

Instructions for Wearers

Frequency[™] 55 Toric Contact Lenses (methafilcon B)

Toric Soft Hydrophilic Contact Lenses
for
Daily and Extended Wear Vision Correction

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Important: This Instructions for Wearer's Booklet contains important information and instructions about the product listed on the front cover.

Caution: Federal Law Prohibits Dispensing Without a Prescription.

INTRODUCTION

The Frequency™ 55 Toric Contact Lenses are made from a plastic, methafilcon B, which has the ability to absorb water (hydrophilic), making it soft and pliable, unlike conventional hard lenses. Your lenses may feel comfortable from the first insertion. You are cautioned, however, to follow the wearing schedule prescribed for you. Do not try to speed up the adaptation process by over-wearing the lenses simply because they remain comfortable.

Your eye care practitioner will review with you the instructions for proper hygiene, handling, cleaning, disinfection and storage of your contact lenses. You will be instructed on proper lens insertion and removal. If you are in doubt about any instruction, request clarification from your eye care practitioner.

WEARING RESTRICTIONS AND INDICATIONS

The Frequency™ 55 Toric Contact Lenses are indicated for daily wear or extended wear from 1 to 7 days between removals for cleaning and disinfecting as recommended by the eye care practitioner. They are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic, hyperopic and have astigmatism of 12.00 diopters or less.

Eye care practitioners may prescribe the lens for frequent replacement wear, with cleaning, disinfection, and scheduled replacement (see WEARING SCHEDULE). **The lens may be disinfected by chemical (not heat) only.**

DO NOT WEAR YOUR CONTACT LENSES WHILE SLEEPING UNLESS INSTRUCTED TO DO SO BY YOUR EYE CARE PRACTITIONER.

CONTRAINDICATIONS (Reasons Not To Use)

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

- Acute and sub-acute 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 (reduce 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 solutions necessary for care of the lenses.

- The patient is unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS

You 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 you follow your eye care practitioner's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case.
- The risk of serious adverse reactions has been shown to be greater 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 you experience **eye discomfort**, excessive tearing, vision changes or redness of the eye, you should **immediately remove your lenses** and promptly contact your eye care practitioner.

PRECAUTIONS

Your eye care practitioners will carefully instruct you 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, you should **immediately** consult your eye care practitioner.

- Always wash and rinse your hands before handling the 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 this manual for all 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 hair spray, 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 your 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

You should be informed by the eye care practitioner 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, scratched area)

- 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 any of the above is note, you should:

- **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, you should thoroughly clean, rinse and disinfect the lenses; the reinsert them. After reinsertion, of the problem continues, you 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. You will 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.

PERSONAL CLEANLINESS FOR LENS HANDLING

1. Preparing the Lens for Wearing:

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substance when you handle your lenses. The procedures are:

- Always wash your hands thoroughly with a mild soap, rinse completely and dry with a lint-free towel before touching your lenses.
- Avoid the use of soaps containing cold cream, lotion or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. Handling the Lenses:

- Develop the habit of always working with the same lens first to avoid mixups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear and free of any nicks or tears.

3. Placing the Lens on the Eye:

- Check to be sure the lens is not inside out. Look at the profile of the lens edge against a light background. If the edge profile appears convex and bowl shaped, the lens is correct side out. If the lens edges tend to point outward, the lens is inside out, simply turn it right-side out by using light fingertip pressure.
- The lens should be positioned on the tip of the index finger of your dominant hand. With the middle finger of the same hand, pull the lower eyelid down. Use the middle finger of the other hand to gently raise the upper eye lid by lifting the lid above the eyelashes.
- With the lens still on the tip of the index finger, hold the head straight and look up as far as possible. Gently place the lens onto the lower white part of your eye.
- Look down and slowly release the upper and lower lids. Close the eye, then open them slowly. The lens should center automatically.
- Repeat the above procedure for the other lens.

There are other methods of lens placement. If the method described in this manual is difficult for you, your

eye care practitioner will provide you with an alternate method.

Note: If after placement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see Centering the Lens section).
- If the lens is centered, remove the lens and check the following:
 - Cosmetics or oils on the lens. Clean, rinse, disinfect and place the lens on the eye again.
 - The lens is on the wrong eye.
 - The lens is inside out.

4. Centering the Lens

It is infrequent that a lens which is on the cornea will be displaced onto the white part of the eye during wear. However, this can easily occur if the insertion and removal procedures are not performed properly. To center the lens, follow one of the procedures below:

- Close your eyelids and gently massage the lens into place through the closed lids, using your index finger.
- Gently push the off-centered lens onto the cornea while the eye is open, using finger pressure on the edge of the upper or lower eyelid.

5. Removing the Lens

Wash, rinse and dry your hands thoroughly with a lint-free towel. Have your storage container or carrying case ready so you can put the lenses in upon removal.

Always be sure that the lens is centered on the cornea before attempting to remove it. Check your vision by covering the other eye. If your vision is blurry, the lens is either on the white part of the eye or it has been lost.

- Look straight ahead and up slightly. With the middle finger of your dominant hand, pull the lower eyelid down slightly.
- Gently pinch the lens between the index finger and thumb of your dominant hand.
- Gently pull the lens away from the eye.
- Repeat the above procedure for the other lens.
- Clean, rinse and disinfect the lenses using the method recommended by your eye care practitioner.

NOTE: If this method of removing your lenses is difficult for you, your eye care practitioner will provide you

with an alternate method.

CARING FOR YOUR LENSES

Basic Instructions

For continued safe and comfortable wearing of your lenses, it is important that you **first clean and rinse, then disinfect** your lenses after each removal, using the care regimen recommended by your eye care practitioner. **Cleaning and rinsing** are necessary to remove mucus, secretions, films or deposits which may have accumulated during wearing. The ideal time to clean your lenses is immediately after removing them. **Disinfecting** is necessary to destroy harmful germs.

You should adhere to a recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS section.

If you require only vision correction, but will not or cannot adhere to a recommended care regimen for your lenses, or are unable to insert and remove lenses or have someone available to insert and remove them, you should not attempt to get and wear contact lenses.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse and dry the hands before handling the contact 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 solution labeling.**
- Always remove, clean, rinse and enzyme (as recommended by the eye care practitioner) and disinfect 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 lubricating or rewetting lenses. Do not put lenses in the mouth.
- Never rinse your lenses in water from the tap. There are two (2) reasons for this:
 - Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
 - Your might lose the lens down the drain.
- **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. Follow the instructions provided in the cleaning solution labeling. Put that 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 your eye care practitioner or lens manufacturer. Follow the instructions provided in the disinfection solution labeling.
- **To store the lenses**, disinfect and leave them in the closed case until ready to wear. Lenses stored longer than 12 hours may require cleaning, rinsing and disinfection **again before use**. You should consult the package insert or your eye care practitioner for information on storage of your lenses.
- **After removing your lenses from the lens case**, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer; then allow the lens case to air dry. When the lens case is used again, refill it with **fresh** storage solution. Replace the lens case at regular intervals.
- Your eye care practitioner may recommend a lubricating/rewetting solution for your use. **Lubrication/Rewetting** solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.

Recommended Lens Care Products

To assure proper lens care and handling, you **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 any Frequency 55 Toric Contact Lens referred to in this package insert. This is not an exclusive list, however, and the eye care practitioner may recommend other solutions.

<i>SOLUTION PURPOSE TO:</i>	<i>LENS CARE SYSTEM</i>
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/Neutralization 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

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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 any Frequency 55 Toric Contact lens. A chemical disinfection system (not heat) must be used. The above table of recommended solutions is not exclusive. The selection of solutions best suited for you should be determined by your eye care practitioner.

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (stops moving) on the eye, apply 2-3 drops of the recommended sterile lubrication or rewetting solution. Wait until the lens begins to move freely on your eye before removing it. If non-movement of the lens continues, **immediately** consult your eye care practitioner.

CHEMICAL (NOT HEAT) DISINFECTION

- **Clean** your contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- **After cleaning**, to disinfect, carefully follow the instructions accompanying the disinfection solution in the care regimen recommended by the lens manufacturer or your 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 your 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 your lenses. Repeated heat disinfection will cause irreversible damage to your lenses.**
- Leave the lenses in the unopened storage case until ready to put on your eyes.
- Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritation 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 your 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 your 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, you should carefully follow the instructions in the enzymatic cleaning labeling.

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a 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 any 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) the lens carefully. Place the lens in its storage case and SOAK the lens in the recommended rinsing and storage solutions for at least 30 minutes. Soak the lens until it returns to a soft state. Clean and disinfect the rehydrated lens using the lens care system recommended by the manufacturer or eye care practitioner. If after soaking, the lens does not become soft, DO NOT USE THE LENS.

EMERGENCIES

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

Instructions for the 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 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 eye care 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 eye care practitioner.
- It is important that you follow your eye care 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 a monovision correction is most appropriately left to the eye care practitioner in conjunction with you, after carefully considering and discussing your needs.

Prescribed Wearing Schedule

Day	Date	Wearing Time
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		

Your eye care practitioner will determine the wearing schedule that is best for you.

CHECK-UP VISITS

Regular check-up examinations by your eye care practitioner are an important and ongoing part of wearing your contact lenses. Keep all appointments for check-up visits.

Visit Schedule

Date	Time	Hours*

*Minimum number of hours lenses are to be worn at the time of appointment.

IMPORTANT: In the event that you experience difficulty wearing your contact lenses or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYE CARE PRACTITIONER IMMEDIATELY.

"Unscheduled" visits may sometimes be necessary to assure eye health. Always contact your eye care practitioner if a lens is torn or damaged, if a lens stops moving on your eye or if you notice a change in comfort, vision or redness of your eyes.