INDICATIONS (USES):
Frequency 55 and Frequency 55 Aspheric lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) in aphatic and non-aphatic 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 aphatic and non-aphatic 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 cleanings and disinfecting as recommended by the eye care practitioner.

PRECAUTIONS:
Special Instructions for Eye Care Practitioners
- Due to the small number of patients enrolled in clinical investigation 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 limitations 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.
- Aortic patients should not be fitted with any Frequency 55 lens. 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
  - Water Content: 55%
  - Light Transmittance: >96%
  - Multifocal Add Powers: +0.50 to +4.00D
  - Multifocal/D Multifocal/D Multifocal/N Multifocal/N Multifocal Add Powers: +0.50 to +4.00D
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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 abrasions, can develop rapidly and lead to loss of vision.
- All contact lens wearers must see their eye care practitioner as directed. If the lenses for extended wear, the eye care practitioner may prescribe more frequent visits.
- 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, beginning with the first overnight use. This risk can be reduced by careful lens care, including cleaning of the lens case.
- Studies have shown that contact lens wearers who have a higher incidence of adverse reactions than nonsmokers.
- If the patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the lens should be immediately removed and promptly contact their eye care practitioner.

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ADVERSE EFFECTS:
The patient should be informed that the following problems may occur:
- Eyes stinging, burning, or itching (irritation), or other eye pain
- Comfort is less than when the lens 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.
- Unusual eye sensations.
- Reduced visibility.
- Reduced sharpness of vision (poor visual acuity).
- Bluured 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.
LENS CASE CLEANING AND MAINTENANCE:

- If the discomfort or the problem stops, then look closely at 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 reinset them. After reinsetion, 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.

FITTING: Conventional methods of fitting contact lenses apply to all Frequency 55 contact lenses. For a detailed description of the fitting technique, refer to the Frequency 55 or Frequency 55 Multifocal Professional Fitting and Information Guide. Copies of which are available from:

CooperVision, Inc.
Scottsville, New York 14546
1-800-341-2020
www.coopervision.com

WEARING SCHEDULE: The wearing and replacement schedules should be determined by the eye care practitioner. Patients tend to over-wear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner are also extremely important.

CooperVision recommends that the all Frequency 55 lenses be discarded and replaced with a new lens on a frequent replacement basis. The eye care practitioner is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

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

<table>
<thead>
<tr>
<th>Day</th>
<th>Hours (less than 24 hours)</th>
<th>Day</th>
<th>Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>14</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>2</td>
<td>12</td>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
<td>6</td>
<td>All wearing hours</td>
</tr>
</tbody>
</table>

EXTENDED WEAR: (greater than 24 hours, including while asleep). Frequency 55 lenses are suitable for extended wear. The wearing time should be determined by the eye care practitioner. First time wearers of contact lenses should begin following the DAILY WEAR SCHEDULE above, as directed by the eye care practitioner.

CAUTION: Not every patient is able to wear Frequency 55 lenses on an extended wear basis, even if able to wear the same lenses for daily wear. The eye care practitioner will determine an appropriate wearing schedule and/or mix for each patient. The patient should start with daily wear of the lenses before extended wear if so directed by the eye care practitioner.

EXTENDED WEAR LENSES MUST BE REMOVED, CLEANED, AND DISINFECTED AT LEAST ONCE EVERY 7 DAYS, as recommended by the eye care practitioner. With extended wear, there may be increased risks of eye problems, increased risk of lens deposits, cellular thickening, and corneal ulcers. Therefore, proper contact lens care and periodic checkups are extremely important.

LENS CASE DI RETIONS:

- Eye care practitioners should review with the patient lens directions, including 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 Disinfected Lenses)

- 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 all instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe to use with all lenses. Do not allow 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 contact lenses. Each lens product contains specific disinfecting force(s) and enzyme(s) and important use information, which should be read and carefully followed.

LENS CARE TABLE

<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, Miralow® Extra Strength Daily Cleaner, Opti-Free® Daily Cleaner</td>
</tr>
<tr>
<td>Rinse</td>
<td>Renu® Multi-Purpose Solution, SoftWear® Saline, Opti-Free® Ringing, Disinfecting and Storage Solution</td>
</tr>
<tr>
<td>Disinfect</td>
<td>Renu® Multi-Purpose Solution, AOESEPT® Disinfection/Neutralizing Solution, Opti-Free® Ringing, Disinfecting and Storage Solution</td>
</tr>
<tr>
<td>Store</td>
<td>Renu® Multi-Purpose Solution, Opti-Free® Ringing, Disinfecting and Storage Solution</td>
</tr>
<tr>
<td>Lubricate &amp; Rewetting</td>
<td>Renu® Rewetting Drops, CIBA Vision™ Lens Drops, Opti-Free® Rewetting Drops</td>
</tr>
<tr>
<td>Enzyme</td>
<td>Renu® Enzymatic Cleaner Tablets, ULTRAZYME® Enzymatic Cleaner, Opti-Free® Enzymatic Cleaner</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 lenses 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 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.
- To 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 storage of lenses.
- After removing the lenses from the lens 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.

CHEMICAL LENS DISINFECTION (Including Hydrogen Peroxide):

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- After cleaning and rinsing, to disinfect, carefully follow the instructions accompanying the disinfecting solution to disinfect the lenses 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 an unopened storage case until ready to put on the eyes.

CAUTION: Lenses that are chemically disinfected may also contain ingredients in 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.

LENSES 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 dry completely before being 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, or if the surface remains dry, the lens should not be used unless it has been examined by 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 brittle and need to be rehydrated. If the lens is adhering to a surface, apply sterile saline solution before handling.

REPORTING OF ADVERSE REACTIONS:

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

CooperVision, Inc. 711 North Road, Scottsville, New York 14546
(800) 341-2020
www.coopervision.com

Lenses should be consulted with the eye care practitioner.

CARE FOR A STICKING (NONMOVING) 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 lens begins to move freely on the eye before removing it. If non-movement of the lens continues, after 5 minutes 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 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, dioptric 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

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

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