

PATIENT INSTRUCTIONS

For Frequency™ 55
(Methafilcon A) Soft (Hydrophilic) Contact Lenses

CooperVision®

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CAUTION: Federal Law Prohibits Dispensing Without a Prescription

INTRODUCTION

Your Frequency 55 contact lenses are made from a plastic material, methafilcon A, which has the ability to absorb water, making it soft and pliable.

Your eye care practitioner will review with you the instructions for proper hygiene, handling, cleaning, disinfecting, and storage of your contact lenses. Carefully read and follow specific directions and use for important safety information for each lens care product. Discard the lens if the lens becomes damaged or you have reached the prescribed wearing period recommended by your eye care practitioner. You should always have replacement lenses or glasses available. Your eye care practitioner will make sure that you learn to insert and remove your lenses properly. To obtain maximum performance and satisfaction from your new lenses, the procedures, methods, and wearing schedule prescribed by your eye care practitioner should always be followed.

For your eye healthy, it is important to wear your lenses as prescribed by your eye care practitioner. It is also important to keep your eye care practitioner fully aware of your medical history. Your eye care practitioner will tailor a total program of care based on your specific needs. He or she will review with you all instructions for lens handling, including how to safely and easily open the package.

If you are in doubt about any instructions, request clarification from your eye care practitioner.

Benefits

Contact lenses provide vision correction.

If you lead an active lifestyle, contacts can provide:

- Close to natural vision
- Excellent peripheral vision for sports and driving
- Advantages for athletes and those with an active lifestyle

If your work or play in an environment in which glasses are not an option, contact lenses are an alternative.

If you prefer the way you look without glasses, contact lenses can provide ease, and convenience.

Risks

Wearing contact lenses puts you at risk of several serious conditions including eye infections and corneal ulcers. These conditions can develop very quickly and can be very serious. In rare cases, these conditions can cause blindness. Other risks of contact lenses include pink eye (conjunctivitis), corneal abrasions and eye irritation. For further detail, see WARNINGS and ADVERSE REACTIONS.

WEARING RESTRICTIONS AND INDICATIONS

Frequency 55 lenses are indicated for daily wear as recommended by the eye care practitioner. They 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.

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

The Frequency 55 lenses described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eye care practitioner.

If prescribed by your eye care practitioner for daily wear, **DO NOT WEAR YOUR FREQUENCY 55 LENSES WHILE SLEEPING.**

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Frequency 55 contact lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not-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 use of contact lens solutions.
- Allergy to any ingredient, such as mercury of thimerosal, in a solution which is to be used to care for Frequency 55 contact lenses.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become red or irritated.
- You are 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 directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Fill your lens case with fresh solution every time you store your lenses, and never re-use solution. Additionally, you should clean and rinse your lens case between uses as recommended by your eye care practitioner. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Daily wear lenses are not indicated for overnight wear, you must not wear your lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- 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

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only the solutions recommended by your eye care practitioner.
 - Never use solutions recommended for conventional hard contact lenses only.
 - Use only chemical (not heat) disinfection with Frequency 55 lenses. Heat disinfection should not be used. Repeated heat disinfection will cause irreversible damage to Frequency 55 lenses.
 - 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. Do not put the lenses in your mouth.
 - 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 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 nonmovement of the lens continues, **immediately** consult your eye care practitioner.
- Always wash and rinse your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as lens damage may occur.
- **Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by your eye care practitioner.**
- Never wear lenses beyond the period recommended by your 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.
- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eye care practitioner about wearing lenses during sporting activities.
- Inform your doctor (health care practitioner) that you wear contact lenses.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always contact your eye care practitioner before using any medicine in the eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require the use of eye protection equipment or may require that you do not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Your eye care practitioner will recommend a follow-up schedule.

Lens Case Precautions:

- Bacteria can grow in contact lens cases. It is important to properly use, clean and replace your cases at regular intervals recommended by the lens case manufacturer or your eye care practitioner.

Who Should Know That You Are Wearing Contact Lenses:

- Inform your doctor (health care practitioner) that you wear contact lenses.
- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may restrict contact lens wear.
- Always contact your eye care practitioner before using any medicine in your eyes.

Other Topics to Discuss with Your Eye Care Practitioner:

- Follow-up visits are necessary to assure the continued health of your eyes. You should be instructed to a recommended follow-up schedule.

ADVERSE REACTIONS

Be aware that the following problems may occur when wearing contact lenses:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Feeling that something is in the eye such as a foreign body or scratched area
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eye
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If you notice any of the above problems, you should:

- **Immediately remove your 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 in your eye. Place the lens in the storage case and contact your 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 both lenses, then reinsert them.

After reinsertion, if the problem continues, you should **keep the lens off the eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage. After reinsertion, if the problem continues, Your eye care practitioner will examine your eyes, to be certain that a serious condition such as infection, corneal ulcer, neovascularization, or iritis is not present.

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 substances 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 mix-ups.
- 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.
- Rinse the lens thoroughly with fresh, sterile saline solution before placing it on your eye.

3. Placing the Lens on the Eye:

- Position the lens 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 eyelid by lifting the lid just above the eyelashes.
- Look straight ahead and gently place the lens on your eye.
- Slowly release the lids, close your eyes, and then open them slowly. The lens should center automatically.

- Repeat the procedure for the other eye.

There are other methods of lens placement. If the above method 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," next in this booklet).
- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:
 - a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
 - b. The lens is on the wrong eye.
 - c. The lens is inside-out (it would also not be as comfortable as normal). Compare the lens edge profile to the illustrations.

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eye care practitioner

4. Centering the Lens:

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens follow one of the procedures below.

- a. Close your eyelids and gently massage the lens into place through the closed lids using your index finger.
- b. 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:

CAUTION: Always be sure that the lens is centered on the cornea before attempting to remove it. Determine this by covering the other eye. If the vision is blurred, the lens is either on the white part of the eye or it is not on the eye at all. To locate the lens, inspect the upper area of the eye by looking down into a mirror while pulling the upper lid up. Then, inspect the lower area by pulling the lower lid down.

Wash, rinse, and dry your hands thoroughly with mild soap, rinse completely, and dry with a lint-free

towel before touching lenses. Have your storage container or carrying case ready to put the lenses in upon removal.

- a. Look straight ahead and up slightly. With the middle finger of your dominant hand, pull the lower lid down slightly.
- b. Gently pinch the lens between the index finger and thumb of your dominant hand.
- c. Gently pull the lens away from the eye.
- d. Repeat the procedure for the other lens.
- e. Follow the required lens care procedures described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE, AND REWETTING/LUBRICATING).

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 (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE, AND REWETTING/LUBRICATING)

1. Basic Instructions

For continued safe and comfortable wearing of your lenses, it is important that you **first clean and rinse, then disinfect** and neutralize (for hydrogen peroxide systems) 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 above.

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

When you first get your lenses, be sure you are able to put the lenses on and remove them while you are in your eye care practitioner's office. At that time you will be provided with a recommended cleaning and disinfecting regimen and instructions and warnings for lens care, handling, cleaning, and disinfection.

Your eye care practitioner should instruct you about appropriate and adequate procedures and products

for your use, and provide you with a copy of the Patient Instructions for Frequency 55 contact lenses.

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

- Always wash your hands thoroughly with a mild soap. Rinse completely. Dry hands with a lint-free towel before handling your 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 for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling.
- Always remove, clean, rinse, enzyme, and disinfect your lenses according to the schedule prescribed by your 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 your lenses. Do not put lenses in your mouth.
- Never rinse your lenses in water from the tap. There are two reasons for this:
 - i. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
 - ii. You might lose a lens down the drain.

Your eye care practitioner should recommend a care system that is appropriate for your Frequency 55 contact lenses. Each lens care product contains specific directions for use and important safety information, which you should read and carefully follow.

Lens Care Table

| <u>Product Purpose To:</u> | <u>Chemical (Not Heat) Lens Care System</u> |
|----------------------------|--|
| 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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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 the instructions.

Cleaning:

- **Clean** one lens first (always the same lens first to avoid mix-ups), 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.
- After cleaning and rinsing, disinfect lenses using the system recommended by your eye care

practitioner and/or the lens manufacturer. Follow the instructions provided in the disinfection solution labeling.

Disinfecting (Chemical-Not Heat)

- Your contact lenses cannot be heat (thermally) disinfected.
- To store lenses **disinfect** and leave them in the closed case until ready to wear. If lenses are not to be used immediately following disinfection, 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 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. **Lubricating/Rewetting** solutions can be used to rewet (lubricate) your lenses while you are wearing them to make them more comfortable.

2. Care for a Sticking (Nonmoving) Lens

If the lens sticks (stops moving or cannot be removed), apply 2-3 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 movement of the lens continues more than 5-10 minutes, immediately consult the eye care practitioner.

3. Chemical Lens Disinfection (Including Hydrogen Peroxide)

- Clean your 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 in the care regimen recommended by your eye care practitioner or the lens manufacturer.
- When using hydrogen peroxide lens care systems, lenses **must be neutralized** before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse your lenses with fresh rinsing solution 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 your eyes. A thorough rinse in fresh, sterile saline solution

prior to placement on your eye should reduce the potential for irritation.

4. 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, carefully follow the instructions in the enzymatic cleaning labeling.

5. 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. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

6. Care for a Dried Out (Dehydrated) Lens

If your 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.

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, **do not use the lens unless it has been examined by your eye care practitioner.**

7. Emergencies

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, FLUSH 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

- Monovision: a treatment technique often prescribed for people age 40 and over who have presbyopia. Presbyopia occurs as part of the natural aging process. The eye's crystalline loses its ability to bring close objects into clear focus. Monovision means wearing a contact lens for near vision on one eye and, if needed, a lens for distance vision on the other eye.

The decision to be fit with a monovision correction is made by careful consideration of your needs with your eye care practitioner.

- 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 for 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 driver's 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 nearest 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.

Wearing and Appointment Schedules

Prescribed Wearing Schedule

| DAY | DATE | WEARING TIME (HOURS) |
|-----|------|----------------------|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |
| 7 | | |
| 8 | | |
| 9 | | |
| 10 | | |
| 11 | | |
| 12 | | |
| 13 | | |
| 14 | | |

PRECAUTION: If prescribed by your eye care practitioner for daily wear, your Frequency 55 lenses should not be worn 24 hours a day.

Check-Up Visits

Regular check-up examinations by your eye care practitioner are an important and ongoing part of wearing your Frequency 55 contact lenses. Keep all appointments for check-up visits.

Appointment Schedule

Your appointments are on:

| DATE | TIME | HOURS* |
|------|------|--------|
| | | |
| | | |
| | | |
| | | |
| | | |

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

PATIENT/EYE CARE PRACTITIONER INFORMATION

| | |
|---------------------------------------|--|
| Name of Practitioner: | |
| Address: | |
| Phone: | |
| Recommended Lens Care Regimen: | |
| Other Information: | |
| | |
| | |

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

NAME AND ADDRESS OF MANUFACTURER

CooperVision, Inc.
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For Package Insert please reference PI01087