The FREQUENCY 55 TORIC (methafilcon B) soft (hydrophilic) contact lenses are available as astigmatic lenses with the following dimensions:

- Diameter: 13.5 mm to 15.5 mm
- Base Curve: 8.0 mm to 9.6 mm
- Center Thickness: 0.04 mm to 0.52 mm
- Power: -20.0 to +20.00D
- Cylinder Power: plano to -12.00D

The lens material, methafilcon B, is a random copolymer of hydroxyethylmethacrylate and methacrylic acid. Produced with a light blue tinting tint, the lens material is coupled with Reactive Blue No. 4. The tinting tint increases the visibility of the lens when not worn on the eye.

The physical properties of the lenses are:

- Refractive Index: 1.40
- Light Transmittance: Approximately 88%
- Surface Character: Hydrophilic
- Water Content: 55%
- Oxygen Permeability: 19.0 x 10-11 (cm2/sec ml O2/ml x mmHg) at 35ºC

DESCRIPTION:

The FREQUENCY 55 TORIC contact lenses are indicated for daily wear 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 near-aphakic persons with non-diseased eyes that are myopic, hyperopic, and have astigmatism of 12.00D or less.

PRECAUTIONS:

Special Precautions for Eye Care Practitioners

Due to the small numbers of patients enrolled in clinical investigation of lenses, all refractive power, designs, parameters, 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 lenses including ocular health, oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

CONTRAINDICATIONS (REASONS NOT TO USE)

Frequency 55 TORIC contact lenses are contraindicated by the presence of any of the following conditions:

- Acute and subacute iritis or inflammation of the anterior chamber of the eye (between the lens and iris and cornea).
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Any active corneal infection (bacterial, fungal, or viral)
- Insufficiency of lacrimal secretion (dry eyes).
- Corneal hyposthesia (reduced corneal sensitivity), if aphakic
- Any systemic disease that 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 contact lenses solutions.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution necessary for care of lenses.
- If eyes become red or irritated.

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

WARNING:

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.
- All contact lens wearers must see their eye care practitioner as directed.
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses. The risk among extended wear users increases with the number of consecutive days that the lenses are worn between removals, in continuity with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens case.
- Studies have been shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If the patient experiences eye discomforts, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove the lenses and promptly contact his or her eye care practitioner.

PRECAUTIONS:

Special Precautions for Eye Care Practitioners

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The potential impact of these factors on the patient’s ocular health should 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 eye care practitioner.

- Aphakic patients should not be fitted with FREQUENCY 55 TORIC contact lenses until the determination is made that the eye has healed and stabilized.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb the 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.
- Before the eye care practitioner’s office, the patient should be able to promptly remove the lenses if a contact lens is not removed on the eye.
- 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 lenses only.
- Use only chemical (not heat) disinfection with FREQUENCY 55 TORIC lenses. Heat disinfection should NOT be used. Repeated heat disinfection will cause irreversible damage to the FREQUENCY 55 TORIC lenses.
- Always use fresh, unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unopened solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use salt or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying may 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 lenses become 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 cleanse, rinse, and disinfect both lenses; then reinsert them. After reinsertion, if the problem continues, the patient should immediately remove the lenses and consult the eye care practitioner.

ADVERSE EFFECTS:

- Eye pain.
- Eye stinging, burn, or itch (irritation).
- Comfort is less than when the lens was first placed on the eye.
- Abnormal feeling that something is in the eye such as a foreign body or a scratched area.
- Excessive watering (tearing) of the eyes.
- Unusual eye secretions.
- Redness of the eyes.
- Reduced sharpness of vision (poor visual acuity).
- Blurred vision, rainbow, 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 the problem stops, then look closer to the lens. If the lens is in some 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 both 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 lenses off the eye and seek immediate professional certification of the problem and prompt treatment to avoid serious eye damage.
NOTE: HEAT DISINFECTION SHOULD NOT BE USED WITH ANY FREQUENCY 55 TORIC LENSES

<table>
<thead>
<tr>
<th>Purpose to:</th>
<th>Product Chemical Lens Care System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean</td>
<td>Renu® Multi-Purpose Solution, Miraflo® Extra Strength Daily Cleaner, Opti-Free® Daily Cleaner</td>
</tr>
<tr>
<td>Rinse</td>
<td>Renu® Multi-Purpose Solution, SoftWear® Saline, Opti-Free® Rinsing, Disinfecting and Storage Solution</td>
</tr>
<tr>
<td>Disinfect</td>
<td>Renu® Multi-Purpose Solution, AODEPT® Disinfection/Neutralization Solution, Opti-Free® Rinsing, Disinfecting and Storage Solution</td>
</tr>
<tr>
<td>Store</td>
<td>Renu® Multi-Purpose Solution, Opti-Free® Rinsing, Disinfecting and Storage Solution</td>
</tr>
<tr>
<td>Lubricate &amp; Rewetting</td>
<td>CIBA Vision™ Lens Drops, Opti-Free® Rewetting Drops</td>
</tr>
<tr>
<td>Enzyme</td>
<td>Renu® Effervescent Enzymatic Cleaner Tablets, ULTRAYME® Enzymatic Cleaner, Opti-Free® Enzymatic Cleaner</td>
</tr>
</tbody>
</table>

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LENS CARE DIRECTIONS:

DAILY WEAR: (less than 24 hours, while awake). The maximum suggested wearing time is:

- Day: 6 hours
- Day: 12 hours
- Day: 14 hours
- Day: 16 hours
- Day: 6 hours
- All waking hours

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.

General Lens Care: (To First Clean and Rinse, the Disinfect Lenses)

Basic Instructions:
- Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh, unexpired lens care solutions.
- Use the recommended chemical (not heat) system of lens care and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe to use with all lenses. Do not alternate or use lens care systems unless indicated on solution labeling.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting. 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.
- Always remove, clean, rinse, enzyme (as recommended by the eye care practitioner) and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of enzyme or any cleaning solution does not substitute for disinfection.
- The eye care practitioner should recommend a care system that is appropriate for Frequency 55 Toric contact lenses. Each lens care product contains specific directions for using and important safety information, which should be read and carefully followed.

NOTE: HEAT DISINFECTION SHOULD NOT BE USED WITH ANY FREQUENCY 55 TORIC LENSES

- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- Do not heat the disinfection solution and lenses.
- 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 in the eye should reduce the potential for irritation.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING:

Enzymatic cleaning may be recommended by the eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed by 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 enzymatic cleaning, the patient 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, and rinsed with solution recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eye care practitioner.

CARE FOR A DRIED OUT (DEHYDRATED) LENS:

If a Frequency 55 Toric lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, apply sterile saline solution before handling. To rehydrate the lens:
- Handle the lens carefully.
- Place the lens in its storage case and soak the lens in a recommended rinsing and storage solution for at least one hour until it returns to a soft state.
- Clean the lens first, then disinfect the rehydrated lens using a recommended lens care system.
- If after soaking, the lens does not become soft, if the surface remains dry, the lens should not be used unless it has been examined by the eye care practitioner.

CARE FOR A STICKING (NOMOVING) LENS:

If the lens sticks (stops moving or cannot be removed), the patient should be instructed to apply 2 to 3 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lenses begins to move freely on the eye before removing it. If non-movement of the lens continues for 5 minutes, the patient should immediately consult the eye care practitioner.

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

HOW SUPPLIED:

Each lens is supplied sterile in a blister pack containing buffered isotonic saline solution. The blister is labeled with the base curve, diameter, dioptic power, manufacturer, lot number, and expiration date of the lens.

DO NOT USE IF THE BLISTER IS DAMAGED OR SEAL IS BROKEN

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the Frequency 55 Toric contact lens or experienced with the lenses should be reported to:

CooperVision
Attn: Product Services 711 North Road
Scottsville, New York 14546 (800) 341-2020
Fax (716) 889-5688
www.coopervision.com

有关于化学品的任何 kind(家庭产品，园艺解决方案，实验室化学，等)都溅入到眼睛的，患者应该FLUSH THE EYES