DESCRIPTION:

The physical/optical properties of the lens are:

- Diameter: 14.2mm to 15.0mm
- Base Curve: 8.0mm to 9.5mm
- Center Thickness: 0.15mm to 0.60mm (varies with power)
- Powers: -20.00 to +20.00D
- Multifocal Add Powers: +0.50 to +4.00D
- Central Zone Diameter: 2.3 to 2.61mm (D)
- Central Zone Thickness: 0.17 to 0.20mm (N)

The physical/optical properties of the lens are:

- Refractive Index: 1.41
- Light Transmittance: >96%
- Surface Character: Hydrophilic
- Water Content: 55%
- Oxygen Permeability: 19.7 x 10^{-11} (cm²/sec)
  (mL O₂/mL x mmHg) at 35°C (Fatt method for
determination of oxygen permeability)

Call our Customer Service Department at
(800) 341-2020 for current availability

INDICATIONS (USES):

- Frequency 55 and Frequency 55Aspheric lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Frequency 55 Multifocal lenses are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Frequency 55, Frequency 55 Aspheric, and Frequency 55 Multifocal are indicated for daily and extended wear from 1 to 7 days between removals for cleaning and disinfecting as required by the eye care practitioner.

Note: Only chemical disinfection may be used with Frequency 55 contact lenses.

Eye care practitioners may prescribe the lenses for frequent replacement wear, with cleaning, disinfecting, and scheduled replacement (see WEARING SCHEDULE).

CONTRAINDICATIONS (REASONS NOT TO USE):

- Do not use any Frequency 55 lens when any of the following conditions exist:
  - Acute and subacute inflammation or infection of the eye
  - Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
  - Serosanguineous or bloody discharge (melting.
  - Corneal hypoplasia (reduced corneal sensitivity), if not aphakic.
  - Any systemic disease that may affect the eye or be exacerbated by wearing contact lenses.
  - Allergic reactions of corneal 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 a solution, which is to be used for care of any Frequency 55 lens.
  - Any active corneal infection (bacterial, fungal, or viral).
  - If eyes become red or irritated.
  - The patient is unable to follow lens care regimen or obtain assistance to do so.

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.
  - All contact lens wearers must see their eye care practitioner’s office if any problems are encountered. If the lenses are not extended wear, the eye care practitioner may prescribe more frequent visits.
  - Daily wear lenses are not indicated for overnight wear, and patient 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 wearers increases with the number of consecutive days that the lenses are worn between replacements, beginning with the first overnight use.

- Care should be made to ensure that all lenses can be reduced by carefully following directions for routine lens care, including cleaning of the lens case.

- If the patient experiences eye discomfort, 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

- Due to the small numbers 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, central 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 correction; therefore, the following guidelines are provided to 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 any Frequency 55 lenses, but 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 the dye and become discolored. Whenever fluorescein is used in the contact lenses during sporting activities.

- Use of non-medicated=contact lenses during sporting activities.

- Inform the doctor (health care practitioner) about being a contact lens wearer.

- Never use tweezers or other instruments to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.

- Do not touch the lens with fingers.

- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient 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 the recommended follow-up schedule.

ADVERSE EFFECTS:

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

- Eye stinging, burning, or itching (irritation), or other eye pain.

- Confort is less than when the lenses was first placed on the eye.

- Feeling that something is in the eye such as a foreign body or a scratched area.

- Excessive watering (tearing) of the eyes.

- Uneven pupils.

- 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.
EXTENDED WEAR PATIENTS REQUIRE FREQUENT AND CAREFUL MONITORING OF LENSES AND OCULAR HEALTH TO MINIMIZE COMPLICATIONS.

LENSES CARE DI RECTIONS:
Eye care practitioners should review the patient lens care directions, lens care information and specific instructions on the lenses 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 care systems instructions on labeling. Different solutions cannot always be used together, and not all solutions are safe to use with all lenses. Do not alternate or mix 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 eye care practitioner's hands.
- 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 disinfected lenses according to the schedule prescribed by the eye care practitioner. The use of enzyme or any cleaning solution does not replace the need for disinfection.
- The eye care practitioner should recommend a care system that is appropriate for Frequency 55 contact lenses. Each lens care product contains specific directions for use and importance of safety information, which should be read and carefully followed.

**Purpose:**
- Product: Chemical Lens Care System
- To: Clean, Rinse, Disinfect, and Store Lenses

**Lens Care Table**

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Product</th>
<th>Chemical Lens Care System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean</td>
<td>Renu® Multi-Purpose Solution, Miraflow® Extra Strength Daily Cleaner, Opti-Free® Daily Cleaner</td>
<td></td>
</tr>
<tr>
<td>Rinse</td>
<td>Renu® Multi-Purpose Solution, SoftWear® Sialine, Opti-Free® Rinse, Disinfecting and Storage Solution</td>
<td></td>
</tr>
<tr>
<td>Disinfect</td>
<td>Renu® Multi-Purpose Solution, AOEPT® Disinfection/Neutralizing Solution, Opti-Free® Ring, Disinfecting and Storage Solution</td>
<td></td>
</tr>
<tr>
<td>Store</td>
<td>Renu® Multi-Purpose Solution, Opti-Free® Ring, Disinfecting and Storage Solution</td>
<td></td>
</tr>
<tr>
<td>Lubricate &amp; Rewetting</td>
<td>Renu® Rewetting Drops, CIBA Vision™ Lens Drops, Opti-Free® Rewetting Drops</td>
<td></td>
</tr>
<tr>
<td>Enzyme</td>
<td>Renu® Effervescent Enzymatic Cleaner Tablets, ULTRAZYM® Enzymatic Cleaner</td>
<td></td>
</tr>
</tbody>
</table>

**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 directions.
- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfection solution to remove cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, and rinsing, disinfect lenses using the system recommended by the manufacturer and/or eye care practitioner.
- Store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care practitioner for information on the recommended storage and handling recommendations. After removing the lenses from the case, empty, and rinse the lens storage case with solution as recommended by the lens case manufacturer, then allow the lens case to air dry. When the lens case is used again, refill it with storage solution. Replace the lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.
- Eye care practitioners may recommend a lubrication/rewetting solution, which can be used to wet (lubricate) the lenses while they are being worn to make them more comfortable.

**CHALLENGING LENS DISINFECTION (Including Hydrogen Peroxide):**
- Clean the contact lenses with a recommended disinfection solution does not thoroughly rinse them with a recommended rinsing solution.
- After cleaning and rinsing, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the frequency regimen recommended by the lens manufacturer or the eye care practitioner.
- When using hydrogen peroxide lens care systems, lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- 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 eyes.
- CALUTION: Lenses that are chemically disinfecting solution may also 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 DISPOSITS AND USE OF ENZYMATIC CLEANING:**
Enzymatic cleaning may be recommended by the eye care practitioner. Enzyme cleaning removes protein deposits on the lenses. 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 then 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 any Frequency 55 lens is exposed to air while off the eye, it may become dry 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.
- The storage of lenses 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 until it has been examined by the eye care practitioner.

**CARE FOR A STICKING (NONMOVING) LENS:**
If the lenses 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 lens begins to move freely on the eye before removing it. If non-movement of the lens continues for more than 5 minutes, the patient should immediately consult the eye care practitioner.

**EMERGENCIES:**
The patient should be informed that if chemicals of any kind (prescription products, laboratory chemicals, etc.) are splashed into the eyes, the patient should
FLUSH THE EYES 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 a blister pack containing buffered isotonic saline solution. The blister is labeled with the base curve, diameter, dioptic power, manufacturing lot number, and expiration date of the lens.

**DO NOT USE IF THE BLISTER PACK IS BROKEN OR THE SEAL HAS BEEN DAMAGED:**
All serious adverse experiences and adverse reactions observed in patients wearing any Frequency 55 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
www.coopervision.com

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