KERASOFT® IC

FITTING MANUAL

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Fitting Manual: Contents

This fitting manual is best used in conjunction with KeraSoft® IC online training.
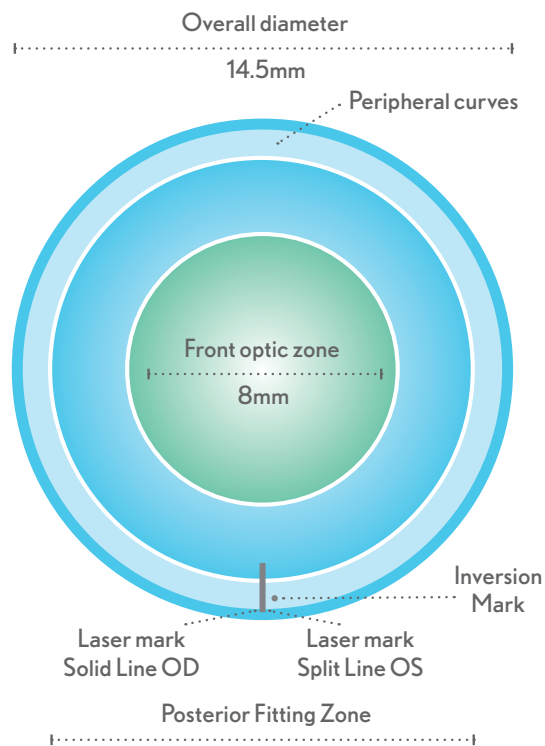To register, please visit www.kerasoft.co.uk/training

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 wavefront 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

Overall diameter
14.5mm
Peripheral curves
Front optic zone
8mm
Inversion Mark
Laser mark Solid Line OD   Laser mark Split Line OS
Posterior Fitting Zone

Standard Diagnostic Fitting Set

Used to determine the following information which 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, 15.00 mm, and 15.50mm can be manufactured to order
Lens design	Front surface asphere or aspheric toric prism ballasted lens with balanced overall thickness and wavefront 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: +30.00D to -30.00D Cylinder: -0.50D to -15.00D (in 0.25D steps) Axis: 1° to 180° (in 1° steps)
Material	[1] Filcon II 2, 77% Water, 12-month replacement [2] Efrofilcon A, 74% Water*, 3-month replacement * Definitive™
DK	[1] 53 x 10^{-11} (cm²/sec)[mlO$_2$/(ml x mmHg)] [2] 60 x 10^{-11} (cm²/sec)[mlO$_2$/(ml x mmHg)]

Standard 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 assist in selecting 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 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 Observe 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

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.

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, when optimal, give the best **V**isual **A**cuity.

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

Up to 2mm movement	These lathe cut lenses naturally move more than disposable lenses and up to 2mm post blink movement is acceptable, as long as the patient is comfortable.
Vertical Laser mark	Rotation of the KeraSoft® IC is a strong indicator that the fit is not correct, unlike normal soft toric lenses where rotation can easily be accounted for by changing the cylinder axis.
Central	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 central.
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.
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.

Mo ↕ The Dynamic Assessment Routine uses the slit lamp to observe three of the MoRoCCo VA characteristics; Movement, Rotation and Centration.

Ro ↻ These three characteristics are observed in straight ahead and upward gaze.

C Lag is assessed on lateral excursions in the straight ahead position.

Movement is observed during the natural blink cycle. **The push-up test is not used to assess movement.**

Hints and Tips

Mo ↕ 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.

Ro ↻ Up to 10 degrees rotation is acceptable, if no other fitting lens gives less rotation.

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

Dynamic Assessment Routine

	Optimal	Tight	Flat
Mo ↕	UP TO 2.0mm	LESS THAN 0.50mm Conjunctival indentation	GREATER THAN 2.0mm Lens may flute
Ro ↻	NO ROTATION Vertical Laser Mark	ROTATION Stable in straight ahead and upward gaze	ROTATION Unstable or rotates on upward gaze
C	CENTRAL	CENTRAL	DECENTERED FOZ drops to or below limbus
Co	COMFORTABLE	COMFORTABLE INITIALLY gradually becomes uncomfortable in one area	UNCOMFORTABLE
VA	STABLE	CLEARER AFTER BLINK	WORSE AFTER BLINK

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 (Green)	Re-assess Fit (Yellow)	Incorrect Fit (Red)
Movement	1.0-2.0mm Vertical Post Blink Up to 2.0mm acceptable if patient is comfortable	<1.0 or >2.0mm <1.0mm - try one step flatter >2.0mm - try one step steeper	Too Mobile OR Immobile Lens that Moves with Push-up If lens too flat - try 0.40mm base curve steeper If lens too tight - try 0.40mm base curve flatter
Rotation	Laser Mark - Vertical Up to 10 degrees stable rotation is acceptable if fitting 0.20mm base curve steeper or flatter does not reduce the angle	Up to 10 Degrees Erratic swing on blink - Flat fit Limited swing on blink - Tight fit	>10 Degrees Erratic swing on blink - Flat fit Limited swing on blink - Tight fit
Centration	Central Minimal decentration is acceptable if visual acuity is good	Decenters on Straight Ahead Gaze/ Front Optic Zone Drops to Limbus on Upward Gaze Try lens 0.20mm base curve steeper	Front Optic Zone Edge Drops Below Limbus on Upward Gaze Try lens at least 0.20mm base curve steeper
Comfort	Comfortable Consistently good comfort	General Discomfort Some edge awareness - Flat fit Discomfort in one location - Tight fit	Very Uncomfortable Comfort does not improve with time
VA	No Fluctuation Visual acuity should not fluctuate on blink	Fluctuation with Blink Worse after blink - Flat fit Clearer straight after blink - Tight fit	Very Poor Vision Poor vision not improved by any over-refraction

Periphery Options

In cases of irregular cornea where STD periphery lenses do not provide an optimal fit, the periphery of the KeraSoft® IC can be steepened or flattened independently of the base curve.

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

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

During the fitting process, record the fitting lens that gives the best fitting characteristics, Best Peripheral Fit (BPF).
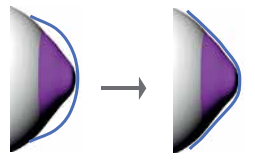
Then record the fitting lens that gives the best possible VA, Best Central Fit (BCF).

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.
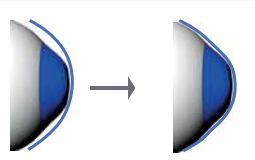
When to use FLAT peripheries	Example
Flattening the periphery allows the lens to correctly drape over the central cornea.	If all STD lenses give stable rotation, this implies the periphery of the cornea is flat compared to the center, e.g., Nipple Cones. When STD lenses show central bubbles, general 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

When to Use Sector Management Control™

Sector Management Control is typically used in cases where:

1. A good fit cannot be obtained with an STD lens or by changing the whole periphery. Such cases include:

- · Low cones and PMD
- · Very irregular post-graft cases

2. Lenses are otherwise a good fit, yet persistently decenter or drop significantly on upward gaze.

3. The optimal fitting STD periphery lens consistently results in ghosting or shadowing of images. Using SMC in these cases can significantly improve Visual Acuity.

4. Decentered cones where the resultant corneal shape consistently causes all lenses to decenter.
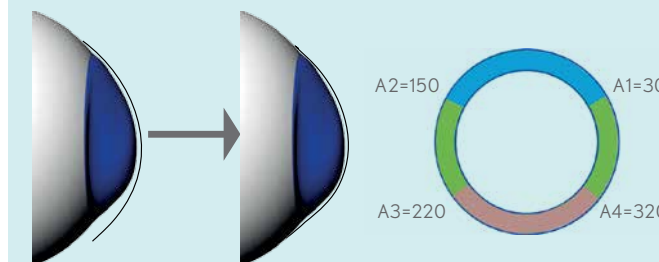
Classic SMC Design Sector Angles

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.

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).

Sector 1

A2   A1

A3   A4

Sector 2

A2   A1

Blended Area   Blended Area

A3   A4
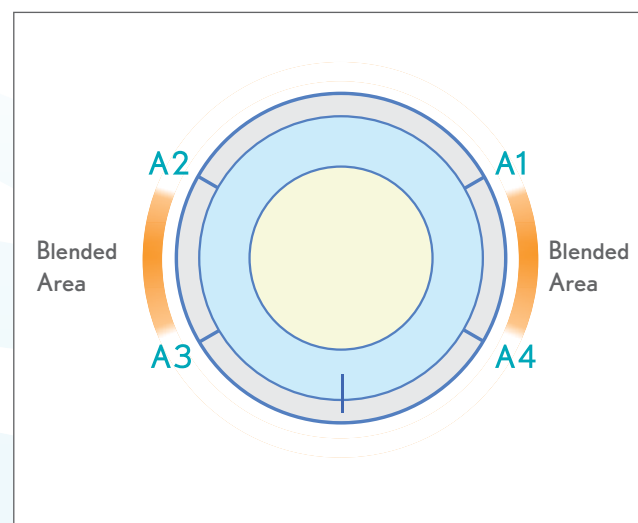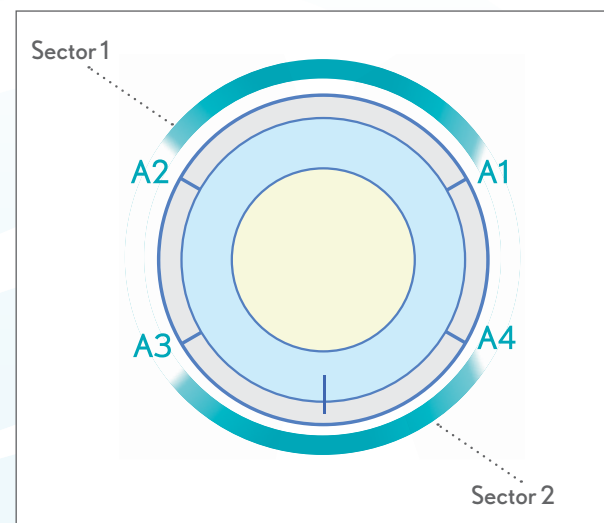
How to define the SMC Sector Angles

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 degrees between each sector.

Example 1:
Classic SMC - Low Cone/PMD

A2=150   A1=30

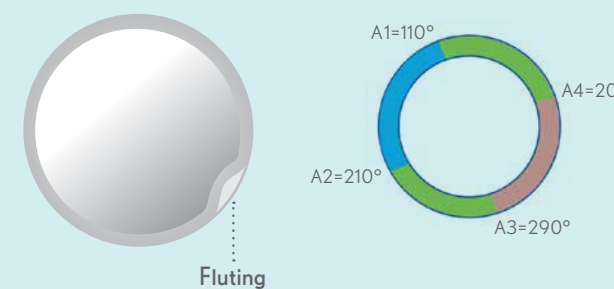A3=220   A4=320

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

A1=110°

A4=20°

A2=210°

A3=290°

Fluting

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°

KERASOFT® IC

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