
PROFESSIONAL FITTING GUIDE
For the
IntelliWave³/KeraSoft[®] IC
(Efofilcon A)
SOFT (hydrophilic) SILICONE HYDROGEL
CONTACT LENS FOR DAILY WEAR

**CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A
LICENSED PRACTITIONER.**

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MATERIAL CHARACTERISTICS
DESCRIPTION OF LENS

The **IntelliWave³/KeraSoft IC** Silicone Hydrogel Soft Contact Lenses are fabricated from (efofilcon A), which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The non-ionic lens material, (efofilcon A) is a group 2, daily wear silicone hydrogel contact lens that is not surface treated and characterized by a high water content. The lens material is composed of silicone monomers cross linked with other monomers. The lenses are made by lathe-cut for custom RX. It consists of 26% efofilcon A and 74% water by weight when immersed in a buffered saline solution. The (efofilcon A) name has been adopted by the United States Adopted Names Council (USAN).

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The (efofilcon A) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The Physical properties of the lens are:

Refractive Index	1.38
Light Transmission	greater than 97%
Surface Character	hydrophilic
Water Content	74 %
Specific Gravity	1.048 (hydrated)
Oxygen Permeability	59.8×10^{-11} (cm ² /sec) (ml O ₂ /ml x hPa @ 35°C), (revised Fatt method).

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 74% water by weight. The lenses will be manufactured in spherical, aspherical, toric, multifocal, multifocal toric and irregular Cornea configurations with the following features and properties.

- Chord Diameter 12.0 mm to 16.00 mm
- Center Thickness 0.01 mm to 0.50 mm
- Base Curve 7.00 mm to 10.0 mm
- Power Range -20.00D to +20.00D in 0.25 steps
- Cylinder Power (Toric) -0.25D to -12.00D
- Cylinder Power (Multifocal Toric) -0.25D to -12.00D
- Add Power (Multifocal) +0.50D to +4.00D

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The **IntelliWave³/KeraSoft IC, (efofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens** has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

ACTIONS

In its hydrated state, the **IntelliWave³/KeraSoft IC, (efofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens**, when placed on the cornea, act as a refracting medium to focus light rays on the retina.

INDICATIONS

INDICATIONS FOR USE:

The **IntelliWave³**, sphere (efofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

The **IntelliWave³**, toric (efofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 12 diopters.

The **IntelliWave³**, multifocal (efofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding .75 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The **IntelliWave³**, multifocal toric (efofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The KeraSoft IC, irregular cornea (efofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons and may be prescribed in otherwise non-diseased eyes that require a soft contact lens for the management of irregular corneal conditions such as Keratoconus and post graft fitting.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Special Precautions for the Eyecare Practitioner

Due to the small number of patients enrolled in clinical investigation of lens, all refractive powers, design configurations, or lens parameters available in the lens material were not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health must be carefully weighed against the patient's need for refractive correction. Therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

CONTRAINDICATIONS (REASONS NOT TO USE)

Please reference Contraindications (Reasons Not to Use) in the Package Insert included at the end of this Fitting Guide.

WARNINGS

Please reference Warnings in the Package Insert included at the end of this Fitting Guide.

PRECAUTIONS

Please reference Precautions in the Package Insert included at the end of this Fitting Guide.

ADVERSE REACTIONS

Please reference Adverse Reactions in the Package Insert included at the end of this Fitting Guide.

PATIENT SELECTION

Patient communication is vital. Patients who require visual correction but cannot adhere to the recommended care of the **IntelliWave³/KeraSoft IC, (efofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens** should not be provided with this lens. All necessary steps in lens care and all precautions and warnings should be discussed and understood by the patient (*Review Package Insert with patient*).

Fitting procedure for the **IntelliWave³ Silicone Hydrogel Sphere and Toric Lenses**:

FITTING PROCEDURE for the Spherical Single Vision Lens.

1) Pre-fitting Examination

A pre-fitting patient history and examination are necessary to:

- determine whether a patient is a suitable candidate for daily wear contact lenses (refer to contraindications)
- collect and record baseline clinical information to which post-fitting examination results can be compared
- make ocular measurements for initial contact lens parameter selection
- Record Horizontal Visible Iris Diameter (HVID)

2) Initial Fitting

It is recommended to use an empirical fitting method for **IntelliWave³ Silicone Hydrogel** contact lenses. When ordering, simply supply us with the information listed below and we will manufacture the lenses to meet your needs:

For each eye supply:

- HVID
- Keratometer readings
- Spectacle Refraction
- Back vertex distance of spectacle Rx

For Astigmatism above 1.25 DC, specify the Toric lens.

Fitting Assessment

Insert the new lenses and allow to settle for 5 to 10 minutes. After the lenses have settled, assess vision and fit including the following points:

- The lens should exhibit good centration on primary (straight ahead) gaze and good corneal coverage in all directions of gaze. The edge should be approximately 1.5mm beyond the limbus.
- Vertical movement on blinking (on upward gaze) should be between 0.5mm and 1mm.
- The push up test (PUT) should show fast and smooth recenteration of the lens.
- There should be no Scleral indentation or blanching. Keratometer mires should be stable on blinking. The patient should experience good comfort.

FITTING PROCEDURE for the Toric Lens.

1) Pre-fitting Examination

A pre-fitting patient history and examination are necessary to:

- determine whether a patient is a suitable candidate for daily wear contact lenses (refer to contraindications)
- collect and record baseline clinical information to which post-fitting examination results can be compared
- make ocular measurements for initial contact lens parameter selection
- Record Horizontal Visible Iris Diameter (HVID)

2) Initial Fitting

It is recommended to use an empirical fitting method for the **IntelliWave³ Silicone Hydrogel** toric contact lenses. When ordering, simply supply us with the information listed below and we will manufacture the lenses to meet your needs.

For each eye supply:

- HVID
- Keratometer readings
- Spectacle Refraction
- Back vertex distance of spectacle Rx

Fitting Assessment

Insert the new lenses and allow to settle for 5 to 10 minutes. After the lenses have settled, assess vision and fit including the following points:

- The lens should exhibit good centration on primary (straight ahead) gaze and good corneal coverage in all directions of gaze. The edge should be approximately 1.5mm beyond the limbus.
- Vertical movement on blinking (on upward gaze) should be between 0.5mm and 1mm.
- The push up test (PUT) should show fast and smooth recenteration of the lens.
- There should be no Scleral indentation or blanching. Keratometer mires should be stable on blinking. The patient should experience good comfort.
- The central axis marking of the lens should be in the vertical position at 6 o'clock and return to a vertical position after the PUT. If the axis is slightly rotated but the patient's vision is acceptable, they can be worn and reassessed at the first follow-up consultation. If the axis is consistently rotated and is delivering unacceptable visual acuity, then return the lens (using our exchange program) stating the direction and degree of rotation of the lens accompanied by an assessment of the fit of the lens.

Fitting procedure for the IntelliWave³ Silicone Hydrogel Multifocal and Multifocal Toric lenses:

Fitting procedure for the IntelliWave³ Silicone Hydrogel, Multifocal lens:

The **IntelliWave³ Silicone Hydrogel**, Multifocal lens is offered to patients who are presbyopic requiring add power of up to +4.00 diopters and is also offered as a Multifocal Toric for patients who are presbyopic and may possess refractive astigmatism not exceeding 4 diopters. The **IntelliWave³ Silicone Hydrogel**, Multifocal lens is a centre-near, simultaneous-vision, soft lens whose multi-aspheric front surface, provides clear distance, intermediate and near vision for presbyopes.

The following procedure covers both the Multifocal and Multifocal Toric lens indications.

Fitting Guidelines

The practitioner provides the following parameters:

- Spectacle refraction including sphere, cyl, axis and add, as appropriate
- Back Vertex Distance (BVD)
- Keratometer readings (preferably with axes)
- Horizontal Visible Iris Diameter (HVID)
- Dominant eye
- Pupil diameter in normal light. Identification of the dominant eye enables a slightly larger area, for the near and near/intermediate powers, to be worked into the lens for the non-dominant eye.

This promotes a more “comfortable” binocular relationship.

Initial Assessment

The lens parameters arising from the measurements provided will usually achieve first-time, optimum all-round vision. However in some cases modification may be required.

If the practitioner is satisfied with the physiological aspects of the fit, it is best to defer any adjustment to power until the patient has completed 7 to 10 days of regular wear. This period permits the patient’s visual system to become accustomed to the specific nature of the aspheric optical system.

Assessing the Fit

At the 2 week consultation, the fit should be assessed, taking note of the points outlined below.

Visual Assessment

For the multifocal design, the use of hand held trial lenses will simplify the evaluation process. To improve near vision, add plus in +0.25 D increments to both eyes until the near vision is acceptable. To improve distance vision, add minus in 0.25 D increments in both eyes. Note the amount of power adjustment required for near and distance, then return the lens (using our exchange program) stating the amount of over refraction required for distance and near accompanied by the assessment of the fit.

For the multifocal toric, the central axis marking of the lens should be in the vertical position at 6 O’clock and return to a vertical position after the PUT. If the axis is slightly rotated but the patients vision is acceptable the lens can be worn and reassessed at the next follow up visit. If the axis is constantly rotated and the vision is unacceptable, perform a sphere-cylinder over refraction in the Phoropter for best distance vision. Place the over refraction in a trial frame and evaluate the near vision. To improve the near vision, add plus in +0.25 D increments to both eyes until the near vision is acceptable. Then return the lens (using our exchange program) stating the amount of over refraction required for distance and near along with the amount and direction of rotation of the central axis mark accompanied by the assessment of the fit.

Characteristics of a Flat Fit

Flat fittings result in excessive movement of the lens and this will affect the optical efficiency of the system with the following symptoms.

- There will be induced astigmatism in the over-refraction
- The over-refraction will require more plus for near vision
- Manual correction of the position of the lens on the eye will usually confirm the above
- For a toric lens the axis will usually rotate. In such cases, steepening of the fit, preferably by diameter increase, will correct the problem.

Characteristics of a Steep Fit

When the fitting is steep, vision is inconsistent and clears only for a brief time following a blink. In most cases, flattening of the fit, by changes to the BOZR, will overcome these problems. The steep fit also negates the effect of the stabilization areas in the toric lens forms and there may be a slow, progressive movement of the cylinder axis away from its prime position.

Cylindrical Axis Mis-location

Where the multifocal is in toric form, axis mislocation will be detrimental to vision. In the case of small deviations (5 degrees or less), a compensating change in the cylinder axis will often rectify. Larger deviations will require additional consideration of the level of ballasting applied to the front surface and/or an increase in the diameter to increase the influence of the sclera in promoting stability. A change in BOZR would be required to maintain the equivalent fit.

Adjustments to Lenses

In the event that adjustments are required, we request that practitioners do not make their own adjustments, and instead supply symptomatic details of any problems along with any refractive information direct to laboratory consultants. The Consultant, who has access to the details of the complex structure of the lenses, will then determine the final specification of the lens to be made. This will enable the laboratory to effect the best combination of adjustments whilst retaining all the benefits of the proprietary technologies being utilized for this design.

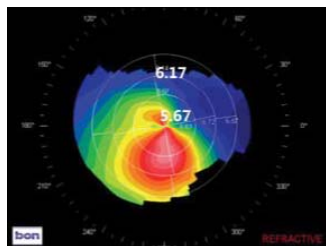
Important Notes on Aftercare Visits

- As with all progressive multifocal corrections, there is an adaptation period of at least one week of regular wear.
- Minor with-the-rule astigmatic errors may be ignored if the patient copes without this correction in their spectacle Rx or single-vision soft lenses.
- Should unsatisfactory vision result from a lens, an over-refraction should be performed*, first for the distance, then, **independently** for the near.

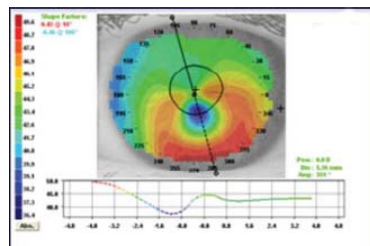
* The use of pinholes or similar techniques in over-refraction of the **IntelliWave³ Silicone Hydrogel** multifocal is ineffective as an aid to evaluating visual results.

Fitting procedure for the /KeraSoft IC Silicone Hydrogel Irregular Cornea lenses:

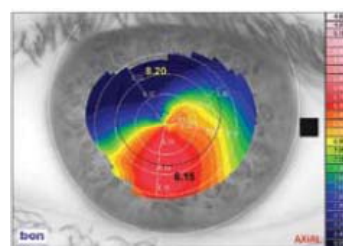
Fitting Keratoconus with /KeraSoft IC Silicone Hydrogel Contact Lenses Keratoconus vs. Pellucid Marginal Degeneration



Keratoconus
Figure 1



Pellucid Marginal Degeneration
Figure 2



Pellucid Marginal Degeneration
Figure 2

Keratoconus vs. Pellucid Marginal Degeneration

KeraSoft IC contact lenses are specifically designed for keratoconus, i.e., for corneas that are steeper centrally with regular peripheral regions and other types of irregular cornea, including advanced or irregular keratoconus.

Checking the corneal shape

Although KeraSoft IC can be fitted without using topography; corneal mapping is a very valuable tool in any keratoconic fitting. It is important that a distinction is made between keratoconus and the related condition, Pellucid Marginal Degeneration (PMD). As can be seen from the topographies in Figures 1, 2 and 3, PMD is characterized by a central flat area with a “kissing birds” or “crabs claw” appearance. Typically, whereas keratoconus usually presents with medium to high myopia, PMD refractions are often low minus to plus with high minus cyls with a vertical axis. The example in Figure 3 shows what initially appears to be a typical inferior keratoconus, with central K of around 6.15; it is in fact PMD with a very flat superior corneal

curvature of 8.20mm. These cases may in fact give relatively steep central Ks on a normal keratometer, which can be misleading.

Choosing the first lens

The standard diameter in a KeraSoft IC trial set is 14.50mm and the BCOR of the lenses range from 8.00mm - 8.60mm. The range of back curves may seem rather flat, compared to an RGP lens. However, this is a soft lens and it needs to be borne in mind that the fitting of the peripheral curve is a key component. The KeraSoft IC product sheet suggests which lens to try first based on approximate keratometer readings. On this basis, the keratoconus example in Figure 1 would be fitted with an 8.00mm BCOR as a first lens.

BCOR	Diameter	Power	Approximate Readings	K
8.00 (A)	14.50	-12.00 and 14.00	<6.00	Recommended initial fitting lens for keratoconus with central cones and normal peripheries
8.20 (B)	14.50	-10.00 and -8.00	6.00-6.50	
8.40 (C)	14.50	-6.00 and -4.00	6.50-6.80	
8.60 (D)	14.50	-2.00 and Plano	6.80-7.20	
8.80 *	14.50	Plano	For flatter peripheries (see below) For Irregular Corneas see KeraSoft@IC Fitting Guide	
9.00 *	14.50	Plano		

* These parameters are not included in the KeraSoft@3 fitting set but can be ordered separately

Once the lens has been inserted, allow to settle for around 10 minutes before trying to assess the fit. Bubbles may form under the lens at first and if they persist, then this can indicate a tight fit. If they disappear after 20 minutes and there is good movement, then this usually indicates the fit is acceptable. Once experience is gained in the appearance of the fits, then one can tell after 10 minutes if a lens is likely to settle properly or not.

In the case of the PMD (Figure 3) central K readings may suggest a first lens choice of 8.00mm or 8.20mm; in fact, a flatter lens would be more suitable. Based on topography, an 8.60mm lens was fitted successfully. Without topography, the steeper first lens choices would give fluctuating vision (clearer after the blink) and poor lens movement. In that situation, the procedure would be to continue to fit ever flatter lenses until an improvement in vision and good lens movement was achieved.

Lens Movement/Laser Mark

The KeraSoft IC has more substance than most lathe-cut soft contact lenses and therefore can demonstrate much more movement than a typical soft lens. One way of assessing the movement is to assess the rotational behavior of the lens, utilizing the laser mark.



Each trial lens has a laser mark that indicates the position of the prism ballasting (see Figure 4). This mark should usually be inferior and vertical, and should remain vertical even if the lens moves 2-3mm post-blink. If the mark rotates back and forth unpredictably with blinking, this is usually an indication that the lens is too flat. Sometimes the laser mark will simply orientate slightly off axis. However, this is acceptable as long as the lens stays rotated in that position. This picture also shows how much a KeraSoft IC lens can drop on upward gaze and still be a good fit. **Important:** The position of the laser mark should always be given when ordering the final lens.

Over Refraction

Accurate refraction is always a problem with keratoconics, so it may be difficult to establish a good starting point for over refraction. When using RGPs, it is typical to think in terms of the spherical over refraction. However, with KeraSoft IC it is

important to assess the astigmatic over refraction as well as the sphere. One good way to get a starting point is to use the autorefractor over the top of the lens. This is usually more accurate using the IOL setting on the autorefractor (if it has this setting). This method will usually give a good indication of any astigmatism present. An extra source of information is that provided by the use of topography over the top of the lens. Although no indication of sphere is given, usually there is a good idea of cyl and axis which, combined with the autorefractor results, can be very helpful. It is always worth looking at the cyl correction, even if the patient can achieve quite good results with a sphere alone. This is due to the fact that keratoconics, especially those who have not yet been fitted with contact lenses, tend to tolerate shadowing and doubling of images very well, so double check to see if giving the cyl will help acuity. If the over refraction gives disappointing or unexpected results, the fit needs to be reassessed. If there is little lens movement and the vision fluctuates on blinking, then it is recommended that a flatter lens is tried. Sometimes, if vision is not as expected and all lenses appear quite tight, this can indicate that a 14.00mm diameter lens is required.

Vision that varies unpredictably can mean the lens is too flat, in which case the rotation should be double checked using the laser mark as a guide. Once the suitable fit and vision are achieved, the initial fitting lens (with warranty included) can be ordered. For this the following information is required:

Trial lens details: BCOR, Diameter and power

Laser mark position
Over refraction
HVID
BVD

Note: If the over refraction axis has automatically been corrected to take into account the position of the laser mark, this should be made clear when placing the order for the lens.

Checking the ordered fitting lens

When the lenses are received, check for fit and vision. If the vision/fit is not as expected, then over refract with the lens in situ, as sometimes adding the cylinder changes the dynamics of the lens slightly and the lens sits in a different position. Over refraction may give a significant cyl at a different axis. This is an induced effect of the cyl sitting at the wrong axis and the correction needed can be calculated from the results achieved. The lens can be re-ordered giving the over refraction results and/or the new rotated position using the laser mark. Again, over refraction using autorefractor is useful in this situation.

POST-Refractive Patient Fitting Guide

Introduction

The KeraSoft IC is a completely configurable soft contact lens system which enables the fitting of all stages of keratoconus and all other irregular cornea types e.g. PMD, post graft and post refractive surgery. The Definitive material has been carefully chosen to deliver optimum performance with the unique KeraSoft® IC design and provide the wearer with the following benefits:

- High levels of comfort
- Consistent, stable vision
- Award winning wavefront optics
- Front surface toric
- Innovative stabilization system
- Extensive range of powers
- Long wearing times, even in dry environments

KeraSoft IC is specifically designed to allow the practitioner to define the periphery to best match the patient's cornea.

Fitting Set

The fitting set comprises 6 x lenses with a Standard periphery (STD), 1 x lens with a Flat periphery (FLT2) and 1 x lens with a Steep periphery (STP2).

BCOR	DIA	PERIPH	POWER
7.80mm	14.50mm	STD	Plano
8.00mm	14.50mm	STD	Plano
8.20mm	14.50mm	STD	Plano
8.40mm	14.50mm	STD	Plano
8.60mm	14.50mm	STD	Plano
8.80mm	14.50mm	STD	Plano
8.20mm	14.50mm	FLT2	Plano
8.60mm	14.50mm	STP2	Plano

The STD periphery design will fit a wide range of corneas and acts as a good base from which to design more complicated KeraSoft IC lenses. All fitting lenses have plano power, as many patients have undergone refractive surgery, or grafting, in which case it is not possible to predict likely powers. When the best fit lens has been established, any further adjustments can be based on the selected lens.

Identifying Corneal Type

Topography is very useful in identifying the type of cornea being fitted. Thus the location of the steepest and flattest areas of the cornea can be established and it can be determined if a reverse geometry lens might be considered e.g. in cases of post graft and post refractive surgery. However, as many topography machines do not record the peripheral cornea, nor the corneo-scleral junction, **KeraSoft IC Fitting Lenses should always be used** when fitting a patient with KeraSoft IC.

Initial Fitting Lens Choice

Corneal Type	Suggested Initial Lens	Follow up Options
Nipple Cone Advanced Keratoconus	7.80 - 8.00/14.50/STD	Fitting Lenses with steeper base curves can be ordered if the 7.80 lens is too flat. For nipple cones: flattening the periphery may give better acuity e.g. 7.80/14.50/FLT2
Moderate Cone	8.20 - 8.40/14.50/STD	If there is excessive movement or displacement, a steeper Fitting Lens can be tried. If the vision is fluctuating and improves after a blink, a flatter Fitting Lens can be tried.
Mild Cones Post Graft Post Refractive Surgery	8.60 - 8.80/14.50/STD	If fluting (lifting of the edge of the lens) is observed in post surgical cases and steeper Fitting Lenses give poor acuity, then the periphery can be steepened independently of the base curve. e.g. 8.60/14.50/STP2
Pellucid Marginal Degeneration (PMD)	8.60/14.50/STP2	This lens is a good starting point for PMD corneas. If all lenses tend to drop or decentre, then an SMC lens with a "tucked in" periphery at the steepest area will help improve fit and reduce ghosting.

Fitting Tip - Post Surgical Patients: Some patients may present having undergone several surgical procedures for IC. For example, a post LASIK ectasia patient may have also undergone INTACs and corneal collagen cross linking. A post graft patient may also have had Astigmatic Keratotomy. These procedures may result in complex corneal shapes not easily interpreted by keratometry or some topography machines. Unless the cornea is very steep centrally, the 8.40/14.50/STD Fitting Lens provides a good starting point. Decisions as to whether to fit steeper or flatter then can be assessed using observation of movement, centration and acuity.

Fitting Tip - Peripheral Adjustment: A lens of base curve 8.40/14.50/STP1 would have a peripheral curve equivalent to that of an 8.20 base curve lens. Similarly, an 8.40/14.50/FLT1 would have a peripheral curve equivalent to an 8.60 base curve lens.

Assessing the Fit

When the most suitable Fitting Lens is inserted it should be allowed to settle for approximately 15 minutes and then assessed again using the following guide.

Optimal Fit

- Movement of up to 3mm on straight ahead gaze is normal when using these lenses, providing the patient is comfortable and there are no other indications of a flat fit.
- Laser mark remains stable in the vertical (6 o'clock, 270°) position for optimal fit.
- Vision should be stable with no fluctuation. Unexpected poor vision usually indicates a less than optimal fit.

Steep Fitting Lenses

- No lens movement or movement of less than 1mm on straight ahead gaze (lens may still move freely on upward gaze).
- Lens rotates significantly (more than 30° from vertical).
- Laser mark stays approximately in position but rotates back and forth ~5° post blink.
- Fluctuating vision that is clearer after a blink is a good indicator of a tight fit.
- Poor vision generally - a very tight lens tends to sit proud of the cornea thus creating a significant tear lens under the optic zone. Blinking causes the lens to flatten and spring back, resulting in fluctuating vision.

Flat Fitting Lenses

- Movement more than 3-4mm post blink.
- Lens decentres - often upwards.
- Lens drops significantly on upwards gaze.
- Lens fluting at edge.
- Lens rotates in an unstable way, swinging back and forth by 10° or more in an irregular manner.
- Lens rotates significantly (more than 30°).

Prescribing only spherical correction, when there is significant astigmatism present, will typically give reduced vision. High levels of astigmatism can be successfully corrected with the KeraSoft IC front toric design due to its rotational stability. It is strongly advised that the full toric refraction is given to maximize acuity.

Over Refraction

After the optimal fit has been achieved over refraction is carried out. The KeraSoft IC will mask low levels of astigmatism. Irregular astigmatism typically becomes more regular with the lens in situ.

Refraction Tips

- Retinoscopy is often difficult when patients have keratoconus, therefore topography or auto-refraction over the top of the lens can give a good estimate of the cyl required.
- The cyl axis is often NOT the same as that in the spectacle refraction. Allowing the patient to rotate the cyl in a trial frame can often establish the axis more accurately than using conventional techniques. If the spherical power is markedly different to the spectacle refraction, this may indicate the fit is not optimal.
- The presence of Higher Order Aberrations tends to confuse the patient, making it difficult for them to choose between "darker but more ghosting" and "fainter but less ghosting" when viewing letters. Initially using 1.00DS steps assists in homing in on the best over refraction.
- When refitting from other lenses in the KeraSoft range, the over refraction with KeraSoft IC is unlikely to be the same due to differences in the lens design.
- An increased minus prescription suggests a steep fit and an increased plus prescription suggests a flat fit.

BVD

If refracting a patient with high astigmatism, several cylinder trial lenses may be required in the front cell of the trial frame. Care should be taken to record the BVD of every lens as well as those of the spherical trial lenses.

LARS Rule

Determining the cyl axis of the final lens is the same as for a prescription soft toric. KeraSoft IC has a vertical laser mark that sits at the 6 o'clock position (270°) which can be used to determine whether the lens is rotated. The LARS rule applies i.e. if the laser mark is rotated to the **L**eft, the amount of rotation is **A**dded onto the axis found by over refraction and if it is rotated to

the **Right**, it is **Subtracted**. Thus it is important, when ordering, to give the angle of rotation in degrees when supplying the over refraction. If ordering the power directly the practitioner needs to compensate for the rotation when calculating the final Rx. KeraSoft® IC lenses now incorporate a dot to the right of the laser mark. This is to assist in determining whether the lens is inside out.

How to Order

Contact Art Optical's Consultation Department, listing the following information:

- KeraSoft IC **Fitting Lens** used, including periphery.
- Over refraction details including **degrees of rotation*** and direction using laser mark as a guide.
- Back Vertex Distance (**BVD**) of over refraction lenses.
- **Peripheral** curve** and **overall diameter** required.

* A significantly rotated laser mark may mean the fit is not optimum and we may ask you to look again at the fit before ordering.

** We cannot assume the periphery is STD if you simply order BCOR and diameter. We will always contact you to confirm the periphery.

- If you require assistance with the fitting, attach **color** sagittal/axial topography maps and/or keratometry information. Faxed monochrome maps cannot be correctly interpreted.
- A supply of KeraSoft IC Order Forms is supplied with the Fitting Set.

An example of a typical order would be:

R: K IC FP / 8.20/14.50/STD/-6.00/-4.50 x 35 / laser mark 10° right.

L: K IC FP / 8.80/15.00/STP3/plano/-5.00 x 110 / laser mark vertical.

From this information, a lens with fitting/exchange warranty can be issued.

If an exchange lens is required, perform a fitting assessment on the current lens and send the following information to Art Optical:

- Information as to fit characteristics; movement, laser mark rotation, visual acuity, vision on blink.
- Over refraction details and BVD.

Technical Support

We have a team of qualified contact lens fitting consultants specializing in different areas who are available to provide help and support. If you have any professional or technical enquiries please contact our Consultation team.

FOLLOW-UP EXAMINATIONS

- a. Follow-up examinations, as recommended by the eyecare practitioner, are necessary to ensure continued contact lens wear. The following is a suggested schedule for follow-up examinations:

- * Within one week of lens dispensing
- * After three weeks of lens wear
- * After seven weeks of lens wear
- * After each six month period of lens wear.

- b. Prior to follow-up examination, the contact lenses should be worn for at least 4 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear. The patient should report good subjective quality of vision. Adaptation to vision with **IntelliWave³/KeraSoft IC Silicone Hydrogel** lenses should occur almost immediately and should definitely be reported within the first (1 week) follow-up visit.
- c. With lenses in place on the eyes, evaluate fitting performance to assure that **CRITERIA OF A WELL FITTED LENS** continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
- d. After the lens removal, conduct a thorough biomicroscopy examination.

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1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
 2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
 3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the **CRITERIA OF A WELL FITTED LENS** are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

At the follow-up examinations, the patient should report good subjective quality of vision. Adaptation to vision with **IntelliWave³/KeraSoft IC Silicone Hydrogel** lenses should occur almost immediately and should definitely be reported within the first (1 week) follow-up visit. At these follow-up visits the practitioner should:

1. Check distance and near acuity with lens in place.
2. Over-refract to verify lens prescription.
3. Observe the position of the lens on the cornea. The lens should be centered and move on upward gaze and with a blink.
4. Evert the lids to examine the tarsal conjunctiva and check for incidence of giant papillary conjunctivitis.
5. Remove the lens. Check corneal curvature. There should be no substantial changes in either meridian.
6. Perform a slit-lamp examination with and without Fluorescein. Check for corneal edema, corneal abrasion, vascularization, corneal infiltrates, and perilimbal injection. Reinsert the lens only after all residual Fluorescein has dissipated from the eye.
7. Clean the lens with a prophylactic surfactant cleaner, and examine for deposits, foreign bodies or physical imperfections of the lens surface.

CRITERIA OF A WELL FITTED LENS

Characteristics of an ideally fitted lens

1. Good corneal alignment.
2. Slight (.5mm to 1mm) vertical post-blinking movement of the lens.
3. A consistent tendency for the lens to return to the primary position when it is displaced.
4. Provides functional binocular visual performance at distance and near.

General Lens Comfort

The **IntelliWave³/KeraSoft IC Silicone Hydrogel lenses** are designed to provide the patient with a high degree of comfort. Some patients may experience initial lens sensation, which should resolve early in the wearing schedule. If a sensation persists, one of the following may exist:

1. The lens is not clean and a foreign contaminant is trapped between the lens and the cornea.
2. The lens is ill fitting (usually loose) and must be changed to one of a more optimal fit.
3. The lens is damaged and must be replaced.
4. The lens has been inserted inside out. The lens should be removed, reversed and reinserted after rinsing.
5. The patient presents either a dry eye syndrome, hypersensitivity syndrome, or some other situation which makes elimination of sensation impossible.

LENS HANDLING (in-office cleaning, disinfecting and storage)

Wash and rinse hands thoroughly, making certain all soap residues have been rinsed away before drying with a lint-free towel. *It is suggested to wet the lens while in the eye using wetting drops before removal.* Always start with the right lens first in order to avoid mixing the lens. In removing the lens, try to avoid touching the inside (concave) surface of the lens. It is possible, though not likely, that the lens might be inside out; therefore, check the lens by placing it on the index finger and examine its profile. If the edges of the lens tend to point outward, the lens is inside out. After removing the lens from its container assure that it is clean, clear and wet.

Each **IntelliWave³ /KeraSoft IC Silicone Hydrogel** received in the eye care practitioner's office is received sterile in a glass vial with sterile buffered normal saline solution and labeled as to the parameters of the lens contained. To assure sterility, the glass vial should not be opened until ready for use.

To open the glass vial, pull back on the top where indicated. Upon removing the top silicone cover, the lens may be removed and is ready for use.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, the lens should be surfaced cleaned and disinfected.

CLEANING

A surfactant cleaner must be used with the **IntelliWave³ /KeraSoft IC Silicone Hydrogel** to ensure a clean lens surface. The manufacturer's instruction for OptiFree cleaner by Alcon is as follows:

DIRECTIONS FOR USE:

1. Place lens in the palm of your hand.
2. Apply 1 or 2 drops of cleaner to each lens surface and gently rub with the forefinger of the opposite hand.
3. Clean for about 15 – 20 seconds
4. Rinse the lens thoroughly with sterile saline solution. DO NOT use water to rinse your lenses.
5. After rinsing, place the lens in a storage case.
6. Repeat the process with the other lens.
7. Disinfect lenses as per manufacturer's instructions.

RINSING

Thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing or multipurpose solution.

CHEMICAL (NOT-HEAT) LENS CARE SYSTEM

A sterile rinsing, storing and disinfecting multipurpose solution should be used to rinse and chemically disinfect **IntelliWave³ /KeraSoft IC Silicone Hydrogel contact lens**. After cleaning the lens, rinse with a liberal amount of fresh multipurpose solution to remove loosened debris and traces of cleaner. The lens should then be placed in the plastic container supplied in a multi-purpose solution kit and filled with enough fresh disinfecting solution to completely submerge the lens. To ensure disinfecting, the lens must remain in the disinfecting solution for the recommended period of time as written on the multipurpose solution bottle. Before reinsertion, lens should be rinsed with fresh sterile rinsing solution.

LENS CARE DIRECTIONS

Please reference LENS CARE DIRECTIONS in the Package Insert included at the end of this Professional Fitting Guide.

STORAGE

The **IntelliWave³ /KeraSoft IC Silicone Hydrogel contact lens** must be stored in the recommended solutions. If exposed to the air, the lens will dehydrate. If a lens dehydrates, it should be soaked ONLY in a soft contact lens storage solution until it returns to a soft, supple state. It should not be put on an eye until it has been put through a complete disinfection cycle.

RECOMMENDED WEARING SCHEDULE

Close professional supervision is recommended to ensure safe and successful contact lens wear. If the patient complains of discomfort, decreased vision, ocular injection or corneal edema, the lens should be removed and the patient scheduled for examination. The problem may be relieved by putting the patient on a different wearing schedule or possibly by refitting the lens.

For the management of irregular corneal conditions, close supervision by the Eyecare professional is necessary. The Eyecare professional should determine the appropriate wearing time and provide specific instructions to the patient regarding lens care, insertion and removal.

Patients tend to overwear the lens initially. It is important not to exceed the initial wearing schedule. Regular check-ups, as determined by the Eyecare practitioner, are also extremely important. The maximum suggested wearing schedule for the **IntelliWave³ /KeraSoft IC Silicone Hydrogel contact lens** is reflected below.

<u>DAY</u>	<u>HOURS</u>
1	6
2	8
3	10
4	12
5	14
6	All Waking hours *

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE IntelliWave³/KeraSoft IC Silicone Hydrogel contact lens IS SAFE TO WEAR DURING SLEEP.

MONOVISION FITTING GUIDELINES

1. Patient selection

A. Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 1.50 diopter) in one eye may not be a good candidate for monovision with the **IntelliWave³ Silicone Hydrogel contact lens**.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

- (1) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
- (2) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternative, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. Ocular Preference Determination Methods

Method 1 – determine which eye is the “sight eye”. Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 – Determine which eye will accept the added power with the latest reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

B. Refractive Error Method

For anisometric corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction correct the eye on that side for near.

Example: A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

3. Special Fitting Consideration

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

Example: A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left without a lens.

A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optical reading performance, prescribe the least plus (most minus) of the powers.

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in the guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions are completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. Other Suggestions

The success of monovision technique may be further improved by having your patient follow the suggestions below.

- i. Having a third contact lens (distance power) to use when critical distance viewing is needed.
- ii. Having a third contact lens (near power) to use when critical near viewing is needed.
- iii. Having supplemental spectacles to wear over monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- iv. Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

- v. Reverse the distance and near eyes if a patient is having trouble adapting.
- vi. Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- vii. Emphasize the benefits of the clear near vision in straight-ahead and upward gaze with monovision.

The decision to fit a patient with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the **IntelliWave³/KeraSoft IC Silicone Hydrogel contact lens Patient Instruction / Wearer's Guide**.

INSTRUCTIONS FOR MONOVISION WEARER

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers license requirements with monovision correction.
- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eyecare practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required. If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.
- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eyecare practitioner.
- It is important that you follow your eyecare practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- The decision to be fit with monovision correction is most appropriately left to the eyecare practitioner in conjunction with you, after carefully considering and discussing your needs.

FREQUENT/PLANNED REPLACEMENT

It is recommended that the **IntelliWave³/KeraSoft IC Silicone Hydrogel contact lens** be discarded and replaced with a new lens every three (3) months. However, as the Eyecare practitioner, you are encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

RECOMMENDED LENS CARE PRODUCTS

The Eyecare practitioner should recommend a care system that is appropriate for the **IntelliWave³/KeraSoft IC Silicone Hydrogel contact lens**. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed. The table below shows solutions that are recommended for use with the **IntelliWave³/KeraSoft IC Silicone Hydrogel contact lens**.

Daily Cleaner:	<ul style="list-style-type: none">• Opti-Free Daily cleaner by Alcon
Rinsing Solution:	<ul style="list-style-type: none">• Opti-Free PureMoist by Alcon
Disinfecting Solution:	<ul style="list-style-type: none">• Opti-Free PureMoist by Alcon
Lubricant/Rewetting Drops:	<ul style="list-style-type: none">• Opti-Free Express by Alcon
Enzymatic/Protein Cleaner:	<ul style="list-style-type: none">• SupracLens by Alcon
Oxidation Systems	<ul style="list-style-type: none">• 3% H₂O₂ with neutralizing disc

EMERGENCIES:

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

REPORTING OF ADVERSE REACTIONS

Practitioners should report any adverse reactions to **IntelliWave³/KeraSoft IC Silicone Hydrogel contact lenses** within 5 days to Art Optical Contact Lens, Inc. Additional Fitting Guides, Package Inserts and Patient Guides are available from:

Art Optical Contact Lens, Inc.

3175 3 Mile Road NW
Walker, Michigan 49534
www.artoptical.com

Toll Free Number: 800-253-9364

HOW SUPPLIED

Each lens is supplied sterile in a sealed glass vial containing buffered normal saline solution. The glass vial is marked with the base curve, diameter, dioptric power, manufacturing lot number, and expiration date of the lens.