causes

1. Lens BC is flat. There is too much touch on the highest point on the cornea that causes the lens to rock resulting in lift off at the lens edge and introducing bubbles at this point. It is very important to note any touch on the highest point of the cornea. This must be avoided.
2. The edge lift is excessive and needs to be reduced.
3. The diameter is too small so the lens does not fit adequately onto the sclera.
4. The sclera is toric.



Bubbling due to small diameter



Bubbles trapped on insertion

Bubbling due to a flat BC causing excessive edge lift at 6 o'clock





# ROSE K2 XL Handling

## Lens insertion

- Place the lens concave side up, onto a large suction holder (see diagram).
- Fill the lens with non-preserved saline solution and add a small amount of fluorescein.
- Have the patient tilt their head down, so it is parallel with the floor, and centrally apply the lens directly onto the cornea so the solution remains in the lens.
- Patients can handle the lens with either a suction holder or by balancing the lens in a tripod formed between the thumb, index and middle finger.



Small insertion bubbles are of no consequence, but larger bubbles will disrupt both vision and assessment of the central fit and must be avoided. If bubbles are obvious under the central part of the lens after insertion, the lens must be removed and the insertion process repeated.

### Handling Tips

If there is difficulty **at the initial fitting** eliminating large bubbles under the lens, substitute saline solution with an appropriate solution of a higher viscosity.

## Lens removal

- Place a small solid and wetted suction holder (see image on right) between the outside of the lens and the temporal pupil margin.
- Remove the lens by pulling outwards and across in an arc towards the nose.
- The lens may also be removed by using the lower lid to lift the lower contact lens edge up and outwards.



Patients should not have lenses dispensed until they have shown competence in being able to remove the lens.

Warning: Do not attempt to remove the lens with the suction holder placed centrally.

## Lens care instructions

1. Gently rub the lens between thumb and forefinger with a few drops of an appropriate multipurpose GP cleaning and conditioning solution (an alcohol based surfactant may also be used - consult with your laboratory to ensure that this type of cleaner is compatible with the lens material used).
2. Rinse the lens with multipurpose solution.
3. Store the lens in an appropriate lens case (flat lens case or large size container) filled with fresh multipurpose GP cleaning and conditioning solution. Alternatively, a hydrogen peroxide system may be used.
4. For the management of proteins and other deposits, treat lenses with Menicon PROGENT weekly.

### Handling Tips

1. Do not rub the lens in the palm of the hand; this may cause lens breakage.
2. Excessive pressure applied to the lens surface during the cleaning procedure must be avoided otherwise lens breakage may result.



# Corneal Staining with fluorescein

- Staining at the highest point on the cornea indicates that a steeper BC is required.
- Circular staining or corneal lens indentation just inside the limbus on lens removal indicates lack of movement. To increase movement, refer to the movement section above.
- In some cases, increasing the diameter can also assist in reducing circular corneal staining.

## Toric and asymmetric options

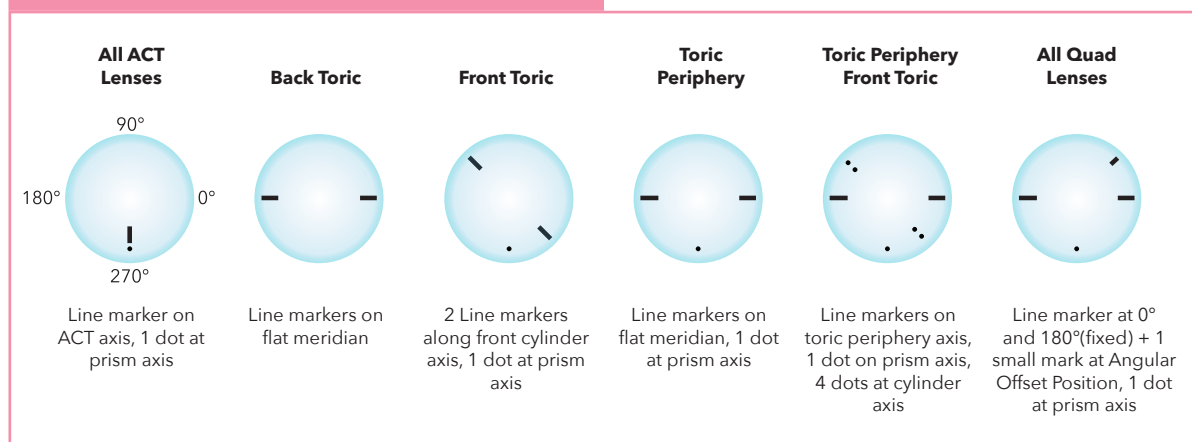
The ROSE K2 XL design is available in several toric and asymmetric options including:

- Front surface toric for the correction of residual astigmatism.
- **Toric Periphery (TP):** used when the lens is tight on the sclera in one meridian and loose in the opposite meridian. The standard TP is 1.2mm but can be ordered in 0.1mm steps from 0.4 to 2.0mm TP.
- **Full back surface toric:** used when the lens over its entire back surface has 2 different toricity values in two meridians, to accommodate high degrees of corneal astigmatism that extends onto the scleral.
- **Asymmetric Corneal Technology (ACT):** used when the lens edge stands off excessively in one or two quadrants only.
- **Reverse ACT:** used when the lens edge is excessively tight in one or two quadrants only.
- **Quadrant Specific Edge Lift (QSEL):** used when a different edge lift is required in different quadrants of the lens. Available in 1 to 4 different quadrants.

Combinations of the above options are also available. A separate guide for toric, asymmetric and bifocal options for ROSE K2 XL is available; please contact your ROSE K distributor or visit [www.roseklens.com](http://www.roseklens.com) for more information.

Please note that all designs have cutting limitations. The more extreme the parameters, the more complicated the lens fabrication. The laboratory will inform you if your order cannot be fulfilled and what options are available.

### Diagnostic Markers



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