ROSE K

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ROSE K2 Soft™

Practitioner's Fitting Guide

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ROSE K2 Soft

Applications

- ROSE K2 Soft is a daily wear soft lens for irregular corneas. ROSE K2 Soft is a 3 month replacement lens when manufactured from silicone hydrogel materials and a 6 month or 12 month replacement lens when manufactured from hydrogel materials.
- Primary indications: Intolerance to GP lenses, new contact lens wearers with irregular corneas, early to moderate irregular corneas, if acuity with conventional soft lenses is unsatisfactory, if the environment is unsuitable for GP wear, if a GP lens may be unstable, e.g. sport.
- Contraindications: Other ocular pathology or when satisfactory acuity cannot be attained at the initial fitting with best sphero-cylinder correction or a pinhole.

Design

- Aspheric back optic zone
- Front surface toric
- Front surface aberration control
- Precise edge lift control
- Prism ballast stabilization
- Reverse geometry

Parameter range

- BC range: 7.20 to 9.20 in 0.20 increments
- Diameter range: 14.30 to 15.30mm in 0.10 increments
  Standard diameter: 14.80 mm
- Power range: -30.00D to +30.00D in 0.25D increments
- Cylinder: -0.25D to -10.00D in 0.25D increments
- Cylinder axis: 0° to 180° in 1° increments
- Prism ballast: Range 0.75D to 2.0D in 0.05 steps. Standard prism 1.2D
- Centre Thickness: 0.25mm to 0.60mm in 0.01 steps
  Standard Centre Thickness: 0.35mm
- Edge lifts: 5 Options - Standard (0), Standard Increased (+1.0), Double Increased (+2.0), Standard Decreased (-1.0) and Double Decreased (-2.0)
- Material: Lagado Silicone Hydrogel (LSH): Water content 49%, Dk 49, handling tint
  Menicon Soft 72 Hydrogel: Water content 72%, Dk 34, handling tint
- Available in single vials for hydrogel and silicone hydrogel lenses and a 2-pack for silicone hydrogel.

Fitting Set

- Eight lenses in 0.20mm increments from 7.40mm to 8.80mm
- Diameter: 14.80mm
- Centre Thickness: 0.35mm
- Material: Lagado Silicone Hydrogel (LSH) or Menicon Soft 72
  Note: As there may be slight differences in the fitting characteristics of these two materials, it is strongly recommended that prescription lenses be ordered from the same material used for your fitting set.
- Standard lift
- Prism ballast 1.2D
- Laser marked at base of prism

Practitioner Trial Lens Care Instructions

It is strongly recommended that lenses in the diagnostic set be treated as single use only. After use, diagnostic lenses should be discarded and replaced.

Patient Handling and Lens Care Recommendations

Eye care practitioners should review lens care directions with the patient, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

Lens care

1. Digital rubbing of the lens surface with a concentrated soft lens cleaner is strongly recommended to remove lens surface debris and contaminants. After lens removal, place the lens on the middle or index finger of the dominant hand, place several drops of the soft lens cleaner on the palm of the other hand, and then rub the lens in circles over the palm for at least 30 seconds. Rinse with multi-purpose soft lens solution before storing the lens in the case.
2. Silicone hydrogel lenses should be replaced every 3 months; hydrogel lenses should be replaced every 6 to 12 months.
3. The materials used in ROSE K2 Soft have been tested with both hydrogen peroxide and multi-purpose lens care regimens. When opting for a multi-purpose system, Menicon recommends MeniCare Soft or SOLOCARE AQUA®.

Recommended Follow-up and Wearing Schedule

- **Day 1:** 4 hours.
- **From Day 2 until the first follow up examination at 2 weeks:** Increase wearing time 2 hours per day, up to a maximum of 8 hours.
- **After the first follow up examination at 2 weeks:** Wearing time may be increased to a maximum of 12 hours.
- **After the second follow up examination at 1 month:** Wearing time can be increased to all day wear. Regular examinations at 6 monthly intervals from then on are recommended.

Refraction (continued)

When dispensing

Allow the lens to settle for 5 minutes and perform an accurate sphero-cylinder over-refraction. Record this result and dispense the lens.

First followup exam (at 2 weeks)

Ensure the patient has worn the lens for at least one hour and perform an accurate sphero-cylinder over-refraction.

- If this is the same or similar to the over-refraction recorded at the dispense a new lens power can be ordered if required.
- If this is significantly different to the over refraction recorded at the dispense, perform a further over refraction at least 3 days later.
- Two similar over refractions must be recorded at subsequent examinations before a new lens power should be ordered.

Refraction Tips

- Push the maximum plus - it is easy to over minus the Rx.
- VA at the fitting is an accurate indication of the best final VA you will obtain with ROSE K2 Soft. Do not proceed with the fitting if the BCVA is not adequate at the fitting.
- Auto-refraction over ROSE K2 Soft is inaccurate and has little or no application for determining the correct power.

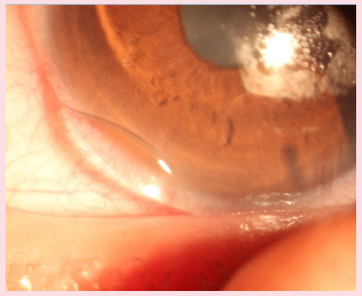
ACT: Asymmetric Corneal Technology

Because of the unusual shape of some irregular corneas, the ROSE K2 Soft lens may, in some rare cases, flute at the edge. This will usually occur in the lower half between 4 o'clock and 8 o'clock, even though the rest of the fit may appear ideal. The ROSE K2 Soft ACT design allows the lens to be tightened (tucked) over a single quadrant with the axis of the steepening exactly defined by the fitter, independent of the prism ballast at 270. Two different grades of ACT are offered:

- Standard ACT (1.0): This is where the fluting may not be apparent in the straight ahead gaze, but becomes obvious when the patient looks up, down or laterally
- Double ACT (2.0): Used when the fluting is always obvious, even in straight ahead gaze.

Unless stated by the fitter, the ACT axis will be placed at 270, the same axis as the prism ballast.

Fitting Tip



Inferior corneal steepening may cause the lens to ride low, and fluting may not be apparent until the lens is pushed up via the lid to centre over the pupil (see above). In these cases use ACT 1.0

ROSE K2 Soft Fitting Procedure

Fitting Overview

ROSE K2 Soft follows the same simple, systematic five step fitting process shared by all ROSE K designs:

Step 1: Base Curve Selection

Select the BC which yields the best visual acuity, fitting as flat as possible.

Step 2: Peripheral Fit

Adjust the periphery to optimize lens fit, location and movement.

Step 3: Diameter

The edge of the lens should extend to approximately 1.5mm beyond the limbus.

Step 4: Location

The lens should centre equally around the limbus.

Step 5: Movement

On blink, approximately 1.0mm of movement should be observed.

Step 1: Base Curve Selection

Objective: Select the BC which yields the best visual acuity, fitting as flat as possible.

Guide to first trial lens by condition

Keratoconus and Corneal inserts: Select a lens 0.80mm to 1.00mm flatter than mean Ks or mean 3mm Sim Ks.

Corneal Grafts, PMD and LASIK: Select a lens with a BC equal to the mean Ks or 3mm Sim Ks.

1. See condition guide above for selection of the first trial lens.
2. After insertion, allow the lens to settle for 3 to 5 minutes before initially assessing the lens.
3. Initially choose the BC which gives the best fit. This is indicated by :
   - Movement of approximately 1.0mm should be observed on blink.
   - No significant decentration on upward gaze - this would indicate a loose fit
   - No scleral indentation on removal - this would indicate a tight fit
   - Lens is comfortable.
   - No fluting. Fluting may indicate a flat BC
   - The laser mark should remain relatively stable and not rotate more than 20 degrees from the 6 o'clock position.
4. Fit as flat as possible. Flatter lenses often give better VA.
5. Once the best fit has been attained, have the patient squeeze the lids tightly with lens *in situ* to ensure that this is the optimum BC that gives the best vision:
   - If, on opening the lids, VA is immediately better but then deteriorates, choose a flatter BC.
   - If, on opening the lids, the VA is worse and slowly improves, this may indicate that a tighter BC is required.

   Note: If the BC requires adjusting but the fit is then not optimal, the periphery can be adjusted to correct this. See *Step 2: Peripheral Fit*.

Step 2: Peripheral Fit

Objective: Adjust the periphery to optimize lens fit, location and movement.

Note that the periphery of the lens can be adjusted independently of the base curve.

- Five peripheral fit options are available: Standard, Standard Increased and Double Increased (to loosen the fit) or Standard Decreased and Double Decreased (to tighten the fit).
- In cases where the vision is acceptable but the overall fit is TIGHT: Small bubbles may be trapped at the limbus, the lens may not move sufficiently, scleral-conjunctival indentation MAY be seen on removal, limbal injection may appear after several hours of wear or initial comfort may be good but deteriorates after several hours of wear. Order increased lift
- In cases where the vision is acceptable but the overall fit is LOOSE: The lens moves excessively, particularly on upward gaze, may flute in one quadrant (more commonly in the lower quadrants), is uncomfortable on insertion and does not settle. Order decreased lift
- Loose lenses may cause the laser line on the lens to locate more than 20 degrees away from the 6 o'clock position.

Fitting Tip

For very steep nipple or oval cones, a flatter periphery may be required.

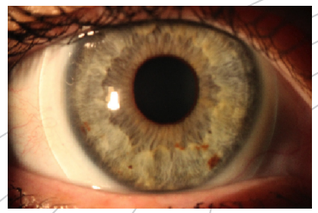
Step 3: Diameter

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

- For smaller HVID's, decrease the diameter to achieve 1.5mm outside the limbus.
- For larger HVID's, increase the diameter to achieve 1.5mm outside the limbus.
- If the lens causes any significant scleral indentation, go smaller (and/or increase the edge lift).

Fitting Tip

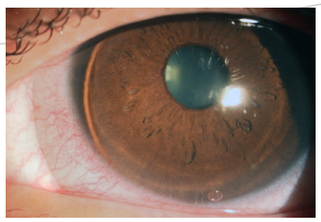
If in doubt, leave the diameter slightly larger rather than smaller.



Step 4: Location

Objective: The lens should centre equally around the limbus.

- The lens should not locate down significantly on upward gaze.
- The laser mark should locate within 20 degrees of 6 o'clock.
- To improve location:
  a. Steepen the base curve.
  b. Increase the diameter.
  c. Decrease the edge lift.



Lens showing low location

Step 5: Movement

Objective: On blink, approximately 1.0mm of movement should be observed..

- With the patient looking straight ahead or slightly up, use the bottom lid against the lower edge of the lens to the push lens upwards and observe how quickly it returns to its original position. This will give a more accurate assessment of how tight or loose the lens is. The lens should return to its natural resting position within seconds.
- To increase movement, increase the edge lift, decrease the diameter and/or flatten the base curve.
- To decrease movement, decrease the edge lift, increase the diameter and/or steepen the base curve.

Fitting Tip

Judge the movement after the lens has settled but not longer than 5 minutes after insertion.

Refraction

Best corrected visual acuity is a primary driver for selection of the appropriate base curve.

An inability to attain satisfactory vision at the fitting is a contraindication for proceeding with the fitting.

The standard of vision can be an excellent indicator of the relationship of the back surface of the lens to the cornea. The base curve should be varied to attain best possible visual acuity and then the peripheral system and/or diameter changed to improve the fit if required.

Generally, fitting flatter base curves gives better VA.

At the fitting

1. Allow the lens to settle for 5 to 10 minutes before performing an over-refraction including any astigmatic component. Repeat after 20 minutes to confirm the final fit and refraction.
2. Perform the final over refraction with the lights on, using a trial frame, as pupil size can affect the final refraction.
3. If the over refraction has a cylinder greater than 2.00D, place this in a trial frame and have the patient manually rotate the lens in the trial frame to choose the best vision. Rotate lens away from best vision and ask patient to repeat the procedure 2 more times.
4. Once the correct cylinder and axis has been established add +1.00D and -1.00D spheres over this final refraction in the trial frame; refine with +0.50 and -0.50 spheres.
5. The Laser mark should locate within 20 degrees of 6 o'clock. Any rotation either nasally or temporally must be compensated for, or alternatively shown in the order so the lab can make the compensation. Use notation for the rotation of either 'NASAL" or "TEMPORAL".