

Professional Fitting Guide

Frequency™ 55 Toric Contact Lenses (methafilcon B)

Toric Soft Hydrophilic Contact Lenses
for
Daily Wear Vision Correction

Table of Contents

Important:	3
Introduction.....	3
Description of the Lenses	3
Lens Parameter Availability	3
Actions.....	4
Indications	4
Contraindications (Reasons Not to Use).....	4
Warnings	4
Precautions.....	5
Adverse Effects	6
Patient Selection.....	7
Pre-Fitting Examination	7
Fitting Procedures for Frequency 55 Toric Contact Lens.....	7
Diagnostic Criteria	8
Monovision Fitting Guidelines.....	10
Diagnostic Lens Care	13
Wearing Schedule	13
Follow-Up Care.....	13
Patient Lens Care Directions	14
Basic Instructions	14
Recommended Lens Care Products	15
Chemical (Not Heat) Disinfection	16
Lens Deposits and Use of Enzymatic Cleaning Procedure	16
Lens Case Cleaning and Maintenance.....	16
Care for a Dried Out (Dehydrated) Lens.....	16
Care for a Sticking (Non-Moving) Lens.....	17
Emergencies.....	17
How Supplied	17
Reporting of Adverse Reactions	17

Caution: Federal Law Prohibits Dispensing Without a Prescription

Important:

This Fitting Guide has been developed to provide practitioners with information covering characteristics of the Frequency™ 55 Toric Contact Lens and to illustrate fitting procedures. Please read carefully and keep this information for future use

Introduction

The Frequency™ 55 Toric (Hydrophilic) Contact Lenses are high quality flexible wear contact lenses designed to fit the majority of patients easily, with good reproducibility, excellent vision and comfort.

For a complete listing of available lens parameters, please refer to the **Lens Description** section.

Description of the Lenses

Frequency™ 55 Toric Contact Lenses resemble small scleral (haptic) lenses in that they overlap onto the sclera by about one millimeter. The lens material, methafilcon B, is a random copolymer of hydroxyethylmethacrylate and methacrylic acid. Methafilcon B has a water content of 55.0% by weight when fully hydrated in normal saline solution. When produced with a handling tint, the lens material is coupled with C.I. Reactive Blue 4. The handling tint increases the visibility of the lens when not worn on the eye.

The Frequency™ 55 Toric Contact Lens is manufactured with a torodial posterior optic zone and a spherical anterior surface with an eccentric lenticular for prism ballast and axis stabilization. This design provides for a uniform edge thickness.

The fitting of the lens is based on a draping effect of a high water lens. Various base curves are achieved when the peripheral portion of the lens flexes to the curvature of the cornea. The high water content of the lens combined with thin lens sections, permits suitable draping across a broad range of corneal curvatures.

The draping effect of the lens automatically adjusts the sagittal height for each cornea. The lens parallels the apex of the cornea providing broad apical contact of the central cornea, vaulting or clearance of the limbus and light scleral bearing.

The physical properties of the lenses are:

- Refractive Index: 1.40
- Light Transmittance: Approximately 88%
- Specific Gravity: 1.09
- Water Content: 55%
- Oxygen Permeability: 19.0×10^{-11} (cm²/sec) (ml O₂/ml x mmHg) at 25°C

¹Measured by Schema Versatae model 920 connected to a polarographic cell.

Lens Parameter Availability*

Diameter:	14.4 mm
Base Curve:	8.4 and 8.7
Spherical Power:	+4.00 to -6.00 Diopters
Cylindrical Power:	-0.75; -1.25 and -1.75
Axis:	10 to 180° in 10° steps
Orientation:	One laser mark at 6 o'clock

* Call our Customer Service Department at (800) 341-2020 for current marketed parameters

Actions

When placed on the cornea, the hydrated Frequency™ 55 Toric Contact Lens acts as a refracting medium to focus light rays on the cornea.

Indications

Frequency™ 55 Toric Contact Lenses are indicated for daily as recommended by the eye care practitioner. They are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, hyperopic and have astigmatism of 12.00 diopters or less.

Contraindications (Reasons Not to Use)

Frequency™ 55 Toric Contact Lenses are contraindicated by the presence of any of the following conditions:

- Acute and subacute inflammation or infection of the anterior chamber of the eye (between the lens and iris and cornea).
- Any eye disease, injury or abnormality which affects the cornea, conjunctiva or eyelids.
- Any active corneal infection (bacteria, fungal or viral).
- Insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic.
- Any systemic disease which may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or thimerosal, in the solution necessary for care of the lenses.
- The patient is unable to follow lens care regimen or unable to obtain assistance to do.

Warnings

Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care practitioner's directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Patients wearing lenses prescribed for daily wear should not wear them overnight unless instructed to do so by their eye care practitioner.
- The risk if serious adverse reactions has been shown to be greatest among users of extended wear lenses than among users of daily wear lenses. The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care practitioner.

Precautions

Special Precautions for Eye Care Practitioners

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

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

- Aphakic patients should not be fitted with the Frequency™ 55 Toric Contact Lens until the determination is made that the eye has healed completely.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in the eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use; and the patient should wait at least 1 hour before replacing the lenses.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

Eye care practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Never use solutions recommended for conventional hard contact lenses only.
- Always use **fresh**, unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solutions when the lenses are not being worn (stored). Prolonged periods of drying will damage the lenses. Follow the lens care directions for Care for a Dried Out (dehydrated) Lens if the lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on the lenses before putting on makeup. Water base cosmetics are less likely to damage lenses than oil base products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in the Instructions for Wearers manual for the Frequency 55 Toric Contact Lenses and other instruction prescribed by the eye care practitioner.
- Never wear the lenses beyond the period recommended by the eye care practitioner.

- If aerosol products such as hairspray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Do not swim with the lenses in place.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the storage solution containing the lens into your hand.
- Do not touch the lens with fingernails.
- Always contact the eye care practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or require that you do not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

Adverse Effects

The patient should be informed that the following problems may occur:

- Eye pain
- Eye sting, burn or itch (irritation)
- Comfort is less than when the lens was first placed on the eye
- Abnormal feeling of something in the eye (foreign body)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of the above he or she should be instructed to:

- **Immediately remove the lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, **do not** put the lens back on the eye. Place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse and disinfect the lenses; then reinsert them. After reinsertion if the problem continues, the patient should **immediately remove the lenses and consult the eye care practitioner.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.**

Patient Selection

Patients who require only vision correction and who would not or could not adhere to recommended regimen for Frequency™ 55 Toric Contact Lenses or are unable to place and remove the lenses should not be provided them. Failure to follow handling and wearing instructions could lead to serious eye infection which might result in corneal ulcers.

Patient communication is vital because it relates not only to patient selection but also ensuring patient compliance. It is also necessary to discuss the information contained in the Patient Information Booklet with the patient at the time of initial examination and to provide a copy of the Patient Information Booklet to patients. Patients selected to wear Frequency™ 55 Toric Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care practitioner must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instruction are essential to their success.

A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, desired lens wearing time (full or part-time), and desired lens usage (reading, recreation or hobbies).

Initial evaluation of the lens should be preceded by a complete eye examination, including visual acuity with and without correction at both distance and near, keratometry and slit lamp examination. See Contraindication, Warnings and Precaution Sections of the Package Insert for additional information on patient selection.

Pre-Fitting Examination

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

- Determine whether a patient is a suitable candidate for contact lenses,
- Make ocular measurements for initial contact lens parameter selection,
- Collect and record baseline clinical information to which post-fitting examination results can be prepared.

A pre-fitting examination should include a thorough eye examination, including visual acuity, keratometry, biomicroscopy and complete patient history.

Fitting Procedures for Frequency 55 Toric Contact Lens

1. Determination of appropriate lens power:

- a. Convert spectacle refraction to minus cylinder form.
- b. Compensate the spectacle refraction power for vertex distance if the power is greater than ± 4.00 diopters.
- c. For **MINUS** lenses, determine the power in this manner:
 - For cylinders between -1.00 and -2.00
add $+0.25$ to sphere power
add $+0.25$ to cylinder power
 - For cylinders between of -2.25
add $+0.50$ to sphere power
add $+0.50$ to cylinder power
- d. For **PLUS** lenses, determine the power in this manner:

- Leave the cylinder power unchanged.
- For cylinders between -1.00 and -2.00
add $+0.50$ to sphere power
- For cylinders between -2.25 and -2.50
add $+0.75$ to sphere power

NOTE: When the sphere power is within one-half diopter of plano, reduce the recommended addition of plus by 50%.

e. For both plus and minus lenses, the lens axis should be the same as the refractive axis.

2. Trial lens selection:

- Choose an 8.7 mm base curve lens when the flatter corneal curvature is no steeper than 44.00 diopters. An 8.4 mm base curve should be selected for when the flattest corneal curvature is steeper than 44.00.
- Place the lens on the patient's eye and allow to equilibrate for 5-10 minutes.
- Check lens positioning.

If the lens does not center properly or moves excessively during blinking and exaggerated eye movements, the lens is too loose (unstable) and a diagnostic lens with a steeper base curve should be selected.

If the lens centers well and does not move on the blink, or if the lens centers well and vision is not clear through the lens, the lens is too steep and a diagnostic lens with a flatter base curve should be selected.

Refract over the lens and check for visual acuity. Allow the lens to settle (approximately 20 minutes) prior to over-refracting. If vision is not clear through the lens with the sphero-cylindrical over-refraction and axis alignment, the fit of the lens should be re-evaluated.

Diagnostic Criteria

Subjective

- Lens awareness or slight discomfort, providing there is no foreign matter under the lens, is usually a sign the lens is too loose.
- Poor or variable vision:
 - Vision clears momentarily immediately after each blink, but vision is blurred in between blinks; the fit may be too tight.
 - Vision is clear between blinks, but blurs after each blink; the fit may be too loose.

Lens Movement

- Move lens with finger or preferably with the reversed end of the suction cup. The lens should move freely and easily with the slightest pressure. If there is resistance to movement, the lens probably too tight.

2. Lens movement on blink with eyes straight ahead should be slight to moderate (0.50 to 1.0 mm). No movement may indicate a tight fit. More than 1.0 mm of movement usually indicates the fit is too loose.
3. Lens movement during lateral eye movements may be very slight and not observable without magnification. Excessive lens movement usually means that the fit is too loose.
4. As the patient looks up, the lens should move down about 1.0 to 2.0 mm. Much less than this may indicate a fit which is too tight, considerably more than 2.0 mm movement may indicate a fit which is too loose.

Lens Positioning

Perfect geometric centering of the lens is not always possible or necessary, and in some instances can only be achieved with a lens which is too tight. The important consideration in evaluating positioning is corneal coverage. If a lens is somewhat decentered, positioning is satisfactory when the entire cornea, including the corneal periphery opposite to the decentration, is completely covered by the lens.

Instrumentation

Slit Lamp

- a. Bubbles under the lens indicate that the fit is too tight.
- b. There should be no impingement of the lens edge on the sclera, which can be seen either as scleral indentation or by a blanching of the scleral blood vessels. When there is pressure on the sclera, the fit is almost certainly too tight, and tight symptoms will usually develop if a lens with a flatter base curve is not used.

Keratometer (readings taken with the lens in place on the eye)

- a. Mire Quality
 - A clear and constant image indicates a proper fit.
 - Any blurring or distortion of the mires may indicate a poor fit.
 - CAUTION: On occasion the mires may be blurred due to some drying out of the anterior surface or mucus on the surface. Whenever mire distortion or blurring is found, have the patient blink rapidly and completely six or more times and recheck. If the mires are still distorted, then lenses of a flatter base curve should be tried.

Retinoscope

- a. The reflex through a properly fitted lens should be clear and indistinguishable from the reflex without a lens in place.
- b. A darkish or irregular area in any part of the reflex may indicate a lens which is not fitting properly.

The patient may not have the best possible vision if results with keratometry and retinoscopy are less than optimal.

Monovision Fitting Guidelines

1. Patient Selection

A. Monovision Needs Assessment

For a good prognosis the presbyopic patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient may not be a good candidate for monovision.

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

- Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised not to drive with this correction, OR may require that additional over-correction (spectacles) 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 bifocals, trifocals or reading glasses. Each patient must understand that monovision, as well as other presbyopic contact lenses, or other alternatives, 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 that the patient understands 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 least 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 the anisometropic 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 Considerations

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic presbyopic 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 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 eye uncorrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides the optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal 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 Procedures described earlier in this guide.

Case history and standard clinical evaluation procedures 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 new 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 the monovision technique may be further improved by having your patient follow the suggestions below:

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

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

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- 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 eye care practitioner in conjunction with the patient after carefully considering the patient's needs.**
- **All patients should be supplied with a copy of the Instructions for Wearers.**

Diagnostic Lens Care

Eye care practitioners should educate contact lens technicians concerning proper care of diagnostic lenses.

Each contact lens is sterilized in a glass vial containing a sterile buffered isotonic saline solution. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the vial should not be opened until immediately prior to use.

Lenses should be surface cleaned and disinfected prior to reusing in a diagnostic procedure or dispensing to a patient. Because of the high water content, heat disinfection cannot be used with any Frequency 55 Toric Contact Lens referred to in this Fitting Guide. A chemical disinfection system must be used. Refer to the section titled **Chemical (not heat) Lens Disinfection**. Do not alternate or mix lens care systems.

Wearing Schedule

THE WEARING SCHEDULE SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER. Patients tend to over wear the lenses initially. It is important to adhere to the initial maximum wearing schedule. Patients should be cautioned to carefully follow the wearing schedule recommended by the eye care practitioner regardless of how comfortable the lenses feel.

Daily Wear (less than 24 hours, while awake)

Daily Wear Schedule Maximum Wearing Time

Day	Continuous Hours
1	6
2	8
3	10
4	12
5	14
6	All Waking Hours

The suggested wearing time may be broken into two periods, separated by a one or two hour rest period of no lens wear.

Follow-Up Care

Follow-up care includes routine periodic progress examinations, management of specific problems, if any, and review of proper lens care and handling

1. Barring complications, the minimum schedule of follow-up examinations should be:
 - a. One week from the day the lenses were delivered to the patient.
 - b. One month from the start of lens wear.
 - c. Three months from the start of lens wear.
 - d. Every 6 months thereafter.
2. Procedures for follow-up visits (with lenses on, preferably at least 6 hours)
 - a. Record patient symptoms (if any).
 - b. Check appearance of sclera and lids.
 - c. Check visual acuity and refract over the lens; check on two different days before making power changes of ± 0.50 diopters or less.

- d. With slit lamp
 - Check for edge impingement of lenses on sclera.
 - Check integrity of lens edges.
 - Check the lens surface, if there is accumulated debris, clean the lenses. Replace the lenses as soon as deposits develop which cannot be removed.
 - e. Take keratometer readings of outside lens surface if best acuity through over-refraction is less than before.
3. Procedure for follow-up visits (with lenses removed)
 - a. Do Slit Lamp examination of the cornea, both with and without fluorescein; check for edema, injection, vascularization and corneal staining.
 - b. Take keratometer readings and compare to original values and mire quality.
 - c. Check for spectacle blur shortly after lenses are removed.

If any abnormal observations are made, use professional judgement to alleviate the problem. If the criteria for successful fit are not reached during follow-up examinations, the patient's trial fitting procedure should be repeated. The patient should be refitted and the necessary follow-up examinations also repeated.

Unscheduled Visits

An unscheduled visit may be indicated whenever the wearer reports a change in vision, ocular discomfort or redness of the eye. If one or more of these symptoms occur advise the patient to remove the lenses immediately and to visit the office as soon as possible.

Patient Lens Care Directions

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

Basic Instructions

- Always wash, rinse and dry your hands before handling the lens.
- Always use **fresh unexpired** lens care solutions.
- Use the recommended system of lens care and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on the solution labeling.**
- Always remove, clean, rinse, enzyme and disinfect the lenses according to the schedule prescribed by the eye care practitioner. The use of an enzyme or any cleaning solution **does not substitute for disinfection.**
- Do not use saliva or anything other than the recommended solutions for lubrication or rewetting lenses. Do not put lenses in the mouth.
- Lenses should be **cleaned, rinsed and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle and follow instructions.
- **Clean** one lens first (always the same lens first to avoid mixups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus and film from the lens surface, and put the lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- **Disinfect** the lenses **after** cleaning, using the system recommended by the manufacturer and/or eye care practitioner.

- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. Lenses stored longer than 12 hours may require cleaning, rinsing and disinfecting **again before use**. The patient should consult the package insert or the eye care practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with the solution recommended by the lens case manufacturer, then allow the lens case to air dry. When the case is used again, refill it with **fresh** storage solution. Replace the lens case at regular intervals.
- Eye care practitioners may recommend a **lubricating/rewetting** solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

Recommended Lens Care Products

To assure proper lens care and handling, each patient **MUST BE** supplied with cleaning, rinsing and disinfecting solutions and a lens case, as well as instructions. The following solutions may be used to care for the Frequency 55 Toric Contact Lens referred to in this Professional Fitting Guide. This is not an exclusive list however, and the eye care practitioner may recommend other solutions.

Solution Purpose To:	Lens Care System
Clean	ReNu® Multi-Purpose Solution SOFT MATE® Daily Cleaning Solution MiraFlow® Extra-Strength Daily Cleaner Opti-Free® Daily Cleaner
Rinse	ReNu® Multi-Purpose Solution SOFT MATE CONCEPT™ 2 Neutralizing and Rinsing Spray SoftWear® Saline Opti-Free® Rinsing, Disinfecting and Storage Solution
Disinfect	ReNu® Multi-Purpose Solution SOFT MATE CONCEPT™ 1 Cleaning and Disinfecting Solution AOSEPT® Disinfection/Neutralizing Solution Opti-Free® Rinsing, Disinfecting and Storage Solution
Store	ReNu® Multi-Purpose Solution Opti-Free® Rinsing, Disinfecting and Storage Solution
Lubricate/Rewet	ReNu® Rewetting Drops SOFT MATE Comfort Drops® CIBA Vision™ Lens Drops Opti-Free® Rewetting Drops
Enzyme	ReNu® Effervescent Enzymatic Cleaner Tablets SOFT MATE® Enzyme Plus Cleaner ULTRAZYME® Enzymatic Cleaner Opti-Free® Enzymatic Cleaner

ReNu® is a registered trademark of Bausch & Lomb, Inc. SOFT MATE®, CONCEPT™ and Comfort Drops® are registered trademarks of Paragon Vision Sciences. AOSEPT®, MiraFlow®, SoftWear® and CIBA Vision™ are registered trademarks of CIBA Vision Corporation. Opti-Free is a registered trademark of Alcon Laboratories, Inc. Ultrazyme® is a registered trademark of Allergan, Inc.

FOR MORE INFORMATION ABOUT THE LENS CARE PRODUCTS, REFER TO THE SOLUTION MANUFACTURER'S PACKAGE INSERT

Because of the high water content, **heat disinfection** cannot be used with Frequency 55 Toric Contact Lens. A chemical disinfection system (not heat) must be used. The above table of recommended solutions is no exclusive. The selection of solutions best suited to the patient should be determined by the eye care practitioner.

Chemical (Not Heat) Disinfection

- **Clean** the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- **Disinfect after cleaning.** Carefully follow the instructions accompanying the disinfection solution in the care regimen recommended by the lens manufacturer or the eye care practitioner.
- When using hydrogen peroxide lens care systems, the lenses **must be neutralized** before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse the lenses with a fresh solution recommended for rinsing before inserting or wearing, or follow the instructions on the disinfection solution labeling.
- **Do not heat disinfect the lenses. Repeated heat disinfection will cause irreversible damage.**
- Leave the lenses in the unopened storage case until ready to put on the eye.
- **Caution:** Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

Lens Deposits and Use of Enzymatic Cleaning Procedure

Enzyme cleaning may be recommended by the eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

Lens Case Cleaning and Maintenance

Contact lens cases can be source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer and allowed to air dry. The lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or by the eye care practitioner.

Care for a Dried Out (Dehydrated) Lens

If the Frequency 55 Toric Contact Lens is left off the eye and exposed to air for 30 minutes or longer, it will become dry and brittle (dehydrated). Handle a dehydrated lens carefully. Place the lens in its storage case and SOAK the lens in the recommended rinsing and storage solutions for a minimum of 30 minutes. Soak the lens until it returns to a soft state. Clean and disinfect the rehydrated lens according to the instructions accompanying the solutions. If after soaking, the lens does not become soft, DO NOT USE THE LENS.

Care for a Sticking (Non-Moving) Lens

If the lens sticks (stops moving) or begins to dry on the eye, apply three drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues, the patient should IMMEDIATELY consult the eye care practitioner.

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 should: **FLUSH THE EYE IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

How Supplied

Each lens is supplied sterile in blister packs containing isotonic saline solution. The blister pack is labeled with the base curve, diopter power (cylinder power and axis are included), diameter, manufacturing lot number, and expiration date of the product.

DO NOT USE IF THE BLISTER PACK HAS BEEN DAMAGED OR BROKEN.

Reporting of Adverse Reactions

All serious adverse reactions observed in any patient wearing the Frequency 55 Toric Contact Lenses should be reported to:

CooperVision, Inc.
Attn: Product Services
711 North Road
Scottsville, NY 14546
1-800-341-2020