KERASOFT® IC

FITTING MANUAL

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Fitting Manual: Contents

This fitting manual is best used in conjunction with KeraSoft® IC online training.
To register, please visit www.kerasofttraining.com

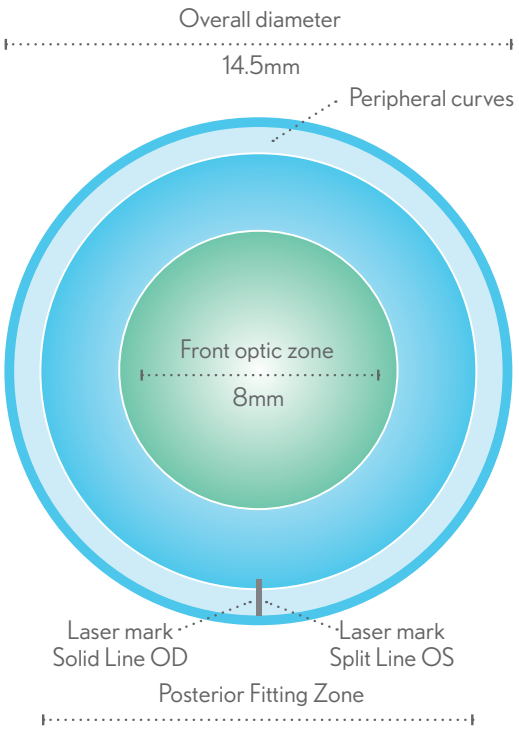
The KeraSoft® IC Lens for Keratoconus and Other Irregular Corneas

The KeraSoft® IC is a front surface asphere or aspheric toric prism ballasted lens with balanced overall thickness and spherical aberration control.

The periphery can be manipulated independently of the base curve if necessary, up to 4 steps flatter or steeper.

Also, up to two sectors of the periphery can be modified independently, the location of which is decided by the practitioner. The peripheries in these sectors can be flattened, steepened or remain standard.

KeraSoft® IC Lens with STD Periphery



What you need to order

All of the following information should be provided to your laboratory when ordering KeraSoft® IC:

- Base Curve
- Diameter
- Periphery (STD, STP or FLT)
- Power of Diagnostic Lens
- Over-refraction
- Vertex Distance of all lenses (including all cyl lenses)
- Laser mark rotation and direction

Specifications

Base curve	7.40mm to 9.40mm (0.20mm steps)
Diameter	14.50mm (0.50mm steps) Diameters of 14.00mm, 15.00mm, and 15.50mm can be manufactured to order
Lens design	Front surface asphere or aspheric toric prism ballasted lens with balanced overall thickness and spherical aberration control
Periphery options	The entire periphery can be steepened or flattened independently of the overall base curve. Additionally, up to two sectors of the periphery can be modified independently of each other (Sector Management Control or SMC). Standard, STEEP1, STEEP2, STEEP3, STEEP4, FLAT1, FLAT2, FLAT3, FLAT4
Power range	Sphere: +20.00D to -20.00D Cylinder: -0.50D to -12.00D (in 0.25D steps) Axis: 1° to 180° (in 1° steps)
Material	Efrofilcon A, 74% Water* *Definitive™
DK	60 x 10^{-11} (cm^2/sec)[mlO_2/(ml x mmHg)]

Standard Diagnostic Fitting Set Parameters

Base Curve	Diameter	Periphery	Power
7.80mm	14.5mm	STD	Plano
8.00mm	14.5mm	STD	Plano
8.20mm	14.5mm	STD	Plano
8.40mm	14.5mm	STD	Plano
8.60mm	14.5mm	STD	Plano
8.80mm	14.5mm	STD	Plano
8.20mm	14.5mm	FLT2	Plano
8.60mm	14.5mm	STP2	Plano

Corneal Profile Chart

The Corneal Profile Chart, along with the following guidelines, will aid in the selection of the initial diagnostic lens.

Corneal Profile

The corneal profile gives important information about the overall corneal shape in the vertical meridian, especially if topography is unavailable or difficult to interpret.

Natural Ectasia

The corneal shape in natural ectasias is influenced by the location of the thinnest area of the cornea. The Corneal Profile Chart shows the characteristic shapes found in central and decentered/low cones and Pellucid Marginal Degeneration.

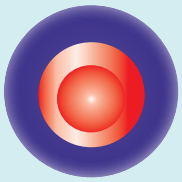
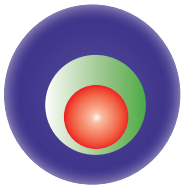
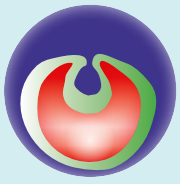
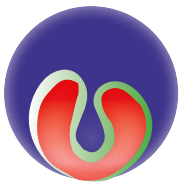
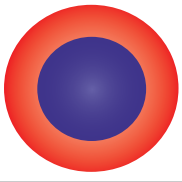
Post-Surgical

Corneas that have undergone one or more surgical procedures may no longer have a natural shape. Observing the corneal profile, however, is a very useful tool, especially in determining whether the cornea is a reverse geometry shape.

To Determine the Corneal Profile

Topography:
Estimate with the classical means of topography or OCT.

Slit Lamp Profile Method:
Move the slit lamp illumination system to the side, ask the patient to look straight ahead and open the beam to the widest setting. Observe the anterior cornea, in profile, from the same side as the illumination system, using the side of the patient's nose as a background.

Natural Ectasias	Topography	Normal	Mild	Moderate	Advanced
Central Keratoconus Steep Periphery					
Central Keratoconus Flat Periphery					
Decentered/Low Cone					
Pellucid Marginal Degeneration					
Post-Surgical					
Post-Surgical			Post-surgical corneas are often flatter centrally and steeper peripherally but this is by no means a general rule.		

Initial Lens Selection

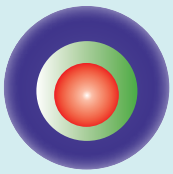
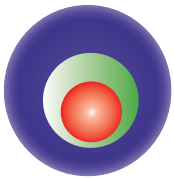
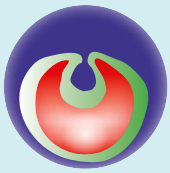
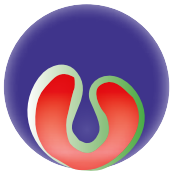
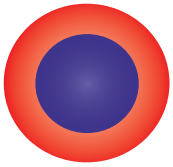
Overall KeraSoft® IC Irregular Cornea Fitting Flow

1. **Aim to fit all cases with STD periphery lenses**
2. **Only change the periphery of the lens if it is clinically indicated from the STD lens fit**
3. **Use Sector Management Control for specific clinical cases, only when certain it is required**

The Corneal Profile Chart assists in identifying the corneal shape being fitted. The table below suggests the diagnostic fitting lens to be used as the first choice for each corneal shape.

In natural ectasia, if there is limited information as to the corneal shape, begin with the **8.20mm base curve: Standard Periphery Diagnostic Lens** and assess using the MoRoCCo VA characteristics (see page 4).

Note: In irregular corneas there is a tendency to fit steeper lenses. Be careful not to confuse a steeper tight fitting lens with the movement of a flat fit. Therefore, if fitting one step steeper results in a more mobile lens, try fitting flatter base curves.

Condition	Topography	Corneal Profile	Mild	Moderate	Advanced	Hints and Tips
Central Keratoconus Steep Periphery			8.60mm: 14.50mm: STD	8.40mm: 14.50mm: STD	8.00mm: 14.50mm: STD	7.60mm BC and 7.40mm BC are also available on request but should only be necessary in very advanced cases. Due to the corneal shape, STP1 peripheries may also be required in some cases.
Central Keratoconus Flat Periphery			8.60mm: 14.50mm: STD	8.20mm: 14.50mm: FLT2	8.00mm: 14.50mm: FLT2 (Not in Fitting Set)	Mild, moderate and advanced cases may all require FLT periphery fitting lenses with the appropriate base curves. These can be ordered as required from your laboratory. For more information view the Advanced Fitting – Natural Ectasia online training module.
Decentered/ Low Cone			8.60mm: 14.50mm: STD	8.40mm: 14.50mm: STD	8.20mm: 14.50mm: STD	In cases where all fitting lenses persist in dropping significantly, it may be necessary to use Sector Management Control™, steepening lenses in the inferior sector only. For more information view the Advanced Fitting - Natural Ectasia online training module.
Pellucid Marginal Degeneration			8.60mm: 14.50mm: STD	8.40mm: 14.50mm: STD	May require Sector Mgnt. Control	In advanced cases the Sector Management Control design that is applied will usually require a superior FLT sector and inferior STP sector to reflect that these corneas are rotationally non-symmetrical. For more information view the Advanced Fitting - Natural Ectasia online training module.
Post-Surgical			8.60mm: 14.50mm: STP2	In post-surgical cases, if there is limited information as to the corneal shape, begin with the 8.60mm: 14.50mm: STD lens. These types of corneas may require STP periphery fitting lenses with the appropriate base curves. Tilted grafts or post refractive surgery ectasias may require a Sector Management Control design. For more information view the Advanced Fitting – Post-Surgical online training module.		

MoRoCCo VA
Introduction and Dynamic Assessment Routine

To successfully fit the KeraSoft® IC lens one must first observe the characteristics of the lens behavior on eye.

These characteristics can be remembered by using the acronym **MoRoCCo VA**, which represents **Mo**vement, **Ro**tation, **C**entration and **Co**mfort, all of which are designed to give the best **V**isual **A**cuity possible.

All of these characteristics are related to each other and have equal importance when assessing the fit of the lens on an irregular cornea.

If only two or three of the **MoRoCCo VA** characteristics are optimal, it will reduce the chance of the final ordered lens behaving as expected.

Optimal Lens Fit Characteristics

	Optimal Fit	
Mo	Up to 2.0mm movement	These lathe cut lenses naturally move more than disposable lenses and up to 2.0mm post blink movement is acceptable in straight ahead gaze, as long as the patient is comfortable.
Ro	Vertical laser mark	Rotation of the KeraSoft® IC is a strong indicator that the fit is not correct, unlike typical soft toric lenses where rotation can easily be accounted for by changing the cylinder axis. Up to 10° rotation is acceptable.
C	Centered	The centration of the lens can be easily determined by observing the Front Optic Zone and is a very useful indicator in assessing flat fits. An optimal fitting lens will be centered.
Co	Comfortable	KeraSoft® IC lenses should be comfortable. General discomfort can indicate the lens is flat and discomfort in one position indicates the lens is tight at that point.
VA	Stable	Visual acuity should be assessed before and after the blink. If VA is clearer after blink, this indicates a tight fit and if VA is worse after blink, this indicates a flat fit.

Dynamic Assessment Routine

Observe the lens within 5 minutes of lens insertion.

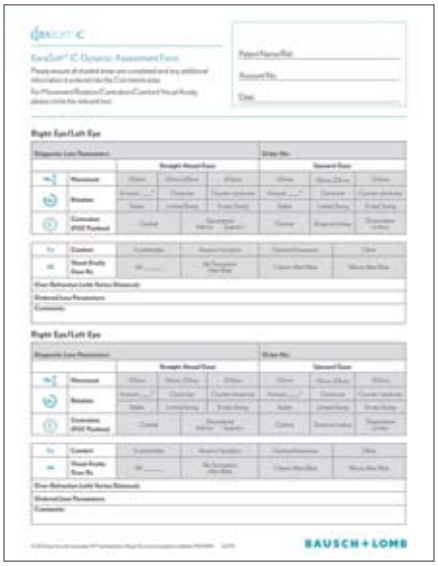
- The Dynamic Assessment Routine uses the slit lamp to observe three of the MoRoCCo VA characteristics; Movement, Rotation and Centration. These three characteristics are observed in straight ahead and upward gaze.
- Lag is assessed on lateral excursions with horizontal eye movement.
- Vertical movement is observed during the natural blink cycle. **The push-up test is not used to assess movement.**

Hints and Tips

If an ordered lens does not behave like the diagnostic lens, it is an indication that the diagnostic fit was not optimal.

- Lenses that fit very tightly can mimic a flat fit and vice versa. The KeraSoft® IC Online Training Module Dynamic Assessment Routine shows how to differentiate between these fits.
- Up to 10° rotation is acceptable, if no other fitting lens gives less rotation.

Dynamic Assessment Form



It is suggested this form is followed when ordering your KeraSoft® IC lenses.

Fit Assessment

Procedure

- Select and insert initial fitting lens
- Assess within 5 minutes to determine which MoRoCCo fitting characteristics below are being achieved (GREEN, YELLOW, RED)
- If any of the MoRoCCo characteristics are in the RED zone, remove lens, then select next fitting lens 1-2 base curves steeper or flatter
- If any of the MoRoCCo characteristics are in the GREEN or YELLOW zone, begin over-refraction while the lens settles further
- If VA is in RED zone, remove and reconsider first lens choice
- If VA is in YELLOW zone, determine whether fit is steep or flat, then adjust fit by 1 step
- When an optimal GREEN fit is achieved, allow to settle for 15-20 minutes then finalize over-refraction and take note of Back Vertex Distance

	Optimal Fit	Reassess Fit	Change the Fit
Mo	**1.0mm - 2.0mm VERTICAL POST BLINK**	**<1.0mm or >2.0mm**	**MOBILE may be too TIGHT OR too FLAT. Reassess fit.**
	Up to 2.0mm acceptable if patient is comfortable	<1.0mm - try one step flatter >2.0mm - try one step steeper	Lens too flat - try 0.40mm BC steeper Lens too tight - try 0.40mm BC flatter
Ro	**VERTICAL**	**ROTATION**	**ROTATION**
	Laser mark should sit at 6 o'clock position and be stable or return rapidly to position post blink	Up to 10° stable rotation acceptable if 0.20mm BC flatter does not rectify problem. Unstable rotation indicates a flat fit. Try 0.20mm BC steeper in this instance	>10° rotation Stable: lens is tight – remove and try progressively flatter lenses Unstable: Try a lens 0.40mm BC steeper
C	**CENTERED**	**DECENTERED**	**SIGNIFICANTLY DECENTERED**
	Minimal decentration is acceptable if visual acuity is stable and acceptable. VA clearer after the blink indicates a TIGHT fit	Laterally on straight ahead gaze Drops to limbus on upward gaze. Indicates a FLAT fit, Try 0.20mm BC steeper	Lateral decentration with significant lag. FOZ drops BELOW limbus on upwards gaze Try 0.40mm BC steeper
Co	**COMFORTABLE**	**NON-SETTLING DISCOMFORT**	**SIGNIFICANT DISCOMFORT**
	Consistently good comfort	General edge awareness= FLAT fit. Try 0.20mm BC steeper Increasingly in one position only=TIGHT fit. Try base curve 0.20mm BC flatter in this instance	STATIC = TIGHT – Remove and fit 0.40mm BC FLATTER MOBILE may be too TIGHT OR too FLAT. Reassess fit.
VA	**STABLE**	**UNSTABLE**	**VERY POOR VISION**
	No fluctuation between pre and post blink acuity	Worse after the blink=FLAT fit Clearer after the blink = TIGHT fit Try 0.20mm BC steeper or flatter accordingly	Usually caused by tears pooling under the lens. Most frequent cause, very flat corneal periphery

Periphery Options

In some cases of irregular cornea, one STD periphery diagnostic lens will give the best overall fit in terms of rotation and movement but a different one will give the best VA.

When choosing a diagnostic lens, both the fit and VA should be optimal. The periphery of the KeraSoft® IC lens can be steepened or flattened independently of the base curve to achieve the correct combination of fit and VA.

It is important to remember that peripheral changes should not be used just to tighten or loosen a fit. **Adjusting the fit should be done in the first instance by changing the base curve of the STD periphery lens.**

How to calculate the periphery change

During the fitting process, record the fitting lens that gives the best fitting characteristics, Best Peripheral Fit (BPF).

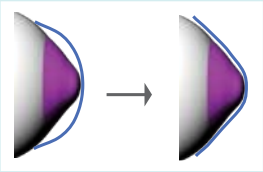
Then record the fitting lens that gives the best possible VA, Best Central Fit (BCF).

The difference in base curves is then calculated: the Periphery Table indicates the periphery required.

Each periphery step is equivalent to a 0.20mm change in base curve.

Note: when a periphery change is made, it affects the diameter of the Posterior Fitting Zone. The Front Optic Zone is not affected.

When to use FLAT peripheries



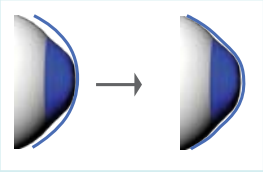
Flattening the periphery allows the lens to correctly drape over the central cornea.

Example

If all STD lenses give stable rotation, this implies the periphery of the cornea is flat compared to the center, e.g., Nipple Cones.

When STD lenses show central bubbles, general poor vision or VA clearer after blink and flattening the base curve improves VA but gives flat fit characteristics.

When to use STEEP peripheries



Example

When STD lenses show fluting or unstable rotation and steepening the base curve improves the fit but gives VA clearer after blink. Such cases include:

- Post-refractive surgery
- Central keratoconus with steep periphery
- Post-graft corneas showing a reverse geometry corneal profile

Periphery Table

BPF-BCF	Periphery to order
-0.80mm	STP4
-0.60mm	STP3
-0.40mm	STP2
-0.20mm	STP1
STD	STD
+0.20mm	FLT1
+0.40mm	FLT2
+0.60mm	FLT3
+0.80mm	FLT4

Example

1 The best possible VA is found using an 8.00mm fitting lens but shows tight fitting characteristics. This base curve is recorded as the Best Central Fit (BCF).

The base curve giving optimal rotation and movement is found to be 8.20mm, however, the VA is now worse after blink. This base curve is recorded as the Best Peripheral Fit (BPF).

BPF - BCF = 8.20mm - 8.00mm = +0.20mm which gives a periphery value of FLT1 from the table.

This would be ordered as 8.00mm: FLT1

2 The best possible VA is found using an 8.40mm fitting lens but shows flat fitting characteristics. This base curve is recorded as the Best Central Fit (BCF).

The base curve giving optimal rotation and movement is found to be 7.80mm, however, the VA is now clearer after blink. This base curve is recorded as the Best Peripheral Fit (BPF).

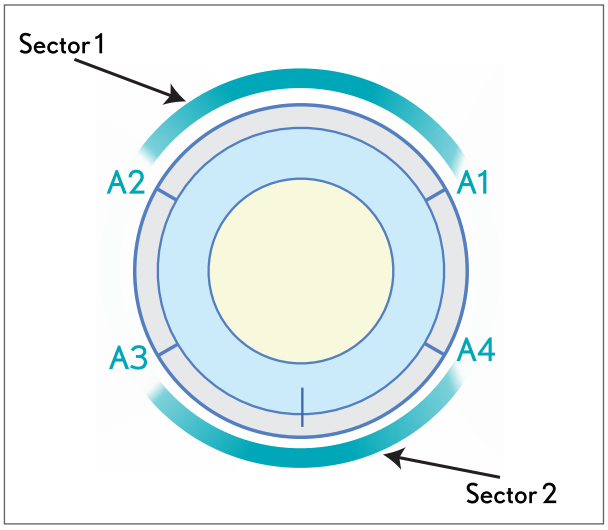
BPF - BCF = 7.80mm - 8.40mm = -0.60mm which gives a periphery value of STP3 from the table.

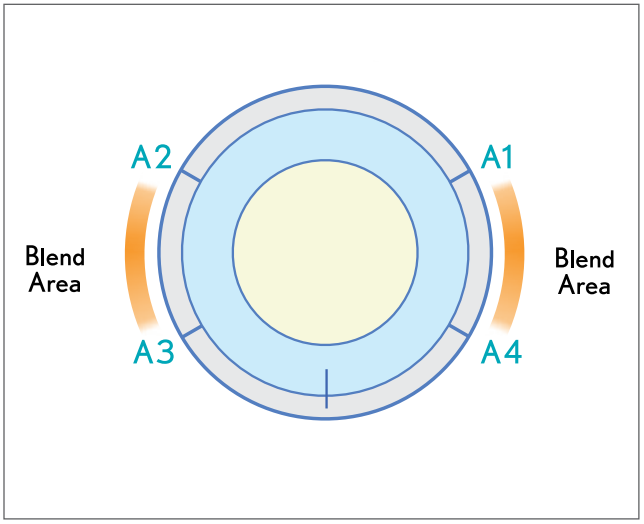
The required lens would be ordered as 8.40mm: STP3

Sector Management Control™ (SMC™)

If choosing this design, you may want to review the Advanced Fitting Module of the training video.

For more irregular corneas, up to two sectors of the periphery can be modified independently of the base curve and customized to the specification of the practitioner (indicated in less than 10% of KeraSoft® IC fits).





How to define the SMC Sector Angles

Record angles counter-clockwise around the lens circumference as A1, A2, A3 and A4.

A1 and A2 define beginning and end of the first sector.

A3 and A4 define beginning and end of the second sector.

Each sector can be ordered as either STD, STP 1-4 or FLT 1-4.

Blend areas are automatically set once sector angles are defined.

There must be a minimum of 30° between each sector.

When to Use Sector Management Control

In all cases it would be advised to use STD lenses first. However, in advanced cases of irregular astigmatism it might be necessary to manipulate the specific sectors of the periphery.

Sector Management Control is typically used for:

1. Low Cones and Pellucid Marginal Degeneration (PMD). These corneal shapes can cause STD periphery lenses to:
   - Decenter, irrespective of the base curve tried
   - Induce ghosting or shadowing of images

   If these issues are present regardless of the STD periphery lens tried, keep the superior sector STD and steepen the inferior sector by STP1.

   To fit advanced cases of PMD or Low Cone, flatten the superior sector by FLT1 and steepen the inferior sector by STP1 (see example 1).
2. Very irregular post-graft cases.

   These corneal shapes have an unnatural shape and may require a more customized design.

   Note the location of the areas of fluting or tightening on the best fitting STD periphery lens. Use this to determine the angles of the sectors you wish to tighten or flatten (see example 2).

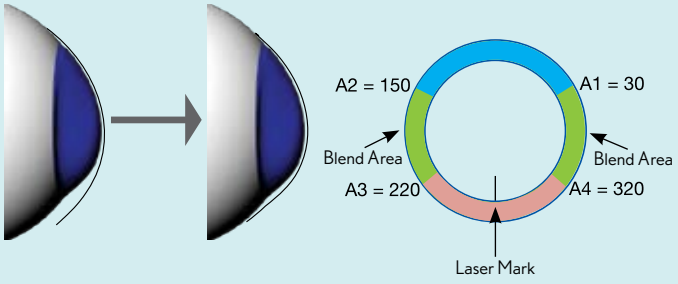
Classic SMC Design Sector Angles

This design can be used for most corneas that have a natural ectasia.

A1 = 30° A2 = 150°
A3 = 220° A4 = 320°

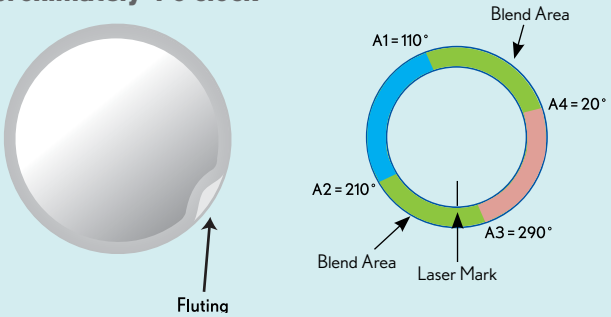
For cases where tightening only in the inferior sector is required, keep the superior sector STD and steepen the inferior sector by STP1. Post-graft corneas may require a more customized design.

Example 1:
Classic SMC - Low Cone/PMD



This SMC would be ordered as:
8.40mm: 14.50mm:
FLT1: A1 = 30° A2 = 150°
STP1: A3 = 220° A4 = 320°
Using the Classic SMC design.

Example 2:
Customized SMC - Fluting on Post-Graft Cornea: Image demonstrates edge lift at approximately 4 o'clock



If the lens requires tightening in the area between 20 and 290 degrees, the order would be written as:
8.60mm: 14.50mm
STD: A1 = 110° A2 = 210°
STP2: A3 = 290° A4 = 20°

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