

INSTRUCTIONS FOR WEARERS MANUAL

Contact Lenses for Frequent Replacement Daily and Extended Wear

Expressions Colors, Frequency Colors, Frequency Aspheric Colors and Frequency Toric Colors

(methafilcon A)

Soft (Hydrophilic) Contact Lenses

CooperVision®

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CAUTION: Federal Law Prohibits Dispensing Without a Prescription

INTRODUCTION

Your Expressions Colors, Frequency Colors, Frequency Aspheric Colors and Frequency Toric Colors contact lenses are made from a plastic material, methafilcon A, which has the ability to absorb water, making it soft and pliable. Whether your eye care practitioner prescribed your lenses for daily or extended wear, they are to be removed, discarded and replaced with a new sterile one on a Frequent Planned Replacement schedule determined by your eye care practitioner. To obtain maximum performance and satisfaction from your new lenses, the procedures, methods and wearing schedule must always be followed.

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

WEARING RESTRICTIONS AND INDICATIONS

1. Expressions Colors, Frequency Colors and Frequency Aspheric Colors Contact Lenses are indicated for daily wear or extended wear from 1 to 7 days between removals for cleaning and disinfecting as recommended by the eye care practitioner. They are also indicated to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for the management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed 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 or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.
2. Frequency Toric Colors Contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfecting as recommended by the eye care practitioner. They are also indicated to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for the management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who have astigmatism of 12.00 diopters or less or for occlusive therapy for conditions such as diplopia, amblyopia an extreme photophobia.

Your Expressions Colors, Frequency Colors have been prescribed for frequent replacement wear and should be removed from your eyes and discarded as recommended by your eye care practitioner.

Note: Only chemical disinfection may be used with Expressions Colors, Frequency Colors.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Expressions Colors, Frequency Colors 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 hypoaesthesia (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 or thimerosal, in a solution which is to be used to care for Expressions Colors, Frequency Colors.
- 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. 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 FOR FREQUENT REPLACEMENT WEAR

- 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 Expressions Colors, Frequency Colors. Heat disinfection **should not be used**. **Repeated heat disinfection will cause irreversible damage to Expressions Colors, Frequency Colors.**
 - 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 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.

ADVERSE REACTIONS

The following problems may occur:

- 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 eyes
- 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 on 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 **immediately remove the lenses and consult your eye care practitioner.**
- When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You should **keep the lens off the eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

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 mixups.
- 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:**

Always remove the same lens first. Wash, rinse, and dry your hands thoroughly. Have your lens storage case ready to put the lenses in upon removal.

Always be sure that the lens is centered on the cornea before attempting to remove it.

- 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 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 Expressions Colors, Frequency Colors.

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

- 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 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:
 - a. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
 - b. You might lose a lens down the drain.
- Your eye care practitioner should recommend a care system that is appropriate for your Expressions Colors, Frequency Colors. Each lens care product contains specific directions for use and important safety information, which you should

read and carefully follow.

Lens Care Table

Product Purpose To:	Chemical (Not Heat) Lens Care System
Clean	ReNu [®] Multi-Purpose Solution MiraFlow [®] Extra-Strength Daily Cleaner Opti-Free [®] Daily Cleaner
Rinse	ReNu [®] Multi-Purpose Solution SoftWear [®] Saline Opti-Free [®] Rinsing, Disinfecting, and Storage Solution
Disinfect	ReNu [®] Multi-Purpose 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 CIBA Vision Lens Drops Opti-Free [®] Rewetting Drops
Enzyme	ReNu [®] Effervescent Enzymatic Cleaner Tablets ULTRAZYME [®] Enzymatic Cleaner Opti-Free [®] Enzymatic Cleaner

Opti-Free[®] is a registered trademark of Alcon Laboratories, Inc. AOSEPT[®], MiraFlow[®], SoftWear[®], and CIBA Vision are registered trademarks of CIBA Vision Corporation. ReNu[®] is a registered trademark of Bausch & Lomb, Inc. LensPlus[®] and ULTRAZYME[®] are registered trademarks 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 the instructions.
- **Clean** one lens first (always the same lens first to avoid mixups), 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.
- **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 nonmovement 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

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 Expressions Colors, Frequency Colors are 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

- 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 drivers 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 clearest 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.
- **The decision to be fit with a monovision correction is most appropriately left to the eye care practitioner in conjunction with you, after carefully considering and discussing your needs.**

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 Expressions Colors, Frequency Colors 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 Expressions Colors, Frequency Colors. Keep all appointments for check-up visits.

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.

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PACKAGE INSERT

IMPORTANT - Please read carefully and keep this information for future use. This package insert is intended for the eye care practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

CAUTION - Federal Law Prohibits Dispensing Without a Prescription.

Expressions Colors, Frequency Colors, Frequency Aspheric Colors and Frequency Toric Colors (methafilcon A)

Soft (Hydrophilic) Contact Lenses for Myopia, Hyperopia and Astigmatism

DESCRIPTION

Expressions Colors, Frequency Colors and Frequency Aspheric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses are available as spherical lenses. Frequency Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses are available as astigmatic (toric) lenses. The lens material, methafilcon A, is a random copolymer of hydroxyethylmethacrylate and methacrylic acid. The lenses are made by modifying the uncolored methafilcon A lens by affixing

a colored pigment on that portion of the front surface that corresponds to the iris. The colored pigments consist of carbazole violet, chromium oxide green, dihydrodinaphtho brown, dihydrodioxo yellow, phthalocyanine green, iron oxide red, iron oxide brown, iron oxide black, phthalocyanine blue, and titanium oxide.

Expressions Colors, Frequency Colors are hemispherical shells with the following dimensions:

- **Diameter:** 14.2mm to 15.0mm
- **Base Curve:** 8.0mm to 9.5mm
- **Center Thickness:** 0.05mm to 0.60mm (varies with power)
- **Lens Powers;**
 - Sphere:** -20.00 to +20.00D
 - Cylinder:** plano to -12.00
 - Axis:** 1° to 180°

The physical/optical properties of the Expressions Colors, Frequency Colors are:

- **Refractive Index:** 1.41
- **Light Transmittance:** >96%
- **Surface Character:** Hydrophilic
- **Water Content:** 55%
- **Oxygen Permeability:** 14.4×10^{-11} (cm²/sec)(ml O₂/ml x mmHg) at 35°C
(Fatt method for determination of oxygen permeability)

The Expressions Colors, Frequency Colors (methafilcon A) Soft (hydrophilic) Contact Lenses may be prescribed for Frequent/Planned Replacement or Disposable Wear.

ACTIONS

When placed on the cornea in its hydrated state, the **Expressions Colors**, Frequency Colors acts as a refracting medium to focus light rays on the retina. The design of the toric lens provides a more even surface over the uneven astigmatic cornea and thus helps to focus light rays on the retina.

INDICATIONS (USES)

1. Expressions Colors, Frequency Colors and Frequency Aspheric Colors are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfecting as recommended by the eye care practitioner. They are also indicated to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for the management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed 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 or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.
2. Frequency Toric Colors lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfecting as recommended by the eye care practitioner. They are also indicated to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for the management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia,

hyperopia and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who have astigmatism of 12.00 diopters or less or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.

FREQUENT/PLANNED REPLACEMENT WEAR

When prescribed for Frequent/Planned Replacement Wear, the Expressions Colors, Frequency Colors, Frequency Aspheric Colors and Frequency Toric Colors lenses are to be cleaned, rinsed and disinfected each time they are removed from the eye and discarded after the recommended wearing period prescribed by the eye care practitioner.

DISPOSABLE WEAR

When prescribed for Disposable Wear, the wearing time prescribed by the eye care practitioner is for either daily wear or extended (single use) from 1 to 7 days. Patients should be instructed to discard the lenses at each removal.

Note: Only chemical and hydrogen peroxide disinfection systems may be used with all Expressions Colors, Frequency Colors.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE Expressions Colors, Frequency Colors 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 or thimerosal, in a solution which is to be used to care for the Encore™ 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 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

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 practitioners as directed. If the lenses are 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 carefully following directions for routine lens care, including cleaning of the lens case.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences **eye discomfort**, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove lenses** and promptly contact his or her eye care practitioner.

PRECAUTIONS

Special Precautions 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 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.

PRECAUTIONS FOR FREQUENT/PLANNED REPLACEMENT WEAR

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 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 Expressions Colors, Frequency Colors.

- 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.
- 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.

PRECAUTIONS FOR DISPOSABLE WEAR

- If the lenses are prescribed for disposable wear, they are to be disposed of once they are removed from the patient's eyes. It is important that patients be instructed to always have available a pair of replacement lenses or spectacles. In the event that a lens must be removed from the eye because dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated, the lens should be removed and replaced with a replacement lens.

PRECAUTIONS FOR FREQUENT/PLANNED REPLACEMENT AND DISPOSABLE WEAR

- Aphakic patients should not be fitted with Expressions Colors, Frequency Colors until 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 this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove the lenses or should have someone else available who can remove the lenses for him or her.
- Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- 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, the patient should be instructed to **immediately** consult his or her eye care practitioner.
- Always wash and rinse 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 the Patient Instructions for Frequency 55 contact lenses and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the 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 the eye care practitioner about wearing lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- 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 the eye care practitioner before using any medicine in the eyes.
- 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 a recommended follow-up schedule.

ADVERSE REACTIONS

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

- 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 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.**
- 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 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 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 Expressions Colors, Frequency Colors. For a detailed description of the fitting techniques, refer to the Expressions Colors, Professional Fitting and Information Guide, copies of which are available from:

CooperVision, Inc.
711 North
Scottsville, NY 14546
1.800.341.2020

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care practitioner. Patients tend to overwear 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.

The wearing schedule and replacement schedule for Expressions Colors, Frequency Colors should be determined by the eye care practitioner based upon the patient's physiological eye condition, since each individual's response to contact lenses varies.

The eye care practitioner may prescribe the lens for either single use **Disposable Wear** or for **Frequent/Planned Replacement Wear** with cleaning, rinsing, disinfecting and scheduled replacement. When prescribed for Frequent Replacement Wear, the lens may be disinfected using a chemical disinfection system.

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

<u>Day</u>	<u>Hours</u>
1	6
2	8
3	10
4	12
5	14
6	All Waking Hours

EXTENDED WEAR: (greater than 24 hours, including while sleeping). The wearing schedule should be determined by the eye care practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgement. CooperVision recommends beginning extended wear patients with the recommended initial daily wear schedule, followed by a period of daily wear, and then gradual introduction of extended wear one night at a time, unless individual considerations indicate otherwise. The eye care practitioner should examine the patient in the early stages of extended wear to determine the corneal response. The lens must be removed, cleaned and disinfected or disposed of and replaced with a new lens, as determined by the eye care practitioner. (See factors discussed in the WARNINGS section). Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the eye care practitioner.

LENS CARE DIRECTIONS

When lenses are dispensed, the patient should be provided with appropriate and adequate instructions and warnings for lens care handling. The eye care practitioner should recommend appropriate procedures and products for each individual patient in accordance with the particular lens wearing schedule and care system selected by the eye care practitioner, the specific instructions for such products and the particular characteristics of the patient.

Frequent/Planned Replacement Wear: For complete information concerning the care, cleaning and disinfection of Expressions Colors, Frequency Colors refer to the Instructions for Wearers Manual for use in a Frequent/Planned Replacement Program.

LENS CASE CLEANING AND MAINTENANCE

Eye care practitioners advise patient's on a **Frequent/Planned Replacement** program that contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, and 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 the eye care practitioner.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

Frequent/Planned Replacement Wear: If any Expressions Colors, Frequency Colors 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.**

Disposable Wear: If any Expressions Colors, Frequency Colors is exposed to air while off the eye, it may become dry and brittle. Dehydrated lenses should be disposed of. Therefore, it is important that the patient always have a pair of new sterile replacement lenses or spectacles available.

CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving or cannot be removed), the patient should be instructed to 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 nonmovement of the lens continues more than 5-10 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 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 sterile buffered isotonic saline solution. The blister pack is labeled with the base curve, diameter, dioptric power (cylinder and axis for toric lens), color, manufacturing lot number, and expiration date of the lens.

Do not use if the blister pack has been broken or damaged.

REPORTING OF ADVERSE REACTIONS

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

CooperVision, Inc.
711 North Road
Scottsville, NY 14546

Product Services
1.800.341.2020
www.coopervision.com

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