



Keratoconus
PMD
Post Graft
Post Surgery

ROSE K2 XL™

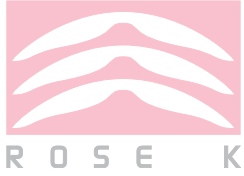
Semi-scleral lens

Practitioner's Fitting Guide

Recommended in

Menicon Z

 **Menicon**



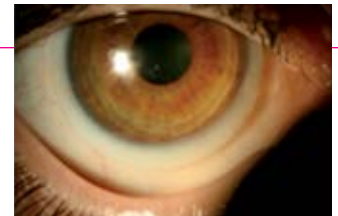
ROSE K2 XL™ semi-scleral lens

Applications

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

Design

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



Parameter range

- BC range: 5.60 to 8.40 mm
- Diameter range: 13.60 to 16.00 mm
Standard diameter: 14.60 mm
- Power range: Varies depending on material
- Edge lifts: 13 options in 0.5 steps from -3.0 decreased lift to +3.0 increased lift
5 standard lifts will optimally fit 90% of cases
Other options are available on request

Diagnostic Set

- 16 lenses manufactured in Menicon Z or Lagado FLOSI material (Dk 26; Tint: Light Pink)
- BC: from 6.00 to 8.00 mm
- Standard diameter: 14.60 mm
- Edge lift: Standard Lift (0)

ROSE K2 XL™ Handling

Lens insertion

- Mount the lens concave side up, onto a large plunger (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 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.

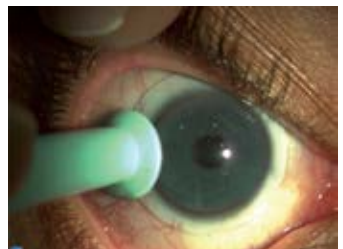


Lens removal

- Place a small solid wetted plunger (see diagram) between the outside of the lens and the temporal pupil margin
- Peel the lens off 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 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 appropriate lens case (flat lens case or large size container) filled with multipurpose GP cleaning and conditioning solution.
4. For the management of proteins and other deposits, treat 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 to the lens surface during the cleaning procedure must be avoided otherwise lens breakage may result.

ROSE K2 XL™ Fitting procedure

Step 1: Base curve evaluation

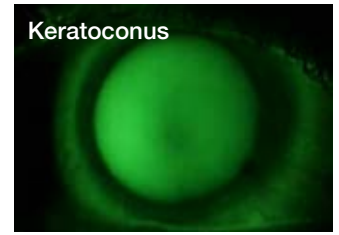
If topography is unavailable to accurately identify the condition you are fitting, choose your first trial lens 0.2 mm steeper than the average K's.

Guide to first trial lens by condition

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

NB : the above is only an approximate guide.

- Instill saline with fluorescein into the concave side of lens
- Judge the central fit immediately after insertion
- Select flatter or steeper base curves until a **very light feather** touch is just discernable at the highest point on the cornea. Feather touch is defined as the Base Curve for FDA CL (BC to achieve the first apical clearance) plus +0.1. NB: This may not be centrally
- **It is critical that the lens does not bear excessively at the HIGHEST point on the cornea or corneal staining and lens binding may result.**
- To check that you have achieved "feather touch", insert a lens with a base curve 0.1mm steeper - no touch should be observed
- Once feather touch is achieved, allow the lens to settle for a further 20 minutes and re-evaluate the fit
- If further fluorescein is required, place 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 edge to encourage fluorescein to flush under the lens

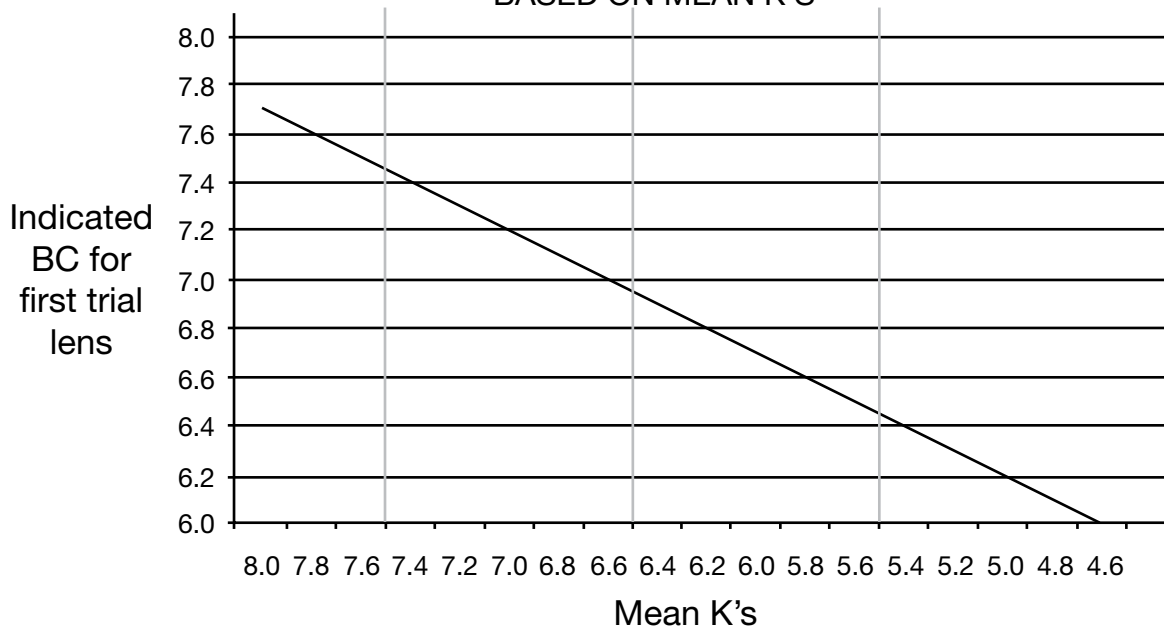


Base Curve - Ideal

Fitting Tips

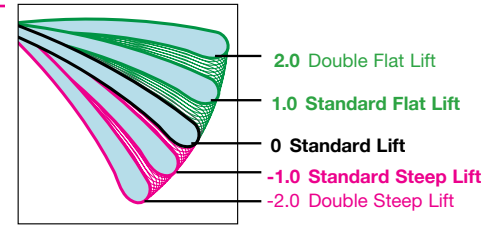
1. Judge fluorescein pattern for BC selection, immediately after insertion and again after 20 minutes.
2. **Excessive bearing** at the highest point on the cornea **must be avoided** as it may result in corneal staining and lens discomfort.

KERATOCONUS GUIDE FOR FIRST TRIAL LENS
BASED ON MEAN K'S



Step 2: Edge lift

- Once the correct Base Curve 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 1.0 mm must be observed (**See diagram A**)
- Judge fluorescein immediately after lens insertion. Fluorescein will flush out from under the lens edge very quickly so further 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 is ideal (**see diagram A**) but the band of fluorescein is too wide, consider decreasing the diameter
- If the fluorescence under the lens 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 to conjunctival vessels just outside the lens



The five standard edge lifts.
+3.0 and -3.0 are also available

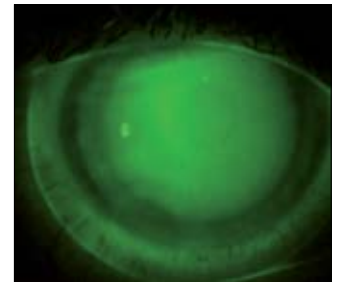


Diagram A: Ideal peripheral fit

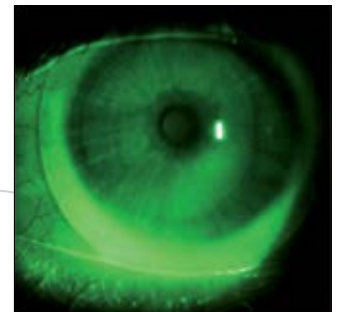


Diagram B: Excessive edge lift

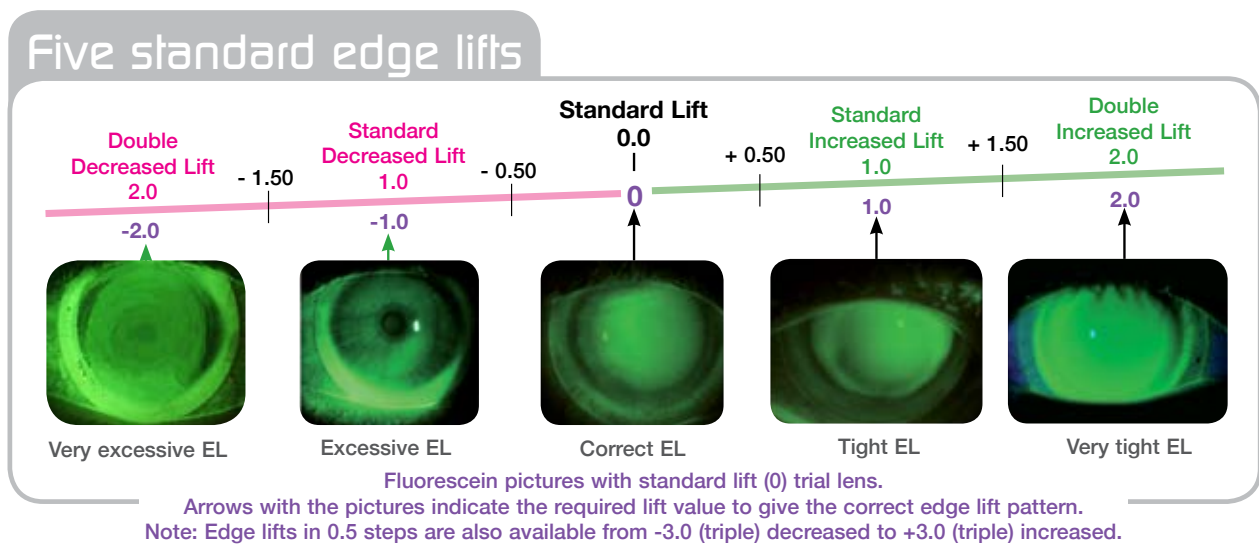


Diagram C: Insufficient edge lift

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 normal 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 effect 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 can still be observed through the fluorescein.**

Step 2: Edge lift (Cont.)

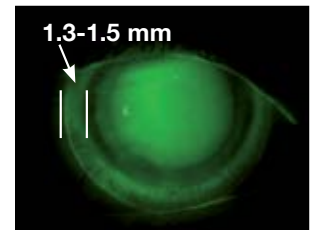


Step 3: Diameter

- Recommended standard diameter: 14.60 mm (60% of fits)
- On the average sized cornea of 11.8 mm, the lens should extend 1.3 to 1.5 mm outside the limbus
- For large corneas, increase the diameter to achieve 1.3 to 1.5 mm outside the limbus
- For small corneas, decrease the diameter to achieve 1.3 to 1.5 mm 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. 0.3 mm 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

- 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

- On first insertion the lens should move about 0.5-1.0 mm on blinking
- Judge movement at 6 o'clock by having the patient look up and blink
- After lens settles, very little movement should be obvious (maximum of 0.5 mm)
- Excessive movement makes the lens less comfortable
- To decrease the movement:
 - Decrease the edge lift
 - Flatten the BC
 - A combination of the above
- To increase the movement:
 - Increase the edge lift
 - Steepen the BC
 - A combination of the above

Fitting Tips

Judge the movement both on initial insertion and after the lens has settled for 20 minutes.

Step 6: Vision

An accurate over refraction should be performed once the lens has settled after 20 minutes.

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

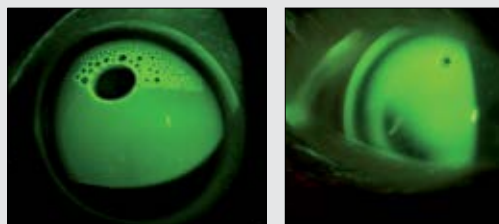
- **Day 1:** 3 hours maximum
- **From day 2 until first follow up visit:** Increase wearing time by 2 hours per day to a maximum of 8 hours per day
- **First follow up visit:** 2 weeks after dispensing lenses. If there are no problems at this visit, wearing time can be increased progressively 2 hours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

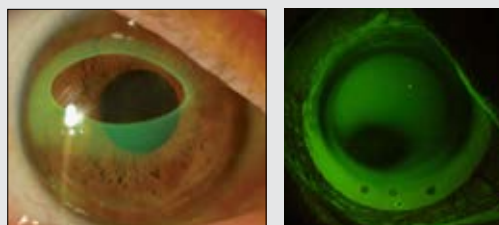
1. Ease of removal of the lens with a suction holder is a good indication of whether the edge lift is sufficient. With the method described here the lens should lift out easily from the eye.
2. Manipulating the lens over the cornea by using pressure on the lower lid and lifting the upper lid will give 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 may not cause any long-term issues.
4. Because of the decreased 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 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 Base Curve or a combination of these to increase the movement.
7. Because of the comfort and reduced tear exchange, semi-scleral 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. Usually, if there are going to be any issues they will show up within the first month of wear. The patient should be advised to remove the lens and consult you IMMEDIATELY should they experience discomfort/pain, injection/hyperemia, photophobia, "cloudy/misty" vision or any other issue they are concerned about.

Bubbling causes

1. Lens flat centrally. There is too much touch on the highest point on the cornea that causes the lens to rock causing lift off at the edge that introduces bubbles at this point. It is very important to note the touch on the highest point. For example, with a corneal graft the highest point may be along the graft/host corneal junction.
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

Corneal Staining with fluorescein

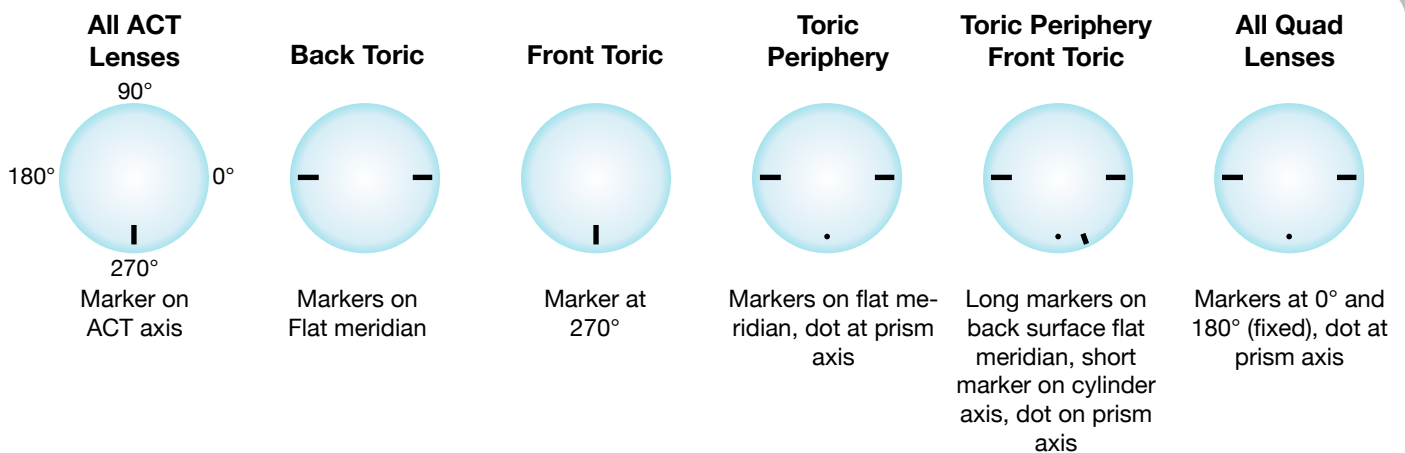
- Staining at the highest point on the cornea indicates that a steeper base curve is required
- Circular staining just inside the limbus indicates lack of movement. To increase movement, refer to the movement section, above
- In some cases, increasing the diameter can also assist in reducing circular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

Toric and asymmetric options

The Rose K2 XL™ design is available in several toric and asymmetric options which include:

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

Diagnostic Markers



Combinations of the above options are also available. Please contact your distributor for further information regarding these designs.

General Editor: Dr. Paul Rose



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