CALL OUR CUSTOMER SERVICE DEPARTMENT AT (800) 341-2020 FOR CURRENT AVAILABILITY

ACTI ONS:
When placed on the cornea in its hydrated state, any Frequency 55 lens in this package acts as a refracting lens medium to focus light rays on the retina.

INDICATIONS (USES):
Frequency 55 and Frequency 55 Aspheric lenses are indicated for the correction of refractive ametropia (myopia and hyperopia), and are presbyopic and apheresic. Persons with near vision and an aspheric annular zone for the correction of intermediate and distance vision. 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 vision in one or both eyes and are aphasic and presbyopic persons with near vision and myopia and 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 wear between removals for cleaning and disinfecting as recommended by the prescribing eye care practitioner.

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

EYE CARE PROFESSIONALS: The manufacturer’s preferred care and disinfection of the lenses are on the eyes. The lenses absorb the dye and move freely on the eye for the continuing ocular health of the patient and lens wearer.

PRECAUTIONS:
Special Precautions for Eye Care Practitioners:
Due to the small number of patients enrolled in clinical investigations of lens power, 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 weighed against the patient’s need for refractive correction; therefore, the continuing ocular health of the patient and lens wearer on the eye should be carefully monitored by the prescribing eye care practitioner.

Aphakic patients should not be fitted with any Frequency 55 contact lenses until the determination is made that the patient has a spherical central zone for the correction of distance vision and an aphakic annular zone for the correction of near vision and an aphakic annular zone for the correction of intermediate and distance vision.

CONTRAINDICATIONS (REASONS NOT TO USE):
Do not use any Frequency 55 lens when any of the following conditions exist:

- Acute and subacute infection or inflammation of the corneal endothelium or the anterior uvea.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hyposthesia (reduced corneal sensitivity), if not aphalic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions to any of the lens materials or adhesives 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 orificial infection (bacterial, fungal, or viral).
- If eyes become red or irritated.
- The patient is unable to follow lens care regimen or unable to 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 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, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning and disinfecting as recommended by the eye care practitioner.
- Studies have been shown that contact lens wearers who smoke have a higher incidence of adverse reactions than non-smokers.
- 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.

ADVERSE EFFECTS:
The patient should be informed of the following problems may occur:

- Eyes stinging, burning, or itching (irritation), or other eye pain.
- Contact 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 grittiness.
- 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). Dryness.

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 continues, 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 another foreign object on it, or if the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect both lenses; then reinset them. After reinset, 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 techniques, refer to the Frequency 55 or Frequency 55 MultiFocus/FitPlus Fitting and Information Guide, copies of which are available from CooperVision, Inc.

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 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>
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<th>Day</th>
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<tbody>
<tr>
<td>1</td>
<td>6</td>
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<td>2</td>
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<td>14</td>
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<td>3</td>
<td>10</td>
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LENSES ON DIRECTION:

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 Clean and Rinse, the Disinfected Lenses)

Basic Instructions:
- Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh, unpreserved lenses.
- Use the recommended chemical (not heat) system of lens care and carefully follow instructions on solution labeling. Different solutions cannot 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 mouth.
- Lenses should be cleaned, rinsed, and disinfected each time they are removed. Cleaning and rinsing is 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 substitute 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 important safety information, which should be read and carefully followed.

LENS CARE TABLE

<table>
<thead>
<tr>
<th>Purpose to:</th>
<th>Procedure to Care for Contact Lens System</th>
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</thead>
<tbody>
<tr>
<td>Clean</td>
<td>ReNu Multi-Purpose Solution, Microflow Extra Strength Daily Cleaner, Opti-Free Daily Cleaner</td>
</tr>
<tr>
<td>Rinse</td>
<td>ReNu Multi-Purpose Solution, SoftWear Saline, Opti-Free Rinse, Disinfecting and Storage Solution</td>
</tr>
<tr>
<td>Disinfect</td>
<td>ReNu Multi-Purpose Solution, AOSEPT 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, Extra Strength Daily Cleaner, Opti-Free Rewetting Drops</td>
</tr>
<tr>
<td>Enzyme</td>
<td>ReNu Effervescent Enzymatic Cleaner Tablets, ULTRAZyme Enzymatic Cleaner, Opti-Free Enzymatic Cleaner</td>
</tr>
</tbody>
</table>

Opti-Free® is a registered trademark of Alcon Laboratories, Inc. AOSEPT®, Microflow®, SoftWear and Ciba Vision® are registered trademarks of CIBA Vision Corp. ReNu® is a registered trademark of Bausch & Lomb, Inc. ULTRAZyme® is a registered trademark of Allergan, Inc.

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. If the lens is 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 case, empty, rinse the lens storage case, and put that lens into the correct chamber of the storage case. Then repeat the procedure for the second lens.

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 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 labeling. Different solutions cannot be used 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 DISINFECTING (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, follow the instructions accompanying the disinfecting solution in the eye care 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.
- 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 lens 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 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. 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 brittle and need to be hydrated. 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 STICKY NG (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 within the eye before removing it. If non-movement of the lens continues 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 (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

REPORTING OF ADVERSE REACTIONS:
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 1-800-341-2401 www.coopervision.com

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