



Keratoconus
PMD
Post Graft
Post Surgery

ROSE K2 XL™

Semi-scleral lens



ROSE K2 XL semi-scleral lens

Applications

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

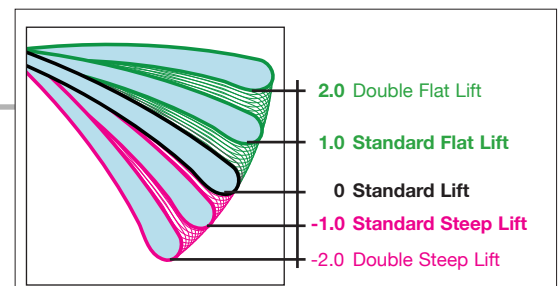
Design

- Aspheric Back Optic Zone which decreases as BC steepens.
- Front surface aberration control.
- Precise Edge Lift control.



Parameter range

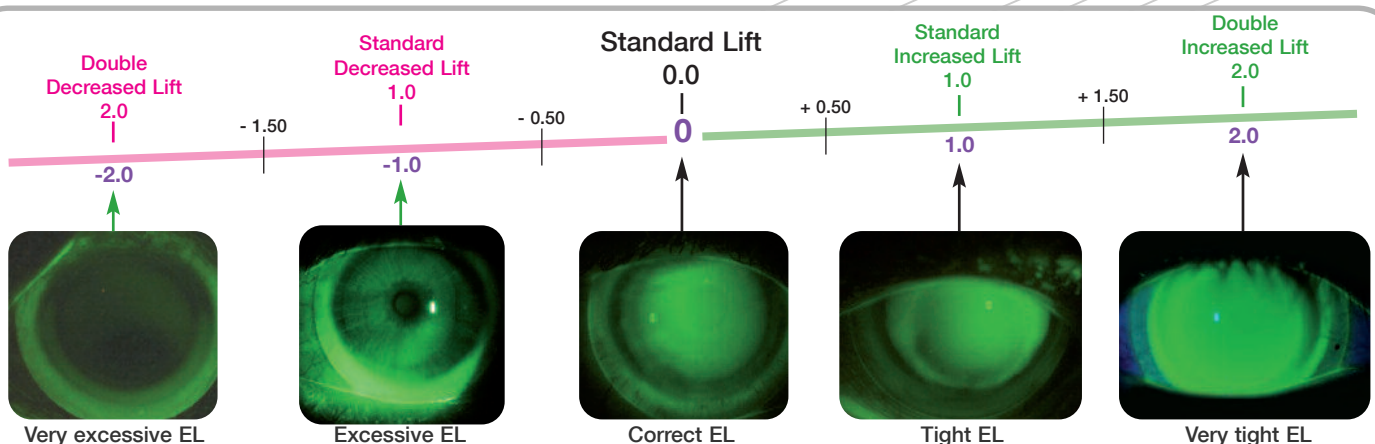
- BC range: 5.80 to 8.40 mm.
- Diameter range: 13.60 to 15.60 mm*
Standard diameter 14.60 mm.
- Power: +30.00 to -30.00 D.
- Edge Lifts: 9 options
5 standard Lifts will optimally fit 90% of cases.
Other options are available on request.
- Material: Menicon Z, Lagado Tyro 97, Boston XO.



*Note: in some very steep BC's maximum diameter is restricted (ie 6.1 mm and steeper).

Fitting set

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



Fluorescein pictures with standard Lift (0) trial lens:
arrows with the pictures indicate the required Lift value to give the correct Edge Lift pattern.

ROSE K2 XL Handling

Lens insertion

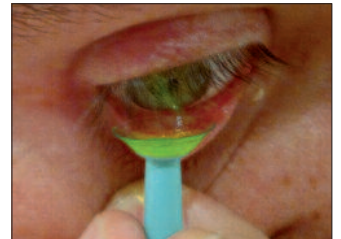
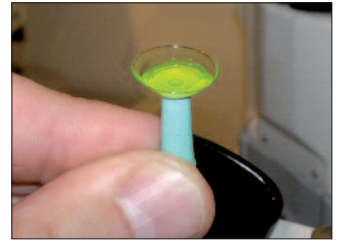
- With the lens concave side up, fill the lens with saline solution and add a small amount of fluorescein.
- Have the patient tilt their head down, so it is parallel with the floor, and centrally apply the lens to the eye so that the solution remains in the lens.
- Patients can handle the lens with either 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 comfort 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 MeniCare Plus solution.

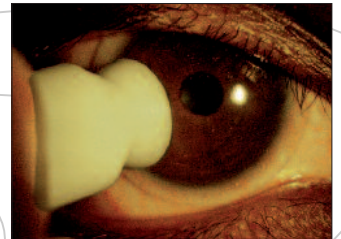


Lens removal

- Place the wetted suction holder on the outside temporal edge of the lens.
- 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 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 MeniCare Plus solution.
- 2 Rinse the lens with MeniCare Plus solution.
- 3 Store the lens in appropriate lens case (flat lens case or large size container) filled with MeniCare Plus solution.

Handling Tips

1. Do not rub the lens in the palm of the hand; this may cause lens breakage.

ROSE K2 XL Fitting procedure

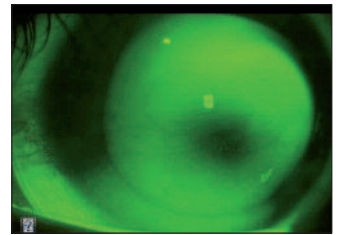
Step 1: Base curve evaluation

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.

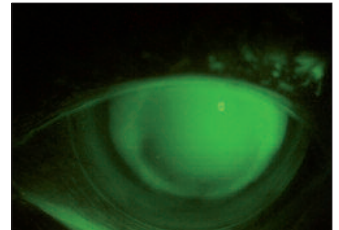
Guide to first trial lens by condition:

- Keratoconus: 0.2 flatter than mean K's
 - PMD: 0.6 steeper than mean K's
 - Post Graft: 0.7 steeper than mean K's
 - Post LASIK: 0.7 steeper than mean K's
 - Corneal Rings: 0.1 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 progressively flatter or steeper BC's until a light feather touch is achieved at the highest point on the cornea.
- 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.



Central fit - Ideal



Fitting Tips

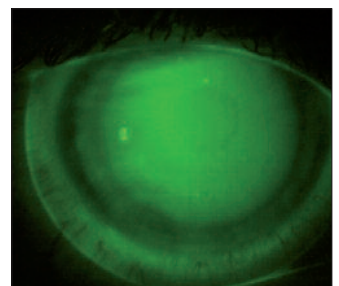
1. Judge initial central fit immediately after insertion and again after 20 minutes.
2. Any staining at the highest point on the cornea indicates the need for a steeper BC.

Step 2: Edge Lift

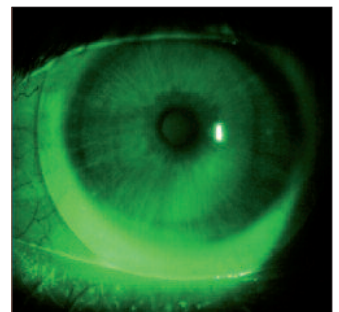
- Once the correct central fit has been achieved, observe the fluorescein pattern at the outer 1 mm of the lens at all positions around the clock.
- A peripheral band about 0.8 to 1 mm wide is ideal.
- Reinsert fluorescein onto the sclera if several minutes elapse.
- Fluorescein should circulate under the edge of the lens.
- If the band is too wide, it may show lift off and bubbling at the edge of the lens with associated discomfort: decrease the lift.
- If the band is too narrow: increase the lift.
- Fluorescein band may be irregular if peripheral astigmatism is present.
- 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.

Fitting Tips

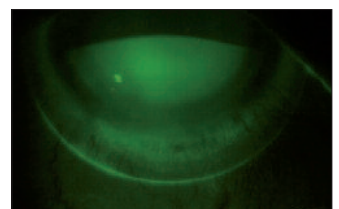
1. 50% of patients can be optimally fitted with the standard edge lift.
2. 90 % of patients can be optimally fitted using the normal 5 Edge Lifts.
3. Judge Edge Lift immediately after insertion and again after 20 minutes.
4. Lens discomfort is most commonly associated with an excessive Edge Lift.
5. 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 fluorescein pattern, the movement of the lens, and how easily fluorescein enters the lens at 6 o'clock with upward pressure.
8. Excessive force should not be required to remove the lens with a suction holder.



Ideal peripheral fit



Excessive loose fit



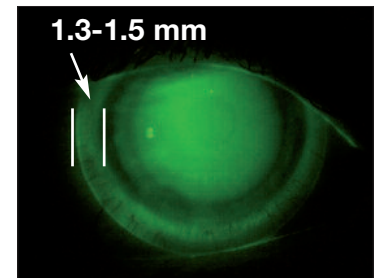
Tight peripheral fit

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.
- For small corneas: decrease the diameter.

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.



Step 4: Location

- The lens should sit evenly around the limbus.
- A decentered apex, may cause the lens to locate inferiorly.
- To improve centration: increase the diameter and/or steepen 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 slightly 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.
 - Steepen the BC.
 - Increase the diameter or a combination of these.
- To increase the movement:
 - Increase the Edge Lift.
 - Flatten the BC.
 - Decrease the diameter or a combination of these.

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

Suggested wearing schedule

- **Day 1:** 3 hours maximum.
- **Day 2:** 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.

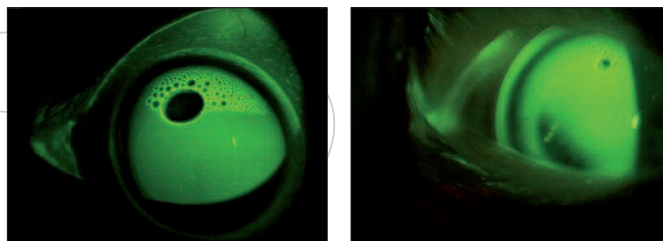
Fitting Tips

1. Ease of removal of the lens off the eye 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 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 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 and/or increasing the Edge Lift.
7. Because of the comfort and reduced tear exchange, semi-scleral lenses can cause corneal issues earlier than corneal lenses and often with less 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.

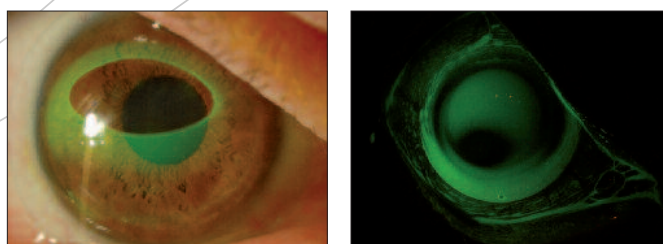
Bubbling causes

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 corneal inserts, the highest point may be directly over the rings.
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.

NB: toric or asymmetric options should be available soon.



Bubbling due to small diameter



Bubbles trapped on insertion

Bubbling due to excessive Edge Lift at 6 o'clock